Contact Lenses and Water Exposure: Current Practice Patterns and Perceptions

Thesis

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By

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Abstract

Water exposure to contact lenses is a well-established risk factor for the development of corneal inflammatory events, with microbial keratitis identified as the most visually devastating potential consequence. *Acanthamoeba* keratitis is one classification of microbial keratitis, and its development is associated with contact lens wear and water exposure. *Acanthamoeba* is a ubiquitous, free-living parasite that has been isolated in lakes, rivers, hospitals, tap water, and numerous other locations. The aim of this study is to learn more about current practice patterns and perceptions of risk among vision professionals and researchers, as well as patients currently wearing contact lenses made of gas permeable materials. The results of the study reveal that both professionals and patients engage in risky behaviors concerning water exposure to contact lenses, and patients consistently minimize the amount of risk associated with many of these behaviors. Continued education concerning the risks associated with contact lens wear and water exposure is necessary.

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Chapter 1. Introduction

In the United States, there are approximately 40.9 million contact lens wearers, with over 90% of those reporting strictly soft contact lens use [1]. Contact lens wear predisposes individuals to anterior segment complications that otherwise would not typically occur. Most of these complications are rather benign and do not have any known long term visual compromise or ocular morbidity associated with them. Other associated complications include pain, light sensitivity, and potential permanent visual impairment. These more significant complications are termed corneal infiltrative events (CIEs). Most CIEs are considered sterile, or aseptic, and are more of a temporary inconvenience for the patient. In rare instances they can be infectious, generically classified as microbial keratitis (MK), which can lead to profound visual loss. Contact lens associated CIEs, MK, and their associated risk factors will be discussed below.

Corneal Infiltrative Events

Non-infectious CIEs are a well-established risk associated with soft contact lens wear, and as mentioned above, are generally not a threat for permanent vision impairment. The incidence of these conditions ranges from 0.14% [2, 3] when looking at symptomatic events across all lens modalities, to 26% when including asymptomatic events and looking at extended soft lens wear [4, 5]. There exist numerous iterations of

classification systems to describe CIEs, but the one developed by Sweeney and colleagues in 2003 [6] is widely used across research settings. This method classifies CIEs as serious and symptomatic, clinically significant and symptomatic, and clinically non-significant and asymptomatic. The first classification contains microbial keratitis as the sole category. The clinically significant and symptomatic group contains the categories of contact lens-induced acute red eye (CLARE), contact lens peripheral ulcer (CLPU), and infiltrative keratitis. The final classification of clinically non-significant and asymptomatic contains both asymptomatic infiltrative keratitis and asymptomatic infiltrates [6].

Demographic and person-based factors, such as age, sex, and high refractive error, are considered non-modifiable factors which play a role in the risk of acquiring a CIE but will not be discussed in detail. Modifiable risk factors are those factors that an individual, the practitioner, or both can adjust to minimize the risk of developing a CIE or MK. Modifiable risk factors include overnight wear, a lack of handwashing [7], smoking [8, 9], the use of non-daily disposable lenses [10, 11], silicone hydrogel material, bacterial bioburden, lens storage case factors, multipurpose solutions, and lens exposure to water.

Smoking is an important factor in the development of CIEs or MK, but the use of water is generally not associated with this factor. Overnight wear, storage case hygiene, lens material, handwashing, bioburden, and lens care solutions can all be affected either directly or indirectly by water exposure and will be discussed in more depth.

The most significant risk factor for CIEs or MK has been extended wear or overnight use of contact lenses [3, 10-17]. When compared to daily lens wear, studies have reported an increased risk for CIEs between 1.6 to 7.0-fold with extended wear [10, 13, 15, 17]. Overnight wear naturally increases the likelihood that an individual will be wearing contact lenses while showering. A univariate analysis has found that showering while wearing lenses is a risk factor for CIEs [12].

Lens hygiene, storage, and disinfection are related to overall CIE risk. Disregarding standard cleaning practices like rubbing lenses prior to storage [18] or replacing disinfection solution within the case daily [12] are associated with contact-lens complications or the development of CIEs, respectively. These practices are very common, with studies reporting some form of non-compliance in 80-99% of contact lens wearers [1, 19]. Failure to ensure proper hygiene of the contact lens storage case is often found as a risk for developing MK. For two-week or monthly lens wearers, a contact lens case is commonly used. Frequent handling of the contact lenses and case itself can lead to microbial contamination, which has been found to occur in 23 to 81 percent of storage cases, with cases six months or older resulting in a nearly eight-fold increased CIE risk [11]. The most effective cleaning procedure for reducing lens case contamination involves rubbing and rinsing the case with disinfection solution, wiping the inside of the case with a tissue, and then leaving the case open to dry [20].

Microbial contamination can occur from commensal or non-commensal microbes. Commensal microbes isolated from the eyelids and conjunctiva often contaminate contact lenses [21, 22] and storage cases with significant bioburden estimated to be present in 40-

79 percent of contact lens wearers [21, 23, 24]. This contact lens bioburden is thought to contribute to the pathogenesis of CIEs [9, 11, 23, 25, 26]. More than half of worn contact lenses routinely harbor microorganisms, including potentially pathogenic strains [27] and the odds of developing a CIE can increase by 2.78 times for every one log increase in colony forming units/mL on the surface of the lens [28]. Contact lens storage cases are more frequently contaminated than either contact lenses or disinfection solutions [29], and the incidence of positive microbial bioburden in storage cases is often higher than 50 percent [26, 30]. Rinsing lens storage cases with water may increase the level of Gram (-) contamination, which elevates the potential for developing a CIE [22, 24].

The type of microbe isolated from the ocular surface, contact lens surface, and storage case has been found to be associated with how a CIE may manifest on the eye. For example, Gram (-) bacteria such as *Serratia marcescens*, *Pseudomonas aeruginosa,* and *Haemophilus influenzae* are associated with CLARE, while a variety of Gram (+) bacteria have been found to be associated with CLPU development [31, 32]. Both *Serratia* and *Pseudomonas* are ubiquitous water-borne microbes [33] which are commonly isolated from care products, as in the example of *Serratia* from lens storage cases [34]. Relatively recently, interest has surrounded the microorganisms *Achromobacter*, *Stenotrophomonas*, and *Delftia*, which also frequently contaminate contact lens storage cases [35, 36]. These species have been associated with a risk of contact lens-related disease, and both *Achromobacter* and *Stenotrophomonas* have demonstrated the ability to form biofilms on the lens surface of keratitis patients [35].

With bioburden being an ever-present threat, it is important to understand the contribution of the contact lens material and surface treatment to the overall risk of acquiring a CIE, with newer silicone hydrogel lenses consistently showing double the risk when compared to older poly HEMA-based hydrogel materials [10, 13, 17]. The higher risk of CIEs associated with the silicone hydrogel material may be related to bacterial adhesion properties and to the lower water content and hydrophobic properties of the material. Additionally, low Dk hydrogel lenses absorb significantly more non-denatured proteins, which retain antimicrobial activities, versus silicone hydrogel materials [37], which may facilitate the development of an antimicrobial surface that decreases the exposure of the ocular surface to bacteria and their byproducts.

Along with the material, the replacement schedule is another lens-related factor that contributes to overall CIE risk. The daily disposable modality negates the risks associated with storage case contamination and disinfection solution interaction, which is reflected in a greatly a reduced risk of CIEs with both silicone hydrogel and hydrogel daily disposable lenses [38]. In a retrospective multicenter study, when compared to daily disposable daily wear lenses, reusable daily wear lenses had a 12.5 times higher risk of a CIE [10]. The use of daily disposable lenses limits exposures to handling, water, the storage case, and commensal microbes.

Contact lens care solutions also play a role in CIE risk. While some studies have not demonstrated a relationship between CIE risk and solution type [10, 23], multiple reports in the literature have documented an increased risk of CIEs with the use of multipurpose solutions (MPS) when compared to hydrogen peroxide-based solutions [11,

13, 39-41]. Any observable association between disinfection solution and CIE development may stem from formulation and/or are secondary to residual contamination of the lens case, particularly with Gram negative (Gram (-)) microorganisms [42].

Microbial Keratitis

The most serious consequence of contact lens wear is MK. Microbial keratitis is a non-specific term that includes bacterial keratitis, fungal keratitis, and protozoan keratitis, which is also known as *Acanthamoeba* keratitis (AK). The incidence of MK varies regionally, with some reported rates published as 3.4 cases per 10,000 in Hong Kong [7], 1.8 per 10,000 wearers in Scotland [43], and in the Netherlands, 1.1 per 10,000 GP wearers, 3.5 per 10,000 daily wear individuals, and 20 per 10,000 soft extended wear individuals [44]. Microbial keratitis is generally associated with ocular pain and light sensitivity, and patients are at risk of developing corneal scarring, which depending on the severity can lead to profound visual impairment.

Studies have demonstrated that certain specific contact lens behaviors are associated with an increased risk of developing MK including poor contact lens case hygiene [7, 45], overnight wear [7, 46], lack of hand washing [46], storing contact lenses in tap water [47], use of multipurpose solution (MPS) [46], swimming while wearing lenses [48], and showering while wearing lenses [46]. Swimming while wearing contact lenses has been shown to lead to an increase in the amount of microbial isolates present on contact lenses, with some of the most prevalent species identified as *Staphylococcus epidermidis*, and *Staphylococcus aureus* [48]. The use of a contact lens storage case is associated with an increased level of risk of infection as microbial contaminants are

present in 81% of lens cases, and protozoa colonization specifically can be found in around 20% of cases [30].

Some studies have demonstrated that certain contact lens materials are associated with more preferential binding of microorganisms [49-51]. A rougher lens surface may contribute to amoebic adhesion, and the earlier generations of soft silicone hydrogel lenses have demonstrated a larger number of *Acanthamoeba* trophozoite adherence when compared to later generations [49, 50]. The water content may also be a contributory factor to amoebic adherence, as both *Acanthamoeba* trophozoites and cysts were present in higher numbers in high water content soft contact lenses when compared to low water content soft lenses and rigid gas permeable lenses *in vitro* [52]. In a different study, the rate of bacterial adhesion increased inversely to the water content of lenses, and it was suggested by the authors that hydrophobic lens surfaces may preferentially attract more bacteria than their hydrophilic counterparts [53]. Alternatively, other studies have demonstrated higher amounts of trophozoite adherence in PMMA and rigid gas permeable lenses compared to hydrogel materials [54], which may demonstrate how results can differ depending on study design.

