Comparison of surgical outcomes between sulcus and anterior chamber implanted glaucoma drainage devices

Ibrahim A. Alobaida, Rizwan Malik, Sameer Ahmad





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Abstract:

PURPOSE: This retrospective case-control cross-sectional study compared the outcomes of sulcus placement of glaucoma drainage devices (GDD) versus traditional anterior chamber (AC) to test the hypothesis that sulcus placement results in fewer complications whilst maintaining similar efficacy.

METHODS: This study included 45 patients in the sulcus group and 60 patients in the anterior chamber (AC) group who had undergone surgery from January 2014 to December 2017. Data were collected on pre-operative demographics, operative details and post-operative intraocular pressure and complications. The IOP, number of medications and complications between the two groups was compared. A *P* value of <5% was considered statistically significant.

RESULTS: The sulcus group had significantly lower overall complications compared to the AC group with a comparable IOP decrease between groups. There were significantly lower rates of hyphaema in the sulcus (3 cases) compared to AC group (17 cases) (P < 0.05). Severe or late complications (implant exposure, corneal decompensation, endophthalmitis, poor vision, choroidal hemorrhage and cornea edema) were significantly lower in the sulcus group [2 eyes; 4.4%] compared to the AC group [13 eyes; 21.7%] (P < 0.05). The sulcus group required fewer medications during the follow-up period.

CONCLUSION: Sulcus implantation of GDD resulted in less postoperative hyphaema and severe complications compared to AC implantation. Our findings concur with the literature that sulcus implantation is safe and effective for controlling IOP for various types of glaucoma. The long-term effects of endothelial cell loss for sulcus versus AC implantation require further evaluation.

Keywords:

Glaucoma drainage implants, glaucoma, anterior chamber, sulcus, angle-closure

INTRODUCTION

The implantation of glaucoma drainage devices (GDD) has steadily increased over the last several years especially in eyes with failed filtration surgery.^[1-5] GDD implantation has also been performed as a primary intervention in cases with a high risk for failed trabeculectomy.^[1-5] The tube versus trabeculectomy (TVT) study, has reported higher success rates with GDD than trabeculectomy.^[1] A recent prospective comparison of the Ahmed valve to the Baerveldt implant reported good success with minor differences between the implants.^[6] However, most studies of these GDD report a risk of

Glaucoma Division, King Khaled Eye Specialist Hospital, Riyadh, Saudi Arabia

Address for correspondence:

lbrahim A. Alobaida, King Khaled Eye Specialist Hospital, PO Box 7191, Riyadh 11462, Saudi Arabia. E-mai: iobaida@kkesh.med.sa

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This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms. corneal decompensation that ranges from 10-16%, which is much higher than that reported after conventional trabeculectomy.^[1,7-9]

The higher rate of corneal decompensation after GDD implantation has been attributed to a number of factors including, the decreased distance between the tube tip and endothelium and mechanical touch during eye rubbing or eye movement and blinking.^[10,11] An increased risk of corneal decompensation has also been correlated to the length of the tube. However, a recent study used multivariate analysis to report that only the distance between the tube tip and endothelium was significantly associated with postoperative endothelial cell loss and tube length was not a factor.^[2] Pars plana insertion of the tube has

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been recommended in patients who are scheduled to undergo penetrating keratoplasty (PKP) or have already undergone PKP.^[10] However, this insertion technique involves an extra surgical procedure with the added risk of posterior segment complications including retinal detachment, endophthalmitis, vitreous hemorrhage or vitreous incarceration within the tube.^[10-13] Additionally, progressive endothelial dysfunction has been reported presumably due to increased postoperative inflammation and mechanical stress during the vitrectomy procedure.^[10,14]

Recent studies have shown that tube implantation through the ciliary sulcus is safe and efficacious for the Ahmed and Baerveldt GDDs.[15-20] Two of these studies describe a similar technique which requires an inferotemporal paracentesis with placement of viscoelastic superiorly to inflate the sulcus.^[14,19] These studies report a 26-28% risk of early postoperative hyphema and 8-9% risk of flat/shallow anterior chamber complications, both of which may place the corneal endothelium at risk for further injury. Notably, these studies included all types of glaucoma, and only one study evaluated GDD implantation in angle closure glaucoma.[21] Therefore, the aim of our study is to evaluate the outcome of sulcus placement of tubes in various types of glaucoma with the majority due to secondary mechanisms. We also describe a unique technique for sulcus tube implantation that mitigates surgical trauma, potentially improving long-term outcomes and decreasing postoperative complications compared to current techniques.

