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Effects of two different contact lenses on ocular physiological parameters and tear function tests

Efeitos de duas lentes de contacto diferentes nos parâmetros fisiológicos oculares e nos testes de função lacrimal

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Abstract

Objective: *To investigate the effects of two types of contact lenses made of two different types of silicone hydrogel material on ocular physiological parameters and tear function tests.* ***Methods:*** *The contact lenses with the appropriate diopters were supplied to the volunteering patients. The patients were evaluated before wearing the contact lenses (visit0:V0), at the first month(visit1:V1) and at the thirth month(visit2:V2) following their wear. At all visits a detailed biomicroscopic examination was done, ocular physiological variables were collected, the tear function tests were performed and the tear meniscus area (TMA) was visualized and measured with anterior segment optical coherence tomography (AS-OCT).* ***Results:*** *The results of Schirmer 1 test were 12.07 ± 1.51 [9-16] mm for the right eyes (samfilcon A group) and 12.09 ± 1.5 [9-16] mm for the left eyes (senofilcon A group) at V0. (p=0.950) At V2, the mean Schirmer 1 test results were 11.92±1.34 [9-15] mm in the samfilcon A group and 12.2±1.41 [9-16] mm in the senofilcon A group (p=0.239). The mean TMA dimensions in the AS-OCT images were 338.42±47.1 [241-401] microns in the samfilcon A group and 338.42±47.1 [241-401] microns in the senofilcon A group at V0. (p>0.05). At V2, the mean TMA dimensions were 337.2±45.53 [241-402] microns in the samfilcon A group and 340.31±48.22 [240-411] microns in the senofilcon A group (p=0.728).* ***Conclusions:*** *Our study has demonstrated that contact lenses containing samfilcon A and senofilcon A silicone hydrogel material do not cause meaningful ocular surface problems.*

Keywords: *Silicone geis; Contact lens; Ocular physiological phenomena; Tears*

Resumo

Objetivo: Investigar os efeitos de dois tipos de lentes de contacto feitas de dois tipos diferentes de material de hidrogel de silicone nos parâmetros fisiológicos oculares e testes de função lacrimal. **Métodos:** As lentes de contacto com as dioptrias apropriadas foram fornecidas aos pacientes voluntários. Os pacientes foram avaliados antes do uso das lentes de contacto (visita0: V0), no primeiro mês (visita1: V1) e no terceiro mês (visita2: V2), após o uso destas. Em todas as visitas, foi realizado um exame biomicroscópico detalhado, as variáveis fisiológicas oculares foram recolhidas, os testes de função lacrimal foram realizados e a área do menisco lacrimal (TMA) foi visualizada e medida com tomografia de coerência óptica do segmento anterior (AS-OCT). **Resultados:** Os resultados do teste de Schirmer 1 foram 12,07 ± 1,51 [9-16] mm para os olhos direitos (grupo samfilcon A) e 12,09 ± 1,5 [9-16] mm para os olhos esquerdos (grupo senofilcon A) em V0. (p = 0,950) Em V2, os resultados médios do teste de Schirmer 1 foram 11,92 ± 1,34 [9-15] mm no grupo samfilcon A e 12,2 ± 1,41 [9-16] mm no grupo senofilcon A (p = 0,239). As dimensões médias do TMA nas imagens AS-OCT foram 338,42 ± 47,1 [241-401] mícrons no grupo samfilcon A e 338,42 ± 47,1 [241-401] mícrons no grupo senofilcon A em V0. (p> 0,05).> Em V2, as dimensões médias do TMA foram 337,2 ± 45,53 [241-402] mícrons no grupo samfilcon A e 340,31 ± 48,22 [240-411] mícrons no grupo senofilcon A (p = 0,728). **Conclusões:** O nosso estudo demonstrou que as lentes de contacto que contêm material de hidrogel de silicone de samfilcon A e senofilcon A não causam problemas significativos na superfície ocular.

Descritores: Géis de silicone; Lentes de contato; Fenômenos fisiológicos oculares; Lágrimas

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Introduction

The availability and popularity of contact lenses keep being on the rise day by day for individuals with refractive errors.[1,2] Furthermore, there is a sustained development in the contact lens technology and there is an extending range of varieties.[3,4] Oxygen permeability is an important parameter for the construction of lens materials.[4-7] Because silicone hydrogel contact lens materials provide better oxygen permeability compared to conventional hydrogel materials, they ensure a more comfortable and safe use for patients.[8-13] Moreover, irritation and foreign body sensation occur less commonly with this type of lenses since their water retention properties are better compared to those made of other types of material.[14-18] Polyvinylpyrrolidone (PVP) has been used in the structure of silicone hydrogel contact lenses for many years.[3,16-19] Manufacturers are continuously in the search of developing contact lenses made of different silicone hydrogel materials.[18-21] These efforts form the grounds of advances in the development of more comfortable and safer contact lenses for use.[7-10,22,23]

The aim of our study is to investigate the effects of two types of contact lenses, which were made of two different types of silicone hydrogel material. To determine the effects of these lenses on the eye, the tear function tests, and the dimensions of the tear meniscus area (TMA) were evaluated.

