Breast Reconstruction Matters

Breast reconstruction.
It matters to me.

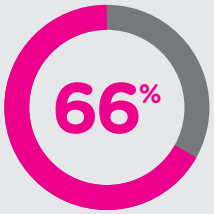
Breast Reconstruction Matters.

At LifeCell, we are dedicated to bringing choice back to a time when choices have been removed by breast cancer. Whether it's immediate or delayed reconstruction, using the patient's tissue or an implant, we know the importance breast reconstruction can play in the restoration of the emotional and physical well-being of the most important patients: yours.

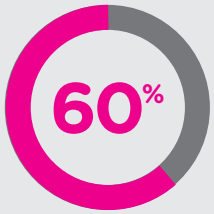
There are many physical and emotional benefits to be gained from immediate breast reconstruction

The National Mastectomy and Breast Reconstruction Audit[1] has provided the numbers to back this up.

Of 3,389 women who underwent immediate reconstruction post-mastectomy:

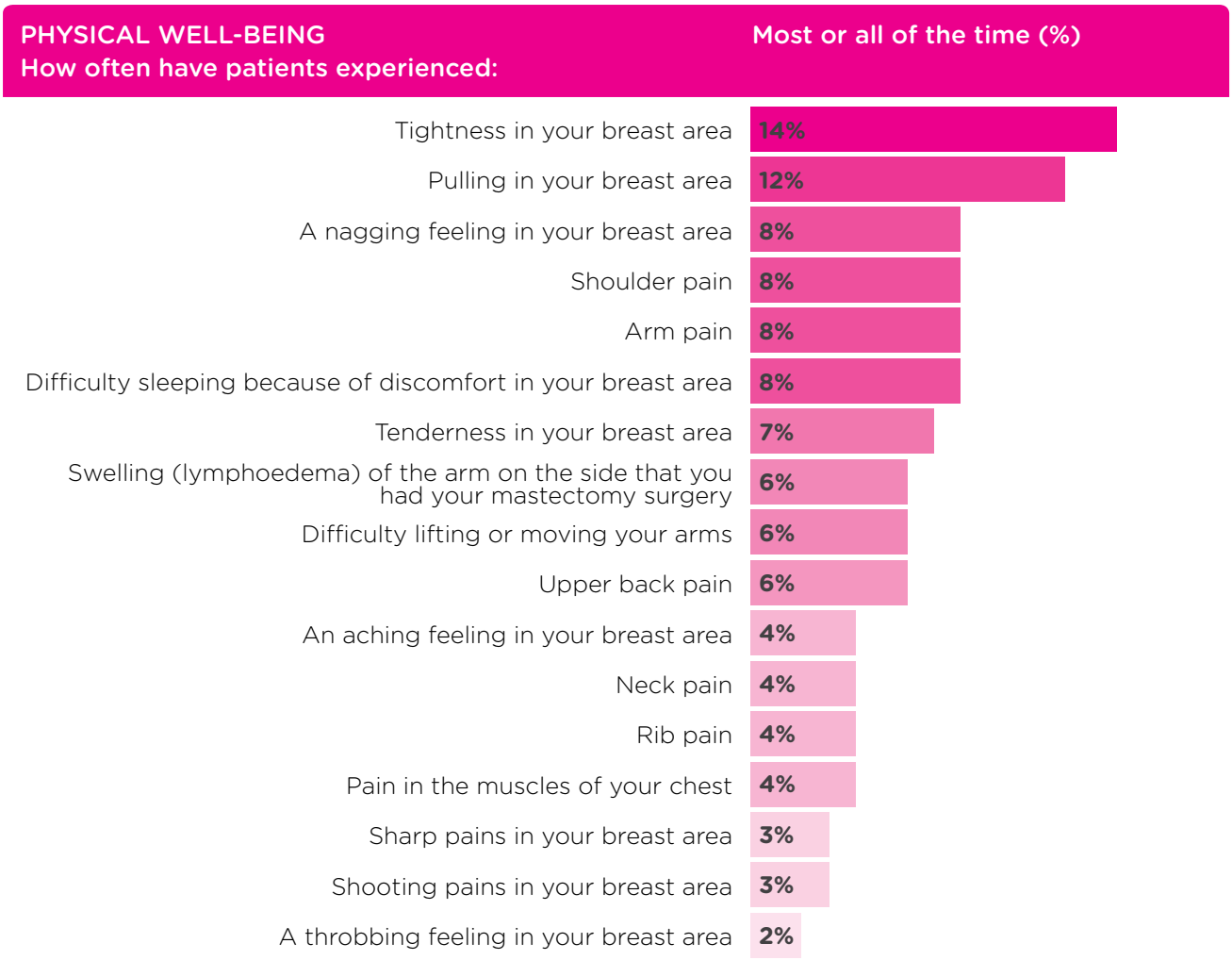


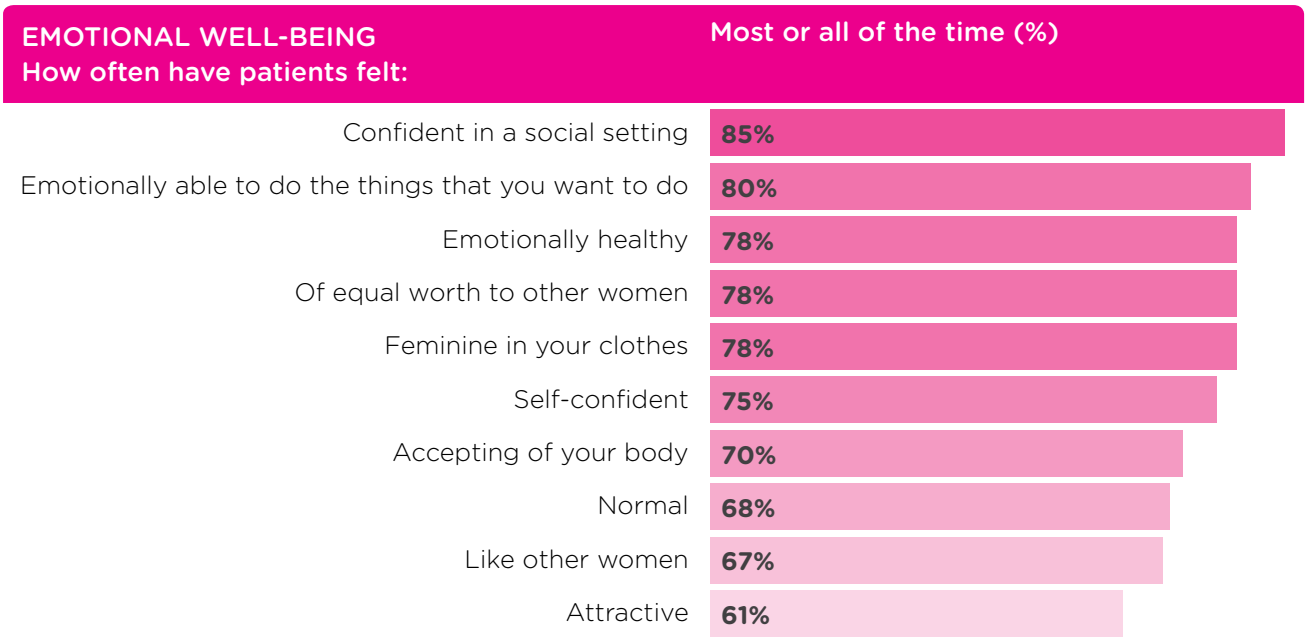
of women were satisfied that their reconstructed breast(s) felt like a natural part of their body

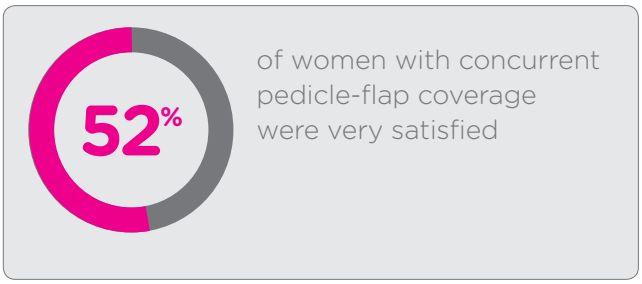


of women felt attractive most or all the time after immediate reconstruction and were satisfied with how they looked in the mirror when unclothed

A further assessment of well-being at 18 months yielded many other positive responses:







Item-level satisfaction scores for the implant scale for women whose immediate reconstruction involved an implant, with or without a flap:

Satisfaction with implants at 18 months postoperatively among women having immediate breast reconstruction

	Women who were satisfied or very satisfied (%)	
	Implant-only	Implant with flap coverage
The amount of rippling (wrinkling or creasing) of your implant that you can see?	72	84
The amount of rippling (wrinkling or creasing) of your implant that you can feel?	71	82

It's important to note that the combined scores for women being either satisfied or very satisfied are slightly higher for implants with flap coverage, and demonstrate a pleasing aesthetic result with limited wrinkling and rippling, bottoming out, and capsular contracture.