The literature has also presented case reports [55] as well as comprehensive reviews of the association between overnight corneal reshaping gas permeable, or orthokeratology, lenses and MK [56-58]. The estimated incidence of MK in orthokeratology lenses is 7.7 per 10,000 years of wear [57] with no statistically significant difference found between children and adults. In a review of the first 50 documented cases of MK in orthokeratology lenses done by Watt and Swarbrick,

Pseudomonas was the predominant causal organism in 52% of cases, but *Acanthamoeba* was not far behind, representing 30% of cases [56]. The mechanisms for the increased risk in orthokeratology patients remain unclear, but theories presented in the literature include an increase in corneal susceptibility due to the compressive forces on the cornea exerted by the lens [55], a reduction in corneal defenses caused by central corneal epithelial thinning [56], or the higher rate of preferential binding of bacteria demonstrated in orthokeratology lenses when compared to alignment fit corneal gas permeable lenses [59].

Bacterial keratitis is the specific type of MK that occurs most often, affecting 4/10,000 daily wear individuals and approximately 20/10,000 EW individuals [45]. *Pseudomonas aeruginosa* and *Serratia marcescens* are the most commonly isolated pathogen in both contact lens and non-contact lens bacterial MK cases [44, 47]. Bacterial pathogens leading to MK can be isolated from contact lenses and their accessories but can also be found in the environment. In a study in Taiwan, Wang and colleagues found that 33% of faucets within hospital intensive care units (ICU) were contaminated with non-fermenting gram-negative bacteria (NFGNB), and they further demonstrated a correlation between the prevalence rate of NFGNB isolated from ICU patients and from ICU faucets [60]. A different study utilized a 5-plex real-time polymerase chain reaction (PCR) Nucleic Acid Diagnostics (NAD) assay to isolate bacterial species contained within a high purity water delivery system, the type of which may be used in healthcare facilities for hand-washing, bathing, and cleaning surface areas and medical devices. This

investigation revealed contamination of the system with *Stenotrophomonas maltophilia* and *Burkholderia* species, which are both opportunistic human pathogens [61].

Fungal keratitis is estimated to be associated with 5% of MK cases, which translates to 1/50,000 contact lens wearers [62]. In a study of surface waters in the United Kingdom, including rivers and lakes, and domestic water supplies, both types of water sources contained very diverse populations of filamentous fungi [63], so although this type of MK is not as prevalent within industrialized nations, the potential for infection is present in the environment. Though bacterial and fungal keratitis are extremely dangerous, the focus of this investigation was on the role of water with contact lens wear, therefore AK will be explored in more depth than the other two.

Basic Science of *Acanthamoeba*

Acanthamoeba is a microscopic, free-living amoeba. *Acanthamoeba* is a genus containing at least 24 different species of amoebic protozoa [64] and 16 different genotypes [65]. *Acanthamoeba castellani* and *Acanthamoeba polyphaga* are the most common species to cause AK [66], and the T4 genotype, *Acanthamoeba culbertsoni*, is the most common genotype isolated in human infection [65], and also has been identified in AK cases [64]. The life cycle of *Acanthamoeba* is characterized by a motile, feeding, and replicating trophozoite form, which is the most common form found in water, and 2 types of double-walled dormant cysts, both mature and immature [64]. They reproduce by asexual binary fission [66] and are thought to feed on keratocytes within the cornea during infection [66].

Acanthamoeba is ubiquitous and has been isolated in seawater, lakes, rivers, streams, tap water, bottled water, drinking fountains, eye wash stations, dental units, dialysis machines, and numerous other locations [64]. Microbiological studies have reported the presence of *Acanthamoeba* species in at least one site in 30-51% of households [67, 68], with detection more likely during the spring and summer months [67], in bathroom taps [68-70], from cold water taps [68], within older structures [69], and in buildings served by water tanks or cisterns [68-70]. *Acanthamoeba* has been isolated from toilet cistern tank biofilm, which demonstrates amoebic survival even when exposed to the chlorination level associated with water treatment systems [71].

Acanthamoeba Keratitis

Acanthamoeba keratitis is a severe condition often associated with a poor visual outcome and with exposure to water [72, 73] (Figure 1). National incidence rates of AK in contact lens wearers vary widely by region and are difficult to determine due to the rareness of the condition. In the United States, the incidence of AK is estimated to be between 1.65 to 2.01 per million, while in the UK it is substantially higher at 17.53 to 21.14 per million. The estimation in Australia is around 4.2 per 10,000, and the rate in Scotland is 1.49 per 10,000 [43, 45, 66, 74].

The first 2 AK cases in US were presented in the literature in 1975, and were associated with trauma followed by water exposure, and with herpes simplex keratitis [75]. Currently, around 80-100% of AK cases are associated with contact lens wear [66, 76-82], while other cases in the United States and the United Kingdom follow trauma,

exposure to contaminated water or soil, the use of tank-fed water in the home, poor socioeconomic conditions, and surgery [66]. In more underdeveloped areas of the world, like India, corneal injury and trauma are the most common predisposing factors for the development of AK [83, 84]. The development of AK is more strongly related to poor lens hygiene [77, 85], such as the use of homemade saline solution [86], topping off of solution [58], the use of chlorine release disinfection systems [85, 87], and water contamination and exposure [58, 77] versus extended wear practices as is seen in bacterial keratitis [66, 74].

Water contamination can take a number of different forms as it pertains to AK risk. AK cases are more likely to have experienced direct exposure to water by rinsing their contact lenses and/or lens cases in tap water [82, 88] or storing their lenses in water [58], and although Cope et al did not find rinsing lenses with tap water to be statistically significant (odds ratio=2.04, p=0.1984), AK cases were two times more likely to report rinsing their lenses with water [58]. It is an unfortunate fact that the majority of GP disinfection systems recommend tap water exposure. In an investigation of the current manufacturer recommendations, Legarreta and colleagues found that although none of the current soft lens or combined soft/GP lens solutions include directions to rinse either the lens or lens case with tap water, 83% of the GP lens cleaners and solutions recommend the use of nonsterile water to rinse lenses and/or lens cases [89]. The authors addressed the issue that this can lead to confusion among patients about best lens hygiene practices. The United States Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) recommend that consumers avoid all lens

exposure to any form of water, yet within the same paragraph also advise consumers to follow the instructions on the product label [90, 91].

AK cases are also more likely to have access to municipal water over well water at their residence [58], and Radford and colleagues found that exposure to hard water is associated with a three-fold increase in the risk of developing AK when compared to soft water [74]. Domestic water supply is a contamination route for contact lenses and is particularly related to the presence of Gram (-) bacteria [22]. One study found that the homes of over half of AK cases tested had *Acanthamoeba* isolated from the home water system [77]. *Acanthamoeba* is often present in contact lens storage cases [34], with a higher incidence among soft contact lens cases versus GP cases [88]. Swimming has also been cited as a commonly reported behavior among AK cases [76, 86].

Diagnosis rates are higher during warmer months [76, 78, 82, 92], and the literature suggests that these seasonal peaks may be related to a bimodal rise in the concentration of pathogens in surface water [92]. Bacterial coinfection is common in AK cases [81] and the presence of co-contaminating bacteria can result in a 1.5 time growth enhancement of *Acanthamoeba* [93]. The presence of bacteria may directly support the growth of *Acanthamoeba* and/or may lead to small corneal breaks as a result of toxin accumulation, which allows corneal entry by *Acanthamoeba*. Finally, there is some suggestion that there may be a immunologic predisposition to the development of AK, as AK cases show lower levels of anti-*Acanthamoeba* IgA antibodies in their tears [94].

The literature contains a number of publications that present AK case reports and cite some of the mechanisms for development of the disease including rinsing GP lenses

with tap water [89], moistening soft contact lenses with tap water [95], and swimming while wearing contact lenses [96, 97].

Figure 1: *Acanthamoeba* Keratitis Image

*Image courtesy of Dr. Rebecca Kuennen

Contact Lens Solutions Standards

Current guidance documents for soft contact lens solutions do not include *Acanthamoeba* as a challenge organism [98] due to a lack of agreed upon testing methods, the absence of validated methods for quantifying viable cysts or trophozoites, and the low prevalence of the condition [64]. The International Organization for Standardization (ISO) 14729 describes the required protocol to achieve labeling as a contact lens disinfecting product. Products must demonstrate a 3 log reduction of bacteria

and a 1 log reduction of molds and yeast in order to pass the stand alone portion of the requirements [98]. The five current challenge microorganisms include the (Gram (-) bacteria *Pseudomonas aeruginosa* and *Serratia marcescens,* the(Gram (+) bacteria *Staphylococcus aureus*, the yeast, *Candida albicans*, and the mold, *Fusarium solani* [98, 99]. Additionally, the antimicrobial preservative efficacy test evaluates the ability of a cleaning system to prevent contamination of the product for 30 days. This procedure involves a rechallenge after two weeks with *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Escherichia coli*, *Candida albicans*, and *Aspergillus niger* [99].

In a 2008 FDA ophthalmic devices panel, the exclusion of *Acanthamoeba* as a challenge organism was one of many hygiene related topics discussed [99]. Along with recommendations concerning written warnings discouraging topping off of disinfection solution, clear package instructions for rubbing and rinsing of lenses, and implementing more real-world testing of disinfection products, the expert panel also supported the inclusion of *Acanthamoeba* as a challenge organism [99]. A 2015 co-sponsored workshop that included the FDA, the American Academy of Ophthalmology, the American Academy of Optometry, the American Optometric Association, and the Contact Lens Association of Ophthalmologists revisited some of the same issues discussed during the aforementioned FDA panel concerning microbiological testing methods for contact lenses, products, and accessories [100]. The panel agreed that both *Acanthamoeba castellani* and *Acanthamoeba polyphaga* should be added to the existing challenge organisms, but addressed the lack of a standardized protocol for testing and interpreting results as a current hurdle. Additionally, the experts strongly agreed that lens care product

manufacturers should prioritize developing appropriate alternatives to rinsing GP lenses with tap water [100].

When the topic of disinfection efficacy against *Acanthamoeba* arises, one of the recurring issues is the difficulty in developing agreed upon methodologies with which to isolate, grow, and identify viable *Acanthamoeba* isolates. Many researchers have discussed this issue when carrying out experiments involving *Acanthamoeba* strains. Some studies utilize a polymerase chain reaction (PCR) amplification method which is suggested to be potentially more sensitive than plate culturing [69], while others cite a most probable number (MPN) enumeration technique as a simple, reproducible, and reliable technique for counting organism density [101]. In a very recent publication, Fedorko et al described a repeatable protocol that was specifically developed to test MPS efficacy against different species of *Acanthamoeba* [102]. This method was demonstrated to be repeatable when carried out multiple times and at multiple laboratory locations, therefore widespread adherence to this protocol may address some of the controversy regarding the lack of a standardized procedure for testing solution efficacy against *Acanthamoeba*.

