

A Comparison of Scleral Tunnel and Pericardial Graft Implantation Techniques in Patients undergoing Ahmed Glaucoma Valve Implantation

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Abstract

The purpose of this study was to compare the two methods autologous scleral flap (scleral tunnel) and pericardial patch graft of tube covered in Ahmed glaucoma valve (AGV) in refractory glaucoma with respect to the tube exposure, infection, level of Intraocular Pressure (IOP), and any other complications due to applications of each technique. A retrospective chart review of 113 eyes in 102 patients with refractory glaucoma who underwent ahmed glaucoma valve (AGV) implantation (39 eyes in scleral tunnel and scleral flap group “first group” and 74 eyes in pericardium graft group” second group”) was performed. The procedures in these eyes were performed between January 2007 and October 2015 in a tertiary eye care hospital in KSA. The mean age was 56 ± 19 (8 months- 83 years) in the Scleral tunnel group and 50 ± 27 (1- 78 years) in the Pericardium group ($p = 0.023$). Fifty-six males and 57 females were included in the study. Medians of the follow-up were 48 ± 25.5 months (3 – 89) for the Scleral tunnel group and 29 ± 21.4 months (2 – 92) for the Pericardium group, and it is statistically significant ($P < 0.001$). According to the findings, preoperative diagnosis in the two groups included neovascular glaucoma (NVG) found in 21 eyes (53.8%) in the Scleral tunnel group versus 18 eyes (24.3%) in the Pericardium group ($p = 0.009$). Exposure of the valve was found in 15 eyes (20.27%) in Pericardium graft group versus 2 eyes (5.12%) only in scleral tunnel group ($p = 0.002$). These exposed valves lead to endophthalmitis in 5 cases in the second group and no single case in scleral tunnel group was detected ($P < 0.001$). The postoperative IOP values were statistically insignificant in all different time periods.

Scleral tunnel method has less exposure rate than the pericardium graft.

Keywords: Ahmed glaucoma valve, neovascular glaucoma, pericardial patch graft, refractory glaucoma, scleral tunnel

1. Introduction

Glaucoma drainage devices (GDD) has been well-established as a treatment of refractory glaucoma in which conventional filtering surgery has failed, or as primary filtration procedure long time ago (Gedde et al., 2012). The refractory glaucoma includes eyes with neovascular glaucoma, congenital glaucoma, uveitic glaucoma, glaucoma in aphakia and pseudophakia, glaucoma associated with trauma, vitreoretinal disorders, penetrating keratoplasty and eyes that have failed previous filtration surgery (Schwartz, Lee, & Gedde, 2006; Assaad, Baerveldt, & Rockwood, 1999; Budenz et al., 2011).

Many devices have been developed to aid angle filtration by shunting aqueous to a site away from the limbus. These devices' tubes are placed in the anterior chamber, in the ciliary sulcus, or through the pars plana into the vitreous cavity in vitrectomized eyes. Aqueous flows to the subconjunctival space where the extraocular plate is located (Budenz et al., 2011; Weinreb & Mills, 1998; Pine & Murphy 2005). According to their resistance to the aqueous outflow, these devices are classified into valved and non-valved tubes. The earliest and the most common use of the non-valved tubes is the Molteno implant and the Baerveldt implant. Major advances were made by Theodore Krupin in 1979 with the introduction of Krupin valve (Lim et al. 1998) and by Abdul Mateen Ahmed with the entry of Ahmed Glaucoma Valve (AGV) to the market in 1993 (Farrokh-Siar et al., 2008). The most

widely used valved device is the Ahmed (New World Medical, Inc, Rancho Cucamonga, Ca), which allows one-way regulation of the flow with a goal of keeping the intraocular pressure (IOP) between 8 and 10 in the early post-operative period (Budenz et al., 2011). It has different models such as FP7, FP8, S2 and S3 (according to patient age and plate surface area) (Coleman et al., 1995; Ayyala et al., 2000).

