



# Risk Factors for Failure in Double-Plate Tube Surgery for Refractory Glaucoma: 25 Years Surgical Experience

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**Purpose:** To investigate risk factors associated with success and failure in double-plate tube surgery.

**Methods:** This retrospective case-series observational study included 243 consecutive eyes that underwent anterior-segment double-plate tube surgery from 1990 to 2015. Evaluation of the efficacy of the device was based on the final intraocular pressure (IOP) and the need for anti-glaucoma medication. We also assessed success and failure according to risk factors for trabeculectomy and an early hypertensive phase (HP).

**Results:** Preoperative IOP was  $37.3 \pm 13.1$  mmHg (mean  $\pm$  SD) with  $3.0 \pm 0.7$  medications. After a median follow-up of 44.3 months, the mean IOP was  $14.6 \pm 6.3$  mmHg with  $0.4 \pm 1.0$  medications. The final IOPs ranged from 6 to 21 mmHg in 87.24% of eyes; however, 25.47% required medication. No risk factors studied were associated with surgical failure. Preoperative IOP, glaucoma type, previous surgery, previous anti-glaucoma drugs, implant type, and HP were associated with partial success ( $p < 0.05$ ). HP and preoperative use of brimonidine reduced the probability of complete success by 66.9% and 68.2%, respectively ( $p < 0.05$ ). HP was more likely when chronic preoperative prostaglandin analogues were administered (odds ratio [OR] 4.286; 95% confidence intervals [CI] 1.593–11.529;  $P = 0.0039$ ) and when the tube was located in the posterior chamber (OR 3.561; 95% CI 1.286–9.861;  $P = 0.0145$ ).

**Conclusion:** Tube surgery is effective and seems to be independent of the major risk factors for glaucoma surgery. However, previous surgery and some chronic preoperative drugs are related to the need for glaucoma medication to achieve the target pressure.

**Keywords:** glaucoma drainage implants, tube shunt, double-plate Molteno implant, glaucoma surgery, hypertensive phase, refractory glaucoma

## Summary Guidelines

Risk factors associated with trabeculectomy failure were analysed in Double-plate implant surgery by reviewing a large cohort of patients operated over a 25-year period.

Double-plate drainage implants are effective in controlling intraocular pressure (IOP) in refractory glaucoma and seems to be independent of the major risk factors for glaucoma surgery. However, prior ocular surgery and some chronic preoperative drugs are related to the need for glaucoma medication to achieve the target IOP.

## Introduction

Glaucoma drainage devices (GDDs) were introduced to control intraocular pressure (IOP) in cases of refractory glaucoma where standard filtering procedures were

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expected to fail, but since the tube versus trabeculectomy study (TVT) showed a higher success rate for tube surgery over trabeculectomy in eyes with previous filtering and/or cataract surgery, there has been an increase in indications for GDD surgery in almost all clinical settings, except as primary surgery in naive eyes with open-angle glaucoma and healthy conjunctival status.<sup>1-4</sup>

Even though both techniques share the complex cell turnover during their bleb and capsular maturation, the filtration capsule of GDDs has different morphologic features and responds differently to anti-mitotic drugs.<sup>5-8</sup> In addition, there is no early postoperative hypertensive phase (HP) after trabeculectomy or any other filtering surgery except for GDDs.

The main cause of the failure of filtering glaucoma surgery remains filtering bleb obliteration due to subconjunctival scarring. The factors responsible are those that stimulate subconjunctival fibrotic proliferation, which varies widely between patients and may be genetic, acquired, or a combination of both. Among the acquired causes are the prolonged use of ocular hypotensive drops that cause long-term ocular surface toxicity, especially those containing preservatives such as benzalkonium chloride, the preoperative intraocular inflammatory status, or the sum of previous intraocular surgeries.<sup>9</sup> However, it is still unclear which preoperative conditions predict the final results of GDD, as little is known about the risk factors for the failure of drainage implants and whether the same risk factors as for trabeculectomy should be considered.

The aim of this study was to analyse the risk factors for GDD surgical outcomes and their association with the HP by review of a large cohort of patients operated on by our department. The patients evaluated had been operated on in a period of 25 years by the same surgeon using the same surgical technique and protocol and assuming that certain differences have been derived from the different follow-up time of the patients.

## Methods

We performed a retrospective 25-year consecutive case-series observational study to analyse the impact of trabeculectomy risk factors on the success of double-plate implant surgery. The study adhered to the tenets of the Declaration of Helsinki and institutional review board approval, from our institution (Hospital Universitario de Bellvitge, L'Hospitalet, Spain) was obtained: document 11/16, Ref# EPA031/16. Data confidentiality and consent for data

review was signed by the patients on their first visit at the clinic following the laws in force in Spain.

