

Molteno3: Design and clinical evaluation

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August 5, 2005

Abstract

We describe the Molteno3 glaucoma implant, its design principles and the differences and similarities with the current generation of Molteno implant. Clinical results from 37 Molteno3 implant procedures for primary open angle glaucoma are compared with a control group of 33 pressure-ridge single plate Molteno implants. The results obtained in cases of primary open angle glaucoma, neovascular glaucoma and secondary glaucoma demonstrate that the Molteno3 implant is a safe and effective alternative to the currently available single plate Pressure Ridge Molteno Implant. Furthermore, the Molteno3 appears to have advantages with respect to reducing early postoperative shallowing of the anterior chamber and improved control of intraocular pressure.

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1 Introduction

The Molteno3 glaucoma drainage device is a development of the Molteno Pressure Ridge implant [1] which in turn was an earlier development of the single and double plate implants [2]. Molteno implants remain the benchmark against which other glaucoma drainage devices are measured [3].

Ongoing research into the factors responsible for the success of drainage surgery [4, 5, 6] and careful analysis of the pressure ridge technology pioneered by Molteno has suggested that a reduction in the height of the outer ridge, combined with improved geometry of the pressure ridge, would further reduce post operative hypotony (which is an important cause of early postoperative complications). In addition these changes would allow an increase in the plate area and simplify the insertion procedure.

2 Description of the Molteno3

The Molteno3 implant was developed as a result of this research. Its method of operation is identical to the previous Molteno implants [2, 1]. The implant comprises an injection molded polypropylene plate and silicone tube. This is unchanged from previous Molteno implants. The only difference in the Molteno3 implant is the *shape* of the episcleral plate. The following changes have been made (see Figure 1):

- It has a thinner and more flexible episcleral plate. The thinner plate allows the implant to sit snugly between and slightly underneath the adjacent extraocular muscles giving improved contact between the upper surface of the implant and the overlying Tenon's tissue.
- The implant is available in two sizes with drainage areas of 175 mm² and 230 mm².
- The height of the outer ridge has been reduced when compared to the earlier style implants, and the boundary shape of the implant has altered so that the larger plates fit snugly between the adjacent extraocular muscles without interfering with the action of the muscles.
- The outline of the pressure-ridge has been modified from triangular to elliptical (see Section 2.1). The pressure ridge principle had been applied in earlier implants [1]. The efficacy of the pressure ridge is expected to be enhanced by the lowering of the circumferential ridge.

These changes are designed to enhance the action of the pressure ridge of the implant in limiting post-operative hypotony and to reduce the intraocular pressure (IOP) to low normal levels in most types of glaucoma by providing sufficient drainage area on a single plate implant.

The surgical procedure for insertion of a Molteno3 implant is identical to previous Molteno implants. The lower outer ridge of the Molteno3 has the added benefit of easier insertion of the implant.

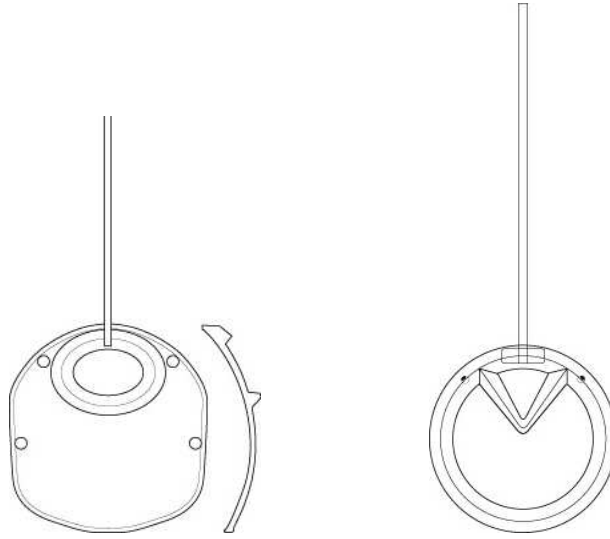


Figure 1: (a) A diagram comparing (a) the Molteno3 implant and (b) the single plate pressure ridge Molteno implant.

2.1 Pressure-ridge

A feature of the new Molteno3 is an elliptical pressure ridge on the upper surface of the plate of the implant around the outlet of the drainage tube. This ridge divides the surface of the implant into primary and secondary drainage areas (see Figure 2). It is designed so that when aqueous first drains through the tube it is restricted to the primary drainage area around the outlet of the tube by the pressure of the overlying tissue on the pressure ridge surrounding the outlet. When the IOP rises sufficiently aqueous lifts the tissues to allow aqueous to escape into the large secondary drainage area over the rest of the plate. This restriction of aqueous to the small primary drainage area in the immediate postoperative period not only reduces postoperative hypotony, it also restricts most of the fibroproliferative cellular response, and which is most vigorous during the 2-3 weeks following surgery, to the primary drainage area i.e. the area within the pressure ridge. Delaying drainage of aqueous into the main bleb cavity in this way results in a more favourable balance between the fibroproliferative and apoptotic fibrodegenerative tissue responses in the main bleb capsule. This produces a significantly thinner bleb capsule with better drainage of aqueous and correspondingly lower IOP.¹

