

# MOLTENO<sup>®</sup> *M-Sphere*<sup>®</sup> Orbital Implant Surgical Guide

A Step by Step Guide to inserting the  
*M-Sphere*<sup>®</sup> Natural Hydroxyapatite Orbital Implant

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# MOLTENO® *M-Sphere*® Natural Hydroxyapatite Orbital Implant

The ***M-Sphere*** orbital implant is manufactured from ***MoaBone***®, the natural hydroxyapatite mineral matrix of cancellous bone. The bone, of New Zealand origin, is treated to remove the organic components leaving only the hydroxyapatite mineral framework. ***M-Sphere*** orbital implants are designed to support and impart movement to an artificial eye (prosthesis) after enucleation. The bony trabeculae within the ***M-Sphere*** implant provide a completely porous structure which is easily and rapidly incorporated into the tissues.

With careful surgical technique it is possible to insert a relatively large ***M-Sphere*** implant into Tenon's space and eliminate dead space in the socket. Cosmetically this is highly desirable as it produces a visible bulge behind closed lids giving the impression of a normal closed eye when an artificial eye is not being worn. Furthermore, the movement of the conjunctiva-covered orbital implant against the tarsal conjunctiva prevents the accumulation of secretions and maintains a healthy socket. Where customised artificial eyes are not available, a smaller ***M-Sphere*** orbital implant can be used with a stock artificial eye.

In most patients where the tissue is healthy it is not necessary to cover the ***M-Sphere*** implant with a cap of sclera, however, if the tissues are deficient, unduly thin or scarred, donor sclera can be placed over the front of the ***M-Sphere*** implant.

- The ***M-Sphere*** implant is made from ***MoaBone***, the hydroxyapatite mineral matrix of mammalian cancellous bone. Its natural chemical composition and the preservation of its natural porous structure makes the ***M-Sphere*** implant fully biocompatible.
- Several cases of reduced implant volume requiring revision surgery have been reported some years after implantation of the ***M-Sphere*** orbital implant. The surgeon must consider the possibility of implant resorption and volume loss requiring revision when selecting an orbital implant to best suit the individual case.
- The ***M-Sphere*** implant is completely porous. When buried in the patient's tissues it is rapidly organised by the patient's fibrovascular tissue.
- When incorporated in the patient's tissue the ***M-Sphere*** implant resists migration and extrusion. It provides a robust, permanent and mobile support for an artificial eye.
- The ***M-Sphere*** implant gives an excellent cosmetic appearance when fitted with an artificial (prosthetic) eye. Drilling or pegging is not recommended.
- The ***M-Sphere*** implant is supplied as 16mm, 18mm, 20mm, and 22mm diameter spheres. This allows the correct size of implant to be selected to suit the individual case.

## Introduction

The orbit is a closed cavity. Complications that arise after inserting an orbital implant are most often due to internal or external pressure. Internal pressure from the swelling of traumatised tissues or the selection of too large an implant may result in exposure of the implant. External pressure applied to the eye after surgery, such as the use of a conformer or over-firm bandaging, may cause ischaemic necrosis of the tissues covering the implant and should be avoided.

**The following steps can be taken to ensure the best results:**

### 1. Select the correct size *M-Sphere*<sup>®</sup> implant.

The correct size *M-Sphere* implant is usually about three-quarters to seven-eighths the diameter of the eye that has been removed. However, if there are complicating factors such as poor blood supply or badly damaged tissues, a smaller *M-Sphere* implant should be selected.

Collaborating with an ocular prosthetist prior to surgery regarding implant size can improve the cosmetic outcome and patient satisfaction.

Example: a 24mm diameter eye has been enucleated. Normally a 20mm *M-Sphere* implant would be considered. However, if the tissues are badly damaged or the patient is old, has vascular disease or there are other factors limiting the vitality of the tissues, an 18mm *M-Sphere* implant should be used.

### 2. Reducing tissue swelling.

Swelling of the orbital tissues may be present before the enucleation, for example, following trauma. Swelling may also occur in response to manipulation of the tissues during the operation. In either case swelling may be reduced or prevented by administering a non-steroidal anti-inflammatory agent (NSAID) by mouth (with the usual precautions) immediately prior to operation. In the presence of marked swelling the NSAID may be continued for some days after operation.

### 3. Avoiding external pressure on the tissues covering the *M-Sphere* implant.

Conformers, such as are used after simple enucleation, may compress the tissues and cause exposure of the *M-Sphere* implant. *Conformers should never be used with any orbital implant.* Firm padding or pressure bandaging may also compress the tissues and cause exposure of the *M-Sphere* implant and should be avoided. Instead a simple gauze eye pad should be held in place by adhesive tape.

Fitting an artificial eye should be delayed for 3 to 6 months to allow for complete healing of the tissues and complete organisation of the *M-Sphere* implant by connective tissue.

## Surgical instruments required

- Eyelid speculum
- Spring scissors
- Non-toothed conjunctival forceps (eg Moorfields non-toothed)
- Fine-toothed forceps
- Small locking needle holder
- Squint (muscle) hooks x2
- 4.0 silk sutures with needles, x4 if single armed or x2 if double armed
- 5.0 Vicryl<sup>®</sup> or silk suture x1
- Fine artery forceps x4
- Enucleation scissors
- M-Sphere implant of the appropriate size
- Cephalosporin / gentamicin or other suitable antibiotic solution in which to dip the *M-Sphere* implant
- Paraffin gauze
- Introducer fashioned from the thumb of a large sterile surgical glove.

