

Patient Compliance with Contemporary  
Contact Lenses:  
Impact on Successful Contact Lens Wear

by

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## **AUTHOR'S DECLARATION**

I hereby declare that I am the sole author of this thesis. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.

I understand that my thesis may be made electronically available to the public.

## Abstract

**Purpose:** Contact lens (CL) materials, modalities of wear and replacement, and care systems have changed considerably since the early studies of CL compliance were first conducted. Silicone hydrogel (SiHy) and daily disposable (DD) lenses are now the most popular lenses worn worldwide and the care systems that are currently available for them have been designed to be straightforward to use. The purpose of this research was to investigate patient knowledge of and compliance with the use of these contemporary CLs and care products, to determine whether non-compliant CL wearers experience ocular complications relating to lens wear more frequently and are more likely to discontinue lens wear, and to try to determine the factors that may constrain or enable patients to follow recommendations for appropriate lens wear and care.

**Methods:** There are many ways in which compliance can be assessed in health care. Several different methodologies were employed during this research:

- A questionnaire was administered to just over 100 current lens wearers to determine whether photographic aids would help them to recognize which products they were using.
- More than 500 contact lens (CL) wearers were recruited by their eye care practitioners (ECPs) and mailed a questionnaire designed to evaluate their compliance with contact lens wear and care and to determine whether they had experienced any contact lens related complications which may have occurred as a result of non-compliance.
- Close to 5000 Current and lapsed CL wearers in Canada were recruited using Facebook to take part in an on line survey investigating CL wearing experiences during 2008 – 2010 and to establish the percentage of participants who temporarily and permanently discontinued CL

wear during the period surveyed, the reasons for discontinuation and whether compliance with lens wear and care may have played a role.

- ECPs and patients independently completed more than 2000 linked questionnaires evaluating their contact lens wear and care. In addition the frequency with which patients attended their ECP's office for eye examinations was assessed to determine whether there was a relationship between this and their patients' compliance.
- More than 800 daily disposable contact lens (DDCL) wearers in four countries completed an online questionnaire designed to investigate how frequently they reused their lenses, the reasons for reuse and how the lenses were stored between uses.
- Quantitative (online questionnaire) and qualitative (focus groups) research methods were used to explore in detail the lens wear and care habits of adapted contact lens wearers in an attempt to seek a better understanding of what enables and constrains patient compliance with appropriate lens wear and lens care.

**Results:** The rates of non-compliance with the wear of contemporary CLs were found to be similar to those previously reported. Non-compliance with recommendations for CL replacement was shown to be associated with a higher rate of CL related problems. CL wearers continue to “drop-out” for reasons of discomfort and dryness with their lenses but the drop out rates were not found to be different between compliant and non-compliant CL wearers. Patients who were non-compliant with lens replacement were found to attend their ECP's offices less frequently. Wearers of DDCLs were the most compliant with lens replacement; however, some did report reusing these lenses and sleeping overnight in them. Focus group participants were able to provide a greater insight into why non-compliant behaviour occurs in CL wearers with the most frequently occurring themes identified as the



“consequences” that may occur if patients are non-compliant with one or more aspects of their contact lens wear and the importance of receiving “instructions” regarding the most appropriate way to wear and care for their lenses. Most of the themes that emerged from this qualitative research study were both constraints to, and enablers of, compliance.

**Conclusions:** Compliance with contemporary CLs and care products remains poor. Non-compliant behaviour can result in serious complications and patients may not always be aware of this. Careful counseling and education on the risks associated with CL wear is required to provide patients with a better lens wearing experience and continued successful contact lens wear. ECPs and the contact lens industry can hopefully apply this greater understanding of why patients fail to wear and care for their lenses as they should and to help them develop strategies and tools to aid compliance and success in contact lens wear.

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## List of Symbols

=	Equal to
>	Greater than
≥	Greater than or equal to
Hr(s)	Hour(s)
<	Less than
≤	Less than or equal to
Min(s)	Minute(s)
Mth(s)	Month(s)
%	Percent
±	Plus or minus
X	Times

## List of Abbreviations

1MR	1-month replacement
2WR	2-week replacement
ANOVA	Analysis of Variance
CI	Confidence Interval
CL	Contact Lens
CCLR	Centre for Contact Lens Research
CRT	Corneal Refractive Therapy
DD	Daily Disposable
DDCL	Daily Disposable Contact Lens
DW	Daily Wear
ECP	Eye Care Practitioner
EW	Extended Wear
FDA	Food and Drug Administration
H2O2	Hydrogen Peroxide
HBM	Health Belief Model
HIV	Human Immunodeficiency Virus
IEE	Interval between eye examinations
IP	Internet Protocol
MPS	Multipurpose Solution

MRRF	Manufacturer Recommended Replacement Frequency
NR	No recommendation
NANSAID	Non-aspirin non-steroidal anti-inflammatory drug
ORRF	Optometrist Recommended Replacement Frequency
PA	Photographic Aid
PHP	PHP Hypertext Preprocessor
RF	Replacement Frequency
SiHy	Silicone Hydrogel
RGP	Rigid Gas Permeable
UK	United Kingdom
US	United States
URL	Uniform Resource Locator

# Chapter 1

## Introduction

*“Keep watch also on the faults of the patients, which often make them lie about the taking of things prescribed”*

Hippocrates. (c. 460 BC – c. 370 BC)

### 1.1 Terminology

Although failure to follow instructions by patients is recognized to be pervasive in the management of many health-related conditions, there has been considerable confusion regarding the terminology that is most appropriate to describe this concept and many different terms and definitions have been used to describe this behaviour.

#### **Compliance**

The title of this thesis is “Patient compliance with contemporary contact lenses: Impact on successful contact lens wear.” The term “compliance” comes from the Latin word *complire*, meaning to fill up and therefore to complete an action, transaction, or process and to fulfill a commitment or promise. It is defined in the Canadian Oxford Dictionary <sup>1</sup> as:

*“The act or an instance of complying: obedience to a request, command etc.”*

“Non-compliance” is defined as:

*“Failure to comply, a lack of compliance.”*

The most relevant definition of compliance in health care is arguably:

*“The extent to which a person’s behaviour (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice”<sup>2</sup>*

The term “non-compliance” was first introduced as an official Medical Subject Heading (MeSH) in the US National Library of Medicine in 1975.<sup>3</sup>

### **Adherence**

Unfortunately “compliance” has a negative connotation and may suggest submission; similarly “non-compliance” may be interpreted to be a failure or refusal to comply and implies disobedience.<sup>4</sup>

In several health care disciplines the term “adherence” is becoming more popular to describe patients’ behaviours with respect to taking medication or following a prescribed treatment. It comes from the Latin word adhaerere, meaning to cling to, keep close, or remain constant. According to the World Health Organization (WHO),<sup>5</sup> the term adherence may be defined as:

*“The extent to which a person’s behavior - taking medication, following a diet and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider.”*

This definition encompasses both interventional and therapeutic treatment regimens and emphasizes the importance of the relationship between the patient and the health care provider. The main difference between these two terms is that adherence requires the patient’s active collaboration in the treatment process whereas compliance suggests that the patient may only be passively following the recommendations given to them by their health care provider.

## **Concordance**

A relatively new term which has started to be used to express both patient and doctor actions is “concordance”.<sup>6-8</sup> Concordance implies that the clinician and the patient should come to an agreement, as equal partners, about the management plan that the patient will follow. It has been defined as:

*Concordance is a shared process leading to an agreement between the patient and prescriber about the aims of treatment and how these are achieved. The process enables the patient to participate fully and to influence the outcome.*<sup>9</sup>

Some concerns have been expressed about this approach however,<sup>6</sup> since this may not be possible for all patients and it is difficult to identify which patients would benefit from participation in making these decisions and from an ethical standpoint, a greater emphasis should arguably be placed on the decisions of the clinician.<sup>10</sup>

## **Persistence**

The term “persistence” describes a different paradigm and represents the ability of a person to continue to follow a prescribed treatment for the intended course of therapy:

*“The duration of time from initiation to discontinuation of therapy.”<sup>11</sup>*

Persistence is particularly relevant in the management of chronic diseases, where therapy may continue for months, years, or even the person's lifetime. In some respects, an analogy could be made between contact lens wear and the management of a chronic disease. A person would be classified as being “non-persistent” if he or she never fills a prescription or stops taking a prescription prematurely.

### ***Terminology adopted for this thesis***

An assessment of the various terms used to describe compliance was given by Feinstein <sup>12</sup> who reported that:

*“No other single word, however, has been available as a preferred substitute for compliance. Adherence seems too sticky; fidelity has too many other connotations; and maintenance suggests a repair crew. Although adherence has its adherents, compliance continues to be the most popular term, for lack of anything better.”*

The majority of publications in eye care and contact lenses use the term compliance to describe patient behaviour with respect to following prescribed treatment, and for the remainder of this thesis, the terms compliance and non-compliance will be used.

### **1.2 Non-compliance in health care**

Although non-compliance in health care has been recognized for hundreds of years, it was not until the 1970s that academics first starting investigating the problem of non-compliance and possible solutions. Two professors at McMaster University in Hamilton, David L. Sackett and R. Brian Haynes conducted some of earliest research into patient compliance, and in 1974 they hosted the first full scale symposium on the failure of patients to comply with therapeutic regimens. <sup>13</sup> Following this meeting, they conducted some of the earliest research investigating whether compliance could be improved and reported on a study involving 38 hypertensive Canadian steelworkers who were not habitually compliant with their treatment. <sup>14</sup> Half of the participants received extensive training on monitoring their blood pressure and were given strategies to improve compliance with taking their medications and half received no intervention. Following six months, the experimental group showed

a decrease in blood pressure and an improvement in overall compliance while the control group showed only a modest decrease in blood pressure and a slight worsening of compliant behaviour. Numerous studies have been conducted since this time to both measure non-compliance and to determine how patient behaviour with respect to following instructions and maintaining treatments can be improved.

### **1.2.1 Types of non-compliance in health care**

Non-compliance can occur at several different stages in the disease process. It can start with a failure to take part in recommended screening programs or a delay in seeking care when symptoms initially develop. Patients who have been diagnosed with a condition can be non-compliant by missing appointments, not following instructions, failing to fill prescriptions, taking incorrect doses of medication, taking doses at the wrong times, forgetting doses and stopping treatment too soon.<sup>12,15-19</sup> Any of these non-compliant behaviours can be intentional or unintentional on the part of the patient. While non-compliance usually refers to patients, it must be recognized that health care providers may also be non-compliant with standards of care.<sup>20</sup>

### **1.2.2 Determinants of non-compliance in health care**

In a comprehensive review of the literature, Jin et al reported on the five main factors that have been shown to affect therapeutic compliance.<sup>21</sup> These factors can be described as patient-centred factors, therapy-related factors, healthcare system factors, social and economic factors and disease factors. Patient-centred factors play a significant role in how compliant a patient may be with their treatment; these factors include demographics, psychosocial (e.g. beliefs, motivation and attitude), the patient-



prescriber relationship, health literacy and patient knowledge and physical difficulties. The type of therapy has also been shown to be important, including the route of administration, the complexity of the treatment, the duration of the treatment period, possible side effects, the degree of behavioural change that is required to administer the treatment and requirements for storage of the treatment. Healthcare system factors include accessibility, waiting times, ease of prescription filling and patient experiences during health care visits. Social and economic factors including having to take time off work for visits, cost of treatment, and the patient or patient's family income can also play a role. Finally, the type of disease being treated and its symptoms and severity are also major factors in how compliant a patient may be in their treatment for the condition.

### **1.2.3 Measurement of non-compliance in health care**

Compliance with taking medication can be measured both directly and indirectly.<sup>16</sup> Accurate assessment of compliance is important in order to be able to attribute any change (either improvement or worsening) to any intervention that may occur. Direct measurement by assessing drug metabolites or markers in blood, urine or feces may be the most accurate method, but it is not always practical. As a result, indirect measures are more commonly reported in the literature. These can include asking the patient using interviews, surveys or diaries; tablet counts; and prescription refill dates. Electronic monitoring with containers that record the frequency and timing that they are opened have become popular too.<sup>22-24</sup> These medication event-monitoring systems (MEMS) have been able to confirm when patients take “drug holidays” or practice “white-coat adherence” and improve their compliant behaviour to coincide with follow-up visits to their health care provider.<sup>12,25</sup>

#### **1.2.4 Prevalence of non-compliance in health care**

A meta-analysis of patient compliance with medical recommendations over a fifty-year period was conducted by DiMatteo.<sup>26</sup> In this review, DiMatteo reported compliance to range from 5% to 100%, with a median level of compliance of 75%. The level of compliance varied according to the type of treatment, with lower levels for studies investigating compliance with a prescribed diet (60%) than for health behaviour (70%) and medication (79%). Compliance was also found to vary according to the condition being treated; sleep disorder treatment (66%) had a similar rate of compliance to treatment for diabetes (68%) and compliance with treatment for ocular conditions was a little higher (73%), but the highest rates were for cancer (79%) and HIV (88%).

#### **1.2.5 Strategies to improve compliance in general health care**

A number of different strategies have been employed in an attempt to improve compliance. These have included further educating the prescribers on the importance of compliance, involvement of the patient in determining the most appropriate form of treatment, simplifying the treatment regimen and tailoring it to the individual patient and their lifestyle, the use of reminder systems, the involvement of family members, monitoring compliance and providing feedback.<sup>16,27,28</sup>

Specific strategies to be employed depend on the condition and type of treatment; however, the role of effective communication between the health care provider and the patient in improving compliance has been recognized for some time as one of the most important strategies regardless of the condition and the treatment method.<sup>29-32</sup> Training health care providers in effective communication skills has also been shown to improve compliance with medications, behavioural treatments (e.g. diet, exercise and smoking cessation) and/or attending follow-up visits.<sup>33</sup> A recent meta-analysis reported that the

odds of a patient complying are 2.16 times higher if the health care provider communicates effectively and compliance was shown to improve by 19%.<sup>34</sup>

### **1.2.6 Possible consequences of non-compliance in health care**

The personal consequences for patients who are non-compliant with their prescribed treatments can range from being relatively insignificant to being life threatening, even with the same medication; for example, a patient taking a diuretic to control premenstrual fluid retention may only suffer from mild inconvenience or discomfort if they fail to take their medication, whereas an elderly patient with congestive heart failure may develop pulmonary congestion and could die if they fail to take diuretic.

<sup>35</sup> The implications of non-compliance for society should also be considered; these include the cost of filling prescriptions which are not taken, increased use of health care services to deal with disease complications, and the cost of patient hospitalization and morbidity.<sup>36</sup> Several attempts have been made to quantify the economic implications of non-compliance with therapeutic regimens. The most recent estimate in Canada was that non-compliance with drugs was costing \$8 to \$10 billion in 2006 and correlated with about 140,000 hospital admissions and 35,000 deaths each year.<sup>37</sup>

### **1.3 A chronological review of soft contact lenses and care systems**

Because the vast majority of studies investigating compliance was with the wear and care of soft (initially hydrogel) lenses and these lenses now represent more than 90% of all lenses fitted and worn worldwide, this review and research will concentrate on these lenses.<sup>38,39</sup> While there have been significant enhancements to contact lens materials since soft lenses were first introduced, the changes which are most likely to have played a role in contact lens compliance are the recommendations which are made for lens replacement by both the manufacturer and the eye care practitioner (ECP).

### 1.3.1 Soft contact lenses

The first successful hydrogel (poly-2-hydroxyethyl methacrylate or polyHEMA) contact lens was developed by Otto Wichterle in the late 1960's.<sup>40</sup> Soft lenses were initially introduced in the early 1970s and are now the most prescribed lens type worldwide.<sup>41</sup> Initially lens replacement was only felt to be necessary when the lenses were either permanently deposited or damaged. It has since been established that frequently replacing lenses diminishes lens spoilage and complications and is considered to offer greater safety for contact lens wear.<sup>42-47</sup>

Soon, lenses began to be classified according to their replacement schedule.<sup>48</sup> The term “conventional replacement” was used to describe lenses that are replaced when they were damaged or when either discomfort symptoms or deposits prevented them from being worn for longer; according to this modality, lenses were typically replaced every six to 24 months. The term “planned replacement” was initially used to describe lenses that were changed according to a pre-determined schedule, usually at intervals ranging from one to six months; however, this modality has more recently been associated with lenses that are replaced at intervals of three to six months. “Disposable lenses” is the term that was initially reserved for lenses which were planned to be discarded and replaced after a single wearing period, with no cleaning and disinfecting ever taking place. In the case of daily disposable lenses this would be a one daytime wearing period and in the case of lenses worn on extended or continuous wear regimen, lenses could be worn for both day and nights for periods of seven to 30 days, depending on the specific approval for the lenses. However, the term “disposable lenses” is now frequently synonymous with lenses which are removed for regular cleaning and disinfection and replaced after a period of one week to one month.

The idea of an extended wear (EW) modality originated in the early to mid 1970s in the United Kingdom with high water hydrogels developed by John de Carle; these lenses were able to provide higher levels of oxygen to the cornea and were therefore prescribed to be worn overnight as well as during the day.<sup>49,50</sup> Preliminary results indicated that these lenses were well tolerated, and EW for cosmetic use for up to 30 consecutive days was approved by the FDA in 1981. Unfortunately it was not long before reports of hypoxic, inflammatory and infectious complications began appearing in journals, and the safety of EW was questioned.<sup>51-57</sup>

Despite these setbacks, higher water content lenses were not abandoned, and all the major contact lens manufacturers continued to develop high water content materials in the early to mid 1980s and their use for daily wear rapidly grew.<sup>58-61</sup> Unfortunately, even in a daily wear modality the lenses were not trouble free, and deposition and durability issues resulted in companies trying to develop materials that could be replaced on a regular basis.<sup>45,62,63</sup> Since lathing proved to be too expensive, new manufacturing methods were required. The first “disposable lens” was introduced in Denmark in the early 1980s.<sup>64</sup> Unfortunately these lenses could not be reproduced in a satisfactory way to be commercially successful; however, the technology behind their development was purchased by Johnson and Johnson in 1984 and resulted in the release of the first true disposable lenses in June 1988 (Vistakon Acuvue). Other manufacturers followed with their own disposable lenses and the ultimate disposable lens became a reality in August 1994, with the introduction of the first daily disposable lenses.<sup>65,66</sup>

The next major advancement in contact lenses was the launch of a new family of hydrogel materials based on silicone technology in 1999.<sup>67-72</sup> Silicone hydrogel (SiHy) contact lenses were able to significantly increase oxygen performance compared with conventional hydrogel contact lenses and

were initially developed for continuous wear (CW) for periods of up to one month.<sup>73</sup> Once again though, lenses that were originally designed for one modality quickly switched to another, and the majority of SiHy lenses are now worn on a daily wear basis and require appropriate lens maintenance procedures. Since the inception of this thesis research, SiHy lens materials have been incorporated into a daily lens wear modality<sup>74-76</sup> and results reporting compliance for patients wearing these lenses are reported in Chapter 6 of this thesis.

### **1.3.2 Contact lens care systems**

Contact lens solutions form the cornerstone of overall care of contact lenses, but for full compliance they are required to be used according to product specific instructions, which generally include digital rubbing and rinsing, soaking and lens case hygiene. Over the past 30 years solutions have gradually evolved towards simpler regimens in an attempt to aid compliance and improve convenience for the patient. However, it is important to recognize that the majority of early studies were conducted when care systems were more complicated and to consider compliance rates in the context of the time over which they were reported and which products were available at that time.

The primary function of a contact lens care system is to disinfect contact lenses satisfactorily prior to their re-insertion and to ensure that the lenses do not act as a vector for the transfer of pathogenic microorganisms to the eyes.<sup>77</sup> This microbial efficacy must be balanced with compatibility with the ocular tissues and the system should be relatively convenient and inexpensive to use.

Some of the first soft lens care systems consisted of a surfactant cleaner and a saline solution that was made at home from distilled water and salt tablets and then thermally disinfected.<sup>78,79</sup> Initially, adapted baby bottle warmers were used to heat the saline solution, but these were later replaced by

electrical units which plugged into the household electrical supply. Unfortunately the homemade soft lens saline solution was easily contaminated and soon became linked to a series of infections, the most serious being *Acanthamoeba spp.*<sup>80,81</sup>

Thermal disinfection soon became replaced by chemical disinfection systems including the popular three bottle set from Burton and Parsons: Normol (saline), Flexol (storage solution and disinfectant) and Preflex (surfactant cleaner); the set also came with rewetting drops (Adapettes).<sup>82,83</sup> This system was used by the author (KAD) in the late 1970s and is pictured in Figure 1-1. An analogy was often made between these early soft contact lens care systems and “chemistry kits”, particularly when they were prescribed with accompanying protein removal tablets. The preservatives used in the early chemical care systems often caused ocular irritation and hyperemia, principally as a result of the degradation of the preservative thimerosal, as well as the uptake and release of the preservative Chlorhexidine from the lens.<sup>84-87</sup> In addition to the irritation which could be caused by the preservatives, the multi-step, somewhat complicated approach to caring for lenses invited non-compliance.



**Figure 1-1: An example of a contact lens care system from the 1970s**

*(photograph courtesy of Andrew Gasson)*

In an attempt to reduce the ocular irritation from the preservatives that were available at the time, non-preserved saline rinsing solutions were introduced that were either in a unit dose format or dispensed from an aerosol to prevent contamination by microorganisms.<sup>87-90</sup> Saline solutions preserved with sorbic acid also became popular because they were generally associated with less irritation on lens insertion.<sup>91</sup> Unfortunately patients could still be non-compliant with the use of these products.

Hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) systems were also introduced for disinfection in the 1970s.<sup>92</sup> These employ 3% (30,000 parts per million or ppm) hydrogen peroxide as the disinfectant. Once the lenses have been disinfected, this peroxide must be neutralized to prevent toxic reactions when the lenses are



reinserted.<sup>93,94</sup> This can either be achieved in a two-step process, where the hydrogen peroxide solution is replaced by a neutralizing solution for a period of time prior to reinsertion, or a one-step process where the neutralization is initiated, but delayed in time to ensure that a sufficient concentration of the H<sub>2</sub>O<sub>2</sub> is maintained for a minimum period of time to allow complete disinfection.<sup>95,96</sup>

When lenses which were designed to be replaced after intervals of two-weeks to one-month were introduced in the 1990s, there was a reduction in the perceived value of using a separate surfactant cleaner. At the same time, products were being developed that incorporated “built-in” surfactants and sequestering agents which helped to remove protein and eliminated the requirement for separate protein removal tablets.<sup>97-99</sup> Solutions started to be labeled as being “no rub” and many patients simply followed this instruction, not realizing that a rinse step was still required to ensure adequate disinfection.<sup>100-103</sup> Rubbing and rinsing may only be seen as a way of “cleaning” lenses by many patients, but it has actually been shown to be extremely important in removing more than 90% of microorganisms from the lens, enabling the disinfection process.<sup>104</sup> Failing to rub and rinse lenses has also been reported to be associated with an increased risk of microbial keratitis.<sup>105</sup>

Modern care regimens basically consist of a combination of antibacterial agents, surfactants or wetting agents, chelating agents, demulcents and a number of other agents that primarily assist with control of pH and osmolality<sup>106,107</sup>.

#### **1.4 An historical review of non-compliance in contact lens wear**

This represents a review of the literature relating to non-compliance in contact lens wear, with an emphasis on soft contact lenses, up until the preliminary work for this thesis was commenced (2009).

Relevant publications subsequent to this time will be examined in the discussion for the thesis in Chapter 8.

#### **1.4.1 First studies of non-compliance in contact lens wear**

Non-compliance with recommendations for contact lens wear and care is extremely common and was first reported in the 1980s. 108,109 Recognizing that the failure to carry out contact lens maintenance procedures could interfere with successful contact lens wear, Collins and Carney conducted a study in which they evaluated the compliance of 100 current contact lens wearers (82 hydrogel lens wearers and 18 RGP lens wearers) at two university clinics in Australia. 108 The study comprised three parts; a series of standardized questions relating to contact lens wearing behaviour, lens care and maintenance; demonstration by the study participants of their current care procedures; and subsequent evaluation of the participants' clinic records to evaluate deposits, corneal staining and subjective symptoms which could potentially be considered to be as a result of poor compliance, and could not be otherwise explained (e.g. not attributable to poor lens fit, lens damage etc.). Fourteen aspects of non-compliance were identified from the standardized questions and demonstrations and these are listed in Table 1-1, along with the proportion of participants reporting or demonstrating each of these aspects.

**Table 1-1: Incidence of specific aspects of non-compliance**

Aspect of non-compliance	Patients (%)
Irregular use of daily cleaner	20
Inadequate technique with daily cleaner	29
Irregular use of rinsing solution	5
Inadequate rinsing technique	20
Reusing rinsing solution	2
Irregular replacement of disinfecting solution	18
Irregular use of thermal disinfection	1
Irregular use of periodic cleaner	3
Leaving lenses too long in periodic cleaner	3
Using daily cleaner after chemical disinfection	9
Using daily cleaner after thermal disinfection	10
Using daily cleaner after periodic cleaner	10
Irregular cleaning of contact lens case	28
Inadequate hand hygiene	16
One or more aspects of non-compliance	74

*Table reproduced from Collins and Carney, Am J Optom Physiol Opt. 1986.*

Overall, 74% of the participants were non-compliant in one or more aspects and the majority of these people were unaware that their procedures were incorrect or inadequate. Clinical record review showed 32% of those who were non-compliant had corneal staining which could not be otherwise explained; 42% had significant lens deposits and 24% had subjective symptoms. A compliance index was generated for all the participants and this was compared with the signs and symptoms recorded. A significant relationship was found between the signs and symptoms and the compliance index, and as non-compliance increased, there was a corresponding increase in the total prevalence of corneal staining, surface deposits and subjective symptoms. The length of wear experience, type of lenses worn, gender and type of disinfection system used, were found to have no influence on the level of compliance.

In a separate publication, the authors further investigated the specific aspects of non-compliance that had been identified and compared these with the incidence of lens wearing problems recorded.<sup>110</sup> Their analysis showed that there was more corneal staining in participants who irregularly changed their disinfecting solution, irregularly cleaned their contact lens cases and irregularly washed their hands; there were more lens deposits for participants who irregularly used a daily cleaner and irregularly changed their disinfecting solution; however, there were no specific aspects that were identified for those with symptoms. In this publication the authors reported that there was a lack of understanding of the function of care and maintenance procedures by up to 20% of participants but that this was not influenced by the level of compliance. In addition, between 12 and 23% were unable to name their care and maintenance solutions and between 4 and 8% were unable to recognize the solution packages when they were shown them.

The first report of a study investigating compliance with contact lens care in North American was by Chun and Weissman.<sup>111</sup> In the study, three criteria were used to assess the history of compliance in 50 patients (29 hydrogel lens wearers and 21 RGP lens wearers). These criteria were (1) always washing hands before lens manipulation, (2) using an FDA-approved care system in an appropriate manner and (3) wearing lenses only on a daily wear schedule for lenses not approved by the FDA for extended wear, or for periods of less than 30 days if the lenses were approved for extended wear. Overall, 60% of the daily lens wearers were considered compliant, however this varied considerably between those who were experienced lens wearers (38%) and those who were new to contact lens wear (72%). Younger patients (ages 10 to 30) and older patients (over 50 years) were also found to be less compliant. No differences were found in the rates of compliance for those in hydrogel versus RGP lenses.

Since the late 1980s, extended wear (EW) of disposable hydrogel contact lenses had been gaining popularity among patients and ECPs. The first study specifically investigating compliance with instructions for lenses worn on an EW basis was conducted in 1986.<sup>112</sup> Compliance with this modality was found to be poor too and 27% of the non-compliant wearers in this study were unaware that they were doing anything wrong.

#### **1.4.2 Types of non-compliance**

A number of ways in which contact lens wearers could be non-compliant with their wear and care procedures was reported by Collins and Carney and summarized previously in Table 1-1. Contact lenses and care systems have progressed since the first compliance studies were conducted and the main aspects of non-compliance which may be associated with a greater risk of corneal infection or inflammation are now considered to be: inappropriate hand washing prior to lens handling;<sup>113,114</sup> failing to clean (rub and/or rinse) lenses;<sup>104,115</sup> topping up or re-using disinfecting solution;<sup>116,117</sup> failure to clean and/or replace contact lens cases;<sup>118</sup> using tap water either directly or indirectly (showering or swimming) with lenses;<sup>118-122</sup> sleeping while wearing lenses when this has not been specifically recommended;<sup>123</sup> and wearing lenses for longer than recommended before replacement.<sup>117</sup> One of the first studies which specifically looked at compliance with planned lens replacement was conducted by Phillips and Prevade.<sup>124</sup> The patients taking part in this study had been instructed to replace their lenses at intervals of six months or less, but were not wearing what were referred to at this time as “disposable lenses” (with replacement intervals of 2-weeks or less).

### 1.4.3 Measurement of non-compliance

Reporting the level of non-compliance with contact lens wear is complicated and depends largely on the method of assessment, the aspects of compliance assessed and the criteria used to determine non-compliance. Recognizing the difficulties in assessing compliance with contact lens care compliance, Turner et al proposed a method to assess compliance in contact lens wearers which they claimed could be adapted for different types of care regimen.<sup>125,126</sup> Their first publication in 1993 described the method when applied to the assessment of compliance with a hydrogen peroxide system, which was popular at this time (AOSept).<sup>125</sup> The manufacturers' instructions for this system mandated the use of a separate surfactant cleaner and a saline rinse to be used after cleaning and after disinfection, prior to lens insertion. In their study, three separate elements were assessed: subjective comfort; the way the system was reported to be used; and a laboratory assessment of the pH and residual amount of hydrogen peroxide remaining after disinfection. Only 1% of participants were found to be fully compliant with the regimen; however, many "steps" were required for patients to be considered compliant in this study and "non-compliant behaviour" was assigned to participants for simply failing to "shake their contact lens case" or "shaking their case too hard" in the analysis. In a follow-up study using the same methodology, the authors reported a slightly higher compliance rate (9%) with a multipurpose care regimen;<sup>126</sup> once again though, in this study 25 individual "steps" were determined to be important for compliant behaviour and it was relatively easy for patients to be considered "non-compliant", when their actions may not have been thought to be particularly hazardous by many clinicians. The so called "non-compliance" rates reported in these studies, where strict adherence to multiple steps was required to achieve full compliance, underlines the importance of keeping the scientific, clinical and "real life" aspects of this topic in perspective when reading the literature.

The majority of studies investigating contact lens compliance have used either self-report or paper questionnaires to evaluate the wearers' behaviour with respect to looking after their lenses. In 2007, Morgan utilized the Internet to conduct a contact lens compliance study in seven European countries.<sup>127,128</sup> More than 1400 contact lens wearers completed a web-based survey about their lens wear and care procedures and their communication with their ECP. A "traffic light" approach to their responses was implemented in which a green response indicated that the wearers was fully compliant with the procedure being evaluated, and amber response indicated a moderate level of non-compliance that could result in a problem if it were to occur frequently, and a red response which corresponded with either very non-compliant behaviour or repeated actions of non-compliance. A total of 14 steps were evaluated and overall only 0.3% of the daily wear respondents and 2.7% of the EW respondents were fully compliant with all 14 steps. The highest level of compliance was reported for using the correct solution; a moderate level of compliance was reported for wearing lenses for no more days than recommended, not wearing lenses overnight unless recommended, hand washing and replacing lens care solution; the lowest level of compliance was reported for napping while wearing lenses, replacing the lens case, cleaning the lens case and checking expiry dates.

#### **1.4.4 Prevalence of non-compliance**

Because of the many different ways in which non-compliance in contact lens wear can be assessed, reporting on the overall prevalence is difficult and it is not surprising that the rates reported vary so dramatically. In an attempt to summarize the prevalence of non-compliance that has been reported from when the early studies were conducted up until the preliminary work for this thesis was initiated, a table has been generated (Table 1-3). This table does not include the non-compliance rates with

respect to swimming in lenses because only two studies have specifically reported on this and the rates varied from 20% to 56% of respondents.<sup>129,130</sup>



**Table 1-2: Prevalence of non-compliance (%)**

Author(s)	Year	Overall	Hand hygiene	Daily cleaning	Rinsing	Disinfection	Case care	Enzyme cleaning	Longer wear time	Overnight wear	Lens replacement	Follow-up visits
Collins & Carney <sup>108,110</sup>	1986	74	16	29	20	18	28	3				
Chun & Weissman <sup>111</sup>	1987	60										
Sokol et al <sup>129</sup>	1990	46	14	32				52	78			56
Collins et al <sup>131</sup>	1993		3 – 22	9 – 15		0 - 4	25					
Phillips & Prevade <sup>124</sup>	1993	68									3	5
Turner et al <sup>125</sup>	1993	91					28 - 86			16 - 50		
Radford et al <sup>132</sup>	1993	87	50				72					
Claydon et al <sup>133,134</sup>	1986 1987	3 - 50	22-23	29 – 47	7 – 40	3 - 7	20 - 32		65		11	39
Coopersmith & Weinstock <sup>135</sup>	1997										31 - 38	
Ky et al <sup>136</sup>	1998			24		5		25 – 43				35
O'Donnell & Efron <sup>137</sup>	2004		16 – 37	6 – 37	9 – 19	3	25 - 28			3 - 7	16	
Yung et al <sup>138</sup>	2007	60	35	35	40	12	65	38			22	
Morgan <sup>127,128</sup>	2007	99.7	28			30	86			35	40 - 60	

### **1.4.5 Comparisons with other types of therapeutic treatment**

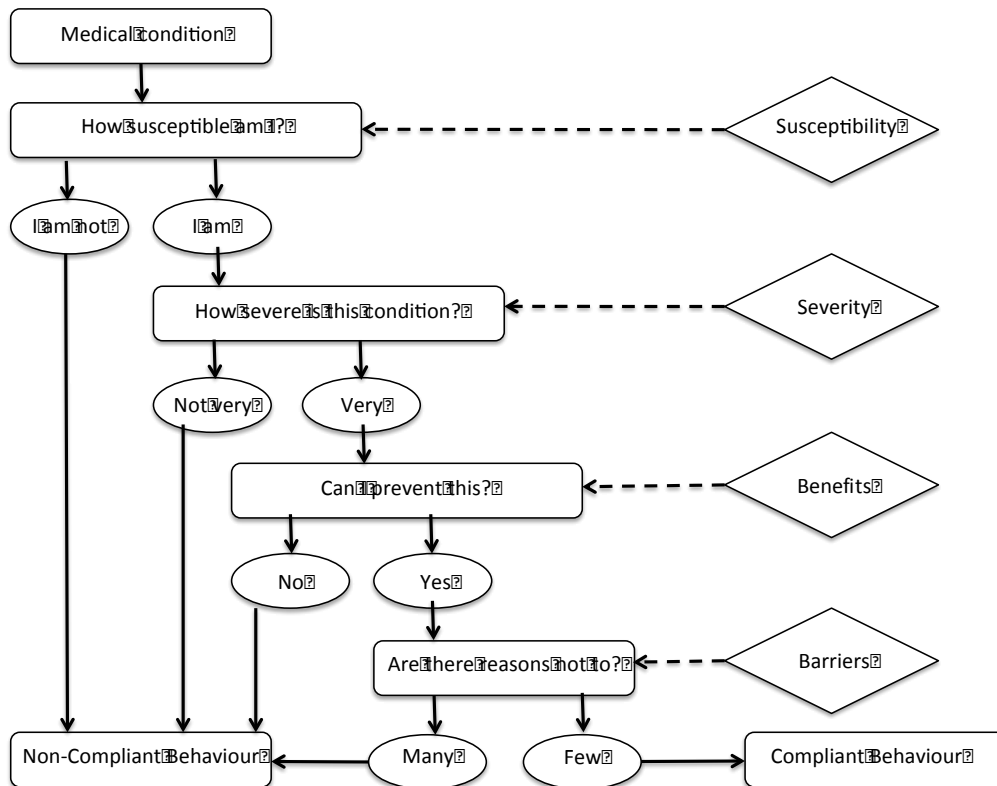
Patient compliance has been widely studied in ophthalmology and in particular in the treatment of glaucoma.<sup>139,140</sup> Non-compliance with glaucoma treatment has been reported to be between 25% and 50%.<sup>140</sup> The first paper to compare patient compliance with contact lens wear with compliance with a form of therapeutic treatment, was published in 1990.<sup>141</sup> This review considered contact lens care to be analogous to chronic diseases with minimal symptoms that required some sort of alteration to the patient's daily routine. The example of glaucoma therapy was used. Forgetfulness, boredom and complacency were given as possible reasons for non-compliance and a similarity between the expense and complicated nature of the treatment for glaucoma and the care for contact lenses was suggested. In addition, it was postulated that just as a patient being treated for glaucoma may not notice a difference when they did not follow their treatment regimen appropriately, a contact lens wearer may not have any symptoms if they failed to care for their lenses exactly as they had been instructed. This review article stressed not only the importance of the optometrist giving instructions to their patient, but also the rapport between the two for ensuring continued compliance.

## **1.5 Determinants of non-compliance in contact lens wear**

### **1.5.1 The Health Belief Model**

In 1990, a well recognized psychological modelling was used for the first time to explore factors which may determine patient compliance with contact lens wear.<sup>129</sup> The Health Belief Model (HBM) had already been used in public health research for some time when this study was conducted.<sup>142-144</sup> In this model, patients with a particular medical condition are thought to behave according to their individual beliefs relating to the condition. Patients will first consider how susceptible they consider themselves to contracting the condition, how severe they consider the condition to be, what the

benefits may be of preventing them from contracting the condition and what reasons or barriers they may face to prevent them from contracting the condition. The HBM hypothesises this decision making process in these four dimensions and an adaptation to this model made by Sokol et al is reproduced in Figure 1-2.<sup>129</sup>



**Figure 1-2: Components of the Health Belief Model**<sup>129</sup>

The key element of this study was the inclusion of a series of statements in the survey that was completed by 50 contact lens wearers. These statements were each rated on their level of importance to the participants, from being “very important” to “somewhat important”, “not important” or “undecided”. A positive association was found between non compliance and: not following the eye

care practitioner (ECP) instructions (susceptibility); lack of concern over ruining their lenses (severity); lack of a sense that a lens hygiene routine can prevent complications (benefits); and media influence, the amount of effort required to take care of lenses and the cost of contact lens care supplies (barriers). The authors concluded that the HBM was an effective model for exploring compliance-related behaviour and that unfavourable beliefs from each of the four dimensions of the HBM were represented in the responses of the non-compliant participants. They also reported that not every belief in the model was considered to be equally significant by their patients, and the concern that correlated positively with non-compliant behaviour was a concern for ruining their lenses. Forty-six percent of participants were judged to be non-compliant in the study in that they followed all the guidelines but two. When evaluating specific aspects of non-compliance, 32% did not clean their lenses appropriately, 52% did not use an enzyme cleaner, 14% failed to wash their hands prior to handling their lenses, 78% wore their lenses for longer than recommended and 56% did not have a regular schedule for follow-up visits.

The HBM was also used by Asbell et al when they conducted a study involving 100 EW disposable lens wearers.<sup>145</sup> The definition of “compliance” that was used in this study related specifically to the use of an EW lens wear modality. Although 90% of participants were classified as being “compliant” because they reported by telephone survey that they replaced their lenses at intervals of no more than the recommended period of two weeks, 62% removed and then reinserted the same pair of lenses during this period, which could be considered to be “non-compliant” dependent on the care and maintenance procedures that they reported to have used. Interestingly, although the HBM was also applied in this study, no significant differences were found between the compliant and non-compliant groups in this study.

### 1.5.2 Patient perceptions

Donshik et al conducted a survey in which they investigated the knowledge, attitudes and practices with respect to lens wear and care of 111 current contact lens wearers.<sup>146</sup> Most of the respondents to the survey considered contact lens complications to be relatively common, but over 60% were unable to name a specific problem that may occur. The respondents were also asked whether they considered a number of activities to be associated with either an increased risk or decreased risk of a complication occurring and the results are shown in Table 1-3. While some of the results are not surprising, it was particularly interesting that some respondents thought that using fresh solution, refilling the solution in the lens case, replacing the lens case and washing their hands actually *increased* their risk of developing a complication. In addition 10% thought that rinsing their lenses with tap water decreased their risk and 13% thought that it had no effect. The respondents were not specifically asked about cleaning their cases in the survey.

**Table 1-3: Perceptions of risk factors**

Activity	Increases risk (%)	Decreases risk (%)	No effect (%)
Sleeping in lenses	85	2	5
Sharing lenses	84	4	5
Wearing time longer than recommended	81	4	6
Replacement longer than recommended	78	5	8
Swimming with lenses	75	2	14
Using fresh solution	17	72	2
Refilling solution in lens case	17	69	5
Rinsing lenses with tap water	69	10	13
Replacing lens case	15	68	7
Washing hands	27	55	5

*Reproduced from Donshik et al, Eye & Contact Lens 2007<sup>146</sup>*

### 1.5.3 Patient instructions and clinician interactions

In 1987 the FDA started to express interest in compliance of contact lens wearers and conducted a survey of DW and EW contact lens wearers.<sup>130</sup> The main areas of non-compliance which were recognized were: poor hand hygiene, lack of case hygiene, wearing lenses for longer than recommended, lack of follow up care and improper solution use. The survey also found that patients frequently reported not having been given any recommendations or instructions with respect to caring for their lenses, or if they had received some information, they showed confusion about what they reported that they had been told. This supports the finding of Davidson and Akingbehin who found that patients forget from one third to one half of what they are told at medical appointments within minutes of leaving the office.<sup>140</sup>

A contact lens compliance study was conducted in 1990, which specifically investigated the relationship between clinicians' interpersonal communications skills and patients' motivation, satisfaction and compliance with care and maintenance instructions.<sup>147</sup> Questionnaires and interviews were used to show that the quality of the contact lens clinician's interpersonal skills was able to substantially influence patient outcomes and perceptions. Shortly after this, Collins et al designed a study to investigate the effect of lens care system instructions on the rate of initial compliance.<sup>131</sup> Novice lens wearers used three different care systems (each according to the instructions provided by the manufacturer) for periods of two weeks, in a randomized order; prior to this, all the subjects were initially adapted to lens wear while using a two-step hydrogen peroxide system. The subjects were concurrently participating in a monovision study and were therefore more mature than subjects previously investigated in contact lens compliance studies. Good compliance with disinfection procedures was demonstrated with all three systems (96% or better), but compliance with daily

cleaning was slightly lower (85 – 91%); there were no differences according to which system was used. Compliance with case cleaning was lower (75%) and did vary according to which system was being used; the instructions for case cleaning also varied from a daily rinse and dry, to a weekly rinse and dry or simply an occasional rinse. Compliance with hand washing was found to improve during the course of the study from an initial low rate of 78% to a higher rate at the end of the study of 97%. The authors concluded that when patients start to initially wear lenses, hand washing and case cleaning appear to be the aspects with which they are least compliant. Regular monitoring and reinforcement of instructions should be conducted in order to improve compliance and minimize the risk of adverse events that may occur as a consequence of poor compliance.

Many of the early studies investigating compliance with contact lens wear were conducted in specialist clinics at universities and hospitals. In an attempt to evaluate compliance in the general population, a study was conducted in the UK in the early 1990s in which more than 200 asymptomatic patients, originating from many different practices, were initially interviewed regarding their habitual lens care procedures and then a sub-sample were evaluated once again following re-instruction regarding appropriate lens maintenance methods.<sup>132</sup> A weighted scoring system was used to classify subjects' compliance. Only 13% were judged to be fully compliant with their care and maintenance; 32% had "fair" compliance and 55% had "poor" compliance. The most commonly reported aspect of non-compliance related to inappropriate case care (72%); this was followed by poor hand hygiene (50%). Age and sex were not found to be factors influencing compliance and there were also no differences between subjects who were working and students. Some differences were found between RGP and soft lens wearers, but these could be attributed to the different procedures required for the care of these different lens types. Once again subjects who had been wearing lenses

for longer were more likely to be non-compliant, as were subjects who wore their lenses longer each day. All subjects received a de-brief session at the conclusion of their interview. Three months after the original survey was conducted, a sub-sample of non-compliant subjects (46 subjects) were contacted by mail and asked to complete a survey which incorporated the same questions as were asked in the original interview, and the responses were scored using the original weighting system. Eighty-three percent of the subjects responded and the authors reported that re-instruction of this population had raised the level of “fair” compliance in this group from 45% to 84%.

In a study involving children aged 11 to 14, Soni et al were able to show that after six months of soft contact lens wear, 85% the children were able to correctly identify the purpose of the lens care solutions that they were using; 90% knew that they should be cleaning their lenses each day; and 96% understood the lens disinfection.<sup>148</sup> They suggested that the reason for the high levels of compliance and understanding were most likely related to the intensive instructions and demonstrations which were given to the children prior to being dispensed with their lenses.

A later study was conducted to determine whether compliance with contact lens wear could be improved when written information was given in addition to oral instructions.<sup>149</sup> The type of instructions provided was determined according to the results from a prior written and oral comprehension test; subjects who performed better in the oral portion received only oral instructions and subjects with higher scores in the written portion received both types of instructions. Overall compliance was reported to be greater than 80%, but no difference was found in the compliance rates of the two groups. Drawing conclusions from these results is somewhat difficult however since the study design was not able to take account of other possible differences between the two groups of individuals.



#### **1.5.4 The role of product cost**

The cost of treatment has been found to be an important barrier to compliance in other areas of health care.<sup>2,150</sup> It is interesting, however, that when treatment is provided at no cost to the patient there may be no improvement in compliance when compared with patients who are required to pay for the treatment.<sup>151</sup> A short-term prospective study was conducted in the United Kingdom to compare the compliance of subjects who were required to pay the full costs for their contact lens supplies with those who only made a nominal payment.<sup>152</sup> In this study a comparison was made between the calculated volume and number of products which should have been used over a four-month period (prorated for part time wearers) and this was compared with the actual quantity used for each of the products. No differences were found in the level of compliance between the two groups of subjects either by direct measurement or indirect assessment requiring demonstration of lens care procedures by the subjects.

#### **1.5.5 Demographics**

In most of the studies investigating compliance with general health care, no association between patient demographics and compliance has been found.<sup>21</sup> In the contact lens literature there are conflicting reports regarding whether patient demographics can be considered determinants of compliance with recommendations for lens wear and care. While no studies have been able to show a difference in compliance according to sex,<sup>110,112,132,147</sup> some studies have reported an association with age. Both younger (less than 30 years) and older (greater than 50 years) have been reported to be less compliant in some studies;<sup>111,129</sup> others have not been able to show a difference.<sup>132,133,147</sup> Socioeconomic background, education and occupation have also not been found to be relevant with respect to non-compliant behaviour.<sup>112,129,132,147</sup> Experience with lens wear however does appear to be

important, but once again this is reported to have been a factor in non-compliance in some studies,<sup>111,132</sup> but not others.<sup>129,133,147</sup>

## **1.6 Strategies to improve compliance with contact lens wear**

### **1.6.1 Prospective studies**

A study was conducted in the 1990s in the UK, which was designed to specifically assess the effect of a “compliance enhancement strategy” on levels of compliance in contact lens wearers over a one year period.<sup>133,134</sup> In this study 80 current soft contact lens wearers were fitted with monthly replacement HEMA lenses (Medalist 38, Bausch + Lomb, Rochester, New York, USA). All subjects were masked with respect to the study purpose and design (being advised that the study was evaluating a new brand of contact lens), and were randomly assigned to one of two groups. The first group simply attended a basic dispensing visit at which they were given their lenses and a supply of the study care system (ReNu multipurpose solution, Bausch + Lomb, Rochester, New York, USA) along with the manufacturer’s instructions. Follow up visits were scheduled after two weeks, three months, six months and 12 months. At all visits sufficient supplies of lenses and care system were provided to last until the next scheduled visit. The second group received extensive instruction at their initial dispensing visit which included a checklist to follow, presentation of a complications poster and discussion of the possible adverse events that could occur as a result of not complying with appropriate lens wear and care instructions, and they all were required to view a video describing appropriate use of the care regimen. The second group were also asked to read and sign a contract describing the instructions for care and maintenance and the goals of successful lens wear. They attended visits at the same intervals as the first group and the instructions that they had been given at

the dispensing visit were reinforced once again up until the three month visit. The six and 12 month visits were identical to those for the first group of participants. At the final visit, all subjects completed a questionnaire regarding their knowledge and understanding of the contact lens care and maintenance regimen that they had been prescribed and were asked to demonstrate how they cared for their lenses. A masked investigator assigned scores for each aspect of compliance assessed.

The overall level of non-compliance ranged from 3% to 50%,<sup>153</sup> which was somewhat lower than had been reported for previous compliance studies.<sup>154</sup> Almost 40% of the subjects failed to attend one or more scheduled visits during the study, but there were no differences between the two groups.

Interestingly, no significant differences were found between the two groups in the compliance scores generated from the demonstration or the questionnaire, with the exception of hand washing; subjects who were not exposed to the compliance enhancement strategy were significantly less compliant when demonstrating this procedure to the investigators.<sup>153</sup> Overall, while 78% reported always washing their hands prior to handling their lenses, only 60% were judged to have washed their hands thoroughly in the demonstrations. Forty-seven percent of the subjects reported non-compliant cleaning procedures (rubbing and rinsing) and knowledge of how the care system worked was poor with only 46% being able to explain this adequately. Sixty-five percent reported that they wore their lenses for longer than the recommended daily wearing time; however, there is no report of how many wore their lenses while napping or sleeping overnight. Eleven percent were non-compliant with the monthly replacement schedule. Several possible explanations were given by the authors for why there were no differences in compliance as a result of the compliance enhancement strategy; these included the relatively simple care system and replacement schedule which were used, the provision of free contact lenses and solutions for the duration of the study, the high proportion of subjects who were

either students or employees of the university at which the study was conducted, the design of the compliance enhancement strategy and the indirect methods of assessment which were used during the study. They also discussed the possible effect of simply taking part in a study which has been shown to affect behaviour and performance.<sup>155</sup> Often referred to as the “Hawthorne effect”, this can occur when subjects are taking part in an experiment or study; the individual attention may bias the response and lead to a change in their behaviour or a perceived improvement in a condition.<sup>156-158</sup>

A second study investigating the effect of a compliance enhancement strategy was conducted more recently.<sup>138</sup> In this study compliance was assessed prior to intervention, along with an assessment of microbial contamination of the subjects’ habitual contact lenses, cases and solution bottles. Sixty percent of the subjects were judged to be non-compliant in that they failed to carry out at least six of the 15 aspects associated with lens care and maintenance which were assessed. Forty-five percent showed microbial contamination of their habitual lenses and/or accessories. All subjects were re-educated on all aspects of lens care and maintenance and then followed for a 12 month period during which one randomly assigned group received a self-review exercise by email after 3 and 9 months and in person at the 6 month follow up visit (test group); the other group simply attended a 6 month follow up visit (control group). At the 12-month visit the compliance was once again assessed and the subjects’ lenses and accessories tested for microbial contamination. Overall compliance improved for both groups at the end of the 12-month period, but the only difference between the two groups that was significant was a greater improvement in case cleaning in the test group when compared with the control group. Microbial contamination decreased slightly too, to 38%, but this was not significant and there were no significant differences between the two groups. The authors concluded that simply taking part in the study resulted in an improvement in compliance, likely as a result of a Hawthorne

effect, but that the only significant improvement as a result of the compliance enhancement strategy was an improvement in the lens case cleaning procedures.

### **1.6.2 Compliance enhancement models**

Predicting and enhancing patient compliance with contact lens wear has proven to be challenging. Regardless of this, compliance enhancement models have been proposed in an attempt to improve compliance among contact lens wearers. The first model was proposed by Efron in 1997.<sup>153</sup> The model comprised four components of principles and guidelines for: (1) The clinic or office and the ECP, (2) the patient, (3) the advice that is given and (4) the contact lens industry. A decade later, Donschik also proposed a model to engage, educate and empower patient compliance for safe contact lens wear.<sup>146</sup> This “model” has five components: (1) Patient education, (2) increased ECP involvement, (3) safer care regimens, (4) education of ECPs, patients and legislators and (5) the importance of conducting further research into the causes of contact lens complications.

