Preliminary Validation of Infant Sucking Measurement System with Healthy Term Infants

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Abstract

Background: Although various methods have been used to objectively evaluate an infant's sucking behavior during breast- and bottle-feeding, variations in instruments and technologies currently employed make it difficult to compare findings across breast and bottle-feeding conditions. Therefore, we developed a new method, the Infant Sucking Measurement System (ISMS) that provides a consistent assessment of sucking across breast and bottle-feeding. The purpose of this study was to present preliminary findings of the feasibility and validity of the ISMS.

Methods: In Phase 1, we examined the ability of the ISMS to differentiate different levels of negative pressure generated by an artificial sucking condition using a breast pump. In Phase 2, we tested the feasibility and validity of the ISMS with data obtained from four mothers and their healthy full-term infants (two bottle-feedings and two breastfeedings). Intraoral pressures were measured using the ISMS along with a video camera simultaneously recording the infant's cheek movements. Mothers provided feedback for improvement of the ISMS design. Following each observation, the team reviewed the findings and refined the system; refinements were trialed with the next study. To test the validity of the ISMS, a one-minute period with the highest quality ISMS signal was selected from each feeding to examine the synchrony between ISMS intraoral pressure measurements and coded cheek movements.

Results: The ISMS differential pressures when low, medium, and high suction pressures were applied by a breast pump were 18.8, 29.6, and 40.3 kPa, respectively. The agreement between direct observation of sucking and ISMS data was high (mean: 90.6%, range: 84.6-100%). With a series of modifications, we found that the ISMS was a feasible method of reliably measuring intraoral pressure during breast-feeding; however, further testing is necessary to optimize methods of securing the catheter to the bottle nipple.

Conclusions: Preliminary data support the validity of the ISMS for identifying sucks and quantifying intraoral pressure generated by sucks in both breast and bottle-feeding. Although further modifications are needed to improve the attachment of the device to the bottle nipple, our initial results support further investigation of the ISMS for use in high-risk infants to evaluate sucking behaviors.

Background

Learning how to safely and efficiently feed is a major developmental task in infancy. Safe and efficient oral feeding requires well-timed coordination of the suck-swallow-breathe sequence, in which the infant must be able to suck sufficiently to meet its nutritional needs for growth, to swallow efficiently to minimize the disruption of breathing and aspiration, and to breathe with adequate depth and frequency to maintain physiologic stability. However, oral feeding is challenging for high-risk infants, such as those born with prematurity or complex medical conditions due to impaired or immature function of their oral-motor, cardiorespiratory, gastrointestinal, or neurological systems. Serious health consequences, including poor nutrition, growth faltering, and altered neurodevelopment, can result if oral feeding

problems persist among these infants (1-3). Therefore, there has been increasing efforts to develop a method to provide more objective feeding measures to improve our understanding of an infant's feeding skill development and to guide clinical assessment.

Sucking, one of the critical components of oral feeding skills, is the most studied variable in the evaluation of an infant's oral feeding ability. Over the past century, multiple methods have been employed to quantitatively evaluate infant sucking behavior. A frequently used method has been a pressure transducer that is coupled with a custom-made bottle/nipple system with and without measurements of milk flow rates to the nipple (4-7). This method has provided objective measurements of intraoral pressure during bottle-feeding, allowing for evaluation of changes in various sucking parameters as an infant matures or in response to feeding interventions. However, this method cannot be used during breastfeeding conditions. This method also requires the use of a bottle nipple specifically modified to work with the measurement device. Infants with feeding difficulty often require, and are therefore accustomed to, certain types of nipple/bottle systems based on their individual needs in the neonatal nursery. Thus, using a different type of bottle nipple that comes with a device may significantly change the feeding condition, possibly affecting an infant's sucking ability, and reduce confidence in the validity of the measurement of sucking for that infant. More recently, several studies have attempted to utilize a method of measuring sucking during breastfeeding. These methods include electromyography attached to the infant's perioral area to capture jaw movements associated with sucking (8), ultrasound imaging of the infant's oral cavity to assess various types of muscle movements involved in feeding (9, 10), and pressure transducers with a catheter placed alongside the breast nipple to assess intraoral pressure (11-13). However, the usability of these methods has not been tested in bottle-feeding conditions. Variations in instruments and technologies used for breast versus bottle-feeding make comparison of findings difficult.

