June 2019 | Issue 15

INCISIONS & INSIGHTS

Look Ma, No Hands! Immediate Breast Reconstruction with No-touch Technique

Henry B. Wilson, MD, FACS
Chair, CMG Board of Directors, Centra Medical Group
Plastic surgeon with CMG Plastic Surgery Center
Clinical Assisstant Professor of Plastic Surgery, Liberty University College of Medicine
Lynchburg, VA

Most breast reconstructions (82%) performed in the United States are prosthetic-based[1], with the vast majority of these utilizing tissue expanders as the initial stage. While many patients arrive in our office focusing on cosmesis and assuming that their reconstruction will be successful, we as surgeons know the reality of the complications that can occur from the procedure. By far the most devastating of these is infection, since it frequently leads to reconstructive failure. Infection rates vary widely (1-35%)[2] in the literature, with recent meta-analyses report average infection rates of around 5%[3,4]. Even 5% seems startlingly high, especially with so many patients opting for bilateral reconstruction, effectively doubling the risk for that patient.

As a result of exposure to these infection rates in the literature, breast reconstruction surgeons have arguably become complacent, accepting an infection rate of 5-10% or higher for immediate breast reconstruction. When compared to the infection rates of other specialties with complex implanted devices, however, we notice that somehow, other surgeons have found ways to place their devices with infection rates of below 1%. Prosthetic joint replacement and penile implant placement are two common implant techniques performed in other specialties with documented infection rates under 1%.[5,6]

Why is the infection rate so high for plastic surgeons performing this procedure? The answer to this is multifactorial. We begin with a patient population that often has baseline comorbidities of obesity, nicotine use, and diabetes, all of which have been proven to increase infection risk.[7] These patients may also have additional risk factors related to their cancer treatment (chemotherapy and radiation treatment history). Next, the reconstruction procedure is performed immediately following another surgeon removing the breast. In these extirpation procedures, the usual emphasis is not on minimizing contamination. There can be breast skin flaps which may be hypoxic as a result of a thin dissection plane, and the breast gland itself may harbor bacteria.[8] Finally, we are implanting foreign body (an implant or expander) that is frequently surrounded by another implant (the acellular dermis), either of which could become contaminated. Even a small amount of bacterial contamination located on an implanted artificial surface can become a clinically-significant infection.[9]

The author's infection rate was 12% several years ago when we began searching for ways to improve this. We were already using many "best practice" techniques, such as preoperative chlorhexidine scrubs for the patients, chlorhexidine alcohol skin preparation, recommended antibiotic coverage from preop through postoperative period, double-gloving, frequent glove changes, minimal implant handling, tunneling drains, and chlorhexidine discs at drain exit sites. None of these measures made a substantial difference and we still had unacceptable, in our mind, rates of both superficial cellulitis and reconstructive failure.

Other surgical specialties, most notably urology and orthopedic specialties, both successfully place complex surgical prostheses—often in high-risk patients--at infection rates less than 1%. In fact, it was an orthopedic technique that first pioneered the use of "no-touch" surgical technique in the 1890s, when William Lane published his technique for treating fractures.[10] He utilized meticulous coverage of the skin and skin edges with cloth towels coupled with long instruments to separate the surgeon's hands from the tissue being manipulated. In the plastic surgical literature, Mladick reported a "No-touch" technique for cosmetic breast augmentation in 1993, reporting 0% device infections in 2863 cases using mechanical barriers to protect the implant from skin contact.[11]

In immediate breast reconstruction using tissue expanders or permanent implants, the surgical field is less controlled and more contaminated than either cosmetic breast augmentation or urologic and orthopedic prosthesis placement. Our surgical field is open for 1-3 hours before we even begin our procedure. Operative time depends on the ablative surgeon's speed, whether it is a unilateral or bilateral mastectomy, and other factors such as sparing the nipple or difficulty locating lymph nodes. Surgical team breaks, or team swaps are frequent when the reconstruction commences, with the attendant room air changes from staff opening and closing the OR doors. Finally, the nipple and areola are notorious harbors of bacteria which may defy normal surgical prep.[12] Because of these challenges, we feel that expander or implant-based immediate breast reconstruction is an appropriate application for the principles of "no-touch" technique.

Process

All patients undergo chlorhexidine skin prep and receive preoperative antibiotics (cephalosporin, clindamycin or vancomycin depending on allergies) and postoperative IV antibiotics for 24-48 hours depending on whether hospital stay is one or two days. Intraoperative antibiotic irrigation consists or rifampin, trimethoprim-sulfamethoxazole and gentamicin. The rifampin imparts an orange tint which can be seen in photographs (a general surgeon colleague began calling it "jungle juice" since it looks like a tropical cocktail; the name stuck).