## **1.7 Possible consequences of non-compliance with contact lens wear**

Non-compliance with recommendations for appropriate contact lens wear and care has been shown to be associated with several undesirable consequences for the wearers.

### **1.7.1 Contact lens deposits**

In the early study conducted by Collins and Carney<sup>108,110</sup> participants who were non-compliant with correct procedures for cleaning and disinfecting their lenses showed higher levels of lens deposits. An increase in protein deposition was later reported by Michaud and Giasson in study participants who

were asked to intentionally wear their daily disposable or two-week replacement lenses for intervals of up to 30 days.<sup>159</sup>

### **1.7.2 Ocular surface changes**

Failure to change disinfecting solution, irregular cleaning of contact lens cases and irregular hand washing were also found to be associated with an increase in corneal staining by Collins and Carney.<sup>108,110</sup> Noncompliance with care system use and failure to replace lenses on schedule were found to be factors contributing to corneal staining in hydrogel lens wearers by Nichols et al.<sup>160</sup> Michaud and Giasson were able to show an increase in the severity of upper conjunctival papillae, upper lid conjunctival hyperemia, and limbal congestion in eyes which had been wearing lenses for longer than would normally be recommended.<sup>159</sup>

### **1.7.3 Subjective symptoms**

As non-compliance with lens wear and care increased, Collins and Carney were able to shown an increase in the subjective symptoms reported by their subjects.<sup>106,108</sup> In a survey of over 100 patients conducted in 2002, Jones and Dumbleton were also able to report that more frequent replacement of lenses was associated with better quality of vision and enhanced comfort at replacement, more stable vision throughout the day and reduced dryness.<sup>161</sup>

### **1.7.4 Complications**

A number of complications can occur as a result of non-compliance with contact lens wear and care but undoubtedly the most serious is keratitis, and in particular microbial keratitis. As early as 1981,

Wilson et al were able to establish a link between poor compliance with care regimens and corneal infection.<sup>162</sup> They were able to culture the same serotype of *Pseudomonas* from the contact lens saline solutions that had been prepared from distilled water and sodium chloride tablets as had been cultured from the patients' corneal ulcers. All of these patients reported inappropriate use of their home-prepared saline as either a wetting agent, eye drop, eyebath, or after it had been used for thermal disinfection of their contact lenses. In a study conducted at Moorfields Eye Hospital in the late 1980s, a significant association was found in patients presenting with sterile keratitis (infiltrates) and contact lens hygiene and contact lens case contamination, particularly for daily wear soft contact lenses.<sup>163</sup> A separate study conducted at a similar time at Wills Eye Hospital, also found a frequent association between contact lens wearers presenting with corneal ulcers and contaminated lens care products and/or improper lens care procedures.<sup>164</sup> In a study evaluating complications with daily wear disposable lenses, Garwood showed that the incidence of corneal infection was ten times greater when the lenses were not cleaned and disinfected.<sup>165</sup>

Shortly after this, Matthews et al reported on the results of a case-control study in which they quantified the relative risk of keratitis in daily wear and EW disposable lens wear by examining cases of keratitis presenting to an eye hospital.<sup>166</sup> Patients presenting with keratitis completed a questionnaire evaluating their habitual lens wear and care procedures. Compliance with lens replacement and instructed hygiene was found to be relatively good among daily wear patients, but less prevalent among EW wearers. The authors concluded that poor hygiene and disinfection system failure may, in part, account for the higher rate of keratitis in these patients. Stapleton et al conducted another study soon afterwards investigating the risk factors for developing keratitis in a group of more than 200 contact lens keratitis patients as compared with a group of contact lens wearers presenting

without complications.<sup>167</sup> A multivariable logistic regression analysis showed that the type of disinfection system and its frequency of use were associated with both microbial keratitis and sterile keratitis in daily wear users.

More recent studies have reported an increased risk of 1.5 times for developing microbial keratitis and two times greater for developing sterile keratitis in patients who fail to wash their hands prior to handling their lenses.<sup>114,168</sup> It has also been shown that rubbing and rinsing contact lenses can play a role in reducing the risk of microbial keratitis, suggesting that contact lens wearers who fail to carry out this important step are at a greater risk of developing microbial keratitis.<sup>105</sup> When patients “top up” their solution rather than completely replacing it with fresh solution, incomplete contact lens disinfection can occur; this may present a significant risk for infection and in both the recent outbreaks of *Fusarium* keratitis and *Acanthamoeba* keratitis, topping up solutions was found to be associated with greater risk for infection.<sup>169,170</sup> Poor case hygiene has also been associated with a greater risk of microbial keratitis,<sup>123</sup> and this, along with failing to replace cases at regular intervals, has been shown to be associated with a build up of a biofilm in contact lens cases over time, and the build up may make patients more likely to develop keratitis.<sup>171,172</sup>

## **1.8 Rationale for thesis**

### **1.8.1 Preliminary work**

Much of the early work investigating compliance and contact lens wear was conducted prior to the introduction of silicone hydrogel lenses and the more widespread use of daily disposable lenses. In 2009, the Centre for Contact Lens Research (CCLR) conducted two studies that were designed to specifically investigate compliance with replacement of silicone hydrogel and daily disposable



contact lenses in the United States and Canada.<sup>173-176</sup> The author of this thesis (KAD) was primarily responsible for the concept and design, the acquisition and compilation of the data, and the data analysis for these studies. KAD was also the first author for three of the four resulting manuscripts; however, these were completed prior to registration in the PhD program and therefore it is not appropriate for them to be included as experimental chapters in this thesis. These manuscripts have however been included in Appendix B (with copyright permissions) in order to provide the reader with further relevant background for this thesis. A brief summary of these studies is also provided here.

The aims of the studies were: To assess current recommendations for replacement frequency (RF) of SiHy and DDCLs; to determine compliance with the manufacturer recommended replacement frequency (MRRF) and to evaluate contact lens care and to investigate the reasons for non-compliance. ECPs in the United States (US) and Canada who chose to take part in the studies were asked to invite the next 20 patients wearing DDCLs or SiHy lenses to complete a survey evaluating their contact lens wear and care procedures. If a patient declined, the next eligible patient was then asked. The surveys were confidentially completed by the patients and then sealed in an envelope provided to them, on which the ECP was required to record the lens type, their recommendation for RF and the lens powers. The ECP then returned all the completed surveys (in their sealed envelopes) to the CCLR. Both the ECPs and the patients taking part in the study retained anonymity from the CCLR.

A total of 1,654 surveys from the US and 578 from Canada were eligible for analysis. DDCLs accounted for 16% of the lenses worn by the US respondents and 18% of the lenses worn by the Canadian respondents. Forty-five per cent of US respondents wore two-week replacement SiHy

lenses as compared with 35% of Canadian respondents; and 39% of US respondents wore one-month replacement SiHy lenses as compared with 47% of Canadian respondents. ECPs recommended RFs which complied with the MRRF more frequently with DDCLs and one-month replacement SiHy lenses than with two-week replacement SiHy lenses. In general, the patients recognized the importance of replacing their lenses on schedule, with 78% of wearers in both countries rating this to be either “extremely important” or “important”. What patients do and what they have been told to do may be quite different. Patients were less compliant with RF than ECPs for all lens types investigated. Patients were most compliant with RF when wearing DDCLs (88% US and 87% Canada) and least compliant when wearing two-week SiHy lenses (48% US and 50% Canada). More than half of those not replacing lenses when recommended reported that this was simply because they forgot which day to replace their lenses. The use of a reminder system to improve compliance with RF was supported, with the suggestions of either a cell phone reminder system or establishing a constant day of the week being the most favoured methods for prompting replacement.

Better communication between the patient and the ECP appeared to facilitate greater compliance with RF; the majority of patients felt that it was either “important” or “very important” for their ECP to explain the replacement schedule in detail, but this proportion was significantly higher in those who were compliant with lens replacement when compared with the non-compliant group. A similar difference was found in the responses relating to the importance of explaining the risks associated with non-compliance between the compliant and non-compliant wearers. One particularly interesting finding in the studies was that a much higher proportion of compliant patients claimed that they followed their recommended replacement schedule because they “have complete confidence in their ECP”, when compared with the non-compliant patients. This supports the assertion in the general

health compliance literature that effective communication and a positive relationship between the patient and the health care practitioner can result in improved compliance.<sup>29-31,33,34</sup> A much higher proportion of the compliant wearers agreed with the statement: “I follow the recommended replacement schedule because it leads to fewer problems with my eyes”.

Compliance with contact lens care was also assessed to some degree in these studies. Specific contact lens care procedures such as hand washing, rubbing and rinsing and the use of new solution each day were not evaluated, but respondents were asked how important they thought it was to clean their lenses every day; a higher proportion of the compliant respondents responded that they considered this to be “extremely important” or “important” when compared with non-compliant wearers.

Cleaning cases was considered to be “extremely important” by more than 50% of respondents in both countries, but only half of the SiHy wearing respondents reported replacing their cases at intervals of three months or less.

Another area of non-compliance which was investigated in these studies was sleeping overnight while wearing contact lenses. Nineteen percent of the Canadian participants and 32% of the US participants reported sleeping while wearing their lenses occasionally, frequently or constantly. Although this could not be directly compared with recommendations that may have been made by their ECPs, both of these figures are considerably higher than the proportion of lenses being specifically fitted for overnight lens wear at the time that the studies were conducted (6% Canada and 7% US).<sup>177</sup>

Interestingly 12% of Canadian and 17% of US DDCL wearers reported overnight lens wear. Not only were the materials which were available in DDCLs at the time not suitable for overnight wear, but also these lenses are designed for single use only and should be removed at the end of each wearing

day and discarded. These participants could therefore be considered to be displaying two types of non-compliant behaviour.

The study participants who were wearing re-usable SiHy lenses were also asked to rate their subjective comfort and vision in the morning, evening, when lenses were new and when they needed replacing. Consistent with findings from other studies,<sup>178-181</sup> superior subjective performance, in terms of both comfort and vision, was reported at the beginning of the wearing period compared to the end of the day. Subjective comfort and vision ratings were also higher when lenses were new compared with when they needed to be replaced. It was particularly interesting to find that when the subjective performance of lenses worn by patients who were compliant with the MRRF was compared with those who were not compliant, the comfort and vision ratings in the evening and when the lenses needed replacing were somewhat higher for the compliant wearers, regardless of the replacement modality that had been prescribed for them. This finding supported the early work of Collins and Carney who reported an increase in the subjective symptoms reported in non-compliant wearers and the previous work by our group with conventional hydrogel lenses.<sup>108,110,161</sup>

In these studies we were unable to find a difference in compliance according to sex, years of experience with contact lens wear or degree of ametropia; however we did find a higher level of non-compliance with lens replacement in younger wearers and in those who were wearing toric lenses. Interestingly, we also found that a higher proportion of participants who did not have spectacles with an up to date prescription were non-compliant with replacement of lenses according to recommendations that had been given to them.

### **1.8.2 Objectives and Importance**

At the time that this area of research for this thesis was conceived, no studies had been conducted to specifically evaluate the compliance of patients with respect to the wear and care of lens types that were being worn by a rapidly increasing proportion of the population. In 2012, more than half of the lenses worn world wide and approximately two thirds of lenses worn in Canada and the US were made from SiHy materials, and one third of the lenses worn worldwide were DDCLs.<sup>38,39</sup> While some of the earlier studies on compliance in contact lens wear had evaluated compliance with the wear of two-week and one-month replacement lenses, these had almost exclusively been conventional hydrogel lenses, and no studies had specifically looked at compliance in SiHy and DDCL wearers. The main objectives for this thesis were: to further investigate a number of different aspects of non-compliance; to determine how frequently non-compliant lens wearers experienced contact lens related problems; to determine whether non-compliant lens wearers were less successful and therefore more likely to discontinue from lens wear; and to evaluate whether there was a difference in the frequency with which compliant and non-compliant lens wearers visited their ECPs for eye examinations. In addition, one study was designed to specifically investigate, for the first time, non-compliance with DDCLs and to determine whether this varied between several countries. Finally, a unique study was designed which employed both quantitative and qualitative research methods to explore in detail the lens wear and care habits of contact lens wearers in an attempt to gain a better understanding of what constrains and enables patients to follow recommendations for appropriate lens wear and care.

### **1.8.3 Notes for the reader**

Since this thesis comprises a series of six manuscripts that were generated for journals based in North America and Europe, a consistent format for spelling is not possible. Canadian spelling convention

has been used for the introduction and discussion chapters and a mixture of US and UK spelling conventions is used for Chapters 2 to 7 that is consistent for the journals in which these have been, or are to be published. Similarly different abbreviations may be used for the same words, dependent upon what was used in the original manuscript; for example, sometimes SH is used for silicone hydrogels and other times SiHy is used and both DD and DDCL are used for daily disposable contact lenses. All the abbreviations used are documented in the list of abbreviations at the beginning of the thesis.

In the following chapter of this thesis a preliminary study is presented, which was designed to determine the proportion of contact lens wearers who know what lens and lens care products they are using. The study also investigated how helpful photographic aids can be for contact lens wearers to recall which products they are using. It is particularly important in any studies investigating compliance with contact lens wear and care that the products that a patient is using are accurately reported. The findings from this study were extremely helpful for the design and conduct of subsequent studies conducted for this thesis.

## Chapter 2

### Do Contact Lens Wearers Know What Products They Are Using?

This chapter is published as follows:

Ability of patients to recall contact lens products and enhancement of recall using photographic aids

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*Contact Lens & Anterior Eye* 2011;34:236-240 – Reprinted with permission

	Concept / Design	Recruitment	Acquisition of data	Analysis	Write-up / publication
Dumbleton	Y	Y	Y	Y	Y
Woods M	-	Y	Y	Y	-
Woods C	Y	-	-	-	Y
Jones	-	-	-	-	Y
Fonn	Y	-	-	-	Y

Figures: 8

## 2.1 Overview

**Purpose:** To determine the proportion of soft contact lens (CL) wearers who are able to recall their habitual products (lenses and care system) correctly from memory, and to evaluate the value of using photographic aids (PAs) to improve recall.

**Methods:** 103 soft lens wearers attended 2 visits to investigate their habitual CL product use. At the first visit they were asked to recall which products they were using and then to identify their products from PAs. They returned for a second visit with their products for confirmation.

**Results:** 51% correctly reported their lens brands from memory alone, which improved to 87% with the use of the PAs ( $p < 0.001$ ). 41% correctly reported their habitual care system from memory alone, which improved to 80% with the use of PAs ( $p < 0.001$ ). Females were better at recalling care system brand names than males (49% versus 27% correct,  $p = 0.040$ ) and wearers with more than 1 years' experience with their habitual CLs had better recall than those with up to 1 years' experience (63% versus 27%,  $p = 0.014$ ).

**Conclusion:** Less than 50% of contact lens wearers were able to recall the names of their habitual lens and lens care products correctly from memory. PAs improved this recall significantly for both contact lenses and contact lens care systems.



## 2.2 Introduction

Contact lenses are worn by approximately 125 million people worldwide.<sup>1</sup> Each year there are publications in the literature reporting the relative breakdown of lens types worn by these individuals.<sup>2,3</sup> These data are generally collected from eye care professionals (ECPs) prescribing these lenses and are therefore considered to be a relatively accurate representation of the contact lens types being currently worn. However, when patients are asked about the contact lens types that they wear, either by an ECP or in a survey, it is not known how accurate their recall of the brand names is, particularly if they do not have the packaging materials for their contact lenses with them at the time they are asked. In two recent studies conducted at the Centre for Contact Lens Research, the lens type worn, as reported by the patients, matched that reported by the prescribing ECP for 66% of participants in Canada and 74% participants in the United States.<sup>4,5</sup> In a separate study,<sup>6</sup> 86% of participants were able to name their current care system, however in this case they were responding to the question from their homes and would therefore be able to check the packaging before responding. Accurate identification of products used by patients is of great importance in most areas of health care, and this is particularly the case for the use of medications. Memory aids in the form of medication pictures and lists have been used with success to evaluate past hormone and oral contraceptive use and also to enhance recall of non-aspirin, non-steroidal anti-inflammatory in patients who had experienced acute, first myocardial infarction.<sup>7-9</sup> To our knowledge, a study has not been conducted to specifically investigate the ability of patients to recall habitual contact lens products and the possible enhancement of recall using photographic aids. The purpose of this study was to determine the proportion of soft contact lens wearers who are able to recall their habitual

products (lenses and care system) correctly from memory, and to assess the value of using photographic aids to improve recall.

## **2.3 Methods**

Ethics approval was obtained through the Office of Research Ethics at the University of Waterloo before commencement of this study, and the study was conducted following the tenets of the Declaration of Helsinki. The study comprised two visits, both conducted on campus at the University of Waterloo. Since the aim of the study was to determine the proportion of wearers who could recognize their contact lens products, prospective participants were not told the purpose of the study until after their eligibility had been confirmed. Initially the prospective participants were simply asked if they would like to participate in a study in which they would be asked a series of questions about the use of their contact lenses and lens care products. Informed consent was obtained from all participants at the first study visit prior to enrollment. The participants were primarily recruited either on the main University campus or at the School of Optometry, when they were attending for an unrelated reason.

Participants were considered eligible if they were current soft contact lens (re-usable or daily disposable) wearers at least 17 years old and had purchased their contact lenses in Canada.

Employees of the School of Optometry, optometry students and graduate students were not eligible to participate. Specific appointments were not scheduled for the first visit, which was conducted at the time that participants agreed to take part in the study, so that they were unable to check their contact lens products prior to attending or to bring their products with them. Informed consent was obtained from participants prior to enrolment in the study.

At the first visit, participants were asked to complete a series of questions regarding their habitual contact lenses and lens care system; they were then presented with a series of laminated photographic aids from which they were asked to identify their habitual products. Participants were asked to return to the Centre for Contact Lens Research (CCLR) at the School of Optometry for a second visit and to bring their products at this time. The investigator recorded the names of the habitual products and compared these to the products initially reported. The participants were then exited from the study. Correct recall of a product from memory required the naming of all parts of that product's brand name (i.e. the name brand provided had to be sufficient to allow an eye care practitioner to determine the "exact" product). As an example, "Acuvue OASYS" or "OASYS" were considered correct, but "Acuvue" was not correct; "OptiFree RepleniSH" or "RepleniSH" were considered correct, but "OptiFree" was not correct. For toric lens wearers, both the brand name and "for astigmatism" or "toric" were required in order to be considered correct.

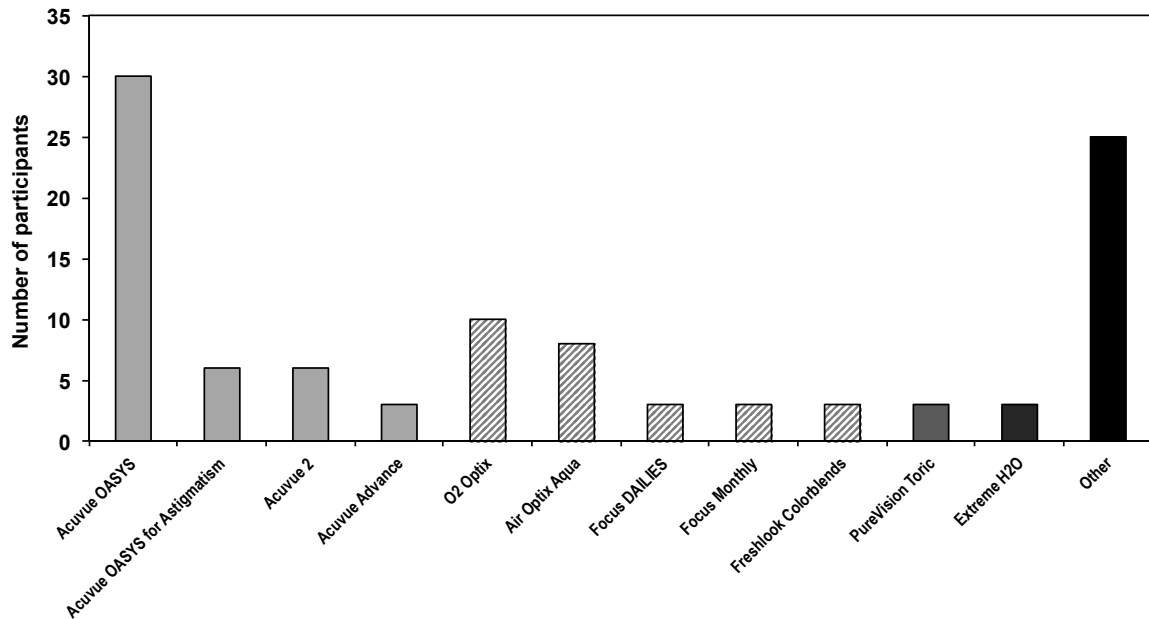
Where relevant, data analyses were conducted using Statistica 9.0 (StatSoft Inc., Tulsa, OK). Data are presented as mean  $\pm$  standard deviation or as frequencies. A two-sided difference between two proportions test was used to compare frequency levels. A significance level of  $\alpha = 0.05$  was used for all analyses.

## **2.4 Results**

One hundred and twenty participants were recruited and enrolled in the study; 103 completed both visits. The data reported are for these 103 participants only (65% female, 35% male). The mean age of the participants was 23 years (median 21 years, ranging from 17 to 55 years). Eighty-seven percent of the participants were students (none from the School of Optometry).

## 2.4.1 Contact Lenses

Figure 2-1 shows the frequency distribution of the lens brands worn by the study participants as confirmed at the second visit. The category “other” includes lens brands worn by less than three study participants (22 brands worn by 25 participants).

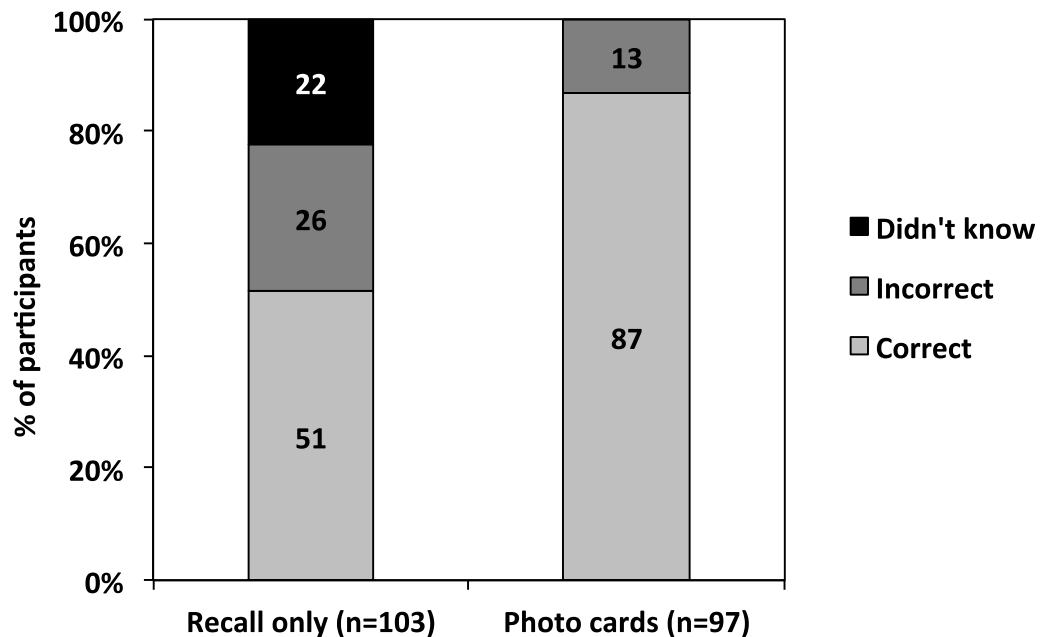


**Figure 2-1: Lens brands worn grouped by manufacturer.**

At the first visit, 51% of the participants correctly reported the lens brand that they were wearing (compared to the packages that were brought in at the second visit). The remaining 49% either incorrectly reported the lens type that they were wearing (26% of total participants) or indicated that they did not know the name (23% of total participants). There was no difference in the proportion of participants who correctly reported their lens type by gender (42% of males correct versus 58% of females correct,  $p = 0.243$ ), but there was a difference with respect to the amount of time that the lens

brand had been worn (27% correct for  $\leq 12$  months wear versus 63% correct for  $> 12$  months wear,  $p = 0.014$ ).

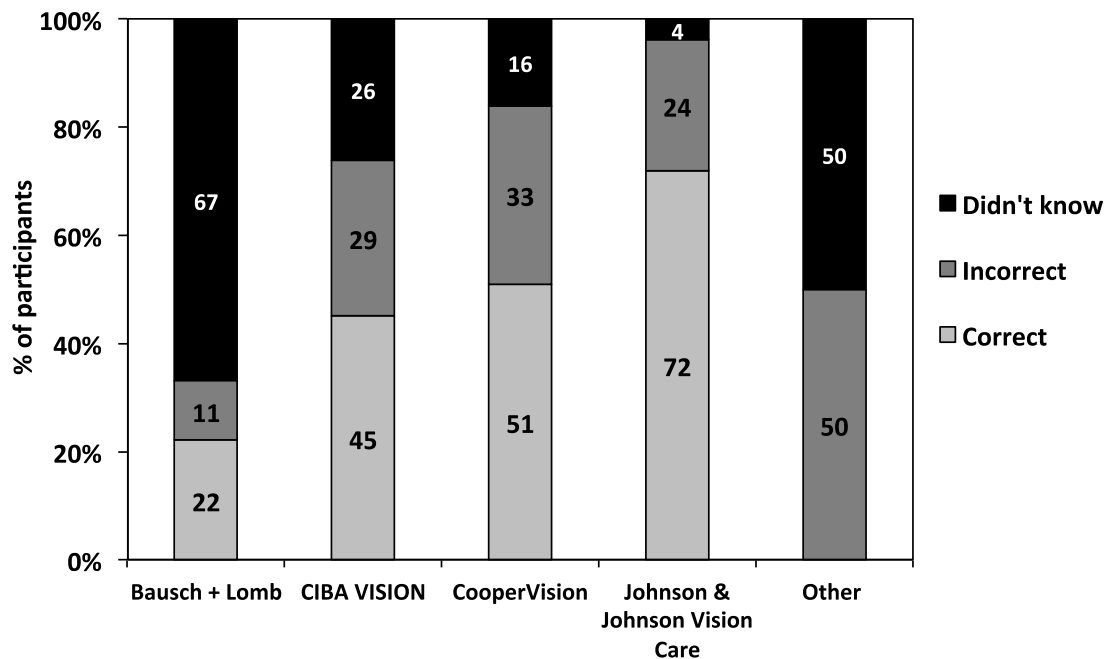
When participants were asked to identify their lens brand using the photographic aids, 87% of participants correctly identified their lenses, which was a significantly greater percentage than found by recall alone ( $p < 0.001$ ). Six percent of the participants were wearing lenses that were not displayed on the photographic aids and so they were excluded from the photographic aids analyses. The participant responses are summarized in Figure 2-2.



**Figure 2-2: Correct recall of lens brand versus recall with photographic aids**

Participants wearing Johnson & Johnson Vision Care lenses had the most accurate recall (without the photographic aids) of their lens brands (47 wearers, 72% correct), followed by Cooper Vision wearers (12 wearers, 51% correct) and CIBA Vision wearers (31 wearers, 45% correct), with the least

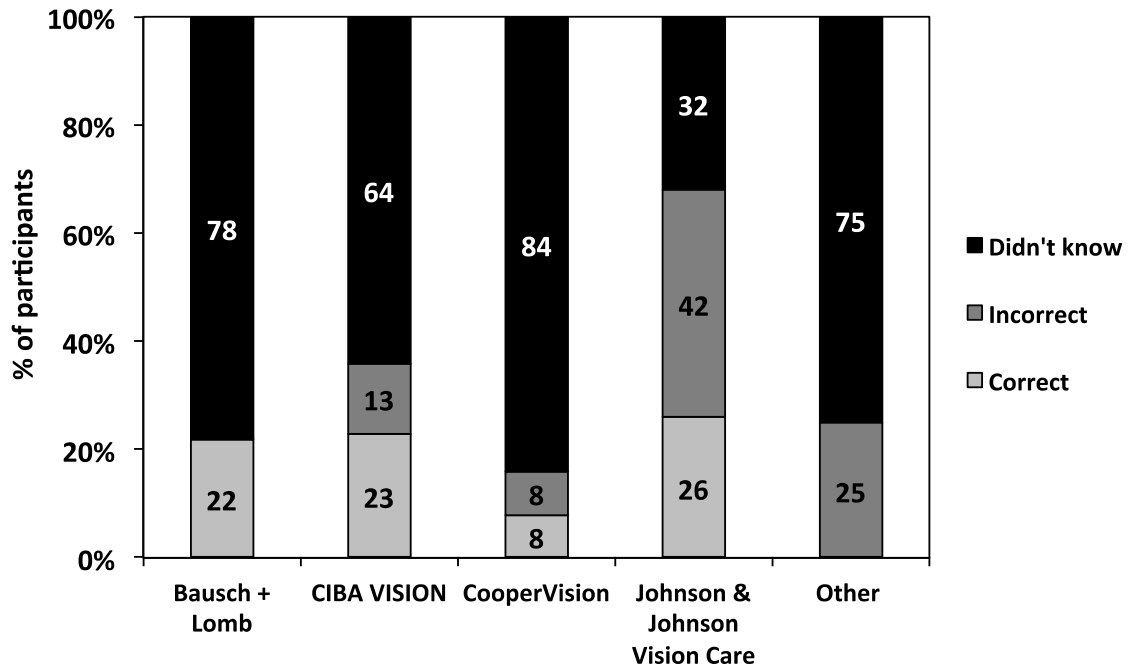
accurate recall by Bausch + Lomb lens wearers (9 wearers, 22% correct). These data are presented in Figure 2-3. Johnson and Johnson Vision Care lens wearers had significantly more accurate recall than Bausch + Lomb lens wearers ( $p = 0.004$ ) and CIBA Vision lens wearers ( $p = 0.016$ ). All other comparisons were not statistically significant. Of those participants wearing lenses manufactured by other companies ( $n = 4$ ), two recalled their lens brand name incorrectly and two responded that they did not know.



**Figure 2-3: Correct recall of lens brand by manufacturer**

Overall, only 21% of participants were able to correctly name the manufacturer of their contact lenses. Twenty-five percent answered incorrectly and 54% said that they did not know. These responses varied by lens manufacturer (Figure 2-4). Participants wearing Cooper Vision lenses were the least able to name their lens manufacturer and gave significantly fewer correct responses than

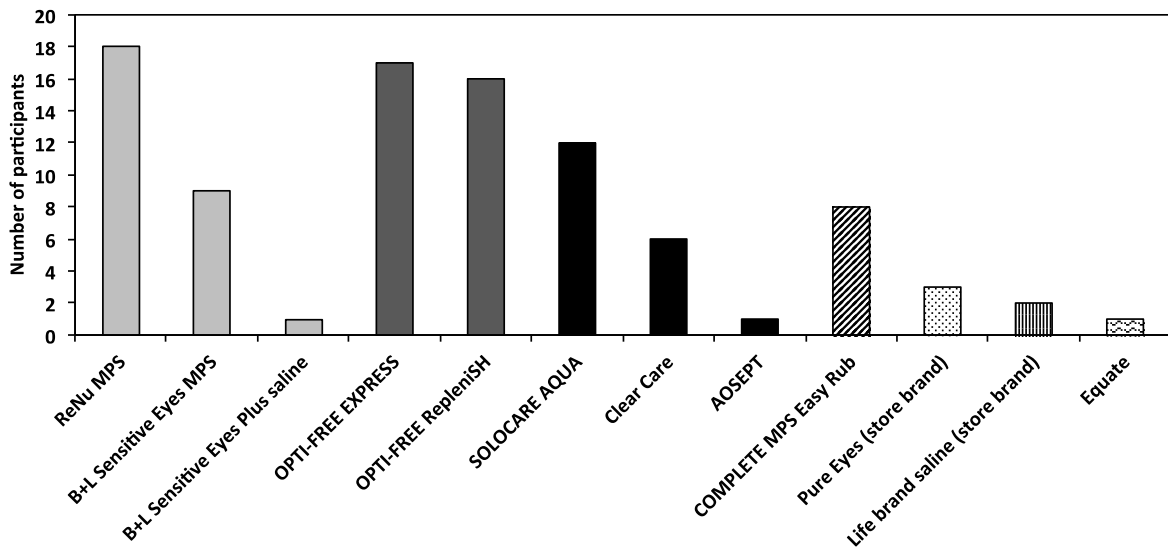
participants wearing lenses manufactured by Bausch + Lomb ( $p = 0.005$ ), CIBA Vision ( $p < 0.001$ ) and Johnson & Johnson Vision Care ( $p < 0.001$ ).



**Figure 2-4: Correct recall of lens manufacturer name**

### 2.4.2 Care System

Ninety-one percent of participants were using a contact lens care system. Figure 2-5 shows the frequency distribution of the lens care systems used by the study participants as confirmed at the second study visit. Nine participants were wearing daily disposable lenses and did not use a care system.



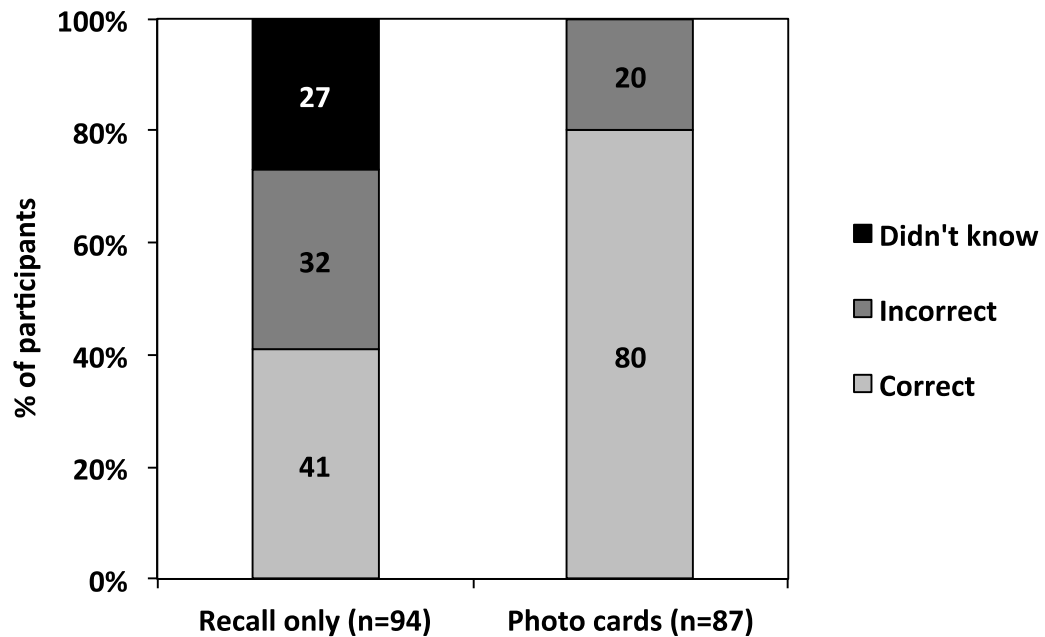
**Figure 2-5: Contact lens care systems grouped by manufacturer**

At the first visit, 41% of the participants correctly reported the name of their habitual lens care system (compared to the packages that were brought in at the second visit). The remaining 59% either incorrectly reported their habitual lens care system (32% of total participants) or indicated that they did not know the name of the system (27% of total participants). There was a significant gender difference in the proportion of participants who correctly reported the name of their lens care system (27% of males correct versus 49% of females correct,  $p = 0.040$ ) but there was no difference with respect to amount of time that the care system had been used (46% correct for  $\leq 12$  months use versus 40% correct for  $> 12$  months use,  $p = 0.617$ ).

When participants using a care system were asked to identify their lens care system using the photographic aids 6% were using care products that were not displayed on the photographic aids and they were excluded from the photographic aids analyses. Eighty percent of the remaining participants



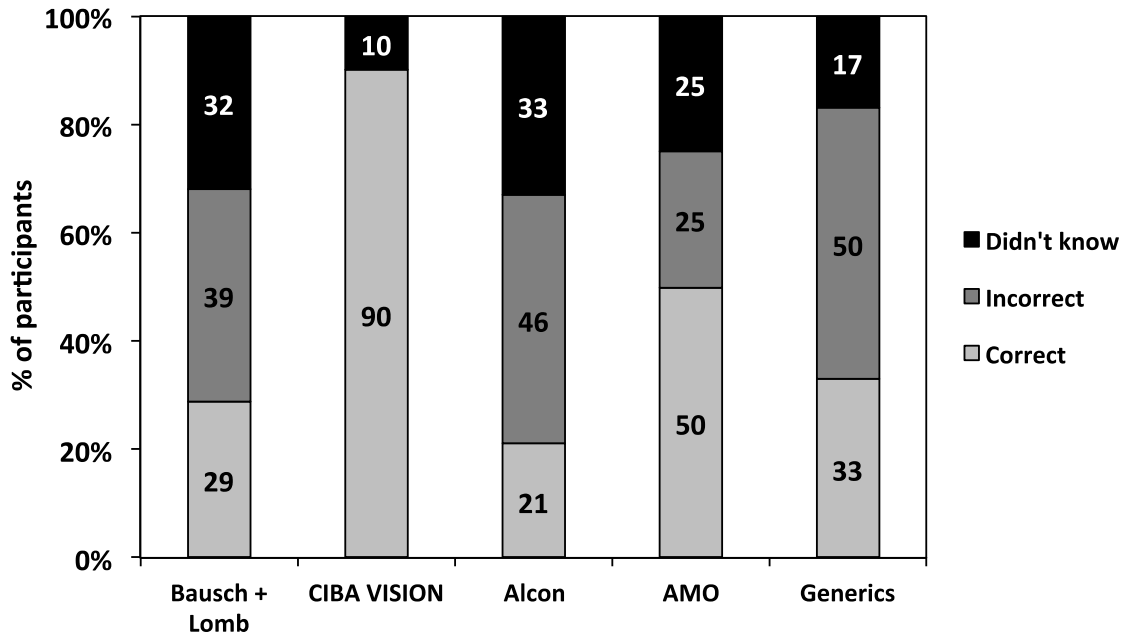
using a care system correctly identified their products from the photographic aids, a significantly higher percentage than from initial recall ( $p < 0.001$ ). The participant responses are summarized in Figure 2-6.



**Figure 2-6: Correct recall of lens care system versus recall with photographic aids**

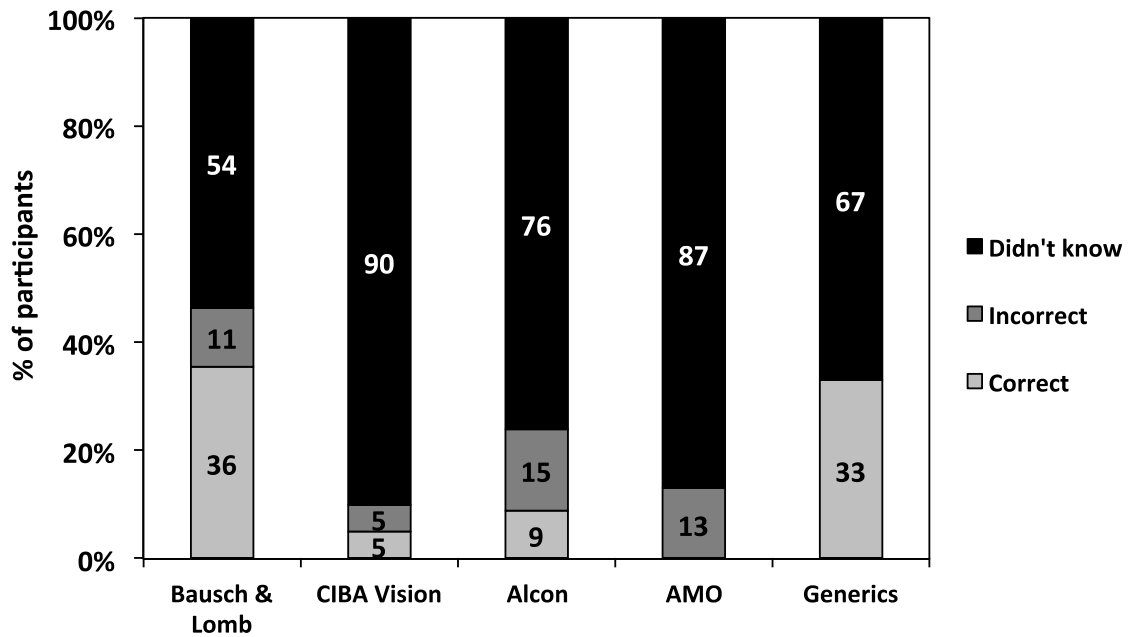
Participants using CIBA Vision lens care systems had the most accurate recall (without photographic aids) of the name of their products (20 users, 90% correct), followed by AMO users (8 users, 50% correct) and Bausch + Lomb (28 users, 29% correct), with the least accurate recall by Alcon users (32 users, 21% correct), Figure 2-7. Participants using CIBA Vision products had significantly more accurate recall than participants using Bausch & Lomb products ( $p < 0.0001$ ), Alcon products ( $p < 0.0001$ ) and AMO products ( $p = 0.022$ ). A further 30% of Alcon users were able to recall that they used “Optifree” but did not state whether it was “Optifree Express” or “Optifree RepleniSH”. All

other differences were not statistically significant. Of those participants using generic care systems (n = 6), two correctly recalled the name of the lens brand, three were incorrect and one responded that they did not know.



**Figure 2-7: Correct recall of care system brand by manufacturer**

Overall, only 16% of participants were able to correctly name the manufacturer of their habitual contact lens care system. Twelve percent answered incorrectly and 72% indicated that they did not know. These responses varied by lens manufacturer (Figure 2-8). Participants using Bausch + Lomb care systems most commonly named the manufacturer of their care system correctly (36% correct) and gave a significantly higher number of correct responses than participants using Alcon ( $p = 0.004$ ), CIBA Vision ( $p = 0.016$ ) and AMO ( $p = 0.047$ ) products.



**Figure 2-8: Correct recall of care system manufacturer name**

## 2.5 Discussion

The results of this study confirm that contact lens wearers are frequently not able to recall the names of their contact lens brands or care systems. Only half of the study participants were able to recall the brand names of their habitual contact lenses from memory, and the proportion was even lower with respect to correctly recalling the brand name of their lens care system. In general, female participants were better able to recall brand names than male participants, but this difference was only statistically significant for the care system. It was interesting that participants who had worn their lens brand for one year or more were better able to recall the name than those who were newer to their products. This differentiation could be related to having less time (and therefore fewer opportunities) to re-

purchase lenses and become familiar with brand names. No comparisons by age were possible in this study as so few older wearers participated.

The photographic aids developed for the study significantly improved recall from 51% to 87% for contact lens brand names and from 41% to 80% for contact lens care system brand names. This improvement is similar to that reported in a study evaluating the use of a pictorial memory aid in the recall of past hormone use, where the display more than doubled the number of women who recalled both the name and the dose of their therapy correctly.<sup>7</sup>

It is of interest that participants were better at recalling the product names of some manufacturers than others, although it should be recognized that there was not an even distribution of wearers across products and that some products were worn or used much more frequently than others in the study population. In the case of contact lenses, the highest correct recall was for Johnson & Johnson Vision Care products and in the case of contact lens care systems, the highest correct recall was for CIBA Vision products. The frequency of lens replacement (i.e. daily, two-weekly or monthly), and therefore the frequency with which participants saw their lens packaging, was not taken into account but may play a role in the ability of lens wearers to recall their product names. In general, participants were not good at naming the manufacturers of their products. Only 21% of wearers were able to name the manufacturer of their contact lenses; there was very little difference in the recall of the main manufacturers, with the exception of Cooper Vision, which was named correctly by only 8% of wearers of these lenses, despite more than half of these wearers correctly recalling Cooper Vision product names. Only 16% of participants were able to correctly name the manufacturer of their contact lens care system, with the best recall by Bausch & Lomb users at 36%.

Increasingly contact lens wearers are purchasing their lenses from a number of different sources, including the Internet. In one recent study, up to 22.5% of college students reported making an internet purchase for their contact lenses.<sup>10</sup> Most online contact lens suppliers provide photographs of the lenses which may assist wearers in their purchase, but it is nevertheless still a concern that some wearers may inadvertently make an incorrect purchase as a result of inaccurate recall of their current lens brand(s) and that this is an area of non-compliance relating to lens wear which could have negative consequences. Purchases for contact lens care systems may be made from a number of sources and while it is expected that wearers will recognize their current brand when they see it on the store shelf, confusion may still occur and a switch to a different brand is possible. In previous studies conducted at the CCLR, 27% of patients in the United States and 31% of patients in Canada reported having changed their care system recently, however in more than half the cases this was as a result of a recommendation by their ECP.<sup>11</sup>

It is important to reiterate that this study was designed to try to accurately assess the ability of contact lens wearers to recall the names of their products when they did not receive prior warning that they would be asked to do so. The accuracy of this recall was confirmed at a second study visit, at which participants were asked to show their habitual product packages to the study investigators. It is also important to recognize that the study design had some limitations. The study was conducted on a university campus and the majority of participants were university students. The results may have been different for an older and broader demographic group. Regardless, the results strongly support the use of photographic aids when asking study participants to report their habitual contact lenses and lens care products. These aids could take the form of laminated cards, such as those used in this study, or could be available for viewing on the internet. This study only assessed current lens wearers; it was

not possible to determine how well photographic aids would help lapsed contact lens wearers in recalling their product names; however, it is anticipated that they should help to some degree for these individuals and may therefore be useful in studies investigating this group.

## **2.6 Conclusion**

Less than 50% of contact lens wearers were able to recall the names of their habitual lens and lens care products correctly from memory. Photographic product recognition cards improved this recall significantly for both contact lenses and contact lens care systems.

## **Funding**

This study was funded by a grant from CIBA Vision, GA, USA.

Chapter 3 describes a study that was conducted to evaluate the relationship between compliance with replacement frequency and the prevalence of contact lens - related problems in silicone hydrogel (SiHy) wearers.

## Chapter 3

### The Relationship Between Non-Compliance and Contact Lens-Related Problems

This chapter is published as follows:

The relationship between compliance with lens replacement and contact lens-related problems in silicone hydrogel wearers

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	Concept / Design	Recruitment	Acquisition of data	Analysis	Write-up / publication
Dumbleton	Y	Y	Y	Y	Y
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Jones	-	-	-	-	Y
Fonn	Y	-	-	-	Y

Tables: 3

Figures: 5



### 3.1 Overview

**Purpose:** To evaluate the relationship between compliance with replacement frequency (RF) and contact lens (CL)-related problems in silicone hydrogel (SiHy) wearers.

**Methods:** 501 SiHy wearers from 7 optometry offices completed surveys regarding their lens wear and any CL related problems which they may have experienced in the preceding 12 months. File review was subsequently conducted at their optometry offices to confirm the information provided.

**Results:** 49% of respondents were wearing two-week replacement (2WR) and 51% one-month replacement (1MR) SiHy lenses. 67% wore their lenses for longer than the manufacturers' recommended RF (MRRF) and 60% for longer than their optometrist's recommended RF (ORRF). The mean RF was 2.6x the MRRF for 2WR and 1.5x for 1MR wearers ( $p < 0.001$ ) with median values of 31 and 37 days respectively. 23% reported signs or symptoms consistent with potential complications relating to CL wear. This rate was significantly higher for wearers who were non-compliant with the ORRF than compliant wearers (26% versus 18%,  $p = 0.028$ ). It was also higher for those multipurpose solution users who reported never/almost never rubbing and rinsing their lenses when compared with those who did this every night (29% versus 17%,  $p = 0.007$ ).

**Conclusions:** Two thirds of the SiHy wearers did not comply with the MRRF and 2WR wearers stretched the replacement interval of their lenses to a greater degree than 1MR wearers. Failing to replace lenses when recommended and failing to rub and rinse lenses were associated with a higher rate of patient-reported CL problems.

### 3.2 Introduction

Silicone hydrogel (SiHy) contact lenses are now the most widely prescribed soft lenses worldwide, accounting for 39% of new soft lens fits in all countries combined and 70% of new soft lens fits in the United States.<sup>1</sup> Since the introduction of SiHy lenses, many of the hypoxia-related problems associated with conventional hydrogel lenses have been essentially eliminated.<sup>2-7</sup> However, other complications do still occur periodically, including cases of corneal inflammation, infection and mechanical disruption.<sup>8-12</sup> While many studies have investigated the impact of lens replacement frequency on contact lens complications in conventional hydrogel lens wearers,<sup>13-18</sup> this has not been extensively evaluated in silicone hydrogel lens wearers.

Unfortunately, many patients are not compliant with respect to their contact lens wear and care, and this may result in a higher occurrence of contact lens-related complications in these individuals.<sup>19-21</sup>

One of the most commonly-reported areas of non-compliance in SiHy contact lens wear relates to lens replacement.<sup>22-24</sup> Yeung et al have recently published the results of a study conducted in two university clinics in the United States.<sup>25</sup> In their study, the relationship between compliance with lens replacement and contact lens-related ocular complications in wearers of both conventional and silicone hydrogel lenses was evaluated. Although Yeung and colleagues found no differences in the average number of complications experienced between patients who were compliant with the manufacturers recommended replacement frequency (MRRF) and those who were not, they did report a trend for patients who replaced their lenses more than three times over the MRRF (the least compliant patients) to have more complications than patients who were compliant with the MRRF.

The aim of this current study was to primarily investigate whether contact lens-related complications that occur in reusable SiHy wearers are related to compliance with recommendations for replacement

frequency (RF) from the manufacturer and from the prescribing optometrist. The study was also designed to evaluate other areas of non-compliance with contact lens wear, specifically relating to contact lens cleaning and disinfection and contact lens case care.

### **3.3 Methods**

Ethics approval was obtained through the Office of Research Ethics at the University of Waterloo before commencement of this study, and the study was conducted following the tenets of the Declaration of Helsinki. Seven optometry offices in Southern Ontario, Canada (including the University of Waterloo School of Optometry Clinic) were invited to participate in the study. The offices were chosen to be representative of the diversity of demographics in the area (large cities, industrial urban areas, high technology cities, university community and rural areas) with the expectation that the offices would be accessed by patients from many differing socioeconomic groups. Each office was asked to identify contact lens patients who had been wearing SiHy lenses which had been dispensed from their office for at least twelve months and to invite them to participate in a study investigating contact lens related complications. The patients were selected in reverse chronological order. Optometry offices were instructed identify eligible patients who had attended their office in the month prior to the start of the study first and send invitations to these patients first. If sufficient patients could not be identified from this group, they were instructed to review the records of patients attending the office in the month prior to this etc. Invitations were sent out by mail from each of the offices in groups of approximately 50 per week. The responses were monitored from each office and invitations were stopped once the target enrolment had been reached for an office (50 to 100) or for the all the offices combined (500).

The invitation packages were sent from the offices by mail and included a cover letter from the office, a letter of explanation from the Centre for Contact Lens Research (CCLR), a questionnaire and a letter of consent giving permission for the patients' records to be viewed by a member of the CCLR. Patients who chose to participate in the study were asked to complete the questionnaire and to return it along with their signed consent letter to the CCLR. Participants were sent a gift card for completing the study questionnaire following receipt of their completed study questionnaires and signed consent letters.

The questionnaire included sections on demographics, the lens type(s) worn and wearing patterns, the recommended and actual RFs, the contact lens care system used and the lens care procedures employed and report(s) of any contact lens problems which had resulted in interruption of normal lens wear during the preceding 12 month period. Up to three problems could be reported, and for each one the patients were asked to describe the nature of the problem, the actions that were taken (including visits to their optometrist or some other health care professional) and the resolution of the problem. Participant eligibility was confirmed after receipt of completed study questionnaires and on review of the corresponding participant optometry records by a research investigator from the CCLR (KAD).

Where relevant, data analyses were conducted using Statistica 9.0 (StatSoft Inc. Tulsa, OK). Data are presented in tables as frequency distributions. Where appropriate, the 95% confidence intervals are also included. A significance level of  $\alpha = 0.05$  was used for all analyses with Chi-square tests being used to compare differences in proportions.