Methods

In the period from January 2018 to November 2018; 116 eyes of 58 patients were included in the study, who applied for the treatment of refractive errors to the Department of Ophthalmology of the Faculty of Medicine of Erzincan University. Informed consent was obtained from all patients. The study was designed as a single-blind, prospective, single-center study. The principles of the Declaration of Helsinki were followed during the conduct of the study.

Inclusion criteria

All patients were contact lens users at least one year. Participants were aged 18 or above, myopic, able to achieve visual acuity of 20/20 (LogMAR:0) with spherical contact lenses and were absent of any ocular or systemic condition and medications, which would preclude contact lens wear or affect ocular health.

Exclusion criteria

Patients who did not attend the regular follow-up visits, and who had astigmatism degrees of more than 0.25 diopters and contact lens user less than one year were excluded from the study.

Lenses

The contact lenses with the appropriate diopters were supplied to the volunteering patients so that the Bausch and Lomb® Ultra contact lenses containing samfilcon A silicone hydrogel material and the Johnson-Johnson Vision® Acuvue Oasys contact lenses containing senofilcon A silicone hydrogel material would be worn to the right (samfilcon A group) and left (senofilcon A group) eyes respectively.

Clinical evaluation

The patients used these contact lenses for three month without knowing which contact lens they wore on which eye. Participants were instructed to wear the contact lenses for a minimum of 6 days/week and 8 hr/day. Participants attended a baseline visit for assessment of their suitability for the trial and were dispensed with contact lenses if suitable. The best-corrected visual acuity according to the Snellen chart and autorefractometer measurements were determined, and detailed biomicroscopic and fundoscopic examinations were performed in all patients. Before the start of the use of contact lenses in the study; all patients were evaluated with tear function tests (Schirmer 1 test and the tear film break-up time (TBUT) test) and the dimensions of the tear meniscus area with anterior segment optical coherence tomography (Nidek Co., Ltd., Japan). They attended follow-up visits at 1st month and 3rd month. At each visit, ocular physiological variables were collected using a 0 to 4 (0.5 steps) CCLRU (Cornea and Contact Lens Research Unit grading scale)[24] and the tear function tests (Schirmer 1 test, TBUT test) were performed and the tear meniscus area was visualized with AS-OCT. Corneal staining was graded using fluorescein strips (Fluorets ophthalmic strips, 1 mg; Chauvin Pharmaceuticals, Essex, United Kingdom) together with a cobalt blue light and yellow Wratten 12 filter.

Statistical analysis

IBM SPSS (Statistical Package for the Social Sciences) Statistics 22 program was used for the statistical analyses. The normality of the distribution of continuous variables was determined by the Kolmogorov-Smirnov test. Descriptive statistics for continuous variables were expressed as means ± SD with ranges [ ] or medians (25th-75th percentile), where applicable. Meanwhile, the categorical data were expressed as numbers of cases and percentages. The independent t-test and ANOVA test were used as the parametric test for comparing the normally distributed data. Post hoc multiple comparisons were adjusted using Bonferroni correction. The Mann Whitney-U analysis was used as the non-parametric test. Analysis of variance in repeated measurements was used for analyzing the repeating data and the Friedman variance analysis was used when the data were not normally distributed. Differences were considered significant if $p \leq 0.05$.

Results

Of the study patients, 31 were males and 27 were females. The mean age of the patients was 27.15 ± 5.73 [18-44] years. The mean refraction values in the study patients were -2.06 ± 1.01 [-0.50_-3.00] D in the samfilcon A group and -2.03 ± 0.92 [-0.50_-3.00] D in the senofilcon A group. There was not a difference between the two eyes with respect to the mean refractive error values (p=0.551). The mean best corrected visual acuity (BCVA) values of all patients included in the study were 20/20 (logMAR:0) for both eyes.

Comparison of 2 groups in terms of tear function tests and AS-OCT measurements are shown in table 1.

The results of Schirmer 1 test were 12.07 ± 1.51 [9-16] mm in the samfilcon A group and 12.09 ± 1.5 [9-16] mm in the senofilcon A group at V0. (p=0.950) At V1; the mean Schirmer 1 test results were 11.89±1.39 [9-15] mm in the samfilcon A group and 12.25±1.38 [8-15] mm in the senofilcon A group. (p=0.113) The mean Schirmer 1 test results were 11.92±1.34 [9-15] mm in the samfilcon A group and 12.2±1.41 [9-16] mm in the senofilcon A group at V2. (p=0.239)

There were no statistically significant differences between the Schirmer 1 test values with in the samfilcon A and senofilcon A groups. (p=0.598 and p=0.854, respectively).

