Ahmed Glaucoma Valve Explantation: Clinical Efficacy and Safety

Ahmed Glokom Valvi Geri-Çıkarımının Klinik Etkinlik ve Güvenliği

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ABSTRACT

Purpose: To evaluate the prevalence and the conditions necessitating an Ahmed glaucoma valve (AGV) explantation.

Material and Methods: This retrospective, noncomparative study includes the medical records of one eye of each 13 patients who underwent an AGV removal.

Results: A total of 324 eyes received an AGV between April 2002 and March 2017 and 21(6.48%) of them had tube exposure. Eight eye of the 21 were successfully repaired by different methods but 13 of them underwent an implant explantation.For the 13 patients, average 2.2±0.4(2 or 3 times) repairing procedures were performed for each patient which include conjunctival pedicle flaps or double layer amniotic membrane graft with/without pericardial patch graft but they required an explantation within 2 months after the last attempt because of recurrent tube erosion.The mean time with the AGV was 38.30±36.94(4-114)months.The mean intraocular pressure(IOP)value was 13±7(3-30)mmHg just before the explantation,and 26±1 (range;3-50) mmHg at the first postoperative morning following the explantation without antiglaucomatous therapy. The mean follow-up period after the removal was 22±14(6-57) months.The mean IOP value was 22±10(5-42) mmHg with/without medical treatment at the last visit.

Conclusions: A tube exposure, which can be considered as both an early and a late complication,is the main reason for an explantation.In this series, uveitis is the most common diagnosis for the valve implantation; hence, it is correct to say that uveitic cases are the most common groups of patients,who not only have a risk of exposure, but also have encountered failure in primary repair of exposure. AGV explantation is a safe and saviour procedure in all tube exposure.

Key Words: Refractory glaucoma, glaucoma drainage implants, Ahmed glaucoma valve explantation, tube exposure.

ÖZ

Amaç: Ahmed Glokom Valvi geri-çıkarımının gerektiği durumları ve prevelansını değerlendirmek amaçlandı.

Gereç ve Yöntem: Ahmed Glokom Valvi geri-çıkarılan 13 olgunun tıbbi bilgileri retrospektif olarak değerlendirildi.

Bulgular: Nisan 2002 ve Mart 2017 tarihleri arasında yerleştirilen 324 AGV olgusundan 21 (%6.48) olguda tüp ekspojuru izlendi. Bu olguların 8'i çeşitli metotlarla onarılabilirken, 13'ü implant çıkarımına gitti. Bu 13 hastada çıkarım öncesi konjonktival pediküllü fleb veya perikardlı ya da perikardsız çift katlı amnion membran örtümünü de içeren ortalama 2.2±0.4 (2/3) kez onarıma rağmen 2 ay içinde tekrarlayan tüp ekspojuru ile karşılaşıldı. İmplantı çıkarılan vakaların AGV ile kalış süreleri ortalama 38.30±36.94 (4-114) ay idi. Ortalama göz içi basıncı (GİB)valv çıkarımı öncesi 13±7(3-30) mmHg iken, geri-çıkarım sonrası 1.günde ilaçsız 26±1 (3-50) mmHg idi. İmplant geri-çıkarımı sonrası ortalama takip süresi 22±14(6-57) aydı. Son vizitte ortalama GİB ilaçlı/ilaçsız 22±10 (5-42) mmHg idi.

Sonuç: Glokom drenaj valv implantasyonunda hem erken hem geç dönemde karşılaşılabilen tekrarlayan tüp ekspojuru implant geri-çıkarımının en temel nedenidir. Bu seride valv implantasyonu için en sık endikasyon üveitik glokomdur ve bu vakaların tüp ekspojuru ve ekspojur onarım yetersizliğinin de görüldüğü en sık grup olduğunu söylemek yanlış olmaz. Tüm cerrahi manevraların yetersiz kaldığı ekspojur vakaları için AGV geri-çıkarımı kurtarıcı ve güvenli bir prosedürdür.

Anahtar Kelimeler: Dirençli glokom, glokom drenaj implantı, Ahmed glokom valv geri-çıkarımı, tüp ekspojuru.

