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Application of Statistical Analysis and Machine Learning to Identify Infants' Abnormal Suckling Behavior

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ABSTRACT Objective: Identify infants with abnormal suckling behavior from simple non-nutritive suckling devices. Background: While it is well known breastfeeding is beneficial to the health of both mothers and infants, breastfeeding ceases in 75 percent of mother-child dyads by 6 months. The current standard of care lacks objective measurements to screen infant suckling abnormalities within the first few days of life, a critical time to establish milk supply and successful breastfeeding practices. Materials and Methods: A non-nutritive suckling vacuum measurement system, previously developed by the authors, is used to gather data from 91 healthy full-term infants under thirty days old. Non-nutritive suckling was recorded for a duration of sixty seconds. We establish normative data for the mean suck vacuum, maximum suck vacuum, suckling frequency, burst duration, sucks per burst, and vacuum signal shape. We then apply computational methods (Mahalanobis distance, KNN) to detect anomalies in the data to identify infants with abnormal suckling. We finally provide case studies of healthy newborn infants and infants diagnosed with ankyloglossia. Results: In a series of case evaluations, we demonstrate the ability to detect abnormal suckling behavior using statistical analysis and machine learning. We evaluate cases of ankyloglossia to determine how oral dysfunction and surgical interventions affect non-nutritive suckling measurements. Conclusions: Statistical analysis (Mahalanobis Distance) and machine learning [K nearest neighbor (KNN)] can be viable approaches to rapidly interpret infant suckling measurements. Particularly in practices using the digital suck assessment with a gloved finger, it can provide a more objective, early stage screening method to identify abnormal infant suckling vacuum. This approach for identifying those at risk for breastfeeding complications is crucial to complement complex emerging clinical evaluation technology. Clinical Impact: By analyzing non-nutritive suckling using computational methods, we demonstrate the ability to detect abnormal and normal behavior in infant suckling that can inform breastfeeding intervention pathways in clinic. Clinical and Translational Impact Statement: The work serves to shed light on the lack of consensus for determining appropriate intervention pathways for infant oral dysfunction. We demonstrate using statistical analysis and machine learning that normal and abnormal infant suckling can be identified and used in determining if surgical intervention is a necessary solution to resolve infant feeding difficulties.

INDEX TERMS Abnormal, ankyloglossia, breastfeeding, clinical, machine learning, diagnosis, digital assessment, Mahalanobis distance, non-nutritive suckling, vacuum.

I. INTRODUCTION

BREASTFEEDING benefits both mothers and infants by protecting their health and development [2]. Evident from a growing body of literature, breastfeeding infants experience lower rates of diabetes, allergies, cardiovascular disease, and other chronic conditions [3], [4], [5],

[6], [7], [8], [9], [10], [11]. Mothers benefit from a decreased risk of breast cancer, ovarian cancer, and postpartum depression [12]. The Center for Disease Control and Prevention (CDC), the World Health Organization (WHO), and the American Academy of Pediatrics (AAP), among many other health organizations, recommend infants exclusively breastfeed for at least six months to attain optimal benefits [13], [14], [15]. Despite the fact that over 80% of mothers attempt to breastfeed, breastfeeding rates fall to a paltry 25% at six months after birth in the United States [16], [17]. While many factors are responsible for breastfeeding cessation, abnormal infant suckling behaviors—such as high intraoral vacuum—are known to contribute to nipple pain and injury, affecting a mother's ability to persistently breastfeed [18], [19], [20]. Other abnormal suckling behaviors, including low intraoral vacuum and suck disorganization, affect latch and milk transfer, causing a down-regulation of the mother's milk supply [21], [22], [23]. Thus, infant suckling competency is an essential aspect of successful breastfeeding.

Infant suckling can be described as nutritive sucking (NS) or non-nutritive sucking (NNS). In nutritive suckling, infants coordinate sucking, swallowing, and breathing to intake fluid from a breast or bottle. In non-nutritive suckling, infants do not receive nutrient flow and the suck is from basic instinct when offered an empty or uninitiated breast, pacifier, finger, or object [24], [25], [26]. Prior studies on preterm infants have shown that non-nutritive suckling establishes the foundation for nutritive suckling [25], [27]. Non-nutritive suckling is characterized by suckling vacuum and expression pressure. In this paper, we focus on suckling vacuum as a starting point as prior research has shown that infant's intraoral vacuum is essential to effective milk extraction [28]. An analysis of NNS vacuum signals can provide infant oral measurement information such as mean oral vacuum, suckling frequency, burst duration, sucks per burst, maximum vacuum, and signal shape, details important in understanding infant suckling behavior [23], [29]. These measurements provide key information on an infant's suckling ability and can be used to determine infant suckling irregularities.

Over the years, there has been considerable work to produce objective NNS measurements using catheters, pneumatic and fluid-based instruments, and compact devices to measure infant non-nutritive suckling [23], [30], [31], [32], [33], [34], [35], [36], [37], [38], [39]. These devices have focused on *preterm* infants. However, there has been little consideration of how abnormal non-nutritive suckling shapes could be detected in *otherwise healthy full-term infants*, a much larger patient cohort. Akbarzadeh et al. developed a sensitized compact pacifier to measure non-nutritive suckling in preterm infants [40]. Features such as oral pressure, suckling duration, and frequency were used in a predictive algorithm to determine preterm infant feeding readiness. Chen et al. proposed a non-nutritive suckling device using pneumatic pressure sensors and performed a comparative study between NNS measurements in bottle feeding versus breastfeeding [23]. Lau et al. introduced a sensitized digital assessment via a catheter attached to the clinician's index finger that measures intraoral vacuum using a pressure transducer [37], [38], [39]. As these NNS measurement systems continue to emerge, approaches such as ultrasound [28], [41] are also being used to provide objective, visual measurements of infant oral mechanics during breast and bottle feeding. Despite the advantages of ultrasound, this approach is difficult to adopt more broadly as a widespread screening tool and would require the investment in trained personnel and specialized equipment to utilize.

Today, despite all these remarkable developments in technology for clinical diagnostics, the wealth of science regarding feeding mechanics, milk supply, and the growth of trained medical assistance for mothers and infants over the last decade, the simple *digital suck examination* remains the standard in clinical practice [42]. In a digital suck examination, the trained clinician inserts a finger into the mouth of the infant to evaluate their suckling vacuum. Evaluating suckling vacuum via the finger, even by a trained clinician, is subjective and suffers from variability among clinicians based on experience. We aim to replace healthy term infant feeding diagnostics with an objective tool.

To provide context for our objective evaluation, we consider ankyloglossia (tongue-tie), a sporadic oral dysfunction that can cause difficulty with breastfeeding [43]. The prevalence of ankyloglossia is unclear, estimated to be 1 to 10% [44] due to the lack of diagnostic criteria, but most often estimated at 7% [45]. However, in recent years, the treatment of suspected ankyloglossia via frenotomy—where a restricted lingual frenulum with tissue tying the tongue to the base of the mouth is cut and released—has grown tenfold in less than a decade. The growth in frenotomies has largely been an attempt to improve breastfeeding rates with little to no evidence to support this course of action [46]. Risks associated with surgical intervention include bleeding, pain, infection, ulceration, and other complications [47], [48], while immediate and long-term direct benefits of prescribing frenotomy remain unclear. The clinical community continues to disagree over the necessity of surgical intervention in ankyloglossia, principally due to a lack of objective assessment tools to serve as a basis for making the decision to pursue a frenotomy. We specifically seek to determine if our NNS data can provide sufficient objective data to make a clinical decision to pursue a frenotomy.

In this paper, we apply an two computational methods using Mahalanobis distance and KNN to detect abnormalities in suckling vacuum signals produced from our real-time NNS system. The algorithms consider the collective contributions of 91 infant suckling measurements. From these infants, we establish normative data for eight measurement parameters in non-nutritive suckling shape: mean suck vacuum, max suck vacuum, suckling frequency, burst duration, sucks per burst, and three frequency parameters that affect the signal shape. In a series of case evaluations, we report the

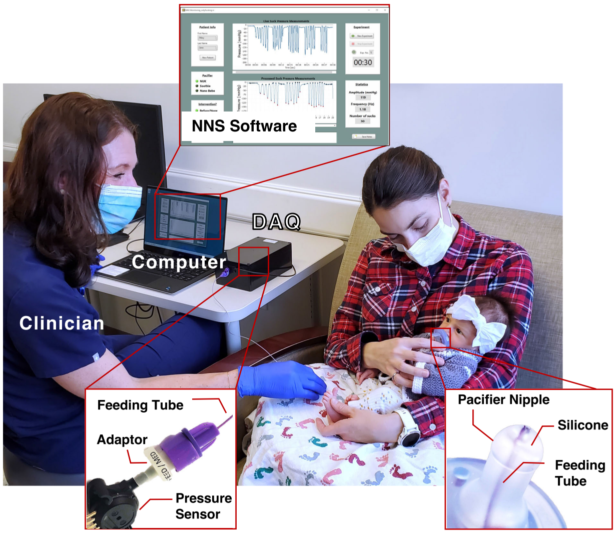

FIGURE 1. An image of the non-nutritive suckling measurement system developed in prior work [1] to measure intraoral vacuum profiles of infants. The system is comprised of an instrumented pacifier, pressure sensor, data acquisition board (DAQ), and computer.

identification of normal versus abnormal suckling behavior using Mahalanobis distance and KNN in healthy newborn infants and infants diagnosed with ankyloglossia, a spontaneous, congenital condition indicated by a restrictive lingual frenulum [44]. Our study establishes a foundation for using computational methodologies applied to objectively collected data to evaluate infant suckling shapes and patterns, with the aim of developing early screening tools to guide interventions to establish, maintain and improve breastfeeding rates.

