

# DISCLOSURI

- Presenter is on speaker's panel/consultant for:
- Alcon, Allergan, Azura, B+L, J&J, Kala, Novartis, OcuSoft, Olleyes, Reichert, Eyevance, Sun Pharma,
- President of MRB Eye Consultants
- Past-President of the Optometric Council on Refractive Technology (OCRT)
- Presenter has NO financial interest in any products mentioned..well except:

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- US patient pool largely untapped
  - More than half of U.S. population require some form of vision correction9
  - Millennial group is the largest generational group with 86 million people, 7% larger than Baby Boomer group<sup>10</sup>
  - ~5 million millennials have had LASIK<sup>11</sup>
  - ~25 million more (5x) are considering LASIK<sup>11</sup>
- · LASIK is the most commonly performed refractive procedure9

December 21, 2020 12



- 262 participants
  - Performed through the DOD primarily at U.S. Naval Medical Center, San Diego
  - There have been over 150,000 LASIK procedures since 2000 performed in the Navy alone
  - Performed using a questionnaire to determine PROs in a patient population undergoing standardized LASIK treatment while developing a questionnaire to better evaluate patients' reporting of visual symptoms and to assess the potential of those symptoms to impact a patient's quality of life after LASIK

# PROWL-2 (CIVILIAN)

• Patient Reported Outcomes with

LASIK (PROWL) study:

• Prowl-1 (military)

• Prowl-2 (civilian)

Completed in 2014

- 312 participants
- Performed through the FDA recruiting subjects at five different locations
- Under the direction of the director of the FDA Division of Ophthalmic and Ear, Nose, and Throat Devices, Office of Device Evaluation, Center for Device and Radiological Health
- Designed to further validate the questionnaire in a national, multicenter clinical study of the civilian population

### COMMON FINDINGS OWL-I AND PROWL-2 TRIAL

- Only one of the 990 eyes lost 3 or more lines of visual acuity, and that eye saw 20/25 or better
- The prevalence of all visual symptoms and bothersome symptoms studied (ghosting, halos, glare, and starbursts) was less at 6 months after surgery without correction than it was preoperatively with best correction (PROWL-1)
- Patients reporting difficulty or the inability to perform usual activities due to visual symptoms improved, or were completely eliminated, following LASIK in both studies
- Visual symptoms throughout these trials must be understood in the context that there
  was no correction of residual refractive error (while the results are excellent, they
  would be even better if patients had been given the option to have additional LASIK or
  to wear glasses)

# PROWL-I SUMMARY

- 99.5% had binocular uncorrected vision of 20/20 or better at 3 months
- 98% were satisfied with the result at 6 months
- 97% were satisfied with their vision at 6 months (73% were dissatisfied preop)
- 3X more patients reported the resolution of preop visual symptoms than reported new visual symptoms
- 3X more patients experienced an improvement in OSDI after LASIK than noticed new OSDI symptoms
- Very few patients reported that visual symptoms negatively impacted their daily activities

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# ROWL-2 SUMMARY

- 96% had binocular uncorrected vision of 20/20 or better at 3 months
- 97% were satisfied with the result at 3 months
- 96.2% were satisfied with their vision at 3 months (55.9% were dissatisfied preop)
- < 1% of subjects, without glasses or contact lenses, experienced a lot of difficulty with or were unable to do usual activities due to visual symptoms at 3 months
- The prevalence of halos decreased from 51% (preoperatively) to 46% (at 3 months) in all patients following LASIK (35% of subjects who had no halos prior to surgery developed new halos at 3 months)
- 28% had a normal preop OSDI noted mild, moderate, or severe dry eye at 3 months
- The majority of the few dissatisfied patients reported visual symptoms, such as glare, halos, ghosting, or starbursts

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- Global Prevalence of Myopia and High Myopia and Temporal Trends from 2000 through 2050.
- · Brien Holden Vision Institute study on the prevalence of myopia.
  - Myopia is projected to affect almost half of the world's population by 2050 - a sevenfold increase

• 5 billion with myopia. • I billion with high myopia (>-6D)

- EyeWire Today: March 28, 2016
- "China is the world's largest market for laser vision correction, with a growing epidemic of myopia. Private providers have taken the lead in commercializing refractive surgery, but prospects for growth are dampened by a fall-off in the number of people entering their twenties. Alternative technologies, such as SMILE (small incision lenticule extraction) and phakic IOLs, are getting a toehold in the market."
- Global refractive surgery market patient fees generate \$5.2 billion in 2015 to \$6.1 billion in 2020, growth rate of 3.1%. http://eyewiretoday.com/2016/03/28/chinas-ophthalmic-market-expected-to-double-by-2021



• United States and Canada increase to 260 million, or close to half

of the population, up from 89 million in 2000

detachment and myopic macular degeneration.

• High myopia cases increase by five times to 66 million.

• High myopia increased risk of cataracts, glaucoma, retinal

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# 2015 Report by American Society for Aesthetic Plastic Surgery (ASAPS) Total Surgical Procedures 2015: \$8.1 Billion

- Age 19-34: 26.8%
- Age 35-50: 39.5%
- Women: 90% (1.7 million procedures)
- Men: 10% (nearly 200,000 procedures)
- Liposuction most common for both women/men
- Total Nonsurgical Procedures 2015: \$5.8 Billion

Cosmetic Surgery National Data Bank Statistics 2015 http://www.surgery.org/sites/default/files/Stats2015.pdf

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LASER REFRACTIVE CATARACT SURGERY

# ORA SYSTEM™: DESIGNED TO OPTIMIZE EVERY CATARACT PROCEDURE



ORA's all new Optiwave™ technology takes intraoperative wavefront aberrometry to a **new level of precision** providing surgeons a **higher level of confidence** 

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ORA (Optiwave Refractive

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# DIFFUSE LAMELLAR KERATITIS (DLK)

Etiology – bacterial exotoxins

Scrapings reveal neutrophils (PMN' s) but no bacteria

Acute reaction thought to be related to some unknown antigens

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# DIFFUSE LAMELLAR KERATITIS (DLK)

- Surgical treatment for severe sands
- High dose steroids for 1-2 weeks
- Flap lifted and interface cleaned
- Careful wipe with Merocel sponge or spatula
- 5 microns of PTK applied
- Hourly topical steroids applied immediately post-op

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DIFFUSE LAMELLAR KERATITIS (DLK)









































ADVANTAGES OF RELEX SMILE
No stromal hydration
No laser fluence projection
No reflection losses
No environmental controls
No tenvironmental controls
Integrity of cornea
Less nerve damage
ONLY VARIABLE IS THE ACCURRACY OF THE LASER









123



for patient eye movement

(DMD) to project UVA

pattern of any design

standard technology

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Spoerl E, Huhle M, Saller T. Induction of cross-links in comeal tissue. Exp. Eye Res. 1998;66(1):97–103. Spoerl E, Saller T. Technques for Stiffening the Comea. J. Patract. Surg. 1999;15:171–713 Goldch Y, et al. Clinical and corneal biomechanical charges after collaper coss-linking with ibcliavin and UV irradiation in patients with progressive keratoconus: results after 2 years of follow-up. Comea. 2012;31(6):609– 14.



























# CONCLUSION LASIK is still King! Complications are minor and treatment can be initiated to solve. Technology is advancing rapidly, yet the premise is still the same.. Things old, are sometimes still the best.

