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CLINICAL STUDY

Insertion of sequential glaucoma drainage implant in a piggyback manner

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Abstract

Purpose **This pilot study, the first of its type, was conducted to determine the clinical outcome of a sequential glaucoma drainage implant (GDI) inserted in piggyback manner, that is into the bleb of a primary GDI.**

Methods **This was a retrospective chart study with a minimum 1-year follow-up involving 16 eyes of 14 uncontrolled glaucoma patients who had previously undergone sequential GDI performed using a technique to convert a one-plate into a two-plate implant system. Surgical success was defined as intraocular pressure (IOP) <21 mm Hg with at least a 30% reduction in IOP from baseline on two consecutive follow-up visits, IOP >5 mm Hg on two consecutive follow-up visits, and neither reoperation of glaucoma nor loss of light perception vision.**

Results **The mean $\pm$ SD baseline IOP was 29.2 ± 5.2 mm Hg, and the mean postoperative IOP was 17.3 ± 3.4 mm Hg, with a mean pressure drop of $39.4 \pm 10.4\%$ ($P<0.001$). Life-table analysis showed an 88% success rate after 12 months of follow-up. The mean preoperative best corrected visual acuity (BCVA) was 0.2 ± 0.2 logMAR (Snellen equivalent 6/9.5), compared with 0.3 ± 0.3 logMAR postoperatively (Snellen equivalent 6/12; $P=0.497$). Postoperative complications included a flat anterior chamber and choroidal detachment (one eye), uveitis and cataract (one eye), diplopia (one eye), and worsening of pre-existing pseudophakic bullous keratopathy (one eye).**

Conclusions **In glaucoma eyes with useful vision the piggyback GDI seems to provide a significant IOP lowering with minimal complications in patients in whom an initial GDI had failed to control the IOP.**

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Introduction

Glaucoma drainage implant (GDI), with or without a flow restriction element, has an important role in the surgical management of glaucoma. The optimal size of the GDI plate is not known at the moment.[1] Intraocular pressure (IOP) sometimes remains uncontrolled, despite the GDI procedure and extra drainage is needed. One treatment option might be to increase the filtration area and insert a second GDI in a different quadrant.

Although there are reports of better pressure control after implantation of a second GDI in the same eye,[2–5] the surgeon might hesitate to insert a second tube into the anterior chamber because of the risk of increasing corneal problems. The presence of a tube in the anterior chamber is known to disturb the normal environment of the corneal endothelium.[6] Previous reports have found corneal decompensation to be the main complication following a second GDI procedure.[2–5]

Another viable procedure option if extra drainage is needed is to add a second GDI piggybacked to the primary GDI bleb, that is, without actually entering the anterior chamber again. The sequential implant is rotated so that its tube is toward the primary device and is inserted into the bleb of the primary implant. To date, there is no published data on clinical results with sequential GDI inserted in piggyback manner. The purpose of this pilot study was to determine the clinical outcome of this modified implantation method in patients with inadequate IOP control after a primary GDI procedure.

Materials and methods

This was a retrospective consecutive case series of patients with uncontrolled glaucoma who had a sequential GDI inserted using a technique to

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convert a one-plate into a two-plate implant with a minimum 1-year follow-up. From 2010 to 2013, 16 eyes of 14 consecutive patients received a sequential GDI with this piggyback technique at Päijät-Häme Central Hospital. All patients had undergone a single-stage GDI procedure once or twice without antimetabolites. Initial GDI implantation included two Baerveldt implant (Abbott Laboratories Inc., Chicago, IL, USA), two Ahmed valves (New World Medical Inc., Rancho Cucamonga, CA, USA), seven Molteno3 implants (Molteno Ophthalmic Limited, Dunedin, New Zealand), and eight single-plate Molteno implants (Molteno Ophthalmic Limited, Dunedin, New Zealand).

One patient had had two single-plate Molteno implants placed into the same eye and two patients had had one single-plate Molteno implant and one Baerveldt implant inserted in the same eye. In all cases, the sequential implants had their own tubes inserted into the anterior chamber. All those previous implantation procedures were performed by the author using the same technique for each patient.[7] However, a 6-0 Rapid Vicryl ligature around the tube was only used in eyes with Molteno or Baerveldt implants.