Methods

Study design

This was a retrospective cross-sectional case-control study. Data were retrospectively reviewed for patients who underwent GDD implantation at King Khaled Eye Specialist Hospital (KKESH), from 2014 to 2017. A comparison was performed between two groups of subjects: 45 eyes of 43 patients with tube shunts implanted through the ciliary sulcus (sulcus group) and 60 eyes of 57 patients with tube shunts implanted in the anterior chamber (AC; control group). The Human Ethics Committee/Institutional review board (IRB) at the King Khaled Eye Specialist Hospital approved this study.

Inclusion criteria

Patients in the sulcus group were included if the tube was implanted through the ciliary sulcus to rest between a posterior chamber intraocular lens (PCIOL) and the iris, with all surgeries performed by the one surgeon. For the control group, various cases were included with tubes implanted through the anterior chamber during the same period by multiple surgeons. Patients with <6 months follow-up data were excluded in both groups.

Data collection

Preoperative data included age, gender, glaucoma diagnosis, visual acuity (VA), intraocular pressure (IOP), number and type of any previous ocular surgeries, and number of glaucoma medications. Intraoperative data included the date of surgery, operative eye, type of GDD (Ahmed or Baerveldt)

and any intraoperative complications. The VA, IOP, number of glaucoma medications at each visit, complications and additional glaucoma surgery was documented. Follow-up visits were scheduled at the surgeon's discretion based on patient availability. Typically follow up visits were performed at 1 day, 1 week, 4 weeks, 3 months, 6 months and then annually postoperatively. The date of the last follow-up visit at KKESH was also recorded.

Surgical technique

After standard preparation and sterile draping of the eye, an eyelid speculum and a #7-0 vicryl corneal traction suture was placed. A conjunctival incision was made at the limbus in a circumlimbal fashion for 3 clock hours. Stevens scissors were used to open the superotemporal quadrant and Westcott scissors were used to free up tissues using combined blunt and sharp dissection. The Ahmed or Baerveldt implant was gently primed with BSS and the plate inserted into the exposed quadrant. The Baerveldt implant had an intraluminal 5-0 nylon or prolene suture which was occluded with a 7-0 vicryl suture to minimize risk of immediate postoperative hypotony. The plate was sutured to the sclera with 9-0 nylon with the anterior edge 9 mm posterior to the limbus. Sulcus tube entry was performed in pseudophakic eyes or performed together with cataract extraction in phakic eves. For the sulcus tube entry, a 30-gauge needle was firstly used to create a guiding sclerostomy track followed by a bent 23-gauge needle was used to make a stab incision 2 mm posterior to the limbus to inflate the ciliary sulcus [Figure 1]. For eyes that received the Baerveldt GDD, the sulcus was inflated with a small volume of air and viscoelastic (Provisc® Ophthalmic Visco-surgical Device, 1% Sodium Hyaluronate, Fort Worth, Texas). For eyes that received the Ahmed GDD, viscoelastic on a 30-gauge needle was used to inflate the sulcus. The tube was trimmed to an appropriate length and inserted into the sulcus usually along the visual axis, Bevel up bevel up within the margin of the pupil, and appropriate placement was confirmed. No paracentesis was made during the procedure for sulcus placement. For AC tube entry, visoelastic (Provisc® Ophthalmic Visco-surgical Device, 1% Sodium Hyaluronate, Fort Worth, Texas) was usually injected through a small temporal paracentesis and left in the eye to prevent postoperative hypotony. A 10-0 nylon suture was used to secure the tube to the sclera. The tube was trimmed to an appropriate length and inserted into the AC with bevel up bevel up, and appropriate placement was confirmed Subsequently, a piece of donor tissue (sclera, pericardium or cornea) was trimmed and sutured to the episclera with a 10-0 nylon suture to cover the tube as a patch graft. The conjunctiva was closed with 8-0 or 9-0 vicryl running sutures and all wounds were watertight at the end of the case. The subconjunctival space was injected with Cefazolin (50 mg/0.5 ml solution (0.5 mL) and Decadron (2 mg/0.5 ml solution (0.5 mL)).

