

# OCULAR COMFORT AND CORNEAL INFILTRATIVE EVENTS WITH CONTACT LENSES COMPARED WITH SPECTACLES AND NO VISION CORRECTION

Percy Lazon de la Jara<sup>1,2,3</sup>, Eric Papas<sup>1,2,3</sup>, Jennie Diec<sup>1</sup>, Pauline Xu<sup>1</sup>, Nikki Peng<sup>1</sup>, Brien Holden<sup>1,2,3</sup>

## INTRODUCTION

- It has been reported that contact lens wear induces changes to the ocular surface.[1] Although many of these are not significant, a percentage of wearers might be classified as unsuccessful due to these adverse events.
- Contact lens wearers suffering from a compromised ocular surface may experience varying degrees of ocular symptoms such as dryness, discomfort and reduced contact lens wearing times which may be related to discontinuation. [2, 3]
- The daily disposable modality is becoming increasingly prescribed by clinicians presumably based on the belief that it is associated with the minimum risk of adverse events.[4] How closely this wearing modality approaches the ideal of no-lens wear has not been established.
- The purpose of this analysis was to compare subjective responses and ocular adverse events between daily disposable soft contact lens (DDSCL) wearers, non-contact lens wearing emmetropes and full time spectacle wearers.

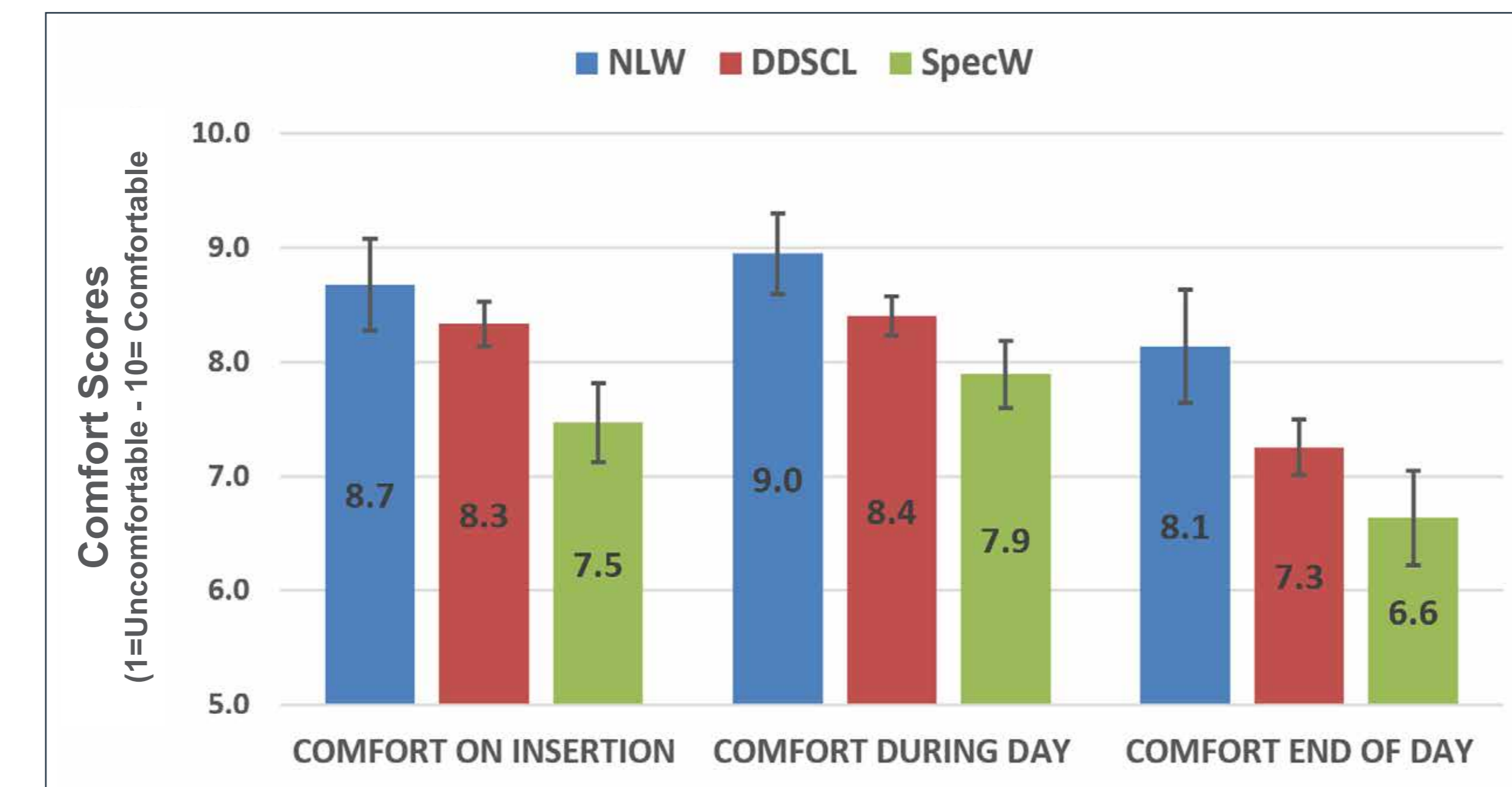
