Outcomes of using a sutureless bovine pericardial patch graft for Ahmed glaucoma valve implantation

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Purpose: *To evaluate the long-term outcomes of a surgical technique using a sutureless bovine pericardial patch graft for the implantation of an Ahmed glaucoma valve (AGV).*
Methods: *This was a pilot study on patients with primary open-angle glaucoma refractory to repeated surgical filtering procedures. All patients underwent AGV implant technique using a sutureless bovine pericardial patch graft. The pericardial membrane was cut using an ordinary corneal trephine with a diameter of 9.0 or 10.0 mm. The anterior part of the tube was covered with the graft and kept in place with fibrin glue. Subsequently, the cap was stitched all around the tube and the dissected conjunctiva was laid over it. Intraocular pressure (IOP) and complications were evaluated 1 week and 1, 3, 6, 12, and 24 months after surgery.*
Results: *The procedure was used to treat 20 eyes of 20 consecutive patients (12 men and 8 women: mean age [SD] 64.8 [7.8] years). Mean IOP was 28.1 mm Hg (SD 4.9) at baseline and decreased to 14.9 mm Hg (SD 1.5) 24 months after surgery ($p<0.001$). The overall mean number of topical medications was 3.1 (SD 0.5) at baseline and decreased to 1.4 (SD 0.8) after 24 months ($p<0.001$). During follow-up, there was no conjunctival erosion, thinning of pericardial patch graft over the tube, or tube exposure; no signs of endophthalmitis were recorded.*
Conclusions: *The results suggest that the sutureless technique using a bovine pericardial graft patch is a safe and rapid procedure for AGV implantation.*

Keywords: *Ahmed glaucoma valve, Complications, Pericardial patch graft, Refractory glaucoma, Sutureless surgery*

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INTRODUCTION

The practice of implanting a glaucoma drainage device (GDD) in patients with surgically refractory glaucoma is rapidly growing (1, 2). Glaucoma drainage devices lower intraocular pressure (IOP) by creating a space between the sclera and the conjunctiva within which aqueous humor may flow. The distal end of the tube can be inserted into the anterior chamber or vitreous cavity. However, if left uncovered, the extraocular part of the tube can erode the conjunctiva, and this represents a major risk factor for endophthalmitis (3, 4). Various tissue patch grafts have been proposed for covering the distal part of the tube (human donor dura mater, fascia lata, human donor sclera, and pericardial tissue) (5-8). The patches of different materials and sizes are anchored to the bulbar sclera using 9-0 or 10-0 nylon sutures, or 7-0 polyglactin sutures. Zeppa et al (9) have recently proposed a sutureless human sclera donor patch technique for Ahmed glaucoma valve (AGV) implantation, but its use has been limited by costs, commercial availability, and the poor uniformity and quality of donor sclera. In this study, we present the outcomes of

a sutureless procedure for AGV implant using Tutopatch® (Tutogen Medical GmbH, Neunkirken am Brand, Germany).

METHODS

Twenty eyes of 20 consecutive patients (12 men and 8 women; mean age [SD] 64.8 years [7.8]) with primary open-angle glaucoma (POAG) refractory to repeated surgical filtering procedures (previous surgeries, mean [SD] 2.7 [0.8]) who were receiving maximal tolerated medical therapy were treated (defined as 3-4 topical drugs in fixed or unfixed combinations). All of the operations were performed by an expert glaucoma surgeon (L.Q.) working at the Glaucoma Service of the University of Brescia.

Informed consent was obtained from all the studied subjects. A fornix-based conjunctival incision was made in the superotemporal quadrant, and a blunt dissection was performed. After identifying the 2 adjacent rectus muscles, the AGV (Model S2, New World Medical, Rancho Cucamonga, Louisiana, USA) was implanted between them approximately 10 mm posterior to the surgical limbus. The plate was then secured to the sclera using interrupted 10-0 nylon sutures (Alcon Surgical, Milan, Italy), and the tube inserted into the anterior chamber through a scleral fistula created by means of a 23-gauge needle.

Tutopatch® is a collagen membrane that is extracted from solvent-preserved bovine pericardium sterilized by means of gamma radiation. Before use, the collagen membrane was rehydrated with saline solution for 5-10 minutes, and the membrane was then cut using an ordinary corneal trephine with a diameter of 9.0 or 10.0 mm. The anterior edge of the patch graft was positioned just anterior to the tube insertion, and kept in place with fibrin glue (Tisseel fibrin glue, Baxter AG, Vienna, Austria) (Fig. 1A). Subsequently, the cap was stitched all around the tube and the dissected conjunctiva was laid over it (Fig. 1B); fibrin glue was then applied to the underside of the conjunctiva and smooth forceps were used to hold the edges in place until adherence was assured, taking care to cover the graft totally (Fig. 1C). The eye was then examined for leaks as the anterior chamber was filled with balanced salt solution through a paracentesis.

The IOP and complications were evaluated 1 week and 1, 3, 6, 12, and 24 months after surgery. Success was defined as an IOP of ≤18 mm Hg, with (qualified success) or without medical hypotensive therapy (complete success) in all study visits during 2-year follow-up.

