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Novel drug delivery system for glaucoma

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Abstract

Lowering intraocular pressure (IOP) with medication or surgery has long been the accepted treatment for glaucoma.IOP can be lowered by a number of excellent drugs available on the market. Usually, eye drops are used to administer these medications. However, patients may not comply to their treatment plans, which lowers the medications' clinical efficacy. Numerous cutting-edge delivery technologies are currently being researched with the goal of resolving the adherence issue and ensuring a consistent drop in IOP. Systems that are surgically implanted, injectables like biodegradable micro- and nanoparticles, and contact lens-releasing glaucoma medicines are a few instances of these delivery techniques. By offering a range of methods of administration. These cutting-edge technologies have the capacity to control IOP over several months. Promise to improve clinical effectiveness. Additionally, there is a wish to havein addition to IOP reduction, supplementary neuroprotective strategies for patients who still exhibit deterioration. For typical oral or drop formulations, many prospective neuroprotective drugs are unsuitable. The development of appropriate delivery mechanisms capable of delivering the medications to the retina and optic nerve in a localized, sustained manner is necessary to realize their promise. Drug delivery methods could improve patient adherence, reduce side effects, increase effectiveness, and eventually help glaucoma sufferers maintain their vision. In this evaluation, we go over the advantages and drawbacks of the existing distribution and application systems as well as those that are in the works.

Keywords: Nano particle, PLGA, drug delivery, clinical trials, glaucoma

Introduction

Glaucoma

Glaucoma is a group of eye conditions that damage the optic nerve, often due to abnormally High pressure in the eye (intraocular pressure). This damage can lead to vision loss and, if untreated, can result in blindness [1].

Glaucoma typically develops slowly, and early stages may Exhibit no symptoms. As the condition progresses, it can cause gradual loss of peripheral vision & eventually central vision. Regular eye exams are crucial for early detection and Management, since therapies like medicine, laser therapy, or surgery can help regulate eye.Pressure and prevent further vision loss.

Fig 1: (Glaucoma)

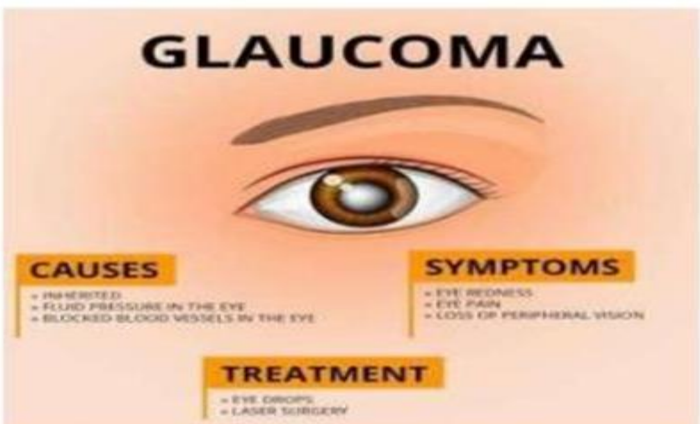

Fig 2: (Glaucoma)

Drugs and targets for glaucoma

With an estimated [2]

2 million cases, glaucoma is the second most common cause of permanent blindness. Million Americans and 67 million people worldwide suffering from the condition [3].

Degeneration of the axons of retinal ganglion cells (RGCs), which comprise the optic nerve, is a disorder known as glaucoma. In the absence of treatment, the loss of RGCs leads to blindness [4].

As people age, glaucoma becomes more prevalent. 4-6 It is predicted that within 15 years, 50% more Americans would suffer from this illness due to the aging of the US population Treatments that reduce intraocular pressure (IOP) constitute the mainstay of current glaucoma. Treatment, and several glaucoma medications can successfully lower IOP. However, a basic issue that worsens with age is poor adherence, and about 20% of patients ultimately need surgery to lower their IOP.

A different approach to treatment could be the use of neuroprotective drugs, which are intended to improve RGC survival independent of IOP [5].

Even in situations where there has been a sufficient IOP drop, some people nevertheless gradually lose their field of vision. That the majority of glaucoma patients can be managed [6].

