The Molteno Story

How glaucoma drainage devices were invented

A young registrar some 40 years ago embarked on what was to become his lifelong pursuit, to provide relief from the progressive and often blinding disease, glaucoma.

Driven because he couldn’t see the problem being too difficult, Professor Anthony Molteno says, “people were still going blind from glaucoma in the mid 1960’s... that seemed wrong. It seemed a simple problem, you’ve got pressure (in the eye) and you should be able to let it out. It shouldn’t be that people go blind from this.”

At the time Professor Molteno was working as a registrar at St John’s Hospital, Soweto, South Africa later transferring to Stellenbosch University in Cape Town after completing his studies.

ANTERIOR IMPLANT: THE RABBIT YEARS

What he thought should have been easy evolved into in-depth research, trial and error and the invention of the first successful draining implant.

This success depended on the unique combination of tube to drain aqueous from the eye, and an episcleral plate attached to the outer surface of the eye. This episcleral plate prevents blockage of the outer end of the tube by fibrous tissue and forms a robust drainage pocket (bleb) in the tissues covering the eye. Aqueous draining from the eye passes into the tissues of the bleb and from there passes into the bloodstream.

The first Molteno implants were placed in the tissues beneath the upper eyelid. These Anterior Implants were trialed initially on rabbits, one of which became a family pet and “lived happily in our backyard for 3 years”.

With the success of the rabbit implant an implant suitable for human eyes was based on the tube and plate design of the rabbit implant and a clinical trial was undertaken.

“At that stage the implants were used as a last resort on the most desperate cases of glaucoma.”

Professor Molteno’s first papers on the findings of the rabbit research and the clinical trial were published in 1969 in the British Journal of Ophthalmology.
“I don’t think I could have got as far as I have, without having made the implants myself.”

“The implants took a day each to make.”

“Having control over intraocular pressure was necessary in that day and age as many of my patients were rural and follow-up was often difficult.”

“Once we knew we had an effective regime for controlling bleb fibrosis, we now knew we could control glaucoma,”

“In some ways we had to wait for technology to catch up.”

**MAKING THE IMPLANT**

With limited options for materials (medical grade silicon and polypropylene were not yet available), Professor Molteno set to work creating his own implants.

“I don’t think I could have got as far as I have, without having made the implants myself.”

Professor Molteno persuaded a dental technician to make a mold of stainless steel, and then made the first implants of acrylic.

“The implants took a day each to make; I boiled the plastic for 6 hours with multiple changes of distilled water to ensure the plastic was inert and would not cause any severe reactions.”

After having established a suitable way of making implants Professor Molteno was able to use them in a wider range of cases. The implants controlled the IOP successfully, and in many cases without the need for pressure lowering medications.

“Having control over intraocular pressure was necessary in that day and age as many of my patients were rural and follow-up was often difficult.”

**ANTI-INFLAMMATORY MEDICATION**

With growing experience in using implants Professor Molteno found that while they were able to control IOP in a great number of patients, others, particularly younger fitter adults, were more difficult as they tended to produce more inflammation after surgery. This resulted in more fibrous tissue in the bleb over the implant, restricting drainage of aqueous from the eye.

For three years Professor Molteno trialed various combinations of anti-inflammatory medications to find a way of controlling inflammation post-surgery that would produce a thinner bleb capsule and relieve post-surgery inflammation.

The regime created used a combination of low dose medications, potent when combined, to produce a thin bleb over the plate which drained well and controlled the intraocular pressure without the need for glaucoma medication. This anti-inflammatory fibrosis suppression (AIFS) regime was given for six weeks post operatively.

“Once we knew we had an effective regime for controlling bleb fibrosis, we now knew we could control glaucoma,” he says.

**MOLTENO 2: LONG THIN TUBING 1973**

The Anterior Implant was technically very demanding to insert. So when silicon tubing became available the implant was modified to make the surgery easier.

“In some ways we had to wait for technology to catch up,” Professor Molteno says.
The plate was shifted back in the eye giving room for a larger plate. It was also safer for the patient.

Setting the plate back in the eye required a long thin tube to connect it to the anterior chamber and the availability of silicon tubing made this possible.

Professor Molteno had reservations about whether the thin tubing would block, but his reservations never eventuated and the second generation of Glaucoma Drainage Devices (GDDs) were invented.

**MODIFIED TECHNIQUE 1973**

As with anything, things do not always go as planned. Professor Molteno emphasises that the “errors are how we get it right, and have allowed us to progress to where we are today.”

One such error was a modification of the surgical technique to divert the aqueous away from the site of the bleb for the first six weeks after operation. The aim was to reduce the amount of aqueous entering the bleb and keep the pressure low allowing the tissue to heal over the plate and produce a thin walled bleb. After six weeks, when the full amount of aqueous was redirected into the bleb cavity the IOP rose rapidly to preoperative levels. This was totally unexpected and the technique was abandoned.