After the oncologic surgeon completes the mastectomy, the skin flaps are evaluated clinically and with icG angiography if necessary (Figures 1,2). Initial surgical steps, such as excision of skin edges or reconstituting the inframammary fold, is performed with the breast surgeon's instruments and cautery. This is done to avoid skin contact with the plastic surgical set prior to the new surgical prep. We currently perform immediate reconstruction using prepectoral technique, so the initial steps are to measure and mark the chest wall for an appropriately-sized tissue expander or implant and the acellular dermis. Long-acting local anesthetic blocks with EXPAREL® are also performed at this stage. For tissue expanders, we use MENTOR® ARTOURA® Breast Tissue Expanders for the natural shape they create, especially for nipple-sparing cases. For direct to implant, we most commonly use MENTOR® MemoryGel® Xtra Breast Implants for their soft feel and apparent resistance to rippling.

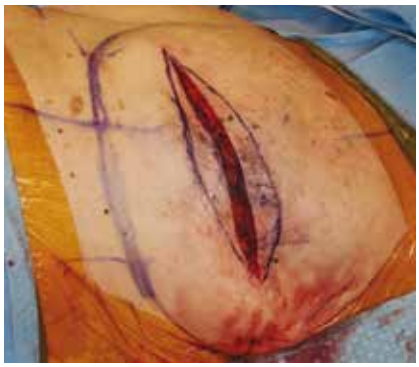


Figure 1: Left mastectomy defect after IcG angiography with marginal skin flaps marked for excision (with oncologic surgeon's instruments).

Figure 2: Skin edges excised and any preliminary dissection steps (including EXPAREL®) completed. Antibiotic sponge is in place and skin is re-prepped with Chloraprep®.

After antibiotic irrigation of each surgical site and placement of an antibiotic-soaked sponge, we perform a repeat chlorhexidine skin prep. The surgical team dons fresh gowns and gloves. A transparent barrier drape (3M) is used to completely cover the exposed skin of the patient, shielding surgical instruments and physician hands from contamination. This is secured to the periphery of the surgical field and to the cut skin edges with surgical staples (Figures 3).

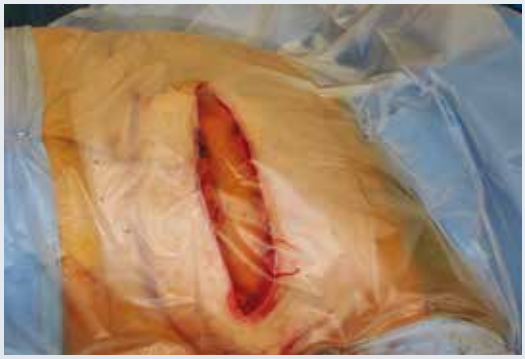


Figure 3: After three minutes for Chloraprep® to dry, transparent drape is placed over the entire previous surgical field and stapled to the periphery to previous drapes. Note that preoperative markings are clearly visible through the drape, which is placed loosely over the skin.

Next, a universal drape is placed over the periphery of the surgical field—both the outer portion of the transparent barrier drape and the drapes previously applied by the oncologic surgeon (Figure 4).

Figure 4: A universal drape is placed and a skin stapler used to secure transparent barrier drape to skin edges.

We use a sterile, previously unused, plastic surgical instrument set including new electrocautery and light handles (Figure 5).

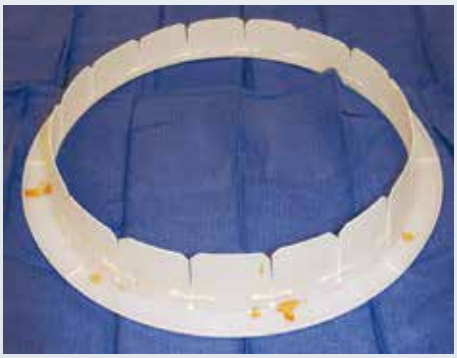
To perform the reconstruction, a slit in the transparent drape is made (Figure 6).

Figure 5: All previously-unused sterile instrumentation used and disposable products like these refreshed with new. All staff renews gowns and gloves.

Figure 6: A slit is made in the drape, leaving enough of the material to wrap around the skin edges, and the self-retaining retractor system is deployed.

A self-retaining retractor system is placed to provide exposure (Figure 7-11) prior to placing the tissue expander, ADM, and drain. This facilitates exposure while at the same time minimizing the need for the assistant to constantly bring retractors into and out of the wound (minimizing new potential sources of contamination). Once the surgical team is familiar with the technique it takes about five minutes to complete this process.

Although "ring and hook" disposable retractor systems exist on the market developed for other surgical applications, their small ring diameter works only for nipple-sparing mastectomy (Figure 11). For standard skin-sparing mastectomies, we have adapted the inverted rim of a disposable surgical water basin as shown in Figures 7-11.



