FACTORS ASSOCIATED WITH DROPOUT FROM SILICONE HYDROGEL CONTACT LENS DAILY WEAR #4839

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INTRODUCTION

- Discomfort, dryness, redness, poor vision and shorter wear time are associated with drop out from low Dk soft lens daily wear (Pritchard *et al* 1999, Young *et al* 2002)
- Refitting with silicone hydrogel lens can alleviate some of these problems (Riley *et al* 2006, Dumbleton *et al* 2006)
- However, drop out from silicone hydrogel lens wear still occurs so we investigated to see if the same factors were leading to discontinutation in silicone hydrogel lens daily wear (SiHy DW).

PURPOSE

- To examine factors related to discontinuation in SiHy DW to see if they differed from those reported in the literature for low Dk lenses

METHODS

- This was a retrospective, case-control analysis of five SiHy lenses and four lens care solutions
- 20 clinical trials were included in the analysis, one for each lens solution combination.
- Lenses/solutions were used for 3 months by approximately 40 participants per combination.
- Lenses: Iotrafilcon A, Iotrafilcon B, galyfilcon A, senofilcon A, balafilcon A
- Solutions: ClearCare/AOSept Plus, AQuify MPS/Focus AQUA, Opti-Free Express, Opti-Free Replenish
- Participants who discontinued after baseline (DC) were compared to those who completed each trial (controls).
- Data from scheduled study visits and a 2 month telephone questionnaire were analysed using chi-square tests and linear mixed model analyses.

RESULTS

- 84.8% of participants who attended visits after baseline successfully completed the 3 month trial (Figure 1). The non-adverse event related discontinuation rate was 10.7% in the first three months.

  The additional 4.5% of participants who discontinued after an adverse event were excluded from the case control analysis.
- Reasons for non-adverse event related discontinuation are shown in Figure 2.
- Compared to those completing each trial, a greater proportion of DC participants were less than 20 years old (p=0.027), and were new to lens wear or SiHy lenses (p=0.001).
- There was no difference in gender, ethnicity, lubricating drop usage, no clinical difference in over-refraction sphere, uncorrected cylinder, visual acuity or slit lamp ocular physiology between the two groups.
- Subjective ratings and symptoms that were significantly different between the DC participants and controls are presented in Figures 3, 4, 5 and 6.

RESULTS

Participant Status			Included in Case Control Analysis
	Frequency		
Discontinued at baseline	43		No
	Frequency	% of Total	
Discontinued after baseline with AE	37	4.5%	No
Discontinued after baseline, no AE	88	10.7%	Yes
Completed the 3 month study	700	84.8%	Yes
Total participants beyond baseline	825		

Figure 1: Frequency of participant discontinuation and inclusion in analysis

Reason	DC (Non-AR) beyond baseline	
	Count	%
Biomicroscopy	0	0%
Discomfort	9	10%
Handling	1	1%
Symptoms & Problems	5	6%
Unacceptable Fit	1	1%
Unacceptable Subjective	4	5%
Other Product Related	4	5%
Unrelated medical problem	1	1%
Time/Job Conflict	13	15%
Disinterest	6	7%
Relocated	5	6%
Lost to Follow-Up	16	18%
Other Non Product Related	13	15%
Unknown	10	11%
Total	**88**	**100%**

Figure 2: Reasons for discontinuation

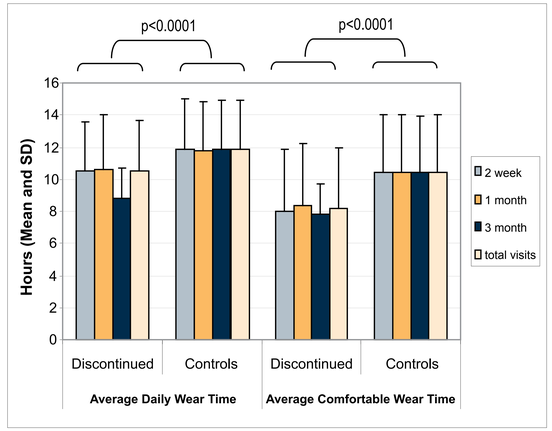

Figure 3: Average daily wear time and average comfortable wear time for each group

