Prevalence of Contact Lens-Related Complications: UCLA Contact Lens Study

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Purpose: This study is a cross-sectional analysis of the types and prevalence of contact lens (CL)-related complications among CL wearing patients seen in a university clinic setting.

Methods: Data on CL material and design, care system, and ocular complications were recorded and statistically analyzed for CL wearers.

Results: Of the 572 patients (846 eyes) recruited during the study, approximately 50% of the eyes had at least one CL-related complication. Rigid gas permeable (GP) CLs had a statistically lower ($P<0.01$) average number of complications (0.54 ± 0.68) than soft contact lenses (SCLs) (0.85 ± 0.82). Papillae and giant papillary conjunctivitis were the most prevalent complications in both GP and SCL wearers. Silicone SCLs (0.79 ± 0.76) had a slightly lower, although not statistically different ($P=0.23$), rate of complication than nonsilicone SCLs (0.90 ± 0.87). Although not statistically significant ($P=0.29$), extended wear CL use had a higher complication rate (0.93 ± 0.84) compared with daily wear (0.73 ± 0.79). Use of "other" solution, including generic and private label solutions, had the highest rate of complications for both SCLs (1.11 ± 1.27) and GPs (0.96 ± 0.93) compared with name brand solutions.

Conclusions: The prevalence of CL-related complications, regardless of lens design, material, and wear modality, highlights the importance of early detection with appropriate professional management and treatment.

Key Words: Complications—Contact lenses—Piggyback—Rigid gas permeable—Silicone—Solutions.

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It has been estimated that approximately 125 million people worldwide, including 38 million people in the United States, wear contact lenses (CLs).[1] As long as patients continue to enjoy using CLs to correct for their refractive error, addressing CL-induced complications will remain an important part of ophthalmic practice.

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Care systems, CL material, durability, spoilage characteristics of the lens, wear schedule, and patient-related factors can all play a part in the etiologies of ocular complications.[2–4] The prevalence of CL-related ocular complications has been reported to be as high as 39%.[3]

It has been established that CL materials with low oxygen permeability are more likely to induce both corneal edema and neovascularization.[5] However, hypoxia-related complications have been reduced through improvements in the oxygen permeability of CL materials, such as the introduction of silicone soft contact lenses (SCLs), and the continued use of rigid gas permeable (GP) CLs.

Increased CL oxygen transmissibility has been linked to increased superficial epithelial cell exfoliation and decreased initial microbial binding to corneal cells,[6] but prevention of microbial keratitis (MK) has not been shown.[7] Although the US Food and Drug Administration has approved several new silicone SCLs for extended wear, the incidence of severe keratitis is still higher under extended wear as opposed to daily wear.[8]

CL solution-related complications also remain a point of concern for eye care practitioners. This is reflected in the recent CL care solution recalls from the market as a result of their association with microbial infection "epidemics" of *Fusarium* sp and *Acanthamoeba* sp.[9,10]

With the emergence of concerns about the biocompatibility of lens solutions and the introduction of new oxygen-permeability-enhanced CL materials, we believe that there is a need to update the literature on the prevalence of ocular complications with CL wear. The prevalence of complications can be affected by the lens type, wear schedule, and care system, which underlines the importance of prescribing recommendations.[3] This study is a cross-sectional analysis of the types and prevalence of complications that occur with GP, nonsilicone SCL, and silicone SCLs among patients in a university setting. In addition to serious complications, such as MK, we also record the prevalence of less severe, but more common, CL-related complications. The goal of this study is to provide the ophthalmic community with a better understanding of the prevalence of complications that may arise with CL wear and their association with different CL designs, wear schedules, and care systems.

METHODS

Subject Identification and Recruitment

For this cross-sectional study, we established a recruitment goal of 500 subjects to provide a sufficiently diverse population to evaluate the prevalence of CL-induced ocular complications and their association with CL designs, wear schedules, and care systems.

