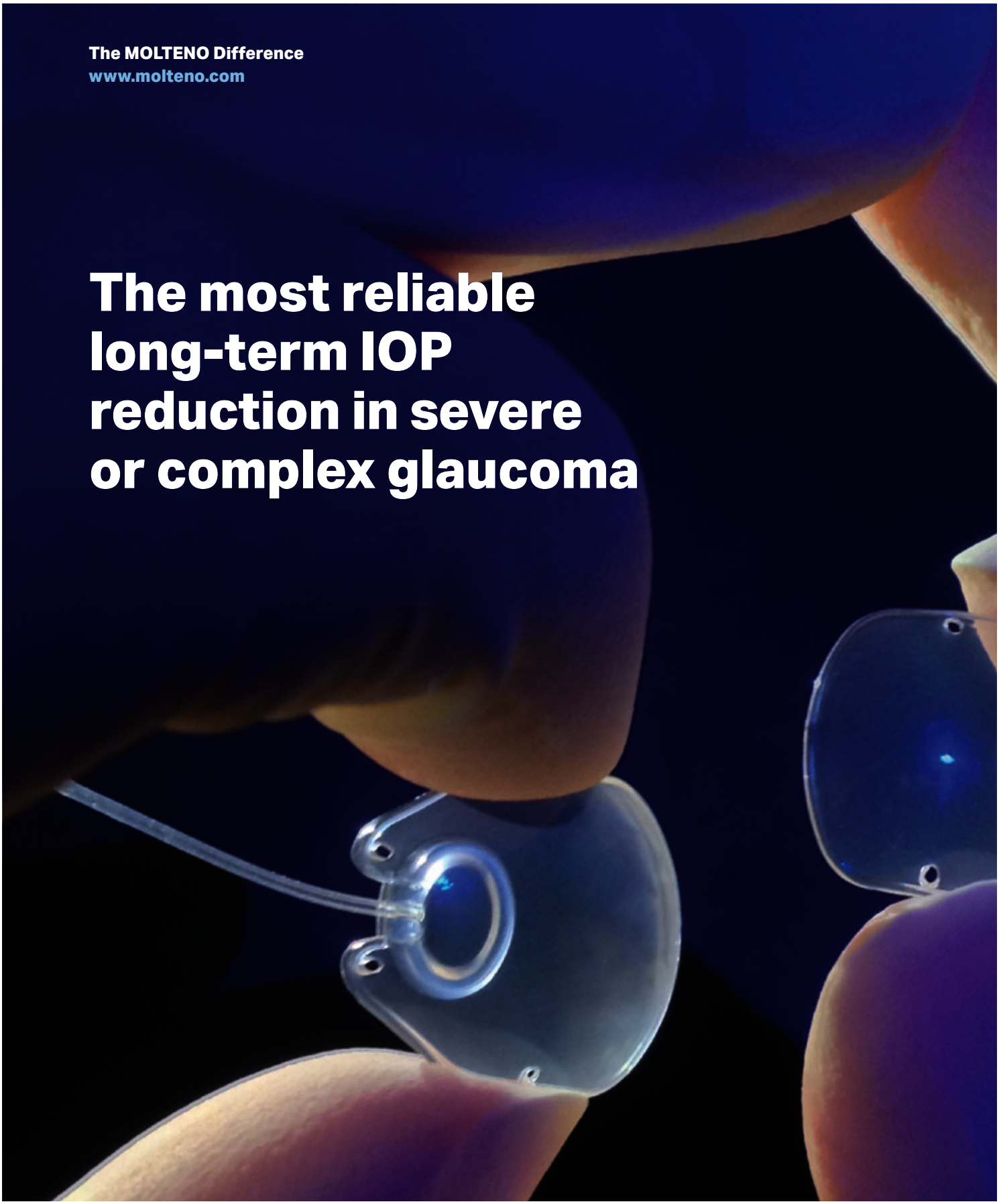
The MOLTENO Difference
www.molteno.com

The most reliable long-term IOP reduction in severe or complex glaucoma



MOLTENO 3®
S-Series Glaucoma Drainage Device

Focused on achieving the best patient outcomes

Photo: Wayan Helmy, John Fawcett Foundation

Helping surgeons save vision and improve lives

Anthony Molteno was training to be an ophthalmologist when he turned his inventive mind to the problem of uncontrolled glaucoma. It seemed a simple problem, "you've got pressure, you should be able to let it out," but the drainage procedures of the day frequently failed. The first breakthrough came when he implanted a small triangular plate to expand the scar tissue which was blocking early drainage procedures.

