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# Soft Robotic Bio-Inspired Breast Pump

Kirsten Lussenburg, Giovanni Colucci, Giuseppe Quaglia, Cosimo Della Santina, *Senior Member, IEEE*, and Aimée Sakes

***Abstract*—Breastfeeding is essential for infant nutrition, but the increasing number of women returning to work before weaning highlights the need for efficient and comfortable milk expression methods. Traditional breast pumps rely solely on vacuum suction, which can cause discomfort, tissue damage, and longer extraction times compared to natural nursing. This study aims to develop a breast pump that better mimics the biomechanics of infant breastfeeding to improve comfort and efficiency. We investigated two actuator designs—membrane and soft pleated—integrated into the breast shield to replicate infant sucking. The pleated actuator proved most effective, offering a wide range of expansion and contraction. Unlike traditional pumps, vacuum is applied through radial expansion, allowing the nipple to widen rather than elongate, closely simulating infant tongue movements. The breast shield was fabricated using additive manufacturing with soft, elastic materials, enabling complex geometries and varied stiffness. The prototype was tested against a commercial pump using an artificial breast phantom. Results suggest this design can enhance milk output, reduce pumping time, and improve user comfort. By merging soft robotics with biological insights, our approach offers a promising alternative to conventional breast pumps.**

***Index Terms*—Breast pump, breast feeding, soft robotics, pneumatic actuation, bio-inspired.**

## I. Introduction

THE USE of a breast pump is a necessity for many breastfeeding mothers. Breast pumps enable mothers to start or sustain their milk supply, providing the flexibility to work away from home while still feeding their child with breast milk. The use of a breast pump can potentially prolong breastfeeding duration by allowing the mother to partake in society as well as nurse their child [1]. Alternatively, mothers may choose to use a breast pump so that others, such as their partner, can participate in infant feeding [2], [3], or because breastfeeding is too painful for them. Many mothers also report that the use of breast pumps provides them with a sense of control over breastfeeding [4].

There are generally two types of breast pumps: hand pumps and electric pumps, both relying on vacuum as their main means of extracting milk. Electric pumps reportedly facilitate gauge pressures of up to −300 mmHg (−40 kPa), applied in a cyclic manner, of which the exact vacuum level can be controlled by the user. For comparison, the vacuum pressure applied by infants peaks at around −197 mmHg (−26 kPa) [5], [6]. Although not every woman will use the breast pump at its highest vacuum level, studies have shown that the highest comfortable vacuum is most effective in terms of milk volume output [7], [8]. Recently, pump manufacturers have started to include different vacuum profiles that more closely mimic the suckling behavior of infants. A suction profile similar to an infant that has just latched on at the start of the pumping session is effective at accelerating the milk ejection reflex [9] and increases the overall milk output [10]. In general, electric breast pumps are at least as effective at emptying the breast as an infant [11].

Although vacuum is the main mechanism for milk extraction in expressing, there is some evidence towards the role of compression of the breast. It is common advice for mothers to massage their breasts in order to establish and sustain lactation. Hand massaging while pumping or breastfeeding has been shown to enhance the milk volume output, prevent painful breasts or nipples, enhance the fat content of the milk, and prolong the oxytocin release responsible for the milk ejection reflex [12], [13]. Ultrasound studies of nursing infants have shown that the infant's mandible and maxilla apply a peripheral pressure on the nipple-areola complex [14]. Alekseev et al. studied the effect of nipple compression in a modified breast pump, which applied pressure at the same time as a vacuum [15], [16]. Their results indicated that during the peak ductal pressure of the milk ejection reflex suction alone is more effective for removing milk, but when ductal pressure is not at its peak, suction combined with compression resulted in faster milk removal.

Despite the fact that breast pumps are a necessity for many mothers nowadays, their use is not without complications. Some level of discomfort or even pain is generally associated with breast pump usage among expressing mothers [17]. In a survey by Qi et al., as much as 62% of 1844 surveyed mothers reported pump-related problems, of which the most common was insufficient milk output, and 15% reported injuries, of which sore nipples was the most common complication [18]. Furthermore, 28% of women reported that the pump was

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uncomfortable or painful, without sustaining an injury. Francis and Dickton analyzed the dimensions of nipples before and after breastfeeding and pumping using two different breast pumps [19]. They showed that both breast pumps significantly increased the length and diameter of the nipple as compared to breastfeeding, with changes lasting longer than 20 minutes. They classify the 'abnormal enlargement' of the nipple as soft tissue damage. As such, comfort is an important part of breast pump usage, although this is highly subjective and often difficult to objectively research [17]. Bartels et al. surveyed mothers' experiences with breast pumps, and found that portability, ease of use, low-weight, fast (perceived) milk extraction, comfortability, low-noise, and discreteness were among the aspects mothers rated as important in their breast pump [20].

Problems related to breast pumps are difficult to investigate, as many mothers will endure discomfort in order to feed their child or quit breast feeding altogether. Since breast milk is considered the best nutritional source for the baby, it is advantageous to make expressing as comfortable and efficient as possible to encourage women to continue breastfeeding for the longest time possible. As such, breast pump related issues need to be addressed. Many women report that breastfeeding their child is more comfortable than using a breast pump [20]. In this research, we hypothesize that this is in part because the current working principle of breast pumps is not effective in mimicking the drinking behavior of the infant. Therefore, we aim to design a bio-inspired breast pump that mimics the biomechanics of a nursing infant and investigate whether such a breast pump has the potential to alleviate common problems associated with breast pump usage. We start by a literature review of the oral mechanics of the infant and factors influencing the output of milk in Section II, which was the inspiration for the development of two soft robotic actuators, described in Section III. We further developed one of the actuators, and performed a pressure characterization, as well as an investigation of nipple elongation as compared to a commercial breast pump in Section IV, of which the results are described in Section V.

## II. Natural Suckling

### A. Infant Suck and Swallow Mechanism

The manner in which infants extract milk from the breast has been extensively researched. As soon as the infant latches onto the breast, a baseline vacuum is applied in order to create a seal, which remains intact throughout the breastfeeding session [21], [22]. The infant has latched on correctly when the complete nipple and a large part of the areola are inside the infant's mouth, and its lips are turned outwards. The period of time needed by the infant to extract and swallow a bolus of milk is referred to as a 'suck cycle'. During the first half of the suck cycle, the infant moves the anterior tongue down. This increases the vacuum, which peaks when the tongue is at its lowest position, releasing milk from the nipple into the oral cavity, as illustrated in Figure 1.2-1.3 [5], [23], [24]. During the second half of the suck cycle, the anterior tongue returns upward, releasing the vacuum back to its baseline.

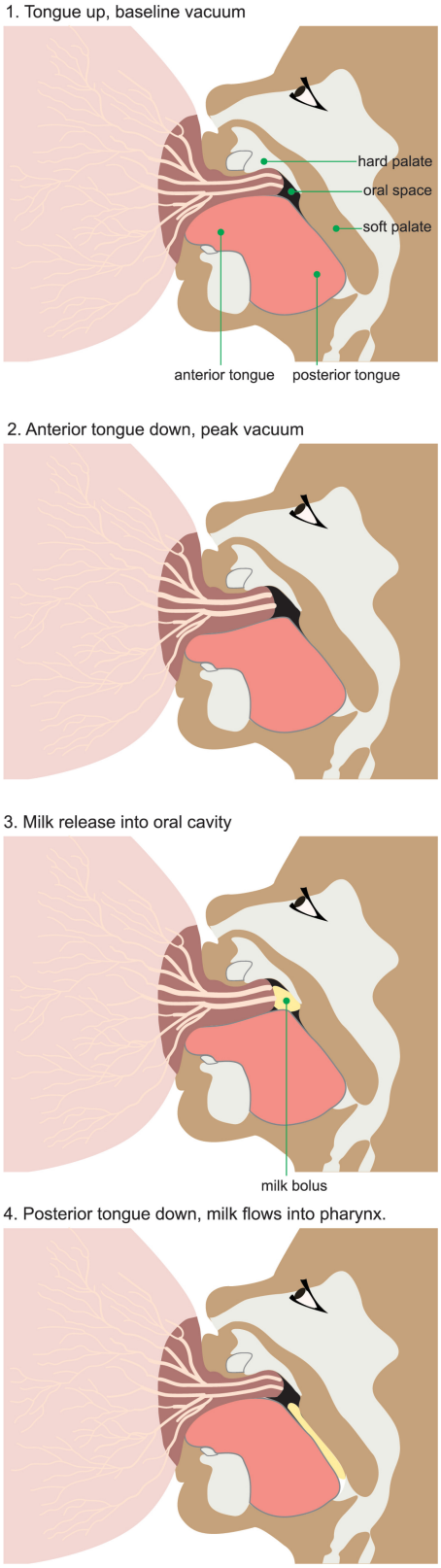


Fig. 1. Depiction of the consecutive movements in the infant mouth during one 'suck cycle'.

