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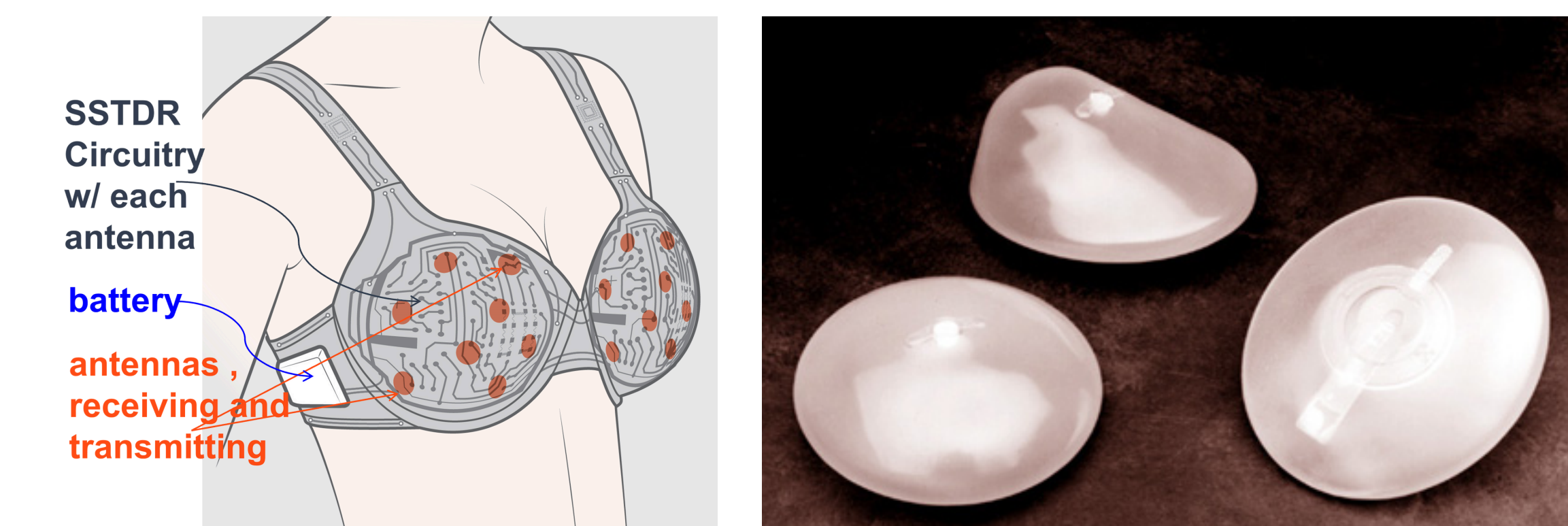
Research Questions

- Can an implant rupture be detected using SSTDR?
- How much silicone needs to leak to be detectable?

Introduction

SSTDR

- Spread-spectrum time-domain reflectometry (SSTDR) measures transmission and reflection of signals over many frequencies
- SSTDR is being researched as a method to detect breast cancer that is low cost, non-intrusive, and quick



Mockup of testing device in use
Credit: Milica Popovic

Late generation silicone breast implants [1]

Silicone Breast Implants

- Ruptured breast implants can cause: swollen lymph nodes, morning sickness, night sweats, and other health complications [2]
- The standard diagnosis for a rupture requires an MRI machine, which is expensive and time consuming
- The body naturally creates a “capsule” of scar tissue around the implant [3]. Around 75% of implant ruptures do not include the capsule rupturing, minimizing silicone leakage while making them harder to detect [2]
- 10%-15% of breast implants rupture within 10 years [4]

