

Bio-inspired Breastfeeding Simulator (BIBS): A Tool for Studying the Infant Feeding Mechanism

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Abstract—Objective: This work introduces a bio-inspired breastfeeding simulator (BIBS), an experimental apparatus that mimics infant oral behavior and milk extraction, with the application of studying the breastfeeding mechanism *in vitro*. **Methods:** The construction of the apparatus follows a clinical study by the authors that collects measurements of natural intra-oral vacuum, the pressure from infant's jaw, tongue and upper palate, as well as nipple deformation on the breast areola area. The infant feeding mechanism simulator consists of a self-programmed vacuum pump assembly simulating the infant's oral vacuum, two linear actuators mimicking the oral compressive forces, and a motor-driven gear representing the tongue motion. A flexible, transparent and tissue-like breast phantom with bifurcated milk duct structure is designed and developed to work as the lactating human breast model. Bifurcated ducts are connected with a four-outlet manifold under a reservoir filled with milk-mimicking liquid. Piezoelectric sensors and a CCD (charge-coupled device) camera are used to record and measure the *in vitro* dynamics of the apparatus. **Results:** All mechanisms are successfully coordinated to mimic the infant's feeding mechanism. Suckling frequency and pressure values on the breast phantom from the experimental apparatus are in good agreement with the clinical data. Also, the change in nipple deformation captured by BIBS matches with those from *in vivo* clinical ultrasound images. **Significance:** The fully-developed breastfeeding simulator provides a powerful tool for understanding the bio-mechanics of breastfeeding and formulates a foundation for future breastfeeding device development.

Index Terms—Breastfeeding mechanism, Infant oral suckling, Nipple deformation, Tongue movement, Pressure generator

I. INTRODUCTION

Breastfeeding is strongly recommended for infants since breast milk contains necessary nutrition and boosts immune system. However, the difficulties in breastfeeding force many mothers to fully or partially stop nursing in the first month postpartum [1]. Early termination is largely associated with neurological and physical health issues for both mothers and children [2]. Infants with neurological disease, like Down syndrome, may have weakened tongue muscles which can lead to abnormal control of the oropharyngeal structures, contributing to an uncoordinated and/or insufficient suck, as well as difficulty swallowing [3]. Similarly, infants who are born with physical diseases, for example a cleft lip and/or a cleft palate, have difficulties in creating the suction needed to breastfeed successfully as their oral cavity cannot be adequately separated from the nasal cavity during feeding [4].

Infants' suckling during breastfeeding exhibits a coordination between facial/tongue muscles, palate compression, and

intra-oral vacuum pressure. Rhythmic intra-oral vacuum pressure and the proper positioning of the nipple in the infant's oral cavity during breastfeeding have been shown to be important for milk extraction [5], [6]. Measurement and analysis of forces involved in natural breastfeeding have focused on intra-oral vacuum pressure and its effect on milk removal [7]. The oral peripheral pressures (compression by jaw, tongue and hard palate) were only recently measured by Alatalo et al. [8].

Majority of the breast pumps that have been used for studying the biomechanics of breastfeeding [9], [10], [11] focus on the vacuum pressure only. The mechanism of milk pumps and natural suckling have many differences. The positive compression of the infant's palate and jaw, as well as tongue movement, are both known to contribute to milk removal in breastfeeding [8]. The effect of compressive forces exerted by the infant on the nipple is important for causing nipple deformation. The authors are not aware of any prior device that can mimic natural breastfeeding with a non-rhythmic infant suckling and oral compression. Our work aims to develop an easy-to-control, fully-coordinated experimental apparatus to mimic various forces that an infant applies on the mother's breast to extract milk.

In this work, a bio-inspired breastfeeding simulator (BIBS) that aims to mimic infant feeding mechanism during breastfeeding is presented based on the clinical observation and data collection by the authors [8]. Unlike previous studies of the oral suckling pattern which have used rigid sensing device [12] or applied vacuum-only stimuli [13], this paper develops an autonomous apparatus that includes all oral movements, such as suction, compression, and swallowing, and analyzes the effect of oral behaviors on the lactating breast. The most innovative part of this work is that the oral dynamics of breastfeeding can be individually controlled by programmable software, ensuring the ability for the BIBS to operate on wide-ranging oral pressures and frequencies, while also objectively evaluating and predicting the breastfeeding process.

One of the challenges in this work is to develop a tissue-like flexible and transparent breast phantom. Many breast phantoms designed with tissue mimicking materials [14], [15] do not have the optical transparency for flow visualization purpose and do not include a ductal structure for milk extraction. This work improves the flexibility and elasticity of the breast phantom with a combination of two materials, one for imitating breast skin and the other for the glandular tissue. To the best of the authors' knowledge, this is also the first known attempt to model a lactating human breast that has three bifurcated ductal structure and the optical clearness for flow visualization.

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In this paper for the BIBS setup, the vacuum pressure was created by the LabVIEW signal generator to mimic infant's arbitrary oral suction. Linear actuators managed the periodic compressive forces on the breast phantom using micro-controller. The soft tongue gear model rotated to generate a tongue motion during natural suckling. Piezoelectric sensors and CCD cameras were used to capture pressures on the breast and oral motion respectively. The experimental data was presented and compared with the clinical data to show that the BIBS simulated the natural breastfeeding pattern accurately.

This paper is organized as follows: Section II-A introduces the clinical study on capturing the *in vivo* oral dynamics on the breast. Section II-B explains the design and fabrication of all components in the apparatus. Section III illustrates the results from real-time measurements, and further compares with *in vivo* clinical data to discuss the performance of the apparatus in Section IV. Section V summarizes the outcomes of this study as well as future directions in human lactation research.

II. EXPERIMENTAL SETUP, METHODOLOGY, MATERIALS, DESIGN & CONSTRUCTION

A. Clinical Study

Breastfeeding involves rhythmic coordination between the infant's maxilla, mandible, and the tongue [16]. Figure 1 shows a schematic configuration of this procedure.

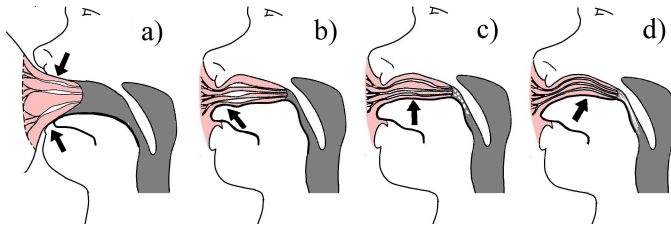


Fig. 1: The infant's natural suckling mechanism: a) infant's maxilla and mandible clamp the nipple-areola complex, b) tongue extends out and pulls the nipple into the oral cavity, c) tongue pushes the nipple to the hard palate, and d) infant's upper palate and lower jaw compress the nipple to squeeze out the milk.

A clinical experiment was conducted to capture the movement of the infant oral cavity and track the nipple deformation via ultrasound imaging [8]. The ultrasound image in Figure 2a indicates the position of the hard palate, soft palate, nipple and tongue in the oral cavity during the breastfeeding procedure.

A tube pressure transducer inside the infant's mouth measured the intra-oral vacuum pressure in parallel with the maxilla and mandible compression pressure captured by a set of thin flexible pressure sensors on the areola during breastfeeding [8]. Figure 2b shows a sample 5-second measurement of intra-oral vacuum pressure and compression on the areola from one of the participate dyads named Infant #3 in clinical study [8]. Rhythmic patterns were found with an average suckling frequency of approximately 1-2 cycles/s. The applied pressure on the breast had an average vacuum range from -12 to 0 kPa, and an average positive pressure between 2-8 kPa, respectively. As discussed in the authors' previous study [8], vacuum pressure and compression pressure both contribute

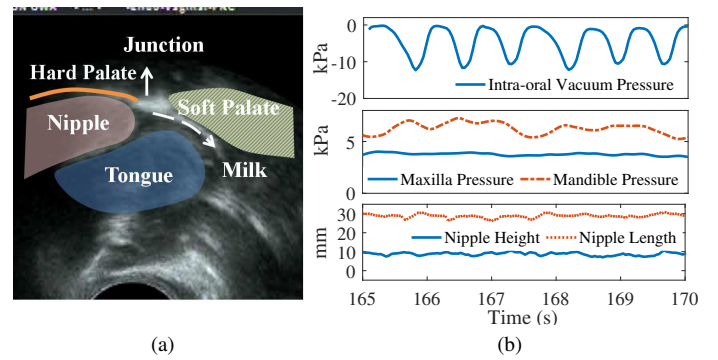


Fig. 2: (a) Ultrasound imaging of Infant #3's oral cavity during breastfeeding with the position of the hard palate, soft palate, hard-soft palate junction, nipple, and tongue; (b) 5 seconds of vacuum pressure, compression and nipple deformation data from oral cavity [8].

to the milk extraction out of the ducts in the nipple. In this paper, a bio-inspired breastfeeding simulator (BIBS) that can mimic infant's coordinated control of oral vacuum and oral compression was developed, which can work as a practical tool to understand the bio-mechanics of breastfeeding *in vitro*.

