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ORIGINAL ARTICLE

Trabeculectomy with Ologen Combined with Mitomycin-C for the Management of Primary Congenital Glaucoma

Tamer Gamal Elsayed [1], [1]***Basma Muhammad***[1], ***Ayman Ahmed Alkawas*** [*], ***Kamal A.M. Solaiman***[1]
[1] Ophthalmology Deparment, Faculty of Medicine, Zagazig University, Zagizag, Egypt

Corresponding author:
Basma Muhammad Zain EL-Abdeen Muhammad
Ophthalmology Deparment, Faculty of Medicine, Zagazig University
Basmamuhammad98@gmail.com

ABSTRACT

Background: Ologen is a collagen matrix designed to promote wound healing with minimal scarring. It has been used to create a prominent and healthy vascular bleb following trabeculectomy. The purpose of this study is to evaluate the adjunctive use of Ologen with mitomycin-C augmented trabeculectomy in eyes with primary congenital glaucoma .

Methods: Ologen was placed in the subconjunctival space and under the scleral flap in 25 eyes of 21 patients with primary congenital glaucoma who underwent trabeculectomy with Mitomycin-C. Patients were examined preoperatively and in the 1st week, 1st, 3rd, 6th and 12th months after surgery. Examination included measurements of the intraocular pressure, corneal diameter, bleb evaluation, and fundus examination. Ultrasound biomicroscopy of the bleb was done at the last follow-up visit. .

Results: The mean age of the patients was 6.6 ± 2.95 months. Mean preoperative IOP was 22.56 ± 0.83 mmHg and the mean final postoperative IOP was 15.52 ± 3.54 mmHg. Complete success (IOP <21mmHg without medications) was observed in 22/25 eyes (88%) and qualified success of surgery (IOP < 21mmHg with the aid of medications) was observed in 3/25 eyes (12%). Total bleb score was favorable in 8/25 eyes at the end of follow up period. None of the patients experienced systemic or ocular complications that were specifically related to Ologen. .

Conclusions: Ologen implant is a safe and effective agent in conjunction with Mitomycin-C for improving the long term success rate, bleb survival and function after trabeculectomy surgery.

Keywords: Primary congenital glaucoma; Collagen matrix; Ologen; Mitomycin-C.

INTRODUCTION

Primary congenital glaucoma (PCG) is the most common type of infantile glaucoma. The incidence of PCG is about 1 in 10,000–18,000 live births and depends heavily on ethnic origin [1-3].

PCG is a term referring to eyes that have an isolated anterior chamber angle anomaly without other developmental ocular anomalies or diseases that can raise intraocular pressure[4].

In the early stage of the disease when corneal diameter is not enlarged, PCG can be treated by goniotomy (if the cornea is clear) or by trabecuolotomy (if the cornea is hazy). In eyes with enlarged corneal diameter and corneal haze, trabeculectomy is indicated for the treatment of [5-7]. Howevere, trabeculectomy in children has a lower success rate compared to adults with a success rate varying from 35-50% [8-10].

Antimetabolites which inhibit fibrosis as mitomycin-C and 5-flurouracil have been introduced as an adjunctive to trabeculectomy in order to increase the success rate. However, the success rate is still low in infants less than 1 year of age [11].

The biodegradable collagen matrix implant has been introduced in the last few years as a new adjunctive to trabeculectomy in order to increase its success rate with promising results in adults. It acts as a space maintainer and as a modulator for the healing response by forcing fibroblasts to grow and deposit their matrix within the pores and around the scaffold. They are degraded within 90-180 days of implantation leaving a well formed and well vascularized bleb [12].

The purpose of this study is to evaluate the additive

effect of collagen matrix implant (Ologen) with MMC as an adjuvant to trabeculectomy in the treatment of PCG.

METHODS

This was a prospective interventional study that was performed through the period from August 2016 to January 2019 in Ophthalmology Department, Zagazig University Hospital, Egypt. It included 25 eyes of 21 patients diagnosed with PCG. Patients were treated by trabeculectomy augmented with collagen matrix implant (Ologen) plus MMC.

