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ORIGINAL RESEARCH

Clinical Performance of Samfilcon A Contact Lenses in Intensive Digital Device Users: A Multicenter, Prospective Clinical Study

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ABSTRACT

Introduction: To evaluate patient satisfaction with samfilcon A contact lenses (CLs) in intensive digital device users with myopia and to compare patient satisfaction with samfilcon A lenses to prior experience with senofilcon A or lotrafilcon B CLs.

Methods: This was a comparative, prospective, national study conducted at 14 centers in Turkey. Subjects were adults aged 18 and 45 years with myopia (range −0.25 D to −6.00 D) who spend a minimum of 3 hours viewing digital devices (e.g., computer, smartphone). A subgroup of patients were habitual lens wearers (senofilcon A or lotrafilcon B lens wear for at least 6 months prior to enrollment). The primary assessment was patient satisfaction with samfilcon A lenses (0–100 Likert scale). Sec-

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ondary assessments included patient satisfaction with samfilcon A lenses compared to patients' habitual lenses, investigator satisfaction with samfilcon A lenses and investigator-evaluated slit lamp examination findings.
Results: Samfilcon A lenses were given high overall ratings from both patients and investigators, with a low incidence of ocular symptoms. Overall, patients were highly satisfied with samfilcon A lenses for comfort, vision and overall performance, and stated that they would consider wearing these lenses in the future. Among habitual senofilcon A or lotrafilcon B lens wearers, samfilcon A lenses were rated significantly better than the habitual lenses in regard to comfort, vision and overall performance. Investigator assessments were also highly favorable, both at initial fit and after 4 weeks of follow-up, with no significant findings noted on slit lamp examination.
Conclusion: Samfilcon A lenses were rated highly by investigators in regard to fit, handling and slit lamp findings, and by novice and habitual lens wearers in regard to comfort, vision and overall performance. These results support the use of samfilcon A lenses among digital device users who seek day-long comfort and good visual acuity.

Keywords: Computer vision syndrome; Contact lens; Contact lens discomfort; Digital eye strain; Dry eye; Myopia; Patient preference/satisfaction; Samfilcon A; Soft contact lens; Visual acuity

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Key Summary Points

Why carry out this study?

The use of digital devices is widespread and contributes to discomfort and visual problems among contact lens (CL) wearers.

This study was designed to evaluate the use of samfilcon A CLs among people with myopia who report intensive digital device use.

What was learned from the study?

Patients and physicians reported that samfilcon A lenses were very good or excellent in terms of visual quality, comfort, handling and maintenance of cleanliness.

The positive findings were consistent among both novice CL wearers and habitual lotrafilcon B or senofilcon A lens wearers.

Habitual lotrafilcon B or senofilcon A lens wearers generally reported that samfilcon A lenses performed better across all metrics studied.

INTRODUCTION

With the recent advances in digital technologies and widespread use of the internet and social media, global use of digital devices has increased substantially over the past several years. Digital platform use has become a part of daily life, common not only to visual display terminal (VDT) workers, but also to the general population. Based on recent data available before the COVID-19 pandemic hit Turkey in spring 2020, an estimated 88% of Turkish citizens had access to the internet at home, and 98% of the population had mobile phone subscriptions [1]. Digital platform use is prevalent across all age groups. In 2016, about 37% of US

adults aged 60 years and over were reported to spend 5 or more hours per day using digital devices [2]. A European study published the same year reported that by 3 years of age, 68% of children regularly use a computer and 54% undertake online activities [3]. Not only is digital technology widely accessible, but typical daily use can be very high. In 2018, US statistics revealed that adults spent an estimated average of more than six and a half hours with digital media every day [4]. The mean daily digital platform use was expected to rise to 11 hours per day in 2019 [4]; however, this number has probably been exceeded, considering the impact of the COVID-19 pandemic in all age groups. While similar statistics are not available for Turkey, it is reasonable to assume that a substantial percentage of the population are intensive digital device users, as is the case globally.

Although digital platform use is extremely common in today's society, there are many problematic issues that can be associated with this use. More than 60 million people around the world suffer from computer vision syndrome (CVS) or digital eye strain (DES), with an estimated one million new cases occurring annually [5–8].

Symptoms of DES fall into two main categories; those linked to accommodative or binocular vision stress, and symptoms linked to dry eye. Patients may complain of eye fatigue, eyestrain, headaches, ocular discomfort, dry eye, diplopia, blurred vision, ocular discomfort or burning [10]. It is difficult to accurately estimate the prevalence of ocular and visual symptoms associated with viewing electronic screens, since working conditions, type of digital device used and the methods used to quantify symptoms tend to vary considerably. However, estimates suggest that the prevalence of DES may be somewhere between 40 and 90% among users of digital platforms, including smartphones [10–14]. A strong association between dry eye and DES has also been reported, with longer periods of computer work being associated with a higher prevalence of dry eye not only in VDT users, but in children with smartphone use as well [6, 15, 16]. Although symptoms of DES are typically transient, they may be frequent and persistent, interfering with quality of life and decreasing work productivity.

The use of digital platforms including smartphones has also been reported to be associated with substantial changes in the tear film and ocular surface. Significant reductions in tear film break-up time [6, 16–21], mucin expression [21] and Schirmer tear test results [20, 22] have been reported in various studies. At least some of these changes were attributed to decreased blink rate [16, 23–25] and increased frequency of incomplete blinks [9, 16, 23] while viewing screens. Incomplete blinks in particular have been reported to be associated with increased DES symptoms [16, 26] and faster tear film break-up [16, 24].