Our goal was to develop an ecologically valid method of measuring sucking that provides a consistent assessment of sucking across different feeding conditions. By ecological, we mean a methodology that minimizes modification of an infant's routine feeding regimen. Building on previously employed methods, we developed a new device we call the Infant Sucking Measurement System (ISMS). The ISMS can be used during both breast and bottle-feeding, as well as during feeding with different nipple/bottle systems. The purpose of this preliminary study was to (1) examine the ISMS's ability to differentiate different levels of negative pressure, (2) test the feasibility of using the ISMS, and (3) validate the ISMS' ability to detect sucks during mother-infant feeding sessions.

Methods

This study was approved by the Human Subject Institutional Review Board at Boston College.

Infant Sucking Measurement System (ISMS)

The preliminary design of the ISMS includes custom-built hardware consisting of a pressure transducer unit and a data recording box, the latter of which is connected to an open-ended, thin, soft medical-grade

silicone catheter (50 cm in length, internal diameter of 0.7 mm; Figure 1). An open-ended catheter was used to increase the sensitivity of the pressure sensor to detect negative pressure. During feeding, the catheter is placed alongside the nipple of the bottle or breast with the tip of the catheter located just beyond the tip of the bottle or breast nipple. Pressure signals are collected at a sampling rate of 1,000 Hz via the data recording box, converted to an analog waveform using the BioNex Amplifier, streamed in real time, and stored to a computer using BioLab Acquisition software (Mindware Technology, Gahanna, OH, USA).

Preliminary Testing

Preliminary testing of the ISMS was completed in two phases.

In *Phase 1*, we tested the validity of the ISMS by examining the ability to differentiate different levels of negative pressure generated by an artificial sucking condition using a breast pump. A Pump in Style Advanced breast pump (Medela Inc, McHenry, IL, USA) was used to create negative pressure. During testing, the ISMS catheter was connected directly to the breast pump tubing using a barbed tubing fitting adapter, allowing for a tight seal between the ISMS catheter and the breast pump tubing. Three levels of negative pressure (low, medium, high) were applied to the ISMS for one minute for each pressure level, and pressure signals were recorded. This observation was repeated to confirm the consistency of the ISMS signals within the same level of negative pressure. There was strong agreement between the first and second measurements at each pressure level.

In *Phase 2*, we tested the feasibility and validity of the ISMS to detect sucking with data obtained from four mothers and their healthy full-term infants. The sample was recruited from parent online support groups using a snowball sampling strategy. To be eligible for the study, mothers had to be over 18 years old and self-report as being literate in English. Infants had to be born full-term (> 37 weeks' gestational age) and free from any known medical diagnoses that may cause sucking difficulty, such as cleft palate, Down syndrome, any form of respiratory distress, or exposure to drugs *in utero*. Following consent, mothers were invited to a research lab for a feeding observation. During the observation, mothers were asked to feed their infant the way they normally do. Intraoral pressure was continuously measured using the ISMS throughout the feeding. Simultaneous with the intraoral pressure measurement, we also recorded a close-up video of the infant's face to capture cheek movements associated with sucking. These data were used to further evaluate the validity of the ISMS for identification of sucks by examining the synchrony between the ISMS-generated intraoral pressure measurements and occurrence of cheek movements. After the feeding, a brief interview was conducted, during which mothers provided feedback for improvement of the ISMS design. Following each observation, the team reviewed the findings and refined the system; refinements were trialed with the next participant.

