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Ologen implant versus mitomycin C in combined trabeculectomy and phacoemulsification

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Purpose: To comparatively evaluate in Indian eyes with coexisting cataract and primary open-angle glaucoma the outcome of mitomycin C (MMC) and Ologen implant as adjunctives in combined phacoemulsification with trabeculectomy. **Methods:** Eyes with primary open-angle glaucoma that underwent trabeculectomy and phacoemulsification with IOL implantation with either MMC application or Ologen implant between June 2019 and February 2020 were followed up for 12 months. Thirty-four eyes of 34 participants were studied. The primary outcome was intraocular pressure (IOP), and the secondary outcomes were the number of ocular hypotensives, best distance visual acuity (BDVA), and bleb morphology. **Results:** In 16 eyes treated with MMC and 18 eyes treated with Ologen implant, it was observed that the mean postoperative IOP (14.62 ± 2.89 mm Hg with MMC and 14.56 ± 4.14 mm Hg with Ologen implant) was not significantly different in both groups (P = 0.47). Number of ocular hypotensives and BDVA were also comparable between the two groups. However, bleb morphology was better with Ologen implantation. One eye in the MMC group developed hypotony which was conservatively managed. **Conclusion:** MMC and Ologen are both effective adjunctives in combined phaco-trabeculectomy. However, the Ologen implant provides better bleb health and safety.

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Trabeculectomy is the most commonly performed filtering surgery for the treatment of glaucoma.[1-3] Bleb failure is a major factor challenging the long-term success of this procedure, caused by subconjunctival fibrosis beneath the bleb.[4,5] To enhance the success of the procedure, we have an array of adjunctives. Selecting the most appropriate one for an individual patient ensures better outcomes.

The most commonly used agents are antimetabolites, such as Mitomycin C (MMC) and 5- fluorouracil (5-FU). MMC is a cell cycle nonspecific antitumor antibiotic obtained from Streptomycin caespitosus, which inhibits the synthesis of DNA, cellular RNA, and protein. Thus, it inhibits fibroblast proliferation and migration and hence the synthesis of collagen by fibroblasts.[6-8] However, MMC is a relatively toxic substance that impairs healing and leads to irregular epithelialization and fibroblast destruction, consequently increasing corneal toxicity and bleb-related complications such as thin avascular blebs, wound leak, overfiltration, hypotony, blebitis, and endophthalmitis.[9,10] Anti-vascular endothelial growth factor agents, amniotic membrane, and other biodegradable implants are devised to prevent fibroblast activation and thus modify wound healing in a safer manner.[11,12]

Ologen®Collagen matrix (Aeon Astron Europe B. V., Leiden, the Netherlands) is a biodegradable, porous, porcine collagen implant aimed at decreasing subconjunctival fibrosis with fewer bleb-related complications. It contains >90% type I atelocollagen (pepsin-treated type I porcine collagen) and <10% lyophilized porcine glycosaminoglycan and has a pore size of 10–300 µm, permitting controlled fibroblast regeneration in a loose, random, nonlinear fashion, thus preventing compression of collagen lamellae and resistance to aqueous outflow. It acts by providing a scaffold for the growth of fibroblasts, thus aiding in tissue remodeling and reducing scar formation and simultaneously preventing adhesions between the episcleral surface and conjunctiva by separating them. The implant can be placed subsclerally or subconjunctivally. After implantation, it degrades within 90–180 days.[13-16]

Studies have shown Ologen blebs to be vascular, thicker-walled, and diffuse, with good bleb height and microcysts in comparison to MMC-treated ones.[17-19] Ologen has also been used with low doses of MMC for treating hypotony after trabeculectomy.[20-22]

Glaucoma is a public health concern as it is one of the leading causes of irreversible blindness.[23] Pigmented eyes have a greater genetic predisposition for subconjunctival fibrosis.[24-29] Thus, the use of adjunctives in trabeculectomy is frequently needed in these eyes. Filtering procedures are a requirement

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owing to late diagnosis as a result of lack of access to quality eye care, noncompliance to medication, and financial constraints. Moreover, there is a rising need for successful trabeculectomy to preserve visual function. Greater proportions of these patients are middle-aged or elderly and are noted to have coexisting cataracts. A combined procedure gives these patients the advantage of one-step management with decreased number of total hospital visits, thus increasing compliance.

