Surgical Outcomes of Ahmed Glaucoma Valve Implantation Without Plate Sutures: A 10-Year Retrospective Study

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laucoma drainage devices (GDDs) are commonly used for the surgical management of glaucoma.1,2 They have been demonstrated as being effective in reducing intraocular pressure (IOP), and to be especially appropriate for eyes that have already undergone 1 or more glaucoma surgeries, and for particular types of glaucoma in which filtering procedures are likely to fail (eg, secondary glaucoma).3,4 The Ahmed glaucoma valve (AGV), approved by the Food and Drug Administration in 1993, is a safe, effective, and popular GDD for use in glaucoma patients with uncontrolled IOP.5 The valve consists of a plate with 2 anterior designated suture holes, a drainage tube, and a valve mechanism, which enables the control of aqueous humor flow and reduces the occurrence of hypotony and its related complications.1,5

The AGV plate is typically placed 8 to 10 mm posterior to the corneoscleral limbus and secured to the sclera with 8-0 or 9-0 nylon sutures, which are passed through the designated suture holes.1,5 The purpose of scleral suturing of the plate is to ensure plate fixation and prevent complications, such as plate migration and intraocular tube elongation or retraction. Although the use of scleral sutures in ophthalmic surgery might have some intraoperative and postoperative disadvantages, such as longer operation time, the risk for scleral microperforation, and providing a nidus for infections or neovascularization,6 in addition to requiring special surgical skills, it is still widely and routinely used as part of the AGV implantation technique.7 The potential disadvantages and the manual difficulties of plate suturing, however, have led to the search for alternative surgical techniques, including no suturing of the plate.8 The purpose of this cohort study is to describe 2 surgeons’ 10-year experience with AGV implantation without suture plate fixation.

METHODS

This is a retrospective cohort study of patients who underwent AGV implantation surgery for uncontrolled IOP without plate fixation between February 2009 and February 2019 at the Goldschleger Eye Institute. The study was approved by the medical center’s institutional review board and adheres to the tenets of the Declaration of Helsinki. Informed consent was waived for this retrospective analysis.

The data of all AGV implantations without plate fixation sutures that were performed by 2 experienced senior glaucoma surgeons (none of the authors) during the study period were reviewed. Only cases of first-time GDD surgery without plate fixation in patients aged 18 years or older and with at least 3 months of postoperative follow-up were included. Each case was followed until the last documented visit, unless AGV removal was required, in which case follow-up was terminated at the time of removal. However, cases in which AGV removal occurred within 3 months, but
had at least 3 months of postoperative follow-up, were included. Baseline demographics, time of glaucoma diagnosis, type of glaucoma, general medical and ocular history, and preoperative data, including preoperative best-corrected visual acuity (BCVA), IOP (measured by Goldman tonometer), and the number of glaucoma medications were retrieved. Findings during the examinations carried out during the postoperative follow-up visits at 1 day, 1 week, and 1, 3, and 6 months, and data from the last available follow-up visit at the glaucoma service were recorded. Intraoperative details were also reviewed, including the type of anesthesia, the identity of the surgeon, location of the AGV, intraocular tube location, and specific review of the surgical notes to verify that plate fixation had not been performed.

Each subject’s medical chart was reviewed by 2 of the authors (N.K. and A.L.) for the presence of complications. These included filtration failure defined as AGV malfunction causing IOP higher than the target pressure (determined for each patient by his/her physician) and requiring additional intervention, hypotony (defined as low IOP with the presence of either shallow anterior chamber and/or choroidal detachment), choroidal hemorrhage, endophthalmitis, tube exposure, AGV extrusion, and plate or tube migration (Fig. 1).