Simultaneously, the posterior tongue moves downward, clearing milk from the oral cavity into the pharynx for swallowing, as illustrated in Figure 1.3-1.4 [5], [23]. Lucas et al. showed that around 50% of the available milk is consumed in the

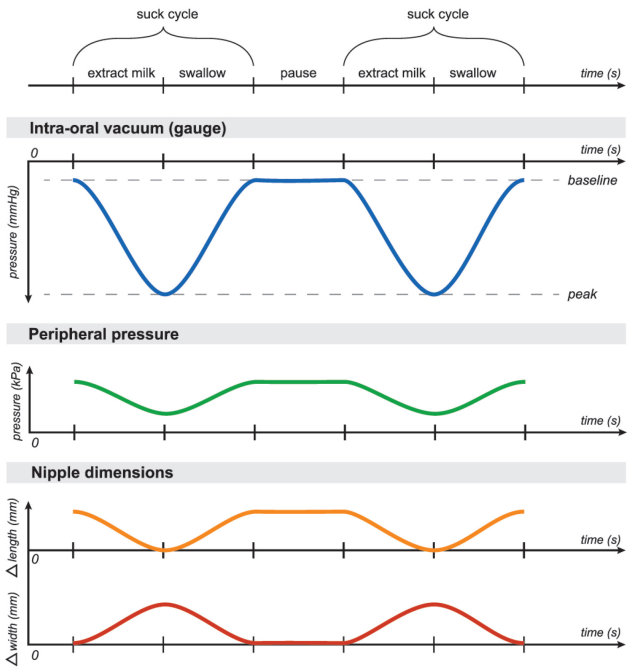


Fig. 2. Schematic depiction of the relationship between intra-oral vacuum, peripheral pressure, and nipple dimensions during one 'suck cycle'. Note that the intraoral vacuum is commonly measured in mmHg, while the peripheral pressure is commonly measured in kPa.

first two minutes of breastfeeding, and 80-90% after four minutes of breastfeeding [25], suggesting that the remainder of the breastfeeding session consists mainly of non-nutritive sucking.

The relation between tongue movement and intraoral pressure is schematically depicted in Figure 2. Ultrasound studies have shown that milk removal only occurs in the first half of the suck cycle, when the tongue of the infant is down [5], [22], [23], [24], [26], [27], thereby disproving older theories that a peristaltic tongue motion exerted on the nipple is responsible for milk extraction. Many studies have measured intraoral vacuum levels applied by infants, an overview is given in Table I for indication. It should be noted when comparing these values that measurement methods differ between studies, for instance whether measurements are taken only during nutritive sucking or also during non-nutritive sucking. In general, vacuum levels vary hugely between mother-child pairs, and over the duration of a breastfeeding session.

### B. Peripheral Pressure

Although intraoral vacuum is the main mechanism for the extraction of milk, the infant also applies a pressure on the breast with its mouth and tongue. The maxilla and mandible have been shown to exert an oscillating peripheral pressure on the nipple-areola complex [14], [31]. Alatalo et al. measured a mean pressure of the maxilla of $2.78 \pm 2.62$ kPa and a peak pressure of $7.88 \pm 6.59$ kPa, as well as a mean pressure of the mandible of $1.67 \pm 1.68$ kPa and a peak pressure of $5.30 \pm 3.6$ kPa [14]. The peripheral pressure peaks when the intraoral vacuum is at its lowest [14], as schematically depicted

TABLE I
OVERVIEW OF MEAN, BASELINE, AND PEAK INTRAORAL VACUUMS (MMHG) INSIDE INFANTS' MOUTH DURING BREASTFEEDING AS REPORTED IN LITERATURE

**Intraoral vacuum** (mmHg)

| Mean | Baseline | Peak | Ref. |
|---|---|---|---|
| $-114 \pm 50$ | $-64 \pm 45$ | $-145 \pm 58$ | [24] |
| — | $-31 \pm 24$ | $-122 \pm 48$ | [22] |
| $-50$ | — | $[-122, -197]$ | [5] |
| $[-26.55, -76.425]$ | — | — | [14] |
| — | $-26 \pm 31^{(1)}$<br>$-33 \pm 34^{(2)}$ | $-130 \pm 62^{(1)}$<br>$-111 \pm 61^{(2)}$ | [26] |
| $[-75.75 \pm 42.45]$ | — | — | [28] |
| $[-74.5 \pm 6.9]$ | — | — | [29] |
| $[-91.55 \pm 21.38]$ | — | — | [30] |
| $[-50 \pm 5.7]$ | — | $-197 \pm 10$ | [6] |

(1) 1st 2 min.
(2) 2nd 2 min.

in Figure 2. Experiments with an artificial nipple showed that infants also apply a positive pressure with their tongue on the nipple, ranging from 0.06 to 2.06 N [32], [33]. It is hypothesized that the compression of the nipple during breastfeeding may aid in the suck-swallow-breathe dynamic of the baby, allowing it to safely swallow the milk [21], [22]. Azarnoosh and Hassanipour performed fluid-structure interaction simulations to investigate the factors influencing milk expression from the nipple [34]. Their simulation showed that while vacuum is important for milk removal, this is facilitated by the pressure of the tongue and jaw, which opens and closes the milk ducts and decreases shear stress in the milk ducts.

### C. Nipple Dimensional Changes

Alatalo et al. observed during ultrasounds that the nipple is elongated and compressed when the infant's tongue is up, coinciding with the application of the baseline vacuum, and expands and shortens when the infant's tongue is down, coinciding with the application of peak vacuum [14], as schematized in Figure 2. They measured an average change in nipple length of $3.05 \pm 0.39$ mm and an average change in width of $1.51 \pm 0.20$ mm, which they attributed to the compression of the nipple between the tongue and the hard palate [23], [35]. Similarly, Jiang et al. found an average change in nipple width of $1.56 \pm 0.24$ mm and in nipple length of $3.00 \pm 0.37$ mm during breastfeeding [31]. The changes in nipple dimensions during breastfeeding are temporary, there is no significant change of the nipple once the infant releases the breast [19]. For comparison, a study measuring dimensional changes in the nipple after the use of two different electric breast pumps found a change of approximately 5 mm in length and 6 mm in width, measured directly after expressing, with changes lasting for more than 20 minutes [19].

### D. Milk Flow

No milk flow can be established without triggering the mother's milk ejection reflex. In order to elicit the milk

ejection reflex, physical and/or psychological stimuli are required, which cause the hormone oxytocin to be released from the posterior pituitary gland into the blood stream [36]. Surrounding the areola are myoepithelial cells, consisting of smooth muscle fiber, which contract in response to oxytocin and thereby release milk from the aveoli into the milk ducts. The diameter of the milk ducts increases in response to oxytocin [37], thus facilitating milk flow. Without the milk ejection reflex, hardly any milk can be removed from the breast [37], indicating that milk removal from the breast is a combination of the intraoral vacuum applied by the infant, and the pressure from the milk ejection [22]. During milk ejections, the milk duct diameter increases from 2.4 to 2.8 mm on average, unaffected by vacuum levels [38].

