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Collagen Matrix Implant (Ologen)[™] in Glaucoma Surgeries; Precautions for a Better Control of Intraocular Pressure

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Authors' contributions

This work was carried out in collaboration between both authors. Author MMH designed the study, performed the surgeries and the follow up, wrote the protocol, and wrote the first draft of the manuscript. Author IMH managed the literature searches. Both authors read and approved the final manuscript.

Article Information

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Method Article

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ABSTRACT

Background: Collagen matrix implant (CM) is used in glaucoma surgery to regulate healing under the conjunctiva.

Purpose: To highlight the precautions that should be taken for a better intraocular pressure (IOP) control with CM in different glaucoma surgeries during and after the operation.

Methods: Thirty five cases of glaucoma were treated surgically with adjunctive Ologen[™].

a) Fifteen subscleral trabeculectomies (SST): for adult Primary Open Angle Glaucoma (POAG).

b) Five SST's for Primary Congenital Glaucoma (PCG).

c) Fifteen Phaco-trabeculectomies for advanced POAG with cataract. One was converted to extracapsular cataract extraction with SST because of a subluxated (270 degree) cataractous lens with advanced glaucoma.

The number of 10/0 nylon stitches to close the scleral flap, the method of closure of the fornix based conjunctival flap and injection of Na hyaluronate at the end of the surgery were evaluated. Postoperatively: Anterior chamber(AC) depth, the need for ocular massage, any additional medications or further surgical intervention were assessed.

Results: Better IOP control was obtained with slightly shallow AC postoperatively and tight

conjunctival closure. Ocular massage may be needed as well as medications for cases which experienced tight closures of the scleral flap. Three SST's and four phaco-trabeculectomies needed supplemental medications after surgeries. Failure in one SST (PCG) and two phacotrabeculectomies was due to presence of additional risk factors in the patients. The rest of cases went successfully with IOP < 21 mm Hg without medications.

Conclusion: CM is a successful adjunct to glaucoma surgeries, intraoperative and postoperative precautions should be taken to maintain proper aqueous drainage and functioning blebs to improve the degree of success.

Keywords: Trabeculectomy; collagen matrix implant; phacotrabeculectomy; congenital glaucoma.

1. INTODUCTION

Glaucoma filtering surgery fails because of scarring of the filtering bleb. Fibroblasts proliferation from the episclera and Tenon's capsule play an important role in the scarring process. The use of antimetabolites in glaucoma filtering surgery has a beneficial effect on the lowering of intraocular pressure (IOP) especially in eyes at poor surgery prognosis. They inhibit the fibroblasts proliferation and subsequent scarring of filtering bleb [1].

Mitomycin C (MMC) is currently the preferred antiproliferative agent [2]. In addition to affecting DNA, it also affects RNA and protein synthesis. It thereby inhibits fibroblast proliferation and is toxic to endothelial cells. It introduces new complications of its own, including chronic hypotony with maculopathy, cystic avascular blebs, bleb leakage, bleb failure, bleb infections and endophthalmitis [3].

Ologen[™] is an artificial porcine extracellular matrix, which is made of atelocollagen crosslinked with glycosaminoglycan. It is a biodegradable scaffolding matrix that induces a regenerative wound-healingprocess in the absence of antifibrotic agents. It is designed to prevent episcleral fibrosis and subconjunctival scarring and minimize the random growth of fibroblasts, instead promoting their growth through the pores in the matrix. This implant is found to be biodegradable within 90–180 days [4]. After degradation, this collagen matrix implant (CM) leaves behind a loose alignment of collagen fibers inside the bleb, which are remarkably similar to normal tissues [5].

Two types of CM (Ologen, Aeon Astron Europe B.V., Leiden, The Netherlands) are used in glaucoma surgery, as per the manufacturer's design: the first is a disc of 6 mm diameter × 2 mm thickness and the second is a disc of 12 mm diameter × 1 mm thickness (Figs. 1a, b). The advantages are claimed to be preventing episcleral fibrosis, subconjunctival scarring, risks of MMC (epithelial toxicity, hypotony, avascular blebs, late endophthalmitis).CM ensures as well a stable vascular bleb.

