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Original Research Article

Trabeculectomy with collagen implant for the treatment of glaucoma

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ABSTRACT

Purpose: The goal is to assess the effectiveness and safety of trabeculectomy with collagen implants for glaucoma patients who cannot be managed medically.**Materials and Methods:** This research is a case series that intervenes without randomization and focuses on potential outcomes. The study consisted of 76 treated eyes of 76 patients with uncontrollable glaucoma. A thorough examination of the eyes was performed on all patients, and the results were documented. Each patient underwent conventional trabeculectomy surgery using the fornix-based approach. Additionally, a subconjunctival collagen implant known as Ologen was also utilized. We recorded preoperative data such as age, gender, best-corrected visual acuity, intraocular pressure, glaucoma type, and a few preoperative antiglaucoma medications. We recorded the intraocular pressure after surgery, the number of glaucoma medications given after surgery, and any complications that occurred during the postoperative period. Each patient was monitored for a minimum of six months.**Results:** Before the operation, the average intraocular pressure (IOP) was 34.21 ± 12.5 , and the patient took at least two IOP-lowering medications (average 2.3). The postoperative IOP was measured after three months and found to be 13.85 ± 5.42 mm Hg, with a p-value of 0.060. On average, the blood pressure decreased by 16.42 ± 6.42 mmHg after six months, with a p-value of 0.056. After six months, it was observed that the medication significantly reduced 1.22 in intraocular pressure ($P < 0.001$), leading to a notable decrease of 17.79 mmHg. The success rate stood at a commendable 97.36% at the three-month mark, but it reduced to an alarming 88.15% by the last visit. Within just one month after the operation, several complications arose, including three cases of hyphaema, one case of the shallow anterior chamber, and two cases of wound leak. All patients showed gradual improvement with conservative management. However, three of them developed cataracts within three months.**Conclusion:** For patients who have not responded to preoperative antiglaucoma medications, to manage intraocular pressure is a dependable and safe surgical procedure that offers an efficient treatment option.This is an Open Access (OA) journal, and articles are distributed under the terms of the [Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License](https://creativecommons.org/licenses/by-nc-sa/4.0/), which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.For reprints contact: reprint@ipinnovative.com

1. Introduction

It's important to mention that glaucoma is the second most common cause of blindness on a global scale.

The gold standard Filtration surgery is trabeculectomy to reduce intraocular pressure, first introduced by Cairns in 1968.¹ However, it is important to remember that surgical failure often occurs due to episcleral fibrosis and subconjunctival scarring. When collagen is deposited linearly during conjunctival scarring, it can cause adhesions

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between the conjunctiva and episcleral, as well as the scleral flap and underlying tissues. This can obstruct the flow of aqueous fluid.^{2,3} To prevent this, Mitomycin-C (MMC) and 5-Fluorouracil (5-FA) are commonly used to limit the proliferation of fibroblasts and discourage scarring. However, it is crucial to note that these treatments are known to cause non-selective cell death and cytotoxicity. As a result, wound healing with thin avascular epithelium may occur.⁴ Anti-metabolites can raise the chances of postoperative complications such as wound leak, hypotony, phlebitis, and endophthalmitis.⁵ A collagen implant containing more than 90% atelocollagen and less than 10% glycosaminoglycans can be utilized during trabeculectomy to enhance the success rate and reduce complications.⁶ This implant is biocompatible, biodegradable, and modulate wound healing may be better option.

The implant is placed above the scleral flap and helps heal by promoting the growth of fibroblasts and myofibroblasts into the pores. This results in the secretion of connective tissue as a loose matrix, which decreases the formation of scars and wound contraction. This implant is believed to enhance the success rate of trabeculectomy surgeries without the need for antifibrotic agents. However, due to the limited published data from Bangladesh on this material's role in trabeculectomy, A thorough investigation was carried out to acquire additional details regarding the impacts of collagen use on the outcome of Trabeculectomy.

2. Materials and Methods

A series of interventions were conducted in the glaucoma department of Chittagong Eye Infirmary and Training Complex in Bangladesh between January 2010 and July 2012. It was a non-randomized, prospective study. A circular collagen implant measuring 6x1 mm was utilized. The review board at CEITC Hospital approved the study which was in accordance with the Helsinki Declaration. The study enrolled 76 patients with various types of glaucoma who were not responding to medication, could not tolerate it, and required trabeculectomy. In the case of cataract surgery, a combined procedure is typically executed, which involves both trabeculectomy with a collagen implant and the insertion of a posterior chamber intraocular lens (IOL). Before the implant and operation, a thorough explanation and written informed consent were obtained. All patients have been successfully followed up, and none have been lost to follow up. Before surgery, data was gathered for each patient, including their age, gender, type of glaucoma, best-corrected visual acuity, intraocular pressure measurement at various times of the day, and the antiglaucoma drugs they had taken. The data provided information on the date of the operation, the surgical method used, and any complications that occurred during the procedure. We analyzed all the recorded postoperative IOP by Non-contact tonometer

