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Breast Implant Classification with MR Imaging Correlation[1]

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Abstract

Rupture is now recognized as an important and common complication of breast implants. Magnetic resonance (MR) imaging is the most accurate method for evaluating implant integrity but requires an understanding of the numerous variations in implant construction that are encountered clinically. To assist in diagnosis, the authors provide an MR-oriented breast implant classification scheme based on data from 4,014 patients (>9,966 current or previous implants), the literature, and other primary documentation. This scheme consists of 14 implant types: 1) single-lumen silicone gel-filled, 2) single-lumen gel-saline adjustable, 3) single-lumen saline-, dextran-, or polyvinyl pyrrolodone-filled, 4) standard double-lumen, 5) reverse double-lumen, 6) reverse-adjustable double-lumen, 7) gel-gel double-lumen, 8) triple-lumen, 9) Cavon "cast gel", 10) custom, 11) solid pectus, 12) sponge (simple or compound), 13) sponge (adjustable), and 14) other. The MR imaging and mammographic appearance of many implant types is correlated with their actual appearance after explantation. A brief history of prosthetic breast augmentation and reconstruction is also provided to allow this classification method to be placed in historical perspective. Knowledge of the variety of breast implant types will help reduce misdiagnoses by providing imagers with better understanding of the expected appearances of breast implants. This classification scheme will allow stratification of data for studying incidence, prevalence, and risk factors for and causes of implant failure, as well as permitting better correlation with patient symptoms and surgical outcome.

Index Terms: Breast, MR, 00.121411, 00.121415 • Breast, prostheses, 00.4543, 00.4544 • Silicone

LEARNING OBJECTIVES

After reading this article and taking the test, the reader will:

• Be familiar with the history and terminology of breast implants.

• Know the typical MR imaging appearances of the various implant types on the basis of an understanding of their actual construction.

• Use knowledge of implant construction and appearance to avoid misdiagnosis of the many types of implants that have been used over the last 50 years.

Introduction

Breast implants have been the object of considerable attention since the U.S. Food and Drug Administration (FDA) imposed a moratorium on silicone gel implants in 1992 (1,2,3,4,5,6,7,8,9,10,11). In particular, the recently released report "Safety of Silicone Breast Implants", prepared by the Institute of Medicine of the National Academy of Sciences, concluded that while the current scientific literature does not demonstrate an association between breast implants and various diseases, *local* complications of implant rupture are frequent[2] (9). The committee noted the difficulties that occur both in imaging diagnosis as well as the conduct of epidemiologic studies of local complications because of the great diversity of implant types and styles.

This report will present a comprehensive breast implant classification scheme based on historical and magnetic resonance (MR) imaging considerations, and in doing so will illustrate the essential components from which breast implants are constructed.

Early history of augmentation

Czerny is credited with the first breast reconstruction in 1895, using a lipoma from a patient to augment her breast after removal of an adenoma (12,13,14). The record is clear that paraffin was used in the 1880s to treat tuberculosis (15); however, the contemporaneous literature from the turn of the (last) century is unclear as to when paraffin was first used for breast augmentation. Gersuny *suggested* in 1900 that it would be *possible* to do this (16), but was referenced by others many years later as having suggested or performed breast augmentation with paraffin in 1899 (17,18,19,20,21,22), and as early as "the 1880's" (unreferenced) by Clarkson and Jeffs (23). In his 1900 paper, Gersuny does report " ... a few therapeutic attempts ... years ago ...", but does not state that they were in the breast (16). Caffee (1997) reported (without references) that the first reported injections of paraffin for breast augmentation occurred in 1904 (24). The unacceptable incidence of complications due to paraffin, including embolization to the lung and brain and solidification into "paraffinomas" and "wax cancer" (15), was the reason its use was discontinued[3] in Europe and the United States in the 1920s (25). Placement of glass balls and ivory for breast augmentation also have been reported (2,17,18,20,22,26,27,28).

Plastic sponges

After several years of use in other parts of the body in the late 1940s (29,30,31), plastic implants, most in the form of a sponge made from polyethylene (Polystan), nylon, polyvinyl alcohol (Ivalon), polyurethane

(Surgifoam, Etheron, Scottfoam), Teflon, silicone (SILASTIC) sponge, or poly-HEMA (Hydron) were experimented with or used for breast reconstruction and augmentation(32,33,34,35,36,37,38,39, 40,41,42,43,44,45,46,47,48,49,50,51). Even though others may have used sponges for breast augmentation earlier (32,40), Pangman is usually credited with first seriously investigating the use of sponges for breast augmentation starting in 1951 (52,53). Complications soon became apparent, including capsular contracture, seroma formation, fistulization, and infection (54). Ivalon sponges were shown to induce sarcoma in rodents (55,56), and to harden and shrink in patients within the first year (57). Following the introduction and rapid acceptance in late 1963 of the new "natural feel" silicone gel-filled implant from Dow Corning (58), the use of sponge implants rapidly declined, with what could be regarded as vestigial use in some custom and other implants until the early 1970s.

Silicone fluid and gel injections

Injections for cosmetic reasons of non-silicone fluids from about 1935, and then silicone fluid preparations sometime in or soon after 1945, are reported to have been performed in Japan (25), and were later introduced in the United States (59). The main problem encountered when a large volume of "pure" liquid silicone is injected into the breast or elsewhere is that it tends to migrate unacceptably away from the site of injection. It was reported in 1968 that "pure silicone oil is so non-reactive that it drifts in subcutaneous fat" (60). Two approaches were devised to minimize this problem: (*a*) addition of a fibrosing agent to the injected silicone fluid and (*b*) injection of the silicone in gel form. Later, to achieve a more "natural feel" than obtained with sponges, Cronin began enclosing the silicone in a bag (58,61). Most practitioners found that the Cronin implants also gave a more natural feel than direct silicone injections.

The first approach for preventing or reducing migration was instituted by Japanese and other practitioners who added fibrosing agents such as vegetable oil, fatty acids, and other materials to "pure" silicone to form what have been referred to as "adulterated" silicones (ie, the *Japanese* or *Sakurai* formula) (25,59,62). Some of these "adulterated" formulas were in use in the United States by about 1963 (59). About 18 years after this practice started, problems were reported in patients with silicone fluid injections, including formation of silicone granulomas, sometimes called "siliconomas" (63,64). This was a longer delay than was seen for the (much) earlier paraffin injections. Siliconomas are not tumors per se, but are masslike focal collections of histiocytes and foreign body giant cells surrounded by and engulfing silicone (65). Intraarterial injection of silicone fluid was shown to be fatal in dogs because of embolization (66), and the death of a patient after injection by a "travelling therapist" of silicone fluid into the breasts has been reported (67). The cause of death was determined to be severe acute bilateral pulmonary edema secondary to intravascular silicone injection (67). Many women in the United States and abroad have received such injections[4]. Some women with paraffin (79) and silicone (79,80) breast injections have undergone and continue to undergo mastectomy to remove the material.

The second approach for preventing or reducing migration was to inject or surgically place silicone in the form of a gel. As per a 1964 release from Japan Medical Plastics Center, Dr Taichiro Akiyama first formulated silicone for injection in 1948, and then later in about 1949-50 developed an injectable form of (cross-linked) silicone gel called Elicon (81,82). Koken offered Elicon for sale in 1964, marketed as "Dr. Akiyama's Natural Fat" (83,84). In the United States, breast injections of silicone gel were used on an experimental basis in patients by Frank Gerow, MD, in 1962 at Baylor University (85). Others also reported silicone gel breast injections (86,87). Freeman reported in 1974 that silicone gel was intentionally removed from an implant shell and then used for breast augmentation (88). Cavon designed and patented an implant that was used from about 1979 to 1985, consisting of cohesive silicone gel without a shell (89,90). The total number of patients in the United States with "native" silicone gel still in place in any of these categories at this time is likely to be small.

The Cronin implant

Dr Thomas Cronin placed silicone gel in a bag consisting of rubberlike silicone sheeting (elastomer), forming what is recognized as the modern silicone gel-filled implant (58). These were investigated experimentally from February 1961 until late 1963, with the first ones placed in a patient in about March 1962 by Cronin and Gerow (Baylor University) in conjunction with the Dow Corning Center for Aid to Medical Research, and produced commercially by Dow Corning starting in about October 1963 (58,91,92,93,94,95). These were considered medical devices, and hence not subject to the FDA rules and regulations of the time regarding drugs, as were silicone injections. In 1976, the FDA began regulating medical devices, at which time breast implants were "grandfathered in", with further investigation planned.

Subsequent implant development

Early silicone gel-filled implants had a thick shell (or envelope), a peripheral seam, and a backing of Dacron mesh meant to promote tissue ingrowth and fixation along the posterior surface. Seamless implants became available in about 1968, and by the early 1970s implants were available without fixation. After a period of experimentation that may have started as early as 1964 (96), silicone gel-filled breast implants fully coated with polyurethane became available in 1968 with a thick shell, a peripheral seam, and an internal Y-shaped baffle[5] (ie, the "Natural-Y", or "Ashley", implant), and then in greater numbers in a variety of styles from about 1982 onward. Implants designed to reduce silicone fluid bleed, called "low bleed" implants, first became available in the early 1980s. Texturing of implant shells in the middle 1980s was intended to reduce capsular contracture. Although saline- (and, earlier, dextran-) filled implants never attained the popularity of the silicone gel-filled implant, they were experimentally placed or used in the early 1960s in the United States (97) and abroad (98). Recent modifications include filling the (silicone elastomer) shell of implants with triglyceride-based fillers (99) and providing fixed-volume prefilled saline implants (100).

Breast implant classification

Initially there was only one style in one size, which was the 1962 Dow Corning experimental single-lumen silicone gel-filled implant[6]. Later, many types, styles, and sizes of implants were introduced by Dow Corning and other manufacturers. We are aware of no current complete published catalogue of breast implants. In 1973, Braley gave a brief history of breast implants (93). In that same year, Snyder also listed styles and sizes of implants available at that time (101). In 1976 and 1978, Gerow updated that information (102,103), as did Baker in 1979 (104). In 1982, Elbaz and Ohana illustrated and described a number of implants that had since become available (105). The description, MR imaging appearance, and mammographic appearance of several implant types have been described (1,2,106), but the issue of classification was not addressed.

We have previously described 14 breast implant types (3,4,5,107), the most common of which is still the single-lumen silicone gel-filled type. For most implant types and styles, there have been variations over the years in shell thickness, method and location of patching, shell marking, type and "thickness" of silicone gel, shape and size, and method of fixation or orientation.

To date we have noted over 240 breast implant styles from American manufacturers alone[7] (108). The actual number of styles is far larger because many implants of a single style from a single manufacturer evolved through many variants over the years. Also, the "custom" implant type alone is diverse.

Summary

Implant rupture has been recognized as an important, if not the most important, complication of breast implants (9). In this report, we will describe and illustrate the various types of implants, with special attention to correlating the MR imaging appearance of implants with their actual construction and appearance. Special emphasis is given to describing the essential features of each implant type. This will allow a better understanding of breast implants by radiologists and aid in implant imaging. Misinterpretation resulting from

unfamiliarity with the variety of implant types may be avoided. This also will permit stratification of research data by implant type and allow investigation of the incidence and causes of rupture, local breast symptoms, systemic symptoms, and outcomes of surgery.

Materials and Methods

The authors have compiled a breast implant catalogue listing manufacturer, implant type, style, size, and other detailed information[7] (108). The material contained there forms part of the basis for this report. Our sources of information have included the following:

1. Medical records of 4,014 patients (more than 9,966 current or previous breast implants), 1,377 of whom underwent 1,524 breast MR scans at the University of California San Diego over the last 8 years[8].
2. Direct visual examination of 4,821 implants from that population, 499 of which were observed at time of removal during 258 explantation operations attended by one of us (M.S.M.).
3. Documents produced in the MDL 926 Class Action Breast Implant Litigation, referenced here by the "Bates" numbers. As noted in the Institute of Medicine Study on the Safety of Silicone Breast Implants, this type of information can "identify directions for inquiry, useful literature, and data" that can assist in inquiries of this sort (9). These documents are in the public domain and can be obtained by contacting Tina J. Crowe, the Document Depository Librarian, at the National MDL 926 Document Depository, 105-D Potter Stewart U.S. Courthouse, 100 East Fifth Street, Cincinnati, OH 45202; telephone: (513) 684-6688; fax: (513) 684-5853; e-mail: tjcrowe@fuse.net.
4. Formal meetings and later correspondence with representatives of Dow Corning Corporation concerning their breast implant products.
5. Informal feedback from representatives of several other breast implant manufacturers, including Bioplasty, Cox-Uphoff International (CUI), Inamed, McGhan, Mentor, Progress Mankind Technology (PMT), Collagen, PIP, and Surgitek, with regard to their products.
6. Published accounts of breast implants.

The MR images shown in this report were obtained with a 1.5-T imager (4.8x software) (GE Medical Systems, Milwaukee, Wis) with dedicated bilateral breast surface coil (Medical Advances, Milwaukee, Wis, and GE Medical Systems). Typically, the field of view was 15 or 20 cm, matrix size was 256 x 256, section thickness was 3 or 4 mm, and a T2-weighted water-suppressed fast spin-echo (FSE) technique was used (repetition time, > 3,000 msec; echo time, 208 or 304 msec; echo train length, eight or 16; bandwidth, 16 kHz) (3). These same types of high-resolution T2-weighted water- (and silicone-) suppressed surface-coil images are also obtainable with other MR imagers, although the names of the sequences may be different. Institutional Review Board approval was obtained to review medical records. Informed consent was obtained for those cases in which MR images were obtained as part of a research protocol.

Description of Implant Types

The proposed breast implant classification scheme is given in Table 1. This scheme is based on implant construction and MR imaging appearance. Saline-filled, dextran-filled, and PVP-filled implants are in the same implant type because they have the same MR imaging appearance. The numbers and percentages of each of the types of implant that our patients at UCSD have or have had are also given in Table 1. A summary of implant valve types (Figs 1–26) is given in Table 2. A summary of fixation and orientation devices (Figs 27–45), implant texturing (Figs 46–47), and reinforcement disks (Figs 48–49) is given in Table 3. A summary of polyurethane-coated implants (Figs 51–56) is given in Table 4.

View this table: TABLE 1. Breast Implant Classification Scheme

View this table: TABLE 2. Implant Valve Types

View this table: TABLE 3. Orientation, Fixation, and Other Features

View this table: TABLE 4. Polyurethane-coated Breast Implant Styles

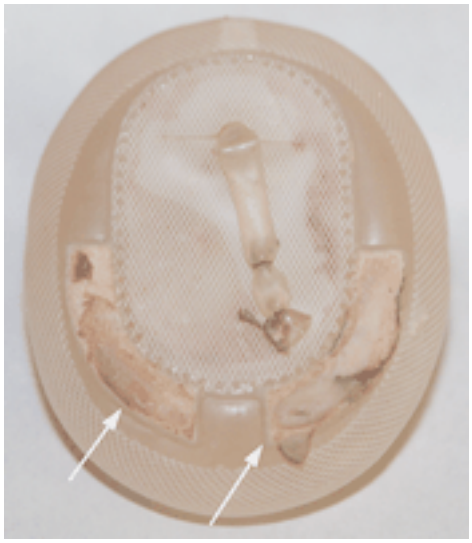

Figure 1. Ligation valve. Style 1400 Heyer-Schulte Tabari saline-filled implant (placed 1972) with a ligation valve seen here pulled out of the pocket in which it can be buried (photographed upside down). A narrow strip of Dacron mesh-reinforced elastomer is present around the entire circumference of the implant inside the implant shell. Two crescent-shaped strips (arrows) of Dacron felt fixation material are present on the posterior superior part of the implant, with some ingrown tissue still attached (143,144).

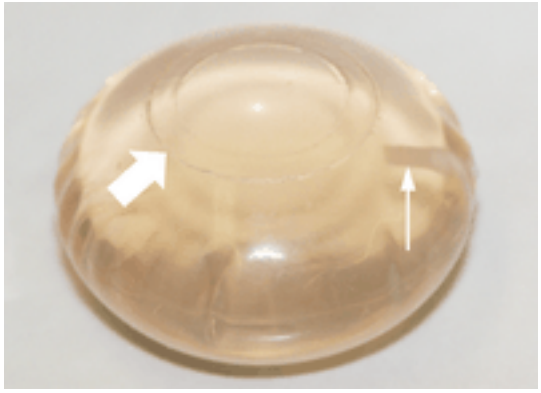

Figure 2. Tube valve. Roger Klein saline-filled implant (placed 1974), originally designed by Dr H. G. Arion (98), imported into the United States by Roger Klein. (New York, NY) from Simaplast (Paris, France) as the Arion implant, and later manufactured by Roger Klein as the Mammatech implant (123,124). These implants had a circumferential seam and a tube protruding from the implant that could be stoppered, inverted into the implant, or both. The valve could be at the side (thin arrow), on the anterior surface, or on the posterior surface of the implant. A large round shell patch is shown here on the posterior surface of the implant (thick arrow). This type of valve has a characteristic appearance at mammography (Fig 3) and probably also on MR images.

Figure 3. Tube valve. Xeromammogram of the Roger Klein saline-filled implant shown in Figure 2, showing the plug valve inverted into the implant and the large round back patch.

Figure 4. Plug valve. One early Surgitek implant, known as the Dahl implant, was inflated with silicone at time of placement (115). Shown here is the "plug valve" of such an implant placed in about April 1975, stoppered with a white plug. The inner edge of the hole in the shell is just discernible. Free gel is present on the implant surface. This type of valve should have a characteristic and identifiable cylindric appearance on MR images.

