

1 TITLE: Systematic occlusion of shunts: control of early postoperative IOP and hypotony-related
2 complications following glaucoma shunt surgery.

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14 Running head: Systematic occlusion of shunts (SOS) study.

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21 **ABSTRACT**

22

23 **Objective**

24 Evaluation of a protocol of total intraluminal occlusion of Baerveldt shunts and its effects on
25 early postoperative IOP control and hypotony related complications.

26 **Design**

27 Non-comparative, prospective, interventional study.

28 **Participants**

29 Glaucoma patients were recruited to undergo Baerveldt shunt surgery. A total of 116 eyes of 112
30 patients were enrolled.

31 **Intervention**

32 During shunt implantation, aqueous outflow was restricted using an intraluminal occluding stent
33 inserted through the entire tube length, with and without external ligation, to halt aqueous flow.
34 Postoperatively, eyes underwent ligature laser suture lysis and partial or complete stent removals,
35 at predetermined time intervals.

36 **Main outcome measure**

37 Loss of postoperative IOP control, categorized as transient or persistent hypotony ($IOP \leq 5$
38 mmHg) or hypertony ($IOP > 21$ mmHg). Patients were followed up for one year.

39 **Results**

40 Preoperatively median IOP was 23 mmHg (mean 26 mmHg, SD 12 mmHg), median number of
41 glaucoma medications was 3.0 (mean 3.0, SD 1.2). During year one, laser suture lysis was

42 performed in 30 eyes (26%) and stent removal in 93 eyes (80%), (23 partial; 70 complete). There
43 was one case of transient hypotony, no cases of persistent hypotony, 10 of transient hypertony
44 and three of persistent hypertony. Nine eyes had IOP \leq 5 mmHg at one or more time points and
45 hypotony related complications occurred in 8 eyes (7%). At one year, median IOP was 12 mmHg
46 (mean 13 mmHg, SD 4 mmHg) with a median of 1.0 glaucoma medications (mean 1.1, SD 1.3).
47 The cumulative probability of failure during the first 12 months follow-up was 6% (n=7). Overall
48 postoperative complications occurred in 11 eyes (9%).

49 **Conclusion**

50 The surgical and postoperative protocol resulted in controlled, step-wise reductions of IOP with
51 low rates of hypotony and related complications.

52 INTRODUCTION

53 Traditionally, aqueous shunts have been reserved for patients with recalcitrant glaucoma or for
54 those in whom previous filtration surgery had failed.^{1,2} The Tube Versus Trabeculectomy (TVT)
55 study highlighted the greater efficacy of shunt implantation compared with trabeculectomy in
56 eyes with previous surgery (although mean IOP was similar, significantly lower failure rates were found
57 with Baerveldt tubes at years 1, 3 and 5).^{3,4} The primary TVT study is currently investigating the role
58 of shunts as first line glaucoma surgery.⁵ These reports support a larger role of aqueous shunts in
59 glaucoma surgery.^{3,5,6}

60 However, postoperative complication rates with shunts remain high.^{4,29} Most early complications
61 commence with postoperative hypotony resulting in choroidal effusions and/or haemorrhages,
62 shallow or flat anterior chambers (AC) with or without induced aqueous misdirection, or
63 maculopathy. With non-valved implants, hypotony usually results from the failure to adequately
64 restrict aqueous outflow, and several surgical techniques have been introduced to reduce
65 hypotony-related complications (HRCs). These include two-stage surgery,⁷ dissolvable ligation
66 sutures⁷⁻¹¹ with or without tube fenestration,^{8,10,12,13} intraluminal rip cord (partial-length),¹⁴⁻¹⁶ and
67 intracameral C3F8 gas injection.¹⁶⁻²⁰

68 In this paper, we demonstrate a technique of Baerveldt shunt implantation in which an occluding
69 stent is inserted throughout the entire length of the silicone tube, with or without an external
70 ligature. Postoperatively, the intraluminal outflow resistance can then be systematically adjusted
71 according to a standardized protocol. We investigated whether this technique can improve
72 control of intra-ocular pressure (IOP) and reduce the rates of hypotony and hypotony-related
73 complications. We compared the data to those from the large multi-centre tube-shunt studies^{4,18,19}
74 as a benchmark of expected outcomes.^{7,8,10,12-20,40}

75 **METHODS**

76 This was a prospective study of 116 eyes of consecutive patients enrolled between January 2009
77 and January 2011 from the Glaucoma Unit at Jules-Gonin Eye Hospital, Lausanne, Switzerland.
78 The surgical methods of Baerveldt (350mm²) tube implantation were standardized prior to
79 enrolment, and performed by a single experienced glaucoma surgeon (ES). The 3.0 Supramid[®]
80 suture (S. Jackson Inc. Alexandria, VA, USA) was used as an intraluminal occluding stent inserted
81 through the full length of the silicone tube to halt aqueous flow. Postoperatively, outflow was
82 increased using argon laser suture lysis (if a ligature had been applied intraoperatively) and
83 through the staged removal of the intraluminal occlusive stent. The postoperative visits and
84 interventions were determined by a predefined protocol, outlined below. All eyes underwent slit
85 lamp biomicroscopy, visual acuity (VA), IOP measurements using Goldmann applanation
86 tonometry, gonioscopy, and dilated fundus examination. Patients with previous aqueous shunt
87 surgery or encircling band retinal surgery were excluded. Ethical approval was granted by
88 Commission Cantonale d'Éthique, Vaud, Switzerland and all patients provided written informed
89 consent.