Research has shown that physical stimuli of the nipple only, not the areola, in the form of touch and light pressure are effective for triggering the milk ejection response, whereas heat or the application of vacuum pressure are less effective [9], [39]. Some women also benefit from psychological stimuli, such as seeing, hearing or smelling their baby, or thinking about nursing or pumping [40]. Psychological stress and the use of alcohol and tobacco have been shown to inhibit the release of oxytocin, and thereby the milk ejection reflex [37], [40]. Within one feeding or pumping session, it was found that between 1 and 17 milk ejections occur lasting on average between 100 and 800 seconds each [38], with more than 50% of the available milk removed during the first two milk ejections [26], [41]. From tests with vacuum breast pumps, it was found that the strength of the vacuum is unrelated to the length or number of milk ejections [38], and that the time for the first milk ejection using a pump was more than twice as long as compared to breastfeeding [9].

Factors influencing the milk output in terms of volume and flow rate are not yet well understood. Several studies suggest that the initial fullness of the breast before pumping or breastfeeding is important [9], [37], [38], [42]. One study showed that an increase in milk duct diameter corresponds to an increase in milk flow rate, as well as a greater volume of milk expressed in a 5-second period [38], although another study could not find a relationship between these factors [9]. Cannon et al. showed that a stronger peak vacuum in breastfeeding babies resulted in larger volumes of milk removed [26]. However, Negin Mortazavi et al. showed with a clinical study and a computational fluid dynamics model that the highest vacuum pressure does not result in the highest milk flow rate [28].

### E. Conclusion

- Infants use cyclic intraoral vacuum and peripheral pressure for suckling, both applied in a cyclic manner, with intraoral vacuum the principal driver of milk removal.
- Current breast pumps implement adjustable vacuum profiles that are controllable by the user.
- Some commercial pumps apply peripheral pressure concurrently with peak vacuum, which can compress milk ducts and potentially inhibit milk flow [43], [44].
- Inspired by infant biomechanics, peripheral pressure should be timed to occur when vacuum is minimal to avoid duct compression.
- Discomfort during expression is common and may result from pump–breast mismatch, inappropriate settings, or prolonged use, although little research into the specifics has been performed.
- One of the few objectively measured defining metrics of comfort are the dimensional changes in the nipple during breast feeding and expressing, showing significantly larger nipple deformation after the use of breast pumps as compared to suckling [19].
- The infant's tongue, hard palate, jaw and lips enable large intraoral adjustability to the mother's anatomy, and to control the vacuum.

Our aim is to incorporate the adjustability of the infant's oral anatomy into the breast pump, by creating a design that is able to modify the intraoral space. As the tongue movement of the infant is mainly responsible for vacuum application, we will attempt to design a soft actuator that mimics the motion of the tongue and can be applied in a breast pump system.

## III. Breast Pump Development

### A. Functional Layout

In Figure 3 the functional lay-outs of a typical manual and electric breast pump are shown, both containing a pumping mechanism, a breast shield, and a milk container. In both types of breast pump, the vacuum inside the breast shield is obtained by means of a volumetric change as a result of the displacement of a diaphragm, forcing the air trapped in the breast shield to expand. In the manual breast pump, the displacement is manually imposed, whereas in the electric breast pump the displacement is generated by an external electric vacuum pump. It should be noted that the breast shield is made of a rigid or semi-flexible material, and its volume itself does not change, therefore, the displacement of the diaphragm is responsible for the vacuum application. In the electric breast pump, the presence of the diaphragm leads to a redundancy, as the external electric vacuum pump is in theory able to apply a vacuum directly to the breast. However, the diaphragm also isolates the milk flow from the vacuum pump, thus preventing the milk from being contaminated by external factors, and preventing undesired flow of milk towards the vacuum pump. Moreover, by means of the linear diaphragm stroke control, the vacuum level within the breast shield can be modulated and constrained.

The breast shield consists of a flange which surrounds the breast and functions as a seal, and a tunnel which surrounds the nipple and transports the milk to the container. Usually, different sizes of breast shields are available, and most pump manufacturers stress the importance of choosing the correct size breast shield, often based on the dimensions of the nipple, although the specific advice varies. A too narrow tunnel will cause nipple tissue to rub against the side of the breast shield causing painful friction, which suppresses the release of oxytocin and therefore inhibits the milk ejection reflex [45]. In addition, the milk ducts become compressed, thus preventing

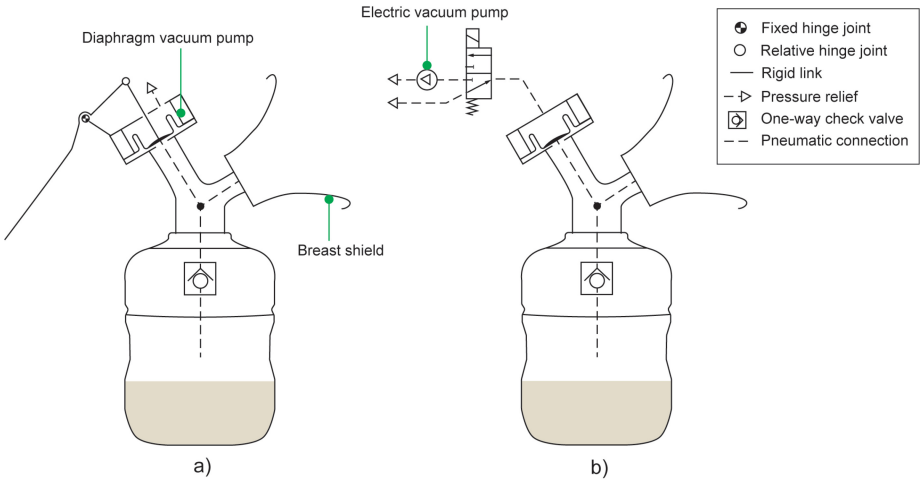


Fig. 3. Functional lay-out of a typical manual (a) and electric breast pump (b).

the breast from emptying correctly or completely. A too large tunnel can cause air gaps to occur between the nipple and the breast shield, leading to a loss of suction, with the risk of using an inappropriately high vacuum to compensate [45]. Little research on breast shield functionality is available. There is some evidence to suggest that a flange opening of 105 degrees is more efficient, effective and comfortable than a 90 degrees opening [46], and that warming the breast shield results in a faster extraction of milk [8], [47].

### B. Design Evolution

*1) Design Goal:* As the breast shield is the only part of the breast pump that comes into direct contact with the breast, we focused on redesigning this part. Our goal was to create a breast shield which can apply peripheral pressure when the vacuum is at its lowest, and allows for radial expansion of the nipple, similar to the oral mechanics of the baby. The breast shield should fit nipples with a width between 9 mm to 30 mm, and a length of 5 mm to 15 mm. In our first design explorations, we explored the design of a flexible insert that can be placed in the rigid breast shield, keeping the rest of the functional lay-out similar to the standard breast pump.

*2) Prototype Fabrication:* Different prototypes, discussed in the following Sections, were designed and 3D printed using a commercial stereolithography (SLA) 3D printer (Form 3B, Formlabs, Somerville, United States). A flexible material was used, called Biomed Elastic 50A, from the same manufacturer, which reportedly has similar characteristics to silicone. From preliminary testing, we determined that the minimum wall thickness without leakage that we could obtain with this material and printer was 0.5 mm. After printing, the prototypes were cleaned and cured according to the manufacturer's instructions for biocompatible materials, and support structures were removed.

*3) Membrane Actuator:* The first designs closely mimicked the oral anatomy of the infant's mouth, with a rigid top section, mimicking the hard palate, and a moving actuator on the bottom, mimicking the tongue, which can move upwards and downwards, shown in Figure 4. The moving actuator consisted of an air chamber with separate outlet, sealed off by a flexible corrugated membrane, as shown in Figure 4a-b. The diameter of the tunnel ($D_{tunnel}$) was kept at 10 mm. The deformation of the actuator should be largest in the center, similar to the tongue of an infant, however the deformation more closely resembled a U-shape (Figure 4c). We attempted to improve on this by adding a flat middle section to the membrane, which resulted in a V-shaped deformation (Figure 4d). Although functional for applying contact force, this solution presents some limitations. With mother-baby dyads, the infant is able to open their jaw and adjust the mouth opening and tongue placement to the mother's anatomy. Within the requirements of the breast shield, this flexibility is difficult to obtain with a corrugated membrane actuator, meaning that the breast shield would only suit a limited range of nipple sizes. Furthermore, this breast shield requires a separate pump for actuation of the moving actuator, in addition to the vacuum pump, leading to an increased complexity for the system as compared to a standard breast pump. Therefore, in our following design exploration, we attempted to increase the adjustability of the breast shield, without further complicating the system.

