

CLINICAL SCIENCE

Clinical experience of e-PTFE membrane implant surgery for refractory glaucoma

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Aims: To evaluate the clinical efficacy of membrane tube implant made of expanded polytetrafluoroethylene (e-PTFE, Gore-Tex) membrane and silicone tube in treating refractory glaucoma.

Methods: A retrospective chart review was performed on 43 eyes of 40 patients who underwent glaucoma tube shunt implant surgery using double layered e-PTFE membrane and silicone tube to treat refractory glaucoma. The surgeries were performed from May 1991 to September 1995, and the subjects were patients with terminal glaucoma without useful vision on the study eye.

Results: The mean follow up period was 32.9 months. The Kaplan-Meier survival for intraocular pressure (IOP) control (IOP between 6 and 21 mm Hg without significant complication) was 80.9% at 1 year, 73.9% at 2 years, and 62.2% at 3 years after surgery. After excluding three eyes of three patients who were dropped within 3 months after surgery and did not have any serious complication or problem in IOP control, the average preoperative IOP was 42.5 (SD 14.6) mm Hg and IOP on the last visit was 17.3 (10.2) mm Hg ($p = 0.000$, $n = 40$). The number of antiglaucoma medications before surgery (2.2 (0.6)) was reduced to 0.5 (0.8) on the last visit ($p = 0.000$). The IOP was controlled within the range of 6–21 mm Hg in 26 eyes (65.0%). In the remaining 14 eyes (35%), we could not control the IOP or additional surgery was needed to control the IOP or to treat severe complications. Two cases of endophthalmitis and three of phthisis were found as serious complications. The other complications were similar to those of other commercially available glaucoma implants.

Conclusion: A comparable clinical result was obtained with this new implant as with the other commercially available implants. This implant with a thin and non-rigid reservoir has a potential to reduce some complications associated with the large volume and rigid consistency of the other implants, although it is not yet proved. This membrane tube implant may be considered as another substitute in the surgery of refractory glaucoma.

The most common causes for failure after filtration surgery are the blockage of fistula by fibrous tissue ingrowth, adhesion of scleral flap to scleral bed, and fibrous breakdown of conjunctival filtering bleb with resultant failure to maintain the function of the filtering bleb. There have been many trials to halt this process such as providing mechanical barriers and applying antiproliferative agents, etc. As a method of establishing a mechanical barrier to halt the blockage of the fistula by fibrous tissue, various kinds of materials and designs have been developed and applied. Nowadays, use of a semirigid tube as a conduit for aqueous from the anterior chamber has been proved to be safe and effective.^{1,2} A reservoir portion is needed to facilitate aqueous outflow and prevent blockage of distal end of the tube. There are various types of materials and designs of the reservoir portion, but all of them have been made of rigid material with large volume. We thus need to make a large incision through the conjunctiva and Tenon's tissue to insert the implant. There are many complications associated with the large volume and rigid consistency of these implants, such as wide area of scar tissue, erosion and exposure of the implant, and limitation of extraocular muscle function, etc.^{3–6} To reduce these problems, we developed a new implant with the same concept of the previous implants but with a different material, a soft and freely malleable membrane, expanded poly(tetrafluoroethylene) (e-PTFE) as a reservoir portion. Since we had successful results in an experimental animal study with this membrane,^{7,8} we performed a clinical study with this new glaucoma implant for the refractory glaucoma.

MATERIALS AND METHODS

Making a membrane tube implant with e-PTFE membrane and silicone tube

As a conduit for aqueous to egress from the anterior chamber, we used a conventional semirigid silicone tube with an external diameter of 0.64 mm and an internal diameter of 0.3 mm. For the reservoir, we cut the expanded poly(tetrafluoroethylene) membrane (e-PTFE, Gore-Tex, Japan Gore-Tex Inc, Tokyo, Japan) to the size of 16 × 12 mm. Then the acute angled margins were trimmed to near oval shape of the reservoir membrane with a surface area of about 160 mm². Between the two layers of this membrane, the silicone tube was placed and fixed with silicone adhesive (Silastic, Dow Corning Corporation, Midland, USA) to the reservoir. The margins of the two membranes were sealed with the silicone adhesive to protect the ingrowth of tissue into the space between the membranes. A thread of 5–0 nylon suture was inserted through the lumen of silicone tube to reduce the lumen and to aid closing the tube with extraluminal temporary occlusion suture for prevention of early postoperative hypotony. We used the e-PTFE membrane with 0.1 mm thickness, so the height of the reservoir portion is 0.84 mm in the small central area involving silicone tube and 0.2 mm in the remaining area (Fig 1).

Subjects and procedure of operation

After we received signed consent from the patients, approved by the clinical research institute of Chungnam National University, we performed membrane tube implant surgery on the 43 eyes of 40 patients who had been treated in our clinic for refractory glaucoma from May 1991 to September 1995. The inclusion criteria were neovascular glaucoma, other refractory

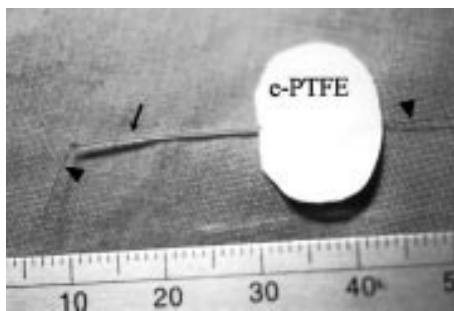


Figure 1 Membrane tube implant made of silicone tube and e-PTFE membrane. Arrow: silicone tube, one end fixed between two layers of e-PTFE membrane. Arrowheads: 5-0 nylon intraluminal suture passing through the silicone tube and between the e-PTFE membranes. e-PTFE = expanded poly(tetrafluoroethylene) membrane reservoir.