Research

The **Molteno** implant transformed the management of glaucoma. In 1977, in a continuing quest for the very best patient outcomes, Molteno established the Otago Glaucoma Surgery Outcome Study (OGSOS), a prospective series of more than 2000 **Molteno** implant and trabeculectomy cases and the longest running glaucoma implant study in the world. An arm of the OGSOS, the Bleb Structure Study, has contributed to understanding the cellular processes that lead to a life-long functioning bleb.

Implant development

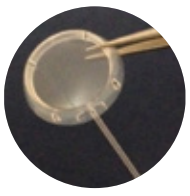
MOLTENO Ophthalmic Ltd started manufacturing the **Single Plate Molteno (S1)** implants in 1982. Ongoing research led to improvements in every aspect of the surgical management of glaucoma; including implant design, surgical technique and pre and post-operative medical management. Improvements addressed complications such as post-operative hypotony, bleb inflammation and bleb fibrosis. Complication rates fell and success rates increased.

Today

Advances in cell biology have led to a new understanding of tissue processes in the bleb. The **Molteno3** implant is a breakthrough based on this comprehensive understanding of bleb formation and fifty years of careful clinical research. The unique primary drainage area is designed to form a naturally thin bleb and ensure long-term IOP control. The versatile **Molteno3 S-Series** implants for severe and complex glaucoma are designed to last a lifetime.

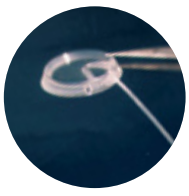
The longest and most comprehensively studied glaucoma implants in the world

1960s
Pioneering Trial Plate

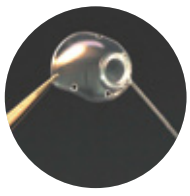


1970s
Single Plate

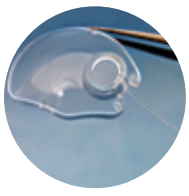
1980s
Double Plate



1990s
Pressure Ridge



2000s
Molteno3



2010s
Molteno3 S-Series

Trigger the natural process of apoptosis for reliable long-term IOP reduction

Nothing short of amazing!

Case example:

37 years after his Molteno implant surgery, Michael's IOP is controlled and his vision is stable.

Michael was a teenager in 1980 when he travelled to New Zealand with his father to try and save his remaining sight: right eye light perception, left eye 1/60.

Michael had been diagnosed with congenital glaucoma and each eye had a history of multiple previous procedures.

Michael's IOPs were intensively controlled with topical agents and oral acetazolamide (he remembers the tingling side effect), prior to implantation of bilateral **Molteno** double plate implants. After the surgery, he was treated with combination anti-inflammatory medication to optimize the outcome.

His vision stabilized at 6/45-6/60 in the left eye. Michael embarked on a career in business and is now a successful entrepreneur and on the board of numerous private companies and charitable foundations.

Michael (right) with his father

"The length of life of my left-eye drain is nothing short of amazing!"

Long-term IOP control: Establishing a functioning bleb for life

The **Molteno3** implant is designed to naturally modify the tissue reaction to aqueous and trigger anti-inflammatory and fibro-degenerative processes (apoptosis) in the bleb. These processes establish a life-long functioning bleb for reliable, long-term control of IOP. The **Molteno3** implant is the most effective and reliable treatment for patients with severe or complex glaucoma requiring drainage surgery.

Unique primary drainage area

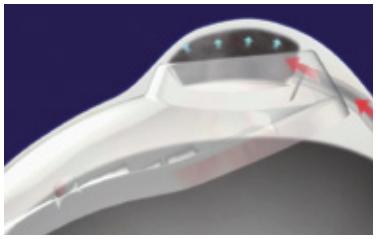


Fig 1 Initial bleb formation

Confines initial aqueous drainage to the small primary drainage area.

- Reduces post-operative hypotony
- Triggers earlier onset of apoptosis
- Apoptosing cells infuse the aqueous with potent anti-inflammatory and fibro-degenerative mediators
- When IOP rises, aqueous containing pro-apoptotic factors flows into the secondary drainage area (fig2)

Long-term permeable bleb

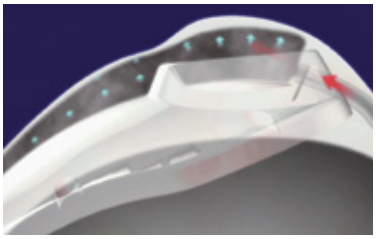


Fig 2 Final bleb formation

Effective permeable bleb from sequential bleb development.

