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Wick technique in subscleral and subconjunctival Ologen™ implantation with trabeculectomy in patients with high risk of failure

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Abstract

Introduction: *Ologen™ is traditionally placed subconjunctivally during trabeculectomy, which limits its area of action. Subscleral implantation of Ologen has been described involving fashioning a gutter beneath the scleral flap. This, however, would not prevent fibrosis at the margins of the scleral flap. We describe a modified technique of Ologen® placement that has the potential to prevent scarring at the margins of the flap without the need to fashion a gutter.*

Materials and methods: *The study involved a retrospective review of patients who had undergone trabeculectomy with Ologen implantation by the wick technique between January 2015 and August 2016. Patients judged to be at high risk of trabeculectomy failure were operated with this technique.*

Results: *A total of six patients with median age of 38.5 years were included in the study. The mean preoperative intraocular pressure (IOP) was 30.8 ± 7.3 mmHg, which reduced to 10.6 ± 2.2 mmHg 18 months after surgery. By 18 months postoperative, all patients had IOP in the low teens (two patients required additional topical medication). One patient had two episodes of hypotony that responded to steroids and cycloplegics. Another patient required two needlings to bring IOP under control. No other complications were noted. Ultrasound biomicroscopy done 3 months after surgery showed two pieces of Ologen in one patient.*

Conclusions: *The results of our study show that this technique may be used effectively in patients at high risk of trabeculectomy failure. Further studies in a larger number of patients with diverse high-risk conditions are required before this technique is recommended for general use.*

Keywords: *subscleral Ologen, trabeculectomy, wick technique*

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Introduction

Long-term success of conventional glaucoma filtering procedures is limited by scarring at various places, including the sclera-sclera interface, episclera-sclera interface, conjunctiva-Tenon episclera interface, and at the internal ostium. Ologen™ (Aeon Astron, Leiden, Netherlands) is a bioengineered collagen matrix that causes fibroblasts to grow through it in a random fashion resulting in a loose scar tissue matrix. Traditionally it is placed subconjuctivally.[1,2,3] Subscleral Ologen implantation has been described with an aim to limit subscleral fibrosis. The technique of implanting subscleral Ologen has been described elsewhere. Briefly, after placing a corneal traction suture, peritomy, and fashioning a rectangular scleral flap, mitomycin C (MMC)-soaked sponges are applied over a wide area for one minute. After removing the sponges, the area is washed off thoroughly with balanced salt solution. A rectangle of deep sclera is dissected 2 mm away from the limbus under the scleral flap to fashion a scleral gutter and place a small piece of subscleral Ologen. The remaining Ologen is placed over the scleral flap after placing the releasable sutures.[1,4] However, as only a small piece is placed subsclerally, the area wherein fibrosis may be limited is also restricted. This may be particularly true at the margins of the scleral flap. Additionally, a gutter needs to be fashioned in the scleral bed to position the implant. There is limited experience with the use of subscleral Ologen, with only three studies having been published so far by a single group.[1,4,5] We describe a novel method in which Ologen is placed subsclerally without the need to fashion a gutter beneath the sclera. After making a scleral flap and punching the ostium as in a routine trabeculectomy, one-fourth of the Ologen is simply tucked under the apex of the scleral flap, with a small portion protruding on either side resembling a "wick", and the apical suture tightly placed. The remaining Ologen is placed on the top of the scleral flap and trabeculectomy completed. This technique offers the potential to limit fibrosis at the margins of the flap in addition to the scleral bed. If the use of subscleral Ologen by the wick technique is proven to be effective, there is an opportunity to enhance the efficacy of trabeculectomy with Ologen implantation and low concentration MMC in high-risk situations.

Materials and methods

Study protocol

Institutional review board approval was obtained for a retrospective review of records of patients who had undergone trabeculectomy along with subscleral implantation of Ologen by the wick technique between January 2015 and August 2016. The study adhered to the tenets of the Declaration of Helsinki.

Data with regards to previous intraocular surgery, baseline intraocular pressure (IOP), antiglaucoma medications, anterior segment fundus findings, visual fields, complications, postoperative IOP, antiglaucoma medications and bleb morphology were collected.

