Design and Development of Plugged Lactiferous Duct Treatment Technology for Nursing Women

by

Xochitl L. Mellor

Submitted to the Department of Mechanical Engineering in Partial Fulfillment of the Requirements for the Degree of Bachelor of Science in Mechanical Engineering at the Massachusetts Institute of Technology

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Abstract

Plugged lactiferous ducts are a common problem that many nursing women encounter. This occurs when the tissue around a milk duct has become inflamed, thus preventing milk from passing through the duct. Women treat and prevent plugged ducts by massaging the affected area on the breast. There are no products currently on the market that use massage techniques to help mothers with plugged ducts. This study proposes a design of a device to treat plugged lactiferous ducts. The problem is explored and formulated into a problem statement. Design requirements of the device are derived from the problem statement and are listed and explained. The concept generation, concept selection, concept refinement, and prototyping phases are described. Finally, recommendations for future development are discussed.

Thesis Supervisor: Alexandra H Techet
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Chapter 1

Introduction

Breast milk is universally known as the best and most nutritious food for infants. It provides the baby with nutritionally balanced meals at the time where human growth rate is at the maximum across its life span [1]. Breast milk helps build up the baby’s immune system and provides protection against common childhood illnesses and infections. A breast fed child has a decreased risk of developing allergies and type 1 diabetes. The American Academy of Pediatrics recommends that infants are exclusively breastfed up until six months of age [2]. However, it can be difficult for mothers to breastfeed their babies up to this recommended time. Devices such as breast pumps are used in order to maintain a frequent supply of milk when mothers are away from their babies. Beside separation, women often face many other challenges that prevent them from breastfeeding their babies. One of the most common challenges is plugged milk ducts. This occurs when the tissue around a milk duct has become inflamed, thus preventing milk from passing through the duct. While it can be exceptionally painful to breastfeed, women are strongly advised to continue nursing. It is best to keep the affected breast as empty as possible and nurse or pump at least every two hours. There can be an increase in complications if nursing is decreased. Women may get abscesses that require surgery if the plugged duct worsens. Currently there is no device on the market that is designed explicitly for plugged milk duct treatment. The most common treatment technique is hand massaging the affected area in a circular and kneading motion.

The goal of the project was to design a hands-free device that assisted nursing women with the prevention and treatment of plugged milk ducts. This study explains the context of the inventive problem to be solved, the design process, and ideas for future development of the device.
1.1 Relevant Anatomy

Dissimilar to other the organs in the human body, the breast is not fully developed until the mammary gland is at a mature functional state. This occurs during the pregnancy-lactation cycle in an adult female. Newborn females are born with a very basic network of milk ducts that do not continue to develop until puberty, for ovulation and a regular menstrual cycle are what prompts breast growth [1]. Besides increasing in size, the breast also changes by elongating existing milk ducts that branch off into secondary ducts. Milk ducts, also known as lactiferous ducts, carry milk from the mammary gland to the nipple. Because there are ducts channeling to it, the nipple has multiple small milk outlet holes. These holes cannot be seen with the naked eye. The nipple is surrounded by the areola. It is dark in color, and gets darker during pregnancy, in order for the infant to see where the milk supply is located. The mammary gland, or milk-producing gland as shown in figure 1.1, is made up of hollow cavities called the alveoli. These cavities are lined with milk-secreting cells (epithelial and myoepithelial cells) that have the ability and function to contract to let milk out through the lactiferous ducts [3]. Inside the mammary gland the alveoli are in groups called lobules. In a mature nulliparous women, women who has not had children, there are three types of lobules that are classified according to their degree of development. There is Lob 1 which is connected to about eleven ductules, Lob 2 with about forty-seven ductules, and Lob 3 with about eighty ductules [1]. A fourth lobule type appears during pregnancy. This lobule consists of more milk ducts and mature alveoli. It is critical that the breast is fully developed during lactation. This ensures that the breast milk has the correct volume and composition to give the child nutrients for protection, growth, and development. To ensure that the breast is a full functioning organ, the female body circulates increasing levels of estrogen, progesterone, and prolactin. These hormones promote ductal branching, alveoli development, and secretory differentiation. The formation and development of the lactating breast is termed mammogenesis [1].
Figure 1.1: Schematic and anatomy of mature lactating breast (image courtesy of imgar-cade.com).
Chapter 2

