

# Council for Refractive Surgery Quality Assurance™

Presentation Regarding

## Quality of Life After Lasik

to

US Food & Drug Administration  
Ophthalmic Devices Panel

by

Glenn Hagele, Executive Director

April 25, 2008



# Disclosure

- No financial interest any medical devices
- Nonprofit refractive surgery patient advocacy
  - Funded through certification fees
- Provide surgeon certification
- Distribute objective patient information
- 50 Tough Questions For Your Lasik Doctor
- Opinions expressed are those of the presenter and not necessarily of USAEyes, its governing board, financial supporters, or those who have been certified by the organization

AVOID WORST LASIK DOCS - Lasik Patient Advocacy Approved Doctors - Lasik Eye Surgery Info - USA - Windows Inter...

http://www.usaeyes.org/

File Edit View Favorites Tools Help

AVOID WORST LASIK DOCS - Lasik Patient Advocacy ...

**LASIK PATIENT ADVOCACY**  
**USA Eyes**  
**SURGEON CERTIFICATION**

Learn About Lasik From Patients  
 Advocacy Certified Doctors

Search

Nonprofit  
 No Ads  
 No Sales

Home | About | Find Doctor | Considerations | Complications | Communication | Patient Forum

**Featured At**

**npr**  
**national  
 public  
 radio**

**How to Pick  
 A Lasik Doctor**

- Find Certified Lasik Doctor
- Why Choose a USAEyes Certified Lasik Doctor
- 50 Tough Questions For Your Lasik Doctor

**Ask Lasik Expert**

- Lasik Q&A Bulletin Board

**Lasik Top Articles**

- All About Lasik
- Lasik Cost
- Wavefront Custom Lasik
- Lasik FAQ

**Lasik Alternative  
 Top Articles**

- Monovision Lasik
- PRK, LASEK, Epi-Lasik
- RLE Lens Exchange

Digg, DeLicio.us, Reddit, Bookmark, etc. This Page



**Recent Lasik News**

**Nonprofit Lasik Patient Advocacy  
 Lasik Doctor Certification  
 Objective Lasik Information**

USAeyes provides frank Lasik information, lists Lasik doctors who meet specific patient outcome requirements, shows you steps to avoid problems, and answers just about all your Lasik questions. USAeyes does not provide Lasik eye surgery, doesn't accept advertising, is nonprofit, and all patient services are free.

Spend some time here and you can have confidence in your decisions about Lasik laser vision correction surgery. Conventional Lasik, wavefront custom Lasik, All-Laser Lasik, PRK, LASEK, Epi-Lasik, P-IOL, CK, and RLE are discussed without a sales pitch. At our Lasik Forum you can receive researched answers to your specific questions about Lasik and Lasik complications.

**How Lasik Works**

Lasik is the most often performed surgery in the US. Occasionally misspelled "Lasic", "Lasec", or "Lasix", Laser Assisted in-Situ Keratomileusis is a surgery that changes the shape of the cornea (clear front) of the eye to reduce the need for glasses or contacts. Lasik may correct nearsighted or farsighted vision, astigmatism, or reduce the need for reading glasses. It is medically safe and Lasik recovery is usually fast, but Lasik is not right for everyone. The most you can expect from Lasik is... [Lasik conf](#).

**PATIENT FORUM**

...discuss vision correction surgery with others

Done

Internet 100%

Quality of life has *always* been the yardstick by which Lasik patients have measured failure or success.

- Not Snellen 20/20
- Not Refraction
- Not any other objective measurement
- Always how Lasik affects a patient's life

# Procedure and Device Evaluation

- Chart data viable, but limited
- Move from doctor's chart to patient's opinion
- Research found three factors on which all success or failure of Lasik is based...

# Procedure and Device Evaluation

- Expectations
  - Fully informed
- Expectations
  - Must be reasonable
- Expectations
  - Realized through surgery

# Are Patients Getting What They Expect From Lasik & Their Doctor?

# USA<sup>E</sup>yes CORE Survey

**CRSQA**  
COUNCIL FOR REFRACTIVE SURGERY  
QUALITY ASSURANCE

**USA<sup>E</sup>yes**  
LASIK PATIENT ADVOCACY  
SURGEON CERTIFICATION

### Doctor Certification Patient Survey

Your surgeon is seeking certification of recertification from the Council for Refractive Surgery Quality Assurance (USA<sup>E</sup>yes), a nonprofit patient advocacy organization that oversees refractive surgery outcomes and patient satisfaction. Your answers to these questions will directly affect your doctor's ability to gain or maintain certification. Your participation is therefore critical and may help future patients.

Return the completed survey directly to USA<sup>E</sup>yes in the accompanying postage-paid envelope.

8540 Eyeglade Drive  
PO Box 217807  
Sacramento CA  
95821-1807

800-USA-EYES  
www.USA-Eyes.org

1) Surgeon's name: \_\_\_\_\_

2) Month and year of visit: \_\_\_\_\_

3) Sex:  
 Male  
 Female

4) Your home zip code: \_\_\_\_\_

5) Before this most recent eye surgery experience have you ever had any kind of eye surgery to which you need for corrective lenses?  
 No Previous Surgery  
 Yes, Previous Surgery  
 Not Sure

6) How many months since surgery?  
 1-3  
 4-6  
 7-12  
 13-18  
 19+

7) Before surgery, were you nearsighted (Myopic)?  
 Nearsighted (Myopic)  
 Farsighted (Hyperopic)  
 Neither  
 Not Sure

8) Before surgery, did you have astigmatism?  
 Yes  
 No  
 Not Sure

9) Did you have surgery on one or both eyes?  
 One eye  
 Both eyes

10) Did you have more than one surgery per eye?  
 Yes  
 No  
 Not Sure

11) Before surgery did you need reading glasses or bifocals?  
 Yes  
 No  
 Not Sure

Copyright © 2007-2008 by USAEyes. All rights reserved. Form USAEYES

# USA*Eyes* CORE Survey

- Competence Opinion Relative to Expectation (CORE)
- Structured with “As Expected” as baseline
  - Much better than expected
  - Better than expected
  - As Expected
  - Worse than expected
  - Much worse than expected

# USA*Eyes* CORE Survey

- Multi-Center
  - Current 6 surgeons, intent to expand
- Retrospective patient opinion survey
- Patients
  - Consecutive
  - All types of refractive procedures (Laser, Lens, Mechanical)
  - Six months postop
- Mailed hard copy surveys
- Responses mailed directly to USA*Eyes*
- Patient anonymity

# USA*Eyes* CORE Survey

- Mailed 1,800 surveys
  - 300 refractive surgery patients per surgeon
  - March 18 through April 16, 2008
- Received 553 responses as of April 20
  - 31% response rate
  - First surgeon distribution 38% response

# USA*Eyes* CORE Survey

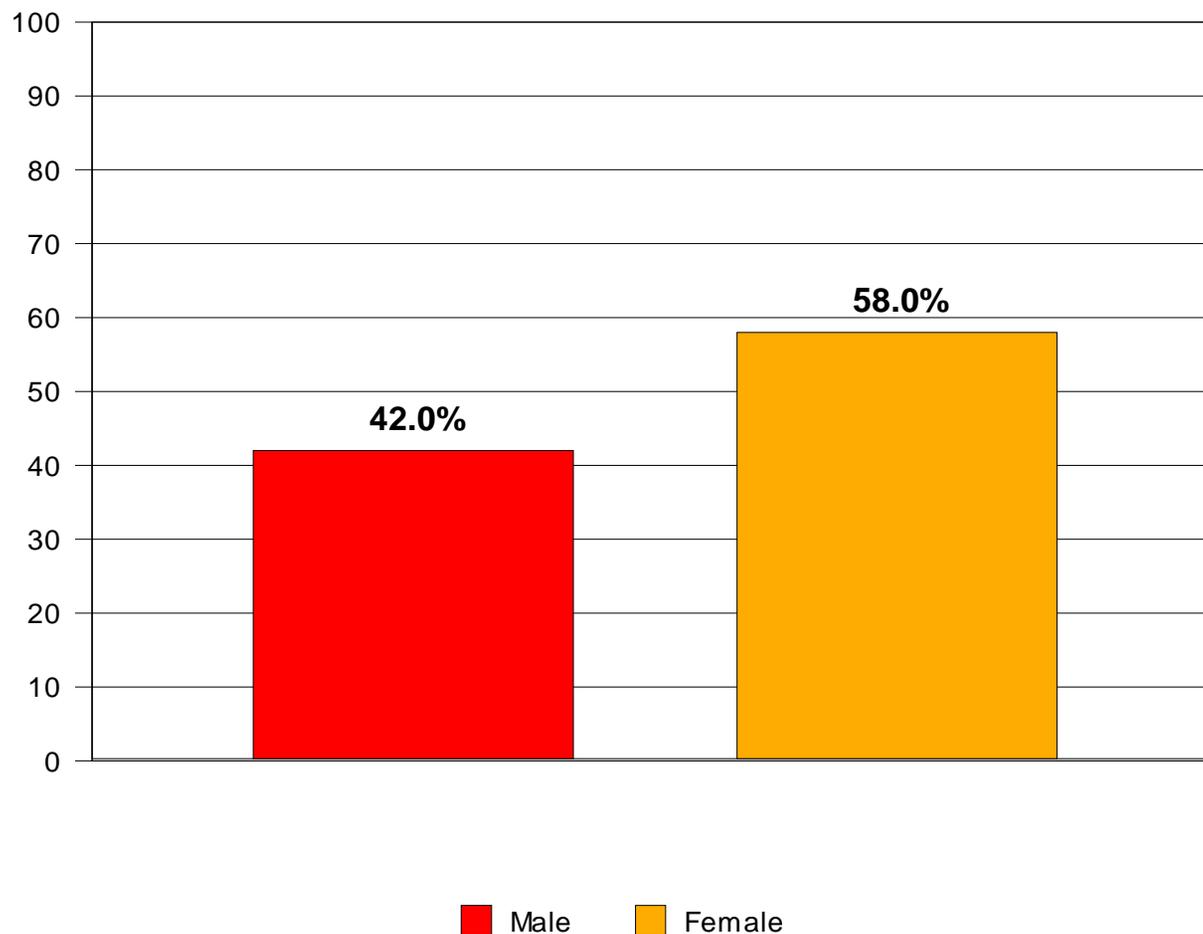
- Excluded patients who reported
  - Less than 6 months postop
  - Prior ocular surgery
  - Non-laser procedures (lens & mechanical)
- Eligible 462
  - 26% eligible response rate

# USA*Eyes* CORE Survey

- Preliminary Data
  - Still receiving survey responses
  - Less than one week from last distribution

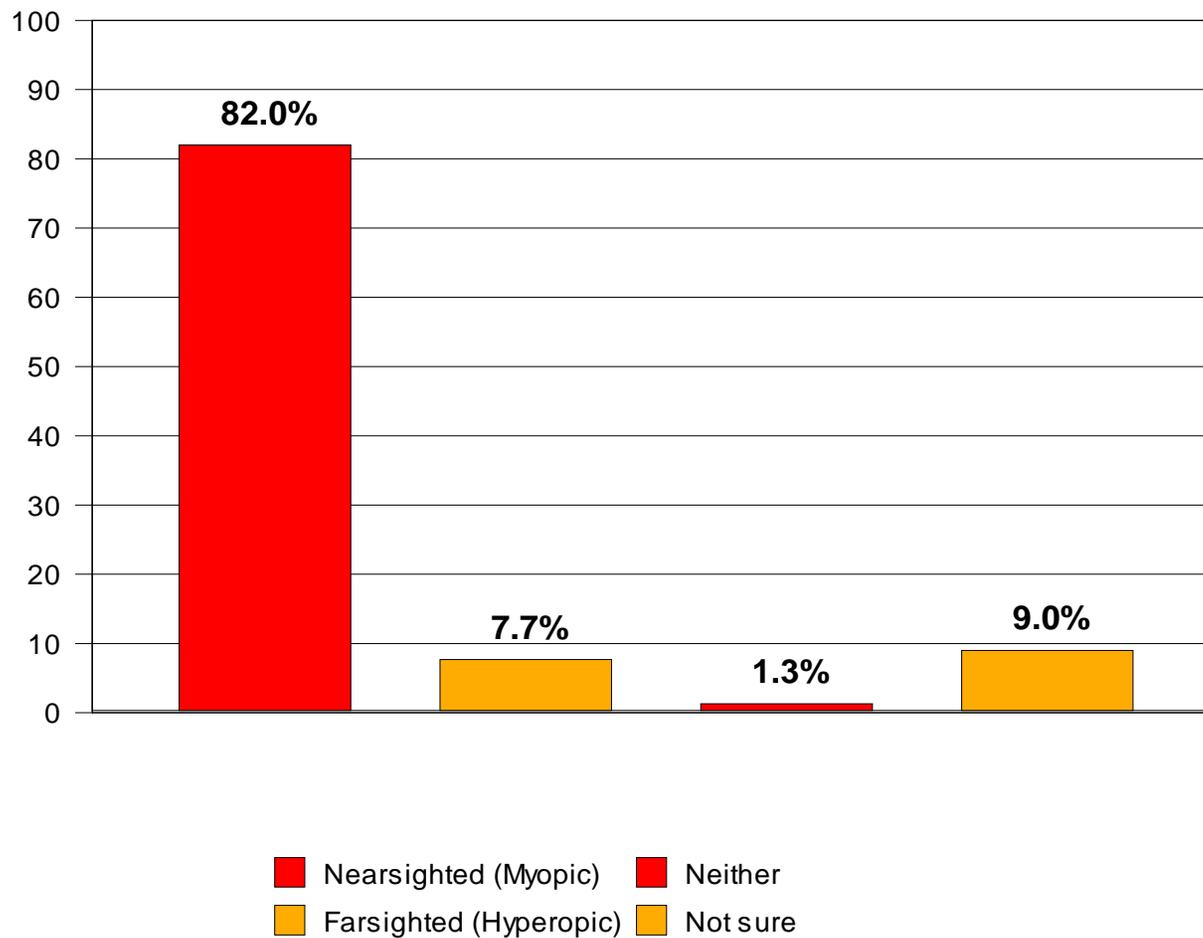
# USAeyes® CORE™ Vision Correction Surgery Patient Survey

