

Comprehensive Strategies for Overcoming Barriers in Ocular Drug Delivery: Current Trends and Future Directions

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ABSTRACT

The human eye is a complex and sensitive organ, making effective drug delivery a major challenge. Its anatomical barriers, such as the precorneal, corneal, and blood-ocular barriers, significantly limit drug penetration and retention. Researchers have long focused on improving topical delivery methods to enhance drug absorption and prolong therapeutic action. Various ocular drug delivery routes have been explored, including subconjunctival, intracameral, intraocular, juxta-scleral, intravitreal, and retrobulbar. Despite these efforts, about 95.0% of available ophthalmic formulations are only available in liquid form. Other dosage forms include solids (powders, inserts, lenses), semi-solids (ointments, gels), and hybrids like *in-situ* gels. Nanotechnology-based carriers have recently emerged as promising tools in ocular drug delivery. These systems improve drug stability, enhance bioavailability, increase ocular permeability, and extend residence time. Additionally, they are capable of encapsulating both hydrophilic and lipophilic drugs, making them highly versatile. Various characterization methods such as *in vitro*, *ex vivo*, and *in vivo* studies are being used to assess the performance of these nanocarriers. This review aims to highlight the anatomical complexities of the eye, current challenges in ocular drug delivery, and the advantages and limitations of various dosage forms and routes. It also discusses recent advancements in nanotechnology-based drug delivery systems.

KEYWORDS ocular delivery, nanocarriers, ocular disease, ocular injections

INTRODUCTION

The human eye poses considerable challenges for effective drug delivery due to its intricate anatomy and physiology. It is divided into anterior and posterior segments, each susceptible to distinct diseases. According to the World Health Organization (WHO), as of 2015 approximately 217 million individuals worldwide experienced visual impairments, potentially resulting in partial or

complete blindness (1). Common ocular conditions include glaucoma, age-related macular degeneration (AMD), and diabetic retinopathy (DR), affecting approximately 76 million, 196 million, and 92.6 million people, world-wide respectively (2). Cataracts remain the leading cause of blindness globally, accounting for 40.0–60.0% of cases which are often linked to mutations in crystallin genes (3).

Over the past decade, significant progress has been made in the development of therapeutic approaches for ocular diseases such as AMD, DR, glaucoma, cataracts, fungal keratitis, and uveitis. However, delivering drugs effectively to ocular tissues remains challenging due to multiple physiological barriers, including the tear film, cornea, conjunctiva, and blood-ocular barriers (4).

Although nearly 90.0% of ophthalmic formulations are administered as liquids, they exhibit limited precorneal retention time and poor bioavailability which hinders therapeutic efficacy. To overcome these limitations, alternative drug delivery systems such as semi-solid formulations, solid dosage forms, and hybrid delivery platforms are being actively explored to enhance ocular drug retention and therapeutic performance (5).

Nanotechnology-based drug delivery systems have emerged as promising solutions for ocular therapy, offering targeted delivery, controlled drug release, and enhanced bioavailability. These platforms can encapsulate both hydrophilic and lipophilic drugs, providing protection from degradation and improving therapeutic outcomes (6).

Recent innovations in ocular delivery include *in situ* gels, ocular inserts, punctum plugs, biodegradable implants, and intraocular injections, all of which aim to overcome the limitations of conventional eye drops. To ensure their safety and effectiveness, these systems undergo characterization involving particle size analysis, zeta potential measurement, encapsulation efficiency, pH evaluation, and *in vivo/ex vivo* studies.

This review aims to address the existing research gaps and provide a comprehensive analysis of the current challenges in ocular drug delivery. It highlights recent advancements in nanocarrier technologies including characterization of those methodologies, with particular emphasis on scalability and quality control, two pivotal factors essential for the successful clinical translation of ocular nanomedicines.

