Management of Double Capsule

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Introduction

Capsular contracture and implant displacement are the leading causes for reoperations in breast implant surgery, according to core studies submitted to the FDA by breast implant manufacturers [1, 2]. Texturing of the implant surface was initially developed to stabilize the implant in the breast pocket with the aim of minimizing movements against the chest wall and surrounding tissue. Accumulated long-term data revealed textured implants to have a lower incidence of capsular contracture compared to smooth ones [3–6].

There are a number of techniques for texturing the initially smooth implant during the manufacturing process. The Allergan Biocell texturization (Allergan Inc., Dublin, Ireland), created by the "salt lost technique," is achieved by applying the implant shell with pressure onto a layer of fine salt. This creates cuboid-shaped wells in dimensions of 200- to 500-μm width and 100- to 200-μm depth, termed "macrotextured." The Mentor Siltex surface (Mentor Worldwide LLC, Irvin, CA, USA) is formed by negative contact imprinting from textured foam. This creates nodules that have an approximate height of 40–100 μm and a diameter of 50–150 μm. This surface is described as being "microtextured," and it is considered to be a less aggressive form of texturization compared to the Allergan Biocell surface [6–10].

The surface of the implant has a key effect on the interaction between the implant and the breast in the formation of a fibrous capsule. Tissue adherence is achieved by periprosthetic capsular tissue ingrowth into the pores of the textured shell surface, thereby essentially anchoring the implant to the surrounding breast tissue. The more aggressive the texturing of the surface, the more prominent the tissue ingrowth [6–10].

A double capsule occurs when two distinct layers form around the breast implant: one is an inner layer that firmly attaches to the implant device, and the other is an outer layer that adheres to the surrounding breast tissue (Fig. 12.1) [6–12]. The capsule layers are separated by the intercapsular space (ICS). This double capsule phenomenon may be partial or complete. A double capsule formation appears around the entire implant in the complete type (see Fig. 12.1). Consequently, the textured implant essentially behaves as a smooth surface, and may cause the implant to be in malposition and malrotation due to the new, smoother interface between the inner and outer capsule layers (Video 12.1) [6–12]. Furthermore, the inner capsule wraps the implant tightly and can cause a feeling of hardening of the implant, mimicking capsular contracture.

The smooth surfaces of both layers which are in contact with the ICS are responsible for micromovements within the double capsules. The clinical relevance of this dynamic relationship, aside from the risk for malposition, is the increased risk of synovial metaplasia, chronic infection, late seroma, and possible breast-implant-associated anaplastic large cell lymphoma (BIA-ALCL) [7].

Pathophysiology

The pathophysiology of the formation of a double capsule is still undetermined, but it is likely to be multifactorial. One potential route involves the macrotexturing of the implant surface, such as that seen in Biocell devices, which has been associated with higher rates of double capsule formation compared to other textured or smooth implants. The Biocell

Electronic Supplementary Material The online version of this chapter (https://doi.org/10.1007/978-3-030-57121-4_12) contains supplementary material, which is available to authorized users.

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J. Y. S. Kim (ed.), *Managing Common and Uncommon Complications of Aesthetic Breast Surgery*,
https://doi.org/10.1007/978-3-030-57121-4_12