A written informed consent was taken by parents of the patients for their clinical records to be used in this study. Local ethics approval was obtained from our hospital before starting the study.

All patients in this study were infants diagnosed as PCG in the first year of life with age below 12 months and horizontal corneal diameter >12 mm. Other types of glaucoma, patients with recurrent congenital glaucoma, history of ocular trauma, previous intraocular surgery and lost patients during the follow-up period were excluded from the study.

All operations were performed in the operating theater under general anesthesia. A full history was taken from the parents of each patient before surgery. All eyes were subjected to a complete preoperative ophthalmic examination, including IOP measurement using Perkin's applanation tonometer, horizontal corneal diameter measurement with a caliper, corneal clarity and cup disc ratio. Follow up visits were carried out in the first day postoperatively, after one week, then at 1st, 3rd, 6th, 12th months. At each visit after surgery, eyes were subjected to full ophthalmic examination as was done before surgery in addition to evaluation of the filtering bleb. UBM examination (ACCUTOME; UBM (48MH): Malvern PA; USA) was performed once at the end of the follow up period.

Procedure:

Stabilization of the globe was done with partial thickness traction suture in the superior part of the cornea by 6/0 Vicryl suture (REF 432086 AssuCryl PGA 8 mm 45 cm; Assut sutures, Switzerland). A fornix based flap including conjunctiva and Tenon's capsule was performed in the superior temporal part of the eye followed by blunt dissection posteriorly towards the fornix and cauterization of the scleral bed. Then about 3 mm x 4 mm ½ thickness scleral flap was started by surgical scalpel 15 (BS 2982/ BS EN 27740; Swann Morton, Sheffield, England) and completed by crescent blade (Cellia Edge Ophthalmic Knife, 2.6mm; Cellia industries, Kyoto, Japan) in the superior temporal part of the eye. The flap extended until 1 mm into the clear cornea with central dissection extending further anteriorly than the sides of the scleral flaps. MMC (0.4 mg/ml) soaked surgical super absorbent sponges were placed subconjunctively and in sub-scleral trapdoor for 3 minutes. Then the sponges were removed and the area was copiously irrigated with 20 cc of ringer lactate.

Trabeculectomy was performed (of about 2x2 mm in size) by incision in the surgical limbus using sharp blade 11(BS 2982/ BS EN 27740; Sheffield, England) or microvitreoretinal blade (MVR) 20 (Joja Surgical Pvt. Ltd., Kolkata, India). Then removing of the trabecular block was carried out by Vannas scissors while the scleral flap was retracted. After that, the iris was grasped by iris forceps or collobri, pulled out of the wound, and peripheral iridectomy was performed by Vannas scissors.

A cylindrical collagen matrix implant (Ologen®) (Aeon Astron Europe B.V., The Netherlands, 12 mm in diameter and 1 mm in height) was used. It was unequally divided into two parts. The smaller part (quarter the disc) was put under the scleral flap before suturing it, and the larger part (the remaining three fourths of the disc) was put under the conjunctiva. After that, closure of the conjunctival flap was done with buried 10-0 nylon sutures (REF ON 105-38 DACLON polyamide 6.4 mm, 38 cm; SMI AG, Steinerberg, Belgium).

Clinical assessment and grading of the bleb:

Grading of the filtering bleb was done according to Wuerzburg bleb classification score (WBCS) [13,14] which includes the items vascularisation, corkscrew vessels, encapsulation and microcysts. Grading was done in the 1st, 3rd, 6th and 12th months postoperatively. The item (microcysts) was replaced with the item (height) as microcysts are difficult to be detected in photos especially over the implant site and it was called modified Wuerzburg bleb classification score (Table 1). The bleb height could be an indicator for the filtration instead of microcysts since the Ologen itself acts as a reservoir for the surrounding aqueous and it is likely that the pockets of aqueous exist within the body of the implant [15,16].

The blebs were given scores from 0-12. Blebs were considered favorable when the score was 10 or more and unfavorable if less than 10 [13].

