Comparison of polypropylene and silicone Ahmed® glaucoma valves in the treatment of neovascular glaucoma: A 2-year follow-up

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Abstract

Background. Inflammation associated with biomaterials of Ahmed® glaucoma drainage devices may cause the formation of a capsule around the device and can thus have a significant influence on the level of intraocular pressure reduction.

Objectives. The objective of this study was to compare the clinical outcomes after the implantation of a polypropylene or silicone Ahmed® glaucoma valve in patients with neovascular glaucoma.

Material and methods. In the study, 27 eyes with neovascular glaucoma (group 1) received silicon Ahmed® valves and 23 eyes (group 2) received polypropylene valves. The best corrected distance visual acuity (BCDVA), intraocular pressure (IOP) and number of anti-glaucomatous drugs were recorded preoperatively and during a follow-up period of 24 months after surgery. Success was defined by the following criteria: 1) intraocular pressure in the range of 6–21 mm Hg; 2) IOP reduction of at least 30% relative to preoperative values. All complications were registered.

Results. One month postoperatively, the mean BCDVA increased significantly in both groups compared to preoperative values ($p < 0.001$). These values did not change during the 24 months of follow-up examinations. The probability of success defined by criterion 1 at 24 months of observation was 66.7% for silicone and 27.3% for propylene valves group ($p < 0.007$). According to criterion 2, the difference in success between the groups was not statistically significant. The total number of complications that occurred in both groups during the 24 months of follow-up examinations was similar, except for a higher occurrence of Tenon's cyst formation in the group with a polypropylene valve (18% vs 35%; $p < 0.04$).

Conclusions. In patients with neovascular glaucoma, the implantation of a silicone valve is associated with a significantly higher probability of long-term reduction of IOP below 21 mm Hg and with a lower risk of valve encapsulation in comparison to polypropylene valves. The obtained results suggest that silicone Ahmed® valves are more effective in the treatment of patients with neovascular glaucoma.

Key words: inflammation, neovascular glaucoma, glaucoma drainage implants, biocompatible materials

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Introduction

Glaucoma drainage devices are increasingly used in the surgical glaucoma treatment. The surveys of the American Glaucoma Society indicate that a selection of aqueous shunts, as the preferred surgical approach, increased from 17.5% in 1996 to 50.8% in 2008.¹ Glaucoma drainage devices are a good treatment option in the cases involving refractory glaucoma, e.g., neovascular or uveitic glaucoma. The devices drain the aqueous humor from the anterior chamber through a tube to the posterior plate inserted under the conjunctiva and Tenon's capsule. Aqueous fluid is then removed by venous capillaries or lymphatics.² One of most frequently used devices is Ahmed® Glaucoma Valve (New World Medical Inc., Rancho Cucamonga, USA). Two types of Ahmed® glaucoma valves are available: polypropylene (S2) and silicone (FP7). In experimental studies, the different materials showed varying degrees of postoperative inflammation and pseudocapsule formation.³ Inflammation associated with biomaterials may contribute to the failure of the glaucoma treatment by drainage devices. The risk of such inflammation is high, especially in patients with neovascular glaucoma.

In the literature, there are few studies suggesting that clinical outcomes are better after the implantation of an Ahmed® glaucoma valve with a silicone plate in comparison to a polypropylene one.^{4–6} Our study was designed to compare the clinical outcome 2 years after the implantation of polypropylene or silicone Ahmed® glaucoma valves in patients with neovascular glaucoma.

Patients and methods

In the study, 50 eyes of 50 patients with diabetic neovascular glaucoma were treated by the implantation of Ahmed® valves – 27 eyes of 27 patients, with a mean of age of 61.8 ± 11.8 years, received silicone valves (model FP7 – group 1) and 23 eyes of 23 patients, mean of age 61.2 ± 13.7 years, received polypropylene valves (model S2 – group 2). Inclusion criteria were as follows: diagnosed diabetic neovascular glaucoma and elevated intraocular pressure (IOP) that was not responsive to conventional medical and surgical therapy. Exclusion criteria included patients younger than 18 years, eyes requiring combined surgery, eyes with previous cyclodestructive treatment, silicone oil treatment or previous glaucoma drainage device implantation.

