



## Original Research Article

# Comparative study between trabeculectomy with collagen implant versus trabeculectomy with mitomycin C in patients requiring glaucoma surgery at a tertiary care hospital in Rajasthan

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## ARTICLE INFO

## Article history:

Received 18-07-2021

Accepted 16-09-2021

Available online 31-03-2022

## Keywords:

Trabeculectomy

Collagen Implant

Mitomycin C

Anti glaucoma medications

## ABSTRACT

**Background:** Glaucoma is a chronic multifactorial degenerative optic neuropathy and is the second leading cause of irreversible blindness worldwide. Aim of this study was to study trabeculectomy with collagen implant versus trabeculectomy with mitomycin C in patients requiring glaucoma surgery

**Materials and Methods:** 50 eyes of 44 patients were assigned randomly to undergo trabeculectomy either with collagen implant (study group) or with MMC (mitomycin C)(control group). Preoperative data included age, gender, IOP (intraocular pressure) and number of preoperative medications. Postoperatively IOP, number of glaucoma medications and postoperative complications if any were recorded on follow up at seven days, one month and three months. Proportion was compared using chi square test while mean using student t test.

**Results:** Baseline characteristics were matched. The intervention arm had lower IOP post operatively at 3 months ( $11.84 \pm 4.21$  vs  $17.72 \pm 5.93$ ,  $p = 0.002$ ) but not at day 7 ( $17.14 \pm 9.88$  vs  $21.37 \pm 11.07$ ,  $p = 0.12$ ), 1 month ( $16.77 \pm 11.54$  vs  $22.91 \pm 9.62$ ,  $p = 0.05$ ); lesser need of anti-glaucoma medication ( $0.48 \pm 0.77$  vs  $1.95 \pm 1.26$ ,  $p = 0.0001$ ); more complete treatment success (15 vs 7), lower treatment failure (1 vs 4), less Postoperative complications were seen in cases than controls, flat AC(12%vs16%), Hyphema (4% vs 8%); However hypotony were comparable(12%).

**Conclusions:** This study supports superiority of collagen implant with trabeculectomy as opposed to trabeculectomy with mitomycin C in terms of better clinical outcome and reduced post operative antiglaucoma medications.

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## 1. Introduction

Glaucoma is an irreversible cause of blindness affecting more than 76 million people worldwide as of 2020 and is projected to be 111.8 million by 2040.<sup>1</sup> From a pathological and therapeutic point of view IOP is the cardinal modifiable risk factor and stops the disease progression if reduced by 30-50%.<sup>2,3</sup> Ophthalmic antiglaucoma medications are currently the mainstay of therapy. Out of these prostaglandin

analogs or beta blockers remain the first line drugs. If monotherapy alone is not effective in controlling IOP, other drugs with different mechanisms like topical carbonic anhydrase inhibitors and alpha adrenergic agonist can be added.<sup>4</sup> Medical management cannot reduce IOP to target levels in all patients, and some continue to experience deterioration of the optic nerve despite maximum medical therapy. In cases like these Argon laser trabeculoplasty or selective laser trabeculoplasty plays an important role in which laser energy is delivered to the trabecular meshwork, with the goal of achieving a lower IOP.<sup>5</sup> Trabeculectomy

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as a surgical approach remains the successful treatment for IOP reduction.<sup>6</sup> The increased success of trabeculectomy, primarily in lowering IOP and decreasing visual field progression, has largely been due to the implementation of antifibrotic agents, specifically MMC and 5 fluorouracil(5-F).<sup>7</sup>

However, the antifibrotics come with their own disadvantages including, hypotony, bleb leakage, cataract formation, avascular filtering blebs, thinning of the conjunctiva, subsequent blebitis, and endophthalmitis.<sup>8</sup> Therefore to get rid of these complications associated with antifibrotics, a novel collagen implant by the name of OLOGEN (Aeon Astron Europe BV, Leiden, the Netherlands; OLO) has been developed. Its use therefore offers an alternative method for wound healing, potentially preventing the complications of antifibrotics and providing long term IOP control.<sup>9</sup>