Figures 7, 8: Making the ring retractor out of inverted disposable wash basin

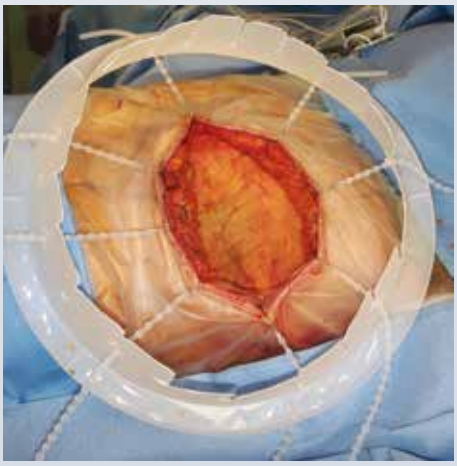


Figure 9, 10: Deploying the self-retaining retractor system.

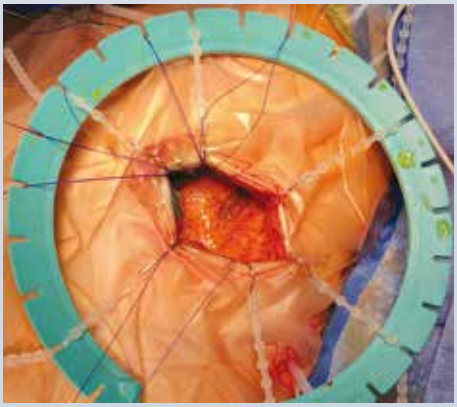


Figure 11: Existing commercial ring retractor suitable for nipple-sparing mastectomies with smaller incision.

We are working with industry to see if this design with associated accessories and drape can be duplicated commercially allowing the breast reconstruction surgeon to access all "no-touch" accessories in one kit. At present, we secure small diameter rings as well as the disposable hooks and rakes commercially (Applied Medical Technology, Brecksville, Ohio). These are large diameter and blunt-tipped (Figure 12) so as not to pierce the drape or implants.

Our current technique utilizes device placement in the pre-pectoral position with either an anterior wrap (Figure 13-18) or subtotal wrap (Figure 19-24) technique, depending on the availability of grafts which are currently in short supply in preferred larger sizes.

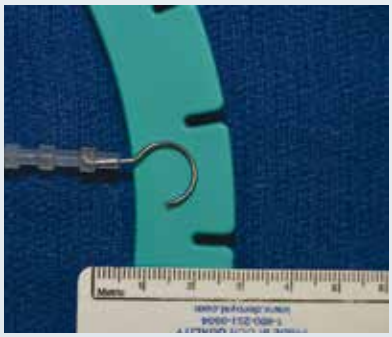


Figure 12: Close-up of hook showing ~1 cm diameter (ideal for wrapping cut edge of transparent drape around the skin edge) and blunt tip that will not pierce implants.

Figure 13: Internal brassiere ADM with UHP MENTOR® ARTOURA® Breast Tissue Expander on back table prior to implantation.

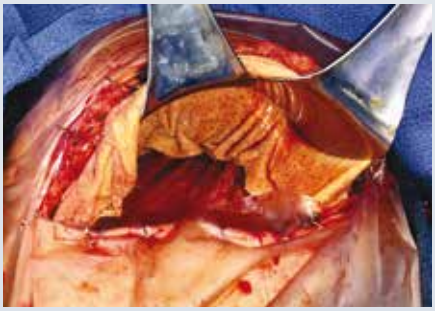


Figure 14: Superior pole inset prior to expander placement. The "pleats" along the line of inset are normal for this prepectoral partial coverage technique.

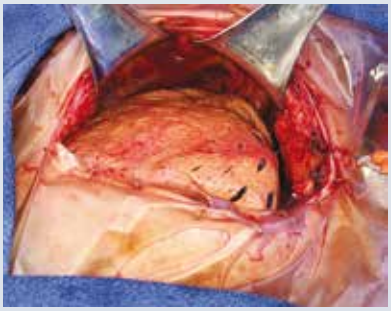


Figure 15: Prepectoral reconstruction with UHP MENTOR® ARTOURA® Breast Tissue Expander after complete graft inset.

