Refractive Surgery Update

LCDR Tyler Miles, O.D., F.A.A.O.

4 June 2021

1500-1600 (ET)

Presenter

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- U.C. Berkeley Optometry School
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Disclosures

- Dr. Tyler Miles has no relevant financial or non-financial relationships to disclose relating to the content of this activity (or presenter(s) must disclose the type of affiliation/financial interest).
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Learning Objectives

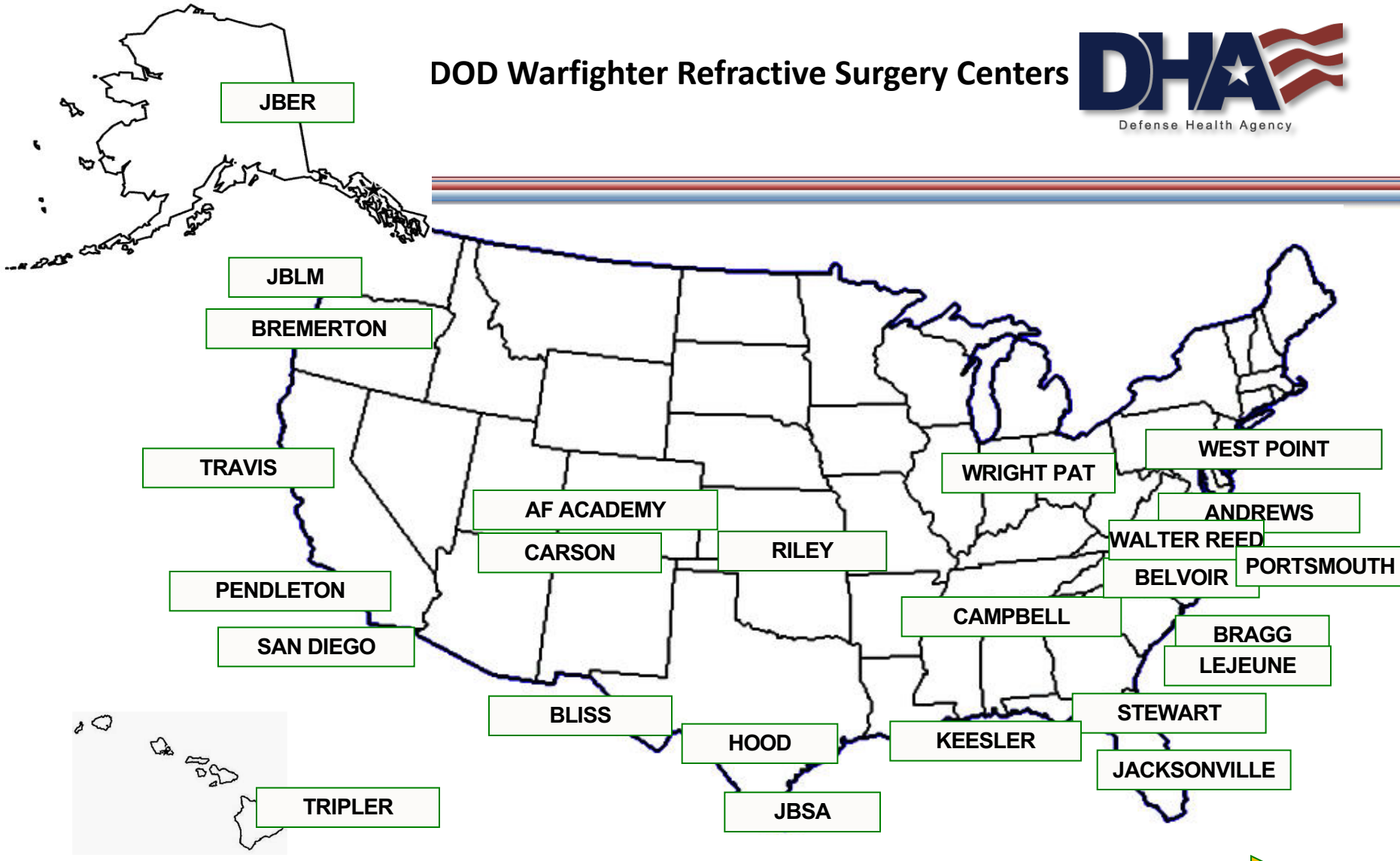
At the conclusion of this activity, participants will be able to:

1. Outline different laser platforms in use at DoD centers and approved treatment ranges for PRK, LASIK, and SMILE.
2. Describe range of outcomes possible from corneal refractive surgery treatments as well as possible complications.
3. Discuss factors important in preoperative screening of refractive surgery candidates and care of post-refractive surgery patients in the Optometry clinic.

