**CLINICAL STUDY** 

# Deep sclerectomy with mitomycin C in eyes with failed glaucoma surgery and pseudophakia

### Abstract

Purpose To report outcomes of deep sclerectomy (DS) with intraoperative mitomycin C (MMC) application in eyes with previous failed glaucoma surgery (GS) and/or cataract extraction (CE). Patients and methods Single-surgeon case series of 82 eyes of 82 patients undergoing DS with MMC. The patients had previous CE with IOL and/or conjunctival GS and treated intraocular pressure (IOP) >18 mm Hg. MMC (0.2 mg/ml) was applied for 2-3 min before scleral flap dissection. Complete success was defined as IOP between 6 and 21 mm Hg or a reduction of 20% from baseline without medications. Reoperation for glaucoma or related complications, or loss of light perception vision was considered as failure. *Results* Mean follow-up was  $57.7 \pm 22.4$ months with 78% of patients completing the 3-year follow-up. Mean IOP decreased from 24.0 mm Hg (22.3-25.6, 95% confidence intervals) to 13.4 mm Hg (12.0-14.2) at 3 years after surgery (P < 0.001). There was a significant decrease in the number of glaucoma medications from 2.0  $\pm$  1 preoperatively, to 0.3  $\pm$  0.7, 3 years after surgery. Kaplan-Meier cumulative success rates were 85.6% at 1 year, 80.0% at 2 years, and 76% at 3 years. At 3 years, IOP was maintained <19 and 15 mm Hg in 83 and 70% of eyes, respectively. Fourteen eyes (17.1%) had complications. Delayed hypotony (IOP < 6 mm Hg) was the commonest complication in five eyes (6.1%). Conclusion DS with MMC appears to be a safe and effective surgical procedure for eyes with previous intraocular surgery. Eye (2012) 26, 70-79; doi:10.1038/eye.2011.238; published online 7 October 2011

*Keywords:* glaucoma surgery; deep sclerectomy; trabeculectomy; glaucoma drainage implant; mitomycin C; ocular hypotony

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#### Introduction

Non-penetrating glaucoma surgery (NPGS) like viscocanalostomy<sup>1</sup> and deep sclerectomy (DS) were popularised in the 1990s as safer alternatives to trabeculectomy.2 The essential differences between NPGS and trabeculectomy are that the surgical procedure entails the creation of a filtration membrane, the trabeculo-Descemet's membrane (TDM) rather than a sclerostomy and the excision of the inner scleral flap creates a subscleral lake. Outflow pathways remain unclear but increased aqueous flow through the Schlemm's canal, intrascleral 'bleb' and subsequent suprachoroidal flow and subconjunctival flow with 'bleb' formation have all been proposed.<sup>3–9</sup> DS is the basic NPGS procedure. A spacer device is often placed on the scleral bed to prevent adhesion of the scleral flap to the bed and help form a subscleral lake and subconjunctival filtration bleb.<sup>2</sup> The comparative efficacy of the various types of NPGS to trabeculectomy remains a subject of some debate but most reports agree that NPGS has a lower rate of complications than trabeculectomy.<sup>10–15</sup> DS has been shown to be equivalent to trabeculectomy in lowering the intraocular pressure (IOP) in some recent publications.<sup>11,16,17</sup> Excellent long-term results have been reported with DS as the primary surgery for open-angle glaucoma.<sup>18–20</sup> The IOP after DS can be further lowered by Nd:YAG laser goniopuncture (LGP) of the TDM.<sup>21,22</sup> Like with trabeculectomy, intraoperative mitomycin C (MMC) application results in lower IOPs in the long term<sup>23,24</sup> and bleb rejuvenation techniques like needle revision can be used.<sup>25</sup> DS with MMC has been reported to be a safe and effective procedure for eyes with failed trabeculectomy.26,27

There has been a lack of consensus among glaucoma surgeons as to the best surgical option

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Received: 4 May 2011 Accepted in revised form: 3 August 2011 Published online: 7 October 2011 in eyes at a high-risk-to-failure, such as previous intraocular surgery. The Tube versus Trabeculectomy (TVT) trial was designed to prospectively assess trabeculectomy and Bearveldt tube implant (BGI) surgery, both augmented with MMC, in eyes with previous cataract surgery and/or failed trabeculectomy.<sup>28–31</sup> The study suggests that better IOP outcomes are achieved after BGI compared with trabeculectomy at 3 years. However, eyes with tube surgery may be prone to more serious long-term complications like corneal decompensation and diplopia. In this report, we have sought to examine the outcomes of DS with intraoperative MMC in combination with the full complement of postoperative procedures in eyes with either previous cataract extraction (CE) or glaucoma surgery (GS) based on the TVT trial criteria of success.

