Long-term Follow-up of Traumatic Glaucoma Treated with Molteno Implants

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Purpose: To determine the long-term outcomes of patients with traumatic glaucoma treated with Molteno implants at Dunedin Hospital, New Zealand.

Design: Prospective, noncomparative, interventional case series.

Participants: Thirty-eight patients with traumatic glaucoma and with a mean follow-up of 10.9 years.

Intervention: Insertion of Molteno implant.

Main Outcome Measures: Intraocular pressure (IOP) and intraocular pressure-related surgical interventions after Molteno implant insertion.

Results: Insertion of a Molteno implant controlled the IOP at 21 mmHg or less (with or without hypotensive medication) with a probability of 0.80 (95% confidence interval [CI], 0.66, 0.93) at 5 years and 0.72 (95% CI, 0.56, 0.88) at 10 years. At final follow-up, intraocular pressure was controlled solely with the implant in 26 cases and controlled with the addition of hypotensive medication in three cases, whereas nine eyes were failures. Eleven patients (29%) underwent intervention for implant repositioning or tube orifice blockage. Thirty-four double- and six single-plate Molteno implants were inserted. Two patients had implants replaced. Seventy-nine percent became aphakic or pseudophakic from their trauma before or at the time of Molteno implant insertion. There were no exclusions resulting from extensive ocular damage.

Conclusions: Insertion of Molteno implants in traumatic glaucoma produced intraocular pressure control at long-term follow-up in 76% of cases. *Ophthalmology 2001;108:1796–1800* © *2001 by the American Academy of Ophthalmology.*

Serious elevation of intraocular pressure (IOP) after trauma is the result of functional impairment of the aqueous outflow pathways. With blunt injury, the typical sequence of events is an initial tearing of the angle structures, leading to angle recession with stretching and tearing of the trabecular tissue (contusion angle injury), which is frequently associated with intraocular bleeding and inflammation and results in scarring and permanent reduction in the facility of outflow, the result of which is chronic open-angle traumatic glaucoma. Chronic closed-angle traumatic glaucoma may result from penetrating eye injuries caused by sharp objects or through traumatic angle closure as a result of rupture of the zonule, disruption of the lens, or subluxation of the lens resulting in pupil block. Closed trauma that is sufficiently severe to produce glaucoma typically causes damage to the lens, zonule, peripheral retina, choroid, and macula. In the case of penetrating trauma, frequently there is also damage leading to decompensation of the cornea.

The risks associated with traumatic glaucoma can be reduced by surgical repair of penetrating injuries combined with measures to prevent angle closure through pupil block and treatment of hyphema and posttraumatic inflammation. However, when glaucoma does develop, the outlook for trabeculectomy and other drainage operations is relatively unfavorable because the previous trauma has made many patients aphakic, and the young age of the patients produces a strong tendency for blebs to scar down and fail. Although the results of trabeculectomy can, to some extent, be improved by the use of cytostatic agents, these have the serious disadvantage of tending to produce dangerously thin blebs in patients who have a long expectation of life.

This communication describes the long-term results of cases of posttraumatic glaucoma treated by Molteno implants at Dunedin Hospital from 1978 to 1998.

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Subjects and Methods

All patients who had a Molteno implant inserted for traumatic glaucoma at Dunedin Hospital between 1978 and 1998 were identified from the computerized database of the Otago Glaucoma Surgery Outcome Study. Surgeries were performed by ophthalmologists or supervised residents in training. There were no exclusions on the basis of extensive ocular damage. A case note review of these eyes was then performed. Data were collected from both clinical notes and the computer database. Surviving patients were recalled for clinical evaluation, which was carried out at Dunedin Hospital, except for one patient, whose review took place in Auckland. Consent for data retrieval was obtained from the Ethics Committee of the Regional Health Authority.

The following data were collected and analyzed.

