# Is Lasik Safe?

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I have no financial relationships with any commercial interest mentioned in this presentation.

# Spoiler Alert

Lasik is the safest, most effective, life changing elective outpatient surgical procedure of any kind of all time.

# Lasik Myths We Still Hear Today

- Lasik is riskier than contact lenses
- Eyes keep changing anyway
- Lasik causes presbyopia
- Can’t treat astigmatism
- Lasik wears off so what’s the point
- You can’t serve in the military after Lasik
- Lasik flap never heals
- Lasik causes dry eyes, glare and halos
- Even Lasik Surgeons don’t get Lasik

ARTICLE

# 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

**PURPOSE:** To determine the prevalence of laser corneal refractive surgery (laser vision correction [LVC]) among ophthalmologists who perform these procedures and to assess the willingness of these ophthalmologists to recommend LVC to immediate family members.

**SETTING:** Online survey with results analyzed at Surgivision Consultants, Inc., Scottsdale, Arizona, USA.

**DESIGN:** Prospective randomized questionnaire study.

**METHODS:** The 22-question Global Survey on Refractive Surgery in Refractive Surgeons was sent by e-mail to 250 ophthalmologists randomly selected from a database of 2441 ophthalmologists known to have performed LVC at some point in the past decade. Responses were solicited by e-mail, with subsequent telephone reminders to nonresponders.

**RESULTS:** Responses were received from 248 (99.2%) of 250 queried individuals, of which 232 (92.8%) met the protocol criteria of currently working as refractive surgeons. Of the 232 subjects, 161 (69.4%) reported that they had refractive errors potentially amenable to treatment with LVC, not including presbyopia. Of the 161 ophthalmologists with treatable refractive errors, 54 (33.5%) reported they were not candidates for LVC for a variety of reasons and 107 (66.5%) reported they were candidates for LVC. Of the LVC candidates, 62.6% reported that they had an LVC procedure in their own eyes. Of the overall 232 subjects, more than 90% recommend LVC for adult members of their immediate family.

**CONCLUSIONS:** Ophthalmologists who perform LVC were significantly more likely than the general population to have LVC in their own eyes. The prevalence of refractive errors was significantly higher among ophthalmologists performing refractive surgery than in the general population.

**Financial Disclosure:** No author has a financial or proprietary interest in any material or method mentioned.

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Laser vision correction (LVC) has been available in the United States since the first excimer laser received U.S. Food and Drug Administration approval for photorefractive keratotomy (PRK) in 1995.[1] Reports of satisfaction with the procedure are high. Metaanalysis of the world's literature on laser in situ keratomileusis (LA-

As of 2014, estimates put the number of patients who had LVC procedures at only 16.2 million in the United States, for an overall penetration rate of 13.1% of appropriate candidates.[7] Reasons cited for low penetration range from general economic condi-

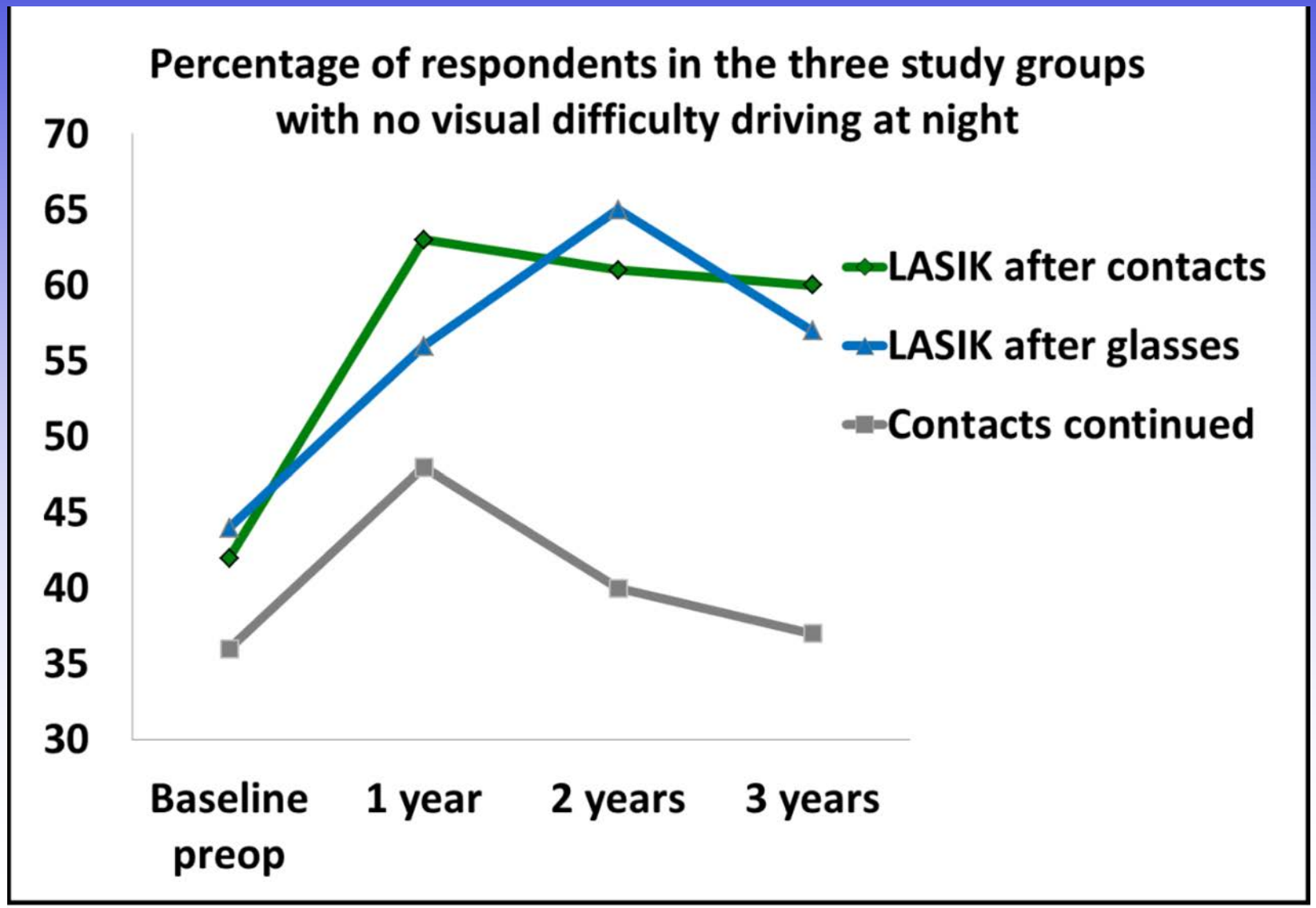
63% of Lasik Surgeons who were candidates for LVC chose LVC

# *Is Lasik as Safe as Contact Lenses?*

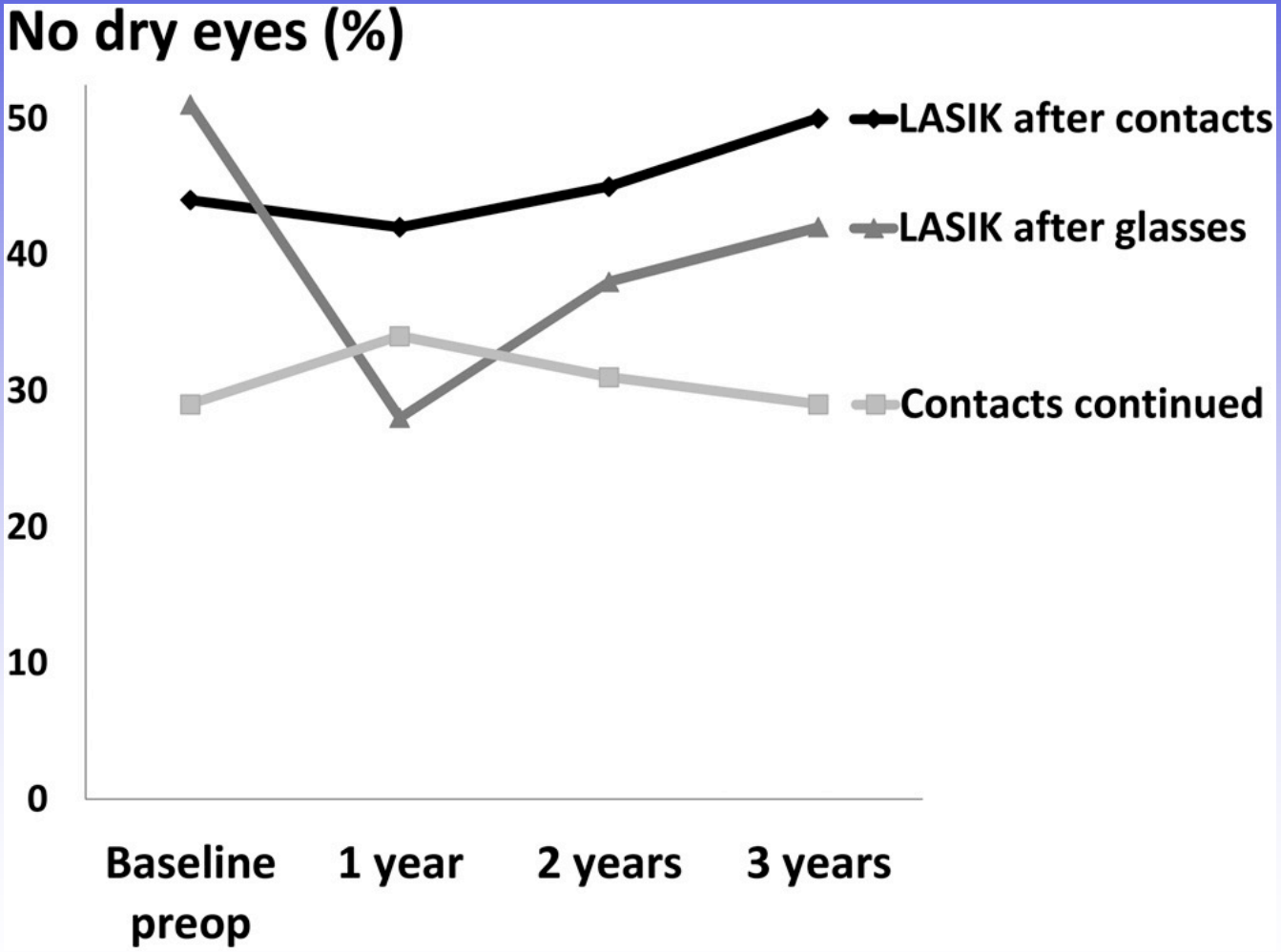
# Lasik vs Contact Lens

- 2016 Prospective Longitudinal Multicenter Study
- 1800 Patients Queried Yearly for 3 Years
- 819 Contact Lens Patients Having Lasik
- 287 Spectacle Patients Having Lasik
- 694 Contact Lens Patients Remained in Contacts