Eyes from adults with glaucoma who had undergone anterior-segment, over or below the iris, superior double-plate implant surgery (Double-plate Molteno [DPM], Ophthalmic Ltd., Dunedin, New Zealand or Double-plate silicone implant [DPSI] FCI S.A.S, Paris, France) by the same surgeon (SD) between 1990 and 2015 were included. Both implants have the same size and design but different plate material. Eyes with follow-up <3 months, clinically relevant missing data, or a follow-up performed in other clinics were excluded.

All devices were implanted in the upper quadrants by passing the second plate beneath the superior rectus muscle under retrobulbar anaesthesia and sedation. Topical 5-fluorouracil (50 mg/mL) was applied in all cases by impregnating the scleral surface with a sponge. A 23-gauge needle entry was made toward the anterior or posterior chamber, according to the surgeon's criteria. A 6/0 polyglactin ligature was used as a complete flow restrictor. In eyes with advanced glaucoma in which the preoperative IOP exceeded 40 mmHg, tube fenestrations or orphan trabeculectomy was performed to prevent high IOP immediately after surgery.

Alcohol-preserved donor scleral graft was used to cover the extraocular portion of the tube. Neovascular glaucoma (NVG) cases underwent pan-retinal photocoagulation, peripheral retinal cryotherapy, or anti-VEGF intraocular injections according to the retina specialist's criteria, prior to GDD implantation.

Postoperative treatment consisted of tobramycin+dexamethasone drops 3 mg/mL + 1 mg/mL (Tobradex<sup>®</sup>, Novartis Farmacéutica, S.A., Barcelona, Spain) and dexamethasone 1 mg/mL drops (Dexametasona<sup>®</sup>, Novartis Farmacéutica, S.A., Barcelona, Spain) three times daily administered together with the preoperative hypotensive medication. Once the tube ligature was released, topical dexamethasone was tapered over 2 months until the eye was quiescent. HP was treated with topical and subconjunctival steroids, oral carbonic anhydrase inhibitors, and other hypotensive ophthalmic drops when needed.

## Primary and Secondary Outcomes

Primary outcomes were the rate of surgical success and failure based on the achievement of target IOP with or without glaucoma medication. Qualified success (QS) was defined as an IOP ranging from 6 to 21 mmHg and a 20% decrease in IOP, with (partial success [PS]) or without (complete success [CS]) the need for anti-glaucoma medication. Failure was defined as an IOP > 21 mmHg or lack

of IOP reduction by at least 20% from baseline, an IOP of  $\leq 5$  mmHg resulting from the implant, the need for additional glaucoma surgery, or removal of the GDD.

Secondary outcomes included the presence and impact of known risk factors for filtering surgical failure upon GDD success rate, the development of HP defined as a sudden and reversible increase in IOP ( $>30$  mmHg) 2 to 4 weeks after the tube opening and initiation of percolation of the aqueous humour through the tube (not being caused by GDD malfunction), and the contribution of surgical technique variations (plate material and intraocular location of the tube) to the final result.<sup>10</sup>

In eyes with complications unrelated to the GDD, the last IOP before the development of the complication was recorded for the study analysis and the follow-up was discontinued.

The statistical analyses were performed using the SPSS software (IBM SPSS Statistics, Version 24). The groups were compared using the Student's *t*-test or the Wilcoxon and  $\chi^2$  or Fisher's exact test for continuous and categorical variables. Multivariate logistic regression was performed to identify risk factors associated with failure, complete and partial success, and the HP event. A *p* value of  $<0.05$  was considered statistically significant.

## Results

We studied 243 consecutive eyes of 240 Caucasian adults with a mean follow-up of  $66.8 \pm 64$  months (mean $\pm$ SD).

The demographic data (Table 1) showed no association with failure or the need for medication at the end of the follow-up.

NVG was the most frequent aetiology (88 eyes, 36.2%), mainly due to diabetic retinopathy (45 eyes, 60.0%), followed by central retinal vein occlusion (21 eyes, 28%), carotid artery ischemia (4 eyes, 5.3%) and other causes (5 eyes, 6.6%). All implants had a similar double-plate design and size but, with respect to the material, DPM has polymethyl methacrylate (PMM) plates and was used in 99 eyes while DPSI with silicon plates was implanted in 144 eyes. The tube was located over the iris in the anterior chamber or below the iris in the posterior chamber in 53.1% (129 eyes) and 46.9% (114 eyes), respectively. Tube fenestrations and orphan trabeculectomy were performed in two and one eyes, respectively.

The mean preoperative IOP of  $37.3 \pm 13.1$  mmHg with  $3 \pm 1$  glaucoma medications fell to a final mean postoperative IOP of  $14.6 \pm 6.3$  mmHg and  $0.4 \pm 1$  medications. At the end of the follow-up, 31 eyes (12.8%) had failed. In the QS group, the mean postoperative IOP was  $13.4 \pm 4$  mmHg. In this group, CS was achieved in 159 (65.4%) eyes, with a mean medication-free IOP of  $12.8 \pm 4$  mmHg and PS in 53 (21.8%) eyes, with a final IOP of  $15.0 \pm 3$  mmHg and  $1.5 \pm 1$  medications. Four eyes in the failure group required another tube surgery and nine eyes underwent diode laser treatment to achieve the target IOP.