1. Patient demographics and status of eyes. Data recorded included patient age, gender, type of injury, associated ocular damage, medical treatment, and surgical interventions between trauma and insertion of Molteno implant.
2. Intraocular pressure. The preoperative IOP for each eye was taken as the mean IOP in the month before surgery. After surgery, IOP was taken as the mean for each postoperative year. The IOP was measured using a Haag-Streit Goldmann applanation tonometer mounted on a slit lamp. Medications used were recorded at each visit. In this paper, "control" was defined as a mean IOP of 21 mmHg or less while the patient took no hypotensive medication, and "medical control" was defined as a mean IOP of 21 mmHg or less while the patient took hypotensive medication. "Failure" was defined as a mean IOP of more than 21 mmHg, phthisis, or enucleation.
3. Visual acuity. The preoperative visual acuity for each patient was the best-corrected visual acuity recorded in the month before surgery. The postoperative visual acuity was the best-corrected visual acuity for each postoperative year.
4. Fields and vertical cup-to-disc ratios. Until 1988, all visual fields were plotted manually on a Goldmann perimeter (Haag-Streit AG, Koniz, Switzerland). From 1988 to 1992, an automated Humphrey static perimeter (Humphrey Instruments, Dublin, CA) was used predominantly, and after 1992, the Medmont (Medmont Pty Ltd, Victoria, Australia) automated static perimeter was used in most cases. Visual fields were graded into one of five equal categories of percentage of field remaining. Field loss was defined when subsequent fields demonstrated a lessened category of field remaining. Cup-to-disc ratios were recorded photographically or visually, as the state of the media permitted.
5. Control of bleb fibrosis. The signs indicating a need to control bleb fibrosis were vigorous capillary dilation with edema of the bleb wall, Tenon's cyst formation and rise in IOP to more than 20 mmHg. When necessary, bleb fibrosis was controlled by a systemic course of prednisone, a nonsteroidal antiinflammatory (flufenamic acid or diclofenac), and colchicine, which was tailored to the patient's individual needs.
6. Further surgical interventions after Molteno implant insertion.
7. Glaucoma medical treatment at final follow-up.

Surgical Procedure

Surgeries before 1983 were two-stage procedures, whereas after 1983, all procedures were one-stage using the polyglactin 910 (Vicryl) tie technique. The conjunctiva and Tenon's capsule were incised at the limbus and dissected posteriorly. Double-plate drains were sutured to the sclera with a 7-0 silk suture on either side of the insertion of the superior rectus, with single-plate drains being sutured to either the nasal or temporal side of the superior rectus insertion. In the two-stage procedure, in the first stage a partial thickness scleral flap was fashioned but the tube was left under the medial rectus until the second stage, when the tube was placed in the anterior chamber. In the one-stage procedure, a partial thickness scleral flap was lifted to the limbus, and a trimmed tube was placed into the anterior chamber via a paracentesis created with either a 22- or 23-gauge needle. In the cases in which it was used, a 5-0 Vicryl tie was then tied around the tube, and its occlusion was confirmed by attempting to irrigate balanced salt solution down the tube. The scleral flap was then replaced and sutured with 7-0 silk. In the two-stage procedure, after 4 to 6 weeks the conjunctiva and Tenon's capsule were lifted and the tube was retrieved from under the rectus muscle. It was then placed in the anterior chamber in the same manner as for the one-stage procedure. At the end of the procedure, a subconjunctival injection of corticosteroid and antibiotic was given. Routine postoperative corticosteroid and antibiotic drops were tapered over the subsequent postoperative weeks.

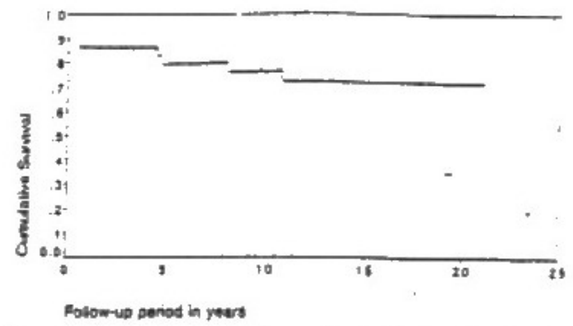

Figure 1. Kaplan–Meier curve showing the probability that the intraocular pressure will be controlled after insertion of Molteno implants.

Statistical Analysis

A Kaplan–Meier analysis was used to demonstrate survival curves for long-term success (Fig 1).

Results

Forty Molteno implants were inserted into 38 eyes. There were no implant-related infections. Four eyes became phthisical less than 6 months after surgery, of which one was enucleated. These patients had sustained major disruptive ocular injury and were considered failures. Four other eyes were enucleated for cosmetic reasons or pain. Two patients died, both within 5 years of last follow-up. Of the remaining 28 patients, 25 remain under active review and 3 were lost to follow-up after 0.3, 9.1, and 13.5 years.

