**Factors influencing XEN gelatin stent outcomes over 24-month follow-up**

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**Abstract**

**Purpose**

Gelatin stent surgery creates a drainage pathway for aqueous humour into the subconjunctival space similar to trabeculectomy. The aims of this study were to determine whether risk factors for trabeculectomy failure similarly influence gelatin stent outcomes and to identify surgical factors which may optimise surgical success.

**Design**

A retrospective, observational study was performed at a single centre in Perth, Western Australia over 24 months.

**Participants**

Two-hundred and seventy-nine eyes of 222 patients over the age of 18 years underwent XEN45 stent surgery with a majority primary diagnosis of primary open angle glaucoma (POAG).

**Methods**

Data was collected and extracted from a specialised database using Microsoft Access. R (version 4.0.3) statistical software was used for data analysis. Linear mixed-effects models, unpaired t-test and Chi-Square test were used to identify significant relationships between explanatory and response variables.

**Main Outcome Measures**

The primary outcome was IOP reduction and secondary outcomes were number of bleb needlings, number of topical glaucoma medications used and complications.

**Results**

Prior trabeculectomy (p = 0.9477) and prior cataract surgery (p = 0.9030) were found to not be associated with IOP reduction. Glaucoma subgroups that experienced a significantly different IOP reduction compared to primary open angle glaucoma (POAG) were congenital glaucoma with anomalies (GCA) with lesser IOP reduction by mean 7.6 mm Hg (p < 0.001) and pseudoexfoliative glaucoma (PXG) with greater IOP reduction by mean 2.6 mm Hg (p = 0.0321). We found that 37.5 μg MMC with depot steroids (p = 0.0020, c = 4.7590 mm Hg), or without depot steroids (p = 0.0055, c = 3.8103 mm Hg) and 5 μg MMC with depot steroids (p = 0.0015, c = 4.5605 mm Hg) had significantly greater IOP reduction than surgery without MMC.

**Conclusions**

Risk factors associated with increased rates of trabeculectomy failure don’t seem to apply to gelatin stent surgery. Stent surgery may be considered following failed trabeculectomy or cataract surgery. A 5 μg dose of MMC with depot steroid intraoperatively may be considered as this combination produces a significant IOP reduction comparable to the 37.5 μg dose of MMC with or without depot steroid.

**Introduction**

Stent surgery is a novel method of creating a channel between the anterior chamber and subconjunctival space similar to trabeculectomy without conjunctival dissection. Our study examines medium term outcomes of a particular cross-linked gelatin stent commercialised as XEN (Allergan, Inc., Irvine, CA). Our aims were to establish whether risk factors known to influence trabeculectomy survival similarly applied to gelatin stent outcomes and to identify surgical variables which may improve surgical success.

Trabeculectomy has long been considered the gold standard in glaucoma surgery since it was described by Cairns over 50 years ago.1 The survival rate of trabeculectomy after 20 years is approximately 60% without topical medication and 90% with topical medication.2 Published studies report up to 20 to 40% of patients fail to maintain their target intraocular pressure (IOP) with trabeculectomy alone within one year of surgery resulting in the recommencement of medical therapy, additional interventions or further surgery.3-5 It is well known that there are several major risk factors for early failure of trabeculectomy which include age, ethnicity, type of glaucoma, previous trabeculectomy or cataract surgery and number of preoperative topical medications used. Patients with primary open angle glaucoma (POAG) tend to have better outcomes with trabeculectomy compared to those with pseudoexfoliative (PXG) or uveitic glaucoma.2 Repeat trabeculectomies generally have worse survival than initial trabeculectomies.2 Caucasian eyes tend to have greater IOP reduction after trabeculectomy than non-Caucasian eyes.6

Trabeculectomy surgery involves creating an artificial route for aqueous humour to flow into the subconjunctival space to achieve a lower IOP.7 Gelatin stents create a channel allowing subconjunctival filtration. We were interested in examining the effects of key variables on gelatin stent outcomes. The primary endpoint of this study was to examine the effect of key explanatory variables on IOP reduction across a medium-term follow up period of 24 months. Secondary endpoints included number of postoperative glaucoma medications, rate of needlings with 5-fluorouracil (5-FU) and postoperative complications.