B. Design and Development of the Apparatus

Different types of simulators were designed and applied in this apparatus in order to imitate the infant's oral behavior involving coordinated vacuum and compression pressure on the breast. All components were inspired by the clinical observation of the natural breastfeeding. The initial input pressure profiles and suckling frequency used in this paper are from the clinical measurements of Infant #3 [8], but the same can be done with other infants. The schematic configuration of BIBS apparatus is shown in Figure 3. The apparatus consists of the following:

- A transparent and flexible breast phantom with bifurcated ductal structure
- A vacuum pump assembly that generates rhythmic intra-oral pressure
- Two linear actuators representing the infant's upper palate and lower jaw motion
- A flexible silicone gear-shaped motor mimicking the tongue motion
- A reservoir filled with milk-mimicking liquid that represents the breast milk and assists the flow visualization in the apparatus
- A set of pressure sensors for measuring the vacuum and compression force
- A CCD camera for capturing the breast-infant interaction
- Drivers and control systems for commanding the inputs and recording the outputs components.

1) *Transparent Tissue Mimicking Breast Phantom*: An optically clear, flexible, and soft breast phantom was designed to mimic a human breast in the setup as shown in Figure 4a. The breast phantom contains a breast shell(or skin), transparent filling gel, and the ductal structure.

The dimensions of nipple, areola and breast were measured from the clinical study with methods reported in [8]. Dimen-

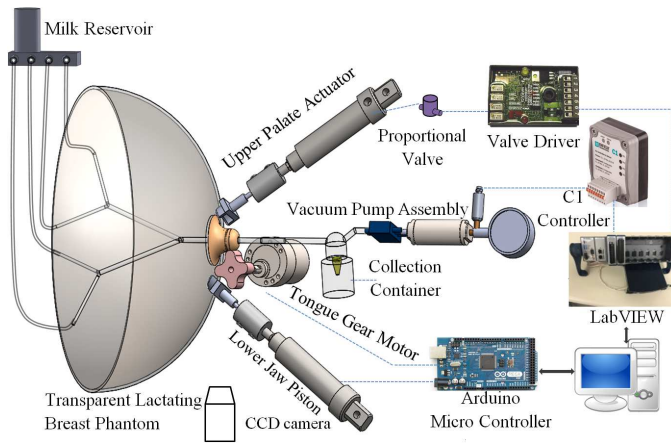


Fig. 3: A schematic configuration of the Bio-inspired Breast-feeding Simulator (BIBS).

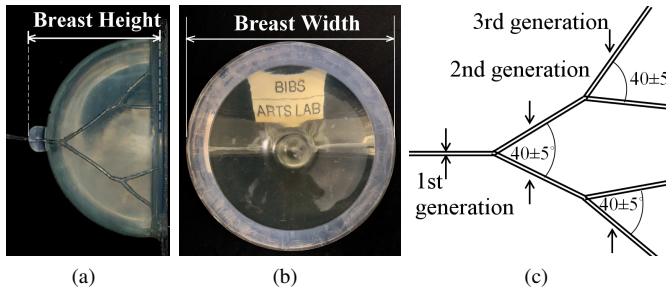


Fig. 4: (a) The breast phantom, (b) Representing the transparency for visualization purposes, (c) The three generation symmetric ductal structure

sions of the nipple and breast from all participants as well as the mother of Infant #3 are shown in Table I.

The thin and flexible breast shell was built with Polydimethylsiloxane (PDMS) (Sylgard 184, Dow Corning, Midland, MI, USA), which has been well accepted as an optimal representative for human skin and vascular mimicking [18], to imitate the breast skin with a non-uniform thickness. The fabrication process of the shell contained three major steps: 1) designing the 3D model in SOLIDWorks, 2) creating the master mold, and 3) casting the mold with a solution of room temperature vulcanized PDMS. The shell of the breast phantom model was 2mm in thickness based on the reported numbers from *in vivo* measurements [17]. The thickness of the nipple part was chosen at 1.5mm to maximize the softness and flexibility. A transparent water-based gel (Zerdine gel, CIRS, Norfolk, VA, USA), which is widely used as the closest mimic of glandular tissue in breast phantom for a Young's moduli at 20-40 kPa [19], was filled into the space between breast shell and the supporting base plate to mimic the softness of a human breast. The optical clearness of the breast and ducts (as shown in Figure 4b) allows the milk flow visualization in bifurcated ducts during experiments.

To simplify the geometry of milk ducts for the physical setup, symmetric bifurcation with three generations of branching (as shown in Figure 4c) was used. The length and inner diameter (ID) of the bifurcated ducts were based on the model

TABLE I: Dimensions of lactating human breasts and the geometric data used for modeling breast phantom.

Geometric Data (mm)	<i>In vivo</i> [8]	Infant #3 in [8]	<i>In vitro</i>
Nipple width	14.44 – 15.09	15.09	15
Nipple length	10.70 – 13.79	12.14	12
Areola diameter	17.46 – 21.84	19.68	20.0
Breast width	116.70 – 166.05	121.50	120
Breast height	48.12 – 71.34	58.78	60
Breast skin thickness	1.44 – 2.05 [17]	N/A	2.0

reported in [20]. The detailed dimension of the ductal system are shown in Table II. The angle between the smaller ducts was $40^\circ \pm 5^\circ$ degrees. Flexible silicone tubing (MasterFlex, Cole-Parmer, USA) with 1.2mm, 1.6mm, and 2 mm ID were used to construct the ductal structure in a lactating breast phantom.

TABLE II: Duct dimensions in the optical clear lactating breast, with standard deviations (SD) reported for inner diameter (ID) and thickness of the ductal tube.

Generation	Length (mm)	ID $\pm$ SD (mm)	Thickness $\pm$ SD (mm)
First	35.75	2.00 ± 0.12	0.50 ± 0.15
Second	30.15	1.60 ± 0.08	0.30 ± 0.10
Third	25.04	1.20 ± 0.10	0.20 ± 0.08

2) *Vacuum Pump Assembly*: The assembly includes a pneumatic proportional valve for creating vacuum pressure, a LabVIEW signal generator, and a tube that connects the vacuum pump to the nipple-areola surface. The vacuum generator, as shown in Figure 5, contains a proportional valve (ES-V15, Enfield Technologies, USA) with a built-in valve driver, a controller, an air tank (AVT 12-1, Clippard, USA), a manual switch, a vacuum pump, a pressure gauge and a pressure transducer (PX209, Omega, USA). The inlet of the proportional valve was connected to the external air supply. One of the outlets of the proportional valve was connected to a vacuum pump (Model No.#6909, with $3 \text{ cu}^3/\text{min}$ capacity, FJC, Mooresville, NC, USA) controlled by a voltage command from the proportional valve until obtaining the required vacuum pressure. The air tank was attached to the other end of the proportional valve to add capacitance to the system for stability. A pressure gauge was added to monitor the pressure change inside the air tank. The pressure transducer detected the vacuum pressure inside the tank and converts the value to a voltage signal feedback to the programmable controller (C1, Enfield Technologies, USA).

