Nipple Deformation and Peripheral Pressure on the Areola During Breastfeeding

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ABSTRACT

Breastfeeding is a complex process where the infant utilizes two forms of pressure during suckling, vacuum and compression. Infant applied compression, or positive oral pressure, to the breast has not been previously studied in vivo. The goal of this study is to use a methodology to capture the positive oral pressure values exerted by infants' maxilla (upper jaw) and mandible (lower jaw) on the breast areola during breastfeeding. In this study, the positive and negative (vacuum) pressure values are obtained simultaneously on six lactating mothers. Parallel to the pressure data measurements, ultrasound images are captured and processed to reveal the nipple deformations and the displacements of infants' tongues and jaw movements during breastfeeding. Motivated by the significant differences in composition between the tissue of the breast and the nipple-areola complex, the strain ratio values of the lactating nipples are obtained using these deformation measurements along with pre- and postfeed 3D scans of the breast. The findings show an oscillatory positive pressure profile on the breast under both maxilla and mandible which differs from clinical indications that only the mandible of an infant moves during breastfeeding. The strain ratio varies between mothers which indicates volume changes in the nipple during feeding and suggests that previous assumptions regarding strain ratio for non-lactating breasts will not accurately apply to breast tissue during lactation.

Nomenclature

A	Denominator parameter vector
a	Denominator parameter
B	Numerator parameter vector
b	Numerator parameter
c	Scalar constant
H	Transfer function
K	Gain of the transfer function
L	Length (mm)
N	Order of the digital filter
n	Number of poles

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s Complex variable in transfer function

W Width (mm)

Greek Letters

Δ Value/Dimension change

ν Strain ratio

ρ Correlation coefficient

ω Filter frequency (Hz)

Subscripts and Superscripts

c Cutoff

f Final

i Initial

Acronyms and Abbreviations

NL Nipple length

NW Nipple width

SD Standard Deviation

1 Introduction

The female human breast contains a unique ductal system for transporting milk to infants. This bio-fluid transport phenomena involves multiple mechanisms, both physical and hormonal [1, 2]. The dynamics of milk removal from the breast by the infant have been studied for decades, and are considered successful when the infant removes milk effectively and efficiently [3]. Early work determined the relationship between nipple stimulation and hormones necessary for milk production and ejection [4]. When the infant was unable to remove milk, expression by hand was the mechanical method of choice as it was thought to more closely imitate the normal forces employed for milk removal [5]. While hand expression can yield adequate volumes of milk for infant consumption, more recent studies have demonstrated that vacuum extraction is more effective at milk removal [6, 7]. Further study investigated the positioning of the infant's mouth and tongue in relation to the nipple that resulted in defining correct technique for suckling to be used in the clinical assessment of breastfeeding [8]. The positioning of the infant's mouth has been explored further with ultrasound studies by Geddes et al. which identified four stages of suckling that alter the shape of the breast [1]. The authors related the positioning of the tongue and changes in the nipple dimensions to the intra-oral vacuum pressure. Their study suggest that vacuum pressure plays a significant role in milk removal from the breast by the infant. The importance of vacuum in milk removal has since been validated with the use of electric breast pumps that rely solely on vacuum [9]. 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 [10–12].

The positive oral pressure, or normal force, exerted by the infant's mouth on the breast has received limited attention in recent decades. As previously noted, early work by clinicians emphasized the use of positive pressure on the surface of the breast for milk extraction in imitation of infants [5]. The combination of compression stimuli and vacuum pumping also results in significant differences in milk ejection and composition. Work done with mothers of preterm infants who were unable to feed at the breast demonstrated an increase in overall daily milk production at 2 weeks and 8 weeks postpartum when hand techniques were used in combination with electric breast pumps [13]. In addition to an increase in daily production, the combined technique of breast massage with vacuum pumping resulted in a higher fat content for mothers of preterm infants [14]. Possible causes for the increased production and fat content include an increase in intramammary and intraductile pressures from breast compression [13, 14].

Infant suckling consistently applies compression only to the nipple-areola complex, not the entire breast. However, studies involving the combination of compression of the nipple-areola complex with electric vacuum pumping show similar findings to breast massage with vacuum. Compression of the nipple-areola complex with vacuum pump results in an increase of basal serum levels of prolactin, whereas women who utilize only the vacuum experienced a decrease in levels on the third postpartum day [15]. Additionally, compression of the nipple-areola complex with vacuum pump increases total milk output by 10-46% when compared to vacuum pumping alone in a single session [16].

Early experiments in Russia compared milk ejection rates using a breast pump that applied both a vacuum and compression [17]. When the compression component was active (pressure amplitude controlled by mother), 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 [16]. Out of all the studies mentioned, only one study measured the peak compression value tolerated by mothers, which was 35-40 kPa [17].

As previously noted, recent works have attempted to examine the mechanics of lactation using computer simulation software. These simulations of milk flow within the breast considered applied vacuum pressure values from clinical experiments and ignored compressive pressure values [10–12]. One recent work declared that from "complex biophysical simulation" they proved that milk extraction from the breast resulted from cycling subatmospheric pressures and "not due to the chewing of the breast nipple" [12].

Despite the confidence of previous researchers, the biomechanics of milk extraction from the breast by infants continues to elude full understanding. The effect of compressive forces exerted by the infant on the nipple requires further study. Since no studies have successfully measured and recorded the positive oral pressure, the purpose of this study is to investigate a methodology for recording positive oral pressures exerted by the infant while breastfeeding and comparing them to recordings of negative vacuum pressures from the same feed.

Additionally, in this paper, the mechanical properties of the breast during lactation are considered with particular focus on the nipple-areola complex. The assumption that the human breast is a homogeneous, incompressible material is commonly made. A review of the literature concerning the mechanical properties of human breast tissue found the majority of studies assumed all breast tissues as quasi-incompressible [18] or totally incompressible [19–22] with Poisson's ratio, when reported, ranging from 0.485 to 0.5. This assumption was also made by researchers measuring the breast skin elasticity *in vivo* [23]. However, *in vivo* measurements of healthy breast adipose and fibroglandular tissue determined Poisson's ratio ranges of 0.347-0.409 and 0.392-0.404, respectively [24]. The non-lactating breast is an inhomogeneous structure consisting of skin, smooth muscle, glandular or fibroglandular tissue, adipose tissue (fat), fibrous connective tissue, a ductal system (epithelium), circularly system with blood, and a lymphatic system with lymphatic fluid [25–28]. During lactation, the breast volume undergoes constant change from milk expression and milk synthesis [29]. On a cellular level, Poisson's ratio for human tissues range from 0.167 for granulation and fibrous tissue to 0.3 for cartilage, immature, and mature bone [30]. The bulk properties of some tissues, like collagen gels, are anisotropic and respond to low levels of loading by reorienting, sliding, buckling, and bending fibrils which results in Poisson's ratio measurements larger than 2 [31].

