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INCREASED FLOW BREAST PUMP

Client: Professor John Webster
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Abstract

Problem
Breast pumps are essential for active, lactating women to obtain and store milk for later use. Current breast pumps use periodic suction to induce the milk ejection reflex. However, in addition to suction, babies use their tongue to massage and compress the nipple to draw milk from the breast. Although there are multiple products already on the market, there are demands from mothers for a more comfortable and efficient pump.

Purpose
The purpose of the Breast Pump with Mechanical Stimulation is to improve the comfort and efficiency of breast pumping by providing mechanical stimulation to the nipple during breast pumping.

Final Design
The device uses compression by means of an expanding and contracting membrane attached to a breast shield.
- Provides cushioning & facilitates milk flow by massaging the nipple
- Biocompatible and sanitary due to a disposable membrane
- Increases comfort and efficiency of breast pumping
- Hygienic and user-friendly interface

Client Information

Professor John Webster
Professor John Webster is a founding pioneer in biomedical engineering. With inspiration from Dr. Erin Girard - biomedical engineer from Stanford University - Professor Webster presented this design in hopes of improving the current model of the breast pump to help breastfeeding mothers.

Motivation

Breast pumps are essential for most lactating women, especially those who return to work soon after giving birth [1]. They allow the breastfeeding mother to maintain a supply of milk for the baby as well as expel milk periodically throughout the day as necessary to prevent pain [2].

Although there are many products already on the market, women still complain of pain, discomfort, and inefficiency during use [3].

It is hypothesized that a redesign of the pump to imitate a baby's movements will increase oxytocin levels in the lactating woman, therefore increasing milk flow [4]. To achieve this, our device will provide stimulation to the nipple to mimic the cyclical compression provided by a baby during breastfeeding[5].

Background

Breast Pumping & Letdown
Letdown involves the delivery of milk from milk ducts in the breast tissue to the nipple. This can be stimulated by:
- Oxytocin
- An infant latching on and suckling
- Breast pumping

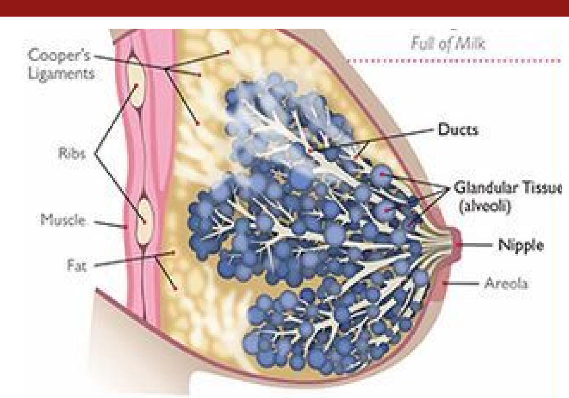


Figure 1. Diagram of the anatomy of the female breast.

Physiology
Prolactin and oxytocin are two hormones found at elevated levels in lactating women [6]
- Prolactin = hormone that sends signals to breast to initiate milk production
- Oxytocin = hormone produced post nipple stimulation; signals for contraction of breast tissues and ejection of milk most commonly known as "letdown" [7]

Milk is stored in the alveoli and released when contracted via stimulation from Oxytocin. The milk in the alveoli is then forced out and is expressed from the nipple. A known inhibitor for this process is adrenaline, a hormone which can be produced when a person is in pain [8].

Competing Devices
NUK Double Electric [9]
- Portable with silicone breast shields
- Multi-phase settings and memory

Medela Freestyle [10]
- Light and portable
- "2-Phase Expression" technology for a faster initial pumping speed and a slower let-down phase

Philips Avent Comfort Double Electric [11]
- Only pump on the market to offers stimulation
- Cyclical pressure applied from 5 circular pads around the shield

Although all three of these pumps offer desirable components such as portability and comfort, the consumers of these products are commonly not satisfied and demand a more comfortable pump with better stimulation and a higher efficiency.