The vacuum pressure profile was based on the clinical data collection [8] of Infant #3, which contained arbitrary pressure frequency and strength during breastfeeding. Figure 6 demonstrates the circuit diagram for creating arbitrary periodic vacuum signals using proportional valve, LabVIEW setup, vacuum pump transducer and controller. Sinusoidal waves, frequency, and vacuum strength varied during the entire breastfeeding session as shown in Figure 7a. Vacuum pressure profile was preloaded in a high logical programmable LabVIEW Real-Time hardware (National Instrument (NI) Compact RIO 9074) for data generation. PID (proportional-integral-derivative) control algorithm was embedded in LabVIEW to control the signal stability. Generated command voltage was the input signal to the propotional valve to control the

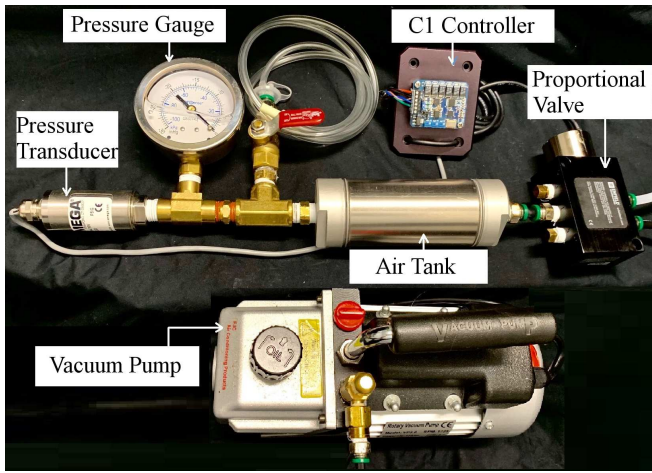


Fig. 5: The assembly for creating sinusoidal vacuum pressure.

vacuum pump. Detailed LabVIEW algorithm and implemented diagram is presented in Appendix Part I. Real-time sensor feedback from the transducer and the LabVIEW command signal profile were compared and shown in Figure 7b. Signal uncertainty was within $\pm 1\%$.

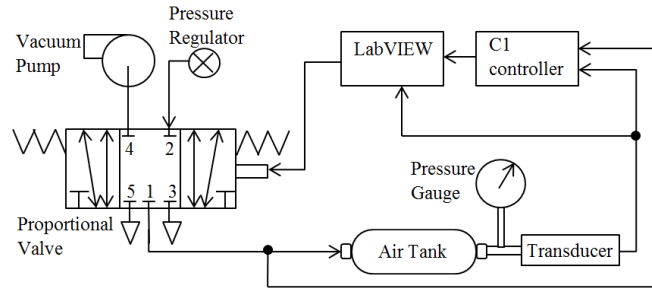


Fig. 6: Pneumatic circuit diagram for the vacuum generator.

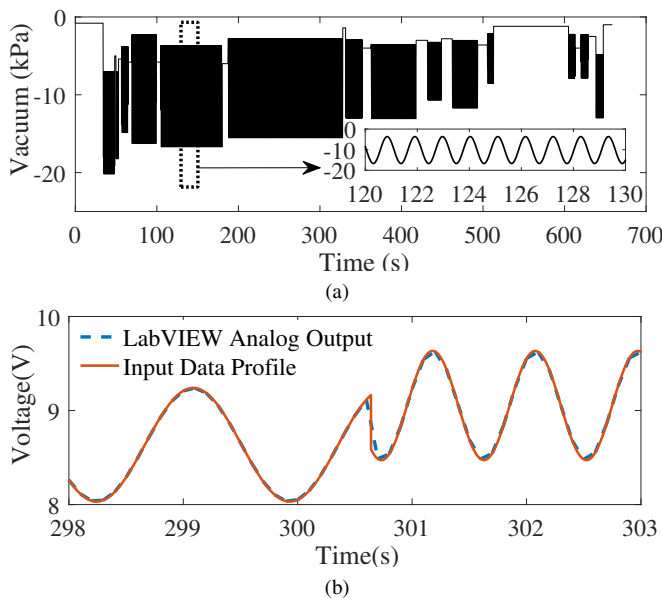


Fig. 7: (a) Profile of an infant's natural vacuum pressure during breastfeeding and (b) LabVIEW data output performance.

3) *Upper Palate and Lower Jaw Actuator*: The clinical observation showed that the infant's upper palate applied a constant pressure on the nipple-areola area and held the nipple in position for initial oral latching [8], whereas, the lower jaw generated periodic wave-shaped force on the areola to compress the nipple and the tissue around it. To mimic this mechanism, the upper palate and lower jaw assemblies contain the 3D prototypes of the oral cavity and two sets of linear actuators.

The palate and jaw prototypes were designed and developed based on the measurements from a set of CT (computerized tomography) scanned images. A sample image is shown in Figure 8 from the infants' oral cavities provided by the Dallas Children Health, Plastic & Craniofacial Surgery Department at The University of Texas Southwestern Medical Center. The saddle-shaped upper palate and D-shaped lower jaw were fabricated by 3D printing using Fortus 250MC (Stratasys Ltd., Edina, MN, USA). The printing material was ABS (acrylonitrile butadiene styrene) plus plastic, which has often been used in traditional casting method [21]. The upper palate and lower jaw models represent the infant's oral skeleton as shown in Figure 8.

The upper palate assembly was controlled by a pneumatic actuator (USN-08-1/2-N, Clippard, Cincinnati, OH, USA) coupled with the 3D printed upper palate model as shown in Figure 9. The actuator was connected to a proportional valve (iQ Valve 930212, iQ Valves, Melbourne, FL, USA) and a valve driver (iQ Valves 5-250). The linear correlation between the input pressure and palate position allows the control of the actuator at a commanded position and thus hold the nipple in the right position.

As shown in Figure 2b, the upper palate (maxilla) pressure changes from 3.5 to 4 kPa for Infant #3, which can be assumed a constant value compared with vacuum pressure (-15kPa to 0kPa) and lower jaw (mandible) pressure (5kPa to 10kPa) changes. Therefore, in the BIBS setup, the input pressure value for upper palate actuator was set at a constant of 3.5 kPa.

The pressure in the pneumatic actuator was controlled by the valve driver triggered with the voltage signal from an analog output module (NI 9264, Austin, TX, USA) with LabVIEW signal generator.

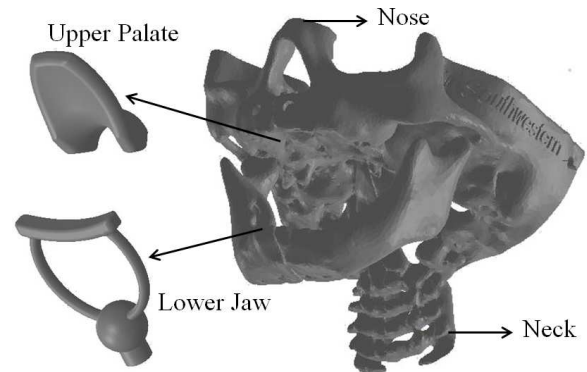


Fig. 8: The infant's oral cavity CT scan and the corresponding designed prototypes of upper palate (maxilla) and lower jaw (mandible).

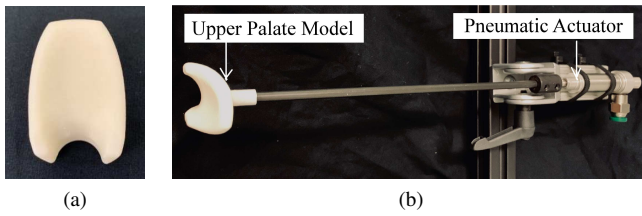


Fig. 9: (a) The 3D printed upper palate model, and (b) The upper palate assembly with pneumatic actuator.

The lower jaw assembly includes a 12V DC linear actuator with a maximum travel speed of 50mm/s (GLA750, Gimson Robotics, UK) coupled with the jaw prototype as shown in Figure 10b. The controllable linear actuator generated the periodic motion of the infant's jaw. The input profile for jaw movement was designed as a non-uniform saw-toothed distance profile in the apparatus (as seen in Figure 11) and imported into the Arduino Micro-controller (Mega 2580, Arduino) to control the jaw actuator. The skin-mimicking material (Eco-Flex 30) was wrapped around the jaw model to imitate the lip tissue.

