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Evaluating the Results of Trabeculectomy with Collagen Matrix Compared with Mitomycin C and Trabeculectomy without Adjuvant in Patients with Open-Angle Glaucoma

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ABSTRACT

Trabeculectomy is a standard method for patients with glaucoma with uncontrollable intraocular pressure (IOP). Biodegradable collagen matrix implant (Ologen) by changing the pattern of cell migration reduces the formation of scar tissue and increasing the success rate of surgery.In a randomized clinical trial, 60 patients with chronic open-angle glaucoma undergoing trabeculectomy surgery, were randomly assigned to one of the 3 groups, group 1 used Ologen implants, group 2 used mitomycin C and group 3 used no adjuvant. IOP and other results after trabeculectomy were studied in time intervals after operation. in this study, Ologen was an effective method in reducing intraocular pressure and reducing the number of anti-glaucoma drug therapies.

KEYWORDS Glaucoma, collagen matrix, trabeculectomy, open-angle glaucoma, mitomycin C

Introduction:

Glaucoma is one of the most common diseases of the eye and is a common cause of blindness (1, 2) accompanied by the progressive loss of ganglion cells of the retina and their axons (2) Treatment is mainly focused on reducing IOP that prevents the deterioration of visual field defects. (2,3) When IOP is so high that patients do not respond to medical treatment, trabeculectomy is performed. (3) Also, initial IOP is not sometimes high, like normal tension glaucoma (NTG) and surgery is performed to achieve the desired IOP and reducing the damage of glaucoma. Now, trabeculectomy is a standard method for glaucoma patients with uncontrolled IOP.(3, 4) newer surgical techniques using 5-fluorouracil (5Fu) and mitomycin C (MMC) has improved the success rate of trabeculectomy results (3)The main reason for the failure of trabeculectomy is scarring and fibrosis after surgery leading to bleb failure and increased IOP.To prevent intraoperative or postoperative scarring, anti-fibrotic agents such as 5-Fu and MMC are used. These chemotherapy substances inhibit the activity of fibroblasts, resulting in decreased postoperative scarring and increased success rate of the surgery but on the other hand the anti-fibrotic agents increase the risk of chronic bleb leak, hypotonia and endophthalmitis.Tendency to increase the success rate of surgery and reduce the complications led to the search for an effective method for preventing postoperative fibrosis.

In this regard, recently the idea of using biodegradable implants derived from tissue engineering as an alternative to anti-fibrotic agents in trabeculectomy surgery has been proposed.The implants use a combination of a polymeric scaffold with a population of precursor and stem cells that in the case of biodegradable polymeric scaffolds leads to the same tissues as normal tissues,this substance by changing pattern of cell migration reduces the formation of scar tissue.

A few studies have been performed on the effects of biodegradable implants in trabeculectomy mostly on primary generations of the implants with the commercial name of Oculogen that in the short term similar results were reported by using mitomycin C in reducing intraocular pressure. (5, 6)In another study performed on the newer generation of bio-implants, OLOGEN, the use of implants compared with mitomycin has accompanied a lower overall success rate, however, complications related to bleb and its morphology were higher for mitomycin (7, 8)In this study, the results of using collagen matrix (OLOGEN) in trabeculectomy surgery in patients with open-angle glaucoma, in terms of controlling intraocular pressure, the number of anti-glaucoma medications required postoperatively, complications and morphology of bleb were studied and results of the two control groups, including the use of mitomycin 0.01 - 0.02 for 40-60 seconds during the operation and the use of no adjuvant were compared.

Materials and methods:

A clinical trial was conducted on 60 eyes of 60 patients with chronic open angle glaucoma (primary or secondary) referred to clinics of Nikookari hospital in Tabriz that given the the lack of control of intraocular pressure (IOP>21 mmHg) with medication or high Cup / disk ratio and progressive and severe visual field defects, despite medical therapy or anti-glaucoma medication intolerance were candidate for trabeculectomy surgery.this study started in january 2013 and finished in july 2014.

Patients after obtaining informed consent for the study were placed in one of three groups, 1- trabeculectomy with Ologen, 2- trabeculectomy with mitomycin C with a concentration of 0.01-0.02 % for 40-60 seconds, and 3- trabeculectomy with matrix collagen implants. Inclusion criteria included patients with primary or secondary chronic open-angle glau-

coma,

Patients with uncontrolled intraocular pressure maximum tolerable anti-glaucoma medications, and patients able to complete the intervention and visit for follow up; criteria included patients with allergies to MMC, patients with allergies to collagen implants, patients with normal tension glaucoma, patients with history of previous eye surgery, eye infection within 2 weeks ago, pregnant and lactating women, patients with hypertension and uncontrolled diabetes. Written consent for participation in the study was taken from all patients after explaining the purpose of the study based on the Helsinki Declaration of tents. The study was discussed and approved at Regional Ethics Committee of the Faculty of Tabriz Medical Sciences and was recorded at the IRCT site with IRCT201212284166N5 code.