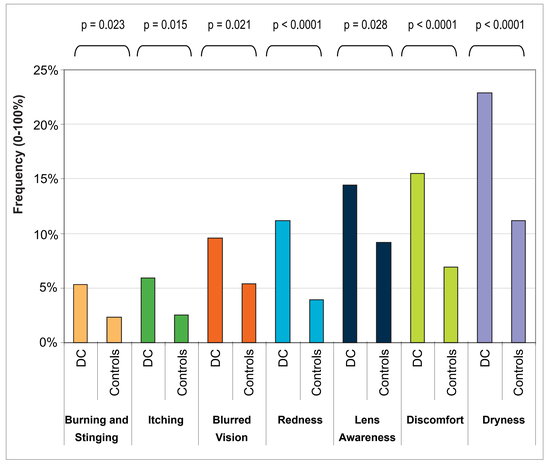

Figure 4: Frequency of symptoms rated moderate to severe in each group

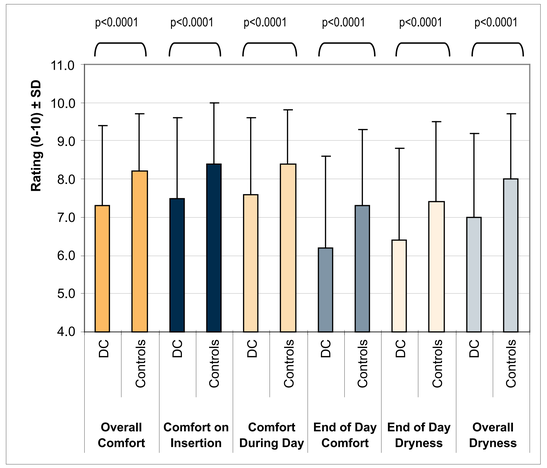

Figure 5: Subjective ratings (0-10) where 0 is poor performance and 10 is excellent (e.g no dryness/excellent comfort)

DISCUSSION

- The discontinuation rates reported here may not be directly applicable to practice population as many discontinuations may have been for specific clinical trial causes.
- Participants who discontinued at baseline were not included in the analysis so their reasons for discontinuation may be under represented.
- The subjective factors and symptoms that are significantly associated with discontinuation are likely to be influenced by lens-solution interactions.
- The analysis was not statistically powered to detect differences in discontinuation rate/reasons between lens solution combinations
- The next step is a multivariate analysis of discontinuations to look at the driving factors and control variables in lenses and solutions.

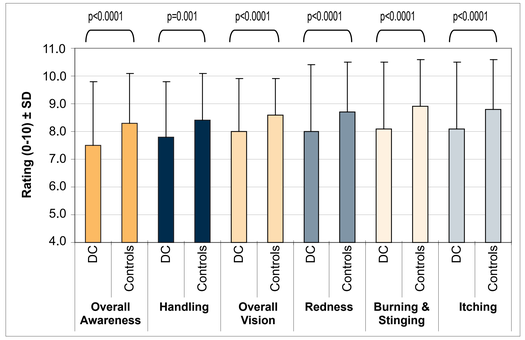

Figure 6: Subjective ratings (0-10) where 0 is poor and 10 is excellent (e.g no adverse symptoms/excellent handling or vision)

CONCLUSION

- In this study, the rate of subjective comfort related discontinuations was greater than those due to adverse events.
- In SiHy DW, poor comfort, dryness, self reported redness, self reported poor vision and reduced wear time remained indicators for drop out from lens wear.

REFERENCES

1. Pritchard *et al* 1999. Int Contact Lens Clin 26(6):157-162
2. Young *et al* 2002. Ophthalmic Physiol Opt. 22(6):516-27
3. Riley *et al* 2006. Eye Contact Lens 32(6):281-6
4. Dumbleton K *et al* 2006. Optom Vis Sci 83(10):758-768

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