In addition to or instead of IOP lowering, these patients would benefit greatly from these techniques. Even so, no Neuroprotective medications have now received FDA approval, neuroprotective medicines that can reduce the degeneration of optic nerve fibers and the loss of RGCs are ideal targets for Therapy [7].

Furthermore, systemic delivery of numerous promising neuroprotective medicines is associated with significant negative consequences. Therefore, before neuroprotective drugs are likely to be useful, the creation of novel, local drug delivery methods for the clinical treatment of glaucoma Mechanisms are necessary [8].

Lowering of IOP

IOP elevation is a major risk factor for primary open-angle glaucoma, even though some occurrences of glaucoma (also known as normal tension glaucoma) occur without IOP elevation [9].

Nonetheless, there is strong evidence that reducing the IOP, even in situations with normal tension glaucoma, slows the progression of glaucoma in about 90% of cases. Topical The most common way to lower IOP is to apply eye drops one or more times a day. Inappropriate administration of topical glaucoma medicines limits their effectiveness. It is necessary to apply topical drugs correctly by placing the eye drop on the globe's surface, administering the medication correctly several times a day, and timing the intervals between dosages or therapies [10].

It calls for diligence and manual skill, which many patients—especially the elderly—find challenging. Less than 50% of patients can reliably maintain a Research indicates that topical timolol lowers IOP, and there is a low level of medical compliance with topical glaucoma medication in clinical settings. Moreover, 1% of topical medication administration enters the aqueous humor. Depending on the kind of drug used, eye drops can cause major systemic absorption (up to 80%), which may have unfavorable side effects.

All these characteristics together make topical treatment challenging, especially in the elderly population, who exhibit lower adherence and higher susceptibility to side effects.Understanding the precise medicine to be administered, its chemical makeup, its mechanism, and any possible side effects are essential from the perspective of drug delivery systems. The IOP is lowered by a number of kinds of topical glaucoma medicines that are effective. Alphaadrenergics (like brimonidine), beta-blockers (like timolol), analogs of prostaglandins (such as latanoprost), and carbonic anhydrase inhibitors (such as dorzolamide), and cholinergics (like pilocarpine) are among them. These medication classes each have unique properties of their own that affect how they are delivered [12].

Thus, it’s critical to understand the unique characteristics of the medications in order to recognize the benefits and potential disadvantages of their distribution. Pilocarpine hydrochloride (HCl), one of the first drugs used to treat glaucoma, Parasympathomimetic that was first identified in 1877.

Twelve It lowers IOP by increasing the aqueous outflow. To maintain a lower IOP, four dosages must be taken daily. In addition to a host of systemic adverse effects, including nausea, vomiting, and diarrhea; it also results in brow pain, impaired vision, and a possible risk of retinal detachment [13].

After other drugs were tried, pilocarpine was used less frequently after they were introduced in the late 1970s and early 1980s. But in the it was one of the first drugs added to a sustained release implant in the 1970s. Avoiding the requirement for daily administration and minimizing adverse effects.Timolol maleate was authorized for use in eye care in 1979.

An average IOP reduction of 20–35% is accomplished by employing the b-adrenergic receptor antagonist timolol maleate. Timolol maleate has been the US Food and Drug Administration's (FDA) "gold standard"medication for lowering intraocular pressure (IOP) since approval [14].

To keep IOP under control, timolol typically needs to be taken twice day due to its considerable cardiac adverse effects. The molecule is attractive for a number of delivery methods, including creative drop formulations, implants, and injectables, due to its exceptional stability and high water solubility. Prescriptions for latanoprost, travoprost, and bimatoprost have surpassed those for timolol in the past several years due to the popularity of prostaglandin analogs. Prostaglandins induce the flow of aqueous humor to reduce intraocular pressure (IOP), despite the fact that timolol reduces its production. The very hydrophobic prodrugs known as prostaglandin analogs are broken into their active form by enzymes [15].

When used topically, the prostaglandin family of drugs usually has few systemic side effects since the enzymes that break these molecules are found in the eye but in low numbers systemically. They are very appealing to patients because they only need to be consumed once daily. The creation of prostaglandin analog drug delivery systems is highly sought after because of their noteworthy performance, as it will further reduce the requirement for daily dose [16].