90

91 **Surgical Procedure**

92 Baerveldt shunts were placed superotemporally using a 3-clock-hour conjunctival peritomy. The
93 tube plate was placed under the bellies of the superior and temporal recti and secured to the
94 sclera with 9.0 prolene sutures. The Supramid was inserted through the silicone tube until it
95 reached the distal end, which was trimmed in a bevel up configuration. The stented distal tube
96 was inserted into the AC through a tight scleral canal, created using a 25-gauge-needle, posterior
97 to the limbus (figure 1A). Tubes were routinely left unligated. However, if aqueous was seen to
98 exit at the shunt plate, a 10.0 nylon ligature suture was tied around the proximal stented tube to
99 halt aqueous flow as a precautionary measure (figure 1A). Processed human pericardium

100 (Tutoplast[®] Pericardium, IOP Ophthalmics, Costa Mesa, USA) was used to cover the tube and a
101 square 4x4 mm window was created over the proximal portion of the silicone tube, enabling
102 argon laser suture lysis postoperatively (figures 1B, 1C). The free end of the Supramid was looped
103 forward, away from the tube plate, tucked under the anterior end of the pericardial patch and
104 sutured to the sclera using 10.0 nylon to ensure easy access of the occlusive stent post-operatively
105 (figure 1B). Finally the conjunctiva was closed with 8.0 vicryl sutures, and subconjunctival
106 cefuroxime and beclamethasone were administered. No viscoelastics were injected into the AC.

107 **Postoperative protocol**

108 Postoperative examinations were performed during study visits on day 1, week 1, 3, 6, month 3, 6
109 and 12, or more frequently if clinically indicated. Postoperative medications included unpreserved
110 topical dexamethasone (Dexafree[®] UD 0.1%) 8 times daily and tapered over 6 weeks and
111 ofloxacin (Floxal[®] UD, Bausch and Lomb, Zug, Switzerland) 4 times daily.

112 Postoperative adjustments to reduce intraluminal outflow resistance and IOP were performed
113 according to the following time points:

- 114 • ≥ 4 weeks postoperatively: argon laser suture lysis (LSL) of the nylon ligature suture
115 (when present), using a Hoskins lens.
- 116 • 6-12 weeks postoperatively: partial stent removal (P-SR), the occluding stent was
117 retracted by 5 mm. This was only performed if IOP remained uncontrolled despite
118 maximal medications.
- 119 • ≥ 12 weeks postoperatively: complete stent removal (C-SR) was performed. In cases of
120 neovascular glaucoma, uveitis or previous cyclodestructive procedures (risk factors for
121 hypotony) P-SR was performed as a first procedure and followed by C-SR if required
- 122 • Stent removals were not performed when IOP dropped to ≤ 10 mmHg without glaucoma
123 medications.

124

125 **Occlusive stent removal**

126 While occlusive stent removal (SR) can be performed at the slit lamp, all study SRs were
127 performed under topical anaesthesia in the operating room. During this procedure, the anterior
128 conjunctiva was incised over the Supramid 3.0 suture, which was then either retracted 5.0 mm
129 and re-sutured to the anterior sclera (P-SR) or completely removed (C-SR). Balanced salt solution
130 was injected into the AC in eyes with all SRs. Viscoelastic (0.05-0.1mls) was routinely injected
131 into the AC of eyes undergoing C-SRs. The conjunctiva was sutured using 8.0 vicryl. Tobradex[®]
132 (tobramycin, dexamethasone; Alcon, Switzerland) was prescribed 4 times daily and tapered over 4
133 weeks. IOP was measured at day 1, weeks 1 and 4, following stent removals.

134 **Primary and secondary outcomes**

135 Primary outcomes:

136 Loss of IOP control, occurring at any time points throughout follow up, was classified as:

137 *Transient hypotony:* IOP ≤ 5 mmHg on two consecutive visits ≥ 3 weeks and < 6 weeks apart.

138 *Persistent hypotony:* IOP ≤ 5 mmHg on two consecutive visits ≥ 6 weeks apart.

139 *Transient hypertony:* IOP > 21 mmHg on two consecutive visits, ≥ 3 weeks and < 6 weeks apart.

140 *Persistent hypertony:* IOP > 21 mmHg on two consecutive visits ≥ 6 weeks apart.

141 Secondary outcomes:

142 Failure was defined as: inadequate IOP control (IOP ≤ 5 mmHg OR > 21 mmHg OR $< 20\%$
143 reduction from baseline on 2 consecutive study visits after stent removal (or after 3 months –
144 where stents were not removed before 6 months, reoperation for glaucoma, loss of light
145 perception vision, or removal of the implant.

146 Success was defined as IOPs ≤ 21 mmHg and ≥ 5 mmHg and $>20\%$ reduction in IOP from
147 baseline on 2 consecutive study visits after stent removal (or after 3 months - where stents were
148 not removed before 6 months). Reoperation for glaucoma was defined as additional glaucoma
149 surgery, such as an additional aqueous shunt or cyclodestruction. Post-operative interventions
150 such as stent removal, needling procedures or laser suture lysis, were not considered glaucoma
151 reoperations, whether performed in the OR or at the slit lamp.

152 **Complications**

153 Macroscopic hyphema was considered present when >1 mm blood was seen in the AC.
154 Hypotony related complications were classified as: choroidal effusions/haemorrhage,
155 shallow/flat AC and hypotony maculopathy. The presence of choroidal effusions and
156 maculopathy were assessed by routine dilated fundus examination.

157 **Statistical analysis**

158 Analysis was performed using R version 2.15.1. Patients lost to follow-up were censored at their
159 last visit. Missing data was assumed to occur at random, and the complete case approach was
160 adopted. Since some of the variables reported here (e.g. IOP and VA) were not normally
161 distributed, median and inter-quartile ranges (IQR) were reported. Mean and standard deviation
162 (SD) were also included to allow comparison with previous studies.

163 **RESULTS**

164 A total of 116 eyes of 112 patients underwent Baerveldt shunt implantation, of these 104 eyes
165 (90%) completed one-year of follow-up. Of the 12 patients who missed the one-year
166 appointment, 4 attended later visits and 8 were lost to follow-up (figure 2). Fewer than 15% of
167 follow-up appointments were missed.

