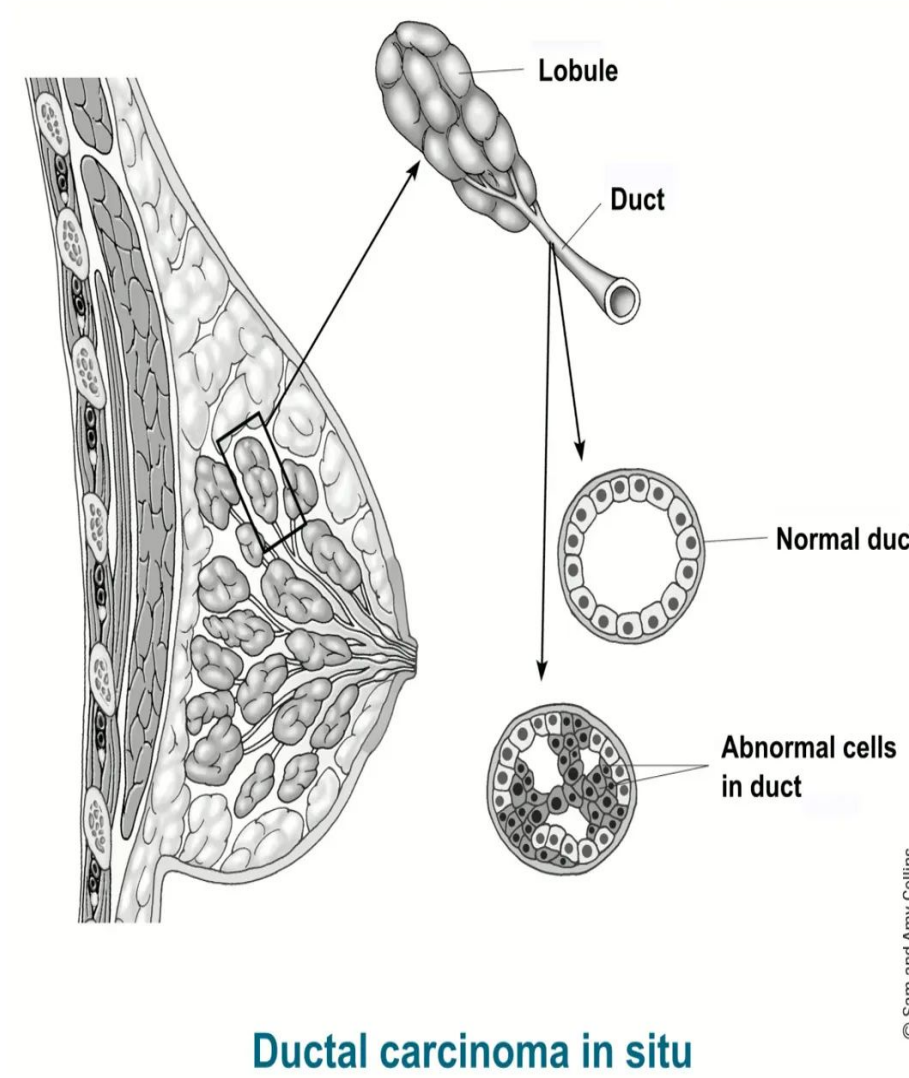


Background

- There are more than **2.3 million new cases** of breast cancer globally every year¹
- About **13% of women in the US** are at risk of developing breast cancer in their lifetimes, and global rates are rising²
- **80% of breast cancers originate in the mammary ducts** and only about 5-10% of them are hereditary³
- There is **no existing prevention strategy** for ductal contaminant entry
- There is also **no known information** on whether the mammary duct stays open during times of no breastfeeding and allows contaminants to enter



- This project develops a **nipple and areolar coverage device** for complete ductal sealing using a skin-safe silicone cover and Libre Patch hypoallergenic adhesive
- This project also allows external volunteer testing through our **IRB submission**