DES has been reported to be aggravated by contact lens (CL) wear. Studies have shown that CL wearers with VDT exposure for more than 4 to 6 hours per day are more likely to suffer from DES compared to non-wearers [15, 17, 27]. CL manufacturers are engaged in constant efforts to meet consumer demands and improve CL material and surface technologies to combat the challenges faced during daily digital use, and improve end-of-day comfort. One such effort is the development of samfilcon A silicone hydrogel CLs (Bausch and Lomb ULTRA, Bausch and Lomb Inc., Rochester, NY). These CLs integrate MoistureSeal® technology, which is designed to retain moisture and provide a smooth optical surface to help prevent dehydration and associated discomfort and blur [28].

The aim of this prospective, comparative, national study was to evaluate patient satisfaction with samfilcon A CLs in intensive digital device users with myopia and to compare patient satisfaction with samfilcon A lenses to that reported with senofilcon A (Acuvue Oasys; Vistakon, Jacksonville, FL, USA) or lotrafilcon B (Air Optix Aqua, Alcon, Ft. Worth, TX) CLs in the subgroup of patients with prior history of CL wear.

METHODS

This was a prospective, national, medical device comparison study conducted at 15 centers in Turkey.

Subjects

The goal for enrollment was 300 patients, including 100 novice CL users, 100 patients with prior habitual use of senofilcon A lenses, and 100 patients with prior habitual use of lotrafilcon B lenses. Approximately 20 patients were planned to be enrolled in each of the 15 participating centers, with approximately seven patients intended to be included in each group at each center.

Inclusion Criteria

To be included in the study, subjects had to be 18 and 45 years of age; spend a minimum of 3 hours in front of an electronic device such as a computer, tablet, e-book reader, smartphone; and have been diagnosed with myopia and requiring correction with lenses between −0.25 and −6.00 diopters (D), with a cylinder of less than 0.75 D.

Patients also had to provide written informed consent for the study and be able to comply with study procedures throughout the study period.

The subgroup of patients who were habitual senofilcon A or lotrafilcon B lens wearers needed to have been wearing their prior lenses for at least 6 months prior to study enrollment, with a minimum daily duration of use of 8 hours for at least 4 days per week, and experience at least one of the following symptoms occasionally, frequently or very frequently during daily contact lens wear: blurry vision, dry eye or eye fatigue. Habitual lens wearers attended the baseline visit with their habitual contact lenses.

Exclusion Criteria

Patients meeting any of the following criteria were excluded from the study: those with any condition affecting the eyelids, tear film/ocular surface, conjunctiva, cornea, or other anatomical structures of the eye; suspected or confirmed pregnancy or lactation; or known hypersensitivity/allergy to study product (CLs and/or multipurpose cleansing solutions) or any of the ingredients.

Patients were advised that they might choose to withdraw from the study at any time or might be excluded from further study participation at the discretion of the investigator (e.g., due to serious adverse event, laboratory abnormality, or any condition jeopardizing the patient safety or due to emergence of a condition that met one of the exclusion criteria during conduct of study, or the recognition of a previously unnoticed exclusion criterion).

Ethics Approval and Informed Consent

Prior to the study, all study documents were submitted to the Ethics Committee for Clinical Research, Medical Faculty of Ankara University, for approval. Following Ethics Committee approval, the protocol was submitted to the Turkish Drug and Medical Devices Agency, Ministry of Health, and the study was initiated only after its final approval.

All recruited patients were informed about the study and were enrolled only after providing written informed consent for participation.

Study Design

The planned study duration was 16 months, consisting of the 15-month enrollment phase and 1-month follow-up phase (see Supplemental Figure S1 for the design schematic).

Study Assessments

Baseline Visit

At baseline, all patients provided personal sociodemographic data. Habitual lens wearers attended the baseline visit with their habitual contact lenses and provided information on their experience with their prior lenses by completing a satisfaction questionnaire (assessing visual quality, comfort and symptoms) (Supplemental file Appendix A1). At the same baseline visit, patients were fitted with samfilcon A lenses. After fitting, both patients and investigators provided their first impressions. Patient impressions were recorded by an

investigator-administered questionnaire gathering information on lens centering, lens movement, patient comfort, visual quality and ease of placement). Investigator impressions were assessed by a questionnaire evaluating the adaptation to lens. A slit lamp examination was conducted, with findings reported using the CCLRU scale (corneal edema, corneal staining with fluorescein, corneal neovascularization, conjunctival injection, papillary hypertrophy and blepharitis) [29]. All patients were provided with Biotrue lens solution (Bausch and Lomb Inc., Rochester, NY, USA) at baseline visit for standardization. Novice lens wearers were instructed on how to handle, clean and care for their contact lenses at the baseline visit. All participants (habitual and novice) were instructed to wear their lenses at least 8 hours a day, and at least 4 days a week.

Follow-Up (Final Visit)

A follow-up final visit was scheduled 4 weeks after the baseline visit. No restrictions were placed on the time of day or minimum lens wearing time for visits. At the follow-up visit, samfilcon A lenses were again assessed by the investigators and the patients. Different investigator-administered questionnaires were used for novice and habitual CL wearers. Habitual CL wearers were asked to compare their habitual lenses with samfilcon A lenses. The following information was gathered at the final visit:

- Primary assessment: Patient satisfaction with samfilcon A lenses on a 0–100 Likert scale: 100–81: excellent; 80–61: very good; 60–41: good; 40–21: fair; 20–0: poor
- Secondary assessments:
  - Questionnaire-based comparison of samfilcon A lenses and prior CL in regard to visual quality and comfort in habitual lens wearers
  - Assessment of investigator satisfaction with samfilcon A lenses by questionnaire
  - Investigator-evaluated slit lamp examination findings (based on CCLRU scale)
- Other assessments: Information on frequency of specific eye complaints was also gathered at the final visit.

