Clinical Evaluation of an Upgraded Silicone Hydrogel Contact Lens during Extended Wear

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Purpose

- Silicone hydrogel (SiH) contact lenses (CL) are becoming increasingly popular for daily and overnight wear.[1]
- CL discomfort is the most common reason for drop-out amongst CL wearers,[2] and many wearers still report dryness associated with SiH CL wear.[3]
- An upgraded Iotrafilcon A (CIBA Vision) CL has been developed incorporating a visibility tint, inversion indicator and comfort additive in the packaging saline, to reduce dryness associated with CL wear.
- The aim of this study was to investigate the clinical and subjective performance of the Iotrafilcon A upgrade over 2 weeks (W) of 6-night extended wear (EW)/flexible wear (FW).

Methods

- A prospective, randomised, double-masked pilot study was conducted.
- 40 experienced soft CL wearers were randomized to wear either Iotrafilcon A upgrade (test) or senofilcon A (control, Vistakon) bilaterally for 2 W of EW/FW, up to maximum of 6 nights per W (see Table 1 for CL characteristics).
- AOSept Plus (CIBA Vision) and Refresh (Allergan) tear supplements provided.
- Clinical and subjective evaluations, including visual acuity (VA), CL movement and surface characteristics, comfort and dryness, were conducted at baseline/CL delivery (Del) and 2 W. A phone survey was conducted at 1 W.
- Statistical analysis: Non-parametric data were analysed using the Mann-Whitney and Wilcoxon matched pairs tests. Two-way ANOVA was used for parametric data and the Chi Square and McNemar's tests were used for proportions. p<0.05 was considered to be statistically significant.

Table 1: Contact lenses under study.

	Test	Control
Material name	Lotrafilcon A	Senofilcon A
Dk	140	103
Dk/t	175	147
Water content (%)	24	38
Modulus (MPa)	1.4	0.72
BOZR (mm)	8.4/8.6	8.4/8.8
TD (mm)	13.8	14.0
Surface treatment	Plasma coated	None
Comfort additive	In packaging saline	PVP - internal wetting agent

PVP = polyvinyl pyrrolidone, Dk = oxygen permeability, Dk/t = oxygen transmissibility,

Results

- n=37 (93%) completed the study (n=18 test group and n=19 control group).
- There were 2 adverse events during the study: n=1 unilateral CL-related papillary conjunctivitis (CLPC) with the test lens and n=1 asymptomatic peripheral infiltrate with the control lens.
- Average wearing time was 4 nights per week for both lens types (p>0.05). Dryness and discomfort were the major reasons for unscheduled overnight removals in both CL groups.
- There were no significant differences in distance VA, limbal and bulbar redness, corneal and conjunctival staining, and superior palpebral conjunctival papillae between the test and control CLs (p>0.05).
- At 2 W, the control CLs showed greater front surface deposits (p<0.05) and reduced wettability (p=0.06) compared to the test CLs (Figure 1) and a greater proportion of control lens wearers had CL surface measures above grade 0 compared to test lens wearers (Figure 2).
- Lens tightness, quality of fit and lens mobility ratings were similar for both test and control CLs. The control CLs had decreased CL movement (p<0.05) and increased superior decentration (p<0.05) compared to the test CLs.
- No statistically significant differences between the test and control CLs were noted for hours of comfortable lens wear or ratings of subjective comfort, comfort on insertion, end of day comfort, handling, dryness (Figure 3), or overall satisfaction.
- Subjective comfort on insertion scores were consistently better than end of day comfort scores for both test and control CLs (Figure 4).

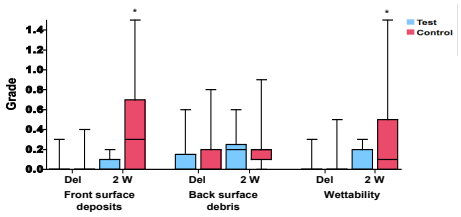

Figure 1. Box plot of lens surface measures (box extends from 25th to 75th percentile, line at median and whiskers showing minimum and maximum values). The control CLs showed significantly greater front surface deposits and and poorer wettability than the test CLs at 2 W (*p<0.05).