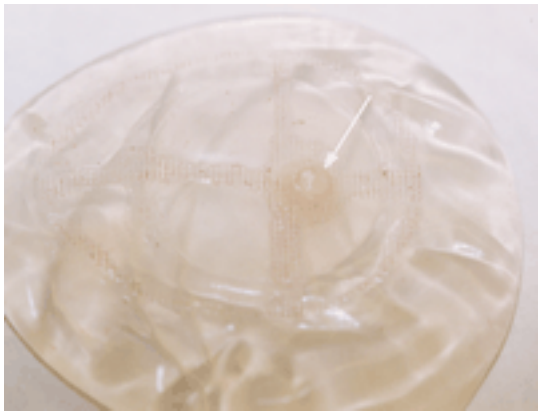

Figure 5. Plug valve. Shown here is an early Koken implant, which we understand also was known as the Akiyama implant[13] , with a plug valve (82). The plug (arrow) is removable, rivet-shaped (or mushroom-shaped), and placed directly into the implant shell hole. The Dacron mesh used to provide fixation for this implant, remnants of which are seen here, has a rather coarse rectangular weave pattern. It is our understanding that this implant was placed in 1980. This type of valve may have a characteristic appearance on MR images.

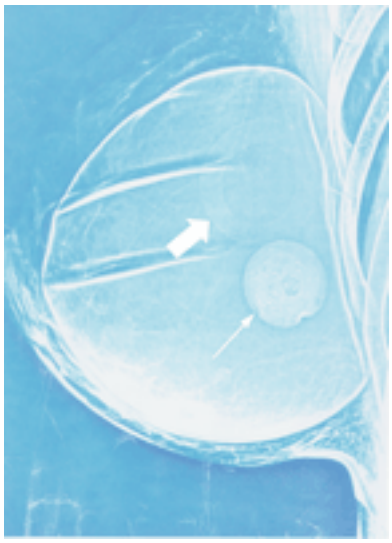

Figure 6. Seal-Seal inflatable (SSI) valve. Xeromammogram of an early Surgitek saline-filled implant (placed 1974). Both the SSI valve (thin arrow) and the implant back patch (thick arrow), on the posterior surface of the implant, are evident.

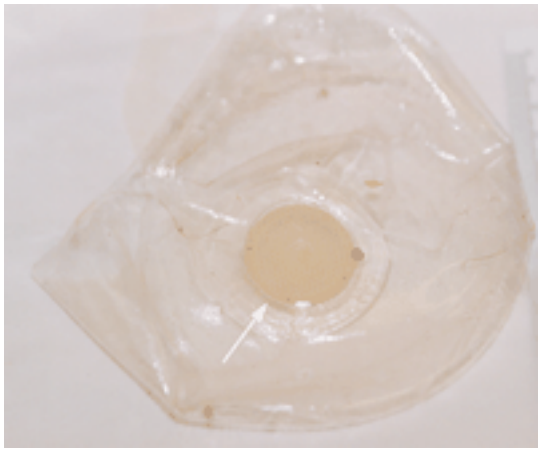

Figure 7. Seal-Seal inflatable (SSI) valve. Surgitek Georgiade contoured standard double-lumen implant (placed 1978), showing the Dacron mesh-reinforced SSI valve (arrow), containing a fairly thick silicone gel, mounted on the inner surface of the back patch on the outer posterior shell. This type of valve also can be found mounted directly on the internal surface of the outer shell of other Surgitek standard double-lumen implants, and is the same type of valve that was used in some Surgitek saline-filled and gel-saline implants in the 1970s and early 1980s. This type of valve has a characteristic appearance on MR images (Fig 8).

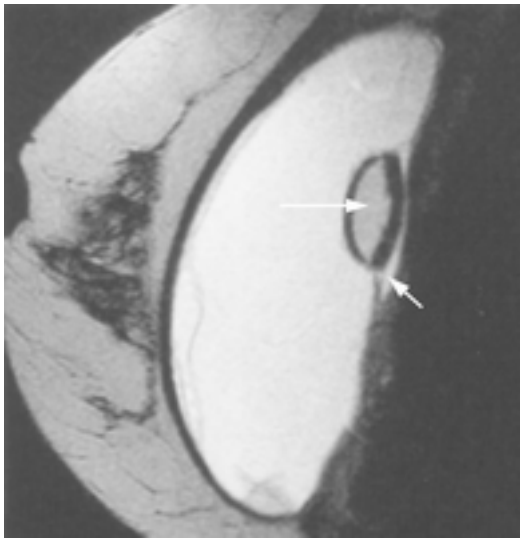

Figure 8. Seal-Seal inflatable (SSI) valve. Sagittal T2-weighted fast spin-echo water-suppressed MR image showing the SSI valve in a round (ruptured) Surgitek Munna standard double-lumen implant (placed 1982). The signal from the silicone in the SSI valve (long arrow) is not as bright as the signal from the silicone gel in the inner (and outer) lumen most likely for two reasons: It is more highly crosslinked, and it is likely that there is suppressed waterlike fluid intermixed with the silicone gel. The presence of silicone outside the (outer shell) SSI valve (short arrow) is a definitive sign that the implant is ruptured. This type of fill-port is shown in Figure 7 on a different style of Surgitek standard double-lumen implant.

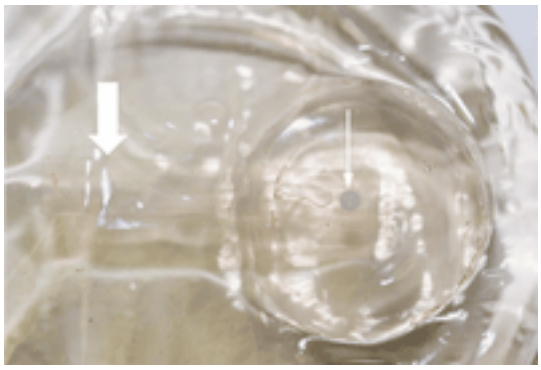

Figure 9. Leaflet valve. Posterior surface of a Surgitek 22000 series round standard double-lumen implant (placed 1983), with the characteristic small white 3-mm dot (thin arrow) with a slit, proximally marking one end of the fill channel. The rectangular leaflet valve, measuring about 10 x 60 mm, is seen here extending to the left (thick arrow). Rarely seen MR images capturing the appearance of this type of leaflet valve are shown in Figures 10 and 11.

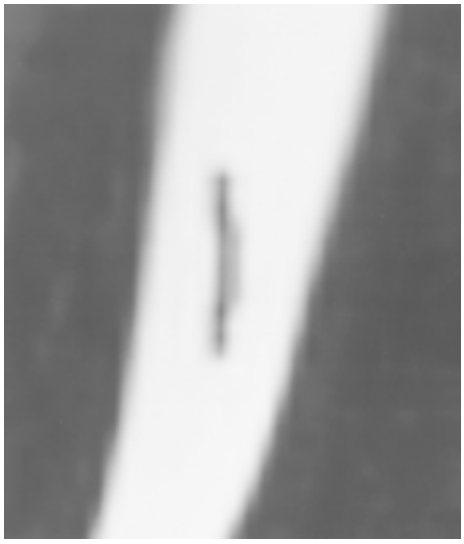

Figure 10. Leaflet valve. T2-weighted fast spin-echo silicone-suppressed MR image (original magnification, x5) of the distal part of the leaflet valve of a Surgitek standard double-lumen implant such as that shown in Figure 9, showing the characteristic appearance of the leaflet valve in cross section. (This cross section is what would be seen at about the location of the thick arrow in Figure 9). In this image the inner-lumen silicone gel is dark and the outer-lumen saline surrounding the leaflet valve is bright. Another more distal (*en face*) MR cross section through this same type of valve is shown in Figure 11.

Figure 11. Leaflet valve. T2-weighted fast spin-echo silicone-suppressed MR image (original magnification, x5) of the distal part of the same type of leaflet valve shown in Figures 9 and 10, showing its characteristic squared-off appearance *en face*. In this image the inner-lumen silicone gel is dark and the outer-lumen saline surrounding the leaflet valve is bright.

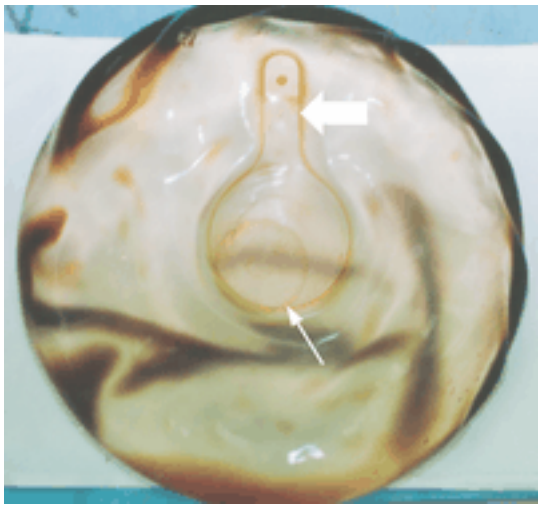

Figure 12. Leaflet valve. Posterior surface of a Dow Corning 380 series standard double-lumen implant (placed 1985), showing the most common configuration for the leaflet valve for this series (thick arrow). Just barely visible on this implant itself (but not in this photograph) were the markings "SILASTIC II 300 cc" on the round inner-lumen back patch (thin arrow). The xeromammographic appearance of this implant is shown in Figure 13, and the characteristic MR imaging appearance of this type of leaflet valve is shown in Figure 14.

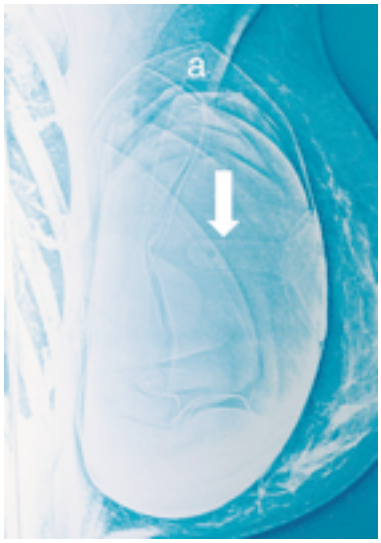

Figure 13. Leaflet valve. The appearance of the distal part of the leaflet valve for the Dow Corning 380 series standard double-lumen implant shown in Figure 12 is demonstrated on this xeromammogram (arrow). The characteristic xeromammographic appearance of saline present in the outer lumen of the standard double-lumen implant is also shown here (a). The characteristic appearance of this type of leaflet valve on MR images is shown in Figure 14.

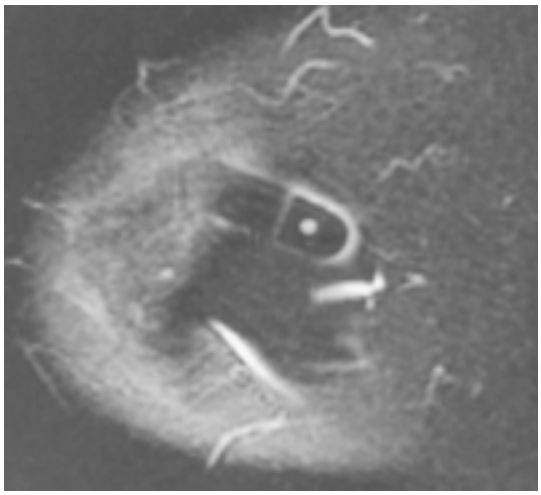

Figure 14. Leaflet valve. T2-weighted silicone-suppressed MR image of the distal part of the leaflet valve in a Dow Corning 380 series standard double-lumen implant, showing the *en face* MR imaging appearance of the type of leaflet valve illustrated in Figures 12 and 13.

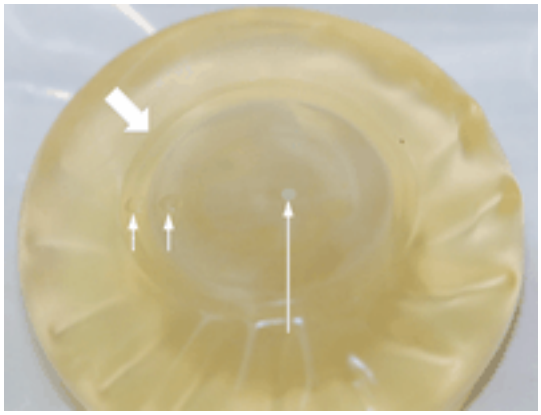

Figure 15. Leaflet valve. Surgitek reverse-adjustable double-lumen implant (placed 1985). Beveled back patch outside implant shell is shown here (thick arrow) with two gel fill points (short arrows), one for each silicone gel-filled lumen. Toward the center of the back patch is the 3-mm white dot and slit (long arrow) marking the entry point to the short Quin-Seal leaflet valve leading to the inner lumen. (The slit is not discernible on this photograph.) The MR imaging appearance of this implant is illustrated in Figures 58 and 59.

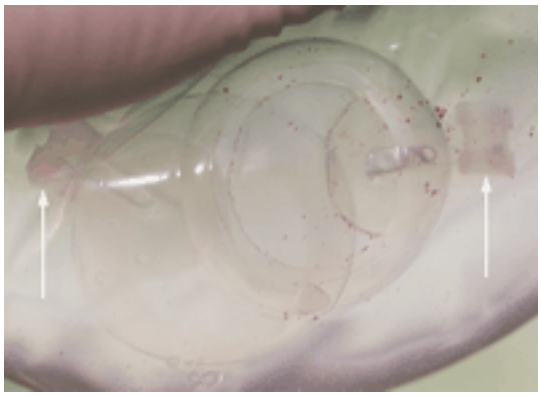

Figure 16. Double leaflet valve. Mentor Becker 25/75 reverse double-lumen implant with a double leaflet valve, one for the inner and one for the outer shell (placed 1986). The fill tube has been withdrawn from this implant, and so both leaflet valves have curled (arrows), giving a "window-shade" appearance. This type of curled window shade appearance can be seen on some MR images. This type of implant also was manufactured with one curled (inner) and one flat (outer) leaflet valve.

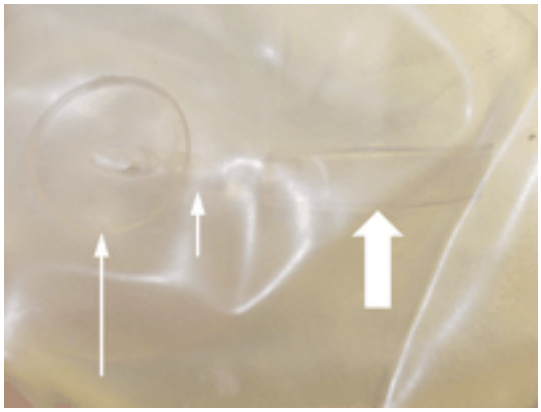

Figure 17. Retention valve. Heyer-Schulte Style 1200 saline-filled breast implant with a retention valve (placed 1976). The valve has a round narrow proximal part (short arrow) and a flat distal part (thick arrow), and is attached to the implant shell through a round patch (long arrow). The cross-sectional MR imaging appearance of this type of valve is shown in Figures 18 and 19.

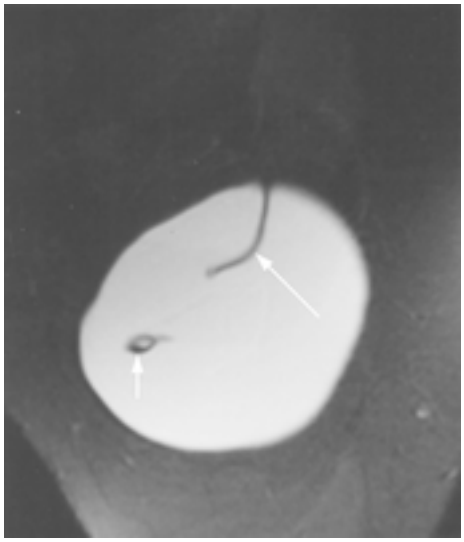

Figure 18. Retention valve. T2-weighted fast spin-echo silicone-suppressed MR image of Heyer-Schulte Style 1200 (or 1300) saline-filled breast implant with a retention valve, showing a cross section through the proximal round neck of the valve (short arrow). A peripheral fold is also seen (long arrow). A photograph of a valve of this type is shown in Figure 17, and the MR imaging appearance of the distal flat part of this valve is shown in Figure 19.

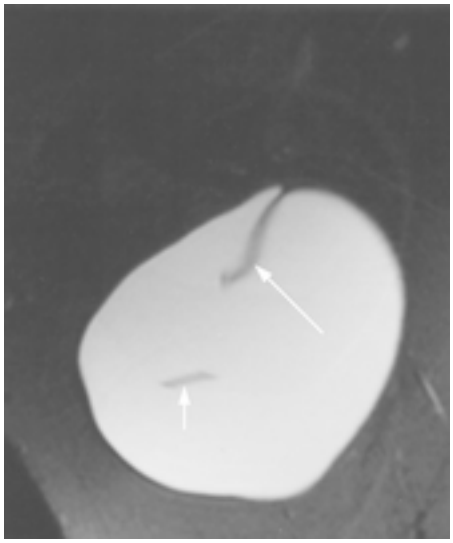

Figure 19. Retention valve. T2-weighted fast spin-echo silicone-suppressed MR image of Heyer-Schulte Style 1200 (or 1300) saline-filled breast implant with a retention valve, showing a cross section through the distal flat part of the valve (short arrow). The peripheral fold is also seen (long arrow). A photograph of a valve of this type is shown in Figure 17, and the MR imaging appearance of the proximal round part of this valve is shown in Figure 18.

