The New Fabric for Sling Method in Expander-Implant Immediate Breast Reconstruction

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COI Disclosure Information

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I have the following financial relationship to disclose.

✓ In-kind support for this activity from GUNZE medical division
Background

There have been several kinds of devices used for sling method in immediate two-stage breast reconstruction with tissue expander (TE).
Object

This presentation is to show a prospective study protocol for assessment of the new bioabsorbable polyglycolic acid (PGA) felt to adapt for immediate two-stage breast reconstruction based on TE with sling method.
Materials and Methods

• The PGA felt (NEOVEIL sheet, GUNZE medical division, Japan) was developed as a scaffold on regenerative medicine.

• This product is commonly used for reinforcing to the suturing part in other surgery.

• This sheet will be absorbed within 15 weeks after implantation.
Materials and Methods

PGA felt was adapted to cover TE in lower lateral pole of breast at first stage.
Participant

✓ Informed consent was available.
✓ Primary breast cancer patient
✓ Immediate two-stage breast reconstruction with TE following mastectomy
✓ January 2010 – September 2011
✓ Target sample size 30
Outcome

• Primary outcome
  Incidence of implant loss within 30 days after surgery.

• Secondary outcome
  - Incidence of any adverse event
  - Postoperative pain
  - Patient-reported outcome (PRO)
  - Aesthetic outcome.
  - Histology of soft tissue around TE
Inclusion criteria

- NSM or SSM
- Age $> 20$ years old
- $\text{BMI} \leq 25 \text{ kg/m}^2$
- Breast ptosis $< \text{Regnault Grade} 3$
- Non-smoker
Exclusion criteria

• Inflammatory breast cancer
• Past history of radiation therapy
• Diabetes mellitus
• Collagen disease
• Any disease administered steroids
Study Flow

Informed consent
Enrollment

Two-staged reconstruction with TE using PGA felt

Exchange to implant

Following up and assessment at 1 month and 3, 6, 12 months

Excluded

Expansion
Adjuvant therapy

Poor skin viability

TE without PGA felt
Advantage

• Low cost
• Soft texture
• High biocompatibility
• Proven safety for several decades in other surgery
Disadvantage

• Inflammatory reaction at early stage during absorption

• Lack of evidence on breast reconstruction
Limitation

This study is not randomized control trial, but prospective observational study in a single-center.