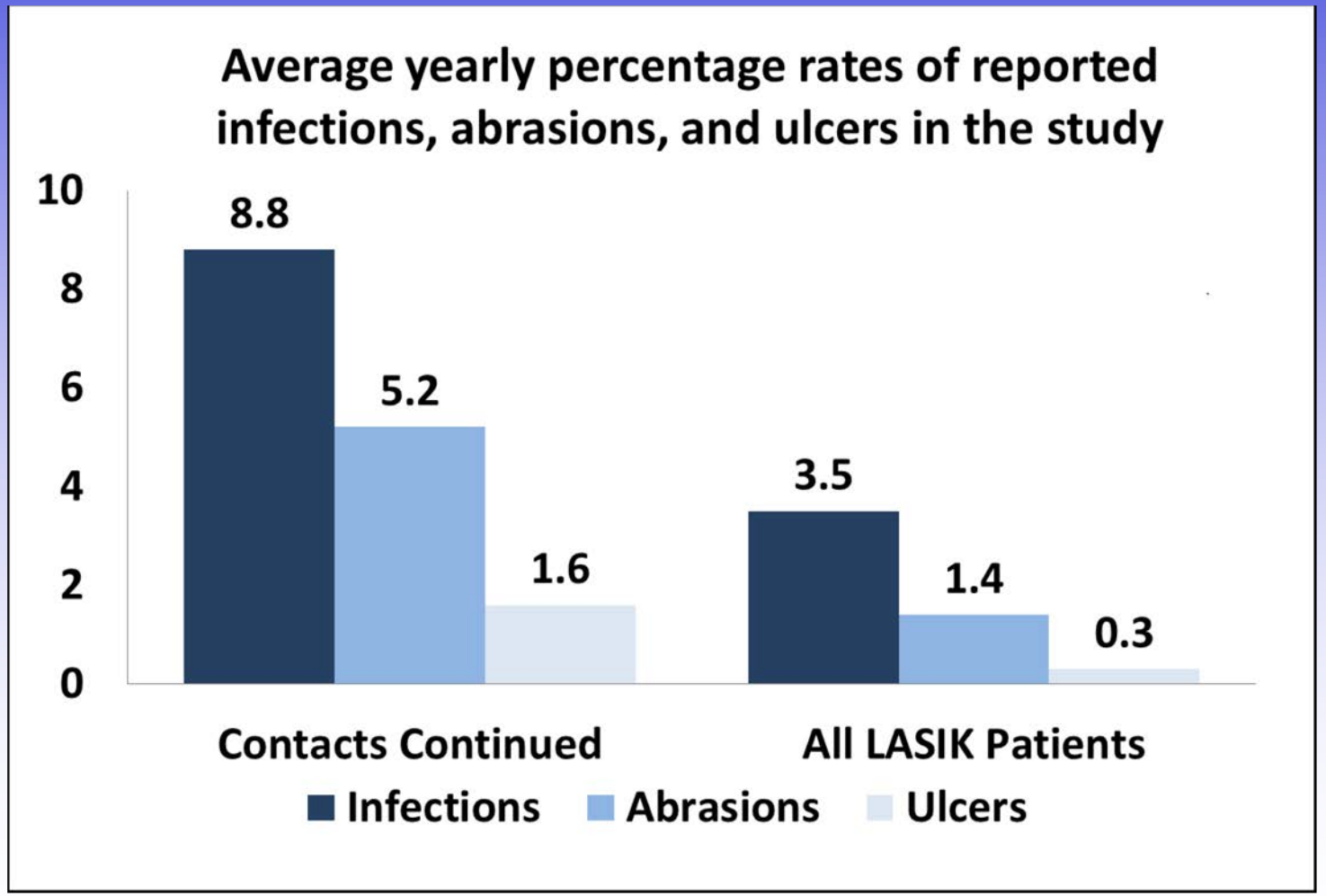
# Lasik vs Contact Lens: Glare



# Lasik vs Contact Lens: Dry Eyes



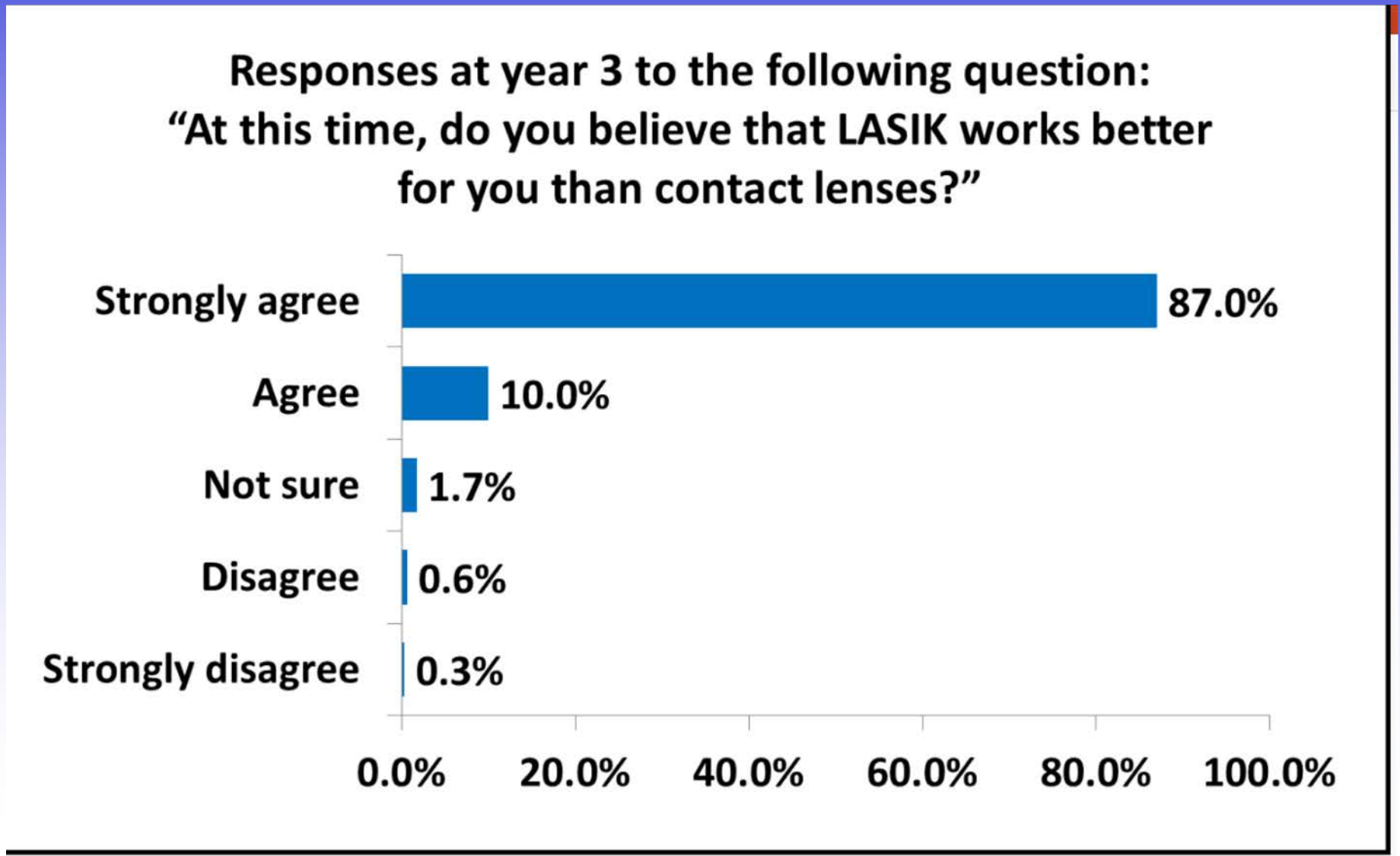
# Lasik vs Contact Lens: Infection



# Lasik vs Contact Lens Infection

- Sight affecting corneal microbial infections are 10 times higher in long term DWSCL patients than after Lasik.
- And 34 times higher in EWSCL patients than after  Lasik.

