Evaluation of corneal biomechanics and bleb in subscleral trabeculectomy augmented with Ologen versus Mitomycin C in open angle glaucoma

Original Article

Ahmed Abu El Aeinein[1], Professor Dr. Ali Khalifa[2],Mohammed El Malah[2],Mahmoud Mustafa Gad[1]

[1]*Glaucoma unit, Military eye hospital, Cairo, Egypt .*

[2]*Glaucoma unit, El Hussein teaching hospital, Cairo, Egypt.*

ABSTRACT

A prospective comparative study between trabeculectomy with MMC versus trabeculectomy with Ologen for patients with open angle glaucoma one year follows up.

Introduction: Recent studies reported that the use of a biodegradable collagen glycosamino-glycan matrix (ologen) implant in the subconjunctival space offers a method for wound healing modulation beside MMC after glaucoma surgery. Ologen is composed of a three dimensional disc-shaped porous structure that implanted over scleral flap before closure of conjunctiva during trabeculectomy. Ologen regulate aqueous flow by keeping pressure on top of the scleral flap and by acting as a reservoir, as aqueous gets absorbed into its porous structure.

Patient and Methods: A prospective randomized clinical study was done in military eye hospital. Fifty eyes were presented by POAG or PEX glaucoma included in this study. 25 eyes treated by trabeculectomy wit MMC (MMC group) and the other 25 eyes treated by trabeculectomy with implant of ologen (ologen group). Follow up for one year was done.

Results: It is found that; mean IOP in ologen group was 13.16±1.68mmHg and in the MMC group mean IOP 16.47±3.56mmHg. Regarding to postoperative antiglaucoma medications, in ologen group, the mean was 0.31±0.48 compared to MMC group 1.06±0.85 drugs, p-value is 0.05. Success rate was 21/25 eyes (84%) in the ologen group, in comparison to MMC group, success rate was 19/25 eyes (76%).

Conclusion: This new degradable collagen implant (ologen) improves and normalizes filtering surgical wound healing with more loosely organized bleb tissue and healthy than blebs augmented with MMC

Key Words: MMC, ologen, ORA, Trabeculectomy, UBM**.**

Received: 10 Sebtember 2024, **Accepted:** 02 january 2025

Corresponding Author: Mahmoud Mustafa Gad, Glaucoma unit, Military eye hospital, Cairo, **Tel.:** 01007551746 **E-mail**: azif111111@gmail.com

ISSN: 2812-5509, 2024

INTRODUCTION

Glaucoma is a multi-factorial optic neuropathy characterized by progressive specific visual field (VF) defects associated with optic nerve excavation. It's classified into primary glaucoma, unrelated to other ocular diseases, and secondary glaucoma which occurs as a consequence of other ocular abnormalities or pathologies [1].

Prediction and diagnosis of open angle glaucoma (OAG) is made by Goldman applanation tonometry (GAT), gonioscopy, perimetry and optic nerve head (ONH) studies including fundus examination and optical coherence tomography (OCT). Diagnosis is aided by by measurement of central corneal thickness (CCT) and corneal hysteresis (CH). Treatment is either medical or surgical. Surgical treatment includes argon laser trabeculoplasty, selective laser trabeculoplasty, subscleral trabeculectomy (SST), valve procedures and diode laser cycloablation [2].

Trabeculectomy has been widely applied as treatment for glaucoma since its introduction in 1968. The outcome of this surgery depends on the formation of a functioning shunt, termed the filtration bleb, to enable egress of aqueous from the eye [3]. Fibroblast growth beneath the conjunctiva plays an important role in bleb failure. Adjunctive anti-metabolites ; like mitomycin C (MMC) and 5- flurouracil (5FU) may enhance the success rate by preventing fibrosis[4].

The use of traditional antimetabolites; like MMC and 5FU increases the risk of post operative wound leak,

DOI: 10.21608/ARCMED.2025.319910.1055

hypotony and endophthalmitis. The use of biodegradable collagen matrix implant (Ologen, Oculus Gen Biomedical Inc. Taipei, Taiwan) beneath the conjunctiva helps in controlling wound healing process & maintain space for drainage without post operative complications common with antimetablites use [5].

Corneal biomechanics, termed as corneal hysteresis (CH) and corneal resistance factor (CRF) are a measure of corneal damping capacity , visco-elasticity and energy absorption capability of the cornea which differ between normal and glaucomatous eyes. The ocular response analyzer (ORA) is an instrument that measures CH and CRF [6].

Bleb morphology after trabeculectomy is an important clinical parameter; it is an indicator of bleb function and a predictor of bleb-related complications [7] Ultrasound bio-microscopy (UBM) produces high resolution images of the anterior segment were used for postoperative evaluation[8].

PATIENT AND METHODS

This study was conducted in Kobry Al Qobba military eye hospital, Cairo, Egypt. The study was carried out over a period of 23 months. The operations started at 15th November in 2015, and ended at 16th June in 2017. The follow up was done along the period from February 2016 to September 2017. Interviews and examinations were done in the outpatient department.

