Implant-Based Breast Reconstruction

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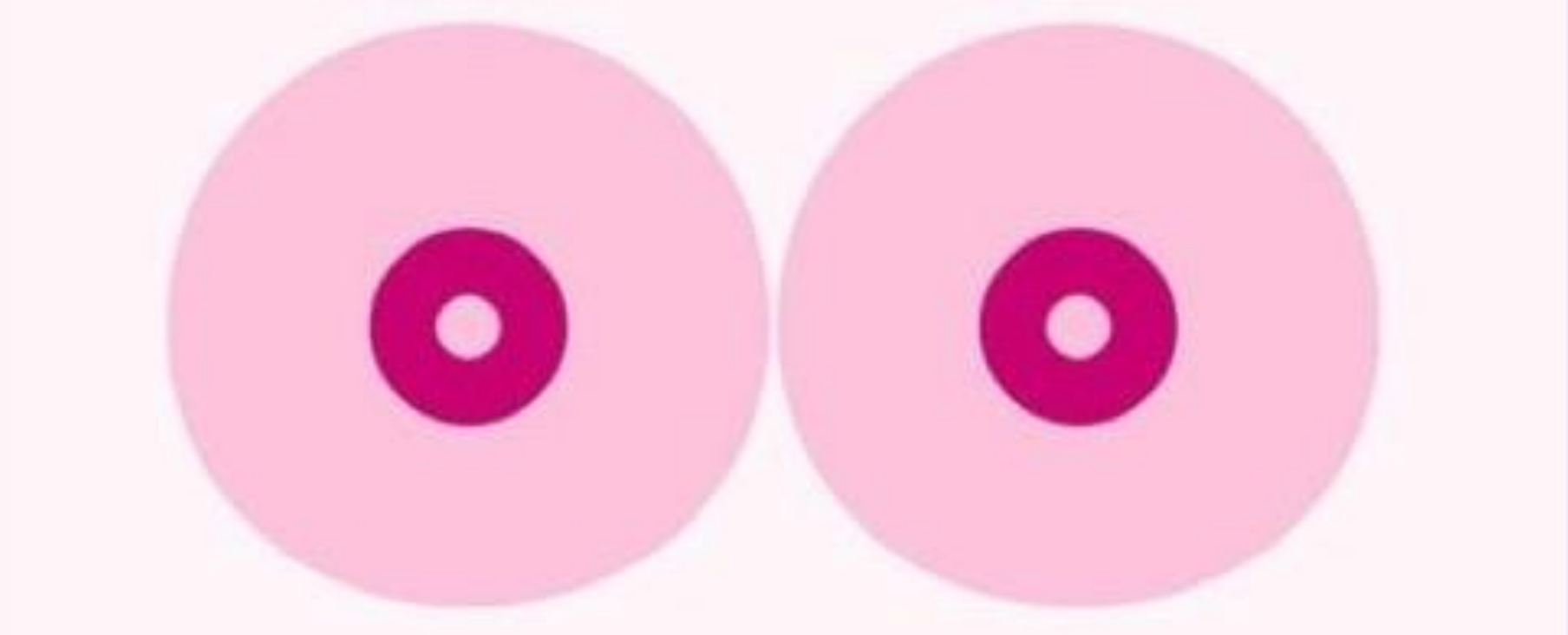

Pink Hope Webinar Aug 2nd 2019

Jane O'Brien

Specialist Oncoplastic Breast Surgeon

thebreastcentre.com.au

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International Reconstruction Rates Post Risk Reducing Mastectomy

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Ann Surg Oncol (2013) 20:3817–3822
DOI 10.1245/s10434-013-3040-4

Annals of
SURGICAL ONCOLOGY
OFFICIAL JOURNAL OF THE SOCIETY OF SURGICAL ONCOLOGY

ORIGINAL ARTICLE – BREAST ONCOLOGY

International Rates of Breast Reconstruction After Prophylactic Mastectomy in *BRCA1* and *BRCA2* Mutation Carriers

John Semple, MD[1], Kelly A. Metcalfe, RN, PhD[1,2], Henry T. Lynch, MD[3], Charmaine Kim-Sing, MD[4], Leigha Senter, MS, CGC[5], Tuya Pal, MD[6], Peter Ainsworth, MD[7], Jan Lubinski, MD, PhD[8], Nadine Tung, MD[9], Charis Eng, MD, PhD[10,11,12,13], Donna Gilchrist, MD[14], Joanne Blum, MD, PhD[15], Susan L. Neuhausen, PhD[16], Christian F. Singer, MD[17], Parviz Ghadirian, PhD[18], Ping Sun, PhD[1], Steven A. Narod, MD[1] and The Hereditary Breast Cancer Clinical Study Group

Ann Surg Onc 2013

- 70 % BRCA 1/ 2 mutation carriers have reconstruction after prophylactic mastectomy
- Compared to 5-29% of women having a mastectomy for breast cancer

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Implant-Based Breast Reconstruction (IBBR)

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Most common reconstruction option in conjunction with risk-reduction mastectomy in high risk individuals

- Patients on average are younger than breast cancer patients
- May not have sufficient autologous donor tissue, especially for bilateral reconstruction
- May wish to upsize
- May prefer to avoid using abdomen if haven't had/finished family
- May have concerns re active lifestyle and flap reconstruction
- May favour faster recovery re return to work, sporting activities, family commitments
- All bilateral- therefore achieving symmetry not as problematic
- No competing oncological factors eg safety of keeping nipple, post Mx radiotherapy

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Personal Practice Audit
Bilateral Risk-Reduction Mastectomy
2015-2019

	% of Bilateral Mastectomy with Reconstruction
Implant Based	90
DIEP	10

*All but one pt underwent Immediate Reconstruction

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Recent Changes in the Implant Reconstruction Landscape

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- Widespread Acceptance of Nipple-Sparing Mastectomy (NSM)- therapeutic and prophylactic
- Availability of "Mesh" Products –biological and synthetic including complications eg "red breast"
- Single Stage Direct-to-Implant (DTI) Reconstruction
- Introduction of "Prepectoral" Implant Based Reconstruction
- Implant Related Issues- "implant illness" and BIA-ALCL
- Australian Breast Device Registry (ABDR)

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Implant-Based Breast Reconstruction (IBBR)

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- Immediate or Delayed
- One or Two stage
- Type of Prosthesis
- Where is Prosthesis Placed

Implant Related Issues

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- Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)
- Silicone Breast Implant Illness
- Regulatory Concerns
- Australian Breast Device (ABDR)

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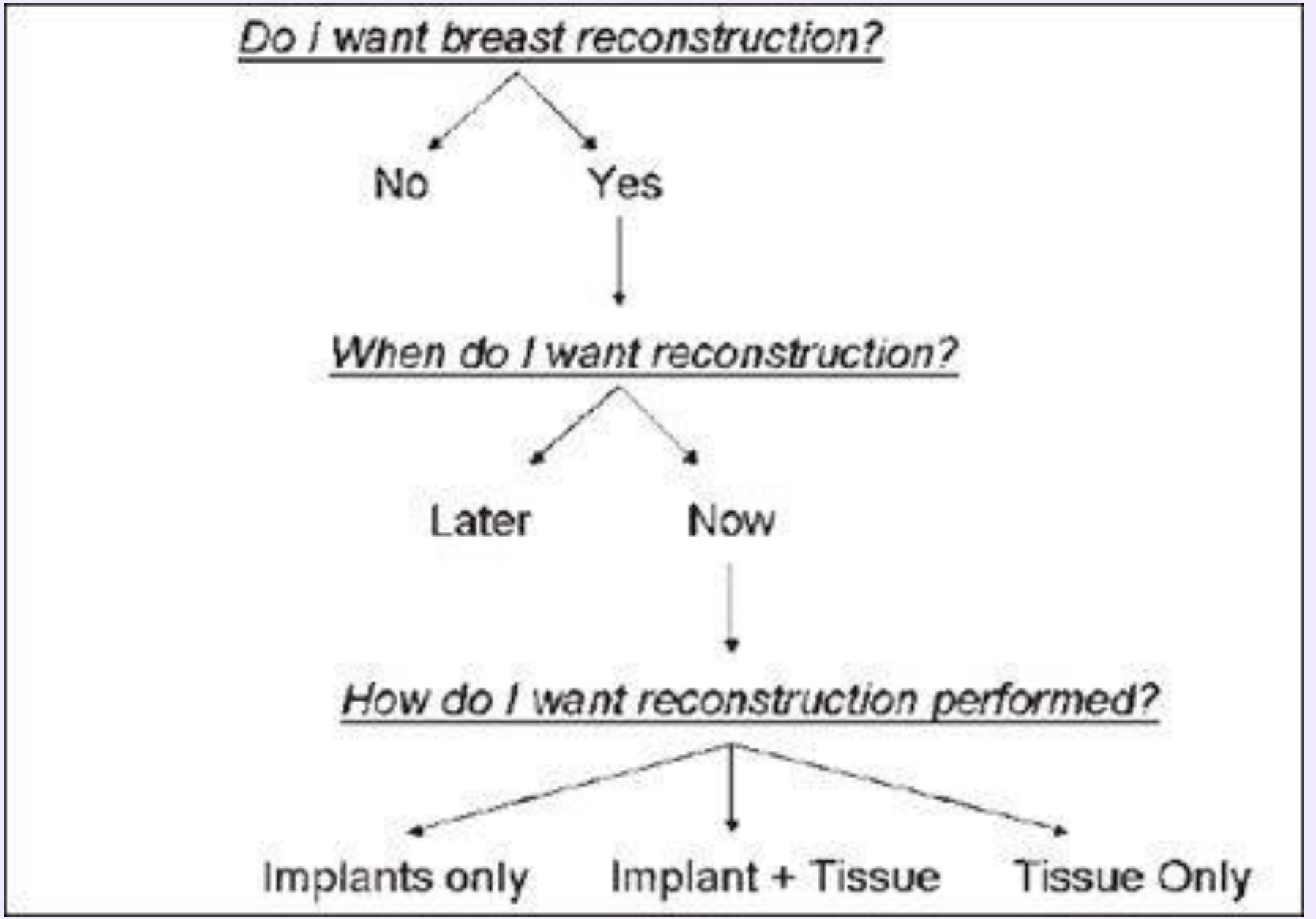

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"Going Flat"

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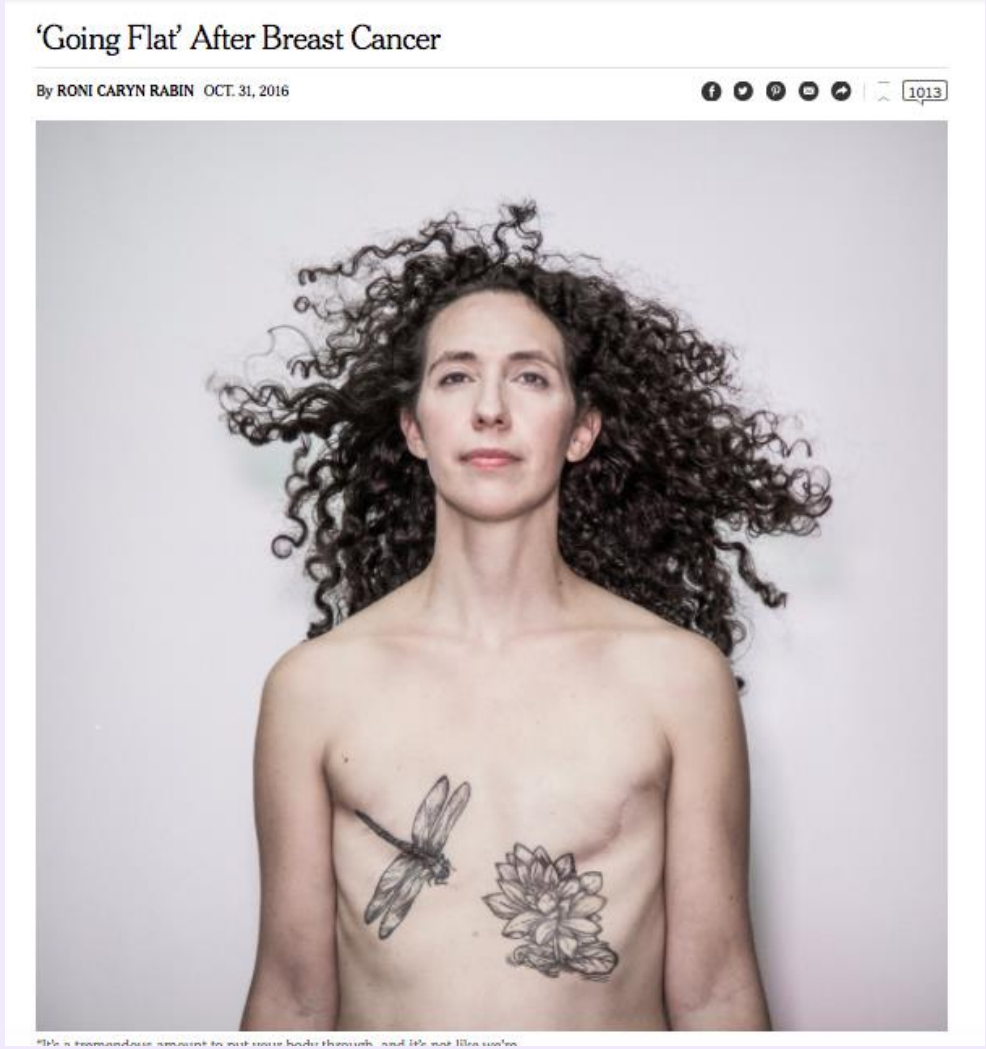
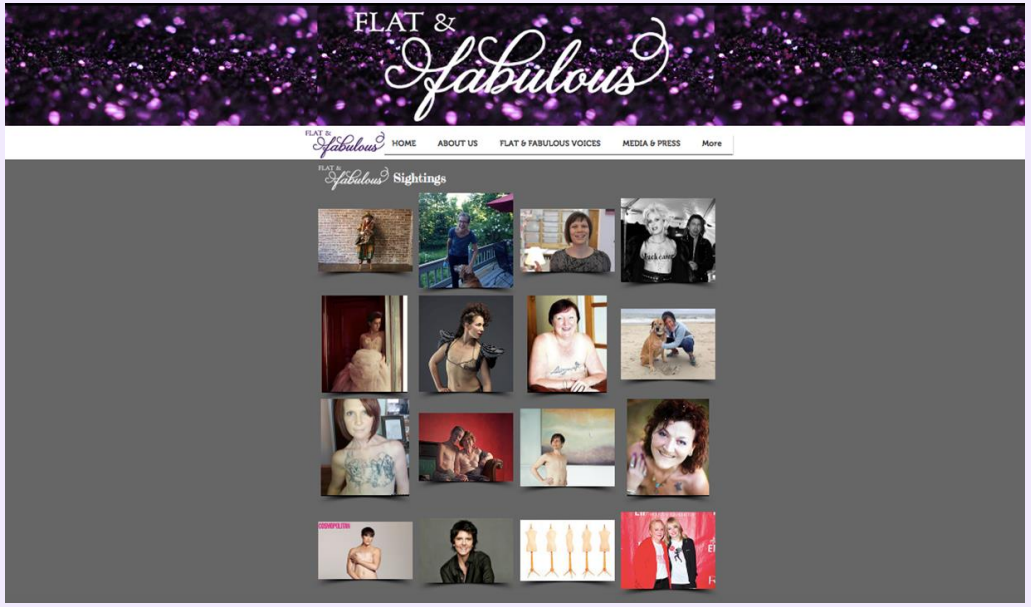


'Going Flat' After Breast Cancer

By RONI CARYN RABIN OCT. 31, 2016

1013



http://www.flatandfabulous.org

New York Times, Oct 2016

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Your Breast Reconstruction Options

Immediate or Delayed Reconstruction?

"Immediate Reconstruction" = the mastectomy and the reconstruction are performed during the same surgery

"Delayed Reconstruction" = the mastectomy is performed first, and after several weeks or months (or even years in some cases) of healing, the reconstruction is performed

Breast Implants or Natural Tissue?

"Breast Implants" = using the same implants typically used during a breast augmentation to restore volume to the breasts

"Natural Tissue" (or "Autologous Reconstruction") = using excess fat, muscle, blood vessels, and potentially skin from your own abdomen or other areas to re-create breasts

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Immediate or Delayed?

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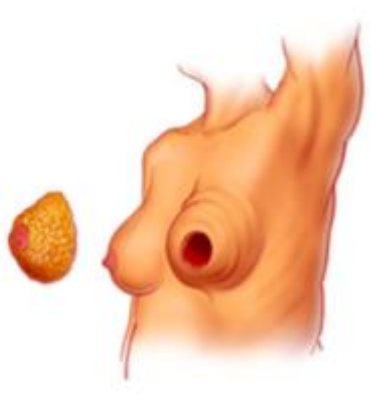
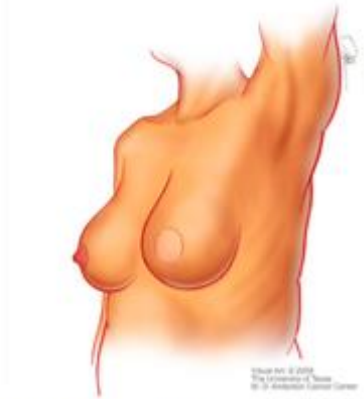
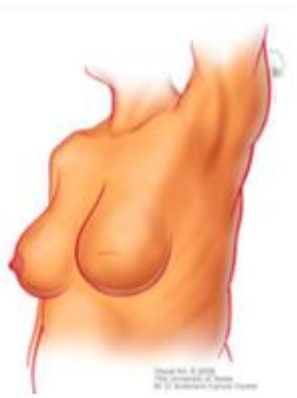
Immediate Reconstruction



Breast tissue is removed during mastectomy surgery, with some skin remaining.

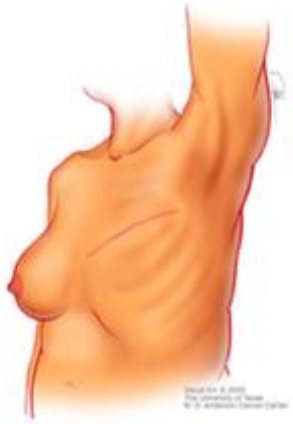


Tissue flap recreates the breast mound immediately with a small patch of skin visible.

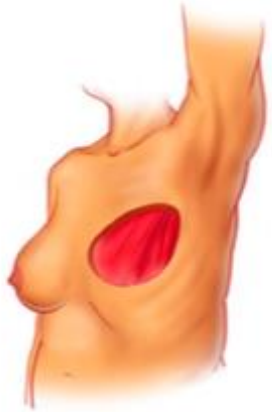


Tissue expander (or implant) recreates a breast mound with a resulting horizontal scar.

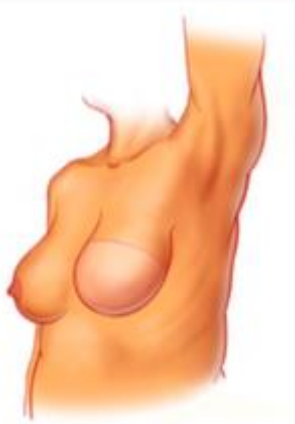
Delayed Reconstruction



Breast tissue and most skin is removed during mastectomy surgery. After surgery, there is no breast mound.



For reconstruction, an additional surgery is needed to attach the tissue flap and/or place an implant to create the breast mound.



A larger patch of skin from the tissue flap is visible on the breast after reconstructive surgery.

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Delayed: Two-Stage Reconstruction

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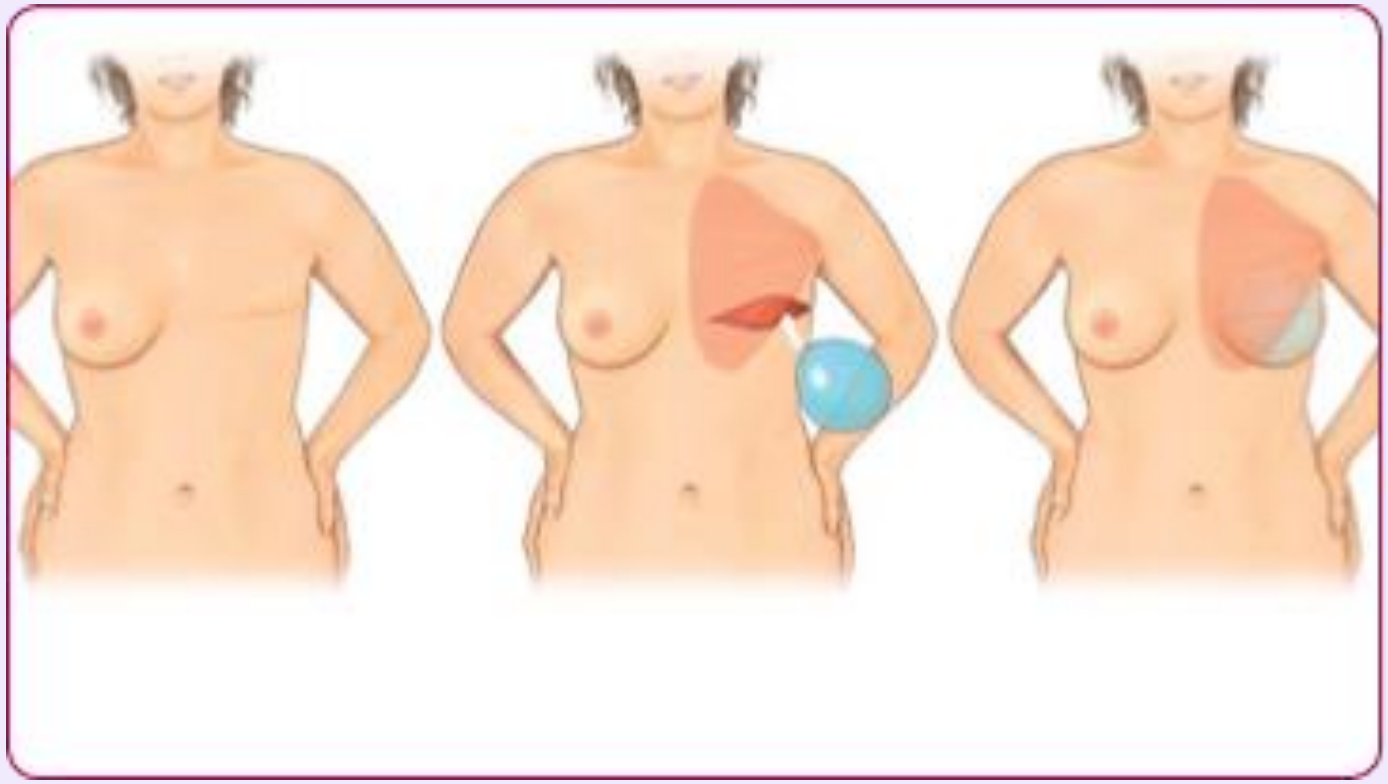

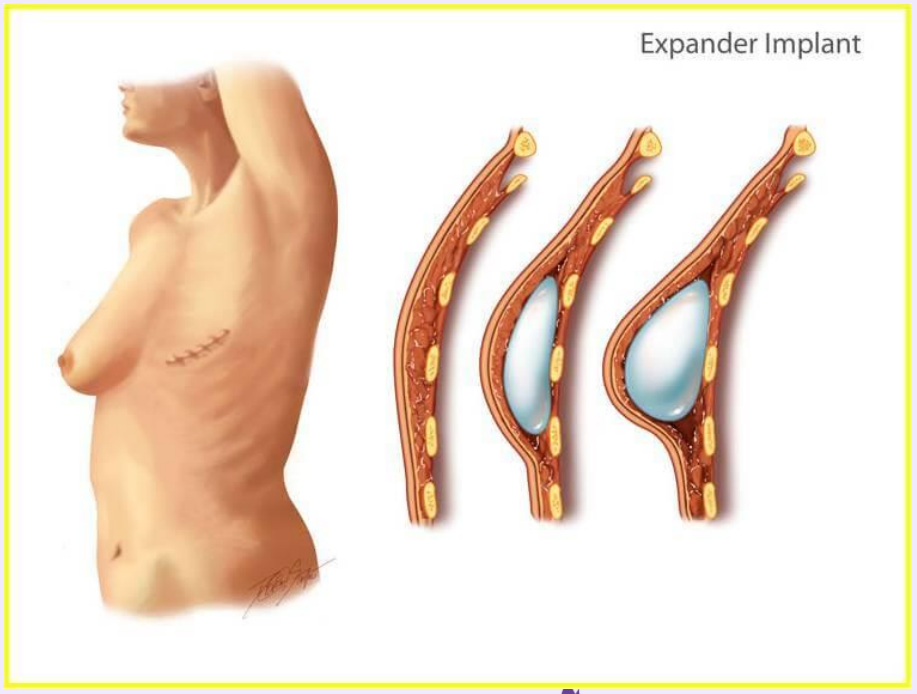

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Your Breast Reconstruction Options

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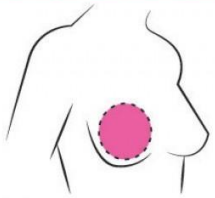
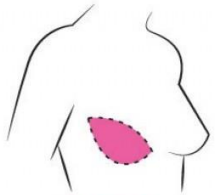
BREAST RECONSTRUCTION SURGERY

Following a Mastectomy, many women choose to undergo breast reconstruction surgery.
There are two main options, and the decision is most often based on the patients' preference.



IMPLANTS/EXPANDERS

Silicone shell filled with silicone gel or saline (salt water solution)



FLAPS

Uses patient's own fat tissue and muscle from abdominal, back, butt or thighs.

IMPLANTS/EXPANDERS		FLAPS
2 separate operations 2-4 hours per procedure under general anesthesia.	SURGERY	1 major operations 4-10 hours for DIEPS and microsurgical flaps under general anesthesia. 3-4 hours for TRAM and latissimus flaps under general anesthesia
1 day surgery or overnight	HOSPITALIZATION	Average 2-3 days for pedicled TRAM Average 5 days for microsurgery and free DIEP
2 weeks after each procedure. +3-5 days after each touch up. Medium range pain	RECOVERY & PAIN	6-8 weeks after major procedure. No straining or lifting. +3-5 days after each touch up. Medium range pain on two sites.
Less natural look. Firmer over time.	SHAPE & FEEL	More natural look. Some natural feel. Soft.

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What to consider – implant reconstruction

Benefits

- Operation takes only a few hours and you usually only stay in hospital for a few days.
- Creates the breast shape without moving tissue (muscle, skin or fat) from elsewhere in the body, so other parts of the body aren't affected.
- Only one scar from the mastectomy.
- Recovery time at home is shorter than for a flap reconstruction. Although the chest area will be swollen and sensitive, you may be able to return to most activities within about a week.
- Implants come in a range of shapes and sizes. You can choose to change your original breast size.
- Doesn't change in size if your weight changes.
- Doesn't cause issues, such as muscle weakness, that may occur as a result of a flap reconstruction.

Drawbacks

- Two or more operations may be required, if you have an expander first or if the expander is used as the implant (see page 37). You will need regular doctor's visits to gradually fill the expander. The whole process may take 3–6 months.
- A breast reconstructed with a tissue expander and/or an implant usually feels firmer than a natural breast. While it won't move like a natural breast, it usually looks the same (symmetrical) in a bra.
- If your other breast changes in shape and size, you may need further surgery to match the two.
- Hardened scar tissue (capsule) may form around the implant. This can distort the shape of the breast and cause pain in some circumstances (see page 41).
- Risk of infection, which may mean removing the implant.
- Implants may need to be replaced after 10–15 years, but some can last for longer.