## Step One: Enucleating the eye

You will be using the four rectus muscles, anterior Tenon's tissue and conjunctiva to cover the anterior surface of the **M-Sphere**® implant. Your aim is to identify and avoid damage to these tissues while at the same time keeping them in their relative positions as you remove the eye.

General anaesthetic is preferred. Remember to handle the tissues gently to minimise swelling. If there is a lot of swelling, administer non-steroidal anti-inflammatory agents and postpone the operation for a few days to allow the swelling to subside.

Insert a speculum between the eyelids. Take a non-toothed conjunctival forceps and spring scissors and incise around the limbus. Lift and retract conjunctiva and Tenon's tissue off the globe. Locate the insertions of the rectus muscles. Mark each rectus muscle with a 4.0 silk suture tied firmly to one margin of the tendon. This prevents loss of the muscle and later makes it easy to open Tenon's space for insertion of the **M-Sphere** implant. Cut off each rectus muscle at the globe. Exert gentle traction on each of the rectus muscles and clip the sutures to the drapes (Fig. 1.1).

Grasp the globe with a toothed forceps. Pull it forward and downwards. Slide a pair of curved scissors into the upper nasal quadrant beneath Tenon's capsule. After checking that Tenon's tissue is out of the way, cut the stretched optic nerve.

Continue the traction on the globe and cut the attachments of the superior and inferior oblique muscles. Remove the eye and place it on a sterile surface. Plug the socket with a gauze swab and leave the swab there to arrest bleeding while you prepare the **M-Sphere** implant.

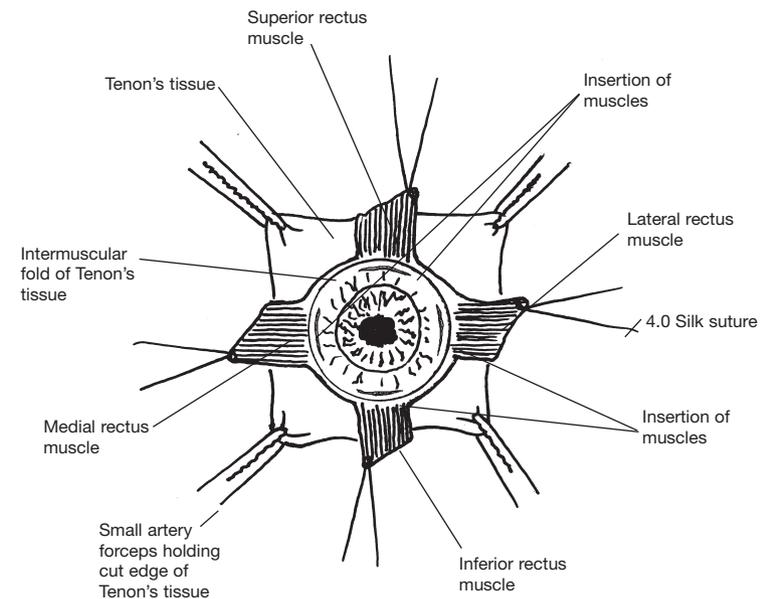


Fig. 1.1 Placement of the sutures before removal of the eye

## Step Two: Selecting the correct size **M-Sphere**<sup>®</sup> implant

*Your aim is to select an **M-Sphere** implant which is large enough to fill the socket and eliminate dead space, yet not so large that it cannot be easily covered by the tissues.*

**M-Sphere** implants are supplied in spheres of 16mm, 18mm, 20mm and 22mm diameter. The spherical shape is suitable where facilities exist for moulding the socket and customising the artificial eye. (In other situations see "shaping the **M-Sphere** implant" - Pg5)

The correct size **M-Sphere** implant is about three-quarters to seven-eighths the diameter of the eye that has been removed. However, if there are complicating factors such as poor blood supply or badly damaged tissues, a somewhat smaller than usual implant should be selected.

Example 1: An eye 24mm in diameter has been enucleated. Normally a 20mm **M-Sphere** implant would be considered. However, if the tissues are badly damaged or the patient is old, has vascular disease or there are other factors limiting the vitality of the tissues, an 18mm **M-Sphere** implant should be used.

Example 2: An eye 25mm in diameter is enucleated.  $25 \times \frac{3}{4} = 18.75$  or about 19mm. Which size should be chosen?  
If the tissues are healthy a 22mm **M-Sphere** implant could be used. If the vitality of the tissues is reduced a 20mm would be suitable.

### Step Three: Preparing the *M-Sphere*® implant

Your aim is to prevent infection by soaking the ***M-Sphere*** implant briefly in an antibiotic solution. You may also need to shape the implant to fit the patient's socket or to accommodate an artificial eye.

Soak the ***M-Sphere*** implant for 1 to 2 minutes in an antibiotic solution such as cephalosporin 500mg with gentamicin 80mg made up as for parenteral injection (other antibiotics or normal saline may be used). The implant will absorb the antibiotics and release them slowly into the tissues over several days.

#### Shaping the *M-Sphere* implant.

Where facilities for manufacturing artificial eyes are not available and a stock prosthesis must be used, the anterior surface of the ***M-Sphere*** implant sphere should be flattened to accommodate the thicker prosthesis. To do this, first soak the ***M-Sphere*** implant for 2 or 3 minutes as above. This softens the implant sufficiently for it to be shaped with a pair of heavy scissors (Fig. 3.1).