The surgery was performed using the standard method with Fornix-based conjunctival flap and triangular scleral flap with dimensions of 3*3 mm, in mitomycin group after preparation of scleral flap, sponge impregnated with mitomycin C with a concentration of 0.01- 0.02% was placed on the site of scleral flap for 40-60 seconds and then the site was washed with 20 ml of BSS serum. In the group of matrix collagen implant at the end, implant of Ologen with dimensions of 2*6 mm was placed in sub-conjunctive and then the limbal conjunctive was sutured to limbus with nylon suture 10-0.

Treatments after surgery was the same in all 3 groups, including the use of topical antibiotic for a week and topical steroids for two to three weeks and homatropine for two weeks. Limbal sutures were removed one week after operation. Visit schedule was 1 day /1 week /1 month /3 months /6 months /12 months after surgery. In addition, in postoperative examinations, depending on the condition of the patient, the anti-glaucoma medication was administered for the patient, if necessary.

The first examination performed on the first postoperative day and the anterior chamber and the amount of inflammation, bleb status and its function, bleb leakage and intraocular pressure were noted. At each postoperative visit, examinations included: measurement of vision, measurement of IOP by Applanation Tonometer, examination with Silt Lamp. evaluation of bleb with high magnification (×16) of slit lamp were performed. For evaluation of bleb, the (IBAG) Indiana bleb appearance system was used and specifications of bleb were evaluated and recorded based on height, extension, vascularization, presence or absence leakage. The presence of postoperative complications including hyphema, choroidal effusion, hypotonia and high filtration and endophthalmitis after surgery and late bleb leaks were evaluated and recorded if presented.

In this study the complete success is defined as IOP less than 21 without anti-glaucoma medication and at least a 20% reduction in IOP at the last preoperative visit. Qualified success is defined as follows:

1- Postoperative IOP less than 21 mmHg with anti-glaucoma medication in patients with preoperative IOP more 21 than mmHg

2- Postoperative IOP equal to or greater than 30 mmHg but a 21% reduction in IOP from baseline with or without anti-glaucoma treatment in patients with pre-operative IOP more than 21 (the maximum reducing treatment of IOP shall not be greater than the preoperative one)

3- Post operative IOP lower or equal to the preoperative IOP and at least reducing 2 IOP-lowering drugs in patients with preoperative IOP less than or equal to 21.

Statistical analysis: Statistical studies of all data were analyzed by spss-17 software and used Wilcoxon test, spearman test, U Mann-whitney, Kruskal-wallis and Fishers exact test.in all evaluations P value < 0.05 was considered statistically significant.

Findings :

In the study performed on 60 eyes of 60 patients with open-angle glaucoma divided into three groups, the average age of the trabeculectomy group was 69.00 ± 1.90 (ranging from 55 - to 82) years and in the trabeculectomy group with Ologen was 66.50 ± 2.59 (ranging from 38 to 82) and in the trabeculectomy group with mitomycin C was 66.45 ± 2.75 years (ranging from 41 to 88). There was no significant difference between the three groups in terms of age distribution (P = 0.74). In the trabeculectomy group, 80% were female (16 patients) and 20% male (4 patients), in Ologen group 80% were female (16 patients) and 20% were male (4 patients) and in trabeculectomy group with mitomycin C 75% were female (15 patients) and 25% male (5 patients) and there was no statistically significant differences between the groups in terms of gender distribution (P = 0.91) and in terms of type of glaucoma in the trabeculectomy group 30% of patients (6 patients) had primary open-angle glaucoma, 70% (4 patients) had secondary open-angle glaucoma,in the trabeculectomy with Ologen 25% (5 patients), primary open-angle glaucoma and 75% (15 patients) had secondary open-angle glaucoma, and in trabeculectomy group with mitomycin C 35% (7 patients), had primary open-angle glaucoma and 65% (13 patients) had secondary open-angle glaucoma. In this sense, there was no significant difference between groups. (P = 0.74) The mean deviation (MD) in perimetry in the trabeculectomy group was -22.98 ± 1.5 (ranging from -7.82 to -30.39), in the trabeculectomy group with Ologen was -19.6 ± 1.69 (ranging from -7.15 to -30.39) and in the trabeculectomy group with MMC was -20.02 ± 2.12 (ranging from -15.56 to -29.39), which there was no significant difference between the 3 groups (P = 0.19). Pattern standard deviation (PSD) in the trabeculectomy group was 6.91 ± 0.73 (ranging from 2.81 to 13.28) and in Ologen group was 7.14 ± 0.54 (ranging from 3.21 to 11.53) and in trabeculectomy group with mitomycin group C was 8.43 ± 0.55 (ranging from 3.49 to13.28), which there is no significant difference between the 3 groups (P = 0.74) and average length of glaucoma diagnosis was 32.04, 58.8 and 68.4 months, in patients with trabeculectomy with Ologen, trabeculectomy and trabeculectomy with mmc, respectively. In this study, the mean preoperative IOP in Ologen and trabeculectomy and trabeculectomy with mmc were 33.85 ± 1.32, 33.5 ± 1.15 and 31.40 ± 0.73, respectively which there was no statistically significant difference (P = 0.31). Results of