## METHODS

- Ocular comfort and dryness scores and adverse event incidences were extracted retrospectively from 5 studies (n=183) where participants wore five different DDSCLs (Delefilcon A, ALCON, USA [DelA], Naraifilcon A, Vistakon, USA [NarA], Omafilcon A, Cooper Vision, USA [OmaA], Nefilcon A, ALCON, USA [NefA], and Filcon II 3, Sauflon Pharmaceuticals, UK [Fil3]), 1 study involving 59 full time spectacle wearers (SpecW) and 1 study involving 40 emmetropic, non-contact lens wearers (NLW).
- These 7 studies followed the same protocol for 3 months. Briefly, participants attended four clinical visits, at two weeks, one month and three months after the initial baseline visit. Forty participants were enrolled into each trial. Ocular physiological clinical variables and subjective responses were collected during each visit.
- Adverse events for the purpose of this analysis were define as Corneal Infiltrative Events (CIE) following the classification of Sweeney et al,[5] where
  - Clinically Significant CIE (mostly symptomatic) were Contact Lens induced Acute Red Eye, Contact Lens Peripheral Ulcer and Infiltrative Keratitis, and
  - Clinically Non-significant CIE (asymptomatic) were Asymptomatic Infiltrative Keratitis and Asymptomatic Infiltrates
- Demographics factors were compared between DDSCL type, NLW and SpecW.
- Subjective responses were compared between DDSCL, NLW and SpecW using a linear mixed model.
- Adverse event incidences reported as percentage patient/month were compared using chi-squared test.