Breastfeeding

While the benefits of breastfeeding are known, the most common reasons why mothers stop breastfeeding is due to not producing enough milk [2]. Too little milk supply may be caused by infrequent feedings, improper technique, obesity and large breasts, separation, and immaturity and illness of infant. The stress from fear of not being able to provide enough milk for a baby can also hinder milk let-down [4]. Milk production can be increased by numerous feedings or milk removal throughout the day. Most breastfed babies feed an average of ten times a day; and by three months of age the daily mean of break milk intake is about 800ml [2, 4].

Nursing is instinctive for infants, however it can take some time for the mother to learn the proper breastfeeding techniques. Skin-to-skin-contact between the infant and the mother immediately after birth is common practice, for studies have shown that it increases the likelihood of breastfeeding for at least two to three months. Babies are able to independently find the mothers breast and self-attach to the nipple to begin suckling within twenty to thirty minutes after birth. The touching of the areola and the suckling from the baby act as a catalyst to the release of plasma oxytocin that causes the milk ejection reflex [4]. This reflex is commonly termed as milk let-down.

2.1 Correct Positioning and Latch-on

In order for the baby to feed efficiently, the mother must make sure that the baby correctly latches on to the breast. The mother should position her baby close to her so that the baby does not have to turn its head to reach the breast. The babys mouth and nose should be facing the nipple. The mother may support her breast to make sure that it is not pressing into her babys chin. The babys lips should be flanged and have at least 1.5" of the breast around the base of the nipple in his/her
mouth. The baby will tell the breast to release the milk let-down by sucking without swallowing as the baby initially positions himself/herself on the nipple [5]. Figure 2.1 shows an image of the correct latch-on position.

![Correct attachment to breast](image.png)

**Figure 2.1:** Correct attachment to breast (image courtesy of nucleuscatalog.org).

As shown in the figure above, the nipple, areola, and lactiferous ducts are between the baby's gums. The nipple is pressed against the palate which is at the roof of the mouth. The palate consists of two sections known as the hard and soft palates as shown in figure 2.2. For correct latch-on, the nipple will be further back in the soft region of the palate. However, the baby can still extract milk if the nipple is only in the hard region. When the baby is nursing, the nipple is periodically compressed by the jaw and tongue at a rate of about 1.17-1.95 Hz [7]. The baby also uses suction, similar to a breast pump, in which sucking lowers the atmospheric pressure in the oral cavity [8].
Figure 2.2: Diagram of healthy child with hard palate (closer to lips) and soft palate (closer to tonsils) (image courtesy of webmd.com).
Chapter 3

Plugged Lactiferous Ducts

80% of mothers and their babies will experience problems with breastfeeding. Some of these problems cause the mother to stop breastfeeding entirely. In a research poll done in 2009, it was found that 47.2% of infants in the United States were breastfed up to six months. Only 16.3% of the infants were fed exclusively on breast milk [4]. One of the most common problems are painful breasts which can occur from plugged milk ducts. A plugged milk duct (lactiferous duct) occurs in an area of the breast where milk flow is impeded. This can exist closer or farther back in the ductal system. It most commonly appears gradually and usually affects one breast at a time. When experiencing a plugged duct most women will notice a hard and tender area of engorgement on the breast. Many women find that it is the most painful before feeding and less tender and swollen after nursing [9]. Some women may also experience low fevers. Their milk supply will most likely temporarily decrease. The milk that is produced may also appear to be stringy and thicker than regular breast milk.