However there is a theoretical risk of increased inflammation in eyes with collagen implant as the implant is non-human (porcine) in origin.<sup>10</sup> While the Ologen implant may be comparable to MMC in regards to efficacy and safety, the cost of the implant may limit its use as a clear disadvantage compared with MMC.<sup>7</sup>

## 2. Materials and Methods

The study was conducted at a state run tertiary care institute in India. This is a prospective study and one eye from consecutive patients requiring glaucoma surgery for IOP control was included. 50 eyes of 44 patients were divided into 2 groups to receive either trabeculectomy with mitomycin C (control group) or trabeculectomy with collagen implant (OLOGEN) (study group).

The study was approved from the institutional ethics and research committee and was in accordance with the Declaration of Helsinki (7<sup>th</sup> revision, 2013). Informed consent from all the patients was taken before the study. Detailed explanation of the procedure along with benefits and risks were explained to the patients. None of the patients refused to enroll and none were lost to follow-up during the course of the study.

Inclusion criteria included cooperative patients with age more than 40 years as glaucoma is more common in this age group, patients with primary open-angle glaucoma and primary angle closure glaucoma that was not controlled on maximum medical therapy.

Exclusion criteria included patients with a history of prior ocular surgery in the same eye (cataract surgery, trabeculectomy, or any surgery that would lead to scarring of the conjunctiva) or laser procedure, pregnant ladies and breastfeeding mothers, patients with age less than 18 years, as safety data for collagen implants is not clear for these, patients with secondary glaucoma or neovascular glaucoma as trabeculectomy is not the treatment of choice for these groups and patients having unable or unwilling to be follow

up less than 6 months.

For every patient the following data was collected preoperatively: age, gender, type of glaucoma, IOP (as measured the day before surgery) and number of preoperative antiglaucoma medications used. The operative data included date of operation, surgical technique and presence of any intraoperative complications. Postoperative IOP, number of postoperative glaucoma medications and post operative complications were also recorded. All IOP measurement were performed using the Goldmann applanation tonometer.

The primary outcome measure was success. Complete success was defined as having an IOP of 21 mmHg or less without antiglaucoma medication; and qualified success defined having an IOP of 21 mmHg or less, with or without antiglaucoma medication.

The IOP < 21 mmHg was chosen in accordance with World Glaucoma Association consensus on defining success of trabeculectomy and was also adopted in other studies.<sup>(10)(9)</sup> Hypotony was defined as an IOP < 6 mmHg. Flat anterior chamber was defined as iridocorneal touch with a depth of less than one corneal thickness centrally. Secondary outcomes were the number of antiglaucoma medications used pre and postoperatively.

## 3. Results

The present study is a case control study conducted for a period of 24 months. A total of 25 cases and 25 controls were recruited. The allocation to either group was done at random. The cases underwent implantation of a collagen implant along with trabeculectomy, while the controls underwent trabeculectomy with mitomycin C. Additionally, antiglaucoma medications were given post operatively in those whom IOP wasn't controlled by surgery alone. The details of IOP and antiglaucoma medications were measured at each visit at 1 week, 4 weeks and 3 months. Additionally post operative complications were recorded.

The baseline characteristics of both the groups were recorded (Table 1). There was no statistical difference in the two groups in terms of age ( $p=0.10$ ), number of preoperative medications ( $p=0.07$ ) and the IOP in the operated eye ( $0.13$ ). The male to female ratio in the control group was 18:7 while that on the cases was 16:9.

