Jan. 1, 1963 E. L. ALLEN 3,070,808

EYEBALL REPLACEMENT BURIED MUSCLE CONE MOTILITY IMPLANT BODY WITH POST-SURGICAL CONFORMER PROSTHESIS

Filed March 1, 1960

FIG. 1

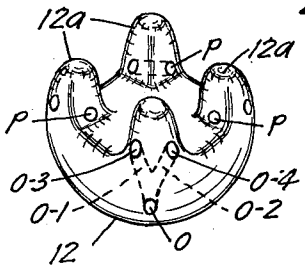


FIG. 2

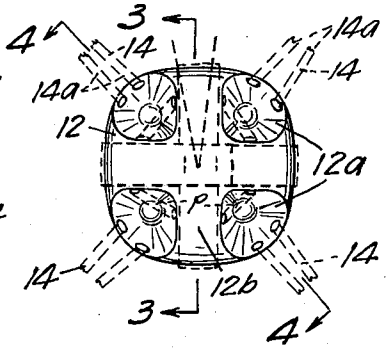


FIG. 3

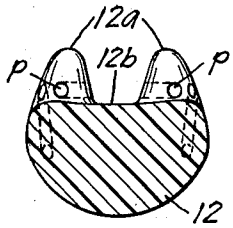


FIG. 4

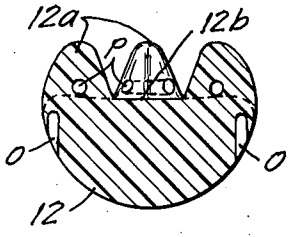


FIG. 5

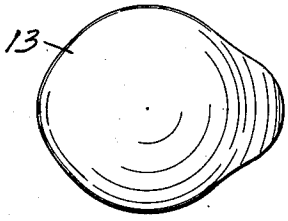


FIG. 6

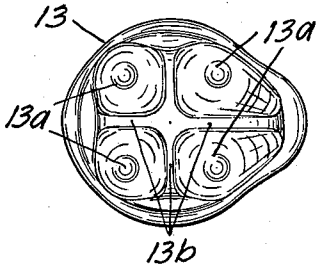


FIG. 7

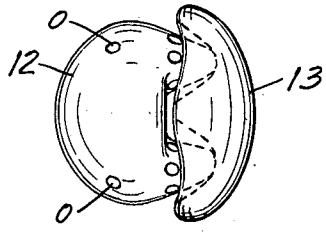


FIG. 8

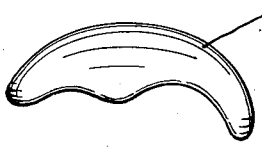
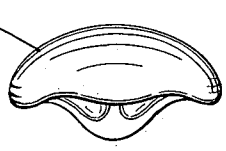


FIG. 9



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EYEBALL REPLACEMENT BURIED MUSCLE CONE MOTILITY IMPLANT BODY WITH POST-SURGICAL CONFORMER PROSTHESIS

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5 Claims. (Cl. 3—13)

This invention relates to artificial or prosthetic eyes and particularly to the production of a scientific and highly efficient implant and functionally related post-surgical conformer and similar prosthesis for a substantial and highly sensitive connection with the rectus muscles retained during surgical removal of the human or animal eye, and for support and mounting of the prosthesis to cause the artificial eye to move in close harmony with the remaining natural eye of the patient or with another artificial eye or cosmetic eye of any type in which the visible portion of both of the subject's eyes may be artificial.

It is a object of my present invention to provide an implant-conformer-prosthesis combination wherein the implant, although completely buried, has all of the desirable features, each to an adequately high degree, of a completely integrated implant; and which includes transmission of motion from the extraocular muscles to the prosthesis, by means of a complex of forms on the front of the implant which key with properly mated forms in the back surface of the artificial eye, said keyed forms serving also to support the prosthesis without major dependence upon the lower lid and fornix. With my improved construction, the combination can be said to be quasi-integrated and the prosthesis and implant are efficiently inter-related, interfitted and keyed together by the mating forms to prevent cyclic rotations between the two parts which can occur rather frequently with some other buried implant and prosthesis constructions of the prior art.

Another object is the provision, in such a combination of prosthesis and implant, of a post-surgical conformer shaped and constructed generally similar to the prosthesis but which is applied in the operating room after all suturing of tissues by placement under the lids of the eyes and against the anterior portion of Tenon's capsule, exerting pressure through action of the lids to prevent post-surgical hemorrhage and also effective to keep the socket and lid in relatively healthy condition and to assist in molding the tissues up to the time the patient is in condition to have the prosthesis applied. Additional specific advantages and cooperation of said conformer with a pressure bandage applied after surgery will be hereafter set forth. Such conformer may be manufactured and supplied with the implant of the original kit utilized by the opthalmologist.