ANATOMY OF THE EYE

The human eye comprises several integral structures that function in unison to facilitate vision. The cornea and lens work together to focus incoming light onto the retina, where specialized photoreceptor cells, rods and cones, detect light

intensity and color (7). The pupil, governed by the iris, regulates the amount of light entering the eye. Aqueous humor and vitreous humor help maintain intraocular pressure, preserve the eye's shape, and supply essential nutrients (8). The optic nerve carries visual information from the retina to the brain for interpretation (9). Surrounding components such as the sclera, choroid, and ciliary body provide structural support, vascular nourishment, and focus regulation. The sclera, a tough, white outer layer, protects the eye, while the conjunctiva serves as a lubricating and protective membrane. The iris adjusts pupil diameter in response to light intensity, and the lens fine-tunes focus for objects at varying distances. Within the retina, photoreceptors convert light into electrical signals, which travel via the optic nerve to the visual cortex. The macula, located at the center of the retina, is vital for high-acuity, detailed vision (10). The choroid, rich in blood vessels, delivers oxygen and nutrients to retinal tissues. The ciliary body, encircling the lens, adjusts its shape to accommodate near and far vision. Zonules, or suspensory ligaments, anchor the lens to the ciliary body, maintaining its position. The aqueous humor, found in the anterior chamber, nourishes the lens and cornea and sustains intraocular pressure. The vitreous humor, a gel-like substance in the posterior chamber, helps preserve the eye's spherical form. Protective structures like the eyelids and eyelashes shield the eye from debris, intense light, and physical harm. Lacrimal glands secrete tears that lubricate and cleanse the ocular surface (Figure 1). Finally, retinal blood vessels ensure a steady supply of nutrients to support retinal function (11).

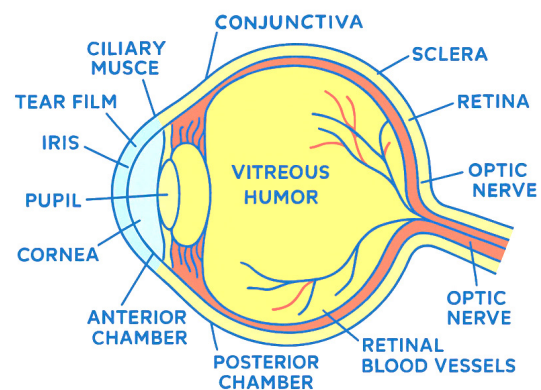


Figure 1. Anatomy of the eye

OCULAR DISEASES

Cataract

Cataracts are the leading cause of vision impairment worldwide, contributing to approximately 40.0–60.0% of blindness globally. In India, they are responsible for 62.6% of preventable blindness, as reported by the National Programme for Control of Blindness and Visual Impairment (12). Characterized by the clouding or opacification of the eye's lens, cataracts impair visual clarity. Risk factors include tobacco use, diabetes, poor nutrition, genetic predisposition, and prolonged exposure to ultraviolet light (13). Cataracts are classified into three main types: nuclear, cortical, and posterior subcapsular. The transparency of the lens is regulated by crystallin proteins, which play a critical role in maintaining optical clarity. Emerging evidence suggests that certain compounds such as metformin, resveratrol, lanosterol, and curcumin may possess protective effects against cataract formation (14).

Glaucoma

“Glaucoma, a group of disorders characterized by progressive optic nerve damage, is primarily linked to elevated intraocular pressure typically resulting from impaired drainage or excessive production of aqueous humor” (15). Often asymptomatic in its early stages, glaucoma can silently progress, making early detection crucial. “It remains a leading cause of irreversible blindness globally, with disproportionately high prevalence in populations of African and Asian descent, and among individuals over the age of 60” (16). Recent estimates suggest that approximately 76 million people worldwide are affected, a number expected to rise to 112 million by 2040 (17). Current therapeutic strategies primarily involve anti-glaucoma medications that target either the reduction of aqueous humor production or enhancement of its outflow. Numerous studies continue to explore improved approaches for effective glaucoma management.

