Baerveldt tube implantation following failed deep sclerectomy versus repeat deep sclerectomy.

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ABSTRACT:

Purpose:

To compare the surgical outcomes of repeat deep sclerectomy (DS) and Baerveldt glaucoma implantation (BGI) in eyes with failed primary deep sclerectomy.

Design: A retrospective comparative case controlled study.

Methods

Fifty-eight eyes of 56 glaucoma patients with a previously failed DS underwent BGI (group BGI) and 58 eyes of 55 patients underwent repeat DS (group DS) at a tertiary referral centre. Visual acuity, IOP, number of glaucoma medications, surgical failure rates and complication rates were compared between groups. Surgical failure was defined as: loss of IOP control; loss of light perception; or need for further glaucoma surgery.

Results

Baseline demographics were similar between groups. Preoperatively median IOP was lower in the DS group than BGI group (19mmHg versus 21mmHg, p=0.10). Postoperatively, at year 1, median IOP was significantly higher in the DS group than BGI group (14 mmHg versus 11mmHg, p=0.02). There were no differences in mean number of medications between DS and BGI groups preoperatively (2.3 versus 2.6), or postoperatively (1.3 versus 1.1). Complication rates were significantly higher in the DS group (41% (n=24) versus 14% (n=8); p=0.01). The failure rate at one year was higher in eyes with repeat DS (30%) than in eyes with BGI (21%), (p =0.07).

Conclusions

Baerveldt implants were more effective in lowering IOP and resulted in significantly fewer complications than repeat deep sclerectomy in eyes with previously failed deep sclerectomy.

Keywords: Baerveldt tube, Deep sclerectomy, glaucoma filtration surgery, repeat surgery.

INTRODUCTION

Deep sclerectomy (DS) is a form of non-penetrating glaucoma filtration surgery, indicated in medically uncontrolled glaucoma. It involves removal of a deep scleral flap, the external wall of Schlemm's canal and corneal stroma, leaving behind the anterior trabeculum and Descemet's membrane, thereby creating an intrascleral space.[1] A recent Cochrane review showed that primary DS was not significantly different than trabeculectomy in terms of IOP lowering.[2, 3] Furthemore, DS has been associated with less postoperative complications mainly due to less surgically induced cataract formation and hypotony related complications. [2-4] As DS filtration blebs are prone to scarring, a number of adjunctive techniques such as intraoperative Mitomycine C, Bevacizumab, insertion of spacer devices and post-operative Nd:YAG laser goniopunture have been used to increase efficacy.[5-13]

Traditionally, aqueous shunts have been reserved for patients with recalcitrant glaucoma or for those in whom previous filtration surgery had failed.[14] Aqueous shunts have been associated with several complications, due to uncontrolled hypotony in the initial postoperative period and long term corneal decompensation and tube erosions. More recently attempts have been made to reduce complication rates by modifying surgical techniques to improve IOP control[14-16] and avoid tube-corneal contact. [15,17,18]

Currently, there is no consensus regarding the surgical approach in eyes with previously failed glaucoma surgery. Once filtration surgery has failed, repeat filtration surgery has been shown to have a reduced success rate.[19-24] The tube versus trabeculectomy (TVT) study highlighted the greater efficacy of shunt implantation compared with trabeculectomy in eyes with previous surgery.[19,20] To the best of our knowledge, there have been no studies reporting outcomes of glaucoma surgery following failed DS and in particular no comparative studies examining the success of DS versus aqueous shunts in eyes with previously failed DS.

The authors set out to compare the surgical outcomes of Baerveldt glaucoma implantation (BGI) versus repeat DS, in eyes with previously failed DS.

METHODS

Eligible patients were identified from the diagnostic database of the Glaucoma Unit of Jules-Gonin Eye Hospital, Lausanne, Switzerland. All eyes had medically uncontrolled glaucoma and one failed DS which was followed by either a repeat DS (group DS) or a Baerveldt glaucoma implant (BGI group). Eyes with previous trabeculectomy, other forms of glaucoma surgery (other than DS), encircling band retinal surgery, or eyes with intraoperative perforations of the trabeculo-descemet's membrane were excluded.

