A web-based survey of contact lens-related adverse events among Japanese female population: Are decorative contact lenses dangerous?

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Abstract

Objectives:

To compare the frequency of contact lens (CL)-related complications and to identify the risk factors for transparent and decorative CL users.

Methods:

A web-based, cross-sectional, observational survey of adverse events related to CL use was performed. The frequencies of complications were compared between two groups. Logistic regression analyses were performed to calculate an odds ratio (OR) for each metric. Age, replacement schedule, total experience, daily wear time, location of purchase, stacking of CLs, CL exchange with friends, compliance to hygiene procedure, replacement of CLs at intervals longer than recommended, and CL wear overnight were considered as confounders.

Results:

A total of 3,803 Japanese females were surveyed. The frequency of adverse events was 33.35% (95%CI: 31.27%-35.43%) and 35.73% (95%CI: 33.53%-37.98%) for transparent and decorative CLs, respectively. In a multivariate model, statistically significant factors associated with complications included the following: quarterly schedule lenses, replacement of CLs at intervals longer than recommended, compliance to hygiene procedure, CL wear overnight, CL purchase at physical shops and on the internet, and longer daily wearing time.

Conclusions:

Most of the risk-increasing behaviors are preventable. The role of public health ophthalmology is to increase awareness and to improve CL use behaviors.

Introduction

Decorative contact lenses (DCLs) appeared in the USA in the early 1980s and were previously prescribed to mask eye flaws and improve the cosmetic appearance of the eye(s) [1]. Today, DCLs are fast becoming an essential fashion item, especially for young females. DCL wearers make up a significant and growing proportion of the contact lens (CL) wearing population in Asian countries [2].

The safety of cosmetic CLs is controversial. More specifically, there have been several negative reports about adverse events related to the use of DCLs [3-5]. A recently published meta-analysis that was conducted by a manufacturing company about their own products summarized six, unpublished results regarding the safety of their DCLs and concluded that they were safe [6]. This report, as written, would be insufficient as a meta-analysis document because it did not provide the calculation of pooled odds ratios

or relative risk assessment. In addition, the time periods considered in each of the studies were too short (1 week to 3 months) to effectively evaluate the safety of DCLs.

Review of existing literature revealed that some aspects in CL use behaviors were strongly associated with adverse events related to CL use [2,7,8]. Regarding safety assessment in clinical trials, we surmise that during the clinical trial period, CL users would be uncharacteristically motivated to keep good hygiene behavior under the supervision of CL specialists. This behavior is in direct contrast to non-compliance reports that vary from 40% to 91% in real world settings [9-12]. The objectives of this study were to assess the safety of DCLs, and to investigate other independent risk factors of CL related complications for Japanese females of reproductive age through online survey methods.

Methods

Two sets of questionnaires were prepared by the survey team. The first was a screening test to recruit participants from internet users. The second was a detailed survey regarding the personal incidence of CL related eye complications, features of the CL purchase location, and personal CL use behaviors.

The preliminary screening survey included: age, sex, type of CL in current use (DCL, transparent CL, or both), replacement schedule (daily, weekly, bi-weekly, monthly, quarterly, annually, or others/unknown), total experience with CLs (years), and daily wear time (hours). Subjects who met the inclusion criteria (i.e., Japanese females aged 16-49, routinely wearing soft CLs) immediately proceeded to next questionnaire. The subsequent survey asked about the location of CL purchase (physical shop, internet, or eye clinic/hospital), their personal experience of CL related eye problems in the previous year (yes or no), and their practice of the following behaviors: stacking CLs during wearing, exchanging CLs among friends, replacing CLs at longer intervals than recommended, sleeping while wearing CLs, and hygiene-related behaviors. To assess hygiene-related behavior, three questions were presented: 1) rinsing and/or preserving with tap water, 2) rinsing and/or preserving with expired disinfectant solution, 3) using the same CL case for more than three months.

The CL related eye complications were defined as the history of tearing, eye pain, and blurred vision. The web-based survey was conducted in November 2018 through a contract with a Japanese professional marketing research *company* (Cross Marketing Ltd.) that was *experienced in many academic research studies*.

Statistical analyses

Females who wore both DCLs and transparent CLs were considered within the DCL group. Regarding compliance to hygiene procedure, females who answered “Never” in all three hygiene-related questions were categorized as “good” compliance, while answers other than “Never” in any of the three hygiene-related questions were categorized as “bad” compliance. We used Student’s t-tests for to assess differences among continuous data variables, and χ^2 tests for categorical variables comparisons between two groups.