Overview

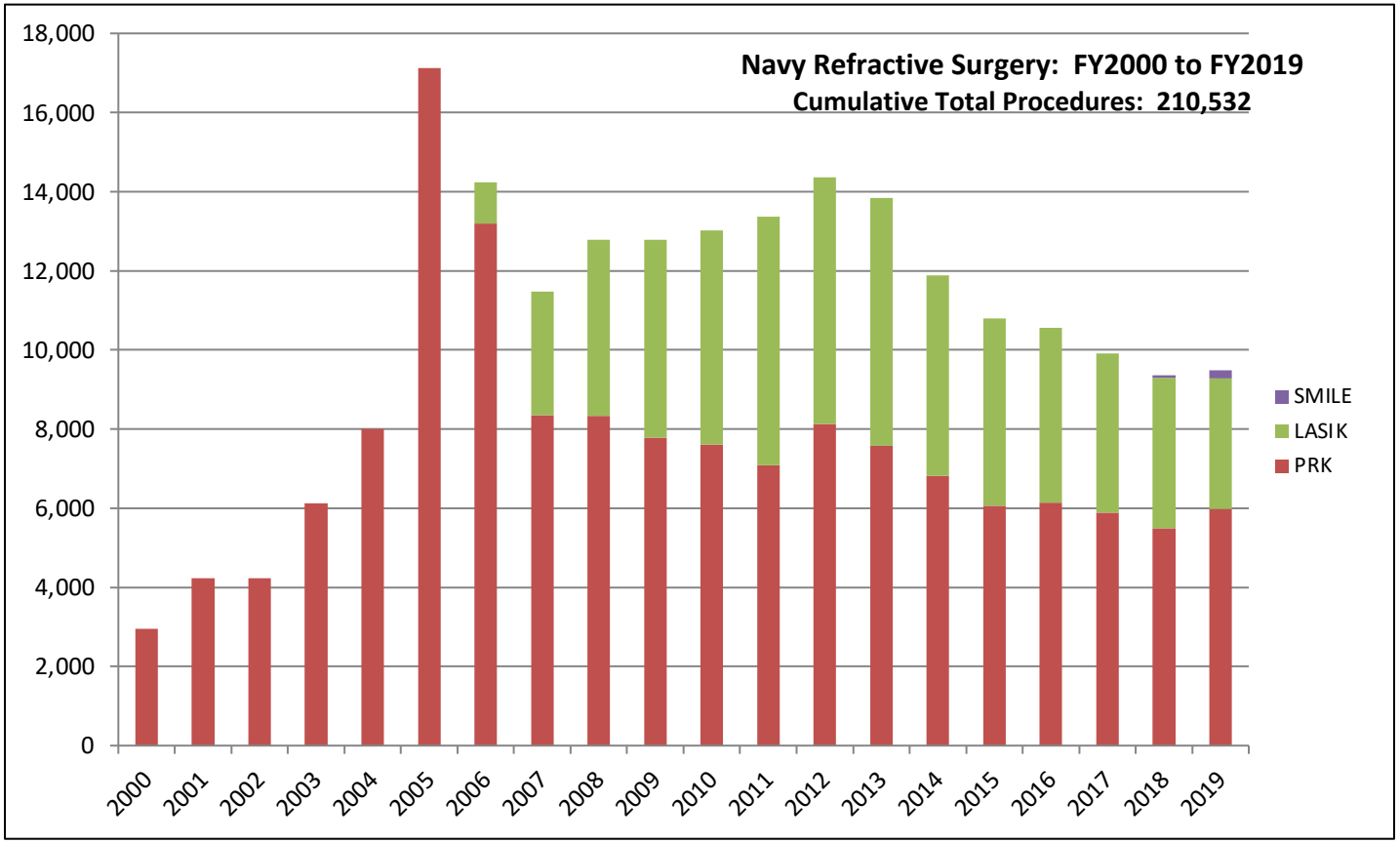
- General information
- Military refractive surgery options: Review
- What's new?
- Refractive surgery knowledge for ODs
  - Complications
  - Refractive Surgery care in the Optometry clinic

DOD Warfighter Refractive Surgery Centers



"Medically Ready Force…Ready Medical Force"

Navy Refractive Surgery



DHA Refractive Surgery Board

- January 2019: VADM Bono keynote speaker at MRSSS conference
- August 2019: Created Refractive Surgery Board Charter
- December 2020: Charter Signed
- Membership (9): Ophthalmology and Optometry Consultants, Refractive Surgery leader for each service

DHA Refractive Surgery Board

- Current Chair: Maj Gary Legault, M.D. (Army)
- Program Manager: Bradley Martinez (GS civilian)
- Ophthalmology Consultants
  - Col Travis Frazier (Army)
  - Col Matt Caldwell (Air Force)
  - CAPT John Cason (Navy)
- Optometry Consultants
  - Col Gary Hughes (Army)
  - Col Darren Rhoton (Air Force)
  - CAPT Todd Lauby (Navy)
- Refractive Advisors
  - Maj Gary Legault (Army)
  - LtCol James Townley (Air Force)
  - CAPT Corby Ropp (Navy)

