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 in 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
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 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 anoniminity
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
USAEyes CORE Survey

• Preliminary Data
  – Still receiving survey responses
  – Less than one week from last distribution
Preop Refractive Error

- Nearsighted (Myopic): 82.0%
- Neither: 1.3%
- Farsighted (Hyperopic): 7.7%
- Not sure: 9.0%

USA Eyes® CORE™ Vision Correction Surgery Patient Survey

US Food & Drug Administration, Ophthalmic Devices Panel, April 25, 2008
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Preop Use of Reading Glasses/Bifocals

- **Yes**: 40.1%
- **No**: 59.0%
- **Not sure**: 0.9%

40% Report Effects of Presbyopia
Selected Monovision Correction

- 61.1% did not need reading glasses or bifocals before surgery
- 16.7% had monovision correction
- 16.7% did not have monovision correction
- 5.6% not sure
Selected Monovision Correction

- **61.1%** I did not need reading glasses or bifocals before surgery
- **16.7%** I had monovision correction
- **16.7%** I did not have monovision correction
- **5.6%** Not sure

17% Specifically Selecting Monovision

17% Specifically Not Selecting Monovision
USAEyes® CORE™ Vision Correction Surgery Patient Survey

Months Postop

- 1-5: 0.0%
- 6-9: 14.5%
- 10-12: 22.1%
- 13-18: 41.2%
- 19+: 22.1%

USA Eyes® Competence Opinion Relative to Expectation™ Vision Correction Surgery Patient Survey
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Postop Use of Corrective Lenses Including Reading Glasses

- 79.6% Never
- 9.1% Seldom
- 8.5% Frequently
- 2.8% Always
Postop Use of Corrective Lenses Including Reading Glasses

89% Never or Seldom Wear Corrective Lenses

USA Eyes® Competence Opinion Relative to Expectation Vision Correction Surgery Patient Survey
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Postop Description of Corrective Lens Use

- 40.6% Much less than expected
- 50.4% As expected
- 4.9% Less than expected
- 2.6% More than expected
- 1.5% Much more than expected
Postop Description of Corrective Lens Use

- 40.6% Much less than expected
- 50.4% As expected
- 4.9% Less than expected
- 2.6% More than expected
- 1.5% Much more than expected

96% Wear Corrective Lenses As Frequent as Expected or Less
Postop Quality Day Vision

- 47.5% Much better than expected
- 23.0% Better than expected
- 27.4% As expected
- 2.0% Worse than expected
- 0.2% Much worse than expected
USAEyes® CORE™ Vision Correction Surgery Patient Survey

Postop Quality Day Vision

- Much better than expected: 47.5%
- Better than expected: 23.0%
- As expected: 27.4%
- Worse than expected: 2.0%
- Much worse than expected: 0.2%

98% Quality of Day Vision As Expected or Better
Postop Quality Night Vision

- Much better than expected: 32.7%
- Better than expected: 26.8%
- As expected: 31.4%
- Worse than expected: 7.8%
- Much worse than expected: 1.3%

USAEyes® CORE™ Vision Correction Surgery Patient Survey

STL Paten® Advocacy

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Postop Quality Night Vision

- 32.7% Much better than expected
- 26.8% Better than expected
- 31.4% As expected
- 7.8% Worse than expected
- 1.3% Much worse than expected

91% Quality of Night Vision As Expected or Better
7% Lower Than Day Vision
Preop With Lenses vs. Postop Without Lenses

- **50.9%** Much better than expected
- **26.7%** Better than expected
- **18.5%** As expected
- **3.3%** Worse than expected
- **0.7%** Much worse than expected
Preop With Lenses vs. Postop Without Lenses

- Much better than expected: 50.9%
- Better than expected: 26.7%
- As expected: 18.5%
- Worse than expected: 3.3%
- Much worse than expected: 0.7%

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

- 49.5% Much better than expected
- 26.0% Better than expected
- 20.4% As expected
- 3.7% Worse than expected
- 0.4% Much worse than expected
Postop Quality of Life

- 48.6% Much better than expected
- 29.6% Better than expected
- 20.9% As expected
- 0.9% Worse than expected
- 0.0% Much worse than expected

USA Eyes® CORE™ Vision Correction Surgery Patient Survey

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Postop Quality of Life

0.0% 0.9%

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

99% Quality of Life As Expected or Better
Would You Have Surgery Now?

- Definitely yes: 90.0%
- Probably yes: 7.0%
- Not Sure/Neutral: 1.5%
- Probably not: 0.7%
- Definitely not: 0.9%
Would You Have Surgery Now?

97% Would Have Surgery Knowing What They Know Now

- Definitely yes: 90.0%
- Probably yes: 7.0%
- Not Sure/Neutral: 1.5%
- Definitely not: 0.7%
- Probably not: 0.9%

**WARNINGS:**
- Compliance with the instructions and directions for use is essential for safe use.
- The device is intended for use in the prescription of lens power for correction of ametropia.
- It should only be used by trained and qualified personnel.

**SAFETY INFORMATION:**
- Before use, carefully follow the instructions and directions for use.
- Use the device only as described in the provided documentation.
- Regularly check for potential safety hazards and take necessary precautions.

**TROUBLESHOOTING:**
- If you encounter any issues during use, refer to the troubleshooting guide or contact customer support.

**CAUTIONS:**
- Use only as intended and in accordance with the device's specifications.
- Avoid exposure to extreme temperatures and environments.

**REMOVAL:**
- The device should be removed from the packaging and set aside in a safe location.
- Follow the instructions provided for removing any additional accessories or components.

