

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## INTERVENTIONAL PROCEDURES PROGRAMME

### Interventional procedure overview of trabeculectomy with a biodegradable collagen matrix implant for glaucoma

Glaucoma causes fluid to build up in the eye, which increases pressure in the eye. This damages the optic nerve, which connects the eye to the brain, and can lead to permanent sight loss. In this procedure, a small flap is cut in the white of the eye (a trabeculectomy) and sewn up with loose stitches. A tiny patch (collagen matrix) is put over the flap to help healing and prevent scarring. Fluid slowly drains out of the flap and the patch dissolves over time (biodegradable). The aim is to reduce pressure in the eye and slow or stop damage to sight.

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## Abbreviations

| Word or phrase | Abbreviation                 |
|----------------|------------------------------|
| ACG            | Angle-closure glaucoma       |
| BCVA           | Best corrected visual acuity |
| CI             | Confidence interval          |
| IOP            | Intraocular pressure         |
| MMC            | Mitomycin C                  |
| POAG           | Primary open-angle glaucoma  |
| RCT            | Randomised controlled trial  |
| RR             | Relative risk                |
| SD             | Standard deviation           |
| SE             | Standard error               |
| VA             | Visual acuity                |
| WMD            | Weighted mean difference     |

## Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and professional opinion. It should not be regarded as a definitive assessment of the procedure.

## Date prepared

This overview was prepared in October 2022.

## Procedure name

- Trabeculectomy with a biodegradable collagen matrix implant for glaucoma

## Professional societies

- Royal College of Ophthalmologists (RCOphth)

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- Royal College of Surgeons Edinburgh -Ophthalmology Surgical Specialty Board
- UK and Éire Glaucoma Society (UKEGS).

## Description of the procedure

### Indications and current treatment

Glaucoma is usually a chronic condition associated with raised intraocular pressure (IOP). It leads to progressive damage to the optic nerve. Early stages are usually asymptomatic. But, as the condition progresses, it can cause visual impairment and, if untreated, blindness. There are several types of glaucoma but the most common type of glaucoma in the UK is primary (or chronic) open-angle glaucoma.

[NICE's guideline on glaucoma](#) describes its diagnosis and management. Treatment usually involves eye drops containing different drugs that either reduce aqueous humour production or increase its drainage. Surgical procedures such as trabeculectomy, drainage tubes, deep sclerectomy, viscocanalostomy, laser trabeculoplasty and cyclodiode laser treatment may also be used.

### What the procedure involves

Trabeculectomy with an adjunctive biodegradable collagen matrix aims to modify wound healing and improve the drainage of aqueous humour to lower IOP. It reduces or avoids the use of antimetabolites and antifibrotic agents (mitomycin C [MMC] and 5-fluorouracil).

In this procedure, usually with the patient under local anaesthesia, the conjunctiva is dissected to access the sclera, and then a partial-thickness scleral flap is dissected. Within the scleral bed a full-thickness opening is created into the anterior chamber, to allow drainage of aqueous humor. Sometimes the trabecular meshwork and adjacent structures are also removed. The scleral flap is then sutured loosely with 1 or 2 loops, to allow the aqueous fluid to drain into the subconjunctival space through the scleral fistula. Viscoelastic may be injected under the scleral flap. Then a subconjunctival biodegradable collagen matrix implant is placed directly on top of the scleral flap, and the conjunctiva is sutured and closed on top of it.

## Efficacy summary

### Intraocular pressure

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A meta-analysis of 11 studies including 443 eyes comparing trabeculectomy plus biodegradable collagen implant with trabeculectomy plus MMC showed that the percentage reduction in IOP was statistically significantly lower in the trabeculectomy plus biodegradable collagen implant than trabeculectomy plus MMC group for 12 months. The mean difference (MD) was -3.69 (95% confidence interval [CI] -6.70 to -0.68,  $p=0.02$ ) at 1 month; -2.69 (95% CI -5.17 to -0.21,  $p=0.03$ ) at 3 months; -3.67 (95% CI -6.09 to -1.25,  $p=0.003$ ) at 6 months; and -3.24, (95% CI -6.08 to -0.41,  $p=0.03$ ) at 12 months. However, there was no statistically significant difference between the groups at 24 months (MD 1.24 [95% CI -9.43 to 11.90],  $p=0.82$ ), and 60 months (MD 1.10 [95% CI -10.11 to 12.31],  $p=0.85$ ) (Song 2019).

A Cochrane review reported a meta-analysis of 8 studies ( $n=327$  participants [333 eyes]), 7 of which compared trabeculectomy plus biodegradable collagen implant with trabeculectomy plus MMC while 1 compared trabeculectomy plus biodegradable collagen implant with trabeculectomy alone. Pooled analysis reported that the reduction in IOP was not statistically significantly different between the 2 groups at day 1 (5 studies [162 eyes], MD 0.51, 95% CI -1.95 to 2.97,  $I^2=55\%$ ,  $p=0.68$ ), 6 months (7 studies [282 eyes], MD 0.43, 95% CI -0.97 to 1.84,  $I^2=54\%$ ,  $p=0.55$ ), 1 year (5 studies [177 eyes], MD 1.40, 95% CI -0.57 to 3.38,  $I^2=54\%$ ,  $p=0.16$ ) and 2-year follow up (2 studies [55 eyes], MD 0.20, 95% CI -1.29 to 1.69,  $I^2=34\%$ ,  $p=0.79$ ). There was substantial heterogeneity between the studies. The mean change in IOP from baseline to 6 months and 1 year between the trabeculectomy plus biodegradable collagen implant group and the trabeculectomy plus MMC group was also not statistically significantly different (6 months, 2 studies [46 eyes], MD -1.24, 95% CI -6.23 to 3.76,  $p=0.63$ ; 1 year, 2 studies [44 eyes], MD -0.32 [95% CI -5.88 to 5.24],  $p=0.91$ ) (Wang 2015).

In a randomised controlled trial (RCT) of 33 patients (40 eyes) comparing trabeculectomy plus shunt device (20 eyes) with trabeculectomy plus biodegradable collagen implant (20 eyes), the change in IOP from preoperative IOP in both groups (23.7 mm Hg in shunt group and 26 mm Hg in collagen implant group), was statistically significant at 1 week (10.8 versus 9.5 mm Hg), 4 weeks (13 versus 14.4 mm Hg), 8 weeks (13.7 versus 14.9 mm Hg), 12 weeks (14.3 versus 15.2 mm Hg) and 6 months (15.8 versus 14.7 mm Hg, all  $p<0.05$ ). There was no statistically significant difference in change of IOP from preop IOP between the 2 groups at any time of observation (Bhatkoti 2021).

### **Complete success rate**

In the meta-analysis of 11 studies, the rate of complete success (defined as IOP, usually 21 mm Hg without medications) was not statistically significantly different between the 2 groups (collagen implant [138/217] versus MMC [156/226], relative risk [RR] 0.91 [95% CI 0.74 to 1.13],  $p=0.39$ ) (Song 2019).

In the RCT of 33 patients (40 eyes) comparing trabeculectomy plus shunt device (20 eyes) with trabeculectomy plus collagen implant (20 eyes), complete success (defined as IOP 21 mm Hg without medications) between the 2 groups was not statistically significantly different 6 months after surgery (70% [14/20] in shunt device group versus 60% [12/20] in collagen implant group, p not significant) (Bhatkoti 2021).

### **Qualified success rate**

In the meta-analysis of 11 studies, the rate of qualified success (defined as the target endpoint IOP, with or without medications) was not statistically significantly different between the 2 groups (implant group 201/217 versus MMC group 198/226, RR 1.02 [95% CI 0.97 to 1.07],  $I^2=1$ ,  $p=0.51$ ) (Song 2019).

In the RCT of 33 patients (40 eyes) comparing trabeculectomy plus shunt device (20 eyes) with trabeculectomy plus collagen implant (20 eyes), qualified success (defined as IOP 21 mm Hg and use of antiglaucoma medications) between the 2 groups was not statistically significantly different 6 months after surgery (15% [3/20] in shunt group versus 25% [5/20] in collagen implant group, p not significant) (Bhatkoti 2021).

### **Reduction in glaucoma medication use**

In the meta-analysis of 11 studies, pooled analysis shows there was no statistically significant difference in the percentage reduction in the number of glaucoma medications between the 2 groups at 6 months (4 studies, MD -6.80, 95% CI -14.75 to 1.16,  $p=0.09$ ) and 24 months (MD 5.33, 95% CI -1.65 to 12.30,  $p=0.13$ ). A statistically significant difference was noted between the groups at 12 months (MD -25.16, 95% CI -45.26 to -5.05,  $p=0.01$ ). The reduction in the number of glaucoma medications between the groups was 2.56 versus 2.88 in the 6th month; 2.63 versus 2.74 in the 12th month, and 2.45 versus 2.40 in the 24th month (Song 2019).

In the RCT of 33 patients (40 eyes) comparing trabeculectomy plus shunt device (20 eyes) with trabeculectomy plus collagen implant (20 eyes), the difference in the number of patients who required IOP-lowering medications at 4, 8, 12 weeks and 6 months between the 2 groups was not statistically significant (Bhatkoti 2021).

