Welcome to the Fellows Doing Research Symposium!

- Robin Chalmers OD, FAAO, 28 minutes Why Observational Research is important in Optometry
- Danielle Leong OD, PhD FAAO 12 minutes The SENSA study
- Barbara Caffery OD, PhD FAAO 12 minutes The Crying Booth
- Gregory Nixon OD, FAAO 12 minutes The DISCO booth
- Jennifer Harthan OD FAAO 12 minutes The DRESS study
- Muriel Schornack OD FAAO 12 minutes The SCOPE study
- Andrew Pucker OD PhD FAAO 12 minutes The SLAPP study

Robin L Chalmers, OD, FAAO
Past Chair, FDR SIG

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Disclosure Statement:

AcuFocus, Ltd.
Alcon Research, Ltd.
Bayer
CooperVision Corp.
Johnson & Johnson Vision Care, Inc.
Santen
Vision Service Plan
Our Mission:
Fellows Doing Research SIG

• To advance the ocular health of the public through training of Academy Fellows in the concepts and techniques of multi-centered clinical research. Early emphasis will be on observational projects to address essential questions such as study of population norms, prevalence of diseases, repeatability and correlation of common clinical tests to symptoms and/or general disease status.

• By establishing research centers in a broad range of Fellows’ practice settings, rather than those of specialists or tertiary care providers, we will gain access to patients with varied ethnic, socio-economic and range of ocular conditions.
FDR Activities

• Annual Exhibit Hall Booth Projects
  – We call for observational projects
    • Competitive
    • Section/SIG must co-sponsor
    • Applications out in winter
  – Work with the Booth team
    • Research design
    • Logistics
    • IRB application
    • Recruitment of volunteers
    • Analysis & writing
  – AAO Attendees are a unique cohort
FDR Activities

• Bi-Annual Training Retreat
  – We call for observational research projects – competitive
    • YOUR ideas, not fully formed
    • Private practice & different institutions
    • Section/SIG must co-sponsor
    • Applications out in winter
  – Weekend Retreat w/ 3-5 Teams
    • Research design
    • Logistics
    • IRB application
    • Recruitment of volunteers
    • Analysis & writing
What can we learn from observational studies in OD offices?

– Study a diverse range of “normal” patients
  • Academic settings have inherent biases
    – Health literacy
    – Socio-economic
    – Referral pool
– Study patients early in disease progression
  • When does normal become disease?
Some good topics for Cross-Sectional Observational Studies

— Age norms
  • Refractive error
    Racial sub-groups
  • Ocular surface signs & symptoms
  • Imaging of Macular region

— Disc/Retinal Anatomy in Glaucoma
  — Racial sub-groups
  — Refractive error sub-groups
What can we learn from Cross-Sectional observational studies?

– Normative Datasets for:
  • New instruments
    – Example: Many OCTs have “normative” datasets that are no larger than the populations tested in the FDR Exhibit Hall Booths
  • Comparison of measures from 2 similar instruments
  • New “distrupters”
    – Opternative
    – Hubble lenses
What can we learn from Longitudinal observational studies?

– Progression of Disease
  • Sjögren’s Syndrome
  • Macular degeneration
  • Myopia
  • Diabetes

– Changes with age in “normals”

– Effects of co-morbidities

– What is “clinically significant” change?
How can you participate in FDR projects?

– Join the FDR SIG
  • Mark FDR SIG on your AAO profile
– Join or form a team from your Section or SIG
  • Bi-annual Training Retreats – 3-5 study teams
  • Annual Exhibit Hall Booth – 1 team/year
– Ask any FDR Steering Committee Member

Let’s learn about what we DON’T know!
The Study of Eye Movements and Number Naming Speed in Adults (SENSA Study)

Danielle Leong, OD, PhD, FAAO

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Disclosure Statement:

Dr. Leong is employed as a director of research at King-Devick technologies, inc.

King-Devick technologies, inc. and the Fellows Doing Research SIG sponsored this project.
Background

- KD Test of rapid number naming
  - Performance based time/error score
- Norms established for ages 6-14
  - Screens for oculomotor dysfunction
  - Performance correlates with reading fluency and academic performance
Background

- Research supporting use in screening for concussion using individualized baseline

- Research indicating KD screening utility in neurological dysfunction when compared to neurologically normal controls:
  - Parkinson’s
  - Alzheimer’s & Dementia
  - multiple sclerosis
  - Sleep disorders
  - Migraine
  - Hypoxia

Background

Aims:
• Establish an adult normative database for KD
• Determine variables that influence KD performance

Clinical Relevance:
• Allow for translation of research findings to clinical practice for the evaluation and management of neurological conditions
Methods

5 clinical study sites (4 private, 1 academic)

Inclusion & Exclusion:
- >15 y/o
- BCVA <20/30 at Near OU
- No history of:
  - Neurological condition
  - Dyslexia
  - Concussion diagnosis within 3mos
  - Previous diagnosis of Post-Concussion Syndrome

