

# Microbial keratitis as a foreseeable complication of cosmetic contact lenses: a prospective study

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## ABSTRACT.

**Purpose:** A recent study shows that the relative risk of contact lenses (CL)-related microbial keratitis (MK) is highly increased with cosmetic contact lenses (CosCL). The aim of our study is to illustrate the implications of the CosCL on the occurrence of MK and to describe the subpopulation of CosCL wearers.

**Methods:** A prospective multicenter study was conducted in 12 French University Hospitals on all lenses wearers presenting with MK between July 2007 and July 2009, including CosCL wearers. Patients had a complete ophthalmological examination and were interviewed by a 50 items anonymous 'questionnaire' to determine subject demographics and lenses wear history. The CosCL-related MK subpopulation (case) was described and finally compared to (noncosmetic) CL-related MK (control).

**Results:** Two hundred and fifty-six patients were included for contact lenses-related MK. Thirty-two of them (12.5%) were seen for MK after wearing CosCL. Compared with CL, CosCL wearers are younger (21 versus 27 years of age) and recent wearers (3 versus 9 years). CosCL were rarely dispensed by eye care professionals increasing the risk of MK (OR, 12.3). Education about lens care and handling was deficient for most of CosCL wearers (OR, 26.5). Sixty per cent of CosCL cases versus 13% of CL-related MK had a final visual acuity less than 20/200.

**Conclusion:** Patients who acquire CosCL are less likely to be instructed on appropriate lenses use and basic hygiene rules. Consequently, CosCL wearers are experiencing acute vision-threatening infections.

**Key words:** contact lenses – cornea – cosmetic contact lenses – microbial keratitis – prevention – questionnaire

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## Introduction

Microbial keratitis (MK) is a significant health concern for the million

wearers of contact lenses (CL) with some potentially modifiable risk factors (Bourcier et al. 2003). Fortunately, MK remains a rare complica-

tion of CL wear, but is of interest because it is both a major cause of new cases of MK in the population and the only sight-threatening complication of an otherwise safe method of vision correction (Dart et al. 1991; Cheng et al. 1999; Keay et al. 2006a,b). Number of risk factors for CL-related MK has been described. Well-designed epidemiologic studies have shown an increase in the risk of MK for daily-wear soft CL when compared with daily-wear rigid CL. MK has an incidence of about 1.1: 10000 for rigid CL, 2: 10000 for daily disposable CL and 3.5: 10000 for soft CL marketed for disposal after 1–4 weeks of wear (Keay et al. 2006a,b; Dart et al. 2008). Overnight wear has also been demonstrated as a risk factor for MK (Schein et al. 1989; Dart et al. 1991). The CL hygiene and storage have been shown to be a principal cause for microbial contamination in CL user's environment (Cheng et al. 1999; Dart et al. 2008; Keay & Stapleton 2008). The MK rates have also been reduced because of development of silicone hydrogel lenses as a result of a lens/ocular surface interactions that may be more important in the development of corneal infection than oxygen levels and CL case contamination as firstly hypothesized (Dart 1999; Dart et al. 2008).

Meanwhile, there have been case reports of MK with cosmetic contact lenses (CosCL) defined as decorative, tinted and plano contact lenses (Snyder et al. 1991; Cavanagh 2003;

Steinemann et al. 2005). A recent study also has shown that the relative risk of contact lenses (CL)-related MK was highly increased with CosCL (Bourcier et al. 2010). These patients, without refractive error, seemed to be particularly at risk of developing severe complications from contact lens wear. In these cases, CosCL were usually dispensed without a prescription or fitting from unlicensed vendors. Lenses are also sold individually and without care instructions. Consequently, uninformed CosCL wearers are experiencing acute, vision-threatening infections (Snyder et al. 1991; Cavanagh 2003; Steinemann et al. 2005). To avoid the eye health problems secondary to the unregulated sale of contact lenses, US and the UK government have decided to regulate the sale and not only the fitting of contact lenses. Because of the lack of published data on CosCL-related MK, national health authorities are reticent about extending the UK or US types law to all of Europe including France (Saviola 2007). Taking into account of this matter, this study has been designed to demonstrate the relative risk of CosCL wear and to put into perspective the individual risk and the societal burden of CosCL-related MK.