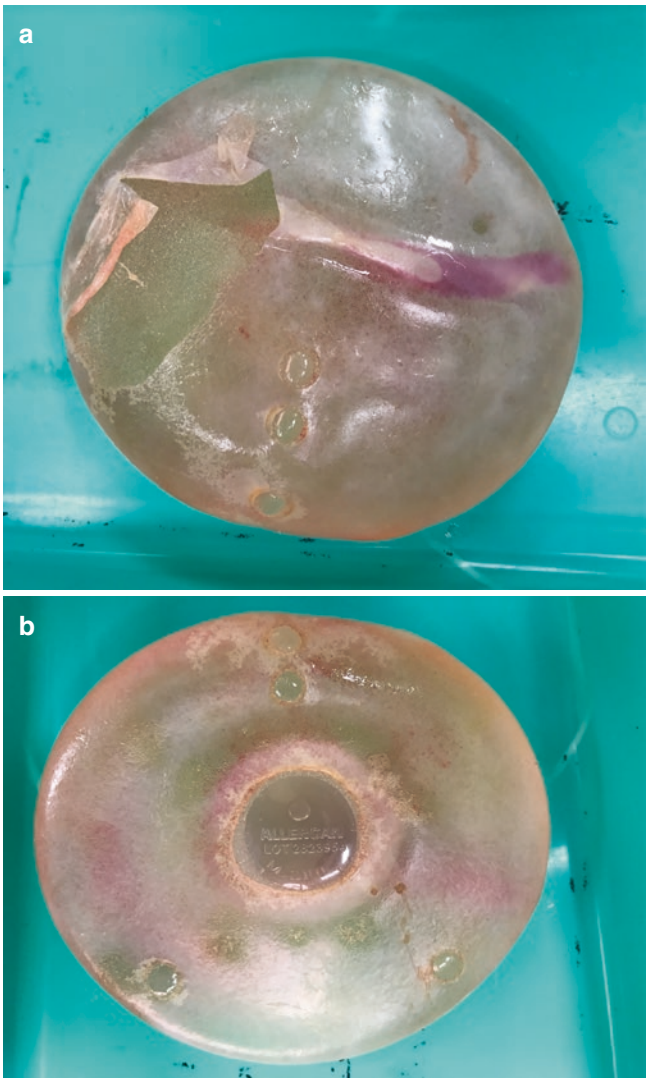

Fig. 12.1 Complete double capsule over an Allergan Biocell macrotextured shaped implant. The inner capsule totally covers the implant except over the smooth tabs (**a**) in the 6 o'clock position and over the smooth posterior filling port and posterior tabs (**b**)

macrotextured topography promotes cellular ingrowth, with histological analysis of capsules demonstrating an almost mirror imprint of the implant's surface [10]. The end result is adherence of the implant to the surrounding breast tissue and reduction of its movement. Disruption of the tissue ingrowth together with the integration of the implant may lead to the formation of two parallel capsules.

Several hypotheses regarding the formation of a double capsule have been described in the recent literature. The first one is based upon movement of the implant inside an oversized pocket. The macro- and micromovements of the implant prevent adhesion of the textured implant surface to the surrounding tissues, leading to the formation of two layers of the capsule [11]. The second hypothesis involves a mechanical etiology in which shear stress applied to the implant capsule complex forces the implant away from the capsule. This separation leads to the subsequent creation of a new inner layer of capsule in direct contact with the implant. Histological studies of double capsules on Biocell expanders have revealed the presence of intracapsular fractures on all tested specimens from the lateral aspect of the expanders. These fractures in the collagen matrix occurred in conjunction with signs of an inflammatory response, as evidenced by the proximity of macrophages on the ICS [12].

The third hypothesis proposes that fluid in the form of a seroma forms around the implant, and that it subsequently leads to the development of a new inner capsule. Such an association between double capsules and late seromas has been proposed by some authors [13–15]. It has also been postulated that continued friction between the textured implant shell and the original capsule leads to a seroma-like fluid accumulation. Secondary seeding of cells derived from that fluid onto the implant surface initiates the development of the new inner layer of adherent capsule [16, 17]. The origin of the serous exudate could be infectious, allergic, or hemorrhagic [7]. Spear et al. found that 96% of their cases of late seroma formation occurred in Biocell textured implants, which further supports this association [13]. Seroma formation can be attributed to bacteria that adhere to the surface of the implant in the form of biofilm [18]. It has been shown that capsular contracture can be potentiated by subclinical infection, as first hypothesized by Burkhardt et al. [19] and later validated by the results of additional studies [20–22]. Furthermore, it was speculated that chronic bacterial activation around the implant might play a role in the development of ALCL. Hu et al. postulated that chronic biofilm infection is associated with T-cell hyperplasia in pigs and humans, and that it is possibly correlated with ALCL [18]. This is especially relevant to textured implants rather than smooth ones because the larger surface area creates an increased risk for the formation of biofilms. The presence of biofilms around breast implants in association with ALCL was reported in 26 patients in a recent multicenter collaborative investigation [23]. Current data have led to speculation that there could be a continuum between double capsules, late seromas, and BIA-ALCL.