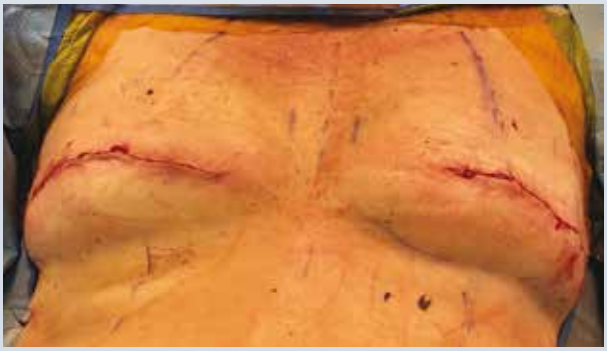
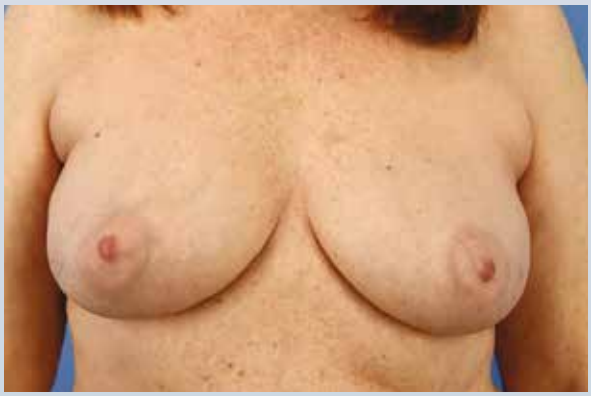


Figure 16: Immediate postoperative result with 300 cc in a 455 cc UHP MENTOR® ARTOURA® Breast Tissue Expander.



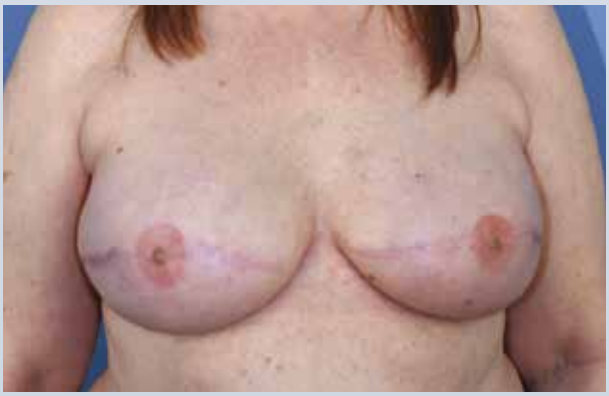


Figure 17, 18: Prepectoral reconstruction with partial anterior wrap. Final result utilizes High Profile MENTOR® MemoryGel® Breast Implants, 550 cc.

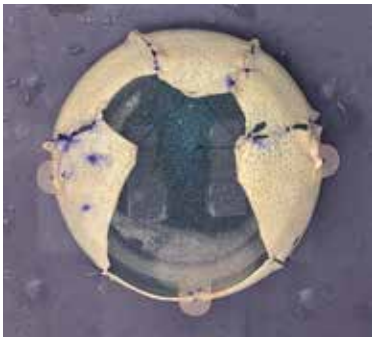
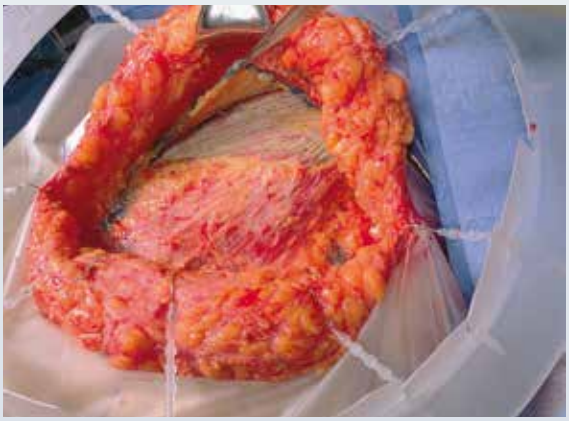
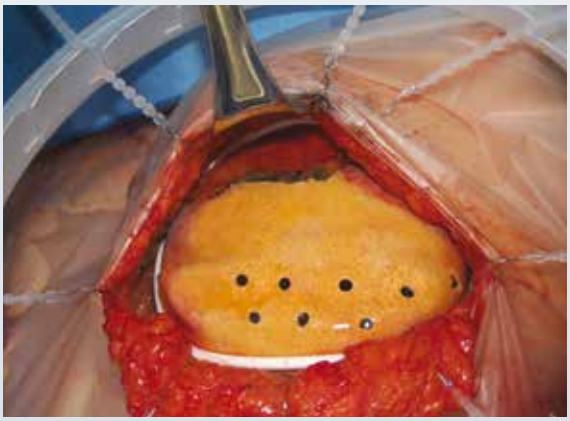
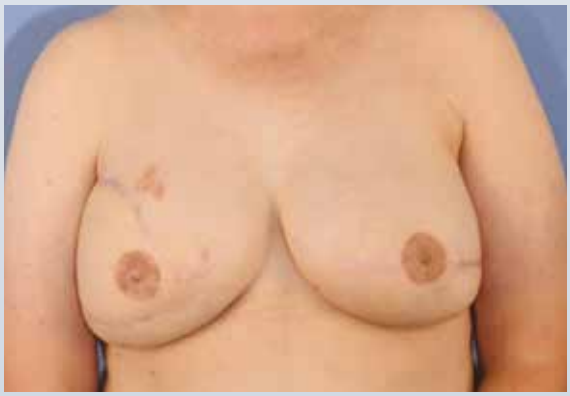


Figure 19-20: Subtotal wrap technique with 375cc HP MENTOR® ARTOURA® Breast Tissue Expander filled here to 250 cc.