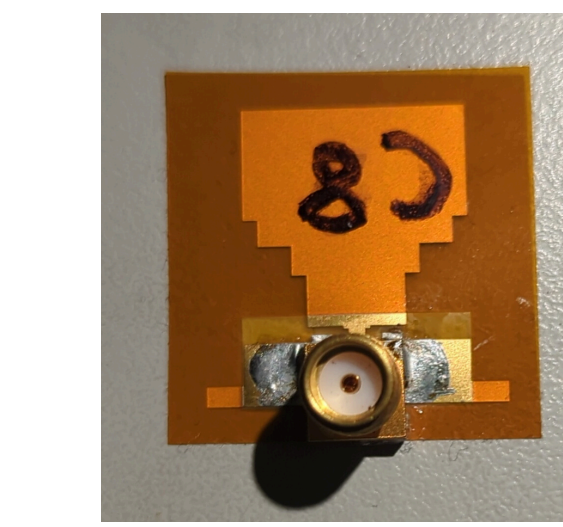
Methods

Implant & Mold Equipment

- Breast mold filled with canola oil
- Silicone breast push-up
- Syringe through center
- Plastic wrap covering syringe and push-up
 - Prevents silicone falling
- Syringe filled with silicone caulk
- 2 broadband antennas
- Keysight’s device for SSTDR

Measurement Procedure

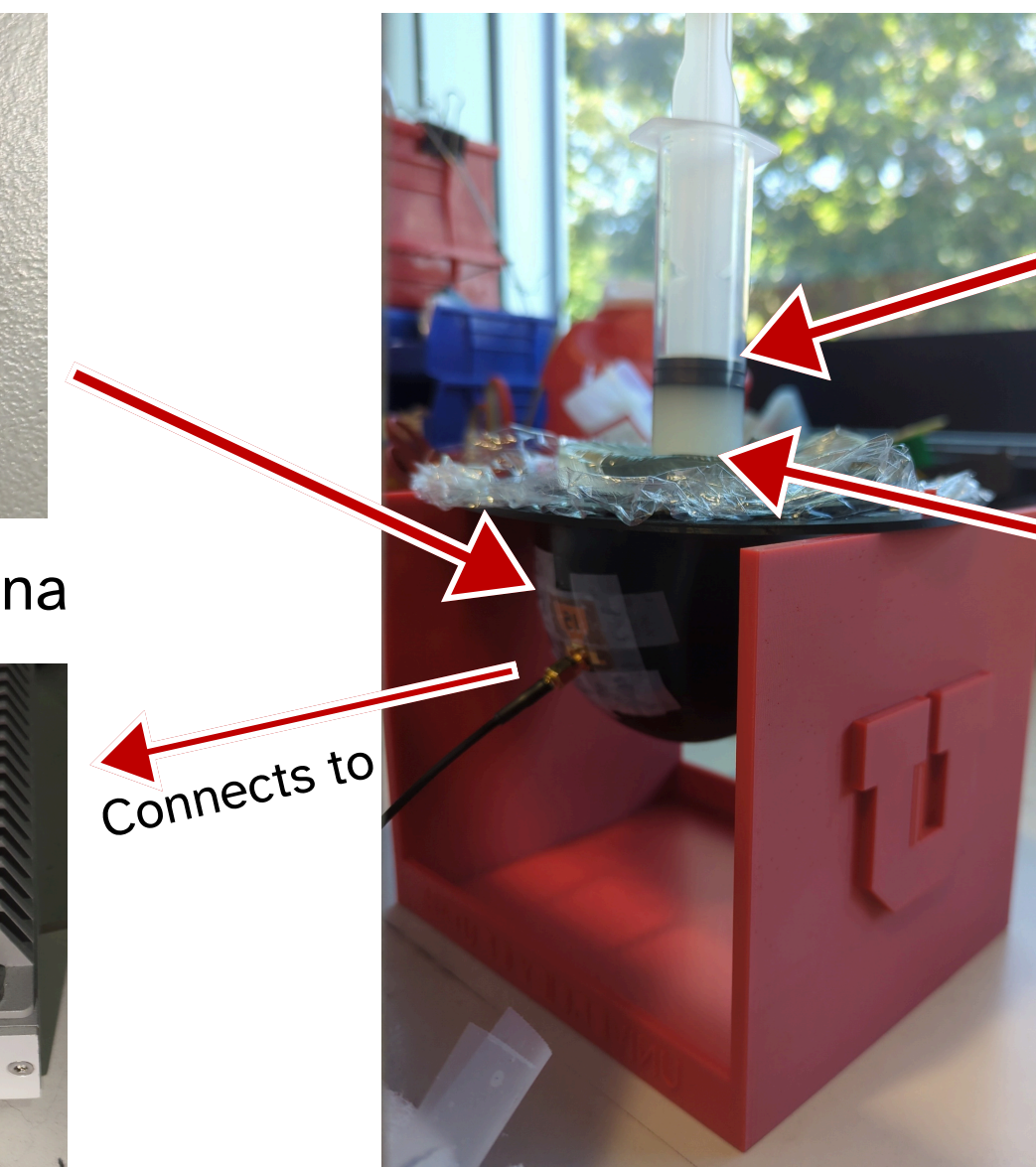
- Started at 0 cc
- Added 2 cc of silicone caulk
- Measured, repeated until 20 cc
- At 10/20 cc, moved syringe around to increase variability
- Other measurements included adding oil, changing implant location, and moving antennas



