ORIGINAL ARTICLES—Clinical science

Survival analysis for success of Molteno tube implants

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Abstract

***Aim*—To apply survival analysis in assessing the long term outcome of Molteno tube implantation and to identify risk factors for failure.**

***Methods*—A retrospective, 10 year, consecutive case series study of 119 eyes that underwent implantation of a Molteno tube. The main outcome measures considered were intraocular pressure (IOP), visual acuity, and complications.**

***Results*—A 30% or greater reduction in IOP was achieved in 68.9% of cases. However, the overall, "complete success" rate (IOP <22 mm Hg with no medications) after a mean (SD) follow up period of 43 (33) months (range 6–120) was only 33.6% despite a fall in mean (SD) IOP from 38.2 (8.2) mm Hg to 20.1 (11.0) mm Hg. The "qualified success" rate (IOP <22 mm Hg with or without medications) was 60.5%. Failure was most common in the first postoperative year but could occur after several years, the survival curve having an exponential shape. The only statistically significant risk factor for failure identified was pseudophakia, although eyes with neovascular glaucoma tended to fare poorly. Postoperative IOP tended to be lower after double plate than after single plate implantation. There was no significant difference in outcome based on age, sex, race, previous penetrating keratoplasty, or previous conjunctival surgery.**

***Conclusions*—In eyes at high risk of trabeculectomy failure, implantation of an aqueous shunt device should be considered. Pseudophakia should be considered an additional risk factor for failure. Early failure appeared relatively more common but long term follow up of all cases is recommended to ensure adequate management of late failures.**

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Despite the introduction of other treatment methods with potential advantages over tube implantation, none are fully accepted worldwide and many clinicians continue to implant aqueous shunts for refractory glaucoma.[1 2] However, there have been few reports of the long term results in a large series of patients who have undergone tube implantation. The aim of this study was to use survival analyses to evaluate the long term outcome of a large series of implanted Molteno tubes in a single Canadian practice.

Patients and methods

The outcome of 119 consecutive, single phase, first Molteno tube implantation procedures performed over 10 years (1986–96) in 119 eyes of 119 patients was determined. Patients underwent surgery either for intractable glaucoma, uncontrolled with maximal medical treatment, laser trabeculoplasty and, usually, failed trabeculectomy, or as a primary surgical procedure in patients considered to be at high risk of failure of trabeculectomy with adjunctive antimetabolite treatment.

DATA ANALYSED

Only 119 cases who had undergone a first single phase implantation technique without antimetabolite augmentation and who were followed up for at least 6 months were included in the analysis. With bilateral surgery, only the first procedure was included. Patient data recorded included age, sex, diagnosis, number and type of previous surgical procedures, visual acuity, the highest previously recorded intraocular pressure (IOP), and the mean of the three most recently recorded preoperative IOP values ("mean preoperative IOP"). Postoperative data included visual acuity at 6 months, IOP after follow up periods of 1 week, 1, 2, 3 and 6 months and 1, 2, 3, 5 and 10 years when applicable. In addition, data obtained at the patient's last clinic visit were recorded. The status of the eye with particular respect to treatment (number and type) and complications, was recorded for each visit. All referring ophthalmologists were contacted to contribute missing information.

SURGICAL TECHNIQUE

A 90° (single plate implants) or 180° (double plate implants) superior conjunctival peritomy was performed, the superior rectus isolated, and one (single plate) or both quadrants (double plate) of the superior subconjunctival space cleared. A single plate implant was inserted in eyes with suspected impaired aqueous production or reduced orbital space. The tube was occluded by a 6/0 Vicryl suture and the plate(s) of the device sutured to sclera in the appropriate quadrant(s) with 6/0 silk, positioning the plate(s) 10 mm posterior to the limbus. With double plate implants the interplate connecting tube was placed beneath the superior