Clinical Measures:
- Gender
- Age
- Race/Ethnicity
- Education
- Concussion history
- Presence/Absence of strabismus and amblyopia
Results

Data collected for n=691 study participants

- Performance did NOT vary by:
  - History of concussion
  - Gender
  - Amblyopia/Strabismus

- High levels of test-retest reliability were observed between the two trials (ICC=0.93)

- Better RNN performance associated with:
  - Younger age (≤ 39yrs vs. >40yrs)
  - Higher education
  - Caucasian or Hispanic race/ethnicity
Conclusion

• Saccadic evaluation reveals important insight in neurological functioning
  – KD test identifies changes in functioning due to traumatic brain injury and neurodegenerative conditions
  – Knowledge of confounding variables is important for application in neurologically diseased populations and its development as a clinical measurement tool

• Normative database allows for early screening and management of conditions that affect visual-cognitive pathways (i.e. Parkinson’s, dementia, Alzheimer’s)
  – Ongoing research collaborations with Mayo Clinic Movement Disorders, Mayo Clinic Sleep Neurology and Boston Alzheimer’s Disease Center
Keys to Team Success

Study Design/Protocol
- Straightforward, practical
- Be mindful of time/effort requirement

Communication is KEY!
- Monthly team meetings
  - Doodle for availability
  - Pre-Meeting Agenda
  - FreeConferenceCall.com
  - Action Items & Follow-up
  - Google Calendar dates/deadlines

Utilize Resources Available
- Secure shared database
- Data Review
- Get students/trainees involved
- FDR Retreat

Grant opportunities:
- Industry sponsors
- Illinois Society for the Prevention of Blindness
- Academy Clinical Research Award
- Young investigators awards
Thank you

Danielle Leong
Leong.Danielle@gmail.com
Please remember to complete your session evaluations on the Academy.18 meeting app

Tweet about this session using the official meeting hashtag

#Academy18
The Importance of Clinical Research and Observational Studies in Optometry

Barbara Caffery
OD, PhD, FAAO

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Disclosure Statement:
Nothing to disclose
The Crying Booth
The correlation of tear osmolarity and dry eye symptoms

Correlation of Tear Osmolarity and Dry Eye Symptoms in Convention Attendees

Barbara Caffery*, Robin L. Chalmers†, Harue Marsden‡, Greg Nixon†, Ron Watanabe†, Wendy Harrison*, and G. Lynn Mitchell§

Financial disclosures

• The AAO provided support for Booth rental, printing and supplies for this study
• TearLab, Inc. loaned instruments and donated chips and technical support
• Foresight Regulatory Strategies, Inc. loaned the I-pads and data management support
Background

• DEWS 2007 Definition:

• Dry eye is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface.

*Lemp M et al. IOVS 2007*
Background – New Instrument

The Tearlab is a commercially available instrument that collects 0.05 microlitres of tears from the lower tear meniscus of a patient.

The instrument then calculates the osmolarity of the tears using electrical conductivity and displays it on a screen.

This instrument was chosen for its ease of use.

The TearLab instrument was the first clinician-friendly tool for osmolarity measurements in regular patient care.”
What was known about tear osmolarity as measured in the lab?

- Osmolarity of 316 mOsmol/L was found to be the most accurate of all single tests in the diagnosis of dry eye using meta-analysis (Tomlinson et al IOVS 2006)

- Osmolarity was found to be the best marker of disease severity across normal, mild to moderate and severe dry eyes. (Sullivan BD IOVS 2010)

- Osmolarity was found to be suitable for dry eye diagnosis mainly in severe dry eye. (Versura P et al Curr Eye Res 2010)
TearLab Instrument
Purpose

- To determine the correlation between tear osmolarity readings and symptoms of dry eye in a non-clinical convenience sample

- To determine how well symptoms and osmolarity correlate with the self-assessment of dry eye
Methods

• 249 attendees in the Exhibit Hall at the 2012 AAO meeting participated during 3 days of testing.

• Contact lens wearers were excluded.

• Pearson correlations determined the relationship between variables.
Methods....

• Informed consent & demographic information
• Completed a 5-item Dry Eye Questionnaire© (DEQ-5) and answered the question “Do you think you have dry eye?”
• Self-administered electronic questionnaire
• Osmolarity was captured via the TearLab instrument on the right then left eyes
5 Questions

Frequency & Late Day Intensity of:

Eye Discomfort

Eye Dryness

Frequency of Watery Eyes

Sum Score

DEQ-5

1. Questions about EYE DISCOMFORT:
   a. During a typical day in the past month, **how often** did your eyes feel discomfort?
      0 Never
      1 Rarely
      2 Sometimes
      3 Frequently
      4 Constantly
   b. When your eyes felt discomfort, **how intense** was this feeling of discomfort at the end of the day, within two hours of going to bed?
      Never Not at All Very
      Intense Intense Intense
      0 1 2 3 4 5

