Comparison of the Capsular Response to the Biocell RTV and Mentor 1600 Siltex Breast Implant Surface Texturing: A Scanning Electron Microscopic Study

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The utility of mammary prosthesis texturing in the prevention of capsular contracture was established some 20 years ago. Various models of implant texturing are currently on the market. We decided to study two of the most popular implants with two different surface texturings: the Biocell RTV and the Mentor 1600 Siltex. An observation at the electron microscopic level of the implants' surfaces was achieved. At the time of a prospective survey on 10 patients, the capsule fragments corresponding to these two prostheses have been analyzed at the electron microscopic level. All prostheses were removed from the patients because of asymmetry or bad positioning. The aim of our study was to establish a correlation between these two frequent texturing surfaces and their corresponding capsules. Our results showed that only the Biocell's capsules present a mirror image with correspondence of the depressions on the prosthesis and contacts on the capsule. This phenomenon seems linked to the existence of a critical size of the pores constituting the implant surface. This observation leads us to the hypothesis of an adhesive effect between the prosthesis and its capsule. If this last is not directly linked to the prevention of capsular contracture, it can have an effect on implant stabilization in the primary mammary reconstruction and in the secondary corrections of asymmetry or bad position. (*Plast. Reconstr. Surg.* 108: 2047, 2001.)

The formation of periprosthetic contracting fibrous capsules represents the most significant complication of aesthetic and reconstructive breast surgery. The first silicone breast implants were covered with a thin layer of textured polyurethane foam.[1] They enjoyed considerable popularity in the 1970s because of their remarkable resistance to the early development of fibrous capsular contracture.[2] Although these devices were removed from the market by federal regulators, their medical and commercial success stimulated interest in surface texturing of silicone implants, and during the last decade there have been many new designs in the surface morphology of the implant. Several prospective and retrospective studies have already demonstrated a significant reduction in adverse contracture using various textured surface implants.[3–11] The purposes of this study were to present both a three-dimensional analysis of two popular implants and a precise evaluation of the soft-tissue response to surface modifications. As a result, we hope to provide selective indications for each kind of surface texturing.

Materials and Methods

We decided to study two saline-filled prostheses: the Biocell RTV (McGhan Medical Corporation, Santa Barbara, Calif.) and the Mentor 1600 Siltex (Mentor Corporation, Santa Barbara, Calif.). These devices were textured silicone shells with two types of surface alterations.

Prosthesis Examination

A 1-cm^2 fragment from the dome of each prosthesis was cut and used for study by scanning electron microscopy. The fragment was

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cleaned with ultrasound then put on slides and coated with gold under a vacuum (Sputter coating JEOL JFC 1100 E, JEOL USA, Peabody, Mass.). The examinations were performed with a JEOL JSM 5200 scanning electron microscope. Pictures were taken with a Polaroid 545 camera (Polaroid, Cambridge, Mass.) and then digitized. The planimetry analyses were performed with the software NIH Image 1.9 (National Institutes of Health, Bethesda, Md.).

Capsule Tissue Examination

A prospective clinical study was performed on 10 patients in the Department of Plastic and Reconstructive Surgery of the Saint-Louis Hospital in Paris, between January and September of 1999, to collect five capsule samples for each prosthesis studied (Table I). All the patients had undergone a modified radical mastectomy because of breast cancer followed several months later by reconstructive mammaplasty. All patients required correction because of an incorrectly sized or located prosthesis. Infections, hematoma, and capsular contraction were excluded because we wanted to study normal capsule formation. The biopsy specimen was immediately placed in glutaraldehyde 2% in 0.1 M for 48 hours for fixation, then placed in cacodylate buffer pH 7.2 at 4°C for 72 hours. The fibrous capsular tissue was cut into small blocks measuring 1 cm^2 and used for study by scanning electron microscopy. The tissue was subjected to dehydration in grade ethanol (30%, 50%, 70%, 80%, 90%, 96%, 3× absolute ethanol) for 30 minutes each. The specimens were dried using the critical point method, glued on aluminum stubs, sputtered with gold under a vacuum (Sputter coating JEOL JFC 1100 E), and analyzed with the JEOL JSM 5200 scanning electron microscope. Pictures were taken with a Polaroid 545 camera and digitized in a computer; the planimetry analyses were performed with the NIH Image 1.9 software.

