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A CLINICAL EXPERIMENT ON INFANT APPLIED PRESSURES DURING BREASTFEEDING

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ABSTRACT

Breastfeeding provides both nutrients and immunities necessary for infant growth. Understanding the biomechanics of breastfeeding requires capturing both positive and negative pressures exerted by infants on the breast. This clinical experimental work utilizes thin, flexible pressure sensors to capture the positive oral pressures of 7 mother-infant dyads during breastfeeding while simultaneously measuring vacuum pressures and imaging of the infants oral cavity movement via ultrasound. Methods for denoising signals and evaluating ultrasound images are discussed. Changes and deformations on the nipple are evaluated. The results reveal that pressure from the infant's maxilla and mandible are evenly distributed in an oscillatory pattern corresponding to the vacuum pressure patterns. Variations in nipple dimensions are considerably smaller than variations in either pressure but the ultrasound shows positive pressure dominates structural changes during breastfeeding. Clinical implications for infant-led milk expression and data processing are discussed.

NOMENCLATURE

IOP Intra-oral Pressure (kPa)
NH Nipple Height (mm)
NL Nipple Length (mm)
 Δ Value/Dimension Change
SD Standard Deviation

INTRODUCTION

It is well accepted that infants obtain both nutrients and immunities required for growth from breast milk [1]. However, 60% of breastfeeding mothers stopped breastfeeding earlier than desired [2]. Early termination was positively associated with mothers' concerns about maternal or child health as well as lactating or milk-pumping problems. The breast contains a unique ductal system for transporting milk to infants after birth. Infants not only utilize their intra-oral vacuum but also take advantage of their peripheral oral compression to extract milk from the breast [3, 4]. Geddes et al. identified four stages of suckling and recorded normal intra-oral vacuum patterns in clini-

cal experimental studies [5]. In recent years the use of simulation software has been used to further explore the mechanics of milk removal with heavy emphasis on negative vacuum pressure [6, 7]. However, the positive oral pressure exerted by the infant's mouth on the breast has received limited attention. Modeling the mechanisms requires obtaining the forces exerted by the infant while breastfeeding. Both breast massage and infant suckling are known to positively affect milk flow [8, 9]. The questions regarding the biomechanics of milk removal by infants during breastfeeding remain unresolved. A primary piece of information is missing from all previous studies, namely the amount of pressure exerted on the nipple-areola complex by the infant.

Infant suckling consistently applies compression to the nipple-areola complex. Niikawa et al., studied the mechanism of infant's tongue during active suction using an artificial nipple with a built-in measurement unit [10]. The tongue force of 25 infants was measured by the artificial nipple sensor unit. Results showed that the force from the root of the tongue is about two times of the force from the tip of the tongue. Moreover, the waveform outputs indicated a periodic motion from infants oral cavity. While this study provides some insight into applied forces during non-nutritive sucking, suckling during breastfeeding differs from sucking on pacifiers, fingers, or other objects [11]. While feeding at the breast, infants control the milk expression to accommodate other bodily functions, such as swallowing and breathing [3, 4].

Mothers who are separated from their babies often express milk to be fed via cup or bottle. Unlike infants who must control milk flow to accommodate swallowing and breathing, when the mother controls milk expression, her main concerns are total volume expressed and time required for expression. This area of research, mother-controlled milk extraction, has produced many clinical studies that investigate methods to maximize milk expression including the relationship between compression and vacuum extraction. Compression of the nipple-areola complex in combination with vacuum pump results in an increase of basal serum levels of prolactin, whereas women who utilize only vacuum for milk expression experience a decrease in prolactin levels on the third postpartum day [9]. Additionally, compressions of the nipple-areola complex with vacuum pump increase total milk output by 10-46% when compared to vacuum pumping alone in a single session [12]. Early experiments in Russia compared milk ejection rates using a breast pump that applied both a vacuum and compression [13]. When the compression component was active¹, milk flow began before the first milk reflex was active, and peaks in milk excretion occurred sooner and more frequently. Further experiments noted that when ductal pressure was not at its peak, suction and compression combined resulted in faster milk release from the breast whereas when ductal pressure was at its peak then suction alone removed milk faster [12]. Only one study measured the peak compression value tolerated by moth-

ers, which was 35-40 kPa [13].