BGI group: All eyes that underwent Baerveldt tube (350mm^2) surgery following one failed DS were identified from a consecutive surgical database. All surgeries were performed by an experienced glaucoma shunt surgeon (ES), between January 2009 and January 2011.

DS group: All eyes that underwent two consecutive deep sclerectomies were identified from a separate consecutive surgical database and surgeries were performed between 1998 and 2008 (repeat DS was not performed at our institution after 2008). Repeat DS were performed by two surgeons experienced in non-penetrating glaucoma surgery (AM, ER).

All medical notes were reviewed and data collected for patient demographics and postoperative outcomes. This retrospective study, had ethical approval from the ethical committee of the canton de Vaud, it conformed to the tenants of the declaration of Helsinki. All eyes underwent slit lamp biomicroscopy, visual acuity (VA), intraocular pressure (IOP) measurements using the Goldmann applanation tonometer and fundus examination. The surgical techniques and postoperative protocols have been detailed in previous reports.[1,7,10,15]

Summary of surgical procedure – Baerveldt shunt implantation (described in detail elsewhere)[15]

A peritomy was performed in the superotemporal quadrant. The superior and lateral rectus muscles were identified and freed from the surrounding tenons. The tube plate was placed under the bellies of the recti and secured to the sclera with 9.0 prolene sutures. The tube was inserted into the AC via a scleral entry, just posterior to the limbus. An occluding stent (3.0 Supramid suture) was inserted intraluminally to obstruct aqueous outflow, however if there was insufficient flow restriction, a ligation suture was placed around the distal end of the tube. Processed human pericardium (Tutoplast® Pericardium, IOP Ophthalmics, Costa Mesa, USA) was placed over the extraocular portion of the tube and secured with one 10.0 nylon overlying mattress suture.

Patients who underwent combined surgery underwent standard small incision phacoemulsification via a temporal approach prior to tube insertion into the AC

Postoperative protocol for the Baerveldt tube

Postoperative management included unpreserved topical dexamethasone (Dexafree® UD 0.1%) 8 times daily, tapered over 4-6 weeks and ofloxacin (Floxal® UD, Bausch and Lomb, Zug, Switzerland) 4 times daily. Argon laser suture lysis (LSL) of the nylon ligature suture was performed using a Hoskins lens ≥ 1 month after the surgery if IOP lowering was clinically required. If sufficient IOP reduction was not obtained after 12 weeks, the occluding stent was either retracted or removed depending on risk factors for hypotony.

Summary of surgical procedure - repeat deep sclerectomy (described in detail elsewhere)[1,7,10]

DS was performed in the superior quadrant. A superficial limbal based conjunctival flap was created and the sclera exposed. A superficial scleral flap measuring 5x5 mm was fashioned using a diamond knife and extended into clear cornea. Mitomycin C 0.2mg/mL was applied under the conjunctiva and scleral flap for 2 minutes. The inner wall of Schlemm's canal was removed and a collagen implant sutured to the scleral bed. The superficial scleral flap was secured over the implant with two loosely tightened sutures. Repeat surgery was carried out adjacent to the primary surgical site, either superotemporally or superonasally.

Patients who underwent combined surgery underwent standard small incision phacoemulsification, via a temporal approach, following dissection of the scleral flap which was sutured after phacoemulsification.

Postoperative protocol for the DS

Postoperative management included topical dexamethasone (1mg) and tobramycin (3 mg) (Tobradex ® Alcon, SA, Switzerland) 4 times daily. Topical steroids were tapered over 4-12 weeks. If IOP lowering was clinically required then a laser goniopuncture was performed (Microruptor II; Lasag AG, Thun, Switzerland; in Q-switch mode at 5 to 8 mJ) this created microscopic holes in the trabeculo-descemet membrane allowing direct passage of aqueous from the anterior chamber into the intrascleral space. If bleb scarring was observed a bleb needling was performed (at the slit lamp) and/or an antimetabolite injection was administered (0.1 mL 50-mg/mL solution 5-FU/ 0.05 mL 0.2 -mg/ml solution mitomycin C)

Failure criteria

Surgical failure was defined by the following criteria:

- Loss of light perception
- Further glaucoma surgery
- Loss of IOP control on two consecutive visits, at least three weeks apart* was classified as:
    - IOP ≤ 5mmHg
    - IOP ≥ 22mmHg
    - < 20% reduction in IOP from baseline

* IOP measures at all study time points were included in the analysis, however if postoperative interventions (goniopuncture, needlings, stent removal or laser suture lysis) were performed within the first six months, then failure was determined following the last postoperative intervention.