The anatomy of the human nipple and areola differs somewhat from the body of the breast and includes lactiferous ducts (epithelium), papillary dermis (collagen bundles and fibroblast), epidermis, smooth muscle, connective tissue, and sebaceous-like glands [26]. The reported number of lactiferous ducts varies among studies, often due to differences in methodologies, with values ranging from 4 to 30 ductal openings with most studies reporting 5-9 milk-yielding ducts [25, 26, 32–36]. Variations in duct diameter within the nipple exist with reported values starting as low as 0.1 mm [32] and measuring as high as 4.4 mm [36]. Studies involving the use of ultrasound to locate and measure milk-yielding ducts noted that ducts were easily compressed and diameter varied with milk ejection and volume [25, 34–36]. In this study, motivated by these significant differences in composition between the body of the breast and the nipple-areola complex, the strain ratio values of the lactating nipples are also obtained using the nipple deformation measurements.

2 Methods

Fifteen mother-infant dyads were initially recruited through Australian Breastfeeding Association and community health centers, 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. Positive and negative oral pressure data are successfully obtained from six of the fifteen dyads. Three dyads attempted different sensor layouts but did not capture useful data. The remaining dyads did not produce sufficient data to include in our analysis for various reasons (i.e. did not feed very long). Ages of infants ranged from 6 days to 18 weeks. All infants were successfully breastfed with the use of a nipple shield which for the purpose of this study means milk transfer occurred.

Images of the exterior surface of the breast were captured using Polhemus FastSCAN 3D imaging technology (see Figure 1.) Scans of the breast surface were made both prefeed and postfeed on participants with each participant standing upright. A small cross was made on the upper breast bone with a marker to act as an origin for both scans and detect changes in volume[1]. Images were exported as .DXF files and later opened in SolidWORKS software for analysis. Two orthogonal cross-sectional areas were used to calculate an average value for nipple width (NW) and nipple length (NL). Three edge points were chosen in the cross-sectional area to create a triangle along the nipple, as seen in Figure 1. The base of the outlined triangle indicates nipple width while the triangle height determines nipple length. Two separate measurements were averaged to calculate the prefeed and postfeed nipple width and nipple length reported in Table 1. The nipple was assumed to be cylindrical in shape, and the prefeed and postfeed measurements were used to calculate volume changes. The difference between the prefeed and

[1] Results not discussed in this paper.

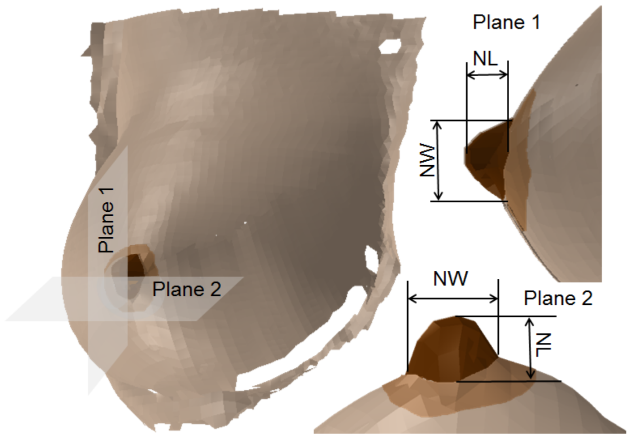
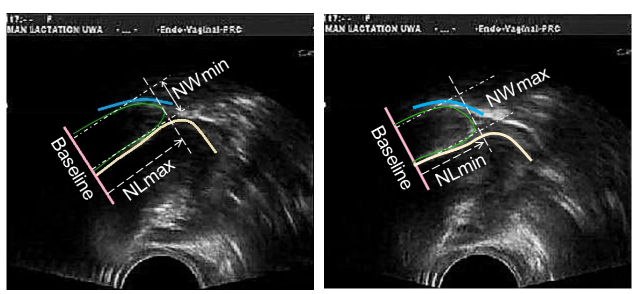


Fig. 1: Nipple dimension measurement with 3D scans, where NL is the nipple length, and NW is the nipple width.

Table 1: Strain ratio of the nipple varies greatly between participants. Volume changes in nipple may contribute to these variations.

Participant No.	Prefeed (mm)		Postfeed (mm)		Volume Change	Strain Ratio (mm/mm)
	Width	Length	Width	Length	(mm^3)	Mean ±SD
1	14.83	13.79	18.24	12.94	999.25	0.49±0.18
2	14.44	11.66	16.78	12.41	834.87	0.27±0.04
3	15.09	11.48	18.30	12.24	1166.29	0.13±0.06
4	14.78	11.82	15.89	10.76	105.84	0.28±0.03
5	15.08	12.80	16.37	10.26	-126.73	0.50±0.05
6	14.73	10.70	12.85	11.63	-315.13	0.65±0.11



(a) (b)

Fig. 2: Nipple dimension measurement with Ultrasound images: (a) Tongue moving up, and (b) Tongue moving down.

postfeed volumes is reported as the volume change in Table 1. Since no clinical signs of tissue damage were noted after feeding, the nipple was assumed to experience total elastic compression/torsion.

Ultrasound images were captured as outlined by Geddes et al. [1]. The ultrasound images were used to determine periods of nutritive and non-nutritive suckling by visualization of milk flow. All ultrasound movie analysis were performed using MATLAB for observing the nipple dimension changes inside infants' mouths during breastfeeding. A self-programmed measurement system was achieved in MATLAB to get average dimensions of the nipple width and length with tongue moving up and tongue moving down. The self-programmed measurement system calibrated the distance indicator with a known dimension in ultrasound images. A manual designation of the approximate edge on each frame was used to outline the boundaries for nipple, hard palate, and tongue. A self-determined baseline or stationary pixel(s) was first fixed for dimension measurements,

Table 2: Nipple width and length changes vs. pressure variations while feeding.

Dyad No.	Nipple Width Change	Nipple Length Change	Vacuum Pressure Change	Positive Pressure Change
	Δ±SD (mm)		Δ±SD (kPa)	
1	1.55±0.32	2.51±0.62	-7.14±0.13	0.86±0.38
2	1.64±0.50	3.03±0.98	-13.79±1.99	2.28±0.15
3	1.80±0.37	3.22±0.28	-10.04±0.34	10.73±0.10
4	1.47±0.35	3.06±0.27	-20.32±1.78	2.04±0.10
5	1.26±0.19	3.66±0.49	-19.56±1.33	2.72±0.04
6	1.32±0.73	2.83±0.37	-11.09±0.57	5.79±0.70

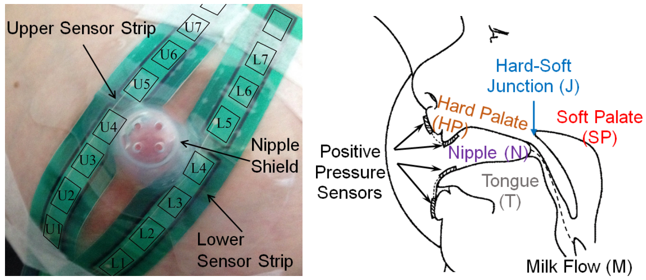
as shown in Figure 2, to eliminate difficulties in distinguishing the nipple from the areola on ultrasound images. The nipple width and length from the baseline were measured for six infants from ultrasound images obtained without the use of a nipple shield for a minimum of one nutritive suck cycle. All nipple dimension changes measured from ultrasound are given in Table 2. To determine the nipple's compressibility, the apparent strain ratio, ν, was calculated as follows [37]:

$$\nu = \frac{\frac{L_f}{L_i} - 1}{1 - \frac{W_f}{W_i}} \tag{1}$$

where L_i and W_i are the nipple's initial length and width, and L_f and W_f are the nipple's length and width at different times during the nutritive suck cycle.

