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EMPOwER Study: Predicting Implant Failure through Tissue Mechanics Analysis in Breast Reconstruction

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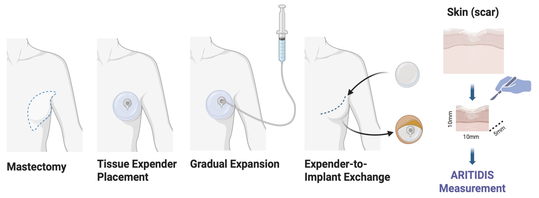
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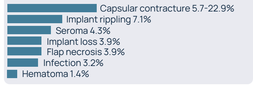
Nanomechanical phenotypes as predictors of breast implant failure

Implant-based breast reconstruction is associated with higher rates of reintervention and failure than autologous techniques, especially in the context of postmastectomy radiation therapy. Breast implants can fail over time due to complications like rupture, contracture, infection, or wound problems. High-risk for failure is commonly associated wtih high BMI, smoking, prior radiotherapy, or prepectoral placement. While imaging can detect some early complications, such as seromas or infections[1-2], it does not capture tissue quality or mechanical risk factors. Nanomechanical phenotyping may help fill this gap by providing early, tissue-based indicators of reconstructive failure.



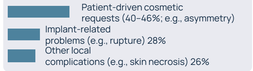
Breast Implants: Complication rates after mastectomy and reconstruction.

Overall, **31%** of women develop at least one adverse event after initial implantation.



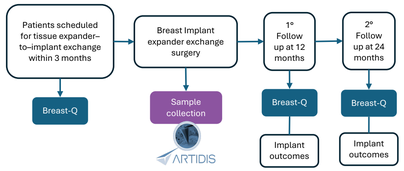
Breast Implants: Reasons for Reintervention After Mastectomy

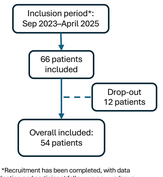
Up to **69.5%** undergo at least one revision within 8 years, and **17.6%** require secondary reconstruction.



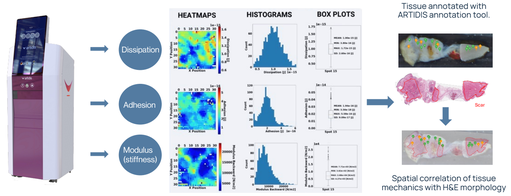
1. Mak, J. C., & Kwong, A. (2020). Complications in Post-mastectomy Immediate breast reconstruction: A Ten-year analysis of outcomes. Clinical Breast Cancer, 20(5), 402–407.
2. Jimenez RB et al. The Timing of Acute and Late Complications Following Mastectomy and Implant-based Reconstruction. Ann Surg. 2023 Jul 1;278(1):e203-e208.

Study design and Artidis technology





The **EMPOwER** study is a prospective, observational biomarker trial measuring skin and soft tissue removed during implant-based reconstruction after mastectomy. By characterizing tissue properties, the study aims to identify factors that influence reconstruction outcomes. As an exploratory study, it is designed to generate hypotheses for future research and support more informed decision-making in breast reconstruction.



The nanomechanical phenotype is derived from all measurements and channels.

Nanomechanical tissue phenotyping results

Table 1. Patient Characteristics (n = 54)

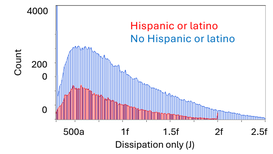
Characteristic	Category	n	%
Age (years)	Mean (SD)	55.17 (11.44)	
BMI (kg/m²)	Mean (SD)	28.14 (5.73)	
Gender	Female	54	100
Reason for breast surgery	Breast cancer	30	55.6
	Breast cancer + prophylactic surgery	12	22.2
	Genetic predisposition (prophylactic)	6	11.1
	NA	6	11.1
Type of mastectomy	Skin-sparing mastectomy	42	77.8
	Nipple-sparing mastectomy	4	7.4
	Modified radical mastectomy	1	1.9
	NA	7	13
Laterality of mastectomy	Bilateral	24	44.4
	Left	11	20.4
	Right	13	24.1
	NA	6	11.1
Axillary procedure	Sentinel lymph node biopsy	24	44.4
	Axillary dissection	3	5.6
	None	19	35.2
	NA	18	33.3
Implant placed after TE removal	Yes	47	87
	No	1	1.9
	NA	6	11.1
Germline mutation	BRCA1	1	1.9
	BRCA2	4	7.4
	CHEK2	1	1.9
BREAST-Q follow-up	Baseline	54	100
	12 months	11	20.4
	24 months	0	0

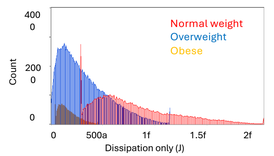
Table 2. Breast Tumor Characteristics (n = 42)