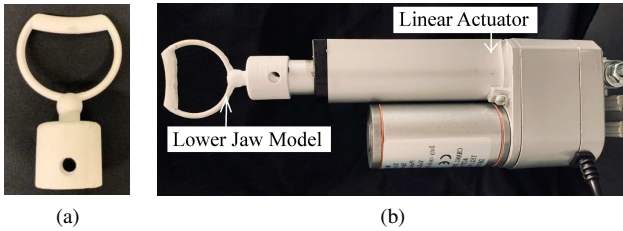


Fig. 10: (a) The 3D printed jaw model, and (b) The lower jaw assembly with linear actuator.

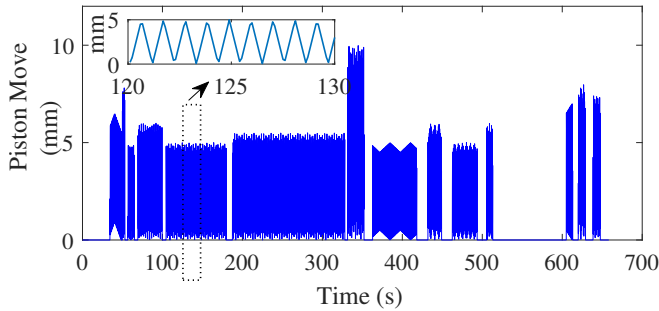


Fig. 11: The input profile for lower jaw movement.

4) *Tongue Gear Motor Assembly*: A tongue gear motor assembly was designed and constructed to mimic the infant's peristaltic tongue movement, as shown in Figure 12. The assembly includes a rotating flexible silicone gear and a DC motor (GB37Y3530-12V-251R, DFRobot, Shanghai, China) with the encoder for speed control as shown in Figure 12a. The silicon gear contains four teeth to create continuous direct contact on the breast while rotating. Each tooth has an ellipse-shaped involuted profile to represent the infant's tongue based on the geometry reported in [22]. The length of the tongue is 36mm and the width of the tongue is 24mm. A previous study [12] showed that the force from the root of the tongue was approximately two times the force from the tip of the tongue. In order to achieve this mechanism, a stiffer tongue root and a softer tongue tip was designed. QM 240T (Quantum Silicone, Richmond, VA) which is relatively

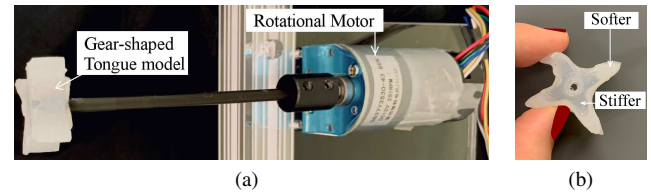


Fig. 12: (a) Tongue-gear assembly, (b) The flexible gear-shape tongue structure.

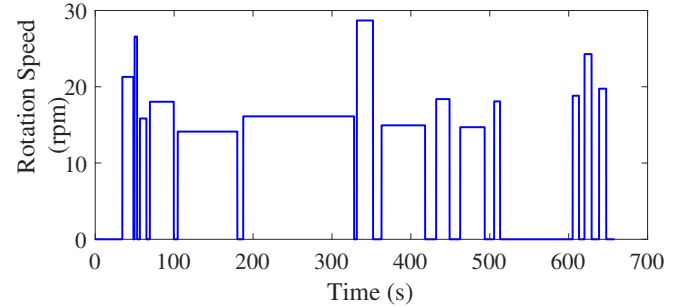


Fig. 13: Input profile for the rotational gear.

stiffer with a Durometer at 20A was used to shape the root of the tongue gear. Eco-flex 30 (Smooth-on Inc., PA, USA) with a Durometer of 00-30 was utilized to shape the softer outer shell of the tongue. The non-uniform rotational speed of the silicone tongue gear resulted in a peristaltic-like tongue movement during breastfeeding. This soft tissue-mimicking gear model (flexibility shown in Figure 12b) was connected to a long shaft toward the end of the rotating motor.

The rotation speed (rpm) was controlled by the DC motor, which was connected to an Arduino Micro Controller updated with a predefined rotational speed profile (see Figure 13) based on Infant #3's suckling frequency. While rotating, the gear imitates the infant's tongue movement by applying a non-uniform periodic positive pressure on the nipple of the breast.

5) *Milk Reservoir*: A milk reservoir was designed to mimic breast milk production during the breastfeeding simulation (as seen in Figure 14). The reservoir assembly includes a milk bottle filled with milk-mimicking liquid, a set of manifolds, a shut-off valve and tubes connected to the ductal system in the breast phantom. The milk bottle with milk-mimicking liquid was held by a bottle holder. A shut-off valve connected the tube from the milk bottle to the manifold. The four tubes that came out of the manifold were connected to the inlets of the ductal structure in the breast model.

A transparent milk-mimicking liquid was prepared with a mixture of 50.21% distilled water, 39.14% glycerol and 10.65% NaI in the lab. The dynamic viscosity of both milk-mimicking liquid and human milk were measured under a shear rate profile (shear ramp from 10^{-2} to 10^3) at room temperature (25°C). Figure 15 provides a comparison of the kinematic viscosity for two types of liquids using a MCR 302 rheometer (Anton Parr, Austria). The kinematic viscosity of the mixture liquid formula used in BIBS was in good agreement with the human milk profile based on R-squared and RMSE (Root Mean Square Error) values. The density of two liquids were measured with DMA 501 density meter

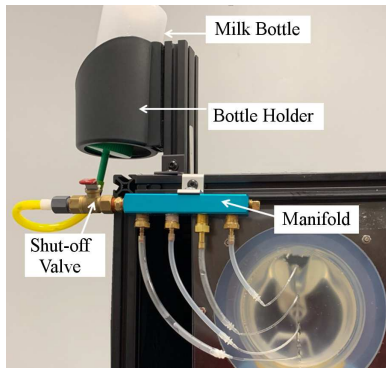


Fig. 14: Breast milk reservoir setup.

(Anton Parr, Austria). Density values of human milk and milk-mimicking liquid at 25°C were $1030 \pm 33\text{kg/m}^3$ and $1060 \pm 7\text{kg/m}^3$ respectively, and were in good agreement. The milk-mimicking liquid flew along the vacuum tube and collected by a container.

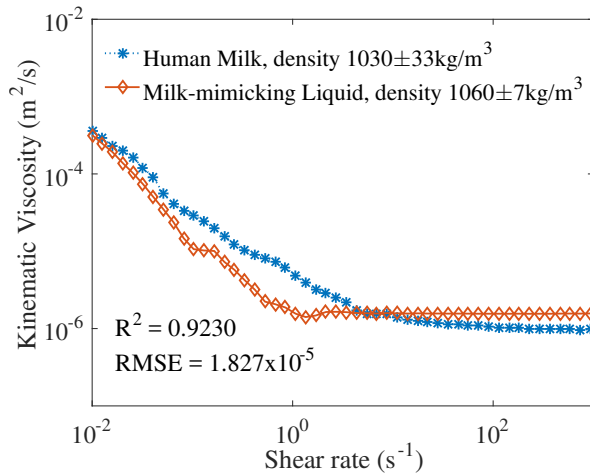


Fig. 15: The kinematic viscosity of human milk and the milk-mimicking liquid (used in this study) at 25°C .

In the clinical experiments, infants were weighted before and after breastfeeding using an electronic balance with 10mg resolution (Medela Electronic Baby-Weigh Scales, Medela AG, Switzerland) to determine the amount of milk removal from the breast. For *in vitro* experiment, we measured the accumulative milk volume in the container before and after the feeding period for each experiment run with a weight scale with 0.1mg resolution (Analytical Balances ML204T, Mettler Toledo, Switzerland).

C. Complete Design, Control System and Measurement Strategy:

The complete experimental setup for bio-inspired breastfeeding simulator (BIBS) with control system is presented in Figure 16a. The flexible and transparent breast phantom with bifurcated ducts represented the lactating human breast in the setup. The vacuum pump assembly generated sinusoidal intra-oral pressure with a LabVIEW control and measurement system. The infant's oral cavity was represented by the silicone soft tongue gear model and 3-D printed palate and jaw. Controllable linear actuators worked as the palate and jaw of the

infant and applied maxilla and mandible pressure on the breast phantom as shown in Figure 16b. The rotational tongue-gear motor mimicked the infant's peristaltic-like tongue movement. This apparatus provides a nonlinear and complete imitation of natural suckling during breastfeeding experiments.