## Gender



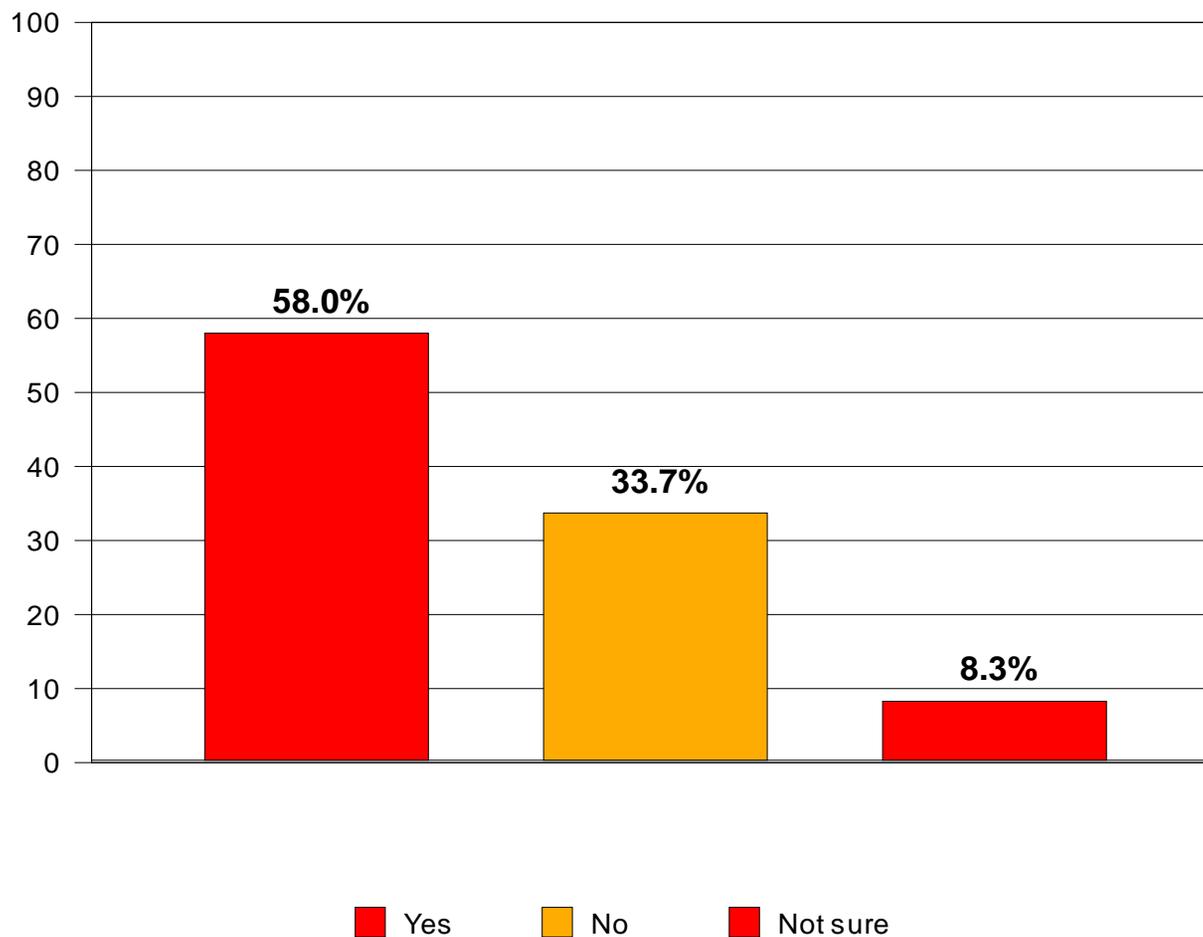
# USAeyes® CORE™ Vision Correction Surgery Patient Survey

## Preop Refractive Error



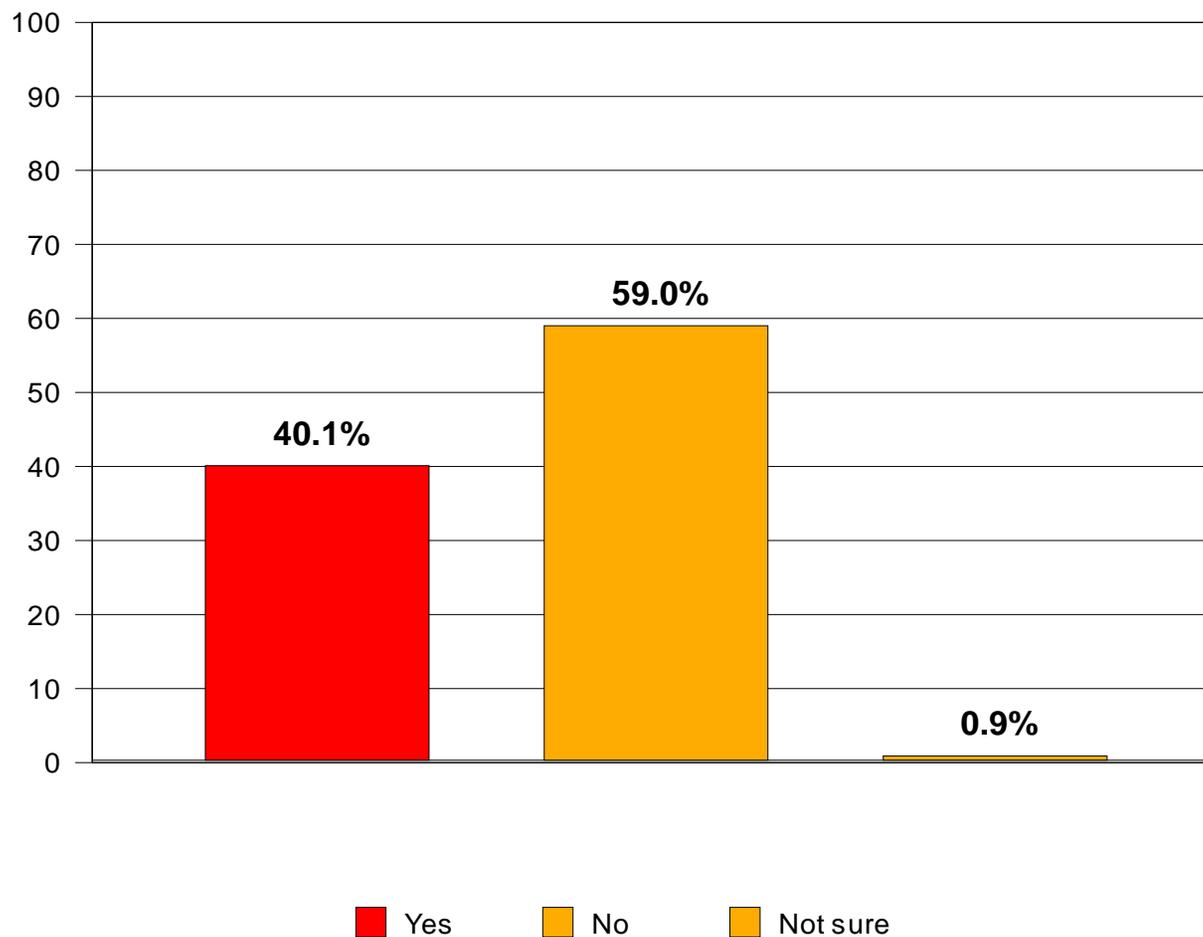
## USAeyes® CORE™ Vision Correction Surgery Patient Survey

### Preop Astigmatism



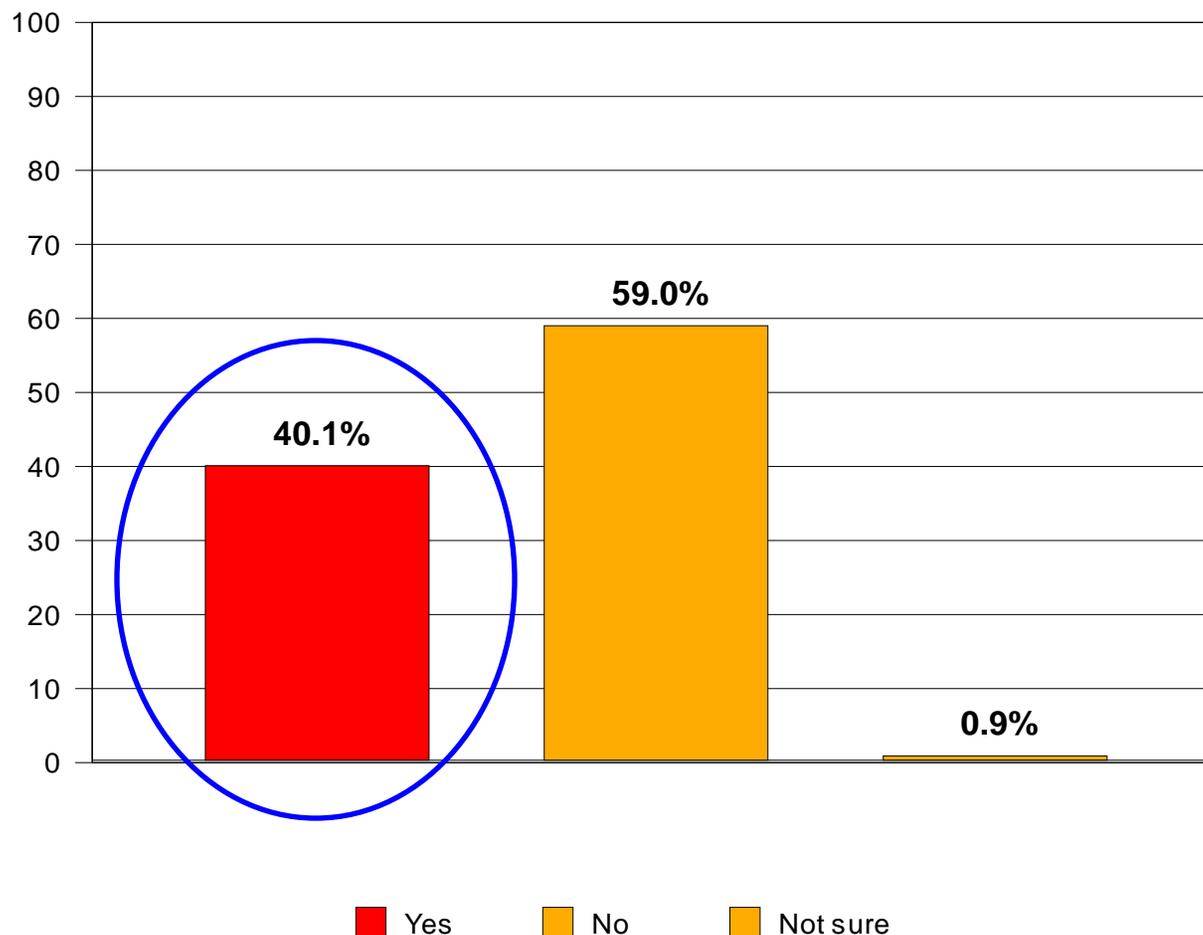
## USAeyes® CORE™ Vision Correction Surgery Patient Survey

### Preop Use of Reading Glasses/Bifocals



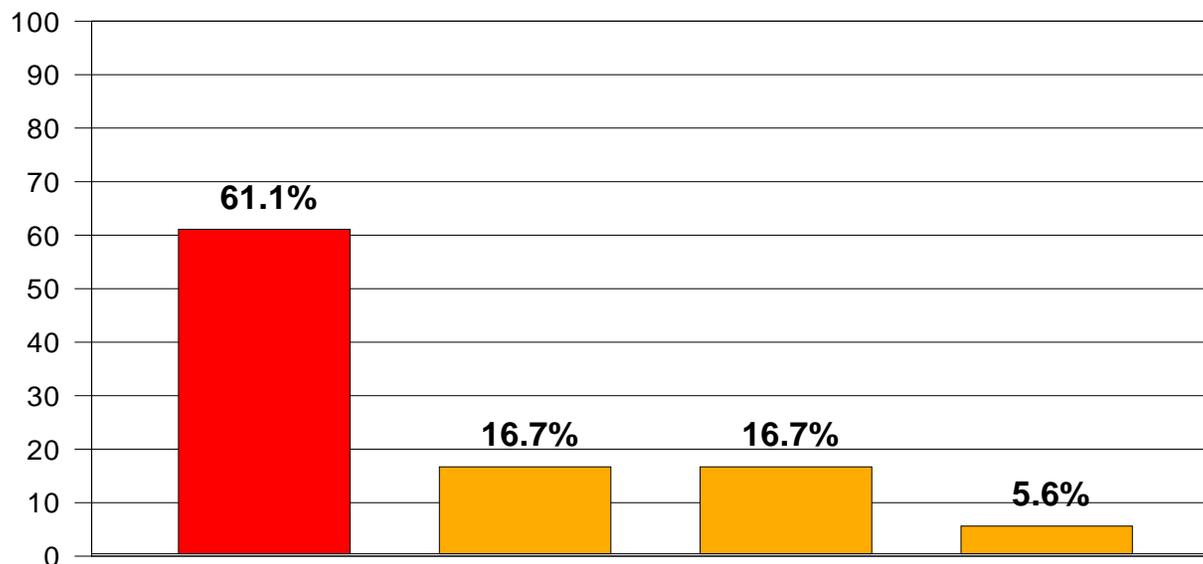
## USAeyes® CORE™ Vision Correction Surgery Patient Survey