Results

For each prosthesis and corresponding capsule, the ultrastructural aspect is described (Tables II and III) and some of the most significant photographs are presented.

Biocell RTV and Corresponding Capsule

The surface of the prosthesis is full of depressions. Their sizes and depths are regular. The diameter of these ranges from 600 to 800 μm for a depth of 150 to 200 μm. An edge raised 70 to 90 μm around each of these depressions increases the total depth. The distribution of these depressions is irregular on the surface of the prosthesis. On average, there are eight depressions for 1.5 mm^2 (Fig. 1, *above*).

The surface of the capsule shelters numerous blood cells; its architecture is nonlinear and disorganized. We note a thrust of the capsular cloth in the pores of the prosthesis to constitute the contacts having features corresponding to the pores of the prosthesis (Fig. 1, *below*). At 3500× magnification, one distinguishes numerous nondeformed red blood cells and some perfectly cylindrical particles at the 7500× magnification (Fig. 2).

Siltex 1600 and Corresponding Capsule

The roughness of this prosthesis is manifested by nodules on the external surface of the envelope. The size of the micronodules ranges from 40 to 100 μm in height to a width of 70 to 150 μm. The distribution of these nodules is regular on the surface of the prosthesis, and their density averages 30 nodules for 1.5 mm^2 (Fig. 3, *above* and *center*). The surface of the capsule appears to be made of linear fibrosis (Fig. 3, *below*). At the 200× magnification, one

TABLE I
Patients Included in the Study

Case No.	Age (yrs)	Implant	Months after Insertion of the Prosthesis	Reason for Intervention
1	30	Biocell	48	Wrong position
2	43	Biocell	24	Wrong position
3	64	Biocell	38	Wrong position
4	45	Biocell	25	Asymmetry
5	51	Biocell	36	Wrong position
6	44	Siltex	37	Asymmetry
7	59	Siltex	240	Asymmetry
8	40	Siltex	55	Wrong position
9	43	Siltex	25	Wrong position
10	54	Siltex	34	Asymmetry

TABLE II
Implant Description

	Depressions or Nodules	Diameter (μm)	Height or Depth (μm)	Edge (μm)	Distribution	Density/1.5 mm^2
Biocell (McGhan)	D	600–800	D 150–200	100–150	Irregular	8
Siltex (Mentor)	N	70–150	H 40–100	0	Regular	15

observes an even surface with some deposits of erythrocytes.

Discussion

Survey of Two Mammary Implants

Mammary implant norms of manufacture were instituted in 1981 by the American Society for Testing and Materials. Biocompatibility, mechanical properties of the envelope, continence of the valves, modes of sterilization, packing, and labeling are governed by these norms. No guidelines exist concerning the formation of the textured surface. The only rule is not to alter the other properties of the prosthesis. The laboratories have been given free rein in the design and conception of the prostheses' surface morphology.[12] In 1987, the Biomedic-Mentor laboratory was the first to get the approval of the Food and Drug Administration for the Mentor Siltex 1600. The electronic microscopy examination shows regular nodules in size and density. The Siltex texturing is a patterned surface created as a negative contact imprint off of a texturing foam.[13] The McGhan Medical Corporation developed the Biocell surface, which is a more aggressive open-pore textured surface created with a lost salt technique. The whole elastomer shell is placed on a bed of finely graded salt with light pressure. This manufacturing process increases the depth of the depressions while creating an important stilted edge. The aim of the second part of our study was to discover whether there is a relation between the texturing surface and the periprosthetic capsular tissue morphology.