A simple open-loop MIMO (Multiple-Input Multiple-Output) control strategy (see Figure 18) is designed to manipulate all the actuators, motors and pumps with one central control system. Feedback from vacuum transducer and position sensor in upper palate piston were captured and controlled by the LabVIEW program using PID algorithm to sustain a stable output profile.

A measurement system with pressure and nipple deformation measurements was designed for validating with clinical measurements. Figure 17 shows the sensor locations on the breast phantom.

1) *Pressure measurements:* Two piezoelectric strip sensors (FSRTM 408, Interlink Electronics, Los Angeles, USA) as shown in Figure 17, measured the surface pressure from the nipple-areola area the maxilla (upper palate) and mandible (lower jaw). The sensors are flexible with thickness of 0.3mm and has a sensing range of 1-1000N. A pin point tip sensor (FSRTM 400) was placed underneath the bottom of the nipple to capture the tongue-nipple contact pressure. The diameter of the tip sensor is 0.16" with a thickness of 0.2mm and has a sensing range of 0.1-100N. The static and dynamic characteristics, which provided the sensitivity and response speed of two types of the sensors, are presented in Appendix part II.

2) *Nipple Deformation Measurement:* A real-time high-speed CCD camera (UNIQ USS-680CL, EPIX, Buffalo Grove, IL, USA) captured images of oral and nipple movements during the experiment with 110 frames per second. The full frame resolution of the camera is 659×494 pixels and frame size is 50×50 mm. A BUTTERWORTH low-pass filter [23] was applied to smooth the images. Nipple deformation measurements from processed images was utilized to study the biomechanics of breast-infant interaction. A programmable measurement system was developed using MATLAB to get dimensions of the nipple width and length with tongue moving up and tongue moving down. The Canny edge detection method [24] was applied on each image frame to outline the nipple, upper palate and tongue. Manual edge designation was also drafted on each frame to validate the detected boundaries. Captured and processed images for tongue-up and tongue-down position from both CCD and ultrasound images are shown in Figures 19.

III. RESULTS AND VALIDATION

A. Infant Applied Pressure

The vacuum profile of Infant #3 from clinical study was imported as inputs, and the measured compression pressures from maxilla and mandible were cross-validated with the results from the BIBS apparatus. Wavelike pressure outputs in BIBS successfully mimicked the infant's suckling patterns in natural breastfeeding. A set of experiments was conducted to test the

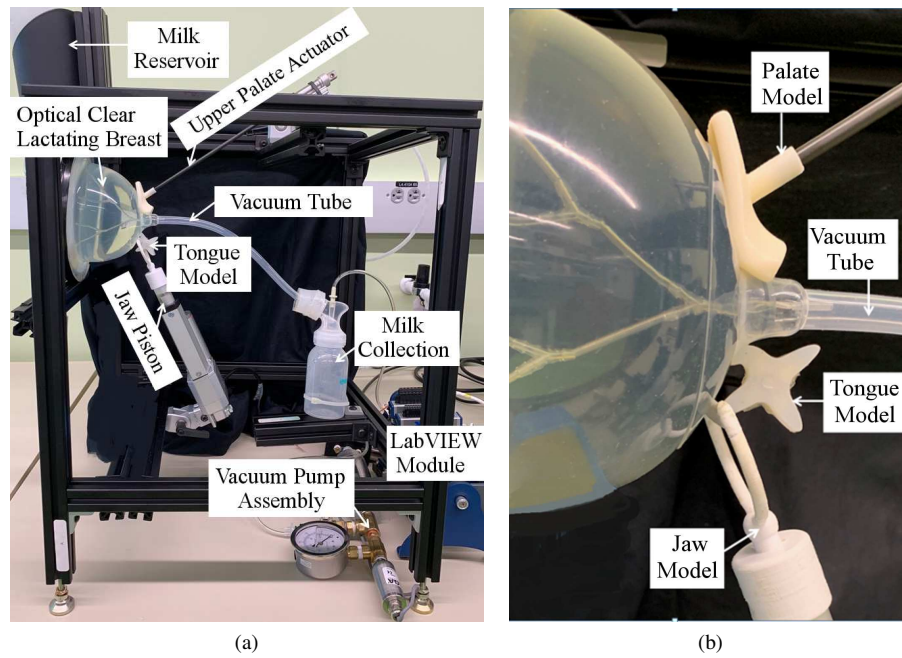


Fig. 16: (a) The complete Bio-inspired Breastfeeding Simulator (BIBS) setup, and (b) zoomed-in oral cavity models on the transparent breast phantom.

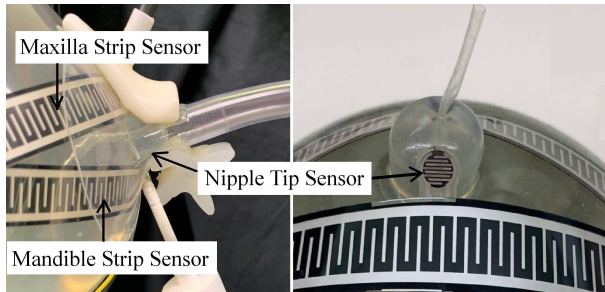


Fig. 17: Side view (left) and top view (right) of the pressure sensors on the lactation breast phantom.

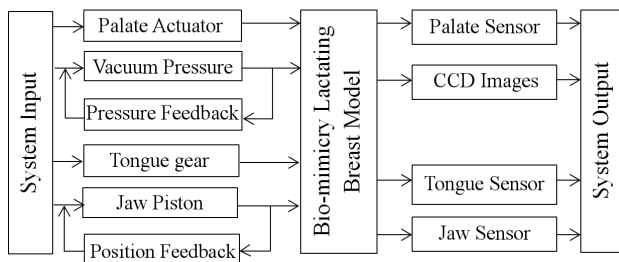


Fig. 18: BIBS open-loop MIMO control architecture.

reliability of the apparatus. Results from the experiment for fifteen runs are presented in Figure 20 with a shade of error range. The results from the BIBS setup include the intra-oral vacuum pressure, upper palate pressure, lower jaw pressure, nipple-tongue contact pressure, nipple width, and nipple length change. The input profile had 489 total suck cycles during 658.2 seconds of total feeding time. Suckling frequency was between 1-2 cycles/s over the feeding period.

Average data for the multiple runs of the apparatus is presented in Table III and compared with the clinical results.

The *in vivo* [8] average oral pressure applied on the breast by Infant #3 was around -10.04 kPa for intra-oral vacuum and 12.93 kPa for peripheral oral pressure. The BIBS setup provided an average -9.98 kPa for vacuum pressure and 13.70 kPa for oral compression pressure.

TABLE III: Averaged output results from both *in vivo* and *in vitro* BIBS experiment

Measurements	<i>In vivo</i> Infant #3 [8]	<i>In vitro</i>
Total Sucks	495	489
Intra-oral Vacuum Change	-10.04 ± 0.34 kPa	-9.98 ± 0.25 kPa
Peripheral Oral Pressure	12.93 ± 4.35 kPa	13.70 ± 5.44 kPa
Nipple Width Change	2.51 ± 0.20 mm	2.48 ± 0.57 mm
Nipple Length change	3.22 ± 0.28 mm	3.08 ± 0.93 mm
Milk Production	105.0 mg	130.2 ± 11.73 mg

Average values, peak-to-peak amplitude and uncertainties of oral dynamics from experiments are shown in Table IV. The upper palate pressure was the lowest in peripheral pressures, whereas lower jaw pressure was the highest. The average pressure values from 15 experiments with the same input profile were 1.76 ± 1.69 kPa for palate pressure, 7.29 ± 3.36 kPa for jaw pressure, and 4.65 ± 2.39 kPa for the nipple-tongue contact pressure. Uncertainties for all pressure results were less than 10%, which indicates a real-time stability and robustness of the BIBS to imitate breastfeeding patterns.

