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**ТИББИЁТДА ЯНГИ КУН
НОВЫЙ ДЕНЬ В МЕДИЦИНЕ
NEW DAY IN MEDICINE**

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EXOSOMES IN OPHTHALMOLOGY: CURRENT ACHIEVEMENTS, CLINICAL AND EXPERIMENTAL RESEARCH

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✓ Resume

Introduction: Exosomes are extracellular vesicles with a diameter of 30 to 150 nanometers. They are actively secreted by virtually all cell types. The structure of exosomes includes proteins, lipids, mRNA, and microRNA. They are involved in the regulation of many biological processes throughout the body. Exosomes are also capable of overcoming the biological barriers of the eye and delivering therapeutic agents. Consequently, exosomes are of particular interest to ophthalmology. This article will analyze clinical and experimental data on the use of exosomes in ophthalmology.

Objective: to analyze current literature data on the possibility of using exosomes in ophthalmology and the prospects for their use to strengthen the sclera.

Methods: This study was conducted in the format of an analytical review of the literature on the current state of research on exosomes and their use in ophthalmology. The review methodology was based on the principles of evidence-based medicine and analysis of experimental studies. The search and selection of publications was carried out using international and national information platforms such as PubMed, eLibrary, CyberLeninka, WIPO Patentscope, Espacenet, Google Patents, Lens.org, Scopus, and Web of Science. For an in-depth analysis of the cited works, publications on the Elsevier, Springer Nature, Wiley Online Library, MDPI, and Frontiers Media platforms were analyzed. Biomedical databases such as Gene Expression Omnibus, miRbase, UniProt, and KEGG were also used to interpret molecular and biological targets ().

Results: Exosomes have anti-inflammatory, regenerative, and neuroprotective properties. Preliminary preclinical studies have demonstrated their positive effect on corneal repair, increased tear production, restoration of retinal function, and reduced expression of vascular endothelial growth factors (VEGF). The main advantages of exosomes include biocompatibility, virtually no risk of immune reactions, and the ability to transport therapeutic molecules. Limitations to their implementation in general clinical practice, particularly in ophthalmology, are related to the lack of standardized methods for isolation, purification, and storage, as well as insufficient data from long-term clinical studies.

Conclusions: Exosomes represent a promising direction in the diagnosis and treatment of ophthalmic diseases. Further research, standardization of technologies, and large-scale clinical trials are necessary for their introduction into clinical practice. Of particular interest is their potential use in strengthening the sclera to control progressive myopia.

Keywords: exosomes, exosome therapy, ophthalmology, myopia, myopia control.

Introduction

Exosomes have anti-inflammatory, regenerative, and neuroprotective effects. Preclinical studies have shown their positive effect on corneal healing, increased tear production, restoration of retinal function, and reduced VEGF expression. In modern ophthalmology, there is growing interest in the use of exosomes in the diagnosis and treatment of eye diseases. Exosomes are being actively researched in pathologies such as myopia, glaucoma, dry eye syndrome, and degenerative retinal diseases. Due to their immunomodulatory effect in inflammatory processes, exosomes promote tissue regeneration and deliver specific molecules to target cells [1,2]. Exosome technology is already widely used in regenerative medicine, oncology, and the treatment of inflammatory diseases, but its use in ophthalmology is still significantly lagging behind. To date, there are a number of studies that confirm their promise in restoring the functions of the organ of vision. This review summarizes the results of recent studies demonstrating the effectiveness of exosome therapy in ophthalmic practice.

Objective: to analyze current literature data on the possibility of using exosomes in ophthalmology and the prospects for their use to strengthen the sclera.

Methods. This study was conducted in the form of an analytical review of the literature on the current state of research into exosomes and their application in ophthalmology. The review methodology was developed taking into account the principles of evidence-based medicine and the analysis of experimental studies. The search and selection of publications was carried out using international and national information platforms such as PubMed, eLibrary, CyberLeninka, WIPO Patentscope, Espacenet, Google Patents, Lens.org, Scopus, and Web of Science. For an in-depth analysis of the cited works, publications on the Elsevier, Springer Nature, Wiley Online Library, MDPI, and Frontiers Media platforms were analyzed. Biomedical databases were also used to interpret molecular and biological targets, such as Gene Expression Omnibus, miRbase, UniProt, and KEGG.

