



# Value of routine evaluation in asymptomatic soft contact lens wearers

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## ABSTRACT

**Objectives:** Limited literature supports the value of routine contact lens examinations. The purpose of this study is to document complications diagnosed when subjectively successful planned replacement soft contact lens patients are evaluated to renew their existing contact lens prescriptions.

**Methods:** Asymptomatic soft contact lens patients who presented to the University Eye Center at Ketchum Health (Anaheim, CA) and the Eye and Vision Center at the Massachusetts College of Pharmacy and Health Sciences (Worcester, MA) for routine contact lens comprehensive exams to renew existing contact lens prescriptions were professionally evaluated and their complications documented. All subjects presented without complaint and had a history of subjectively successful planned replacement soft lens wear for at least 1 year.

**Results:** A total of 202 subjects were recruited from both sites (age range 16–72 years; 76 male, 126 female; spherical contact lens optical power equivalent range: +7.75D to −19.25D). Considering health issues, one hundred and five (52%) patients were found to exhibit at least one undiagnosed complication (95% CI: 0.45–0.59); 70% were diagnosed with contact lens driven ocular complications; 54% were diagnosed with non-contact lens driven ocular health issues; and 4% showed signs of undiagnosed systemic disease. Of note, complication prevalence increases to 72% overall if both contact lens fit issues and contact lens care compliance problems are included as complications in analysis.

**Conclusions:** A striking ocular health and contact lens complication rate in asymptomatic soft contact lens wearers is demonstrated across two different study sites. This data suggests that asymptomatic as well as symptomatic contact lens wearers require routine professional evaluations.

## 1. Introduction

Health care practitioners appreciate the value of routine asymptomatic patient evaluations in identifying and treating early disease. Notably, however, there is limited literature supporting such practice in regards to comprehensive eye examinations [1–4] and even less regarding contact lens practice [5,6]. Although the vast majority of contact lens users wear their lenses successfully, complications ranging from ocular dryness to microbial keratitis with contact lens wear have been well documented throughout the last several decades [7]. This work identifies and quantifies the variety of complications diagnosed in a cohort of subjectively successful (asymptomatic) soft contact lens patients presenting solely to renew their existing contact lens prescriptions. The authors of this study are aware of one other recent study

similarly documenting such complications, and that study only noted complications encountered during professional dispensing of replacement rigid gas permeable lenses [6].

Numerous studies and case reports identify a small percentage, but substantial number, of patients who suffer ocular complications during contact lens wear [5,7–15]. Vision-threatening microbial keratitis, for example, is more likely when contact lenses are worn overnight and/or when contact lens hygiene is compromised [10–14]. While much focus has rightfully been placed on such major complications, most contact lens complications are not immediately vision-threatening and may be remedied with clinical management. Many of these seemingly minor complications, however, left untreated, may lead to discomfort, tissue morbidity, discontinuation of contact lens wear, and perhaps even loss of vision and permanent disability. Corneal neovascularization is one

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example of an initially asymptomatic complication which can eventually lead to vision loss if left undiagnosed and untreated [15].

Regulation of contact lenses varies by country. In the United States, contact lens wearers are legally required to have valid prescriptions to purchase contact lenses [16]. Enforcement of this regulation, however, appears unreliable. There are many anecdotal instances where patients report filling expired prescriptions, or even purchasing contact lenses without prescriptions. Some of these purchases have resulted in reported adverse events [17,18]. Practitioners, moreover, often note unanticipated and asymptomatic complications diagnosed incidentally during progress visits in contact lens wearers possessing valid contact lens prescriptions.

This study documents the frequency and variety of complications diagnosed when asymptomatic and presumably “successful” planned replacement soft contact lenses wearers (monthly, bimonthly, daily modalities) presented to their annual examinations to renew their existing contact lens prescriptions. These complications would have been unseen (and therefore undiagnosed and untreated) if patients self-renewed their prescriptions, i.e. without professional evaluation.

