The Effect of Altitude on Vision in Military Personnel Following SMILE Refractive Surgery

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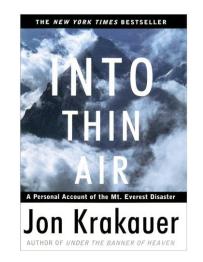
DISCLAIMER

- The views expressed herein are those of the author and do not necessarily reflect the official policy or position of the Defense Health Agency, Brooke Army Medical Center, the Department of Defense, nor any agencies under the U.S. Government.
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Corneal Refractive Surgery (CRS)- Changes at Altitude

Corneal flattening with associated hyperopic shift in post-RK patients exposed to high altitudes

- 1988 case report¹
 - Proposed that decreased barometric pressure is the cause of worse vision in post-RK patients at altitude
- 1995 case series report²
 - Exposure to 12,000' in Bolivia → progressive hyperopic shift and corneal flattening in post-RK patients
 - Hypothesized that hypoxia causes increased stromal hydration with focal corneal expansion
- 1996 study³
 - Significant and progressive corneal changes after 24 hrs of exposure to 14,100' (Pike's Peak)
- 1996 case report⁴
 - Physician s/p bilateral RK suffered disabling RE changes at 27,000' (Mt Everest)
- 1998 prospective study⁵
 - Air-tight goggles \rightarrow proved that corneal changes due to hypobaric hypoxia



Corneal Refractive Surgery (CRS)- Changes at Altitude

Few case reports of myopic shift at altitude in post-LASIK eyes

- 2000 case report⁶
 - Post-LASIK patient experienced noticeable nearsightedness while mountain climbing (Peru)
- 2001 case report⁷
 - 2 physicians post-LASIK with moderate loss of UDVA with normal UNVA at 22,841' (Argentina)
- 2001 prospective study⁸
 - Air-tight goggle system \rightarrow myopic shift
- Case reports of normal vision at altitude in post-LASIK patients^{9,10}

No significant corneal changes reported in post-PRK eyes at altitude^{11,12}

Study Question: Do post-SMILE corneas remain stable when exposed to a hypobaric hypoxic environment under operational conditions?

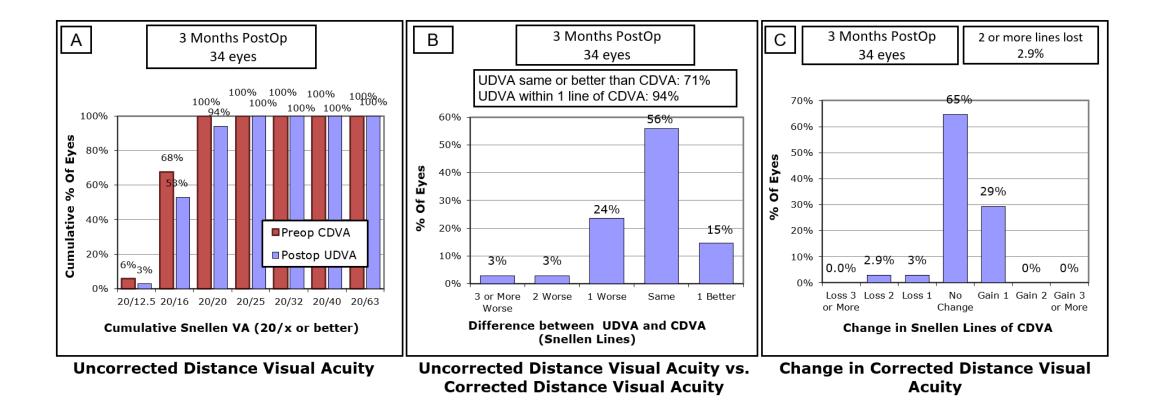
"SMILE at Altitude" Study Design & Patient Demographics

Design: Non-randomized prospective study

Subjects:

- 17 active-duty personnel at least 1 month s/p SMILE OU (Zeiss VisuMAX femtosecond laser) performed at the Joint Warfighter Refractive Surgery Center (Lackland AFB)
 - 15 males, 2 females
 - Age: 21-39 (mean: 28.4)
 - Days from SMILE procedure: 31-387 (mean: 142 days)
 - Inclusion criteria
 - AD military age 21-54
 - Undergone bilateral standard of care SMILE refractive surgery for myopia correction, at least 30 days earlier
 - Cleared to participate by a flight surgeon
 - Attended the required Altitude Chamber Research Training (ACRT)
 - Agree to avoid hyperbaric and hypobaric environmental conditions for 72 hrs after chamber flight
 - Exclusion criteria
 - Pregnancy or planning to become pregnant
 - Pre-existing medical conditions found by flight surgeon that would DQ subject from altitude chamber participation