### **Best corrected visual acuity**

In the Cochrane review comparing trabeculectomy plus biodegradable collagen implant with trabeculectomy plus MMC, 1 study (including 32 eyes) reported that there was no statistically significant difference in best corrected visual acuity (BCVA) at 6 weeks follow up (MD -0.24 logMAR, 95% CI -0.58 to 0.10) (Wang 2015).

In an RCT of 33 patients (40 eyes) comparing trabeculectomy plus shunt device (20 eyes) with trabeculectomy plus biodegradable collagen implant (20 eyes), the reduction in visual acuity from the preoperative period at 1 week was statistically significant ( $p < 0.05$ ) in the shunt group. Change in visual acuity at 4, 8, 12 weeks and 6 months in the shunt device group was not statistically significant. In the biodegradable collagen implant group, the reduction in visual acuity from preoperative visual acuity at 1 and 4 weeks were statistically significant. At 8, 12 weeks and 6 months, change in visual acuity was not statistically significant (Bhatkoti 2021).

## Safety summary

### Hypotony (IOP <5mm Hg)

In the meta-analysis of 11 studies, comparing trabeculectomy plus collagen implant with trabeculectomy plus MMC, pooled analysis of 10 studies reported a statistically significantly higher incidence of hypotony in the MMC group (collagen implant 25/183 versus MMC 40/193, RR 0.64 [95% CI 0.42 to 0.98],  $p = 0.04$ ) (Song 2019).

In a Cochrane review, pooled analysis of 6 studies (including 233 eyes) comparing trabeculectomy plus collagen implant with trabeculectomy plus MMC reported no statistically significant difference between the groups for hypotony (collagen implant 19/112 versus trabeculectomy plus MMC 27/121, RR 0.75 [95% CI 0.47 to 1.19],  $p = 0.22$ ) (Wang 2015).

### Hypotony maculopathy

In the meta-analysis of 11 studies, 1 study reported that the rate of hypotony maculopathy was similar between the groups (collagen implant 4/20 versus MMC 8/20, RR 0.50 [95% CI 0.18 to 1.40],  $p = 0.19$ ) (Song 2019).

### Surgical revision

In the Cochrane review, pooled analysis of 4 studies (including 150 eyes) comparing trabeculectomy plus collagen implant with trabeculectomy plus MMC reported no statistically significant difference between the groups in the rates of surgical revision within 3 months (collagen implant 7/75 versus MMC 3/75, RR 1.7 [95% CI 0.38 to 7.63],  $p = 0.49$ ) (Wang 2015).

### Endophthalmitis or blebitis

In the meta-analysis of 11 studies, pooled analysis of 3 studies reported that the rate of blebitis was similar between the groups (collagen implant 3/109 versus MMC 5/118, pooled RR 0.73 [95% CI 0.21 to 2.47],  $p = 0.61$ ) (Song 2019).

In the Cochrane review, pooled analysis of 3 studies (including 164 eyes) comparing trabeculectomy plus collagen implant with trabeculectomy plus MMC reported no statistically significant difference between the groups for endophthalmitis or blebitis (collagen implant 2/78 versus MMC 1/86, RR 1.57 [95% CI 0.25 to 9.70],  $p=0.63$ ) (Wang 2015).

### **Bleb leakage**

In the meta-analysis of 11 studies, pooled analysis of 8 studies reported that the rate of bleb leakage was similar between the groups (collagen implant 12/135 versus MMC 15/137, RR 0.81 [95% CI 0.41 to 1.63],  $p=0.56$ ) (Song 2019).

In the Cochrane review, pooled analysis of 4 studies (including 129 eyes) comparing trabeculectomy plus collagen implant with trabeculectomy plus MMC reported no statistically significant difference between the groups for bleb leakage (collagen implant 7/64 versus MMC 9/65, RR 0.85 [95% CI 0.33 to 2.2],  $p=0.73$ ) (Wang 2015).

### **Hyphaema**

In the meta-analysis of 11 studies, pooled analysis of 9 studies reported that the rate of hyphaema was similar between the groups (collagen implant 18/165 versus MMC 11/167 RR 1.65 [95% CI 0.83 to 3.29],  $p=0.16$ ) (Song 2019).

In the Cochrane review, pooled analysis of 6 studies (including 229 eyes) comparing trabeculectomy plus collagen implant with trabeculectomy plus MMC reported no statistically significant difference between the groups for hyphaema (collagen implant 16/114 versus MMC 9/115, RR 1.46 [95% CI 0.51 to 4.19],  $p=0.48$ ) (Wang 2015).

### **Encapsulated bleb**

In the meta-analysis of 11 studies, pooled analysis of 2 studies reported that the rate of encapsulated bleb was similar between the groups (collagen implant 3/38 versus MMC 2/46, RR 1.68 [95% CI 0.30 to 9.43],  $p=0.56$ ) (Song 2019).

### **Flat avascular bleb**

Flat non-filtering blebs were reported in 10% (2/20) of eyes in the shunt device group and 15% (3/20) of eyes in the collagen implant group in the RCT of 33 patients (40 eyes) at 6 months follow up (Bhatkoti 2021).

### **Choroidal detachment**

In the meta-analysis of 11 studies, pooled analysis of 5 studies reported that the rate of choroidal detachment was similar between the groups (collagen implant 9/95 versus MMC 10/97, RR 1.10 [95% CI 0.56 to 2.15],  $p=0.78$ ) (Song 2019).

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In the Cochrane review, pooled analysis of 4 studies (including 129 eyes) comparing trabeculectomy plus collagen implant with trabeculectomy plus MMC reported no statistically significant difference between the groups for choroidal detachment (collagen implant 7/64 versus MMC 9/65, RR 0.83 [95% CI 0.33 to 2.09],  $p=0.7$ ) (Wang 2015).

### **Shallow anterior chamber**

In the meta-analysis of 11 studies, pooled analysis of 9 studies reported that the rate of shallow anterior chamber was similar between the groups (collagen implant 17/162 versus MMC 20/171, RR 0.88 [95% CI 0.50 to 1.53],  $p=0.65$ ) (Song 2019).

In the Cochrane review, pooled analysis of 5 studies (including 213 eyes) comparing trabeculectomy plus collagen implant with trabeculectomy plus MMC reported no statistically significant difference between the groups for shallow anterior chamber (collagen implant 7/102 versus MMC 9/111, RR 0.79 [95% CI 0.32 to 1.93],  $p=0.6$ ) (Wang 2015).

### **Anterior chamber reaction**

In the meta-analysis of 11 studies, pooled analysis of 5 studies reported that the rate of anterior chamber reaction was similar between the groups (collagen implant 18/100 versus MMC 17/102, RR 1.09 [95% CI 0.61 to 1.93],  $p=0.78$ ) (Song 2019).

In the Cochrane review, pooled analysis of 2 studies (including 99 eyes) comparing trabeculectomy plus collagen implant with trabeculectomy plus MMC reported no statistically significant difference between the groups for anterior chamber reaction (collagen implant 10/49 versus MMC 9/50, RR 1.21 [95% CI 0.56 to 2.6],  $p=0.62$ ) (Wang 2015).

### **Positive Seidel test**

In the Cochrane review, pooled analysis of 3 studies (including 164 eyes) comparing trabeculectomy plus collagen implant with trabeculectomy plus MMC reported no statistically significant difference between the groups for positive Seidel test (collagen implant 3/78 versus MMC 1/86, RR 1.93 [95% CI 0.32 to 11.54],  $p=0.47$ ) (Wang 2015).

### **Tenon's cysts**

In the Cochrane review, pooled analysis of 3 studies (including 124 eyes) comparing trabeculectomy plus collagen implant with trabeculectomy plus MMC reported no statistically significant difference between the groups for Tenon's cysts (collagen implant 5/58 versus MMC 6/66, RR 0.88 [95% CI 0.21 to 3.66],  $p=0.86$ ) (Wang 2015).

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## **Suture lysis**

In the meta-analysis of 11 studies, 1 study reported a statistically significantly higher incidence of suture lysis in the MMC group (collagen implant 3/20 versus MMC 10/20, pooled RR 0.30 [95% CI 0.10 to 0.93],  $p=0.04$ ) (Song 2019).

## **Needling**

In the meta-analysis of 11 studies, 1 study reported that the rate of needling was not significantly different between the groups (collagen implant 0/20 versus MMC 4/20, pooled RR 0.11 [95% CI 0.01 to 1.94],  $p=0.13$ ) (Song 2019).

## **Central retinal vein occlusion**

Central retinal vein occlusion following trabeculectomy with biodegradable collagen implant in the early postoperative period was reported in 3 cases in a case report. Two patients had decreased visual acuity and 1 patient had blurred vision and retinal haemorrhages involving the macula (Tranos 2010).

## **Cataract**

One eye in each group developed a cataract in the RCT of 33 patients (40 eyes) comparing a shunt device (20 eyes) with collagen implant (20 eyes) at 6 months follow up (Bhatkoti 2021).

## **Postoperative complications**

The rate of postoperative complications was lower in the shunt group compared to the collagen implant group, in both early (within 30 days) (35% [7/20] versus 50% [10/20]) and late follow up (20% [4/20] versus 30% [6/20]) in the RCT of 33 patients (40 eyes) (Bhatkoti 2021).

## **Anecdotal and theoretical adverse events**

In addition to safety outcomes reported in the literature, professional experts are asked about anecdotal adverse events (events that they have heard about) and about theoretical adverse events (events that they think might possibly occur, even if they have never happened). For this procedure, no adverse events were reported.