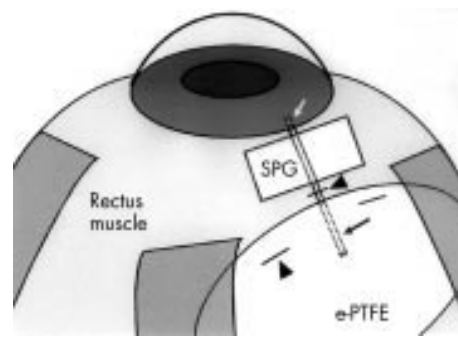


Figure 2 Scheme of the membrane tube implant surgery. Arrows: silicone tube connecting from the anterior chamber to the membrane reservoir. Arrowheads: anchoring sutures for silicone tube and e-PTFE membrane onto sclera with 10-0 nylon. SPG = donor scleral patch graft, e-PTFE = expanded poly(tetrafluoroethylene) membrane reservoir.

glaucomas with high intraocular pressure that was not controlled by medication after more than one incisional intraocular surgery, and glaucomas with extensive conjunctival scar or keratoconjunctival disease. The subjects were limited to patients who had poor visual acuity (less than 20/200) in the study eye, or eyes that had no useful vision (far worse visual acuity compared to the other eye), as we had not proved long term clinical safety for this implant.

The patients were admitted 1 day before the operation and underwent a thorough clinical examination; and they were told to discontinue all pressure lowering medications on admission. The operation was performed under the local retrobulbar anaesthesia with 2% lignocaine (lidocaine) the next day. A limbus based conjunctival flap of about 8 mm was made at 6 mm posterior to the limbus. The superior and lateral recti muscles were isolated through this incision. Although we inserted the implant in the upper temporal quadrant if possible, the medial rectus was isolated when we had to insert it in the upper nasal quadrant. In 13 eyes of 13 patients in whom the operator expected poor pressure control (those who had extensive conjunctival scar by trauma or previous surgery), mitomycin C soaking (0.4 mg/ml solution for 3 to 5 minutes) followed by copious irrigation with balanced salt solution was applied. The membranous reservoir was inserted in folded form through the conjunctival opening, and then unfolded underneath the Tenon's capsule with its both ends to be located under the two recti muscles. The anterior margin of the membrane was fixed onto the sclera at 10 mm posterior to the limbus with 10-0 nylon on both sides. We estimated the appropriate length of the silicone tube, 1.5 mm of tube to be set within the anterior chamber, and then cut the tube with an oblique angle. After paracentesis with a 23 gauge needle at the limbus, the silicone tube was inserted through the needle tract in the bevelled side up position. Then the tube was fixed on the sclera by two anchoring sutures with 10-0 nylon (Fig 2). To prevent the early postoperative overfiltration, we occluded the tube on the outside with a 9-0 nylon releasable suture with the 5-0 nylon intraluminal suture located within the tube. Both releasable and intraluminal sutures were exposed partially through the conjunctiva to be pulled out after postoperative day 3. The criteria for the removal were as follows; if intraocular pressure went over 40 mm Hg within 1 week after surgery, over 30 mm Hg between 1 and 2 weeks after surgery, or over 20 mm Hg after 2 weeks. All temporary occlusion sutures were removed if they remained at the postoperative week 4. The anterior portion of the silicone tube over the limbus was covered by a donor scleral patch graft, size 4 × 5 mm, and it was sutured with 10-0 nylon onto the sclera. The incisions of conjunctiva and Tenon's capsule were closed with separate 10-0 nylon sutures. The operation was finished with gentamicin (80 mg/ml, 0.5 ml) and betamethasone (4 mg/ml,

0.5 ml) injections in the inferior subconjunctival space. In patients with severe conjunctival scar, subconjunctival injection of triamcinolone (40 mg/ml, 0.3 ml) on the posterior conjunctiva in superior quadrants was applied.

Analysing the results

We reviewed the medical records of the subjects retrospectively and collected preoperative data about the age at surgery, sex, diagnosis, visual acuity, number of previous operations, number of antiglaucoma medications and preoperative intraocular pressure. The data after surgery were also collected; intraocular pressure, number of medications, visual acuity, and complications if present at postoperative 1 week, 2 weeks, 1 month, 2 months, 4 months, 6 months, 1 year and each year thereafter. We performed standardised echographic examinations (A and B-scan by Ophthascan S, Biophysic Medical, France) over the explant after surgery in patients who agreed to undergo sonographic evaluation.

We classified the case as a success when the patient's intraocular pressure was controlled between 6 and 21 mm Hg without or with one or two antiglaucoma medications. Cases in which intraocular pressure was not controlled within the range of 6–21 mm Hg, or cases that needed additional surgery to control intraocular pressure or to treat the complication, if any, were classified as "failures." Intraocular pressure during the first month was not assessed in classifying the result, because there might be a large variation of IOP during this period. Kaplan-Meier survival analysis was done for all 43 study eyes.

Five eyes were not followed for more than 3 months. Two of them had additional procedures done to control severe complications after surgery and they were classified as a failure. The other three eyes did not show any significant complications or serious problems in intraocular pressure control until the last follow up. Because the clinical data such as visual acuity, intraocular pressure, and number of antiglaucoma medications might vary greatly during the first 3 months, we excluded the clinical data of these three eyes in analysing the result. Therefore, the final number was 40 eyes of 37 patients in assessing the result (except for the Kaplan-Meier survival analysis (n = 43)).

We used the SPSS program (Ver 10.0, SPSS Inc, Chicago, IL, USA) for the statistical analysis. In evaluating the numerical values such as change of intraocular pressure and number of antiglaucoma medications, we used the non-parametric test (Wilcoxon paired *t* test). Pearson's correlation analysis was performed for estimating the relation between filtering bleb height (measured by A-scan echography) and the intraocular pressure. Kaplan-Meier survival analysis was performed for the successive intraocular pressure control. All subjects were

Table 1 Characteristics of the subjects

| | | |
|-------------------------------|----------------------------------|---------------------|
| Sex | Male 24 (26 eyes) | Female 16 (17 eyes) |
| Age (years) | 24–78 (average 50, median 50) | |
| Follow up (months) | 1–83 (average 33, median 30) | |
| Preoperative diagnosis (eyes) | Neovascular glaucoma | 21 |
| | Failed previous filtration | 9 |
| | Secondary glaucoma* | 7 |
| | Aphakic or pseudophakic glaucoma | 6 |

*Includes secondary glaucomas came from trauma, epithelial downgrowth after cataract surgery, Sturge-Weber syndrome, marginal degeneration of cornea, and a case of elevated intraocular pressure after scleral buckling procedure for retinal detachment.

grouped by sex, success and failure, visual outcome, and preoperative diagnosis, then the non-parametric test was applied for the analysis of the difference among the groups. The Mann-Whitney test was used for comparison between the two groups and Kruskal-Wallis test was used for comparison among three or more groups.

