

RESIDUAL CAPSULES AND INTRACAPSULAR DEBRIS AS LONG-TERM RISK FACTORS

Capsule Genesis, Characteristics, and Health Impact

Contamination of the space between the capsules and the implants by microorganisms, silicone oils, degradation products, and gel impurities constitutes a major problem which potentiates the risk of implants. Such problems include inflammation, infection, deposition of mineral debris, as well as certain autoimmune phenomena. These problems can be present when implants are in situ and are often attributable to the implant. The logical expectation is that, upon removal of implants, adverse effects will cease. This is an unjustifiably optimistic view. It is well documented from case histories that removal and/or replacement of implants, without exhaustive debridement of the prosthetic site, leads to failure and post-surgical complications.

Plastic surgery procedures tend to favour speed and immediate cosmetic results. For these reasons, leaving or “reusing” tissue from an existing capsule may seem more “gratifying”. However, adverse effects resulting from this practice are widespread but have not been well documented. Typically, patients who require removal of faulty implants and undergo immediate re-implantation in the same prosthetic site habitually relapse with the same problem that motivated the previous surgery; the most common example is exchange of implants and/or sectorizing or bisecting the capsule without removing it completely.

Such patients rarely achieve significant capsule correction and habitually return for more surgery. A more illustrative situation is where patients do not receive replacement implants. Problems of this nature have been described by many authors and derive primarily from immune phenomena and inflammatory syndromes with pain, swelling, serological abnormalities and alarming radiologic presentation. The process is described in a paper published in 1993 (Copeland, M.; Kressel, A.; Spiera, H; Hermann, G.; Bleiweiss, I.J.; Systemic Inflammatory Disorder Related to Fibrous Breast Capsules after Silicone Implant Removal; *Plastic and Reconstructive Surgery*; 92 (6), 1179-1181 (1993). Risks arising from remaining capsular tissue are also described.

Numerous similar cases have been noted amongst implant users but there are few publications. Some are cited in FDA Adverse Reaction Reports. Others appear in the U.S. Pharmacopeia Reporting Programs. In the early nineties, capsule removal became an issue in the context of health care and surgery standards. Several articles appeared on the topic. In September 1998, the *Journal of Plastic Reconstructive Surgery* published guidelines on removal of capsules. The document, authored by Dr. V.L. Young, entitled “Guidelines and Indications for Breast Implant Capsulectomy”; *Plastic & Reconstructive Surgery*, 102(3), 884-891 (1998), set forth the rationale, methodology, and the indications for capsule removal.

Normal and Pathological Capsule Presentation – Imaging Techniques

Surgeons do not remove capsules in a uniform way. Some only remove the implant and its loose debris. They may not remove capsules at all. Numerous journal publications address the advisability of removing capsules and the consequences of leaving such residuals within the surgical site. Capsule removal incidental to explantation of prostheses, termed “capsulectomy” or “ablative capsulectomy” is most often performed with supplemental extracapsular tissue debridement. These ablative procedures are a generally accepted standard of health care in implant adverse-reaction management.

Several capsule resection techniques are used, the most common being the simultaneous removal of capsules, which contain the implant, and its residuals entrapped within the distinct capsular tissue layer, much like an encapsulated tumour. Such a procedure, termed “extracapsular capsulectomy with incarcerated implant” is a logical procedure derived from the experience of surgical oncologists. It is the preferred procedure for surgeons skilled in such arts. The technique is the most expeditious and least troublesome of the several alternatives insofar as it retains all oily debris that is habitually encountered with failed prostheses. It forestalls gross contamination of the surgical field and often circumvents the need for multiple surgical instrument kits incidental to such surgery. Discontinuities in surgical procedures involving removal of implants are commonplace but are least frequent for the incarcerated implant resection procedure. This technique may avoid contamination of instruments which result from working in calcified or oil and gel-contaminated fields. When a surgical pocket flooded with oil and gel is encountered, normal surgical protocols require change of instruments and regloving of personnel. Thus, containment of the debris within the tissue capsule is frequently the most conservative form of implant removal.