**Methods**

This work conformed to the Declaration of Helsinki and was conducted with approvals from the Human Ethics Committee of the University of Western Australia (Ref: RA/4/20/5284).

***Study Design***

This was a retrospective, non-randomised clinical study. It was conducted at a single centre, the Lions Eye Institute in Perth, Western Australia. All gelatin stent surgeries were performed by a single surgeon. Clinical information was gathered from a specialised database created using Microsoft Access (Microsoft Corporation, Redmond, WA, United States) to record clinical information of patients who underwent gelatin stent surgery. The database was stored on a secured, password protected server which could only be accessed by study investigators. Recorded baseline data included patient demographics such as age, sex and ethnicity, primary diagnosis and previous ocular surgery. A unique database form was created to document specific information relating to gelatin stent surgery. This included date of surgery, site of entry through the angle, bleb extent, dose of antimitotic used intraoperatively and use of depot steroid. Data was extracted from the database for analysis and results were analysed up to 24 months after surgery.

Inclusion criteria was any patient over the age of 18 years with primary or secondary (pseudoexfoliative or pigmentary) open-angle glaucoma who had gelatin stent surgery. There was no baseline IOP cut-off for inclusion. Patients with a prior history of glaucoma filtration surgery (e.g. trabeculectomy) or cataract surgery were included. Patients with neovascular glaucoma were excluded.

All patients were diagnosed with glaucomatous optic neuropathy by an ophthalmologist subspecialising in glaucoma following a comprehensive evaluation with slit lamp examination, gonioscopy, IOP measurement by Goldmann applanation tonometry, corneal pachymetry, standardised automated perimetry (24-4 Humphrey field analyser) and optical coherence tomography (OCT). During preoperative assessment, patients were required to have healthy, mobile conjunctiva at the anticipated filtration bleb site and an open angle with visible trabecular meshwork to allow gelatin stent implantation.

***Surgical Technique***

All surgeries were performed by a single surgeon using a standardised technique in an operating theatre. Surgical implantation was routinely performed under local anaesthesia with a combination of oxybuprocaine hydrochloride 0.4% w/v and subconjunctival lignocaine 2% injection. Patients received either 0 μg, 5 μg (low dose) or 37.5 μg (high dose) of mitomycin C (MMC) intraoperatively. MMC dose was determined based on clinical factors such as prior glaucoma surgery with previous administration of antimitotic medication. MMC was injected subconjunctivally at the bleb site with a 30-gauge needle prior to gelatin stent implantation and directed posteriorly away from the limbus.

A Morgan – Yu (ASICO, Westmont, IL), speculum was used to stabilise the eye by fixing the inferotemporal limbus to an adjustable arm of the speculum with three 6-0 silk sutures to provide counter-traction during implantation. An inferotemporal clear corneal incision was made to introduce the needle of the preloaded handheld device into the anterior chamber. The position of this incision allowed the XEN45 gelatin stent to be placed superonasally. This resulted in placement of gelatin stents around the limbus at 1 and 2 o’clock in right eyes and 10 and 11 o’clock in left eyes. In a small number of eyes, superior placement was precluded due to subconjunctival scarring from previous ocular surgery or presence of an implant (e.g. scleral buckle) resulting in inferior placement of the gelatin stent. Sodium hyaluronate (ProVisc®) was injected to deepen the anterior chamber and improve visualisation of the angle. The needle was passed across the anterior chamber and engaged the angle aiming for trabecular meshwork. The needle was advanced through the sclera until the needle tip emerged approximately 3 mm posterior to the limbus in the subconjunctival space. The gelatin stent was carefully delivered with automatic retraction of the needle. A single-use mirrored goniolens was used to visualise the anterior chamber angle through the operating microscope while advancing the introducer needle into and through the angle. The silk sutures were removed as well as the ProVisc® from the anterior chamber. The clear corneal incision was hydrated to achieve wound closure. Some patients were given subconjunctival depot steroid (triamcinolone 40mg/ml, Aspen Pharma, St Leonards, Australia) into the inferior fornix. A single dose of chloramphenicol ointment was administered at the conclusion of surgery and a clear plastic shield was placed for protection.