## Materials and methods

Patients were identified from a database of all patients undergoing GS by one surgeon (NA) between August 2001 and March 2008. Data entry was completed at the time of surgery and contemporaneously at each postoperative visit. Inclusion and exclusion criteria and outcome measures were similar to those of the TVT trial. Primary open-angle glaucoma patients older than 20 years with previous CE with IOL implantation and/or conjunctival GS (mainly trabeculectomy) were included. Clear corneal incisions were done for all cataract surgeries, phaco-emulsification or extracapsular technique. Eyes with aphakia and uveitic glaucoma were excluded. Eyes with previous vitreo-retinal surgery were included (excluded from TVT trial). In patients where both eyes were eligible, the eye operated on first was included. Data extracted from database included, Snellen visual acuity (VA), IOP, postoperative complications, subsequent procedures including reoperation for glaucoma, use of supplemental medical therapy.

Peribulbar or subtenon's regional anaesthesia was used for most cases and general anaesthesia in some cases according to the patient's preference. A 6-0 vicryl traction suture was used to infraduct the globe and a fornix-based conjunctival flap was fashioned. MMC was applied at a dose of 0.2 mg/ml for 2-3 min on four PVA sponge fragments placed under the conjunctival flap. The surgical area was then irrigated with 10 ml Balance salt solution. A  $5 \times 5$  mm superficial scleral flap, hinged at the limbus, was created to approximately one-third scleral depth and reflected 1 mm into the clear cornea. Within the bed of the superficial flap, a 90% depth scleral flap was fashioned and the ends of Schlemm's canal cut. Dissection of the deep scleral flap was continued into clear cornea to expose a trabeculo-descemetic window (TDM) of  $\sim$  3–4 mm width. Juxtacanalicular trabecular

meshwork was peeled using blunt-tipped capsulorhexis forceps. The deep scleral flap was then excised. Topical 1% fluorescein was applied to assess egress of aqueous humour across the TDM and stain residual tissue to be removed in the dissection. A 3.5-mm reticulated hyaluronic acid absorbable spacer implant (SKGel Corneal Laboratories, Paris, France) was placed under the superficial scleral flap, which was then sutured with 10-0 nylon. Porcine collagen implants (Aquaflow, STAAR, Nidau, Switzerland) were used in later cases as SKGel Implant manufacture had stopped. The outer scleral flap and conjunctiva were then closed with 10-0 nylon-interrupted sutures. If a microperforation occurred without prolapse of iris, then the surgery was continued as described above. If a macroperforation occurred then a peripheral iridotomy was made in the presenting iris and the procedure was converted into trabeculectomy. Postoperatively patients received prednisolone acetate 1% drops six times a day continued for a minimum of 8 weeks. Patients were followed up at day 1 and then at weeks 1 and 6, or more frequently if required. Thereafter, follow-up was determined by clinical need. Where there was an elevation of the IOP at any stage, Nd:Yag LGP was performed with a CGAL (Haag-Streit, Koeniz, Switzerland) contact gonioscopy lens. Needle revision with 5-Fluorouracil (5-FU) or MMC was performed on the slit-lamp biomicroscope if the IOP was still elevated. Argon and Nd:YAG iridoplasty were done either prophylactically to avoid iris prolapse into the goniopuncture or to remove iris incarcerated in the goniopuncture. These postoperative interventions were recorded contemporaneously as part of data collection. The techniques for LGP and iridoplasty are described in detail in a previous publication.<sup>21</sup>

Definitions were derived from the TVT trial.<sup>28</sup> Reoperation for glaucoma or a complication was defined as additional surgery requiring a return to the operating theatre. Interventions performed in the outpatient's clinic setting, such as needling procedures or LGP, were not considered reoperations. Serious complications were defined as surgical complications associated with loss of two or more lines of Snellen VA for >6 months and/or reoperation to manage the complication. Eyes that tested Seidel positive within the first month of follow-up were classified as wound leaks, and those occurring after 1 month were categorized as bleb leaks. Patients who underwent additional GS were censored from analysis of complications after the reoperation for glaucoma. Cataracts were considered to have progressed if there was loss of two or more lines of Snellen VA that was attributed to cataract, or if cataract surgery was performed.