In some instances, only portions of the capsules can be removed because of peculiarities of the patient or earlier misadventures involving implants. Mastectomy patients can be problematic. Inadequate tissue cover, breaching into the thoracic cavity (pneumothorax) or risk of damaging key chest muscles may limit the amount of resection that can be safely performed. Such situations are rare for augmentation patients but can sometimes be encountered in users with a history of multiple failed implants, unresected residual capsules, and other chronic phenomena associated with capsule fibrosis and large volume foreign body phenomena.

When capsular tissue is submitted to pathology centers, it may contain the implant or parts thereof entrapped within the tissue. The pathologist is thus tasked with separating the implant from the tissue in order to perform an assessment of the pathological material. Alternatively, a separated capsule, dissected as a separate surgical procedure following removal of the implant, may be provided where implants and tissue are already separate entities. On rare occasions, only a small fragment of capsular or extracapsular tissue may be removed and submitted to pathology primarily for oncologic evaluation (cancer screening) which is required

statutorily or by malpractice insurance agencies in many instances. In such circumstances, the pathology study does not address the capsule tissue.

Capsules for implants of a dwell time exceeding 5 years are always coherent tissue in the sense that they are made up of strong material with well demarcated cleavage planes in reference to adjacent tissue. They always have an 'open' side which was contiguous to the prosthesis or the prosthetic debris. The converse side forms a recognizable boundary either with the breast gland (anterior side) or with the chest wall muscles (posterior side). Even if capsules are comparatively thin (less than 0.5 mm) and have fenestrations (openings), they still remain together as palpable resectable entities.

The presence of thick areas or bands within such capsules may account for large variations from point-to-point in the capsular tissue. The thickness of capsular tissue for average users is approximately 0.3-0.5 mm for the part that consists only of dense connective tissue. Such capsular material is comparatively uniform for most normal implant users without rupture, and who do not have a history of unresected capsules from prior implants. Irregular and thicker capsules are found almost invariably for users with dwell times beyond 5 years. Even grossly symptom-free users often have capsules in the range of 1-2 mm, in particular for users of foam-coated implants. Users of tissue expanders may have extremely thick capsules reflecting complex surgery, chronic infective processes, and other situations that are often related to mastectomy and/or reconstruction procedures. However, such users habitually report deformity, pain, and severe contracture.

Conventional pathology procedures, as performed on capsule fragments, may include measurements of capsule thickness. Not all pathologists differentiate actual hyalinized capsular tissue from integrated capsular tissue with attached peripheral material. Yet, such differentiation is easily achieved on re-examining microscopy slides on tissue from explanation surgeries and performing measurements retrospectively. Thicker capsule parts in the 1-5 mm range nearly always show clusters of retractile material consistent with pools of non-birefringent, non-stainable, partly retractile material. Such descriptions are consistent with the findings of silicone oil and gel distributed in cystic pockets within the hyalinized tissue. Granulomata resembling hyalinized tissue may be intimately incorporated within the capsule. There can be differences amongst observers of capsules inasmuch as some may not differentiate the hyalinized zone from attached non-hyalinized fibrofatty breast tissue or skeletal muscle, often attached to the outer part of capsules. Most experienced pathologists nevertheless make such a differentiation, at least when they perform services in the context of research.

Specialized hyalinized tissue of this kind forms only after the implant is inserted. It remains distinctly visible from the surroundings, even when seen with the unaided eye. The difference is unavoidably perceived on examination of stained microscopy slides. Such tissue is termed the "hyalinized zone", a dense area of fibrous collagen unlike normal breast material. Locally

thickened collagenous areas, consisting of multi-layered hyalinized tissue greater than about 0.7 mm integrated into the capsule, is not habitually present, unless there is focal leakage from the implant or a history of multiple procedures to the same site. Situations leading to such thickened tissue include a history of prior implants with unresected capsules; compression of breasts for resolution of capsule contracture (“squeeze” or “Baker” technique); and radiographic procedures with forward displacement of the breast gland, strong compression, and traction on the anterior part of the breast, such as the “Eklund” technique.