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INTRODUCTION

Glaucoma drainage implants (GDIs) are useful in the management of a refractory glaucoma. Although numerous complications such as hypotony, corneal decompensation, diplopia, cataract, pupillary irregularities, infectious endophthalmitis, and tube-related complications limit their benefit, they are indispensable alternative to a trabeculectomy and cyclodestructive procedures[1,2]. The most commonly used implant is the Ahmed glaucoma valve (AGV) which incorporates a valve mechanism to prevent hypotony during the early postoperative period. An encapsulated cyst formation is one of the main reasons for AGV failure, wherein the surgical success rates range from 31 % to 84 % in various patient groups[3-6]. Conjunctival erosion with an exposure of the tube is a complication which occurs in a range of 3%–8% of cases, mostly in the late postoperative periods[7,8], and the patients are confronted with a compulsory surgical revision. Although there are many reports in the literature related the prevalence and risk factors of a tube exposure, the published data about the removal of an implant is limited to individual case reports or small series[9,10].

In this study, our aim was to report the prevalence and efficacy of AGV explantations in our AGV surgery series.

MATERIAL AND METHODS

This retrospective, noncomparative study was approved by the Review Board of Ankara Training and Research Hospital and adhered to the provisions of the Declaration of Helsinki for research involving human subjects. The medical records of 13 patients who underwent an AGV removal between April 2002 and March 2017 were analyzed. The collected data were as follows; indication for placement, AGV model, the age at time of surgery, gender, diagnosis, intraocular pressure (IOP) values before and after AGV implantation, surgeries prior to the AGV implantation, the duration with AGV, the reason for the explantation, repairing attempts prior to the explantation, medications, and the outcomes without an implant in the patients. A surgical success for an AGV implantation was defined as a postoperative IOP value between 5 and 22 mmHg without any glaucoma medication.

All the implants were located at superior temporal conjunctiva, and the tubes were inserted into the anterior chamber. Although AGV implantation surgeries were performed by different surgeons, all of the explantations were performed by a single surgeon (Ü.E.).

The Implantation Technique

Under peribulbar or general anesthesia, a 8-0 silk suture was inserted into the superior limbal cornea. A conjunctival dissection was performed posteriorly by a blunt dissection in superior-temporal quadrant, and a fornix-based opening was created. The AGV (New World Medical, Inc., Rancho Cucamonga, CA) were irrigated with 2 ml of balanced saline solution (priming). The plate was secured to superficial sclera 8 mm from limbus using two interrupted 6-0 absorbable sutures after passing through the holes. The tube was cut to extend from 1 mm to 3 mm beyond posterior surgical limbus. The anterior chamber was entered 2 mm posterior to the limbus by a 22-gauge needle directed parallel to and just anterior to iris plane, and a viscoelastic was administered. The tube was inserted with a smooth forceps through the needle tract ensuring that there is no contact with the iris and the cornea. The tube was secured against the sclera using 10-0 nylon sutures. Following this, one donor graft was used to cover it. A conjunctival closure was then performed using a 10-0 nylon suture. A subconjunctival antibiotic and steroid injection was administered.

The Explantation Technique

Under peribulbar or general anesthesia, a conjunctival dissection was performed over the area of tube erosion, and the tube was removed from the anterior chamber. One or two 7-0 vicryl scleral sutures were placed at the entrance of the tube. Because of the fragility of the conjunctiva, a conjunctival dissection was carefully performed towards the side of the tube-plate conjunction. Although, successful removal of plate was very difficult, and most surgeons leave the plate in situ, if there was no plate exposure, we preferred to remove it in all cases to prevent consecutive plate-related complications. Extensive relaxing incisions were performed both above and below the AGV plate to disconnect the soft tissue integration inside the holes of the plate. In most cases, there was a fibrous tissue around the plate almost the same thickness as the sclera (Figure 1 and 2). The plate was mobilized, and removed. If there was an aqueous leak or a large scleral opening, an additional pericardium/dura