**Table 1** Sociodemographic and Clinical Data

	Failure (N = 31)		Qualified Success (N = 212)		Total (N = 243)		P value
Age (years)							
Mean (SD)	56.2	(19)	60.6	(16)	60.1	(17)	0.1693
Median (IQR)	56	(41;71)	63	(52;73)	63	(51;73)	
Min-Max		22–87		18–92		18–92	
Sex, (%)							0.2955
Male	14	(45.2)	117	(55.2)	131	(53.9)	
Female	17	(54.8)	95	(44.8)	112	(46.1)	
Follow-up time (months),							0.9216
Mean (SD)	69.7	(76)	66.4	(63)	66.8	(64)	
Median (IQR)	44.3	(23;84)	44.4	(22;93)	44.3	(22;92)	
Study eye, (%)							0.6794
Right eye	16	(51.6)	101	(47.6)	117	(48.1)	
Left eye	15	(48.4)	111	(52.4)	126	(51.9)	

**Notes:** Ages compared using the Student's *t*-test (normal distribution checked). Sex and study eye compared using the  $\chi^2$  test. Follow-up time: comparison performed using the Wilcoxon test (distribution not normal). There were no significant between-group differences regarding age, sex, and follow-up time.

**Abbreviations:** SD, standard deviation; IQR, interquartile range.

We consider three exceptions: Patients number 53, 32, and 381 who, despite not achieving a 20% decrease in IOP, reached their target pressures between 6 and 21 mmHg and the withdrawal of the three drugs to which they were local and systemically intolerant were therefore regarded as success cases.

There were no significant differences between the failure and QS groups ( $p=0.0879$ ) and between the CS and PS groups ( $p=0.3746$ ) with respect to changes in visual acuity three months after surgery. One line of vision was gained in 52 (21.7%) eyes and lost in 19 (7.9%) eyes. More than one line was lost in 45 (18.8%) eyes.

None of the known risk factors for trabeculectomy failure studied were associated with the probability of achieving QS versus failure (Table 2), although comparison of the PS and CS groups showed some significant differences (Table 3).

Follow-up time was significantly longer in the PS group than in the CS group ( $62.4 \pm 63$  vs.  $78.2 \pm 61$  months,  $p=0.0117$ ). Eyes with a higher mean preoperative IOP had a lower final IOP. With respect to aetiologies, NVG significantly attained CS in 88.46% of the QS, whereas the other types of glaucoma showed a higher proportion of PS over CS cases ( $p=0.0022$ ).

With respect to the effect of previous surgeries that changed the ocular anatomy and conjunctival conditions, naive eyes achieved CS in 60 (84.5%) eyes compared with 98 (70%) of previously operated eyes ( $p=0.0217$ ). Univariate analysis showed a higher risk of a requirement for glaucoma medication in eyes with previous surgery (OR 0.428; 95% CI 0.205–0.894;  $p=0.0240$ ). Eyes with DPM required fewer hypotensive drugs than DPSI with a silicone plate ( $p=0.0095$ ) (Table 4), but the multivariate model did not show the implant type was a risk factor for PS (OR 3.593; 95% CI 0.969–13.313;  $p=0.0557$ ).

Almost all patients were on maximum medical treatment before surgery (median of 3 and mean of  $3 \pm 1$  drug administered via a median of five drops for all three groups). Comparison of the CS and PS groups showed significant differences in the use of two drugs: atropine ( $p=0.0022$ ) and brimonidine ( $p=0.0034$ ). The logistic multivariate model adjusted for aetiology, implant type, and HP did not show an increased probability of CS with the preoperative use of atropine, while preoperative treatment with brimonidine showed a higher probability of PS than CS (OR 0.318; 95% CI 0.108–0.94;  $p=0.0383$ ) when adjusted for glaucoma type, implant type, and preoperative atropine treatment.

Forty-eight eyes (19.8%) had HP: 10 (32.3%) failed eyes, 18 (34%) PS eyes, and 20 (12.6%) CS eyes ( $p=0.0004$ ). Multivariate analysis adjusted for aetiology, implant type, and preoperative atropine treatment showed that HP was associated with a 66.3% reduction in the odds of CS (OR 0.331; 95% CI 0.127–0.866;  $p=0.0242$ ).

Analysis of the differences between eyes with and without HP showed a significantly higher rate of HP when some risk factors were present (Table 5).