MMC is the most commonly used adjunctive in trabeculectomy. However, bleb safety remains a concern with its use as the long-term rate of visually debilitating complications is reported to be around 23% (over 5 years). Thus, safer but effective alternatives to MMC are much required.[10]

Some studies have found MMC and Ologen to provide comparable IOP reduction,[13,16,27,30] whereas some others suggest that Ologen is either inferior[15,28,29] or superior. Moreover, in eyes with coexisting cataract and glaucoma, cataract has been seen to progress after trabeculectomy. Combined phacoemulsification and trabeculectomy has been performed in our study as vision is one of the variables, and coexisting cataract progressing after surgery may be a confounding factor. In this study, we aim to compare the efficacy and safety of Ologen implant with MMC in combined phacoemulsification and trabeculectomy in Indian eyes.

Methods

This study was conducted in accordance with the tenets of the Declaration of Helsinki. Approval of the ethics committee of the institution was obtained. Informed consent was obtained from all the participants. It was a prospective, open, randomized controlled trial. A total of 34 eyes of 34 patients, all over 45 years of age, were enrolled, with 18 eyes randomly assigned to Ologen implantation and 16 eyes to MMC, recruited from June 2019 to February 2020 in a tertiary referral center. Following trabeculectomy with the respective adjunctive combined with phacoemulsification and IOL implantation, the eyes were followed up for a period of 12 months. Eyes with coexisting cataract and primary open-angle glaucoma with IOP not reaching the threshold value despite maximal compliance and medication were included in the study. Eyes with other comorbidities compromising the outcome, that is, secondary glaucoma or corneal or retinal pathology were excluded from the study. Parameters evaluated included IOP, number of ocular hypotensive medications required, best distance visual acuity (BDVA), and bleb morphology by using the Moorfields bleb grading system.[31]

Surgical technique

This was a single-surgeon study. All participants were operated under peribulbar anesthesia. Trabeculectomy was performed with fornix-based conjunctival flap superiorly, 8 mm in dimension. A 4.5 mm × 4 mm rectangular scleral flap was dissected, and two 10-0 monofilament nylon releasable sutures were preplaced. In MMC eyes, pledgets soaked with 0.2 mg/cm^3 were placed subsclerally and subconjunctivally, sparing the cut ends of the conjunctiva, and care was taken to avoid the cornea. After 1 min, the pledgets were removed and a thorough wash was given with 30 ml of balanced salt solution. After completion of standard phacoemulsification with IOL implantation, Descemet's membrane was punched and the anterior chamber was entered. Releasable sutures were completed and anterior chamber integrity was ensured. Ologen implant of 6 mm × 2 mm dimensions (Model 830601, Aeon Astron Europe B.V.) was placed subconjunctivally. The conjunctival flap was sutured back with continuous 9-0 monofilament nylon sutures to form the bleb, and bleb integrity was ensured through the side port. In the postoperative period, all eyes were treated with topical antibiotic-steroid combination (moxifloxacin 0.5% and prednisolone acetate 1%) eye drops six times daily, tapered over 6 weeks, and cyclopentolate 0.5% eye drops for 1 week. Ocular hypotensives were added as per the requirement, titrated against the IOP. Releasable sutures were released when bleb height was inadequate or IOP rose to over 15 mm Hg. Patients were assessed at day 1, 6 weeks, 3 months, 6 months, and 12 months post-operatively.

Mean postoperative IOP was the primary outcome variable. Success was defined as IOP between 5 and 21 mm Hg with (qualified success) or without (complete success) use of ocular hypotensives. The number of ocular hypotensives used post-operatively, BDVA, and bleb morphology were the secondary outcome variables. IOP was measured by Goldmann Applanation tonometry, BDVA was assessed by Snellen chart for distance and converted to logMAR, and bleb morphology was assessed by slit-lamp examination and anterior segment optical coherence tomography. Blebs with IOP moderate wall thickness and vascularity and with microcystic spaces were considered successful, whereas those with extremely thin walls, avascularity, scarring, or absence of microcystic spaces, or other complications were considered to have failed. Statistical analysis was done using paired *t* test ($P < 0.05$) and Kaplan–Meier analysis. A random number table was used for randomization. The sample size was calculated to be 18 in each group with a confidence interval of 95%, significance level of 0.05, and power of 80% in accordance with a study by Senthil *et al*.[16] which gave comparable results at 12 months with both Ologen and MMC. One patient had to be excluded owing to inadequate follow-up.