***Postoperative Management***

Patients were instructed to cease all preoperative glaucoma medication in the operated eye on the day of surgery. Patients were routinely evaluated postoperatively at day 1; 1 and 4 weeks; and 2, 3, 6, 9 and 12 months. Additional postoperative reviews were conducted based on clinical need. A standard postoperative eye drop regime was commenced the day after surgery. This consisted of prednisolone acetate (1%)/phenylephrine hydrochloride (0.12%) (Prednefrin® Forte) 6 times a day and ketorolac tromethamine 0.5% (Acular®) and chloramphenicol 0.5% (Chlorsig®) 4 times a day. Chlorsig® was ceased 2 weeks after surgery. Prednefrin® Forte was reduced to 4 times a day after 1 month and continued with Acular® four times a day for 3 months postoperatively. Patients who had a history of cataract surgery in the operated eye were commenced on fluorometholone 0.1% eye drops once daily indefinitely after the 3-month postoperative period.

Bleb needling was performed at the discretion of the surgeon when clinical signs of bleb failure were observed such as elevated IOP, encapsulation, a flat bleb or fibrosis surrounding the subconjunctival portion of the gelatin stent. There was no specific minimum or maximum time period postoperatively for needling to be considered. Needling was performed at the slit lamp under topical local anaesthetic with oxybuprocaine hydrochloride 0.4% w/v using a 26-gauge needling to dissect fibrous tissue at the bleb site followed by the injection of 5-FU (50 mg/mL). Post-needling, patients were prescribed prednisolone acetate (1%)/phenylephrine hydrochloride (0.12%) and chloramphenicol 0.5% (Chlorsig®) 4 times a day for 2 weeks.

***Data Collection***

Data was collected and entered into the database prospectively at time of clinical review and retrospectively from chart reviews to complete the dataset. Patients underwent routine follow-up as clinically appropriate and their IOPs were recorded at each clinical visit. IOP was measured by Goldmann applanation tonometry. Preoperative IOP was defined as the IOP recorded within 40 days prior to gelatin stent surgery. If there were two or more visits in this period, an average of the IOP measurements was calculated and taken to be the preoperative IOP. There was no medication washout period prior to surgery and patients remained on their regular glaucoma medication until the day of surgery.

Ethnicity was recorded on the initial visit under patient demographic information. Analysis of ethnicity was performed on two groups, Caucasians and non-Caucasians, due to the small proportion (14.4%) of non-Caucasian ethnicities in total included in our cohort. Prior ocular surgery was recorded based on history and examination. Primary diagnosis was determined at initial visit and groups included were POAG, ocular hypertension, angle closure glaucoma (ACG), low tension glaucoma, pseudoexfoliative glaucoma (PXG), pigmentary glaucoma, uveitic glaucoma, secondary traumatic glaucoma, juvenile glaucoma, congenital glaucoma with anomalies, congenital glaucoma without anomalies, aniridia and ICE syndrome. Gonioscopy was performed at the slit lamp to determine the site of entry of the gelatin stent through the iridocorneal angle. This was recorded as through ciliary body, scleral spur, trabecular meshwork, Schwalbe’s lines or cornea. Bleb extent was recorded by slit lamp examination and documented as less than 1, 1 to 2, 2 to 4 or more than 4 clock hours around the limbus.

ACG was defined as eyes who had primary angle closure with iris to trabecular meshwork contact with or without synechiae formation and who had laser iridotomy or cataract extraction with resultant significant angle opening. Gonioscopy was performed on all subjects to confirm partial or total angle opening with no signs of ciliary block to ensure these eyes were suitable for gelatin stent implantation. The site of gelatin stent insertion was always through a region of angle that was open.

5-FU needling was recorded under procedures in the database at the time of needling. IOP-lowering medications were simultaneously recorded and prescribed using the database software. Any change in prescribed medication would be updated on the database and reflected in the data collected. Postoperative complications were recorded on the database when observed during follow-up.

***Statistical Analysis***

Data was extracted from the database and converted to a CSV spreadsheet and imported into R (version 4.0.3) statistical software for data analysis. IOP trends were analysed by calculating the mean, standard deviation, median and range values. Results were described as means and standard deviations as well as counts and percentages. A *P*-value of < 0.05 was considered statistically significant.