Implant vs. Flap reconstruction
Potential advantages and disadvantages

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Advantages over flap

- shorter, less complex surgery
- uses the mastectomy incision for procedure (doesn't create new scars)
- sometimes can be completed in one step
- gaining or losing weight won't change the size of the reconstructed breasts
- Often easier to find qualified surgeons

Disadvantages vs. flap

- overall reconstruction process can take longer (multiple steps, multiple office visits to receive tissue expander injections)
- less likely to feel, look, or move like a natural breast
- subject to future problems such as rupture, deflation, capsular contracture
- opposite healthy breast often needs surgery to match the implant
- generally not a good option if skin has undergone radiation
- implant won't last a lifetime

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Immediate Implant-Based Breast Reconstruction (IBBR)

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One or Two stage?

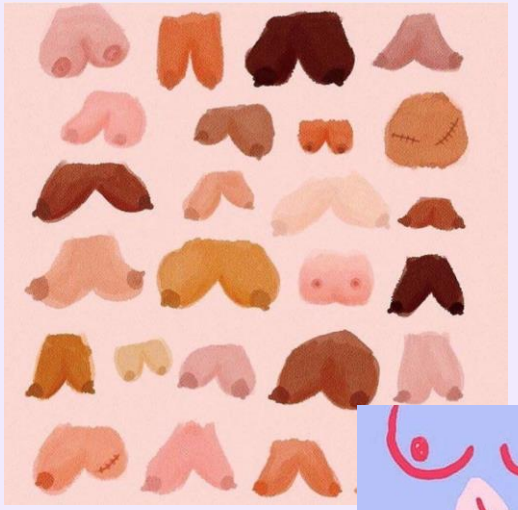
- Tissue Expander/ Implant Reconstruction (Two Stage)
- Direct-to-Implant (DTI) (One Stage) Reconstruction with Acellular Dermal Matrix (ADM)

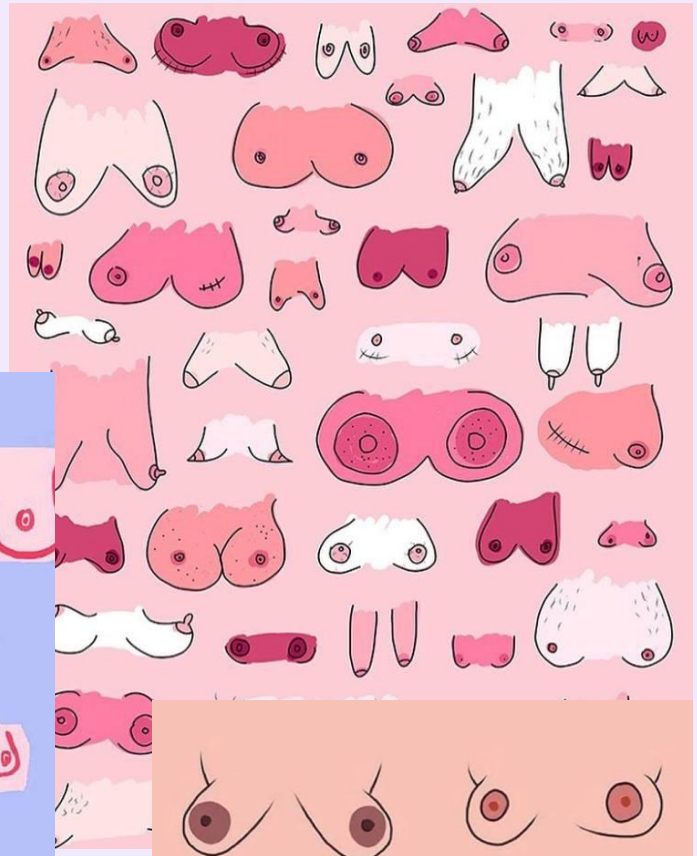
Type of Prosthesis ?

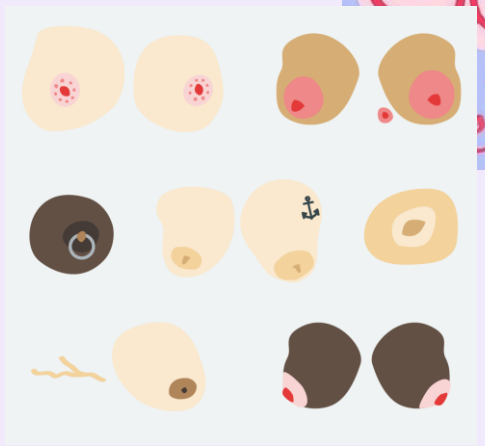
- Smooth or Textured
- Silicone or Saline
- Round or Anatomical (teardrop)

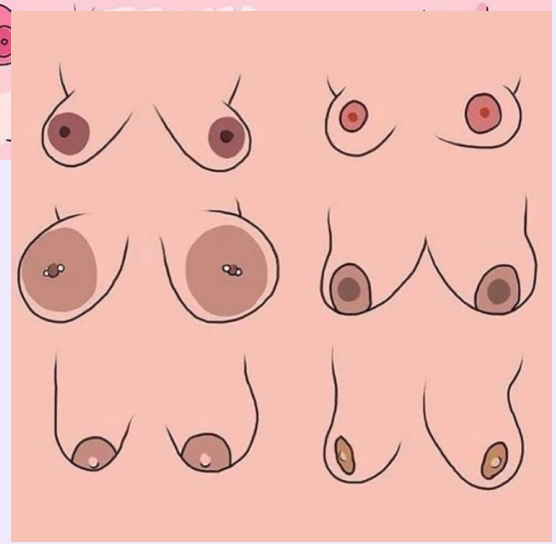
Where is Prosthesis Placed?

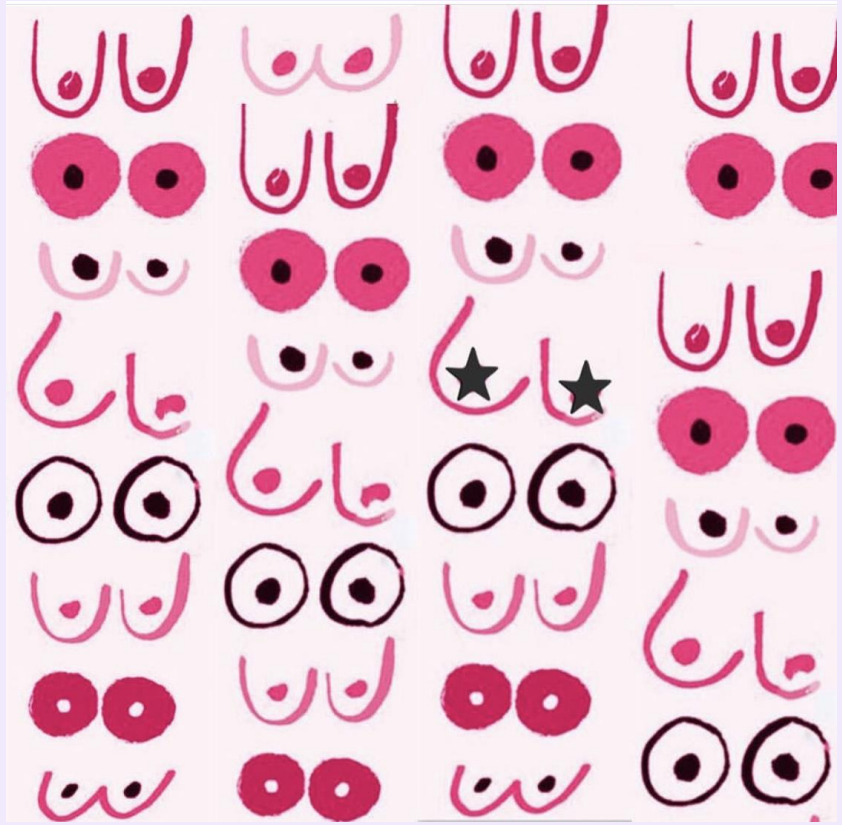
- Submuscular
- Dual Plane (with ADM)
- Prepectoral (with ADM)











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Breasts come in all shapes and sizes

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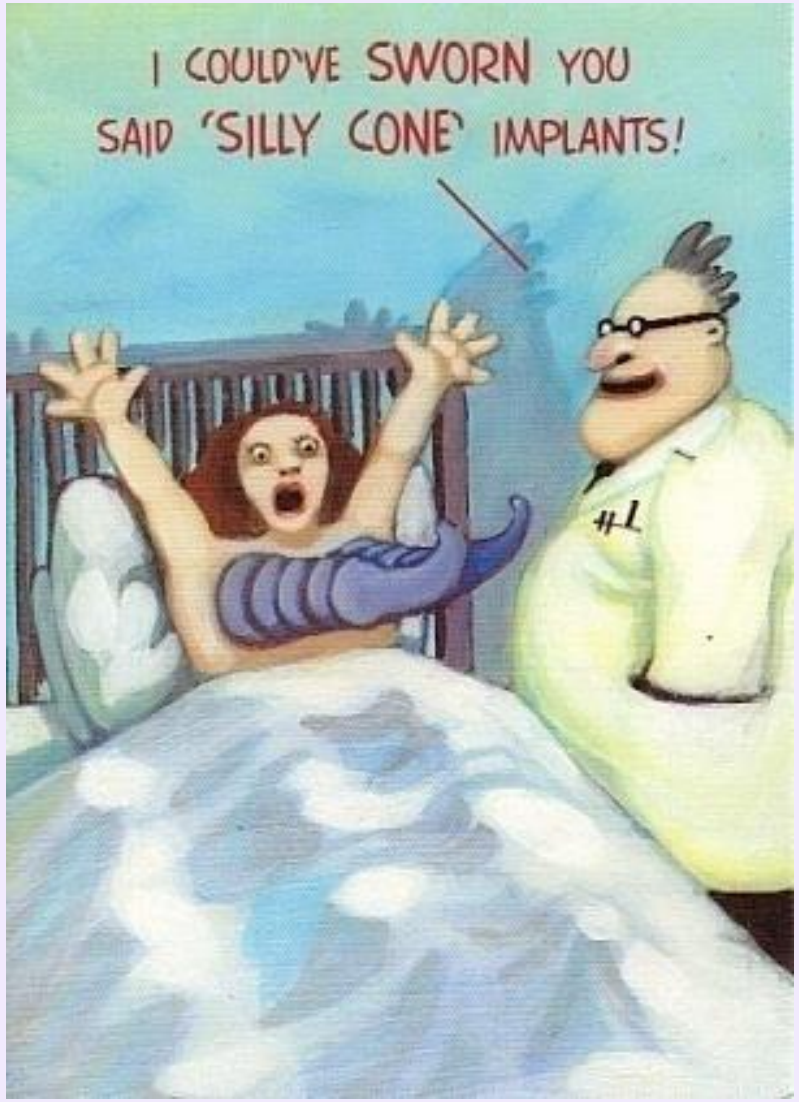

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Expectations need to be be realistic and achievable

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Types of Risk-Reducing Mastectomy

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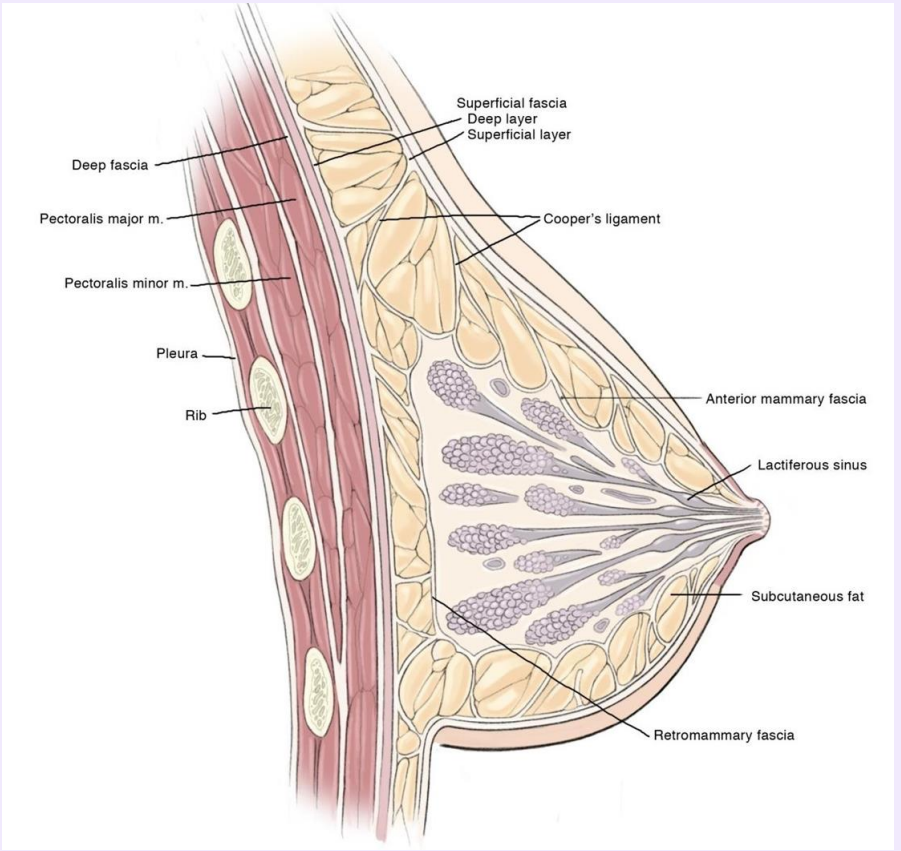
- Simple Mastectomy
- Skin-Sparing (SSM)
- Skin-Reducing Mastectomy
- Nipple-Sparing (NSM)



Type of mastectomy depends on:
- Whether there is to be immediate reconstruction
- Patient characteristics and preference

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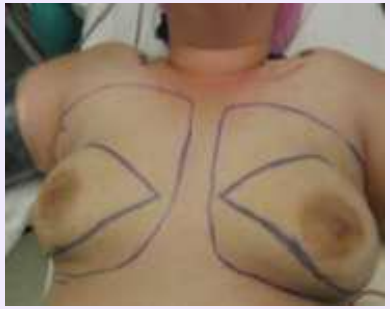
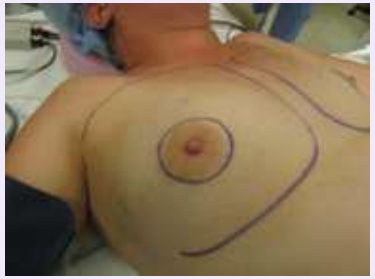
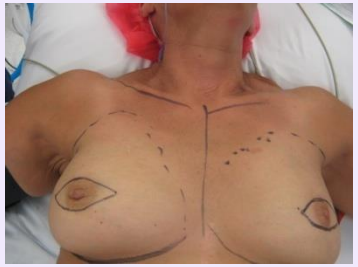
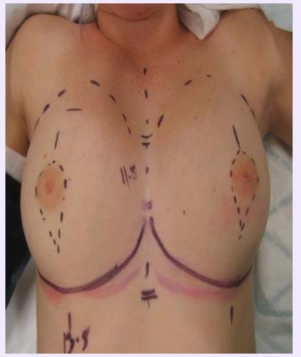
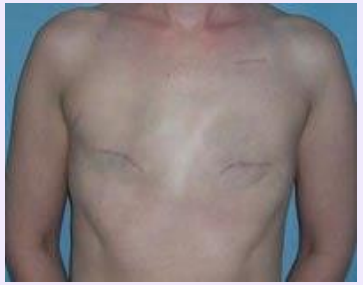
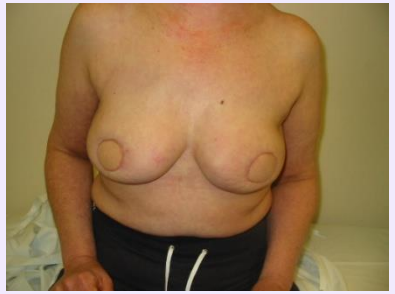
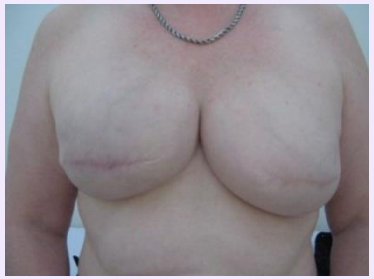
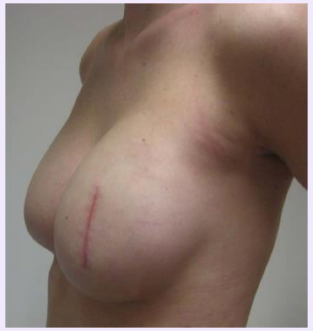
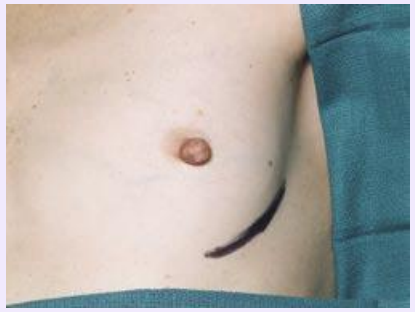
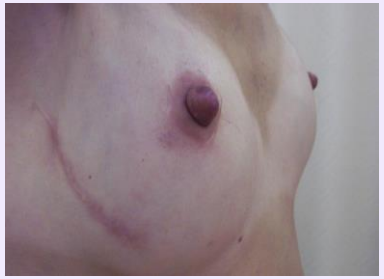
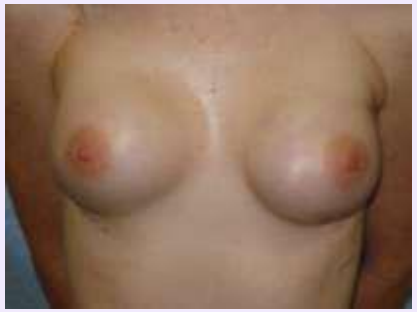
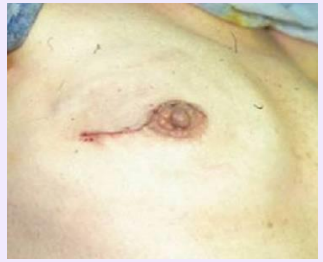









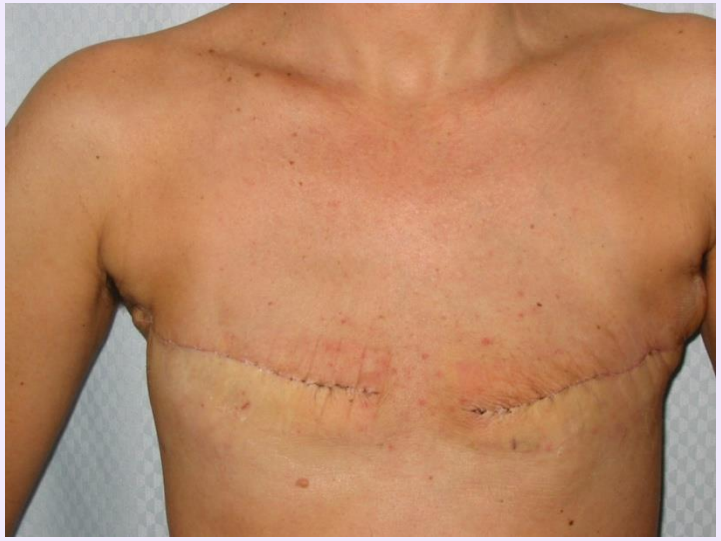
Simple Mastectomy

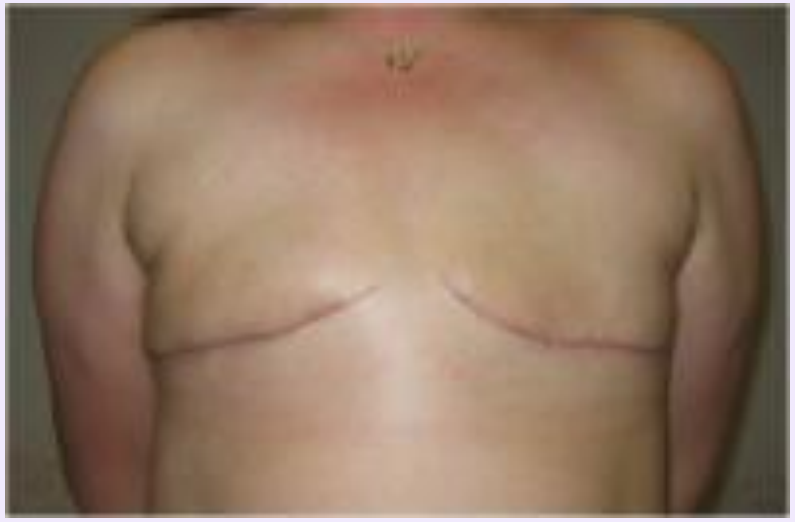
Skin-Sparing Mastectomy

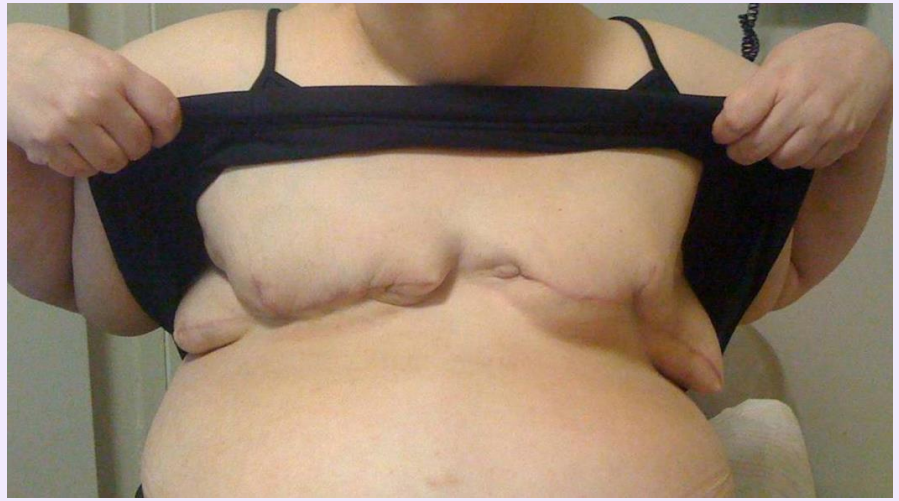





Nipple-Sparing Mastectomy

Simple Mastectomy







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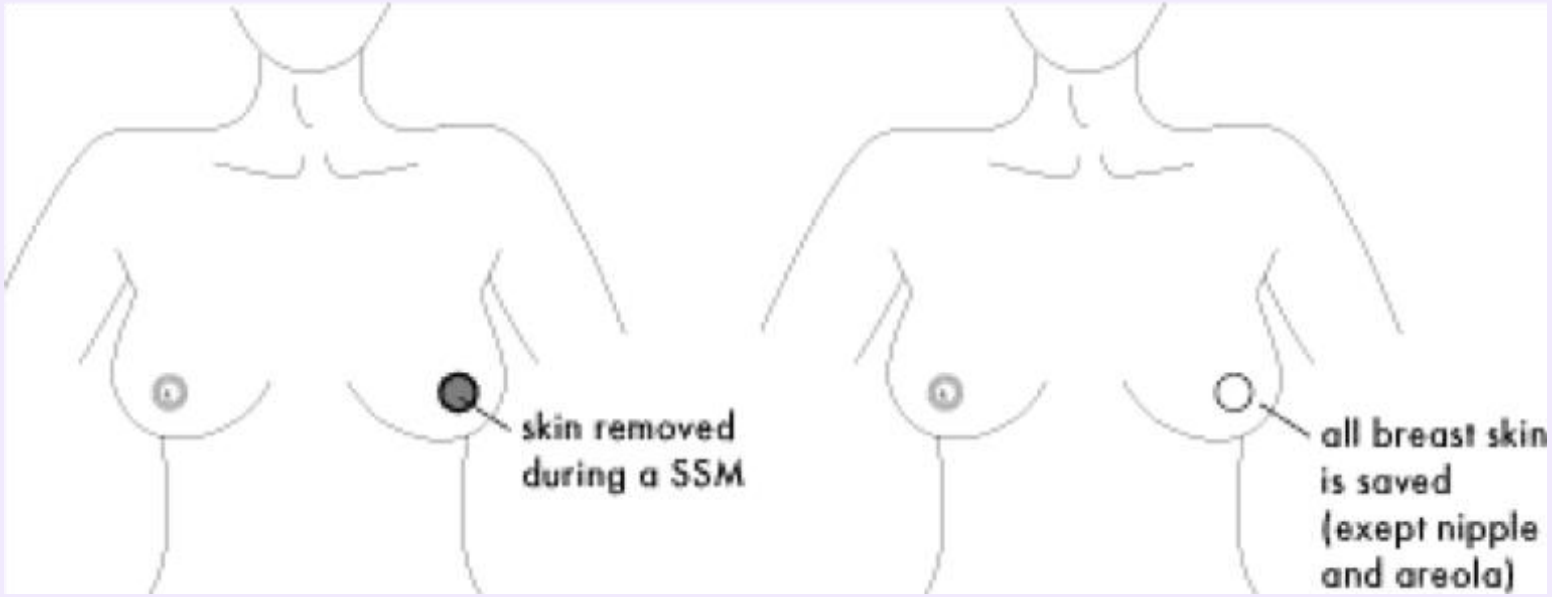
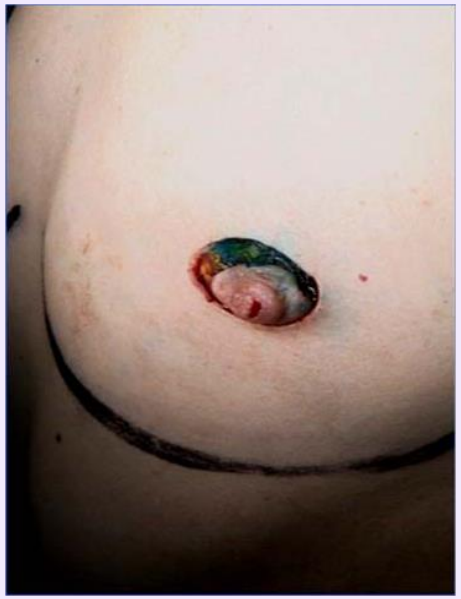
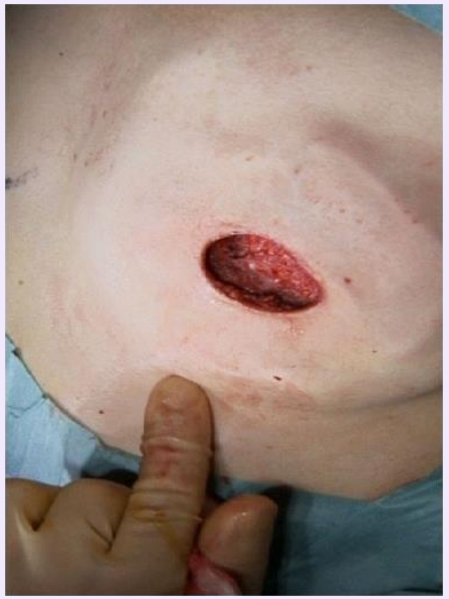
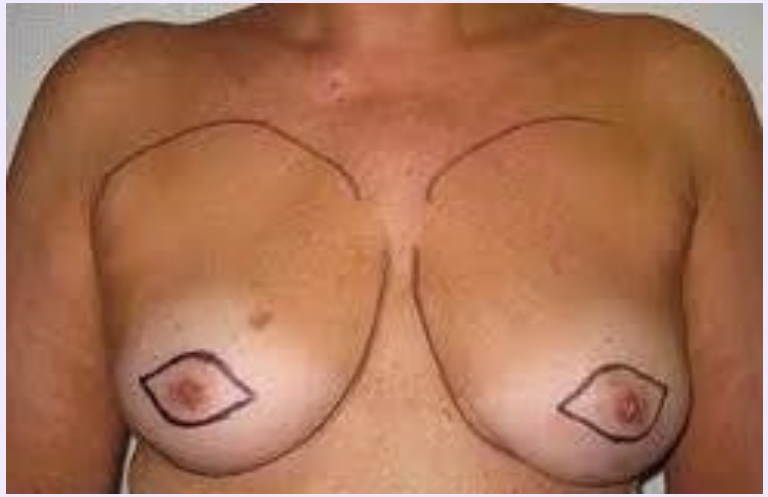
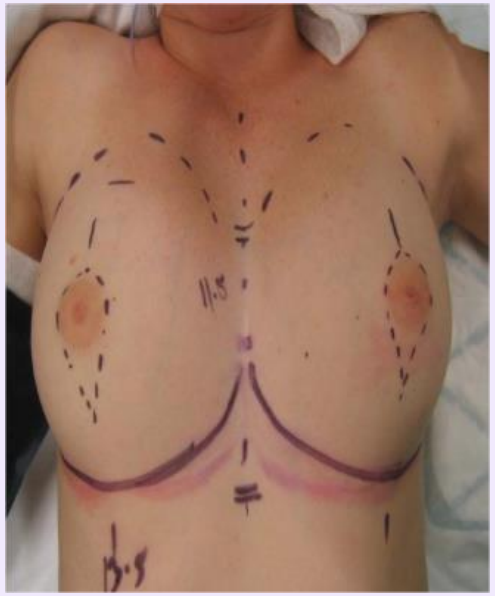
Skin-Sparing Mastectomy (SSM)