Due to their high hydrophobicity, these drugs can be supplied using a range of widely used hydrophobic polymers, such as poly (ethylene-co-vinyl acetate) and poly (lactic acid), which are used to administer drugs to the eyes.

Neuroprotection

While most glaucoma patients benefit from lowering their intraocular pressure, there is growing interest in as an additional or alternative treatment, in figuring out how to safeguard the nerve cells in the eye. Currently, there are no FDAapproved drugs specifically for this kind of nerve protection in Glaucoma. The way these potential treatments are administered must be thoughtfully created for every medication. Numerous medications have been tested to safeguard central nervous system nerve cells. These comprise both larger proteins like glial cells and smaller molecules like progesterone and statins. Ciliary neurotrophic factor (CNTF) and derived neurotrophic factor (GDNF) [17].

However, these Drugs often have serious side effects when given throughout the body. As an illustration, CNTF can cause coughing and weight loss, which restricts the safe dosage and influences how, the medication is effective.

One possible way to deal with this is to administer these medications directly to the eye in a manner that minimizes side effects while offering a consistent, targeted treatment. In particular, proteins difficult to deliver because they are large, need to maintain their structure to work properly, and is easily disassembled. They also don't cross easily into the eye tissue and are expensive to produce.

To overcome these challenges, new methods are being developed to deliver these protective factors directly to the eye. Among them is the use of genetic methods to induce the production of the needed factors or transplanting stem cells that are engineered to produce them. These innovative delivery methods might offer new options alongside the traditional treatments that reduce glaucoma-related eye pressure.

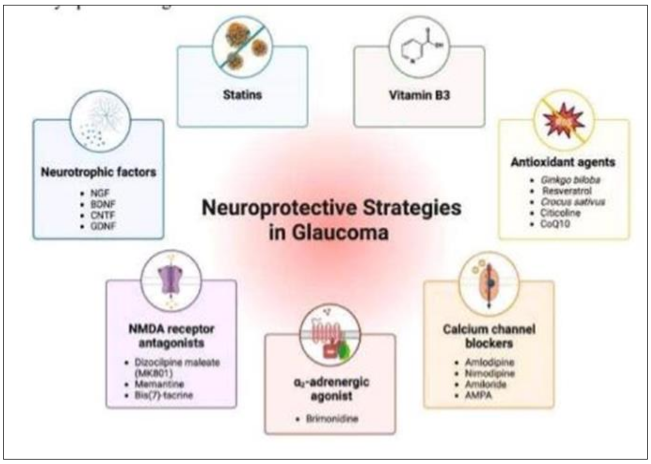

Fig 3:

Clinically Available Delivery Systems

Oral medications

Acetazolamide and other oral carbonic anhydrase inhibitors have long been used to reduce eye pressure and continue to be very successful. However, they can cause significant side effects throughout the body, such as tiredness, increased urination, and imbalances in electrolytes. These medications are usually given for a short period when eye pressure remains high despite using the strongest eye drops [18].

Oral timolol can also be used to lower eye pressure, but it's not as effective as the eye drops.