Linear mixed-effects models were applied to analyse the data to identify significant relationships between explanatory and response variables. The response variable was IOP reduction defined as pre-operative IOP minus post-operative IOP. A Poisson distributed, zero inflated generalised linear mixed model was also used to analyse the non discrete uniformity (leftward truncation of results with all results being greater than or equal to zero) of medication usage and 5-FU needling post gelatin stent surgery. Multiple measurements in both models were taken from each eye over time and from one or both eyes of the same patient. To account for correlation between multiple measures of the same eye and also between both eyes when this occurred, we incorporated random factors of eye nested within each patient identity.

The explanatory variables in our linear mixed-effects models were: sex, prior trabeculectomy surgery, prior cataract surgery, age, total number of 5-FU needlings post gelatin stent surgery, site of XEN insertion, ethnicity, mitomycin C, depot steroids, medication usage pre gelatin stent surgery, primary diagnosis of glaucoma, time after surgery, baseline IOP, and medication usage post gelatin stent surgery.

Unpaired t-test was performed to analyse the association between bleb extent and IOP reduction. Bleb extent was not included into the linear mixed model due to limited amount of data available at varying time points. Chi-Square test was performed to analyse the frequency of 5-FU needling postoperatively and also the frequency of complications in various subgroups.

We used two survival and qualified survival definitions to allow for comparison with existing studies. One was Caronia’s definition of survival, which was defined as having IOP between 4 mm Hg and 22 mm Hg with a 20% reduction from preoperative IOP without glaucoma medications at 2 years.8 Caronia’s qualified survival was the same as above but also allowing for glaucoma medication use.8 We also used Schlenker’s definition of survival, which was defined as having IOP between 6 mm Hg and 17 mm Hg at 2 years without using glaucoma medications in the first month but with or without glaucoma medications thereafter.6 Schlenker’s qualified survival was defined as having IOP between 6 mm Hg and 21 mm Hg with or without glaucoma medications.6

**Results**

A total of 279 eyes of 222 patients who underwent gelatin stent implantation were analysed over a 24-month period. The mean age of patients was 70.9 (± 11.9) years. Our dataset included a higher proportion of female eyes (62.0%) and predominance of Caucasian eyes (85.6%, n = 190). In addition, our cohort included patients of East Asian (9.5%, n = 21), South Asian (4.0%, n = 9) and African (0.9%, n = 2) descent. The majority of eyes were diagnosed with POAG (77.4%, n = 216), ocular hypertension (4.3%, n = 12), ACG (3.9%, n = 11), low tension glaucoma (3.6%, n = 10), PXG (2.5%, n = 7), juvenile glaucoma (2.2%, n = 6), congenital glaucoma with anomalies (2.2%, n = 6), pigmentary glaucoma (1.0%, n = 3), uveitic glaucoma (1.0%, n = 3), congenital glaucoma without anomalies (0.7%, n = 2), aniridia (0.4%, n = 1), ICE syndrome (0.4%, n = 1) and secondary traumatic glaucoma (0.4%, n = 1). Forty-seven (16.8%) eyes had undergone prior trabeculectomy and 66 (23.7%) had undergone prior cataract surgery.

Number of medications used across the entire cohort was reduced from 2.75 (± 1.01, n = 182) preoperatively to 0.83 (± 1.08, n = 129) at 12 months after gelatin stent surgery. The number of medications used at 12-month follow-up were similar between the high (0.66 ± 0.97) and low (0.89 ± 1.17) dose MMC groups.

Baseline IOP for eyes on 0, 1, 2, 3 and 4 medications preoperatively were 22.8 (± 8.2) mmHg, 18.4 (± 4.6) mmHg, 19.8 (± 6.3) mmHg, 20.9 (± 6.1) mmHg and 21.8 (± 6.0) mmHg, respectively. At 12 months following gelatin stent surgery, IOP was 19.2 (± 6.8) mmHg, 13.9 (± 2.7) mmHg, 13.4 (± 3.6) mmHg, 14.2 (± 3.3) mmHg and 14.5 (± 4.0) mmHg, respectively. At 24 months after surgery, IOP was 15.0 (± 2.8) mmHg, 17.0 (± 6.1) mmHg, 14.1 (± 3.6) mmHg, 14.7 (± 4.5) mmHg and 13.6 (± 3.2) mmHg, respectively.

