BioBalance: Continuous Intervaginal Monitor for Cycle Tracking and Diagnostics Research

Sofia Andrade, Ruhi Dharan, Ashley Hill, Sheetal Jha, Lillian Moffatt

Jenna Clark R.N., Sarah Stabenfelt Ph.D.

School of Biological and Health Systems Engineering, Arizona State University, Tempe, AZ

SBHSE
School of
Biological and
Health Systems
Engineering

Background

1 in 6 adults will be affected by infertility globally and 1.3 million women in the U.S. are experiencing menopause annually according to the World Health Organization. One study showed 40% of women could not correctly identify how many phases are in a menstrual cycle and 48.9% reported that they do not understand their menstrual cycle.

Mission statement

BioBalance's mission aims to advance female reproductive healthcare and empower women by developing research and diagnostic models using cervical mucus qualitiative metrics and quantitative hormone analytics.

Final Technical Model

The final technical model confirms the effective ability of pH and Temeperature to accurately monitor cycle changes. The Basal Body Temperature Model is used to quantify daily changes in temperature and determine the cycle phase. With continued data from varying cycles, this temperature determination will be useful in monitoring variations and potential infections. Similarly, pH has a direct correlation with progesterone levels intervaginally. The model is used to accurately determine the phase of the cycle, but can also make predictions about the vaginal microbiome and the potential for incidence of infection.
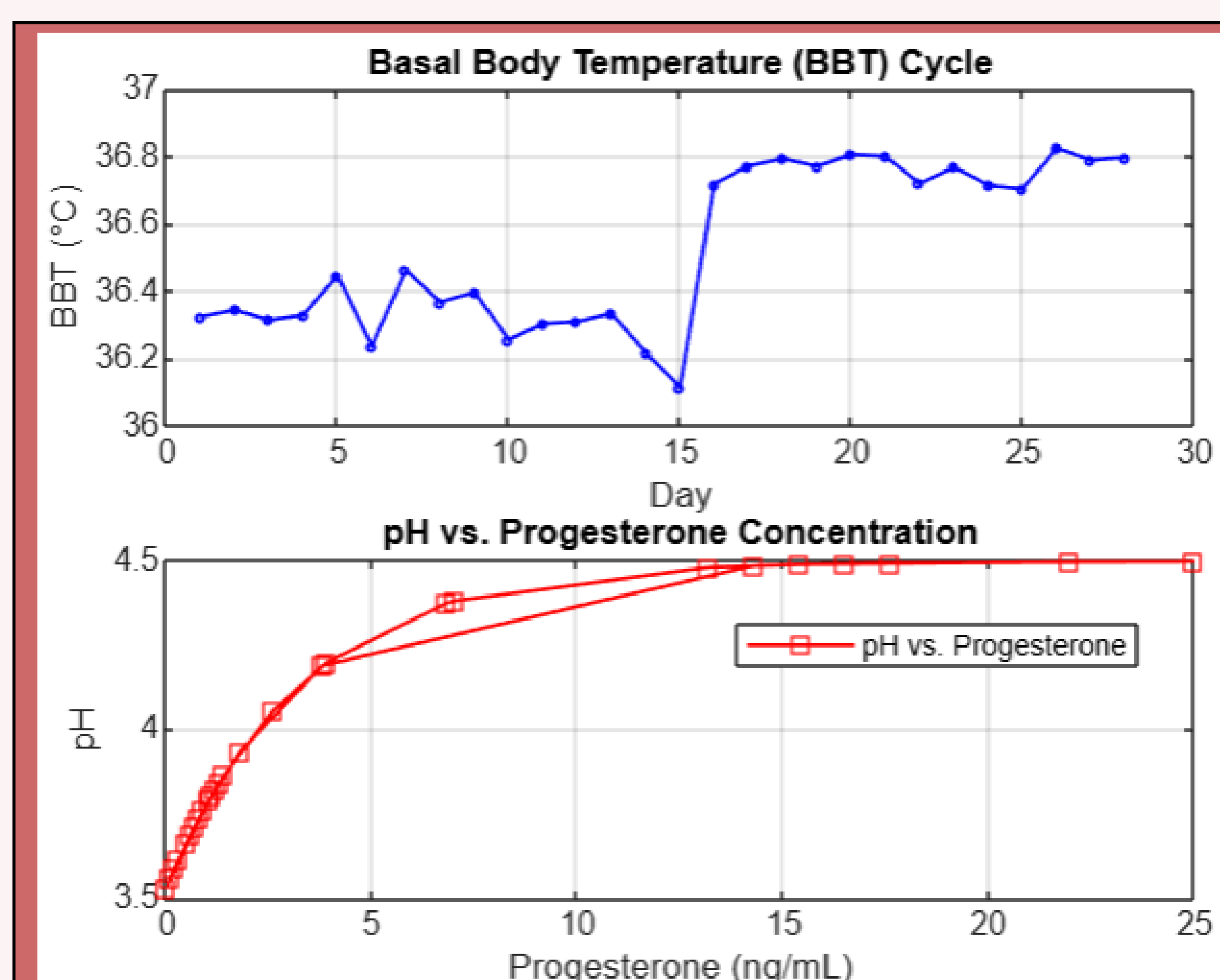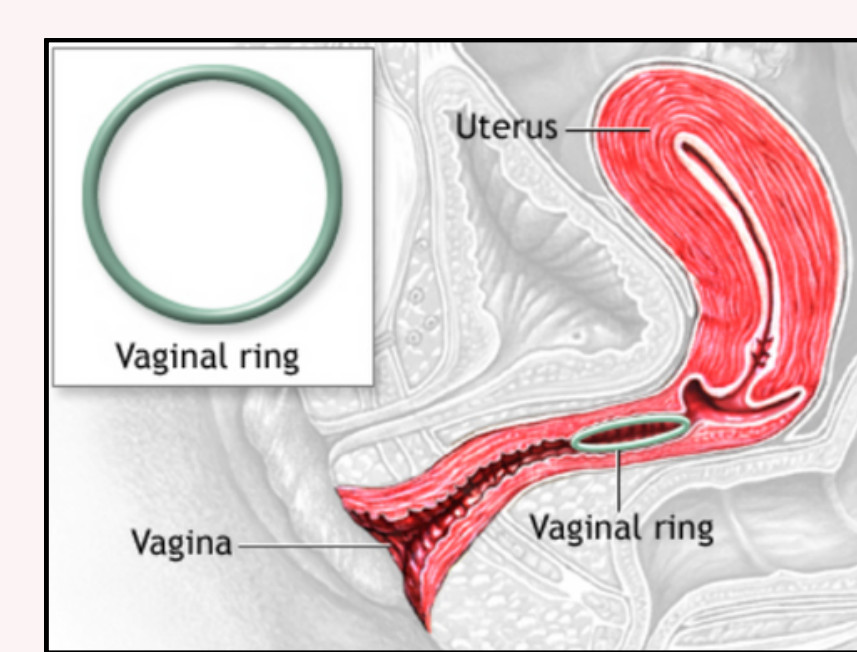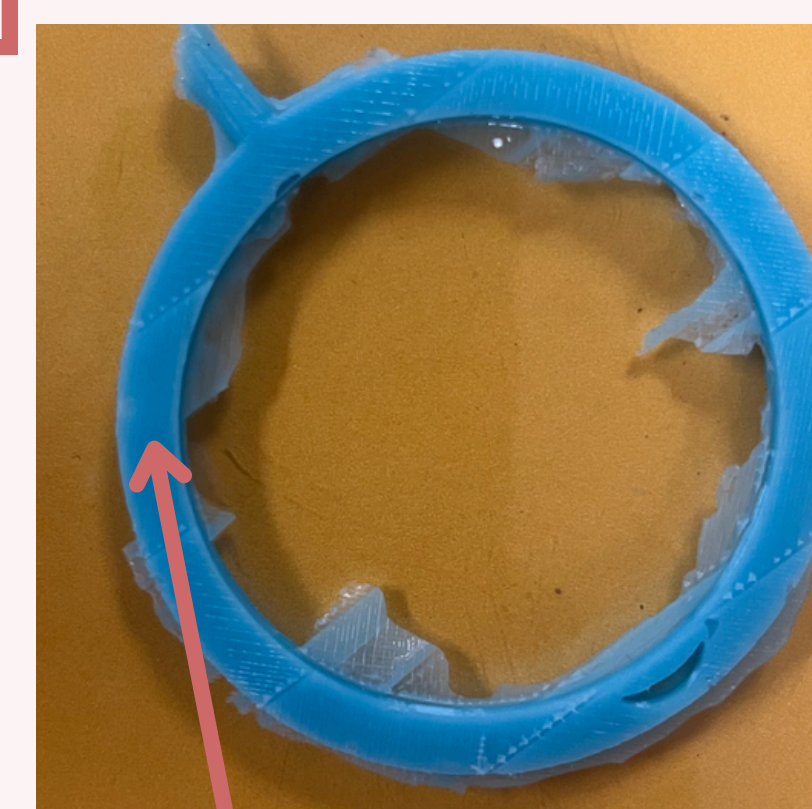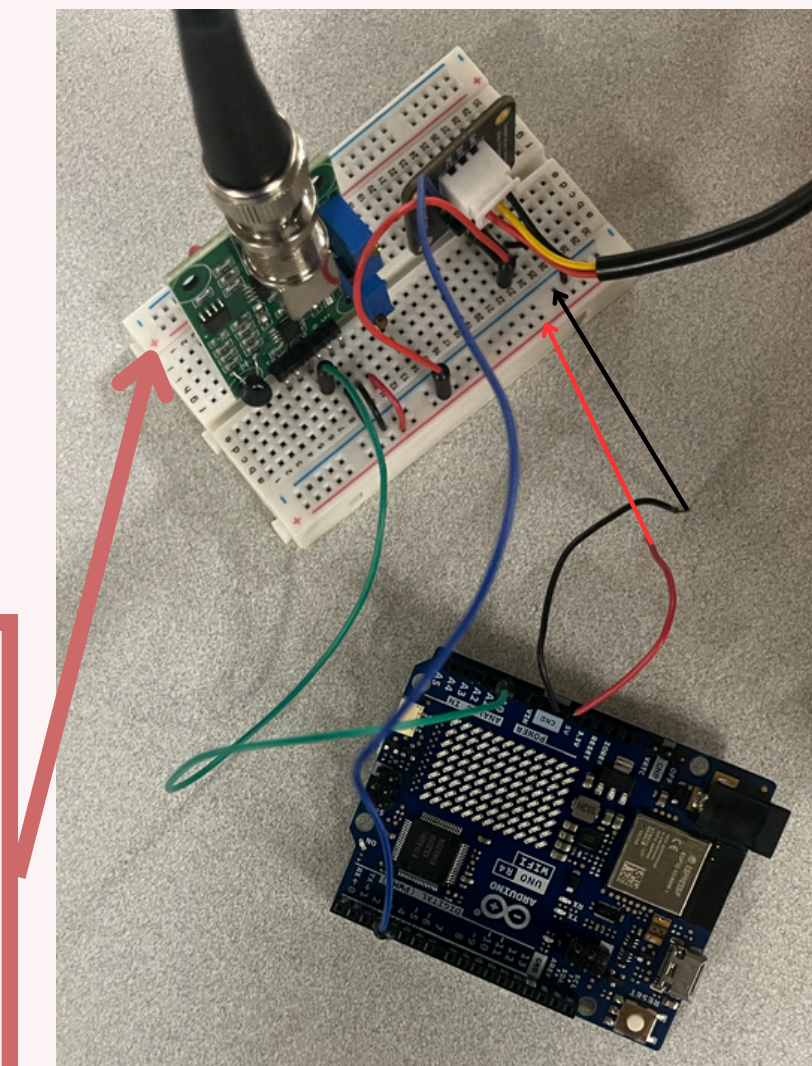