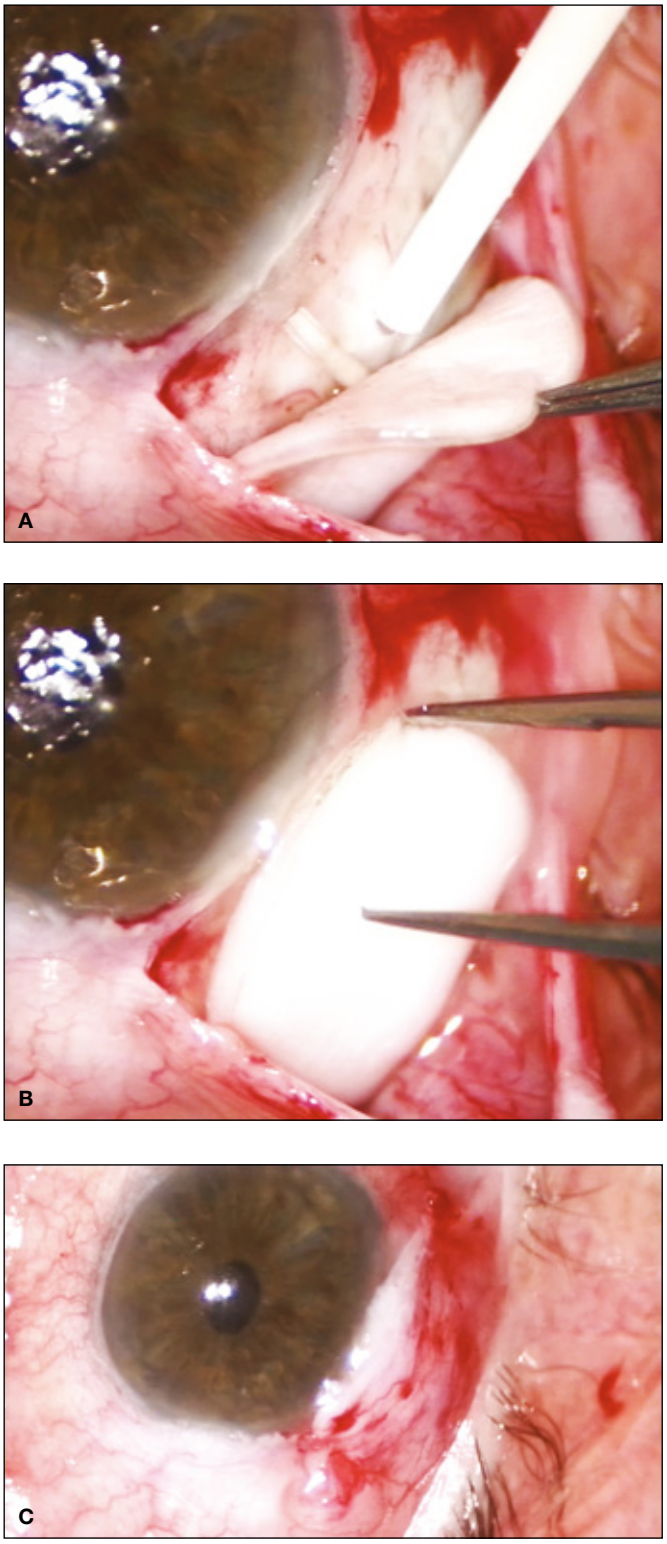

Fig. 1 - ***(A)*** *The patch graft is positioned just anterior to the tube insertion, and kept in place with fibrin glue.* ***(B)*** *The patch graft is stitched all around the tube by using fibrin glue.* ***(C)*** *Final result: full approximation of the conjunctiva to the limbus.*

TABLE I - INTRAOCULAR PRESSURE AND MEDICAL HYPOTENSIVE THERAPY[a]

	Baseline	1 wk	1 mo	3 mo	6 mo	1 y	2 y
IOP, mm Hg	28.1 (4.9)	8.1 (3.1)	13.5 (2.8)	14 (2.2)	14.3 (2.3)	14.7 (2.2)	14.9 (1.5)
Paired *t* test[b] (p value)		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Glaucoma medications	3.1 (0.5)	0	0.5 (0.6)	0.9 (0.7)	1.2 (0.7)	1.3 (0.8)	1.4 (0.8)
Paired *t* test[b] (p value)		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

IOP = intraocular pressure.
[a]Results are reported as mean (SD).
[b]Comparison versus baseline.

TABLE II - POSTOPERATIVE COMPLICATIONS AFTER AHMED GLAUCOMA VALVE IMPLANTATION

Complications[a]	No. (%) of eyes
Increased intraocular pressure[b]	4 (20)
Hypotony[c]	2 (10)
Shallow or flat anterior chamber	3 (15)
Anterior chamber bleeding	2 (10)
Choroidal effusion	4 (20)

[a]Some patients had more than one complication.
[b]Intraocular pressure >21 mm Hg during maximal medical therapy.
[c]Intraocular pressure <6 mm Hg.