With either technique, if prepectoral fascia is available, we often dissect it free to be inset onto the ADM anteriorly, which helps to minimize the superior pole contour deformity of prepectoral placement (Figures 21-24). Rectangular 16 x 20 cm sizes work well for wraps up to 500 cc (Figures 19-20), while oval-shaped larger grafts work well for any volume as an anterior wrap (Figures 13-16) and may also be adapted to subtotal wrap applications if desired (Figures 26-30). There does not seem to be clear superiority of either technique in terms of cosmetic or complication outcomes, but a subtotal wrap technique facilitates back-table prep during the oncologist's extirpation procedure, potentially saving the patient total anesthesia time. With an oncologic surgeon known for healthy mastectomy flaps, we can complete two subtotal wraps (Figure 25) on the back table in about 30-40 minutes, leaving less than an hour additional operative time after mastectomy completion.





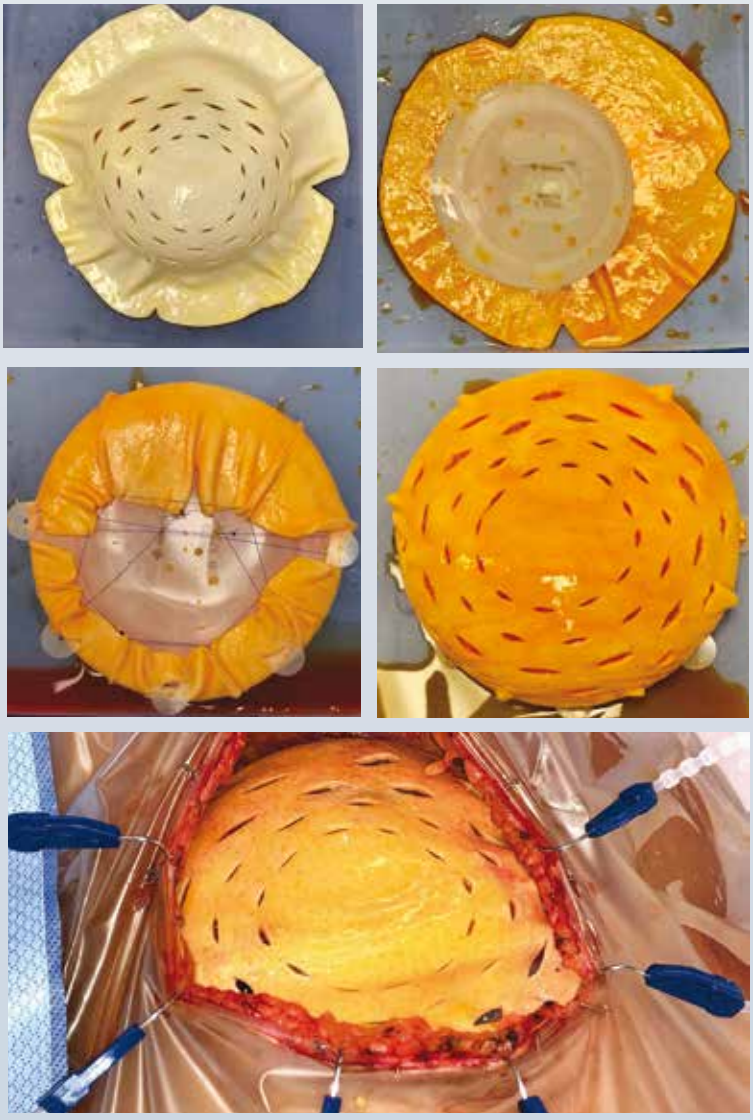


Figures 21-24: Prepectoral reconstruction with subtotal wrap technique demonstrating pectoralis fascia dissection. This fascial flap has been inset to the anterior aspect of the reconstruction to minimize superior pole contour deformity. 375 cc MENTOR® ARTOURA® Breast Tissue Expander and subtotal ADM wrap is pictured on the left reconstruction. Right breast was reconstructed with latissimus flap and 375 cc ARTOURA Expander. Final result utilizes Moderate Plus profile MENTOR® MemoryGel® Breast Implants, 375 cc right and 575 cc left.

