The benefits of phacotrabeculectomy using 10-0 polyglactin sutures

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Abstract

Purpose To determine the efficacy of a small scleral flap sutured with 10-0 polyglactin (Vicryl).

Methods One hundred and sixty-five eyes underwent clear cornea punch trabeculectomy under a 5.0 mm wide scleral flap that was closed with two 10-0 Vicryl sutures after phacoemulsification and insertion of a singlepiece PMMA lens. Complications, tonometric and visual results were assessed at regular intervals. Statistical analysis was by Fisher's exact test.

Results One hundred eyes that were followed for 1 year showed a mean intraocular pressure (IOP) of 14.7 mmHg, representing a fall of 36.5%. At 2 years the mean IOP was 16 mmHg (33 eyes). At final follow-up 87% had a corrected acuity of 6/12 or better and 96% had IOPs below 22 mmHg without additional medication. Complications included 11.5% fibrin reaction, 5.5% secondary hyphaema and 7.3% hypotony. There was a significant association of fibrin with both hypotony and pseudoexfoliation.

Conclusions These mid-term results show that 10-0 Vicryl compares favourably with other suture materials the results of which have been reported, and obviates the need for routine use of antimetabolites or for postoperative manipulations at the slit-lamp.

Key words Clear cornea punch, Non-foldable lenses, Phacotrabeculectomy, 10-0 Polyglactin (Vicryl)

The triple procedure of combined cataract extraction, posterior chamber lens implantation and trabeculectomy has over the past two decades become increasingly accepted when glaucoma and cataract coexist.^{1–8} Phacoemulsification through the trabeculectomy wound with round capsulorhexis has minimised complications that may be attributed to cataract surgery, but success may be marred by complications that can be attributed to the trabeculectomy. These include hyphaema, uveitis and hypotony.

Current debate relates to how the trabeculectomy flap should be fashioned in order to establish filtration but without hypotony, and whether cytotoxic agents should be used.⁹⁻¹⁵ We have previously suggested that use of 10-0 polyglactin (Vicryl) aids the technique of phacotrabeculectomy since sutures can be tied relatively tightly yet, because of absorption, the trabeculectomy flap will loosen in a controlled fashion without inflammatory changes.¹⁶ The incidence and complications of hypotony are reduced and use of antimetabolites is rendered unnecessary in routine cases. Further advantages are that slitlamp manipulations of conjunctiva and release or lysis of nylon sutures are rendered unnecessary.

The present study focuses on the mid-term control of intraocular pressure in a large cohort of patients and the possible complications that may arise from the technique that is now recommended.

Patients and methods

This study concentrates on 165 consecutive eyes of 152 patients who underwent phacotrabeculectomy using the technique described below. In order to provide conformity of technique, 5 high-risk eyes have been excluded because of the need for intraoperative mitomycin C for failed past trabeculectomy or neovascular changes. Thirty-seven other eyes have been excluded that received foldable lenses through a smaller wound than our standard incision.

The prospective trial was commenced in July 1995. Criteria for selection of cases were poorly controlled glaucoma on medical therapy, glaucoma with extensive field defect on first presentation, or ocular hypertension of 27 mmHg or more, together with clinically significant cataract or initial lens opacities with a high refractive error. All patients were Caucasian. Prior to surgery patients were receiving 0 to 4 medications with a mean of 1.6 medications. The mean cup/disc ratio was 0.70. Forty-nine patients had received pilocarpine four times a day for more than a year before A.V. Vyas P.J. Bacon S.P.B. Percival Department of Ophthalmology Scarborough District Hospital Scarborough, UK

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Table 1. Diagnoses	
Primary open angle glaucoma	119
Pseudoexfoliation syndrome	18
Low tension glaucoma	11
Angle closure glaucoma	14
Ocular hypertension 27 mmHg or more	12
Pigmentary glaucoma	1

surgery and 7 patients had received neutral adrenaline. Sixty-seven eyes were from male patients and 95 from female patients. The mean age was 78.9 years (range 51-94 years). Pre-operative diagnoses are documented in Table 1. Demographics are shown in Table 2. All patients were operated on as in-patients and had a hospital stay of 1–4 nights. Those on pre-operative pilocarpine drops were asked to discontinue them 2 days before surgery.