Statistics

Analyses of the data were performed using the Statistical Package for Social Science (SPSS) program, version 20 (IBM, Chicago, Inc. USA). Data were expressed as the mean values (with standard

deviations [SDs]). ANOVA test of variance was used to compare preoperative and postoperative results. P values of <0.05 were considered to indicate the statistical significance.

RESULTS

The study included 25 eyes of 21 patients with PCG treated by trabeculectomy augmented with Ologen implant plus MMC. The mean age of the patients was 6.6 ± 2.95 months with age ranging from 2 to 12 months. The mean preoperative IOP was 22.56 ± 0.83 mmHg. The mean postoperative IOP during the follow-up period was 9.62 ± 1.46 mmHg at 1 week, 10.5 ± 1.65 mmHg at 1 month, 12.68 ± 2.0 mmHg at 3 months, 13.64 ± 3.93 mmHg at 6 months, and 15.52 ± 3.54 mmHg at 12 months postoperatively (Table 2, Figure 1).

As concerns the success of surgery at the end of follow up period, complete success (IOP<21mmHg without medications) was observed in 22/25 eyes (88%) and qualified success (IOP < 21mmHg with medications) was present in 3/25 eyes (12%) (Table 3).

Correlation of the total bleb score with IOP and success rate at the end of follow up period (at 12th month postoperatively) showed that, in eyes with complete success the mean IOP was 14.27±3.17 mmHg. The total bleb score was ≥10 in 8/22 eyes (36%). The bleb score ranged from 7-9 in 12/22 eyes (54%) while it was < 7 in 2/22 eyes (9%) only. In contrast to eyes with qualified success, the mean IOP was 19.1±0.2 mmHg and the total bleb score ranged from 7-9 in 2/3 eyes (66%), while it was < 7 in 1/3 eye (33%) only. No eyes with qualified success attained a score of 10 or more (Table 4).

Regarding UBM findings at the end of follow up period, the cavity of the bleb could be seen in 20/22 eyes (90%) of complete success cases and in 2/3 eyes (66%) of qualified success. Low bleb wall reflectivity was identified in 7/22 eyes (32%) of complete and 1/3 eye (33%) of qualified success cases. Bleb wall reflectivity was medium in 15/22 eyes (68%) of complete success and 2/3 eyes (66%) of qualified success cases. The track under the scleral flap was identified in 22/22 eyes (100%) of complete success and 3/3 eyes (100%) of qualified success cases (Table 5).

Table (1): Modified Wuerzburg bleb classification score

Parameters	Scoring
Vascularization	*3=avascular. *2=equal to surrounding conjunctiva. *1=enhanced. *0=massive.
Corkscrew blood vessels	*3=no. *2=in one third. *1=in two thirds. *0=entire bleb.
Height	*3=High. *2=moderate. *1=low. *0=flat.
Encapsulation	*3=no *2=in one third. *1=in two third. *0=entire bleb.

Table (2): Patient data preoperatively and during the follow up period

	IOP (mmHg)
Preoperatively	22.56 ± 0.83
1 week postoperatively	9.62 ± 1.46
1 month postoperatively	10.5 ± 1.65
3 months postoperatively	12.68 ± 2.0
6 months postoperatively	13.64 ± 3.93
12 months postoperatively	15.52 ± 3.54
P(F)	<0.001**

*Values are mean ± SD. F repeated measure ANOVA **p≤0.001 is statistically highly significant*

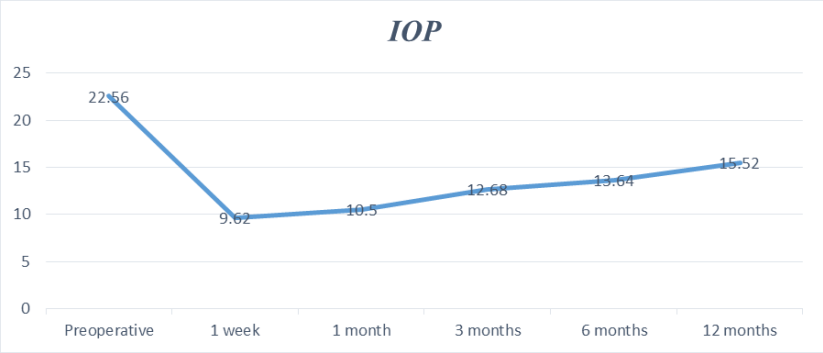

Figure (1): Mean preoperative and postoperative IOP along the follow up period.

