

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

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COI Disclosure Information

Lead Presenter
Satoko Watanabe

I have the following financial relationship to disclose.

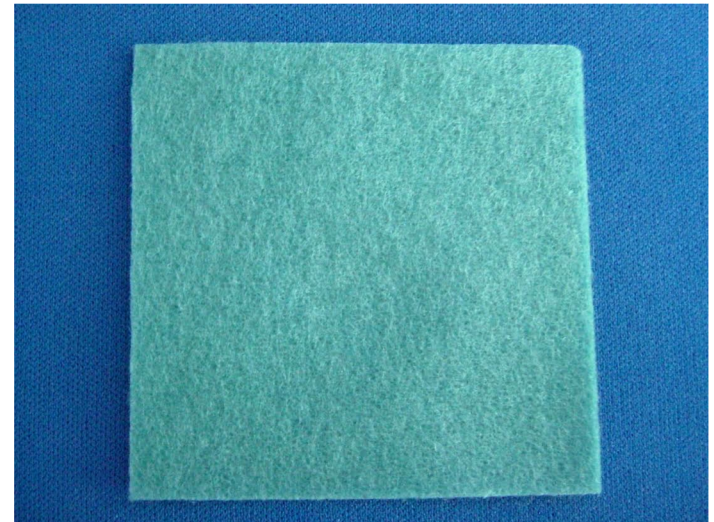
- ✓ In-kind support for this activity from GUNZE medical division

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.

