# TEXTURED SURFACES AND THEIR PROBLEMS

Textured surfaces figure prominently amongst the history of breast augmentation devices. Their popularity is credited to W.J. Pangman who, in the sixties, suggested that a rough surface would have an ability to attach itself to a slippery tissue surface. He reasoned that tissue would grow into the irregularities causing the implant to lock in place and become an integral part of its surroundings, a situation which he perceived as desirable. This concept, termed 'tissue fixation', had been borrowed from vascular, cardiac and abdominal wall repair surgery where implants made of porous fabric were successfully employed. For example, woven fabric tubes were widely used to replace large arteries. The fabric, with time, would become coated with new tissue which rendered the structures impermeable and permanently integrated into natural vasculature through fibrosis. The open fabrics induced rapid formation of thick, smooth connective tissue termed 'pannus'. Rough metal surfaces were also used in orthopaedic implants to induce bone ingrowth causing parts which required strength and stability such as hip and knee implant components to lock into adjacent bone.

The belief that immobilization of a breast implant against the chest wall and surrounding tissue was necessary became entrenched in plastic surgery circles and pervaded breast implant designs in the sixties and seventies. Porous tissue fixation parts or textured coatings were incorporated in nearly all early breast implants such as the "Cronin", the "Pangman-Wallace", the "New Polyplastic", the "Ashley Natural-Y" and many others. By the seventies, serious problems associated with tissue fixation were well known. It took another decade to abandon the concept. Only polyurethane foam-covered breast prostheses remained as anachronistic examples of tissue fixation devices. These were the Ashley Natural-Y implants and their later successors, such as the Vogue®, Optimam®, Meme® and Replicon®.

These polyurethane foam-coated devices were all initially predicated on the principle of tissue fixation. This would have been a reasonable assumption had the textured surface remained unaltered during the lifetime of the device. However, as reported by many surgeons and pathologists, this was not the case. The foam coating disintegrated and disappeared, thus invalidating claims that fixation served any purpose, let alone a beneficial one. Promoters of foam implants later dissembled, asserting that polyurethane foam-covered devices had resorbable and bioactive coatings which reduced their propensity to initiate capsular contracture. This claim was also ill-founded. The only definitive finding is that these devices soon lost their coatings which disintegrated and scattered in the surrounding breast tissue, frequently inducing severe adverse effects including a worsening type of contracture that resulted from very thick capsules containing large quantities of debris.

The concept of rough surfaced implants was reintroduced in the mid eighties by other manufacturers who sought to duplicate the texture of polyurethane without the risks of dissolution and disintegration. Textured products were investigated by American Heyer-Schulte (AHS) in the mid seventies and led to other types of polyurethane foam-covered devices and implants textured though the imprinting of rough textures through contact with foam surfaces. These were later abandoned because of fabrication problems and the uncharacterized toxicology of the adhesive and elastomers necessary for incorporating the texture.

Early commercial examples of textured surface implants using direct texturing processes investigated by AHS were followed by other products made by its successor, the Mentor Corporation. They include the Mentor Siltex™ breast implant lines introduced circa 1985. The Siltex™ shells used rough texturing molds to generate fine replicated irregularities on the surface of otherwise conventional prostheses. McGhan/Inamed introduced competing Biocell™ lines, a class of device made by casting a supplemental finishing film of silicone elastomer on top of a conventional shell and then contaminating this layer with water-soluble particles. The soluble particles would then be redissolved in water to produce an irregular, partly vacuolated surface. Variations of this technique were later introduced which caused the irregularities to be more of a bubble-like character. Aggressive washing of the finished products followed by mechanical processes would then erode a portion of the surface to create additional roughness from the rupture of closed bubbles.

The Biocell™ texturing process was accident-prone. The requirements for a soluble sacrificial substance to create holes into a cast elastomer surface had a tendency to leave closed cell surfaces which retained debris and chemical impurities. Upon aggressive washing, the sacrificial material would dissolve but the residual cavities would be nearly impossible to clean exhaustively. The process also produced frangible surfaces which readily spallated debris into adjacent tissue. The closed cells and the poor permeability of the surfaces would facilitate growth of bacteria and the accumulation of denatured tissue. When infection occurred at the prosthesis-tissue interface, a common situation, colonization within the textured surface would become uncontrollable and self-propagating.