## Patients and methods

### Design

A prospective case-control study was carried out in 12 University Hospitals all over France (Besançon, Bordeaux, Dijon, Fort de France, Grenoble, Limoges, Lyon, Nancy, Nantes, Paris, Marseille and Strasbourg) during a 2-year period beginning in July 2007. The inclusion criterion was the presence of MK after wearing contact lenses. Microbial keratitis was defined as a suppurative corneal infiltrate and overlying epithelial defect associated with the presence of micro-organism on corneal scraping and/or that was cured with antibiotic therapy. Among CL-related MK patients, CosCL wearers (case) were studied and compared with CL wearers (control). CosCL were defined as a plano, decorative and tinted contact lenses. All patients with CL-related MK had first a slit-lamp examination to determine the severity and the treatment of the corneal abscess. Severe MK was defined with the following features leading to hospi-

tal care: (i) presence of anterior chamber flair; (ii) any part of the lesion being in the central 3 mm of the cornea and (iii) lesion diameters >2 mm (Bourcier et al. 2003). If one or more criterion for severe MK was observed, it was decided to do a corneal scraping for microbial identification and a hospitalization was ordered. All patients were secondly asked to fill in a 50 items anonymous standardized questionnaire.

### Questionnaire

Patients completed a 50 items anonymous standardized 'questionnaire' (Annex 1) providing data on possible risk factors, including demographic data (age, gender and educational level), medical history and concomitant treatment (usually checked with the general practitioner) CL wear history (age of first prescription, years of wear), reason for wearing CL (ametropia, cosmetic plano lenses), lens type (soft or rigid), wear schedule (frequency of disposal, delay of replacement, overnight wear) and CL hygiene compliance (hand washing, lens care).

### Statistical analysis

We examined distributions for all variables of interest by determining the frequencies, means, medians and measures of variance. To evaluate the statistical significance of the unadjusted associations between case (Cos CL wearers-related MK) and control (CL-related MK) status and participants' characteristics, we used either Fisher's exact tests or Pearson's chi-square tests for categorical variables. We used unconditional logistic regression to compute adjusted odds ratios (OR) and 95% confident interval (CI) of independent

variables.  $p < 0.05$  was determined to be significant. The statistical software used was GRAPHPAD PRISM 5 (GraphPad Software Inc., San Diego, CA, USA).

## Results

The study design resulted in 256 CL-related MK. Thirty-two patients on 256 were CosCL cases. So, 224 (non-cosmetic) CL-related MK were compared to 32 CosCL-related MK. CosCL-related MK had significant history of psychiatric disease in 35% of cases, versus 10% for CL-related MK ( $p = 0.0311$ ), including depression (6/32) and mental anorexia (3/32). Cosmetic contact lenses-related MK patients were significantly younger (median: 21.5 years of age; [17.4–25.6]) than the CL-related MK patients (27.0 years of age; [25.5–28.5];  $p < 0.0001$ ). Compared with CL-related MK patients, CosCL-related MK were recent CL wearers (2.9 years [1.9–3.9] versus 9.2 [8.2–10.2] for CLRMK;  $p < 0.0001$ ). Table 1 shows the demographics data and the lens types for the 32 CosCL cases and the 224 non-cosmetic CL-related MK.

In the CosCL-related MK group, lenses were rarely dispensed by eye care professionals. The prescription was given by an ophthalmologist for 19% of the CosCL cases and 74% of CL-related MK (OR, 12.3× [4.8–31.5];  $p < 0.0001$ ), by an optician for 53% of CosCL cases and 30% of CL-related MK (OR, 2.6× [1.2–5.6];  $p = 0.0148$ ), provided by a 'friend' or internet for 29% of CosCL cases and 0% of CL-related MK (OR, 85.3× [10.3–704.1];  $p < 0.0001$ ). The delay of the last visit to an ophthalmologist was more than 1 year for 86% of CosCL cases and 57% for CL-related MK (RR, 2.9 [1.1–7.4];  $p = 0.0249$ ).

**Table 1.** Demographics data and lens types for the 32 cosmetic contact lenses wearers (CosCL) and the 224 (noncosmetic) contact lenses-related microbial keratitis (MK).