## **The evidence assessed**

### **Rapid review of literature**

The medical literature was searched to identify studies and reviews relevant to trabeculectomy with a biodegradable collagen matrix implant for glaucoma. The

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following databases were searched, covering the period from their start to 31 October 2022: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the internet were also searched. No language restriction was applied to the searches (see the [literature search strategy](#)). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The [inclusion criteria](#) were applied to the abstracts identified by the literature search. If selection criteria could not be determined from the abstracts the full paper was retrieved.

### Inclusion criteria for identification of relevant studies

| Characteristic           | Criteria   |
|--------------------------|--|
| <b>Publication type</b>  | Clinical studies were included. Emphasis was placed on identifying good quality studies.<br>Abstracts were excluded if no clinical outcomes were reported, or if the paper was a review, editorial, or a laboratory or animal study.<br>Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature. |
| <b>Patient</b>           | Patients with glaucoma.  |
| <b>Intervention/test</b> | Trabeculectomy with a biodegradable collagen matrix implant.   |
| <b>Outcome</b>           | Articles were retrieved if the abstract contained information relevant to safety and/or efficacy.  |
| <b>Language</b>          | Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.   |

### List of studies included in the IP overview

This IP overview is based on 819 eyes of 806 patients from 2 meta-analyses, 1 RCT and 1 case report. There is an overlap of primary studies included in the 2 meta-analyses.

Other studies that were considered to be relevant to the procedure but were not included in the main [summary of the key evidence](#) are listed in the [appendix](#).

## Summary of key evidence on trabeculectomy with a biodegradable collagen matrix implant for glaucoma

### Study 1 Song DS (2019)

#### Study details

|   |   |
|---|---|
| <b>Study type</b>                             | Systematic review and meta-analysis   |
| <b>Country</b>                                | Egypt (n=4), Germany (n=2), China (n=1), India (n=1), UK, (n=1), Italy (n=1), Iran (n=1)  |
| <b>Recruitment period</b>                     | Search period: April 1966 to April 2018   |
| <b>Study population and number</b>            | n = 11 studies<br>443 eyes in patients with glaucoma (n=217 trabeculectomy with biodegradable collagen implant versus n=226 trabeculectomy with MMC)  |
| <b>Age and sex</b>                            | Biodegradable collagen implant group: Mean age 48 to 67.9 years, sex not reported<br>MMC group: Mean age 45 to 65 years, sex not reported   |
| <b>Patient selection criteria</b>             | <u>Inclusion criteria:</u> Prospective cohort studies; study including patients with glaucoma where traditional therapies have been unsuccessful; studies comparing the outcome of trabeculectomy with biodegradable collagen implant implant versus trabeculectomy with MMC; minimum follow up of 6 months; at least 1 of the outcomes of interest included.<br><u>Exclusion criteria:</u> Retrospective studies; studies involving other types of glaucoma surgery; studies including paediatric cases or patients with repeated glaucoma surgery; conference abstracts, editorials, duplicate publications, letters, or reviews. |
| <b>Technique</b>                              | Trabeculectomy followed either by implantation of biodegradable collagen matrix implant (Ologen Collagen Implant, Aeon Astron Europe, Netherlands) or application of MMC depending on the allocated group.  |
| <b>Follow up</b>                              | <b>Varied across studies (range 1 to 60 months)</b>   |
| <b>Conflict of interest/source of funding</b> | No conflicts of interest reported. Study funded by Young Medical Talents Foundation of Jiangsu Province (grant no. QNRC2016080).  |

#### Analysis

##### Study design issues:

Systematic searches were done, studies were screened and data extracted by 2 independent researchers; disagreements were resolved through discussion with a third researcher. Quality of the included studies was evaluated based on the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) methodology which were classified into levels of very low, low, moderate, and high. High risk of detection and performance bias was observed across the included studies.

The primary outcome of interest was the IOP reduction (IOPR) following trabeculectomy. The secondary outcome measures included complete success and qualified success rate, and the reduction in glaucoma medications.

Study population issues: one study (with 20 patients with juvenile open-angle glaucoma) was included in the analysis.

Other issues: One study (Yuan 2015) which presented a higher baseline IOP (>40mmHg) was excluded from pooled analyses by the authors to decrease between-study heterogeneity.

The total number of eyes in the biodegradable collagen implant group was counted twice in 1 included study (Eldaly 2017), which reported 2 separate analyses for different MMC concentrations using the same set of collagen implant eyes for both analyses.

There is an overlap of 6 primary studies (122 patients) included in study 2.

## Key efficacy findings

Number of patients analysed: 443 eyes (217 trabeculectomy plus biodegradable collagen implant versus 226 trabeculectomy plus MMC).

### Reduction in IOP

| Follow-up period | No of studies                                    | MD (95% CI)                   | I <sup>2</sup> | P value |
|------------------|--|-------------------------------|----------------|---------|
| 1 month          | 8 studies (165 collagen implant versus 173 MMC)  | -3.69 (-6.70 to -0.68)        | 0%             | 0.02    |
| 3 months         | 9 studies (179 collagen implant versus 187 MMC)  | -2.69 (95% CI -5.17 to -0.21) | 0%             | 0.03    |
| 6 months         | 10 studies (186 collagen implant versus 194 MMC) | -3.67 (95% CI -6.09 to -1.25) | 16%            | 0.003   |
| 12 months        | 7 studies (122 collagen implant versus 122 MMC)  | -3.24 (95% CI -6.08 to -0.41) | 51%            | 0.03    |
| 24 months        | 2 studies (27 collagen implant versus 28 MMC)    | 1.24 (95% CI -9.43 to 11.90)  | 0%             | 0.82    |
| 5 years          | 1 study (20 collagen implant versus 20 MMC)      | 1.10 (95% CI -10.11 to 12.31) | -              | 0.85    |

Reduction in IOP after 1 month: WMD -3.69 (95% CI -6.70 to -0.68), I<sup>2</sup>=0%, p=0.02 (8 studies; 165 biodegradable collagen implant and 173 MMC)

Reduction in IOP after 3 months: WMD -2.69 (95% CI -5.17 to -0.21), I<sup>2</sup>=0%, p=0.03 (9 studies; 179 biodegradable collagen implant and 187 MMC)

Reduction in IOP after 6 months: WMD -3.67 (95% CI -6.09 to -1.25), I<sup>2</sup>=16%, p=0.003 (10 studies; 186 biodegradable collagen implant and 194 MMC)

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Reduction in IOP after 12 months: WMD -3.24 (95% CI -6.08 to -0.41),  $I^2=51%$ ,  $p=0.03$  (7 studies; 122 biodegradable collagen implant and 122 MMC)

Reduction in IOP after 24 months: WMD 1.24 (95% CI -9.43 to 11.90),  $I^2=0%$ ,  $p=0.82$  (2 studies; 27 biodegradable collagen implant and 28 MMC)

Reduction in IOP after 5 years: WMD 1.10 (95% CI -10.11 to 12.31),  $p=0.85$  (1 study; 20 biodegradable collagen implant and 20 MMC)

### Pooled estimates for IOP and glaucoma medication reduction from baseline

| Outcome                            | Follow up (months) | Number of studies reporting outcome | Collagen implant group mean $\pm$ SD | MMC group mean $\pm$ SD |
|------------------------------------|--------------------|-------------------------------------|--------------------------------------|-------------------------|
| IOP (mmHg)                         | 1                  | 10                                  | 17.13 (10.07)                        | 18.06 (6.23)            |
|                                    | 3                  | 9                                   | 17.05 (7.44)                         | 16.51 (5.53)            |
|                                    | 6                  | 12                                  | 14.99 (7.50)                         | 15.56 (3.78)            |
|                                    | 12                 | 9                                   | 27.70 (9.43)                         | 15.73 (6.60)            |
|                                    | 24                 | 2                                   | 12.17 (3.3)                          | 10.64 (2.49)            |
|                                    | 60                 | 2                                   | 27.70 (9.43)                         | 17.37 (6.91)            |
| IOP (mmHg) (excluding Yuan study)* | 1                  | 9                                   | 14.45 (8.70)                         | 16.32 (4.71)            |
|                                    | 3                  | 8                                   | 14.53 (4.59)                         | 14.91 (4.10)            |
|                                    | 6                  | 11                                  | 12.66 (4.96)                         | 14.08 (3.95)            |
|                                    | 12                 | 8                                   | 12.84 (6.14)                         | 13.51 (5.04)            |
|                                    | 24                 | 2                                   | 12.17 (3.3)                          | 10.64 (2.49)            |
|                                    | 60                 | 1                                   | 12.10 (5.2)                          | 10.90 (4.51)            |
| No. of medications used            | 6                  | 4                                   | 2.56 (1.02)                          | 2.88 (1.14)             |
|                                    | 12                 | 3                                   | 2.63 (1.27)                          | 2.74 (1.24)             |
|                                    | 24                 | 2                                   | 2.45 (1.54)                          | 2.40 (1.48)             |

\*excluded this outlier study from pooled analyses which presented a higher baseline IOP (>40mmHg) to decrease between-study heterogeneity.