Data Analysis

Phase 1. Pressure signals obtained from the ISMS at each pressure level were imported into the AcqKnowledge software (BIOPAC System Inc., Goleta, CA, USA). Mean amplitudes of sucks in kPa

(absolute values of suction pressure are cited throughout this manuscript) were calculated for one minute of each pressure level. *Phase 2.* Feedback from mothers and investigators' observations from each feeding observation were summarized. Intraoral pressure waveforms obtained from the ISMS were zeroed to adjust for baseline drift using the mean value at a time when no sucking signals were present, using the AcqKnowledge software. The adjusted waveforms and video recordings were imported into the Observer XT software program (Noldus Information Technology, Inc., Asheville, NC, USA) for coding. A 1-minute period with the highest quality ISMS signal was selected from each feeding observation. A trained research assistant separately coded peaks of negative pressure based on the ISMS signals and infant cheek movements, *i.e.*, when the cheek starts to rise based on the videotape. Percent agreements between the timing of the ISMS intraoral pressure measurements and coded check movements were calculated.

Results

Phase 1: Pressure differentiation testing using a breast pump

Figure 2 displays negative pressure signals obtained from the ISMS at a magnified time scale when low, medium, and high suction pressure were applied using a breast pump. Mean maximum negative pressures were 18.8, 29.6, and 40.3 kPa, respectively, demonstrating the ISMS was able to differentiate different levels of negative pressure.

Phase 2: Feasibility and validity testing with four mother-infant dyads

Four mothers and their healthy, full-term infants participated in this phase of the study. Of the four infants, three were female (one was 4 weeks old, two were 4 months old) and one was male (6 months old). Two mother-infant dyads were observed during breastfeeding and the other two were observed during bottle-feeding. During bottle-feeding, the bottle/nipple system the mothers brought for feeding was used. Table 1 summarizes results of the feasibility testing from these four trials, which include testing setup, problems identified, and changes discussed for the next trial. With a series of modifications, we found that the ISMS was a feasible method of measuring intraoral pressure reliably during breastfeeding. However, during bottle-feeding, even if the ISMS was able to provide reliable measurements when the catheter was positioned well in an infant's mouth, the catheter did not consistently remain stable alongside the bottle nipple, which caused the infant a delay in time to latch onto the nipple.

The validity of the ISMS was further evaluated by assessing the synchrony between the ISMS intraoral pressure measurements and the coded cheek movements associated with sucking. With data obtained from four infant-mother dyads, mean percent agreement between the timing of the ISMS measurements and coded cheek movements was 90.6% (range: 84.6 to 100%) within a one second tolerance window, indicating the ISMS measurements were synched in time with measurements from the observation of cheek movement during sucking. Example data demonstrating the synchrony of the ISMS measurements and cheek movements are displayed in Figure 3.

Discussion

In this pilot study, we described a new method of evaluating infant sucking behavior that can be used across both breast and bottle-feedings. Preliminary findings for the feasibility and validity of this method were presented using data obtained from four mothers and their healthy full-term infants. Our preliminary findings suggest that the ISMS has the potential to validly identify sucks and quantify intraoral pressure generated by sucks in both breast and bottle-feeding conditions. In both feeding conditions, the ISMS was able to generate pressure signals that were synched in time with infants' cheek movements associated with sucking. The ISMS was also able to reliably differentiate different levels of negative pressure generated by an artificial sucking condition using a breast pump. However, we also found some limitations of the ISMS from this pilot study. Although we found that the ISMS catheter remained stable alongside the breast nipple throughout the feeding, the catheter was not stable alongside the bottle nipple, affecting the quality of the pressure signals. Unlike bottle nipples, the human breast nipple is compliant in response to an infant's sucking activity; the elasticity of the breast nipple allows it to transform to fit the shape, size, and positioning of the infant's mouth. The flexibility of the breast nipple could have allowed the catheter to be better secured within the infant's mouth. Despite this limitation, the ISMS was able to provide reliable measurements of intraoral pressure during sucking when the catheter was positioned well in the infant's oral cavity. Further testing is necessary to identify strategies to improve the attachment of the ISMS catheter to the bottle nipple and optimize positioning of the catheter to provide the best ISMS signals during bottle-feeding.