*4) Pleated Actuator:* In order to incorporate a large range of motion, inspired by the movement of the infant's mouth and jaw, we designed a radial actuator that utilizes the entire circumference of the tunnel for its deformation, shown in Figure 5a-b. The design consists of a flexible insert with thin wall thickness and a pleated structure that allows the tunnel to expand radially. A major advantage of this design is that due to the large volumetric displacement that can be obtained this way, the insert can replace the diaphragm actuation that is applied in the standard breast pump, as discussed in Section III-A. The insert allows for separation of the milk flow from the pump, and its radial expansion allows for the application of a vacuum to the nipple as well as a contact pressure. This means the functional lay-out of the entire breast pump can be described as shown in Figure 5c. There are two important considerations for this design:

- The volumetric displacement of the pleated actuator should be similar to the volumetric displacement of the

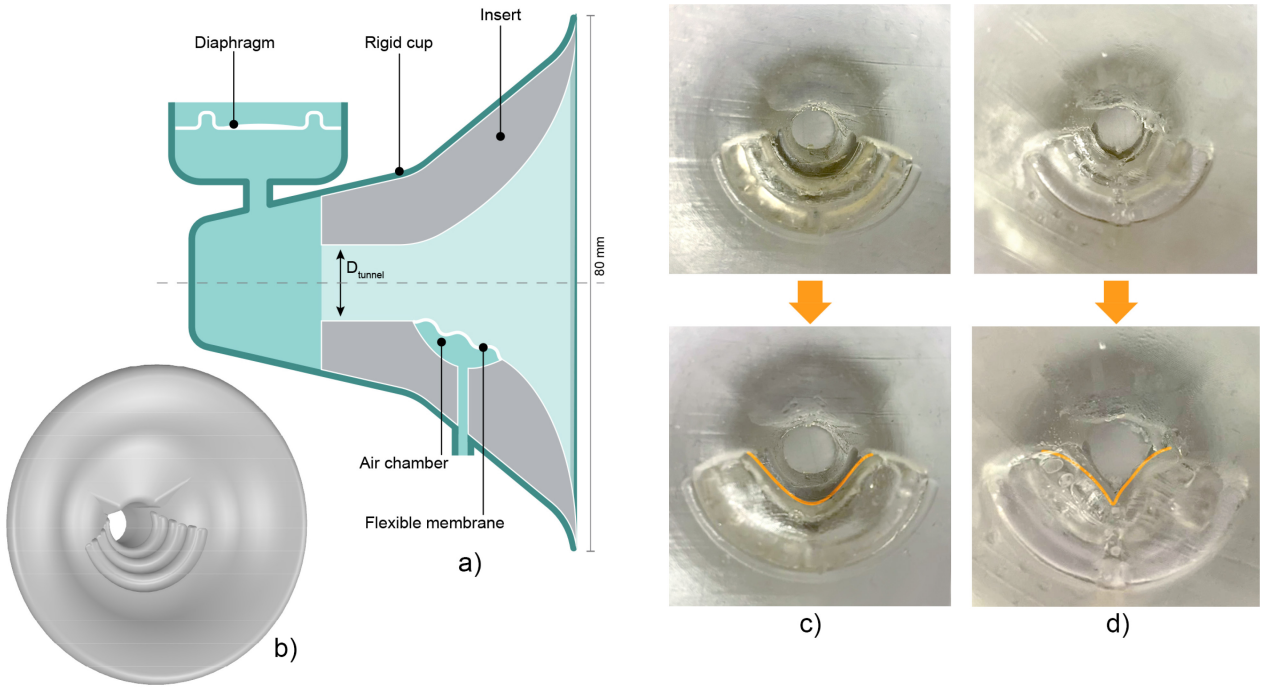


Fig. 4. Design of a breast shield closely mimicking the oral anatomy of an infant. a) Schematic cross-section of the design showing the rigid breast shield with an insert containing a moving actuator, which mimics the tongue motion of an infant by applying positive and negative air pressure. The tunnel diameter ($D_{tunnel}$) is 10 mm. b) CAD render of the membrane actuator with corrugated membrane. c) Deformation of the moving actuator with a corrugated membrane, which results in U-shaped deformation when pressure is applied (indicated by the orange line). d) Deformation of the moving actuator with a corrugated membrane with flat middle section, which results in V-shaped deformation when a pressure is applied (indicated by the orange line).

diaphragm of a standard breast pump, in order to obtain a similar intraoral vacuum.

- The pleated actuator should have the highest radial deformation at the location of the nipple, to mimic the infant's tongue motion.

Different design variations of the pleated actuator were created, in which the tunnel diameter ($D_{tunnel}$), wall thickness ($t_{wall}$), and ridge depth ($t_{ridge}$) were varied. The theoretical volumetric displacement of the pleated actuator was determined from the CAD models, by calculating the volume of the air chamber in between the pleated actuator and the rigid breast shield. In practice, this volumetric displacement can only be obtained if the actuator is able to completely deform to the rigid breast shield, therefore the practical volumetric displacement is expected to be less.

To examine the deformation of the different designs, prototypes were 3D printed and a vacuum was applied using a syringe. The deformation of some of the prototypes is shown in Figure 6, with dimensions and the theoretical volumetric displacement given in Table II. Prototype 1 showed that deep ridges were unable to fully expand, resulting in a too restricted radial deformation. Prototype 2 showed that the deformation of shallow ridges with the same tunnel diameter was not an expansion in width, but rather linear. Therefore, we settled on Prototype 3, with a shallow ridge depth and larger tunnel diameter, which showed the largest radial expansion. In the following Sections, we tested this prototype in order to find whether it was able to obtain a similar intraoral vacuum as a commercial breast pump, to further examine its movement, and to find whether it reduced elongation of the nipple during expressing.

TABLE II
RELEVANT DIMENSIONS OF THE PROTOTYPES SHOWN IN FIGURE 6. THE THEORETICAL VOLUMETRIC DISPLACEMENT WAS DETERMINED USING CAD-SOFTWARE. FOR COMPARISON, THE VOLUMETRIC DISPLACEMENT OF THE DIAPHRAGM IN A COMMERCIAL BREAST PUMP IS 29705 $mm^3$

| | **Tunnel diam.** | **Wall thickness** | **Ridge depth** | **Theor. volumetric displacement** |
|---|---|---|---|---|
| 1 | 9 mm | [0.5,1.5] mm | 10 mm | 35355 $mm^3$ |
| 2 | 10 mm | 0.6 mm | 2.9 mm | 34649 $mm^3$ |
| 3 | 15 mm | [0.5,1.5] mm | 4.3 mm | 26159 $mm^3$ |

## IV. MATERIALS AND METHODS

### A. Breast Phantom

In order to test the breast shield in a realistic setting, we created a breast phantom which mimics the mechanical properties of a lactating breast. A human breast consists of glandular, adipose, and connective tissue, surrounded by skin, including the nipple and areola. The different mechanical properties of these tissues were found in literature. The phantom was produced using silicone in Shore-00 and Shore-25, with hardener to increase the stiffness and deadener to decrease the stiffness, in order to approach the mechanical properties of the different tissues. A 3D printed breast mold with inserts was used to cast the different tissues in the appropriate places, containing an inner part, to create a layer of skin with consistent thickness, and a simplified insert simulating glandular tissue. To mimic the size fluctuation of the glandular tissue during lactation, a cavity with a total volume of 4665 $mm^3$ was created using the insert. This cavity can be pneumatically inflated to adjust the stiffness of the phantom in order to