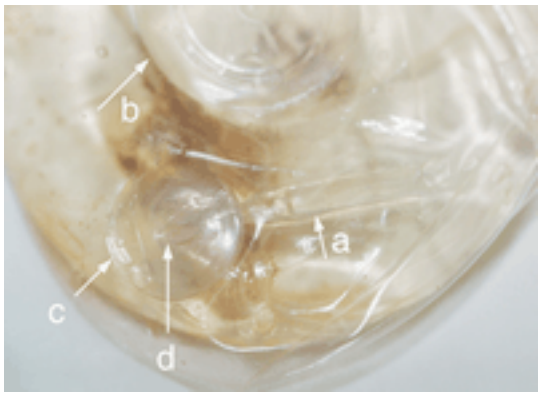

Figure 20. Retention valve. Heyer-Schulte Style 7000 Hartley-type standard double-lumen breast implant (late version with slit in shell patch, placed 1982), showing the retention valve (a) on the posterior shell adjacent to the central back patch (b). The valve is attached to the shell through an elastomer disk (c). The opening to the valve (d) is placed just under the slit in that disk. The MR imaging appearance of this type of implant is shown in Figure 21.

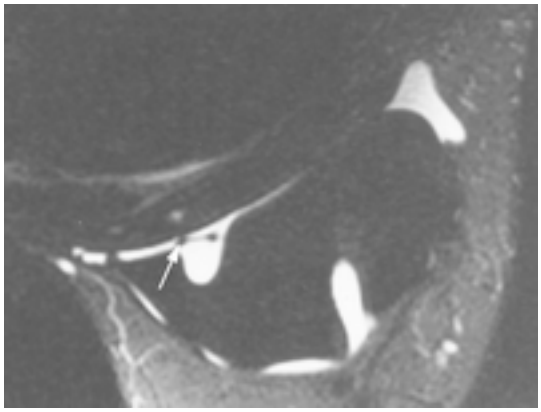

Figure 21. Retention valve. Axial T2-weighted silicone-suppressed MR image of Heyer-Schulte standard double-lumen implant with a retention valve (placed 1983). This MR image illustrates the slightly curled (thickened) edges of the distal flat part of the valve (arrow). A photograph of this type of implant is shown in Figure 20.

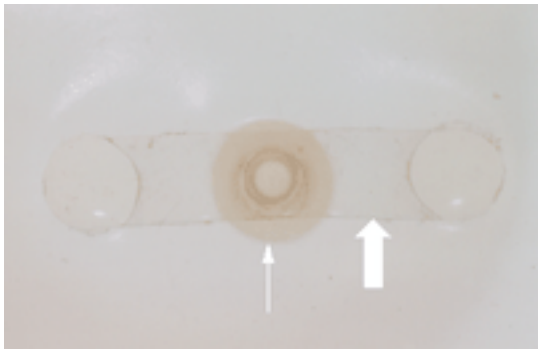

Figure 22. Diaphragm valve. Style 1600 Heyer-Schulte saline-filled implant (placed 1982), showing the anterior diaphragm valve (thin arrow) with a strap (thick arrow) and attached central plug, bonded to the implant shell on both sides. The MR imaging appearance of this type of valve is shown in Figure 24. Earlier saline-filled implants from this manufacturer had a larger so-called Jenny valve, named after Dr Henry Jenny, who was the first to design saline implants, in 1968, with a diaphragm valve[14] . Those earlier implants had a plug attached to the shell with a strap on only one side.

Figure 23. Back patch of Heyer-Schulte Style 1600 implant. Same Heyer-Schulte implant as shown in Figure 22, showing the posteriorly placed back patch and annulus inside the implant shell, with an "M" on the overlap portion of the shell and the back patch (arrow). The back patch on saline-filled implants such as this are necessary to close the shell hole remaining after the shell is formed on a mandrel. These patches can sometimes be seen at mammography, and also on MR images (Fig 24).

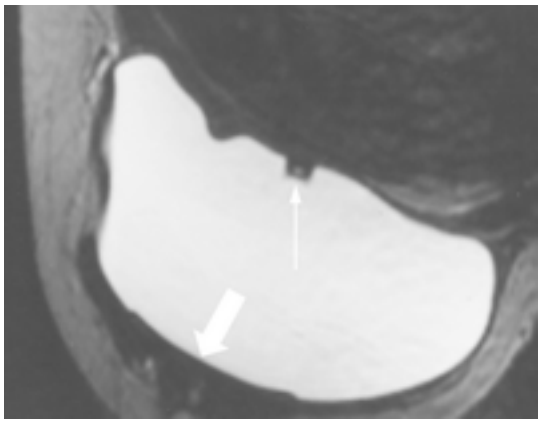

Figure 24. Diaphragm valve. Axial T2-weighted fast spin-echo silicone-suppressed MR image of a Style 1600 Heyer-Schulte saline-filled implant (placed 1983) showing the diaphragm valve and back patch. The usually anterior-facing diaphragm valve is posterior here (thin arrow), and the usually posterior-facing back patch is seen anteriorly (thick arrow). (This implant position is occasionally seen and does not have any clinical or cosmetic significance.) Photographs of the type of diaphragm valve and back patch used on this kind of implant are shown in Figures 22 and 23.

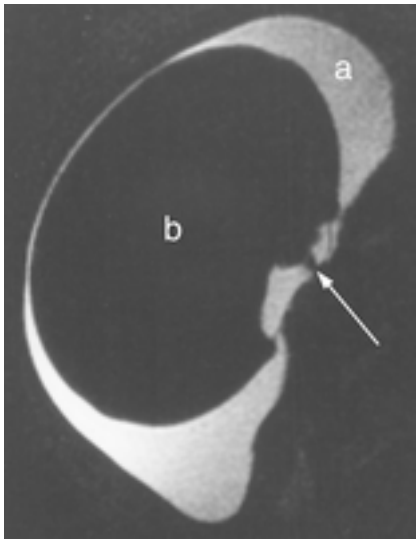

Figure 25. Internal tube valve. Sagittal T2-weighted fast spin-echo water-suppressed MR image of a Mentor Becker Siltex (textured) reverse double-lumen implant (placed 1991), with bright(er) outer-lumen silicone gel (a) and dark inner-lumen saline (b), showing portions of the posterior valve assembly (arrow). These were available in a 50/50 or a 25/75 gel-to-saline ratio. The appearance of this implant with silicone-suppression MR imaging is shown in Figure 26.

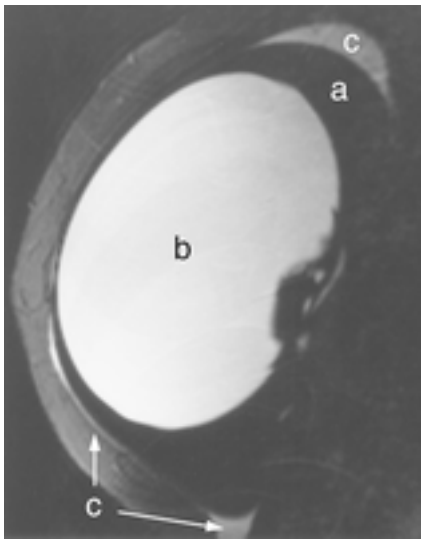

Figure 26. Internal tube valve. Sagittal T2-weighted fast spin-echo silicone-suppressed MR image (same section as in Fig 25) of a Mentor Becker Siltex (textured) reverse double-lumen implant, with dark outer-lumen silicone gel (a) and bright inner-lumen saline (b). Bright intracapsular waterlike fluid is seen surrounding the implant (c), a common finding for implants with a textured surface.

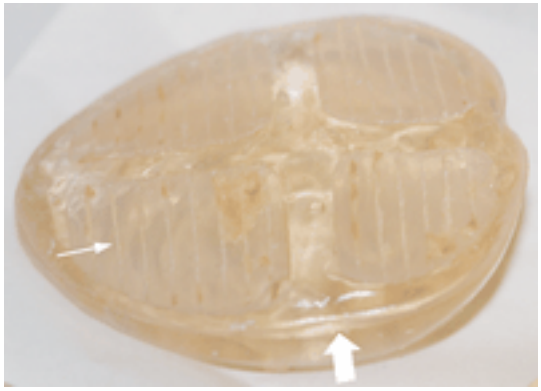

Figure 27. Four-quadrant fixation patches. Dow Corning 830 series implant showing the four-quadrant fixation patch design (placed 1965). The outer layer of loose Dacron mesh has been cut from each of the Dacron mesh-reinforced elastomer fixation patches. Seen here are the cut sutures that originally joined those two layers (thin arrow). Those sutures compartmentalize the fixation patches, producing a characteristic "zebra-stripe" appearance on MR images (Fig 28). The posterior surface of the implant is shown here, photographed from the side. Most early versions of the 830 series implants, such as this one, have a non-everted peripheral seam (thick arrow); later versions have an everted peripheral seam.

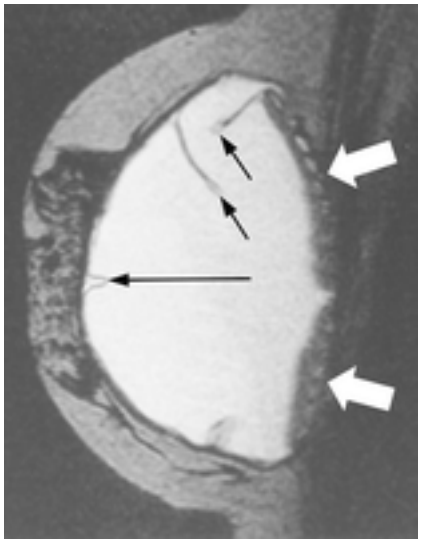

Figure 28. Four-quadrant fixation patches. Sagittal T2-weighted fast spin-echo water-suppressed MR image of a Dow Corning 830 series implant (single-lumen silicone gel-filled, placed 1965) (Fig 27), showing its characteristic four-quadrant Dacron mesh-backed fixation patches. On water-suppressed MR images this type of fixation patch has a "zebra-stripe" appearance (thick arrows). This implant is in a state of uncollapsed rupture, as evidenced by the "keyhole" (short arrows) and "pull-away" (long arrow) appearances peripherally (4), confirmed at surgery.

Figure 29. Dow Corning 530 series fixation patches. Posterior surface of a contoured Dow Corning 530 FP series implant (placed 1970, not ruptured) showing the dumbbell-shaped inferior Dacron mesh fixation patch and three additional fixation disks bonded directly to the implant shell. Each patch consists of a layer of loose Dacron mesh, which is sewn to a layer of Dacron mesh-reinforced elastomer. The outer mesh layer has been cut away from this implant and is not shown here. Portions of it with ingrown tissue are shown in Figure 30. The dumbell-shaped patch overlies two shell holes separated by a slit (not shown here). This was the first "seamless" style of Dow Corning implant. The fixation patches can often be seen on MR images, depending on the imaging protocol used (Fig 31).

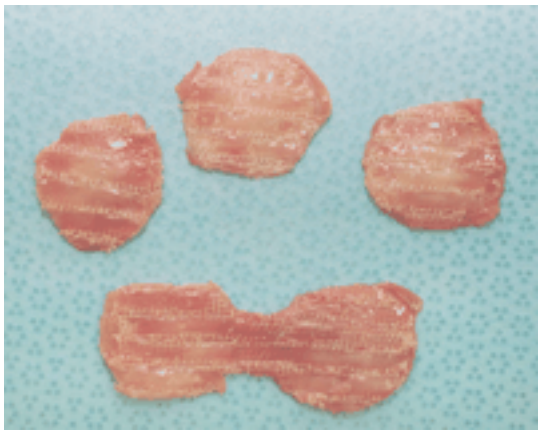

Figure 30. Dow Corning 530 series fixation patches. Shown here are portions of the outer Dacron mesh layer that were dissected from the fixation patches at the time of explantation, for the Dow Corning 530 FP series implant (placed 1970) shown in Figure 29. Tissue has grown directly into the Dacron mesh layer of these fixation patches. The fixation patches can often be seen on MR images, depending on the imaging protocol used (Fig 31).

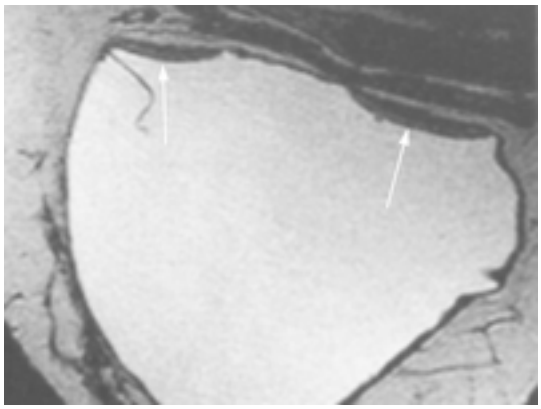

Figure 31. Dow Corning 530 series fixation patches. Axial T2-weighted fast spin-echo water-suppressed MR image of the Dow Corning 530 FP series implant (placed 1970) shown in Figures 29 and 30, with the "dumbbell plus 3 round disk" pattern of fixation patches, showing no evidence of rupture. This image shows a cross section through the upper part of the "dumbbell." The fixation patches (arrows) can appear solid, as shown here, or can have the zebra-stripe appearance seen in Figure 28.

Figure 32a. Dow Corning 900 series fixation patches. In about 1973, a new pattern of fixation disks was introduced by Dow Corning in which the outer Dacron mesh layer was embedded into the elastomer disk in a pleated fashion rather than sewn into it. These implants had two, three, or four such round fixation disks bonded to their posterior surface, one of which was over the shell hole, usually with a separate back patch (thick arrow) and reinforcement disk (not shown here) inside the shell hole (see Figs 48 and 49). Shown here is an example of this method of fixation on a catalogue no. 965 Dow Corning implant with four fixation disks, placed in 1975. The mandrel marking "5" is faintly seen centrally (thin arrow) in **a** (close-up view shown in **b**), about 4 mm in height, indicating the implant size.

Figure 32b. Dow Corning 900 series fixation patches. In about 1973, a new pattern of fixation disks was introduced by Dow Corning in which the outer Dacron mesh layer was embedded into the elastomer disk in a pleated fashion rather than sewn into it. These implants had two, three, or four such round fixation disks bonded to their posterior surface, one of which was over the shell hole, usually with a separate back patch (thick arrow) and reinforcement disk (not shown here) inside the shell hole (see Figs 48 and 49). Shown here is an example of this method of fixation on a catalogue no. 965 Dow Corning implant with four fixation disks, placed in 1975. The mandrel marking "5" is faintly seen centrally (thin arrow) in **a** (close-up view shown in **b**), about 4 mm in height, indicating the implant size.

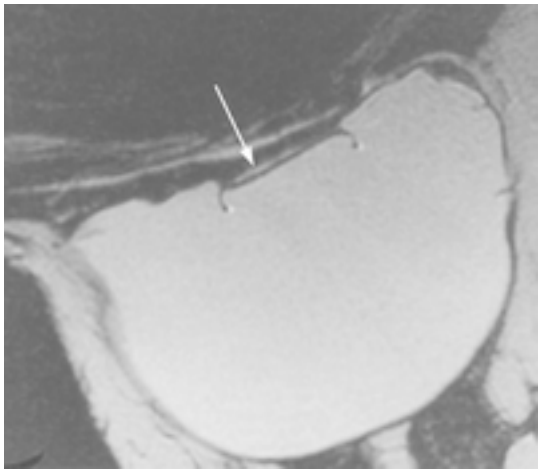

Figure 33. Dow Corning 580 series fixation patches. Axial T2-weighted fast spin-echo water-suppressed MR image of the same type but an earlier style of implant than is shown in Figure 32. The four round fixation disks on this implant are thinner than the older four-quadrant patches, and so the "zebra" pattern is rarely if ever seen. This Dow Corning implant, placed in 1973, was intact, confirmed at surgery. The *appearance* of silicone outside the implant shell posteriorly on this MR image (arrow) is probably due to the presence of a small amount of silicone fluid (not gel) between the layers of one of the fixation disks. This was one our false-positive findings.

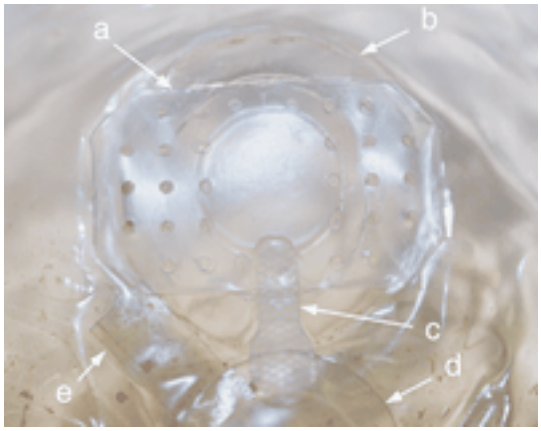

Figure 34. Fenestration-style fixation patch. Some of the early McGhan and McGhan/3M nonround implants, such as this standard double-lumen implant placed in 1980, had an octagonal-shaped fenestration-style fixation device (a) attached to the back patch (b). It consisted of a thin sheet of silicone elastomer with numerous small holes into which tissue was meant to grow. This was called the "silicone fixation option" by the manufacturer(s). Also shown is a Dacron mesh-reinforced elastomer "keyhole"- (or "paddle"-) shaped suture tag (c), such as was used on some McGhan and McGhan/3M implants (Fig 42), a second shell patch (d) for the leaflet valve, and the leaflet fill valve itself (e). These fenestration-style fixation patches will rarely, if ever, be discernible on MR images.