The following guidelines were used as indications of a candidate for a piggyback GDI procedure: complicated glaucoma with uncontrolled IOP > 25 mm Hg, or a < 20% reduction in IOP from baseline on three consecutive follow-up visits with maximal tolerated antiglaucoma therapy at least 4 months after the previous GDI surgery. Candidates also had to have some useful vision left. The author used the same technique and a single-plate Molteno implant for each patient.

Surgical technique

All piggyback implants were inserted in one stage with a fornix-based 160° conjunctival incision under peribulbar anesthesia. All implants were placed under the Tenon's tissue. One implant was placed in the inferonasal quadrant, five implants were placed in the inferotemporal quadrant and the remaining ten implants in the superonasal quadrant. 4-0 silk sutures were used under two rectus muscles to rotate and fix the eye. The piggyback implant was rotated so that its tube was toward the quadrant containing the original implant. The edge of the sequential plate was fixed to the sclera 8–10 mm posterior to the limbus between the rectus muscles with two 6-0 polyester (Mersilene, Ethicon) sutures through the two anterior holes. A 6-0 polyglactin (Vicryl Rapide, Ethicon) ligature, which absorbs approximately in 2 to 4 weeks, was used in all implants around the tube. Balanced salt solution was irrigated through the Molteno tube to confirm tube ligation status after ligature placement.

The conjunctival flap was carefully dissected from the fibrotic bleb capsule wall. The tube of the piggyback implant was placed under the rectus muscle and inserted into the existing bleb through the fibrotic capsule. Before the capsule wall penetration a clear corneal paracentesis was performed with a microsharp blade and sodium hyaluronate solution was injected into the anterior chamber to prevent a flat anterior chamber. The tube was cut with the bevel downward to extend about 6–7 mm into the bleb cavity through a 23-gauge puncture and fixed to the episclera with one 8-0 silk (Virgin silk, B. Braun Melsungen AG, Melsungen, Germany) suture. Another suture was placed near the region where the tube goes through the bleb fibrous wall to tighten the tube track.

The conjunctival incisions were closed with an interrupted 8-0 silk suture. If the eye had become hypotonic after removal of viscoelastic material, a balanced salt solution was injected into the anterior chamber through the previously placed paracentesis tract. The postoperative medical regimen included a combination of topical antibiotics and corticosteroids five times daily for the first week, with subsequent tapering based on intraocular inflammation during the next 4–5 weeks. The antiglaucoma medication was used as needed until the tube opened. 5-fluorouracil and mitomycin C were not used in any patient.

Comparisons were made using the Wilcoxon signed-rank test for continuous data between the eyes before and after sequential GDI procedure. Conventional methods and Kaplan–Meier analysis were used to determine the surgical outcome. Surgical success was defined as IOP < 21 mm Hg with at least a 30% reduction in IOP from baseline on two consecutive follow-up visits, IOP > 5 mm Hg on two consecutive follow-up visits and neither reoperation of glaucoma nor loss of light perception vision. All patients who met these criteria and were not on supplemental antiglaucoma therapy were considered complete successes. Patients who had succeeded but required supplemental antiglaucoma medication were defined as qualified successes. Cataracts were considered to have progressed if there was loss of 2 or more lines of Snellen best corrected visual acuity (BCVA) attributed to cataract at the last follow-up visit, or if cataract surgery had been carried out. The study met the criteria set by the local ethical review board of the institution. The research was performed according to the Declaration of Helsinki. Statistical analyses were performed using SSPS version 21.0 for Windows (IBM, Armonk, NY, USA).

Results

Demographic and ocular characteristics are presented in Table 1. The mean ± SD baseline IOP before sequential

GDI was 29.2 ± 5.2 mm Hg, and the mean IOP at the last follow-up visit was 17.3 ± 3.4 mm Hg, with a mean pressure drop of 39.4 ± 10.4% ($P < 0.001$). The mean follow-up time from piggyback procedure to the last visit was 16.6 ± 6.8 (range 12–35) months and the mean duration between the previous GDI and the piggyback implant was 53.6 ± 45.3 (range 4–121) months.