Surgical technique involved an incision based on the 11 o'clock meridian for both right and left eyes. An inverted 'L'-shaped fornix-based conjunctival flap was fashioned in all cases. Surface blood vessels were lightly cauterised. Transverse keratotomy was performed before the anterior chamber was opened in 10 eyes that had preoperative keratometric astigmatism greater than 2.0 D.

A 5 mm \times 2.5 mm half-moon-shaped scleral flap was dissected just short of the anatomical limbus in all cases. Any perforating vessels found under the flap were cauterised. A side port was made with a 1 mm diamond knife stab in clear cornea at 3 clock-hours distant from the scleral flap. A clear corneal tunnel 1.5 mm long was made from the base of the scleral flap with a 3.2 mm keratome before entering the anterior chamber. Sodium hyaluronate 1% was used routinely to deepen the anterior chamber. Nineteen eyes required pupil stretch; this was performed using two hooks when the pupil diameter was less than 4.5 mm after mydriasis. Hydrodissection and hydrodelamination followed continuous curved capsulorhexis. After an initial groove all eyes received bimanual divide-and-conquer nucleofractis phacoemulsification. The epinucleus was removed separately. Residual cortex was then aspirated. The balanced salt solution used throughout surgery had 10 mg vancomycin, 4 mg gentamicin and 0.5 cm³ 1:1000 adrenaline added to each 500 ml bottle.

Prior to lens insertion the capsular bag was expanded with viscoelastic and the internal wound was extended to exactly 5.2 mm using a diamond spring calliper. Each eye received a single-piece PMMA lens, optic 5.0 mm \times 6.0 mm (Rayner 235U). The trabeculectomy was performed with a punch aiming to remove a 2 mm \times 1.5 mm block of clear cornea from the endothelial side of the corneal tunnel. This was followed

Table 2.	Demographics	of	165	eyes	

Male eyes	67
Female eyes	98
Mean age (range) years	78.9 (51–94)
Mean cup/disc ratio	0.70
Mean pre-operative medications	1.6
Pre-operative pilocarpine q.d.s. > 1 year	49 (29.7%)
Pre-operative adrenaline b.d. > 1 year	7 (4.2%)

Table 3. Additional surgical procedures performed

Pupil stretch	19
Transverse keratotomy	10
Return to theatre for aspiration of retained	1
nuclear chip	
Insertion of capsule tension ring	6
Suture cut or lysis	0

by a peripheral iridectomy. The viscoelastic was removed and the scleral flap was sutured with two radially placed 10-0 Vicryl sutures. The angle of the inverted 'L'-shaped conjunctival flap was then sutured to the limbus using the same 10-0 Vicryl. All patients received g. prednisolone acetate 1% q.d.s., g. chloromycetin q.d.s., g. flurbiprofen 0.03% t.d.s. for 3 weeks and g. cyclopentolate 1% b.d. for 2 weeks. Those with severe uveitis or a fibrin reaction received more frequent steroid drops together with orbital floor injections of 1 cm³ betamethasone 0.4%. Additional surgical procedures performed are shown in Table 3.

Patients were examined after surgery at 1 day, 4 days, 1 week, 1 month, and thereafter every 3-6 months with respect to Goldmann tonometry, the state of the anterior segment, filtering bleb and visual acuity. Statistical analysis was by Fisher's exact test. Means were compared using Student's *t*-test and where means were skewed by outliers the non-parametric Mann-Whitney U-test was applied.

Results

Follow-up ranged from 6 to 30 months with a mean of 13.7 months. One hundred and fifty-eight eyes were examined at 6 months, 7 being unavailable because of death or removal from the district. One hundred eyes were examined at 12 months, 59 at 18 months and 23 at 24 months.

Intraocular pressure control

The mean intraocular pressure (IOP) of the 165 eyes preoperatively was 23.0 mmHg (range 12-44 mmHg) and post-operatively at final follow-up was 14.6 mmHg (range 6–23 mmHg), giving a mean fall of 8.4 mmHg (36.5%) as shown in Table 4. Of the 158 eyes examined at 6 months, the mean IOP was 14.4 mmHg, representing a 37.4% drop from the pre-operative level, and in 141 of these eyes the pressure was less than 22 mmHg. The number of medications used per eye is shown in Table 5.