Ultrasound imaging has been used extensively to study the anatomy of a lactating breast [14] and the mechanism of breastfeeding [3, 5, 7]. A natural-looking oral movement of infants during breastfeeding is expected to be derived from captured sensor data with various clinical experiments, although the methods of processing these data are not discussed. Since different sensor products and measuring systems are utilized in clinical experiments, fusion of data from multiple sensors is essential for researchers to achieve optimal results in clinical applications [15]. In addition to that, even with high-quality sensors and good accurate data acquisition equipment, the output signal may still contain noise and unexpected outliers that must be removed before further analysis. Biomechanical motion involves unpredictable movements and unknown independencies between degrees of freedom [16]. The most widely used low-pass filtering methods called butterworth filter in biomechanics data processing was first published by Winter et al. [17] in 1974 and a method of calculating the filtering coefficients was later presented by Winter in Chapter 2 and Chapter 3 of [16]. The advantage of using butterworth filter is that it not only rejects the unwanted frequencies but also have a uniform sensitivity of the wanted frequencies.

In this paper, the raw data extracted from the vacuum pressure, oral pressure, and ultrasound images of the oral cavity including the time dependent motion of the tongue during breastfeeding are captured and analyzed. The noise and unexpected outliers from the pressure data are removed and a processed oral pressure for both infants maxilla and mandible analyzed. A natural-looking oral movement of infants during breastfeeding is derived from captured sensor data. The objective of this study is to capture the oral peripheral pressure of infants while breastfeeding in combination with the negative vacuum pressure. With the clinical experimental work in this paper on capturing the pressure values applied on the nipple-aerola complex by infants, mechanical boundary conditions can be utilized in bio-fluid simulation to imitate oral cavity motion and its affect on the breast for the first time.

DATA ACQUISITION

This study was approved by the Internal Review Board at The University of Texas at Dallas (IRB 16-41) and the Human Research Ethics Committee of The University of Western Australia.

Participant Recruitment

Fifteen mother-infant dyads were initially recruited through either Australian Breastfeeding Association or community health centres in Western Australia. Positive oral pressure and negative vacuum data were successfully obtained from seven dyads, with one dyad providing two sets of data on separate days. Ages of

¹pressure amplitude controlled by mother

infants ranged from 6 days to 21 months. All infants were successfully breastfed with the use of a nipple shield.

Intra-oral Pressure and Ultrasound Imaging

The ultrasound images and vacuum pressure were obtained by an endocavity convex transducer placed under infant chin and a silicon vacuum tube connected to a disposable pressure transducer as outlined by Geddes et al. [5], except the supply line for the pressure transducer was filled with water instead of mother's expressed breastmilk and placed alongside the nipple on top of the nipple shield, when in use. Raw data of Infant 6's intra-oral pressure is given in Figure 1 and shows a periodic pattern during the entire nursing period. The ultrasound imaging is used to determine periods of nutritive and non-nutritive suckling, as well as to visualize the changes in the nipple dimensions from infant pressures. Figure 2 shows a single image from ultrasound videos of Infant 6 during his clinical experiment.

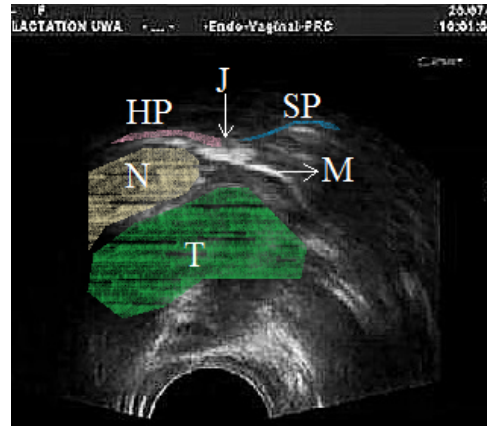


FIGURE 2: Ultrasound imaging of Infant #6's oral cavity during breastfeeding: hard palate (HP), soft palate (SP), hard-soft junction part (J), nipple (N), and tongue (T)

