Increased Flow Breast Pump

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Abstract

It can be difficult for a nursing mother to breastfeed periodically throughout the day as her baby requires. Breast pumping is the obvious solution to this problem, but women come across various obstacles in this process, including a decreased flow rate compared to natural feeding, irritation and pain to the breast and nipple, and an overall lack of stimulation. There is a lack of breast pumps on the market that attend to these problems. We intend to design a breast pump that incorporates ample stimulation of the nipple and breast by mimicking the physiological response created by the baby's sucking and tongue. After a design matrix evaluation of three potential ideas, we decided on the bead bracelet design which incorporates beads on a flexible band moving up and down the breast to massage and encourage milk flow. The design may be further modified to capitalize on known successful technology used in the dairy industry. Once these modifications are made, we will start to fabricate the device and prepare it for testing.

Client information

Professor John Webster is a founding pioneer in the field of biomedical engineering. Although he is no longer teaching, Professor Webster invests his time developing an implantable intracranial pressure monitor and a miniature sternal skin-attached hot flash monitor (2). With inspiration from Erin Girard - nursing mother and 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.

Introduction

Motivation

Breast pumps are essential for most breastfeeding women, especially those who return to work soon after giving birth. They allow the breastfeeding mother to establish a supply of milk for the baby as well as expel milk periodically throughout the day as necessary to prevent pain. Although there are many products already on the market, women still complain of pain, discomfort, and inefficiency while utilizing these breast pumps. It is hypothesized that a redesign of the pump to imitate a baby's movements will increase oxytocin levels in the breastfeeding woman, therefore increasing milk flow. To achieve this, our device will increase comfort and stimulation of milk ducts.

There are two main consumers in need of breast pumps: hospitals and mothers, for the use at home and in public. Hospital-grade pumps tend to be much larger and therefore not as easily transportable. They are comprised of a closed system as to be used by multiple women and eliminate the transmission of diseases. By the request of our client, we will be focused on designing a pump for home and public use. Creating an efficient pump for home use is especially relevant in today's society, as working mothers must find the time to juggle both their career and child care. Demographically speaking, our consumers are women who are expecting or recently delivered children. Pump users are typically between their early twenties and mid thirties and are of lower to upper middle-class socioeconomic status. As previously mentioned, many breast pump users are working mothers who do not have the time to feed their baby throughout the day. Breast pumps allow these women the ability to generate a supply of milk for their infant's later use.

Competing Designs

Breast pumps that are currently on the market include the NUK Double Electric Breast Pump, the Medela Freestyle, and the Philips Avent Comfort Double Electric. The NUK Breast Pump is a portable system with silicone breast shields rather than a hard plastic. The silicone shield increases the comfort of the device, one of the most common complaints among breastfeeding women. This breast pump has multi-phase settings and memory to store them and costs $204.99 (3). The second major competitor, the Medela Freestyle, is a light and portable breast pump. It includes "2-Phase Expression" technology that offers a faster initial pumping speed, similar to a baby's actions when first latched on, and a slower let-down phase. This product costs $399.99 (5). The third leading breast pump on the market is the Philips Avent Comfort Double Electric. This pump is the only design that attempts to mimic the suckling of a breastfeeding baby, as it offers a gentle stimulation mode that applies cyclic pressure changes in 5 circles around the breast shield. This product costs $199.99 (1). 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 pump which will operate more efficiently and with better stimulation.

Problem Statement

Many working women use breast pumps to obtain milk for their baby to be used later when they are unavailable. Current breast pumps use periodic suction to induce the expression of milk. In addition to sucking, babies use their tongue to massage the nipple to increase flow. Issues women have with current breast pumps and the process of pumping include a decreased flow rate relative to feeding, discomfort and pain from suction, and an overall lack of nipple stimulation. We will be designing a comfortable breast pump that mimics the action of a human baby by massaging the nipple to increase milk flow.

Background

Breast Feeding Process

Breastfeeding is the process of releasing milk from the milk ducts in the breast tissue to feed a baby. It is done by the baby latching onto and sucking on the nipple. Pumps can be used to collect milk as well. A general breast pumping procedure is as follows: first, the mother places her nipple in the center of the flange. Then, she puts the pump on a low setting and pumps for a maximum of 15 minutes on each side. She can compress her breasts using her hands if she is not getting enough flow (9).