Statistical Analysis

The enrollment goal was based on the calculation that 282 subjects were required (94 patients for each of senofilcon A, lotrafilcon B habitual wearers, and novice lens users) to detect a 20% difference between the groups with respect to comfort and visual quality at a significance level of 0.05 with 80% power. Considering potential dropouts, a total of 300 patients (100 in each group) were planned to be enrolled in the study.

All data collected throughout the study period were summarized with descriptive statistics; numerical variables were expressed as mean, standard deviation, median, 25th percentile (Q1), 75th percentile (Q3), minimum and maximum, while categorical variables were expressed using numbers and percentages. The normality of the variables was tested using visual (histogram and probability graphs) and analytical (Kolmogorov–Smirnov/Shapiro–Wilk tests) methods.

For the before–after analyses of baseline to 4 weeks, a sampled t test was used if the assumption of normality was met, and Wilcoxon signed-rank test was used when the assumption of normality was not met; categorical variables were assessed using the McNemar test. The comparison of numerical variables between groups utilizing different lens materials was performed using the t test if assumption of normality was met, and using the Mann Whitney U test when the assumption of normality was not met; for categorical variables, Chi-square analysis was used. The level of statistical significance was set at $p < 0.05$.

The exception to the above is the frequency of specific eye complaints, which is presented as observed, with no assessment of statistical significance carried out between subgroups.

RESULTS

Patient Flow

The study was initiated at all study centers in December 2017 and prematurely terminated in March 2019, before reaching the planned number of subjects, due to enrollment

Table 1 Baseline sociodemographic characteristics

	Novice CL wearers ***n*** **= 80**	**Habitual senofilcon A wearers** ***n*** **= 61**	**Habitual lotrafilcon B wearers** ***n*** **= 46**
Age			
Mean ± SD	25 ± 5	26 ± 5	25 ± 5
Median (Q1–Q3)	23 (21–27)	25 (22–29)	25 (21–28)
(min.–max.)	(18–44)	(18–42)	(18–41)
Gender, *n* (%)			
Female	62 (77.5)	45 (73.8)	38 (82.6)
Male	18 (22.5)	16 (26.2)	8 (17.4)
Marital status, *n* (%)			
Married	15 (18.8)	11 (18.3)	9 (19.6)
Single	65 (81.3)	49 (81.7)	37 (80.4)
Education, *n* (%)			
Primary school	1 (1.3)	0 (0.0)	1 (2.2)
Secondary school	0 (0)	0 (0)	0 (0)
High school	16 (20)	7 (11.7)	9 (19.6)
University	52 (65)	44 (73.3)	35 (76.1)
Master degree	10 (12.5)	9 (15)	1 (2.2)
Work status, *n* (%)			
Worker	3 (3.8)	1 (1.7)	0 (0)
Civil servant	12 (15)	19 (31.7)	12 (26.1)
Housewife	2 (2.5)	0 (0)	2 (4.3)
Student	36 (45)	18 (30)	21 (45.7)
Unemployed	4 (5)	7 (11.7)	1 (2.2)
Self-employed	1 (1.3)	3 (5)	3 (6.5)
Other	22 (27.5)	12 (20)	7 (15.2)

SD standard deviation, *Q* quartile

difficulties. A total of 252 subjects were enrolled, the majority of whom were students. However, 20 subjects were deemed ineligible during data analysis, leaving 232 patients for assessment (102 novice users, 77 habitual senofilcon A wearers and 53 habitual lotrafilcon B wearers). Baseline sociodemographic characteristics of the 232 patients are shown in Table 1. Among patients included in the analysis, 45 patients discontinued the study; follow-up data were not available for those individuals. Reasons for discontinuation were as follows: lost to follow-up (n = 17), the duration between first and follow-up visit exceeding 25- to 35-day window period (n = 25), adverse events (n = 2) and "red eye" complaint, which was not assessed as an adverse event by the investigator (n = 1).

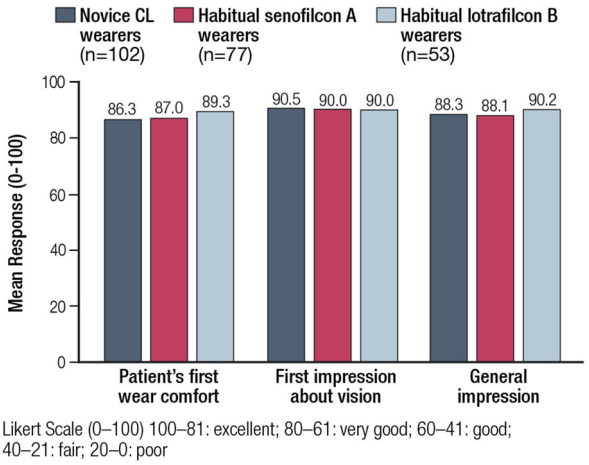


Fig. 1 Patient first impressions of samfilcon A lenses (baseline visit). *CL* contact lens. Likert Scale (0–100) 100–81: excellent; 80–61: very good; 60–41: good; 40–21: fair; 20–0: poor

Patient Impressions

Baseline: Initial Impressions

Regarding the baseline questionnaire, overall mean first impressions were in the "excellent" range (i.e., 81–100 on the Likert scale) for each investigated parameter in each patient group (Fig. 1).

Four-Week Follow-Up: Overall Patient Ratings

At the 4-week follow-up visit, patient impressions of visual quality, comfort and handling with the samfilcon A lenses were favorable overall, among subgroups and across specific situations (Fig. 2). Novice and habitual lens wearers rated vision, comfort and overall satisfaction with their lenses above 80 (out of 100) (Fig. 3), and the majority of patients indicated they would continue wearing samfilcon A lenses in the future if recommended by their ophthalmologists (Fig. 4).