Although we found some limitations in this pilot study, our initial results support further investigation of the ISMS as a method to objectively measure an infant's sucking. We have several projects currently underway. The ISMS is currently being used to collect sucking data from a group of high-risk infants enrolled in a NIH-funded project (R01 NR018192-01A1, PI: S. Thoyre) that prospectively examines trajectories of symptoms of problematic feeding in hospitalized infants who are at risk for a chronic feeding disorder from discharge through age 24 months. Using data obtained from this sample, we will further investigate the performance of the ISMS in high-risk preterm and term infants' breast and bottle-feedings; adjustments to the system will be trialed, documented, and reported. We also plan to examine common sucking metrics (*e.g.*, number of sucks per sucking burst, duration and number of sucking bursts per feed, mean peak negative pressure) in relation to other concurrent measures of infant biological function (*e.g.*, neonatal biological risk, cardio-respiratory stability, and gastrointestinal function) and to long-term feeding and neurodevelopmental outcomes.

Conclusions

Preliminary findings suggest that the ISMS is a device that has the potential to validly measure intraoral pressure during both bottle and breast-feeding conditions. Although further modifications are needed to improve the attachment of the device to the bottle nipple, our initial results support further investigation of the ISMS for use in high-risk infants to document sucking behaviors. Testing with a group of high-risk

infants is underway to further investigate the performance of this proposed method to evaluate their sucking behavior.

Abbreviations

ISMS - Infant Sucking Measurement System

Declarations

Ethics approval and consent to participate: This study was approved by the Intuitional Human Subject Review Board for Boston College. Inform consent form was obtained from all study participants.

Consent for publication: Not applicable

Availability of data and materials: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests.

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Authors' contributions: JP conceptualized and designed the study, conducted the data collection and analysis, and drafted the initial manuscript. LAD, AHR, and MJN designed and created the new sucking measurement system used in this study and contributed to the conceptualization of the study and interpretation of the data. EP conducted the data collection and analysis. SMT contributed to the conceptualization and design of the study and interpretation of the data and revising the manuscript. All authors read and approved the final manuscript.

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Table

Table 1. Summarized results of feasibility testing with four mothers and their healthy full-term infants

Study participant	Set-up used for testing	Problems identified	Changes discussed for the next trial
Breastfeeding			
4-week old girl	The ISMS pressure transducer unit was placed in a necklace pouch worn by the mother during feeding.	The mother felt the necklace pouch was in her way during feeding.	We switched to an armband pouch to hold the ISMS pressure transducer unit.
	A U-shape chamber to trap liquid during feeding was placed between the ISMS catheter and pressure transducer unit to prevent liquid damage to the pressure sensor.	The connections between the ISMS catheter, U-shape chamber, and pressure transducer unit were easily disconnected with movements of the infant and mother.	Because no liquid was collected in the U-shape chamber, we decided to eliminate the U-shape chamber and connected the catheter directly to the pressure transducer unit. To improve the connection between the catheter and pressure transducer unit, we used a screw-in connector.
	A catheter was secured with hydrogel tape at the base of the mother's breast, i.e., outside the edge of the areola. The tip of the catheter was located	No problems were identified.	We used the same method for the next trial.

	just beyond the tip of the mother’s nipple.		
4-month old girl	The ISMS pressure transducer unit was placed in an armband pouch worn by the mother during feeding.	No problems were identified.	
	No U-shape chamber was used; a screw-in connector was used to connect the ISMS catheter to the pressure transducer unit.	No problems were identified; the connection between the catheter and the pressure transducer unit remained intact throughout the feeding.	
Bottle-feeding			
6-month old boy	The ISMS pressure transducer unit was placed in a necklace pouch worn by the mother during feeding.	The infant was distracted by the necklace pouch and pulled on it during feeding, which disconnected the catheter from the pressure transducer unit.	We attached the pressure transducer unit to the side of the bottle with a 3M Coban self-adherent wrap.
	A U-shape chamber to trap liquid during feeding was placed between the ISMS	The connections between the ISMS catheter, U-shape chamber, and pressure transducer unit	Because no liquid was collected in the U-shape chamber, we decided to eliminate the U-shape