Contact Lenses and Water Exposure

A study by the Contact Lens Assessment in Youth (CLAY) study group and the CDC was interested in the behaviors, knowledge, and perceptions of contact lens wearers as it relates to contact lens exposure to water [103]. The study group used the previously validated Contact Lens Risk Survey (CLRS) [12, 103] to gather information from a

national sample of contact lens wearers about their contact lens hygiene practices, exposure of lenses to water, and perceptions toward contact lens wear and care behaviors, among other things. 91% of gas permeable contact lens wearers reported rinsing their lenses (more often than never) with tap water, compared with 31% of soft contact lens wearers. Storing lenses in tap water was reported by 33% of gas permeable lens wearers versus 15% of soft lens wearers. Soft contact lens wearers perceived a higher level of risk of developing an eye infection when rinsing lenses with tap or distilled water compared to GP lens wearers. Additionally, GP wearers who ever rinsed with or stored lenses in tap water reported a lower perceived risk of infection regarding the aforementioned behaviors when compared to those that did not report such behaviors [103]. The results from this paper influenced the study described within this thesis.

Cope et al found similar water rinsing trends as the previously mentioned study, and additionally reported that almost all (99%) of contact lens wearers surveyed reported at least one contact lens hygiene risk behavior, including showering and swimming in lenses and rinsing or storing lenses in tap water [1]. Young adults are more likely to store or rinse their contact lenses with tap water when compared to an older population [19].

Outbreaks of *Acanthamoeba* Keratitis

The first documented outbreak of *Acanthamoeba* keratitis occurred in the US and UK during the mid 1980s to early ‘90s. This outbreak was associated with daily wear soft contact lens use, homemade saline solutions, chlorine release disinfection, and poor

overall lens hygiene [64, 76, 80, 104] and coincided with the introduction of disposable daily wear lenses.

The second major outbreak of AK began around 2003. AK is not a reportable condition, but due to concern raised by the University of Illinois at Chicago Cornea Service of a gradual increase in AK cases, the CDC reached out to ophthalmology centers and laboratories around the country to obtain case numbers and diagnosis methods for potential AK cases [105, 106]. The investigation found that there had been a marked increase in the number of AK cases from 2004 to 2007, which was determined to be associated with Complete Moisture Plus (CMP; Advanced Medical Optics at the time, now Johnson & Johnson) multipurpose solution [107, 108] with an OR of 16.9 [108], and with 52.8% of cases reporting exclusive use of that specific solution [109]. The investigation into the outbreak also determined that AK cases were more likely to report topping off of solution and showering while wearing their lenses [108, 109].

A cohort study in Chicago of cases from 2003-2005 reported a seven times higher risk of AK in the time studied versus historical data, and also reported that 95% of AK cases were contact lens wearers [106]. Additionally, the risk of disease varied by geographical location, and upon further investigation, the authors suggested that this finding may have been related to the distance between cases and water treatment facilities [106]. Specifically, in light of recent changes to EPA guidelines regarding the reduction in disinfection by-products, disinfection products themselves were required to be reduced within the domestic water supply [106]. The CDC's investigation into the outbreak determined that there was a lack of intrinsic contamination of the indicated solution,

therefore the association was attributed to the disinfection properties of the solution [107]. In vitro testing revealed rapid development and aggregation of mature cysts within CMP and encapsulation of cysts by dried residues [110]. The dried films are deficient in anti-amoeba properties, and the literature shows that the dried propylene glycol derivatives complexed with hemicellulose in CMP may harbor cysts and precysts for long periods of time [110].

A similar outbreak of *Fusarium solani*-associated keratitis (FK) occurred in contact lens wearers from 2004-2008. Similar to the AK outbreak, the rise in cases was associated with a specific contact lens disinfection solution, ReNu with MoistureLoc (Bausch + Lomb, Rochester, NY). As with the AK outbreak, *Fusarium* was not recovered from the factory, warehouses, solution filtrate, or unopened solutions bottles [111]. It was demonstrated that when exposed to elevated temperatures, ReNu with MoistureLoc lost more *in vitro* fungistatic activity than the other solutions tested [112]. Additionally, univariate analysis showed that reusing the solution in the contact lens case was associated with a higher risk of FK [111]. Following the removal of the offending product, FK levels dropped back to pre-outbreak levels [111]. In contrast to this, following the global recall of Complete Moisture Plus, AK levels have remained at pre-outbreak levels with a new baseline level which is around 10 times higher than prior to 2004 [105, 113]. An ophthalmology clinic located at a major referral hospital in Iowa investigated the potential relationship between an increase in the number of AK cases and previous regional flooding [114]. Their investigation found that both contact lens wear and fishing were independent risk factors for AK in their patient population.

Additionally, they reported that the incidence of AK was 10 times higher in the counties containing water facilities affected by the flood versus counties without [114].

Intent of Study

The intent of this study was to learn more about the disinfection protocols currently utilized by both practitioners and gas permeable lens wearers, with particular attention paid to the role of water in lens cleaning and care. Additionally, another goal of the study was to explore what level of risk both practitioners and patients associated with certain lens-related scenarios.

Methods

The study protocol was approved by the Institutional Review Board at The Ohio State University and was carried out in accordance with the tenets of the Declaration of Helsinki. This study was a survey-based observational dichotomous study with one arm designed to survey patients and the other arm designed to survey a population of practitioners, researchers, and industry personnel.

Professional Arm

The professional arm consisted of clinicians, researchers, and industry personnel that were recruited by partnering with various institutional and professional organizations. Professional participants were contacted about the survey if they were indexed on the email listservs of The Ohio State University College of Optometry alumni (n=2,130), The American Academy of Optometry Section on Cornea, Contact Lens, and Refractive Technologies (n=1,808), The American Optometric Association (n=2,269), the Optometristen Vereniging Nederland (the Optometric Association of the Netherlands) newsletter (n=1,000), and an international ophthalmology group. The survey also permitted “snowball sampling”, which allowed for potential participants who were part of the aforementioned listservs to forward the link to colleagues who were not. Aside from survey link access, there were no additional exclusion criteria for the practitioner and researcher population. Many potential participants are involved in multiple organizations, therefore the same individual may have received a link to the survey more than once. The link to the survey was presented along with a small description of the nature of the

survey, which instructed potential participants not to participate if they had already answered the survey previously. If an individual chose to participate in the survey by clicking the link, they were directed to a web page with a statement of consent, followed by the survey.

The survey was a branched logic survey that asked the professionals questions regarding current practice patterns and perceptions regarding contact lens wear and water exposure. For contact lens water exposure, the professionals were asked if they rinse GP lenses in office, rinse lenses in front of patients, and whether or not they advise patients to avoid rinsing lenses with water, showering while wearing lenses, and swimming while wearing lenses.

Other practice pattern questions included the type of contact lenses the individual typically fits, the type of care solutions they recommend for lens care, and whether they recommend a rinsing product other than water for formulations that require a rinsing step. For lens care, the participants were asked to rank hydrogen peroxide-based, 1 step, 2 step, and other solutions they typically recommend for a specific lens, with 1 being the most likely, and 4 being the least likely. Questions about GP lenses/accessories and water exposure were also administered, such as rinsing GP lenses with tap water, rinsing a patient's lenses with tap water, and rinsing a storage case with water. Another question explored whether practitioners and researchers recommended a specific replacement interval for the contact lens storage case. The response options included "*every 1-3 months*", "*every 4-6 months*", "*every 7-12 months*", "*less frequently than annually*", and "*it is not necessary to replace contact lens cases*". The professionals were also presented

with a hypothetical scenario of what type of vision correction would be most appropriate for a moderately myopic patient who regularly swims.

Perception questions surveyed the level of perceived risk of infection associated with rinsing lenses with tap water, rinsing lenses with distilled water, rinsing the storage case with water, swimming while wearing contact lenses, and showering while wearing contact lenses. For the perception questions, available responses for assigning a level of risk included *increases risk of infection*, *no effect on risk of infection*, or *decreases risk of infection*. The professionals were also asked if they felt that current GP lens solutions that included a water rinsing step should either "*stay on the market as is", "be pulled from the market", or "instructions should be modified".* Additional questions such as occupation, professional organization affiliation, and year of graduation were asked.

After the initial distribution of the survey, the investigators were made aware of some international interest in participating, therefore a few questions were edited and added in order to make the survey more representative of the participant population. One additional question asked for the participant's location of residence in order to explore potential geographical differences in practice patterns and risk perception. Another added question asked the participant to select one or multiple descriptions of their profession. The options included optometrist, ophthalmologist, researcher, industry, and contact lens specialist.

The practitioner and researcher participant survey questions are included in Appendix A.

Patient Arm

The patient arm consisted of 17 current gas permeable lens wearing individuals who were recruited from The Ohio State University College of Optometry contact lens clinic. This population was recruited when they presented to the clinic for a scheduled appointment. The co-investigator (KS) reviewed the daily patient schedule and informed the appropriate clinicians that recruitment may be attempted. If the patient did not meet the study exclusion criterion, which included being a current GP wearing patient that was entering the clinic for an exam (not a follow-up), if they had not worn their lenses within one week of their visit, if they were a student or staff member at the College of Optometry, or if they were under the age of 18, they were eligible to be enrolled. Participants were required to be able to read English in order to complete the survey.

Upon agreement to participate, the individual was assigned a participant number and presented with the informed consent documentation. The co-investigator went over the informed consent and answered any questions pertaining to the study prior to proceeding. Once the individual agreed to participate, they were given an iPad (Apple Inc, Cupertino, CA) on which to take the electronic survey. The participants also had access to a two-page document with color photographs of many different contact lens disinfection solution brands in order to better assist them when answering one of the survey questions.

The survey was a web-based, branched logic survey that asked questions regarding lens type, current contact lens hygiene, lens care products, rinsing behaviors, lens storage in water, and the source of water at their residence. Participants were also

questioned regarding their perceived level of risk associated with specific behaviors related to water and contact lenses such as rinsing GP lenses with tap or distilled water, swimming while wearing lenses, and showering while wearing lenses. Some of the questions included in the survey were very similar to those used in a collaborative effort with the CLAY study group and the CDC [103]. Approval from both entities was obtained before the survey was administered.

Any patient participant that responded that they rinsed lenses with tap water was asked about their reasoning for that behavior. Options included "*my doctor instructed me to do so", "the package insert instructed me to do so", "convenience", "I was unaware of other options", "cost",* or *"other"*. The patient participants were also asked whether their eye care practitioner ever discussed with them rinsing lenses with tap water with response options including "*yes", "no",* and *"unsure"*.

The patient cohort was asked how they wash their hands and how frequently they wash their hands prior to applying contact lenses on the eye. Options for hand washing included "*with soap and water", "only water", "cleansing wipe,"* or *"hand sanitizer/gel."* They were then asked how they dry their hands prior to applying contact lenses. Options included "*I do not dry my hands"*, "*drip dry/air dry", "wipe hands on clothing", "paper towel",* and "*cloth towel"*.

