Galician medical journal 2016 Vol. 23, Issue 4, E201647 DOI: 10.21802/gmj.2016.4.7

**Research Article** 

## Compliance as an Integral Part of the Dry Eye Syndrome Prevention Using Silicone Hydrogel Contact Lenses

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#### Abstract

The probability of dry eye syndrome (DES) in the patients using the Silicone-Hydrogel Contact Lenses is examined in many researches. Therefore, adhering to clinical recommendations is an important factor for DES prevention. The urgent issue is also a comprehensive assessment of functional parameters as pathogenetic base of DES.

The objective of the research was tostudy DES development depending on compliance of silicone hydrogel contact lenses users.

**Matherials and methods.** 97 patients (194 eyes) were included into the research. They formed 2 groups: group I with incomplete compliance (36 persons) and group II with complete compliance (61 persons). All the patients underwent the Norn's test, Schirmer's test, Jones test, tear film stability was defined. The probability of the dry eye syndrome development due to the subjective signs was also analysed.

**Results.** The reliable decrease in the total (p<0.05) and basale lacrimation (p<0.05) indexes, the increase in osmolarity (p<0.05) and decrease in tear film stability (p<0.05) were detected in the patients who did not follow the clinical guidance during the Silicone-Hydrogel Contact Lenses wearing. In the same group the higher risk of dry eye syndrome development was verified (p<0.05).

**Conclusion.** Compliance disorder in the patients using Silicone-Hydrogel Contact Lenses was found to induce the reliable decrease in total and basale lacrimation, increase in osmolarity and tear stability disorder. All of this factors increase the risk of dry eye syndrome.

#### Keywords

compliance; Silicone-Hydrogel Contact Lenses; dry eye syndrome; lacrimation; osmolarity

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# Problem statement and analysis of the recent research

According to various authors, dry eye syndrome (DES) is observed in 15.0-17.0% of adults on average and its incidence grows every year [10]. Among patients who visited an ophthalmologist DES constituted a significant part of cases identifying a direct dependence on the patients' age, namely 12.0% of patients under 40 years of age and over 67.0% of patients older than 50 [12]. However, the application of contact correction of DES refraction is diagnosed in 21.0% of patients. Most of the DES cases are proved to be pathogenetic basis for inflammation development [11].

Nowadays, the term "dry eye syndrome" is understood as a number of diseases. Accordingly, the destruction of ocular surface is a complex pathology, the presence of which may affect a particular layer of the tear film, namely lipid, watery, mucin. Each of the layers plays a special role in protecting the ocular surface [17].

Soft contact lenses (SCL) are known to be currently widely

used as a means of correcting different types of ametropia [4]. Silicone Hydrogel Contact Lenses (SHCL) have a higher oxygen transmission coefficient compared to other SCL, which is more acceptable to the cornea. Hydrophilic phase in the lenses of this group provides excellent surface moistening of lenses, sufficient lacrimation and fluid transporting through the lens. Numerous studies confirm that SHCL have the best rate of oxygen transmission nowadays due to its properties and are the most suitable contact lenses from a physiological point of view. At the same time, silicon increases the lens elasticity, therefore some patients cannot tolerate silicone component of silicone hydrogel. In addition, high oxygen passing promotes the activation of cornea protein peroxidation. One of the causes of dryness and discomfort is also dehydration of contact lenses. Taking into account the structure, silicone hydrogel lenses have a high content of moisture and at the same time, greater water content of the lens leads to faster evaporation, and as a result, dehydrated SCL becomes adsorbent of water which is in the tear film [16]. In connection with the

above mentioned factors, SHCL are related to those artificial factors, which lead to the decrease in the tear film stability at the presence of a number of factors. This, in its turn, can cause the development of SCL clinical manifestations [5].

Dehydration of contact lenses is considered to be one of the reasons for dryness and discomfort. Taking into account their structure, silicone hydrogel lenses have a high content of moisture. Greater water content of the lens leads to faster evaporation, and as a result, dehydrated SCL becomes water adsorbent in the tear film [15].

In this case, it is essential to stick to the regimen of replacement and maintenance of contact lenses [7]. Compliance is understood as the complex of measures aimed at patient's flawless and deliberate adherence to medical advice. Difficulties with treatment can occur in any age group, equally among men and women, among people with different levels of education, among patients of any socio-economic status.

A number of studies have shown that only 50.0% of patients using one- or two-week soft contact lens follow the replacement schedule [6]. Another important issue is following the rules of lens care. In general, 70.0% of patients are believed to clean and disinfect lenses properly. Thus, about 75.0% of patients wash their hands before handling contact lenses. However, only 60.0-64.0% of patients wipe their lenses according to instructions. Every step in contact lenses care is known to be important. Therefore, for the foregoing reasons, almost 40.0% of users are at risk of having discomfort or complications caused by wearing them [6, 18]. Thus, complete compliance is a voluntary following the orescribed regimen, incomplete compliance is its deliberate violation.

