SURGICALLY IMPLANTABLE HUMAN BREAST PROSTHESIS

Filed Aug. 12, 1965

Fig. 1

Fig. 2

Fig. 3

Fig. 4

INVENTOR.
THOMAS D. CRONIN
BY Robert F. Fleming

ATTORNEY
This invention relates to a breast prosthesis suitable for implanting within the human breast.

Hereinafter there have been two general types of breast prostheses. The first type is worn externally in some type of brassiere arrangement and is generally employed when breasts or portions thereof have been removed by surgery. A second type involves a prosthesis for inserting into the breast in order to change the contour thereof. This type is generally used in cosmetic purposes and it is to this type of prosthesis that the present invention primarily relates.

Heretofore prostheses for inserting into the breast have been made of a sponge material. This suffers from two critical disadvantages. The principal one is that body tissue invades the sponge forming a hard scar which is quite uncomfortable and in no way resembles the consistency of the natural breast. The second disadvantage is that even without the invasion of body tissue the sponge implant does not have the feel of a natural breast.

It is the primary object of this invention to provide a breast prosthesis for insertion into the breast which duplicates almost precisely the consistency of natural breast tissues which cause the formation of scar tissue only against the chest wall for the purpose of securely anchoring the prosthesis to the body. Other objects and advantages will be apparent from the following description.

This invention relates to a breast prosthesis comprising (1) a flexible container approximating the shape of the human breast, (2) a soft gel filling said container and (3) a layer of porous material attached to one side of said container so that the tissue can grow into said porous material to anchor the prosthesis to the chest wall.

In order to understand the invention more clearly one should inspect the accompanying drawings in which FIGURE 1 is a sectional view showing the assembly of the prosthesis in place. FIGURE 2 is an exploded perspective view showing the assembly of the container and FIGURES 3 and 4 are sections along the lines 5, 5 of FIGURE 2 showing one method of applying a porous layer to one side of the prosthesis.

FIGURE 1 shows the prosthesis in place. The container is made up of two sections, a cup section 6 which is the general shape of a human breast and a back section 7 which is generally flat and adapted to fit against the chest wall 8. The container is filled with a soft gel 11 which provides the proper consistency for the breast tissue in the area of the breast.

This gel can be of any suitable material but the preferred material is a silicone gel as is described in more detail infra. The back section 7 has attached thereto a porous material into which tissue can grow thereby anchoring the prosthesis securely to the chest wall. In the illustration shown in FIGURE 1 this porous material is a fabric which has been corrugated and adhered to the back section 7 by means of daubs of cement 10.

The porous layer can be of any suitable material which can be invaded by tissue and which will not be absorbed by the body. The preferred material is a fabric of polyester fibers commonly sold under the name Dacron. If desired, however, a sponge-like material can also be used in which case the sponge is adhered only to section 7. After the prosthesis has been inserted into the breast as more fully described hereinafter, the incision is closed and

the natural breast tissue 12 also acts to support the prosthesis and hold it in the proper place.

The prosthesis can be assembled in any suitable manner but one way is shown in FIGURE 2. The flexible cup 6 and the back panel 7 are molded separately and the two are then assembled and secured together either by vulcanizing in place or by the use of a suitable cement. After the container has been assembled, the porous layer such as a fabric is adhered to the back panel 7. When fabric is used, it is best to employ a corrugated fabric as shown in FIGURES 3 and 4. One way of accomplishing this is to place the fabric on back panel 7 and then cement it to the panel by means of a daub of cement 10, FIGURE 3. The fabric is then crinkled and a series of daubs 10, FIGURE 4 are then placed along the base of the crinkle 9. This process is then repeated until a series of corrugations are formed across the entire length of section 7.

After the container and porous material have been assembled, a fluid which will gel in place is then inserted into the container by any suitable means. The best way of doing this is to inject a fluid through the walls of the container by means of a hypodermic needle. Once the fluid has gelled, there is little or no tendency to leak through the hole left by the hypodermic needle if the hole happens to be too large. It can easily be sealed by using a cement or other suitable material.

The size of the prosthesis can be varied to suit individual needs. In general, for a medium size prosthesis about 270 cc. of fluid is injected into the container and allowed to gel in place. However, smaller or larger devices can be made as desired.