RESULTS

After excluding three eyes from three patients that were lost from follow up within the first 3 months, the number was 40 eyes of 37 patients, including 24 eyes of 22 male patients and 16 eyes of 15 female patients. The ages of patients varied from 24 to 78 years and the average was 50. The most prevalent preoperative diagnosis was neovascular glaucoma (19 eyes) and it was followed by failed previous filtration surgery (eight eyes), secondary glaucoma from trauma or other diseases (seven eyes), and aphakic/pseudophakic glaucoma (six eyes). The secondary glaucoma group consisted of secondary glaucomas resulting from trauma in two eyes, a case of epithelial downgrowth after cataract surgery, a patient with Sturge-Weber syndrome, two cases of marginal degeneration of cornea, and a case of elevated intraocular pressure after scleral buckling procedure for retinal detachment (Table 1).

The average preoperative intraocular pressure was 42.5 (SD 14.6) mm Hg and the average number of antiglaucoma medications was 2.2 (0.6). The follow up period in this study was from 1 month (a case whose follow up was stopped because of a second operation to treat hypotony and choroidal detachment, classified as a failure) to 83 months, the average follow up was 32.9 months, and median was 30.0 months. The temporary occluding sutures (extraluminal and intraluminal sutures) were removed at 17.9 (9.5) days after surgery. The intraocular pressure at the last follow up visit was 17.3 (10.2) mm Hg (significantly lower than preoperative intraocular

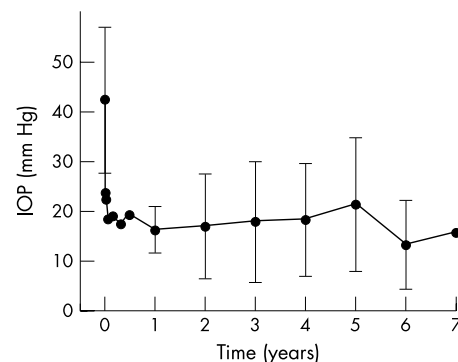


Figure 3 The change of intraocular pressure (IOP) before and after membrane tube implant surgery. The number of study eyes at each time interval were as follows; 40 at 1 week, 38 at 1 month, 33 at 6 months, 28 at 1 year, 22 at 2 years, 18 at 3 years, 17 at 4 years, 11 at 5 years, 6 at 6 years, and 1 at 7 years.

pressure, Wilcoxon paired *t* test, $p = 0.000$), and the number of antiglaucoma medications was 0.5 (0.8) ($p = 0.000$) on average. Among 40 patients, 26 eyes (65%) were under good pressure control at the last follow up visit, whereas 14 eyes (35%) were out of control during the study periods. The course of intraocular pressure change and change in the number of the antiglaucoma medications at each time interval are shown in Table 2 and Figure 3. The postoperative intraocular pressures and numbers of medications at all time intervals were significantly different from the preoperative ones (Wilcoxon paired *t* test, $p < 0.05$, Table 2).

The Kaplan-Meier survival analysis for all 43 eyes (26 eyes of 24 males and 17 eyes of 16 female patients) showed the survival rate of 90.3% at 3 months, 87.4% at 6 months, 80.9%

Table 2 Change in intraocular pressure (IOP) and number of medications

| Time | IOP (mm Hg) | | No of medications | | No of eyes |
|---------------|-------------|------|-------------------|-----|------------|
| | Mean | SD | Mean | SD | |
| Preoperative | 42.5 | 14.6 | 2.2 | 0.6 | 40 |
| Postoperative | | | | | |
| 1 week* | 23.8 | 16.7 | 0.8 | 0.9 | 40 |
| 2 weeks* | 22.5 | 18.4 | 0.7 | 0.9 | 40 |
| 1 month* | 18.5 | 12.1 | 0.3 | 0.6 | 38 |
| 2 months* | 19.1 | 11.1 | 0.4 | 0.6 | 37 |
| 4 months* | 17.5 | 10.1 | 0.5 | 0.7 | 35 |
| 6 months* | 19.5 | 12.7 | 0.4 | 0.7 | 33 |
| 1 year* | 16.4 | 4.7 | 0.4 | 0.6 | 28 |
| 2 years* | 17.1 | 10.6 | 0.5 | 0.7 | 22 |
| 3 years* | 18.0 | 12.2 | 0.6 | 0.7 | 18 |
| 4 years* | 18.5 | 11.3 | 0.6 | 0.7 | 17 |
| 5 years* | 21.5 | 13.3 | 0.7 | 0.8 | 11 |
| 6 years* | 13.5 | 8.9 | 0.7 | 1.0 | 6 |
| 7 years | 16 | – | 2 | – | 1 |

*Postoperative intraocular pressure and number of antiglaucoma medications were significantly decreased compared to the preoperative values (Wilcoxon paired *t* test, $p < 0.05$).

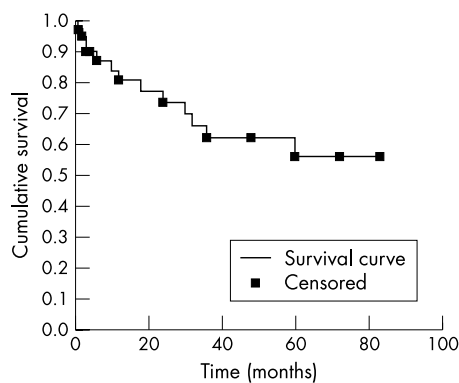


Figure 4 The Kaplan-Meier survival curve for the intraocular pressure control (between 6 and 21 mm Hg).

at 1 year, 73.9% at 2 years, 62.2% at 3 years, and 56.0% at 5 years postoperatively (Fig 4).