Results

Thirty-four eyes of 34 patients were studied. All the patients underwent trabeculectomy and phacoemulsification with IOL implantation in one eye and were followed up for a period of 12 months.

There was no significant difference between the preoperative parameters and demographics between the two groups as shown in Table 1.

There was a significant decrease in IOP ($P < 0.00001$) and number of ocular hypotensive medications ($P < 0.00001$) used and improvement in BDVA ($P < 0.00001$) from the first follow-up visit, and this was maintained until the 12-month follow-up in both groups. However, there was no significant difference between the two groups regarding the abovementioned parameters. The postoperative outcomes of both groups are summarized in Tables 2 and 3.

In the MMC group, mean IOP dropped from 30.12±3.78 mm Hg preoperatively to 11.94 ± 2.35 mm Hg ($P < 0.00001$) on day 1, 12 ± 1.97 mm Hg ($P < 0.00001$) at 6 weeks, 13.56 ± 2.39 mm Hg ($P < 0.00001$) at 3 months, 13.62 ± 2.66 mm Hg ($P < 0.00001$) at 6 months, and 14.62 ± 2.89 mm Hg ($P < 0.00001$) at 12 months postoperatively. In the Ologen group, it dropped

Table 1: Preoperative parameters and demographic data of participants in the MMC group and Ologen group

	MMC group (*n*=16)	Ologen group (*n*=18)	*P*
Mean age	54.96±2.02 years	56.32±2.31 years	0.36
Male: Female	9:7	11:7	
Mean IOP	30.12±3.78 mm Hg	29.44±3.48 mm Hg	0.27
Mean BDVA	0.91±0.13 logMAR	0.91±0.12 logMAR	0.1
Number of antiglaucoma medications used	2.94±0.77	2.89±0.67	0.42

Table 2: Primary and secondary outcomes of trabeculectomy in eyes treated with MMC and Ologen at 12 months

	MMC group	Ologen group	*P*
Mean IOP	14.62±2.89 mm Hg	14.56±4.14 mm Hg	0.47
Mean BDVA	0.17±0.09 logMAR	0.17±0.09 logMAR	0.33
Number of antiglaucoma medications	0.75±1	0.78±0.94	0.47
Reduction in IOP	51.06%	50.58	

Table 3: Bleb morphology of eyes post-trabeculectomy in the MMC group and Ologen group

	MMC group	Ologen group
Microcystic	5	7
Diffuse	5	10
Flat	4	Nil
Encapsulated	1	1
Overhanging	1	Nil

from 29.44 3.48 mm Hg preoperatively to 12.89 ± 1.96 mm Hg ($P < 0.00001$) on day 1, 15.22 ± 2.48 mm Hg ($P < 0.00001$) at 6 weeks, 14.33 ± 4.82 mm Hg ($P < 0.00001$) at 3 months, 14.33 ± 4.82 mm Hg ($P < 0.00001$) at 6 months, and 14.56 ± 4.14 mm Hg ($P < 0.00001$) at 12 months postoperatively.

Number of ocular hypotensives used reduced from median 2 (IQR 1–3) preoperatively to IQR 0–0 on day 1 ($P < 0.00001$), IQR 0–1 ($P < 0.00001$) at 6 weeks, IQR 0–1 ($P < 0.00001$) at 3 months, IQR 0–1 ($P < 0.00001$) at 6 months, and median 1 (IQR 0–1) ($P < 0.00001$) at 12 months postoperatively in the MMC group. In the Ologen group, it reduced from median 2 (IQR 1–3) preoperatively to IQR 0–0 ($P < 0.00001$), IQR 0–1 ($P < 0.00001$), IQR 0–1 ($P < 0.00001$), median 0.5 (IQR 0–1) ($P < 0.00001$), and median 0.5 (IQR 0–1) ($P < 0.00001$) on day 1, at 6 weeks, 3 months, 6 months, and 12 months, respectively.