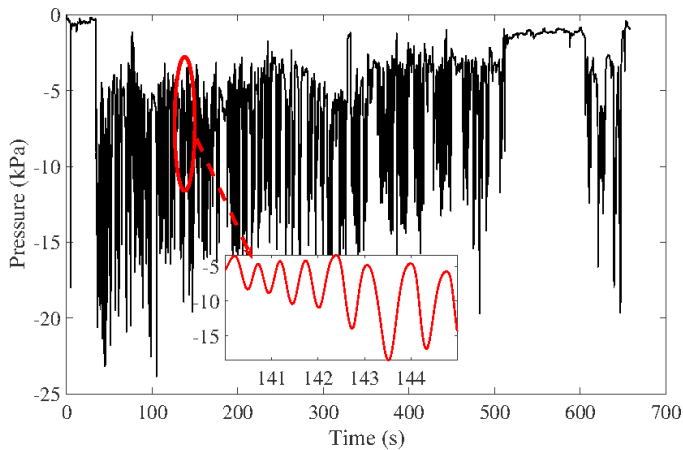


FIGURE 1: Raw intra-oral pressure data for Infant #6

Peripheral Oral Pressure Capturing

Two flexible resistance pressure sensor strips 9801 and 9830 (see Figure 3) with the I-Scan System (Tekscan Inc. Boston, MA, USA) are attached to the breast with tape² and covered with a breast shield to minimize moisture exposure to the strips and prevent the strips from entering the mouth of the infant (see Figure 4). Each sensor has been cut and edges smoothed to prevent the sensor edge from cutting into the mother's skin. For infants who regularly breastfed without a nipple shield, the tip of the shield is cut off to allow the nipple to move normally within the oral cavity. Since the width of the strips is too wide to comfortably fit around the nipple under a shield, the strips are placed

along the top and bottom of the areola as close to the base of the nipple as possible. Initial experiments attempted different layouts (see Figure 4) using Sensor 9830 to approximate pressure ranges. The T-type and V-type sensor layouts were not considered as the sensor strips distracted infant's attention and interfered greatly on infants' oral mechanics. Additionally, the data from these initial layouts with those dyads are incomplete and not included in these findings. On the final layout, the strips are oriented to approximate the location of the upper and lower gums and lips of the infant while suckling as seen in Figure 5. The position of sensors during experiments can be seen in Figure 4c, where U1-U7 represents the displacements of the sensor cells that were under the maxilla of infants while L1-L7 represents the sensors cells placed under infant's mandible. Since the amount of areola that each infant takes into the mouth differs, the exact location of sensels varies as seen in Figure 6.

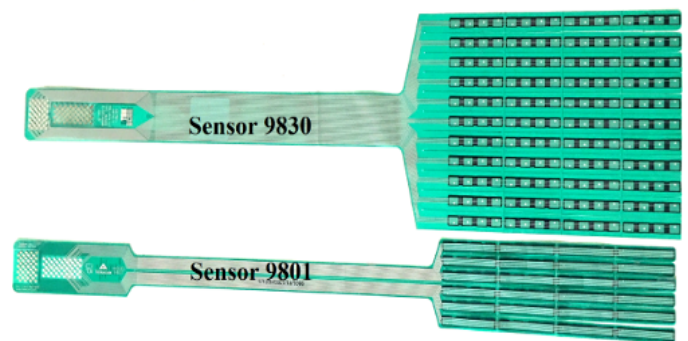


FIGURE 3: Peripheral pressure sensor strips

²The tape is placed away from the areola.

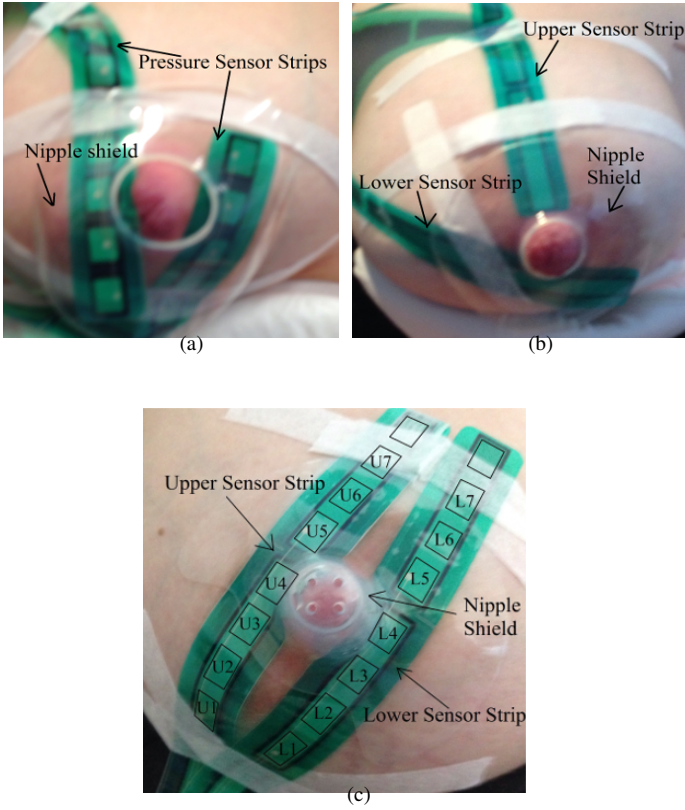


FIGURE 4: Multiple layouts for peripheral pressure sensor strips on mothers: T-type placement (a), V-type placement (b), Parallel placement (c)

