Biocompatibility of a high Dk fluorosilicone hydrogel during extended wear

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Abstract

Purpose: To determine the protein and lipid deposition and bacterial colonisation of a high Dk fluorosilicone hydrogel during 30NEW.

Methods: The protein and lipid uptake in 35 asymptomatic patients during a 12 month EW trial in Focus® Night & Day™ (24% H_2O, Dk/t 175 barrers/cm) was established using fluorescence spectrofluorimetry. The lenses were worn for 30 nights, either as weekly removal and replacement, or continuously. In a separate group of 69 patients in the same wear regimens, lenses were aseptically collected and placed in 2mL sterile PBS. After sonication, each lens was cultured and a portion of the sonicate was grown up on a variety of media, and incubation conditions, designed to maximize the identification of organisms present on the lens.

Results: Focus® Night & Day™ over 30NEW had very low protein deposition, as low as many conventional materials worn on a DW basis. The protein remained at the surface, as confirmed by plasma emission and monitoring (PEEMS). Lipid deposition was on the lower side of levels observed for DW conventional lenses, using the same technique. No abnormal accumulation of lipid classes was found by extraction and high performance liquid chromatography (HPLC). Bacteria (mostly normal eye flora) were present on the lens at the same frequency and numbers at all points during the 30NEW cycle and were below the levels found on some conventional DW lenses. Protein and lipid uptake and bacterial colonization were equivalent for 30 nights, worn either continuously, or removed and replaced weekly.

Conclusions: The protein and lipid deposition on Focus® Night and Day™ during 30NEW is maintained at very low levels. There is also no bacterial build up during extended wear over 30 nights.

Introduction

Protein and lipid build-up and bacterial contamination of contact lenses during wear has been demonstrated to symptomatic wearers[1] and may contribute to CL-related infection and inflammation. The aim of this study was to evaluate the protein and lipid deposition and bacterial contamination rate during extended wear of the highly oxygen permeable fluorosilicon hydrogel Focus NIGHT&DAY (24% H_2O, Dk/t 175 barrers/cm).

Lenses for protein & lipid uptake

At least 35 subjects wore CIBAVision Focus NIGHT&DAY (FND) 30 nights, either weekly replinishment and replacement (Set 1) or continuously (Set 2). The lenses were collected aseptically at the 6, 9 and 12-month point in the trial and stored in a small volume of sterile saline prior to analysis.

The spoilation profiles were compared to other hydrogel contact lenses, which had been worn on a daily wear replacement schedule for between two weeks and three months.

Lenses for bacterial colonisation

69 subjects wore FND for 30 nights with either weekly replacement (6 NEW) or continuously (30 NEW). A control group of 44 subjects wore AcuVue for 6 nights.

	AcuVue	FND	
Wear Schedule	6NEW	6NEW	30NEW
No of Patients	44	38	31
No of Samples	284	251	150
Average days of continuous wear	4.3	4.3	19.8
Maximum days of continuous wear	11	14	39

Methods for protein & lipid uptake

Two non-destructive analytical techniques were used to analyse the deposition profiles of the lenses.

1 *Fluorescence Spectrophotofluorimetry.*
The protein and lipid spoilation profiles were assessed on the front and back surfaces of the lenses using a specially modified Hitachi F4500. The protein was assessed using an excitation wavelength of 280nm and the lipid using a wavelength of 360nm. A calibration curve can be applied to convert the protein fluorescence values to mg/lens.

2. *Ultra-violet spectroscopy*
The matrix absorbed or bulk protein was assessed using a Hitachi U2000 spectrometer. The absorbance values were converted to concentrations (mg/lens) using a calibration curve. The UV measures total protein i.e. surface + matrix absorbed.

Statistical analysis (paired t-test) was carried out to test for significant differences between front and back surfaces, and left and right eyes, both within the time periods for each Set, and regardless of the time period and Sets.

Methods for bacterial colonisation

At the end of the wear period, lenses were removed aseptically and placed in 2 ml sterile saline. After sonication (30 seconds), each lens was cultured and a portion of the sonicated solution was plated out and grown up under a variety of conditions described below.