BDVA improved from 0.91 ± 0.13 logMAR preoperatively to 0.16 ± 0.09 logMAR ($P < 0.00001$), 0.16 ± 0.09 logMAR ($P < 0.00001$), 0.16 ± 0.09 logMAR ($P < 0.00001$), 0.17 ± 0.09 logMAR ($P < 0.00001$), and 0.17 ± 0.09 logMAR ($P < 0.00001$) on day 1 and at 6 weeks, 3 months, 6 months, and 12 months, respectively, in the postoperative period in the MMC group. In the Ologen group, BDVA improved from 0.91 ± 0.12 logMAR preoperatively to 0.17 ± 0.09 logMAR on day 1 ($P < 0.00001$), at 6 weeks ($P < 0.00001$), 3 months ($P < 0.00001$), 6 months ($P < 0.00001$), and 12 months ($P < 0.00001$).

Visual deterioration was seen in only one eye in the MMC group which developed hypotony in the immediate postoperative period. It was managed with bandage contact lens and atropine 1% eye drops and improved by 6 weeks. None of the other eyes in either group had any complications.

The mean change in IOP did not vary significantly ($P = 0.35$) between the two groups. No significant correlation was seen between the study parameters and the age or gender of the participants.

At the end of 12 months, the overall success rates were 93.75% and 94.44% in the Ologen and MMC groups, respectively. Complete success was achieved in 48.63% of eyes in the Ologen group, and the remaining 45.12% of eyes achieved qualified success. In the MMC group, 47.85% of eyes achieved complete success and 46.59% of eyes achieved qualified success.

Blebs in the Ologen group showed better morphology as compared to those in the MMC group, as shown in Table 3. Fig. 1 demonstrates the difference in bleb morphology between a MMC bleb and an Ologen bleb.

None of the eyes underwent any further surgical procedures for IOP reduction.

Discussion

Combined phacoemulsification with IOL implantation and trabeculectomy was performed with either MMC or Ologen as the adjunctive. A significant drop in IOP was recorded after the procedure in both groups, and the decrease in IOP was comparable between the groups. The number of ocular hypotensives used postoperatively, BDVA, and success rates were also comparable between the two groups. However, there was one isolated event of hypotony in the MMC group which was managed medically. However, bleb morphology was noted to be better in the Ologen group.

The concern with the use of Ologen is that Ologen blebs fail to achieve the same IOP-lowering effect as MMC blebs as these blebs are more vascular and have lesser height.[32] As reported by some previous studies,[27,30] our study also found Ologen to be non-inferior to MMC in its IOP lowering effect, with a mean IOP reduction of ~51% in the MMC group and ~ 50.5% in the Ologen group. This is comparable with the IOP reduction obtained with trabeculectomy in other studies comparing the two adjunctives.[33]

Though the criterion for success of the procedure in our study was an IOP of <21 mm Hg, studies suggest a value of <17 mm Hg to be more appropriate.[34] This might have been a confounding factor.