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All patients who presented to either of two university optometry clinics for their CL examination (i.e., annual eye examinations with CL evaluation) or CL progress appointments (i.e., CL follow-up examinations) were potential subjects for the study. One clinic was at UCLA Arthur Ashe Student Health Optometry, and the other was at a specialty CL practice in the Department of Ophthalmology at the Jules Stein Eye Institute, David Geffen School of Medicine at UCLA. Patients presenting at the Arthur Ashe were predominantly self-referred UCLA students and staff, whereas patients presenting at the Jules Stein were a mixture of self-referred and ophthalmologist referred.

All the participants of this study were CL wearers who presented to the clinics during the research period. Data were collected at a patient's first visit during the sample period, regardless of whether they were routine or unscheduled visits. Patients were excluded from the study if they were below 18 years or if they declined to participate.

The data were prospectively collected from the subject's examination and medical records and included, but were not limited to, entering visual acuities of each eye (with or without CLs), refractive errors of each eye, best corrected visual acuities of each eye, keratometric readings, type of CLs worn, lens care system used, wear schedule, CL fit assessment, complications related to CL wear (identification and description), treatments, refit of CL (material and parameter), and finally outcome of the complication, if any. Wear schedule was determined as either daily or extended wear, with extended wear defined as continuous wear of CL without removal for more than 2 to 3 days; the extended wear classification did not include patients who occasionally napped with their lenses. Data were collected on the following complications commonly associated with CL wear: giant papillary conjunctivitis (GPC), injection of the conjunctiva, chemosis of the conjunctiva, papillae, follicles, other conjunctival complications, corneal abrasion, corneal edema, corneal infiltrates, neovascularization of the cornea, 3–9 staining, diffused superficial punctuate keratitis (SPK), localized SPK, corneal ulcer, superior epithelial arcuate lesion, and other corneal complications. Because the focus of this study was to measure the prevalence of complications, the data used in this study record only the presence or absence of each complication. A patient was recorded as having the complication if they had an Efron rating of 1 or greater.[11] We recorded papillae with an Efron rating of 4 as GPC.

Data were collected prospectively at the time of each visit. The clinicians involved were all licensed optometrists and were advised of the grading scale and set of complications to measure before collecting the data. Any procedures or treatments related to CL-related ocular complications were standard of care (i.e., no experimental treatments were given).

This study was approved by the UCLA Institutional Review Board with informed consent provided by all patients.

Data Collection, Storage, and Confidentiality

Data were only collected during a patient's first visit to either clinics during the study period. Subsequent examinations for these patients were not included in our study sample. All data were prospectively recorded and collected from the patient's medical record. For patients with CL-related ocular complications, the complications were identified and recorded. Subject's year of age, sex, and description of complications were extracted to a password-protected computer for further analysis using Stata 8.0 (Stata Corporation; College Station, TX).

RESULTS

Demographics

The study period ranged from April 2006 to March 2007. Our study cohort consisted of a total of 572 patients using CLs to correct for refractive error (846 eyes). The surprisingly large fraction of patients wearing CLs in just one eye is likely a result of the fact that the sample includes a large number of patients, many with unusual ocular conditions such as keratoconus, from a tertiary care center. Of the patients in our sample, 199 (35%) were men and 373 (65%) were women. Patients' ages ranged from 18 to 78 with an average age of 35 and a median age of 29. All patients were existing CL wearers. Of the 547 patients who presented for a single recorded reason, 59.2% were for a CL examination, 33.3% for a CL progress evaluation, 3.3% for a CL refitting, 0.6% for CL intolerance, 0.6% for red eye, 0.2% for decreased visual acuity, and 2.9% for other or did not report.

Common diagnoses included myopia (84%), astigmatism (51%), presbyopia (26%), and keratoconus (25%). Less common diagnoses included penetrating keratoplasty (6%), hyperopia (4%), aphakia (1%), and other (4%). The rate of keratoconus is unusually high because a large number of patients in our sample are tertiary care patients.