2.2 Surgical technique

Delaying the drainage of aqueous can also be achieved by the Vicryl-tie technique in which the translimbal tube of the implant is tied off with an absorbable suture before inserting it into the anterior chamber. The suture takes around

¹This is the reason why so-called ‘valved’ implants, which allow the drainage of aqueous over the entire area of the plate before the tissues have healed around the plate, often produce thicker, more encapsulated blebs.

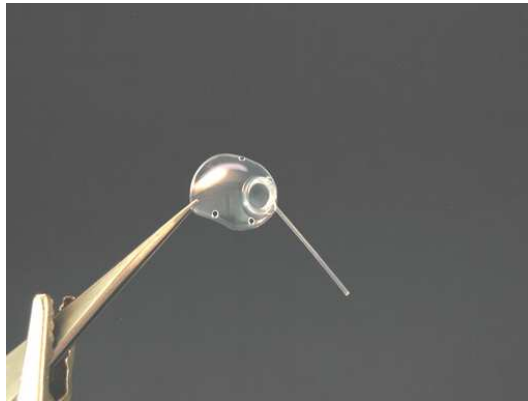


Figure 2: The Molteno3 implant.

4-5 weeks to dissolve before the tube opens and aqueous begins to drain into the thin bleb capsule that has formed around the plate. The presence of this thin layer limits hypotony as well as starting the apoptotic fibrodegenerative phase much earlier than would otherwise be the case. The result is a thinner more permeable capsule with better control of the IOP than is the case with immediate drainage. This Vicryl-tie technique is recommended for all cases that can tolerate a delay in the onset of drainage which includes most types of glaucoma apart from cases of neovascular glaucoma.

3 Clinical evaluation

Clinical evaluation of the Molteno3 was undertaken by ophthalmic surgeons at Dunedin Public Hospital. Written approval from the Regional Ethics Committee was obtained. As the materials and manufacturing processes were identical to previously approved implants manufactured at the same ISO 13485 accredited facility, laboratory testing of the materials was considered not to be necessary. As described in Section 2, the changes in the design features are restricted to modification to the geometry of the episcleral plate.

All glaucoma cases of primary glaucoma that receive Molteno implants at Dunedin Public Hospital have one or more additional risk factors. These include factors such as failed trabeculectomy, previous cataract or other intraocular operations, marked lens opacities, extensive field loss extending to fixation or very poor general health including dementia. Molteno implants are used as initial drainage operation in most cases of secondary glaucoma and neovascular glaucoma.

All glaucoma drainage procedures performed at Dunedin Public Hospital since 1977 are recorded and followed prospectively. This database, which currently includes more than 743 Molteno Implant and 872 trabeculectomy procedures, forms the basis for the Otago Glaucoma Surgery Outcome Study [5, 7, 8, 9, 10, 11]. Data for this study were extracted from this database.

Number of Cases	Type of glaucoma
24	Primary Open Angle
6	Neovascular
7	Secondary

Table 1: Diagnostic Categories of eyes receiving Molteno3 implants.

Group	N	Mean Age	Age Range	Male	Female
Molteno3	24	79.58	65 - 97	10	14
Control	23	79.26	63 - 93	15	8

Table 2: Demographic Characteristics: Molteno3 vs Control Group (POAG patients).

3.1 Case selection

Between 1 January 2004 and 30 June 2005 49 Molteno implant drainage procedures were performed at Dunedin Public Hospital. Molteno3 implants were inserted into all those cases which would previously have been drained by a single plate pressure ridge² Molteno implant. A total of 38 Molteno3 implants were inserted in this period³. This group of cases were used to evaluate the safety and efficacy of the Molteno3 implant, by comparison with a control group of similar cases (see Section 3.3). The demographics of the Molteno3 group are shown in Table 2.

The diagnostic categories of the Molteno3 cases are shown in Table 1. The secondary glaucoma cases comprise: Traumatic (1); uveitic (2); silicone (1); iris melanoma (1); aphakic (1) and secondary angle closure (1).

3.2 Molteno3 Implant selection

Twenty-two of the 24 cases of POAG received 175mm² Molteno3 implants, the remaining 2 received 230mm² Molteno3 implants. All 6 cases of neovascular glaucoma received 230mm² Molteno3s.

