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MINISCLERAL LENSES IN THE TREATMENT OF PATIENTS WITH DRY EYE SYNDROME (FIRST OWN EXPERIENCE)

© K. Fedotova, V.R. Grabovetsky, S.A. Novikov, M. Ezugbaya

Academician I.P. Pavlov First St. Petersburg State Medical University of the Ministry of Healthcare of the Russian Federation, Saint Petersburg, Russia

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✧ ***Background.*** Scleral lenses, due to their benefits, hold a specific position among all types of contact lenses. Some years ago, they began to be used successfully not only for the correction of complex types of refractive errors, when other types of correction failed to achieve satisfactory visual function and visual rehabilitation of patients, but also as a therapeutic system in the management of ocular surface disease. ***Purpose.*** To evaluate the efficacy of rigid gas permeable miniscleral contact lenses as a therapeutic system in the management of patients with dry eye syndrome by filling the space under the lens with a non-preserved sodium hyaluronate solution. ***Materials and methods.*** In the study, 7 patients (11 eyes) with keratectasias after corneal surgery and concomitant dry eye syndrome were included. In the treatment and rehabilitation of these patients, miniscleral contact lenses were used during daytime with additional filling of the space under the lens with a non-preserved sodium hyaluronate solution. ***Results.*** As a criterion of the effectiveness of miniscleral contact lens use for therapeutic purposes, along with a significant increase in visual function in patients with complex corneal pathology, the elimination of discomfort due to restoration of the corneal epithelium integrity and improvement of their quality of life is considered.

✧ ***Keywords:*** scleral lenses; rigid gas permeable miniscleral contact lenses; dry eye syndrome; ocular surface disease.

МИНИСКЛЕРАЛЬНЫЕ КОНТАКТНЫЕ ЛИНЗЫ В ЛЕЧЕНИИ ПАЦИЕНТОВ С СИНДРОМОМ СУХОГО ГЛАЗА (ПЕРВЫЙ СОБСТВЕННЫЙ ОПЫТ ПРИМЕНЕНИЯ)

© К. Федотова, В.Р. Грабовецкий, С.А. Новиков, М. Эзугбая

ФГБОУ ВО «Первый Санкт-Петербургский государственный медицинский университет им. акад. И.П. Павлова» Минздрава России, Санкт-Петербург

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✧ ***Введение.*** Склеральные линзы в силу своих свойств занимают особо место среди всех типов контактных линз. Несколько лет назад они стали успешно применяться не только для коррекции сложных видов аномалий рефракции, когда другие способы коррекции не позволяют достигнуть удовлетворительных зрительных функций и визуальной реабилитации пациентов, но и в качестве терапевтического средства, когда в подлинзовое пространство дополнительно вводят лекарственный препарат для лечения заболеваний глазной поверхности. ***Цель*** — оценить эффективность применения жёстких газопроницаемых минисклеральных контактных линз в качестве лечебного средства у пациентов с синдромом сухого глаза посредством введения в подлинзовое пространство бессконсервантного раствора гиалуроната натрия. ***Материал и методы.*** В исследовании приняли участие

7 пациентов (11 глаз) с кератэктазиями после оперативных вмешательств на роговице с сопутствующим диагнозом — «синдром сухого глаза». В лечении и реабилитации этих пациентов применяли минисклеральные контактные линзы в дневном режиме ношения с дополнительным введением в подлинзовое пространство бесконсервантного раствора гиалуроната натрия. ***Результаты.*** Критерием эффективности применения миниклеральных контактных линз в лечебных целях наряду со значительным улучшением зрительных функций у пациентов со сложной патологией роговицы является также устранение дискомфорта благодаря восстановлению целостности эпителия роговицы и повышению качества их жизни.

✧ ***Ключевые слова:*** склеральные линзы; жёсткие газопроницаемые миниклеральные контактные линзы; синдром сухого глаза; заболевания глазной поверхности.