Determinants	Demographics data		
	CosCL-related MK	(Noncosmetic) contact lenses (CL)-related MK	p
Number of patients	32	224	
History of CL wear (years; mean [95% CI])	35	18	0.0311
Age (years; median [95% CI])	21.5 [17.4–25.6]	27.0 [25.5–28.5]	<0.0001
History of systemic disease (%)	2.9 [1.9–3.9]	9.2 [8.2–10.2]	<0.0001

$p < 0.05$  was determined to be significant.

Education about lens care and handling was significantly deficient in all CosCL cases. Only 13% of CosCL cases (versus 74% of CL-related MK patients) had received information (OR, 19.9 [6.7–59.2];  $p < 0.0001$ ). Sixty-one per cent of CosCL cases had no education about how to dispose the lenses compared with 10% for CL-related MK (OR, 26.5 [10.0–70.2];  $p < 0.0001$ ). Hand washing was not done before lenses insertion for 53% of CosCL cases and 32% of CL-related MK (OR, 2.4 [1.1–5.1];  $p = 0.0274$ ) and lenses removing for 62% of CosCL cases and 34% of CL-

related MK (OR, 3.3 [1.5–7.0];  $p = 0.0029$ ). Sixty-four per cent of CosCL cases did not know the brand name of their cleaning solution, versus 19% of CL-related MK (OR, 7.8 [3.3–18.3];  $p < 0.0001$ ). Lenses and storage case cares were made with water for 59% of CosCL cases and 38% of CL-related MK (OR, 2.4 [1.1–5.1];  $p = 0.0325$ ). Compared data of lenses prescription, education about lens care and handling and hygiene are showed in Table 2.

Because of severe condition, 23/32 (79%) CosCL cases had corneal scraping in hospital care. Microbial

identification was obtained for 57% of them (13/23). Gram-negative bacillus was identified for 9 (69%) including *Pseudomonas* for 3 (23%) and *Acanthamoeba* for 4 (31%) patients. Sixty per cent (19/32) of CosCL cases had a final visual acuity less than 20/200. In comparison, 115/224 (51%) CL-related MK patients had corneal scraping. Identification was obtained for 57 (49%) patients. Gram-negative bacillus was identified for 41 (71%), including *Pseudomonas aeruginosa* for 11 (19%), Gram-positive cocci for 12 (21%), *Acanthamoeba* for 3 (5%) and fungi for 2 (3%) patients. Thirteen per cent (29/224) of CL-related MK patients had a final visual acuity  $< 20/200$ . Microbiological data are summarized in Table 3.

**Table 2.** Compared data of contact lenses prescription, education about lens care and handling and hygiene between cosmetic contact lenses wearers (CosCL)-related microbial keratitis (MK) and the 224 (noncosmetic) contact lenses-related MK.

Risk factors	Relative risk of MK (Cosmetic versus noncosmetic lenses wearers)	95% CI	p-value
<b>CCL prescription</b>			
No ophthalmologist supervision	12.3	4.8–31.5	$< 0.0001$
Ophthalmologist's last visit $> 1$ year	2.9	1.1–7.4	0.0249
CCL dispensed by an optician only	2.6	1.2–5.6	0.0148
CCL dispensed by a friend, a local market or internet only	85.3	10.3–704.1	$< 0.0001$
<b>Information about handling, lens care and hygiene</b>			
No information at all	19.9	6.7–59.2	$< 0.0001$
Lack of handling instructions	26.5	10–70.2	$< 0.0001$
Absence of hand washing before disposal	2.4	1.1–5.1	0.0274
Absence of hand washing before removal	3.3	1.5–5.1	0.0029
Ignorance of cleaning solution's commercial name	7.8	3.3–18.3	$< 0.0001$
Use of tap water for contact lenses (CL) or CL-box care	2.4	1.1–5.1	0.0325

Results are expressed as relative risks.  $p < 0.05$  was determined to be significant.

**Table 3.** Microbiological determinants for the 32 cosmetic contact lenses (CosCL) wearers and the 224 (noncosmetic) contact lenses-related microbial keratitis (MK).

	Microbiological determinants		
	CosCL-related MK	(Noncosmetic) contact lenses-related MK	p
Severe conditions and corneal scraping (n, %) 23/32 (79%)	115/224 (51%)	0.031	
Microbial identification (n, %)	13/23 (57%)	57/115 (51%)	ns
<b>Micro-organism repartition</b>			
Gram-negative bacillus Including	9 (69%)	41 (71%)	ns
<i>Pseudomonas</i>	3 (23%)	11 (19%)	
Gram-positive cocci	0 (0%)	12 (21%)	ns
<i>Acanthamoeba</i>	4 (31%)	3 (5%)	0.012
Fungi	0 (0%)	2 (3%)	ns
Final visual acuity $< 20/200$	19/32 (60%)	29/224 (13%)	0.004

Corneal scraping was done if one or more criterion for severe MK was observed.  $p < 0.05$  was determined to be significant.