Broadband antenna



Keysight’s device for SSTDR



Breast mold with simulated implant leakage



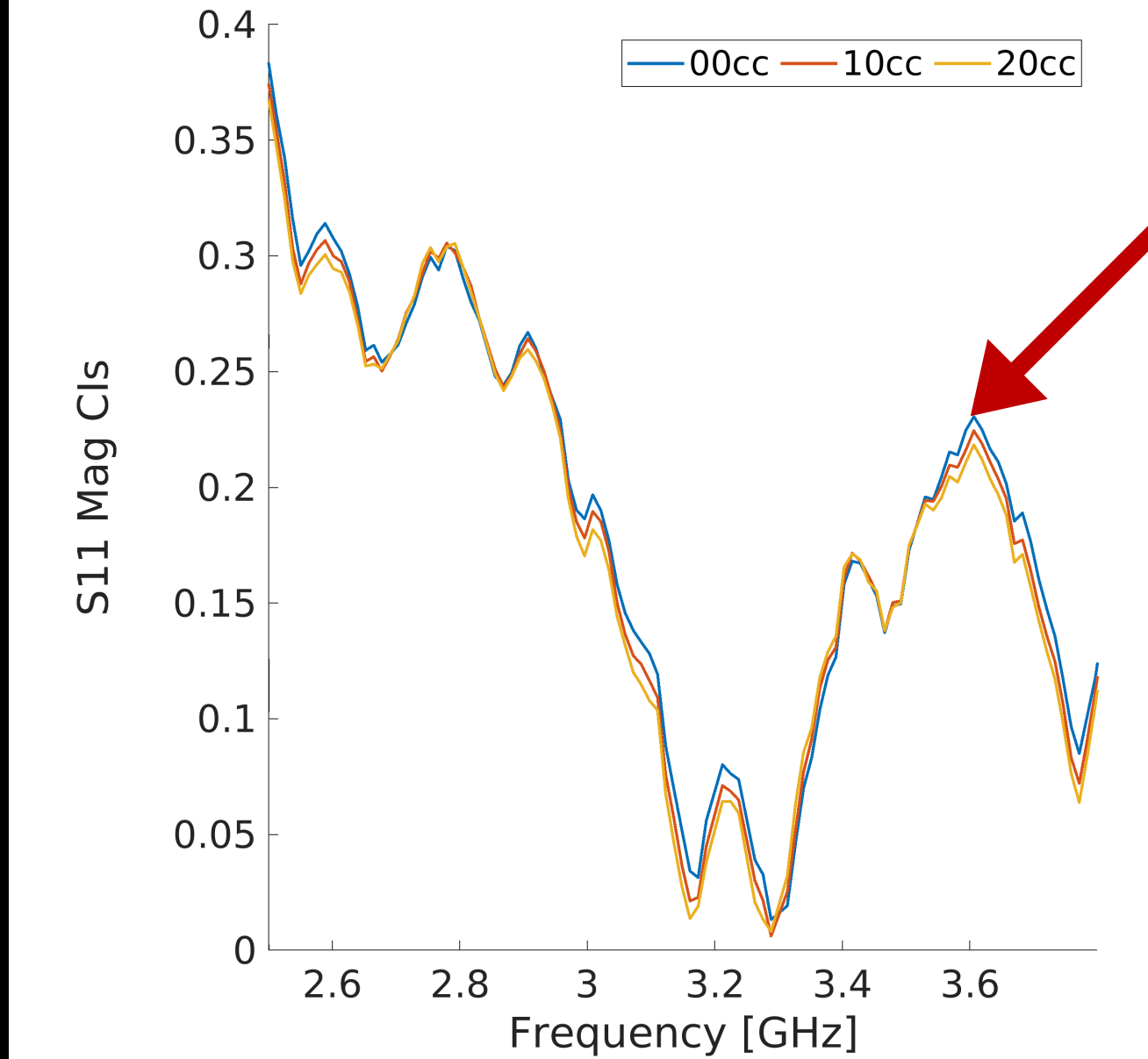
20 cc silicone caulk

Simulated breast implant