Twenty five eyes with OAG who were undergo SST augmented with Ologen (a collagen matrix of 1% collagen / C-6-S copolymer – Oculus Gen Biomedical Inc. Taipei, Taiwan. The selected size is 2×6 or 1×12 mm's for all cases) versus twenty five eyes undergo SST augmented with MMC as a filtration procedure and had completed 12 months follow-up postoperatively. The study included eyes with OAG and had no ongoing other ocular problems that might affect their final outcome other than glaucoma. The study excluded eyes with closed/narrow angles or secondary glaucoma. It is a hospital based prospective, interventional study. Each patient was followed up preoperatively, 3 months, 6 months and one year postoperatively by ORA (figure 1) and UBM (figure 2).

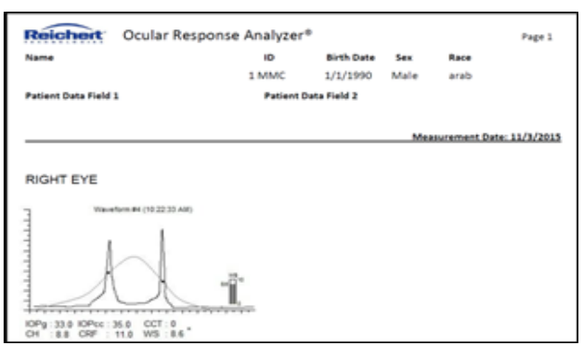

Fig. (1) Measurement of CH, CRF, IOPg and IOPcc one day preoperatively (Measuered at 3/11/2015)

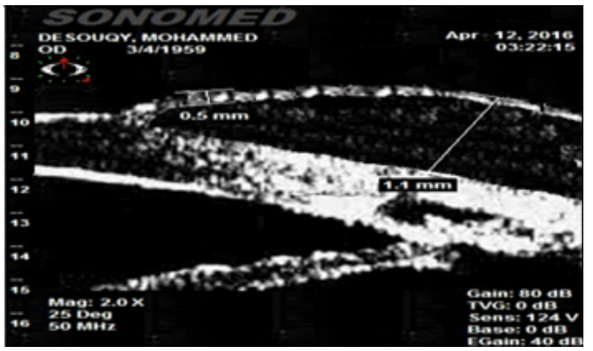

Fig. (2) : Bleb assessment by UBM 3 months postoperatively. It reveals a diffuse bleb; type L according to the Yamamoto UBM bleb classification. It shows an echo-free fluid-filled space, its height is 1.5 mm and conjunctival wall thickness is 0.5 mm (Imaged at 12/4/2016)

RESULTS

A total of fifty eyes were included in the study; they had attended the final follow up one year post-operatively. Demographic and diagnostic data before operation are described in table 1. There were no significant differences between the groups in terms of age, gender, eye laterality, diagnosis, pre operative ORA parameters and number of anti glaucoma medications. Operations were uncomplicated in both groups.

Table (1). Basic data

	MMC group	Ologen group	*P value*
No. of eyes	25	25	——
Age	55±15	58±16	0.33
Family history	10 (40%)	8 (32%)	——
Medical problems	13(52%)	14 (56%)	——
Other ocular problems	——	——	——
No. of preoperative drugs	2.45±0.54	3.0±0.61	0.07

Complete success was defined in cases had mean IOP ≤ 21 with functioning blebs and did not need any postoperative surgical interference or medical treatment along one year postoperatively. Failure was defined in cases had mean IOP > 20±SD with non-functioning blebs although simple postoperative surgical interference or medical treatment during the follow up period.

Mean postoperative IOP was calculated in all postoperative visits and as reported in table (2), shows also no statistically significant difference between two groups. It is found that; mean IOP in ologen group 13.16±1.68mmHg and in the MMC group mean IOP

16.47±3.56mmHg. Also, mean of last visit IOP for both groups was, ologen group 14.06±1.91mmHg and MMC group 18.69±3.05mmHg, p-value 0.46. Regarding to postoperative antiglaucoma medications, in ologen group, the mean was 0.31±0.48compared to MMC group 1.06±0.85 drugs, p-value is 0.05. Success rate was 21/16 eyes (84%) in the ologen group, as ologen matrix was removed in one eye that complicated by severe hypotony, in spite of interferences by viscoelastic injection in anterior chamber twice and tighten the sutures of scleral flap. In comparison to MMC group, success rate was

Table (2) Postoperative complications and anti-glaucomatous medications

	MMC group	Ologen group	P value
Post op. mean IOP	13.16±1.68 mmHg	16.47±3.56 mmHg	0.1
Encapsulated bleb	5/25 (20%)	3/25(12%)	——
Flat bleb	3/25 (12%)	2/25 (4%)	———
Mean postop. drugs	0.25±0.33	0.32±0.41	0.09
Success rate	19/25 (76%)	13/25 (48%)	0.14

DISCUSSION

The data obtained from fifty eyes at one year postoperatively were analyzed. Selection of cases according to the inclusion and exclusion criteria resulted in a balanced distribution of the study population for most of the demographic and clinical measures assessed at enrollment. Mean values of the preoperative parameters of ORA is almost the same in the MMC group and the ologen group. The operated eyes have been examined by ORA and UBM to determine the functional and structural out-come of the trabeculectomy; examination is done three months, six months and one year postoperatively to obtain more reliable results.