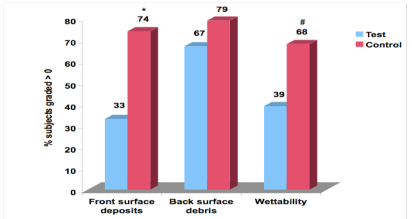

Figure 2. At 2 W, a greater proportion of control CL wearers had CL surface measures greater than grade 0 compared to test CL wearers (*p<0.05, #p=0.07).

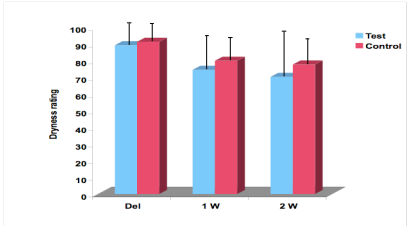

Figure 3. There were no significant differences in subjective dryness ratings (where 0 = extremely dry and 100 = no dryness) between the two CL types at any time point (p>0.05). Mean dryness ratings decreased (i.e. increased dryness) with both CL types at 1 W and 2 W compared to Del (p<0.05).

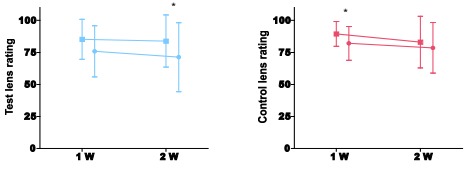

Figure 4. Subjective comfort on insertion (■, where 0 = extremely uncomfortable and 100 = extremely comfortable) was rated better than end of day comfort (●, where 0 = cannot be worn at the end of day and 100 = cannot be felt at end of day) with both CL types (*p<0.05).

Table 3: Subjective ratings (mean ± SD) or [median (IQR)].

Measure	Visit	Test	Control	p-value
Overall comfort	Del	84 ± 20	92 ± 7	p>0.05
	1 W	83 ± 14	89 ± 7	p>0.05
	2 W	82 ± 20	86 ± 20	p>0.05
End of day comfort	1W	76 ± 20	82 ± 13	p>0.05
	2 W	71 ± 27	79 ± 20	p>0.05
Comfort on insertion	Del	81 ± 23	89 ± 9	p>0.05
	1 W	85 ± 16	89 ± 10	p>0.05
	2 W	84 ± 20	83 ± 20	p>0.05
Handling	Del	93 ± 7	91 ± 11	p>0.05
	1 W	87 ± 11 *	87 ± 11	p>0.05
	2 W	84 ± 17 *	84 ± 12 *	p>0.05
Dryness	Del	89 ± 13	91 ± 11	p>0.05
	1 W	74 ± 20 *	80 ± 14 *	p>0.05
	2 W	70 ± 27 *	78 ± 15 *	p>0.05
General vision quality	Del	93 (85 - 95)	92 (84 - 97)	p>0.05
	1 W	95 (90 - 100)	95 (90 - 100) *	p>0.05
	2 W	95 (86 - 98)	91 (85 - 98)	p>0.05
Overall satisfaction	Del	83 ± 20	89 ± 10	p>0.05
	1 W	82 ± 19	90 ± 7	p>0.05
	2 W	80 ± 23	89 ± 10	p>0.05

* Significantly different to Del (p<0.05)

Conclusions

- The Iotrafilcon A upgrade and senofilcon A CLs performed comparably for the majority of subjective and objective measures over 2 W of EW/FW.
- Some statistically significant differences were found between the CL types with respect to CL fitting and surface characteristics; however, the differences were not considered to be clinically significant.
- End of day comfort scores were consistently lower than comfort on insertion scores for both CL types and remain issues to be addressed for successful long-term CL wear.

References

1. Morgan PB, Woods CA, Knajian R, Jones D, Efron N, Tan K, et al. International Contact Lens Prescribing in 2007. *CL Spectrum*. 2008;23(1):36-41.
2. Richdale K, Sinnott, T, Skadahl E, Nichols JJ. Frequency of and factors associated with contact lens dissatisfaction and discontinuation. *Cornea*. 2007;26(2):168-74.
3. Riley C, Young G, Chalmers R. Prevalence of ocular surface symptoms, signs, and uncomfortable hours of wear in contact lens wearers: the effect of refitting with daily-wear silicone hydrogel lenses (senofilcon a). *Eye Contact Lens*. 2006;32(6):281-86.

Acknowledgements & Address for Correspondence

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