Table 4. Mean $(\pm SD)$ int	raocular pressure and pressure range
(mmHg) in 165 eyes	

	Mean (± SD)	Range
Before surgery	23.0 (± 5.1)	12-44
At 6 months (158 eyes)	14.4 (± 2.8)	8–26
At 1 year (100 eyes)	14.7 (± 2.8)	6–26)
At 2 years (33 eyes)	16.0 (± 2.8)	10-21
At final follow-up (all eyes)	14.6 (± 3.0)	6–23
Fall from before surgery to final follow-up	8.4 mmHg (36.5%)	

Table 5. Number of medications per eye

_	No. of medications				
	0	1	2	3	4
Before surgery	11	62	78	13	1
At final follow-up	158	7	0	0	1

One hundred and fifty-eight eyes (96%) did not require medication at final follow-up. Fig. 1 shows the overall stability of IOP over a period of 2½ years. Fig. 2 shows the Kaplan–Meier survival curve, again indicating satisfactory mid-term control. Of the 100 eyes examined at 1 year the mean IOP was 14.7 mmHg. All except one had an IOP of less than 22 mmHg, 96 eyes (96%) being without medication.

It will be seen from Fig. 1 that there was considerable variation in IOP during the first week. At day 1 pressures ranged from 2 to 38 mmHg. Thirty-four eyes (21%) had pressures of more than 21 mmHg, although only 7 of these had a spike above 27 mmHg. None of these received ocular massage. Recordings at 1 week showed a lower mean of 12.9 mmHg but a range of 2–40 mmHg. Twenty-one (12.7%) of these received light ocular massage. Twelve others suffered hypotony. In no case was there a need for suture release or lysis. At final follow-up only 4 eyes were noted to have bleb failure. Diffuse blebs were present in the majority, a moderately raised bleb was noted in 23 eyes and a severely raised bleb in 2 eyes.

Visual acuity

Of the 165 eyes at final follow-up, 143 (86.7%) could see 6/12 or better with correction (Table 6). Reasons for visual acuity less than 6/12 are shown in Table 7. None of these failures was the result of the surgical procedure. Nine eyes underwent YAG laser posterior capsulotomy

and one underwent YAG laser sphincterotomy of the anterior capsule for capsular phimosis during the followup period.

Operative complications

There were 4 cases of posterior capsule rupture. Two required sulcus placement after anterior vitrectomy; the other 2 underwent bag placement without vitrectomy. There were 3 cases of zonular rupture, all occurring in association with the pseudoexfoliation syndrome and during the first year of the study when capsule tension rings were not available to us. One led to bag placement of a PMMA lens, one to sulcus placement of a PMMA lens, and a third required total removal of the lens capsule with insertion of an anterior chamber lens. In an eighth case there was a technical problem with the phaco machine after nucleofractis. The segments were removed manually but a retained nuclear chip in the anterior chamber required aspiration at a later date.

Post-operative complications

Post-operative complications are tabulated in Table 8. Secondary hyphaema was noted in 9 eyes (5.5%). Hypotony, defined as persistent pressure below 5 mmHg, with or without shallowing of the anterior chamber or choroidal detachment, was noted in 12 eyes (7.3%).

Fibrin reaction developed during the first 4 days in 19 eyes (11.5%). The main associations were with pseudoexfoliation (4/14 eyes, 26.7%) and with hypotony (6/12 eyes, 50%), but not with pupil stretch (2/19 eyes, 10.5%). A breakdown in incidence is shown in Table 9. Fibrin was treated with 1-hourly prednisolone 1% drops, orbital floor betamethasone 4 mg repeated on alternate days when necessary, topical flurbiprofen three times a day and full mydriasis with topical cyclopentolate 1% and phenylephrine 2.5%.

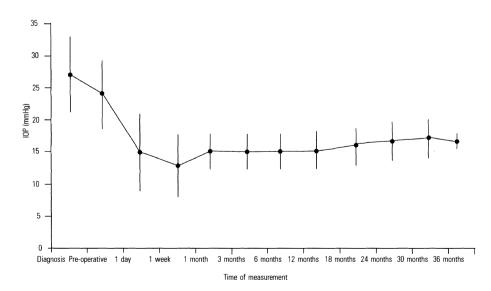


Fig. 1. Mean intraocular pressure (vertical bars = standard deviation) before and after phacotrabeculectomy.