II. MATERIALS AND METHODS

A. NON-NUTRITIVE SUCKLING MEASUREMENT SYSTEM

In prior work, the authors have demonstrated the application and use of a non-nutritive suckling system in a clinical environment with 30 full-term infants. The system shown in Figure 1 consists of a modified disposable pacifier with an integrated feeding tube that is connected to a pressure sensing unit. A data acquisition board (DAQ) is used to collect measurements and a custom LabVIEW (National Instruments) software interface was developed to enable clinicians to immediately visualize and interact with the collected NNS signals.

B. SUBJECT RECRUITMENT

Healthy full-term infants (37 to 42 weeks) under 30 days old ($n = 91$) were recruited from the UC San Diego Center for Voice and Swallowing, UC San Diego Health La Jolla Pediatrics, and the UC San Diego Jacobs Medical Center. Approval from the Institutional Review Board (#80070, 13 September 2021) was obtained before recruitment started. The research aimed to study infant non-nutritive suckling using an objective measurement system. Mothers and infants were recruited to participate in the study during routine postpartum care with their general pediatrician or while consulting with feeding specialists at their respective locations. Infant inclusion criteria included full-term healthy infants establishing breastfeeding and without significant birth or postpartum complications. Mothers provided written and informed consent to participate in the study.

C. STUDY DESIGN

Infants were evaluated using standard clinical assessments: a digital (finger-based) suck assessment of their intraoral vacuum, the Hazelbaker Assessment Tool, and the Bristol Tongue Assessment Tool. The Hazelbaker Assessment Tool [49] and the Bristol Tongue Assessment Tool [50] are both validated clinical assessment scales for evaluating the lingual frenulum's appearance and tongue mobility. We define the digital suck assessment scale to be 0 is no vacuum, 5 is normal vacuum, and 10 is high vacuum. Collectively, these assessments are used to identify infants with ankyloglossia and provide general metrics for oral dysfunction. Clinicians were blinded to device data in this study and performed evaluations solely based on standard practice. After clinical assessments, parents were provided the opportunity to introduce the non-nutritive suckling system to acquire a sixty second measurement of their infant's intraoral suckling vacuum.

D. SIGNAL PROCESSING

Measurement of the infant's suckling vacuum using our non-nutritive suckling (NNS) device over a period of sixty seconds produces valuable data reflecting the characteristics of non-nutritive suckling. Data was collected on 91 subjects to compute the mean suck vacuum, maximum suck vacuum, suckling frequency, burst duration, sucks per burst, and the *suckling shape*, all for each individual. In prior work [1], we explained how the mean suck vacuum, maximum suck vacuum, suckling frequency, burst duration, and sucks per burst were extracted from infant NNS signals. In this work, we provide an additional evaluation: the infant's suckling shape, describing the shape of the vacuum versus time measurement. Normal infant suckling is described as smooth and regular, almost sinusoidal [28], [37], [51], [52]. Deviations in the smoothness and periodicity of this suckling shape may be correlated to irregularities in the infant's suckling and can be detected using frequency analysis [1].

In prior work [1], we showed there were three distinct infant suckling shapes: smooth sinusoidal, "sharp valley", and "double valley", arbitrary definitions that indicate information in the signal that might be correlated to disordered suckling. The NNS signals can vary in amplitude and period over the measurement time. To determine contributions caused by the shape of the suckling vacuum signal with respect to time, each suckling event was isolated and normalized in both amplitude (-1 to 0) and period (0.5 sec). Each suckling cycle is defined as the peak-valley-peak profile during suckling as described in prior work [1]. The complete

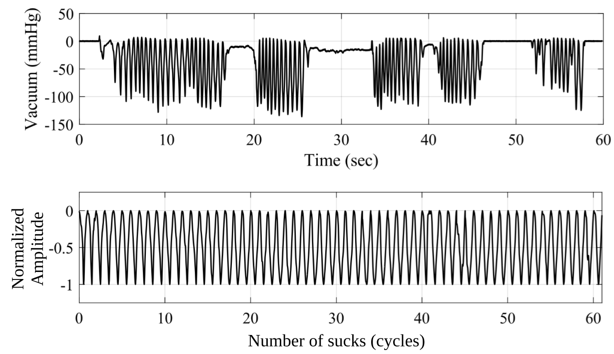

FIGURE 2. An example (top) of a 60-second non-nutritive suckling shape as measured using the NNS shows the irregular nature of suckling by a typical infant. Normalization of each suckling event—there were 61 total events in this measurement—produces (bottom) a far more regular signal while retaining suckling shape. The normalized parameters are unit-less in the lower plot. Note the aperiodic details in this normalized signal that will be useful later.

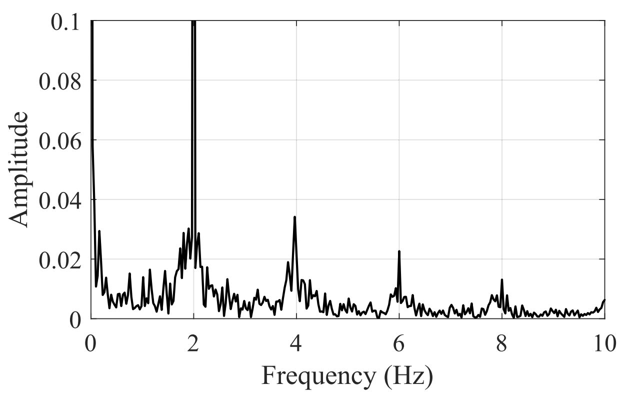

FIGURE 3. A typical example of the FFT-transformed normalized NNS data, indicating the clear appearance of principal frequency contributions at 4, 6, and 8 Hz to the NNS signal. For this reason, the amplitude of the signal at these frequencies was tracked and included in each infants' profile. Note that the 2 Hz response is omitted from the later analysis as it is generally present [1], [53], [54] in the suckling data of all infants.

normalized NNS signal of typically >60 suckling events was passed through a fast Fourier transform (FFT) to identify the principal frequencies at 4 Hz, 6 Hz, and 8 Hz in most NNS signal data. These frequencies are known to appear in infant suckling measurements [1]. Figure 2 and Figure 3 show our analysis to isolate the principal frequency components that contribute to the shape of the NNS signal. Consequently, the signal amplitudes produced at these frequencies were recorded and retained as a part of each infant's suckling shape.

E. ANOMALY DETECTION USING ROBUST AND MAHALANOBIS DISTANCE

In this application, we use the Mahalanobis distance to detect and identify a subgroup of neonates that exhibit NNS measurements that appear to be outliers from the majority of the population. The NNS characteristic data collected from 91 neonates were found to be normally distributed and verified using the Shapiro-Wilk test [55]. Among many statistical distance measuring tools, the Mahalanobis distance, the distance between a subject and the mean of the distribution in terms of the number of standard deviations, is known for its ability to identify outliers, particularly multivariate outliers in normally distributed data. It and its many variations have been used in applications from finance [56] and neurocomputing [57] to medical diagnosis [58]. The Mahalanobis distance may be determined from

$$\mathrm{MD} = \sqrt{(X-\mu)^T S^{-1}(X-\mu)}. \tag{1}$$

In Equation 1, the vector X contains all eight NNS measurement parameters, namely, mean suck vacuum, max suck vacuum, suckling frequency, burst duration, sucks per burst, and three frequency parameters affecting signal shape (4 Hz, 6 Hz, and 8 Hz), representing the sucking behavior of each neonate; μ is the arithmetic mean vector; and S is the covariance matrix. Neonates with a large Mahalanobis distance are classified as outliers [59]. The robust Mahalanobis distance (RMD) was used in this analysis to reduce effects of outliers on the mean value of the population. The minimum covariance determinant method introduced by [60] of the robust Mahalanobis distance is defined as:

$$\mathrm{RMD} = \sqrt{(X-\mu_R)^T S_R^{-1}(X-\mu_R)}. \tag{2}$$

In this equation, μ_R and S_R are the robust estimate of the mean vector and the covariance matrix, respectively.

Neonates' data points whose distance away from the mean exceeded the threshold value, $\xi = \sqrt{\chi^2_{p,r}}$, were identified as outliers. This threshold value is a function of the number of degrees of freedom (p) and the outlier fraction (r). Since the Mahalanobis distance has a chi-square distribution, we determine the threshold value by calculating the inverse cumulative distribution function of the chi-square distribution with degree of freedom p = 8 (number of NNS measurement features), and outlier fraction r = 0.07 (7% prevalence of ankyloglossia in infants) [45].

In this way, we are able to delineate infants with outlier suckling behavior from the main group of infants with normal suckling behavior, without requiring any additional information or graphical interpretation. In the results that follow, the plots are provided for the reader's understanding, and show the results of this process *which already identify the outliers prior to plotting*: there is no graphical fitting being performed.