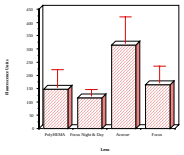
Material	Media	Atmosphere	Temp (°C)	Time (d)
Lens	Chocolate Agar	5% CO_2	37	7
Sonicate Solution	Chocolate Agar	5% CO_2	37	7
	BAP	5% CO_2	37	7
	BAP (CDC)	Anaerobic	37	14
	Sabouraud Dextrose Agar	Aerobic	25	14

If growth on all plates was negative, the remaining sonicate solution was filtered. The filter was cultivated on chocolate agar for 7 days at 37°C. 3 strains of *Pseudomonas aeruginosa* were tested for the ability to survive sonication. Only after 20 minutes sonication was there a significant drop in viability.

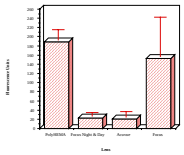
Statistical analysis between wear regimens was carried out via a hierarchical linear model, whereas for time of wear a general linear model was used. Both these models took into account the fact that multiple samples came from each subject.

Results of protein & lipid uptake

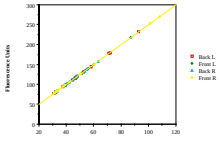
Surface protein on FND (30 night EW) compared to DW lenses



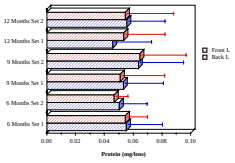
Surface lipid on FND (30 night EW) compared to DW lenses



Total versus surface protein on FND (30 night EW)



Surface protein on FND (30 night EW) at various time points in the study



The straight line relationship between total and surface protein in all samples is indicative of no penetration of protein into FND. Thus, the surface fluorescence units can be converted into mg/lens using a calibration curve.

Results of microbial colonisation

Frequency of microbial colonisation per sampling occasion

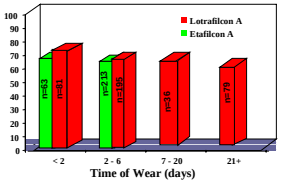
	AcuVue	FND	
	6 night EW	6 night EW	30 night EW
Total	67.3	74.9	65.3
Aerobic	50.4	66.5*	56.0
Anaerobic	38.0	27.5*	36.7

p<0.01

Number of organisms recovered for all sampling occasions

		AcuVue	FND	
		6 night EW	6 night EW	30 night EW
Total	Median (Range)	8 (2200)	20 (7400)	20 (1074)
	Mean	81.1	111.1	66.2
Aerobic	Median (Range)	1 (2100)	20 (7400)	2 (924)
	Mean	51.2	87.9	38.9
Anaerobic	Median (Range)	0 (960)	0 (600)	0 (401)
	Mean	29.9	23.2	27.3

Frequency of microbial colonisation during 30 night EW



Number of organisms recovered during 30 night EW

Cfu	Total Mean	Total Median (Range)	Aerobic Mean	Aerobic Median (Range)	Anaerobic Mean	Anaerobic Median (Range)
< 2 days (n=311)	100	20 (2936)	72	20 (2896)	28	0 (560)
2 – 6 days (n=851)	99	20 (7400)	75	4 (7400)	24	0 (600)
7 – 20 days (n=216)	157	20 (3400)	134	2 (3400)	23	0 (401)
21 days (n=279)	49	20 (502)	23	2 (282)	26	0 (340)

Conclusions

Protein & lipid uptake on Focus NIGHT&DAY (extended wear)

- FND had the lowest protein deposition of all the lenses tested.
- The protein is surface located rather than matrix absorbed.
- The lipid deposition falls between the limits of the levels observed with the daily wear lenses and is on the lower side.
- Although individual patients showed left to right eye variability there was no significant difference in the overall (accumulated) left versus right eye results.
- There were no significant differences between anterior and posterior surface protein or lipid.
- There were no statistically significant differences between protein or lipid uptake between weekly replacement (6 NEW) and continuous (30 NEW) wear, i.e. Set 1 and Set 2.
- The lipid deposition is much more patient dependent than the protein deposition but still driven by material/surface considerations.

Microbial colonisation on Focus NIGHT&DAY (extended wear)

- There was no significant difference between the frequency of colonisation of all organisms on both lens types, and for 6NEW or 30NEW.
- There were some statistical differences between 6 NEW (FND) and 30 NEW (FND) and 6 NEW (AcuVue). The frequency of colonisation of aerobics was higher, whereas that for anaerobics was lower for FND 6 NEW.
- The range of organism species found on both lens types and in both wear modalities was the same.
- There was no steady build-up of organisms on the fluorosilicone hydrogel lens during 30 nights. The frequencies of colonisation and the cfu recovered were equal at any point during the wear schedule.

Reference

1. Mowrey-McKee, M.F. et.al. CLAO, 1992, v. 18, 87-91.