Design Criteria

Breast pump with increased milk flow and mechanical stimulation
- Stimulation function mimics the natural movement of a baby's tongue
- Fast & efficient
- Safe and comfortable to use
- Weighs between 3 and 4 kilograms
- Budget of $100

Final Design

Materials
2 Medela Pump In Style Advanced Breast Pumps
1 Breastshield
1 Arduino Uno
1 Beefcake Relay
1 Force Sensitive Resistor
1 Toggle Switch
3 DC Power cords (Two 9 V, One 5 V)
1 Breastpump bag
1 Latex Membrane
Several jumper wires
Breast pump tubing

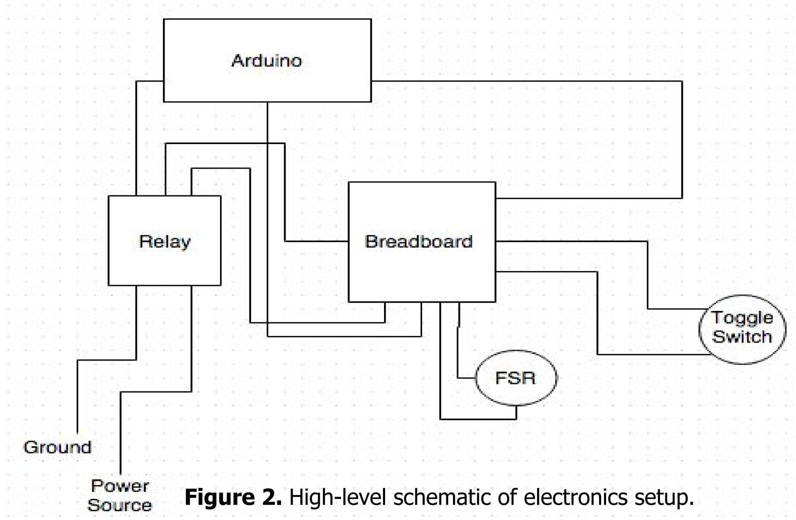
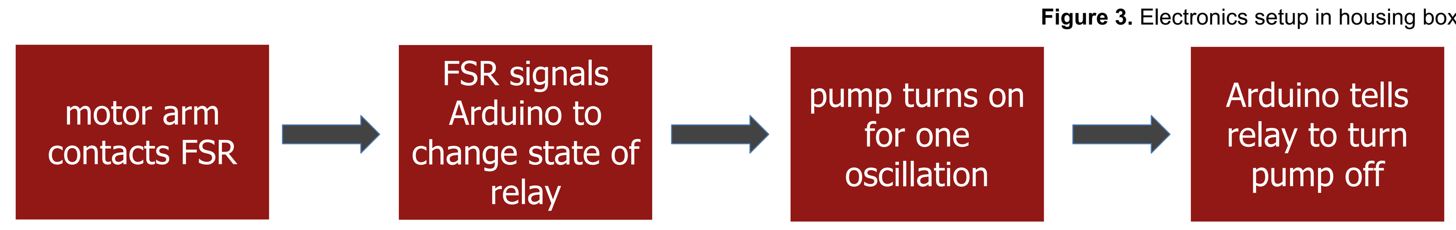


Figure 2. High-level schematic of electronics setup.

Electronics Setup
An Arduino was used to communicate between a force sensitive resistor (FSR), toggle switch, relay, and two breast pumps.
- FSR is contacted once per oscillation of primary pump
- FSR delivers a voltage to the Arduino each time it is tapped
- Relay is signaled to turn the secondary pump on/off
- Toggle switch to change compression pattern

Turning the secondary motor on and off will allow the user to control the suction and compression rhythm.


Figure 3. Electronics setup in housing box.



Modified Breast Shield Design
The breast shield features a small hole on one side for tube insertion and an elastic membrane that provides stimulation.
- The membrane is stretched around this breast shield, creating an airtight seal
- Membrane is made of latex tubing
- Membrane is affordable and easy to manufacture
- This feature provides a clean, isolated pathway for milk discharge into the bottle


Figure 4. Breastshield with latex membrane.

Current Project Status


Figure 5. Two motors in breast pump bag.

- Completed an Institutional Review Board Application - in the IRB Review stage
- Experimental protocol has been completed and will be implicated pending the acceptance of our IRB
- Completed an Intention Disclosure Report form through the Wisconsin Alumni Research Foundation
- We have a meeting with Stephanie Whitehorse and Jessica Wartenweiler on Monday, December 12th at 3:45pm to discuss the protection of intellectual property

Testing and Results

Mechanical Function Testing
- Controlled tests were conducted on the prototype to determine the rate (mL/min) at which the pump retrieves liquid from a Tommee Tippee® baby bottle
- Pump was tested under different conditions:
  - (A) suction pump only with no membrane
  - (B) suction pump with membrane, and compression pump every third cycle
  - (C) suction pump with membrane, and compression every other cycle
  - (D) suction pump only with membrane
  - (E) no suction or compression
- Welch T-Test with a p-value of .05 will be performed to test conditions A and B, using R, to test the hypotheses:

H_0: $\mu_A = \mu_B$
H_A: $\mu_A \neq \mu_B$


Figure 6. Tommee Tippee bottle used for testing different conditions.