F. K-NEAREST NEIGHBORS (KNN) CLASSIFICATION

In addition to employing a statistical approach to autonomously classify normal versus abnormal NNS patterns, we leverage the K-Nearest Neighbors (KNN) algorithm to further explore the dataset. The KNN algorithm is a widely utilized machine learning method for classification tasks, including discerning various patterns in data [61]. Using the same dataset with eight NNS measurement features from 91 infants, we employ KNN to distinguish normal from abnormal infants. The KNN algorithm assesses the similarity between a data point and its nearest neighbors in a feature

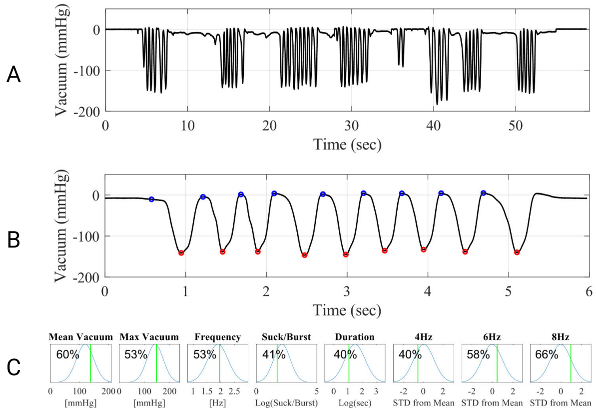

FIGURE 4. Subject 18: A typical infant's NNS suckling response and the results of computing the eight parameters that describe its principal characteristics. (a) Full 60 s NNS measurement, (b) 6-second sample from the third suckling burst, and (c) statistical distribution plots of all eight NNS measurements.

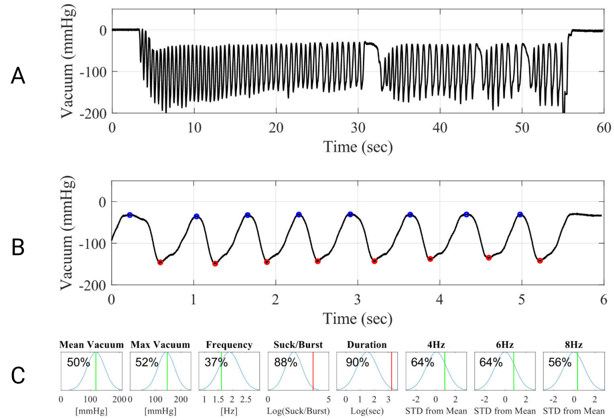

FIGURE 5. Subject 25: An infant with extended bursts of suckling. (a) Full 60 s NNS measurement, (b) 6-second sample from the first suckling burst, and (c) statistical distribution plots of all eight NNS measurements.

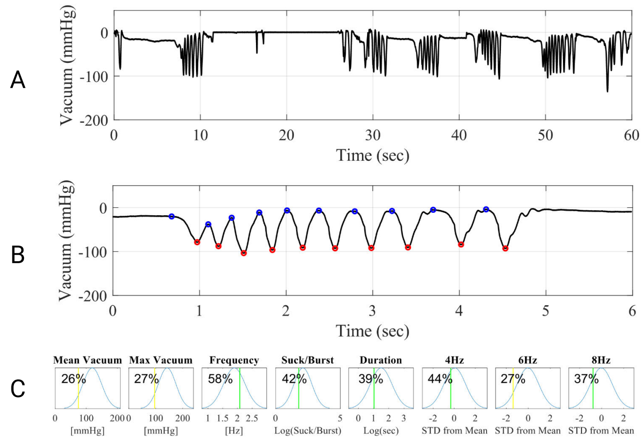

FIGURE 6. Subject 36: An infant with weak and infrequent suckling. (a) Full 60 s NNS measurement, (b) 6-second sample from the fifth suckling burst, and (c) statistical distribution plots of all eight NNS measurements.

space and classifies the data point as a member of one of the surrounding data point's sets based on the classification of the majority of its neighboring data points. Given the multivariate nature of the dataset, KNN provides a robust method for classifying suckling patterns based on the collective behavior of these features.

Prior to conducting the KNN analysis, the dataset containing NNS parameters was imported into MATLAB's Classification Learner application, a component of the Statistics and Machine Learning Toolbox. The KNN model was then created and optimized using the application, which included options for feature selection, distance metric, and number of neighboring points (k value). In this work, we discuss two KNN models: analysis with only two NNS features (mean suck vacuum and number of sucks per burst) and analysis on all 8 NNS features introduced earlier. We limit the number of neighboring points to $k = 5$ in the analysis, taking into account the expected number of outliers present in the data set to be around six (7% outlier fraction) [45].

III. RESULTS

A. NORMAL AND ABNORMAL SUCKLING DATA

We first seek to determine if a simple measurement of the suckling vacuum is sufficient to identify breastfeeding problems, and to explore whether a collection of parameters defined from this measurement may be used to characterize the infant's feeding behavior. We present three exemplary normal and abnormal cases of the suckling profiles and the distributions of the eight NNS parameters in Figs. 4, 5, and 6 in the context of our entire data set from 91 infants. Each Figure presents the (a) NNS recording over sixty seconds, a (b) six-second extraction, and a (c) statistical evaluation of eight potentially important parameters. The vertical lines in the statistical plots represent the values obtained for the case under consideration. Figure 4 plots data taken from a healthy 12-day old infant exhibiting normal suckling behavior, with the measurements each within one standard deviation from the mean values of the entire population. Moreover, the suckling shape appears to be rhythmic and roughly sinusoidal.

By contrast, Figure 5 provides measurement data from a 6-day old infant that is approximately two standard deviations outside the mean values for at least some of the measurement parameters. Moreover, the suckling shape appears to be irregular over the entire data collection period—notice there are three pauses, two of which are exceptionally brief—and each suckling event exhibits a non-sinusoidal pattern, altogether indicating abnormal suckling behavior. In this case evaluation, the clinician reported hemorrhagic nipple lacerations, severe nipple pain, and infant choking caused by poorly coordinated suck-swallow-breathe events. The continuous suckling without rest, evident from the NNS data, may underpin these adverse outcomes.

The third infant's suckling behavior plotted in Figure 6 produces reasonable values from most of the measurement parameters. The NNS data was taken on day 18 of life.

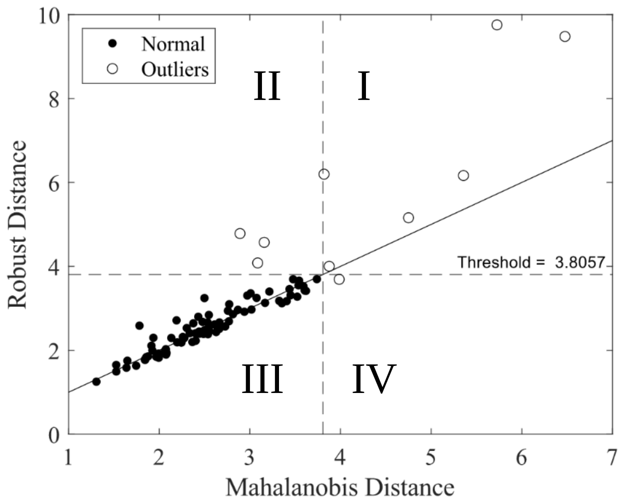

FIGURE 7. Robust distance versus Mahalanobis distance plot for the NNS data from all 91 subjects. The vertical and horizontal threshold (dashed) lines were calculated to be 3.8 standard deviations based on the expected 7% outlier fraction from clinical data [45] and the 8 degrees of freedom of the data set. The lines create four distinct quadrants; quadrant III contains all the neonates with normal NNS results. Quadrants II and IV contain the outliers according to either the Mahalanobis distance or the robust distance, respectively. Quadrant I contains the outliers according to both definitions.

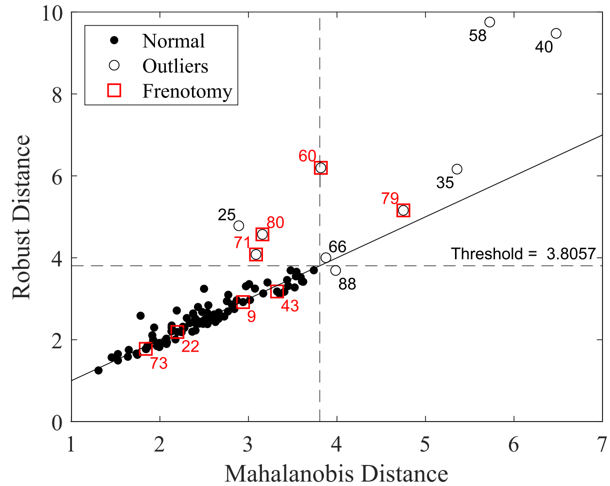

FIGURE 8. Eight of the 91 infants eventually underwent frenotomies, identified with red boxes. Four are outliers in the robust distance versus Mahalanobis distance plot of the NNS data; four are in the normal group. The identification of outliers was based upon computation of the threshold ξ from *a priori* knowledge of the number of degrees of freedom in the system, $p = 8$, and the outlier fraction, $r = 0.07$, based upon clinical incidence data.