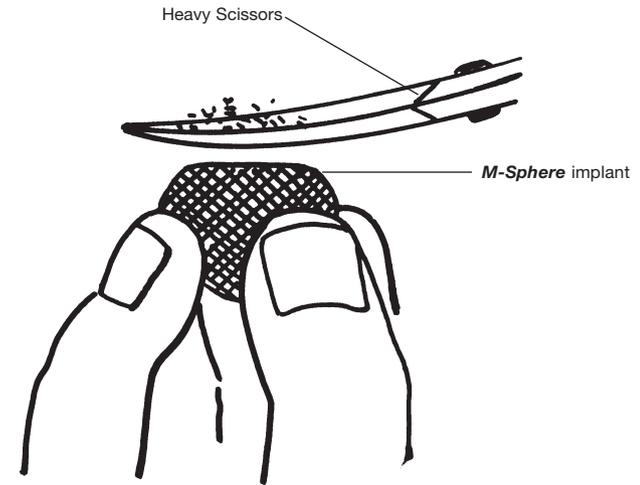


Fig. 3.1 Shaping the ***M-Sphere*** implant with a pair of heavy scissors to fit a stock prosthesis

## Step Four: Inserting the prepared *M-Sphere*<sup>®</sup> implant into Tenon's space

Your aim is to place the ***M-Sphere*** implant deep into Tenon's space. This will ensure that there is sufficient Tenon's tissue and conjunctiva to cover the implant without having to stretch them. Avoiding stretch prevents internal pressure on the overlying tissues which could result in exposure of the implant.

Note: The tissues tend to stick firmly on contact with the ***M-Sphere*** implant. This makes it difficult to adjust the position of the ***M-Sphere*** implant after it has been placed in the orbit. This difficulty is overcome by using an introducer fashioned from the thumb of a large sterile surgical glove to cover the ***M-Sphere*** implant while it is being positioned in the orbit.

Cut the thumb off a sterile, preferably latex, surgical glove and remove the tip to make a short, tapered rubber sleeve (Fig. 4.2).

Moisten the sleeve with saline and push the prepared ***M-Sphere*** implant down into the bottom of the sleeve. The ***M-Sphere*** implant should not protrude beyond the rubber sleeve at this stage (Fig. 4.3). If the anterior surface of the ***M-Sphere*** implant has been flattened to accommodate a stock prosthesis, care should be taken to make sure the surface is correctly orientated.

Remove the gauze swab from the socket. To open and expose the posterior part of Tenon's space pull on the sutures holding the four rectus muscles and reattach them to the drapes. Use four small artery forceps to grasp the edge of Tenon's capsule between the rectus muscles and pull it forward to maximise exposure of the interior of Tenon's capsule (Fig. 4.1).

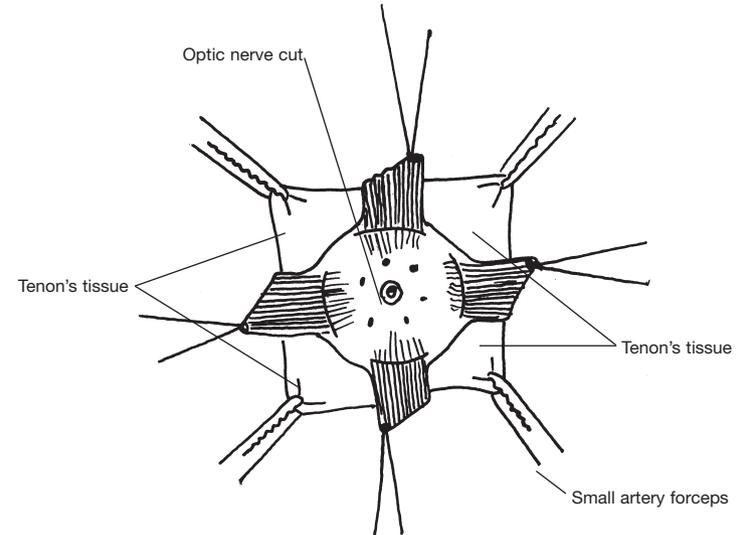


Fig. 4.1 Traction on sutures to expose Tenon's space for insertion of the ***M-Sphere*** implant



Fig. 4.2 Introducer cut from the thumb of a sterile surgical glove

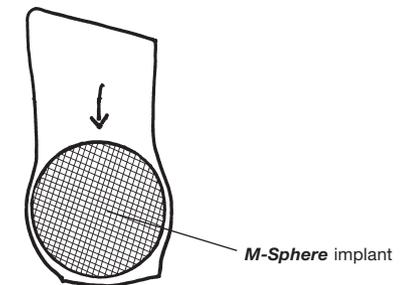


Fig. 4.3 ***M-Sphere*** implant correctly placed inside the introducer fashioned from the thumb of a sterile surgical glove

## Step Four: Inserting the prepared *M-Sphere*<sup>®</sup> implant into Tenon's space (continued...)

While maintaining traction on the four muscles and on Tenon's capsule, slide the rubber-covered *M-Sphere* implant as far back into Tenon's space as possible (Fig. 4.4). Then put a finger into the rubber sleeve and, pressing firmly on the *M-Sphere* implant, ease the rubber sleeve forward off the implant (Fig. 4.5).