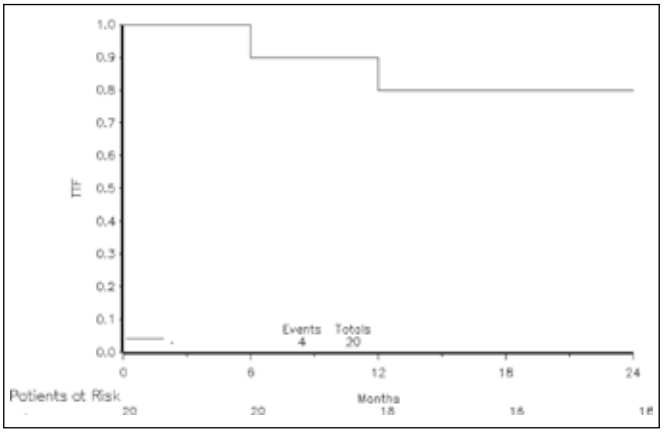

Fig. 2 - *Ahmed glaucoma valve implantation: time to treatment failure.*

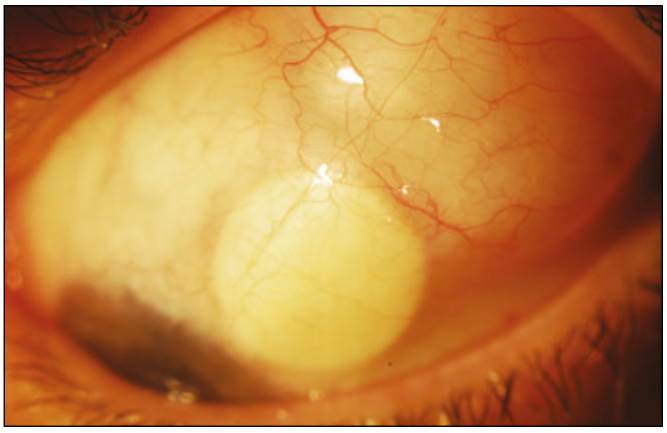

Fig. 3 - *Patch graft 2 years after Ahmed glaucoma valve implantation.*

The comparison of the postoperative IOP values with the baseline was performed by means of the paired *t* test. The Bonferroni approach was adopted in order to make allowance for multiple tests; therefore, statistical significance level was set to 0.008, calculated as 0.05 divided by 6 comparisons.

The time to treatment failure was calculated as the time from the date of registration to the date in which the IOP was >18 mm Hg; patients with an IOP always within the normal values were censored at the end of observation interval. Time to treatment failure was described using the Kaplan-Meier method.

RESULTS

Sixteen patients (80%) were followed up for two years with an IOP ≤18 mmHg; the remaining four patients withdrew due to not sufficiently controlled IOP (Fig. 2). At the end of the 2-year follow-up, complete and qualified success was obtained in 3 and 13 eyes respectively. In the 16 patients followed up for 2 years, the IOP significantly decreased from the first postoperative visit to the end of the follow-up

after 24 months (mean IOP preoperatively 28.1 mm Hg [SD 4.9], mean IOP 24 months postoperatively 14.9 mm Hg [SD 1.5]; $p<0.001$). In all the follow-up visits, the number of topical hypotensive medications was significantly decreased when compared with the baseline ($p<0.001$) (Tab. I).
Table II shows the postoperative complications. Throughout the period of follow-up, there was no conjunctival erosion, thinning of the patch graft over the anterior part of the tube, or tube exposure; no signs of endophthalmitis were recorded (Fig. 3).

DISCUSSION

The advantages of using fibrin glue in ocular surgery are well-known and include a shorter operative time and less postoperative pain (10-13). Furthermore, the absence of sutures is also of some advantage postoperatively, because they can promote inflammation and provide a nidus for infection or neovascularization.
As the components of fibrin glue often come from pooled human plasma, there is a theoretical risk of human disease transmission. However, to our knowledge, there have not been any documented cases of disease transmission despite the extensive use of these products in various surgical fields (14), and so the risk appears to be minimal. The total sterility of the Tutopatch® material is guaranteed by gamma radiation and chemical treatments. The relatively high cost of fibrin glue is counterbalanced by the low cost of Tutopatch®, when compared with human sclera donor patch.
The reported sutureless surgical technique is similar to that described by Kahook and Noecker (15). However, differently from our technique, they had applied a 6 × 6-mm bovine pericardial patch graft at the level of tube entry site, sealed with fibrin glue. There is a substantial advantage to using a round patch graft of 9.0 to 10.0 mm in diameter. As a matter of fact, it allows to cover the majority of the length of the tube, and it offers greater safety in avoiding conjunctival erosion and tube exposure.
Limitations of the present study include limited follow-up, small sample size, and lack of inclusion of cases more at risk for conjunctival erosion (uveitic glaucoma, congenital and juvenile glaucoma).
In conclusion, this sutureless technique using a bovine pericardial graft patch seems to be a safe and rapid procedure for AGV implantation. There is a need for longer follow-up in order to determine whether there are any long-term complications.

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Conflict of Interest Statement: The authors report no proprietary interest.

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