### Percentage reduction in the number of glaucoma medications

| Follow up | MD (95% CI)              | P value |
|-----------|--------------------------|---------|
| 6 months  | -6.80 (-14.75 to 1.16)   | 0.09    |
| 12 months | -25.16 (-45.26 to -5.05) | 0.01    |
| 24 months | 5.33, (-1.65 to 12.30)   | 0.13    |

## Procedural success

| Complication                   | No of studies reporting outcome | Collagen implant % (no of patients) | MMC % (no of patients) | Pooled RR (95% CI) | I <sup>2</sup> (%) | P value between groups |
|--------------------------------|---------------------------------|-------------------------------------|------------------------|--------------------|--------------------|------------------------|
| Complete success*              | 11                              | 8.9 (138/217)                       | 10.9 (156/226)         | 0.91 (0.74,1.13)   | 59                 | 0.39                   |
| Qualified success <sup>^</sup> | 11                              | 10.9 (201/217)                      | 6.6 (198/226)          | 1.02 (0.97,1.07)   | 1                  | 0.51                   |

\*defined as target endpoint IOP (usually 21mm Hg) without medications.

<sup>^</sup>defined as the target endpoint IOP with or without medications.

## Key safety findings

### Rate of adverse events

| Complication              | No of studies reporting | Collagen implant % (no of eyes) | MMC % (no of eyes) | Pooled RR (95% CI) | I <sup>2</sup> (%) | P value between groups |
|---------------------------|-------------------------|---------------------------------|--------------------|--------------------|--------------------|------------------------|
| Bleb leak                 | 8                       | 8.9 (12/135)                    | 10.9 (15/137)      | 0.81 (0.41,1.63)   | 5                  | 0.56                   |
| Hyphaema                  | 9                       | 10.9 (18/165)                   | 6.6 (11/167)       | 1.65 (0.83,3.29)   | 9                  | 0.16                   |
| Shallow Anterior chamber  | 9                       | 10.5 (17/162)                   | 11.7 (20/171)      | 0.88 (0.50,1.53)   | 0                  | 0.65                   |
| Hypotony                  | 10                      | 13.7 (25/183)                   | 20.7 (40/193)      | 0.64 (0.42,0.98)   | 0                  | 0.04                   |
| Encapsulated Bleb         | 2                       | 7.9 (3/38)                      | 4.3 (2/46)         | 1.68 (0.30,9.43)   | 0                  | 0.56                   |
| Blebitis                  | 3                       | 2.8 (3/109)                     | 4.2 (5/118)        | 0.73 (0.21,2.47)   | 0                  | 0.61                   |
| Hypotony maculopathy      | 1                       | 20 (4/20)                       | 40 (8/20)          | 0.50 (0.18,1.40)   | -                  | 0.19                   |
| Choroidal detachment      | 5                       | 9.5 (9/95)                      | 10.3 (10/97)       | 1.10 (0.56,2.15)   | 0                  | 0.78                   |
| Anterior chamber reaction | 5                       | 18 (18/100)                     | 16.6 (17/102)      | 1.09 (0.61,1.93)   | 0                  | 0.78                   |
| Suture lysis              | 1                       | 15 (3/20)                       | 50 (10/20)         | 0.30 (0.10,0.93)   | -                  | 0.04                   |
| Needling                  | 1                       | 0 (0/20)                        | 20 (4/20)          | 0.11 (0.01,1.94)   | -                  | 0.13                   |

## Study 2 Wang X (2015)

### Study details

|   |  |
|---|--|
| <b>Study type</b>                             | Cochrane systematic review and meta-analysis   |
| <b>Country</b>                                | Individual studies from Italy (n=1), India (n=3), Germany (n=2), Egypt (n=1), Greece (n=1)   |
| <b>Recruitment period</b>                     | Search date: December 2014   |
| <b>Study population and number</b>            | n=327 patients (333 eyes) with glaucoma (8 studies; 162 eyes across 159 patients with trabeculectomy plus biodegradable collagen implant versus 151 eyes across 148 patients with trabeculectomy plus MMC, 20 eyes across 20 patients with trabeculectomy alone)   |
| <b>Age</b>                                    | Mean age 46 to 66 years, 40% to 59% male   |
| <b>Patient selection criteria</b>             | Inclusion criteria: RCTs comparing devices used during trabeculectomy with trabeculectomy alone; RCTs where antimetabolites were used in one or both treatment groups were also included.<br>Exclusion criteria: Non-RCTs or insufficient confirmation of RCT status; inclusion of children under 18 years of age where outcomes for adult participants were not reported separately; insufficient follow-up time. |
| <b>Technique</b>                              | 7 studies compared trabeculectomy followed either by implantation of biodegradable collagen matrix implant (Ologen Collagen Implant, Aeon Astron Europe, Netherlands) or application of MMC depending on the allocated group. One study compared trabeculectomy alone versus trabeculectomy and biodegradable collagen implant without any use of MMC. No specific surgical techniques were reported.              |
| <b>Follow up</b>                              | Varied across studies (range 6 to 24 months)   |
| <b>Conflict of interest/source of funding</b> | One author reported receiving grants from the National Eye Institute, National Institutes of Health (US) and the Agency for Healthcare Research and Quality (AHRQ). Study funded by the National Eye Institute, National Institutes of Health and the NIHR.  |

### Analysis

Follow-up issues: 7 studies reported outcomes at 6 months, 5 studies reported outcomes at 1 year and 2 studies reported outcomes at 2 years.

Study design issues: This systematic review and meta-analysis aimed to evaluate the efficacy and safety of different devices as adjuncts to trabeculectomy compared with standard trabeculectomy in eyes with glaucoma. 33 studies were included, but 8 studies assessed the use of a biodegradable collagen matrix implant. Evidence on other devices is out of the scope of this overview and is not presented here.

Studies were screened independently and data extracted by 2 authors; disagreements were resolved through discussion with a third author. Quality of the included studies was evaluated based on the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) methodology which were classified into levels of very low, low, moderate, and high. The overall quality of the included studies relating to a biodegradable collagen implant was classed as "very low" and the majority of studies were at high or unclear risk of detection and selection bias.

IP overview: Trabeculectomy with a biodegradable collagen matrix implant for glaucoma



The primary outcome of interest was change in IOP after one year, and secondary outcomes of interest included BCVA, visual field change, quality of life and frequency of complications

Study population issues: The studies included in this systematic review were very heterogenous and covered various types of glaucoma (including open-angle, angle-closure, and uncontrolled IOP). Studies did not stratify data by type of glaucoma.

Other issues: For the collagen implant studies, one study compared trabeculectomy without MMC versus trabeculectomy and collagen implant (Papaconstantinou 2010). The authors state that the lack of use of MMC in this study may have reduced the success rate of the trabeculectomy-alone group in comparison to the trabeculectomy-with-collagen implant group (favouring the trabeculectomy-with-collagen implant group).

There is overlap of 6 included primary studies (122 patients) with study 1.

## Key efficacy findings

- Number of patients analysed: 327 (333 eyes)

## Outcome measures

| Outcome                                   | Illustrative comparative risks* (95% CI) |                                      | No of eyes (studies) | Comments  |
|---|--|--------------------------------------|----------------------|---|
|   | Trabeculectomy plus MMC                  | Trabeculectomy plus collagen implant |                      |   |
| Postoperative mean IOP at 1 year          | 15.2 mm Hg (range 11 to 19.3 mm Hg)      | MD 1.40 mm Hg (95% CI 0.57 to 3.38)  | 177 (5 studies)      | Analysed using the generic inverse method   |
| Postoperative mean logMAR* BCVA at 1 year | See comment                              | See comment                          | -                    | Senthil 2013 reported BCVA for 32 eyes at 6 weeks post-surgery: MD -0.24 logMAR, 95% CI -0.58 to 0.10 |

\*logMAR = logarithm of the minimum angle of resolution.

The quality of evidence was assessed for postoperative mean IOP at 1 year and reported as “very low” due to limitations in the design and implementation of available studies, high probability of reporting bias and imprecision in results (i.e. wide confidence intervals).

