

# Duration of Discontinuation from Silicone Hydrogel Extended Wear Due to Non Infectious Adverse Responses

Katie Edwards, Thomas Naduvilath, Nina Tahhan, Renee Du Toit, Eric Papas, Angela Kalliris, Jerome Ozkan, Deborah F Sweeney

CCLRU, School of Optometry and CRCERT, University of New South Wales, Kensington, Australia.

## Background

- Adverse ocular events (AE) with continuous wear of silicone hydrogel contact lenses are mostly self limiting.
- These AEs resolve with temporary discontinuation of lens wear. The exception is microbial keratitis, an infectious AE, where antibiotic intervention is required.
- Few studies to date have considered the duration of this discontinuation from lens wear<sup>1</sup>.

## Purpose

- Assess the length of time of discontinuation from silicone hydrogel continuous wear due to AEs.
- Determine if there is a relationship between this duration and clinical findings at event presentation.
- Provide clinical guidance in the management and follow up of adverse events with silicone hydrogel continuous wear.

## Method

- Retrospective analysis of data from dispensing clinical studies conducted at Cornea and Contact Lens Research Unit, Sydney Australia

Total number enrolled	282
Average age (range) yrs	31 ± 7 (18-52)
Average time in study (range) months	25 ± 14 (1-47)
Number of subjects with AEs	65
Gender distribution (male:female)	33:32

Figure 1: Subject profile

## Study Conduct

- Subjects wore bilateral silicone hydrogel lenses on a 30 night extended wear schedule.
- Clinical review at 1 night, 1 week, 1 month, then at 3 monthly intervals.
- Subjects were instructed to present to the clinic in the event of unusual signs or symptoms.
- If an AE was diagnosed, lens wear was discontinued until the condition had completely resolved.
- Ocular findings were graded using the CCLRU Grading Scales (fig.2).
- Additional variables only considered for AEs included; severity of event, and density (0-4 scale), size (mm), and number of infiltrates.
- AEs were classified as (fig 3);
  - Corneal Inflammatory Events (CIE): Contact Lens Peripheral Ulcer (CLPU), Contact Lens induced Acute Red Eye (CLARE), Infiltrative Keratitis (IK), and
  - Mechanical Events (ME): Superior Epithelial Arcuate Lesion (SEAL), Corneal Erosion (CE).

## Method Continued

**CCLRU GRADING SCALES**  
Cornea and Contact Lens Research Unit, School of Optometry and Vision Science, University of New South Wales

**APPLICATION OF GRADING SCALES**  
• Patient management is based on how much the normal color is compromised (no change)  
• In general, a rating of slight grade 2 or less is considered self-limiting and does not require intervention  
• A rating of 3 or more or more at follow-up visits is considered clinically significant

**PALPEBRAL CONJUNCTIVAL GRADES**  
• The redness is divided into five zones to grade redness and severity  
• 1 = mild  
• 2 = moderate  
• 3 = severe  
• 4 = very severe

**ADVERSE EFFECTS WITH CONTACT LENSES**  
**CLPU CONTACT LENS PERIPHERAL ULCER**  
• Redness  
• Discharge  
• Contact lens intolerance  
• Pain  
• Foreign body sensation  
• Blurred vision  
• Inflammation to lens

**INFILTRATES**  
Accumulation of inflammatory cells in corneal subepithelial stroma  
• Usually appear (faint) or grey haze  
• Usually confined to 2mm from limbus  
• Localized  
• Progressive  
• Associated with irritation or contact lens wear  
• Redness, tearing and photophobia possible

**CLARE CONTACT LENS INDUCED RED EYE**  
An acute corneal inflammatory response associated with deeping in sub-epithelial stroma  
• Redness  
• Discharge  
• Contact lens intolerance  
• Pain  
• Foreign body sensation  
• Blurred vision  
• Inflammation to lens

**POLYMERIZATION**  
• Contact lens intolerance  
• Pain  
• Foreign body sensation  
• Blurred vision  
• Inflammation to lens

**VASCULARIZATION**  
• Redness  
• Discharge  
• Contact lens intolerance  
• Pain  
• Foreign body sensation  
• Blurred vision  
• Inflammation to lens

**STROMAL STRIAE and FOLDS**  
• Contact lens intolerance  
• Pain  
• Foreign body sensation  
• Blurred vision  
• Inflammation to lens