- Deposition of collagen in the secondary drainage area is limited by pro-apoptotic factors present in the aqueous
- A dynamic equilibrium between deposition of collagen and apoptotic breakdown of collagen is established early in bleb development
- Naturally results in a thinner, more permeable bleb capsule

Lasting IOP control

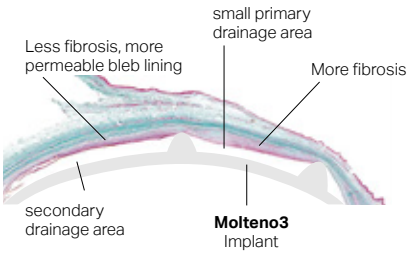
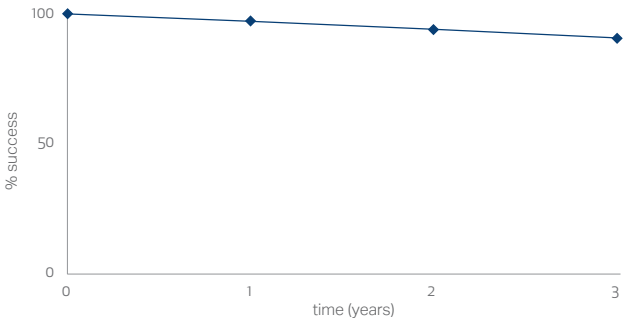


Fig 3 Functioning bleb

Effective implant for excellent, naturally long-lasting IOP control.

- The bleb is established 6-8 weeks after the onset of drainage
- Fibrous tissue degrades as quickly as it is deposited, allowing aqueous to disperse through the tissues for sustained IOP control
- Achieved by limiting the initial fibro-proliferative response and triggering beneficial cellular responses in the bleb

Excellent success rates



Success rates in 106 patients with POAG, PEXG, NVG or uveitic glaucoma who underwent **Molteno3** implantation as primary glaucoma surgery. Tube occlusion with *Vicryl* tie and scleral flap in all cases. No antimetabolites and no patch grafts were used. Failure defined as: IOP >21, ≤ 5mmHg or <20% reduction in IOP at 2 consecutive visits after 3 months' follow-up, reoperation for glaucoma or loss of light perception.[2]

[1] Ref: Molteno AC, Fucik M, Dempster AG, Bevin TH. Otago Glaucoma Surgery Outcome Study: factors controlling capsule fibrosis around Molteno implants with histopathological correlation. Ophthalmology. 2003 Nov 30;110(11):2198-206)

[2] Välimäki JO, Ylilehto AP. Molteno3 implantation as primary glaucoma surgery. Journal of Ophthalmology. 2014 Mar 11;2014.

Next generation design for faster, easier, safer implantation

Photo: Wayan Helmy, John Fawcett Foundation

One versatile implant for every indication

The **Molteno3 S-Series** distils more than fifty years of research into a single device, to produce long term IOP reduction designed to last the patient's lifetime. The implant is indicated for every type of glaucoma needing drainage surgery*. Studies show the **Molteno3 SS (185mm²)** to be as effective as larger devices[3] therefore, for easy stock management, all you need is **Molteno3 SS (185mm²)**.

Lowest plate profile

- Slides easily between tissue planes, tucks under adjacent extraocular muscles.
- Suitable for cases with limited space in the orbit.

Lower risk of diplopia

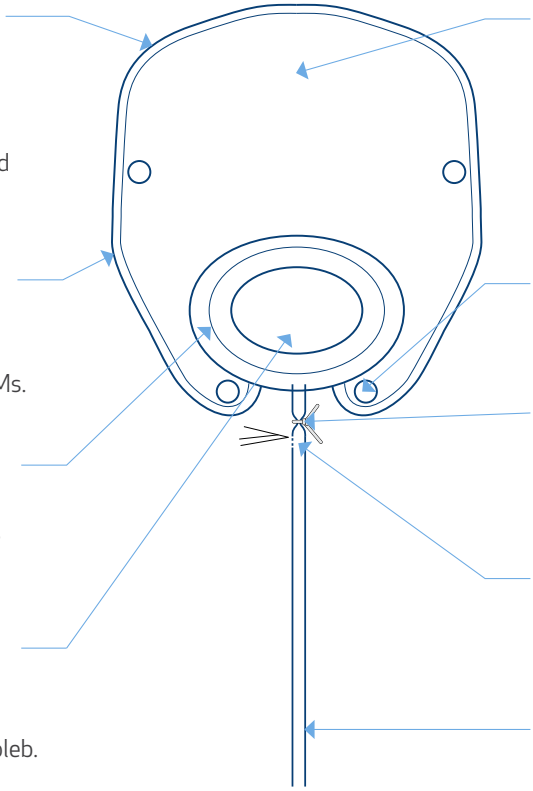
- No bulky implant under the muscles.
- Reduced manipulation of EOMs.