Complications

Macroscopic hyphema was considered present when >1 mm blood was seen in the AC.

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

The presence of choroidal effusions/hemorrhages and maculopathy was assessed by routine dilated fundus examination.

Statistical analysis

Analysis was performed using R version 2.15.1. Patients lost to follow-up were censored at their last visit. Missing data was assumed to occur at random. Since the parameters reported here (e.g. IOP, GM and VA) are not normally distributed, median and inter-quartile range (IQR) were reported. Mean values were included to enable comparisons with other studies.

RESULTS

A total of 58 eyes of 56 patients underwent BGI implantation and 58 eyes of 55 patients underwent repeat DS. Baseline demographics and follow up for the two groups are summarised in table 1. Preoperatively, there were more pseudophakic patients in the BGI group 83% (48) vs 52% (30) in the DS group. Also, preoperative IOP was significantly lower in the DS group (median/mean 19/20 mmHg) than the BGI group (median/mean 21/24mmHg; p=0.10; table 1, figure 1).

Baseline and follow up IOP measures are reported in table 1, table 2 and figure 1. Both DS and BGI lead to IOP lowering but the IOP profiles were markedly different between groups (figure 1). During the early postoperative period a larger IOP reduction was observed in the DS group (day 1: median IOP 9mmHg versus 19mmHg, figure 1). At week one, IOP in 13 eyes (22%) from the DS group fell within the hyptony range (≤5mmHg) versus 1eye (2%) from the BGI group, conversely, in the BGI group IOP in 14 eyes (24%) fell within the hypertony range (> 21mmHg) versus 1 eye (2%) from the DS group. These significant differences in early postoperative IOP between groups persisted until week 6 ($p<0.02$). Between six weeks and six months postoperatively, the majority of the occlusive stent removals were performed (BGI group), therefore at three and six months, a large reduction in median IOP was observed in the BGI group. At month 12, the median IOP in the BGI group was significantly lower than in the DS group (p=0.02).

Cumulative failure curves are shown in figure 2. Five eyes in the BGI group had failed due to insufficient IOP control (<20% reduction). Seven eyes in the DS group had failed due to insufficient IOP control (<20% reduction n=4, IOP<5mmHg n=3). Using the Kaplan-Meier analysis to examine failure (accounting for loss of follow up), at year one failure was estimated to be 21% (confidence interval 10-31%) in the BGI group and 30% (confidence interval 14-42%) in the DS group, this difference approached statistically significance. p=0.07 (figure 2). None of the eyes in the BGI group underwent a reoperation during the first year; four eyes in the DS group underwent a glaucoma reoperation during the first year (1 cyclodiode, 1 tube, 1 DS revision, 1 DS surgery at a different surgical site).

Table 1 shows the number of glaucoma medication in both groups at baseline and follow up. A significant reduction in glaucoma medication use was observed in both groups. There was no difference between groups.

Complication rates were different between the DS group and BGI groups (41% (n=24) versus 14% (n=8), $p<0.01$, chi-squared test; table 3). In the BGI group, three complications were related to hypotony (3 choroidal effusions), three were tube related (1 conjunctival erosion, 1 tube retraction, 1 tube tip damage). There was one case of hyphema and one case of Descemets' membrane detachment; the latter was treated successfully with an anterior chamber gas injection at the slit lamp. Of the eight eyes with complications, 3 required treatment in the operating room (3 tube-related complications). None of the eyes undergoing Baerveldt shunt implantation required further glaucoma surgery during the first year of follow-up. In the DS group, postoperatively one fifth of eyes had a seidel positive wound leak (n=11), half of these lasted less than 1 week (n=6), and one eye required surgical revision. Other complications were hypotony related: four choroidal detachments and one hypotony maculopathy.