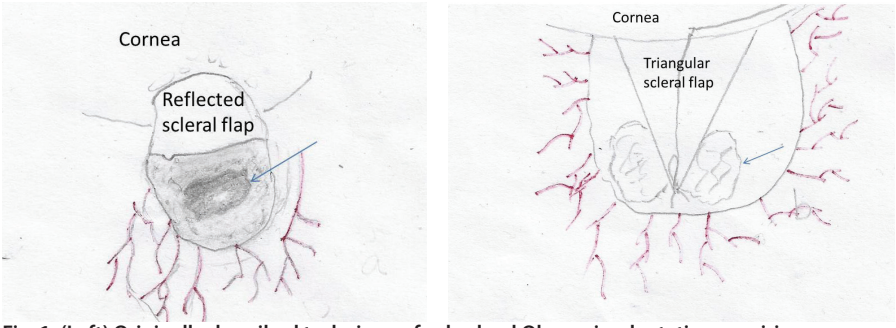

Fig. 1. (Left) Originally described technique of subscleral Ologen implantation requiring fashioning of gutter for Ologen placement (arrow). (Right) Technique used in the present study. A piece of Ologen is simply tucked at the apex of the scleral flap (arrow) and the releasable suture tied tightly. The piece juts out on either side, resembling a "wick".

Video 1. The video shows the steps in the technique from punching the ostium onwards. A 5 x 5 mm triangular scleral flap is made. A Kelly Descemet's punch is used to make the ostium and a peripheral iridectomy is done. The iris is swept off the ostium through the side port with a spatula. A releasable suture is placed at the apex of the scleral flap following Cohen and Osher's technique. One-fourth of the Ologen is positioned under the apex of the scleral flap and the releasable suture tightly tied. Note that the Ologen gets compressed in the process. A second releasable suture is placed at the temporal border of the scleral flap. Viscoelastic is washed off from the anterior chamber with a Symcoe cannula and air injected into the anterior chamber. In view of an air leak from the nasal margin of the scleral flap, an additional releasable suture is placed in the nasal border of the flap. No further air leaks are noted on injecting air into the anterior chamber. The remainder of the Ologen is placed over the scleral flap. The conjunctiva is closed over the Ologen implant with 8-0 vicryl sutures.

Table 2. Postoperative findings of six patients who underwent trabeculectomy with Ologen implantation by wick technique

Patient	Age (years)	Ocular risk factors	Gonioscopy	Antiglaucoma medications	BCVA	IOP (mmHg)
1	27	PK	Closed angles	3T + 1S	20/32	36
2	8	Developmental cataract surgery	NA (Child did not cooperate for gonioscopy)	3T	20/40	24
3	37	Failed trabeculectomy	180° closed angles	4T	20/60	23
4	44	Failed trabeculectomy in fellow eye	Open angles	3T + 1S	20/20	36
5	67	PK	Closed angles	3T + 2S	20/200	40
6	40	None	Narrow angles	3T + 1S	20/20	26

BCVA: best corrected visual acuity; IOP: intraocular pressure; NA: not available; PK: penetrating keratoplasty; S: systemic antiglaucoma medication; T: topical antiglaucoma medication

Surgical technique

Patients judged to be at high risk of failure (risk factors mentioned in Table 1) with conventional trabeculectomy were offered subscleral Ologen implantation (in addition to subconjunctival Ologen placement). Written informed consent was obtained from the patient/legal guardian. All surgeries were performed by a single surgeon (MR) under peribulbar anesthesia. Under surgical asepsis, trabeculectomy was performed using a standard technique. Multiple pledgets (approximately 2 x 1 mm) soaked in 0.1 mg/ml MMC were placed in the subconjunctival space for 1 minute over 4 clock hours. The area was washed with 30 ml of saline. A triangular scleral flap with base 5 mm and height 5 mm was made. Viscoelastic was injected into the anterior chamber after entering with a 15° side port blade. Kelly Descemet's punch (Indo-German Surgical Corporation, Mumbai, India) was used to make the ostium after entering the anterior chamber. A peripheral iridectomy was done. A 6 x 2 mm Ologen implant was inserted for all cases. It was cut into two pieces: three-fourths for subconjunctival placement and one-fourth for subscleral placement (Video 1). The smaller implant was positioned at the apex of the scleral bed and an apical releasable suture tightly placed using the technique described by Cohen and Osher.[5] This resulted in the Ologen showing up on either side of the apex of the scleral flap resembling a wick (Video 1, Fig. 1). An additional releasable suture was placed on the temporal border of the scleral flap. Viscoelastic was washed off from the anterior chamber and air was injected into the anterior chamber. A suture was placed on the nasal border of the scleral flap if air leaks were noted. The conjunctiva was then closed with 8-0 vicryl.