INTRODUCTION

The possibilities of using rigid gas-permeable miniscleral contact lenses (RGMCLs) are currently expanding due to development of polymer materials with a high rate of oxygen transmission, advent of automated computerized lens manufacturing technologies that involve the possibility of considering individual parameters for each patient, and gradual increase in the patient register and the accumulation of practical experience. Scleral lenses are rigid, gas-permeable, large-diameter contact lenses that rest completely on the sclera while avoiding contact with the surface of the cornea since the space under the lens is filled with physiological saline solution. During wear, the lens and the reservoir of fluid formed beneath it, together with the refractive media of the eye, create a new regular optical surface that corrects the irregularity of the cornea.

The pioneers of contact vision correction were A. Fick, E. Kalt, and A. Muller, who first created scleral lenses and started to use them at the end of the 19th century to achieve the correction of visual acuity in patients with high degrees of myopia, astigmatism, and keratoconus. Early lenses were made of mineral glass. The space under the lens was filled with various solutions, but rather quickly arising corneal edema hindered significantly the wearing time of these lenses. Later on, it was proposed to fill the space under the lens with physiological saline solution, which turned out to be more effective than water and glucose solution used earlier. In 1937, scleral lenses began to be made from polymethyl methacrylate by way of a compression process. After some time, the adoption of the lathe turning method became widespread. However, production difficulties inherent in manufacturing and selecting lenses, and the lack of oxygen permeability of the material limited interest in scleral lenses until the creation of new gas-permeable materials [1].

The scleral lens is an individual optical medical device designed to correct complex types of refraction anomalies associated with a change in the shape and structural aspects of the cornea. Recently, in the foreign literature, there are more and more clinical examples being published of the successful therapeutic use of scleral lenses in patients with ocular surface diseases [2]. The data of the Scleral Lenses in Current Ophthalmic Practice Evaluation research group indicate that, in 74% of cases, this type of lens was prescribed as an optical device to a patient with an irregular cornea surface shape; in comparison, in 10% of cases, it was prescribed to those having regular corneas with refraction anomalies, while, in 16% of cases, diseases of the ocular surface were the indications for the scleral lens use [3].

In 2013, the Scleral Lens Education Society developed an international nomenclature that characterizes rigid, gas-permeable contact lenses by the location of the lens support portion. Scleral lenses belong to the category of lenses that have a scleral support. They are further classified according to diameter into miniscleral and large scleral lenses. The diameter of miniscleral lenses exceeds the horizontal visible diameter of the iris by up to 6 mm, while the diameter of large scleral lenses exceeds it by more than 6 mm [4].

The advantages of rigid gas-permeable lenses for complex corneal pathology have been proven. First of all, wearing them enables one to achieve high visual functions in the context of primary and secondary keratectasia and after surgical interventions (e.g., keratoplasty, anterior radial keratotomy) [5]. They also create a physical barrier and provide mechanical protection for the cornea from the effects of blinking movements of the eyelids and from the environment. As a result of high oxygen permeability of the material, the presence of a fluid reservoir between the cornea and the posterior lens surface, and the absence of contact between the lens and the surface of the cornea, optimal conditions are created for maintaining homeostasis and constant moistening of the corneal surface.