postoperative studies are shown in Tables 1 to 4:

Time interval		Pre Op	1 day		1 week		1 month	p-value*	3 month	p-value*	6 month	p-value*	12 month	p-value*
IOP	Ologen Rang	32.85± 1.32 24-45	8.70± 0.60 3-12	<0.001	9.75± 0.53 3-14	<0.001	12.5±0.96 5-22	<0.001	14.15±1.14 6-30	<0.001	15.30±1.51 9-34	<0.001	13.65±0.52 10-18	<0.001
	Tbx Range	33.5 ± 1.15 26-50	13.45 ± 0.71 10-22	<0.001	14.40 ± 0.53 11-20	<0.001	15.8±0.70 11-23	<0.001	20.60±1.58 12-40	<0.001	20.35±1.53 14-42	<0.001	16.65±0.84 11-26	<0.001
	Tbx & mmc Range	31.40±0.73 26-40	9.70±0.55 4-18	<0.001	10.10±0.64 3-16	<0.001	15.15±1.53 2-37	<0.001	16.40±1.23 10-35	<0.001	16.10±1.06 10-28	<0.001	14.60±1.07 8-28	<0.001
p- value**		0.31	<0.001		<0.001		0.03		0.001		0.002		0.04	
UCVA	Ologen Range	0.83±0.13 0.05-1.80	1.28±0.19 0.2-4	<0.001	1.02±0.12 0.15-1.80	<0.001	0.89±0.12 0.10-1.90	0.03	0.88±0.12 0.05-2.00	0.07	0.90±0.12 0.05-2.00	0.03	0.92±0.12 0.05-2.00	0.008
	Tbx Range	0.93±0.14 0.1-0.12	1.19±0.13 0.3-1.85	<0.001	1.06±0.14 0.2-1.85	<0.001	0.94±0.14 0.10-0.80	0.18	0.95±0.14 0.10-1.80	0.29	0.96±0.14 0.10-1.80	0.12	0.97±0.14 0.10±1.80	0.08
	Tbx & mmc Range	0.96±0.12 0.20-1.90	1.30±0.11 0.50-1.90	<0.001	1.19±0.12 0.15-2.00	<0.001	1.00±0.13 0.10-2.00	0.001	1.01±0.13 0.20-2.00	0.34	1.05±0.13 0.20-2.00	0.11	0.95±0.13 0.20-2.00	0.51
p- value**		0.80	0.73		0.54		0.86		0.80		0.69		0.97	
wilcoxon* Kruskal-wallis**														

Table1: Evaluation of IOP and UCVA (uncorrected visual acuity) at time intervals of the study

Time interval	1 day	p-value*	1 week	p- value*	1 month	p- value*	3 month	p- value*	6 month	p- value*	12 month	p- value*
Ologen Range	8.70± 0.60 3-12	<0.001	9.75± 0.53 3-14	<0.001	12.5±0.96 5-22	0.007	14.15±1.14 6-30	<0.001	15.30±1.51 9-34	<0.001	13.65±0.52 10-18	0.009
Tbx Range	13.45 ± 0.71 10-22		14.40 ± 0.53 11-20		15.8±0.70 11-23		20.60±1.58 12-40		20.35±1.53 14-42		16.65±0.84 11-26	
Tbx & mmc Range	9.70±0.55 4-18	0.66	10.10±0.64 3-16	0.48	15.15±1.53 2-37	0.14	16.40±1.23 10-35	0.10	16.10±1.06 10-28	0.19	14.60±1.07 8-28	0.68
Ologen Range	8.70± 0.60 3-12		9.75± 0.53 3-14		12.5±0.96 5-22		14.15±1.14 6-30		15.30±1.51 9-34		13.65±0.52 10-18	
*Mann-Whitney U												