	catheter and pressure transducer unit to prevent liquid damage to the pressure sensor.	were easily disconnected with movements of the infant and mother.	chamber and connected the catheter directly to the pressure transducer unit. To improve the connection between the catheter and pressure transducer unit, we used a screw-in connector.
	The catheter was secured with hydrogel tape at the nipple rim. Similar to breastfeeding, the tip of the catheter was located just beyond the tip of the bottle nipple.	The catheter did not remain securely alongside the nipple with hydrogel tape.	We used 3M Transpore surgical tape which offers stronger adhesion to secure the catheter onto the nipple rim. We taped the catheter to the top of the nipple rim, allowing the catheter to be more closely located alongside the nipple. We also used 3M Coban self-adherent wrap to additionally secure the catheter onto the nipple rim.
4-month old girl	No U-shape chamber was used; a screw-in connector was used to connect the ISMS catheter to the pressure transducer unit.	No problems were identified.	

The pressure transducer unit was attached to the bottle. The catheter was taped to the top of the nipple rim with 3M Transpore surgical tape and additionally secured to the nipple rim with 3M Coban self-adherent wrap.	The catheter did not remain secure alongside the bottle nipple throughout the feeding. The infant turned away from the nipple; the mother believes the scent of the 3M Coban self-adherent wrap caused this behavior based on previous home feeding experiences.	We discussed using a different wrap with a scent that is not as noticeable to secure the catheter around the nipple rim. Discussion on strategies to improve attachment of the catheter to the bottle nipples are underway.

