

*Natural
Movement
for your
Artificial Eye*



the original
HA
orbital imp

Hydroxyapatite
Bio-eye[®]
Orbital Implant

Life Support
for Artificial Eyes[®]

Change and movement

When our bodies change in some way, due to injury or disease, we are understandably concerned about how our lives may be affected. This is especially true of changes that involve some part of the face, such as the eyes.

Until 1985, those facing the loss of an eye had little hope of obtaining an artificial eye that had the natural movement of the normal eye. Most of us know someone who has an artificial eye that lacks movement or a natural appearance. Patients now have the opportunity, when faced with the need for an artificial eye, to have a Bio-eye implant. This implant allows the potential for natural movement and support of the artificial eye.

Many thousands of people have already benefited from this advanced technology that can create a more natural-looking artificial eye. In fact, you may have met one of these people, unaware that the person had an artificial eye.

Orbital implants and artificial eyes

When an eye is removed, an orbital implant is used to replace the volume in the orbit (bony cavity) that was occupied by the eye. This spherical implant maintains the natural structure of the orbit and provides support for the artificial eye. The implant itself is not visible however.

An artificial eye is used to restore the natural appearance of the eye and surrounding tissues, and is the visible part of the surgical changes to the socket (Fig.1). Artificial eyes

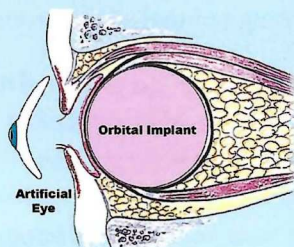


Fig. 1. Orbital implant with artificial eye (shown removed).

are usually made of plastic (acrylic) or glass. Custom artificial eyes are handcrafted by highly skilled ocularists (eye makers) to precisely match the look of the natural eye.

While artificial eyes have been made for thousands of years, the first orbital implants were developed about 125 years ago. These spheres of glass or gold were later replaced by plastic or silicone spheres. Until 1985, when the Bio-eye Hydroxyapatite Implant was developed, the basic design of these “first-generation” implants had changed little over the years.

The need for a better implant

The first-generation orbital implants were a major improvement for those wearing an artificial eye, but they were unable to deliver natural movement and support to the artificial eye.

This lack of movement was a major obstacle to restoring a natural appearance, which made the adjustment to wearing an artificial eye much more difficult.

The first-generation implants also tended to drift (migrate) in the orbit and were often rejected (extruded) by the tissues of the body, making further surgeries necessary. These problems inspired researchers to develop a better orbital implant.

Hydroxyapatite: the natural choice

The goal of a more natural appearance was finally achieved with the help of a natural material: ocean coral. A remarkable similarity

was noticed between the porous structure of certain coral species and that of human bone.

Soon after this discovery, a method was developed to transform the mineral in coral to match that of human bone, known as hydroxyapatite (HA).

This new, naturally derived hydroxyapatite has both the porous structure and the chemical structure of human bone (Figs. 2 and 3).

Thus, the tissues of the body will accept --- even grow into ---the naturally derived hydroxyapatite implant, and the implant essentially becomes a "living" part of the body.

The first Hydroxyapatite Orbital Implant

The first orbital implant made of hydroxyapatite was implanted in 1985 by Dr. Arthur Perry, after several years of preliminary research.

The eye muscles can be attached directly to this implant, allowing it to move within the orbit---just like the natural eye.

Some of this movement may be transferred to the artificial eye, which fits over the implant. If

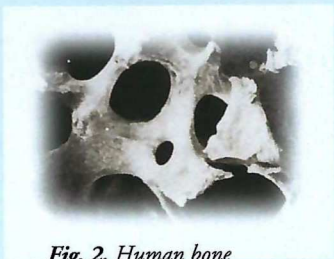


Fig. 2. Human bone (magnified)



Fig. 3. Bio-eye Hydroxyapatite (magnified)



Fig. 4. Natural movement with the Bio-eye HA orbital implant.

more normal movement is desired, then a peg is used to connect the artificial eye to the implant. In this way, even the small, darting movements of a natural eye can be delivered directly to the artificial eye. The result is a more natural-looking artificial eye that can be difficult to distinguish from the normal eye (Fig. 4).