Success criteria were similar to that of the TVT trial.<sup>32</sup> Failure was defined as IOP > 21 mm Hg or < 20%

reduction below baseline on two consecutive follow-up visits after 3 months. IOP  $<5 \,\mathrm{mm}\,\mathrm{Hg}$  on two consecutive follow-up visits after 3 months, reoperation for glaucoma, or loss of light perception vision were considered as failure. Eyes that met these criteria and were not on any supplemental medications were defined as complete success. Eyes that had not failed but required supplemental medical therapy were defined as qualified successes. Needle revision and LGP were not considered as failure.

The time to failure was defined either as the time from surgical treatment to reoperation for glaucoma or as the time from surgery to the first visit in which the patient had hypotony (IOP 5 mm Hg) or inadequately reduced IOP (IOP 21 mm Hg or not reduced by 20% below baseline). This implies that if a patient had an unsuccessful LGP or needle revision, failure was considered to have occurred on the visit when the decision to do these procedures was taken. IOP changes over time and comparison of IOPs between groups was done by analysis of variance and of glaucoma medications by the Kruskal-Wallis test. Univariate comparisons between treatment groups were performed using the two-sided Student's *t*-test for continuous variables and the Yates corrected  $\chi^2$  test or the Fisher's exact test. Treatment comparisons of time to failure were assessed with Kaplan-Meier survival analysis, log-rank test, and Cox's regression analyses. All tests were twotailed, and P-values < 0.05 were taken to be significant. Data presentation adheres to the guidelines suggested by Jabs for clinical case series.<sup>33</sup>

## Results

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Patient demographics are shown in Table 1. Eighty-two patients fulfilled the study criteria and were included in the analyses. Of these, 30 had previous GS, 17 had both cataract surgery and GS, and 34 had previous cataract surgery. The details are shown in Table 2. Grouping was done as in the TVT study and eyes with both cataract surgery and GS were included in the GS group. Thirtyseven eyes (45.1%) had two or more surgeries before the DS and only six of these eyes were in the CE group. The GS group had significantly higher number of previous intraocular surgeries  $(1.9 \pm 0.7)$  compared with the CE group (1.2  $\pm$  0.5, *P* < 0.00). The mean follow-up duration was  $57.7 \pm 22.4$  months. All patients completed the first year's follow-up, 75 (91.5%) completed the second year's follow-up, and 64 (78%) the third year's follow-up. Twenty patients (24.2%) died during the observation period and two (2.4%) became too ill to attend the clinic.

There was a significant drop in IOP from baseline to 5 years after surgery. Mean IOP decreased from 24.0 mm Hg (22.3–25.6, 95% confidence intervals (CIs)) to Table 1 Patient demographics and perioperative variables

Number of patients and eyes	82
Age in year (mean ± SD)	$76.1 \pm 10.5$
Sex $(M/F)$	45/37
Laterality (RE/LE)	42/40
Race	
Caucasian	79
Afro-Caribbean	02
Indian	01
Glaucoma diagnoses	
Primary open-angle	76
Pigmentary	01
PXF	01
Others	04
Co-existing ocular morbidities	
Age-related macular degeneration	07
Retinal vein occlusions	03
Tanical modication intolerance	03
Ocular surface disease	04
Penetrating injury with corneal scarring	01
renetrating injury with contear scarring	01
Follow-up in months (mean $\pm$ SD)	$57.7 \pm 22.7$
Median follow-up in months	62.5
Preoperative IOP in mm Hg (mean $\pm$ SD)	$23.9 \pm 7.5$
Cup: Disc Ratios	
< 0.8	06
0.8–0.9	07
≥0.9	69
Visual field loss, mean deviation	
No visual fields	02
Less than $-12.01 \mathrm{dB}$	14
-12.01 to $-20$ dB	22
-20.01 dB or worse	44
Preoperative medications (mean ± SD)	$2.0\pm~0.9$
Number of previous surgeries (mean $\pm$ SD)	$1.6 \pm 0.7$
Mitomycin C concentration and application duration	
0.2  mg/ml for 2 min	44
0.2  mg/ml for $3  min$	28
0.4 mg/ml for 3 min	10
Spacer device	
None	5
SKGel	12
Aquatlow	65

