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
Outline

• SCOPE I - Scleral lens prescription and management
• SCOPE I^{1/2} - Patient experiences with scleral lenses
• SCOPE III - Patient experiences with keratoconus
• SCOPE IV - describe common strategies for scleral lens fitting parameters
SCOPE I - Scleral lens prescription and management

Muriel Schornack
Introduction

• SCOPE: Scleral Lenses in Current Practice Evaluation
• Study Team Members:
  – Jenny Fogt
  – Jennifer Harthan
  – Amy Nau
  – Cherie Nau
  – Muriel Schornack
  – Ellen Shorter
  – Joe Barr (advisor)
SCOPE Study Team

• Formed in 2014 under the auspices of the FDR SIG of the AAO
• Goal is to perform translational research in the area of scleral lenses
SCOPE I:  
Scleral Lens Prescription and Management Survey

• Background:
  – Widespread interest in scleral lenses is relatively recent
  – Retrospective case reports and case series describe only the use of a limited number of lens designs in a limited number of practices
  – Information on general prescription and management practices related to scleral lenses was lacking
SCOPE I  Methods:

• Survey design:
  – Mayo Clinic Survey Research Center
  – Qualtrics

• Survey administration:
  – Direct e-mail invitation
  – Link included in electronic newsletters
  – Up to 3 reminders sent to individuals who did not respond to initial invitation
SCOPE I Survey Administration

- Survey was available from January 15 – March 31 2015
- 4,407 individuals were initially invited to participate
- Additional 226 potential survey participants were identified by respondents
- Total of 989 responses (partial and complete) received
SCOPE I Results: Demographic Data

- Gender: 61% male
- Practice setting:
  - Group practice (31%)
  - Private practice (29%)
  - Ophthalmology (14%)
  - Academic institutions (14%)
  - Hospital-based practice (6%)
  - Retail (4%)
  - HMO, military, research, lab (≤1% each)
- Country of residence:
  - 72% US
  - Total of 50 countries represented
SCOPE I Results:

• Experienced fitters were defined as those who had fit 5 or more patients with scleral lenses
• Total of 723 experienced fitters identified
• Completed entire survey
SCOPE I Results: Number of Patients

- Mean number of patients: 125 (range 5-3,600)
  - 21% had fit 10 or fewer patients
  - 65% had fit 50 or fewer patients
  - 13% had fit more than 200 patients
- Estimate of total number of patients represented: 84,375
SCOPE I Results: Indications

- **74%**: Corneal Irregularity
- **16%**: Ocular surface disease
- **10%**: Uncomplicated refractive error
SCOPE I Results: Conditions
SCOPE I Results: Care Products Recommended

- Most commonly recommended filling solutions:
  - Non-preserved single-use vials of saline: 62%
  - Bottled non-preserved saline: 58%
  - Non-preserved artificial tears: 34%

- Most commonly recommended disinfection product:
  - Clear Care™: 61%
SCOPE I Limitations:

• Sampling bias
  – <20% response rate
  – Predominantly US-based respondents
  – Mode of survey delivery

• Options for some items have changed
  – New care products
  – New lens designs
SCOPE 1 Conclusions:

• Current interest in scleral lenses is a relatively recent phenomenon
• Providers outside of academic/hospital-based practice are fitting scleral lenses
• Corneal irregularity is the most common indication for their use
• Mid-diameter lenses are most commonly prescribed
SCOPE I^{1/2}- Complications and f/u MK Survey

Amy Nau
SCOPE 1\(^{1/2}\)- Survey Recap

- 989 individuals responded to the survey
- Of all respondents, 723 had fit 5 or more sclerals and qualified to participate
- Data presented here represents 84,375 scleral lens patients
#10 Approximately how many of your scleral patients have experienced each of the following complications?

- Corneal bullae
- Corneal edema
- Corneal infiltrates
- Episcleritis/scleritis
- Giant papillary conjunctivitis
- Handling error (application error)
- Intracorneal hemorrhage
- Microbial keratitis
- Neovascularization
- Toxic keratopathy
- Other (up to 3 free text responses were allowed)
Number of patients (out of an estimated 84,375 patients represented by survey respondents) reported to have experienced each of the complications listed above. The asterisk indicates free text responses. All listed complications were reported by 10 or more respondents.
Additional Free Text Responses - Summary

These complications were indicated by fewer than 10 respondents:

- Conjunctival prolapse (n=9)
- Conjunctival blanching/thinning (n=8)
- Conjunctivochalasis (n=6)
- Conjunctival hypertrophy (n=5)
- Corneal scarring (n=4)
- Tear film disruption (n=3)
- Graft rejection (n=2)
- Change in intraocular pressure (n=1)
- Retinal detachment (n=1)
- Uveitis (n=1).
Recap

Handling errors can be mitigated with proper patient selection and training.