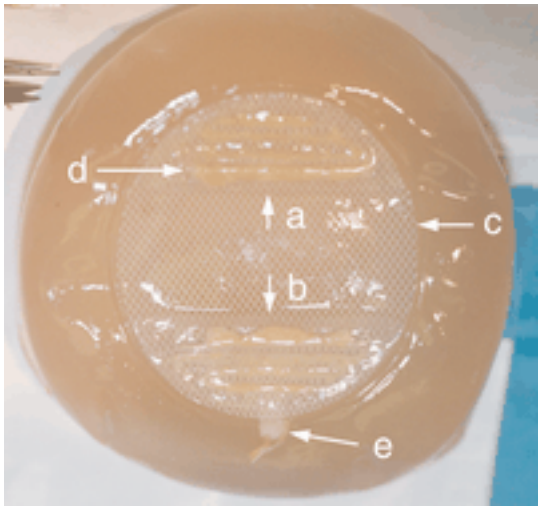

Figure 35. Fenestration-style fixation patches. Early Heyer-Schulte Style 2000 single-lumen silicone gel-filled implant, placed in 1972, with "double hemicircle" fenestration-style fixation patches (a and b) overlying a large oval Dacron mesh-reinforced back patch (c). Tissue (d) was meant to grow through the holes into the fixation patches, thereby affixing the implant to the surrounding tissues. Also shown is a Dacron mesh full-loop suture tag inferiorly (e) (see Fig 38).

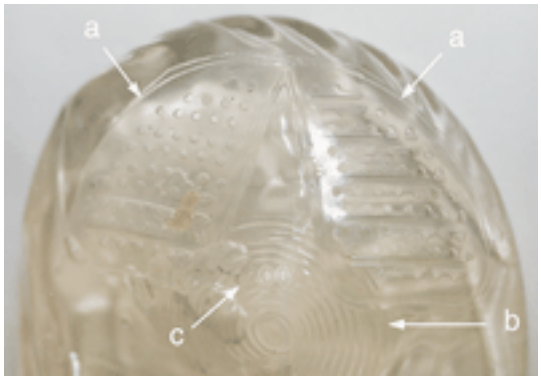

Figure 36. Fenestration-style fixation patch. Heyer-Schulte single-lumen silicone gel-filled implant (placed 1984) with a "butterfly"-shaped fenestration-style fixation patch (a) overlying a "spiral" (multiple concentric circles) back patch (b) on which is marked "200" (c, the implant size in cubic centimeters). Tissue was meant to grow through the holes in the fixation patch, thereby affixing the implant to the surrounding tissues. This style of fenestration patch will rarely if ever be discernible on MR images.

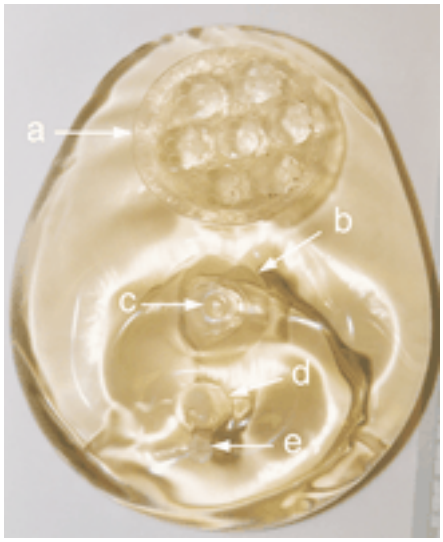

Figure 37. Fenestration-style fixation patch. Cox-Uphoff International (CUI) single-lumen silicone gel-filled implant with a round fenestration-style fixation patch (a) overlying the superior portion of the posterior shell. Tissue was meant to grow through the holes in the fixation patch, thereby affixing the implant to the surrounding tissues. Also present is a back patch outside the implant shell (b) with a central gel fill point (c), and a small elastomer disk (d) holding a Dacron mesh suture tag (e) on the inferior implant shell.

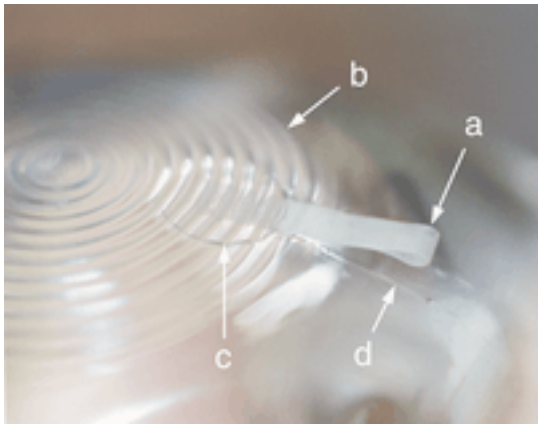

Figure 38. Full-loop suture tag. Full-loop Dacron fine-mesh suture tag (a) on a Heyer-Schulte implant placed in 1975, bonded to the underlying spiral patch (b) with a small overlying round elastomer disk (c). This style of suture tag was used by Heyer-Schulte until about 1978. Note the indentation into the shell by the suture tag (d). Such indentations may potentially be sites of shell failure (ie, rupture). Although suture tags such as these may rarely be visualized on MR images, their MR imaging appearance is neither manufacturer nor style specific.

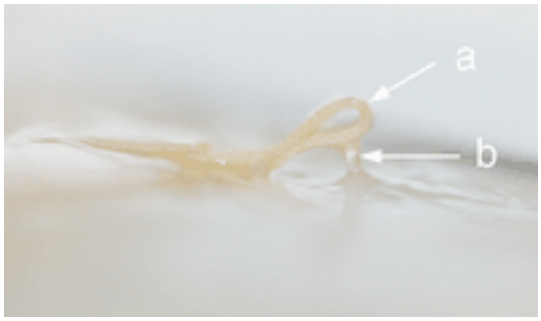

Figure 39. Partial-loop suture tag. Side view of a ruptured Surgitek (MEC) 10140 single-lumen teardrop-shaped silicone gel-filled implant with an attached 4-mm-wide Dacron coarse-mesh partial-loop suture tag (a) inserted between the implant back patch and the shell (placed 1976). This type of suture tag formed a partial loop, as shown here, and could be sewn to surrounding tissue, providing a degree of fixation to surrounding tissue. Free silicone gel is seen on the implant surface extending to the suture tag (b). A top view of this same suture tag is shown in Figure 40.

Although suture tags such as these may rarely be visualized on MR images, their MR imaging appearance is neither manufacturer nor style specific.

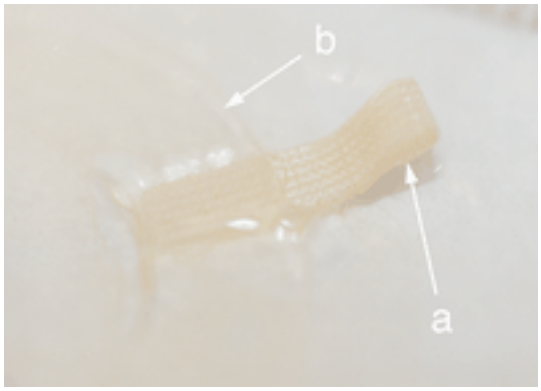

Figure 40. Partial-loop suture tag. Top view of the same suture tag (a) shown in Figure 39, showing edge of overlying back patch (b).

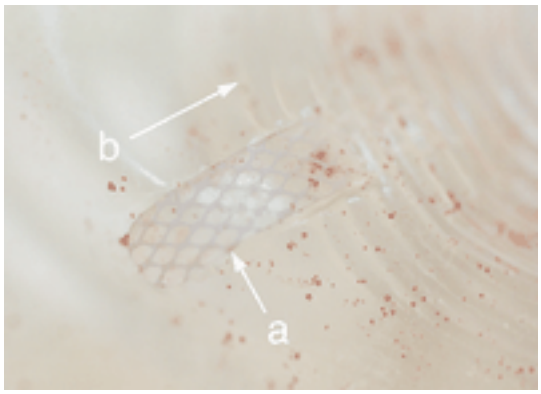

Figure 41. Dacron mesh-reinforced round-tip elastomer suture tag. Dacron mesh-reinforced round-tip elastomer suture tag (a) on a Style 6000 Heyer-Schulte single-lumen silicone gel-filled implant (placed 1982). Just the edge of the "spiral" (multiple concentric circles) back patch is seen here (b). This style of suture tag was used by Heyer-Schulte from about 1978 to 1984 and by Mentor after that. Although suture tags such as these may rarely be visualized on MR images, their MR imaging appearance is neither manufacturer nor style specific.

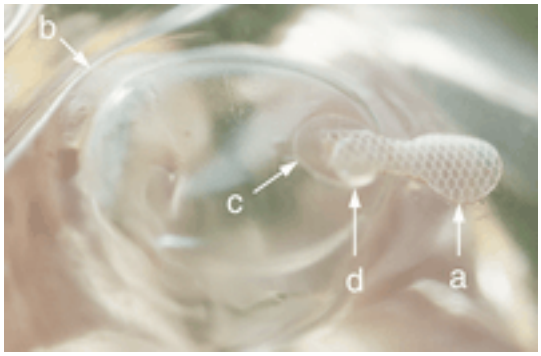

Figure 42. Keyhole-shaped Dacron mesh-reinforced suture tag. Dacron mesh-reinforced keyhole- (or paddle-) shaped elastomer suture tag (a) on a Style 82 McGhan single-lumen silicone gel-filled implant (placed 1977). This style of suture tag was used by McGhan and McGhan/3M on some of their nonround implants. The suture tag is bonded just outside the implant shell patch (b), under a small elastomer disk (c), with the gel-fill point just on top of that (d). Note the tendency of the distal part of the tag to assume a curved shape, which may have contributed to the indentation in the implant shell under the tag (not shown here). Although suture tags such as these may rarely be visualized on MR images, their MR imaging appearance is neither manufacturer nor style specific.

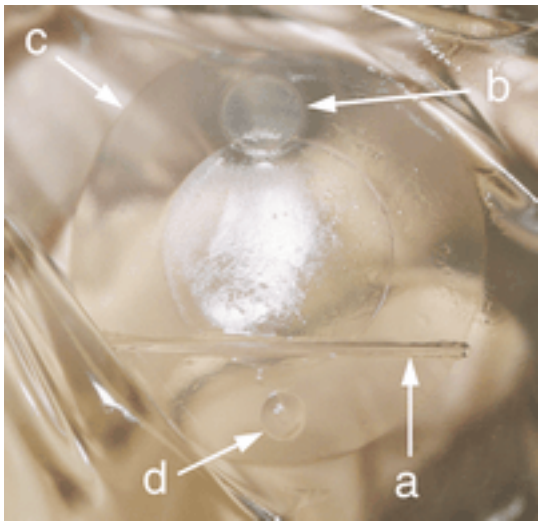

Figure 43. Elastomer orientation bar and disk. An inferior horizontal orientation bar (a) and superior round disk (b) are placed directly external to the back patch (c) and shell of this specially ordered variation of a McGhan/3M Style 81 implant (1981, Tampa, Fla). The implant patch is set inside the shell and has a "hammertone" appearance (ie, an irregular fine-scale roughening). A small raised gel fill point is seen inferior to the bar on the inferior edge of the patch (d). The shell was marked "265" in a "filled" numeral typeface inferior to the back patch and facing away from the patch (not shown here), in a configuration sometimes used by this manufacturer. A horizontal bar and external disk also were used on some specially ordered Heyer-Schulte (1975-76) and Surgitek (1984-86) implants from Tampa, Florida. These orientation features will rarely if ever be discernible on MR images.

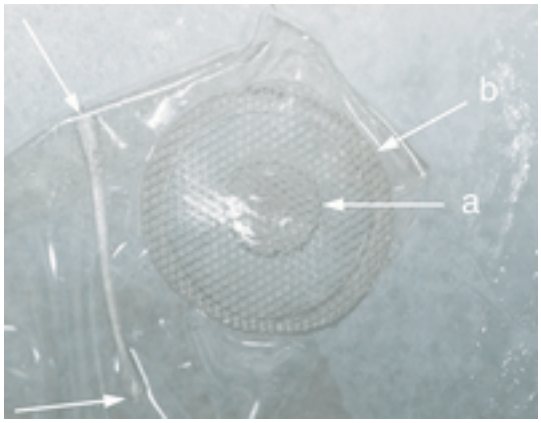

Figure 44. Orientation bar on implant shell. Dow Corning 930 series implant (placed about 1979) with a vertical 40-mm bar (unlabeled arrows) on the posterior inferior implant shell next to the back patch, meant to assist the surgeon in aligning the implant properly at time of placement. Note also the Dacron mesh-reinforced elastomer reinforcement disk (a) seen here internal to the Dacron mesh-reinforced elastomer back patch (b) (see Figs 48 and 49). The orientation bar will rarely if ever be discernible on MR images; however, with adequate resolution and experience, the MR imaging appearance of the internal Dacron mesh-reinforced elastomer disk can be specific for some Dow Corning implants from this period.

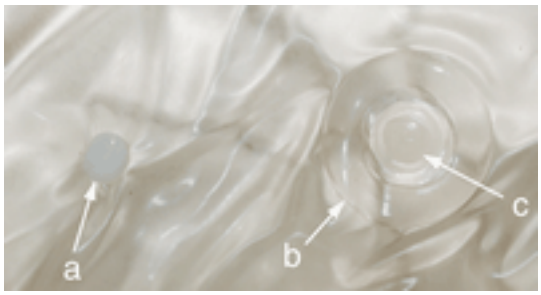

Figure 45. Orientation dot on implant shell. A white orientation dot (a) is seen here attached directly to the implant shell of this Cox-Uphoff International (CUI) implant (placed 1977), adjacent to its back patch (b). The inner projection of the white dot is disklike with squared edges, about 8-9 mm in diameter, and its projection outside the implant shell is domelike. The raised gel-fill point (c) is seen centrally on the back patch. These dome-shaped white orientation dots were sometimes placed centrally on the back patch. They may sometimes be seen on MR images and, given adequate resolution and experience, may be distinguishable from the internal reinforcement disks used on Dow Corning implants from about the same period or earlier.

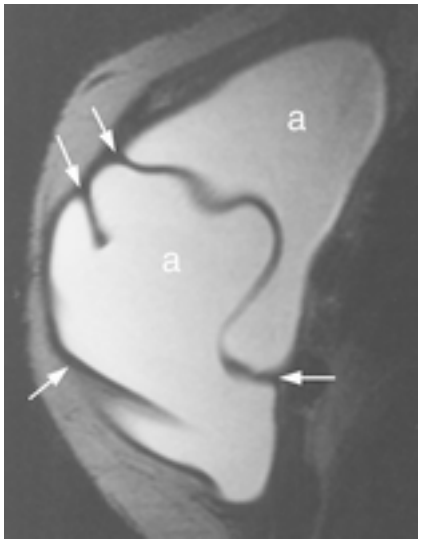

Figure 46. Textured implant surface. Sagittal T2-weighted fast spin-echo water-suppressed MR image of an intact Dow Corning SILASTIC MSI single-lumen silicone gel-filled breast implant (placed 1991). Note that the intracapsular waterlike fluid surrounding this implant, and within the implant folds, is dark (arrows). Silicone gel within the implant is bright (a). The large fold extending all the way across the implant is a normal appearance of some implants.

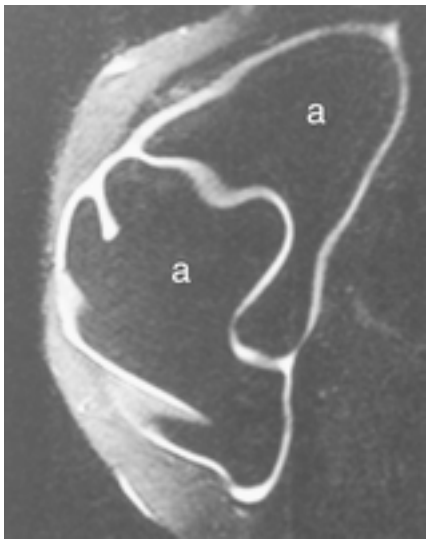

Figure 47. Textured implant surface. Silicone-suppressed T2-weighted MR image of the same Dow Corning SILASTIC MSI single-lumen silicone gel-filled breast implant shown in Figure 46. A layer of intracapsular waterlike fluid (high signal intensity) is often present around textured implants, such as is seen here, with what has been called a "picture frame" appearance (3). The silicone gel (a) in this implant has low signal intensity on this type of image.

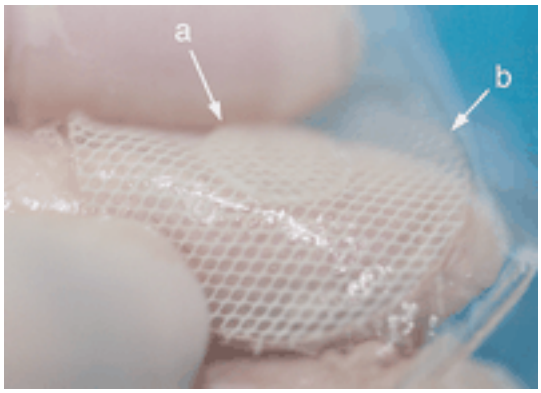

Figure 48. Internal reinforcement disk. From about 1971 to 1977, Dow Corning placed a small elastomer disk (a) centrally along the internal surface of the back patch (b) of many of their implants. These disks were about 12 mm in diameter, mostly Dacron mesh-reinforced like the one shown here. Their purpose was to help seal the hole through which silicone gel was originally placed into the implant. This patch and disk are from a Dow Corning no. 956 implant placed in 1977, and both are Dacron mesh reinforced, viewed here showing their inner surface. With adequate resolution and experience, most of these disks can be seen on MR images, as shown in Figure 49, and their appearance on MR images may be specific for some Dow Corning implants.

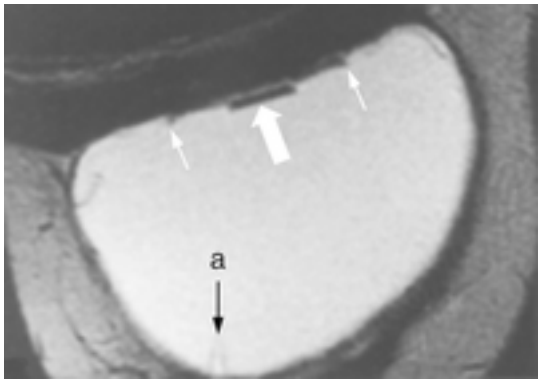

Figure 49. Internal reinforcement disk. Axial T2-weighted fast spin-echo water-suppressed MR image of the type of Dow Corning implant with an internal reinforcement disk (placed 1977) shown in Figure 48. The ends of the back patch are indicated with thin arrows, and the internal reinforcement disk with a thick arrow. This MR image shows a "pull-away" sign (3), indicating that this implant is in a state of uncollapsed rupture (a), confirmed at surgery.