DHA Refractive Surgery Board

- Coordination
  - Quarterly teleconferences
  - Website (HRN network- CAC enabled)
    - https://info.health.mil/sites/hro/sscc/rsb/sitepages/home.aspx
- Standardization
  - Customer satisfaction (QR code survey)
  - Outcomes
  - Metrics (Dashboard?)
- Funding / Logistics
  - Supply agreements, ECAT, Equipment standardization
- Marketing

DHA Refractive Surgery Board

- Engaging with potential BIG improvements
  - ❑ Standardized tri-service refractive surgery consult system
  - ❑ Standardized OD Co-management training

DoD Refractive Surgery Laser Platforms

Now for Some review …

Laser Platforms used by DoD

- Johnson & Johnson
  - iFS femtosecond laser
  - VISX Star 4 Excimer laser
- iDesign aberrometery: Wavefront-Guided procedures
- WaveScan aberrometer service / customVue treatments discontinued: January 2021

Laser Platforms used by DoD

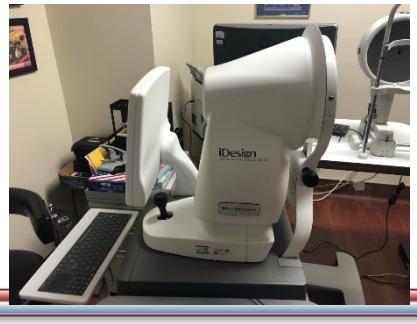
- Johnson & Johnson (AMO) VISX Star 4 **LASIK**
- iDesign Aberrometer must be within 0.625 D of MR
- FDA-approved Ranges:

	Spherical Refractive Error	Astigmatism
Myopia	Up to -11.00 D SE	Up to -5.00 D
Hyperopia	Up to +4.00 D SE	Up to +2.00 D
Mixed Astigmatism		From 1.00 D to 5.00 D

Laser Platforms used by DoD

- Johnson & Johnson (AMO) VISX Star 4 **PRK**
- iDesign Aberrometer must be within 0.625 D of MR
- FDA-approved Ranges:

	Spherical Refractive Error	Astigmatism
Myopia	Up to -8.00 D SE	Up to -3.00 D



Laser Platforms used by DoD

- Alcon
  - FS200 Femtosecond laser (wins for most conj hemes!)
  - EX500 Excimer laser
- Wavefront-Optimized treatments
- Wavefront-Guided treatments
- Topography-Guided treatments (Vario topolyzer)

Laser Platforms used by DoD

- What is Wavefront ”Optimized” vs “Guided”
- Guided = custom ablation based on aberrometer measurement
- Optimized = ablation based on results from large group of treatments on average

Laser Platforms used by DoD

MILITARY MEDICINE, 182, 11/12:e2061, 2017

Retrospective Analysis of the Post-Operative Changes in Higher-Order Aberrations: A Comparison of the WaveLight EX500 to the VISX S4 Laser in Refractive Surgery

Capt Donovan S. Reed, USAF MC; Col Douglas Apsey, USAF MC (Ret.)†; CDR Walter Steigleman, MC USN‡; Lt Col James Townley, USAF MC‡; Lt Col Matthew Caldwell, USAF MC‡*

- 240 Eyes of Active Duty patients treated at Wilford Hall (San Antonio)
- Retrospective analysis comparing RMS values (aberrometry) of wavefront-guided to wavefront-optimized treated eyes (PRK and LASIK treatments)
- Wavefront-guided treatments on average induced less aberration, but not statistically significant

Laser Platforms used by DoD

MILITARY MEDICINE, 00, 00:1 2020

Wavefront-guided and Wavefront-optimized LASIK: Visual and Military Task Performance Outcomes

Rose K. Sia, MD[*]; Denise S. Ryan, MS[*]; COL Richard D. Stutzman, MC, USA (Ret.)[†]; CAPT Joseph F. Pasternak, MC, USN (Ret.)[†]; Jennifer B. Eaddy, OD[*]; Lorie A. Logan, OD[*]; COL Bruce A. Rivers, MC, USA (Ret.)[*]; COL Kraig S. Bower, MC, USA (Ret.)[‡]

- 214 Eyes treated with wavefront-guided or wavefront-optimized LASIK
- Compared induced aberrations, marksmanship performance and subjective

Laser Platforms used by DoD

- Alcon EX500 **Wavefront-Guided LASIK**
- FDA-approved Ranges:

	Spherical Refractive Error	Astigmatism
Myopia	Up to -7.00 D SE	Up to -3.00 D

Laser Platforms used by DoD

- Alcon EX500 **Wavefront-Optimized LASIK**
- FDA-approved Ranges:

	Spherical Refractive Error	Astigmatism
Myopia	Up to -12.00 D	Up to -6.00 D
Hyperopia	Up to +6.00 D SE	Up to 5.00 D
Mixed Astigmatism		Up to 6.00 D

Laser Platforms used by DoD

- Alcon EX500 **Wavefront-Optimized PRK**
- FDA-approved Ranges:

	Spherical Refractive Error	Astigmatism
Myopia	Up to -6.00 D	Up to -3.00 D

Laser Platforms used by DoD

- Zeiss
- LASIK flaps
  - ”gentler”
  - Curved patient interface
- SMILE

Laser Platforms used by DoD

- Zeiss Visumax **SMILE**
- FDA-approved Ranges:

	Spherical Refractive Error	Astigmatism
Myopia	-1.00 D to -10.00 D SE	-0.75 D to -3.00 D

Non-Corneal Procedures

- Refractive Lens Exchange
  - Have seen more of these recently
  - >+4.00 hyperopes at recommendation of glaucoma specialists
  - Multifocal / EDOF IOLs
  - No data yet for military population
- Phakic IOL
  - STAAR surgical Visian posterior chamber IOL
  - Toric approved in 2019

What's New? SMILE!

- Early NRSC San Diego evaluation
  - Waved off in 2012, reengaged in 2016 with Visumax FDA approval
- Why SMILE? … PRK does have complications
  - Pain/Recovery
  - RCE
  - Haze
- LASIK flap
  - Perceived vs actual risk?
- Preserve corneal biomechanics, nerve sensitivity

What's New? SMILE!

- Fast uptake in San Diego – word of mouth
- Easy sell to patients nervous about LASIK flap
- Can go to lower 250 micron ERB (preserved anterior fibers)
- Better to not go for a -1.00 sph treatment- thicker lenticules easier to work with.
- "Trickier" surgery depends on good setting of laser energy, dissection technique

What's New? SMILE!

- SMILE in DoD Study
  - 3 sites: San Diego, San Antonio, Fort Belvoir
  - About 50% enrolled
  - Specifically evaluating low astigmatism treatments (treatment group vs SPH only group)
- Our experience with SMILE to date
  - Surgeon learning curve
  - Few Epi ingrowth cases
  - Longer steroid taper? Haze in pocket

What's New? Phorcides

- Alcon topography-guided treatments with EX500 laser (contoura)
- Initial FDA results difficult to replicate
  - Cylinder correction not accurate when corneal cyl doesn't match manifest cyl
- Attempts to improve refractive outcomes
  - Dr. John Kanellopoulou- lot's of manual calculations: 50% difference between MR cyl and measured cyl.
  - Mark Lobanoff- use of geographic imaging software and then predict optical effect

What's New? Phorcides

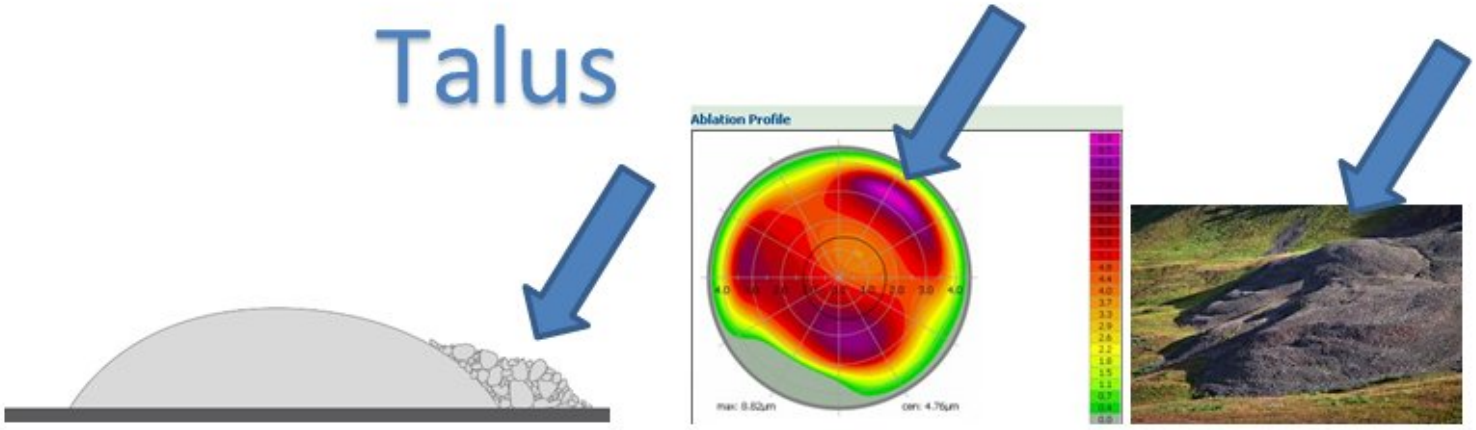
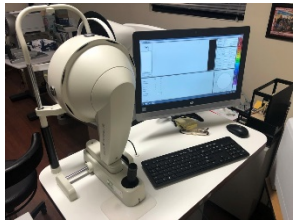