# Lasik vs Contact Lens Satisfaction

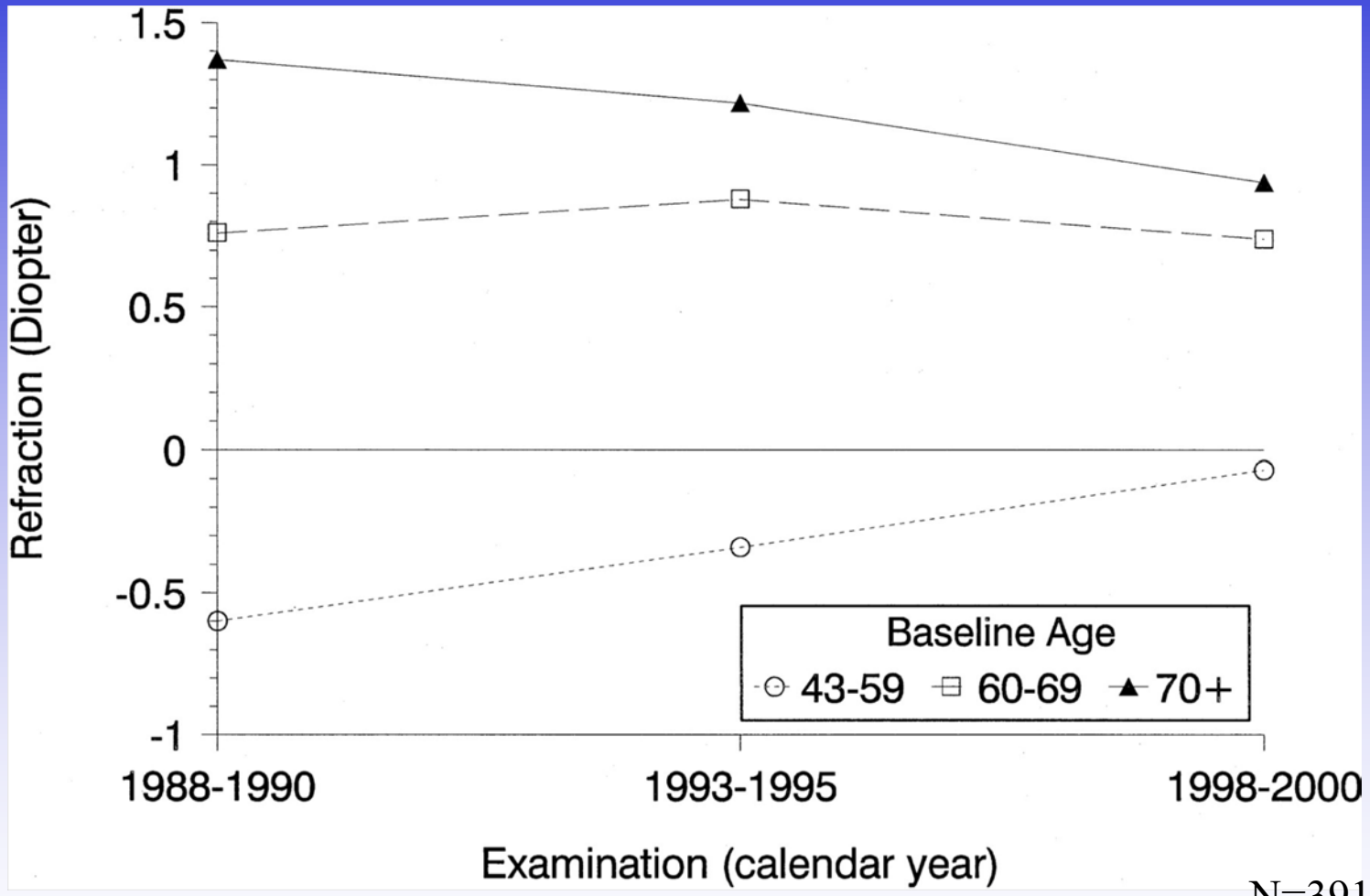


# Lasik vs Contact Lens: Conclusion

Lasik has fewer side effects and a higher satisfaction rate than contact lenses.

# *Does the Manifest Refraction Change in Adult Life*

# Beaver Dam Study




N=3917

From: Changes in Refraction over 10 Years in an Adult Population: The Beaver Dam Eye Study
Invest. Ophthalmol. Vis. Sci.. 2002;43(8):2566-2571.

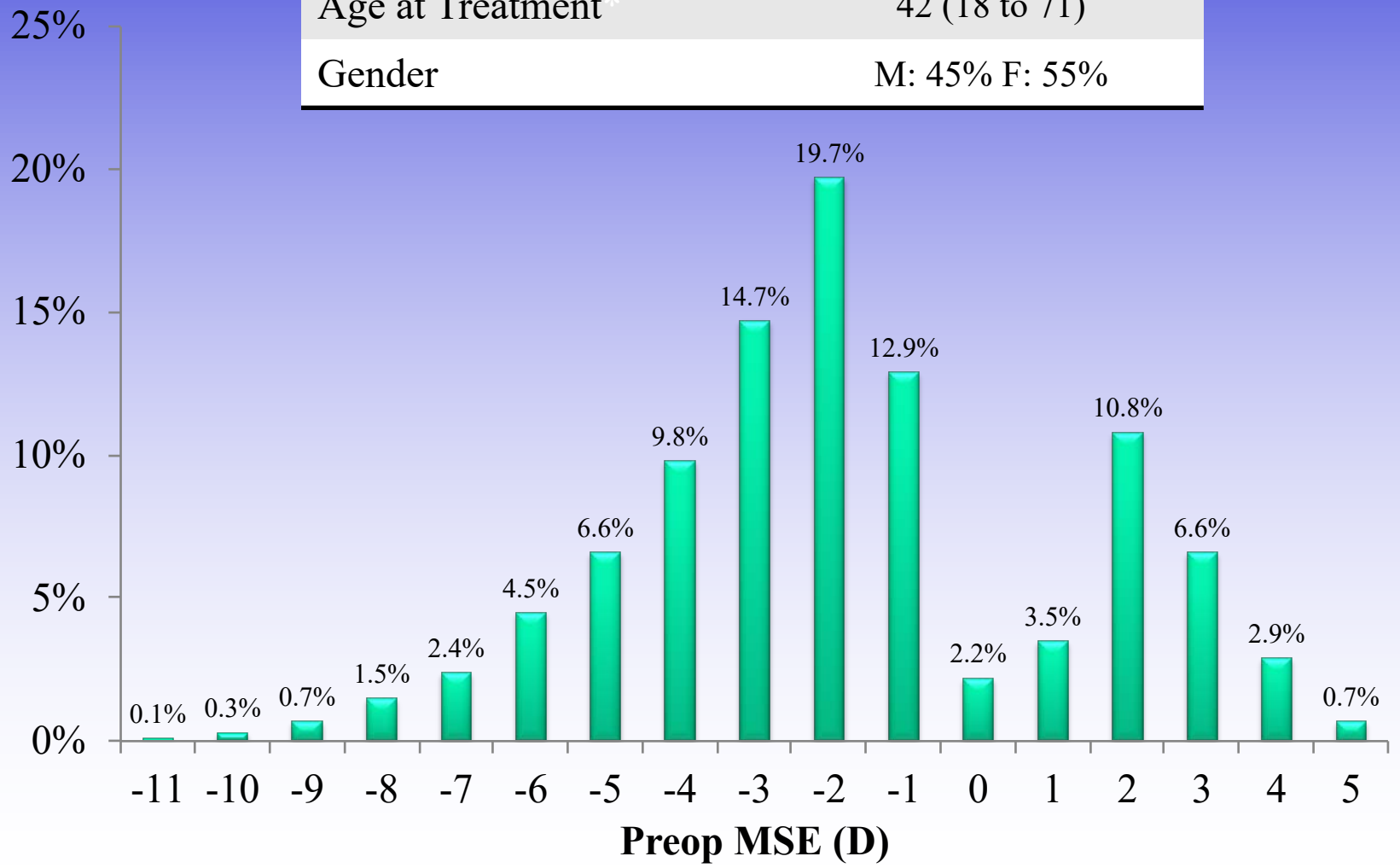
# Beaver Dam Study

Conclusion: The Refraction Does Not Change Significantly Over Time in Adults

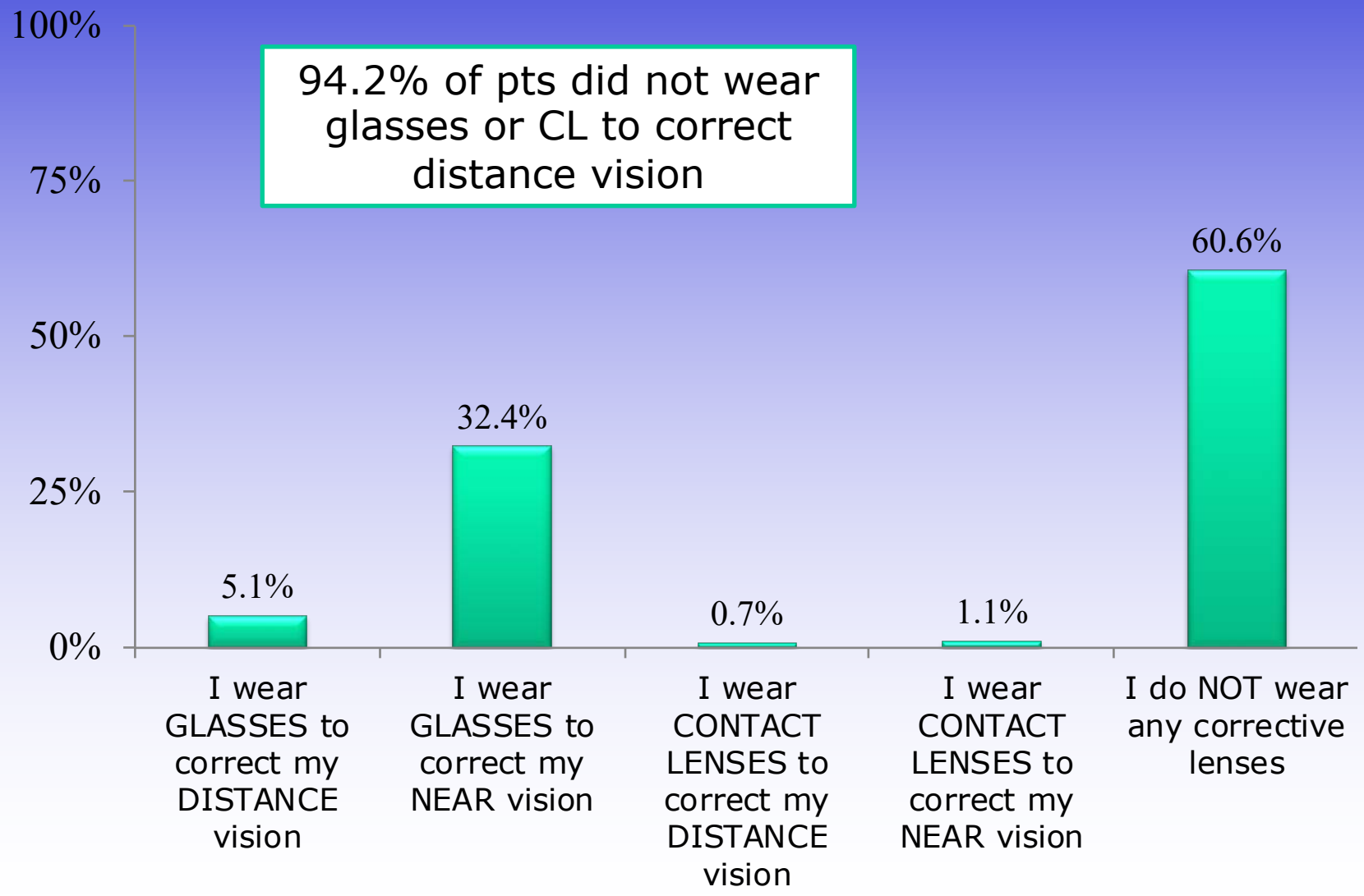
# *Does Lasik Wear Off?*

# Optical Express 5 Year Post-LASIK Evaluation

| Patients (Eyes) | 3,317 (6,465) |
|---|---|
| Age at Treatment* | 42 (18 to 71) |
| Gender | M: 45% F: 55% |