IOPg measurement revealed that mean IOPg decreased by the same ratio (61%) in the two groups three months postoperatively ($p = 0.35$), while mean IOPcc decreased by about 55% in MMC group and by about 57% in ologen group ($p = 0.33$). Mean IOPg increased by about 17% in MMC group and by about 3% in ologen group six months postoperatively ($p = 0.36$). Mean IOPcc increased by about 9% in MMC group and by about 3% in ologen group six months postoperatively ($p = 0.33$). Mean IOPg decreased in MMC group one year postoperatively more than preoperative by 51%, while mean IOPg decreased in ologen group one year postoperatively more than preoperative by 56% ($p = 0.48$). Mean IOPcc decreased in MMC group one year postoperatively more than preoperative by 48%, while mean IOPcc decreased in ologen group one year postoperatively more than preoperative by 53% ($p = 0.49$). Statistically there was no significant difference between two groups at each follow-up. But there was a significant difference between preoperative and postoperative IOP at each follow-up ($p < 0.001$). It was noted that there was an association between the results of mean IOPg, IOPcc and mean CH value changes.

In a pilot study done by Papaconstantinou et al, forty eyes were assigned randomly to undergo trabeculectomy either with ologen implant (study group) or without implant (control group). They found that no difference in IOP was observed between the 1-day and 6-month visits in the two groups. Postoperative IOP levels were significantly lower than preoperative levels for both groups at all intervals (One day, one week, one, two, three, four, five and six months postoperatively $P < 0.05$). None of the eyes in the study group had an IOP > 21 mmHg at the 6-month visit. IOP was > 21 mmHg in only one eye from the control group at the 6-month visit. They concluded that trabeculectomy with ologen does not seem to offer any significant advantages compared with trabeculectomy alone 9. In comparison to this study, postoperative IOP levels were significantly lower than preoperative levels for both groups 3,6 and 12 months postoperatively ($P < 0.05$). None of the eyes in the both groups had an IOP > 21 mmHg at the 3- month and 6-month visits.

CONCLUSION

From this study, despite its limitation, It can come out with that IOP value changes are inversely related to is corneal biomechanical changes. IOP is more controlled in eyes underwent trabeculectomies augmented with ologen implants than that augmented with MMC. There is a correlation between CH and CRF changes in response to IOP reduction. Ologen implants have the advantage over MMC for better control of wound healing processes and minimizing fibrosis, then allow higher facility of aqueous outflow through more patent sclerostomies. Also it maintains thinner and less cystic bleb conjunctival walls. So, trabeculectomies augmented by ologen result in blebs with better appearance on UBM examination. Reduction of IOP is associated with lower bleb internal reflectivity. This conclusion may require further study to be more clear.

REFERENCES

1. Rosentreter A, Schild A, Jordan J, Krieglstein G, and Dietlein T. A prospective randomised trial of trabeculectomy using MMC vs an ologen implant in OAG. Eye. 2010; 24 (9): 1449–57.

2. Kasuga T, Chen YC and Bloomer MM. TM length in men and women by histological assessment. Curr Eye Res. 2013; 38: 75-79.

3. Meira-Freitas D, Tatham AJ, Lisboa R, Kuang TM and Zangwill LM. Predicting progression of glaucoma from rates of frequency doubling technology perimetry change. Ophthalmol. 2014; 121(2): 498-507.

4. Park J, Jun R and Choi K. Significance of corneal biomechanical properties in with progressive NTG. Br J Ophthalmol. 2015; 99(6): 746- 51.

5. Cook JA, Botello AP and Elders A. Surveillance of OHSG. Systematic review of the agreement of tonometers with Goldmann applanation tonometry. Ophthalmology. 2014; 119(8): 1552-57.

6. Ursea R and Silverman R. Anterior segment imaging for the assessment of glaucoma. Expert Rev Ophthalmol. 2013; 5(1): 59-74.

7. Golez III and Latina M. The use of anterior segment imaging after trabeculectomy. Semin in Ophthalmol. 2014; 27, 155–59.

8. Papaconstantinou D, Georgalas I, Karmiris E, Diagourtas A, Koutsandrea C, Ladas I and Georgopoulos G. Trabeculectomy with OloGen versus trabeculectomy for the treatment of glaucoma: a pilot study. Acta Ophthalmologica 2010; 88: 80–85.

9. Yuan F, Li L, Chen X, Yan X and Wang L. Biodegradable 3D-porous ologen compared with MMC for treatment of POAG: results at 5 years. J Ophthalmology. 2015; 63 (7): 53-60.

Contact: email: azif14@ymail.com