Rounded ridge, gentle on tissues

- Sub-Tenon's or supra-Tenon's placement.[5]

Unique primary drainage area

- Reduce hypotony.
- Forms a thinner, long-lasting bleb.



SS(185mm²) or SL (245mm²)

- Equivalent to **Molteno** double plate (266mm²) implants[4] and larger area competitor brand[3].
- Single quadrant surgery.
- Significantly reduced surgery time.

Accessible suture holes

- Fast, easy suturing.

Option of delayed drainage (with *Vicryl* tie)

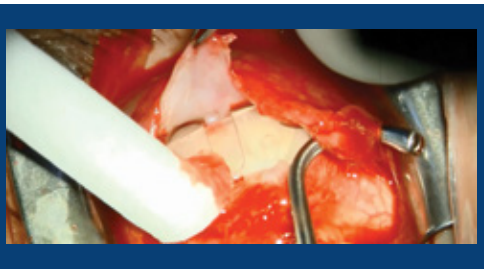
- Reduce hypotony and improve bleb function.

Option of relieving slit

- Control post-op IOP in cases with delayed drainage.

Silicone tube

- Trans-limbal or pars plana insertion.



Biological valve

The biological valve of the **Molteno3** implant resists blockage by cellular ingrowth, blood clot or cellular debris, reducing the need for further surgery.

Fig 4 Mechanical valve blocked by fibrous tissue

* Eyes ≥17mm axial length

[3] Patel SR, Silverman A, Patel S, Reiss, G. Comparison of surgical outcomes of the Molteno 185mm² and the 245mm² shunt: is there a difference? Unpublished data related to poster Patel SR, Silverman AL, Patel SS, Reiss GR. Comparison of surgical outcomes of the Molteno 185mm² and the Baerveldt 250mm²: is there a difference? 25th Annual Meeting of the American Glaucoma Society (AGS), Coronado, California. February 27, 2015.

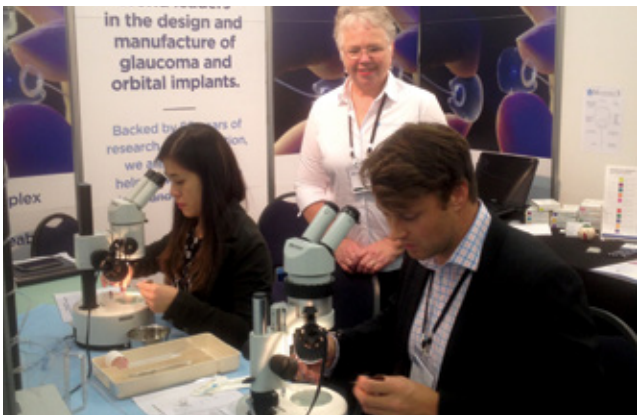
[4] Thompson AM, Molteno AC, Bevin TH, Herbison P. Otago glaucoma surgery outcome study: comparative results for the 175mm² Molteno3 and double-plate Molteno implants. JAMA Ophthalmol. 2013 Feb;131(2):155-9)

[5] Freedman J, Bhandari R. Supra-Tenon capsule placement of original Molteno vs Molteno3 tube implants in black patients with refractory glaucoma: a single-surgeon experience. Arch Ophthalmol. 2011 Aug; 129(8):993-7.)

Training, professional development and support tools

The key to success in severe and complex glaucoma is a combination of the **Molteno3** implant, surgical technique and medical management. MOLTENO Ophthalmic staff and international distributors have a wealth of knowledge and can equip you with the resources and support you need to effectively care for your patients.

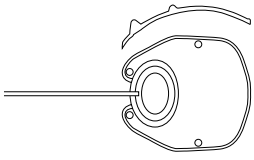
One to one phone or email advice from experienced ophthalmologists can be arranged and there is a library of materials, from detailed surgical guides to how-to videos, that may be accessed at **www.molteno.com**



Ordering Information

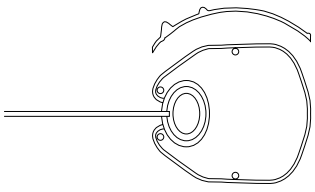
Molteno3 SS (185mm²) Glaucoma Drainage Device

Order Code: SS-185



Molteno3 SL (245mm²) Glaucoma Drainage Device

Order Code: SL-245



Molteno Paediatric/ Microphthalmic (80mm²) Glaucoma Implant

Order Code: P1

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