



# Comparison of the performance of high Dk Soft Lens performance on a 6 and 30 night Extended Wear schedule

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## PURPOSE

To compare the performance of high Dk silicone hydrogel contact lenses worn on a 6 night (6N) or 30 night (30N) extended wear (EW) schedule.

## MATERIALS AND METHODS

- 12 month prospective clinical trial.
- 161 patients.

Table 1: Patient characteristics and lens wear schedule

	6N	30N
n	45	116
Females:Males	30:15	58:58
Age (yrs) (mean ± SD, range)	31 ± 7 19 to 50	33 ± 7 19 to 50
Previous CL history (n)		
- Neophytes	2	0
- SCL DW*	19	21
- SCL 6N EW*	24	95
Lens removal	Every 6N or as required	Every 30N or as required
Lens replacement	Monthly	Monthly

\* Low Dk SCLs

- Bilateral wear of high Dk SCL (Iotafilcon A®, 24% H<sub>2</sub>O, 175 Dk/t -3.00D).
- Scheduled visits at 1 week, 1 month, 3 months, then 3 monthly until 12 months.

Variables Monitored:

- Lens Related Discontinuations (%)
- Physiological Performance (Figure 1: CCLRU Grading Scales)
  - Limbal hyperemia (worst case, 0-4)
  - Bulbar hyperemia (worst case, 0-4)
  - Microcysts (number)
  - Corneal staining (worst case, 0-4)
- Lens Performance:
  - Front surface deposits (0-4)
  - Back surface deposits (0-4)
  - Wettability (0-5)
  - Mucin balls (numbers)
- Symptomatology:
  - Overall comfort (1-100)
  - End of day comfort (1-100)
  - Overall vision (1-100)
- % of subjects conforming to wear schedules

Statistical Analysis:

- Differences between groups: Mann-Whitney, Independent Student's t-test

## RESULTS

### Physiological Performance

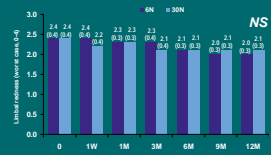


Figure 1: Limbal redness

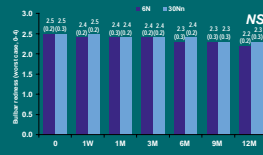


Figure 2: Bulbar redness

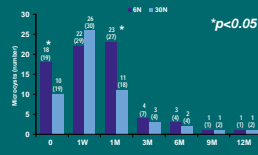


Figure 3: Microcysts

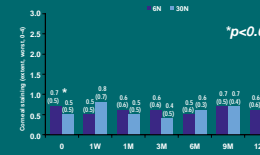


Figure 4: Corneal staining (extent)

### Lens Performance

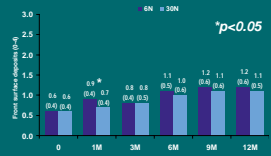
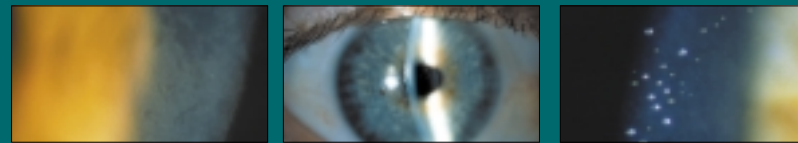


Figure 5: Front surface deposits

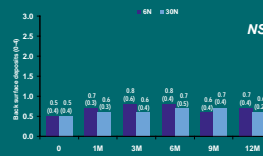


Figure 6: Back surface deposits



Figure 7: Wettability



Figure 8: Mucin balls

### Symptomatology

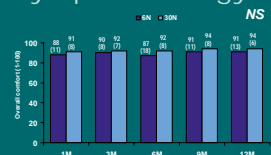


Figure 9: Overall comfort

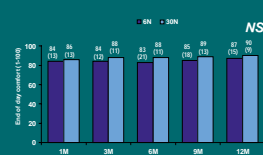


Figure 10: End of day comfort



Figure 11: Overall vision



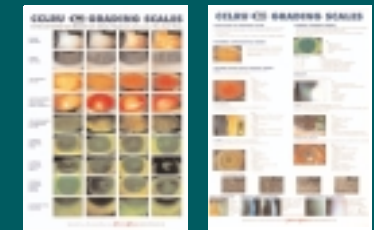
Figure 12: % of subjects conforming to wear schedules

## SUMMARY

Table 2: Summary of 12 month results

Variable	6N	30N	p
LR discontinuations	9% (4/45)	6%(7/116)	0.49
Limbal hyperemia (worst case, 0-4)	2.0 ± 0.3	2.1 ± 0.3	0.13
Bulbar hyperemia (worst case, 0-4)	2.2 ± 0.2	2.3 ± 0.3	0.08
Microcysts (number)	1 ± 1	1 ± 2	0.63
Corneal staining extent (worst case, 0-4)	0.6 ± 0.6	0.7 ± 0.5	0.29
Front surface deposits (0-4)	1.2 ± 0.6	1.1 ± 0.5	0.41
Back surface deposits (0-4)	0.7 ± 0.4	0.6 ± 0.2	0.07
Wettability (0-5)	1.8 ± 0.3	1.9 ± 0.3	0.13
Mucin balls (number)	15 ± 20	23 ± 29	0.11
Overall comfort (1-100)	91 ± 13	94 ± 6	0.20
End of day comfort (1-100)	87 ± 15	90 ± 9	0.30
Overall vision (1-100)	88 ± 12	93 ± 8	0.05
% of subjects conforming to wear schedules	75	71	0.58

Figure 13: CCLRU Grading Scales



## CONCLUSIONS

With high Dk SCL EW, the physiological response and lens performance were excellent.

No significant differences ( $p < 0.05$ ) were found between the 6N and 30N wear groups for the variables assessed, with the exception of overall vision.

Patient satisfaction was extremely high as was conformance with wear schedule for both groups.

## ACKNOWLEDGEMENTS

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