## RESULTS

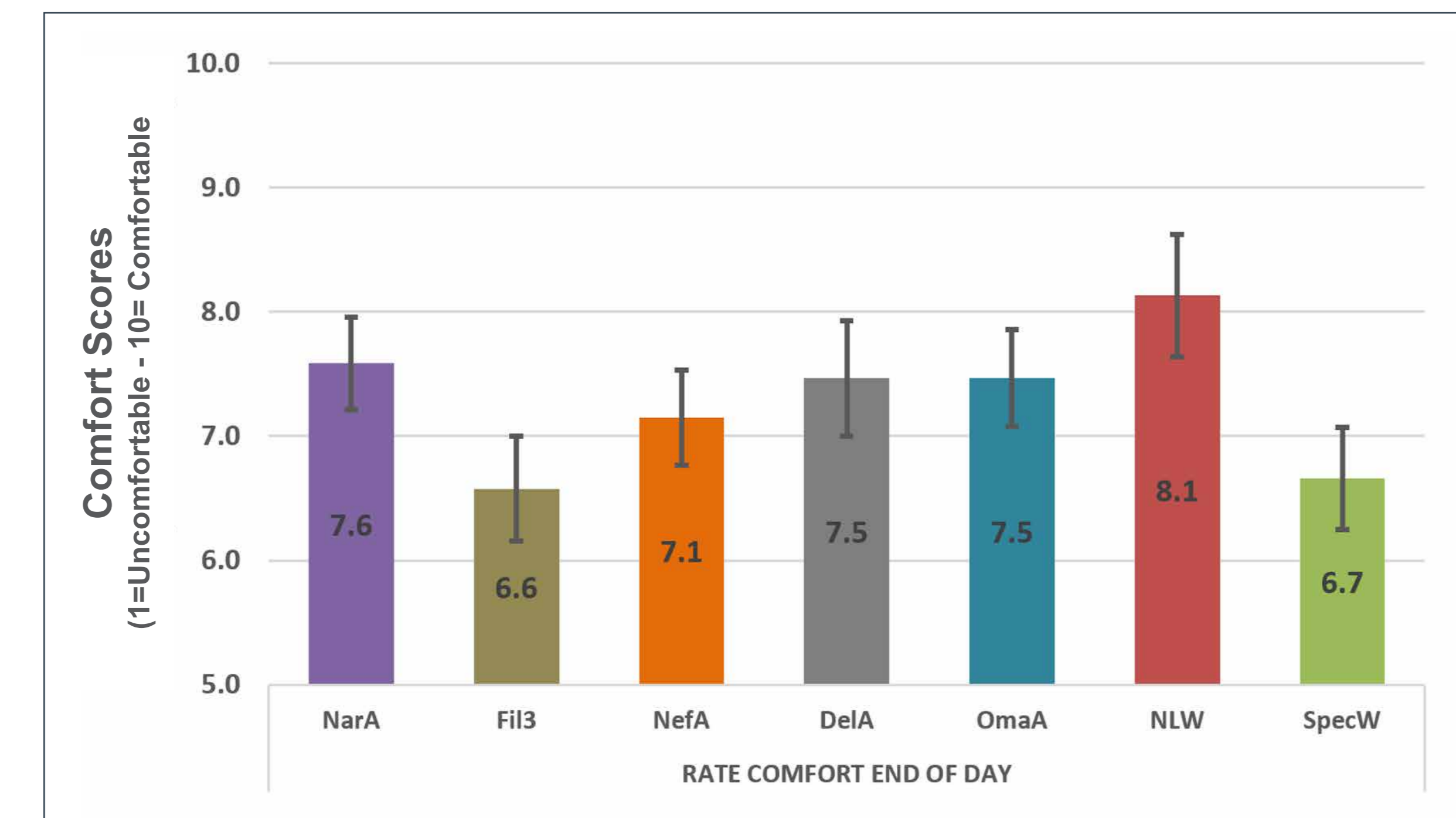
- There was no difference in the demographic factors of gender, ethnicity and contact lens wearing experience and age between the groups.
- Ocular comfort at the beginning of the day, during the day and end of day was significantly lower for the SpecW (7.5 [95% CI 7.1-7.8], 7.9 [95% CI 7.6-8.2] and 6.6 [95% CI 6.2-7.1], respectively) when compared to DDSCL (8.3 [95% CI 8.1-8.5],  $p < 0.001$ , 8.4 [95% CI 8.2-8.6],  $p = 0.010$  and 7.3 [95% CI 7.0-7.5],  $p = 0.032$  respectively) and NLW (8.7 [95% CI 8.3-9.1],  $p < 0.001$ , 9.0 [95% CI 8.6-9.3],  $p < 0.001$  and 8.1 [95% CI 7.6-8.6],  $p < 0.001$  respectively). (Figure 1).
- During the day and end of day comfort scores were significantly better for NLW compared to DDSCL ( $p = 0.019$  and  $p = 0.006$  respectively). (Figure 1).
- Ocular dryness at the end of the day scores were significantly better for NLW (8.2 [95% CI 7.7-8.8]) compared to DDSCL (7.1 [95% CI 6.9-7.4],  $p = 0.002$ ) and SpecW (7.0 [95% CI 6.4-7.4],  $p = 0.002$ ). However, dryness scores at the end of the day were similar between SpecW and DDSCL ( $p = 1.0$ ).
- Comfort scores at the end of the day were significantly different ( $p < 0.001$ ) between lens type, NLW and SpecW (Figure 2). Comfort change during the wearing period was also significantly different ( $p < 0.018$ ) between lens types, NLW and SpecW (Figure 3).
- Significant CIE occurred only in the DDSCL (0.5%,  $p > 0.05$ ). The incidence of non-significant CIE was 1.5% for SpecW, 1.2% for DDSCL and 0% for NLW ( $p > 0.05$ ). (Figure 4).