For the perception questions, available responses were the same as for the professionals. At the conclusion of the survey, participants were presented with educational information regarding water exposure to contact lenses, which was presented on the screen.

The patient participant survey questions are included in Appendix B.

Analysis

Descriptive statistics and chi-square analyses were done through the Qualtrics (Qualtrics, Provo, UT) system. Chi-square analysis and logistic regressions were performed using SPSS (SPSS Inc, Chicago, IL) software. For perceptions, chi-square analyses were performed within groups and between groups (i.e. professionals vs. patients) and professional perceptions were also compared to the published perceptions from a larger sample of GP wearers [103].

Results

Professional Survey

The survey link was sent out 7207 times (some individuals may have been on multiple listservs), and 317 individuals (4.4%) initiated the survey. Of the 317 that began the survey, 294 responded to at least one question. The majority of the participants (94.9%) responded that they fit contact lenses of any type, and 89.6% of those 279 participants fit both hard and soft contact lenses, 9% fit only soft contact lenses, and 0.72% fit only hard contact lenses. Table 1 represents the specific types of lenses fit.

Table 1: Lens Type

Lens Type	**Participants Fitting Lens Type, n (%)**
Corneal	241 (97.6%)
Scleral	140 (56.7%)
Hybrid	129 (52.2%)
Orthokeratology	112 (45.3%)

Of the participants who reported fitting specialty lenses of any type, the frequency of this type of fitting varied. 67.4% of participants reported specialty lens encounters at least once per week and 32.5% reported less than one specialty contact lens patient encounter per week. The participants were surveyed on a number of in-office behaviors and patient education topics. The results from these questions are reflected in Table 2.

Table 2: Practitioner and Researcher Behaviors

Behavior	Yes, n (%)	No, n (%)	Total, n
Rinse GP lenses in water	147 (60.5%)	96 (39.5%)	243
Rinse lenses in front of patients	81 (33.6%)	160 (66.4%)	241
Advise avoidance of water on lenses	149 (63.1%)	87 (36.9%)	236
Recommend rinsing product	157 (70%)	67 (30%)	224
Advise avoidance of water in case	110 (45.3%)	133 (54.7%)	243
Advise case replacement	203 (83.9%)	39 (16.1%)	242
Advise refraining from lens wear when showering	121 (50.2%)	120 (49.8%)	241
Advise refraining from lens wear when swimming	219 (90.9%)	22 (9.1%)	241

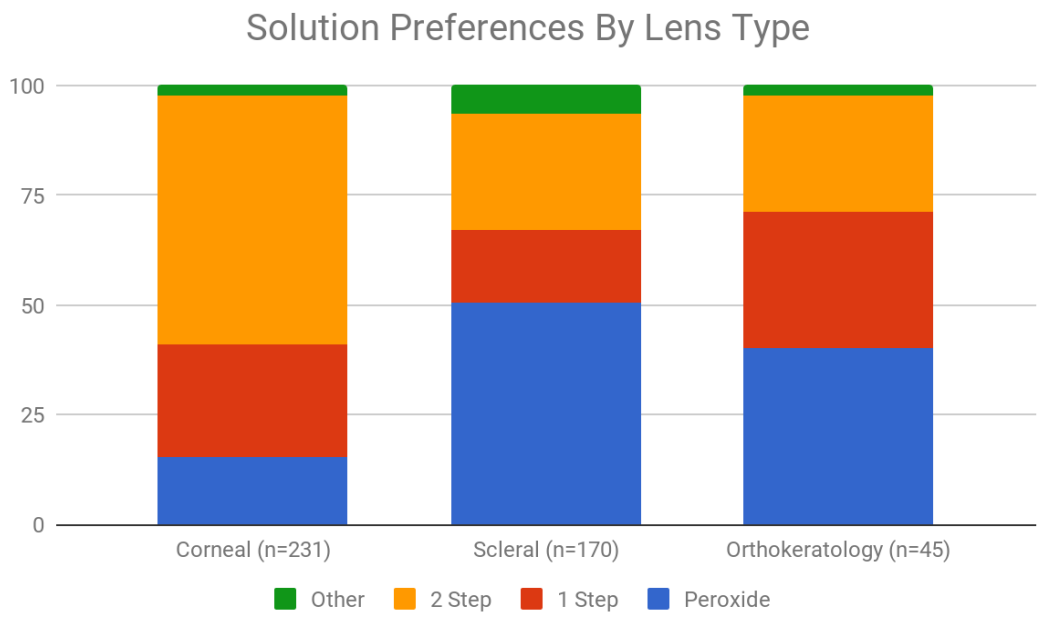
Using Chi-square analysis, a significant relationship ($p<0.0001$) was present between those participants who ever rinsed lenses with water and those who rinsed lenses with water specifically in front of patients, as those who did not report rinsing lenses themselves also did not engage in this behavior in front of patients. For those respondents who reported rinsing lenses in front of patients, a follow up question asked which lens types they rinsed in front of patients. Of those who fit corneal lenses, 37% rinse them in front of patients, while 27.1% of scleral fitters, 25% of hybrid fitters, and 1.6% of orthokeratology fitters report the same behavior. Chi-square analysis also revealed a significant relationship ($p<0.0001$) between respondents who ever rinsed lenses with water and those who advised their patients to avoid water exposure to contact lenses.

Participants who reported never rinsing lenses with water were more likely to advise their patients to do the same. Further analysis with logistic regression demonstrated that this relationship remained significant ($p<0.0001$) when tested along with the reported year the participant began participating in vision care and/or vision research.

Respondents who indicated that they actively recommended a specific timeframe for contact lens case replacement were asked to select the response that included their typical recommendation. Of those that recommended a case replacement schedule, 162 (80.2%) recommended every 1-3 months while 35 (17.3%) and 5 (2.5%) chose every 4-6 months and every 7-12 months, respectively. No practitioner selected the remaining options.

If participants reported that they fit corneal, scleral, and/or orthokeratology lenses, they were asked about their preferred disinfection regimen for each type of lens. If the participant ranked "other" as their number one choice for a particular lens design, they were then prompted to free type their solution of choice. Among the few participants who answered the questions this way, almost all of the typed options were solutions that would fall under the 3 other categories. The results from this question are presented in Figure 2.

Figure 2: Practitioner and Researcher Solution Preference by Lens Type



One question presented the hypothetical situation of a moderately myopic patient who swims regularly. The participants were questioned regarding their clinical recommendation for vision correction. Daily disposable lenses were selected by 179 participants (74.3%), 21 recommended orthokeratology lenses (8.7%), 30 recommended refraining from contact lens wear when swimming (12.9%), 8 recommended no change to the patient's regular contact lens modality aside from avoiding overnight wear of lenses (3.3%), and 3 participants recommended either a 2-week or monthly disposable contact lens (1.2%). Of the participants who recommended some form of contact lens wear while swimming, 174 (91.6%) recommended the concomitant use of goggles, while 16 (8.4%) did not.

The next set of questions explored perceptions of risk associated with certain contact lens behaviors. The response options for the behavior questions included “this behavior increases the risk of infection”, “this behavior has no effect on the risk of infection”, and “this behavior decreases the risk of infection”. The first question was “what is your perception of rinsing gas permeable lenses with tap water as it relates to eye infection?” The second question was identical, aside from the substitution of distilled water for tap water. The next two questions asked about perceptions regarding contact lens wear while swimming and showering, and the final perception question surveyed the participants about their opinions concerning rinsing contact lens cases with water. In Table 3, the results from these questions is further divided into the group that reported ever rinsing a patient’s, lab supplied, or diagnostic contact lens with water and the group that did not report this behavior. These separate groups will be referred to as “rinsers” and “non-rinsers” going forward.

Table 3: Practitioner and Researcher Perceptions of Risk

Behavior	**Rinsers, n (%)**	**Non-Rinsers, n (%)**	**p**
Rinsing GP lenses with tap* water			**<0.0001**
Decreases the risk of infection	0 (0%)	3 (3.6%)	
No effect on risk of infection	66 (48.9%)	10 (12%)	
Increases the risk of infection	69 (51.1%)	70 (84.3%)	
Rinsing GP lenses with distilled* water			**<0.0001**
Decreases the risk of infection	6 (4.4%)	7 (8.4%)	
No effect on risk of infection	85 (63%)	28 (33.7%)	
Increases the risk of infection	44 (32.6%)	48 (57.8%)	
Showering while wearing contact lenses			0.176
Decreases the risk of infection	0 (0%)	1 (1.2%)	
No effect on the risk of infection	54 (40%)	25 (30.1%)	
Increases the risk of infection	81 (60%)	57 (68.7%)	
Swimming while wearing contact lenses			0.339
Decreases the risk of infection	0 (0%)	1 (1.2%)	
No effect on the risk of infection	8 (5.9%)	3 (3.7%)	
Increases the risk of infection	127 (94.1%)	78 (95.1%)	
Rinsing contact lens case with water			**0.044**
Decreases the risk of infection	9 (6.7%)	5 (6.1%)	
No effect on the risk of infection	57 (42.2%)	21 (25.6%)	
Increases the risk of infection	69 (51.1%)	56 (68.3%)	

Chi-square analysis was utilized to look for a significant relationship between rinsing lenses with water and the perceived risk associated with contact lens hygiene practices and behaviors. There were significant relationships between lens rinsing behavior and the reported perceptions regarding rinsing with tap water ($p<0.0001$), rinsing with distilled water ($p<0.0001$), and rinsing the lens case with water ($p=0.044$). Due to the fact that there were so few respondents that chose the response option "decreases the risk of infection" for all three perceptions, the Chi-square analyses were run a second time excluding those small cells, and the relationship between lens rinsing and perceptions remained significant for tap water rinse ($p<0.0001$), distilled water rinse ($p<0.0001$), and lens case water rinse ($p=0.011$).

To further explore these relationships and confirm true significance, logistic regression was performed comparing the behavior of rinsing lenses with water to the aforementioned perceptions. When comparing rinsing behavior to all three perceptions, only tap water rinse remained significant ($p=0.001$), while both distilled water rinse ($p=0.660$) and lens case water rinse ($p=0.372$) were no longer significant. When isolating two perceptions at a time, tap water rinse remained significant when comparing only to distilled water rinse and only to lens case water rinse ($p=0.001$, $p<0.0001$, respectively). Distilled water rinse showed significance ($p=0.021$) in the logistic regression model when compared only to lens case water rinse. As presented in Table 3, neither the perception of swimming or showering with lenses showed a significant relationship to the behavior of rinsing lenses with water.

The next question was concerned with the current disinfection products on the market that require a rinsing step and asked the participants about the most appropriate action. The response options included “the current solutions should remain on the market as is”, “the solution manufacturers should consider modifying the product instructions regarding the rinsing step”, and “the FDA should pull the current solutions from the market so that the safety of the rinsing step can be reevaluated”. The results from this question are presented in Table 4, and the respondents are further divided into rinsers and non-rinsers.

