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The double capsules in macro-textured breast implants

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ABSTRACT

Breast implants are amongst the most widely used types of permanent implants in modern medicine and have both aesthetic and reconstructive applications with excellent biocompatibility. The double capsule is a complication associated with textured prostheses that leads to implant displacement; however, its etiology has yet to be elucidated. In this study, 10 double capsules were sampled from breast expander implants for in-depth analysis; histologically, the inner capsular layer demonstrated highly organized collagen in sheets with delamination of fibers. At the prosthesis interface (PI) where the implant shell contacts the inner capsular layer, scanning electron microscopy (SEM) revealed a thin layer which mirrored the three-dimensional characteristics of the implant texture; the external surface of the inner capsular layer facing the intercapsular space (ICS) was flat. SEM examination of the inner capsule layer revealed both a large bacterial presence as well as biofilm deposition at the PI; a significantly lower quantity of bacteria and biofilm were found at the ICS interface. These findings suggest that the double capsule phenomenon's etiopathogenesis is of mechanical origin. Delamination of the periprosthetic capsule leads to the creation of the ICS; the maintained separation of the 2 layers subsequently alters the biostability of the macro-textured breast implant.

1. Introduction

1.1. Breast implant double capsules: definition and current controversy

An increasing number of reports have recently been published regarding double capsule formation around textured breast implants, mostly notably those with Biocell® type texturing [1]. The double capsule refers to the finding of 2 distinct capsular layers, separated by an intercapsular space (ICS), around an implant. The inner capsule is adherent to the prosthetic device at the prosthesis interface (PI) and the outer capsule to the surrounding subglandular/subcutaneous breast tissue [2]. Clinically, the respective surfaces of the inner and outer capsules that are in contact with the ICS are very smooth; variable amounts of seroma-like fluid can be found within the ICS. This double capsule phenomenon may be partial or complete. In the latter situation, double capsule formation appears around the entire prosthesis, rendering the implant particularly prone to micro-movements and dynamic malrotation due to the new, smoother interface between the inner and outer capsule layers. Consequently, the textured implant essentially acts as a smooth implant since the desired tissue in-growth into the textured surface and resultant implant stability are obviated [1,3]. Moreover, frictional forces between the 2 capsules may lead to development of synovial metaplasia, secondary infection and late seroma, thereby necessitating revision procedures [2]. The pathophysiology of double capsule formation is controversial; some authors propose a mechanical etiology while others suggest that normal periprosthetic fluid accumulation is the root cause [1,3–10].

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1.2. Biostability of breast implants

Breast implants are amongst the most widely used types of permanent implants in modern medicine and have both aesthetic and reconstructive applications. The biocompatibility of these prostheses is considered excellent and has been studied for over 50 years ever since their inception [11–13]. Still, numerous factors affect « capsule-implant » stability or biostability over time. Biostability of the expander implant device within the breast pocket helps prevent implant displacement and rotation, both of which may lead to undesirable greater expansion in the superior pole (subclavicular) or axillary regions [3,14]. For the round-shaped prosthesis, rotation in a plane parallel to the chest is only minimally discernable, but displacement over the rib cage from its intended position will result in a grossly abnormal appearance of the breast. In aesthetic and reconstructive surgery, implant stability is crucial to the overall success of the procedure; methods of monitoring implant biostability through 3D analyses have been recently proposed [15]. Currently, the most commonly utilized expander implants are anatomically shaped in the form of a teardrop in order to allow preferential expansion of the tissue in the lower pole of the breast envelope to better reestablish a natural breast shape. In such implants, malrotation and displacement leads to profound distortion of breast shape [3,16,17]. According to core studies performed by two of the principal breast implant manufacturers, asymmetry is the second leading cause of reoperation and was most commonly secondary to implant rotation or displacement. Capsular contracture was found to be the most frequent cause of reoperation [18,19].