Figure 1. Ocular comfort scores between groups.



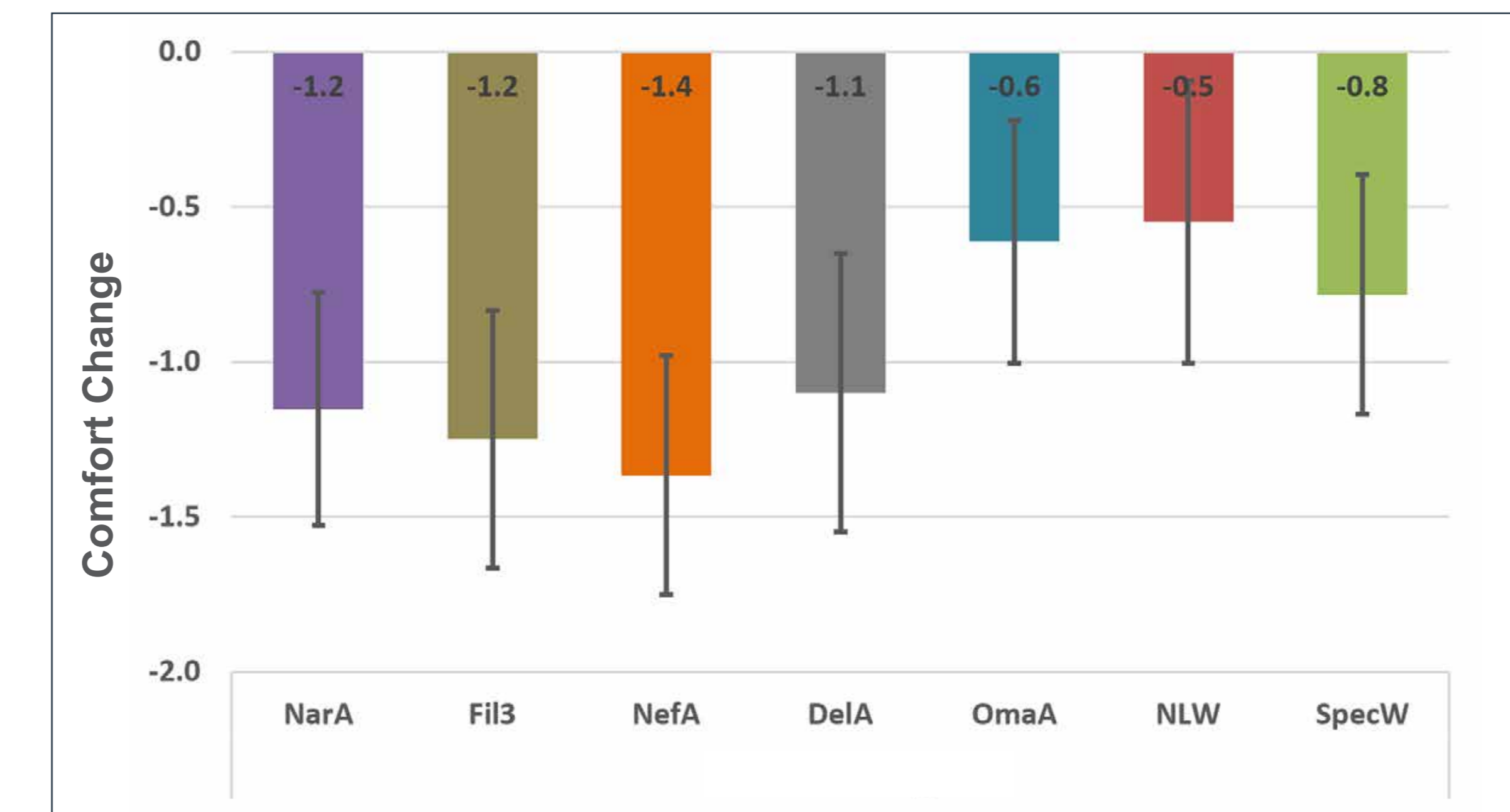
Error bars represent 95% CI

Figure 2. End of day comfort mean score for each lens type, emmetropes and spectacle wearers.



