European Journal of Ophthalmology / Vol. 17 no. 5, 2007 / pp. 696-701

A comparison of the polypropylene plate Ahmed™ glaucoma valve to the silicone plate Ahmed™ glaucoma flexible valve

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PURPOSE. *To compare surgical outcomes following implantation of the polypropylene plate Ahmed glaucoma valve (AGV) (S-2) and the newer silicone plate AGV (FP-7) with minimum 12 months follow-up in patients with intractable glaucoma.*
METHODS. *Retrospective chart review of 25 eyes of 22 patients who underwent FP-7 and 26 eyes of 22 patients who underwent S-2 AGV implantation by a single surgeon. Main outcome measures included surgical outcomes in terms of intraocular pressure (IOP) control, hypertensive phase, and postoperative complications.*
RESULTS. *There were no significant differences in diagnoses, pre- and postoperative IOP, pre- and postoperative visual acuities at all time points, and in the number of pre- and postoperative medications between the groups. Significant IOP reductions occurred after FP-7 implantation (29.6 ± 13.1 to 12.1 ± 3.4, $p < 0.001$) and S-2 implantation (31.4 ± 11.7 to 16.1 ± 5.7, $p < 0.001$). The FP-7 group had a statistically lower IOP compared to the S-2 group at 6 ($p<0.05$), 9 ($p<0.01$), and 12 months ($p<0.01$). There was no significant difference in the hypertensive phase between the two groups ($p=0.41$).*
CONCLUSIONS. *FP-7 model silicone plate AGV resulted in lower IOP compared to the older S-2 polypropylene plate AGV at 1 year. This may suggest that the plate material may influence clinical outcome. (Eur J Ophthalmol 2007; 17: 696-701)*

KEY WORDS. *Glaucoma drainage devices, Biomaterials, Intraocular pressure*

Accepted: April 23, 2007

INTRODUCTION

Glaucoma drainage devices are used in the management of glaucoma that does not respond to conventional medical and surgical treatments. The Ahmed glaucoma valve (AGV) (New World Medical, Inc., Rancho Cucamonga, CA) is one such device that has a unidirectional valve incorporated into a 184 mm^2 endplate (1).

The overall success rate of different implants currently available is between 75% and 80% at 1 year. Inflammation around the endplate, resulting in excessive scar tissue formation, is the leading cause of glaucoma drainage device failure (2). Failure appears to be more common in the first postoperative year than subsequent years (3). The intensity of the fibrous reaction may vary depending on a number of factors such as the biomaterial, size, and/or design of the endplate and the individual patient's immune reaction to the operation, the glaucoma drainage device itself, the introduction and the timing of the glaucomatous aqueous into the subconjunctival space (2-6), and factors that are not well understood at the present time.

Biomaterials causing the bleb fibrosis and subsequent

1120-6721/696-06$15.00/0

Presented as a poster at the American Glaucoma Society annual meeting; Snowbird, UT; March 2005 and at the Association for Research in Vision and Ophthalmology; Fort Lauderdale, FL; May 2005

failure is a relatively new concept. Ayyala et al have demonstrated in animal experiments that the flexible silicone endplate is less inflammatory compared to the rigid polypropylene plate in the rabbit subconjunctival space (7, 8). Based on these studies, the Ahmed valve endplate was changed from rigid polypropylene (S-2) to flexible silicone plate (FP-7) with the same surface area (184 mm^2) and was introduced into the market in 2003.

This retrospective study compares the surgical outcomes of patients who underwent implantation of the Ahmed™ Glaucoma Valve with a polypropylene plate (model S-2) or the silicone plate Ahmed™ Glaucoma Flexible Valve (model FP-7).