The fourth hypothesis is also mechanically based and suggests that shear forces cause detachment of the implant capsule complex from the surrounding breast tissue, thereby leaving the original capsule intertwined with the textured implant. A new outer capsule layer then develops, thus producing the double capsule phenomenon [24–26]. This hypothesis is supported by the electron microscopic findings in double capsule samples from Biocell expanders that show a very low bacterial load and biofilm presence within the ICS in contrast to bacteria having been seen repeatedly in the prosthesis interface (i.e., between the prosthesis and the inner capsule). This finding indicates that the prosthesis

interface and the ICS were not sharing the same initial fluid, as would necessarily be the case in the other three hypotheses [27].

Double Capsule Incidence

There are sparse data in the literature on the actual incidence of a double capsule since most articles refer to it as an incidental finding in reoperations for other reasons. Most publications describe double capsules occurring in macrotextured Biocell implants and very rarely in microtextured devices or smooth implants. Two cases of double capsules were reported with the use of the Trilucent (soya bean oil-filled) breast implant [28].

Allergan's 3-year postapproval studies reported very low rates of double capsules with the Biocell implant (2/10,000). Robinson described a 2% double capsule rate in his 100 cases of primary subglandular breast augmentations with Biocell implants [26], and Maxwell et al. observed double capsule incidence of approximately 1% in over 7000 patients with Biocell implants [7]. Contrarily, Hall Findley described 14 cases of double capsules out of 105 (13.3%) in Biocell textured breast implants for primary breast augmentation or augmentation mastopexy. The double capsule cases were discovered during reoperations for other reasons (e.g., size change, implant malposition, capsular contracture, and late seroma) [16]. Van Slyke et al. reported a much higher rate (36.6%) of double capsule in their 123 cases of Biocell implant removals for various reasons during a 13-year study period and noted that double capsule was not observed with any other implant type in their practice [29]. Their cases of double capsule typically were unilateral.

Management

Since most cases of double capsule are asymptomatic and not associated with any complication, they do not require any surgical or nonsurgical intervention. In cases of symptomatic capsular contracture or late seroma, the management is according to the conventional treatment protocols that include a preoperative assessment, surgery involving the implant (removal or exchange), the implant site (neo-pocket), the capsule (capsulectomy, capsulotomy), and appropriate postoperative management [13, 17, 30, 31]. The capsule and fluid are analyzed for pathology and bacteriology. Other procedures can be combined to the surgical management and include fat grafting, addition of meshes (biologic or synthetic), and other surgical and nonsurgical procedures.

Cases of implant malposition caused by a double capsule and nonadhesion of the device to the surrounding tissue require surgical intervention for correction. Although nonadhesion can occur with macrotextured implants in the absence of double capsule formation, greater tissue adhesion reduces the likelihood of seroma. Maxwell et al. published a consensus list of recommendations for promoting tissue adhesion with Biocell macrotextured implants [6]. The surgical recommendations included formation of an inframammary fold skin incision for creating a subpectoral pocket that accommodates the implant precisely, use of an atraumatic operative technique and meticulous hemostasis, and leaving a drain to minimize fluid collection. Postoperative management emphasized immobilization of the implant and surrounding tissue for up to 3 months. These recommendations follow the concept of minimal implant movement and friction to promote tissue adhesion.

In cases of implant exchange to a new and similar macrotextured device, the implant is placed in a new pocket, leaving a drain. A subglandular implant is shifted to a subpectoral plane, and a subpectoral implant is shifted to a neo-subpectoral pocket formed between the underlying muscle and the anterior surface of the old implant capsule [32]. Another option is to exchange the implant by a microtextured or smooth surface device, thus reducing the likelihood of recurrent double capsule. In the latter option, the implant can be inserted in the previously formed pocket after excision of the old capsule. Exchanging the implant to one with a smoother textured surface reduces the amount of tissue adhesion of the device and, thus, may require device support and tissue reinforcement in the form of a mesh or acellular dermal matrix to reduce the risk of implant malposition [6, 7, 33–35].

Conclusion

A double capsule occurs primarily with macrotextured implants. It is largely asymptomatic and a finding, usually incidental, that is not necessarily associated with complications. Intervention is reserved for complications and otherwise symptomatic cases, and usually entails implant exchange and implant pocket shift.

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