Overall, the audit demonstrates the many physical and emotional benefits of breast reconstruction for women post mastectomy.

Patients should always consult with their healthcare professional for decisions on whether or not to have breast reconstruction surgeries, risks and benefits of complex procedures, and long term issues that may arise as a result of the surgery and ancillary treatments.

There are marked differences between types of breast reconstruction

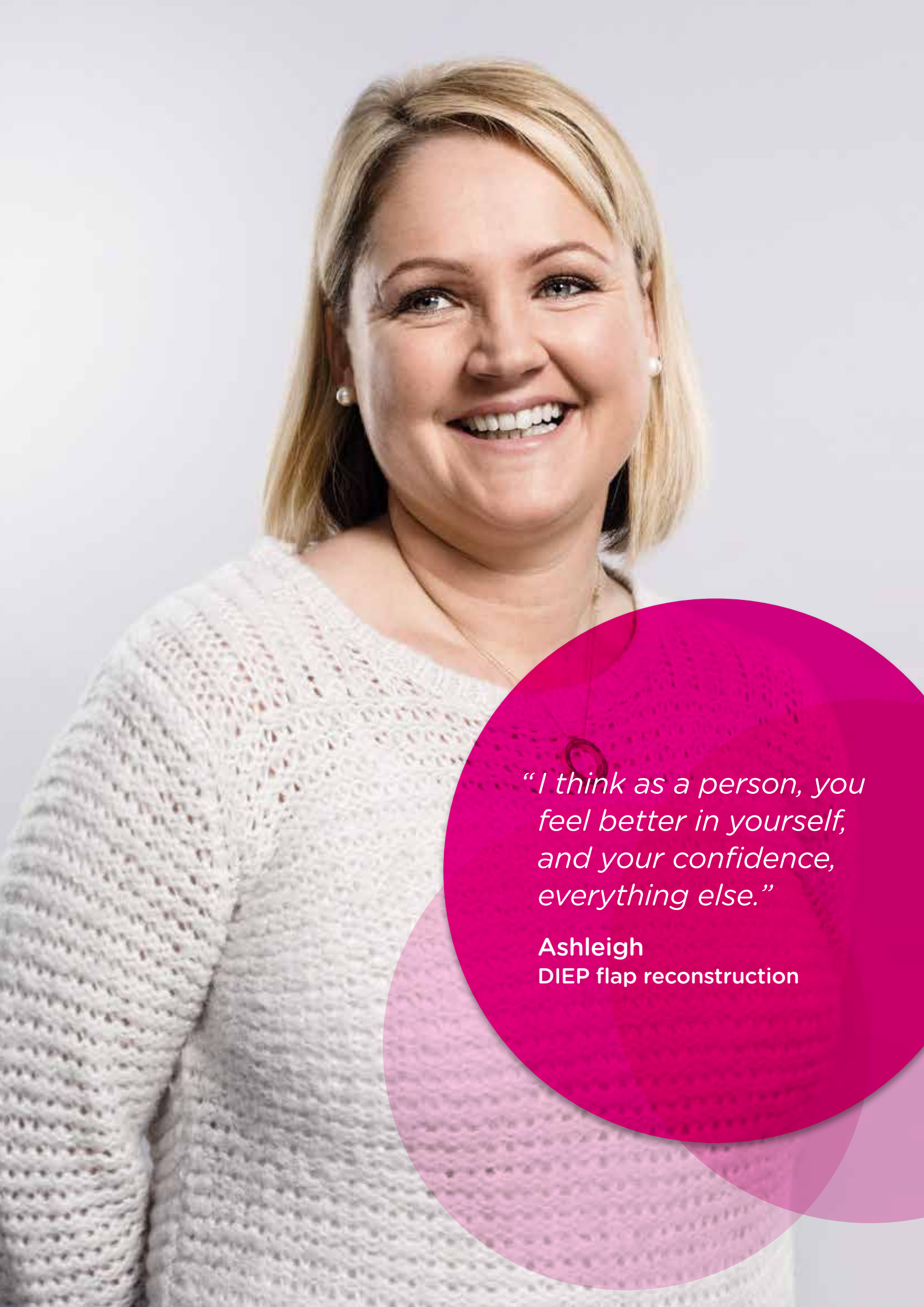
We know it's important to understand every option when it comes to breast reconstruction techniques for your patients. Having the right information for full and transparent conversations with all women is integral to their journey through breast cancer. In order to aid your discussion with your patients, the following pages will serve as a comprehensive overview of the options for breast reconstruction, including:

- Autologous breast reconstruction
- Tissue matrix and implant reconstruction
- Implant-only reconstruction
- Tissue expander-to-implant reconstruction

Patients should always consult with their surgeon about the best choice of breast reconstruction for them.