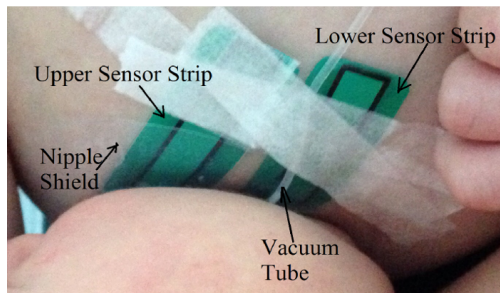


FIGURE 5: Tekscan sensor strip clinical experiment setup for Infant #6

The maximum pressures are 69 kPa and 34 kPa for Sensors 9830 and 9801, respectively. Sensors with lower pressure ranges are more sensitive and will be more inclined to produce readings induced by curvature of the sensor [18]. Once the final layout of sensor strips is determined, Sensor 9801 with lower sensitivity captures data for the first 5 dyads reported here. As the curvature

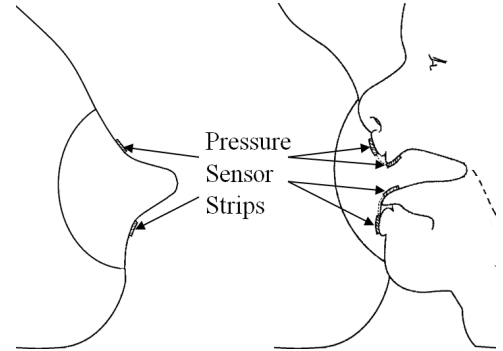


FIGURE 6: Pressure sensor strips position during experimentation

of surface increases, the level of accuracy changes. The sensors are zeroed and calibrated according to manufacturer guidelines using the I-Scan built in multi-point calibration algorithm. Examination of individual sensel cells reveal that one sensel displays a constant value, likely caused by wrinkling, crimping, or folding of the individual sensel that results in the high pressure reading [18]. Prior to data processing, those sensel values are removed to keep the pattern of the original data. Figure 7 elaborates the raw data from each sensel cell of Sensor 9830 used by Infant #6 in this clinical experiment. Data from each sensel varies significantly with their positions. Sensels placed right under the infants' mouth have more contact space with infant's maxilla and mandible. However, not all sensels are placed exactly under infant's mouth during the whole nursing period due to the pressure strip curvature and infant's feeding position change. To demonstrate the average pressure applied on mum's breast, average raw values of all sensels are calculated to analyze the total pressure applied on the breast by infant's oral cavity with different sensor strips.

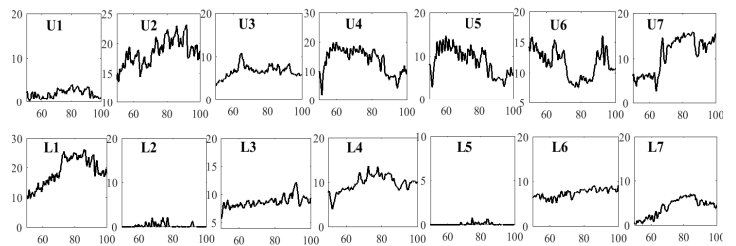


FIGURE 7: Raw peripheral oral pressure data of Infant #6 from Sensor 9830

IMAGING AND DATA PROCESSING

All ultrasound movie analyses were performed using MATLAB for observing the nipple dimension changes inside infants' mouths during breastfeeding. The original ultrasound images extracted from the ultrasound video clips show a large space of speckle noise that may contain information useful for evaluation (see Figure 8a). Although the ultrasound imaging equipment already has a filter embedded in the recording system, the biomedical images during breastfeeding clinical experiments contain tremendous uncertainties and variabilities. Taking that into account, a local statistic filter called Wiener filter [19] is applied on the original images to deduct the signal-to-noise ratio. However, after smoothing the images, the contrast of the images is decreasing due to the signal elimination by the Wiener filter. To solve this, imaging sharpening is applied on the filtered image to better display the outlines in Ultrasound images.