Because we selected subjects with poor vision, the preoperative visual acuity was worse than 20/200 in 34 eyes (85%), and the best visual acuity among the remaining six eyes was 20/70. Visual acuity in logMAR was 1.78 (equivalent to 20/1211 in Snellen acuity) (SD 0.87) preoperatively, and the acuity at the last visit was 1.95 (20/1801 in Snellen acuity) (0.91). While 12 eyes (30%) showed deterioration of visual acuity of more than 2 Snellen lines, 28 eyes (70%) showed no decrease in visual acuity. We tried to find the factors that might affect the visual acuity change, and we found the number of previous intraocular surgeries affected visual outcome; the more surgery the worse visual acuity ($p = 0.045$). But the other clinical variables such as age, sex, preoperative intraocular pressure, the number of preoperative

antiglaucoma medications, use of mitomycin C soaking, intraocular pressure at the last visit, and the number of antiglaucoma medications at the last visit showed no effect on the visual acuity outcome ($p > 0.05$, Table 3).

Twenty six eyes (65%) were classified as a success because of satisfactory pressure control. The age of the successful group was 52.2 years; intraocular pressure was 38.3 mm Hg; and the number of antiglaucoma drugs was 2.2 on average before surgery. The mean follow up period was 37.2 months. The intraocular pressure average was 14.6 mm Hg, and the average number of antiglaucoma medications was 0.4 at the last visit. Fourteen eyes (35%) were classified as failure; the patients' age was 45.5 years; intraocular pressure was 50.4 mm Hg; and the number of antiglaucoma medications was 2.1 on average before surgery. The mean follow up period in this group was 24.1 months; the intraocular pressure was 22.4 mm Hg; and the number of medications was 0.7 on average at the last visit (Table 4).

There was no difference between male and female groups in terms of age, preoperative intraocular pressure, the number of antiglaucoma medications, the number of previous surgery, and percentage of cases with mitomycin C soaking ($p > 0.05$). But the female group showed a better result in controlling intraocular pressure after membrane tube implant surgery ($p = 0.016$). In the male group, success and failure were 12 eyes each. But in the female group, there were 14 successes compared to only two failures. With this result, we might say that the sex of the subject affected the course of the intraocular pressure; female patients might be expected to show favourable pressure control than male patients.

The preoperative intraocular pressure was 38.3 (14.9) mm Hg in the successful group, and 50.4 (10.5) mm Hg in the failure group. There were significant differences in preoperative intraocular pressure among the groups ($p = 0.013$).

Table 3 Characteristics of the treated eyes: related to the visual outcome, comparing the visual acuity before surgery and at the last visit

| Visual acuity change | Improved /no change | Worsened* | All eyes |
|--------------------------------|---------------------|-------------|-------------|
| Age (years) (SD) | 49 (14) | 51 (14) | 50 (14) |
| Sex (male/female) | 17/11 | 7/5 | 24/16 |
| IOP (mm Hg) | | | |
| Preoperative | 41.9 (16.3) | 44.0 (10.4) | 42.5 (14.6) |
| At last visit | 18.2 (10.9) | 15.3 (8.5) | 17.3 (10.2) |
| No of antiglaucoma medications | | | |
| Preoperative | 2.1 (0.7) | 2.3 (0.5) | 2.2 (0.6) |
| At last visit | 0.6 (0.8) | 0.3 (0.7) | 0.5 (0.8) |
| No of previous surgery† | 0.9 (1.3) | 2.3 (2.1) | 1.3 (1.6) |
| Mitomycin C (used/not used) | 8/20 | 5/7 | 13/27 |
| Number of subjects (%) | 28 (70) | 12 (30) | 40 (100) |

*Worsened visual acuity by more than 2 snellen lines.

†Statistically different between two groups (Mann-Whitney test, $p=0.045$).

Table 4 Characteristics of the treated eyes: related to the surgical success

| Group | Success | Failure | Total |
|-----------------------------------|---------------------|---------------------|---------------------|
| Age (years) (SD) | 52 (14) | 45 (13) | 49 (14) |
| Sex* (male/female) | 12/14 | 12/2 | 24/16 |
| No of previous surgery | 1.5 (1.9) | 0.9 (1.0) | 1.3 (1.6) |
| Intraocular pressure (mm Hg) | | | |
| Preoperative* (SD, range) | 38.3 (14.9) (15–68) | 50.4 (10.5) (34–65) | 42.5 (14.6) (15–68) |
| At last visit (SD, range) | 14.6 (4.1) (8–21) | 22.4 (15.5) (1–48) | 17.3 (10.2) (1–48) |
| No of antiglaucoma medication | | | |
| Preoperative (SD, range) | 2.2 (0.7) (1–3) | 2.1 (0.5) (1–3) | 2.2 (0.6) (1–3) |
| At last visit (SD, range) | 0.4 (0.6) (0–2) | 0.7 (1.0) (0–3) | 0.5 (0.8) (0–3) |
| Mitomycin soaking (used/not used) | 11/15 | 2/12 | 13/27 |
| Number of subjects (%) | 26 (65) | 14 (35) | 40 (100) |

*Statistically different between two groups (Mann-Whitney test, $p < 0.05$).

Table 5 Characteristics of treated eyes: related to the preoperative diagnosis

| Group | NVG* | Failed filter | Secondary glaucoma | Aphakic/pseudophakic glaucoma | Total |
|---|-------------|---------------|--------------------|-------------------------------|-------------|
| Age (average, year) | 56.1 | 46.1 | 37.0 | 49.8 | 49.8 |
| No of previous surgery (average) | 0.3 | 3.6 | 0.9 | 2.0 | 1.3 |
| Intraocular pressure (mm Hg), mean (SD) | | | | | |
| Preoperative | 49.3 (13.5) | 35.6 (14.5) | 41.7 (12.3) | 31.3 (11.9) | 42.5 (14.6) |
| At last visit | 19.3 (13.2) | 15.3 (5.8) | 15.1 (9.1) | 16.5 (4.2) | 17.3 (10.2) |
| No of antiglaucoma medications, mean (SD) | | | | | |
| Preoperative | 2.4 (0.6) | 2.3 (0.5) | 1.7 (0.5) | 2.0 (0.6) | 2.2 (0.6) |
| At last visit | 0.5 (0.7) | 0.5 (0.8) | 0.3 (0.5) | 1.0 (1.3) | 0.5 (0.8) |
| Result, eyes (%) | | | | | |
| Success | 12 (63.2) | 6 (75.0) | 3 (42.9) | 5 (83.3) | 26 (65.0) |
| Failure | 7 (36.8) | 2 (25.0) | 4 (57.1) | 1 (16.7) | 14 (35.0) |
| No of subjects | 19 | 8 | 7 | 6 | 40 |

*Neovascular glaucoma.