**MICROCYSTS and VACUOLES**  
• Contact lens intolerance  
• Pain  
• Foreign body sensation  
• Blurred vision  
• Inflammation to lens

Figure 2: CCLRU Grading Scales

## Data Collection

- The length of discontinuation due to different AEs was established for each event
- Discontinuation times were compared among event classes using analysis of variance (ANOVA)
- Associations between length of discontinuation, severity ratings and clinical variables were examined using correlation analysis

**CCLRU/LVPEI GUIDE TO CORNEAL INFILTRATIVE CONDITIONS**  
SEEN IN CONTACT LENS PRACTICE

**CLPU CONTACT LENS PERIPHERAL ULCER**  
• Redness  
• Discharge  
• Contact lens intolerance  
• Pain  
• Foreign body sensation  
• Blurred vision  
• Inflammation to lens

**CLARE CONTACT LENS INDUCED RED EYE**  
• Redness  
• Discharge  
• Contact lens intolerance  
• Pain  
• Foreign body sensation  
• Blurred vision  
• Inflammation to lens

**IK INFILTRATIVE KERATITIS**  
• Redness  
• Discharge  
• Contact lens intolerance  
• Pain  
• Foreign body sensation  
• Blurred vision  
• Inflammation to lens

**SEAL SUPERIOR EPITHELIAL ARCuate LESION**  
• Contact lens intolerance  
• Pain  
• Foreign body sensation  
• Blurred vision  
• Inflammation to lens

**CE CORNEAL EROSION**  
• Contact lens intolerance  
• Pain  
• Foreign body sensation  
• Blurred vision  
• Inflammation to lens

Figure 3: CCLRU/LVPEI guide to Corneal Infiltrative Conditions

## Results

- One hundred and twelve adverse events were analyzed.
- Fig 4 shows group mean discontinuation for each condition.
- Mean duration of discontinuation for was 15 ± 15 days for CIEs and 5 ± 3 days for MEs (p<0.01). (fig 4)
- There were no differences in length of discontinuation between different types of CIEs (p=1.0), or between different types of MEs (p=1.0).
- Length of discontinuation following CIEs correlated with severity rating, density of infiltrate and depth of corneal staining (Fig 5) but not with size of infiltrate or number of infiltrates.
- Length of discontinuation following MEs was not correlated with severity rating, or depth of corneal staining (Fig 5).
- As a proportion of the total lens wear time, duration of discontinuation was low with both CIEs (4 ± 7%) and MEs (2 ± 4%) for the 65 subjects with AEs.