The most common devastating shunt-specific delayed complication is tube exposure due to conjunctival erosion. Tube exposure following conjunctival erosion in AGV implant appeared to be a major risk factor for the development of endophthalmitis (Chen, Bhatia & Walton, 2005; Al-Torbak & Edward, 2001; Minckler et al., 2008; Al-Torbak et al., 2005). Different mechanisms were mentioned explaining the cause of conjunctival melting and erosion. Tube exposure may be due to immune mediated process (Lama & Fechtner, 1999), ischemic changes of conjunctiva (Dubey et al. 2013) or due to mechanical pressure by the eyelid blinking (Byun, Lee & Park, 2009).

There are two surgical methods for tube coverage that are generally involved before it is inserted into the anterior chamber used in AGV implantation. The first method requires covering the drainage tube with an autologous scleral flap (Heuer, Budenz & Coleman, 2001). In the second method, the drainage tube is covered with preserved tissues that include donor sclera (Freedman, 1987), Tutoplast (pericardium) (Smith, Doyle & Tierney Jr, 2002), dura (Brandt, 1993), preserved cornea (Rojanapongpun & Ritch, 1996), autologous fascia lata (Wigton et al., 2014), amniotic membrane (Tanji et al., 1996; Papadaki et al., 2007; Anand et al., 2011) or Perichondrium (Chun, Kim & Kim, 2013), etc.

Since few studies were found comparing the two methods of tube covering by scleral flap and pericardial patch from the complication and IOP control sides (Huddleston et al., 2013), this study aims to compare the long-term surgical outcomes between these two methods.

2. Method

This study retrospectively reviewed the medical records of all the patients who underwent AGV implantation in a tertiary eye care hospital in Saudi Arabia between January 2007 and October 2015 after research and ethics committee in Al Imam Abdulrahman Bin Faisal University accepted the proposal. Pre-operative data were collected including age, sex, preoperative IOP, the number of pre-operative anti glaucoma medications used and the preoperative best-corrected visual acuity (BCVA).

All the patients underwent Optic nerve OCT analysis, corneal pachymetry measurement, and Humphrey Visual field 24-2 test. The date of surgery and type of anesthesia were recorded by the researcher. Post-operative data were collected including IOP in 7 time periods, AC formation, complications, valve explanation, number of post-operative antiglaucoma medication if needed, the post-operative best-corrected visual acuity (BCVA), and follow up duration.

The patients included in the study were: (1) all cases of refractory glaucoma including NVG, congenital glaucoma, uveitic glaucoma and other types of secondary glaucoma; (2) all cases with IOP >21mmHg in spite of using full anti glaucoma medications; (3) all patients with progressive glaucomatous optic neuropathy and maximum anti glaucoma medication usage; and (4) patients who underwent failed trabeculectomy. The patients excluded from the study were: (1) all the cases with visual acuity of hand motion vision or worse; (2) all immunocompromised patients; (3) all the patients implanted with any glaucoma drainage device before AGV or implanted AGV as second valve procedure.

Young patients under age of 20 years underwent general anesthesia while other older patients underwent local anesthesia. A total of two surgical methods were performed: First one was the scleral flap, which comprised of silicon AGV implantation (models FP7 or FP8 according to the age of the patient) using a standardized surgical technique by two surgeons. After administration of regional or general anesthesia, a fornix-based conjunctival flap was fashioned in the superotemporal quadrant. Then, a U-shaped partial thickness scleral flap 4x5 mm, medial or lateral canthus based was formed. After the excision of redundant Tenon's capsule, a large single Weck-cell sponge soaked in a 0.2 mg/mL solution of MMC was placed under the conjunctiva and the Tenon's capsule at the site where the implant plate was to be placed, for a contact time of 2 minutes. The application of the sponge was followed by irrigation with at least 50 mL of balanced salt solution (BSS). The anterior edge of the plate was then secured with 7-0 Prolene sutures (PROLENE® Polypropylene Suture; Ethicon, Inc, Somerville, New Jersey, USA) to the sclera at least 8-10 mm away from the limbus. The tube tip was cut obliquely beveling up to avoid the tube lumen obstruction by the iris tissue and to protect the cornea from being touched by the tip of the tube. Viscoelastic was injected to maintain the anterior chamber before tube implantation, then a 23-gauge needle tract was used to enter the anterior chamber through the limbus. The tube in the anterior chamber was positioned anterior to the iris and away from the corneal endothelium. Scleral flap was sutured by 7-0 Prolene sutures (PROLENE®

