

# Efficacy And Safety of Ologen Augmented Trabeculotomy-Trabeculectomy in Primary Congenital Glaucoma

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## Abstract

**Purpose:** To evaluate the efficacy and safety of using Ologen implant as an augmentation to combined trabeculotomy and trabeculectomy surgery (CTT) in patients with primary congenital glaucoma (PCG)

**Patients and method:** Retrospective analysis of medical records of patients with PCG who had CTT augmented with Ologen implant as a primary surgery were reviewed. 24 patients fulfilled the inclusion criteria and were included in statistical analysis. Patient demographic data, pre-operative examination records as well as the records of follow up visits were recruited to assess for surgical efficacy and recording intra-operative and post-operative complications. Complete success was considered when IOP  $\leq$  16 mmHg without the addition of medical treatment or further glaucoma surgery to lower IOP. Failure was considered when IOP is  $>$  16 mmHg with 3 antiglaucoma topical eye drops or the requirement of another surgical intervention to lower IOP.

**Results:** 24 patients were included, 22 patients had surgery in one eye, and 2 patients had surgery bilaterally. successful IOP reduction was achieved in 21 eyes (80.7%) and this reduction was maintained during follow up visits. Failure was recorded in 5 eyes (19.2%). Of the reported complications intraoperative hyphema was recorded in 9 eyes (34.6%), improvement of corneal edema was achieved in most cases, as well as reversal of disc cupping. No implant related complications occurred including allergic reaction or graft extrusion.

**Conclusion:** Ologen implant used as an augmentation for CTT surgery in patients with PCG is a safe and effective adjunctive with high success rates

**Keywords:** primary congenital glaucoma; combined trabeculotomy-trabeculectomy; Ologen implant.

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## Introduction:

PCG is an ocular anomaly caused by arrested development of the anterior chamber angle and the trabecular meshwork. The anomaly resulting in obstruction in aqueous humor outflow pathways, with subsequent elevation in intraocular pressure (IOP) and globe enlargement. The disease needs surgical intervention to control IOP, as antiglaucoma medications are used for temporary IOP control <sup>(1-4)</sup>.

In some populations with high rates of consanguinity marriage; like Middle East the disease is challenging due to higher prevalence compared to western countries, with earlier presentation and more severe form <sup>(5-7)</sup>. Although angle surgeries have good results in mild to moderate form of the disease, they have less efficacy in severe familial form, so combined trabeculotomy with trabeculectomy (CTT) was preferred as a primary surgery, in these cases. The procedure has the benefit of creating two pathways for aqueous drainage; through Schlemm's canal by trabeculotomy and through sclerectomy fistula by trabeculectomy. The procedure showed favorable results and high success rates <sup>(8-10)</sup>.

Some surgeons preferred the addition of antimetabolites like Mitomycin-C (MMC) as an adjunctive to glaucoma surgery to achieve higher success rates and maintain long-term disease control. This addition increased success rates as well as early and late bleb related complications like early flat anterior chamber, hypotony, choroidal effusion, retinal detachment, and late thin avascular, cystic bleb with late leak and bleb related infection. <sup>(11,12)</sup>

Due to the higher complications rates of MMC, the biodegradable porous collagen-glycosaminoglycan matrix implant (Ologen) was used as a substitution, which has high efficacy and fewer complications. The implant degrades into nontoxic end products in the site of implantation without the need for surgical removal, and is widely used for adult glaucoma. However, its use in pediatric glaucoma is still limited <sup>(13-16)</sup>. The aim of this study is to report the safety and efficacy of CTT surgery augmented with Ologen implant.

## Patients and method:

**Patient selection:** the medical records of PCG patients treated with CTT surgery with added Ologen implant at Ophthalmology Department, Zagazig University Hospital were retrospectively reviewed. We excluded cases with secondary glaucoma, previous eye surgery and associated eye anomalies. Also, cases lost during follow up or those didn't complete at least one year of follow up were excluded.

