The AeroForm Tissue Expander System

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Janet’s Law

Woman was denied reconstructive surgery after mastectomy

Plastic surgeon began crusade for law requiring insurance companies to pay for reconstruction after mastectomy

Women's Health and Cancer Rights Act (WHCRA) was passed into federal law in 1998

It requires all group health plans that cover mastectomies to also provide coverage for reconstructive surgery

However…

Even after the passage of Janet’s Law –

- Less than half of all women requiring a mastectomy were offered breast reconstruction surgery

- One-fifth of women who did not undergo breast reconstruction reported a lack of knowledge regarding the procedure


In response …

The American Society of Plastic Surgeons lead a campaign for federal legislation aimed at improving awareness of certain rights afforded to breast cancer patients.

The Breast Cancer Patient Education Act (BCPEA) was passed by Congress in December 2015.

2017 Statistics

252,710 Invasive Breast Cancer cases

More than one third of mastectomy patients had breast reconstruction

Three quarters of patients receiving bilateral mastectomies had breast reconstruction

Reconstruction Types

Autologous – relocate tissue from patient’s body to create breast mound

Implants – insert prosthesis to create breast mound
Autologous Reconstruction

Advantages

Breast shape can be customized to achieve better symmetry with the contralateral natural breast

Symmetry less affected by ageing and weight changes

Breast is warm and feels more natural

Single stage procedure in most cases

Disadvantages

Longer operation, hospital stay, and recovery time

Risk of flap failure

Scar to donor site and its potential effects on physical well being

Requires surgeon with advanced training and skill
**Autologous Reconstruction**

- **DIEP** = Deep Inferior Epigastric Perforators
- **TRAM** = Transverse Rectus Abdominis Myocutaneous
- **LD** = Latissimus Dorsi muscle

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**ReSensation**

Innovative surgical technique whereby nerves are reconnected to restore feeling to breast

*Size, Shape, Symmetry, Softness, and Sensation*

https://www.resensation.com/
Implant Reconstruction

Advantages

- Shorter operations, hospital stays, and recovery time
- No scars to donor site
- Widely available

Disadvantages

- Long term complications including rupture and capsular contracture
- Usually requires two operations and several tissue expansions
- Breast feels cold and unnatural
- Loss of sensation in breast
Implant Reconstruction

Expander / Implant may be under or over the pectoralis muscle

Under the muscle

Advantages

Results look more natural

Reduced risk of visible rippling

Reduced risk of capsular contracture

Less distortion of mammograms
Under the muscle

**Disadvantages**

- Surgical process more difficult and invasive
- Longer recovery time
- Breasts appear to sit high until muscle relaxes
- Become distorted when muscle is flexed

Over the muscle

**Advantages**

- Surgery is easier and less invasive
- Faster recovery time
- More cleavage can be created
- Do not become distorted when muscles are flexed
Over the muscle

Disadvantages

Less natural look with pronounced roundness

More susceptible to visible rippling as less tissue covers implant

Risk of capsular contracture is higher

Creates mammogram distortions so need more views

AlloDerm

Acellular dermal matrix created from donated human cadaver skin
Provides foundation for new tissue regeneration
Developed in 1994 by LifeCell as graft for burn patients
Filling a Saline Expander

Artifacts
Injection Port

Permanent Implants
TE/Implant Most Common

Timing Issues for Implants

Immediate versus Delayed Reconstruction

Expander to Implant Exchange

Patient and Physician decision
The patient has a what?

What’s an AeroForm?

Do we agree to treat?

Or wait until exchange?

If treat, how do we plan it?