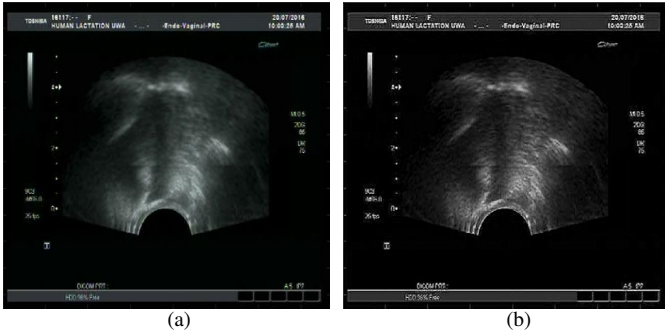


FIGURE 8: Original ultrasound image from Infant# 6 (a), Enhanced ultrasound image from Infant # 6 (b)

Calibration is made with a self-decided baseline in images. A manual designation of the approximate edge on each frame was used to outline the boundaries for nipple, infant's hard palate and tongue, pictured in Figure 2. A self-programmed measurement system was achieved in MATLAB to get average dimensions change of the nipple width and length with tongue moving up and tongue moving down. Figure 9 shows a schematic description of nipple dimension change measurement. Nipple Height at its maximum value (NH_{max}) and Nipple Length at its minimum value (NH_{min}) are chosen in ultrasound imaging as a start point when tongue is at the lowest position during one effective nursing cycle. The amount of deformation is recorded when nipple length reaches its maximum length and nipple height is at its minimum height observed in ultrasound images. Average nipple dimension changes plus standard deviations are derived from multiple NS suckling cycles for statistic evaluation purposes.

Two different sensor systems are used to measure both the

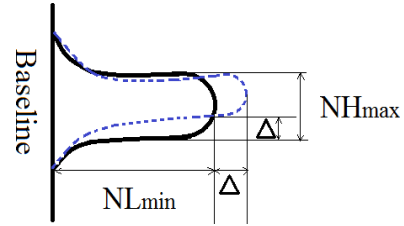


FIGURE 9: Schematic description of nipple dimension measurement in ultrasound imaging

intra-oral vacuum and the peripheral oral pressures, thus time-line matching for relating both sets of pressure data with infant's suckling during breastfeeding is essential in the data analysis part. Tekscan I-scan measuring system and ultrasound transducer are two different modules used in this clinical experimentation. Each sensor module includes a sensor responsive to time recording, as well as data storing for information.

The relationship between infants' mouth movements and the creation of vacuum are well documented [5]. Using the ultrasound to visualize milk ejection, the dynamic pattern of infants' peripheral oral pressures are correlated to the intra-oral vacuum pressures for six infants to eliminate the experimental time gaps.

Files of raw sensor readings are downloaded from software specific for each measuring system and imported into MATLAB with user defined programs. After applying unit conversions, all sensor data are organized and stored in MATLAB files. Raw sensor data shows an arbitrary range of white noise and some unpredictable outliers that needed to be eliminated before any analysis. A post-processing filter based polynomial de-noising algorithm known as BUTTERWORTH with a MATLAB command BUTTER [20] are applied for the overlapped experimental and the noise signals.

Average values of all sensors were calculated to analyze and evaluate the total pressure applied on the breast by infants' maxilla and mandible. Second order BUTTERWORTH filter was tested to be sufficient for both vacuum and oral pressure sensor capturing systems.

RESULTS

The filtered and sharpened ultrasound images capture milk ejection during suck cycle known as Nutritive Suckling (NS) [5]. Figure 2 demonstrates a proper attachment of Infant # 6 to the breast with sensor strips as the nipple is able to reach the hard and soft palate junction [21]. As observed in Figure 2, the tongue, hard palate, and soft palate are wrapped around the nipple during milk ejection during one suck cycle. In ultrasound movies, cycling motion of infants' anterior tongue and palate is visualized. Figure 10a represents a minimum vacuum with tongue moving up when the infant compresses the nipple with his max-

illa, tongue, and mandible, causing the nipple to stretch and elongate significantly inside infants oral cavity. Figure 10b shows that the tongue is wrapped around the nipple at its lowest position when vacuum is at its peak value.