## 2. Methods

This is a prospective, cross-sectional, non-interventional study. Subjects were recruited during routine exams to which they self-presented. Soft lens wearers (hydrogel or silicone-hydrogel) were enrolled only if they presented for their exam without any complaint and wished to renew their current contact lens prescription.

Data was collected at Ketchum Health KH, the clinical facility of the Southern California College of Optometry at Marshall B Ketchum University in Anaheim, California, between August 24, 2016 to August 9, 2018, and at the Eye and Vision Center, the clinical facility of the Massachusetts College of Pharmacy and Health Science School of Optometry MCPHS in Worcester, Massachusetts between October 13, 2017 and June 11, 2018. A diverse patient cohort was recruited, as both clinic locations are located in major metropolitan areas. The total number of comprehensive contact lens exams seen during the recruitment period at KH and MCPHS was 1,000 and 122, respectively. From these exams, qualified patients were recruited; however it should be noted that not all qualified patients were actively recruited, as busy clinic flow did not always allow time for enrollment.

Subjects who presented using planned replacement soft lenses (hydrogel or silicone-hydrogel material) successfully for at least one year (fitted at KH, MCPHS, or elsewhere), were asymptomatic, and wished to renew their contact lens prescriptions, were recruited to this study. All subjects agreed to participate by providing Informed Consent, and signing to acknowledge understanding and receipt of their Subject Bill of Rights and Patient Authorization of Use and Release of Health and Research Study Information Forms. Subjects age 15 years and above were included in the study, but for patients between the ages of 15–18 years, parental/guardian consent and patient assent was obtained. Subjects were not provided any compensation for participation.

Any symptomatic patient with a chief complaint upon presentation

was excluded from the study. Additional exclusion criteria may be found in Table 1.

Subjects at each site completed their routine comprehensive eye exams under the care of licensed optometrists. Examinations consisted of: a thorough patient history; visual acuities and over-refractions; confrontation tests including visual fields; optical refraction; binocular vision evaluation; evaluation of both anterior and posterior (dilated or un-dilated as appropriate) segments; intraocular pressure measurement; evaluation of contact lenses’ optical and mechanical fit; and physiologic adaption with contact lens wear. Each subject was asked to report the age of their current contact lenses and provide their contact lens wear and care regimen. Following examination, the clinician input exam findings onto a de-identified standardized study form. The research study forms were collected on a daily basis and maintained in a locked cabinet. Data from all collected forms were entered into a password-protected digital Microsoft Excel (Microsoft Corporation, Redmond, Washington USA) file, in a password-protected computer, on a weekly basis.

This study specifically documented complications diagnosed in five general areas:

- 1 Systemic health issues suspected that required referral to primary care physician for management, such as diabetes and hypertension;
- 2 Ocular health issues diagnosed not directly related to contact lens complications (e.g. glaucoma, retinal disease, optic nerve disease);
- 3 Contact lens driven ocular health issues such as: corneal neovascularization, infiltrative keratitis, giant papillary conjunctivitis, contact lens papillary conjunctivitis and other ocular allergies.

If there were complications noted in any one or more of these identified areas, the patient was documented to exhibit “complications.” Examiners further quantified diagnosed complications according to standardized clinical grades [7]. If complications were discovered, then the patient was appropriately professionally managed (discussion of such management is beyond the scope of this study’s protocol). If no complications in any of the above three areas above were found, the patient was notated to exhibit “no complications” for the purpose of this study.

