

e-PTFE

. . . *

= =

가 가
expanded polytetrafluoroethylene

1991 5 1995 9
37 40
6~21mmHg
6~21mmHg
가
32.6 , 40 26 (65%)
14 (35%) . Kaplan-Meier
3 87.5%, 6 84.7%, 1 78.4%, 2 71.6%, 3 60.3%
가
e-PTFE
가 , 가
(41:184~196, 2000).

< : 1999 7 6 , : 1999 11 3 >

Address reprint requests to Yong-Baek Kim, M.D.
Department of Ophthalmology, College of Medicine, Chungnam National University
#640 Daesa-dong, Jung-ku, Taejon, 301-721, Korea
Tel : 82-42-220-7608, FAX : 82-42-255-3745

*

Department of Ophthalmology, Sungkyunkwan University School of Medicine, Seoul, Korea*

* 1997

≡ Abstract ≡

Intermediate-term Result of e-PTFE Membrane Implant Surgery for Refractory Glaucomas

Chang-Sik Kim, M.D., Yong-Baek Kim, M.D.,
Hang-Jin Cho, M.D., Byung-Heon Ahn, M.D.*

Recently, various tube-shunt implants have been used in treating refractory glaucomas. They have large volumed reservoir portion made of hard materials. We made a new implant with soft and freely malleable membrane(expanded polytetrafluoroethylene, e-PTFE) as a reservoir portion attached to the conventional silicone tube. Based on the encouraging result from experimental animal study, we performed a clinical trial for the membrane-tube implant.

We performed Glaucoma Tube-Shunt Implant surgery using double layers of e-PTFE membrane and silicone tube with its one end fixed between the two layers. The subjects had refractory glaucomas without useful vision who visited our hospital from May 1991 to Sep. 1995.

There were 40 eyes of 37 patients and their mean follow-up period was 32.6 months. We could control the IOP within 6~21mmHg in 26 eyes(65.0%, Success). In remaining 14 eyes, we could not control the IOP or additional surgery was needed to control the IOP or treat severe complications(35.0%, Failure). The Kaplan-Meier Survival for IOP control was 78.4% at 1 yr, 71.6% at 2 yr, and 60.3% at 3 yr. The complications were similar to those of other commercially available Glaucoma implants.

This new implant is made of soft, freely malleable membrane for the reservoir portion with small volume which can be inserted with smaller incision on the conjunctiva with less complication. We have obtained comparable result from this membrane-tube implant to other implants, and it may be considered as an another substitute for the treatment of refractory glaucomas(J Korean Ophthalmol Soc 41:184~196, 2000).

Key Words : Glaucoma implant, Tube-shunt implant, Membrane implant, e-PTFE membrane

가 가 가 .
가 가 , , 가 가
가 ,
가
1,2)

가 . 가 가 , 5-0 nylon
Molteno , Krupin , Ethylene Oxide
Baerveldt , Ahmed (Fig. 1).

가 , 가 2.
가 ,

1 ,
,
,
,
3-6) . 가
0.01 가 ,

가 expanded polytetra-
fluoroethylene(e-PTFE, Gore-Tex , Japan
Gore-tex Inc., Tokyo, Japan) . 1991 5 1995 9 40
43 e-PTFE membrane-Silicone tube
implant(MT)

가
,
7,8) .
MT
e-PTFE
3 3 3
37 40

1. e-PTFE

0.3mm 0.64mm,
e-PTFE 18×24mm
160mm²가
23gauge

(Silastic , Dow Corning Corporation,
Midland, USA)

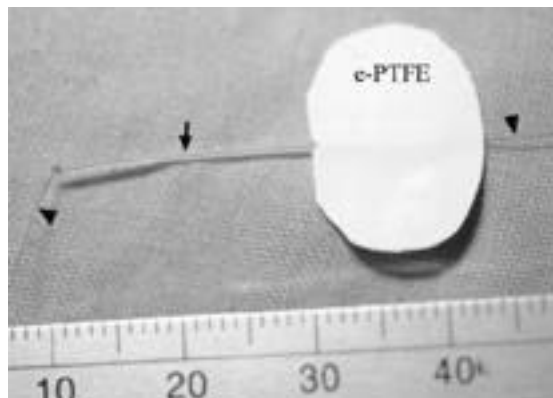


Figure 1. Membrane-Tube implant made of e-PTFE and silicone tube.
Arrow: Silicone Tube, one end fixed between 2 layers of e-PTFE membrane, Arrowhead: 5-0 nylon intraluminal stent passing through the silicone tube and between the e-PTFE membranes, e-PTFE: e-PTFE membrane reservoir