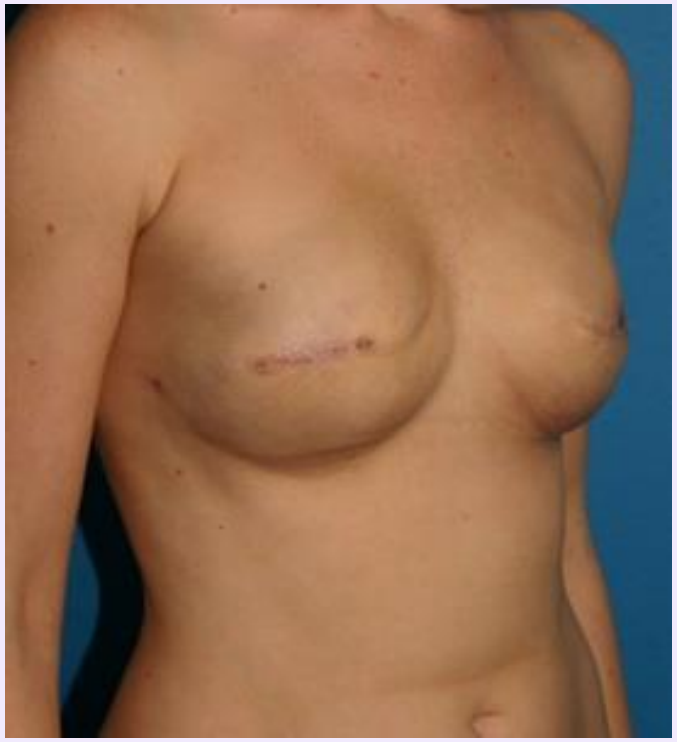


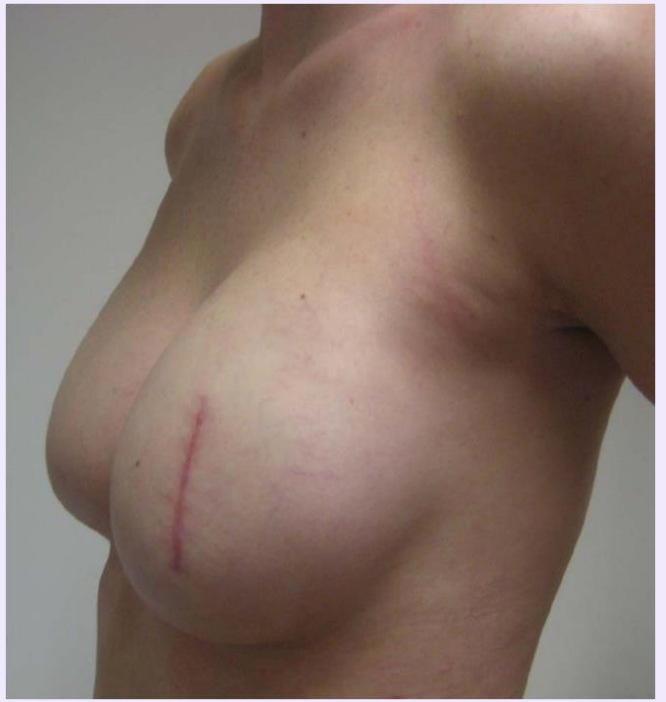












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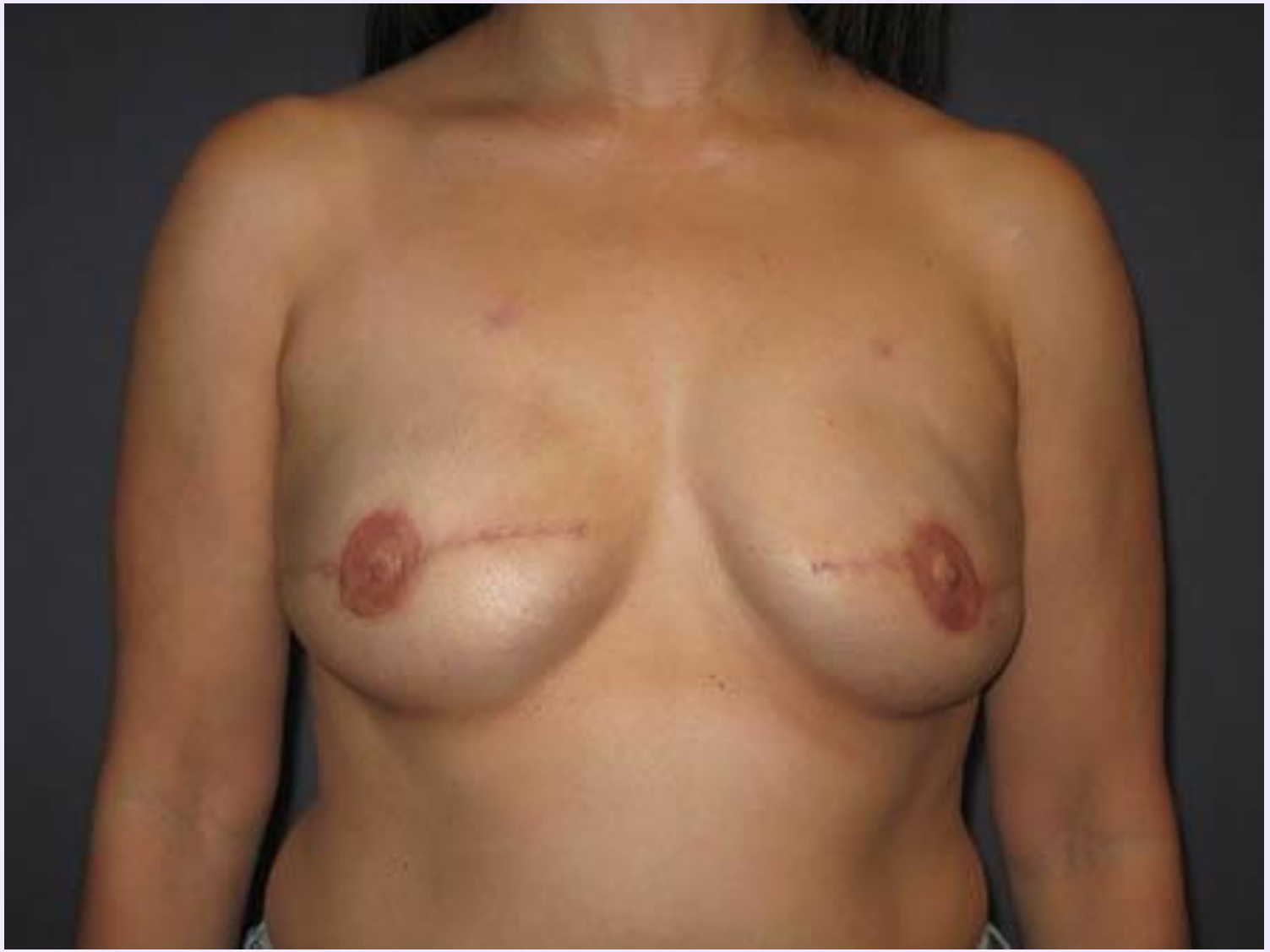

Nipple-Sparing Mastectomy (NSM)

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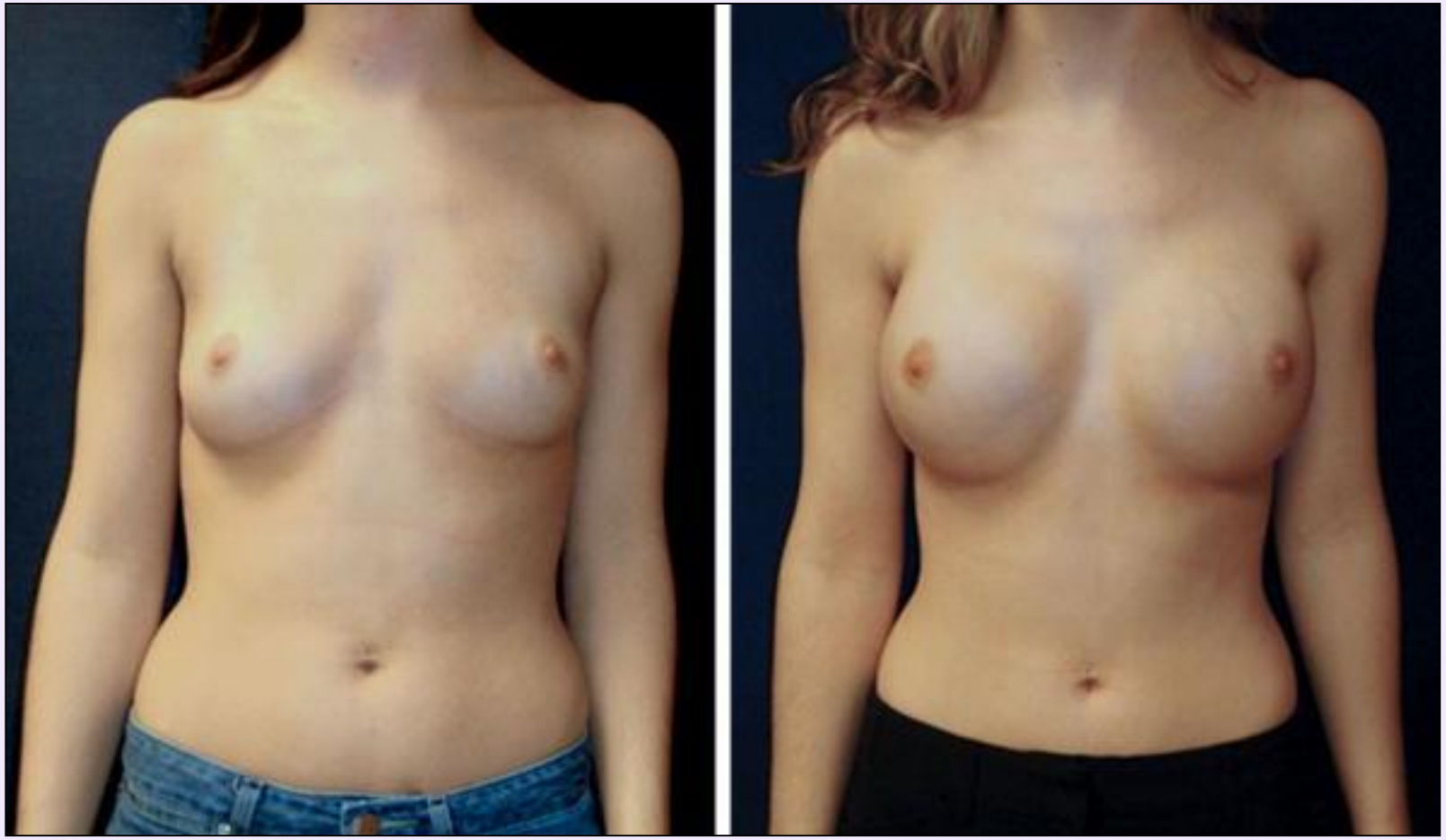

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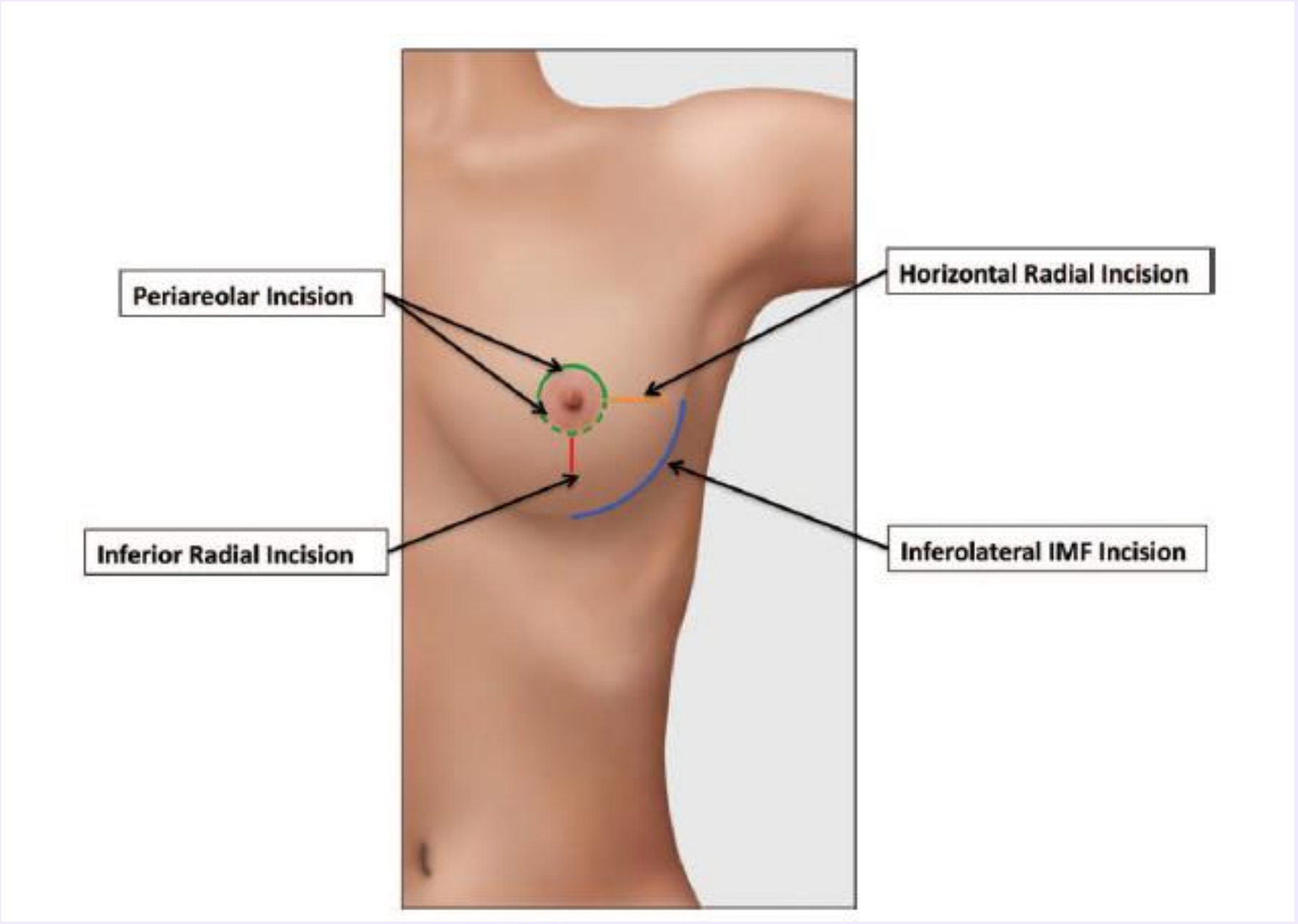

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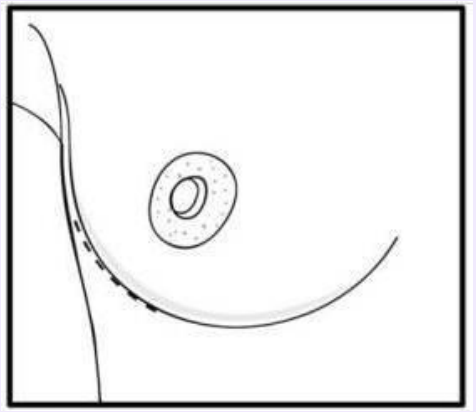

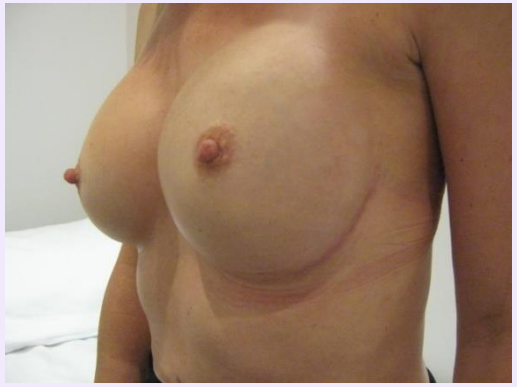

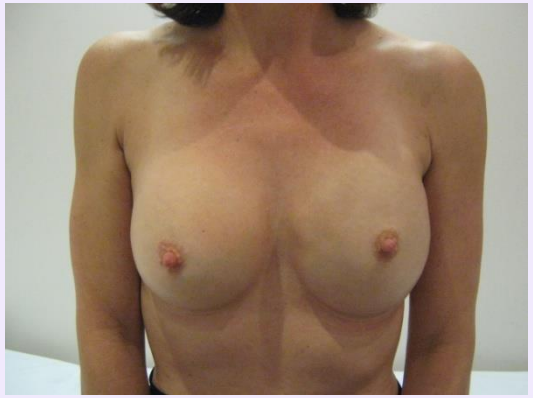

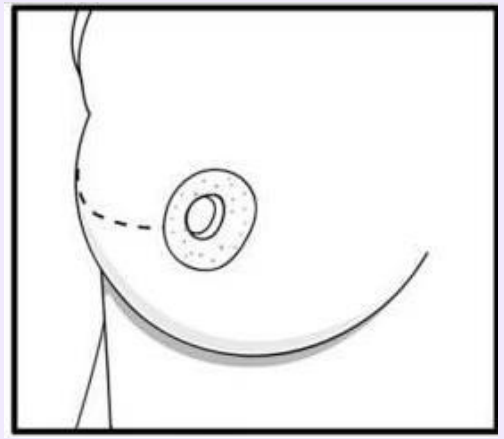

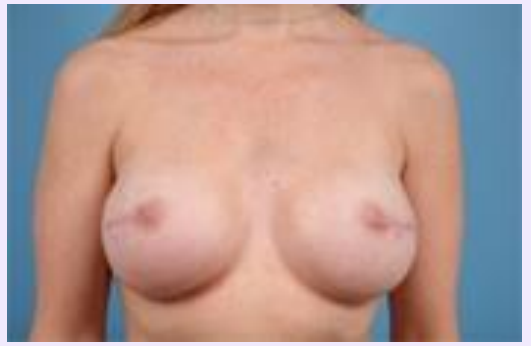

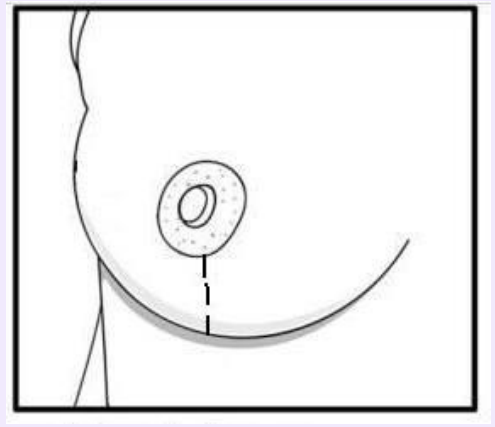

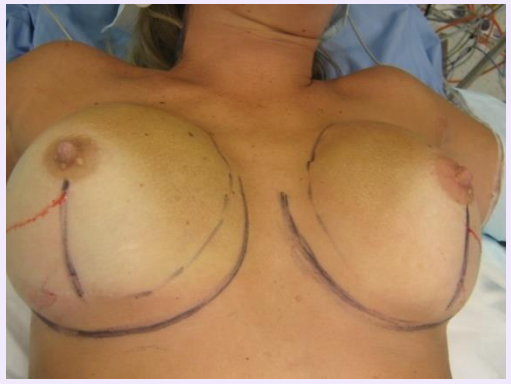

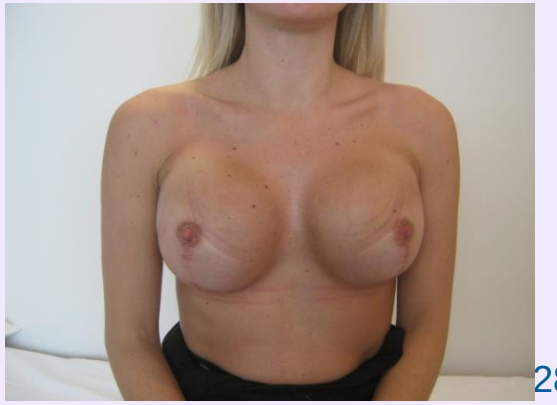

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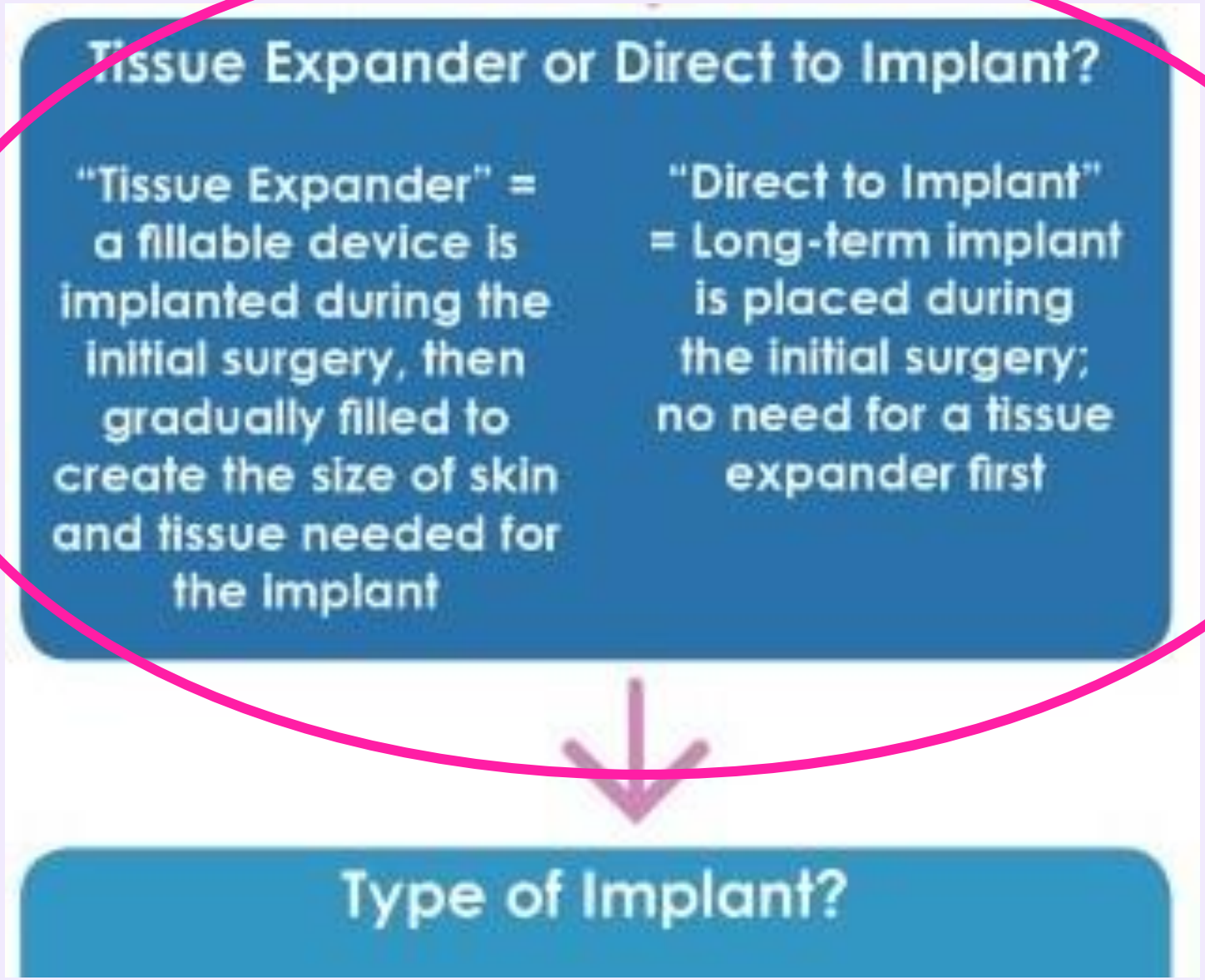
Personal Practice Audit
Bilateral Risk-Reduction Mastectomy
2015-2019

	%
NSM	81
SSM/Skin Reducing Mastectomy	14
NSM undergoing prior nipple-delay	88

One or Two Stage?



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Tissue Expanders

Can be placed on top or under the pec muscle. Used to expand the breast tissues. Replaced by a permanent silicone or saline implant. Usually includes the use of ADM.

Direct to Implant

Permanent silicone or saline implant placed at time of mastectomy. Avoids expansion process altogether.
ADM usually used for implant support and shaping.

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Personal Practice Audit
Bilateral Risk-Reduction Mastectomy
2015-2019

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	% of Implant Based Reconstructions
Single Stage DTI with ADM	89
2 stage tissue expander/implant	11
	% of DTIs
Dual Plane	83
Prepectoral	17 (60% of DTIs in last 12 months)

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WHERE IS THE PROSTHESIS PLACED?

