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Concerns Regarding the Use of Acellular Dermal Matrix at the Time of Primary Breast Augmentation

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Recent publications promote acellular dermal matrix (ADM) insertion at the time of a primary breast augmentation to reduce the risk of capsular contracture and long-term expense in women deemed to be at a high risk of capsular contracture.[1–3] According to manufacturer core study data, capsular contracture occurs in 8% to 19% of women after primary breast augmentation.[2,4–6] Its treatment remains the most common reason for redo surgery after breast augmentation.[7] Should this product be offered to our patients?

Wagner and Mirhaidari[2] recently published their experience using Strattice Reconstructive Tissue Matrix (Allergan plc, Dublin, Ireland) along with new implants, capsulectomy, and site exchange in women with capsular contracture. These authors reported 2 recurrences in 43 women (4.7%), comparing favorably with a cohort of 24 women treated without Strattice (6 recurrences, 25%). The authors excluded 3 recurrences that occurred in their first 4 patients, in whom the Strattice was placed posteriorly in the pocket, as opposed to anteriorly. Wagner and Mirhaidari[2] also inserted this material in 4 women undergoing primary breast augmentation. The first author disclosed his conflict as a paid consultant for LifeCell (Branchburg, NJ), the manufacturer of Strattice before LifeCell was acquired by Allergan in 2017.[2]

Hester et al[4] were the first plastic surgeons to insert ADM prophylactically in primary breast augmentation patients, reporting zero capsular contractures in 49 women. These investigators cautioned that the number of patients in their retrospective study was small and the length of follow-up (mean, 11 months) was short.[4] No published, controlled study supports the use of any mesh, biologic or synthetic, in reducing capsular contracture risk in primary breast augmentation patients.

The regulatory status of ADM is often overlooked. Strattice is not approved by the US Food and Drug Administration (FDA) for breast surgery.[2,8] Similarly, SERI Surgical Scaffold (Sofregen, Inc, Medford, MA), a silk-derived fibrous netting, is not approved by the FDA for breast surgery.[9] These products are intended as a patch for soft tissue reinforcement.[8,9] Indications include abdominal wall repair and the repair of parastromal and inguinal hernias.[8,9] In fact, no mesh material, of any type, is approved for use in the breast, including reconstruction.[2]

Inserting a second avascular material adjacent to breast implants is not without risk. Complications from ADM include infections and seromas.[2,5] These complications must be weighed against any presumed benefit in lowering the risk of capsular contracture. Many surgeons insert a drain,[2,5] for periods up to a week,[2] which is not otherwise needed in a primary breast augmentation without mesh. Drains may act as a portal for infection. A surgical bra and breast band are recommended for 2 weeks, and vigorous physical activity is deferred for 4 weeks to reduce the seroma risk.[2] The additional expense is US $3200 per patient for inserting Strattice anteriorly over the lower pole of the implant.[1,2] The additional operating time is about 30 minutes.[2] A 10-cm incision is recommended to provide adequate exposure when using an inframammary approach,[2] doubling the length of the scar.

Acellular dermal matrix is a biological product derived either from humans or, in the case of Strattice, pig skin. Manufacturers caution that there is a risk of transmission of an infectious disease such as human immunodeficiency virus or hepatitis, and a theoretical risk of the Creutzfeldt-Jakob agent, despite careful donor selection and serological testing.[10,11] Although Creutzfeldt-Jakob disease has not been reported in a patient receiving cadaveric dermis, more than 130 patients have died from this incurable and horrific infection after receiving cadaveric dura mater as a patch material during brain surgery. In some cases the disease developed more than 20 years after implantation.[12] Acellular dermal matrix is aseptically processed to remove cells but preserve the extracellular dermis; these products are not sterile and cannot be sterilized before insertion.[10,11] The manufacturer tries to remove all donor hair; if any is present, it is to be removed before implantation.[10,11]