Postoperatively, the patients were treated with topical prednisolone acetate 1% 8 times a day tapered over 3 months, topical homatropine twice a day for 3 weeks, and topical gatifloxacin 0.3% QID for 6 weeks. Patients were reviewed weekly for the first 3 weeks, once every 10 days for the next 2 weeks, and every 3 months thereafter for 18 months. All releasable sutures were removed between 3 and 6 weeks. At each visit, IOP as well as anterior and posterior segment findings were recorded.

Outcome measures

IOP was the primary outcome measure. Absolute success was defined as IOP < 15 mmHg without antiglaucoma medications and qualified success as IOP < 15 mmHg with a maximum of two topical antiglaucoma medications at 18 months. Failure was defined as IOP > 15mmHg with topical antiglaucoma medications or < 6 mmHg with hypotony maculopathy. Secondary outcome measures included best-corrected visual acuity (BCVA), number of antiglaucoma medications used, and bleb morphology.

Table 2. **Postoperative findings of six patients who underwent trabeculectomy with Ologen implantation by wick technique**

Patient	Complications/ additional interventions	IOP 6 weeks	IOP 3 months	IOP 12 months	IOP 18 months	BCVA 18 months	Bleb morphology (MBGS) 18 months	Antiglaucoma medications 18 months
1	Underwent cataract surgery a year after trabeculectomy	11	7	10	11	20/32	CA: 1; PA: 2; H: 1; V: 3	0
2	None	10	11	13	12	20/40	CA: 1; H: 3; V: 2	0
3	None	12	10	12	14	20/60	CA: 2; PA: 3; H: 1; V: 2	0
4	Two episodes of hypotony with shallow AC and SCE at month 7 and 11	18	18	12	10	20/20	CA: 2; PA: 2; H: 1; V: 1	1T
5	Required two needle revisions	8	8	14	9	20/200	CA: 2; PA: 3; H: 3; V: 2	2T
6	None	10	10	6	8	20/20	CA: 2; PA: 2; H: 2; V: 2	0

AC: anterior chamber; BCVA: best corrected visual acuity; CA: central area; H: height; IOP (mmHg): intraocular pressure; MBGS: Moorfields Bleb Grading System; PA: peripheral area; PK: penetrating keratoplasty; S: systemic antiglaucoma medication; SCE: serous choroidal effusions; T: topical antiglaucoma medication; V: vascularity

Results

A total of six patients were included in the study. Preoperative patient data is summarized in Table 1; postoperative patient data is summarized in Table 2. The median age was 38.5 years. All patients had advanced glaucomatous field loss and optic nerve cupping at presentation. Mean preoperative IOP was 30.8 ± 7.3 mmHg. The mean number of antiglaucoma medications (topical and systemic) prior to surgery was four. Four patients (Patients 2, 3, 4, and 6) were deemed to be at high risk of failure on account of young age. Two patients (Patients 1 and 5) had previous penetrating keratoplasty, one (Patient 3) had a failed trabeculectomy, and one (Patient 4) had a failed trabeculectomy in the fellow eye. No intraoperative complications were noted. Median IOP at week 1 postoperative was 11 mm Hg. Mean IOP at week 6 postoperative was 12 ± 3.4 mmHg. All releasable sutures were removed in the postoperative period in all patients by week 6 postoperative. Patient No. 4 developed two episodes of shallow anterior chamber with hypotony and serous choroidal effusions that responded to topical steroids and cycloplegics. Patient No. 5 required two needle revisions to keep the IOP low. IOP reduction at 3 months postoperative was 20.2 ± 8.3 mmHg. At 12 months postoperative, mean IOP was 12.2 ± 1.5 mmHg. Patient 1 underwent uneventful cataract surgery a year after trabeculectomy; no substantial change in IOP was noted after the cataract surgery. At 18 months postoperative, mean IOP was 10.7