Corneal edema may be due to excessive vaults. This is a modifiable risk factor.

Giant papillary conjunctivitis is a concern if the lens is not clean and/or lubricity between the upper lid and lens surface is not adequate. Tangible Hydra-PEG and optimizing meibomian glands should be pursued.

SCOPE I^{1/2} - Complications and f/u MK Survey

- The most common adverse event was handling or application error (n=448, 0.53%).

- The most commonly reported corneal complication was edema (n=385, 0.45%)

- The most commonly reported conjunctival complication was giant papillary conjunctivitis (n=138, 0.16%).
Of the 723 respondents, 58 who had consented to participate in additional studies reported one or more cases of microbial keratitis.

A total of 70 cases of microbial keratitis were reported out of 84,375 patients (.082%)

An invitation to participate in a follow up survey was sent with two reminders at 3 week intervals

5 individuals responded to the supplemental survey (0.86%)
## Demographics

<table>
<thead>
<tr>
<th>Case</th>
<th>Gender</th>
<th>Age</th>
<th>Duration (years)</th>
<th>Indication</th>
<th>VA prior</th>
<th>VA post</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>64</td>
<td>1</td>
<td>Neurotrophic keratopathy</td>
<td>20/20</td>
<td>20/20</td>
<td>Prophylactic vigamox</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>49</td>
<td>1</td>
<td>GVHD</td>
<td>20/25</td>
<td>20/40</td>
<td>Severely immunocompromised, emycin ung</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>75</td>
<td>1</td>
<td>Exposure keratopathy</td>
<td>20/100</td>
<td>&lt;20/400</td>
<td>Fungal keratitis x3, PKP x 2</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>24</td>
<td>0.5</td>
<td>Keratoconus</td>
<td>20/30</td>
<td>20/30</td>
<td>n/a</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>63</td>
<td>7</td>
<td>s/p corneal trauma</td>
<td>20/30</td>
<td>20/30</td>
<td>Active psoriatic arthritis</td>
</tr>
</tbody>
</table>

Indications for scleral lens wear

No patients were taking prophylactic steroids,
No patients had had sx w/in 6m of MK,
No patients were smokers
## SCOPE 1½— Microbial Keratitis Case Series
### Dx, Presentation and Management

<table>
<thead>
<tr>
<th>Case</th>
<th>Causative Organism</th>
<th>Location</th>
<th>Diameter (mm)</th>
<th>Treatment</th>
<th>Specialist Referral</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cx neg</td>
<td>Mid periphery</td>
<td>1-2.9</td>
<td>Fortified tobramycin</td>
<td>yes</td>
</tr>
<tr>
<td>2</td>
<td>Coag – staph</td>
<td>Mid periphery</td>
<td>1-2.9</td>
<td>Vancomycin</td>
<td>Yes</td>
</tr>
<tr>
<td>3</td>
<td>Moraxella</td>
<td>Mid Periphery</td>
<td>1-2.9</td>
<td>Fortified gentamycin</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>No cx</td>
<td>Periphery</td>
<td>&lt;1</td>
<td>Ofloxacin</td>
<td>No</td>
</tr>
<tr>
<td>5</td>
<td>No cx</td>
<td>Mid periphery</td>
<td>1-2.9</td>
<td>Moxifloxacin</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Lens wear was resumed following resolution of keratitis in all patients except patient 3.

All patients except patient 4 experienced some residual corneal scarring or opacification following resolution of active infection.

Pt 4 was the only one given steroid post re-epi

Midperiphery is defined as 2-4 mm from the limbus
Periphery is defined as <2 mm from the limbus
SCOPE 1¹⁄₂— Microbial Keratitis Case Series

None of the patients were reported to rinse their lenses with tap water.

Scleral lens fit was deemed appropriate by the provider in all cases.

Pt 1 stored lens in NP saline during the day.

Pt 4 reported chronic mid-day fogging.