Statistical analysis

Data were collected in an Excel 2010 spreadsheet (Microsoft Corp., Redmond, WA, USA). Data were analyzed using SPSS

version 20.0 (IBM Corp., Armonk, NY, USA). Descriptive analysis was performed and categorical variables are presented as frequencies and percentages. Continuous variables are presented as mean (±standard deviation). The Chi^[2] test was used to test the differences between categorical variables in the case and control groups. The between-group differences in continuous variables were evaluated with the Student's t-test. The Wilcoxon signed-rank test was used to test for differences between glaucoma medications preoperatively and post-operatively between groups. We defined 'severe complications' as implant exposure, corneal decompensation, endophthalmitis, decrease of visual acuity by two lines of Snellen acuity or more, choroidal hemorrhage. The frequency of severe complications was compared for the AC and sulcus groups. A P value less than 0.05 was considered statistically significant.

RESULTS

One hundred consecutive eligible patients met the entry criteria and were enrolled in the study. The mean follow-up period was 14.2 months (range, 6–26 months) in the study group and 16.5 months (range 7–28) in the control group (P = 0.167). All sulcus tube patients were pseudophakic. Patients in the sulcus group who were phakic at the time of surgery underwent cataract extraction and tube insertion same time.

There were 20 eyes with chronic angle closure glaucoma (CACG), 10 eyes with secondary angle closure glaucoma, 25 eyes with neovascular glaucoma (NVG), 14 eyes with uveitic glaucoma, 8 eyes with primary congenital glaucoma (PCG) and, 14 eyes with primary open angle glaucoma (POAG) [Tables 1 and 2].

Table 1: Demographics of patients who underwent sulcus placement of tubes or anterior chamber placement for primary and secondary angle closure plaucomas

primary and secondary angle closure gradoonias			
Demographic feature	Cases $n = 45$	Controls n=60	Р
Age in years, Mean±SD	52.7±19.3	53.5±24.0 [2-99]	0.427
Gender			
Male (%)	20 (44.4)	29 (48.3)	0.693
Female (%)	25 (55.6)	31 (51.7)	

SD=standard deviation; P<0.05 is statistically significant

The two groups were similar in age, gender, visual acuity, preoperative IOP, and previous glaucoma surgery. The types of glaucoma were similar between groups except CACG, which was higher in the sulcus group, while PCG was more prevalent in the control group. The number of prescribed pre-operative topical or systemic anti-glaucoma medications was higher in the control group. The history of previous ocular surgery was similar between groups, except for cataract surgery, which was higher in the control group [Table 2].

The type of implants was similar between groups and no intraoperative complications occurred in either group [Table 3].

The duration of follow was similar between groups. Visual acuity and final IOP were similar between groups [Table 4]. Both control and sulcus group had a statistically significant decrease in a number of medications post operation in case group the mean number of medication was 4.4 and 1.9 postoperatively with *P*-value <0.001. For sulcus group the mean number of medication pre-operative was 4.2 and 2.1 post-operatively with with P-value <0.001. The incidence of hyphema was statistically significantly lower in the sulcus group compared to the control group [3 and 17 respectively (P < 0.05)]. There was no statistical difference between groups with regards to other complications. Severe or late complications (such as implant exposure, corneal decompensation, endophthalmitis, poor VA, choroidal hemorrhage or cornea edema) were statistically significantly lower in the in the sulcus group (2 eyes) compared to the control group (13 eyes) (P < 0.05) [Table 4].