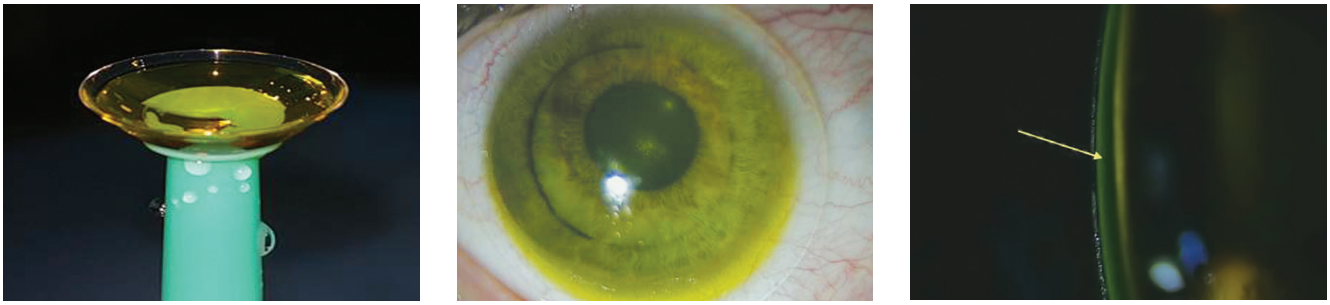
There are numerous studies and clinical examples suggesting the safety and efficacy of scleral lenses in the treatment of diseases such as dry eye syndrome (DES) of various severity [6–8], Stevens-Johnson syndrome [9], Sjogren's disease [10], and neurotrophic keratopathy [11]. Scleral lenses are also successfully used to treat persistent corneal epithelial defects [12]. RGPCLs are commonly applied in cases when traditional methods of treating the above diseases are ineffective. Studies have shown that, after 12 months of wearing scleral lenses, a decrease in the osmolarity of the tear film can be registered; moreover, a significant improvement in subjective symptoms and an increase in the quality of life of patients are also reported [13].

Although scleral lenses have many potential advantages in ocular surface diseases, they are not recommended for use as initial therapy. According to the 2017 TFOS DEWS II report, therapeutic contact lenses (both soft and rigid) are recommended to be used at the third stage of DES treatment [14]. Soft therapeutic contact lenses are widely incorporated not only as a biological dressing for relief from pain and for mechanical protection of the cornea but also as an ophthalmic prolonged-release drug dosage delivery modality for the treatment of various pathological conditions of the anterior segment [15–19].

There are few reports that discussed the possibility of the therapeutic use of scleral lenses as a promising and effective way to deliver drugs by introducing them into the space under the lens. Thus, for the treatment of persistent corneal epithelium defects that are resistant to other therapeutic methods, scleral lenses are worn continuously, with the exception of one or two short breaks per day when the lens is removed for disinfection and to replace the fluid reservoir. In addition to the preservative-free sterile physiological saline solution, one drop of a fourth-generation fluoroquinolone, 0.5% moxifloxacin, is generally added into the space under the lens. After the corneal epithelial defect healing is achieved, patients are typically transferred to soft lens wear to minimize the risk of relapse. According to the results of studies in which this method of treatment was used, there were no cases of bacterial keratitis [20]. In comparison, in the very first studies, the incidence of bacterial keratitis amounted to 11%, 14%, and 29% of cases, respectively [21–23]. As a rule, bacterial keratitis developed in patients who did not add a drop of antibiotic into the reservoir under the lens, or who added a drop of a topical glucocorticoid instead. In the foreign literature, a notable case has been described on the treatment of corneal neovascularization by the addition of an anti–vascular endothelial growth factor drug into the space under the lens [24]. A clinical example of severe DES treatment with a scleral lens in a patient with lagophthalmos due to facial nerve paralysis has also been described. In this instance, a preservative-free ophthalmic gel was used to fill the space under the lens before the lens was placed. Additionally, instillations of artificial tears on the outer surface of the lens were applied. The patient wore the lens daily for intervals of six hours, cleaning and refilling the lens with the ophthalmic gel in between. As a result, after three months of treatment, punctate keratopathy, revealed by staining of the cornea and conjunctiva with lissamine green, had decreased and the patient's quality of life had improved [25].

In 2016, the first preclinical study on rabbits was performed, which aimed to assess the local tolerance and intraocular diffusion of a 0.3% ofloxacin solution filled into the space under the lens. As a result, it was found that the average concentration of ofloxacin in the intraocular fluid and the corneal homogenate exceeded the minimum inhibitory concentration for 90% of the microorganisms responsible for the development of keratitis. In addition, an analysis of optical microscopy findings showed minimal inflammation with several neutrophilic granulocytes in the limbal area. The central corneal epithelium was further examined using scanning electron microscopy, which revealed that the epithelium remained intact [26]. The data thus far obtained indicate the need for further research, and the presence of signs of inflammation may justify reducing the concentration of the administered dose of the antibiotic.