The suckling shape itself shows brief suckling bursts separated by relatively long interludes of no suckling; the detail of the fifth burst shows some irregularity near the end. Most importantly, the NNS measured relatively weak mean and max suckling vacuum at the 26th percentile and 27th percentile, respectively. This correlates with clinical notes that report ineffective latch. This infant was fussy and had gastroesophageal reflux; a condition which may be related to disengagement during feeding.

There are evident differences between normal and abnormal suckling behavior in the NNS data. Next, we examine NNS data taken from several clinically identified cases of abnormal feeding behavior.

B. DISTANCE-DISTANCE PLOT

In this section, we show the results of anomaly detection using the statistical approach. We calculated the Mahalanobis distance and the robust distance for each of the 91 neonates and plotted them together in a distance-distance plot as shown in Figure 7. It is important to note that the plotted results are completely determined from the calculation of the Mahalanobis and robust distances. The threshold ξ was set at 3.8 standard distributions from the mean of the data set defined *a priori* based on the number of degrees of freedom $p = 8$ and the outlier fraction $r = 0.07$ based upon the expected incidence from the literature [45]. Among the 91 neonates, 81 fall within the normal quadrant (quadrant III of Figure 7). Ten of the 91 neonates were classified to be outliers with either the Mahalanobis distance *or* the robust distance—or both values—being greater than the predefined threshold.

C. DETECTING ANOMALIES ASSOCIATED WITH ANKYLOGLOSSIA

We now examine NNS data captured from healthy full-term infants that were diagnosed with ankyloglossia, seeking to determine if our NNS data provides insight and perhaps a stronger basis to make a decision on frenotomies.

Out of 91 neonates, eight were clinically diagnosed with ankyloglossia and treated with frenotomies. Ankyloglossia was diagnosed based on clinical assessment of persistent nipple pain, inability to maintain latch, feeding fatigue, high feeding frequency, insufficient weight gain, down-regulation of milk supply, and visual inspection of tethered lingual frenulum. NNS data was collected prior to surgical intervention to determine if abnormalities could be detected in their suckling measurements. Clinical evaluation to determine frenotomies was performed blinded to the NNS data. We replot this data in Figure 8, labeling with red boxes all the infants that went on to have a frenotomy. Four cases (9, 22, 43, and 73) were within the normal region while another four cases (60, 71, 79, and 80) were outliers. Frenotomy cases falling within the normal region indicate infants with normal NNS characteristics, but were prescribed a frenotomy. These cases highlight on whether a frenotomy could have been delayed or avoided to remedy breastfeeding struggles. There are six other cases (25, 35, 40, 58, 66, and 88) in the outlier region that are not frenotomy cases. These cases indicate abnormal suckling behavior based on NNS measurements and require further evaluation and follow up with mother and infant to determine causality.

D. THE EFFECT OF FRENOTOMIES ON THE NNS DATA

An important part of the controversy regarding surgical intervention in ankyloglossia is whether there is a long-term

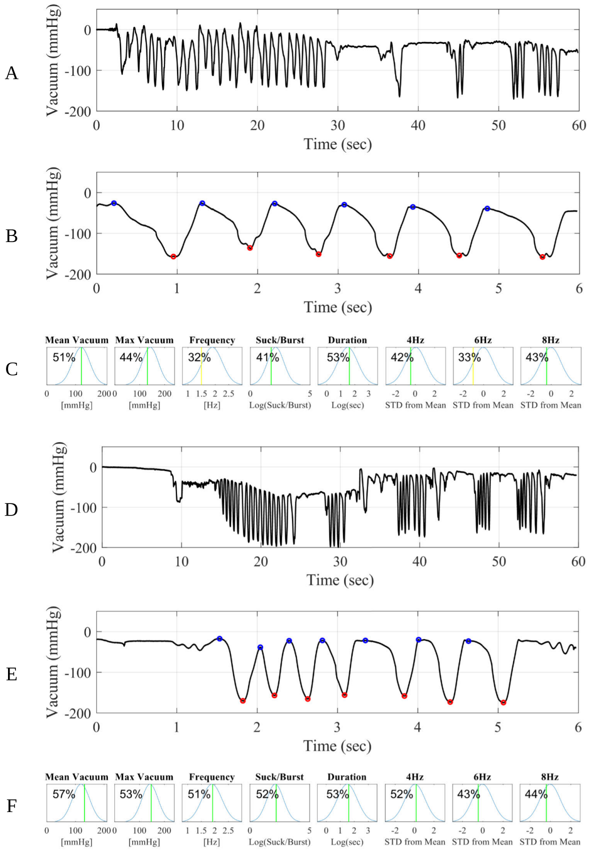

FIGURE 9. The effect of a frenotomy is apparent in subject 71. Plots (a,b,c) and (d,e,f) show NNS data for the full 60 seconds, a 6-second sample, and statistical evaluation of the eight tracked parameters before and after frenotomy, respectively. The frequency of suckling and the suck/burst value moved towards the mean of the entire data set after the intervention. The NNS data was captured day 1 of life prior to the frenotomy; the frenotomy was performed on day 1; and the post-frenotomy NNS data was collected on day 18.

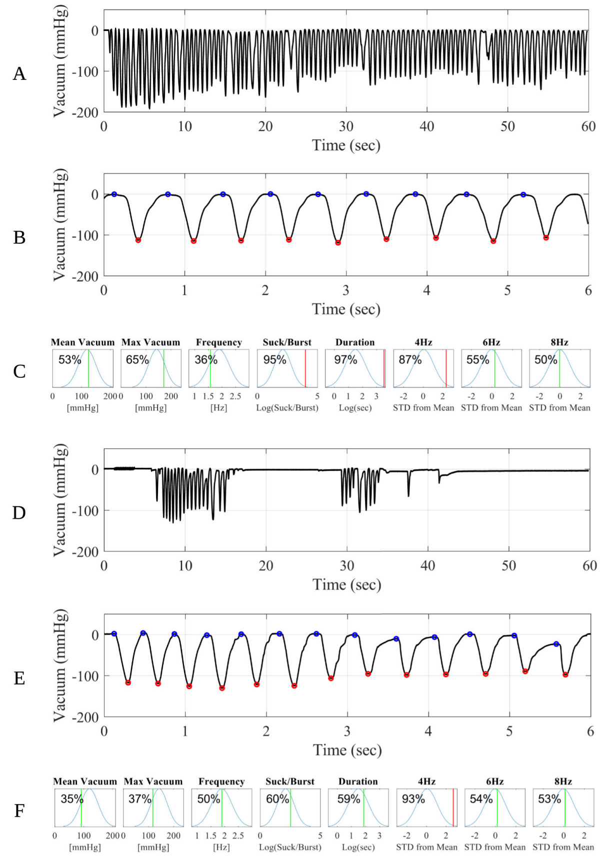

FIGURE 10. The effect of a frenotomy is also apparent in subject 60. Plots (a,b,c) and (d,e,f) show NNS data for the full 60 seconds, a 6-second sample, and statistical evaluation of the eight tracked parameters before and after frenotomy, respectively. The NNS data was captured immediately before and immediately after the frenotomy procedure, all within the first day of life. All parameters—except mean vacuum and the 4-Hz amplitude parameter—moved closer to the mean, falling within half a standard deviation of the mean after the frenotomy.

benefit to the infant from a frenotomy [62]. Here we use the NNS to evaluate the impact of the frenotomy. We discuss two cases: Subject 71 and 60 to explore the changes before and after surgical intervention. A pair of complete NNS data sets is provided in Figure 9 for case 71: before and after a frenotomy. Before the frenotomy, the subject received a digital suck vacuum score of 3 out of 10, a Hazelbaker score of 5 out of 14 for function and 2 out of 10 for appearance, and a Bristol score of 2 out of 8, indicating tongue restriction caused by tethering of the lingual frenulum sufficient to recommend a frenotomy. The clinician may also utilize the digital suck exam to assess infant suckling irregularity using a gloved finger. The NNS data was captured day 1 of life prior to the frenotomy; the frenotomy was performed on day 1; and the post-frenotomy NNS data was collected on day 18. After the frenotomy, case 71 showed a change in frequency and suck per burst results, with both moving towards the mean of the entire data set. Whether these changes are permanent in the long term was not studied within the scope of this work and will be explored in future studies.

Figure 10 shows subject 60 before and after a frenotomy. In this case, the subject received a Hazelbaker score of 9 out 14 for function and 3 out 10 for appearance, a Bristol score of 3 out 8, and a digital suck vacuum score 8 out of 10. The NNS data was captured immediately before and immediately after the frenotomy procedure, all within the first day of life. Before the frenotomy, the magnitude of the suck per burst, burst duration, and the 4 Hz components of the suckling profile in the frequency domain were in the 95th, 97th, and 87th percentiles, respectively. All parameters—except the 4-Hz amplitude parameter—moved closer to the mean, falling within half a standard deviation of the mean after the frenotomy. There were minimal changes to the magnitudes of the three frequency components before and after the procedure, indicating that there were few changes to the shape of the suckling profile. This can be observed in plots (b) and (e) of Figure 10.