Figure 51. Polyurethane-coated implants. Posterior surface of an early Natural-Y polyurethane-coated implant (placed 1979) after removal, showing the polyurethane remaining in the adhesive coat, partially denuded in places. The back patch (arrow) is not easily visible because of the layer of adhesive and polyurethane. The internal Y-shaped baffle is not discernible on this photograph. The internal baffle in this type of implant is usually evident on MR images, as shown in Figure 52.

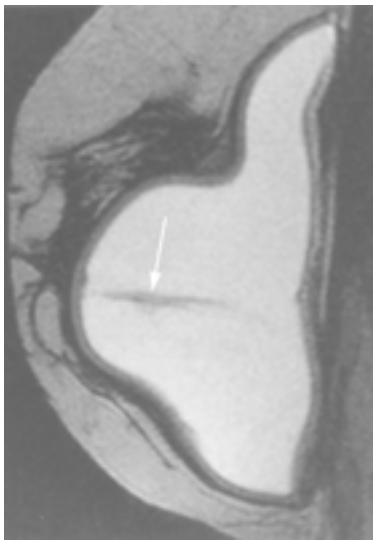

Figure 52. Polyurethane-coated implants. Sagittal T2-weighted fast spin-echo water-suppressed MR image of a much earlier version (placed 1970) of the same type of implant (Natural-Y) shown in Figure 51, with a portion of the internal baffle (arrow) well visualized. Note the unusually thick implant shell and the rather abrupt angles at the edges of the base of the implant, where the posterior flat shell piece is "seamed" to the anterior contoured shell piece, typical of the earlier polyurethane-coated implants. In our experience, this type of polyurethane-coated implant has the specific appearance of the Y-shaped internal baffle seen here[5] .

Figure 53. Polyurethane-coated implants. The surface of this Optimam implant (placed 1984) is mostly denuded of polyurethane. Note the cream-colored shell, rather than the usual clear shell, and the cream-colored back patch (arrow) placed outside the shell that is smaller than the patch used on some of the earlier Natural-Y implants. This kind of patch was also used in the Vogue implants and some Natural-Y infraclavicular implants. The Optimam and Vogue implants commonly had an internal Y-shaped baffle, recognizable on MR images.

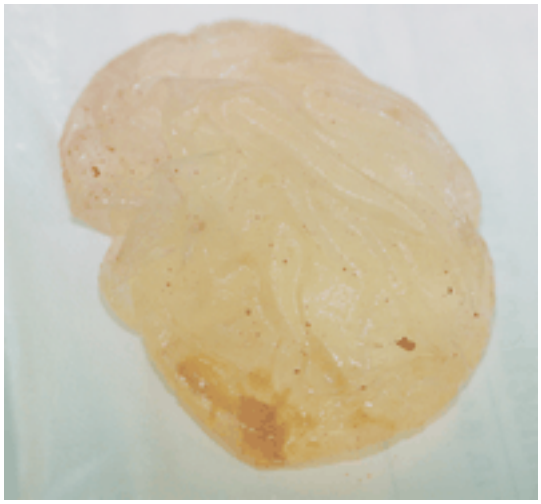

Figure 54. Polyurethane-coated implants. Aesthetech Même ME single-lumen silicone gel-filled implant (placed 1984), intact, with a layer of surface adhesive still present. Most of the polyurethane layer is no longer present, a common finding in explanted implants of this style. The shells of these implants were sometimes extremely thin, making their detection after rupture difficult. The gel often has some degree of "memory", and so it is common that the implant will show deep persistent folds and involutions in its shape, even when explanted and only under the influence of gravity and not subjected to compression. Most of these were created by forming silicone gel into the desired shape and then dipping into more silicone and "curing" to form the shell. The MR imaging appearance of this kind of implant is shown in Figure 55.

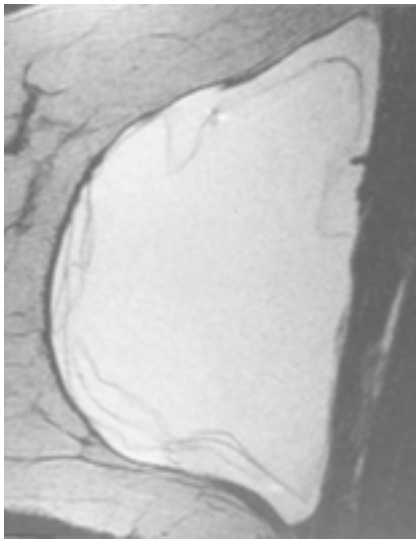

Figure 55. Polyurethane-coated implants. Sagittal T2-weighted fast spin-echo water-suppressed MR image of a ruptured Aesthetech Même ME implant (placed 1984), similar to the one shown in Figure 54. Note the very thin implant shell, which has a crinkled appearance that we have seen associated with only this style of implant, consistent with the persistent folds and "gel with a memory" that are commonly found in these implants. Internal gas bubbles, which are common in polyurethane-coated implants, are also seen.

Figure 56. Polyurethane-coated implants. Posterior surface of an Aesthetech Replicon implant (placed 1988) shows the characteristic "ring" appearance (arrow) of the back patch, seen in no other implant of which we are aware. The ring appearance is usually caused by the overlap of the implant shell itself, a larger patch inside the implant shell and a smaller patch outside the shell.

Several styles were typically offered for most implant types by each manufacturer. An implant "style" is typically characterized by a unique combination of basic implant features, such as shape, shell, profile, and fixation (Table 5). Each style was usually offered in a range of sizes that could vary from 70 mL to more than 1,000 mL. Availability of special order and custom implants further increases the number of possible variations.

View this table:	TABLE 5. Factors Characterizing an Implant "Style"

The remainder of this section contains a description of the 14 breast implant types. A summary of the figure numbers for the various types of implants is given in Table 6.

View this table:	TABLE 6. Figure Numbers by Topic

1. Single-lumen silicone gel-filled

Of breast implants we have seen at UCSD, 79.6% are single-lumen silicone gel-filled implants (Table 1). Of these, 6.9% have been polyurethane-coated (Figs 51–56). Implants without polyurethane coating can have either a smooth (Fig 50) or textured (Figs 46, 47) silicone elastomer shell. The latter first became available in about 1986. Different patterns of surface texturing (without polyurethane coating) were used by the different manufacturers (Siltex by Mentor, SILASTIC MSI by Dow Corning [silicone gel-filled and standard double-lumen only], MicroCell by CUI [saline-filled only], and Biocell by McGhan).

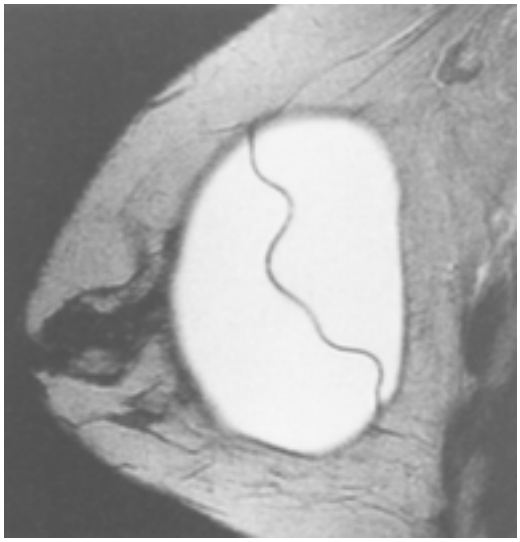

Figure 50. Smooth implant shell. Sagittal fast spin-echo T2-weighted water-suppressed MR image of an intact Cox-Uphoff International (CUI) single-lumen silicone gel-filled smooth shell implant (placed 1987). A normal fold of the implant shell, seen here as a dark thin line "within" the gel, can be seen extending all the way across the implant.

For polyurethane-coated implants we have seen that were placed after 1981, most, or nearly all, of the polyurethane is absent at the time of explantation; only the underlying adhesive with some attached or

embedded polyurethane still remains. In this state, these implants can have a quasi-textured appearance. For the earlier Natural-Y implants and other early implants partially (109) or fully coated with polyurethane foam, the literature and at least one implant manufacturer recognized as early as the late 1970s that polyurethane tends to dissolve and fragment within 4-6 months, embed itself in capsular tissue, and migrate outside the fibrous capsule into surrounding tissues (110,111,112,113,114) . The intended purpose of the polyurethane coating is to promote tissue ingrowth and reduce capsular contracture.

Most single-lumen silicone gel-filled implants are manufactured by first forming the shell on a form called a mandrel, which necessarily has a hole where the stem attaches to the mandrel. The hole is then "patched", usually posteriorly, with what has been called a "back patch" or "shell patch" (Fig 57). Gel is then added under pressure through a needle by the manufacturer, and the hole sealed with a small amount of silicone adhesive. With adequate experience, one can often determine the manufacturer of an implant by direct examination of the implant, back patch, and shell markings, even when the actual name of the manufacturer is not marked on the implant.

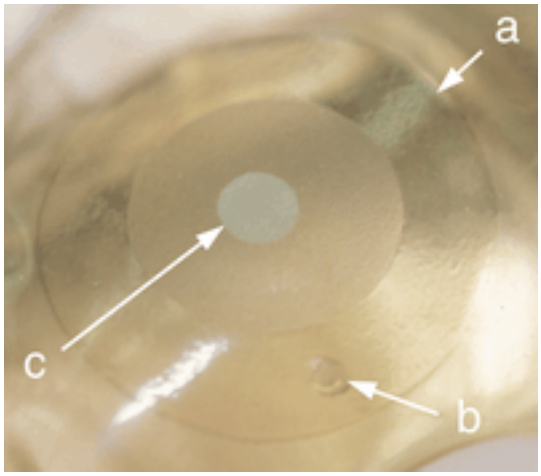

Figure 57. McGhan/3M Style 80 back patch. Back patch of intact McGhan/3M Style 80 smooth-shell single-lumen silicone gel-filled implant (placed 1979). This implant is identifiable because of the presence of a "hammertone" (textured-looking) back patch set just inside the implant shell hole (a), a peripheral gel fill point (b), where the back patch overlaps the implant shell, and a flat approximately 7.5-mm white dot (c) centrally placed outside the back patch. Not shown are shell markings "240" just inferior to and facing away from the back patch in a typeface characteristic for this manufacturer. This style of back patch from this manufacturer generally is not identifiable as such on MR images.

Essentially all implants of this type are prefilled with silicone gel by the manufacturer. However, two early implants (the Surgitek Dahl implant (115) and the Koken Akiyama implant (82) were intended to be inflated with silicone gel by the surgeon at time of placement (Figs 4, 5).

2. Single-lumen gel-saline adjustable

Of the implants we have seen, 0.9% are of the single-lumen adjustable (ie, gel-saline) type (Table 1). These are single-lumen implants prefilled with silicone gel by the manufacturer. To adjust size, the surgeon could add a variable amount of saline directly to the gel at time of placement, usually through a leaflet (Fig 61) or self-seal inflatable (SSI) (Fig 62) valve.

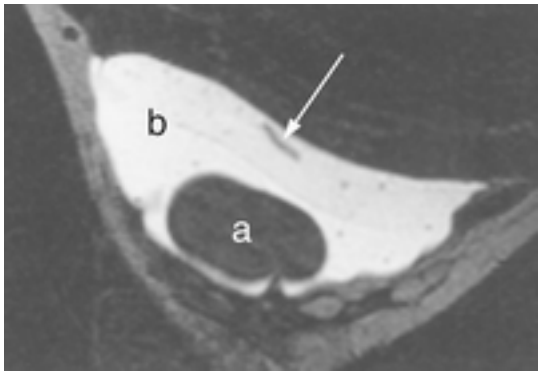

Figure 61. Single-lumen gel-saline implant. Axial T2-weighted fast spin-echo water-suppressed MR image of an intact Surgitek gel-saline single-lumen implant (placed 1986) with a leaflet valve, showing the normal appearance of numerous waterlike bubbles (a, dark) mixed with silicone gel (b, bright). A cross section through the distal flat part of the leaflet valve is shown (arrow). The presence of numerous waterlike bubbles within what appears to be a single-lumen silicone gel-filled implant should, especially when a leaflet valve is visualized, indicate that one is probably dealing with a single-lumen adjustable implant. The same appearance can be seen in cases in which the surgeon injects large amounts of saline directly into the implant with a small-gauge needle at the time of placement.

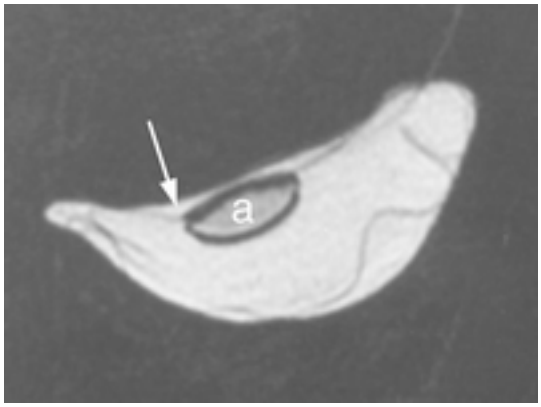

Figure 62. Single-lumen gel-saline implant. Fast multiplanar inversion-recovery fat-nulled T2-weighted water-suppressed MR image of a gel-saline Surgitek implant (placed 1981) with an SSI valve (a). Note that the valve contents do partially suppress on this water-suppressed image because of the saline that remains from time of placement or from waterlike fluid that has leaked into it from outside the implant. The contents of the valve also usually do not entirely suppress on silicone-suppressed images (not shown here). The presence of silicone gel outside the SSI valve indicates that this implant is ruptured (arrow). The MR appearance of the SSI valve shown here (a) is specific for this implant.

One rare 1973 Heyer-Schulte implant had no valve, but saline could be added via a needle directly placed through the shell, and later, if necessary, percutaneously in the same fashion (116,117,118). These were discontinued as catalogued product within about 2 years of their introduction but could be ordered as custom product with possible modifications after that (119).

By about 1979, gel-saline breast implants with valves had become available. Dow Corning called their "standard" double-lumen implant a "gel-saline" implant but clearly noted that it was a double-lumen and not a single-lumen type.

3. Saline, dextran, and polyvinyl pyrrolodone (PVP)-filled

Of the implants we have seen, 6.2% have been of this type (Table 1). They could be inflated through a ligation (Fig 1), tube (Figs 2, 3), SSI (Fig 4), leaflet, retention (Figs 17, 18, 19), or diaphragm (Figs 22, 24) valve. We image patients with these implants only when the question is whether residual soft-tissue silicone remains from

a prior silicone gel-filled implant or from silicone injections, and so this percentage may not represent the percentage of saline-filled breast implants in the general population[9]. We have grouped these implants as a single implant type because they have an identical appearance on MR images. Saline-filled implants can have a smooth or textured elastomer surface.

The Arion implant was an early saline- or dextran-filled implant, designed by Dr H. G. Arion, manufactured and distributed by Simaplast in France in the early 1960s, and distributed (and later manufactured) by Roger Klein in America as the Mammatech implant (Figs 2, 3) (98,120,121,122,123,124). Early dextran-filled implants were either smooth or polyurethane coated.

There are two styles of PVP-filled implants: prefilled and inflatable. PVP-filled implants all have a textured silicone elastomer shell. The Bioplasty MISTI Gold implant is filled with PVP, which has the same appearance as saline on MR images. The NovaGold implants are also prefilled with PVP (125).

Most saline- and dextran-filled implants are inflated at the time of surgery through a valve. Recently, fixed-volume prefilled saline implants have become available (100).

In addition to the simple single-lumen dextran-, saline-, and PVP-filled devices described above, numerous other devices also may be classified in this category (ie, "Type 3"). For example, all tissue expanders are in this category, some of which have more than one lumen. Also, saline-filled expander implants, such as the Spectrum series from Mentor, are in this category. Many types of tissue expanders have been used in the breast as well as other parts of the body. They have been manufactured in a wide variety of shapes and sizes. Radiologists rarely see tissue expanders in the course of implant evaluation because they are intended to be temporary devices and do not require MR imaging evaluation.

4. Standard double-lumen

Of the implants we have seen, 11.1% are of the standard double-lumen variety, with silicone gel in the inner and saline in the outer lumen (Table 1). Their outer lumen could be inflated through an SSI (Figs 7, 8), leaflet (Figs 9, 10, 11, 12, 13, 14), or retention (Figs 20, 21) valve mounted on the outer shell or back patch. The intended primary purpose of this implant type was to allow size adjustability at the time of and after implant placement (126,127).

After a period of experimentation starting in late 1972 (96,128), standard double-lumen implants first became available commercially in about 1975. The initial so-called Hartley design used a larger saline-to-gel ratio than most later standard double-lumen implants (Figs 20, 21). In 1980, the Style 5000 Hartley standard double-lumen implant was introduced with a lower capacity outer lumen.

There are two patterns of back patch placement. In the shared back patch configuration, both inner and outer shells share the same posterior back patch. In the bag-in-a-bag configuration, there is a freely floating inner silicone gel-filled implant contained entirely within a second outer shell, and each implant shell has its own separate back patch. Heyer-Schulte, McGhan, McGhan/3M, and Mentor implants (very early designs) have a shared back patch configuration; CUI, Bioplasty, Dow Corning (Figs 12, 13, 14), Mentor (later designs), and Surgitek (Figs 7, 8, 9, 10, 11) have a bag-in-a-bag design. Often implant manufacturer names and sizes can be seen on one or both back patches when the implant is visually examined ex vivo (CUI, Dow Corning, McGhan, and McGhan/3M).