13.4 mm Hg (12.0–14.2, 95% CI) at 3 years after surgery (P < 0.001). IOP changes after surgery are shown in Figure 1. There was a significant decrease in the number of glaucoma medications from  $2.0 \pm 1$  (SDS) preoperatively, to  $0.3 \pm 0.7$ , 3 years after surgery. Table 3 shows the IOP and medications at baseline to 5 years after the surgery. No statistical difference was noted at



## **Table 2**Details of previous surgeries

	of eyes
Cataract extraction as index surgery	37 (45%)
Phaco-emulsification	24
Anterior vitrectomy	01
Posterior vitrectomy	02
Repair of corneal perforation	01
Penetrating keratoplasty	01
Extracapsular cataract extraction	13
Anterior chamber implant	01
Anterior vitrectomy	01
Glaucoma drainage procedure as index surgery	45 (55%)
Trabeculectomy	30
Two trabeculectomies	02
Intraoperative MMC augmentation	01
Revision of trabeculectomy with MMC	03
Scheie's sclerostomy	01
Needle revision with 5-FU	02
Needle revision with MMC	02
Phaco-emulsification	07
Extracapsular cataract extraction	11
Drainage of choroidal effusions	01
Combined phaco-trabeculectomy	08
Intraoperative 5-FU augmentation	01
Intraoperative MMC augmentation	01
Needle revision with 5-FU	03
Deep sclerectomy	06
Intraoperative MMC augmentation	01
Phaco-emulsification with bleb revision (MMC)	01
Trabeculectomy with MMC	01
Delimiting sutures with conjunctivoplasty	01
Combined phaco-deep sclerectomy	01

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Some eyes had more than one previous surgery and details of these are given under each index surgery. Clear corneal incisions were done for all cataract surgeries, phaco-emulsification, or extracapsular technique.



**Figure 1** IOP changes with 95% CIs (error bars) after DS. CE, previous cataract extraction; GS, previous glaucoma surgery; M0, baseline IOP; M, months after surgery.

 Table 3
 IOP and medications at baseline to 5 years after the surgery

	All eyes	Previous cataract extraction	Previous glaucoma surgery	Р
Baseline				
IOP	$24.0\pm7.5$	$24.9\pm8.8$	$23.2\pm6.3$	0.32
Glaucoma medications N	$2.0 \pm 1$ 82	$\begin{array}{c} 2.0\pm0.9\\35\end{array}$	$\begin{array}{c} 2.0\pm1.0\\ 47\end{array}$	0.96
6 months				
IOP	$14.1\pm5.0$	$14.3\pm5.2$	$14.0\pm4.9$	0.83
Glaucoma medications	$0.2 \pm 0.5$	$0.2\pm0.6$	$0.1 \pm 0.76$	0.76
Ν	82	35	4.7	
12 months				
IOP	$13.4 \pm 4.0$	$13.4\pm4.3$	$13.3 \pm 3.8$	0.90
Glaucoma medications	$0.2 \pm 0.6$	$0.3\pm0.8$	$0.1 \hspace{0.1in} \pm \hspace{0.1in} 0.41 \hspace{0.1in}$	0.23
Ν	82	35	47	
2 years				
IOP	$13.4\pm4.1$	$13.0\pm4.3$	$13.6\pm4.7$	0.54
Glaucoma medications	$0.3 \pm 0.7$	$0.3\pm0.7$	$0.3\pm0.6$	0.90
Ν	76	31	45	
3 years				
IOP	$12.9 \pm 4.0$	$12.6\pm4.0$	$13.1\pm5.0$	0.68
Glaucoma medications	$0.3 \pm 0.7$	$0.3\pm0.8$	$0.3\pm0.7$	0.87
Ν	64	26	39	
4 years				
IOP	$12.3\pm4.6$	$12.3\pm4.2$	$12.2\pm4.9$	0.94
Glaucoma medications	$0.3 \pm 0.7$	$0.3\pm0.8$	$0.3\pm0.7$	0.85
Ν	45	21	24	
5 years				
ĨOP	12.9 ±5.2	$13.2\pm6.1$	$12.6\pm4.9$	0.71
Glaucoma medications	$0.5 \pm 0.9$	$0.3 \pm 0.9$	$0.6 \pm 0.9$	0.14
Ν	42	18	24	