More specifically it is an object of my invention to provide a plurality, preferably four, forwardly extending quasi-integrating or "keying" mounds on the front of the implant around which Tenon's capsule and conjunctiva are molded surgically to present the mound forms well padded on the posterior wall of the healed socket. Said covered mounds (male form) are interfitted into complementary corresponding depressions (female form) in the back of the plastic eye. Such depressions are kept adequately approximated to the covered mounds by the pressure of the lids, especially the upper lid, against the front of the prosthesis.

With such an improved construction, substantially the effect of full integration is obtained with the result that the prosthesis moves quickly with the fellow eye and rotates as far as is necessary in common casual situations such as might be described as conversational situations.

Because the lower lid and fornix are of less importance in supporting the prosthesis than with many implants or

in sockets where no implant has been used, my new implant offers a substantial advantage, especially in elderly persons who are possessed of poor tonus in the lower lid. In the use of my improved construction, the lower lid is not, except in rare cases, deformed downwardly in an unsightly manner as is common with many prior art implants.

A still further object of my invention is the provision in combined structure of the class described, of certain spaced recessed portions, small tunnels, and/or simple drilled and geometrically related holes formed in the said mounds of the implant, serving both in the function of facilitating proper placement and location, by use of accessory tools or appliances, of the implant in the socket; and further serving to constitute an improved and highly efficient retaining or anchoring means for receiving growing scar tissue from the cut rectus muscles of the enucleated eye.

Another object in contrast with some prior art implants is the provision of a combined implant and post-surgical conformer and prosthesis whereby closure of Tenon's capsule and conjunctiva around the face or anterior of the implant is obtained with distribution of tissues and tensions within said tissues in the most favorable manner so that, in cases not complicated by defects present before the eye removal with implant surgery, no undesirable stretching is created in the tissues directly overlying the quasi-integrating mounds which otherwise could cause the tissue to erode through, thus uncovering the implant, a result and condition proven to endanger the permanence of any orbital implant.

The foregoing objects and advantages of my invention will more fully appear from the following description made in connection with the accompanying drawings wherein like reference characters refer to similar parts throughout the several views and in which:

FIG. 1 is a side and partially front perspective view on an enlarged scale, of an embodiment of my implant;

FIG. 2 is a front plan view of the embodiment illustrated in FIG. 1;

FIG. 3 is a cross section taken along the line 3—3 of FIG. 2;

FIG. 4 is a cross section taken along the line 4—4 of FIG. 2;

FIG. 5 is a front or exterior plan view of a suitable embodiment of prosthesis and also of the post-surgical conformer having combinative relationship with the implant of FIGS. 1 to 4;

FIG. 6 is a posterior plan view of said prosthesis and also of said conformer;

FIG. 7 is a side elevation showing the interfitting and cooperative relation of implant and prosthesis and the same relation of implant and conformer with the covering and intervening living tissues of Tenon's capsule and conjunctiva omitted for the sake of diagrammatic simplicity;

FIG. 8 is a side elevation of the prosthesis or of the post-surgical conformer, shown without the presence of the implant; and

FIG. 9 is an end elevation taken from the left hand end of FIG. 8 of said prosthesis or of said post-surgical conformer.

Referring now to the embodiment of my present invention illustrated, the essential implant body designated as an entirety by the numeral 12 is basically in the form of a hemisphere on a diameter usually approximately 21 mm. with a maximum axial dimension from the posterior center of the body to the outer surface defined by the forward tip portions of the mounds 12*a* approximating 15 mm. It will of course be understood that both larger and smaller sizes may be utilized, depending

on the specific prerequisites of the patient as long as the basic cross eye-integrating principle is retained.

The peripheral surface of the body **12** is spherical and smooth, to facilitate oscillation and partial revolution in the human eye socket. However, variations wherein openings, tunnels or recesses open onto this spherical surface may be desirable in certain cases, and it is to be understood that these may be incorporated. My implants as well as the post-surgical conformer and the prosthesis later to be described, are preferably fabricated from plastics of various types and compositions. A processed methyl methacrylate resin is highly satisfactory but a number of different plastic compositions well known in the art may be successfully employed.

The forward or anterior portion of the body **12** is provided with a plurality of circumferentially spaced, outwardly tapered projections or mounds **12***a* which as shown in the embodiment illustrated are four in number and are integrally formed from the body proper.