Objectives

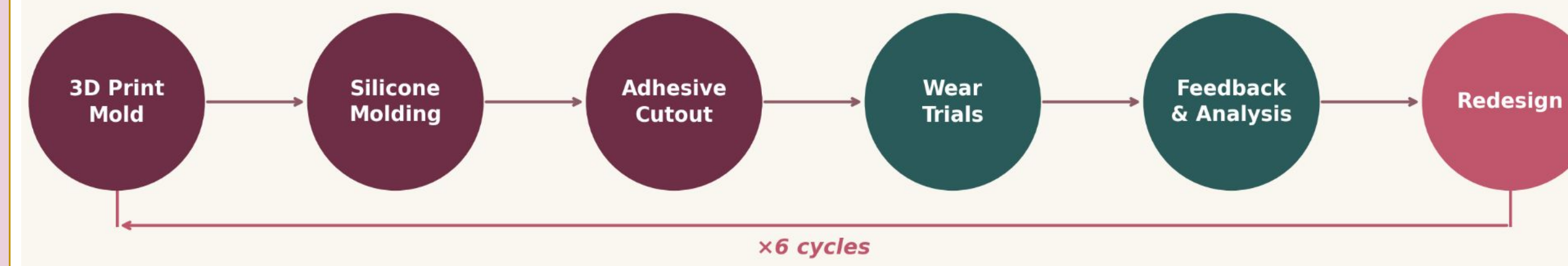
Device Performance

- **Seal ductal openings:** Block all lactiferous duct openings to prevent contaminant entry during 12+ hours of daily wear
- **Maintain secure adhesion:** Achieve displacement-free adhesion across dry, wet, and active conditions
- **Ensure biocompatibility:** Use hypoallergenic, skin-safe materials to eliminate adverse reactions across all skin types
- **Prioritize comfort and discretion:** Conform to diverse anatomies and remain undetectable under clothing

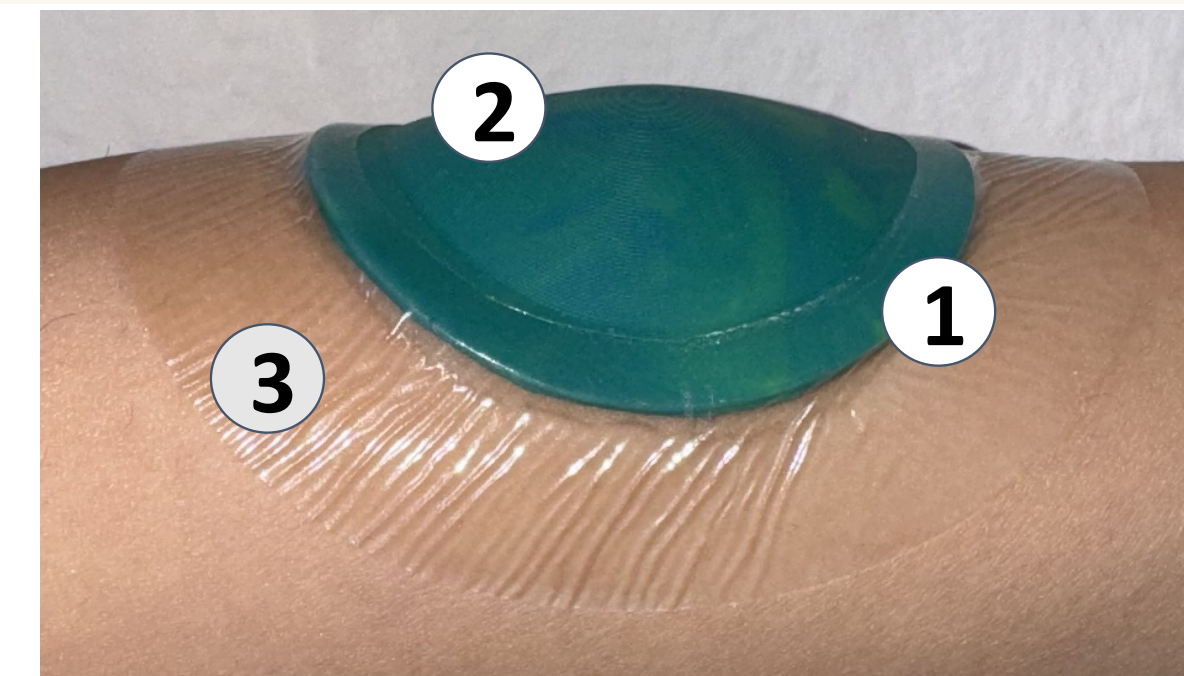
Clinical & Research Goals

- **Obtain IRB approval:** Enable external volunteer recruitment and clinical validation of safety and efficacy
- **Address an unmet clinical need:** Offer ~12 million at-risk U.S. women a non-invasive, affordable prevention alternative