Both models of Ahmed® glaucoma valves had the same plate surface area (184 mm²) and a similar design and shape. The surgery was performed by one of the 2 experienced

glaucoma surgeons (WL, LK) under Möller HI-R 900 microscope with magnification of $\times 5$. The choice of the Ahmed® glaucoma valve – polypropylene (S2) or silicone (FP7) – was done randomly for each patient. The same surgical implantation procedure was used for both implants. After regional anesthesia, a fornix-based conjunctival-subtenon flap was created in the supratemporal quadrant. The anterior edge of the plate was fixed with 9–0 nylon sutures to the sclera 8 mm from the limbus. A 2/3 thickness limbal-based scleral flap was made and the valve tube was inserted into the anterior chamber through a 23-gauge needle puncture under the flap. The scleral flap and then Tenon-conjunctiva flap were sutured using 10–0 nylon sutures. The anterior chamber was reformed with balance salt solution through paracentesis. After surgery, topical antibiotics and steroids were installed for a period of 2 months. To achieve the desired IOP reduction, anti-glaucomatous drops were added as required.

The best corrected distance visual acuity (BCDVA – Snellen chart), IOP and number of used antiglaucomatous drugs were recorded preoperatively, on postoperative days 1 and 7, and in postoperative 1, 3, 6, 12, and 24 months after surgery. Any complications were registered.

Surgical success was assessed using 2 different criteria. Criterion 1 was IOP in the range of 6–21 mmHg, with or without the use of additional antiglaucomatous drops. Criterion 2 was IOP reduction of at least 30% relative to preoperative values. Eyes requiring additional antiglaucomatous interventions (including cyclophotocoagulation) or the removal of the implant, or eyes that lost light perception were classified as failures.

The approval by the local Ethical Committee from Pomeranian Medical University in Szczecin (Poland) was

Table 1. Demographic and preoperative data for patients treated with silicone or polypropylene Ahmed® glaucoma valves

Demographic and preoperative data	Silicone plate (FP7) n = 27 (100%)	Polypropylene plate (S2) n = 23 (100%)	p-value
Age, years (mean $\pm$ SD) range	61.8 $\pm$ 11.8 38–82	61.2 $\pm$ 13.7 36–86	ns
Gender male/female	17 (62.0)/10 (38.0)	14 (60.0)/9 (40.0)	ns
Lens status phakic pseudophakic	9 (33.0) 18 (67.0)	8 (35.0) 15 (65.0)	ns
Previous surgery	23 (85.0)	20 (87.0)	ns
Number of procedures (mean $\pm$ SD) range	1.7 $\pm$ 1.2 1–3	1.8 $\pm$ 1.1 1–4	ns
Previous laser therapy	10 (38.0)	8 (35.0)	ns
Preoperative visual acuity (mean $\pm$ SD) range	0.07 $\pm$ 0.01	0.07 $\pm$ 0.01	ns
≥ 0.2	3 (11.0)	3 (13.0)	
0.1–0.15	8 (30.0)	6 (26.0)	
0.05	9 (33.0)	8 (35.0)	
CF	5 (19.0)	4 (17.0)	
HM	2 (7.0)	2 (9.0)	

CF – counting fingers; HM – hand movements; ns – nonsignificant statistically.

obtained for this prospective study, and all 50 patients signed informed consent before surgery.

Statistical analysis

Preoperative and postoperative data was compared between FP7 and S2 Ahmed® glaucoma valve groups. The Mann-Whitney U test was used to compare continuous variables between the 2 groups. The Wilcoxon signed-rank test was used to compare continuous parameters within the groups. The χ^2 test and Fisher's exact test were used for categorical variables. Success rates in both groups were compared using the Kaplan-Meier survival curves and long-rank test. The Cox proportional hazard regression model was used for the analysis of risk. The p-values < 0.05 were considered statistically significant.