Patient Demographics and Status of Eyes

The mean age at surgery was 39 years (range, 9–81 years), and the mean length of follow-up was 10.9 years (range, 0.4–20.7 years). There were 33 male and 5 female patients. Two patients died during follow-up. There were 22 right and 16 left eyes. Nineteen eyes had sustained blunt trauma and 19 had penetrating trauma. All 19 surgeries before 1983 were two-stage procedures, and all 21 surgeries after 1983 were one-stage procedures. All but six patients received double-plate implants; these six were at risk of ciliary body compromise (see Table 1). For the 31 patients for whom the data were available, the mean time between trauma and implant surgery was 10.2 years (range, 0.1–45 years; see Table 2). Thirty patients (79%) became aphakic or pseudophakic before or at the time of Molteno implant insertion. Most patients had widespread anterior segment trauma, including disruption to the lens and major iris root contusion injury. In those eyes that were still phakic,

Table 1. Number of Operations with Different Types of Molteno Implants Showing One- and Two-stage Surgical Technique

Surgical Technique	Implant Style	
	One Plate	*Two Plates*
One-stage technique	3	18
Two-stage technique	3	16

Table 2. Time between Trauma and Molteno Implant Insertion in Years

Time from Trauma to Implant (yrs)	Number (%), N = 31
0–1	12 (39%)
1–5	1 (3%)
6–10	5 (16%)
11–15	5 (16%)
16–20	3 (10%)
21–30	3 (10%)
31+	2 (7%)

gonioscopic angle recession was found in all cases. Twenty-seven patients had had no previous surgery for their traumatic glaucoma, whereas five had undergone one trabeculectomy, three patients underwent two trabeculectomies, and one patient underwent three trabeculectomies. Two patients underwent Krasnov's external sinusotomy. The mean number of preoperative glaucoma medications was 2 per patient (range, 0–4).

Intraocular Pressure Outcome

The mean preoperative IOP was 34.6 mmHg (standard deviation, 12.4 mmHg). This fell to 16.8 mmHg (standard deviation, 3.6 mmHg) in the first postoperative year and then varied between 12 and 16.2 mmHg over subsequent years of follow-up. Of the 38 eyes, control occurred in 26, medical control in 3, and failure in 9 (including 4 cases of early phthisis). Insertion of a Molteno implant controlled the IOP with or without hypotensive medication at 21 mmHg or less with a probability of 0.80 (95% confidence interval [CI], 0.66, 0.93) at 5 years and 0.72 (95% CI, 0.56, 0.88) at 10 years. There was no difference in outcome between the penetrating trauma group, with 14 of 19 achieving IOP control or medical control, compared with 15 of 19 in the blunt trauma group. Of the 35 eyes that did not have an implant removed, there were 6 single-plate and 29 double-plate implants. In the single-plate group, three eyes were deemed controlled: one was medically controlled and there were two failures. In the double-implant group, 22 eyes were deemed controlled: two were medically controlled and there were five failures.

Visual Acuity Outcome

Immediately before Molteno implant insertion, four patients had a visual acuity of 6/18 or better. This increased to 10 patients at final follow-up. Of the six patients whose vision improved, five had undergone either cataract extraction or penetrating keratoplasty either during or after Molteno implant insertion. The sixth case had significant hyphema at time of implant insertion, the subsequent resolution of which led to visual acuity improvement. Three patients remained with light perception only throughout follow-up.

Visual Field and Vertical Cup-to-Disc Ratio Outcome

It was not possible to perform field estimation either before or after surgery because of inadequate visual acuity in 14 patients. Fifteen patients showed no field loss during follow-up, whereas five lost field. In 11 patients, at either preoperative or postoperative assessment, vertical cup-to-disc ratio was not recorded because of inadequate fundus view. Nineteen patients showed no change in their vertical cup-to-disc ratio, and four demonstrated an increased vertical cup-to-disc ratio during follow-up. Of these four, two eyes lost visual field, one was recorded as having a stable field, and field data were not available on the fourth.