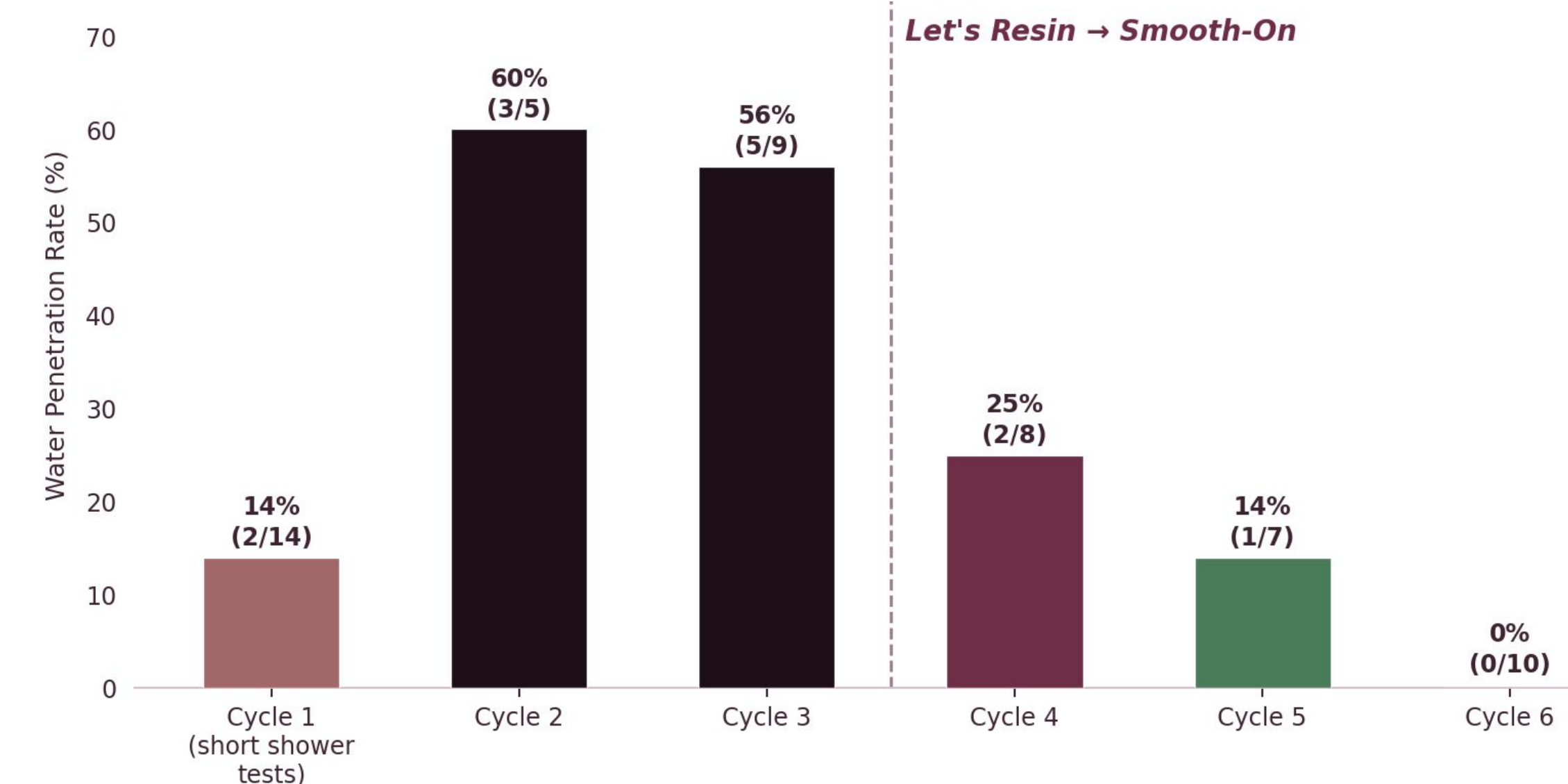
Device Design & Testing



1. **Thin rim** for a flush, discrete fit
 2. **Dome-like geometry** to prevent nipple compression
 3. **Libre-Patch Adhesive** for device adherence to skin surface
- *Skin-safe components