2. Questions about EYE DRYNESS:
   a. During a typical day in the past month, **how often** did your eyes feel dry?
      0 Never
      1 Rarely
      2 Sometimes
      3 Frequently
      4 Constantly
   b. When your eyes felt dry, **how intense** was this feeling of dryness at the end of the day, within two hours of going to bed?
      Never Not at All Very
      Intense Intense Intense
      0 1 2 3 4 5

3. Question about WATERY EYES:
   During a typical day in the past month, **how often** did your eyes look or feel excessively watery?
   0 Never
   1 Rarely
   2 Sometimes
   3 Frequently
   4 Constantly

Score: \[ 1a + 1b + 2a + 2b + 3 = \text{Total} \]
Scoring DEQ-5©

≥ 6 < 12 suspect:
  - non-Sjögren’s dry eye
  - Mild to Moderate dry eye

≥ 12 suspect:
  - Sjögren’s Syndrome
  - Severe dry eye
Demographic and questionnaire data entry

Osmolarity testing: right then left eye
Age vs Osmolarity

No Correlation

Figure 1: Scatter plot of age versus average osmolarity

![Scatter plot of age versus average osmolarity](image)
Age vs DEQ-5 score

No Correlation
Figure 1: Scatter plot of DEQ-5 score and average osmolarity, by self-assessment of DE.

NO CORRELATION with Osmolarity but CORRELATION with DEQ-5
Differences between eyes

Figure 3. Bland-Altman Plot of Inter-Ocular Agreement in Osmolarity
Time of day vs average osmolarity

No Correlation
Results

• No significant correlation between:
  – DEQ-5 scores and average tear osmolarity (correlation coefficient = 0.02)
  – DEQ-5 score and highest osmolarity (correlation coefficient = 0.03)
  – Osmolarity between subjects by self-reported dry eye status (average osm p=0.23, high osm p=0.14)

• Mean DEQ-5 score was **significantly higher** among subjects who self-reported dry eye compared to those who did not (mean=11.3 vs 5.4, p<0.0001).
• Ours was a non clinical population
• Ours was a well-educated and knowledgeable group
• Knowledge couldn’t change their osmolarity readings
• Ours likely contained mild dry eye subjects
• No other dry eye test were performed (Schirmer, slit lamp, staining, MG assessment)
• This study took place in a dry environment in late fall in Phoenix, Arizona
• These tests should be considered complimentary, not correlated!
Conclusions

• In this non-clinical cross-section, there was no significant correlation between tear osmolarity and ocular symptoms as reported with the DEQ-5

• or

• between tear osmolarity and a Gestalt self-assessment of dry eye

• Must query symptoms & perform tear tests!
The Clinical Question

• How do we diagnose and monitor dry eye?
• What is important: osmolarity, inflamma dry, corneal staining, conjunctival staining, BUT, Schirmer test?
• What is symptomatic dry eye without high osmolarity?
• What is a high osmolarity eye without dry eye symptoms?
Influence of Optic Disc Size on Identifying Glaucomatous Optic Neuropathy

Gregory J. Nixon OD, FAAO; Ron Watanabe OD, FAAO
Michael Sullivan-Mee OD, FAAO; Anthony DeWilde OD, FAAO
Lisa Young OD, FAAO; G. Lynn Mitchell M.A.S.

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Disclosures

- The content of this COPE approved lecture was prepared independently without input or sponsorship from any industry source.

- Speakers have no direct financial or proprietary interest in any products or services contained within the presentation.
Background

- Early detection and intervention is key to limiting glaucoma related blindness

- Challenges of early Glaucoma detection
  - Lack of public health awareness
  - Asymptomatic nature of early disease
  - Access to professional eyecare services
  - Can occur with normotensive IOP
  - ONH evaluation is highly subjective
ONH Factors to Evaluate

- Size, depth, and configuration of optic cup
- Integrity of neuroretinal rim
  - Thinning, excavation, notching
- Disc hemorrhage
- NFL defect
- β-zone peripapillary atrophy
- Change in cup and rim appearance over time
Previous Research

- Low number of glaucoma experts (12 subjects) evaluating a high number (100) of ONH images
- Large degrees of diagnostic inaccuracy in identifying glaucomatous neuropathy
  - Glaucomatous ONH correctly identified 17-63% of the time
  - Normal ONH correctly identified 8-68% of the time

“DISCO” Booth Study Purpose

To use a large group of observers to determine the influence of optic disc size on practitioners ability to accurately identify glaucomatous optic neuropathy in optic nerve photographs and to determine the correlation of the ISNT rule with normal and glaucomatous optic nerves.
Methods: Test Images

- Deidentified ONH images were obtained with consent from practices of study investigators
- EXCLUSION CRITERIA
  - Optic nerve drusen, optic pits, malinserted or other anomalous discs, non-glaucomatous optic neuropathy, i.e. no other ocular disease which would impact ONH photo or OCT measurement
  - Refractive Error:
    - Spherical refraction > ± 5.0D
    - Cylindrical refraction > 3.0D
  - Trabeculectomy or other drainage procedure
Inclusion Criteria FOR ALL PATIENT IMAGES:

- VF testing must be conducted using Humphrey SITA testing strategy showing:
  - <15% False Positives
  - <20% Fixation Losses