5. Reverse double-lumen

Less than 1% of the implants we have seen are of the reverse double-lumen type, with silicone gel in the outer and saline in the inner lumen (Table 1). The inner lumen can be filled through a leaflet valve or valves (Fig 16), a tube passing through the outer (silicone gel-filled) lumen to the inner lumen (Figs 25, 26), or some

combination of these methods. These implants are most often used after reconstructive surgery. Size adjustability is provided by adding saline to the inner lumen, while preserving the feel of a silicone gel-filled implant. The final volume is determined by the amount of saline the surgeon adds to the inner lumen. Smooth-walled and textured models have been offered. These can be complicated devices, sometimes with more than one valve. The most common implants of this type in use in the United States at this time are the Becker implants from Mentor, which are usually recognizable on MR images.

The McGhan Style 150 implant is also of this type. It has been in use for 3 years outside the United States, and its manufacturer intends to bring it to the American market[10]. It has a textured outer surface, responsive outer-lumen silicone gel[11], and a permanent mini-remote injection port attached to the posterior implant surface for postimplantation volume adjustment. The tube and subcutaneous injection port should be evident on MR images.

6. Reverse-adjustable double-lumen

Less than 1% of the implants we have seen are of the reverse-adjustable double-lumen variety, with silicone gel in the inner and outer lumen (Table 1). A variable amount of saline may be added through a leaflet valve directly to the relatively underfilled inner lumen to provide size adjustability (Figs 15, 58, 59, 60). These implants are used mainly for breast reconstruction. They were manufactured as commercial product only by Surgitek and are usually identifiable at MR imaging and sometimes xeromammography. Occasionally, no saline was placed in the inner lumen.

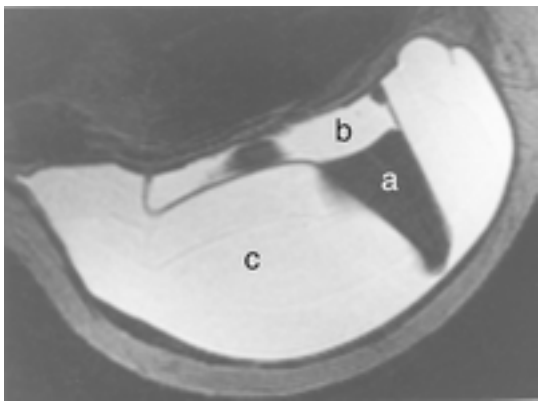

Figure 58. Reverse double-lumen adjustable implant. Axial T2-weighted fast spin-echo water-suppressed MR image of the Surgitek reverse-adjustable double-lumen implant (placed 1985) shown in Figure 15. This image shows the normal water-suppressed appearance of mixed saline (a, dark) and silicone gel (b, bright), both in the inner lumen, and silicone gel in the outer lumen (c). In this case, the inner lumen is not fully "inflated" and so has the characteristic "plateau next to a peak" appearance. The silicone-suppressed appearance of this implant is shown in Figure 59, and the xeromammographic appearance is shown in Figure 60. In our experience, this type of implant from this manufacturer is identifiable on MR images.

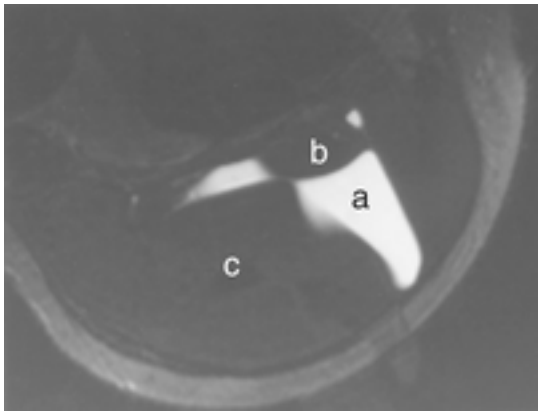

Figure 59. Reverse double-lumen adjustable implant. Axial T2-weighted fast spin-echo silicone-suppressed MR image of the Surgitek reverse-adjustable double-lumen implant (placed 1985) shown in Figure 15. This image shows the normal silicone-suppressed appearance of mixed saline (a, bright) and silicone gel (b, dark), both in the inner lumen, and silicone gel in the outer lumen (c). The water-suppressed appearance of this implant is shown in Figure 58, and the xeromammographic appearance is shown in Figure 60.

Figure 60. Reverse double-lumen adjustable implant. Xeromammogram of the Surgitek reverse-adjustable double-lumen implant (placed 1985) shown in Figures 15, 58, and 59, showing the same internal structure seen in more detail on the MR images.

7. Gel-gel double-lumen

A recent gel-gel double-lumen implant, McGhan Style 153 (not illustrated here), has an inner lumen relatively overfilled with silicone gel (attaining a near-spherical shape), an outer lumen less filled with silicone gel, two gel fill points on the back patch, an anatomic shape, and a textured surface. There is no valve or saline-filled compartment in this implant. It has been in use for 3 years in the United States on a limited basis, and its manufacturer intends to broaden its availability in the future[10] . We have not imaged any implants of this style.

Earlier gel-gel Birnbaum-style implants from McGhan or McGhan/3M (129,130,131) were custom oval

implants with a hemispheric, nearly flat pocket with rounded edges situated in the upper part of the implant and containing a silicone gel of greatly increased cross-linking (Figs 63, 64, 65). These were used mainly for reconstruction.

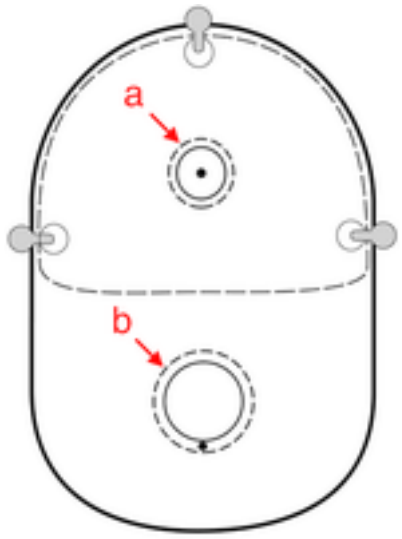

Figure 63. Birnbaum custom gel-gel double-lumen implant. Schematic of the McGhan and McGhan/3M Birnbaum-style custom gel-gel double-lumen implant. Illustrated here are three "keyhole"- (or "paddle"-) shaped Dacron mesh-reinforced suture tags (see Fig 42), a hemispheric inner flat gel-filled lumen (dotted line) with its shared back patch (a), and the outer silicone gel-filled lumen with its separate back patch (b). The actual appearance of an implant of this type is shown in Figure 64, and the MR imaging appearance is shown in Figure 65.

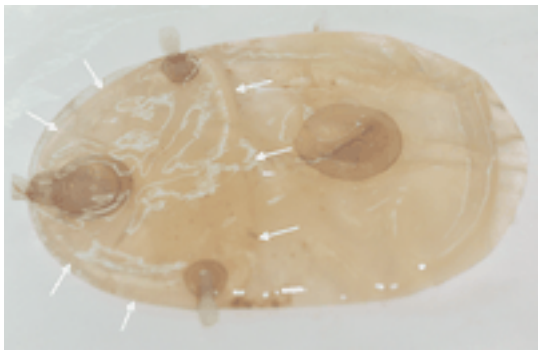

Figure 64. Birnbaum custom gel-gel double-lumen implant. View of the posterior surface of a McGhan/3M implant (placed 1978) of the type shown in Figure 63. The patches are darkened compared with the color usually seen. One possible explanation is that this represents an extreme case of the yellowing with age that has been reported to be likely due to the formation of colloid platinum with crystallites larger than 2.2 nm, where the platinum serves as a catalyst for hydrosilylation reactions that form the gel and shell (147). This darkening, sometimes more marked than seen here, is not uncommonly seen in some McGhan/3M and Heyer-Schulte implants from the late 1970s and early 1980s. The inner upper lumen is shaped like a folded-over pita bread (delineated by arrows). The implant is photographed here from the side.

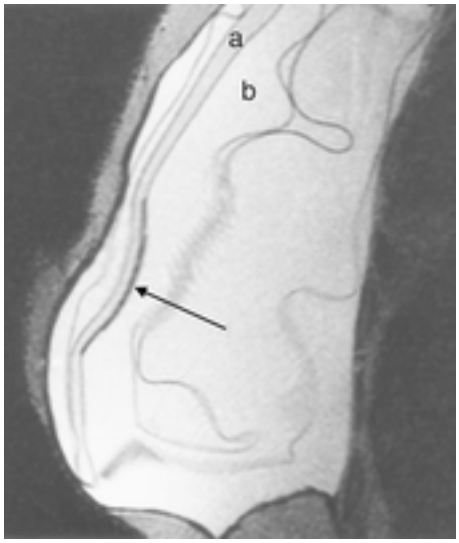

Figure 65. Birnbaum custom gel-gel double-lumen implant. Sagittal T2-weighted fast spin-echo water-suppressed MR image of the type of implant (McGhan, placed 1987) shown in Figures 63 and 64. Shown here is the decreased T2 signal from the more highly crosslinked inner-lumen gel (a) and the brighter gel from the (ruptured) outer lumen (b). The smaller (shared) upper back patch for the inner lumen is seen here as a darker, thicker line adjacent to the thicker gel layer of the inner lumen (arrow). Although the appearance of this kind of implant can be complicated, together with the patient history, this type of implant should be identifiable on MR images.

8. Triple-lumen

Less than 1% of the implants we have seen are of the triple-lumen variety (Table 1). These implants have silicone gel in an inner, high-profile (relatively overfilled) lumen, silicone gel in a middle low-profile (relatively underfilled) lumen, saline in an outer lumen, and a leaflet valve mounted on the shared back patch (Fig 66). These are used mainly in a reconstructive, rather than a purely cosmetic, setting. These implants were produced as commercial product by CUI (smooth-walled), McGhan/3M (smooth-walled), and McGhan (smooth-walled or textured).

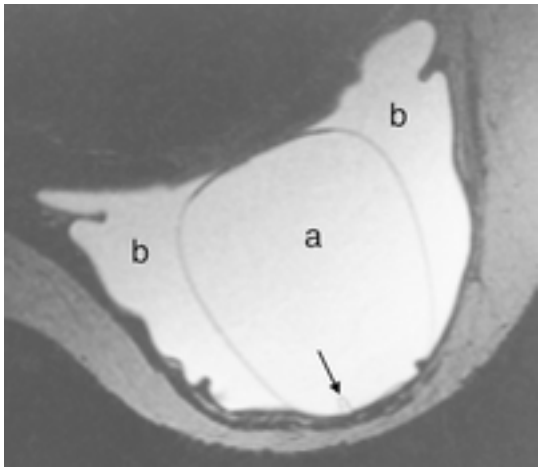

Figure 66. Triple-lumen implant. Axial T2-weighted fast spin-echo water-suppressed MR image showing silicone gel in the inner (a) and middle (b) lumens of this triple-lumen McGhan implant placed in 1988. The saline is gone from the outer lumen of this implant. Note the usual buckled appearance (arrow) of the fold in the inner lumen shell anteriorly, adjacent to the middle lumen, a nearly constant feature for the McGhan and McGhan/3M triple-lumen implants (3). This is not a sign of rupture.

Custom Birnbaum-style oval triple-lumen implants from McGhan/3M also became available in the late 1970s, and these were similar to the double-lumen gel-gel Birnbaum implant described in the gel-gel double-lumen section, surrounded by an additional lumen meant to be filled with saline through a leaflet valve on the outer shell.

9. Cavon "cast gel"

Dr Joseph F. Cavon designed and patented a breast implant with very cohesive gel and no shell (Figs 67, 68). It was made available by CUI and then Aesthetech from about 1980 to 1985 (89,90). Reportedly, only several hundred were ever made (132).

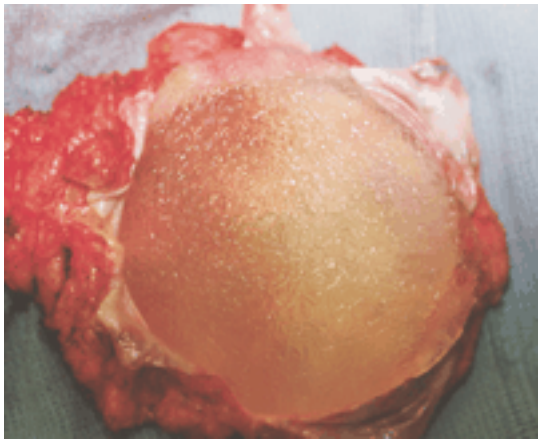

Figure 67. Cavon implant. The surface of this Cavon "cast gel" implant (placed 1985), shown here just as it was being removed from the fibrous capsule at surgery, has the distinctive "elephant skin" appearance we have seen only for this kind of implant. No discernible shell or back patch is present. The MR imaging appearance of this implant is shown in Figure 68.

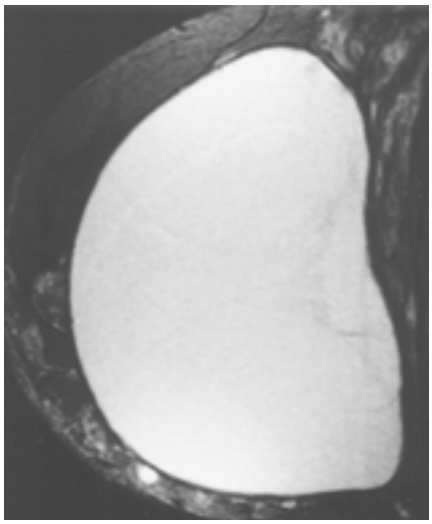

Figure 68. Cavon implant. Sagittal T2-weighted fast spin-echo water-suppressed MR image of the Cavon implant (placed 1985) shown in Figure 67. Some ill-defined internal lines are seen that do not have the appearance of implant shell. At surgery, the implant was found to have an appearance suggesting that it had been injected with some substance, probably steroid and/or antibiotic, possibly accounting for the irregular internal lines. Incidentally noted is some (bright) silicone fluid in the soft tissues surrounding this implant due to previous silicone fluid injections.

10. Custom

Custom implants are provided by prescription to meet the special needs of individual patients, especially to provide correction of acquired (eg, postmastectomy) or congenital (eg, Poland syndrome) breast deformity (Figs 69, 70, 71).

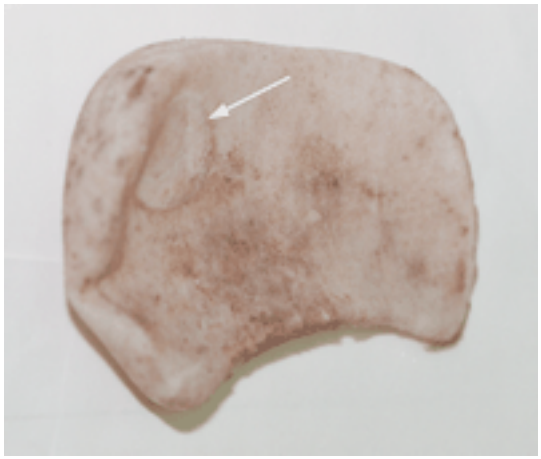

Figure 69. Custom implant. Ruptured custom infraclavicular Natural-Y polyurethane-coated breast implant (placed 1979), posterior surface. The characteristic type of external shell patch for this type of implant is seen in the upper left part of this photograph of the implant (arrow).

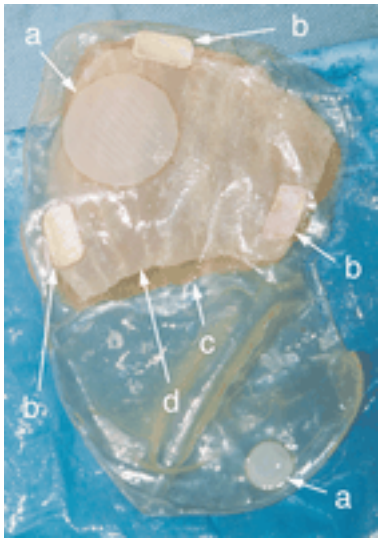

Figure 70. Custom implant. Custom Heyer-Schulte implant specially designed for patient with Poland syndrome (placed 1973). Two Dacron mesh-reinforced elastomer back patches are seen on the posterior surface of the implant (a), along with three (of the original four) Dacron felt strips (b). Also seen within the implant is a polyurethane sponge (c), to which is sewn a layer of loose Dacron mesh (d). This type of implant should have a distinctive appearance on MR images, although we have never imaged one.

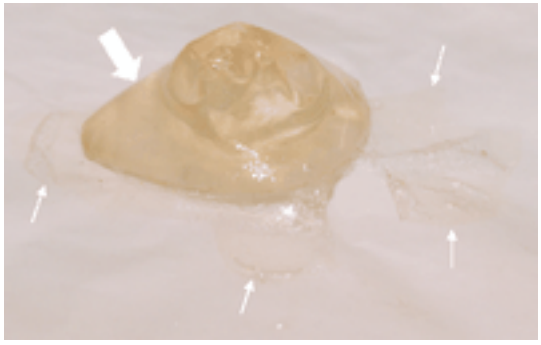

Figure 71. Custom implant. Custom "piggyback" Custom "piggyback" Georgiade Surgitek implant (placed 1978), consisting of a smaller (100 mL) anterior contoured single-lumen silicone gel-filled implant (in a state of uncollapsed rupture) (thick arrow), shown here maintaining its original contoured shape, attached directly to a larger (185 mL) posterior single-lumen silicone gel-filled implant, shown here ruptured with the attached fragments of its shell laid out symmetrically (thin arrows) (148).

