Implant Selection: Getting it right “the first time”

Bruce Cunningham MD, MSc
Professor of Surgery
University of Minnesota
USA Surgeon Survey

• Mentor Memory-Gel implants became available in November of 2006
• A post approval study was required
  – Mentor has recruited approximately 30,000 of a required 41,000 patients for the study
  – Mentor expects to conclude enrollment this summer
• What are the trends in usage
• A series of surveys have been done….
Quick Quiz

• What percentage of augmentations do you do with gel/saline?
  – 40% gel/60% saline
  – 50% each
  – 60% gel/40% saline
  – Pretty much all gel
  – Pretty much all saline
Quick Quiz

• What style implants do you use?
  – Smooth, textured

• What incision do you use
  – Axillary, infra-mammary, circum-aroelar
Conclusion

• 300,000+ augmentation operations (+4%)

• Most USA surgeons are migrating away from saline implants and to gel (45%)
  – Patients are happier with them

• Most surgeons are using smooth walled implants (80%)
  – Texture more palpable
  – No belief that it makes a difference
Conclusion

- Most surgeons place them in the subpectoral location
- Most surgeons are using the infra-mammary incision site.
- Average size is 400cc
- Most High or Moderate-+ profile
- Awaiting new technologies:
Breast implants
Tissue expanders
Testicular implants
Facial implants
Silicone sheetings
PERouse Breast Implants

Silicone gel

- All the PERTHES® breast implants are filled with a soft and cohesive silicone gel (one of the softest gel available on the market)
- New Texturing process with real benefits
PERTHESE® line is available with a textured or with a smooth shell. The shell used for all the implants has a trilaminar structure.

- **Internal and external layers**
- **Multi-layers of high mechanical silicone**
- **Elastomer Type 1**
- **Barrier layer**
- **Multi-layers of silicone elastomer Type 2**

- **Limits the gel bleed and should prevent the risk of formation of capsular contracture**
The texturation of the PERTHESSE® breast implants is a micro-texturization which is very soft. The micro-texturization of the shell of the breast implants PERTHESSE® is unique and reproducible. No element is added on the shell to obtain texture.

- No alteration of the mechanical properties;
- A gentle adherence with the tissues (no “velcro effect”);
- One of the factor which should reduce the risk of formation of capsular contracture.
Quick Quiz

• What is the most painful complication of augmentation mammoplasty?
  – Infection
  – Capsule contracture
  – Re-operations
  – Rupture
Quick Quiz

• What is your re-operation rate for Aug?
  – 0-2%
  – 2-5%
  – 5-10%
  – 10-15%
3-Year Kaplan-Meier Analysis: Reoperation

- 27.9% - Rev
- 26.6% - Recon
- 15.2% - Aug
Primary Reason for Reoperation: Patient Request

- Augmentation: 29.8% (of 104 re-operations)
- Reconstruction: 19.2% (of 78 re-operations)
- Revision: 18.2% (of 77 re-operations)
3-Year Kaplan-Meier Analysis: Explantation

A majority were re-implanted with a study device.

13.6% - Rev
12.7% - Recon
4.9% - Aug
Conclusion

• Women were happy with the implants, but not with the result!
• As in many things “Size Matters!!”
• And we are not getting it right for our patients
We need to do better with planning
What are the options?

- Creative Artistic judgment:
- Cold Science and Mathematics:
We need to do better with planning

What are the problems?

• Creative Artistic judgment: lacks precision!!
• Cold Science and Mathematics: very limited options!!!
Communication is Key

• Patients want a choice
• They need to be heard, but the surgical planning must be realistic for their anatomy
Why BodyLogic?

Experience with Shaped Devices

We know that helping surgeons focus on the process helps improve outcomes
Comparison of Outcomes

• Where does the data come from?
  – How similar are the studies?
  – What is the patient profile

• What does it show?
  – Does it make sense?