Common causes for plugged milk ducts include engorgement and inadequate removal of milk. The mother may have difficulty extracting milk if the baby is not correctly latching on to the breast and is suckling ineffectively. Other causes for inadequate removal of milk are sleepy or distracted babies, hurried feedings, and blocked nipple pores. Women who are breastfeeding multiple babies, such as twins, can be very prone to plugged milk ducts, for it can be easy for womens breast to become engorged due to the increase in demand. External pressure on milk ducts from tight undergarments/clothing and sleeping positions can also cause plugged ducts [9]. If the problem is not taken care of, the woman can get mastitis, an inflammation in the breast that can result in infection. This is a very painful condition that can hospitalize women and lead to breast abscesses [10].
3.1 Current Technology and Treatment

The most important treatment practice is to continue expressing milk from the affected breast. Further complications will arise if the mother decreases or stops nursing [9]. Current technology on the market such as breast pumps, as shown in figure 3.1, can be used to express milk when the mother is unable to breastfeed her child. They work by applying a vacuum to the breast. A flange over the nipple and areola creates a seal for the vacuum. When the vacuum is applied, the nipple is drawn into the plastic tubing and the areola is pressed against the flange [11]. This mechanism is designed to mimic how a baby uses suction to express milk. While breast pumps are great for helping keep the breast empty, they do not specifically target the affected area.

![Medela breast pump](image-courtesy-of-medela.com)

Figure 3.1: Medela breast pump, one of the electric breast pumps on the market (image courtesy of medela.com).

Massaging the troubled area is an effective technique that many nursing women use. Women are advised to use a kneading motion that successively moves closer to the lump and pushes away towards the nipple [4]. Before nursing, women are recommended to use heat and gentle massage. There is a technique called the basin soak in which women submerge their breasts in warm water while massaging the affected area. Then while nursing, women can continue to massage and compress the breast. Mothers can also nurse while leaning over the baby to let gravity help milk flow. After nursing, mothers are then encouraged to express milk manually or
with a pump [9]. Women can also take anti-inflammatory medicine.

The author interviewed nursing mothers about their experience with plugged milk ducts. One mother in particular experienced a plugged duct every other day for six months. She explained that frequent problem was due to her baby not making a good latch onto her breast. This caused the baby to do non-nutrient suckling. The mother knew she had a plugged duct because the area was tender and had a burning sensation. She described that the affected region was a little hard and felt like a string of pearls. For prevention and treatment, the mother said that massaging was very effective. She used a circular motion along with a back and forth kneading motion. She would also massage in conjunction with nursing and pumping. When the blockage worsened, the mother could tell where the problem was because there was a small white on the nipple. She would then use a safety pin and pick out the congealed milk from her nipple.
Chapter 4

Development of the Design

4.1 Problem Statement

Plugged lactiferous ducts are a very common problem among nursing mothers. They cause pain and take extra energy to prevent and treat. Currently, there are no devices on the market that use massage techniques to help mothers with the plugged ducts. If a device were developed that assisted mothers with the prevention and treatment of plugged ducts, the percentage of mothers nursing their babies throughout six months may increase.

4.2 Design Requirements

The design requirements are presented in table 4.1. These requirements will be carefully considered when in the concept selection phase of the design process. This will be described in further detail in section 4.4.

Table 4.1: Design Requirements

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reliability</td>
<td>The device must be able to consistently operate and function after many uses.</td>
</tr>
<tr>
<td>Easy to Operate</td>
<td>The device must be easy to operate for the users at home.</td>
</tr>
<tr>
<td>Cost Effectiveness</td>
<td>The device must be cost effective for the manufacturer and users.</td>
</tr>
<tr>
<td>Decreased Discomfort</td>
<td>The device must cause less discomfort to the users than that of current technology.</td>
</tr>
<tr>
<td>Adequate Pressure</td>
<td>The device must apply enough pressure to be just as effective as massaging by hand.</td>
</tr>
<tr>
<td>Hands-Free</td>
<td>The device must be able to use without hands.</td>
</tr>
<tr>
<td>Portable</td>
<td>The device must be able to be easily taken to different locations.</td>
</tr>
<tr>
<td>Safe-Failure Mode</td>
<td>If the device fails, it will not harm the user.</td>
</tr>
<tr>
<td>Relatively Quiet</td>
<td>The device must not be louder than current technology.</td>
</tr>
<tr>
<td>Easy to Manufacture</td>
<td>The device should be designed with the fewest amount of parts as possible.</td>
</tr>
</tbody>
</table>
4.3 Concept Generation

To develop potential concept solutions, general brainstorming used during the concept generation phase of the project. The problem statement was approached as two distinctive design challenges. First, was the challenge of designing a mechanism that could treat and/or prevent a plugged duct. The second challenge was keeping the mechanism on the breast. It was important that the mechanism was pressed against the breast so that it could apply enough pressure to the affective area. Four concepts were created.