Age, total experience with CLs, and daily wear time were treated as continuous variables, while the other variables from the surveys were treated as categorical. Simple and multivariate logistic regression analyses were performed to calculate crude and adjusted odds ratios (ORs) and 95% confidence intervals (95%CI) to assess the risk associated with adverse events related to CL use.

A *P*-value <0.05 in each statistical test for differences between population was accepted as significant. STATA SE/15.1 for Windows (STATA CORP LLC, Texas, USA) was used for statistical analyses.

Ethical considerations

The protocol of this study was approved by the Institutional Review Board of Juntendo University, School of Medicine, and the National Institute of Health Sciences. All participants provided informed consent electronically prior to commencing the survey. The study adhered to the tenets of the Helsinki Declaration.

Results

The screening test was distributed to 22,300 randomly selected, nationwide female panels aged 16-49 in accordance with the Japanese demographic structure. We received 8,508 responses. We distributed a detailed survey questionnaire to randomly selected 4,000 individuals. Those with an incomplete survey (n=19), and surveys with an inconsistent response between screening test and second resurvey (n=178) were excluded (Figure1). After exclusions, a total of 3,803 surveys were analyzed in this study (response rate: 95.1%).

The mean age $\pm$ standard deviation of participants in this study was 28.70 ± 7.73 (Table 1). Tables 1 and 2 show the differences between the transparent and the decorative groups. Overall, 34.50% (95%CI: 32.99%-36.03%) of the females surveyed experienced CL related eye problems in the previous year. The frequency of eye complication(s) was 33.35% (95%CI: 31.27%-35.43%), and 35.73% (95%CI: 33.53%-37.98%) for transparent and decorative group, respectively, and did not differ significantly between the CL types ($p > 0.05$).

Crude and multivariate-adjusted ORs are shown in Table 3. Lens type was not associated with adverse events related to CL use. Factors associated with an increase in CL related eye complications include: quarterly replacement of CL versus daily CL replacement, longer daily wear duration, CL purchase at physical shops and/or over the internet versus purchases at eye clinics/hospitals, poor compliance to recommended hygiene procedures, replacement of CLs at longer intervals than recommended, and sleeping in CLs.

Discussion

The research group of the Ministry of Health, Labor and Welfare, Japan, investigated the risk factors on CL-related eye problems among middle school and high school students throughout Japan. According to this survey [13], a higher school grade, and female sex as well as poor compliance with CL care were

associated with the CL-related eye problems. Thus Just over 3,800 Japanese females aged 16-49 years were surveyed and those results were analyzed.

Our analysis revealed that there was no significant difference in the frequency of CL-related eye disorders between DCL and transparent CL groups. This result was contrary to our expectations as we expected there would be a different set of CL-related habits between the two groups. In fact, as Tables 2 and 3 show, the DCL wearers seemed to live a less risk-averse lifestyle regarding CL habits. In the multivariate analysis model, factors associated with increased frequency of eye complications included quarterly replacement schedule versus daily disposable use, longer wear times, purchases of CLs from shops and over the internet rather than from health professionals, poor compliance to hygiene procedures, extending the recommended CL replacement schedule, and the wearing of CLs while sleeping. A majority of the findings above are consistent with previous publications.

Replacement schedule is an important factor used to predict eye complication risk. In theory, the risk of adverse events related to CL use for daily disposable CLs was less than any other type of CL. The decrease in risk associated with daily disposable CLs is attributed to the avoidance of CL solution interaction, CL case contamination, and reduced likelihood of the introduction of biofilm to the CL or case. Despite these assumed benefits of disposable daily CL, a significant difference was not observed between daily disposable CLs and other CLs. Our results showed similar safety or risk to other CLs when users behaved similarly. The reason of significantly higher OR for eye complication for quarterly CLs was unclear and should be investigated further. But considering a wide 95%CI of quarterly CL use amongst survey participants, a major reason might be due to the small number of them recruited in this study. Another confounding factor we did not consider was the potential that CL properties might be affected by other cosmetic item uses such as eyelash liners and/or hand creams that could result in eye damage.

Longer daily usage of CLs was associated with more eye complications in our analysis. The reason might be due to the potential that users with longer daily wear times included both extended wear CL users and overnight wearers. Corneal hypoxia due to longer CL usage makes the cornea vulnerable to infection [14]. Morgan et al.[15] described higher cumulative incidence rates of keratitis for extended CLs than for daily disposable CLs, regardless of lens materials used in manufacturing. Overnight CL wearing was also a well-known independent risk increase behavior [16, 17] and our result was consistent with those findings (OR: 1.27 [95%CI: 1.09-1.47]). In a biological sense, extended CL wear and overnight CL wear were associated with the presence of IL-8 and epidermal growth factor [18,19], both of which indicate mechanical trauma.