The mean IOP of patients with Trabeculectomy with Collagen Implant at presentation was  $32.61 \pm 9.59$  mmHg while in those with Trabeculectomy with mitomycin C was  $34.79 \pm 6.48$  mmHg which did not statistically differ from the former ( $p=0.13$ ) The IOP in patients undergoing Trabeculectomy with Collagen Implant was statistically lower at 3 months followup  $11.84 \pm 4.21$  than those who underwent Trabeculectomy with mitomycin C  $17.72 \pm 5.93$  ( $p=0.002$ ). (Table 2) It was also noteworthy that the number of antiglaucoma medications used postoperatively in the cases was significantly lower than

**Table 1:** The baseline characteristics of the two groups

Characteristic	Cases	Controls	P value
Age	51.16±14.16	52.91±9.06	0.10
Sex M:F	18:7	16:9	NA
Preoperative Medications	4.08±1.15	3.78±0.85	0.07

**Table 2:** The post intervention characteristics of the two groups

Characteristic	Cases	Controls	P Value
IOP before surgery (mmHg) (In the concerned eye)	32.61±9.59	34.79±6.48	0.13
IOP before surgery (mmHg) (In the other eye)	21.78±8.60	22.68±9.76	0.15
IOP Post operative Day 7 (In the concerned eye)	17.14±9.88	21.37±11.07	0.12
IOP Post operative Day 7 (In the other eye)	21.44±9.03	24.86±11.58	0.06
IOP Post operative 1 month (In the concerned eye)	16.77±11.54	22.91±9.62	0.05
IOP Post operative 1 month (In the other eye)	18.98±8.24	25.80±11.79	0.01
IOP Post operative 3 months (In the concerned eye)	11.84±4.21	17.72±5.93	0.002
IOP Post operative 3 months (In the other eye)	16.90±8.21	23.41±10.73	0.02
Postoperative Medications	0.48±0.77	1.95±1.26	0.0001

those used in the control arm ( $p=0.0001$ ). The cases had a mean 0.48 antiglaucoma medications as opposed to 1.95 in the control arm.

15 patients receiving a collagen implant achieved complete success as opposed to 7 in the control arm. However, 7 cases achieved a qualified success as opposed to 14 controls. There was only one treatment failure in the collagen implant arm against 4 treatment failures in the control arm. The one case who had a treatment failure in the cases was noticed to be a case of Neovascular glaucoma.

Additionally, postoperative complications were also studied at all follow-ups. 3 patients who underwent trabeculectomy with collagen implant developed a flat anterior chamber as compared to 4 controls. Patients with flat anterior chamber had additional suturing performed along with anterior chamber formation with air on 1<sup>st</sup> postoperative day. Hypotony was noticed in 3 cases which was similar to controls in which also 3 patients developed hypotony. It was managed conservatively and was later on subsequent visits found to be normal.

One patient amongst the cases developed postoperative hyphaema as compared to 2 in the control group. Hyphema in the collagen group would probably be due to the loose apical scleral suture recommended with collagen implant which would have let the blood from cut ends of the sclera to ooze out into the anterior chamber.

The data was analysed using Statistical Package for Social Sciences SPSS Version 21.0. Categorical data is described in proportion and continuous data as mean ±

standard deviation. Proportion was compared in the two groups by chi square test. For comparing mean, student “t” test was applied. A chi square test was performed on this. The chi-square statistic was 11.0519. The p-value was found to be .003982. Thus the result was significant at  $p < .05$ . This supports our hypothesis of superiority of a collagen implant with trabeculectomy as opposed to trabeculectomy with mitomycin C in terms of better clinical outcome and reduced post operative antiglaucoma medications.

#### 4. Conclusions

In this study we found that IOP in patients undergoing Trabeculectomy with Collagen Implant was consistently statistically lower than those who underwent Trabeculectomy with mitomycin C.

In conclusion this 24 months prospective study supports our hypothesis of superiority of a collagen implant with trabeculectomy as opposed to trabeculectomy with mitomycin C in terms of better clinical outcome and reduced post operative antiglaucoma medications.

Though studies with larger number of patients and longer followup will be required to confirm and examine the longterm outcomes of trabeculectomy with collagen implant.

#### 5. Source of Funding

None.

## 6. Conflict of Interest

None.

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**Cite this article:** Mathur P, Porwal R. Comparative study between trabeculectomy with collagen implant versus trabeculectomy with mitomycin C in patients requiring glaucoma surgery at a tertiary care hospital in Rajasthan. *Indian J Clin Exp Ophthalmol* 2022;8(1):20-23.