Development of a Soft Contact Lens Risk Assessment Survey


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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
- 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 pilot and patient focus groups were conducted with teenager 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 (Kw), floor-ceiling effects, and age-related differences.

SURVEY DEVELOPMENT

Record Review and Expert CL Focus Group

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

Known or presumed risk factors

- Oversight 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 surveys in distinct populations of 18 - 21 year olds

Further refinement using classical and item response theory methods

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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.

SURVEY DEVELOPMENT

Literature Review

- Planned development of the 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

- Planned 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 225B 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 K2 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

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