Results

Both groups were comparable with respect to age, gender, lens status, previous surgery, the number of procedures, laser therapy and preoperative visual acuity. The preoperative data for the 2 groups of patients treated with silicone or polypropylene Ahmed® glaucoma valves is summarized in Table 1.

The following mean intraocular pressure values were detected in patients treated with silicone (FP7 group) and polypropylene (S2 group) plates, respectively: 48.63 ± 11.34 mm Hg and 45.59 ± 14.14 mm Hg preoperatively ($p = 0.72$); 11.2 ± 6.45 mm Hg and 12.8 ± 5.9 mm Hg at day 1 ($p = 0.65$); 15.4 ± 9.1 mm Hg and 16.6 ± 5.6 mm Hg at 3 months ($p = 0.064$); 14.2 ± 4.6 mm Hg and 15.3 ± 5.1 mm Hg at 6 months ($p = 0.068$); 13.6 ± 3.3 mm Hg and 15.3 ± 3.5 mm Hg at 12 months ($p = 0.062$); and 13.8 ± 3.3 mm Hg and 15.7 ± 4.2 mm Hg at 24 months ($p = 0.061$). The data is presented in Fig. 1.

The mean preoperative IOPs did not differ significantly between polypropylene and silicone valves ($p = 0.72$). The mean IOP in silicone valve group (FP7) was lower at 3, 6 and 12 months after surgery in comparison to propylene group (S2), but this difference was not statistically significant ($p = 0.06$). In both groups, on postoperative day 1 initial reduction of IOP was obtained. Then, the mean IOP gradually increased to a peak at 1 month, and then decreased and stabilized between 6 and 24 months in both groups.

The mean number of antiglaucomatous drops which were necessary to normalize IOP in both groups at all follow-up visits is shown in Fig. 2. The average drop number of medication was reduced from 3.74 ± 0.52 and 3.32 ± 0.59 before

Table 2. Preoperative status and postoperative outcome at 24 months, a postoperative follow-up visit in patients treated with silicone or polypropylene Ahmed® valves

Preoperative status and postoperative outcome	Silicone plate (FP7) n (%)	Polypropylene plate (S2) n (%)	p-value
IOP, mm Hg (mean $\pm$ SD)			
preoperative	48.63 ± 11.34	45.59 ± 14.14	0.72
postoperative	13.81 ± 3.3	14.72 ± 4.2	0.07
Glaucoma medications (mean $\pm$ SD)			
preoperative	3.74 ± 0.52	3.32 ± 0.59	0.61
postoperative	0.92 ± 1.3	1.27 ± 1.3	0.18
Postoperative visual acuity (mean $\pm$ SD)	0.14 ± 0.07	0.12 ± 0.06	0.34
Surgical outcome by criterion 1 (IOP 6–21 mm Hg)			
success	26 (96.0)	19 (82.0)	0.007
failure	1 (4.0)	4 (17.0)	
Surgical outcome by criterion 2 ($\downarrow$ IOP > 30%)			
success	26 (96.0)	20 (86.0)	0.06
failure	1 (4.0)	3 (13.0)	

Table 3. Postoperative complications after the implantation of silicone or polypropylene Ahmed® glaucoma valves

Postoperative complications	Silicone plate (FP7) n = 27 (100%)	Polypropylene plate (S2) n = 23 (100%)	p-value
Number of eyes with complications	12 (44.0)	16 (69.0)	0.061
Choroidal effusion	1 (3.7)	2 (8.7)	0.923
Hypotony			
early (within 3 months)	1 (3.7)	1 (4.3)	1.000
late (after 3 months)	0	0	1.000
Shallow chamber	0	1 (4.3)	0.641
Tube obstruction	1 (3.7)	1 (4.3)	1.000
Corneal edema	0	1 (4.3)	0.641
HypHEMA	5 (18.0)	7 (30.4)	0.063
Tenon's cyst	5 (18.0)	8 (34.7)	0.042

surgery to 0.92 ± 1.3 and 1.27 ± 1.3 at 2 years after treatment in patients with silicone and polypropylene plates, respectively. There were no statistically significant differences in the mean number of antiglaucomatous medications at all time points between the groups. However, a tendency for greater reduction of the mean of antiglaucomatous medications was detected with the implantation of a silicone valve (FP7) during 2 years of observation time (Fig. 2).