The posterior tissues will be drawn forward, adhere to the porous surface of the *M-Sphere* implant and hold it in position deep in the orbit. The anterior tissues will lie loosely over the implant so that the tissues can be closed without tension (Fig 4.6).

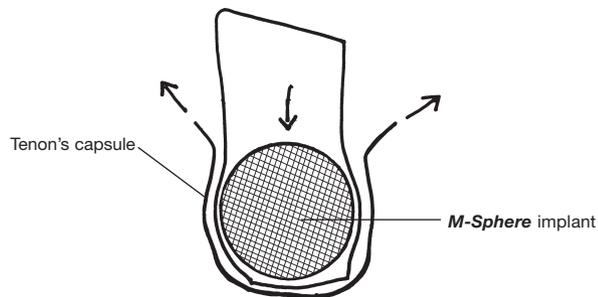


Fig. 4.4 *M-Sphere* implant covered by a rubber sleeve fashioned from the thumb of a sterile surgical glove and inserted deeply into Tenon's space

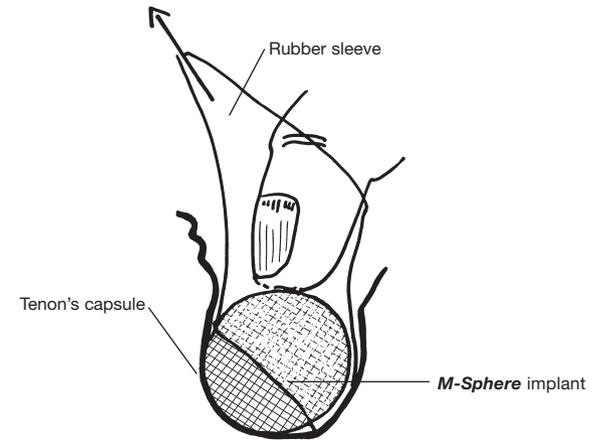


Fig. 4.5 Removal of the rubber sleeve while pressing the *M-Sphere* implant deep into the orbit

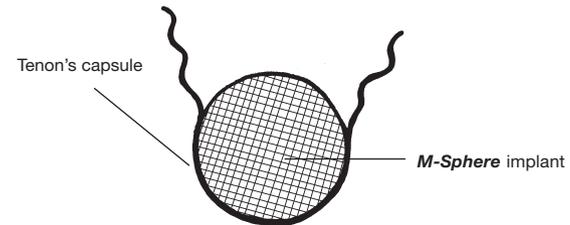


Fig. 4.6 *M-Sphere* implant held in position by posterior Tenon's tissue

## Step Five: Covering the *M-Sphere*® implant with the first layer of Tenon's tissue

(May be omitted when using a scleral cap)

Your aim is to cover the ***M-Sphere*** implant with a layer of the thick equatorial Tenon's tissue held in position by suturing opposite intermuscular folds to each other. In patients with poor orbital blood supply, uniting the muscles (step six) prior to the intermuscular folds (step five), may improve organisation of the implant.

Identify the thickened fold of Tenon's tissue which passes between the adjacent edges of the superior and lateral rectus muscles. Grasp the fold halfway between the muscles and pass a 4.0 silk suture through it. Repeat the procedure with the fold passing between the medial and the inferior rectus muscles and pass the suture back through the first fold again to form a horizontal mattress stitch (Fig. 5.1). Tie the suture firmly and check that the tissue covers the ***M-Sphere*** implant evenly without undue tension. (Fig. 5.2)

Repeat the process with the remaining pair of intermuscular folds. (Fig. 5.3)

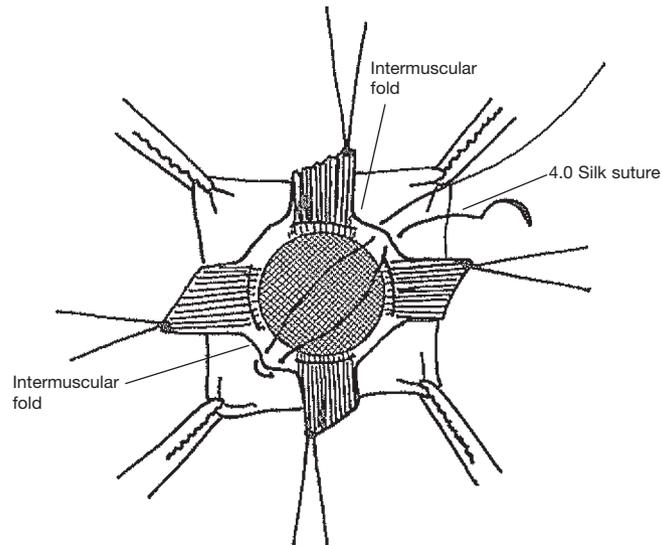


Fig. 5.1 A 4.0 silk mattress suture is placed through opposite intermuscular folds of Tenon's tissue