- OCT must be conducted with Zeiss Cirrus and show signal strength of $\geq 7$

- The submitted stereo photos, OCT printout, and VF must have been taken/measured within 6 months of each other
Inclusion Criteria FOR NORMAL ONH IMAGES:

- **VF**
  - Only 1 reliable test required
  - MD less than -2.5dB
  - No cluster of 3 contiguous points flagged below 5% level of pattern deviation plot
  - Normal GHT

- **NFL**
  - Normal (within 95% of normative database) average thickness and quadrants thicknesses

Methods: Test Images
Methods: Test Images

Inclusion Criteria FOR GLAUCOMATOUS ONH IMAGES:

- **VF**
  - 2 reliable tests that show repeatable loss measuring the following:
    - MD less than -6dB for 30-2, MD less than -5dB for 24-2
    - A cluster of 3 contiguous points flagged below 5% level of pattern deviation plot, with at least 1 point flagged below the 1% level
    - <25 % of points depressed below 5% level and <15 % points depressed below 1% on pattern deviation plot
    - All points in the central 5deg are ≥15dB

- **NFL**
  - Reduced (thinner than 95% of normative database) average NFL or NFL superior quadrant or NFL inferior quadrant
Methods: Test Subjects

- After consent, 261 exhibit hall attendees volunteered to serve as subjects.

- Each subject completed questionnaire detailing his/her:
  - Provider type (student, resident, practicing OD, vision scientist)
  - ± Residency training
  - Years of experience
  - Mode of practice
  - Degree of glaucoma exposure in practice
Methods: Test Sequence

- Each subject was presented (in random order) stereoscopic photographs of 6 optic nerves.

<table>
<thead>
<tr>
<th>Normal ONH small size (NS)</th>
<th>Normal ONH medium size (NM)</th>
<th>Normal ONH large size (NL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glaucomatous ONH small size (GS)</td>
<td>Glaucomatous ONH medium size (GM)</td>
<td>Glaucomatous ONH large size (GL)</td>
</tr>
</tbody>
</table>

- Optic nerve size was determined using the following disc area values as measured on the Cirrus OCT:
  - $<1.63\text{mm}^2 = \text{small}$, $1.63-1.97\text{mm}^2 = \text{medium}$, $>1.97\text{mm}^2 = \text{large}$
Each subject answered the following (3) YES/NO questions for each photo.

1. Does this optic nerve follow the ISNT rule?

2. Is this optic nerve glaucomatous?

3. Based on this optic nerve appearance, is this a patient you would typically order an OCT for further glaucoma evaluation?
## Results: Subject Characteristics

- **Optometry Students**: 21.84%
- **Optometry Residents**: 12.26%
- **Practicing Optometrist**: 59.00%
- **Vision Scientist**: 6.90%

After excluding current students and residents,
- **Residency Trained**: 47.13%
- **No Residency**: 52.87%

- Approximately equal distribution of practitioners across six slide orders
Results: Overall

- Overall 65% of all ONH presentations were correctly identified
- 67% of the NORMAL ONH images were correctly identified
- 62% of the GLAUCOMATOUS ONH images were correctly identified
Results: Subject Performance

None of the practitioner characteristics had a significant impact on correctly identifying a normal from a glaucomatous optic nerve. The diagnostic accuracy of each subgroup was as follows:

- Optometry Residents 65.1%
- Optometry Students 64.6%
- Practicing ODs 64.3%
- Vision Scientists 60.2%
FIGURE 1: Percentage of ONH images in which nerve type was correctly identified

<table>
<thead>
<tr>
<th>Nerve type and size</th>
<th>Percentage correctly identified as Glaucomatous/Normal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal Optic Nerve</td>
<td>Small: 74.1%  Medium: 91.6%  Large: 34.2%</td>
</tr>
<tr>
<td>Glaucomatous Optic Nerve</td>
<td>Small: 8.8%  Medium: 87.5%  Large: 89.4%</td>
</tr>
</tbody>
</table>
FIGURE 2: Percentage of ONH images judged as following the ISNT rule

- Normal Optic Nerve:
  - Small: 39.5%
  - Medium: 76.1%
  - Large: 45.6%

- Glaucomatous Optic Nerve:
  - Small: 63.9%
  - Medium: 31.9%
  - Large: 31.2%

Percentage following ISNT rule:
- Normal Optic Nerve: 54%
- Glaucomatous Optic Nerve: 42%
FIGURE 3: Percentage of ONH images for which additional follow up would be ordered

- Normal Optic Nerve:
  - Small: 38.8%
  - Medium: 17.5%
  - Large: 82.9%

- Glaucomatous Optic Nerve:
  - Small: 19.0%
  - Medium: 93.9%
  - Large: 95.0%
Conclusions

- There is consistent difficulty in detecting early glaucomatous neuropathy regardless of study subject size, level of training, or years of experience.

- Optic disc size is an important component to accurately diagnose glaucoma.