## Reduction in IOP

| Follow-up period                 | No of studies   | MD (95% CI)           | I <sup>2</sup> value (%) | P value |
|----------------------------------|---|-----------------------|--------------------------|---------|
| Day 1                            | 5 studies (162 eyes; 81 trab + collagen implant versus 81 trab+MMC)     | 0.51 (-1.95 to 2.97)  | 54.81                    | 0.68    |
| 6 months                         | 5 studies (114 eyes, 114 trab + collagen implant versus 122 trab + MMC) | 0.43 (-0.97 to 1.84)  | 53.5                     | 0.55    |
| Change from baseline to 6 months | 2 studies (46 eyes, 23 trab + collagen implant versus 23 trab + MMC)    | -1.24 (-6.23 to 3.76) | 0                        | 0.63    |
| 1 year                           | 5 studies (177 eyes, 82 trab + collagen implant versus 95 trab + MMC)   | 1.4 (-0.57 to 3.38)   | 53.49                    | 0.16    |
| Change from baseline to 1 year   | 2 studies (44 eyes, 21 trab + collagen implant versus 23 trab + MMC)    | -0.32 (-5.88 to 5.24) | 0                        | 0.91    |
| 2 years                          | 2 studies (55 eyes, 27 trab + collagen implant versus 28 trab + MMC)    | 0.2 (-1.29 to 1.69)   | 33.57                    | 0.79    |

Mean change of IOP from baseline to one year (biodegradable collagen implant group) = WMD: -0.32 (95% CI -5.88 to 5.24, 2 studies, n=21 eyes; I<sup>2</sup>=0%, p=0.91)

Postoperative IOP at one year (biodegradable collagen implant group) = WMD: 1.40 (95% CI 0.57 to 3.38, 5 studies, n=82 eyes; I<sup>2</sup>=53%, p=0.16)

Postoperative IOP at day one (biodegradable collagen implant group) = WMD: 0.51 (95% CI -1.95 to 2.97, 5 studies, n=82 eyes; I<sup>2</sup>=54.8%, p=0.68)

Change in IOP from baseline to 6 months = WMD: -1.24 (95% CI -6.23 to 3.76, 2 studies, n=23 eyes; I<sup>2</sup>=0%, p=0.63)

Postoperative IOP at 6 months (biodegradable collagen implant group) = WMD: 0.43 (95% CI -0.97 to 1.84, 5 studies, n=114 eyes; I<sup>2</sup>=53.5%, p=0.55)

Postoperative IOP at 2 years (biodegradable collagen implant group) = WMD: 0.20 (95% CI -1.29 to 1.69, 2 studies, n=27 eyes; I<sup>2</sup>=33.6%, p=0.79)

## Key safety findings

### Rate of adverse events

|  | Illustrative comparative risks* (95% CI) | Collagen implant | No. of studies | I <sup>2</sup> value (%) | P value |
|--|--|------------------|----------------|--------------------------|---------|
|--|--|------------------|----------------|--------------------------|---------|

IP overview: Trabeculectomy with a biodegradable collagen matrix implant for glaucoma

| Complication<br>(follow-up range<br>6-24 months) | Trabeculectomy<br>plus MMC | Biodegradable<br>collagen<br>implant | versus<br>trab+MMC<br>Relative<br>effect<br>(95% CI)        |   | No.<br>of<br>eyes |      |      |
|--|----------------------------|--------------------------------------|---|---|-------------------|------|------|
| Hypotony   | 223 per 1000               | 167 per 1000<br>(105 to 265)         | 19/112<br>versus<br>27/121,<br>RR 0.75<br>(0.47 to<br>1.19) | 6 | 233               | 0    | 0.22 |
| Shallow anterior<br>chamber                      | 90 per 1000                | 71 per 1000<br>(29 to 174)           | 7/102<br>versus<br>9/111, RR<br>0.79 (0.32<br>to<br>1.93)   | 5 | 213               | 0    | 0.60 |
| Bleb leakage                                     | 138 per 1000               | 117 per 1000<br>(46 to 304)          | 7/64<br>versus<br>9/65, RR<br>0.85 (0.33<br>to<br>2.20)     | 4 | 129               | 0    | 0.73 |
| Hyphaema   | 78 per 1000                | 114 per 1000<br>(40 to 327)          | 16/114<br>versus<br>9/115, RR<br>1.46 (0.51<br>to<br>4.19)  | 6 | 229               | 25.3 | 0.48 |
| Surgical revision<br>within 3 months             | 40 per 1000                | 68 per 1000<br>(15 to 305)           | 7/75<br>versus<br>3/75, RR<br>1.70 (0.38<br>to<br>7.63)     | 4 | 150               | 17.9 | 0.49 |
| Blebitis or<br>endophthalmitis                   | -                          | -                                    | 2/78<br>versus<br>1/86, RR<br>1.57 (0.25<br>to<br>9.70)     | 3 | 164               | 0    | 0.63 |
| Choroidal<br>detachment                          | -                          | -                                    | 7/64<br>versus<br>9/65, RR<br>0.83 (0.33<br>to 2.09)        | 4 | 129               | 0    | 0.70 |

IP overview: Trabeculectomy with a biodegradable collagen matrix implant for glaucoma

|                           |   |   |   |   |     |      |      |
|---------------------------|---|---|---|---|-----|------|------|
| Anterior chamber reaction | - | - | 10/49 versus 9/50, RR 1.21 (0.56 to 2.60) | 2 | 99  | 0    | 0.62 |
| Positive Seidel test      | - | - | 3/78 versus 1/86, RR 1.93 (0.32 to 11.54) | 3 | 164 | 0    | 0.47 |
| Tenon's cysts             | - | - | 5/58 versus 6/66, RR 0.88 (0.21 to 3.66)  | 3 | 124 | 19.1 | 0.86 |

The quality of evidence was assessed for hypotony, shallow anterior chamber, bleb leakage, hyphaema and surgical revision – all were reported as “very low” due to limitations in the design and implementation of available studies, high probability of reporting bias and imprecision in results (i.e. wide confidence intervals). Follow up in studies ranged from 6-24 months.

## Study 3 Bhatkoti B (2021)

### Study details

|   |  |
|---|--|
| <b>Study type</b>                             | Randomised controlled trial  |
| <b>Country</b>                                | India  |
| <b>Recruitment period</b>                     | Not reported.  |
| <b>Study population and number</b>            | N=33 patients (40 eyes) with primary open-angle glaucoma (POAG trabeculectomy with Ex-PRESS shunt (20 eyes) versus biodegradable collagen matrix implant (20 eyes)   |
| <b>Age and sex</b>                            | Mean age: Group A $65.7 \pm 1.75$ years; Group B $64.6 \pm 1.68$ years<br>Sex: Group A: 17/20 eyes in men; Group B: 14/20 eyes in men  |
| <b>Patient selection criteria</b>             | Inclusion criteria: patients with POAG, more than 40 years of age, with inadequate IOP control ( $>21$ mm Hg) measured by Goldmann Applanation tonometry (GAT), on 3 or more topical antiglaucoma drugs over 4 weeks.<br>Exclusion criteria: patients with other form of primary or secondary glaucoma, aphakic or pseudophakic patients with anterior chamber/iris fixated or sclera fixated Intraocular lens, uveitis, any intraocular surgery and those with retinal pathologies. |
| <b>Technique</b>                              | Augmented trabeculectomy under peribulbar anaesthesia<br>Group A: 20 eyes (trabeculectomy with Ex-PRESS shunt) versus<br>Group B: 20 eyes (trabeculectomy with Ologen implant)<br>Both procedures included surface modification with MMC before implant insertion.   |
| <b>Follow up</b>                              | <b>6 months</b>  |
| <b>Conflict of interest/source of funding</b> | None; study was funded by the Directorate General Armed Forces Medical Services and Defence Research Development Organization, Government of India.  |

### Analysis

Follow-up issues: short follow-up period.

Study design issues: small randomised double blinded study. Single surgeon performed all surgeries.

### Key efficacy findings

Number of patients analysed: 33 (40 eyes)

**Reduction in IOP**

| IOP (mm Hg) | Group A (Ex-PRESS shunt) Mean $\pm$ SD | Mean difference (SE) | P value | Group B (biodegradable collagen implant) Mean $\pm$ SD | Mean difference (SE) | P value |
|-------------|--|----------------------|---------|--|----------------------|---------|
| Baseline    | 23.70 $\pm$ 4.6                        |                      |         | 26.00 $\pm$ 4.0  |                      |         |
| 1 week      | 10.80 $\pm$ 4.9                        | 12.9 (1.05)          | <0.05   | 9.50 $\pm$ 5.7   | 16.5 (1.83)          | <0.05   |
| 4 weeks     | 13.00 $\pm$ 5.7                        | 10.7 (1.29)          | <0.05   | 14.40 $\pm$ 4.9  | 11.6 (1.36)          | <0.05   |
| 8 weeks     | 13.70 $\pm$ 4.7                        | 10.0 (1.39)          | <0.05   | 14.90 $\pm$ 4.6  | 11.1 (0.89)          | <0.05   |
| 12 weeks    | 14.30 $\pm$ 3.7                        | 9.4 (1.04)           | <0.05   | 15.20 $\pm$ 5.2  | 10.8 (1.12)          | <0.05   |
| 6 months    | 15.80 $\pm$ 4.5                        | 7.9 (1.17)           | <0.05   | 14.70 $\pm$ 4.1  | 11.3 (1.17)          | <0.05   |

P<0.05 between groups at baseline.

**Change in best corrected visual acuity (using LogMAR chart)**

| Visual acuity (mean LogMAR) | Group A (Ex-PRESS shunt) Mean $\pm$ SD | Mean difference (SE) | P value | Group B (biodegradable collagen implant) Mean $\pm$ SD | Mean difference (SE) | P value |
|-----------------------------|--|----------------------|---------|--|----------------------|---------|
| Baseline                    | 0.35 $\pm$ .44                         |                      |         | 0.28 $\pm$ 0.36  |                      |         |
| 1 week                      | 0.67 $\pm$ .49                         | -0.317 (0.039)       | <0.05   | 0.67 $\pm$ 0.41  | -0.389 (0.061)       | <0.05   |
| 4 weeks                     | 0.44 $\pm$ .45                         | -0.089 (0.028)       | 0.070   | 0.53 $\pm$ 0.40  | -0.243 (0.045)       | <0.05   |
| 8 weeks                     | 0.39 $\pm$ .44                         | -0.037 (0.019)       | 0.965   | 0.53 $\pm$ 0.40  | -0.127 (0.041)       | 0.085   |
| 12 weeks                    | 0.39 $\pm$ .43                         | -0.039 (0.028)       | 1.000   | 0.31 $\pm$ 0.43  | -0.030 (0.044)       | 1.000   |
| 6 months                    | 0.41 $\pm$ .44                         | -0.054 (0.041)       | 1.000   | 0.31 $\pm$ 0.43  | -0.030 (0.044)       | 1.000   |

P<0.05 between groups at baseline.

