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

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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[1].

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

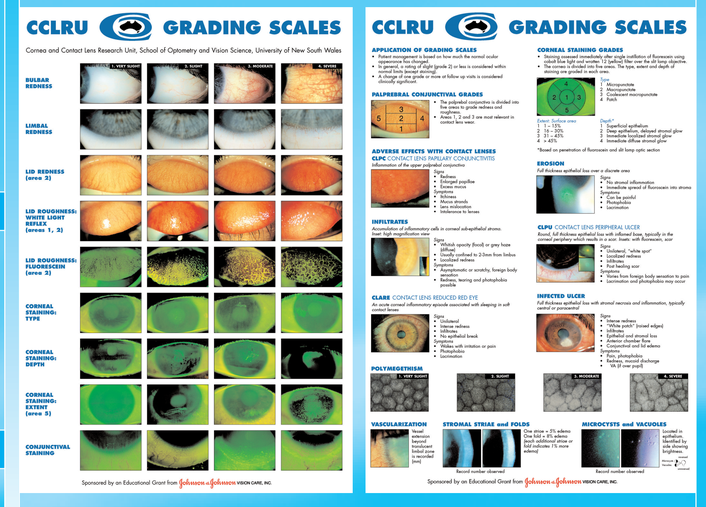

Figure 2: CCLRU Grading Scales

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

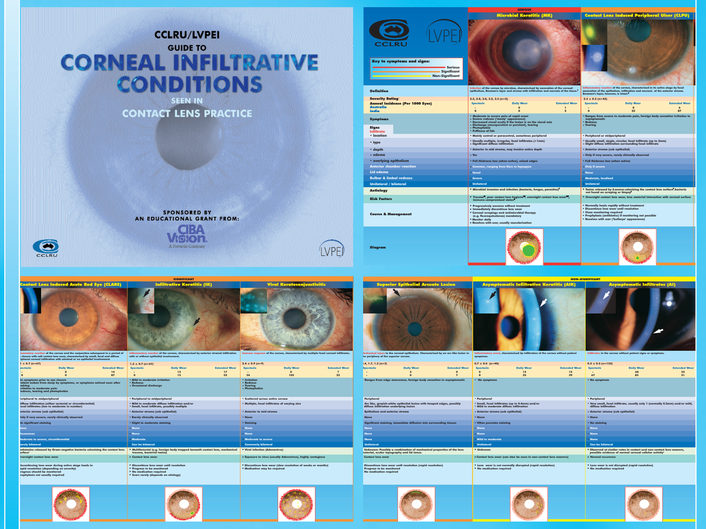

Figure 3: CCLRU/LVPEI guide to Corneal Infiltrative Conditions

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.

Average Days of Discontinuation with Adverse Events

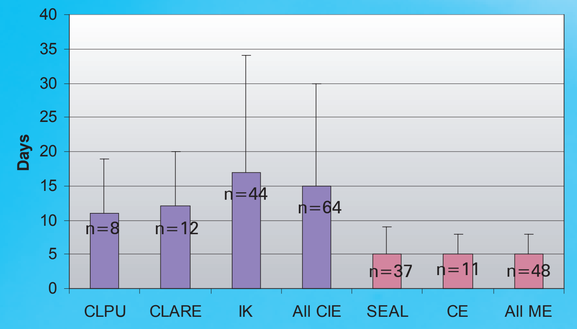

Figure 4

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

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