• What conclusions can we draw?
The Patient Populations

• CPG and MemoryGel Core studies
  – Approximately 1000 patients each cohort
• Protocol was identical
• Data collection forms were identical
• Many of the sites were the same
• Data presented to the FDA and to Health Canada with updates
### Experience with Shaped Devices

#### Key Complications

<table>
<thead>
<tr>
<th>Condition</th>
<th>Primary %</th>
<th>Revision %</th>
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<tbody>
<tr>
<td>Re-operations</td>
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<tr>
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<td>Implant Removal without Replacement</td>
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<td>Infection</td>
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<tr>
<td>Rupture (MRI Cohort)</td>
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#### Other Key Complications ≥ 1%²

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<thead>
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<td>Breast Sensation Changes</td>
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<td>Breast Pain</td>
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<td>Seroma</td>
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<td>Trauma</td>
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<td>Implant Malposition</td>
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<td>Implant Extrusion</td>
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<td>Inflammation</td>
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#### Core Gel Data

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<td>0.5, 2.6</td>
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<td>0.4, 2.5</td>
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<td>Infection</td>
<td>0.7</td>
<td>0.3, 1.9</td>
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<td>Rupture (MRI Cohort)</td>
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#### CPG Data

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<tr>
<td>Infection</td>
<td>1.0</td>
<td>0.4, 2.6</td>
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Comparison of Outcomes

• So what was different?
• Shaped devices are intrinsically more difficult to use than round devices!!
  – They can rotate
  – They can shift and be noticed
• The Core MemoryGel physicians used the techniques from their saline experience
• The CPG surgeons received an intensive educational program prior to the study
Why BodyLogic?

The only difference was that CPG surgeons received training program that provides the basis for the BodyLogic Program.
So what is out there?

Five Critical Decisions in Breast Augmentation Using Five Measurements in 5 Minutes: The High Five Decision Support Process

John B. Tebbetts, M.D., and William P. Adams, M.D.
Dallas, Texas

Works because the patient has such limited choices for size, and no re-operations allowed.
Mentor convened an international team began working on a predictable patient-centered alternative with choices.
Why BodyLogic?

Mentor desired a predictable patient-centered alternative with choices.
BodyLogic™ System

BodyLogic™ helps the surgeon focus on what is most important
Objectives of BodyLogic

- Improve surgeon analysis of anatomy
- Create a record/worksheet for future
- Increase patient participation
- Increase patient confidence in implant choice
- Improve outcomes/reduce re-operations
Developed by an international team

“Bodylogic” Implant Selection System
Breast Implant Selection

**Observations:**

- For a given patient, there are any number of different devices which may be equally optimal, and even more that are practically acceptable

- Shape, texture, dimension and fill can all mix and match in countless ways to provide good, consistent results
In our opinion:

There is a need for a system that describes the involved variables and provides leeway in making choices for individual patients and circumstances.
Breast Implant Selection

“Bodylogic” Implant Selection Tools
Selection-Data & Judgement

Data Sheet

- Factual information
- Positional measurements
- Relationships
- Sizing measurements
- Patient expectations
Breast Implant Selection

Data Sheet

- Factual information
- Positional measurements
- Relationships
- Sizing measurements
- Patient expectations
Breast Implant Selection

Positional Measurements

<table>
<thead>
<tr>
<th>Component</th>
<th>Right</th>
<th>Left</th>
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<tr>
<td>Sternal Notch to Nipple (SN-N)</td>
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<td>Clavicle to Nipple (C-N)</td>
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<td>Breast Base Width (BBW)</td>
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<tr>
<td>Breast Height (BH)</td>
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<td>Medial Pinch</td>
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<td>Lateral Pinch</td>
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<td>Nipple to IMF (stretched)</td>
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<td>Upper Pole Pinch</td>
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<tr>
<td>Areolar Diameter</td>
<td>X vert</td>
<td>X horiz</td>
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<tr>
<td>Intermammary Distance</td>
<td></td>
<td></td>
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</tbody>
</table>
Breast Implant Selection