Thus, analyzing the safety and comfort of silicone hydrogel SCL it can be noted that the probability of DES development is considered against the background of their use in the majority of researches [8, 9]. However, the dynamic research of the clinical picture of the dry eye having developed after systematic use of SCL according to clinical recommendations is undoubtedly important [13]. A topical issue is the comprehensive assessment of functional parameters reflecting lacrimation and tear film stability during the development of pathological process.

The need for such research is obvious, since the problem of DES among SCL wearers due is urgent and requires careful study to the growing popularity of contact correction.

The objective of the research was to analyze the tolerance of silicone hydrogel contact lenses and to verify the likelihood of dry eye syndrome depending on the patients' compliance.

#### 1. Material and methods

The research included 97 patients (194 eyes) from 18 to 49 years of age (average age  $33.8 \pm 7.15$  years) with diopter myopia 1.5-6.5. In order to correct refraction all patients for a long time were using silicone hydrogel SCL allowed for continuous wear for 30 days. Depending on adherence to recommendations regarding the care and regimen of wearing, according to the survey, the patients under research were di-

vided as follows: 36 patients indicated certain violations of SCL using (37.1%, incomplete compliance, group I), wearing schedule was not violated in 61 people (62.9% complete compliance, group II). Average length of wearing constituted 7.89  $\pm$  3.21 years (2-10 years), this indicator constituted 7.7  $\pm$  4.31 years in group I and 7.4  $\pm$  4.5 years in group II.

Such special tests as the study of total lacrimation (Shirmer's test) [1], the stability of the tear film (Norn's test) [2] and determining osmolarity of tears were used to achieve this goal in addition to conventional methods (visiometry, pneumonometry, biomicroscopy, ophthalmoscopy). Tear osmolarity was studied using the instrument Tearlab Osmolarity System (Tearlab Corp., USA).

Analysis of the results was performed using software Statistica for Windows 7.0 (StatSoft Inc., USA) and Excel - 2007 (Microsoft, USA). Data were presented as  $M \pm m$ , where M average, m - standard deviation. The reliability of differences was determined using Student t-test. Additional assessment of the compliance role was conducted taking into account clinical consequences, absolute (AR%) and relative (RR) risks and odds ratio (OR), with the calculation of confidence intervals and test accuracy of RR and OR. Discrete values were presented as frequencies (percentage of the total number of examined patients).  $\chi^2$  Pearson criterion was used to compare discrete variables in the independent groups. Values of p<0.05 were considered statistically significant [3].

## 2. Results of the research and their discussion

The results of the research indicated that among 36 patients referred to the group of incomplete compliance the majority of them did not stick to the term of contact lenses wearing (91.7%, 33 people) and continued to use them till the emergence of discomfort. The duration of use after the expiration ranged from 3 to 26 days ( $12.9 \pm 7.89$ ). In addition, 58.3% (21 people) did not visit an ophthalmologist for over a year, despite some discomfort while wearing contact lenses (47.2%, 17 people.), also 33.3% (12 people) indicated independent increase in the lenses refraction during subjective feeling of reduced visual acuity, some patients (16.7%, 6 pers.) changed the way they cared for lenses themselves, while only one of them (2.8%) consulted the doctor on this matter.

According to the result of Norn's test, patients with contact correction of refraction using silicone hydrogel contact lenses with complete compliance had significantly higher levels of tear film stability (p < 0.05) (Table 1).

A similar regularity was found in the study of parameters during Shirmer's test and Jones test (Table 2). Probable decrease in parameters of both total (p<0.05) and basal lacrimation (p<0.05) were marked in case of violation of wearing conditions, recommendations for SCL care and selection.

On assessing the level of osmolarity a slight increase in both groups was noticed. However, values of this indicator were higher in patients using silicone hydrogel contact lenses **Table 1.** Indicators of the tear film stability in case of incomplete and complete compliance during the use of silicone hydrogel contact lenses.

	Group I n=36	Group II n=61
The stability of the tear film	10.1±2.13	14.2±1.84*

Note.

\* - significant difference in indices between the study groups

**Table 2.** Indicators of total and basal lacrimation in case of incomplete and complete compliance during the use of silicone hydrogel contact lenses.

	Group I n=36	Group II n=61
Shirmer's test	$12.4{\pm}2.14$	16.3±3.12*
Jones test	9.5±1.87	11.8±1.56*

Note.

\* - significant difference in indices between the study groups

in case of incomplete compliance than in those patients, who carefully followed the regimen of wearing and care (Table 3).