The I-Scan System by Tekscan, Inc. along with two pressure mapping sensors #9801 and #9830 were used to capture the peripheral oral pressure applied by infant oral cavity. The thickness of the sensors are 0.178 *mm* and are designed to be cut into strips for use over 10 μm thick curved surfaces. The maximum pressures are 34 kPa and 69 kPa for #9801 and #9830 sensors, respectively. Since no prior studies were found to provide a range of pressures applied while at the breast, initial layouts and measurements were made with Sensor #9830. Once maximum pressures were determined to be less than 34 kPa (max recorded pressure was 23.6 kPa), Infants 1 and 2 were measured with Sensor #9801 at manufacturer default sensitivity level of S-21 to allow for smaller incremental pressure resolution. When Sensor #9801 became worn, the remaining infants were measured with Sensor #9830 and sensitivity was raised to yield smaller incremental pressure resolutions and maximize data acquisition, particularly for the younger participants. Sensor and sensitivity for each dyad is reported in Table 3. Each sensor was cut along the guidelines provided on the sensor and the raw cut edges were smoothed with a 600 grit file to prevent the sensor edges from cutting into the mother's skin. Once the final layout was determined by experimentation on 3 dyads, two strips from the sensor were attached to the breast with tape away from the nipple and covered with a 0.1 *mm* thin breast shield to minimize moisture exposure to the strips and prevent the strips from entering the mouth of the infant. For infants who regularly breastfed without a nipple shield, the tip of the shield was cut off to allow the nipple to move normally within the oral cavity. Since the width of the strips was too wide to comfortably fit around the nipple under a shield and the angle between areola and nipple was too sharp, the strips were placed along the top and bottom of the areola as close to the base of the nipple as possible (≤ 5 *mm*). Prior to placement, the mother was asked to demonstrate how she would hold the infant and the strips were oriented to approximate the location of the maxilla, or upper jaw, and mandible, or lower jaw, and lips of the infant while suckling (see Figure 3). The position of sensors with individual sensels are marked, where U1-U7 indicates the sensels below the maxilla and L1-L7 show the sensels below the mandible. The sensels that were not located under infant's mouth were ignored. The sensors were zeroed and calibrated according to manufacturer guidelines using the I-Scan built in multi-point calibration algorithm. Once each data set was calibrated, the data became comparable with other data sets with an accuracy specification of ±10% of calibrated saturation pressure. The data acquisition hardware yielded 256 levels of pressure resolution between 0 and calibrated saturation level. Dyad #4 had the largest range with saturation pressure of 63.4 kPa which provided incremental pressure resolution of approximately 0.25 kPa. The sampling frequency was 100 Hz.

Intra-oral vacuum pressure was captured as outlined by Geddes et al. [1], except the supply line for the pressure transducer was filled with water instead of mother's expressed breast milk and placed alongside the nipple on top of the nipple shield when used. The sampling frequency for the vacuum pressure was 1000 Hz. When possible, both vacuum pressure and ultrasound



(a) (b)

Fig. 3: Tekscan sensor strip placement, where U1 - U7 are the sensels below the maxilla, and L1 - L7 are the sensels below the mandible.

Table 3: Clinical data for vacuum pressure and positive pressure experiment.

Dyad No.	Infant Age	Nursing Time(s)	Vacuum Pressure (kPa)		Maxilla Pressure (kPa)		Mandible Pressure (kPa)		Sensor No.	Sensitivity Level
			Mean±SD	Max	Mean±SD	Max	Mean±SD	Max		
1	18 weeks	296.0	-9.07±9.15	-40.78	2.70±4.18	19.02	0.36±0.26	3.49	9801	S-21
2	6 days	198.6	-6.77±6.82	-25.98	1.01±0.60	5.73	0.84±0.28	3.97	9801	S-21
3	4 weeks	404.7	-3.54±3.69	-21.65	7.92±1.81	12.48	5.01±2.54	10.8	9830	S-24
4	10 weeks	355.7	-8.49±8.94	-29.54	0.96±0.31	1.68	1.03±0.24	1.51	9830	S-21
5	11 weeks	537.6	-10.19±11.13	-42.66	2.37±0.27	3.23	1.24±0.92	3.24	9830	S-28
6	3.5 weeks	50.4	-4.62±5.83	-9.47	1.40±0.82	5.17	1.54±0.95	8.76	9830	S-24

images were recorded without the use of a nipple shield prior to testing for peripheral oral pressure. When ultrasound was not available, the changes in frequency of suckling from the vacuum pressure readings were used to estimate periods of nutritive and non-nutritive suckling.

Two different sensor systems were used to measure both the intra-oral vacuums and the peripheral oral pressures simultaneously, thus timeline matching for relating the pressure data with infant's suckling during breastfeeding was essential for the purpose of data analysis. The relationship between infants' mouth movement and the vacuum pressure are well documented by Geddes et. al. [1]. Using ultrasound images to visualize milk ejection, the dynamic pattern of peripheral oral pressure was correlated to the intra-oral vacuum pressure for six infants to eliminate the experimental time gaps. Ignoring time periods when the infants were not actively suckling, the average pressure values plus standard deviation were calculated for all infants, and shown in Table 3.

Files of raw sensor readings were downloaded from the related Tekscan software for each measuring system and imported into MATLAB with user defined programs. After applying unit conversion, all sensor data were organized and stored in MATLAB files. Two out of 6 infants were tested using Sensor 9801, and the other 4 infants were tested using Sensor 9830. Sensor 9801 showed step-like increases for Infants #1 and #2, whereas Sensor 9830 did not record significant step-like patterns for Infants #3, #4, #5, and #6. Step-like data for Sensor 9801 appeared after these infants had been nursing for some time ($\geq$100 seconds). Examination of individual sensel cells revealed that one sensel displayed a constant value, likely caused by wrinkling, crimping, or folding of the individual sensel that resulted in the high pressure reading [38]. For data processing purposes, those values were removed to keep the pattern of the original data (see Figure 4). Variations in denoised pressure values on individual sensels on sensor strips under the maxilla and mandible for Infant #3 is shown in Figure 5.

Raw sensor data still showed an arbitrary range of white noise and some unpredictable outliers that needed to be eliminated before analysis. A post-processing filter based polynomial denoising algorithm known as BUTTERWORTH with a MATLAB command BUTTER [39] was applied for the overlapped experimental and the noise signals. Beginning with the transfer function for an all-pole system of order n, the frequency response of a filter can be modeled as a polynomial of complex