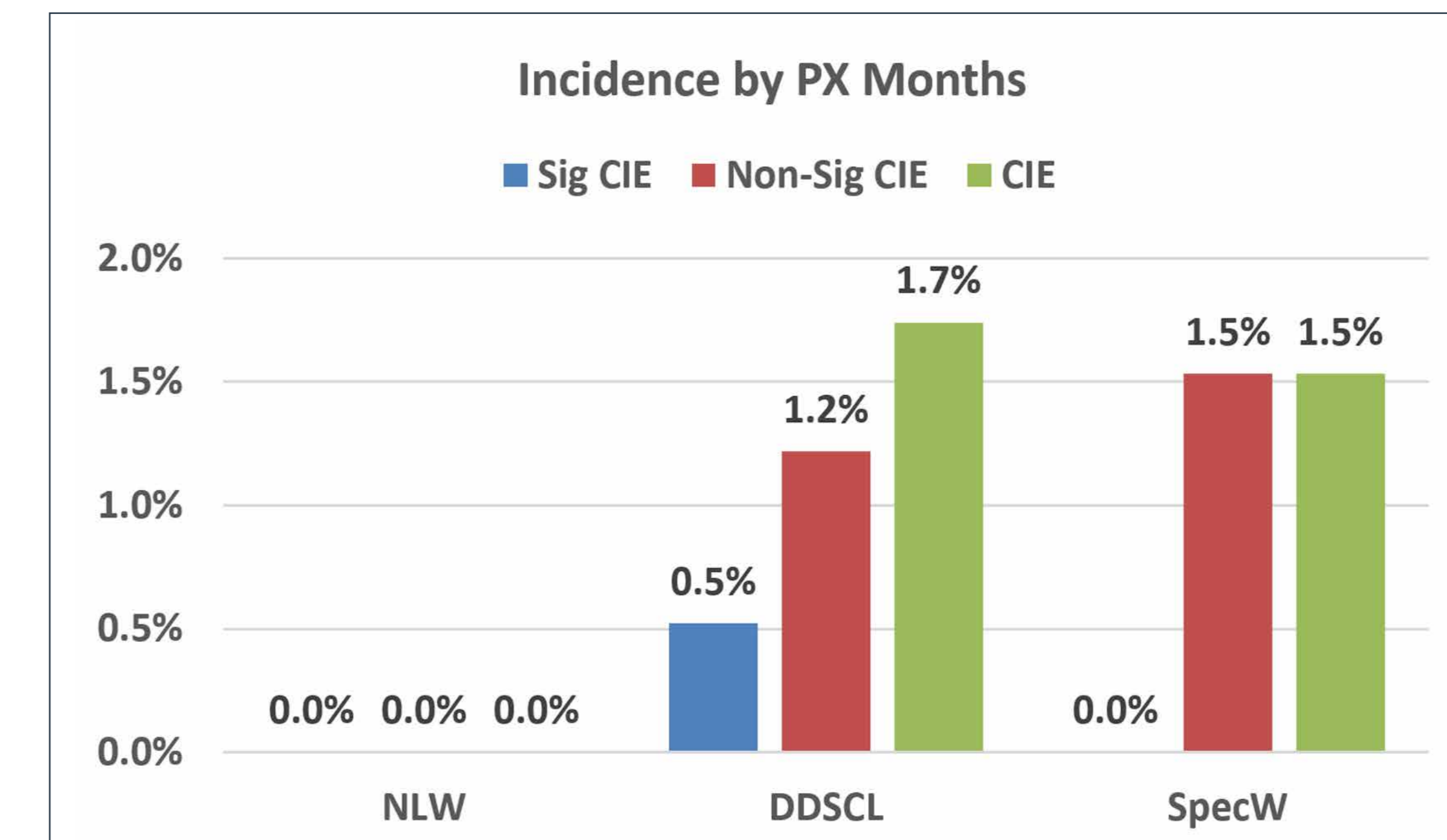
Error bars represent 95% CI

Figure 3. Comfort change during the day between DDSCL types, emmetropes and spectacle wearers.



Error bars represent 95% CI

Figure 4. Significant, non-significant and total corneal infiltrative events by participants/ months per group.



## DISCUSSION

- As expected, NLW reported higher comfort scores, however a declined towards the end of the day was observed. Our results indicate that the groups wearing DDSCL and spectacles reported more symptoms of ocular discomfort and dryness. The presence of the contact lens might be activating protective neural responses through the sensory nerve supply of the ocular surface triggering the discomfort and dryness sensation.[6] Spectacle wearers may use different criteria to rate ocular comfort than contact lens wearers that could result in the observed differences.
- The magnitude of the decrease towards the end of the day for DDSCL and SpecW was above the detection threshold for this type of numeric rating scale to be clinical significant. [7] Interestingly, the change in the NLW group was below it.
- Contact lens design and/or material influence the subjective performance of DDSCL.
- This analysis indicates that DDSCL offered a low rate of CIE which was not significantly different from NLW and SpecW. The rate of CIE in the DDSCL group is similar to that reported previously in non-contact lens wearers, [8, 9] although in the present case there were three Significant CIE, two cases of IK and one CLPU.

## CONCLUSION

- Contact lens and spectacle wear influence the subjective responses perceived by their wearers. Some DDSCL offered similar comfort levels to those experienced by NLW. Rates of CIE were generally low and similar between DDSCL and SpecW. SpecW had worse comfort and slightly more CIEs than NLW.