Polypropylene Suture; Ethicon, Inc, Somerville, New Jersey, USA). The conjunctiva and Tenon capsule were re-approximated to the limbus with 8-0 Polyglactin sutures (Vicryl; Ethicon, Inc, Somerville, New Jersey, USA) or 10-0 Nylon sutures (ETHILON® Nylon suture; Ethicon, Inc, Somerville, New Jersey, USA) were used based on the preferences of researchers.

In scleral tunnel technique, Beaver blade was used to make a horizontal half thickness scleral wound 6-8 mm from the limbus. With crescent blade, two consecutive tunnels of 3 mm width and 3-4 mm length were made till the limbus to facilitate the tube manipulation. After that, engagement of anterior chamber was done by 23-gauge needle under viscoelastic material in anterior chamber and implantation of the tube after trimming its tip.

In the second method, pericardium graft was used where same technique creates the conjunctival flap. After securing the plate to the sclera, 5 mm x 4 mm pericardial graft was applied over the tube till the limbus and secured with 4 sutures of 10-0 Nylon suture (ETHILON® Nylon suture; Ethicon, Inc, Somerville, New Jersey, USA) at the corners of the graft.

The postoperative regimen included topical antibiotics for 2 weeks, topical cycloplegics and topical steroids for approximately 1 month. Anti-glaucoma medication was added when required to improve IOP reduction. Patients were examined in the following intervals; the next day of the surgery, the 1st week, the 1st month, the 3rd month, the 6th month and then annually after surgery as follow up.

2.1 Statistical Analysis

Statistical analysis was done by SPSS version 20.0 (SPSS Inc., Chicago, IL, USA). Preoperative and postoperative data were compared using the paired t-test. Two groups were compared using the Mann-Whitney U-test and Chi square or Fisher's exact test. The postoperative complications were compared using Chi-square test or Fisher's exact test. A p-value of less than 0.05 was considered statistically significant.

3. Results

This study investigated 113 eyes in 102 patients, in which 39 eyes underwent scleral flap method of AGV implantation in upper temporal quadrant and 74 eyes underwent the pericardium graft method. One valve on each group (2 total) was implanted in inferio-nasal side due to severe conjunctival fibrosis in upper temporal quadrant after previous glaucoma surgery.

The mean age were 56±19 years (8 months-83 years) in the Scleral tunnel group and 50± 27.7 years (1- 78 years) in the Pericardium group (p = 0.023). Fifty-six patients were males and fifty-seven were females in the two groups with no statistically difference (p=0.897). Median with range of the follow-up periods were 48 ± 25.5 months (3 – 89) for the Scleral tunnel group and 29 ± 21.4 months (2 – 92) for the Pericardium group, and it was statistically significant (P <0.001). Diabetes mellitus was found in around half of the overall patient, while hypertension was found in around 34% of all patients (Table 1). The means of preoperative IOP were 39.58 ± 12.13 mmHg in scleral tunnel group and 32.80 ± 8.04 mmHg in pericardium graft group, which is statistically significant (P= 0.003).

Table 1. Characteristics of patients

	Scleral flap group	Pericardium group	P value
Age	56±19 (8 months- 83 years)	50±27.7 (1- 78 years)	0.023*
Sex			0.897
Male	19 (48.7%)	37 (50%)	
Female	20 (51.3%)	37 (50%)	
DM	23 (58.97%)	33 (44.59%)	0.231
HTN	12 (30.76%)	28 (37.83%)	
Pre op IOP	39.5897 ± 12.13	32.8028 ± 8.04	0.003*
Follow up	48 ± 25.5 (3 – 89)	29 ± 21.4 (2 – 92)	< 0.001**

* significant at p <0.05; ** significant at p <0.10

The mean number of pre-operative anti-glaucoma medications number was 3.97± 0.4 in scleral tunnel group versus 3.35 ± 0.9 in pericardium graft group (p<0.001). In comparison, post-operative medication number shows

higher reduction in pericardium graft group than in scleral tunnel group. The mean number post-operative anti glaucoma medications was 2.64 ± 1.4 in scleral tunnel group and 1.9 ± 1.6 in pericardium graft group ($P=0.02$) (Table 2).