Table 1 Patient demographic data

Diagnosis	*No of eyes*	*Mean (SD) age (years)*	*Sex (M:F, %)*	*Race (W:O, %)*	*Eye (R:L, %)*	*Implant (S:D, %)*	*Mean (SD) follow up (months)*
All patients	119	46 (27)	47:53	87:13	50:50	25:75	43 (33)
1 Developmental	38	21 (20)	47:53	90:10	42:58	18:82	50 (34)
2 POAG	13	73 (10)	23:77*	85:15	54:46	8:92	55 (33)
3 CCAG	10	62 (15)	70:30	90:10	70:30	10:90	54 (34)
4 Uveitic	19	54 (22)	47:53	90:10	53:47	32:68	45 (39)
5 Traumatic	15	36 (18)	67:33†	60:40‡	33:67	13:87	33 (29)
6 Neovascular	19	66 (21)	47:53	95:5	53:47	58:42¶	28 (25)
7 Miscellaneous	5	59 (24)	0:100	100:0	80:20	40:60	10 (7)
Statistics:							
χ^2/Fisher's test			*p=0.06 †p=0.09	‡p=0.001	NS	¶p=0.0003	
ANOVA		p<0.00001					p=0.02
Duncan's (p<0.05)		1<2–7 5<2–4,6,7 2>1,4,5					6<1,2 7<1–3

SD = standard deviation; M:F = male:female; W:O = White:Oriental; R:L = right:left; S:D = single:double; POAG = primary open angle glaucoma; CCAG = chronic closed angle glaucoma; NS = not significant.
*Most patients with POAG were female.
†Most patients with traumatic glaucoma were male.
‡Compared with other diagnoses, traumatic glaucoma was more common in eyes of non-white patients.
¶Single plate implants were more commonly inserted in eyes with neovascular glaucoma, compared with other diagnoses.

rectus. A radial scleral groove was fashioned with blade and cautery. Entry into the aqueous chamber was achieved with a 22 gauge needle on a syringe containing sodium hyaluronate, some of which was injected into the chamber before the appropriately trimmed tube was inserted. The extraocular portion of the tube was sutured into the scleral groove and covered with a scleral patch graft using 8/0 Vicryl. The conjunctival flap was closed with 8/0 Vicryl and subconjunctival antibiotic/steroid was administered. A topical antibiotic was prescribed for 1 month postoperatively and steroid for up to 3 months.

DEFINITIONS OF SUCCESS/FAILURE

"Complete success": IOP 6–22 mm Hg without antiglaucoma medication.

"Partial success": IOP 6–22 mm Hg with medication at the time of the last visit.

"Qualified success": combination of "complete" and "partial" success.

"Partial failure": IOP >21 mm Hg despite additional medications.

"Complete failure": loss of light perception, the requirement of a cyclo-destructive procedure, or further glaucoma surgery.

Eyes with an IOP of <6 mm Hg with no loss of best corrected visual acuity were included as successes. In addition, success was defined on the basis of achieving a "target IOP" of at least a 30% reduction (from the mean of the three most recent preoperative IOP measurements) with either no or reduced anti-glaucomatous treatment.

Visual field changes and transient IOP spikes were ignored in defining success.

STATISTICS

Group comparisons were made using a *t* test, an analysis of variance for continuous data (ANOVA with Duncan's correction), and Pearson's χ^2 or Fisher's exact test (when expected cell value was <5) for categorical data. The Wilcoxon matched pairs signed rank test was used to compare differences between mean IOP values. Kaplan-Meier survival curves were drawn using each definition of success. Curves were constructed for the whole group and for risk factor subgroups, differences in success being compared using the log rank test. A Cox multivariate analysis was performed to investigate the effect of certain continuous variables. A p value of ≤ 0.05 was considered significant.

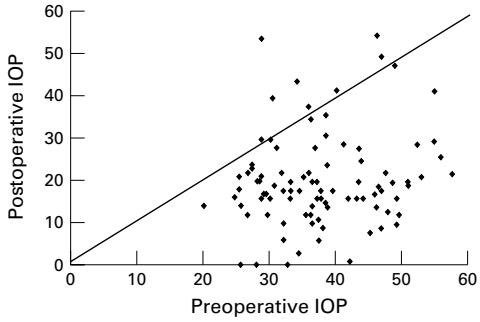

Figure 1 Scatter plot of mean preoperative intraocular pressure (IOP) against final postoperative IOP for all eyes. Some points overlie others and may represent more than one case. The oblique line of no change in IOP is drawn to show that there was a reduction in IOP for the majority of cases.

Results

Demographic data for all patients are given in Table 1. The mean age was 46 years, mean follow up was 43 months, and most of the patients were white, making assessment of racial factors unreliable. The mean preoperative IOP (38.2 mm Hg) was reduced in 92.4% of cases by the end of the follow up period to achieve a mean IOP of 20.1 mm Hg (Fig 1).