“It is only with recent advancements in cell biology that we now understand the factors responsible for the deposition and removal of scar tissue during bleb formation which explains why this technique was a failure.”

**POLITICAL DIFFICULTIES IN SOUTH AFRICA 1973-77**

The Apartheid years made it difficult to get work published or recognised in the international community. Professor Molteno had submitted an article describing his success in using implants to treat neovascular glaucoma. The paper was rejected. “I was sure they just didn’t believe me,” he says.

On a scheduled visit to Cape Town, Sir Stephen Miller, the editor of the British Journal of Ophthalmology, saw some of Professor Molteno’s patients. On observing the results of an implant, he was astounded, informing the implant patient that “anywhere else in the world you would have lost your eye.”

Sir Stephen Miller urged Professor Molteno to resubmit his paper on Neovascular Glaucoma, and it was published in the British Journal Of Medicine in October 1977.

**THE MOVE TO NEW ZEALAND 1977**

Prompted by the political situation in South Africa and wanting to extend his research, Professor Molteno and his family moved to New Zealand in 1977, settling their family in Dunedin.

The close proximity of the University and Dunedin Public Hospital together with the high incidence of glaucoma in Dunedin’s Scottish settlement provided excellent conditions for long-term study.
“I would not have been able to do the research without their support and the support of their families.”

As surgeon’s demand increased, “Even our children helped by cutting the tubing to exactly the right length,”

“Hypotony requires careful nursing and can produce serious complications.”

The two stage procedure “meant that we obtained much lower IOP and that fewer patients needed anti-inflammatory medication after surgery.”

“The results were gratifying.”

We “increased the area of the plates by linking plates together.”

“New Zealand has social medicine”, he says, “and this aided our research”.

“The people here are public spirited and community minded. By donating their eyes after death my glaucoma patients have helped advance our understanding and improve our treatment of the disease. I would not have been able to do the research without their support and the support of their families” he says.

For quite a few years and with an increasing number of surgeons around the world requesting the implants, the family made the implants from their own home. “Even our teenage children helped by cutting the tubing to exactly the right length,” Professor Molteno says.

Later, with help from a Dental Technician and with the use of polypropylene, (considered the best plastic of the time), production of the implants became easier.

2 STAGE PROCEDURE 1977

Using implants combined with anti-inflammatory medication in selected cases, Professor Molteno was able to control the IOP in the majority of cases, even the most severe and complex types of glaucoma.

There remained the problem of hypotony, that is, a period of excessive drainage that occasionally follows glaucoma surgery, especially if the eye has had several previous surgeries. “Hypotony requires careful nursing and can produce serious complications,” he said.

Professor Molteno solved this problem very neatly through using a 2-stage procedure, a modification of the surgical technique used to insert the implant. This technique divided the implant surgery into two separate operations. In the first operation the plate of the implant was attached to the eyeball and covered by the tissues. The tube of the implant was not inserted into the eye at this time but tucked away under a rectus muscle. Five to six weeks later in a second much shorter operation the free end of the tube was uncovered and inserted into the anterior chamber of the eye.

This technique gave the tissues time to heal around the plate of the implant and form a thin fibrous bleb capsule. When the tube was inserted into the eye at the second operation, this pre-formed bleb capsule offered sufficient resistance to the escape of aqueous to prevent hypotony.

Professor Molteno says, “an unexpected advantage of this technique was that we found that pre-forming the bleb capsule in this way reduced the amount of bleb scarring. This meant that we obtained much lower IOP and that fewer patients needed anti-inflammatory medication after surgery. The results were gratifying.”

MULTIPLE PLATES 1981

The 2-stage procedure gave Professor Molteno the chance to increase the area of the plates by linking plates together. He found that four plates were too many but one or two were excellent. This gave him the opportunity to select the ideal drainage area for different cases with younger, fitter patients...
“Again we had to wait until advancements were made in the knowledge of cell biology ... and that’s when everything fitted into place”.

“It soon became the procedure of choice.”

The tissues covered the plate acting as “biological valve.”

“The benefits of Molteno3 include a 20% reduction in estimated surgery time, reduced risk of hypotony, and improved long term control of intraocular pressure.”

“Different stages of the implant have produced improved scientific understanding”

generally needing a greater drainage area than the very elderly.

**ABSORBABLE POLYGLYCOLIC ACID SUTURES - THE VICRYL TIE 1986**

The 2-stage procedure was greatly simplified when absorbable polyglycolic acid sutures (for example, Vicryl) were invented. These sutures, when placed in the tissues dissolve after four weeks or so.

Professor Molteno found that instead of having to do two separate operations he could achieve the advantages of a 2-stage procedure in one operation by tying an absorbable suture around the tube of the implant (temporarily closing the tube) before inserting it into the eye. This allowed the tissues to heal around the implant for about 4 weeks before the suture dissolved and aqueous drained into the pre-formed bleb capsule.