### Preop Use of Reading Glasses/Bifocals



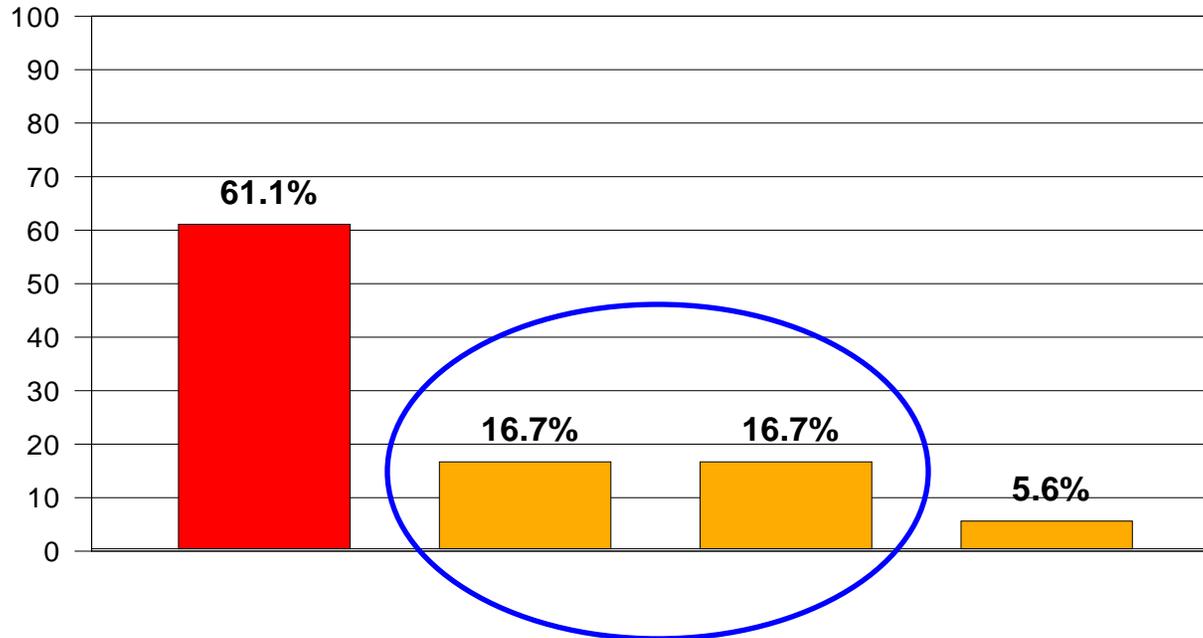
**40%** Report Effects of Presbyopia

## Selected Monovision Correction



- I did not need reading glasses or bifocals before surgery
- I had monovision correction
- I did not have monovision correction
- Not sure

## Selected Monovision Correction



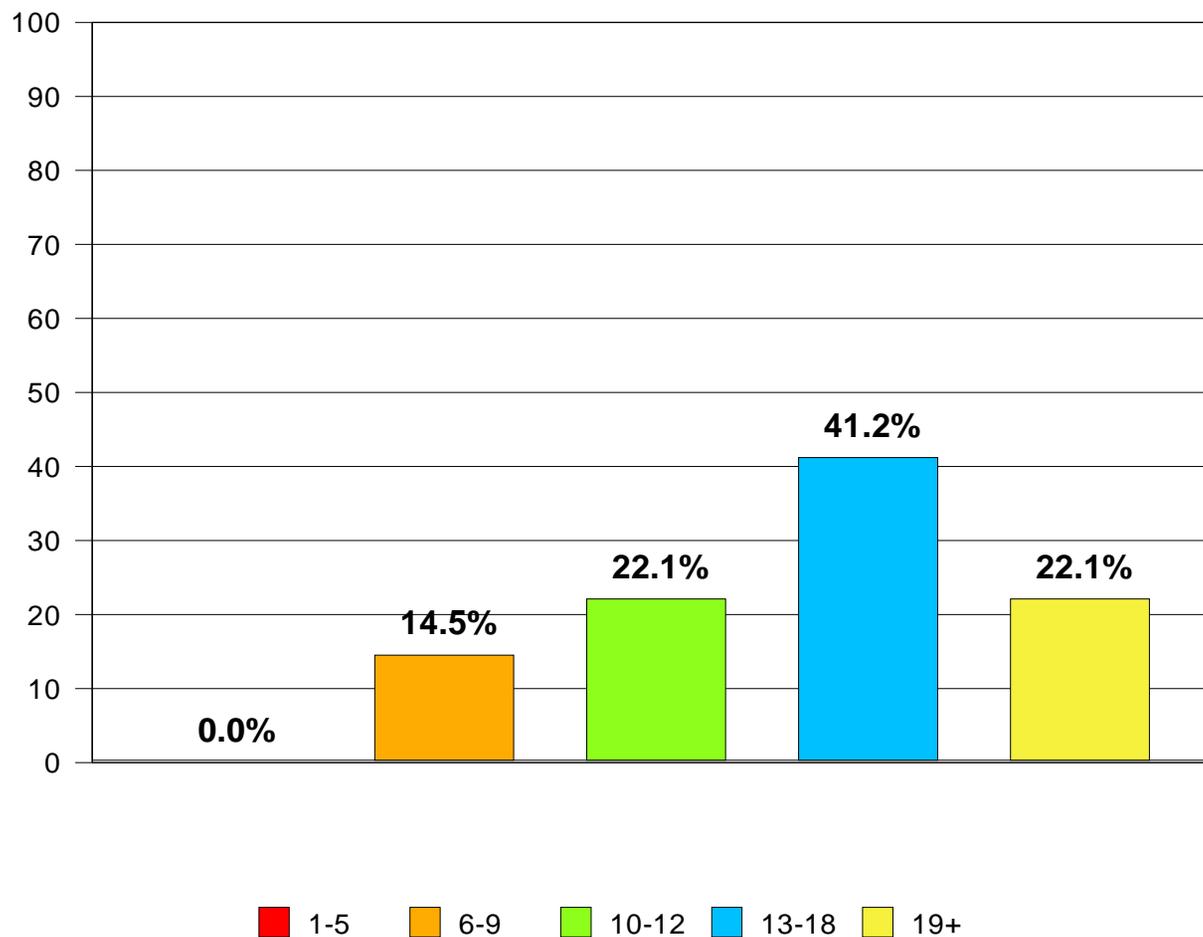
- I did not need reading glasses or bifocals before surgery
- I had monovision correction
- I did not have monovision correction
- Not sure

**17%**  
Specifically  
Selecting  
Monovision

**17%**  
Specifically Not  
Selecting  
Monovision

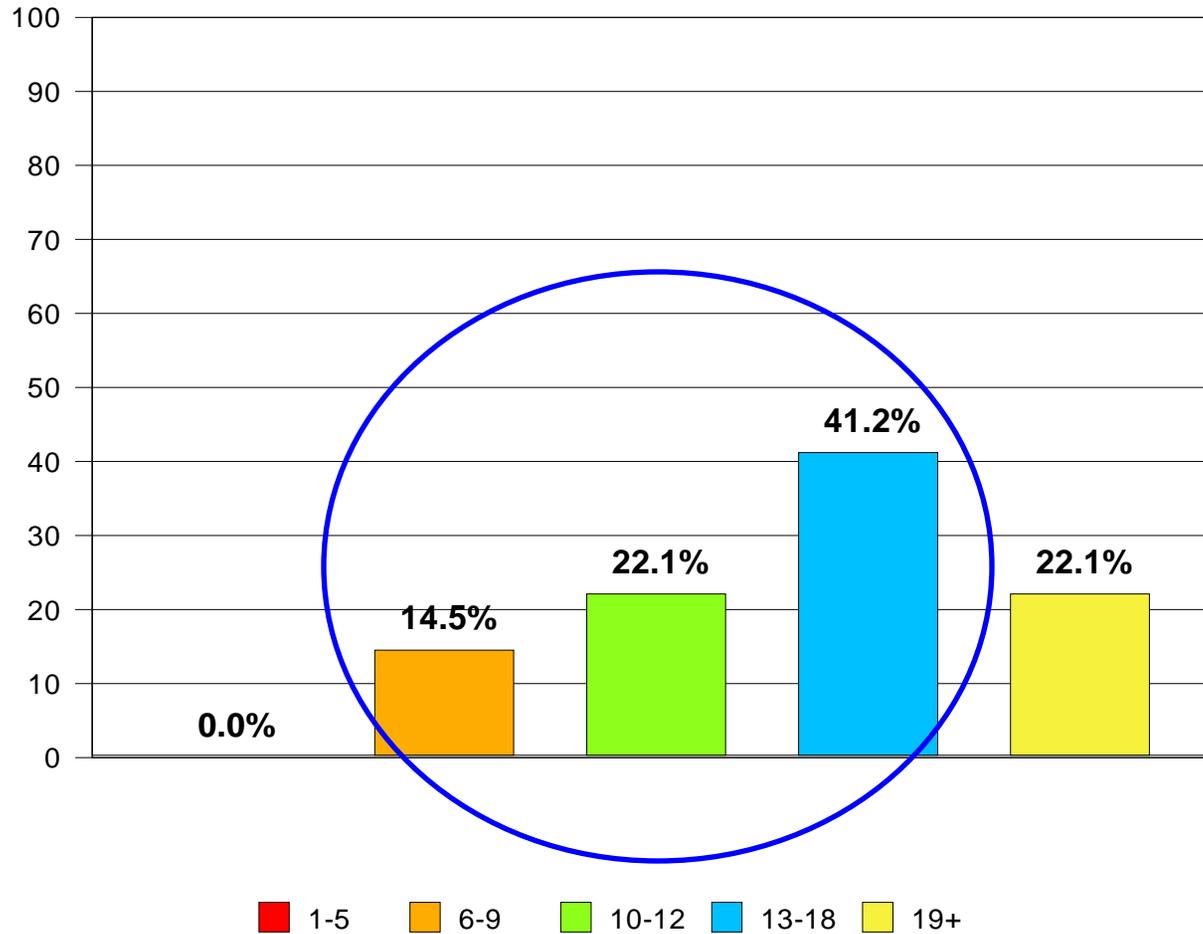
# USAeyes® CORE™ Vision Correction Surgery Patient Survey