Abbreviations: IOP, intraocular pressure; N, number of patients. Data presented as mean ± SD. Data censored after a reoperation for glaucoma.

any time between the groups in the number of medications and IOP. At last follow-up 18 eyes (22%), 13 from the GS group and 5 from the CE group were on glaucoma medications (P = 0.2).

The complete success rates by Kaplan–Meier survival analysis were 85.4% at 1 year, 80.0% at 2 years, and 76% at 3 years (Figure 2). Table 4 summarizes cumulative success rates by different criteria at 3 years after DS. Figure 3 depicts the comparative outcome plots between the two groups for success defined as IOP <18 and 15 mm Hg. A Cox's regression analyses model suggested a significantly higher failure rate for eyes with two or more previous intraocular surgeries (hazards ratio, 4.6; 95% CI, 1.6–11.5; P = 0.004) and surgeries complicated by intraoperative perforation of the TDM

(HR 3.9, 95% CI, 1.2–13.2; P = 0.03) after adjusting for age, sex, laterality, baseline IOP, previous exposure to MMC or 5-FU, MMC dose and duration of application, and use of or type of spacer device. Univariate comparison by the log-rank tests confirmed significantly lower success rates in eyes with more than two previous



**Figure 2** Kaplan–Meier plots showing probability of complete success (IOP between 5 and 21 mm Hg or >20% drop from baseline without medications) with 95% CIs after DS.

**Table 4**Summary of cumulative success rates (Kaplan–Meiersurvival analyses) by different criteria at 3 years after deepsclerectomy

	All eyes (%)	Previous cataract extraction (%)	Previous glaucoma surgery (%)	P log-rank test
Complete success	76.0	82.8	71.3	0.02
Qualified success	90.0	91.4	89.1	0.18
IOP <19 mm Hg	86.0	91.4	82.3	0.06
IOP <15 mm Hg	71.8	83.4	63.3	0.009

intraocular surgeries (P = 0.001) and with intraoperative perforation of the TDM (P = 0.01).

Treatment failures over the follow-up period were not uncommon and 27 eyes (32.9%) failed. The most common cause was inadequate IOP reduction in 19 eyes (23.2%) and the highest number of failures was in the subgroup of eyes with previous cataract surgery and GS (13 eyes). Repeat procedure was cause of failure in two eyes (3.7%) and hypotony in five eyes (6.1%). Eyes in GS group were more likely to be treatment failures than those in CE group (P = 0.008). Kaplan– Meier survival plots showed that eyes with both previous cataract surgery and GS fared worse than eyes with either previous cataract surgery or GS alone (P = 0.03; Figure 4).

Intraoperative perforation of the TDM was noted in eight eyes (9.8%). All perforations occurred in pseudophakic eyes and there was no iris prolapse.



**Figure 4** Kaplan–Meier survival plot showing comparative complete success rates of DS in subgroups. Both = both previous cataract surgery and GS.



**Figure 3** Kaplan–Meier plots of the cumulative probability of success defining adequate IOP reduction as IOP >17 mm Hg (left) or IOP >14 mm Hg (right). Patients with persistent hypotony, reoperation for glaucoma, and loss of light perception vision are classified as failures. CE, previous cataract surgery; GS, previous glaucoma surgery.

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Therefore, peripheral iridectomy was not required in any of these cases. Intraoperative suprachoroidal haemorrhage after a perforation was seen in an eye, which also had a corneal graft. The haemorrhage was drained partially through two inferior *L*-shaped choroidotomies. The eventual outcome was favourable, with good IOP control and no change in VA from baseline until the patient's death 2 years later.