## REFERENCES

- Jones, L.W. and D.A. Jones, *Non-inflammatory corneal complications of contact lens wear*. Contact Lens and Anterior Eye, 2001. **24**(2): p. 73-79.
- Richdale, K., et al., *Frequency of and factors associated with contact lens dissatisfaction and discontinuation*. Cornea, 2007. **26**(2): p. 168-174.
- Pritchard, N., D. Fonn, and D. Brazeau, *Discontinuation of contact lens wear: a survey*. International contact lens clinic, 1999. **26**(6): p. 157-162.
- Efron, N., et al., *Daily disposable contact lens prescribing around the world*. Contact Lens and Anterior Eye, 2010. **33**(5): p. 225-227.
- Sweeney, D.F., et al., *Clinical characterization of corneal infiltrative events observed with soft contact lens wear*. Cornea, 2003. **22**(5): p. 435-442.
- Belmonte, C. and J. Gallar, *Cold thermoreceptors, unexpected players in tear production and ocular dryness sensations*. Investigative ophthalmology & visual science, 2011. **52**(7): p. 3888-3892.
- Papas, E.B., L. Keay, and B. Golebiowski, *Estimating a just-noticeable difference for ocular comfort in contact lens wearers*. Investigative ophthalmology & visual science, 2011. **52**(7): p. 4390-4394.
- Hickson, S. and E. Papas, *Prevalence of idiopathic corneal anomalies in a non contact lens-wearing population*. Optometry & Vision Science, 1997. **74**(5): p. 293-297.
- Sankaridurg, P.R., et al., *Comparison of adverse events with daily disposable hydrogels and spectacle wear: results from a 12-month prospective clinical trial*. Ophthalmology, 2003. **110**(12): p. 2327-2334.