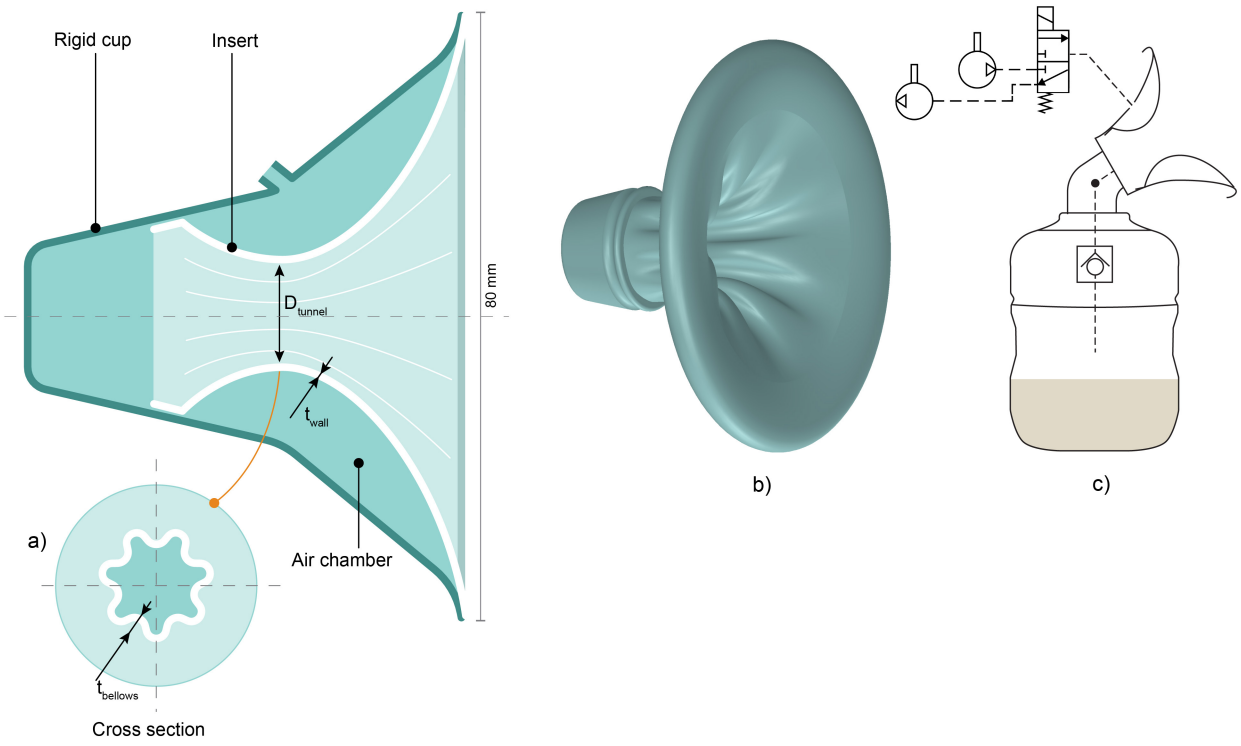


Fig. 5. Design of a breast shield insert with a radially expanding pleated actuator, which is placed as a flexible insert into a standard rigid breast shield. a) Schematic side cross section (top) and front cross section (bottom), showing the tunnel diameter ($D_{tunnel}$), wall thickness ($t_{wall}$), and ridge depth ($t_{ridge}$). b) CAD render of the pleated actuator. c) Simplified functional lay-out because of the pleated actuator.

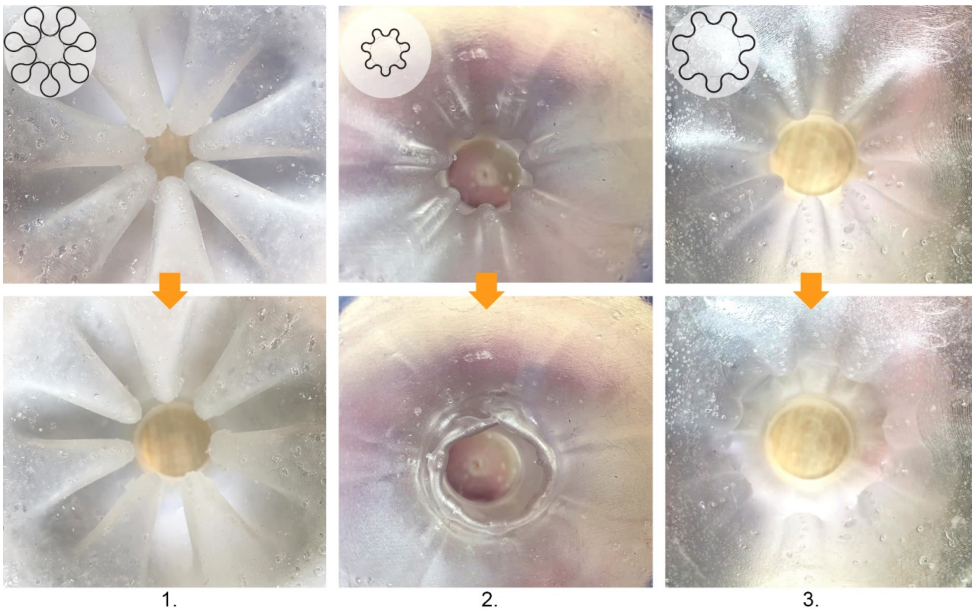


Fig. 6. Three selected prototypes and their radial expansion. The top row shows the undeformed state including a schematic of the designed cross section at nipple height. The bottom row shows the deformed state. Dimensions are given in Table II.

mimic milk fullness. The responsiveness of various areas of the breast phantom was tested by applying a local vacuum pressure of 20 kPa and measuring the displacement of the outer skin layer, at an inflation between 0 kPa and 3.33 kPa. Based on this displacement, the Young's modulus (E) of the tissue was determined. We found values of $E_{avg}$ for the skin ranging between 123.7 kPa and 193.7 kPa, and $E_{avg}$ for the areola between 23.3 kPa and 58.0 kPa. The deformation of the nipple ranged between 4.2 and 6.0 mm. These results are comparable to results of in-vivo tests performed by Alatalo et al. and Sutradhar and Miller [14], [48].

### B. Pump Set-Up

A prototype pump set-up was created to measure the vacuum level applied to the breast with the new breast shield. The