- Poor correlation between subjective assessment of an ONH following the ISNT rule and glaucoma determination.
Conclusions

- Whether done subjectively or with the aid of an objective imaging device, all optic nerve assessments for glaucoma should include optic disc size evaluation.

- To avoid the risk of underdetection, a thorough evaluation is warranted to determine glaucomatous risk when small optic nerves are noted.
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Alanna Louie    Debby Yeung
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THE COURSE OF DRY EYE IN SJOGREN’S SYNDROME (DRESS)

JENNIFER HARTHAN OD, FAAO, FSLS
Disclosure Statement:

Nothing to disclose
Goals

• Determine how Sjogren’s Syndrome (SS) is diagnosed in a variety of clinical settings.

• Describe the course of dry eye disease (DED) in SS.

• Provide guidance on the prognosis and management of DED to SS patients.
Initial Project

- Multicenter, retrospective review of a large sample of SS patients.

*Hypothesis:* DED signs and symptoms become worse over time in patients with SS.
### 6 Study Sites

<table>
<thead>
<tr>
<th>Site</th>
<th># charts</th>
<th>Location</th>
<th>Type of practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Waterloo School of Optometry and Vision Science Clinic</td>
<td>n=23</td>
<td>Waterloo, Ontario</td>
<td>Academic</td>
</tr>
<tr>
<td><strong>Sruthi Srinivasan PhD, BS Optom, FAAO</strong></td>
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<tr>
<td>Toronto Eye Care</td>
<td>n=36</td>
<td>Toronto, Ontario</td>
<td>Private Practice</td>
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<tr>
<td><strong>Mira Acs OD, FAAO</strong></td>
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<tr>
<td><strong>Barbara Caffery OD, PhD, FAAO</strong></td>
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</tr>
<tr>
<td>Eyelabs Optometry and Centre for Ocular Surface Disease</td>
<td>n=9</td>
<td>Brampton, Ontario</td>
<td>Private Practice</td>
</tr>
<tr>
<td><strong>Cornea Center for Clinical Excellence, Illinois College of Optometry</strong></td>
<td>n=19</td>
<td>Chicago, Illinois</td>
<td>Academic</td>
</tr>
<tr>
<td><strong>Jennifer S. Harthan OD, FAAO, FSLS</strong></td>
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<tr>
<td>Edmonds, Husz and Pemberton Eye Center</td>
<td>n=19</td>
<td>Tucson, Arizona</td>
<td>Private Practice</td>
</tr>
<tr>
<td><strong>Charles Edmonds OD, FAAO</strong></td>
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<tr>
<td><strong>Bart Pemberton OD, FAAO</strong></td>
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<tr>
<td>UC Davis Health System</td>
<td>n=17</td>
<td>Sacramento, California</td>
<td>Academic</td>
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<td><strong>Melissa Barnett OD, FAAO, FSLS</strong></td>
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<td><strong>Larisa Johnson-Tong OD, FAAO</strong></td>
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Consultants: Dominik Papinski PhD (Statistician), Susan Kelly PhD (Statistician), Peter Bergenske OD, FAAO, Robin Chalmers OD, FAAO, Lyndon Jones Bsc, PhD, FAAO (Academic Partner)
Study Design and Implementation

- Inclusion criteria:
- Diagnosis of SS
  - American-European Consensus Criterion (AECC)
  - Optometrist, ophthalmologist, physician and/or rheumatologist
- Minimum 2 visits within 10-15 consecutive months
  - Data from up to 500 patient years from the year 2000 onward
  - The first visit was considered the diagnostic visit
  - 6-month period for review
Results

• 123 charts of SS patients were included
• Seventy-five (61%) of the charts had clear physician diagnostic records while the remaining had patient reported history of SS.
• 93.5% (115) of the patients were female
• Average age of patients: 56.1 years + 11.9 (range 24 to 84 years)
• Average time since diagnosis: 7.2 ± 5.1 (range 0 to 17)
Clinical Grading Methods

• Harmonized Symptom Score

<table>
<thead>
<tr>
<th>AECC (1 site)</th>
<th>Harmonized Score (1-8)</th>
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<tbody>
<tr>
<td>1-3</td>
<td>2</td>
</tr>
<tr>
<td>4-6</td>
<td>5</td>
</tr>
<tr>
<td>7-10</td>
<td>8</td>
</tr>
<tr>
<td>SPEED (1 site)</td>
<td></td>
</tr>
<tr>
<td>1-7</td>
<td>2</td>
</tr>
<tr>
<td>8-14</td>
<td>5</td>
</tr>
<tr>
<td>15-28</td>
<td>8</td>
</tr>
<tr>
<td>Descriptive (6 sites)</td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>2</td>
</tr>
<tr>
<td>Moderate</td>
<td>5</td>
</tr>
<tr>
<td>Severe</td>
<td>8</td>
</tr>
</tbody>
</table>

Table 2: Harmonized Symptom Score

Symptoms of DED were recorded in 110 (89.4%) charts

Most Common Symptoms at First Visit

- Dryness: 110
- Irritation: 52
- Burning: 38
- Vision Problems: 37
- Photophobia: 28
Corneal fluorescein staining was the most commonly recorded objective test.  
- 78% (96/123) in at least one eye