3.3 Control Group

For statistical purposes, the 24 primary open angle glaucoma (POAG) cases in the Molteno3 group are compared to a *control group* of 23 POAG cases. The 6 cases of neovascular glaucoma in the Molteno3 group are compared to a control group of 10 neovascular glaucomas. The 7 cases of secondary glaucoma are

The Control group comprised the 23 consecutive cases of POAG in the period 1st January 1999 to 31st December 2003 immediately prior to the introduction of the Molteno3 and the 10 consecutive cases of neovascular glaucoma treated by Pressure Ridge single plate Molteno implant in the period 1st January 1999 to 31st December, 2003. These cases were drawn from the departmental database,

²Molteno Ophthalmic catalogue number D1.

³The 11 cases which did not receive Molteno3 included 7 cases of buphthalmos or juvenile glaucoma which received double plate Pressure ridge implants, 1 neovascular glaucoma; 1 angle closure glaucoma; 1 aphakic glaucoma and 1 complex case of open angle glaucoma.

Description	Molteno3	Control
Hyphaema	5	6
Shallow AC - slight	3	0
Shallow AC - marked	0	2
Choroidal detachment	6	4
Iritis - mild	3	2

Table 3: Frequency of transient postoperative complications in cases of POAG.

an ongoing prospective database containing details of all cases undergoing glaucoma drainage surgery (including conventional drainage surgery, predominantly trabeculectomy, and Molteno implant) from 1977 up to the present.

3.4 Surgical technique

Preoperative management, surgical technique and postoperative management followed the standard protocols for the Otago Glaucoma Surgery Outcome Study [8].

In the Molteno3 POAG cases the onset of drainage was delayed for up to 4 weeks by occluding the tube with a vicryl-tie. In all 6 cases of neovascular glaucoma the Vicryl-tie technique was not used on the translimbal tube as immediate drainage of aqueous was considered imperative in these cases.

In all 23 cases of the POAG Control group drainage was delayed by Vicryl-tie. The Control neovascular group no Vicryl-tie was used on the translimbal tube.

4 Results

For the purposes of analysis cases of neovascular glaucoma which form a distinct group, are considered separately from cases of POAG as are cases of secondary glaucoma.

4.1 Primary open angle glaucoma

4.1.1 Postoperative Complications

Transient postoperative complications are shown in Table 3. The frequencies of these transient complications are similar in both groups.

Subsequent cataract extraction, which was to be expected as the presence of lens opacities was one of the indications for using implants, was performed in 4 Molteno3 cases and 2 of the controls and did not interfere with the control of the glaucoma.

In the control group a second implant to provide additional drainage was added in one case, in another an implant, the tube of which had been incorrectly inserted, became blocked by iris and was removed one week postoperatively.

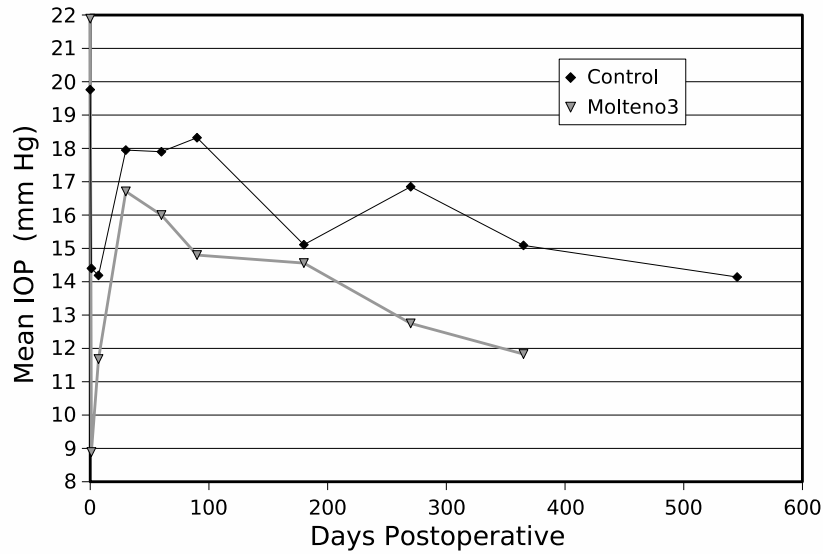


Figure 3: Post-operative IOP in cases of primary glaucoma.

4.1.2 Intraocular Pressure

The results (see Figure 3) show that the intraocular pressures (IOP) of cases treated with the new Molteno3 are consistently lower than those treated with the earlier design of implant (14.8 vs 18.3 mm Hg at 3 months, 14.6 vs 15.1 mm Hg at 6 months, 12.75 vs 16.8 mm Hg at 9 months and 11.83 vs 15.1 mm Hg at 12 months).

4.1.3 Hypotensive medication

The two groups are closely comparable with respect to medication use (see Figure 4). More cases and longer follow up are necessary to determine whether the two groups could be distinguished.