In assessing the effect of the application of mitomycin C on the result, there were no differences in age, sex, preoperative intraocular pressure, number of antiglaucoma medications, and the number of previous surgery between the two groups that had and had not undergone mitomycin C soaking. The success was 11 out of 13 in the group that had mitomycin C soaking, and 15 out of 27 in the group that had not had mitomycin C soaking. Although the success rate was better in the mitomycin C group, there was no significant difference between the two groups ($p = 0.075$). The age, preoperative number of antiglaucoma medications, number of previous surgery, and follow up period did not affect the result ($p > 0.05$, Table 4).

We divided the patients into four groups according to the diagnosis to find if there were any differences in preoperative parameters or result of the surgery in terms of pressure control: neovascular glaucoma group, failed filter group, secondary glaucoma group, and aphakic/pseudophakic glaucoma group. The aphakic/pseudophakic glaucoma group showed the most favourable outcome, a 83.3% success. They

were followed by the failed filtration group (75.0% success) and neovascular glaucoma group (63.2% success). The secondary glaucoma group showed the worst success rate, 42.9%. But statistical assessment was not possible because of the small numbers of subjects in each groups (Table 5).

We performed standardised echographic examinations over the explant for 23 eyes of 23 patients who agreed to undergo ultrasound evaluation after surgery. The time of examination was 17 (9) months (range 6–33 months) after surgery. In 21 eyes (91.3%) we noticed a filtering bleb around the explant; the other two eyes had no fluid space around the explant. The maximum height of filtering blebs, measured from the outer margin of scleral echo to the inner surface of the filtering bleb over the explant, was 2.4 (1.3) mm (range 1.1–5.5 mm, median 2.7 mm) measured by A-scan echography in 21 eyes with filtering bleb. Typical examples of the filtering blebs by transverse scan are shown in Figure 5. The shape of the filtering bleb varied from no filtering space (Fig 5A) to a large filtering bleb with scleral flattening (Fig 5D). In most cases, we could identify the echo of the silicone tube (Fig 5C), but we did not notice the echo

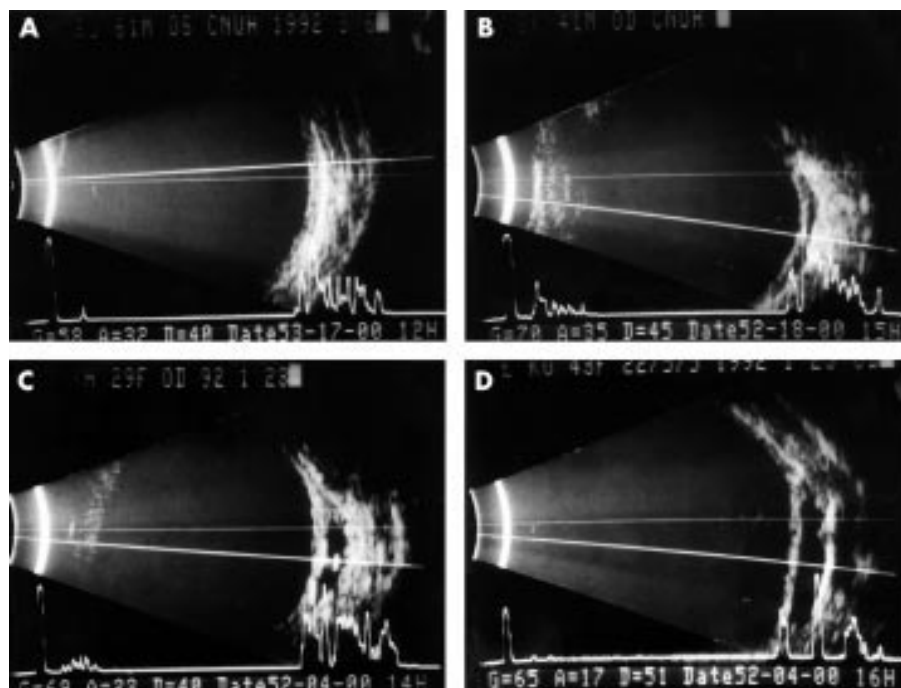


Figure 5 The examples of filtering blebs around the membrane-tube implant, transverse view by standardised echography (Ophthascan S, Biophysic Medical, France); (A) no visible filtering space, (B) a narrow fluid space, (C) moderate height filtering bleb with central echo relevant to the silicone tube, (D) a large filtering bleb with scleral flattening. No echo associated with the thin e-PTFE membrane was noticed.

Table 6 Complications after membrane tube implant surgery

| Complications | Number | Frequency (%) |
|-------------------------|--------|---------------|
| Transient hyphaema | 9 | 22.5 |
| Hypotony | 5 | 12.5 |
| Transient flat chamber | 3 | 7.5 |
| Choroidal detachment | 1 | 2.5 |
| Obstruction of the tube | 3 | 7.5 |
| Fibrinous iridocyclitis | 3 | 7.5 |
| Tube-corneal touch | 2 | 5.0 |
| Corneal graft failure* | 1 | 2.5 |
| Focal cataract | 2 | 5.0 |
| Retinal haemorrhage | 2 | 5.0 |
| Vitreous haemorrhage | 1 | 2.5 |
| Exposed implant | 2 | 5.0 |
| Endophthalmitis | 2 | 5.0 |
| Phthisis | 3 | 7.5 |
| Total subjects | 40 | 100 |

*One corneal graft failure developed from two corneal grafts.

relevant to the thin e-PTFE membrane reservoir. We tried to find any correlation between bleb height and the intraocular pressure, but we found no statistical correlation between bleb height and the intraocular pressures both at the time of echography ($p = 0.378$) and at the final visit ($p = 0.703$).