## **3.4 Results**

### **3.4.1 Questionnaires Received**

The seven optometry offices taking part in the study sent out a total of 1,220 invitations to participate in the study. Five hundred and thirty-five completed questionnaires were returned (44% of the total sent), but only 501 were eligible for inclusion. The reasons for ineligibility included the consent form not being completed, the patient being 16 years old or younger, the patient not being a current SiHy lens wearer and the patient not having worn SiHy lenses for at least one year. The overall response rate was 41% (ranging from 28% to 55% for the seven offices taking part in the study) and the number of responses received from each office ranged from 57 to 86.

### **3.4.2 Patient Demographics and Contact Lenses Worn**

The brands of lenses worn by the patients completing the questionnaire are listed in Table 3-1. The brand names were obtained from the patient questionnaire and confirmed from the record review. Forty-nine percent of the lenses worn had a MRRF of two weeks (2WR) and 51% had a MRRF of one month (1MR). Toric lenses were worn by 14.6% of all patients and multifocal lenses were worn by 7.4% of all patients.

The contact lens prescription for each of the patients was determined from the record review. Ninety-three percent of patients had a myopic contact lens prescription, with a mean of  $-3.79 \pm 2.10$  D (median  $-3.50$ D) and 7% had a hyperopic contact lens prescription, with a mean of  $+3.07 \pm 1.49$  D (median  $+3.00$ D). Contact lenses were purchased from the patients' optometrist by 95.4% of patients. They were purchased from an optician or optical store by 2.8% of patients and from the Internet in 1.8% of patients.

The mean age of the patient respondents was  $36.4 \pm 13.0$  years (range 17 to 75, median 36 years). Seventy six percent of patient respondents were female. The average number of years of lens wear was  $14.8 \pm 10.3$  years (range 1 to 42, median 12 years) and the average number of days per week that lenses were worn was  $6.1 \pm 1.6$  days (range 1 to 7, median 7 days).

**Table 3-1: Distribution of lens brands worn**

	Number	% Lens Type	% Group
<b>2WR lenses</b>	<b>245</b>		
Acuvue Advance	31	12.7	
Acuvue Advance for Astigmatism	17	6.9	
Acuvue OASYS	155	63.2	49
Acuvue OASYS for Astigmatism	31	12.7	
Acuvue OASYS Multifocal	8	3.3	
Avaira	3	1.2	
<b>1MR lenses</b>	<b>256</b>		
Air Optix / Air Optix Aqua	116	45.3	
Air Optix for Astigmatism	11	4.3	
Air Optix Multifocal	2	0.8	
Air Optix Night & Day	36	14.1	
Biofinity	10	3.9	51
Biofinity Toric	2	0.8	
PureVision	29	11.3	
PureVision Toric	23	9.0	
PureVision Multifocal	27	10.5	

Eleven percent of lenses were prescribed for extended or continuous wear (as reported by the patient on the questionnaire) but only 6% of patients reported wearing times of 24 hours. For the patients reporting wearing lenses on a daily wear basis, the average daily wearing time was  $12.5 \pm 3.0$  hours (range 2 to 21 hours). Fifty-seven percent of patients reported that their lenses became less comfortable later in the day; the mean number of hours of reported lens discomfort was  $2.4 \pm 1.4$  hours (range 1 to 10, median 2 hours).

One third of patients reported that they never “slept” while wearing their lenses. Fifty-one percent reported that they only napped in their lenses, 9% that they occasionally slept in their lenses, 1% that they frequently slept in their lenses and 6% that they slept in their lenses almost every night.

### 3.4.3 Recommended Replacement Frequency

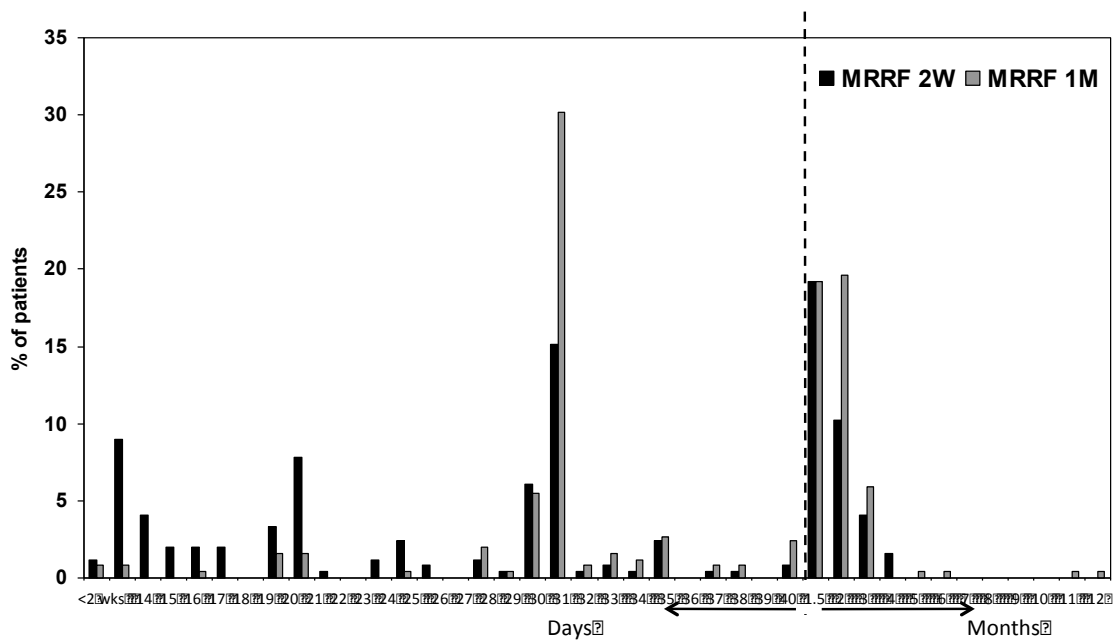
The distribution of responses for Replacement Frequency (RF) recommended by the optometrist (ORRF), as reported by the patient on the questionnaire for 2WR lenses and 1MR lenses, is listed in Table 3-2. The highlighted cells represent those ORRFs that were compliant with the MRRF for the lens type. “NR”, indicates that no recommendation was given. Overall, optometrists were compliant with the MRRF for 73% of their prescribing but the percentage was significantly higher for wearers of 1MR lenses (94%, 95% CI: 90 - 96%) than wearers of 2WR lenses (51%, 95% CI: 45 - 57%) ( $p < 0.001$ ).

**Table 3-2: Optometrist-recommended replacement frequency (ORRF)**

ORRF								
	< 1 week	1 week	2 weeks	3 weeks	1 mth	2 mths	≥ 3 mths	NR
<b>2WR</b>	0	2.5%	47.9%	6.2%	40.1%	1.2%	0	2.1%
<b>1MR</b>	0	0	5.1%	0.8%	88.2%	3.5%	0	2.4%

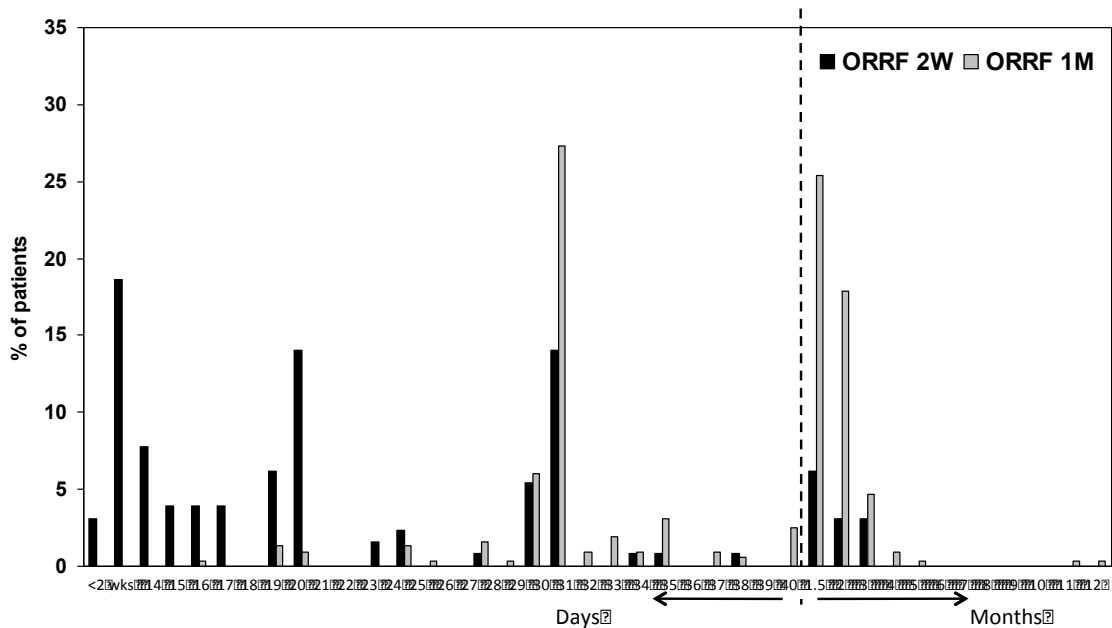
The actual RF reported by the patients, by MRRF, (Figure 3-1) was  $37 \pm 21.9$  days for lenses with a MRRF of 2 weeks (range 10 to 124 days, median 31 days) and  $47 \pm 34.5$  days for lenses with a MRRF of 1 month (range 10 to 365 days, median 37 days). Relative to the MRRF, these mean values represent 2.6 times the MRRF for 2WR lenses and 1.5 times the MRRF for 1MR lenses (t-test,  $p < 0.001$ ).

The actual RF reported by the patients, by ORRF, (Figure 3-2) was  $26 \pm 15.6$  days for patients who reported a recommendation by their optometrist of 2 weeks (range 10 to 93 days, median 21 days) and  $45 \pm 30.0$  days for patients who reported a recommendation by their optometrist of 1 month (range 17 to 365 days, median 40 days). Relative to the optometrists' recommendations, these mean values represent 1.8 times the ORRF for 2WR lenses and 1.5 times the MRRF for 1MR lenses (t-test,  $p < 0.001$ ).



**Figure 3-1: Actual replacement frequency reported by patients, by MRRF**





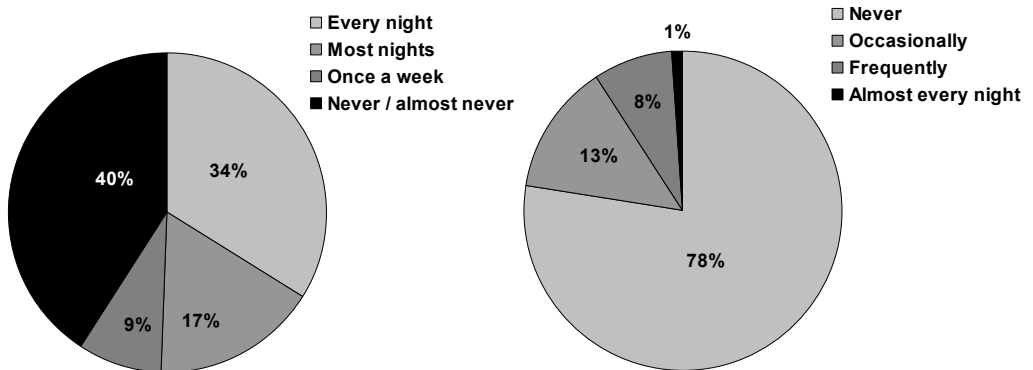
**Figure 3-2: Actual replacement frequency reported by patients, by ORRF**

An actual RF of more than 17 days (i.e. less frequently than twice a month) was considered to be non-compliant with the MRRF for 2WR lens wearers and an actual RF of more than 34 days was considered to be non-compliant with the MRRF for 1MR lens wearers. Overall, 67% of patients wore lenses for longer than these respective intervals. The non-compliance rate for 2WR lens wearers was 82% (95% CI: 76 - 86%) and for 1MR lens wearers was 53% (95% CI: 47 - 59%) ( $p < 0.001$ ). Using the same maximum intervals, 60% of patients wore lenses for longer than the ORRF with rates of 66% (95% CI: 60 - 72%) for 2WR wearers and 55% (95% CI: 48 - 61%) for 1MR wearers ( $p = 0.012$ ). The primary reason given for wearing the lenses for longer was “forgetting which day to replace the lenses” (39% of 2WR and 42% of 1MR) and the secondary reason was “to save money” (30% of 2WR and 22% of 1MR).

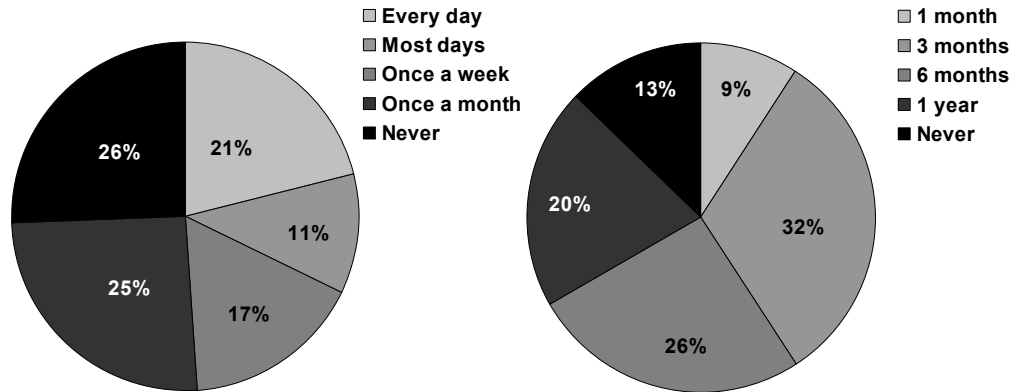
### 3.4.4 Contact Lens and Contact Lens Case Care

Eighty-six percent of patients were able to give a name for their current lens care solution. Seventy-seven percent of these patients were using a brand name multipurpose solution, 20% were using hydrogen peroxide and 3% were using private label multipurpose solutions. Sixty-six percent of the patient records reviewed had the name of the patients' lens care solution recorded and 82% of these records indicated that a brand name multipurpose solution was being used, with the remaining 18% recording the use of hydrogen peroxide.

Patients using multipurpose solutions were asked how frequently they rubbed and rinsed their lenses before storage each night and the how often they topped up their contact lens cases with solution rather than completely replacing it after use; these results are depicted graphically in Figure 3-3. Patients were also asked how frequently they cleaned and replaced their contact lens cases (Figure 3-4). When asked what they used to clean their case, 21% responded "lens care solution", 51% responded "tap water" and the remainder either did not respond or selected "other".



**Figure 3-3: Multipurpose solution users reports for rubbing and rinsing lenses (left) and topping up solution (right)**



**Figure 3-4: Reported frequency of contact lens case cleaning (left) and contact lens case replacement (right)**

### 3.4.5 Patient Reported Contact Lens-Related Complications

Thirty eight percent of the patients reported one or more “problem” over the preceding one year period. In total, 268 problems were reported, with 71% of patients reporting only one problem, 20% reporting two problems and 9% reporting three problems. Some of the reported problems were not considered to be contact lens-related ocular complications; these included cases of lost or mislocated lenses, handling problems, damaged lenses, intermittent dryness symptoms and visual symptoms which were prescription related (i.e. change in prescription, onset of presbyopia). After removing these problems from the data set, 113 patients (23%) reported problems in which the signs and/or symptoms were consistent with potential complications relating to contact lens wear. These complications were categorized as abrasions, conjunctivitis, discharge, discomfort (excluding

intermittent dryness), eyelid problems, infection or keratitis, photophobia, redness and sudden pain.

The total number and frequency of reports of these complications are presented in Table 3-3.

**Table 3-3: Patient reported problems**

<b>Problem</b>	<b>Total number reported</b>	<b>Number of wearers</b>	<b>% of all wearers</b>
Abrasion	13	11	2.2
Conjunctivitis / pink eye	12	9	1.8
Discharge	5	5	1.0
Discomfort (excluding dryness)	52	44	8.8
Eyelid problems	12	12	2.4
Infection / keratitis	13	12	2.4
Photophobia	3	3	0.6
Redness	21	20	4.0
Sudden pain	6	6	1.2

Patients reporting contact lens-related problems on their questionnaires were not statistically significantly different from those not reporting problems, with respect to age (35 versus 37 years), gender (79% female versus 76% female), years of lens wear (15 years for both), days per week of lens wear (6.0 versus 6.1 days), hours per day of lens wear (13.1 hours for both), spherical component of the contact lens prescription (-3.3 D for both), proportion of toric lens wearers (11% versus 16%), proportion of multifocal lens wearers (12% versus 6%) or proportion of patients who reported that they slept in their lenses occasionally, frequently or almost every night (12% versus 15%). However, a higher proportion of the patients reporting these problems also reported that their lenses became less comfortable as the day progressed (68% versus 54%,  $p = 0.009$ ).

A higher proportion of patients who reported that they “never” or “almost never” rubbed and rinsed their lenses (29%) experienced these more serious self-reported problems when compared with patients who reported that they “always” rubbed and rinsed their lenses (17%) ( $p = 0.007$ ). There

were no differences with respect to “topping off” with lens solution, cleaning contact lens cases or replacing contact lens cases ( $p>0.05$ ).

Lens wear was temporarily stopped for 91% of the problems reported. The average number of days without lens wear was  $11.8 \pm 19.3$  (range 1 to 150), with a median of 5 days per problem. No visit to an eye care professional or doctor was reported to have occurred in 53% of cases with the remainder reporting visiting one or more health care professionals for the problem (Figure 3-5). When describing how the problem was solved (one or more possible actions could be selected), 49% said that their lenses were replaced, 38% reported using over the counter drops of same nature, 18% said that they were given a prescription for the problem and 10% said that they simply ignored the problem.

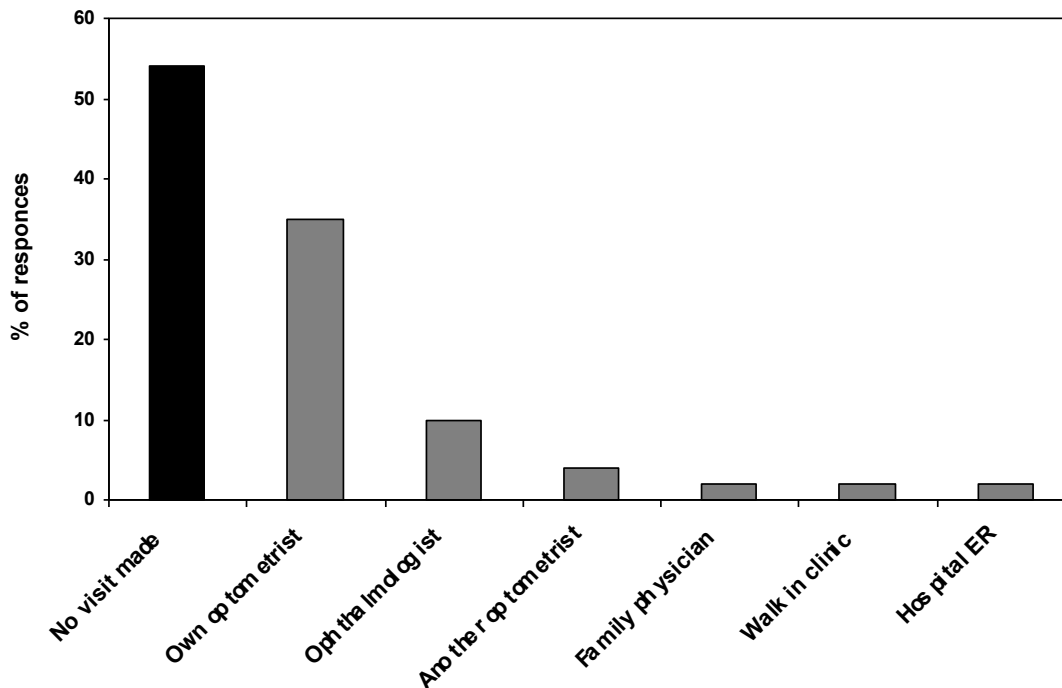


Figure 3-5: Visits to health care practitioners made by patients experiencing problems

### 3.4.6 Results by Compliance Group

Patients who were compliant with the MRRF were not statistically significantly different from those who were not compliant with the MRRF with respect to age (36 versus 37 years), gender (74% female versus 78% female), days per week of lens wear (6.2 versus 6.0 days), hours per day of lens wear (13.3 versus 13.0 hours) report of decreased comfort as the day progressed (54% versus 60%), or proportion of toric lens wearers (15% for both). There was a higher proportion of multifocal lens wearers in the group of patients who were compliant with the MRRF compared with those who were not (11% versus 6%,  $p=0.034$ ) and patients who were non-compliant with the MRRF had worn contact lenses for significantly longer than those who were compliant with the MRRF ( $15.6 \pm 10.1$  years versus  $13.3 \pm 10.6$  years,  $p=0.019$ ).

There were no differences between patients who were compliant with the MRRF and those who were not with respect to the proportion rubbing and rinsing their lenses every night (40% versus 34%), the proportion never “topping off” the case with solution (81% versus 76%) and the proportion cleaning their case every day (21% for both). However, a higher proportion of non-compliant patients reported that they either replaced their case only annually or that they never replaced their case, when compared with compliant patients (37% versus 25%,  $p=0.007$ ).

The rate of patient reports of the more significant contact lens related problems was compared between patients who were compliant with the MRRF (18%; 95% CI: 13 - 25%) and those who are not compliant with the MRRF (25%; 95% CI: 20 - 30%). Although a lower rate was observed in the compliant group, this difference was not statistically significant ( $p = 0.112$ ). However, a statistically significant difference ( $p = 0.028$ ) was found between those patients who were compliant with the

ORRF (18%; 95% CI: 13 - 24%) and those who were not compliant with the ORRF (26%; 95% CI: 21 - 31%).

### **3.5 Discussion**

This study was somewhat unique in its approach of collaborating with optometrists working in clinical practice to recruit study participants. A much higher participation rate (44%) was achieved when invitations to take part in the study were sent by the patients' own optometrist, when compared with other compliance studies conducted at the CCLR.<sup>22-24</sup>

The main aim of the study was to investigate how frequently SiHy lens wearers experienced problems with their lenses over a one-year period and whether there was a difference in the frequency of problems in patients who were compliant, compared with those who were non-compliant, with recommended RF. A recent retrospective study investigating the rate of occurrence of contact lens complications in clinical practices in the United States employed a clinical chart review methodology.<sup>26</sup> Since some contact lens patients may not consult their eye care professional when experiencing problems with their lenses, relying on file review alone may result in fewer reports of contact lens related complications and can make comparisons between compliant and non-compliant patients more difficult. Conversely, relying on patient responses alone can lead to inaccuracies, particularly with respect to the lens types worn and the care systems used. By employing a study design which incorporated both a patient questionnaire and a follow-up file review, it is believed that the data collected is more robust and representative of the SiHy wearing population.

Overall, the recommendations made by the optometrists in the study were in agreement with the MRRF for almost three quarters of the patients, but this level of agreement was much lower for

patients prescribed 2WR lenses than for patients prescribed 1MR lenses. Consistent with our previous studies investigating compliance with lens replacement, the patients in this study frequently did not follow the MRRF or the recommendations for lens replacement given to them by their optometrists. Two thirds of patients reported replacement intervals which were not compliant with the MRRF, which is somewhat higher than the overall rates of 40% and 44% reported in our previous studies.<sup>22-24</sup> Once again though, the rate was significantly higher in 2WR wearers compared with 1MR wearers. Since not all optometrists' recommendations for lens RF were in agreement with the MRRF, it was also important to evaluate the proportion of patients who were non-compliant with their optometrist's recommendation for RF. Overall, 60% of patients wore their lenses longer than their optometrist recommended and again this was somewhat higher for wearers of 2WR lenses than for wearers of 1MR lenses.

Since the current study was not a prospective controlled study, it is not possible to report on the incidence rates for contact lens-related complications. The patient questionnaire allowed for the reporting of contact lens related problems and symptoms which resulted in temporary discontinuation of wear and/or a visit to their optometrist or other doctor or medical practitioner. Using this approach it was hoped that the majority of symptomatic complications experienced by patients would be captured in addition to less serious complaints. More than one third of patients did report having experienced one or more problems with their lenses during the preceding one-year period. Several of the problems reported by patients would not be expected to be related to compliance with RF; these included lost or mislocated lenses, handling problems, damaged lenses and visual symptoms relating to prescription issues (under or over correction and presbyopia). A number of the other reported problems were considered to be more significant; these included abrasions, conjunctivitis, discharge,



discomfort (excluding intermittent dryness), eyelid problems, infection or keratitis, redness, sudden pain and photophobia. Just under one quarter of the patients reported experiencing one or more of these more significant problems. The original power calculations that were used for the study design were based on a non-compliance rate of 50%. However, the non-compliance rate actually found was considerably higher, at 67%. With this greater disparity in the proportion of compliant compared to non-compliant patients, a larger sample size and therefore a greater number of patients reporting problems may be required for these differences to become significant. Our results are consistent with those from the university clinic study conducted by Yeung et al,<sup>25</sup> where a trend was reported for the least compliant patients to have more complications than patients who were compliant with the MRRF.

Demographic differences have been reported between those that experience infiltrates and microbial keratitis and those that do not.<sup>11,12,26-30</sup> In the current study, no demographic differences were found between those patients who reported experiencing problems and those who did not. A higher proportion of patients with problems did however also report that their lenses became less comfortable as the day progressed.

Although more than half of the problems reported by the patients did not result in a visit to an eye care professional or doctor, lens wear was stopped temporarily for 91% of the reported problems and the median length of time before lens wear resumed was reported to be five days. This could represent considerable inconvenience for many patients, particularly those who reported significantly longer periods of time without contact lens wear. When a visit was deemed necessary, the vast majority of patients reported seeing their own optometrist, but a small number either visited another medical practitioner or had visits to more than one health care provider.

It was interesting to find that 95% of the patients reported purchasing their lenses from their optometrist, with only 3% reporting purchases from an optician or optical store and only 2% purchasing lenses over the Internet. The low rate of third party and Internet purchases is most likely due to the study sample selected (i.e. patients who had attended their optometrist's office within the previous year). If the general contact lens wearing population in Canada had been surveyed, it is likely that more respondents would have reported purchasing lenses from a third party as has been reported in one study conducted in the United States.<sup>31</sup> Even with a high proportion of patients purchasing lenses from their optometrist however, there was a high rate of non-compliance, and it may be that the purchase source does not influence compliance or that non-compliance would be even higher in the general contact lens wearing population, but a separate study would be required to investigate this further.

Another important aspect of non-compliance in contact lens wear is the daily care and maintenance required for both the contact lenses and the lens storage case. In general, the care system reported to be used by the patient matched that reported in the optometrists' files. However, a high percentage failed to be compliant with recommended lens care procedures. Failure to use a rub and rinse step prior to storing lenses and "topping up" solution may put patients at greater risk of infection,<sup>32</sup> and while eye care practitioners and contact lens care system manufacturers are hopefully reinforcing the importance of patients rubbing and rinsing and replacing solution each day,<sup>33</sup> patients do not appear to be adhering to this advice. Interestingly, patients in our study who reported that they did not rub and rinse their lenses were found to have a higher rate of self-reported problems than those who regularly carried out these procedures.

Contact lens case hygiene is also extremely important, but more than half of the patients in this study reported that they cleaned their cases infrequently, if ever. The majority of those who were cleaning their cases were using tap water to do so, sometimes in conjunction with lens care solution or soap. These figures are very similar to those recently reported by Wu et al.<sup>34</sup> Also consistent with the results of Wu et al, a significant proportion of patients reported failing to replace their contact lens case regularly and in our study this was more common in patients who were also non-compliant with lens replacement.

### **3.6 Conclusion**

Higher rates of non-compliance with the MRRF were found in this study compared with previous studies conducted at the Centre for Contact Lens Research; however, consistent with the other studies, non-compliance was more prevalent for 2WR compared to 1MR silicone hydrogel lens wearers. In addition, the relative mean replacement interval (actual replacement as compared with recommended replacement) for lenses recommended to be replaced after 2 weeks was significantly longer than for lenses recommended to be replaced after 1 month. This was found to be the case for recommendations made by both the manufacturers and the patients' optometrists.

Twenty-three percent of patients reported experiencing a significant problem with their lenses during the preceding one-year period. Patients who were compliant with the ORRF had a lower rate of these self-reported problems than those who were non-compliant. In order to accurately determine the frequency with which SiHy contact lens wearers experience contact lens-related complications, a prospective study design would be required and conducted with a larger sample size over a longer period of time.

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Chapter 4 describes a study in which current and lapsed contact lens wearers completed an online questionnaire regarding their current lens wear and care practices to evaluate the possible impact of non-compliance with recommendations for lens replacement on discontinuation from contact lens wear. Contact lenses and care systems were selected by the participants using photographic aids which were developed during a previous study which was described in Chapter 2.

## Chapter 4

### The Possible Impact of Non-compliance on Contact Lens

#### Discontinuation

This chapter is published as follows:

The Impact of Contemporary Contact Lenses on Contact Lens Discontinuation

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Dumbleton	Y	Y	Y	Y	Y
Woods C	Y	-	-	-	Y
Jones	-	-	-	-	Y
Fonn	Y	-	-	-	Y

Tables: 3

Figures: 2

## 4.1 Overview

**Objectives:** Discontinuation or “drop-out” from contact lens (CL) wear continues to afflict the contact lens industry. This study was conducted to determine whether the advent of new CL materials and designs has impacted the drop-out rate and the reasons for discontinuation.

**Methods:** Current and lapsed CL wearers residing in Canada were recruited using Facebook to take part in an on line survey investigating CL wearing experiences during 2008 – 2010 and to establish the percentage of participants who temporarily and permanently discontinued CL wear during the period surveyed.

**Results:** 4207 eligible surveys were received (64% female; median age 27 years). 40% had lapsed from lens wear for at least 4 months; however, 62% of lapsed wearers (LW) resumed wear. There were no differences between LW and non-lapsed wearers (NLW) with respect to gender, however LW were older, started wear when older and had not worn lenses for as long as NLW (all  $p < 0.001$ ). More NLW than LW wore SiHy CLs (49% versus 38%,  $p < 0.001$ ) and more LW than NLW wore daily disposable lenses (DD) and hydrogel CLs (24% versus 19% and 22% versus 18% respectively  $p \leq 0.001$ ). Primary reasons for discontinuation were discomfort (24%), dryness (20%), red eyes (7%) and expense (7%). Compliance with lens replacement was no different between LW and NLW (48% versus 45%).

**Conclusions:** 23% of those surveyed had discontinued CL wear permanently. The primary reasons for dropping out continue to be discomfort and dryness. Drop-out rates were lower in SiHy wearers.

## 4.2 Introduction

Discontinuation or “drop out” from contact lens wear continues to impact the contact lens industry. In two separate studies conducted in Canada in the 1990s, between 34% and 51% of wearers reported discontinuing from contact lens wear for some period of time.<sup>1,2</sup> The most common reasons reported for discontinuing wear were discomfort, dryness and the onset of visual problems associated with presbyopia.<sup>1-6</sup> However, since these studies were conducted, many new lens materials, modalities and designs have been introduced to the market. Arguably the most radical changes have been the introduction of daily disposable (DD) contact lenses and silicone hydrogel (SiHy) materials.<sup>7,8</sup>

SiHy lenses have eliminated many of the hypoxia-related problems associated with conventional hydrogel lenses<sup>9-13</sup> and improved comfort with these materials has also been reported in several studies.<sup>14-18</sup> These lenses may also be prescribed for extended and continuous wear<sup>19-21</sup> which offers an extremely convenient modality for patients who either prefer a permanent correction of their ametropia or not to have to clean and disinfect their lenses on a daily basis; however, extended wear shows a higher incidence of microbial keratitis compared to daily wear regardless of lens design or material.<sup>22,23</sup> In a similar way, DD lenses also offer many lifestyle advantages and the ultimate in convenience for contact lens wearers; in addition, these lenses have been shown to be beneficial for patients who suffer from seasonal allergies<sup>24,25</sup> and other complications, which can result from reusable contact lens wear including contact lens papillary conjunctivitis.<sup>26</sup> In general very few complications have been reported to occur in DD lens wearers when compared with spectacle wearers;<sup>27</sup> however, serious complications including microbial keratitis can still occur with this modality, particularly if patients are not compliant with their replacement.<sup>22</sup> Recently enhancements have been made to some DD lenses which have been shown to result in improvements in comfort.<sup>28,29</sup>



It is not known whether these innovations in lens materials and modalities have impacted the drop-out rate from contact lens wear or the reasons for discontinuation.

This study was designed to investigate the current rates and reasons for discontinuation from contact lens wear. The specific objectives of the study were to establish the percentage of study participants who had temporarily and permanently discontinued contact lens wear during the qualifying period of two years (2008 – 2010), to investigate the causes of discontinuation and to determine whether there was a difference in the rate of discontinuation based on lens materials or designs, and compliance with recommended intervals for lens replacement. It was decided that the study should be conducted in Canada to allow comparison with the results from the two previously reported Canadian studies.<sup>1,2</sup> Since it is possible that people who “drop out” may actually successfully return to lens wear, the terms ‘lapse’ and/or ‘lapsed wearer’ are used rather than “drop outs”. The reasons for resuming lens wear were also evaluated for the lapsed wearers.

### **4.3 Materials and Methods**

#### **4.3.1 Study design**

Ethics approval was obtained through the Office of Research Ethics at the University of Waterloo before commencement of this study, which was conducted following the tenets of the Declaration of Helsinki. The study comprised of an online survey. Current and lapsed contact lens wearers residing in Canada were recruited to take part in the survey via the social media website Facebook ([www.Facebook.com](http://www.Facebook.com)). The target sample size was 4500. Previous studies on contact lens discontinuation have been smaller (approximately 1500 in the most recent Canadian study<sup>2</sup>), however since the current study was conducted online, a larger sample size was possible.

Prior to completion of the survey, prospective participants were invited to read an online information letter and were required to indicate their consent to participate by clicking on a radio button, which took those prospective participants to the first page of the survey. On this page, a series of preliminary questions were asked to confirm eligibility. Only Canadian residents who were at least 17 years old, had purchased contact lenses in Canada between 2008 and 2010, and had worn contact lenses for at least six consecutive months during this period were eligible to participate. In order to be considered a lapsed wearer, participants were additionally required to have discontinued contact lens wear for a period of at least four consecutive months during the same time period. Multiple entries from identical Internet protocol (IP) address were not permitted. Ineligible participants were advised that they did not meet the criteria for the study and were not able to continue with the survey.

The first phase of enrollment involved general advertising on Facebook for both current and lapsed wearers (17 or older). Age monitoring throughout the study revealed a high initial response rate from patients under the age of 30 years. A recruitment strategy targeting account holders over the age of 30 years was implemented after two thirds of the study participants had been recruited.

Lapsed and non-lapsed wearers completed different versions of the survey. In addition to collecting general demographics and responses relating to contact lens wear, which were asked for all wearers, lapsed wearers were asked several additional questions. These were the main reason for stopping lens wear, whether they resumed wear again during the period of time evaluated, and if so, the primary reason for resuming lens wear.

The questions relating to contact lenses worn were asked in a sequence which was designed to aid selection of the lens type worn. Participants were asked first if they wore rigid (RGP) or soft lenses. Those responding soft, were then asked if they wore DD lenses (*“lenses disposed of at the end of*

*each day*”), all were asked if they were wearing toric lenses (“*designed to correct astigmatism*”) and if they were wearing multifocal or bifocal lenses (“*designed to correct presbyopia*”). After responding to these questions, participants were asked to select their contact lens brand (with the exception of RGP wearers) from a linked page with photographic aids and names of the possible products used; i.e., participants selecting DD lenses were only directed to a linked page with images of DD lenses, etc.. Participants who did not make a selection from the product photographs were asked to manually enter the name of the brand of their lenses.

Participants selecting re-usable soft lenses were also asked to select their contact lens care products from a linked page listing images with photographic aids and names of contact lens products available in Canada at the time that the study was conducted. Once again, participants who did not make a selection from the product photographs were asked to manually enter the name of the brand of their care products. All re-usable soft lens wearers were also asked whether and how often they rubbed and rinsed their lenses prior to storage and whether and how frequently they “topped up” their contact lens case (i.e., added new lens care solution on top of the previous day’s solution, in the lens case). Upon completion of the survey participants were given the opportunity to receive a \$10 gift card by mail if they chose to provide their name and address.

#### **4.3.2 Data analysis**

Where relevant, data analyses were conducted using Statistica 9.0 (StatSoft Inc. Tulsa, OK). Data are presented in tables and charts as frequency distributions. A significance level of  $\alpha = 0.05$  was used for all analyses with Chi- square tests used to compare differences in counts and two-sided difference between two proportions tests when comparing proportional differences between the groups investigated. Student t-tests were used to compare differences between the two study populations.

For the purposes of analysis, lapsed wearers included those who were permanently lapsed and those who may have resumed wear during the period evaluated. In these cases the responses used were those for lenses worn when these participants first lapsed from lens wear.

## **4.4 Results**

### **4.4.1 Study participants**

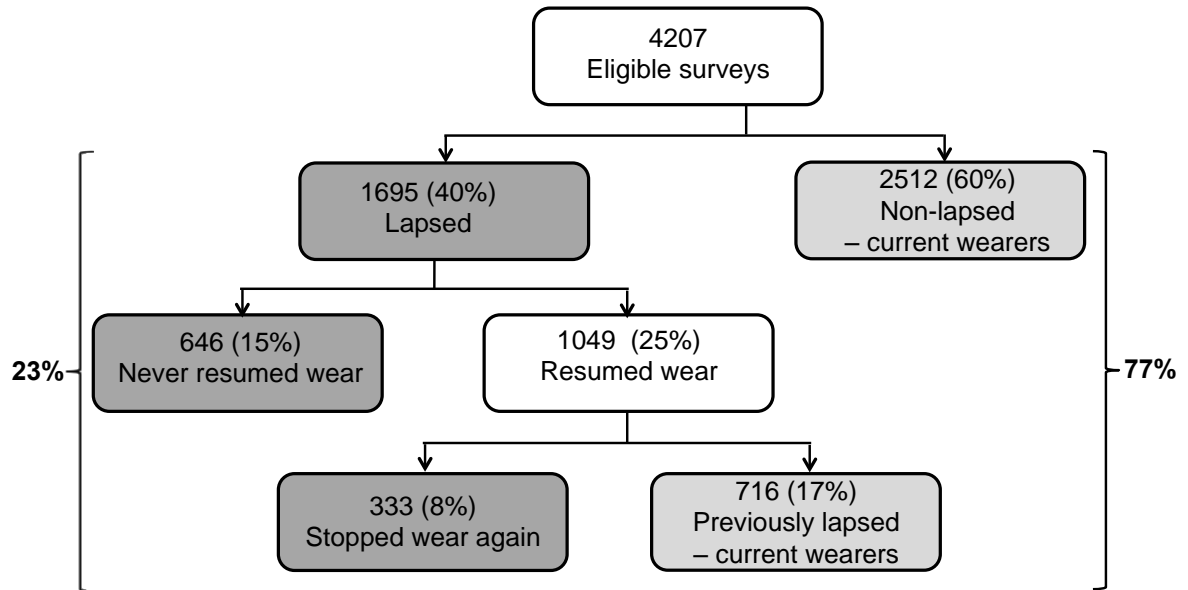
In total, 4851 participants completed the online survey. Of these, 4207 surveys were eligible for analysis. The remaining 644 were excluded for the following reasons:

- 513 dubious repeats (duplicate address, names etc.);
- 142 questionable RGP respondents (lenses replaced at intervals of less than three months);
- two respondents who were too young to participate (under 17 years) and;
- two respondents who were ineligible with respect to country of residence (Russia and Lithuania).

Completed surveys were received from every province and territory in Canada, with the highest number of responses coming from Ontario (69%) followed by British Columbia (13%).

Sixty four percent (64%) of participants were female. The mean age was 30 years (median 27 years, ranging from 17 to 77 years). Sixty percent (60%, 2512) of the participants were identified as current lens wearers and 40% (1695) were identified as lapsed wearers. Almost two thirds of these (1049) did resume wear again during this period, but approximately one third of these (333) later stopped once again. This resulted in a final rate for lapsed wearers of 23% (979). Figure 4-1 shows the distribution of participants and Table 4-1 summarizes the participant demographics. There were no differences between lapsed and non-lapsed wearers with respect to gender; however, lapsed wearers were older,

had started wear when older and had not worn lenses for as long as non-lapsed wearers (all,  $p < 0.001$ ).



**Figure 4-1: Distribution of survey participants**

**Table 4-1: Survey participants' demographics**

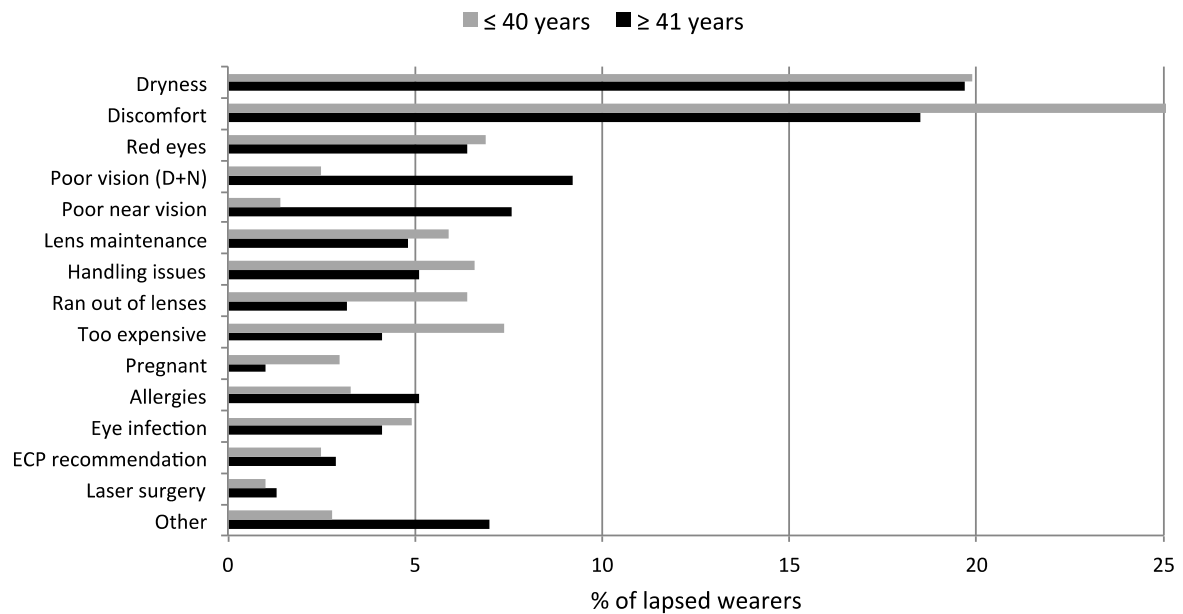
	All participants	Non-lapsed	Lapsed	p values
% Female	64.4	64	65	0.555
Current age (years)	29.6 ± 10.2	28.7 ± 9.8	30.9 ± 10.6	< 0.001
Median age (years)	27	26	28	
Age range (years)	17 - 77	17 - 77	17 - 72	
Age started wear (years)	20.4 ± 7.5	19.1 ± 6.3	22.4 ± 8.7	< 0.001
Median age started wear	18	18	20	
Years of wear*	8.9 ± 7.6	9.5 ± 7.7	5.9 ± 6.4	< 0.001

\* Only includes lapsed wearers with wearing experience of > 1 year

#### **4.4.2 Reasons for lapsing from and resuming lens wear**

Twenty-seven percent (27%) of lapsed wearers reported wearing their lenses for only six months prior to stopping lens wear; 38% reported wearing their lenses for more than six months up to 12 months and 35% reported wearing their lenses for more than one year. For those wearing lenses for longer than a year before discontinuing, the mean length of wear was  $5.9 \pm 6.4$  years (median three years, range one to 35 years).

The main reasons for stopping lens wear (only one response per participant) are shown in Figure 4-2 and Table 4-2. The reason most frequently given was discomfort (24%) followed by dryness (20%). Responses have been separated by age into participants aged forty and younger and participants aged 41 and older. The distribution of responses is similar, except that a higher proportion of the older participants cited poor distance and near vision, or just poor near vision, than the younger participants. A higher proportion of the younger participants cited discomfort, running out of lenses, lenses being too expensive and becoming pregnant.



**Figure 4-2: Reasons for lapsing from lens wear**

Sixty-two percent (62%) of the lapsed wearers (n = 1049) resumed lens wear after the first period of stopping wear. The most common reason for resuming wear was preferring their appearance in contact lenses (32%) followed by preferring the convenience of contact lenses (21%). Fourteen percent (14%) of those resuming wear said that it was because their eye care practitioner (ECP) had recommended a different contact lens type. Thirty-two percent (32%) of those who resumed lens wear discontinued again during the time period evaluated (n = 333) with the primary reasons given once again being dryness and discomfort.

**Table 4-2: Reasons for lapsing from lens wear**

<b>Reason</b>	<b>% of lapsed wearers</b>
I experienced discomfort with the lenses	24.4
I experienced dryness with the lenses	19.9
I experienced red eyes when wearing my lenses	6.8
I found that it was too expensive to maintain the lenses	6.8
I disliked or found handling the lenses too much bother	6.3
I ran out of lenses and did not buy any more	5.8
I found caring for the lenses too much bother	5.7
I experienced an eye infection	4.7
I had poor vision with my lenses (distance and near)	3.7
I had seasonal allergies and could not tolerate the lenses as well	3.6
I had poor near vision with my lenses	2.6
I became pregnant and could not tolerate the lenses as well	2.6
My eye care practitioner recommended that I discontinue lens wear	2.5
I had laser eye surgery to correct my vision	1
Other (only select this if your reason does not fit into one of the above)	3.6

#### **4.4.3 Contact lenses**

Forty-five percent (45%) of lenses worn were reported to be SiHy lenses, 21% of lenses worn were daily disposable (DD), 20% hydrogel (not DD) and 5% rigid gas permeable (RGP). The remaining 10% of lenses worn were classified as “unknown soft”; these included surveys in which the participants had selected “soft” as the lens type but had not selected a picture from those provided, and the lens name that they entered could not be definitively identified as a SiHy, DD or hydrogel lens.

The distribution of lens type worn by group is presented in Table 4-3. A higher proportion of non-lapsed than lapsed wearers reported wearing SiHy lenses (49% versus 38%,  $p < 0.001$ ) and a higher



proportion of lapsed than non-lapsed wearers reported wearing DD lenses (24% versus 19%,  $p < 0.001$ ) and hydrogel lenses (22% versus 18%,  $p = 0.001$ ).

Twenty-four percent (24%) of participants reported wearing toric lenses and there was no difference between the lapsed and non-lapsed groups (25% versus 23%,  $p = 0.461$ ). Twelve percent (12%) of participants over 40 years of age said that they were wearing bifocal or multifocal lenses and there was no difference between the lapsed and non-lapsed groups (11% versus 13%,  $p = 0.278$ ). Thirteen percent (13%) of participants over 40 years of age said that they were wearing monovision lenses but once again there was no difference between the lapsed versus non-lapsed groups (12% versus 14%,  $p = 0.352$ ).

**Table 4-3: Distribution of lens types and materials worn**

	All participants	Non-lapsed	Lapsed	p values
Silicone Hydrogel	45	49	38	$p < 0.001$
Hydrogel	20	18	22	$p = 0.001$
Daily Disposables	21	19	24	$p = 0.001$
RGPs	5	5	5	NS
Unknown soft	10	9	12	NS

Thirty-eight percent (38%) of participants reported purchasing their lenses from an optometrist, 43% from an optician or optical store and 14% over the Internet. Five percent responded “other”. This purchase pattern was similar for all lens types with the exception of RGP lens wearers where the vast majority purchased lenses from their optometrist. A significantly higher proportion of lapsed wearers purchased their lenses from an optician, compared with non-lapsed wearers (48% versus 39%,  $p <$

0.001) and a significantly higher proportion of non-lapsed wearers reported purchasing their lenses from the Internet, compared with lapsed wearers (16% versus 12%,  $p < 0.001$ ).

#### 4.4.4 Wearing schedules

Overall, 85% of participants reported wearing lenses for daily wear only; 9% reported occasional overnight wear (wearing lenses during sleep for two to three nights a month); 3% reported frequent overnight wear (two to three nights a week); and 3% reported extended or continuous wear almost every night. Significantly more lapsed wearers reported *any overnight wear* compared with non-lapsed wearers (16% versus 13%,  $p = 0.024$ ); however, there was no significant difference between lapsed and non-lapsed wearers with respect to the average number of *nights per month* that they reported wearing lenses during sleep (5 nights,  $p = 0.493$ ). The average wearing time reported was  $12.3 \pm 3.1$  hours per day (median 13 hours) and  $5.6 \pm 1.6$  days per week (median six days). Lapsed wearers reported significantly shorter wearing times ( $12.0 \pm 3.0$  versus  $12.4 \pm 3.1$  hours) and fewer days per week ( $5.3 \pm 1.7$  versus  $5.8 \pm 1.6$  days) of wear than non-lapsed wearers (both  $p < 0.001$ ).

Fifty-three percent (53%) of participants reported that they wished that they could wear their lenses longer. When asked why they could not, 45% of participants responded that it was because their eyes became dry; 43% because the lenses became uncomfortable; 8% because their eyes became red; and 4% because their vision was no longer acceptable. A higher proportion of lapsed than non-lapsed wearers reported that it was because the lenses became uncomfortable (49% versus 38%,  $p < 0.001$ ) and a higher proportion of non-lapsed than lapsed wearers reported that it was because their eyes became dry (50% versus 37%,  $p < 0.001$ ).

#### 4.4.5 Care systems

Fifty eight (2%) of the participants wearing re-usable soft lenses did not select a picture from the contact lens care systems displayed or give a care system name. Of those selecting a picture or giving a name, 85% reported using a brand name multipurpose solution (MPS), 2% reported using a private label MPS and 13% reported using a hydrogen peroxide system. There was no difference in the proportion of lapsed versus non-lapsed wearers using a hydrogen peroxide care system ( $p = 0.110$ ) or using a brand name or private label MPS care system ( $p = 0.646$ ). Overall, 57% of participants using a care system reported rubbing and rinsing their lenses with solution before storage every night. Significantly more lapsed wearers reported rubbing and rinsing their lenses every night compared with non-lapsed wearers (64% versus 53%,  $p < 0.001$ ). Overall, 41% of participants using a care system reported topping up their solution in their lens case occasionally, frequently, or almost every night, instead of replacing the solution each day. A significantly higher proportion of non-lapsed wearers than lapsed wearers reported *never* topping up their solution (61% versus 56%,  $p = 0.010$ ).

#### 4.4.6 Replacement frequency

A replacement frequency (RF) of more than one day was considered to be non-compliant with the Manufacturer Recommended Replacement Frequency (MRRF) for DD wearers; a RF of 17 days (i.e. less frequently than twice a month) was considered to be non-compliant for lenses with a MRRF of two-weeks; and a RF of more than 34 days was considered to be non-compliant for lenses with a MRRF of one-month. Compliance rates were highest with DD lenses and lowest with two-week replacement lenses ( $p \leq 0.007$ ); overall 46% of the participants were compliant with the MRRF. Compliance with the MRRF was 45% in non- lapsed wearers and 48% in lapsed wearers ( $p = 0.053$ ).

Compliance with the MRRF was higher for SiHy lens wearers than for hydrogel lens wearers (45% versus 38%,  $p = 0.002$ ).

Forty-eight percent (48%) of RGP wearers reported replacing their lenses at intervals of 12 months or less while the remainder reported replacing their lenses at intervals of greater than one year. There was no option for recording the exact length of time before replacement when it was greater than one year and it is not therefore possible to determine compliance with replacement for RGP wearers.

