Revisiting an Old Place: Single-Surgeon Experience on Post-Mastectomy Subcutaneous Implant-Based Breast Reconstruction

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Abstract: Significant advances have been made to the reconstructive tools available to plastic surgeons allowing for the re-exploration of subcutaneous breast reconstruction. The purpose of the current study is to examine the safety, efficacy, and aesthetic results of subcutaneous breast reconstruction by a single-surgeon. A retrospective chart review was performed on all patients undergoing subcutaneous implant-based breast reconstruction between April 2012 and September 2014. All implants were fully wrapped in Alloderm and placed in the subcutaneous (pre-pectoral) plane. Primary outcome was a successful subcutaneous breast reconstruction. All complications were recorded. Aesthetics of the preoperative and postoperative photographs were examined. A total of 135 breasts (79 patients) were reconstructed. Direct-to-implant reconstruction was performed in 8 patients (10%). Successful breast reconstruction was achieved for 130 breasts in 76 patients (96%). Sixty-nine patients (87%) had a course free of any unexpected event or complication. There were no patients with implant extrusion or skin necrosis requiring operative intervention. When comparing pre-mastectomy breasts with post-mastectomy reconstructions, there was an improvement in the overall aesthetic outcome. Subcutaneous post-mastectomy breast reconstruction is safe and effective with comparable complication rates to standard techniques. Yet, this minimally invasive approach does not sacrifice the aesthetic results. Long-term studies will be required to prove the durability of aesthetic results overtime.

Key Words: breast reconstruction, breast implants, subcutaneous breast reconstruction

Over the past 20 years, strides have been made in developing and refining the techniques, devices, and technology available to reconstructive surgeons to reconstruct a woman’s breast. Nearly, 70% of breast reconstruction in the United States is implant-based (1,2). From 1998 to 2008 there was a 78% increase in the immediate breast reconstruction and 203% rise in implant use (3). These trends continue today as advancements in technology allow plastic surgeons to improve techniques and subsequent outcomes of prosthetic-based breast reconstruction. The constellation of refined ablative techniques, acellular dermal matrices (ADM), the latest generation of devices (tissue expanders and silicone implants), fat grafting, and tools for intraoperative perfusion assessment re-opened the door for total-ADM covered devices in the subcutaneous (pre-pectoral) plane.

A crucial change in breast reconstruction is what reconstructive surgeons are given to work with. Oncologic principles and therapies for breast cancer are fundamentally different today from its aggressive past. Extirpative surgery has evolved from a radical approach to a more conservative one where by the skin and/or nipple are spared (4,5). By maintaining the native breast envelope and infra-mammary fold, reconstruction of a natural, cosmetically appealing breast is achievable (6,7). Ongoing communication among all medical specialties involved during the planning stages allows for avoidance of potential postoperative complications and provides the best possible outcome for the patient. “A good reconstruction always begins with a good mastectomy” (8).

Innovation in tissue expander and implant device engineering and design has allowed reconstructive surgeons that ability to reconstruct an anatomically appropriate breast. The first tissue expanders used for breast reconstruction were smooth, dome-shaped devices with external filling ports (9). Currently, there
are tear drop-shaped devices with variable height and projection with a textured surface and suture tabs to precisely control the placement of the device to prevent rotation. Furthermore, the textured surfaces facilitate the engineering of a device/tissue interface to reduce the formation of capsular contracture (10,11) and allow for preservation of the breast footprint while expanding a naturally appearing breast.

Similarly, breast implants have undergone radical changes since their first introduction in the 1960s. The original implants developed by Cronin and Gerow consisted of a thick silicone shell with a less viscous silicone filling. Unfortunately, in the 1970s, the early generation implants had high failure rates with rupture, capsular contracture, and subsequent deformities which ultimately led to the temporary Federal Drug Administration’s moratorium on silicone gel implants for breast augmentation (12). Finally, in 2006, after multiple studies reported safety of the device, the FDA reversed this ban. Subsequent generations of breast implants have focused on the creation of a higher fidelity shell to prevent silicone bleed, textured surfaces to prevent implant rotation and capsular contracture, cohesive silicone gels for a more natural feel, and anatomically shaped implants for a more natural appearance. Today’s silicone implants, although made of similar material, are fundamentally different from that of early generations (13). The highly cohesive form stable silicone has decreased the incidence of rippling deformity, which in the past had to be concealed with subpectoral placement of implants.