AeroForm by AirXpanders
AirXpanders Key Milestones

- 2005: Company Founded
- 2009: First Feasibility Study (AUS)
- 2009: PACE I – First Implant in the XPAND US IDE Pivotal Trial
- 2011: CE Mark Approval
- 2011: TGA Approval for Australia
- 2012: Listed on the ASX and Commercial Launch in Australia
- 2013: 510k Clearance
- 2015: 1st Commercial Case in the US
- 2016: 510k Clearance
- 2017: FDA Approval
- 2017: 1st Commercial Case in the US

4000 AeroForm devices implanted as of December 2018

AeroForm Components

EXPANDED VIEW
- CO2 RESERVOIR
- POSTERIOR PANEL
- ANTENNA
- NUSIL MED-420 (~1 mL) SILICONE LUBRICANT
- OUTER BARRIER (V2.5 ADDED LAYER)
- INNER BARRIER (ORIGINAL DOUBLE LAYER BARRIER)
- SILICONE SHELL
**CO₂ Reservoir (Driver) Components**

Section 1  Stainless Steel Bottle filled with compressed CO₂ gas
Section 2  Stainless Steel Valve Assembly
Section 3  Copper Windings with Stainless Steel Solenoid and Electronics
Tail End  Electronics embedded in near water equivalent epoxy

Powered by RF signal from Dose Controller coupled to Antenna

**CO₂ Reservoir (Driver) Dimensions (2 Sizes)**

Reservoir for 400cc and 600cc

Reservoir for 800cc
The following physical densities and dimensions for each compartment of the tissue expander can be used for radiation treatment planning purposes. Refer to AAPM TG-63 guidelines as appropriate.

### AeroForm® Reference Table

<table>
<thead>
<tr>
<th>Outer Compartment</th>
<th>Stainless Steel Canister</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>CO&lt;sub&gt;2&lt;/sub&gt; in expanded inner pillow</td>
<td>0.002 g/cc</td>
</tr>
<tr>
<td>Inner bag films</td>
<td>1.1 g/cc</td>
</tr>
<tr>
<td>Silicone rubber shell</td>
<td>1.1 g/cc</td>
</tr>
<tr>
<td>Nominal thickness:</td>
<td></td>
</tr>
<tr>
<td>Shell (anterior side)</td>
<td>0.040&quot; = 1.0 mm</td>
</tr>
<tr>
<td>Shell (posterior side)</td>
<td>0.055&quot; = 1.4 mm</td>
</tr>
<tr>
<td>Inner bag film (anterior)</td>
<td>0.010&quot; = 0.3 mm</td>
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</tbody>
</table>

Total volume of stainless steel components:

- Small (400 cc): 8.14 cc
- Medium (600 cc): 8.14 cc
- Large (800 cc): 9.20 cc
- Total volume copper windings + insulation: 2.80 cc

### Transmission

**6 MV, d=0.7 cm**

<table>
<thead>
<tr>
<th>Dose (Normalized)</th>
<th>Inline Distance (cm)</th>
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<tbody>
<tr>
<td></td>
<td>-5</td>
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<tr>
<td></td>
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<td>6</td>
</tr>
</tbody>
</table>

- No Cartridge
- Cartridge Perpendicular
- Cartridge Horizontal
AeroForm

Advantages

Patient can self inflate at her own pace

No weekly office visits nor needles

More natural anatomic shape

Shorter expansion time

AirXpanders Announces New Data Demonstrating Reduced Infection Rates and Decreased Utilization of Healthcare Resources Associated with AeroForm

April 3, 2019
San Jose, CA, United States – AirXpanders, Inc. (ASX: AXP), a medical device company focused on the design, manufacture, sale and distribution of the AeroForm® Tissue Expander System, today announced the publication of a large retrospective clinical study by Chopra, et al. which concluded that the use of AeroForm tissue expanders offers notable advantages for breast reconstruction. The paper noted that when employed in the prepectoral space, the AeroForm device may be associated with reduced infection rates and decreased utilization of healthcare and patient resources.