Additionally, the majority of patients stated that samfilcon A lenses provide clear vision all day long (total percentage answering "strongly agree," "agree" or "somewhat agree" = 94.6%), provide a clear sharp image immediately after insertion (95.7%), provide clear vision consistently (88.6%), and provide clear vision even when they rub their eyes (90.0%), during long-term digital device use (90.2%), during physical activity (96.1%), while driving at night (94.9%), while reading a book/newspaper (94.0%) or when they lie down (97.3%) (Supplemental Table S1). The majority of patients also stated that samfilcon A lenses provide long-term comfort (total percentage answering "strongly agree," "agree" or "somewhat agree" = 88.0%), comfort during long-term digital device use (88.6%), during physical activity (92.7%), while driving at night (92.1%), or while reading a book/newspaper (90.8%) (Supplemental Table S2). Patients also indicated that samfilcon A lenses center quickly when placed in the eye (total percentage answering "strongly agree," "agree" or "somewhat agree" = 96.2%), reduce halo and glare even in low light (97.3%), help maintain eye health (92.4%) and are easy to hold (96.2%) (Supplemental Table S3).

Four-Week Follow-Up: Comparative Patient Ratings

In habitual lens wearers, samfilcon A lenses scored statistically higher in every category of visual quality (Fig. 5) and almost every category of comfort (Fig. 6) compared to senofilcon A or lotrafilcon B lenses.

Comparative satisfaction for vision, comfort and overall satisfaction was also in favor of samfilcon A lenses as compared to the habitual lenses in most categories (Fig. 7).

Four-Week Follow-Up: Frequency of General Symptoms

The patient assessment at the 4-week visit included quantification of general symptoms. The proportions of patients reporting symptoms "often" or "very often" with samfilcon A lenses were low (Fig. 8i). The frequency of symptoms was also numerically lower among habitual lens wearers when compared to the baseline assessment of their habitual lenses, although no statistical analysis was performed for these comparisons (Fig. 8ii and 8iii). Similar results were observed for symptoms in the specific situation "after intensive use of digital screen" (Fig. 9). No additional complaints were noted apart from those mentioned in the questionnaires.

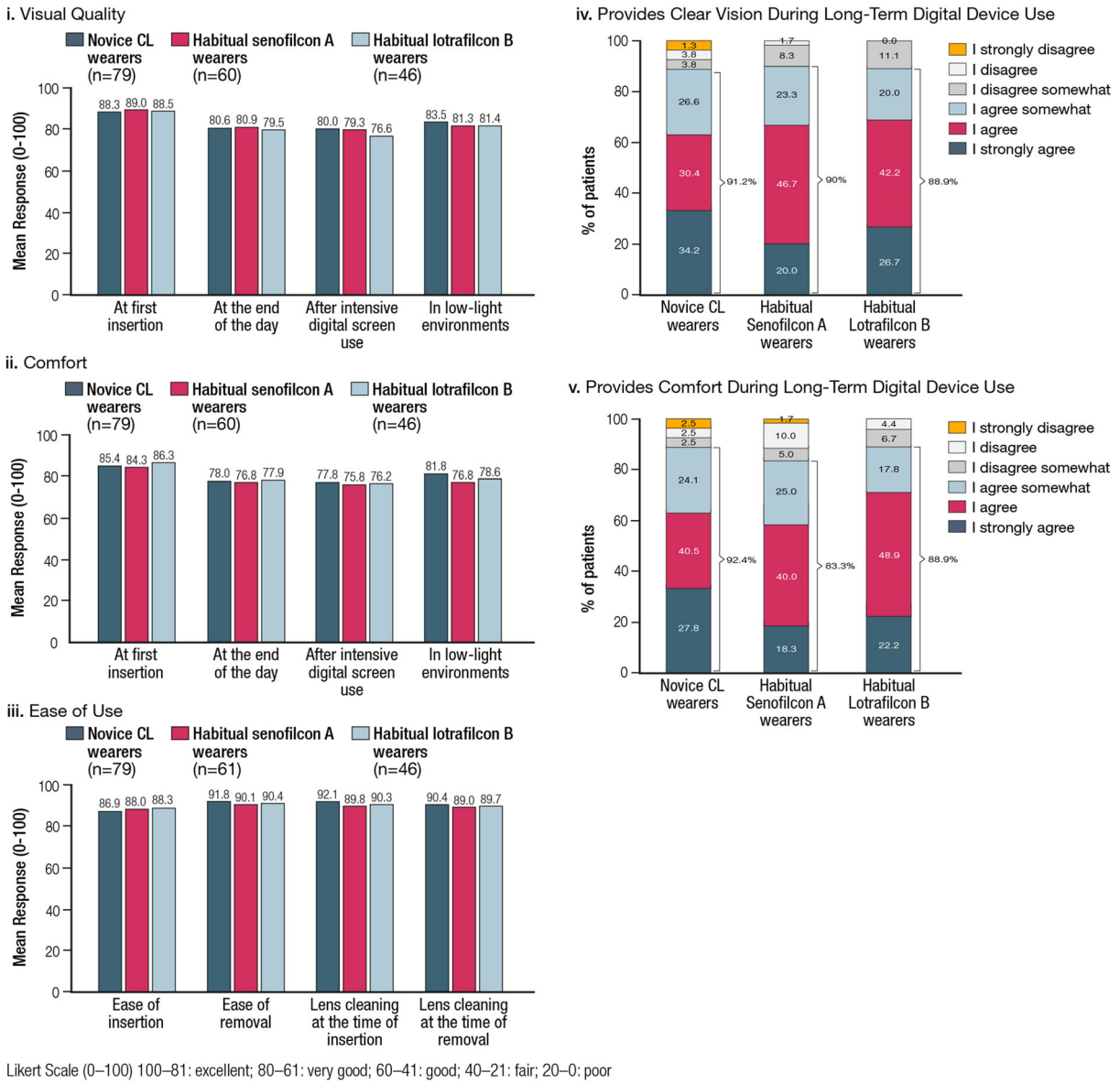
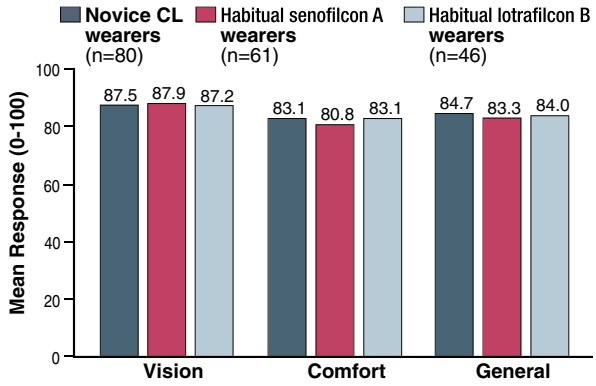