While ADMs have revolutionized the ability to control the breast pocket and maintain a natural breast footprint at the first stage, fat grafting has revolutionized the ability to camouflage the implant. In the past, a consistent problem restricting the aesthetic outcome for prosthetic-based breast reconstruction was implant visibility and mastectomy flap irregularities leading to contour deformities. Placement of a round implant beneath a thin skin envelope consistently generated an unnatural, cone-shaped mound with obvious stepoff between the rippled implant and chest wall with fundamental lack of a naturally shaped aesthetic appearing breast. The solution to this problem is twofold: anatomically shaped breast implants and fat grafting.

Transplantation of fat from remote areas to the breast and chest wall was first reported by Viktor Czerny in 1895 when he transplanted a lipoma to a breast after a partial mastectomy (14). It was not until the 1980s with the advent of liposuction that fat grafting gained popularity as surgeons were now able to take a small aliquot of fat and inject it to fill contour deformities (15). Fat grafting techniques have undergone its share of extensive scrutiny over the years. Its safety and efficacy in breast reconstruction has been widely reported (16). Extensive research has been carried out to support the viability of fat grafting, allowing it to be part of the algorithm in a successful breast reconstruction (17). Fat grafting in the subcutaneous plane between the dermis and underlying ADM capsule improves on breast flap thickness and thus allowing for better contour of the reconstructed breast (18).

Lastly, tools for intraoperative perfusion assessment namely, laser-assisted indocyanine green angiography (LA-ICGA), have transformed our ability to quantitatively access the impact the resection and reconstruction has on perfusion of the mastectomy flaps. The nature of a mastectomy is inherently an ischemic process relative to the skin envelope. The process of removing the glandular tissue eliminates the perfusion traversing through the underlying breast and potentially from the other sources, particularly when the boundaries of the natural breast are violated. Skin necrosis, which was reported to occur in up to 25% of reconstructions, was a plaguing complication early in the evolution of breast reconstruction, particularly in the immediate setting (19). Assessment of skin flap perfusion with intraoperative LA-ICGA allows for real-time visualization of skin perfusion, providing the surgeon with an objective marker to facilitate surgical decision-making. The Mayo Clinic adopted the technology in 2011 since has dropped the rate of skin necrosis in immediate breast reconstruction by 83% (20). LA-ICGA allows the surgeon to tailor fill volume of the tissue expander or potentially full volume reconstruction in a single stage without compromising perfusion of the mastectomy flap (20). Ultimately, successful reconstruction relies on a well-perfused wound bed with good vascularity of breast flaps which is highly reliant on collaborative efforts between the oncologic resection and reconstructive teams.

Subcutaneous (pre-pectoral) placement of the prosthetic device has become an attainable and advantageous technique for breast reconstruction through the combination of refined ablative techniques, ADM, the latest generation of devices (tissue expanders and silicone implants), fat grafting, and tools for intraoperative perfusion assessment. The purpose of this study is to examine the safety, efficacy, and aesthetic results of subcutaneous breast reconstruction by a single-surgeon.
METHODS

An approval from Internal Review Board at our institution was obtained prior to beginning the data collection. A retrospective chart review was performed on all patients with a subcutaneous breast reconstruction from April 2012 to September 2014 by senior author (S.R.J.). All patients were reconstructed immediately following skin- or nipple-sparing mastectomies by one of three breast surgeons. Patients receiving pre-mastectomy or post-mastectomy radiation were excluded because of the increased complexity radiation therapy has on implant-based reconstruction.

Primary outcome was a successful implant-based breast reconstruction in the subcutaneous plane. Secondary outcomes included: hematoma, infection, seroma, dehiscence, skin necrosis, implant extrusion, explantation of device, and flap salvage. Patient demographics including age, BMI and comorbidities (diabetes mellitus and hypertension) were recorded.

The second aim of the study was to evaluate the aesthetics of subcutaneous reconstruction. Preoperative and postoperative photographs of all 79 patients were compared. Subjective aesthetic assessment of breast reconstruction was performed by having 7 reviewers (senior plastic surgery residents) evaluate the reconstructed results in a blinded fashion with a 4-point subjective scale (1 – poor, 2 – fair, 3 – good, 4 – excellent). Each breast was scored individually in the pre-mastectomy and post-reconstruction phase and the overall reconstruction was scored.

Surgical Procedure

Once the mastectomy specimen is sent for pathology evaluation, reconstruction is initiated with clinical evaluation of the flaps. Intraoperative perfusion assessment with LA-ICGA, SPYElite (Novadaq, Bonita Springs, FL, USA) was used to confirm and document perfusion of the mastectomy flaps.