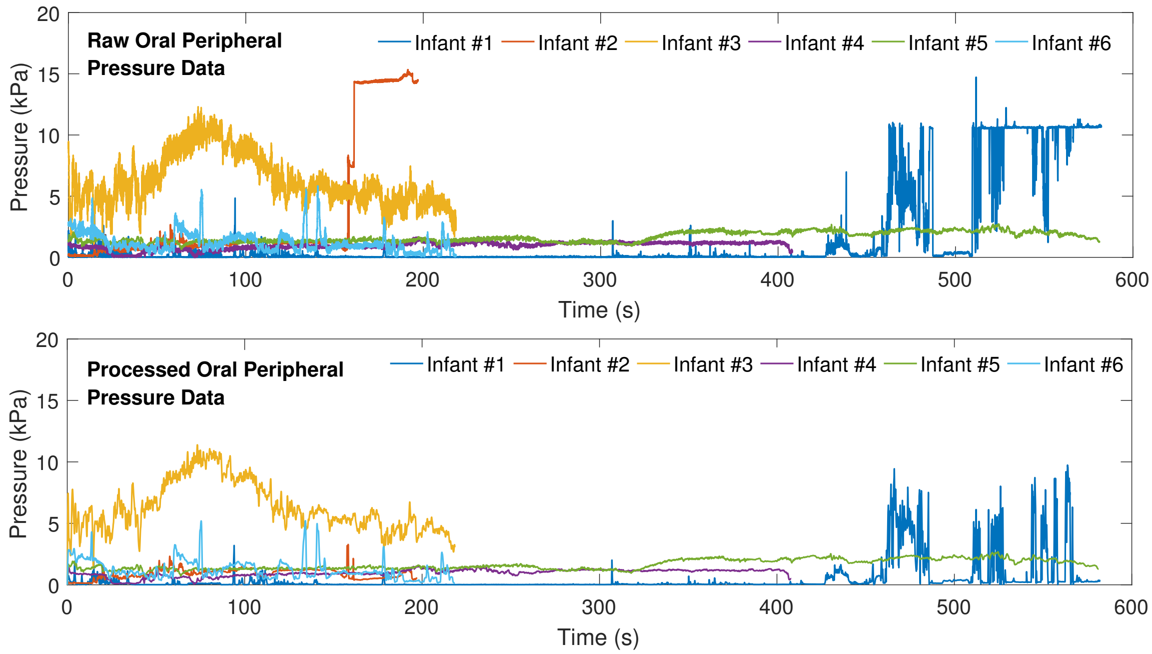


Fig. 4: A comparison of raw data (upper figure) and processed data (lower figure) of sensor strips demonstrates the benefits of additional filtering and presents a clearer picture of peripheral oral pressures applied to the areola.

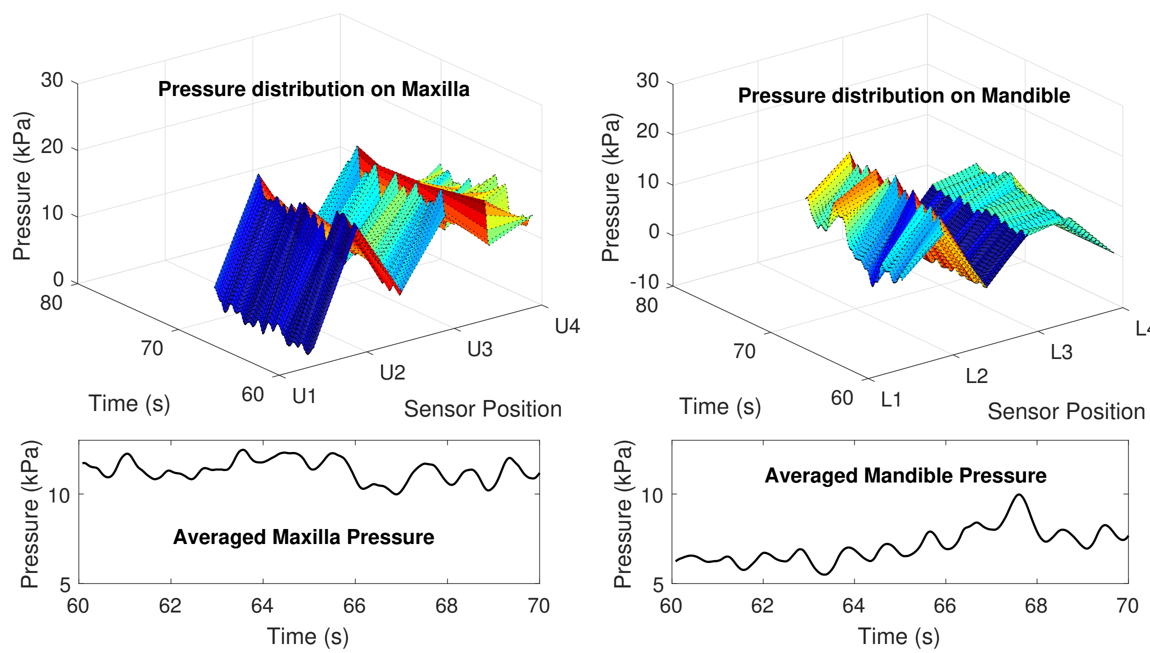


Fig. 5: Denoised pressure distribution along the sensor position (upper) and average for maxilla pressure and mandible pressure of Infant #3 (lower) with milk transfer.

variable $s = \sigma + j\omega_c$ [40]. The resulting transfer function appears as:

$$H(s) = \frac{K}{1 + c_1(s/\omega_c) + c_2(s/\omega_c)^2 + ... + c_n(s/\omega_c)^n} = \frac{b_n s^n + b_{n-1}s^{n-1} + ... + b_0}{a_n s^n + a_{n-1}s^{n-1} + ... + a_0}, \quad (2)$$

where $c_1, c_2, ..., c_n$ are the scalar constants in the denominator of $H(s)$ for the all-pole system, K is the gain of the system,

$a_0, a_1, ..., a_n$ are denominator parameters, and $b_0, b_1, ..., b_n$ are numerator parameters. The frequency domain behavior of a BUTTERWORTH filter allows one to attenuate the noise at the unwanted frequency. This method has its advantages in analyzing discontinuities and in keeping the spikes which would reflect some of the oral patterns during breastfeeding. MATLAB achieves the command by [B, A] = butter(N,ω_c,'low'). The first parameter N in this command denotes the order of a digital 'BUTTERWORTH' filter. The order $N = 2$ was chosen because 2nd order is sufficient for typical sensor data. The second parameter ω_c is the normalized cutoff frequency. The cutoff frequency ω_c must be $0.0 < \omega_c < 1.0$, with $\omega_c = 1.0$ corresponding to half of the sample rate. The last string 'low' indicates that the function returns low-pass filter coefficients. The 'BUTTERWORTH' algorithm in MATLAB returned a denominator vector $A = [a_0, a_1, ..., a_n]$ and an numerator vector $B = [b_0, b_1, ..., b_n]$, which were used to construct the filter $H(s)$ to obtain the denoised data. The comparison of denoised data and the original data is presented in Figure 4.

3 Results and Discussion

Milk ejection was visualized in the ultrasound images. The suck cycle showing milk ejection is known as nutritive suckling [1]. Figure 3a demonstrates a proper attachment to the breast with sensor strips as the nipple was able to reach the hard and soft palate junction [8]. As observed in Figure 3b, the tongue, hard palate, and soft palate were wrapped around the nipple during milk ejection during one suck cycle. In ultrasound movies, cycling motion of infant's anterior tongue and palate was visualized. Also, as observed in Figures 2a and 2b, nipple was observably elongated and compressed when infants moved their tongue up verses when they moved their tongue down. Maximum nipple width and minimum nipple length were observed when infant's tongue was moving to the lowest position in ultrasound movies during nutritive suckling cycles. As the infant was moving his tongue up, the nipple width was decreasing and the nipple length was increasing until reaching its maximum change with infant's tongue at its highest position.