Overall, "complete success" was 34% although "qualified success" was significantly greater at 60.5%. A 30% or greater reduction in IOP was achieved in 68.9% with a fall from the highest mean (SD) preoperative IOP of 46.3 (9.8) mm Hg to 20.1 (11.0) mm Hg. The Kaplan-Meier survival plots for all eyes are shown in Figure 2. The IOP profile with time for the whole group is shown in Figure 3.

GLAUCOMA DIAGNOSIS

There were significant demographic differences between the diagnostic groups (Table 1), but a reduction in IOP occurred in all (Table

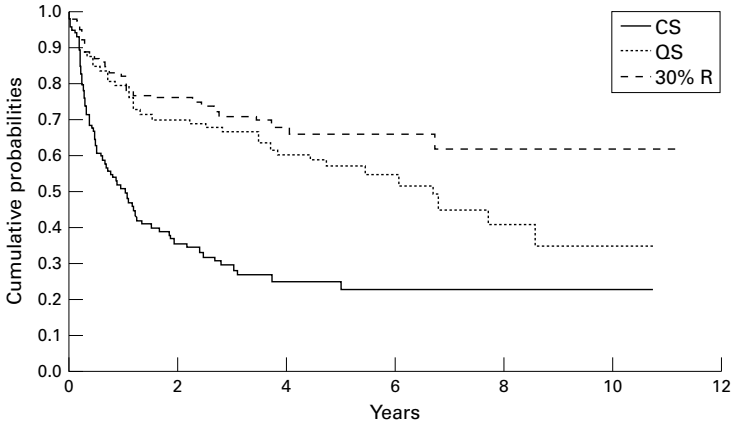

Figure 2 Kaplan-Meier survival curves for all patients, plotting the cumulative probabilities against time that (i) the intraocular pressure (IOP) remains below 22 mm Hg without additional medical treatment ("complete" success: CS), (ii) the IOP remains below 22 mm Hg with or without additional medical treatment ("qualified" success: QS); and (iii) the IOP remains below the target IOP (set as a 30% reduction from the mean preoperative IOP; –30%R) following tube implantation.

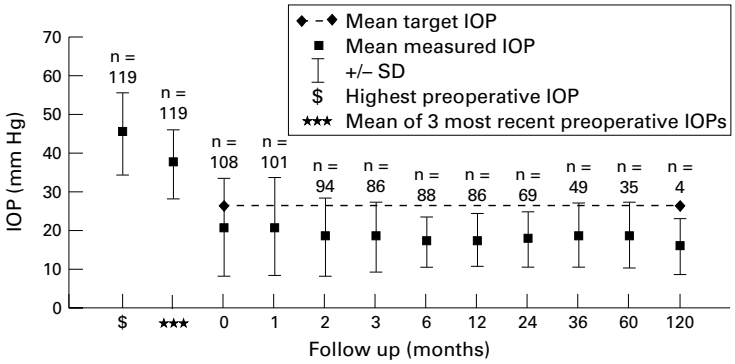

Figure 3 Intraocular pressure (IOP) versus time profile for the whole patient group. The first point represents the highest recorded preoperative IOP levels and the second point the mean of the three most recent preoperative IOP values. The other points represent the mean IOP values for the appropriate postoperative time point.

Table 2 Reduction in intraocular pressure (IOP) by diagnosis

Diagnosis	*n*	*Mean preop IOP (mm Hg)*	*Final postop IOP (mm Hg)*	*% reduction*	*p Value*
All patients	119	38.2 (8.2)	20.1 (11.0)	47.4	0.00001
Developmental	38	34.9 (7.3)	18.6 (8.7)	46.7	0.00001
POAG	13	36.8 (7.5)	20.2 (11.6)	45.1	0.01
CCAG	10	43.6 (5.3)	16.4 (13.3)	62.4	0.007
Uveitic	19	39.4 (9.2)	19.4 (9.8)	50.8	0.0001
Traumatic	15	39.9 (10.0)	22.5 (12.7)	43.6	0.002
Neovascular	19	39.9 (7.1)	24.0 (12.1)	39.8	0.0003
Miscellaneous	5	40.6 (7.9)	19.8 (15.5)	51.2	0.1

POAG = primary open angle glaucoma; CCAG = chronic closed angle glaucoma.
Values are mean (SD).