The forward or anterior portion of the body between said mounds provides a cross shaped, preferably slightly concave surface **12***b* for receiving the severed rectus muscles of a human eye together with the skin or fabric of Tenon's capsule and of conjuctiva as will later be more specifically described. The mounds protrude outwardly from this cross shaped surface **12***b* for maximum distances approximating 5 mm.

Each of the mounds or projections **12***a* is provided with one or more multi-functional apertures having openings disposed in the base portion of the respective mound and their openings at the periphery of the body **12**.

As shown in FIGS. 1, 3 and 4, the opening O for each mound communicates with two upwardly diverging passages O–**1** and O–**2** which penetrate the respective mounds **12***a* at openings O–**3** and O–**4**. Said passages and openings provide for the reception of devices for supporting the implant temporarily during the implantation surgery; but in addition, they provide tunnels for reception of scar tissue from muscles and/or other proximal tissue and fabric in facilitating the permanent location of the implant in the socket and in further serving to constitute an anchoring means.

In addition to the passages O–**1** and O–**2** for each mound, a transverse passage P is provided as shown in each mound disposed slightly outwardly of the cross shaped receiving surface **12***b* and extending generally circumferentially of the body. While the two sets of passages are preferred for each mound or projection of the implant, it will be understood that one set might prove adequate for the multi-purpose functions of scar tissue anchoring and insertion-device-accommodating means. It will be understood that while the two sets of passages are preferred, the addition of still more passages for the said multi-purpose functions would not constitute a basic change in the concept.

Closely cooperating with the implant element of my invention is a specially formed prosthesis **13** illustrated in FIGS. 5 to 9 inclusive having a generally convex anterior surface configuration in conformity with the exposed scleral and corneal portions of the natural human eye and having a posterior recessed portion as illustrated in FIG. 6 provided with four circumferentially spaced recesses **13***a* shaped complementary to the respective mounds or projections **12***a*. A post-surgical conformer substantially identical in configuration, physical construction and contour with the prosthesis **13** is provided and constitutes in use an important part of my combination invention. It of course does not have pictured or illustrated or colored upon the anterior portion thereof as does the prosthesis, the scleral and corneal representation of a natural human eye. It is illustrated in FIGS. 5 to 9 inclusive of the drawings (as is the prosthesis) and it is identified in entirety and in its several cooperating parts with the same reference characters as the prosthesis. Both the post-surgical conformer **13** and the prosthesis **13** are constructed from a single homogeneous unit, preferably of integral plastic construction and in both conformer and prosthesis, divisions or ribs **13***b* are arranged in the shape of a cross, being positioned between the respective (see FIG. 6) recesses **13***a*, said ribs when the conformer is applied at the time of surgery and/or when the prosthesis **13** is applied after preparation and fitting to the socket, being disposed adjacent and often in contact with the membranes formed by Tenon's capsule and conjunctiva which are disposed over the overlapped rectus muscles in the cross shaped surface **12***b* of the implant.

The conformer and/or the prosthesis as applied thus interlock and interfit with the completely covered and buried implant **12** and are nonrotatably and nearly positively connected therewith to the end that the parts are adequately keyed together to assure oscillation and rolling of the prosthesis through fixation of the rectus muscles upon the implant.

Surgery and fitting and quasi-integration with my implant body of the prosthesis is facilitated through my improved combinative structure. The implant in use is completely buried, the anterior portion thereof being covered by Tenon's capsule and conjunctiva. In the surgical technique, before careful enucleation of the eye, the implant is carefully sterilized and preferably a series of insertion clips **14** of suitable form are employed, the tips only of one of a number of forms already devised being illustrated in FIG. 2, each having a pair of spring rods or fingers **14***a*, the extremities of which are received and held in the external apertures O–**1** and O–**2** of each of the mounds **12***a*. The conjunctiva and Tenon's capsule are incised as close to the cornea of the eye to be removed as possible and the muscle insertions are exposed. Sutures are then used preferably with a double arm of lock suture approximately 1.5 mm. back from the end of each rectus muscle. Each muscle is sectioned and freed from all facial attachments 14.0 mm. back except on the inferior rectus. The latter may be freed 10.0 mm. or more as long as care is taken to not cut through the ligament of Lockwood. Each pair of sutures is preferably for identification secured with a serrefine clamp.

The optic nerve is then sectioned, care being used not to cut the applied sutures. nor to cut Tenon's capsule in any undesirable manner.

The implant with the holding or insertion clips is then positioned within the Tenon's space and these holding devices or clips may be employed to prevent the implant from dropping too deeply into the muscle cone. These clips may retract the surrounding tissue and act as guides for arrangement of muscles and sutures.