Results

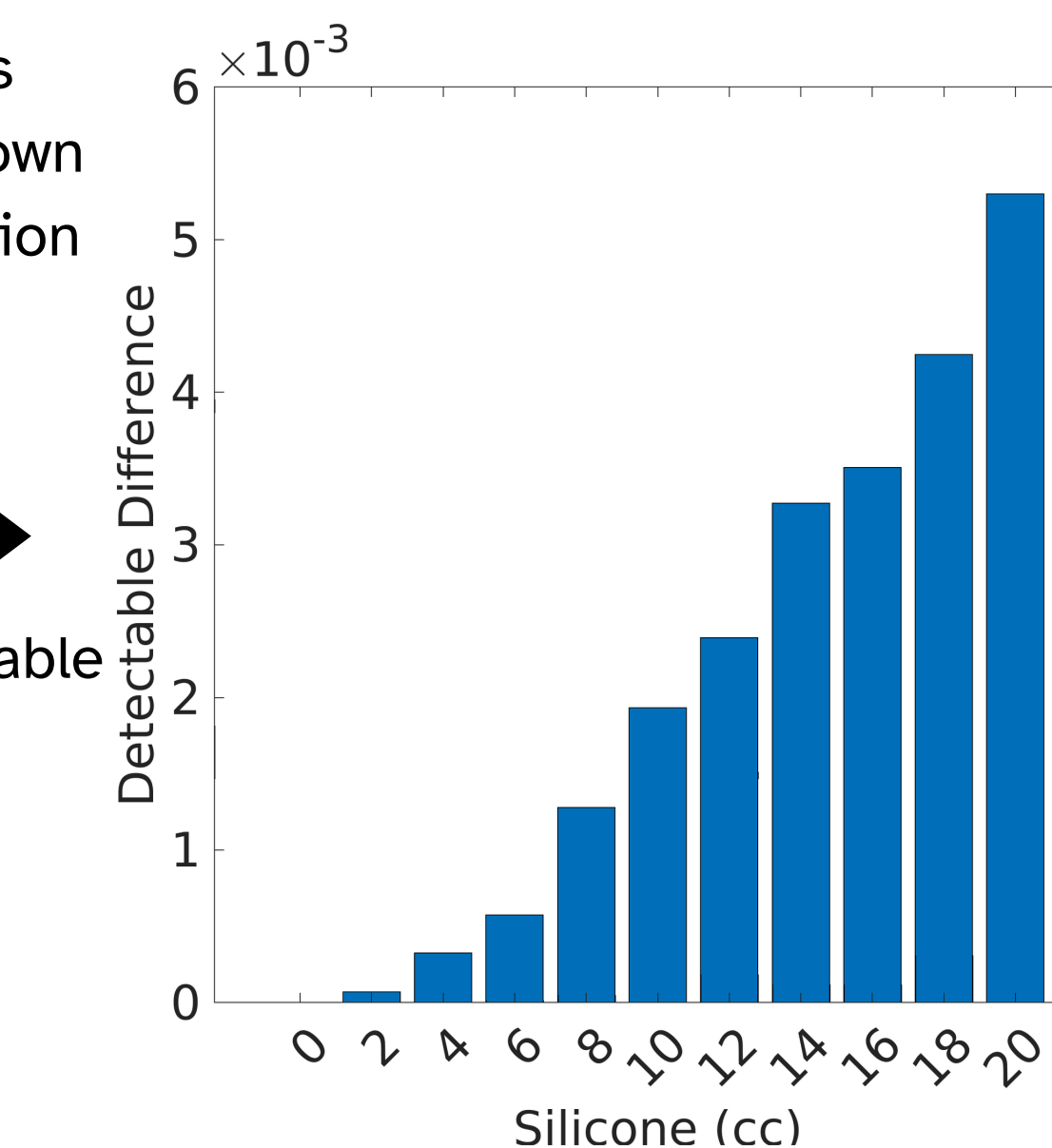
Silicone Added

Magnitude of reflected signal for different amounts of silicone caulk



Difference is detectable, shown by line separation