**Data collection:** History taking about symptoms, family history, parents' consanguinity, prematurity, previous ophthalmic medications or surgical intervention, laterality, ocular parameters in either pre-operative or post-operative follow ups. All data was taken from patients' records. Pre-operative examination under general anesthesia for all patients was done to confirm PCG diagnosis with elevated IOP, corneal edema, large corneal diameter and disc cupping.

**Surgical procedures:** Surgeries were conducted by a single surgeon in the period between (January 2019 and January 2021), after signing an informed consent by the parents of all patients. Surgical intervention was in the form of trabeculotomy using Harms trabeculotome combined with trabeculectomy and peripheral iridectomy. An Ologen disc was divided and inserted in the sub-scleral and sub-conjunctival space. The surgical intervention was approved by Ethical Committee in Zagazig Faculty of Medicine.

## Success criteria:

Complete success was considered when  $IOP \leq 16$  mmHg without the need for addition of medical treatment or needing further glaucoma surgery to lower IOP. Failure was considered when IOP is  $> 16$  mmHg with 3 antiglaucoma topical eye drops or the requirement of another surgical intervention to lower IOP.

**Statistical analysis:**

Data collected from the records of patients including patients' history, surgical technique, intra and post operative complications, and the records of patient examination either at pre-operative or post-operative follow up visits. All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS version 22.0.). Qualitative data were represented as number and percentage, quantitative continues data represented by mean with standard deviation [SD].

**Results:**

The medical records showed that CTT surgery with added Ologen implant was performed on 33 eyes of patients with PCG in the period between January 2019 to January 2021. Only 26 eyes of them met our criteria mentioned before for patient selection. 22 patients had the surgery performed in one eye, and 2 patients had bilateral surgery. The totally included 24 patients were 17 (70.8%) males, and 7 (29.1%) females. Mean patients' age at time of diagnosis and surgical intervention was  $6.95 \pm 3.8$  months (range 2-12 months).

By reviewing patients' history, 6 patients (25%) had at least one family member with PCG, while the other 18 (75%) didn't report any family history of ocular anomalies. Consanguinity marriage was reported in 8 (33.3%) patients, while 16 (66.6%) were unrelated. Patients' demographic data are recorded in Table 1.

Pre-operative records of patient's examination under general anesthesia showed elevated IOP, with mean at  $29.74 \pm 4.9$  mmHg, and a range of (25-37 mmHg). Ocular enlargement was recorded in all cases and mean corneal diameter was  $12.8 \pm 0.64$  mm (range 11.5-14.5 mm). All cases showed pre-operative corneal edema and some cases had Haab's stria crossing the pupil. This edema didn't allow fundus examination and cupping assessment in the pre-operative examination of some cases. In cases with mild to moderate corneal edema optic disc was assessed and Cup/Disc (C/D) ratio was recorded with mean  $0.50 \pm 0.14$  and a range of (0.3-0.8) (Table 1).

Surgical records showed completed surgery with trabeculotomy performed in both right and left direction of all selected cases. Intra-operative hyphema was recorded in 9 eyes (34.6%), during passage of trabeculotome, and it was minimal and resolved by AC wash.

In post-operative follow up visits IOP was recorded and showed significant reduction compared to pre-operative records using Paired sample T test. (Table 2)

successful IOP reduction was achieved in 21 eyes (80.7%) and this reduction was maintained during follow up visits (ranging from 12-24 months), with mean follow up  $18.5 \pm 4.36$  months. Failure was recorded in 5 eyes (19.2%). Corneal edema resolved in most cases after successful IOP control, while in few cases permanent corneal opacity developed and persisted after surgery, with transverse Haabs stria crossing pupillary area.

No reports of major intraoperative complications like scleral perforation, iris or ciliary body prolapse. No post-operative hypotony was recorded, Also, no reported cases of lost AC, retinal detachment, endophthalmitis or graft extrusion.