Table 1
Comparison of 2 groups in terms of tear function tests and anterior segment OCT measurements

	Samfilcon -A group	Senofilcon -A group	p-value
Schirmer V0	12,07±1,51	12,09±1,5	0,950
Schirmer V1	11,89±1,39	12,25±1,38	0,113
Schirmer V2	11,92±1,34	12,2±1,41	0,239
TBUT V0	11,96±1,44	11,96±1,44	>0,05
TBUT V1	11,93±1,33	12,1±1,5 0,507	
TBUT V2	12,22±1,29	11,96±1,31	0,272
TMA V0	338,42±47,1	338,42±47,1	>0,05
TMA V1	336,6±46,5	341,88±48,12	0,562
TMA V2	337,2±45,53	340,31±48,22	0,728

The mean tear film breakup time (TBUT) was 11.96±1.44 [9-15] sec in both two groups at V0.(p>0.05) At V1, the mean TBUT was 11.93±1.33 [9-15] sec in the samfilcon A group and 12.1±1.5 [9-16] sec in the senofilcon A group (p=0,507). The mean TBUT was 12.22±1.29 sec in the samfilcon A group and 11.96±1.31 sec in the senofilcon A group at V2. (p=0,272) There were no statistically significant differences between the TBUT values with in the samfilcon A and senofilcon A groups. (p=0.329 and 0.789 respectively)

The mean TMA dimensions in the AS-OCT images were 338.42±47.1 [241-401] microns in the samfilcon A group and 338.42±47.1 [241-401] microns in the senofilcon A group at V0. (p>0.05). The average TMA measurements were 336.6±46.5 [244-402] microns in the samfilcon A group and 341.88±48.12 [240-402] microns in the senofilcon A group at V1. (p=0.562) At V2, the mean TMA dimensions were 337.2±45.53 [241-402] microns in the samfilcon A group and 340.31±48.22 [240-411] microns in the senofilcon A group. (p=0.728)

There were no statistically significant differences between the TMA measurements with in the samfilcon A and senofilcon A groups. (p=0.889 and p=0.829 respectively)

Ocular physiological variables for samfilcon A and senofilcon A groups for all lens wear visits are shown in table 2.

Table 2
Ocular physiological variables for Samfilcon-A and Senofilcon-A groups

	Samfilcon-A group	Senofilcon-A group	P1 value	P2 value	P3 value
Bulbar redness V0	0.09±0.29	0.09±0.29	>0.05		
Bulbar redness V1	0.15±0.44	0.11±0.31	0.623	0.867	0.899
Bulbar redness V2	0.13±0.38	0.13±0.38	>0.05		
Limbal redness V0	0.25±0.51	0.25±0.51	>0.05		
Limbal redness V1	0.31±0.57	0.29±0.56	0.867	0.374	0.789
Limbal redness V2	0.33±0.51	0.31±0.5	0.851		
Upper lid redness V0	0.24±0.42	0.24±0.42	>0.05		
Upper lid redness V1	0.25±0.51	0.24±0.5	0.853	0.782	0.924
Upper lid redness V2	0.27±0.59	0.25±0.58	0.871		
Upper lid roughness$^{\alpha}$ V0	0.15±0.35	0.15±0.35	>0.05		
Upper lid roughness$^{\alpha}$ V1	0.18±0.39	0.16±0.37	0.803	0.534	0.778
Upper lid roughness$^{\alpha}$ V2	0.22±0.41	0.18±0.39	0.637		
Corneal stain. type V0	0.35±0.48	0.35±0.48	>0.05		
Corneal stain. type V1	0.38±0.49	0.36±0.48	0.845	0.556	0.689
Corneal stain. type V2	0.42±0.49	0.4±0.49	0.848		
Corneal stain. depth V0	0.2±0.4	0.2±0.4	>0.05		
Corneal stain. depth V1	0.25±0.44	0.24±0.42	0.827	0.458	0.582
Corneal stain. depth V2	0.27±0.45	0.25±0.44	0.831		
Corneal stain. extent V0	0.25±0.44	0.25±0.44	>0.05		
Corneal stain. extent V1	0.31±0.46	0.33±0.47	0.840	0.155	0.142
Corneal stain. extent V2	0.33±0.47	0.35±0.48	0.842		
Conjunctival staining V0	0.29±0.45	0.29±0.45	>0.05		
Conjunctival staining V1	0.31±0.45	0.33±0.47	0.840	0.637	0.574
Conjunctival staining V2	0.33±0.46	0.36±0.52	0.703		

P1 value: shows p value of difference between the two groups. P2 value: shows p value of parameters within Samfilcon-A group. P3 value: shows p value of parameters within Senofilcon-A group. α: lid roughness which are evaluated with fluorescein staining. stain.: staining.