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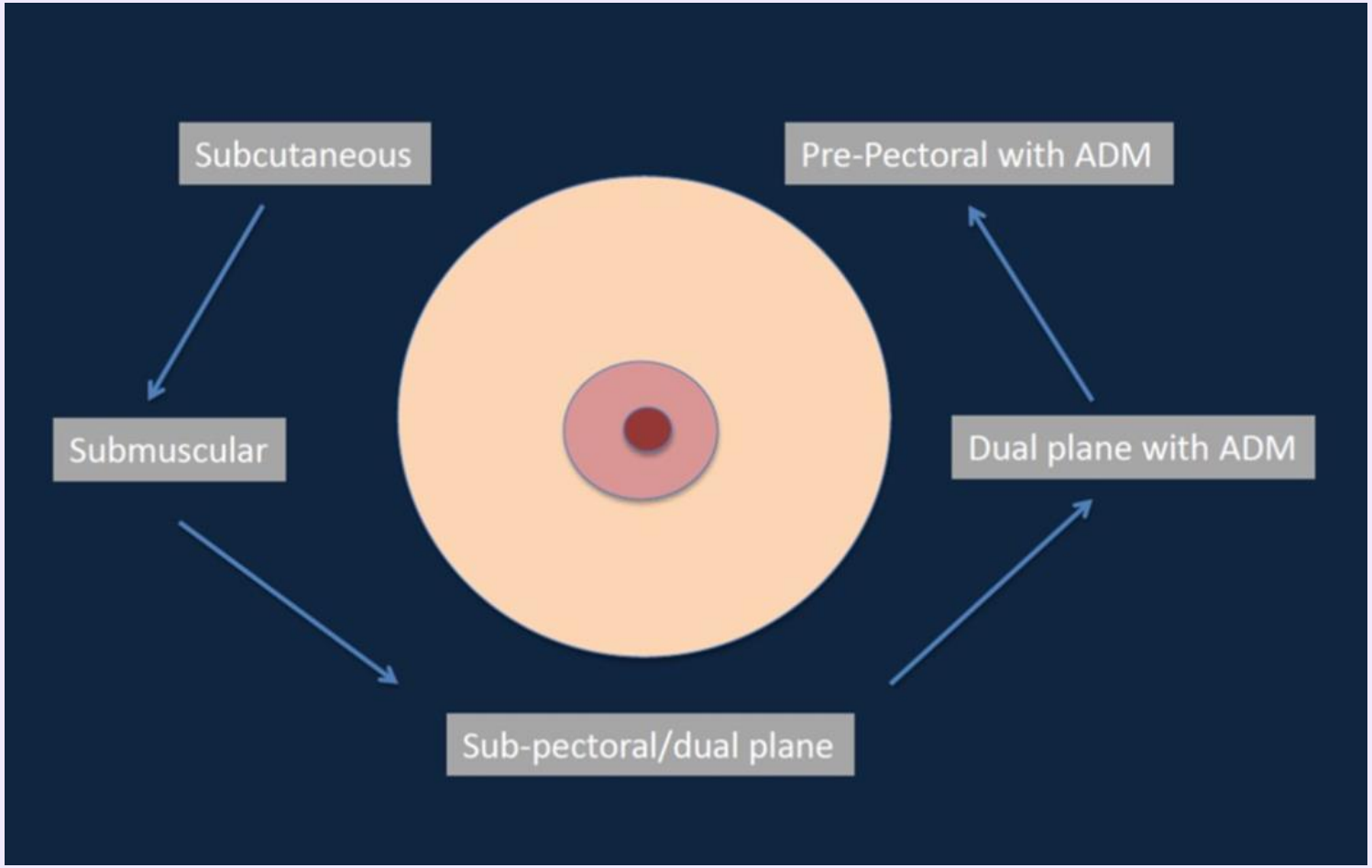

- Submuscular
- Dual Plane (with ADM)
- Prepectoral (with ADM)

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Personal Practice Audit
Bilateral Risk-Reduction Mastectomy
2015-2019

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	% of DTIs
Dual Plane	83
Prepectoral	17 (60% of DTIs in last 12 months)

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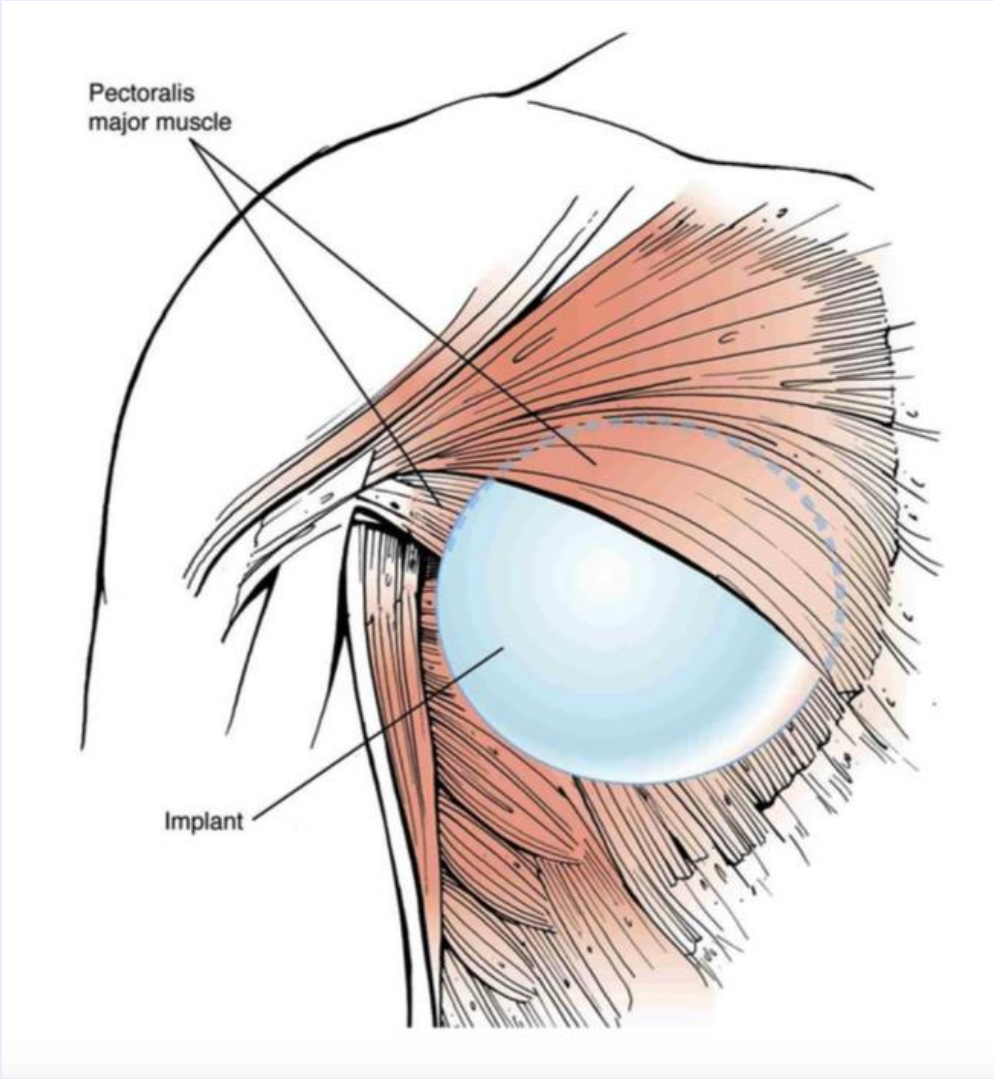
Submuscular



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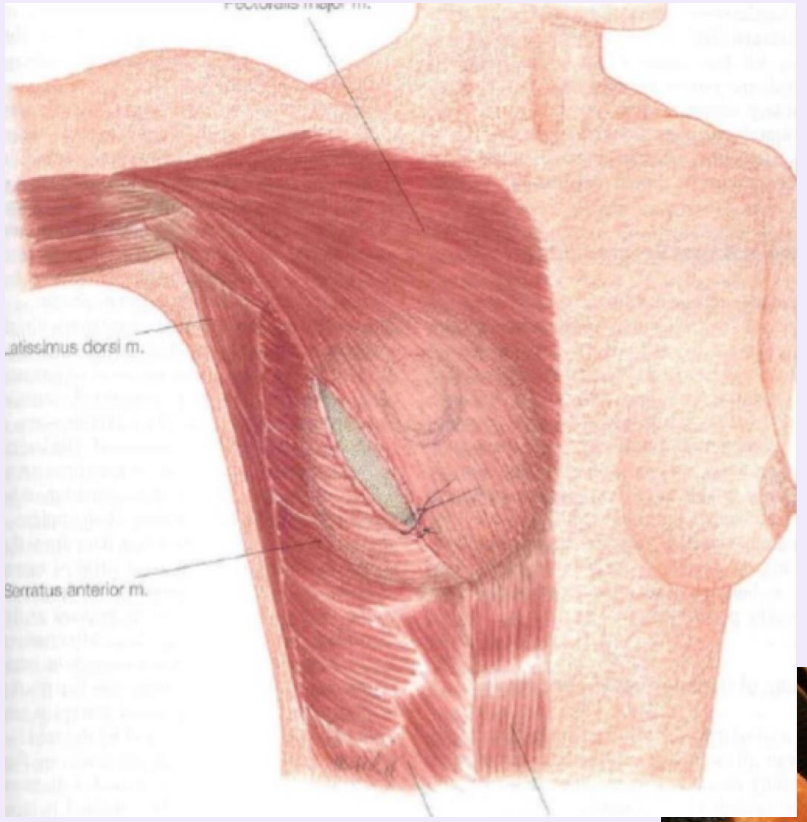

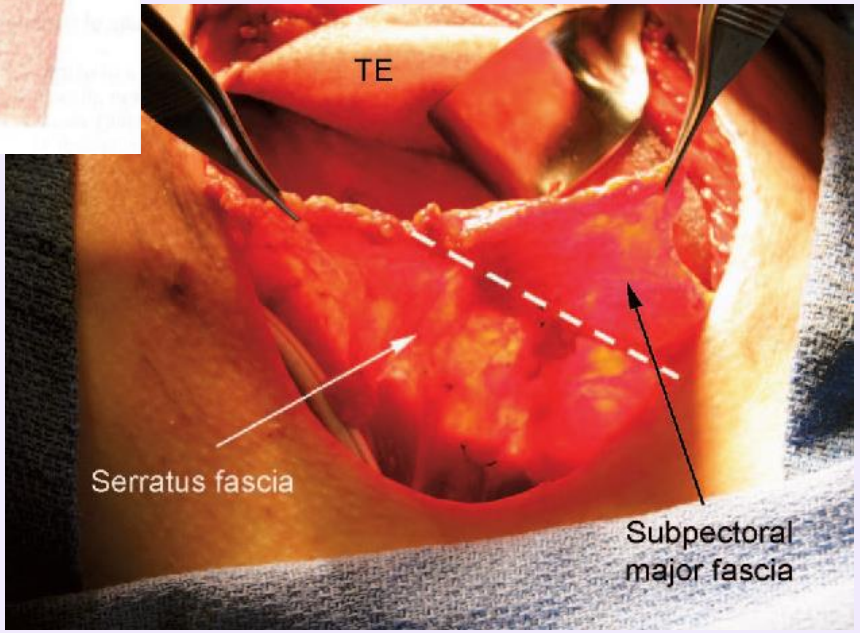

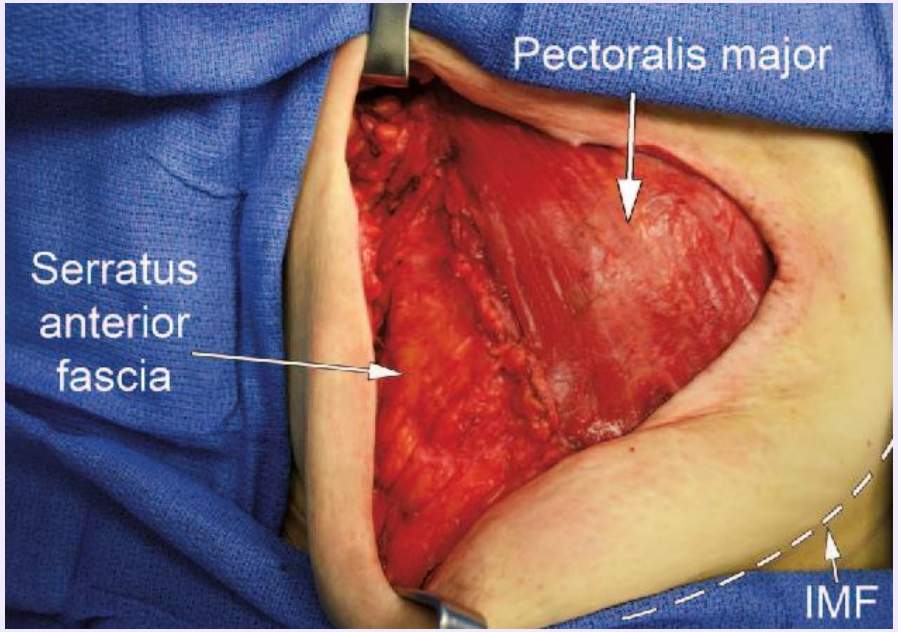

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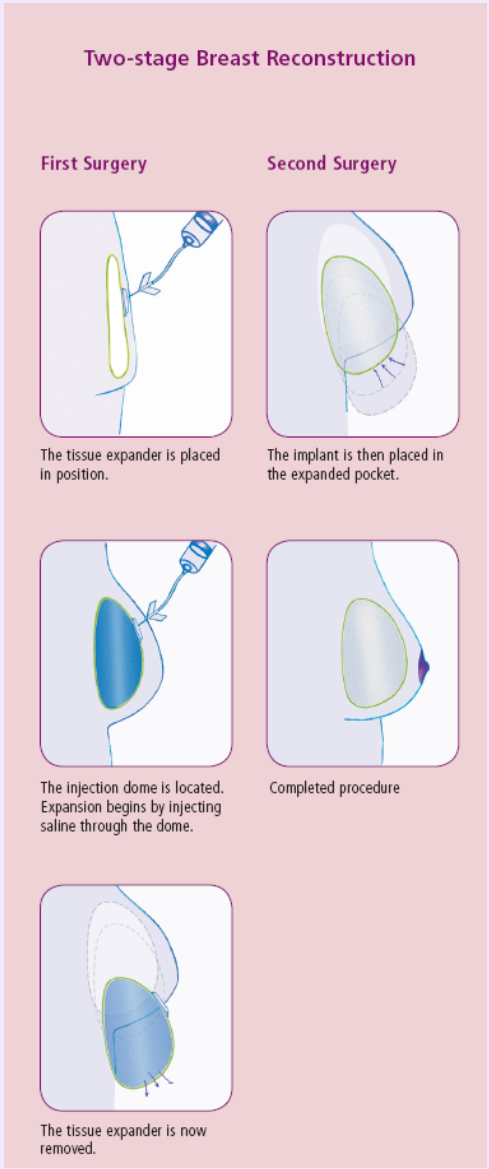
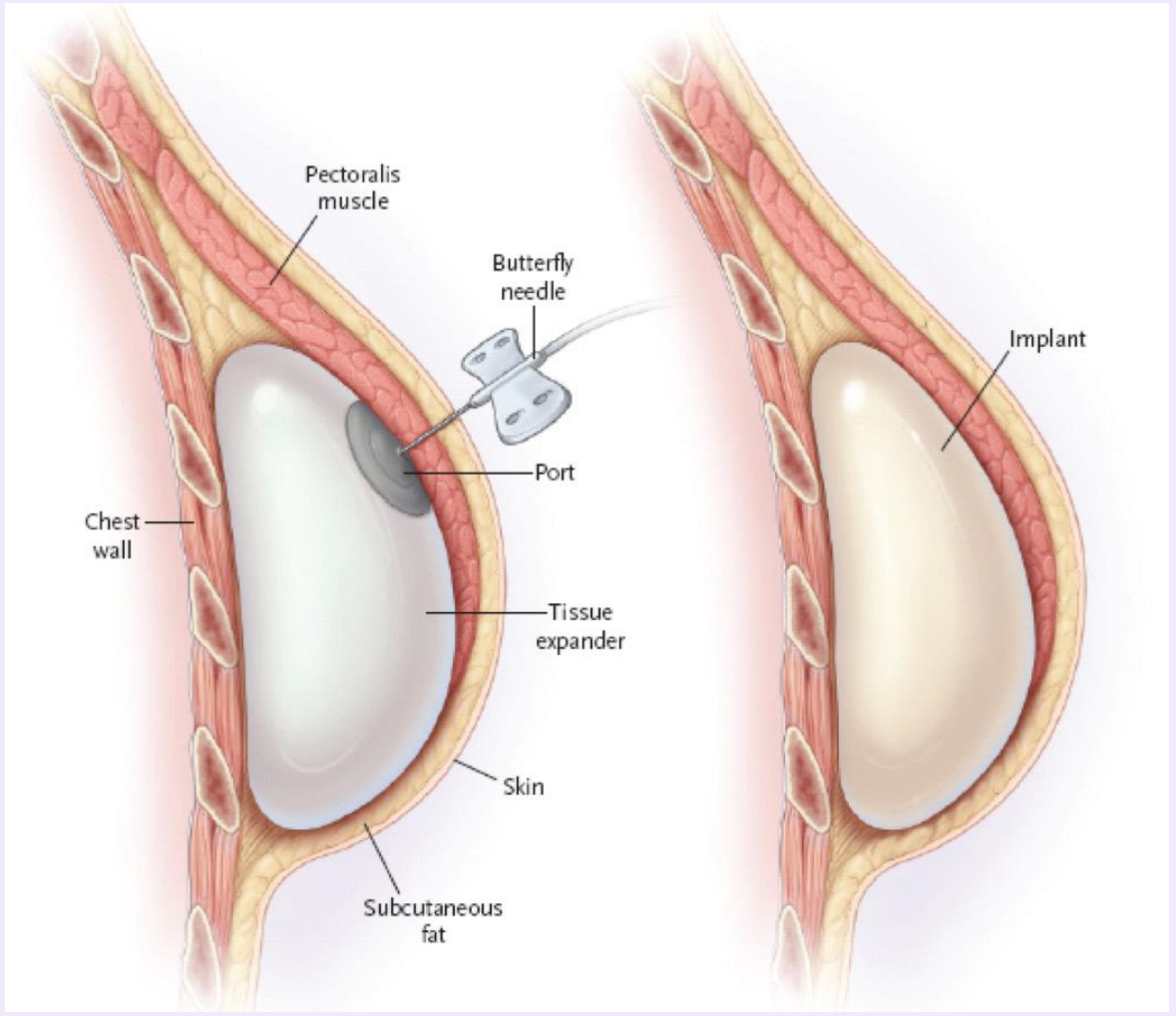
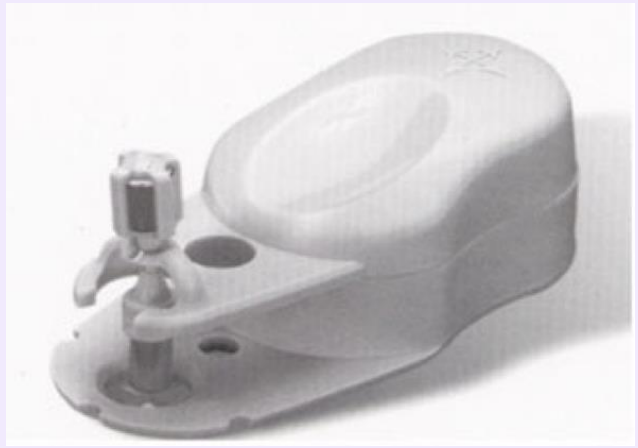
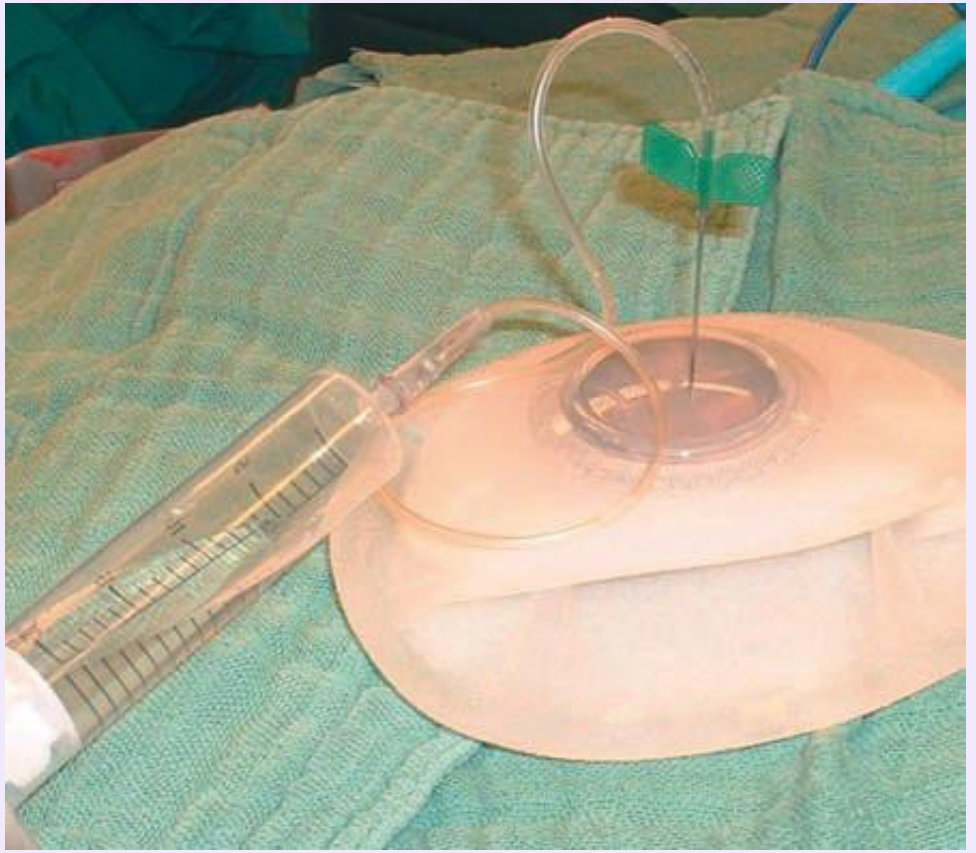
Tissue Expander/ Implant Reconstruction (Two Stage)





Tissue Expander/ Implant Reconstruction (Two Stage)





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Dual Plane
Single Stage Direct-to-Implant (DTI) Reconstruction

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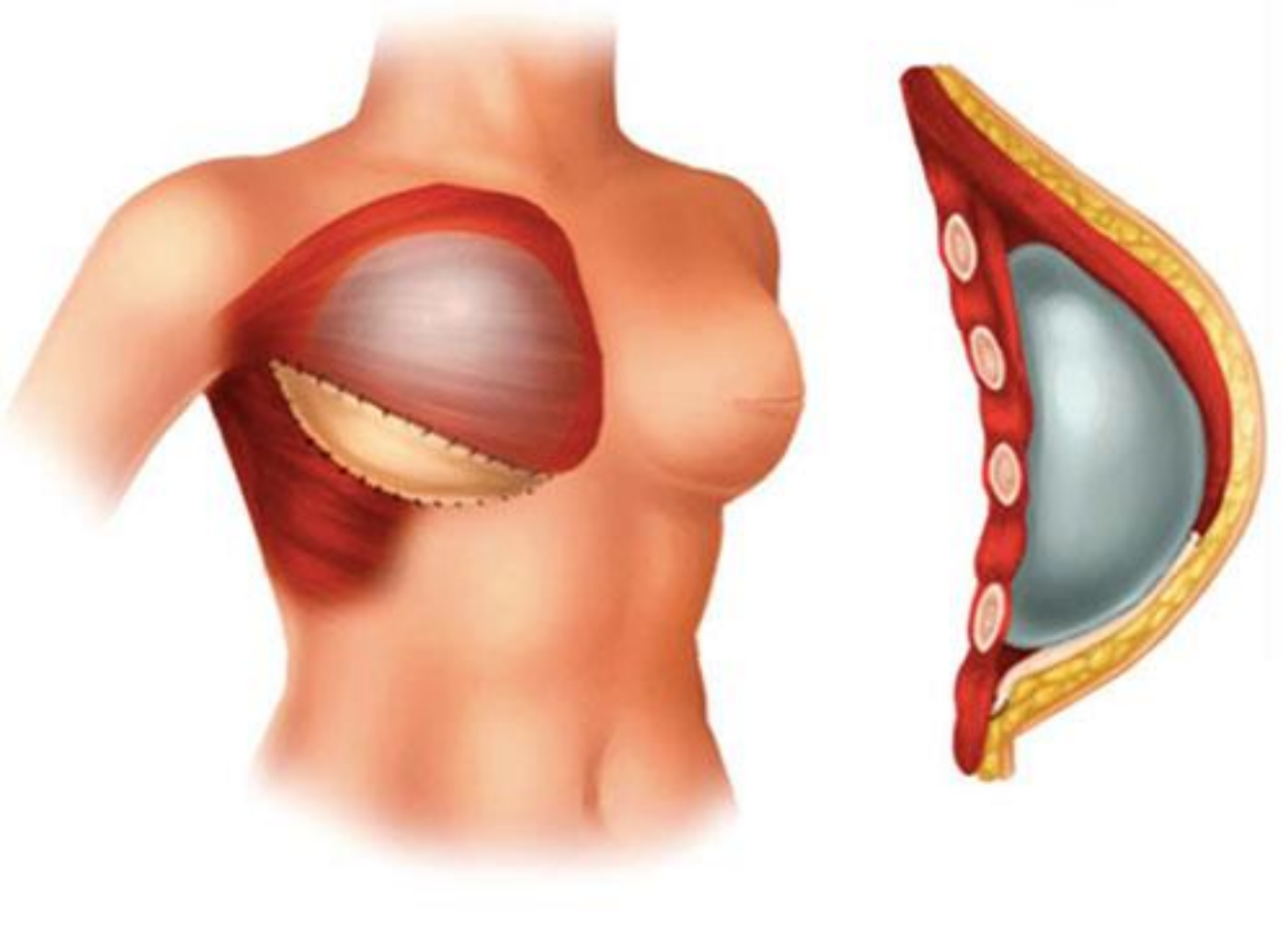

Dual-plane Reconstruction- Partial muscle overage + ADM approach:
the pectoralis muscle reinforces the upper pole and ADM reinforces the lower pole

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Acellular Dermal Matrices (ADM)

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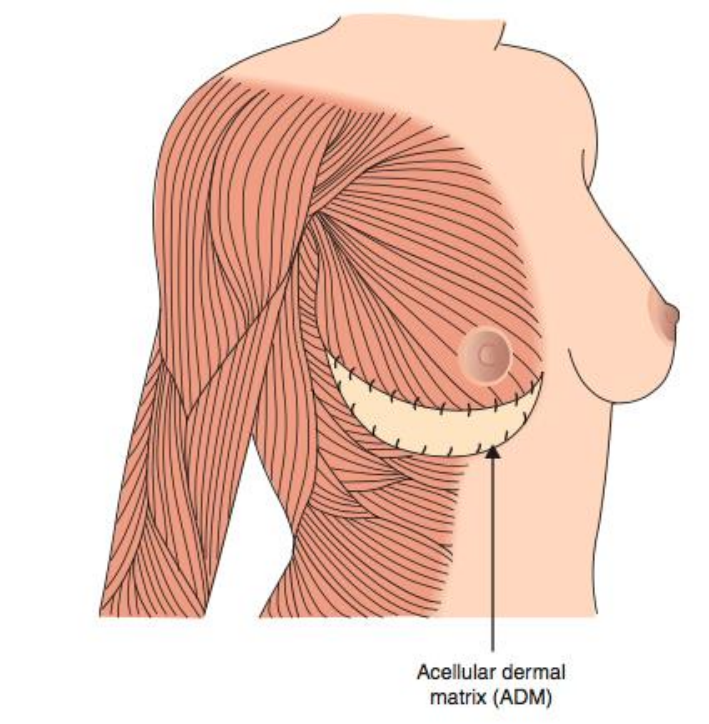