Fig. 2 Patient impressions with samfilcon A lenses at 4-week follow-up visit. i Visual quality. ii Comfort. iii Handling. iv Provides clear vision during long-term digital device use. v Provides comfort during long-term digital device use. *CL* contact lens. Likert Scale (0–100) 100–81: excellent; 80–61: very good; 60–41: good; 40–21: fair; 20–0: poor

Investigator Impressions

Overall mean investigator impressions were generally favorable (good, very good or excellent for the vast majority of parameters) for each parameter assessed at baseline and at 4-week follow-up (Fig. 10).

No clinically significant findings were observed at slit lamp biomicroscopy examination (Supplemental Table S4).



Likert Scale (0–100) 100–81: excellent; 80–61: very good; 60–41: good; 40–21: fair; 20–0: poor

Fig. 3 Patient satisfaction with samfilcon A lenses: comfort, visual quality and in general (4-week assessment). *CL* contact lens. Likert Scale (0–100) 100–81: excellent; 80–61: very good; 60–41: good; 40–21: fair; 20–0: poor

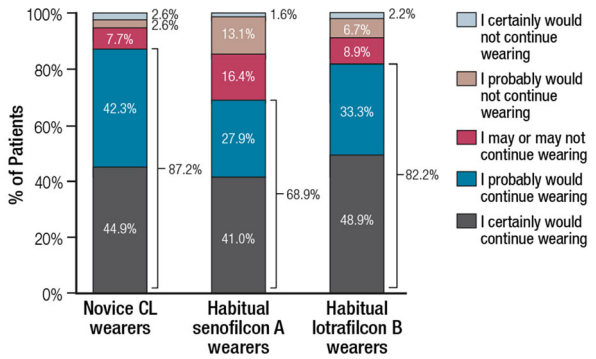
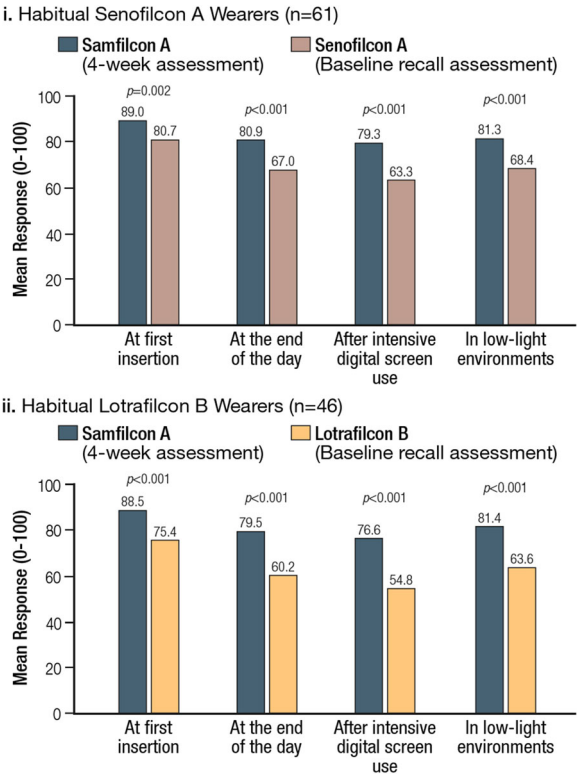


Fig. 4 Patient likelihood of continuing to wear samfilcon A lenses in the future if recommended by their ophthalmologists (4-week assessment). *CL* contact lens

DISCUSSION

In this prospective, multicenter, comparative study, samfilcon A lenses performed very well in digital device users in the Turkish population, with high overall ratings from both patients and investigators and a low incidence of DES symptoms. Overall, patients were highly satisfied with samfilcon A lenses in terms of comfort, vision and overall performance, and stated their interest in wearing these lenses in the future. When subject ratings were compared to those obtained for prior habitual lenses (senofilcon A or lotrafilcon B), samfilcon A lenses were rated



Likert Scale (0–100) 100–81: excellent; 80–61: very good; 60–41: good; 40–21: fair; 20–0: poor

Fig. 5 Habitual contact lens wearers: patient impressions of visual quality with samfilcon A lenses at 4 weeks vs. the habitual lens. i. Habitual senofilcon A wearers (n = 61). ii. Habitual lotrafilcon B wearers (n = 46). Likert scale (0–100) 100–81: excellent; 80–61: very good; 60–41: good; 40–21: fair; 20–0: poor

significantly better in terms of overall performance, visual quality and comfort. Overall frequency of symptoms of DES, including dry eye, glare in low light, blurred vision, eye strain and delayed focusing, were very low with samfilcon A lenses in both novice and habitual contact lens wearers. Investigator assessments were also highly favorable for samfilcon A lenses in regard to ease of fit and handling, both at initial fit and at the final follow-up examination, with no significant slit lamp biomicroscopy findings.