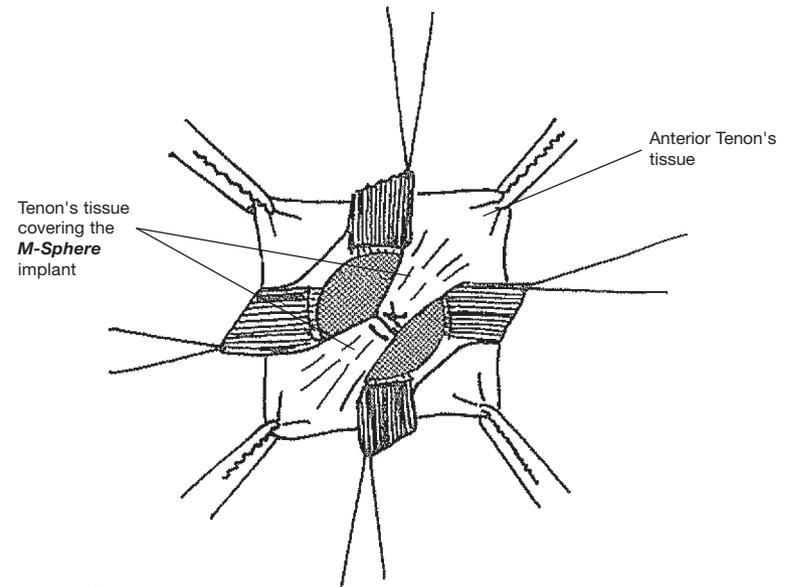


Fig. 5.2 Opposite intermuscular folds are sutured together over the ***M-Sphere*** implant

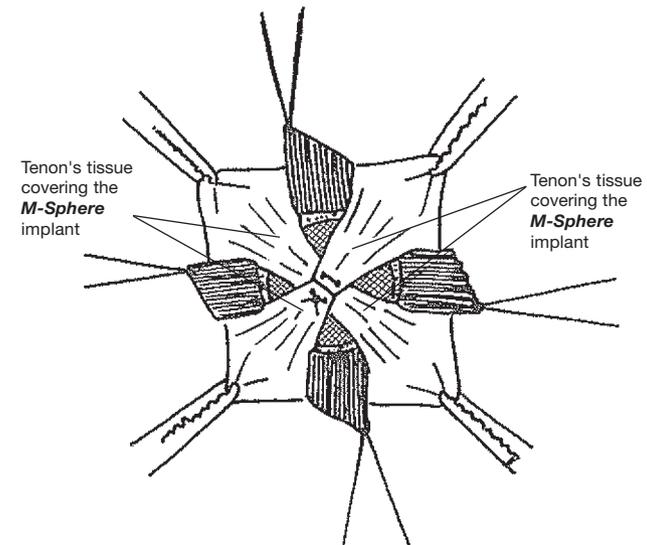


Fig. 5.3 The second pair of intermuscular folds are sutured together over the ***M-Sphere*** implant

## Step Six: Attachment of the rectus muscles

Your aim is to attach the rectus muscles to each other so as to form an even sheet of well vascularised muscular tissue covering the **M-Sphere**<sup>®</sup> implant. Care should be taken to ensure that the rectus muscles maintain their positions so that the artificial eye moves naturally.

Find the tendons of the superior rectus and inferior rectus muscles. With the 4.0 silk sutures\* already attached to the tendons, suture them together end to end over the front of the **M-Sphere** implant, spreading the muscles out as widely as possible. The joined ends should lie centrally (Fig. 6.1).

Find the suture holding the medial rectus muscle. Grasp the muscle with a conjunctival forceps and pull it laterally to expose the medial check ligament. Use a pair of spring scissors to free the medial check ligament from the rectus muscle. (Leaving this ligament in place may limit the range of movement of the **M-Sphere** implant) Spread the muscle to its full width and suture the free end to the medial edge of the joined superior and inferior rectus muscles using two or three interrupted sutures of 4.0 silk (Fig. 6.2).

Now find the suture holding the lateral rectus muscle and free the lateral check ligament as described above. Spread the muscle to its full width and suture the free end to the lateral edge of the joined superior and inferior rectus muscles with two or three interrupted sutures of 4.0 silk (Fig. 6.2)

\* Note: Silk is used in this situation rather than an absorbable suture such as Vicryl<sup>®</sup> or Dexon<sup>®</sup>. This is because it is important that the sutures should hold until the tissues are completely healed. Absorbable sutures sometime break down too soon and should therefore be avoided.

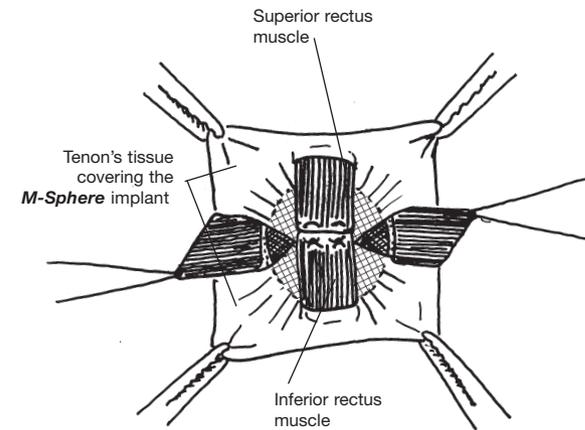


Fig. 6.1 Tendons of the superior and inferior rectus muscles sutured over Tenon's tissue and the **M-Sphere** implant

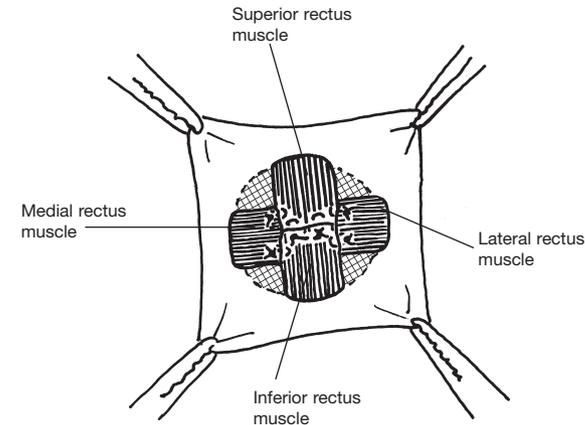


Fig. 6.2 Tendons of the medial and lateral rectus muscles sutured to the margins of the joined superior and inferior rectus muscles

## Step Seven: Closure of Tenon's tissue and conjunctiva

Your aim is to ensure that the **M-Sphere**® implant is completely covered by a layer of well vascularised connective tissue. This tissue must be very carefully sutured so as to cover the **M-Sphere** implant without undue tension.

