

## ORIGINAL ARTICLE

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## Ahmed glaucoma valve tube erosion

# A retrospective review of autologous scleral flap versus donor scleral graft

### ABSTRACT

#### Objective

This study determined the rates of tube erosion and associated complications among patients implanted with the Ahmed glaucoma valve (AGV) using autologous scleral flap versus donor scleral graft.

#### Methods

The clinical records of consecutive patients who underwent AGV implantation using either autologous scleral flap or donor scleral graft between August 2001 and April 2006 with a minimum follow-up of four months were reviewed. Data were collected using a standardized form and subjected to statistical analyses.

#### Results

A total of 25 eyes of 25 consecutive patients who underwent AGV implantation were included. Fourteen received donor scleral grafts and 11 autologous scleral flaps. There were no tube erosions in the autologous scleral group. Transconjunctival erosion was seen in 71% of eyes in the donor scleral group, half of them occurring during the first 3 months postoperatively. Two eyes with erosion developed endophthalmitis.

#### Conclusion

The use of autologous scleral flap in AGV implantation appears to be an effective technique in preventing transconjunctival tube erosions. Exposure of the tube is a major risk factor in the development of endophthalmitis.

**Keywords:** Glaucoma drainage device, Ahmed glaucoma valve, Autologous scleral flap, Donor scleral patch, Glaucoma

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GLAUCOMA drainage devices (GDD), such as the Ahmed glaucoma valve (AGV) (New World Medical, Rancho Cucamonga, CA, USA), play an important role in the treatment of certain types of glaucoma where trabeculectomy is likely to fail. These include neovascular glaucoma, uveitic glaucoma, aphakic and pseudophakic glaucoma, and in scarred conjunctiva after failed filtering procedures or multiple intraocular surgeries.

A silicone tube connects the anterior or posterior chamber to the equatorial region of the globe where the AGV plate is implanted. Aqueous is shunted in a unidirectional manner through the valve mechanism and pools in the space between the valve plate and the posterior bleb encapsulation. The aqueous humor then penetrates the posterior bleb encapsulation and is eventually absorbed by orbital tissues and capillaries. Wilcox and colleagues demonstrated movement of latex microspheres as large as 0.2  $\mu\text{m}$  passing freely through the capsular wall.<sup>1,2</sup>

Upon implantation of the AGV, the subconjunctival and sub-Tenon's portions of the tube are covered with a graft of donor sclera or human allograft tissue (gamma sterilized pericardium, dura mater, fascia lata, or tectonic corneal graft). Alternatively, one could use a limbal-based scleral lamellar flap similar to scleral flaps employed in trabeculectomy procedures.<sup>3</sup>

Although studies have shown the efficacy of the AGV in the treatment of complicated glaucomas, several complications have also been reported. These include hypotony,<sup>4</sup> tube blockage or valve failure,<sup>5</sup> loss of visual acuity,<sup>6</sup> strabismus and diplopia,<sup>7</sup> epithelial downgrowth<sup>5</sup> calcification of the implant,<sup>8</sup> transconjunctival tube erosion,<sup>9</sup> transconjunctival plate erosion, plate extrusion, and associated endophthalmitis.<sup>9</sup>

Retrospective studies have shown that endophthalmitis is a rare complication after glaucoma drainage devices.<sup>9</sup> In a retrospective review of 542 eyes implanted with the AGV, endophthalmitis developed in 9 (1.7%) eyes.<sup>9</sup> It was suggested that a Seidel positive transconjunctival AGV tube erosion in a younger patient represents a major risk factor for the development of endophthalmitis. In all of the surgeries, the tube was covered with either sclera, dura, or pericardial graft. Autologous scleral flap was not used in any of the procedures.