Control of Bleb Fibrosis

Nineteen patients took oral fibrosis suppression because of threatened bleb failure from overfibrosis. This consisted of daily treatment of up to 30 mg of prednisone, 0.9 mg colchicine, and a nonsteroidal antiinflammatory taken for a mean of 8 weeks (range, 4–29 weeks). One further patient was prescribed the above, but without the prednisone, for 8 weeks. There was no difference in outcome between those who took oral fibrosis suppressants and those who did not, with 15 of 19 in the treated group achieving IOP control or medical control compared with 14 of 19 in the untreated group.

Further Surgery

Twenty-three eyes required further surgery consisting of one or more procedure.

Implant Removal (Three Cases). Two eyes required second double-plate implants. In one case, the double implant was removed because of a corneal graft related to presumed fungal keratitis. There was no evidence of infection around the implant. However, for safety, the implant was removed while the infection was treated. The IOP rose and a second implant was inserted 1 year after the first, which once again controlled the IOP. Another patient had a second implant inserted after 20 years when vitreous blocked the tube of the implant. A longer silicone tube was needed, so the implant was removed and replaced. A third double implant was removed and not replaced in an eye that became phthisical 6 months after implantation.

Implant Manipulations (11 Cases). Eleven cases underwent position adjustment or orifice clearing of the intraocular portion of the drainage tubes. Four patients had their tubes reinserted into the posterior chamber via the pars plana, and four had their tubes trimmed and reinserted into the anterior chamber combined with penetrating keratoplasties. Three cases had vitrectomies to clear the inner opening of the tubes. In two of these patients, elevated IOP developed, in one after 6 years and in the other after 16 years of excellent IOP control. Slit-lamp examination demonstrated implant orifice occlusion by vitreous in both cases. Vitrectomy resulted in immediate return to the IOP levels preimplant orifice blockage in both.

Enucleations (Five Cases). Five eyes were enucleated. Two eyes were enucleated less than 6 months after implant insertion, one because of phthisis and the other because of pain despite an IOP of 21 mmHg or less. There were two further enucleations for pain at 5 and 9 years after implantation, both with intraocular pressures of 21 mmHg or less. A further eye was enucleated 8 years after implantation because the eye was enlarged and unsightly, and the IOP was 21 mmHg or less. These cases were considered failures, although the intraocular pressures were within normal limits.

Other Procedures (12 Cases). Two further patients had penetrating keratoplasty, five underwent cataract extraction, four of which had a lens implant, one had vitrectomy, three had squint surgery, and one had laser retinopexy to a peripheral retinal break.

Glaucoma Medical Treatment at Final Follow-up

The mean number of glaucoma medications required at final follow-up was 0.2 per patient (range, 0–2). Four of the 30 eyes (13%) that were neither phthisical nor enucleated were receiving glaucoma treatment at final follow-up. This included the three controls and one failure with an IOP of more than 21 mmHg.

Discussion

This noncomparative case series with long-term follow-up documents the outcome of the use of the Molteno implant in cases of traumatic glaucoma.

Traumatic glaucoma is often refractory to conventional treatment. Before implant insertion, patients in this series had undergone 11 drainage procedures and were taking a mean of just more than two glaucoma medical therapies, reflecting the lack of response to more conventional treatment. In this study, there was a mean of 10.2 years between trauma and implant surgery, which is typical of traumatic glaucoma. Traumatic angle recession is a risk factor for bleb failure after trabeculectomy.[1] The mean age at surgery was 39 years, so these cases were at higher risk of drainage failure because of their relative youth.[2]

Traumatic glaucoma encompasses a spectrum of disease. Opacification of the cornea and loss of the lens at the initial injury or subsequently reflects more significant damage. In this series, 30 of 38 eyes (79%) became aphakic and 4 eyes were lost to phthisis within 6 months of surgery (of which 1 was enucleated), representing the greater severity of the eye trauma in these cases. In addition, four further eyes were enucleated for pain control or appearance despite mean intraocular pressures of 21 mmHg or less between drain implantation and eye removal. These cases were considered failures. Of the nine failures, there was only one that was the result of an IOP of more than 21 mmHg, the remainder being the result of phthisis or enucleation.