## Discussion

The design of this study has provided the largest CosCL-related MK case series to date and a sample of control patients (CL-related MK) from all over France, which may allow the extrapolation of our findings to lenses users from similar environments. A recent study has showed that wearing CosCL increased 16.5 times the risk of developing a MK (Bourcier et al. 2010). Consequently, CosCL wearers are experiencing acute vision-threatening infections with a very high relative risk, while this subpopulation of patients has no refractive error. One should wonder whether this risk is acceptable and about the reasons surrounding CosCL wear. Cosmetic contact lenses wear are mainly wear on aesthetic purpose without any medical indications, contrary to the use of hand-painted contact lenses for medical indications after eye trauma or phthisis for example. In these particular cases, provided lens care is satisfactory and the patient does not have unreasonable expectations, so a tinted contact lens can be a useful device (Cole & Vogt 2006). Contrary to this statement, this study has pointed the highly increased risk of CosCL wear and its potential cost implication when CosCL are dispensed without a prescription or fitting from unlicensed vendors. For the last 2 years in France, 32 patients have complained about MK leading to hospitalization and severe visual loss for most of them (visual acuity  $< 20/200$  for 60% of them).

Our work has demonstrated some determinants which may explain the higher risk of lenses-related MK with cosmetic CL. As suggested by previously published case series report (Snyder et al. 1991; Woo 2003; Steinemann et al. 2005), this study has allowed the determination of a CosCL wearer's profile. Cosmetic contact lenses are young and recent lenses wearers. A high frequency of systemic disease, including notably anorexia and depression, has been noted in the CosCL-related MK group, suggesting self-imaging trouble as a possible purpose for the lenses wear. Our study has also demonstrated that CosCL are significantly less likely to be instructed on appropriate lenses use and care by eye care professionals, notably because their lenses are being frequently dispensed without a prescription, directly in a local market, an optician, a friend or via internet. Cosmetic contact lenses wearers do not know the basis of lens care and handling provided in some published studies leading to severe infectious complications (Keay & Stapleton 2008). Thus, a negative feedback loop is created, in which the lack of instruction leads to lenses' use and care mistakes and finally to an increased risk of MK.

As previously published in case report (Johns & O'Day 1988; Snyder et al. 1991; Steinemann et al. 2003), CosCL-related MK has a poor prognosis resulting in hospital care for 79% of CosCL cases and severe visual loss for 60% of them. Corneal scraping was done for these patients, and microbial identification was obtained for most of them. Cosmetic contact lenses wearers are mostly infected with micro-organism associated with a poor prognosis, as Gram-negative bacillus (69%, including 23% of *Pseudomonas*) and *Acanthamoeba* (31%). For comparison and as previously published (Bourcier et al. 2003), we have demonstrated that Gram-negative bacillus and *Pseudomonas* (72% including 19%) are certainly predominant for (noncosmetic) CL-related MK, but staphylococcus is also present in 21% of cases and *Acanthamoeba* (5%) is less frequent than in CosCL wearers (Lee et al. 2007; Kerr & Ormonde 2008). This particular microbial environment may be explained by the ignorance of the basic hygiene's rules and

the absence of education about lenses care. Notably, most of CosCL wearers are usually using tap water to clean their lenses or storage case, which may be the beginning of *Acanthamoeba* colonization (Anger & Lally 2008; Patel & Hammersmith 2008).

In conclusion, CosCL are being frequently dispensed without a prescription in numerous countries. Patients who acquire CosCL are significantly less likely to be instructed on appropriate lens use by eye care professionals. Education of the CL wearers has to be for avoiding problems such as MK, leading to a severe personal and societal cost. With the increasing availability of CosCL, notably through internet or local market that are legal way of CL selling in numerous countries, this study serves to highlight the increasingly documented dangers of freely available CosCL without professional supervision, as it is the case notably in France.

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## Supporting Information

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**Appendix S1.** French Study Group author details.

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