The breast stimulation process to encourage the milk ejection reflex consists of six main elements. The mother first washes her hands, and then applies a warm, wet cloth to her breast. She then can massage her breast in small circular motions. Additionally, she can gently stroke her breast with her fingernails in a downward motion toward the nipple, and then lean forward and shake her breasts slightly. Lastly, she can gently roll the nipple between her finger and thumb. Stimulation can also be encouraged by thinking about the baby being in her arms or looking at pictures of it (4).

Physiology

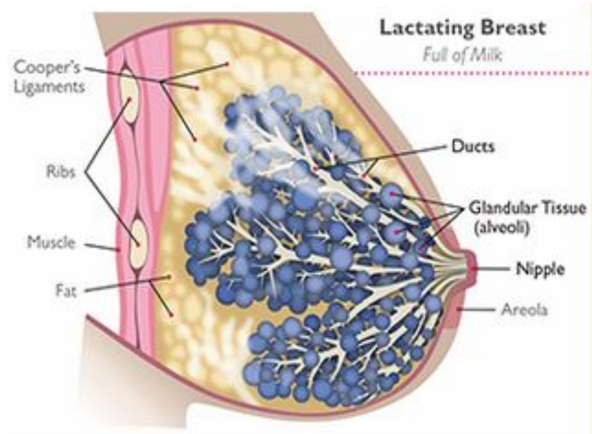


Figure 1. Diagram of the anatomy of the breast. http://www.ameda.com/breastfeeding/anatomy-physiology

The physiology of breastfeeding involves a multitude of hormones. Prolactin and oxytocin are two hormones found at elevated levels in lactating women (10). Prolactin is produced prior to birth and peaks as the baby is born. This hormone signals to the breasts to start milk production and is readily available in the body at all times during the lactation period. Unlike prolactin, oxytocin is not readily available in the body. Production of oxytocin begins as soon as the nipple is stimulated and the baby latches on. The milk ejection reflex, commonly referred to as "letdown", is initiated when oxytocin signals for the contraction of the breast tissue (8). The milk is then released from the alveoli, which are tiny grape-like ducts that hold the milk as seen in Figure 1. The contraction of the alveoli forces milk out of the nipple; this process does not require suction, however, does require stimulation of the nipple and breast (11). This is why massage is typically used in conjunction with pumping (11). Milk can be continuously produced, but without oxytocin, will never be delivered to the nipple. A known inhibitor of oxytocin release is adrenaline, which is another hormone produced by the body when in pain. Research done in 1961 by R. Chaudhury proved that injection of adrenaline blocked the milk ejection reflex in 8 out of 10 lactating rats (11). It is very important that breast pumping is a comfortable experience for the mother in order to stimulate the release of oxytocin and initiate letdown.

There are a few different physical stimuli that women have reported to aid in the increase of milk flow. Lactation Specialist Sharon Marshall of Meriter Hospital has stated that through her work with nursing mothers, she has found that the application of heat to a mother's breast can aid tremendously in stimulating the flow of milk from the nipple. In addition to the element of heat, it is believed that massage of the nipple, breast, and surrounding areas of the breast can aid in increasing milk flow. This may be due to the physical stimulation that massage provides to the milk-containing alveoli, which are densely packed in the breast and near the nipple (Figure 1). It is also recommended that mothers engaging in either breastfeeding or breast pumping make sure to relax and control their breathing to assist in optimization of milk flow.

Due to the recent emergence and drive to establish greater women's rights within the workplace, the use and sale of personal breast pumps could see a fairly sizable increase. As part of the 2010 Affordable Care Act, stated in section 4207, employers are now required to allow their employees the opportunity pump breast milk while at work (12). Already standing at a worth of 1.2 billion dollars (last noted in 2013), it is expected that with the increased acceptance of public breast pump use the global breast pump market is estimated to top 2.5 billion dollars by 2022 as this law continues to become more socially accepted (7).

Design Specifications

Professor Webster and Erin presented a list of design requirements that are essential for achieving the desired product. In order for us to complete a successful design, we must develop a breast pump that is faster and more efficient and has a massage or stimulation component to increase milk flow. The massage or stimulation component must mimic the natural movement of a baby's tongue but must not harm the breast during pumping. Additionally, our device must weigh between seven and nine pounds to allow for easy transportation for use at home or in an office setting. We will be working with the standard flange size of 24mm, however, there are multiple breast shield sizes to accommodate variations in breast size. Overall, our breast pump design must be comfortable to wear and use during the breast pumping period.

We were allotted $100 for our materials this semester and we will be able to focus that money on new components that we will add to the Medela breast pump that Professor Rogers so graciously lent us for the semester (refer to Appendix A for full Product Design Specifications).