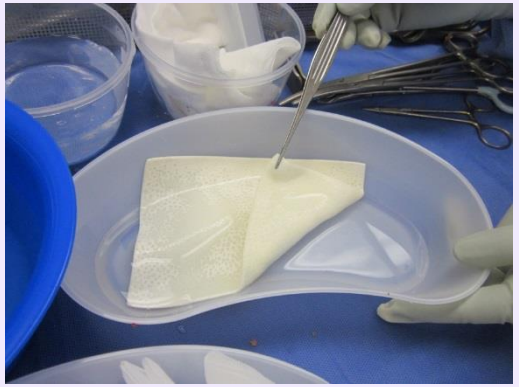

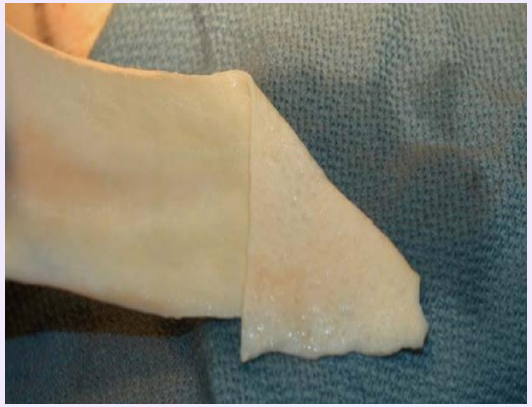

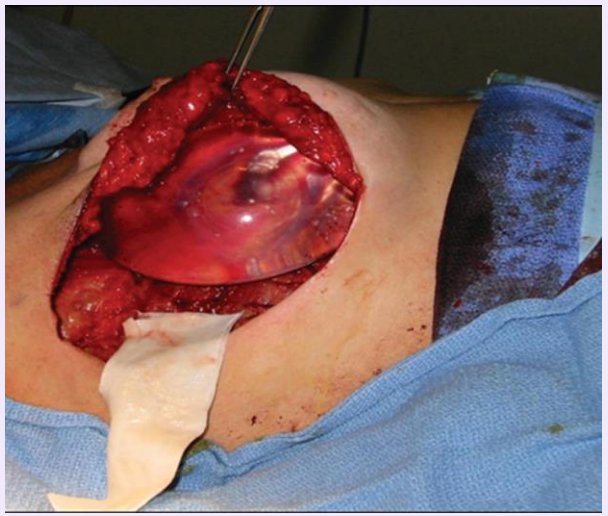

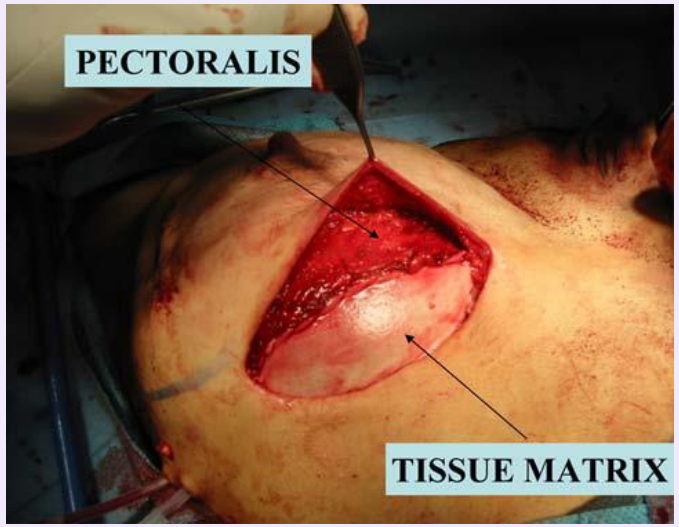

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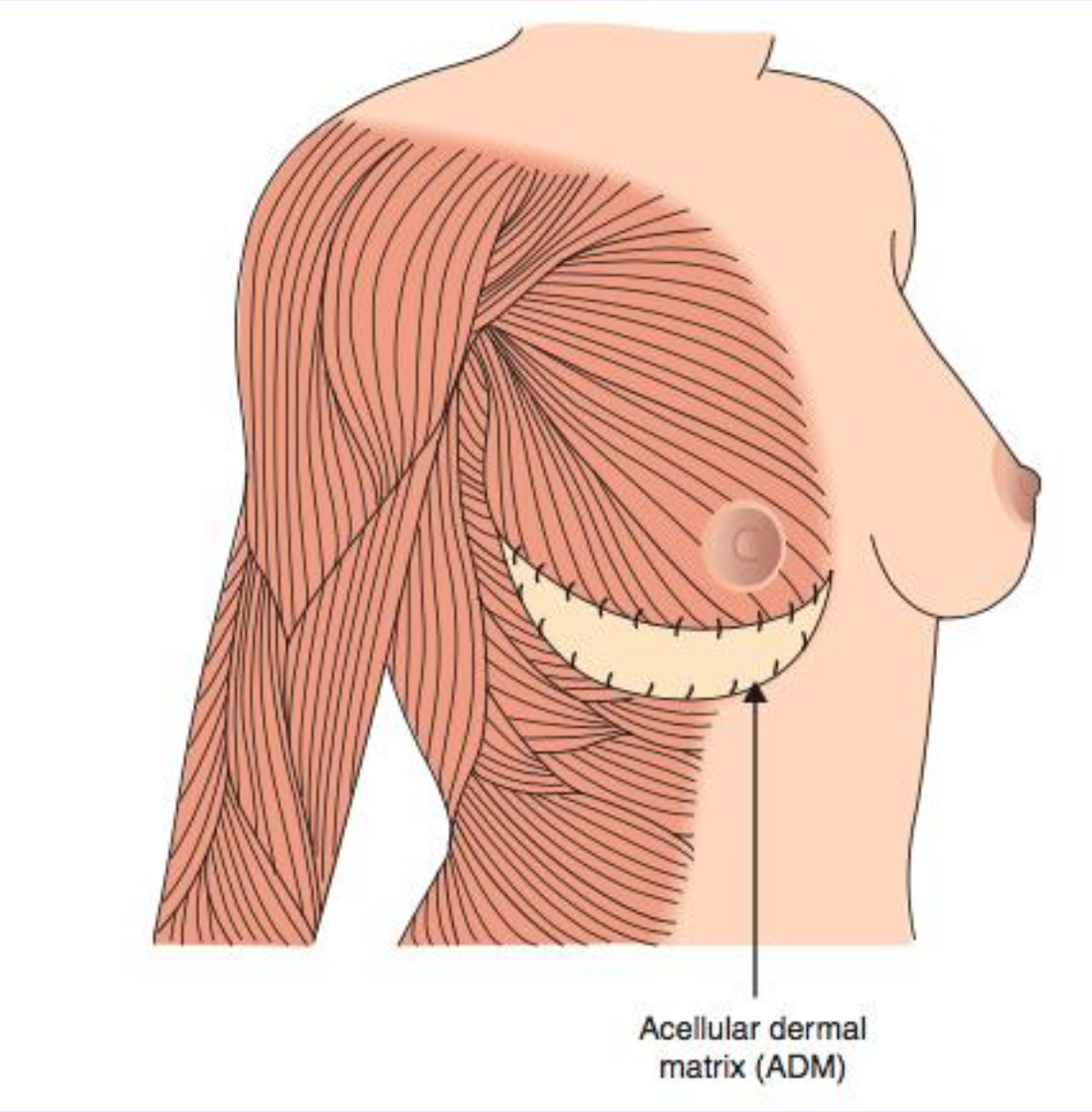

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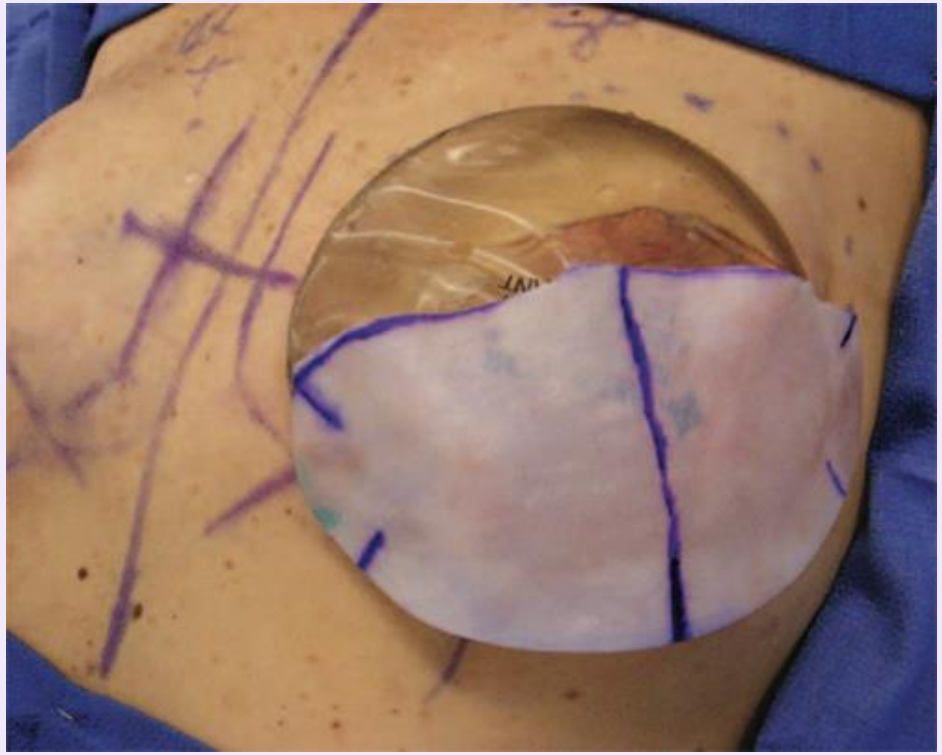

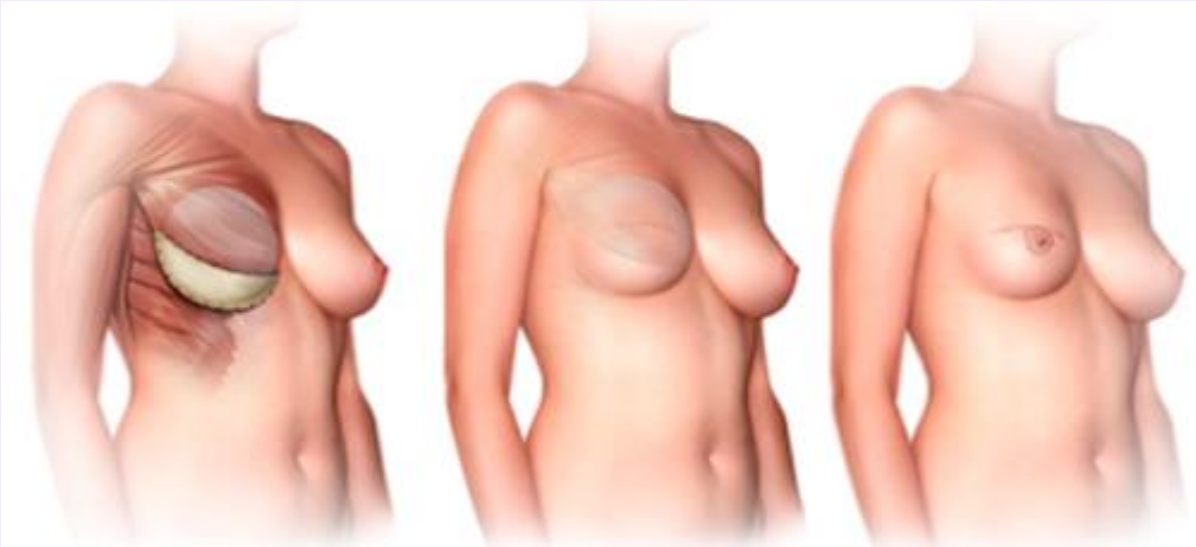

Embrace the Change: Incorporating Single-Stage Implant Breast Reconstruction into Your Practice

Jose Rodriguez-Feliz, M.D.
Mark A. Codner, M.D.
Atlanta, Ga.

Background: Multiple studies have reported on the safety of nipple-sparing mastectomy and low complication rates associated with single-stage implant breast reconstruction. Yet many plastic surgeons continue to be resistant to change. This article presents the senior author's (M.A.C.) experience during his transition period from the latissimus dorsi flap with adjustable implants to a "one-and-done" approach using shaped implants and fetal bovine acellular dermal matrix.
Methods: A literature review was performed selecting articles discussing single-stage implant reconstruction, indications, outcomes, technique, and complications. Additional articles were selected after review of the references of identified articles. Clinical pearls discussed include patient selection, implant selection, and mastectomy incision choices, with a detailed description of the senior author's operative technique.
Results: Twenty-seven single-stage implant reconstructions were performed. Average mastectomy weight was 343.82 g. The average implant volume was 367 cc. Shaped implants were most commonly used. Acellular dermal matrix was used in all breasts. Complications included erythema requiring intravenous antibiotics (three patients), skin ischemia caused by methylene blue (one patient), seroma (one patient), unilateral partial nipple necrosis (one patient), mastectomy skin necrosis (one patient), and exposed/infected implants that were salvaged using a sequential irrigation protocol described by Sforza et al. in 2014 (two patients).
Conclusions: Breast reconstruction after mastectomy has evolved toward less invasive, single-stage procedures. Aesthetic refinements include nipple-sparing mastectomy, use of acellular dermal matrix, shaped implants, and fat grafting. Selected patients will benefit from a one-and-done breast implant reconstruction with no additional oncologic risk. Surgeons must embrace the change and provide their patients with a procedure that will offer the best aesthetic outcomes. (*Plast. Reconstr. Surg.* 136: 221, 2015.)
CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, IV.

4 THERAPEUTIC

"Breast in a Day": Examining Single-Stage Immediate, Permanent Implant Reconstruction in Nipple-Sparing Mastectomy

Mihye Choi, M.D.
Jordan D. Frey, M.D.
Michael Alperovich, M.D.
Jamie P. Levine, M.D.
Nolan S. Karp, M.D.
New York, N.Y.

Background: Nipple-sparing mastectomy with immediate, permanent implant reconstruction offers patients a prosthetic "breast in a day" compared to tissue expander techniques requiring multiple procedures.
Methods: Patients undergoing nipple-sparing mastectomy with immediate, permanent implant reconstruction were reviewed with patient demographics and outcomes analyzed.
Results: Of 842 nipple-sparing mastectomies from 2006 to June of 2015, 160 (19.0 percent) underwent immediate, permanent implant reconstruction. The average age and body mass index were 46.5 years and 23.3 kg/m². The majority of implants were either Allergan Style 20 (48.1 percent) or Style 15 (22.5 percent). The average implant size was 376.2 ml, and 91.3 percent of reconstructions used acellular dermal matrix. The average number of reconstructive operations was 1.3. Follow-up was 21.9 months. The most common major complication was major mastectomy flap necrosis (8.1 percent). The rate of reconstructive failure was 5.6 percent and implant loss was 4.4 percent. The most common minor complication was minor mastectomy flap necrosis (14.4 percent). The rates of full-thickness and partial-thickness nipple necrosis were 4.4 and 7.5 percent, respectively. Age older than 50 years ($p = 0.0276$) and implant size greater than 400 ml ($p = 0.0467$) emerged as independent predictors of overall complications. Obesity ($p = 0.4073$), tobacco use ($p = 0.2749$), prior radiation therapy ($p = 0.4613$), and acellular dermal matrix ($p = 0.5305$) were not associated with greater complication rates.
Conclusion: Immediate, permanent implant reconstruction in nipple-sparing mastectomy provides patients with a breast in a day in less than two procedures, with a low complication rate. (*Plast. Reconstr. Surg.* 138: 184e, 2016.)
CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, IV.

4 THERAPEUTIC

PRSJ, Aug 2016

31% reoperation rate

Role of Two Stage Procedure in the ADM Era

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- ADM not available
- Patient wishing to upsize significantly
- Mastectomy skin flap viability felt to be questionable intraoperatively

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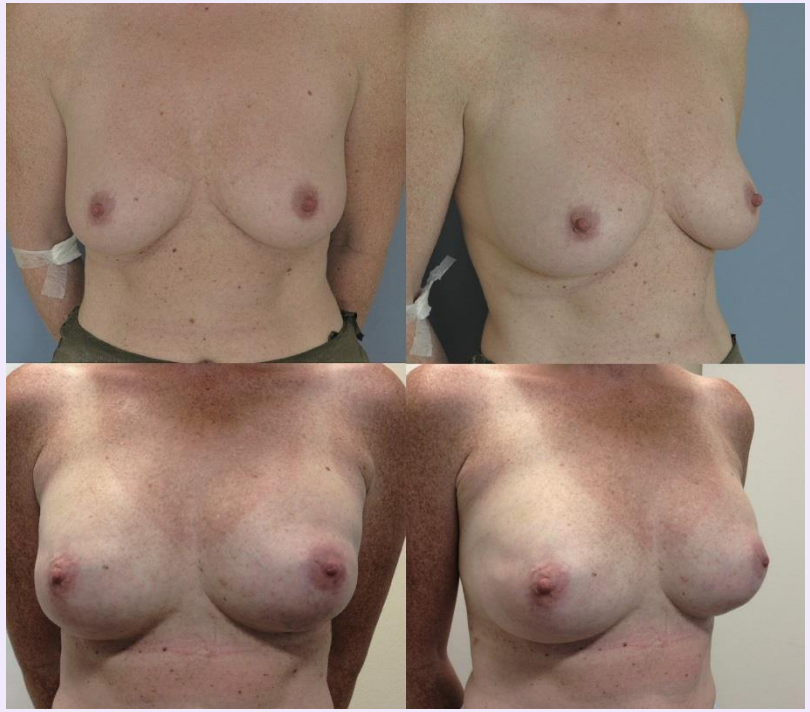
Ideal Candidate for DTI Reconstruction:

- Healthy, non-smoker
- Small to moderate sized breast
- Undergoing NSM and desires to be a similar breast size
- Undergoing SSM and desires to be a smaller breast size



Animation Deformity

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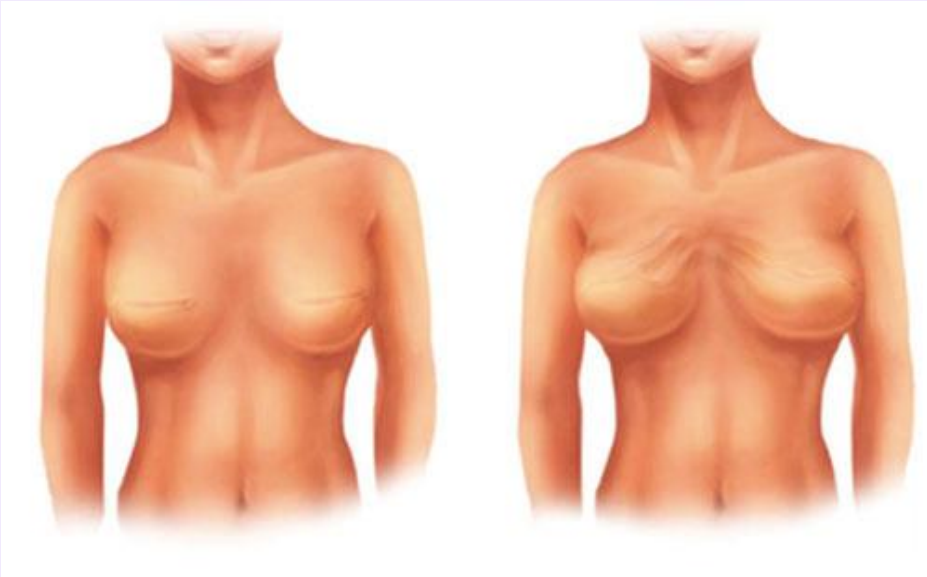
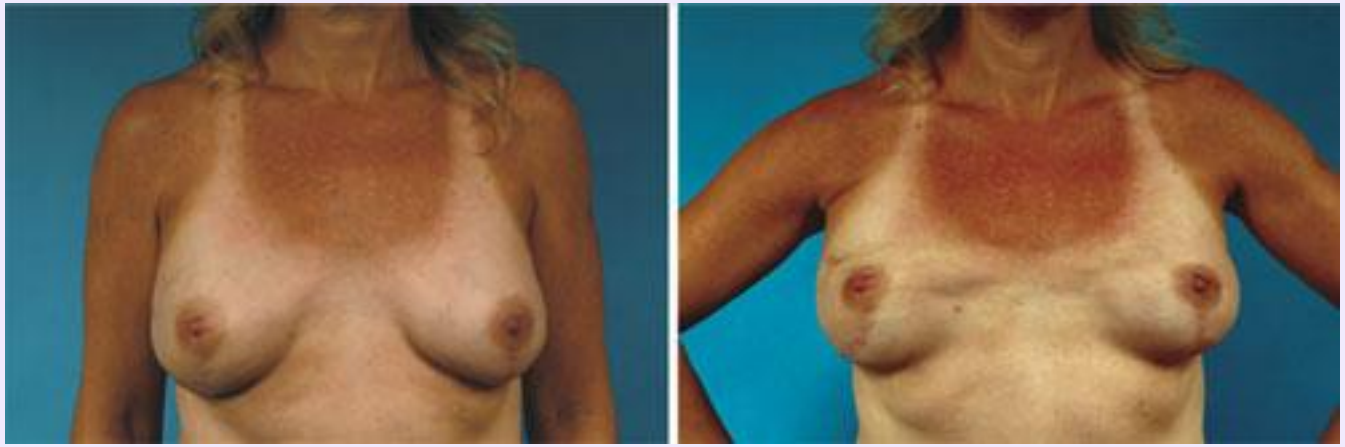


- The unnatural movement of the breast when the pectoral muscle is activated
- It occurs with any movement of the pectoralis major muscle, and results in visible contraction and displacement of the breast
- The unnatural movement wrinkles the skin and pushes the implant down and outward.



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"Prepectoral" Implant Based Reconstruction

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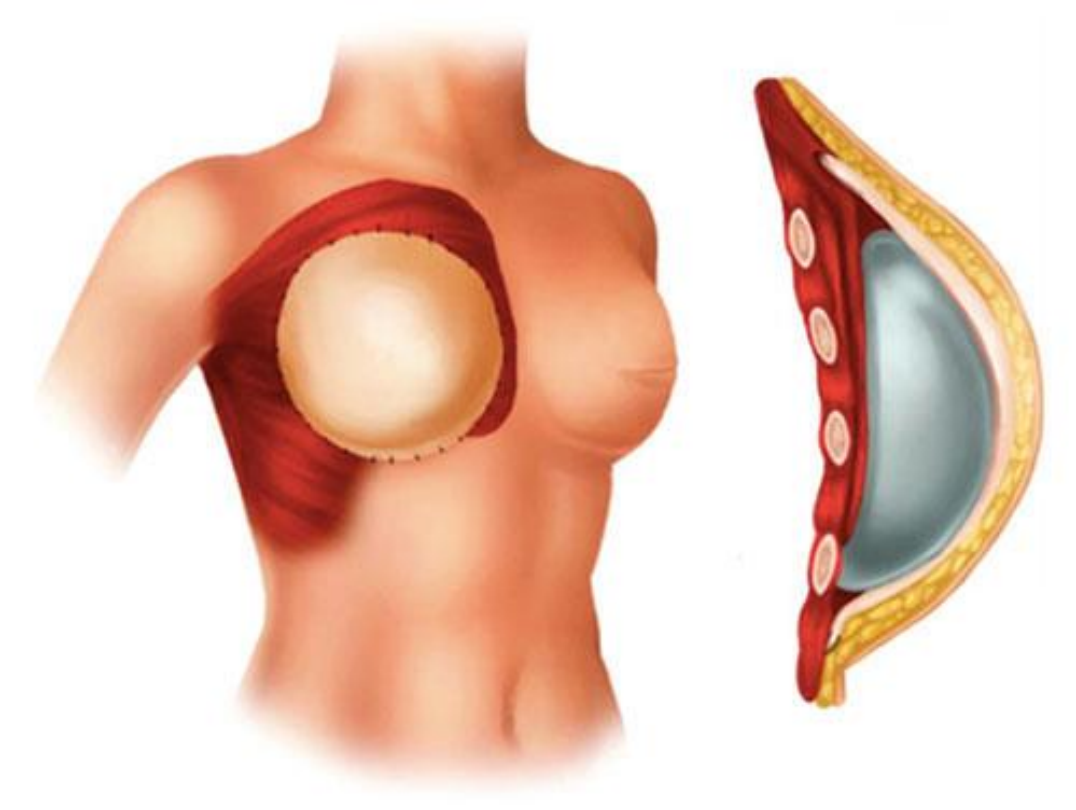

Prepectoral approach:

- Implant is placed in the subcutaneous, prepectoral plane
- ADM provides overlying reinforcement

- Prepectoral reconstruction is an alternative to the more common "subpectoral" and "dual-plane" approaches
- Autologous tissue flap reconstructions such as DIEP flaps are routinely placed prepectorally

3 Benefits of Pre-Pectoral Reconstruction

- The patient experiences less pain compared to implants placement under the chest muscle.
- Movement and contraction of the chest muscle will not affect the implant and therefore limits animation deformity.
- A more natural-appearing, shaped breast can be achieved with this method.