Table2: Evaluation of IOP between the study groups in the postoperative time intervals

Time interval		Pre Op	1 day	p-value*	1 week	p- value*	1 month	p- value*	3 month	p- value*	6 month	p- value*	12 month	p- value*
Number of Medication	Ologen Range	3.60±0.13 2-4	0. 0±0.0 0-0	<0.001	0. 0±0.0 0-0	<0.001	0.40±0.18 0-3	<0.001	0.45±0.22 0-4	<0.001	0.65±0.24 0-4	<0.001	0.95±0.31 0-4	<0.001
	Tbx Range	3.45±0.11 3-4	0.25±0.14 0-2	<0.001	0.20±0.12 0-2	<0.001	1.15±0.29 0-4	<0.001	1.95±0.22 0-4	<0.001	2.25±0.25 0-4	0.001	2.05±0.26 0-4	0.001
	Tbx & mmc Range	3.25±0.12 2-4	0.05±0.05 0-1	<0.001	0.05±0.05 0-1	<0.001	0.70±0.18 0-2	<0.001	1.35±0.29 0-4	<0.001	1.60±0.33 0-4	0.001	1.60±0.30 0-4	0.001
p- value**		0.74	0.15		0.15		0.09		<0.001		<0.001		0.02	
wilcoxon* Kruskal-wallis**														

Table3: Evaluation of the number of anti-glaucoma drugs in studied groups at time intervals

Number of medication														
Time interval	Pre Op	1 day	p-value*	1 week	p-value*	1 month	p-value*	3 month	p-value*	6 month	p-value*	12 month	p-value*	
Ologen Range	3.60±0.13 2-4	0. 0±0.0 0-0	0.43	0. 0±0.0 0-0	0.43	0.40±0.18 0-3	0.07	0.45±0.22 0-4	<0.001	0.65±0.24 0-4	<0.001	0.95±0.31 0-4	0.005	
Tbx Range	3.45±0.11 3-4	0.25±0.14 0-2		0.20±0.12 0-2		1.15±0.29 0-4		1.95±0.22 0-4		2.25±0.25 0-4		2.05±0.26 0-4		
Tbx & mmc Range	3.25±0.12 2-4	0.05±0.05 0-1	0.80	0.05±0.05 0-1	0.80	0.70±0.18 0-2	0.20	1.35±0.29 0-4	0.02	1.60±0.33 0-4	0.03	1.60±0.30 0-4	0.09	
Ologen Range	3.60±0.13 2-4	0. 0±0.0 0-0		0. 0±0.0 0-0		0.40±0.18 0-3		0.45±0.22 0-4		0.65±0.24 0-4		0.95±0.31 0-4		

Table4: Evaluation of the number of anti-glaucoma medicationsduringthe medications during the study interval between study groups

In this study, , in terms of side effects, in the second group, two cases ofhyphema(10%) of hyphema (10%) and two cases of positive Seidel testing (early leak) (10%) and one case of Choroidal effusion (5%) were reported and in the first group,1 case of Choroidal effusion (5%) was observed, that all effects improved with conservative treatment, without the need for surgical intervention.

In the morphologic study of bleb in terms of bleb extension atmonths 3 and 12, there was significant difference between the 3 groups (p-values were 0.045 and 0.02, respectively) and the largest extension of the bleb was for Ologen group followed by mitomycin C group. the difference in bleb height at day 1, week 1, month 3 , months 6 and months 12 after surgery between 3 groups, was significant and was greater in the first group than the other two groups (p-values were 0.002, 0.008, 0.04, 0.04 and 0.01, respectively). And alsoin the examination of bleb vascularity, minimal vascularity was in the mitomycin group which is statistically significant at months 1, 3, 6 and 12 (p-values, were 0.04, >0.001, >0.001 and 0.009, respectively).