The retrospective data are reported in an article titled, “Two-stage Prosthetic Prepectoral Breast Reconstruction: Comparing Tissue Expansion with Carbon Dioxide and Saline,” and appear in the March 25, 2019 online issue of the prestigious Plastic and Reconstructive Surgery – Global Open, an open access, peer reviewed, international journal focusing on global plastic and reconstructive surgery. The principle author, Kiran Chopra, is Chief Resident in the Department of Plastic & Reconstructive Surgery, Johns Hopkins University, Baltimore, MD. Co-authors included Devinder Singh, MD, Chief of Plastic Surgery at Anne Arundel Medical Center, Annapolis, MD and Luther Hilton III, MD from the Division of Plastic Surgery, Anne Arundel Medical Center, Annapolis, MD.
AeroForm

Disadvantages

Complicates radiotherapy treatment planning

Complicates radiotherapy treatment delivery

FAQ

Can the AeroForm Expander be deflated, if necessary?

No, volume cannot be removed except by deflating the expander with a needle, which will disable the device.
FAQ

Can a patient continue expanding while undergoing radiation treatment?

No, active expansion should not be done during the time the patient is undergoing radiation treatment.

FAQ

Will the volume of the AeroForm be constant over the course of radiation?

Yes, the AeroForm Expander has a permeation rate of approximately 0.4-0.5cc per day, thus over the course of radiation treatment the loss of volume is minimal and should not affect the treatment plan.
FAQ

Is it safe to irradiate AeroForm?

Yes. The electronics inside the AeroForm Expander continue to function properly after exposure to radiation levels up to 75 Gy, well above maximum total dose typically used in postmastectomy radiation therapy.
Dosimetric impact of the AeroForm tissue expander in postmastectomy radiation therapy: An ex vivo analysis, Moni et al, PRO Volume 5, e1-8, 2015

Dosimetric assessment of brass mesh bolus for postmastectomy photon radiotherapy, Manger et al., JACMP, Volume 17, Number 6, 2016

FB                    DIBH

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Contouring

EZFluence by Radformation

EZFluence is a Varian Eclipse plugin script that generates optimal fluences for producing a homogeneous dose distribution for plans consisting of opposed or nearly opposed fields such as breast tangents.

https://www.radformation.com/ezfluence/ezfluence
EZFluence Process

Generate plan with shaped tangents
Tools \ Scripts \ EZFluence
Generates multiple plans for your choice
Step and Shoot or Sliding Window
Export to Directory / Import from Directory
Calculate with Preset Dose
Adjust normalization if desired
Merge Subfields

Unmodulated Tangents
Run the script

Choose the DVH
Export Fluence

Export successful
Import Plan

Calculate with Preset Values
Calculation in progress

Unmodulated Plan      EZFluence Plan
DVH Comparison

Merge the fields
CMD Testimonial

“We use EZFluence for every plan which uses parallel opposed fields – breasts, brains, spines, extremities, …”

TS and BR

Left Breast with IMC
Bolus

Pract Radiat Oncol (2014) 4, 464-472

Original Report

Radiation practice patterns among United States radiation oncologists for postmastectomy breast reconstruction and oncoplastic breast reduction

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Received 15 September 2013; revised 19 March 2014; accepted 15 April 2014

Figure 2  Bolus utilization with tissue expanders after mastectomy. In regard to bolus utilization with tissue expanders after mastectomy, a majority of respondents (52.2%) state that bolus is used in the setting of tissue expanders while 36.7% indicate that no bolus is used. (For color version, see online at www.practicalradonc.org).
Bolus with AeroForm

Saline expanders provide full scatter within the reconstructed breast

AeroForm expander provides little scatter within the reconstructed breast

This complicates the bolus question

Daily IGRT

Use Free Breathing scan to create AP and Lateral KV pair to be used for alignment of Spine and Humeral Head during Free Breathing

Use DIBH scan to create Lateral KV to be used for alignment of Sternum during DIBH
Medial Tangent DIBH

Lateral Tangent DIBH
Conclusions

It is reasonable to treat patients with AeroForm

Requires thorough contouring and density overrides

Use Acuros algorithm if available

Keep in mind patients prefer AeroForm

Communicate with your plastic surgeons so you are not caught off guard

Finale

Thanks to Michelle Svatos, PhD for many of the AeroForm slides. She is an independent Medical Physics Consultant supporting AirXpanders

Thanks to Bruce Ryder, CMD for the planning screenshots. He is a dosimetrist colleague.