— : e-PTFE —

2
2 2
8mm
5~6mm
가
MT
3.
가
3
6~21mmHg
13 13
0.4mg/Ml Mitomycin
3 ~5
MT
가
10-0nylon
10mm
23gauge
1.5mm가
가
0.1, 0.01,
10-0nylon 2
5-0nylon 가
9-0nylon
9-0nylon
5-0 nylon
4 × 5mm
10-0nylon
10-0nylon
(Fig. 2). Genta-
micin(80mg/Ml) Betamethasone(4mg/Ml)
0.5Ml
MT 가
Triamcinolone(40
mg/Ml) 0.3Ml

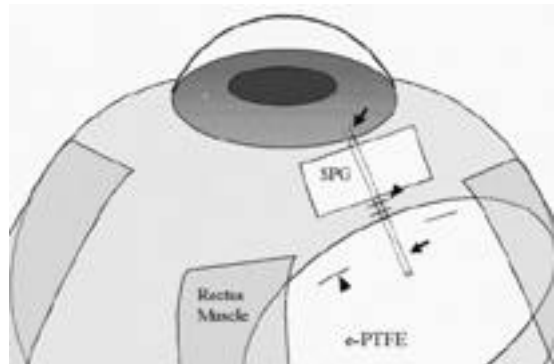


Figure 2. Scheme of Membrane-Tube implant surgery.

Arrow: Silicone Tube connecting form anterior chamber to membrane reservoir, Arrowhead: Anchoring sutures for silicone tube and e-PTFE membrane onto sclera with 10-0 nylon, SPG: Donor Scleral Patch Graft, e-PTFE: e-PTFE membrane reservoir

SPSS , 16mmHg (Table 2, Fig. 3).
 Wilcoxon 2.2
 signed ranks test , 1 0.8 , 1
 (non-parametric test) 0.3 , 2 0.4 , 4 0.5 , 6
 Mann-Whitney 0.3 , 1 0.4 , 2 0.5 , 3
 , Kruskal-Wallis 0.6 , 4 0.6 , 5 0.7 , 6 0.7 ,
 . 7 1 2가
 . 6
 가 (p<0.05).
 37 40 22 34 (85%)
 24 , 15 16 . 0.1 , 가
 24 78 50 . 가 0.3 .
 19 가 , 1.2
 가 8 , .
 7 , 3 (7.5%) 가 ,
 6 25 (62.5%) 가 1
 (Table 1). , 12 (30%)
 42.5±14.6mmHg 2 . 12 7
 2.2±0.6 . ,
 1 83 5 .
 32.6 . 17.3 14 6
 ±10.2mmHg 1 ,
 0.5±0.8 . 2 3 (Table
 , 1 3).
 23.8mmHg, 2 22.5mmHg, 1 가
 18.5mmHg (p=0.035).
 2 19.1mmHg, 4 17.5mmHg, 6 , ,
 19.5mmHg, 1 16.4mmHg . , mitomycin ,
 1 2 ,
 17.1mmHg, 3 18.0mmHg, 4 18.6mm
 Hg, 5 21.5mmHg, 6 13.5mmHg 가
 7 가 1 26 65%

Table 1. Characteristics of the Subjects

sex	male 22(24 eyes)	female 15(16 eyes)
age(yr)	24 78 (average 50)	
follow-up (mo)	1 83 (average 32.6)	
preop diagnosis	neovascular glaucoma	19
(eyes)	failed previous filtration	8
	secondary glaucoma	7
	aphakic or pseudophakic G	6

Table 2. Change in intraocular pressure and number of medications before and after Membrane-Tube implant surgery

Time	IOP(mmHg) mean $\pm$ SD		No. of Medications mean $\pm$ SD		No. of Subjects eyes
preop	42.5	14.6	2.2	0.6	40
postop 1 wk*	23.8	16.7	0.8	0.9	40
2 wk*	22.5	18.4	0.7	0.9	40
1 mo*	18.5	12.1	0.3	0.6	38
2 mo*	19.1	11.1	0.4	0.6	37
4 mo*	17.5	10.1	0.5	0.7	35
6 mo*	19.5	12.7	0.4	0.7	33
1 yr*	16.4	4.7	0.4	0.6	28
2 yr*	17.1	10.6	0.5	0.7	22
3 yr*	18.0	12.2	0.6	0.7	18
4 yr*	18.6	11.7	0.6	0.7	16
5 yr*	21.5	13.3	0.7	0.8	11
6 yr*	13.5	8.9	0.7	1.0	6
7 yr	16	-	2	-	1