CM acts as a three dimensional porous scaffolding matrix. It promotes regenerative wound healing by allowing organized fibroblasts growth and physiological regeneration. Thus, a loosely structured filtering vascular bleb is formed. It has also a tamponading effect in the early postoperative course. This may promote long term IOP control.

CM is widely used in SST; according to Marey and co-workers, SST gave comparable successful results when assisted by Ologen[™] as with adjunctive MMC [6].

Ologen is getting to be assessed in phacotrabeculectomy by many surgeons, Narayana Swamy and his colleagues found it to be suboptimal in performance as compared with in MMC combined glaucoma and phacoemulsification [7]. Biodegradable CM (Ologen) can be used to reduce the surgical risks and complications of SST with MMC in infants [8].

2. PATIENTS AND METHODS

This is a retrospective study conducted from January 2011 to December 2013. It is considered as a collective overview on all cases in which OlogenTM was used. All of them were done in the Department of Ophthalmology in Ain Shams University Hospitals and in Magrabi Eye Hospital in Cairo. All cases were operated upon by a single surgeon (the first author). The primary objective was to highlight the precautions that should be taken for a better intraocular pressure (IOP) control with CM in different glaucoma surgeries during and after the operation; this would help to evaluate the

efficacy and safety of CM (Ologen, Aeon Astron Europe B.V., Leiden, The Netherlands) in order to reach the target IOP and stabilize the changes in the optic nerve head and visual field.

The authors have no financial interest with this product.

All patients were operated upon after taking informed consent from them if adults or from their parents in cases with PCG.

Thirty-five cases were studied including the following:

- Fifteen subscleral trabeculectomies (SST): for adult Primary Open Angle Glaucoma (POAG).
- Five SST's: for Primary congenital glaucoma (PCG).
- Fifteen phaco-trabeculectomies:
 - Fourteen for advanced POAG with cataract.
 - One converted to extracapsular cataract extraction with SST (asubluxated (270 degree) cataractous lens with advanced pseudo- exfoliative glaucoma).



(a)



(b)

Fig. 1. Types of Ologen

2.1 Inclusion Criteria For

2.1.1 A- SST for adults

 POAG confirmed by gonioscopy with IOP>21 mm Hg despite maximally tolerated anti glaucoma treatment and/or progressive visual field changes.

2.1.2 B- SST's for Primary congenital glaucoma (PCG)

- Age from newborn to 5 years.
- Corneal diameter>13 mm with cloudy cornea.
- IOP>21 mmHg.
- Both unoperated or previously operated eyes.

2.1.3 C- phaco-trabeculectomies

 Visually significant cataract with BCVA worse than 20/40 associated with POAG confirmed by gonioscopy with IOP>21 mm Hg despite maximally tolerated anti glaucoma treatment and/or progressive visual field changes.

2.2 Exclusion Criteria

2.2.1 A- SST for adults

- Primary Angle Closure Glaucoma
- Secondary glaucoma (neovascular, uveitic, traumatic).
- Previous glaucoma surgery or other ocular operations.

2.2.2 B- SST's for Primary congenital glaucoma (PCG)

 Secondary congenital glaucoma e.g (retinoblastoma, Peter's anomaly, nanophthalmous).

2.2.3 C- phaco-trabeculectomie

Same as SST for POAG.

2.3 A-Subscieral Trabeculectomy (SST)

A fornix based conjunctival flap was done then the episcleral blood vessels were cauterized. A scleral flap measuring 3 mm × 4 mm was performed. The latter was sutured with one or two loose 10.0 nylon stitches and CM was placed over it. A watertight closure of the fornix based conjunctival flap with buried 10.0 nylon stitches at the limbus was performed(2 peripheral stitches or 2 peripheral+1 middle continuous stitch). A combination of steroid– antibiotics (dexamethasone–tobramycin) eye drops q.i.d. was prescribed for six weeks then tapering over the following two weeks.