168 Patient demographics and surgical outcomes are shown in table 1. Details of postoperative IOP
169 throughout follow-up are presented in figure 3. The median preoperative IOP was 23 mmHg
170 (mean 27 mmHg). A marked IOP reduction was noted at all time points after week 1 (figure 3).
171 The median IOP at 12 months was 12 mmHg (mean 13 mmHg). None of the eyes had IOP \leq 5
172 mmHg on postoperative day 1. Nine eyes (8%) experienced a postoperative IOP \leq 5 mmHg at
173 any study time point. This comprised of one patient with transient hypotony (lasting 3 weeks),
174 and 8 patients with IOP \leq 5 mmHg lasting between 2 and 8 days. Almost all eyes had a gradual
175 and controlled reduction in IOP (figure 3). None of the eyes developed persistent hypotony. Ten
176 eyes (9%) had transient hypertony (IOP $>$ 21 mmHg), and 3 eyes (3%) had persistent hypertony.

177 Of the 116 eyes, 38 eyes (33%) underwent tube ligation during shunt implantation. In 8 eyes the
178 nylon sutures could not be located postoperatively because Tenon's capsule was too thick. The
179 remaining 30 eyes underwent LSL on average 6.8 ± 3.1 weeks postoperatively. The median IOP
180 prior to LSL was 26 mmHg [IQR 19-33 mmHg], which dropped significantly to 14 mmHg [IQR
181 11-21 mmHg], one week later and remained lower one month later (19 mmHg [IQR 14-22
182 mmHg]). There were no cases of hypotony or HRCs following LSL. Of the 30 eyes that
183 underwent LSL, subsequent stent removal was necessary in 25 eyes (8 P-SR; 17 C-SR). Details of
184 postoperative IOP following LSL, P-SR and C-SR are summarised in table 2 and figure 4. There
185 were no significant differences between the preoperative and final postoperative IOP of the
186 ligature stent group versus non-ligature stent group ($p=0.60$ and $p=0.40$, respectively).

187 Stent removals were required in 80% of eyes ($n=93$). Prior to SR the median IOP was 19 mmHg
188 [IQR 14-26 mmHg], which reduced to 14 mmHg [IQR 11-20 mmHg] one week later and
189 remained low after one month (16 mmHg [IQR 12-20 mmHg]). Both C-SR ($n=70$) and P-SR
190 ($n=23$) resulted in significant IOP reduction. Following stent removal 5% ($n=5$) of eyes required
191 an increase in medications; only 2 eyes experienced both an increase in IOP and an increase in
192 glaucoma medications (figure 4). There was no significant difference between IOP reduction

193 following C-SR and IOP reduction following P-SR at one week ($p=0.65$) however at one month
194 IOP after C-SR was significantly lower than IOP after P-SR ($p<0.01$). P-SRs did not result in any
195 HRCs. Early P-SR (3 and 5 weeks) was required in 2 eyes with uncontrolled elevated IOP despite
196 maximal tolerated medications. One eye required viscoelastic injection into the AC due to low
197 IOP following C-SR (lasting 2 days). Two eyes required reinsertion of the Supramid stent (via
198 AC).

199 The median number of glaucoma medications reduced from 3 [IQR 2-4] preoperatively to 1 [0-2]
200 postoperatively at year one (figure 3). A significant drop in medications was observed following
201 SRs, which persisted throughout all subsequent visits. Prior to stent removal the mean number of
202 glaucoma medications was 3.6 ± 1.5 , which reduced to 0.5 ± 1.2 one week later and remained
203 significantly reduced one month after SR (0.9 ± 1.3). The IOP reduction following stent removal
204 was not significantly associated with the reduction in number of medications between pre-
205 removal and one-month post-removal ($p=0.16$, 2 way ANOVA).

206 Failure occurred in 7 eyes (6%) due to inadequate IOP reduction. However, there were no cases
207 of persistent hypotony, glaucoma re-operation, or loss of light perception. In the eyes considered
208 as surgical failure, one eye was lost to follow-up. In the remaining 6 eyes, median pre-operative
209 IOP was 15mmHg and postoperatively 13mmHg and mean pre-operative glaucoma medications
210 was 3.3 and postoperatively 1.2. At month 12, qualified success (with or without medications)
211 was achieved in 94% ($n=98$) of eyes and complete success in 32% ($n=33$) of eyes.

212 Intraoperative hyphema was observed in 2 patients, and no other intraoperative complications
213 were observed. Postoperative complications occurred in 11 eyes (9%) and were non-sight
214 threatening: hyphema ($n=1$), transient diplopia ($n=1$), Descemet's membrane detachment ($n=1$);
215 HRCs occurred in 8 eyes: transient hypotony ($n=1$), shallow AC ($n=2$) and transient choroidal

216 effusions (n=5) (table 3). There were no tube blockages, retractions, erosions or cases of
217 endophthalmitis.

218 **DISCUSSION**

219 The importance of early flow control following non-valved shunt implantation has previously
220 been highlighted.^{8-10,14-16,21,23} This is the first study of aqueous shunts to report IOP data following
221 full-length intraluminal occlusion and stepwise reductions of flow restriction using laser suture
222 lysis and partial/complete stent removals, according to requirements (some eyes did not require
223 stent removal). Complete stent removals were delayed until after 12 weeks of bleb
224 maturation,^{7,8,12,32,36} which is in contrast to the traditional use of a rapidly dissolving tie, where
225 maximal outflow occurs indiscriminately as early as three to six weeks after surgery. The staged
226 approach in this study resulted in low rates of hypotony (1%) and overall HRCs (7%), and
227 consequently the total complication rate was 9%. To our knowledge these are amongst the lowest
228 reported in the literature (table 3, figure 5).^{3,8,10,12,13,18-20,22,24,29}

229 In vitro, unligated partial-length Supramid occlusion of Baerveldt shunts does not always provide
230 sufficient intraluminal resistance to prevent hypotony.²³ The full-length occluded shunts used in
231 our protocol offer additional outflow resistance due both to increased Supramid length and its
232 passage through the tight intrascleral canal (which obviated the need for ligation in two thirds of
233 tubes). Postoperatively, scleral squeeze around the stented tube is likely to have gradually relaxed,
234 allowing aqueous flow into a relatively mature bleb (suggested by the lowering of IOP prior to
235 stent removal). This delayed and gradual increase in flow may circumvent inflammatory bleb wall
236 thickening associated with copious early flow,^{7,8,12,32,36} and could explain why a hypertensive phase
237 following removal of flow restriction^{8,10,12,19,24,32,36} was not observed in study eyes. Further studies
238 are required to establish whether final IOP is affected by delaying aqueous flow into the maturing
239 bleb.