Positive oral pressure data were separated into two groups based on which pressure mapping sensor was used to collect the data. The first two data sets were recorded on Sensor 9801 capable of measuring a maximum pressure of 34 kPa. The sensitivity setting was kept at the manufacturer default value of S-21. For peripheral oral pressures, mean values ranged from 1.01 to 2.70 kPa for maxilla and 0.36 to 0.84 kPa for mandible. The difference between maxilla and mandible pressures for each infant varied from 0.17 to 2.34 kPa with both infants applying greater mean pressure with the maxilla. The differences in maximum positive pressures between maxilla and mandible showed even greater variations between infants, 1.76 to 15.53 kPa. The remaining 4 data sets were recorded on Sensor 9830 which is capable of measuring a maximum pressure of 69 kPa. As with the first group of infants, the second group demonstrated variations between infants, 0.96 to 7.92 kPa for maxilla and 1.03 to 5.01 kPa for mandible, and between maxilla and mandible for individual infants, 0.07 to 2.91 kPa difference.

All infants exhibited an oscillatory pattern for positive oral pressures for both maxilla and mandible. The oscillatory pattern of pressure under the maxilla has not been previously reported and would not be obvious to external observers since the maxilla does not appear to move after forming a teat. Rather movement of the mandible is generally evaluated for correct suckling patterns. While the mean pressure values were below 3 kPa for all infants except Infant #3, the maximum pressure values showed greater variations. The mean positive pressure for all infants combined was 2.78 ± 2.62 kPa for maxilla and 1.67 ± 1.68 kPa for mandible. Peak pressure values averaged 7.88 ± 6.59 kPa and 5.30 ± 3.63 kPa for maxilla and mandible, respectively. The higher mean applied pressure exerted by Infant #3 likely was from sensor placement. As seen in Figure 3a, the sensor strips were placed close to the base of the nipple (≤ 5 *mm*) but with enough distance to prevent the edges from rubbing against the nipple base and causing damage to the skin. The border beside the sensels in Sensor 9801 is 3.2 *mm* and in Sensor 9830 is 5.4 *mm*. So the pressure measurements were recorded no further than 8.2 *mm* and 10.4 *mm* from the base of the nipple for Sensors 9801 and 9830, respectively. The actual placement of the sensor during suckling varied since the amount of areola drawn into the infant's mouth differed for each dyad. As a result, some sensels may have captured lip or chin pressure values instead of gum pressures. However, since a large portion of the areola must be drawn into the oral cavity for the nipple to reach the hard-soft palate junction, it is more likely that the pressure values are from maxilla or mandible.

Studies involving the intra-oral vacuum pressure exerted by infants show great variations of normal values that change over the duration of a single nursing session [3,41,42]. In this study, all infants' intra-oral vacuum pressures are within normal ranges although periods of milk expression did occur when intra-oral vacuum pressure was positive, such as the suck cycles for Dyad #1 shown in Figure 6a. The cause for the milk flow under positive intra-oral vacuum pressure is not clear but could be a result of positive intra-ductal pressures from the let-down reflex or momentum of the milk. Scatterplots comparing the peripheral oral pressure and intra-oral vacuum pressure during milk transfer over a 2 second period, as shown in Figure 6, showed no strong correlations using Method of Least Squares. The strongest correlations were for Infants #2 and #6 (see Figures 6b and 6f) with $\rho = 0.56924$ and 0.71585, respectively. Other regression methods were attempted but failed to provide a uniform shape for all data sets. These two infants were the youngest in the study and thus had the least mature suckle. Previous studies have reported correlations between tongue movement and vacuum pressure [1,3], but none have studied positive oral pressure on the areola. The lack of strong correlation between peripheral oral pressure caused by mandible movement and intra-oral vacuum pressure caused by tongue movement may indicate that the two movements function independently, particularly as an infant matures,

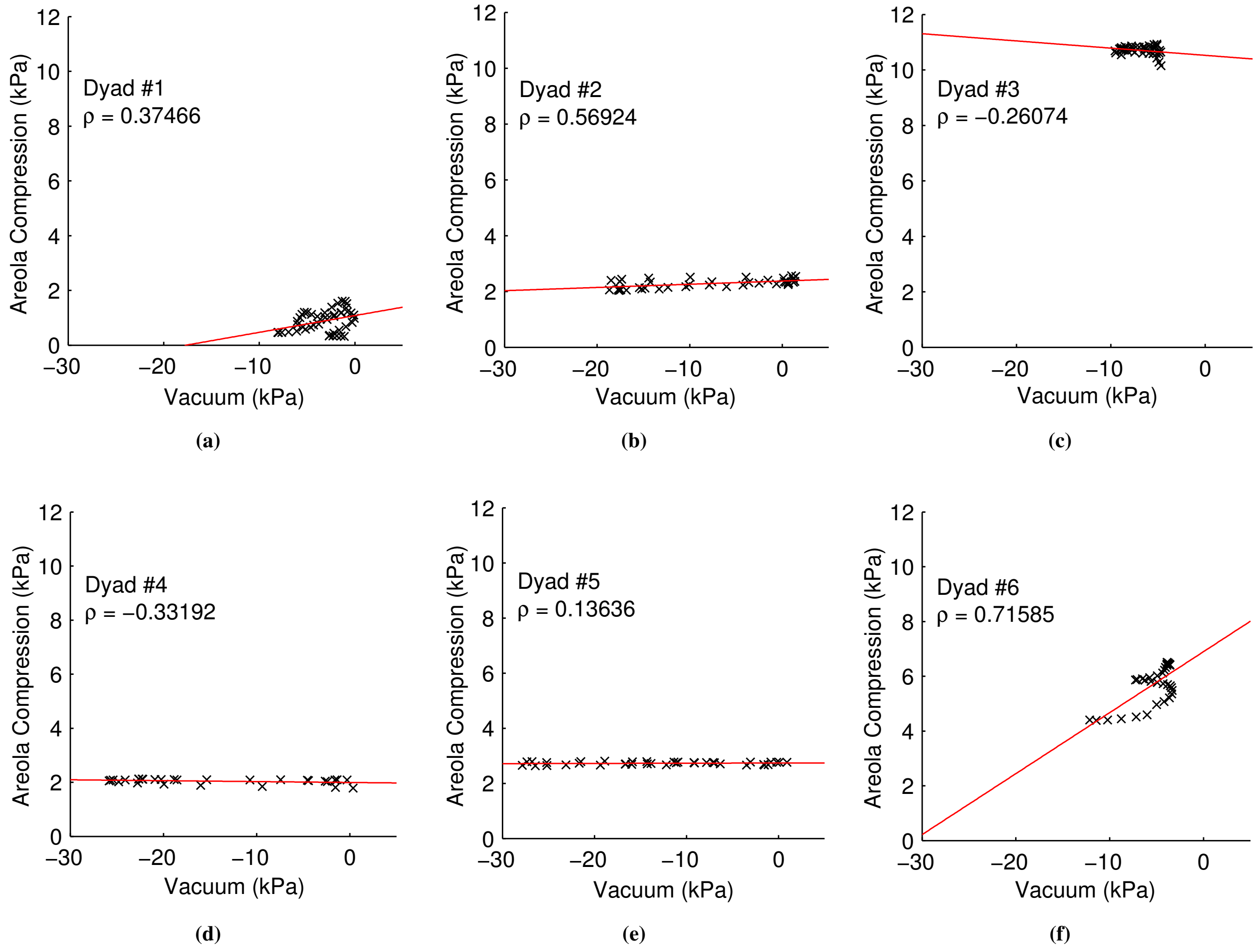


Fig. 6: Most dyads lacked strong correlations between areola compression and vacuum pressures as seen on these scatterplots with estimated regression line and correlation coefficient (ρ).

which would allow the infant two methods of controlling milk extraction by varying pressure on the ducts under the areola and pressure on the nipple. Further study is planned.