# "Please check ALL that apply. During a typical day…"



# Longitudinal Lasik Studies

Conclusion: Lasik Does Not Wear Off

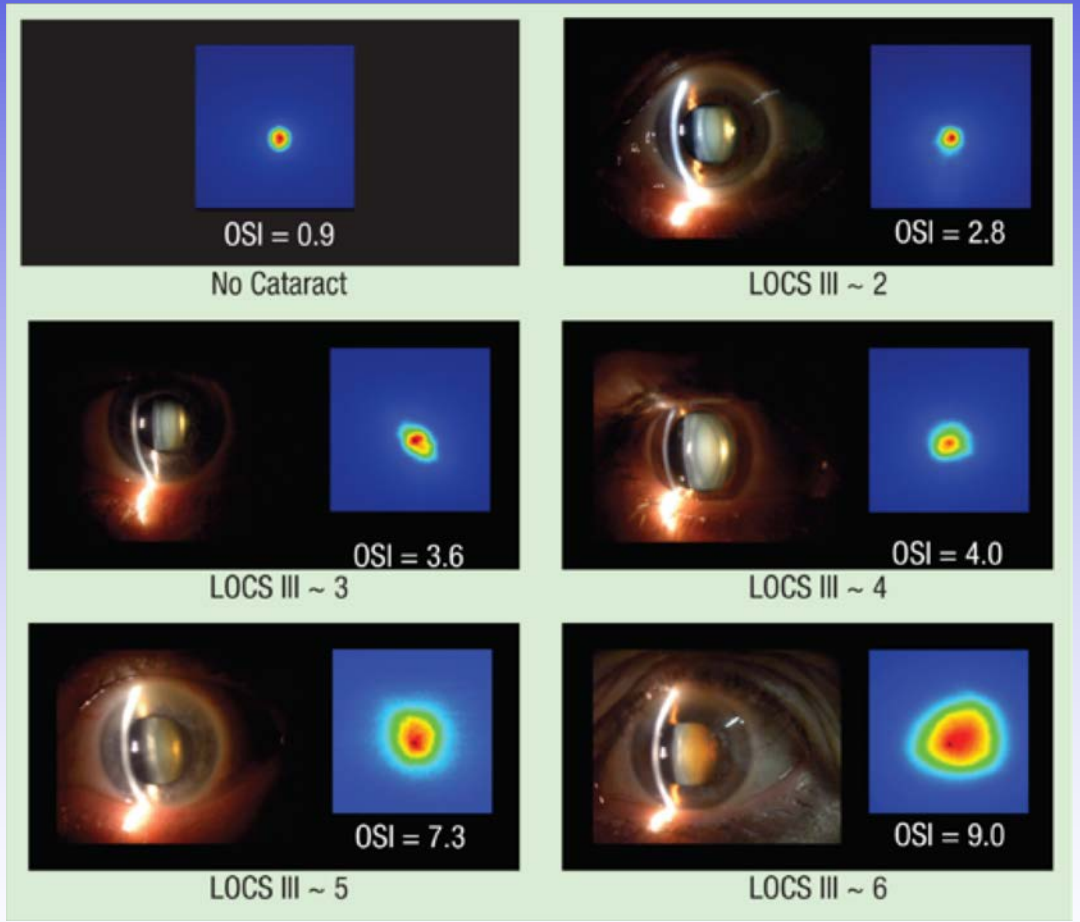
# *Does Lasik Cause Presbyopia?*

# Lasik Effect on Presbyopia

- Advent of presbyopia is commonly misunderstood as Lasik ‘wore off’.
- Low presbyopic myopes need repeated pre-op explanations to understand the effect of Lasik on their near vision.

# Early Cataract Formation

- Objective assessment measuring the ocular scatter index can identify early lens changes not seen on SLE
- Increased ocular scatter causes decreased quality of vision
- …and dissatisfaction with prior Lasik



# *Can You Serve in the Military After Lasik?*

# Lasik in Naval Aviators

- Cost to train aircraft carrier based pilot = $5M
- Modern combat headgear incompatible with glasses
- Lasik studied as an alternative in 2011

# Lasik in Naval Aviators

- 651 eyes of 330 airmen studied
- -11.40 to +3.75 with up to 3.50 cyl
- 98.2% 20/20
- 100% BDVA 20/20
- No complications, no retreatments
- No subjective visual complaints (glare, halos, etc)

# Lasik in Naval Aviators

## Laser in situ keratomileusis in United States Naval aviators

David J. Tanzer, MD, Tyson Brunstetter, OD PhD, Richard Zeber, OD, Elizabeth Hofmeister, MD, Sandor Kaupp, MS, Neil Kelly, PhD, Myah Mirzaoff, William Sray, MD, Mitch Brown, OD, Steven Schallhorn, MD

**PURPOSE:** To evaluate the safety and efficacy of femtosecond-assisted wavefront-guided laser in situ keratomileusis (LASIK) as well as higher-order aberrometric changes in a population of active-duty United States Naval aviators.

spherical aberration, respectively. Of the patients, 95.9% said they believed that LASIK had helped their effectiveness as Naval aviators and 99.6% would recommend the same treatment to others.

**CONCLUSION:** Femtosecond-assisted wavefront-guided LASIK was an efficacious and safe option for refractive correction in Naval aviators, enabling a quick return to flight status.

Conclusion: Lasik is an efficacious and safe option for naval aviators, enabling a quick return to flight status

# Lasik in the Military To Date

- Aviators having had Lasik = 8593
- Lasik in Military Personnel = 662,000
- Approved for all fighting troops, aviators and NASA astronauts
- Myopia > -8.00 is restricted and needs a waiver to serve due to increased risk of RD, etc.

*Will the Lasik flap survive high altitude?*

# Lasik Flap Stability

- 1 person developed snow blindness after RK
- 40 million procedures worldwide with no reported flap-related altitude issues
- The word ‘flap’ was a bad choice to begin with, maybe ‘cap’ or ‘cover’ would have been better
- The modern Femto Lasik Flap heals completely and after about a year is virtually impossible to manipulate

# Lasik Flap after Ejection at Altitude

## Laser in situ keratomileusis flap stability in an aviator following aircraft ejection

Christopher J. Richmond, MD, Patrick D. Barker, MD, Edgar M. Levine, MD, Elizabeth M. Hofmeister, MD

We present the case of a 28-year-old male F/A-18F Super Hornet naval flight officer who ejected from an aircraft at 13 000 feet at a speed in excess of 350 knots 7 years after uneventful laser in situ keratomileusis (LASIK). The patient was evaluated the day after the ejection. No LASIK flap complications or epithelial defects were found, and the corrected distance visual acuity was 20/15 in both eyes.

**Financial Disclosure:** None of the authors has a financial or proprietary interest in any material or method mentioned.

*J Cataract Refract Surg 2016; 42:1681–1683 © 2016 ASCRS and ESCRS*

Traumatic flap dislocation is a serious potential complication of laser in situ keratomileusis (LASIK), of particular concern for the military aviation community due to the windblast and G-forces typically experienced during ejection. Although LASIK has been shown to be safe and effective, traumatic flap dislocations can be visually devastating.[1] Two animal studies have demonstrated the safety and stability of the LASIK flap during simulated ejection environments.[2,3]

To our knowledge, this is first case of an aviator ejecting from a high-performance aircraft after having LASIK.

### CASE REPORT

A 28-year-old white man presented the day after he ejected from an F/A-18F Super Hornet with the chief complaints of eye redness and photophobia. Laser in situ keratomileusis had been performed 7 years previously in September 2009. The preoperative sphere was −3.50 diopters (D) in the right eye and −3.25 D in the left eye, and the corrected distance visual acuity (CDVA) was 20/20 in both eyes. The preoperative scanning-slit topography (Orbscan, Bausch & Lomb) showed corneal thicknesses of 625 µm and 620 µm, respectively.

Submitted: September 6, 2016.

*Does Lasik Cause Dry Eye, Glare or Halos?*

# PROWL

**P**atient **R**eported **O**utcomes **W**ith **L**asik

- 2008 Lasik Quality of Life Project
- FDA/NIH/DOD
- Grew out of a public hearing on the safety of Lasik
- Format: Patient Online Questionnaire
- PROWL 1: 262 Naval Personnel
- PROWL 2: 312 Civilians at 5 Private Practices

# Patient-Reported Outcomes

Any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician, industry or anyone else

# Existing Questionnaires Studied

- National Eye Institute Refractive Error Quality of Life (NEI-RQL-42)
- National Eye Institute Visual Functioning Questionnaire (VFQ-25)
- Ocular Surface Disease Index (OSDI)
- Life Orientation Test Revised (LOT-R)
- Brien Holden Vision Institute Multidimensional Quality of Life (BHVI QOL) Scale for Myopia
- Work Productivity Activity and Impairment (WPAI)
- Patient Health Questionnaire (PHQ-4)
- Marlowe-Crowne Socially Desirable Response Set

# NEI Visual Functioning



10. How much difficulty do you have driving in difficult conditions, such as in bad weather, during rush hour, on the freeway, or in city traffic?