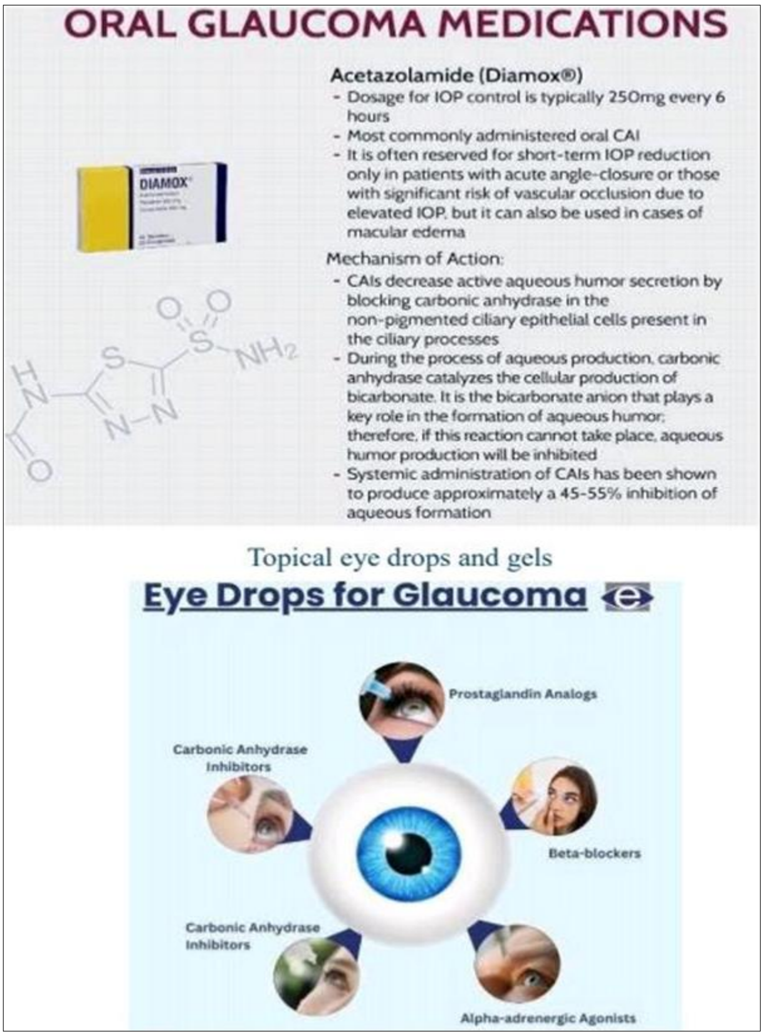

Fig 4 & 5:

Because it's hard for oral medications to cross into the eye, they don't work well there. So, the usual way to treat glaucoma is by applying medication directly to the eye. However, only about 1% of the medication from eye drops actually reaches the inside of the eye, and multiple applications each day may be needed to be effective. Delivering these drugs to the deeper parts of the eye, like the vitreous and retina, is difficult, as many drugs don't penetrate well due to factors like increased tear drainage and low absorption through the cornea and other eye tissues. Gel-based eye drop solutions have been created to assist with this. For example, timolol can be applied using gels that are designed to last all day, like Timoptic-XE and Nyogel. These gels are thicker than standard eye drops, reducing the frequency of dosing and Might lessen side effects. However, they can sometimes cause blurred vision.

Inserts

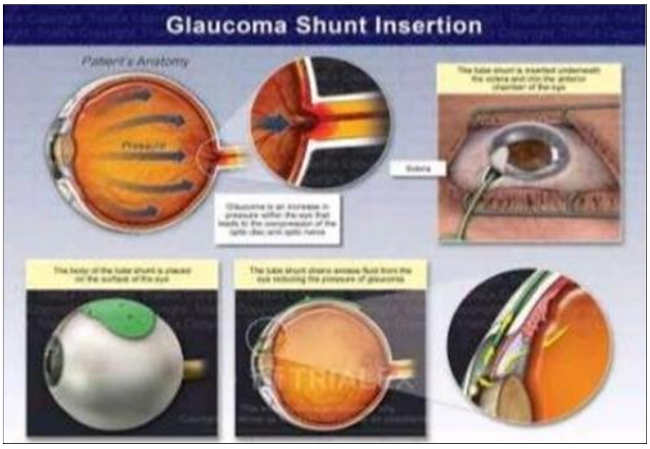

Fig 6:

Medication can now be administered over a number of days using ocular inserts. A well known example is the Ocusert system, which contains pilocarpine inside a small ring made of a special material [19].

This insert is placed in the lower part of the eye and releases the medication for up to 7 days. Although it's effective, some people find that the insert can fall out or be awkward. Enhancements have been made to create inserts that fit better and are less likely to to fall out. Additionally, comparable devices have been created for other glaucoma drugs like timolol [20].

However, these devices still have limitations, such as needing proper patient training and proficient manual skills to operate them properly. Younger patients are therefore more likely to successfully use and benefit from these devices compared to older patients.