<table>
<thead>
<tr>
<th>Case</th>
<th>Daily Use</th>
<th>Hours</th>
<th>Disinfection/Storage</th>
<th>Application Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>n</td>
<td>8-11</td>
<td>H₂O₂</td>
<td>Bottled NPS</td>
</tr>
<tr>
<td>2</td>
<td>y</td>
<td>12-15</td>
<td>Rgp MPS</td>
<td>Bottled NPS</td>
</tr>
<tr>
<td>3</td>
<td>y</td>
<td>8-11</td>
<td>H₂O₂</td>
<td>Bottled NPS</td>
</tr>
<tr>
<td>4</td>
<td>y</td>
<td>8-11</td>
<td>RGP MPS</td>
<td>RGP MPS</td>
</tr>
<tr>
<td>5</td>
<td>n</td>
<td>4-7</td>
<td>H₂O₂</td>
<td>Bottled MPS</td>
</tr>
</tbody>
</table>
SCOPE 1 1/2—Microbial Keratitis Case Series Summary

• The overall incidence of adverse events associated with scleral lens wear appears to be low.
• Handling error was the largest single cause of adverse events.
• Corneal changes, which could potentially be vision threatening, were reported in 1.25% of patients represented by respondents to this survey.
• Conjunctival complications were reported in less than 0.05% of these patients.
• This survey identified 3 important areas for future research:
  – Amelioration of corneal edema
  – Patient selection and education regarding lens handling
  – Preventing development of giant papillary conjunctivitis
SCOPE III - Patient experiences with keratoconus

Cherie Nau

Support from: National Keratoconus Foundation
SCOPE III - Keratoconus
Patient perspective

• SCOPE keratoconus patient survey
  – Survey distributed by National Keratoconus Foundation
    • Survey link shared among other keratoconus groups
  – October 2016 through March 2017
SCOPE III- Keratoconus
Patient perspective

- 421 individuals with keratoconus completed the survey
  - 380 both eyes
  - 17 right eye
  - 25 left eye
- 38% Male, 62% Female
- 74% US, 5% UK, 35 other countries
- 77% White, 9% African American, 7% Asian, 7% Other
SCOPE III - Keratoconus
Patient perspective

• Age at questionnaire
  – 47 ± 15 years (range: 15-87)

• Age at diagnosis
  – 26 ± 11 years (range: 4-60)

• Years with keratoconus:
  – 21 ± 16 (range: <1 – 61)
SCOPE III - keratoconus
Patient perspective

• Primary Eye Care Providers
  – 41% Optometrist
  – 51% Ophthalmologist
  – 8% Contact Lens Technician

• Does your provider keep you up to date?
  – 69% Yes  31% No

• Is it easy to find an expert provider for Keratoconus?
  – 29% Yes  71% No
SCOPE III - Keratoconus
Patient perspective

Initial treatment or correction prescribed
SCOPE III - Keratoconus
Patient perspective

Initial and current correction

![Bar chart showing initial and current corrections for various treatments: RGP, Glasses, Soft, No Treatment, Scleral, Piggyback.]
SCOPE III - Keratoconus
Patient perspective

• 37% reported having had a surgical procedure:
  – 70 Both eyes
  – 30 Right eye
  – 47 Left eye

• 61 reported surgery was most helpful for vision
  – PK 61%
  – DALK 14%
  – INTACs 14%
  – Crosslinking 12%
SCOPE III- Keratoconus
Patient perspective

Correction after surgery

- **Corneal Transplant**: Glasses/None
- **Crosslinking**: RGP, Scleral, Other
- **INTACs**: Glasses/None, Scleral
- **DALK**: Glasses/None
SCOPE III - Keratoconus
Patient perspective

Current contact lens correction:
SCOPE III - Keratoconus
Patient perspective

Contact lens; most helpful:

- RGP
- Scleral
- Hybrid
- Soft
- Piggyback

Current
Helpful

[Bar chart showing comparison between current and helpful preferences for different types of contact lenses.]
SCOPE III - Keratoconus
Patient perspective

Contact lens; most helpful, most comfortable:
SCOPE III- Keratoconus
Patient perspective

Contact lens; most helpful, most comfortable, easiest to manage:

- RGP
- Scleral
- Hybrid
- Soft
- Piggyback

Bar chart showing:
- Current
- Helpful
- Comfortable
- Easiest
SCOPE III- Keratoconus
Patient perspective

• 76 patients wearing scleral lenses in each eye
  – Age: 48 ± 14 years (range 15-82)
  – Diagnosed at age: 28 ± 11 (12-55)
  – 24 males/52 females
  – 89% from US (2-Australia, 1 each: Canada, Denmark, Finland, Israel, Jordan, Sri Lanka, and UK)
SCOPE III- Keratoconus
Patient perspective