DISCUSSION

Many studies have reported that patients with glaucoma have lower endothelium cell counts compared to agedmatched controls.^[22] This is especially true for angle closure glaucoma.^[23] The lower counts in angle closure cases are likely due to additional endothelial stress during acute and subacute angle closure attacks.^[23,24]. Previous studies have also reported a statistically significant association between the degree of preoperative peripheral anterior synechiae (PAS) and a postoperative decrease in corneal cell density after tube insertion in the AC.^[25] Many studies have reported that both AC and pars plana tube placement cause higher rates of corneal



Figure 1: Surgical technique of sulcus tube implantation. (a) Initial 30-guage needle entry to guide the position of the sclerostomy (arrow shows needle tip); (b) 23-guage needle sclerostomy entry with injection of small amount of Provisc (1% Sodium Hyaluronate, Alcon, Fort Worth, Texas) into the cilary sulcus along the same track as the initial 30-guage entry; (c) final position of tube in the ciliary sulcus (arrow)

decompensation.^[10,13,25-27] Some studies have reported that sulcus implantation is safe, effective and has the potential for lower risk of corneal decompensation.^[2,14,19] Our current study further validates the safety and efficacy of sulcus placement of GDD while introducing a unique technique that is less traumatic to the eye, without requiring a paracentesis, and is reproducible and more efficient than current techniques reported in the literature. Posterior segment tube insertion into the pars plana may have theoretical advantages for protecting against future lamellar or full-thickness corneal procedures. However, sulcus tube placement may carry this same advantage given the increased distance of the tube from the endothelial surface with far less surgical trauma to the eye [Figures. 2 and 3]. Prospective comparisons of the various tubes entry sites are required to determine if any carry an advantage for future graft survival.

Table 2: Pre-op	perative di	iagnostic a	and treatmen	it
characteristics	of sulcus	and anter	rior chamber	groups

Preoperative assessment	Sulcus group, (n=45)	AC group, (n=60)	Р	
Type of glaucoma				
1-POAG	4 (8.9)	10 (16.7)	0.246	
2-CACG	13 (28.9)	7 (11.7)	0.026*	
3-PXEF	1 (2.2)	4 (6.7)	0.287	
4-Uveitic glaucoma	8 (17.8)	6 (10.0)	0.246	
5-Aphakic glaucoma	3 (6.7)	2 (3.3)	0.427	
6-2 nd PKP LKP	0 (0.0)	1 (1.7)	0.384	
7-NVG	10 (22.2)	15 (25.0)	0.741	
8-PCG	0 (0.0)	8 (13.3)	0.011*	
9-SCG	2 (4.4)	0 (0.0)	0.099	
10-Secondary ACG	2 (4.4)	8 (13.3)	0.125	
11-JOAG	1 (2.2)	1 (1.7)	0.854	
12-Other	2 (2.2)	0 (0.0)	0.251	
Number anti-glaucoma	4.4 (0.9)	4.2 (0.7)	0.026*	
Medication: Mean±SD [Range]	[0-5]	[3-6]		
Previous glaucoma surgery				
1-Trab	12 (26.7)	18 (30.0)	0.708	
2-DS	1 (2.2)	5 (8.3)	0.182	
3-Trab revision	2 (4.4)	2 (3.3)	0.769	
4-AVI	1 (2.2)	4 (6.7)	0.29	
5-CPC	5 (11.1)	7 (11.7)	0.929	
6-Laser	0 (0.0)	4 (6.7)	0.078	
7-Other	0 (0.0)	3 (4.1)	0.171	
Previous ocular surgery				
1-Cataract	19 (42.2)	39 (65.0)	0.020*	
2-Cornea	2 (4.4)	2 (3.3)	0.769	
3-Retina	7 (15.6)	5 (8.3)	0.25	
4-Other (primary repair)	0 (0.0)	1 (1.7)	0.384	
BCVA LogMAR Mean±SD	1.4 (0.9)	1.3 (1.0)	0.445	
[Range]	[0-3]	[0-3]		
IOP (mmHg) Mean±SD	31.6 (10.2)	32.2 (9.9)	0.724	
[Range]	[11-62]	[10 60]		