240 On post-operative day one, none of the study eyes had IOP below 6 mmHg. This lack of
241 immediate hypotony compares favourably with other techniques.^{3,8-29} Intraoperative viscoelastic
242 AC injections were never required during tube implantation. These can cause erratic IOPs in
243 occluded shunts.^{3,4,32} Since flow control was central to this protocol, LSL was preferred over a
244 dissolving tie as this enabled the clinician to determine the need and the timing of resistance
245 reduction.^{3,5,8,10,13,18-20} Similarly, partial stent retractions provided an intermediate stage of
246 resistance reduction when complete removal posed a risk of HRCs (for example in patients with
247 uveitis, previous cyclodiode, and small eyes). Neither LSL nor P-SR resulted in hypotony related
248 events. A total of 16% of eyes achieved sufficiently low IOP without requiring stent removal.
249 Removal of these stents may have resulted in hypotony.^{8,12,20,22} Emerick et al reported hypotony
250 in 25% of eyes following ligature autolysis, where no occluding stent was present.¹²

251 Early post-operative complications (predominantly HRCs) using non-valved shunts are largely
252 preventable using surgical and post-operative strategies,^{7,19,27} and are not necessarily associated
253 with surgeon experience.¹⁸ The case-mix, prospective protocol and analysis methods of this study
254 are not unlike those of the ABC study,^{18,25} yet here the complication rate was markedly lower
255 (9% versus 58%); (54% in AVB¹⁹; 34% in TVT³; table 3, figure 5). A major confounder is that
256 the detection of and reporting of complications varies between studies – not all previous studies
257 report all complications (figure 5; table 3). However, the mean of each reported HRC was
258 calculated separately in order to estimate a cumulative HRC rate of 35%^{3,8,10,12,13,18-20,22,24,29} (table 3;
259 figure 5). This is substantially greater than the 7% reported here. Transient hypotony (12-
260 25%)^{8,12,20,22} and persistent hypotony (0-5%)^{12,18,19,29} were also markedly lower in this study (1%
261 and 0% respectively).

262 There were no occurrences of new onset corneal decompensation in this cohort during the first
263 year of follow-up. Care was taken to leave the intracameral tube short and position it away from
264 the cornea, and this may have helped to reduce corneal endothelial cell loss. However corneal

265 decompensation following prolonged endothelial cell loss is a recognized late-onset complication
266 of shunt implantation and as such is more likely to feature in reports with longer follow-up.

267 In contrast to complication rates, the success and failure rates at year one (which are
268 predominantly IOP determined), were similar to previous studies that included Baerveldt shunts
269 (figure 6). This supports the notion that given similar ocular characteristics, it is implant
270 type^{18,19,29,32,33} and surface area,^{30,31} rather than surgical technique, that principally determine the
271 mature bleb characteristics and therefore final IOP.^{30,31,34,35} At year one, failure rates (6%) were
272 not dissimilar to those reported with Baerveldt shunts in the TVT and ABC studies (4%³ and
273 14%¹⁸ respectively). The recent large shunt studies report failure using different IOP criteria,
274 making it difficult to compare, and therefore we have given the full range of outcomes for the
275 cumulative probability of failure at month 12 (figure 6). Here the most frequently reported failure
276 criterion of IOP and $\leq 20\%$ reduction from baseline is shown (figure 6). To facilitate comparison,
277 the three failure rates at month 12 of the TVT, ABC and AVB studies have been superimposed.

278 Notably in the 6 eyes that failed within the first year of follow-up, there were no re-operations for
279 glaucoma. In this subgroup mean IOP reduced by 8% from baseline and there was a 64%
280 reduction in medications. The reduction in the number of medications due to drug intolerance
281 was an important preoperative consideration in these patients.

282 One of the drawbacks of non-valved shunt surgery is the delay in IOP lowering due to flow
283 restriction. During the early postoperative period (prior to stent removals) the delayed IOP
284 lowering was not regarded as surgical failure. We therefore presented IOP values and glaucoma
285 medications for all eyes at all study time points in figure 3 (strip plot). During the first 3 months,
286 according to clinical requirements, medications were frequently altered, LSL and/or stent
287 removals were performed, and hence IOP values across subsequent time points rarely
288 correspond to the same eye. This prompted the stratification of hypertony (IOP>21mmHg) into

289 transient and persistent. Ten eyes (9%) experienced transient hypertony (3-6 weeks) and a further
290 3 eyes had persistent hypertony (>6 weeks). Thus it is apparent that prolonged periods of high
291 pressure were a rare phenomenon with this systematic approach.

292 During stent removals a small incision is made in the anterior conjunctiva to access the free end
293 of the stent. This added step does increase healthcare costs, but the lower complication rates may
294 make this approach more acceptable. When resources are scarce, this approach could be reserved
295 for monocular patients or eyes with advanced disease, vulnerable to visual damage ensuing from
296 hypotony and its complications.^{1,10,32} In patients unsuitable for a second postoperative
297 intervention (e.g, geographical location, expenses, medical reasons) suture removal may be carried
298 out at the slit lamp.

299 The outlined surgical methods and postoperative protocol have been described in a manner to
300 facilitate reproducibility. This method resulted in low rates of hypotony and its related
301 complications and prevented persistent hypotony in all study eyes. Given the rising rates of
302 aqueous shunt implantation, continued development of safer implantation techniques and
303 postoperative treatment strategies are essential.