POM3



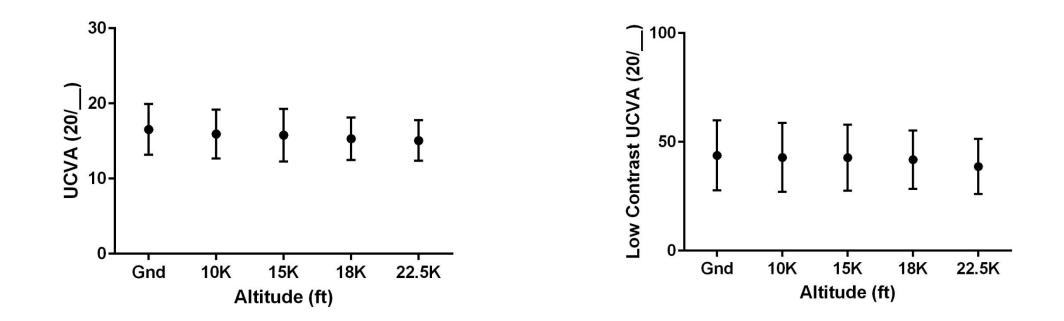
"SMILE at Altitude" Study Methods

Examinations

- KBR Hypobaric Chamber at Brooks City-Base (San Antonio, TX)
 - Ground-level (GL, approx. 675'), 10000', 15000', 18000', and 22500'
 - Ascent/descent rate: 5000'/min
 - 10-30 mins at each altitude
 - Subjects and testers wear USAF approved aircrew oxygen masks with 100% oxygen
- Measured parameters
 - High- and low-contrast (5%) visual acuity
 - Rear-illuminated light box (Precision Vision) at 13 feet under dark room conditions
 - Sloan ETDRS High and 5% Low Contrast
 - Refractive error (NIDEK ARK-530A Auto Refractor)
 - Keratometry (OCULUS Pentacam HR)
 - Slit-lamp exam at ground level and at 22500' (Kowa SL-15 portable slit lamp)



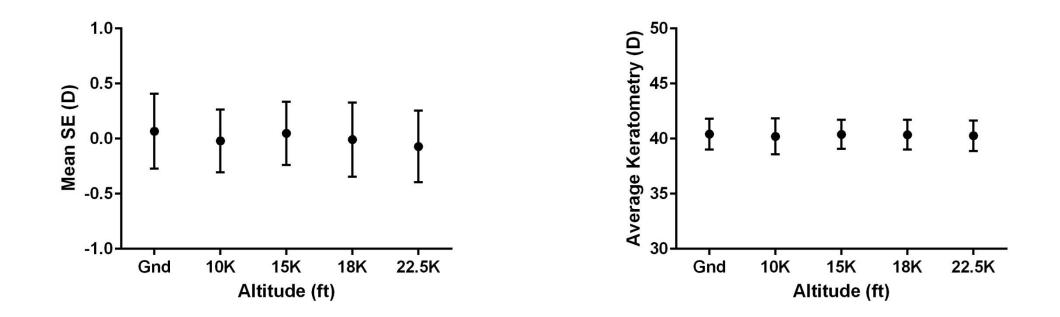
"SMILE at Altitude" Study Data- UCVA & LCVA



P-value: 0.0692

P-value: 0.0602

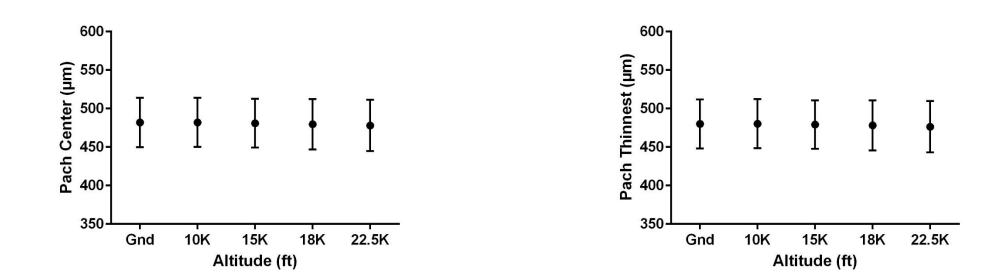
"SMILE at Altitude" Study Data-Refractive Error & Keratometry



P-value: 0.0615

P-value: 0.1798

"SMILE at Altitude" Study Data- Pachymetry



P-value: 0.0581

Study Conclusions

- No significant change in high- and low-contrast uncorrected visual acuity, corneal thickness, or refraction up to 22,500' simulated altitude
- Post-SMILE corneas demonstrate stability in a hypobaric hypoxic environment over a 30 min 1 hour time period
- Hypotheses
 - Corneal incision depth plays a role in corneal stability
 - Undiagnosed corneal endothelial dysfunction in case reports of swelling and refractive changes

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