The gelatin stent entry points analysed in this study were TM Scleral Spur (2.4%, n = 5), TM (46.6%, n = 96), Schwalbes Line (9.2%, n = 19), Cornea (1.5%, n = 3), Scleral Spur (26.7%, n = 55) and Ciliary Body (13.6%, n = 28) (Figure 1).

Preoperative medication use was lowest in eyes without prior ocular surgery (2.66 ± 1.03) compared to eyes having undergone cataract surgery (2.78 ± 1.11) or trabeculectomy (3.0 ± 0.82). Postoperative medication use was also lowest in eyes without prior ocular surgery at 12 (0.49 ± 0.88 in eyes without prior surgery, 0.78 ± 1.05 prior trabeculectomy, 0.76 ± 1.06 prior cataract surgery) and 24 months (0.58 ± 0.93 no prior surgery, 0.67 ± 0.93 prior trabeculectomy, 0.78 ± 1.09 prior cataract surgery) (Figure 2).

Eighty-two subjects had gelatin stent follow up visits for 2 years or more with a 29% survival using Caronia’s definition of survival and an 84% survival rate using Schlenker’s definition of survival. The eighty-two gelatin stent implants that reached the two year point of the study were then analysed with the definitions of qualified survival. A 65% qualified survival rate was found using Caronia’s definition while an 89% qualified survival rate was found using Schlenker’s.

A univariate analysis was performed to analyse the association between bleb extent and IOP reduction. This revealed that greater bleb extent was associated with greater IOP reduction over 12 months postoperatively (p < 0.001, n = 74). However, this association was not demonstrated at 24 months (p = 0.12) which may have been attributed to a smaller sample size (n = 39).

One hundred and seventeen (41.9%) eyes required at least one bleb needling with 5-FU within the first 12 months. In these eyes, the mean number of needlings were 1.75 (± 1.2). Thirty-one (47.7%) eyes who had prior cataract surgery (n = 66) and 29 (61.7%) eyes who had prior trabeculectomy (n = 47) required at least one needling during the first 12 months after surgery. The mean needling rate in these eyes were 2.13 (± 1.31) in the cataract surgery group and 2.17 (± 1.36) in the trabeculectomy group.

We performed a linear mixed model analysis and found the following factors were not significantly associated with IOP reduction; age (p = 0.8576), sex (p = 0.9952), ethnicity (p = 0.4546), prior trabeculectomy (p = 0.9477) (Figure 3), prior cataract surgery (p = 0.9030) (Figure 4), site of entry (all p > 0.6958) and total number of postoperative 5-FU needlings (p = 0.7174). The significant factors that were associated with greater IOP reduction were 37.5 μg dose of MMC (p = 0.0224, c = 1.2459 mm Hg / MMC), depot steroids (p = 0.0021, c = 1.8753 mm Hg), number of preoperative medications (p = 0.0421), time after surgery (p < 0.001, c = 0.5968 mm Hg / year) and baseline IOP (p < 0.001, c = 0.8225 mm Hg / mm Hg). Medication usage post gelatin stent surgery (p < 0.001, c = -2.0025) was found to be associated with lesser IOP reduction. While the only glaucoma subgroups that experienced a significantly different IOP reduction compared to POAG were congenital glaucoma with anomalies with lesser IOP reduction by mean 7.6 mm Hg (p < 0.001) and PXG with greater IOP reduction by mean 2.6 mm Hg (p = 0.0321) (Figure 5).

We noted a correlation (r = 0.706) between MMC and depot steroids. In order to understand which of MMC or depot steroids were exerting a significant influence on IOP reduction, we constructed a further linear mixed model to analyse the interaction between the two factors. We found that 37.5 μg MMC with depot steroids (p = 0.0020, c = 4.7590 mm Hg), or without depot steroids (p = 0.0055, c = 3.8103 mm Hg) and 5 μg MMC with depot steroids (p = 0.0015, c = 4.5605 mm Hg) had significantly greater IOP reduction than surgery without MMC. Using 5 μg MMC without depot steroids did not result in greater IOP reduction compared to surgery without MMC (p = 0.3094). There was no significant difference in IOP reduction between 37.5 μg MMC with or without depot steroid, or 5 μg MMC with depot steroid (all p > 0.1625) (Figure 6).