All compression events of this kind can lead to subtle internal breast injuries followed by healing and proliferative fibrosis culminating in thick areas and bands of strongly contractile capsular tissue. These markedly increase the thickness and strength of capsules making them more coherent and able to retain their integrity during removal procedures in spite of discontinuities and fenestrations (holes) that may have formed in the capsule over the dwell time. Thickened areas of this kind, sometimes called “focal hyperplasia”, may grossly distort implants. They are almost always present in tissue adjacent to implant parts, such as patches and valves, which appear to have markedly fibrotic influence on contiguous tissue. Late capsules, in particular when there is leakage of content with uniform flooding of the capsule space by prosthetic-filling substances, are always thickened and very strong, sometimes exceeding tensile properties of normal connective tissue. These capsules have a thick sac-like character.

Radiographically, capsular tissue appears as preferentially radiodense material. Even without mineralization, this tissue is distinct from the surrounding normal breast when viewed from favorable angles with good quality radiocontrast conditions. Capsules with or without incorporated implants can be visualized through X-ray techniques such as film mammography, xeromammography, and high-resolution, computer-assisted tomography (CAT) scan. Such techniques are often employed for evaluation of breast anomalies. They may yield valuable radiographic information in the context of implant and capsule condition. Radiographic plates of this kind may allow extraction of precise information about implants, deployment of prosthetic debris within the surgical site, the formation of capsules, the thickness of capsule walls, and the extent of mineralization. Contrary to frequently expressed views in some quarters, conventional radiographic techniques are ill-suited for discerning malignancies in fields where there is foreign debris, implants, and capsule phenomena.

Capsule Evolution Following the Implant Removal

A residual capsule is not a stable entity. It may collapse initially upon completion of surgery and remain asymptomatic for some time; however, it will fill with extracellular fluid and remain as fluid-filled space with added blood and prosthetic debris. As the wall matures and the breast remodels to accommodate the loss of the prosthesis, the capsular tissue shrinks. Water, as well as electrolytes, is expelled gradually from the pocket, or else the mixture is concentrated from leakage of water from the semipermeable capsular membrane wall. In most cases,

calcium salts precipitate during that stage and may render the capsule visible as a radiodense and speckled zone in radiographic projections. Prosthetic debris is radiodense and may be imaged to further complicate the presentation. The average size of the residual capsules, after 6-12 months, is in the 2-7 cm range; most are compact, comparatively small, and dense. Surgical removal should present no difficulty for most patients if adequate radiographic information is available.

Later stages of maturation include the thickening of the capsule wall, sometimes reaching 0.5-1 cm. Compression of the debris into a cluster of nodules, which usually become calcified, follows for some patients. A few mimic malignancies. Others appear as small “prostheses” during mammographic studies. They are alarming to oncologists and are habitually signalled for further studies or biopsies by oncologic radiologists.

In the light of present knowledge, and considering the probable content of these residual closed capsules, an open or needle biopsy is not advisable. The risks of releasing significant amounts of hazardous contamination, and possibly spreading infective entities, outweighs the advantages of the diagnostic. At any rate, such a capsule requires removal for mitigation of symptoms and a more direct surgical approach more economical and less risky.

In summary, a capsule with a dense fibrocollagenous wall behaves as bioreactor. Worse, it is fitted with a semipermeable wall that may periodically open to release its content into the breast. The probability of finding the space colonized with atypical microorganisms is elevated and control of infective processes by classic pharmacologic approaches is difficult, if not impossible.

Such closed capsular spaces may be comparable to “artificial organs” of unpredictable functions. Their behaviour will depend on the content and the age of the structure, its maturity, and the history of the patient. There is a high probability that these capsules will continue to evolve for many years, adding more layers of fibro-collagenous tissue and possibly granulomatous material. If bacterial entities are present within the capsule space, they can culminate in large breast abscesses which resist conservative treatment.

Even with less active capsules containing mostly oily and calcific debris, the thickening of the wall leads eventually to solid “tumour-like structures” and are, by themselves, alarming on auscultation and self-examination. At best, such structures are unique environments for protein denaturation and aberrant biochemical reactions with unknown long-term consequences.