Methodology Used in Comparisons Across CL Types, Materials, and Patient Demographics

When comparing probabilities and averages across samples (e.g., average number of complications for different lens types), both Bartlett's and Levene's test for equal variances found the variances to be significantly different across groups for almost all comparisons. Inequality of variances violates a basic assumption of analysis of variance (ANOVA). Although it is often argued that ANOVA F-tests are robust to inequality of variances as long as sample sizes are equal, the sample sizes used in this study were often quite different. Therefore, ANOVA could not be relied on for many of the comparisons. To provide a consistent method of testing statistical significance, results based on weighted least squares are reported throughout.[12]

Our sample included patients wearing CLs in more than one eye, and we found the occurrences of CL-related complications in both eyes of a patient to be highly correlated. If this correlation is not accounted for, statistical tests using this data will tend to understate the true P value and find significant differences where none exist. We took the accepted approach of using the method of unweighted means when analyzing the data. As such, the sample that we use for statistical analysis consists of individual-level average complication rates. For individuals wearing a CL in just one eye, this average is equal to the number of complications in their CL-wearing eye. For individuals with CLs in two eyes, we use the average complication across both eyes. Instead of weighting individual-level averages by their number of CL-wearing eyes, which is equivalent to taking a simple average across all eyes, we use an unweighted average of individual-level averages. This is because analysis using the weighted average described above understates the true P value (i.e., finds significant differences where none exist) whereas the unweighted average does not.[13]

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TABLE 1. *CL-Induced Ocular Complication Rates by CL Type*

Category	Complication	GP, %	Soft, %	Piggyback, %
Conjunctiva	GPC	10.3	32.6	17.6
	Papillae	15.5	9.6	5.9
	Conjunctival injection	0.0	2.4	0.0
	Other	1.1	0.5	0.0
	Follicles	0.8	0.4	0.0
	Chemosis	0.0	1.1	0.0
Cornea	Neovascularization	5.4	34.1	14.7
	Diffused SPK	7.3	1.6	11.8
	Localized SPK	3.3	0.3	5.9
	3–9 staining	7.3	0.3	0.0
	Other	2.2	1.3	0.0
	Corneal abrasion	0.5	0.1	0.0
	Infiltrates	0.0	0.7	0.0
	SEAL	0.0	0.1	0.0
	Corneal ulcer	0.0	0.1	0.0
	Corneal edema	0.0	0.0	0.0

CL Care Solutions for Both GP and SCL Groups

Out of the 846 eyes that relied on CLs to correct for refractive error, 487 eyes (58%) wore SCLs alone, including 1 hybrid lens with GP center and SCL skirt, 330 eyes (39%) wore GPs alone, and 29 (3%) eyes wore both SCL and GP as piggyback contact lenses (PBCLs). SCL wearers used Opti-Free Express ([28.0%], Alcon, Fort Worth, TX), ReNu Moisture Loc ([19.1%], Bausch & Lomb, Rochester, NY), Clear Care ([10.8%], CIBA VISION, Duluth, GA), Complete Moisture Plus ([10.0%], Advanced Medical Optics, Santa Ana, CA), Opti-Free RepleniSH ([7.8%], Alcon, Fort Worth, TX.), Aquify ([1.3%], CIBA VISION, Duluth, GA), and other solutions including generic solutions (13.5%). GP wearers used Boston Original ([65.2%], Bausch & Lomb, Rochester, NY.), Boston Advance ([14.7%], Bausch & Lomb, Rochester, NY.), Boston Simplicity ([6.5%], Bausch & Lomb, Rochester, NY.), Unique PH ([3.8%], Alcon, Fort Worth, TX.), Optimum ([3.3%], Lobob Laboratories, San Jose, CA.), Clear Care (0.5%), and other GP solutions (3.3%). Fifty percent of patients wearing GP and 1.1% of patients wearing SCL reported the use of supplemental enzyme cleaners.