At the Department of Ophthalmology, Academician Pavlov St. Petersburg State Medical University, studies to increase the treatment efficacy of patients with corneal dystrophy using collagen crosslinking are being conducted. An important step in this procedure is the full saturation of the cornea with a photosensitizer. The first studies in this area concerned the use of a soft contact lens with an ultraviolet filter to protect against limb stem cell irradiation. Using a trepan, a hole was created in the lens, with a diameter corresponding to the de-epithelialization zone, and the lens was turned out so that the photosensitizer would contact the cornea surface for longer during instillation. Later, a new methodology was developed for the use of miniscleral lenses to optimize the process of cornea saturation with a photosensitizer, which brokered the granting of a patent (reference no. 039233, registra-



a *b* *c*

Fig. 1. A method for cornea saturation with a photosensitizer using a miniscleral lens: *a* – the posterior aspect of the miniscleral lens is filled with photosensitizer solution; *b* – regular distribution of the photosensitizer over the entire surface of the cornea; *c* – biomicroscopic image – the arrow shows the space under the lens filled with photosensitizer

Рис. 1. Способ насыщения роговицы фотосенсибилизатором при помощи мини-склеральной линзы: *a* — внутренняя поверхность мини-склеральной линзы заполнена раствором фотосенсибилизатора; *b* — равномерное распределение фотосенсибилизатора по всей поверхности роговицы; *c* — биомикроскопическая картина при надетой склеральной линзе — стрелкой показано подлинзовое пространство, заполненное фотосенсибилизатором

tion no. 2018124705) for the invention "A method for conducting collagen crosslinking of the cornea of the eye," dated May 7, 2018 (Fig. 1). The advantages of the proposed method consisted in significant reduction and simplification of the process of cornea saturation, decrease in the photosensitizer consumption, and increased patient comfort during collagen crosslinking of the cornea.

This study aimed to evaluate the efficacy of the use of RGPCLs as therapeutic agents in patients with DES by introducing a preservative-free sodium hyaluronate solution into the sublens space.

MATERIALS AND METHODS

The present study was conducted in the Ophthalmology Department of the Academician Pavlov St. Petersburg State Medical University. It involved seven patients (11 eyes), including three women and four men, with an average age of 41.6 ± 20.6 years (range: 20–79 years). A complex corneal pathology was diagnosed in each of the study participants—specifically, primary or secondary keratectasia after surgical intervention, anterior radial keratotomy, penetrating keratoplasty, or laser-assisted *in situ* keratomileusis (LASIK). All patients had a concomitant pathology in the form of DES of the second or third degree of severity. Patients reported using artificial tear preparations, but, despite this, they felt discomfort and presented with complaints typical of this condition. In five patients (seven eyes) using vital stains, punctate defects of the epithelium, clinically manifested by keratopathy, were recorded.

A comprehensive ophthalmologic examination was performed, including auto refractokeratometry, visual acuity testing, biomicroscopy of the anterior segment, and indirect ophthalmoscopy. To diagnose pathological changes, cornea and conjunctiva were stained using sterile diagnostic fluorescein strips. In addition to routine diagnostic methods, keratotopography and optical pachymetry were performed using a keratotopograph with a TMS 5 Sheimpflug camera (Tomey Corporation, Nagoya, Japan). Next, miniscleral lenses were chosen. Using optical coherence tomography of the anterior segment (Cirrus HD-OCT; Carl Zeiss Meditec, Jena, Germany), the position of the lens was evaluated, including the central clearance (the distance between the lens and the anterior surface of the cornea), change in clearance from the center to the periphery of the cornea, limbal clearance, and position of the peripheral support area. Based on the individual parameters obtained, customized miniscleral lenses were made of a material with high oxygen permeability (Dk = 100) using high-precision computerized machines.

Patients wore the manufactured lens as part of their daily regimen and filled them with a preservative-free sodium hyaluronate solution before each use. If necessary, artificial tear preparations were additionally instilled on the anterior surface of the lens throughout the day.