Results. Experimental data on the positive effect of local application of exosome therapy for dry eye syndrome (DES) in laboratory animals have been published. Very recent studies demonstrate that exosomes derived from MSCs (mesenchymal stem cells) promote the proliferation and migration of corneal epithelial cells in vitro, accelerating healing processes [3,4]. In these animal model studies, it was proven that the use of exosomes significantly accelerated the healing of corneal damage [5,6]. Moreover, other studies have shown that exosome therapy promotes the restoration of corneal transparency after trauma [7,8]. Subsequent studies have demonstrated an increase in tear secretion, prolongation of tear film breakup time, preservation of goblet cells, and a reduction in the degree of corneal damage [9-11]. Of particular interest is the study by Ma et al. (2022), which showed that the combination of exosomes with ascorbic acid significantly enhances the therapeutic effect in the treatment of dry eye syndrome (DES). This approach led to a reduction in oxidative stress, improvement in the morphology of the epithelium and microvilli, an increase in the number of chondriosomes and desmosomes, and a decrease in the expression of pro-inflammatory genes [12]. Based on these encouraging data, a clinical study (NCT042113248) is currently underway to evaluate the effectiveness of exosomes isolated from umbilical cord mesenchymal stem cells (UC-MSCs) in the treatment of dry eye syndrome (DES) symptoms. The first results are expected within the next two years. In addition, another clinical trial (NCT06543667) will start in January 2025, dedicated to the use of exosomes obtained from limbal stem cells (LSC-Exos) in patients with DGS (dry eye syndrome) who have not responded to standard therapy [13].

Experimental data confirming the effectiveness of exosome therapy for Sjögren's syndrome have been published. This is due to the pronounced immunomodulatory effect of exosomes [13–18]. It has been proven that exosomes are capable of influencing T-lymphocyte activity, the balance between regulatory and effector T-cells, and modulating the activity of myeloid suppressor cells, thereby reducing the severity of autoimmune inflammation characteristic of Sjögren's syndrome.

There is evidence in the literature that exosomes play an important role in the pathogenesis of glaucoma and represent a potential therapeutic tool. These extracellular vesicles are involved in maintaining the homeostasis of the trabecular meshwork and retina through intercellular interactions between donor cells and target cells. Their ability to penetrate biological barriers, particularly the

blood-retinal barrier, ensures the effective delivery of signaling molecules via both paracrine and endocrine pathways.

In addition, exosomes have been shown to participate in the regulation of the immune response and contribute to the formation of chronic neuroinflammation in glaucoma. Exosomes derived from mesenchymal stem cells have demonstrated neuroprotective properties in a number of preclinical studies in animal models. However, despite these promising results, questions remain regarding the pharmacokinetics, safety, long-term efficacy, and standardization of exosome drug production. The active development of clinical trials of exosomes in other areas of medicine indicates the promise of their use in the treatment of glaucoma [19–23].

In vitro studies have shown that exosomes have a positive effect on models of diabetic retinopathy. They promote the proliferation of Müller cells and reduce oxidative stress, inflammation, and apoptosis. The use of exosomes leads to a decrease in glucose and HbA1c concentrations, an increase in body weight and hemoglobin levels, as well as the suppression of inflammatory factors and VEGF expression, improving the overall condition of the retina [24–29].

The other two studies focused on investigating the potential application of exosome therapy in AMD (age-related macular degeneration). It was found that exosomes reduce VEGF-A expression in retinal pigment epithelial (RPE) cells after exposure to blue light in vitro, as well as reduce tissue damage in vivo, improving the structure of choroidal neovascularization and visual function. These studies demonstrated the ability of exosomes derived from mesenchymal stem cells to inhibit or even partially reverse the pathological process in wet AMD (age-related macular degeneration), reducing the need for frequent injections of anti-VEGF drugs [30,31].

The study of exosomes significantly expands the current possibilities for their use in the mechanisms of regulating the functions of the visual analyzer under physiological and pathological conditions. It has been shown that exosomes are important mediators of intercellular communication, ensuring the transmission of biologically active signals between pigment epithelial cells and retinal structures [32].

A number of other studies suggest that exosomes are involved in the preservation of visual functions, as they contain microRNAs circulating in the vitreous body. At the same time, a significant part of these microRNAs coincide with those contained in exosomes. This opens up the possibility of using exosomes as a source of prognostic and diagnostic biomarkers [32–34].

Locke C et al. (2014) describe the possibility of isolating exosomes from various biological fluids of the eye, such as the culture medium of retinal pigment epithelial cells, the vitreous body, the aqueous humor of the anterior chamber, and tear fluid. The data obtained show the potential for the promising use of exosomes as a source of molecular biomarkers in ophthalmic pathology, including myopia, age-related macular degeneration, and uveal melanoma. Thus, a comparative analysis of the microRNA profile in vitreous exosomes in patients with uveal melanoma revealed a significant increase in miR-146a expression compared to the control group [35].

During the study of the molecular basis of the glaucomatous process, the protein myocilin was identified, the secretion of which into the extracellular space occurs with the participation of exosomes. It has been found that mutations in the MYOC gene encoding myocilin occur in approximately 3% of patients with primary open-angle glaucoma [35]. The expression of this gene has been detected in trabecular meshwork cells, retinal ganglion cells, and pigment epithelium [36,37].