In a retrospective study by Aslanides involving 17 eyes with a mean follow-up of 14.8 months (range 6 to 62 months) using a variety of glaucoma drainage devices and autologous scleral flap, all eyes showed no clinical evidence of tube erosion, or graft-related intraocular complications.<sup>3</sup> Smith reported that no tube-covering material was superior than the other.<sup>10</sup>

We hypothesize that the use of autologous scleral flap, which is easily available, is an effective, safe, and inexpensive alternative to donor scleral graft. It offers the

advantage of minimizing the risk of transmitting infectious diseases<sup>3, 11-13</sup> and is effective in preventing transconjunctival tube erosion. This study compared the rates of transconjunctival tube erosions between autologous scleral flap and donor scleral graft in AGV implantation and their associated complications and management.

## METHODOLOGY

The clinical records of consecutive patients who underwent AGV implantation using either autologous scleral flap or donor scleral graft at the Asian Eye Institute between August 2001 and April 2006 were reviewed. Included were those with a minimum follow-up of four months from the date of implantation, with regular slitlamp biomicroscopy. Photos were taken as needed.

Data collected using a standardized form included demographic characteristics, preoperative indications for surgery, visual acuity (VA), intraocular pressure (IOP), type of glaucoma, operative techniques of AGV implantation, manner of preparing the donor sclera, postoperative VA and IOP, and presence of tube erosion. Transconjunctival tube erosion was defined as any part of the AGV tube exposed through the conjunctiva visible by biomicroscopic examination. The time to appearance of tube erosion postoperatively was noted, plus any associated complications and subsequent interventions.

## Surgical Procedure

Two surgeons performed the AGV implant procedures. All patients received intraoperative sedation. One surgeon used topical anesthetic with supplemental subconjunctival lidocaine, while the other surgeon used retrobulbar block. One surgeon used donor scleral graft in all procedures while the other surgeon initially used donor scleral graft followed by autologous scleral flap consecutively. General anesthesia was used for a 9-year-old patient with congenital aniridia. Both surgeons utilized the same operative technique of AGV implantation.

After administration of the anesthetic, a limbal corneal 6 or 7-0 silk traction suture was applied. A 3-clock-hour superotemporal fornix-based conjunctival flap was created. Spring tenotomy scissors were used to carry the dissection posteriorly toward the equator to create a pocket between the superior and lateral recti muscles. Bleeding was controlled with bipolar cautery. The AGV was primed with balanced salt solution (BSS) using a 27 G cannula and the plate inserted into the posterior pocket with the anterior border approximately 8 mm away from the limbus. The plate was anchored to the underlying sclera with 2 interrupted 9-0 nylon sutures. Viscoelastic solution was injected into the anterior chamber (AC) through a paracentesis. The site of tube insertion into

the AC was initially created with a 23 G needle at the limbus, followed by trimming of the tube to adequate length and its subsequent insertion into the AC. The body of the tube was anchored to the sclera with interrupted 9-0 nylon sutures.

A donor graft soaked in BSS for 30 minutes was cut to size and used to cover the body of the tube near the limbus. 9-0 sutures anchored the donor sclera to the host sclera. Alternatively, a 7 mm x 7 mm limbal-based lamellar-scleral flap was constructed with a crescent knife and the tube inserted through a limbal sclerostomy under the flap anchored with 9-0 nylon sutures. The conjunctiva was reattached to the limbus with interrupted 10-0 nylon sutures.

### Statistical Analysis

The following variables were evaluated: age and sex of patients, indications for AGV implantation, number and type of previous conjunctival surgeries, type of glaucoma, time from implantation of the AGV to recorded transconjunctival erosion, complications associated with erosions, and interventions after erosions were noted.

Descriptive statistics consisted of measures of central tendency (mean and standard deviation) for continuous numerical data and percentage-frequency distribution for categorical variables. Chi-square test was used for comparison of categorical data and Mann-Whitney U test for continuous numerical data. Comparison of proportion of subjects with tube erosion in both groups was facilitated using z-test of two proportions.

All tests of significance were carried out at 0.05 alpha level of significance using Statistica version 1999 (Statsoft Inc., Tulsa, OK, USA).