11. Soft pectus

Pectus implants were designed to provide cosmetic correction for acquired or congenital absence of the pectoralis muscle(s). These implants were generally constructed of solid silicone elastomer. They image dark with all MR pulse sequences (Figs 72, 73). There are rare notes in the literature of SILASTIC silicone elastomer "space retainers" that may have been precursors of the modern tissue expander (123). We include these as examples of this implant type because they consist of a layer of solid silicone elastomer.

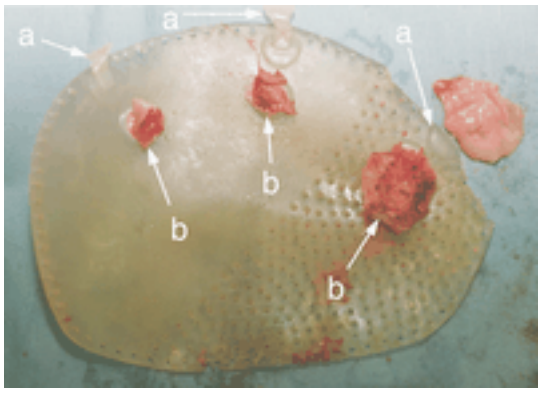

Figure 72. Soft pectus implant. This McGhan/3M soft pectus implant placed in 1984 uses fenestration-style fixation (small holes around the edge of the implant and in the right lower part of the implant on this photograph), three keyhole-shaped Dacron mesh-reinforced elastomer suture tags (a), one partially torn off the implant (see Fig 42), and three Dacron felt fixation disks (b, with some tissue still attached). Tissue has grown into the holes in the fenestration part of the implant and into the Dacron felt fixation disks. The MR imaging appearance of this implant is shown in Figure 73.

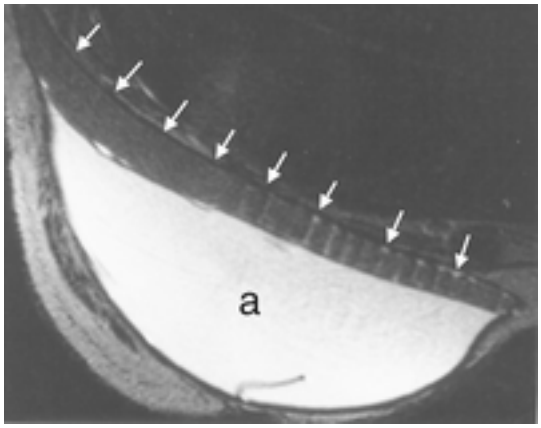

Figure 73. Soft pectus implant. Axial T2-weighted fast spin-echo water-suppressed MR image of a McGhan/3M solid pectus implant (arrows along posterior border) placed in 1984, shown in Figure 72. It is posterior to a standard double-lumen implant (a) with the saline gone from the outer lumen. The tissue filling the holes in the (medial) fenestration part of the implant are seen here with a distinctive appearance of numerous parallel lines. These implants are made of solid silicone elastomer and so will be dark with all MR sequences.

12. Sponge and other early implants

Breast implant sponges (Figs 74, 75, 76, 77) were carved on an individual basis from blocks or provided preshaped by manufacturers. They could be coated with silicone (ie, "siliconized" (134)). Some were "simple" sponges that could be implanted as is, or placed within polyethylene bags that were heat-sealed or tied with a suture. They could be made from various materials, the most common of which were polyethylene, polyvinyl alcohol, polyurethane, and silicone. Some were hollow (48), and still others, called compound sponges, consisted of a sponge core contained within a bag, which was itself surrounded by more sponge (38,135,136,137).

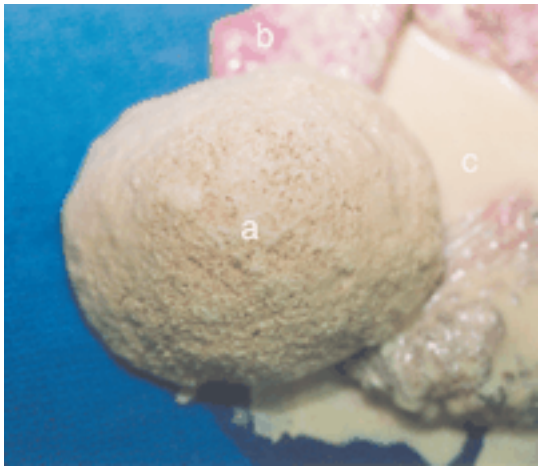

Figure 74. Sponge implant. A formed simple polyurethane sponge implant (a) placed in about 1956 is shown here just after removal from the surrounding fibrous capsule. Just behind the implant are seen parts of the fibrous capsule, which was up to 1 cm thick in places (b), and some of the yellow fluid that surrounded the implant within the fibrous capsule (c). The MR imaging appearance of this implant is shown in Figure 75.

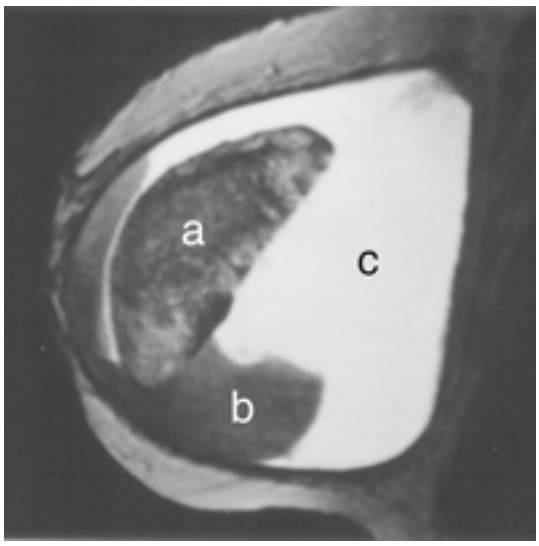

Figure 75. Sponge implant. Sagittal T2-weighted fast spin-echo silicone-suppressed MR image of the simple formed polyurethane sponge implant (placed in about 1956) shown in Figure 74, showing the sponge itself (a) centrally, a layer of dark sludge (b) that turned out to be polyurethane "sand" at surgery, and a large yellow colored intracapsular seroma (c) that had a granular feel due to the polyurethane sand that had not settled.

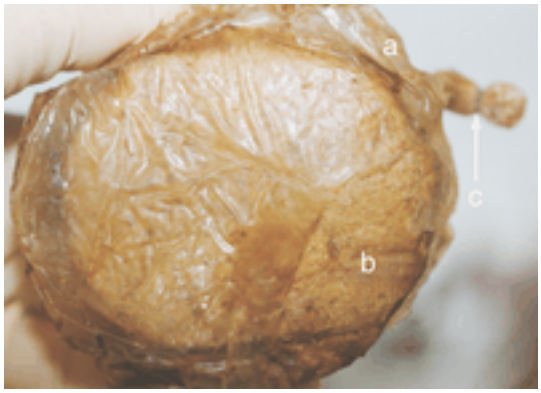

Figure 76. Sponge implant. Shaped implant, probably polyvinyl alcohol (Ivalon), encased in a plastic bag (placed in 1954 by Dr Pangman, Beverly Hills, Calif). The plastic bag (a) is seen overlying the sponge implant inside (b). These are the oldest breast implants we have seen to date. The bag is tied with a suture wrapped around a shoulder of the plastic bag, seen just out of focus on the right (c).

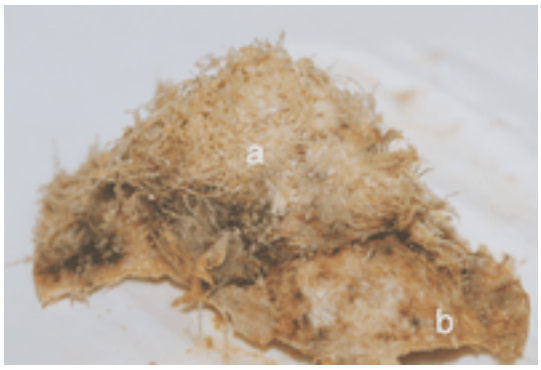

Figure 77. Sponge implant. Spongelike implant consisting solely of shredded plastic strips (a), probably polyethylene, placed in about 1964 in Germany (50,51). Shown here beneath it is the fibrous capsule that formed around it, laid out for display (b). We were not able to detect any evidence of silicone in the construction of the implant.

13. Sponge adjustable

Two models of sponge adjustable implant were available briefly in the early 1970s from Polyplastics: the Polyplastic Adjustable (1971) and the New Polyplastic Adjustable (138,139,140). Both consisted of a polyurethane sponge contained within a silicone elastomer shell, which itself was surrounded by a thin coating of polyurethane. They were intended to be inflated with dextran or saline via a needle placed though the implant shell. These implants represented a theoretical endpoint of implant development by Pangman, who thought that implants should consist of a central area impervious to ingrowth and be surrounded by a thin layer meant to allow limited ingrowth. These principles were first embodied in his compound sponges (135,136,137) and finally led to the development of the sponge adjustable implants, as well as to the Natural-Y (Ashley) single-lumen silicone gel-filled polyurethane-coated implants (141,142).

14. Other

At this time, this implant type includes only the recent experimental triglyceride-filled implant (99), which we have not yet imaged.

Discussion

An accurate and complete understanding of the various types of implants and their component features is necessary for diagnostic accuracy. The recent Institute of Medicine report (9) emphasizes the complexity facing both diagnosticians and statisticians because of the large number of implant styles that have been used for the last 50 years. The less frequently seen and rare implant types may result in misdiagnosis even by experienced breast imagers. Adding to these difficulties are some inconsistencies in the terminology employed by breast implant manufacturers.

We chose an historically based, MR imaging-oriented method of classification because MR imaging can demonstrate implant construction more clearly than most other modalities, particularly with respect to internal structure. Other organizing criteria could have been used to categorize breast implants, such as implant manufacturer, surface type, fill material, method of fixation, number of lumens, and so forth. In fact, any of the categories mentioned in Table 5 could have been used, and

have in some cases been used by others to describe implants. Focusing on the MR imaging appearance of implants will assist radiologists when interpreting MR examinations of implants.

The importance of evaluating breast implants derives from the clinical importance of knowing whether an implant is ruptured. Rupture is a common and important complication of breast implants in patients presenting for implant evaluation (11). The Institute of Medicine study found that "the diagnosis of rupture of a gel implant is important because the release of silicone gel and fluid into tissues may result in local complications", and that "local and perioperative complications are frequent enough to be a cause for concern and to justify the conclusion that they are the primary safety issue with silicone breast implants" (9).

The absolute incidence and prevalence of implant rupture in the population of all women with implants is not known, not to mention the rates specific to given manufacturers or implant styles. Conservative low estimates of implant failure are in the range of 1%-2%, as determined mainly from industry analyses of failed returned prostheses, such as that conducted by Heyer-Schulte in 1980 (149). Gabriel et al (1997) found that 3.9% of the implants in their study were ruptured and that 1.0% showed "leakage, sweating of implant" when medical records from 749 patients receiving implants from 1964 to 1991 were analyzed (150). In all of those studies, however, mammographically and clinically silent ruptures were not measured, and the increased propensity of implants to fail as they get older was not considered. Perhaps the earliest indication that silent rupture is not uncommon was the study by Nelson in 1981, in which it was reported that 15.9% of implants were ruptured in a survey of 583 surgeons who performed 5,579 open capsulotomies (151). That study probably heavily sampled the thin-shell implants of the middle and late 1970s, many of which are still in patients today, 19 years later. If future studies find that silent *or* symptomatic rupture is more common than previously estimated and confirm that early rupture detection is clinically worthwhile, the demand for all types of breast implant imaging will probably increase.

We have intentionally included older and rare implants that now will only infrequently be seen. It is important that these rare implants be described for the same reason that infrequently encountered diseases are described, so that radiologists who may not have seen them before can recognize them when they do come across them. Also, it is important that an effort to describe all implant types be made so that radiologists and others relying on this type of report can be assured that they are not missing anything.

Finally, any useful classification scheme should include provision for the future. The 14 implant types described here should suffice, in part because at least of two of the type definitions are sufficiently broad to provide for whatever may be developed in the future. Type 3, which currently includes all forms of dextran-, saline-, and PVP-filled devices whether they have one or more lumens, also will include any future such devices filled with these substances or any other "waterlike" fluid or gel. Type 14, which is the "other" category, currently includes triglyceride-filled implants, and in the future will cover other similarly filled devices, as well as implants filled with other substances should they be developed.

Conclusions

We have described and illustrated a breast implant classification scheme consisting of 14 types, emphasizing the correlation between the actual appearance of these devices and their appearance on MR and mammographic images. This scheme directly addresses the need to understand the varied appearances of the many types of breast implants that have been manufactured over the last half century, as underscored in the recent Institute of Medicine study (9). Adoption of this scheme will help the radiologist interpret breast implant evaluation examinations and will facilitate a better understanding of the normal appearance of common and unusual implants. Also, this scheme will allow stratification of future research data concerning the incidence, prevalence, and risk factors for and causes of implant failure, as well as permit better correlation with patient symptoms and surgical outcome.[121314]

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The condition, appearance, or manufacturer of implants shown in this report are not intended to imply anything about the rupture rate or prevalence of those products or possible local or systemic effects caused by those products.

The opinions presented in this report are those of the authors and are not meant to convey that any of the parties referenced or acknowledged agree with, or do not agree with, the facts or opinions presented here.

Disclosure Statement

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Footnotes

1. Corresponding author: M.S.M.

2. Local complications of breast implants include rupture, capsular contracture, infection, hematoma, spontaneous extrusion, nipple areolar necrosis, abnormal skin sensation or loss of sensation, soft tissue gel cyst and silicone granuloma formation, possible interference with mammography, and disfigurement.

3. There are documented cases of paraffin injections into the breast as recently as the 1970s and later that have been described in the literature, but mostly they are from Japan and Europe.

4. There is continued controversy as to whether silicone fluid was considered a "new drug" by the FDA during the period 1962-65. One footnote in a 1963 paper by Kagan (59) and one letter produced in response to a Freedom of Information Act (FOI) request in 1977 (68) suggest that it may have been so considered. The absence of a clear notice or publication to that effect in that period suggests that it may not have been. Since mid-1965, however, the record is clear that the FDA has considered silicone fluid with or without additives to be a "new drug" for purposes of investigation, with the mammary area specifically being excluded. Aside from recently approved ophthalmic applications, to our knowledge, there has never been FDA sanction or approval for distribution of silicone fluid, with or without additives, for noninvestigational injection into humans. Aside from those ophthalmic applications, the only approval by the FDA in the United States for distribution of silicone fluid for human injection since mid-1965 has been mainly in conjunction with the Investigation of New Drug application (IND 2702) sponsored by Dow Corning during the periods 7/9/65 to 10/67, 3/19/69 to 9/14/76, and 3/1/78 to 2/81 involving 1,462 patients (69,70,71,72,73,74,75,76,77,78). These Dow Corning studies explicitly excluded injections of silicone fluid into the "mammary area". Regardless, many women in the United States underwent silicone fluid breast injections in and after 1962 separate and apart from the Dow Corning study. One of us (M.S.M.) has evaluated 41 patients with MR imaging who underwent silicone fluid breast injections in the United States between 1962 and 1974, but in none of these cases was the source or purity of the silicone known or determinable from the MR images. There was an earlier application for exemption from Section 505 of the Food Drug and Cosmetic Act for the Sakurai formula for silicone injections as a "new drug" in or about 1963 (IND 6), as noted in the footnote in the November 1963 paper by Kagan (59). That study was not sponsored by Dow Corning. We have no evidence, however, that this effort persisted past about 1965.

5. Internal septations divide the Natural Y implant into three compartments, intended to minimize bulging of one part of the implant when another part was compressed.

6. It is thought that (injectable) Elicon was developed by the Japanese circa 1949 (82), used since about 1950 in humans (81), and documented to have been used in humans by about 1956 (82). It is thought that by about 1966, Japanese silicone gel was being placed within an elastomer bag (82). However, from our readings, it is not known exactly when the Japanese first placed silicone gel in a bag, and whether this predates the Cronin implant work in the early 1960s.

7. Middleton MS, McNamara MP Jr. Breast implant imaging. Philadelphia, Pa: Williams-Lippincott, 2000 (in preparation).

8. Statistics as of 12/20/99 were obtained from the database we created to record these data.

9. Moreover, as patients usually present to us for known or suspected implant-related problems, this percentage also may be affected by selection bias and therefore may not be indicative of the percentage of saline-filled implants in the general population with implants.

10. Personal communication, Jeff Barber, Inamed Corporation, Santa Barbara, Calif, June 17 and July 1, 1999.

11. The earliest silicone gel-filled implants from Dow Corning contained a thick cohesive gel, sometimes colloquially referred to as Cronin gel, after Dr Thomas D. Cronin, who helped develop their first implants. A change was made by Dow Corning in 1975 for most of their implants to a less cohesive gel with a lower degree of cross-linking. That newer gel was referred to as being "responsive", a descriptive term meant to convey that implants containing this type of gel return to their original shape more easily and quickly when the implant is handled than those filled with the older type of gel. Many, but not all, other manufacturers also used Dow Corning "responsive" gel in their implants. Others, such as McGhan, for the implant referenced here, use the term "responsive" to convey the character of the gel and not its manufacturer; in fact, the gel used in this particular implant is not from Dow Corning.

12. Personal communication, Eugene R. Jakubczak, Dow Corning Corporation, December 20-21, 1995.

13. Personal communication, Pierre Blais, PhD, Innoval, Ottawa, Canada, 1999.

14. Personal communication, Henry Jenny, MD, Palm Springs, Calif, 1999.

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77. Supplement to Final Clinical Report for IND # 2702 dated 9/21/90 (Bates P-000006550) .