Early and late complications are presented in Table 5. Fourteen eyes (17.1%) had complications. Delayed hypotony was the commonest complication in five eyes (6.1%) and three of these had macular changes. All eyes with hypotony were from the GS group. Details and management of each case is presented in Table 6. Corneal oedema was noted after a scleral patch graft procedure for hypotony in one eye. In another eye, there was corneal oedema after reactivation of herpes simplex keratitis. The patient also had subconjunctival MMC of

Table 5 Early and delayed complications after DS

	Number (%)
Intraoperative expulsive haemorrhage	01 (1.2)
(in eye with perforation)	
Hyphema	01 (1.2)
Conjunctival edge-leak	04 (4.9)
Peripheral choroidal detachment	02 (2.4)
Corneal decompensation	01 (1.2)
Bleb dysaesthesias	03 (3.7)
Hypotony	05 (6.1)
With maculopathy	02 (2.4)
Blebitis with delayed bleb leak	01 (1.2)
Total number of patients with postoperative complications	14 (17.1%)

Complications after subsequent procedures for failure, including for hypotony are not included.

<b>Table 6</b> Details of hypotony as a complication of D5 with Mi
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0.02 mg before a needle revision procedure, which may have contributed to corneal endothelial cell loss. Serious complications resulting in reoperation and/or loss of two or more Snellen VA lines occurred in six eyes (7.3%). Three eyes each had surgery for bleb dysaesthesia and delayed ocular hypotony.

Procedures after DS are presented in Table 7. The Kaplan–Meier probability of performing LGP was 57.3% at 1 year and 63.6% at 3 years and there was no significant difference between the groups (P = 0.34, log-rank test). Argon laser iridoplasty was done in 10 (12.2%) eyes. The indication was iris contact with the TDM in three, iris plugging the goniopuncture in one,

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Procedure	Number of eyes (%)
Nd:YAG laser goniopuncture	53 (64.6)
Needle revision	26 (31.7)
MMC	19
5-FU	07
Argon laser iridoplasty	10 (12.2)
Revision of deep sclerectomy with MMC	03 (3.7)
Bleb dysaesthesia procedures	3 (3.7)
Suture-less conj excision	02
Bleb revision	01
Compression sutures on bleb for hypotony	02 (2.4)
Scleral patch graft for hypotony	03 (3.7)
Phaco-emulsification	01 (1.2)
Penetrating keratoplasty	01 (1.2)
Nd:YAG laser capsulotomy	04 (4.9)
Excision of avascular bleb and conjunctival advancement for delayed bleb leak	01 (1.2)

Some eyes had more than one procedure.

Age at surgery in years	Previous MMC exposure	Onset of hypotony <sup>a</sup>	LGP <sup>a</sup>	NR <sup>a</sup>	IOP before NR/LGP	Maculopathy	Cystic bleb	Management	Comments/outcome
87	No	14	02	12	12	No	Yes	Nil	IOP 4 mm Hg,
83	No	39	Nil	Nil		No	No	Nil	VA 6/9 at 75 months IOP 4 mm Hg, VA 6/9 at 57 months
85	No	21	04	Nil	19	Yes	No	Scleral patch graft	Died IOP 23 mm Hg at 37 months VA preop 6/9, on last visit 6/60
49	Yes	71	08	06	19	Yes	Yes	Compression sutures, scleral patch graft	BRVO, corneal edema High Myope IOP 14 on 2 medications
64	Yes	39	17	Nil	19	Yes	No	Compression sutures, scleral patch graft	VA 6/6 preop, on last visit 6/24 IOP 13 mm Hg at 59 months, VA 6/6

Abbreviations: LGP, laser goniopuncture; NR, needle revision.

<sup>a</sup>Months after surgery.

and prophylactically in six eyes. The latter were eyes with either a narrow entry into the angle (Shaeffer's grades 1 and 2) or antero-posteriorly narrow TDM windows with a posterior goniopuncture and where iris incarceration was anticipated. LGP was effective in lowering IOP by 20% and below 21 mm Hg without medications or needle revision in 19 eyes of the 53 eyes over the follow-up period. Needle revision of the failing filtration bleb was performed in 26 eyes (31.7%) and was successful in lowering IOP by the same criteria in 12 of these eyes. Needle revision with MMC was repeated in four eyes and with 5-FU in two eyes. Corneal decompensation occurred in one eye, which underwent two needle revisions (as reported in previous paragraph). Revision of the failing DS by reopening the surgical site, further MMC application, and a peripheral iridectomy was done in three eyes (3.7%). Repeat penetrating keratoplasty was done on an eye with a corneal graft, which had failed before eye had undergone DS.