1.3. The advent of breast implant texturation

To better stabilize the prosthesis on the thorax, manufacturers implemented implant texturation through modifications of the initially smooth silicone implant near the end of the manufacturing process. The Allergan Biocell® texturation, created by the “lost salt technique”, is achieved by applying the implant shell with pressure onto a layer of fine salt. The Mentor Siltex® surface is made via negative contact imprinting from textured foam; the Siltex® surface is considered to be a less aggressive form of texturization than its Biocell® counterpart. Adherence is achieved by periprosthetic capsular tissue ingrowth into the pores of the textured shell surface, thereby essentially anchoring the silicone implant to the surrounding breast tissue. The senior author previously described the “Velcro effect” in which the periprosthetic capsule adheres to the implant surface in such a way that forceps are required in order to peel it off intraoperatively, hence simulating the feel of separating 2 actual Velcro surfaces apart [20]. The Velcro effect is typically observed with more aggressively textured implants.

1.4. Hypotheses

Based on the current literature, we propose 4 main hypotheses for the etiopathogenesis of double capsule formation (Fig. 1). The first hypothesis is based on movement of the prosthesis inside an oversized tissue pocket; the macro- and micro-movements of the implant prevents adhesion of the textured implant surface to the surrounding tissues [4]. The second hypothesis suggests a mechanical etiology whereby shear stress applied to the prosthesis–capsule complex pries the prosthesis away from the capsule; this separation leads to the subsequent creation of a new inner layer of capsule in direct contact with the prosthesis. As proposed by Hall-Findlay, continued friction between the textured implant shell and the original capsule leads to seroma-like fluid accumulation; secondary seeding of cells derived from this fluid onto the implant surface initiates the development of this new inner layer of adherent capsule [1,5]. The basis of the third hypothesis is that a seroma of varying etiology forms around the prosthesis, which subsequently leads to the development of a new inner capsule. The origin of the serous exudate could be infectious, allergic or hemorrhagic [6]. The fourth hypothesis is also mechanically based and proposes that shear forces cause detachment of the implant–capsule complex from the surrounding breast tissue, thereby leaving the original capsule *en-bloc* with the textured implant. Subsequently, a new outer capsule layer develops to produce the double capsule phenomenon [3,7,8].

1.5. Objectives

Using scanning electron microscopy, routine microbiology and histology, double capsule ultrastructural characteristics as well as the presence of biofilm and bacteria within both the PI and ICS were assessed in order to help elucidate the specific etiopathogenesis of this phenomenon.

2. Materials and methods

2.1. Definitions

As defined by Maxwell, the inner capsule is the membrane attached to the prosthesis. This inner capsule has 2 surfaces, one being at the interface with the prosthesis, referred to as the PI; the outer surface faces the space between the two capsules, referred to as the ICS. The separate and distinct outer capsule layer is adherent to the overlying breast tissue and also has two surfaces; the inner one is in contact with the ICS and the outer one is attached to the overlying muscle or breast parenchyma (Fig. 2) [2]. When the 2 distinct capsular layers do not envelope the entire implant, it is considered to represent a partial double capsule.

2.2. Patients

Following total mastectomy in breast cancer patients, approximately 90% of implant-based reconstructions are carried out in 2 stages [21]. In the first stage, a textured expander prosthesis is placed in the mastectomy breast pocket and placed underneath the thoracic muscles for partial to total coverage (pectoralis major muscle with or without serratus anterior muscle digitations). Postoperatively, after an initial wound healing period ranging from 2 to 6 weeks, the expander prosthesis is inflated with saline at regular intervals over the course of several weeks; once the desired breast mound volume is obtained, the expander is exchanged for a permanent silicone-filled prosthesis [22].

Ten patients with double capsule identified intraoperatively during second-stage expander to definitive implant exchange surgery were prospectively included in this study. Patients gave written consent for inclusion in this study, which was approved by the institutional review board. All included patients were treated at the same university hospital center by 1 of 4 plastic surgeons specialized in breast reconstruction. Baseline demographic data was collected for all patients and medical charts were reviewed for medical history, including radiotherapy status.

2.3. First-stage surgery: expander implant insertion

Prophylactic antibiotics were administered at induction (1st generation cephalosporin for 9 patients and clindamycin for 1 patient due to penicillin allergy). Skin prepping was performed using the standard solution of chlorhexidine with alcohol. Dissection of a submuscular plane under the pectoralis major muscle for expander