SURGICALLY IMPLANTABLE COMPOUND BREAST PROSTHESIS


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ABSTRACT

A compound prosthesis for surgical implantation is provided that has an elastic sack or envelope which is adapted to contain a foam core and a quantity of a liquid in the cells of the core. The envelope has a flexible tube for adding the liquid at the time of implantation so that the size of the implant can be adjusted as desired. The flexible tube can then be tied off and concealed in a pocket in the outer layer of foam or sponge material.

5 Claims, 6 Drawing Figures
SURGICALLY IMPLANTABLE COMPOUND BREAST PROSTHESIS

BACKGROUND OF THE INVENTION

The present invention relates generally to prostheses and more particularly to an improved compound prosthesis which can be implanted within the human body and is particularly adapted to implantation in the female breast.

In the field of plastic surgery, it has now become a frequent practice to implant a prosthesis in the area of a female breast under any one of several conditions. In some cases, cancerous, precancerous, or other abnormal or damaged tissue has been removed. This creates a void where the tissue has been removed and it is possible to insert a prosthesis through the incision to fill this void. The prosthesis then becomes a replacement for the damaged tissue removed and its purpose is to restore the body contour to its original configuration. The prosthesis then furnishes support for surrounding body tissue and organs to preserve as closely as possible the original appearance of the body.

One of the main difficulties encountered in an operation of this type is the proper sizing of the prosthesis in order to obtain the desired external appearance. It is not always possible to decide in advance exactly how much tissue will be removed, and consequently it is difficult, if not impractical, to prepare an implant of the proper size and shape prior to the operation. Instead, it has been found advantageous to be able to vary the size of the prosthesis after insertion and while the patient is still on the operating table, since it is at this time that a determination can first be made of the desired volume or size of the prosthesis.

Another problem with an implant of this character is the need for providing a prosthesis having a softness and resiliency comparable to that of the body tissue removed.

It is also desirable to use carefully selected materials for the different components of the prosthesis, each being especially adapted to carrying out its particular function and at the same time being compatible with the human body.

Thus it becomes a general object of the present invention to provide a surgical prosthesis that is capable of being changed in size at the time of implantation, both to facilitate insertion and to restore more accurately the desired body contours.

It is also an object of the present invention to provide a compound prosthesis that can be filled with aqueous solution.

SUMMARY OF THE INVENTION

The above objects and advantages of the present invention are achieved in a compound prosthesis having an inner core of a pliable open-cell, foam-type plastic material having numerous interconnected pores extending throughout it. The shape of this core determines the basic shape of the prosthesis. For purposes of this disclosure, the prosthesis illustrated has a core which is particularly suitable for replacing substantially the entire female breast; but it is to be understood that this shape is illustrative only of a prosthesis for a specific purpose and is not limiting upon the invention.

A choice of materials is available to the manufacturer for the core. It is preferred that the core be a foamed plastic material, for example a polyurethane or polyester, as synthetic resins of this type are relatively inert, are pliable and resilient, can be sterilized, and the fibers are nonabsorbent. Other suitable materials are available. For example, a foamed polyvinyl material, known to the trade as Ivalon, has been used for this purpose.

Surrounding core 12 is an elastic envelope 14 which acts as a barrier membrane to retain within the envelope and core 12 any fluid which is introduced into the envelope, such as designated at f. Since it is desired that this envelope be elastic and also fluid-impermeable, a preferred material for this envelope is a silicone rubber. Not only does the envelope 14 act as a barrier to keep fluids within the envelope, but being fluid-impermeable, it excludes body fluids from the core and prevents the core from being invaded by cellular tissue from the body.

In order that fluid may be introduced into envelope 14, it is provided with a flexible tube 15 which is sealed to the envelope and at that end opens to the interior of the envelope. A suitable fluid from a source not shown in the drawing can be introduced into the envelope and, after a suitable quantity has been introduced, the tube can then be tied tightly as illustrated in FIGS. 2 and
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4, thereby maintaining the contents of the envelope in place.

As a fluid to be placed within the envelope, it is satisfactory to use clinical dextran which is a solution commonly used as a blood plasma substitute. This liquid has the advantage of being readily available, and furthermore is entirely compatible with body tissue should the envelope break and leak for any reason at all.

The open-cell foam of core 12 absorbs the liquid added and though the liquid moves easily within the envelope and sponge, the sponge tends to maintain the relative contour of the prosthesis as the wearer changes position. Thus the core gives a relatively stable shape to the prosthesis. This is also true, even though envelope 14 is not completely filled with liquid, and if the envelope should be ruptured the sponge sucks in and holds the liquid and thus prevents complete collapse.

The quantity of liquid introduced can be varied, within limits, due to the elasticity of the nature of the envelope 14. This allows the surgeon at the time of inserting the prosthesis in the patient to adjust the size of the implant, within limits, in order to obtain as closely as possible the desired external body contours.

Shown here as completely surrounding envelope 14 is an outer layer or cover 16 which is also an open-cell, foam type sponge material. Like the core, a suitable material for this outer layer is a foam polyester or polyurethane. Outer layer 16 is preferably characterized by relatively small pores. The porosity of this layer is provided in order to enable it to become invaded by body cellular tissue, thereby causing the implant to adhere firmly to the wall of the chest and also to the covering skin and tissue. As a consequence, the prosthesis becomes firmly attached to the body tissue over substantially its complete surface. This sponge covering 16 may be optionally omitted from the front surface of the prosthesis.

Since the prosthesis illustrated is designed to replace tissue in the female breast, it is shaped with one side, i.e., its base, substantially flat, this being the side that lies against the chest wall. The same general shape is assumed by envelope 14 so that the rear wall 14a of the envelope is likewise substantially flat. It will be noted in FIG. 3 that filler tube 15 is attached to the envelope at this rear wall.