Ashleigh


Joanna
Jenny
Pauline


"I think as a person, you feel better in yourself, and your confidence, everything else."
Ashleigh
DIEP flap reconstruction

Autologous Breast Reconstruction

In an autologous reconstruction, the breast is shaped from existing muscle, fat and skin (tissue) taken from other areas of the body.

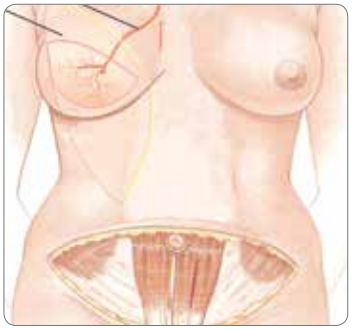
There are 5 common areas of the body from which a breast flap can be formed for reconstruction:

- A TRAM (Transverse Rectus Abdominis Muscle) Flap uses tissue from the stomach area
- A Latissimus Dorsi Flap uses tissue from the upper back and/or shoulder
- A DIEP (Deep Inferior Epigastric Artery Perforator) Flap uses tissue from the stomach area whilst preserving the abdominal muscle
- A SGAP (Superior Gluteal Artery Perforator) Flap uses tissue from the buttocks
- TMG/TUG (Transverse Myocutaneous Gracilis) Flap uses tissue from the inner thigh

POTENTIAL ADVANTAGES	POTENTIAL DISADVANTAGES
More natural look and feel	Recovery may be longer and more difficult than other reconstruction techniques
No risk of implant-related complications	Risk of blood-supply issues to the autologous flap
Breast will behave as the patient's natural body, possibly fluctuating in size depending on weight gain or loss (this may be lessened in radiated breasts)	Risk of muscle weakness at the donor site
	Scarring at the breast and from the donor site
	Possibility of relative postoperative pain, relative infection
	Differences in skin tones and textures between skin and donor-site skin

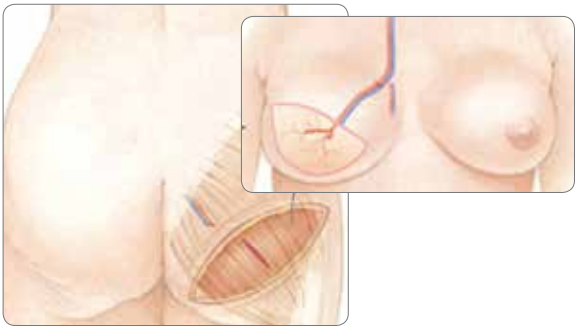
Because healthy blood vessels are needed for the tissue's blood supply, autologous procedures are not usually recommended for women with connective tissue or vascular disease, or those women who smoke or present other comorbidities. Women with diabetes or high BMIs may have this surgery but need to be aware they are at higher risk of wound complications.

A DIEP Flap



A Latissimus Dorsi Flap

A SGAP Flap



Artist's renderings

“ I wanted reconstruction straight away. I wanted to wake up with something there.”

Joanna
LD flap reconstruction

Implant Reconstruction

Breast reconstruction using an implant can be accomplished through one of two types of staged breast reconstruction: in an implant-only reconstruction ("one-stage reconstruction"), or in a tissue expander-to-implant reconstruction ("two-stage reconstruction").