Table 2. Comparison between pre- and post-operative medication number in both groups

	Scleral tunnel	Pericardium	P value
Pre op Medication	3.97 ± 0.4	3.35 ± 0.9	<0.001
Post op Medication	2.64 ± 1.4	1.9 ± 1.6	0.020*

* significant at $p < 0.05$.

The most common pre-operative diagnosis in this study was neovascular glaucoma (NVG) followed by congenital glaucoma. In the two groups, NVG associated with proliferative diabetic retinopathy (PDR) or central retinal vein occlusion (CRVO) was found in 21 eyes (53.8%) in the Scleral tunnel group versus 18 eyes (24.3%) in the Pericardium group ($p = 0.009$). On the other hand, congenital glaucoma was found in 2 eyes (5.12%) in the scleral tunnel group versus 22 eyes (29.72%) in the pericardium graft group ($p = 0.009$). Other pre-operative diagnoses are listed in Table 3.

Table 3. Preoperative diagnoses of patients

	Method		Total Eyes/Patients	P value
	Scleraltunnel Eyes/ Patients	Pericardium Eyes/ Patients		
NVG	21 (53.84%)/19	18 (24.32%)/17	39/36	
Congenital glaucoma	2(5.12%)/2	22(29.72%)/17	24/19	
Advance primary open angle	2 (5.12%)/2	13 (17.56%)/12	15/14	
Secondary closed angle	4 (10.24%)/4	11 (14.86%)/11	15/15	
ICE syndrome	2 (5.12%)/2	1 (1.35%)/1	3/3	
Diagnose Juvenile glaucoma	1 (2.55%)/1	2 (2.70%)/2	3/3	0.009
PXF	1 (2.55%)/1	1 (1.35%)/1	2/2	
Combined mechanism	1(2.55%)/1	1 (1.35%)/1	2/2	
Uvetic glaucoma	2 (5.12%)/2	4 (5.40%)/3	6/5	
Aphakic glaucoma	3 (7.59%)/2	1 (1.35%)/1	4/3	
Total	39/36	74/66	113/102	

The mean pre-operative IOP value in the Scleral tunnel group was 39.56 ± 12.1 mmHg versus 32.8 ± 8.0 mmHg in the Pericardium group and it was statistically significant ($p = 0.003$). The postoperative IOP was taken in different time periods. The first reading was taken in the first day post-operatively, where the mean IOP was 9.47 ± 5.4 mm in scleral tunnel group “toward hypotony side” and the mean IOP was 11.7 ± 6.4 mm in the other group with no significant p value. IOP was taken regularly for all the patients in the first week, the first month, the third month, the sixth month after the surgery, and then yearly afterwards. All of these values were statistically insignificant between both groups as shown in Table 4 and Figure 1.

Table 4. IOP values on 7 follow up time periods

Time Periods	Scleral tunnel	Pericardium	P value
First day post op	9.47 ± 5.4	11.7 ± 6.4	0.079
First week Post Op	10.8 ± 7.8	10.7 ± 5.7	0.993
First month Post Op	17.10 ± 9.6	15.4 ± 8.4	0.366
Third month Post OP	16.5 ± 8.7	16.0 ± 7.4	0.799
6th month Post Op	18.0 ± 10.1	15.9 ± 8.7	0.314
First Year Post OP	18.16 ± 14.2	15.4 ± 6.6	0.236
Second year post op	15.9 ± 6.2	16.7 ± 8.4	0.664