Figures 25: Two subtotal wrap constructs ready for implantation await completion of the second mastectomy by the surgical oncologist.

Figure 26-30

Subtotal wrap technique with oval-shaped 19 x 22 cm ADM and 375cc HP MENTOR® ARTOURA® Smooth Breast Tissue Expander filled here to 375 cc (during wrap) and 150 cc (upon implantation).



Results

Comparing well-matched patient cohorts operated before and after the institution of this technique, our rate of infection dropped dramatically with this enhancement.[13, 14] Postoperative cellulitis responsive to antibiotics dropped from 15% to 5.8%, and the rate of reconstructive failure due to infection dropped from 11.5% to 1.8%--a factor of six. No other technique or process change has made such a dramatic difference in infection rates in our practice, and this occurred despite ever-increasing sizes of ADM. The above statistics pre-date the use of prepectoral technique with even larger pieces of ADM, but preliminary evidence suggests a similarly low rate of complications after the change to pre-pectoral device placement. We have not had to remove an infected device in over two years on more than 70 pre-pectoral reconstructions. Two sample cases are shown in figures 31 to 42.

Rationale of the No-touch technique

Prosthetic breast reconstruction is a complex, multi-step endeavor with several factors that can lead to increased incidence of infection. Early infections of all medical devices implanted in humans result from exogenous bacterial seeding at the time of device placement, and several factors can increase the amount of that seeding.[15,16] Adams distilled best practice protocols into a Surgical 14-point Plan that is designed to reduce bacterial load/contamination at the time of surgery.[17] We followed all of these steps and focused our efforts on two aspects: use of a barrier drape and steps to minimize handling of the tissue during placement of the implant and graft.

If the "no-touch" technique is not employed following extirpation of the diseased breast, there are vast expanses of the patient's chest wall exposed. Despite meticulous antiseptic preparation of the skin, bacteria are present on these wide expanses of skin. Therefore, it makes sense to minimize contact with the patient's skin for instruments, surgeon gloves, breast expander and adjunctive graft. The "no-touch" discipline takes the open incision created by the ablative surgeon and makes that the only area of the patient possible for the surgeon, his instruments, his assistants or the prosthetics to touch. The rest of the patient's skin surface is shielded from causing bacterial contamination of instruments, gloves or grafts.

After the plastic surgeon takes over the operating theatre from the breast surgeon and completes preliminary surgical site dissection if necessary, the first portion of the "no-touch" enhancement is to irrigate the field with antibiotics, reprep the skin, and drape with fresh sterile drapes. We call doing all of the things related to reprep and drape "resetting the surgical field", since we are assuming contamination is present from the previous breast removal and are attempting to bring the field back to a sterile baseline. Incorporation of the clear plastic coverings of the skin (Figures 3-6) into the re-drape using and the self-retaining retractor (Figures 7-12) insures that the reset surgical field undergoes minimal subsequent inoculation of bacteria.

The transparent drape creates a sterile barrier between the skin and the implant/graft. If most bacterial contamination during surgery is exogenous and comes from airborne particles,[15] this will protect against those particles that have settled onto the skin during the mastectomy portion. We could depend on the second chlorhexidine for this exclusively, but the freshly opened transparent drape seems more secure because it is a known sterile entity and provides a mechanical barrier. The self-retaining retractor system minimizes the need for separate hand-held retractors going into and out of the wound, potentially introducing bacteria from the retractor or something that it touches. For much of the procedure, the assistant's role is to cut suture, not manipulate the wound.