A reduction of VA by two or more Snellen lines from baseline at the 6-month follow-up visit or after was noted in 18 eyes (22.0%) by last follow-up. The commonest cause was progression of age-related macular degeneration in six eyes. Progression of glaucomatous optic neuropathy was the cause in two eyes, including one patient with a preoperative visual field mean deviation of more than -30 dB. The patient's VA decreased from 6/18 to perception of hand movements only, 3 years after surgery. Hypotony with associated maculopathy was the cause of reduced VA in two eyes. Progression of cataract, diabetic macular oedema, macular hole, corneal oedema, severe dry eye, dementia, and no refraction were the cause of VA reduction in one eye each.

## Discussion

The final route for aqueous outflow after DS has been a subject of research and controversy. Manifestly, it is a bleb-dependent NPGS procedure. A recent experimental study in porcine eyes suggests that the outflow routes could be all three-the subconjunctival pathway, the functional deep scleral lake, and the opening of the Schlemm's canal.<sup>4</sup> However, as shown by ultrasound biomicroscopy (UBM) studies, there is a poor correlation between the intrascleral lake dimensions and IOP control. It is likely that in most eyes after DS, the subconjunctival outflow route is essential for lowering IOP. Therefore, techniques that promote bleb survival in trabeculectomy may be applicable to DS. A prospective randomized trial has shown that intraoperative MMC application during DS improves long-term IOP control.23 A case-control study showed MMC use and a low IOP on the first postoperative day (an indicator of adequate deep scleral flap dissection) were significantly related to

maintaining an IOP <18 mm Hg, 2 years after DS.<sup>24</sup> While there is no reported study of comparison in morphology between DS and trabeculectomy blebs, we have reported that anterior limbal MMC application results in a high frequency of avascular and thinwalled blebs in both DS and trabeculectomy.<sup>34</sup> In trabeculectomy, intensive postoperative management may lead to lower IOPs in the long term.<sup>35</sup> Our postoperative regime for DS, besides topical steroids, consists of subconjunctival 5-FU injections for failing blebs, LGP and needle revision with subconjunctival MMC or 5-FU. Interestingly, no eye in this study was given postoperative subconjunctival 5-FU. A UBM study has demonstrated that lower IOP after DS is correlated with the thickness of the TDM.<sup>5</sup> Nd:YAG LGP can be done in the early postoperative period if there was difficultly in deep dissection or if the IOP is raised significantly in the early postoperative period. We now tend to delay LGP to after 3 months, after topical steroid withdrawal. In this case series, LGP was done within the first 3 months in 50% of cases. Needle revision was done after unsuccessful LGP and 48% of the eyes that had LGP went on to have needle revision. In effect this probably converts the DS to a partial-thickness fistula, not unlike a trabeculectomy without a peripheral iridectomy. These postoperative manipulations may have contributed to improving the success rates of DS in 37.8% of eyes in this case series.

The TVT trial has provided a benchmark to evaluate glaucoma procedures in high-risk-to-failure eyes.<sup>28-31</sup> The mean IOP was  $\sim$  13 mm Hg at 3 years in both, the trabeculectomy and tube groups, similar to that of DS in our study. Complete (medication-free) success rates at 3 years were much lower than our study. They were 28 and 33% for the tube and trabeculectomy groups, respectively, compared with 74% for DS. Failure rates (100% minus partial and complete success rates) were significantly higher at 30.7% in the trabeculectomy compared with 15.1% at 3 years in the tube group. Using the same criteria for failure as the TVT trial, the failure rates of DS were 10.0% at 3 years. The mean number of medication for DS at  $0.3 \pm 0.7$  in 3 years compared with  $1.3 \pm 1.3$  for the tube and  $1.0 \pm 1.5$  for the trabeculectomy group in the TVT study. This is probably due to the aforementioned positive effect on IOP of LGP and needle revision on DS. Success rates may also have been enhanced by the fact this is a single-surgeon series. Cataract surgery in the United Kingdom (and in our centres) is performed through corneal sections. In contrast, in the United States, most surgeons use the posterior limbal section with conjunctival flaps. It is possible that this makes previous cataract surgery a more significant risk factor in the TVT trial than in our study.