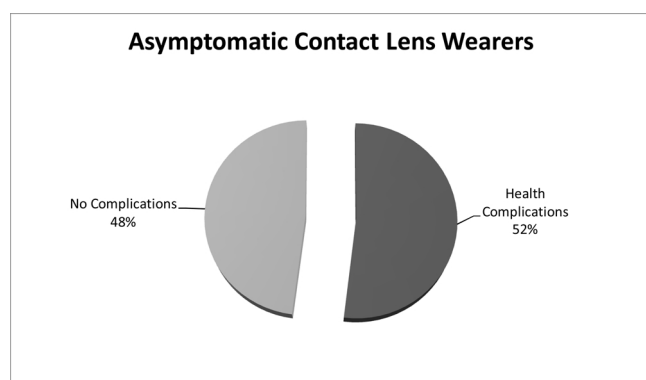
The study also documented complications in the areas of:

- 4 Contact lens fit issues (i.e. too flat or steep base curve, too large or small overall diameter, too weak or strong optical power, soiled/damaged lens);
- 5 Contact lens care non-compliance (i.e. improper handwashing, improper case care, over wear beyond prescribing doctor’s recommendation, over use beyond manufacturer’s recommended replacement schedule).

Identified defects in both of these categories (contact lens fit issues and non-compliance) may also be considered by many to be complications of contact lens wear, however these categories were not included in overall complications calculation as they are not discoverable

**Table 1**  
Study Exclusion Criteria.

Exclusion Criteria	Example
Any chief complaint/symptoms upon presentation to exam	
Virgin contact lens wearer	
Less than 1 year of contact lens wear history	
Previous non-refractive ocular disease diagnosis	e.g. dry eye, keratoconus, uveitis, glaucoma, bacterial or viral infection(s)
Previous ocular surgery	e.g. laser-assisted in situ keratomileusis (LASIK), cataract surgery
Use of ocular medications (excluding over the counter lubricant drops)	
Non-disposable contact lens wearers	e.g. rigid gas permeable, hybrid, custom soft
Medical or ocular conditions that investigators deemed inappropriate for participation in this study	e.g. rheumatoid arthritis and other auto-immune diseases
Patients who declined participation in study	



**Fig. 1.** Percent of asymptomatic soft contact lens wearers with health complications. Fifty-two percent (52%) of 202 asymptomatic “successful” soft contact lens wearers were diagnosed with at least one complication in the areas of systemic health, ocular health, and/or contact lens driven ocular health complications (95% CI: 0.45–0.59).

clinical findings on or in the eye itself.

Data was analyzed and confidence intervals calculated for each descriptive statistic utilizing the exact method (Fig. 1).

### 3. Results

Two hundred two (202) subjects were recruited overall (76 subjects recruited from MCPHS and 126 from MBKU). Subjects ranged in age from 16 to 72 years with average age of 32 years (SD 13.9) and a median age of 27.5 years. Age distribution, in more detail, was: 9% age 12–≤18, 63% 18–≤40, 11% 40–≤50, 16% ≥50. Gender distribution was 76 male, 126 female. Note that these demographics appear representative of contact lens users in the United States [19]. Spherical equivalent refractive errors ranged from +7.75D to −19.25D.

Fifty-two percent ( $n = 105$ ), of subjects were found to exhibit at least one or more health complication not previously diagnosed (95% CI: 0.45–0.59) in the areas of systemic health, ocular health, and/or contact lens driven ocular health complications. Of these 105 subjects with complications: 70% were diagnosed with contact lens driven ocular complications, 54% were diagnosed with non-contact lens driven ocular health issues; and 4% showed signs of not previously diagnosed systemic disease (Fig. 2).

Of note, 19% of subjects ( $n = 20$ ) with complications had them in multiple categories, and 21% ( $n = 22$ ) had more than one complication

in the same major category. Of the subjects who displayed contact lens driven complications, 34% were also found to present issues with either contact lens fit or compliance ( $n = 25$ ). Of all 202 recruited subjects, 22% ( $n = 44$ ) displayed contact lens fit issues and 23% ( $n = 47$ ) displayed contact lens care non-compliance. While contact lens fit issues and contact lens care non-compliance was not included in the analysis of overall complication prevalence, if these categories were included, the complication rate of asymptomatic contact lens wearers would increase to be 72% overall (41 additional subjects would be coded to have complications) (Fig. 3, Table 3).