Clavicle to Nipple

- Highlights asymmetry in NAC position
- Highlights asymmetry in clavicle and shoulder position
Breast Implant Selection

Sternal Notch to Nipple

- Stable unchanging landmark, same from side to side
- Better indicator of NAC asymmetry
Breast Implant Selection

Intermammary Distance

- Based on existing medial borders
- Highlights “cleavage” discussion
- Bodylogic form actually a useful medicolegal document
Breast Implant Selection

IMF to Nipple: Under Stretch

- “Objective” measure of skin laxity
- Highlights asymmetry in NAC and fold position
- Highlights asymmetry in skin laxity (radiation), tuberous breast
Breast Implant Selection

Areolar Dimensions

- Documents NAC size
- Triggers periareolar discussion
Breast Implant Selection

Implant Height

- Measured from proposed fold
- For use with anatomically shaped cohesive gel implants
Breast Implant Selection

Implant Height

- Measured from proposed fold
- For use with anatomically shaped cohesive gel implants
Breast Implant Selection

Implant Height

- Measured from proposed fold
- For use with anatomically shaped cohesive gel implants
Breast Implant Selection

Data Sheet

- Factual information
- Positional measurements
- Relationships
- Sizing measurements
- Patient expectations
Breast Implant Selection

Nipple Level Discrepancy
Breast Implant Selection

Breast Volume

- Highly subjective determination, still useful
- Triggers discussion about different volume implants
Breast Implant Selection

Chest Wall Asymmetry
Breast Implant Selection

Skin Envelope

- Right: [ ] Tight [ ] Moderate [ ] Loose [ ] with Ptsosis

- Left: [ ] Tight [ ] Moderate [ ] Loose [ ] with Ptsosis

Patient Dimensions:

Sternal Notch to Nipple (SN-N): ______
Clavicle to Nipple (C-N): ______
Breast Implant Selection

Skin Envelope

- Graded as tight, moderate, and loose
- Generally speaking will use:
  - moderate profile for tight
  - moderate plus for moderate
  - High profile for loose
- Taken into account with other variables
- Can avoid implant/soft tissue mismatch
Breast Implant Selection

Data Sheet

• Factual information
• Positional measurements
• Relationships
• Sizing measurements
• Patient expectations
Breast Implant Selection

Base Diameter

- A subjective measurement
- Actually is more of a range
- Depends on body habitus
- Depends on breast size, shape
- Not as precise a number as has been reported previously
Breast Implant Selection

Implant Measurements

- Skin fold calipers, slide rule
- Measure desired base diameter ($X$)
- Measure medial skin fold ($Z$)
- Measure lateral skin fold ($Y$)

Implant Base Diameter

$$X - \left(\frac{1}{2}Y + \frac{1}{2}Z\right)$$
Breast Implant Selection

Medial and Lateral Pinch

Implant Base Diameter = \[ X - \left( \frac{1}{2}Y + \frac{1}{2}Z \right) \]
Breast Implant Selection

Upper Pole Pinch

- Skin fold calipers
- Measure skin pinch at proposed upper border of implant
- Actual thickness is ½ measured width
- Guides decision for subpectoral versus subglandular
- Guides selection of saline versus silicone versus anatomic
Breast Implant Selection

Skin fold measurements

- Allow objective data to be obtained
- Directly relates to implant choice
- Is reliable, yet flexible
- Satisfies the “measurers”
Breast Implant Selection

Data Sheet

- Factual information
- Positional measurements
- Relationships
- Sizing measurements
- Patient expectations
Breast Implant Selection

Desired Outcome – The Breast “Bling”

1 - A nominal augmentation, patient doesn’t want anyone to know she had it done
2 - As full a breast as possible without any excessive upper pole fullness, still looks natural
3 - A full breast, rounded contours desired, including upper pole where an artificial appearance is desired
4 - As big as can be done, size concerns override nuanced breast aesthetics, breast is remarkably artificial in appearance
Breast Implant Selection