As indicated by the case evaluations and prior research [62], surgical intervention may help improve infant suckling function in cases in which frenulum restriction is truly interfering

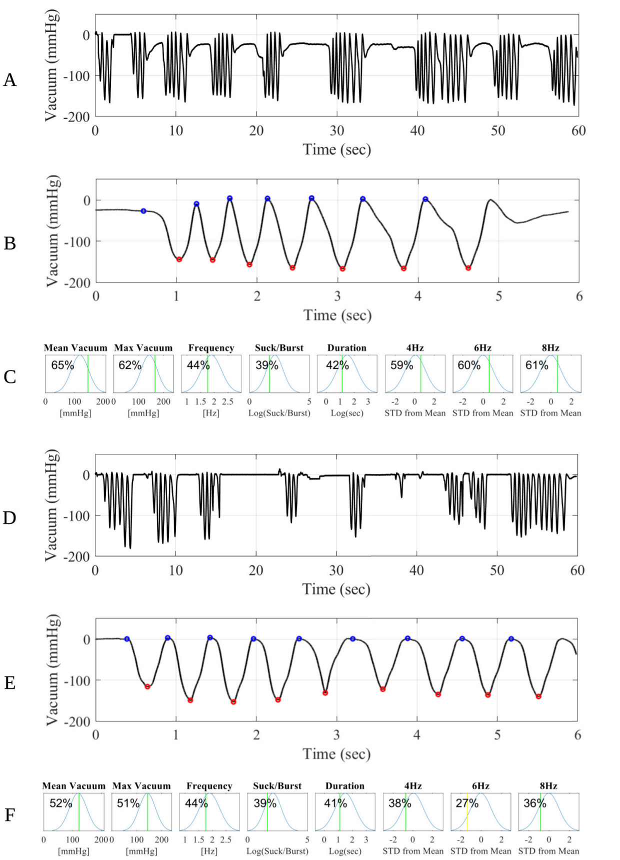

FIGURE 11. **The effect of a frenotomy was not apparent in subject 22. The 6-second NNS sample data and the statistical evaluation of the eight tracked parameters were largely unchanged before (b,c) and after (e,f) the frenotomy, with all parameters—except the 4, 6, and 8-Hz amplitude parameters—remaining unchanged or moving slightly closer to the mean (statistically insignificant). The 4, 6, and 8-Hz amplitude parameters all shifted farther away from the mean after the frenotomy.**

with suckling mechanics. For infants with corresponding clinical evaluation and outlier measurements from the NNS, our results show the abnormal NNS measurements shift to normal ranges post-frenotomy.

We next consider those cases—9, 22, 43, 73—where a clinical decision was made to perform a frenotomy and the NNS indicated normal suckling behavior. We present case 22 in Figure 11, where the subject was 8 days old and received a Hazelbaker score of 7 out of 14 for function and 7 out of 10 for appearance, a Bristol score of 6 out of 8, and a digital suck vacuum score 3 out of 10. The NNS-based evaluation was normal based on the distance-distance plot (*see* Figure 8). The suckling shape and most of the statistical data remained statistically similar before and after the frenotomy. The only significant changes in the data were adverse changes in the response amplitudes at 4, 6, and 8 Hz to lie farther from the mean after the surgery. In this case, it would have been possible to recommend breastfeeding without a frenotomy.

More broadly, we next consider the effects of a frenotomy in all eight cases where it was performed in Figure 12. The robust distance is plotted with respect to the Mahalanobis distance the same as in Figure 8. In Figure 12 (left)—cases 60, 71, 79, and 80 (in red boxes)—indicate those cases identified as outliers via the NNS data. In every case, these outliers moved to the normal region (quadrant I) after the frenotomy, indicating that the frenotomy moved their suckling behavior towards the mean of the overall infant population. In Figure 12 (right), for infants possessing NNS results already considered to be in the normal region (quadrant I) before the frenotomy (cases 9, 22, 43, and 73 (in red boxes)), there were modestly significant improvement for cases 9 and 43 towards the mean of the population in our study and no significant change to cases 22 and 73. Altogether, the effect of a frenotomy was significant on the NNS measurement results for those infants that had adverse NNS results beforehand. For those infants with normal NNS results, the effect was weakly significant to insignificant.

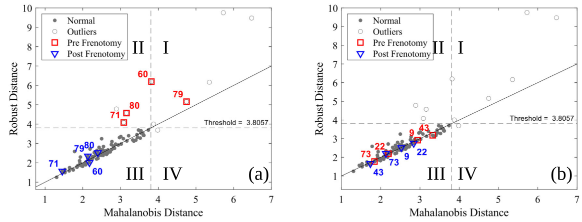

FIGURE 12. **Robust distance versus Mahalanobis distance plot of the NNS data for cases where a frenotomy was performed. Four cases (a; 60, 71, 79, 80) were identified as abnormal (red) via the NNS measurement; post-frenotomy, all four cases produced normal (blue) suckling behavior. Another four cases (9, 22, 42, 73) were clinically identified as abnormal but were identified as normal from NNS measurements. These four cases produced no change in suckling behavior according to NNS measurements after frenotomies. These discrepancies highlight the controversial nature of the frenotomy procedure: some infants benefit from frenotomies while others appear to not require the procedure and produce no suckling improvement after having it done. By using statistical methods, infants who can potentially benefit from a frenotomy can be objectively identified and improvements from the procedure, if any, can be objectively quantified.**

E. DETECTING ANOMALIES WITH KNN MODELS

Due to the multivariate and high dimensional nature of the data set, we first perform analysis of normal versus outliers with two features to provide a simplified understanding of the KNN model's behavior. Building on this understanding, we then perform analysis on all eight features of NNS using KNN and rely on performance metrics to interpret the results.

The 2-parameter KNN model classified subjects number 43, 58, and 79 as outliers. Subjects 43 and 79 were clinically diagnosed with tongue-tie and received a frenotomy. The more comprehensive 8-parameter KNN model also classified subject 43 and 79 as outliers, however, it classified subject 58 as normal. This observation shows the importance of considering the collective features of all eight parameters versus only two features. In the sucks per burst versus mean suck vacuum shown in Figure 13, four out of the eight frenotomy cases are located within the main cluster: subjects 9, 22, 71, and 73. The two KNN models classified these four as normal due to their close proximity with other normal subjects. These subjects, however, were clinically diagnosed with

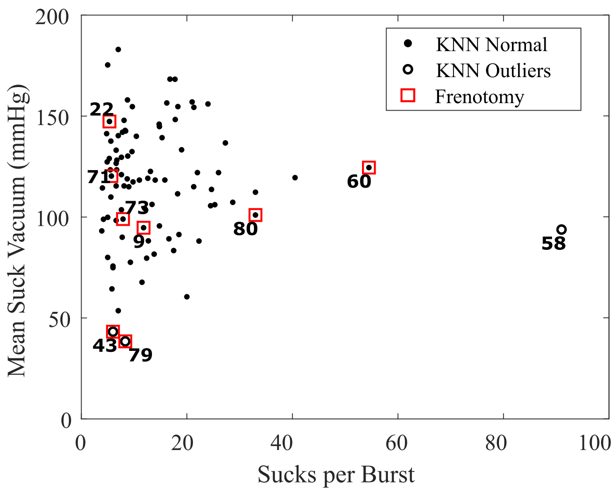

FIGURE 13. Comparison between clinical evaluation and KNN model classification using 2 parameters (mean suck vacuum and sucks per burst).

ankyloglossia. This suggests that subjects diagnosed with ankyloglossia do not necessarily exhibit abnormal NNS characteristics. Frenotomy may not change the suckling behavior and feeding outcomes for these subjects, which may explain the highly controversial nature of surgical intervention to resolve breastfeeding difficulties.

The confusion matrices in Figure 14 show a summary of the performance of the two KNN models. The classification outcomes of the two KNN models agreed well with the clinical evaluation with an accuracy of 92.3% for the 2-parameter model and 93.4% for the 8-parameter model. Both models performed well in identifying normal subjects, and in particular the 8-parameter model agreed with the clinical evaluation in all 83 normal cases. However, both models showed noticeable discrepancies versus clinical evaluation in detecting abnormal cases, as shown by the "false negative" boxes. Both KNN models identified the same six subjects (9, 22, 60, 71, 73, and 80) as normal. However, these six subjects were clinically evaluated as abnormal (diagnosed with ankyloglossia) and all underwent frenotomy.

The area under the curve (AUC) value of the receiver operating characteristic (ROC) curve is another effective way to evaluate the accuracy of the KNN models. An AUC value higher than 0.7 is generally viewed as acceptable accuracy on a diagnostic test [63]. The AUC values for the 2-parameter and 8-parameter KNN models were determined to be 0.6913 and 0.7214, respectively. The higher number of false negatives in comparison to the number of false positives indicated that the two KNN models are quite conservative in detecting outliers in the data set.

F. ABNORMAL NNS MEASUREMENTS WITH NORMAL CLINICAL EVALUATION

We finally consider cases in which the NNS identified potential issues but for which the clinical evaluation was normal. Subject 58 shown in Figure 15 was clinically evaluated to

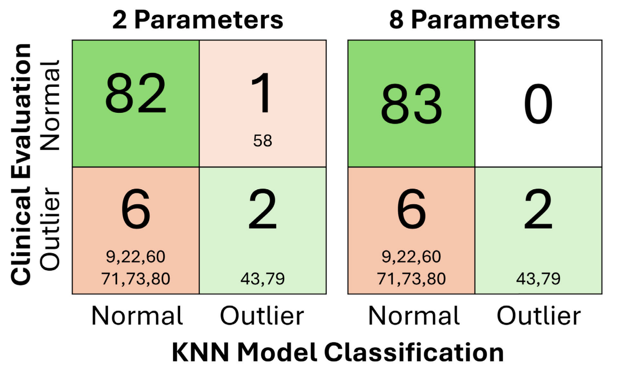

FIGURE 14. Confusion matrices illustrating the classification performance of the 2-parameter and 8-parameter KNN models, comparing the results of the KNN classification values for normal cases and outlier cases against their clinical evaluation results.