Figures

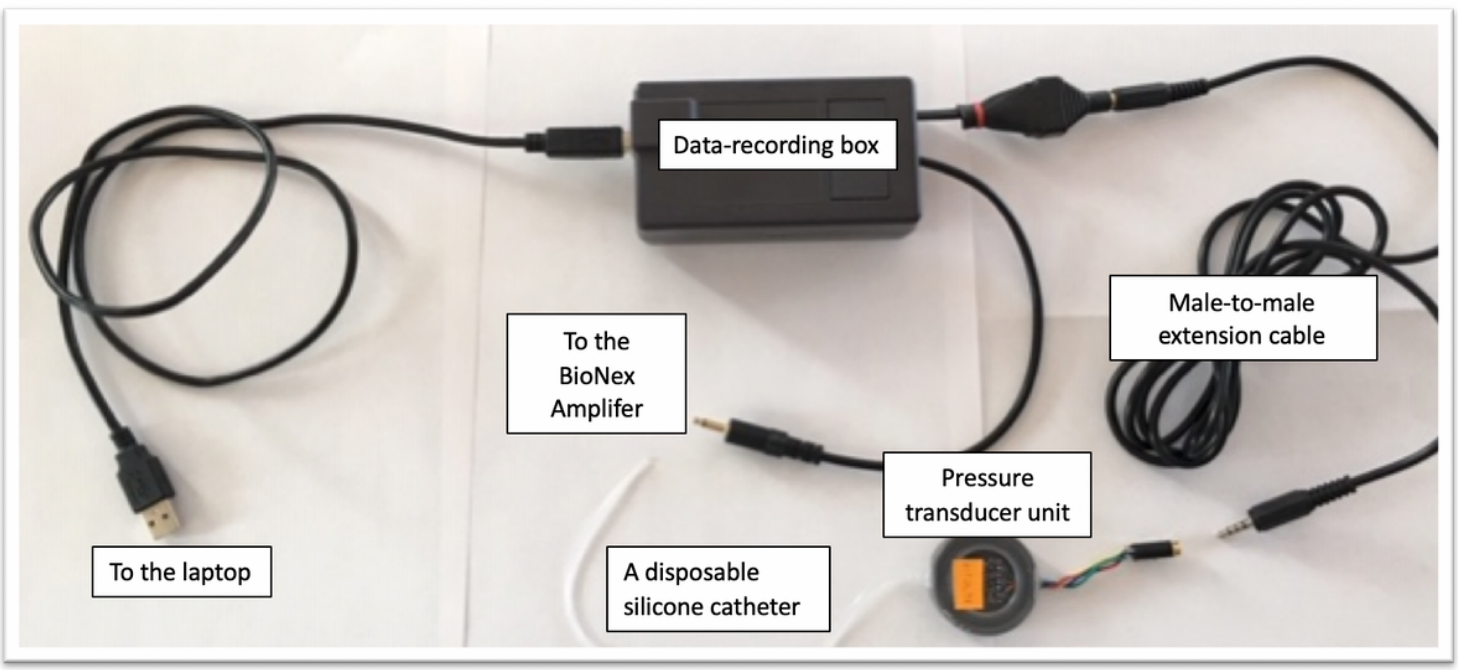

Figure 1

Preliminary design of the Infant Sucking Measurement System

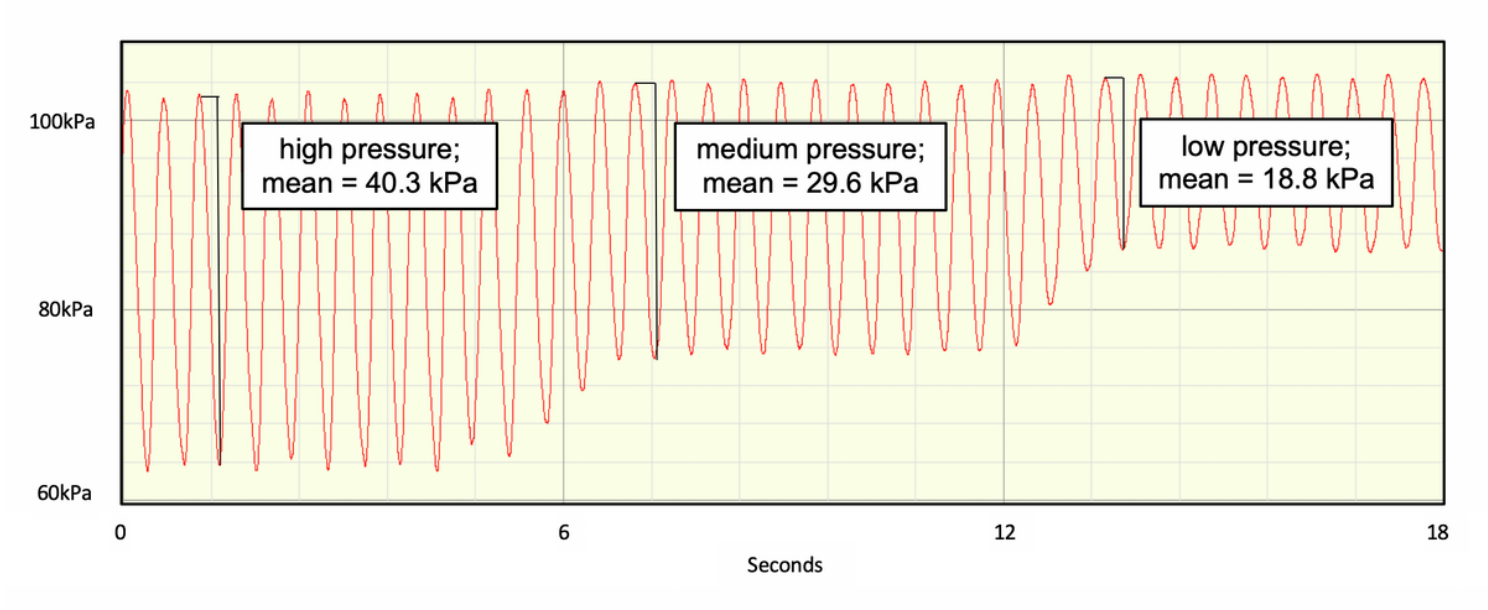

Figure 2

The ISMS differential pressures at low, medium, and high negative pressures applied by a breast pump.