Table 3 Success rates by diagnosis using differing success criteria

Diagnosis	*n*	*Complete success (%)*	*Qualified success (%)*	*Target success (%)*
All patients	119	33.6	60.5	68.9
Developmental	38	31.6	57.9	65.8
POAG	13	30.8	69.2	76.9
CCAG	10	40.0	70.0	70.0
Uveitic	19	42.1	68.4	89.5
Traumatic	15	33.3	60.0	66.7
Neovascular	19	26.3	52.6	57.9
Miscellaneous	5	40.0	40.0	40.0

POAG = primary open angle glaucoma; CCAG = chronic closed angle glaucoma; target success = reduction in IOP of >30%.

2). The mean percentage reduction in IOP was greatest for eyes with angle closure (62.4%) and uveitic glaucoma (50.8%) and least for eyes with neovascular (39.8%) or traumatic glaucoma (43.6%). Success rates were different for the various diagnostic groups of patients (Table 3). When considering both "complete" and "qualified" success, the analyses demonstrated relatively higher success rates for patients with chronic closed angle glaucoma (CCAG; 40%, 70%) and low success for those with neovascular glaucoma (26.3%, 52.6%), but the differences failed to reach statistical significance by survival analysis. Glaucoma diagnosis was, however, a marginal predictor of success (p=0.05) when considering success as a reduction in IOP of at least 30% (Figure 4), the highest success being for eyes with uveitic glaucoma (89.5%) or primary open angle glaucoma (POAG; 76.9%) and the lowest for eyes with neovascular glaucoma (57.9%).

AGE GROUP

There were significant demographic differences between the age groups (Table 4). Survival analysis revealed a statistically significant difference (p=0.02) between the results when considering "complete success" (Fig 5), being worse for patients aged 31–60 years. However, age had no significant effect on outcome in any other analysis.

SINGLE PLATE VERSUS DOUBLE PLATE TUBE IMPLANTATION

Most eyes had double plate rather than single plate tubes implanted. "Complete success" was achieved in 36.0% of eyes with a double plate and "qualified success" in 60.7% with a fall in IOP of 46.9% (from 39.0 (8.7) mm Hg to 20.7 (11.8) mm Hg), the target IOP being achieved in 70.8% of eyes. The success rate in eyes with a single plate implant was similar, "complete success" being lower at 26.7% and "qualified success" being similar at 60%; the mean reduction in IOP was higher at 49% (from 35.9 (5.6) mm Hg to 18.3 (9.1) mm Hg), but with a lower attainment of target IOP (63.3%). Despite the overall tendency for the double plate to be more effective than the single plate, by survival analysis there was no statistically significant difference (Fig 6).

PREVIOUS OCULAR SURGERY

Eighty nine of the 119 eyes (74.8%) had undergone previous surgery involving conjunctival incision, and by survival analysis such surgery had no statistically significant effect on outcome.

Fifty nine of the 119 eyes (49.6%) had undergone previous glaucoma filtration surgery (GFS). In virtually all the eyes with POAG (92.3%) one or more trabeculectomies had been performed, significantly more than for patients with other diagnoses (p=0.001), especially neovascular glaucoma (10.5%; p=0.0002). By categorical group analysis, the younger patients had undergone previous GFS less frequently than patients in the older groups (p=0.007), the mean age of those who had undergone GFS being 53 (22) years compared with 39 (31) years for those who had not (p=0.001). "Complete success" was achieved in 28.8% of eyes that had undergone previous

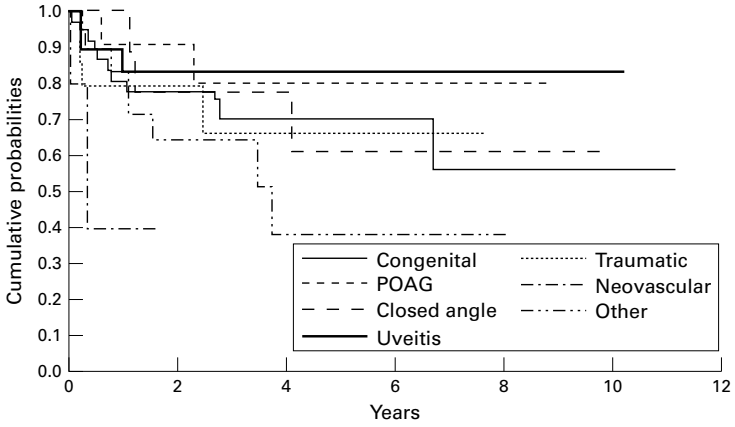

Figure 4 Kaplan-Meier survival curves based on diagnostic category, plotting the cumulative probabilities against time that intraocular pressure (IOP) remains below the target IOP (set as a 30% reduction from the mean preoperative IOP) following tube implantation. POAG = primary open angle glaucoma.