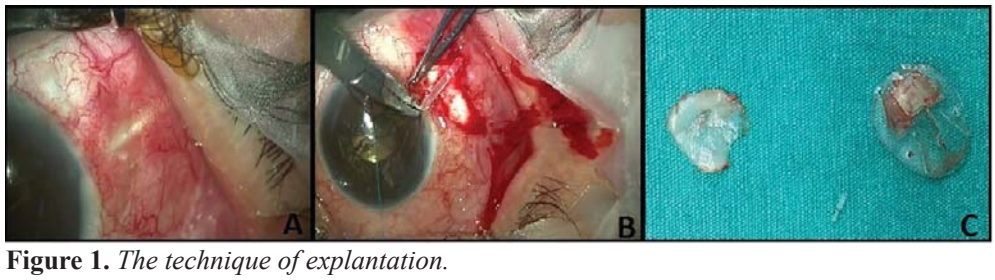

Figure 1. *The technique of explantation.*

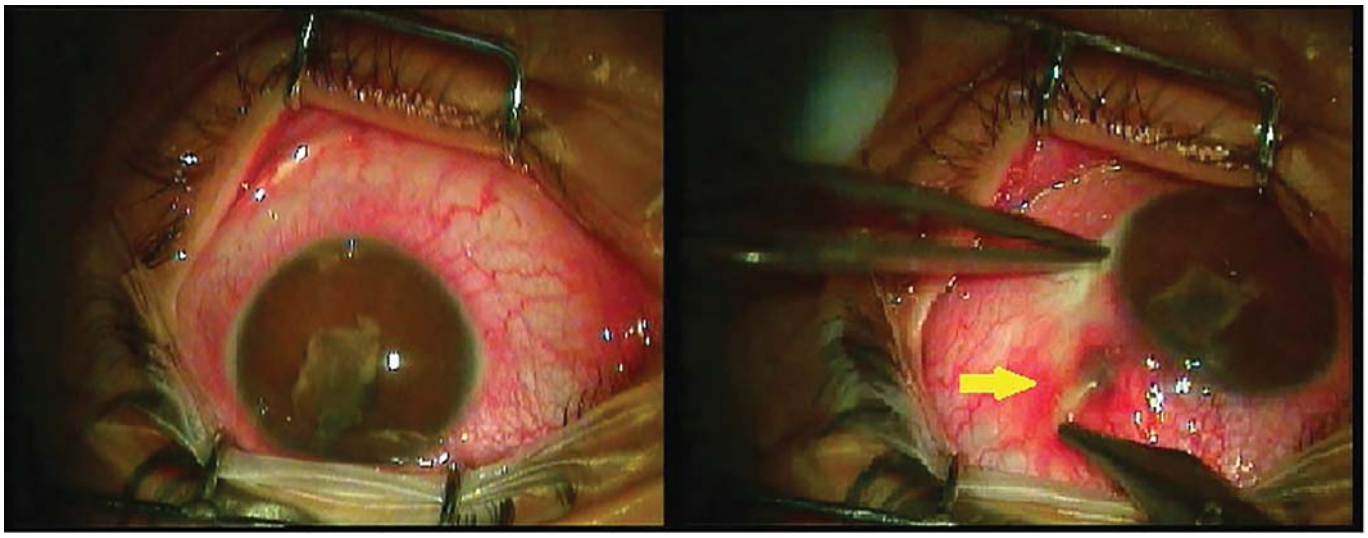

Figure 2. *The technique of explantation.*

graft was used, if not the conjunctiva was closed with a continuous 8-0 vicryl suture. The patients were examined the postoperative first day, and a steroid and antibiotic drop was initiated and continued for approximately 4 weeks. Anti- glaucomatous therapy was varied according to the IOP value. The following intervals of the visits were determined by the clinical condition.

RESULTS

Twenty-one (6.48%) of 324 eyes who received an AGV (123 S2; 68 FP7 models) between April 2002 and March 2017 had tube exposure. 13 (4.01%) of them (6 by S2 model, 7 by FP7 model) underwent an implant explantation. In 13 explantation cases, 7 of them (53.8%) were female and 6 of them (46.2%) were male. Mean age was 27.7 (8-55) years. Primary diagnosis for AGV implantation was uveitis in 8 patients (61.5%), congenital cataract surgery and pseudophakic glaucoma in 2 patients (15.3%), congenital cataract surgery and aphakia in 2 patients (15.3%) and angle recession in 1 patient (7.7%). 8 patients were successfully repaired by different methods. For the 13 explantation patients, average 2.23±0.43 (2 or 3 times) repairing procedures were performed for each patient which include conjunctival pedicle flaps or double layer amniotic membrane graft with/without pericardial patch graft but they required an explantation within 2 months after the last attempt because of recurrent tube erosion. All patients underwent AGV implantation because they were refractory to maximum medical treatment, and 4 of them also underwent trabeculectomy with mitomycin-C (MMC).

The mean IOP value was 33.5 ± 7.7 (range; 15-46), and 14.5± 5.7 (range; 5-24) mmHg before and 1 month following the AGV implantation, respectively. The surgical success was achieved in 8 (61.53%) patients during the postoperative first month, and in all the post-AGV implantations, IOP values were less than 22 mmHg with/without medical treatment during the first postoperative month, except for one eye which was diagnosed as a case of aphakic glaucoma (Case 4).