The type of mastectomy performed (nipple-sparing versus skin-sparing) was based first on oncologic principles and secondly on patient desires. Likewise, the decision to perform a one- or two-stage reconstruction was based not only on patient goals but also on mastectomy flap quality and perfusion. During the study period, all patients who desired implant-based reconstruction were reconstructed in an immediate fashion, i.e., no patients were deferred for reconstruction based on intraoperative findings. A 2-stage reconstruction is preferred by our senior author as the tissue expander allows for preservation of the natural breast footprint (width, projection, and height) and secondly allows for expansion of the skin envelope to desired volume if needed. Furthermore, a tissue expander can first be filled with air as to not stress the (already relatively ischemic) mastectomy flaps with the weight of saline or silicone. Choosing the correct device remains the key to an excellent result. The choice of tissue expander or implant is based on (in order of importance): base width, projection, height, and lastly volume. The goal is to create a “hand-in-glove fit” for the device and mastectomy flaps as to engineer the desired breast shape and fully occupy the overlying skin envelope. Single stage reconstructions, therefore, were reserved for patients who had a fixed patient preference to only undergo a single stage reconstruction.

The device is wrapped with a thick piece of 16 cm x 20 cm RTU Alloderm (LifeCell, Bridgewater, NJ, USA) after it has been fenestrated throughout. If the chosen device is an expander then it is inflated with air until it is full, but not taut. Air is preferred over saline to prevent the weight of saline from impairing mastectomy flap perfusion and thus decreases the risk of wound healing complications. The ADM is then wrapped around the device and held together using absorbable 2–0 vicryl sutures. Excess ADM is trimmed to avoid overlapping layers of ADM. The tabs of the tissue expanders are delivered through a fenestration of the ADM. In direct-to-implant reconstructions, the implant is wrapped similarly with ADM. Excess ADM standing cones are left in situ to act as anchoring tabs. Direct-to-implant reconstructions are only performed in select patients with exceptional mastectomy flap perfusion as the weight of the implant can impair perfusion and increase risk of wound healing complications. In cases where larger than 14 cm base width tissue expander or implant are used, circumferential coverage is not possible with the 16 cm x 20 cm Alloderm sheet, the ADM is preferentially wrapped inferiorly.

The breast pocket is irrigated first with pulse lavage then with antibiotic solution. Two 15 French channel drains are placed exiting laterally in the breast pocket. The ADM-wrapped device is placed onto the pectoralis muscle. The tabs are then sutured in place with 2–0 PDS sutures. The mastectomy flaps are draped over the devices. The expanders are deflated to a point where the mastectomy flaps are allowed to come
together without tension. All incisions are then closed using a single layer absorbable 3-0 monocryl with meticulous dermal alignment. After closure of the skin, LA-ICGA is again performed to ensure continued adequate perfusion of mastectomy flaps after placement of device. The incision is then reinforced using Dermabond Prineo tape (Ethicon, Inc., Raleigh, NC, USA). A Tegaderm (3M, St. Paul, MN, USA) “bra” is constructed by placing Tegaderm circumferentially on and around each reconstructed breast. Reston foam (3M) is placed for lateral support and compression. The skin surrounding the drain exit site is dressed with BioPatch (Ethicon, Inc.) and Tegaderm.

Patients are routinely kept in hospital overnight. They return to clinic at 2 weeks post-mastectomy to exchange air for saline and subsequently begin the process of expansion. The Tegaderm and Reston bolster dressing is removed at this visit to allow the skin to stretch with expansion. Drains are routinely removed by this time. The Prineo tape is allowed to fall off when the underlying wound is healed. After exchange for saline, patients wear a supportive bra continuously for the first 4 weeks 24 hours/day. Rapid expansion is performed on a weekly basis, with most requiring 1–3 expansions. Final implant exchange to highly cohesive anatomically shaped silicone implants is performed at approximately 3 months in conjunction with fat grafting to correct any contour deformity and provide a smooth transition from implant to chest wall.

RESULTS

A total of 135 subcutaneous breast reconstructions in 79 patients were performed between April 2012 and September 2014. Unilateral reconstructions were performed for 23 patients and 56 patients underwent bilateral reconstructions. Baseline patient demographics are listed in Table 1. The average age was 50.2 years (range of 26–76 years). Two patients had diabetes and 19 patients had hypertension. The mean body mass index (BMI) was 26.9 (range 17.9–44.6). All patients were nonsmokers as the senior surgeon does not perform implant-based reconstruction in patients who smoke. The mean follow-up was 10 months (range 2 months–3 years).