At 24 months, significant reduction of IOP was achieved in both silicone (FP7) and polypropylene (S2) group, although there were no significant differences between the groups (Table 2). Significant and similar reduction of the mean number of antiglaucomatous medication drops was obtained in both groups (Table 2). The number of patients who had a hypertensive phase within 3 months postoperatively was 8 (29%) in silicone group (FP7) and 14 (60%) in polypropylene group (S2) ($p < 0.006$) (Table 2).

A slight, similar improvement of the mean BCDVA was achieved in both groups 2 years after the surgery (FP7 – from 0.07 to 0.14; S2 – from 0.07 to 0.12; $p < 0.34$).

BCDVA was stable in most patients in both groups. Worsening of visual acuity (VA) of more than 2 lines of Snellen chart was observed in 5 patients (18%) in FP7 group and in 4 patients (17%) in S2 group ($p < 0.69$). No patient lost light perception.

In FP7 and S2 plate groups, the success rates were 96% (26 out of 27 eyes) and 82% (19 out of 23 eyes) as defined by criterion 1 ($p = 0.007$), and 96% (26 out of 27 eyes) and 86% (20 out of 23 eyes) as defined by criterion 2 ($p = 0.06$), respectively (Table 2).

The Kaplan-Meier analysis demonstrated a difference in the probability of success as defined by criterion 1 in adequate IOP control between FP7 and S2 groups (Fig. 3). The probability of success at 24 months of observation was 66.7% for silicone and 27.3% for polypropylene valve groups. The difference between the Kaplan-Meier survival curves was statistically significant (log-rank test = -2.7 ; $p = 0.007$). The use of a silicone valve presented a significantly lower risk of failure in terms of achieving adequate IOP and increased the chance for achieving adequate IOP in postoperative time by 35% (hazard ratio = 0.35).

Postoperative complications after the implantation of silicone or polypropylene Ahmed® glaucoma valves are presented in Table 3. The occurrence of valve encapsulation with the formation of Tenon's cyst was the only statistically significant difference in the number of complications between the 2 valve groups. The number of encapsulation and Tenon's cyst formation cases was lower in silicone valve group (18.0% vs 34.7%). The complication was successfully managed by surgically releasing the adhesions around the valve. The device tube obstruction that occurred in 2 cases (1 in each studied group) was managed surgically by flushing the device with balanced salt solution (BSS). No other surgical eye procedures were performed in the patients during the follow-up period.

Discussion

Neovascular glaucoma, a type of secondary glaucoma, is caused by retinal hypoxia, which results in the release of a vascular endothelial growth factor (VEGF) into the vitreous and anterior chamber. The subsequent growth of a fibrovascular membrane covering the trabecular meshwork and sometimes peripheral anterior synechiae causes an increase of IOP through secondary open-angle or secondary closed-angle mechanisms.⁷ Adequate treatment should be primarily directed toward treating retinal ischemia by the use of pan-photocoagulation, cryotherapy and/or anti-VEGF agents. Surgical lowering of IOP is, however, essential in most cases.⁸

Conventional trabeculectomy for the treatment of neovascular glaucoma is often complicated by intraoperative intraocular bleeding and the postoperative progression of the fibrovascular membrane, leading to a limited rate of success.^{9,10}

Fig. 1. Graph demonstrating the mean intraocular pressures (IOPs) before and after the implantation of silicone or polypropylene Ahmed® glaucoma valves

D – day; M – month(s); Pre – before surgery; W – week.