Image from http://support.phorcides.com/documentation/

What's New? Phorcides

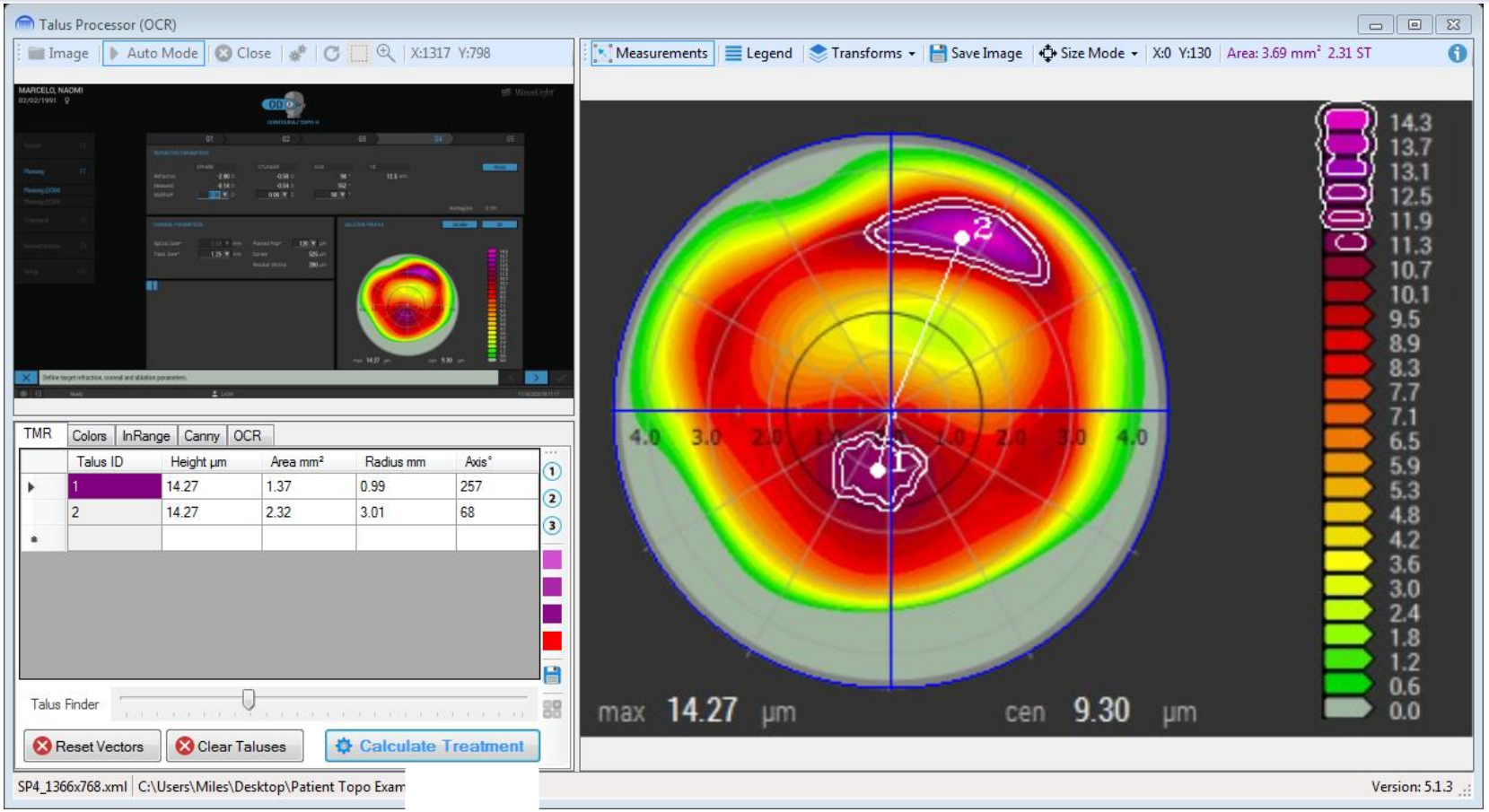
Exam Data

Treatment Laptop



Phorcides Laptop

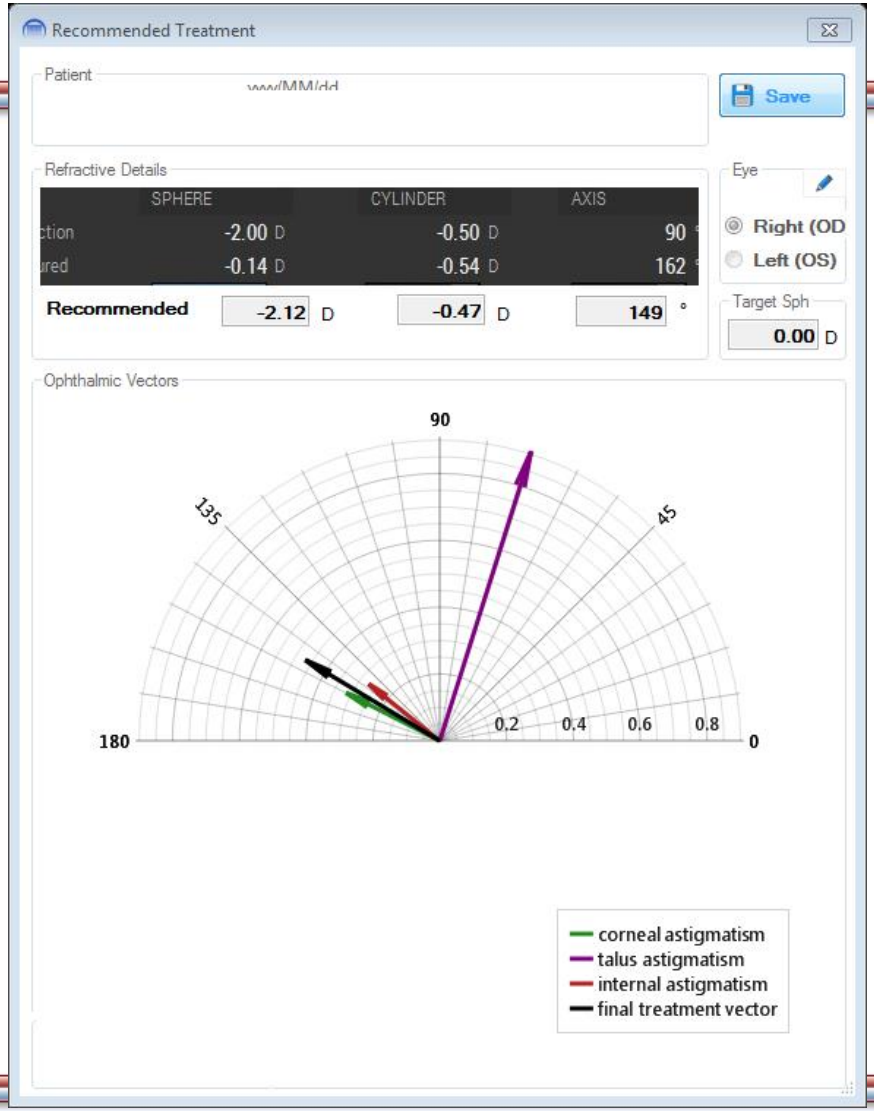
What's New? Phorcides



What's New? Phorcides

"Medically Ready Force…Ready Medical Force"

What's New? Phorcides