Post-operative interventions:

In the DS group 41% (n=24) required at least one goniopuncture, 9% (n=5) required needling revision at the slit lamp, and 43% (n=25) required subconjunctival antimetabolite injections (table 4). In the BGI group, ligature suture lysis with argon laser was required in 13 of the 18 eyes where ligation had been performed. All eyes had occluding intraluminal stents to prevent hypotony. The mean time of occlusive stent removal was 17 weeks after surgery. In 17% (10 eyes) the stent removal was not required, in 64% (37 eyes) total stent removal was performed and in 19% (n=11) a partial stent removal was performed due to risk factors for hypotony. In 8 of these, total stent removal was required at a later date. One eye in the BGI group required a viscoelastic injection at the slit lamp and one eye required a bleb needling.

The majority of DS eyes (n=45, 78%) underwent single surgery and 13 (22%) eyes underwent combined surgery (with phacoemulsification). There were no significant differences in IOP, complications, number of interventions or failure rates between eyes that underwent DS alone and those that underwent combined surgery ($p>0.3$). Likewise, for the BGI group , where 53 eyes underwent single surgery and 5 (9%) eyes underwent combined surgery .

Mitomycin C was used intraoperatively in the majority of eyes in the DS group (n=47; 81%). Postoperatively at one year, there were no differences in failure or complications rates between DS eyes that received MMC intraoperatively and those that did not ($p>0.1$).

DISCUSSION

This is the first study to compare surgical failure rates and complications following Baerveldt shunt implantation and deep sclerectomy. Greater IOP reduction was observed following repeat DS in the first 3 months postoperatively. The IOP reduction in the BGI group continued to decrease up to six months post-operatively coinciding with the removal of flow restrictors (occlusive stents). By 12 months, median IOP was significantly lower in the BGI group than DS group. This may have important implications in reducing glaucoma progression.[25] A common definition of surgical failure is a reduction in IOP of less than 20% from baseline or outside the range of 5 to 21mmHg.[19-21] Using this criterion lower surgical failure was observed in the BGI group, which approached statistical significance (p=0.07).

A significantly greater number of postoperative complications were observed following repeat DS (41%) than BGI (14%). Complications in both groups were usually transient and did not result in permanent visual loss. Complication rates of repeat DS have not been previously reported but considering previous reports on repeat trabeculectomy,[19] these were expected to be greater than those with primary surgery (32 to 49 complications per 100 eyes table 3).[7,8,10] In recent multicentre trials, complications rates of Baerveldt tubes are higher than those reported here (ranging between 34% and 58% table 3) however approximately half of the reported complications were hypotony related.[20,22,23,27] In this report the BGI implantation technique and postoperative management were specifically modified to reduce postoperative hypotony related complications.[15,28]

Glaucoma surgery is a known risk factor for cataract progression, except possibly in non-penetrating surgery.[2,17] In the present report, visual acuity remained stable during the first year in both groups, however the reason for this may have differed between groups: DS may not have induced cataract formation, whereas most patients in the BGI group were pseudophakic at the time of surgery.

A significant difference between groups was observed in baseline preoperative VA , which could indicate there was a selection bias between samples. The lower VA of the BGI group suggests more advanced disease, which may also imply a longer duration of glaucoma medication use. There was however no difference in the mean number of preoperative medications. Such a difference might favour the DS group and does not serve to undermine the results reported here.

Retrospective data are known to result an under sampling of data and under reporting of complications, this is an obvious weakness of this study. However, both groups suffered equally from this weakness as surgeries were performed in the same tertiary centre. Overall, these results indicate reduced surgical success in eyes undergoing repeat DS, similar to previous reports on repeat trabeculectomy.[19,20] However these results need confirmation in prospective, randomised studies.