Figure 1: pH and Temperature Model

Device Prototype

Rechargeable Battery
Lithium Polymer

Sensors:
• pH Sensor
• Thermocouple

The final design concept is similar in shape to existing vaginal ring technologies. It is made of medical grade silicone for flexibility to ensure comfortable self-insertion.
The device sits in the vagina near the cervix, held in place by the pelvic bone. The device uses two sensors to quantitively monitor cervical mucus. It is designed with silicone-encased circuity which processes information from the integrated sensors.

The two sensors take daily measurements of pH and basal body temperature to monitor patients' cycles and indicate when variations are indicative of infection or infertility
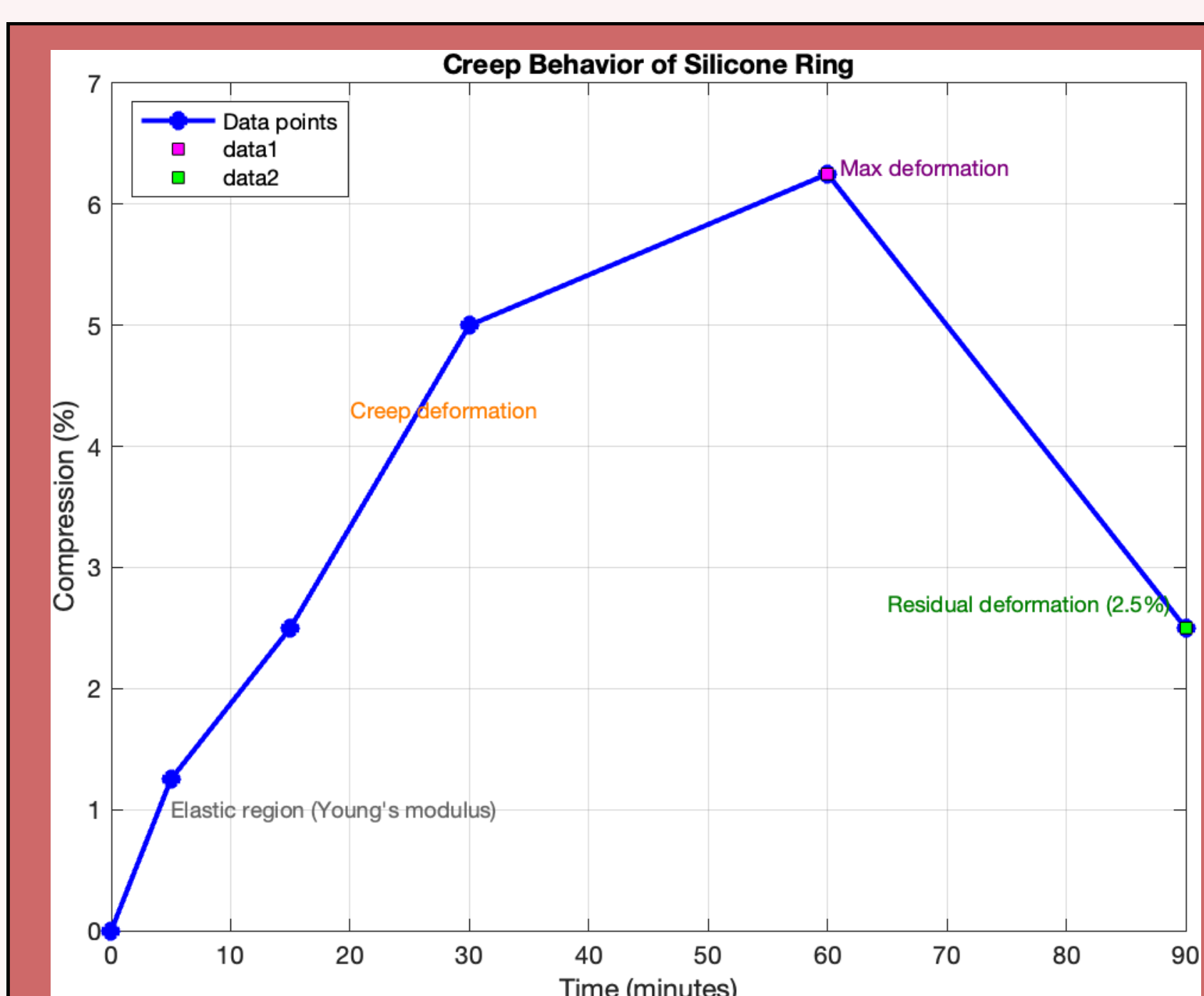
Final Concept Silicone Injection Mold