4.2 Neovascular glaucomas

There were small numbers of neovascular glaucomas in both groups. The results of draining cases of neovascular glaucoma are mixed and depend on the extent of the underlying vascular disease and the patient's general health. Insertion of implants in these cases is used to preserve residual vision where possible and to control pain in those cases where the eye is blind. Of the 6 cases treated by Molteno3 five followed central retinal vein occlusion and one was associated with diabetic retinopathy in a patient with end-stage renal failure. All cases presented acutely with grossly elevated IOP, painful eyes and severely reduced vision. Surgery was performed as an emergency in all cases with insertion of the implant without a Vicryl-tie. The postoperative course was smooth in all cases with transient shallowing of the anterior chamber in only one case. The

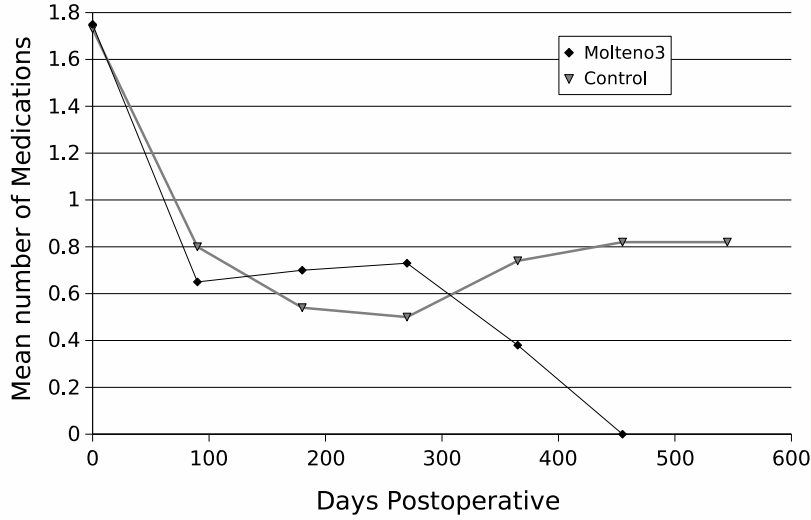


Figure 4: Hypotensive medication use in cases of primary glaucoma.

IOP controlled in 5 of the 6 cases. The exception was a case where medical treatment was discontinued when the eye lost light perception.

Of the 10 cases in the control group of neovascular glaucoma treated by Pressure Ridge single plate implants, 8 were associated with central retinal vein occlusion and 2 with diabetic retinopathy. Again, all cases presented acutely and surgery was performed as an emergency. The postoperative course was smooth in 5 of the 10 cases, transient shallowing of the anterior chamber occurred in 4 eyes and a flat anterior chamber in one eye. The IOP was controlled in 7 of the 10 eyes.

4.3 Secondary glaucomas

The results in this diverse group of secondary glaucomas are very promising. There were no transient postoperative complications. The IOP was controlled in all cases with a final mean IOP of 13 mm Hg (range 8-16 mm Hg). Only one case needed additional hypotensive medication postoperatively.

4.4 Adverse Incidents

No implant related adverse incidents occurred during this clinical evaluation.

5 Conclusions

The performance of the Molteno implant in high risk cases of primary glaucoma is substantially equivalent to the previous single plate Pressure Ridge Molteno implant. There was essentially no difference between the test and control groups with regard to mean age, age range and gender. The groups were equivalent in

preoperative use of hypotensive medication while the mean preoperative IOP was slightly higher in the Molteno3 than the control group.

The results to date suggest that in cases of primary open angle glaucoma the Molteno3 results in an IOP that is about 3 mm Hg lower than the earlier Pressure Ridge single plate Molteno implant at 3, 6, 9 and 12 months after operation. We conclude that the safety and efficacy of the Molteno3 implant in this group of cases is comparable to or better than the pressure-ridge single plate Molteno Implant.

The results in cases of neovascular glaucoma are promising in that there were proportionally fewer cases of shallowing of the anterior chamber, 1 of 6 compared to 5 of 10. While these numbers are too small to be statistically meaningful, the performance of the Molteno3 in this most demanding group is in the direction predicted and is very encouraging.

The results of Molteno3 in cases of secondary glaucoma have been uniformly good and are comparable to those reported in published studies [7, 4] of cases of secondary glaucoma treated by Molteno implants drawn from the Otago Glaucoma Surgery Outcome Study database. These results suggest that Molteno3 Implants can be safely used and are very effective in treating cases of secondary glaucoma.

Taken together the results obtained in cases of primary open angle glaucoma, neovascular glaucoma and secondary glaucoma demonstrate that the Molteno3 implant is a safe and effective alternative to the currently available single plate Pressure Ridge Molteno Implant. Furthermore, the Molteno3 appears to have advantages with respect to reducing early postoperative shallowing of the anterior chamber and improved control of intraocular pressure.

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