While sutures from the muscles or other tissues may be placed through the transverse passages P of the mounds in unusual cases or for reassurance, upon personal choice of the individual surgeon, it is not necessary in any typical cases to utilize such passages for reception of the sutures.

In suturing the rectus muscles across the front of the implant as indicated in dotted lines in FIG. 2, the superior and inferior rectus muscles are overlapped preferably 5.0 to 5.5 mm., with exceptions in unusual cases, and the arms of the suture in the inferior rectus muscles may be passed through the superior rectus from underneath and the two tied to each other across the center, saving one arm and cutting the other. Each arm of the suture in the superior rectus muscle may be passed, one around its nearby edge of the inferior rectus muscle and up through from its underside then continuously through the end of the superior rectus muscle and the two tied to each other across the end of the superior rectus muscle, saving one arm and cutting the other. Thus, a total of two arms are saved for further use as will be described later. The rectus muscles are very nicely accommodated and contained in two of the channel portions of the cross shaped space **12***b* between the appropriate mounds.

The horizontal muscles are overlapped, sutured and

tied in the same amount and manner as the verticals but are placed in the remaining two channel portions of the cross shaped space **12***b*. All suture arms of the horizontal muscles are tied and cut, but the surgeon continues to save the arms previously referred to of the vertical muscles. These two arms are passed upward through the overlying horizontal muscles and are tied together across the center of said horizontal muscles and both arms are again saved for the closure of Tenon's capsule described in the next paragraph. A junctional suture is employed adjacent to each mound of the implant (as, for example, a suture is placed through the nasal edge of the superior rectus muscle, then through the superior edge of the medial rectus muscle) at points far enough back along the edges of the muscles to lay the muscles fairly firmly against the sides and bases of the mounds and each suture is pulled snug and tied and cut.

Tenon's capsule is then closed by a carefully calculated modified purse-string suture formation using the sutures saved from the vertical muscles and from the suturing together of the vertical and horizontal muscles. One of the suture arms previously saved is placed exactly in line with one of the rectus muscles into the Tenon's capsule substance for 5.0 mm. along its inside surface and 3.0 mm. back from the cut edge, then an expanse of the capsule is skipped and the same suture arm is placed in exactly the same manner into Tenon's capsule in line with an adjacent rectus muscle and laid aside. The other saved suture arm is next placed into Tenon's capsule at a point diametrically opposite the first placement of the first saved suture, then after skipping is placed into Tenon's capsule in line with the remaining rectus muscle. Thereafter the holding or insertion clips are removed and the suture arms drawn together, pulling Tenon's capsule down against the center of the overlapped rectus muscles and the suture arms tied to each other and cut. The foregoing closure leaves four small openings each of which lies adjacent and just medial to one of the mounds of the implant. The opening next to the superior temporal mound is closed with two separate interrupted sutures so that the line of the now approximated cut edges points toward the peak of the mound. Each of the remaining three openings is closed by one suture so that the closure points toward its related mound. This cruxiate closure constituting a modified-purse-string closure, is the most important single concept of the surgery directed toward permanence of the implantation.

Conjunctiva is then closed over Tenon's capsule with a plurality of four or five sutures as near to a horizontal line as the irregularities of the edge allow.

The conformer previously referred to as the post-surgical conformer furnished with the implant is now used, immediately placed within the socket with the narrowest end or apex towards the nose of the patient and the eyelids are then closed and pressed thereover and a pressure dressing applied and the pressure continued for four to five days after which time the pressure dressing is removed, but the conformer is worn until the surgeon judges the socket to be ready to be fitted by the application of the prosthetic eye.

As illustrated in FIGS. 5 to 9 of the drawings, it will be noted that the conformer has continuous, smooth and nicely rounded marginal edges at both anterior and posterior. The posterior marginal edge contacts with and applies pressure to the tissues imposed upon the anterior of the implant and upon the peripheral anterior portion of the socket and the tissues thereof. The anterior marginal edge in post-surgical use distends and engages with the undersides of the eyelids providing substantially the same contour and contact as the exposed marginal scleral portion of a natural eye.

With my new construction the prosthesis may often be fitted substantially earlier than a month following implantation.

The final eye or prosthesis can be based upon the shape of the conformer or upon slight modifications of the conformer for those patients who cannot afford a completely custom type of fitting. Preferably an impression is taken of the anterior of the implant with Tenon's capsule and conjunctiva closed thereover. Such impression is translated into a wax model for the prosthesis and then altered, for best physiologic and cosmetic results.

The prosthesis with the recesses or indentations **13***a* closely conforming to and interlocking with the covered mounds **12***a* is then prepared, following exactly or closely the form of the wax model and installed being held in place by the lids and fornix.