The surgical technique consisted of a fornix-based conjunctival flap and a subtenon pocket that were created between 2 adjacent recti muscles. All AGV devices (model FP7; New World Medical Inc., Rancho Cucamonga, CA) were irrigated with balanced saline solution by means of a 27G cannula in order to prime the valve mechanism. The plate was then inserted into the equator area of the globe without suturing to the sclera. The drainage tube was trimmed (ie, beveled up, away from the iris, to an angle of 30 degrees) to permit its insertion 2 to 3 mm into the anterior chamber. A 23G needle was used to enter the anterior chamber parallel to the iris plane and away from the corneal endothelium. The tube was inserted into the eye through the needle tract and the scleral portion of the tube was sutured to the sclera using a single suture. A human donor scleral patch graft was placed over the extraocular part of the tube and secured to the sclera with 7-0 or 8-0 Vicryl sutures (2-4 sutures). Finally, the conjunctiva was reapproximated and anchored to the limbus with absorbable sutures. Topical antibiotic ointment was applied into the eye. A topical steroid (Dexamycin; TEVA Pharmaceutical Industries Ltd, Israel) and prophylactic antibiotic drops (Oflox; Allergan Pharmaceuticals, Ireland) were routinely prescribed for each patient to be used on the postoperative days.

All analyses were performed on a patient level since only 1 eye per patient was included. As the outcome measures from a person’s 2 eyes are usually correlated, we selected to use only 1 eye per subject to avoid bias, which might arise from bilateral cases. When both eyes from the same patient qualified for study entry, the eye with the longer follow-up duration was included. Snellen visual acuity measurements were converted to logarithm of the minimum angle of resolution for the purposes of data analysis. The subjects were divided into 2 groups on the basis of the presence or absence of AGV-related complications. The χ² test and Student t test were used for comparison of baseline and operation characteristics between the 2 groups. A repeated measure analysis was applied to check for differences between the 2 groups in terms of IOP, BCVA, and number of IOP-lowering medications during the first 6 months of follow-up. A P-value of <0.05 was considered statistically significant. Data were analyzed with SPSS software version 25.0 (SPSS Inc., Chicago, IL).

RESULTS

In total, 109 patients underwent AGV implantation without plate fixation during the study period, of whom 14 failed to meet the inclusion criteria. The remaining 95 eyes
of 95 patients were included in the final analysis, with a mean follow-up duration of 687 ± 673 days (range, 90 to 3085 d). The demographic and baseline clinical characteristics of the study population are listed in Table 1, and the clinical intraoperative data are listed in Table 2.

In total, 37 patients (38.9%) had AGV-related complications. In total, 28 (29.5%) required an additional intervention, and in 10 eyes (10/95, 10.5%) the AGV was removed. The 2 most common complications that could be directly related to the lack of suturing were AGV migration in 13 eyes (13/95, 13.7%) and tube exposure/AGV extrusion in 9 eyes (9/95, 9.5%). The IOP was considered too high in 10 cases, 3 cases (13/95, 13.7%) and tube exposure/AGV extrusion in 9 eyes (9/95, 9.5%).

**DISCUSSION**

This retrospective cohort study reviewed the 10-year experience of 2 glaucoma surgeons in performing AVG required internal washing of the tube, 2 cases required cyclophotocoagulation, and 2 cases required needling. The complication profile and the required interventions are shown in Supplemental Table 3 (Supplemental Digital Content 1, http://links.lww.com/IJG/A530). Women had a significantly higher rate of complications compared with men (21/42, 50% vs. 16/53, 30.2%, respectively, P = 0.049). No significant differences in baseline characteristics were observed between the groups with and without complications (Table 1). The repeated measures analysis also revealed that the clinical course during the first 6 months was similar in terms of IOP, BCVA, and number of IOP-lowering medications among subjects for which all 6 time points were available in both groups.

In total, 18 (18.9%) of the complications occurred within 4 months since surgery, 24 (25.2%) within 6 months, 28 (29.4%) within 12 months, and 31 (32.6%) within 24 months. Figure 2 displays the Kaplan-Meier survival analysis for AGV without plate fixation. The mean time to complication onset was longer among subjects who had previously undergone cataract surgery or trabeculectomy (Fig. 3). However, in contrast, the Kaplan-Meier survival analysis showed longer survival rates over time among phakic patients and patients who had not undergone a previous trabeculectomy, although the differences did not reach a level of statistical significance (Fig. 4). Anesthesia type, plate location, and medical history of diabetes, hypertension, and inflammatory disease had no significant effect on the rate of complications or time to surgical failure onset. Time to surgical failure onset was also unaffected by sex.