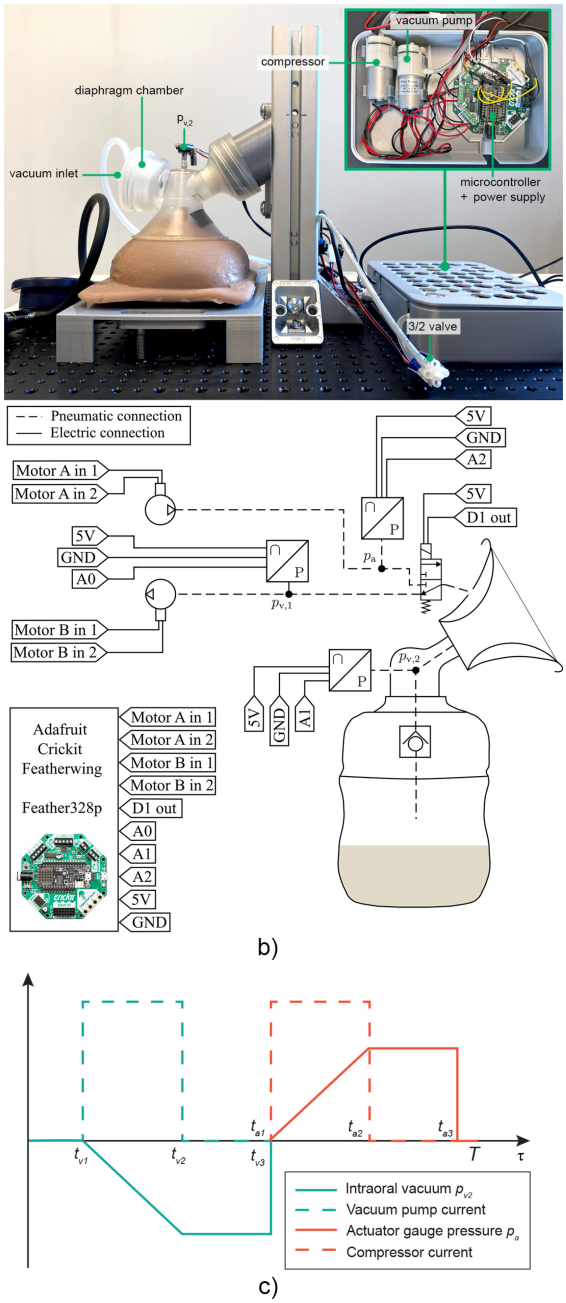


Fig. 7. Breast pump test set-up. a) Test set-up showing the breast phantom, standard breast shield, and electrical components. b) Electrical lay-out of the microcontroller and driver board, that allows alternatively vacuum and pressure to be applied to the breast shield, in which $p_{v1}$ is the vacuum applied by the pump, $p_{v2}$ is the intraoral vacuum, and $p_a$ is the positive pressure supplied to the actuator. c) Schematic variables of the pressure profile, in blue the variables corresponding to the negative pressure applied by the vacuum pump, in red the variables corresponding to the positive pressure applied by the compressor, in which $\tau$ is the x-axis label, T is the total cycle time, and $t_v$ and $t_a$ represent various phases within T, as explained in text.

entire set-up is shown in Figure 7a, and the electric lay-out in Figure 7b. The set-up consists of two pumps (specifications in Table III), one driven as a vacuum pump applying a vacuum to the breast, and one compressor applying a pressure to the actuator. Two vacuum sensors were used to measure the vacuum produced by the pump ($p_{v1}$) and the vacuum applied in the chamber (intraoral vacuum, $p_{v2}$), and a pressure sensor

TABLE III
LIMIT PHYSICAL VALUES OF THE PROTOTYPE

| | |
|---|---|
| $p_{a,max} = \lvert p_{v1,max} \rvert$ [1] | 55 kPa |
| $p_{v1}$, $p_{v2}$ [2] | $[0, -100]$ kPa |
| $p_a$ [2] | $[0, 50]$ kPa |

[1] Imposed by both the vacuum pump and compressor.
[2] Full-scale range (gauge).

was used to measure the positive pressure applied to the actuator ($p_a$). As the vacuum pump and compressor can be driven separately, a pressure and a vacuum can be applied in a cyclic pattern similar to natural suckling, as illustrated in Figure 7c. The pressure output of the pumps is controlled by driving them for a certain amount of time until the desired level is reached, which peaks at −60 kPa and 60 kPa after approximately 1000 ms. The latter is similar to the control of commercial breast pumps, which allow the timing and intensity of vacuum to be controlled by the user to a certain extent.

The pressure profile of positive and negative pressure can be designed by the following variables, indicated in Figure 7c: one total cycle time T is comprised of rest until $t_{v1}$ is reached, from $t_{v1}$ to $t_{v2}$ the vacuum pump is driven to reach a desired vacuum level, from $t_{v2}$ to $t_{v3}$ the vacuum level is maintained, and at $t_{v3}$ the vacuum is released. At $t_{a1}$ the compressor is driven to reach a desired positive pressure, from $t_{a2}$ to $t_{a3}$ the pressure is maintained, and at $t_{a3}$ the pressure is released.

### C. Intraoral Vacuum Test

The intraoral vacuum was measured for the new pleated actuator insert, as well as for the standard rigid breast shield cup for comparison. For the latter, the top part of the standard breast pump, containing the rigid breast shield cup and the diaphragm chamber, similar to the one shown in Figure 3b, was modeled in CAD software and 3D printed in a rigid, clear material (Clear V4, Formlabs, Somerville, United States), with added connectors to place the sensors. We reused the diaphragm and check valve from an existing commercial breast pump. For the pleated actuator insert, we 3D printed a similar top part, omitting the diaphragm chamber and relocating the vacuum inlet to between the insert and the rigid cup, as shown in Figure 8a. During the test, the breast shields were placed onto the mechanical breast phantom, which was inflated to 40 mmHg using air pressure to mimic milk fullness (Figure 8b-c). Table IV shows the variables which were used to control the pressure profile. Pressures of −10 kPa to −60 kPa with step sizes of 10 kPa were applied, corresponding to driving times for the vacuum pump ranging from 200 ms for −10 kPa to 1000 ms for −60 kPa. For each total cycle, the test was run for 20 seconds, corresponding to four instances of peak vacuum application. The output data was processed using MATLAB. A moving average filter with a window size of 30 has been applied on the data.

### D. Nipple Elongation Test

The nipple deformation in length and width is one of the few factors researched in literature to which we can compare

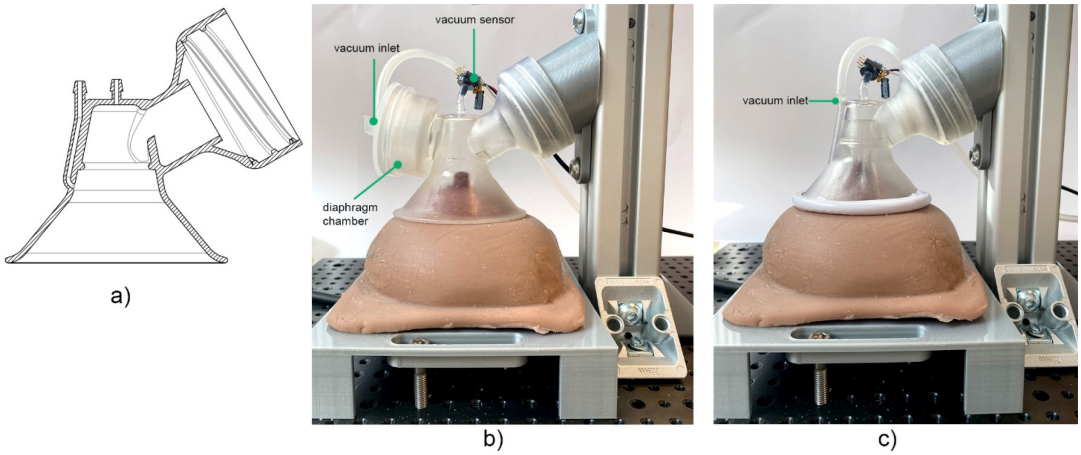


Fig. 8. Set-up of the intraoral vacuum test. a) Schematic cross-section of the custom rigid top of the breast pump designed for the bellows actuator insert. b) Test set-up without insert, in which the vacuum pump is connected to the diaphragm chamber, as is the case in common breast pumps. c) Test set-up with bellows actuator insert, in which the vacuum pump is connected to the air chamber between the insert and the rigid cup.

TABLE IV
VARIABLES USED TO CONTROL THE PRESSURE PROFILE IN THE INTRAORAL VACUUM TEST FOR ONE CYCLE

| | | |
|---|---|---|
| $T$ | Total cycle time | 500 ms |
| $t_{v1}$ | Rest | 2000 ms |
| $t_{v2} - t_{v1}$ | Intraoral vacuum generation | $[200, 1000]$ ms |
| $t_{v3} - t_{v2}$ | Intraoral vacuum holding time[(1)] | 500 ms |

[(1)] At $t_{v3}$ the intraoral vacuum goes to zero

TABLE V
MEAN PEAK VALUES AND STANDARD DEVIATION OF THE INTRAORAL VACUUM TEST FOR THE DIFFERENT TESTED PRESSURE LEVELS (N = 4)

| **Applied vacuum** $p_{v1}$ (kPa) | **Peak intraoral vacuum** (kPa) | |
|---|---|---|
| | No insert | Insert |
| $-10$ | $-7.8 \pm 5.1$ kPa | $-6.1 \pm 2.6$ |
| $-20$ | $-10.3 \pm 6.7$ kPa | $-5.8 \pm 2.9$ |
| $-30$ | $-15.1 \pm 0.3$ kPa | $-6.4 \pm 3.1$ |
| $-40$ | $-13.1 \pm 7.2$ kPa | $-7.8 \pm 3.7$ |
| $-50$ | $-14.4 \pm 7.8$ kPa | $-10.5 \pm 0.3$ |
| $-60$ | $-18.3 \pm 0.8$ kPa | $-14.3 \pm 0.9$ |

the performance of our breast shield. Preliminary testing showed that the breast phantom nipple did not have the same elastic behavior as actual nipples, due to the shape and the silicone material. Therefore, we were not able to measure the expansion in width of the nipple, only the elongation in length. We recorded videos while applying a vacuum of $-60$ kPa, both for the rigid breast shield cup and the pleated actuator insert. The nipple of the breast phantom was colored dark blue in order to increase the visibility through the breast shield. Image frames were extracted from the videos when no vacuum was applied and when peak vacuum was applied. Using the ImageViewer function in MATlAB, the difference in distance of the top of the nipple was measured between the image frames.