The effect of both types of pressures on the breast tissue, specifically the nipple, was evaluated using 3-D scans and ultrasound imaging. Before feeding, a 3-D scan of the breast was made with participants standing, and the width and length of the nipple were measured. Then during feeding, the width and length of the nipple inside the infant's oral cavity were measured for 2 or 3 continuous nutritive suck cycles. It is important to note that the width of the nipple inside the infant's mouth may not match the direction of the width measurement taken from the 3-D scans since many of the infants were held in the cradle position. The nipple was assumed to be approximately circular for this analysis. The percentage of change from rest in width and length were calculated and compared with values found by Smith et al. [43] and found to be comparable to this study at 67±10% and 217±42% for mean±SD horizontal lateral compression and horizontal length changes, respectively.

During the suck cycle, the changes in pressures were compared with the changes in nipple dimensions resulting from the movement of the infant's tongue. The average change in width and length was 1.51±0.20 mm and 3.05±0.39 mm, respectively, while the average pressure change was -13.66±5.32 kPa and 4.07±3.65 kPa for intra-oral and peripheral oral pressures, respectively. The mean values for individual participants are displayed in Table 2. The variations in nipple dimensions were considerably smaller than the variations in both types of pressure and showed no direct correlation to indicate which pressure dominates structural changes to the nipple. However, ultrasound videos provided a clearer understanding between structural changes in the nipple and pressures. As noted earlier, when infant's tongue was in lowest position, the vacuum pressure was at its strongest while compression pressure was at its minimum. At this point, the maximum nipple width and minimum nipple length were observed. Conversely, when infant's tongue was in highest position with weakest vacuum and strongest compression, the nipple length was maximum and width was minimum. These results show that the maximum nipple elongation occurs when oral peripheral pressure peaks and not when intra-oral vacuum peaks. This finding indicates that compression between the tongue and hard palate dominates dimensional changes in the nipple.

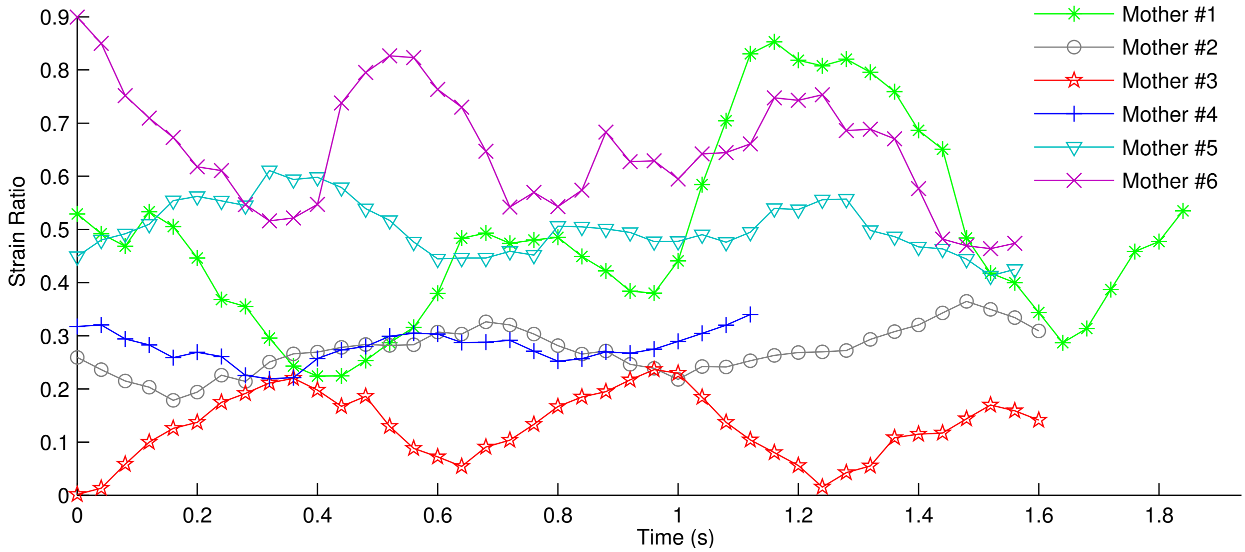


Fig. 7: Non constant strain ratio variations between suck cycles.

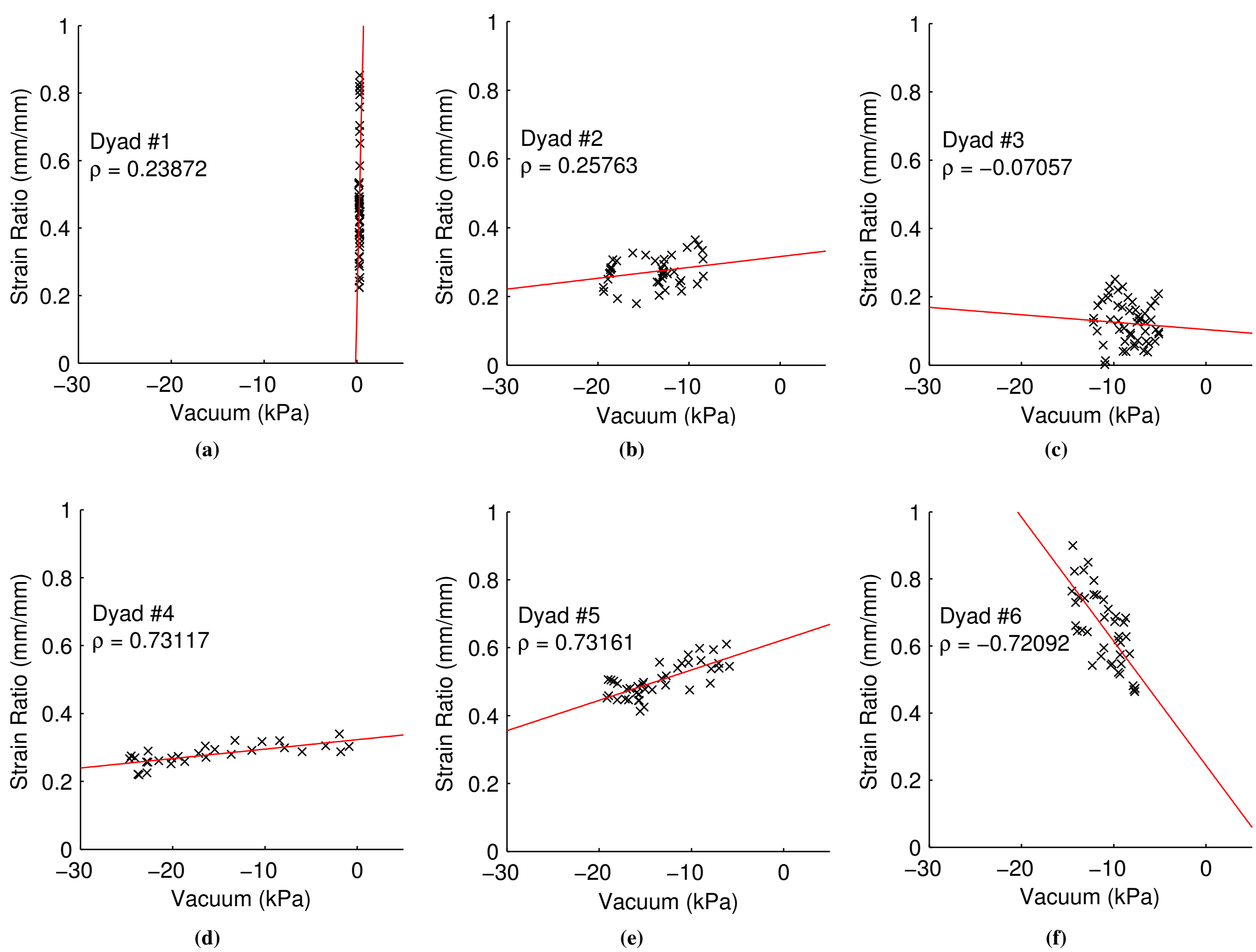
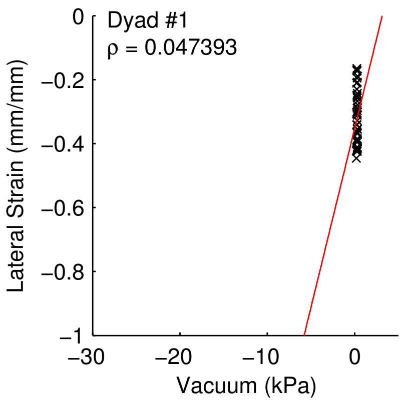
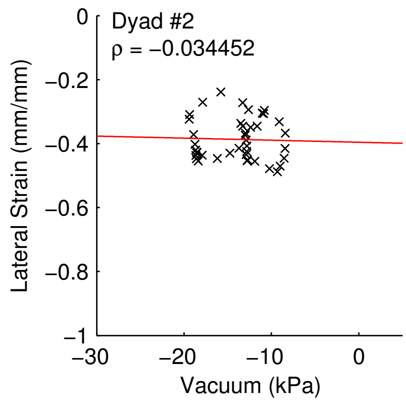