*(Mark One)*

- No difficulty at all ..... 1 ☐
- A little difficulty ..... 2 ☐
- Moderate difficulty ..... 3 ☐
- A lot of difficulty ..... 4 ☐
- Never drive in these conditions because of vision ..... 5 ☐
- Never do this for other reasons ..... 6 ☐

11. Because of your eyesight, how much difficulty do you have with your daily activities?

*(Mark One)*

- No difficulty at all ..... 1 ☐
- A little difficulty ..... 2 ☐
- Moderate difficulty ..... 3 ☐
- A lot of difficulty ..... 4 ☐

12. Because of your eyesight, how much difficulty do you have taking part in active sports or other outdoor activities that you enjoy (like hiking, swimming, aerobics, team sports, or jogging)?

*(Mark One)*

- No difficulty at all ..... 1 ☐
- A little difficulty ..... 2 ☐
- Moderate difficulty ..... 3 ☐
- A lot of difficulty ..... 4 ☐
- Never try to do these activities because of vision ..... 5 ☐
- Never do these activities for other reasons ..... 6 ☐

# Ocular Surface Disease Index© (OSDI©)[2]

Ask your patient the following 12 questions, and circle the number in the box that best represents each answer. Then, fill in boxes A, B, C, D, and E according to the instructions beside each.

## HAVE YOU EXPERIENCED ANY OF THE FOLLOWING *DURING THE LAST WEEK*:

| | All of the time | Most of the time | Half of the time | Some of the time | None of the time |
|---|---|---|---|---|---|
| 1. Eyes that are sensitive to light? | 4 | 3 | 2 | 1 | 0 |
| 2. Eyes that feel gritty? | 4 | 3 | 2 | 1 | 0 |
| 3. Painful or sore eyes? | 4 | 3 | 2 | 1 | 0 |
| 4. Blurred vision? | 4 | 3 | 2 | 1 | 0 |
| 5. Poor vision? | 4 | 3 | 2 | 1 | 0 |

**Subtotal score for answers 1 to 5** (A)

## HAVE PROBLEMS WITH YOUR EYES LIMITED YOU IN PERFORMING ANY OF THE FOLLOWING *DURING THE LAST WEEK*:

| | All of the time | Most of the time | Half of the time | Some of the time | None of the time | |
|---|---|---|---|---|---|---|
| 6. Reading? | 4 | 3 | 2 | 1 | 0 | N/A |
| 7. Driving at night? | 4 | 3 | 2 | 1 | 0 | N/A |
| 8. Working with a computer or bank | 4 | 3 | 2 | 1 | 0 | N/A |
| 9. Watching TV? | | | | | | |

**Subtotal score for answers 6 to 9** (B)

## HAVE YOUR EYES FELT UNCOMFORTABLE IN ANY OF THE FOLLOWING SITUATIONS *DURING THE LAST WEEK*:

| | All of the time | Most of the time | Half of the time | Some of the time | None of the time | |
|---|---|---|---|---|---|---|
| 10. Windy conditions? | 4 | 3 | 2 | 1 | 0 | N/A |
| 11. Places or areas with low humidity (very dry)? | 4 | 3 | 2 | 1 | 0 | N/A |
| 12. Areas that are air conditioned? | 4 | 3 | 2 | 1 | 0 | N/A |

**Subtotal score for answers 10 to 12** (C)

**ADD SUBTOTALS A, B, AND C TO OBTAIN D**
**(D = SUM OF SCORES FOR ALL QUESTIONS ANSWERED)** (D)

**TOTAL NUMBER OF QUESTIONS ANSWERED**
**(DO NOT INCLUDE QUESTIONS ANSWERED N/A)** (E)

**Please turn over the questionnaire to calculate the patient's final OSDI© score.**

# Patient Health Questionnaire

| PHQ-4 | | | | |
|---|---|---|---|---|
| **Over the last 2 weeks, how often have you been bothered by the following problems?** *(Use "✔" to indicate your answer)* | Not at all | Several days | More than half the days | Nearly every day |
| 1. Feeling nervous, anxious or on edge | 0 | 1 | 2 | 3 |
| 2. Not being able to stop or control worrying | 0 | 1 | 2 | 3 |
| 3. Little interest or pleasure in doing things | 0 | 1 | 2 | 3 |
| 4. Feeling down, depressed, or hopeless | 0 | 1 | 2 | 3 |

***(For office coding: Total Score T___ = ___ + ___ + ___)***

Measures Current State of Mind

# Life Orientation Test

**Revised Life Orientation Test (LOT-R)**

**Instructions:**
Please answer the following questions about yourself by indicating the extent of your agreement using the following scale:

[0] = strongly disagree
[1] = disagree
[2] = neutral
[3] = agree
[4] = strongly agree

Be as honest as you can throughout, and try not to let your responses to one question influence your response to other questions. There are no right or wrong answers.

_____ 1. In uncertain times, I usually expect the best.
_____ 2. It's easy for me to relax.
_____ 3. If something can go wrong for me, it will.
_____ 4. I'm always optimistic about my future.
_____ 5. I enjoy my friends a lot.
_____ 6. It's important for me to keep busy.
_____ 7. I hardly ever expect things to go my way.
_____ 8. I don't get upset too easily.
_____ 9. I rarely count on good things happening to me.
_____ 10. Overall, I expect more good things to happen to me than bad.

**Scoring:**
1. Reverse code items 3, 7, and 9 prior to scoring (0=4) (1=3) (2=2) (3=1) (4=0).
2. Sum items 1, 3, 4, 7, 9, and 10 to obtain an overall score.

*Note* Items 2, 5, 6, and 8 are filler items only. They are not scored as part of the revised scale.

The revised scale was constructed in order to eliminate two items from the original scale, which dealt more with coping style than with positive expectations for future outcomes. The correlation between the revised scale and the original scale is .95.

**Reference:**
Scheier, M.F., Carver C.S., and Bridges, M.W. (1994). Distinguishing optimism from neuroticism (and trait anxiety, self-mastery, and self-esteem): A re-evaluation of the Life Orientation Test. *Journal of Personality and Social Psychology*, **67**, 1063-1078.

Measures Belief System and Attitudes

# Marlowe-Crowne Social Desirability

Do you say what you think, or do you tend to misrepresent your beliefs to earn the approval of others? Do you answer questions honestly, or do you say what you think other people want to hear?

Telling others what we think they want to hear is making the socially desirable response. Falling prey to social desirability may cause us to distort our beliefs and experiences in interviews or on psychological tests. The bias toward responding in socially desirable directions is also a source of error in the case study, survey, and testing methods. You can complete the Social-Desirability Scale devised by Crowne and Marlowe to gain insight into whether you have a tendency to produce socially desirable responses.

*Directions:* Read each item and decide whether it is true (T) or false (F) for you. Try to work rapidly and answer each question by clicking on the T or the F. Then click on Total Score to access the Scoring Key and interpret your answers.

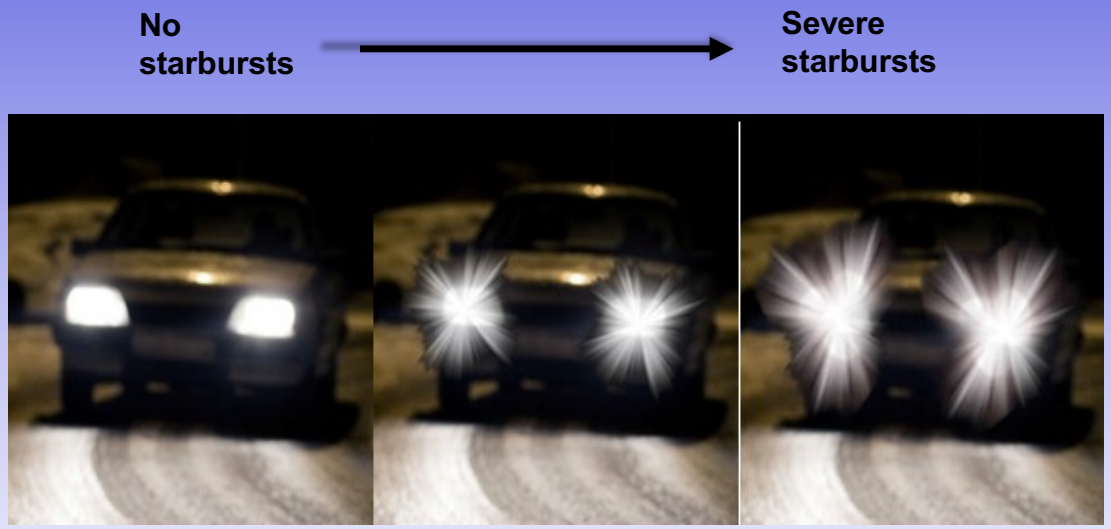
1. T F Before voting I thoroughly investigate the qualifications of all the candidates.
2. T F I never hesitate to go out of my way to help someone in trouble.
3. T F It is sometimes hard for me to go on with my work if I am not encouraged.
4. T F I have never intensely disliked anyone.
5. T F On occasions I have had doubts about my ability to succeed in life.
6. T F I sometimes feel resentful when I don't get my way.
7. T F I am always careful about my manner of dress.
8. T F My table manners at home are as good as when I eat out in a restaurant.
9. T F If I could get into a movie without paying and be sure I was not seen, I would probably do it.
10. T F On a few occasions, I have given up something be- cause I thought too little of my ability.
11. T F I like to gossip at times.
12. T F There have been times when I felt like rebelling against people in authority even though I knew they were right.
13. T F No matter who I'm talking to, I'm always a good listener.
14. T F I can remember "playing sick" to get out of some- thing.
6. T F There have been occasions when I have taken advantage of someone.
7. T F I'm always willing to admit it when I make a mistake.
17. T F I always try to practice what I preach.
18. T F I don't find it particularly difficult to get along with loudmouthed, obnoxious people.
19. T F I sometimes try to get even rather than forgive and forget.
20. T F When I don't know something I don't mind at all admitting it.
21. T F I am always courteous, even to people who are dis- agreeable.
22. T F At times I have really insisted on having things my own way.
23. T F There have been occasions when I felt like smash- ing things.
24. T F I would never think of letting someone else be punished for my wrong-doings.
25. T F I never resent being asked to return a favor.
26. T F I have never been irked when people expressed ideas very different from my own.
27. T F I never make a long trip without checking the safety of my car.
28. T F There have been times when I was quite jealous of the good fortune of others.
29. T F I have almost never felt the urge to tell someone off.
30. T F I am sometimes irritated by people who ask favors of me.
31. T F I have never felt that I was punished without cause.
32. T F I sometimes think when people have a misfortune they only got what they deserved.
33. T F I have never deliberately said something that hurt someone's feelings.