All the eyes have formed an anterior chamber and a clear cornea just before the explantation. The tube position in the anterior chamber was at the supero-temporal quadrant.

The mean IOP value was 13 ± 7 (range;3-30) mmHg just before the explantation, and 26 ±11 (range; 3-50) mmHg at the first postoperative morning following the explantation without antiglaucomatous therapy.

The mean time period with an AGV was 38 ± 37 (range; 4-114) months. The earliest one removed (4 months after implantation) was in an 8-year-old child (Case1) after the AGV was implanted. The diagnosis of the case, that had longest duration time with implant, was that of the pediatric aphakic glaucoma (Case 4).

In 199 patients uveitic glaucoma was the primary diagnosis (61.4%) for the AGV implantation in this series. 8 of 13 (61.5%) cases who had required an explantation were uveitic patients.

Table 1 demonstrates the patients characteristics, indication for implantation and removal, medications, and the post-explantation IOP values at the first postoperative day, without antiglaucomatous therapy.

Table 2 demonstrates the last visit findings of patients after removal of the valve with appropriate medical therapy. The mean follow-up period after removal was 22±14 (range; 6-57) months. The mean IOP value was 22±10 (range; 5-42) mmHg with/without medical treatment.

Table 1.

	Age	Gender	Reason for placement	Type of AGV	Prior Surgiries	Pre-AGV IOP	Post-AGV IOP (1 m)	Post-AGV Tx (1 m)	Time with AGV (m)	Management of exposure	Pre Removal IOP	IOP at 1st day removal
1	8	M	CC+AG	FP7	CE	40	6	None	4	conjunc.pedicle flap double layer amnion	6	38
2	23	M	AR	FP7	None	46	19	Cos, Alp	66	conjunc.pedicle flap double layer amnion	3	3
3	30	F	Uveitis	FP7	Trab+ mmc	28	10	Cos	7	conjunc.pedicle flap double layer amnion +pericard	14	30
4	25	F	CC+AG	S2	CE	35	24	Aza, Alp, Lu	114	conjunc.pedicle flap conjunc.pedicle flap+pericard	30	50
5	9	M	Uveitis	FP7	None	30	5	None	28	conjunc.pedicle flap x2 double layer amnion +pericard	5	16
6	9	F	Uveitis	FP7	Trab+ mmc	15	15	None	4	conjunc.pedicle flap+pericard double layer amnion +pericard	15	30
7	55	F	Uveitis	FP7	None	35	18	Cos, Alp, Lu	5	conjunc.pedicle flap double layer amnion +pericard	4	17
8	23	F	Uveitis	S2	CE	27	20	Cos, Alp	108	conjunc.pedicle flap double layer amnion +pericard	12	30
9	33	M	CC+PG	S2	CE+ Trab+ mmc	36	20	None	36	conjunc.pedicle flap conjunc.pedicle flap+pericard	11	22
10	37	F	CC+PG	S2	CE	40	12	None	45	conjunc.pedicle flap conjunc.pedicle flap+perica x2	16	24
11	45	M	Uveitis	FP7	None	35	10	None	24	conjunc.pedicle flap double layer amnion +pericard	14	27
12	38	F	Uveitis	S2	Trab+ mmc	38	14	None	25	conjunc.pedicle flap+pericard conjunc.pedicle flap+pericard	16	21
13	26	M	Uveitis	S2	None	31	16	None	32	conjunc.pedicle flap conjunc.pedicle flap+perica x2	17	25

AGV: Ahmed glaucoma valv*; AG:* Aphakic glaucoma*; Alp:* Alphagan; *AR:* Angle recession; *Aza:* Azarga*; CE:* Cataract extraction; *CC:* Congenital cataract; *Cos:* Cosopt; *Exp:* Exposure*; F:* Female*; IOP:* Intraocular pressure*; Lu:* Lumigan; *M:* Male; *mmc:* mitomycin C; *m:* month; *PG:* Pseudophakic glaucoma; *Trab:* Trabeculectomy; Tx: Treatment