In most cases there will be plenty of tissue available to cover the **M-Sphere** implant. If the tissue cannot be closed without undue tension make relieving incisions through Tenon's tissue behind the point of reflection of the superior fornix (Fig. 7.1).

Close the anterior portion of Tenon's capsule in a horizontal direction using several interrupted sutures of silk, cutting these off close to the knots (Fig. 7.2).

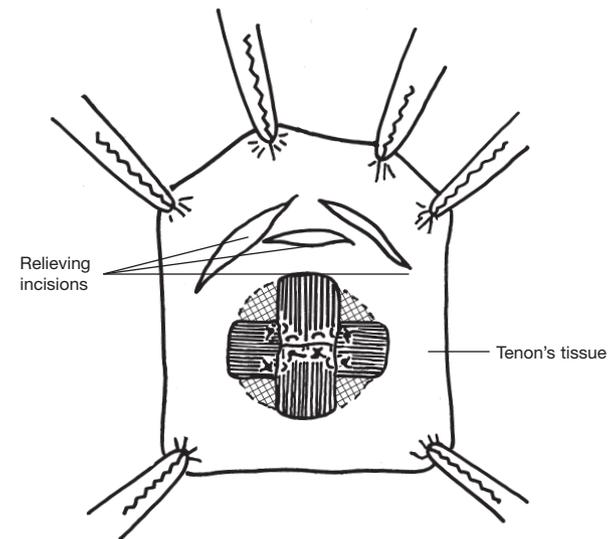


Fig. 7.1 Position of the relieving incisions where necessary to reduce tension in the tissue covering the **M-Sphere** implant

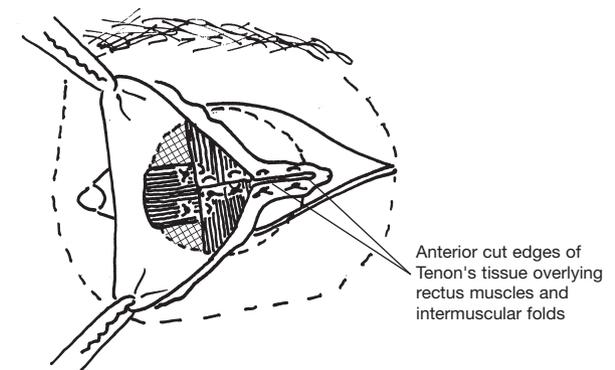


Fig. 7.2 Horizontal closure of the anterior cut-edge of Tenon's tissue using interrupted mattress sutures of 4.0 silk

## Step Seven: Closure of Tenon's tissue and conjunctiva (continued...)

Carefully check the horizontal closure of Tenon's tissue and place additional sutures as necessary before closing the conjunctiva (Fig. 7.3).

### Closure of the conjunctiva

The conjunctiva should be closed with a continuous suture of 5.0 Vicryl® or equivalent absorbable material (Fig. 7.4).

At the end of the operation a small piece of paraffin gauze is tucked into the lateral and inferior fornix. This serves to maintain the depth of the fornix in the first three to four days after operation. Pad the eye lightly and give antibiotic drops until the conjunctival wound is completely healed. If marked tissue swelling occurs give a non-steroidal anti-inflammatory agent (with the usual precautions) until the swelling is relieved.

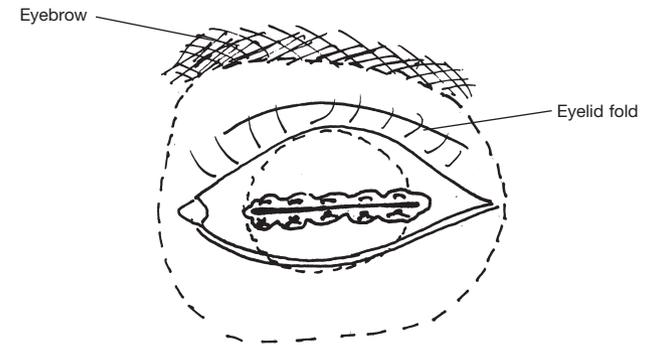


Fig. 7.3 Anterior closure of Tenon's tissue complete

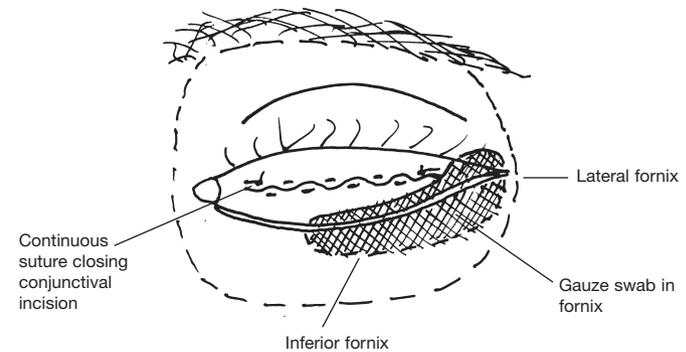


Fig. 7.4 Closure of conjunctiva showing position of paraffin gauze swab to maintain the fornix

## Postoperative Care

*Your aim is to maintain a good blood supply to the tissues covering the **M-Sphere**® implant.*

Avoid over-packing the socket, firm padding, pressure bandaging or the use of a conformer as these may cause pressure necrosis of Tenon's tissue and conjunctiva where they press on the rigid **M-Sphere** implant.