Complication Rate for GP Group

Of the 184 patients wearing GPs alone, the average number of complications was 0.54 ± 0.68 per eye. The most common complications for GP wearers were papillae (15.5%), GPC (10.3%), 3–9 staining (7.3%), and diffused SPK (7.3%) (Table 1).

Complication Rate for SCL Group

Of the 371 patients using SCLs alone (including 1 hybrid lens with GP center and SCL skirt), the average number of complications was 0.85 ± 0.82 per eye. The most common complications for SCL wearers include neovascularization (34.1%), GPC (32.6%), and papillae (9.6%) (Table 1). Only one corneal ulcer was recorded (0.1%) in one silicone SCL wearer. This patient presented for a "red-eye" examination and was using silicone SCL lenses on a combination of both extended wear and daily wear modality.

Complication Rate for SCL Types

Of the 487 eyes wearing SCLs alone, 212 wore silicone SCLs and 275 wore nonsilicone SCLs. Although not statistically significantly different ($P=0.23$), eyes with silicone SCLs had a slightly lower rate of complication (0.79 ± 0.76) than with nonsilicone SCLs (0.90 ± 0.87). The frequency of specific complications was broadly similar across silicone and nonsilicone SCLs (Table 2).

TABLE 2. *CL-Induced Ocular Complication Rates by SCL Type*

Category	Complication	Silicone hydrogel, %	Nonsilicone hydrogel, %
Conjunctiva	GPC	27.6	36.2
	Papillae	12.2	7.9
	Conjunctival injection	2.6	2.4
	Chemosis	1.3	1.0
	Follicles	1.0	0.0
	Other	0.0	1.0
Cornea	Neovascularization	30.4	36.7
	Diffused SPK	0.6	2.4
	Other	1.3	1.4
	Infiltrates	1.0	0.5
	Localized SPK	0.6	0.0
	3–9 staining	0.0	0.5
	Corneal abrasion	0.3	0.0
	SEAL	0.3	0.0
	Corneal Ulcer	0.3	0.0
	Corneal Edema	0.0	0.0

Overall Complication Rate

The overall average number of complications was 0.67 ± 0.79 per eye. The modal number of complication was zero, and the median number of complications was one. A total of 35.4% of eyes examined had a single complication, and 14.3% of eyes examined had two or more complications. The most number of complications found in a single eye was four (Figure 1).

Complication Rate Comparison

The average complication rate for GPs (0.54) was lower than for SCLs (0.85). The difference was statistically significant ($P<0.01$). Silicone SCLs had lower average complication rates (0.79) than nonsilicone SCLs (0.90), but the difference was not statistically significant ($P=0.23$).

"Other" CL solutions were associated with the highest average number of complications for both GP (0.96) and SCL (1.11) wearers. Optimum was associated with the lowest average number of complications for GP lens solutions (0.25). Opti-Free RepleniSH was associated with the lowest average number of complications for SCL (0.50) users. The highest average number of complications were statistically significantly different from the lowest average number of complications for GP ($P=0.01$) but not for SCL ($P=0.17$). The lack of statistical significance for the SCL solutions may be due to the small sample size and large variance in the number of complications for other lens solutions (Table 3).

Men had an almost identical number of complications as women in our study—rounded to the nearest hundredth they were both 0.74

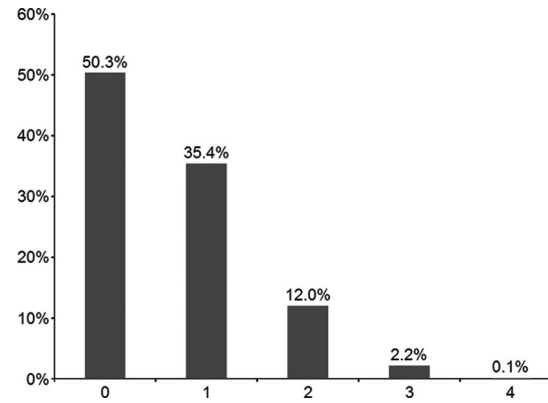

FIG. 1. Histogram of complications per eye.