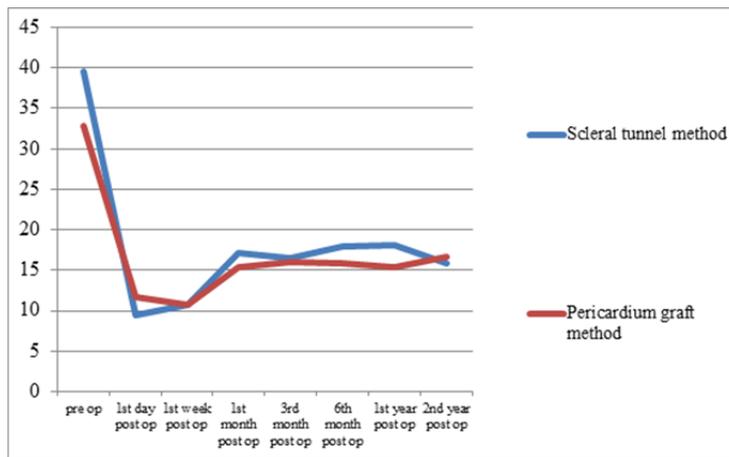


Figure 1. IOP values on 7 follow up time periods

There was no significant difference in preoperative and postoperative BCVA in the two groups (p= 0.171 and p = 0.239, respectively) (Figure 2).

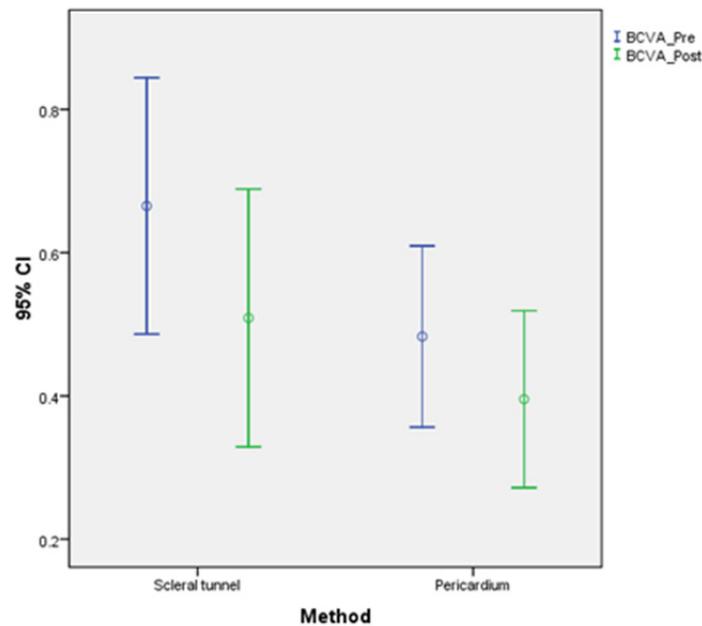


Figure 2. Preoperative and postoperative BCVA

This study mainly focuses on the complications occurred after each method of tube covering. Tube exposure occur in 2 cases only of scleral tunnel method compared with 15 cases of pericardium graft method, which was highly statistically significant ($p=0.002$). Hence, endophthalmitis occurred in 5 cases with exposed valve in pericardium graft versus no exposed valve in scleral tunnel group develop endophthalmitis ($p < 0.001$). In contrast, choroidal detachment was discovered in 5 cases of patient who underwent scleral tunnel method only, which could be explained by hypotony that occurs in the first few days after the flap surgery ($p < 0.001$). Other complications with insignificant difference between each group are listed in Table 5.

Table 5. Postoperative Complications

Complications	No of Eyes		
	Scleral tunnel	Pericardium	p-value
Exposure	2 (5.12%)	15 (20.27%)	0.002*
Endophthalmitis	0 (0%)	5 (6.75%)	< 0.001**
Bollus keratopathy	4 (10.25%)	8 (10.81%)	0.248
Occlusion	5 (12.82%)	6 (8.10%)	0.763
Choroidal detachment	5 (12.82%)	0 (0%)	< 0.001**
Hyphema	1 (2.56%)	2 (2.70%)	0.564

* significant at $p < 0.05$; ** significant at $p < 0.10$.