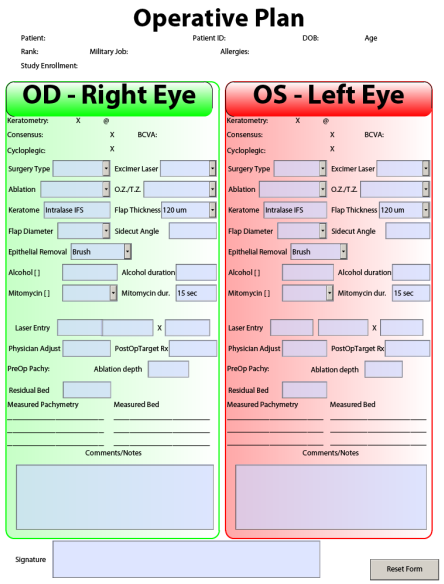


What's New? CRS Outcomes

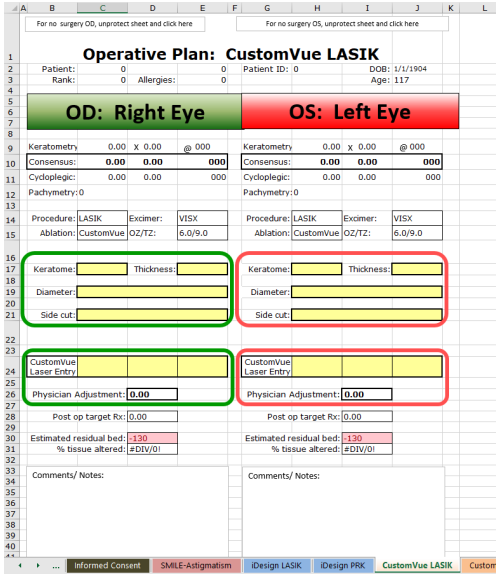
- Many great, high quality studies specific to military refractive surgery
- Lt Col Richard Townley (USAF Refractive Surgeon) developed clinical data and surgical planning form.
- At NRSC San Diego we have been testing for about 9 months.