## Months Postop



# USAeyes® CORE™ Vision Correction Surgery Patient Survey

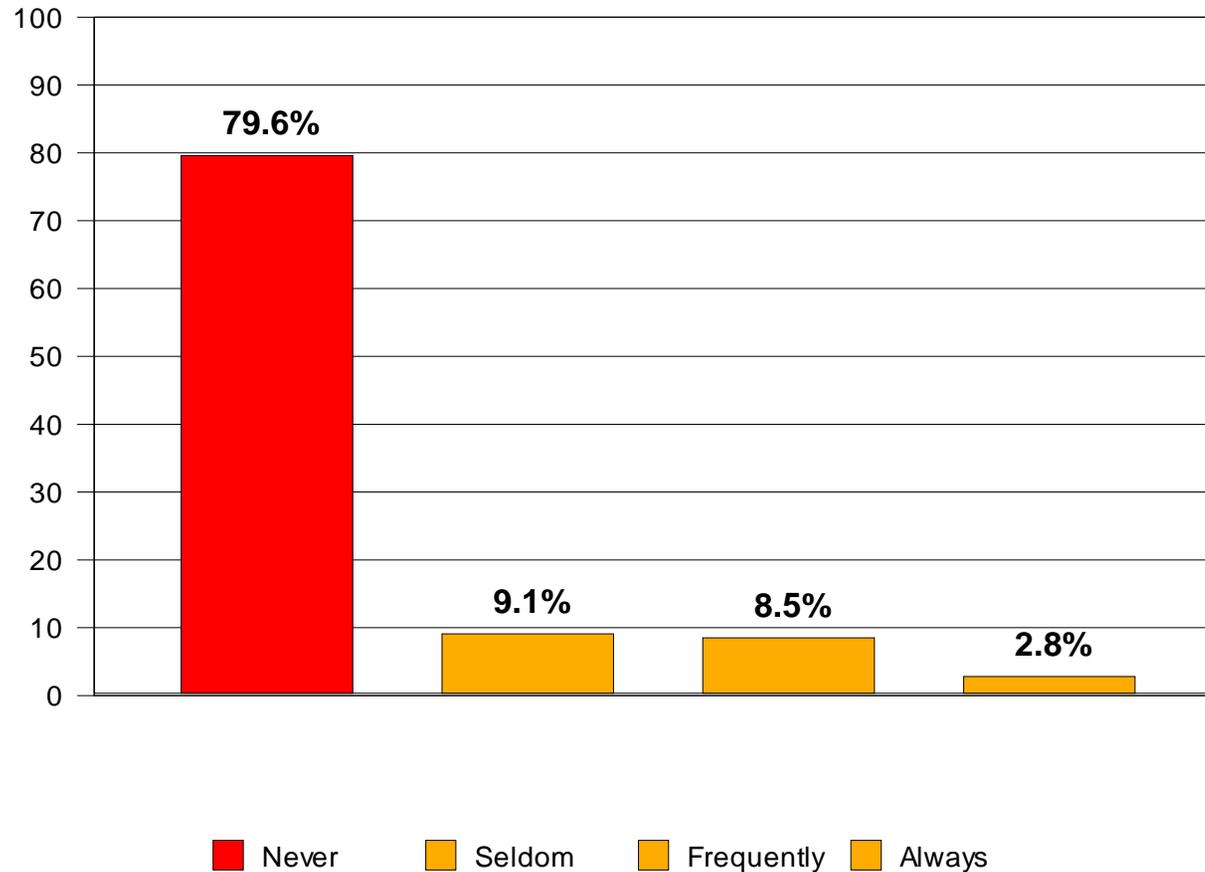
## Months Postop



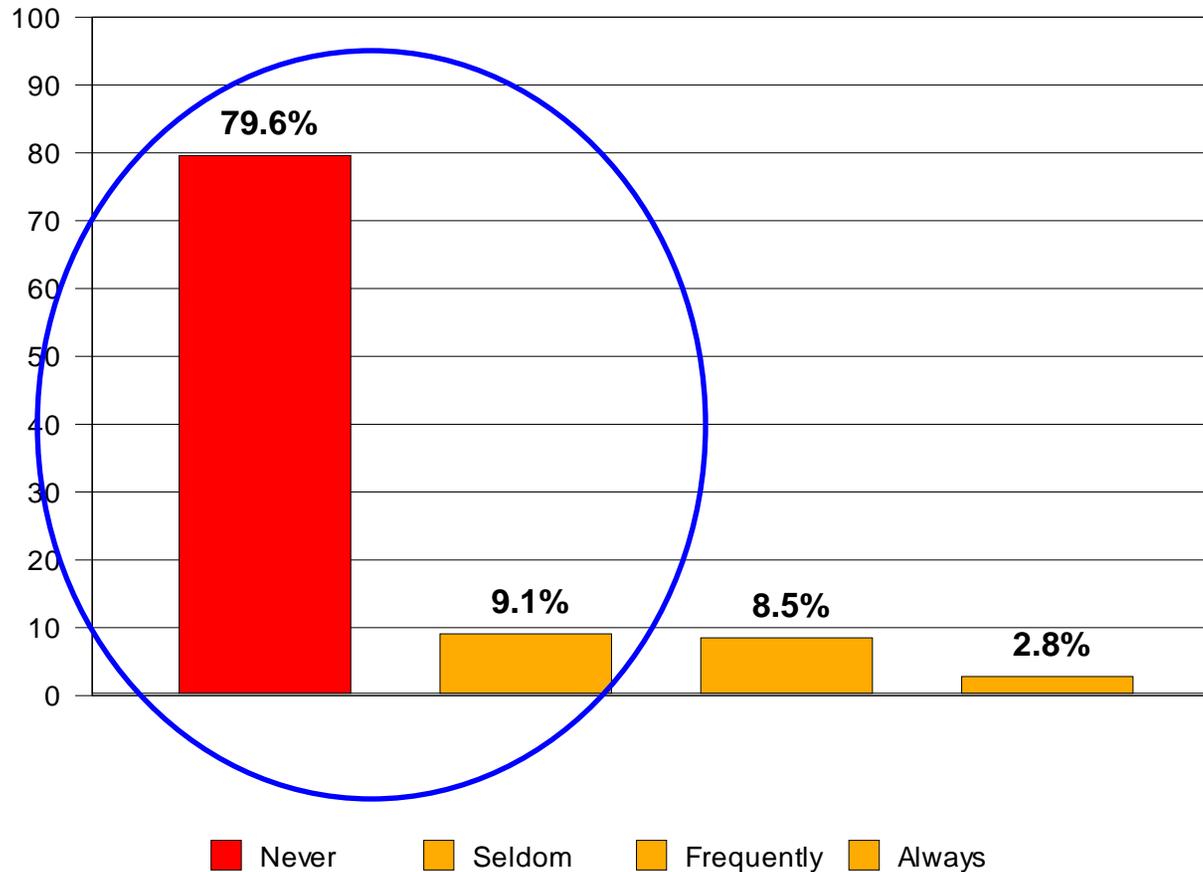
**78%** 6-18  
Months Postop

## USAeyes® CORE™ Vision Correction Surgery Patient Survey

### Postop Use of Corrective Lenses Including Reading Glasses

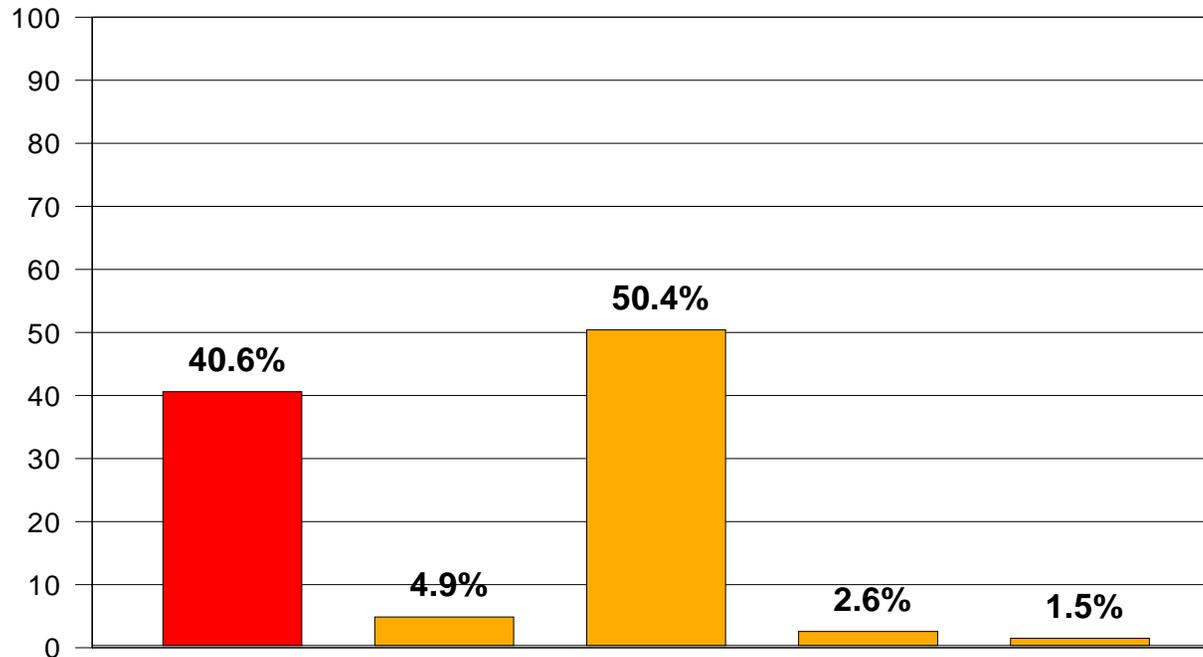


## Postop Use of Corrective Lenses Including Reading Glasses



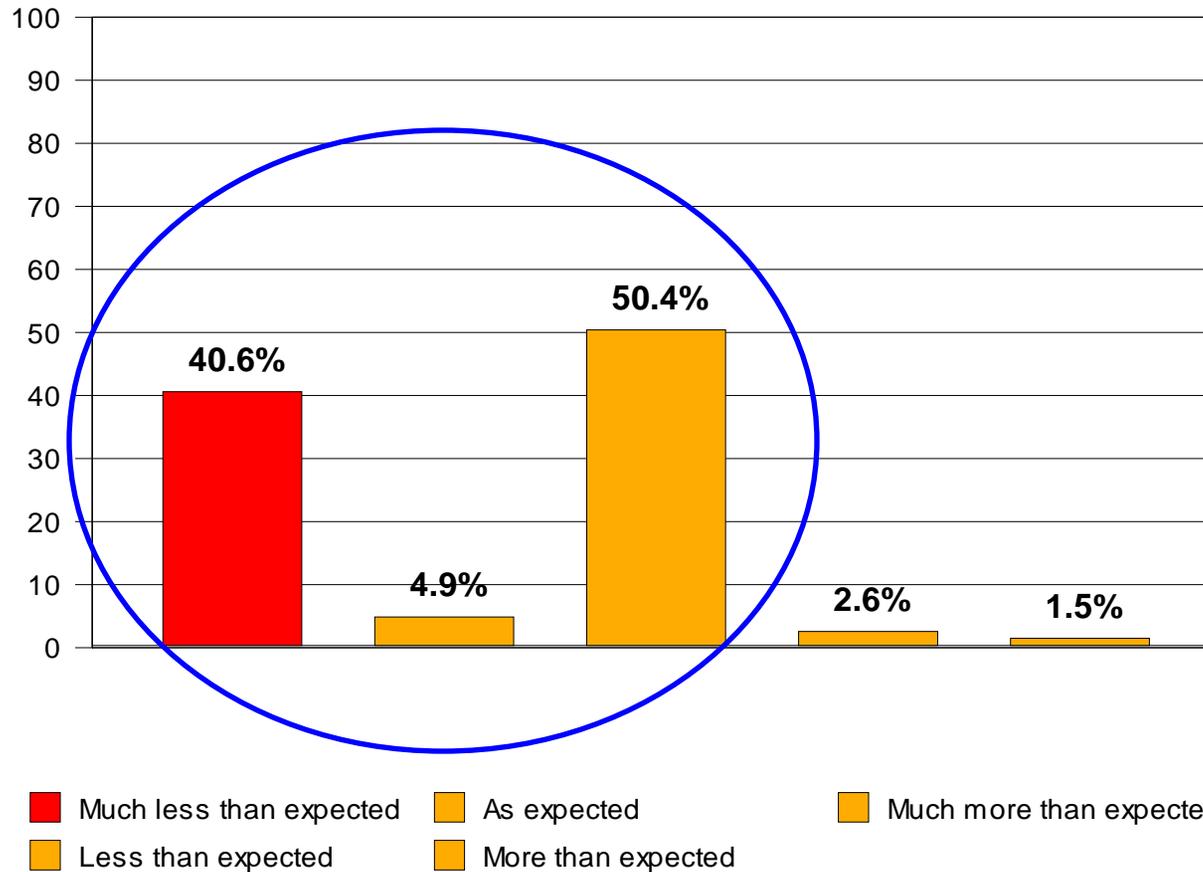
**89%** Never or Seldom Wear Corrective Lenses

## Postop Description of Corrective Lens Use



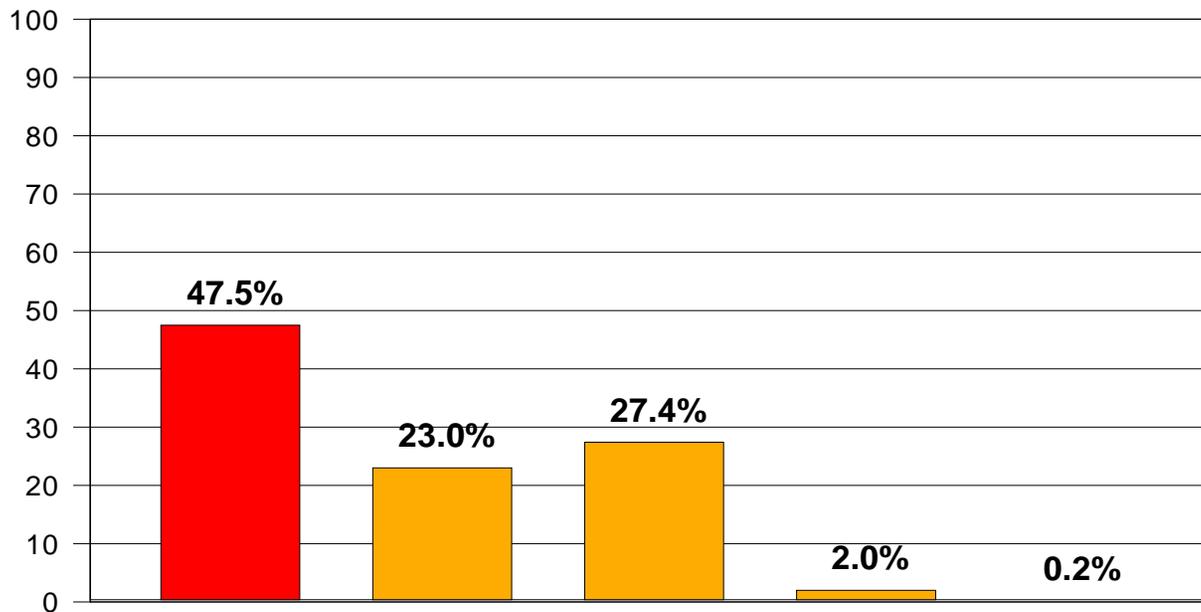
■ Much less than expected   ■ As expected   ■ Much more than expected  
■ Less than expected   ■ More than expected

## Postop Description of Corrective Lens Use



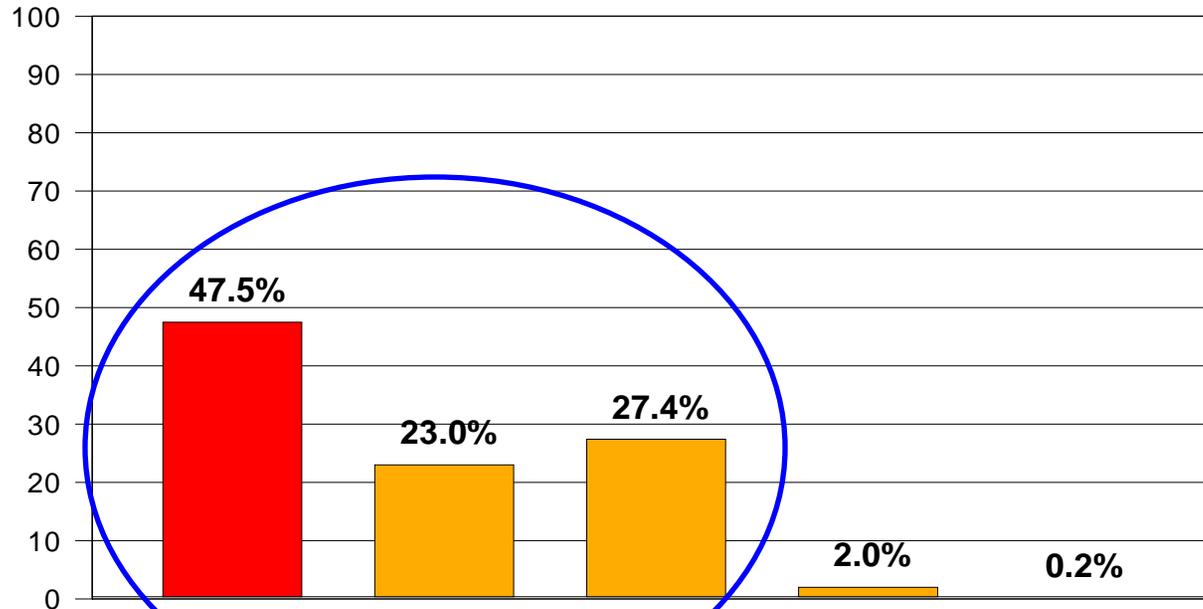
**96%** Wear Corrective Lenses As Frequent as Expected or Less

## Postop Quality Day Vision



- Much better than expected
- Better than expected
- As expected
- Worse than expected
- Much worse than expected

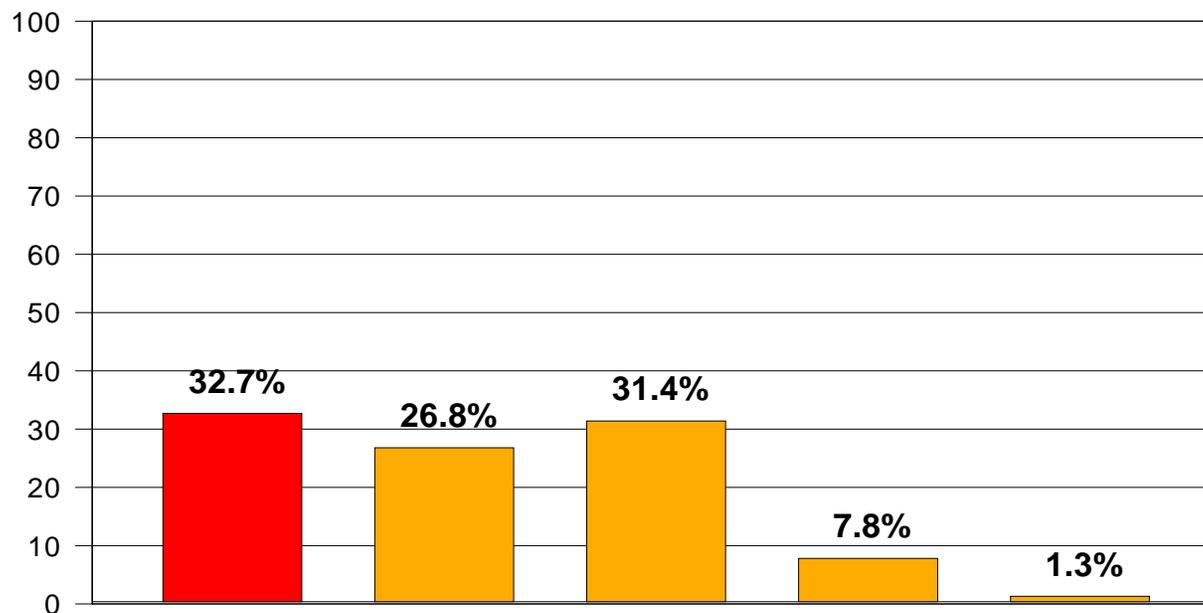
## Postop Quality Day Vision



- Much better than expected
- Better than expected
- As expected
- Worse than expected
- Much worse than expected