Study of the Periprosthetic Breast Capsules

The periprosthetic breast capsule has been described by most investigators as a foreign body response involving inflammatory cells, giant cells, and fibroblasts with collagenous cicatrix formation. Various factors can influence the capsular formation[14]: implant shape, the silicone itself, surgical technique, bleeding, subclinical infection, implant surface morphology, and patient sensitivity.[15] All of the implants used in this study were saline-filled silicone with different surface morphology. Taylor and Gibbons[16] demonstrated in 1983 that the surface texture of an implant is a critical variable in determining the soft-tissue response to a material, and they established a capsule devel-

TABLE III
Capsular Description

Case No.	Implant	Capsule Texturing	Diameter (μm)	Height (μm)	Density (μm)	Cells
1	Biocell	Mirror image	500	150	8	Red blood cell, macrophage, cylindrical particle
2	Biocell	Mirror image	550	150	8	Red blood cell, macrophage, cylindrical particle
3	Biocell	Mirror image	560	160	9	Red blood cell, macrophage, cylindrical particle
4	Biocell	Mirror image	650	170	7	Red blood cell, macrophage, cylindrical particle
5	Biocell	Mirror image	700	200	8	Red blood cell, macrophage, cylindrical particle
6	Siltex	Linear fibrosis	—	—	—	Red blood cell
7	Siltex	Linear fibrosis	—	—	—	Red blood cell
8	Siltex	Linear fibrosis	—	—	—	Red blood cell
9	Siltex	Linear fibrosis	—	—	—	Red blood cell
10	Siltex	Linear fibrosis	—	—	—	Red blood cell
TOTAL						
Five cases	Biocell	Mirror image	500–700	150–200	8	Red blood cell, macrophage, cylindrical particle
Five cases	Siltex	Linear fibrosis	—	—	—	Red blood cell

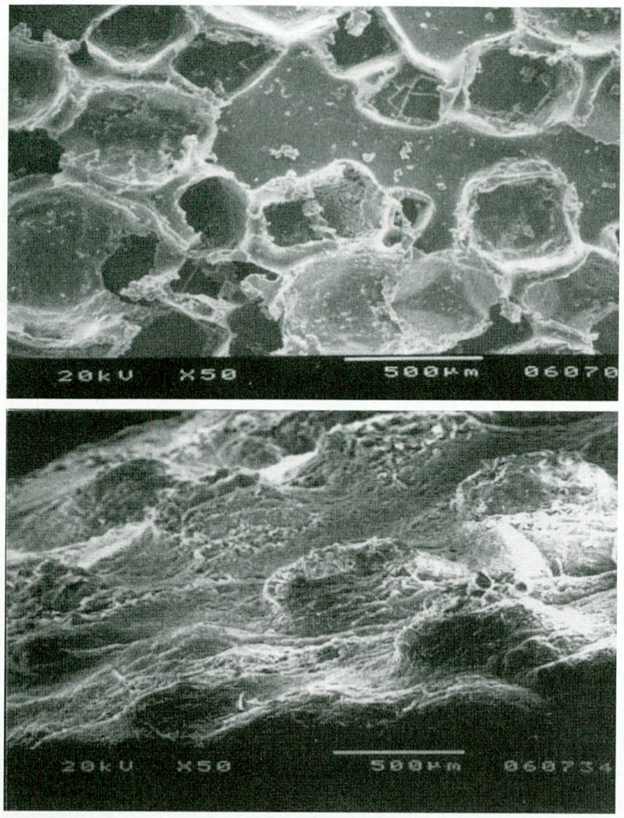

FIG. 1. (*Above*) Scanning electron microscopy image of a Biocell RTV implant (50×). (*Below*) Scanning electron micrograph of the corresponding capsular surface (50×).

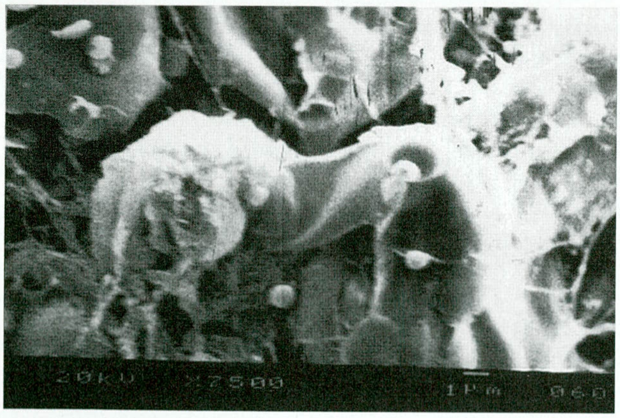

FIG. 2. Suspicion of silicone globule in a scanning electron microscopic view of a Biocell's capsular surface (7500×).

opment for textured implant of at least 18 weeks' duration. We opted for a delay of 24 weeks from implantation before including the patients in our study.