n=number of patients; SD=standard deviation; IOP=intraocular pressure; AC=anterior chamber; POAG=primary open angle glaucoma; CAGC=closed angle glaucoma; PXEF=pseudoexfoliation glaucoma; PKP=penetrating keratoplasty; LKP=lamellar keratoplasty; NVG=neovascular glaucoma; PCG=primary congenital glaucoma; SCG=secondary glaucoma; ACG=angle closure glaucoma; Trab=trabeculectomy; DS=deep sclerectomy ; AVI=Ahmed valve implantation; CPC=cyclophotocoagulation; BCVA=best corrected visual acuity; *P*<0.05 is statistically significant Our results concur with previous studies that establish the efficacy and safety of GDD insertion in the ciliary sulcus.^[14-20] However, posterior capsular rupture or dislocated IOLs are important contraindications to sulcus implantation of GDD. In these circumstances, AC placement is advisable due to protection of the iris from any potential vitreous obstruction [Figure 4]. It is also not advisable to perform sulcus placement



Figure 2: Ultrasound biomicroscopy (UBM) Photo showing tube in the sulcus (arrow)



Figure 3: Ultrasound biomicroscopy (UBM) Photo showing tube in the sulcus (arrow)



Figure 4: Ultrasound biomicroscopy (UBM) Photo showing tube in the AC (arrow)

in eyes with pseudoexfoliation given the potential for zonular weakness and potential vitreous prolapse.

The current study included 8 uveitic patients with sulcus tube placement which is the largest cohort reported to date in peer reviewed literature. The safety of sulcus placement of tubes in these challenging high-risk patients is established by our observation of the lack of chronic CME or refractory uveitis postoperatively.

The three largest studies of sulcus implantation of glaucoma tube shunts reported postoperative hyphema in 26% and 32% of cases.^[14,19,28] Similarly we noted postoperative hyphema in 28% of cases the underwent AC placement. Notably, the incidence of postoperative hyphema was statistically significantly lower for sulcus placement compared to AC placement (6.6% vs. 28% respectively). This outcome may be due to our unique technique of tube entry using viscoelastic on a 30-gauge needle as described above or due to insertion of the tube away from the iris vasculature. Subjectively, we have noted this technique results in a more STABLE AC with minimal shallowing or decompression. Hence, an extra inferior paracentesis is not required with our technique compared to previous surgical techniques for inflating the ciliary sulcus.^[18,27,16] Secondary glaucomas tend to have more peripheral anterior synechiae (PAS) which can increase the incidence of bleeding with AC

Table 3: Distribution of glaucoma tubes and intraoperative
complications among among patients who underwent
sulcus placement of tubes or anterior chamber placement
for primary and secondary angle closure glaucoma

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	Sulcus group n=45 n (%)	AC group n=60 n (%)	Р
Type of implant			
1-Ahmad	38 (84.4)	49 (81.7)	0.709
2-Baerveldt	7 (15.6)	11 (18.3)	
Eye			
1-OD	16 (35.6)	34 (56.7)	0.032*
2-OS	29 (64.4)	26 (43.3)	
Intraoperative complication	0 (0.0)	0 (0.0)	
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n=number of patients; P < 0.05 is statistically significant

tube placement. In these angle closure cases, there is often more accessible space in the ciliary sulcus than in the AC in pseudophakes. Once mastered, this tube entry technique resulted in less surgical time and tissue trauma. Additionally, the posterior tube entry with sulcus placement compared to AC placement potentially decreases the risk of future tube exposure and secondary infection.