### E. Pleated Actuator Motion

To evaluate the ability of the pleated actuator to apply a positive pressure to the breast, we measured the deformation of the actuator while applying pressure. Blue dots were applied in regular intervals on the moving parts of the actuator. The pleated actuator was connected to the compressor of the pump set-up, and a pressure of 40 kPa was applied for 500 ms. Videos were recorded from the top of the breast shield, without the breast phantom for visibility. However, without applying a counter pressure, the insert only deformed in length, towards the camera. To simulate a breast being present, a clear glass plate was pressed on top of the actuator to prevent its deformation in length, while still being able to see the motion in the tunnel. The videos were uploaded in Tracker software (Tracker, open source physics, https://physlets.org/tracker/) to analyze the motion, by measuring the position difference of the blue dots before applying pressure and at peak pressure.

## V. RESULTS

### A. Intraoral Vacuum

The results of the intraoral vacuum measurements are shown in Figure 9a-b and in Table V. The intraoral vacuum of the breast shield without the pleated insert peaked at $-18.3$ kPa ($\pm 0.8$ kPa) on average at a pump pressure of $-60$ kPa, while that of the breast shield with insert peaked at $-14.3$ kPa ($\pm 0.9$ kPa) on average. From Table V, it can be seen that there is a large variance in the data, which we attribute to inconsistencies in the actual vacuum level that is being applied by the pump. In Figure 9b, it is clear that the intraoral vacuum does not fully return to zero, which corresponds to the applied vacuum not fully returning to zero.

### B. Nipple Elongation

Figure 10 shows the nipple in its utmost position at a pressure of $-60$ kPa both without (a) and with insert (b). The measured nipple elongation with no insert was 10.4 mm,

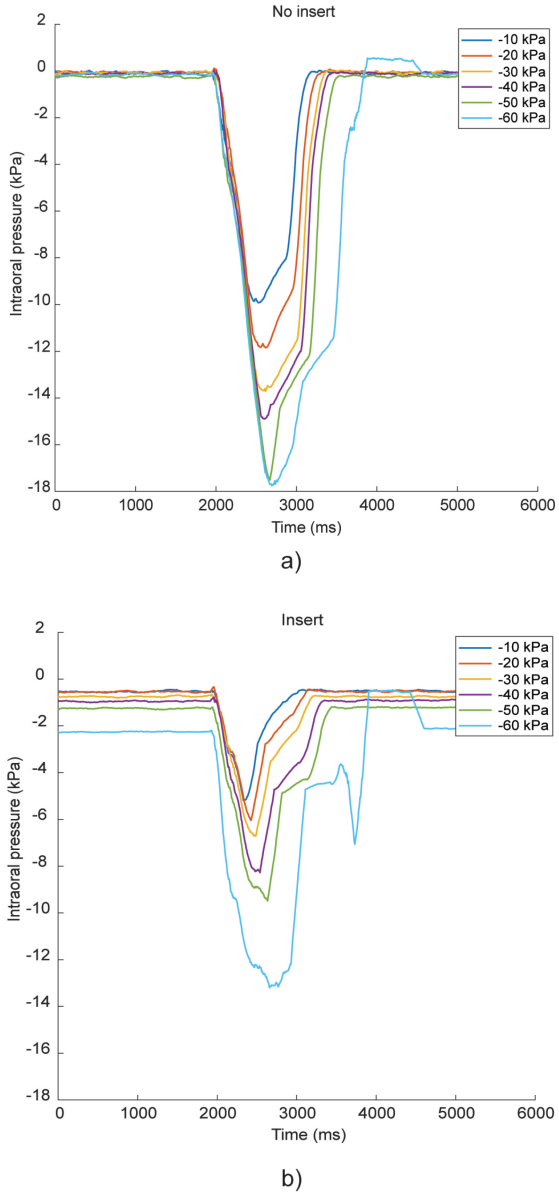


Fig. 9. Graph of a single peak for the intraoral vacuum test of different pressure levels without insert (a) and with insert (b).

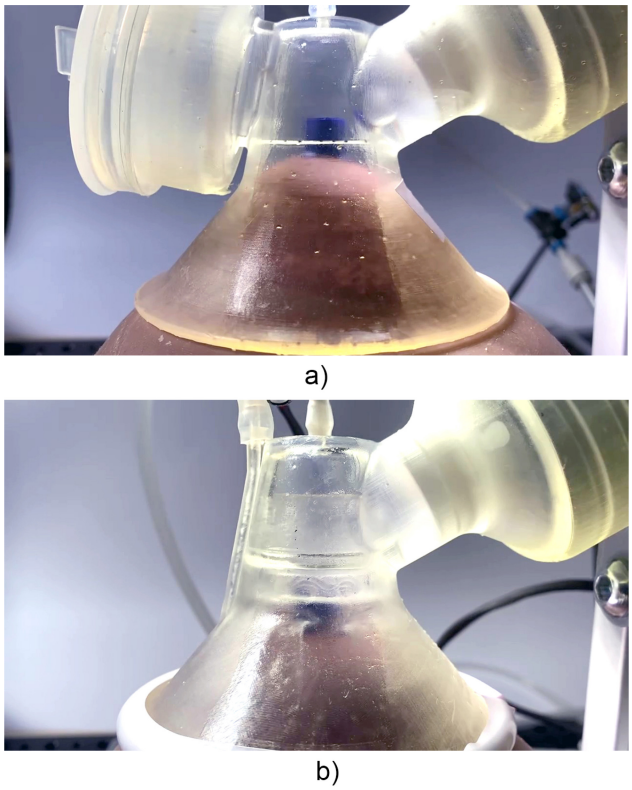


Fig. 10. Image frames showing the nipple (wrapped in blue tape) elongation at peak intraoral vacuum of −60 kPa without insert (a) and with insert (b).

while with insert the elongation was 4.7 mm. Considering that the intraoral vacuum was lower in the test with the insert, we also calculated the displacement per 1 kPa, which gives 0.6 mm/kPa without insert and 0.3 mm/kPa with insert.

### C. Pleated Actuator Motion

The actuator showed radial deformation towards the center while a counter pressure was applied using a glass plate, otherwise only a longitudinal deformation was observed. In Figure 11 the position magnitude difference of each blue dot is given (in mm), the average displacement was $1.01 \pm 0.15$ mm.

## VI. Discussion

### A. Test Results

The intraoral vacuum test showed that the vacuum in the breast shield without insert is higher than with the insert at the same applied value of $p_{v1}$. This can be attributed to the behavior of the flexible insert as compared to the diaphragm in the standard breast pump. The theoretical volume displacement of the standard breast pump using the diaphragm (29705 $mm^3$) is somewhat larger than that of the insert (26159 $mm^3$). During the experiments, it was noticeable that at −60 kPa, the volume displacement of the diaphragm of the standard breast pump was at its maximum, i.e., the diaphragm was in its utmost position, while the insert was not at its utmost deformation, which was limited by the size of the rigid cup. We speculate that with optimization of both the shape of the insert and the wall thickness, it will be possible to obtain the maximum deformation. Alternatively, a higher pump vacuum can be applied to see if full deformation of the insert is possible, however the pump used in this research was not able to generate a higher vacuum.