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Rationale for Prepectoral Implant Placement

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- Breast is naturally in the prepectoral position
- Immediate DIEP flap is placed prepectorally
- Large piece of ADMcan be used to mimic muscle coverage and avoid pitfalls of subcutaneous placement
- Procedure potentially associated with less morbidity, less pain and faster recovery

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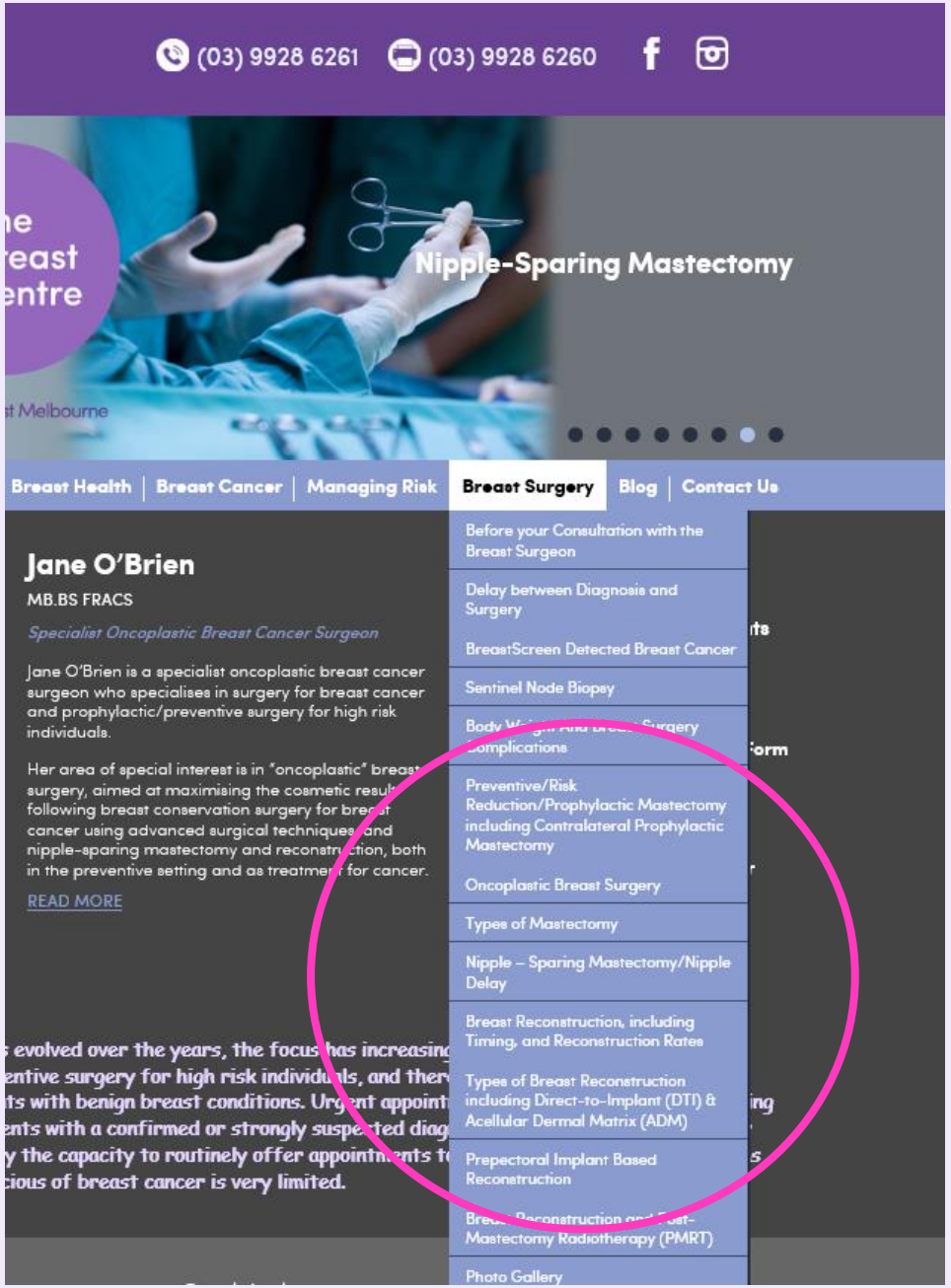

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Evolution of the Surgical Technique for "Breast in a Day" Direct-to-Implant Breast Reconstruction: Transitioning from Dual-Plane to Prepectoral Implant Placement

Anuja K. Antony, M.D., M.P.H., M.B.A.
Jennifer Poirier, Ph.D.
Andrea Madrigrano, M.D.
Katherine A. Kopkash, M.D.
Emilie C. Robinson, M.D.
Chicago and Evanston, Ill.

Background: Direct-to-implant breast reconstruction offers the intuitive advantages of shortening the reconstructive process and reducing costs. In the authors' practice, direct-to-implant breast reconstruction has evolved from dual-plane to prepectoral implant placement. The authors sought to understand postoperative complications and aesthetic outcomes and identify differences in the dual-plane and prepectoral direct-to-implant subcohorts.
Methods: A retrospective review of a prospectively maintained database was conducted from November of 2014 to March of 2018. Postoperative complication data, reoperation, and aesthetic outcomes were reviewed. Aesthetic outcomes were evaluated by a blinded panel of practitioners using standardized photographs.
Results: One hundred thirty-four direct-to-implant reconstructions were performed in 81 women: 42.5 percent were dual-plane ($n = 57$) and 57.5 percent were prepectoral ($n = 77$). Statistical analysis was limited to patients with at least 1 year of follow-up. Total complications were low overall (8 percent), although the incidence of prepectoral complications [$n = 1$ (2 percent)] was lower than the incidence of dual-plane complications [$n = 7$ (12 percent)], with the difference approaching statistical significance ($p = 0.07$). Panel evaluation for aesthetic outcomes favored prepectoral reconstruction. Pectoralis animation deformity was completely eliminated in the prepectoral cohort.
Conclusions: The authors present the largest comparative direct-to-implant series using acellular dermal matrix to date. Transition to prepectoral direct-to-implant reconstruction has not resulted in increased complications, degradation of aesthetic results, or an increase in revision procedures. Prepectoral reconstruction is a viable reconstructive option with elimination of animation deformity and potential for enhanced aesthetic results. (*Plast. Reconstr. Surg.* 143: 1547, 2019.)
CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, III.

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Patient Selection Criteria for Prepectoral Reconstruction

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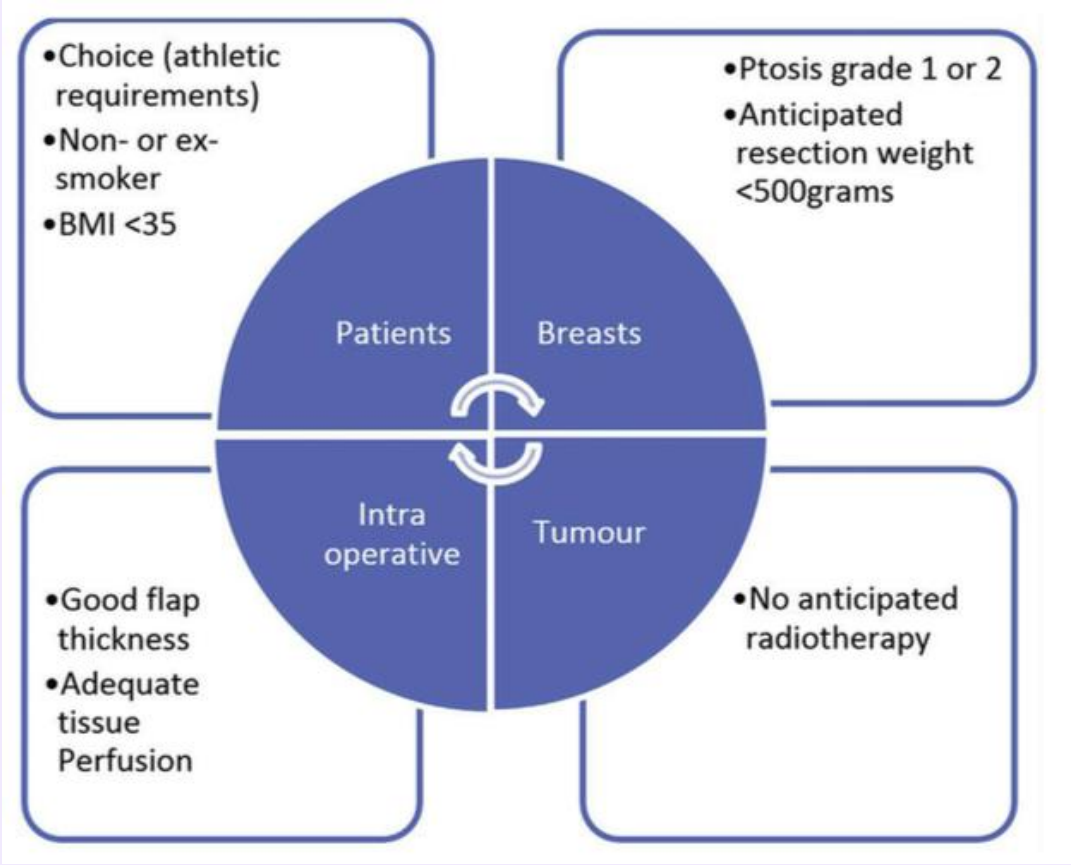
- Patients with minimal comorbidities, an active lifestyle, small- to medium-sized breasts, and good intraoperative tissue perfusion are good candidates for this surgery
- Body mass index (BMI) < 35 kg/m2
- Non or ex-smokers
- Grade 1 or 2 ptosis (ie breasts that are not very saggy)
- Anticipated breast volume of resection less than 500g
- Patient lifestyle should be taken into consideration, particularly athletes who require extensive pectoralis major use and require preserve shoulder functionality.



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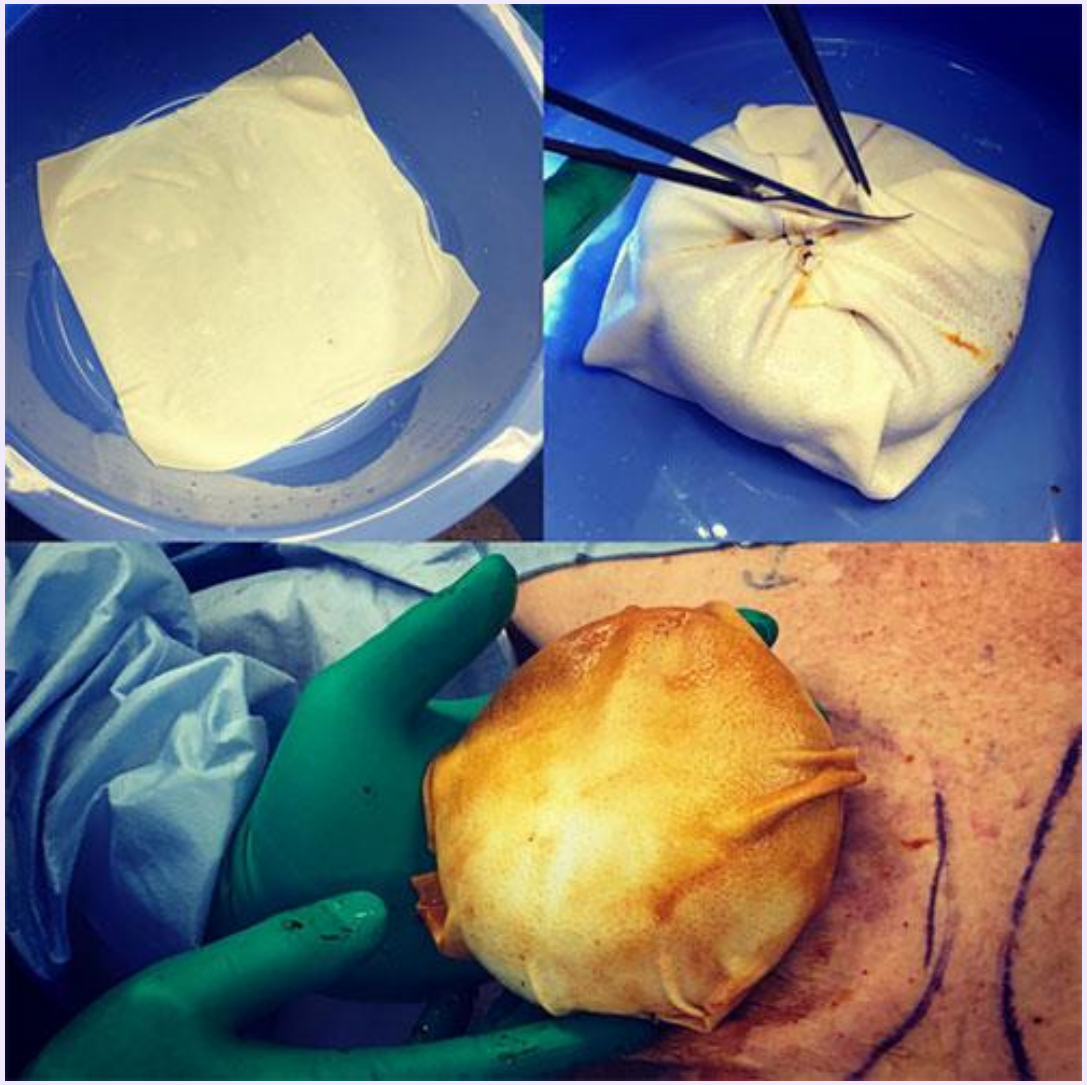

In last 12 months in my practice:

* 38% implant based reconstructions at the time of mastectomy for breast cancer were prepectoral (with ADM)

*60% of patients undergoing bilateral risk reduction mastectomy with implant based recon underwent prepectoral direct-to-implant (DTI) reconstruction with ADM.

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Downsides to Prepectoral Implant Placement

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- Larger piece of ADM = much greater cost +++
- Thin skin envelope = implant rippling
- Poor skin flap perfusion, delayed wound healing

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Prepectoral placement is the next step in the evolution of implant based breast reconstruction

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- Provides a more appropriate anatomic reconstruction, similar to immediate DIEP flap
- Offers less pain, less morbidity, less animation deformity and faster recovery
- Requires larger pieces of ADM which increase cost and may increase seroma rates

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Rippling

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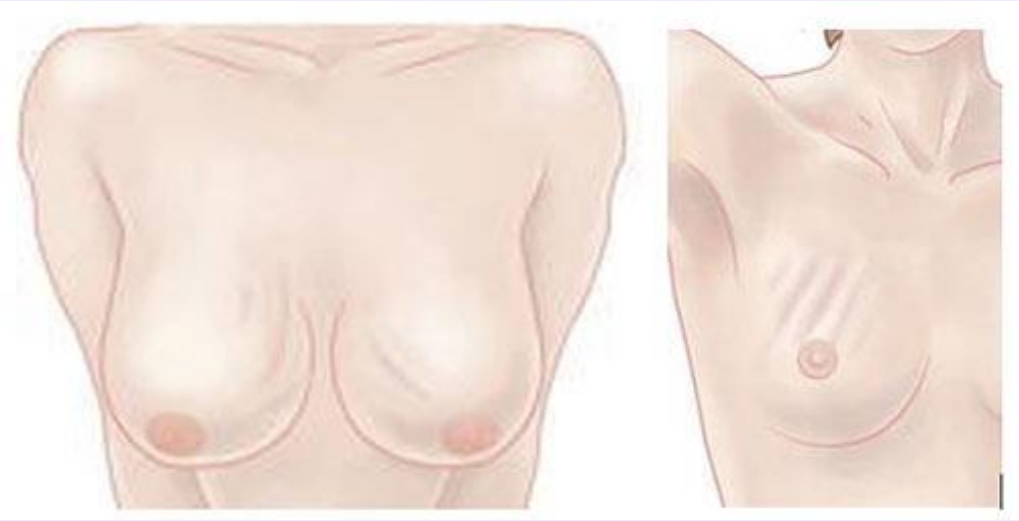

- Rippling refers to visible folds on the surface of the reconstructed breast, transmitted from an underlying breast implant, and is typically most apparent in the upper inner portions of the breast
- In prepectoral breast reconstruction, the pectoralis major muscle is not available to provide an additional layer of soft tissue coverage over the upper pole of the implant
- The thinner flaps provide less fullness in the upper pole of the breast and do less to camouflage the edges of the implant or wrinkles in the outer shell that manifest themselves as skin rippling or contour irregularities.
- One potential risk of prepectoral breast reconstruction therefore is a higher rate of visible "rippling" over the permanent implants, given the thinner upper pole coverage, compared with submuscular/dual plane reconstruction.

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Fat Grafting

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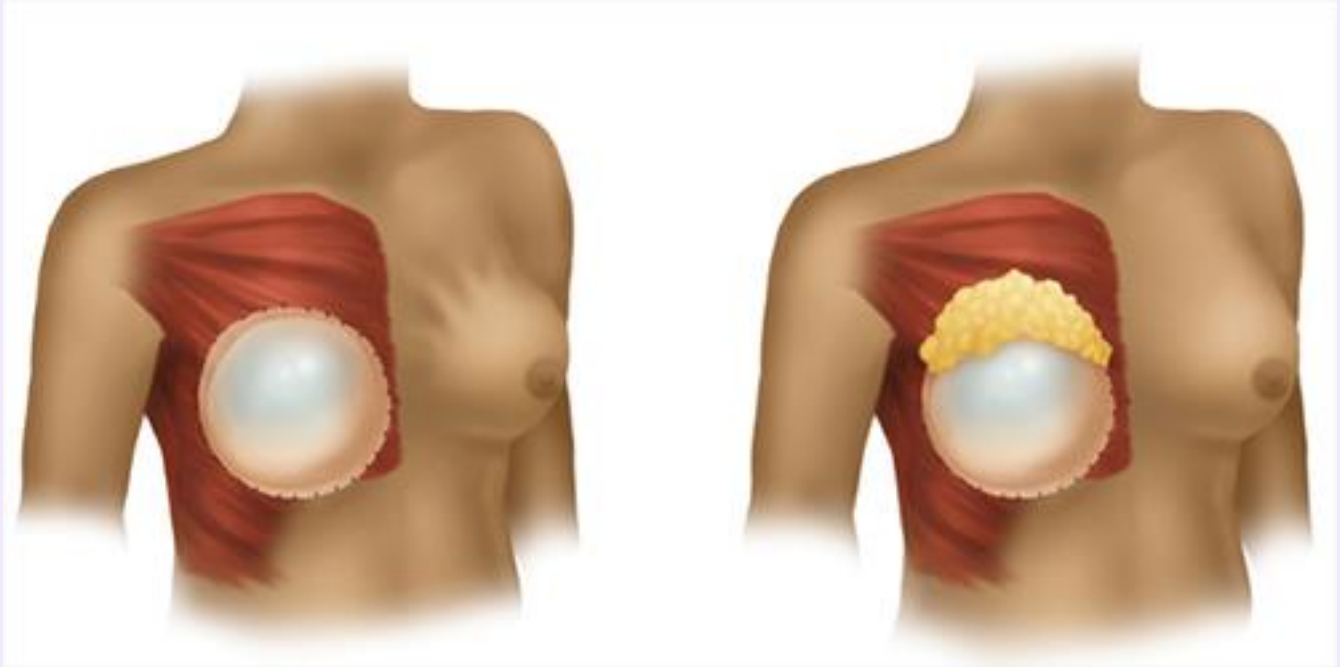
- Without submuscular or partial subpectoral placement of the implant, there may be a clear "step-off" visible between the chest wall and the prepectoral implant

- The primary means for correcting these deformities is autologous fat grafting.



Prepectoral implant reconstruction (left), demonstrating "rippling" deformity. Fat grafting to upper pole (right) corrects defect.

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Ann Surg Oncol (2012) 19:3171–3176
DOI 10.1245/s10434-012-2528-7

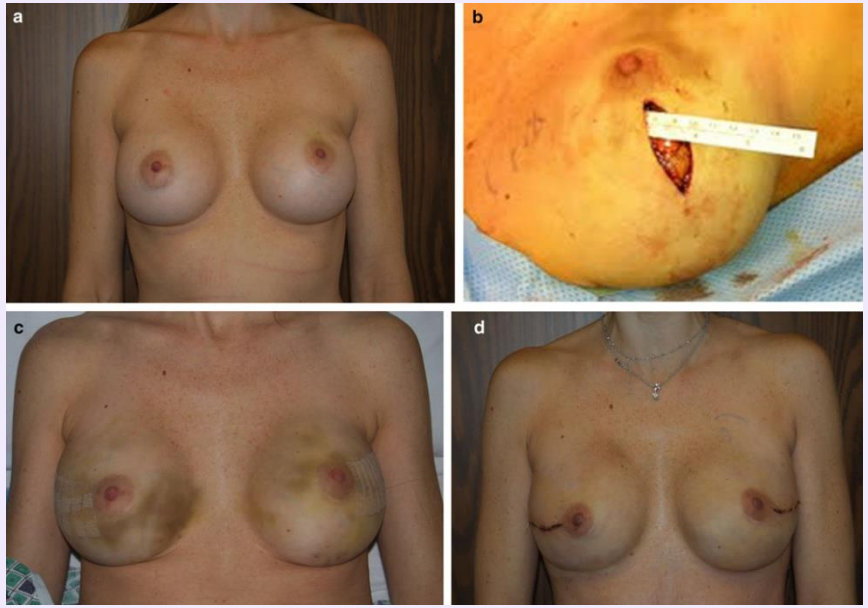
Annals of
SURGICAL ONCOLOGY
OFFICIAL JOURNAL OF THE SOCIETY OF SURGICAL ONCOLOGY

ORIGINAL ARTICLE – BREAST ONCOLOGY

Surgical Delay of the Nipple–Areolar Complex: A Powerful Technique to Maximize Nipple Viability Following Nipple-Sparing Mastectomy

J. Arthur Jensen, MD[1,2], Jennifer H. Lin, MD[2], Nimmi Kapoor, MD[2,3], and Armando E. Giuliano, MD[2,4]

[1]Division of Plastic Surgery, Geffen School of Medicine at U.C.L.A., Los Angeles, CA; [2]Division of Surgical Oncology, John Wayne Cancer Institute at Saint John's Health Center, Santa Monica, CA; [3]Division of Surgery, Cedars Sinai Medical Center, Los Angeles, CA; [4]Division of Surgical Oncology, Cedars-Sinai Medical Center, Los Angeles, CA



Ann Surg Onc 2012

Risk Analysis and Stratification of Surgical Morbidity after Immediate Breast Reconstruction

John P Fischer, MD, Ari M Wes, BA, Charles T Tuggle, MD, Joseph M Serletti, MD, FACS, Liza C Wu, MD, FACS

BACKGROUND: Surgical complications after breast reconstruction can be associated with significant morbidity, dissatisfaction, and cost. We used the ACS-NSQIP datasets from 2005 to 2011 to derive predictors of morbidity and to stratify risk after immediate breast reconstruction (IBR).

STUDY DESIGN: Surgical complications after implant and autologous reconstruction were assessed using the ACS-NSQIP 2005 to 2011 datasets. Patient demographics, clinical characteristics, and operative factors were associated with the likelihood of experiencing a surgical complication. A "model cohort" of 12,129 patients was randomly selected from the study cohort to derive predictors. Weighted odds ratios derived from logistic regression analysis were used to create a composite risk score and to stratify patients. The remaining one-third of the cohort (n = 6,065) were used as the "validation cohort" to assess the accuracy value of the risk model.

RESULTS: On adjusted analysis, autologous reconstruction (odds ratio [OR] 1.41, $p < 0.001$), American Society of Anesthesiologists physical status ≥ 3 (OR 1.25, $p = 0.004$), class I obesity (OR 1.38, $p < 0.001$), class II obesity (OR 1.91, $p < 0.001$), class III obesity (OR 1.70, $p < 0.001$), and active smoking (OR 1.46, $p < 0.001$) were associated with complications. Risk factors were weighted and patients were stratified into low (0 to 2, n = 9,133, risk = 7.14%), intermediate (3 to 4, n = 1,935, risk = 10.90%), high (5 to 7, n = 1,024, risk = 16.70%), and very high (8 to 9, n = 37, risk = 27.02%) risk categories based on their total risk score ($p < 0.001$). Internal validation of the "model cohort" using the "validation cohort" was performed demonstrating accurate prediction of risk across groups: low (7.1% vs 7.1%, respectively, $p = 0.9$), intermediate (10.9% vs 12.0%, respectively, $p = 0.38$), high (16.7% vs 16.8%, respectively, $p = 0.95$), and very high (27.0% vs 30.0%, respectively, $p = 1.0$).

CONCLUSIONS: Surgical complications after IBR are related to preoperatively identifiable factors that can be used to accurately risk stratify patients, which may assist with counseling, selection, and perioperative decision-making. (J Am Coll Surg 2013;217:780–787.

- Obesity
- Smoking

J Am Coll Surg 2013

EJSO 2002; **28**: 815–820
doi:10.1053/ejso.2002.1308, available online at http://www.idealibrary.com on IDEAL®

EJSO
European Journal of Surgical Oncology

Smoking as a risk factor for wound healing and infection in breast cancer surgery

L. T. Sørensen*, J. Hørby*, E. Friis*, B. Pilsgaard* and T. Jørgensen†

*Department of Surgical Gastroenterology K, Bispebjerg University Hospital, Copenhagen Hospital Corporation, Denmark and †Centre for Preventive Medicine, Glostrup University Hospital, Copenhagen County, Denmark

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- Pts with a smoking history have a 6.5 times greater risk of complications following breast surgery
- Wound infection increased by 3.46 in heavy smokers and 2.95 in light smokers
- Flap necrosis- 9.22 times in heavy and 6.85 in light smokers

Options in the Larger or Ptotic (droopy) Breast

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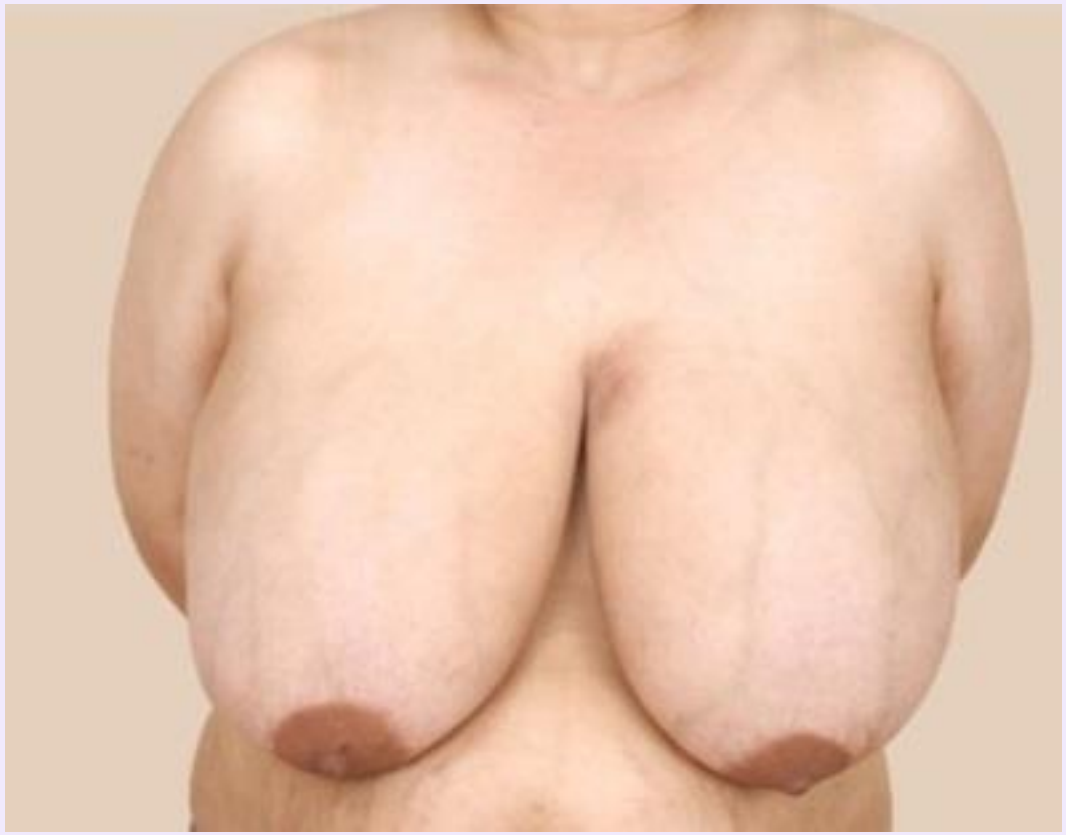
- Skin Reducing Mastectomy
- Staged NSM following mastopexy or reduction