#### **4.5 Discussion**

To our knowledge, this is the largest survey conducted to investigate discontinuation of contact lens wear since the introduction of SiHy and DD lenses to the market. Forty percent of participants were identified as lapsed wearers and had discontinued contact lens wear for a period of at least four months during the period surveyed (2008 to 2010). Almost two thirds of these participants did resume wear again during that same period, but approximately one third of those resuming wear later stopped once again. The rates for temporary and permanent lapses from lens wear in the current study are somewhat higher, at 40% and 23% respectively, than those of 34% and 12% respectively, which were reported in the 1999 study.<sup>2</sup> In another previous study specifically investigating success in refitting lapsed contact lens wearers, the short-term success rate was reported to be 77%,<sup>6</sup> however in that study lapsed wearers were recruited specifically to determine their success with being refitted compared to the current study in which participants simply reported whether they had resumed wear during the period investigated.

Almost two thirds of participants were female and the median age of participants was 27 years. There were no differences between lapsed and non-lapsed wearers with respect to gender; however, lapsed

wearers were older, had started wearing contact lenses at an older age, and had not worn lenses for as long as non-lapsed wearers. These differences, although some are only small, are consistent with those of Richdale *et al.*<sup>3</sup> The somewhat younger demographic of participants in this survey is not surprising since a social networking website was used for recruitment and participation in the study required completion of an online survey. The distribution of participant age appeared to be somewhat biased towards younger wearers when compared with data collected in Canada over a similar time period as part of the international prescribing survey;<sup>30</sup> however, it should be noted that the current study included contact lens wearers who had obtained their lenses from a variety of sources and not just their eye care practitioner. While the majority of participants purchased their lenses from an optometrist, optician or an optical store, 14% reported purchasing their lenses from the Internet. This is lower than that reported in a study involving college students where the rate reported was 22.5%.<sup>31</sup> It is interesting that more than half of the lapsed wearers reported only wearing lenses for six to twelve months before discontinuing from lens wear. Further study of this finding may provide additional insight into the reasons for discontinuing from lens wear but was beyond the scope of this study.

The reasons given by the lapsed wearers for discontinuing wear appear to be very similar in this study population as those previously reported.<sup>1-6</sup> Discomfort and dryness were the most frequent reasons, followed by red eyes, visual problems and expense. The distribution of responses was somewhat different, however, between presbyopic participants or those who were approaching presbyopia (over 40 years of age), compared with pre-presbyopic or younger participants. A higher proportion of participants in the older group reported poor vision (either distance and near or near only), while a higher proportion of those in the younger participants reported prohibitive expense, running out of

lenses or pregnancy as reasons for discontinuing lens wear. These results are not surprising given the demographics of both groups of wearers.

The reported wearing time for lapsed wearers of daily wear lenses was significantly shorter each day, and these participants reported wearing lenses for fewer days each week, compared to non-lapsed wearers. This finding is perhaps not surprising since the main reason for discontinuing lens wear has been reported to be discomfort, which would probably lead to shorter wearing times. Over half of the participants reported that they wished they could wear their lenses longer. The most commonly reported reasons given for not being able to wear lenses longer were “dryness” in the non-lapsed wearers and “because the lenses become uncomfortable” in the lapsed wearers. This result appears to indicate that the lapsed wearers’ symptoms were more extreme than that of the non-lapsed wearers, and may have ultimately led to discontinuation of lens wear. Lapsed wearers wishing to wear their lenses longer also reported shorter daily wearing times than non-lapsed wearers.

When a study of this nature is conducted via the Internet, participants’ recall of the type of contact lenses they wear, as well as brand names, may not be accurate. This study incorporated photographs of contact lens packaging since photographic aids have been shown to significantly improve lens wearers’ ability to recall their lens brands.<sup>32</sup> Overall, 95% of participants were wearing soft lenses and 5% were wearing rigid gas permeable (RGP) lenses. The proportion of participants wearing RGP lenses was somewhat higher than reported for Canada in 2010 in the Morgan *et al.* international prescribing survey;<sup>30</sup> however, our study included all wearers rather than only patients being fitted or refit and this could explain the higher proportion. Almost half the participants were wearing SiHy lenses and 21% were wearing DD lenses; these proportions were slightly lower and higher respectively when compared with the data from Morgan *et al* for Canada from 2010.<sup>30</sup> The

differences could possibly be attributed to the method of data collection, i.e. an online survey completed by wearers versus a fitting survey completed by ECPs. It is also possible that some SiHy wearers did not recognize their packages and some re-usable lens wearers selected a DD package with a similar name to their actual lens type.

One of the specific objectives of this study was to determine whether there was a difference in the rate of discontinuation from lens wear based on lens materials worn, lens replacement schedules and compliance with recommended intervals for lens replacement. The study showed that a higher proportion of non-lapsed lens wearers were wearing SiHy lenses when compared with lapsed wearers. While it is recognized that this finding could be attributed to a number of factors, one that should certainly be considered is that fewer SiHy wearers lapse from lens wear because of greater comfort afforded by lens materials, which has been reported.<sup>14-18,33</sup> If the overall comfort and end of day comfort with SiHy lenses is superior to the comfort achieved with conventional materials, this could well contribute to their overall success with contact lens wear. There have also been significant innovations in lens design and parameter availability in recent years and many of these features are available in current SiHy lenses.<sup>34-37</sup> Optimal correction of vision for astigmats<sup>38</sup> and presbyopes<sup>37</sup> should also result in lower rates of discontinuation from lens wear.

A perhaps surprising finding was that a higher proportion of lapsed wearers were wearing DD lenses. Despite improvements in comfort reported with some DD lenses,<sup>28,29</sup> DDs are not prescribed by North American ECPs as frequently as they are in many other countries.<sup>30</sup> This may be because they are regarded as the lens of choice for either part-time wearers or patients already experiencing problems with their lenses. These individuals may be more likely to lapse from lens wear. It is also possible that when prospective wearers do not seek contact lens care and advice from an ECP and simply order

lenses over the Internet without a prescription, the lenses they choose are more likely to be DDs. Without the appropriate lens fitting and instruction on lens wear and care, these wearers are more likely to be unsuccessful. Non-compliance with lens replacement for this modality may also play a role in success with this modality; with increased emphasis on the importance of compliance with lens replacement a higher success rate may be found in DD lens wearers. At the time that this study was conducted, SiHy DD lenses were not in widespread use in Canada. It was therefore not possible to evaluate the combined role of a DD modality with SiHy materials. Further study of this group of lens wearers is required to better understand this finding.

A high proportion of participants wearing all types of soft lenses did not comply with the MRRF. In the current study it was not possible to determine compliance with the ECPs recommendations for lens replacement, since only the wearers' report of replacement interval and the known MRRF for the lens types that were worn were available. Consistent with previous studies, the compliance rate was highest for DD wearers and lowest for two-week replacement wearers.<sup>39-41</sup> Although it has been suggested that contact lens wearers who are not compliant with their contact lens wear and care may be more likely to lapse from lens wear, no difference was found in this study in the compliance rate for lens replacement between lapsed and non-lapsed wearers. This suggests that non-compliance with lens replacement is not a major factor driving drop-out from lens wear.

In agreement with the work of Yeung *et al*, compliance with the MRRF was higher for wearers of SiHy lenses when compared with wearers of hydrogel lenses.<sup>42</sup> There are several possible reasons for this difference. It may be that lens replacement with SiHy lenses is driven by a deterioration in subjective vision and comfort.<sup>43</sup> The differences in surface deposition with SiHy lenses when compared with hydrogel materials should also be considered as a possible reason for replacing SiHy



lenses sooner than hydrogel lenses.<sup>44-49</sup> A prospective study investigating subjective and objective lens performance with contemporary lens materials would however be required to further investigate this finding.

The distribution of care systems used suggest relatively low use of private label care systems (2%); however, it is possible that the actual percentage was higher since some wearers of reusable soft lenses did not select or name their care system, possibly because it was a private label one for which there was no picture, and some wearers may have selected a brand name care system because it looked similar to their private label care system. A higher proportion of lapsed participants reported topping up their cases with solution rather than completely replacing the solution each day; however, since this study did not fully investigate compliance with all aspects of lens care, it is not known whether wearers who do not look after their lenses appropriately are more likely to lapse from lens wear. Previous studies have shown a higher rate of complications in patients who are not compliant with lens wear and it is possible that these patients may discontinue lens wear as a result of the complications.<sup>42,50</sup>

## **4.6 Conclusion**

Despite the introduction of new contact lens materials, modalities and designs to the market, discontinuation from lens wear continues to occur at a similar rate to that reported in the 1990s. The rate does appear to be slightly lower in wearers of SiHy lenses but the difference is relatively small and the introduction of these materials does not appear to have had a profound effect on a perpetual problem of discontinuation of lens wear, although they do seem to represent a step in the right direction. Wearers of SiHy lenses were also found to be more compliant with the MRRF.

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The authors wish to thank Dr. Tyler Anderson for generating the online survey.

Chapter 5 describes a study which was conducted in eye care practitioners' offices in the United States to determine whether patients who were non-compliant with recommendations for lens replacement attended for eye examinations less frequently than patients who were compliant.

## Chapter 5

# Compliance with Lens Replacement and the Interval Between Eye Examinations

This chapter has been accepted for publication as follows:

Compliance with lens replacement and the interval between eye examinations

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	Concept / Design	Recruitment	Acquisition of data	Analysis	Write-up / publication
Dumbleton	Y	Y	Y	Y	Y
Woods C	Y	-	-	-	Y
Jones	-	-	-	-	Y
Fonn	Y	-	-	-	Y

Tables: 6

Figures: 5

## 5.1 Overview

**Purpose:** Eye Care Practitioners (ECPs) acknowledge that their patients do not always follow recommendations for lens replacement, but many may not realize the possible implications for their offices. The study was conducted to investigate whether there is a relationship between contact lens compliance and the interval between eye examinations (IEE).

**Methods:** The study was conducted in ECP offices in the United States. ECPs and patients independently completed linked questionnaires evaluating their contact lens wear and care. Patients were required to be current wearers of daily disposable (DD) lenses or re-usable silicone hydrogel lenses with a manufacturers' recommended replacement frequency (MRRF) of 2 weeks (2WR) or 1 month (1MR).

**Results:** 2147 questionnaires from 141 offices were eligible. 54% of patients were wearing 2WR, 37% 1MR and 9% DD lenses. Wearers of 2WR lenses were significantly less compliant with replacement than wearers of both DD and 1MR lenses (34% versus 74% and 67%, both  $p < 0.001$ ); patients purchasing an annual supply were more compliant (55% versus 45%,  $p < 0.001$ ). The mean IEE was 16 months and was longer for wearers who were non-compliant with the MRRF (17.4 months versus 14.5 months,  $p < 0.001$ ). Other factors affecting IEE were household income ( $p = 0.030$ ), insurance ( $p < 0.001$ ), purchase source ( $p < 0.001$ ) and gender ( $p = 0.007$ ).

**Conclusions:** Patients who were not compliant with the MRRF had longer IEEs and were less likely to purchase an annual supply of lenses. Patients who purchased lenses from their ECP, had a higher household income, had eye-examination insurance, and were female had shorter IEEs. Patients failing to replace their lenses when scheduled were also found to be less compliant with lens care procedures. ECPs should reinforce the importance of all aspects of lens wear and care with their patients with the

overall aim of reducing possible complications and retaining successful contact lens wearers in their offices.

## 5.2 Introduction

Non-compliance in health care has been a topic of concern for many years. Rates of compliance can vary considerably depending on the type of treatment or intervention; compliance with the use of long-term medication therapies has been reported to be between 40% and 50%, with higher rates for the use of short-term medications but much lower rates for compliance with lifestyle changes.<sup>1</sup> A number of factors have been reported to contribute to non-compliance with therapeutic interventions; these factors have been categorized as “patient-centered factors, therapy-related factors, social and economic factors, healthcare system factors, and disease factors”.<sup>2</sup> Non-compliance with recommended contact lens wear, care and replacement is extremely common and was first reported in the 1980s;<sup>3,4</sup> since this time there have been numerous studies investigating non-compliance with many aspects of contact lens wear.

While eye care practitioners (ECPs) generally accept that patients may be non-compliant with contact lens wear, care and replacement recommendations, they often assume that their own patients are more compliant than the general contact lens wearing population. In a study previously conducted by the Centre for Contact Lens Research (CCLR), six private optometric offices showed a similar level of non-compliance with lens replacement.<sup>5</sup> Providing information on ECPs’ own patients may be a valuable tool in improving compliance with contact lens wear and care. It would also be interesting to determine whether patients who visit their ECPs more frequently for eye examinations are more likely to be compliant in the contact lens wear and care in general. The main purpose of this study was to investigate whether there is a relationship between contact lens compliance and the frequency of eye examinations.

### 5.3 Methods

Ethics approval was obtained through the Office of Research Ethics at the University of Waterloo before commencement of this study, and the study was conducted following the tenets of the Declaration of Helsinki. Letters of invitation to participate in the study were sent by the CCLR to approximately 500 Eye Care Practitioners (ECP) offices in the United States. An office was considered eligible to participate in the study if the office had a minimum of 1000 contact lens wearing patients; the office prescribed daily disposable (DD) and two-week and one-month replacement silicone hydrogel (SiHy) lenses. Study materials were subsequently delivered to those eligible ECPs who indicated that they would like to participate in the study.

A target of 50 patient participants at each office was set for the study. Patients were considered eligible to take part in the study if they were at least 16 years of age; were existing contact lens wearers of DD or SiHy lenses who had received a previous eye examination at the ECP's office; and were attending the ECP office for a routine full eye examination on the day that they were asked to participate. Eligible contact lens wearers were given a letter of explanation by their ECP and, if they agreed to participate, were asked to complete the patient portion of a two-part questionnaire about their lens wear and lens care. Patients were instructed to seal their part of the completed questionnaire and return it to the office staff. Patients participating in the study were eligible to receive a VISA® gift card upon completion of the questionnaire. The ECP then completed a separate part of the questionnaire with details regarding the interval between eye examinations, the contact lenses prescribed and instructions for contact lens wear and care for the patient. Both parts of the questionnaire were coded with a unique number for the office and a participant identification number



for the patient. This combination of numbers ensured that the responses from the ECP and the patient were linked when the data were analyzed.

The completed questionnaires, along with an office questionnaire in which ECPs reported their office demographics and prescribing patterns, were sent to an independent data reading centre (DATACORE Marketing LLC). The data reading centre generated a “report card” for each of the ECPs participating in the study detailing the results from their patients. These report cards and the data from all the patients completing questionnaires were sent to the Centre for Contact Lens Research (CCLR). The CCLR sent the report cards to the ECP offices and data analysis for the entire cohort was conducted by the CCLR. This manuscript reports on the entire data set and not on the individual ECP report cards.

Where relevant, data analyses were conducted using Statistica 10.0 (StatSoft Inc. Tulsa, OK). Chi-square tests were used to compare differences in counts and two-sided difference between two proportions tests were used when comparing proportional differences between the groups investigated. Student t-tests were used where relevant. General linear models were used to analyse “days between eye exams” and “lens care compliance score” with the following factors: age (continuous predictor), gender (f/m), insurance (yes/no) and household income (5 categories). A significance level of  $p \leq 0.05$  was used for all analyses. For all variables, cases were omitted if more than one response was selected by the participant when only one was expected.

## **5.4 Results**

### **5.4.1 Questionnaires**

A total of 3384 ECP questionnaires and 3433 patient questionnaires from 141 offices were received by the data reading centre. Data from these questionnaires were sent to the CCLR and data from ineligible patients (not current DD or SiHy wearers, insufficient lens type information and/or wearers under the age of 16), and data from questionnaires for which there were not corresponding sections from both the ECP and the patient, were removed prior to analysis. The total number of questionnaires eligible for analysis was 2147.

### **5.4.2 Demographics**

The average number of contact lens patients at each of the offices was reported to be  $2122 \pm 1202$  (range 1000 to 8000). The average proportion of daily disposable lens wearers was reported to be 9%, two-week replacement wearers 47% and one-month replacement wearers 44%. The participant demographics are shown in Table 5-1.

### **5.4.3 Contact lenses**

Information for the lens types worn (right eye only) was taken from the ECP questionnaire. The lens brands worn are listed in Table 5-2: Lens types worn. The Manufacturers Recommended Replacement Frequency (MRRF) for lenses worn and the ECP recommendations for lens replacement are shown in Figure 5-1. Eighty-five percent (85%) of the spherical component of lenses worn were minus powers and 15% were plus powers. Seventy percent (70%) of patients reported that they purchased their contact lenses from their ECP, 21% from a discount store, 7% from an Internet

supplier and 2% from another optical supplier. Forty-three percent (43%) purchased the recommended amount for a one-year supply, 32% purchased the minimum they could purchase, and 25% purchased more than the minimum but not a full year supply.

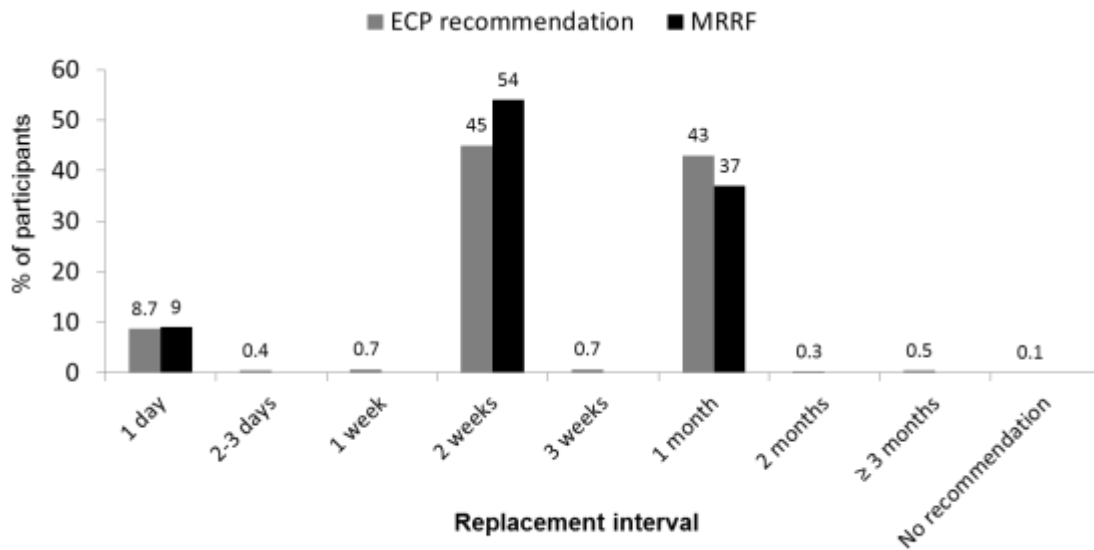
**Table 5-1: Participant Demographics**

<b>Participant Demographics</b>	
Age	36 ± 13 years median 34 years (16 to 81 years)
Gender	68% female, 31% male 1% no response
Years in CL	14 ± 10 years median 12 years (one month to 54 years)
Household Income	
<\$20,000	11%
\$21,000 to 40,000	25%
\$41,000 to 80,000	33%
\$81,000 to 120,000	21%
>\$120,000	10%
Have Vision care insurance?	62%
Insurance covers annual exam?	56 % (91% of those with insurance)

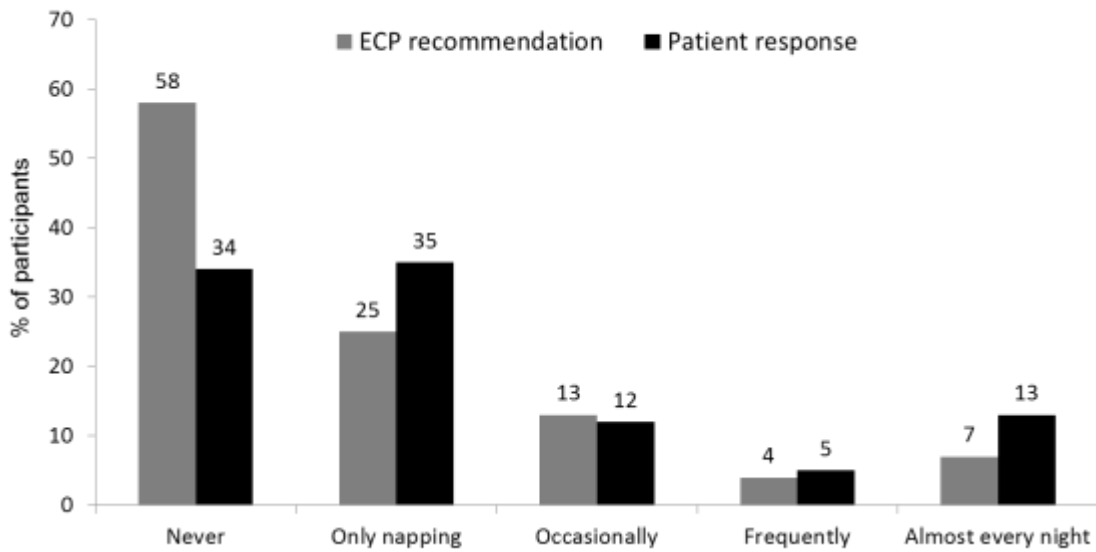
Seventy-five percent (75%) of patients reported wearing their contact lenses every day. The average reported wearing time was 14.3 ± 4.5 hours (median 14 hours), with an average comfortable wearing time of 13.0 ± 4.9 hours (median 12 hours). The proportion of patients reporting sleeping while wearing their lenses, and the proportion for which this was recommended by the ECP are shown in Figure 5-2.

**Table 5-2: Lens types worn**

<b>Lens Name</b>	<b>Number reported</b>	<b>% by lens type</b>
<b>DD lenses</b>		<b>9% DD</b>
1 DAY Acuvue	12	
1 DAY Acuvue Moist	33	
1 Day Acuvue TruEye	26	
Biomedics 1 Day	2	
Dailies / Dailies Aqua Comfort Plus	90	
Proclear 1 Day	10	
Soflens DD	10	
Other	10	
<b>Total – Daily Disposables</b>	<b>193</b>	
<b>Spherical SiHy lenses</b>		<b>63.5% Spherical SiHy</b>
Acuvue Advance	199	
Acuvue OASYS	635	
Air Optix AQUA	191	
Air Optix Night & Day	116	
Avaira	27	
Biofinity	70	
O2 Optix	57	
PureVision	70	
<b>Total – Spherical SiHy</b>	<b>1365</b>	
<b>Toric SiHy lenses</b>		<b>20.5% Toric SiHy</b>
Acuvue Advance for Astigmatism	55	
Acuvue OASYS for Astigmatism	205	
Air Optix for Astigmatism	81	
Biofinity Toric	61	
PureVision Toric	41	
<b>Total – Toric SiHy</b>	<b>443</b>	
<b>Multifocal SiHy lenses</b>		<b>7% Multifocal SiHy</b>
Acuvue OASYS for Presbyopia	32	
Air Optix AQUA Multifocal	65	
PureVision Multifocal	48	
Biofinity Multifocal	1	
<b>Total – Multifocal SiHy</b>	<b>146</b>	
<b>Total – all lens types</b>	<b>2147</b>	<b>100%</b>



**Figure 5-1: The Manufacturers' Recommended Replacement Frequency (MRRF) for lenses worn and the Eye Care Practitioners' (ECP) recommendations for lens replacement.**



**Figure 5-2: The proportion of patients reporting sleeping while wearing their lenses, and the proportion for which this was recommended by the Eye Care Practitioner (ECP).**

#### 5.4.4 Interval between eye examinations

ECPs recommended an interval between full eye exams (IEE) of one year for 98% of patients. The actual mean IEE was 482 days or 16 months (median 420 days or 14 months). IEE did vary somewhat by category of recommended replacement; the mean interval for DD wearers was 441 days or 14.7 months (median 401 days), for two-week replacement wearers 492 days or 16.4 months (median 431 days) and for one-month replacement wearers 478 days or 15.9 months (median 412 days). The differences were however only significant between wearers of two-week replacement lenses and DD lenses ( $p=0.034$ ). The influence of a number of factors on the IEE is summarized in Table 5-3. The IEE also varied across the income brackets ( $p=0.030$ ) with a trend towards a greater interval for the two lowest income brackets.

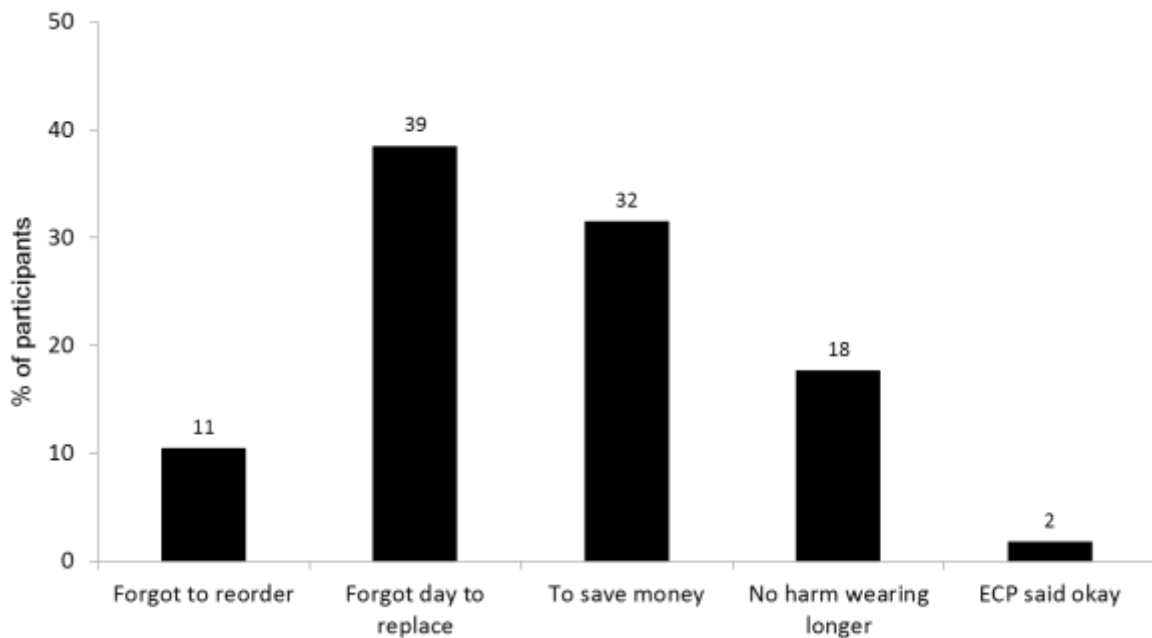
**Table 5-3: The influence of various factors on the interval between eye examinations**

Factor	Mean IEE in Days	p value
Gender	M 521 F 479	0.007
Insurance covers eye exam	Yes 470 No 530	<0.001
Income	Varies indirectly with income	0.030
Purchase source	ECP 465 Other 522	<0.001
Purchased annual supply	Yes 485 No 480	0.66

#### 5.4.5 Compliance with lens replacement

The actual replacement frequency (RF) was not always in compliance with the MRRF. Wearers of two-week replacement lenses were significantly less compliant (34%) with the MRRF than wearers of

both DD (74%) and one-month replacement lenses (67%) ( $p < 0.001$ ) but there was no significant difference in compliance with the MRRF between wearers of DD and one-month replacement lenses ( $p = 0.066$ ). The reasons that the patients gave for wearing their lenses for longer than recommended are shown in Figure 5-3.

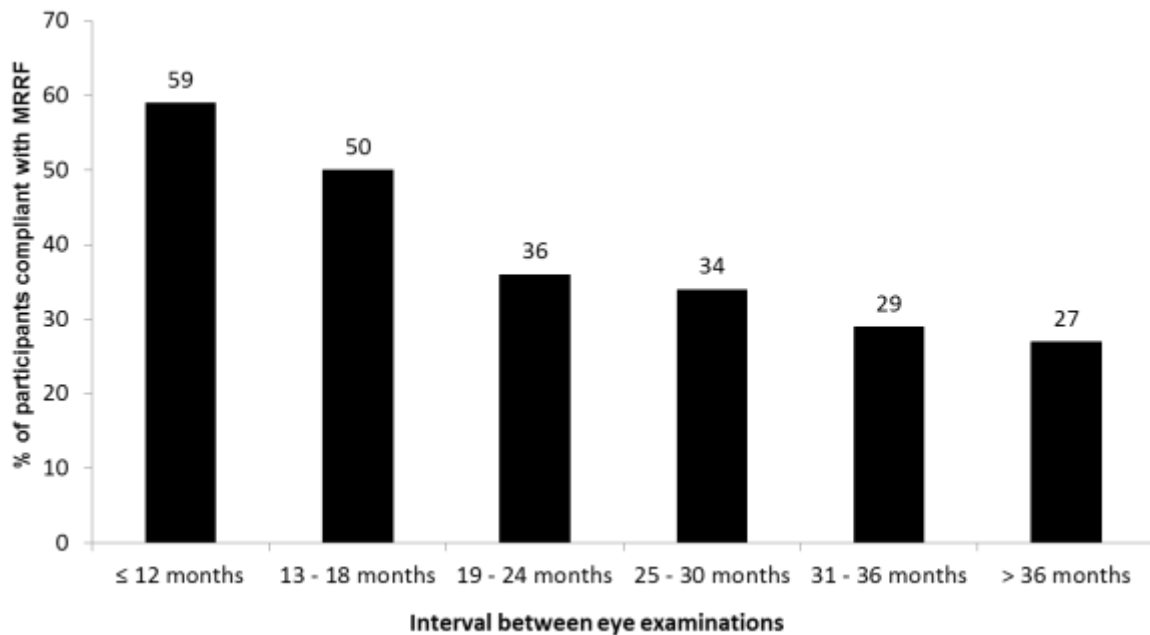


**Figure 5-3: Patient reported reasons for wearing their lenses for longer than recommended.**

The mean age of MRRF compliant lens wearers was slightly higher ( $38.2 \pm 13.5$  years) than for MRRF non-compliant lens wearers ( $34.3 \pm 12.5$  years) ( $p < 0.001$ ). The MRRF compliance rate was similar for females (50.1%) and males (48.3%) ( $p = 0.45$ ). A higher proportion of patients who purchased lenses directly from their ECP were compliant with the MRRF when compared with patients who purchased their lenses from other sources (51.5% versus 44%,  $p = 0.002$ ). A higher proportion of patients who reported purchasing a one-year supply of lenses were compliant with the

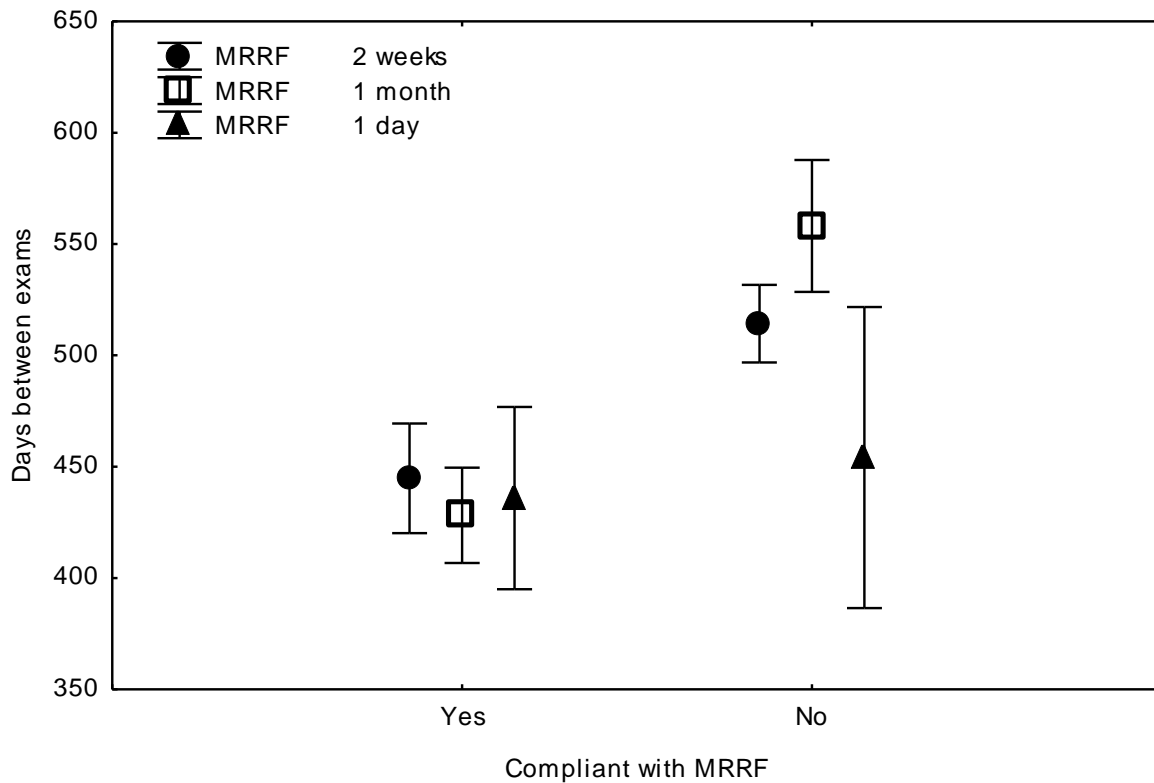
MRRF compared with those who purchased less than a one-year supply (55% versus 45%,  $p < 0.001$ ). Compliance with MRRF was also found to increase across five household income brackets and was significantly greater in the higher income bracket ( $> \$120,000$ , 60%) when compared with the lower income bracket ( $< \$20,000$ , 39%) ( $p < 0.001$ ).

Figure 5-4 shows the proportion of patients who were compliant with the MRRF for increasing IEE. The actual IEE for each of the lens wearing modalities and for both MRRF compliant and non-compliant groups is shown in Figure 5. The average interval between eye examinations was longer in the MRRF non-compliant group for wearers of one-month and two-week replacement lenses (ANOVA and Tukey post-hoc,  $p < 0.001$ ).



**Figure 5-4: The proportion of patients who were compliant with the MRRF for increasing Interval between Eye Examinations.**





**Figure 5-5: Interval between Eye Examinations (IEE) according to the Manufacturers' Recommended Replacement Frequency (MRRF).**

#### 5.4.6 Contact lens care

Eighty eight percent of patients using a care system reported using a multipurpose system and 12% reported using a hydrogen peroxide system; these were reported by the patient selecting a picture image of their care regimen on the questionnaire. The frequency of hand washing (before insertion and removal), rubbing and rinsing lenses and topping up solution are summarized in Table 5-4. The proportion of wearers always washing their hands before insertion was significantly greater than those

always washing their hands before removal ( $p < 0.001$ ). The frequency of contact lens case cleaning and replacement are shown in Table 5-5.

**Table 5-4: Contact lens care**

<b>Frequency of hand washing</b>		
	Prior to lens insertion %	Prior to lens removal %
Every time	70	62
Most of the time	25	29
Never, or Almost never	5	9
<b>Lens Care</b>		
	Rub & Rinse %	Top Off solution %
Every night	29	6
Most nights	19	7
Once a week	13	19
Never, or Almost never	38	71

**Table 5-5: Contact lens case care and replacement**

<b>Clean case %</b>	
Every day	19
Most days	13
Once a week	21
Once a month	25
Never, or Almost never	22
<b>Replace case %</b>	
Every month	15
Every 3 months	21
Every 6 months	22
Once a year	26
Never, or Almost never	15

An overall lens care compliance score was calculated for each patient using the responses to the contact lens and contact lens case care questions using the scoring system shown in Table 5-6. Using this system, patients could have a minimum score of 0 (extremely poor compliance) and a maximum

sore of 28 (excellent compliance). The mean compliance score for wearers who were compliant with lens replacement was significantly higher than those who were non-compliant (17.2 versus 15.4,  $p < 0.001$ ) regardless of the MRRF. Factors affecting the compliance score were age and gender. Both of these effects were small; the correlation between age and lens care compliance score was positive but low ( $r = 0.20$ ,  $p < 0.001$ ), and the mean score for females was 16.4 compared to 15.5 for males ( $p = 0.0019$ ).

**Table 5-6: Lens care compliance scores**

Content of Question	Score / Response				
	4	3	2	1	0
Hand wash removal	Every time		Most times		Never / almost never
Hand wash insertion	Every time		Most times		Never / almost never
Rub and rinse	Every night	Most nights		Once /week	Never / almost never
Top off	Never		Occasionally	Frequently	Every night
Clean case	Every day	Most days	Once /week	Once/month	Never
Store case*	Caps off/down		Caps off / up		Caps on
Replace case	Every month	3 months	6 months	Every year	Never

\* Patients using AQuify® with a Pro-Guard® case would be considered compliant if they stored their case with the caps on, however no patients specifically reported using this care system.

## 5.5 Discussion

While ECPs may recognize that their patients do not always follow their recommendations for lens wear, care and replacement, many may not realize the possible implications for their offices. The purpose of this study was to evaluate contact lens compliance and its possible role in the frequency with which patients visit their ECP for routine eye examinations. Compliance issues considered included lens replacement, overnight wear and lens care. Possible relation of the interval between eye

examinations to purchase practice (where and how many), income, and insurance coverage were also explored.

Just over two thirds of patients taking part in this study were female and the median age was 34 years so it was felt this was representative of the general contact lens wearing population <sup>6</sup>. The patients were established wearers, with a median of 12 years of lens wear and the majority wore their lenses most days of the week, with a median wearing time of 14 hours each day. The majority of patients were wearing spherical SiHy lenses; toric and multifocal designs were worn by 21% and 7% of the patients, respectively. Only 9% of the patients taking part in the study were wearing DD lenses; this value is somewhat lower than that reported by Morgan *et al* for the US population in 2011, but consistent with the prescribing patterns of the offices involved in the study. <sup>6</sup> The difference in the proportion of DD lens wearers in the current study from that reported by Morgan *et al* may simply relate to differences in study design and sample size.

The American Optometric Association recommends intervals of two years for healthy adults aged 18 to 60 but the recommendations by ECPs for contact lens wearers are usually shorter. <sup>7</sup> In this study, almost all ECPs recommendations for their patients were for an interval of one year between eye examinations. The mean reported actual interval between eye examinations was however somewhat longer than this.

Interestingly, the interval did vary somewhat by recommended replacement frequency, with the shortest interval for DD wearers and the longest interval for two-week replacement wearers; the reason for these differences is not clear, but may be related to the higher compliance with replacement by DD wearers prompting a return visit to the ECP for a renewed supply of lenses. This is supported

by the finding that non-compliant wearers of lenses with a MRRF of two-weeks and one-month were found to attend their ECP offices for eye examinations at significantly longer intervals than wearers who were compliant with the MRRF.

Longer intervals between visits were also found for males than females and for patients who did not have insurance which covered the costs of an eye examination. The interval between eye examinations was also longer in patients reporting a lower household income and patients who purchased their lenses directly from their ECP returned for an eye examination more frequently than patients who purchased their lenses from another source.

Consistent with previous studies investigating compliance with replacement of contact lenses,<sup>8,9</sup> this study has found that DD lens wearers have the highest rate of compliance with the MRRF, followed by one-month MRRF wearers and two-week MRRF wearers have the lowest rate of compliance with lens replacement. In this study monthly replacement compliance was not significantly different from DD compliance.

Previous studies conducted by the CCLR which have investigated compliance with recommendations for lens replacement have found that ECPs do not always recommend the same replacement interval as the MRRF.<sup>5,8-10</sup> This was also the case in the current study. In agreement with previously conducted studies, patients who were compliant with the MRRF were older than non-compliant patients but in contrast to previous studies, no difference was found with respect to gender.<sup>8,9</sup> In this study however, we found that patients with a lower household income had significantly lower rates of compliance with the MRRF than patients in the higher income brackets. This is not entirely surprising though; patients who may not have as much disposable income may be more inclined to stretch the

life of their lenses in order to save money. Interestingly, a higher proportion of patients who purchased lenses directly from their ECP were compliant with the MRRF. The primary reason given for failing to replace lenses when recommended was once again forgetting which day to replace lenses,<sup>8,9,11-16</sup> but the second most reported reason was to save money. Despite the consistent finding that faulty memory is the most cited reason for failing to replace lenses on schedule, it could well be that financial status is the common thread that connects replacement compliance, where and how many lenses are purchased and frequency of eye examinations.

Seventy percent of patients reported purchasing their lenses from their ECP and only 7% purchased lenses from an Internet supplier. These figures may not however be fully representative of the contact lens wearing population in the US, since this study was conducted through ECP offices and patients had to be attending the offices to be eligible to participate; a recent Internet study conducted in Canada reported that 14% of contact lens wearers had purchased their lenses on the internet.<sup>17</sup>

When purchasing contact lenses, less than half of the patients reported purchasing an annual supply. Interestingly, compliance with the MRRF was higher in patients who purchased an annual supply than for those who did not purchase an annual supply; suggesting that having more lenses available may improve compliance with recommendations for lens replacement. A similar finding has also been recently reported by Schnider and Jedraszczak.<sup>18</sup>

When compared with the recommendations regarding sleeping while wearing lenses made by the ECPs, many patients reported wearing their lenses while napping or overnight beyond what had been recommended. It is of particular concern that patients are not following the recommendations of their ECP with respect to this modality, as overnight wear with soft lenses, regardless of material has been

shown to be associated with a higher incidence of microbial and infiltrative keratitis than daily wear.

19-21

Non-compliance with contact lens care is a common and frequently reported issue.<sup>11-16</sup> In this study a higher proportion of patients reported failing to always wash their hands prior to lens removal when compared with prior to lens insertion. This finding is interesting and suggests that patients place greater importance in having clean hands before they put their lenses in when compared with removing the lenses, when they will either be discarded or cleaned and disinfected with the care system. Consistent with previous studies,<sup>5,14</sup> a high proportion of patients reported failing to rub and rinse their lenses prior to disinfection after each wearing period. While some of these may have been using a care system where this was not specifically recommended in the package insert or on the packaging, failure to rub and rinse still represents poor compliance with a step that has been shown to play a significant role in the safe wear of contact lenses.<sup>22,23</sup> A significant proportion of patients also reported “topping off” their contact lens cases with solution rather than completely replacing the solution after each use, another area of concern with respect to the safety of contact lens wear.<sup>24-26</sup>

There have been several recent publications on the appropriate care for contact lens cases.<sup>27-30</sup> The results from the current study confirm that patients frequently fail to care for and replace their lens cases appropriately. For most patients, the methods for case storage while lenses were being worn did not meet the hygiene guidelines recommended by Wu *et al*, with only 12% reporting storing their case with the wells facing down and the caps off.<sup>28,31</sup> Recommendations for case replacement vary, but the general consensus is that cases should be replaced at intervals of between three and six months.<sup>27</sup> In the current study only one third of patients reported replacing their case at least every three months.

Based on the responses to questions relating to compliance with lens care, a score was generated for each patient wearing re-usable lenses. Patients who were compliant with the MRRF had significantly higher scores (i.e. more compliant with lens care procedures) than those who were not compliant with the MRRF, regardless of whether they were wearing lenses with a MRRF of two-weeks or one-month. This seems to indicate that if a patient is non-compliant with respect to one aspect of contact lens wear, they are more likely to be non-compliant in other areas too and supports the finding of Carnit *et al* that a higher risk taking personality style of contact lens wearers was associated with less compliant behaviour.<sup>32</sup> Other factors which were found to affect the compliance score were age (younger patients had a lower score) and gender (lower scores for males than females); however, the correlations were relatively low and may not be clinically meaningful.

## **5.6 Conclusions**

In this study we have shown that wearers of lenses with a MRRF of two weeks and one month who are not compliant with recommendations for lens replacement attend their ECP offices for eye examinations at significantly longer intervals than wearers who are compliant with the manufacturers' recommendations for lens replacement.

Additional interesting findings were that patients who purchased an annual supply of lenses were more compliant with lens replacement, patients reporting a lower income were less compliant with lens replacement and had longer intervals between their eye examinations and patients who reported poor compliance with lens care in general were also more likely to fail to replace their lenses when scheduled.



The findings from this study support the concept that practitioners need to continually remind patients about the importance of replacing their lenses on a regular basis and that cases must be cleaned and replaced regularly, if they are to maintain optimum – and safe – performance with their lenses. ECPs may be able to improve patient compliance with lens replacement by encouraging their patients to purchase an annual supply of lenses. This may, in turn, result in shorter intervals between eye examinations. Both of these factors can only enhance compliance of their contact lens patients, with the overall aim of helping patients to have a better lens wearing experience and retaining successful contact lens wearers in their offices.

## **Acknowledgements**

This study was supported by research funding from Alcon. Peter Bergenske is an employee of Alcon.

Chapter 6 describes a survey that was conducted in four countries to investigate compliance with recommendations for wear and replacement of daily disposable contact lenses. To our knowledge, this is the largest study of its kind, to date, reporting specifically on compliance with the use of daily disposable lenses.

## Chapter 6

### A Multi-country Assessment of Compliance with Daily Disposable Contact Lens Wear

This chapter has been submitted as follows:

A multi-country assessment of compliance with daily disposable contact lens wear.

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*Contact Lens and Anterior Eye; submitted*

	Concept / Design	Recruitment	Acquisition of data	Analysis	Write-up / publication
Dumbleton	Y	Y	Y	Y	Y
Richter	-	-	-	Y	Y
Woods	Y	Y	-	-	Y
Aakre	-	Y	-	-	Y
Plowright	-	Y	-	-	Y
Morgan	Y	-	-	-	Y
Jones	Y	-	-	-	Y

Tables: 6. Figures: 7

## 6.1 Overview

**Purpose:** To investigate compliance with daily disposable contact lens (DDCL) wear and investigate re-use of lenses according to country and DDCL material worn.

**Methods:** Optometrists invited eligible DDCL patients from their practices to participate in a survey on DDCL wear in Australia, Norway, the United Kingdom (UK) and the United States (US). Eligible participants completed an online or paper version of the survey.

**Results:** 805 participants completed the survey (96% online): Australia 13%, Norway 32%, UK 17%, US 38%. The median age was 38 years; 66% were female. Silicone hydrogel (SiHy) DDCLs were worn by 14%. Overall, 9% were non-compliant with DDCL replacement; Australia 18%, US 12%, UK 7% and Norway 4%. There were no differences with respect to sex, years of contact lens wear experience or DDCL material (SiHy versus hydrogels). The primary reason for re-use was “to save money” (60%). Re-use of DDCLs resulted in inferior comfort at insertion and prior to lens removal ( $p = 0.001$ ). 75% reported occasional napping and 28% reported sleeping overnight for at least one night in the preceding month, while wearing their DDCLs.

**Conclusion:** Non-compliance with replacement of DDCLs occurred in all countries investigated; the rate was highest in Australia and lowest in Norway. Re-use of DDCLs was associated with reduced comfort. DDCL wearers often reported wearing lenses overnight. It is important for optometrists to counsel their patients on the importance of appropriate lens wear and replacement for DDCLs in order to reduce their risk of developing complications.

## 6.2 Introduction

Daily disposable contact lenses (DDCLs) are becoming increasingly popular among patients and eye care practitioners (ECP)s worldwide.<sup>1,2</sup> In addition to the benefits and convenience of a fresh new lens each day and no requirement for a contact lens care system, this modality of lens wear has been shown to offer many health benefits when compared with reusable contact lenses.<sup>3</sup> Superior comfort, vision and relief from allergies have also been reported with the use of DDCLs.<sup>4-7</sup>

Unfortunately, not all patients wearing DDCLs are compliant with their replacement. In previous studies conducted in Canada and the United States, non-compliance with DDCL replacement has been reported to occur at rates between 12 to 13%;<sup>8-10</sup> however, the numbers of DDCL wearers in these studies were relatively low and the figures reported may not be representative of compliance with wear and replacement of DDCLs in other countries. At the time that these studies were conducted, silicone hydrogel DDCLs were not commercially available,<sup>11,12</sup> and compliance rates for replacement of these lenses has not been investigated to date.

The purpose of this survey was to further evaluate compliance with replacement of DDCLs since the introduction of silicone hydrogel materials, and to investigate any differences in compliance with the replacement of DDCL among several countries around the world. The survey was also designed to investigate the reasons for non-compliance; the frequency of overnight lens wear with DDCLs; the regular source of purchase of the participants' lenses; the lens storage procedures and care system or solutions commonly used during non-replacement; an estimation of the participants understanding of the risk of non-replacement; and the reported subjective comfort of DDCLs when they are re-used.

### 6.3 Methods

This survey was conducted in four countries: Australia, Norway, the United Kingdom (UK) and the US. These countries were selected because they have different approaches to lens prescribing and supply<sup>2</sup>. Norway has an extremely high proportion of DDCL wearers (44%).<sup>1</sup> The UK also has a high proportion of DDCL wearers (38%)<sup>1</sup> and it is thought that the vast majority of patients who are prescribed their lenses by their eye care practitioner in the UK are linked with a Direct Banking Debit / Order; this system allows the eye care practitioner to receive payment for the contact lenses directly from the patient's bank account at regular intervals and is linked to automatic re-ordering, and usually delivery of replacement lenses directly to the patient. Australia also has a relatively high penetration of DDCL wearers (24%),<sup>1</sup> but probably with a less well developed Direct Banking Debit / Order system. The US has the largest worldwide contact lens market and although penetration of DDCL is not as high as in many other countries at only 16%,<sup>1</sup> there are offices where this modality is more popular and only offices prescribing at least 20% of their patients with DDCLs were selected to take part in this survey.

Ethics approval was obtained through the Office of Research Ethics at the University of Waterloo and the Research Review Boards at the University of Manchester, United Kingdom and Deakin University, Australia. The Norwegian Social Data Science Services, Norway was also informed of this survey. The survey was conducted following the tenets of the Declaration of Helsinki.

The survey was conducted using similar methodology to that employed in a previous CCLR study, in which ECPs (optometrists) in one region in Canada identified eligible participants and invited them to complete a questionnaire on behalf of the CCLR.<sup>13</sup> In the current survey, participation in each country was coordinated by a local investigator: Australia (CAW), Norway (BMA), UK (PM and AP)

and US (KD). Coordination of the entire survey was carried out by the CCLR (KD). The local coordinator was asked to recruit optometry offices / practices to take part and to invite eligible DDCL wearers from their offices to complete the questionnaire. In Australia, Norway and the USA, ten practices or offices took part and each practice or office was asked to identify approximately 300 DDCL wearers who would be eligible to participate. In the UK, one group, which comprised fifteen offices with centralized patient records, agreed to take part in the survey and to identify approximately 3000 DDCL wearers who would be eligible to participate. The survey was conducted from April to October 2012.

Patients were considered eligible to participate if they were at least 18 years of age; were current wearers of DDCLs and not any other lens type; had worn DDCLs for at least 6 months; were currently wearing DDCLs for at least one day each week; and had given implied consent to participate in the survey at the start of the online questionnaire.

Prospective participants were mailed a cover letter from their optometrist explaining the survey purpose and procedures and inviting them to complete an online questionnaire regarding their wearing experiences with DDCLs. Each participant was provided with a Uniform Resource Locator (URL) which pointed to the web page describing the survey and allowed participants to give their permission to participate. Participants were advised to have their lens packages available when completing the questionnaire in order to be able to report which lens brand they were currently wearing. There were two versions of the web page and the online questionnaire, one version in English (for Australia, the UK and the US) and one in Norwegian. A paper version of the questionnaire was also made available to prospective participants in the US and Australia towards the end of the survey period. Participants were provided with a code to enter into the questionnaire that

identified their country, and practice or office (or group of practices in the case of the UK) at which they were registered as a patient. A series of preliminary questions were used to confirm eligibility before the questionnaire started. Individuals whose responses indicated that they were not eligible were advised of this and were not able to continue with the online questionnaire. Further attempts at entry to the questionnaire were also declined for repeated Internet Protocol (IP) addresses.

The questionnaire included specific questions to evaluate the following:

- Demographic and lens wearing history questions;
- Ranking of various aspects of DDCL wear;
- Selection of current lens brand;
- Regular source of lens supply;
- Method of payment
- Recommendations given for lens replacement;
- Current DDCL wearing patterns;
- Re-use of lenses over the course of the day and if so, method of storage;
- Re-use of lenses for more than one day and if so, for how long and method of storage;
- Reasons for re-use;
- Frequency of napping and/or sleeping in lenses;
- Comfort ratings for new and, where applicable, re-used lenses;
- Participants' understanding of the risk(s) of non-replacement.



The online version of the questionnaire was developed by the CCLR using PHP, an open source general purpose server-side scripting language designed to produce dynamic Web pages. A MySQL database was used. The questionnaire incorporated forced choice questions, ranking questions and rating scales. A series of self-populating questions were also incorporated into the online version, which were presented according to participants responses to preceding questions.