**Table 3.** Osmolarity indices in case of incomplete and complete compliance during the use of silicone hydrogel contact lenses.

	Group I n=36	Group II n=61
Osmolarity	323.8±22.1	312.2±12.4*

Note.

\* - significant difference in indices between the study groups

In addition, significantly (p < 0.05) less number of "normoosmolar" patients was detected in group I constituting 16.7% against 50.8% (Table 4).

Thus, the non-adherence of silicone hydrogel contact lenses wearing resulted in decrease in Shirmer's and Jones's tests reflecting insufficient lacrimation and the increase in absorption of water part of tears by lenses, and, consequently, increased osmolarity and decreased stability of the tear film, which eventually led to the development of DES.

The dry eye syndrome is characterized by symptoms of discomfort, visual impairment and damage of the surface of the eyeball. Pathogenetic basis of the syndrome is increase in the tears osmolarity and ocular surface inflammation [14].

According to the analysis of clinical symptoms, subjective manifestations of DES of AR and RR and OR was assessed in patients using silicone hydrogel contact lenses with varying **Table 4.** Distribution of the studied patients depending on

 the degree of osmolarity and compliance level during the use
 of silicone hydrogel contact lenses.

	Group I n=36	Group II n=61
Normoosmolarity, %	6 (16,7)	31 (50,8)*

Note.

 \* - difference in the indices of the study groups according χ<sup>2</sup> Pearson criterion

degrees of compliance (Table 5).

AR and RR of pain and dryness were found to be higher when compliance was violated (22.0 and 36.0%, against 10.0 and 19.0%, RR – 2.26 [0.85-5.99] and 1.90 [0.96-3.79]). A similar trend was also obtained for such subjective sensations like burning sensation and fluctuations in visual acuity in case of non-compliance with recommendations (AR 17.0 and 25.0% versus 7.0 and 10.0%, RR - 2.54 [0. 77-8.42] and 2.54 [0.99-6.56]). Reliable RR and OR indices in patients with incomplete compliance were established for such subjective symptoms as a foreign body sensation (AR - 25.0 versus 8.0%, RR - 3.05 [1.11-8.40] OR - 3.73 [1.14-12.24]) and the tolerance of the wind (AR - 25.0 versus 10.0%, RR – 1.89 [1.14-3.15] OR – 2.89 [1.22-6.85]).

Thus, complications appearing due to SCL wearing schedule violation were associated with inadequate levels of lacrimation that, ultimately, increased the risk of DES.

#### 3. Conclusions

According to the analysis of compliance level as a risk factor for dry eye syndrome of patients using silicone hydrogel contact lenses, violations of wearing were found to be accompanied by a decrease in total and basal lacrimation, increased osmolarity and instability of the tear film.

On the background of the identified physiological disorders a significant increase in clinical subjective manifestations of dry eye syndrome, their absolute and relative risk and odds ratio of patients who had indicated incomplete compliance when using silicone hydrogel contact lenses during the survey were detected.

### 4. Prospects for further research

Promising research trend involves a thorough analysis of other risk factors for dry eye syndrome such as social background, namely age, sex, environmental factors, professional orientation and medical prerequisites, namely concomitant somatic and ophthalmic diseases.

The relevance of this trend is caused by the fact that such studies based on evidence-based medicine principles have not been conducted in our country yet. An interesting issue is the introduction of such method as lacrimal fluid crystallography

<b>Table 5.</b> Distribution of the studied patients depending on the degree of osmolarity and compliance level during the use of		
silicone hydrogel contact lenses.		

Manifestations	Groups	AR	RR	OR
Pain on instillation of eye drops	Group I Group II	22.0% 10.0%	2.26 [0.85-5.99]	2.62 [0.83-8.30]
Dryness	Group I Group II	36.0% 19.0%	1.90 [0.96-3.79]	2.42 [0.94-6.22]
Foreign body sensation	Group I Group II	25.0% 8.0%	3.05 [1.11-8.40]	3.73 [1.14-12.24]
Burning sensation	Group I Group II	17.0% 7.0%	2.54 [0.77-8.42]	2.85 [0.75-10.9]
Poor tolerability of wind	Group I Group II	53.0% 28.0%	1.89 [1.14-3.15]	2.89 [1.22-6.85]
Fluctuations in visual acuity throughout the day	Group I Group II	25.0% 10.0%	2.54 [0.99-6.56]	3.06 [0.99-9.58]

Note.

\* - difference in the indices of the study groups according  $\chi^2$  Pearson criterion

into ophthalmic practice providing an opportunity to study the pathogenetic basis for tear film formation more thoroughly.

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Received: 23 September 2016

Revised: 20 October 2016

Accepted: 24 October 2016