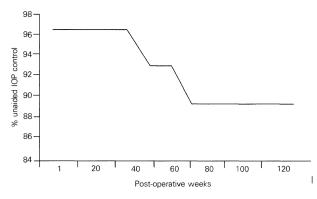


Fig. 2. Kaplan–Meier survival curve showing survival of unaided intraocular pressure of < 22 mmHg

Decentration of the lens optic by 1.0 mm or more was noted in 7 eyes (4.2%). This was probably related to asymmetric capsular fibrosis but was not associated with symptoms such as lens edge glare, even though 3 of these patients had undergone pupil stretch at surgery. In no case was the optic edge visible through the undilated pupil. Implant precipitates were noted in 18 eyes (10.9%) but did not have any impact on visual acuity.

Anterior capsule phimosis leading to a capsulorhexis diameter of 3.0 mm or less was noted in 5 eyes (3%). These cases all occurred among the first 30 eyes to be operated on at a time when the anterior capsulorhexis was usually left alone if of a diameter of less than 5.0 mm. Later in the study such openings would be enlarged after lens implantation by making small tears with scissors and forceps in the capsulorhexis rim.

Discussion

We believe that the use of 10-0 Vicryl in phacotrabeculectomy has several advantages. Inflammatory reaction is minimal, and the tensile strength (0.45 newtons) is greater than for nylon (0.35)newtons) yet is halved at the end of 1 week. Vicryl is absorbed by hydrolysis and disappears by 1 month. This means that sutures can be tied relatively tightly to lessen the risk of overfiltration and hypotony in the immediate post-operative period. The fact that in one-fifth of our cases the IOP was 22 mmHg or more on day 1 was of little concern since by 1 week pressures were considerably lower. Light ocular massage was required in 12.5% of eyes between day 4 and day 8 but we found no need to cut or lyse the sutures because Vicryl is absorbed naturally. One eye required scleral manipulation at the slit-lamp at 3 weeks after operation as the IOP was 34 mmHg. Ninety-six per cent of eyes maintained good filtration without the need for additional medication.

Table 6. Visual acuity at final follow-up (165 eyes)

	Visual acuity			
	6/9 or better	6/12	6/18 or worse	
Before surgery	41	36	88	
At final follow-up	131	12	22	

Table 7. Reasons for visual acuity less than 6/12 with correction

Pre-operative optic atrophy	4
Pre-operative macular degeneration	5
Optic atrophy and macular degeneration	3
Cystoid macular oedema ^a	1
Macular haemorrhage	1
Diabetic maculopathy	1
Macular hole ^a	1
Central retinal artery occlusion 2 months after surgery	1
Post-operative vitreous haemorrhage	1
Non-arteritic ischaemic optic neuropathy	1
Amblyopia	2

^aThese cases were not associated with post-operative hypotomy.

There have been many suggestions as to how best to make phacotrabeculectomy effective. The chief problems are an incidence of hyphaema, fibrin reaction, hypotony and failure in filtration. Hyphaema was reported in 26–28% of eyes of authors constructing a scleral flap without a clear cornea punch.^{13,17,18} It was reported in 64% and 51% of cases by authors using a sutureless technique.^{19,20} Our incidence of secondary hyphaema was 5.5%. This compares with less than 5% by other authors who constructed a sutured scleral flap, ensured accurate haemostasis underneath it and used a punch for clear cornea trabeculectomy.^{12,14} One should emphasise the importance of confining the punch to clear cornea in order to avoid capillary bleeding from the inner lip of sclera.

The incidence of post-operative fibrin reaction has been reported to vary from 1% to 54%.^{8,17,19,20} Our overall incidence was 11.5%. Interestingly this was not increased in eyes that had undergone pupil stretch (Table 9). The two main factors associated with fibrin were pseudoexfoliation (26.7%) and hypotony (50%). Pseudoexfoliation is a well-known predisposition for fibrin and the association with hypotony was also noted by Kosmin *et al.*²¹ Fibrin can be limited by topical prostaglandin inhibitors, by hourly 1% prednisolone drops and by orbital floor injections of betamethasone in the immediate post-operative period for those eyes considered most susceptible.

The third major problem of phacotrabeculectomy is how to strike a balance between useful post-operative drainage and the complications of hypotony. Current opinion suggests that antimetabolites such as mitomycin C should be used routinely for phacotrabeculectomy.^{10,11,13–15} However, this does

increase the risk of diffusely leaking blebs with chronic hypotony and possible endophthalmitis.²² We believe these adjuvants to be unnecessary except when high or

 Table 8. Post-operative complications

Secondary hyphaema	9 ^a (5.5%)
Hypotony	12 (7.3%)
Flat peripheral anterior chamber	0
Choroidal effusion	11 (6.7%)
Fibrin reaction	19 (11.5%)
Decentration 1.0 mm or more	7 (4.2%)
Anterior capsule phimosis	5 (3%)

^aOne of these eyes was fully anticoagulated with warfarin.