Conjunctivitis

Conjunctivitis is among the most prevalent ocular conditions, commonly presenting as conjunctival irritation. It affects individuals across all ages, races, and sexes. Its classification as either infectious or non-infectious indicates whether

it is contagious. Infectious conjunctivitis results from microbial agents, whereas non-infectious forms arise from allergens or irritants. Common symptoms include eye redness, irritation, tearing, and excessive discharge. Notably, allergic conjunctivitis affects approximately 40.0% of the global population (18).

Age related macular degeneration (AMD)

AMD is a leading cause of vision loss in developed countries, predominantly affecting individuals over the age of 50. It accounts for approximately 8.7% of global blindness. Although there is currently no definitive cure for AMD, appropriate treatments can effectively slow disease progression. AMD is classified into two primary forms: dry and wet. Dry AMD is characterized by the accumulation of drusen and progressive thinning of the macula, whereas wet AMD involves abnormal choroidal neovascularization that can lead to rapid central vision loss.

A novel therapeutic approach, currently under clinical investigation, involves juxtascleral injection of anecortave cortisone, which has demonstrated sustained drug release in the choroid and retina for up to six months. Similarly, a biodegradable inhibitor targeting Rho kinase and protein kinase C has shown prolonged release for approximately six months following intravitreal administration, offering therapeutic potential for macular edema associated with diabetic retinopathy and neovascular AMD (19).

Diabetic retinopathy (DR)

Diabetic retinopathy is a common vascular complication associated with both type I and type II diabetes mellitus. Within ten years of diagnosis, it affects approximately 100.0% of individuals with type I diabetes and around 60.0% of those with type II. The condition arises from chronic hyperglycemia, which triggers inflammation and oxidative stress, leading to elevated levels of pro-inflammatory mediators. Diabetic retinopathy is the third leading cause of vision loss in the United States. Current therapeutic strategies include anti-VEGF agents such as ranibizumab and aflibercept, which differ in dosing frequency and molecular structure. Aflibercept is often administered less frequently due to its longer intravitreal half-life. Biosimilars are also emerging as cost-

effective alternatives with comparable efficacy (20). These agents effectively reduce vascular leakage and macular edema by inhibiting VEGF expression, thereby improving visual acuity and stabilizing retinal vasculature in patients with diabetic retinopathy (21).

Retinoblastoma

Retinoblastoma, a malignant tumor of the retina, primarily affects children under the age of five. If left untreated, it can lead to blindness and, in severe cases, death. The incidence of retinoblastoma is approximately one in 20,000 live births, with an equal occurrence in both sexes. The condition is caused by mutations in the RB1 gene, which encodes the retinoblastoma protein (22). Retinoblastoma can present as either unilateral (60.0%) or bilateral (40.0%). Treatment options include radiation therapy, cryotherapy, systemic radiation therapy, and surgical intervention. Recent studies suggest that therapeutic approaches for retinoblastoma should focus on promoting angiogenic blood vessel formation and enhancing the secretion of proangiogenic factors to support recovery (23).

Fungal keratitis

Fungal keratitis typically occurs when the cornea is compromised, as healthy corneas are resistant to fungal infections. Fungi such as *Candida albicans*, *Candida tropicalis*, *Candida glabrata*, *Candida krusei*, and *Candida parapsilosis* are common culprits. In developing countries, fungi account for approximately 40.0% of infectious keratitis cases. Factors such as ocular trauma, contact lens use, a history of corneal surgery, topical steroid use, and circulatory issues can increase susceptibility. Symptoms of fungal keratitis include corneal ulceration, delayed wound healing, and stromal inflammatory infiltration (24). Treatment typically involves topical or oral antifungal medications, with corneal surgery being considered when pharmacological therapies fail (25). Extensive research has focused on improving the management of fungal keratitis including improving the safety and antifungal activity of topical Sertaconazole nitrate. Figure 2 shows several eye diseases.