The complications of the surgery were found in 22 eyes (55%). The most frequent one was transient hyphaema, found in nine eyes (22.5%), but it resolved spontaneously without treatment within a few days in all cases. Hypotony lasting more than 1 week was found in five eyes (12.5%); three of them showed hypotony after the initial insertion of the tube and intraocular pressure recovered to normal range in the third to seventh week after surgery. The other two eyes fell into hypotony after release of temporary occlusion sutures with pressure recovery in the third and sixth weeks each. A transient flat anterior chamber was found in three eyes (7.5%), two of them noted after initial surgery and the other one developed after release of the suture. All of the anterior chamber depth recovered between 3 and 10 days. There was one case (2.5%) of choroidal effusion right after surgery which required a drainage procedure. Tube blockages by iris and cyclitic membrane were found in three patients (7.5%) each. Minor ectropion uvea was found in one eye. In two eyes (5.0%), the tube touched the cornea and corneal opacity developed. One of them required full thickness corneal transplantation, the other developed endophthalmitis and eventually phthisis.

There were two cases that received full thickness corneal transplantation in this study. In the case of a patient who developed corneal opacity and needed full thickness penetrating keratoplasty after e-PTFE membrane implant surgery as described previously, the graft was well maintained for 5 years until the last follow up visit. On the other hand, in the other case which had corneal transplantation before e-PTFE membrane implant surgery, graft failure developed 2 years after implant surgery.

There were two cases where tube lens touch developed in phakic eyes, and focal lens opacities developed. But they showed no progression of the cataract until the last follow up visit (average of 26 months after implant surgery). Minor retinal haemorrhages in two eyes and intravitreal haemorrhage in one eye were found after surgery, but they resolved spontaneously without any treatment. Exposure of the implant was found in two eyes, and of two cases of endophthalmitis and three of phthisis were found including the cases mentioned earlier; they were classified as failures (Table 6). These three cases of phthisis developed in one patient with neovascular glaucoma and two patients with secondary glaucoma, one from a severe ocular trauma and the other from an epithelial downgrowth after cataract surgery.

DISCUSSION

The e-PTFE membrane (Gore-Tex) has been widely used in preventing adhesion after cardiovascular surgeries, gynaecological surgeries, etc.⁹⁻¹⁰ In the ophthalmological field, there are a few reports about using this membrane—for example, as a substitute for silicone sponge for the scleral buckling procedure and as a reinforcement material over the tubes of glaucoma drainage implants in rabbits, etc.¹¹⁻¹² To reduce the complications resulting from the rigid implant with large volume, we developed a new implant made of soft and freely malleable membrane. We had reported a pilot animal study about safety and effect of the e-PTFE membrane implant as a new glaucoma implant.⁷ With the encouraging result from this study, animal study was continued with different size and designs of the membrane tube implant. We employed silicone tube as the conduit portion, and we found that a reservoir with double layers was more effective in preventing blockage of the tube than single layer of the membrane. Although the silicone tube and the e-PTFE membrane had been proved to be safe materials in human tissue, as far as we know, this material had not been used in human glaucoma patients yet. So we chose subjects with poor visual acuity for this clinical study. The purpose of the surgery in most patients was not maintaining the visual acuity but reducing the number of the antiglaucoma medications or reducing the complications of high ocular pressure including intractable ocular pain.

Following the surgery of any kind of glaucoma implant, a fibrovascular capsule is known to be formed surrounding the foreign material. This capsule is different from that of filtering bleb formed after conventional trabeculectomy in that the former is a membrane composed of connective tissue positioned between Tenon's capsule and the implant, located around the equator. The aqueous is absorbed in the orbital capillaries or lymphatics after exiting the intercellular spaces of this capsular membrane.³ The resistance to aqueous outflow may be decided mainly by the permeability of this membrane,¹³ and the resultant intraocular pressure is controlled by the passive, pressure dependent flow through this membrane.¹⁴ So, the main factors that control the intraocular pressure are the surface area, thickness, and permeability through this membrane.¹⁵⁻¹⁸ In this study we used the implant with a reservoir portion of 160 mm² in size, which showed optimal result in both effect and ease of surgical manoeuvre in the previous study.^{7,8} This is larger than the single Molteno implant, but smaller than the double plate Molteno, Ahmed, Baerveldt, and ACTSEB implants. The membrane formed around this new implant was not different from the tissue formed around the other glaucoma implants in histology.³ The permeability of this membrane might be reduced over time, so topical β blockers and steroid drops are needed to maintain the intraocular pressure after implant surgery in many cases.¹⁹⁻²⁰ For that reason, we did not consider whether the patient used one to two antiglaucoma medications or not in assessing the result of the surgery.

In comparing the efficacy of controlling the intraocular pressure among many implant types, each study might have different criteria in selecting the patient and classifying the results, so simple horizontal comparison is not appropriate. Our result showed a similar result to those of other commercially available implants in controlling the intraocular pressure by Kaplan-Meier survival analysis. The survival rate in our study were 87.4% at 6 months, 80.9% at 1 year, 73.9% at 2 years, 62.2% at 3 years, and 56.0% at 5 years. These are not much different from the reports that had similar criteria for selecting subjects and classification; survival of 78% at 1 year and 75% at 2 years of Ahmed valve implant,^{4,6} 60.3% and 71% at 2 years of Baerveldt implant,^{5,21} and 54% at 5 years of Molteno Implant.³