In Table I, we gave an overview of the intraoral vacuum applied by infants, according to literature, which shows that peak intraoral vacuum can reach approximately −26 kPa. In our test set-up, the vacuum pump ($p_{v1}$) was able to reach −60 kPa maximum, which resulted in an intraoral vacuum of approximately −18 kPa for the commercial breast shield. Most commercial breast pumps report an even lower maximum vacuum pump strength ($p_{v1}$) of −40 kPa (−300 mmHg), which in our test corresponds to an intraoral vacuum of −13.1 kPa. This indicates that most commercial breast pumps will not be able to reach an intraoral vacuum of up to −26 kPa as some infants can apply, in turn suggesting that the intraoral vacuum of breast pumps may actually be too low for a group of mothers to be effective. More research is necessary to understand how large this group is and the implications for their successful breast feeding.

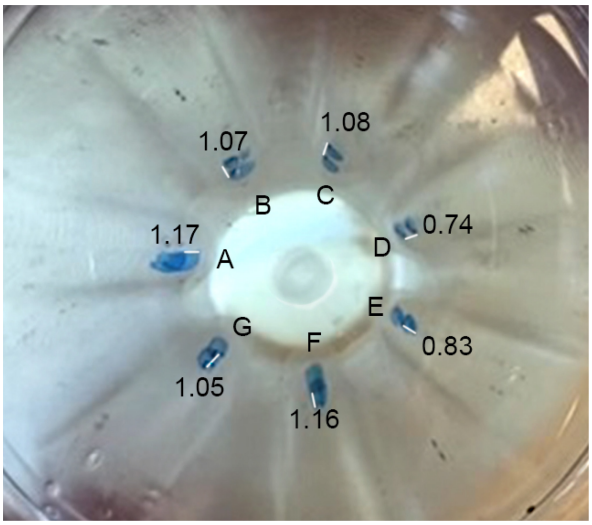


Fig. 11. Two superimposed images illustrating the pleated actuator displacement before applying pressure and at peak pressure. The displacement of the blue dots (indicated by the white lines) was measured using Tracker software in mm.

By measuring the nipple elongation, we showed that we successfully limited the elongation of the nipple by approximately 50%, when corrected for the lower overall intraoral vacuum. This can partially be attributed to the shape of the insert, which physically limits the breast tissue from entering, as an unintended consequence of the design. Without clinical testing, we are unsure whether this is beneficial or not. It should be noted that due to the limitations of the breast phantom, this test was not completely representative of the behavior of actual tissue, as we cannot distinguish the difference between true nipple elongation and possible deformation of surrounding breast tissue. Previous studies used nipple deformation measurements by measuring the dimensions of the nipple before and after pumping or breastfeeding, but not during. Real breast and nipple tissue swells as a result of accumulation of blood, however our phantom cannot replicate this behavior. Clinical studies should be performed to measure the actual deformation in both length and width of the nipple, as well as over a prolonged period of pumping.

The motion of the pleated breast shield showed that the current design of the insert is not optimal to apply a positive pressure to the breast. It was possible to counteract the longitudinal deformation of the insert by applying a pressure; however, in a real pumping scenario the breast shield might push itself away from the breast, which is undesirable. In our tests, a rigid glass plate was used to create a sealed breast shield volume and quantify the free-load motion of the pleated actuator. While this setup was useful for characterizing actuator behavior, it does not accurately represent its interaction with soft breast tissue. To counteract the longitudinal displacement in practice, the breast shield insert needs to be redesigned, and a more advanced testing setup would be required to assess its behavior under realistic conditions. Currently, there is no conclusive evidence that the application of positive pressure to the breast improves milk output or user experience. Infants use peripheral pressure to manage swallowing and breathing [21], [22], which is not necessary in a breast pump. Therefore, we recommend that further research, including clinical testing, be performed to determine the influence of positive pressure on pumping efficiency. However, before performing additional testing, the design of the insert should be optimized to reflect the intended design characteristics.

### B. Design and Production

We used SLA 3D printing to produce prototypes of the breast shield inserts, which enabled us to quickly create design iterations regardless of geometrical complexity. A disadvantage of this printing method is that the minimum wall thickness that we could obtain was 0.50 mm, but only when combined with sections with higher thickness. The material also tended to rupture easily when pressure was applied in those places. When compared to silicone for instance, which is often used for flexible breast shields in commercial breast pumps, this limits the efficiency and durability of the breast shield. A major advantage of 3D printing is the ability to personalize the breast shield, for instance by adjusting the tunnel diameter and depth to the individual user, which shows potential to increase the comfort of breast pumps [49]. With increasing developments in printing technologies and biocompatible flexible materials, it is likely that 3D printing of personalized breast shields can be commercialized in the near future.

The design of the pleated breast shield insert shows potential to be implemented in commercial breast pumps, although it should be optimized for several factors. First, the design presented here was adjusted to the dimensions of the rigid cup of a commercial breast pump, in order to have a more objective comparison, which limited the geometrical options. This was visible in the fact that the insert did not fully expand when the highest vacuum was applied, and in the slight buckling of the pleats, which is visible in Figure 10b. Further, the insert was not able to apply a radial positive pressure to the breast, instead showing a longitudinal deformation that pushes the breast shield away from the breast. Further research into the behavior of the pleated actuator performed by both computational simulations and prototype testing should be performed in order to optimize its performance.

### C. Further Research

As we have shown the potential of the breast shield insert experimentally, as a next step simulation of the breast shield and nipple expansion is useful, in order to optimize the shape of the pleated actuator. Due to the limitations of the artificial breast phantom, we were unable to test whether the breast shield allows the nipple, and thus the milk ducts, to expand, which would require an artificial nipple with anatomically correct elastic properties. Research into simulation of mechanical breast properties can be used to obtain more insight into the behavior of the nipple under such circumstances.

The initial design of the membrane actuator was very closely inspired by the anatomy of the infant's mouth. Although we chose to not develop this concept further in this research, it shows potential to be used for clinical studies to determine the effect of positive pressure on the milk output during pumping, since it is possible to separately control the intraoral vacuum and peripheral pressure.

Whether the pleated actuator insert can contribute to a more comfortable and efficient pumping experience for mothers can only be proven during long term clinical testing. Previous research has shown that it is possible to measure milk output in a consistent and objective manner [9], [11], [47], [50], however measuring comfort is more challenging and subjective. Usually, questionnaires or interviews are employed to get an idea of the comfort of the breast pump. Since comfort is dependent on many factors, it is important not to test in too early stages of the breast pump development, as factors not related to the breast shield, such as noise or aesthetics, may influence the perception of comfort.

Although the pleated actuator attempts to reproduce the coordination between suction and tongue movement, this alone may not be sufficient to fully replicate infant feeding behavior. While we based our design on available studies, these often simplify the complex dynamics of tongue motion, without considering the relationship between intraoral pressure and tongue momentum, as well as the movement of the jaw and other intraoral muscles. Further research is needed to better understand these mechanisms and refine future actuator designs accordingly.

Shortening the time to milk ejection reflex can make the pump more efficient by shortening total pumping time. Each mother has a consistent pattern, timing, and number of milk ejections, which suggests a predetermined release of oxytocin [41]. This leaves potential for tailoring for the duration of expression, for instance by incorporating sensors into the breast shield that detect the milk flow and adjust the vacuum level correspondingly. Referring to Figure 7, the effect of the control parameter on the breast pump performances, such as amount of extracted milk, comfort, total time, can be evaluated as well.

## VII. Conclusion

In this research, we explored the design of a novel soft robotic breast pump insert inspired by natural suckling. The proposed pleated actuator simplifies the functional lay-out of commercial breast pumps, and facilitates a radial expansion of the nipple for unobstructed milk flow, rather than a linear expansion of the nipple. Testing showed that the intraoral vacuum obtained in this manner is lower than the vacuum obtained by commercial breast pumps, however the vacuum profiles are similar. The nipple elongation with the new breast shield was significantly lower than that of the commercial breast shield. These tests show that there is potential for the pleated actuator to be further developed for use in breast pumps, although optimization of the shape and behavior is required.

## Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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