Surgical implants

Long-term medication delivery in the eye is possible with surgical implants. For instance, long-term steroid implants such as Ozurdex and Retisert are already accessible. Delivery, with Retisert delivering dexamethasone for six months and Ozurdex providing fluocinolone acetonide for up to 30 months. Another implant, the I-vation by Surmodics, It has been tested in early clinical trials and releases triamcinolone acetonide for up to 36 months. Despite their long-term effectiveness, these implants have disadvantages like high costs, the need for initial surgery, and the possibility of requiring additional surgery if complications emerge. This can make them less appealing for many glaucoma patients who are concerned about these dangers [21].

Surgical implants may be a good option for neuroprotective medications. They can deliver the medication to the retina for an extended period of time. For instance, a small implant delivering CNTF has been tested and shown to be well-tolerated, with some patients experiencing improved vision an ideal drug delivery system for glaucoma would allow for sustained drug release for 3 to 4 months with just a single application in an office setting, rather than requiring surgery. This approach might be a better choice for older people and would work well with routine glaucoma examinations. Individuals who might find it difficult to use daily eye drops [22].

Innovative delivery methods

Contact lenses as delivery vehicles

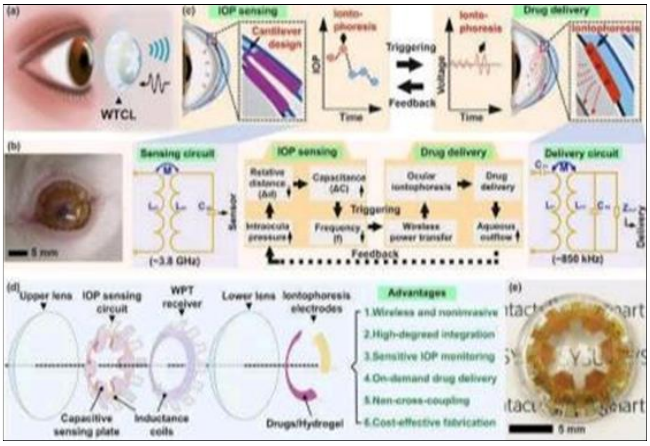

Fig 7:

At least 38 million Americans wear contact lenses, and interest in them is rising. In using these lenses for drug delivery due to their familiarity and patient experience. Soft Hydrogels, which are water-soluble polymers wAt least 38 million Americans wear contact lenses, and interest in them is rising. In using these lenses for drug delivery due to their familiarity and patient experience. Soft Hydrogels, which are water-soluble polymers with numerous biomedical applications, such as medication administration. But a significant obstacle is that water-soluble drugs, such as those used for glaucoma, often wash out too quickly from these highly hydrated polymers.25ith numerous biomedical applications, such as medication administration. But a significant obstacle is that water-soluble Drugs, such as those used for glaucoma, often wash out too quickly from these highly hydrated Polymers [25].

Nevertheless, some soft contact lenses composed of polymers such as N, N-diethylacrylamide and Timolol has been administered by methacrylic acid for approximately twenty-four hours. A brief investigation with three Patients demonstrated that timolol-containing contact lenses could successfully reduce intraocular pressure. This indicates that contact lenses could be a promising alternative to traditional eye drops for Glaucoma treatment [26].

However, there are some limitations. Patients need to wear the contact lenses continuously, and Since the lenses are kept in a hydrated state, there is a risk that the drug might gradually leach. Out over time.

Sophisticated surgical implants

Surgical implants can deliver medication to the eye for a long time, and new, more advanced Implants are under development. A system should ideally enable the administration of medication in an Ophthalmologist's office with minimal invasiveness and lasts for 3–4 months until the patient's Next visit.

One innovative approach is a reservoir system implanted in the area just under the conjunctiva. This system, called a microelectromechanical system (MEMS), uses electrolysis to create bubbles that push the drug out of the reservoir. It has demonstrated the ability to be refilled repeatedly. Favorable outcomes in early research on rabbits [27].