Implant-only reconstruction (one-stage reconstruction)

- This surgery places an implant in the breast pocket without prior expansion — which means a second surgery is not usually needed
- No expansion process may mean less discomfort, fewer operations and visits, and less inconvenience

Some potential advantages and disadvantages include:

POTENTIAL ADVANTAGES	POTENTIAL DISADVANTAGES
Shorter operation	Possibility of multiple operations
Quicker recovery	Foreign implant in patient's body could lead to complications
Shorter hospital stay	Risk of scar tissue formation and capsular contracture (particularly in radiated breasts)
No donor-site complications (such as muscle weakness, pain, bleeding or infection)	Possible differences in size and shape of both breasts
Fewer scars	Bleeding, pain, wound infection and bruising may occur after operation
May be less painful versus autologous reconstruction	Risk of damage or rupture of the implant
Avoids a second operative site	Risk of infection and implant loss

Tissue expander-to-implant reconstruction (two-stage reconstruction)

Expanding the muscle for enough breast pocket volume to create shapely, proportioned breasts

- An expander is placed in the breast pocket prior to the implant
- Saline is added to the expander until desired breast pocket size is achieved
- Requires two-stage operation to later swap expander for implant to create the breast mound

Some potential additional advantages and disadvantages include:

ADDITIONAL POTENTIAL ADVANTAGES	ADDITIONAL POTENTIAL DISADVANTAGES
Allows surgeon greater control of the final breast shape (an improved aesthetic result)	Risk of rejection by the body
Allows surgeon greater control of the final location of the implant	Potential skin flap damage if the tissue is over expanded

"...my daughter looks at me, and she's really envious. She says I'm better than her, and wants hers to look as good as mine."

Jenny
Strattice™ Tissue Matrix with implant reconstruction

Tissue matrix and implant reconstruction: an innovative and proven technique in breast reconstruction

A tissue matrix is a natural, biological piece of material used by a surgeon to create additional tissue with which to work. The matrix enables lower breast pole coverage of the implant without any associated donor-site morbidity. Without the matrix, only the upper part of the implant would be covered by muscle, while the lower part would be in direct contact with the skin.

This technique has been used successfully for many years in the NHS as a viable and safe technique for breast reconstruction. It has also been used successfully in reconstructive revision surgery.

Strattice™ Reconstructive Tissue Matrix is a biological tissue matrix derived from porcine dermis and may help surgeons recreate breasts that are more natural looking and feeling than traditional breast implant reconstruction techniques. That's because Strattice™ Tissue Matrix forms an "internal bra" which serves as a hammock in which the implant sits. It also allows for greater control of the implant position, which helps achieve the desired breast shape and size. Since Strattice™ Tissue Matrix can be used for a single-stage operation, it also significantly reduces procedure time versus other reconstructive techniques.

In order to prevent unwanted setbacks, Strattice™ Tissue Matrix may help cover the implant, cushioning the feel of it, masking any visibility of the implant through the skin.

Artist's rendering

POTENTIAL ADVANTAGES	POTENTIAL DISADVANTAGES
Shorter operation and may allow for one-stage reconstruction implant-only procedures by providing a larger implant pocket	Bleeding, pain, wound infection and bruising may occur after operation
Shorter hospital stay	Presence of implant still presents foreign object in patient's body
Tissue matrix masks the surface of the implant, which may lead to more natural looking and feeling breasts	Risk of infection and loss of implant
Holds the implant in place which may help to avoid complications	
Strattice™ Tissue Matrix promotes rapid revascularisation	
Anchors the muscle to the chest wall	

If you have religious concerns about the use of a porcine-based product, please consult with your local leader.

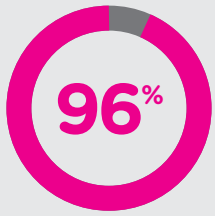
Strattice™ Tissue Matrix is a CE marked product

Positive results, pleasing aesthetic outcomes

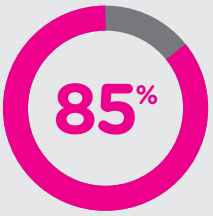
Patients demonstrated significant satisfaction rates with their reconstructed breasts using Strattice™ Tissue Matrix

In a study conducted by Johnson R.K. at University Hospital South Manchester, patients demonstrated significant satisfaction rates with their reconstructed breasts using Strattice™ Tissue Matrix.[2]

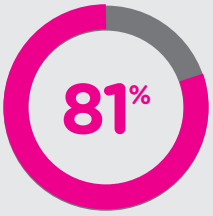
How satisfied are you with how you look in the mirror unclothed?



How satisfied are you with the size?



How satisfied are you with how natural your breasts look?

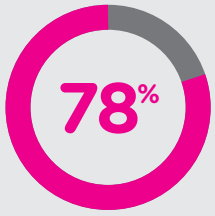


Source: Patient survey carried out in UHSM Trust. Presented at ABS 2013, Manchester.