HP was seen in 9 (10.2%) eyes with NVG, 9 (19.1%) aphakic eyes with or without anterior chamber IOL, 10 (22.2%) eyes with previous complicated intraocular surgery, 4 (25.0%) Uveitic eyes, 9 (32.1%) eyes with previous failed glaucoma surgery, and 7 (36.8%) cases with juvenile/congenital/syndromic glaucoma ( $p=0.0390$ ). Tube location in the posterior chamber ( $p<0.0001$ ), double-plate silicone implant ( $p<0.0001$ ), and a history of previous ocular surgery ( $p=0.0012$ ) were associated with a higher frequency of HP, while a higher preoperative IOP was associated with a lower incidence of HP ( $p=0.0057$ ). The number of preoperative drugs were similar in both groups: mean $\pm$ SD  $3 \pm 1$ ; median 3; and range 0–5. Preoperative use of prostaglandin analogs, carbonic anhydrase inhibitors and brimonidine was significantly associated with HP, but preoperative atropine, beta-blocker, and dipivalil-epinephrine were associated with a lower frequency of HP (Table 6).

Logistic multivariate analysis, adjusted for aetiology, implant type, and preoperative atropine use, identified the following predictors of HP: posterior chamber location of the tube (OR 3.561; 95% CI 1.286–9.861;  $p=0.0145$ ) and preoperative use of prostaglandin analogs (OR 4.286; 95% CI 1.593–11.529;  $p=0.0039$ ). The rate of complications related to the GDD implantation and complications that have not been considered derived from the implant surgery are listed in Tables 7 and 8.

## Discussion

The results of this study show that double-plate implant surgery is very effective in lowering IOP in refractory glaucoma, with a QS rate of 87.3% at 5 years. We did not include eyes with light perception loss, postoperative hypotonia, or any other complication not due to implant surgery or the tube per se, which may be the reason for the low percentage of failures compared with other studies that reported a QS of 60.5% based on similar success criteria.<sup>11</sup> In our study, tube surgery resulted in IOP reductions of 60.8% to a postoperative mean IOP of  $14.6 \pm 6.3$

**Table 2** Determination of Failure and Qualified Success by Comparison of the Risk Factors Studied

	Failure (N = 31)		Qualified Success (N = 212)		Total (N = 243)		P value
<b>Preoperative IOP</b>							0.8605
Mean (SD)	36.9	(13)	37.3	(13)	37.3	(13)	
Median (IQR)	36	(24;48.2)	35	(28;46)	35	(26;46)	
Min – Max		18–60		12–72		12–72	
<b>Etiology, n (%)</b>							0.2248
NVG	10	(32.3)	78	(36.8)	88	(36.2)	
Juvenile/congenital glaucoma and syndromes	5	(16.1)	14	(6.6)	19	(7.8)	
Aphakia/pseudophakia and AC IOL	5	(16.1)	42	(19.8)	47	(19.3)	
Previous failed glaucoma surgery	6	(19.4)	22	(10.4)	28	(11.5)	
Penetrant keratoplasty/trauma/complicated intraocular surgery	3	(9.7)	42	(19.8)	45	(18.5)	
Uveitis	2	(6.5)	14	(6.6)	16	(6.6)	
<b>Tube localization, n (%)</b>							0.5746
AC	15	(48.4)	114	(53.8)	129	(53.1)	
PC	16	(51.6)	98	(46.2)	114	(46.9)	
<b>Type of implant, no. (%)</b>							0.3536
Double-plate Molteno® Ophthalmic (Dunedin)	15	(48.4)	84	(39.6)	99	(40.7)	
Double-plate implant (FCI S.A.S Paris, France)	16	(51.6)	128	(60.4)	144	(59.3)	
<b>Categorized previous surgery, no. (%)</b>							0.3845
No previous surgery	8	(25.8)	71	(33.6)	79	(32.6)	
Previous surgery	23	(74.2)	140	(66.4)	163	(67.4)	
<b>Number of previous surgeries, no.</b>							
Missing data, no.	0		1		1		
Mean (SD)	1.7	(2)	1.4	(2)	1.5	(2)	
Median (IQR)	2	(0;2)	1	(0;2)	1	(0;2)	
Min – Max		0–13		0–9		0–13	
<b>Hypertensive phase, no. (%)</b>							0.0612
No	21	(67.7)	174	(82.1)	195	(80.2)	
Yes	10	(32.3)	38	(17.9)	48	(19.8)	
<b>Treatment before surgery (compounds), no.</b>							
Mean (SD)	3	(1)	3	(1)	3	(1)	
Median (IQR)	3	(3;3)	3	(3;3)	3	(3;3)	
Min-Max		2–4		0–5		0–5	
<b>Number of eyedrops before surgery, no.</b>							0.3568
Missing data, no	1		18		19		
Mean (Std)	4.7	(2)	4.5	(1)	4.5	(1)	
Median (IQR)	5	(4;5)	5	(4;5)	5	(4;5)	
[Min - Max]		[2–7]		[0–8]		[0–8]	
<b>Preoperative atropine, no. (%)</b>							0.5606
No	22	(73.3)	132	(68.0)	154	(68.8)	
Yes	8	(26.7)	62	(32.0)	70	(31.3)	
<b>Preoperative beta-blockers, no. (%)</b>							1.0000
No	2	(6.7)	13	(6.7)	15	(6.7)	
Yes	28	(93.3)	181	(93.3)	209	(93.3)	
<b>Preoperative PGA, no. (%)</b>							0.6871
No	25	(83.3)	154	(80.2)	179	(80.6)	
Yes	5	(16.7)	38	(19.8)	43	(19.4)	