CONCLUSION

Eyes with Baerveldt shunt implants had greater IOP reduction and fewer complications one year post-operatively. This supports the supposition of Minckler that aqueous tube implantation should be considered when planning second line glaucoma surgery.[14]

Conflict of interest statement:

All authors certify that they have NO affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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Ethical approval:

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This was a retrospective study and no formal study individual consent was required.

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Table 1 Baseline characteristics

	DS n= 58, N=55	BT n=58, N=56	P-value
Mean age	70.9 years	73.0 years	0.42*
Sex (M/F)	17/41	26/32	0.09†
Diagnosis			
POAG	24	26	
PEXG	20	14	
PACG	8	6	
Neovascular glaucoma	0	2	
Juvenile glaucoma	2	2	
Uveitis	2	2	
Pigment dispersion glaucoma	1	3	
Traumatic	0	2	
Aphakic	1	1	
Pre-operative measures			
IOP Median [IQR] Mean (SD)	19 [15,23] 19.9 (6.1)	21 [17,23] 23.9 (10.2)	0.10‡ 0.01*
No.medications, Median [IQR] Mean (SD)	2.0 [2,3] 2.4(1.0)	3.0 [1,4] 2.6 (1.2)	0.04‡ 0.11*
VA (LogMAR) Median [IQR] Mean (SD)	0.2 [0.0, 0.3] 0.2 (0.2)	0.3 [0.2, 1.0] 0.7 (0.8)	<0.01‡ <0.01*
Post-operative measures (at one year)			
IOP Median [IQR] Mean (SD)	13.5 [11,16] 14.1 (±5.2)	11 [10,13] 11.6 (±3.7)	0.02‡ 0.01*
No.medications, Median [IQR] Mean (SD)	0.0 [0,2] 0.8 (±1.1)	1.0 [0,2] 1.1 (±1.2)	0.23‡ 0.53*
VA (LogMAR) Median [IQR] Mean (SD)	0.3 [0.2, 1.0] 0.1 (±0.2)	0.2 [0.1, 0.5] 0.5 (±0.5)	<0.01‡ <0.01*

POAG, primary open angle glaucoma; PEXG, primary exfoliation glaucoma; PACG, primary closed angle glaucoma; IQR, interquartile range; SD standard deviation; DS, deep sclerectomy group; BT Baeverdlt tube group; *two-sample t-test ; † McNemar test; ‡ Mann-Whitney test;** Chi-squared test

Table 2 Postoperative summary measures

Post-operative measures (at one year)	DS N=29	BT N=55	P-value
Mean IOP	14.1 (±5.2)	11.6 (±3.7)	0.01
Mean GM	0.8 (±1.1)	1.1 (±1.2)	0.52
Mean VA	0.1 (±0.2)	0.5 (±0.5)	0.01

Table 3 Complications				
	BT group % (n)	Previous Baerveldt tube studies %	DS group % (n)	Previous primary DS studies %
Total number of complications	14(8)	(n/sample size); (58/100)[4] (129/116)[20] (118/114)[21]	41 (24)	(n/sample size); (29/90)[11] (49/100)[10] (47/105)[12]
Eyes with complications	12(7)	34,[1] 39,[2] 54,[21]58,[20]	31(18)	
MINOR COMPLICATIONS				
Persistent hypotony	0 (0)	2,[20]	5 (3)	0,[9] 1,[10] 2,[12] 3,[13]
Shallow anterior chamber	0 (0)	11,[2,4] 14,[21, 28] 20,[20]	0 (0)	0,[12,1,10] 1,[14] 5,[9] 8,[13]
Choroidal effusion	5 (3)	10,[20] 14,[2,21] 15,[27] 16,[4] 23,[25]	7 (4)	0,[9] 8,[12] 11,[10] 13,[11]
Hyphema	2 (1)	2,[2] 7,[27] 20,[28] 22,[20]	2 (1)	0,[1] 1,[14] 7,[10] 8,[13] 9,[12] 11,[11] 18,[9]
Diplopia	0 (0)	3,[21,28]5,[2,20,27]	0 (0)	
Descemet's membrane detachment	2 (1)		0 (0)	
Iris incarceration	0 (0)		7 (4)	4,[14]
Seidel -Seidel lasting > 2 visits <1 week -Seidel requiring revision	0 (0) 0 (0) 0 (0)		17 (10) 7 (4) 2 (1)	2,[11] 9,[12] 10,[10] 12,[1] NA NA
Tube complications -exposure -blockage -retraction	 2 (1) 2 (1) 2 (1)	 1,[20] 1,[25] 9,[20] 4,[25] 2,[4]	 NA	
SIGHT THREATENING COMPLICATIONS				
Hypotonus maculopathy	0 (0)	1,[2,4] 2,[20]	2 (1)	0,[10]
Persistent corneal oedema	0 (0)	3,[25] 9,[2] 10,[27] 12,[21] 22,[20]	0 (0)	
Endophthalmitis	0 (0)	0,[21] 1,[20,2] 2,[27] 3,[28]	0 (0)	0,[14]
The indexed number is the associated reference number of the report where this complication rate was published; NA- not applicable				