In a further study conducted by Himsl et al., the use of a porcine acellular dermal matrix (Strattice™ Tissue Matrix) for implant-based breast reconstruction "*...yielded predictable and acceptable aesthetic and haptic results by preventing capsular contracture, rippling, implant malposition, soft-tissue thinning, and failure of the silicone implant-based breast augmentation*" and "*...eliminated many of the current disadvantages of implant-based reconstruction.*"

The above reported statement has not been evaluated and approved by regulatory agencies.

Of the 23 patients (27 breasts)



were "very satisfied" or "satisfied" with the aesthetic and haptic outcome after reconstruction using Strattice™ Tissue Matrix with an implant when reviewed after 6 months.

Strattice™ Tissue Matrix is an **intact** acellular reconstructive tissue matrix designed to support tissue regeneration. It is derived from porcine dermis, which undergoes non-damaging proprietary processing that removes cells and significantly reduces the key component believed to play a major role in the xenogeneic rejection response.

Strattice™ Tissue Matrix allows for tissue regeneration by supporting rapid revascularisation, white cell migration and cell repopulation, all of which may lead to increased resistance to infection at the surgical site as shown in an animal model.*[3] Strattice™ Tissue Matrix ultimately transitions into host tissue for a strong, natural repair.

*Correlation of these results to results in humans has not been established.

Capsular contracture is one of the most common side effects of breast reconstruction operations

Artist's renderings

Strattice™ Tissue Matrix has been used in revisionary surgery for capsular contracture; outcomes have been published in a number of studies.

The Baker Grading System for Capsular Contracture:

- Baker I capsule is a soft breast without significant scar tissue
- Baker II capsular contracture is a palpable type of scar tissue; however, it is not visible
- Baker III capsular contracture is associated with visible and palpable hardening, leading to a deformed shape to the breast
- Baker IV capsular contracture, the most severe, is associated with visible, palpable hardening, and often a cold, hard breast that is very painful to even mild touch

Strattice™ Tissue Matrix has not been approved for the indication of reducing capsular contracture.

Regardless of classification, Strattice™ Tissue Matrix successfully covers the lower pole of the implant in cases of recurrence, or when adequate muscle cannot be found. As a biologic matrix, Strattice™ Tissue Matrix promotes good incorporation into the patient's own, natural tissue, with similar intrinsic properties that potentially can minimise formation of capsule as reported for acellular dermal matrix.[4,5]

The role of Lipomodelling

This technique involves removing fat from one area of the body, processing it, then injecting it in tiny amounts to other areas of the body that need more volume.

It is a useful tool to fine tune the results post-reconstruction with either implants or a patient's own tissue (DIEP/TRAM). It is important to note that additional treatments may be needed. Early results for lipomodelling as an adjunctive treatment to post-mastectomy reconstruction have been quite promising, though this does not mean that all women are suitable for reconstruction and/or lipomodelling.

A look at the before and after of Autologous Reconstruction

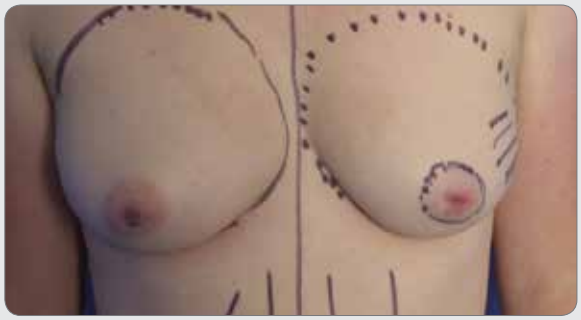
Delayed Latissimus Dorsi

Before

After

Immediate TRAM

Before



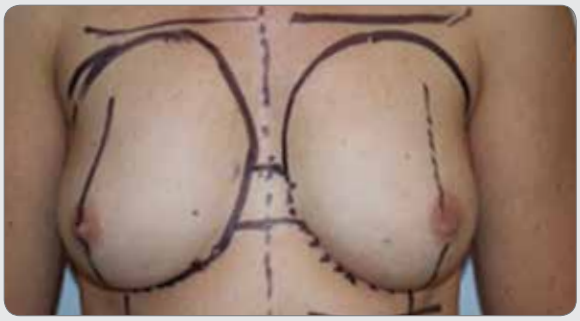
After

Photos courtesy of Mr. Sheikh Ahmad MB, MCh, FRCS, FRCSI, FRCS Eng

A look at the before and after of Reconstruction with Strattice™ Tissue Matrix

Immediate one-stage breast reconstruction after left-nipple-sparing mastectomy with Strattice™ Tissue Matrix

Before



After

Delayed one-stage breast reconstruction with Strattice™ Tissue Matrix

Before

After

Photos courtesy of Mr. Sheikh Ahmad MB, MCh, FRCS, FRCSI, FRCS Eng

An important point about patient recovery time:

A patient's recovery time will depend on the type of breast reconstruction operation she has had. There is a good chance she will be out of bed within a few hours. In fact, she may be able to go home the next day. However, if the patient has had a more extensive operation, it may take longer, and she may need to stay in hospital for several days.