Desired Outcome - Patient’s Goals

- Major part of preop evaluation
- Communicates very effectively the patients desires for the procedure
- Prevents postoperative dissatisfaction with size
- Guides implant choice
- Prevents reoperation for size change?
- Respects patients opinion
A major innovation in selection thinking

**Implant Selection Booklet**

Choose among a range of implant options based on **base width diameter**

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<thead>
<tr>
<th>Base Width (mm)</th>
<th>Base Width (cm)</th>
<th>Base Width (inch)</th>
<th>Base Width (mm)</th>
<th>Base Width (cm)</th>
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</tbody>
</table>
Breast Implant Selection

Let's see how it works

- Measure maximum BD
- Measure medial and lateral pinch
- Calculate “optimal” implant BD
- Measure upper pole pinch
- Assess skin envelope
- Assess patients desires

2 Minutes!!!
Breast Augmentation
Mentor Round Smooth Saline

Upper pole thickness - >2cm
Base diameter - 11 to 12 cm
Existing breast parenchyma - Moderate
Skin laxity - Loose
Inframammary fold - Maintain

Subglandular
Moderate profile
High profile
# Breast Implant Selection

## Mentor Round Smooth Saline - Mod Profile

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<tr>
<th>Fill Volume</th>
<th>Base Diameter</th>
<th>Projection</th>
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<tbody>
<tr>
<td>200-225 cc</td>
<td>11.0 cm</td>
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<td>225-250 cc</td>
<td>11.5 cm</td>
<td>3.5 cm</td>
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<tr>
<td>250-275 cc</td>
<td>11.9 cm</td>
<td>3.6 cm</td>
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*Patient expectations - Large natural result (2+)*
**Breast Implant Selection**

**Mentor Round Smooth Saline - High Profile**

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<th>Fill Volume</th>
<th>Base Diameter</th>
<th>Projection</th>
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<tr>
<td>290-350 cc</td>
<td>10.5 - 10.8 cm</td>
<td>4.7 - 5.9 cm</td>
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<tr>
<td>310-375 cc</td>
<td>10.7 - 11.0 cm</td>
<td>4.8 - 6.0 cm</td>
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<tr>
<td>330-400 cc</td>
<td>11.0 - 11.3 cm</td>
<td>4.8 - 6.2 cm</td>
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<tr>
<td>380-450 cc</td>
<td>11.4 - 11.7 cm</td>
<td>5.2 - 6.4 cm</td>
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*Patient expectations - Large natural result (2+)*
Breast Augmentation

Mentor Round Smooth Saline – High Profile

Location - Subglandular
Incision - Inframammary
Size - 310 cc implant filled to 350 cc, high profile

Base Diameter - 11.0 cm
Projection - 4.8 cm
**Breast Augmentation**

Mentor Round Smooth Saline – High Profile

Location - Subglandular
Incision - Inframammary
Size - 310 cc implant filled to 350 cc, high profile

Base Diameter - 11.0 cm
Projection - 4.8 cm
Breast Implant Selection

BodyLogic: Focus on what is important!

- Straightforward
- Reproducible
- Easily taught
- Uses measurements
- Uses judgment
- Wide appeal
Breast Implant Selection

BodyLogic System

- Straightforward
- Reproducible
- Easily taught
- Uses measurements
- Uses judgment
- Wide appeal
“Bodylogic” Implant Selection System

Mentor has one for YOU at the booth
Breast Reconstruction Issues

• What is the goal?
• How to get the most from STE reconstruction
• How to manage radiation patients
• What happens when it fails to achieve results?
3-Year Kaplan-Meier Analysis:
Baker III & IV Capsular Contracture

% OF PATIENTS WITH CONTRACTURE

Months

0 4 8 12 16 20 24 28 32 36

% 0 5 10 15 20 25 30

18.0%-Rev
8.3%-Rec
8.1%-Aug
3-Year Kaplan-Meier Analysis: Reoperation

- 27.9% - Rev
- 26.6% - Recon
- 15.2% - Aug
How can we do better?