On postoperative day 1, the IOP ranged from 6 to 42 mm Hg with a mean value of 24.1 ± 10.9 mm Hg. Preoperative and postoperative mean number of antiglaucoma medications are shown in Figure 1 and mean IOPs in Figure 2 for the 12 months' follow-up period. The number of medications used to control IOP declined from a mean of 3.5 ± 1.1 preoperatively (range 2–5) to 1.6 ± 0.7 postoperatively (range 0–2; $P = 0.002$). The mean number of previous incisional intraocular surgeries was 2.4 ± 1.0. Table 2 describes the demographics of previous surgeries, piggyback implants, and complications after piggyback procedures.

The conventional success rate on the last visit was 81% (13 of 16 eyes). Ten (77%) of 13 eyes were classified as qualified successes and three eyes (23%) were complete successes. The Kaplan–Meier life-table analysis showed an 88% success rate after 12 months of follow-up (Figure 3). The Snellen BCVA remained within 1 line of the preoperative level or improved in 14 (87.5%) of the

Table 1 Demographic characteristics of 16 eyes of 14 study patients

Patient no.	*Eye*	*Age (years)*	*Glaucoma diagnosis*	*Previous GDI type (number)*	*Previous GDI location*	*Baseline IOP (mm Hg)*	*Final IOP (mm Hg)*	*% IOP reduction*
1	Right	19	Uveitis	Molteno (2)	ST, IT	38	18	52
2	Right	64	POAG	Molteno3 (1)	ST	21	12	42
2	Left	64	POAG	Molteno3 (1)	ST	23	12	47
3	Left	67	Uveitis	Molteno3 (1)	ST	20	14	30
4	Left	60	Pigment	Moleno3 (1)	ST	35	18	48
5	Left	81	PXFG	Ahmed (1)	ST	32	20	37
6	Left	13	Infantile	Molteno (1)	ST	32	16	50
6	Right	13	Infantile	Ahmed (1)	ST	28	17	39
7	Left	14	Juvenile	Molteno (1)	ST	32	22	31
8	Left	74	POAG	Molteno3 (1)	ST	34	12	64
9	Right	24	Uveitis	Baerveldt (1), Molteno (1)	ST, IN	28	18	35
10	Right	55	Uveitis	Molteno (1)	ST	32	20	37
11	Left	17	Uveitis	Molteno (1)	ST	30	20	33
12	Left	67	PXFG	Baerveldt (1) Molteno (1)	ST, IN	22	16	27
13	Right	72	POAG	Molteno3 (1)	ST	30	20	33
14	Left	78	POAG	Molteno3 (1)	ST	30	22	26

Abbreviations: GDI, glaucoma drainage implant; IN, inferonasal quadrant; IOP, intraocular pressure; IT, inferotemporal quadrant; POAG, primary open-angle glaucoma; PXFG, pseudoexfoliative glaucoma; ST, superotemporal quadrant.

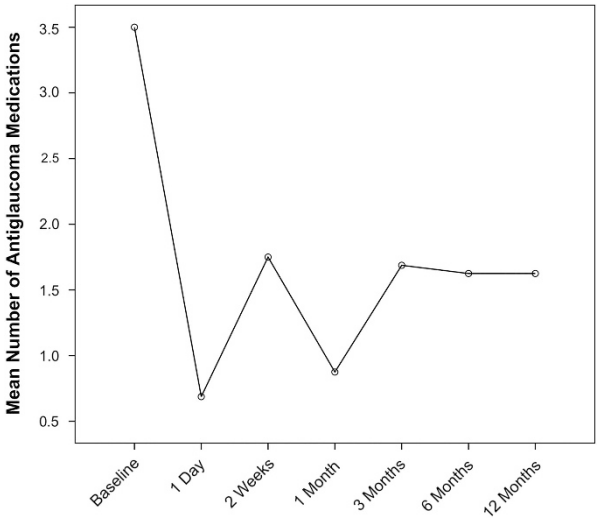

Figure 1 Mean number of antiglaucoma medications of 16 eyes (14 patients) at baseline and over the 12 months' time.