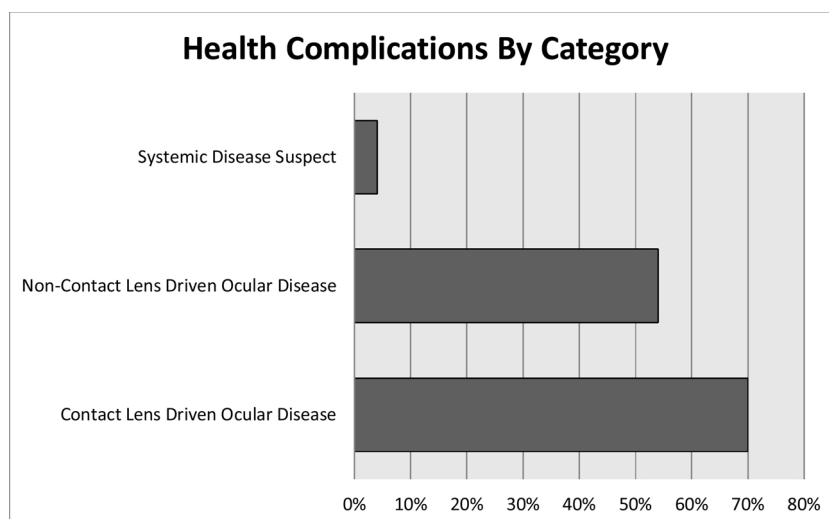
Binary Logistic Regression was employed to illuminate if contact lens wear replacement modality (daily disposable, 2 week planned replacement, or monthly replacement lenses), gender, or age, were predictive of whether a patient had diagnosed complications. These were all found not to be predictive:  $p$  values were all greater than 0.05 (age:  $P = 0.28$ ; contact lens wear replacement modality  $P = 0.74$ , and female gender  $P = 0.48$ ). Further, Odds Ratios (odds of having a complication in a group divided by the odds of having complications in another group) were calculated between replacement modalities and revealed no statistical significance: monthly compared to daily modality Odds Ratio 0.78 (95% CI: 0.42–1.45), 2 week compared to daily modality Odds Ratio 0.93 (95% CI: 0.41–2.10), 2 week compared to monthly modality Odds Ratio 1.23 (95% CI 0.51–2.75). Since the confidence interval of each statistic contains 1 in the interval, these odds are not statistically significantly different, therefore one modality does not have more odds of having complications than another (Table 2).

### 4. Discussion

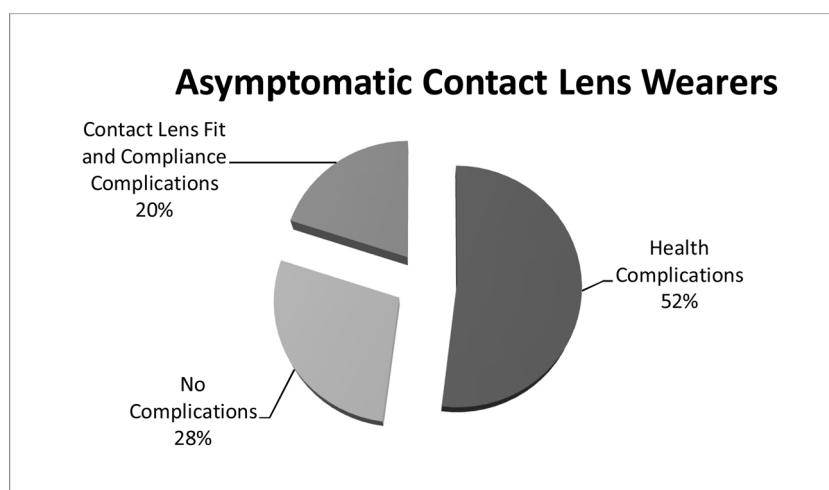
A striking ocular health and contact lens complication rate in asymptomatic soft contact lens wearers is demonstrated in this study. Although it may be hypothesized that daily disposable lenses might be associated with fewer complications due to lack of need for cleaning and storage, results of this study did not find that this modality was less predictive of complications overall. The data strongly supports that all soft contact lens wearers should be regularly professionally examined regardless of contact lens modality, age, or gender.