Of the 79 patients, 8 patients (10%) received direct-to-implant reconstruction. Four patients (5%) received planned autologous reconstruction after tissue expander placement and 67 (85%) patients received subcutaneous tissue expanders for planned 2-staged implant-based reconstruction.

Successful subcutaneous breast reconstruction was achieved in 76 patients (96%). Seventy-two patients (91%) completed implant-based reconstruction and 4 patients (5%) completed planned autologous reconstruction after first placement of a subcutaneous tissue expander placement. Sixty-nine patients (87%) had no complications and underwent a seamless reconstructive process. Three patients developed infection with subsequent explantation. One case was bilateral infection requiring explantation of both tissue expanders. Two of the three subsequently underwent final implant exchange. One patient was lost to follow-up after placement of tissue expander with no known complication arising. One patient is currently undergoing expansion. One patient deceased secondary to unrelated cause. See Fig. 1 for details of adverse events in this group.

Aesthetic evaluation of subcutaneous breast reconstruction revealed an overall postoperative aesthetic score of 2.95 (out of a maximum of 4) (Table 2). Comparing preoperative to postoperative photographs 95% of patients has similar or improved aesthetic outcome. 5% had a poorer aesthetic outcome post-reconstruction. Aesthetic ratings of the breasts are given in Table 3.

DISCUSSION

The first documented implant-based breast reconstruction was published in 1962 by Bromley Freeman (21). As plastic surgeons were frustrated with high rates of complications since that time, refinements in techniques were sought and the transition from subcutaneous to submuscular plane was pioneered (22,23). Subsequently, total muscle coverage became the mainstream. Today, reconstructive surgeons have a whole new armamentarium including: new generation tissue expanders and breast implants, acellular dermal

| Table 1. Patient Demographics |
|-------------------------------|
| Total patients | 79 |
| Total breasts reconstructed | 135 |
| 23 Unilateral |
| 56 Bilateral |
| Age Range | 26–76 |
| Mean 50.2 |
| BMI Range | 17.9–44.6 |
| Mean 26.9 |
| Diabetes | 2 |
| Hypertension | 19 |
matrices, intraoperative perfusion analysis, and fat grafting allowing for re-exploration of subcutaneous breast reconstruction.

This is the largest series to date demonstrating the efficacy and safety of subcutaneous breast reconstruction. In this cohort, 129 breasts (95.5%) were successfully reconstructed in the subcutaneous plane with 82% of patients completing reconstruction without experiencing any complications. The most common complication experienced included: hematoma (2%), infection (2%), seroma (1%) and wound dehiscence (1%). Since the adoption of this technique, there has been no cases implant extrusions or malposition. This compares favorably to other large series of prosthetic-based breast reconstructions. A retrospective review of all tissue expander/implant reconstructions performed at Memorial Sloan-Kettering Cancer Center over a 2-year period included 1170 breast

Table 2. Adverse Events

| Complications (per breast) | n (%) |
|----------------------------|-------|
| Hematoma                   | 3 (2) |
| Seroma                     | 2 (1) |
| Infection                  | 3 (2) |
| Wound dehiscence           | 2 (1) |
| Skin necrosis              | 0     |
| Implant extrusion          | 0     |
| Flap salvage               | 0     |
| No complication            | 122 (90) |

*1 = poor, 2 = fair, 3 = good, 4 = excellent.

Table 3. Aesthetic Ratings

|                          |       |
|--------------------------|-------|
| Overall postoperative aesthetic score* | 2.95  |
| Mean preoperative aesthetic score*    | 2.25  |
| Better aesthetic outcome          | 74%   |
| Same aesthetic outcome           | 21%   |
| Worse aesthetic outcome          | 5%    |

*1 = poor, 2 = fair, 3 = good, 4 = excellent.
reconstructions in 884 patients revealed 15% of patients experienced one or more perioperative complications (24). Complications included: mastectomy flap necrosis in 8.7%, seroma/hematoma in 3.2%, and infection requiring implant removal in 1.5% of reconstructions. With the constellation of ADM in combination with the latest generation of devices (tissue expanders and silicone implants), fat grafting and tools for intraoperative perfusion assessment, the current study has demonstrated complication rates of subcutaneous breast reconstruction to be similar to previously published series of prosthetic-based breast reconstruction.