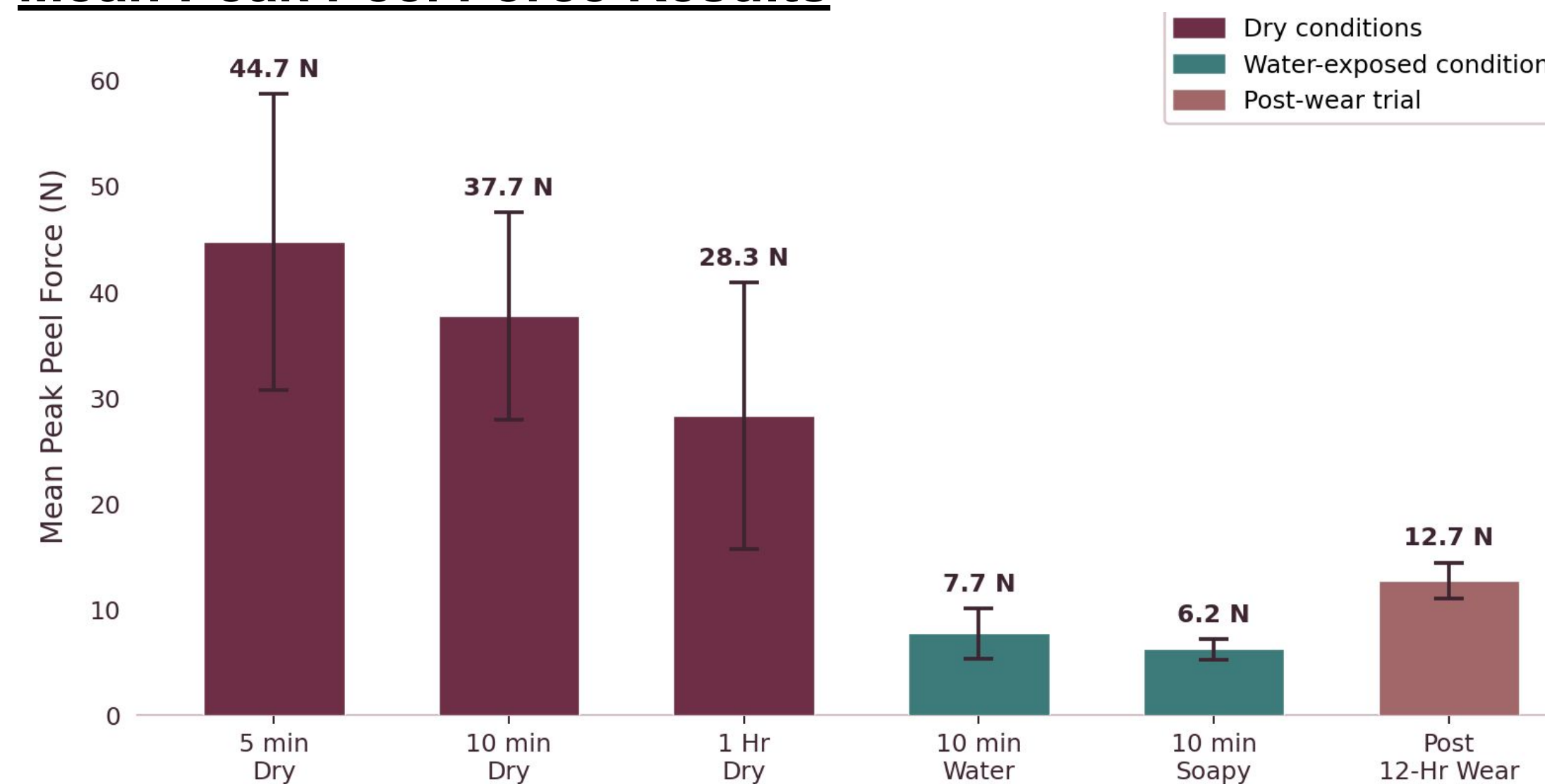


Water Penetration Results



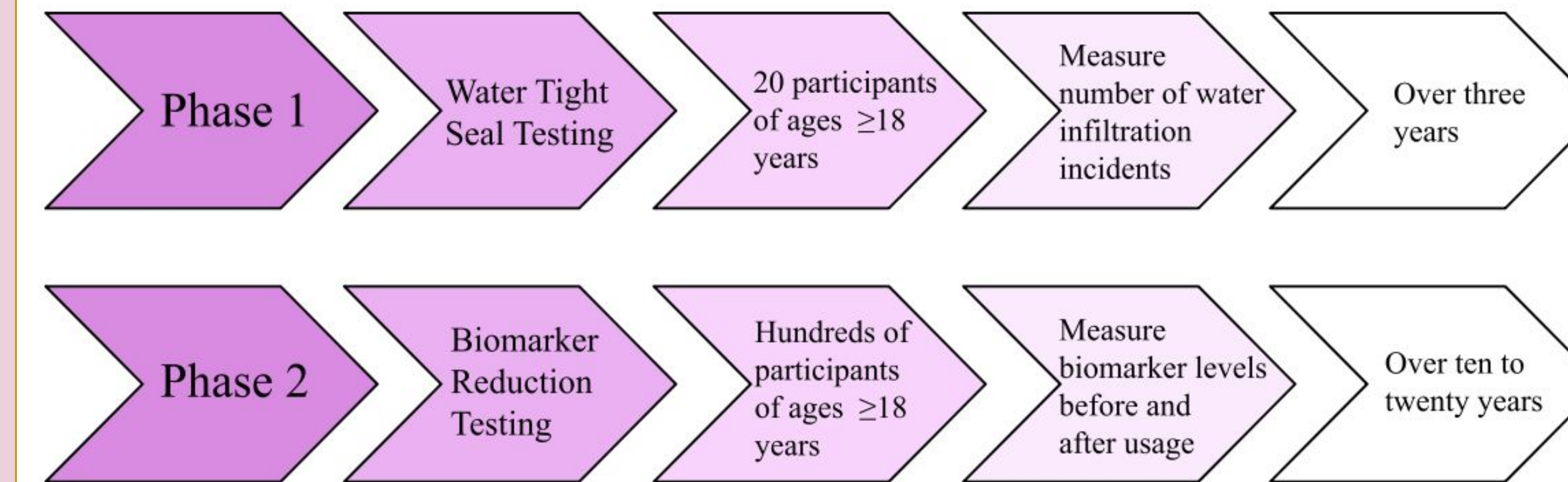
Proportion of wear trials with water penetration per cycle, with 12–20 hr daily wear and n = 5 participants. Cycle 1 short shower-only sessions are shown for reference only. Dashed line marks material transition, which drove the largest improvement in seal performance.

Mean Peak Peel Force Results



Peel force testing assessed whether the Libre Patch adhesive maintains sufficient hold during extended wear and water exposure. Force was measured in six conditions using a calibrated digital force sensor at 1"/sec perpendicular pull on the volar forearm (± 1 SD, n = 3–6 per condition). Water exposure reduced adhesion ~80–84% vs. dry baseline.

Trial Design



Phase 1: Water Tight Seal Testing (Preclinical)

- Water infiltration will be defined as visible water beneath the device upon removal or clear separation of the adhesive border that would allow entry
- Primary study outcome: determine whether the device can stop water infiltration at the nipple surface

Phase 2: Long Term Biomarker Reduction Testing

- Biomarker levels will be measured via nipple fluid samples both before and after device usage to determine overall change
- Primary study outcome: sustained device usage will lead to a decrease in breast cancer related biomarkers