In studying the connection between bleb morphology and IOP in terms of bleb extension there was no significant relationship in the first and the third groups but in the second group at months 3 and 6, there was a significant correlation between the extension of the bleb and IOP (P-values were 0.02 and 0.04, respectively), meaning that patients with more diffuse bleb, had lower IOP. And in studying the connection between IOP and bleb height there was a significant relationship in first and third groups one day after surgery, (P=0.03) but there was no such relationship in the rest intervals,. In trabeculectomy group with MMC, in studying the relationship between bleb height and IOP a significant relationship was found in month 3 (P = 0.02). In studying relationship between between bleb vascularity and IOP in the first group and the third group there was no significant relationship and in the second group, in the third month there was a significant correlation between IOP and bleb vascularity, this means that in lower bleb vascularity, patients had less IOP (P = 0.02) and in study of the bleb by Seidel testing, the test was positive in only 2 patients in group II (10%) and the rest of the groups, showed no positive test results.

Complete and Qualified success results in comparison of the groups were 100% and 100% in the first group, 95% and 95%, in the second group and 90% and 95% in the third group, respectively and there was no statistically significant difference between 3 groups. differencebetween3groups.

Discussion:

Bleb is a visible part of trabeculectomy that in the postoperative phase plays an important role in its success or failure and its complications. (9) The success of glaucoma surgery is related to wound healing response failure to create a new way of filtration. Anti-glaucoma agent especially adrenergic agonists have long-term effects on conjunctive and tenon capsule, especially cause sub-conjunctiva inflammation and increased inflammatory cells and fibrosis. Such histological changes cause fibroblast response after surgery and increase fibrosis. Therefore, it increases bleb failure followed trabeculectomy. (10) Wound healing process is effective in determining the final postoperative IOP and bleb function and with extensive scarring, reduces surgical success. Both MMC and Fu-5 reduce proliferation of fibroblasts in the subconjunctival space. (5) However, as mentioned earlier, there are complications, in the study by sauder et al, after trabeculectomy with mitomycin C, it was stated that patients in a 1.5-year study showed considerable problems such as thinning of the cornea and the melting of sclera. (11) In the study by mietz et al also after administrating mitomycin C during trabeculectomy 2 cases of severe corneal endothelial damage and bullous keratopathy, adjacent to filtering bleb were reported that for these patients, specular microscopy showed striking irregularities of endothelial cells and necrosis in corneal areas adjacent to filtering bleb. (12)

In this regard, extensive research was done to find a replacement for the use of the above adjuvant. An alternative approach is the use of the collagen matrix during trabeculectomy. In the study by chen et al, it was stated that implanted collagen matrix in the sub-conjunctival space is a new method for preventing scar formation and long-term control of IOP. (13) Ologen consists of more than 90% of collagen but less than 10% of glycosaminoglycan (Chondroitin-6-sulfate) both is degradable and has 95% of the pore space, pore size ranges from 20 micrometers to 200 micrometers. After planting the material in sub-conjunctival space, the pores guide fibroblasts that propagate randomly during wound healing process and thus reducing the formation of scar tissue. After the implant, Ologen between days 30 and 60 may be degraded. (14)

In our study, the reduced IOP in trabeculectomy group with Ologen compared with trabeculectomy without adjuvant was significantly higher in all postoperative months, probably due to the lower formation of scar tissue, however, in comparison with the results of IOP in trabeculectomy with Ologen and trabeculectomy with mmc, although the average IOP in Ologen group was lower but there was no significant difference in the studied postoperative time intervals.