What's New? CRS Outcomes

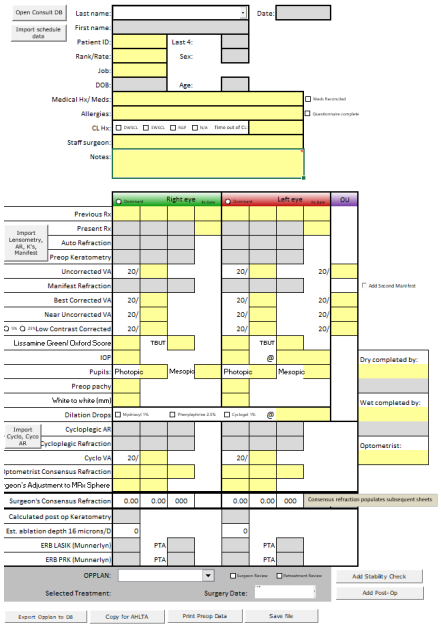
2013



2015



2018



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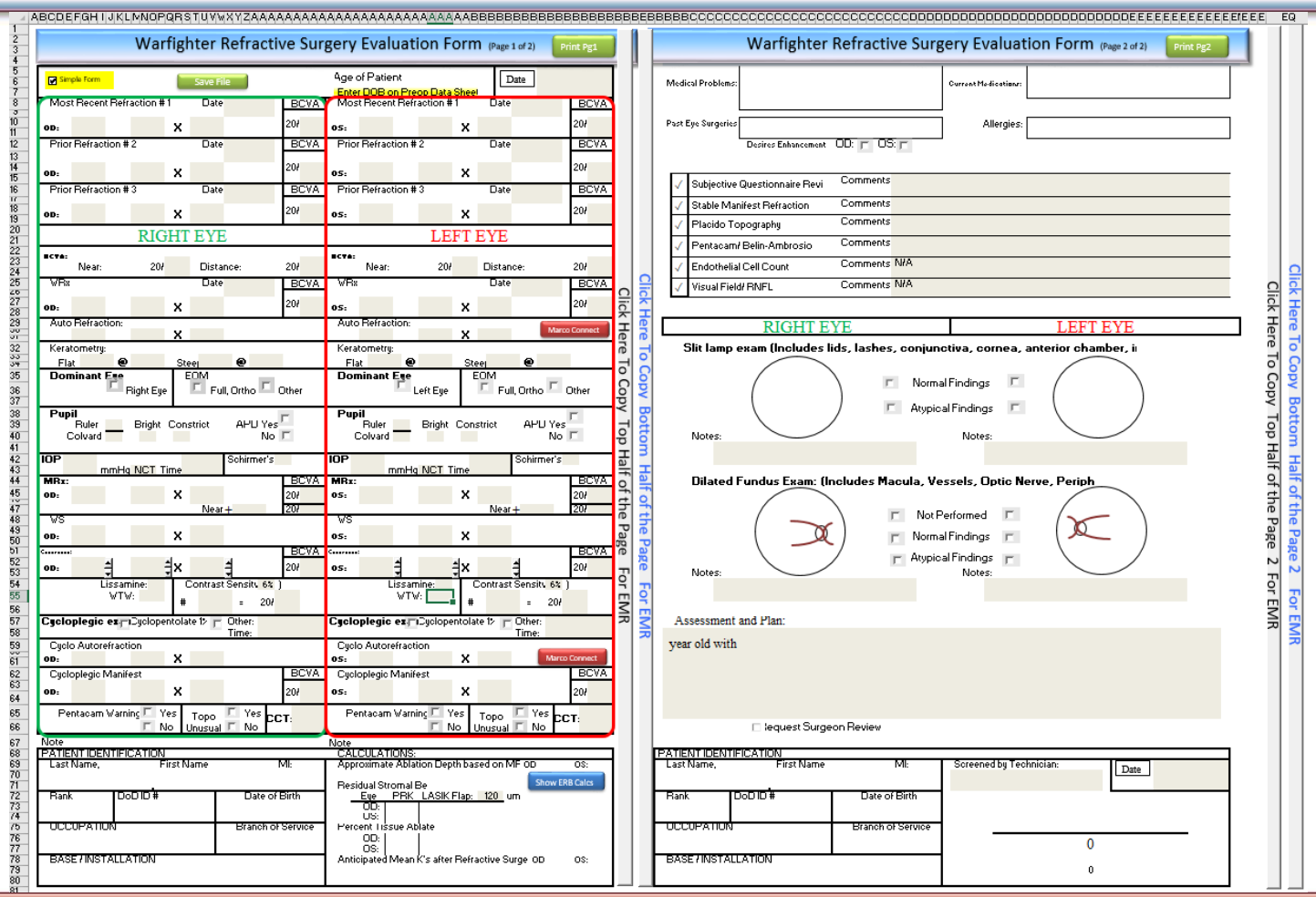
Whats New? CRS Outcomes



"Medically Ready Force…Ready Medical Force"

Refractive Surgery Complications

Chronic dry eye in PRK and LASIK: manifestations, incidence and predictive factors

Kraig S. Bower, MD[1], Rose K. Sia, MD[2], Denise S. Ryan, MS[2], Michael J. Mines, MD[3], and Darlene A. Dartt, PhD[4]

- 143 Active duty Army personnel undergoing LASIK or PRK
- Dry eye evaluation performed and questionnaire administered pre and post-operatively
- 12 months postoperatively 5% of PRK and 0.8% of LASIK patients had developed chronic dry eye

PRK Complications

- Haze (sunglasses!)
- Recurrent Corneal Erosion
- Infection

PRK Complications: RCE

Symptoms of dry eye and recurrent erosion syndrome after refractive surgery

John A. Hovanesian, MD, Sujal S. Shah, MD, Robert K. Maloney, MD

- 2001 Study surveying 1731 patients that had LASIK or PRK at least 6 months previously
- 231 PRK and 550 LASIK patients replied
- 20.4% of PRK and 8% of LASIK patients reported sharp pain episodes
- 14.7% of PRK and 5.6% of LASIK patients reported “eyelid sticking to eyeball”
- Most do not come into clinic, but doesn’t mean it isn’t happening!