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- 399
- 400

401 **Table legends**

General	
Eyes, n	116
Sex M/F, n (%)	63 (54%) / 53 (46%)
Ethnicity <ul style="list-style-type: none"> • Caucasian • Black • Latin American • Asian • Other 	<ul style="list-style-type: none"> • 95 • 9 • 4 • 2 • 6
Mean age, years (± SD)	62.3 years (±22.1)
Primary glaucoma diagnosis n (%) <ul style="list-style-type: none"> • Open angle • Angle closure • Pseudoexfoliation • Aphakic • Neovascular • Congenital • Pigmentary dispersion • Traumatic • Uveitic 	<ul style="list-style-type: none"> • 39 (34) • 18 (16) • 17 (15) • 5 (4) • 11 (9) • 8 (7) • 7 (6) • 6 (5) • 4 (3)
Previous incisional surgery, n (%) <ul style="list-style-type: none"> • IOP implantation • Deep Sclerectomy • Trabeculectomy • Express tube • Visco canalostomy • Tube 	<ul style="list-style-type: none"> • 93 (80) • 48 (41) • 32 (28) • 10 (9) • 3 (3) • 1 (1)
Pre-operative measures, Median [IQR] (mean± SD)	
IOP mmHg	23 [18,32] (26.9 ± 11.6)
Glaucoma medications	3.0 [2,4] (3.0 ±1.2)
Visual acuity LogMAR	0.5 [0.2,1.0] (0.9 ±1.0)
Post-operative measures Median [IQR] (mean± SD) – month 12	
IOP mmHg	12 [10,15] (12.8 ±3.7)
Glaucoma medications	1 [0,2] (1.1 ±1.3)
Visual acuity LogMAR	0.4 [0.2,1] (0.7 ±0.7)

402

403 Table 1. Summary of the patient demographics and surgical outcomes. (POAG, primary open
 404 angle glaucoma; PEXG, pseudoexfoliation glaucoma; ACG, angle closure glaucoma; PDG,
 405 pigmentary dispersion glaucoma.)

406

407

Type of postoperative adjustment	IOP before adjustment Median [IQR]	IOP 1-week later Median [IQR]	IOP 1-month later Median [IQR]
Ligature laser suture lysis (LSL) only	21 [15, 26]	16 [11, 18]	17.5 [12, 20]
Partial stent removal	21 [16.5, 30]	14 [11.5, 18.5]	20 [13, 23.5]
Complete stent removal	19 [14, 24.5]	15 [11, 20]	15 [12, 18.75]
All stent removals	19 [14, 26]	14 [11, 20]	16 [12, 20]
Stent removal (without prior LSL)	19 [14.25, 26]	14 [10.25, 20]	16 [12, 20]
Stent removal (underwent prior LSL)	21 [14.75, 26.5]	16 [11.75, 18.5]	18 [12, 21]

408

409 Table 2. Intraocular Pressure (IOP) before and after postoperative adjustments.

410

Complication type	Systematized Occlusion of Shunts (%)	Studies of Baerveldt shunts: Reported complication rates (%)^{publication reference}
Overall complication rates	9	34, ⁴ 38, ¹³ 58, ¹⁸ 54, ¹⁹
Shallow AC	2	11, ⁴ 20, ¹⁸ 14, ¹⁹ 14 ²⁴
Choroidal effusions	4	16, ⁴ 3-9, ⁸ 22, ¹⁰ 17-18, ¹² 10, ¹⁸ 13, ¹⁹ 19, ²² 23 ²⁴
Choroidal haemorrhage	0	2, ⁴ 1, ¹⁰ 0-1, ¹² 2, ¹³ 2, ¹⁸ 3, ¹⁹ 3, ²⁰ 4, ²² 2 ²⁹
Hypotonous maculopathy	0	1, ⁴ 2, ¹⁸ 5 ²⁴
Transient Hypotony	1	14-23, ⁸ 24-26, ¹² 38, ²⁰ 20 ²²
Persistent Hypotony	0	2, ⁴ 2, ¹⁸ 2 ²⁹
Descemet detachment	1	1, ⁴ 0, ¹⁰ 1, ¹³ 1, ¹⁹ 1, ²² 3, ²⁴ 3 ²⁹
Hyphema	1	2, ⁴ 14, ¹⁰ 6-7, ¹² 2, ¹³ 6, ¹⁸ 20 ²⁴
Diplopia	1	5, ⁴ 1-5, ¹² 2, ¹³ 5, ¹⁸ 6, ¹⁹ 3 ²⁴
Macular edema	0	3, ⁴ 4, ¹³ 2, ¹⁸ 9 ²⁴
Requirements for AC reformation	0	1, ⁴ 0 ¹⁰
Endophthalmitis	0	1, ⁴ 0, ¹⁰ 0-1, ¹² 1, ¹³ 1, ¹⁸ 0, ¹⁹ 3, ²² 3 ²⁴
Tube related complications	0	11 ¹⁹
Occlusion	0	2, ⁴ 2, ¹⁰ 0-1, ¹² 4, ¹³ 9, ¹⁸ 10, ¹⁹ 3, ²⁰ 5 ²² 8 ²⁴
Malposition	0	1-2, ¹² 1, ¹³ 6, ¹⁸ 2, ¹⁹ 3 ²⁴
Erosion	0	3-5, ¹² 3, ¹³ 1, ¹⁸ 3, ¹⁹ 2, ²⁰ 2 ²²

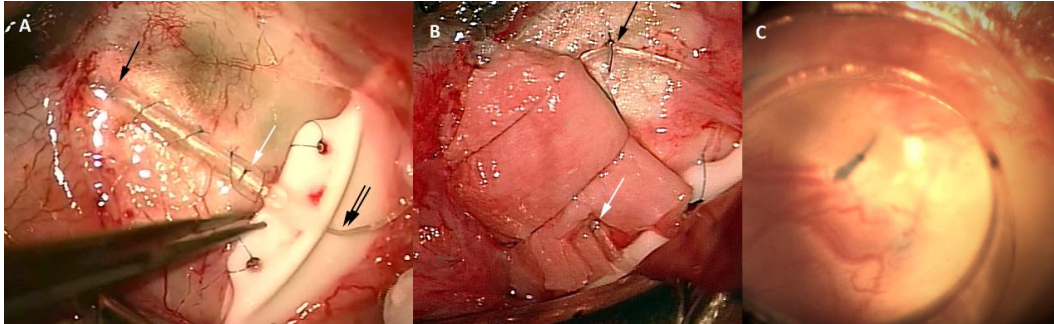
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413 Table 3. List of complications reported with Baerveldt shunts.