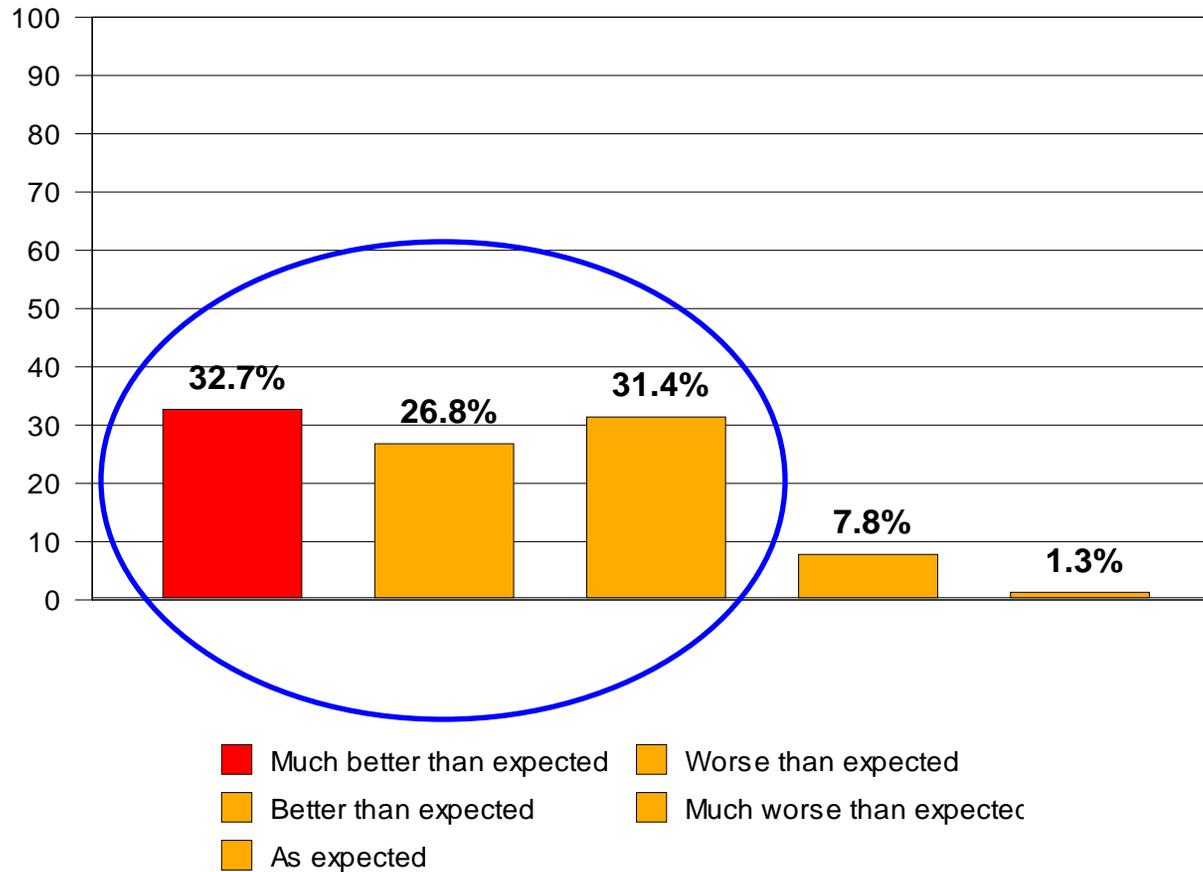
**98%** Quality of Day Vision As Expected or Better

## Postop Quality Night Vision



- Much better than expected
- Better than expected
- As expected
- Worse than expected
- Much worse than expected

## Postop Quality Night Vision

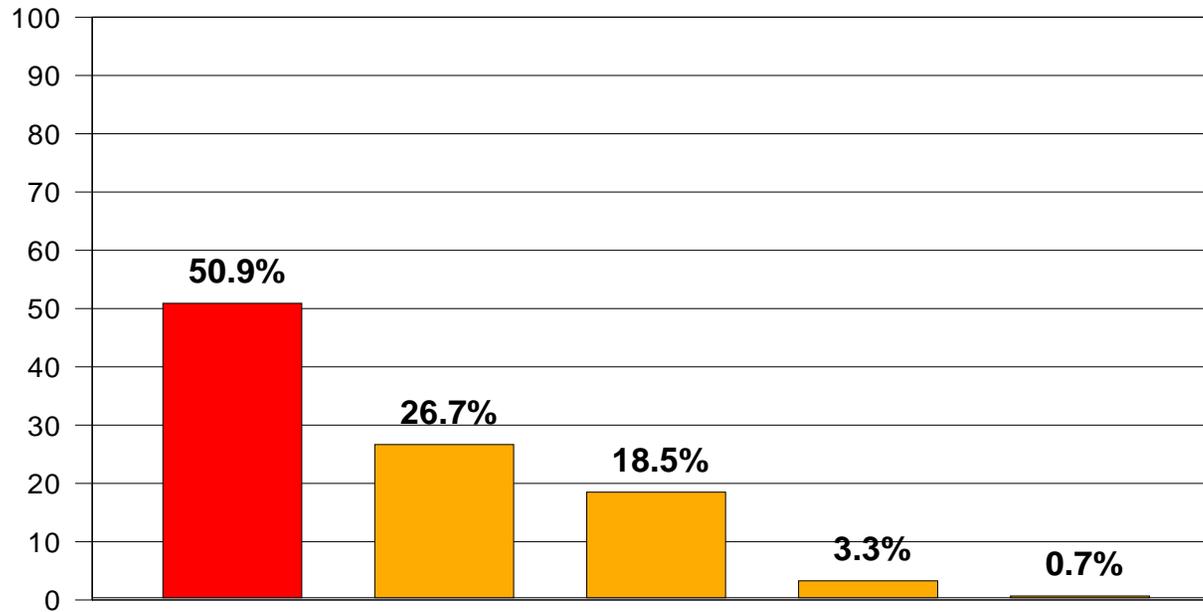


**91%** Quality of Night Vision As Expected or Better

**7%** Lower Than Day Vision

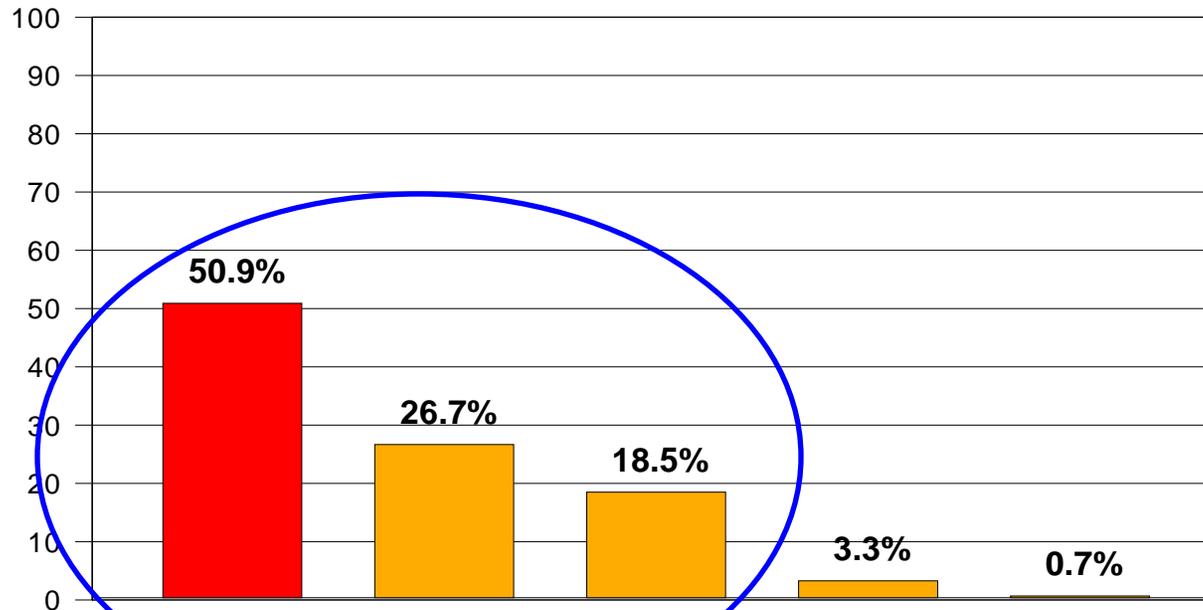
# USAeyes® CORE™ Vision Correction Surgery Patient Survey

## Preop With Lenses vs. Postop Without Lenses



- Much better than expected
- Better than expected
- As expected
- Much worse than expected
- Worse than expected

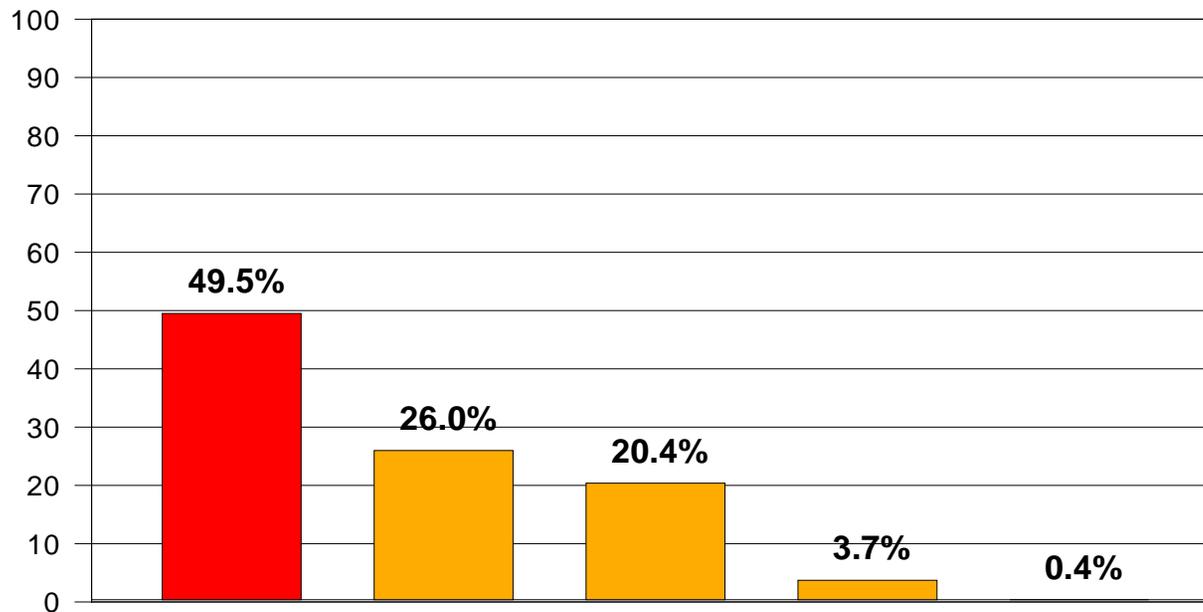
## Preop With Lenses vs. Postop Without Lenses



- Much better than expected
- Better than expected
- As expected
- Worse than expected
- Much worse than expected

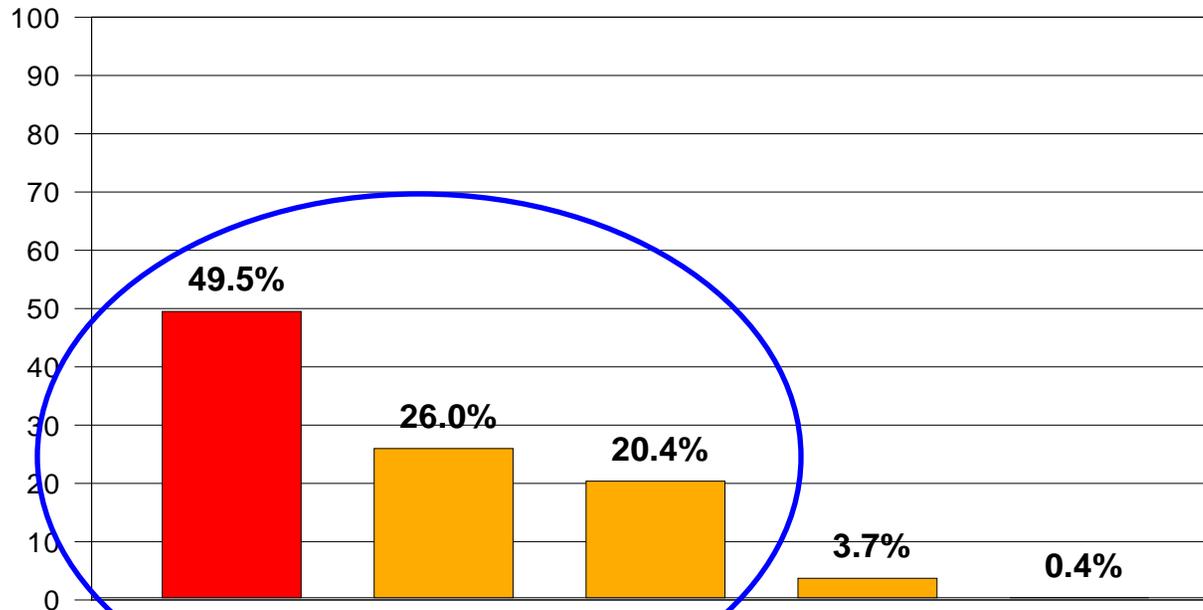
**96%** Postop Compared to Preop Quality of Vision As Expected or Better