## Managing Post-operative Complications

Complications that arise after inserting an orbital implant are most often due to internal or external pressure. Internal pressure from the swelling of traumatised tissues or the selection of too large an implant may result in exposure of the implant. External pressure applied to the eye after surgery, such as the use of a conformer or over firm bandaging, may cause ischemic necrosis of the tissues covering the implant and should be avoided.

### **Breakdown of the overlying tissues with exposure of the sclera or *M-Sphere* implant**

Treat promptly to avoid infection. Remove any exposed **M-Sphere** implant material using a dental drill. Then close the defect using local Tenon's tissue.

### **Exposed suture ends**

These should be removed to prevent access of infection to the **M-Sphere** implant which remains susceptible to infection until such time as it is fully incorporated into the patient's tissue.

## Fitting an artificial eye

Fitting an artificial (prosthetic) eye should be delayed for at least three months to be sure that the tissues are completely healed. By this time the **M-Sphere** implant should be organised by the patient's connective tissue. In certain circumstances, such as when the patient is old or ill, healing may be markedly delayed and fitting of an artificial eye should be postponed until slit-lamp examination shows that the tissues overlying the **M-Sphere** implant are completely healed.

# Surgical steps summarised

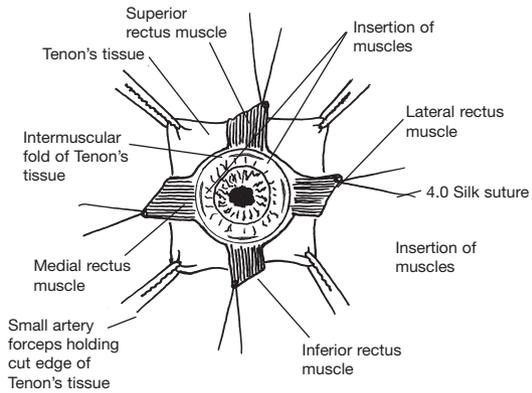


Fig. 1.1 Placement of the sutures before removal of the eye

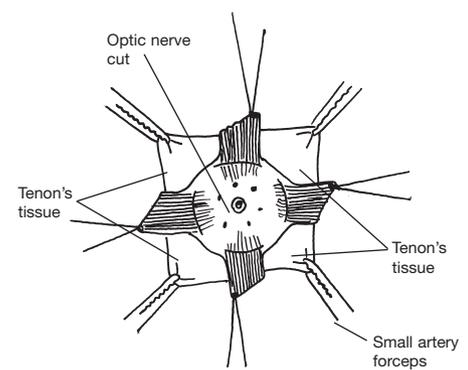


Fig. 4.1 Traction on sutures to expose Tenon's space for insertion of the **M-Sphere** implant

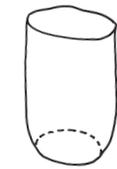


Fig. 4.2 Introducer cut from the thumb of a sterile surgical glove

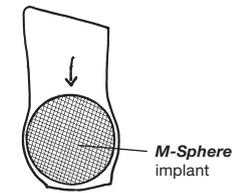


Fig. 4.3 **M-Sphere** implant correctly placed inside the introducer fashioned from the thumb of a sterile surgical glove

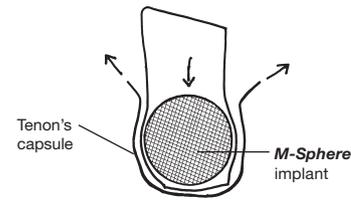


Fig. 4.4 **M-Sphere** implant covered by a rubber sleeve fashioned from the thumb of a sterile surgical glove and inserted deeply into Tenon's space

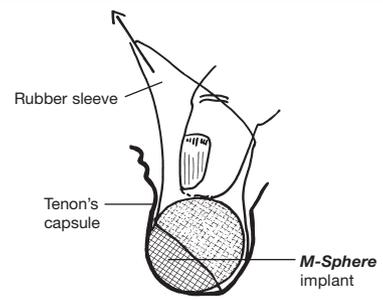


Fig. 4.5 Removal of the rubber sleeve while pressing the **M-Sphere** implant deep into the orbit

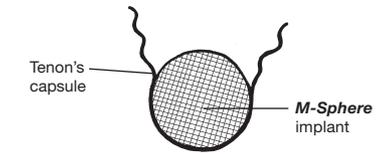


Fig. 4.6 **M-Sphere** implant held in position by posterior Tenon's tissue

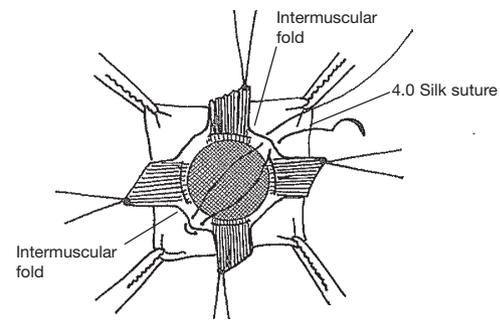


Fig. 5.1 A 4.0 silk mattress suture is placed through opposite intermuscular folds of Tenon's tissue