(NCT), the number of glaucoma medications after surgery, and the occurrence of postoperative complications. At each postoperative visit, the examination included BCVA, intraocular pressure assessment, the anterior segment, cells and flare, and bleb condition, which were assessed using a slit-lamp biomicroscope and fundus was examined. Postoperatively, the subjects underwent examinations on days 1, day seven, 1, 3, and 6 months. In some cases, close follow-ups were needed. The IOP was measured utilizing Goldmann applanation tonometry. The study's success was measured based on two criteria: There are two levels of success when managing glaucoma: complete success and qualified success. Complete success means that the intraocular pressure (IOP) is 21 mmHg or lower without antiglaucoma medication. Qualified success means that the IOP is 21 mmHg or lower but with the use of antiglaucoma medication. Hypotony is when the intraocular pressure (IOP) drops below six mmHg. The presence of iridocorneal touch identifies a flat anterior chamber or when the depth of the anterior chamber is less than one corneal thickness at its centre.



Figure 1: A piece of ologen

2.1. Surgical technique

During surgeries, the necessary procedures are performed by individual surgeons. After administering peribulbar anaesthesia and appropriate draping, a fornix-based incision is made around 12 o'clock. A triangular, superficial scleral flap measuring 4x4mm is confidently created, with the apex facing the superior fornix. Then, precise deep sclerectomy and peripheral iridectomy procedures measuring 2x1 mm were successfully performed. The scleral flap is then closed using a single suture made of 10/0 nylon, ensuring the best possible outcome. After drying the surgical site, Ologen is placed beneath the conjunctiva, specifically at the uppermost part of the triangular flap, to ensure a successful operation. The conjunctiva is then closed like a wing using two 10/0 nylon sutures. Following the surgery, all the patients received Atropine 1% treatment thrice a day for two

weeks. The recommended treatment is to take Moxifloxacin four times a day for one week and use Prednisolone acetate eye drops six times a day for three weeks., gradually tapering off afterwards.

We conducted a statistical analysis using Windows SPSS. We analyzed preoperative and demographic data, as well as IOP comparison, using students' T-tests. The c2 test analyzed surgical failure, success, and complications. Using the long-rank test, we conducted a Kaplan-Meier survival analysis to determine surgical success. Statistically, p-values less than 0.05 is significant.

3. Results

Seventy-six patients with an average age of 45.03 ± 7.5 (ranging from 11 to 80 years) were included in this study. There were 56 men and 20 women. The 76 patients were grouped into three different age categories to understand the results better. All patients fell within three age groups: 11-30, 31-50 and over 50 (Table 1). There are three groups of patients with percentages of 27.6 (n=21), 43.4 (n=33), and 29.0 (n=22), respectively.

Before the operation, 33 patients (43.4%) had poor visual acuity of 3/60 or less. Approximately 20 patients (26.3%) had borderline visual acuity of 6/60 to 4/60, and 23 (30.3%) had good visual acuity. After one month, 53.9% of the patients achieved a "good" visual acuity between 6/6-6/36. Six months later, 67.1% (n=51) of the patients had achieved good vision. (Table 2)

Of the patients, 35.5% were diagnosed with primary angle closure glaucoma. Primary open-angle glaucoma was diagnosed in 18 out of the patients, representing a percentage of 23.7%. Nine patients were diagnosed with glaucomatocyclitic crisis. Eight patients were presented with Steroid-induced Glaucoma, 7.9% of patients presented with neovascular glaucoma, 6.6% with Secondary Glaucoma and 3.9% with normal tension glaucoma. (Table 3)

Among the patients under observation, 29 individuals (38.15%) were found to have been on a regimen of three medications before the surgery. However, only one patient (1.3%) continued the same medication protocol post-surgery. The average number of medications prescribed for reducing intraocular pressure (IOP) before the surgery was 2.3 (with a range of 1 to 3), but post-surgery, the number significantly decreased to just 1.2 (Table 4).

Out of 69 patients, 90.8% underwent trabeculectomy with collagen implantation. Five (6.6%) patients underwent trabeculectomy with collagen and posterior chamber lens implantation. Two patients received a re-trabeculectomy procedure using a collagen implant.