Staining showed no difference in age or duration of disease  
- (n=119, r=-0.17, p=0.065)  
- (n=71, r = 0.048, p = 0.691)

Conjunctival Lissamine Green Staining

- Not recorded regularly
- Used by one site
  - 32 of the 36 charts (89%) had documented using the AECC system
    - 0-3 nasal and 0-3 temporal staining score
    - Range OD = 3-6
    - Range OS = 2-6

Monitoring of DED in SS is Not Uniform Across Practices

Customary practices in the monitoring of dry eye disease in Sjogren’s syndrome

<table>
<thead>
<tr>
<th></th>
<th>Academic sites (n = 59)</th>
<th>Private practice sites (n = 64)</th>
<th>Chi test significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>No symptom scale</td>
<td>42/59 (71.2%)</td>
<td>15/64 (23.4%)</td>
<td>*p ≤ 0.001</td>
</tr>
<tr>
<td>Use of DE questionnaires</td>
<td>0/59 (0%)</td>
<td>22/64 (34.3%)</td>
<td>*p ≤ 0.001</td>
</tr>
<tr>
<td>Schirmer test</td>
<td>14/59 (23.7%)</td>
<td>24/64 (37.5%)</td>
<td>No significance</td>
</tr>
<tr>
<td>TBUT</td>
<td>31/59 (52.5%)</td>
<td>21/64 (32.8%)</td>
<td>*p ≤ 0.001</td>
</tr>
<tr>
<td>Corneal stain</td>
<td>44/59 (74.6%)</td>
<td>49/64 (76.5%)</td>
<td>No significance</td>
</tr>
<tr>
<td>Conjunctival stain</td>
<td>35/59 (59.3%)</td>
<td>41/64 (64.1%)</td>
<td>No significance</td>
</tr>
<tr>
<td>Tear quality</td>
<td>13/59 (22.0%)</td>
<td>11/64 (17.2%)</td>
<td>No significance</td>
</tr>
<tr>
<td>Tear meniscus height</td>
<td>17/59 (28.8%)</td>
<td>8/64 (12.5%)</td>
<td>*p ≤ 0.001</td>
</tr>
<tr>
<td>Anterior blepharitis</td>
<td>38/59 (64.4%)</td>
<td>52/64 (81.2%)</td>
<td>*p ≤ 0.001</td>
</tr>
<tr>
<td>MGD</td>
<td>49/59 (83.1%)</td>
<td>45/64 (70.3%)</td>
<td>No significance</td>
</tr>
</tbody>
</table>

Dissemination of Results
Comparison of the Severity of Dry Eye in Sjogren’s Syndrome versus Aqueous Deficient Dry Eye

Paper, AAO 2017

- Authors:
  - B. Caffery OD, PhD, FAAO, J. Harthan OD, FAAO, M. Acs OD, FAAO,
  - M. Barnett OD, FAAO, L. Johnson-Tong OD, FAAO, S. Kelly PhD,
  - D. Papinski PhD, B. Pemberton OD, FAAO, S. Srinivasan PhD, FAAO
Purpose: To compare the severity of dry eye (DED) of Sjogren’s Syndrome (SS) patients with aqueous deficient dry eye (ADDE) patients using the Delphi grading scale (1-4).

Results:
- 123 SS and 89 ADDE charts were reviewed
- Symptoms were not different in the two groups (p=0.07).
- SS patients had significantly greater worst eye corneal staining (2.72±1.1, ADDE 1.06±1.38, p≤0.001)
- SS patients had significantly greater worst eye conjunctival staining (3.05±0.88, ADDE 1.73±1.27, p≤0.001).
- SS global severity scores, worst eye, were higher than ADDE scores (3.12±0.99, ADDE 2.69±0.94, p = 0.001).
- In the SS group, 43% (n=53) had global severity grade 4 while only 17.4% (n=15) of the ADDE group had grade 4 severity.
CUSTOMARY PRACTICES IN THE MANAGEMENT OF DISEASE IN SJOGREN'S SYNDROME

Mira Acsc, Barbara Cafferyd, Melissa Barret, Larisa Johnson-Tongb, Richard Maharajc, Jennifer Harthanb, Sruthi Srinivasana

a Toronto Eye Care, 55 Bloor Street West, Toronto, ON, Canada
b UC Davis Eye Center, 4860 Y Street, Suite 2400, Sacramento, CA, USA
c Edmonds, Hess & Pemberton Eye Center, 4730 E. Pima Street, Phoenix, AZ, USA
d eyeLABS Optometry and Center for Ocular Surface Disease, Centre for Vision Research, School of Optometry & Vision Science, University of Waterloo, ON, Canada

Accepted 25 May 2018; published online 26 May 2018

SJOGREN'S SYNDROME IN OPTOMETRIC PRACTICES IN NORTH AMERICA

Barbara Cafferya, Jennifer Harthanb, Sruthi Srinivasanb, M. Acsc, Melissa Barnettb, Charles Edmondsc, Larisa Johnson-Tongc, Richard Maharajb, Bart Pembertonc, Dominik Papinski

a Toronto Eye Care, Canada
b Centre for Vision Research, School of Optometry & Vision Science, University of Waterloo, Canada
c UC Davis Eye Center, United States

Contents lists available at ScienceDirect

Contact Lens and Anterior Eye
journal homepage: www.elsevier.com/locate/clae
Future of DRESS

• Next manuscript: Does DED change over time in SS?
  – Describe variables over time

• Prospective study
What Have We Learned?