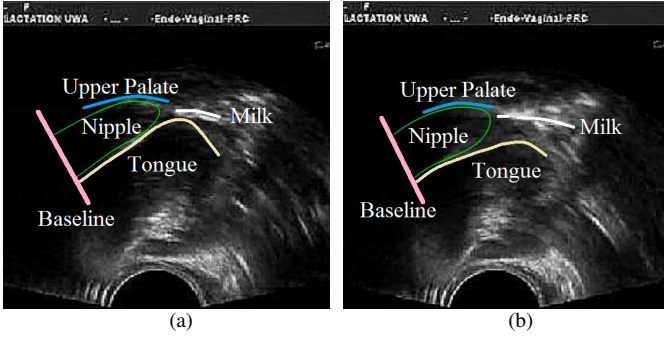


FIGURE 10: Ultrasound image for Infant #6 during sucking with tongue moving up (a), and with tongue moving down (b)

Average dimension changes (Δ) in elongation of Nipple Height (NH) and Nipple Length (NL) for all NS cycles with observable tongue up and tongue down are measured and presented in Table 1 for all mother and infant dyads. The elongation of nipple length ranges from 2.51 mm to 3.66 mm, and the compression of the nipple in the height ranges from 1.26 mm to 1.91 mm. Nipple dimension change in length is approximately twice of height change. Among the suck cycles, the changes in pressures are compared with the changes in nipple dimensions resulting from the movement of the infant's tongue. The average change in height and length is 1.56 ± 0.24 mm and 3.00 ± 0.37 mm, respectively, while the average pressure change is 13.77 ± 4.86 kPa and 3.63 ± 3.53 kPa for intra-oral and peripheral oral pressures.

During clinical experiments with mother and infant dyads, we observe multiple resting time of infants during nursing. Pressure values are relatively smoother and lower during resting times than suckling time. With the evidence of multiple resting time from infants during breastfeeding, time frame matching of different recoding system from multiple sensor modules is resolved. Optimal results of pressure data can be obtained based on this time-matching method. Ignoring time periods when the infants are not actively suckling, the average pressure values from both maxilla sensor strip and mandible sensor strip plus standard deviation are calculated for all infants and are reported in Table 2.

The denoised peripheral oral pressure sensor data for Infant 6 gives smooth sinusoidal signals, as well as, keeps the original peaks of the waves as shown in Figure 11. The peripheral oral pressure demonstrates a rhythmic, oscillatory pattern with pressure changes for both the maxilla and mandible. A closer look at

TABLE 1: Clinical Experiment Data on Nipple measurement and Vacuum change of Participants

Participants	NH (mm)	NL (mm)	IOP (kPa)
No.	$\Delta \pm SD$	$\Delta \pm SD$	Mean $\pm$ SD
# 2	1.91 ± 0.53	2.71 ± 0.69	-14.43 ± 0.35
# 3	1.55 ± 0.32	2.51 ± 0.62	-7.14 ± 0.13
# 4	1.64 ± 0.50	3.03 ± 0.98	-13.79 ± 1.99
# 6	1.80 ± 0.37	3.22 ± 0.28	-10.04 ± 0.34
# 7a	1.47 ± 0.35	3.06 ± 0.27	-20.32 ± 1.78
# 7b	1.26 ± 0.19	3.66 ± 0.49	-19.56 ± 1.33
# 8	1.32 ± 0.73	2.83 ± 0.37	-11.09 ± 0.57

TABLE 2: Clinical Experiment on 8 infants

Infant & Age	Maxilla Pressure Mean $\pm$ SD (kPa)	Mandible Pressure Mean $\pm$ SD (kPa)
#1 4.5m	2.14 ± 2.06	1.27 ± 1.62
#2 10w	0.18 ± 0.09	1.86 ± 3.35
#3 4.5m	2.70 ± 4.18	0.36 ± 0.26
#4 6d	1.01 ± 0.60	0.84 ± 0.28
#5 21m	0.37 ± 0.33	1.57 ± 2.16
#6 4w	7.92 ± 1.81	5.01 ± 2.54
#7a 10w	0.96 ± 0.31	1.03 ± 0.24
#7b 11w	2.37 ± 0.27	1.24 ± 0.92
#8 3.5w	1.40 ± 0.82	1.54 ± 0.95

10 seconds of nutritive suckling for Infant 6 (seen in Figure 11) provides new insights in breastfeeding biomechanics with implications for clinical application. During this time period, the total pressure of 11.23 kPa is applied on the breast from the maxilla and 5.65 kPa is from the mandible motion of the infant during breastfeeding. The deviation in maxilla movement is 1.81 kPa compared to deviation in mandible movement at 2.94 kPa which indicates maxilla moves steadier than the mandible during these 10 seconds of nutritive suckling. The pattern of maxilla and mandible pressures match the vacuum peaks during these suck

cycles. When the vacuum experiences a local minimum (around -20 kPa) the maxilla and mandible pressures reach a local minimum value. This phenomenon matches observations in the ultrasound images where the infant's mandible drops to create a vacuum. Thus positive pressure on all sides of the areola are used by infants to control milk extraction and this bilateral pressure application should be observed by clinicians during normal breastfeeding.