While this technique was very successful they still didn’t understand why. “Again we had to wait until advances were made in the knowledge of cell biology to understand completely the formation of scar tissue around the bleb and that’s when everything fitted into place.”

“It soon became the procedure of choice among the majority of glaucoma surgeons,” said Professor Molteno.

**PRESSURE RIDGE IMPLANT 1990**

The Vicryl-tie technique was very successful in reducing post-operative hypotony and in providing a thin bleb that drained well in cases where the patient could tolerate a delay in the onset of drainage.

In eyes with neovascular glaucoma however, immediate drainage is vital if the eye is not to go blind. To prevent post-operative hypotony in these cases a subsidiary ridge was added to the upper surface of the plate, forming a small primary drainage area to receive the aqueous from the eye. The tissue covering the plate acted as a “biological valve” by pressing on the ridge and restricting the aqueous to this small area within the ridge until the pressure rose enough to lift the tissue off the plate allowing aqueous into the main bleb cavity.

**MOLTENO3**

Molteno3 is a refinement in the design of the current glaucoma drains. This is made possible through international advances in the understanding of cell biology and the findings from the past decade of research undertaken with Professor Molteno’s supervision, a near impossibility if it weren’t for the donation of eyes from community minded New Zealanders.

“Molteno3’s advanced technology includes a slightly larger plate and thinner design which makes it easier to insert on the surface of the eye.” Professor Molteno said.

Molteno3 offers substantial advantages to patients as well as to the surgeons implanting them.

“The benefits include an estimated 20% reduction in surgery time, reduced risk of hypotony, and improved long-term control of intraocular pressure”,

MOLTENO

Third Generation®
“It’s easy to put in, it knows its place.”

“An awful lot of medicine is knowing when to operate and when not to operate. The best medicine is long-term follow up.”

Demand for implants grew rapidly...

..when demand increased so much he could no longer make all the implants himself, the implant production was outsourced.

“You don’t learn anything from admiring your successes”

Professor Molteno said.

Professor Molteno has been monitoring the success of his drainage devices for over 30 years and he is confident that the third generation of devices will further increase success rates, and will be substantially easier to implant.

Twenty-seven Molteno3 devices have been implanted in patients so far, the first being in January 2004. The results to date show the implant is working very well and surgeons implanting the new Molteno3 have been delighted by how quick and easy it is to insert. At the RANZCO NZ Branch Conference held this month in Dunedin Professor Molteno explained the promising results received from initial clinical trial of Molteno3 implants showing reduced IOP and medication compared in a matched series of cases.

The Molteno3 glaucoma drain is scheduled for release in the second half of this year and selected surgeons around the world will be given Molteno3’s to implant in patients within the next few months.

REFLECTING

Having trained an average of one surgeon per year for the last 30 years, surgeons that have trained under Professor Molteno, can be found in most countries around the world.

A rather modest Professor Molteno said, “You don’t learn anything from admiring your successes, it’s the second sin of surgeons. You learn a lot from your failures if you can bring yourself to look honestly at them.”

“When things have gone unexpectedly like the failure of the modified technique, it sits in the back of your mind for years. Nearly 40 years later you know why, because technology has caught up.”

MOLTENO OPHTHALMIC LIMITED 1980

Molteno Ophthalmic Limited (MOLTENO) is a privately owned, limited liability company. The company was established in 1980 when Professor Molteno applied for and received a grant from the Development and Finance Corporation of New Zealand to patent the double plate form of the drain.

At this time Professor Molteno was supplying his glaucoma drains to colleagues in various parts of the world that he had worked with or who had heard of the drains and wanted to use them.

Demand for the implants grew rapidly and in 1986, when volumes increased so much he could no longer make all the implants himself, the implant
Tess Molteno became the driving force behind the company.

production was outsourced to a resourceful dental technician.

In 1992 with growing demand internationally for quality assurance in the manufacture of medical devices the company built a class 350 clean-room production facility on its present site conveniently close to both the University of Otago and Dunedin Public Hospital.

Professor Molteno’s wife Tess Molteno became the driving force behind the company, leaving the Professor to further pursue his life’s work of performing operations, teaching, and researching.

Molteno Ophthalmic Limited employs six dedicated staff to service a worldwide market, exporting up to 90% of their implants through a network of distributors and agents.

THE FUTURE

When asked of the future of Molteno Ophthalmic Ltd, Professor Molteno is optimistic that further advances can be made with the help of the New Zealand community in assisting research by donating their eyes. Their extensive database with a 97% follow-up rate is practically unheard of, and the largest database of implants to their knowledge in the world. This provides an excellent source of information for the future of glaucoma research.

Professor Molteno admits, “we have already improved the outlook for certain groups of patients enormously.” But he knows there is more to be done. “We haven’t solved old age. Most glaucomas are diseases of old age.”

For further information regarding Molteno please refer to www.molteno.com

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