DISCUSSION

Trabeculectomy is considered as one of the gold standard operations in lowering the intraocular pressure in patients with glaucoma. Anti-scarring medications including mitomycin-C and 5-Flurouracil have been widely used adjuncts in improving the long-term success of the operation [17].

Researchers and clinicians have looked for alternative wound healing modulators to avoid the risks of antimetabolites and to increase the rate of success. Children undergoing filtering surgery do not enjoy the same success rate as do those of older age groups. The barriers to success of filtering surgery in children include thick tenon's capsule, rapid wound healing response and large buphthalmic eyes with thin sclera[18]. Ologen implant may be placed over the scleral flap during trabeculectomy, serving as a reservoir for bleb formation and optimizing wound healing [19].

To the best of our knowledge, this is the first study to describe the use of both Ologen and MMC augmented trabeculectomy in one group in patients with PCG.

For this purpose, 25 eyes of 21 patients with primary congenital glaucoma were included in this study. They were subjected to trabeculectomy with Ologen implant plus MMC. The age of the patients ranged from 2 to 12 months.

Regarding IOP, the mean preoperative IOP was 22.56± 0.83mmHg and the mean IOP postoperatively was 10.5 ± 1.65 mmHg, 12.68 ± 2.0 mmHg, 13.64 ± 3.93 mmHg, and 15.52 ± 3.54 mmHg in the 1st , 3rd , 6th , and 12th months, respectively. IOP significantly decreased from the preoperative level, as evidenced by a significantly lower values at all follow-up visits as shown by repeated measures ANOVA test (P<0.001), (Table 2).

Our results were comparable to a study that was conducted by *Hamdi* [20]. He evaluated the results of subscleral trabeculectomy assisted by Ologen in patients with primary congenital glaucoma. The study reported a mean preoperative IOP of 34.3 mmHg and a mean postoperative IOP of 14.33 mmHg at the 6th month after surgery (range 11-17mmHg).

Elhefney et al. [21] evaluated the efficacy of trabeculotomy-trabeculectomy augmented with Ologen in infantile glaucoma. They reported a preoperative IOP of 25.95±3.08 mmHg and a postoperative IOP of 16.11 ± 3.62 mmHg at 6 months and 17.70 ± 3.5 mmHg at 12 months with statistically significant difference between preoperative and postoperative IOP (P<0.05).

Another study conducted by *El-Sayyad et al.* [22] evaluated the intraocular pressure lowering effect of trabeculectomy augmented with Ologen compared to mitomycin-C in juvenile open-angle glaucoma. They reported a mean preoperative IOP of 34.7±5.1 mmHg and at 1 year postoperatively, the mean IOP was 12.0±0.9 mmHg in Ologen group. The IOP drop was significantly lower in Ologen group than in MMC group (12 mmHg versus 13.7 mmHg).

In the present study, we have chosen IOP value of 21mmHg as a cut off point for success of trabeculectomy surgery as reported by many studies [23]. Our study showed that complete success (lowering IOP more than 21mmHg without the aid of medications) was observed in 22/25 (88%) eyes, Qualified success (lowering IOP with the aid of timolol maleate 0.05%) was observed in 3/25 (12%) eyes. No reported cases of failure (Table 3).

These results were comparable to the results of *Hamdi* [20] study which evaluated subscleral trabeculectomy assisted by collagen matrix in primary congenital glaucoma. This study was carried out in three patients only, with satisfactory success (IOP < 21 mmHg with clear cornea) observed in two

cases (66.6%) and poor success (IOP < 21 mmHg with medication) in one case (33.3%). The follow up was only for 6 months postoperatively. Another study conducted by *El-sayed et al.* [24] evaluated the outcome of adding Ologen to trabeculotomy-trabeculectomy in PCG reported a full success rate of 100% after 6 months and 94.12% after 1 year. *Dada and colleagues* [25] who used Ologen implant with low dose MMC (0.1 mg/ml/1 min) in trabeculectomy for primary open angle glaucoma patients also reported a high success rate (94%) at 12 months postoperatively.