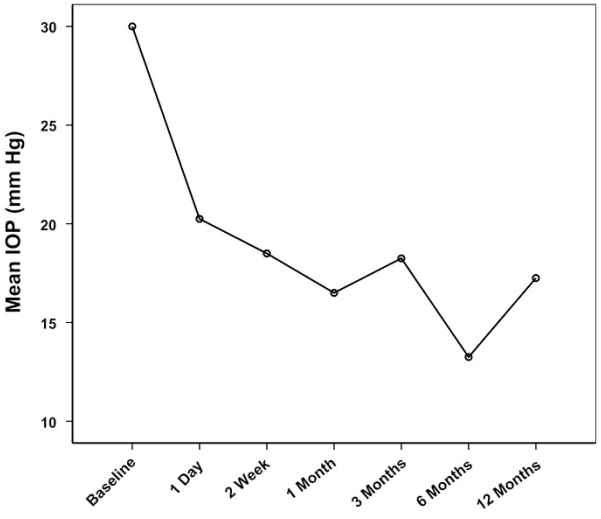

Figure 2 Mean intraocular pressure (IOP) of 16 eyes (14 patients) at baseline and over the 12 months' time.

Table 2 Ocular and piggyback glaucoma drainage implant characteristics and complications in 16 eyes of 14 study patients

Patient no.	*Lens*	*PIOS*	*Piggyback implant type*	*Piggyback location*	*Time 1 (months)*	*Time 2 (months)*	*Complication*
1	IOL	3	Molteno	IN	46	27	None
2	IOL	3	Molteno	SN	6	29	None
2	IOL	2	Molteno	SN	9	18	None
3	IOL	3	Molteno	IT	7	15	None
4	Phakic	1	Molteno	SN	4	24	Uveitis, cataract
5	IOL	3	Molteno	IT	45	14	Worsened pre-existing PBK
6	Phakic	2	Molteno	SN	108	15	None
6	Phakic	2	Molteno	SN	121	13	None
7	Phakic	1	Molteno	SN	96	13	None
8	Phakic	1	Molteno	SN	7	13	Flat anterior chamber, choroidal detachment
9	IOL	3	Molteno	SN	37	12	Diplopia
10	IOL	3	Molteno	SN	80	12	None
11	Phakic	1	Molteno	IT	105	12	None
12	IOL	4	Molteno	IT	120	12	None
13	IOL	3	Molteno	SN	61	12	None
14	IOL	3	Molteno	IT	6	12	None

Abbreviations: IN, inferonasal quadrant; IOL, intraocular lens; IT, inferotemporal quadrant; PBK, pseudophakic bullous keratopathy; PIOS, prior intraocular surgery; SN, superonasal quadrant.
Time 1, time between last previous GDI and piggyback implant.
Time 2, time from piggyback GDI to last visit.

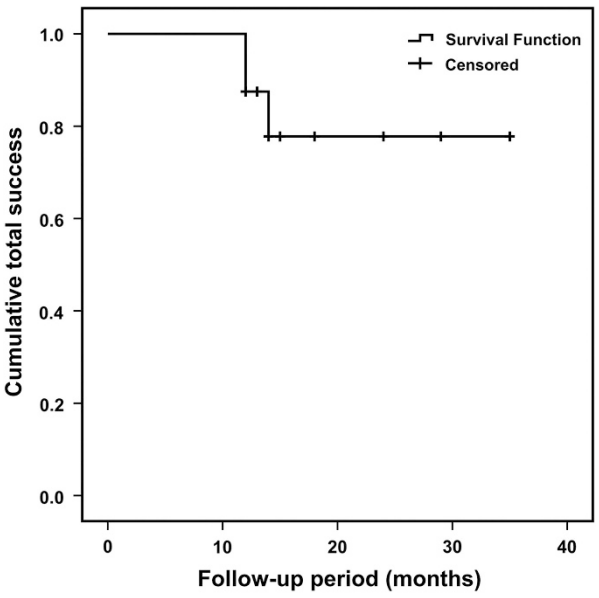

Figure 3 Kaplan–Meier survival curve after piggyback glaucoma drainage implantation for 16 eyes of 14 patients with uncontrolled glaucoma. Surgical success was defined as IOP <21 mm Hg with at least a 30% reduction in IOP from baseline on two consecutive follow-up visits, IOP >5 mm Hg on two consecutive follow-up visits, neither reoperation of glaucoma nor loss of light perception vision.