Initial treatment for current scleral lens wearers:
SCOPE III- Keratoconus

Patient perspective

• Patients had previously tried other vision correction (158 eyes)
  – 50% glasses only
  – 34% tired soft lenses
  – 71% RGP
  – 25% Hybrid

• Surgeries
  – 13% Crosslinking
  – 7% INTACs
  – 4% PK
  – 2% DALK
SCOPE III- Keratoconus

Patient perspective

- No longer wearing scleral lenses:

<table>
<thead>
<tr>
<th>Currently wearing</th>
<th>Number of eyes</th>
<th>Number that tried scleral lenses</th>
<th>% tried scleral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corneal RGP’s</td>
<td>189</td>
<td>17</td>
<td>9%</td>
</tr>
<tr>
<td>Soft contact lenses</td>
<td>46</td>
<td>6</td>
<td>13%</td>
</tr>
<tr>
<td>Hybrid lenses</td>
<td>62</td>
<td>8</td>
<td>13%</td>
</tr>
<tr>
<td>Piggyback lenses</td>
<td>33</td>
<td>5</td>
<td>15%</td>
</tr>
<tr>
<td>Glasses</td>
<td>164</td>
<td>14</td>
<td>9%</td>
</tr>
<tr>
<td>No correction</td>
<td>82</td>
<td>16</td>
<td>20%</td>
</tr>
</tbody>
</table>
SCOPE III - Keratoconus
Patient perspective

- Somewhat or very satisfied with vision: 
  - 85% (67/79)
- Somewhat or very satisfied with comfort: 
  - 80% (63/79)
- Somewhat or very satisfied with ease of use: 
  - 62% (49/79)
SCOPE III- Keratoconus
Patient perspective

• Have you had difficulty seeing with your usual correction over the past two years?
  – 75%
• Have you experienced halos, sunbursts or starburst around objects over the past two years?
  – 72%
• Have you experience cloudy or foggy vision over the past two years?
  – 59%
SCOPE III- Keratoconus
Patient perspective

• Discomfort wearing contact lenses over the past two years
  – 76%

• Have you experienced difficulty applying or removing contact lenses over the past 2 years?
  – 63%

• Have you experience cloudy or foggy vision over the past two years?
  – 59%
SCOPE III- Keratoconus
Patient perspective

• Study limitations
  – Small sampling of patients
  – No record of degree of keratoconus
  – Different providers, different perspectives on how to approach keratoconus
Conclusions

– Many options for treatment of keratoconus
– Scleral lenses are beneficial for many, but not all keratoconus patients
– Scleral lenses can provide good vision and comfort
SCOPE IV- strategies for scleral lens fitting

Ellen Shorter
SCOPE IV- Fitting Parameters Methods

• An electronic REDCap survey (REDCap) was distributed to attendees of the 2017 GSLS meeting

• 22 survey items included:
  – Initial criteria for selecting diagnostic lenses
  – Technology utilized
  – Methods used to assess fit
  – Definition of successful scleral lens fit (ideal central corneal clearance, limbal clearance, etc.)
SCOPE IV - Results

- 95 participants
- # of years fitting scleral lenses:
  - Less than 5 years - 58%
  - 6-10 years - 23%
  - 11-15 years - 16%
- # of scleral lens fittings/month:
  - <5 - 42%
  - 6-10 - 28%
  - 11-15 - 15%
  - 16-20 - 10%
  - >21 - 5%
SCOPE IV- Initial fit

• Which of the following do you use when selecting the first lens for a patient?
  – Topographic/tomographic analysis of the cornea - 63%
  – Corneal profile - 23%
  – OCT - 6%

• Do you apply diagnostic lenses in the office before ordering a lens?
  – No - 2%
  – Yes - 98%
SCOPE IV- How many scleral lens fitting sets do you currently use?

- 2 fitting sets - 27%
- >5 fittings sets - 22%
- 4 fittings sets - 20%
- 3 fitting sets - 17%
- 1 fitting set - 8%
- 5 fittings sets - 5%
SCOPE IV- What parameter do you consider FIRST when making your initial lens selection?