(Continued)

**Table 2** (Continued).

	Failure (N = 31)		Qualified Success (N = 212)		Total (N = 243)		P value
<b>Preoperative CAI, no. (%)</b>							0.8877
No	21	(70.0)	134	(68.7)	155	(68.9)	
Yes	9	(30.0)	61	(31.3)	70	(31.1)	
<b>Preoperative brimonidine, no. (%)</b>							0.5338
No	23	(76.7)	154	(81.5)	177	(80.8)	
Yes	7	(23.3)	35	(18.5)	42	(19.2)	
<b>Preoperative dipivalil-epinephrine, no. (%)</b>							0.4316
No	13	(43.3)	96	(51.1)	109	(50.0)	
Yes	17	(56.7)	92	(48.9)	109	(50.0)	
<b>Preoperative pilocarpine, no. (%)</b>							1.0000
No	27	(90.0)	167	(88.8)	194	(89.0)	
Yes	3	(10.0)	21	(11.2)	24	(11.0)	

**Notes:** Comparison of study eye, tube localization, previous surgery, preoperative atropine, prostaglandins analogues, topical carbonic anhydrase inhibitor, brimonidine and dipivalil-epinephrine treatment performed using the Chi<sup>2</sup> test. Comparison of etiology and beta-blockers and pilocarpine preoperative treatment performed using the Fisher's exact test. There is no significant difference between the two groups regarding distribution of all the risk factors studied.

**Abbreviations:** NVG, neovascular glaucoma; AC IOL, anterior chamber intraocular lens; AC, anterior chamber; PC, posterior chamber; SD, standard deviation; IQR, interquartile; PGA, prostaglandin analogs; CAI, carbonic anhydrase inhibitor.

**Table 3** Determination of Partial Success and Complete Success by Comparison of the Risk Factors Studied

	Complete Success (N = 159)		Partial Success (N = 53)		Total (N = 212)		P value
<b>Preoperative IOP no.</b>							0.0054
Mean (SD)	38.8	(14)	33	(11)	37.3	(13)	
Median (IQR)	38	(28;50)	32	(25;37)	35	(28;46)	
Min-Max	-	12–72	-	15–64	-	12–72	
<b>Aetiology, no. (%)</b>							0.0022
NVG	69	(43.4)	9	(17.0)	78	(36.8)	
Juvenile/congenital glaucoma and syndromes	8	(5.0)	6	(11.3)	14	(6.6)	
Aphakia/pseudophakia and AC IOL	31	(19.5)	11	(20.8)	42	(19.8)	
Previous failed glaucoma surgery	12	(7.5)	10	(18.9)	22	(10.4)	
Penetrant keratoplasty/trauma/complicated	31	(19.5)	11	(20.8)	42	(19.8)	
Intraocular surgery							
Uveitis	8	(5.0)	6	(11.3)	14	(6.6)	
<b>Previous ocular surgery, no. (%)</b>							0.0217
No previous surgery	60	(38.0)	11	(20.8)	71	(33.6)	
Previous surgery	98	(62.0)	42	(79.2)	140	(66.4)	
<b>Hypertensive phase, no. (%)</b>							0.0004
No	139	(87.4)	35	(66.0)	174	(82.1)	
Yes	20	(12.6)	18	(34.0)	38	(17.9)	
<b>Preoperative atropine, no. (%)</b>							0.0022
No	93	(62.4)	39	(86.7)	132	(68.0)	
Yes	56	(37.6)	6	(13.3)	62	(32.0)	
<b>Preoperative brimonidine, no. (%)</b>							0.0034
No	124	(86.1)	30	(66.7)	154	(81.5)	
Yes	20	(13.9)	15	(33.3)	35	(18.5)	

**Notes:** Preoperative IOP and aetiology compared using Fisher's exact test. Previous surgery, hypertensive phase, and preoperative atropine and brimonidine compared using the Chi<sup>2</sup> test.

**Abbreviations:** NVG, neovascular glaucoma; SD, standard deviation; IQR, interquartile range; AC IOL, anterior chamber intraocular lens; IOP, intraocular pressure.