**Measures the Extent We Tell Others What We Think They Want To Hear**

# PROWL Questionnaire

- Vision quality
- Symptoms of aberration (glare, halos, starbursts)
- Dry eye symptoms
- Work productivity
- Depressive/anxiety symptoms
- Optimism
- Coping
- Expectations prior to surgery
- Satisfaction after surgery
- Social Desirability

# Example of Visual Aberration




In the last 7 days, have you seen any **starbursts**?

1. Yes, but ONLY when NOT wearing glasses or contact lenses
2. Yes, but ONLY when wearing glasses or contact lenses
3. Yes, when wearing AND when not wearing glasses or contact lenses
4. No, not at all

# 3-Month Visual Acuity Outcomes

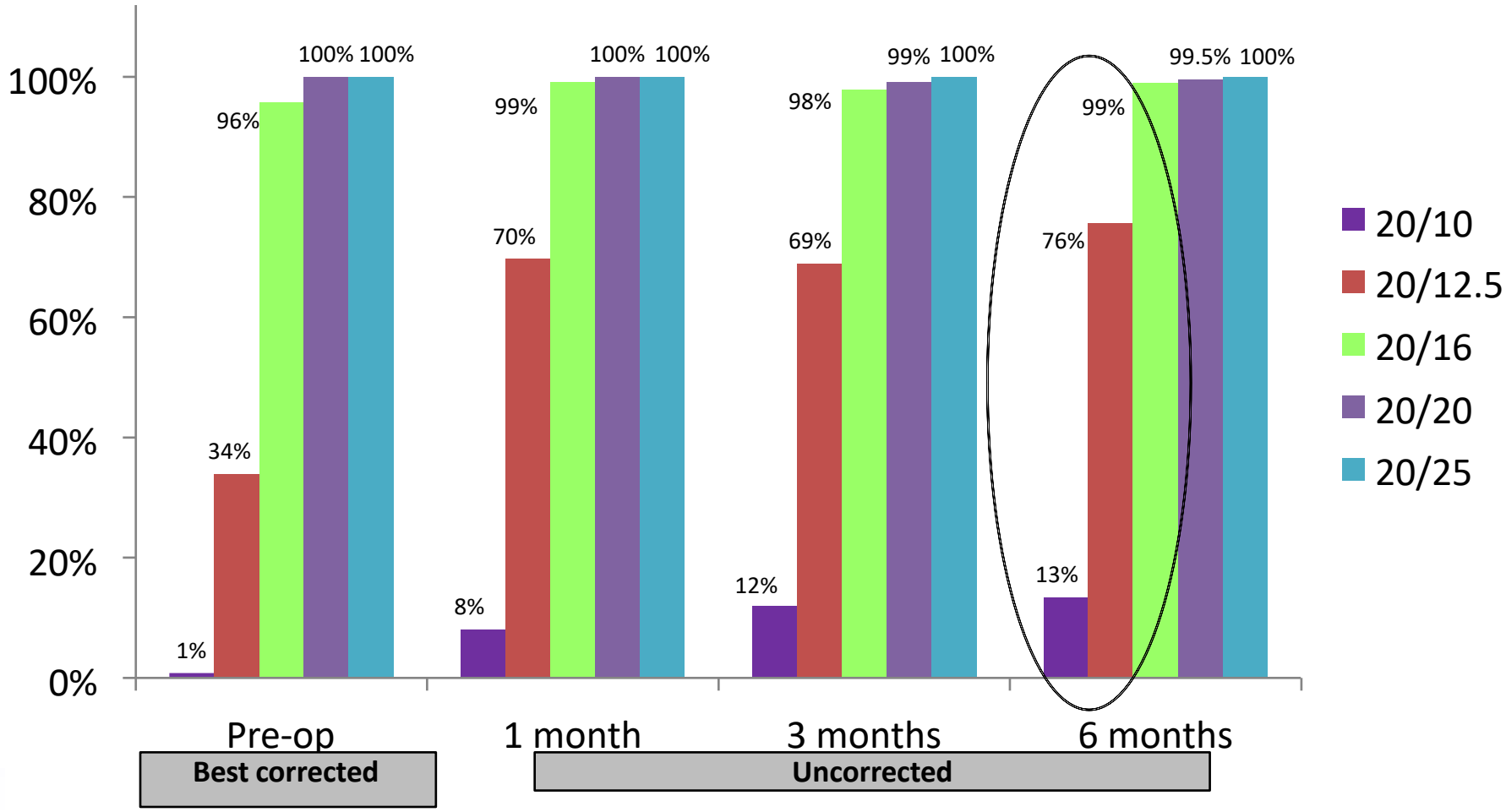
| UCVA 20/20 or better | PROWL-1 N=225 | PROWL-2 N=270 |
|---|---|---|
| | | |
| OD | 97% | 91% |
| OS | 98% | 92% |
| OU | 99% | 96% |