METHODS

Approval by the Tulane University Health Sciences Center Institutional Review Committee on Use of Human Subjects was obtained for this retrospective study, which was conducted on 25 consecutive eyes of 22 patients (9 male, 13 female) and 26 consecutive eyes of 22 patients (10 male, 12 female) who underwent implantation of the silicone plate Ahmed™ Glaucoma Flexible Valve (FP-7) and polypropylene plate Ahmed™ Glaucoma Valve (S-2), respectively. The inclusion criteria included any patient who underwent Ahmed valve insertion at one institution (Tulane University Health Sciences Center) performed by a single surgeon (R.S.A.) with a minimum of 12 months of follow-up. Because the FP-7 AGV was introduced in 2003, the study was limited to those patients who underwent AGV implantation between November 2002 and November 2004. Patients received only S-2 AGVs until November 2003. Our hospital instituted a formulary conversion of the glaucoma drainage devices from S-2 to the FP-7 in November 2003. Since then all patients received the FP-7 exclusively.

A total of 57 eyes were implanted with the AGV during the study period. Six patients were excluded from the study due to lack of 12 months of follow-up. The following information was collected from the chart review. The diagnosis, age, race, sex, best-corrected visual acuity (BCVA), intraocular pressure (IOP), and number of glaucoma medications were recorded preoperatively, on postoperative days 1 and 7, at postoperative months 1, 2, 3, 6, 9, and 12, or the last follow-up visit. Any complications were recorded. All surgeries were performed in a standard fashion (1).

Statistical analysis

The two-sample Student *t*-test was used to compare the silicone and polypropylene Ahmed glaucoma valve groups with respect to age and number of medications. Gender, race, and diagnosis were compared with the chi-square test. Repeated-measures analysis of variance (ANOVA) was used to assess changes in IOP over the postoperative time course between the FP-7 and S-2 groups with Bonferroni comparisons at specific time points (9). Visual acuities in logMAR units were compared between the two groups by ANOVA. Postoperative complications and interventions were compared using Fisher exact test for binomial proportions. A power analysis indicated that the sample sizes provided 80% power to detect a difference in IOP of 5 mmHg between the two groups assuming a standard deviation of 4 mmHg (effect size 0.80) using ANOVA and differences in success rates of 20% using Fisher exact test for binary proportions (version 5.0, nQuery Advisor, Statistical Solutions Ltd., Cork, Ireland). Statistical analysis was performed using the SPSS software package (version 13.0, SPSS Inc., Chicago, IL, USA). Two-tailed values of $p<0.05$ were used as the criterion for statistical significance.

Success was defined as final IOP at least 20% less than the preoperative IOP and >5 mmHg and <22 mmHg, without additional glaucoma surgery, loss of vision, or devastating complications, with or without medications.

RESULTS

The FP-7 and the S-2 groups were similar with no group differences with respect to patient demographics: age, 64.8 ± 19.5 vs 62.8 ± 18.8 for FP-7 and S-2, respectively (p=0.73, Student *t*-test); gender, 41% male, 59% female vs 45% male and 55% female (p=0.76, Fisher exact test); race, 68% white and 32% African American vs 50% white and 50% African American (p=0.36, Fisher exact test). The preoperative BCVA, IOP, and number of medications were not statistically significantly different between the two groups. The two most common diagnoses in the groups were neovascular glaucoma and open angle glaucoma (Tab. I). All the open angle glaucoma patients in both groups and two of the congenital glaucoma patients in the S-2 group had previous failed trabeculectomy operations. There were six pseudophakic eyes in the S-2 group and eight in the FP-7 group.