During the follow-up period, at each visit, visual acuity was determined while wearing the miniscleral lenses; anterior segment biomicroscopy was performed; and the severity and degree of punctate corneal epitheliopathy as well as the nature of the subjective sensations experienced when wearing the lenses were evaluated.

RESULTS AND DISCUSSION

Previously, the patients in this study did not use vision correction means due to the limited avail-

able selection of lenses and their intolerance to lens wear. Table 1 presents the nosological forms and results of visual acuity testing during the follow-up. According to autorefractometry, in most cases, it was not possible to determine reliably the degree of refractive error. Thus, the spherical component was in the range of −14.25 to +6.0 diopters (D), while the cylindrical component ranged from −3.0 to −11.5 D. The maximum value of keratometry according to computer keratotopography data presented a wide range of values, from 33.25 to 53.7 D, and the central thickness of the cornea in the center ranged from 398 to 654 μ. The average value of uncorrected visual acuity (VASC, visual acuity sine correction) was 0.23 ± 0.21, while the best corrected visual acuity (BCVA) using trial lens set was 0.52 ± 0.29. After fitting of miniscleral lenses, the mean value of BCVA was 1.04 ± 0.15. Miniscleral lenses of various parameters were chosen, with a diameter of 14.9 or 15.2 mm and a base curvature of 7.0 to 8.3 mm. According to anterior segment optical coherence tomography data, the average value of central clearance was 238.2 ± 48.1 μ.

The patients followed in this study filled the space under the lens with non-preserved sodium hyaluronate solution. As a result, on the first day, they noticed a significant reduction in unpleasant subjective symptoms characteristic of DES. The average lens wear time during the day was 12.8 ± 2.5 h. During the wear time, the patients did not experience discomfort in overall. In addition, the frequency of instillations of artificial tear preparations during the day was reduced. In patients who previously had punctate keratopathy, the integrity of the epithelium was completely restored (six eyes) in a period of one week to two months, with the exception of one patient (one eye, after penetrating keratoplasty), in whom, despite the treatment, signs of superficial keratopathy persisted. The mean follow-up period was 10.14 ± 5.84 months. During this time, no complications were detected, and all patients continue to wear the lenses successfully.

A clinical example of the use of miniscleral lenses in a male patient aged 22 years old is presented henceforth. In 2015, he underwent excimer laser correction of refractive error in both eyes according to the femto-super-LASIK method; in 2016, the same method was used to correct further a mild degree of residual myopia. Six months later, the patient began to notice a decrease in visual acuity, and secondary keratectasia was subsequently diagnosed. In 2017, with an interval of two months, collagen corneal crosslinking of the cornea was performed, first in the right eye and then in the left eye. After four months, the patient came to our clinic for the fitting of miniscleral lenses. His keratometry data are presented in Table 2. The VASC of the right eye was 0.02, while the BCVA amounted to 0.2. Separately, the VASC of the left eye was 0.4, and correction was not possible to achieve. The central thickness of the cornea of the right (RE) and left eye (LE) were 398 and 416 μ, respectively. Both subjective symptoms and objective signs of DES were

Table 1 / Таблица 1

Clinical entities, visual acuity and follow-up time
Нозологические формы, острота зрения и сроки наблюдения пациентов

Patient	Diagnosis	Eye	VASC	BCVA	BCVA in miniscleral lenses	Follow-up, months
1	Keratoconus, deg. II	OS	0.13	0.6	1.0	6
2	State after anterior radial keratotomy	OD	0.25	1	1.33	18
		OS	0.2	0.8	1.0	
3	State after LASIK. Secondary keratectasia	OD	0.02	0.2	0.8	14
		OS	0.4	n/c	1.0	
4	State after PK	OD	0.5	n/c	1.0	14
5	Keratoconus, deg. III	OS	0.13	0.2	1.0	2
6	Cicatricial corneal opacity, macula type	OD	0.05	n/c	1.0	5
	State after LASIK	OS	0.66	n/c	1.0	
7	State after PK	OD	0.1	0.35	1.0	12
		OS	0.08	0.35	1.33	