414

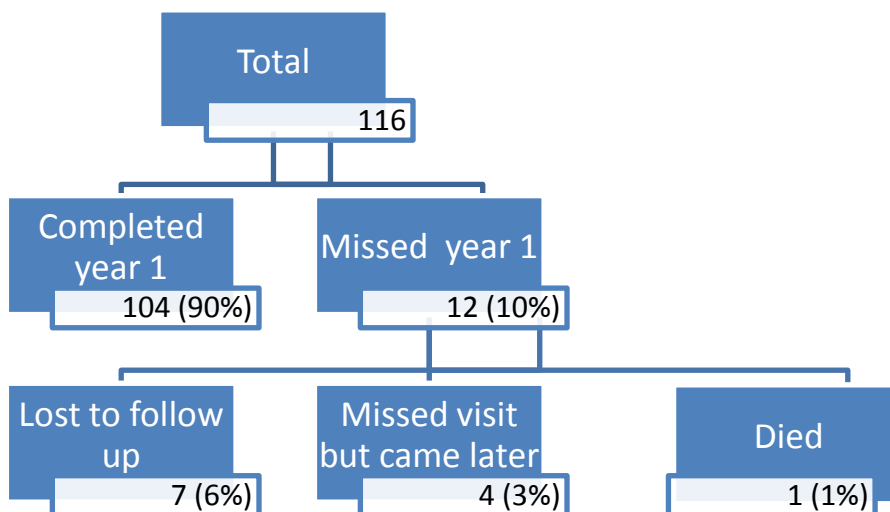
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416 **Figure legends**



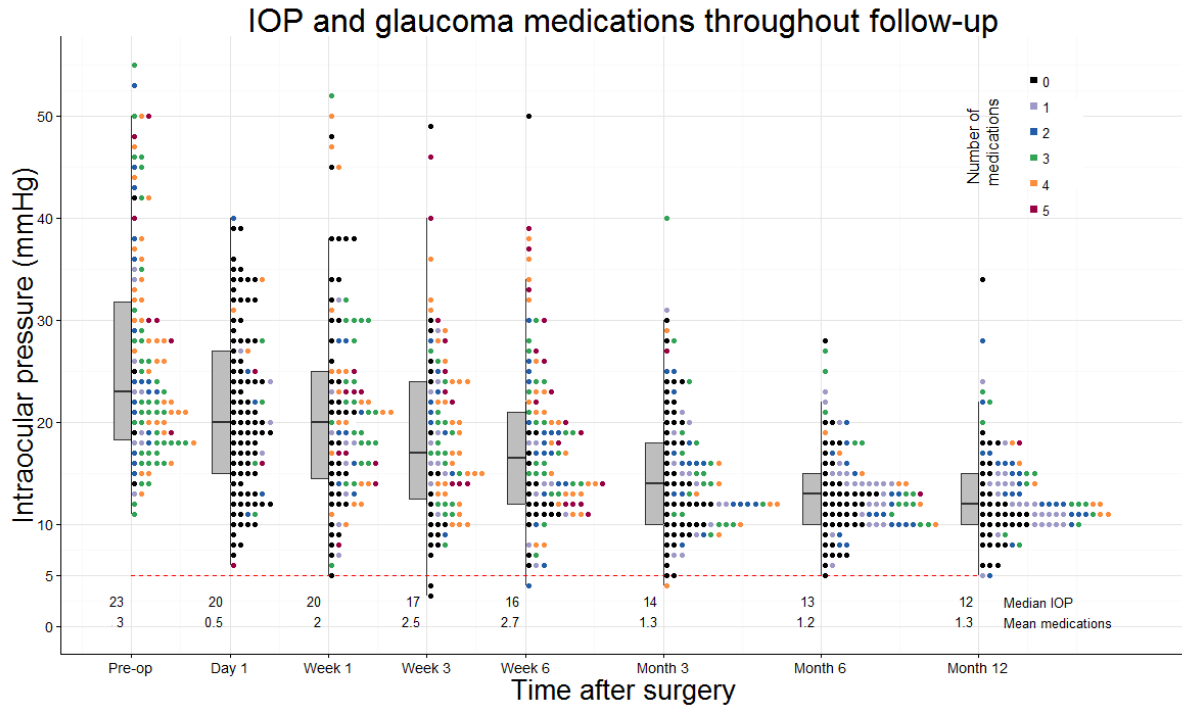
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418 Figure 1. (A) Intraoperative photograph of fully-stented Baerveldt tube entering the AC through
419 a tight intrascleral canal (black arrow). Supramid occluding stent can be seen at tube plate (double
420 black arrow). The 10.0 nylon ligation suture (white arrow) is tied around proximal tube to halt
421 aqueous egress if detected at tube plate. (B) A photo showing pericardial patch covering tube,
422 with a posterior window enabling postoperative laser suture lysis (white arrow). The free end of
423 the Supramid is sutured with 10.0 nylon (black arrow) and tucked under the pericardial patch
424 near the limbus, to facilitate retraction/removals post-operatively (C) The 10.0 nylon ligation
425 suture seen through Hoskins lens prior to laser suture lysis