The mean pre-operated intraocular pressure was 34.21 ± 12.50 mm of Hg, ranging from 4 mm to 58 mm Hg. During the follow-ups, the mean postoperative intraocular pressure was observed as 16.71 ± 6.38 mm of Hg, ranging

from 4 to 48 mm Hg in month 1. The mean intraocular pressure was 13.85 ± 5.42 mm Hg (range 4-28) in month three and 16.42 ± 6.42 mm of Hg (range 4-50) in month 6. The difference in intraocular pressure preoperatively and six months of surgery was statistically significant ($P < 0.05$). The mean IOP reduction at the end of month three and the last visit was 20.36 mm Hg (59.5%) and 17.79 mm Hg (52%), respectively (Table 5).

The average Intraocular pressure (IOP) before surgery for individuals diagnosed with primary angle closure glaucoma was 37.8 ± 13.1 mm Hg. In the first month after surgery, the average IOP dropped to 18.2 ± 11.8 mm Hg and decreased to 16.3 ± 10.9 mm Hg in the third month. By month six, the average IOP slightly increased to 18.1 ± 11.1 mm Hg. Patients diagnosed with steroid-induced glaucoma had an average IOP before surgery of 45.0 ± 13.0 mm Hg. After one month, the average IOP dropped to 20.8 ± 6.4 mm of Hg, and after six months, it decreased further to 15.5 ± 4.8 mm. For individuals with POAG, the average initial IOP was 34.1 ± 8.8 mm of Hg. After six months, the average IOP had decreased to 13.6 ± 3.4 mm of Hg. Before the surgery, the intraocular pressure was measured at 41.3 ± 8.4 mmHg in NVG patients. After one month, the IOP decreased to 21.3 ± 20.9 mmHg. Six months later, the IOP was measured at 26.6 ± 18.27 mmHg (Table 6).

Three patients experienced hyphaema as a postoperative complication; a shallow or flat anterior chamber was found in 1 patient, and a wound leakage was observed in 2 eyes post-operatively. All three occurred within one month. 6.75% (n=5) of patients develop cataracts within three months. According to our criteria for success, during the 3rd month, the complete success rate was 97.36%, and the qualified success rate was 2.63%. However, during the last visit, the complete success rate decreased to 88.15%, while the qualified success rate increased to 9.21%. Unfortunately, 2.64% of the cases failed.



Figure 2: The outcome of implanted collagen during filtration surgery

4. Discussion

In 1968, Cairns introduced trabeculectomy, the most frequently performed surgical procedure for glaucoma. During this procedure, a section of the trabecular meshwork must be removed, and a partial thickness scleral flap should cover the sclerotomy. A fistula is formed between the front part of the eye and the space below the conjunctiva.^{1,2,7} Excessive scarring after surgery can cause

Table 1: Displays the percentage distribution of age and gender among the patients who underwent surgery

Age group	Male N %		Female N %		Total N %	
11-30	15	71.4	6	28.6	21	27.6
31-50	24	72.7	9	27.3	33	43.4
≥ 51	17	77.3	5	22.7	22	29.0
Total	56	73.64	20	26.36	76	100

The Mean Age \pm SD: 45.03 \pm 7.5**Table 2:** Displays the visual acuity of both pre-and post-operation

Visual acuity	Preoperative VA N %		VA @ One month of Surgery N %		VA @ 3 Months of Surgery N %		VA @ 6 Months of Surgery N %	
6/6-6/36	23	30.3	41	53.9	49	64.5	51	67.1
6/60-4/60	20	26.3	18	23.7	14	18.4	13	17.1
≤ 3/60	33	43.4	17	22.4	13	17.1	12	15.8
Total	76	100	76	100	76	100	76	100

Table 3: Enumerates the various kinds of glaucoma

Different Types of Glaucoma	Frequency	Percentage
Primary angle closure glaucoma	27	35.5
Primary open-angle glaucoma	18	23.7
Glaucomatocyclitic crisis	09	11.8
Steroid Induced Glaucoma	08	10.5
Neovascular Glaucoma	06	7.9
Secondary Glaucoma	05	6.6
Normal tension glaucoma	03	3.9
Total	76	100

Table 4: Pre and postoperative antiglaucoma medication

Preoperative Medications	Preoperative		Postoperative	
	Number	Percentage	Number	Percentage
Using one drug	07	9.2	07	9.2
Using two drugs	42	55.3	01	1.3
Using three drugs	29	38.2	01	1.3
Total	76	100	09	11.84
The mean \pm SD	2.3 \pm 0.62		1.22 \pm 0.67	

Table 5: Initial intraocular pressure (IOP) comparison between operated and non-operated eye