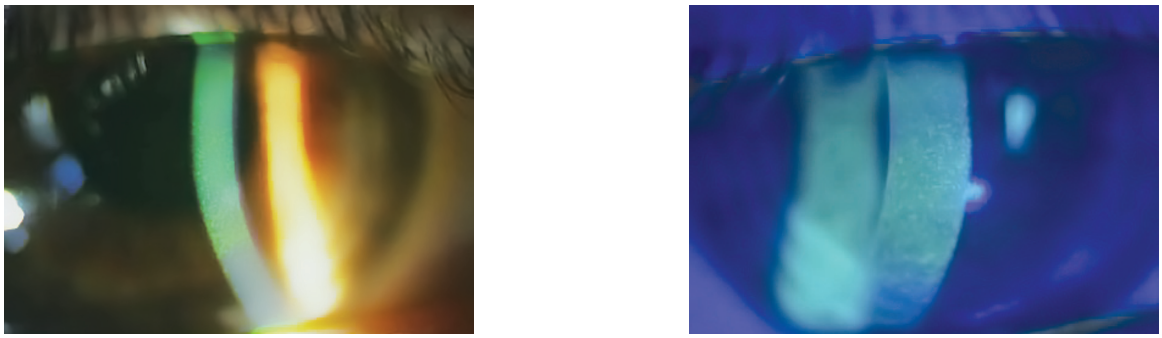
Note. UCVA – uncorrected visual acuity; MCVA – maximum corrected visual acuity with the use of trial spectacle lenses; n/c – visual acuity is not corrected; PK – penetrating keratoplasty.

Table 2 / Таблица 2

Keratometry data
Данные кератометрии

Eye		Radius of curvature, mm	Refraction, diopter	Axis, deg.
Right	R1	8.08	41.75	93
	R2	6.79	49.7	3
Left	R1	8.89	37.95	4
	R2	8.45	39.95	94

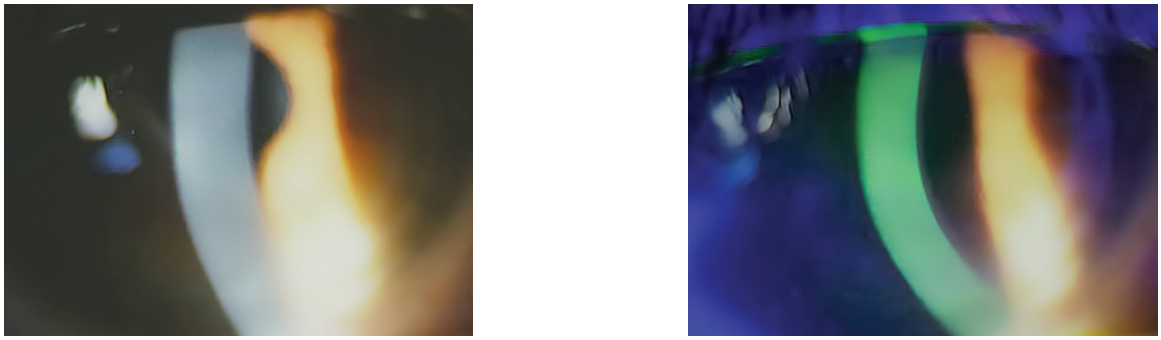
Note. R1 and R2 represent the results of measurements in the maximum and minimum meridians of the cornea.



a *b*

Fig. 2. Cornea of the right eye in a patient with a secondary keratectasia before miniscleral lens wear: *a* – corneal punctuate epitheliopathy (fluorescein staining); *b* – biomicroscopy with a blue cobalt filter

Рис. 2. Роговица правого глаза у пациента с вторичной кератэктазией до ношения минисклеральной линзы: *a* — точечная эпителиопатия роговицы (окраска раствором флюоресцеина); *b* — биомикроскопия в синем кобальтовом фильтре



a *b*

Fig. 3. Cornea of the right eye in a patient with a secondary keratectasia after one month wear of miniscleral lens filled with non-preserved solution of sodium hyaluronate: *a* – significant decrease in corneal punctuate epitheliopathy (fluorescein staining); *b* – biomicroscopy with a blue cobalt filter

