Efficacy of Utilizing a Biodegradable Collagen Matrix in Trabeculectomy: The First Jordanian Experience

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Abstract

Purpose: To evaluate the efficacy and safety of using a biodegradable collagen matrix in glaucoma filtering surgery

Methods: We treated nine eyes of nine patients with moderate to advanced open angle glaucoma and uncontrolled intraocular pressure (IOP) on maximally tolerated medical treatment. Fornix-based trabeculectomy was performed in all patients and a biodegradable collagen matrix implant was inserted over the flap and underneath the conjunctiva.

Results: Mean age was 37.9 years (range: 16-68). Mean follow up was 7.9 months (range: 3-18). With successful IOP control defined as IOP ≤ 21 mmHg with at least 20% reduction from baseline on the same or fewer number of pre-trabeculectomy medications, 8 out of 9 eyes (88%) fit the criteria for success over the course of follow up. Among all eyes with ≥ 3 months of follow up there was a significant drop in IOP from pre-trabeculectomy 3 months postoperatively (p ‹ 0.05). The percentage of patients requiring › 2 medications declined from 100 %(9/9) at pre-trabeculectomy to 11% (1/9) at 3 months (p ‹ 0.05). The patient who did not meet the criteria of success regained successful IOP control with bleb needling done 6 weeks after the initial surgery. One eye developed postoperative hypotony for which bleb revision was required.

Conclusion: The use of biodegradable collagen matrix implant appears to hold promise as a tool to increase success rate of glaucoma filtration surgery. Further studies are needed to evaluate the long term results and compare this against the use of antifibrotics in trabeculectomy.

Keywords: Trabeculectomy, Intraocular pressure, Biodegradable collagen matrix.

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Introduction

Trabeculectomy was introduced by Cairns in 1968.(1) It is still considered the golden standard glaucoma surgery and still the one most commonly adopted by glaucoma surgeons worldwide among all other glaucoma surgeries. The most common cause of late trabeculectomy failure is scarring at the conjunctival–Tenon's capsule–episcleral interface.(2) Other causes of failure are Tenon's cyst formation and scarring at the level of the episclera, the scleral flap, or the internal ostium.(3)

Although the use of 5-fluorouracil and mitomycin-C has resulted in increased success

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rates, particularly in high-risk patients,[4–13] late failure may occur. These agents, also, can cause many complications, including hypotony, wound leaks, and endophthalmitis.[14]

A newly introduced in the market collagen matrix implant, named Ologen™ (Aeon Atron Europe, Netherlands) for wound modulation may reduce these problems. This artificial extracellular matrix is made of atelocollagen cross-linked with glycosaminoglycan. Ologen is a biodegradable scaffolding matrix that induces a regenerative wound healing process without the need for antifibrotic agents. The surgeon places the device over the scleral flap during the filtering procedure.[14]

Up to our knowledge, this study is the first in Jordan that aimed to assess the outcomes and the success rates of trabeculectomy with the use of this collagen implant.

Materials and Methods

This study involved a retrospective chart review of patients who had had trabeculectomy using this collagen implant (Ologen™). This study was approved by the IRB (Institutional Review Board) committee in King Abdullah University Hospital (KAUH). Variables including demographics, type of glaucoma, IOP level before and after surgery, number of glaucoma medications before and after surgery as well as complications were recorded and analyzed. Each patient was followed up for at least 3 months.

All surgeries were done at KAUH by the same surgeon (WS). The technique involved a fornix-based conjunctival incision. The rectangular scleral flap was closed with two relatively loose stitches. The collagen matrix is then placed over the scleral flap. No suture is required to secure the implant, and as soon as it touches the sclera, it absorbs aqueous and molds to the sclera tissue. Collagen matrix therefore need not be presoaked or prepared in any way.[14] After that, meticulous closure of the conjunctiva is done to achieve a watertight wound.

Results

We treated nine eyes of nine patients with moderate to advanced open angle glaucoma and uncontrolled intraocular pressure (IOP) on maximally tolerated medical treatment. Mean age was 37.9 years (range: 16-68). Mean follow up was 7.9 months (range: 3-18).

With successful IOP control defined as IOP ≤ 21 mmHg with at least 20% reduction from baseline on the same or fewer number of pre-trabeculectomy medications, eight out of nine eyes (88%) fit the criteria for success over the course of follow up. Among all eyes with ≥ 3 months of follow up there was a significant drop in IOP from pre-trabeculectomy 3 months postoperatively ($p < 0.05$).

The percentage of patients requiring › 2 medications declined from 100% (9/9) at pretrabeculectomy to 11% (1/9) at three months ($p < 0.05$). The patient who did not meet the criteria of success regained successful IOP control with bleb needling done six weeks after the initial surgery.

Complications were few; one eye developed postoperative hypotony for which bleb revision was required. No other complications were encountered.

Discussion

It is well known that episcleral fibrosis and subconjunctival scarring are the major causes of failure in glaucoma filtering surgery.[2,3] Collagen matrix is designed to prevent or reduce such scarring. Specifically configured to facilitate the repair of connective and epithelial ocular tissue, the implant is designed to minimize the random growth of fibroblasts and instead promote their growth through the pores in the matrix.[14] No significant side effects were reported from collagen implants.

The efficacy of collagen matrix has been demonstrated in animal models.[15-17] Chen and colleagues performed standard trabeculectomy on 17 rabbits, with their left eye receiving the collagen matrix implant and their right eye serving as surgical controls. During the first few days, the postoperative reduction in IOP (15%) was equal in both groups. Pressure had decreased to 55% below baseline values at day 28 in the treated eyes but had returned to preoperative levels by day 21 in the control eyes. Histological examination showed a prominent bleb in the treated eyes compared with scarring and limited bleb formation in the control eyes.[16]

In our retrospective series, the success rate of trabeculectomy using this collagen implant was fairly high (88%) over the course of follow up (averge: 7.9 months). Perez et al reported the outcomes on a larger series of 65 eyes and showed a significant mean IOP reduction (from 21.4± 9.2 to 12.3± 3.7 mmHg) over the period of follow up (36 months).[18]

These promising results could offer an alternative method for modulating wound healing following filtration surgery. However, further comparative studies against the use of antifibrotics are warranted.

Conclusion

The use of biodegradable collagen matrix implant appears to hold promise as a safe tool to increase success rate of glaucoma filtration surgery. Further studies are needed to evaluate the long term results and to compare the outcome and safety of using this collagen implant against the use of antifibrotics in trabeculectomy.

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فاعلية استخدام الكولاجين المتحلل في عمليات النافذة: أول خبرة في الأردن

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الملخص

يعتبر داء الزرق (الجلوكوما) من الاسباب الهامة لفقدان البصر. حيث ان ارتفاع ضغط العين النسبي يؤدي الى تلف العصب البصري والانحسار التدريجي في المساحة البصرية.

تعتبر عملية النافذة او المصرف (Trabeculectomy) من أشهر عمليات الزرق إلا ان نسب نجاحها تهبط بسبب التليفات التي تغلق ذلك المصرف. في هذه الدراسة بيّنا ان استخدام مادة الكولاجين يزيد من فرص النجاح. يعزى ذلك الى ان الكولاجين يلعب دوراً هاماً في منع الالتصاقات والتليفات. بالمقابل فإن الكولاجين يعتبر أكثر اماناً من المواد الكيميائية التي تستخدم لمنع هذه التليفات.

الكلمات الدالة: عمليات النافذة، داء الزرق، الكولاجين المتحلل.