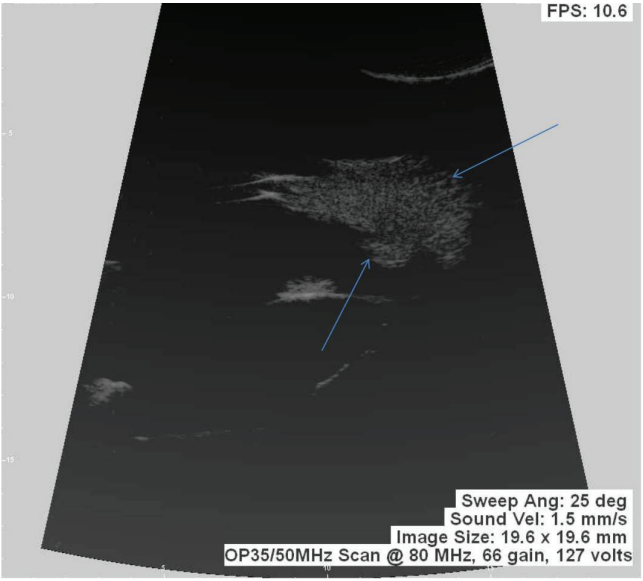

Fig. 2. Ultrasound biomicroscopy of Patient 1 performed 3 months after surgery showing two pieces of Ologen.

± 2.2 mmHg. Two patients were on topical antiglaucoma medications. Thus, four out of six patients met the criteria for absolute success and the remaining two had qualified success. None of the patients had a reduction in BCVA. At 18 months, the bleb area had vascularity similar to the adjacent conjunctiva and all patients had elevated, diffuse blebs. Ultrasound biomicroscopy conducted at 3 months postoperative in Patient 1 showed two pieces of Ologen (Fig. 2).

Discussion

Trabeculectomy with adjunctive MMC is currently the gold standard for lowering IOP in patients with advanced glaucoma. The use of MMC is however associated with a number of complications such as late hypotony, scleral melts, bleb leaks, and blebitis, to name a few. Biodegradable collagen implants such as Ologen were introduced to avoid the complications of MMC. Ologen causes the fibroblasts to grow in a random fashion, thereby reducing scar formation. It also acts as a spacer between the sclera and conjunctiva, preventing adhesions. However, Ologen can only act over a small area 6 mm in diameter and may not be effective in preventing fibrosis in the surrounding areas. Some studies have shown that the use of Ologen with trabeculectomy gives lower success rates than trabeculectomy with MMC. Combining Ologen implantation with a low concentration of mitomycin application has been shown to give higher success rates without any vision-threatening complications.[1-5]

Failure of trabeculectomy over the long term may occur because of scarring at the conjunctiva-sclera interface, sclera-sclera interface and at the internal ostium.[6] Subscleral implantation of Ologen has been described after making a gutter under the scleral flap.[1] However, as mentioned earlier, this may not be effective in preventing scarring at the margins of the flap. We have also noted that it is very difficult to make a deep gutter without risking perforation. Our technique of implantation may be easier and allows for the implant to be in position at the margins and under the scleral flap. Our study shows that trabeculectomy with Ologen implantation by the wick technique may be effective in lowering IOP in these high-risk cases. As MMC was used in a very low concentration for one minute (as is recommended for use with Ologen implantation),[1,4,6] it is unlikely that this alone may have been the only reason for success. Only one patient had a late hypotony. The presence of subscleral Ologen on UBM (Fig. 2) after releasable suture removal may be proof of efficacy. The releasable sutures were tightly placed across the Ologen implant. We have noted that Ologen becomes very soft and compressible once it comes in contact with saline. All releasable sutures were removed in the postoperative period to facilitate Ologen expansion at the margins and under the scleral flap. Patients with higher baseline IOP had a greater drop in IOP.

The limitations of our study include a small number of patients, its retrospective nature, and the lack of a control group. This technique has not been studied in other high-risk conditions, such as neovascular glaucoma. We recommend further studies on a larger number of patients before this technique can be recommended for general use.

Declarations

Competing interests
None to declare..

Funding
None to declare.

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None to declare.

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