Verification Results

Figure 2: Creep Test for Silicone Ring

The temperature accuracy for small surface areas of the thermocouple was tested and shown to have an average error of ~26% for the smallest surface area. The ability to detect minute variability can help indicate inconsistencies. Further usability tests must be performed in order to move the product forward in the premarket approval process.
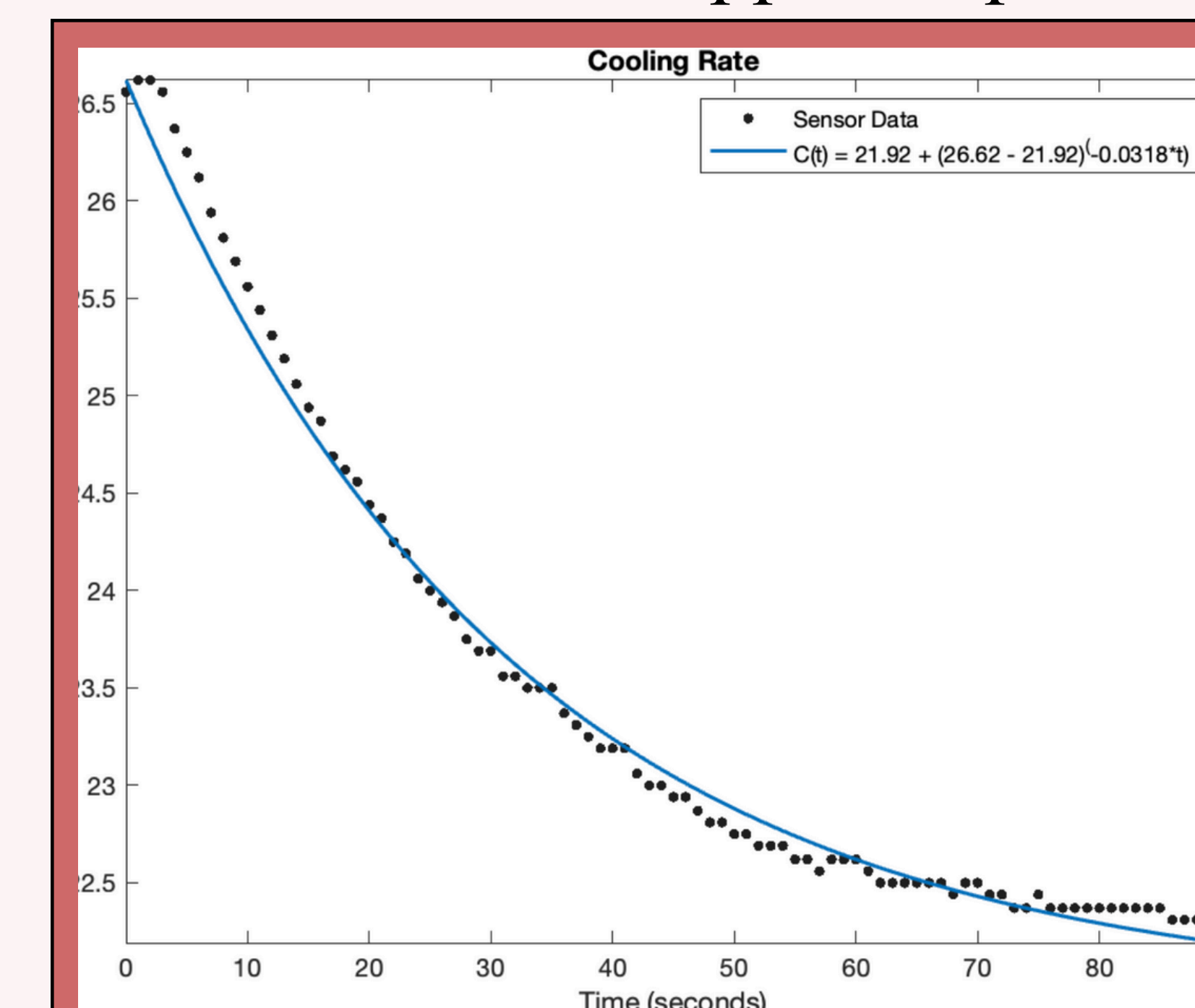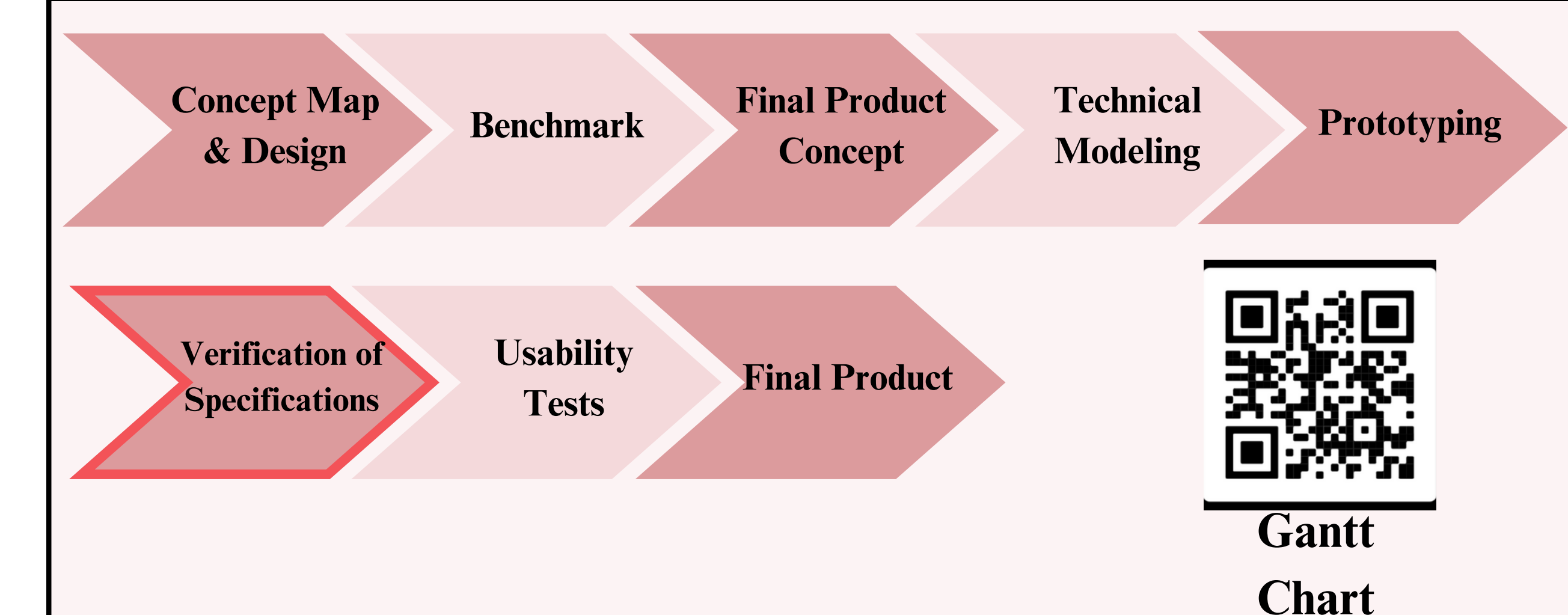