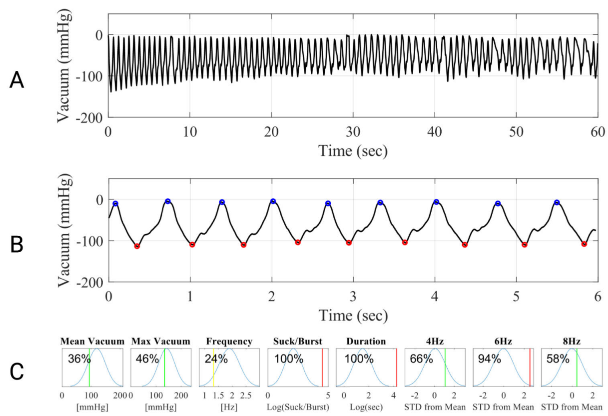

FIGURE 15. This infant, subject 58, was clinically evaluated to be normal, yet objective measurements indicate abnormal suckling behavior.

be normal with Hazelbaker scores of 14 out of 14 and 10 out of 10 for function and appearance, respectively. The Bristol score was 8 out of 8 and the digital suck vacuum was 10 out of 10. However, this neonate was classified as an extreme outlier based on the Mahalanobis distance (*see* Figure 8) and the 2-parameter KNN model Figure 14. The NNS measurements indicated that this subject produced an abnormally long burst duration and a very large number of suckling events per burst: both were in the 100% percentile. Also, in assessing the sucking profile, the 6 Hz component of the signal was two standard deviations away (94th percentile) from the mean value of the whole group. Though the average suckling frequency for this neonate is relatively low at 1.4 Hz, it is within the expected range for infants fewer than 1 day old [40]. This case is an example of an infant identified to need further clinical follow up to determine if suck-breathe coordination improves, to identify any early nipple trauma due to sustained suckling, and if the infant exhibits choking during breastfeeding due to lack of resting in between bursts. This case emphasizes that not all abnormal NNS is due to ankyloglossia. Other causes of oral motor dysfunction may exist and could explain the nature of irregularities in suckling upon further evaluation. The use of devices and systems along with Mahalanobis distance algorithm may help clinicians gather more objective data to investigate suck irregularities.

IV. DISCUSSION

Our NNS device appears to have sufficient sensitivity to identify infants with suckling irregularities affected by ankyloglossia and general infant vacuum suckling abnormalities. Outlier NNS measurements reflecting symptomatic lingual restriction normalized after frenotomy. Conversely, normal NNS measurements did not change with surgical intervention. This highlights the controversy of a subjective clinical diagnosis and conflicting literature about frenotomy benefit in breastfeeding dyads [43], [46].

Our approach in the use of this technology in the clinical setting has been the following:

- Keep the technology as simple as possible with off-the-shelf cost-effective components to facilitate its adoption in the clinic. Some devices and approaches employ ultrasound, force sensors, arrayed sensors, and cameras, which may improve the veracity of the measurements but at the cost of data complexity, difficulty in use, and expense. By contrast, our approach seeks to make as much use of one quantity—the suckling vacuum—as possible. It may be necessary to later incorporate other sensing methods, but the richness of the suckling vacuum versus time data indicates much can be learned from this single parameter alone.
- Make the measurement results immediately available to the clinician. Measurements are always challenging when using technology, and nowhere more so than with fussy infants in an unfamiliar clinical environment. By having the measurement results immediately available, the clinician can identify faulty measurements, refusal to suckle on a particular pacifier, problems with the technology, and then overcome these problems by changing the pacifier type [1], repositioning the infant, and so on. This application is particularly helpful in the first days of life as milk supply and breastfeeding practices are being established.
- Present the measurement results in a graphical manner in comparison to the population mean and standard deviation. This helps the clinician to quickly identify outliers that may represent abnormal suckling in a quantitative manner but without the complexity of tabulated data.

From the specific cases demonstrated in the results, we show how these principles can be used to provide quantitative evaluation sufficient to judge whether a frenotomy may be necessary, and whether or not the infant benefited from having a frenotomy.

In this study, two computational models, Mahalanobis and KNN, were used to detect outliers in the NNS characteristic of the 91 subjects. In our first analysis, we implemented the robust and Mahalanobis distances to identify outliers in Figure 8, with the threshold from normal to abnormal being calculated *before presentation* using an expected 7% outlier fraction of the overall data corresponding to the clinical incidence of ankyloglossia [45]. Ten infants produced NNS data that were outliers from the 91 comprising the entire data set. Of these ten, four went on to have frenotomies; these four infants showed significantly improved NNS results as a consequence of having a frenotomy. Of the 81 infants found to have normal NNS results, four had frenotomies. Two cases—9 and 43—were relatively close to both thresholds defined by the robust and Malahanobis distances and showed modest improvements in their NNS results after their frenotomies. However, two others—cases 22 and 73—were well within the normal NNS data and showed slight adverse changes in their NNS results post-frenotomy.

The importance of the statistical approach is perhaps best exemplified through case 71, with ostensibly normal NNS data provided in Figure 9. Manual interpretations of the suckling shape and the distributions of the eight parameters suggest that the subject's NNS is normal, however, the robust distance placed this infant's NNS data above the threshold, indicating abnormality. Moreover, this infant was clinically diagnosed to need a frenotomy, and the NNS results indicated a significant improvement in suckling behavior in Figure 12. Casual inspection of the NNS data is sometimes helpful, but statistical analysis is necessary to identify the collective deviations of all the measurement parameters that may produce an abnormal classification.

In our KNN models, both the 2-parameter and 8-parameter KNN models performed reasonably well with high accuracy (∼92%) and acceptable AUC values (∼.7). However, both models were more conservative in classifying outliers, detecting only 2-3 abnormal cases compared to clinical evaluation with 8 cases, and the Mahalanobis model with 10 cases. The Mahalanobis and KNN methods' approach to identifying outliers within the dataset is significantly different, offering alternative avenues to analyzing the NNS dataset. The Mahalanobis model centers on the relative distance of a subject from the mean value of the entire dataset, while the KNN model focuses on the relative distances from a subject to its nearest neighbors. This fundamental difference resulted in disparate classification outcomes between the two methods. For instance, although subject 35 exhibited generally normal NNS characteristics across all eight features, falling within the 29th–69th percentile range, the Mahalanobis distance flagged it as an outlier. Conversely, both KNN models, prioritizing local patterns, classified this subject as normal. Notably, the KNN algorithm's performance relies on labeled data for training, typically based on clinical evaluations, which may be susceptible to inaccuracies. Any misdiagnoses could potentially undermine the model's accuracy. By comparison, the Mahalanobis approach only requires advance knowledge of the expected incidence of outliers, which is reasonable in ankyloglossia in infants [45], but may require refinement or wholesale changes as the targeted malady changes.

Furthermore, the KNN algorithm operates on the assumption that similar subjects are located close to each other in the feature space. Its localized classification approach makes it particularly suitable for grouping subjects with similar conditions (abnormal NNS characteristics). This highlights the intricate nature of medical diagnosis, especially concerning the evaluation of neonatal suckling behavior. Objective evaluation of NNS characteristics such as using the models presented in this paper can help clinicians make more informed decisions on how to best treat the subjects.

Our study here focused upon the diagnosis of abnormalities influenced by ankyloglossia. Improvements in use of the NNS data for other oral dysfunction requires the collection of more clinical evaluation data correlated to NNS measurements to identify and characterize these relatively rare oral deficiencies. Moreover, there is undoubtedly a benefit in pursuing ultrasound studies [28] alongside the clinical and NNS-based evaluations in order to improve the veracity of the diagnosis and interpretation of the NNS data, particularly when including a broader array of possible suckling dysfunction phenomena. It is hoped, however, that the simple NNS-based approach will provide a useful triage tool in the clinical diagnosis of suckling issues.

A limitation with all existing methodologies remains continuous and long-term monitoring of infant suckling maturation. As with any single-point measurement, infants mature and learn beyond the clinical evaluation time that may lead to improvements, regression, or sustained suckling patterns not captured by the data. Future studies will need to consider multiple time points in infants with and without intervention to determine and distinguish between intervention impact versus infant maturation. With computational analysis, infant suckling maturity (affected by age and infant learning) can be overcome with significantly more data to intrinsically account for age (suckling data from every age group can contribute to the establish a norm for each age point).

Our study reflects vacuum data and in the future will incorporate expression pressure as another parameter to consider in the algorithm. While expression pressure is important to infant suckling, vacuum is a significant contributor to milk extraction [28] and was the focus of this paper.

V. CONCLUSION

Infant oral suckling is a highly complex biomechanical process that requires a comprehensive evaluation. While ultrasound, force sensors, sensor arrays, and similar methods provide powerful measurement capabilities for understanding infant oral motor function, it can be challenging to translate this technology to front-line clinical use due to the equipment, training, and time required to collect and interpret such data. A simpler approach may be beneficial in the context of early screening, where simple abnormality indicators represent a first step to providing timely intervention and comprehensive care.