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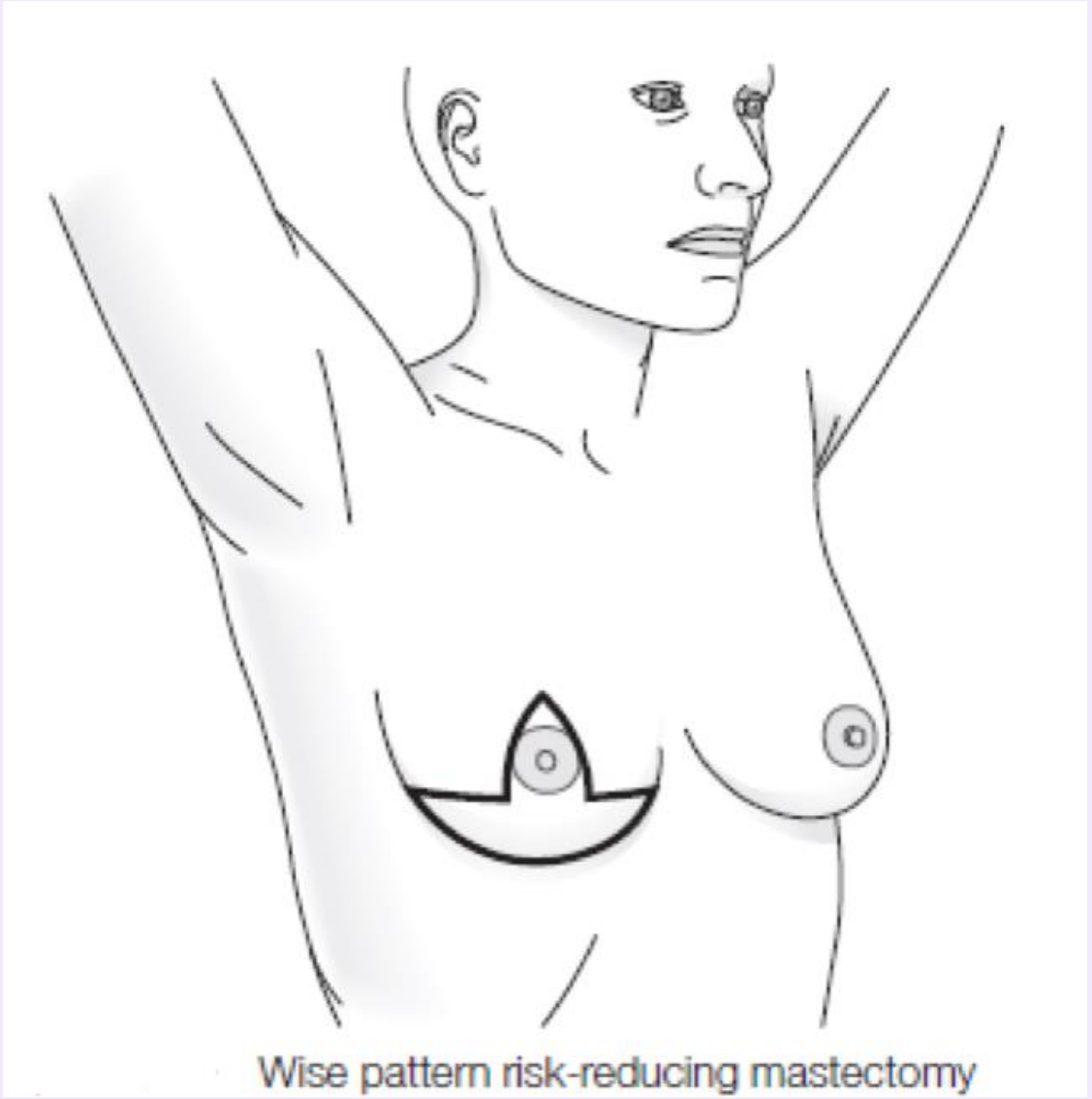
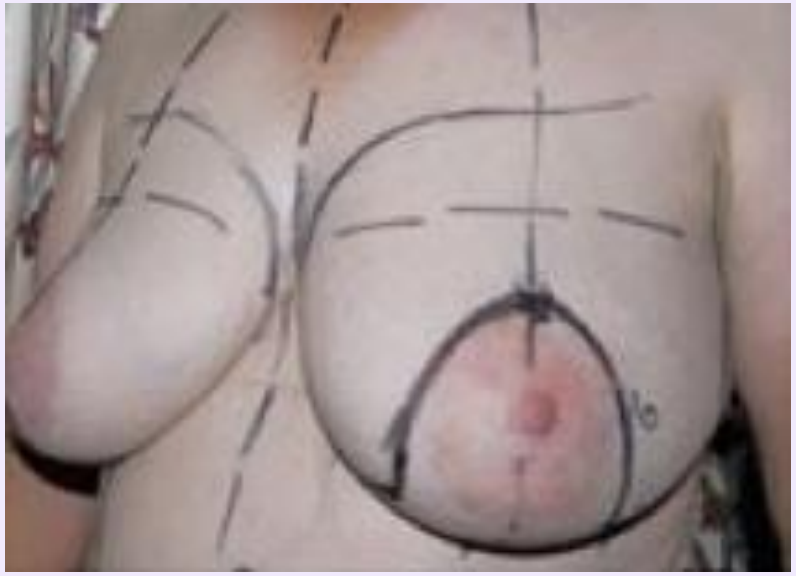
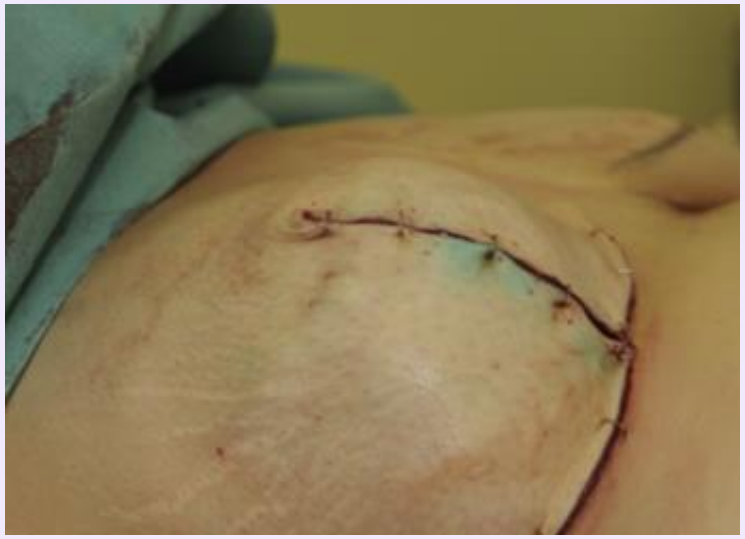
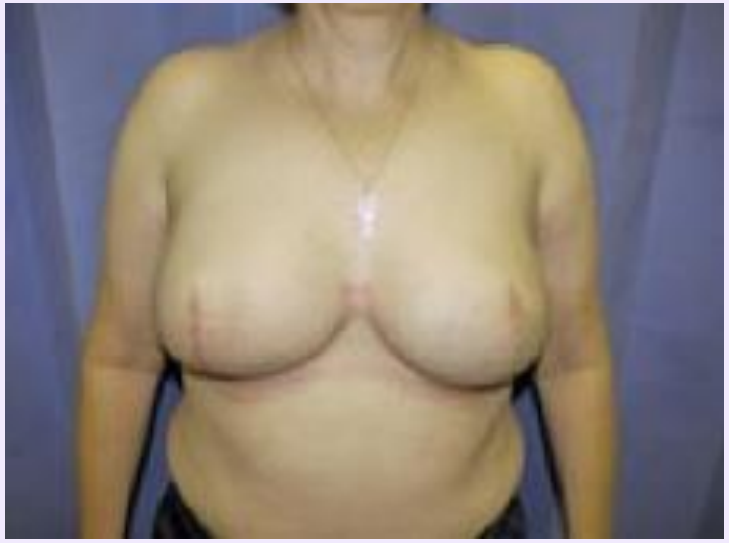
Skin-Reducing Mastectomy
"Wise Pattern"

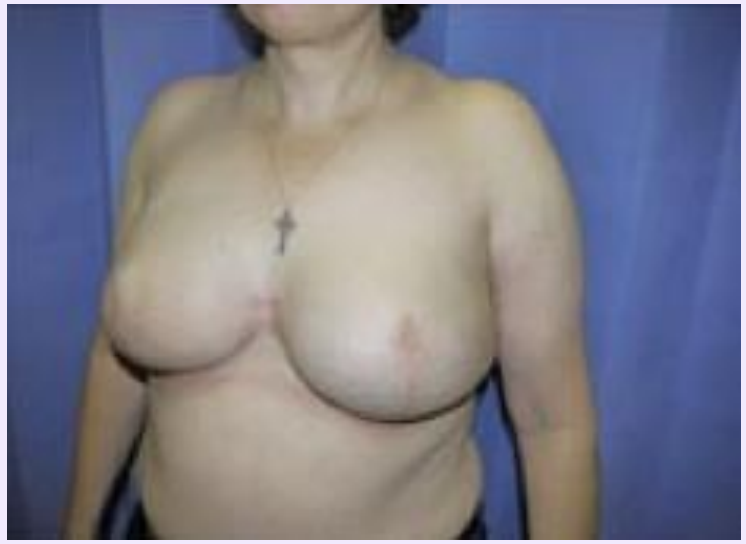


Wise pattern risk-reducing mastectomy









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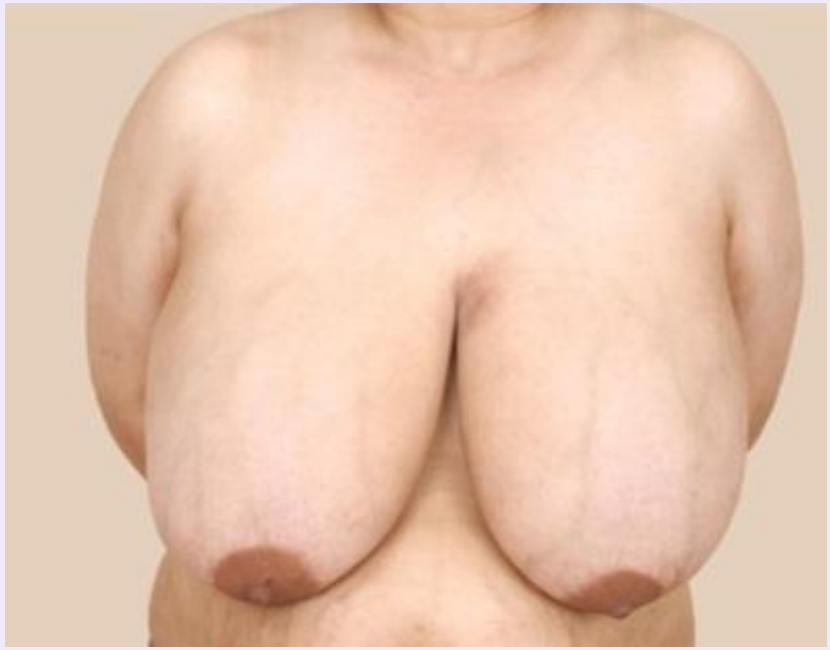

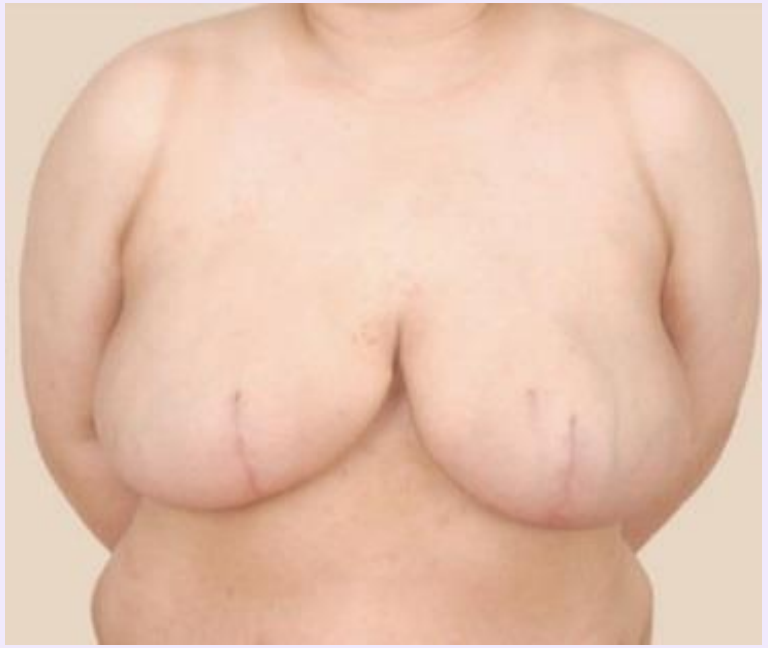

Skin Reducing Mastectomy
"Hemibatwing Pattern"

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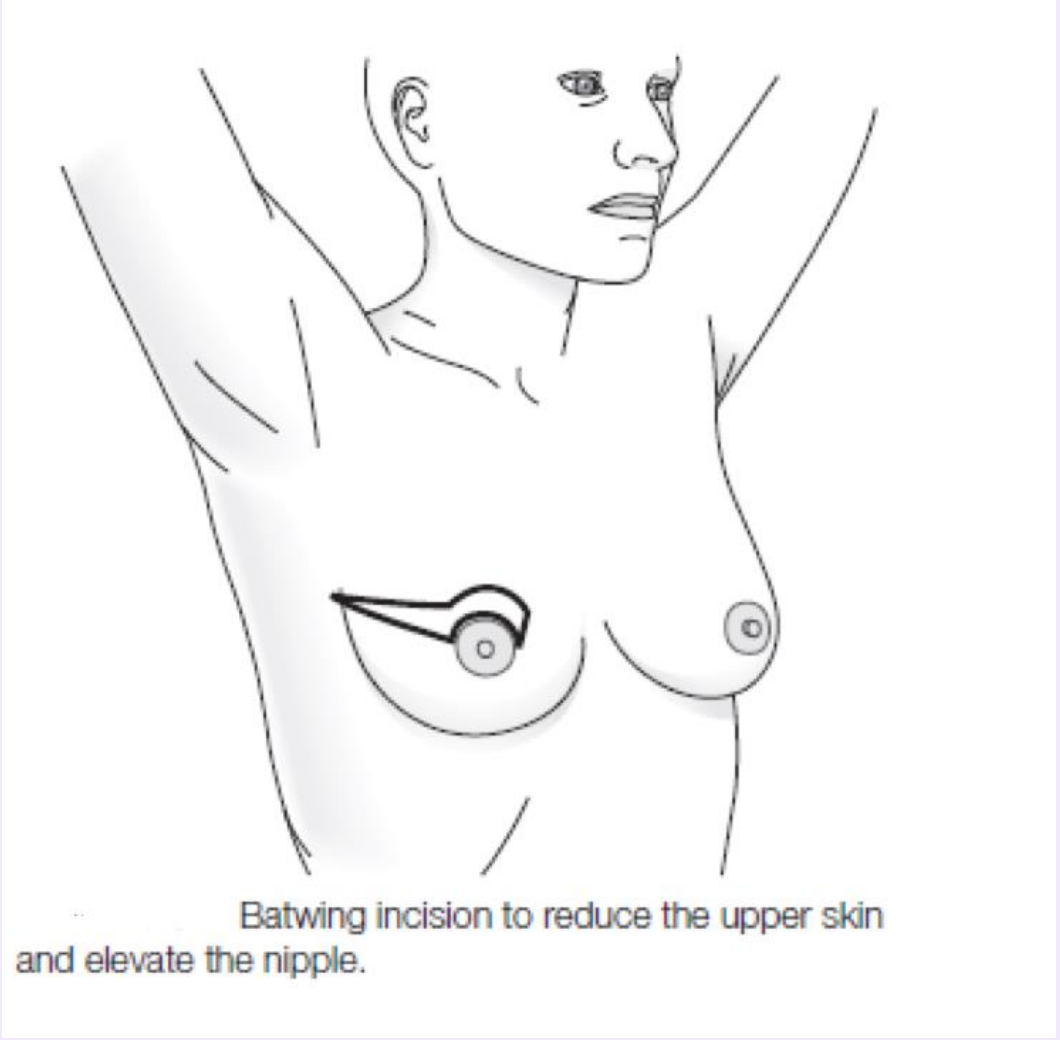

Batwing incision to reduce the upper skin and elevate the nipple.

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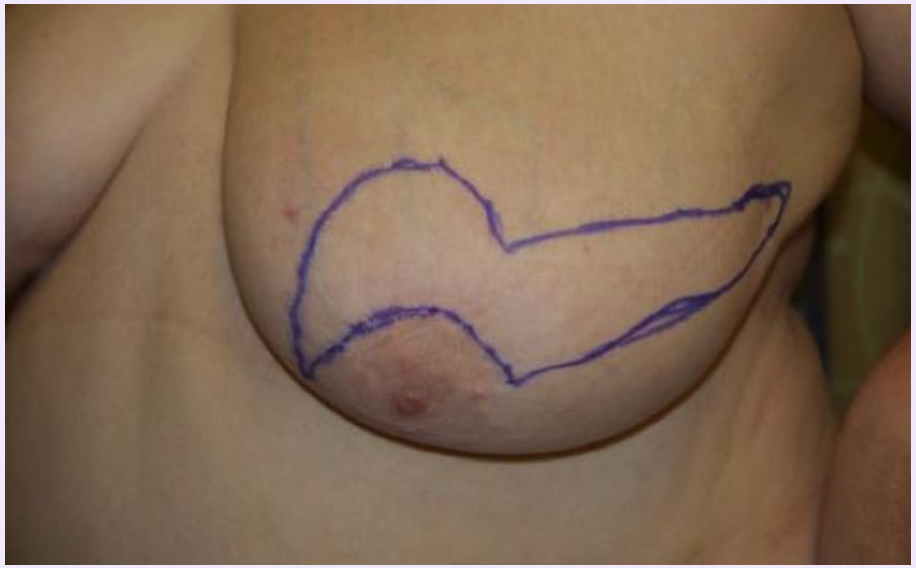

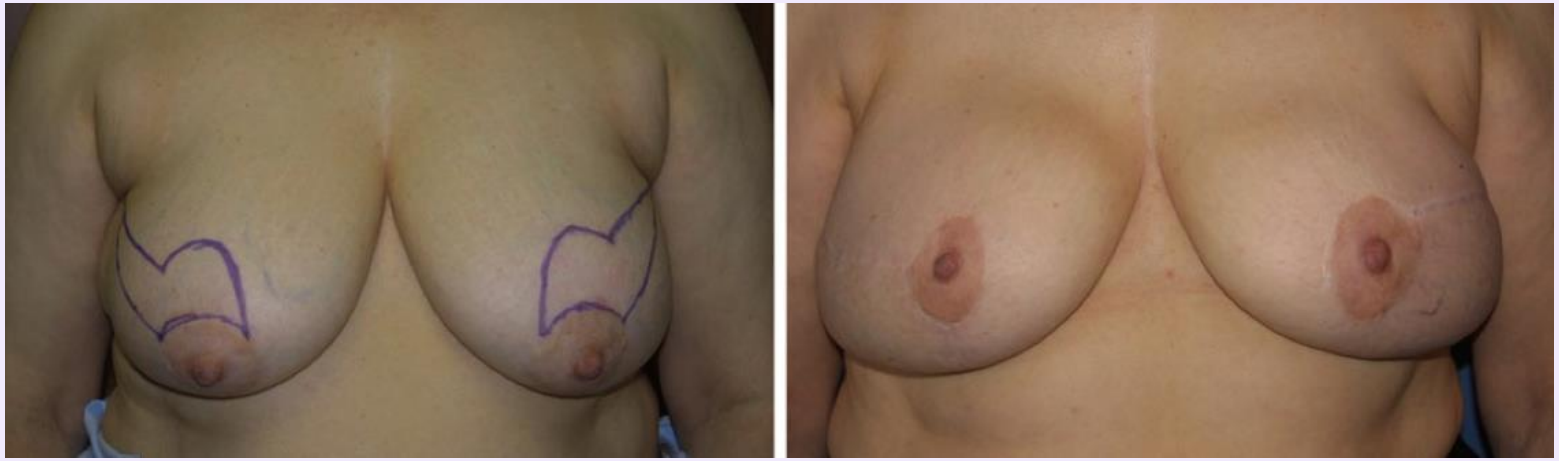

Extending NSM Eligibilty

The Larger or Ptotic Breast

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BREAST

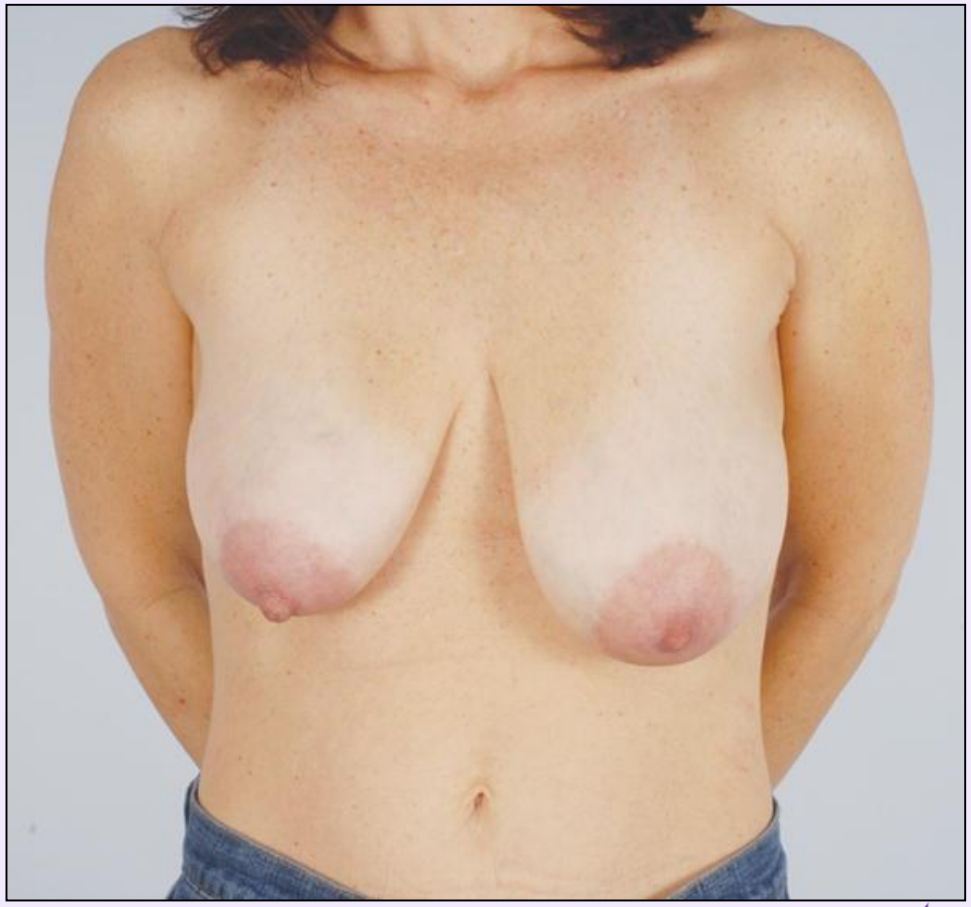
Breast Reconstruction Using a Staged Nipple-Sparing Mastectomy following Mastopexy or Reduction

Scott L. Spear, M.D.
Steven J. Rottman, M.D.
Laura A. Seiboth, M.D.
Catherine M. Hannan, M.D.
Washington, D.C.

Background: To address those patients who do not meet anatomical criteria for nipple-sparing mastectomy, the authors use a staged approach: (1) mastopexy or breast reduction, (2) nipple-sparing mastectomy through the mastopexy incisions after a minimum of 3 to 4 weeks, and (3) the final reconstruction.
Methods: Fifteen patients underwent nipple-sparing mastectomy at Georgetown University Hospital between 2007 and 2010 after planned or unrelated mastopexy or reduction. An institutional review board–approved retrospective chart review recorded demographic information and outcomes such as skin necrosis and device failure.
Results: Fifteen patients (24 breasts) underwent nipple-sparing mastectomy after mastopexy or reduction with an average follow-up of 13 months. The staged procedure was planned in 10 patients [19 breasts (79 percent)] and unplanned, or coincidental, in five [five breasts (21 percent)]. The mastectomy was prophylactic in 17 breasts (71 percent) and therapeutic in seven (29 percent). Four of the 24 operated breasts (17 percent) experienced a complication. Two patients [two breasts (8 percent)] developed skin flap necrosis. Two patients [three breasts (13 percent)] developed minimal partial nipple-areola complex necrosis. One patient [one breast (4 percent)] had an expander explanted for infection related to skin flap necrosis. Fourteen patients [23 breasts (96 percent)] successfully recovered following nipple-sparing mastectomy and prior mastopexy or reduction without residual effects of nipple-areola complex or skin flap necrosis.
Conclusions: The authors are comfortable offering the staged approach to nipple-sparing mastectomy to patients with moderately large or ptotic breasts. It may not be suitable for the very large or ptotic breast. (*Plast. Reconstr. Surg.* 129: 572, 2012.)

4 THERAPEUTIC

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, IV.



Plastic and Reconstructive Surgery 2012

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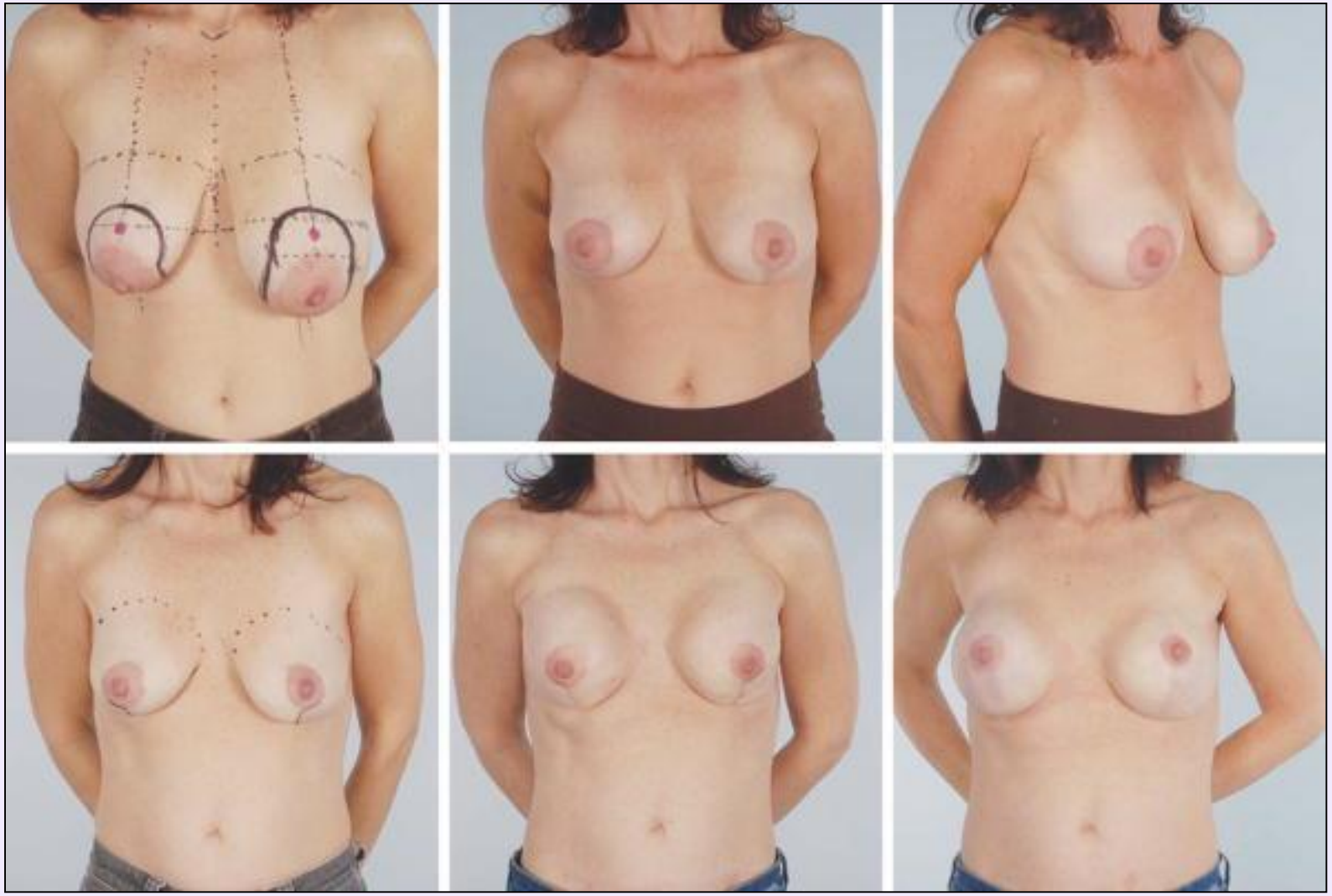

Personal Practice Audit
Bilateral Risk-Reduction Mastectomy
2015-2019

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- Patient undergoing bilateral risk reduction mastectomy: age range 22-57 years
- Average age 39
- Increasing numbers of younger women: 22, 27, 27, 28, 28, 29

	%
Interstate	29
Regional Victoria	33

- All but 3 patients proven mutation carriers

Preparation for Risk-Reducing Surgery

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- No Smoking
- Healthy weight (BMI 20-25)
- Core Strength eg pilates

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Breast Implant Illness

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SPECIAL TOPIC

Silicone Implant Illness: Science versus Myth?

