Development of a Soft Contact Lens Risk Assessment Survey

K. Richdale[1], G.L. Mitchell[2], H. Wagner[3], L. Sorbara[4], D. Y. Lam[5], B. T. Kinoshita[6], M.E. Jansen[7], R.L. Chalmers[8]

[1]SUNY College of Optometry New York, NY; [2]Ohio State University College of Optometry, Columbus, OH; [3]NOVA Southeastern University College of Optometry, Ft. Lauderdale, FL; [4]University of Waterloo School of Optometry and Vision Science, Waterloo, ON, Canada; [5]Southern California College of Optometry, Fullerton, CA; [6]Pacific University College of Optometry, Forest Grove, OR; [7]Indiana University School of Optometry, Bloomington, IN; [8]Clinical Trial Consultant, Atlanta, GA

BACKGROUND

Introduction

- More children & teens will be prescribed CLs for both cosmetic and medical purposes.
- CLAY retrospective study showed ↑ risk of complications in 14 - 25 year olds
- Limited evidence of CL risks outside clinical trials

CLAY
Contact Lens Assessment in Youth
SIGHT: Survey Investigating Good Health Trends

- The CLAY study group developed a survey to assess age-specific risk factors for soft contact lens wear in children, teenagers and young adults.

Purpose

To describe the ongoing development and validation of a contact lens risk assessment survey, CLAY Survey Investigating Good Health Trends (SIGHT) using FDA Patient Reported Outcomes Guidelines.

METHODS

- Initial survey items were selected via literature review, review of optometric records from inflammatory & infectious CL events, gap analysis, and a focus group with CLAY members.
- Items were piloted and patient focus groups were conducted with teenage soft CL wearers.
- Flesch-Kincaid readability statistics were assessed.
- The survey was fielded to non-clinical populations of soft CL wearers in Forest Grove OR, Fullerton CA, Bloomington IN, Fort Lauderdale FL and New York NY.
- Retesting was conducted in a subset of patients.
- Refinement of the survey is ongoing and currently includes assessment of weighted Kappa (K_w), floor-ceiling effects, and age-related differences.

SURVEY DEVELOPMENT

Record Review and Expert CL Focus Group

In record and deemed important	Often not recorded but important
Ocular signs	Care regimen
Ocular symptoms	Back-up spectacles
CL replacement	Systemic problems
Overnight wear	Napping in CLs
	Swimming in CLs

Literature Review

Known or presumed risk factors
Overnight wear
CL replacement
Water exposure
Poor hygiene
Multipurpose LCPs
Smoking or poor health

Developed a 31-question, branching-logic, electronic survey examining:
Wearer demographics • Health and hygiene • Living environment • Access to care • Soft CL brand and care products • CL wear, care and replacement behaviors
Response categories included: Yes/No • Likert-type scales • Mark all that apply

↓

Piloted in 18 – 25 year olds (n=30) and 26 – 33 year olds (n=30)
Focus groups held with 14 – 17 year olds (n=10)
Minor wording and instruction changes
Reading level set to a 5th grade comprehension

↓

Surveyed 18 – 33 year old soft CL wearers (n=363)
Age balanced; 2:1 female to male ratio
Emailed survey for retesting 2 weeks later (119 subjects age 18 – 25 years)

↓

Surveyed 12 – 21 year old soft CL wearers (n=180)
Age balanced; 2:1 female to male ratio

↓

Initial analysis of survey included:
Assessment of age-related differences in behaviors and known risk factors
Agreement between repeat surveying in distinct populations of 18 – 21 year olds
Test-retest analysis with K_w
Examination of floor/ceiling effects and frequency distribution of responses

⇩ *Planned*

Further refinement using classical and item response theory methods
Assessment of responsiveness to education/intervention

DISCUSSION

Completed development of CLAY SIGHT instrument

- Defined aims of survey
- Identified initial pool of survey items
- Refined questions with pilot testing and focus groups
- Fielded to 543 soft contact lens wearers age 12 to 33 years at five diverse US sites
- Began initial survey analysis:
  - Significant differences by age were shown for: living environment, stress, compliance with CL care and replacement, closed-eye wear and exposure to water.
    (See abstract #120976 on Thursday at 4:15 in Room 225A-B for more details)
  - Agreement in fielding to separate groups of 18-21 year olds was excellent.
    Only differences were likely related to different testing times (stress level, cold/flu, etc).
  - Test-retest reliability was generally high: Initial K_w ranged from 0.46 to 0.98, with most > 0.8
    Items with lower reliability were reassessed for wording/interpretation
  - Floor/ceiling effects and missing/skipped questions were limited and response categories collapsed, as appropriate for future fielding
- We are unable to test convergent validity as there is no other tool currently available that is designed to assess soft contact lens risk factors

Planned development of the CLAY SIGHT instrument

- Item reduction and assessment of subscales (i.e., CL factors, hygiene, water exposure, etc.)
- Determination of scoring methods
- Responsiveness to education/intervention in an active red-eye population

CONCLUSIONS

- The CLAY SIGHT tool was able to demonstrate age-related differences in environmental and behavioral factors , showed high test-retest agreement and good agreement with repeat fielding.
- Prospective fielding in an active red-eye population will inform further refinement of the survey and allow the assessment of responsiveness to intervention.
- The CLAY SIGHT tool could eventually be used in-office to assess potential risk factors and target prescribing and education for safe and healthy CL wear for children, teenagers and adults.

ACKNOWLEDGMENTS

The CLAY study group has been supported by unrestricted grants from Alcon Research, Ltd. (formerly CIBAVision), a Chancellor's Grant from Nova Southeastern University (HW), and logistical support from the AAO Research Committee and AOA Council on Research.