Table 4: Practitioner and Researcher GP Solution Recommendations

GP Solution Recommendation	**Rinsers, n (%)**	**Non-rinsers, n (%)**	**Total, n**
Remain on the market as is	51 (38.1%)	13 (16.3%)	64
Modification of product instructions	80 (59.7%)	66 (82.5%)	146
FDA should pull solutions from the market	3 (2.2%)	1 (1.3%)	4

The non-rinsing group was more likely to recommend modifying the product instructions compared to those in the rinsing group ($p=0.002$) when using Chi-square analysis.

Participants were asked for how long they have been involved in vision care and/or vision research. The respondents were divided into 10-year groupings, apart from

the participants who reported the longest period of activity, who were combined into a 20 year group as there were so few of them. Again, participants were further divided based on whether or not they rinsed contact lenses with water, and this information is presented in Table 5.

Table 5: Initial Practice Year vs. Rinsing Behavior

Began to Practice (Year)	Rinsers, n (%)	Non-rinsers, n (%)	Total, n
1950-1969	4 (57%)	3 (43%)	7
1970-1979	16 (80%)	4 (20%)	20
1980-1989	37 (71.2%)	15 (28.8%)	52
1990-1999	29 (60%)	19 (40%)	48
2000-2009	33 (62%)	20 (38%)	53
2010+	14 (42%)	19 (58%)	33

Chi-square analysis was performed to look for a relationship between the first year of practice and lens rinsing behavior, but there was no significant association ($p=.097$). The group that reported the longest amount of activity was also the smallest, and once they were removed and the analysis was performed again, the relationship approached significance ($p=.056$), but still did not meet the requirements. Simply looking at the percentage of each group that reported rinsing and not rinsing, it appears as though

there is a trend that the newer generation is less likely to engage in lens rinsing with water, but this trend was not explored with a statistical model.

An additional analysis was performed to search for a relationship between start year and the behavior of advising patients to avoid rinsing their lenses with water. This data is presented in Table 6.

Table 6: Initial Practice Year vs. Rinsing Advice

Began to Practice (Year)	Advise to Avoid Water Rinse, n (%)	Do Not Advise to Avoid Water Rinse, n (%)	Total, n
1950-1969	4 (66.7)	2 (33.3)	6
1970-1979	11 (55)	9 (45)	20
1980-1989	23 (44.2)	29 (55.7)	52
1990-1999	30 (62.5)	18 (37.5)	48
2000-2009	37 (71.2)	15 (28.8)	52
2010+	23 (71.9)	9 (28.1)	32

Chi-square analysis revealed no significant relationship ($p=0.064$) between participants who advise their patients to avoid exposing their contact lenses to water and the year participants began providing vision care and/or taking part in vision research. The analysis was run a second time, excluding the smallest group, and a significant relationship ($p=0.035$) was present. When logistic regression was carried out comparing the behavior of advising patients to avoid water to both the behavior of rinsing lenses

with water and the starting year of vision care and/or research activity, this relationship was no longer significant (p=0.262).

The responses from the previous solution preference by lens type question were divided by year of initiating practice and the three smallest groups were combined. Corneal and scleral lens solution recommendations are presented in Tables 7 and 8.

Table 7: Corneal Lens Solution Recommendation by Initial Practice Year

Began to Practice (Year)	Peroxide, n (%)	1 Step System, n (%)	2 Step System, n (%)
1950-1979	5 (18.5)	5 (18.5)	17 (63)
1980-1989	4 (7.7)	8 (15.4)	38 (73)
1990-1999	3 (6.4)	12 (25.5)	31 (66)
2000-2009	10 (19.2)	16 (31.1)	25 (49)
2010+	11 (34)	12 (37.5)	8 (25)

Table 8: Scleral Lens Solution Recommendation by Initial Practice Year

Began to Practice (Year)	Peroxide, n (%)	1 Step System, n (%)	2 Step System, n (%)
1950-1979	8 (33)	6 (18.2)	4 (12.5)
1980-1989	19 (54.3)	2 (5.7)	9 (25.7)
1990-1999	14 (46.7)	5 (16.7)	11 (36.7)
2000-2009	24 (60)	8 (17.5)	9 (22.5)
2010+	14 (51.9)	7 (26)	5 (18.5)

In the second version of the survey, one of the additional questions surveyed the participants about their country of residence. The majority of respondents (87.3%) who answered this question were from the United States, but 11.8% were from the Netherlands, and .9% were from Canada. The final question asked about organizational affiliation. The participants were instructed to select as many groups as applied to them, and the options included the American Optometric Association (AOA) Contact Lens and Cornea Section, Diplomates of the Cornea, Contact Lens, and Refractive Technology (CCLRT) Section of the American Academy of Optometry (AAO), AAO Fellow and/or Diplomate of a Section other than CCLRT, The British Contact Lens Association, "others", and none. The responses are displayed in Table 9 and are divided into rinsers and non-rinsers. This chart does not reflect only mutually exclusive participation in an organization. The organizations were tallied any time they appeared as a response, including when a participant selected more than one organization.

Table 9: Organization Affiliation vs. Rinsing Behavior

Organization	**Rinsers, n (%)**	**Non-rinsers, n (%)**	**Total, n**
Diplomate CCLRT	24 (14.3)	7 (7)	31
FAAO and/or Diplomate of other section	47 (28.1)	36 (36)	83
AOA Contact Lens & Cornea	49 (29.3)	32 (32)	81
Others	6 (3.6)	5 (5)	11
None	41 (24.6)	20 (20)	61

Patient Survey

17 participants began and completed the patient survey; 10 (58.8%) were female and 7 (41.2%) were male. There was one participant between the ages of 18-20, one between ages 21-30, two between ages 31-40, 2 between ages 41-50, 7 between ages 51-60, 3 between ages 61-70, and 1 between ages 71-80. Eleven participants wore corneal GP lenses, five wore scleral lenses, and one wore hybrid lenses. Following these few demographic questions, participants were asked about their hand washing methods prior to handling their lenses. When asked about the method utilized to wash their hands, all respondents selected “with soap and water”. The options “only water”, “cleansing wipe”, or “hand sanitizing gel/foam” were not selected. Participants were also asked how often they wash their hands prior to handling their lenses, and also which method they use to dry their hands whenever they do wash them. These results are presented in Table 10.

Table 10: Patient Hand Hygiene Behavior

Frequency (column) and methods for drying (row) hands	**I do not dry my hands**	**Drip dry/air dry**	**I wipe my hands on my clothing**	**Paper towel or facial tissue**	**Cloth towel**
Always	2 (11.8)	0	0	4 (23.5)	3 (17.6)
Most of the time	0	1 (5.9)	0	0	6 (35.3)
Some of the time	0	0	0	0	1 (5.9)
Rarely	0	0	0	0	0
Never	0	0	0	0	0

All participants but one reported that their household water supply source was from the city, and only one reported that well water was the primary water source at his or her primary residence. Participants were asked how frequently they rinsed their contact lenses with water. The results from these questions are presented in Table 11, and the responses are grouped by lens type.

Table 11: Frequency of Lens Rinse by Lens Type

Lens type (column) and rinsing frequency (row)	Every day	Few times per week	Every week	Less than 1x per month	Never	Total
Corneal	4	3	1	2	1	11
Scleral	1				4	5
Hybrid	1					1

Further analysis was performed to determine if there was a relationship between the type of lens and the likelihood that the wearer would report rinsing their lens with water. Chi-square analysis with Fisher's Exact criterion was utilized to determine that a significant relationship was present ($p = 0.01$), and patients who wear corneal GP lenses are the most likely to report rinsing lenses with water versus those who wear either scleral or hybrid lenses. Those participants who reported any frequency of lens rinsing with water were then asked about their reasoning for that behavior.

Five respondents selected the convenience response, three reported that they were unaware of alternative options, one followed the instructions of the doctor, and one followed the package insert instructions. If a participant chose "other" as an option, he or she was prompted to give a free text response. The three responses were "I was unaware I shouldn't use water", "in situation without solution", and "worried about getting cleaning solution in eye". When asked how frequently they store their contact lenses in water, all but one participant selected the option "never". That single respondent reported the use of

corneal GP lenses and cited convenience as the reasoning behind storing his lenses in water. Participants were then asked about a few other contact lens behaviors, the results of which are presented in Table 12.

Table 12: Patient Water Exposure Behaviors

Behavior (column), Frequency (row)	**Every day**	**A few times per week**	**Every week**	**A few times per month**	**Less than once per month**	**Never**
Store lenses in water	0	0	0	0	1	16
Rinse CL case with tap water	6	1	2	2	2	4
Shower with CLs	3	4	0	5	2	3
Pool/hot tub with CLs	0	0	1	3	7	6
Swim in lake, ocean, river, or sea with CLs	0	0	0	0	5	12

The participants were then asked if their eye care professional has ever specifically discussed contact lens exposure with them at any of their appointments. Ten

participants (58.8%) chose “no”, two (11.8%) were “unsure”, and five (29.4%) chose “yes”. There was no significant relationship ($p = 0.173$) between rinsing contact lenses with water and patient education of avoiding contact lens water exposure by an eyecare provider. When surveyed about the solution brand they used most often, eight participants reported using a 2-step system (e.g. Boston Advance or Optimum by Lobob), five reported using a 1-step system (e.g. Boston Simplus), and four reported using a hydrogen peroxide-based system (e.g. Clear Care). All participants reported that they have read the cleaning directions accompanied by their respective cleaning systems at some point.

Finally, the participants were surveyed on their perceptions of the risk involved with specific contact lens behaviors. As with the provider and researcher participants, the patient participants were further divided into the categories of rinsers and non-rinsers. This information is presented in Table 13.

Table 13: Patient Perceptions of Risk

Behavior	Rinse, n (%)	No Rinse, n (%)	p
Rinsing GP lenses with tap* water			**.050**
Decreases the risk of infection	1 (8.3)	0 (0)	
No effect on risk of infection	7 (58.3)	0 (0)	
Increases the risk of infection	4 (33.3)	5 (100)	
Rinsing GP lenses with distilled* water			.052
Decreases the risk of infection	4 (33.3)	0 (0)	
No effect on risk of infection	7 (58.3)	2 (40)	
Increases the risk of infection	1 (8.3)	3 (60)	
Storing contact lenses in tap water			.485
Decreases the risk of infection	0	0	
No effect on the risk of infection	2 (16.7)	0	
Increases the risk of infection	10 (83.3)	5 (100)	
Showering while wearing contact lenses			.515
Decreases the risk of infection	0 (0)	0 (0)	
No effect on the risk of infection	11 (91.7)	4 (80)	
Increases the risk of infection	1 (8.3)	1 (20)	
Swimming while wearing contact lenses			.278
Decreases the risk of infection	0 (0)	0 (0)	
No effect on the risk of infection	6 (50)	1 (20)	
Increases the risk of infection	6 (50)	4 (80)	

Further analysis was performed to explore whether relationships were present between rinsing behavior and the perception of the risk of specific water exposure behaviors. Chi-square analysis with Fisher's Exact criterion was utilized to determine that patients who do not rinse their lenses with water are more likely to believe that this behavior increases the risk of eye infection ($p = 0.050$). The remainder of the analyses did not result in significant relationships, but the relationship between rinsing behavior and perception of risk with distilled water was just shy of significance ($p=.052$).