Ten-second sample pressure results from the BIBS are presented in Figure 21. Upper palate pressure, jaw pressure and nipple-tongue contact pressure was measured spontaneously *in vitro* for the first time. The experimental data from 15 runs were in good agreement with clinical data in terms of the R-squared and RMSE (Root-Mean-Square-Error) values, shown in Table V. Experimental data explained the majority of the clinical data over time as $R^2 \geq 0.6322$. Also, the

TABLE IV: Average, peak-to-peak amplitude and the corresponding uncertainties for captured dynamics from experiments

Measured Results	Intra-oral Vacuum (kPa)	Peripheral Oral Pressure (kPa)			Nipple Width (mm)	Nipple Length (mm)
		Upper Palate	Lower jaw	Nipple-Tongue Contact		
Average	-9.98	1.76	7.29	4.65	16.78	13.84
Peak-to-peak amplitude	6.35	1.69	3.36	2.39	2.48	3.08
Uncertainty	0.99%	8.72%	9.53%	6.46%	1.23%	1.54%

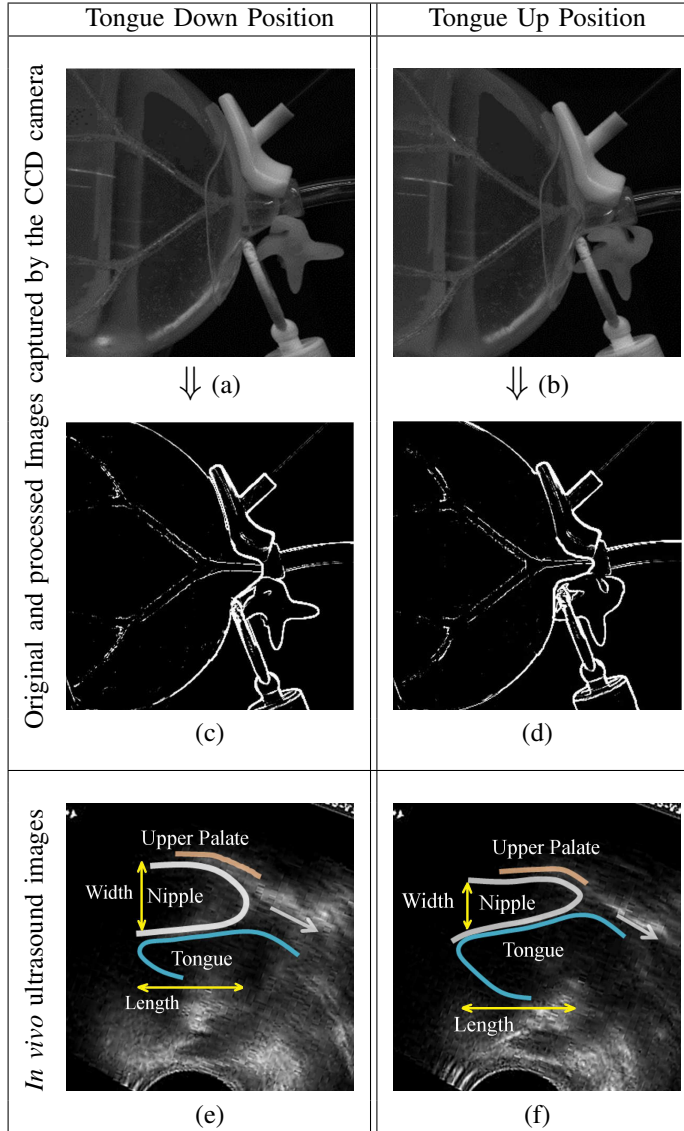


Fig. 19: Nipple-mouth interaction during one suck cycle (tongue up and down position); (a) and (b) are CCD captured images, (c) and (d) are processed images with detected boundaries, (e) and (f) are *in vivo* ultrasound images.

calculated RMSE values were all under 2kPa. The results showed that pressure values in BIBS were in good agreement with clinical values over time. As observed from the outlined experimental results in Figure 21, mouthing frequency was in good agreement with the intra-oral vacuum frequency. All pressures matched the clinical study by the authors [8]. When the vacuum experienced a local minimum (around -15kPa), the maxilla, mandible and nipple pressure were mostly above 70% of the maximum strength, whereas, when vacuum was at a local maximum (close to atmosphere pressure), the maxilla,

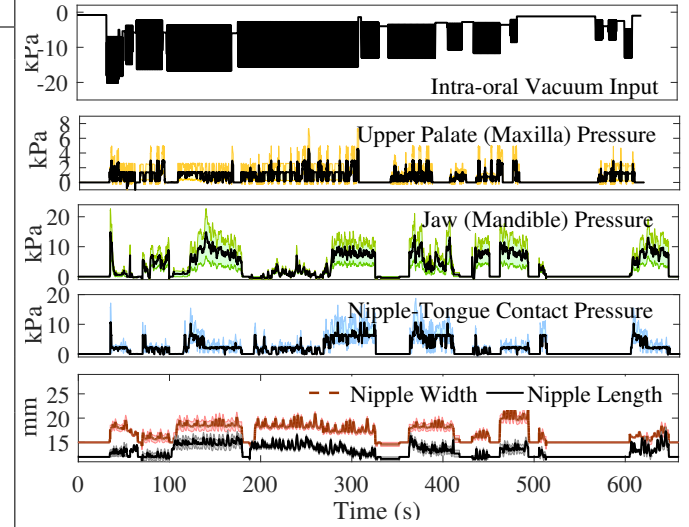


Fig. 20: Output profile of intra-oral vacuum pressure, positive pressures (maxilla, mandible and nipple-tongue contact pressure), nipple width and length change.

mandible and nipple pressure were mostly less than 30% of the maximum strength.

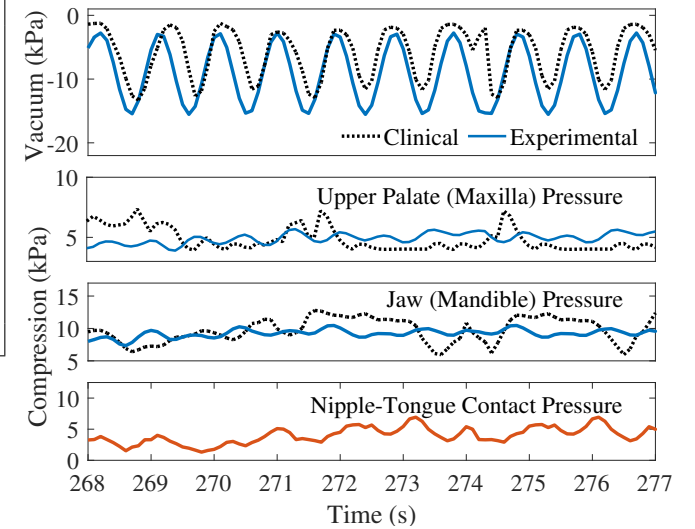


Fig. 21: Comparisons between clinical results and experimental results in ten seconds.

B. Nipple Deformation

From the captured and processed CCD images, the average of nipple width and length changes were $2.48 \pm 0.57\text{mm}$ and $3.08 \pm 0.93\text{mm}$, respectively. In the authors' clinical study [8], the average change that was measured in ultrasound images in nipple width and length for Infants was $2.51 \pm 0.20\text{mm}$ and $3.22 \pm 0.28\text{mm}$, respectively, over the entire feeding period.

TABLE V: R-square and RMSE to evaluate and compare the experimental data outputs with clinical measurements

Pressures	R-square	RMSE (kPa)
Vacuum	0.8842 ± 0.0246	1.4775 ± 0.2107
Upper Palate	0.9404 ± 0.1730	0.6013 ± 0.2301
Lower Jaw	0.7624 ± 0.1302	1.5327 ± 0.4289

Nipple deformations from *in vitro* experiments were found to be comparable with those from *in vivo* clinical results.