**TABLE 1. Baseline Clinical Characteristics of the Study Population**

| Variables                        | Uncomplicated Course (N = 58) | Complicated Course (N = 37) | All Patients (N = 95) | P     |
|----------------------------------|------------------------------|-----------------------------|-----------------------|-------|
| Age, mean ± SD (y)              | 67.1 ± 16.8                  | 61.5 ± 18.2                 | 54.9 ± 17.5           | 0.123 |
| Sex, n/N (%)                    |                              |                             |                       |       |
| Male                             | 37/58 (63.8)                 | 16/37 (43.2)                | 53/95 (55.8)          | 0.049 |
| Female                           | 21/58 (36.2)                 | 21/37 (56.8)                | 42/95 (44.2)          |       |
| Glaucoma type, n/N (%)           |                              |                             |                       |       |
| POAG                             | 16/58 (27.6)                 | 12/37 (32.4)                | 28/95 (29.5)          |       |
| PCAG                             | 2/58 (3.4)                   | 1/37 (2.7)                  | 3/95 (3.2)            |       |
| PXFG                             | 19/58 (32.8)                 | 8/37 (21.6)                 | 27/95 (28.4)          |       |
| Secondary                        | 10/58 (17.2)                 | 2/37 (5.4)                  | 12/95 (12.6)          |       |
| Congenital                       | 2/58 (3.4)                   | 8/37 (21.6)                 | 10/95 (10.5)          |       |
| Uveitic                          | 6/58 (10.3)                  | 6/37 (16.2)                 | 12/95 (12.6)          |       |
| Other/unknown                    | 3/58 (5.2)                   | 0/37 (0)                    | 3/95 (3.2)            |       |
| Lens status, n/N (%)             |                              |                             |                       |       |
| Phakic                           | 19/58 (32.8)                 | 8/37 (21.6)                 | 27/95 (28.4)          | 0.241 |
| Pseudophakic                     | 39/58 (67.2)                 | 29/37 (78.4)                | 68/95 (71.6)          |       |
| BCVA, logMAR (mean ± SD)         | 0.55 ± 0.42                  | 0.71 ± 0.54                 | 0.61 ± 0.47           | 0.116 |
| IOP, mean ± SD (mm Hg)           | 33.7                         | 33.6                        | 33.7                  | 0.964 |
| C/D ratio (mean ± SD)            | 0.82 ± 0.18                  | 0.86 ± 0.18                 | 0.83 ± 0.18           | 0.324 |
| No. glaucoma medications (mean ± SD) | 3.48 ± 0.98                 | 3.51 ± 1.01                 | 3.49 ± 0.99           | 0.883 |
| Previous trabeculectomy, n/N (%) | 39/58 (67.2)                 | 31/37 (83.8)                | 70/95 (73.7)          | 0.074 |
| Medical history                  |                              |                             |                       |       |
| Diabetes mellitus, n/N (%)       | 18/58 (31.0)                 | 6/37 (16.2)                 | 24/95 (25.3)          | 0.105 |
| Hypertension, n/N (%)            | 27/58 (46.6)                 | 14/37 (37.8)                | 41/95 (43.2)          | 0.403 |
| Rheumatologic, n/N (%)           | 3/58 (5.2)                   | 5/37 (13.5)                 | 8/95 (8.4)            | 0.153 |

Bold value indicates significance.

BCVA indicates best-corrected visual acuity; C/D, cup-to-disc; IOP, intraocular pressure; PCAG, primary closed-angle glaucoma; POAG, primary open-angle glaucoma; PXFG, pseudo exfoliative glaucoma.