The first concept was inspired by the authors previous product design class. In this class, the author worked with a group of five students to design a breast pump. Unlike current products, the device would use compression instead of suction to extract milk. Pressure was exerted on the breast by the inflation of two concentric air bladders that fit around the breast. The air bladders would fill with air and tighten around the breast to release milk. This was designed to mimic a woman manually compressing her breasts. This extraction technique is termed hand expression [12]. Figure 4.1 shows the design model. The sponge represented the breast and was compressed as the air bladders inflated. The device was able to exert 7N on the sponge.

![Figure 4.1: Air bladder compression rings that tighten to compress breast (image courtesy of web.mit.edu).](image)

In order to keep the air bladders around the breast, a breast shield was created. The shield was thermoformed and functioned by exerting a normal force on the concentric rings. The breast shield was attached to bottles that collected the expressed
milk. Figure 4.2 displays the fully assembled prototype.

Though the prototype focused on expressing enough milk for a feeding, the concept could be used to help prevent and treat plugged milk ducts. A device could be designed in which the compression rings would be used in conjunction with an existing breast pump. Thus the device could massage the affective area while emptying the breast.

The following three concepts were generated by researching existing massage products on the market. A current form of massage therapy is an electric pulse massager. This sends an electrical signal to an electrode pad that is placed on the skin. The pad stimulates the muscles to contract or release tension. The electrical signal has parameters which include wavelength, pulse width, intensity, and frequency [13]. Figure 4.3 shows an at-home electronic pulse massage device. The user can select different types of massage such as beat and knead. This technology has received increasing attention over the past years, for the electrical signals produce
an effect similar to that caused by a massage specialist [14, 15].

It is also used as a recovery device for athletes. It increases muscle blood flow to help the body repair itself [14]. The idea was to have these discrete electrode pads woven into a bra. Women would then be able to select which area to stimulate. However, upon further research it became unclear if this technology would helpful or safe to facilitate milk flow.

The third concept was inspired by vibrating massage chairs. A massage chair cushion was taken apart (as seen in figure 4.4). The device consisted of vibrational motors and a heating pad. Since heat and massage are both plugged milk duct treatment, the concept was to sew small vibrational motors used in cellular phones along with a heating pad into a nursing bra. After interviews with nursing mothers and further research it was discovered that vibration helps relieve pain caused by plugged ducts. However, vibration is not a terribly effective treatment for getting rid of plugged ducts.
Lastly, the fourth concept was modeled after a shiatsu inspired massager. Shiatsu massage, also known as finger pressure massage, originated in Japan. This massage can target specific areas on the body. The masseuse applies pressure using his/her fingers, knuckles, thumbs, palms, feet, or elbows [16]. Prospera created a shiatsu inspired kneading massager as shown in figure 4.5.

The device was then taken apart to understand how it worked. After taking off the first layer, two injection molded pieces were revealed (figure 4.6). These were the
pieces that produced the kneading sensation on the body.

Figure 4.6: Prospera kneading massager without first layer.

The two pieces were able to rotate via a motor as seen in figure 4.7. A worm gear was connected to a 30 toothed gear. Worm gears are used to reduce rotational speed and allow a higher torque to be applied. In this case, it was important that there was a high torque so that the device would not stall when pressing down on the user. The two white gears pictured below had a 38:30 gear ratio.
The idea for this concept was to produce a kneading effect on the breast using this technology. However, instead of worm gear and gears, the cap would be directly attached to the motor. Figure 4.8 shows this concept as it was first generated.
4.4 Concept Selection

After the concepts were generated, the Pugh Selection Matrix methodology was used to select the concept for this project. This method works by evaluating each concept to a set of selected criteria. The design requirements that were derived from the problem statement were selected as the criteria. In a Pugh Chart, the must be a datum concept. This is a concept that is chosen to compare to all the other concepts. Here, the vibrational massager concept was chosen as the datum. Each concept was then compared to the datum for each criterion and was given a score of either 0, -,-, or ++. After each concept has been evaluated the scores are added up. Table 4.2 shows the evaluation criteria, the criteria scores, and the concept scores.