PROWL 1 US Naval Base San Diego, CA

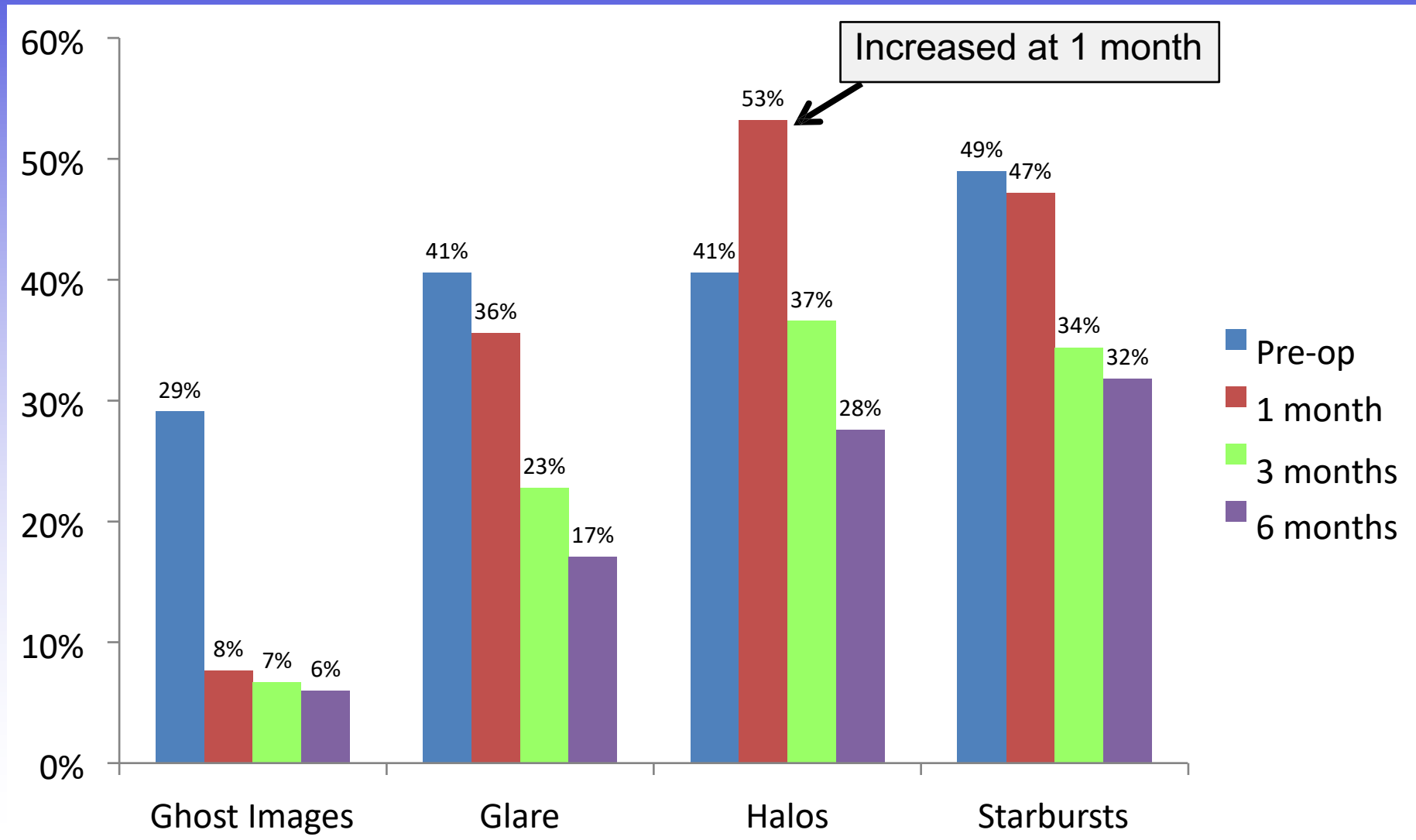
PROWL 2 5 Commercial US Sites

# Pre-op Best Corrected Visual Acuity vs. Post-op Binocular Uncorrected Visual Acuity

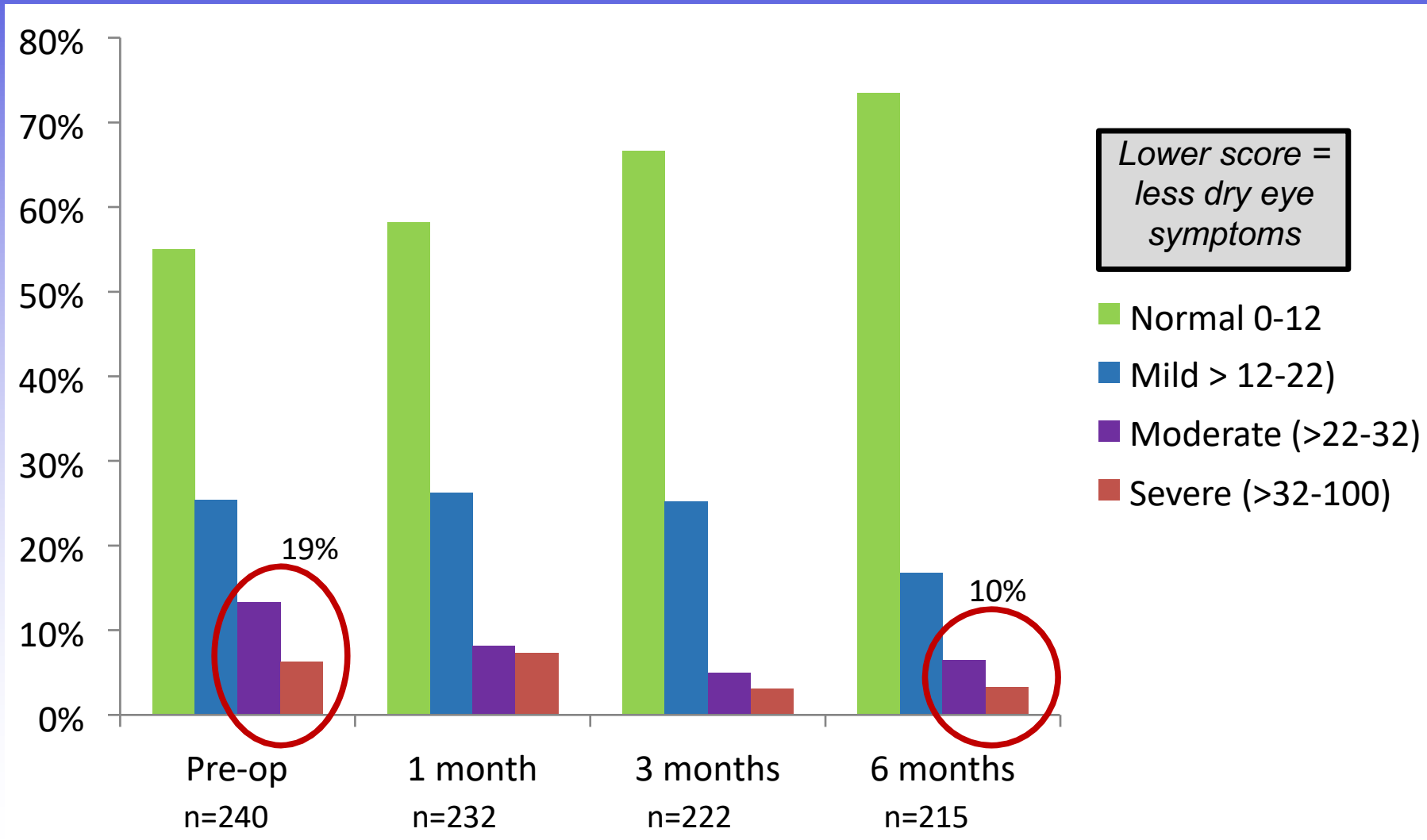
*Efficacy of All Treatments*



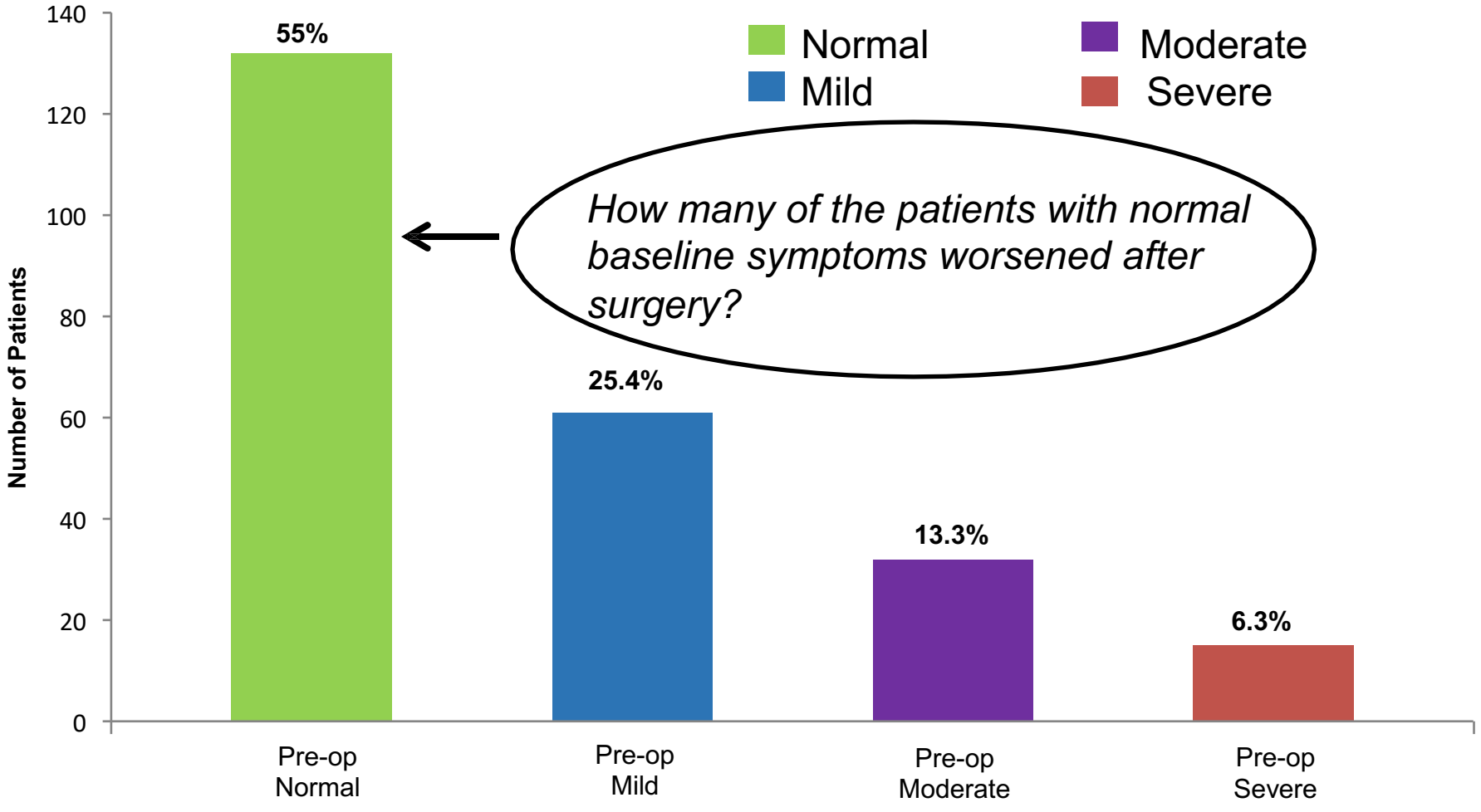
# Prevalence of *any* Visual Symptoms: Baseline vs. 1, 3, and 6 months



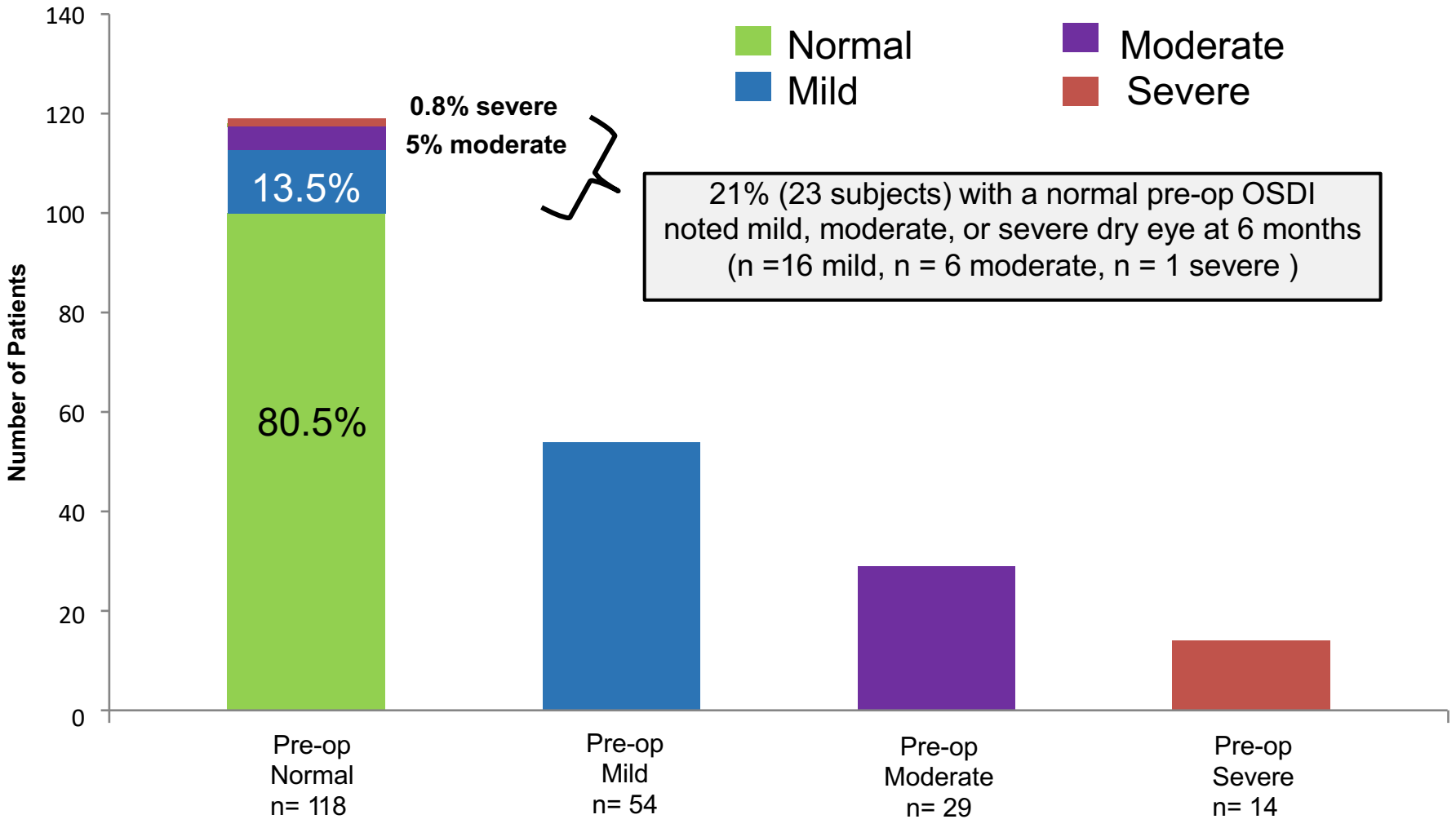
# Ocular Surface Disease Index (OSDI)