• We do not fully understand the natural history of SS.
• Chart reviews can be challenging
  – Documentation is critical
• One statistician from beginning to end of study
• Same methodologies to measure and grade variables are essential to be able to provide clear guidance on the prognosis and management of dry eye in SS patients.
References


SCOPE Study Summary

Muriel Schornack, OD, FAAO, FSLS

Please silence all mobile devices and remove items from chairs so others can sit. Unauthorized recording of this session is prohibited.
Disclosure Statement:
Nothing to disclose
Goal: To spearhead clinical research in scleral lenses, and to engage clinicians and basic scientists on a global scale.
Scleral Lenses: A Literature Review

Muriel M. Schornack, o.d.

• Review of scleral lens-related literature from 1943-May 2014
• 139 papers published after introduction of RGP sclerals in 1983
  – 50% case reports/case series
  – 50% abstracts, observational and descriptive studies
  – Only 12 studies described more than 50 patients
  – No multicenter studies were available
Questions

• Who is fitting scleral lenses?
• Who is wearing scleral lenses?
• How are scleral lenses being prescribed?
• What complications have been experienced by patients wearing scleral lenses?
Inaugural Project

• Purpose: Describe international scleral lens prescription and management practices

• Method: Cross-sectional survey of scleral lens providers
  – Members of the Scleral Lens Education Society
  – Members of AOA and AAO cornea/contact lens sections
  – Members of CLAO
Study Implementation

• Cross-sectional survey of scleral lens providers
• Funded by an unrestricted grant from Research to Prevent Blindness and Mayo Clinic Department of Ophthalmology
• Design and implementation assistance provided by Mayo Clinic Survey Research Center
• Biostatistical analysis provided through Mayo Clinic
Results

• 989 respondents
  – Demographic data collected on all respondents
• 723 respondents had fit 5 or more patients with scleral lenses
  – Full survey was completed by these respondents
• Approximately 84,375 patients were represented
• Results provided a “snapshot” view of scleral lens prescription and management practices as of early 2015.
Dissemination of Results

- Posters
- Oral presentations
- Publications
Posters

• GSLS
  – Demographics of scleral lens fitters
  – Scleral lens fitting trends
  – Indications for scleral lens wear

• ARVO
  – Role of scleral lenses in treatment of corneal irregularity and OSD
  – Complications of scleral lens wear

• AAO
  – Current consensus of prescribers’ scleral lens wearing and care recommendations
Oral Presentations

- CLAO: Bridging the Gap with Scleral Lenses
- AAO: Scleral Lens Practices: The SCOPE Studies
- GSLS: Summary of SCOPE Results
- EVER: Scleral Lens Practices: The SCOPE Studies
- IFSLR: Adverse Events Associated with Scleral Lens Wear
- GPLI Webinar: Update on Scleral Lenses: Review of the SCOPE Study
Publications

• Peer-reviewed:

• Non-peer reviewed:
Additional Studies

- Scleral lens fitting strategies
- Patient experience with scleral lenses
- Patient assessment of contact lenses in keratoconus
- Patient assessment of management of ocular surface disease
- Further studies are under development
The Practitioner’s Perception of Scleral Contact Lens Complications

Andrew D. Pucker, OD, PhD, FAAO
Carolina Kunnen, BOptom, PhD
Lisa A. Jones-Jordan, PhD, FAAO
Katherine M. Bickle, OD, MS, FAAO
Jamie Kuhn, OD, FAAO
Justin T. Kwan, OD, FAAO
Jessica Mathew, OD, PhD, FAAO
Disclosure Statement:

The following organizations have supported me over the past three years:

- National Eye Institute
- American Academy of Optometry
- Optikal Care, Inc.
- Alcon
- Oculus, Inc.
- TearLab Corporation
- Bausch + Lomb
- Contamac
- Euclid Systems

I have written newsletters for the following organizations:

- Contact Lens Spectrum
- Contact Lenses Today
- Contact Lens Update
- Optometry Times

None of these entities have directly affected the content of this presentation.
Background

- Scleral lenses are the fastest growing specialty CL modality (Harthan 2017)

- Scleral lenses are commonly used to treat corneal disease, dry eye, and relatively normal eyes (Walker 2016)

- Scleral lenses are considered safe, though complications have been reported such as midday fogging, redness, and discomfort (Walker 2016)

- Frequency of practitioner and patient reported minor scleral lens complications (midday fogging, redness, ocular discomfort) are unknown
Purpose