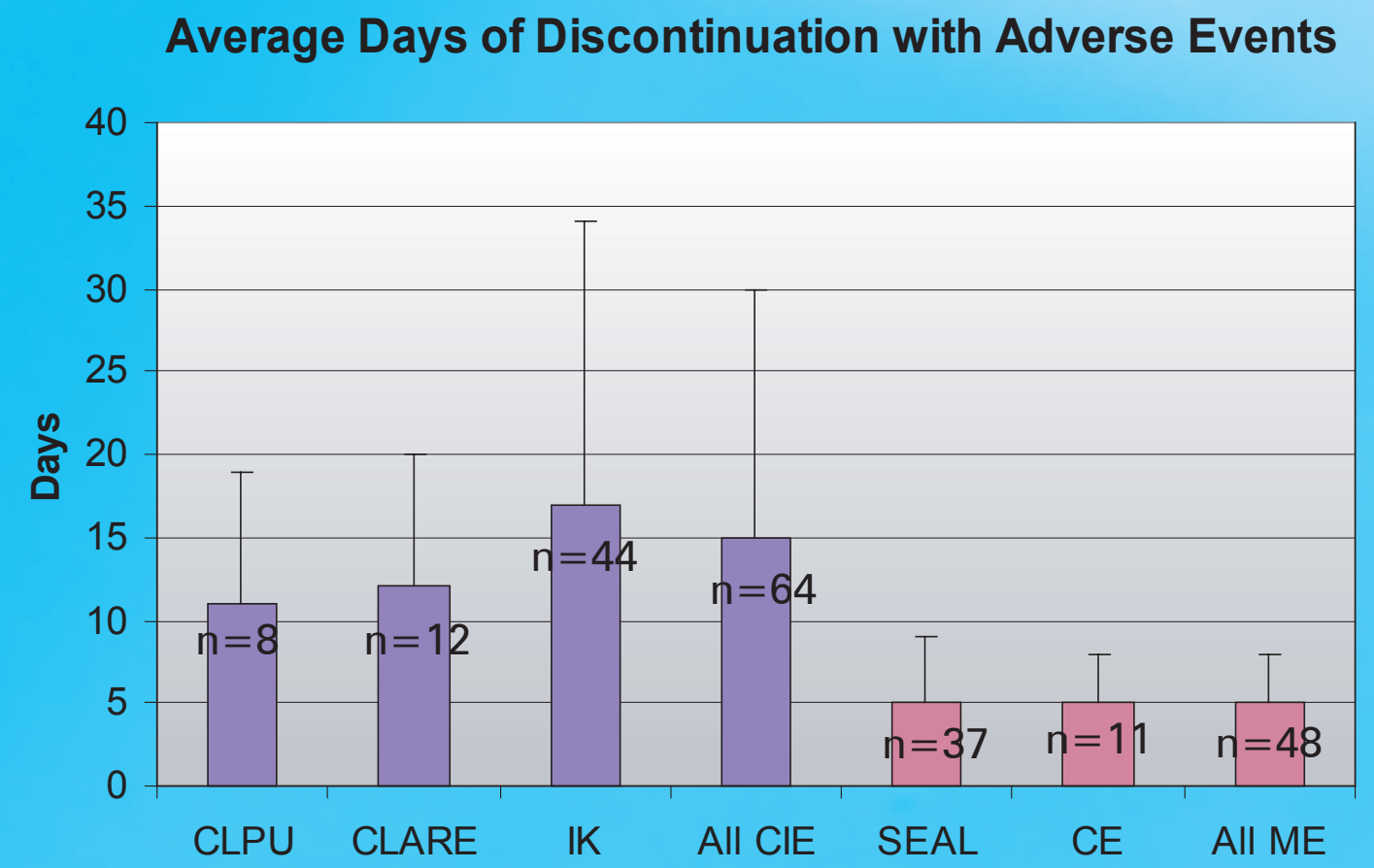


Figure 4

Clinical variable	CIE r (p)	ME r (p)
Severity rating	0.46 (<0.01)	-0.01 (0.98)
Infiltrate Density	0.27 (0.04)	0.25 (0.35)*
Infiltrate Size	0.02 (0.89)	0.92 (0.27)*
Number of Infiltrates	-0.00 (0.98)	-0.06 (0.82)*
Depth of Corneal Staining	0.27 (0.03)	0.01 (0.95)
Extent of Corneal Staining	0.12 (0.36)	-0.21 (0.16)

Figure 5

\*Not all MEs had infiltrates

## Discussion

- On average, CIEs caused longer durations of discontinuation than MEs. This reflects the fact that MEs usually represent epithelial damage, which is capable of rapid resolution, while CIEs are inflammatory events with relatively long natural histories.
- All CIEs, and all MEs, in general showed about the same duration of discontinuation, indicating that the two classes of event are aetiologically distinct, with all events within a class having a similar outcome.
- The lack of association between duration of discontinuation following MEs and any clinical variable, may be a reflection of the rapidity of the epithelial healing process.
- There is an association between duration of discontinuation following CIEs and infiltrate density, but not size or number. A denser infiltrate usually indicates a severe lesion with an increased host response (ie greater number of leukocytes, cellular debris and greater tissue disorganization). It is probable that these events take a longer time to resolve.

## Conclusion

- Non infectious AEs associated with silicone hydrogel CW are self limiting, resolving, on average, within 15 days of lens removal for CIEs and 5 days for MEs.
- In general, the denser the infiltrate and the deeper the corneal staining, the longer will be the period required without lens wear.

## References

1. Grant T, Chong MS, Vajdic C, Swarbrick HA, Gauthier C, Sweeney DF, Holden BA. Contact lens induced peripheral ulcers during hydrogel contact lens wear. CLAO J, 1998; 24(3):134-136.

## Acknowledgements

This study was supported by the Australian Federal Government through the CRC program as well as CIBA Vision Novartis, USA. The authors would like to thank i-media communications for their assistance with the poster.