CL purchase by internet order [16] or at unlicensed vendor shops [20] were reported to increase the risks of adverse events because these purchase locales never provide eye examinations and/or sufficient counseling. Our results are consistent with these findings and we implore the need to improve health literacy for CL users. Regulation of purchase channels for CLs would be a considerable challenge for public health ophthalmology, but may reduce the incidence of adverse events related to CL use.

Bacterial contamination of CLs or cases was associated with the onset of ocular infections and mainly resulted from tap-water exposure [21], use of expired CL solution, and poor CL case hygiene [22]. In line with these findings, we obtained a convincing result of higher ORs for “poor compliance to hygiene procedure”. However, even greater ORs would likely be observed if we included more detailed hygiene-related behavior questions, such as, hand washing habits when handling CLs, personal practice of rubbing CLs, and/or the storage case after removing CLs.

Stacking one contact on top of another could change the fitting of CL and would reduce how much oxygen the cornea receives throughout the duration of CL wear. In our study, however, stacking behavior was not associated with CL-related eye complications. This result is likely due to relatively short wear time from either poor vision and/or discomfort. Exchanging CLs among friends was not related to adverse events, either. The reason for the lack of eye complication as a result of CL sharing might be due to the exchange a new pack of CLs with similar power and curve, or the friend wore the CLs for a short amount of time.

Age and total years of experience were not associated with a difference in rate of complications. The reason might be related to the correlation between age and experience. Regardless of the potential correlation, the significant relationship was not observed (results not shown) even when either experience or age was selected in multivariate logistic regression analysis. This result did not confer a greater level of the safety for experienced CL users and may be influenced by survival bias, meaning that only subjects who had no complications in the past with CLs, keep using CLs.

A major strength in this study was the large sample size that was recruited nationwide, in Japan. We do note that there were several limitations to this study. First, CL-related eye complications ranged from slight to severe, sight-threatening conditions. For this study, we considered all eye complications to be either present or not. Due to the survey aspect of this study, it would be not realistic to receive the information about medical diagnosis and severity from non-medical professionals, and may result in uncontrollable information bias. Second, we had no data on lens materials or CL brand for survey respondents. In our analysis, there was no significant difference in CL-related eye complications between transparent and DCLs. In general, those who participate in the health survey are said to have greater health literacy. These kinds of people might develop customer loyalty to brands that provide consistent, high-quality products. If counterfeit brands were on the market, the DCL wearing group, especially young females, might suffer disproportionately from eye injuries due to exposed pigments and surface roughness [23,24] or from microbial contamination [25]. Third, we included confounding factors determined from our literature review. Confounders, such as, refraction, lens fitting, tobacco use, systemic disease, and socioeconomic status were not included. Due to the nature of online surveys, there might be a higher chance that some questions would be ignored or left unanswered. To avoid this bias, we selected only the most important questions.

Several studies indicated the higher risk of eye complications as a result of DCL use [3-5]. Our study found that there was no significant difference in adverse events related to CL use between the transparent CL

group and the DCL group. CL-related complications are preventable by improvement of CL user behaviors. All CL users should reduce daily wear time by avoiding overnight wearing and CL users should maintain compliance to recommended hygiene procedures and lens disposable/replacement schedules under the supervision of eye health professionals. The findings from this research support the mission of public health ophthalmology that aims to create awareness of adverse events related to CL use, and to improve CL user behaviors to maintain their health and safety.

Declarations

Acknowledgements

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Author Contributions

K.O., A.M., and Y.H. conceptualized the project. K.O. performed all data analyses with input from A.M.. Y.H. supervised the project. K.O. drafted the manuscript. All authors read and approved the final manuscript.

Additional information

The authors declare no competing interests

Data Availability Statement

The data that support the findings of this study are available from the corresponding author, KO, upon reasonable request.