Questions patients may have during breast reconstruction consultation

- How will breast reconstruction impact my cancer treatment?
- What are all my options for breast reconstruction?
- Which reconstruction option is best for me, and why?
- Can I choose to make my breast(s) smaller or bigger?
- How many operations and office visits will a breast reconstruction require?
- How long will my entire reconstruction take?
- What is the best result I can expect?
- Do you have before-and-after photos for different procedures that I can look at?
- What should I expect when I wake up after an operation?
- What will my recovery be like?
- How long will my recovery take?
- What are the potential risks, side effects, and complications of each type of reconstruction?
- How many and what kind of procedures do you perform a year?
- When will I be able to return to my normal routine (go back to work, return to my normal physical activities, exercise, etc.)?
- What will my scar(s) look like?

Summary

- Only 32%* of women in the United Kingdom are currently choosing breast reconstruction post mastectomy[1]
- There are many techniques that can provide women with the best choice to suit their needs, and all should be discussed as appropriate
- There are many physical and emotional benefits to be gained from breast reconstruction[1]
- Newer devices such as tissue matrices, may help surgeons recreate breasts that are more natural looking and feeling than traditional breast implant reconstruction techniques

*Boston Consultancy Group, 2013

Glossary of Useful Terms

Areola: The darkened area of breast around the nipple.

Autologous: Reconstruction made possible from the muscle, fat and skin (tissue) from other areas of your body.

Capsular contracture: Shrinking or tightening of the scar tissue around the breast implant, making the breast harden, it may also cause pain.

Chemotherapy: A chemical used to kill cancerous cells in your body.

Delayed breast reconstruction: When your breast reconstruction is performed in a separate operation on a date after the mastectomy procedure is complete.

DIEP (Deep Inferior Epigastric Artery Perforator) Flap: Flap reconstruction which uses fat and skin from the lower stomach but does not cause removal of any muscle.

Exposure of implant: When the skin covering the breast is too thin, causing the implant to break through the skin.

Free Flap: When the skin, fat, blood vessels and muscle are cut from the original location and then attached to blood vessels in the chest.

Full muscle coverage: When muscles in the immediate area of the breast are used to fully cover and support the implant.

High-riding breast: When implants are too high on the chest wall.

Immediate breast reconstruction: When both the mastectomy and breast reconstruction are performed during the same procedure.

Implant: A prosthetic device used to recreate the breast shape following mastectomy. The most common type of implant is silicone.

Implant visibility: When the skin covering the breast is too thin, the implant may become visible through the skin.

Mastectomy: The surgical removal of all or part of a breast, usually performed as a treatment for cancer.

One-Stage Reconstruction: When the breast is reconstructed without the use of a tissue expander in a single procedure.

Partial muscle coverage: When the top part of the implant is covered with the chest muscle, leaving the lower portion of the implant unsupported.

Pedicle Flap: When a flap of tissue is attached to its original blood supply and the blood vessels are tunneled under the skin to the breast region.

Porcine: Derived from a pig.

Radiation therapy: Treatment with high-energy rays that damage cancer cells to stop them from growing and dividing, in order to stop the spread of cancer.

Scar tissue: Tissue that forms in the body as part of the natural healing process but is typically less functional and not identical to the original tissue.

SIEA (Superficial Inferior Epigastric Artery) Flap: Like the DIEP flap procedure, this uses the lower abdominal skin and fatty tissue to make a natural, soft breast following a mastectomy.

Surgical drain: A tube used to remove fluids from a surgical site after an operation.

Tissue expander: A device like a balloon which is put under the skin and chest muscle. The surgeon fills the expander over time (this can take up to several weeks) in order to stretch the skin and muscle over the breast.

Tissue matrix: A medical device derived from animal or human tissue.

Two-Stage Reconstruction: When the breast pocket is stretched with an expander and then an implant is put in place (up to several weeks later).