Table 4.2: Pugh Chart for Concept Selection

<table>
<thead>
<tr>
<th>Evaluation Criteria</th>
<th>Vibration</th>
<th>Compression</th>
<th>Electronic Pulse</th>
<th>Kneading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reliability</td>
<td>0</td>
<td>-</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Easy to Manufacture</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Easy to Operate</td>
<td>0</td>
<td>-</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Portable</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Relatively Quiet</td>
<td>0</td>
<td>-</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Adequate Pressure</td>
<td>0</td>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Hands-Free</td>
<td>0</td>
<td>0</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total Score</strong></td>
<td>0</td>
<td>-3</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>

The kneading shiatsu massager concept had the highest score, thus it was selected for the project. The vibrational motor massager concept had the second highest score. Therefore if the first concept was abandoned, the vibrational massager would be the next concept in line.
Chapter 5

Plugged Lactiferous Duct Massager

5.1 Concept Refinement Stage 1

After the concept was selected a first stage of design refinement was performed. The kneading shiatsu massager concept was not fully developed, thus there were design requirements that needed to be solved. First, the kneading mechanism needed to be thought through. The Prospera massager produced its kneading sensation with its rotating caps as shown in figure 5.1. Two of these caps rotated continuously with one motor. Though the rolling/kneading sensation was felt due to the difference in diameters of the two balls on the top of the cap. The ratio between the larger to smaller diameters was 1.3:1. Thus, to get a kneading affect with this mechanism, the design needed to have balls with a difference in diameters similar to 1.3:1 ratio.

Figure 5.1: Rotating cap (from Prospera kneading massager) that produces the kneading sensation on the body.
A softer material than plastic was desired since the device would be kneading the breast instead of a more robust body part. Two silicone balls could replace the plastic ones. Figure 5.2 shows this idea.

![Kneading massager with silicone balls](image.png)

Figure 5.2: Kneading massager where the silicone balls contact the skin.

In order to make the device hands-free, the idea was to incorporate it into a bra. An idea was to have a track in the bra that allowed the motor to be moved around in order to massage different areas of the breast. The breast would be covered with a first layer so that the massager would not directly touch the skin. Then the motor would be supported by an outer layer which kept the massager firmly on the breast. This would make sure that the device applied adequate pressure to the problem area on the breast. Figure 5.3 shows this concept as it was first generated.
Figure 5.3: Massager attached to the bra in order to make it hands free.

5.2 Sketch Model

To show the underlying functionality of the concept, two sketch models were built. Sketch models are helpful for designers to visualize and further understand their ideas. The balls for the kneading cap were analyzed in these two sketch models. Rubber balls of varying dimensions and compliance were used. These two sketch models would then be attached to their own individual motors to form two different devices. Figure 5.4 displays the two sketch models.
The sketch model on the left of figure 5.4 was made out of a more compliant rubber ball. The ratio between the larger and small diameters was 1.7:1. After testing this sketch model it was discovered that in order to be an affective massager the rubber balls needed to be stiffer. Thus, the second sketch model was developed. In this sketch model the balls were taken from bouncy balls that were sliced into hemispheres. The ratio of the larger and smaller diameters was 1.3:1, which is the same ratio as the balls on the Prospera product. It was found that the balls used in the second sketch model were large and stiff enough to give a massaging effect. The sketch models revealed some important geometric and material problems that needed to be addressed. First, the two balls cannot be placed too close to each other. In the Prospera device, the outside perimeter of the two balls were 0.6" from each other. The first sketch model had the balls too close together to be an effective massager. The second problem was the realization that the rubber balls had a relatively high coefficient of friction. When the sketch models were placed on the body, the ball would catch on to the clothing as it rotated. A proposed solution was to cover the balls in a slippery fabric/material. In order to get a better understanding of the concept the design was created on SolidWorks as shown in figure 5.5. Here a motor would be attached at the bottom of the cap below the rubber balls.
5.3 Detailed Design and Refinement Stage