**Change in medication use**

| Time since surgery | Group A (Ex-PRESS shunt) | Group B (biodegradable collagen implant) | P value |
|--------------------|--------------------------|--|---------|
| 1 week             | 0                        | 0  | -       |
| 4 weeks            | 1                        | 1  | 1.000   |
| 8 weeks            | 2                        | 7  | 0.58    |
| 12 weeks           | 6                        | 8  | 0.507   |
| 6 months           | 6                        | 7  | 0.736   |

## Success rates

| Time since surgery | Group A (Ex-PRESS shunt) | Group B (biodegradable collagen implant) | P value         |
|--------------------|--------------------------|--|-----------------|
| Complete success*  | 70% (14/20)              | 60% (12/20)                              | Not significant |
| Qualified success^ | 15% (3/20)               | 25% (5/20)                               | Not significant |
| Failure            | 15% (3/20)               | 15% (3/20)                               | Not significant |

\*defined as IOP of less than or equal to 21 mm Hg at 6 months postoperative.

^ use of additional antiglaucoma medications.

## Key safety findings

### Rate of adverse events

| Complication   | Group A (Ex-PRESS shunt) % (n=20) | Group B (biodegradable collagen implant) % (n=20) |
|--|-----------------------------------|---|
| Early complications (within 30 days) total               | 35 (7)                            | 50 (10)   |
| Hyphaema   | 5 (1)                             | 15 (3)  |
| Lens cornea touch due to malignant glaucoma              | 5 (1)                             | 0   |
| Hypotony with shallow anterior chamber (over filtration) | 20 (4)                            | 25 (5)  |
| Bleb leak  | 5 (1)                             | 0   |
| Choroidal detachment                                     | 0                                 | 10 (2)  |
| Late complications total                                 | 20 (4)                            | 30 (6)  |
| Encapsulated bleb  | 5 (1)                             | 10 (2)  |
| Cataract   | 5 (1)                             | 5 (1)   |
| Flat avascular bleb                                      | 10 (2)                            | 15 (3)  |

## Study 4 Tranos P (2010)

### Study details

|   |  |
|---|--|
| <b>Study type</b>                             | Case report  |
| <b>Country</b>                                | Greece   |
| <b>Recruitment period</b>                     | Not reported   |
| <b>Study population and number</b>            | n = 3 patients with glaucoma   |
| <b>Age and sex</b>                            | Age range: 73-89 years, 1 male and 2 female  |
| <b>Patient selection criteria</b>             | Not applicable   |
| <b>Technique</b>                              | Trabeculectomy followed by implantation of biodegradable collagen matrix implant (Ologen Collagen Implant, Aeon Astron Europe, Netherlands). |
| <b>Follow up</b>                              | <b>6-8 months</b>  |
| <b>Conflict of interest/source of funding</b> | None   |

### Key safety findings

#### Patient 1

A 73-year-old man with end-stage POAG underwent uncomplicated trabeculectomy with biodegradable collagen implant.

Three days after uncomplicated trabeculectomy with biodegradable collagen implant, IOP was 8 mmHg with an elevated microcystic filtration bleb and visual acuity (VA) 6/24. A day later the patient complained of blurred vision and visual acuity decreased to 6/60. Fundoscopy revealed central retinal vein occlusion (CRVO) with retinal haemorrhages involving the macula. Six months later, VA improved to 6/24 following absorption of macular haemorrhage.

#### Patient 2

Routine trabeculectomy with biodegradable collagen implant was performed in an 89-year-old hypertensive woman with end-stage glaucoma. Preoperative IOP was 26 mm Hg and vertical cup disc ratio was 0.95. Two days postoperatively, IOP was 10 mmHg and the anterior chamber well-formed, but she developed CRVO and experienced mild VA reduction from 6/36 to 6/60, which remained unchanged 6 months later.

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**Patient 3**

A 73-year-old hypertensive woman underwent uncomplicated trabeculectomy with biodegradable collagen implant. Six days postoperatively CRVO was noted with IOP of 11 mmHg (lower end of normal range). Because there was no macular involvement her VA remained unchanged at 6/18; 8 months later disc collateral vessels, were evident.

Authors assume that there are no mechanisms that could link biodegradable collagen implant with CRVO in any of the patients.

## Validity and generalisability of the studies

- 2 meta-analyses comparing trabeculectomy plus biodegradable collagen implant with trabeculectomy plus antimetabolites were included. There is some overlap of primary studies between the 2 meta-analyses. Studies included were small and heterogenous in terms of design, population, types of glaucoma, duration, and outcomes. The majority of the studies were specific to Egyptian and Asian populations. Only 4 studies were from Europe. The follow-up period ranged from 6 to 60 months. Studies included mainly patients with open-angle glaucoma and few with angle-closure glaucoma but results are not stratified according to the type of glaucoma.
- One RCT compared another implant (Ex-PRESS shunt) plus trabeculectomy with biodegradable collagen implant trabeculectomy. Both procedures received surface modification with MMC prior to implant insertion. This study was specific to Asian population and results may not be generalisable.

## Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

## Related NICE guidance

Below is a list of NICE guidance related to this procedure.

### Interventional procedures

- Repetitive short-pulse transscleral cyclophotocoagulation for glaucoma. NICE interventional procedures guidance 692 (2021). Available from <https://www.nice.org.uk/guidance/IPG692>
- High-intensity focused ultrasound for glaucoma. NICE interventional procedures guidance 661 (2019). Available from <https://www.nice.org.uk/guidance/IPG661>

- Microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma. NICE interventional procedures guidance 612 (2018). Available from <https://www.nice.org.uk/guidance/IPG612>
- Ab externo canaloplasty for primary open-angle glaucoma. NICE interventional procedures guidance 591 (2017). Available from <https://www.nice.org.uk/guidance/IPG591>
- Trabecular stent bypass microsurgery for open-angle glaucoma. NICE interventional procedures guidance 575 (2017). Available from <https://www.nice.org.uk/guidance/IPG575>
- Trabeculectomy ab interno for open angle glaucoma. NICE interventional procedure guidance IPG397 (2011). Available from <https://www.nice.org.uk/guidance/IPG397>

### **NICE guidelines**

- Glaucoma: diagnosis and management. NICE guideline NG81 (2017). Available from <https://www.nice.org.uk/guidance/NG81>

## **Additional information considered by IPAC**

### **Professional experts' opinions**

Expert advice was sought from consultants who have been nominated or ratified by their professional Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by professional experts, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, when comments are considered voluminous, or publication would be unlawful or inappropriate. One professional expert questionnaire for trabeculectomy with a biodegradable collagen matrix implant for glaucoma were submitted and can be found on the [NICE website](#).

### **Patient commentators' opinions**

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

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## **Company engagement**

A structured information request was sent to 1 company who manufacture a potentially relevant device for use in this procedure. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

## **Issues for consideration by IPAC**

- The biodegradable collagen matrix implant contains animal (porcine) collagen and may not be acceptable to those with certain religious beliefs or strict vegetarians or those with known allergy to the material.
- Omnigen human amniotic membrane-derived matrix (referred by the specialist adviser) is different from the porcine collagen implant (Ologen) and therefore has not been considered in this IP overview.
- Studies on paediatric, congenital and juvenile glaucoma are not considered in this review.

## References

1. Song D-S, Qian J, Chen Z-J. (2019) Ologen implant versus mitomycin-C for trabeculectomy A meta-analysis. *Medicine*, 98:25 (e16094).
2. Wang X, Khan R, Coleman A. (2015) Device-modified trabeculectomy for glaucoma. *Cochrane Database of Systematic Reviews*, Issue 12. Art. No.: CD010472. DOI: 10.1002/14651858.CD010472.pub2.
3. Bhatkoti B, Kumar P, Verma G et al. (2021) Trabeculectomy with Ologen implant versus trabeculectomy with P 50 Ex-PRESS shunt in primary open-angle glaucoma. *Medical journal, Armed Forces India*, <https://doi.org/10.1016/j.mjafi.2020.12.013>
4. Tranos P, Georgalas I, Zota E et al. (2010) Central retinal vein occlusion following trabeculectomy with OloGen in patients with advanced glaucoma: a possible side-effect? *Acta Ophthalmologica* doi: 10.1111/j.1755-3768.2009.01518.x

## Literature search strategy

| Databases   | Date searched | Version/files              |
|---|---------------|----------------------------|
| MEDLINE (Ovid)  | 22/08/2022    | 1946 to August 19, 2022    |
| MEDLINE In-Process (Ovid)   | 22/08/2022    | 1946 to August 19, 2022    |
| MEDLINE Epubs ahead of print (Ovid)   | 22/08/2022    | August 19, 2022            |
| EMBASE (Ovid)   | 22/08/2022    | 1974 to 2022 August 19     |
| EMBASE Conference (Ovid)  | 22/08/2022    | 1974 to 2022 August 19     |
| Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)           | 22/08/2022    | Issue 8 of 12, August 2022 |
| Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library) | 22/08/2022    | Issue 7 of 12, July 2022   |
| International HTA database (INAHTA)   | 22/08/2022    | -                          |