In this study, we could control the intraocular pressure within the range of 6 and 21 mm Hg in 26 (65%) of 40 patients

with average follow up of 32.9 months. But if we consider the visual acuity in assessing the result, only 19 eyes (47.5%) showed good intraocular pressure control while maintaining the visual acuity. We looked for all possible clinical variables that might affect the result, and we found sex and the preoperative intraocular pressure had a significant effect on the success rate. Interestingly, females showed 87.5% success rate that was much higher than 50.0% of the males. We tried to find any other differences between female and male groups, but there were no significant differences in clinical variables in both groups. Douglas and associates had reported that males had a significantly poorer prognosis than females in their 94 cases with a Molteno implant,²² but most reports did not show difference between males and females. Because this study was done with a small number of patients and performed retrospectively, we think a further study with a large number of subjects might yield a different result. Although Siegner and associates reported the preoperative intraocular pressure did not affect the result in their study with the Baerveldt implant,⁵ we had a contrary result that is consistent with the reports of Mills and associates with a Molteno implant and of Huang and associates with an Ahmed implant, which states that the case with high preoperative intraocular pressure showed high risk of failure after the implant surgeries.³⁻⁶ The result of implant surgeries may differ according to the type of glaucoma. Although statistical analysis was not possible in our study, each type of glaucoma showed different success rate. The group with the worst result was the secondary glaucoma group (success rate of 42.9%) which included two cases with primary insult of severe trauma, two corneal disorders (two eyes of Terriens marginal dystrophy of a patient), an epithelial downgrowth after cataract surgery, a case after complicated retinal surgery, and a case with Sturge-Weber syndrome. Except for this secondary glaucoma group, the neovascular glaucoma group showed the worse result (63.2% success) than the failed filter group (75.0% success) and the aphakic/pseudophakic group (83.8% success). This result agreed with the previous reports showing a poor result in neovascular glaucoma patients after implant surgeries.^{3-6, 23} Molteno used anti-inflammatory medications such as steroid, fluphenamic acid, adrenaline, colchicine, and atropine when he performed glaucoma implant surgery to reduce the fibrotic reaction around the implant.²⁴ There have been contradictory reports about the effect of antifibrotic agents on glaucoma implant surgeries.²⁵⁻³⁰ In this study, when the subjects were divided into two groups, the mitomycin C treated group and the untreated group, there was no difference not only in preoperative variables such as age, sex, preoperative intraocular pressure, and number of preoperative antiglaucoma medications but also in the intraocular pressure at the last visit. The success rate was higher in the mitomycin C group, but it was not significant statistically. As mentioned in the methods section, application of mitomycin C was done in a selected group of patients; in those who had extensive conjunctival scar, simple comparison is not possible, therefore we could not determine the effect of mitomycin C in this study.

Ultrasound echography revealed good posterior filtering bleb in most cases in this study with membrane reservoir. Although we did not perform this examination in routinely, 91.3% of selected cases showed noticeable filtering space with variable height (bleb height of 2.4 (1.3) mm) around the explant. In contrast with the other explant with rigid consistency, we could not find an echo associated with the membrane reservoir. As reported by Lloyd and associates the stated bleb size did not necessarily correlate with the levels of intraocular pressure control,³¹ and Pearson correlation analysis failed to reveal a statistical correlation between bleb height and intraocular pressure in this study.

In treating refractory glaucoma, the implant surgery offers a better result in long term control of intraocular pressure, but there have been many reports about various complications

after implant surgeries from transient hypotony to phthisis. Among many complications, leaking of conjunctival wound, limitation of ocular motility, and exposure of the implant might be associated with the rigid consistency and large volume of the previous implants, and these problems might be reduced if we substitute the reservoir with the soft, thin membrane. Ocular motility dysfunction after implant surgery was not encountered infrequently, and it was improved as the oedema around the eyeball subsided in most cases. Although it can happen in all types of the glaucoma implants, it was more frequent with the Baerveldt implant, which had the largest volume, and up to 77% of ocular motility restriction with this implant was reported by Smith and associates.^{32, 33} We expected less of an ocular motility problem with the new implant, and we detected no ocular motility problem during the study period. Our subjects had poor vision in the operated eyes, so we agree that the chance to find the motility problem might be reduced, and a more objective result could be obtained with the patient group with good visual acuity in both eyes. In the meantime, we expected lower frequency of exposure of the implant or infection with the new implant, but we found no difference in the frequency of these complications compared to the previous reports.

With our soft and freely malleable membrane reservoir, contraction of the fibrovascular capsule surrounding the implant after surgery and the resultant contraction of the reservoir with functional loss might be expected. Although we had no necropsy specimen, we had found no histological difference in the fibrous capsule formed around the e-PTFE membrane compared with the other implants in our previous animal study,⁷ and we have not found any complication related to such contraction on clinical examination, including ultrasound sonography over the fibrous capsule formed around the implant in cases with poor intraocular pressure control.

The complications found in this study were not much different from the other reports with rigid implants in general. The most striking complications found more frequently than in recent reports were phthisis and endophthalmitis. Phthisis was found in three eyes (7.5%) in our patients while the Baerveldt implant resulted in 1.9% with this complication and the Ahmed implant showed 1.3% in other reports.³⁻⁶ But phthisis developed in 8% in the initial report of the Molteno implant³; this initial study usually selected the subjects with a poor prognosis, such as terminal glaucoma, and this might be one of the reasons for this high frequency of phthisis as a devastating complication. There were two cases of endophthalmitis encountered in our study. One case had severe intraocular inflammation due to corneal ulcer that had developed before the implant surgery; this inflammation was not controlled and continued after surgery, eventually ending up with endophthalmitis. The other was the case of developed implant exposure after surgery, and even though we recommended replacement of the implant with repair of the surface wound, the patient refused to have a further operation on that blind eye after five disappointing glaucoma procedures. That eye resulted in endophthalmitis and phthisis.

Although our subjects were confined to terminal glaucoma cases, we think that our new implant showed comparable intraocular pressure lowering effect and complications with other commercially available implants. This membrane tube implant has some advantages. Because this implant's reservoir is made of soft and malleable membrane, it can be inserted through a smaller incision in a folded form. Also some complications that are associated with the rigid consistency and large volume might be reduced, although it was not proved in this study. We have a plan to report a comparison study between this membrane tube implant and another implant with random sampling of the subjects. With the encouraging result from this study, we think that this new membrane tube implant can be used as another substitute for

the currently used implants without losing efficacy, without increasing the risk of complications, and with possible advantages.