• A survey was conducted at the 2017 Global Specialty Lens Symposium to determine the frequency of practitioners who report scleral lens complications
Subject Eligibility

• Protocol was approved by the University of Houston’s Institutional Review Board

• Eligibility Criteria
  – Scleral lens fitters who attended the 2017 Global Specialty Lens Symposium
  – Participants were required to have fit at least one scleral lens
Questionnaire

• Fitters completed an online Qualtrics survey
  – Practitioners were queried about their scleral lens experience
  – Practitioners were asked about patient reported and fitter detected scleral lens complications
  – Frequencies and logistic regression were calculated with SAS Version 9.3

Midday Fogging
Results
## Included Subjects

<table>
<thead>
<tr>
<th>Practitioner Experience</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practitioner Experience (years)</td>
<td>16.3 ± 13.4</td>
</tr>
<tr>
<td>Scleral Lens Fitting Experience (years)</td>
<td>5.5 ± 5.0</td>
</tr>
<tr>
<td>New Scleral Lens Fits (fits/month)</td>
<td>7.4 ± 7.1</td>
</tr>
</tbody>
</table>
### Included Subjects

<table>
<thead>
<tr>
<th>Lifetime Scleral Lens Fits</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;10</td>
<td>20 (12.2)</td>
</tr>
<tr>
<td>10-25</td>
<td>31 (18.9)</td>
</tr>
<tr>
<td>25-50</td>
<td>34 (20.7)</td>
</tr>
<tr>
<td>50-100</td>
<td>23 (14.0)</td>
</tr>
<tr>
<td>&gt;100</td>
<td>57 (34.8)</td>
</tr>
</tbody>
</table>
## Complications Ever Encountered

<table>
<thead>
<tr>
<th>Complication</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor Lens Wetting</td>
<td>90.8</td>
</tr>
<tr>
<td>Lens Fogging</td>
<td>84.8</td>
</tr>
<tr>
<td>Blurred Central Vision</td>
<td>40.2</td>
</tr>
<tr>
<td>Ocular Redness</td>
<td>34.8</td>
</tr>
<tr>
<td>Ocular Dryness</td>
<td>24.4</td>
</tr>
<tr>
<td>Ocular Pain/Discomfort</td>
<td>20.7</td>
</tr>
<tr>
<td>Blurred Side Vision/Halos</td>
<td>12.8</td>
</tr>
</tbody>
</table>
Detection of Complications

• More years of fitting scleral lenses was associated with…
  – Practitioner-reported scleral lens fogging ($r = 0.26; p < 0.001$)
  – Patient-reported blurring ($r = 0.18, p = 0.02$)
  – Patient-reported ocular dryness ($r = 0.19, p = 0.02$)

• Encountering all other conditions was independent of the three measures of practitioner experience level
# Top Treatments

<table>
<thead>
<tr>
<th>Condition with Methods</th>
<th>n</th>
<th>Mean Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Poor Wetting</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remove, Clean, and Reapply Scleral Lens</td>
<td>120</td>
<td>45.8 ± 25.9</td>
</tr>
<tr>
<td>Remove, Clean, Soak, and Reapply Scleral Lens</td>
<td>76</td>
<td>44.3 ± 29.0</td>
</tr>
<tr>
<td><strong>Fogging</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remove, Clean, and Reapply Scleral Lens</td>
<td>105</td>
<td>55.1 ± 28.7</td>
</tr>
<tr>
<td>Remove, Clean, Soak, and Reapply Scleral Lens</td>
<td>48</td>
<td>42.4 ± 29.9</td>
</tr>
<tr>
<td><strong>Ocular Redness</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change Peripheral Scleral Lens Curve</td>
<td>45</td>
<td>68.3 ± 25.6</td>
</tr>
<tr>
<td>Artificial Tears</td>
<td>21</td>
<td>35.1 ± 32.0</td>
</tr>
<tr>
<td><strong>Ocular Discomfort</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change Peripheral Scleral Lens Curve</td>
<td>28</td>
<td>59.1 ± 29.5</td>
</tr>
<tr>
<td>Remove, Clean, and Reapply Scleral Lens</td>
<td>9</td>
<td>32.8 ± 25.9</td>
</tr>
</tbody>
</table>
Conclusions

• Most fitters at least occasionally encountered minor scleral lens-related complications

• Scleral lens wetting and scleral lens fogging were at least occasionally detected by almost all fitters

• Experience level was only associated with detecting scleral lens fogging, blurring, and ocular discomfort

• More experienced fitters may have an enhanced ability to detect or elicit symptoms from their patients
Conclusions

• A registry study is needed to better understand the prevalence (major and minor) of scleral lens complications

• Studies aimed at understanding the mechanisms leading to scleral lens complications are needed
Acknowledgments

• Peter D. Bergenske, OD, FAAO

• Harue J. Marsden, OD, MS, FAAO (posthumously)

Disclaimer: This study (6) has been previously presented at the 2018 Global Specialty Lens Symptoms in Las Vegas, NV, USA.
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