Table 4: Post-operative interventions during the first six months following 2nd surgical intervention

Post operative DS interventions						
Number of interventions	Goniopuncture n (%)	Needling n (%)	Antimetabolite injections n (%)	Total no interventions per eye n (%)	Surgical intervention for complication n (%)	Reoperation for glaucoma n (%)
1	16 (28)	3 (5)	14 (24)	13 (22)	1 (2)*	4 (7)**
2	8 (14)	2 (4)	3 (5)	10 (17)	0	0
3+	0 (0)	0 (0)	8 (14)	12 (21)	0	0
Total no.	32	7	51	90	0	0
Total no. of eyes	24 (41)	5 (9)	25 (43)	35 (60)	1 (2)	4(7)
Postoperative BT interventions						
Laser suture lysis n (%)	Partial stent removal (%)	Total stent removal n (%)	Other interventions n (%)	Total no eyes with interventions n (%)	Surgical intervention for complication n (%)	Reoperation for glaucoma n (%)
13 (22)	11 (19)	37 (64)	3 (5)‡	51 (88)	3 (5)†	0

POAG, primary open angle glaucoma; PEXG, primary exfoliation glaucoma; PACG, primary closed angle glaucoma; IQR, interquartile range; SD standard deviation; DS, deep sclerectomy group; BT Baeverdlt tube group; *two-sample t-test † McNemar test ‡ Mann-Whitney test,** Chi-squared test