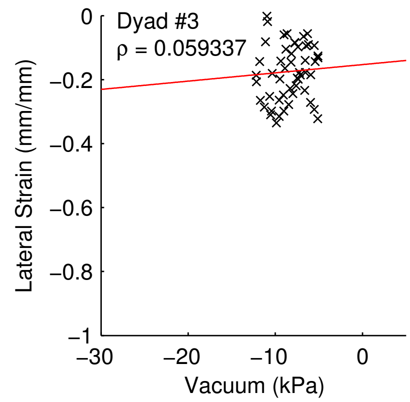
Fig. 8: The effect of vacuum pressure on strain ratio is not consistent between dyads based on scatterplots with estimated regression line and correlation coefficient (ρ). Strain ratio was determined by Equation 1.



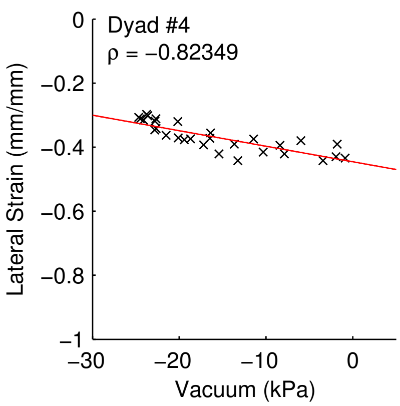
(a)



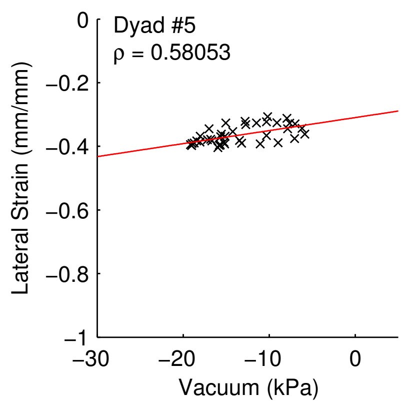
(b)



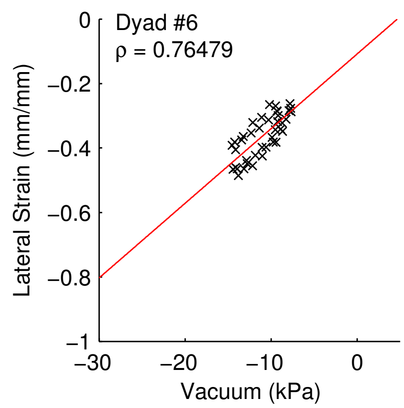
(c)



(d)



(e)



(f)

Fig. 9: Vacuum pressure may influence lateral strain in Dyads #4-6 (Subfig. d-f) based on scatterplots with estimated regression line and correlation coefficient (ρ). Lateral strain was determined by denominator of Equation 1.

From the data collected, the strain ratio for the nipple is calculated on the sagittal plane during a suck cycle with milk transfer. The mean values range from 0.13 to 0.65 and the difference between tongue up and tongue down values, or standard deviation, are all less than 0.18, as shown in Table 1. The variation of strain ratio over the period of a suck cycle is shown in Figure 7[2]. As previously noted, the mechanical properties of the breast have never been studied during lactation nor have the properties of the nipple or areola been measured. Statistical analysis comparing the strain ratio and vacuum showed 3 dyads had weak or no correlation and 3 had moderate correlation. Scatterplots for all 6 dyads are displayed in Figure 8. For the 3 dyads with moderate correlation, Dyads #4 and #5 experienced a decrease in the strain ratio as vacuum strengthened whereas for Dyad #6, the stronger vacuum resulted in higher strain ratio. To understand the effect of the vacuum on nipple changes better, both the lateral and axial strains were compared to the vacuum. For lateral strain, only Dyads #4 and #6 showed moderate to strong correlations although the relationships were opposite to each other (see Figure 9). Dyad #5 showed only a moderate correlation between lateral strain and vacuum. The other 3 dyads showed no correlation. The correlation between axial strain and vacuum was weak for Dyad #4, moderate for Dyads #1 and #2, and strong for Dyad #5 (see Figure 10). The moderate to strong correlations all demonstrated increases in axial strain when vacuum pressure decreased, although despite Dyad #2 having a moderate correlation, their scatterplot (see Figure 10b) shows that axial strain also increased when vacuum was at its mid-point. The lack of consistently strong correlations demonstrate the complexity of infant suckling effects on nipple deformation. Multiple factors need to be considered when evaluating these results.