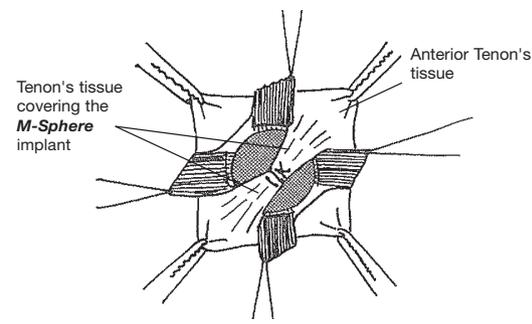


Fig. 5.2 Opposite intermuscular folds are sutured together over the **M-Sphere** implant

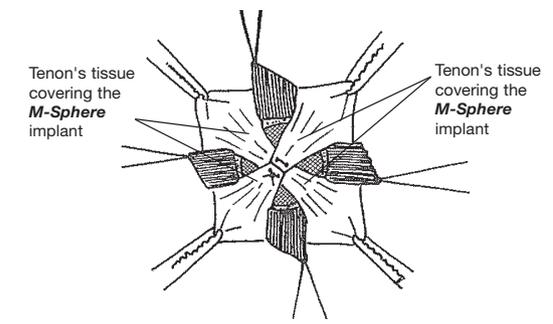


Fig. 5.3 The second pair of intermuscular folds are sutured together over the **M-Sphere** implant

## Surgical steps summarised

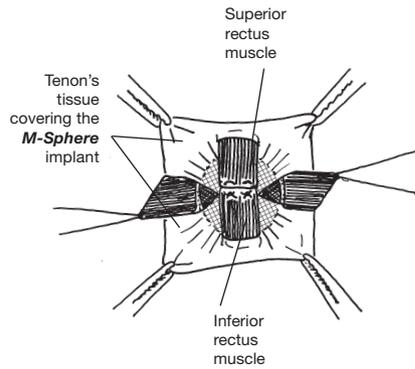


Fig. 6.1 Tendons of the superior and inferior rectus muscles sutured over Tenon's tissue and the **M-Sphere** implant

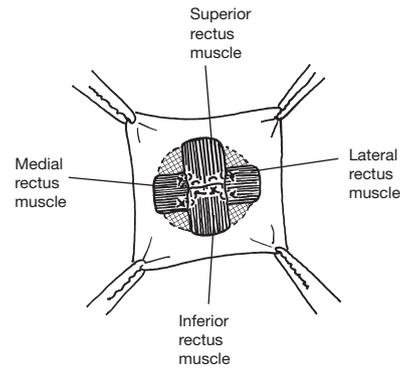


Fig. 6.2 Tendons of the medial and lateral rectus muscles sutured to the margins of the joined superior and inferior rectus muscles

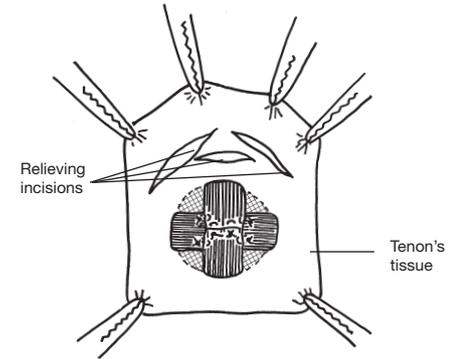


Fig. 7.1 Position of the relieving incisions where necessary to reduce tension in the tissue covering the **M-Sphere** implant

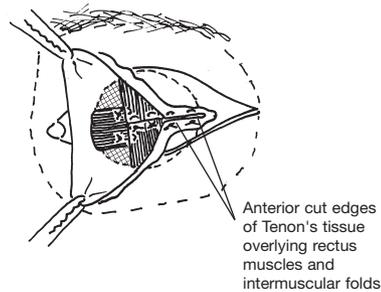


Fig. 7.2 Horizontal closure of the anterior cut-edge of Tenon's tissue using interrupted mattress sutures of 4.0 silk

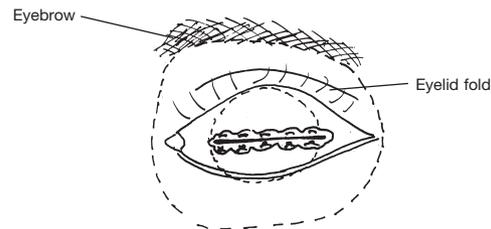


Fig. 7.3 Anterior closure of Tenon's tissue complete

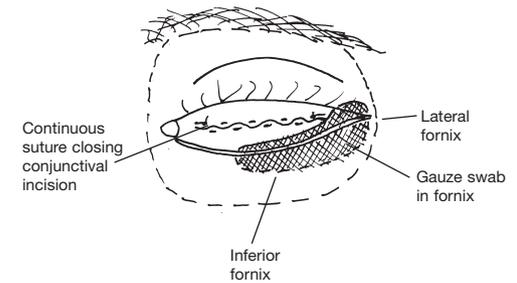


Fig. 7.4 Closure of conjunctiva showing position of paraffin gauze swab to maintain the fornix

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