## Postop Overall Quality of Vision



- Much better than expected
- Better than expected
- As expected
- Worse than expected
- Much worse than expected

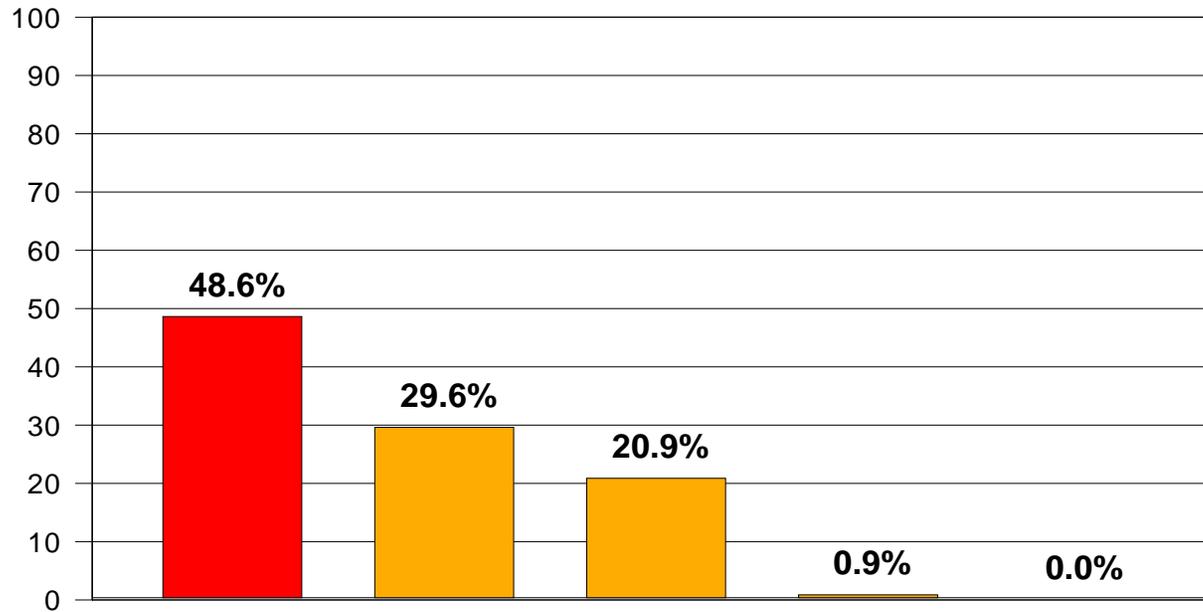
## Postop Overall Quality of Vision



- Much better than expected
- Better than expected
- As expected
- Worse than expected
- Much worse than expected

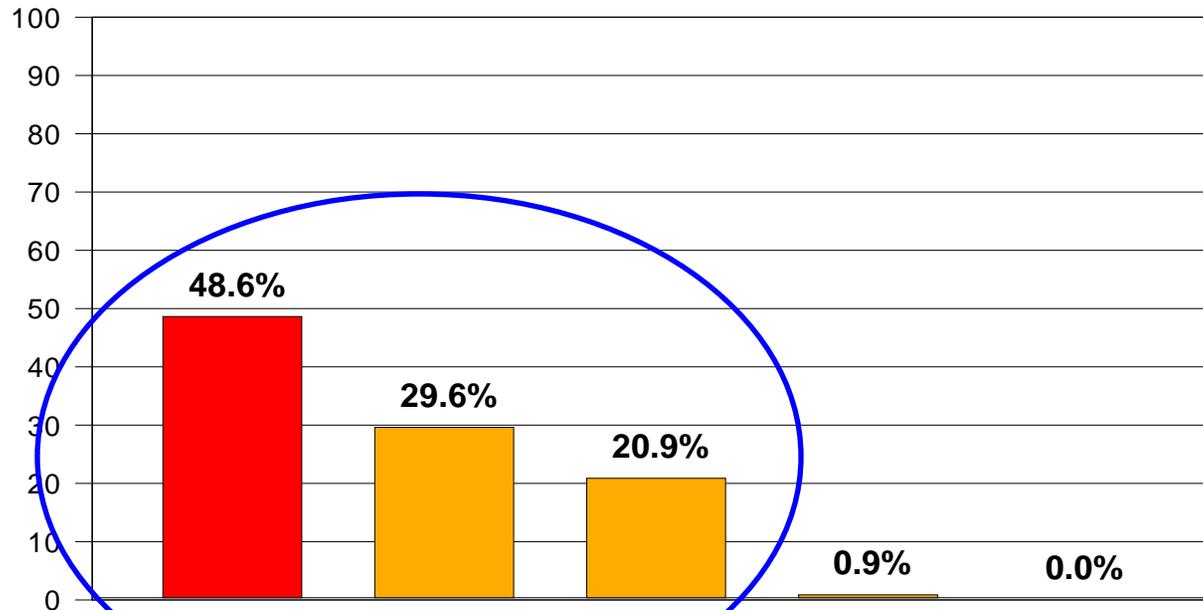
**96%** Overall  
Quality of  
Vision As  
Expected or  
Better

## Postop Quality of Life



- Much better than expected
- Better than expected
- As expected
- Worse than expected
- Much worse than expected

## Postop Quality of Life

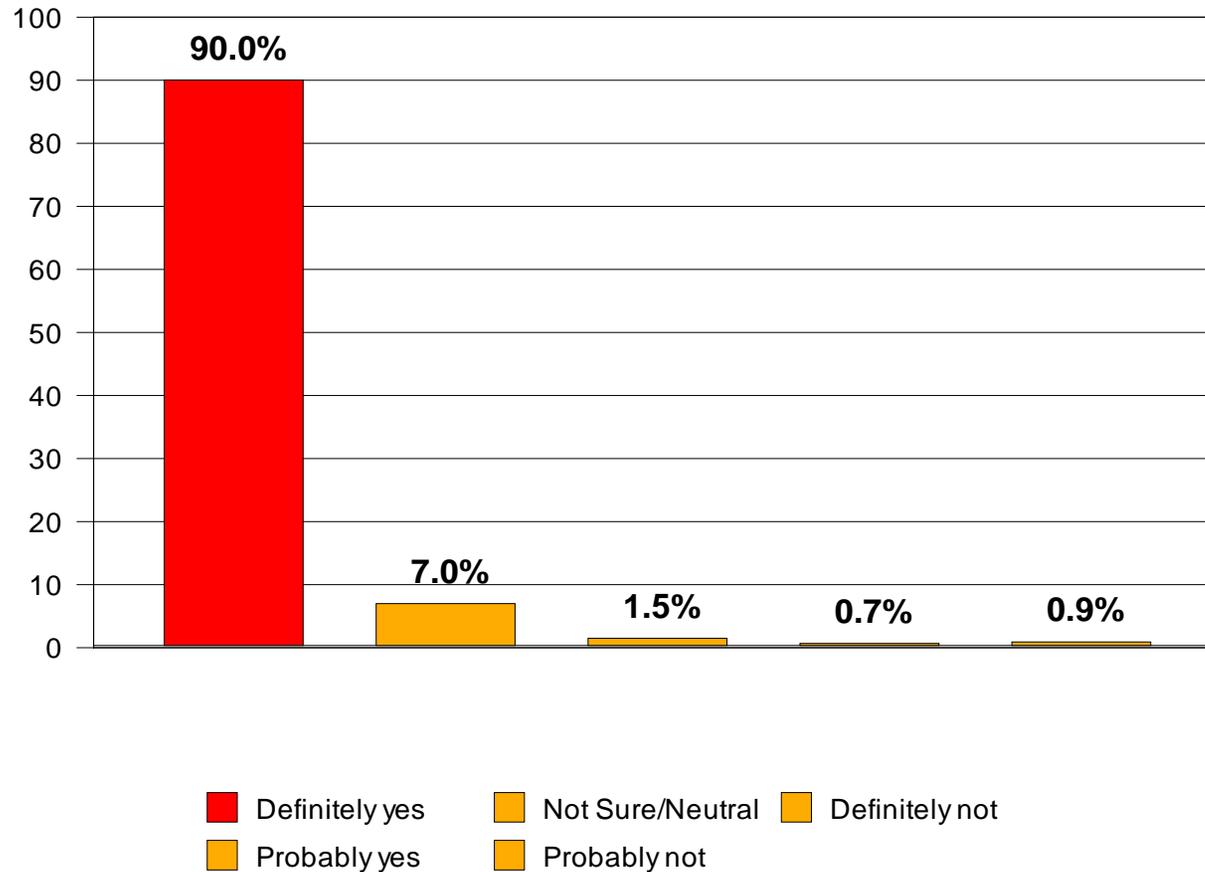


- Much better than expected
- Better than expected
- As expected
- Worse than expected
- Much worse than expected

**99%** Quality of Life As Expected or Better

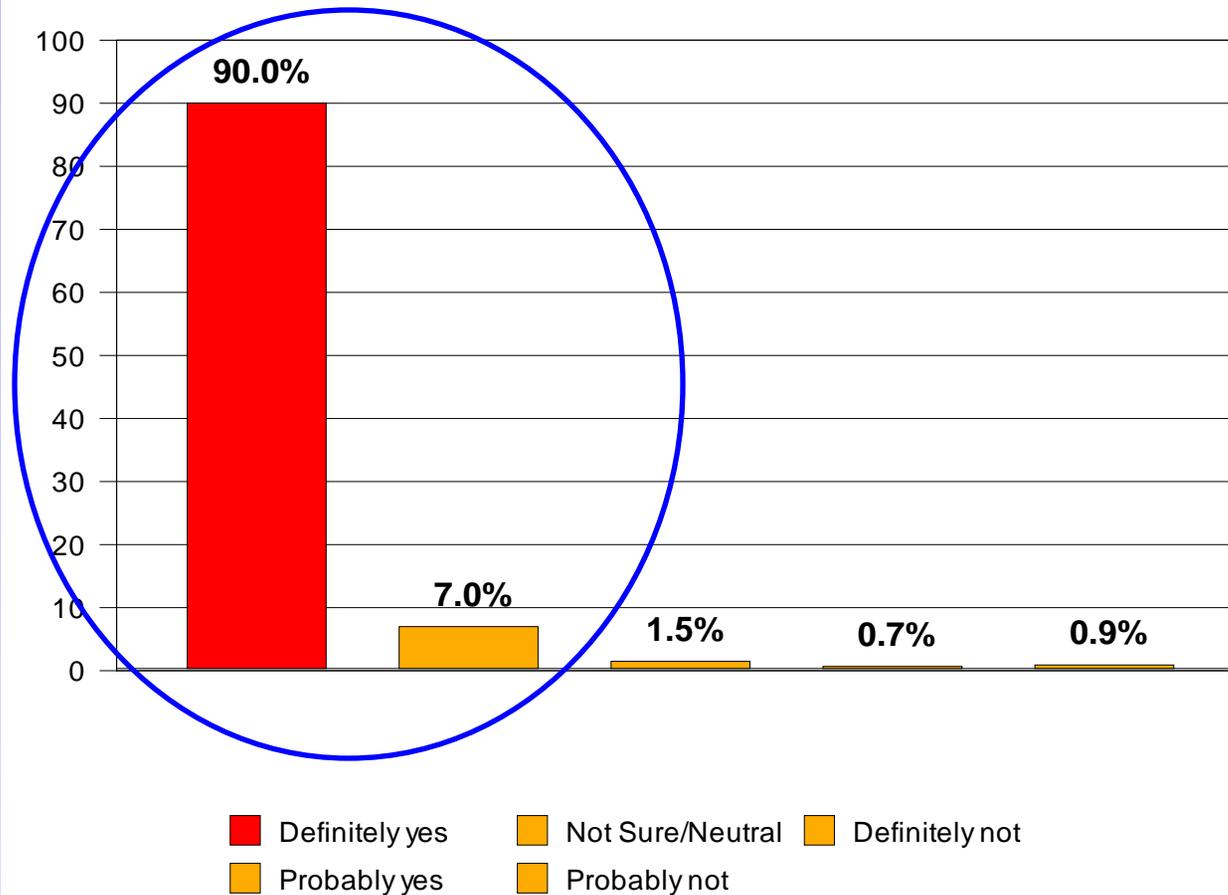
# USAeyes® CORE™ Vision Correction Surgery Patient Survey

## Would You Have Surgery Now?



# USAeyes® CORE™ Vision Correction Surgery Patient Survey

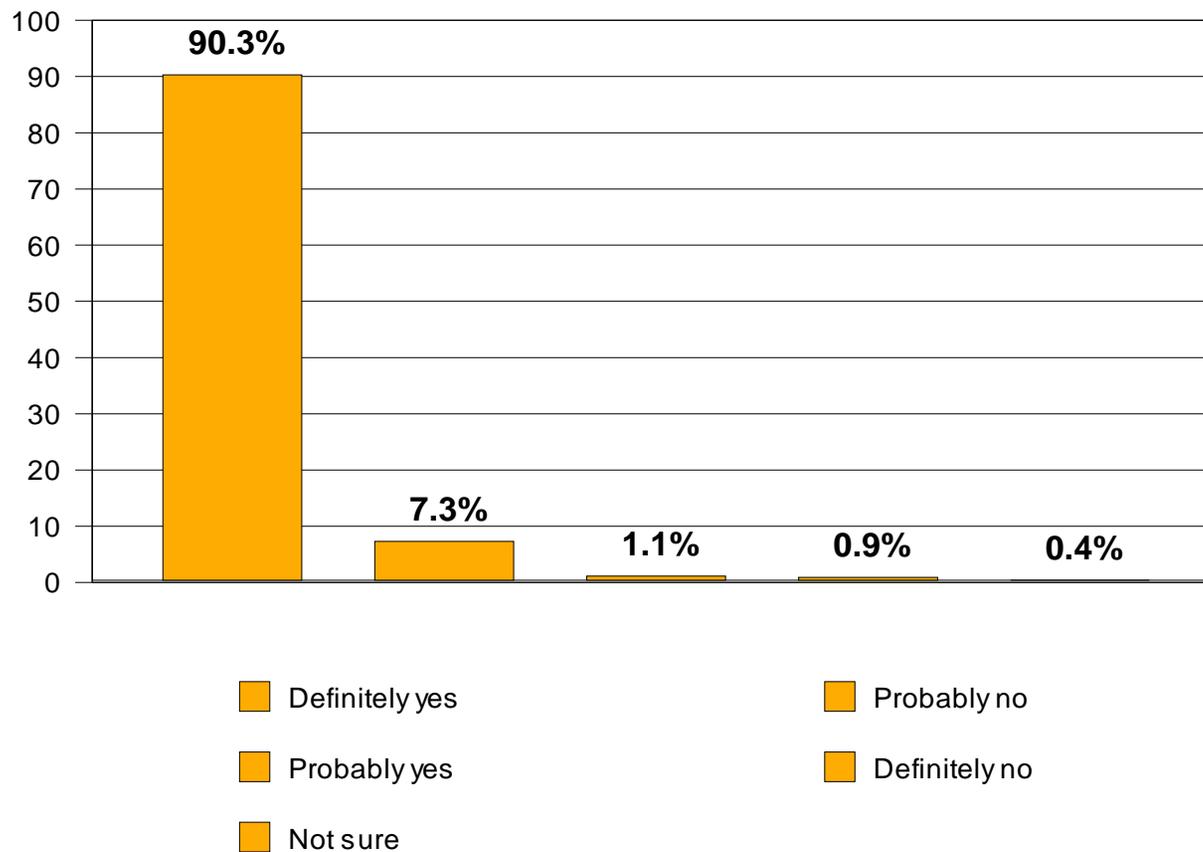
## Would You Have Surgery Now?