CLs represent a popular, effective and relatively safe means of refractive correction. There are an estimated 140 million CL wearers worldwide [30]; the total number of wearers has not grown in a number of years, because of constant dropouts. Between 12 and 51% of

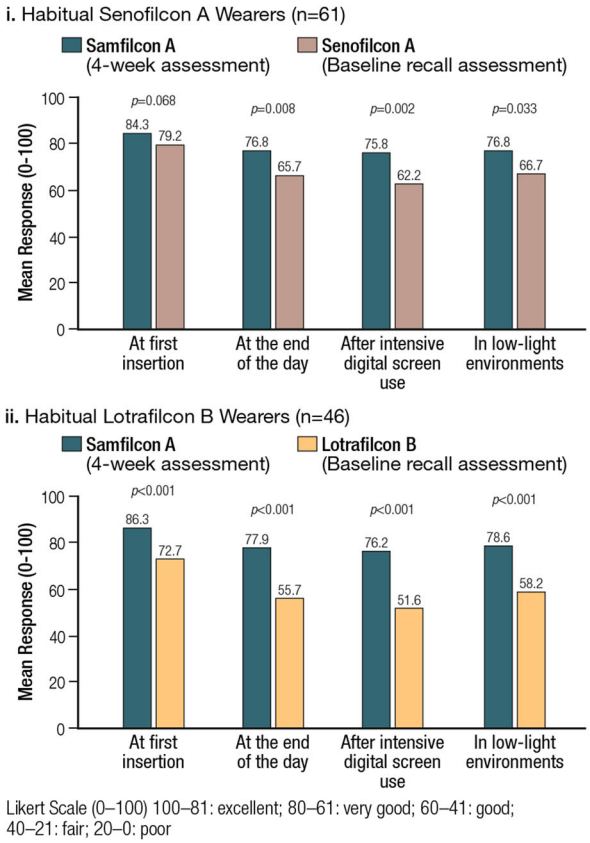


Fig. 6 Habitual contact lens wearers: patient impressions of comfort with samfilcon A lenses at 4 weeks vs. the habitual lens. i. Habitual senofilcon A wearers (n = 61). ii. Habitual lotrafilcon B wearers (n = 46). Likert scale (0–100) 100–81: excellent; 80–61: very good; 60–41: good; 40–21: fair; 20–0: poor

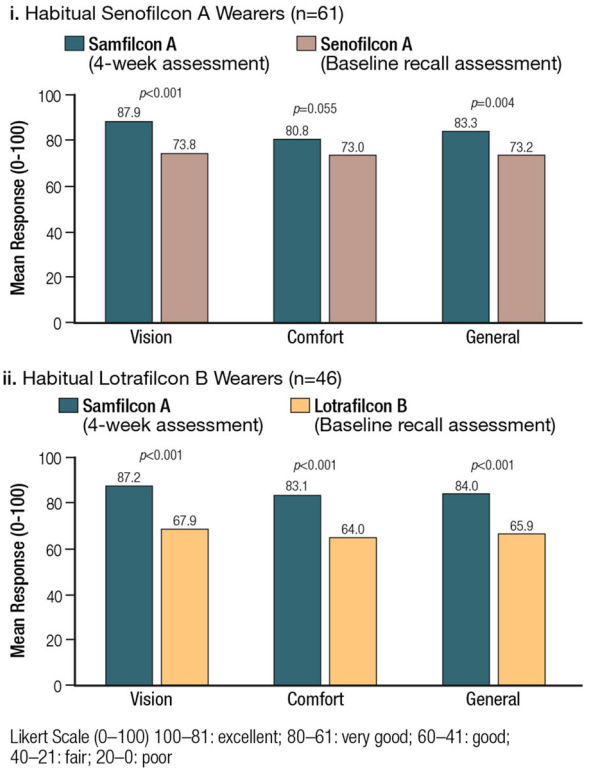


Fig. 7 Habitual lens wearers: patient satisfaction with samfilcon A lenses: comfort, visual quality and in general. i. Habitual senofilcon A wearers (n = 61). ii. Habitual lotrafilcon B wearers (n = 46). Likert scale (0–100) 100–81: excellent; 80–61: very good; 60–41: good; 40–21: fair; 20–0: poor

patients will discontinue CL wear, with "lack of comfort" being the most frequently cited reason for discontinuation [30]. About 50% of CL wearers are known to experience dryness or discomfort of some degree related to contact lens wear despite introduction of new materials, the advancements in silicone hydrogel lenses, and the development of improved care regimens [31]. Although the exact reasons for CL discomfort are unknown, in 2013, the Tear Film & Ocular Surface Society (TFOS) Contact Lens Discomfort Workshop categorized the possible relevant factors as lens-related (material, design, fit and wear, and lens care) and environmental (inherent patient factors, modifiable patient factors, ocular environment and external environment) factors [30, 31]. With CL wear, the tear film is divided into a pre- and post-lens tear film, leading to a series of extensive biophysical and biochemical changes, and creating a less stable tear film on the front surface of the lens and less well-defined changes in the post-lens tear film layer [31]. The resulting pre-lens tear film has reduced lipid layer thickness and decreased tear film stability, increased mucin degradation, reduced tear flow rate and volume, and increased evaporation rate compared to the normal tear film [31]. Such changes occurring in the presence of a CL in the ocular environment have been thought to increase overall frictional forces between the ocular surface/lid margin and the contact lens, leading to CL discomfort [31]. Although CL discomfort may be reported in the absence of any clinical signs related to