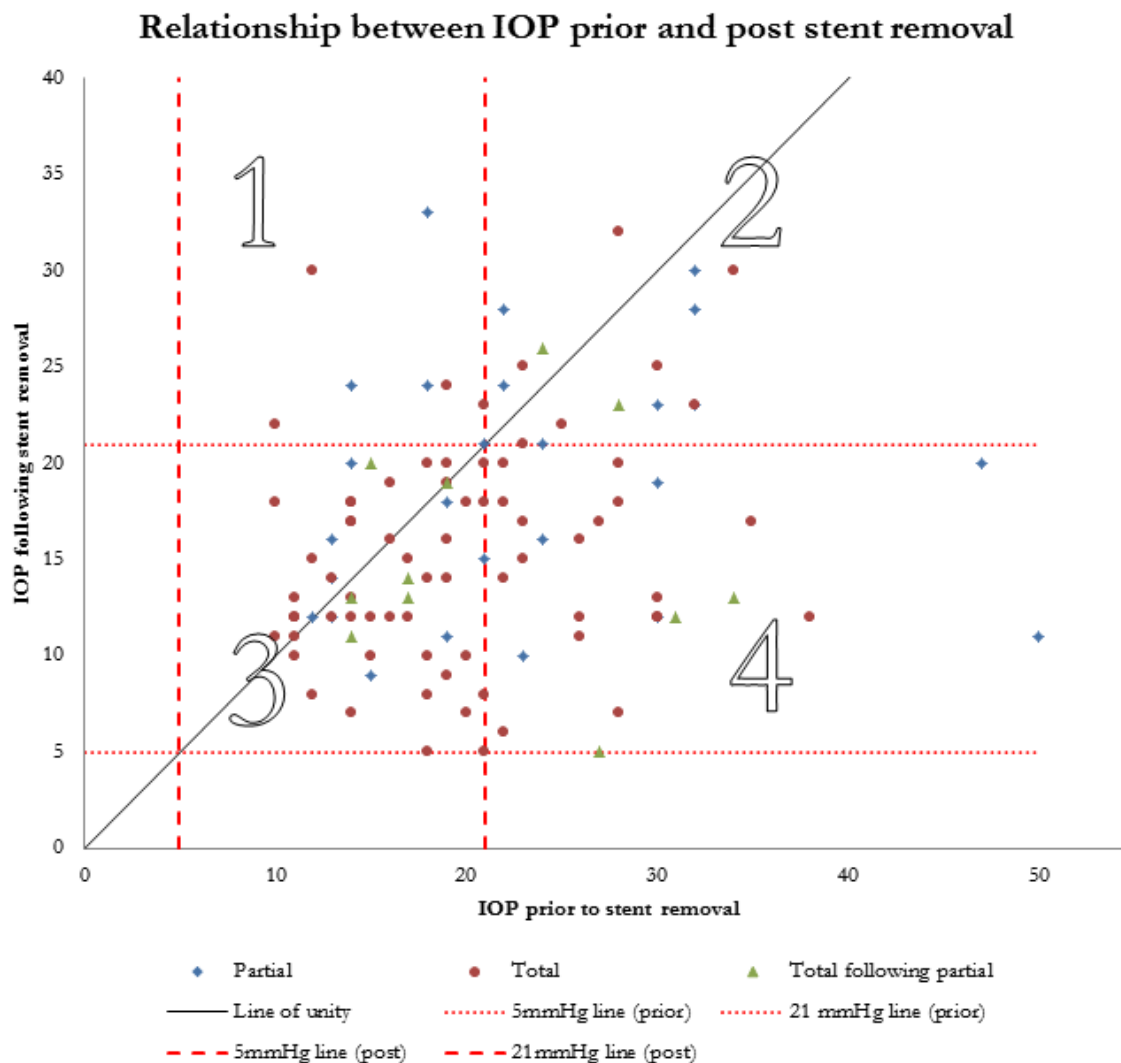
426

427 Figure 2. Flow chart of follow-up achieved at year 1.



428

429 Figure 3. Summary of postoperative intraocular pressure (IOP) measurements and number of
 430 glaucoma medications throughout follow up. A box and whisker plot summarises IOP values
 431 recorded at each time point, the height of the box represents lower and upper inter-quartile range
 432 (50% of the range), the ends of the whiskers extend to 95% of the range (2.5%-97.5%). The line
 433 bisecting each box represents the median IOP. Additionally to the right of each box a strip plot
 434 is shown, here with each marker denoting an individuals' IOP value. These markers are colour
 435 coded where the colour denotes the number of medications. Please note: in strip plots, the same
 436 location at subsequent study points is highly unlikely to correspond to the same eye. The
 437 horizontal red dashed line marks the lower IOP limit associated with hypotony (≤ 5 mmHg). The
 438 mean IOP and number of medications are also shown beneath this line, at each time point.