Figure 20 shows the dynamic pattern for nipple deformation in the entire feeding period. Significant nipple width deformation happened when jaw piston and tongue moved up and down on the breast phantom. The compression from palate and jaw piston caused $31\% \pm 14\%$ in nipple width change and $25.6\% \pm 7.8\%$ in nipple length change, and was found comparable to the study by Smith et al. [25] at $67\% \pm 10\%$ and $21\% \pm 42\%$ for horizontal lateral compression and horizontal length changes, respectively. The changes in nipple deformation were not sensitive to the intra-oral vacuum pressure but actively responsive to the compression pressure from maxilla, mandible and tongue movement. The small differences between the clinical and experimental nipple deformation was due to the mechanical property discrepancy between human tissue and silicone model, which are still under investigation and need further study for both *in vivo* and *in vitro* experiments.

IV. DISCUSSION

In this study, a bio-inspired breastfeeding simulator (BIBS) was designed and constructed based on clinical observations. The apparatus includes easy-to-control actuators and motors to create infant's rhythmic oral movement during breastfeeding to reveal the biomechanics of breastfeeding. The setup mimics natural breastfeeding by utilizing a transparent and flexible breast model, a vacuum generator, a tongue-shaped gear, and hard palate and jaw actuators to create both positive oral compression and negative oral vacuum pressure that extracting milk from the breast.

Inspired by infant's oral motor skills during breastfeeding, this novel apparatus is the first known attempt to successfully mimic both the compression and vacuum pressures exerted by an infant on a transparent and flexible breast phantom. The setup was equipped with flexible thin-film sensors. Using these sensors, the BIBS apparatus recorded the pressure at upper palate, lower jaw and tongue and nipple contact area and reports a complete set of pressure results. A CCD camera captured the movement from BIBS to compare with *in vivo* ultrasound images in terms of nipple deformation change.

Measured pressures from the BIBS apparatus, including maxilla (upper palate), mandible (lower jaw), and intra-oral vacuum, were cross-validated with the results from the clinical study. The results showed that the upper palate pressure was lower than the lower jaw pressure but similar to the pressure from nipple-tongue contact area. Lower jaw pressure was the main force causing the nipple width change, whereas the tongue and vacuum pressures contributed to the nipple length change. Jaw movement produced the strongest peripheral

pressure on the breast. These results were in good agreement with the previous clinical studies [8].

We briefly note several challenges in the process of designing and building this apparatus. Some issues were related to inevitable limitations of available materials and mechanical design. For example, mechanical properties of PDMS and the human breast were not identical, therefore the nipple elongation in BIBS couldn't fully match the stretch-ability of human breast tissue. This may be addressed by the advent of new materials in the future. Future work may also increase the number of bifurcations of the breast ducts, and possibly the number of lobes. Also, while careful construction of the apparatus has considerably reduced the effect of vibrations and noise on the measurements, this effect has not been completely eliminated.

Despite challenges, this study has achieved its goal to mimic natural breastfeeding suckling behavior *in vitro* with remarkable fidelity. Compared with the previous tools that have been used for studying the biomechanics of breastfeeding [9], [10], [11], the BIBS apparatus provides several advantages and benefits, including an optically clear breast phantom with an improved flexibility and softness in the breast and milk ducts. The apparatus can run simulations under various suckling patterns to find an optimal milk consumption, considering the fact that each mother and infant dyad is different. BIBS can be used as a potential screening tool for developmental disabilities such as infants' oral abnormalities and mothers' physical lactation problems. BIBS can also be applied towards an educational purpose for understanding the mechanism of breastfeeding. Following the same approach as in the current work, the model can be extended to better breast pump design by introducing oral compression pressure.

While the model parameters were identified for a specific infant, the model structure is directly applicable to simulate any boundary conditions, especially infants with abnormal oral movement or mothers with breast dysfunctions, to predict the oral behavior and quantify milk production. BIBS is able to adapt to any shape of breast, upper palate, lower jaw and tongue model, which makes it useful for studying infants with physical oral abnormalities when *in vivo* experiment is not practicable. Understanding oral behavior with *in vitro* experiments can also provide objective suggestions for future breast pump design and breastfeeding methods.

V. CONCLUSION

In this paper, a bio-inspired breastfeeding simulator (BIBS) was designed and developed to mimic the infants, complex natural suckling pattern, including both the intra-oral vacuum and the peripheral oral pressures. The complete design included a transparent lactating breast phantom, a vacuum pump, two actuators that represent infant's oral maxilla and mandible, a rotating tongue-gear motor, a milk reservoir, and a set of measurement systems. Vacuum pressure and compression inputs were inspired by the infant's oral movement mechanism from the clinical study by the authors. The intra-oral vacuum pressure and the peripheral oral pressure values from BIBS were found to be comparable to *in vivo* clinical

data. Results indicated that the BIBS setup performance is in good agreement with the infant's oral motion and successfully imitate the effect of infant applied forces on the breast with the real-time oral pressures and nipple deformation measurement. BIBS provides a non-invasive and practical assessment tool to imitate and monitor an infant's oral behavior during breastfeeding *in vitro*.

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APPENDIX PART I: LABVIEW PROGRAMMING AND CONTROL DIAGRAM

A high-speed programmable coordinator (NI Compact RIO 9074, see Figure 22) was loaded with a customized arbitrary periodic vacuum pressure profile before initiating the experiment. Using LabVIEW software, the first step was to build a front panel (see Figure 23a) to include command data and control diagram. On the NI hardware platform, an analog module (NI 9264) commanded a voltage output and then an analog reading module (NI 9201) monitored feedback signals from the vacuum pressure sensor.

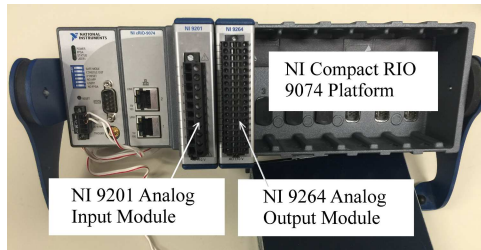


Fig. 22: NI Device, including Compact RIO platform, Analog output and reading modules.

Real-Time First In First Out (RT FIFO) function was chosen to read data from a measured profile and analog signal was generated with NI 9264 Real-Time module in NI compact RIO platform (see Figure 23b). The RT FIFO function allows users to access each Input/Output (I/O) device for maximum flexibility and performance in data processing at a consistent rate. Scan mode with a 100ms scanning period per data update was employed in LabVIEW output. Each data was imported into the data buffer, and then was exported following first-in-first-out principle every 100ms(10HZ). Once the program deployed and began running, the front panel was updated with current I/O values plotted on the waveform chart. Figure 23b presents the control diagram, which includes (a) Initialization (reading and loading data points from the measurement and creating the RT FIFO), (b) Main processing (data preparation, PID control algorithm, and FIFO scanning) and (c) Shut down.

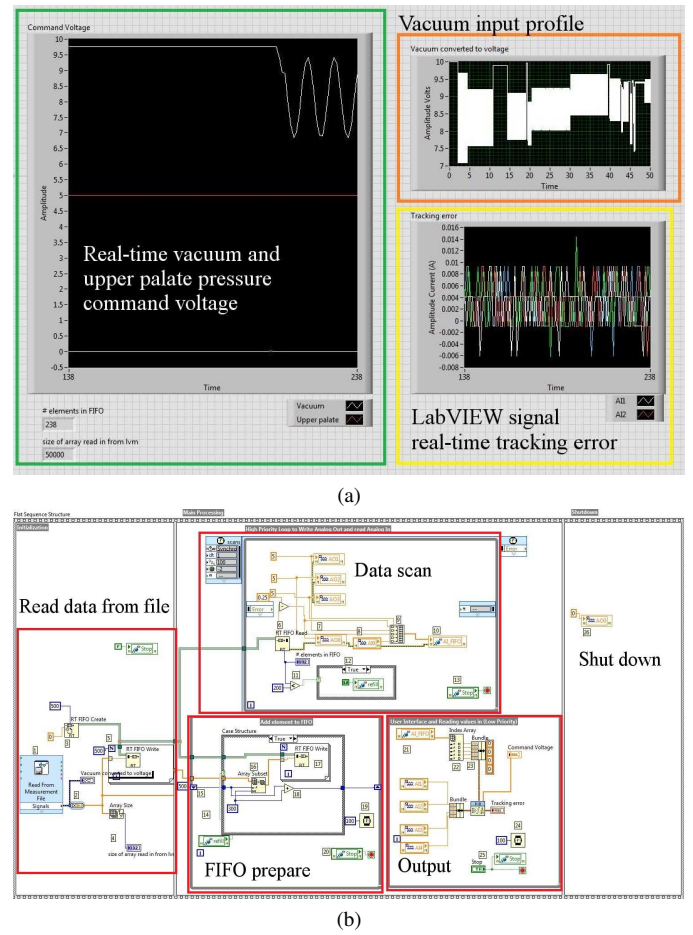


Fig. 23: LabVIEW Programming: a) Front Panel; b) Scan-Mode Block Diagram.