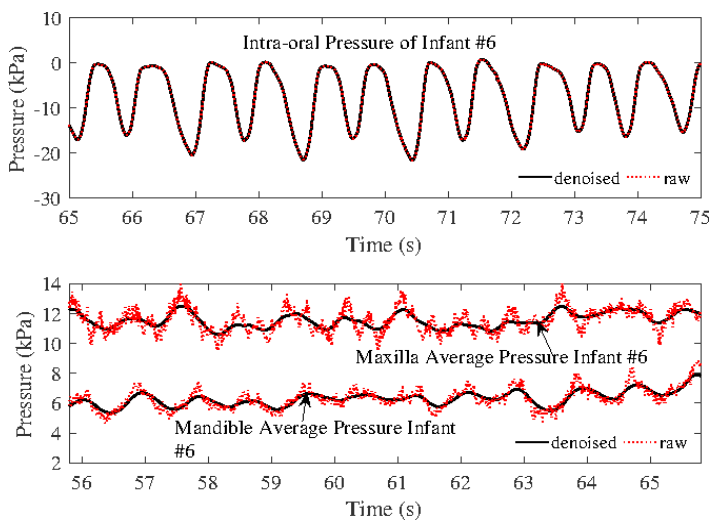


FIGURE 11: Intra-oral pressure and peripheral oral pressure during 10 seconds nutritive breastfeeding of Infant#6

DISCUSSION

The use of positive and negative pressures in combination are known to positively affect milk flow [8, 9], yet the amount of pressure exerted on the nipple-areola complex by the infant is missing from all previous studies. By utilizing two separate measuring systems, this clinical experimental work successfully captures intra-oral vacuum pressure simultaneously with positive peripheral oral pressure applied on the breast by an infant's maxilla and mandible while breastfeeding. By using the well established relationship between oral movements and vacuum pressure, time matching between the two systems is possible. The resulting data provide new insight into the peripheral oral pressure exerted by infants during breastfeeding. The raw data demonstrates an oscillatory pattern with pressure changes for both maxilla and mandible. The distribution of pressure from the maxilla on the breast at times exceeds that of pressure from the mandible. So while the mandible is the only moving joint during suckling [4], the pressure distribution on the breast is distributed around the areola. The second order butterworth filter sufficiently removed

unwanted noise originating from the measuring system leaving a smooth sinusoidal pattern that matches the sinusoidal vacuum pressure pattern.

Image contrast is essential for distinguishing between anatomical markers in the infant's oral cavity. The use of Wiener filter smooths the spaces in ultrasound imaging adaptively while the image sharpening enhances the contrast and thus allows for differentiating between nipple, palates, and tongue. From these images, the dominant pressure that results in nipple deformation is clearly identified as compression since images show that when the infant is creating the vacuum, its oral cavity opens and the nipple expands in height and shortens in length. No correlation between variations in nipple dimensions and variations in either pressure are found. Periods of nutritive suckling are identified by milk sprays in the infant's mouth.

Peripheral oral pressure and intra-oral pressure varies considerably among mother-infant dyads. The oscillatory motion of the maxilla with pressure values that can exceed mandible pressures indicates a more active role in milk extraction beyond anchoring of mouth to breast. Among all the mother and infant dyads, Infant 7 applies the strongest vacuum load on the breast and his mother verbally complained of nipple pain. During Infant 7's first session he initially nursed with sensor strip and exerted peripheral pressures of 1.0 kPa for both maxilla and mandible with strong vacuum pressure of 8.5 kPa. Infant 7's second session began with him nursing without the sensor strip. His vacuum pressure was slightly stronger without the sensor strip, 11.5 kPa versus 10.2 kPa, than with sensor strip. The oral peripheral pressure is stronger than during the first session at 2.4 kPa for maxilla and 1.2 kPa for mandible. A closer look at Infant 7's mandible pressure over time shows a step up that is not attributed to any sensor saturation. Comparison of peripheral pressures and vacuum pressure during that step up reveals that Infant 7 created a vacuum that he did not lose for over 2 minutes. It has been documented that infants adjust the frequency of their suckling based on milk flow [4], so likely infants adjust their applied peripheral pressures as well. This theory is supported by the periodic spikes in the pressure readings (see Figure 12). These spikes may originate from repositioning of infants (either by mother or infant). However, these spikes may also be from a deliberate action of the infant to control milk extraction. In all the studies that investigated the use of positive and negative pressures for milk extraction, the focus of the studies was on mother-controlled milk extraction using hand or pump expression. Breastfeeding is an infant-led process where the infant controls milk extraction. Thus infants apply pressures to control expression in response to appetite and suck-swallow-breathe requirements. So while a mother-led control system will maximize expression by utilizing pressure values at the maximum of their tolerances, an infant-led control system may operate at lower pressure values with increases as needed to meet infant's needs. These fundamental differences in control systems are important considerations for