Preliminary Designs

Paint Roller Design

In order to mimic the movement of a baby's tongue on the nipple during breastfeeding, our team came up with design similar to a small paint roller. This design features a rolling cylinder on a wire that will brush back and forth under the nipple to provide tactile stimulation and increase the flow of milk. The cylinder will be made out of a moist sponge to simulate the texture of the tongue or a soft plastic. It will provide stimulation to the nipple without heavy friction and will be attached to a track through a slit on the underside of the flange. The air pressure generated by the pump will power the roller to slide back and forth on the track.

Massage Chair Design

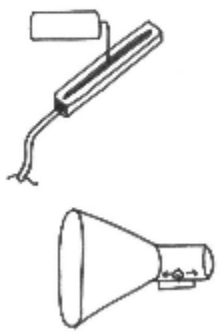
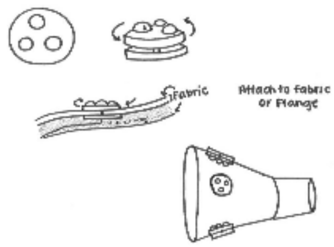
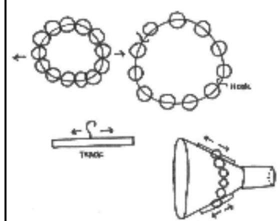
The massage chair design consists of several circular plates positioned throughout the breast shield or on an attachment to the breast shields as an accessory. A pin to the adjacent plates will attach each circular plate and the plates will continuously rotate. There will be small spheres held in each plate that will freely roll within the plate. These spheres will be the only component of the design that will come in contact with the breast. The plates will receive power from a small motor, located on a belt or in a wearable bra-like contraption. This design will promote massage of the breast tissue in order to stimulate the milk ducts, easing the release of milk. The coverage of the massage plates may reduce the need for hand massage of the breast during pumping.

Bead Bracelet Design

The bead bracelet design consists of many small beads on an elastic band that will move the length of the breast shield. The bracelet will be fitted over a soft silicone breast shield and will be attached with two hooks. The hooks will run back and forth on a track, powered by the pump, and will pull the bead bracelet up and down the breast shield. The elastic band will hold the beads tight against the breast shield and will gently massage the breast. The motion of the beads toward and away from the nipple will allow the milk ducts to release more milk, therefore increasing the flow rate. This design may also eliminate the need for women to hand massage the breast during pumping.

Preliminary Design Evaluation

Design Matrix

Design	Paint Roller		Massage Chair		Bead Bracelet	
Criteria (Weight)						
Comfort (25)	3/5	15	4/5	20	5/5	25
Milkability (20)	5/5	20	2/5	8	3/5	12
Ergonomics(15)	2/5	6	3/5	9	5/5	15
Safety (15)	4/5	12	5/5	15	5/5	15
Weight/Bulk (10)	4/5	8	3/5	6	4/5	8
Cost (5)	3/5	3	1/5	1	4/5	4
Ease of Fabrication (5)	2/5	2	2/5	2	3/5	3
Durability (5)	3/5	3	5/5	5	4/5	4
Total (100)		**69**		**66**		**86**

Design Criteria

We ranked our designs based on the following criteria: comfort, milkability, ergonomics, safety, weight/bulk, cost, ease of fabrication, and durability. Comfort was weighted the highest because in order to induce letdown, the mother must be comfortable and relaxed. Adrenaline as a result of discomfort can block the release of oxytocin, thus, not allowing for the intitiation of the milk ejection reflex. The next criterion that we considered was milkability. Milkability refers to the success of receiving milk in the most efficient way possible, which is one of the main goals of our design. Ergonomics and safety received equal rankings because we find those equally important - the design must be sleek and discrete as well as safe for the mother. In addition, it must also be lightweight and portable, making the pump easier for working mothers to use. Current breast pump models range from $200 - $400, so we are aiming to create a more affordable device. Ease of fabrication and durability were ranked lowest among our considered criteria. We are aware that all of our designs are going to be equally difficult to fabricate because we are dealing with a small and isolated area, human contact, and electrical components. The lifetime of the breast pump will be based on how long the mother wishes to breastfeed and how many children she may be planning to have.

Proposed Final Design

After evaluating the three designs featured in the design matrix, we concluded that the bead bracelet design is our proposed final design, shown to the right in Figure 2. This design outcompeted the other two in many of the criteria categories and achieved a score of 86 out of 100. It was chosen based on comfort and simplicity of the design. The bead bracelete design will be lightweight, the least invasive, and will offer effective stimulation to increase milk flow.