At months 6 and 12, the average IOP in trabeculectomy with mmc was closer to trabeculectomy with Ologen, which is probably due to the that in the first months Ologen acted as a pseudo-pored asapseudo-pored space, but over time, as previously stated biological degradation occurred and was not as efficient as of early postoperative period. . And in the studies on the number of anti-glaucoma in a comparative study, there was a significant correlation between trabeculectomy with Ologen and trabeculectomy without adjuvant at months 3, 6,12, where it was lower in thetrabeculectomygroupwith Ologen, probably due to the higher formation of scar tissue in the trabeculectomy group without adjuvant and increased IOP in this group as well, requiring anti-glaucoma medication to achieve desired IOP in the postoperative follow-ups .And in a comparative evaluation,therewas a significant relationship between trabeculectomy with Ologen and trabeculectomy with mitomycin C, in the number of medications used in months 3, 6 after surgery and further reduced number of drugs in trabeculectomy with Ologen was observed, thedifference may be due to thelow concentration andthe shorterduration of exposure to mmc during operation in trabeculectomywith mitomycin C.Incomparisonwith other studies, in thestudy by NaveedNilforushan et al, on the effects of Oculogen, the overall success rate was 80% in the last study. (5), whereas in our study the overall success was 100%.In the study by S cillino et al performed on 40 eyes, the use of Ologen and mitomycin in reducing IOP has similar effects but bleb was higher for the users of Ologen in the 6-month follow-up period. (7) In the study by Aptel f et al, after the use of implant a substantially reduction in IOP and reduced *trabeculo*-corneal membrane thickness were reported.(14) The IOP results are in accordance with those of our study. In the studyby Ji Q et al, it was stated that implants of Ologen lead to a further reduction in IOP compared with mmc but there is no significant decrease in ficant decreasein the number of anti-glaucoma drugs, the success rate of bleb and postoperative complications.(15) In another study by Nilforoushan et al performed on 14 eyes of 7 patients with primary open-angle glaucoma it was expressed that he cumulativesuccess rate in the last visit was 100% in MMC group and 71.5% in oculusgen group (P=0.008) and it was stated that trabeculectomy with oculusgen is a sa fe method to reduce IOP, at least in the short term compared with trabeculectomy with MMC, it considerably requires more IOP lowering drugs compared with MMC.(6) In our study, reduction IOP was not statistically significant between two groups, however definite and qualified success rate was higher in Ologen group, but the difference was not significant compared to other groups, but for anti-glaucoma treatment, there is a significant decrease in Ologen group at months 3, 6 and 12compared tomitomycin groupandhigher need for medical treatment in mitomycin group may be due to the low-dose and the shorter use of mi-

tomycin in our study. In the study **by** Rosentreter et al on 10 patients, no anti-glaucoma treatment was required in mmc group, in the first year of study, whereas 5 patients in Ologen group needed topical treatment, complete success was 100% in mmc group, and 50% in Ologen group. (P=0.01) and the bleb morphology in mitomycin C group faced more problems likeavascularity thanologen group(8), difference may be due to the longer duration of mmc use in the study compared with our study (3 minutes vs. 40-60 seconds), in terms of anti-glaucoma treatment, ologen group required fewer treatments that was significant in months and 6 after surgery, this was probably due to the fact that Ologen acts as a space occupier in early months, , but with the passage of time, it loses its efficiency due to degradation. In our study, the vascularity of mitomycin group was lower than that of the Ologen group and it was fo rmonths 1, 3, 6 and 12. In the study by Dimitris et al, average IOP for both groups was significantly lower than the preoperative levels (P<0.05) and the number of drug treatments were significantly (P<0.001)reduced.There was no considerable difference between the two groups in postoperative complications. (16) However, in our study, ologen groups needed lower drugs than mmc groups in months 3, 6 (p=0.02, p=0.03 respectively) .in the study by Miao et al, no significant difference was observed in drug reduction or complete and qualifiedsuccess incomparingthe twogroups and the complicationrateswere not significant between the two groups(17) In another study by Rosentreter, et al., one year after surgery, the mean IOP in Ologen group was reduced by 43% (P<0.01) and 54% in mmc group (P<0.01), and the success rate of surgery, 12 months after surgery was 93.3% in mmc and 40% in Ologen group(P=0.01) (18), and the difference may be due to longer duration of intra operative mitomycin in study compared to that of our study. In the study by S Senthil et al, the average reduction in Iop in mmc group compared with Ologen group was significantly lower. (P=0.01), but in the months 12 and 24 between the two groups, complete success rate was 100% at the end of 6 months in Ologen group and 93.8% in mmc group.(19) And the differences from our study may be due to the type of glaucoma of studied patients (Both POAG and PACG) and also the higher concentration and longer use of mitomycin(0.4 mg /ml for2minutes). In the study by Marey et al, no significant difference was observed between groups in mean IOP. And also, , there was no significant difference between the two groups with regard to side effects. (20) And the results are similar to those of our study.

In the study that we carried out, there were some limitations, one is that the severity of glaucoma was not identical in all groups and desired Iop was different in each case, and thus taking ethical considerations into account, wherever the examinations of cup/disc and IOP after surgery required to lower intraocular pressure of the patients, anti-glaucoma medication was added and other limitation was the duration of anti-glaucoma medication before the procedure that was different among groups. And due to drug reaction and fibrosis, lower bleb scarring was achieved; this reduces success in the postoperative results.

Conclusion:

this study, Ologen was effective in reducing intraocular pressure and reducing the number of anti-glaucoma drug therapies compared with trabeculectomy without adjuvant and trabeculectomy with mitomycin and can be considered as an effective and safe method in trabeculectomy surgery.

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