A Poisson distributed generalised linear mixed model was used to analyse the effect of gelatin stent surgery on medication usage and 5-FU needling post gelatin stent surgery. We found that prior trabeculectomy (p = 0.3947) and prior cataract surgery (p = 0.6033) were not associated with differing postoperative medication usage. Time after surgery (p < 0.001, c = 0.1073 drugs / year) was associated with an increase in postoperative medication usage. Of note, IOP reduction (p < 0.001, c = -0.0495 drugs / mmHg) was associated with a reduction in medication usage.

The second Poisson model found that prior cataract (p = 0.7865), medication usage (p = 0.7879) and IOP reduction (p = 0.2715) were not associated with 5-FU needling after surgery. There appeared to be an increased use of 5FU needling in subjects who had undergone prior trabeculectomy (p = 0.0848, c = 0.5623 5-FU) but it did not reach formal statistical significance.

The complications and their frequency are described in table 1. A Chi-Square test was performed to analyse the association between explanatory variables and complication rates. Prior surgery (Table 1), dose of MMC, sex and ethnicity were found to not affect the rates of complications in our study (all p value > 0.15).

**Discussion**

We found gelatin stent induced pressure reduction over two years was generally not influenced by classical risk factors for trabeculectomy failure.2, 9, 10 Our results demonstrated no statistically significant effect of ethnicity on IOP. However, our dataset was biased as the majority of our cohort were Caucasian (86%). The number of South Asian, East Asian and African eyes were too small to conduct subgroup analyses with meaningful results thus, we were unable to make a confident statement that ethnicity has no effect on gelatin stent success rates.

Pseudoexfoliation (PXG) has generally been considered a risk factor for reduced bleb survival and trabeculectomy failure. The proposed mechanisms are thought to be related to increased expression of proinflammatory cytokines and interleukins in eyes with PXG and a greater disruption of the blood-aqueous barrier after surgery associated with increased inflammation promoting bleb fibrosis.11-14 Eyes with PXG tended to have greater IOP reduction (p = 0.0321) by a mean 2.6 mmHg than POAG which was surprising. However, only 7 eyes (2.5%) had PXG.

There have been mixed reports in the literature about the possible effect of the number and duration of topical glaucoma medication on bleb survival related to increased inflammatory mediators which have been found in the conjunctiva and Tenon’s capsule of eyes receiving long-term glaucoma medication.2, 15-17 We found a significant association between number of preoperative medications and IOP reduction. We identified a trend of greater IOP reduction in eyes which had been using more glaucoma medication prior to surgery. This is most likely explained by the higher preoperative IOP in these eyes as mean postoperative IOP among all groups were similar. However, this trend suggests that greater numbers of preoperative medications do not adversely affect IOP reduction after gelatin stent surgery. There was a small number of eyes (n = 9, 4.7%) that were not using any glaucoma medication preoperatively which demonstrated a lesser IOP reduction. We were unable to draw definitive conclusions from this result due to the small sample size.

Steroids are commonly used in the perioperative period to reduce excessive inflammation and modulate wound healing to maintain bleb function.18 We examined the effect of depot steroid in conjunction with two different doses of intraoperative MMC. Our data revealed a significant IOP reduction in eyes which received 37.5 μg MMC with or without depot steroid and 5 μg MMC with depot steroid compared to eyes which did not receive any MMC. The use of MMC produced a significant IOP reduction compared to no MMC. However, the additional benefit of depot steroid in combination with MMC seemed to only apply to the 5 μg group and did not augment IOP reduction in the 37.5 μg group compared to MMC alone. Furthermore, there was no difference in rates of complications among eyes receiving different doses of MMC. The use of a lower dose of MMC is desirable due to the risk of antimitotic toxicity and potential complications. Thus, 5 μg of MMC in combination with depot steroid may be a suitable intraoperative regime which may lead to effective IOP reduction.