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

### MEDLINE search strategy

Glaucoma, Open-Angle/  
 ((Primary or second\* or refract\* or compensat\*) adj4 open angle glaucoma\*).tw.  
 Ocular Hypertension/  
 Intraocular Pressure/  
 Pseudo-exfoliative glaucoma.tw.  
 (POAG or COAG or IOP or PACG or PG or PXF).tw.  
 ((Ocular\* or intraocul\* or eye) adj4 (hypertens\* or pressure\*)).tw.  
 (open adj4 angle\* adj4 glaucoma\*).tw.  
 Pigment\* glaucoma\*.tw.  
 (simpl\* adj4 glaucoma).tw.  
 or/1-10  
 Trabeculectomy/  
 Trabeculect\*.tw.  
 or/12-13  
 Collagen/ad [Administration & Dosage]  
 ((absorb\* or collagen\* or atelocollag\* or biodegrad\*) adj4 (implant\* or matrix)).tw.  
 Absorbable Implants/  
 biodegradable collagen matrix implant.tw.  
 Glycosaminoglycans/

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(Glycosaminogly\* adj4 scaffold\*).tw.  
 or/15-20  
 11 and 14 and 21  
 Ologen.tw.  
 Ex-Press.tw.  
 E-PFTE.tw.  
 GelFilm.tw.  
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 limit 30 to english language  
 31 limit 30 to -20220831

## Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the [summary of the key evidence](#). It is by no means an exhaustive list of potentially relevant studies.

### Additional papers identified

| Article  | Number of patients/followup   | Direction of conclusions  | Reasons for non-inclusion in summary of key evidence section |
|--|---|---|--|
| Angmo D, Falera D, Singh A, et al. (2014) Outcomes of combined subconjunctival with subscleral ologen implant in glaucoma filtration surgery. Investigative Ophthalmology & Visual Science. 55, 3165 | 15 eyes had trabeculectomy with Ologen implant both subsclerally and subconjunctivally (double Ologen) Follow-up 12 months. | Trabeculectomy with implantation of biodegradable collagen implant both subsclerally and subconjunctivally appears to offer encouraging short-term results in terms of IOP control in eyes with primary adult glaucoma. | Double implant used in procedure                             |
| Cillino S, Pace FD, Cillino G et al. (2011) Biodegradable collagen matrix  | Parallel group RCT N=40 (40 eyes) patients with   | Results suggest that OLO implant could be a new, safe, and effective alternative to MMC,  | Study included in systematic review added to the             |

IP overview: Trabeculectomy with a biodegradable collagen matrix implant for glaucoma

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| <p>implant vs mitomycin-C as an adjuvant in trabeculectomy: a 24-months, randomized clinical trial. Eye; 25 (12):1598-606.</p>   | <p>uncontrolled IOP, POAG, PEXG, trabeculectomy + Ologen (n=20) versus trabeculectomy (n=20) follow-up 24 months</p>  | <p>with similar long-term success rate.</p>  | <p>summary of evidence.</p>  |
| <p>Cillino S, Casuccio A, Pace FD et al. (2016) Biodegradable collagen matrix implant versus mitomycin-C in trabeculectomy: five-year follow-up. BMC Ophthalmology (2016) 16:24</p>                                | <p>RCT<br/>40 patients with glaucoma (40 eyes)<br/>trabeculectomy with MMC (n=20) or Ologen (n=20)<br/>follow-up 5 years</p>  | <p>Our extended follow-up results confirm that biodegradable collagen implant yields efficacy and long-term success rates quite similar to MMC, with at least equivalent safety.</p>   | <p>Study included in systematic review added to the summary of evidence.</p> |
| <p>Elbably A, Rezq H, EIDakkak M et al. (2021) Efficacy and Safety of Sutureless Trabeculectomy with Using Porous Collagen (Ologen) in Management of Glaucoma Patients. Korean J Ophthalmol 2021;35(4):304-310</p> | <p>Prospective cohort study<br/>N=25 eyes from 24 patients with advanced glaucoma (primary or secondary)<br/>trabeculectomy with the Ologen<br/>Follow-up 18 months</p>   | <p>This technique can provide safety, effectiveness and short learning curve for ophthalmology trainees with lower incidence of perioperative and postoperative complications.</p>   | <p>Small pilot study. Larger studies included in summary of evidence.</p>    |
| <p>El-Sayyad F, El-Saied HMA, Abdelhakim MASE. (2017) Trabeculectomy with ologen versus mitomycin c in juvenile open-angle glaucoma: a 1-year study. Ophthalmic Res; 57:230–8.</p>                                 | <p>Prospective comparative study<br/>20 patients (40 eyes) with medically uncontrolled juvenile OAG, Trabeculectomy with Ologen (20 eyes) versus trabeculectomy with MMC (20 eyes).<br/>Follow-up 12 months</p> | <p>biodegradable collagen implant resulted in a lower long-term postoperative IOP, a better bleb morphology, and fewer complications. Our results suggest that biodegradable collagen implant may be a useful alternative to MMC in juvenile OAG</p> | <p>Study included in systematic review added to the summary of evidence.</p> |

IP overview: Trabeculectomy with a biodegradable collagen matrix implant for glaucoma



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| <p>Elwehidy AS, Bayoumi NHL, El Nokrashy A et al. (2022) Long-term outcomes of trabeculectomy with ologen implant versus combined viscotrabeculotomy-synechiolysis in uncontrolled uveitic glaucoma. <i>Int Ophthalmol</i> 42, 411–421.</p> | <p>Retrospective review<br/>N=47 patients with uncontrolled uveitic glaucoma (UG)<br/>Trabeculectomy with Ologen (n=23 eyes) versus combined viscotrabeculotomy-synechiolysis (VTS, n=24 eyes)<br/>Follow-up 48 months.</p>                       | <p>Trabeculectomy with biodegradable collagen implant and viscotrabeculotomy-synechiolysis were equally effective in lowering IOP in uncontrolled UG. There was no statistically significant difference in the success rates between the 2 procedures.</p> | <p>Secondary glaucoma not POAG.</p>  |
| <p>Marey HM, Mandour SS, Ellakwa AF. (2013) Subscleral trabeculectomy with mitomycin-C versus Ologen for treatment of glaucoma. <i>Journal of Ocular Pharmacology and Therapeutics</i>; 29(3):330-4.</p>                                    | <p>parallel-group RCT<br/>n=60 patients (60 eyes)<br/>indications POAG, ACG, PEXG, uveitic glaucoma, uncontrolled pseudophakic glaucoma<br/>trabeculectomy + Ologen (30 eyes) versus trabeculectomy + MMC (n=30 eyes)<br/>follow-up 12 months</p> | <p>The use of the biodegradable collagen implant in sub-scleral trabeculectomy is comparable to the use of MMC with advantage of avoiding the potentially dangerous complications related to MMC use in the early (12 months) follow-up period.</p>        | <p>Study included in systematic review added to the summary of evidence.</p> |
| <p>Maheshwari D, Gupta A, Ramakrishnan R (2012). Comparative study of MMC augmented trabeculectomy vs an Ologen implant in open angle glaucoma. <i>Glaucoma-II Free Papers</i>. 363-5.</p>  | <p>parallel-group RCT<br/>n=40 patients with OAG (40 eyes)<br/>trabeculectomy + Ologen (n=20) versus trabeculectomy + MMC (n=20)<br/>follow-up 12 months</p>  | <p>Study reveals that trabeculectomy with implantation of a biodegradable collagen implant is a safe method without any serious complications but IOP lowering was more with trabeculectomy with MMC.</p>  | <p>Study included in systematic review added to the summary of evidence.</p> |
| <p>He M, Wang W, Zhang X et al. (2014) Ologen</p>   | <p>Systematic Review and Meta-Analysis<br/>7 RCTs (227 eyes)</p>  | <p>The biodegradable collagen implant is comparable with</p>   | <p>More comprehensive and recent reviews</p>                                 |

IP overview: Trabeculectomy with a biodegradable collagen matrix implant for glaucoma

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| <p>Implant versus Mitomycin C for Trabeculectomy: A Systematic Review and Meta-Analysis. PLoS ONE 9(1): e85782.</p>  |  | <p>MMC for trabeculectomy in IOP-lowering efficacy, reduction in the number of glaucoma medications, success rates, and tolerability. The results should be interpreted cautiously since relevant evidence is still limited.</p>           | <p>added to the summary of evidence.</p>   |
| <p>Mitra A, Krishnan R, Kadar MA et al. (2012) To compare the outcome, complications and management of complications of trabeculectomy with Ologen implant versus trabeculectomy with MMC. Glaucoma-II Free Papers. 330-5.</p> | <p>Parallel group RCT<br/>N=64 (64 eyes) patients with uncontrolled OAG trabeculectomy + Ologen (n=28) versus trabeculectomy + MMC (n=36)<br/>follow-up 6 months</p> |  | <p>Study included in systematic review added to the summary of evidence.</p>     |
| <p>Papaconstantinou D, Georgalas I, Karmiris E et al. (2010) Trabeculectomy with OloGen versus trabeculectomy for the treatment of glaucoma: a pilot study. Acta Ophthalmologica; 88(1):80-5.</p>                              | <p>Parallel group RCT<br/>N=40 (40 eyes) patients with glaucoma trabeculectomy + Ologen (n=20) versus trabeculectomy (n=20)<br/>follow-up 6 months</p>               | <p>In this pilot study, trabeculectomy with biodegradable collagen implant does not offer any significant advantages compared with trabeculectomy alone. There were no statistical differences between the 2 groups for complications.</p> | <p>Study included in systematic review added to the summary of evidence.</p>     |
| <p>Perez CI, Mellado F, Jones A et al. (2017) Trabeculectomy combined with collagen matrix implant (Ologen). J</p>   | <p>Retrospective review<br/>N=65 eyes of 58 patients with mainly POAG had trabeculectomy</p>   | <p>Trabeculectomy surgeries with biodegradable collagen implant performed by the same surgeon were effective in</p>  | <p>Larger studies with longer follow-up included in the summary of evidence.</p> |