2.4 B-phacotrabeculectomy

Phacotrabeculectomy was performed using two different sites: a temporal clear corneal incision for the phacoemulsification and a superior scleral flap measuring 2 mm x 3 mm. Fornix based conjunctival flap was used and episcleral blood vessels were cauterized. The scleralflap was sutured with one or two loose 10.0 nylon stitches and CM was placed over it. A watertight closure of the fornix based conjunctival flap with buried 10.0 nylon stitches at the limbuswas performed (2 peripheral stitches or 2 peripheral+1 middle continuous stitch).^{*} A combination of steroid– antibiotics (dexamethasone–tobramycin) eye drops q.i.d. was prescribed for 6 weeks, tapering over the following two weeks.

One phacotrabeculectomy was converted to extracapsular cataract extraction with SST (a subluxated (270 degree) cataractous lens with advanced glaucoma). The capsulorrhexis failed, the cataractous lens was retrieved by a scoop after enlarging the temporal corneal incision, limited anterior vitrectomy was done. Anterior chamber IOL was implanted and the corneal incision was closed by four interrupted 10.0 nylon stitches. The glaucoma surgery was continued as described.

2.5 Intraoperative measures to be evaluated

- Number and tightness of 10/0 nylon stitches to close the scleral flap (one or two).
- Method of closure of the fornix based conjunctival flap with buried 10/0 nylon stitches (2 peripheral stitches or 2 peripheral+1 middle continuous stitch).
- Na hyaluronate injection in AC at the end of surgery.

*As the cases enrolled in this study were considered the beginning of the learning curve using CM, closure of the scleral flap was done by one loose stitch in some cases or two in others. The variation in closure of the fornix based conjunctival flap as well by two or three stitches was due to the same reason.

2.6 Postoperative Evaluation Included

- Anterior chamber (AC) depth.
- Need for ocular massage.
- Need for supplemental steroids.
- Additional IOP lowering medication(s).

2.7 The definition of success was as follow for SST treating POAG and phacotrabeculectomies

- Complete success (IOP < 21 mm Hg without medications).
- Qualified success (IOP<21 mm Hg with IOP lowering medication(s)).
- Failure (IOP >21 mm Hg not responding to medications).

The previous definition of success has been frequently used in the literature by many researchers [9-11].

2.8 The definition of success for PCG**

2.8.1 (**Based on a study by the first author that was published in 2013.(8)

- Full success: IOP less than 15 mmHg without medications; clear cornea.***
- Satisfactory success: IOP less than 21 mmHg without medications; clear cornea.
- Poor success: IOP less than 21 mmHg with medications.
- Failure: IOP more than 21 mmHg.

*** Complete success in PCG was considered 15 mmHg rather than 17 mmHg as this level might be more suitable for better corneal clarity and the target IOP for such young age group should be lower than adults with POAG.

3. RESULTS

3.1 A-SST for POAG

Ragarding the fifteen SST's with CM done for POAG the following remarks and results were noted:

- Flat AC and hypotony occurred in fou rcases (26.6%) in early postoperative period. In two of them, one10/0 nylon stitch was applied for closure of the scleral flap (overfiltration). In the two other cases, loose conjunctival closure was done with only two10/0 nylon stitches(aqueous leakage).
- Two cases (13.3%) needed supplemental medications to lower IOP. Tight closure of the scleral flap was done by two 10/0 nylon stitches. Ocular massage and frequent topicalsteroids were needed for few weeks postoperatively.

- Five cases (33.3%) showed very stable postoperative AC with Na hyaluronate injection at the end of the surgery, one loose 10/0 nylon stitch for closure of the scleral flap but with tight closure of the conjunctiva with three 10/0 nylon stitches.
- Bleb morphology was monitored by frequent photography, vascularity of the bleb was more intense in the first two weeks after the operation, and gradually faded in the following weeks under frequent topical dexamethasone eye drops to be nearly the same vascularity as the neighboring conjunctiva after four months. (Figs. 2 a, b,c).
- The success rate was: 13 cases (86.6%) with complete success and two cases (13.4%) with qualified success.

3.2 B-SST for PCG

Regarding the five cases of SST with CM for PCG, the following was noted:

- One case (20%) showed flat AC and hypotony in the early postoperative period; one very loose 10/0 nylon stitch was applied for closure of scleral flap.
- One case (20%) needed supplemental medications to lower IOP. The last two cases had more risk factor as they were recurrent PCG after previous SST.
- Bleb morphology revealed normal vascularity and flattened bled at 4-6 months follow up both in superiorly located bleb as in Fig. 3 and in temporally located bleb as in Fig. 4.