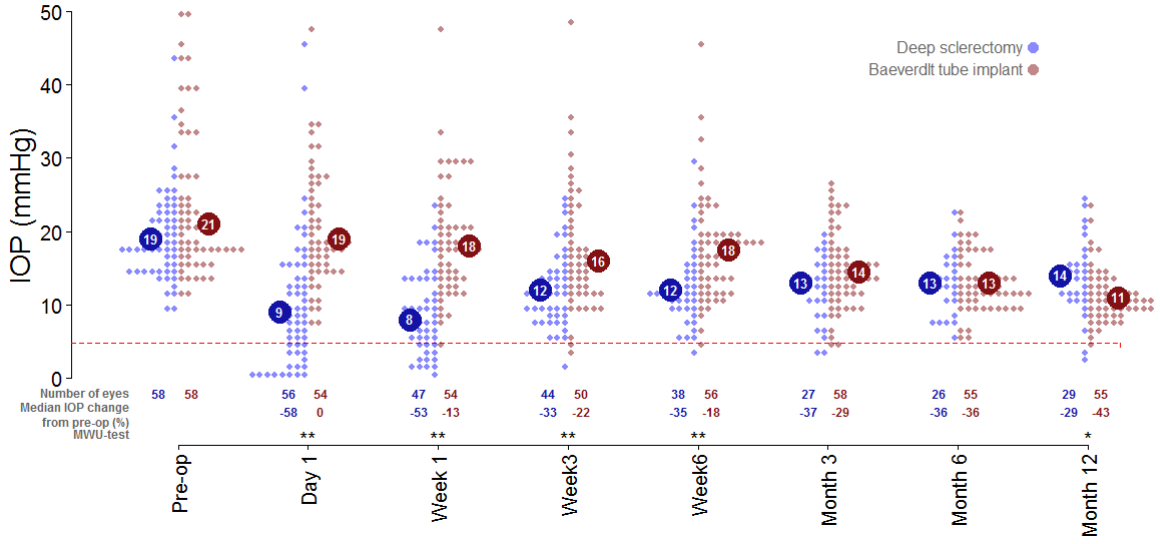

Figure 1. Strip-plots displaying intraocular pressures (IOP) of Baerveldt tube eyes (blue) and repeat deep sclerectomy eyes (red), during the first year of follow-up. The median IOP for both groups is shown within the solid circle at each time point. The red horizontal dashed line shows the 5mmHg limit for hypotony. The number of eyes at each time point is given, as is the median percentage change in IOP from baseline. Significance between groups was derived using Mann-Whitney U-tests (MWU), ** denotes p<.01, and * denotes p<.05.

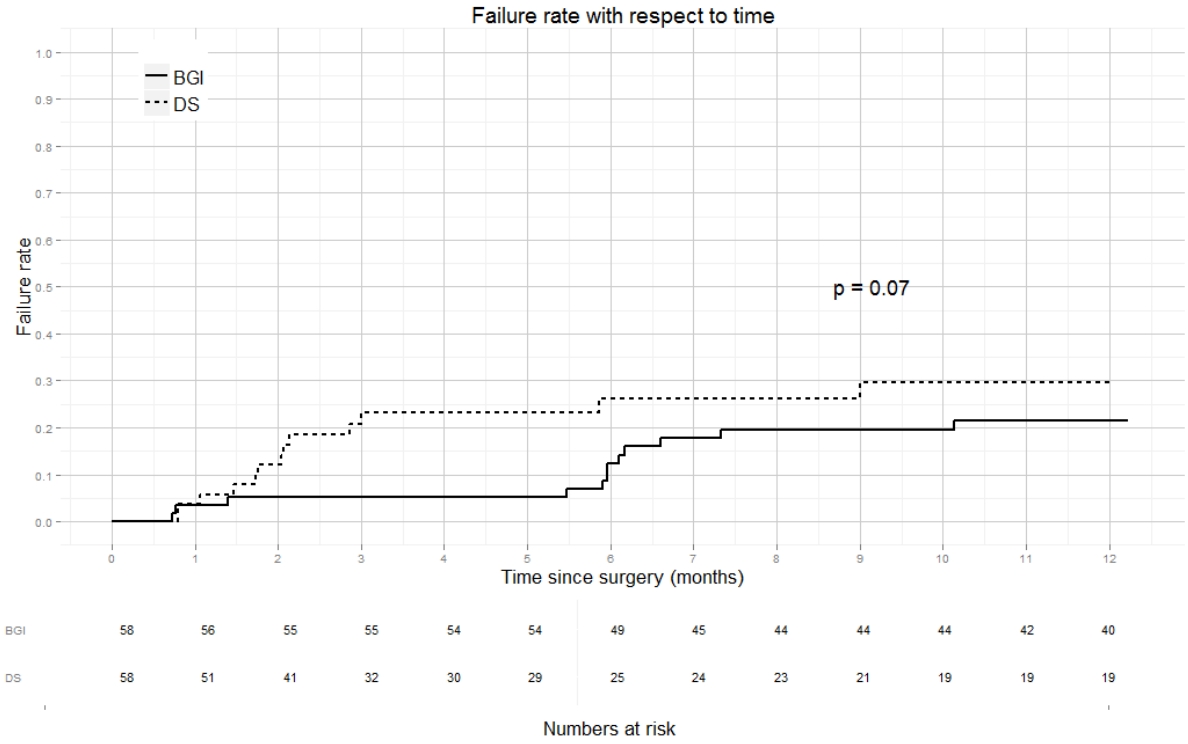

Figure 2. Kaplan-Meier cumulative failure curve for DS group (gray/solid lines) and BGI groups (black/dashed lines). Using the log-rank statistic the difference between the failure curve of the DS and BGI groups was assessed, the associated p-value was 0.07.