Historically, the combination of aggressive mastectomies, limited and unreliable options for tissue expanders and breast implants forced reconstructive surgeons to modify their techniques which ultimately led to the placement of the device in the submuscular plane. The use of a submuscular pocket, however, comes with a price. Because of the forces of the overlying muscle there is failure to develop lower pole fullness and loss of a naturally ptotic appearing breast. With the use of skin-sparing techniques, there can be disunion between overlying mastectomy flap skin and underlying device; the mastectomy flap contracts and scars down while the muscular pocket is slowly expanded. Furthermore, difficulty with infra-mammary fold definition, high riding expanders, and lateral deviation of the breast implant are common when placed submuscularly. These drawbacks of total submuscular coverage led to the use of ADM in breast reconstruction. Breuing and Warren were the first to report use of ADM as an inferolateral sling resulting in a partial subpectoral, partial sub-ADM pocket resulting in precise control of the lower pole and lateral mammary fold as well as reduced time to full expansion (25).

Acellular dermal matrices have since revolutionized prosthetic breast reconstruction. Acting as internal support for the device, they provide long-term precise control of the infra-mammary and lateral mammary folds, prevent retraction of the pectoralis muscle, shorter expansion times, reduce implant visibility and rippling, and have protective effects against radiation changes and capsular contracture (26–30). Fortunately, the advances ADMs provide have been associated with minimal additional risks (31). Acellular dermal matrices have disrupted the dogma of total muscular coverage with the current technique of partial subpectoral, partial-ADM coverage being routinely used. Patients, however, still routinely experience muscle spasm during the expansion process because of the muscle stretching and animation deformity will still ultimately be the resulting effect on the

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**Figure 2.** Subcutaneous implant reconstruction. 48-year old woman with right breast cancer underwent bilateral nipple-sparing mastectomy with immediate implant-based breast reconstruction in the subcutaneous plane. Oblique photographs show the stability of reconstruction overtime. Note no descent of the implant over a 28-month period.
reconstructed breast given the partial pectoral coverage (32).

The primary benefit derived by placing a fully ADM-wrapped prosthetic device over the pectoralis muscle is the precise control and definition of the breast pocket. The fully wrapped ADM takes the ideal shape of a natural appearing breast, i.e., takes on the shape of the anatomically designed tissue expander. Such that when the second stage reconstruction takes place, the expander is replaced for the implant with minimal to no pocket manipulations required for a hand-in-glove fit. The prefabricated breast pocket then dictates implant selection at the second stage. The implant chosen is based on base width of the original tissue expander such that is never smaller than the original tissue expander's base width thereby eliminating risk of device rotation. Furthermore, operative time is shortened through both pre-construction of the ADM-wrapped devices while the breast surgeon is performing the mastectomy and second less dissection as there is no need for elevation of the pectoralis muscle. This also does not violate tissue planes that otherwise would not have been potentially exposed to the tumor. Lastly, there is no animation deformity present.

Figure 3. Single stage, direct-to-implant reconstruction. (a) Pre-mastectomy. (b) 5 months postoperative single stage, direct-to-implant reconstruction through a wise-pattern reduction approach.

Figure 4. Unilateral implant reconstruction. (a) Pre-mastectomy. (b) 10 months postoperative unilateral implant reconstruction.
and theoretically less pain without manipulation of the chest muscles.

The current study is not without its limitations; most notably there is a lack of long-term follow-up, simply because of the recent adoption of the technique. The first patient reconstructed in the subcutaneous plane was in 2012. Pictures in Fig. 2 show no descent or malpositioning of the implant over time (at 28 months follow-up). Additional consideration has to be taken regarding financial impact of using a larger sheet of ADM to fully line the breast pocket. Inarguably, a larger sheet of ADM has higher costs. However, the costs may be potentially offset by the shorter operative times during both the first and second stage procedures; this is a topic of current investigation (Fig. 3–5).

CONCLUSION

Breast reconstruction over the past decade has been completely revolutionized by the technical advances in oncologic management of breast cancer, development of anatomically shaped prosthetic devices, application of bioprosthetic materials, intraoperative perfusion technology, and autologous fat grafting. Subcutaneous breast reconstruction is safe and effective with comparable complication rates to standard techniques. The early aesthetic evaluation show excellent promise in results. Long-term studies are needed to evaluate maintenance of early excellent shape of the reconstructed breast over time.

DISCLOSURE

Senior surgeon serves as a consultant to Acelity and Novadaq. No funding was received for this study. The other two authors have no financial disclosures.

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