The post-surgical conformer conforms to the anterior portion of the socket and to the undersides of the eyelids. It is pressed against and keyed with the outer, tissue-covered portions of the mounds **12***a* of the implant. It holds the lids in normal condition and assists in molding the tissues of conjunctiva, Tenon's capsule and tissues in the anterior part of the socket. Pressure and contact provided by the marginal portions of the conformer tend to prevent hemorrhage since the conformer together with the implant transfers pressure from the post-surgical pressure dressing to the apex of the muscle cone where blood vessels have been cut.

The mibomium glands beneath the lids normally secrete an oil or waxy substance to the lid margin which prevents tears from running. With my conformer, surfaces are pressed against these glands approximating the normal pressure of the human eye and thus serving a valuable function in massaging and maintaining normal excretion, thereby reducing the danger of complications such as infections, up to the time the prosthetic eye is fitted.

From the foregoing description it will be seen that I have provided a comparatively simple, scientific and highly efficient combination of implant and conformer and prosthesis which substantially facilitates surgery and conformance of an artificial eye in the enucleated socket while achieving most of the desirable effects of integrating the implant and effectively keying the prosthesis therewith, with provision for fixation of the rectus muscles upon the implant and keying the latter with the prosthesis.

What is claimed is:

1. An implant and prosthesis forming an artificial eye, having in combination an implant body having a rear, approximately semi-spherical portion and having a face provided with a plurality of individual, forwardly protruding mounds tapering outwardly from the base portions thereof and terminating in rounded extremities and being spaced apart proper distances to nicely accommodate between them the severed ends and a portion of the bodies of the four rectus muscles of a human or animal eye, a prosthesis shaped to fill the forward opening of the enucleated socket and the eyelids of the user, and having a rear face provided with a plurality of depressions equal in number to said mounds and of precisely complementary shape thereto, the said complementary surfaces of said mounds and depressions serving to engage and clamp marginal portions of Tenon's capsule and conjunctiva to seal the said portions between structure and said mounds and depressions interlocking or keying said implant and prosthesis together.

2. An implant and prosthesis forming an artificial eye, having in combination an implant body provided with a rear substantially semi-spherical portion, a plurality of forwardly extending blunt mounds rigidly secured to said body and spaced apart distances for reception of cut ends and a further portion of the surgical freed rectus muscles of the eye, four of said mounds being formed on the forward face of said implant body, said mounds tapering outwardly from the base portions thereof attached to said body and terminating in round extremities, a prosthesis having a rear face provided with a plurality of recesses corresponding in number to said mounds and shaped in

complementary conformance to said mounds to prevent cyclic rotation between said prosthesis and said implant, the latter having a series of laterally placed small recesses, holes or tunnels near the base portions of said mounds for functioning to facilitate handling and placement of the implant through application of tool means and further to function to engage growing scar tissue to assist in permanently affixing the implant in predetermined relation to the rectus muscles with which it is partially held and to Tenon's capsules within which it is enclosed and held.

3. The structure set forth in claim 2 wherein the rear face of said prosthesis when the same is applied to the mounds of said implant, leaves between the portions thereof extending between said recesses, surfaces for accommodation of the inturned bodies and ends of the rectus muscles of the eye.

4. An implant and prosthesis forming an artificial eye having in combination an implant body having a substantial rear portion thereof of substantially semi-spherical shape for fitting the orbit from which a human eye has been enucleated and having a forward face provided with forwardly extending, quasi-integrating mounds integrally formed with said body and tapering from their base portions to rounded extremities thereof, the forward face of said implant between said mounds being smooth and preferably contoured slightly in concave fashion for receiving part of the bodies and turned ends of cut rectus muscles of an eye, a prosthesis shaped to fill the forward opening of the eye socket and to conform to or to reform the shape of the lids of the eye, said prosthesis having a rear face provided with a plurality of recesses similar in number to said mounds and shaped complementary to the shape of said mounds for engaging beyond intervening tissue the same to prevent relative cyclic rotations between said parts, the mounds of said implant adjacent the bases thereof being provided with small lateral recesses for facilitating manipulation and placement of the implant into the socket and for also furnishing tunnels to receive growing scar tissue to assist in the overall permanent fixation of the implant and device to the rectus muscles of the eye and to Tenon's capsule.

5. The structure set forth in preceding claim 4 and said implant including for each mound thereof, also small passages extending through said mounds to receive sutures or not, upon the decision of the surgeon, and to receive growing scar tissue to assist in the permanent fixation of the implant and device within the overlapped rectus muscles of the eye and the space within Tenon's capsule.

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