Alloderm Ready to Use products are subjected to electron beam irradiation and come with a sterility assurance level of 10^{-3}, representing a 1/1000 risk of contamination.[13,14] Another ADM product is promoted as having less residual DNA, and a sterility assurance level of 10^{-6}.[14] Sterility is usually considered an absolute. Any risk greater than zero is unlikely to be comforting to patients. Certainly, this standard would not be acceptable for an autoclave. Many women, when informed of the material's origin, would understandably decline to have foreign genetic material inserted in their bodies (especially in the climate of a pandemic linked to RNA from a coronavirus of animal origin[15]). There is

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also a moral consideration; it is not clear that the donors intended to have their remains used for cosmetic breast augmentation.

Kornstein[1] has recently stopped using Strattice and started using SERI instead, which he finds more pliable, less palpable, and more consistently integrative than Strattice or other ADMs, which begs the question as to why he still promotes ADM. Kornstein[1] believes that older women who have experienced substantial weight loss or have a history of pregnancy and breast feeding seem to be at higher risk of experiencing capsular contracture. He suggests that a deficient soft-tissue structure is a potential risk factor,[1,5] despite a lack of scientific support. Previous capsular contracture, infection, and hematoma are recognized as risk factors.[2–7] Weight loss, pregnancy, and breast-feeding are not. Women with low-quality breast structure[1] may be candidates for a mastopexy with or without implants.[16] These patients are not known to be at a higher risk of capsular contracture.[16]

Other indications are offered for ADM insertion at the time of a primary breast augmentation.[1–3] Kornstein[1] believes that women are likely to benefit from a scaffold to stabilize the implant, referencing an experience of 3 women who received prophylactic Strattice without complications.[5] In his preliminary report that received funding from LifeCell,[5] the author considers this material mandatory in women seeking very large (492 cm^3) implant sizes.[5] Prospective patients are advised that this material reduces the risk of capsular contracture[1–3] and adds support, like an internal bra,[5] despite a lack of evidence-based support for either claim.[17,18]

Patients need to know that they are involved in a study of a non–FDA-approved method.[2] Alarmingly, there is no mention of institutional review board (IRB) approval in any of the studies promoting ADM use in breast augmentation.[1–5] All human research must be approved by an IRB before study initiation, as mandated by the Department of Health and Human Services.[19] The IRB assesses the ethics of the research and its methods, and ensures that the proposed informed consent process is appropriate and complete.[20] Plastic surgeons in private practice are not exempt from this requirement and have several options available,[20] including commercial IRBs accredited by the Association for the Accreditation of Human Research Protection Programs.

In his disclosure, Kornstein[1] reports no potential conflicts of interest. However, according to the Propublica website,[21] this plastic surgeon received US $13,612 in consulting fees in 2017 from Sofregen Medical Inc. (Medford, MA) related to the SERI Surgical Scaffold product that he recently adopted as his mesh of choice and now promotes as superior to Strattice. Disclosure of financial conflicts is a requirement of all medical journals. This problem is particularly relevant to studies evaluating ADM.[22] Sponsored studies typically underreport complications.[22]

An alternative to costly open capsulectomy and insertion of ADM in women with capsular contracture is simply to perform an open capsulotomy.[6] The expense is minimal and the recovery time is a few days.[6] Capsulectomy is not mandatory.[6,23] Capsulectomy adds morbidity and is properly reserved for thickened and calcified capsules, or any capsule that may be pathologic.[23] The recurrence risk after open capsulotomy is 22.7% and even less for intact implants (13.6%).[6]

Plastic surgeons need to be sensitive to the financial impact of their recommendations. These patients are often young women who have already spent (in the case of capsular contracture) or about to spend several thousand dollars for their breast augmentation. The extra fee for ADM is likely to cause them financial hardship. Indeed, in considering the lack of scientific evidence, the unapproved regulatory status, the risk of disease transmission, the inability to predict affected patients, and the availability of safe alternatives, the case for ADM insertion at the time of breast augmentation is indefensible.

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