Compliance with replacement of DDCLs was defined as replacing lenses at an interval which is equal to the Manufacturer Recommended Replacement Frequency (MRRF), i.e. reuse of a DDCL on a subsequent day was considered to be non-compliant. Where relevant, data analyses were conducted using Statistica 10.0 (StatSoft Inc. Tulsa, OK). Fisher's Exact tests were used to compare differences in counts and two-sided difference between two proportions tests were used when comparing proportional differences between the groups investigated. Where appropriate, Mann-Whitney U tests were used to compare non-parametric data from two independent groups. A significance level of  $p \leq 0.05$  was used for all analyses.

## **6.4 Results**

### **6.4.1 Participant demographics and lenses worn**

A total of 805 participants completed the questionnaire (770 on-line and 35 using a paper version); since only 4% of the questionnaires received were completed on paper, the results from all the questionnaires were combined and no separate analyses were conducted from the paper versions. The participant demographics are shown in Table 6-1. The median number of years of contact lens wear was 14 (range of 6 months to "greater than 20 years") and 56% of participants had worn DDCLs for at least five years. Seventy-five percent of participants reported wearing other lens types prior to

DDCLs; of these, 6% reported wearing rigid gas permeable lenses, 25% two-week replacement soft lenses, 51% one-month replacement soft lenses, 16% soft lenses with no scheduled replacement and 2% another lens type (corneal refractive therapy lenses, hard lenses, two-monthly replacement soft lenses and yearly replacement soft lenses). The median time for wearing their current DDCLs was three years (range one month to “10 or more years”). Participants ranked having a “clean new lenses every day” as the aspect they liked the most about DDCLs; this was followed by “convenience”, “no solutions required” and “safer than re-usable lenses”.

**Table 6-1: Study participants**

Country	Number of Surveys	Age (years)			% Female
		Mean	Median	Range	
<b>Australia</b>	106	39.7 ± 13.4	38	18 - 70	67
<b>US</b>	303	36.8 ± 12.8	34	18 – 73	70
<b>UK</b>	135	44.2 ± 12.8	44	18 – 78	64
<b>Norway</b>	261	38.0 ± 10.6	38	18 - 69	60
<b>All countries</b>	805	38.8 ± 12.5	38	18 - 78	66

**Table 6-2: Lens brands worn**

Lens Brand Name	USAN	Number	%
B + L Soflens	hilafilcon A	75	9
Alcon DAILIES	nelfilcon A	364	45
Alcon DAILIES Total 1 (DT1)	delefilcon A	15	2
Cooper Vision Proclear 1-Day	omafilcon A	45	6
Cooper Vision Biomedics 1 Day	ocufilcon B	50	6
Cooper Vision store brand	Unconfirmed	12	2
Johnson & Johnson Vision Care 1-Day Acuvue	etafilcon A	141	18
Johnson & Johnson Vision Care 1-Day AcuvueTruEye	narafilcon A/B	49	6
Sauflon Clariti 1Day	Filcon II 3	51	6
<b>Total</b>		<b>802</b>	<b>100</b>

The distribution of lens brands worn is shown in Table 6-2. Not all lens brands were available in all countries at the time that the survey was conducted. Lens brands are reported by the manufacturers' name and lens material, not the store brand name, with the exception of the "CooperVision store brand" lenses, which could not be accurately identified as being CooperVision Proclear or CooperVision Biomedics lenses (CooperVision, Pleasanton, CA, USA). Alcon DAILIES, DAILIES All Day Comfort, DAILIES Aqua Comfort Plus and Freshlook 1-Day (Alcon, Fort Worth, TX, USA) are grouped together, as are Johnson & Johnson 1-Day Acuvue and 1-Day Acuvue Moist (Johnson and Johnson Vision Care, Jacksonville, FL, USA). It is most likely that the 1-Day Acuvue TruEye (Johnson and Johnson Vision Care, Jacksonville, FL, USA) lenses were narafilcon A in the UK, Norway and Australia and narafilcon B in the United States; this cannot however be confirmed and therefore both material types are grouped together. The lens types for three participants could not be accurately identified and these are not included in the table, however the results for these participants are included in the overall analyses. The distribution of lenses worn did vary by country; the most frequently worn lenses in the US and Norway were Alcon DAILIES and in Australia and the UK, Johnson & Johnson 1-Day Acuvue. Silicone hydrogel lenses (Alcon DAILIES Total 1 (Alcon, Fort Worth, TX, USA), 1-Day Acuvue TruEye (Johnson and Johnson Vision Care, Jacksonville, FL, USA) and Clariti 1Day (Sauflon Pharmaceuticals, Twickenham, UK)) were worn by 115 participants (14%). Fifty-nine (7%) of participants reported wearing toric lenses, one participant reported wearing progressive DDCLs and two participants reported wearing cosmetic tinted DDCLs (each <1%).

The purchase source for participants by country is shown in Table 6-3. A lower proportion of participants reported purchasing their DDCLs over the Internet in the UK than in Australia, the US and Norway ( $p < 0.001$ ,  $p = 0.012$  and  $p < 0.001$  respectively) and a lower proportion of participants

reported purchasing their DDCLS over the Internet in the US than Norway ( $p = 0.012$ ). There were no significant differences in the proportions of participants reporting internet purchase between Australia and the US ( $p = 0.156$ ) and Australia and Norway ( $p = 0.739$ ). The method of payment for participants by country is shown in Table 6-4.

**Table 6-3: DDCL purchase source (%)**

Country	Own ECP	Another ECP	Optical Store	Internet	Other
Australia	77	1	8	12	2
US	84	2	6	7	1
UK	92	0	6	2	0
Norway	79	2	5	14	0
All countries	83	2	6	9	<1

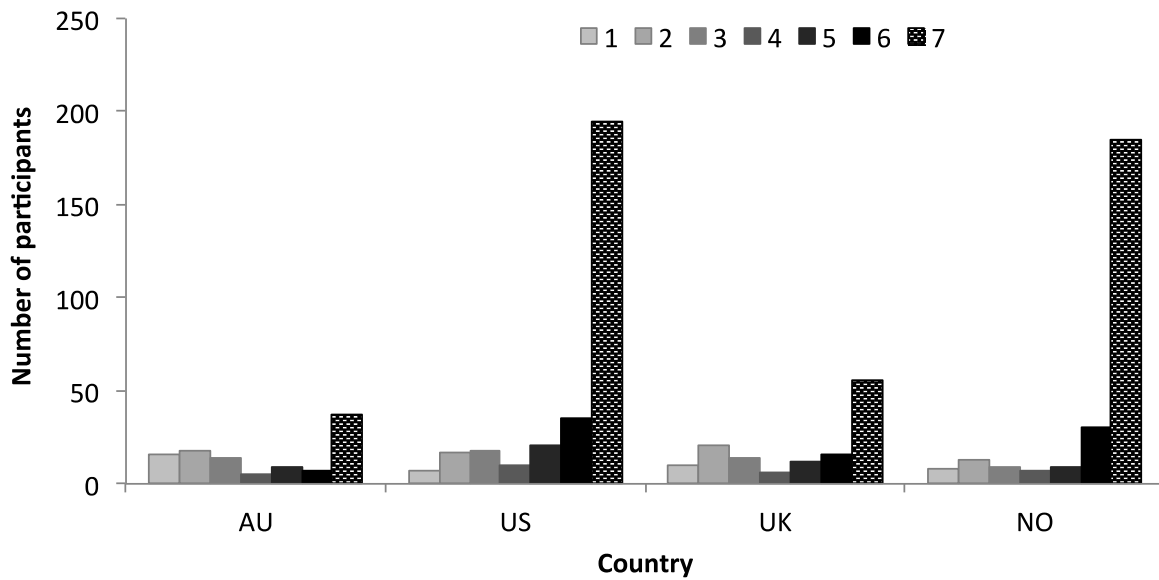
**Table 6-4: Method of payment (%)**

Country	Credit card	Direct debit	Cash / Cheque	PayPal	Other	Not asked
Australia	64	6	8	0	2	20
US	72	8	13	1	2	4
UK	1	98	0	0	1	0
Norway	84	8	3	2	3	0
All countries	63	23	7	1	2	4

#### 6.4.2 Reported wearing schedule

The number of days each week that participants reported wearing their DDCLS is shown in Figure 6-1. Overall, 59% of participants reported wearing their lenses for seven days per week. A significantly higher proportion of participants reported seven days per week in the US and Norway (64% and 71% respectively) than in Australia and the UK (35% and 41% respectively;  $p < 0.001$ ). The mean wearing time each day was  $13.8 \pm 2.8$  hours (median 14 hours, range 2 to 23 hours) but this

did vary between countries and was slightly longer in the US and Norway (median 15 hours in both countries) when compared with Australia and the UK (medians of 14 and 13 hours respectively,  $p < 0.001$ ).



**Figure 6-1: Number of days per week of lens wear by country**

Fifty percent of participants reported greater lens awareness as the day progressed. This also varied somewhat by country with 55% reporting greater awareness in Australia, 53% in the US, 52% in the UK but only 44% in Norway. For these participants the mean total wearing time was  $13.3 \pm 2.9$  hours (median 14 hours) and the mean comfortable wearing time was  $9.9 \pm 3.2$  hours (median 10 hours). The difference between the comfortable wearing time and the total wearing time varied by country; in Australia this difference was 5 hours, in Norway 4 hours, in the US 3 hours and in the UK 2.5 hours.

The difference in the UK was significantly less than the other countries ( $p \leq 0.001$ ), but this may be because participants in the UK reported the shortest number of total hours of lens wear.

#### **6.4.3 Closed eye lens wear**

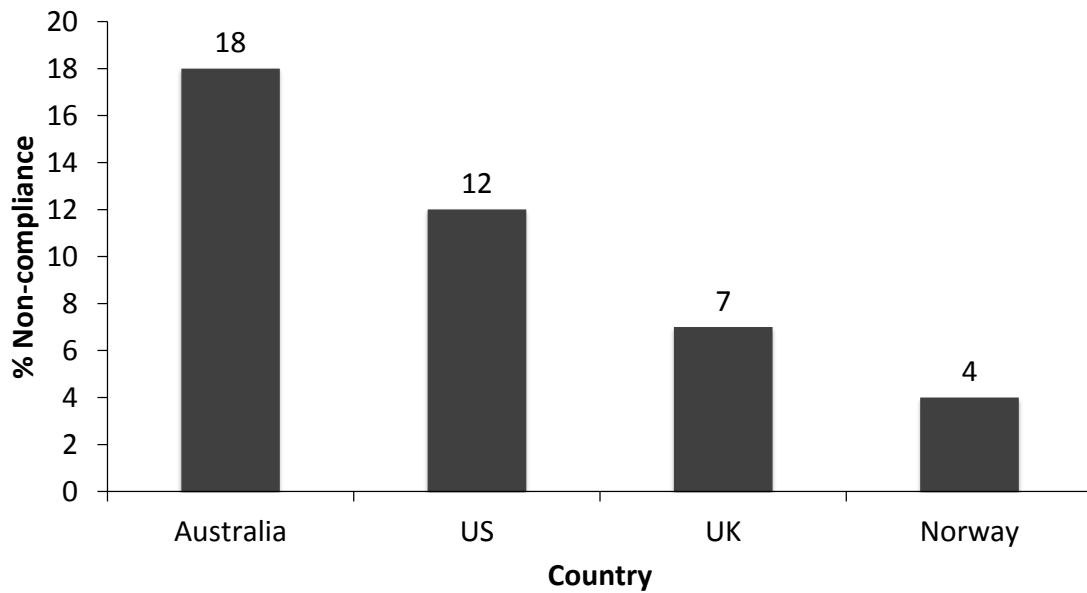
Seventy-five percent of participants reported napping while wearing their DDCLs in the month preceding completing the online questionnaire. The median number of days for napping while wearing DDCLs in the preceding month was two. Overall, 28% of participants reported sleeping overnight while wearing their DDCLs in the preceding month; the proportion of participants reporting overnight lens wear was higher for participants under the age of 25 than for those 25 years and older (48% versus 24%,  $p < 0.001$ ) and although the proportion varied somewhat by lens type worn, these differences were not statistically significant. When overnight wear was reported, it was for only one overnight wearing period during the month for 48% of participants under the age of 25 and for 52% of participants 25 years and older; there was no significant difference in the number of nights of overnight wear reported in the preceding month between the two age groups ( $p = 0.274$ ).

#### **6.4.4 Lens replacement and re-use**

Seventy-six percent of participants reported that a recommendation for lens replacement had been made by their optometrist, 14% reported not being given a specific recommendation and 10% did not remember. Of those given a recommendation, only 5 (<1%) reported this to be for more than one day (three responded 2 days, one 3 days and one 7 days).

Overall, nine percent of participants were non-compliant with lens replacement and reported sometimes failing to discard their lenses at the end of the day and reusing them on a subsequent day or days. The level of non-compliance with DDCL replacement was found to vary by country (Figure

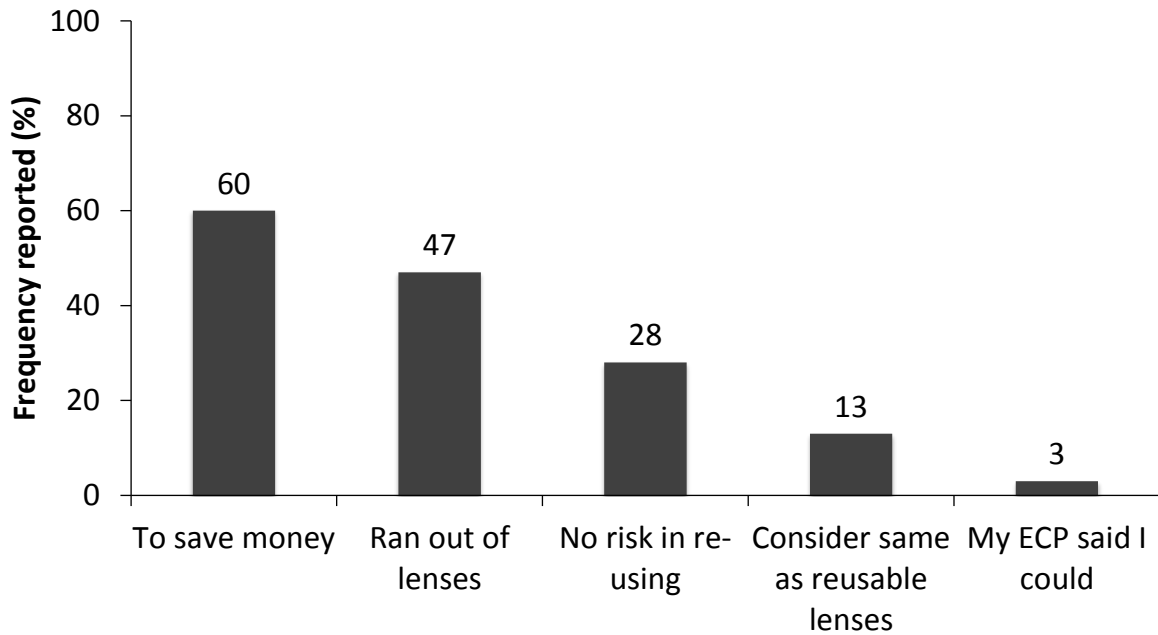
6-2); the frequency was lowest in Norway at only 4%, followed by 7% in the UK, 12% in the US, with the highest frequency of re-use being in Australia at 18%. These differences were statistically significant between Norway and Australia ( $p < 0.001$ ), Norway and the US ( $p = 0.001$ ) and the UK and Australia ( $p = 0.007$ ) but not between the UK and the US ( $p = 0.08$ ), the US and Australia ( $p = 0.14$ ) or Norway and the UK ( $p = 0.28$ ).



**Figure 6-2: Non-compliance with lens replacement by country**

Sixty-four percent of those wearing lenses for more than one day reported that they only re-used lenses for one further day; 27% wore the same pair of lenses for between two and six more days and seven participants (9% of those reporting re-use and only 0.6% of all participants) continued to wear the same pair of lenses for more than one week. Three participants reported wearing their lenses for 20 or more days before replacing them (4% of those reporting re-use and only 0.4% of all participants). The reasons for re-use of contact lenses on subsequent days are shown in Figure 6-3.

Participants who re-used their lenses on subsequent days were able to select one or more of the reasons given.



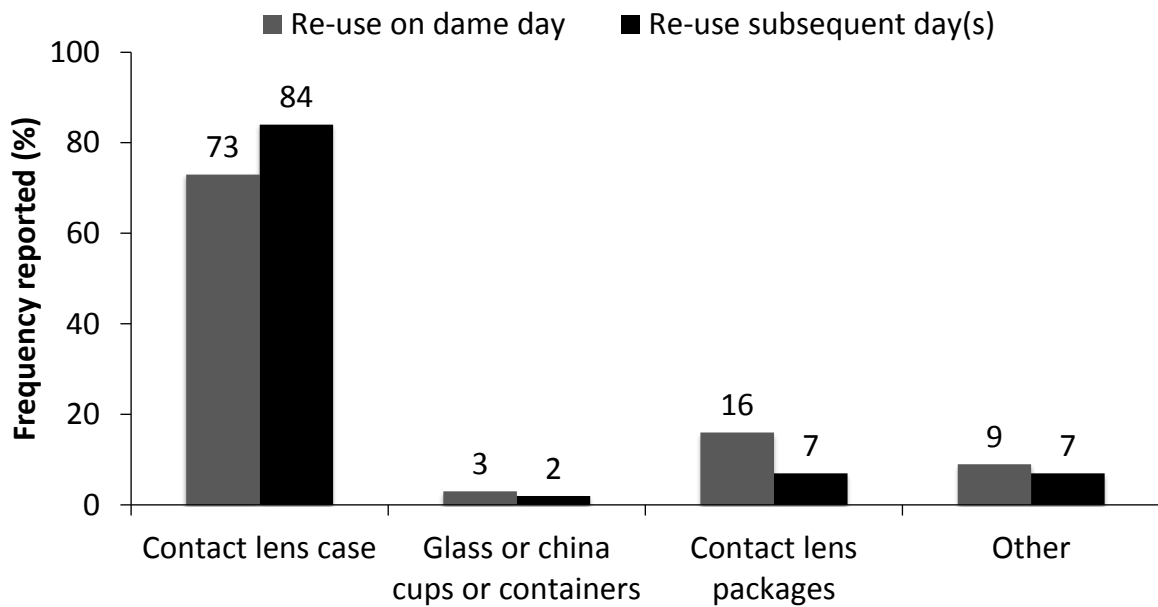
**Figure 6-3: Reasons for re-use**

Another form of non-compliance with single use DDCLs is the removal of lenses during the day with reinsertion of the same lenses later on the same day. Eighty participants (10%) reported that they sometimes did this. A very small number of participants (23 or 3% of all the participants ) reported sometimes re-using of lenses on the same day and sometimes re-using lenses on subsequent days; fifty seven (7%) participants reported re-use on the same day but no re-use on subsequent days and 53 participants (7%) reported sometimes re-using lenses on subsequent days but not re-using lenses on a

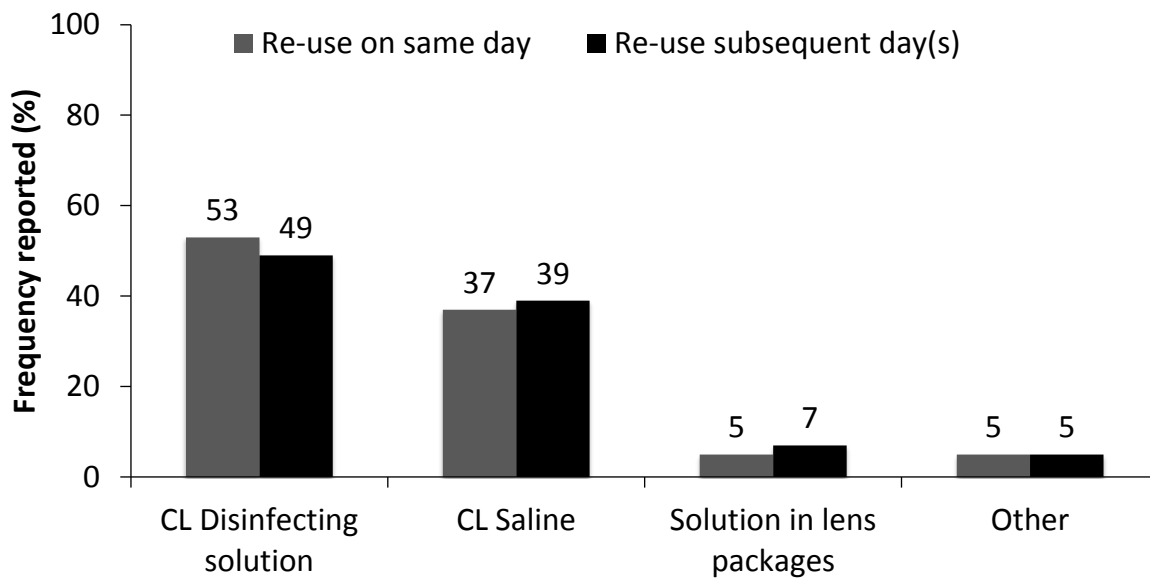


single day. The total number of participants reporting re-use of their DDCLs of any kind was therefore 133 (17%).

Those participants who reported re-use of contact lens wear were asked how they stored their lenses between wearing periods. These results are shown in Figure 6-4 and Figure 6-5. When re-using lenses on a subsequent day, 82% reported simply soaking their lenses and 18% reported rubbing and rinsing them.



**Figure 6-4: Storage methods between re-use of DDCLs**



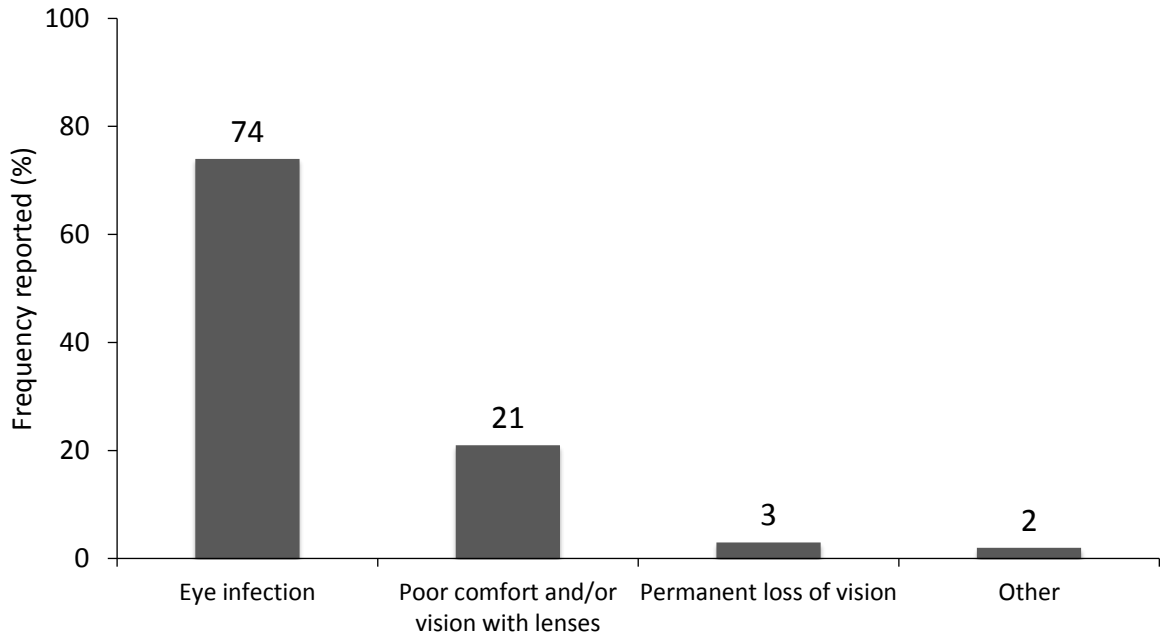
**Figure 6-5: Solution used for storage between re-use of DDCLs**

#### 6.4.5 Participants' perceptions

The participants were asked how important they considered it to be to replace their DDCLs every day, 65% responded “extremely important”, 27% “somewhat important”, 6% “important” and 2% “not important”. Participants were also asked how much of a risk they considered re-using DDCLs to be to the health of their eyes, and if they did consider it to be a risk, what the main risk was. The results are shown in Table 6-5 and Figure 6-6 respectively.

**Table 6-5: Perceived level of risk associated with re-using DDCLs (%)**

Country	Yes Significant risk	Yes Moderate risk	Yes Slight risk	No Insignificant risk
Australia	44	28	13	15
US	37	30	20	13
UK	56	27	12	5
Norway	31	30	19	20
All	39	24	17	14



**Figure 6-6: Perceived risk associated with re-use of DDCLs**

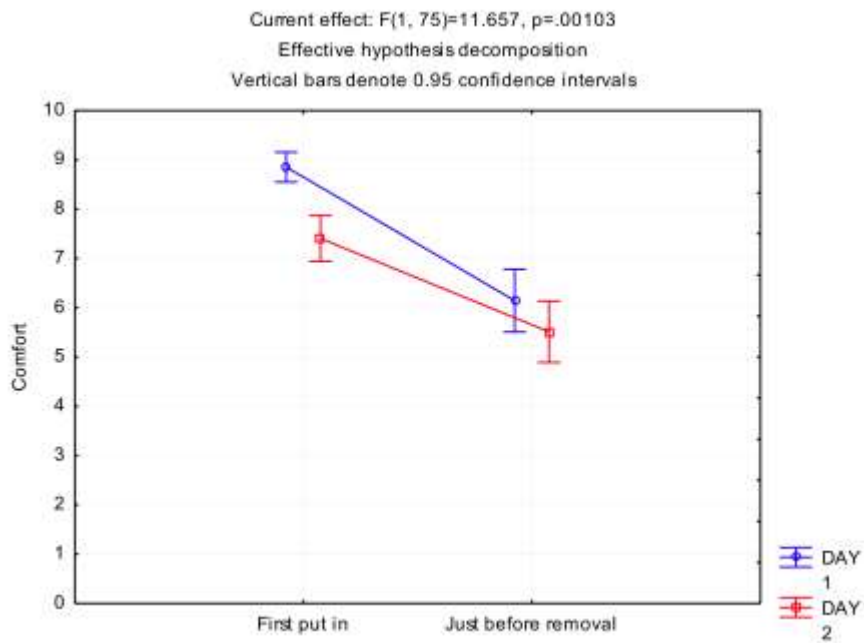
#### **6.4.6 DDCL Comfort**

Participants were asked to rate their comfort on a scale of 0 (very poor) to 10 (excellent) at several times during the wearing period; when they are first put in, halfway through the wearing day, towards the end of the wearing time / in the evening and just before lens removal. Comfort was reported to decrease significantly during a one day period with new lenses ( $p < 0.001$ ). The results are shown in Table 6-6. Participants who reported that they re-used lenses on subsequent days were asked to additionally rate the comfort of their re-used lenses when they first put them in and just before removing them. These ratings were compared with the same time points with new lenses. The comfort ratings given for the second day with the re-used DDCLs were significantly lower than those

with new lenses ( $p = 0.001$ , Tukey HSD, all comparisons  $p < 0.001$ ). These results are shown in Figure 6-7.

**Table 6-6: DDCL comfort ratings (0, lowest rating – 10, highest rating)**

Country	New – on insertion	Halfway through day	Later in day	Prior to removal
Australia	$8.5 \pm 1.4$	$8.2 \pm 1.5$	$6.7 \pm 2.4$	$6.1 \pm 2.8$
US	$9.2 \pm 2.0$	$8.5 \pm 1.5$	$6.9 \pm 2.2$	$6.2 \pm 2.6$
UK	$8.8 \pm 1.3$	$8.6 \pm 1.6$	$6.9 \pm 2.2$	$6.2 \pm 2.8$
Norway	$8.8 \pm 1.3$	$8.8 \pm 1.4$	$7.2 \pm 1.9$	$6.4 \pm 2.4$
All	$8.9 \pm 1.3$	$8.6 \pm 1.5$	$7.0 \pm 2.4$	$6.2 \pm 2.6$



**Figure 6-7: Comfort ratings for DDCLs on Day 1 (new) and Day 2 (re-used)**

#### **6.4.7 Factors relating to non-compliance with DDCL use**

A number of factors were evaluated to determine whether they were related to the re-use of DDCLs. The age and the number of years of contact lens wear was no different between those who were compliant with disposal of lenses after each wearing day and those who were not (t-test,  $p=0.553$ , Mann-Whitney U,  $p = 0.248$ ). There was also no difference according to sex ( $p = 0.526$ ). It was not possible to determine whether participants who wore their lenses for fewer hours during the day were more or less compliant with replacement since very few wore their lenses for six hours or less. The non-compliance with lens replacement for participants wearing their lenses for fewer days per week (1 to 3 days) was not significantly different from those wearing their lenses for 4 or more days each week (10% versus 9% respectively,  $p = 0.656$ ). Compliance with daily replacement was not significantly different between silicone hydrogel (CIBA TD1, Acuvue TruEye and Sauflon Clariti 1Day) and hydrogel DDCLs ( $p = 0.54$ ). Overall, 33% of all participants were non-compliant with DDCL use and reported sleeping overnight and/or re-using their DDCLs on another day.

### **6.5 Discussion**

Participant demographics did not vary between countries with respect to sex, and overall 66% of the participants completing the questionnaire were female, which is consistent with the proportion of DDCL wearers internationally.<sup>2</sup> With a median age of 38 years, the participants were slightly older than the mean reported for worldwide contact lens prescribing.<sup>1,2</sup> This finding is consistent with the recent findings of Efron et al.<sup>14</sup> There was some variation between the countries surveyed, with the youngest participants in the US and the oldest in the UK. Contact lens wearing experience also varied by country, with the fewest years of lens wear being reported in the US and the most in Norway. DDCLs were not the only lens type to have been worn by the majority of participants; three quarters

reported having worn other lens types, with the most common being monthly replacement lenses. The participants had considerable experience with the DDCL modality, with 85% reporting at least two years of DDCL wear, although this was not always with the same brand of DDCLs. A higher proportion of participants from Norway and the UK reported having worn one or more other DDCL brand than participants from the UK, with the lowest proportion in the US. These differences in demographics are most likely a result of the earlier acceptance of the daily disposable modality in Norway and the UK, when compared with the relatively later adopters and lower penetration of DDCLs in Australia and the US.<sup>15</sup>

Participants reported wearing a number of different DDCL brands. Silicone hydrogel DDCLs were worn by only 14% of participants, consistent with the proportion recently reported internationally;<sup>2</sup> this is probably because these lenses have only been introduced to the market relatively recently and have been available in some of the countries for longer than others.<sup>2,15</sup> Very few participants reported wearing complex design DDCLs, with only 7% wearing toric lenses, which is much lower than would be expected compared to what has been reported for all soft lens fits in these countries (23 to 37%)<sup>16</sup> and somewhat lower than the proportion reported worldwide for DDCLs.<sup>2</sup> It may be that ECPs are choosing to fit their astigmatic contact lens patients with re-usable toric soft lenses because of the greater cost of the toric designs in DDCLs.

The majority of participants in the survey reported purchasing their DDCLs from their optometrist. This is not surprising, since the survey was conducted through the optometrists' practices or offices. It was however interesting to see that some participants reported purchasing their lenses from another optometrist, optician or optical store and that nine percent reported Internet purchases. This is higher than the rate of internet purchases reported in the previous Canadian study, which recruited

participants in a similar way (2%),<sup>13</sup> but not as high as that reported in other studies using different methods of recruitment (14 to 23%).<sup>17,18</sup> In Australia, the US and Norway, the majority of participants reported having paid for their DDCLs by credit card. The method of purchase was very different in the UK, with 98% of participants reporting that they made payments by monthly direct debit. Using this method of payment, patients provide their bank account details to their ECP along with permission to transfer a set amount from their account to the ECP each month. A fixed number of lenses (and for re-usable lens types, sometimes solutions) are then sent directly to the patient at regular intervals. This method of payment and lens supply is somewhat unique to the UK and may account for the much lower rate of reported Internet purchases of DDCLs in this country (2%) in the survey. Participants in Australia and Norway reported significantly more internet purchases of DDCLs, which is of concern since this method of lens supply has been shown to be associated with inferior compliance with contact lens wear and care and a higher risk of developing ocular complications.<sup>19,20</sup>

More than half of all the participants reported wearing their lenses for seven days per week, and this proportion was highest in the US and Norway, with far fewer participants reporting part time lens wear. The reported number of days per week of lens wear in the UK and Australia were somewhat different and showed a bimodal distribution with peaks at two and seven days per week; this finding is consistent with that of Efron and Morgan, but specific differences in wearing time between countries was not evaluated in their study.<sup>21</sup> In general, participants reported wearing their lenses all day, however half of the participants did report greater lens awareness as the day progressed; this finding is similar to that reported for re-usable contact lenses.<sup>22</sup> The difference between the total and

the comfortable number of hours of lens wear for these participants varied from 2.5 hours in the UK to 4 hours in Norway.

It is recognized that contact lens wearers do sometimes nap while wearing their lenses. In previous studies conducted by the CCLR, the proportion of DDCL wearers reporting napping, but not sleeping overnight, while wearing their lenses has varied between 36% and 45%.<sup>8</sup> In the current survey, 75% of participants reported napping while wearing their DDCLs. What is more surprising is that some DDCL wearers also report overnight wear with their lenses. In previous studies the proportion of patients reporting wearing their DDCLs occasionally, frequently or almost every night has varied from 12-17%<sup>8</sup> and in the current survey, this proportion was found to be even higher at 28%. It is not clear why patients would choose to wear a lens overnight when it is designed to be discarded after a day of lens wear. It is possible that some patients simply forget that they are wearing the lenses when they go to bed and then remove and replace their lenses when they realize this in the morning, or it may be that they end up wearing their lenses overnight if they are away from home and do not have other lenses or spectacles with them. This theory may be supported by the higher proportion of younger participants who reported overnight lens wear with their DDCLs; this younger group have been previously reported to be more likely to sleep while wearing their lenses.<sup>23</sup> Regardless of the reason, this is a disturbing finding since overnight wear has repeatedly been shown to be associated with a higher risk of both inflammation and infection in contact lens wearers<sup>20,24-26</sup> and may in part explain why DDCL wear has been reported to be associated with a higher risk for microbial keratitis.<sup>20</sup> ECPs would be wise to carefully consider what materials they are dispensing for DDCL wearers who may be napping and sleeping in their lenses. Several silicone hydrogel options are now available on the market<sup>11,12</sup>;<sup>11,12</sup> these lenses are able to offer significantly higher oxygen transmission than



hydrogel DDCLs,<sup>27</sup> however this alone may not be protective against inflammation and infection when the lenses are worn under closed eye conditions.<sup>20,24,26</sup>

Specific recommendations for DDCL replacement were reported to have been made by the patients' optometrists by more than three quarters of participants. Only 1% of the recommendations made were for replacement intervals of more than one day. This is considerably lower than was found in previous studies where ECPs were found to recommend longer replacement intervals for four to six percent of their patients.<sup>8</sup>

As discussed previously, DDCLs offer many benefits to patients; in the current survey, the highest ranked benefit from those presented, was that the modality offers "clean new lenses every day".

Despite this patients did report sometimes re-using their DDCLs. Re-use of DDCLs on either the same day and/or on a subsequent day was reported by 17% of the participants, with 10% reporting sometimes removing their lenses during the day and then reinserting them later in the day and 9% reporting sometimes failing to discard their lenses at the end of each day of lens wear. The primary reason given for reusing DDCLs was "to save money" and this was followed by "running out of lenses". The proportion of participants re-using DDCLs on a subsequent day did vary by country, with the lowest level of non-compliance with lens replacement occurring in Norway (only 4%) and the highest in Australia (18%). The rate of non-compliance in the US was the same as has been previously reported for this country (12%)<sup>9</sup> but the rate for the UK was slightly higher than reported in a previous study by Morgan (7% in the current survey versus only 3% in the study by Morgan).<sup>28</sup> The reason for the difference between the countries may relate to a number of factors, including differences in behavior, health and risk perception, and is beyond the scope of this survey. One factor that may be relevant is the relatively low rate of non-compliance with DDCL replacement in the UK,

which may be related to the unique method of payment and lens supply in this country, possibly reducing the incentive for patients to re-use their lenses. Although some participants reported re-use of their DDCLs, 98% responded that they considered it to be important not to do so and 86% reported that they perceived there to be some level of risk associated with the re-use of DDCLs, principally “eye infection”.

When lenses were re-used, two thirds of patients reported that they only wore them for one subsequent day. Participants generally reported storing their lenses in a contact lens case when re-using them, but a number of patients also reported storing the lenses in the contact lens blister packages. Approximately half of the participants re-using lenses used a contact lens disinfecting solution, with the remainder using either contact lens saline or the solution from the packages. Unsuitable methods of lens storage and disinfection of re-used DDCLs have been reported previously,<sup>29</sup> and in the same study the blister pack solutions of twenty young adults were cultured after a worn lens had been replaced in the package and contamination was found for 19 of the 20 study participants.<sup>29</sup> The failure to use appropriate contact lens disinfection solutions to store DDCLs before they are re-used is likely to place these wearers at a significantly greater risk of developing microbial keratitis.<sup>30</sup> Unfortunately patients are not always provided with adequate education regarding the care of their lenses and the risks associated with their mis-use, even though these strategies have been shown to be associated with greater compliance.<sup>31-34</sup>

DDCLs have been reported to provide improved comfort when compared with re-usable soft contact lenses.<sup>6</sup> In the current survey, while participants reported good levels of comfort on insertion of a new lens, there was still a decrease in comfort reported during the day, which is consistent with that reported with other lens types.<sup>22, 35-37</sup> Non-compliance with lens replacement of two-week and one-

month replacement lenses has been shown to adversely affect both the end of day comfort and the overall lens comfort when lenses need to be replaced.<sup>38</sup> In this survey we found both a reduction in comfort on lens insertion and just prior to lens removal with DDCLs re-used on a second day when compared with the ratings reported on the first day of lens wear. It is not clear whether this may be as a result of lens spooliation or the absence of the comfort enhancing agents which are incorporated into the blister package solution of many DDCLs.<sup>39-43</sup>

A number of factors that could be related to the re-use of DDCLs were evaluated. No differences in the rates of non-compliance were found with respect to the sex of the wearer, the number of years of lens wear, or the number of days per week of lens wear. The introduction of DDCLs in silicone hydrogel materials has raised some concern that patients wearing lenses of these materials may be more likely to re-use their lenses (because of the higher cost of the lenses) but no differences were found between the rates of re-use among wearers of DDCLs of these materials. The differences in proportions of participants reporting purchasing their lenses on the internet between countries was interesting; however, this is probably not directly related to compliance with lens replacement, since the countries reporting the highest rates of internet purchase were Australia and Norway and these countries represented the least and most compliant countries respectively.

It should be recognized that there are some limitations to conducting a survey of this nature. The survey was only conducted in four countries and the results from other countries may differ from those reported on in this manuscript. Using an online survey can be a problem in that the lens types that are worn by the participants cannot be confirmed; however the current survey design did at least ensure that only current DDCL wearers were invited to complete the questionnaire. In addition, it is not possible to confirm the actual practices that have been reported by the DDCL wearers taking part

in the survey. Despite these limitations, the findings make an important addition to the literature regarding non-compliance with replacement of DDCLs and the frequency with which DDCLs are worn overnight.

## **6.6 Conclusion**

A similar level of non-compliance with DDCL replacement (re-use on a subsequent day) was found in this survey to that previously reported; however, there was some considerable variation in compliance with replacement across the four countries investigated. No differences in compliance with lens replacement were found with respect to total length of contact lens wear, sex, days per week of lens wear or lens material.

The primary reason given for re-using DDCLs was to save money, but simply running out of lenses, and presumably forgetting to reorder more, was also given. Although non-compliance with DDCL replacement is much lower than it is for re-usable lens types, any degree of non-compliance is a concern, particularly if lenses are not being appropriately disinfected and stored between lens wearing periods. Many participants reported using only contact lens saline or the solution from the DDCL blister packs to store their lenses and this may be placing them at a greater risk for microbial keratitis.

It is also important to recognize that some of the DDCLs on the market are manufactured from materials that have not been tested with contact lens care systems. The vast majority of the participants recognized that the re-use of contact lenses posed some sort of risk to them and the majority of these participants identified an eye infection to be the type of risk that they were concerned about.

Overnight lens wear is another form of non-compliance with DDCL use and was reported by more than one quarter of the DDCL wearers; this may also be placing these individuals at a greater risk of developing an infection. The overall level of non-compliance with DDCL use (re-use on subsequent days and/or sleeping in lenses) was in fact 33%. Re-use of DDCLs was also shown to be associated with inferior performance in terms of comfort, both on initial insertion and at the end of the wearing day.

It is important for ECPs to continue to counsel their patients on the importance of appropriate lens wear, care and replacement for all lens types including the ever more popular DDCLs. Continuing education on the risks of re-use of these lenses should be reinforced at all follow up visits and methods of lens ordering and supply should be optimized for these patients in order to improve their overall compliance.

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All of the previous experimental chapters have described quantitative studies designed to evaluate compliance with contemporary contact lenses and its impact on the continued success of contact lens wear. This final experimental chapter describes the results of a study in which both quantitative and qualitative research methods were used to further explore *why* contact lens wearers practice behaviours which can be considered to be non-compliant.

## Chapter 7

### Exploring compliance: A qualitative study of contact lens wearer perspectives

This chapter has been accepted for publication as follows:

Exploring compliance: A qualitative study of contact lens wearer perspectives?

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*Optometry and Vision Science; in press.*

	Concept / Design	Recruitment	Acquisition of data	Analysis	Write-up / publication
Dumbleton	Y	Y	Y	Y	Y
Spafford	Y	-	-	-	Y
Sivak	-	-	Y	Y	Y
Fonn	-	-	-	-	Y
Jones	Y	-	-	-	Y

Tables: 8

Figures: 1

## 7.1 Overview

**Purpose:** Using both quantitative and qualitative research methods, this paper explores in detail the lens wear and care habits of adapted contact lens wearers and seeks a better understanding of what enables and constrains patient compliance with appropriate lens wear and lens care.

**Methods:** The study was conducted in two phases: a preliminary online questionnaire (quantitative phase), identifying types of non-compliance, and a series of sequentially conducted focus groups (qualitative phase), exploring constraints to, and enablers of, compliance.

**Results:** 100 participants completed the on-line questionnaire; 12 of them also participated in one of four focus groups. The most frequently reported aspects of non-compliance revealed were: 1) failure to replace lenses when scheduled, 2) inappropriate lens purchase and supply, 3) sleeping while wearing lenses, 4) use of tap water with lenses and failure to wash hands, 5) failure to clean and replace cases regularly and 6) inappropriate use of care systems. Using an iterative process, a number of “themes” associated with non-compliance were identified in the focus group discussions. The most frequently occurring themes related to the “consequences” that may occur if patients were non-compliant with one or more aspects of their contact lens wear and the importance of receiving “instructions” regarding the most appropriate way to wear and care for their lenses. Most of the themes that emerged during the analysis were both constraints to, and enablers of, compliance.

**Conclusions:** This study confirms frequent types of non-compliance while offering a greater understanding of what constrains and enables contact lens wear and care compliance. These findings may help eye care practitioners and the contact lens industry to develop strategies and tools to aid compliance and success in contact lens wear.



## 7.2 Introduction

Excerpts from two study participants (P2 and P5):

*No one ever told me what to do with the cases. (P2)*

*Replacement is a little random, whenever they don't feel good anymore. (P5)*

These voices, taken from focus group interviews of contact lens wearers, point to two central drivers of their compliance: instructions and consequences.

Non-compliance with recommendations for contact lens wear, care and replacement was first reported in the 1980s.<sup>1,2</sup> Since then, there have been numerous studies investigating patient actions with respect to many aspects of contact lens wear and the possible implications for patients who are non-compliant. Some of the consequences of non-compliant behaviour are more severe than others. The less serious effects include deposition on the contact lenses,<sup>1-3</sup> corneal staining,<sup>1,2,4</sup> and increases in papillae and hyperemia.<sup>5</sup> Wearers who are non-compliant have also been shown to report an increase in subjective symptoms, including dryness, inferior vision and comfort at the end of the day when their lenses are due to be replaced.<sup>1,2,6,7</sup> The more serious complications include sterile infiltrates and microbial keratitis. Infrequent use of care systems has been shown to be a risk factor for both microbial keratitis and sterile keratitis in daily wear users,<sup>8</sup> as has failure to wash hands.<sup>9,10</sup> Failure to rub and rinse lenses also carries a greater risk of developing microbial keratitis.<sup>11</sup> In both the recent outbreaks of *Fusarium* keratitis and *Acanthamoeba* keratitis, topping up, rather than completely replacing solutions, was found to be associated with greater risk for infection.<sup>12,13</sup> Poor case hygiene has also been associated with a greater risk of microbial keratitis as has occasional overnight use of lenses.<sup>14,15</sup>

Unfortunately, non-compliance among contact lens wearers continues to be a problem worldwide, despite improved options for lens replacement and simplified care regimens.<sup>16-18</sup> Several factors have been reported to affect compliance in contact lens wearers, including gender, age, magnitude of refractive error, recommended lens replacement interval and recommended care system.<sup>19-23</sup> To date, the reasons described by contact lens wearers for not following these instructions have not been evaluated to the same degree as the prevalence of this issue.

Research in the area of contact lens compliance has been predominantly quantitative in nature, mainly using questionnaire-based surveys. Qualitative research methods, for example interviews or focus groups, may offer a different perspective and provide a more comprehensive understanding of wearers' beliefs, knowledge and attitudes towards contact lens wear and care.

Qualitative research is a method of scientific inquiry commonly used by social scientists.<sup>24,25</sup> It is usually conducted to find out why individuals do or do not behave in a certain way. The proportions of people behaving in a certain way are not reported, but rather the underlying motivations to specific behaviours and attitudes. Fewer participants are involved in qualitative research when compared with quantitative methods, but each participant is studied more closely. Focus groups, interviews and observation are used to obtain audio or video recordings of conversations and behaviours. Qualitative research methods are used routinely to investigate compliance in the health care field and there are several publications which have reported on studies of compliance with the treatment of glaucoma.<sup>26,27</sup> To our knowledge, qualitative research methods have not been previously used to study compliance with contact lens wear and care.

The purpose of this study was to combine quantitative and qualitative research methods to explore in detail the lens wear and care habits of adapted contact lens wearers and to gain a better understanding

of what constrains and enables patients to follow recommendations for appropriate lens wear and lens care.

## **7.3 Methods**

### **7.3.1 Study Design**

The study was conducted in two phases: a preliminary online questionnaire (quantitative phase) and a subsequent series of sequentially conducted focus groups (qualitative phase). A grounded theory (or constant comparative method) approach was followed for the focus group phase of the study.<sup>28,29</sup> This is a cyclical process of data collection, analysis and development of tentative theory, which continues until a point of “theoretical saturation” is reached. At this point, the data are considered to be sufficiently “rich” and the emergent themes “dense” enough to form a conceptual framework, which should provide information as to the factors that inform compliance with contact lens wear and care from the perspective of the wearer.

Informed consent was obtained from all participants prior to participation in the focus groups.

Institutional ethics clearance was obtained prior to commencement of the study.

### **7.3.2 Sample size and study population**

Due to the nature of qualitative research, sample size calculation was not appropriate for this study and purposive sampling was used to target specific age and compliance groups.<sup>30</sup>

One hundred current contact lens wearers were recruited for the first phase of the study using Centre for Contact Lens Research (CCLR) records and advertising approved by the University’s Office of Research Ethics. Two distinct age groups were targeted in the recruitment phase: individuals aged 17

to 25 (“younger group”) and individuals aged 35 and over (“older group”). These distinct age groups were targeted based on recent findings from studies investigating contact lens compliance and complications reporting that younger contact lens wearers are more likely to be non-compliant with lens replacement, wear and care than older wearers.<sup>21-23,31</sup> All respondents completed the first phase of the study, which was an online questionnaire regarding current contact lens wear and care procedures. There are no validated questionnaires that assess compliance with contact lens wear but this questionnaire was developed using a subset of questions that had been incorporated into previous questionnaires that have been administered in several CCLR studies that involved approximately 7,500 participants.<sup>32-34</sup> The questionnaire was also piloted with CCLR staff to assess clarity of the survey instructions and items.

A smaller subset of the questionnaire respondents was then invited to take part in the subsequent focus groups in the second phase of the study. Prospective participants for the focus groups were selected following review of the data from the online questionnaires; respondents were “ranked” from being the most compliant with all aspects of lens wear and care evaluated in the questionnaire (i.e. replacing lenses when scheduled, not sleeping in lenses, etc.), to being the least compliant with respect to all or almost all aspects. Two distinct groups were identified from this ranking and the respondents who were considered to be “generally compliant” or “generally non-compliant” were invited to take part in the subsequent focus groups. These focus groups were scheduled separately because we did not want the non-compliant wearers to be silenced by the compliant ones. Respondents who were considered to be equivocal (i.e. reporting a mixture of compliant and non-compliant behaviors with respect to their contact lens wear and care) were advised by email that they would not be continuing in the second phase of the study.

Focus group participants were assigned a unique identifier (P1 to P12).

### **7.3.3 Study procedures**

Two investigators conducted the focus groups. One investigator (AS) led the focus groups; AS has formal training in the collection of qualitative research data and a professional background in the field of contact lenses, but is not an eye care practitioner. The second investigator (KD) took field notes during the focus groups and ensured reliable audio recording. KD has formal optometric training, experience with use of qualitative research methods and significant experience with research on compliance with contact lens wear and care. This approach to qualitative data collection and analysis is referred to in the research literature as an “insider/outsider” or emic/etic approach<sup>24,35</sup> Utilizing this approach allowed the research team to take advantage of both optometric understanding and experience while ensuring that the focus group discussions were still able to follow the thought processes of the study participants.

### **7.3.4 Outline for focus groups**

Discussions during the focus groups covered six aspects of contact lens wear and care that have been recognized to be associated with poor compliance.<sup>1,13,19,21,23,36-41</sup> These included lens replacement, lens supply, care system use, storage cases, the use of water (including hand washing) and sleeping or napping while wearing lenses. The discussion followed a basic outline and led the participants through some scenarios relating to their habitual contact lens wear and care procedures. In addition, participants were asked about factors which may better enable or constrain compliance. The order in which these topics were discussed varied from one focus group to another, dependent on the comments and issues raised.

### **7.3.5 Data analysis**

Where relevant, data from the online questionnaires were analyzed using Statistica 10.0 (StatSoft Inc. Tulsa, OK). Fisher's Exact tests were used to compare differences in counts and two-sided difference between two proportions tests were used when comparing proportional differences between the groups investigated. A significance level of  $p \leq 0.05$  was used.

An inductive approach using thematic content analysis was used to analyze the qualitative data.<sup>42</sup> This process involves analyzing transcripts, identifying categories and themes within textual data and bringing together examples of these themes. Consistent with qualitative research methodology, the analysis began immediately after the first data were collected and continued throughout the study. The primary analysis and coding were conducted by KD. AS and two optometric researchers were also consulted during the data collection and analysis to allow refinement of the thematic structure.

In this study, because there are a number of ways in which contact lens wearers can be considered to be non-compliant with their wear and care, textual data were initially grouped into several recognized aspects of non-compliance with contact lens wear (both those identified in the online questionnaire and others which emerged during the focus group discussions). The data were then coded from the transcripts by highlighting categories that were emerging from the segments of text. Analyses subsequently continued by sorting the data into broad themes. Conceptual links were considered to develop connections or relationships between the themes and their properties. When no further categories, themes or links were disclosed from the data that had been collected, a grounded theory or explanation of the reasons for non-compliance was developed.

## 7.4 Results

### 7.4.1 Questionnaires

One hundred online questionnaires were completed. Sixty-two were completed by the younger group (mean age  $20.0 \pm 2.3$  years, 77% females) and 38 were completed by the older group (mean age  $48.5 \pm 8.7$  years, 75% females). The responses to the online questionnaire for all respondents are summarized in Table 7-1 to Table 7-5. There were some differences in the distribution of responses according to age groups. A slightly higher proportion of the younger group reported Internet purchases, overnight wear, and failure to wash their hands before inserting their lenses, but these differences were not statistically significant. A significantly higher proportion of the older group reported leaving their cases open to dry after inserting their lenses (50% versus 9%,  $p < 0.001$ ).