Barone et al.[17] in 1992 showed in a rabbit experimental study that the Biocell capsule surface resulted in tissue ingrowth and adherence to the prosthetic surface. In a study of the tissue/biomaterial interface reactions of four elastomers selected as candidates for scaffolding for tympanic membrane tissue in a total alloplastic middle ear prosthesis, Baker et al.[18] established a critical size of the pore to get a tissue to grow into it. Drubaix et al.[19] and Muller-Mai et al.[20] define minimal pore sizes to get a thrust of fibrous cloth in varied polymers. Bobyn et al.[21] showed that in a porous surfaced metal implant, a pore size of 100 μm allows

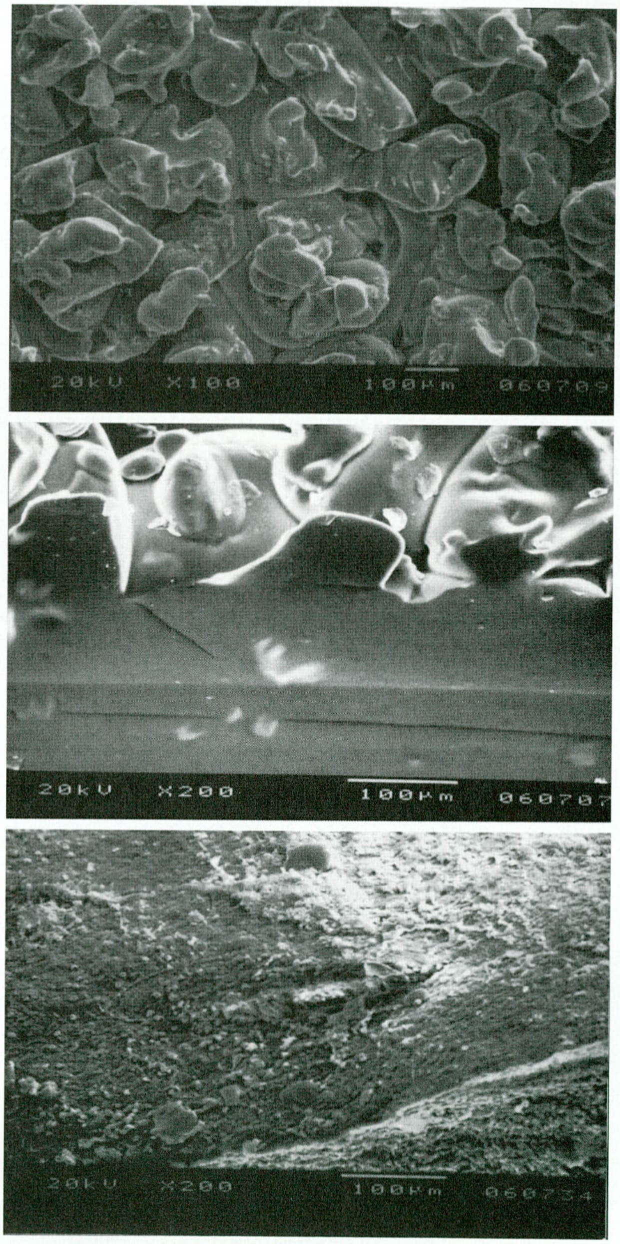

FIG. 3. (*Above*) Scanning electron microscopy image of a Mentor 1600 Siltex implant (superior view, 100×). (*Center*) Scanning electron microscopy image of a Mentor 1600 Siltex implant (tangential view, 200×). (*Below*) Scanning electron microscopy image of the corresponding capsular surface (tangential view, 200×).

bone ingrowth, but a pore size greater than 150 μm is required for bone formation. Our survey confirms the critical importance of the porous surface to induce tissue formation; it also permits us to conclude that the aggressive texturing of the Biocell can reach the depth doorstep of the pores on the prosthesis to get a mirror-image capsular response.