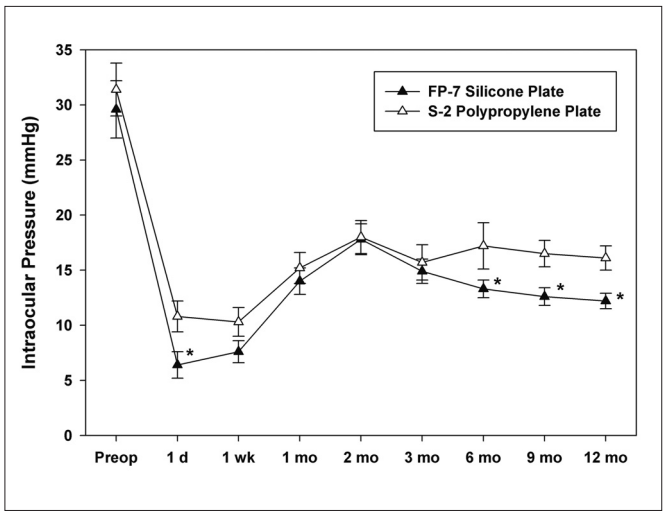

Fig. 1 - *Intraocular pressure over 12 months between the FP-7 and S-2 Ahmed valve groups. Note the error bars are standard errors.*

The IOP was lower in the eyes in the silicone group at all time points compared to those in the polypropylene group. Two-way repeated-measures ANOVA indicated significant differences in IOP between the groups over time ($F=10.77$, $p=0.002$) and post hoc Bonferroni comparisons identified differences between the groups with pressure significantly lower in the FP-7 group at 1 day ($p<0.05$), 6 months ($p<0.05$), 9 months ($p<0.01$), and 12 months ($p<0.01$) (Tab. II and Fig. 1).

A hypertensive phase (defined as an IOP >21 mmHg in the first 6 months) occurred in 58% of eyes in the polypropylene group (n=15) and 44% of eyes in the silicone group (n=11) ($p=0.41$, Fisher exact test) (Tab. III). Five patients in the polypropylene group and two patients in the silicone group had bleb revision with needling during the hypertensive phase (Tab/ IV). Bleb revision, the most common surgical intervention in both groups, was performed in the clinic at the slit lamp when patients with hypertensive phase did not respond to topical glaucoma medications and digital massage.

The need for medications was reduced by more than half in both groups. The mean number of preoperative and postoperative medications was 3.2 and 1.3 in the FP-7 group compared to 2.5 and 0.7 in the S-2 group and was not statistically significant either in the preoperative or postoperative period (Tab. II). There were 9 patients in the silicone group and 12 patients in the polypropylene group with controlled IOP on no medications at 12 months. The mean IOP in this subgroup of patients was 12±2 in the silicone group and 13±4 in the polypropylene group.

Best-corrected visual acuity was not significantly changed in either group following glaucoma device implantation (Fig. 2). Postoperative complications and interventions were similar between the two groups (Tabs. IV and V). Choroidal effusions and hyphema were the most common postoperative complications in both groups, resolving without surgical intervention in every case. One patient in

TABLE I - STUDY POPULATION BASELINE CHARACTERISTICS

Variable	Silicone group	Polypropylene group	p value
No. of eyes/patients	25/22	26/22	
Age, yr, mean (SD)	64.8 (19.5)	62.8 (18.8)	0.73
BCVA, mean	20/132	20/175	0.52
IOP, mmHg, mean (SD)	29.6 (13.1)	31.4 (11.7)	0.60
Medications, mean (SD)	3.2 (1.2)	2.5 (1.7)	0.07
Diagnosis			
Diagnosis, n			0.97
Neovascular	4	6	
Open angle	13	12	
Uveitic	2	5	
Congenital	4	1	
Angle closure	1	1	
ICE syndrome	1	1	
Gender	9 Male,13 female	10 Male,12 female	0.75
Race	7 African American,15 white	11 African American,11 white	0.36