16 eyes studied during the follow-up period. The mean $\pm$ SD preoperative BCVA was 0.2 ± 0.2 logMAR (Snellen equivalent 6/9.5), compared with 0.3 ± 0.3 logMAR postoperatively (Snellen equivalent 6/12; $P = 0.497$).

Complications

No intraoperative complications were present in any study eyes. A total of 6 postoperative complications were documented in four eyes (25%; Table 2). There was a loss of ≥ 2 lines of Snellen BCVA in two eyes (12.5%), the reasons being advancing lens opacity (one eye) and worsening of pre-existing pseudophakic bullous keratopathy (one eye). The patient with cataract progression underwent phacoemulsification with intraocular lens during the follow-up.

In one patient (patient 7), the IOP rose from 32 to 42 mm Hg owing to inadvertent discontinuation of the antiglaucoma medication on the first postoperative day. This patient was considered a failure owing to a high final IOP despite the maximal tolerated antiglaucoma medications. Other reasons for failure were $<30\%$ IOP reduction in one eye (patient 12) and hypertension in one eye (patient 14). No evidence of marked peritubular filtration under the conjunctiva was present in any of the eyes. The surgical site was Seidel negative in all eyes. After the tube opening, one eye presented with a flat anterior chamber and choroidal detachment. One patient suffered diplopia during the first 2 months but this proved only transient. All ligation sutures around the tube of the piggyback implant dissolved spontaneously between the second and fifth postoperative weeks. None of the study patients required additional surgery due to complications.

Discussion

Excessive postoperative scarring around the implant plate is the main reason why a GDI fails to achieve the target IOP. Capsule excision after GDI surgery might offer a treatment alternative for better IOP control in these eyes. However, capsule excision has been reported to control the IOP at the last visit in only 50% of eyes.[8] Other options might be needling of the bleb with or without antimetabolites, cyclophotocoagulation (CPC) or sequential GDI. The success rate of needling is within the same range as the success of capsule excision.[9] CPC has usually been reserved for patients with little hope of maintaining vision.[10]

Sequential GDI is one treatment option before CPC in eyes with useful vision. The present study is the first clinical investigation to show that sequential GDI implantation in piggyback manner seems to provide significant IOP lowering with minimal complications in eyes with inadequate IOP control following a primary GDI. The possibility of converting a single-plate GDI into a two-plate system offers reasonable safety. The piggyback procedure resulted in a 39.4% reduction in IOP from the baseline IOP. This is comparable to an earlier report with sequential GDI not inserted in piggyback manner in refractory glaucoma (44.1%).[5] The success rate in the piggyback GDI life-table at 12 months was a little lower than that for sequential glaucoma implants not inserted in piggyback fashion (88% *vs* 92.9%, respectively).[5] The criteria for success and failure were not, however, directly comparable.

To the best of my knowledge, the name 'piggyback procedure' in GDI surgery was first used and the surgical technique itself described by Anthony C. B. Molteno ('Adding extra drainage some time after insertion of a Molteno glaucoma drainage device, Molteno Glaucoma Drainage Devices, The Molteno 'Piggy-Back' Procedure surgical instructions', 2010. Available at: http://www.molteno.com/information/glaucoma-drainage-devices/faq/extending-single-plate-implants). There were some differences in surgical technique between the present study and that described by Molteno on the website. In the present study the connecting tube was inserted under the rectus muscle and fixed to the surface of the bleb capsule and the episclera to avoid the tube involuntarily migrating away from the bleb cavity. In addition, a 23-gauge needle was used in the present study instead of a 22-gauge needle to penetrate the primary GDI bleb wall. Also, viscoelastic material was used in the present study to maintain IOP during the connecting tube insertion.