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

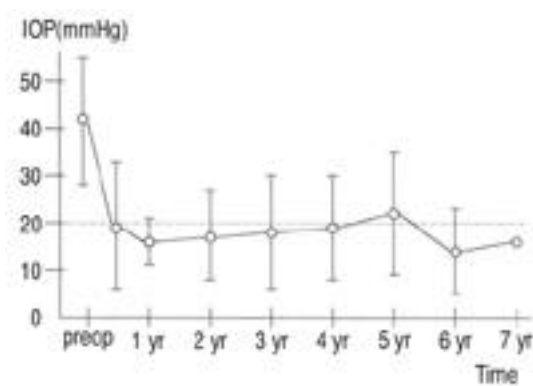


Figure 3. Intraocular pressure changes before and after Membrane-Tube implant surgery.

15.4mmHg, 0.6
14 35%
45.5, 50.4
mmHg, 2.1
22.4mmHg,
0.7 (Table 4).
, Mitomycin
($p > 0.05$).
12
12
14, 2
($p = 0.016$).
52.2, 3
38.3mmHg, 2.2
14.6mmHg,
0.4 19 47.5%
51.8, 38.1
mmHg, 2.2
14.3mmHg, 0.4
7 17.5%
53, 38.7mmHg,
2.4
($p = 0.013$).
38.1 $\pm$ 16.9mmHg, 7
38.7 $\pm$ 8.5mmHg, 14 50.4 $\pm$
10.5mmHg,
($p = 0.013$).
(189)189

Table 3. Characteristics of treated eyes : Related to visual outcome

VA change	improved/no change	worsened*	All eyes
subjects(%)	28(70)	12(30)	40(100)
factors			
age(yr)	49±14	51±14	50±14
sex(M/F)	17/11	7/5	24/16
IOP(mmHg)			
preoperative	41.9±16.3	44.0 ± 10.4	42.5±14.6
last visit	18.2±10.9	15.3± 8.5	17.3±10.2
antiglaucoma medications			
preoperative	2.1±0.7	2.3 ± 0.5	2.2± 0.6
last visit	0.6±0.8	0.3 ± 0.7	0.5± 0.8
previous surgery [†]	0.9±1.3	2.3 ± 2.1	1.3± 1.6
MMC(Yes/No)	8/20	5/7	13/27

* : worsened visual acuity by more than 2 lines

[†] : statistically different between two groups(Mann-Whitney test, p<0.05)

VA: visual acuity, IOP: intraocular pressure, MMC: mitomycin soaking

Table 4. Characteristics of treated eyes : Related to surgical success

Group	Success			Failure	Total
	Unqualified	Qualified	Subtotal		
Number of subjects(%)	19(47.5)	7(17.5)	26(65.0)	14(35.0)	40(100)
sex* Male(eyes)	8	4	12	12	24
Female(eyes)	11	3	14	2	16
age(yr)	52±14	53±13	52±14	45±13	49±14
No. of previous surgeries*	1.0±1.4	3.0±2.3	1.5±1.9	0.9±1.0	1.3±1.6
Intraocular pressure(mmHg)					
preoperative*	38.1±16.9	38.7±8.5	38.3±14.9	50.4±10.5	42.5±14.6
at last follow up visit	14.3± 4.0	15.4± 4.4	14.6± 4.1	22.4±15.5	17.3±10.2
No. of antiglaucoma medications					
preoperative	2.2±0.7	2.4±0.5	2.2±0.7	2.1±0.5	2.2±0.6
at last follow up visit	0.4±0.6	0.6±0.8	0.4±0.6	0.7±1.0	0.5±0.8
Mitomycin soaking					
Used	7	4	11	2	13
Not used	12	3	15	12	27

* : statistically different among 3 groups(Kruskal-Wallis test, p<0.05)

, , 3 가 , ,
 (p=0.045). 가 (p>0.05), Mytomy-
 3 가 , cin 13 11 ,
 0.9 27 15
 가 . Mitomycin 가
 Mitomycin 가
 , , (p=0.075). ,

Table 5. Characteristics of treated eyes : Related to Diagnosis

Group	NVG	failed filter	secondary glaucoma	aphakic or pseudophakic glaucoma	Total
No. of subjects	19	8	7	6	40
age(average)	56.1	46.1	37.0	49.8	49.8
previous operations(No.)	0.3	3.6	0.9	2.0	1.3
Intraocular pressure(mmHg)					
preoperative	49.3±13.5	35.6±14.5	41.7±12.3	31.3±11.9	42.5±14.6
last visit	19.3±13.2	15.3± 5.8	15.1±9.1	16.5± 4.2	17.3±10.2
Antiglaucoma medications(No.)					
preoperative	2.4±0.6	2.3±0.5	1.7±0.5	2.0±0.6	2.2±0.6
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)
unqualified	10(52.6)	2(25.0)	3(42.9)	4(66.7)	19(47.5)
qualified	2(10.5)	4(50.0)	0(0.0)	1(16.7)	7(17.5)
failure	7(36.8)	2(25.0)	4(57.1)	1(16.7)	14(35.0)

NVG: neovascular glaucoma

(Table 4).