Figure 3: Newton's Law of Cooling

A creep test simulating ~7 kPa uterine pressur was performed. The results show 6.25% max strain at 60 minutes and 2.5% residual deformation after recovery. These results indicate the ring maintains shape and elasticity, supporting its suitability for extended vaginal wear.

Final Concept Specifications

	Specification	Quantity
1.	Accurate Cycle Monitor	Temperature Changes +/-0.6 °C
2.	Bioinert	Dermal LD50>5000mg/kg
3.	Month-Long Battery Life	2500mAh
4.	Infection Detection	pH > 3.8 - 4.5
5.	Pressure Tolerance	1.50 - 27.0 MPa
6.	Longterm Wearability	<15mmHg for Vessel Protection
7.	Callibration	
8.	Silicone Encapsulation	Circuit Casing

Design Status & Future Steps

Concept Map & Design → Benchmark → Final Product Concept → Technical Modeling → Prototyping

Verification of Specifications → Usability Tests → Final Product

Gantt Chart

The BioBalance team is currently verifying our product specifications and ensuring that our final technical model is accurate. The final prototype is being developed and future steps include usability tests which will require clinical trials. Should clinical trials confirm the product usability, premarket approval will follow.

Acknowledgements

Ira A. Fulton Schools of Engineering
Arizona State University