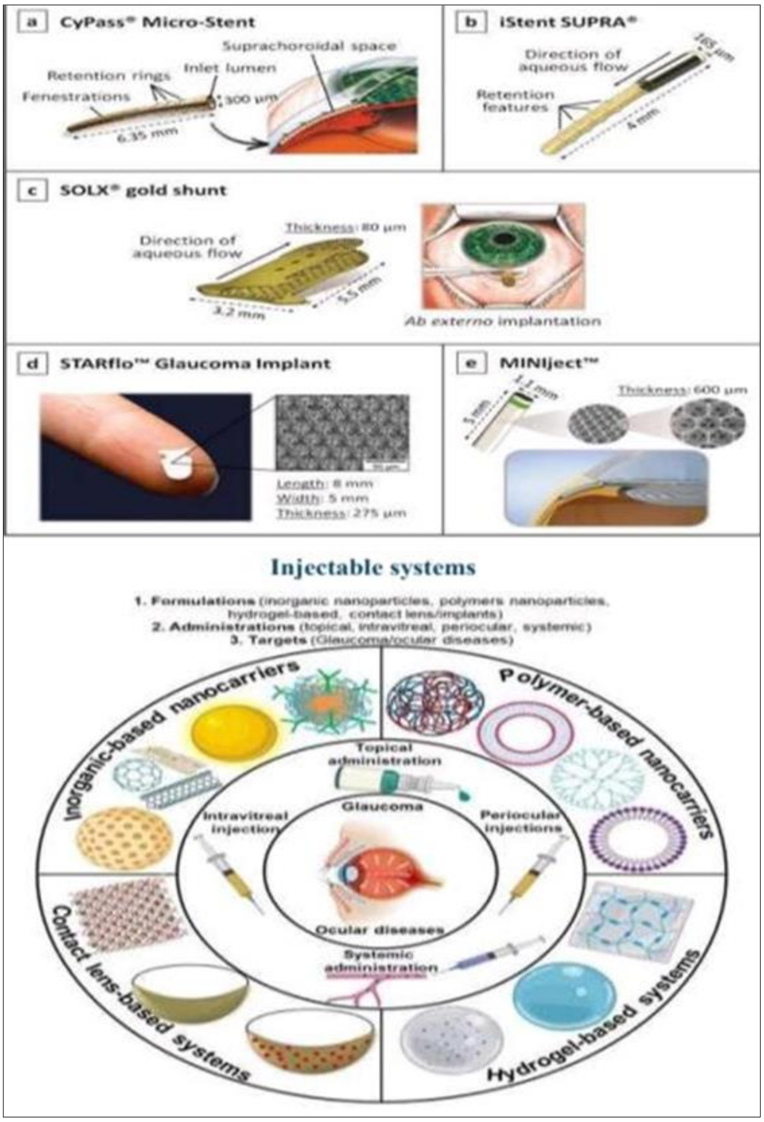

Fig 8 & 9:

This system could potentially deliver both small and large molecules, like growth factors.A major benefit of the MEMS system is that it allows for controlled drug release by adjusting the electrolysis. This means the clinician can change how quickly the drug is delivered based on the patient's needs. It could also be used for delivering drugs directly into the eye or for administering multiple drugs with slight adjustments. Long-term research is necessary, though, to make sure the gadget stays reliable and functions well over time. The main drawback is that the device requires surgical implantation, which involves both short-term and long-term risks [28].

It's possible to create long-term release formulations of glaucoma medications that can be injected in an office setting, offering a more convenient option for patients. These formulations can avoid the problem of patient adherence, unlike MEMS devices, as they are passive systems that offer long-term, consistent drug delivery.

Injecting medications into the subconjunctival space can lead to longer delivery than just topical drops, lasting hours to days. For even longer delivery periods of weeks or months, using a polymer-based delivery vehicle is promising. Polymers that are both biodegradable and nonbiodegradable have been investigated for this reason [29].

Polymers that are not biodegradable, such as polyethylene-co-vinyl acetate) offer consistent drug delivery over time but can cause immune responses since they stay inside the body. Degradable polymers, such as poly (lactic acid) or poly (lactic-co-glycolic acid), are appealing since they can lessen the drug release burst and degrade over time.effect with thoughtful formulation. These polymers degrade through hydrolysis, and their degradation rate can be controlled by adjusting their compositio.

Degradable polymer systems are suitable for office-based injections and have been used for Delivering drugs like antibiotics, carboplatin, and celecoxib. But providing conventional IOP-lowering glaucoma medications with these polymers are challenging due to poor drug-Rapid drug diffusion from the polymer particles and polymer interaction.