With such instrumentation and computational methodologies, families and clinicians are more informed on objective metrics that may guide next intervention steps. This work provides a methodology via a simple non-nutritive device to quickly assess infant suckling and identify abnormalities. Non-nutritive suckling has long been established as an important foundation to understanding nutritive suckling [25], [27], and our NNS device supports this perspective. Non-nutritive measurements using our simple pacifier combined with a vacuum sensor and computer interface with a classification algorithm is sufficient to provide early and rapid identification of ankyloglossia. More importantly, in contexts where resources are limited, leveraging neonatal sucking reflex (NNS) data enables breastfeeding medicine providers to allocate their efforts more effectively towards maternal care, particularly when infant sucking patterns are within normal range.

It also appears to identify cases where ankyloglossia is not impacting suck vacuum, and cases that might need further evaluation and treatment of suckling problems. Moreover, it appears to indicate a beneficial outcome from frenotomies in those infants exhibiting outlier NNS results before intervention. Early intervention is necessary during the critical period in which milk supply is being established to prevent damaged tissue and pain that may lead to breastfeeding cessation.

Equally important is the possibility such an NNS device may assist with determining infant-focused interventions versus mother-focused interventions. Clinicians may use these tools to build intuition grounded on objective data as they compare their own tactile feedback with objective measurements. Often, a mother's perception of infant inability to suckle as a result of ankyloglossia may not truly reflect the infant's suckling competence. An objective determination based on NNS measurements and computational analysis can guide intervention strategies and overcome biases associated with breastfeeding, turning focus to the mother as necessary.

With respect to the diagnosis of ankyloglossia, while tongue-tie may be indicated based on current clinical metrics such as Hazelbaker or Bristol Assessment tools, our data shows frenotomies may not be a blanket solution to resolving breastfeeding difficulties in infants with ankyloglossia. As identified by our computational analysis, infants with normal NNS mechanics exhibit very little changes from such procedures. Future longitudinal studies will follow infants long term to determine the true benefits and changes induced by surgical intervention.

While there are numerous research activities underway to understand the detailed mechanics of breastfeeding and its disorders, evidence of diagnosis and treatment problems in breastfeeding infants together with the data collected from our relatively simple approach demonstrate the need for more objective screening tools in the clinical setting. Due to the harried nature of outpatient clinical care in healthcare today, simple tools that are easy to use for an initial screening are clearly needed. Our interdisciplinary approach to solve this problem has produced a NNS tool that we have translated to clinical research use, and hopefully such an approach can be used to produce better tools for the outpatient clinic, paired with comprehensive follow up and support for mother and infant to reduce misdiagnosis, overtreatment, and improve breastfeeding outcomes.

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REFERENCES

[1] P. Truong, E. Walsh, V. P. Scott, T. Coleman, G. Tilvawala, and J. Friend, "Non-nutritive suckling system for real-time characterization of intraoral vacuum profile in full term neonates," *IEEE J. Transl. Eng. Health Med.*, vol. 23, no. 11, pp. 107–115, 2022.

[2] A. J. Blincoe, "The health benefits of breastfeeding for mothers," *Brit. J. Midwifery*, vol. 13, no. 6, pp. 398–401, Jun. 2005.

[3] B. L. Horta, C. Loret de Mola, and C. G. Victora, "Long-term consequences of breastfeeding on cholesterol, obesity, systolic blood pressure and type 2 diabetes: A systematic review and meta-analysis," *Acta Paediatrica*, vol. 104, no. S467, pp. 30–37, Dec. 2015.

[4] C. G. Victora et al., "Breastfeeding in the 21st century: Epidemiology, mechanisms, and lifelong effect," *Lancet*, vol. 387, no. 10017, pp. 475–490, Jan. 2016.

[5] S. Bartz and M. Freemark, "Pathogenesis and prevention of type 2 diabetes: Parental determinants, breastfeeding, and early childhood nutrition," *Current Diabetes Rep.*, vol. 12, no. 1, pp. 82–87, Feb. 2012.

[6] C. Lodge et al., "Breastfeeding and asthma and allergies: A systematic review and meta-analysis," *Acta Paediatrica*, vol. 104, no. S467, pp. 38–53, Dec. 2015.

[7] J. W. Anderson, B. M. Johnstone, and D. T. Remley, "Breast-feeding and cognitive development: A meta-analysis," *Amer. J. Clin. Nutrition*, vol. 70, no. 4, pp. 525–535, Oct. 1999.

[8] C. G. Owen, R. M. Martin, P. H. Whincup, G. D. Smith, and D. G. Cook, "Effect of infant feeding on the risk of obesity across the life course: A quantitative review of published evidence," *Pediatrics*, vol. 115, no. 5, pp. 1367–1377, May 2005.

[9] S. M. Virtanen, N. C. Räihä, P. Ahlqvist, J. Tuominen, and C. Kronberg-Kippilä, "Relation of maternal diet, breastfeeding, and development of type 2 diabetes mellitus in children," *BMJ*, vol. 317, no. 716, Jun. 1998.

[10] S. Schinner, "Breast-feeding and type 2 diabetes in the youth of three ethnic groups: The search for diabetes in youth case-control study," *Yearbook Endocrinol.*, vol. 2009, pp. 23–25, Jan. 2009.

[11] M. B. Belfort et al., "Infant feeding and childhood cognition at ages 3 and 7 years: Effects of breastfeeding duration and exclusivity," *JAMA Pediatrics*, vol. 167, no. 9, pp. 836–844, 2013.

[12] A. D. C. Franca-Botelho, M. C. Ferreira, J. L. Franca, E. L. Franca, and A. C. Honorio-Franca, "Breastfeeding and its relationship with reduction of breast cancer: A review," *Asian Pacific J. Cancer Prevention*, vol. 13, no. 11, pp. 5327–5332, Nov. 2012.

[13] Centers for Disease Control and Prevention (CDC). *Breastfeeding: Recommendations & Benefits*. Accessed: Jul. 22, 2023. [Online]. Available: https://www.cdc.gov/nutrition/infantandtoddlernutrition/breastfeeding/recommendations-benefits.html

[14] World Health Organization (WHO) and United Nations Children's Fund (UNICEF), Geneva. (2021). *Indicators for Assessing Infant and Young Child Feeding Practices: Definitions and Measurement Methods*. Accessed: Jul. 22, 2023. [Online]. Available: https://www.who.int/publications/i/item/9789240018389

[15] A. A. of Pediatrics, "Breastfeeding and the use of human milk," *Pediatrics*, vol. 129, no. 3, pp. e827–e841, 2012.

[16] CDC National Immunization Survey. *Breastfeeding Among U.S. Children Born 2013—2020*. Accessed: Apr. 17, 2024. [Online]. Available: https://www.cdc.gov/breastfeeding/data/nis_data/results.html

[17] N. K. Sriraman and A. Kellams, "Breastfeeding: What are the barriers? Why women struggle to achieve their goals," *J. Women's Health*, vol. 25, no. 7, pp. 714–722, Jul. 2016.

[18] H. McClellan, D. Geddes, J. Kent, C. Garbin, L. Mitoulas, and P. Hartmann, "Infants of mothers with persistent nipple pain exert strong sucking vacuums," *Acta Paediatrica*, vol. 97, no. 9, pp. 1205–1209, Sep. 2008.

[19] H. McClellan, J. Kent, A. Hepworth, P. Hartmann, and D. Geddes, "Persistent nipple pain in breastfeeding mothers associated with abnormal infant tongue movement," *Int. J. Environ. Res. Public Health*, vol. 12, no. 9, pp. 10833–10845, Sep. 2015.

[20] S. L. Perrella, C. T. Lai, and D. T. Geddes, "Case report of nipple shield trauma associated with breastfeeding an infant with high intra-oral vacuum," *BMC Pregnancy Childbirth*, vol. 15, no. 1, pp. 1–5, Dec. 2015.

[21] J. Lauwers and A. Swisher, *Counseling the Nursing Mother: A Lactation Consultant's Guide: A Lactation Consultant's Guide*. Burlington, MA, USA: Ones & Bartlett Learning, 2020.

[22] N. M. Hurst, "Recognizing and treating delayed or failed lactogenesis II," *J. Midwifery Women's Health*, vol. 52, no. 6, pp. 588–594, Nov. 2007.

[23] L. Chen, R. F. Lucas, and B. Feng, "A novel system to measure infants' nutritive sucking during breastfeeding: The breastfeeding diagnostic device (BDD)," *IEEE J. Transl. Eng. Health Med.*, vol. 6, pp. 1–8, 2018, doi: 10.1109/JTEHM.2018.2838139.

[24] D. S. Finan and S. M. Barlow, "Intrinsic dynamics and mechanosensory modulation of non-nutritive sucking in human infants," *Early Hum. Develop.*, vol. 52, no. 2, pp. 181-197, 1998, doi: 10.1016/S0378-3782(98)00029-2.

[25] J. P. Foster, K. Psaila, and T. Patterson, "Non-nutritive sucking for increasing physiologic stability and nutrition in preterm infants," *Cochrane Database Syst. Rev.*, vol. 10, no. 10, pp. 1–49, Oct. 2016, Art. no. CD001071, doi: 10.1002/14651858.CD001071.pub3.