Anterior chamber (AC) formation has been studied in this study and showed a shallow AC in 7 eyes in scleral tunnel group versus two eyes in pericardium graft group ($p < 0.001$). Only 2 cases from the first group were associated with choroidal detachment. Moreover, four eyes (44.44%) of these 9 eyes with shallow AC were in need of AC reformation (by air or viscoelastic material only) and they were from the first group. The remaining eyes with shallow AC were spontaneously formed. Table 6 compares the AC formation between the two groups.

Table 6. AC formation in both groups

AC formation	Scleral tunnel	Pericardium	P value
Formed	32 (82.05%)	72 (97.29%)	< 0.001*
Shallow	7 (17.94%)	2 (2.70%)	

* significant at $p < 0.05$.

Regarding tube's explanation, 6 tubes (15.38%) were explanted in scleral tunnel group versus 10 tubes (13.51%) in pericardium graft group with no statistically significant difference ($p=0.808$) (Table 7). Out of those 16 tubes, 10 tubes were explanted due to tube exposure, 3 tubes were explanted due to persistence hypotony and other 3 tubes were explanted due to bollus keratopathy after corneal touch.

Table 7. Number of explanted tubes in both groups

Valve explanation	Scleral tunnel	Pericardium	P value
Not Explant	33 (84.61%)	64 (86.48%)	0.808
Explant	6 (15.38%)	10 (13.51%)	

The complete success is defined as the percentage of patients post AGV implantation with IOP < 21 mm Hg without using any anti glaucoma medication. Qualified success was defined as the percentage of patients post AGV implantation with IOP < 21 mm Hg and with intake of anti-glaucoma medication. Finally, failure rate was defined as all patient post AGV implantation with IOP > 21 mm Hg in spite of using maximum anti glaucoma medication. In additional to eyes requiring further glaucoma surgery (including needling, encapsulated cyst

excision, cyclophotocoagulation or removal of the implant) or eyes that lost light perception were classified as failures. These rates between the 2 groups are shown in Table 8.

Table 8. Success and failure rates

	Scleral tunnel	Pericardium	p-values
Complete success rate	3 (7.69%)	19(25.67%)	>0.001
Qualified success rate	23 (58.97%)	39 (52.7%)	>0.001
Failure rate	13 (33.33%)	16 (21.62%)	>0.001

4. Discussion

To the best of researcher's knowledge, there were just a few studies that discussed the scleral flap covering AGV. This study has compared the surgical outcomes of the two methods covering the tube for AGV implantation. In our study, the scleral tunnel group and pericardium graft group did not show significant differences in terms of postoperative IOP. The complete success was higher in Pericardium graft group. Qualified success was higher in scleral flap group compared to the pericardium graft group by 6% only. While failure rate was higher in scleral tunnel group.

The findings regarding valve exposure & IOP control were dissimilar to those recently reported by Ho Young Lee et al. (2011), who retrospectively reviewed experiences between Scleral Graft and Scleral Flap, and found no difference between flap and graft group in exposure side. This study found a big difference between the two groups, as the exposed valve was found in 15 out of 74 eyes (20.2%) of pericardium graft group and 5 of them (33.3%) developed Endophthalmitis. In the first group, only 2 out of 39 (5.12%) cases had exposed valve without endophthalmitis. These 2 cases of scleral tunnel whose tubes got exposed were treated with Pericardium graft in same year of implantation. Unfortunately, one case ended with blind painful eye and was managed with cyclophotocoagulation. Raviv et al. (1998); in a similar study, evaluated 44 eyes that underwent glaucoma drainage device "GDD" surgery with the use of pericardium patch graft. Findings reported diffuse graft thinning in 5 cases without overlying erosion.