IOP	Preoperative IOP		IOP @ One month of Surgery		IOP @ Three months of Surgery		IOP @ Six months of Surgery	
	N	%	N	%	N	%	N	%
0-10			28	36.84	25	32.89	14	18.42
11-20	14	18.42	40	52.63	49	64.47	53	69.73
21-30	12	15.78	5	6.57	2	2.63	7	9.21
31-40	23	30.26	1	1.31	0	0	0	0
41-50	09	11.86	2	2.62	0	0	2	2.64
51+	18	23.68	0	0	0	0	0	0
Total	76		76	100	76	100	76	100

Table 6: Compares the IOP levels before and after surgery for various types of glaucoma

Diagnosis	Mean IOP (Preoperative)	Mean IOP @ 1 Month of S urgery	Mean IOP @ 3 Months of S urgery	Mean IOP @ six months of S urgery
Primary angle closure	37.8±13.1	18.2±11.8	16.3±10.9	18.1±11.1
GCC	19.4±2.3	11.8±2.4	11.2±2.9	15.2±7.1
Steroid Induced	45.0±13.0	20.8±6.4	15.3±4.7	15.5±4.8
Primary Open angle	34.1±8.8	15.3±3.1	13.8±3.7	13.6±3.4
Neovascular	41.3±8.4	21.3±20.1	21.3±5.2	26.6±18.3
Normal-Tension	18.1±2.0	12.3±4.7	16.5±2.7	16.6±5.1
2° Glaucoma	36.3 ±3.8	16.1±7.79	14.6±2.00	13.3±2.06

fibrosis, which may block the flow of aqueous solution and greatly decrease the success of trabeculectomy.⁸ To reduce fibroblast proliferation in the subconjunctival space and the Tenon's capsule, MMC and 5-FU are used. Trabeculectomy is a surgical procedure that can be improved using agents such as MMC.⁹ In 1990, MMC was first used during trabeculectomy as an anti-metabolite. Studies have shown that trabeculectomy with MMC has a success rate ranging from 62% to 93% after three months to three years of follow-up.^{10–12} However, this success comes with some adverse effects, such as vascularization of the blebs, conjunctival thinning over the bleb, endophthalmitis and phlebitis.¹³ Marked hypotony can cause some complications, like choroidal detachment, bleb failure, cataracts, corneal oedema, maculopathy, and vision loss.^{14,15}

Furthermore, using 5-FU may lead to corneal epithelial toxicity, manifesting as discomfort, tearing, and blurred vision. Similarly, MMC has the potential to cause damage to various eye structures, such as the ciliary body, corneal endothelial cells, and limbal stem cells, ultimately resulting in hypotony and subconjunctival space occupation.^{16–18} Therefore, alternative intraoperative anti-scarring treatments, such as collagen implants, have been developed to guide fibroblast growth randomly inside a biodegradable collagen glycosaminoglycan matrix.¹⁹

Our study involved patients who suffered from medically uncontrolled glaucoma. Male was preponderance probably easily accessible to hospital and clinic. Trabeculectomy with collagen implant was performed on all participants, and the study was non-randomized. The most prevalent form of glaucoma is primary open angle glaucoma rather than angle closure in our subcontinent, in people over 40 years, the prevalence of POAG is 2.5%, while PACG having of 0.4%.²⁰ In developing countries, patients often have significant vision loss in one or both eyes and experience a painful acute attack when diagnosed with primary angle closure glaucoma. Non-reacting pupil and peripheral anterior synechiae are common findings in such cases. Individuals who do not experience positive results from medication for treating glaucoma must undergo a trabeculectomy operation. However, primary angle closure glaucoma patients often experience long-

term postoperative ocular inflammation, shallow anterior chamber, failed trabeculectomy, and secondary cataract. Our study found that after six months of collagen implantation in PACG patients, the intraocular pressure (IOP) measured 18.07±11.13 mm Hg, and there were no instances of shallow anterior chamber or significant inflammation after the surgery. Further follow-up for longer periods is necessary.

Patients with primary open-angle glaucoma and glaucoma caused by steroid use successfully managed their intraocular pressure after trabeculectomy with implant collagen. This positive outcome was observed six months after the surgery. Before the surgery, 59.7% of patients had visual acuity (VA) 6/60 or less, and 30.3% had VA between 6/6 and 6/36. After the surgery, 67.1% of patients maintained their vision between 6/6 and 6/36. Blurry vision was caused by high IOP, leading to cornea swelling. In addition, it is worth noting that trabeculectomy with collagen and posterior chamber lens implantation was performed on five patients with glaucoma and cataracts.