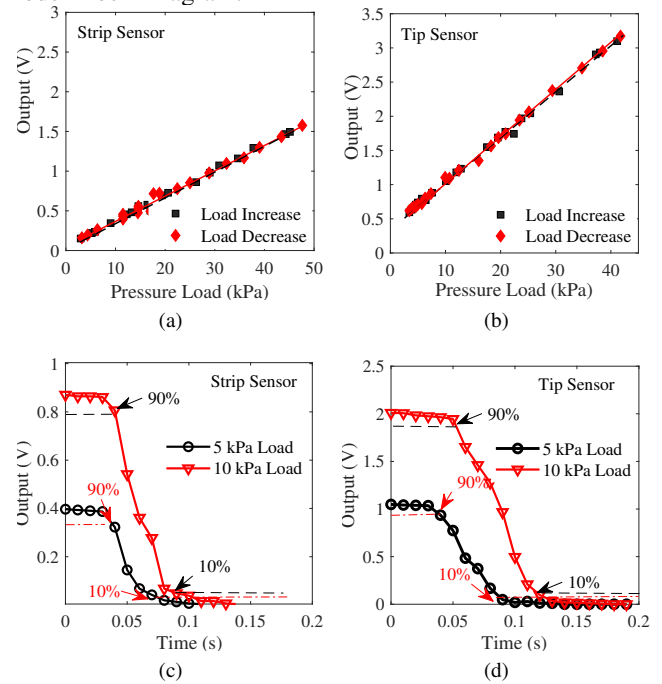


Fig. 24: Static characteristic by increasing and decreasing pressure load on the (a) strip and (b) tip sensor, and dynamic characteristic by applying pulse pressure and test the response delay on the (c) strip and (d) tip sensor.

APPENDIX PART II: PIEZOELECTRIC SENSOR CHARACTERISTICS

Static and dynamic characteristics [26] of the force sensors were evaluated before the experiments. For sensor static characterization, increasing and decreasing random loads were applied to the force sensors from 0 to 50 kPa. Scattered data of static characterizations for both type of sensors are presented in Figures 24a and 24b. Both types of force sensors showed strong linearity. For dynamic characterization, 5 and 10 kPa pressure were separately applied on both strip and tip sensors and were manually removed to test the sensor sensitivity. The response time was recorded when the pressure was instantly removed. Figures 24c and 24d show that the time required for the output to drop from 90% to 10% ranges from 0.03-0.07 seconds, which was less than the profile updating rate at 0.1 second during experiments. These sensors proved to have a sufficient dynamic characteristic for the measurement response purpose.

REFERENCES

- [1] K. Schwartz, et al., "Factors associated with weaning in the first 3 months postpartum," *J. Fam. Pract.*, vol. 51, no. 5, pp. 439–445, 2002.
- [2] E.C. Odom et al., "Reasons for earlier than desired cessation of breastfeeding," *Pediatrics*, pp. e726–e738, 2013.
- [3] Q. Spender et al., "An exploration of feeding difficulties in children with down syndrome," *Dev. Med. Child. Neurol.*, vol. 38, no. 8, pp. 681–694, 1996.
- [4] J. Reid, "A review of feeding interventions for infants with cleft palate," *Cleft Palate Craniofac J*, vol. 41, no. 3, pp. 268–278, 2004.
- [5] F. Weber et al., "An ultrasonographic study of the organisation of sucking and swallowing by newborn infants," *Dev. Med. Child. Neurol.*, vol. 28, no. 1, pp. 19–24, 1986.
- [6] E.C. Goldfield et al., "Coordination of sucking, swallowing, and breathing and oxygen saturation during early infant breast-feeding and bottle-feeding," *Pediatr. Res.*, vol. 60, no. 4, p. 450, 2006.
- [7] D.T. Geddes et al., "Tongue movement and intra-oral vacuum in breast-feeding infants," *Early Hum. Dev.*, vol. 84, no. 7, pp. 471–477, 2008.
- [8] D. Alatalo et al., "Nipple deformation and peripheral pressure on the areola during breastfeeding," *J. Biomech. Eng.*, vol. 142, no. 1, 2020.
- [9] D.T. Ramsay et al., "The use of ultrasound to characterize milk ejection in women using an electric breast pump," *J. Hum. Lact.*, vol. 21, no. 4, pp. 421–428, 2005.
- [10] A. Eglash and M. L. Malloy, "Breastmilk expression and breast pump technology," *Clin. Obstet. Gynaecol.*, vol. 58, no. 4, pp. 855–867, 2015.
- [11] V. Ilyin et al., "Comparative assessment of excretion of milk from two breast pumps with different vacuum strength and duration," *Breastfeeding Medicine*, vol. 14, no. 3, pp. 177–184, 2019.
- [12] T. Niikawa et al., "Measurement of tongue-artificial nipple contact pressure during infant sucking," *IEEJ Trans. Electr. Electron. Eng.*, vol. 7, no. 2, pp. 190–196, 2012.
- [13] S. M. Barlow, "Central pattern generation involved in oral and respiratory control for feeding in the term infant," *Curr. Opin. Otolaryngol Head Neck Surg.*, vol. 17, no. 3, p. 187, 2009.
- [14] E.L. Madsen et al., "Tissue mimicking materials for ultrasound phantoms," *Medical physics*, vol. 5, no. 5, pp. 391–394, 1978.
- [15] M.O. Culjat, et al., "A review of tissue substitutes for ultrasound imaging," *Ultrasound Med. Biol.*, vol. 36, no. 6, pp. 861–873, 2010.
- [16] M. W. Woolridge, "The 'anatomy' of infant sucking," *Midwifery*, vol. 2, no. 4, pp. 164–171, 1986.
- [17] K. Berggren et al., "In vivo measurement of the effective atomic number of breast skin using spectral mammography," *Physics in Medicine & Biology*, vol. 63, no. 21, pp. 5023–5032, 2018.
- [18] J.D. McNamara et al., "Development of a vessel mimicking material for use in anatomical flow phantoms," *Ultrasound Med. Biol.*, vol. 35, no. 8, pp. 813–826, 2009.
- [19] L.M. Cannon et al., "Novel tissue mimicking materials for high frequency breast ultrasound phantoms," *Ultrasound Med. Biol.*, vol. 37, no. 1, pp. 122–135, 2011.
- [20] S.N. Mortazavi et al., "Mathematical modeling of mammary ducts in lactating human females," *J. Biomech. Eng.*, vol. 137, no. 7, p. 071009, 2015.
- [21] M. Dawoud et al., "Mechanical behaviour of abs: An experimental study using fdm and injection moulding techniques," *J. Manuf. Processes*, vol. 21, pp. 39–45, 2016.
- [22] J. Siebert, "A morphometric study of normal and abnormal fetal to childhood tongue size," *Arch. Oral. Biol.*, vol. 30, no. 5, pp. 433–440, 1985.
- [23] S. Butterworth, "On the theory of filter amplifiers," *Wireless Engineer*, vol. 7, no. 6, pp. 536–541, 1930.
- [24] J. Canny, "A computational approach to edge detection," *IEEE Trans. Pattern Anal. Mach. Intell.*, no. 6, pp. 679–698, 1986.
- [25] W.L. Smith, et al., "Imaging evaluation of the human nipple during breast-feeding," *American J. of Diseases of Children*, vol. 142, no. 1, pp. 76–78, 1988.
- [26] J.G. Dabbling et al., "Static and cyclic performance evaluation of sensors for human interface pressure measurement," in *Conf Proc IEEE Eng Med Biol Soc*, 2012, pp. 162–165.