Future Directions

- **Size variants:** incorporate a range of diameters to account for anatomical diversity
- **Colors:** develop silicone skin-tone color options to help wearing the device feel more discreet and visually appealing
- **Standardized durability testing:** testing device performance under sweat, friction, and repeated wear cycles
- **Material characterization:** better characterize the silicone material and determine its effective pore size
- **Ductal contaminant entry mechanism** as research platform

Acknowledgements

We sincerely thank our faculty mentors, Dr. Geert Schmid-Schoenbein and Dr. Alyssa Taylor, for their invaluable guidance and support throughout this project. We also thank the prior senior design team and the UCSD Makerspace for their contributions and support.

[1] Breast Cancer—Epidemiology, Risk Factors, Classification, Prognostic Markers, and Current Treatment Strategies—An Updated Review - PMC <https://pmc.ncbi.nlm.nih.gov/articles/PMC8428369/>
 [2] U.S. Census Bureau. (2023). Age and Sex Composition in the United States: 2023. <https://www.census.gov/data/tables/2023/demo/age-and-sex/2023-age-sex-composition.html>
 [3] Johns Hopkins Medicine. Invasive Ductal Carcinoma (IDC). <https://www.hopkinsmedicine.org/health/conditions-and-diseases/breast-cancer/invasive-ductal-carcinoma-ids>