Conclusions

Discussion

At the beginning of the semester, Professor Webster and Erin Girard presented us with the challenge to design and develop a breast pump that will be more comfortable, offer nipple stimulation, and increase milk flow more than current breast pumps. Thus far, we have proposed three design alternatives that consider the design specifications given by Professor Webster and Erin and have evaluated each of the design based on eight important criteria. Comfort and the ability to increase milk flow without harming the breast have become priorities for our designs and this has directed us to seek information from other sources. Because breast pumps are relatively new commercial products, sufficient research is lacking (6). Consequently, we decided to focus on research and advice from the dairy industry, which has the common goal of high efficiency pumping. We have to be careful to not make too many generalizations from this research, as it cannot directly translate to human subjects.

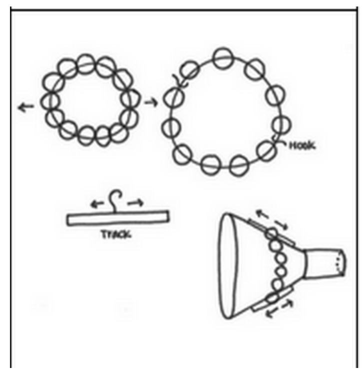


Figure 2. Proposed final design - bead bracelet.

Future Work

After meeting with Professor Paul Thompson, a professor in the biomedical engineering department with a research focus on pumping in the dairy industry, our team decided to take a different approach on our breast pump design. It will incorporate technology that is currently being used in the dairy industry, similar to the mechanism pictured in Figure 3. Our new design idea includes a tube of silicone inside the breast shield. This layer will be inflated in cycles to apply pressure in addition to the suction of the pump. The tube will offer compression to the milk ducts, the nipple, and areola for tactile stimulation. Suction and compression will occur simultaneously to mimic the motions that a baby makes during

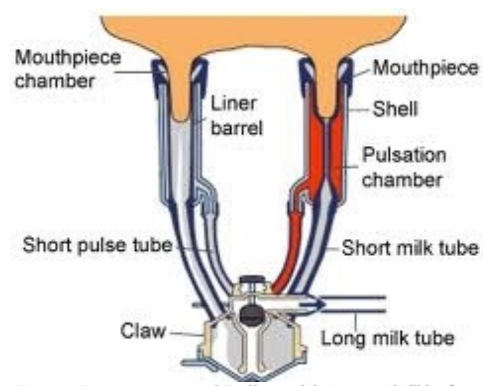


Figure 3. Dairy industry pump. http://www.dairynz.co.nz/milking/in-the-dairy/milking-tasks/milk-let-down/

breastfeeding. It will stimulate the nipple to increase the release of oxytocin as well as promote blood circulation to relieve pain in the nipple.

Fabrication Plans

The remainder of our semester will be spent developing and fabricating our final prototype. We will be finalizing the materials necessary for our design and will order them within the next week. We will be using silicone and a non-toxic glue to fabricate massage component of the design and will harness the power of the pump to cycle the suction and compression of the silicone layer. It is necessary for us to continue researching the tactile stimulation of the breast and nipple to ensure the most comfortable and efficient milk flow. Our meeting with Professor Thompson left us with new ideas to create a more effective and comfortable breast pump that is sure to satisfy breast pumping mothers.

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Appendix

A. Product Design Specifications

Title: Increased Flow Breast Pump
Function:
There are numerous reasons nursing women choose to use breast pumps over naturally breastfeeding. One huge advantage is the convenience of collecting milk while away from the baby, allowing opportunity to pump milk at a convenient time and place to store for later infant consumption. It is quite common for mothers to use a breast pump at work so that they have milk readily available later in the day, which opens up time to spend on other activities. However, breast pumps do have some disadvantages compared to natural breastfeeding. They can be uncomfortable to use, even causing pain and distress at times. Furthermore, it takes significantly more time to collect milk when pumping as opposed to breastfeeding. Breast pumps currently on the market focus on suction magnitude, rate, and cycle, but do not take into consideration the inherent behavior of the baby's mouth while feeding. The baby's tongue massages the nipple, which increases the milk flow rate from the breast. Some breast pump designs attempt to mimic the movement of the infant's tongue by altering pressure in the breast shield, but there is still ample room for improvement in the industry to increase breast milk flow using massaging and stimulation [1]. Enhancing this mechanical aspect of a breast pump design will decrease the time a mother has to spend pumping, while at the same time lowering the discomfort and pain a mother experiences during the pumping process.
Client Needs and Requirements:
Design Requirements:
1. Physical and Operational Characteristics:
a. Performance Requirements