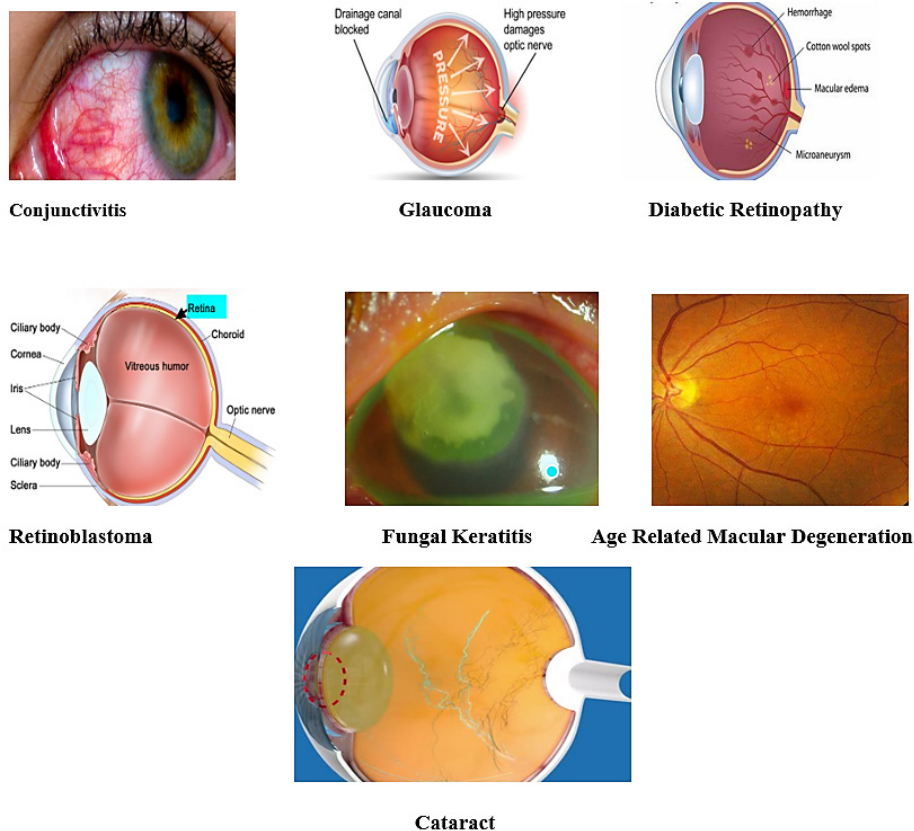


Figure 2. Various ocular diseases affecting the two segments of the eye

CHALLENGES IN OCULAR DELIVERY

Loss of drug from lacrimal fluid

The flow of ocular fluid in the precorneal area presents a significant challenge in drug delivery. Loss of medication from lacrimal fluid can occur due to factors such as lacrimation, fluid elimination, and inadequate conjunctival absorption. Additionally, drug absorption may be further impaired by degradation and protein binding. Ocular hydration, maintained by the continuous replacement of lacrimal fluid, is essential for protecting the eye from infections and dust. Various strategies exist to extend the residence time of the administered formulation, which is crucial for ensuring effective therapeutic outcomes (26).

Corneal barriers

The cornea serves as a protective barrier, enduring various mechanical and chemical stresses. It also aids the endothelium in focusing light. The epithelium consists of five to seven layers of tightly packed cells, while the stroma is a compact layer of water. The endothelium selectively permits the entry of hydrophilic medications and proteins into the aqueous humor, while maintaining corneal transparency (27). Factors such as the drug's electrical charge, ionization, hydrophilic properties, and molecular weight influence its ability to penetrate the cornea. Consequently, trans-corneal permeability is considered the rate-limiting step in the transfer of medications from the lacrimal fluid to the aqueous humor (28).