**Table 7-1: Non-compliance with lens replacement**

Recommended replacement interval	Number	Non-compliance
1 day	16	12.5%
2 weeks	19	63%
1 month	54	52%
Other (e.g. 3 weeks, 3 months)	6	33%
Could not remember	5	N/A

**Table 7-2: Lens purchase and closed eye wear**

Lens purchase		Closed eye wear	
Optometrist	54%	None	44%
Optical store / optician	32%	Only napping	47%
Internet	12%	Occasional sleeping	7%
Other	2%	Frequent sleeping	2%

**Table 7-3: Hand washing**

Wash hands - insertion		Wash hands - removal		Wash hands with?	
Every time	63%	Every time	45%	Soap and water	86%
Most times	32%	Most times	36%	Just water	13%
Rarely	5%	Rarely	18%	Antibacterial wipes	1%
Never	-	Never	1%		

**Table 7-4: Care system use**

Care solutions		Rub and Rinse?		Top off solution?	
Hydrogen Peroxide	15%	Every night	39%	Never	73%
Multipurpose	66%	Most nights	18%	Occasionally	21%
Saline	5%	Once/week	32%	Frequently	6%
Solution from packs	5%	Never	11%		
Nothing	9%				

**Table 7-5: Storage case care**

Clean case?		Clean case with?		Caps on or off?		Replace case?	
Every day	17%	Tap water	67%	On	76%	1 month	12%
Most days	8%	CL solution	18%	Off, face up	14%	3 months	40%
Once /week	29%	Don't clean	15%	Off, face down	10%	6 months	19%
Once/month	24%					1 year	18%
Never	22%					Never	11%

### 7.4.2 Focus Groups

Seventeen respondents were considered to be “generally compliant” and 16 respondents “generally non-compliant”. The remaining 67 respondents were equivocal and were not invited to continue in the second phase of the study. The following individuals were invited to take part in the subsequent focus groups:



- Nine “generally compliant” individuals, aged 17 to 25;
- Nine “generally non-compliant” individuals, aged 17 to 25;
- Eight “generally compliant” individuals, aged 35 or greater;
- Seven “generally non-compliant” individuals, aged 35 or greater.

An initial series of four focus groups were conducted during October and November 2012. Not all the individuals invited to take part in the focus groups were able to attend at the times scheduled. Focus group participants were grouped according to their age and whether they had reported generally compliant or non-compliant behaviours relating to their contact lens wear. The groups were divided up in this way in order to facilitate comfortable discussion between the participants and to reduce the possibility that participants may be hesitant in discussing their contact lens wearing habits. Each focus group lasted for 60 to 90 minutes. After the first four focus groups had been conducted and the data analysed, it was decided that theoretical saturation had been reached and no further focus groups were scheduled. Although the participants had been divided into groups according to their responses to the online questionnaire, individuals in all four of the focus groups reported various aspects of non-compliant behaviour during the focus group discussions, thus the analysis of the transcripts was combined. Table 7-6 summarizes the groups and participants included.

**Table 7-6: Focus group demographics**

	<b>Younger compliant</b>	<b>Younger non-compliant</b>	<b>Older compliant</b>	<b>Older non-compliant</b>
<b>Number</b>	3	4	3	2
<b>Ages (years)</b>	18, 19, 20	18, 19, 19, 23	41, 58, 64	43, 49
<b>Sex (F or M)</b>	F, F, M	M, F, F, F	F, F, F	F, M
<b>Employment status</b>	ST, ST, ST	ST, ST, ST, ST	SE, OF, HM	SE, SA
<b>Marital status</b>	All single	All single	All married	All married
<b>Lens type worn</b>	1MR, 2WR, DD	1MR, 2WR, 1MR, 1MR	DD, 1MR, DD	2WR, 1MR
<b>Care system used</b>	MPS, MPS, N/A	MPS, H2O2, MPS, MPS	N/A, MPS, N/A	MPS, MPS

ST = student; SE = self employed; OF = office worker; HM = homemaker; SA = sales manager

### **7.4.3 Coding framework from focus group transcripts**

The data were broadly grouped into six aspects of non-compliance, which are commonly recognized to occur with contact lens wear. These were: 1) failure to replace lenses when scheduled, 2) inappropriate lens purchase and supply, 3) sleeping while wearing lenses, 4) the use of water with lenses and failure to wash hands, 5) failure to clean and replace cases regularly and 6) inappropriate use of care systems. Table 7-7 outlines the coding framework that was developed from the data. The categories emerging from the initial coding are listed in the left hand column and the seven themes emerging from the initial coding are listed in the right hand column.

**Table 7-7: Coding framework for analysis of qualitative data**

<b>Initial coding framework (Categories)</b>	<b>Final coding framework (Themes)</b>
Similar performance Complications Discomfort Blurriness Infection Deposits Physical appearance	Consequence
Written materials Advertising Eye care practitioner advice Parental advice Knowledge No instructions	Instructions
Habits Forgetfulness Fatigue Change of location Travel	Routine
Travel Shopping Location No care Replacements	Convenience
Unwilling to take time Laziness	Time
Safety Fears Health beliefs and attitudes	Values
Too expensive Save money Shop around	Financial

***Excerpts from transcripts that relate to the common aspects of non-compliance***

In the following excerpts, the participants' comments, as taken from the transcripts, are in italics. Additional explanatory words have been added in square brackets where necessary. The relevant themes are highlighted in underlined font. In most cases only one exemplar of the theme is given,

although many more similar comments were recorded in the original transcripts. The participant identifier is given in brackets following the exemplars.

### ***1: Replacement***

Some participants, who failed to replace their lenses on schedule, reported that this was sometimes because they simply forgot when it was time to replace them (routine):

*I usually replace my lenses every other Monday morning. I suppose sometimes I don't remember and do 3 weeks, which is bad. For the most part I am okay. (P11)*

Others reported relying on cues or triggers to replace their lenses (consequences):

*I might go from 6 to 7 to 8 weeks, but you start to see some deposits, they start to lose their shape. At that point you don't want to put them in your eyes, you are getting dry eyes and some blurred, obscured vision, and it is time to toss them. (P4)*

Participants also discussed whether anything would help them to remember when to replace their lenses (routine, instructions):

*Dates on the case with masking tape or a magic marker. (P3)*

*Probably a reminder on my phone, like a reminder for when I have a test. (P11)"*

Several participants were wearing daily disposable lenses. None of them reported failure to replace these lenses daily, but one participant reported that her sons, who also wore daily disposables, did re-use their lenses for sporting activities (routine).

*My boys use dailies too but they only wear them for 2 hours at a time so we don't throw them out. We put them in a case. They will wear them for two practices and a game, which is about 6 hours, and then throw them out. (P2)*

Participants offered numerous advantages of daily disposable lenses, including (convenience, consequences):

*I really like the no care and the comfort of them and I can wear them longer which is really important. (P2)*

*Every day when I put one in, they are clean, they are sterilized... (P1)*

Some disadvantages and reasons for not wearing daily disposable lenses were also offered (values, financial, instructions):

*I think there is a lot of waste in daily disposables. Would the packages be recyclable? (P3)*

*I haven't tried them because they are more expensive to wear every day versus the monthly replacement. (P7)*

*I have never thought about dailies. I am sticking with what was recommended to me 10 years ago. (P6)*

## **2: Lens supply**

Not all the participants reported getting their lenses from the eye care practitioner who provided their primary eye care. Usually the reason given for this was to save money (financial):

*I have ordered them online before. Anywhere where the best deal is. (P2)*

Purchasing lenses from another source can be relatively straightforward (convenience):

*You just keep on hitting the refill my last order button. It is as easy as that. I provided a prescription initially. (P5)*

Some participants were more hesitant about their contact lens purchases, though (values):

*I don't think I would ever go through online. I don't think they are something you should get online. (P12)*

### ***3: Sleeping or napping while wearing lenses***

The major themes which emerged with respect to sleeping or napping while wearing lenses were routine and consequences:

*A few days ago I fell asleep with them on and forgot they were still in in the morning so I put another set (daily disposables) on top. (P10)*

*It is generally when I go over to a friend's house or something. I just tend to forget about them and will just sleep in them. (P9)*

When specifically asked about what may be happening during overnight wear, examples were given of relatively minor and possibly more serious outcomes (consequences):

*I feel like there is more protein build-up. I don't think it damages your eyes because it is just one night. (P11)*

ECPs are very concerned about complications, but contact lens wearers may either not consider these to be as important or simply do not know about them. This was supported by the relative silence of each group when specifically asked about what they thought could go wrong with their eyes as a result of sleeping while wearing contact lenses; for example, when specifically asked about

infections, the participants did not appear to know what these would be like or consider the possible outcomes (consequences):

*I guess it would be painful to the point where they would not look normal, be red. (P6)*

#### **4: Use of water**

The importance of hand washing prior to handling lenses was discussed by the participants. The themes, which commonly emerged during these discussions, were time and routine:

*I generally just wash my hands a bit, nothing super clean, I just run them under the tap for about 10 seconds with a bit of soap. (P9)*

*In the morning I am better at remembering to wash my hands, than at night, when I am tired. (P4)*

Participants also seemed to be concerned about transferring food and cosmetics from their hands onto the lenses and this prompted hand washing on some occasions. (consequences):

*I don't wash my hands unless I have had spicy wings or something on my hands. (P6)*

Some of the participants reported showering while wearing their lenses for convenience or because they did not know that this may not be recommended (instructions), but others preferred not to because of possible consequences:

*I always shower with my contacts in. I didn't know that you weren't supposed to? (P7)*

*I have [showered with my lenses on] before, but I don't like it. I feel like it is not just water, there are minerals and stuff that I don't want in my eyes. (P11)*

Similarly, some participants reported swimming with their lenses for convenience but concerns were also expressed about losing the lenses and discomfort (consequences):

*I go to amusement (water) parks a lot. I go in my contacts and most of the time they feel fine. I generally wear my daily disposables when I go. (P8)*

*I just won't open my eyes under the water or they will be gone. (P4)*

Participants were also asked whether they used water directly on their lenses. This was often reported to occur as a result of a change in routine:

*I went camping and lost my solutions so had to use water. It was really uncomfortable, but my fault. (P4)*

#### **5: Storage cases**

In general, the participants did not appear to place great importance on cleaning their contact lens cases. The major theme appeared to be instructions:

*I would just empty the solution out, rinse it with hot water and maybe every 2 or 3 weeks I would clean it with some soap too. My mom told me to do this. (P10)*

There was also some confusion and concern about emptying the solution and leaving the case open during the day (consequences, instructions and convenience):

*I leave the (used) solution in the case all day. It has to sit for 6 hours (hydrogen peroxide) so I can't just dump it out. I need to keep some solution available in case I need to rinse my lenses. (P7)*



*Are you supposed to leave it open during the day? I just screw the caps back on, I think if you leave it open stuff can get in there, especially in the bathroom with the toilet flushing. (P2)*

Participants did seem to recognize that perhaps they should be cleaning their cases or replacing them but only when they were concerned with the appearance of the case. None of the participants reported being concerned with bacterial contamination of the cases (consequences):

*This is kind of really disgusting but I never rinse my case or anything so then you have brown stuff around the edges and that is when I chuck it out. (P8)*

Participants reported replacing their lenses every two to six months, but they did not seem to have a clear understanding of how frequently they should replace their cases (instructions). The cue to replacing cases was frequently reported to be receiving a new case when they purchased solutions. The convenience of replacement cases being provided was a commonly reported theme:

*Whenever I buy new solution, I get the one that has the case in it and that is when I replace it. So I would say once every 6 months. (P6)*

#### **6: Care system use**

Inappropriate care system use is a frequently reported aspect of non-compliance with contact lenses. Time and routine were frequently occurring themes in the participants' discussions regarding the use of these solutions, but consequence was also reported:

*My routine is really bad. I know you are supposed to wash them every time, but sometimes I am really lazy. I just take them off, put them in the case and then cap it off. (P8)*

*I don't rub because I am afraid of tearing the lens. (P5)*

Those who did report being more careful with cleaning gave a variety of reasons but these were usually associated with their character (values), advice they had been given (instructions), automatic habit (routine) or problems that may occur otherwise (consequences).

*I rub around the lens, flip it over, clean it off some more and put it in the case. I don't know why. Someone might have told me but I feel that I am supposed to clean both sides. Both sides have contact with something. (P12)*

*I do it because it is important. I don't want to wreck my eyes, have an infection or build up debris on my contacts. (P3)*

*Now it gets to be an automatic habit, it has to be cleaned both sides. It just happens now. (P12)*

Participants often reported that the reason for cleaning their lenses was to remove deposits from their lenses (consequences) under the advice of their eye care practitioner (instructions):

*I did rub and rinse to get off the lipid and protein build up. My optometrist told me to. I think it may form some sort of barrier for bacteria to get caught in. (P10)*

*To clean it, the dust and all the proteins. (P7)*

Information on the packages and no apparent differences in performance were also reported to play a role in participants' cleaning procedures (instructions, convenience):

*You don't really have to rub, it says 'no rub', so I 'no rub', just put it right in the case. (P4)*

*It is saving you one step. It's convenience. I don't notice that the lenses are deteriorating any sooner. (P4)*

Failing to completely empty the case and “topping off” the solution already in the case with new solution is another aspect of non-compliance. When participants reported doing this it was usually as a result of self-reported laziness (time); participants also expressed concern about topping off (consequences):

*Sometimes I just top it off, I don't always do that, it depends how lazy I am, but most of the time I put in fresh solution. I have left the [used] solution in all day and either throw it away or top it up. (P6)*

*I don't top it up. I feel like it is dirty solution so I wouldn't put it back in my eyes again, there is a build-up of something. (P12)*

#### **7.4.4 Constraining and enabling factors**

Each of the themes that emerged from the data could also be considered in the context of whether they would be either barriers (i.e. constrain) or aids (i.e. enable) to compliance. Examples of constraints and enablers that were discussed in the focus groups as they related to each of the themes are presented in Table 7-8.

**Table 7-8: Factors or behaviours that may constrain or enable compliance with contact lens wear**

<b>Theme</b>	<b>Example of constraint</b>	<b>Example of enabler</b>
Consequences	Not rubbing lenses because afraid of tearing them	Rub lenses to remove dust, proteins and lipids
Instructions	Not being told how to care for storage case	Optometrist explaining importance of and reasons for cleaning lenses
Routine	Forgetting to remove lenses when away from home	Having a set routine to follow every time lenses are handled
Convenience	Swim in contact lenses because it is inconvenient to use spectacles or prescription goggles	Daily disposable lenses – no schedule to remember and no cleaning required
Time	Not prepared to take time to rub and rinse lenses	<i>None discussed in focus groups</i>
Values	Willing to purchase lenses online without recommendation from optometrist	Place significant importance on eyesight and maintaining healthy eyes
Financial	Care system choice based on cost not recommendation	<i>None discussed in focus groups</i>

***Schematic description of themes relating to non-compliance with contact lens wear***

The aspects and themes relating to non-compliance in contact lens wear are given in Figure 7-1. This figure provides a summary of the seven principal reasons for patients either complying or not complying with their contact lens wear and care in the context of each of the main aspects relating to contact lens wear. Connections are shown between each of the aspects, and the themes which were reported, to either enable patients to be more compliant or constrain them from being compliant. Links are also shown between some of the themes which emerged from the data.

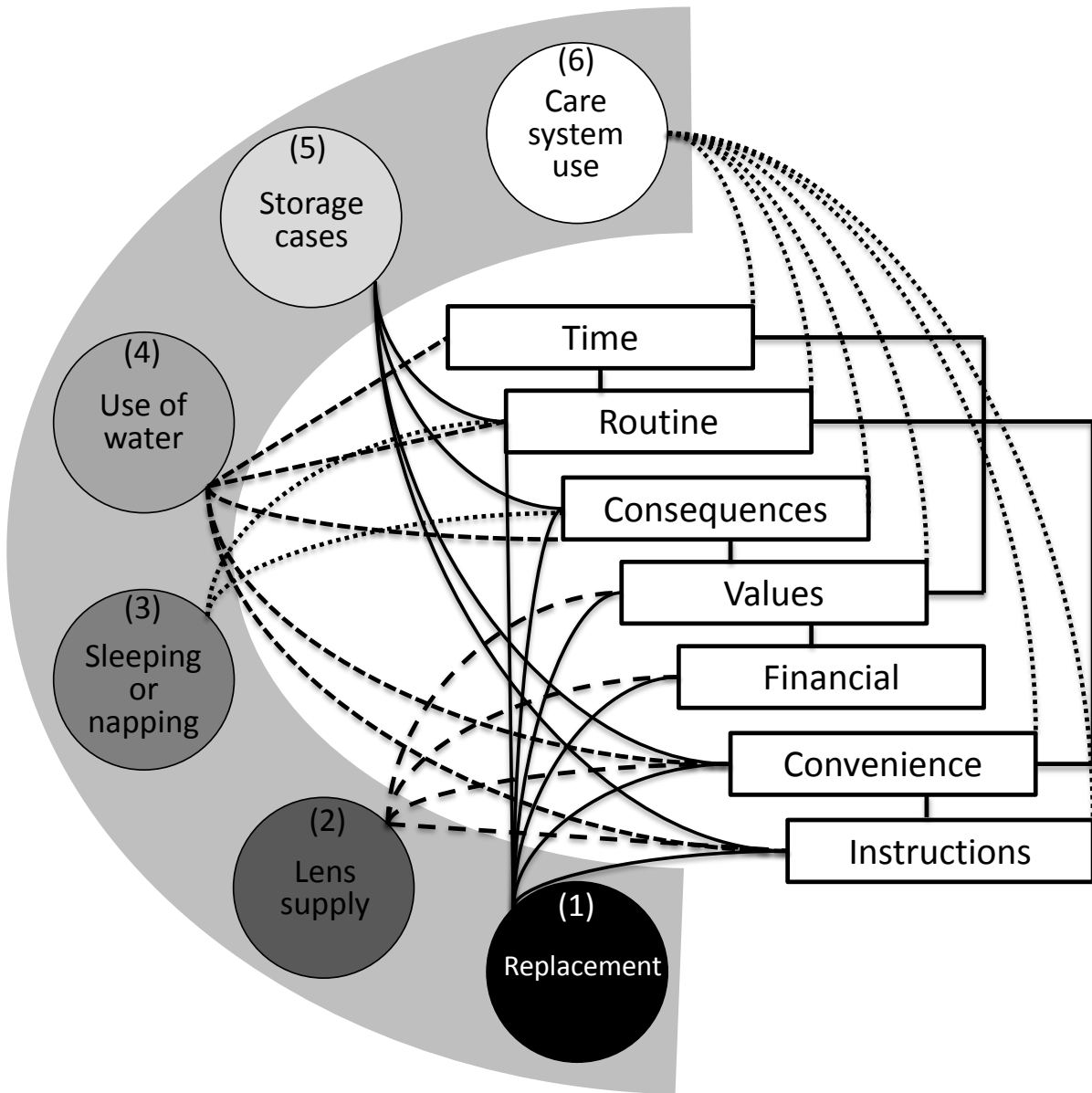


Figure 7-1: A grounded theory of themes relating to non-compliance with contact lens wear

## 7.5 Discussion

The aim of this study was to explore the reasons for non-compliance in contact lens wearers and to gain a better understanding of the constraining and enabling factors that may be involved in wearers' behaviours with respect to contact lens wear. The on-line survey revealed that the most frequently reported aspects of non-compliance were (1) failure to replace lenses when scheduled, (2) inappropriate lens purchase and supply, (3) sleeping while wearing lenses, (4) the use of water with lenses and failure to wash hands, (5) failure to clean and replace cases regularly and (6) inappropriate use of care systems. These findings are consistent with previously conducted studies by our group.<sup>32-34,40</sup>

A complex web of factors that may influence compliance was uncovered during the second part of the study using focus group discussions. Seven primary themes associated with non-compliance were identified: (1) possible consequences of non-compliance, (2) instructions (or lack thereof) with respect to contact lens wear, (3) changes in routine, (4) level of convenience, (5) time limitations, (6) wearer values and (7) financial constraints.

Multiple themes were often associated with the contact lens wearing experiences reported by the study participants. The most frequently occurring themes related to "consequences" and "instructions". These themes emerged during the focus group discussions relating to all six of the identified aspects of contact lens wear. "Routine" and "convenience" also featured prominently, and although "time", "values" and "finances" were also identified as themes, these did not emerge in the data as frequently. A helpful direction for future study will be to pursue a more in-depth examination of how the most prominent patient perspectives of "consequences" and "instructions" interact with contact lens wear and care compliance.

Most of the themes that emerged during the analysis could be considered to be both constraints to and enablers of compliance. For example, a lack of instructions regarding contact lens case care could be considered to be a constraint to compliance, while clear instructions regarding contact lens cleaning strategies and rationale enabled better compliance with lens care. Examples of both constraining and enabling factors or behaviours were discussed by participants for most themes except for ‘time’ and ‘values’ for which only constraining factors were discussed.

There were a number of unexpected beliefs and experiences revealed by this study’s participants. Unanticipated participant findings included: (1) blur and noticeable lens deposits, rather than discomfort, were cues to replace lenses, (2) re-use of part-time worn lenses was considered compliant behavior, (3) reluctance to wear daily disposables included a concern for the environment and storage limitations, (4) on-line lens orders did not always require verification of an up-to-date prescription or recommendation of a specific lens brand by an eye care practitioner, (5) use of storage cases and water appeared to be less emphasized parts of practitioner instructions and (6) a lack of understanding of the serious complications (e.g., infections) that could occur as a result of non-compliant behaviour. Additional study into these patient perspectives may help to further explicate the drivers of contact lens wear and care compliance.

Self-declared “laziness” (which could be interpreted to be a failure to see the value in investing the time required) was given as the reason for not appropriately caring for lenses by many of the participants; however, the participants also attributed several of the non-compliant behaviours that were reported to a change in routine. This was particularly apparent in the younger age group when they unexpectedly found themselves away from home and their contact lens supplies. A large proportion of the participants thought that the purpose of cleaning their lenses was to simply remove

deposits which may build up on the surfaces and not to remove microorganisms. A similar lack of concern was expressed for the build-up of “crusty, brown stuff” around the storage case caps when the cases were not cleaned or replaced frequently; while this was considered to look “gross”, there seemed to be a lack of appreciation of the risk posed by using dirty cases. The general lack of awareness with respect to hygiene was also apparent with respect to hand washing; several participants reported that they were careful to wash their hands in order to prevent transferring spices or cosmetics to their lenses but did not express concern about the importance of preventing microbial contamination of their lenses. Some of the participants did report purchasing their lenses over the Internet; this practice prevents patients from receiving the education, clinical care and follow-up that is recommended for successful, complication free lens wear and is often considered to be an issue for compliance, particularly since it has been shown to be associated with a greater risk of developing microbial keratitis.<sup>14,15</sup>

There are no comparable studies with which to compare our findings. Similar studies have been conducted to investigate non-compliance with the glaucoma management. Poor education, lack of motivation, forgetfulness and faulty drop application have been found to be obstacles to compliance with the treatment regimen,<sup>27, 43</sup> whereas the motivation for adherence has been the fear of blindness and faith in drop efficacy.<sup>43</sup> These themes are analogous to those discovered in our study, even though they relate to treatment for a disease rather than compliance with the use of a prescribed medical device.

This study’s qualitative methodology is criticized by some for its presumed lack of rigor, thus we took steps to ensure the determinants of the ‘trustworthiness’ of our findings: credibility (internal



validity), conformability (objectivity), dependability (reliability) and transferability (external validity or generalizability).<sup>44,45</sup>

Credibility was addressed, in part, through “triangulation” of data types (i.e., using data questionnaire and focus groups). Diversity of the focus groups was also incorporated into the study design with the involvement of two distinct age groups of contact lens wearers, who have previously been reported to behave differently with respect to contact lens wear.<sup>21-23,31</sup> In addition, peer debriefing was performed and discussions regarding developing ideas and interpretations were conducted throughout the data collection and analysis among some of the study’s investigators and with colleagues within the CCLR.

A number of steps were taken to ensure that our study’s findings were the result of the experiences and ideas of the participants and not the investigators. These included: (1) the facilitator did not interject opinions or speak more than participants, (2) the audio recordings were accurately transcribed for each focus group, (3) careful observation notes were made, and (4) accurate records were kept to enable a subsequent audit trail by an independent researcher. With the aim of ensuring the dependability of the research, the study design and implementation were clearly described in the methods section. These details serve as a means of quality assurance and should aid others in replicating similar research at another time.

Focus group studies involve relatively small numbers of people and therefore the opinions expressed by the participants may not be representative of the general contact lens wearing population. A possible limitation of this study is that only 12 participants took part in the focus groups. It became clear that thematic saturation had been reached after the conclusion of four focus groups (12 participants) thus there was no additional value to adding additional groups. The richness of the data

collected however, hopefully surmounts the relatively small sample size. While transferability of these findings to a broader population could also be considered to be a limitation of the study, relevance rather than generalizability is the primary goal of qualitative research of this nature.<sup>44</sup>

In addition to the possible consequences that individual patients may face as a result of non-compliance with contact lens wear and care, the financial implications for society should also be considered. An analysis was conducted in Australia to evaluate the morbidity of the most serious complication that can occur as a result of poor compliance—microbial keratitis.<sup>46,47</sup> Costs for cases of microbial keratitis were calculated to range from \$1,191 to \$1,779 Australian dollars. It was also calculated that the burden of disease might be reduced by as much as 76% if contact lens wearers were to change their habits and be more compliant with their lens wear and care procedures.<sup>48</sup>

To our knowledge, this is the first time that qualitative research methods have been used to evaluate patient compliance with contact lens wear and care. Future work in this area may be able to provide an increased understanding of which aspects of contact lens wear and care are considered by contact lens wearers to either constrain or enable compliance and help eye care practitioners to counsel their patients on the importance of appropriate lens wear and care procedures. The results from qualitative research studies may also aid in the development of specific approaches and tools to enable compliance. For example, contact lens wearers may be more compliant if they are advised that their comfort will be better if they replace their lenses when scheduled (gain-framed) rather than being advised that they will experience discomfort if they fail to replace them on schedule (loss-framed). This is known as “Prospect theory” and has been tested in smoking cessation research where it has been reported that individuals are more likely to stop smoking when presented with specific benefits of quitting (gains) compared with being presented with the financial costs of continuing (losses).<sup>49</sup>

The expansion of products offering greater convenience at an affordable price may also play a role in improving contact lens care compliance in the future. Ensuring that adequate instructions are available and conducting ongoing patient education should be considered crucial to compliant and successful contact lens wear.

## **7.6 Conclusion**

This research study has provided a new approach to understanding non-compliance with contact lens wear and care. The qualitative aspect of the study is complementary to past quantitative studies, while deepening our understanding of contact lens non-compliance. It is important to understand more than the “who” and the “what” of non-compliance; the “why” of this behaviour may also help us develop strategies to address it. Several key themes relating to non-compliance emerged during the conduct of the study, including consequences, instructions, routine, convenience, time, values and finances. Eye care practitioners and the contact lens industry can hopefully apply this greater understanding of why patients fail to wear and care for their lenses as they should, to help them develop strategies and tools to aid compliance and success in contact lens wear.

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## Chapter 8

### Discussion

This thesis is essentially comprised of six separate manuscripts, each with a discussion relating to the specific study design and results. This chapter will not simply repeat the impressions and theories debated in the previous individual discussions, but will rather take the approach of discussing the overall findings from the studies in a more global way, based upon the rationale behind the thesis. In addition, the key findings from this thesis research will be discussed in the context of the results from studies by other authors that have been published or presented during a similar time frame to when this body of research was conducted.

#### 8.1 Methodologies

As described earlier, there are many ways in which compliance can be assessed in health care. The research portrayed in this thesis utilized several different methodologies, each with its relative advantages and disadvantages. Employing a number of different approaches is advantageous and strengthens the reliability of the data collected.

(1) In the first study that is described in this thesis, a questionnaire was administered by the investigators to just over 100 current lens wearers to determine whether they knew the names of their contact lens products and whether photographic aids would help in their recognition; the study did not evaluate compliance with the use of the products and participants were simply asked to respond to a set series of questions regarding which lenses and lens care products they were using.

(2) For the second study, eligible prospective participants were identified by their ECPs mailed a questionnaire that was to be completed at home by the participants and returned directly to the CCLR. The participants' ECPs did not see the individual responses, and confirmation of the lenses and care

products used, along with recommendations given for lens wear and replacement was subsequently obtained from chart review by the investigator.

(3) The third study was able to involve several thousand participants across Canada since it was conducted using the Internet. The advantages of administering a questionnaire on the Internet include the possibility of a larger sample size and the ability to ensure that all questions are answered and that responses are only possible from a predetermined selection or range. In addition, self-populating questions can be included which will appear dependent on the responses given to earlier questions. The disadvantage of this methodology is that it could not be confirmed that all the study participants were indeed contact lens wearers or that the lens types and the care systems used were accurately reported. Fortunately the demographics of the respondents closely matched what would be expected of a contact lens wearing population, and the participants' ability to select their products with the online photographic aids hopefully improved the accuracy of their self-report.

(4) The fourth study involved a questionnaire that was completed by contact lens wearers in their ECPs' offices. Each questionnaire was labeled with a unique code, which allowed the responses of the participants to be matched with those of their ECP, which were completed separately. Both this study and the earlier one in which participants completed a questionnaire at home, unfortunately suffered from the drawbacks of administering a paper-based questionnaire which allows participants to skip questions or enter invalid responses which cannot be checked or corrected at a later time.

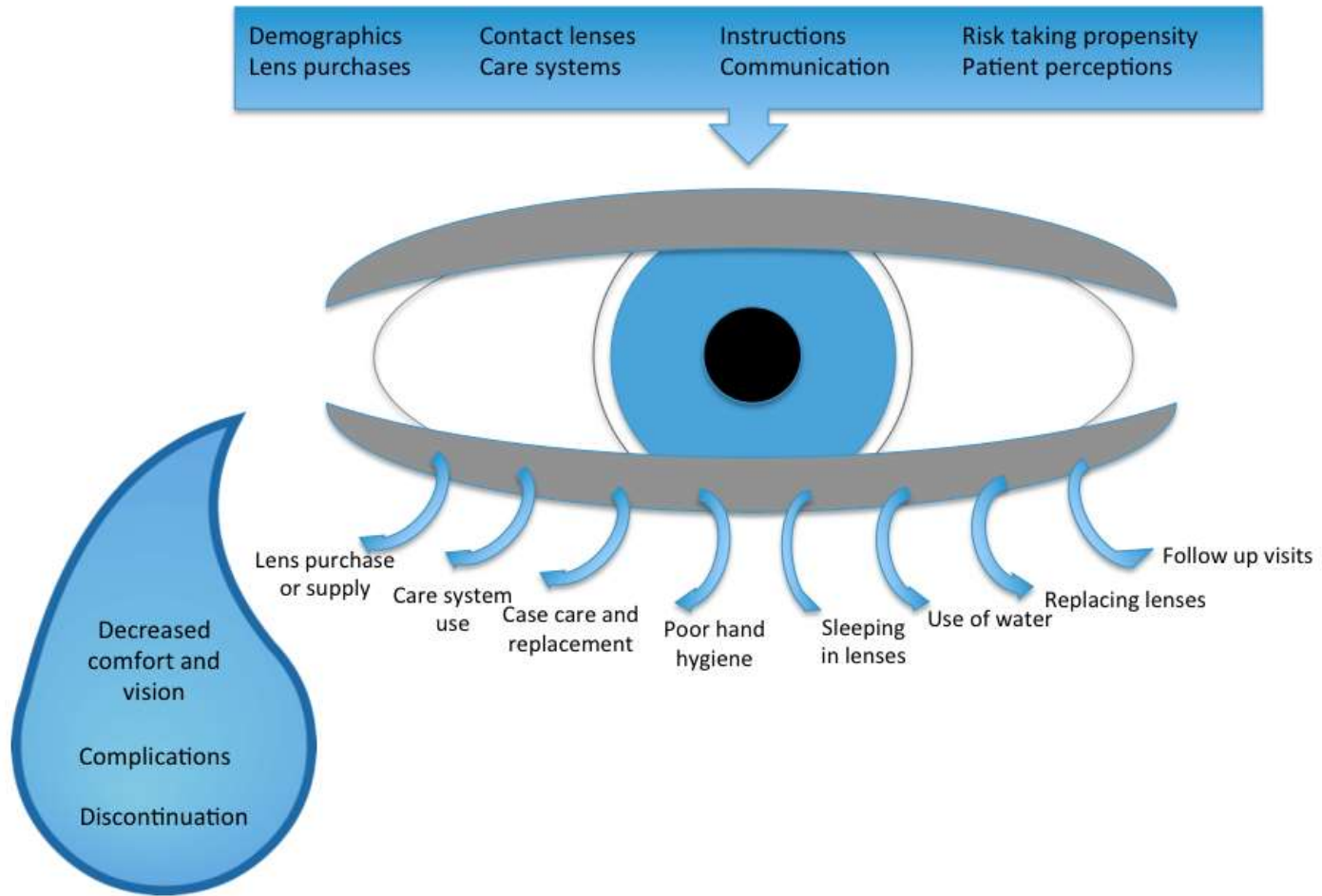
(5) The fifth study combined the designs of two of the previous studies. Prospective participants who were considered eligible for the study were identified by their ECPs and invited to take part in the study, which was administered using an online survey. The study population could therefore be controlled, while still allowing a larger sample size and the many advantages of Internet based

questionnaires. An additional benefit of an Internet based questionnaire utilized in this study was the ability to include participants from several countries and to compare their responses. Two versions of the questionnaire were made available, one in English and one in Norwegian, but the responses from both could be combined into one dataset.

(6) Finally, in the sixth study, a series of focus groups were conducted with current contact lens wearers. This methodology, employing direct encounters with individuals, is frequently used in qualitative research but has not been used to evaluate compliance with contact lens wear before. While quantitative research methods can measure how often or to what extent contact lens wearers are non-compliant, qualitative methods, try to find out why they behave in the way they do. These research methods may be criticized for their inability to be generalized to a larger population, but the methods that were used to ensure rigour were described in detail in this chapter and the use of these qualitative methods was considered to be extremely valuable in looking at the “big picture” with respect to compliance with contemporary contact lens wear.

## **8.2 Modeling contact lens compliance**

In Chapter 7, a schematic description of the “themes” relating to non-compliance with contact lens wear was presented. As somewhat of an extension to this, a “model” of contact lens compliance has been developed which represents the types of non-compliance that can occur with contact lens wear and have been presented in this thesis (the lower eyelashes), the determinants of contact lens compliance (the pressure exerted by the upper lid on blinking) and the consequences of non-compliance (the tears). While it is recognized that this is somewhat of an over simplification of a much more complex topic, it is hoped that the reader will benefit from this visual representation. The model is presented in Figure 8-1.



**Figure 8-1: Model depicting non-compliance with contact lens wear**

### **8.3 Types of non-compliance and their prevalence**

While contact lens materials, replacement intervals and care regimens have changed considerably since the first studies investigating contact lens compliance were conducted, the behaviour of the people wearing them has not. The types and prevalence of non-compliance described in this body of research are similar to those previously reported.

#### **8.3.1 Lens replacement**

It is important to recognize that lens replacement modality does not cause non-compliance but may be a barrier to compliance. Contact lens wearers continue to fail to replace their lenses according to both the manufacturers' recommendations and those given by the ECP. In the study investigating the relationship between compliance with replacement of re-usable SiHy lenses and contact lens related problems, 67% of participants were not compliant with the MRRF and 60% did not follow the recommendations given to them by their optometrists.<sup>1</sup> Non-compliance rates were slightly lower in the Internet-based study conducted across Canada, at 54%,<sup>2</sup> and in the office-based survey study conducted in the United States the non-compliance rate was 48%;<sup>3</sup> however, both of these studies also investigated non-compliance with the replacement of DDCLs which has consistently been reported to be lower than with re-usable lens types.<sup>3-6</sup> Studies conducted by other groups in the United States during a similar period of time reported non-compliance with lens replacement to vary between 35% and 63%,<sup>7-9</sup> and an international analysis reported overall non-compliance with lens replacement to be 60%, confirming that this continues to be a significant problem among contact lens wearers worldwide.<sup>10</sup> The way in which non-compliance with lens replacement is expressed has also changed to not only report the absolute proportion of wearers who exceed the recommended intervals between replacement, but also to evaluate how much longer they continue to wear their lenses beyond this point.<sup>1,8,9</sup>



Compliance with one-month replacement contact lenses continues to be better than with two-week replacement lenses; <sup>1,3 8</sup> however, the best compliance with replacement is with DDCLs, and in the Internet study conducted in four countries an overall rate of non-compliance with replacement of 9% was found. <sup>11</sup> In this study, the non-compliance rate for wearers in the US was 12%, the same as reported in a previous study and similar to the rate of 14% reported by Yeung et al. <sup>4,8</sup> The study conducted in US ECP offices yielded the highest rate of non-compliance with replacement of DDCLs at 26%. <sup>3</sup> It is not clear why this rate was so much higher than that reported in the other studies; however, one possible reason is that in some cases the ECP may have reported the lens type that they had just refitted their patients with (and the ECP's report of lens type was used in the data analyses) while the participants were reporting their replacement habits with re-usable lenses that they had been wearing up until the visit where they completed the questionnaire. The re-use of daily disposable lenses is of particular concern if they are simply stored in the blister packs from which they came since 95% of lenses stored in this way have been shown to be contaminated. <sup>12</sup> Another type of non-compliance which is more relevant to DDCLs is the removal of lenses during the day and re-insertion later in the day; this behaviour was reported by 10% of the participants in the DDCL study and raises similar concerns for how the lenses are stored during the periods of time that they are not being worn. In the focus group discussions it was apparent that contact lens wearers may not even consider the re-use of daily disposable lenses to be non-compliant if the lenses are only being worn for short periods of time, for example during sporting activities. <sup>13</sup>

The reasons given for failing to replace two-week and one-month replacement lenses according to recommendations continue to be simply forgetting which day they should replace their lenses (approximately 40%) and to save money (approximately 30%). <sup>1,3</sup> For DDCL wearers the primary

reason given is to save money (60%) followed by running out of lenses (47%).<sup>11</sup> These findings were supported by the discussions during the focus groups in the qualitative study of compliance although some participants in this study also reported relying on cues or triggers to replace their lenses, such as deposits on the lenses or a decrease in visual quality while wearing the lenses.<sup>13</sup>

### **8.3.2 Wearing times and overnight wear**

End of day discomfort with contact lens wear is a frequently reported problem and many patients report that their comfortable wearing time is significantly less than their total wearing time.<sup>14,15</sup> In the study investigating discontinuation from lens wear, more than half of the questionnaire respondents indicated that they wished they could wear their lenses for longer each day and the lapsed wearers reported shorter overall wearing times than the current wearers.<sup>2</sup> A similar proportion of re-usable SiHy wearers and DDCL wearers reported discomfort later in the day but continued to wear their lenses for an average of between 2.4 and 3.4 hours beyond this time.<sup>1,11</sup>

Despite these relatively frequent reports of end of day discomfort, many study participants (15 – 30% across the four studies where this was evaluated) reported that they wore their lenses overnight occasionally, frequently, or almost every night; napping while wearing lenses was reported by 35 to 75% of the participants in these studies.<sup>1-3,11</sup> It was particularly disturbing to find such a high proportion of DDCL wearers reporting occasional overnight lens wear, even if this was just for one night in the preceding month.<sup>11</sup> Overnight lens wear continues to be one of the major risk factors for microbial keratitis.<sup>16</sup> The most extensive recent study of compliant and non-compliant behaviour with respect to overnight wear of soft contact lenses was conducted by Jansen et al.<sup>17</sup> In this study, overnight wear was reported at one quarter of the patient visits and non-compliant overnight wear was reported at a rate of 6%. Overnight wear was also reported for DDCL wearers in this study, and all

these cases were considered to be non-compliant. Patients reporting overnight wear were more likely to be male, college students, smokers and wearers of SiHy lenses. In the international analysis of compliance with contact lens wear, Morgan et al reported that almost half of the questionnaire respondents slept in lenses that were prescribed for daily wear only.<sup>10</sup>

Participants in the focus groups also reported sleeping or napping while wearing their lenses.<sup>13</sup> This was often reported to occur when they were tired and inadvertently fell asleep while still wearing their lenses or when there was a change in routine, such as staying over at a friend's house. The participants seemed to be more concerned about how their eyes felt when they did this however, than that they were putting themselves at greater risk of infection.

### **8.3.3 Lens supply**

Unquestionably one of the most significant changes to have occurred since the first studies investigating contact lens compliance three decades ago is the advent of Internet purchase of contact lenses. The FDA recognized that this might be a problem in 2001.<sup>18</sup> Subsequently serious complications associated with purchase over the Internet were reported,<sup>19</sup> but it was not until 2008 that the frequency of Internet contact lens purchases was reported.<sup>20</sup> In this study of college students, almost 23% reported purchasing their lenses over the Internet and these individuals were also reported to purchase lenses less often and had higher "time pressure scores" than those who purchased lenses from more conventional sources. In the same year, Stapleton et al identified Internet purchase to be a significant risk factor for microbial keratitis.<sup>21</sup> Internet purchase in the studies included in this thesis has ranged from a low of 2% in the study investigating the relationship between compliance with contact lens replacement and contact lens problems,<sup>1</sup> to 14% in the online study investigating discontinuation from contact lens wear.<sup>2</sup> There is concern among ECPs that patients

who are prescribed DDCLs are more likely to fill their prescription over the internet;<sup>22</sup> interestingly, in the study investigating compliance with DDCLs, only 9% reported Internet purchase of their lenses. Wu et al have also reported on the Internet purchase of contact lenses in relation to compliance with contact lens wear, and in their study in Australia, 17% of participants reported having purchased their lenses over the Internet.<sup>23</sup>

Purchasing contact lenses over the Internet is convenient and may be less expensive when compared with purchases made from ECPs. These sentiments were echoed in the focus groups who reported looking for the “best deal” and the ease with which Internet purchases can be made, often without confirmation of a valid prescription.<sup>13</sup> The other concern with purchases over the Internet is that there is no accompanying counseling on the risks associated with contact lens wear and the procedures required for appropriate and safe contact lens wear and care. Wu et al reported that individuals who purchased their lenses over the Internet were almost four times as likely to forget their schedule for important follow visits when compared with those who purchase their lenses from their ECP.<sup>23</sup>

#### **8.3.4 Contact lens care systems**

While the requirements for maintaining a clean, disinfected soft contact lens that can be safely reinserted into the eye have remained the same since these lenses were first introduced, the methods for achieving this goal have most definitely been simplified with the introduction of multipurpose and single step H<sub>2</sub>O<sub>2</sub> contact lens care systems. As a consequence one might expect compliance with daily contact lens maintenance would have improved; however, this unfortunately does not appear to be the case. In our studies, the majority of re-usable contact lens wearers are using brand-named multipurpose solutions (77% to 88%); hydrogen peroxide systems were used by 12% to 20% and private label solutions were used by 3% or fewer of the wearers.<sup>1-3</sup>

The majority of ECPs recognize the importance of rubbing and rinsing lenses that are to be re-used every evening with a multipurpose solution. Unfortunately this information is not being passed on to their patients; approximately two thirds of re-usable contact lens wearers report not rubbing and rinsing their lenses every night and between 22% and 41% report topping up their cases with solution at night rather than replacing it with unused solution.<sup>1-3</sup> These reports closely match those from other research groups conducting compliance studies at a similar time. Wu et al reported that 63% of participants in their study failed to rub their lenses, Hickson-Curran reported a failure rate of 75% and Morgan et al, 80%.<sup>9,10,23</sup> In these same studies up to 54% of participants reported sometimes topping-up their cases with solution.

Once again, the results from the quantitative studies are endorsed by the patient reports in focus groups.<sup>13</sup> Contact lens wearers may know that rubbing and rinsing their lenses is important, but they are often unwilling to take the additional time for this important step at the end of the day. An interesting finding in this research was that some wearers intentionally did not rub their lenses because they were worried about them tearing. Others were not really sure why they were “cleaning” their lenses and were more concerned about the possibility of a build up of “deposits” than the risk of transferring potentially sight-threatening microorganisms from their lenses to their eyes.

### **8.3.5 Contact lens cases**

In recent years, contact lens researchers have increasingly began to recognize the importance of appropriate contact lens case cleaning and replacement.<sup>24</sup> Less than one third of the participants in reported cleaning their lens cases every day or most days.<sup>1,3</sup> This finding is consistent with the other studies which were being conducted at a similar time,<sup>9,10</sup> and in the international analysis of compliance only 0.4% of participants were found to be practicing correct case care.<sup>10</sup> In these studies,

more than 50% of wearers reported using tap water to clean their lens cases.<sup>1,9,23</sup> Wu has carefully looked at both the current recommendations for contact lens case care and the most effective ways of cleaning contact lens cases in order to reduce microbial contamination.<sup>25-29</sup> The instructions that are available for patients to follow come from a number of sources; those printed on the packaging from the manufacturers, information that may be provided from their ECPs and information that may be available on the Internet. Wu et al examined all of these carefully, comparing instructions from different products, the results of a survey from Australian optometrists and the information that is available on the FDA website.<sup>25</sup> While rinsing the case was common to all sources, rubbing the case was only recommended by some of the optometrists and air drying the case was recommended on the FDA web site (face down) and by the optometrists (usually face up). Recommendations for replacing the case varied from once a month to intervals of up to six months. In a separate study, 58% of cases that were collected from current wearers were found to be contaminated with microorganisms and cases that were less than nine months old showed less contamination.<sup>26</sup> Two further studies, one *in vitro* and one with cases used by patients, showed that the most effective way of reducing the number of colony forming units of microorganisms in the cases was to follow a rub, rinse, tissue wipe and air dry regimen.<sup>28,29</sup> Because there also seemed to be conflicting information provided on the best way to air dry cases, an additional study was conducted looking at the impact of both location and placement of cases to air dry.<sup>27</sup> Humid locations such as the bathroom and specifically near to the toilet resulted in significantly higher rates of contamination than dryer locations such as the bedroom and bathroom, but only when the cases were left to dry facing upwards. The contamination rates were significantly lower for all cases that were left to dry facing downwards but were similar for all locations tested. The build up of a biofilm in contact lens cases is known to be frequently associated with a greater risk for microbial keratitis since it can provide a favourable environment for proliferation of certain

microorganisms.<sup>30</sup> A recent study has confirmed infrequent case replacement to be a significant risk factor for the development of moderate and severe microbial keratitis,<sup>16</sup> and there is now concern that there is an increasing diversity of bacterial types in the biofilm forming in cases, with particular interest in *Achromobacter spp*, *Stenotrophomonas maltophilia*, and *Delftia spp* and their link with contact lens-related inflammatory complications.<sup>31</sup>

There was considerable confusion among the focus group participants with respect to appropriate contact lens case care and replacement; this is hardly surprising when several participants reported that no one ever told them what to do with the case.<sup>13</sup> Many participants reported using water to clean their cases, when they remembered to clean it, and some participants provided rationale for leaving the case closed because of concerns for contamination in the bathroom. It was somewhat disturbing that several of the focus group participants recognized that their cases appeared “dirty” but did not seem to appreciate that the “dirt” may be putting them at risk of infection and that they should be cleaning or replacing their cases. Undoubtedly this is an area where considerably clearer guidelines and more education is required for both the patient and the ECP. Stapleton et al recently reported that: “Almost 50% of moderate and severe disease in daily wear could be eliminated by better attention to lens case hygiene and 27% by frequent storage case replacement alone.”<sup>16</sup>

### **8.3.6 Hand washing**

The frequency of hand washing was assessed in two studies during this thesis research.<sup>3,13</sup> It is interesting that a higher proportion of participants report that they always wash their hands prior to inserting their lenses, with a lower proportion reporting doing so prior to removing their lenses. This finding is consistent with that of Bowden et al.<sup>32</sup> The proportion of participants who reported failing to wash their hands was somewhat higher than has been recently reported in some recent studies,<sup>7,23</sup>

but lower than that reported in others.<sup>9,10,33</sup> The differences are most likely due to the way in which contact lens wearers are asked the question, and the criteria which are used to assess the adequacy of the procedures used. Unfortunately failure to wash hands appropriately before handling contact lenses can result in the lens becoming a vector carrying microorganisms from the skin on the hands to the eye. Campbell et al report on the differences between a “social hand wash” and a hand wash technique recommended by health care professionals.<sup>34</sup> The former takes approximately 11 seconds to complete, but frequently misses the finger tips and palms of the hands, while the latter requires 34 seconds. Contact lens wearers are more likely to perform a cursory wash and therefore may still be placing themselves at greater risk for inflammation and infection. This hypothesis is supported by comments from the focus group participants:<sup>13</sup> “I generally just wash my hands a bit, nothing super clean, I just run them under the tap for about 10 seconds with a bit of soap.” Similarly, the higher rate of hand washing prior to lens insertion was mirrored by comments such as: “In the morning I am better at remembering to wash my hands, than at night, when I am tired.”

### **8.3.7 Use of water**

The qualitative studies conducted for this thesis research did not specifically investigate the use of water with, and while wearing, contact lenses; however, as reported earlier, more than half the participants in one of the studies reported using tap water to clean their lens cases.<sup>1</sup> Participants in the focus groups also recounted situations where they had used water directly on their lenses; fortunately these occurred infrequently and the discomfort reported following subsequent reinsertion of the lenses is hopefully a deterrent against repeating this behaviour.<sup>13</sup> Swimming and showering while wearing contact lenses is also troublesome and has been considered to be a non-compliant behaviour. Showering while wearing lenses has been reported by approximately one third of wearers in one



recent study,<sup>32</sup> and swimming by up to two thirds of wearers in other contemporary studies.<sup>7,23,33</sup> The majority of contact lens wearers reporting swimming while wearing their lenses did so without using goggles;<sup>23</sup> the use of goggles has been shown to offer some protection against bacterial colonization of contact lenses while swimming.<sup>35</sup> These data would support the recommendation encouraging lens wearers to use goggles while swimming. Participants in the focus groups also reported engaging in water activities and there were several references made to wearing lenses at water parks and the impracticalities of wearing spectacles in these situations.<sup>13</sup> While ECPs may be having discussions with their patients about swimming as a sport and making appropriate recommendations with respect to contact lens wear, they may not be considering the other times when patients are coming into contact with water while wearing their lenses and suggesting ways to reduce the risk of contamination of their lenses, such as the use of daily disposable lenses and goggles.

## **8.4 Determinants of non-compliance**

If it were possible to identify which contact lens wearers were more likely to be non-compliant with respect to wearing and caring for their lenses, resolving this issue would be much simpler.

Unfortunately this has not proved to be straightforward in the past. During the course of this thesis research, a number of different factors were considered and are reviewed in the context of the relevant recent research by others on this topic.