IP overview: Trabeculectomy with a biodegradable collagen matrix implant for glaucoma

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| Glaucoma; 26:54–58  | with Ologen implant.<br>Average follow-up 14.2 months.  | lowering IOP with a low complication rate at mid-term follow-up.  |   |
| Ji Q, Qi B, Liu L, et al. (2015) Efficacy and safety of Ologen implant versus mitomycin C in primary trabeculectomy: A meta-analysis of randomized clinical trials. J Glaucoma 2015;24:e88–e94.                         | Systematic review and meta-analysis 6 studies (n=224) trabeculectomy with Ologen implant versus trabeculectomy with mitomycin C (MMC)                         | Trabeculectomy with a biodegradable collagen implant is comparable to the use of MMC with a similar long-term success rate. However, it does not seem to offer significant advantages of avoiding the potential complications related to MMC. | More comprehensive reviews added to the summary of evidence.          |
| Rosentreter A, Schild AM, Jordan JF et al. (2010) A prospective randomised trial of trabeculectomy using mitomycin C vs an Ologen implant in open angle glaucoma. Eye; 24(9):1449-57.                                   | Parallel group RCT N=20 (20 eyes) patients with uncontrolled IOP, OAG<br>trabeculectomy + Ologen (n=10) versus trabeculectomy +MMC (n=10) follow-up 12 months | The complete success rate using trabeculectomy with the biodegradable collagen implant is lower than that achieved by trabeculectomy with MMC. However, the bleb morphology caused more problems in the MMC group.                            | Study included in systematic review added to the summary of evidence. |
| Rosentreter A, Gaki S, Cursiefen C et al. (2014) Trabeculectomy using mitomycin C versus an atelocollagen implant: clinical results of a randomized trial and histopathologic findings. Ophthalmologica; 231(3):133-40. | Parallel group RCT N=30 (30 eyes) patients with uncontrolled IOP, OAG<br>trabeculectomy + Ologen (n=10) versus trabeculectomy +MMC (n=10) follow-up 6 months  | With the atelocollagen-glycosaminoglycan matrix OLO it was not possible to reach the surgical success rate and pressure reduction achieved in the MMC group. The surgical success rate 12 months after surgery was 93.3% in the MMC           | Study included in systematic review added to the summary of evidence. |

IP overview: Trabeculectomy with a biodegradable collagen matrix implant for glaucoma

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|   |   | group and 40% in the OLO group ( $p = 0.01$ )   |   |
| Sarker D, Kumer B, Sadiq M. (2019) Outcome of trabeculectomy with Ologen versus Mitomycin C: A comparative prospective study in Bangladesh. European journal of ophthalmology. 29 (2), 183-188. | RCT<br>Patients with primary glaucoma<br>Trabeculectomy with Ologen (52 eyes) versus MMC (55 eyes).<br>Follow-up 12 months  | Trabeculectomy with biodegradable collagen implant appears to be safe and successful as trabeculectomy augmented with MMC, with no reported adverse reaction to biodegradable collagen implant .  | 22 patients with juvenile glaucoma were included.                     |
| Senthil S, Rao HL, Babu JG et al. (2013) Comparison of outcomes of trabeculectomy with mitomycin C vs. Ologen implant in primary glaucoma. Indian Journal of Ophthalmology; 61(7):338-42.       | Parallel group RCT<br>N=33 (39 eyes) patients with uncontrolled POAG, PACG<br>trabeculectomy + Ologen (n=19) versus trabeculectomy +MMC (n=20)<br>follow-up 24 months   | The success of trabeculectomy and complications were similar in both biodegradable collagen implant and MMC groups at the end of 6 months. The incidences of early post-operative complications were similar in the 2 groups, except hyphaema, which was significantly more in biodegradable collagen implant group ( $P = 0.02$ ). | Study included in systematic review added to the summary of evidence. |
| Shalaby HS, Hashem NH. (2021) Trabeculectomy with OloGen versus Mitomycin C for the Treatment of Silicone Oil-Induced Glaucoma. Klin Monatsbl Augenheilkd<br>DOI 10.1055/a-1500-8230            | RCT<br>40 eyes of 40 patients with silicone oil-induced glaucoma, trabeculectomy with OloGen (20 eyes) versus trabeculectomy with MMC (20 eyes).<br>Follow-up 24 months | biodegradable collagen implant lowers IOP to a similar extent as MMC when combined with trabeculectomy for the treatment of silicone oil-induced glaucoma, and with comparable success rates. The rate of postoperative   | Not POAG  |

IP overview: Trabeculectomy with a biodegradable collagen matrix implant for glaucoma

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|  |  | complications is similar for biodegradable collagen implantation and MMC.  |  |
| Singh K, Bhattacharyya M, Mutreja A et al. (2018) Trabeculectomy with subconjunctival collagen implant in Indian eyes: Long-term results. Indian J Ophthalmol; 66:1429-34.   | Case series<br>N=30 eyes of 28 patients with glaucoma had trabeculectomy with Ologen implant<br>Median follow-up 36 months   | biodegradable collagen implant -augmented trabeculectomy is effective in controlling IOP over a long-term follow up from minimal 3 to maximal 7 years (in 8 eyes). No untoward events jeopardizing bleb safety were noted at any time. | Larger studies included in table 2.  |
| Shihadeh W, Massad I, Khader Y et al. (2017) Comparison of the outcomes of trabeculectomy with 5-fluorouracil versus Ologen implant in primary open-angle glaucoma. Ophthalmic Res 2017;58:94–98                       | Retrospective review<br>N=47 patients (58 eyes) with POAG underwent trabeculectomy using either Ologen (n=28 eyes) or 5-FU (n=30)<br>Follow-up 12 months                         | The efficacy and safety of trabeculectomy with 5-FU was similar to that with biodegradable collagen implant . Further studies with a larger number of patients and longer follow-up periods are needed.                                | Larger studies included in table 2.  |
| Tanna AP, Rademaker AW, de Moares G et al. (2016) Collagen matrix vs mitomycin-C in trabeculectomy and combined phacoemulsification and trabeculectomy: a randomized controlled trial. BMC Ophthalmology (2016) 16:217 | RCT<br>N=94 (95 eyes) patients with mainly uncontrolled POAG.<br>Collagen matrix (45 eyes) versus MCC (48 eyes) in trabeculectomy (85 eyes) and combined phacoemulsification and | Use of the collagen implant at the time of trabeculectomy or combined phacoemulsification and trabeculectomy is associated with similar complete success rates compared to adjunctive MMC; however, the risk of persistent hypotony    | Few patients had combined phacoemulsification and trabeculectomy in both groups and outcomes were not reported separately. |

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|  | trabeculectomy (10 eyes).<br>Follow-up 24 months   | is higher with MMC.  |   |
| Tanuj D, Amit S, M Saptorshi M et al. (2013) Combined subconjunctival and subscleral ologen implant insertion in trabeculectomy. Eye, 27, 889–897.   | Case report<br>Trabeculectomy using Ologen implant under the subscleral flap and subconjunctival area  | By placing the implant subsclerally, an additional advantage of lesser subscleral fibrosis might be obtained with better control of IOP.   | Larger studies included in table 2.                                   |
| Yuan F, Li L, Chen X. (2015) Biodegradable 3D-porous collagen matrix (Ologen) compared with mitomycin C for treatment of primary open-angle glaucoma: results at 5 years. J Ophthalmol; Article ID 637537, 7 pages | Parallel group RCT<br>N=63 eyes of 44 patients with POAG trabeculectomy with Ologen (n=21, 31 eyes) versus trabeculectomy + MMC (N=23, 32 eyes)<br>Follow-up 5 years | biodegradable collagen implant provides higher rates of surgical success compared with mitomycin C for patients with POAG undergoing trabeculectomy. It is safe, simple, and effective therapeutic approach for treating primary open-angle glaucoma.  | Study included in systematic review added to the summary of evidence. |
| Zeleftsky JR, Hsu WC and Ritch R(2008) Biodegradable collagen matrix implant for trabeculectomy. Expert Rev. Ophthalmol. 3(6), 613–617.  | Review   | Preliminary studies have demonstrated that the biodegradable collagen matrix is effective for use in trabeculectomy, although it may be associated with an increased risk of early postoperative hypotony. Future randomized, controlled trials should help determine its place in glaucoma surgery. | Review  |

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