Results

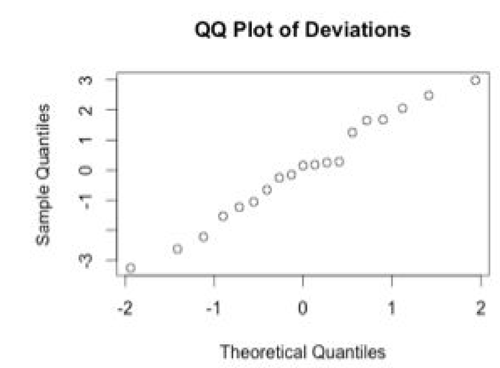


Figure 7. QQ Plot of Deviations.

Figure 8. Boxplot of test data.

With a P-value = 1.518^{-10}, it can be concluded that condition A and condition B result in different volumes of liquid collection.

Summary Statistics	(A) Standard Pump	(B) Prototype
Mean (mL/min)	21.25	8.22
Standard Deviation	1.52	2.05

Table 1. Standard deviation and mean values of performed pumping test.

The tests conducted on the pump are not an accurate representation of the performance of the pump because it does not take into account physiological factors. The success of the prototype cannot be determined until experiments are implemented using lactating women.

Future Work

- Conduct human testing after IRB approval
  - Evaluate the success of our design
  - Alter to increase comfort & efficiency
- Second FSR to better regulate the compression pattern
- Addition of several compression patterns for user to choose from based on clinical results
- Design simplification:
  - Use of one motor
  - Better membrane attachment
- Find a membrane material that is biocompatible and sanitary

Acknowledgements

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References

[1] K. Bonyata. (2015). *Do all breastfeeding mothers need a pump?* [Online]. Available: http://kellymom.com/bf/pumpingmoms/pumping/is-pump-necessary/
[2] P. Berens, M.D., 'Breast Pain: Engorgement, Nipple Pain, and Mastitis', *Clinical Obstetrics & Gynecology,* vol. 58, no. 4, pp. 902-914, 2015.
[3] Children's Hospitals and Clinics of Minnesota. (2014, July). *Breast pumping shouldn't hurt! Treatments for mothers who pump breast milk.* [Online]. Available: http://www.childrensmn.org/Manuals/PFS/TestProc/140316.pdf
[4] R. Drewett, A. Bowen-Jones and J. Dogterom, 'Oxytocin levels during breast-feeding in established lactation', *Hormones and Behavior*, vol. 16, no. 2, pp. 245-248, 1982.
[5] S. H. Foster-Cohen, *The Communicative Competence of Young Children: A Modular Approach*. United Kingdom: Taylor & Francis, 1990.
[6] O'Connor, Mary. "Anatomy & Physiology: Hormones Involved in Breast Development and Breastfeeding." *Anatomy & Physiology: Hormones Involved in Breast Development and Breastfeeding*. N.p., 1998. Web. 24 Sept.2015. http://www.breastfeedingbasics.org/cgi-bin/deliver.cgi/content/Anatomy/physiology.html>.
[7] HealthCentral, 'Breastfeeding', 2015. [Online]. Available: http://www.healthcentral.com/encyclopedia/hc/breastfeeding-3168758/. [Accessed: 03- Oct- 2015].
[8] R. Chaudhury, 'Release of oxytocin in Unanesthetized Lactating Rats', *British Journal of Pharmacology and Chemotherapy*, vol. 17, no. 3, pp. 297-304, 1961.
[9] "Double Electric Breast Pump." *NUK*. NUK USA LLC, 2015. Web. 14 Sept. 2015. <http://www.nuk-usa.com/breastfeeding/double-electric-breast-pump/>.
[10] "Freestyle® Breastpump | Medela." *Freestyle® Breastpump | Medela*. Medela, Inc.,n.d. Web. 14 Sept. 2015.<http://www.medelabreastfeedingus.com/products/463/freestyle-breastpump>.
[11] "Avent Comfort Double Electric Breast Pump." *Comfort Double Electric Breast PumpSCF334/04*. Philips Electronics N.V., n.d. Web. 14 Sept. 2015. <http://www.usa.philips.com/c-p/SCF334_04/avent-comfort-double-electric-breast-pump>.