**TABLE 2. Clinical Intraoperative Data**

| Variables                        | Uncomplicated Course (N = 58) | Complicated Course (N = 37) | All Patients (N = 95) | P     |
|----------------------------------|------------------------------|-----------------------------|-----------------------|-------|
| Operated eye, n (%)              |                             |                             |                       | 0.194 |
| Right                            | 33 (56.9)                   | 16 (43.2)                   | 49 (51.6)             |       |
| Left                             | 25 (43.1)                   | 21 (56.8)                   | 46 (48.4)             |       |
| Anesthesia                       |                             |                             |                       |       |
| Local                            | 54 (93.1)                   | 28 (75.7)                   | 82 (86.3)             | 0.016 |
| General                          | 4 (6.9)                     | 9 (24.3)                    | 13 (13.7)             |       |
| AGV plate location, n (%)        |                             |                             |                       |       |
| Supertemporal                    | 45 (77.6)                   | 34 (91.9)                   | 79 (83.2)             | 0.069 |
| Other                            | 13 (22.4)                   | 3 (8.1)                     | 16 (16.8)             |       |
| Superonasal                      | 12 (20.7)                   | 3 (8.1)                     | 15 (15.8)             |       |
| Inferotemporal                   | 1 (1.3)                     | 0                           | 1 (1.1)               |       |

Bold value indicates significant.

AGV indicates Ahmed glaucoma valve.
implantation without plate suturing. This report represents the most extensive investigation to date on the outcome and complication profile of AGV implantation without plate fixation in terms of number of patients and duration of follow-up. Avoiding sutures, whenever possible, may simplify technically challenging procedures, decrease some intraoperative and postoperative complications, and reduce surgery time. Attempts to reduce the need for sutures in ophthalmic surgeries are reported in different ophthalmology disciplines, from the replacement of a wide gauge trocar in retina surgeries to the use of glue in corneal perforation and pterygium excision.9–11

The AGV implant was designed to be sutured to the sclera. However, alternative surgical techniques for AGV implantation that avoid the suturing of its plate have been reported over the years. Sanvicente et al8 suggested positioning the plate posterior to the globe equator, relying on globe anatomy to provide stability and resist migration of the plate. Pham et al12 used limited dissection to create an undersized Tenon pocket that would hold the plate placed > 8 mm posterior to the limbus, and a 5 mm long scleral tunnel designed to hold the tube in place. In their attempt to omit any suturing, the conjunctiva was sealed with Tisseel fibrin sealant in place of sutures.

The present study results revealed a relatively high percentage of complications, with additional interventions needed in 29.5% and removal of the AGV in 10.5%. In a large prospective series of traditionally sutured AGV, Budenz et al13 reported 3 cases (a rate of 2.9%) of tube erosion, and 3 cases (3/143, 2.1%) of AGV removal during a 5-year study period. Only 16 of their patients (a rate of 14.3%) needed reintervention over 5 years.

Among the other studies on traditionally sutured AGV, Chen et al14 reported 3 cases (a rate of 1.4%) of AGV extrusion during a 4-year study period, and a rate of reoperations for complications encountered within 3 months after tube shunt surgery of only 3.1%. The rate in the current study was about 6 times higher at approximately the same time point. In their study, 1.2% of the reinterventions were because of tube exposure, which was the most common reason for reoperation, and tube/plate-related problems related to either migrations and/or exposure were among the most common causes of complications in the current study as well.

The complication rates of the present cohort was also higher compared with that of the other 2 studies that reported surgical results of AGV implantation without suturing of the plate. Sanvicente et al8 presented the results of 94 sutureless AGV implantations followed-up for 11.2 ± 7.4 months. There was no case of device migration. Those authors also noted a low rate of tube erosion/exposure, specifically, in 1 (2.7%), 3 (3.7%), 1 (1.5%), and 1 (2.7%) case at 1 week, and 3, 6, and 12 months, respectively. The difference in the results between their study and the current one may lie in the use of a different surgical technique. Sanvicente and colleagues inserted the plate...
posteriorly to the equator of the globe, and its position and stability were confirmed by gently pulling on the tube and observing significant resistance accompanied by slight infraction of the globe. They performed further dissection and posterior placement of the plate if they noted anteriorization of the plate during this maneuver. In the current work, the plate was placed around the equator area of the globe (and not necessarily posterior to it), and, in addition, no pulling maneuver was executed. It is therefore proposed by the authors of this investigation that micro-movements of the plate and tube can eventually lead to conjunctival erosion and tube exposure. However, Sanvicente et al\(^6\) suggest that further research is needed before a definitive opinion can be formed regarding the avoidance of AGV suturing.