The complication rate in the present study compares favourably with the TVT study in terms of both overall complication rate and serious complications.<sup>31</sup> This may be interpreted with some caution because of the retrospective nature of our study. On the other hand, mean follow-up was about 5 years, increasing the probability of observing delayed complications like bleb leak, bleb-related infections and dysaesthesia and ocular hypotony. The high incidence of hypotony (6.1%) after DS in this study was unexpected. We have previously reported hypotony with maculopathy in 1.5% of eyes after primary phakic DS augmented with MMC.25 Hypotony was observed only after a postoperative procedure to lower IOP was performed in all except one eye (Table 6). The outer scleral flap after DS is very thin offers minimal resistance to aqueous outflow. MMC and cautery may cause further thinning of the scleral flap. In some eyes with minimal subconjunctival resistance, LGP or needle revision with antimetabolites may precipitate hypotony. To avoid hypotony, we have made some technical modifications like increasing the thickness of the outer scleral flap, minimising cautery, and avoiding MMC contact with the flap. LGP is delayed for a few months after surgery and not done in eyes with an IOP of < 18 mm Hg. Subconjunctival and repeat MMC use is altogether avoided. MMC is not used in patients over the age of 80 years, regardless of risk status. Another indicator of the safety of the procedure is the number of procedures required for complications. In this study, 8 (9.8%) eyes required 10 procedures to deal with complications such as bleb dysaesthesia, hypotony, and delayed bleb leak. In the TVT study, 15% of eyes the tube group and 9% of eyes in the trabeculectomy group had procedures for complications.

DS may have some advantages over trabeculectomy in high-risk-to-failure eyes. Trabeculectomy is associated with an increase in anterior chamber (AC) inflammation, which may compromise bleb survival.<sup>36</sup> AC activity, as measured by a flare-meter, is significantly lower after DS than trabeculectomy and this may be advantageous for bleb survival in high-risk eyes.<sup>37</sup> Excessive flow in the early postoperative period may result in a number of complications with trabeculectomy. The presence of the TDM in DS ensures a predictable steady flow of aqueous and a low IOP in the early postoperative period, a favourable prognostic sign. After DS, shallow AC, hyphema, and AC inflammation are infrequently seen. There are some disadvantages of DS, the most important in this setting being the technical difficulty of performing the procedure in the nasal or temporal quadrant where the limbus is narrow, making it more difficult to dissect a wide TDM window. The long-learning curve of DS is a serious limitation.

This study, in common with other retrospective studies, has several limitations. Observer bias is inherent in study design. A significant proportion of the patients, about 30%, were lost to follow-up. The number of early complications may have been underestimated. The report includes cases over an 8-year period and DS has a long-learning curve. In addition, the postoperative management has been poorly defined in the literature and it evolved during the course of the study. The patients in this study were almost exclusively of Caucasian origin, limiting the extent to which comparisons with the TVT trial can be made. The glaucoma procedure of choice in the setting of previous failed GS remains controversial and an unresolved issue. While the TVT generally points towards the superiority of tube shunt surgery in the event of tube failure options for further surgery are limited.<sup>38</sup> Another researcher has pointed out that the outcomes of trabeculectomy in the TVT study are significantly inferior to those reported from their institution.<sup>39</sup> The complication rates of trabeculectomy are quite similar to those reported by our group on surgical reopening of the scleral flap with MMC application in eyes with failed trabeculectomy. We had concluded that the complication rates were too high with surgical reopening of the failed filter and it may be preferable to perform repeat surgery at a fresh site.<sup>40</sup> Perhaps, the choice of surgery will always be dictated by the training and individual skills of the surgeon. In conclusion, this report shows that DS has IOP outcomes similar to trabeculectomy and tube surgery in eyes with previous cataract surgery and/or GS.

#### Summary

What was known before

• The recently published tube versus tarbeculectomy (TVT) trial had concluded that in eyes with previous failed glaucoma surgery and pseudophakia, tube surgery was superior to trabeculectomy in controlling IOP and the complication rates of the two procedures were similar.

#### What this study adds

• Deep sclerectomy has better medication-free success rates than trabeculectomy and tube surgery and a lower rate of complications in eyes with previous failed glaucoma surgery and pseudophakia.

#### Conflict of interest

The authors declare no conflict of interest.

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