### **8.4.1 Demographics**

Some of the early studies on compliance reported that younger wearers may be less compliant than older ones.<sup>36,37</sup> This finding was repeated in our earlier studies investigating compliance with lens replacement.<sup>4,6</sup> In the studies specifically conducted for this thesis, age was found to be a factor for

compliance with lens replacement and care system use only once and, consistent with the earlier studies compliance, was better for the older wearers. In addition, in the DDCL study, younger wearers reported overnight wear with their lenses more frequently than older wearers.<sup>11</sup> Younger wearers were also reported to be more likely to demonstrate non-compliant behaviour in the studies being conducted at a similar time by Bui et al, Yeung et al and Morgan et al.<sup>7,8,10</sup> In addition, in the preliminary quantitative phase of the focus group study, a slightly higher proportion of the younger group reported Internet purchases, overnight wear, and failure to wash their hands before inserting their lenses, but the sample size for this study was comparatively small and these differences were not statistically significant.<sup>13</sup>

The role of gender in non-compliant behaviour has also been investigated, but in the early studies no differences were found between male and female wearers. This has not been found to be the case in some recent studies of compliance, where a higher proportion of male wearers were reported to be non-compliant when compared with females.<sup>4,6</sup> Gender was not found to play a role in non-compliant behaviour with respect to compliance with lens replacement in the current studies;<sup>1,3,11</sup> however, females were found to more compliant with the use of care systems and showed better recognition for which system they were using and were less likely to wear daily.<sup>3,38</sup> Males have been reported to be less compliant than females with respect to overall compliance, compliance with lens replacement and sleeping while wearing lenses, in studies conducted during a similar period of time.<sup>7,8,10</sup>

Wearing time (hours per day and days per week) and experience with lens wear (number of years of lens wear) were also evaluated as possible factors relating to compliance. No differences were found with respect to wearing time, but in the study investigating compliance with replacement and contact lens related problems, a higher proportion of participants who had been wearing lenses for longer

were found to be non-compliant.<sup>1</sup> This is consistent with the findings of Chun and Weissman from their early study investigating overall compliance with contact lens wear.<sup>36</sup> Morgan et al reported part-time wearers to be more compliant than full time wearers in their international study.<sup>10</sup>

As reported in the introduction, previous studies have not been able to show a relationship between socioeconomic status and non-compliant behaviour in contact lens wearers. The studies described in this thesis did not specifically evaluate the possible role of education and occupation; however in one study, participants were asked about their household income and a higher proportion of participants with lower incomes were found to be non-compliant with lens replacement than those in the higher income brackets.<sup>3</sup> As reported earlier, one of the reasons given for not replacing lenses when recommended is to save money and therefore this finding could be anticipated to some degree.

#### **8.4.2 Lens purchase patterns**

A number of different factors relating to the purchase of lenses were evaluated in these studies. These included purchase source (ECP, Internet etc.), purchase quantity and method of payment. Participants who reported purchasing lenses directly from their ECP were generally more compliant with respect to replacing their lenses, as were those who purchased a one year supply.<sup>3</sup> Previous studies have reported better compliance with lens replacement in the UK, where patients frequently have a pre-arranged payment agreement.<sup>39</sup> In the DDCL study, a relatively high rate of compliance with lens replacement was also found in the UK, but it is not clear whether this, or other factors may be contributing to this difference.<sup>11</sup>

### 8.4.3 Contact lenses and care systems

It was not surprising to once again find that the MRRF played a role in compliance with lens replacement and this has been discussed earlier. Other factors should also be considered however, including lens materials, lens designs and prescriptions. Interest has been expressed in whether compliance with replacement of SiHy lenses is any different compared with conventional materials. In the Internet-based study conducted to investigate discontinuation from contact lens wear, a significantly higher proportion of re-usable SiHy wearers were compliant with the MRRF when compared with hydrogel lens wearers.<sup>2</sup> A similar finding was also reported by Yeung et al, but the one-month replacement SiHy wearers were found to “stretch” the interval between lens replacement for longer than one-month replacement hydrogel wearers in the study conducted by Hickson-Curren et al, suggesting that it may be too simplistic to solely consider the broad classification of material and there are likely to be differences according to specific lens brands.<sup>8,9</sup> While degree of refractive error does not appear to influence lens wearer behaviour with respect to compliance with replacement,<sup>4,8</sup> wearing toric or multifocal lens was reported to be a factor but this was not the case for all the studies conducted. Toric lens wearers were found to be less compliant in our earlier studies,<sup>4,6</sup> but not in the studies reported on in this thesis, and multifocal lens wearers were only found to be more compliant with replacement in one of the more recent studies.<sup>1</sup> Speculation that the higher cost of specialty lens may result in a lower rate of compliance with replacement is not supported by the findings among the multifocal lens wearers; however, these wearers are also older.

We have not been able to find a difference in compliance with respect to lens replacement according to the types of care system being used, although Yeung et al have reported a higher rate of compliance with lens replacement among users of hydrogen peroxide when compared with those who

used multipurpose solutions,<sup>8</sup> and a similarly higher rate of overall compliance with instructions for care product use in users of hydrogen peroxide systems has been reported in another study.<sup>40</sup>

#### **8.4.4 Risk taking propensity**

It would be helpful for ECPs to be able to recognize which of their patients are most likely to be non-compliant. Carnt et al conducted a study in which optometrists rated how compliant they thought their patients were and the attitude of their patients towards following instructions.<sup>41</sup> The patients independently completed both a questionnaire assessing their compliance with contact lens wear and care and a recognized risk taking survey. Risk taking was found to be associated with the overall compliance score and the scores for lens disinfection and case hygiene. Younger patients and male patients were found to be less compliant and these individuals were also reported to have a higher propensity to take risks. The optometrists' perception of their patients' compliance, and the length of time that the patients had been wearing lenses, were not found to be associated with the overall compliance scores. Risk taking was found to be the only independent risk factor, suggesting that a higher risk taking propensity may be a much better predictor of non-compliance with lens wear and care than many of the other factors considered. These results may also help to explain why younger males are more likely to display non-compliant behaviour when wearing and caring for their lenses.

#### **8.4.5 Patient perceptions, knowledge and attitude**

Recent studies have reported that a much higher proportion of contact lens wearers consider themselves to be compliant than in actual fact are.<sup>7,33</sup> In order for a patient to change their behaviour and become more compliant, they first need to recognize that they are susceptible to developing a complication, such as microbial keratitis, and that the consequences of the complication are severe.

This model of “health beliefs” was described in more detail in the introduction.<sup>37</sup> The qualitative study that was conducted towards the end of this body of research, supported the importance of patient beliefs or perceptions and knowledge, in their attitude towards contact lens wear.<sup>13</sup> While many of the participants in the focus groups were aware that they might experience an infection as a result of wearing contact lenses, they considered this to be extremely unlikely and did not appear to realize that they were increasing their risk of developing this condition as a result of certain behaviours (e.g. sleeping in lenses, poor hygiene etc.). There was also a lack of knowledge regarding the severity and possible outcome of developing a sight threatening infection. A similar theme was apparent in the study investigating contact lens related problems, where more than half of the patients who experienced a contact lens related problem, failed to consult with an eye care professional or other doctor regarding the problem.<sup>1</sup> The majority of the DDCL wearers recognized that there was a risk associated with the re-use of their lenses and this risk was generally perceived to be developing an eye infection; however, interestingly only three percent expressed their major concern as being permanent loss of vision.<sup>11</sup>

Patient knowledge of complications has also been investigated by others. In the two studies conducted by authors from Southwestern Medical Center in Dallas, patients attending the university clinic believed contact lens complications to be more common than patients from private optometric practices in the area and a higher proportion were able to name a complication.<sup>7,33</sup> The patients attending the university clinic named “infection” most frequently, while those attending private practice responded “comfort and handling” more often. This demonstrates that even patients from the same geographical area can have quite different perceptions and beliefs according to where they obtain their eye care.

It was interesting to find a difference in compliance with replacement of DDCLs according to the country in which the wearer lived in.<sup>11</sup> Differences in compliance were also reported by Morgan et al in their international analysis of contact lens compliance.<sup>10</sup> There could be many reasons for the differences between countries and a full discussion of these is beyond the scope of this thesis; however, it is important to recognize that when compliance with contact lens wear is investigated in one country, the results may be very different to those from another country. Interestingly, in the two earlier studies of compliance with replacement of lenses which the CCLR conducted in the US and Canada, the results were almost identical; these two countries are on the same continent though and the provision of eye care and products available for patients are very similar in both countries. This is certainly not the case around the world, and many other factors are likely involved.

#### **8.4.6 Instructions**

Providing information to patients regarding the way to wear and care for their lenses is extremely important. This information should be correct; patients do not consider themselves to be non-compliant when they are following advice given to them by their ECP. An example of this was reported in the focus groups when one participant reported that her optometrist had given her a trial pair of continuous wear lenses but said that although they were supposed to be replaced every month, since she was only going to be wearing them during the day, she could extend their life to three months.<sup>13</sup> Constraints to compliance also occur when no information is provided to patients on how to wear their lenses and look after their lenses and lens cases.

Re-instruction can always be provided at follow-up visits. Morgan et al reported better compliance in patients who had seen their ECP more recently.<sup>10</sup> In the study evaluating compliance with lens replacement and the interval between eye examinations, we found that the participants who were

compliant with lens replacement attended their ECP's offices more regularly than those who were not compliant.<sup>3</sup> The reason for the improved compliance may be the reinforcement of instructions at these regular visits or it could be that because they have come into the office for a visit they are more likely to purchase a replacement supply of lenses. Either way, both the ECP and the patient derive benefit from this positive behaviour.

## **8.5 Consequences of non-compliance**

When such a high proportion of contact lens wearers are non-compliant with one or more aspects of their contact lens wear and care, it is surprising that there are not more serious complications.

McMonnies has made a useful analogy to the lottery:

*“The more tickets you buy and the more frequently you buy them, and the longer you continue to buy them, the better are the odds that you will win a prize. The same principles apply to the odds of experiencing contact lens problems. The more often you break the rules, the greater the number of ways you break them, and the longer you continue to break them, the better the odds are that you will experience problems. However, instead of winning, you lose.”*<sup>42</sup>

There are a number of different consequences that can occur as a result of not complying with appropriate lens wear and care and these have also been evaluated in this thesis research. Compliance with contact lens wear can be considered to be similar to compliance with treatment for conditions in which patients do not experience deleterious consequences of not following the prescribed course of treatment, until the consequences are manifested in an acute way. Examples of such conditions include hypertension and glaucoma. Unfortunately these consequences can be severe and therefore compliance with regimens to decrease the likelihood of them occurring is extremely important.



### **8.5.1 Problems or complications**

Unarguably, the most serious complication that can occur as a result of non-compliant behaviour is microbial keratitis. The studies conducted during this thesis research did not specifically investigate the role of non-compliance in the development of microbial keratitis, but this is already well documented in the literature and has been reported on in the introduction to this thesis.

In the thesis study that was specifically designed to investigate patient reported problems, the patients who were compliant with the recommendations given to them by their ECP for lens replacement were found to be less likely to experience contact lens related problems than those who were not compliant with these recommendations.<sup>1</sup> A similar trend was seen with respect to compliance with the MRRF; however, this difference was not statistically significant. Yeung et al have also reported a correlation between compliance with lens replacement and contact lens complications.<sup>8</sup> In their study, a range of conditions were included and a higher number of complications were seen per eye in those wearers who were extremely non-compliant with lens replacement.

### **8.5.2 Comfort and Vision**

A consequence of non-compliance, which is not acute in presentation, is a gradual deterioration in comfort and or vision that may occur while wearing re-usable lenses. A decrease in both the subjective report of comfort and vision, has been described in a previous study investigating compliance with lens replacement.<sup>43</sup> A similar decrease in the subjective comfort of DDCLs when they were used on a subsequent day was reported in the DDCL study that is included in this body of research.<sup>11</sup> During the focus group discussions in the qualitative study, participants reported that a decrease in visual performance was a cue that lenses were due to be replaced.<sup>13</sup>

### **8.5.3 Discontinuation from contact lens wear**

The ultimate consequence of non-compliance for both the patient and the ECP, is discontinuation from contact lens wear. One of the studies conducted for this thesis was designed to determine which factors may lead to abandonment; in this study, compliance with recommendations for contact lens replacement was not found to be a factor in lapsing from contact lens wear; however, the participants in the study who reported poor compliance with contact lens care (specifically “topping up” disinfecting solution) were found to be more likely to discontinue from lens wear. It is not clear whether these non-compliant behaviours resulted in inferior comfort or vision with these lenses, or other problems, but was an interesting finding nonetheless. <sup>2</sup>

### **8.6 Improvement of compliance**

Compliance with contact lens wear and care could be improved with a number of different strategies. The first stage is to recognize the barriers or constraints to compliance and hopefully the qualitative research study conducted as part of the thesis has been able to add considerably to our understanding of the experience and perspectives of contact lens wearers. The next stage is to develop a number of specific approaches and tools that can enable contact lens wearers to be more compliant and successful with contact lens wear. The most frequently occurring themes that developed during the focus group discussions were “instructions” and “consequences”. Undoubtedly communication between the contact lens wearer and his or her provider is an extremely important factor. While this is most often in the more traditional form of a verbal discussion between the ECP and the patient along with supplementary written instructions, other approaches may also be relevant, particularly with the increasing number of individuals purchasing their lenses from other sources including the Internet. Clear instructions need to be provided and frequently re-enforced; explaining the reasons for

replacing lenses on schedule, cleaning lenses and cases et cetera. is also extremely important and patients are much more likely to follow the instructions that they have been given if they understand why they are carrying them out. In our first study evaluating compliance with replacement of SiHy and DDCLs, a higher proportion of compliant wearers recognized the importance of effective communication with their ECP when compared with non-compliant wearers.<sup>4</sup> Understanding the possible consequences of not complying with the instructions that they have been given is also a crucial component in improving compliance, particularly for those patients who have a higher propensity for taking risks or who have been determined to be more likely to be non-compliant. If these wearers understand that they are indeed susceptible to serious complications (e.g. microbial keratitis) and that these complications can result in severe outcomes (e.g. loss of vision) but that they can decrease their chances of experiencing them by being compliant (e.g. not sleeping in lenses, improving their hygiene when handling their lenses), they may be more likely to follow the instructions that they have been given if they do not foresee any significant reasons or barriers not to (e.g. financial constraints). The importance of providing ongoing education to contact lens wearers cannot be overstated; contact lens wearers often become somewhat complacent with respect to their contact lens wear and maintenance, particularly if they have not experienced any problems as a result of small lapses in compliant behaviour; the analogy of the lottery ticket purchase can be extremely helpful here.<sup>42</sup>

In the first study described in this thesis, a significant improvement in the recognition of the habitual products used by contact lens wearers was demonstrated with the use of photographic aids.<sup>38</sup> Other pictorial aids may help to improve compliance with contact lens wear and care. An example is the guide to “Healthy Soft Contact Lens Habits” which has been developed by the Association of Contact

Lens Educators.<sup>44</sup> This clear patient guide is downloadable from the Internet (available in English, French and Spanish) and provides a list of illustrated instructions which the ECP can review with their patients. The guide can then be taken home for patients to review at regular intervals. The Contact Lens and Cornea Section of the American Optometric Association has also developed a patient hand out and a web site designed to explain contact lens safety to patients. This web site addresses many of the questions that contact lens wearers may have.<sup>45</sup> There are also many videos available on the Internet that show patients how to wear and care for their lenses. There are some problems with patients using the Internet to find health related information though and the advent of search engines such as Google has unfortunately resulted in patients often finding too much and frequently conflicting information. A different approach to providing health related information and education, has been developed by Dr. Mike Evans, a University of Toronto professor of family medicine and public health. He has developed a series of short public health videos designed to educate patients.<sup>46</sup> In these videos key health issues are presented in an entertaining yet informative manner using whiteboard illustrations drawn while the viewer watches (speeded up from real time) with a simultaneous audio soundtrack. A similar approach may be extremely helpful to educate contact lens wearers.

Manufacturers of contact lenses and contact lens care products can also play a role in improving compliance among wearers by continuing to simplify and improve their contact lens products to encourage compliance while still being safe and effective when used by contact lens wearers worldwide.

## **8.7 Limitations of current research**

It should be recognized that there are some limitations to the research presented in this thesis. A number of different methodologies were used, all with their own advantages and disadvantages. All of the studies relied heavily on indirect methods in which the contact lens wearers reported their behaviours with respect to contact lens wear and care. Indirect assessments of compliance generally result in higher levels of compliance being reported since the respondents frequently reply with the answer that they think is correct rather than the one which actually describes their behaviour. This limitation was hopefully minimized by allowing participants to complete questionnaires either anonymously or independently from their ECP which should have encouraged the participants to respond honestly.

None of the study designs were prospective, controlled, masked or randomized. Conducting studies investigating compliance using these tenets of scientific investigation could be extremely costly and in many ways may not be ethical, particularly if the wearers are actually instructed to be non-compliant. In addition, many different factors considered to be important in describing and predicting non-compliant behaviour were investigated; however, in most cases the effects of these were considered in isolation of other factors being tested or evaluated. Human behaviour is extremely complex and often unpredictable, and applying rigorous statistical analysis techniques was not considered to be entirely appropriate when evaluating the results from these studies. Presenting the data as frequency distributions and, in the case of the qualitative study as direct quotes from the transcripts, was considered to be more applicable for this topic of research.

The participants in the studies were primarily from Canada and the United States and it should be recognized that although contact lens wearers in both of these countries appear to exhibit similar

behaviours with respect to contact lens wear and care, this may not be the case in other countries which were not investigated in these evaluations. Many cultural differences exist worldwide and these may influence the behaviour of contact lens wearers and the results from these studies could therefore not be generalizable to other populations. With the exception of the Internet study conducted in Canada and the focus group study, all the participants were patients recruited through their ECPs and may not be representative of the full spectrum of contact lens wearers in their countries of residence.

## **8.8 Conclusions and future directions**

The rate of non-compliance with contact lens wear and care, similar to infection rates, does not appear to have changed significantly in the past quarter of a century. Non-compliance with recommendations for contact lens replacement was shown to be associated with a higher rate of contact lens related problems. Contact lens wearers continue to “drop-out” for reasons of discomfort and dryness with their lenses but this may not be as a direct result of non-compliant behaviour with respect to their lens wear and maintenance. Patients who are non-compliant with recommended lens replacement intervals also attend their ECP’s offices less frequently. Compliance with lens replacement is better in patients who purchase an annual supply of lenses and encouraging this practice may increase compliance and result in patients attending their ECP’s offices more regularly for follow-up care and eye examinations. An association was found between contact lens wearers who are non-compliant with lens replacement those who are non-compliant with lens care, supporting the theory that personality plays a significant role in determining whether a patient will be compliant or not.

Non-compliance with instructions for replacement also occurs in DDCL wearers, but is less common than for two-week and one-month replacement lens wearers. Prescribing DDCL can therefore be used

as a strategy to improve compliance and since these lenses do not require daily cleaning and maintenance and no case is required, many of the ways in which a patient can be non-compliant are eliminated; however, patients do sometimes abuse these lenses by re-using them or sleeping in them, both of which behaviours result in a greater risk of infection.

Qualitative research methods were able to provide a new approach to understanding why contact lens wearers are sometimes non-compliant and were able to give insights into what strategies could be employed to improve compliance. Careful counseling and education on the risks associated with contact lens wear is required to provide patients with a better lens wearing experience and continued successful contact lens wear.

The issues of non-compliance with contact lens wear and care are unlikely to be solved in the near future. Further research should be conducted to investigate how instructions can help patients to become more compliant and to avoid the possible consequences associated with inappropriate contact lens wear and maintenance. Prospective studies of compliance over a significant period of time could be conducted to determine the effects of extensive instructions and the possible consequences of non-compliance.

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## **Appendix B**

### **Manuscripts published prior to registration in PhD program**

## Patient and Practitioner Compliance With Silicone Hydrogel and Daily Disposable Lens Replacement in the United States

Kathy Dumbleton, M.Sc., Craig Woods, Ph.D., Lyndon Jones, Ph.D., Desmond Fonn, M.Optom., and David B. Sarwer, Ph.D.

**Objective:** The objectives of this study were to assess current recommendations for replacement frequency (RF) of silicone hydrogel (SH) and daily disposable (DD) lenses, to determine compliance with these recommendations, and to investigate the reasons given for noncompliance.

**Methods:** A package containing 20 patient surveys was sent to 309 eye care practitioners (ECPs) in the United States who had agreed to participate in the study. One thousand eight hundred fifty-nine completed surveys were received from 158 ECPs and 1,654 surveys were eligible for analysis. Questions related to patient demographics, lens type, lens wearing patterns, the ECP instructions for RF, and the actual patient reported RF. ECPs were asked to provide lens information and their recommendation for RF after the surveys had been completed and sealed in envelopes. All responses were anonymous.

**Results:** Sixty-six percent of patients were women and their mean age was  $34 \pm 12$  years. Eighty-eight percent of lenses were worn for daily wear,  $12.8 \pm 3.2$  hours a day,  $6.2 \pm 1.5$  days a week. Lens type distribution was 16% DD, 45% 2 week (2W) SH, and 39% 1 month (1M) SH. ECP recommendations for RF varied according to the lens type: 1% of 1M (95% CI 0.2–1.7), 4% of DD (95% CI 2.1–7.2), and 18% of 2W (95% CI 15.1–20.7) patients were given instructions that did not conform to the manufacturers' recommended RF (MRRF). When considering only those patients who were given the correct instructions for RF, 38% were not compliant with the MRRF; noncompliance rates varied according to the lens type and were 12% for DD (95% CI 8.6–17.2), 28% for 1M (95% CI 24.9–32.1), and 52% for 2W (95% CI 47.8–55.8). The most frequent reasons for over wearing lenses were "forgetting which day to replace lenses" (51%) and "to save money" (26%). Fifty-three percent believed that a reminder system would aid compliance; the most popular methods being a cell phone reminder or text message (29%) and a nominated day each week or month (26%). Discussions between the ECPs and the patients were more extensive for patients who were compliant with the MRRF.

**Conclusions:** ECPs recommended RFs more frequently with DD and 1M SH lenses than with 2W SH lenses, consistent with manufacturers' recommendations. Patients were less compliant with RF than ECPs for all lens types investigated. Patients were most compliant with RF when wearing DD lenses and least compliant when wearing 2W SH lenses. Better communication facilitated greater compliance with RF. More than half of

those not replacing lenses, when recommended, reported that this was because they forgot which day to replace their lenses.

**Key Words:** Silicone hydrogel—Daily disposable—Contact lens—Replacement frequency—Compliance.

(*Eye & Contact Lens* 2009;4: 164–171)

The majority of soft lenses worn worldwide today are designed to be replaced at intervals ranging from 1 day to 1 month and many studies have shown that frequent replacement results in fewer deposits, less complications, and enhanced clinical performance compared with lenses that are worn for longer periods of time.<sup>1–9</sup> Despite the advantages offered by frequent replacement of soft lenses, some eye care practitioners (ECPs) and many patients do not comply with the recommended replacement frequencies (RFs) and fail to discard their lenses after the scheduled time period.<sup>10–14</sup>

Some studies have shown that the noncompliance rates vary according to the recommended RFs of the lenses that are worn. In a study conducted in Canada and the United States, 43% of patients were reported to be noncompliant with replacement of their 2-week lenses compared with 33% of those using lenses that were recommended for monthly replacement.<sup>12</sup> Donshik et al.<sup>13</sup> also reported better compliance with replacement schedules of 1-day, 1-week, and 1-month compared with 2-weeks in a 2007 survey conducted in the United States. A similar difference in noncompliance rates was found in a European survey, with an overall noncompliance rate of 66% in patients wearing lenses with recommended replacement intervals of 2 weeks, compared with 40% for monthly replacement.<sup>14</sup> Previous studies investigating compliance with frequency of replacement have not looked specifically at silicone hydrogel (SH) lenses which, together with daily disposables (DDs), now account for more than 50% of the contact lenses prescribed and worn worldwide.<sup>15</sup> Preferences for some replacement schedules over others vary among ECPs and around the world. Most European countries were very quick to adopt the DD modality and generally favor monthly over 2-weekly replacement, whereas in the United States, lenses intended for 2-week replacement are the most commonly prescribed.<sup>16</sup>

The aim of this study was to assess current recommendations by ECPs for RF of SH and DD contact lenses in the United States. In addition, the rates of noncompliance with manufacturer recommended RF (MRRF) by both the ECP and the

Centre for Contact Lens Research (K.D., C.W., L.J., D.F.), School of Optometry, University of Waterloo, Waterloo, Canada; and Clinical Psychologist (D.B.S.), Department of Psychiatry, University of Pennsylvania, Philadelphia, PA.

This study was supported by CIBA Vision Corporation.

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patient were determined and the reasons for noncompliance were investigated.

## METHODS

### Study Design

Approximately 20,000 ECPs in the United States were sent e-mails inviting them to participate in the study. The e-mails were sent on behalf of the Centre for Contact Lens Research (CCLR) by Review of Optometry Online through Jobson Professional Publishing. ECPs practicing outside the United States and practicing in educational institutions were excluded from the e-mail list. In addition, the same invitation was sent by e-mail, on behalf of the CCLR, to a list of 3,000 CIBA Vision account holders in the United States. ECPs choosing to participate were directed to a CCLR Web site on which they could register and enter their contact details onto a secure online database at the University of Waterloo. A target enrollment of approximately 300 ECPs was set and enrollment at the registration Web site closed when this was reached. Ethics clearance was obtained through the Office of Research Ethics at the University of Waterloo before commencement of the study.

### Study Procedures

Survey packages, containing all the necessary study materials, were sent by mail to the registered ECPs who had agreed to participate in the study. Each package contained an explanatory covering letter, which instructed them to ask the next 20 soft contact lens-wearing patients attending their practice, wearing SH (2-week or 1-month replacement) or DD soft lenses, to complete a short survey. The wearing schedule for the patients was not specified. A picture sheet was also provided showing lens types eligible for inclusion in the study.

The three-page survey consisted of a series of demographic questions regarding the patient and their contact lens history, including recommended and actual contact lens RF. Questions were also included to determine the reasons for not complying with recommended replacement intervals and to investigate instructions provided by the ECP regarding contact lens replacement. A series of questions evaluating current lens care practices were also incorporated at the conclusion of the survey. After completing the survey, each patient was asked to seal it in a study-specific envelope and then to hand over this envelope to their ECP. The ECP was then directed to record that particular patient's lens type, powers for each eye, and their recommended replacement schedule for the patient on the outside of that envelope to ensure that the patient details and ECP information remained linked. Completion of the survey by the patients was voluntary and the patients completing it retained anonymity from the CCLR. If a patient declined to complete the survey, the next patient was asked by the ECP, until a maximum of 20 surveys were completed. The ECP then returned all completed surveys (in their sealed envelopes) to the CCLR in a postage-paid envelope.

### Data Analysis

In relevant cases, data analyses were conducted using Statistica 7.0 (StatSoft Inc., Tulsa, OK). Data are presented in tables as mean  $\pm$  standard deviation or as frequency distributions. The 95% confidence intervals are also included in parentheses after reported

frequency data, when appropriate. A significance level of  $\alpha$  equal to 0.05 was used for all analyses. In the case of nonparametric analyses, Mann-Whitney *U* tests were used for unpaired ranked comparisons between compliance groups, and Kruskal-Wallis ANOVA by ranks tests were used for comparisons between the different lens groups (1 day, 2 weeks, and 1 month).

## RESULTS

### Respondents

Three-hundred nine ECPs from 44 states had agreed to participate in this study when enrollment was closed; 158 returned patient surveys (51% return rate) and 1,859 patient surveys were returned by the cutoff date (30% of the total sent out). The data from 1,654 patient respondents were eligible for the analysis (89% of completed surveys received). The remaining surveys did not have sufficient information recorded for analysis or were completed by patients who were not wearing DD or SH (2-week and 1-month replacement) lenses. Eleven percent of ECPs returning surveys were affiliated with a corporate entity (e.g., optical chain), and the remainder were independent practitioners.

### ECP Completed Data

From the information recorded by the ECP on the study-specific envelopes, 16% of the lenses worn were DD, 45% were 2-week replacement SH, and 39% were 1-month replacement SH. The brands of lenses worn are listed in Table 1.

The distribution of responses for the ECP-recommended RF for each lens group is listed in Table 2. The shaded cells represent those recommended RFs that are considered to be compliant with the MRRF for the lens type (intervals of less than or equal to the MRRF). Four percent (2.1–7.2%) of recommendations for RF by ECPs were longer than the MRRF for DD lenses, 18% (15.1–20.7%) were longer than the MRRF for 2-week lenses, and 1% (0.2–1.7%) were longer than the MRRF for 1-month lenses. These rates can be considered to be significantly different because the 95% confidence intervals for the three lens groups do not overlap. Shorter RFs were recommended by ECPs for 1% of 2-week lens wearers and for 18% of 1-month lens wearers; in most of these cases, the lens type worn was Air Optix (O2 Optix, CIBA Vision).

Ninety-two percent of patients were myopic. The mean spherical lens power was  $-3.09 \pm 2.56$  diopter (D) (median,  $-3.00$ D). The spherical power was not significantly different between lens groups ( $P > 0.05$ ). Sixteen percent of patients were wearing lenses for astigmatism. The mean cylindrical lens power for these wearers was  $-1.21 \pm 0.45$ D (median,  $-1.25$ D).

### Patient Survey Data

#### Demographics and Lens Wearing Patterns

Sixty-six percent of the surveys analyzed were completed by female patients. The mean age of all patients was  $34.2 \pm 12.3$  years (range, 14–79 years) with a median patient age of 32 years. The patients surveyed were experienced contact lens wearers with a mean number of years wearing contact lenses of  $12.9 \pm 9.6$  (range, 0.08–50 years) with a median of 11 years. There was no difference in the distribution of sex and no significant difference in the mean age or the total years of lens wear between groups ( $P > 0.05$ ) were observed.

TABLE 1. Distribution of Lens Brands Worn

Lens name	Manufacturer	Number	% Category	% Total sample	
<b>DD lenses</b>					
1 Day Acuvue (and Moist)	Johnson & Johnson	63	24	16	
Focus Dailies (and Aqua, Aqua Plus)	CIBA Vision	133	50		
Focus Dailies Toric	CIBA Vision	11	4		
Focus Dailies Progressive	CIBA Vision	2	1		
Proclear 1 Day	CooperVision	35	13		
Soflens 1 Day	Bausch & Lomb	11	4		
Clearsight 1 Day	CooperVision	7	3		
Clearsight 1 Day Toric	CooperVision	3	1		
<b>Two-week lenses</b>					
Acuvue Advance	Johnson & Johnson	149	20		45
Acuvue Advance for Astigmatism	Johnson & Johnson	98	13		
Acuvue OASYS	Johnson & Johnson	405	55		
Acuvue OASYS for Astigmatism	Johnson & Johnson	69	9		
Avaira	CooperVision	20	3		
<b>One-month lenses</b>					
Air Optix (O2 Optix)/Air Optix Aqua	CIBA Vision	167	26	39	
Air Optix for Astigmatism	CIBA Vision	37	6		
Night & Day	CIBA Vision	202	31		
Biofinity	CooperVision	68	10		
PureVision	Bausch & Lomb	67	10		
PureVision Toric	Bausch & Lomb	66	10		
PureVision Multifocal	Bausch & Lomb	41	7		

DD, daily disposable.

Lenses were reported to be worn  $6.2 \pm 1.5$  days each week (median, 7 days; range, 1–7 days). The days lenses were worn each week varied significantly by group ( $P < 0.001$ ) with post hoc testing showing that DD lenses were worn for fewer days each week than 2-week and 1-month lenses ( $P < 0.001$ ). Overall, 12% of patients reported wearing lenses for 24 hrs each day; this varied significantly by lens group, with the rates being 0.8% (0.3–2.9%) for DD lenses, 6.7% (5.1–8.8%) for 2-week lenses, and 21.7% (18.8–25.1%) for 1-month lenses. The mean wearing time of lenses worn for daily wear was  $12.8 \pm 3.2$  hrs each day (median, 13 hrs). There were no significant differences between groups with respect to hours per day that lenses were worn ( $P > 0.05$ ). Forty-seven percent of patients reported that their lenses become less comfortable later in the day. These patients reported wearing their lenses for  $2.7 \pm 2.1$  hr after this time point. There were no significant differences between the lens groups, with respect to the percentage of patients reporting late day discomfort, or in the number of hours they continued to wear lenses ( $P > 0.05$ ).

#### Lens Type and Replacement Frequency Reported by Patients

The lens type worn, as reported by the patients, matched that reported by the ECP for 74% of the participating patients. In 6% of cases, the lens types did not match, and 20% of patients were unsure of the lens type they were wearing. The distribution of responses for the patient reported recommendation of RF, for each lens group is listed in Table 3. The shaded cells represent those RFs that are compliant with the MRRF for the lens type. The lens type reported by the ECP was used in these calculations. Ten

percent (6.8–14.4%) of the patient reported RFs were longer than the MRRF for DD lenses, 22% (19.2–25.4%) for 2-week lenses, and 2% (1.3–3.8%) for 1-month lenses. These rates were significantly different because the 95% confidence intervals for the three lens groups do not overlap. No recommendation was reported to be given for RF by 4% of patients. Less than 1% of patients did not respond to this question, and in these cases it was possibly because they could not recall a recommendation being given to them.

The actual RF for the patients was evaluated with two separate questions. In the first question, patients were asked to respond when they replaced their lenses relative to what was recommended to them. These results are presented in Table 4. When compared across groups, the proportion responding that they “always” replaced their lenses according to the recommendations varied; this proportion was 82% (76.9–86.2%) for DD lenses, 25% (22.2–28.5%) for 2-week lenses, and 34% (30.6–37.9%) for 1-month lenses. These rates were significantly different because the 95% confidence intervals for the three lens groups do not overlap.

In the second question, patients were asked after how many days or months they replaced their lenses. An actual RF of more than 1 day was considered to be noncompliant for DD lenses, more than 17 days (i.e., less frequently than twice a month) was considered to be noncompliant for 2-week lenses, and more than 31 days (once a month) was considered to be noncompliant for 1-month lenses. Overall, 40% of patients wore lenses longer than the MRRF. This varied significantly by lens group, with the lowest rate occurring in DD lens wearers (15%, 10.9–19.7%) followed by 1-month lens wearers (29%, 25.3–32.4%) and with the highest rate

TABLE 2. Replacement Frequency Recommended by ECP

Lens group	ECP recommended replacement frequency (%) (as reported by ECP)								
	1 d	2 d	3–6 d	1 wk	2 wk	3 wk	1 mo	2 mo	$\geq 3$ mo
DD	96.0	0	0	2.8	0.4	0	0.8	0	0
Two weeks	0.1	0	0	0.8	81.3	3.0	14	0.4	0.3
One month	0.2	0	0	0.3	16.3	0.8	81.7	0.3	0.3

DD, daily disposable; ECP, eye care practitioner.

**TABLE 3.** Replacement Frequency Recommended by ECP, as Reported by Patient

Lens group	ECP recommended replacement frequency (%) (as reported by patient)									
	1 d	2 d	3–6 d	1 wk	2 wk	3 wk	1 mo	2 mo	≥3 mo	NR
DD	85.6	0.4	0.4	3.4	3.8	0	1.5	0	0	4.9
Two weeks	1.1	0.7	0.7	2.4	70.1	3.1	16.7	0.7	0.8	3.7
One month	1.2	0.2	0	1.7	18.5	0.9	72.3	0.9	1.2	3.0

DD, daily disposable; ECP, eye care practitioner; NR, no recommendation given.

occurring in 2-week wearers (59%, 55.5–62.7%). Because ECPs were not always compliant with the MRRF, it may be considered inappropriate to include those patients in whom the recommended wearing periods (as stated by the ECPs on the envelopes) were longer than the MRRF in the calculations for noncompliance rates. When these cases were excluded from the analysis, the overall noncompliance rate between the actual RF and the MRRF was 38% (n = 1414). There was still significant variation in the noncompliance rates between groups with the lowest rate occurring in DD lens wearers (12%, 8.6–17.2%) followed by 1-month lens wearers (28%, 24.9–32.1%) and with the highest rate still occurring in 2-week wearers (52%, 47.8–55.8%). The noncompliance rates are shown in Figure 1.

When the actual RF was compared with the patient-reported RF, 36% of patients wore their lenses longer than the recommendation that they recalled being given by their ECP. Patients who did wear their lenses longer than recommended were asked to select the primary reason; the distribution of responses is presented in Figure 2.

**Perceived Importance of Replacing Lenses on Schedule**

The perceived importance of replacing contact lenses on schedule for the different lens groups and for all patients combined is presented in Table 5. The distribution of responses was significantly different between groups (P<0.001). The DD group had the highest number of patients responding that it was “extremely important” or “important” to replace their contact lenses on schedule (93%, 89.0–95.4%), followed by the 1-month group (80%, 76.4–82.7%), with the 2-week group having the lowest proportion of patients with these responses (71%, 67.9–74.4%).

**Reminder Systems**

Overall, 53% of patients believed that a reminder system would help them to comply with recommended replacement schedule. This varied by group with 24% (19.3–29.7%) of DD wearers, 57% (53.2–60.3%) of 2-week wearers, and 60% (55.7–63.2%) of 1-month wearers responding that they believed a reminder system would be useful. Patients selected one or more types of reminder systems which they believed would be helpful from a list of suggestions. Twenty-nine percent of patients selected a cell phone

**TABLE 4.** Replacement Frequency Relative to Recommended Replacement Frequency

Lens group	Replacement of contact lenses relative to what was recommended (%)			
	Always	Often	Sometimes	Rarely
DD	82	11	3	3
Two weeks	25	34	22	19
One month	34	32	22	12
All lenses	38	29	19	14

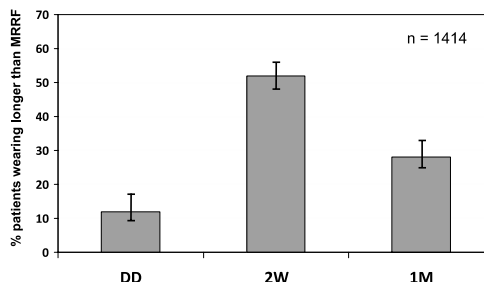
DD, daily disposable.

or text message, 26% selected establishing a particular day each week or month, 21% selected an email reminder, 14% selected a paper calendar, and 22% selected a countdown display on the lens case.

**Results by Compliance Group**

When a patient over wore their lenses in comparison with the MRRF they were considered to be noncompliant. Some data for compliant and noncompliant patients were analyzed further to investigate the possible associations with and reasons for noncompliance. Noncompliant patients were younger (33.1 ± 11.0 years) than compliant patients (35.0 ± 12.8 years), and the difference was statistically significant (P=0.006). There was no difference in sex distribution between compliant (67% women, 63.5–69.6%) and noncompliant patients (65% women, 60.4–68.7%), and there were no significant differences with respect to total years of lens wear, days per week of lens wear, or hours per day of lens wear (P>0.05). There was no significant difference in the mean spherical contact lens power of compliant and noncompliant patients (P>0.05), but a significantly higher proportion of noncompliant patients wore contact lenses for astigmatism (20%, 16.9–23.9%) than compliant patients (14%, 11.6–16.1%). A significantly greater proportion of compliant patients also reported having a pair of spectacles with an up to date prescription (92%, 90.0–93.6) compared with noncompliant patients (86%, 83.2–89.2%).

Table 6 shows the distribution of patients, according to compliance group, responding important or very important for their ECP explaining the replacement schedule, explaining the risks associated with noncompliance, and providing written materials on risks. A significantly higher percentage of the compliant group responded that it was “important” or “very important” that their ECP explained the replacement schedule and the risks associated with noncompliance, compared with the noncompliant group. The proportion was also higher for providing written materials, but the



**FIG. 1.** Noncompliance with manufacturer recommended replacement frequency (MRRF) according to lens type worn (DD = daily disposables, 2W = 2-week silicone hydrogels, 1M = 1-month silicone hydrogels).

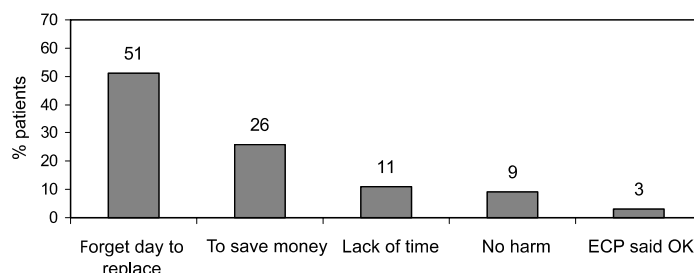


FIG. 2. Distribution of responses for the primary reason for wearing lenses for longer than recommended.

differences were not statistically significant. Results from a separate question showed a slightly higher proportion of compliant patients compared with noncompliant patients reporting having discussed the health effects (88% vs. 84%), the comfort effects (79% vs. 73%), and the cost aspect (42% vs. 37%) of replacing contact lenses on schedule with their ECP; these differences were not statistically significant. Five percent of compliant patients and 8% of noncompliant patients reported not discussing these aspects with their ECP (also not significantly different).

Table 7 shows the distribution of patients responding that they “agreed” or “strongly agreed” with 10 statements relating to their ECP and contact lens wear. For seven of the nine statements, a statistically significantly higher proportion of the compliant group gave either of these responses; these differences are indicated in bold responses in the table. A statistically significantly higher proportion of the noncompliant group agreed or strongly agreed with the statement: “The quality of my vision tells me it is time to replace my contact lenses.”

**Lens Care Practices**

Thirty percent of patients wearing 2-week or 1-month lenses were unsure of the name of the care system they were using; a statistically significantly higher proportion of patients who were noncompliant with the MRRF were unsure of their system (34%, 29.5–38.0%) compared with patients who were compliant (25%, 22.2–28.6%). A statistically significantly higher proportion of patients who were compliant with the MRRF felt that cleaning their lenses every day was “extremely important” or “important” (86%, 82.9–88.3%) when compared with noncompliant patients (77%, 72.5–80.4%). A slightly higher proportion of noncompliant patients reported having changed their care solutions recently (29%, 24.9–33.3%) compared with compliant patients (24%, 21.0–27.5%) but the difference was not statistically significant. Thirty percent of patients reported replacing their lens case only every year or “never”; this proportion was significantly different between compliance groups with those patients who were noncompliant with

TABLE 5. Perceived Importance of Replacing Lenses on Schedule

Lens group	Importance of replacing contact lenses on schedule (%)			
	Extremely important	Important	Somewhat important	Not important
DD	67	26	6	1
Two weeks	28	43	25	4
One month	34	46	18	2
All lenses	36	42	19	3

DD, daily disposable.

the MRRF giving either of these responses in 39% (34.3–43.3%) of cases compared with 23% (20.2–26.7%) of cases of wearers who were compliant with the MRRF.

**DISCUSSION**

This is the second time that a study investigating compliance relating to contact lens replacement has been conducted where the responses of both patients and their ECPs have been assessed anonymously and simultaneously. The first study evaluated compliance with replacement of conventional lens materials.<sup>12</sup> In both the previous and current studies, patients were required to complete a survey relating to their contact lens wearing patterns and RF; the patients’ ECPs were then required to complete details relating to the patients’ lenses and recommendations for RF on the outside of an envelope in which the patient had sealed their survey. In this manner, it was anticipated that the patient would be “honest” in their responses because their ECP could not see them and that the ECP would provide accurate lens information and be candid in their report of recommended RF, because their responses were also returned anonymously to the study coordinators. Although it is assumed that patients did not choose whether to participate based on their compliance with instructions given by their ECP, it is possible that only patients who recalled their ECP recommendation or patients who believed that they were relatively compliant completed the survey. The results may therefore not be representative of the contact lens wearing population as a whole and the levels of noncompliance may actually be higher than are reported in this article.

TABLE 6. Interactions With the ECP According to Compliance Group

Question	Patients responding important or very important (%)	
	Compliant	Noncompliant
How important is it that your eye care professional explain the replacement schedule to you in detail?	72 (68.7–74.6)	59 (55.0–63.5)
How important is it to you that during your appointment your eye care professional explains the risks associated with noncompliance to you?	75 (72.3–77.9)	67 (63.4–71.6)
How important is it to you that your eye care professional provides you with written materials on the risks associated with noncompliance?	45 (41.5–47.9)	41 (37.9–46.6)

ECP, eye care practitioner.

**TABLE 7.** Agreement With Statements According to Compliance Group

Statement	Patients responding "agree" or "strongly agree" (%)	
	Compliant	Noncompliant
If my eye care professional tells me to do something to care for my contact lenses, I do it.	94 (92.6–95.6)	76 (71.6–79.1)
My eye care professional clearly explained the replacement schedule for my current lenses.	95 (92.9–95.9)	87 (83.4–89.4)
I follow the recommended replacement schedule because I have complete confidence in my eye care professional.	90 (87.7–91.7)	54 (49.4–58.2)
I definitely don't dare miss replacing my contacts on the regular schedule.	66 (62.4–68.6)	19 (16.1–23.0)
I follow the recommended replacement schedule because it leads to fewer problems with my eyes.	85 (82.0–86.7)	38 (33.4–42.0)
Uncomfortable lenses make me more likely to follow the recommended replacement schedule.	85 (82.9–87.5)	83 (79.7–86.3)
The quality of my vision tells me it is time to replace my contact lenses.	62 (58.7–65.0)	70 (65.5–73.6)
If I don't replace my lenses on the recommended schedule, I have problems with my vision.	54 (50.6–57.1)	44 (39.2–47.9)
I use a calendar or other system to remind me to replace my lenses on the schedule recommended by my eye care professional.	52 (49.1–55.6)	28 (24.2–32.0)

This study cohort consisted of patients wearing DD or 2-week or 1-month SH contact lenses. These patients seemed to be representative of the current contact lens wearing population in the United States in sex and age.<sup>16</sup> The patients responding to the survey generally wore their lenses most days of the week, on a daily wear basis. The most commonly prescribed RF was 2-weeks (45%), followed by 1-month (39%), with 16% of patients wearing DD lenses: these proportions are also consistent with previous reports for wearers in the United States.<sup>15,16</sup> ECPs reported recommending longer intervals than the MRRF for 4% of their DD patients, 18% of their 2-week SH patients, and 1% of their 1-month SH patients. Although it has been recognized for some time that ECPs may recommend longer intervals between replacement in some cases, it is disturbing that a few are also recommending reuse of DD lenses, particularly because the relative risk of developing microbial keratitis has been shown to increase with DD lenses when compared with planned replacement soft lenses.<sup>17</sup> There are a number of possible reasons for the ECPs not following the MRRF including trying to increase patient retention by endeavoring to reduce the cost of lens wear; making allowances for part-time wear; and the ECP having a perception that some lens types do not "degrade" in performance when worn for longer periods and that their RF can therefore be extended.

In some cases, a shorter RF was recommended when compared with the MRRF; this occurred only for 1% of 2-week lenses but for 18% of 1-month lenses. When these shorter RFs were recommended for 1-month lenses, the predominant lens brand was Air Optix or O2 Optix. The reasons for shorter times are not clear but may be related to individual patient requirements, the ECP misunderstanding the MRRF for some lens types or, most likely, that

these lenses were previously marketed as a 2-week replacement lens and the ECP had continued with that schedule.<sup>18</sup>

The study design allowed a separate report of the instructions given by the ECP for recommended RF within the survey itself. According to these patients' survey responses, a greater proportion of patients were instructed to replace their lenses at intervals that were longer than the MRRF when compared with the ECPs own reports. Longer intervals were reported for DD lens wearers in 10% of cases, for 2-week SH lens wearers in 22% of cases, and for 1-month SH lens wearers in 2% of cases. No recommendation was apparently given for 5% of DD wearers, 4% of 2-week SH wearers, and 3% of 1-month SH wearers. The disparity between the rates of noncompliance as reported by the ECP directly and the patient reports is most likely due to the ECPs feeling obliged to record the MRRF on the envelope, even though the study was conducted anonymously, rather than what they had actually recommended to their patients. Patients may also have forgotten what recommendation had been given by their ECP. It is also possible that some of these patients were actually wearing a different lens type from that recorded by the ECP, which could account for some of the differences in noncompliance rates. A discrepancy between the ECPs recorded lens brand and the patient's recorded lens brand occurred in only 6% of cases and a further 20% of patients were unsure of what lens type they were wearing.

Despite the ECP instructions and the MRRF, many patients reported actual RFs that did not comply with these recommendations. When considering only those patients who were given the correct instructions for RF, the DD wearers were the "least" noncompliant (most compliant) with the MRRF, with 12% of wearers reporting that they did not replace their lenses every day. Twenty-eight percent of wearers of 1-month SH lenses were considered to be noncompliant with RF, reporting that they replaced their lenses after a period of more than 31 days. The most noncompliant lens wearing group were the 2-week SH wearers: 52% reported replacing their lenses after a period of more than 17 days (less frequently than twice a month). Although the proportion of DD patients wearing their lenses for longer than a 1-day period may seem to be low, the consequences of reusing a lens specifically designed for a single day of use could be catastrophic.<sup>19,20</sup> The high proportion of patients who were noncompliant with replacement of 2-week SH lenses is also an important finding, particularly because 2-week replacement is the most commonly prescribed modality in the United States.<sup>15</sup> The consequences of wearing a SH lens for longer than the MRRF are not known at this time because there have been no studies to-date specifically investigating this issue. The only published study that has compared replacement schedules with SH materials was an overnight study comparing complications with differing periods of overnight wear where no benefits were found with respect to corneal physiology, lens deposition, or subjective comfort and vision symptoms.<sup>21</sup> A study conducted in Singapore reported that 55% of patients who developed *Fusarium* keratitis reported having worn their contact lenses for longer than the MRRF, and using lenses past their recommended replacement date was reported to increase the likelihood of developing keratitis by a factor of almost five times; however, this study included many lens types and was not specifically investigating SH materials and DD lenses.<sup>22</sup>

The reasons given for not replacing lenses on schedule in our study varied according to the type of lens worn. For 2-week SH



and 1-month SH wearers, the most frequently reported reason (53%) was that they forget which day to replace them. Forgetting when to replace the lenses could theoretically result in a shorter or a longer RF. Usually, these patients end up wearing their lenses for longer periods, possibly with the aim of saving money. DD wearers were the most compliant with replacement schedule, but when they did fail to replace lenses as recommended, the most frequently reported reason given was "to save money" (29%). Twenty-three percent of DD wearers also said that they forgot which day to replace them, which seems curious since these lenses should be replaced every day. Twenty-six percent of DD wearers also cited "lack of time" which could possibly be interpreted as not getting around to reordering replacement lenses, although this is strictly speculating and cannot be confirmed from the study data. It is possible that some DD wearers are unaware that their lenses should be replaced each day, possibly because of incorrect or insufficient information being provided by the ECP, or the patients simply not adhering to their ECPs advice.

Notwithstanding these compliance rates, 78% of patients believed replacing their lenses on schedule was extremely important or important; this proportion did vary according to the lens group, with 93% of DD wearers, 80% of 1-month SH wearers, and 71% of 2-week SH wearers giving these responses. To facilitate compliance with lens replacement, reminder systems can be helpful for some patients. Greater than half the patients in the study wearing 2-week SH and 1-month SH lenses felt that a lens replacement reminder system would be useful. Electronic methods were chosen most frequently with 50% favoring a cell phone, text message, or e-mail reminder. This was followed by a constant day each week or month (26%), a countdown display on the lens case (22%), and a paper calendar reminder (14%). Interestingly, 52% of patients who were compliant with scheduled lens replacement reported using a calendar or other system to remind them to replace their lenses, when compared with only 28% of noncompliant patients.

This study also demonstrated that the "Patient and Doctor interaction" can be a key component to compliance. In this study, the majority of patients felt that it was important or very important for their ECP to explain the replacement schedule in detail, but this proportion was significantly higher in the compliant group when compared with the noncompliant group. A similar difference was found in the responses relating to the importance of explaining the risks associated with noncompliance between the compliant and noncompliant wearers. However, providing written materials on these risks was regarded as less important by both the groups.

Although patients reported that their ECPs generally explained their lens replacement schedule clearly and that they followed their ECP instructions, the proportion of compliant patients agreeing with these assertions was higher than the noncompliant patients. An astoundingly higher number of compliant patients (90%) claimed that they followed their recommended replacement schedule because they "have complete confidence in their ECP," when compared with noncompliant patients (54%). Intuitively, this finding suggests that better communication may facilitate improved compliance although a study conducted by Claydon et al.<sup>23</sup> specifically investigating this theory did not support the assertion. The disparities between compliance groups were even more extreme in the responses to the statements: "I definitely do not dare miss replacing my contacts on the regular schedule" (66 vs. 19%) and "I follow the recommended replacement schedule because it leads

to fewer problems with my eyes" (85 vs. 38%). A high proportion of both compliant and noncompliant groups indicated that discomfort was a signal for lens replacement, but there was no difference between compliant and noncompliant patients. A higher proportion of noncompliant patients reported that "The quality of my vision tells me it is time to replace my contact lenses" (70%) compared with compliant patients, suggesting that a degradation in vision may be more of an indication that lens replacement is required in these individuals than discomfort.