**97%** Would Have Surgery Knowing What They Know Now

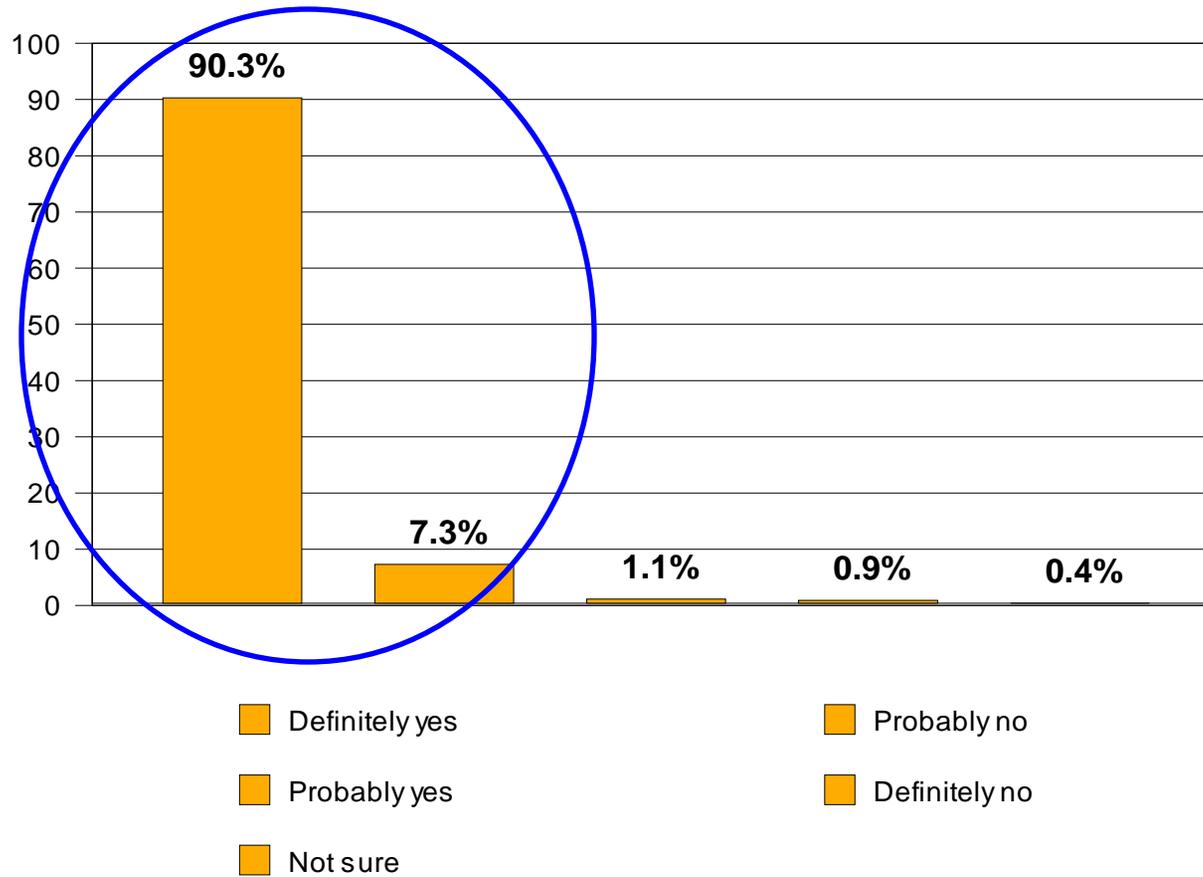
## USAeyes® CORE™ Vision Correction Surgery Patient Survey

### Would You Recommend Surgery?



# USAeyes® CORE™ Vision Correction Surgery Patient Survey

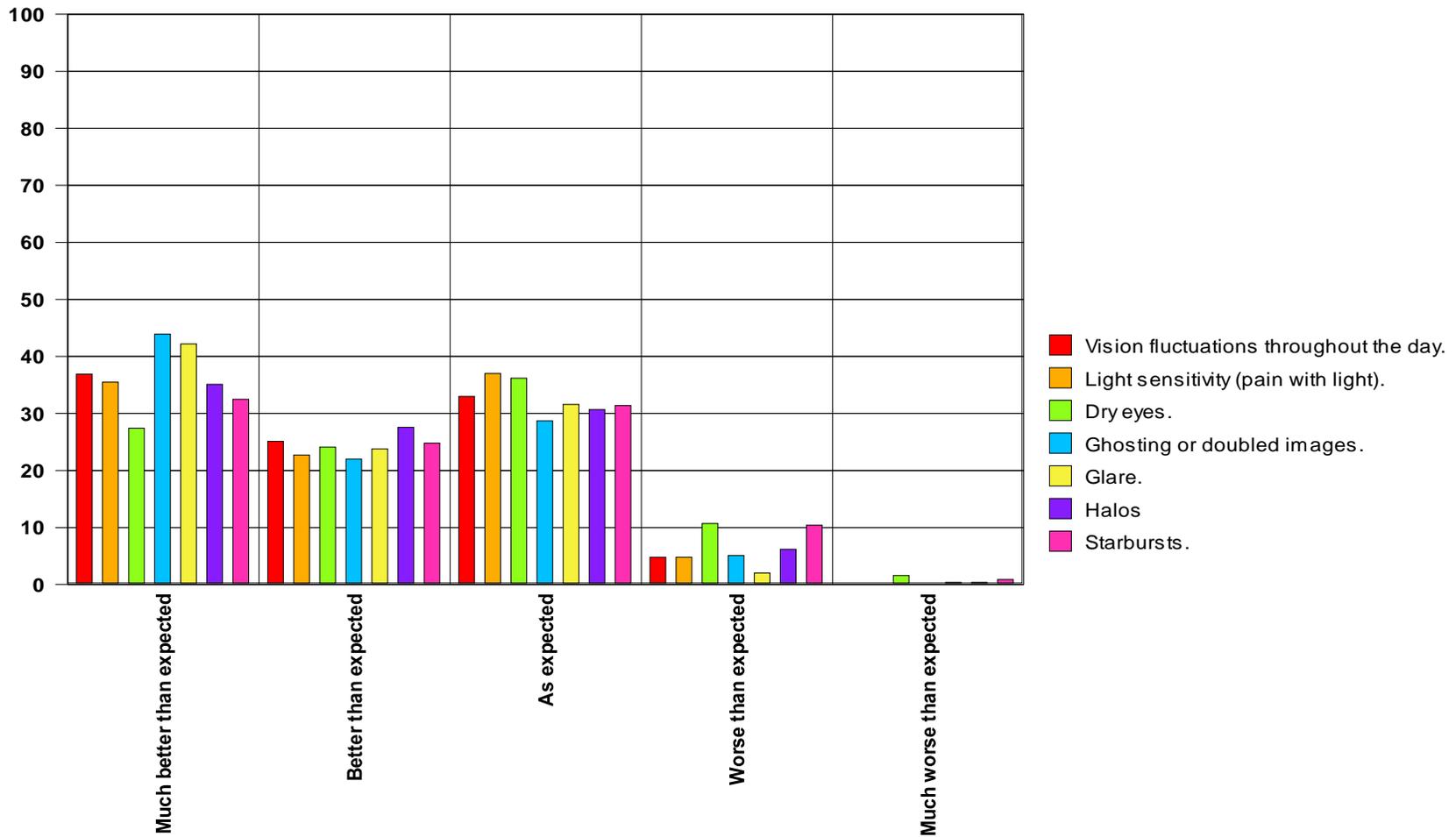
## Would You Recommend Surgery?



**98%** Would Recommend Surgery Knowing What They Know Now

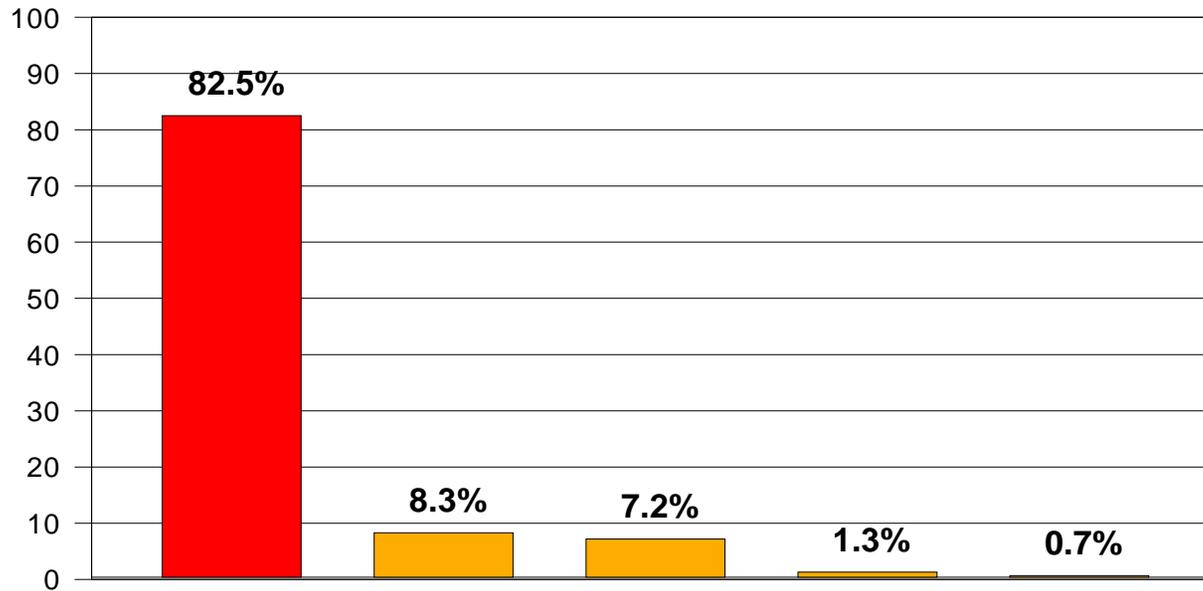
# USAeyes® CORE™ Vision Correction Surgery Patient Survey

Current Incidence of Adverse Events



# USA Eyes® CORE™ Vision Correction Surgery Patient Survey

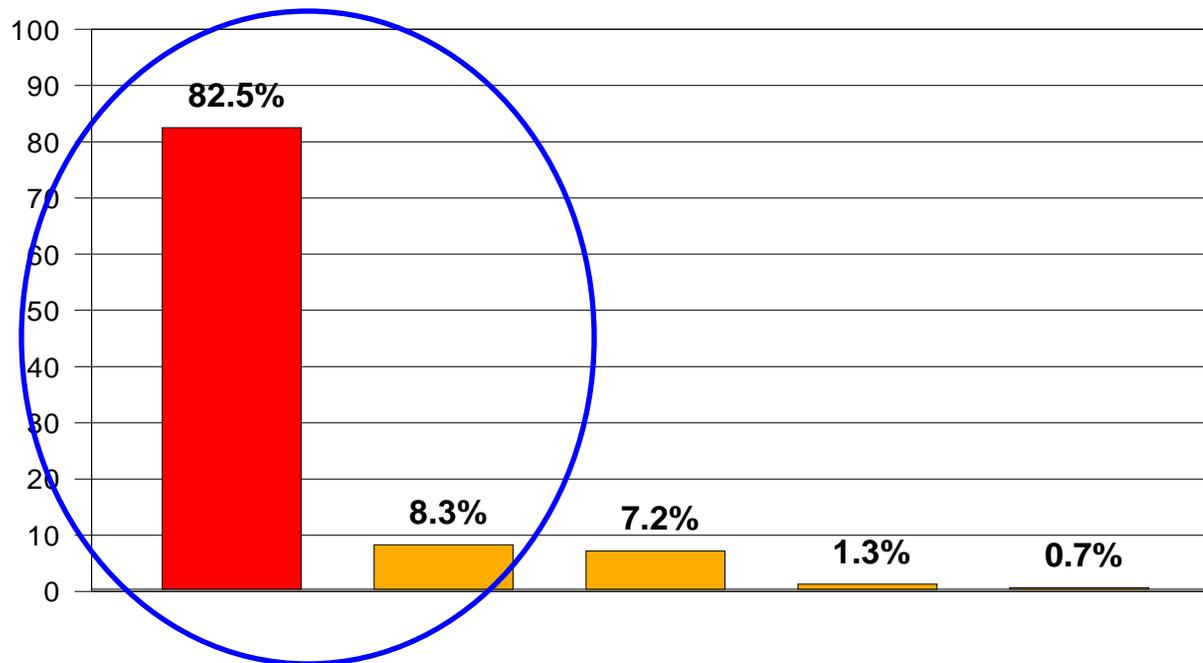
## Complications



- I did not have unexpected complications.
- I had unexpected complications, which are now resolved.
- I currently have unresolved complications that are seldom problematic.
- I currently have unresolved complications that are frequently problematic.
- I currently have unresolved complications that are always problematic.