Sums of detectable differences

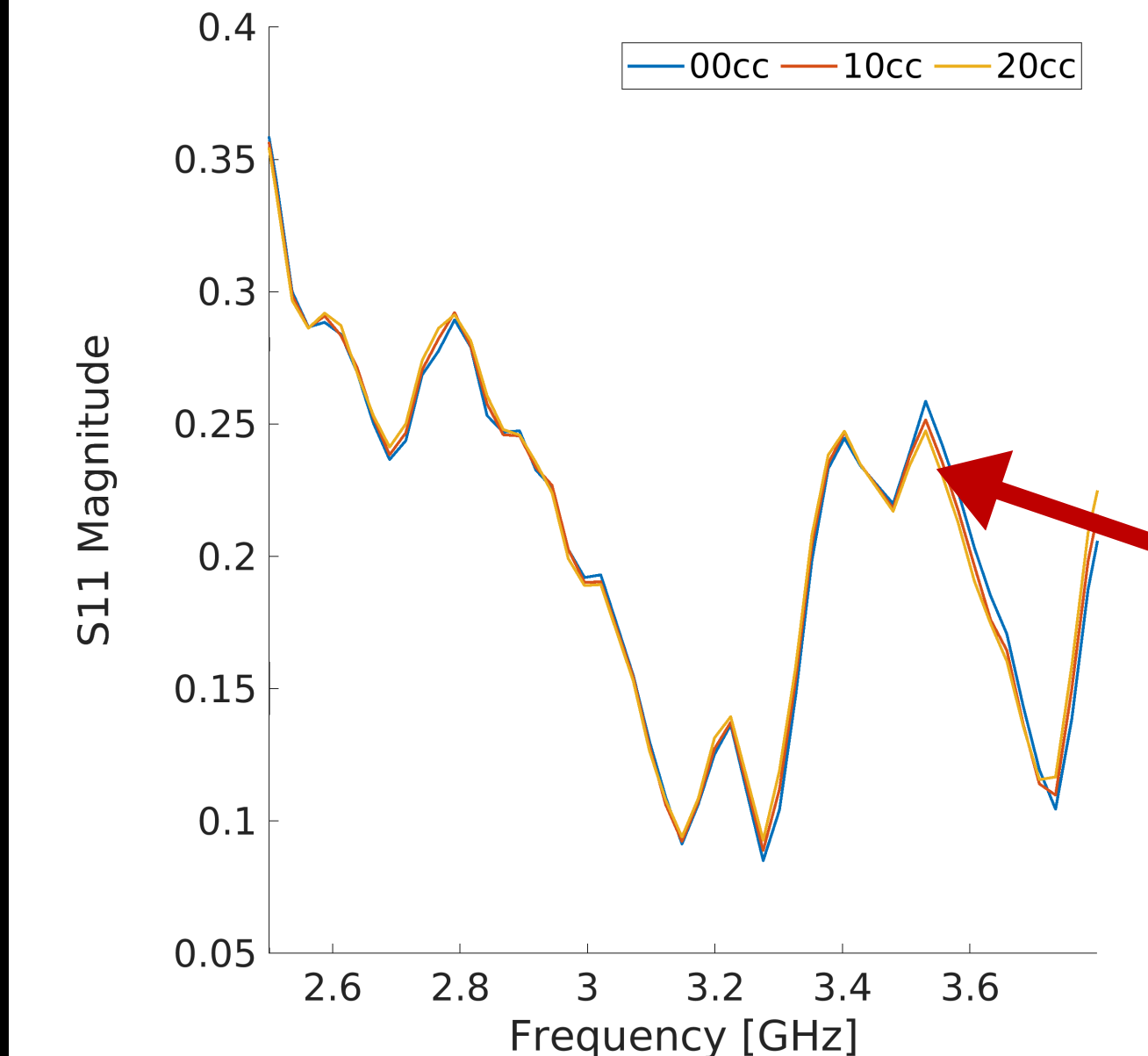
Detectable difference from 0cc to target cc with a confidence interval of 95%