As mentioned above, any suitable material which does not cause tissue reaction and which is soft and flexible can be employed herein. However, the preferred material for the container is silicone rubber and the preferred gel is a silicone gel. One such gel can be made in accordance with U.S. Patent 3,020,260 (which is hereby incorporated herein by reference) by adjusting the ratio of atoms of silicon-bonded H in (2) per gram molecular weight of (1) to about 1.3 (SiH/mol (1) in Table I). The ingredients (1), (2) and (3) are mixed in the proper proportions to give the above ratio and the resultant fluid mixture is injected into the silicone rubber container and then the container containing the mixture is heated four hours at 300° F. to gel the liquid. It should be understood, however, that the silicone gel can be prepared in other ways such as, for example, by injecting a mixture of a hydroxylated siloxane and ethylsilicate into the container along with a suitable catalyst such as stannous octoate. The fluid will then set in place forming a soft gel. Regardless of the type of gel employed, it is preferred that the gel have a soft consistency as measured by a precision universal penetrometer, Catalog No. 73.510 of the Precision Scientific Company. Instead of using the standard cones supplied with the penetrometer, a brass head 14" in diameter and 7/8" high and having rounded edges was attached to the shaft. The total weight of the shaft and head was 51.9 g. A sample of the gel at room temperature was placed against the bottom of the shaft head. The clutch of the shaft was depressed for five seconds and the depth of penetration into the gel was then measured. For the preferred embodiment in this invention, the penetration should be from 30.0 to 20.0 mm., although for some uses a higher or lower penetration is desirable.

It should be understood that the above specifications represent the preferred embodiment of this invention and that in some cases a harder or softer material can be advantageously employed. However, regardless of the precise penetrometer readings of the gel, the material should be sufficiently soft and flexible to approximate the...
3,293,663

consistence of the natural breast. In addition, the gelled material should be one which is inert toward the container.

To insert the prosthesis, one makes the usual sub-mammary incision about 3" long and dissects the breast free of the pectoral muscle and chest wall. The cavity should be of adequate size to freely receive the prosthesis. The implant is inserted with the thin edge uppermost and directed slightly towards the anterior auxiliary fold. When the prosthesis has been inserted, there is often an excessive prominence of the upper part of the implant. This can be corrected after the wound has been closed by applying firm pressure with some foam rubber pads and adhesive tape across the top of the prosthesis. This forces the gel into the lower part, stretching the overlying tissues and making the breast more prominent as desired. This pressure may be continued for a week to 10 days. The breast now has a natural appearance with the upper surface tending to be slightly concave when unsupported by a brassiere.

It is highly desirable that the porous layer, for example, Dacron mesh which is adhered to the back of the prosthesis, be trimmed off as close to the margin of the implant as possible. This will prevent an excessive formation of scar tissue and yet will give firm anchoring of the prosthesis to the chest wall. A particularly suitable fabric for use in this invention is coarse tricot weave polyester fiber mesh sold under the designation D2000 by the Mohawk Fabric Company.

That which is claimed is:

1. A breast prosthesis comprising (1) a flexible container approximating the shape of the human breast, (2) a soft gel filling said container and (3) a corrugated fabric attached to one side of said container so that the tissue can grow through the fabric and anchor the prosthesis to the chest wall.

2. A breast prosthesis comprising (1) a silicone rubber container approximating the shape of the human breast, (2) a soft silicone gel filling said container and (3) a corrugated polyester fabric attached to one side of said container so that the tissue can grow through said fabric and anchor the prosthesis to the chest wall.

3. A breast prosthesis suitable for implanting within the human breast comprising (1) a container made of a flexible material and having a front section which approximates the shape of the human breast and a rear section which is adapted to fit against the chest wall, (2) a soft gel filling said container and (3) a fabric attached to the rear section of said container at spaced intervals and having a corrugated configuration so that tissue can grow through the fabric in those areas where it is spaced away from the rear section of the container thereby anchoring the breast prosthesis to the chest wall.

4. A breast prosthesis suitable for implanting within the human breast comprising (1) a container of silicone rubber having a front section which approximates the shape of the human breast and a rear section which is adapted to fit against the chest wall, (2) a soft silicone gel filling said container and (3) a polyester fabric attached to the rear section of said container at spaced intervals and having a corrugated configuration so that the tissue can grow through the fabric in those areas where it is spaced away from the rear section of the container thereby anchoring the breast prosthesis to the chest wall.

5. A surgically implantable human breast prosthesis comprising (1) a flexible container having a substantially tissue impermeable front section approximating the shape of a human breast and a tissue impermeable rear section adapted to fit against the human chest wall, (2) a soft gel filling said container, and (3) tissue permeable anchoring means of sponge-like material attached solely to said rear section for allowing human tissue to grow into said sponge-like material and thereby anchor said material to the chest wall.

References Cited by the Examiner

UNITED STATES PATENTS

1,250,875 12/1917 Heuchan -------------- 128—462
2,542,619 2/1951 Bernhardt -------------- 3—36
2,543,499 2/1951 Kausch -------------- 3—36
2,836,182 4/1958 Freedman -------------- 3—36
2,842,775 7/1958 Pangman -------------- 3—36

RICHARD A. GAUDET, Primary Examiner.
R. L. FRINKS, Assistant Examiner.