The perceptions of the two groups was compared to see if there was a significant difference between the beliefs of a lens-wearing patient population versus the professionals. This comparison is presented in Table 14.

Table 14: Perceptions of Risk - Study Participants

Behavior	**Practitioner/Researcher Frequency (%)**	**Patient Frequency (%)**	**p**
Rinsing GP lenses with tap* water			0.31
Decreases Risk of Infection	3 (1.4)	1 (5.9)	
No Effect on Risk of Infection	76 (34.9)	7 (41.1)	
Increases Risk of Infection	139 (63.8)	9 (53.0)	
Rinsing GP lenses with distilled* water			0.02
Decreases Risk of Infection	13 (6.0)	4 (23.5)	
No Effect on Risk of Infection	113 (51.8)	9 (53.0)	
Increases Risk of Infection	92 (42.2)	4 (23.5)	
Showering while wearing contact lenses			<0.0001
Decreases Risk of Infection	1 (0.5)	0 (0.0)	
No Effect on Risk of Infection	79 (36.2)	15 (88.2)	
Increases Risk of Infection	138 (63.3)	2 (11.7)	
Swimming while wearing contact lenses			<0.0001
Decreases Risk of Infection	1 (0.5)	0 (0.0)	
No Effect on Risk of Infection	11 (5.1)	7 (41.2)	
Increases Risk of Infection	205 (94.0)	10 (58.8)	

This comparison shows that there is no significant difference in perception between the two groups concerning tap water rinse of lenses, but all other behaviors are

statistically different from each other. The patient participants were much more likely to downplay the amount of risk associated with the behaviors discussed versus the practitioners and researchers. The same practitioner and researcher data collected through our study was compared to historical patient data from a similarly designed study by Zimmerman and colleagues [103]. The perception questions that were compared are identical, but the perception answer options vary slightly. This comparison is presented in Table 15.

Table 15: Perceptions of Risk - Study and Historical Participants

Presented to historical patients as “likely to cause infection”, “has little/no effect” and “prevents infection

[ɣ]Data obtained from *Cornea* 2017;36:995-1001.

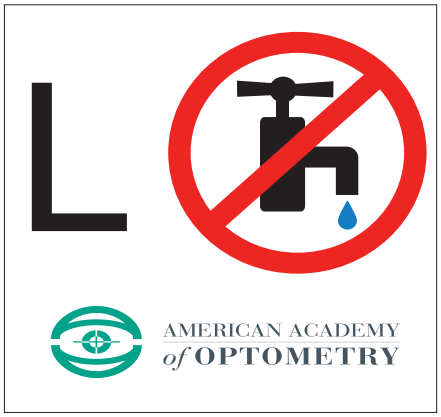
Behavior	Practitioner/Researcher Frequency (%)	Historical Patient[ɣ] Frequency (%)	p
Rinsing GP lenses with tap water			<0.0001
Decreases Risk of Infection*	3 (1.4)	15 (19.0)	
No Effect on Risk of Infection*	76 (34.9)	49 (62.0)	
Increases Risk of Infection*	139 (63.8)	15 (19.0)	
Rinsing GP lenses with distilled water			<0.0001
Decreases Risk of Infection	13 (6.0)	38 (48.1)	
No Effect on Risk of Infection	113 (51.8)	39 (49.4)	
Increases Risk of Infection	92 (42.2)	2 (2.5)	
Showering while wearing contact lenses			<0.0001
Decreases Risk of Infection	1 (0.5)	0 (0.0)	
No Effect on Risk of Infection	79 (36.2)	73 (92.4)	
Increases Risk of Infection	138 (63.3)	6 (7.6)	
Swimming while wearing contact lenses			<0.0001
Decreases Risk of Infection	1 (0.5)	0 (0.0))	
No Effect on Risk of Infection	11 (5.1)	33 (41.8)	
Increases Risk of Infection	205 (94.0)	46 (58.2	

Similar to the comparison between this study's two populations, the comparison to the historical patient data demonstrated a statistically significant difference between the perceptions of the two groups. Again, the patient participants were more likely to minimize the amount of risk involved with the various behaviors. The historical patients often chose the "has little/no effect" option versus the practitioner and researcher population, who were more likely to choose report that the behavior of concern increases the risk of infection.

Discussion

The results from this study further demonstrate a well-established and pervasive issue concerning contact lens wear; patients, practitioners, and researchers do not strictly adhere to the standards of care regarding contact lens hygiene practices. Some of the more perplexing results occurred when participants reported the belief that a specific behavior was associated with an elevated infection risk, but then also reported engaging in that behavior themselves. While the topic of *Acanthamoeba* was not specifically addressed through the questions contained in the surveys, one of the goals of the study was to assess the frequency with which participants are involved in activities correlated with *Acanthamoeba* keratitis. Despite the fact that both the American Academy of Optometry and the British Contact Lens Association have joined the "No Water" campaign (Figure 3) started by Ms. Irenie Ekkeshis, an AK patient and winner of a Health Service Journal Patient Leader Award [115], 60.5% of practitioners and researchers surveyed reported rinsing diagnostic, lab supplied, and/or patient's own lenses with water.

Figure 3: "No Water" Campaign Graphic



This high number is present despite the findings that about half of those who reported rinsing believe that rinsing lenses with tap water increases the risk of eye infection. Additionally, the percentage of practitioners and researchers that reported rinsing lenses with water themselves is almost identical to the number of people from the same group who reported advising their patients to avoid using water with contact lenses. In the case of the practitioners, some appear to subscribe to a "do what I say, not what I do" philosophy. Alternatively, the number of participants who reported rinsing lenses with water was 1.8 times larger than the amount who reported engaging in this behavior in front of patients. The philosophy of these participants can then be modified to "do what I say (and model in front of you), not what I do (behind your back)". Practitioners may potentially believe that their own exposure of lenses to water is less risky due to the short-term nature of the exposure. It is possible that practitioners may not be worried about brief water exposure but become more concerned with habitual exposure resulting from daily tap water rinse. There was also a disconnect among the water exposure

recommendations made by practitioners and researchers in that 63.1% advised patients to avoid rinsing lenses with water, the vast majority advised patients to refrain from wearing lenses while swimming, but only half advised patients not to wear contact lenses when showering.

Although the CDC and FDA recommend removing lenses prior to activities like showering, swimming, and using a hot tub [90, 91, 107], far more practitioner and researcher participants advise their patients to avoid contact lens exposure when swimming versus showering. This correlates well to the results from the practitioner and researcher perception questions, which reveal that a little bit over half of rinsers and non-rinsers believe that showering while wearing contact lenses increases the risk of eye infection, but the vast majority of rinsers and non-rinsers believe that swimming while wearing contact lenses increases the infection risk. Research has demonstrated that showering while wearing contact lenses is the most common exposure to water in soft contact lens wearers, as GP lens wearers are more likely to actively expose their lenses to water by rinsing or storing their lenses in water, versus more passive exposure [103]. As was previously discussed, microorganisms such as *Acanthamoeba* are commonly isolated from showers, bathroom taps, and cisterns and tanks that store household water [67-70]. Showering in lenses is a common practice [1, 74, 78, 86], and it has been suggested by Joslin and colleagues that the shower may act as a fomite for infection due to aerosolization of water-borne pathogens [109]. Consequently, showering in lenses is associated with an increased risk of developing both microbial keratitis [46, 108, 109] and corneal infiltrative events [12].

The association with swimming in lenses and infection risk appears to be less contentious when looking at the participant behaviors and perceptions. With the question asking about recommendations for a hypothetical moderately myopic patient who swims frequently, the daily disposable option was selected most often, followed by refraining from contact lens wear, and orthokeratology. Most of the participants' recommendations fall in line with the standard of care, which favors an option that either avoids swimming pool water exposure to lenses completely, or one that utilizes a single use lens. The daily disposable option allows for optimal vision correction, while minimizing long-term chlorine exposure to the cornea. Choo and colleagues demonstrated bacterial colonization of contact lenses following swimming, and some of the most common species encountered included *Staphylococcus epidermidis*, *S. aureus*, and *S. salivarius* [48]. Swimming with contact lenses can increase the risk of *Acanthamoeba* contamination [56, 82, 104] and case reports in the literature have detailed such occurrences [96, 97]. The other most popular options avoid lens exposure to chlorine altogether, but may not provide optimal vision correction, especially the option to avoid the use of contact lenses completely. It is possible that the respondents that selected the latter option would recommend prescription goggles to their moderately myopic swimmers, but that answer was not an option within the survey.

When surveyed about their solution preferences, overall, the majority of respondents recommended hydrogen peroxide-based solutions for scleral and orthokeratology lenses, and 2 step systems for corneal lenses. Scleral lenses are large, and it is difficult to maneuver within the various lens curves when attempting to clean this

lens type with a solution system that requires a rubbing step, therefore hydrogen peroxide makes the most sense for this lens type. Corneal GP lenses and orthokeratology lenses are manufactured out of similar materials and interact with the same ocular structures, therefore it is unclear as to why there is a difference in recommendations for these two lens types. One explanation may be related to the demographics of orthokeratology wearers, as these lenses are primarily prescribed for a much younger population [56, 57], and hydrogen peroxide-based solutions may be preferred due to the ease of use. Additionally, many practitioners who have been fitting corneal GP lenses for decades may be most comfortable recommending the 2-step cleaning systems that they are more familiar with and have historically used.

The selection of a disinfection system is important when considering the risk of AK development. Inadequate disinfection and the use of chlorine release solutions were cited as causative factors during the first recorded AK outbreak during the 1980s and ‘90s [64, 76, 80, 104]. Prior to the widespread use of multipurpose solutions, commercially available heat-disinfection units were popular options for lens disinfection. During the first reported AK outbreak, researchers investigated the efficacy of these units and demonstrated a relationship of faster and more significant *Acanthamoeba* inactivation rates with higher temperatures [116]. The authors suggested that some units may not reach the appropriate temperatures needed for full disinfection, especially when considering reports of isolation of *Acanthamoeba* in contact lenses cases in patients that reported use of such devices [116].