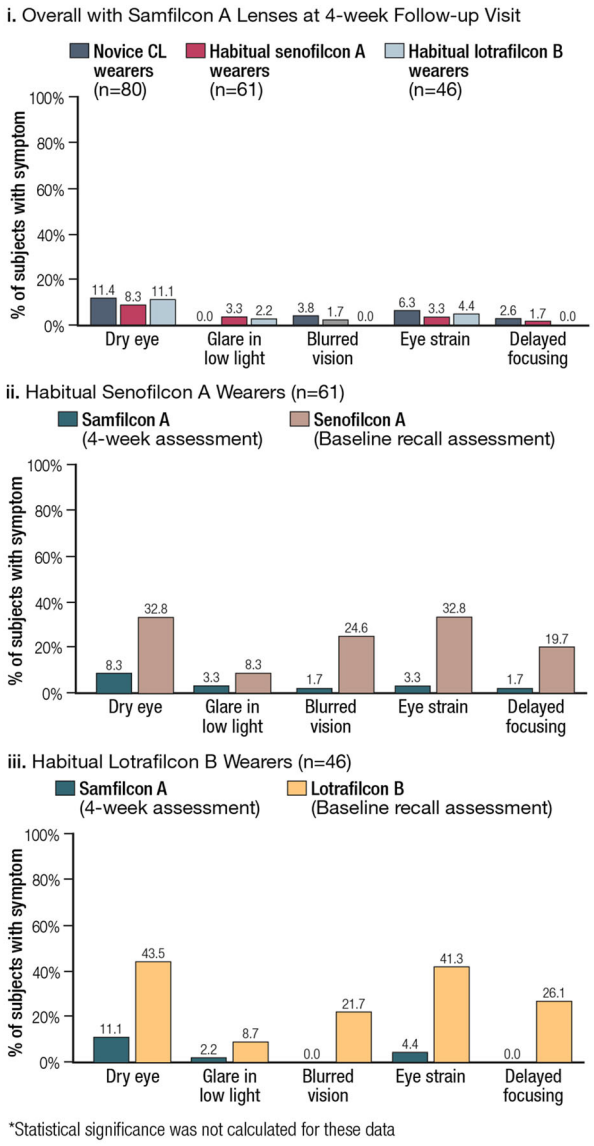


Fig. 8 Eye symptoms reported "often" or "very often."* i. Overall with samfilcon A lenses at 4-week follow-up visit. ii. Habitual senofilcon A wearers (n = 61). iii. Habitual lotrafilcon B wearers (n = 46). *Statistical significance not calculated for these data

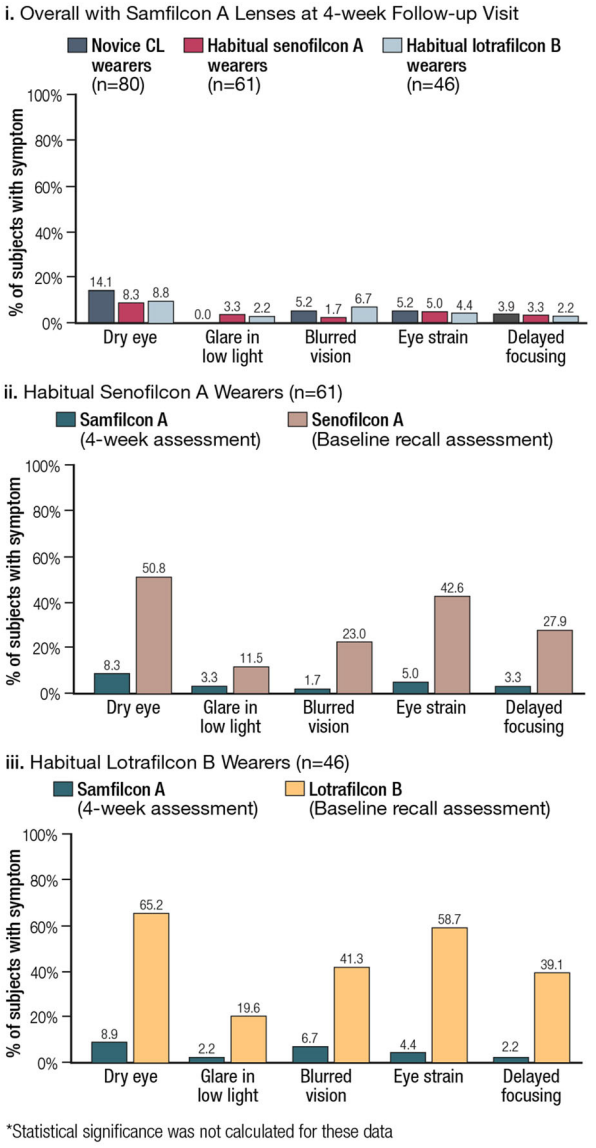


Fig. 9 Eye symptoms reported "often" or "very often" after intensive digital screen use.* i. Overall with samfilcon A lenses at 4-week follow-up visit. ii. Habitual senofilcon A wearers (n = 61). iii. Habitual lotrafilcon B wearers (n = 46). *Statistical significance not calculated for these data

the ocular surface or tear film [32], over years, CL wear is known to lead to a 2.01- to 2.96-fold increase in the risk of developing dry eye [33].

The CL industry constantly strives to improve CL materials, in particular the widely prescribed, highly oxygen-permeable silicone hydrogel lens materials. To negate or overcome the stiffness and hydrophobicity/low wettability of the silicone monomer, technologies such as surface coatings or moisturizing agents, water-gradient technologies or the addition of intrinsic wetting agents have been utilized, rendering these lenses much more flexible and highly wettable. Indeed, in a recent crossover study investigating the isolated effect

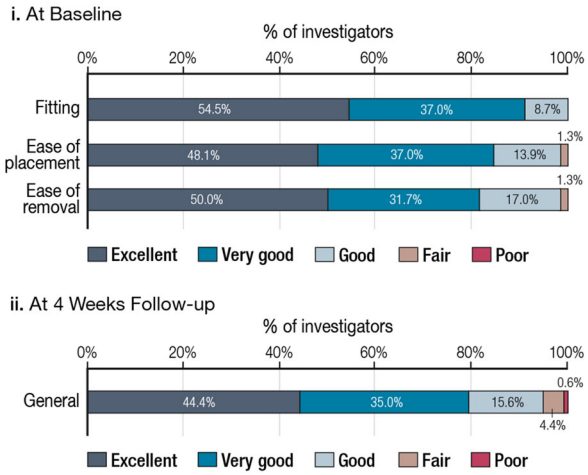


Fig. 10 Investigator impressions of samfilcon A lenses. i. At baseline. ii. At 4-week follow-up

of reducing lens surface friction on lens comfort and wettability by adding an ultrathin coating to a standard silicone hydrogel soft CL, significant improvement in subjectively rated wearer comfort was achieved [34].