## RESULTS

A total of 41 AGV implantations were performed between August 2001 and April 2006. Sixteen eyes were excluded because of insufficient data or failure to meet the criteria of minimum 4 months of follow-up postoperatively. Four patients in the donor group were lost to follow-up but completed the minimum follow-up period, while none in the autologous group was lost to follow-up. Out of the 25 eyes included in this study, 21 received the AGV model S2 (polypropylene plate) while 2 in the donor sclera graft and 2 in the autologous sclera flap received the AGV model FP7 (silicone plate).

Eleven (44%) underwent implantation using autologous scleral flap, while 14 (56%) had donor scleral graft (Table 1). The mean age was  $51 \pm 3$  years (range, 9 to 84). There were more males (72%) in this series. The right eye was more commonly involved (68%). Baseline demographic variables did not show any significant difference between the 2 groups (Table 1).

No tube erosions were observed among those who had autologous scleral flap (Table 2). Seventy-one percent (71%) of those who received donor scleral graft had tube erosion, half of which occurred during the first 3 months postoperatively, the earliest at 1 month and the latest between 37 and 39 months (Tables 2 and 3). The difference in proportions between the 2 groups was, however, not statistically significant ( $p = 0.29$ ). This may be attributed to the small samples of the study groups.

The number of previous conjunctival surgeries did not differ statistically between the 2 groups (Table 1). Previous conjunctival procedures accounted for most of the indications for AGV implantation, with a greater proportion seen in the donor group than the autologous group. Neovascular glaucoma was the second most frequent indication for both the donor and the autologous groups (Table 1).

Two eyes developed endophthalmitis (Table 4) associated with transconjunctival tube erosion that required explantation of the AGV. In one eye, tube culture studies yielded *Staphylococcus sp* (Figure 1). Both eyes underwent

Table 1. Demographic and clinical characteristics of the study population (n = 25).

Characteristics	Donor Scleral Graft (n = 14)	Autologous Scleral Flap (n = 11)	p*
Age (years)			
Mean	58 ± 21	48 ± 25	0.28 <sup>a</sup>
Range	18–86	9–77	
Sex			
Male	12 (86%)	6 (54%)	0.06 <sup>b</sup>
Female	2 (14%)	5 (46%)	
Affected Eye			
Right	9 (64%)	8 (73%)	0.22 <sup>b</sup>
Left	5 (36%)	3 (27%)	
Preoperative VA <sup>1</sup>			
Mean	2.22 ± 0.74	1.87 ± 0.93	0.37 <sup>a</sup>
Range	1.3–3.0	0.54–3.0	
Preoperative IOP <sup>2</sup>			
Mean	35.5 ± 14	36.2 ± 9	0.57 <sup>b</sup>
Range	19–68	22–49	
Types of Glaucoma			
Post ECCE <sup>3</sup> OAG <sup>4</sup>	2 (14%)	1 (9%)	0.69 <sup>b</sup>
Post RD <sup>5</sup> surgery OAG	2 (14%)	2 (18%)	0.79 <sup>b</sup>
Post filter CACG <sup>6</sup>	6 (43%)	3 (27%)	0.42 <sup>b</sup>
Neovascular glaucoma	3 (21%)	4 (36%)	0.41 <sup>b</sup>
Uveitic	1 (7%)	1 (9%)	0.85 <sup>b</sup>
Previous Ocular Surgeries	10 (71%)	6 (55%)	0.38 <sup>b</sup>

\*Significant difference if  $p$  is < .05

<sup>a</sup>Computed using Mann-Whitney U test

<sup>b</sup>Computed using Chi-square

<sup>1</sup>Visual acuity

<sup>2</sup>Intraocular pressure

<sup>3</sup>Extracapsular cataract extraction

<sup>4</sup>Open-angle glaucoma

<sup>5</sup>Retinal detachment

<sup>6</sup>Chronic angle-closure glaucoma

Table 2. Outcomes of AGV implantation with donor scleral graft versus autologous scleral flap.