OCULAR INJECTIONS

Intracameral injections

Intracameral injection refers to the direct administration of an antibiotic into the vitreous cavity or anterior segment of the eye. This procedure is typically performed following cataract surgery to prevent endophthalmitis, a postoperative eye infection. A recent study reported the use of a polyvinyl sulfone and thiol group-modified gel as a scaffold for intracameral injections in the treatment of glaucoma (29).

Retrobulbar injection

A needle is inserted into the retrobulbar space through the orbital fascia and eyelid to deliver medication behind the globe using the retrobulbar technique. Amphotericin B exhibits enhanced

antifungal efficacy when administered retrobulbarly compared to intravenous delivery. Retrobulbar injection of chlorpromazine is used to alleviate pain in the eyes and to prevent blindness. Additionally, triamcinolone injections administered retrobulbarly can effectively manage macular edema associated with retinal vein occlusion (30).

Juxtasccleral injections

When conventional topical treatments fail to address posterior symptoms, juxtasccleral injections offer an alternative. Conditions such as cystic macular edema, trauma, and diabetic complications can benefit from this approach. A novel treatment for AMD involves injecting anecortave cortisone into the choroid and retina through juxtasccleral openings, which has demonstrated sustained release over six months. Additionally, specialized transscleral micro-needles have been developed for delivering adeno-associated viruses in retinal gene therapy (31).

Intravitreal injections/implants

Intravitreal injection is a method used to deliver medication directly into the vitreous body, located at the back of the eye near the retina. A novel approach for glaucoma treatment combines neurotrophic factors derived from glial cells with vitamin E-enriched polylactic-co-glycolic acid microspheres in a single intravitreal injection, providing a continuous release for up to six months. Similarly, when administered intravitreally, a reusable inhibitor of Rho kinase and protein kinase C demonstrated sustained release for approximately six months in patients with diabetic macular edema and neovascular age-related macular degeneration (32).

Subconjunctival injection

Subconjunctival injection is a widely used method to address the issue of topical medications not effectively reaching the front of the eye. In patients with uveitis, subconjunctival injections of steroid-loaded PEGylated liposomes have demonstrated sustained anti-inflammatory effects for at least one month, targeting the required ocular tissues. In another study, brinzolamide nanoparticles, delivered via the subconjunctival space, successfully controlled intraocular pressure for up to ten days. Furthermore, in mice

with graft-versus-host disease, subconjunctival injections of human mesenchymal stromal cells significantly reduced corneal inflammation and squamous metaplasia (33).

IONTOPHORESIS

Iontophoresis is a technique used to deliver medication to the back of the eye, leveraging a voltage gradient. Advanced systems employ microneedle-based technologies to enhance this delivery method. Compared to suprachoroidal injection, iontophoresis allows for the administration of double the amount of the formula to the back of the eye (Figure 3). Studies have shown that short-duration iontophoresis improves the penetration and bioavailability of acyclovir prodrugs. Additionally, ocular iontophoresis with dexamethasone phosphate has demonstrated greater efficacy than alternative treatments for non-infectious anterior uveitis (34).

Ocular biocompatibility

The Hen's Egg Test is a method for assessing potential ocular irritation caused by nanosystems through the vascularization of human mucosal tissue (35). The scoring is based on the presence of blood vessel hyperemia, clotting, and bleeding in the chorioallantoic membrane. Mahboobian et al. evaluated the safety of their nanoemulsion by using both negative (PBS, pH 7.4) and posi-