Rod J. Rohrich, M.D.
Jordan Kaplan, M.D.
Erez Dayan, M.D.
Dallas, Texas

Summary: The purpose of this Special Topic article is to present the current state of scientific evidence related to the safety of silicone breast implants. There is presently overwhelming evidence to support the safety of silicone breast implants. Ultimately, the decision to obtain, keep, or remove breast implants is the choice of the patient. If a patient chooses to have her breast implants removed, it is important to find a board-certified plastic surgeon with expertise in breast surgery. Ongoing studies are strongly encouraged in all areas, from cancer detection to autoimmune disease, as we strive for improved patient safety, patient awareness, and patient education. To the best of our body of scientific knowledge to date, there have not been any concrete or evidence-based studies or peer-reviewed data concerning the formation of a new syndrome: "silicone implant illness." Silicone breast implants are used in nearly 300,000 breast augmentation and 100,000 breast reconstruction operations annually in the United States.[1] Silicone gel–filled implants were first approved by the U.S. Food and Drug Administration in 1962. Since that time, few medical devices have been studied as closely for their safety and associated adverse outcomes. Despite multiple generations of implant shells and gel fillers, the basic components remain as originally designed.[2,3] (*Plast. Reconstr. Surg.* 144: 98, 2019.)

DISCUSSION

Discussion: Silicone Implant Illness: Science versus Myth?

Amy S. Colwell, M.D.
Babak Mehrara, M.D.
Boston, Mass.; and New York, N.Y.

PRS 2019

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BREAST

Breast Implant Illness: A Way Forward

Mark R. Magnusson, MBBS, FRACS
Rod D. Cooter, MBBS, PhD, FRACS
Hinne Rakhorst, MD
Patricia A. McGuire, MD
William P. Adams, Jr, MD
Anand K. Deva, BSc(Med), MBBS, MS, FRACS

Gold Coast, Queensland; and Sydney, New South Wales, Australia; St Louis, Mo.; and Dallas, Texas

Summary: The link between breast implants and systemic disease has been reported since the 1960s. Although many studies have looked at either supporting or refuting its existence, the issue still persists and has now been labeled "breast implant illness." The rise of patient advocacy and communication through social media has led to an increasing number of presentations to plastic surgeons. This article summarizes the history of breast implants and systemic disease, critically analyzes the literature (and any associated deficiencies), and suggests a way forward through systematic scientific study. (*Plast. Reconstr. Surg.* 143: 74S, 2019.)

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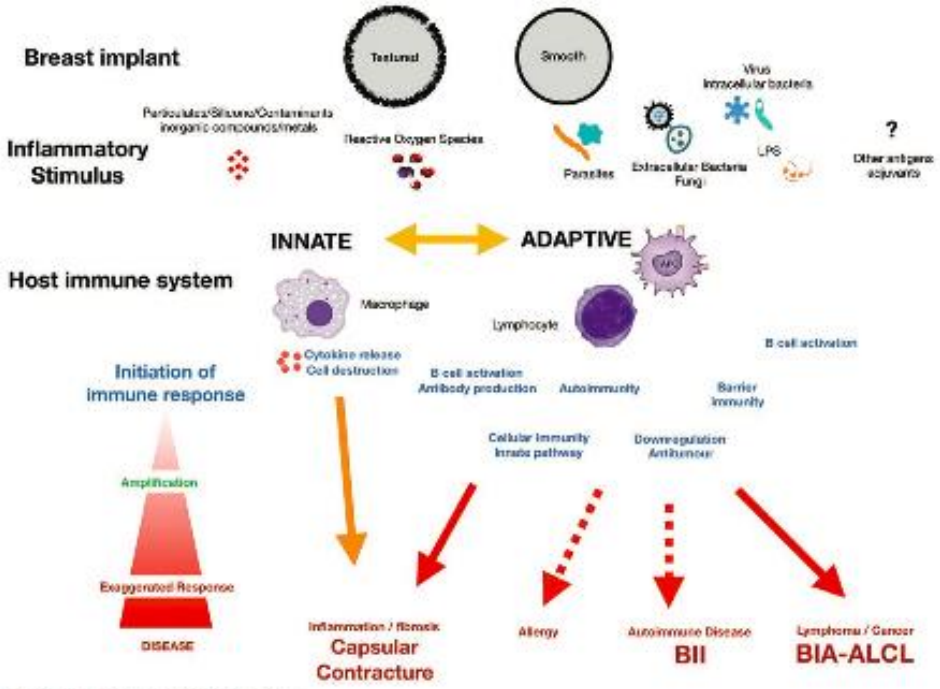

Fig. 2. Likely pathogenetic pathway for BII.

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Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

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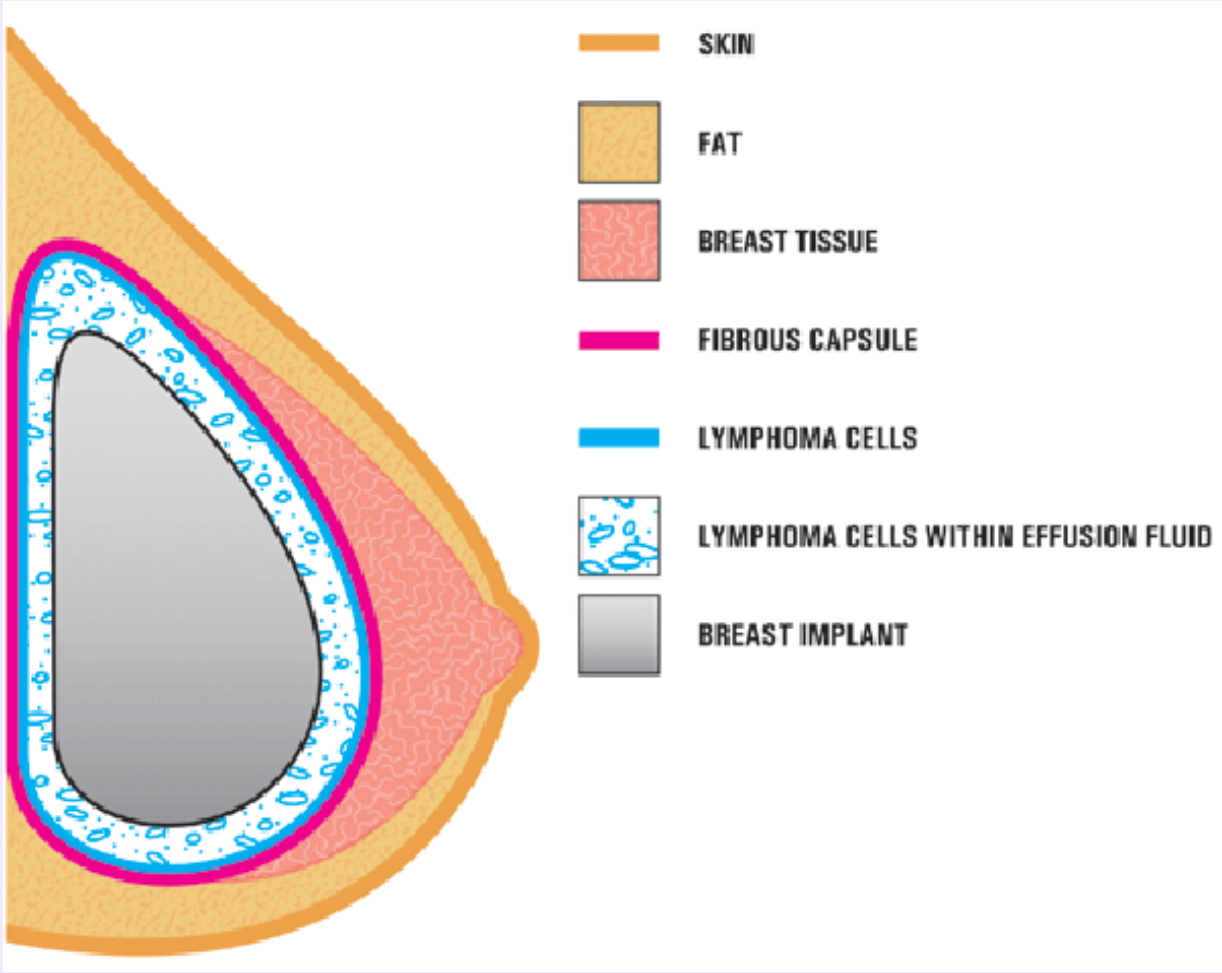

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Implant Type

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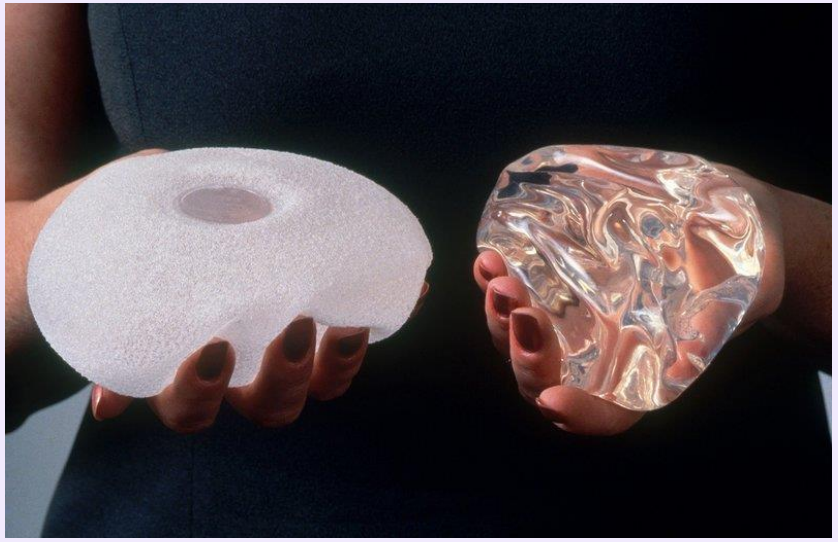

Process	Polyurethane foam	Salt Loss (Biocell/ Eurosilicone)	Gas Diffusion	Salt Loss (Nagotex)	Imprinting	Smooth/Nano
Surface Area	High	Intermediate	Intermediate	Low	Low	Minimal
Roughness	High	Intermediate	Low	Low	Low	Minimal
SURFACE TYPE	4	3	3	2	2	1

Fig. 1. Functional classification of breast implant surface based on surface area and roughness.[32]

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BREAST

Current Risk Estimate of Breast Implant–Associated Anaplastic Large Cell Lymphoma in Textured Breast Implants

David J. Collett, MBBS
Hinne Rakhorst, MD, PhD
Peter Lennox, FRCSC
Mark Magnusson, MBBS, MS, FRACS
Rodney Cooter, MBBS, FRACS
Anand K. Deva, BSc(Med), MBBS, MS, FRACS

Sydney, New South Wales, Brisbane, Queensland, and Melbourne, Victoria, Australia; Almelo, The Netherlands; and Vancouver, British Columbia, Canada

Background: With breast implant–associated anaplastic large cell lymphoma (BIA-ALCL) now accepted as a unique (iatrogenic) subtype of ALCL directly associated with textured breast implants, we are now at a point where a sound epidemiologic profile and risk estimate are required. The aim of this article is to provide a comprehensive and up-to-date global review of the available epidemiologic data and literature relating to the incidence, risk, and prevalence of BIA-ALCL.

Methods: All current literature relating to the epidemiology of BIA-ALCL was reviewed. Barriers relating to sound epidemiologic study were identified, and trends relating to geographical distribution, prevalence of breast implants, and implant characteristics were analyzed.

Results: Significant barriers exist to the accurate estimate of both the number of women with implants (denominator) and the number of cases of BIA-ALCL (numerator), including poor registries, underreporting, lack of awareness, cosmetic tourism, and fear of litigation. The incidence and risk of BIA-ALCL have increased dramatically from initial reports of 1 per million to current estimates of 1/2,832, and is largely dependant on the "population" (implant type and characteristics) examined and increased awareness of the disease.

Conclusions: Although many barriers stand in the way of calculating accurate estimates of the incidence and risk of developing BIA-ALCL, steady progress, international registries, and collegiality between research teams are for the first time allowing early estimates. Most striking is the exponential rise in incidence over the last decade, which can largely be explained by the increasingly specific implant subtypes examined—driven by our understanding of the pathologic mechanism of the disease. High-textured high-surface area implants (grade 4 surface) carry the highest risk of BIA-ALCL (1/2,832). (*Plast. Reconstr. Surg.* 143: 30S, 2019.)

Table 1. Global Numbers of BIA-ALCL Cases and Related Deaths

Country	Cases	Deaths
Argentina	6	
Australia	81	3
Belgium	10	
Brazil	3	1
Canada	25	
Chile	2	
China	0	
Colombia	6	
Czech Republic	1	
Denmark	7	
Egypt	1	
Finland	7	
France	55	3
Germany	7	
Ireland	1	
Israel	8	
Italy	28	
Japan	0	
Mexico	4	
Netherlands	40	1
New Zealand	13	1
Norway	3	
Romania	0	
Russia	2	
Singapore	0	
South Africa	1	
South Korea	1	
Spain	29	
Sweden	6	2
Switzerland	4	
Taiwan	Not reported	
Thailand	1	
Venezuela	2	
United Kingdom	45	1
United States	257	5
Total	656	17

As of November 2018, a total of 656 cases have been identified worldwide with 17 deaths reported.

The Breast Centre
thebreastcentre.com.au

PRS 2019

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Regulatory Action

The Breast Centre
thebreastcentre.com.au

Australian Therapeutic Goods Administration (TGA) – July 11th 2019

- Announcement of a potential 6 month suspension on ALL textured devices

US Food and Drug Administration (FDA) –July 24th 2019

- Requested that Allergan recall its BIOCELL textured breast implants and tissue expanders.
- Reported total of 573 unique BIA-ALCL cases including 33 patient deaths
- Of the 573 cases of BIA-ALCL, 481 are reported to have Allergan breast implants at the time of diagnosis
- 12 of 13 deaths occurring in patients with BIA-ALCL where the manufacturer was known occurred in patients implanted with an Allergan breast implant at the time of their BIA-ALCL diagnosis
- The manufacturer and/or texture is unknown for the remaining 20 reported deaths from BIA-ALCL.

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Australian Society of Plastic Surgeons

Australian Society of Plastic Surgeons

12 July 2019

Textured Breast Implants: What do I need to know?

The TGA (Therapeutic Goods Administration) has notified manufacturers that certain textured breast implants may be removed from the market (cancelled) and others may be suspended for 6 months for review depending on the nature of the texturing of their surface.

This is a notice of intent only and nothing has changed in legislation at the present. The breast implant manufacturers will have util the 24th of July to respond to this proposal. The TGA is responding to international scientific papers, including many from Australia, which show a possible link between the degree of texturing of an implant and the risk of developing a Breast Implant Associated Anaplastic Large Cell Lymphoma. (BIA: ALCL) Until the TGA announce their final decision, textured implants and tissue expanders are available for insertion. **ASPS encourage their members to consider the least textured implant that will achieve a satisfactory result for their patient.**

Commonly, the surface types are broken into Polyurethane, Macro-textured (heavily textured silicone surface) Micro-textured (less textured silicone surface), and smooth. The risks with these devices are the highest with Polyurethane covered implants, then Macro-textured, then Micro-textured. Smooth implants are thought to carry no risk or negligible risk.

The TGA has reinforced international expert opinion that current implants do not need to be removed from patients in the absence of symptoms. Patients who have implants should know about the symptoms that are relevant. A swelling of the breast or a lump in the breast should be checked and investigated. It is important for a patient to know the type of surface on their implant or tissue expander. This information should be available from your surgeon or from the breast implant registry if you are registered and your surgeon is no longer in practice.

The majority of ALCL cases occur in free fluid (seroma) around the implant and are cured by removal of the implant and the implant capsule. Occasionally, a solid tumour arises and this can be more advanced disease and may require more extensive treatment. In Australia over the last decade, out of the total 99 confirmed cases, 4 women have died. Whilst tragic, the individual risk of death from this disease is low and the risk of developing the disease itself is very low. The rise in risk of death from ALCL in a given patient with textured implants is thought to be in the range of the rise in risk from riding a bike for 17miles or living 2 days in NYC (Sieber and Adams ASJ 2017) Monitoring of polyurethane and heavily textured implants will likely be recommended at more frequent intervals than minimally textured implants. We await consensus internationally on this topic. There is no thought that smooth implants require special attention or monitoring because of this release.

ASPS has international representation on committees that advise on policy and guidelines for the safe use and monitoring of implants.

Other jurisdictions such as France and Canada who have preceded us with this change have not restricted the use of minimally textured breast implants and tissue expanders.

The Breast Centre

thebreastcentre.com.au

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BreastSurgANZ

The Breast Centre

thebreastcentre.com.au

BREASTSURGANZ BULLETIN

BreastSurgANZ

Message from BreastSurgANZ President to Members - 17 July 2019

Re: TGA announcement on Textured Breast Implants

Dear Colleagues,

I am writing to BreastSurgANZ members regarding a potential TGA ban on all microtextured breast implants in Australia. The BreastSurgANZ Councillors have significant concerns regarding the TGA approach.

1. What is the proposed ban?

The TGA announced on 11th July completion of their review and laboratory assessment of **textured** breast implants available on the Australian market. TGA issued an updated announcement of **proposed regulatory actions around all textured implants currently available in Australia** (except Motiva), including:

- ceasing availability of all textured breast implants and expanders in Australia. This will not affect any device already implanted (however we are concerned that patients may request removal);
- cancellation of Allergan (Natrelle implants & expanders);
- suspension for six months of textured implants from Nagor, Emagin, Aeroform (AirXpanders), Eurosilicone (Cristaliine), Polytech, J&J (Siltex implants & Mentor expanders).

2. What is the Society position on breast implants?

Our society supports the TGA ban on macrotexture and polyurethane implants (Grade 3 and 4 implants), following recent decisions in France and Canada - but not on microtexture expanders and implants, which have high volume use throughout Australia for immediate breast reconstruction post mastectomy.

Ultimately, we understand it is the role of the TGA to ensure the safety of the public, which is of paramount importance also to our Society. However we do not support the suspension of microtextured implant and expander options, including the following concerns:

- Detrimental impacts that the proposed suspension would have on patients needing a mastectomy and reconstruction during the 6 month suspension period, and the effect of this stop on implant supply on patients completing reconstructions that are in progress, or patients who develop ruptures and other complications in their existing anatomical implants;
- Reducing treatment options during the suspension period for immediate implant reconstruction, limiting results for the patient where implants allow skin and possibly nipple preservation for a staged reconstruction;
- Despite no recall currently being mandated, many patients are likely to request removal of the suspended implants. This would add a significant burden to the public and private hospital breast surgery sectors, and an increased risk to patients undergoing any unnecessary operations.
- If the suspension subsequently progresses to cancellation of the microtextured devices, serious longterm limitation of patient choice in breast cancer treatment choices may result, including alternate options which each carry their own significant risks. Considering the risk of ALCL solely is not taking into account the full risk profile of implants. ALCL is only one very rare risk of implants, and there are many other potential complications, which have been acknowledged and accepted by doctors and their patients making informed decisions on individual treatment plans based on best evidence practice.

3. Our response to TGA

We are preparing a draft submission to the TGA stating the fact we do not support this ban on the currently available evidence, particularly as it will affect immediate reconstruction. We also seek TGA's direct engagement with our Society regarding the proposed bans, have invited the TGA to share and justify the relevant evidence upon which it bases its decisions for our review and provide the Society an opportunity to make formal submissions to the TGA prior to proceeding with any bans or suspensions. A decision of this magnitude needs to be completely evidence based.

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BREASTSURGANZ BULLETIN

BreastSurgANZ

Message from BreastSurgANZ President to Members - 2 August 2019

UPDATE on TGA announcement on Textured Breast Implants

Dear Colleagues,

I am writing to BreastSurgANZ members to update you on the potential TGA ban on all microtextured breast implants in Australia.

BreastSurgANZ Councillors have been closely monitoring this issue and we have provided a submission to the TGA stating our significant concerns regarding the current TGA approach. Council has been working to get information that can be potentially used by our members.

I have now had the opportunity to meet directly both with the TGA, and the Federal Minister for Health, Hon. Greg Hunt MP. They have taken on board our views reiterating why we feel expanders are important to breast cancer patients and the potential low risk from microtextures, and have agreed to consider our submissions when making a final determination.

What are the next steps?

Our next meeting with TGA is on the 15th of August. This meeting may involve a final decision regarding expanders and microtextures, although it also may just be an update.

What should members do about breast implants in the interim?

As we are unsure at this stage what the TGA final decision will be, BreastSurgANZ Council recommends in the interim that our breast surgeon members:

1. Communicate with and Inform patients

a. **TALK** to your patients who have textured breast implants about the implications for them. In the symptomatic patient we recommend review plus ultrasound +/- aspiration (biopsy). In the asymptomatic patient there is no current evidence to support regular review or ultrasound and we recommend discussion with your reconstructive surgeon/team about a plan. For some surgeons and hospital units this plan may include annual clinical assessment of all implant patients, and/or retrospective ABDR entry.

b. **REVIEW** your patients who notice any sudden changes around their implant, such as new swelling or a lump, consider ultrasound +/- aspiration (biopsy) for BIA-ALCL.

c. Provide **INFORMATION** about textured implants to your patients, including patient information sheets and letters - see example Patient Information Sheet and example Letter to Allergan (and Silimed) Implant Patients which our Council has provided as a possible approach you may wish to adapt for your patients, to be modified depending on your practice needs;

d. For any interim use of microtextured Expanders prior to the TGA final decision, provide an **INTERIM CONSENT FORM** approved by your hospital to consent patients awaiting implant surgery about the current risks of using textured implants, pending the final TGA decision;

e. Assist your patients who are unsure, to **CLARIFY** whether they have textured or smooth implants, and which type - records may be obtained from the hospital where the surgery was performed. The proposed ban does not affect smooth breast implants.

AUSTRALIAN Breast Device REGISTRY

The Breast Centre
thebreastcentre.com.au

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The Breast Centre

thebreastcentre.com.au

Table 8a: Device characteristics – Breast implants

Device characteristics BREAST IMPLANTS		TOTAL ABDR (2012-2017)		ABDR 2016		ABDR 2017	
		N	(%)	N	(%)	N	(%)
Device Shell	Textured	35,744	(74.7%)	12,153	(72.8%)	17,238	(74.5%)
	Smooth	9,380	(19.6%)	3,401	(20.4%)	4,814	(20.8%)
	Polyurethane	2,700	(5.6%)	1,139	(6.8%)	1,086	(4.7%)
	Not stated	26	(0.1%)	8	(<0.1%)	0	(0.0%)
Device Fill	Silicone	47,199	(98.6%)	16,433	(98.4%)	22,895	(98.9%)
	Saline	509	(1.1%)	223	(1.3%)	185	(0.8%)
	Silicone/Saline*	116	(0.2%)	37	(0.2%)	58	(0.3%)
	Not stated	26	(0.1%)	8	(<0.1%)	0	(0.0%)
Device Shape	Round	28,859	(60.3%)	9,889	(59.2%)	14,658	(63.4%)
	Anatomical	18,965	(39.6%)	6,804	(40.7%)	8,480	(36.6%)
	Not stated	26	(0.1%)	8	(<0.1%)	0	(0.0%)

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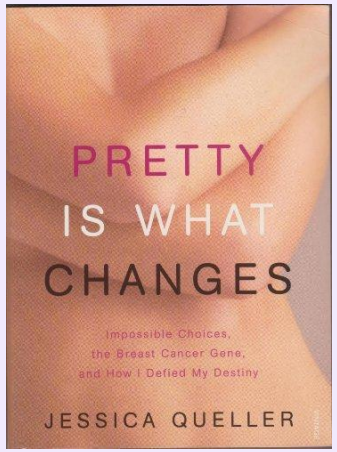
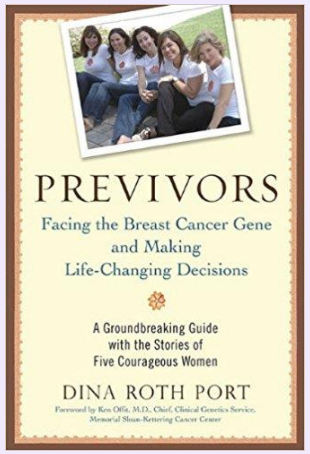
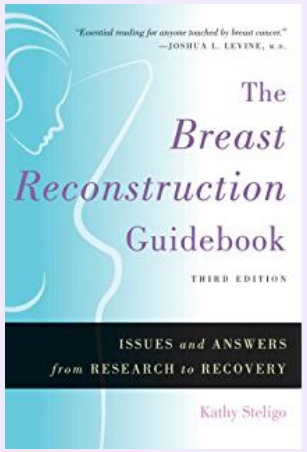
Resources







- Books
- Organisations
- Online Groups
- Social Media

- **Pink Hope**

http://pinkhope.org.au

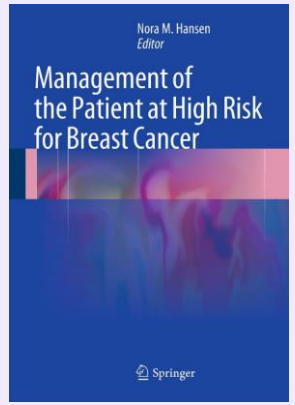
- **Force**

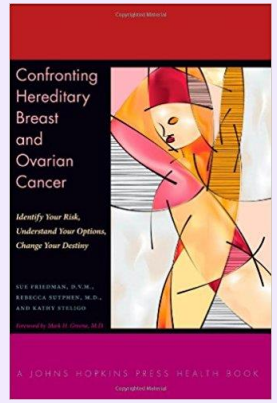
http://www.facingourrisk.org/index.php

- **Bright Pink**

https://www.brightpink.org/high-risk-support/high-risk-resources/

- **Basser Center for BRCA**
- https://www.basser.org





The Breast Centre

at St Vincent's Private Hospital East Melbourne

The Breast Centre

thebreastcentre.com.au

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