Table 2.				
Case	**Follow-up period (m)**	**IOP (mmHg)**	**Tx**	**Final Outcome**
1	23	16	Cos, Alp	*Controlled with medical glaucoma treatment*
2	7	5	None	Hypotony maculopathy, choroidal detachment
3	14	21	Cos, Alp, Tra	*Controlled with medical glaucoma treatment*
4	6	42	Aza, Alp, Lu, Sys CAI	Recieved a new implant at inferior conjunctiva and under control without medical treatment by approximately 15mmHg at postoperative third month
5	57	18	Cos, Alp	*Controlled with medical glaucoma treatment,* posterior synechiae
6	32	34	Aza, Alp, Lu	Not considered any surgery due to severe inflamed conjunctiva
7	21	15	Cos, Alp, Sys steroid	*Controlled with medical glaucoma treatment* and steroid therapy for uveitis
8	15	35	Cos, Alp, Lu	Refused any surgery
9	26	20	Aza, Alp	*Controlled with medical glaucoma treatment*
10	16	19	Cos, Alp, Lu	*Controlled with medical glaucoma treatment*
11	12	33	Cos, Alp, Tra	Not considered any surgery due to only perception positive visual acuity
12	22	17	Cos, Alp	*Controlled with medical glaucoma treatment*
13	33	15	Aza, Alp, Lu	*Controlled with medical glaucoma treatment*

Alp: Alphagan*; Aza: Azarga; CAI:* Carbonic anhydrase inhibitor*; Cos:* Cosopt; *IOP:* Intraocular pressure: *Lu:* Lumigan M:month, Sys:systemic, Tra:travatan, Tx:treatment.

CONCLUSION

Aqueous shunt surgery is an indispensable procedure in cases with a high risk for a filtration failure. However, corcerns about bleb-related complications and higher rates of the failure of filtration surgery makes shunt implantation an alternative to trabeculectomy rather than being a desperate measure. The tube versus trabeculectomy study is a well-known multicenter randomized clinical trial, designed to compare the safety and efficacy of tube shunt surgery and trabeculectomy with MMC in patients with a previous cataract and/or glaucoma surgery[11]. It has been reported that the cumulative probability of failure was 29.8% in the tube group and 46.9% in the trabeculectomy group. In addition, the rate of a reoperation for glaucoma was higher in the trabeculectomy group relative to the tube group; however, all complications were not equal in severity, and the rate of serious complications was the same in both groups[11]. Therefore, tube shunt surgery seems to be safe and effective as trabeculectomy, but it may present with more serious complications that may be difficult to repair.

To our knowledge, this is the largest series presenting the causes and results of a successful removal of the implant with 13 subjects.

A tube exposure is the only reason for an explantation in all of these subjects. Ayyala et al. found a 7% rate of tube erosion in their study that include 85 patients similar to our rate (6.48%)[12]. To our knowledge, when faced with tube or plate exposure, observation is not logical due to its predisposing potential for devastating complications such as endopthalmitis. However, exposed devices may be recovered by some techniques which include a conjunctival advancement with/without patch grafts such as sclera, pericardium, dura, or fascia lata, if there is sign of infection or primary repairing has failed, the implant should be removed. In our eight successfully repaired cases, only 1 of them had undergone previous trabeculectomy surgery and the duration of medical treatment with glaucoma diagnosis was less than 5 years in all. So the healthier conjunctiva can be the cause of the success of the repair.

The possible causes of tube erosion through the conjunctiva are not totally clear. The primary cause for AGV implantation was uveitic glaucoma in 61.54% of our cases, so uveitis with prolonged use of topical steroid should be monitored regularly because of being prone to conjunctival erosion resulting in a tube expoure. Although uveitis was not reported as a risk factor for significantly increasing the chronic risk for exposure in clinical studies, early tube and plate erosion in inflamed eyes have been previously described.[13,14] Moreover, plate exposures are more difficult to correct; however, a successful revision of

an early postoperative shunt plate exposure repaired with a scleral patch graft with intensive medical immunomodulator therapy including oral and topical steroids, oral doxycycline for its anti-metalloproteinase action, tacrolimus ophthalmic ointment, and topical cyclosporine A in an uveitic eye with glaucoma was reported.[14] This successful repair may be attributed to the carefully reduced surface inflammation with medications.