The success rate was: one case (20%) full success, two cases (40%) with satisfactory success, one (20%) case with poor success and one case (20%)with failure for which glaucoma drainage implant was planned.



(a) Bleb at 2 weeks postop



(b) Bleb at 6 weeks postop



(c) Bleb at 4 months postop

Fig. 2. Bleb morphology in SST

3.3 C-Phaco-trabeculectomies

Regarding the fifteen cases of phacotrabeculectomies with CM, the following was noted:

- Four cases (26.6%) showed flat AC and hypotony in early postoperative period due to loose closure of the conjunctiva with two10/0 nylon stitches.
- Four cases (26.6%) needed supplemental medications to lower IOP. In these cases, tight closure of the scleral flap with two 10/0 nylon stitches was used and concurrently deep AC was noted in first week. Ocular massage and frequent topical steroids (dexamethasone) were needed few weeks postoperatively.
- Five cases (33.3%) showed very stable postoperative AC with Na hyaluronate injection at the end of the surgery, one loose 10/0 nylon stitch for closure of the scleral flap but with tight closure of the conjunctiva with three 10/0 nylon stitches.
- Tortuous vascluarized bleb was frequently noted four weeks after phacotrabeculectomy with corck screw

vessels (Fig. 5); which improved after three months with more intensive topical steroids and ocular massage (Fig. 6).

The success rate was: nine cases (60%) with complete success, four cases (26.6%) with qualified success and two cases (13.4%) with failure for which glaucoma drainage implant was planned.

SST in PCG with superior bleb



Fig. 3. shows successful SST in PCG with a superior bleb

SST in PCG with temporally located bleb



Fig. 4. shows successful SST in PCG with temporally located bleb



Fig. 5. tortuous vascluarized bleb 4 weeks after phacotrabecuctomy



Fig. 6. Improved vascularization after 3 months with more topical steroids and ocular massage

4. DISCUSSION AND CONCLUSION

CM is a successful adjunct to glaucoma surgeries. Intraoperative and postoperative precautions should be taken to maintain :proper aqueous drainage, functioning blebs, and better degree of success; thus, reaching the desired target IOP. The latter would stop optic nerve head changes and allow for stable visual field changes in the long term follow up.

Operative precautions to ensure filtration entail mainly loose closure of the scleral flap by two 10/0 nylon stitches. This should be supported by avoiding leakage through tight closure of the fornix based conjunctiva flap by two peripheral and one middle continuous 10/0 nylon stitches buried at the limbus. Na hyaluronate injection in AC at the end of the surgery promote a stable AC in the early few days following the operation; which is likely to resist hypotony and prevent production of plasmoid aqueous that may block the trabeculectomy. Closure of the scleral flap by one loose 10/0 nylon stitch can be done but with more experience regarding the degree of looseness at the end of the learning curve of CM use.

Post operative precautions include frequent ocular massage in the first few weeks, more frequent topical steroids for up to three months. Additional IOP lowering medication may be needed with some cases not achieving the planned target IOP.

Complete success (IOP < 21 mm Hg without medications) was found more with cases which had slightly shallow AC in the 1st week postoperatively with raised bleb. This would promote filtration and smooth incorporation of the CM into the bleb. Proper filtration necessitates loose scleral flap closure with tight conjunctival closure.

Qualified success (IOP<21 mm Hg with IOP lowering medication) was encountered with cases in which there was tight closure of scleral flap, very deep AC in day-1 postoperative.Ocular massage and frequent steroids were needed few weeks postoperatively up to three months to normalize the IOP.

Failure (IOP >21 mm Hg not responding to medications) occurred in the presence of one or more additional risk factors mainly ocular surface disease, dark race, younger age etc. These cases were candidates for glaucoma drainage implants later.

The relatively smaller number of cases with primary congenital glaucoma (PCG) can be justified by two reasons: 1st this study is a collective overview on all cases in which Ologen[™] was used rather than specifically for PCG, 2nd PCG cases are rare and unfortunately a very few number was available with big difficulty in scheduling the follow up visits with the parents living usually far from our center.

The relative disadvantages of CM is the need for experience with the implant to adjust filtration, as well as possible infection and shallow AC (as any SST complication).