- Choose the right expander
- Expand early and over-expand
- Hold over-expansion as long as possible
- Choose the right implant
- Revise both sides at implant placement
First: Choose the correct tissue expander

- For years I measured the mastectomy volume and chose the STE
- For many women the expander was too wide for the chest
- Most women choose to have the other breast reduced!!!
Choose the expander based on the mastectomy volume

• It works well for this patient
Choose the expander based on the mastectomy volume

• But not for this one
Choose the appropriate Tissue Expander based on the breast anatomy.
Choose the expander based on the breast width, not the mastectomy volume.
Prolonged over-expansion to obtain some ptosis
Prolonged over-expansion for ptosis
Balanced functional result
Bilateral patients:
Soft Tissue Expanders and Implants

- Similar technique for both sides
- Similar result for both sides
- Preserves the TRAM for salvage
- Minimal trauma-maximum result
Now 25% of patients are bilateral.....
18% of our patients are now bilateral.....
Bilateral STE and Implant
Don’t violate the inframammary fold

• Try to leave the attachments to fascia
• It is far easier to preserve a fold than to recreate one
• Use a-cellular dermis to reconstruct the fold when needed
Extend the length of the Pectoralis
At the Implant Placement Procedure

• Pay attention to the “anatomy”
• Use the opportunity to revise the reconstruction
  – Revise the pocket
  – Perform capsulectomy/capsulectomy
  – Liposuction where needed
• Balance the second side at the time of implant placement
Choose the correct Breast Implant

- Pay attention to the “anatomy”
- Choose the implant based on breast diameter
- Generally require a High Profile or Anatomic projection
STE-Implant and Reduction
Ongoing Issues-Future considerations

- Delayed-Immediate vs. Immediate
  - The problem is with radiation therapy damage
  - Need to await path results to plan care
- Patients with greater likelihood of radiation
  - Defer all types of reconstruction
- More delayed reconstructions
  - Address late effects of radiation
- More correction of contralateral side
Reported Adverse Outcomes with Implant/Expander Reconstruction Followed by Radiation

• 1998 Forman et al;
• 2000 Vandeweyer et al;PRS 106(1)2000
Reported Good Cancer Outcomes for Implant/Expander Reconstruction Followed by Radiation

• 2004 Hazard et al Local
  - Regional Radiation Therapy After Breast Reconstruction: What is the Appropriate Target Volume?: A Case-Control Study of Patients Treated with Electron Arc Radiotherapy…(with EBR)
    AmJClinOncol, 27(6) Dec 2004
  - 224 pts (no reconstruction)/18 pts irradiated, 1/18 TRAM (?)p/f), 13/18 one stage Becker ((2/13 Si+Saline/ 11/13 Saline) 61 mo median f/u, 1-2 nodes
  - Results: No patients failed deep to prosthetic device, no sig dif of local regional control and disease free survival, significant Capsular contracture in 3/17 (18%) 11/17 Good (85%)
Staged Breast Reconstruction with Saline-Filled Implants in the Irradiated Breast: Recent Trends and Therapeutic Implications

Spear et al PRS 105(3), March 2000, pp 930-942

- Retrospective review, 40 consecutive pts, two-stage reconstruction with saline-filled implants and radiation, controls 40pts with two stages without radiation
- “Cosmetic evaluations of the saline implant radiated breasts reveal that on average, good results can be obtained with implants, even in the presence of radiation
Patients having radiation

- **Prove** STE will not work first
- Place the STE; begin expansion on table
- Over expand as rapidly as possible
- Hold until effects of radiation are done
- Retain the latissimus as the safety boat
Some patients will need a lat flap
Implant with Skin-sparing mastectomy & radiation
Implant with Skin-sparing mastectomy & radiation
Reconstruction algorithm

• Understand the patient’s goals and limitations—how driven by “perfection” are they?

• Accomplish the most difficult reconstructive task first
  – make the best breast mound in the best place

• Match the two mounds, then the two nipples
  – can usually do masto-pexy to match and the nipple reconstruction at the same time
Thank You

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