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Tables

Table1: Characteristic of studied population by lens type
(Continuous variables)

	All (n=3,803)	Transparent CL (n=1,970)	Decorative CL (n=1,833)	P-value (t-test)
Age	28.70±7.73	29.02±7.95	28.36±7.48	0.0084
Total experience (years)	11.11±7.44	11.42±7.78	10.76±7.04	0.0062
Daily wear time (hours)	11.23±3.80	11.73±3.64	10.70±3.89	0.0000
				Mean±Standard Deviation
				CL: contact lens

Table2: Characteristic of studied population by lens type (Categorical variables)

		ALL (n=3,803)		Transparent CL (n=1,970)		Decorative CL (n=1,833)		P-value (χ^2 -test)
		n	%	n	%	n	%	
Replacement schedule	Daily	1,985	52.20	895	45.43	1,090	59.47	0.003
	Bi-weekly	1,188	31.24	918	46.60	270	14.73	
	Monthly	380	9.99	83	4.21	297	16.20	
	Quarterly	36	0.95	5	0.25	31	1.69	
	One Year	179	4.71	46	2.34	133	7.26	
	Others	35	0.92	23	1.17	12	0.65	
Location of purchase	Eye clinic/hospital	1,587	41.73	1,058	53.71	529	28.86	0.000
	Physical shop	786	20.67	414	21.02	372	20.29	
	Internet	1,430	37.60	498	25.28	932	50.85	
Stacking of CLs	No	3,609	94.90	1,883	95.58	1,726	94.16	0.047
	Yes	194	5.10	87	4.42	107	5.84	
CL exchange with friends	No	3,647	95.90	1,903	96.60	1,744	95.14	0.024
	Yes	156	4.10	67	3.40	89	4.86	
Compliance to hygiene procedure	Good	868	22.82	540	27.41	328	17.89	0.003
	Bad	2,935	77.18	1,430	72.59	1,505	82.11	
Replacement of CL at intervals longer than recommended	No	2,031	53.41	1,084	55.03	947	51.66	0.038
	Yes	1,772	46.59	886	44.97	886	48.34	
CL wear overnight	No	2,272	59.74	1,184	60.10	1,088	59.36	0.640
	Yes	1,531	40.26	786	39.90	745	40.64	

CL: contact lens

Table3: Factors associated with adverse events-related to CL use

Variables		Crude ORs	95% CIs		p-values	Adjusted ORs	95% CIs		p-values
			Lower Limit	Upper Limit			Lower Limit	Upper Limit	
Lens type	Transparent	1	-	-	-	1	-	-	-
	Decorative	1.11	0.97	1.27	0.122	0.96	0.83	1.12	0.631
Replacement schedule	Daily	1	-	-	-	1	-	-	-
	Bi-weekly	1.01	0.86	1.17	0.930	0.93	0.76	1.14	0.476
	Monthly	1.38	1.10	1.73	0.005	1.28	1.00	1.65	0.054
	Quarterly	2.26	1.17	4.38	0.016	2.22	1.12	4.40	0.022
	Annually	1.36	0.99	1.86	0.054	1.33	0.95	1.86	0.096
	Others	1.52	0.77	2.98	0.228	1.68	0.83	3.38	0.147
Age	(per year)	0.98	0.97	0.99	0.000	0.99	0.98	1.01	0.380
Total experience	(per year)	0.99	0.98	0.998	0.018	1.00	0.98	1.01	0.615
Daily wear time	(per hour)	1.05	1.03	1.07	0.000	1.03	1.01	1.05	0.001
Location of purchase	Eye clinic/hospital	1	-	-	-	1	-	-	-
	Physical shop	1.36	1.13	1.62	0.001	1.28	1.06	1.54	0.010
	Internet	1.31	1.13	1.52	0.000	1.23	1.05	1.45	0.013
Stacking of CLs	No	1	-	-	-	1	-	-	-
	Yes	1.24	0.92	1.66	0.160	0.97	0.66	1.43	0.872
CL exchange with friends	No	1	-	-	-	1	-	-	-
	Yes	1.19	1.02	1.40	0.032	1.01	0.65	1.56	0.973
Compliance to hygiene procedure	Good	1	-	-	-	1	-	-	-
	Bad	1.57	1.32	1.87	0.000	1.29	1.06	1.58	0.013
Replacement of CL at intervals longer than recommended	No	1	-	-	-	1	-	-	-
	Yes	1.76	1.54	2.02	0.000	1.59	1.37	1.86	0.000
CL wear overnight	No	1	-	-	-	1	-	-	-
	Yes	1.55	1.36	1.78	0.000	1.27	1.09	1.47	0.002

CI: confidence interval

OR: odds ratio

CL: contact lens

Figures

Figure 1

Flow diagram of study participants HCL: Hard contact lens, SCL: Soft contact lens