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TABLE 3. *Average Number of CL-Induced Ocular Complications as Associated With Various CL Solutions*

CL type	Solution	*N*	Average	SD
GP	Other	47	0.96	0.93
GP	Boston Simplus	9	0.72	0.67
GP	Boston Advance	10	0.70	0.63
GP	Unique pH	4	0.50	0.41
GP	Boston Original	60	0.49	0.66
GP	Optimum	4	0.25	0.50
GP and SCL	Clear Care	42	0.75	0.72
GP and SCL	Enzyme	104	0.51	0.66
SCL	Other	9	1.11	1.27
SCL	Aquify	5	1.00	0.00
SCL	Opti-Free Express	101	1.00	0.89
SCL	Complete Moisture Plus	37	0.95	0.74
SCL	ReNu Moisture Loc	64	0.80	0.74
SCL	Opti-Free RepleniSH	28	0.50	0.71

per eye, with very similar standard deviations of 0.80 and 0.78, respectively. The difference in average complications between the sexes was statistically insignificant ($P=0.97$).

Of the patients whose wear schedule was recorded for this study, 97% wore their CLs in a daily wear modality and 3% wore them in an extended wear modality. For both modalities, roughly one third wore nonsilicone SCLs. For extended wear, two thirds of the patients wore silicone SCLs. In the daily wear modality, GPs made up the majority (40.6%), followed by nonsilicone SCLs (34.3%), and silicone SCLs (25.1%) (Figure 2).

Patients using the extended wear modality had an average of 0.93 ± 0.84 complications per eye, which was slightly higher than the value of 0.73 ± 0.79 found for the daily wear, although not statistically significantly different ($P=0.29$).

DISCUSSION

Our study encompassed a wide range of CL modalities. Approximately half of the eyes seen in our clinics presented with CL-induced complications, the most common being GPC, papillae, and neovascularization. This is slightly higher than the study by Keech et al.,[3] which reported CL-induced complications in approximately two fifths of their patients. Their most common complications, however, were SPK and neovascularization. Our study is consistent with the study by Cunha et al.,[5] which showed that approximately 50% of their SCL wearers developed CL-induced complications during a 3.5-year study. The number of complications is high considering that 95% of the patients presented for routine CL examinations or progress evaluations.

Our study is consistent with previous studies showing that GP wear has a lower prevalence of complications than does SCL wear,[14–16] the most prevalent complications for GP being papillae, GPC, 3–9 staining, and diffused SPK. It is unfortunate that the popularity of GPs is diminishing given the significantly lower rate of complications compared with both silicone and nonsilicone SCLs.

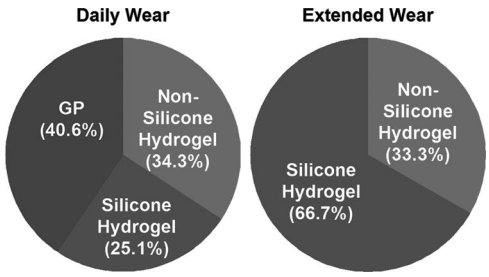

FIG. 2. Lens material by wear schedule.

Interestingly, silicone SCL wearers have complication rates similar to nonsilicone SCL wearers. Consistent with Keech et al.,[3] neovascularization, papillae, and GPC were the most prevalent. The rate of neovascularization may be artificially high in our silicone SCL group because neovascularization is a permanent corneal abnormality and eyes with neovascularization from previous wear of nonsilicone SCLs are often refitted into silicone SCLs. This was a single cross-sectional study evaluating prevalence; to truly compare the rate of neovascularization between silicone and nonsilicone CL wearing eyes, a longitudinal study on virgin CL eyes should be conducted in the future.