In the series by Pham et al,\(^12\) 122 eyes of 99 subjects were followed for a mean of 25.8±14.7 months after sutureless AGV implantation. During the first 12 months, they reported a single case of conjunctival erosion, 2 cases of tube migration, a single case of tube extrusion, 3 cases of choroidal effusion, 5 cases of persistent corneal edema, and 10 cases of the shallow anterior chamber. Overall, 13 eyes (10.7\%) returned to the operating room because of a complication.

Another important AGV-related complication, although rare, is the occurrence of endophthalmitis. Two cases of endophthalmitis were noted in the current study group, and the AVG was removed in both cases. The long duration of follow-up from the primary surgery to diagnosis (878 and 1939 days, Supplemental Table 3, Supplemental Digital Content 1, http://links.lww.com/JIGA/A530) makes it difficult to establish causal relations. Notably, however, no additional surgery had been performed between the AGV implantation and the presentation of endophthalmitis in either case. A review of the literature yielded a large retrospective study by Al-Torbak et al\(^13\) who reported 9 cases (9/542, 1.7\%) of endophthalmitis that were related to sutured AGV implantation. Those authors observed, as did the current ones, that the onset of AGV-related endophthalmitis was usually delayed, and that conjunctival erosion over the AGV tube seemed to represent a major risk factor for endophthalmitis. Conjunctival erosion was noted in both of the cases in the present study. Al-Torbak et al\(^15\) also stated that no glaucoma surgery had been performed after the initial implant surgery until the endophthalmitis event. It should be noted that their study included a large pediatric population (113 eyes of 102 patients under 18 y of age), with a higher percentage of endophthalmitis in the pediatric population (4.4\%, 5/113) compared with the adult population (0.9\%, 4/429). The current study excluded the pediatric population, and the endophthalmitis rate for the nonsutured AGV implantation among the adult cases was 2.3 times greater (2.1\% vs. 0.9\%) than that of Al-Torbak and colleagues. There are other AGV-related publications that have reported different percentages of endophthalmitis (Djodeyre et al\(^16\) reported 2.6\% and Morad et al\(^17\) reported 5\%), however, their study groups were small (Djodeyre and colleagues’ study included only 35 patients and Morad and colleagues’ study included only 60 patients), and both studies were conducted solely on pediatric populations. Budenz et al\(^13\) reported no case of endophthalmitis in 5 years (143 adult cases, 0\%). Using no sutures, Sanvicente et al\(^8\) reported 1 case of endophthalmitis/blebitis at 12 months postoperatively (37 adult cases, 2.7\%).

Interestingly, the meantime to the complication was longer among patients who had previously undergone cataract or trabeculectomy. Although the difference was not statistically significant it might suggest that these cases were referred for primary AGV implantation as they were considered complicated explaining the earlier onset of complications.

Although the procedure of AGV implantation without plate fixation may have gained popularity, the most common and well-accepted technique worldwide remains AGV plate fixation with 2 nonabsorbable sutures, such as nylon sutures,\(^1,5\) which are monofilaments composed of polyamides and have long-standing tensile strength.\(^18\) Conceivably Vicryl or other absorbable sutures can be used, with the thought that adequate fibrosis over 6 to 8 weeks can prevent anterior plate migration. We are currently analyzing and plan to publish our experience with this technique.

This study has several limitations that bear mention. One is its retrospective design, and another is the inclusion of patients that may have needed surgical reoperation in another medical center who could have been missed and led to under-reporting of complications (presumed to be a very small number of patients). The data were limited to the experience of 2 experienced fellowship-trained surgeons, and there was no control group available for comparison of cases performed with traditional suturing by the same surgeons. Our cohort is limited to the use of AGV and our conclusions cannot be extended to the use of other drainage devices such Baerveldt or Molteno. Future studies may also analyze how different anatomic quadrant insertion affects tube stability.

In summary, the findings of this retrospective case series demonstrated that AGV implantation without plate fixation resulted in a high rate of complications related to plate or tube movement, increasing the need for additional interventions and, specifically, of AGV removal.

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