



Comparison

The common management of filtration surgery (trabeculectomy) is having intra- or postoperative anti-proliferative therapy (such as 5-fluorouracil or mitomycin-C). The remedy so often causes an aggressive postoperative fibroblast-mediated scarring process, widespread cell death, acellularity, apoptosis, alter bleb morphology, and increase the risk of complications such as hypotony maculopathy, corneal toxicity, wound leakage, infection and endophthalmitis

Traditional	VS.	ologen™
<ul style="list-style-type: none"> Reduce the physiologic barrier - MMC, 5 FU Focus on Scleral tunnel - most implants may create long term risks, such as thin conjunctiva, soft orbital, hypotony - the damage of ciliary body Hypotony - may happen by tube like - implant if the scleral flap not well sutured Poor dynamic balance - plastic implant Non-biodegradable - long term complications Side Effects 		<ul style="list-style-type: none"> Maintain the subconjunctival space with prevention of scleral tunnel scarring and create the size of the bleb; even after partial degradation Maintain the physiologic barrier by regeneration (normal epithelium, stroma, goblet cells, vessels) Prevention of hypotony - by the pressure implant created on top of scleral tunnel Maintain the physiologic conjunctival barrier Dynamic aqueous balance with normal, safe conjunctival system Bio-degradable No risk in long term after complete degradation

Complications

Antimetabolite Therapy	Tube-Shunt Surgery	ologen™
<ul style="list-style-type: none"> Hypotony: <ul style="list-style-type: none"> IOP < 5 mmHg Incidence: 30 - 37.3% Maculopathy: young, myopia Longer exposure & "high risk" absence Racial difference Intraocular Toxicity <ul style="list-style-type: none"> Corneal endothelial Ciliary Body Wound Leakage <ul style="list-style-type: none"> Delay wound healing Thin avascular blebs Infection & Endophthalmitis 	<p>Early Complications:</p> <ul style="list-style-type: none"> Excessive Outflow Flat AC / Hypotony Tube Obstruction Elevated IOP Inflammation Hyphema <p>Late Complications:</p> <ul style="list-style-type: none"> Tube-Cornea Touch Tube Movement / Migration Conjunctival Dehiscence with Exposure of the Drainage Device Epithelialization of the Fibrous Capsule Surrounding the Reservoir Strabismus and Diplopia Late Failure (blockage of orifice) 	<ul style="list-style-type: none"> Bio-degradable No risk in long term after complete degradation

ologen™

Collagen Matrix for glaucoma & selected ophthalmic surgeries

About ologen™



ologen™ Collagen Matrix has been developed to increase the success rate of glaucoma filtration surgery and other selected ocular procedures. The super Matrix may significantly increase the success rate by reducing fibrosis and eliminating MMC induced complications. ologen™ may normalize the subconjunctival wound healing process, maintain the functional bleb with normal conjunctiva, and be biodegraded around 90 days.

ologen™ Collagen Matrix is a biodegradable and implantable scaffold. It induces a regenerative non-scarring wound healing process without using anti-fibrotic agents. The Matrix improves the regenerating tissue re-modeling and prevents scar formation or further infection. The implantation of ologen™ is simply required the ophthalmologists perform the operation base on their own traditional procedure and technique (such as trabeculectomy). Just implant ologen™ on the top of the sclera flap within the subconjunctival space before suture the conjunctiva. The aftercare is as normal, without anti-fibrotic agents or anti-proliferative drugs.

A New, Safe and Effective Treatment for Trabeculectomy

The principal of ologen™ Collagen Matrix is to induce the fibroblast grows randomly and leads the wound healing normally, intending to reduce intraocular pressure after trabeculectomy surgery.

The Collagen's porous structure can work as a reservoir, a buffering system, and a controlled drainage. It randomizes the growth of myofibroblasts and creates a new physiologic environment between anterior chamber and subconjunctival space. Distinct from anti-metabolites reduce the physiologic barrier by inhibition, ologen™ maintains the physiologic barrier by regeneration which keeps the function of bleb and normalize the dynamic aqueous balance to create a safe conjunctival system.

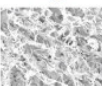


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Device Description



Microstructure of ologen™
SEM, Pore size: 10 - 300 μm

Formula

- Collagen-glycosaminoglycan scaffold matrix
- Pore diameter is 10 - 300 μm

Description

Model No.	Specification
830601	6.0mm(D) x 2.0mm(H)
830661	7.0mm(D) x 4.0mm(H)
862051	12.0mm(D) x 1.0mm(H)
870051*	10.0 mm(L) x 10.0mm(W) x 2.0mm(H)

*Non-penetration glaucoma surgery: Cut a small piece for scleral tunnel and major piece put on the top of scleral flap.

ologen™ could be considered :

- Failed Trabeculectomy
- Neovascular glaucoma
- Severe conjunctival scarring following surgery
- Impending need for PKP
- Glaucoma with uveitis
- Primary Trabeculectomy
- Refractory glaucoma

Features & Benefits

- Guide the fibroblast to grow through the matrix pore randomly for preventing the scar formation
- Acts as aqueous humor shunt immediate after the glaucoma filtration microsurgery conducted.
- Acts as aqueous humor reservoir
- Create buffer zone to prevent flat or shallow anterior chamber
- Facilitate the aqueous system grow naturally
- Faster the eye related surgical wound healing
- No anti-metabolite is needed which reduces side-effects.
- The surgical technique is not changed except simply implant ologen™ on top of sclera flap under subconjunctival space.
- Drastically decrease contraction and promote the formation of a nearly normal subconjunctival stroma.
- Long term effectiveness intending to reduce and keep intra ocular pressure in its lowest tens after trabeculectomy surgery.

Contraindication

ologen™ is contraindicated under the following condition:
★ Known allergic reaction to collagen.

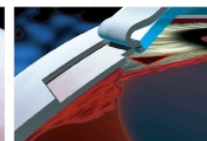


Surgical Procedure

ologen™ - Implanting procedure for Trabeculectomy



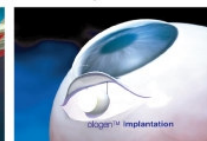
1. Preparation of the conjunctival and scleral flaps.



2. Create the fistula beneath the scleral flap.



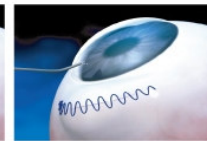
3. Suture the scleral flap loosely with one single stitch.



4. Implant ologen™ directly on the top of the scleral flap.



5. Close the conjunctival flap.



6. Reform the anterior chamber.

Post operation care

- Topical antibiotic four times daily for at least 5 days.
- 1% Prednisolone acetate every two hours while awake for six weeks prior to tapering.
- Topical cycloplegic as necessary.
- Combination antibiotic-steroid ointment at bedtime for at least one week.

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