Tests of solution efficacy reveal that many of the disinfection products that are currently available are inadequate against *Acanthamoeba*. In general, *Acanthamoeba* cysts are much more resistant to contact lens solutions than the trophozoite form [117, 118], and immature cysts are even more sensitive to disinfection than their mature counterparts [119]. Soft contact lens MPSs are relatively ineffective against *Acanthamoeba* [120], but show better efficacy against the trophozoite form [101, 117] versus the mature cyst form [119]. When combining sensitivity data of both forms, a previous study found that 94% of the pathologic strains of *Acanthamoeba* demonstrated treatment tolerance to MPS [117]. Hydrogen peroxide-based solutions demonstrate the best efficacy against *Acanthamoeba* [118, 121], yet a solution study detected the presence of cysts following 6 hours of solution exposure, including hydrogen peroxide-based solutions [121].

Rinsing and non-rinsing groups were generally in agreement concerning the level of risk related to swimming and showering with contact lenses, but in the univariate analysis, the non-rinser group was significantly more likely to believe that rinsing lenses in tap and distilled water and rinsing contact lens storage cases with water increases the risk of eye infection compared to the rinser group. This makes logical sense, as their beliefs regarding the risk of those behaviors likely influence their own behaviors and recommendations to patients. Upon further examination of the multivariate results, the relationships of rinser vs. non-rinser to both the risk of distilled water rinse and of lens case water rinse were no longer significant. This is likely because the participant's belief regarding tap water rinse is related to their judgment regarding the other two questions. It

is unlikely that a practitioner would believe that rinsing a lens case with water increases infection risk but rinsing a lens with water does not.

When comparing the results from the FDA recommendation question, non-rinsers were significantly more likely believe that solution manufacturers should reevaluate and modify the current product instructions in regard to the water rinsing step when compared to the rinser group. Yet even in the rinser group, over half share this opinion, which is in line with the 2008 FDA ophthalmic devices panel [99] and 2015 microbial test methods workshop [100] that were previously discussed. This significant relationship may be explained by other characteristics of the non-rinsing group. As previously mentioned, those respondents more frequently advise their patients to avoid water rinse, so they may have direct experience speaking with patients who are confused by conflicting messages between their eye care professional and the manufacturer recommendations. They may also be interested in finding additional, FDA approved alternatives to offer such patients who are in search of an appropriate rinsing product. The tides may soon change with regard to package insert instructions, as contact lens product companies like Bausch + Lomb are currently working to modify their package instructions to eliminate the tap water rinsing step from their packaging [122], and hopefully other companies will follow their lead.

No significant relationship was present between starting year and rinsing behavior, but the pattern appears to be following a trend. If this is the case, it is possible that more recent clinicians and researchers are more up to date on the latest research and best hygiene practices. This theory is supported by the presence of a significant

relationship between starting year and the likelihood of advising patients to avoid rinsing lenses with water, and we have already discussed that rinsing behavior and advising water avoidance are related. There also appears to be a trend between starting year of practice and recommending hydrogen peroxide-based solutions. The percentage of clinicians and researchers who recommend hydrogen peroxide solutions for both corneal and scleral lenses increases as the data approaches a more recent starting year. This may also be related to access to more recent training and education, but also may be related to the steady increase in popularity of hydrogen peroxide solutions over the past 10 years.

Corneal GP wearing patients were statistically most likely to report rinsing their lenses with water, and this correlated well to the practitioner and researcher data that revealed that corneal lenses were the most commonly reported lenses to be rinsed with water by that population. The most common explanations given by the patient participants for this behavior were convenience and a lack of education on superior alternatives. The latter of the responses is in line with a later question concerning whether the participant's eye care provider had discussed water exposure to lenses. The majority of patient respondents were either unsure, or reported no such discussion, although there was no significant relationship between water rinsing behavior and patient education of water rinse avoidance. A 2-step system was the most popular disinfection solution recommendation for corneal GP lenses made by the provider and researcher population, and as previously discussed, this regimen explicitly recommends a tap water rinse within the product instructions. Although doctor recommendation was not cited as the most common reason that patients rinsed their lenses with water, the patient sample is small,

and the rinsing question asked why they rinsed their lenses with water, not why they use the specific solution that they reported.

The final analyses compared practitioner and researcher responses to the study patient data and to historical patient data from a previous similar study by CLAY/CDC [103]. The two analyses correlated relatively well by showing identical results for all questions but one. The comparisons demonstrated that both the current study patient population and the historical patient population are more likely to minimize the amount of risk associated with rinsing lenses in distilled water and showering and swimming with lenses. This discrepancy between practitioner and researcher risk perceptions and patient beliefs reflects a widespread lack of thorough patient education. It is imperative that clinicians stay up to date on the standards of care regarding lens care and disinfection and actively disseminate this information to their contact lens wearing patients.

Limitations

As with any survey-based study, there is the potential for a participation bias for the clinician and researcher arm of the study. The potential participants that chose not to participate may have certain characteristics that are not represented in the data. It is possible that individuals who are more interested in research and pay closer attention to scientific updates were more likely to participate, thereby altering the data.

There may be a selection bias for the patient arm of the study. Only one recruiter (KS) was responsible for approaching participants to participate. There may be specific patient characteristics not represented due to many potential patients not being

approached due to scheduling or timing issues. Additionally, the patient arm of the study was limited by the small sample size overall, and the small number of hybrid wearers and absence of orthokeratology wearers. Further study would ideally expand patient recruitment to provide more power to this portion of the study and to recruit a participant group more representative of the overall population.

Conclusion

Water exposure to contact lenses and their accessories is a well-established risk factor for the development of infectious eye disease, as these products can act as reservoirs for inoculation of microorganisms. The consequences of water exposure to contact lenses can range from minor inconvenience to permanent vision loss. Both a clinician and/or researcher and contact lens-wearing patient population report risky behaviors concerning the handling and care of contact lenses. Further, these two populations also report some perceptions of risk that are at odds with the literature. Dissemination of the currently accepted best practices for contact lens hygiene to practitioners, researchers, and contact lens patients is vital in order to reduce the potential risk for complications and potential vision loss.

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Appendix A: Practitioner and Researcher Participant Survey Questions

Contact Lenses and Water Survey for Providers and Researchers

Q1 Researchers at The Ohio State University College of Optometry are interested in the behaviors and attitudes of contact lens wearers. The information you share will help us understand practitioner practices and perceptions regarding the relationship of water and gas permeable contact lenses. The survey should take you 10 to 15 minutes to complete. There is no risk of loss of privacy. There will be no link between your name and your answers to the survey. There are no other expected risks of participation. Taking the survey is voluntary. You can decide not to take the survey or to stop at any time.

If you have already taken this survey, please do not take the survey again.

If you have any additional questions about this research, please feel free to contact us at zimmerman.178@osu.edu. Thank you!

Q2 Do you fit contact lenses?
Yes (1)
No (2)

Skip To: Q24 If Do you fit contact lenses? = No

Q3 Which type of contact lenses do you fit?
Only soft lenses (1)
Only hard lenses (2)
Both hard and soft lenses (3)

Skip To: Q17 If Which type of contact lenses do you fit? = Only soft lenses

Q4 Which of the following types of gas permeable lenses do you fit? (please select all that apply)

Scleral (1)
Corneal (2)
Hybrid (3)
Orthokeratology (4)

Q5 Per week, how many patients do you see who are gas permeable lens wearers (on average)?

Fewer than 1 per week (1)
1-2 per week (2)
3-5 per week (3)
About 1 per day (4)
Multiple patients each day (5)

Q6 Do you or your staff ever rinse diagnostic, lab supplied, or a patient's own gas permeable lenses with water?

Yes (1)
No (2)

Q7 Do you or your staff ever rinse diagnostic, lab supplied, or a patient's own gas permeable lenses with water **in front of patients**?

Yes (1)
No (2)

Display This Question:

If Do you or your staff ever rinse diagnostic, lab supplied, or a patient's own gas permeable lenses... = Yes

Q8 Which of the following types of gas permeable lenses do you rinse with water in front of patients? (select all that apply)

Scleral (1)
Corneal (2)
Hybrid (3)
Orthokeratology (4)

Display This Question:

If Which of the following types of gas permeable lenses do you fit? (please select all that apply) = Corneal

Q9 Do you advise patients to refrain from rinsing gas permeable lenses with water?

Yes (1)
No (2)

Display This Question:

If Which of the following types of gas permeable lenses do you fit? (please select all that apply) = Corneal

Q10 Which modality of gas permeable lens cleaning solution do you most often recommend with corneal lenses? (please rank the options from most to least likely with 1 being the most likely and 4 being the least likely)

_____ Peroxide based (i.e. Clear Care, Peroxiclear) (1)
_____ 1-step cleaner (i.e. Boston Simplus and Unique pH) (2)
_____ 2-step cleaner (i.e. Boston Advance and Original, Optimum by Lobob CDS) (3)
_____ Other (4)

Display This Question:

If Which modality of gas permeable lens cleaning solution do you most often recommend with corneal l... [Other] = 1

Q11 Please list the specific gas permeable lens cleaner you recommend to your patients in corneal lenses.

_____

Display This Question:

If Which of the following types of gas permeable lenses do you fit? (please select all that apply) = Scleral

Q12 Which modality of gas permeable lens cleaning solution do you most often recommend with scleral lenses? (please rank the options from most to least likely to recommend with 1 being the most likely and 4 being the least likely)
_____ Peroxide based (i.e. Clear Care, Peroxiclear) (1)
_____ 1-step cleaner (i.e. Boston Simplus and Unique pH) (2)
_____ 2-step cleaner (i.e. Boston Advance and Original, Optimum by Lobob CDS) (3)
_____ Other (4)

Display This Question:

If Which modality of gas permeable lens cleaning solution do you most often recommend with scleral l... [Other] = 1

Q13 Please list the specific gas permeable lens cleaner you recommend to your patients in scleral lenses.

Display This Question:

If Which of the following types of gas permeable lenses do you fit? (please select all that apply) = Orthokeratology

Q38 Which modality of gas permeable lens cleaning solution do you most often recommend with orthokeratology lenses? (please rank the options from most to least likely to recommend with 1 being the most likely and 4 being the least likely)

_____ Peroxide based (i.e. Clear Care, Peroxiclear (1)

_____ 1-step cleaner (i.e. Boston Simplus and Unique pH (2)

_____ 2-step cleaner (i.e. Boston Advance and Original, Optimum by Lobob CDS (3)

_____ Other (4)

Display This Question:

If Which modality of gas permeable lens cleaning solution do you most often recommend with orthokera... [Other] = 1

Q39 Please list the specific gas permeable lens cleaner you recommend to your patients in orthokeratology lenses.

_____

Q14 After cleaning and disinfection of gas permeable lenses, do you recommend a product to rinse lenses with other than water?