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REFERENCES

- Williams AS**. Setons in glaucoma surgery. In: Albert DM, Jakobiec FA, eds. *Principles and practice of ophthalmology*. Philadelphia: WB Saunders, 1994:1655–67.
- Rosenberg LF**, Krupin T. Implants in glaucoma surgery. In: Ritch R, Shields MB, Krupin T, ed. *The glaucomas*. 2nd ed. Philadelphia: Mosby, 1996:1783–807.
- Mills RP**, Reynolds A, Emond MJ, et al. Long-term survival of Molteno Glaucoma Drainage Device. *Ophthalmology* 1996;**103**:299–305.
- Coleman AL**, Hill R, Wilson MR, et al. Initial clinical experience with the Ahmed glaucoma valve implant. *Am J Ophthalmol* 1995;**120**:23–31.
- Siegner SW**, Netland PA, Urban Jr RC, et al. Clinical experience with the Baerveldt Glaucoma Drainage Implant. *Ophthalmology* 1995;**102**:1298–307.
- Huang MC**, Netland PA, Coleman AL, et al. Intermediate-term clinical experience with the Ahmed Glaucoma valve implant. *Am J Ophthalmol* 1999;**127**:27–33.
- Ahn BH**, Kim CS, Kim YB. Use of e-PTFE membrane for glaucoma drainage surgery. *J Korean Ophth Soc* 1990;**31**:603–14.
- Bae HB**, Kim CS, Ahn BH. A membranous drainage implant in glaucoma filtering surgery: animal trial. *Korean J Ophthalmol* 1988;**2**:49–56.
- Imai Y**, Hashimoto A, Hayashi H, et al. Clinical application of a new material "expanded polytetrafluoroethylene." *Kyobu Geka* 1978;**31**:23–9.
- Meux PJ**, Wernly JA, Campbell CD, et al. Long-term evaluation of pericardial substitutes. *J Thorac Cardiovasc Surg* 1983;**85**:54–8.
- Tawakol ME**, Peyman GA, Kaufman HE. Gore-tex soft tissue bands as scleral explants in rabbits: A preliminary histologic study. *Ophthalmic Surg* 1989;**20**:199–201.
- Jacob JT**, LaCour OJ, Burgoyne CF, et al. Expanded polytetrafluoroethylene reinforcement material in glaucoma drain surgery. *J Glaucoma* 2001;**10**:115–20.
- Minckler DS**, Shammam A, Wilcox M, et al. Experimental studies of aqueous filtration using the Molteno implant. *Trans Am Ophthalmol Soc* 1987;**84**:368–92.
- Wilcox MJ**, Minckler DS, Ogden TE. Pathophysiology of artificial aqueous drainage in primate eyes with Molteno implants. *J Glaucoma* 1994;**3**:140.
- Molteno ACB**, Strachan J, Ancker E. Long tube implants in the management of glaucoma. *S Afr Med J* 1995;**50**:1062–6.
- Molteno ACB**. Use of Molteno implants to treat secondary glaucoma. In: Cairns JE, eds. *Glaucoma*. London: Grune and Stratton, 1986:211–38.
- Loeffler KU**, Jay JL. Tissue response to aqueous drainage in a functioning Molteno implant. *Br J Ophthalmol* 1990;**72**:29–35.
- Prata JA**, Mermoud A, LaBree L, et al. In vitro and in vivo flow: characteristics of glaucoma drainage implants. *Ophthalmology* 1995;**102**:894–904.
- Krupin T**, Kaufman P, Mandell AI, et al. Long-term results of valve implants in filtering surgery for eyes with neovascular glaucoma. *Am J Ophthalmol* 1983;**95**:775–82.
- Forestier F**, Salvane-Bouccara A. An evaluation of the Krupin-Denver valve implant in glaucoma. *Glaucoma* 1986;**8**:92.
- Krishna R**, Godfrey DG, Budenz DL, et al. Intermediate-term outcomes of 350-mm² Baerveldt glaucoma implants. *Ophthalmology* 2001;**108**:621–6.
- Douglas GR**. The Molteno implant and other setons. In: Drance SM, Van Buskirk M, Neufeld AH, eds. *Pharmacology of glaucoma*. Baltimore: Williams & Wilkins, 1992:52–63.
- Mermoud A**, Salmon JF, Alexander P, et al. Molteno tube implantation for neovascular glaucoma: long-term results and factors influencing outcome. *Ophthalmology* 1993;**100**:897–902.
- Molteno ACB**. Mechanism of intraocular inflammation. *Trans Ophthalmol Soc NZ* 1980;**32**:69–72.
- Cantor L**, Burgoyne J, Sanders S, et al. The effect of mitomycin C on Molteno implant surgery: A 1-year randomized, masked, prospective study. *J Glaucoma* 1998;**7**:240–6.
- Diestelhorst M**, Krieglstein GK. Effect of mitomycin-C on aqueous humor flow after trabeculectomy. *Ophthalmology* 1995;**92**:542–5.
- Perkins TW**, Gangnon R, Ladd W, et al. Molteno implant with mitomycin C: Intermediate-term results. *J Glaucoma* 1998;**7**:86–92.
- Prata JA**, Minckler DS, Mermoud A, et al. Effects of intraoperative mitomycin-C on the function of Baerveldt glaucoma drainage implants in rabbits. *J Glaucoma* 1996;**5**:29–38.
- Perkins TW**, Cardakli F, Eisele JR, et al. Adjunctive mitomycin C in Molteno implant surgery. *Ophthalmology* 1995;**102**:91–7.
- Tribble JR**, Brown DB. Occlusive ligature and standardized fenestration of a Baerveldt tube with and without antimetabolites for early postoperative intraocular pressure control. *Ophthalmology* 1998;**105**:2243–50.
- Lloyd MA**, Minckler DS, Heuer DK, et al. Echographic evaluation of glaucoma shunts. *Ophthalmology* 1993;**100**:919–27.
- Assaad MH**, Baerveldt G, Rockwood EJ. Glaucoma drainage devices: pros and cons. *Curr Opin Ophthalmol* 1999;**10**:147–53.
- Smith SL**, Starita R, Fellman RL, et al. Early clinical experience with the Baerveldt 350-mm² glaucoma implant and associated extraocular muscle imbalance. *Ophthalmology* 1993;**100**:914–8.



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