Characteristics	Donor Scleral Graft (N = 14)	Autologous Scleral Flap (N = 11)	p*
Postoperative VA			
Mean	2.58 ± 0.74	1.73 ± 1.1	0.62 <sup>a</sup>
Range	0.70–3.0	0–3	
Postoperative IOP			
Mean	12.1 ± 2.8	13.4 ± 3.5	0.40 <sup>a</sup>
Range	8–18	10–20	
Duration of follow-up			
Mean (months)	53 ± 3	20 ± 1	0.03 <sup>a</sup>
Range	36–70	4–36	
Tube Erosion			
Present	10 (71%)	0 (0%)	0.03 <sup>c</sup>
Time to appearance			
Mean	5.6 ± 1	–	
Range	0–39	–	
Absent	4 (29%)	11 (100%)	
Number of previous surgeries			
Mean	3	1	0.45 <sup>a</sup>
Range	1–4	1–3	
Complications	10 (71%)	6 (54%)	0.43 <sup>b</sup>

<sup>a</sup>Computed using Mann-Whitney U test

<sup>b</sup>Computed using Chi-square

<sup>c</sup>Computed using Z-test of two proportions

Table 3. Occurrence of tube erosion (months) in patients with donor scleral graft.

Interval in Months at which Erosion Occurred	Tube Erosion Rate	
	Number	Percent
0-3	5	50
7-9	1	10
16-18	1	10
19-21	1	10
25-27	1	10
37-39	1	10
Total	10	100

Table 4. Complications and interventions for tube erosions.

Complication	Intervention
Endophthalmitis	1 – Valve explanted, vitrectomy, infective agent unknown 1 – Valve explanted, <i>Staphylococcus sp.</i> on tube culture, diode transcleral cycloablation done
Sterile hypopyon (anterior uveitis)	2 – Tube amputated, valve plate retained, trabeculectomy with mitomycin done 1 – Tube amputated, valve plate retained, new AGV implanted inferiorly
Erosion with no intraocular sequelae	1 – AGV explanted, new AGV implanted, no erosion
Eroded with no intraocular complication so far	1 – 36 months since eroded* 1 – 43 months since eroded* 2 – 48 months since eroded*

\*Seidel negative; maintained on third- or fourth-generation fluoroquinolone drops once a day.

diode cycloablation for subsequent IOP control. Three eyes with tube erosions had “sterile hypopyon;” two of these underwent amputation of the exposed tube, leaving behind a short tube stump and the AGV plate untouched. The limbal sclerostomy and conjunctival defects were closed and trabeculectomy with mitomycin C was performed in adjacent area where the conjunctiva was deemed mobile. The other eye had the AGV explanted and replaced with a new AGV using a donor scleral graft. No new erosion was seen during the follow-up period. Resolution of the hypopyon occurred within the first week of the intervention.

Three eyes with tube erosions showed no intraocular sequelae for more than 36 months from the time the erosion was noted. They were Seidel negative and were maintained on rotating third- and fourth-generation topical antibiotics once a day.

Patients who received donor scleral graft were followed up for a period of 36 to 70 months whereas those who had autologous scleral flap were seen over a period of 4 to 36 months.

## DISCUSSION

Occurrence of tube erosion ranged from 0 to 3 in GDD implantation<sup>14</sup> and about 3% in AGV.<sup>15</sup> In this study, the incidence was 40%, which is rather high compared to the rates in other reports. And all erosions occurred with the donor scleral group and none in the autologous scleral group. Other studies reported that no tube coverage in glaucoma drainage implant was more prone to melting.<sup>16</sup>

Several factors may contribute to transconjunctival erosion of the AGV tube in the donor scleral group. For instance, small amounts of absolute alcohol retained in the donor sclera can be toxic to ocular tissues.<sup>17</sup> Using gas