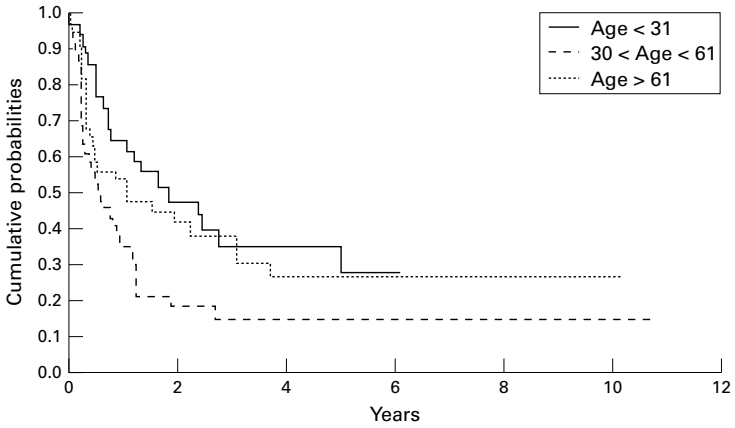

Figure 5 Kaplan-Meier survival curves based on age group (0–30 years, 31–60 years, 61–91 years), plotting the cumulative probabilities against time that intraocular pressure (IOP) remains below 22 mm Hg without additional medical treatment ("complete" success) following tube implantation.

GFS, "qualified success" in 57.6% with a fall in IOP of 46.5% (from 37.6 (8.5) mm Hg to 20.1 (11.1) mm Hg), and the target IOP was achieved in 66.1%. The results for those that had not undergone GFS, although tending to be better, were not statistically different, the "complete" and "qualified" success rates being higher at 38.3% and 63.3%, respectively, with the mean reduction in IOP of 48.3% (from 38.9 (7.9) mm Hg to 20.1 (11.0) mm Hg) being similar, and the target IOP being achieved in 71.7%. Survival analysis confirmed these findings (Fig 7) and Cox multivariate analysis showed that the number of previous GFS procedures had no statistically significant effect on outcome.

Only 24 eyes had undergone previous penetrating keratoplasty (PK), mainly in younger patients (33 (25) *v* 49 (27) years; p=0.01) with traumatic glaucoma (46.7%) or developmental glaucoma (26.3%). The "complete" and "qualified" success rates for eyes that had undergone PK were 41.7% and 62.5%, respectively, with a fall in IOP of 55.6% (from 39.2 (6.8) mm Hg to 17.4 (11.8) mm Hg), the target IOP being achieved in 62.5%. The results for those that had not undergone PK were similar ("complete" success 31.6%; "qualified" success 60%; mean reduction in IOP 45.3% (from 38.0 (8.5) mm Hg to 20.8 (10.7) mm Hg), although more achieved the target IOP (70.5%). However, survival analysis revealed no effect of previous PK on outcome.

Fifty four of the 119 eyes (45.4%) were phakic, 35 (29.4%) pseudophakic, and 30 (25.2%) aphakic at the time of tube implantation, large incision cataract surgery having been used. Patients with pseudophakia were significantly older (66 (16) years) than those with phakia (38 (28) years) or aphakic patients (36 (26)

Table 4 Patient data according to age group

Age group	*0–30 years (n=36)*	*31–60 years (n=39)*	*61–91 years (n=44)*	*p Value*
Mean (SD) age	10.9 (10.1)	46.0 (9.0)	74.3 (7.7)	
Sex (M:F, %)	39:61	69:31	34:66	0.03
Race (W:O, %)	83:17	80:20	66:34	0.04
Diagnosis (%)				
Developmental	72	23	7	<0.000001
POAG	0	3	27	0.00006
CCAG	0	8	16	0.04
Uveitic	8	23	16	NS
Traumatic	14	26	0	0.002
Neovascular	3	15	27	0.01
Miscellaneous	3	2	7	NS
Lens status (%)				
Phakic	61	48	30	0.02
Aphakic	36	26	16	NS
Pseudophakic	3	26	54	<0.000001
Previous surgery (categorical, %)	83	87	86	NS
Previous GFS (categorical, %)	72	62	57	0.007
Previous PK (%)	28	26	9	NS
Conjunctival incision (%)	53	85	84	0.0008
Implant (S:D, %)	22:88	15:85	36:64	NS
Mean (SD) follow up (months)	44.9 (26.3)	43.6 (38.2)	39.8 (34.3)	NS
Mean (SD) preop IOP (mm Hg)	37 (8)	39 (10)	39 (7)	NS
Mean (SD) highest IOP (mm Hg)	43 (9)	48 (11)	47 (9)	NS
Mean (SD) final IOP (mm Hg)	19 (9)	22 (13)	20 (11)	NS
Reduction in IOP (%)	49.5	44.9	47.9	NS
Complete success rate (%)	44.4	20.5*	36.4	0.02
Qualified success rate (%)	61.1	48.7	70.5	NS
IOP reduced by >30% (%)	75.0	56.4	75.0	NS