In a previous design class, the author was part of a team that measured the amount of force nursing women exerted on themselves when massaging their breasts. It was found that women exert a range of 1-5N. In order to fulfill the design requirement of exerting enough pressure on the breast the chosen motor must have been able to withstand a certain amount of torque. The coefficient of friction, normal force, and moment arm needed to be defined in order to estimate this torque. Since the rubber balls would be covered in a fabric, the coefficient of friction between the fabric and skin was estimated to be 0.3 [17]. The max force of 5N was used and the moment arm was estimated to be the distance from the center of the cap to the center of the largest ball. A safety factor of 5 was multiplied into the calculation. The torque was estimated to be 0.20Nm. Therefore two motors were chosen that had a max torque larger than 0.2Nm.

Originally a high torque DC motor was going to be used, however a servo motor was used in the final design. A high torque servo motor was selected due to the convenience of the gear box and potentiometer tightly packaged into a small product. The two servo motors selected had a max torque of 0.44Nm and 0.47Nm.

As discovered in the sketch model, the two kneading balls needed to be a certain distance away from each other. Therefore, on the design refinement stage, the outside perimeter of the two balls were set a distance of 0.6”. This is the same distance that the two plastic balls were set in the Prospera product. The two balls also needed to be at the same height in order to have them both effectively touch the breast. Figure 5.6 shows this design.
The caps were 3D printed and rubber balls with a ratio of 1.3:1 were inserted as seen in following figures.

Figure 5.7: 3D printed massaging cap.
Figure 5.8: Assembled cap with bare rubber balls.
5.4 Alpha Prototype

After assembling the massaging cap to the servo motor it became apparent that the device was too large to be placed inside of a bra. Therefore handles were printed in order to make it a hand held. To reduce friction between the balls and the skin, cloth was placed over the balls. The electronics were housed in a black box with a switch protruding out of it. This setup made the device very easy to operate. The connecting wires from the electronics to the device were also made longer in order for the user to easily place it on the breast. The final alpha prototype can be seen in the following figures.

Figure 5.9: Final assembled prototypes.
Figure 5.10: Final assembled battery operated prototype.
Figure 5.11: Device placed on chest.
Chapter 6

Final Analysis

6.1 Future Development

If the device is continued after the completion of this study, there are some design questions and factors that need to be considered. The chosen motors were able to withstand the torque exerted on it while massaging the breast. However, a motor with a high torque and speed would be an improvement. The servos used rotated at 70rpm. A damping mechanism would be useful in order to make the device quieter. Though the prototypes were relatively small (they only weighed 78g), they were still too wide to be placed inside of a bra. The author started to look at small DC motors. If a motor was used instead of a servo motor, a piece would have to be designed to hold up the motor. For future iterations, the motor and motor housing should be designed in order to be small enough to become a hands-free device. The massaging cap should be scaled down to be able to massage a more specific area of the breast.

Further consideration for the design and assembly of the device would also have to be considered. Currently the device has five pieces. For manufacturing, the cap with balls and the handle would be injection molded. To reduce production costs and assembly time, the device could be designed to contain fewer parts.

Finally, if the design process is continued, there would need to be testing of the device. This testing would be necessary to support design decisions to make sure that it effectively treated plugged milk ducts. Design variables that would need to be determined from testing include the geometry of the massaging cap and the material of the balls. When the design is finalized, it should be tested to determine the life of the device along with its reliability. Due to the time constraints, elaborate testing could not be conducted as part of this project.
6.2 Conclusion

Plugged lactiferous ducts are a common problem that many nursing women encounter. Women treat and prevent plugged ducts by massaging the affected area. Currently, there are no products on the market that use massage techniques to help mothers with the plugged ducts. Over the course of this project, multiple concepts for solutions to this problem were developed. The selected concept then went through more stages of refinement and prototype construction.

Though, there needs to be further testing of the device, it was able to produce a kneading sensation on the body. The device was able to withstand the torque exerted on it. The device presented at the end of the study does provide a solid foundation to a solution to this inventive problem.
References


