clinical studies

breast

Evaluating Mechanical Properties of Post-Mastectomy Skin Flaps to Estimate Reconstruction Risks (EMPOwER)

PRINCIPAL INVESTIGATOR

Benjamin D. Smith, MD
Professor Radiation Oncology
MD Anderson Cancer Center

SITE ENROLLING

MD Anderson Cancer Center
Houston, Texas, USA

ClinicalTrials.gov ID:
NCT06584396

artidis

Timely Diagnosis | Optimized Therapy

Clinical Performance Study | Type: **Observational** | Design: **Prospective, Single-Center Cohort Study**
Interventional Model: **Single Arm** | Masking: **Blinded** | Primary Purpose: **Diagnostic & Treatment Optimization**

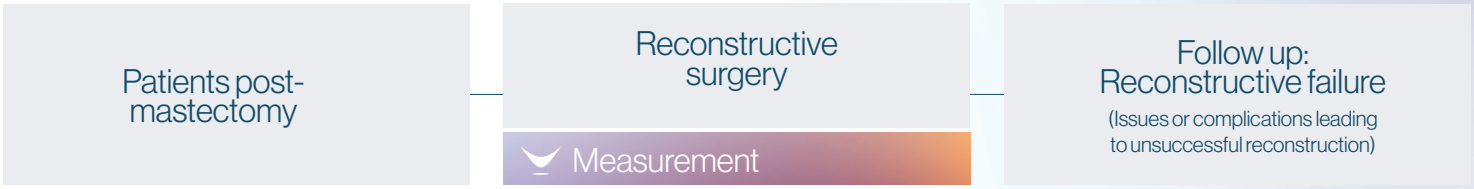
Brief summary

This study evaluates the skin and surrounding soft tissue that is removed during an implant reconstruction after a mastectomy.

Clinical relevance

At present, there is no reliable way to determine which patients are suitable for implant reconstruction, and more than 20% of all breast reconstructions fail, particularly after post-mastectomy radiation therapy. The Nanomechanical Signature may correlate with reconstruction failure, and thus could allow the further optimization breast reconstruction strategies.

Study schema



Study population

Female patients currently in the tissue-expander phase of reconstruction, with planned expander-to-implant exchange within 3 months.

No. of patients: 110

Age: ≥18y

Study duration & readouts

Enrollment start: Q3 2023

Expected duration: 4 years

Clinical follow-up: 2 years

Key end-point readouts at

12 months
24 months

Key inclusion criteria

- Age 18 years or older.
- Patient with history of mastectomy with tissue expander placement.
- Tissue expander in place at time of study enrollment
- Patient plans to undergo surgery to exchange tissue expander for permanent breast implant within the next 3 months of signing the informed consent.
- Ability to understand and provide written informed consent in accordance with institutional policies.

Key objectives

1. Characterize the nanomechanical properties of the skin and adjacent soft tissue removed at the time of postmastectomy implant reconstruction.
2. Evaluate if the Nanomechanical Signature can predict the reconstructive surgery failure.

SPONSOR & PARTNERS

Sponsor
MD Anderson Cancer Center

Collaborator
Artidis AG

PRINCIPAL INVESTIGATOR

Benjamin D. Smith, MD
Professor Radiation Oncology
MD Anderson Cancer Center

For any questions about this study or to express your interest in participating, please reach out to our research team at:

Basel · Houston · Barcelona · Zagreb
communication@artidis.com
www.artidis.com
Follow us on in

 ISSUE DATE: 2026-04 MAR-CLP-004-v002