TRAM (Transverse Rectus Abdominis Muscle) Flap: When tissue is taken from the lower abdomen (abdominal wall) and moved into the chest.

Strattice™
RECONSTRUCTIVE TISSUE MATRIX

USEFUL GUIDELINES AND CONSIDERATIONS FROM THE ASSOCIATION OF BREAST SURGERY

1. OPBS should be discussed with 100% of patients requiring a mastectomy.
2. When a referral for OPBS is made from one MDT to another MDT, full information is made available at the time of the referral and reciprocated following treatment.
3. The oncological and reconstructive management is discussed at the MDM. A treatment plan and subsequent modifications are agreed and recorded, including plans for onward referral.
4. Medical photography (pre- and postoperative) is part of the clinical record in 100% of BR patients.
5. Patients have access to a BCN or equivalent key worker with expertise in OPBS and psychological assessment and management.
6. Patients receive information in a format and level of detail that meets their individual needs. The letter to the GP summarises the information provided and is copied to the patient. Written information about the risks and benefits of breast reconstruction should be provided to 90% of mastectomy patients.
7. 100% of patients are MRSA (+MSSA in implant cases) screened prior to admission and have topical suppression where positive in accordance with national/local policy prior to admission.
8. Risk assessment for thromboembolic risk, and thromboprophylaxis occurs in 100% of patients.
9. Patients are admitted to a single sex ward with dedicated, elective beds.
10. The site of operation is marked preoperatively and checked with patients, and correlated with imaging and histopathology records and hospital notes.
11. Patients undergoing implant-based reconstruction are given a single intravenous dose of appropriate antibiotic(s) on induction.
12. A formal flap and pain monitoring protocol is in place in 100% of cases.
13. Patients have their postoperative pain levels assessed and recorded. The Audit Commission recommends that less than 5% of patients should report severe postoperative pain.
14. BCN, physiotherapy and psychological reviews take place at key points, including preoperatively and before discharge in 100% of cases prior to discharge
15. Implant loss at 3 months following BR is assessed and audited.
16. Unplanned return to theatre following BR is assessed and audited.
17. Unplanned re-admission is assessed and audited. There should be a regular audit and discussion of all patients with postoperative complications.
18. Patients' satisfaction with BR outcome is measured using standardised assessment tools. At 18 months, over 90% of BR patients should report satisfaction with their appearance clothed.
19. Local recurrence rates following OPBS should be no higher than for breast cancer operations as a whole ABS at BASO Surgical guidelines for the management of breast cancer state that local recurrence rates should be less than 5% at 5 years with a target of less than 3% at 5 years.
20. 100% of OPBS patients are invited to take part in local and national clinical trials and audits of OPBS.
21. Senior trainees with a subspecialty interest in Breast Surgery attend at least one Royal College, Association or International postgraduate meeting or course annually.
22. Consultant surgeons performing OP operations attend at least one Royal College, Association or International postgraduate meeting which includes OP topics annually.
23. Other MDT members providing an OP service attend at least one educational event annually to support further professional development.

References:

1. NHS National Mastectomy and Breast Reconstruction Audit, 2011. A national audit of provision and outcomes of mastectomy and breast reconstruction surgery for women in England Fourth Annual Report 2011.
2. Patient survey carried out in UHSM Trust. Presented at ABS 2013, Manchester.
3. Sandor M, et al. Host Response to Implanted Porcine-Derived Biologic Materials in a Primate Model of Abdominal Wall Repair. *Tissue Eng Part A*. 2008 Dec;14(12):2021-31.
4. Xu H, et al. A porcine-derived acellular dermal scaffold that supports soft tissue regeneration: removal of terminal galactose-α-(1,3)-galactose and retention of matrix structure. *Tissue Eng Part A*. 2009;15:1807-1819.
5. Basu CB, Leong M, Hicks MJ. Acellular cadaveric dermis decreases the inflammatory response in capsule formation in reconstructive breast surgery. *Plast Reconstr Surg.* 2010;126:1842-1847.

For more information on your patients' options, and to see why breast reconstruction matters to other women, please visit **www.breastreconstructionmatters.co.uk** and speak with your LifeCell Business Manager.

TOUCHSURGERY Download our free surgical technique app, "**TOUCHsurgery**", from the App Store and learn how Strattice™ Tissue Matrix is used. To begin, simply search **TOUCHsurgery** and start using it today.

For use by healthcare professionals.

LifeCell™