**Table 4** Determination of Partial Success and Complete Success by Implant Characteristics and Intraocular Location

	Complete Success (N = 159)		Partial Success (N = 53)		Total (N = 212)		P value
Tube location, no. (%)							0.8736
Anterior chamber	86	(54.1)	28	(52.8)	114	(53.8)	
Posterior chamber	73	(45.9)	25	(47.2)	98	(46.2)	
Type of implant, no. (%)							0.0095
Double-plate Molteno® Ophthalmic (Dunedin)	71	(44.7)	13	(24.5)	84	(39.6)	
Double-plate silicone implant (FCI S.A.S., France)	88	(55.3)	40	(75.5)	128	(60.4)	

**Notes:** Implant type and tube location compared using the  $\chi^2$  test. There was a significant difference between the two groups regarding the type of implant.

**Table 5** Determination of the Hypertensive Phase by Comparison of the Risk Factors Studied

	No (HP) (N = 195)		Yes (HP) (N = 48)		Total (N = 243)		P value
Preoperative IOP	38.4	(13)	32.6	(13)	37.3	(13)	0.0057
Previous surgery, no.(%)							0.0012
No previous surgery	73	(37.4)	6	(12.8)	79	(32.6)	
Previous surgery	122	(62.6)	41	(87.2)	163	(67.4)	
Aetiology, no. (%)							0.0390
NVG	79	(40.5)	9	(18.8)	88	(36.2)	
Juvenile congenital glaucoma and syndromes	12	(6.2)	7	(14.6)	19	(7.8)	
Aphakia/pseudophakia AC IOL	38	(19.5)	9	(18.8)	47	(19.3)	
Previous failed glaucoma surgery	19	(9.7)	9	(18.8)	28	(11.5)	
Penetrant keratoplasty/trauma/complicated intraocular surgery	35	(17.9)	10	(20.8)	45	(18.5)	
Uveitis	12	(6.2)	4	(8.3)	16	(6.6)	
Tube localization, no. (%)							<0.0001
AC	117	(60.0)	12	(25.0)	129	(53.1)	
PC/retroiris	78	(40.0)	36	(75.0)	114	(46.9)	
Type of implant, no. (%)							<0.0001
Double-plate Molteno® Ophthalmic (Dunedin)	95	(48.7)	4	(8.3)	99	(40.7)	
Double-plate silicone implant (FCI S.A.S France)	100	(51.3)	44	(91.7)	144	(59.3)	

**Notes:** Preoperative IOP compared using the Student's *t*-test (normal distribution checked). Aetiology, tube location and type of implant compared using the  $\chi^2$  test. There was a significant difference between the two groups regarding preoperative IOP, distribution of the aetiology, tube location, and type of implant.

**Abbreviations:** NVG, neovascular glaucoma; AC IOL, anterior chamber intraocular lens; AC, anterior chamber; PC, posterior chamber.

mmHg on  $0.4 \pm 1$  medications. Likewise, Thompson et al reported similar results, with a probability of IOP control below 21 mmHg of 0.79 (95% CI; 0.71–0.87), and a mean IOP of  $14.5 \pm 3.4$  mmHg on 0.7 medications.<sup>12</sup>

We found significant differences between the CS and PS groups regarding the type of glaucoma, which is frequently a heterogeneous factor in other reports. Some authors have reported, although in smaller series, that the type of glaucoma is a predictor of the success of borderline significance ( $p=0.09$ ).<sup>13</sup> In contrast with studies in which neovascular glaucoma achieved lower success rates (40–53%), we found that NVG needed fewer anti-glaucoma medications than other types of glaucoma, with 88.6% achieving QS and 88.5% of those achieving CS.<sup>11,13,14</sup> A possible explanation is that some

NVG eyes developed hypotony or lost light perception due to retinal detachment (not associated with the implant), long after the tube surgery, and therefore we did not consider them as failures, unlike other studies that did.<sup>13</sup>

In these eyes, there is lower aqueous humour inflow due to reduced production rates as a consequence of the chronic ischemic status of the ciliary body. The same rationale may explain why the group with a miscellaneous condition (complicated previous intraocular surgery and severe trauma) had such a high QS rate (93.3%), of whom 73.8% achieved CS, confirming the impression of previous studies that verify that drainage implants are especially efficient in traumatic eyes.<sup>15</sup>

The expression of inflammation mediators from the cytokine interleukin family increases in the aqueous humour of