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96. "Augmentation mammaplasty" by Robert H. Pudenz, MD, Heyer-Schulte Corporation, dated July 1978 (Bates MB 104861) .

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112. 57-page Heyer-Schulte file containing papers with signature approval dates of 3/18/83, 3/21/83, and 4/6/83, pertaining to a 510(k) application for premarket approval for a low-bleed implant shell, in which it is stated on page 9 that "polyester velour, when used as an internal fixation patch, will eventually deteriorate and may result in separation and/or migration of fragments into the surrounding tissues" (Bates MB 173514) .

113. Heyer-Schulte document dated 9/23/77, interoffice correspondence, and 8 pages of attachments related to polyurethane, in which it is stated "it tends to fragment and undergo dissolution in tissue", and "the polyurethane cover tends to separate from the silicone shell producing a composite encapsulation ..." (Bates MB 174362) .

114. 17-page Heyer-Schulte internal circular titled "Heyer Sales" dated 8/79 in which it is stated "polyurethane foam may eventually deteriorate and may result in separation and/or migration of fragments into surrounding tissues" (Bates MC 227518) .

115. Dahl CH, Baccari E, Arfai P. A silicone gel inflatable mammary prosthesis. Plast Reconstr Surg 1974; 53:234-235.

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117. Document entitled "Introductory Data Sheet", "Gel-saline reconstructive mammary prosthesis", "©1973 Heyer-Schulte Corporation" dated "6/73" (partially illegible), with a footnote reference to Richard P. Jobe MD, Los Altos, CA (Bates MB 123114) .

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124. 2-page Dow Corning memo dated 4/29/70 documenting a 4/21/70 telephone call with a Dow Corning employee during which the current status of Roger Klein as a distributor and possible manufacturer of inflatable breast implants was discussed. (Bates DCC-007 118521) .

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139. Responses to Interrogatory No. 12, contained in the responses submitted by Baxter Healthcare Corporation dated 12/6/93 (Case JCCP - 2754, Superior Court of the State of California, County of San Diego), with regard to the "Polyplastic Adjustable Volume" and the "New Polyplastic - Silicone Compound" prostheses .

140. Data sheet entitled "Polyplastic Adjustable Volume Mammary Prosthesis", "Manufactured for Polyplastic Silicone Products by Schulte Medical Products", dated 2/71 (Bates BAX 93520) .

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142. Ashley FL. A new type of breast prosthesis: preliminary report. Plast Reconstr Surg 1970; 45:421-424.

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144. Document entitled "Introductory Data Sheet", "Tabari inflatable mammary prosthesis", "Heyer-Schulte Corporation", dated 9/71 (Bates BAX 94287) .

145. References are made in 13 documents to tubes attached to early Dow Corning experimental implants, contained in memoranda of phone calls, letters, and fabrication requests from 8/9/61 to 10/22/62 (Bates # M-320001, 440028, 440043, 440046, 440049, 440050, 440051, 440054, 440056, 440108, 440122, 820032) .

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TABLE 1. Breast Implant Classification Scheme

No.	Implant Type	Description	No. of Patients	No. of Implants	Percentage of Implants
1	Single-lumen gel	Silicone gel-filled	3,449	7,935	79.62
2	Single-lumen adjustable	Silicone gel-filled, to which can be added a variable amount of saline at time of placement	40	85	0.85
3	Saline-filled, dextran-filled,	Dextran-filled (some early implants), PVP-filled (Bioplasty), and the rest saline-filled	310	621	6.23
4	Standard double-lumen	Silicone gel inner lumen, saline outer lumen	530	1,108	11.12
5	Reverse double-lumen	Saline inner lumen, silicone gel outer lumen	27	48	0.48
6	Reverse-adjustable PVP-filled*	Silicone gel inner and outer lumens, variable amount of saline added to inner lumen at time of placement	15	22	0.22
7	Gel-gel double-lumen	Silicone gel inner and outer lumens	4	5	0.05
8	Triple-lumen double-lumen	Silicone gel inner and middle lumens, saline outer lumen	26	42	0.42
9	Cavon "cast gel"	Cohesive silicone gel, no shell	7	15	0.15
10	Custom†	Nonstandard implant type, size, shape, fill (individualized)	10	13	0.13
11	Soft pectus	Solid silicone elastomer pectoralis muscle replacement implant	4	5	0.05

Table 1 continues on next page

12	Sponge (not adjustable) ‡	Ivalon, Etheron, polyethylene, plastic strips, etc (solid or hollow, simple or compound, some encased in plastic bag)	33	65	0.65
13	Sponge (adjustable)	Silicone elastomer shell (polyurethane-coated), polyurethane sponge inside, dextran- or saline-filled	1	2	0.02
14	Other	Triglyceride, or other fill than noted above	0	0	0.00
Total			**4,014**§	**9,966**	**100.00**

Note: The numbers listed here are for all current and previous implants that any of our patients at UCSD have had, whether or not we performed MR imaging of them. Implants were classified as single-lumen silicone gel-filled if no other source of information was available, and so the percentage of this type may be slightly higher than was actually the case. The relative percentages reported here may be different for other practices, and may vary in the future depending on what implant types are available. This table was modified and adapted from reference 4.

*Most saline-filled implants, tissue expanders, and expander/implants are single-lumen, and all of the dextran-filled devices in these categories that we know of are single-lumen. However, recently so-called "piggyback" tissue expanders have been introduced that can be thought of as having two internally connected lumens.

†Custom implants that are only slight variations of another type, such as specially underfilled round single-lumen implants, are classified as that type. The custom implant type is reserved for specially shaped implants, perhaps with custom fixation, containing a sponge, etc.

‡Sponge implants are classified as Type 12 unless they are definitely known to be Type 13.

§This is not the sum of the numbers in the column above, but the total number of patients who have or had the 9,966 implants. Each entry in the column above is the number of patients who have or had the particular type of implant. The numbers overlap because patients may have had more than one type of implant.

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TABLE 2. Implant Valve Types

Valve Type	Implant Type	Description
No valve	Gel-saline	One early polyurethane-coated gel-saline implant had no valve (116,117). Saline was added directly to the silicone gel by placing a needle through the shell. Saline could be added later percutaneously via the same route. This design was intended to allow delayed final inflation in mastectomy patients (118).
Ligation and invertable tube valve	Saline or dextran	Some early saline- or dextran-filled breast implants, such as the Tabari implants (Fig 1), used a tube that was meant to be folded and ligated with a silicone rubber ring (143,144). Others, such as the Arion implant from the early 1960s (98,120,121,122,123,124), had a tube valve that was plugged with a Teflon stopper and inverted into the implant (Figs 2, 3). These were manufactured by Simaplast (France), and later marketed and manufactured in the United States as Mammatech by Roger Klein.
Plug valve	Single-lumen gel (inflatable)	Aside from a small number of experimental Dow Corning implants in 1962 (145), only one early Surgitek implant called the Dahl implant (115) (Fig 4) and the early Koken Akiyama implant (82) (Fig 5) were designed to be inflatable with gel, and then closed with a plug. These are only rarely seen now.

Table 2 continues on next page

Self-seal inflatable (SSI) valve	Saline	Surgitek used an SSI valve in some saline-filled implants starting about 1974, similar to that used in their later gel-saline and standard double-lumen products and which is identifiable at mammography (Fig 6) and MR imaging. It was an ovoid, lens-shaped structure about 27 mm in diameter made of silicone elastomer shell containing a small quantity of silicone gel. Dow Corning, in a limited number of experimental saline-filled implants in about 1969-70, may also have used such a valve[12] (146).
	Gel-saline	Surgitek used an SSI valve in some of their gel-saline implants starting in 1979, at latest. These valves were either mounted inside a patch over the shell hole or were mounted inside the shell, adjacent to a patch over the shell hole. These valves can be recognized on MR images and sometimes at mammography.
	Standard double-lumen	Surgitek used an SSI valve in some of their standard double-lumen implants starting in about 1977 (Figs 7, 8). These implants had a patch over the outer shell hole adjacent to or coincident with the SSI valve, as well as another one over the inner shell hole. These valves can be recognized on MR images and sometimes at mammography.
Leaflet valve	Saline	A leaflet valve was used in some Dow Corning, Mentor, McGhan, McGhan/3M, and CUI saline-filled implants. It most often consists of two pieces of silicone elastomer that form a leaflet. Within the leaflet is a central channel with a hole on one side through which saline is introduced and another hole at the other end of the leaflet through which saline enters the implant.
	Gel-saline	A leaflet valve was used in gel-saline breast implants starting from about 1979 by McGhan/3M, 1981 by Surgitek, and 1987 by CUI.
	Standard double-lumen	Dow Corning, CUI, Mentor, McGhan, McGhan/3M, and Surgitek used leaflet valves in at least some of their standard double-lumen breast implants. In our experience, only rarely can the manufacturer of the implant be suggested solely on the basis of the MR imaging appearance of this valve in standard double-lumen implants (Figs 9, 10, 11, 12, 13, 14).

Table 2 continues on next page

	Reverse double-lumen	A leaflet valve can be used that allows introduction of saline directly into the inner lumen through a shared back-patch structure. CUI, McGhan/3M, and McGhan used this type of valve.
	Reverse double-lumen adjustable	Only Surgitek manufactured this type of implant, and in all of them a leaflet valve was used (Fig 15).
	Triple-lumen	Leaflet valves also were used in triple-lumen implants, such as those provided by McGhan, McGhan/3M, and CUI.
Double-leaflet valve	Reverse double-lumen	An early smooth-walled Mentor Becker "25/75" (25% outer-lumen gel, 75% inner-lumen saline, by volume) implant used a bag-in-a-bag construction with identical back patch-valve assemblies on each of the implant shells. The inner saline-filled lumen was filled through a tube that entered the implant through the outer shell leaflet valve, went through the outer-lumen gel, and then through the leaflet valve of the inner lumen. When the inner lumen was filled, the tube was pulled completely, and each of the leaflets rolled up like a windowshade (Fig 16). A similar implant of the same style was manufactured with an outer flat leaflet valve and an inner window-shade-like leaflet valve.
Retention valve	Saline	This type of valve was used in some saline-filled breast implants from McGhan and Heyer-Schulte (Figs 17, 18, 19). They consist of a variable-length proximal round part and a distal flat part. Although usually mounted to the shell separately and away from the back patch, they may also be mounted directly on the back patch.
	Standard double-lumen	All Hartley-type standard double-lumen implants, such as those manufactured by Heyer-Schulte (Styles 3000, 3100, 3200, 5000, 6000, and 7000) had retention valves, typically mounted with a separate patch to the posterior outer shell next to the main (shared) back patch facing inward at an angle to the main back patch (Figs 20, 21). Occasionally, they were mounted on the anterior outer-lumen shell. These valves are round in cross section proximally (about 3 mm in diameter) and flat with slight edge thickening distally (about 7-8 mm in width). Together with the appearance of the back patch, the appearance of this type of valve can be used to identify an implant as being of the standard double-lumen Hartley type.

Table 2 continues on next page

Diaphragm valve	Saline	This type of valve is commonly used in saline-filled breast implants (Figs 22, 23, 24). A plug mounted on a strap fits into the valve. Early Heyer-Schulte (Jenny Style 1000, and Birnbaum Style 1100) implants had the strap attached to the shell only on one side. These earlier valves were about 10 mm in diameter with six side holes. Later saline-filled implants with this type of valve had the strap attached on both sides to the shell, with four side holes (Heyer-Schulte, CUI, Lab Sebbin, McGhan, McGhan/3M, and Mentor).
Internal tube valve	Reverse double-lumen	Some reverse double-lumen implants contain a tube connecting the fill port outside the implant to the saline-filled lumen inside, which can sometimes be directly visualized on MR images (Figs 25, 26). We have seen these on only Mentor Becker and CUI implants, which have been of the bag-in-a-bag design.

Note: This table was modified and adapted from reference 4.

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TABLE 3. Orientation, Fixation, and Other Features

Feature	Description
Fixation patches	Some implants have an additional patch or patches attached to the implant into which tissue is meant to grow for the purpose of providing fixation of the implant to surrounding tissues. Up to six fixation patches may be seen. The use of fixation patches was largely discontinued by the middle-to-late 1970s and was stopped except for custom implants by about 1984. Dacron mesh (Figs 27, 28, 29, 30, 31, 32, 33) and fenestrated silicone elastomer (Figs 34, 35, 36, 37) were two common mechanisms of fixation. Another one was the Dacron felt patch or strip attached to the posterior implant surface (Fig 1). Rarely, a polyurethane patch was applied to the posterior surface of an implant to provide fixation (128).
Suture tags	Fixation could also be accomplished with suture tags attached to the back patch inferiorly. Although rarely actually used for this purpose, these were meant to be sewn to adjacent tissue to prevent implant migration and rotation. These could be of a full-loop design using a fine denier Dacron mesh (Fig 38), a coarser weave Dacron mesh partial-loop design (Fig 39, 40), or a lock-stitch Dacronmesh-reinforced elastomer (Fig 41, 42).
Orientation devices	Bars could be attached to the outside of the back patch (Heyer-Schulte, Surgitek, and McGhan/3M) (Fig 43) or to the shell directly (Cox-Uphoff and Dow Corning) (Fig 44). Palpable dots could be attached to the back patch or the shell (McGhan and Cox-Uphoff) (Fig 45).
Shell texturing	From the middle 1980s onward, the outer surface of some smooth elastomer non-polyurethane-coated implants was textured. Mentor Siltexand CUI MicroCellimplants had a "fine grain" random texturing, whereas the McGhan Biocell and Bioplasty MISTI implants had a "coarse grain" random texturing. Dow Corning SILASTICMSI implants used regularly spaced micropillars (4) that allow a uniform thickness of waterlike fluid to surround the implant (Fig 46, 47).

Table 3 continues on next page

Internal disks	Dow Corning used a small, approximately 12-mm-diameter silicone elastomer disk centrally placed on the internal surface of some of their breast implant back patches from about 1971 to 1984 (Fig 44, 48, 49). The purpose of the disk was to help seal the hole through which silicone gel was introduced into the implant[12] . Given adequate MR imaging resolution, this disk often can be seen along the internal surface of the back patch of these implants. A similar disk is used by CUI in some of their implants (Fig 45), but it is less than 10 mm in diameter, is usually not centrally located on the internal surface of the back patch, and is found in implants generally placed later than the Dow Corning implants. More rarely, Heyer-Schulte also used a similar disk internal to some patches on their early custom implants, of which we have seen one example. Cox-Uphoff used a 10-13-mm-diameter internal disk in some of their early implants, which is too thin to see with currently available MR techniques.
Baffles	These were used in the early Natural-Y implants from Polyplastics, Heyer-Schulte, and Cox-Uphoff. They were continued by Aesthetech in some of the Optimam and Vogue implants. They consisted of internal septations in the shape of the letter Y and were intended to give the implant a more natural feel when indented.

Note: This table was modified and adapted from reference 4.

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TABLE 4. Polyurethane-coated Breast Implant Styles

Feature	Description
Natural-Y	This is a term used to denote both an implant style and the name of a distributor (Natural-Y Surgical Specialties, Los Angeles, Calif) of polyurethane-coated implants (Figs 51, 52). We use it here to denote only the implant style. After a period of development starting in about 1964 (96), these implants were first available in about 1968. They had a Y-shaped baffle internally, hence the name Natural-Y.
Optimam (MM)	The closest successor to the early Natural-Y style, with or without a baffle, with a cream-colored shell and a contoured profile (Fig 53).
Vogue (VP)	A low-profile version of the Optimam, cream-colored and with a contoured profile, with or without a baffle.
Même (ME)	Round low-profile version of the Optimam without a baffle (Figs 54, 55). These were manufactured by casting the gel into the desired form and then dipping it into liquid silicone, which was then "cured" to form the shell.
Même Moderate Profile (MP)	Round moderate-profile version of the Même ME, clear shell. These were manufactured by filling a preformed shell with silicone gel.
Replicon (RE)	Contoured high-profile cream-colored implant, no baffle, thick shell (Fig 56).

Note: Polyurethane coating is achieved by covering all or part of the surface of an implant with silicone adhesive and then placing a layer of polyurethane foam outside that. The letters in parentheses after the implant names (ie, MM, VP, ME, MP,and RE) are used in the catalogue numbers of these implants, and in some cases are considered part of the actual implant name. This table was modified and adapted from reference 4.

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TABLE 5. Factors Characterizing an Implant "Style"

Characteristic	Variations
Shape	Round (normal width vs extra wide)
	Oval
	Contoured (or teardrop)
	Crescent
	Custom
Shell	Smooth vs textured elastomer outer surface
	Single layer vs multiple layers (ie, "low bleed")
	Presence (or absence) of partial (or complete) polyurethane coating on top of smooth elastomer
	Opacity
	Thickness
Profile	Special fill (eg, specially underfilled, very low profile)
	Low profile
	Moderate profile
	High profile
Fixation	None
	Dacron mesh patches
	Dacron felt strips
	Fenestration patches
	Dacron suture loops/tabs
	Polyurethane patches
Orientation	None
	External disk
	External bar
	Palpable dot
	Dacron mesh-reinforced orientation tab
Seam	None
	Everted
	Non-everted
	Flanged

Note: This table was modified and adapted from reference 4.

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TABLE 6. Figure Numbers by Topic

Topic	Figure Nos.
Valve types	1-26
Fixation and orientation devices	27-45
Textured shell implants	46-47
Internal reinforcement disks	48-49
Smooth shell implant	50
Polyurethane-coated implants	51-56
Back patch	57
Reverse double-lumen adjustable implants	58-60
Single-lumen adjustable gel-saline implants	61-62
Birnbaum custom implants	63-65
Triple-lumen implant	66
Cavon implant	67-68
Custom implants	69-71
Soft pectus implant	72-73
Plastic sponge implants	74-77

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