The risk of failure is higher in repeat trabeculectomy compared to primary trabeculectomy with generally inferior IOP control and a higher number of medications required to maintain target IOP.2, 19-21 Furthermore, studies have suggested that pseudophakic patients have higher rates of trabeculectomy failure than phakic patients.6, 22, 23 Our results demonstrated that eyes with prior trabeculectomy or cataract surgery had comparable reduction in IOP and medication use compared with eyes with no prior surgery. 5 Fluorouracil needling rates were not significantly different between subjects who had undergone prior trabeculectomy or not. We can’t explain why there is an apparently reduced impact of prior trabeculectomy upon gelatin stent IOP reduction.

We investigated the effect of site of entry through the iridocorneal angle to determine whether this surgical variable could be modified to optimise outcomes. Our results revealed no significant effect of the site of entry on IOP. This is not an unexpected result as the function of the gelatin stent is to provide a channel between the anterior chamber and subconjunctival space by passing through the angle. It should be noted that very few stents were implanted through the cornea (n = 3) and so our results cannot be used to draw conclusions regarding corneal entry.Consistent with previous studies we found greater IOP reduction was associated with larger drainage bleb area following gelatin stent surgery.24, 25

The complication rates in our largely Caucasian cohort appear favourable compared to the UK national survey of trabeculectomy complications.26 We found hyphaema occurred in 15.8% of eyes post gelatin stent implantation compared to 24.6% of eyes post trabeculectomy, hypotony with shallow anterior chamber occurred in 7.2% of eyes post gelatin stent implantation compared to 23.9% of eyes post trabeculectomy and choroidal effusions occurred in 4.0% of eyes post gelatin stent implantation compared to 14.1% of eyes post trabeculectomy.26

One of the major limitations of this study was its retrospective, noncomparative design with small subgroup sample sizes particularly within the ethnicity and glaucoma subtype groups. This was a medium-term study with positive results in favour of reduced risk factors for gelatin stent failure however, these results may change over a longer follow up period as surgical failure tends to increase over time. Additionally, the total number of eyes that had completed 24 months follow-up was relatively small compared to those who had completed 12 months.

Our study highlights that many risk factors for trabeculectomy failure do not appear to influence gelatin stent outcomes over medium-term follow up. Demographic factors, including ethnicity, had no significant effect on gelatin stent success. A higher number of preoperative medications did not have an adverse impact on IOP reduction. Our PXG group performed well over the follow up period with comparable IOP control to the POAG group. A low dose of 5 μg of MMC with depot steroid intraoperatively may be considered as this combination produces a significant IOP reduction comparable to a higher dose of 37.5 μg of MMC with or without depot steroid. Importantly, prior trabeculectomy or cataract surgery were not associated with worse IOP outcomes or higher rates of complications. In eyes with previous ocular surgery, gelatin stent surgery may be considered as an effective surgical option prior to proceeding to a glaucoma drainage device.

**Tables**

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| --- | --- | --- | --- | --- |
| Complication | Overall(%) | No prior trab (%) | Prior trab (%) | *p*-value |
| Hyphaema | 15.8 | 16.5 | 11.9 | 0.46 |
| Dellen | 4.0 | 4.2 | 2.4 | 0.57 |
| Hypotony with shallow AC | 7.2 | 8.0 | 2.4 | 0.19 |
| Hypotony viscoelastic fill | 0.4 | 0.4 | 0 | 0.67 |
| Choroidal effusions | 4.0 | 4.6 | 0 | 0.15 |

Table 1. Complication rates between eyes having gelatin stent surgery with and without prior trabeculectomy.

**Figures**



Figure 1. Boxplot illustrating mean IOP among eyes based on gelatin stent site of entry following surgery over 24 months.



Figure 2. Boxplot illustrating number of medications used over 24 months in eyes with no prior surgery, prior trabeculectomy or prior cataract surgery.



Figure 3. Boxplot illustrating mean IOP between eyes with and without prior trabeculectomy following gelatin stent surgery over 24 months.



Figure 4. Boxplot illustrating mean IOP between eyes with and without prior cataract surgery following gelatin stent surgery over 24 months.



Figure 5. Boxplot illustrating mean IOP between eyes with primary open angle glaucoma (POAG), glaucoma with anomalies (GCA) and pseudoexfoliative glaucoma (PXG) following gelatin stent surgery over 24 months.

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Figure 6. Boxplot illustrating mean IOP of eyes receiving varying intraoperative doses of MMC during gelatin stent surgery over 24 months.

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