**Table 6** Determination of the Hypertensive Phase by Comparison of Topical Treatment

	No (N = 195)		Yes (N = 48)		Total (N = 243)		P value
Preoperative treatment, no.	195		48		243		
Mean (SD)	3	(1)	3	(1)	3	(1)	
Median (IQR)	3	(3;3)	3	(3;3)	3	(3;3)	
Min-Max		0–5		0–5		0–5	
Preoperative atropine, no. (%)							0.0003
No	116	(63.4)	38	(92.7)	154	(68.8)	
Yes	67	(36.6)	3	(7.3)	70	(31.3)	
Preoperative beta-blockers, no. (%)							0.0362
No	9	(4.9)	6	(14.6)	15	(6.7)	
Yes	174	(95.1)	35	(85.4)	209	(93.3)	
Prostaglandin analogues, no. (%)							<0.0001
No	159	(87.4)	20	(50.0)	179	(80.6)	
Yes	23	(12.6)	20	(50.0)	43	(19.4)	
Preoperative topical carbonic anhydrase inhibitor							0.0004
No	135	(74.2)	20	(46.5)	155	(68.9)	
Yes	47	(25.8)	23	(53.5)	70	(31.1)	
Preoperative brimonidine, no. (%)							<0.0001
No	155	(86.1)	22	(56.4)	177	(80.8)	
Yes	25	(13.9)	17	(43.6)	42	(19.2)	
Preoperative dipivalil-epinephrine, no. (%)							<0.0001
No	76	(42.5)	33	(84.6)	109	(50.0)	
Yes	103	(57.5)	6	(15.4)	109	(50.0)	
Preoperative pilocarpine, no. (%)							0.5823
No	158	(88.3)	36	(92.3)	194	(89.0)	
Yes	21	(11.7)	3	(7.7)	24	(11.0)	

**Notes:** Atropine, prostaglandin analogues, topical carbonic anhydrase inhibitor, brimonidine and dipivalil-epinephrine compared using the Chi<sup>2</sup> test. Beta-blockers and pilocarpine compared using Fisher's exact test. There was a significant difference between the two groups regarding all preoperative drops except for pilocarpine.

**Abbreviations:** SD, standard deviation; IQR, interquartile range.

certain types of glaucoma such as uveitic glaucoma.<sup>16</sup> This stimulates the fibroproliferative process and increases trabeculectomy failure rates.<sup>17</sup> However, in our series, tube surgery was resistant to active intraocular inflammation, with 87.5% of QS in uveitic glaucoma. These results are in agreement with those of other studies with QS rates between 75% and 89.5% and suggest that GDD surgery in patients with uveitis has a similar effect on IOP as in patients without uveitis.<sup>11,13,18,19</sup> Nevertheless, the uveitic group in our study showed less IOP control than other aetiologies, since only 57.1% of the QS eyes achieved CS.

Various studies have investigated the efficacy of GDD in developmental glaucoma, but the few that used double-plate implants reported differing results, with success rates ranging from 100% to 59%.<sup>20,21</sup> Ah-Chan reported a probability of achieving an IOP below 21 mmHg of 0.71 (95% CI

0.58–0.85) at 15 years of follow-up, with no mention of hypotensive treatment, similar to the 73.7% of QS in our series.<sup>22</sup>

Previous conjunctival surgery for glaucoma or any other type of surgery with conjunctival scarring is considered a strong risk factor for trabeculectomy failure, but was not a risk factor for tube surgery failure in our study, in concordance with other authors, although it did affect the ultimate need for hypotensive agents.<sup>11,13</sup>

In our study, 47 aphakic and pseudophakic eyes had an unexpected QS rate of 89.4%, in contrast to smaller series with lower success rates (58–78%), but, in which, the type of cataract extraction technique or intraoperative complications plausibly affecting overall glaucoma surgery success were not described.<sup>13,22</sup>



**Table 7** Complications Related to the GDD

Fibrine clot	17(22)
Persistent corneal oedema	9(11.7)
Corneal graft rejection	6(7.8)
Shallow or flat anterior chamber	6(7.8)
Diplopia	6(7.8)
Tube repositioning	6(7.8)
Choroidal effusion	4(5.2)
Suprachoroidal haemorrhage	3(3.9)
Aqueous misdirection	3(3.9)
Cystoid macular oedema	3(3.9)
Tube exposure	3(3.9)
Tube retraction	2(2.6)
Tube obstruction	2(2.6)
Dellen	2(2.6)
Sterile endophthalmitis	2(2.6)
Plate exposure	2(2.6)
Severe hypema (>50%)	2(2.6)
Tube breakage	1(1.3)
Tube explantation	1(1.3)
Total number of patients with complications related to the GDD*	77

**Notes:** \*Some patients had more than 1 complication. Data presented in number of patients (percentage).

**Table 8** Complications Not Related to the GDD

Retinal detachment/PVR	34(70.8)
Vitreous haemorrhage	3(6.2)
Epi-retinal membrane	3(6.2)
Corneal ulcer/abscess	3(6.2)
Orbital cellulitis	2(4.1)
Age related maculopathy	1(2)
Corneal stromal haemorrhage	1(2)
Neovascular subretinal membrane	1(2)
Total number of patients with complications not related to the GDD*	48

**Notes:** \*Some patients had more than 1 complication. Data presented in number of patients (percentage).

High-pressure glaucoma is associated with higher levels of proinflammatory cytokines and thicker filtering capsules, which are predictors of poor success rates.<sup>23</sup> However, we found high preoperative IOP and preoperative atropine treatment were more prevalent in the CS group, possibly because both conditions are frequent in NVG, the most favoured glaucoma type regarding CS. However, logistic multivariate analysis did not confirm the increased probability of CS with preoperative use of atropine (OR 3.003; 95% CI 0.674, 13.38;  $p=0.1493$ ) and should be considered a confounder.