- Diameter (based on HVID) - 40%
- Base curve (based on keratometry or topography) - 35%
- Sagittal depth (based on Scheimpflug imaging or ocular surface profile assessment) - 24%
- Other - 1%
SCOPE IV - Do you routinely use any imaging during scleral lens evaluations? (select all)

- Anterior segment OCT - 59%
- Pentacam - 30%
- Surface Profiler - 5%
- sMap3DEye - 6%
- No - 21%
SCOPE IV- How do you use fluorescein during a fitting? (select all)

• Instilled on the ocular surface prior to lens application- 16%
• In the bowl prior to application- 82%
• Instilled on the ocular or lens surface following lens application- 42%
• I do not routinely use fluorescein- 5%
SCOPE IV: Who primarily teaches patients application and removal?

- Optometrist - 24%
- Technician - 50%
- Student - 20%
- Optician - 5%
- On-line videos - 0%
- Other - 1%
SCOPE IV- How do you assess central clearance? (select all)

• Slit lamp beam comparison of central clearance to scleral lens thickness- 78%
• Slit lamp beam comparison of central clearance to corneal thickness- 31%
• Overall fluorescein pattern under the lens- 36%
• Anterior segment OCT or Scheimpflug imaging – 55%
SCOPE IV- How do you assess limbal clearance? (select all)

• Slit lamp beam comparison of limbal clearance to scleral lens thickness - 66%
• Slit lamp beam comparison of limbal clearance to corneal thickness - 18%
• Overall fluorescein pattern under the lens - 47%
• Anterior segment OCT or Scheimpflug imaging - 51%
SCOPE IV - How do you assess conjunctival alignment? (select all)

- Slit lamp evaluation of haptic assessing for blanching/compression or edge lift - 92%
- Overall fluorescein pattern - 27%
- Anterior segment OCT or Scheimpflug imaging - 43%
- Lens spin test - 23%
- Time needed for fluorescein applied to the surface of the eye to migrate under the lens - 33%
SCOPE IV- Which would prevent you from dispensing a lens?

- Excessive central clearance - 38%
- Insufficient central clearance - 93%
- Excessive limbal clearance - 20%
- Insufficient limbal clearance - 82%
- Blanching/compression at edge - 80%
- Excessive edge lift - 61%
SCOPE IV- How do you define excessive central clearance?

- >200 microns - 5%
- >300 microns - 34%
- >400 microns - 34%
- > 500 microns - 19%
- > 600 microns - 5%
- > 700 microns - 1%
SCOPE IV- How do you define insufficient central clearance?

• Any corneal touch - 18%
• <50 microns - 30%
• <100 microns - 31%
• <150 microns - 17%
• <200 micron - 4%
• <300 microns - 1%
SCOPE IV- How do you define excessive limbal clearance?

- >100 microns - 13%
- >200 microns - 42%
- >300 microns - 26%
- >400 microns - 5%
- >500 microns - 2%
- >600 microns - 1%
- Other I do not estimate in microns - 12%
SCOPE IV- How do you define insufficient limbal clearance?

• Touch- 52%
• <50 microns- 28%
• <100 microns- 14%
• <150 microns- 2%
• <300 microns- 1%
• I do not estimate in microns- 3%
SCOPE IV- How much scleral lens movement do you consider acceptable? (select all)

- No movement is needed- 46%
- 0.25 mm movement- 37%
- 0.50 mm movement- 17%
- 0.75 mm movement- 4%
- Lens must move when nudged- 30%
- Lens must spin when touched- 25%
SCOPE IV- How much vascular blanching/compression is acceptable?

- None - 46%
- 1 clock dial (30 degrees) - 42%
- 1 quadrant - 12%
- 2 quadrants - 1%
SCOPE IV - How much conjunctival billowing (entrapment/prolapse) is unacceptable?

- No conjunctival billowing is acceptable - 24%
- 1 clock dial (30 degrees) - 25%
- 1 quadrant - 29%
- 2 quadrants - 13%
- 3 quadrants - 4%
- 4 quadrants - 5%
SCOPE IV - Do you generally schedule your scleral lens follow-ups at a specific time of day?

- No - 24%
- Yes - 76%
  - If Yes how much times is ideal?
    - At least 30 min – 1 hour - 4%
    - 2-4 hours - 70%
    - 5-6 hours - 25%
    - 7-8 hours - 1%
SCOPE IV - Which do you assess after scleral lens removal?

- Conjunctival compression impression - 81%
- Conjunctival staining - 74%
- Corneal staining - 86%
- Corneal thickness - 18%
- 3% do not evaluate the eye following lens removal
Conclusion

- Descriptive data generated will help define future clinical questions for prospective scleral lens-related studies
- More research needed on complications
Questions?
Please remember to complete your session evaluations online.

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#academy17
Thank you