Effect of Implant Texturing on the Tendency to Capsular Contracture

Much has been written about the nature of the fibrous capsule around a static implant. Baker et al.[18] pointed out the role of the myofibroblast, but most other authors[22–25] disagreed. They felt that an inelastic arrangement exists of large amounts of collagenous material that creates the feeling of a tight capsule. The capsular contracture becomes detectable weeks to years after the implantation, meaning that it does not occur within a defined postoperative proliferation or remodeling phase. Over the past 15 years, the baseline incidence of capsular contracture has been reported to be from 0 to 80 percent in different series; among the variables are the length of follow-up and the means of estimating the degree of firmness.[26] The association with some factors is fairly clear[8,14,27–30]: hematoma around the implant, infection, diffusion of silicone through the envelope of gel-filled breast prostheses, and smooth surface of the implant. Steps to prevent contracture are determined on the basis of an individual surgeon's commitment to the merits of one or more of the associated factors that have been reviewed. The most popular practices include steroids, antibiotics, retromuscular positioning of the implant, the use of textured prostheses, and the use of drains to prevent hematoma.

The data we have reviewed strongly support that both the McGhan Biocell textured surface[6,7] and the Mentor Siltex textured surface[3,4] are generally effective in reducing the incidence of capsular contracture. There is no clear relationship between the aggressiveness of the textured implant surface and the incidence of capsular contracture.

Adhesive Effect

Raso et al.[15,31,32] published a case of true synovial metaplasia of a periprosthetic breast capsule 4 months after the placement of a textured Mentor Siltex implant. According to Drachman and Sokoloff,[33] synovial metaplasia is induced by repeated micromovements in the embryo. Del Rosario et al.[34] showed that synovial metaplasia never occurred around the Biocell textured implant. We explain these results by the absence of micromovement between the Biocell implant and the surrounding periprosthetic capsule. The adhesive effect is characterized at the ultrastructural level by a mirror-image tissue response of the periprosthetic capsule to the textured surface of the implant (Fig. 4). Textured Biocell implants have demonstrated a better stability attributable to tissue adherence.[35,36] A textured implant with adhesive effect seems to us the best choice for breast reconstruction.

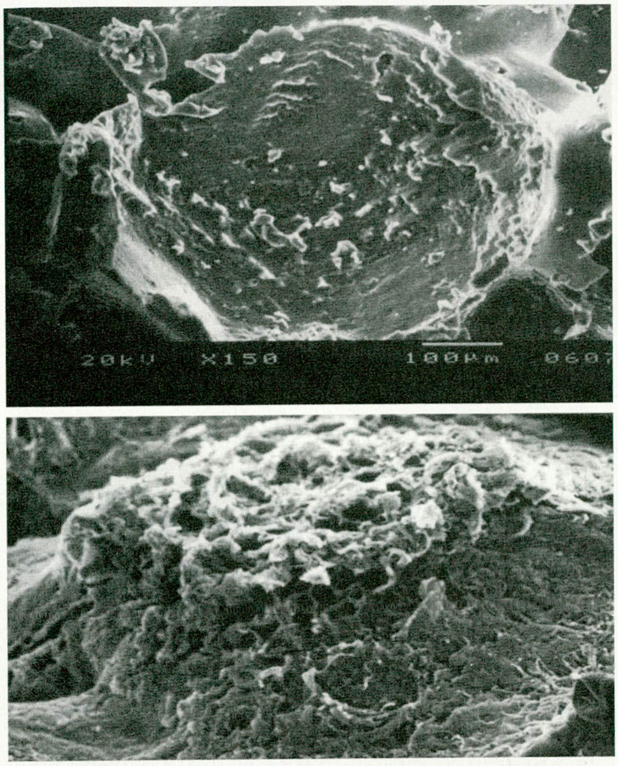

FIG. 4. Scanning electron microscopy view of the adhesive effect. (*Above*) Biocell implant's pore (150×). (*Below*) Capsular mirror image (150×).

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