LASIK Complications

- Complications
- LASIK
  - Intraoperative (suction loss)
  - DLK
  - Flap dislocation
  - Epi ingrowth
  - Macro/Microstriae
  - Infection
  - Post-operative ectasia

LASIK Complications: DLK

- **D**iffuse **L**amellar **K**eratitis aka “Sands of Sahara”
- Inflammation present in flap interface, sometimes caused by trapped particles in interface, laser energy
- Usually asymptomatic patient, white eye
- Typically seen early: post-op day 1
- Treatment: frequent topical steroids, sometimes oral steroids, flap irrigation

LASIK Complications: Flap dislocation

Early Flap Displacement after LASIK

Gerry Clare, FRCOphth, Tara C. B. Moore, PhD, Claire Grills, PhD, Antonio Leccisotti, MD, PhD, Johnny E. Moore, FRCOphth, PhD, Steve Schallhorn, MD

- 2011 study of 81,238 eye who underwent LASIK at Optical Express in UK, followed for 12 months
  - 23,997 with mechanical microkeratome, rest with femto
  - 10 flap dislocations, all within 48 hours and with associated trauma (0.012%)
  - Femto flaps less likely to dislocate than microkeratome flaps

LASIK Complications: Ectasia

- Postoperative Corneal Ectasia
- Estimated incidence of 0.04%-0.60% after LASIK
- Less common after PRK
- Treatments
  - RGP (scleral/miniscleral)
  - Intrastromal rings
  - Corneal cross linking (with PRK?)
  - Corneal Transplant

SMILE Complications

Safety and Complications of More Than 1500 Small-Incision Lenticule Extraction Procedures

Anders Ivarsen, MD, PhD, Sven Asp, MD, DMSci, Jesper Hjortdal, MD, DMSci

- Epithelial abrasions 6%
- Cap tears 1.8%
- Difficult lenticule extraction 1.9%
- Suction loss 0.8%

- Trace Haze 8%
- Interface inflammation (abrasion) 0.3%
- Interface infiltrate 0.3%
- Irregular corneal topography 1%

SMILE Complications

Refractive Surgery Knowledge for ODs

- Preop Care
- Get to know your local refractive surgery center
  - What constitutes abnormal topography?
  - Corneal scars?
  - Pachymetry measurement required?
  - Medications/medical screening
  - Other

Refractive Surgery Knowledge for ODs

- Preop Care
- At minimum: Refractive stability
  - Understanding of overminused Rx, hyperopic variability in measurement
- San Diego perspective
  - Respect ODs in busy clinic
  - No judgement!

Refractive Surgery Knowledge for ODs

- Preop Care
  - OD has important role as knowledgeable advisor for patient
  - Help patient in Risk/Potential benefit decision
  - Education upfront helps all along the way
  - Can you send someone who falls outside the laser refractive limits? Yes*

Refractive Surgery Knowledge for ODs

- Preop Care
  - Setting Expectations
    - PRK recovery timeline
    - Hyperopes
    - High Astigmatism
    - High Myopes
    - Low Treatments
    - Dry Eyes (manage MGD/lid disease aggressively)
    - Halos/Glare/Starbursts
    - Local Process, administrative “tips”

Refractive Surgery Knowledge for ODs

- Post-op Care
  - Likely complications to be encountered in Optometry clinic
    - DRY EYE
    - RCE (20% post-PRK reported sharp pains in eye 6 months + after surgery)
    - Epi Ingrowth
    - Primary undercorrection
    - Regression
    - Loss of BCVA/quality of vision

Key Takeaways

- DHA Refractive Surgery Board is active and will be an important part in supporting refractive surgery in the military going forward
- DoD utilizes multiple refractive surgery laser platforms to treat all types of refractive error
- SMILE is gaining popularity and will increasingly fill a role in refractive treatment in the military
- Topography-guided corneal refractive surgery with Phorcides may have a role in treating normal and abnormal corneas
- Complications of refractive surgery are typically manageable, but reinforce the need for good informed consent

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To receive CE/CME credit, you must register by 1000 ET on 5 June 2021 to qualify for the receipt of CE/CME credit or certificate of attendance. You must complete the program posttest and evaluation before collecting your certificate. The posttest and evaluation will be available through 18 June 2021 at 2359 ET. Please complete the following steps to obtain CE/CME credit:

1. Go to URL https://www.dhaj7-cepo.com/
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4. Follow the onscreen prompts to complete the post-activity assessments:
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