Richter et al established the first relationship between encapsulated trabeculectomy blebs and chronic use of hypotensive eye drops.<sup>24</sup> We found no relationship between preoperative topical treatment and failure, since almost all eyes

were on maximum hypotensive therapy; however, we found differences in the types of drugs used preoperatively and the need for hypotensive medication postoperatively.

There was a direct prognostic relationship with the use of brimonidine, which reduced the CS by 68.2%, in agreement with studies that demonstrated that its chronic use causes inflammatory changes in conjunctival cellularity.<sup>25</sup>

Until 2006, the Cochrane review found no advantages between commercially available implants.<sup>26</sup> More recently, a pooled data analysis showed some differences between valved and non-valved drainage systems but no differences have been detected between non-valved implants of similar dimensions.<sup>12,27,28</sup> In the current study, the same surgeon, implant design, surgical technique, and flow restrictive measures ensured procedural homogeneity. With respect to the two implant models, DPM has a circular polypropylene endplate and the DPSI circular plates are similar but made of flexible silicone. *In vitro* studies have shown that polypropylene seems to result in the least adherence of cultured Tenon fibroblasts and an animal model registered slightly higher inflammatory infiltrates than did silicone plates.<sup>29,30</sup> The material of the two implants in the current study showed no differences regarding success or failure rates, but the silicone one was related to the use of more postoperative glaucoma medications.

The aqueous permeability of the mature capsule depends on the delicate balance between the fibroproliferative and fibro-degenerative processes that occur around the plates during the early postoperative period and seems to be affected by early contact with the aqueous humour.<sup>31,32</sup> HP may be considered a consequence of an excessive intramural inflammatory reaction during capsular development, which would be decisive regarding the final permeability. We found that HP was related to a 67% increase in the probability of PS versus CS, in agreement with another report in which a significantly greater proportion of eyes with HP after Ahmed valve surgery required additional glaucoma surgery compared with eyes without HP.<sup>33</sup> In our study, 19.8% of cases had HP, in accordance with the known prevalence in Molteno implants (20–30%), and in contrast with the Ahmed valve, which is more frequently associated with this complication (82%), as in valved implants there is an immediate contact between the aqueous humour and the subconjunctival tissue.<sup>34,35</sup>

Prostaglandin analogs, which increase cytokines levels, could also be a key factor in stimulating the inflammatory infiltration that precedes scarring.<sup>36</sup> However, in our very

homogeneous surgical scenario, prostaglandin analogues did not appear to be a direct risk factor for PS as was brimonidine, but they increased the probability of HP fourfold, which in turn is a risk factor for PS.

The same was observed when the tube was located in the posterior chamber which, despite not being a risk factor for surgery failure, as other reports suggested, seems to be a risk factor for HP, as it requires iris manipulation such as peripheral iridectomy, which increases intraocular inflammation.<sup>37–39</sup> Surprisingly, unlike other reports, we found that preoperative IOP was lower in eyes with HP ( $p = 0.0057$ ). HP during the early postoperative period predicts the future need for long-term hypotensive medication, which may be prevented by reported measures such as the early initiation of aqueous suppressant therapy to avoid capsular stretching, antifibrotic treatments to modulate future capsular development and permeability and, in some cases, the use of MMC intraoperatively if it is considered beforehand. Once HP becomes established, improvement is less likely and the need for hypotensive medication is greater.<sup>15,40–44</sup> Study limitations: This is a retrospective design. All patients were Caucasian which limits the generalizability of the study and the therapies for some of the populations studied (NVG and uveitis glaucoma) have changed in the past 25 years with newer anti-VEGF agents, newer steroids, and immunomodulating therapies. The two drainage implants used have the same design but different material. However, the tight handling of the variables, the proactive control of patients throughout the follow-up, and the use of a similar surgical technique and follow-up by the same surgeon diminished the bias.

In conclusion, we found that glaucoma surgery with drainage implants is minimally affected by risk factors for trabeculectomy failure, making the double-plate drainage implant a robust and predictable surgical technique that is useful in most glaucomatous eyes with poor surgical prognoses. Some types of glaucoma, i.e., NVG, aphakic glaucoma, and eyes with previous complex ocular surgery achieved better results with respect to the need for glaucoma medication in the long run.

## Abbreviations

IOP, intraocular pressure; MMC, mitomycin C; GDD, glaucoma drainage devices; AGV, Ahmed glaucoma valve; BCVA, best-corrected visual acuity; NVG, neovascular glaucoma; VEGF, vascular endothelial growth factor; HP, hypertensive phase.

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