Table 1 Preoperative patient's demographic data

Gender No (%)	
Male	17 (70.8%)
Female	7 (29.1%)
Age (months)	
Mean± SD	6.95 ± 3.8
range	(2-12 months)
Family history of PCG	
No history	18 (75%)
Positive history	6 (25%)
Consanguinity marriage	
Negative	16 (66.6%)
positive	8 (33.3%)
Pre-operative IOP (mmHg)	
Mean± SD	29.74 ± 4.9
range	(25-37 mmHg)
Pre-operative corneal diameter (mm)	
Mean± SD	12.8 ± 0.64
range	(11.5-14.5 mm)
Pre-operative C/D ratio	
Mean± SD	0.50±0.14
range	(0.3-0.8)

Table 2 Mean IOP before and after surgery

	IOP± SD <sup>a</sup>	P value <sup>b</sup>
Pre-operative	29.74 ± 4.9 (25-37 mmHg)	
Post operative		
1 month	13.22±4.55 (10-22 mmHg)	< 0.0001
3 months	12.98±5.9 (11-26 mmHg)	< 0.0001
6months	13.62±3.55 (13-20 mmHg)	< 0.0001
12months	14.22±2.47 (12-22mmHg)	< 0.0001
18 months	15.9±4.25 (14-25 mmHg)	< 0.0001
24 months	16.44±5.69 (15-27 mmHg)	< 0.0001

<sup>a</sup> intraocular pressure in mmHg± standard deviation

<sup>b</sup> P value (paired sample T test)

## Discussion:

Primary congenital glaucoma is a significant ophthalmic problem that requires surgical intervention. Angle surgery alone including goniotomy or trabeculotomy is effective in mild to moderate cases, while the more advanced cases need more aggressive surgical intervention like CT<sup>T</sup> surgery <sup>(8-10)</sup>. Surgical results of CT<sup>T</sup> showed high success rates regarding IOP control especially in more sever cases with

large corneal diameter, disturbed limbal anatomy and significant corneal edema obscuring angle visibility<sup>(8,10,17,18)</sup>. In the present study we reported complete success rate of 80.7%, this is comparable with Essuman et al, who reported success in 79% of cases<sup>(19)</sup>, and Mandal et al, who reported success probability of 94.4% in one study and 68.9% in a study performed on advanced cases with large corneal diameter<sup>(10,17)</sup>.

Al-Hazmi et al recommended the addition of MMC as an adjunctive to CTT especially in moderate and severe forms with success rates ranging from 70% in severe cases and 100% in mild cases<sup>(8)</sup>. However, the addition of MMC is associated with many complications including early hypotony and AC loss, together with late cystic bleb with risk of bleb leakage and endophthalmitis<sup>(11,12)</sup>.

Ologen was investigated by many surgeons for adult glaucoma and it proved its efficacy in maintaining IOP control<sup>(13,14)</sup>. Their results in pediatric glaucoma proved its efficacy as reported by Singab et al, and Elhefney et al<sup>(15,16)</sup>. Elhefney et al reported overall success rates at 80% using Ologen augmented CTT, without Ologen related ocular complications, graft rejection or extrusion, which is comparable with our results. The author stated that Ologen implant undergoes complete degradation after 6 months of follow up, without the need for graft removal<sup>(16)</sup>.

We reported no cases of hypotony or AC loss in the present study, this is comparable with Singab et al who reported no hypotony cases in his Ologen group compared to 3 cases (20%) in MMC group.

Clearance of corneal edema in most of cases after successful IOP control was reported in the present study. This is comparable with Essuman et al who reported clear cornea postoperatively in 90% of eyes out of 100% with pre-operative corneal edema<sup>(19)</sup>.

The mentioned results can prove that Ologen is a safe substitution for MMC with less risk of early hypotony and lost AC. However, the study is limited by the small number of the patients and short follow up period.

**Conclusion:** Ologen implant used as an augmentation for CTT surgery in patients with PCG is a safe and effective adjunctive with high success rates

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