These findings were also in-line with Smith, Doyle and Tierney Jr (2002) who showed that graft melting could occur as a result of a low grade, possibly immune-mediated, long term, atrophy process, with consequent gradual graft thinning or due to a mechanical process, where if the tube was not sutured totally flush to the sclera but no tube erosion per se. Tamçelik et al. (2010) found that the long scleral tunnel technique was a good way to prevent tube exposure except in congenital glaucoma cases because sclera was inherently very thin in these cases and most of the patients have had multiple previous surgeries. The exposure rate through conjunctival erosion in their study was seen in 3 of 32 patients (9.4%). In this study, only 2 cases out of 39 (5.12%) from the scleral tunnel group had exposed valve and both were not a congenital glaucoma cases.

Ollila, Falck, and Airaksinen (2005) studied the technique of scleral tunneling without a patch graft and documented the experience with 96 eyes. A mean follow up of 22 months was achieved with no exposures occurring.

Regarding the timing of valve exposure, this study found that; in scleral tunnel group, 1 case developed exposure in 2 months while in another case it was developed in the duration of 2 years. In pericardium graft group, this study has found that around 2 cases of exposed valve happen in less than 1-month period, 7 cases in less than 1 year and 6 cases in less than 2 years, respectively.

A meta-analysis of the incidence of conjunctival erosion after any GDD implantation suggests that tube exposure of glaucoma implants was unusual and the incidence does not differ between the Ahmed, Baerveldt, and Molteno implants. However, exposure may occur at any time within the first 5 years following implantation. This result is similar to the findings of the present study that showed different timing of valve exposure and implantation (Stewart et al., 2010).

In comparison, 5 eyes from the first group developed choroidal detachment post operatively while none had the same in the second group. Most of these cases were managed medically with Steroid and Atropine Drops and no surgery were needed. Coleman et al. (1995) found that choroidal detachment was the most common complication that usually occurs after AGV implantation "regardless of tube's cover type". It was reported in 13 out 60 patients (22%) (Coleman et al., 1995).

Two cases had shallow anterior chamber or early hypotony in the pericardium graft group, which were spontaneously resolved in the postoperative first week. In comparison, four eyes that had persistent shallow anterior chamber “AC” in the flap group were treated with AC formation by intra-cameral injection of viscoelastic or air. This can be explained by the leaking aqueous through the wide opening created for tube insertion in the angle that seems wider than the tube diameter itself. This can be avoided by tightening the sutures or increasing its numbers. In Lee et al. (2011) study, shallow AC was found in four eyes (40.0%) in flap group versus seven eyes (38.9%) with shallow AC in scleral graft group.

A 31 years old male, known case of Uveitic Glaucoma underwent AGV implantation by scleral tunnel method in Jan 2009 after being on 4 types of topical anti-glaucoma medications. The implanted tube touched the corneal endothelium 3 years after, and corrected surgically by tube repositioning. The patient developed corneal decompensation and the tube was rotated 2 times after first correction and then corrected with repositioning for the second time. The tube was finally explanted in September 2013. Corneal decompensation was managed by Penetrating Keratoplasty in 2015.

Majority of explanted valves (16 valves) were based on valve exposure (62.5%) while (18.75%) were explanted due to hypotony, and other (18.75%) were due to bullous keratopathy. Byun, Lee & Park (2009) found that tube exposure was hard to be corrected, especially in case of infection. The best solution could be to remove the implant.

One of the main limitations found with Pericardium covered tubes was orbital cellulitis. One-year-old male and another 65 years old male patient developed orbital cellulitis in 2 months and 1-month post AGV implantation respectively. Unfortunately, evisceration was done in both cases after failure of medical treatment. Lee et al. (2011) found migration of the tube in 30% of the flap group while in our study no migration of the tubes were noticed in both groups.

The limitations of our study are variation of follow up period between 2 months and 92 months in some patients. The unequal number of cases between each group is another limitation. Third limitation is the wide range of patient’s ages.

Scleral tunnel method of covering AGV implanted in refractory glaucoma has less exposure rate than the pericardium graft where some exposed valves in pericardium graft cases developed endophthalmitis. However, Scleral tunnel method shows significantly decreased IOP values post-operatively and this hypotony lead to choroidal detachment in some cases but it is limited.

Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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