For coarsely textured implants such as the McGhan/Inamed Biocell™, the rough surface would form a separate layer of adhering tissue which frequently was unconnected to the main external capsule. This adhering tissue, termed 'pannus', would grow to significant thickness, sometimes exceeding several millimeters. With movement and aging of the pannus, some deterioration would take place. This resulted in maceration and fragmentation of this intervening capsular tissue which would lodge within recesses of the capsule and compact to thick, friable material. The dispersion of fragmented, partly denatured tissue within the capsular space would create additional problems which aided colonization and capsular contracture.

The resulting composite capsule and its associated internal pannus would inevitably become much thicker than conventional capsules. Worse, it would have marked contractile characteristics. Thus, claims of control of capsular contracture from textured surfaces had no basis. With the intracapsular space filled by fragmented tissue and other assorted by-products from intracapsular reactions, the capsule would become the nidus of aberrant processes.

Implants such as the Biocell™ and the Siltex™ have much thicker shells, are less compliant and more prone to form invaginations within the shell surface. Within several months, pannus grows within pleats and invaginations, further complicating the structure of these capsules. Rupture of such prostheses takes place within about the same timeframe as the older, non-textured prostheses and the failures take the form of clusters of adjacent perforations which usually take place near puckers and pleats.

Erosion of the fragile textured surface accelerates the process, resulting in ruptures which release large quantities of gel into the intracapsular space. The gel reverts to oily components which infiltrate the porous surface, creating a more complex composition for intracapsular debris. The oil, intermingled with tissue fragments, becomes a paste-like substance, some of which incorporates into capsular tissue. Inflammation and tissue remodeling are habitually encountered within such tissue. With time, granulomatous masses form in proximity to the capsules. Adhesions between the capsule and the granulomata later create additional problems.

Removal of coarsely textured implants presents problems. The capsules are thicker and form a larger fraction of the explanted mass. Frequently vascularized, they increase the risk of bleeding. The shape is more irregular and requires cautious dissection, necessitating extensive hemostasis. Capsules erode to fine elastomeric debris, heavily contaminated with silicone fragments. Electrosurgery pyrolizes the debris to silica, adding another category of impurity to the site. If there is a need to remove the implant from the capsule to facilitate its extraction from a constrained surgical site, the process is much more difficult inasmuch as portions of such implants are tenaciously bound to the capsule and require strong traction to separate. Many users develop thick, multilayered capsules bound to the prosthesis and through adjacent muscle tissue within about 24-36 months following implantation, making removal particularly laborious and strongly dependent on electrosurgery cauterization for control of bleeding.

In the context of implant texturing, a novel technology emerged in the late eighties. The development is credited to reduction in costs of laser machining processes. Dow Corning employed laser micromachining of implant mandrels (molds) to create finely textured surfaces. Commercial implants using this process were briefly made by Dow Corning circa 1989 when microtextured implant surfaces were incorporated into several types of existing mammary prostheses creating the MSI line. The texturing consisted of microscopic columnar surface elements created through direct molding processes. Serially-made molds using laser micromachining the surface were employed to create fine, deep, closely spaced cavities.

Textured implants were costly to make and the quality of the texture varied widely depending on processing conditions. Because the molded microtextured element was very small and many were needed, the process for mold-making was laborious and erratic. It required the creation of very small holes to produce a plastic surface with fine columns of polymer with an average diameter below 0.05 mm. This was not feasible with precision machine tools. It relied on lasers. The lasers produced burnt polymer surfaces which released crumbly, degradable mold debris. The fine holes had a tendency to occlude debris. After several cycles of use, cleaning could not be performed exhaustively and the holes collected adventitious impurities and viable micro-organisms. The service life of the molds was short and the reconditioning was costly.

In the final analysis, the ability of textured implant surfaces to reduce contracture proved illusory. Texture is not a major benefit but in most cases it becomes a liability with enhanced risks of infection. Implant removal is more difficult. In combination, these features increase the risk of adverse events, mainly because of the ability of porous surfaces to retain contamination, including extravasated filling material. Sub-clinical infections are common amongst users and often lead to rapid contracture of a kind worse than in conventional implants.