Table 9. Incia	dence of p	ost-operative	fibrin	reaction
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	No. of eyes	No. of eyes with fibrin	(%)
Total incidence	165	19	11.5
Eyes excluding pseudoexfoliation or hypotony	138	9	6.5
Eyes with pseudoexfoliation and/or hypotony	27	10	37
Pseudoexfoliation alone	15	4	26.7
Hypotony	12	6 ^a	50

 $^{a}p < 0.0001.$

multiple risk factors are present. Lederer,¹⁴ for example, reported good results at 12 months follow-up following phacotrabeculectomy combined with intraoperative mitomycin 0.4 mg/ml and a fornix-based conjunctival flap. However, this achievement necessitated a timeconsuming mattress suture to the limbus as well as a complicated post-operative regime to ensure scleral flow. This included conjunctival manipulations at the slitlamp, scleral flap elevations, possible cautery to conjunctival perforations, staged cutting of scleral sutures and, in 26 of their 56 patients, post-operative injections of 5-fluorouracil as well. Although the mean post-operative IOP in their patients was only 10.7 mmHg they had to accept an incidence of hypotony with choroidal detachment of 16% and reduced acuity due to probable macular oedema of 9%. Overall the percentage fall in IOP from the pre-operative level was 36.5% and there were no cases of reduced acuity resulting from a complication of surgery. All eyes maintained an IOP of less than 23 mmHg, 96.3% without additional medication. Other authors have achieved similar results without additional medication in 71%,^{11,18} 75%,⁸ 80%,²¹ $88\%_{t}^{19} 92\%^{17}$ and $96\%^{14}$ of cases. To achieve these results Arnold¹⁹ used a sutureless technique but suffered a shallow anterior chamber in 40% and hyphaema in 64% of cases. Others have used suture removal, lysis or cutting techniques or have used antimetabolite adjuvants. We believe that the beauty of 10-0 Vicryl is that these additional measures with their potentially dangerous side-effects are rendered completely unnecessary in routine cases. Expense is reduced because the same suture is used for closure of conjunctiva.

In our series 86.7% of eyes achieved an acuity of 20/40 or better with correction, which is comparable to the results of others.^{8–11,14,19}

We now prefer the single-piece PMMA lens to a threepiece foldable lens with flexible loops because the stiffer loops appear to splint the anterior segment and prevent flattening of the peripheral chamber if the chamber shallows in association with hypotony. In a previous study a flat anterior chamber developed in 5 of 35 eyes with three-piece silicone lenses (14%) compared with none of the 85 eyes with single-piece PMMA lenses (p < 0.002). Three of the 5 eyes also developed iris capture of the silicone optic that had been capsule fixated – a situation that did not occur PMMA lenses. Kosmin *et al.*²¹ noted an increase in post-operative complications with silicone plate haptic lenses when compared with PMMA lenses but with a recognised difference in the way that the trabeculectomy flap was sutured. They had an incidence of 16.6% hypotony with silicone lenses and in one eye there was also iris capture with a plate haptic dislocating into the anterior chamber. However, in both Kosmin *et al.*'s study and our own, and in agreement with other workers,^{23,24} there appears to be no detectable difference in long-term IOP control or visual acuity whether a small wound with a foldable lens or a larger wound with an unfoldable lens is used.

Concerning refractive consequences, in an earlier study we were unable to detect a significant difference in wound-induced astigmatism whether rigid or foldable lenses were used.¹⁶

In conclusion, we have found excellent results in terms of pressure control from the use of 10-0 Vicryl and a 5 mm wide half-moon trabeculectomy flap. We believe that early surgery should be preferred to the use of topical miotics, and that a capsule tension ring enhances safety in cases of pseudoexfoliation. Attention to the capsulorhexis size and possible need for additional tears at its rim towards the end of surgery will prevent capsular phimosis, and prompt treatment with intensive topical steroids should be given to eyes predisposed to additional inflammation. Finally we can see little merit in opting for a foldable lens for this operation and continue a preference for the more rigid and less expensive singlepiece PMMA implant.

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