Рис. 3. Роговица правого глаза у пациента с вторичной кератэктазией через месяц ношения минисклеральной линзы, заполненной бесконсервантным раствором гиалуроната натрия: *a* — значительное уменьшение точечной эпителиопатии роговицы (окраска раствором флюоресцеина); *b* — биомикроскопия в синем кобальтовом фильтре

noted (Fig. 2). Miniscleral lenses were fitted, the space under the lens was to be filled with a non-preserved sodium hyaluronate solution before each use. During the day, additional artificial tear preparations were not used. After a month of lens wear, the patient noted improvement and lack of discomfort; at the examination, the degree of severity of staining with the fluorescein solution of punctate defects of the corneal epithelium significantly decreased (Fig. 3). After two months of miniscleral lens wear, the surface of the corneal epithelium had fully recovered.

CONCLUSION

The results of the study showed that, due to the presence of sodium hyaluronate solution in the space under the lens, miniscleral lenses provide constant moisturization of the corneal surface, which helps to restore the epithelium integrity, while reducing the need for permanent instillations of tear substitutes. In addition to the therapeutic effect, miniscleral lenses are also an effective mean of optical rehabilitation of patients with complex corneal pathologies.

Scleral lenses are of significant scientific interest and require further research and the development of new methods for use as a therapeutic system for the treatment of ocular surface diseases.

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There are no conflicts of interest.

Contribution of authors: *S.A. Novikov* and *V.R. Grabovetsky* created the research concept and design and wrote the text; *K. Fedotova* and *M. Ezugbaya* collected and processed the materials, performed the analysis of the data, and wrote the text.

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Information about the authors

Karolina Fedotova — MD, Postgraduate Research Student, Ophthalmology Department. Academician I.P. Pavlov First St. Petersburg State Medical University, Saint Petersburg, Russia. SPIN: 6935-9837. E-mail: karo-luna@mail.ru.

Valeriy R. Grabovetsky — MD, PhD, Ophthalmologist. Academician I.P. Pavlov First St. Petersburg State Medical University, Saint Petersburg, Russia. E-mail: grabdoctor@yandex.ru.

Sergey A. Novikov — MD, PhD, DMedSc, Professor, Ophthalmology Department. Academician I.P. Pavlov First St. Petersburg State Medical University, Saint Petersburg, Russia. E-mail: serg2705@yandex.ru.

Maggie Ezugbaya — Clinical Resident, Ophthalmology Department. Academician I.P. Pavlov First St. Petersburg State Medical University, Saint Petersburg, Russia. E-mail: Maggie-92@mail.ru.

Сведения об авторах

Каролина Федотова — аспирант, кафедра офтальмологии с клиникой. ФГБОУ ВО «Первый Санкт-Петербургский государственный медицинский университет им. акад. И.П. Павлова» Минздрава России, Санкт-Петербург. SPIN: 6935-9837. E-mail: karo-luna@mail.ru.

Валерий Русланович Грабовецкий — канд. мед. наук, офтальмолог высшей категории, клиника офтальмологии. ФГБОУ ВО «Первый Санкт-Петербургский государственный медицинский университет им. акад. И.П. Павлова» Минздрава России, Санкт-Петербург. E-mail: grabdoctor@yandex.ru.

Сергей Александрович Новиков — д-р мед. наук, профессор, кафедра офтальмологии с клиникой. ФГБОУ ВО «Первый Санкт-Петербургский государственный медицинский университет им. акад. И.П. Павлова» Минздрава России, Санкт-Петербург. E-mail: serg2705@yandex.ru.

Мегги Эзугбая — клинический ординатор кафедры офтальмологии с клиникой. ФГБОУ ВО «Первый Санкт-Петербургский государственный медицинский университет им. акад. И.П. Павлова» Минздрава России, Санкт-Петербург. E-mail: Maggie-92@mail.ru.