Silicone SCL wearers did not have higher rates of GPC than nonsilicone SCL wearers, even though silicone lenses have been found to have a higher rate of lipid deposition.[17,18] The generalized form of GPC across the entire palpebral conjunctiva and localized GPC on the tarsal conjunctiva, both associated with high-Dk lenses,[2] were not differentiated in our study.

GPC and neovascularization were also the most common complications for PBCL wearers (Table 1). We had expected that PBCL wearers would have the highest rate of CL complications because both GP and SCL materials are used. Surprisingly, the PBCL rate of GPC was less than those of SCLs. This could be the result of lower rates of extended wear and better compliance due to more frequent visits to an eye care professional, and hence more frequent CL care and instruction. Also, it should be noted that the difference in neovascularization and GPC between PBCL and SCLs were not statistically significantly different ($P>0.1$ for both comparisons). Compared with GPs and SCLs, PBCL wear resulted in both more diffuse and localized SPK; these differences were statistically significant for PBCL compared with SCL ($P<0.01$ for both) but not for GP ($P>0.1$ for both). PBCLs may have a higher rate of diffuse and localized SPK partly because of the use of PBCLs on more problematic eyes or the lower oxygen transmission and tear exchange anticipated with PBCLs. Previous studies have not reported complication rates for PBCL wearers.

We found minimal differences in conjunctival injection between silicone SCLs and traditional nonsilicone SCL wear, in contrast to the findings of Papas et al.,[19] perhaps because most of our patients only used CLs for daily wear and not extended wear.

All of our patients wearing GP wore their CLs on a daily wear basis and only a very small percentage of our SCL wearing patients wore CLs on an extended wear basis. Extended wear had slightly higher complication rates than daily wear, but this difference was statistically insignificant, possibly due to the small sample size of extended wear users. Similar to previous studies,[20,21] one third of our patients wore silicone SCLs.

When evaluating care solutions, other solutions had the highest complication rate in both SCL and GP wearers. Other solutions include both generic and private label solutions. The higher rate of complication may be a reflection on patients who are already noncompliant because they may not be using the CL solution that their practitioner had originally prescribed. Chun and Weissman[22] found that 16% of all patients switch away from the brand of CL solution that was originally recommended for them.

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Of interest, Optimum, an alcohol-based GP solution, had the lowest prevalence of complications. This result may be driven by the small sample size, as this solution was only used by four of the patients in this sample, who had a total of one complication. Had one additional complication occurred in these patients, the average for Optimum would have matched that of Boston Original, the solution with the second lowest prevalence of complications.

In our study, the hydrogen peroxide solution Clear Care had a higher rate of complication than one of the multipurpose solutions, Opti-Free RepleniSH. Nonpreserved CL systems, however, although more complicated, are expected to generally clean and disinfect more thoroughly and eliminate complications from solution toxicity, compared with multipurpose solutions.[23] Because hydrogen peroxide CL solutions are generally reserved for patients who are prone to or have had episodes of CL complications, this may explain the unanticipated higher rate of complications compared with Opti-Free RepleniSH. To determine a more accurate complication rate for hydrogen peroxide based systems, a longitudinal study is necessary.

The findings in this study are subject to the caveat that the patient base was drawn from a university clinic setting and may not be representative of the general optometric patient population. As mentioned earlier, many of the individuals in our sample had ocular conditions that may not commonly present at a general optometric practice. An area for future research is to repeat this study in a general practice setting.

Regardless of CL lens modality, clinicians know that complications, both minor and severe, can occur with any CL wear. We found an overall prevalence of complications of approximately 50% of all eyes or 57% of all CL wearers. Although we do not report grading here, most of our complications were mild, asymptomatic (0.6% CL intolerance, 0.6% red eye, and 0.2% decreased visual acuity), and not vision threatening (we only documented one corneal infection in our cohort). Because most of these complications are asymptomatic, our data stress the importance of recommending that patients maintain a timely and appropriate professional CL care schedule.

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