M:F = male:female; W:O = White:Oriental; POAG = primary open angle glaucoma; CCAG = chronic closed angle glaucoma; GFS = glaucoma filtration surgery; PK = penetrating keratoplasty; IOP = intraocular pressure; S:D = single:double.
*By survival analysis complete success was lower for patients aged 31–60 than for patients in the other age groups.

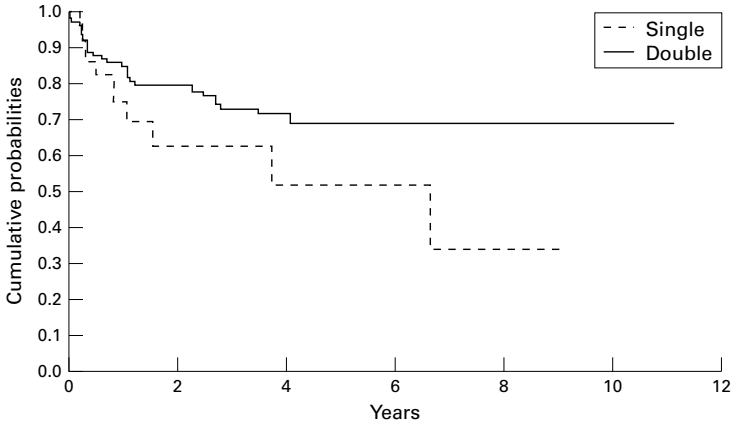

Figure 6 Kaplan-Meier survival curves based on type of Molteno tube implanted (single v double plate), plotting the cumulative probabilities against time that intraocular pressure (IOP) remains below the target IOP (set as a 30% reduction from the mean preoperative IOP) following tube implantation.

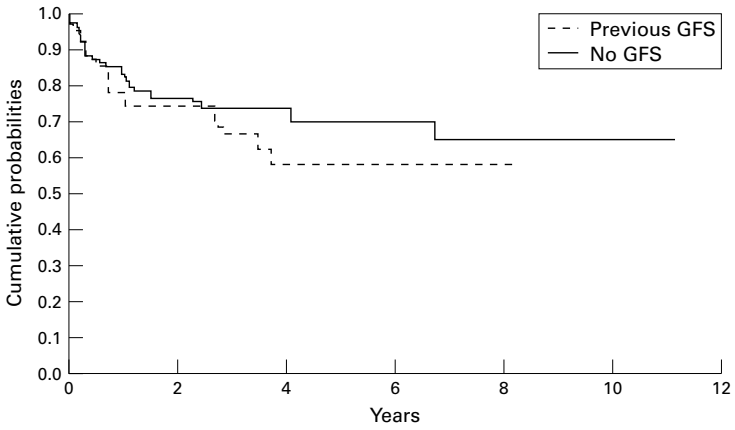

Figure 7 Kaplan-Meier survival curves based on whether or not the eye had undergone previous glaucoma filtration surgery before tube insertion, plotting the cumulative probabilities against time that intraocular pressure (IOP) remains below the target IOP (set as a 30% reduction from the mean preoperative IOP) following tube implantation.