The Bio-eye HA Orbital Implant

This unique implant was released by the US Food and Drug Administration (FDA) in 1989. Today thousands of people worldwide have benefited from this natural alternative, which is now known as the Bio-eye Hydroxyapatite Orbital Implant. In addition to natural eye movement, the Bio-eye orbital implant offers



Fig. 5. Implant is available in four sizes.

many less-obvious benefits. It reduces implant migration and extrusion, which were common with the first-generation implants,

and it can prevent drooping of the lower lid by lending support to the artificial eye by way of a peg connection. These are important benefits that can eliminate the need to choose between further corrective surgery and an unsatisfactory appearance.

The benefits of natural movement and fewer long-term problems have made the Bio-eye HA Orbital Implant the implant of choice among leading ophthalmic surgeons worldwide.

You may be a candidate for the Bio-eye HA Orbital Implant

You may be a candidate for this procedure if you must have an eye removed (enucleation) or the contents of an eye removed (evisceration), or if you have previously had one of these procedures and are not satisfied with your first-generation

implant (secondary implantation).

You should consult your eye care specialist or ophthalmologist to determine whether you could benefit from the Bio-eye HA Orbital Implant.

The procedure

The Bio-eye HA orbital Implant is surgically placed within the orbit at the time the eye is removed, and the tissues are closed over the implant. A temporary conformer is then placed over the implant and under the eyelids to maintain the space for the artificial eye.

Six to eight weeks later, a visit is made to an ophthalmologist. This highly skilled specialist will remove the conformer and create a detailed artificial eye---often astonishing in its lifelike appearance---that matches your natural eye. The artificial eye fits in place over the implant and under the eyelids.

If maximum movement is desired, your eye surgeon can perform a procedure to connect the artificial eye to the implant, by means of a peg (Fig. 6). In this optional procedure, a hole is created in the implant and a peg is inserted into the hole. Your ophthalmologist then modifies the back of the artificial eye to accept the head of the peg

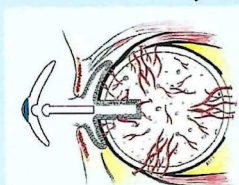


Fig. 6. Bio-eye HA Orbital Implant after tissue ingrowth (optional peg system shown).

thus forming a ball-and-socket joint.

The peg placement procedure is performed after the implant has had time to be filled with vascular tissue from the orbit--usually about six months

after implantation. A bone scan or magnetic resonance imaging (MRI) test can confirm whether the implant is ready to accept a peg.

Once your ophthalmologist has properly fit the artificial eye, the full benefits of the Bio-eye

HA Orbital Implant will be available to you. Of course, the final results in each case will vary depending on the condition of the orbit, muscles, and surrounding tissues.

Consult a medical professional

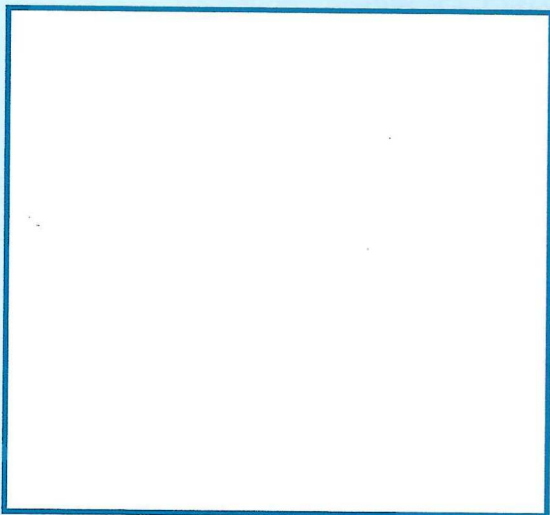
The Bio-eye Hydroxyapatite Orbital Implant has been described as "a dream come true" by eye care specialists, ophthalmologists, and those patients familiar with the older, first-generation orbital implants. The benefits of a more natural appearance, more lifelike movement and more stable implant material have made this unique orbital implant the natural choice for those who wear an artificial eye.

Consult your eye care specialist or ophthalmologist to determine whether you can benefit from the Bio-eye Hydroxyapatite Orbital Implant.



Hydroxyapatite
Bio-eye[™]
Ocular Implant
*Life Support
for Artificial Eyes*[™]

PATIENT BROCHURE
Enucleation, Evisceration
and Secondary Implant



*Life Support Systems
for Artificial Eyes™*

**For further information
and free educational
videos, contact:**

Integrated Orbital Implants, Inc.

11230 Sorrento Valley Road • Suite 135

Phone: 858-677-9990 or 800-424-6537 • Fax: 858-677-9993

haimplants@ioi.com • website: www.ioi.com

I00105 rev 10/21/2012