Because of the greater chance of failure of primary trabeculectomy in traumatic glaucoma, it has been suggested that this type of glaucoma would be best managed by trabeculectomy combined with antimetabolites or the use of an artificial draining device. However, the use of antimetabolites with drainage surgery has a significant risk of late infection and consequent visual loss.[3]

Postimplant bleb fibrosis was threatened in 20 cases, so a course of systemic antifibrosis treatment[4] was administered for a mean of 8 weeks without significant complications. Locally administered antimetabolites were not used in this series.

Long-term follow-up studies of the outcome of trabeculectomy contain only a few cases of traumatic glaucoma. Mills[5] showed a 33% success rate (one of three cases), and Ridgway[6] demonstrated a 67% success rate (four of six cases) for primary trabeculectomy in cases of traumatic glaucoma.

Long-term follow-up studies of refractory glaucoma treated with Molteno implants contain patients with traumatic glaucoma. Freedman[7] showed success in one of two cases of traumatic glaucoma treated with single-plate Molteno implants at 12 months follow-up. Mermoud et al[8] treated 30 cases of traumatic glaucoma with single-plate Molteno implants, and 56% (17/30) of cases had control of their IOP at 21 mmHg or less with or without topical treatment at mean follow-up of 20 months. Mills et al's[9] study of Molteno drainage devices contained eight cases of traumatic glaucoma and demonstrated a 62% success rate at 44 months follow-up; however, the details of these cases are not given.

A retrospective, comparative, non–case-controlled study by Mermoud et al[10] of 87 cases of traumatic glaucoma compared trabeculectomy (47 cases; 53% success rate), trabeculectomy combined with antimetabolite (20 cases; 70% success rate), and Molteno implants (20 cases; 60% success rate). However, 74 patients had been excluded, 48 because of associated lens damage, 10 because of angle closure, and 16 because of less than 3 months of follow-up. Patients were defined on the gonioscopic finding of angle recession. In contrast, in our study[10] no exclusions were made. In the study by Mermoud et al, follow-up was for a mean of only 23 months and there was no statistically significant difference between the treatment groups beyond 6 months follow-up. Of the 87 procedures, 51 (59%) were successful. However, in this study, 3 of the 20 patients in the antimetabolite group experienced bleb-related infections some months after drainage, 1 of whom lost all sight. There are a number of factors that make comparison with this study difficult. The implants were single plate, and double-plate implants may have produced better IOP control. This was not a case-controlled trial, and significant differences exist between the groups. For example, in both the Molteno implant and augmented trabeculectomy group, almost half the patients had already undergone a trabeculectomy, making direct comparison with primary trabeculectomy unreliable. Total follow-up was for a mean of 23 months, but only for a mean of 8.8 months in the augmented trabeculectomy group.

The longest follow-up in these studies is less than 5 years, and we are unaware of any other long-term data.

Our case series documents the long-term follow-up of all cases of traumatic glaucoma treated with Molteno implants at Dunedin Hospital in Otago, New Zealand. No exclusions were made no matter how severe the glaucoma or concomitant ocular damage. In four cases, phthisis developed within 6 months of implant insertion, and these cases were considered failures. Of the remaining 34 cases, 4 were enucleated for appearance or pain relief. These 4 cases had mean intraocular pressures 21 mmHg or less before enucleation and were considered failures. Three cases were lost to follow-up, two of which were controlled by the implant and one medically controlled at last visit. In this series, the mean preoperative IOP fell from 33 mmHg to 14 mmHg at final follow-up, with a mean follow-up of 10.9 years, whereas the mean number of glaucoma medications was 2.0 before implant insertion and 0.2 at final follow-up.

At final follow-up, 26 cases had their intraocular pressures controlled taking no medication, 3 cases were taking hypotensive medication, and 9 cases failed.

Conclusions

This prospective, long-term study of the outcome of Molteno implants for the management of traumatic glaucoma showed 76% control of IOP at final follow-up. No patients were excluded because of the extent of ocular damage.

There were 11 IOP-related surgical interventions, most related to blockage or malposition of the internal end of the tube. Currently, modern vitrectomy techniques allow a more

thorough clearance of vitreous when dealing with cases of complex trauma. Therefore, these complications should be less likely to occur now than at the start of this series in 1978.

The documented acute IOP rise resulting from implant orifice blockage and IOP fall on clearance confirmed the anatomic role of the implant in draining aqueous from within the eye.

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