Characteristic	Category	n	% (of 42)
Laterality of breast cancer	Right	21	50.0
	Left	18	42.9
	Bilateral	3	7.1
Estrogen receptor (ER)	Positive	35	83.3
	Negative	7	16.7
Progesterone receptor (PR)	Positive	33	78.6
	Negative	9	21.4
HER2 status	Positive	5	11.9
	Negative	26	61.9
	Unknown	11	26.2
Tumor grade	Grade 1 (low)	2	4.8
	Grade 2 (intermediate)	15	35.7
	Grade 3 (high)	4	9.5
	NA	21	50.0
Histology	DCIS	12	28.6
	Invasive ductal carcinoma	23	54.8
	Invasive lobular carcinoma	3	7.1
	Mixed ILC and IDC	1	2.4
	Adenoid cystic	1	2.4
	Other	2	4.8
Treatment received	Neoadjuvant therapy	9	21.4
	Adjuvant therapy	10	23.8
	Radiotherapy	11	26.2
Tumor size (T stage)	T0	2	4.8
	Tis	7	16.7
	T1a–c	6	14.3
	T2	4	9.5
	T3	1	2.4
	NA	22	52.4
Nodal stage (N stage)	N0	13	31.0
	N1a	3	7.1
	N2a	1	2.4
	Nx	4	9.5
	NA	21	50.0

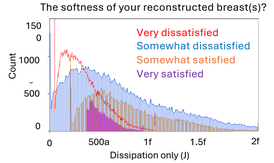
Baseline tissue nanomechanical phenotype correlates with body composition and BREAST-Q physical well-being

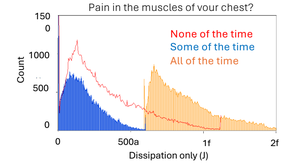
Histogram of baseline characteristics vs dissipation only





Histogram of baseline Breast-q vs dissipation only





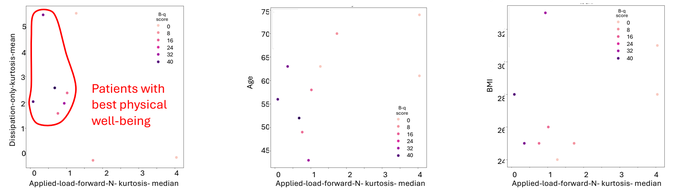
These baseline findings support the use of nanomechanical dissipation as a non-subjective, predictive tool to guide personalized reconstructive planning and improve patient satisfaction in post-mastectomy breast reconstruction.

Nanomechanical tissue phenotypes stratify patient-reported chest discomfort at 12 months after breast reconstruction

Rasch model was applied to transform raw breast-q answers into scaled scores (0–100) for chest domain. The scaled scores obtained are correlated with nanomechanical parameters.

- A low score (e.g., 20/100) suggests significant pain, tightness, or discomfort
- A high score (e.g., 90/100) suggests little or no physical limitation or pain

Scatter plot of applied load forward vs dissipation only vs age vs BMI

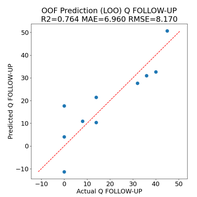


- Age and BMI were included as covariates in the analysis but showed no significant association with nanomechanical features.
- This may be due to the limited sample size at 12 months follow-up timepoint. Further analysis in a larger cohort is planned to validate these findings.

Nanomechanical phenotypes measured at surgery show promise as predictors of patient well-being one year after reconstruction. Applied load kurtosis reflects how tissue absorbs mechanical force; higher values indicate increased stiffness or ECM irregularity. These early mechanical markers may help guide more personalized and patient-centered care.

Predicted vs. actual BREAST-Q Physical Well-Being scores at 12-month follow-up using a linear regression model trained on nanomechanical features

Out-of-fold (OOF) predictions Leave-One-Out Cross-Validation (LOOCV)



Model performance:

- R^2 = 0.764 → The model explains 76.4% of the variation in BREAST-Q follow-up scores.
- MAE = 6.96 → On average, the prediction is off by about 7 points.
- RMSE = 8.17 → Root mean squared error suggests low overall prediction error

Conclusion & perspective

- Nanomechanical phenotyping captured at surgery correlated well with patient-reported outcomes and demonstrated strong predictive potential. These findings demonstrate the promise of nanomechanical tissue parameters as early biomarkers for guiding personalized surgical planning to allow patient-bespoke breast reconstruction.
- Future work will focus on validating nanomechanical measurements as biomarkers in larger, multi-center cohorts and integrating them into clinical decision-making workflows. This has the potential to enhance risk stratification, optimize reconstruction strategies, and improve long-term patient outcomes.

Lay summary

- Nanomechanical features measured in tissue at time of tissue expander replacement were linked to patient-reported breast softness and chest discomfort. The results demonstrate that the ARTIDIS device can objectively identify patients with chronic chest pain.
- One year after reconstruction, these measurements could distinguish patients who experienced more chest pain from those who recovered more comfortably. Our predictive model showed that nanomechanical features can help forecast physical well-being after breast reconstruction.
- These findings suggest that tissue nanomechanics may serve as a new biomarker. Identifying patients at higher risk earlier, will allow more personalized surgical planning, improving long-term patient comfort and outcomes.y

Disclaimer: The EMPOwER study and the data presented herein are exploratory and intended for research purposes only. ARTIDIS technology is not cleared or approved for predicting implant failure, guiding surgical planning, improving patient outcomes, or determining response to therapy. The findings should not be interpreted as diagnostic, prognostic, or therapeutic recommendations.