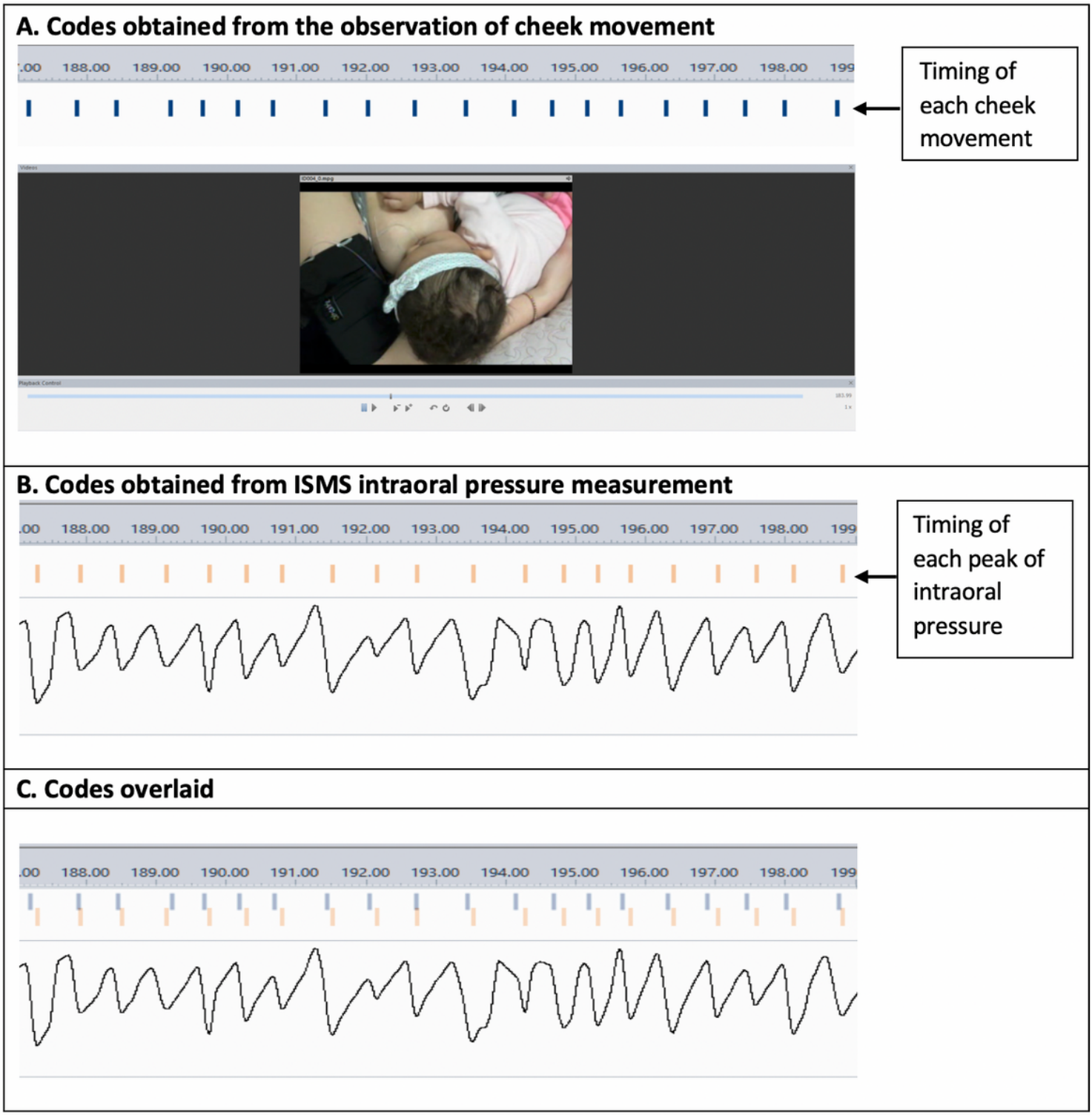

Figure 3

Example data for the synchrony of intraoral pressure measurements obtained from the Infant Sucking Measurement System (ISMS) and direct observation of cheek movements (data in seconds).