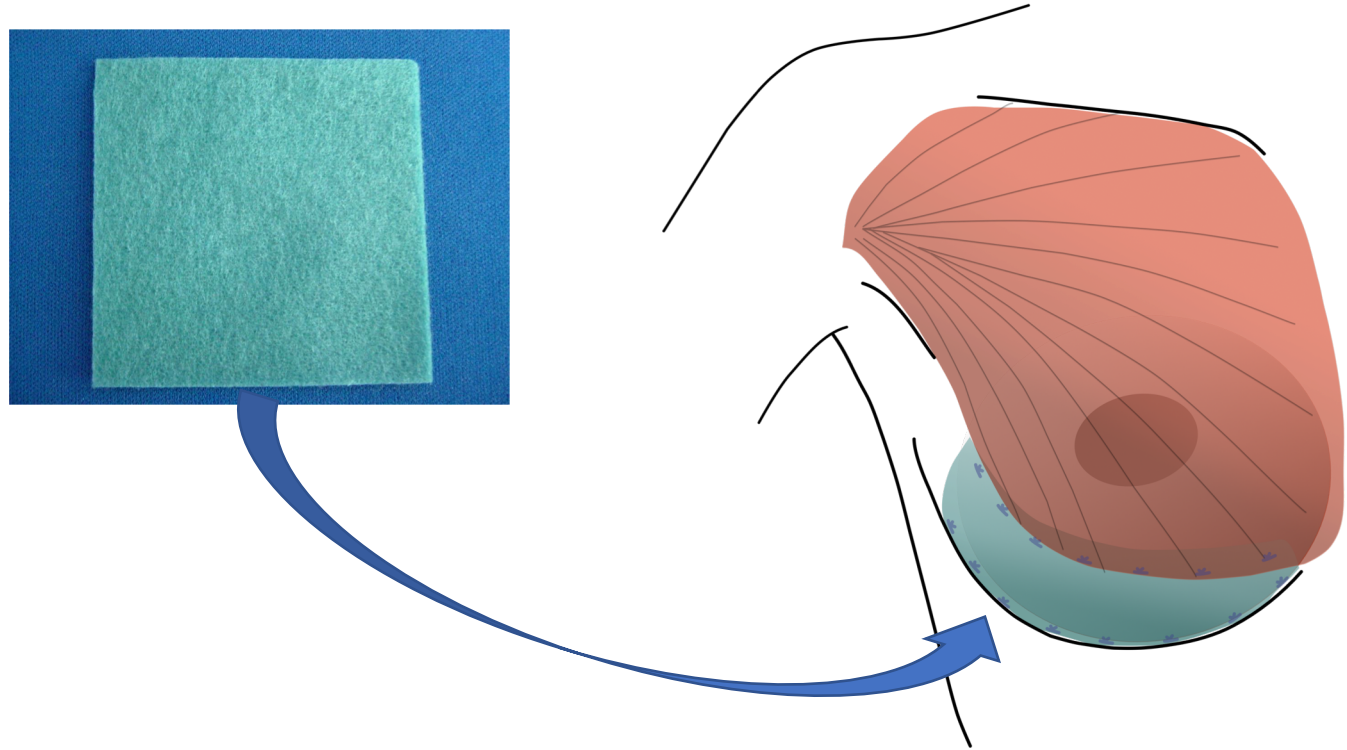


Materials and Methods

- 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

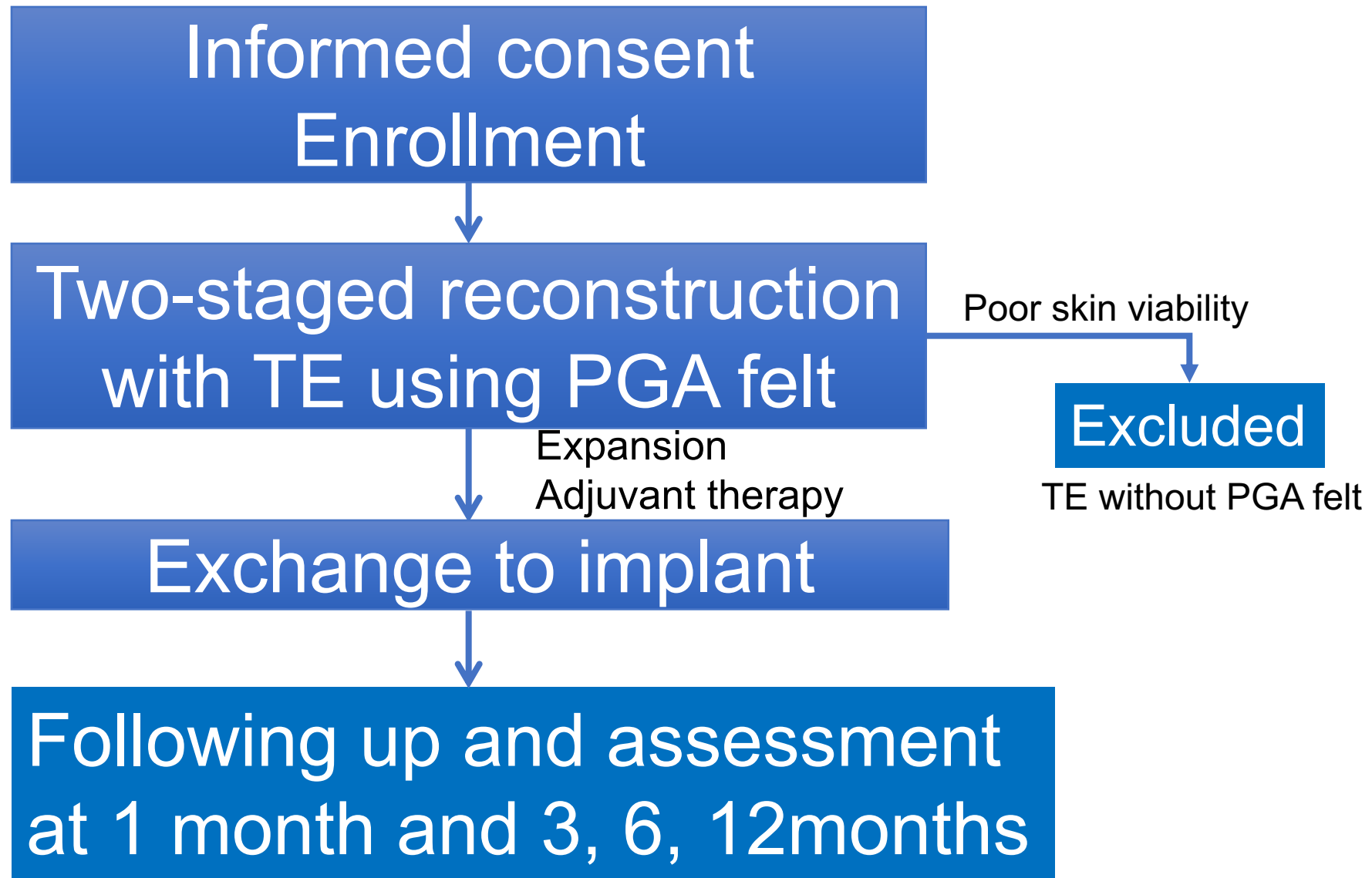
Inclusion criteria

- NSM or SSM
- Age > 20 years old
- BMI ≤ 25 kg/m²
- Breast ptosis $<$ Regnault Grade3
- Non-smoker

Exclusion criteria

- Inflammatory breast cancer
- Past history of radiation therapy
- Diabetes mellitus
- Collagen disease
- Any disease administered steroids

Study Flow



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.