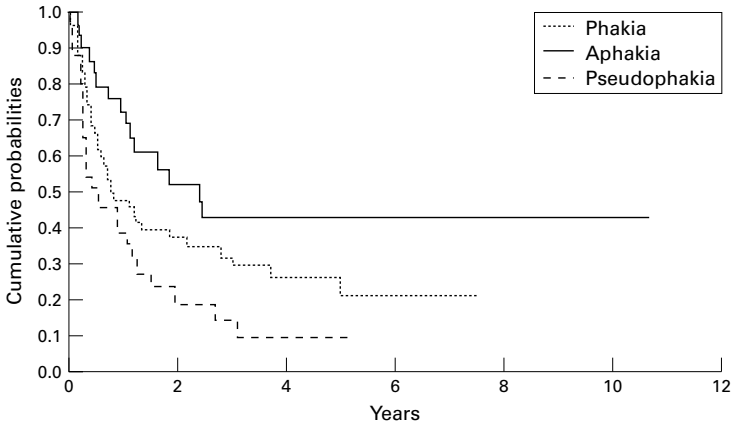

Figure 8 Kaplan-Meier survival curves based on lens status (phakia, pseudophakia, aphakia), plotting the cumulative probabilities against time that intraocular pressure (IOP) remains below 22 mm Hg without additional medical treatment ("complete" success) following tube implantation.

years; p<0.00001) and their duration of follow up was significantly less (30.3 (28.1) *v* 46.8 (30.9) and 49.4 (39.7) months; p=0.03).

For phakic eyes there were significantly more with either developmental (46.3%; p=0.003) or neovascular glaucoma (24.1%; p=0.03) and fewer with uveitic glaucoma (5.5%; p=0.005); for pseudophakic eyes there was a tendency for there to be more with uveitic glaucoma (25.7%; p=0.06) and significantly fewer with developmental glaucoma (5.7%; p=0.00007); and for aphakic eyes there were significantly more eyes with traumatic glaucoma (23.3%; p=0.04) and fewer with neovascular glaucoma (3.3%; p=0.03). The "complete" and "qualified" success rates for phakic eyes were 31.5% and 51.9% with a fall in IOP of 45.9% (38.1 (8.8) mm Hg to 20.6 (11.4) mm Hg), the target IOP being achieved in 61.1%. For pseudophakic eyes the results were similar: "complete success" in 20%; "qualified success" in 65.7%; mean reduction in IOP 46.4% (from 39.0 (7.8) mm Hg to 20.9 (11.0) mm Hg), although there was a higher attainment of target IOP (71.4%). The success rate was higher for aphakic eyes with "complete success" in 53.3%, "qualified success" in 70%, mean reduction in IOP of 50.9% (from 37.7 (7.5) mm Hg to 18.5 (10.4) mm Hg), and 80% attained the target IOP. By survival analysis (Fig 8) "complete success" was significantly greater for aphakic eyes than for pseudophakic eyes (p=0.002), and tended to be greater than the success for phakic eyes (p=0.06). "Complete success" for pseudophakic eyes also tended to be greater than for phakic eyes (p=0.06). With respect to "qualified success", the rate in aphakic eyes tended to be higher than for phakic eyes (p=0.07).

Table 5 Complications

Complication	*n (%)*
Choroidal effusion	18 (15.1)
Tube obstruction	10 (8.4)
Implant extrusion/malposition	9 (7.6)
Persistent uveitis	9 (7.6)
Flat anterior chamber	9 (7.6)
Corneal decompensation	9 (7.6)
Corneal graft failure	3 (2.5)
Retinal detachment	6 (5.0)
Hypotony	5 (4.2)
Strabismus	3 (2.5)
Cataract	3 (2.5)
Significant hyphaema	1 (0.8)
Choroidal haemorrhage	1 (0.8)

PREOPERATIVE IOP, SEX, AND RIGHT/LEFT EYE

The level of preoperative IOP (mean or highest recorded IOP), sex, and side of procedure had no statistically significant effects on the outcome of tube implantation.

CHANGE IN VISUAL ACUITY AND COMPLICATIONS

Visual acuity outcomes, defined as a change of two or more Snellen lines, were improved in 9%, unchanged in 70%, and worse in 21% at the end of the follow up period. Complications considered to have occurred as a consequence of tube insertion are listed in Table 5.

Discussion

Although success rates of 90–100% have been reported following tube implantation,[3–5] the overall results in the present study were similar to those of most previous studies.[3–9] However, variation in case selection, diagnostic categorisation, implant type, surgical technique, duration of follow up, and criteria for success in