Yet, today's typical CL wearers are totally different from what they were 10 years ago. They have lifestyles that present increasing challenges to the CL in terms of maintaining lubricity and comfort from morning to evening. They are constant users of digital platforms in the form of computers, tablets or smartphones, which have been shown to have detrimental effects on tear film homeostasis, leading to dry eyes [35]. The deleterious changes associated with digital device use further exacerbate the negative impact of CL wear on the ocular surface and tear film. As such, the dual impact from lens wear during digital device use is a growing concern. To address these additional challenges, Bausch and Lomb has introduced Ultra (samfilcon A) material, which involves a brand-new polymerization process and makeup of the silicone material [36]. Bausch and Lomb Ultra utilizes an optimal combination of three distinct types of silicone with slightly different characteristics to provide a balance of high oxygen transmissibility and low modulus [36]. The two-phase polymerization process of the material is also unique. The silicone components polymerize first in the mold when subjected to specific radiant energy, forming a basic structure or framework for the eventual silicone hydrogel CL. In a time-delayed second phase, polyvinylpyrrolidone (PVP) is then polymerized through and around this silicone lattice-like framework in order to allow more PVP to be incorporated into the silicone hydrogel, which should result in enhanced moisture retention characteristics for the material [36]. This so-called MoistureSeal® technology aims to enhance durability and retain moisture and lubricity both within the lens material and on the smooth, wettable surface, while maintaining very high oxygen permeability [36].

Samfilcon A lenses were previously evaluated in a prospective, single-arm, open-label clinical study among myopic patients ($n = 341$) who spent at least 3 hours each workday using a computer or electronic device [37]. In that study, the subjects consistently rated samfilcon A lenses more favorably across a wide range of subjective measures compared to their habitual lenses, including higher ratings for working long hours on a computer, when focusing for a long time at digital devices, in dry environments and while driving at night.

In a cross-sectional study specifically analyzing the effect of CL wear on DES symptoms, Tauste et al. [27] reported that VDT workers who wore CLs more than 6 hours a day were significantly more likely to suffer from DES symptoms than non-lens wearers. Because of small subgroup sizes and various CL materials, types and replacement schedules used, this study could not identify whether DES is more likely to occur in hydrogel or silicone hydrogel wearers. An earlier study analyzing comfort with CLs during computer use had found increased comfort in persons who were refit with senofilcon A silicone hydrogel lenses after previously using conventional hydrogels [38]. However, this study was also limited by uneven sample size across environmental exposure and lens groups, and short follow-up (2 weeks) after refitting with silicone hydrogels. In addition to DES symptoms, long-term VDT use at work was reported to be associated with significantly worse tear film break-up time, ocular surface staining and tear meniscus height in CL wearers

compared to non-wearers [13, 16, 26], particularly with more than 4 to 8 hours of daily exposure [13, 16]. The more recent study by Tauste et al. [20] reported that regular CL use during VDT exposure at work was associated with higher risk of bulbar, limbal and lid redness, and lid roughness in soft CL wearers compared to non-wearers. Although conventional hydrogel wearers seemed to be at higher risk of developing ocular surface abnormalities, this study was also limited with regard to subgroup sizes and variable environmental factors [20]. Therefore, although CL wear accentuates symptoms of DES and is associated with ocular surface and tear film abnormalities, any influence of CL material is controversial and awaits further studies.

In our study, in the subgroup of patients who were habitual wearers of senofilcon A or lotrafilcon B lenses, samfilcon A CLs seemed to provide better comfort compared to the habitual lenses. This result reflects the favorable influence of innovations in silicone hydrogel lens material on CL comfort in digital device users. Owing to the multicenter design, one limitation of our study was the inability to control for environmental conditions, such as humidity or temperature. A longer follow-up might have shed more light on symptom evaluation and longitudinal change in symptom scores; however, this was not possible, for practical reasons. Therefore, future prospective, controlled studies with large numbers of patients and long-term follow-up are needed to establish the influence of new-generation silicone hydrogel lens materials, surface modifications or designs on CL comfort in digital platform users. In the meanwhile, continuous advances in polymer chemistry, manufacturing and lens design innovations can help achieve the desired balance of health, vision, comfort and handling, rendering CL wear more comfortable and decreasing undesired dropout.

CONCLUSION

In conclusion, samfilcon A lenses were rated "very good" to "excellent" in terms of visual quality, comfort, handling and maintenance of cleanliness, with only a few eye complaints among both novice lens wearers and habitual lotrafilcon B or senofilcon A lens wearers with intensive digital device use. Investigator impressions were also highly favorable for ease of fit and handling, with no significant slit lamp biomicroscopy findings. These results support the use of samfilcon A lenses among digital device users who seek day-long comfort and good visual acuity.

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Compliance with Ethics Guidelines. This study was performed in accordance with the Helsinki Declaration of 1964, and its later amendments. Prior to the study, all study documents were submitted to the Ethics Committee for Clinical Research, Medical Faculty of Ankara University for approval. Following Ethics Committee approval, the protocol was submitted to the Turkish Drug and Medical Devices Agency, Ministry of Health, and the study was initiated only after its final approval.

Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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