The most peculiar finding which had to be managed vigorously was the foreign body like reaction and encapsulation around the CM as manifested by vcorck-screw vessels; which occurred few weeks postoperatively risking failure. The latter happened in phacotrabeculectomies mainly due to the severe postoperative inflammation and breakdown of blood aqueous barrier that accompanies phacoemulsification; the release of inflammatory mediators leads to reduced bleb function [12].

It can be also explained by the indolent episcleral fibrosis that produces a dense coat around an extrascleral foreign body such as a scleral buckle [13].

Phacotrabeculectomies in general are considered less effective in reducing IOP than SST as demonstrated by Lochhead and his colleagues [14].

There is evidence in the literature to suggest that IOP control is not as great in combined procedures as with trabeculectomy alone and that blebs from combined procedures tend not to be as well established at 6 months. The prospective studies that have looked at this suggest that there is a 1.7-8.1-mmHg further decrease in IOP with trabeculectomy relative to combined procedures [15-17].

In a research work by Rosentreter in 2012 to study the reaction of the subconjunctival tissue and the histopathologic findings in explanted Ologen Implant, Ologen matrices and scar tissue were explanted in revision surgery in case of failed trabeculectomies or after glaucoma drainage device surgery. Histological sections were studied by hematoxylin-eosin (HE) staining. Further immunohistochemic stainings were performed for α -smooth muscle actin (α -SMA),

Table 1. Success rate with CM use

	Complete success	Qualified success	Failure
SST for POAG (n=15)	13 (86.6%)	2 (13.4%)	0
SST for PCG (n=5)	3 (1 full +2 satisfactory) (60%)	1 (20%)	1 (20%)
Phacotrabeculectomy(n=15)	9 (60%)	4 (26.6%)	2 (13.4%)

Table 2. Postoperative Problems

*Success rate is briefly shown in Table 1.

	Flat AC and hypotony	Supplemental medications	Others
SST for POAG	4 (26.6%)	2 (13.4%)	vascularity of the bleb was more intense in the first two weeks
SST for PCG	1 (20%)	1 (20%)	Bleb morphology revealed normal vascularity and flattened bled at 4-6 months follow up
Phacotrabeculectomy	4 (26.6%)	4 (26.6%)	Tortuous vascluarized bleb at four weeks with corck screw vessels

v **postoperative problems in Table 2 fibronectin (FN), collagen III (COL3) and CD68.9 In case of failed trabeculectomies, HE staining of the explanted Ologen revealed an invasion of fibroblasts into the implant. The implants were enclosed by a collagenous pseudocapsule and surrounded by a loose connective tissue. α -SMA staining showed an accumulation of myofibroblasts predominantly in the ologen implant, whereas COL3 was mainly detected at the border area of the implant and the pseudocapsule around the implant. FN showed an Immunehistochemistry for intensive staining inside the implant and at the pseudocapsule [18].

Based on the last study by Rosentreter and the close follow up of our cases, CM should be "floating" within the bleb. CM would not "float" unless ample aqueous is being filtered from underneath the scleral flap within a tightly closed conjunctiva. In such a condition, there will not be direct strong contact between the implant and the conjunctiva; thus, minimizing the previously mentioned foreign body reaction which manifest by corck screw vessels as in Figure 6. These tortuous vessels are more encountered with phacotrabeculectomies in which postoperative reaction are more intense than SST. This explains also the need for prolonged topical steroids to inhibit inflammation and ocular massage to break any possible fibrous threads or pseudo capsule around the implant to promote aqueous filtration.

This study focuses mainly on the operative and postoperative precautions with CM in glaucoma surgeries. These tips are important in the learning curve of using this product. Other studies on OlogenTM focused on the final IOP results only. Modification of some steps in glaucoma surgery and special postoperative care are essential for the success of CM to smoothly reach the target IOP. Longer follow up period and larger number of cases are needed to consolidate the conclusion.

CONCLUSION

Ologen is a promising product in assisting different glaucoma surgeries, the success of its use could be reached with both intraoperative and postoperative precautions

ETHICAL APPROVAL

All authors hereby declare that all manouvers have been examined and approved by the

appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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