previously published studies makes simple comparison inappropriate. Since many patients requiring tubes are young, long term results[6] and those that have applied survival analysis are of particular interest.[7–9] After a mean follow up of 30 months, a relatively high "qualified success" rate of 72% has been reported in a group of 82 black patients with refractory glaucoma and single plate tube implantation.[6] "Qualified success" rates for the diagnostic groups were 83% for aphakic/pseudophakic, 80% for uveitic, 73% for POAG, 67% for neovascular, and 50% for developmental glaucoma. In agreement with the present study and that of Lloyd *et al*,[7] therefore, success appeared to be higher in eyes with aphakic glaucoma than in those with various phakic glaucomas. Interestingly, in the present study, by splitting aphakic eyes from pseudophakic eyes, it appeared that pseudophakia was a significant risk factor for tube failure. No obvious compounding factors could be identified to explain this; indeed, the pseudophakic group consisted of older patients and more with uveitic glaucoma, factors more likely to be protective than deleterious. In addition, the results of the present study revealed an increased tendency for failure in eyes with traumatic, developmental and, in particular, neovascular glaucoma, eyes with the latter two diagnoses faring least well in other studies.[6 7]

Mills and coworkers reported the results of either single or double plate Molteno tube implantation in 77 eyes after a mean follow up of 44 months, comparable with that of the present study.[9] The overall "qualified success" rate was 57%, similar to our rate of 60.5%. Their group with uveitic glaucoma had the highest "qualified success" rate of 75%, the same as that in our study when attainment of target IOP was considered as the criterion for success. As suggested by other studies,[7 8] Mills *et al* found neovascular glaucoma to be a significant risk factor for failure with an overall "qualified success" rate of 50%, similar to that reported in the present study.[9] An additional risk factor for failure identified by Mills *et al* was young age, but only after controlling for diagnostic category.[9] In the present study no convincing effect of age was identified, although multiple confounding factors may have masked a true effect of age.

The use of single plate tubes versus double plate tubes has been studied by Heuer *et al*[10] who concluded that double plate implantation more frequently afforded IOP control; a similar tendency was found in our study and that of Mills *et al*.[9] Since patients were not randomised to the type of implant and selection was based on preoperative factors including IOP, the difference was probably reduced in these studies.

As shown in this study and those of others,[7–9] "qualified success" showed a steady, almost linear, decline over time whereas the decline occurred in a more exponential manner for "complete success". In considering "complete success", the results are not influenced by the differing degrees and variable timing of additional medical treatment so the pattern of failure can be more readily related to the mechanism of failure. The exponential pattern of failure indicated that, if failure occurred, early loss of IOP control was more common than late failure but there was a continual slow attrition rate for up to at least 4 years after surgery. Since failure is more likely in the first postoperative year than in subsequent years, postoperative management should take this into account and the frequency of postoperative visits should be more frequent in the early postoperative period and less often later on. Furthermore, the propensity for early rather than late failure provides clues as to the mechanism of failure, perhaps indicating that the major cause of early failure is the same as with trabeculectomy—namely, "excessive" wound healing[11] with a slower wound remodelling process and other factors playing a part in late failure. Histopathological[12–19] and immunohistochemical[19] studies indicate that this is likely.

The key factors determining adequate flow and IOP reduction are the resistance of the capsular wall to aqueous flow and the total surface area of encapsulation.[20–22] Histological studies have supported this by demonstrating that, in comparison with functioning implant blebs, failed blebs have thicker walls made of higher density, relatively hypocellular and avascular connective tissue. Thus, improved results following tube surgery have involved the modulation of early postoperative wound healing with adjunctive mitomycin C.[23 24] In a larger study, however, Lee and coworkers[25] reported no advantage with adjunctive mitomycin C.

Complications of tube surgery are relatively common[6–9 26–28] and there is evidence that the adjunctive use of mitomycin C increases the rate of complications and, in particular, early postoperative hypotony,[25] tube blockage,[24] and tube erosion through the conjunctiva.[23] The authors believe that, in certain eyes thought to be at high risk of tube failure, the use of antiproliferative agents should be considered in a manner similar to the selection of such adjunctive therapy with augmented trabeculectomy. It is probable that, in eyes at particularly high risk of failure, mitomycin C will offer the best chance of IOP control. Postoperative subconjunctival 5-fluorouracil injections should also be considered in cases where failure appears to be imminent. However, the use of potent agents such as mitomycin C should be used with caution and the risk:benefit ratio considered before surgery.

In conclusion, this study has shown that, although tube implant surgery is useful in the management of eyes considered to be at high risk of trabeculectomy failure, there is still a significant rate of failure, particularly in the early postoperative period. Pseudophakia was identified as a significant risk factor for failure. Inhibition of early postoperative wound healing with adjunctive antiproliferative agents may help to improve the outcome, and the results of controlled randomised studies are eagerly awaited.

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