Measurements of the nipple inside the mouth are based on ultrasound images that may not include the base of the nipple which would also cause errors in calculating axial strain. It should be noted that results for Dyads #5 and #6, which have calculated strain ratios at or above 0.5, are the only two with infants who are imaged while feeding from the left breast although these measurements are within normal limits when compared to other studies [43]. All other images are obtained while feeding

[2]These time periods differ from time periods displayed in Figures 5 and 6

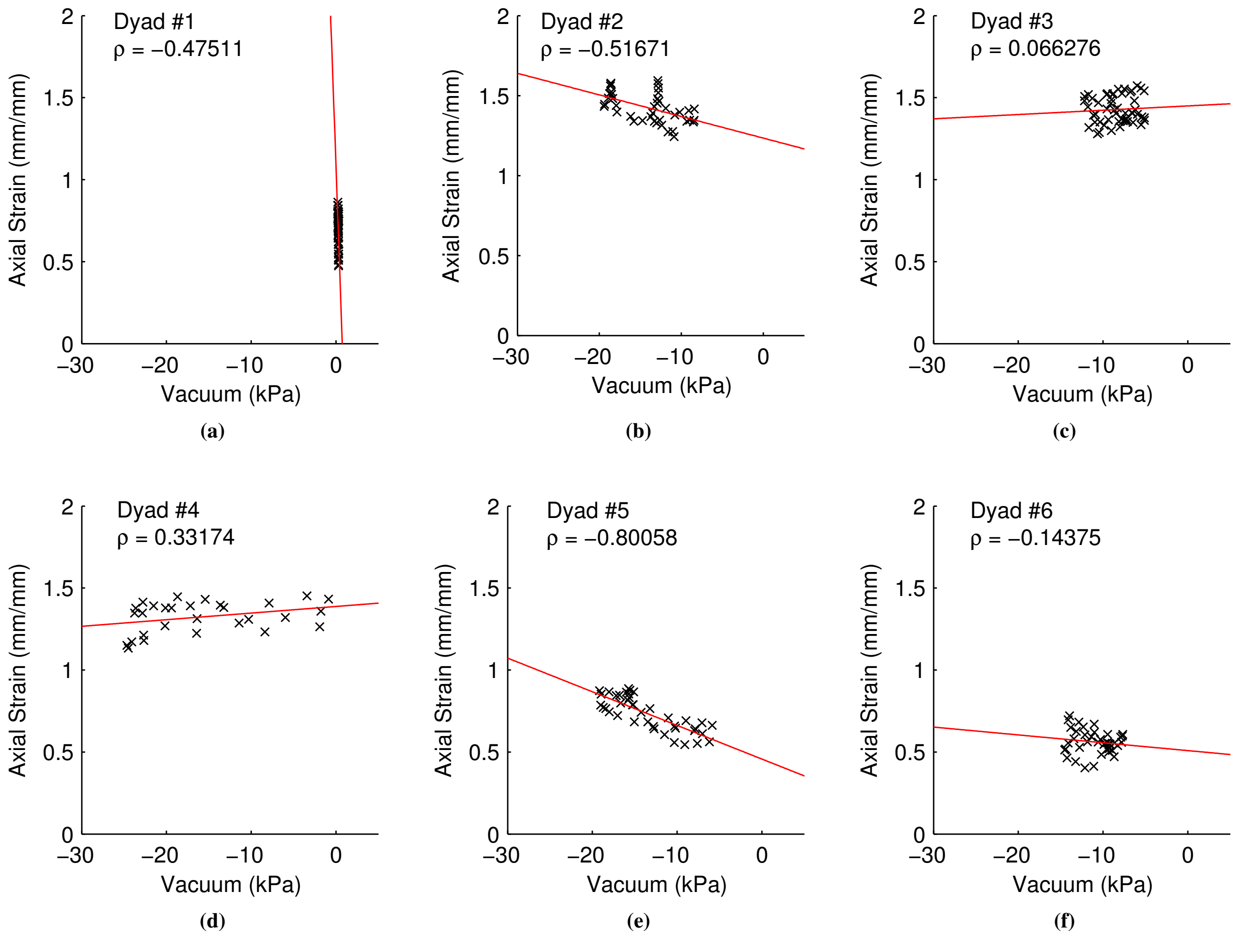


Fig. 10: Vacuum pressure to influence axial strain for only Dyad #5 (Subfig. e) based on scatterplots including estimated regression line and correlation coefficient (ρ). Axial strain was determined by numerator of Equation 1.

from the right breast. Thus, the angle of imaging, which may vary based on which side the infant feeds from, may alter the measurements. While these factors may cause some variance in the data, a greater consideration is the anatomy of the nipple.

During breastfeeding, volume changes within the nipple occur in response to changing pressures. For example in the tongue down position, fluid is moving through the ducts and exerting pressure along the duct walls. If the duct diameter increases during this time, along with the added pressure from the milk flow, then the lateral strain would be lower and the calculated strain ratio would also be lower. Additionally, swelling within the cells of the nipple occurs – as evident from the differences in nipple dimensions postfeed and volume changes in Table 1 – and would impact both lateral and axial strain. Based on the aforementioned facts, the variations in strain ratio between participants is not unreasonable. The small differences between strain ratio for tongue up and tongue down positions suggests that for small strains the strain ratio can be assumed constant even during lactation. However, further investigation into the mechanical properties of the human lactating nipple is planned.

In general, these experimental methods presented limitations that future research should consider when planning further *in vivo* studies in breastfeeding. Breastfeeding is a dynamic process primarily controlled by infants with an auxiliary control system by mothers for lactation, the biological process of producing milk. Many aspects were impossible to control since the infants could not be directed, such as regulating the pressure applied to the breast, feeding position (which impacts angle of imaging), and the volume of breast tissue drawn into the oral cavity. An external recording of the dyads feeding would have assisted in interpreting data and identifying critical data points like pressure from mothers hand on breast. The pressure mapping sensors used were able to handle the curvature of the breast but could not precisely match the interface between the infants mandible/maxilla and areola nor could they capture pressure applied on the nipple. Despite these limitations, additional insight into the biomechanics of breastfeeding has been gained.

4 Conclusion

The dynamics of breastfeeding are extremely complex and require novel methods to capture data. This study investigated the two major pressures exerted by infants during breastfeeding and examined the effect of these pressures on the nipple deformation during suckling. Despite limitations, Tekscan pressure mapping sensors captured the peripheral oral pressure applied to the areola by infants with the maxilla and mandible. Both maxilla and mandible peripheral pressures varied in an oscillatory pattern that corresponded to the oscillatory pattern of the intra-oral vacuum pressure, although the system could not determine the presence of any time lag. All but one infant applied low mean peripheral pressures when compared to the mean intra-oral vacuum pressure with occasional spikes of higher pressures noted. Although most modern studies deemed unimportant the low external pressures applied to the surface of the breast with regard to milk expression, clinical studies with ultrasounds noted milk ducts compressed with very little applied pressure [25, 34–36]. The compression of the milk ducts during expression changes the ductal geometry which then affects the wall shear stress experienced by the milk. The Tekscan system utilized to collect peripheral oral pressures lacked the capability to capture the pressure values applied to the nipple.

After application of initial stresses to form a teat, the nipple during continuous suckling deforms primarily from positive pressure applied to the circumference of the nipple rather than negative vacuum applied to the end. Strain ratio between participants varied with possible causes originating from the non-homogeneous anatomy of the nipple, constriction from the nipple shield, and in response to volume changes. As with most human tissues, strain ratio varies greatly on the cellular level and responds at times by sliding or buckling of fibrils [30,31]. For each individual, the standard deviation for strain ratio during suckling was no more than 0.18 and may be approximated as a constant over the course of a suck cycle. Further investigation of the material properties of the human lactating breast and the pressure applied on the surface of the breast during suckling is required before the relationship between positive and negative pressures can be conclusively determined with regard to milk flow.

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