[26] C. Harding, "Non-nutritive sucking for infants: What are the issues?" *Infant J.*, vol. 10, no. 2, pp. 50–53, 2014. [Online]. Available: https://www.infantjournal.co.uk/pdf/inf_056_utr.pdf

[27] C. Harding, "An evaluation of the benefits of non-nutritive sucking for premature infants as described in the literature," *Arch. Disease Childhood*, vol. 94, no. 8, pp. 636–640, Aug. 2009.

[28] D. T. Geddes and V. S. Sakalidis, "Ultrasound imaging of breastfeeding—A window to the inside: Methodology, normal appearances, and application," *J. Hum. Lactation*, vol. 32, no. 2, pp. 340–349, May 2016.

[29] M. Torabinia, S. D. Rosenblatt, and B. Mosadegh, "A review of quantitative instruments for understanding breastfeeding dynamics," *Global Challenges*, vol. 5, no. 10, Oct. 2021, Art. no. 2100019.

[30] A. Grassi, F. Cecchi, A. Guzzetta, and C. Laschi, "Sensorized pacifier to quantify the rhythmicity of non-nutritive sucking: A preliminary study on newborns," in *Proc. 37th Annu. Int. Conf. IEEE Eng. Med. Biol. Soc. (EMBC)*, Aug. 2015, pp. 7398–7401.

[31] M. Pereira, O. Postolache, and P. Girão, "A smart measurement and stimulation system to analyze and promote non-nutritive sucking of premature babies," *Meas. Sci. Rev.*, vol. 11, no. 6, p. 173, Jan. 2011.

[32] T. Niikawa, C. Hagino, E. Nishi, R. Kawachi, K. Minato, and Y. Takada, "Measurement of tongue–artificial nipple contact pressure during infant sucking," *IEEJ Trans. Electr. Electron. Eng.*, vol. 7, no. 2, pp. 190–196, Mar. 2012.

[33] Z. Ebrahimi, H. Moradi, and S. Jafarabadi Ashtiani, "A compact pediatric portable pacifier to assess non-nutritive sucking of premature infants," *IEEE Sensors J.*, vol. 20, no. 2, pp. 1028–1034, Jan. 2020.

[34] K. Aron, D. L. Stalling, J. Kean, and A. Ingling, "Handheld cordless non-nutritive suck assessment device," U.S. Patent 9 974 476, May 22, 2018.

[35] M. D. Nascimento et al., "Reliability of the S-FLEX device to measure non-nutritive sucking pressure in newborns," *Audiol. Commun. Res.*, vol. 24, p. e2191, 2019, doi: 10.1590/2317-6431-2019-2191.

[36] G. J. Capilouto, T. J. Cunningham, P. J. Giannone, and D. Grider, "A comparison of the nutritive sucking performance of full term and preterm neonates at hospital discharge: A prospective study," *Early Human Develop.*, vol. 134, pp. 26–30, Jul. 2019.

[37] C. Lau and I. Kusnierczyk, "Quantitative evaluation of Infant's non-nutritive and nutritive sucking," *Dysphagia*, vol. 16, no. 1, pp. 58–67, Jan. 2001.

[38] C. Lau, "Development of suck and swallow mechanisms in infants," *Ann. Nutrition Metabolism*, vol. 66, no. 5, pp. 7–14, 2015.

[39] C. Lau, "Systems for monitoring infant oral motor kinetics during nutritive and non-nutritive feeding," U.S. Patent 9 561 002, Feb. 7, 2017.

[40] S. Akbarzadeh et al., "Predicting feeding conditions of premature infants through non-nutritive sucking skills using a sensitized pacifier," *IEEE Trans. Biomed. Eng.*, vol. 69, no. 7, pp. 2370–2378, Jul. 2022.

[41] J. F. Bosma, L. G. Hepburn, S. D. Josell, and K. Baker, "Ultrasound demonstration of tongue motions during suckle feeding," *Develop. Med. Child Neurol.*, vol. 32, no. 3, pp. 223–229, Mar. 1990.

[42] F. Neiva, C. Leone, and C. Leone, "Non-nutritive sucking scoring system for preterm newborns," *Acta Paediatrica*, vol. 97, no. 10, pp. 1370–1375, Oct. 2008.

[43] R. L. Martinelli, I. Q. Marchesan, R. J. Gusmão, H. M. Honório, and G. Berretin-Felix, "The effects of frenotomy on breastfeeding," *J. Appl. Oral Sci.*, vol. 23, no. 2, pp. 153–157, 2015, doi: 10.1590/1678-775720140339.

[44] S. Becker, M. Brizuela, and M. D. Mendez. (Jun. 9, 2023). Ankyloglossia (Tongue-Tie). StatPearls. Accessed: Jul. 22, 2023. [Online]. Available: https://www.ncbi.nlm.nih.gov/books/NBK431083/.penai.com/c/4320df53-04e8-4d2eb43b-5c54738a1b12

[45] P. V. Cruz et al., "Prevalence of ankyloglossia according to different assessment tools," *J. Amer. Dental Assoc.*, vol. 153, no. 11, pp. 1026–1040.e31, Nov. 2022.

[46] J. Walsh, A. Links, E. Boss, and D. Tunkel, "Ankyloglossia and lingual frenotomy: National trends in inpatient diagnosis and management in the United States, 1997–2012," *Otolaryngology–Head Neck Surgery*, vol. 156, no. 4, pp. 735–740, Apr. 2017.

[47] P. I. Opara, N. Gabriel-Job, and K. O. Opara, "Neonates presenting with severe complications of frenotomy: A case series," *J. Med. Case Rep.*, vol. 6, no. 1, pp. 1–4, Dec. 2012.

[48] J. Campbell, "Frenotomy for tongue-tie in newborn infants," *Int. J. Nursing Stud.*, vol. 91, pp. 146–147, Mar. 2019.

[49] A. K. Hazelbaker, "Assessment tool for lingual frenulum function (ATLFF)," *Clin. Lactation*, vol. 8, no. 3, pp. 132–133, 2017.

[50] J. Ingram, D. Johnson, M. Copeland, C. Churchill, H. Taylor, and A. Emond, "The development of a tongue assessment tool to assist with tongue-tie identification," *Arch. Disease Childhood-Fetal Neonatal Ed.*, vol. 100, no. 4, pp. F344–F349, Jul. 2015.

[51] D. T. Geddes, J. C. Kent, L. R. Mitoulas, and P. E. Hartmann, "Tongue movement and intra-oral vacuum in breastfeeding infants," *Early Human Develop.*, vol. 84, no. 7, pp. 471–477, Jul. 2008.

[52] D. T. Geddes et al., "Tongue movement and intra-oral vacuum of term infants during breastfeeding and feeding from an experimental teat that released milk under vacuum only," *Early Human Develop.*, vol. 88, no. 6, pp. 443–449, Jun. 2012.

[53] D. Elad et al., "Biomechanics of milk extraction during breast-feeding," *Proc. Nat. Acad. Sci. USA*, vol. 111, no. 14, pp. 5230–5235, Apr. 2014.

[54] M. Hack, M. M. Estabrook, and S. S. Robertson, "Development of sucking rhythm in preterm infants," *Early Human Develop.*, vol. 11, no. 2, pp. 133–140, Jul. 1985.

[55] B. W. Yap and C. H. Sim, "Comparisons of various types of normality tests," *J. Stat. Comput. Simul.*, vol. 81, no. 12, pp. 2141–2155, Dec. 2011, doi: 10.1080/00949655.2010.520163.

[56] S. Stöckl and M. Hanke, "Financial applications of the Mahalanobis distance," *SSRN Electron. J.*, vol. 1, no. 2, pp. 78–84, 2014.

[57] H. Ghorbani, "Mahalanobis distance and its application for detecting multivariate outliers," *Facta Universitatis, Series, Math. Informat.*, p. 583, Oct. 2019.

[58] W. H. Woodall, R. Koudelik, K.-L. Tsui, S. B. Kim, Z. G. Stoumbos, and C. P. Carvounis, "A review and analysis of the mahalanobis—Taguchi system," *Technometrics*, vol. 45, no. 1, pp. 1–15, 2003.

[59] H. Aguinis, R. K. Gottfredson, and H. Joo, "Best-practice recommendations for defining, identifying, and handling outliers," *Organizational Res. Methods*, vol. 16, no. 2, pp. 270–301, Apr. 2013.

[60] P. J. Rousseeuw, "Multivariate estimation with high breakdown point," *Math. Statist. Appl.*, vol. 8, nos. 283–297, p. 37, 1985.

[61] A. A. Soofi and A. Awan, "Classification techniques in machine learning: Applications and issues," *J. Basic Appl. Sci.*, vol. 13, pp. 459–465, Aug. 2017.

[62] K. Ganesan, S. Girgis, and S. Mitchell, "Lingual frenotomy in neonates: Past, present, and future," *Brit. J. Oral Maxillofacial Surg.*, vol. 57, no. 3, pp. 207–213, Apr. 2019.

[63] J. N. Mandrekar, "Receiver operating characteristic curve in diagnostic test assessment," *J. Thoracic Oncol.*, vol. 5, no. 9, pp. 1315–1316, Sep. 2010.