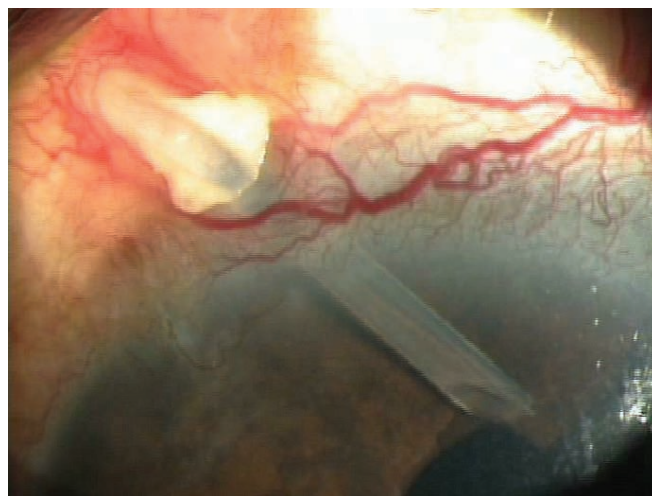


Figure 1. Tube erosion with exudates (*Staphylococcus sp.*) seen 3 months after AGV implantation with donor scleral graft. Patient developed endophthalmitis, underwent AGV explantation and vitrectomy. Diode transcleral cycloablation was done to control IOP.



chromatography studies, Enzenauer showed that for scleras preserved in 95% alcohol, soaking in BSS for 20 minutes or longer leached only 98% of the alcohol, while 2% remained in the sclera.<sup>18</sup> Thus there was no certainty that soaking the donor sclera in BSS for 30 minutes during the surgeries was enough to leach out the absolute alcohol that the local eye bank used as preservative.

Mechanical friction, such as constant rubbing of the eyelids against the conjunctiva and scleral graft, may also contribute to tube erosion, but the exact mechanism is unclear.<sup>19</sup> Heuer et al. suggested that burying the tube under an autologous lamellar scleral flap would reduce the overall height of the tube and the graft, thereby subjecting the overlying conjunctiva to less tension and mechanical friction. This may be even more significant in eyes with preexisting scarred conjunctivae resulting from multiple surgeries, as were most of the cases in this study. A thick donor sclera may result in more mechanical friction against the eyelids, and lead to early tube erosion. The area of the donor sclera immediately posterior to the insertion of the rectus muscle may be more ideal to use as a patch graft as this is anatomically thinner (0.3 mm versus 1.0 mm in the region surrounding the optic nerve).<sup>20</sup>

The high occurrence of transconjunctival erosions observed among the patients who received donor scleral graft prompted a shift by one surgeon to an alternate technique involving the use of autologous scleral flap, explaining the shorter follow-up period of the latter group. Moreover, surgeon's experience in AGV implantation may also have contributed to the occurrence of tube erosion. Most of the tube erosions occurred in the early years of the 2 surgeons who performed the surgeries. Since the 2 techniques were not performed simultaneously, but rather the autologous scleral flap was done much later in the surgical experience of one surgeon, modifications in surgical technique, including much gentle handling of tissues and familiarity with the procedure could affect this comparison. This limitation should be addressed in future studies.

Complications related to tube exposure included endophthalmitis which developed in 2 eyes (8%). Early treatment given to 3 patients with erosion and hypopyon may have helped avoid this devastating complication. Four eyes with erosion remained Seidel negative with no intraocular signs of inflammation after 36 to 48 months (Table 4). They were maintained on once-a-day topical antibiotic and followed up closely. Some authors suggested that exposed glaucoma-device implant tubes may be observed in the absence of a leak (Seidel-negative test) or ocular irritation.<sup>21</sup> It is not clear whether maintaining these eyes on prophylactic topical antibiotics may be of

any clinical benefit.

In summary, the use of autologous scleral flap in AGV implantation showed significantly better outcomes than the use of donor scleral graft in this study. To validate the results, a prospective randomized trial involving comparison of the 2 groups with standardized surgical technique and similar follow-up periods should be conducted simultaneously to eliminate surgeon's experience as a confounding factor. Furthermore, collateral studies looking into the proper technique of preparing the donor sclera prior to its use may help determine the amount of residual alcohol in the graft. A comparison of the different solutions used in rinsing the alcohol may also be undertaken. To investigate the effect of mechanical friction on the conjunctiva overlying the patch graft, ultrabiomicroscopic studies measuring graft heights may provide valuable information.

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