In other studies on compliance with contact lens wear and care, a number of differences have been considered and reported between compliant and noncompliant patients.<sup>24-29</sup> In this study, we found that noncompliant patients were slightly younger than compliant patients but we did not find a difference in sex distribution. It was interesting to find that patients who did not have a pair of spectacles with an up to date prescription were also more likely to be noncompliant with lens replacement, which supports the notion that some patients are simply prone to be less compliant to general recommendations relating to their eye care. Although there was no difference in compliance with replacement according to the degree of spherical refractive error, those patients requiring a correction for astigmatism were less compliant with RF than patients wearing a spherical correction. The most likely explanation for this finding is the higher cost of toric contact lenses that may compel some patients to extend the replacement interval for their lenses to save money. The pattern of noncompliance with frequency of lens replacement also seemed to be associated with poor compliance with lens care procedures including knowledge of the name of their care system and frequent replacement of their lens case, which has been associated with a higher risk of microbial keratitis but has also been reported to be a modifiable behavior with compliance enhancement strategies.<sup>30,31</sup>

## CONCLUSIONS

Contact lens manufacturers specify a MRRF based on the material and surface characteristics of their lenses. Although some patients may be able to wear their lenses longer than the MRRF, there is usually a degradation of performance of the lens over time which may affect comfort, comfortable wearing time, and visual performance. It is also possible that wearing lenses longer than recommended time may be associated with greater risk of contact lens-related complications. This study has investigated both patient and ECP behaviors with respect to RF for the most commonly prescribed lenses around the world today.

ECPs recommended RFs which complied with the MRRF more frequently with DD and 1-month SH lenses than with 2-week SH lenses. Patients were less compliant with RF than ECPs for all lens types investigated. Patients were most compliant with RF when wearing DD lenses and least compliant when wearing 2-week SH lenses. Better communication between the patient and the ECP seemed to facilitate greater compliance with RF. More than half of those not replacing lenses when recommended reported that this was simply because they forgot which day to replace their lenses.

Compliance with recommended RF is extremely important for continued success in contact lens wear. ECPs and manufacturers should strive to develop strategies to improve compliance with RF. In this study, the use of a reminder system to improve compliance with RF was supported, with the suggestions of a cell phone

reminder system or establishing a constant day of the week being the most favored methods for prompting replacement.

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ORIGINAL ARTICLE

## Compliance with Contact Lens Replacement in Canada and the United States

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### ABSTRACT

**Purpose.** To assess eye care practitioners (ECPs) recommendations for replacement frequency (RF) of silicone hydrogel (SH) and daily disposable (DD) lenses in Canada and the U.S. and to compare noncompliance (NC) with manufacturer recommended RF by the ECP and patient, and the reasons given for NC.

**Methods.** Invitations to participate were sent by e-mail to ECPs in Canada and the U.S. Twenty patient surveys were sent to 420 ECPs, and 2232 eligible surveys were received from 216 ECPs (26% Canada, 74% U.S.). Questions related to patient demographics, lens type, wearing patterns, ECP instructions for RF, and actual patient RF. ECPs provided lens information and their recommendation for RF after the surveys were completed and sealed in envelopes. Responses were anonymous.

**Results.** DD accounted for 18% (Canada) vs. 16% (U.S.) of wearers ( $p > 0.05$ ); 35% (Canada) vs. 45% (U.S.) wore 2-week replacement SH (2WR;  $p = 0.011$ ); and 47% (Canada) vs. 39% (U.S.) wore 1-month replacement SH (1MR) lenses ( $p = 0.025$ ). Thirty-four percent (Canada) vs. 18% (U.S.) of ECPs recommended longer RFs than the manufacturer recommended RF for 2WR lens wearers ( $p < 0.001$ ); 6% (Canada) vs. 4% (U.S.) for DD wearers; and 2% (Canada) vs. 1% (U.S.) for 1MR lens wearers. NC rates for actual RFs reported by patients were not different between countries ( $p > 0.05$ ) and were lowest for DD (13% Canada, 12% U.S.), followed by 1MR (33% Canada, 28% U.S.). The highest NC rates were with 2WR (50% Canada, 52% U.S.). The most frequent reason for NC with 2WR and 1MR was "forgetting which day to replace lenses" (54% Canada, 53% U.S.) and in DD wearers "to save money" (56% Canada, 29% U.S.,  $p < 0.001$ ).

**Conclusions.** 1MR lenses are more frequently prescribed in Canada. ECPs in Canada were NC with 2WR lenses more frequently than U.S. ECPs, but patient NC rates were the same in both countries for all lens types. ECP and patient NC rates were highest for 2WR lens wearers.

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Key Words: silicone hydrogel, daily disposable, contact lens, replacement frequency, compliance

There is considerable variation in the prescribing patterns of eye care practitioners (ECPs) worldwide. Although daily disposable (DD) lenses are frequently the lens of choice in the United Kingdom, Scandinavia, and Japan, their popularity in North America has not grown as quickly, with 2-week and 1-month replacement modalities remaining more popular in Canada and the U.S.<sup>1-4</sup> According to the 2008 International Contact Lens Prescribing Survey, daily wear silicone hydrogel (SH) lenses currently account for approximately one-half of the lenses prescribed in Canada and the U.S.<sup>4</sup> There is, however, disparity between the two countries in the fre-

quency with which 2-week or 1-month replacement schedules are recommended, with 2-week replacement being more common in the U.S. and 1-month replacement being more popular in Canada.<sup>5</sup>

Frequent replacement of conventional non-SH lenses has been shown to offer many advantages over lenses that are worn for several months or even longer, including fewer deposits, fewer complications, and improved subjective and clinical performance.<sup>6-14</sup> Unfortunately, compliance with recommended replacement frequency (RRF) is frequently poor, and many patients continue to wear their lenses for longer than advised.<sup>15-19</sup> The noncompliance (NC) rates have been shown to vary according to the RRF of the lenses that are worn.<sup>17-19</sup> In a previous study evaluating compliance with contact lens replacement in Canada and the U.S., 43% of patients were reported to be noncompliant with replacement of their 2-week replacement lenses, compared with 33% of those using lenses that were recommended for 1-month replacement.<sup>17</sup> When this study was conducted, however,

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very few DD and SH lenses were worn in North America, and no specific comparisons were made between the two countries.

Similar studies have recently been separately conducted in Canada and the U.S., specifically to investigate compliance with replacement of DD and SH lenses.<sup>20,21</sup> The purpose of this analysis was to compare and contrast the current recommendations by ECPs for RF of SH and DD contact lenses and the rates of NC with manufacturer recommended RF (MRRF) in Canada and the U.S. In addition, the reasons for NC were investigated in both countries.

## METHODS

### Study Design and Procedures

The study design and procedures used in Canada and the U.S. have been described in detail previously.<sup>21,22</sup> Approximately 2500 ECPs in Canada and approximately 20,000 ECPs in the U.S. were sent e-mails inviting them to participate in the study. The study was conducted in both countries in the late fall and early winter of 2008. Ethics clearance was obtained through the Office of Research Ethics at the University of Waterloo, before commencement of the study, and the study was conducted following the tenets of the Declaration of Helsinki.

An identical survey was used in Canada and the U.S. It included questions regarding the patient demographics, contact lens wearing history, recommended RF, and actual length of time wearing lenses before replacement. In addition, a series of questions were also included to evaluate the reasons for not replacing lenses when scheduled, discussions with their ECP regarding lens wear and replacement, and current practices for contact lens care. The responses from both the patients and their ECPs were collected anonymously.

### Data Analysis

Where relevant, data analyses were conducted using Statistica 8.0 (StatSoft, Tulsa, OK). Data are presented in tables as mean  $\pm$  standard deviation or as frequency distributions. A significance level of  $\alpha = 0.05$  was used for all analyses. Differences between proportion tests were applied where appropriate. Where nonparametric analyses were required, Mann Whitney U tests were used for unpaired ranked comparisons between compliance groups, and Kruskal-Wallis analysis of variance by ranks tests were used for comparisons between the different lens groups (DD, 2-week, and 1-month replacement).

## RESULTS

### Respondents (ECPs and Patients)

Four-hundred twenty ECPs agreed to participate in the study (111 from Canada and 309 from the U.S.); 216 returned patient surveys (ECP return rate: Canada 52%, U.S. 51%) and 2513 patient surveys were returned by the cutoff date (Canada  $n = 654$ , U.S.  $n = 1859$ ). The data from 2232 patient respondents were eligible for analysis (Canada 88%, U.S. 89% of completed surveys received). The remaining surveys either did not have sufficient information recorded for analysis or were completed by patients who were not wearing DD or SH (2-week and 1-month replacement) lenses.

### Lens Brands and Powers

The lenses worn most frequently by the patients completing the surveys (as reported by the ECPs on the survey envelopes) in Canada were 1-month replacement SH (47%), followed by 2-week replacement SH (35%) and DD (18%). The lenses worn most frequently by the patients completing the surveys in the U.S. were 2-week replacement SH (45%), followed by 1-month replacement SH (39%) and DD (16%). There was no difference in the proportion of DD lenses between the two countries ( $p = 0.642$ ), but there were significant differences between the proportions of 2-week ( $p = 0.011$ ) and 1-month ( $p = 0.025$ ) replacement lenses. The brands of lenses worn are listed in Table 1.

Ninety percent of lenses in Canada and 92% of lenses in the U.S. were prescribed for myopic refractive errors ( $p = 0.138$ ). The mean spherical lens power was  $-3.09 \pm 2.56$  D (median  $-3.00$  D) in Canada and  $-3.27 \pm 2.67$  D (median  $-3.25$  D) in the U.S. ( $p = 0.079$ ). Sixteen percent of lenses in the U.S. were toric, when compared with 19% in Canada ( $p = 0.097$ ).

Both ECPs and patients were asked about the brand name of the lenses worn. In the majority of cases, the ECP and patient responses matched (66% Canada, 74% U.S.). The reported lens brands did not match for 6% of patients from Canada and 5% of patients from the U.S. A significantly higher proportion of patients in Canada (29%) than the U.S. (20%) were either unsure of the lens brand they were wearing or could not recall the name when they completed the survey ( $p < 0.001$ ).

### Demographics and Lens Wearing Patterns

The patient demographics and lens wearing patterns as reported by the patients completing surveys in Canada and the U.S. are presented in Table 2. Fifty-five percent of patients in Canada and 47% of patients in the U.S. reported that their lenses become less comfortable later in the day ( $p < 0.001$ ). These patients reported wearing their lenses for  $2.4 \pm 1.8$  h (Canada) and  $2.7 \pm 2.1$  h (U.S.) beyond the time point where they became aware (discomfort) of their lenses ( $p = 0.024$ ). There were no significant differences between the lens groups, in either country, with respect to the percentage of patients reporting discomfort later in the day or in the number of hours they continued to wear lenses (all,  $p > 0.05$ ).

ECPs were not asked to record the wearing schedules that they recommended for their patients (i.e., daily wear or number of nights of overnight wear), but the frequency with which patients from Canada and the U.S. reported sleeping while wearing their lenses is given in Table 3. Significantly, more patients in the U.S. reported wearing lenses during sleep "frequently" or "almost every night" when compared with patients in Canada ( $p < 0.001$ ). In Canada, 12% of patients wearing DD lenses reported sleeping overnight while wearing lenses "occasionally," "frequently," or almost "every night" compared with 17% of DD wearers in the U.S. ( $p = 0.234$ ).

### ECP Compliance with RRF

#### Data Obtained From ECPs

The distribution of responses for the ECP RRF, as recorded on the envelopes, for each lens group is listed in Table 4. Three percent of ECPs did not record a RRF. A higher proportion of ECPs in Canada

**TABLE 1.**  
Distribution of lens brands worn

Lens name	Manufacturer	N		Percentage of category	
		Canada	USA	Canada	USA
<b>DD lenses</b>					
1 Day Acuvue (and Moist)	Johnson & Johnson	27	63	26	24
1 Day Acuvue for Astigmatism	Johnson & Johnson	1	—	1	—
Focus dailies (and Aqua, Aqua Plus)	CIBA Vision	56	133	54	50
Focus Dailies Toric	CIBA Vision	8	11	8	4
Focus Dailies Progressive	CIBA Vision	3	2	3	1
Proclear 1 Day	CooperVision	3	35	3	13
Freshlook 1 Day	CIBA Vision	2	—	2	—
Biomedics (Clearsight) 1 Day	CooperVision	1	7	1	3
Biomedics (Clearsight) 1 Day Toric	CooperVision	2	3	2	1
Soflens 1 Day	Bausch & Lomb	1	11	1	4
Total DD lenses		104	265	18	16
<b>Two-week replacement lenses</b>					
Acuvue Advance	Johnson & Johnson	49	149	24	20
Acuvue Advance for Astigmatism	Johnson & Johnson	38	98	19	13
Acuvue OASYS	Johnson & Johnson	100	405	49	55
Acuvue OASYS for Astigmatism	Johnson & Johnson	16	69	8	9
Avaira	CooperVision	—	20	—	3
Total 2-week replacement lenses		203	741	35	45
<b>One-month replacement lenses</b>					
O <sub>2</sub> OPTIX/Air Optix Aqua	CIBA Vision	91	167	34	26
Air optix astigmatism	CIBA Vision	14	37	5	6
Night and Day	CIBA Vision	54	202	20	31
Biofinity	CooperVision	25	68	9	10
PureVision	Bausch & Lomb	28	67	10	10
PureVision Toric	Bausch & Lomb	34	66	13	10
PureVision Multifocal	Bausch & Lomb	25	41	9	7
Total 1-month replacement lenses		271	648	47	39

**TABLE 2.**  
Demographics and lens wearing patterns

	Canada	USA	p
No. respondents	578	1654	
Female (%)	70	66	0.082
Age (yr ± SD)	34 ± 13	34 ± 12	0.221
Length of lens wear (yr ± SD)	12.1 ± 9.4	12.9 ± 9.6	0.115
Percentage daily wear (DW)	94	88	<0.001
Wearing time—DW (h ± SD)	11.9 ± 3.4	12.8 ± 3.2	0.223
Wearing time (d/week ± SD)	5.6 ± 1.9	6.2 ± 1.5	<0.001
Percentage with current spectacles	93	90	0.034

(35%), compared with the U.S. (18%), reported RRF that were longer than the MRRF for 2-week replacement lenses ( $p < 0.001$ ). The percentages were lower for DD lenses (6 and 4%) and 1-month replacement lenses (2 and 1%), but not significantly different between countries ( $p = 0.408$ ,  $p = 0.221$ ). Shorter RRF were recommended by ECPs for 7% (Canada) and 18% (U.S.) of 1-month replacement lens wearers ( $p < 0.001$ ). In 89% of these cases, the lens brand worn was O<sub>2</sub>Optix (marketed in other countries as Air Optix; CIBA Vision).

### Data Obtained From Patients

The distribution of responses for the patient-reported recommendation of RF, for each lens group in Canada and the U.S. is listed in Table 5. The lens brand reported by the ECP was used in these calculations. A higher proportion of the patient-reported recommendation of RF in Canada (40%), compared with the U.S. (22%), were longer than the MRRF for 2-week replacement lenses ( $p < 0.001$ ). The percentages were lower for DD lenses (6 and 10%,  $p = 0.224$ ) and 1-month replacement lenses (6 and 2%,  $p = 0.002$ ). No recommendation was reported to be given for RF by 3% of patients wearing 2-week and 1-month replacement lenses, with no difference between countries, and by 12.5 and 4.9% of DD wearing patients in Canada and the U.S., respectively ( $p = 0.010$ ).

### Patient Compliance with RRF

Seventy-eight percent of patients in Canada and the U.S. rated the importance of replacing their lenses on schedule as being either “extremely important” or “important.” DD lens wearers gave either of these responses more frequently (Canada 88%, U.S. 93%) than wearers of 2-week and 1-month replacement lenses (range 71 to 80%).

The actual RFs as assessed on a Likert scale are presented in Table 6. The distribution of responses for Canada and the U.S. was

**TABLE 3.**  
Reported frequency of wearing lenses during sleep

Lens group	Frequency of sleeping in lenses				
	Never (%)	Only napping (%)	Occasionally (%)	Frequently (%)	Almost every night (%)
Canada					
DD	52	36	7	3	2
Two-week replacement	42	46	8	2	1
One-month replacement	38	35	13	3	11
All lenses	42	39	10	3	6
U.S.					
DD	39	45	14	1	2
Two-week replacement	30	42	14	6	8
One-month replacement	26	29	15	6	24
All lenses	30	38	14	15	13

More patients in the USA reported wearing lenses during sleep “frequently or almost every night” than in Canada ( $p < 0.001$ ).

**TABLE 4.**  
Replacement frequency recommended by ECP

Lens group	ECP RRF (as reported by ECP)								
	1 d (%)	2 d (%)	3–6 d (%)	1 Week (%)	2 Weeks (%)	3 Weeks (%)	1 Month (%)	2 Months (%)	≥3 Months (%)
Canada									
DD	<b>94.1</b>	0	0	0	1.0	0	4.9	0	0
Two-week replacement	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>65.0</b>	1.5	32.0	1.5	0
One-month replacement	<b>0.4</b>	<b>0</b>	<b>0</b>	<b>0.4</b>	<b>6.5</b>	<b>0</b>	<b>90.4</b>	0.4	1.9
U.S.									
DD	<b>96.0</b>	0	0	2.8	0.4	0	0.8	0	0
Two-week replacement	<b>0.1</b>	<b>0</b>	<b>0</b>	<b>0.8</b>	<b>81.3</b>	3.0	14	0.4	0.3
One-month replacement	<b>0.2</b>	<b>0</b>	<b>0</b>	<b>0.3</b>	<b>16.3</b>	<b>0.8</b>	<b>81.7</b>	0.3	0.3

The values in bold represent those RRF that we considered to be compliant with the MRRF for the lens brand (intervals of  $\leq$  MRRF).

**TABLE 5.**  
Replacement frequency recommended by ECP as reported by patient

Lens group	Patient reported recommendation for RF									
	1 d (%)	2 d (%)	3–6 d (%)	1 Week (%)	2 Weeks (%)	3 Weeks (%)	1 Month (%)	2 Months (%)	≥3 Months (%)	NR (%)
Canada										
DD	<b>80.8</b>	1.0	1.0	0	1.0	0	2.9	0	0	12.5
Two-week replacement	<b>1.5</b>	<b>0</b>	<b>0.5</b>	<b>2.5</b>	<b>53.2</b>	3.9	34.0	1.5	0.5	2.0
One-month replacement	<b>1.1</b>	<b>0</b>	<b>0</b>	<b>1.5</b>	<b>7.0</b>	<b>1.8</b>	<b>79.0</b>	4.1	1.8	3.0
U.S.										
DD	<b>85.6</b>	0.4	0.4	3.4	3.8	0	1.5	0	0	4.9
Two-week replacement	<b>1.1</b>	<b>0.7</b>	<b>0.7</b>	<b>2.4</b>	<b>70.1</b>	3.1	16.7	0.7	0.8	3.7
One-month replacement	<b>1.2</b>	<b>0.2</b>	<b>0</b>	<b>1.7</b>	<b>18.5</b>	<b>0.9</b>	<b>72.3</b>	0.9	1.2	3.0

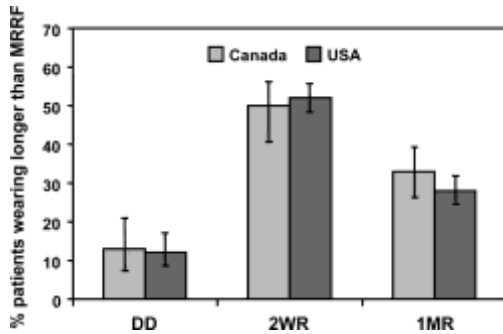
The values in bold represent those RRF that we considered to be compliant with the MRRF for the lens brand (intervals of  $\leq$  MRRF). NR, no recommendation given.

very similar, with a higher proportion of DD wearers reporting “always” replacing their lenses when recommended (74 and 82%, respectively) compared with 1-month (36 and 34%, respectively) and 2-week (29 and 25%, respectively) replacement wearers. The typical wearing period before replacement was also reported in

days and/or months. An actual RF of more than 1 day was considered to be NC for DD lenses; more than 17 days (i.e., less frequently than twice a month) was considered to be NC for 2-week replacement lenses and more than 31 days (once a month) was considered to be NC for 1-month replacement lenses. Overall,

**TABLE 6.**  
Replacement frequency relative to recommended replacement frequency

Lens group	Replacement of contact lenses relative to what was recommended			
	Always (%)	Often (%)	Sometimes (%)	Rarely (%)
<b>Canada</b>				
DD	74	13	4	7
Two-week replacement	29	38	17	15
One-month replacement	36	32	19	13
All lenses	40	30	16	12
<b>U.S.</b>				
DD	82	11	3	3
Two-week replacement	25	34	22	19
One-month replacement	34	32	22	12
All lenses	38	29	19	14



**FIGURE 1.**  
The percentage of patients (with 95% confidence intervals) wearing their lenses for longer than the MRRF by lens category in Canada and the U.S. Patients whose ECPs recommended longer intervals than the MRRF are excluded from this analysis.

44% of patients in Canada and 40% of patients in the U.S. reported wearing their lenses longer than the MRRF. This varied significantly by lens group, with the lowest rate occurring in DD lens wearers (18 and 15%, respectively), followed by 1-month

replacement lens wearers (34 and 29%, respectively), and with the highest rates occurring in 2-week replacement wearers (69 and 59%, respectively). Because ECPs were not always compliant with the MRRF, it may be considered inappropriate to include those patients where the recommended wearing periods (as stated by the ECPs on the envelopes) were longer than the MRRF in the calculations for NC rates. When these cases were excluded from the analysis, the overall NC rates for replacement were 34% in Canada and 35% in the U.S. ( $p = 0.700$ ). There was still significant variation in the NC rates between groups, with the lowest rate occurring in DD lens wearers (13 and 12%, respectively), followed by 1-month replacement lens wearers (33 and 28%, respectively), and with the highest rate still occurring in 2-week replacement wearers (50 and 52%, respectively); these rates were not different between countries however ( $p = 0.812$ ,  $p = 0.149$ , and  $p = 0.693$ , respectively). These NC rates are shown in Fig. 1.

**Reasons for NC with RF**

Patients who did wear their lenses longer than recommended were asked to select the primary reason; the responses are given in Table 7. The overall distribution of responses is similar between Canada and the U.S. For 2-week and 1-month replacement wear-

**TABLE 7.**  
Primary reason for wearing lenses for longer than recommended

Lens group	Reason for wearing lenses longer than RRF				
	Save money (%)	Forget day (%)	No harm (%)	Lack of time (%)	ECP said OK (%)
<b>Canada</b>					
DD (n = 25)	56	16	8	12	8
Two-week replacement (n = 153)	22	60	7	8	3
One-month replacement (n = 175)	22	53	11	10	5
All lenses	24	53	9	9	5
<b>U.S.</b>					
DD (n = 65)	29	23	20	26	2
Two-week replacement (n = 580)	26	53	10	7	4
One-month replacement (n = 440)	25	53	10	9	2
All lenses	26	51	11	9	3

ers, the primary reason was “forgetting which day to replace them” (53 to 60% of respondents), and for DD wearers, it was “to save money;” in Canada, 56% of DD wearers gave this response when compared with only 29% of DD wearers in the U.S. ( $p < 0.001$ ). A higher proportion of DD wearers in the U.S. reported “lack of time” (26 vs. 12%,  $p = 0.004$ ) and “there is no harm in wearing them longer” (20 vs. 8%  $p = 0.001$ ).

### Reminder Systems

Fifty-percent of patients in Canada and 53% of patients in the U.S. thought a reminder system would help them to comply with replacement. This varied by group, with 35 and 24% (Canada and U.S., respectively) of DD wearers, 61 and 57% (Canada and U.S., respectively) of 2-week replacement lens wearers, and 57 and 60% (Canada and U.S., respectively) of 1-month replacement lens wearers responding that they thought a reminder system would be useful. From the suggestions offered, the most popular option in the U.S. was a cell phone or text message (29% U.S., 20% Canada), and the most popular option in Canada was a countdown display on the lens case (29% Canada, 22% U.S.); this was followed by establishing a particular day each week or month (26% U.S., 24% Canada), and then an e-mail reminder (21% U.S., 19% Canada). The least popular option in both countries was a paper calendar reminder (17% Canada, 14% U.S.).

### Contact Lens Care

The most popular lens care systems in Canada and the U.S. were brand name multipurpose solutions (48% in both countries), with a similar distribution between brand names in each country. Hydrogen peroxide systems were more popular in Canada than the U.S. (18 vs. 9%,  $p < 0.001$ ). More patients in the U.S. reported using a generic or pharmacy brand of lens care system when compared with Canada (3.5 vs. <1%,  $p = 0.004$ ). A high proportion of patients in both countries were unsure of the brand of care system they were using (Canada 34%, U.S. 40%,  $p = 0.018$ ).

Twenty-percent of U.S. patients and 31% of Canadian patients reported having changed their lens care systems recently ( $p < 0.001$ ). The most common reason given was practitioner recommendation (Canada 52%, U.S. 54%) followed by cost and/or convenience (Canada 29%, U.S. 31%). Product recall accounted for 14% of changes in Canada and 5% of changes in the U.S. and friend or family recommendations for 6% of changes in Canada and 8% of changes in the U.S. Advertising was cited as the reason for changing solutions by 1% of Canadian patients and 3% of U.S. patients.

More than 50% of patients thought that cleaning their contact lenses every day was “extremely important” (57% Canada, 54% U.S.); 32% of Canadian patients and 28% of U.S. patients thought that this was “important;” and 8% of Canadian patients and 11% of U.S. patients replied “somewhat important;” and 3% of Canadian patients and 7% of U.S. patients replied “not important” to this question.

When non-DD wearers were asked how frequently they replaced their contact lens case, 26% of Canadian and U.S. patients responded every month, 32% of Canadian patients and 24% of U.S. patients responded every 3 months, and 21% of Canadian

patients and 20% of U.S. patients responded every 6 months. Lens cases were replaced annually by 12 to 16% of patients (Canada and U.S. respectively). Nine percent of Canadian patients and 14% of U.S. patients reported never replacing their lens case.

### DISCUSSION

Two separate, but related, studies were conducted in Canada and the U.S. to investigate ECP and patient compliance with recommended replacement schedules for DD, 2-week replacement SH, and 1-month replacement SH contact lenses. The results from the two countries have been reported separately elsewhere.<sup>20,21</sup> In both studies, the patient’s responses were not known by their ECP, and their ECP’s identity was not known to the study coordinators. It was hoped that by using this design, both the ECPs and their patients would be honest in their answers to the survey questions. Only a small proportion of the ECPs who were invited, registered to participate in the study, and completion of the study surveys by patients was voluntary. Consequently, the results may not accurately represent all ECPs and the entire contact lens wearing population; NC may in fact be more prevalent than is reported in this article.

In Canada, the most frequently worn lenses, from the cohort investigated in this study, were 1-month replacement SH (47%), whereas in the U.S., 2-week replacement SH lenses were the most commonly worn lenses (45%). The reason for this difference is not immediately obvious and may be a combination of a number of factors, including the earlier release and, therefore, adoption of 1-month replacement SH lenses in Canada, and different methods for billing and fees in the two countries. A similar proportion of respondents in both countries wore DD lenses, but the percentage of patients for whom these lenses were prescribed was significantly lower than reported in many European countries and Japan.<sup>4</sup>

The demographics of the patients choosing to participate in the study were remarkably similar in the two countries and appeared to be representative of the contact lens wearing population in Canada and the U.S. in terms of gender and age.<sup>5</sup> A higher proportion of patients in the U.S. wore lenses on an extended wear basis and/or reported wearing lenses during sleep, occasionally, frequently, or almost every night. This is also consistent with reported prescribing patterns for the extended wear modality.<sup>5</sup> Contact lens wearers in Canada reported less days per week of lens wear than wearers in the U.S. ( $5.6 \pm 1.9$  vs.  $6.2 \pm 1.5$  days). The reason for the difference between the two countries is not clear, but the results for the Canadian wearers are more consistent with those reported for United Kingdom wearers.<sup>22</sup> Interestingly, a higher proportion of patients in Canada reported that their lenses became less comfortable later in the day. A possible reason for this finding could be the climatic differences between the two countries; the study was conducted over the winter months when all Canadians would be living and working in centrally heated environments when compared with a smaller proportion of patients in the U.S.

Almost twice as many ECPs in Canada, compared with the U.S., recommended RFs for 2-week replacement SH lenses, which were longer than the MRRF. This may be because Canadian ECPs prescribe 1-month replacement lenses more often and are, therefore, more likely to recommend this interval for SH lenses regardless of the MRRF. The opposite may be true in the U.S., because



more than twice as many ECPs in the U.S. recommended RFs for 1-month replacement SH lenses, which were shorter than the MRRF, suggesting a preference for a 2-week replacement SH modality in this country. Another consideration is that the O<sub>2</sub>Optix contact lens, although currently marketed as a 1-month replacement lens, had previously been available as a 2-week replacement lens in the U.S. and some ECPs may have kept some patients who continue to wear that lens on a 2-week replacement schedule. ECPs in both countries rarely recommended RFs of longer than the MRRF for DD and 1-month replacement SH lenses. Although the proportions are low (4% U.S., 6% Canada), it is unclear why any ECPs would recommend a RF of more than 1-day for DD lenses. It is possible that some of the longer RFs may have been reported in error or that some practitioners choose to base their recommendations for RF on the lens material and their clinical experience, rather than the MRRF and the package labeling. In addition to the ECPs report of their recommendation for RF, patients were asked to record their recollection of the ECPs recommendation for lens replacement. These results were similar to the ECPs recommendations, in that, longer RFs were recommended most often for 2-week replacement SH lenses and least often for 1-month replacement lenses. There were also analogous differences between the two countries, with more patients in Canada reporting that their ECPs recommended intervals that were longer than the MRRF for all lens types, but in particular for 2-week replacement SH lenses. These data must be considered carefully, however, because the lens brands reported by the ECP and the patients did not match in approximately 5% of cases. The reason for this is not clear and could be in part because of patients having switched brands without their ECP's knowledge or as a result of patients incorrectly remembering their lens brand names.

What patients do and what they are told to do may be quite different, and for this reason, the actual RF as reported by the patient is perhaps of greatest interest when investigating compliance. The lowest rates of NC were reported by DD lens wearers, and the highest rates were reported by 2-week replacement lens wearers. There were some differences in the rates between countries, particularly for 2-week replacement SH lens wearers, where a greater proportion from Canada reported the highest NC rates. These differences can, however, most likely be attributed to the differences in the ECP recommendations between the two countries, with a higher proportion of Canadian ECPs recommending longer intervals before replacement for 2-week replacement SH lenses. When considering only those patients who were given the correct instructions for RF, there were no significant differences in the rates between Canada and the U.S. for each of the lens types.

The outcome of wearing a DD lens or 2-week or 1-month replacement SH lenses for longer than the MRRF is not clear, and to our knowledge, there have been no studies to date specifically investigating this issue. One study did compare replacement schedules with SH materials worn on an overnight basis, and no benefits were found with respect to corneal physiology, lens deposition, or subjective comfort and vision symptoms.<sup>23</sup> A separate study reported 55% of patients developing *Fusarium* keratitis in Singapore reported having worn their contact lenses for longer than the MRRF, and the risk of developing keratitis increased by a factor of almost five by wearing lenses for longer than the recom-

mended RF in this study; however, the study included many lens types and was not specifically investigating SH and DD lenses.<sup>24</sup>

The reasons given for not replacing lenses on schedule were similar in Canada and the U.S. For 2-week replacement SH and 1-month replacement SH wearers, the primary reason was that they forget which day to replace them. When wearers of DD lenses failed to replace their lenses as recommended, the most frequently reported reason given was "to save money." One-fifth of patients in the U.S. who were noncompliant with the DD modality chose "there is no harm in wearing them longer" as their reason; this could indicate that some ECPs are not taking the time to appropriately explain the possible risks associated with reusing a lens specifically designed for single use with disposal each day.

A reminder system could be of benefit for some patients in facilitating compliance with lens replacement, and more than one-half of the respondents in both countries concurred with this suggestion. The most popular method selected in Canada was a countdown mechanism on the lens case, and in the U.S., it was a cell phone call or text message. This disparity could possibly relate to the higher rates for cell phone charges in Canada. The other methods were selected approximately equally for the two countries, and in order of popularity were; establishing a particular day each week or month for replacement, an e-mail reminder, and finally a paper calendar reminder.

Another area where patients are frequently not compliant with the instructions given by the manufacturers and their ECPs is the area of contact lens care. It should be recognized that there may be some selection bias in these studies because the patients completing the surveys were already relatively compliant with their ECPs as they had elected to attend the office for eye care. It is, however, interesting to look at the data relating to contact lens care in this cohort. Brand name multipurpose solutions were the most popular care systems in both countries, being used by at least 48% of wearers of reusable SH lenses. Hydrogen peroxide systems were reported to be used twice as frequently in Canada as the U.S., and more patients in the U.S. were using a generic or pharmacy brand of lens care system. Unfortunately, more than one-third of patients in both countries could not name their lens care system, although it is likely that a good proportion of these patients would recognize their bottle on retail shelves. Approximately one-quarter of patients reported having changed their care system recently. It is encouraging for the professions that for more than one-half of these patients, the reason given was recommendation by the ECP. It is possible that the heightened interest in possible incompatibilities between some SH materials and lens care products may be the reason for some of these changes to patients' care systems.<sup>25,26</sup> Patients in both countries also frequently cited cost and/or convenience as the reason for changing lens care system; many of them may simply make the decision on which system to buy when they reach the retail shelves and make their purchase accordingly. Product recall was given as the reason for switching more frequently in Canada than the U.S., which may be associated with a number of factors including differences in product availability, country specific recalls, and/or the timing of recalls being different in the two countries. Interestingly, a very low proportion of patients in both countries had changed their solutions as a result of advertising.

Because high levels of microbial contamination and biofilm build up have been reported in contact lens storage cases,<sup>27,28</sup>

frequent replacement of lens cases is recommended to reduce the chance of microbial keratitis occurring.<sup>29</sup> Replacement of cases at intervals of at least every 3 months is suggested, but in this study, only one-half of the patients reported replacing their cases this frequently. Patient counseling regarding lens storage case replacement is strongly encouraged to reduce the risk of developing serious complications, including microbial keratitis.

## CONCLUSIONS

This study has examined both patient and ECP behaviors with respect to RF for DD and SH lenses in Canada and the U.S. In both countries, ECPs recommended RFs that complied with the MRRF more frequently, with DD and 1-month replacement SH lenses than with 2-week replacement SH lenses. ECPs in Canada were NC with RF of 2-week replacement SH more frequently than the U.S. ECPs. Patients were less compliant with RF than ECPs for all lens types investigated; they were most compliant with RF when wearing DD lenses and least compliant when wearing 2-week replacement SH lenses. There were no differences in the patient NC rates between the two countries. More than one-half of the SH lens wearers not replacing lenses when recommended reported that this was simply because they forgot which day to replace their lenses. The most common reason among the DD lens wearers was to save money. Because compliance is generally considered to be important for continued success in contact lens wear, ECPs and manufacturers should strive to develop strategies to improve compliance with RF.

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ORIGINAL ARTICLE

# Comfort and Vision with Silicone Hydrogel Lenses: Effect of Compliance

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## ABSTRACT

**Purpose.** Silicone hydrogel (SH) lenses are usually replaced after 2 weeks (2W) or 1 month (1M); however, many patients do not comply with the manufacturers' recommended replacement frequency (MRRF). The purpose of this analysis was to investigate the effect of compliance with MRRF on comfort and vision in SH wearers.

**Methods.** As a part of a larger study investigating compliance with MRRF, patients were asked to rate their subjective comfort and vision from 0 (very poor) to 10 (excellent) in the morning, at the end of the day (EVE), when lenses were new, and needed replacing (NR).

**Results.** One thousand three hundred forty-four patients wore 2W replacement modality (2WR) (n = 717) or 1M replacement modality (1MR) (n = 617) SH lenses. Comfort and vision in the morning and when lenses are new were significantly higher than for EVE and NR ( $p < 0.001$ ). Twenty-nine percent (95% confidence interval 25.3–32.4) of 1MR and 59% (95% confidence interval 55.5–62.7) of 2WR wearers were non-compliant with the MRRF. Compliance had a significant effect on EVE ( $p = 0.002$ ,  $p = 0.008$ ) and NR ( $p < 0.001$ ,  $p < 0.001$ ) comfort and vision. After accounting for compliance, EVE and NR comfort and EVE vision were higher for 1MR than 2WR ( $p = 0.015$ ,  $p = 0.044$ ,  $p = 0.019$ ).

**Conclusions.** Compliant patients had better EVE and NR comfort and vision than non-compliant patients, regardless of replacement modality. Optimal subjective performance with SH lenses seems to be facilitated by replacing lenses as recommended.

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Key Words: comfort, vision, silicone hydrogel, contact lens, compliance

Silicone hydrogel (SH) lenses were first launched in 1999 and are now available in a wide range of materials, parameters, and designs. Eye care practitioners (ECPs) are recognizing the benefits offered by these lenses as a result of their oxygen performance,<sup>1–3</sup> and currently, more than 50% of new fits and refits in the United States are estimated to be with SH materials.<sup>4</sup> The majority of SH lenses prescribed by ECPs are for either 2-week (2W) or 1-month (1M) replacement; however, a 3-month replacement made-to-order SH lens is also available (O<sub>2</sub>OPTIX Custom/Air Optix Individual, CIBA Vision),<sup>5</sup> and a daily disposable SH lens (Acuvue TruEye; Johnson & Johnson) has been launched recently in Europe, Australia, and Hong Kong and will soon become available in other markets around the world.<sup>6</sup>

Frequent replacement of conventional hydrogel lenses has been

shown to result in fewer deposits, less complications, and enhanced clinical performance, when compared with lenses that are worn for longer periods of time.<sup>7–15</sup> Despite the similarities between SH lenses in terms of their chemical composition, there are a number of significant differences in material characteristics, which may result in differences in their clinical performance.<sup>2</sup> Indeed, patient comfort responses have been reported to vary with different SH contact lens designs.<sup>16–20</sup>

Even though there are many advantages in replacing lenses frequently, some ECPs and many patients do not comply with the manufacturers' recommended replacement frequencies (MRRFs) and fail to discard their lenses after the intended time period.<sup>21,22</sup> Compliance with replacement frequency (RF) of conventional hydrogel lenses has been shown to be associated with better quality of vision and enhanced comfort at replacement.<sup>22</sup> However, to date, no studies have been conducted in which the clinical performance of SH lenses has been examined over various replacement periods.

As a part of a larger study investigating compliance with RF in the United States, subjective ratings for comfort and vision with contact lenses were recorded by patients.<sup>23</sup> The purpose of this

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**TABLE 1.**  
Distribution of lens brands worn

Lens name	Manufacturer	Number	Category (%)	Total sample (%)
<b>Two-week replacement modality</b>				
Acuvue Advance	Johnson & Johnson	145	20	53
Acuvue Advance for Astigmatism	Johnson & Johnson	97	14	
Acuvue OASYS	Johnson & Johnson	390	54	
Acuvue OASYS for Astigmatism	Johnson & Johnson	65	9	
Avaira	CooperVision	20	3	
<b>One-month replacement modality</b>				
O <sub>2</sub> Optix/Air Optix Aqua	CIBA Vision	154	25	47
Air Optix for Astigmatism	CIBA Vision	35	6	
Night & Day	CIBA Vision	194	31	
Biofinity	CooperVision	65	11	
PureVision	Bausch & Lomb	67	11	
PureVision Toric	Bausch & Lomb	63	10	
PureVision Multifocal	Bausch & Lomb	39	6	

**TABLE 2.**  
Patient demographics

Variable	MRRF	
	2WR	1MR
Gender (% female)	67% (63.6–70.4)	64% (60.6–68.0)
Age (yr)	33.4 ± 11.9	34.7 ± 12.5
Days worn/week	6.2 ± 1.5	6.3 ± 1.3
Hours worn/d	13.0 ± 3.1	12.8 ± 3.1

analysis was to investigate the effect of compliance with MRRF on subjective assessments of comfort and vision in patients wearing 2W replacement (2WR) and 1M replacement (1MR) SH lenses.

## METHODS

A study examining compliance with RF in the United States was conducted by the Centre for Contact Lens Research. ECPs were recruited to take part in the study by email invitation. ECPs registering to participate in the study were sent packages containing 20 patient surveys. The ECPs were instructed to ask all eligible patients attending the practice to complete one of the surveys. If a patient declined to complete the survey, the next patient was asked by the ECP, until a maximum of 20 patients were recruited. Patients were asked to seal their completed survey in a study specific envelope on which the ECP was asked to record the patient's lens brand. Completion of the survey was anonymous, and the responses of the patients remained confidential from their ECP. The completed surveys were then returned to the Centre for Contact Lens Research for data entry and analysis. The study methodology is described in detail in a separate publication.<sup>23</sup> Ethics approval was obtained through the Office of Research Ethics at the University of Waterloo before commencement of this study, and the study was conducted following the tenets of the Declaration of Helsinki. In addition to questions regarding RF of their contact lenses, patients were also asked to rate their subjective comfort and vision with their current brand of lenses. Data were collected for

the following time points: in the morning (AM), at the end of the day (EVE), when their lenses were new (NEW), and when their lenses needed replacing (NR). All ratings were made on scales of 0 (very poor) to 10 (excellent). ECPs were required to provide information regarding the patients' lens type. The surveys were completed in the ECP's offices.

Where relevant, data analyses were conducted using Statistica version 8.0 (StatSoft Inc., Tulsa, OK). Data are presented in tables as mean ± standard deviation or as frequency distributions and percentages. The effects of compliance replacement modality (2WR and 1MR) on comfort and vision were analyzed using a factorial analysis of variance (ANOVA) with two independent factors. The ANOVA was conducted using Type III sum of squares, and the reported effects are the marginal least-square mean differences. Where appropriate, the 95% confidence intervals are also included in parentheses.

## RESULTS

Surveys were received from 158 ECP offices across the United States. A total of 1344 patients wearing SH lenses provided complete survey data. Seven hundred seventeen patients were wearing 2WR SH lenses (53%) and 617 patients were wearing 1MR SH lenses (47%). The distribution of lens brands worn is shown in Table 1, and the demographics of the patients wearing lenses of the two replacement modalities are shown in Table 2. There were no statistically significant differences between patient demographics for those wearing 2WR lenses and those wearing 1MR lenses ( $p > 0.05$ ).

Patients were asked after how many days and/or months they typically replaced their lenses. An actual RF of more than 17 D (i.e., less frequently than twice a month) was considered to be non-compliant (NC) for 2WR lenses and an actual RF of more than 31 D (once a month) was considered to be NC for 1MR lenses. Fifty-nine percent of wearers of 2WR lenses (55.5 to 62.7%) and 29% of wearers of 1MR lenses (25.3 to 32.4%) were considered to be NC with the MRRF.

The subjective comfort and vision ratings for the wearers of the two replacement modality lenses by compliance group are given in

**TABLE 3.**  
Subjective comfort and vision ratings (0–10 scale)

Variable	Time	Compliant		Non-compliant	
		2WR	1MR	2WR	1MR
Comfort	AM	9.4 ± 1.1	9.3 ± 1.3	9.0 ± 1.6	9.2 ± 1.5
	EVE	7.8 ± 2.1	8.1 ± 1.8	7.5 ± 2.2	7.7 ± 2.0
	NEW	9.6 ± 1.0	9.6 ± 0.8	9.5 ± 1.0	9.6 ± 1.1
	NR	6.8 ± 2.2	7.1 ± 2.1	6.1 ± 2.4	6.3 ± 2.4
Vision	AM	9.4 ± 1.0	9.2 ± 1.3	9.2 ± 1.3	9.2 ± 1.4
	EVE	8.3 ± 1.7	8.5 ± 1.6	8.0 ± 1.9	8.2 ± 1.8
	NEW	9.6 ± 0.8	9.5 ± 1.0	9.5 ± 1.0	9.6 ± 1.1
	NR	7.4 ± 2.1	7.6 ± 1.9	6.8 ± 2.2	6.9 ± 2.5

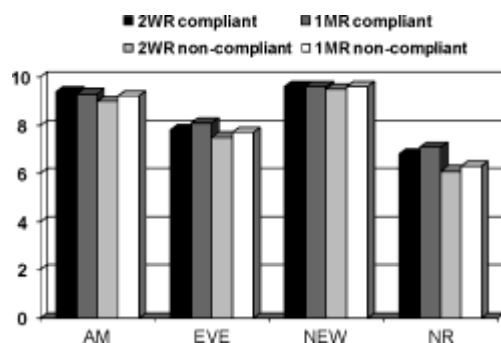
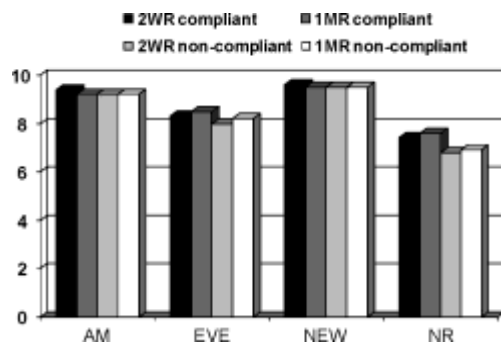
**FIGURE 1.**  
The subjective comfort ratings for the 2WR and 1MR wearers by compliance group, in the morning (AM), at the end of the day (EVE), when the lenses were new (NEW), and when the lenses needed replacing (NR).**FIGURE 2.**  
The subjective vision ratings for the 2WR and 1MR wearers by compliance group, in the morning (AM), at the end of the day (EVE), when the lenses were new (NEW) and when the lenses needed replacing (NR).

Table 3 and graphically in Figs. 1 and 2. The AM and NEW comfort ratings were significantly higher than the EVE and NR comfort ratings ( $p < 0.001$ ). The results of the factorial ANOVA for comfort are presented in Table 4. After accounting for the effect of replacement modality (2W or 1M replacement), compliance

had a statistically significant effect on EVE comfort ( $p = 0.002$ ) and NR comfort ( $p < 0.001$ ). EVE comfort ratings were higher for compliant patients by 0.4 (0.13 to 0.60), and NR comfort ratings were higher for compliant patients by 0.8 (0.50 to 1.02). The replacement modality also had a small but statistically significant effect on comfort ratings (EVE,  $p = 0.015$  and NR,  $p = 0.044$ ). After accounting for the effect of compliance, comfort ratings were higher by 0.3 (0.06 to 0.53) for patients wearing 1MR lenses compared with patients wearing 2WR lenses for EVE ( $p = 0.015$ ), and higher by 0.3 (0.01 to 0.53) for NR ( $p = 0.044$ ). The interaction between compliance and replacement modality was not statistically significant for EVE ( $p = 0.72$ ) or NR ( $p = 0.95$ ).

The vision ratings for AM and NEW were significantly higher than the vision ratings for EVE and NR ( $p < 0.001$ ). The results of the factorial ANOVA for vision ratings are presented in Table 5. After accounting for the effect of replacement modality (2W or 1M replacement), EVE and NR vision ratings were higher for compliant patients by 0.3 (0.07 to 0.47) ( $p = 0.008$ ) and 0.61 (0.36 to 0.85) ( $p < 0.001$ ), respectively. The replacement modality also had a small but statistically significant effect on EVE vision ratings ( $p = 0.019$ ). After accounting for the effect of compliance, EVE vision ratings were higher by 0.2 (0.04 to 0.44) for patients wearing 1MR lenses compared with patients wearing 2WR lenses ( $p = 0.019$ ). The interaction between compliance and replacement modality was not statistically significant for EVE ( $p = 0.89$ ).

## DISCUSSION

The SH lens wearers in this study reported superior subjective performance, in terms of both comfort and vision, at the beginning of the wearing period (AM) compared with the end of the day (EVE). This is consistent with findings from previous studies with both SH and conventional hydrogel materials.<sup>24–27</sup> Perhaps not surprisingly, comfort and vision ratings were also higher for NEW compared with NR.

When the subjective performance of lenses worn by patients who were compliant with the MRRF was compared with those who were not compliant, the comfort and vision ratings for EVE and NR were somewhat higher for the compliant wearers. To our knowledge, to date, no daily wear studies have been conducted specifically investigating the consequences of wearing a SH lens for longer than the MRRF.

**TABLE 4.**  
ANOVA results for comfort

Variable	Effect	F	p	Least-square mean difference		
				Estimate	−95% confidence limit	+95% confidence limit
Comfort EVE	LRM	5.89	0.015	0.291	0.056	0.526
	Compliance	9.31	0.002	0.366	0.131	0.600
	LRM × Compliance	0.13	0.718	0.087	−0.383	0.556
Comfort NR	LRM	4.08	0.044	0.270	0.008	0.532
	Compliance	32.11	<0.001	0.757	0.495	1.019
	LRM × Compliance	<0.01	0.949	0.017	−0.507	0.541

LRM, lens replacement modality.

**TABLE 5.**  
ANOVA results for vision

Variable	Effect	F	p	Least-square mean difference		
				Estimate	−95% confidence limit	+95% confidence limit
Vision EVE	LRM	5.55	0.019	0.241	0.040	0.442
	Compliance	7.01	0.008	0.271	0.070	0.471
	LRM × Compliance	0.02	0.885	0.030	−0.372	0.430
Vision NR	LRM	1.60	0.206	0.159	−0.087	0.405
	Compliance	23.54	<0.001	0.608	0.362	0.854
	LRM × Compliance	0.49	0.484	0.176	−0.316	0.667

LRM, lens replacement modality.

A previous patient-based survey of wearers of 2W and 1M replacement soft lenses found that the monthly replacement wearers reported a decline in lens comfort in weeks 3 and 4 of wear with both SH and conventional materials.<sup>28</sup> In our study, contrary to what may have been expected, the EVE comfort and vision ratings, and the NR comfort ratings, were slightly higher for wearers of 1M lenses than for wearers of 2W lenses. This was the case regardless of whether patients were compliant with the RF.

It is important to recognize that this study was an observational study and not a prospective study with a control group and as such it is only possible to speculate as to the possible factors affecting lens comfort. Lenses intended for 2W replacement are manufactured from different materials than lenses intended for 1M replacement. It is possible that some lens materials are optimally replaced every 2W, whereas other lens materials may be comfortably worn for 1M. A number of studies have been conducted to investigate the differences in lipid and protein deposition on SH materials over time. Based on the data from *in vitro* studies it would seem that some materials with a MRRF of 2W (specifically senofilcon A and galyfilcon A) would be likely to provide enhanced performance if replaced every 2W rather than after a longer period.<sup>29–31</sup> However, it is not possible to assume that this would apply to the replacement of all SH materials. There is also potential that practitioners may be more likely to prescribe lenses with a replacement modality of 2W than lenses with a replacement modality of 1M for patients who experience discomfort with their lenses. The difference in subjective ratings between lenses with the two replacement modalities may, therefore, be more a reflection of the patients wearing those lenses than the lenses themselves.

Consideration must be given to the finding that a significantly higher proportion of 2WR wearers did not comply with the MRRF when compared with 1M replacement modality wearers. Because compliance with RF seems to have a positive effect on the subjective performance of SH lenses, it would be beneficial to explore the possibility that a 1M replacement schedule may be more conducive to compliance than a 2W replacement schedule.

In this analysis, it was not possible to investigate the effect of wearing schedule (daily wear vs. extended wear) or lens design (spherical, toric, or multifocal) on comfort and vision ratings, and it is important to recognize that this may also have an impact on lens performance in terms of comfort and/or vision. Similarly, the effect of lens care regimen was not specifically investigated in this study. A further limitation of this study was that the effects were small on the scale used for measurements (0 to 10), and this scale potentially lacked sensitivity in comparison with a 0 to 100 scale.

## CONCLUSIONS

Patients who were compliant with the MRRF were found to have better end of day comfort and vision and better comfort and vision when their lenses needed replacing than NC patients, regardless of the replacement modality that was prescribed for them. Achieving optimal subjective performance with currently prescribed SH lenses in the United States seems to be facilitated by replacing lenses as recommended.

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