- Clear ability to detect difference in silicone levels
- Detectable difference appears roughly linear
- Baseline measurement needed due to large variability

Canola Oil Added — Was above difference just because of oil displacement?

Magnitude with added oil



Difference in line shape compared to silicone

- Measurements repeated adding oil instead of silicone
- Effect of oil displacement is measurable
- Smaller effect than the silicone tests, with different frequency response
- Were the silicone tests only measuring oil displacement? **No**, the silicone itself can be detected

Discussion

Conclusions

- Results detected change in the amount of silicone
- The change is more significant than mere displacement of oil
- Many aspects of the testing come with a large amount of variability, making it hard to compare tests
- A baseline test is needed

Next Steps

- Because implants are typically behind the pectoralis muscle, can our target frequencies penetrate the muscle?
- Can in-capsule ruptures be detected?
- How much does placement of implant affect measurements?
- How important is antenna placement?
- Are there specific rupture locations that are easier to detect?
- Can this research be extended to other domains?

References:

- [1] FDA http://www.fda.gov/oc/features/995_implants.html, Public Domain
- [2] Hillard, Christopher et al. "Silicone Breast Implant Rupture: A Review." *Gland surgery* 6.2 (2017): 163-168. Print.
- [3] Healdon H, Kasem A, Mokbel K. Capsular Contracture after Breast Augmentation: An Update for Clinical Practice. *Arch Plast Surg*. 2015 Sep;42(5):532-43. doi: 10.5999/aps.2015.42.5.532. Epub 2015 Sep 15. PMID: 26430623; PMCID: PMC4579163.
- [4] Karilinde A, Split, Siham Azahaf, Christel J.M. de Blok, Katya M. Duivivier, Oliver T. Wiebenga, Prabath W.B. Nanayakkara, Ultrasound versus MRI for evaluation of silicone leakage from silicone breast implants. *Heliyon*. Volume 10, Issue 12, 2024, e33325, ISSN 2405-8440, <https://doi.org/10.1016/j.heliyon.2024.e33325>.

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Disclaimer:

Dr. Cynthia M. Furse is a co-founder of Livewire Innovation, Inc. (recently acquired by Viper innovation), which is commercializing SSTDR technology, and therefore has a financial conflict of interest with this company.