The breast pump must function faster and more efficiently than current products on the market, utilizing a massage or stimulation to increase flow rate.

b. Safety

The device will exhibit massage apparatus stability to ensure the mechanical stimulus does no harm to the breast. It will have a maximum suction magnitude to prevent over-suction, which could result in discomfort. There will be no exposed wires or moving parts, and the motor used will have a safety factor ensuring its normal operating conditions are much lower than its maximum operating specifications to prevent overheating and malfunction.

c. Accuracy and Reliability

The massage function must work properly for the duration of each pumping session, accurately applying stimulation as close to infant tongue massaging as possible.

d. Life in Service

The device will function at its optimal performance rate for one year [5].

e. Shelf Life

The breast pump can be stored before use indefinitely.

f. Operating Environment

The breast pump will be portable and will be mainly used at home or in an office setting.

g. Ergonomics

The breast pump will be comfortable to wear and use and will maintain its durability throughout its lifetime of one year. It will be used in a sitting position, but will weigh light enough for easy transport.

h. Size

The breast pump will be made in one size (24mm and 27mm are standard size). However, the size could be altered for future application to 21, 30, or 36mm.

i. Weight

It is expected to weigh between 7 and 9 pounds.

j. Materials

The current list of materials include:

-Silicone cups for breast shield
-Pre-assembled, purchased breast pump
-Motor
-Materials for massage apparatus to come

k. Aesthetics, Appearance, and Finish

The breast pump will be portable, have a discreet and lightweight massage insert, and will have a pleasant and comfortable looking finish.

2. Production Characteristics:

a. Quantity:

The product consists of one breast pump.

b. Target Product Cost:

The top-rated breast pumps on the market range from $100-$400

3. Miscellaneous:

a. Standards and Specifications:

The breast pump device will mimic an infant suckling onto the nipple. It will be competitively priced with current models on the market, and will pump the same amount of milk as a current model does in less time. Breast pumps are medical devices that are regulated by the Food and Drug Administration [4].

b. Customer:

Nursing women are the customers.

c. Patient-Related Concerns:

Concerns include nipple irritation, mastitis (infection of the breast tissue), milk quantity, and pumping duration.

d. Competition:

Philips Avent Comfort Double Electric

The Philips Avent breast pump offers a gentle stimulation mode that simulates a baby suckling with cyclic pressure changes in 5 circles around the breast shield. This product is $199.99 [1].

Medela Freestyle

The Medela Freestyle is a light and portable breast pump that is on the market today. It includes “2-Phase Expression” technology that offers a faster initial pumping speed, similar to a baby’s actions when first latched on, and a slower let-down phase. This product costs $399.99 [3].

NUK Double Electric Breast Pump

The NUK breast pump is a portable system with silicone breast shields instead of hard plastic. This breast pump has multi-phase settings and memory to store them. This product costs $204.99 [2].

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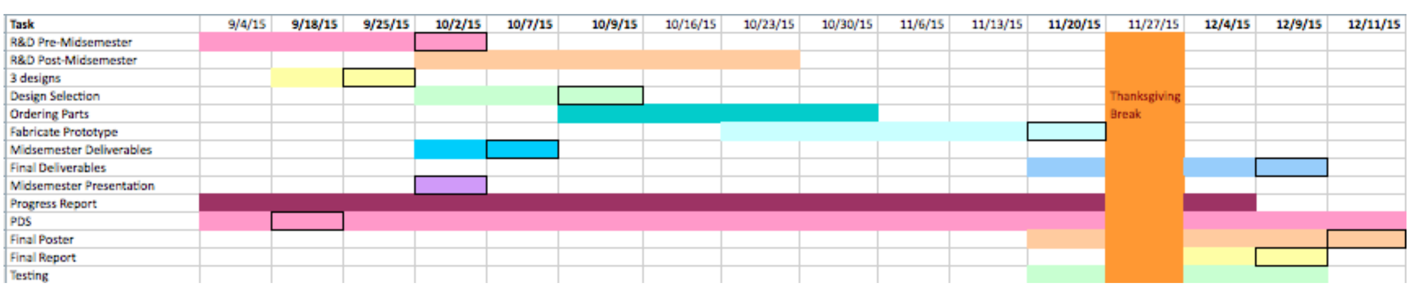
B. Materials

Material	Source	Cost
Medela FreeStyle	Professor Rogers	Free - donation

C. Gantt Chart



D. Expense Report

There are no expenses as of now.