A retrospective study was conducted at two separate centers in India. According to the findings, the study was non-randomized and non-comparative; trabeculectomy with collagen implant boasts a high success rate, 70% in Madurai and 91.42% in Coimbatore after six months. The reduction in antiglaucoma medications was 52.98% in Madurai and 57.80% in Coimbatore, with medication decreasing from 2.68 to 1.26 and 2.37 to 1, respectively. There was no difference in reduction in antiglaucoma medications or qualified success rates between the ologen and MMC groups.²¹ Our study achieved complete success in 97.36% of patients after three months and 88.15% after six months. The reduction in antiglaucoma medications was from 2.3 to 1.2.

A research study conducted by Scott and colleagues observed the success rates of trabeculectomy with MMC for 68 patients over one and two years. The results showed a success rate of 85.4% and 77.9% for one and two years, respectively. The average IOP significantly decreased from 26.3 to 11.3 mm Hg in one year and 11.9 mmHg in two years.²² A study conducted by Rosentreter et al. found that a 50% reduction in IOP was observed in the trabeculectomy with the MMC group. A 43% reduction was observed in

the trabeculectomy with the collagen group one year after the surgery.²³ Our study found that the mean IOP reduction was 20.36 mmHg (59.5%) at three months and 17.79 mmHg (52%) at six months. These successes are like the success rate of trabeculectomy with MMC in many countries.

Managing intraocular pressure in cases of neovascular glaucoma can be difficult. Out of a group of patients, six individuals (accounting for 7.9% of the group) were diagnosed with neovascular glaucoma and had a preoperative IOP of 41.3 ± 8.4 . After six months, the mean IOP was 26.6 ± 18.3 mm Hg. Unfortunately, in two of these patients, trabeculectomy with collagen implant was unsuccessful, resulting in an IOP of 50 after six months post-operation.

Some complications were observed in the trabeculectomy with collagen study by Papaconstantinou D and colleagues. One patient experienced hypotony, while another presented hyphaema in one eye. Additionally, two patients had a shallow or flat anterior chamber. By the end of the first month after surgery, two eyes had an encapsulated bleb. Regrettably, endophthalmitis developed in one patient's eye. After the surgery, adding two extra 10-0 nylon sutures to the conjunctiva was necessary to manage a flat anterior chamber with a positive Seidel test. To effectively treat the encapsulated bleb, a needle must be used to inject 5-FU (5 mg) twice a week directly at the operation site as part of adjuvant therapy.¹³

Despite their findings, we did not experience any notable complications. Our research found that one patient experienced a shallow anterior chamber after surgery, while two had a wound leak. Fortunately, these issues were resolved without further intervention by administering a subconjunctival dexamethasone injection and patching the affected area with Atropine 1% for two days. Additionally, three patients experienced hyphaema during the first three days after surgery, likely caused by blood leaking from the scleral flap angle into the anterior chamber. Finally, five patients developed cataracts, and two were recommended for cataract surgery.

We noted no initial postoperative problems like hypotony or choroidal detachment, indicating that less likely complications in trabeculectomy with collagen implant. There were no bleb avascularity, phlebitis, endophthalmitis, or bleb dysesthesia symptoms during the last visit. We did not identify any collagen-specific adverse effects, including implant translocation or conjunctiva erosion, nor did anyone in our study exhibit an allergic reaction to collagen. On histologic examination, a prominent bleb was observed in the collagen matrix implanted bleb.²⁴ However, biodegradation occurred slower than the previously mentioned 60-90 days period. Even after six months post-filtration surgery, partial passive and enzymatic biodegradation of the implant was still evident in the collagen group.

Collagen implants are a promising alternative to anti-metabolites for reducing intraocular pressure (IOP) after trabeculectomy. It offers comparable results with a lower risk profile. This study's limitations are the short follow-up duration and the lack of a control group of trabeculectomy with other widely accepted antifibrotic agents like MMC. Our study reveals that trabeculectomy with the implantation of a collagen implant is a safe method for penetrating filtration surgery.

Recommendations, evidence supports trabeculectomy with biodegradable collagen implant for glaucoma with proper clinical governance, consent, and audit.

5. Conclusion

In summary, providing regular postoperative check-ups for patients who have had filtration surgery in developing countries like Bangladesh can be challenging. This is due to various factors, including low awareness and education about health, low socio-economic backgrounds, and remote locations. Having a safe and effective surgical option for glaucoma is essential. A safer option for treating Glaucoma is trabeculectomy with biodegradable collagen implantation, which provides a higher level of safety. It is important to conduct a longer follow-up period with a larger number of patients to determine the long-term effectiveness of collagen.

6. Source of Funding

None.

7. Conflict of Interest

None.

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