Analysis of blood plasma exosomes from patients with age-related macular degeneration showed significant shifts in the expression levels of microRNA-361, microRNA-301, and microRNA-424, which are involved in the regulation of angiogenesis [38]. These molecules are currently being evaluated as potential therapeutic targets for the development of new treatment approaches aimed at suppressing pathological vascular growth in age-related macular degeneration and diabetic retinopathy.

In another study of the proteome of exosomes isolated from the aqueous humor of patients with myopia, specific proteins associated with disease progression were identified. It was also found that exosomes contain molecules that can be used as biomarkers for early diagnosis and prognosis of myopia [39,40].

In studies by You et al. (2023), the microRNA profile in vitreous exosomes was analyzed in patients with myopic maculopathy. Key microRNAs—miR-143-3p and miR-145-5p—closely

associated with the progression of myopia were identified [41]. They can be used to monitor and control myopia. A study by Tomarev et al. (2021) showed that the microRNAs they contain play an important role in neuroprotection and can be used for the early diagnosis of glaucoma and myopia [42]. Proteins associated with the progression of myopia have been identified in exosomes derived from scleral epithelial cells.

Exosomes obtained from MSCs (mesenchymal stem cells) are a very promising area in ophthalmology due to their ability to enhance the survival of retinal ganglion cells and reduce intraocular pressure. In a study by Xie et al. (2024), a hybrid exosome platform was developed for the delivery of small interfering RNAs (siRNAs) aimed at suppressing inflammation in dry eye syndrome. Other authors have demonstrated the effectiveness of this technology in regulating inflammatory processes [43,44].

Experiments were also conducted to study exosomes isolated from corneal epithelial cells. These exosomes successfully delivered siRNA to corneal tissue, suppressing the expression of inflammatory cytokines and improving the morphological condition of the cornea in an experimental mouse model. These results indicate the significant potential of exosomes as non-invasive carriers of therapeutic agents for the treatment of inflammatory eye diseases.

One promising direction is the introduction of exosomes into the subtenon space, which allows active molecules to be delivered directly to the posterior segment of the eye, which is at risk in progressive myopia.

Despite the high potential efficacy of exosomes in the treatment of myopia, there is currently no reliable experimental data on the direct effect of exosomes on the morphological and biomechanical properties of the sclera. Existing studies focus on the effect of exosomes on the retina, optic nerve, and inflammatory reactions. However, the effect of exosomes on scleral tissue during subtenon injection remains unknown.

In modern ophthalmology, various approaches are used to control myopia, including optical methods (glasses and contact lenses), pharmacological effects (e.g., the use of atropine), and surgical interventions. However, none of these methods has a direct effect on the structure of the sclera and does not provide its strengthening. Moreover, surgical methods, including the introduction of implants or stem cells, are accompanied by high costs and significant ethical restrictions.

Exosomes in this context represent a safer and more affordable therapeutic approach. Their use does not require the introduction of living cells, which significantly reduces the risk of immune and other adverse reactions. Exosomes containing regulatory molecules are capable of activating cellular mechanisms that stimulate collagen production in the sclera, which helps to strengthen its structure and prevent further progression of myopia.

Exosomes are a promising biological tool for the diagnosis and treatment of various ophthalmic diseases. Due to their ability to transport therapeutic molecules, modulate inflammatory processes, and overcome biological barriers, exosomes have unique properties that make them highly sought after in ophthalmic practice.

Thus, to date, convincing experimental data have been accumulated on the effectiveness of exosomes in the treatment of corneal diseases, dry eye syndrome, glaucoma, diabetic retinopathy, and age-related macular degeneration. Their neuroprotective and anti-inflammatory properties have been demonstrated, as well as their ability to deliver microRNA and other active molecules.

Discussion of results

Thus, the use of exosomes in ophthalmology is a particularly promising direction in the diagnosis and treatment of eye diseases. However, further research, standardization of technologies, and large-scale experimental and clinical studies are necessary for their introduction into clinical practice. Their use for strengthening the sclera in myopia is of particular interest. The introduction of exosomes into the subtenon space as a method of delivering therapeutic agents to the posterior segment of the eye opens up new prospects in the treatment and control of myopia. However, this requires further research to assess their impact on the structure and biomechanics of the sclera.

Conclusions

Exosomes may become a new promising direction in the development of minimally invasive and highly effective therapies that combine biological activity, safety, and technological reproducibility. For the widespread use of exosomes in clinical practice, it is necessary to standardize methods for their isolation, purification, and storage, as well as to conduct large-scale experimental clinical studies.

Artificial intelligence tools were used exclusively for language editing and clarity improvement. The scientific content of the article, data analysis, and conclusions belong entirely to the authors.

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