BCVA = Best-corrected visual acuity; IOP = Intraocular pressure

TABLE II - IOP AND MEDICATIONS DATA

IOP (mmHg)	FP-7: silicone, mean (SD)	S-2: polypropylene, mean (SD)	p value
Preoperative IOP	29.6 (13.1)	31.4 (11.7)	0.60
IOP at 1 day	6.4 (6.0)	10.8 (7.0)	<0.05*
IOP at 1 week	7.6 (3.8)	10.4 (6.3)	0.06
IOP at 1 month	14.0 (6.5)	15.3 (7.5)	0.52
IOP at 2 months	17.8 (6.8)	18.0 (7.3)	0.80
IOP at 3 months	14.9 (5.4)	15.7 (8.0)	0.67
IOP at 6 months	13.3 (3.2)	17.2 (10.4)	<0.05*
IOP at 9 months	12.2 (3.1)	16.5 (6.1)	<0.01*
IOP at 12 months	12.1 (3.4)	16.1 (5.7)	<0.01*
No. of medications			
Preoperative	3.2 (1.2)	2.5 (1.7)	0.07
Postoperative	1.3 (1.3)	0.7 (1.2)	0.08

*Statistically significant.
IOP = Intraocular pressure

TABLE III - HYPERTENSIVE PHASE DATA (IOP >21 MMHG)

Time point	FP-7 silicone plate group (25 eyes)	S-2 polypropylene plate group (26 eyes)	p value
1 day	1 (4.0)	2 (7.7)	1.00
1 week	0 (0.0)	3 (11.5)	0.24
1 month	4 (16.0)	6 (23.1)	0.73
2 months	5 (20.0)	8 (30.8)	0.52
3 months	2 (8.0)	5 (19.2)	0.42
6 months	0 (0.0)	5 (19.2)	0.06
Any time above	11 (44.0)	15 (57.7)	0.41

Data represent numbers of eyes in each group with IOP >21 mmHg. Percentages are shown in parentheses. Groups were compared with Fisher exact test and no significant differences were found.
IOP = Intraocular pressure

each group developed corneal decompensation. In the silicone group, the patient had glaucoma following cataract extraction and subsequent anterior chamber IOL implantation that resulted in corneal decompensation. In the polypropylene group, the corneal decompensation was secondary to a severe chemical burn that eventually required a keratoprosthesis. Wound revision was performed in two patients in the silicone group and one patient in the polypropylene group. These patients had wound leakage at the limbus 1 day after the surgery. The wound was revised at the slit lamp with additional interrupted 10-0 Vicryl sutures.

The overall success rate between the two groups was as follows. In the silicone plate (FP-7) group, 24 of 25 eyes had at least 20% preoperative IOP at 12 months and IOP for all 25 eyes were >5 mmHg and <22 mmHg; therefore the success rate in the FP-7 group was 96%. All 26 eyes in the polypropylene (S-2) plate group had postoperative IOP at 12 months at least 20% of their preoperative values, although 5 eyes had IOP >21 mmHg at 12 months, indicating a success rate of 81%. There were no significant differences in the success rates between the FP-7 and S-2 groups (p=0.19, Fisher exact test).

DISCUSSION

The current study demonstrated that the silicone endplate AGV resulted in a statistically significant lower IOP compared to the polypropylene endplate AGV at 1 year after

TABLE IV - POSTOPERATIVE COMPLICATIONS

	Polypropylene	Silicone
Shallow chamber	3	6
Hyphema	3	2
Bleb leak	1	0
Choroidal effusion	3	5
Diplopia	0	1
Corneal decompensation	1	1

TABLE V - POSTOPERATIVE INTERVENTIONS

	Polypropylene	Silicone
Bleb needling	5	2
tPA injection	0	1
Viscoelastic injection	0	1
Wound revision	1	2
Cataract extraction	2	1
Keratoprosthesis	1	0

the surgery. The incidence of hypertensive phase was also lower (though not statistically significant) with the silicone endplate AGV compared to the polypropylene AGV. We have made no attempt to evaluate the blebs clinically between the two groups in terms of bleb wall thickness and permeability. However, since the only major variable between the two groups was the biomaterial of the AGV (surgeon and surgical technique being the same), these results may suggest that biomaterial may influence the inflammatory response and consequently the overall success rate of the operation. The fact that success is not seen in every case and also the persistence of the hypertensive phase even in the silicone group suggest that the biomaterial is not the only factor that influences the degree of inflammation and fibrosis.