Fig. 2. The mean number of glaucoma medication drops after the implantation of silicone or polypropylene Ahmed® glaucoma valves

D – day; M – month(s); Pre – before surgery; W – week.

Fig. 3. The Kaplan-Meier survival curves show the probability of success as defined by criterion for silicone (FP7) and polypropylene (S2) valves

Probability of success at 24 months of observation was 66.7% and 27.3% for silicone and polypropylene valve group, respectively. The difference between the survival curves was statistically significant ($p = 0.007$).

Aqueous drainage implants may have higher success rates, but the results may vary not only due to different implant designs but also the valve material.^{11,12}

In the present study, differences in clinical outcomes in treating neovascular refractory glaucoma using 2 types of Ahmed® glaucoma valves with similar dimensions but different materials were found.

The mean IOP did not differ significantly between polypropylene and silicone valve groups at any of the study milestone points (i.e., preoperatively, at day 1, and 1, 3, 6, 12, 24 months after surgery). However, the mean IOP in a group of patients could not be considered as a good statistical indicator of proper IOP control in an individual patient. Thus, the success of the implantation surgery was defined by the 2 criteria described above. Criterion 1 (IOP in the range of 6–21 mm Hg, with or without the use of additional antiglaucomatous drops) was met in 96.0% of patients with a silicone valve vs 82% of patients with a polypropylene valve ($p = 0.007$). Criterion 2 (IOP reduction of at least 30% relative to preoperative values) was met in 96% of patients with a silicone valve and 86% of patients with a polypropylene valve ($p = 0.06$). Thus, statistically, patients with neovascular glaucoma have a slightly better chance of achieving an acceptable level of IOP when silicone valves are used.

The results are consistent with the results of the study performed by Ishida et al., which showed an even bigger difference between silicone and propylene valves in achieving the same defined criteria of success: 82.4% vs 56.7% for criterion 1 and 78.3% vs 68.5% for criterion 2.⁴

The study, however, included a more heterogeneous group of refractory glaucoma patients, including patients with significant conjunctival scarring or inflammation. Also, the study of Mackenzie et al. showed greater success in achieving >30% IOP reduction at 2-year follow-up in patients with silicone valves: 82% vs 72%.⁵ Both studies included quite a heterogeneous group of patients. Our study is, to our knowledge, the first study comparing 2 different valve materials in patients suffering only from diabetic neovascular glaucoma. We did not include any other type of refractory glaucoma patients to have a more homogenous group of patients.

The lower occurrence of valve encapsulation with the formation of Tenon's cyst in silicone valve group was the only statistically significant difference in the complication number between the 2 valve groups. We believe that this is the reason of the higher success rates in the silicone valve group.

Secondary scar formation around the valve is considered to be the most important reason for glaucoma surgery failure.¹³ Ayyala et al. in an animal experimental study showed that polypropylene is more inflammatory than silicone.¹⁴

In addition to valve material, other factors may influence the success rate after implant glaucoma surgery. Greater surface of the end-plate of the valve may be associated

with lower IOP, still with the upper limit of the surface area beyond which the valve implantation will stimulate a greater inflammatory response.^{15–17} Some studies, however, do not show such an association.^{18,19} The valve construction also may contribute to the final results. Some studies indicate that Ahmed® valves have a higher rate of encapsulation when compared to double-plate Molteno or Baerveldt implants.²⁰ However, Ahmed® valves were shown to be associated with fewer early postoperative complications, especially those related to hypotony.²¹ Patients with Ahmed® implants are also at a lower risk of vision loss or the need of secondary glaucoma surgery.²² In our study, none of the patients experienced vision loss.

To conclude, our results provide clinical evidence that different materials may influence the visual outcome after Ahmed® valve implantation in neovascular glaucoma patients, most likely because of the differences in biocompatibility of the materials.

The obtained results confirm the effectiveness of the valve mechanism in both devices, though the use of a silicone valve in patients with neovascular glaucoma increases the chance for achieving adequate IOP in postoperative time by 35%.

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