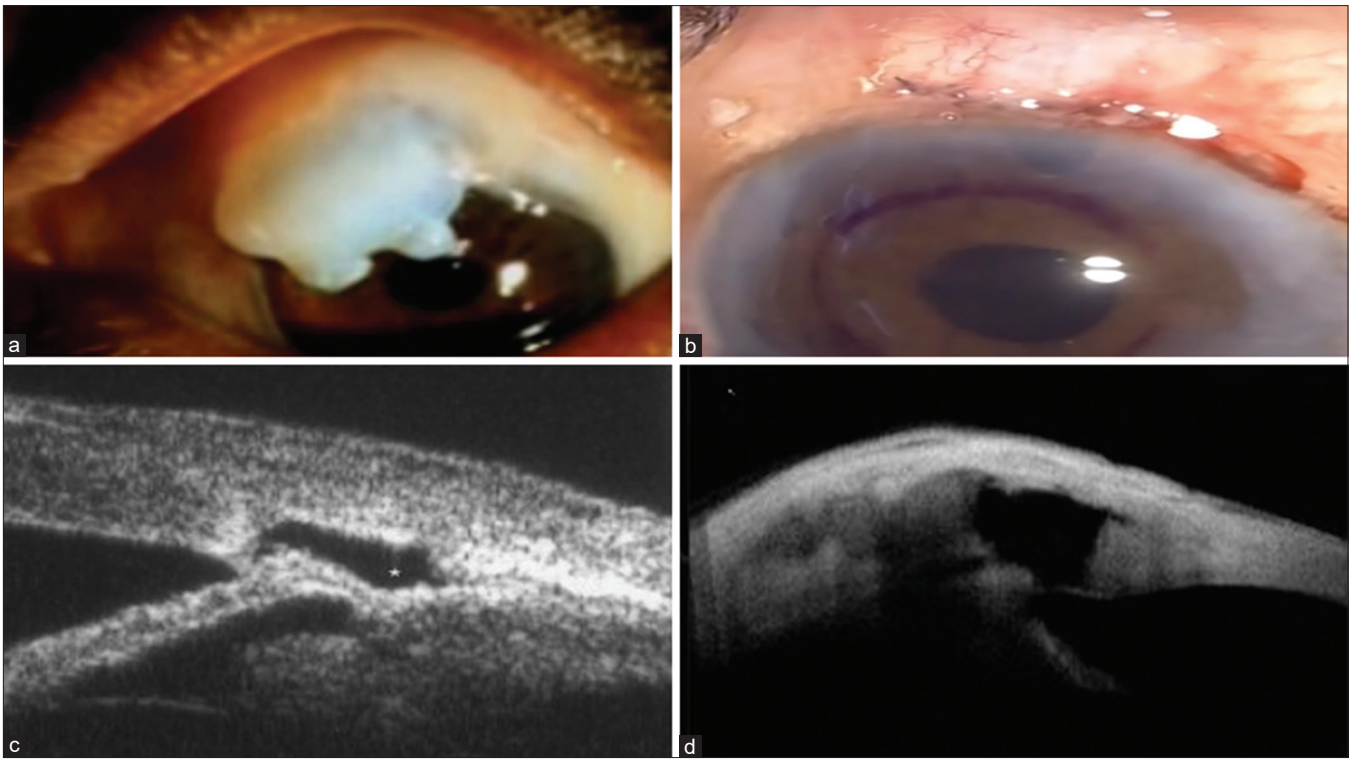

Figure 1: (a) Slit-lamp biomicroscopy image of an overhanging bleb in an eye treated with Mitomycin C. (b) Slit-lamp biomicroscopy image of a diffuse bleb in an eye with Ologen implant. (c) Ultrasound biomicroscopy image of the eye in image (a) showing lesser bleb height and fewer microcystic spaces in comparison with (d) which is the ultrasound biomicroscopy image of the eye in (b)

One eye in the MMC group developed hypotony in the first week with an IOP of 6 mm Hg. A shallow anterior chamber and minimal bleb leak were observed, and this was managed conservatively with a bandage contact lens and 1% atropine eye drops daily. The IOP eventually improved to 8 mm Hg and remained the same 6 weeks postoperatively.

Although there was only a single eye with hypotony, the bleb morphology was observably better in the Ologen group in comparison with the MMC group. El-Sayyad *et al.*[35] also reported better scoring (Moorfields bleb grading system) with Ologen blebs. Though less frequent, bleb leakage, implant exposure, encapsulated blebs, and blebitis have also been reported in Ologen blebs.[32,33]

None of the eyes studied had any toxicity or allergy in the postoperative period. Though there is a theoretical risk of increased inflammation with Ologen,[33] none have been reported. MMC has been shown to cause have toxic intraocular effects.[36] The risk is higher in combined phacoemulsification with trabeculectomy. As phacoemulsification itself brings down IOP by ~ 2 mm Hg, Ologen as an adjunctive would suffice to further decrease the IOP to the desired levels, as would be possible with MMC which is significantly more toxic.[37]

The main limitations of this study are the small sample size and short follow-up duration. The data is from a single center. Thus, institutional practices may have affected the outcome. In addition, healing responses vary between individuals. A multi-center randomized control trial of patients with bilateral primary open-angle glaucoma with one eye receiving MMC and the other receiving an Ologen implant followed up for a longer duration is recommended.

Conclusion

Our study demonstrated similar outcomes for combined trabeculectomy and phacoemulsification with MMC and Ologen. However, bleb morphology and bleb health were better in Ologen blebs.

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Conflicts of interest

There are no conflicts of interest.

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