Susanna[11] introduced a modification of the single-plate Molteno implant to convert it into a two-plate system. However, no clinical data on the use of this implant modification in sequential GDI implantation is available so far. In addition, there are two models commercially available to increase the drainage area of an existing implant (Model FX4, Model B4, New World Medical Inc., Rancho Cucamonga, CA, USA). In my opinion, the tubes of both models are too short to use in piggyback fashion with the present surgical technique. I prefer the single-plate Molteno because of its ideal size, round profile, the extra suture holes in the episcleral plate, and the long tube option, which makes it easy and safe to piggyback, especially in the superonasal quadrant.

GDI has been reported to increase the influx of oxidative, apoptotic and inflammatory proteins in the aqueous humor, which could cause corneal endothelial damage.[12] Central corneal endothelial cell density (CCED) has been found to decrease with time after GDI surgery.[13] The same study also showed that the number of previous operations is related to a decrease in CCED. Corneal decompensation following GDI surgery has been reported to be in the range 5–27%.[7,14,15]

Corneal decompensation was a frequent occurrence in the study of sequential tube shunts by Burgoyne *et al*.[2] In their study, 10 of 22 patients (45.5%) experienced new onset bullous keratopathy or had worsening of pre-existing pseudophakic keratopathy. One study, comparing GDI bleb revision with an additional GDI procedure after failed GDI surgery found corneal edema to be a common complication, especially in the additional tube group.[4] Another study reported that progressive corneal decompensation occurred in 7 of 43 eyes (16.3%) following second tube implants.[5] However, in the latter study nearly 50% of the sequential GDI tubes were placed in the sulcus or vitreous cavity instead of the angle insertion.

In this study, the corneal decompensation rate (8.3%) was lower than in previous reports. However, the power of the present study to detect incidence rates of complications was limited by the small number of eyes. It is difficult to determine whether the worsening of pre-existing bullous keratopathy in one eye was due to intraocular lens, glaucoma with high IOP spikes, or the piggyback procedure itself. However, it is reasonable to assume that the piggyback implant did not increase the risk of tube–corneal touch problems, because no extra tube was needed in the anterior chamber.

Another late complication after GDI surgery is erosion of the tube through the conjunctiva. Reported estimates of the prevalence of this complication range between 3 and 5%.[7,15,16]

In most cases, tube erosion was seen in the limbus area of the bulbus. Therefore, inserting the sequential GDI in piggyback fashion might be expected to reduce this risk. There were no tube erosions among the study patients during the mean follow-up of 16.1 months.

A potential problem of piggyback implantation is the leak of aqueous humor around the external surface of the tube. Presumably, enough aqueous humor could drain out of the filtration bleb of the primary GDI via the tube track to form a temporary filter and cause early onset hypotony. To prevent immediate postoperative hypotony one suture was placed in lamellar manner through the surface of the fibrous capsule to form a watertight seal between the tube and the capsule. None of the study eyes faced early or late onset hypotony (≤5 mm Hg), although it is possible that hypotony may have developed and resolved between follow-up visits, especially in one eye with a choroidal effusion.

In conclusion, I have successfully used the piggyback technique in all cases where extra drainage was needed after previous GDI surgery. The limitations of this study are its retrospective design and small number of study patients. Further research is needed to determine the long-term success of this procedure. However, the piggyback procedure seems to be very effective in lowering IOP with minimal complications in glaucoma eyes with useful vision in patients in whom an initial GDI has failed to control IOP.

Summary

What was known before

- Insertion of a second glaucoma drainage implant (GDI) offers an alternative in glaucoma eyes where intraocular pressure (IOP) remains uncontrolled despite the primary GDI.
- Previous reports have found corneal decompensation to be the main complication following a second GDI procedure.

What this study adds

- A second GDI is possible to insert so that its tube is towards the primary device and is placed into the bleb of the primary implant that is, in piggyback manner.
- The piggyback procedure seems to be very effective in lowering IOP with minimal complications in glaucoma eyes with useful vision in patients in whom an initial GDI has failed to control IOP.
- It is reasonable to assume that the piggyback implant did not increase the risk of tube–corneal touch problems, because no extra tube was needed in the anterior chamber.

Conflict of interest

The author declares no conflict of interest.

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