One successful example is polyester microspheres that release timolol for over 90 days *in vitro*. and can be injected through a small needle. For large molecules that may protect nerves, like growth factors, there are additional challenges such as maintaining the drug's activity and ensuring it reaches target tissues like the retina. Despite these challenges, intravitreal injection of medications such as glial cell-derived neurotrophic factor and brain-derived neurotrophic factor (BDNF) factor (GDNF) has shown promise in animal studies.

In summary, any slow-release injectable system must address three main issues: the effective the medication's dosage, stability, and interactions with the polymer, as well as whether the Remains active after being released.

Punctal plugs

Punctal occlusion with the plugs prevents natural tears by blocking the tear drainage process. From escaping the eye's surface [31].

Numerous solid or semisolid changes combined with another Drug-eluting components to the punctal plugs have been developed in recent years for use in Glaucoma to deliver a three- to four-month-long sustained release of medication [32].

It is a widely Employed drug delivery technique since the plugs are simple to implant in an outpatient setting. However, for some people, the feeling of a foreign body following insertion could be extremely Hurdle [33].

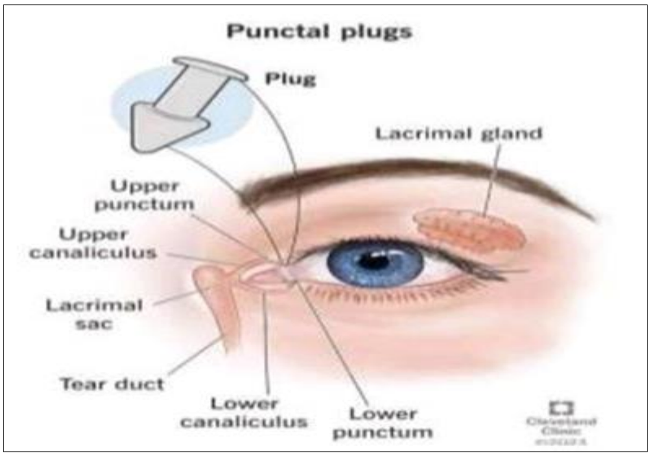

Fig 10:

Delivery method for Latanoprost punctual plugs In order to reduce IOP in patients with OAG, Goldberg and Williams74 employed the Latanoprost Punctal Plug Delivery System (L-PPDS) [34].

The authors' Findings revealed a 5.7 mmHg drop in mean IOP. The study also revealed that 47% of the individuals had an IOP decrease of at least 6 mmHg, and 60% of the subjects had an IOP decrease of at least 5 mmHg. Subjects with L-PPDS showed a statistically significant mean decrease in IOP of 22.3% when compared to controls [35].

Pentablock gels of copolymers

Drugs for glaucoma, such as bimatoprost, are delivered topically and intraocularly using Pentablock copolymer gels. For use in the eye, the Food and Drug Administration (FDA) has five different pentablock copolymers are currently approved [36]. These include PLA, PLGA, PCL, Polyglycolic acid (PGA) and PEG. When the medicine is applied as an eye drop, its physical properties alter depending on the Body temperature of the patient [37].

Microneedles

The drug delivery devices known as microneedles are made of metals or polymers and range in size from 10 to 200 µm. These devices' ultradimensions make drug delivery more precise and less obtrusive at the action sites [38]. Using coated stainless steel microneedles that ranged in length from 500 to 750 µm, Jiang and colleagues administered pilocarpine intrasclerally into the anterior chamber. 39. The authors found that the absorption of the Compared to conventional eye drops, the medication was 45 times more.

Conclusion

The review highlights the challenges and innovations in drug delivery systems for glaucoma. Treatment, highlighting the necessity of enhancing clinical efficacy and patient adherence. Traditional Despite their effectiveness, eye drops have drawbacks such as low drug absorption and poor patient compliance. Innovative delivery techniques, such as contact lenses, surgically implanted systems, and Injectables offer promising alternatives by ensuring sustained, localized drug release and reducing the frequency of administration. Furthermore, these systems might make the Delivery of neuroprotective drugs, which are crucial for patients who continue to experience IOP reduction is accompanied by vision loss. As these technologies evolve, they hold the potential to significantly enhance treatment outcomes and preserve vision in glaucoma patients.

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