The polypropylene group had lower mean number of medications at 12 months compared to the silicone group (0.7 vs 1.2; p=0.08), even though it was not statistically significant. This may have influenced the outcomes. The fact that more patients in the polypropylene group had needling following hypertensive phase (resulting in lower IOP and lower number of medications needed) may explain this difference in the number of medications at 12 months.

These results are similar to the results Ishida et al (10) reported recently. In a prospective, multicenter, comparative series involving 132 patients, they reported the average IOP to be 13.8±3.9 mmHg and 17.3±6.5 ($p<0.0001$) and the mean number of glaucoma medications to be 1.9±1.3 and 2.1±1.4 ($p=0.48$) in the silicone plate and polypropylene plate groups, respectively. The life table success rates for the silicone plate and polypropylene plate groups were 94.2% and 83.2% at 12 months. These results are similar to our study results (12.1±3.4 in the silicone group and 16.1±5.7 in the polypropylene group). The silicone group had a statistically lower IOP compared to the S-2 group at 6 ($p<0.05$), 9 ($p<0.01$), and 12 months ($p<0.01$) in both our study and in the study by Ishida et al.

The incidence of complications and postoperative interventions appears to be similar between the two groups in our study and comparable to those reported in previous publications. In a retrospective study comparing the silicone plate AGV with the polypropylene plate, Law et al reported a higher rate of non-tube-related complications in the silicone group (11). This was not the case in our study. Also, they did not find statistically significant difference in the IOP control between the two groups except at 3 months, even though the IOP was lower in the FP-7 group at all time points. Both our study and the Ishida et al study found the IOP difference to be statistically significant between the two groups.

Apart from the biomaterial, the size of the endplate may influence the IOP control but only up to a certain level (12). In a case-controlled, retrospective, multisurgeon study comparing the Baerveldt-350 silicone implant with the old polypropylene AGV (S-2), Syed at al concluded that there were no significant differences in the surgical success rate, hypotony, and IOP control at 1 year (13). In a retrospective review of the same two implants, Tsai et al found that the Ahmed valve group exhibited a higher prevalence and earlier onset of the hypertensive phase/bleb encapsulation, although the overall success was similar at 1 year (14). These authors speculated that the early exposure of the subconjunctival tissue to the glaucomatous aqueous following Ahmed valve implantation may account for the higher incidence of the hypertensive phase. However, they did not take into consideration the structural differences in the implants, including their biomaterial.

Although we postulate that the study results are primarily related to the change in the biomaterials, it should be noted that the FP-7 model differs from the S-2 model in other ways: the FP-7 model has fenestration holes in the plate

with a tapered posterior edge. Also, the trapezoidal box containing the two elastomers for flow resistance was still made with polypropylene material and was transferred onto the flexible silicone plate. We do not know if these differences influenced the study results. The other limitations of the study include relatively small number of patients in each group, the inherent weaknesses of a retrospective study with a possible selection bias, and the lack of true randomization involving patients with different demographics (although not statistically significant) between the two groups.

However, the use of the different AGVs based only on their availability in the hospital and the study period being restricted to 1 year before and after the conversion date minimized the selection bias. Also, this study analyzed the surgical results of a single surgeon using the same surgical technique thus avoiding the variations from different surgical techniques by different surgeons.

In conclusion, the present study suggests that the implantation of the silicone endplate AGV resulted in lower IOP compared to the polypropylene AGV at 1 year. Future research should be directed toward identifying other factors contributing to bleb inflammation following glaucoma drainage device surgery in an attempt to minimize the fibrous reaction around the bleb. Prospective, randomized patient- and investigator-masked studies are needed to confirm the results of this study.

ACKNOWLEDGEMENTS

Supported by the Tulane Glaucoma Research Fund.

Proprietary interest: None.

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