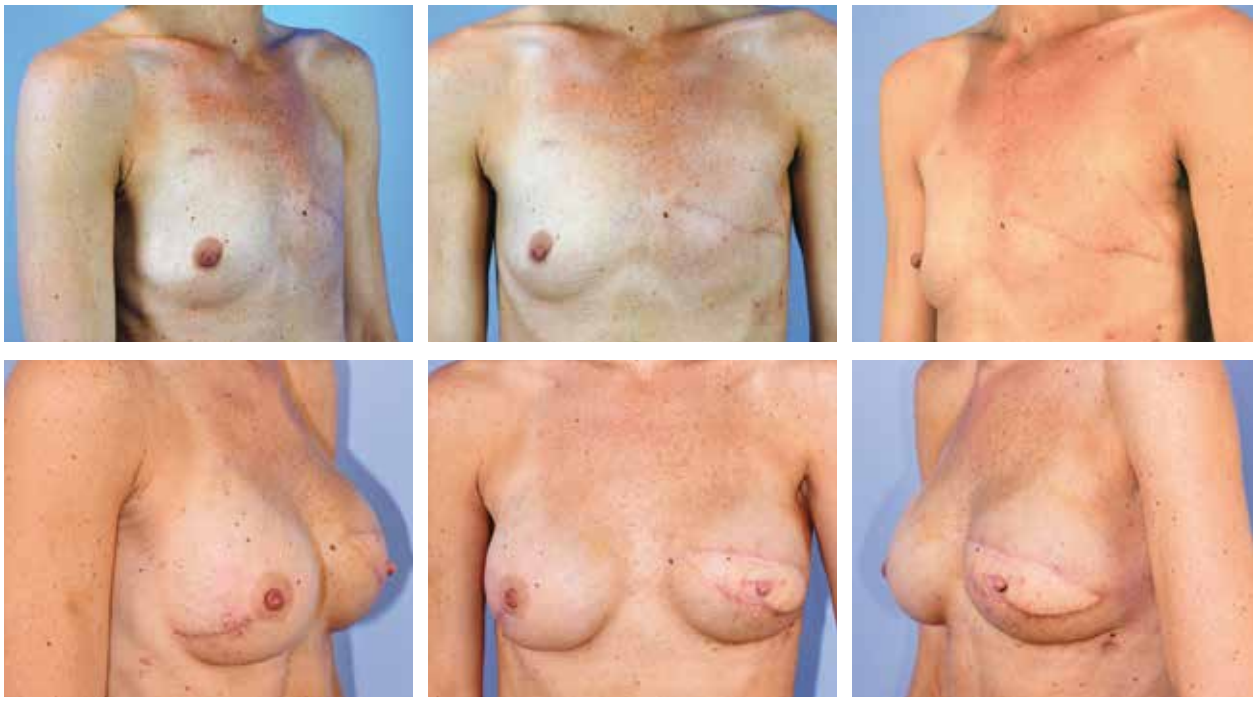
Conclusion

Addition of the "no-touch" enhancement to breast reconstruction with tissue expander and acellular dermis markedly decreased the rate of implant removal for infection from 12% to less than 2% in our practice. These principles are well established and have allowed other specialties to achieve less than 1% infection rate in their implant cases. We encourage others to add this "no-touch" enhancement to their technique tool chest, particularly those who operate on patients with obesity and comorbidities. The "no-touch" enhancement adds minimal additional time and cost, but can dramatically reduce infectious complications.

Case Histories

CASE 1:

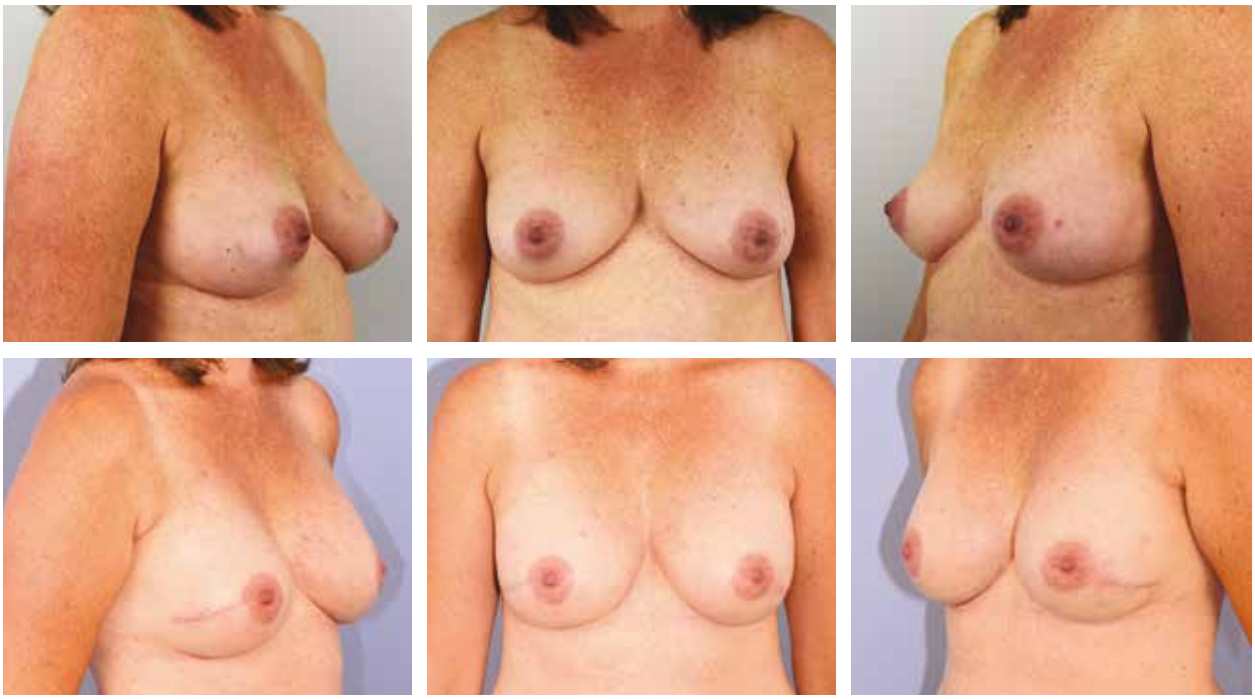
39 year-old woman with delayed left and immediate right breast reconstruction utilizing no-touch technique. The left chest had been radiated. First stage with pre-pectoral 300cc High Profile (HP) MENTOR® ARTOURA® Breast Tissue Expanders, partial anterior ADM wrap to right and latissimus to left. Second stage with 350 cc Moderate Plus (M+) MENTOR® MemoryGel® Xtra Breast Implant (right), 325 cc HP MemoryGel Implant (left) and autologous fat grafting. She has not yet had left nipple/areola tattoo. Soft tissue coverage was thinner on the right side since the left expander was covered with the latissimus muscle. This case took advantage of higher fill volume in the right MemoryGel Xtra Implant for subtle symmetry improvement and reduction of rippling visibility in the very thin right mastectomy flaps.