# USAeyes® CORE™ Vision Correction Surgery Patient Survey

## Complications



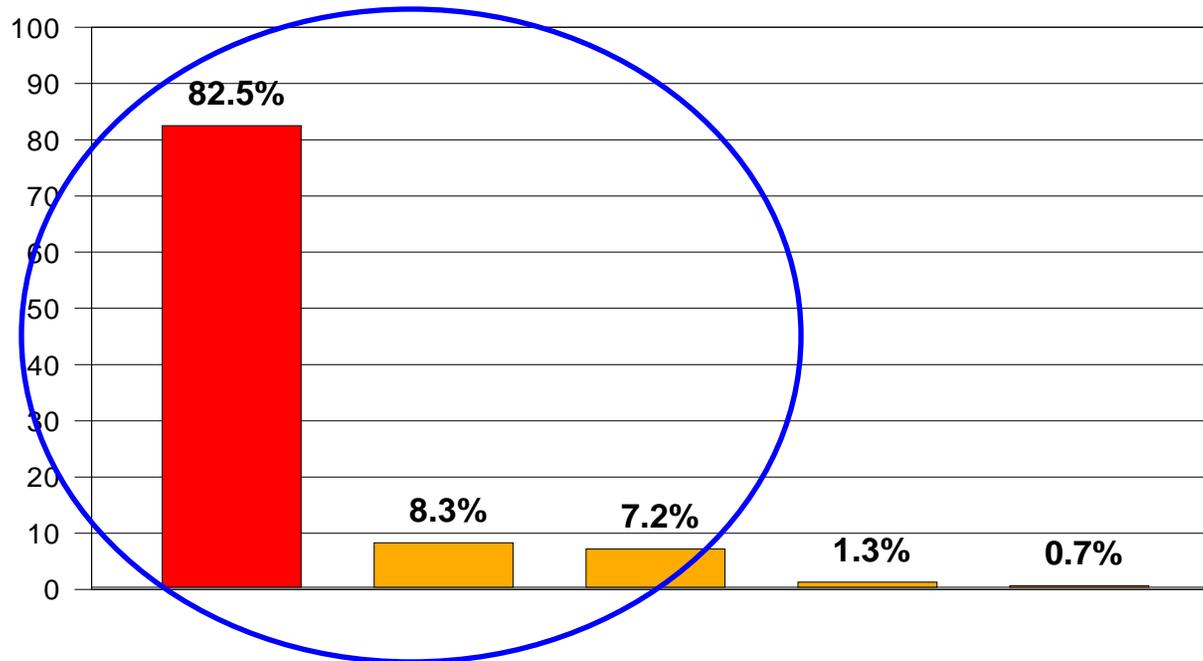
- I did not have unexpected complications.
- I had unexpected complications, which are now resolved.
- I currently have unresolved complications that are seldom problematic.
- I currently have unresolved complications that are frequently problematic.
- I currently have unresolved complications that are always problematic.

**91%**

Currently Have  
No  
Complications  
At Any Time

# USAeyes® CORE™ Vision Correction Surgery Patient Survey

## Complications

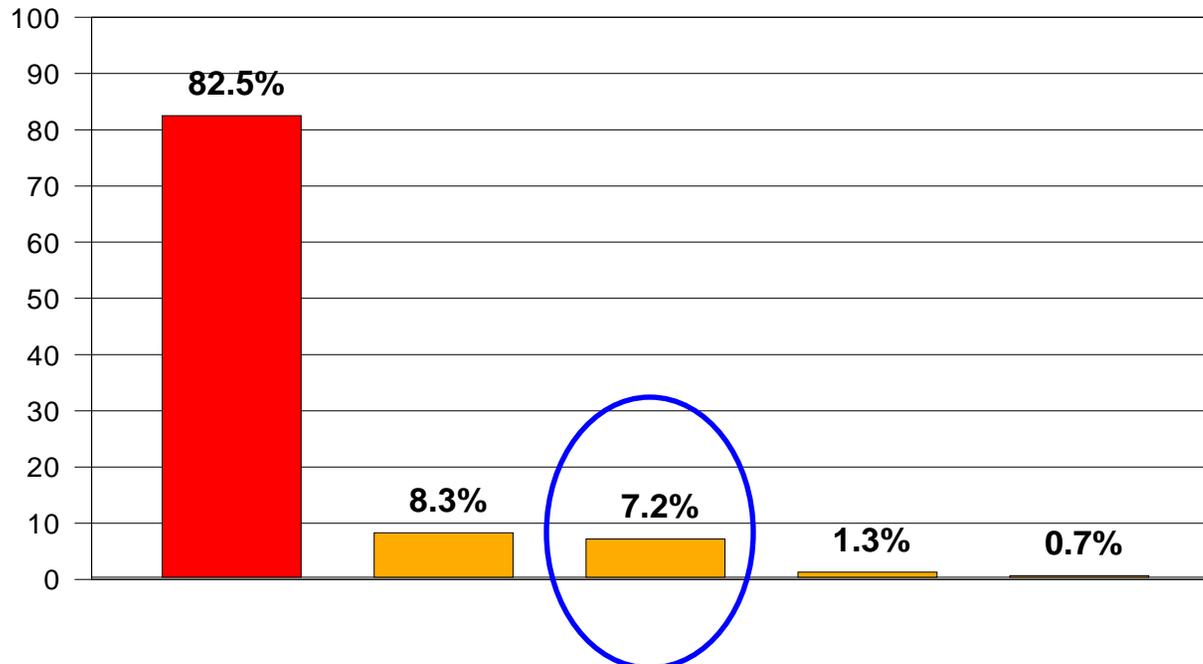


- I did not have unexpected complications.
- I had unexpected complications, which are now resolved.
- I currently have unresolved complications that are seldom problematic.
- I currently have unresolved complications that are frequently problematic.
- I currently have unresolved complications that are always problematic.

**98%** No Complications, Resolved Complications, or Complications Seldom Problematic

# USAeyes® CORE™ Vision Correction Surgery Patient Survey

## Complications

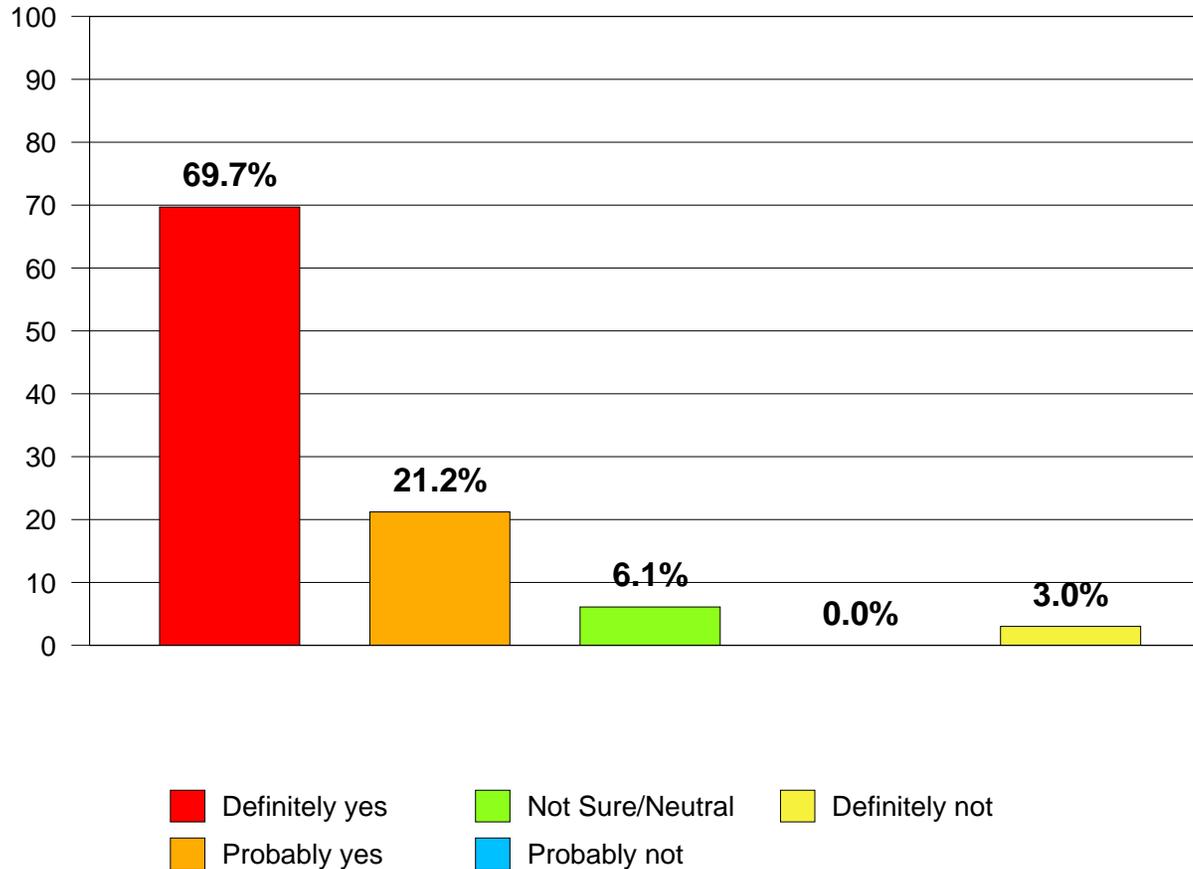


- I did not have unexpected complications.
- I had unexpected complications, which are now resolved.
- I currently have unresolved complications that are seldom problematic.
- I currently have unresolved complications that are frequently problematic.
- I currently have unresolved complications that are always problematic.

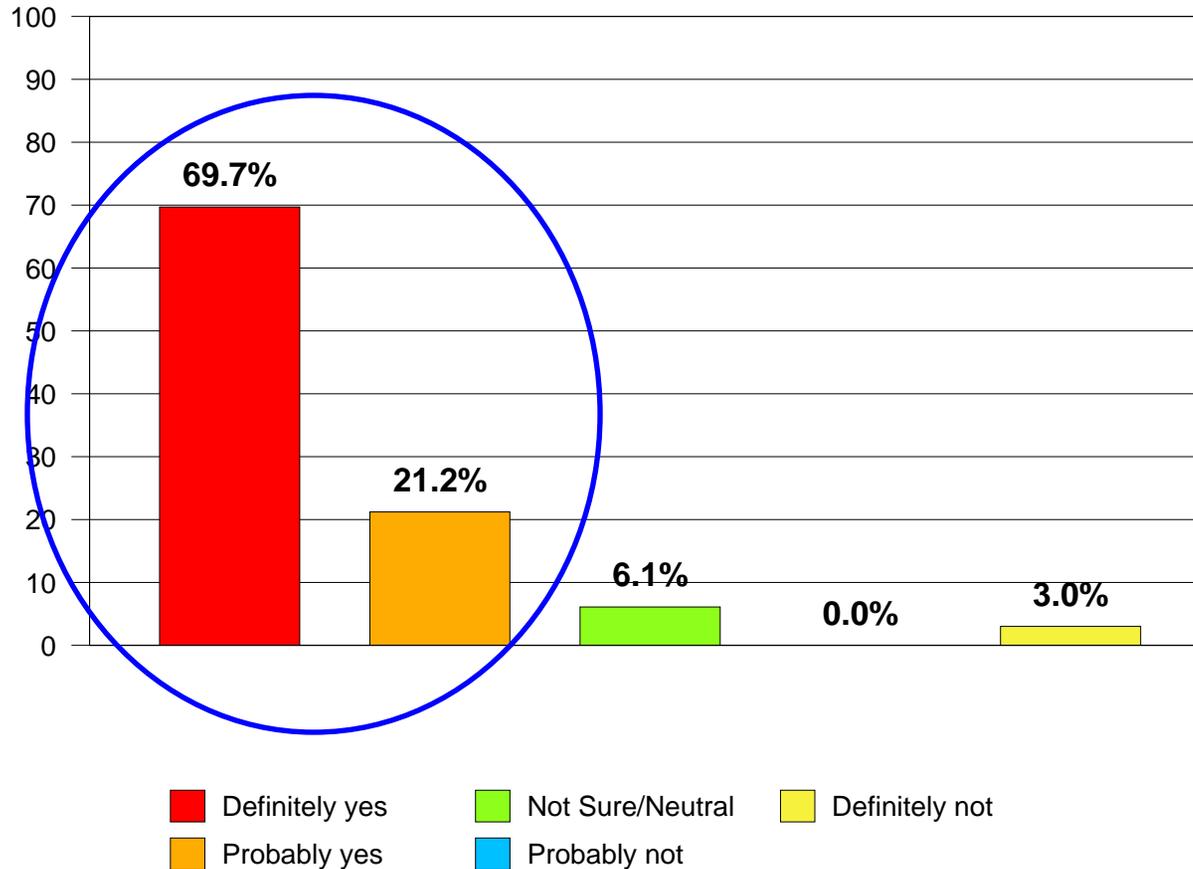
### Drill Down

Complications  
Seldom  
Problematic

## Complications Seldom Problematic: Do It Again?



## Complications Seldom Problematic: Do It Again?



### Drill Down

**91%** Of Those Who Report Seldom Having Complications Would Have Surgery Again

# USA<sup>Eyes</sup>® CORE™ Survey

## Preliminary Results Summary

- 99% report quality of life as expected, better, or much better
- 98% day vision as expected, better, or much better
- 98% no complications or issues are seldom problematic
- 98% would recommend surgery to family and friends.
- 97% would have surgery again, knowing what they know now
- 96% wear corrective lenses as often as expected, less, or much less than expected
- 96% report postop vision without lenses as expected, better, or much better than expected when compared to preop vision with lenses
- 96% report overall quality of vision as expected, better, or much better than expected
- 91% no complications at any time
- 91% night vision as expected, better, or much better
- 7% complications seldom problematic
  - 91% would have surgery again
- 2% complications frequent or always problematic
  - 22% would have surgery again

# Council for Refractive Surgery Quality Assurance™

[www.USAEyes.org](http://www.USAEyes.org)  
[glenn.hagele@usaeyes.org](mailto:glenn.hagele@usaeyes.org)  
1-800-USA-EYES

Google: “Lasik Doctors”