The outcomes of our study indicate that sulcus tube implantation is as effective as AC placement in reducing IOP with pre-operative IOP mean in both control group and sulcus group (31.6 and 32.2 respectively) and Post-operative IOP mean (16.7 and 18.1 respectively with P < 0.05). In the current study, the sulcus entry group used a greater number of medications preoperatively and ended up with a lower number of medications postoperatively compared to patient who underwent AC tube placement. Another previous retrospective study also found a similar need for medication in the sulcus compared to AC group, although the sulcus group had lower post-operative IOP.^[20] Although not adequately studied, tube placement in the AC may alter the existing trabecular outflow facility given the proximity of the tube to potentially functional trabecular meshwork. With tube insertion in the ciliary sulcus, no direct disruption of trabecular outflow occurs which may result in an additive IOP lowering effect. Further investigation of the effect of sulcus placement on aqueous drainage is warranted.

In current study, grouping of severe complications such as tube exposure, endophthalmitis, and corneal decompensation resulting in a statistically significantly higher number of complications in the AC group (21%) compared to sulcus group (4.4%) (P < 0.05). This outcome was likely due to the more posterior scleral entry of the tube with sulcus insertion and the reduced number of surgical incisions with our technique, although there is limited evidence in the literature to verify this claim. Perhaps there is a lower risk of tube exposure due to lower tube profile under the eyelid with more posterior scleral entry. We performed a subanalysis of complications in patients with congenital glaucoma and found only 2 out of 13 patients

Table 4: Postoperative assessment of pat	atients who underwer	t sulcus or	anterior chamb	er
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	Cases $n = 45$ Mean \pm SD [Range]	Controls <i>n</i> =60 Mean±SD [Range]	Р
Length of follow-up in months	14.2±6.6 [0.6-26]	16.5±5.2 [7-28]	0.167
Final BCVA LogMAR	1.3±1.1 [0-3]	1.3±1.1 [0-3]	0.645
Final visit IOP (mm Hg)	16.7±5.5 [5-34]	18.1±6.2 [7-35]	0.385
Final visit medications	1.9±1.5 [0-4]	2.1±1.4 [0-4]	0.026*
Complications:	n (%)	n (%)	
1-Hypotony	2 (4.4)	0 (0.0)	0.099
2-Flat AC	1 (2.2)	6 (10.0)	0.114
3-Tube blocked	1 (2.2)	4 (6.7)	0.29
4-severe complication*	2 (4.4)	13 (21.7)	0.013*
5-Hyphema	3 (6.6)	17 (28.3)	0.005*
6-Aqeous Misdirection	1 (2.2)	1 (1.7)	0.854
7-Choroidal Detachment	1 (2.2)	2 (3.3)	0.738
8-Fibronous Reaction	0 (0.0)	2 (3.3)	0.221

BCVA=best corrected visual acuity; IOP=intraocular pressure; SD=standard devi-ation; AC=anterior chamber. *P*<0.05 is statistically significant. * Patients with implant exposure, corneal decompensation, endopthalmitis, poor VA, choroidal hemorrhage or cornea edema

with severe or late complications. Prospective comparisons of endothelial cell counts and GDD exposure rates in both groups may help validate our subjective impressions of the possible advantages of sulcus tube placement in pseudophakic patients.

The theoretical disadvantage of our technique involves a moderately steep learning curve and potential difficulty accessing the tube if future surgical revision is required. However, intraoperative anterior segment

OCT and ultrabiomicroscopy can be used to locate the ciliary sulcus in vivo and may provide additional safety for tube insertion.

The limitations of this study include its retrospective nature and short duration of follow-up. A prospective comparison of endothelial cell morphology in both groups would ideal for testing the hypothesis that tube placement in the sulcus is safer for the cornea than traditional AC placement in pseudophakic eyes. A potential bias in this study is that a single experienced glaucoma surgeon performed the sulcus tube placement while multiple experienced surgeons including those in glaucoma fellowships performed surgery in the control group. In our study we investigated different types of glaucoma implant in both groups (Ahmed and Baervedlt) and our study was not confined to one type of GDD. However, we assume that there is no difference between the two GDDs in term of complications of corneal decompensation or hyphaema as the composition of both tubes is similar.

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Conflicts of interest

There are no conflicts of interest.

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