Case Histories

CASE 2:

43 year-old woman with 4 mm left breast cancer who is BRCA2+ and underwent bilateral mastectomy with immediate reconstruction with no-touch technique (see also Figure 11). First stage was with pre-pectoral 375cc High Profile (HP) MENTOR® ARTOURA® Breast Tissue Expanders and subtotal ADM wrap. Second stage was with 325 cc Moderate Plus (M+) MENTOR® MemoryGel® Xtra Breast Implants and autologous fat grafting.



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Important Safety Information:

MENTOR® MemoryGel® Breast Implants, MENTOR® MemoryShape® Breast Implants, and MENTOR® Saline-filled Breast Implants are indicated for breast augmentation in women (at least 22 years old for MemoryGel® Implants and MemoryShape® Implants, and 18 years old for Saline Implants) or for breast reconstruction. Breast implant surgery should not be performed in women with active infection anywhere in their body, with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions, or who are currently pregnant or nursing.

Breast implants are not lifetime devices and breast implantation may not be a one-time surgery. The most common complications for breast augmentation and reconstruction with MemoryGel® Implants include any reoperation, capsular contracture, and implant removal with or without replacement. The most common complications with MemoryShape® Implants for breast augmentation include reoperation for any reason, implant removal with or without replacement, and ptosis. The most common complications with MemoryShape® Implants for breast reconstruction include reoperation for any reason, implant removal with or without replacement, and capsular contracture. A lower risk of complication is rupture. The health consequences of a ruptured silicone gel breast implant have not been fully established. MRI screenings are recommended three years after initial implant surgery and then every two years after to detect silent rupture. The most common complications with MENTOR® Saline-filled Implants include reoperation, implant removal, capsular contracture, breast pain, and implant deflation.

For MemoryGel® Implants, patients should receive a copy of Important Information for Augmentation Patients about MENTOR® MemoryGel® Breast Implants or Important Information for Reconstruction Patients about MENTOR® MemoryGel® Breast Implants. For MemoryShape® Implants, patients should receive a copy of Patient Educational Brochure – Breast Augmentation with MENTOR® MemoryShape® Breast Implants or Patient Educational Brochure – Breast Reconstruction with MENTOR® MemoryShape® Breast Implants, and a copy of Quick Facts about Breast Augmentation & Reconstruction with MENTOR® MemoryShape® Breast Implants. For MENTOR® Saline-filled Implants, patients should receive a copy of Saline-Filled Breast Implants: Making an Informed Decision. Your patient needs to read and understand the information regarding the risks and benefits of breast implants, with an opportunity to consult with you prior to deciding on surgery.

The ARTOURA® Breast Tissue Expander or CONTOUR PROFILE® Breast Tissue Expander can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision, and tissue defect procedures. The expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months. Do not use the ARTOURA® Tissue Expander nor CONTOUR PROFILE® Tissue Expander in patients where an MRI may be needed. The device could be moved by the MRI causing pain or displacement, potentially resulting in a revision surgery. The incidence of extrusion of the expander has been shown to increase when the expander has been placed in injured areas.

For detailed indications, contraindications, warnings, and precautions associated with the use of all MENTOR® Implantable Devices, which include MENTOR® Saline-filled Implants, MemoryGel® Implants, MemoryShape® Implants, ARTOUR® Expanders, and CONTOUR PROFILE® Expanders, please refer to the Instructions for Use (IFU) provided with each product or visit www.mentorwwllc.com.

Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, side effects, warnings and precautions.
Caution: US law restricts this device to sale by or on the order of a physician.

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Mentor Worldwide, LLC
31 Technology Drive
Irvine, California 92618 USA