가 가
83.4%
75.0%,
63.1%
42.9% 가 가
가

(Table 5).

40 26 (65%)

, 14

(35%)

Meier

Kaplan-

,

3 87.5%, 6

84.7%, 1 78.4%, 2 71.6%, 3 3

60.3%, 5 54.3% (Fig. 4).

22 (55%)

1

2 9

9

,

1

(22.5%)

1

5

5 (12.5%),

3

가 2 2

(7.5%)

1

MT

가 1 (2.5%)

,

Table 6. Complications after Membrane-Tube Implant Surgery

complications	No.	frequency(%)
total subjects	40	100.0
subjects with complication(s)		
transient hyphema	9	22.5
hypotony	5	12.5
transient flat AC	3	7.5
choroidal detachment	1	2.5
obstruction of tube	3	7.5
fibrinous iridocyclitis	3	7.5
tube-corneal touch	2	5.0
corneal graft failure*	1	2.5
cataract	2	5.0
retinal hemorrhage	2	5.0
vitreous hemorrhage	1	2.5
exposed implant	2	5.0
endophthalmitis	2	5.0
phthisis	3	7.5

* : one corneal graft failure developed from 2 corneal grafts

AC : anterior chamber

가

11)

e-PTFE

e-PTFE

2

가

160mm²

2

e-PTFE

가

1

MT

가

가 2

2 , 1

Tenon

가

가 2

가 3

1

1

1

(Table 6).

13)

passive, pressure-depen-

dent flow

14-17)

7)

가

9,10)

가

160mm² e-PTFE

192(192)

가 . , 160mm² 87.5% 50% single-plate Moltano (p=0.044). , double-plate Moltano , 가 Ahmed , Baerveldt , ACT- 가 가 SEB 가 가 가 Siegner 가 7) . 5) , Mills Huang 3,6) (p=0.046). 18,19) , 0.1 . 12 30% 2 12.6% ~ 33% 3-6) Kaplan-Meier 3 87.5%, 6 84.7%, 1 78.4%, 2 71.6%, 3 60.3%, 5 54.3% , Ahmed 가 12 78%, Baerveldt . 2 60.3% Ahmed 2 75%, Moltano 5 가 가 3-6) 가 / MT 가 , 40 40 6 ~ 21mmHg 26 65.0% , 26 , Cantor 가 20) , mitomycin-C 가 19 47.5% . 가 (p=0.246). , , , Mitomycin C ,

