

The Rate of Corneal Infiltrative Events and SEALs in Silicone Hydrogel Continuous Wear Studies

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Purpose

To evaluate the rate of corneal infiltrative events and superior epithelial arcuate lesions (SEALs) in a newly developed silicone hydrogel contact lens (CooperVision Biofinity™), compared to currently marketed continuous wear lenses (CIBA Vision Night & Day™ (N&D) or Bausch & Lomb PureVision™ (PV)).

Methods

Subjects wore Biofinity, N&D or PV lenses on a continuous wear basis at five study centers (Brennan Consultants, CCLR, CVRA, VisionCare, and Synoptik) over a 12 to 24 month period. Three of the study sites used a contralateral design, while two used a bilateral design. The Biofinity lens was worn by 323 subjects at five centers for a total of 5485 months. The PV lens was worn by 95 subjects at three centers for a total of 1040 months, and the N&D was worn by 92 subjects at three centers for a total of 1427 months. Adverse events were tracked at each of these studies and infiltrative events categorized as microbial keratitis (MK), contact lens peripheral ulcer (CLPU), contact lens acute red eye (CLARE), infiltrative keratitis (IK) or asymptomatic infiltrative keratitis (AIK). Because recurrences are not independent events, only initial infiltrative events and the time of lens wear prior to the event are included in this analysis.

Materials

		Dk/t	Water Content	Modulus (MPa)
Biofinity	Comfilcon A	160	48	0.75
PureVision	Balafilcon A	110	36	1.1
Night & Day	Lotrafilcon A	175	24	1.5

Results

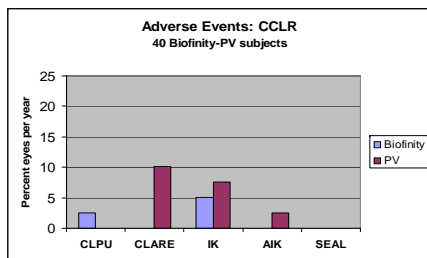
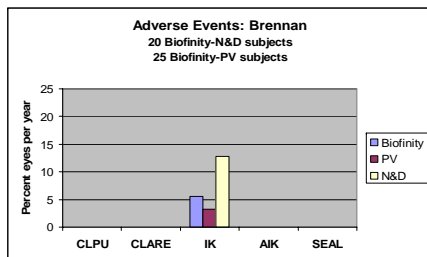
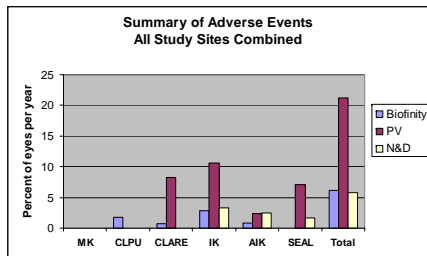
Adverse Event Rates (Percent of eyes per year) – Data combined from all study centers

	MK	CLPU	CLARE	IK	AIK	SEAL	Total
Biofinity	0.0	1.7	0.7	2.3	0.9	0.0	6.1
B&L PV	0.0	0.0	8.3	10.6	2.4	7.1	21.3
Ciba N&D	0.0	0.0	0.0	3.3	2.5	1.7	5.8

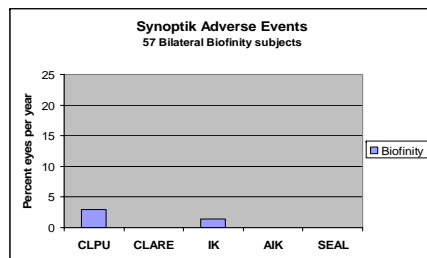
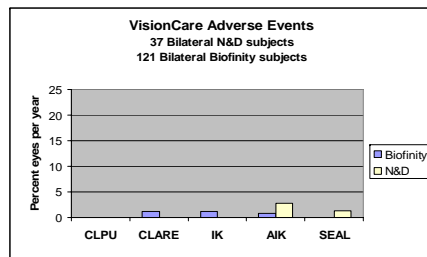
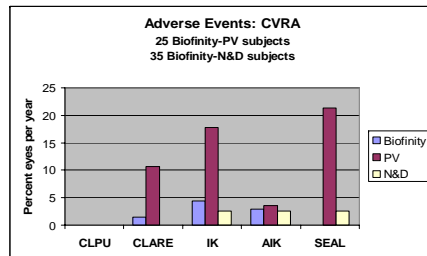
Published Rates for Extended/Continuous Wear (Percent of eyes per year)

	MK	CLPU	CLARE	IK	AIK	SEAL	Total
Conventional hydrogels	0.10 ^{1,2} , 0.48 ³	6.8 ⁴	6.1 ⁵	4.8 ⁶	--	--	3.6 ⁶
Silicone hydrogels	0.10 ^{3,5,6,9,10} , 0.09 ¹¹	7.2 ⁶	0.8 ⁷	2.5 ⁷	--	4.5 ⁸	6.7 ⁹ , 5.0 ⁶

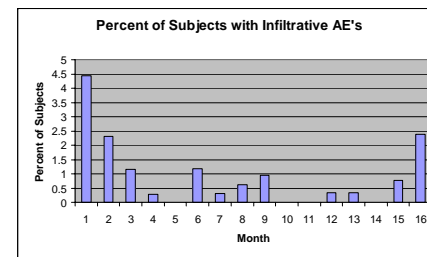
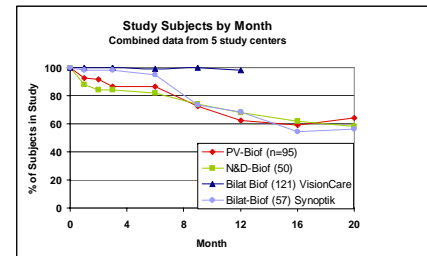
Results



Results



Results



Conclusions

The overall rate of corneal infiltrative and SEAL events were similar for the Biofinity and N&D lenses, while the PV rate was higher.

The rates of both SEALs and infiltrative adverse events differed markedly among study sites, which highlights the importance of conducting multi-center studies.

The distribution of adverse events over time is skewed toward the initial period of wear.

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Acknowledgements

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