Most of the studies that evaluated the risk factors for GDI tube exposure, have included one type of implant and have focused on the outcome differences based on patch grafts materials, demographics, and diagnosis of the patients.[8,15] In a recent study, which included multiple types of GDI, a difference in the exposure rates was not found.[7]

Similarly, Muir et al. did not find a difference in exposure outcomes related to type of GDI in their study which included 598 AGV and 470 Baerveldt implants.[16] In our study, there were two types of AGV: a S2 polypropylene and a FP7 silicone model. The valve explantation rate is higher in those with silicone valve. Most of the studies in the literature, which compare the two AGV types, showed similar efficiency but fewer serious complications in silicone valve.[17-19] In a study that evaluates the incidence of a conjunctival exposure in various drainage valves, no difference was found between the silicone and polypropylene valves.[20] The difference in the explantation rate in contrast to the silicone valve in our series is not very consistent with the literature which showed more positive results for the silicone valves. Therefore, we suggest that this finding is a coincidental outcome due to the small number of cases.

In our series, most of the patients underwent previous surgeries, and 4 of them underwent trabeculectomy with MMC. A previous conjunctival surgical scar and the residual tissue effects of MMC may be contributing factors to the erosion of the conjunctiva, but many cases that had an implanted GDI had previously undergone a trabeculectomy with MMC and without any exposure, which suggests that there are other reasons that caused the tube erosion, such as individual factors in wound healing. Huddleston et al.[21] retrospectively analyzed 43 eyes that underwent aqueous shunt implantation with tube exposure. Of these, 8 eyes were treated with an aqueous shunt removal, 3 of them at the first leakage, 5 of them after 3, 8, 50, 52, and 56 weeks following the initial repair. Out of the 43 eyes, most (35 eyes) were repaired without the need for removal and any further complication. Although a tube exposure can usually be reparied by some patch graft methods, it must be examined in later periods, and a long-term follow-up is vital.

Especially in pediatric cases due to excessive eye rubbing, a mechanical abrasion of the conjunctiva over the tube by the eyelid can cause conjunctival erosion.[22] In addition, ocular surface dryness may contribute to erosion.[22] Minimizing eye rubbing and using supplemental ocular lubrication can decrease the risk of conjunctival tube erosion.

The patch graft over the tube is the most commonly used method to prevent the conjunctiva from erosion**.** In our cases, we used routine pericardial patch grafts for both in primary tube insertion and an attempt to repair any tube exposure. However, there are many advantages of a pericardial patch graft such as not requiring an eye bank, a lower cost, immunologic safety, and a reduced risk of viral transmission, erosion due to graft melting resulting has been reported in the literature.[23-25] It can be explicitly said that any patch graft material may be complicated with a tube exposure. In our series, 3 out of the 13 eyes were pediatric cases, and to reduce the risk for an exposure in this kind of at-risk patient; donor sclera or double-thickness pericardium patch grafts can be used instead single-thickness pericardium grafts. Huddleston et al.[21] showed a correlation between a higher number of glaucoma medications used before the initial tube shunt implantation with an increasing number of re-exposures. They also established a list of additional risk factors, including belonging to a colored race, having diabetes mellitus, having a history of multiple glaucoma laser procedures, and undergoing a combination surgery. None of these factors was identifed as a common cause for explantation in our series.

Although, corneal decompensation is one of the main complications and has been reported in up to 30% of the patients following GDI surgery,[26] it did not occur as a reason for removal in our series.

As a remarkable result, when looking at the last visit's findings after removal of the valve, it was observed that the IOP was controlled better with medical treatment compared to that before the valve implantation in 8 out of the 13 patients. These findings suggest that a drainage area which facilitates an aqueous outflow may have occured during insertion or extraction of the valve. Another possible explanation may be that interrupting medical treatment for a period after valve implantation may increase the drug receptor sensitivity. These theories may be the subject of a further research.

Consequently, while it is essential the intense suppression of inflammation before and after the implantation of an aqueous shunt to avoid exposure in patients with uveitic glaucoma, in pediatric cases, taking additional precautions, such as minimizing eye rubbing and using double-thickness grafts to prevent exposure, appears very important. In addition, it should be noted that a regular and long-term follow-up and a carefully examination of the conjunctiva during every visit is essential in order to avoid devastating complications in patients who undergo an aqueous shunt implantation. Lastly, especially in patients with uveitis, unless the IOP value remains very high for a long time or optic disc is under a

risk, there should not be a rush to perform an implantation of glaucoma drainage valve. In addition, uveitic cases are the most common groups of patients who are not only at a risk of exposure, but have also encountered a failure in the primary repair of an exposure. AGV explantation is a safe and saviour procedure in all tube exposure patients when other surgical maneuvers were not adequate.

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