THE INCIDENCE OF GENERAL AND LOCAL CONTACT LENS INDUCED PAPILLARY CONJUNCTIVITIS IN SILICONE HYDROGEL CONTACT LENS WEAR

BACKGROUND

- The reported incidence of contact lens induced papillary conjunctivitis (CLPC) varies significantly, ranging from 1.5%¹ up to 47.5%² in soft hydrogel lens wear.
- Two presentations of CLPC, general and local, have previously been reported in the literature in soft hydrogel lens wear but the incidence for each type is not known.³⁻⁵
- Little is known about the recurrences of CLPC, if any, with silicone hydrogel extended wear (EW).

PURPOSE

To determine

- 1. the incidence of general, local and all CLPC in subjects wearing low Dk and silicone hydrogel contact lenses (CL) EW and the incidence of local and general CLPC with these lens types;
- 2. the recurrence rate and risk of general and local CLPC in silicone hydrogel CL EW.

MATERIALS AND METHODS

Incidence Study

- Retrospective study two collaborative sites, Australia and India, from 1993 to 2003 1,820 subjects (Table 1);
- Bilateral wear of low Dk (6N EW) or silicone (30N EW) hydrogel lenses (Table 2);
- Scheduled visits at 1 week, 1 and 3 months and then 3 monthly;
- Incidence rate = total number of new events

total number of patient eye years

Patient eye years = the sum of the time in EW for all subjects in the studies; • Incidence (%) = number of events per 100 patient eye years.

Recurrence Study

- Prospective clinical trial: selected cases and controls from population with silicone hydrogel CL wear experience;
- Cases: 52 previous CLPC events from 37 subjects

Controls: 30 subjects with no adverse events

- ◆ Bilateral wear of silicone hydrogel CL 30N EW (lotrafilcon A®, 24% H20, 175 Dk/t -3.00D lens);
- Wash out period of minimum 3 months daily disposable lens wear in low Dk hydrogel lenses;
- Scheduled visits at 2 weeks, 1, 3, 5 and 6 months and then 3 monthly until end of trial;
- Rate of recurrence (%) and risk of recurrence presented as odds ratio.

Criteria for CLPC

- Enlarged papillae \geq 0.3 mm in diameter;
- Increased hyperemia of the upper palpebral conjunctiva (UPC);
- CLPC classified as general (Figure 1) if papillae present and distributed across > 2 areas of the UPC and local (Figure 2) if confined to \leq 2 specific areas of the UPC:³⁻⁵
- Associated with or without symptoms of itching, increased mucus production, lens awareness, coated lenses, blurred vision and lens intolerance.

Statistical Analysis

Fisher's Exact test to determine differences between lens types and events p<0.05.

MATERIALS AND METHODS

Incidence Study:

TABLE 1: Combined Australian and Indian demographic data in Low Dk and Silicone Hydrogel

	Low Dk lens wearers (n = 909)	Silicone hydrogel lens wearers (n = 911)	p-Value
Mean age (yrs \pm SD)*	23.4 ± 4.7	27.4 ± 6.3	<0.001
Female : male	370 : 539	407 : 504	0.09
Mean spectacle refraction sphere (D ± SD) Range	-3.11 ± 1.43 -0.50 to -6.50	-2.93 ± 1.43 -0.50 to -6.50	0.007
Mean spectacle refraction cylinder (D ± SD) + Range	-0.29 ± 0.35 0 to -1.75	-0.39 ± 0.36 0 to -1.75	<0.001

* Majority of low Dk hydrogel lens wearers were from the Indian population which comprised a vounger age group than silicone hydrogel lens wearers

+ Difference was <0.12D and not considered clinically significant

TABLE 2: Lens properties

Lens type	lonicity (FDA classification)	Base curve (mm)	Water content (%)	(Dk/t)*	Center thickness (mm) @ -3.00D lens
Etafilcon A	Ionic (IV)	8.8	58	40	0.07
Polymacon A	Non-ionic (I)	8.7	38.6	24	0.035
Ocufilcon D	Ionic (IV)	8.6 8.9	55	28	0.07
Lotrafilcon A	Non-ionic (I)	8.6 8.4	24	175	0.08
Balafilcon A	lonic (III)	8.6	36	110	0.09

* Dk/t, oxygen transmissibility X 10° (cm X ml O2)(s X ml X mm Hg)⁻¹

Recurrence Study:

TABLE 3: Demographic data: Recurrent events vs. Contols

	General cases (n = 8)	Local cases (n = 29)	Controls (n = 30)	p-Value
Mean age (yrs. ± SD)	36.3 ± 8.6	36.2 ± 9.4	37.4 ± 8.9	0.9
Female : male	5:3	18 : 11	17 : 13	0.8
Mean spectacle refraction sphere (D ± SD) Range	-2.79 ± 2.02 -0.50 to -5.25	-2.85 ± 2.02 -7.25 to 4.00	-2.12 ± 1.78 -5.50 to 2.75	0.3
Mean spectacle refraction cylinder (D ± SD) Range	-0.19 ± 0.25 0 to -1.00	-0.24 ± 0.30 0 to -0.50	-0.30 ± 0.31 0 to -0.75	0.4

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Incidence Study:

Identified 163 cases of CLPC in 3,410 patient eye years



FIGURE 1: General case of CLPC (10x mag)

p<0.0001 for general events +p<0.0001 for local events #p=0.06 (low Dk cf silicone hydrogel Low Dk

> General CLPC Vertical bars represent 95% confidence intervals hydrogel lens wear

Recurrence Study:



FIGURE 4: % Recurrent CLPC events in silicone hydrogel lens wear





RESULTS



FIGURE 2: Local case of CLPC (10x mag)



Silicone hydrogel

Lens types

Local CLPC

FIGURE 3: Incidence of general and local CLPC in low Dk and silicone



FIGURE 5: Risk of CLPC recurrence compared to first incidence

DISCUSSION

- was no statistical difference, p = 0.06.
- Dk hydrogel CL wear (p < 0.0001) (Figure 3).^{6,7}
- events.
- EW (Figure 4).

CONCLUSIONS

- Dk and silicone hydrogel lens wear.
- Silicone hydrogel lens wear is associated with a higher incidence of local CLPC compared to general CLPC.
- if patients were to return to silicone hydrogel EW.

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This was the first study to report the incidence of CLPC in silicone hydrogel lens wear, while the incidence was slightly higher with silicone hydrogels there

The incidence of general CLPC was significantly higher in low Dk hydrogel CL wear compared to silicone hydrogel lens wear (p < 0.0001) and the incidence of local CLPC was significantly higher in silicone hydrogel CL wear than in low

Previous studies have shown that general events are asociated with an immunological etiology^{8,9} and that local events are associated with a mechanical etiology.^{10,11} The high incidence of local events in silicone hydrogels may indicate that mechanical etiology has a strong association with these

At least 6 out of 10 CLPC events recurred when returned to silicone hydrogel

Risk of developing a recurrent event in silicone hydrogel lens wear was $\sim 19x$ (95% Cl = 10 - 37) higher than the risk of developing a first event (Figure 5).

There was a greater risk of a general event recurring as a general event $(\sim 79x 95\% CI = 26 - 248)$ and an equal risk of local (14x 95% CI = 7 - 26) or general events (12x 95% CI = 5 - 27) recurring from a local event (Figure 5).

Incidence of CLPC is not significantly different between low

While managing events of CLPC with silicone hydrogels, practitioners need to be aware of the high risk of recurrence

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