clinical investigations in milk extraction.

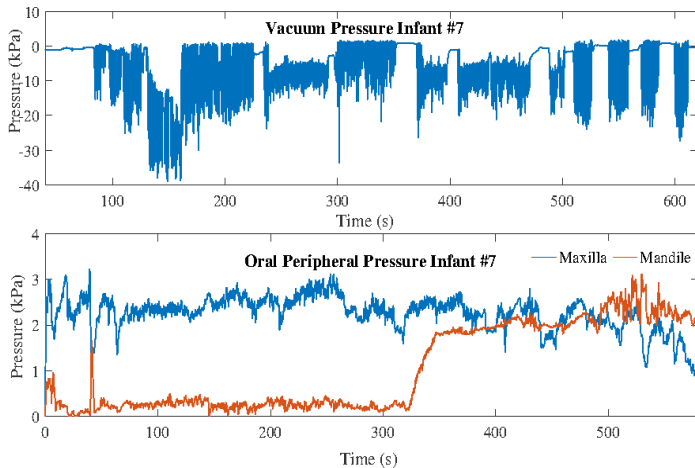


FIGURE 12: Intra-oral pressure and peripheral oral pressure during whole nursing period of Infant #7

CONCLUSION

Infant-led breastfeeding utilizes both positive compression and negative vacuum pressure to extract milk from the breast. Previous studies on infant feeding biomechanics lacked positive pressure values as applied by infants. This study investigated the two major pressures exerted by infants during breastfeeding and examined the effect of these pressures on the nipple during suckling using a novel method to measure *in vivo* oral pressure forces. Multiple challenges in studies such as this one exist for engineers and clinicians. Using clinical observations, time matching between two separate systems allowed for new insights into the biomechanics of breastfeeding. Data processing, filtering, and image sharpening provided realistic picture of infant-led milk extraction. TekscanTM pressure mapping sensors captured the peripheral oral pressure applied to the areola by infants with their maxilla and mandible while intra-oral vacuum pressure and ultrasound video clips were captured and recorded simultaneously. The nipple during continuous suckling deforms primarily by positive pressure applied by the infants to the circumference of the nipple. The maxilla and mandible peripheral pressures varied in an oscillatory pattern that corresponded to the oscillatory pattern of the intra-oral vacuum pressure. Infant's applied pressure on mother's breast was distributed around the areola and varied for both maxilla and mandible. This clinical experiment provides a powerful and practical tool for clinicians and researchers to monitor multiple assessments in biomechanical processes, including sensor system timeframe matching, imaging modality choosing and processing, and data de-noising. These preliminary findings

provide insight into the amount of positive pressure the areola experiences during breastfeeding. Differences between mother-led control of milk expression and infant-led control are highlighted and show that infants do not always apply maximum pressures while breastfeeding. Additional work is underway to capture the pressure exerted on the nipple by the tongue.

Certain aspects and limitations of the study methods should be noted as these factors may influence the ability to compare results with future works. The age range of infants was broad so maturity of latch on and suckling may evolve with age. The crinkling sound of the Tekscan strips that were not in use and the number of study personnel in the room distracted some older infants and led to them turning their heads frequently to find the source of noise and conversations. Although pressure measurements were eliminated during periods when suckling was not occurring, infants can often maintain suckling while turning their heads if the range is not great enough to cause loss of vacuum. Lastly, the use of a nipple shield adds another layer of material between infants mouth and breast tissue. Although this layer is thin, medical grade silicone could have a damping effect [22] on the infant applied force.

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