**ADDITIONAL RECOMMENDATIONS:**
- Keep the device in a dry and clean environment.
- Regularly inspect the device for any signs of wear or damage.

**DISPOSAL:**
- Follow local regulations and guidelines for proper disposal of the device and its components.

**PRECAUTIONS FOR USE:**
- Prior to use, ensure the device is free from any defects or malfunctions.
- Use the device only when it is in a stable and secure environment.

**ENVIRONMENTAL CONSIDERATIONS:**
- The device is designed to be environmentally friendly and recyclable.
- Dispose of the device responsibly according to local environmental laws and regulations.

**REGULATORY INFORMATION:**
- The device complies with all relevant safety and performance standards.
- Additional certifications and approvals may be available upon request.

**LEGAL NOTICES:**
- This device is not intended for use in life support systems or medical emergencies.
- The manufacturer is not responsible for any misuse of the device or its components.

**FOR MORE INFORMATION:**
- Contact the manufacturer's customer support for any questions or concerns.
- Visit the manufacturer's website for the latest product information and updates.

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- The content of this document is protected by copyright law.
- Unauthorized reproduction or distribution is strictly prohibited.

**CONTACT INFORMATION:**
- Manufacturer's name and address
- Customer support contact information

**TECHNICAL SPECIFICATIONS:**
- Detailed specifications and technical data are available in the product documentation.
- Any changes or modifications to the device are subject to prior notice and approval.

**PRODUCT REGISTRATION:**
- Register the device with the manufacturer to receive updates and support.

**ENVIRONMENTAL COMPLIANCE:**
- The device is designed to meet or exceed all applicable environmental standards.
- The manufacturer is committed to sustainability and reducing its environmental impact.

**SAFETY FEATURES:**
- The device incorporates safety features to prevent unauthorized access and use.
- Regular maintenance and inspection are required to ensure safe operation.

**DISASSEMBLY AND REASSEMBLY:**
- Follow the instructions provided for disassembly and reassembly.
- Use the correct tools and equipment to ensure safe and proper handling.

**REPAIR AND MAINTENANCE:**
- Regular maintenance is essential to maintain the device's performance and safety.
- Contact authorized service providers for any repairs or maintenance.

**PRODUCT QUALITY ASSURANCE:**
- The device undergoes rigorous testing and quality control processes.
- The manufacturer's commitment to quality and performance is a key feature.

**EFFECTIVENESS AND SAFETY:**
- The device is designed to be effective and safe for its intended use.
- Risk assessments and clinical trials are conducted to ensure safety and efficacy.

**RECOMMENDATIONS FOR USERS:**
- Follow the manufacturer's guidelines and recommendations for optimal use.
- Keep the device in a clean and organized environment.

**LEGAL DISCLOSURES:**
- The manufacturer's legal disclosures and disclaimers are included in the product documentation.
- All legal notices and disclaimers are intended to protect the manufacturer's rights and the user's rights.

**FURTHER INQUIRIES:**
- For any additional inquiries or information, contact the manufacturer's customer support.
- Visit the manufacturer's website for the latest product updates and support resources.
Would You Recommend Surgery?

- 90.3% Definitely yes
- 7.3% Probably yes
- 1.1% Not sure
- 0.9% Probably no
- 0.4% Definitely no
98% Would Recommend Surgery Knowing What They Know Now

Would You Recommend Surgery?

- 90.3% Definitely yes
- 7.3% Probably yes
- 1.1% Not sure
- 0.9% Probably no
- 0.4% Definitely no
Current Incidence of Adverse Events

- Vision fluctuations throughout the day.
- Light sensitivity (pain with light).
- Dry eyes.
- Ghosting or doubled images.
- Glare.
- Halos
- Starbursts.
I did not have unexpected complications.
- 82.5%
I had unexpected complications, which are now resolved.
- 8.3%
I currently have unresolved complications that are seldom problematic.
- 7.2%
I currently have unresolved complications that are frequently problematic.
- 1.3%
I currently have unresolved complications that are always problematic.
- 0.7%
Complications

- **82.5%** I did not have unexpected complications.
- **8.3%** I had unexpected complications, which are now resolved.
- **7.2%** I currently have unresolved complications that are seldom problematic.
- **1.3%** I currently have unresolved complications that are frequently problematic.
- **0.7%** I currently have unresolved complications that are always problematic.

91% Currently Have No Complications At Any Time
Complications

- 82.5%: I did not have unexpected complications.
- 8.3%: I had unexpected complications, which are now resolved.
- 7.2%: I currently have unresolved complications that are seldom problematic.
- 1.3%: I currently have unresolved complications that are frequently problematic.
- 0.7%: I currently have unresolved complications that are always problematic.

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

- 82.5% I did not have unexpected complications.
- 8.3% I had unexpected complications, which are now resolved.
- 7.2% I currently have unresolved complications that are seldom problematic.
- 1.3% I currently have unresolved complications that are frequently problematic.
- 0.7% I currently have unresolved complications that are always problematic.
Complications Seldom Problematic: Do It Again?

- 69.7% Definitely yes
- 21.2% Probably yes
- 6.1% Not Sure/Neutral
- 0.0% Probably not
- 3.0% Definitely not
Complications Seldom Problematic: Do It Again?

- Definitely yes: 69.7%
- Probably yes: 21.2%
- Not sure/Neutral: 6.1%
- Probably not: 0.0%
- Definitely not: 3.0%

Drill Down: 91% of those who report seldom having complications would have surgery again.
USA Eyes® CORE™ Vision Correction Surgery Patient Survey

USA Eyes® 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
- 98% 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
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Google: “Lasik Doctors”