Yes (1)

No (2)

Display This Question:

If After cleaning and disinfection of gas permeable lenses, do you recommend a product to rinse lens... = Yes

Q15 Please list any rinsing products you specifically recommend to gas permeable lens wearers following lens disinfection:

Q17 Do you advise patients to avoid contact with water when cleaning contact lens cases?

Yes (1)

No (2)

Q18 Do you actively recommend a specific contact lens storage case replacement schedule?

Yes (1)

No (2)

Display This Question:

If Do you actively recommend a specific contact lens storage case replacement schedule? = Yes

Q19 How frequently do you recommend patients replace their contact lens cases?

Every 1-3 months (1)

Every 4-6 months (2)

Every 7-12 months (3)

Less frequently than annually (4)

It is not necessary to replace contact lens cases (5)

Q20 Do you specifically discuss with patients contact lens wear when showering?

Yes (1)

No (2)

Q21 Do you specifically discuss with patients contact lens wear when swimming?

Yes (1)

No (2)

Q22 In the case of a moderately myopic patient who swims regularly, which option would you recommend?

Refraining from contact lens wear completely (1)
Daily disposable contact lens wear (2)
2 week or monthly contact lens wear (3)
Only no overnight wear of contact lenses (no specific modality recommended) (4)
Orthokeratology lenses (5)

Display This Question:

If In the case of a moderately myopic patient who swims regularly, which option would you recommend? = Daily disposable contact lens wear

Or In the case of a moderately myopic patient who swims regularly, which option would you recommend? = 2 week or monthly contact lens wear

Or In the case of a moderately myopic patient who swims regularly, which option would you recommend? = Only no overnight wear of contact lenses (no specific modality recommended)

Q23 In the previous example, would you recommend goggle usage while swimming?

Yes (1)
No (2)

Q24 What is your perception of rinsing gas permeable lenses with **tap** water as it relates to eye infection?

This behavior decreases the risk of infection (1)
This behavior has no effect on the risk of infection (2)
This behavior increases the risk of infection (3)

Q25 What is your perception of rinsing gas permeable lenses with **distilled** water as it relates to eye infection?

This behavior decreases the risk of infection (1)
This behavior has no effect on the risk of infection (2)
This behavior increases the risk of infection (3)

Q26 What is your perception of showering while wearing contact lenses as it relates to eye infection?

This behavior decreases the risk of infection (1)
This behavior has no effect on the risk of infection (2)
This behavior increases the risk of infection (3)

Q27 What is your perception of swimming while wearing contact lenses as it related to eye infection?

This behavior decreases the risk of infection (1)

This behavior has no effect on the risk of infection (2)

This behavior increases the risk of infection (3)

Q28 What is your perception of rinsing contact lens **cases** with water as it relates to eye infection?

This behavior decreases the risk of infection (1)
This behavior has no effect on the risk of infection (2)
This behavior increases the risk of infection (3)

Q29 Regarding current gas permeable lens solutions that require a rinsing step, which option do you think is most appropriate?

The current solutions should remain on the market as is (1)
The FDA should pull the current solutions from the market so that the safety of the rinsing step can be reevaluated (2)
The solution manufacturers should consider modifying the product instructions regarding the rinsing step (3)

Q30 Since which year have you been involved in vision care and/or vision research?

2016 (1) ... 1950 (67)

Q36 In which country do you currently reside?*

Q35 Please select the most appropriate description of your occupation. (select all that apply)

Optometrist (1)
Ophthalmologist (2)
Researcher (3)
Industry (4)
Other (5) _____

Q31 Please indicate if you are a current member in any of the following groups or organizations. (select all that apply)

Diplomates of the Cornea, Contact Lens, and Refractive Technology (CCLRT) Section of the American Academy of Optometry (AAO) (1)
AAO Fellows and/or Diplomates of a Section other than CCLRT (2)
American Optometric Association (AOA) Contact Lens and Cornea Section (3)
The British Contact Lens Association (BCLA) (4)
The Contact Lens Association of Ophthalmologists (CLAO) (5)
None (6)
Others (7) _____

Q37 Please feel free to share and comments or suggestions regarding the survey. We appreciate your feedback!

_____

The online version of the survey included a drop-down list of country options. This is not included in the Appendix

Appendix B: Patient Participant Survey Questions

Contact Lenses and Water Survey for Patients

Q1 Please enter the subject and study number (xx-xx).

_____

Q2 Thank you for choosing to participate in this survey. The purpose of this study is to determine current practices and patient perceptions regarding water exposure to gas permeable contact lenses. Please answer the following questions honestly. Your answers are anonymous and will not be linked to your name or email address. Thank you!

Q3 What is your gender?
Female (1)
Male (2)
Other (3)

Q4 What is your age?
16-20 (1)
21-30 (2)
31-40 (3)
41-50 (4)
51-60 (5)
61-70 (6)
71-80 (7)
81-90 (8)

Q5 What type of contact lenses do you wear? (select all that apply)
Soft lenses (1)
Small, hard lenses during the day (corneal GP lenses) (2)
Small, hard lenses only to sleep (orthokeratology lenses) (3)
Large, hard lenses that are filled up with fluid (scleral) (4)
Lenses that are hard in the center and soft around the edges (hybrid) (5)
Other (6) _____

Q6 How often do you wash your hands prior to handling your contact lenses?
Always (1)
Most of the time (2)
Some of the time (3)
Rarely (4)
Never (5)

Display This Question:

If How often do you wash your hands prior to handling your contact lenses? != Never

Q7 How do you wash your hands prior to handling your contact lenses?
With soap and water (1)
Only water (4)
Cleansing wipe (3)
Hand sanitizing gel/foam (2)

Display This Question:

If How do you wash your hands prior to handling your contact lenses? = With soap and water

Or How do you wash your hands prior to handling your contact lenses? = Only water

Q8 By which method do you dry your hands prior to handling your contact lenses?
I do not dry my hands (1)
Drip dry/air dry (2)
I wipe my hands on my clothing (3)
Paper towel or facial tissue (4)
Cloth towel (5)

Q9 Which of the following is the source of your water at your primary place of residence?
Well water (1)
City water (2)

Q10 How often do you rinse your contact lenses with water?
Never (1)
Less than once per month (2)
A few times per month (3)
Every week (4)
A few times per week (5)
Every day (6)

Display This Question:

If How often do you rinse your contact lenses with water? != Never

Q11 Why do you rinse your contact lenses with water? (select all that apply)

My doctor instructed me to do so (1)
The package insert on my cleaning solution instructed me to do so (2)
Convenience (3)
I was unaware there were other options for rinsing lenses (4)
Cost (5)
Other (6) _____

Q12 How often do you store your lenses in water?

Never (1)
Less than once per month (2)
A few times per month (3)
Every week (4)
A few times per week (5)
Every day (6)

Display This Question:

If If How often do you store your lenses in water? Never Is Not Selected

Q13 Why do you store your contact lenses in water? (select all that apply)

My doctor instructed me to (1)
The package insert on my cleaning solution instructed me to (2)
Convenience (3)
I was unaware there were other options for storing lenses (4)
Cost (5)
Other (6) _____

Q14 How often do you rinse your contact lens **case** with tap water?

Never (1)
Less than once per month (2)
A few times per month (3)
Every week (4)
A few times per week (5)
Every day (6)

Q15 How often do you shower while wearing contact lenses?
Never (1)
Less than once per month (2)
A few times per month (3)
Every week (4)
A few times per week (5)
Every day (6)

Q16 How often do you use a pool or hot tub while wearing contact lenses?
Never (1)
Less than once per month (2)
A few times per month (3)
Every week (4)
A few times per week (5)
Every day (6)

Q17 How often do you swim in a lake, ocean, river, or sea while wearing contact lenses?
Never (1)
Less than once per month (2)
A few times per month (3)
Every week (4)
A few times per week (5)
Every day (6)

Q18 Has your eyecare professional ever specifically discussed contact lens exposure to water with you?
Yes (1)
No (2)
Unsure (3)

Q19 Which type of solution do you typically use to disinfect your lenses? (Please feel free to use to solution handout provided to help you identify your preferred brand)

Boston Simplus (1)
Boston Advance (2)
Boston Original (3)
Optimum by Lobob (4)
Menicare (5)
Unique pH (6)
Clear Care (7)
PeroxiClear (8)
Equate (Walmart) (9)
Up & Up (Target) (10)
Walgreens (11)
CVS (12)
Other (please indicate) (13)
_____

Q20 Have you read the recommended cleaning directions on either the box or the package insert for your lens cleaning system?

Yes (1)
No (2)
Unsure (3)

Q21 In a situation where the preferred method of lens storage is not available, please rank the following substances from the most to least appropriate substitution with the most appropriate as number 1, and the least appropriate as number 6.

_____ Eyewash (1)
_____ Distilled water (2)
_____ Tap water (3)
_____ Soft contact lens solution (4)
_____ Non-preserved saline solution (5)

Q22 What is your perception of rinsing contact lenses with tap water as it relates to eye infections?

This behavior increases the risk of infection (1)
This behavior has no effect on the risk of infection (2)
This behavior decreases the risk of infection (3)

Q23 What is your perception of rinsing contact lenses with **distilled** water as it relates to eye infections?

This behavior increases the risk of infection (1)
This behavior has no effect on the risk of infection (2)
This behavior decreases the risk of infection (3)

Q24 What is your perception of storing contact lenses in tap water as it relates to eye infections?

This behavior increases the risk of infection (1)
This behavior has no effect on the risk of infection (2)
This behavior decreases the risk of infection (3)

Q25 What is your perception of wearing contact lenses while showering as it relates to eye infections?

This behavior increases the risk of infection (1)
This behavior has no effect on the risk of infection (2)
This behavior decreases the risk of infection (3)

Q26 What is your perception of wearing lenses while swimming as it relates to eye infections?

This behavior increases the risk of infection (1)
This behavior has no effect on the risk of infection (2)
This behavior decreases the risk of infection (3)

Q27 Please type your preferred email address

_____

Q28 Thank you for taking this survey! Your participation is greatly appreciated.

The following information is based on results from scientific studies that have been conducted to determine the causes of eye infection and the effects of water exposure to contact lenses. Though the true level of infection risk has not been fully established for showering with lenses or for rinsing lenses with water, the following recommendations are considered the current best practices.

-Both soft and hard contact lenses and their cases should never be exposed to any water including tap, bottled, distilled, or purified water. This recommendation is also applied to water exposure related to showering, swimming, and using a hot tub. If you swim while wearing lenses, they should be removed following that activity and properly disinfected. Lenses should never be worn overnight.

-Contact lens exposure to water increases the risk of eye infections, including infection

by *Acanthamoeba,* which although rare, can have devastating visual consequences.

-Although the product information included with rigid gas permeable lens disinfection systems often recommends a rinsing step with water, the safest clinical practice is to instead rinse with a saline solution.

Please ask your doctor if you have any specific questions about your lens cleaning routine.