As regards the correlation between IOP, total bleb score, complete and qualified success at the end of follow up period, the total bleb score in the present study was ≥10 in 8/22 (36%) eyes, 7-9 in 12/22 (54%) eyes. The total bleb score was ≥7 in 20/22 (90%) and less than 7 in 2/22 (9%) eyes. These cases represented eyes with complete success. In qualified success cases, total bleb score was ≥7 in 2/3 (66%) eyes and less than 7 in 1/3 eye (33%) (Table 4). These results may reflect that the addition of collagen matrix implant has a better effect on long-term survival of the bleb.

In agreement with these results, *Furrer et al.* [26] studied the agreement between IOP and the WBCS after trabeculectomy. They studied 57 eyes of 51 consecutive patients, and they found that 25 eyes only reached a WBCS score of ≥10 points (43.9%), 36 eyes attained a score of ≥9 points (63.2%), 47 eyes ≥8 points (82.5%), 48 eyes ≥7 points (84.2%). They reported poor agreement between target IOP and WBCS of ≥10 points, ≥9 points, ≥6 points and ≥5 points. From the 25 eyes reaching a WBCS of ≥10 points, 21 also reached the target pressure (84%).

Furrer et al. [26] also found that, after expanding the definition of 'success' on the morphological findings of WBCS scoring system, the best agreement was found between target IOP and WBCS of at least 7 points. Their conclusion was that evaluating filtering blebs after trabeculectomy by using the Wuerzburg bleb classification score is a good technique for predicting IOP control in eyes attaining a minimum score of seven points (not 10 points as what was reported in the study of *Klink et al* [13].

As regards the correlation between UBM parameters and type of success at the end of follow up period in the present study, 20/22 eyes (90%) showed persistent bleb cavity, 7/22 eyes (32%) showed low bleb wall reflectivity and 15/22 eyes (68%) eyes showed medium bleb wall reflectivity. The track under the scleral flap was identified in 22/22 eyes (100%). These eyes represented cases of complete success. As regards cases with qualified success, the bleb cavity couldn't be identified in 1/3 (33%) eye, with medium wall reflectivity in 2/3 (66%) of cases (Table 5). These data reflected that the presence of the bleb cavity, low to medium bleb wall reflectivity, and the identification of the track under the scleral flap were correlated with complete success of trabeculectomy surgery.

Similar to the previous reported findings, *Jinza et al.* [27] observed that eyes with medium to low bleb wall reflectivity and visible route under the scleral flap showed lower IOP than eyes with high bleb wall reflectivity and invisible route under the scleral flap. Scleral route visibility by UBM failed to be correlated with IOP control after deep sclerectomy with Ologen in the study conducted by *Aptel et al.* [28] and this may be attributed to the type of surgery. *Elhefney and collegues* [21] reported approximately similar results to our results. They studied safety and efficacy of collagen matrix implantation in infantile glaucoma. They reported that regarding UBM, at last follow-up examination, the scleral route was visible with low bleb wall reflectivity and persistent bleb cavity in 10 eyes (50% of cases), representing cases with complete success. In 6 eyes (30% of cases), the scleral route was visible with medium bleb wall reflectivity and persistent bleb cavity, representing cases with qualified success. In the remaining 4 eyes (20% of cases), there was no visible scleral route and the wall reflectivity was high with absent bleb cavity, representing cases with failure.

In conclusion, Ologen implant is a safe agent and has an additive effect in conjunction with MMC for improving the long-term success of trabeculectomy surgery in primary congenital glaucoma. Its advantages include reduction of the postoperative intraocular pressure, improvement of the bleb score clinically and better UBM parameters. It has no specific complications and no special precautions. The main drawback of Ologen was its cost.

Conflict of interest: None

Financial disclosure: None

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