There wasn't any significant increase in bulbar redness compared to baseline visit (V0) both in samfilcon A and senofilcon A groups. (p=0.867 and 0.899 respectively) There was no difference between two groups in terms of bulbar redness for all visits (V0,V1 and V2). (p>0.05, 0.623 and >0.05 respectively)

There wasn't any significant increase in limbal redness compared to baseline visit (V0) both in samfilcon A and senofilcon A groups. (p=0.374 and 0.789 respectively) There was no difference between two groups in terms of limbal redness for all visits (V0,V1 and V2). (p>0.05, 0.867 and 0.851 respectively)[9]

There was no statistically significant change in upper lid redness compared to V0 both in samfilcon A and senofilcon A groups. (p=0.782 and 0.924 respectively) There wasn't any difference between two groups in upper lid redness for all visits (V0,V1 and V2). (p>0.05, 0.853 and 0.871 respectively)

There wasn't any significant increase in upper lid roughness compared to baseline visit (V0) both in samfilcon A and senofilcon A groups. (p=0.534 and 0.778 respectively) There was no difference between two groups in terms of limbal redness for all visits (V0,V1 and V2). (p>0.05, 0.803 and 0.637 respectively)

There was no significant increase in the grade of the corneal staining type compared to V0 both in samfilcon A and senofilcon A groups. (p=0.556 and 0.689 respectively) There wasn't any difference between two groups in the grade of the corneal staining type for all visits (V0,V1 and V2). (p>0.05, 0.845 and 0.848 respectively)

There wasn't any significant increase in the grade of the corneal staining depth compared to baseline visit (V0) both in samfilcon A and senofilcon A groups. (p=0.458 and 0.582 respectively) There was no difference between two groups in terms of the grade of the corneal staining depth for all visits (V0,V1 and V2). (p>0.05, 0.827 and 0.831 respectively)

There was no significant increase in the grade of the corneal staining extent compared to V0 both in samfilcon A and senofilcon A groups. (p=0.155 and 0.689 respectively) There wasn't any difference between two groups in the grade of the corneal staining extent for all visits (V0,V1 and V2). (p>0.05, 0.840 and 0.842 respectively)

The increase in conjunctival staining wasn't statistically significant compared to baseline visit both in samfilcon A and senofilcon A groups. (p=0.637 and 0.574 respectively) There was no difference between two groups in conjunctival staining for all visits (V0,V1 and V2). (p>0.05, 0.840 and 0.703 respectively)

Discussion

The aim of our study was to compare the effects of two different types of contact lenses on the tear function tests and ocular physiological parameters. These lenses were different in their structures, containing samfilcon A and senofilcon A silicone hydrogel material. The statistical analyses showed that there were no differences between these two different types of silicone hydrogel material in the contact lenses in regards to their effects on the tear function tests and on the ocular physiological variables.

The number of studies evaluating the comparative effects of these two different silicone hydrogel materials is limited in the literature. Schafer et al. evaluated the contact lenses containing either samfilcon A or senofilcon A silicone hydrogel material in regards to their effects on the results of the blink test in their study, reporting that the need for blinking occurred later and better visual stability was obtained with the use of the contact lenses containing samfilcon A compared to those lenses containing senofilcon A.[25]

Tasci et al. compared three types of contact lenses containing senofilcon A, balafilcon A, and comfilcon A silicone hydrogel materials respectively in their study and they found no significant differences between these three different silicone hydrogel materials in causing dry eye symptoms.[26]

Diec et al. compared two types of contact lenses containing silicone hydrogel and hydrogel material in regards to the side effect profile and the degree of comfort experienced by the users.[27] It is stated that contact lenses containing silicone hydrogel material can be preferred to reduce hypoxia-related side effects because lenses containing this agent provided a higher level of oxygen permeability.[27]

Mukherjee et al. compared bandage contact lenses containing comfilcon A and senofilcon A silicone hydrogel material after photorefractive keratectomy surgery, finding out that the pain scores were lower in the senofilcon A group in their study.[28]

A limitation to our study was that only two types of silicone hydrogel materials (samfilcon A and senofilcon A) were evaluated. Another limitation of the study was that the patients had only three month follow-up time.

Conclusion

Our study has demonstrated that contact lenses containing samfilcon A and senofilcon A silicone hydrogel material do not cause any meaningful dry eye symptoms and ocular physiological disorders. Furthermore, no differences were seen between the use of these two types of contact lenses in regards to the emergence of any untoward effects on the ocular surface.

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