Outer covering 16 has an opening 17 at the rear wall through which filler tube 15 may extend. Around this opening layer 16 is bonded to envelope 14, as at 16a, 16b, 16c, 16d, etc., and the outer layer may or may not be bonded to the envelope over the remaining portion.

Bonding outer layer 16 to the envelope around the opening therein leaves a free portion 20 of the envelope which, like a hinged cover or flap, can swing down to cover the opening. When filler tube 15 is tied off and folded into the area adjacent its point of entry into the envelope, the flap 20 covers the filler tube so that the entire external surface of the prosthesis is a layer of open-cell foam.

It has been found advantageous to make the external layer 16 substantially uniform in thickness and relatively thin. A layer having a thickness of the order of 1 to 2 millimeters, and preferably not over 2 millimeters, has been found to be quite satisfactory. A layer of this character is one that can become thoroughly invaded by human tissue for anchoring the implant, yet the total mass of the outer layer is sufficiently small that shrinkage of the fibroblasts as the tissue ages and hardens has little effect in shrinking or changing the shape of the implant. Thus the small volume of the implant which can become invaded by the tissue keeps shrinkage within acceptable limits.

Because the external layer is backed up by the imperious envelope 14, tissue cannot penetrate into the prosthesis beyond the external layer. Likewise, body fluids are excluded from the prosthesis, except in the external layer. In order to carry farther this characteristic of limiting invasion of the prosthesis by body tissue, the underside of flap 20 is preferably lined as at 21 with a coating of silicone rubber or the like which renders the flap impervious on its inner side to body tissue. This layer 21 joins or is bonded to the envelope around the portion of the flap which forms the hinge with the remainder of the layer 16. Thus, the lining 21 and the opposed portion of rear wall 14a of the envelope form a pocket to receive the tied end of filler tube 15, said pocket being impervious to invasion by human tissue.

It has been found not necessary to sew the free edge of flap 20 to the outer layer since the pressure of the prosthesis against the chest wall keeps the flap in sufficiently tight contact with the layer 16 around the lower edge of the flap to prevent infiltration of body tissue into the pocket.

An advantage over fixed-size types of breast prostheses is that the air can and should be completely pressed out of the device and a clamp applied to the ingress tube before insertion beneath the breast. The size of the skin incision may therefore be smaller than is required for a prosthesis that is not compressed. After insertion, dextran or other liquid may be admitted to the prosthesis, the volume being regulated to obtain the desired size of the prosthesis.

Variational Embodiment

An open-cell foam is characterized by intercommunication of the pores or voids within the foam, and as a consequence the liquid filling core 12 is ordinarily capable of some movement within or through the core. It is obvious that this movement is facilitated by increasing the size of the pores; but it is likewise obvious that as the percentage of voids increases, the foam becomes softer and more easily deformed.

In the event that it is desired to maintain the pore size relatively small in order to increase the ability of the core to maintain more closely its original given shape, mobility of the liquid through the core can be increased by the construction shown in FIGS. 5 and 6. In this embodiment of the invention, the core 12a is provided with a number of slits 30 cut into the core from the periphery and with one or more slits or passages 31 that extend entirely through the core. Slits 30 and passages 31 serve to limit the maximum travel of the liquid through the body of the sponge before reaching a slit 30 or passage 31 affording a location of relatively free movement. They thus serve to provide a controlled increase in the ease of movement of liquid within the core, when this is desired. These slits or fluid passages are located in planes which are generally longitudinal of, and preferably, in the best form, generally radial in.
relation to an axis of approximate symmetry that intersects the central portion of the base of the core and the apex region thereof, as illustrated. The slits 30 and 31 will also be seen to terminate short of the apex of the core, so as to leave the apex region unsevered from the base; and they also terminate at their opposite ends short of the base, so as to avoid severance of the base from the "segments" defined or formed by the slits. The slits thus do not cut transversely across the core, so as to disconnect the apex of the core from the base, and the several "segments" of the core, thus individually intact from base to apex, result in the slitted core retaining its "memory" through these segments, so as to tend inherently to return to its original form when deformed therefrom. The contained liquid flows partly via the pores of the core material and partly via the slits 30 and 31 to move with external pressures, or relief thereof, or of change of position, to simulate natural movement and mobility.

From the foregoing description, it will be understood that various changes in the detailed construction of the prosthesis may occur to persons skilled in the art without departing from the spirit and scope of the present invention. For example, the size of shape of the implant can be designed to fit within voids other than those resulting from surgery on the female breast. Accordingly it is to be understood that the foregoing description is considered as being illustrative of rather than limitative upon the invention as defined by the appended claims.

1 claim:

1. A surgical female breast prosthesis comprising:
a pliable, foamed plastic, open cell, porous core of normal breast-simulating form, having a generally flat base, and an apex;
said core having deep slits in spaced planes which are generally longitudinally disposed relative to an axis that intersects the central portion of the base and the apex of said core, said slits terminating short of the apex of the core at one end and short of the base of the core at the other; and
a fluid impervious elastomeric sac disposed closely about said core;
said core being adapted to hold a liquid within its pores and slits, and said pores and slits affording mobility for said liquid within said core.

2. The prosthesis of claim 1, wherein said slits are in angularly spaced planes which are generally radially disposed in relation to said axis.

3. The prosthesis of claim 2, wherein at least some of the slits extend only part way from the exterior surface of the core to said axis.

4. The prosthesis of claim 2, wherein at least some of the slits extend from the exterior of the core to said axis.

5. The prosthesis of claim 2, wherein at least some of the slits extend inwardly from one location on the exterior surface of the core to the general region of said axis, and thence therebeyond to an opposite location on the external surface of the core.

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