EVIDENCE BASED MEDICINE IN SPACE FLIGHT: EVALUATION OF INFLIGHT VISION DATA FOR OPERATIONAL DECISION-MAKING

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Disclosure Information

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Mary Van Baalen, PhD

I have no financial relationships to disclose.

I will not discuss off-label use and/or investigational use in my presentation.
Ophthalmology/Optometry Examinations Requirements

**Pre-flight:**

- AME L-21/18 m
  - MRI brain and orbits

- AME L-21/18 m and AME L-9/6 m
  - Ocular questionnaire
  - Visual acuity, distance and near
  - Refraction – manifest and cycloplegic
  - Threshold visual fields
  - Amsler grid
  - Contrast sensitivity
  - Pupil reflexes
  - Extraocular muscle balance
  - Biomicroscopy (slit lamp)
  - Dilated fundoscopic examination including video fundoscopy with training
  - Retinal photography
  - Tonometry
  - Optical coherence tomography (high resolution)
  - Optical biometry

- L-9/6 m
  - 2-D imaging ultrasound

**In flight:**

- L+30; L+100; R-30
  - Ocular questionnaire
  - Visual acuity distance and near
  - Amsler grid
  - Contrast sensitivity
  - Threshold visual fields

- L+30; R-30
  - Fundoscopy
  - Tonometry
  - 2-D imaging ultrasound
  - Optical coherence tomography (high resolution)

- MRI brain and orbits

**Post-flight:**

- R+1/3
  - Ocular questionnaire
  - Visual acuity, distance and near
  - Refraction – manifest and cycloplegic
  - Threshold visual fields
  - Amsler grid
  - Contrast sensitivity
  - Pupil reflexes
  - Extraocular muscle balance
  - Biomicroscopy (slit lamp)
  - Dilated fundoscopic examination including video fundoscopy
  - Retinal photography
  - Tonometry
  - Optical coherence tomography (high resolution)
  - Optical biometry
  - 2-D imaging ultrasound
  - MRI brain and orbits
In-flight Tonometry Exam

- Medically required exam conducted 3 times during an increment
- Privatized cabin video and restricted audio utilized during exam
- Remotely Guided exam (Think Telemedicine)
- Operator performs tap technique on eye simulator under direction of a remote guider
- Operator performs exam on Subject
  - Minimum of three data takes per session

Desired Cabin View of Subject during exam

Immobilization during In-flight exam
Pooled By VIIP CPG CLASS

Class 0 (N=4)

Class 1 (N=1)

Class 2 (N=8)

Class 3 (N=2)
Data Caveats

IOP and Outcome

• Not all subjects had measurements at every time point.

• Not all crewmembers who have data for classification have inflight IOP data

<table>
<thead>
<tr>
<th>VIIP CPG Class</th>
<th>Total</th>
<th>w/ Inflight Tonometry</th>
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Gold Standard vs Tonopen

• Comparison of the results from Tonometry using Goldmann Applanation (TAP) and Tonopen did not show consistent measurements:
  • Trained Operators (JSC Optometrists)
  • Same visit
Comparison TAP vs Tonopen Terrestrial

• Mean Difference (Tonopen-TAP): 1.67 (95%CI: 1.01, 2.33) p=2.8e-6
• Permutation Test p-value: 2e-6
• Proportion more than 4 units apart: 26.8%
Contrast Sensitivity Ground Training

• No ground training provided to crew
• Exposed to software and testing flow during pre-flight Baseline Data Collection exam

In-flight Contrast Sensitivity

• Medically required exam conducted 3 times during an increment
  • One of four exams in the Visual Acuity suite
• Remotely Guided exam (Think Telemedicine)
• Restricted audio only utilized during exam
• RG commands laptop while crew reads eye charts per direction
• Performed at a distance of 15 feet from the laptop (same as distance acuity testing)
Pooled Data

*One subject out of range or not correctable to 20/20
Pooled By VIIP CPG CLASS*

Class 0 (N=4)

Class 1 (N=1)

Class 2 (N=8)

Class 3 (N=2)
Subject 1

![Graph showing data for Subject 1 with 'Percent' on the y-axis and 'PRE', 'L+30', 'L+90', 'R-30', 'POST' on the x-axis. The graph includes two categories: 'OD' and 'OS'.]
Rationale for Removal

• Anatomical changes associated with contrast sensitivity issues occur late in the pathological process, often outside of 6-month mission timeframe.

• Precursors to these anatomical changes can be identified by OCT scans and Fundocsopic imaging.

• VIIP Research & Clinical Advisory Panel (RCAP) agreed in-flight contrast sensitivity testing would be better suited ‘as clinically indicated’ to assess a crewmember as required.

• No change is being requested to the pre- or post-flight testing requirements.

• Performing contrast sensitivity on-orbit has technical challenges that translate into extensive crew time.
Outcomes

• Expedition 40 NASA discontinued routine in-flight tonometry and contrast testing as part of the medical requirement,

• Although these capabilities will continue to be available as needed for clinical care.

• Future evaluation of routine on-orbit ultrasound, OCT, and fundoscopy testing is planned in order to maximize medical resources and crew time.