Ahmed 1.3%, Baerveldt 1.9% 10% Molteno 가 8% 가 2 1 가 5 가 가 MT 가 e-PTFE

REFERENCES

- 1) Williams AS : Setons in glaucoma surgery: In Albert DM, Jakobiec FA, ed. Principles and Practice of Ophthalmology: Clinical Practice. Philadelphia, WB Saunders, 1994, pp. 1655-1667.
- 2) Rosenberg LF, Krupin T : Implants in glaucoma surgery: In Ritch R, Shields MB, Krupin T, ed. The Glaucomas, 2nd Ed, Philadelphia, Mosby, 1996, pp. 1783-1807.
- 3) Mills RP, Reynolds A, Emond MJ, Barlow WE, Leen MM : Long-term survival of Molteno Glaucoma Drainage Device. Ophthalmol 103:299-305, 1996.
- 4) Coleman AL, Hill R, Wilson MR, Choplin N, Kotas-Neumann R, Tam M, Bacharach J, Panek WC : Initial clinical experience with the Ahmed glaucoma valve implant. Am J. Ophthalmol 120:23-31, 1995.
- 5) Siegner SW, Netland PA, Urban Jr RC, Williams AS, Richards DW, Latina MA, Brandt JD : Clinical experience with the Baerveldt Glaucoma Drainage Implant. Ophthalmol 102:1298-1307, 1995.
- 6) Huang MC, Netland PA, Coleman AL, Siegner SW, Moster MR, Hill RA : Intermediate-term clinical experience with the Ahmed Glaucoma valve implant. Am J. Ophthalmol 127:27-33, 1999.
- 7) Bae HB, Kim CS, Ahn BH : A membranous drainage implant in glaucoma filtering surgery: Animal trial. Korean J. Ophthalmol 2:49-56, 1988.
- 8) : e-PTFE 31:603-614, 1990.
- 9) Imai Y, Hashimoto A, Hayashi H, Sakamoto T, Koyanagi H : Clinical application of a new material "expanded polytetrafluoroethylene". Kyobu Geka 31:23-29, 1978.
- 10) Meux PJ, Wernly JA, Campbell CD, Takanashi Y, Pick RL, Zhae-Kun Q, Replogle RL : Long-term evaluation of pericardial substitutes. J Thorac Cardiovasc Surg 85:54-58, 1983.
- 11) Tawakol ME, Peyman GA, Kaufman HE : Gore-tex soft tissue bands as scleral explants in rabbits: A preliminary histologic study. Ophthalmic Surg 20:199-201, 1989.
- 12) Minckler DS, Shammass A, Wilcox M, Ogden TE : Experimental studies of aqueous filtration using the Molteno implant. Trans Am Ophthalmol Soc 84:368-392, 1987.
- 13) Wilcox MJ, Minckler DS, Ogden TE : Pathophysiology of artificial aqueous drainage in pri-

- mate eyes with Molteno implants. *J Glaucoma* 3:140-151, 1994.
- 14) Molteno ACB, Strachan J, Ancker E : Long tube implants in the management of glaucoma. *S Afr Med J* 50:1062-1066, 1995.
- 15) Molteno ACB : Use of Molteno implants to treat secondary glaucoma. In Cairns JE, ed, *Glaucoma*. London, Grune & Stratton, 1986, pp. 211-238.
- 16) Loeffler KU, Jay JL : Tissue response to aqueous drainage in a functioning Molteno implant. *Br J. Ophthalmol* 72:29-35, 1990.
- 17) Prata JA, Mermoud A, LaBree L, Minckler DS : In vitro and in vivo flow: characteristics of glaucoma drainage implants. *Ophthalmol* 102: 894-904, 1995.
- 18) Krupin T, Kaufman P, Mandell AI, Terry SA, Ritch R, Podos SM, Becker B : Long-term results of valve implants in filtering surgery for eyes with neovascular glaucoma. *Am J Ophthalmol* 95:775-782, 1983.
- 19) Forestier F, Salvanet-Bouccara A : An evaluation of the Krupin-Denver valve implant in glaucoma. *Glaucoma* 8:92-99, 1986.
- 20) Cantor L, Burgoyne J, Sanders S, Bhavnani V, Hoop J, Brizendine E : The effect of mitomycin C on Molteno implant surgery: A 1-year randomized, masked, prospective study. *J. Glaucoma* 7:240-246, 1998.
- 21) Mermoud A, Salmon JF, Alexander P, Straker C, Murray ADN : Molteno tube implantation for neovascular glaucoma: long-term results and factors influencing outcome. *Ophthalmol* 100: 897-902, 1993.
- 22) Molteno ACB : Mechanisms of intraocular inflammation. *Trans Ophthalmol Soc NZ* 32:69-72, 1980.
- 23) Diestelhorst M, Krieglstein GK : Effect of mitomycin-C on aqueous humor flow after trabeculectomy. *Ophthalmol* 92:542-545, 1995.
- 24) Perkins TW, Gangnon R, Ladd W, Kaufman PL, Libby CM : Molteno implant with mitomycin C: Intermediate-term results. *J. Glaucoma* 7:86-92, 1998.
- 25) Prata JA, Minckler DS, Mermoud A, Baerveldt G : Effects of intraoperative mitomycin-C on the function of Baerveldt glaucoma drainage implants in rabbits. *J. Glaucoma* 5:29-38, 1996.
- 26) Perkins TW, Cardakli F, Eisele JR, Kaufman PL, Heatley GA : Adjunctive mitomycin C in Molteno implant surgery. *Ophthalmol* 102:91-97, 1995.
- 27) Assaad MH, Baerveldt G, Rockwood EJ : Glaucoma drainage devices: pros and cons. *Cur Opin Ophthalmol* 10:147-153, 1999.
- 28) Smith SL, Starita R, Fellman RL, Lynn JR : Early clinical experience with the Baerveldt 350- μ m glaucoma implant and associated extraocular muscle imbalance. *Ophthalmol* 100:914-918, 1993.