Within the category of ocular health complications diagnosed, 3.5% of subjects had new diagnoses of suspected glaucoma, and 16% were diagnosed with retinal and optic nerve diseases, all of which could directly lead to vision loss if not managed.

Within the category of contact lens driven complications, while all findings could conceivably eventually lead to problems, it could be reasoned that contact lens peripheral ulcers, corneal staining,



**Fig. 2.** Health complications by category. Percentage of subjects diagnosed with complications in each of 3 categories.



**Fig. 3.** Complications percentage with fit and compliance included in analysis. Overall percentage of asymptomatic soft contact lens wearers with complications is 72% if contact lens fit and care compliance complications are included in analysis.

**Table 2**

Complication count by replacement modality of contact lens replacement. By binary regression analysis, there was no statistically significant differences between the groups.

	2 Week	Monthly	Daily
No Complications	16	35	45
Complications	16	46	43
Total	32	81	88

Note: 1 subject with complications was not included in this data, as subject was unable to report modality of lens.

subepithelial infiltrates, and superior limbic keratoconjunctivitis in particular have increased possibility of sequelae leading to corneal scarring; therefore, the complications found in this particular category have direct potential for vision loss if left untreated. Additionally, although contact lens papillary conjunctivitis does not likely directly lead to vision loss, this disease can eventually result in substantial patient discomfort and tissue disruption: notably 18 of the asymptomatic subject patients were diagnosed with these complications.

While the overall complication rate was calculated using only clinically diagnosable health complications, it is important not to discount contact lens care non-compliance as an important public health issue. Lack of proper lens care has been documented in several studies across the contact lens literature as a correlative factor in many problems including increasing likelihood of infection [14,20–22]. As 23% of all asymptomatic soft contact lens wearers recruited to the study exhibited improper contact lens care, this research supports the importance of contact lens care re-education at comprehensive ophthalmic evaluations.

The results of this study results suggest that all contact lens wearers should be considered at risk for complications, and therefore should benefit from regular professional examination even if asymptomatic.

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**Table 3**

Frequency of disease noted in subjects who exhibited complications (105 subjects with complications, n = 202). Note, if a subject had multiple complications in the same category, or had complications across multiple categories, it was only analyzed as a single complication in calculation of overall complication rate.

Complication Category	Complication	Frequency
<b>Systemic Complications</b> Total Frequency = 6	Diabetes	3
	Hypertension	3
<b>Ocular Health Complications</b> Total Frequency = 67	Blepharitis	17
	Glaucoma	2
	Lens Disease	1
	Meibomian Gland Dysfunction	24
	Ocular Allergy	7
	Other Anterior Segment Disease <sup>a</sup>	7
	Retinal/Optic Nerve Disease	9
	Conjunctival Injection	17
	Contact Lens Papillary Conjunctivitis	16
	Contact Lens Peripheral Ulcer	4
	Corneal Edema	1
	Corneal Scar	2
	Corneal Staining	23
	Endothelial Polymegathism	1
<b>Contact Lens Driven Complications</b> Total Frequency = 86	Giant Papillary Conjunctivitis	2
	Limbal Injection	6
	Neovascularization	9
	Subepithelial Infiltrates	2
	Superior Limbic Keratoconjunctivitis	3
	Damage	1
	Optical Power Too Strong	15
	Optical Power Too Weak	27
	Too Steep	1
	Other	2
	Hand wash	5
	Case Care	2
	Over wear	5
	Extended Wear (Non-prescribed)	12
<b>Contact Lens Care Complications</b> Total Frequency = 69	> Recommended Replacement	28
	Solution Issue	6
	Soiled Lenses	4
	Other (lens removal, use of water)	7

<sup>a</sup> Other Anterior Segment Disease: iris nevi (2), conjunctival cyst (2), pinguecula (2), trichiasis.

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