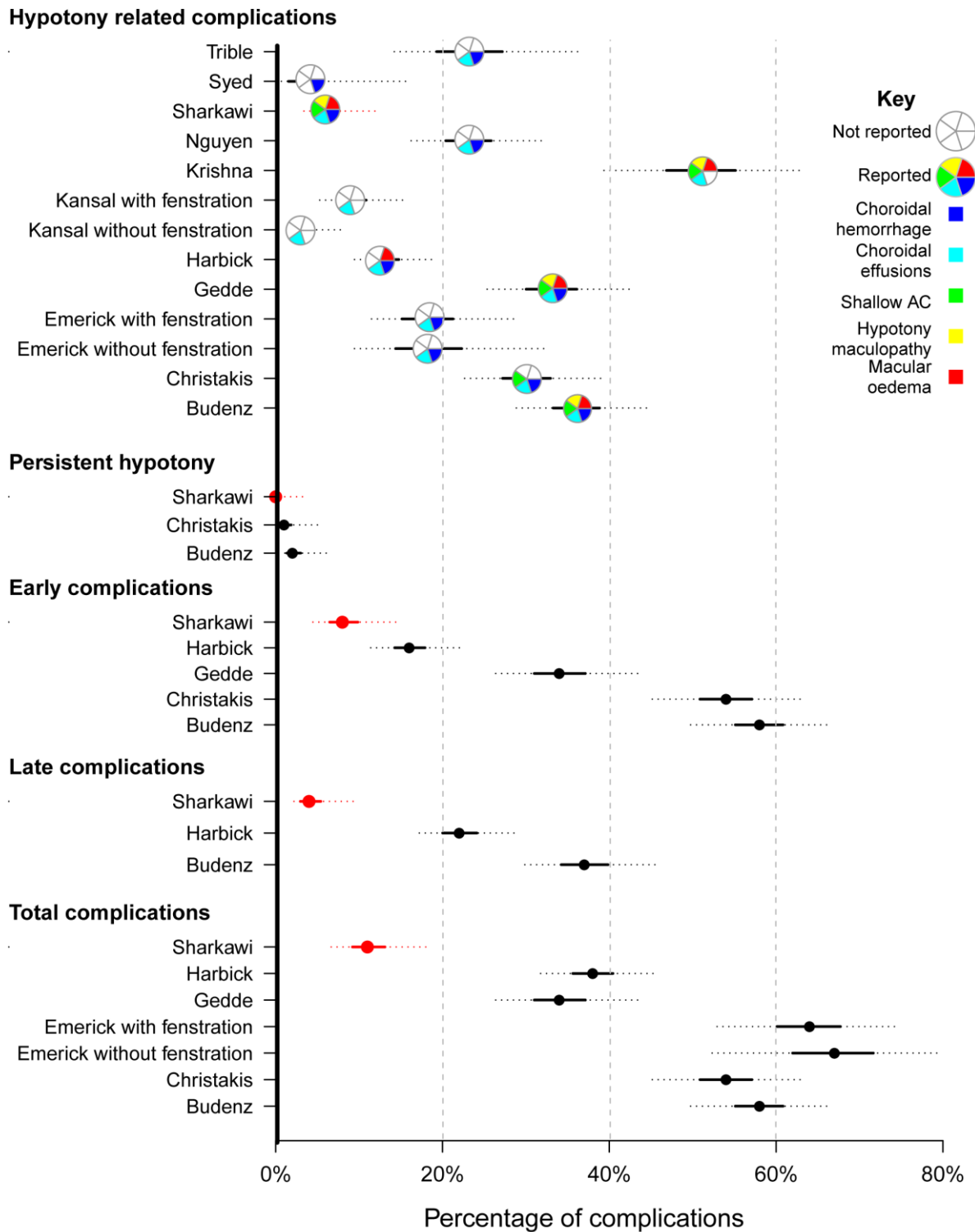


439

440 Figure 4. Summary of the relationship between intraocular pressure (IOP) measures prior to stent
 441 removal (SR) and IOP recorded at 1 month following partial SR (circle) and complete SR
 442 (triangle). The dashed and dotted red lines represent the lower and upper IOP limits defining
 443 hypotony (5mmHg) and hypertony (21mmHg) prior to and following SR. The (solid black) line
 444 of unity representing no change in IOP. Each marker has been colour coded to denote the
 445 change in glaucoma medications following stent removal, with green denoting no change, red
 446 indicates an increase in medications and blue indicates decrease, and the intensity of the colour
 447 denoting the amount of change.

448

Complications rates reported with Baerveldt shunts



449

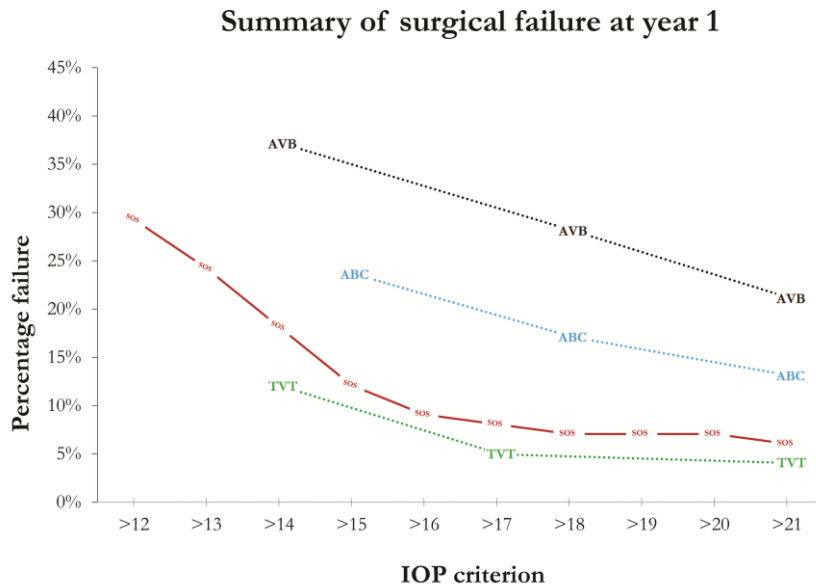
450 Figure 5. Summary of the complication rates reported in studies of Baerveldt (350) shunts. The

451 percentage rates of hypotony related complications, persistent hypotony, early, late, and total

452 number of complications for each study are illustrated. Hypotony related complications include

453 choroidal haemorrhage, choroidal effusion, shallow anterior chamber, hypotony malculopathy
454 and macular oedema. However since not all studies report all hypotony related complications, a
455 coloured key has been added to denote which complications are reported in each study.

456



457

458 Figure 6. Failure as a function of intraocular pressure (IOP): a summary of the cumulative
459 probability of failure, at 12 months from this study, is given for 10 different criteria in 1
460 continuous graph labelled with “SOS”. The three failure rates at month 12 reported in recent
461 ABC, AVB and TVT studies using Baerveldt shunts have been superimposed. A dotted line has
462 been used to connect the reported values

463