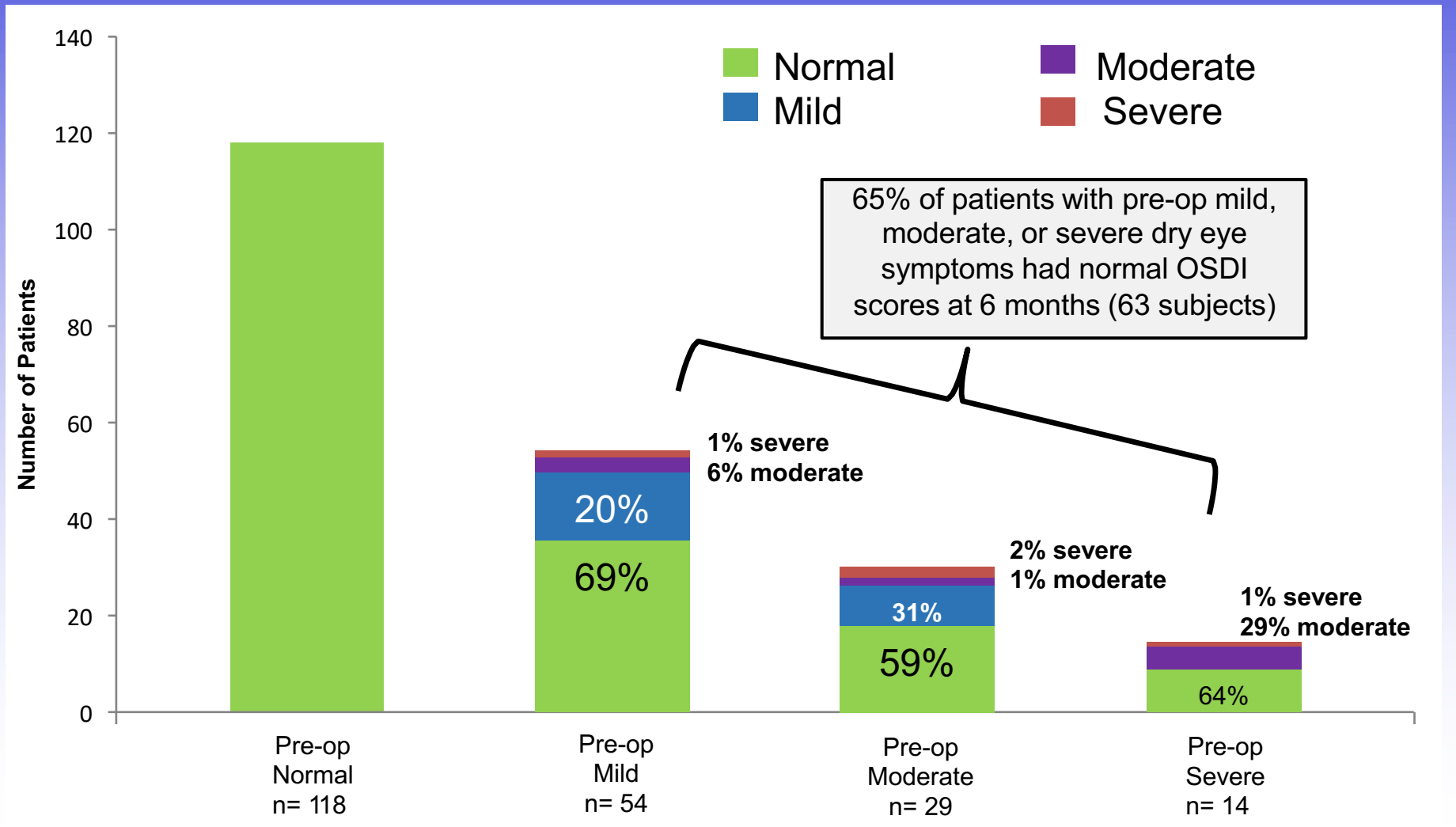
# Preoperative Ocular Surface Disease Index (OSDI) Scores



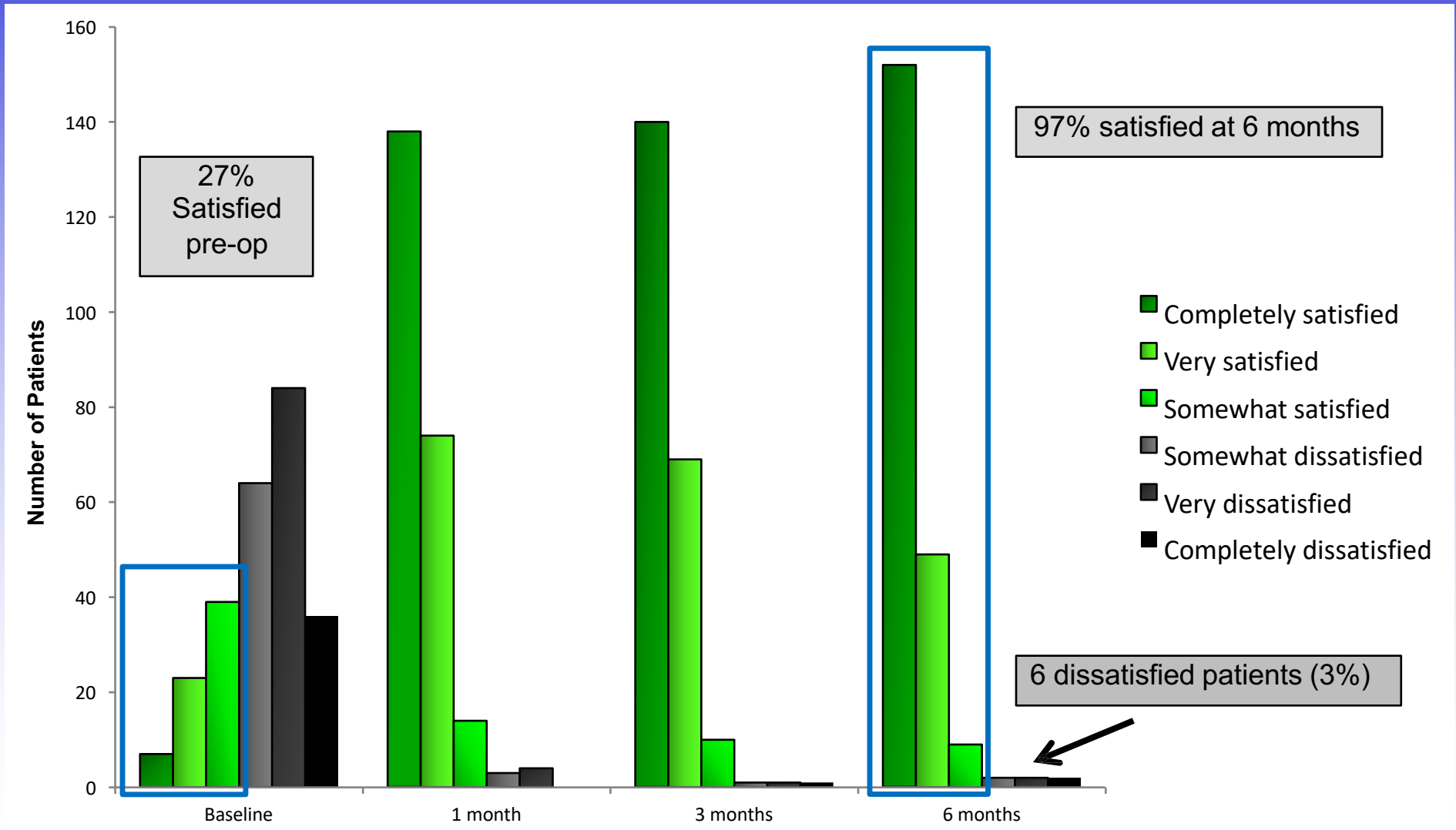
# Prevalence of Subjects with Normal Pre-op OSDI Scores Who Had Worsening OSDI Scores at 6 Months



# Prevalence of Subjects with Mild/Moderate/Severe OSDI Scores Who Had Normal OSDI Scores at 6 Months



# How satisfied are you with your present vision?



# PROWL Conclusions Support What We Already Knew

- Lasik is safe and effective
- Quality of life is improved with Lasik
- Lasik does not cause dry eye
- ODSI responses improved after Lasik
- Lasik does not cause glare and halos
- Symptoms are actually less after Lasik

*Lasik is so easy anyone can do it.*


E
F P
T O Z
[adult swim]

# Thank You