tive (sodium dodecyl sulfate) pH controls. Over 10 days, fertilized chicken eggs were maintained at $37 \pm 0.5^\circ\text{C}$ and $67 \pm 5\%$ humidity, with visual inspection for irritant effects (36). The Draize test, a traditional *in vivo* method, is used to assess irritants in nanosystems and cosmetics by evaluating the conjunctiva, iris, and cornea on a scale from 0 to 3. Corneal permeation was evaluated through *in vivo*, *ex vivo*, and *in vitro* models using rodent eyes and various permeation chambers to assess permeability parameters like drug flux and enhancement ratio (37). Strategies to improve corneal retention include the use of excipients, such as viscosity-enhancing polymers. In situ gels, which are responsive to pH, ions, or temperature, can extend drug contact time; for instance, ciprofloxacin in an ion-sensitive gel demonstrated prolonged retention (38). Mucoadhesive polymers, such as chitosan, and cyclodextrins can also improve ocular drug retention and solubility. Sayed et al. utilized β -cyclodextrin to enhance itraconazole delivery, while solid polymeric inserts provided sustained drug release (39). Corneal permeability may be increased with the use of surfactants, enhancers, and iontophoresis, which involves the application of a low electrical current (40). Finally, extracellular vesicles, such as exosomes derived from stem cells, offer a promising approach for delivering bioactive molecules and promoting corneal epithelial healing (41).

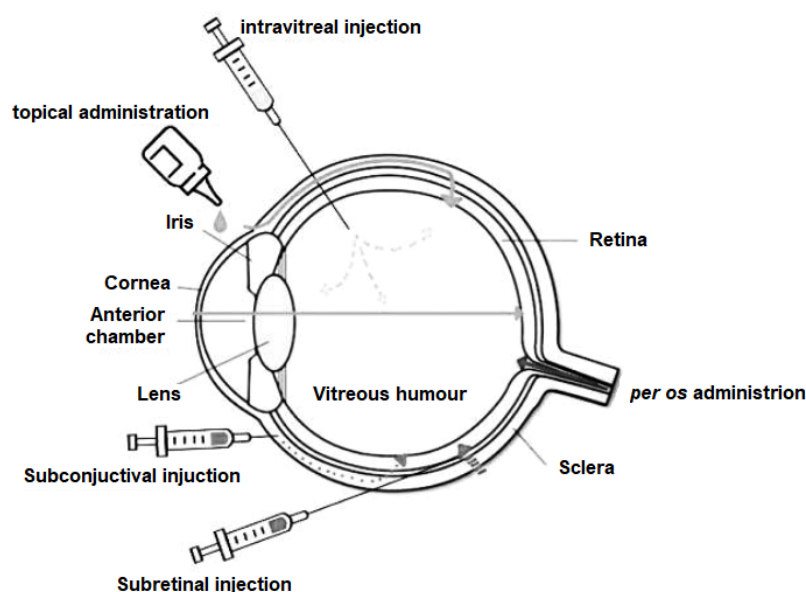


Figure 3. Different routes for ocular drug delivery

CONCLUSION

The effective treatment of ophthalmic diseases is hindered by multiple ocular barriers in both the anterior and posterior regions of the eye. To overcome these challenges, ocular devices are combined with various delivery routes, including intraocular, periocular, and topical methods. Sustained and regulated drug delivery systems are employed to enhance ocular bioavailability, improve drug permeation, and extend retention time. These systems aim to reduce dosing intervals, minimize the administered dose, and limit adverse effects. A range of strategies and technologies has been developed to achieve these objectives. Given their high biocompatibility and enhanced therapeutic efficacy, these innovations are expected to play a significant role in the treatment and management of ocular diseases. Future advancements in ocular drug delivery systems are likely to improve patient compliance, promote better eye health maintenance, and yield more effective treatment outcomes for ocular disorders.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to this review.

ADDITIONAL INFORMATION

Author contribution

E.N.: wrote, edited, and revised the manuscript content, separate topics, revised, and proof-read the manuscript; S.R.: wrote separate topics, edited, revised, and proof-read the manuscript, edited the manuscript, guided, and administered the work; K.V.: wrote separate topics, edited, revised, and proof-read the manuscript, edited the manuscript, guided, and administered the work

All authors have read and approved the final manuscript.

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