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Technical note

Sensorized pacifier to evaluate non-nutritive sucking in newborns

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ABSTRACT

We developed a device for an objective measurement of non-nutritive sucking (NNS). NNS is newborns' spontaneous action that is a predictor of their neural system development and can be adopted as an intervention to train oral feeding skills in preterms.

Two miniaturized digital pressure sensors were embedded into a commercial pacifier and the two signals were simultaneously acquired using the Inter-Integrated circuit (I^2C) interface. This solution traced a complete pressures profile of the sucking pattern in order to better understand the functional aspects of the two NNS phases, the suction and the expression.

Experimental tests with nine newborns confirmed that the sensorized pacifier is an adequate tool for measuring NNS burst-pause patterns.

The identified parameters related to the suction/expression rhythmicity could be used as indicators of the NNS ability. This device might be used both for exploring the possible diagnostic data contained in NNS pattern and for monitoring the sucking skills of premature infants.

1. Introduction

Non-nutritive sucking (NNS) is a basic ability for newborns [1,2]. It is a reflexive oromotor behavior that follows a specific developmental trajectory from the early fetal period, 15-18 weeks of the gestational age [3], through the first year of life. NNS is a stable pattern organized in alternating epochs of burst and brief pause periods [4–8]. Typically, the burst consists of 6–12 suck cycles that occur approximately at 2 Hz followed by pause periods to accommodate respiration [9]. Each suck consists of two phases: suction and expression. Suction is related to changes in negative intraoral pressure. Expression corresponds to the stripping and/or compression of the teat between the tongue and the palate [10,11].

The assessment of NNS is relevant for two main reasons:

(i) To give insight about the integrity of the central nervous system. Recently, sensorized toys and other objects for quantitative measuring of infants' development in the first months of life have been proposed [12,13]. However, these tools are not suitable in the first days of life, since infants show a relatively poor motor repertoire and a disinterest in interaction with objects. Instead, NNS represents an excellent marker of neural system functioning in the first weeks of life [9]. This assertion is confirmed by Prechtl [14]; according to him, spontaneous motility of infants could be considered as the expression of spontaneous neural activity.

(ii) To train preterm infants with nutrition problems and to objective evaluate their readiness to oral feeding. Sucking behavior is principally controlled by a neuronal network, the suck central pattern generator (sCPG) [1]. The development of this specialized neural circuit can be delayed as a consequence of premature birth. Indeed, preterm infants (<34 weeks of GA) rarely show a coordinated sucking. In these cases, the NICU practice is the gavage feeding. Infants are fed by a small tube that is placed through the nose or mouth into the stomach. Hereafter, their readiness to oral sucking is assessed; the therapist places a gloved finger inside the mouth.

In addition, NNS via pacifier represents an efficient intervention to stimulate and accelerate the maturation of the sucking reflex [15–18]. Such strategy promotes a better

Abbreviations: NNS, non-nutritive sucking; I^2C, Inter-Integrated circuit; GA, gestational age; GUI, graphical user interface.

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nutrition and growth of infants and facilitates an earlier discharge from the hospital.

Despite the relevance of this issue, the clinical procedures are already based on qualitative and subjective assessments.

Different studies try to investigate the NNS pattern using biomedical devices. Lindner [19] presented a standard commercial pacifier that containing a transducer to measure the intraoral negative pressure. The perforated nipple allowed for equalize the pressure between the airspace inside the nipple and the intraoral airspace. The Pacifier Activated Lullaby (PAL®) [20,21] is a system that utilizes music reinforcement therapy to stimulate the NNS coordination. It delivers a specifically timed lullaby each time the infant correctly sucks and meets the pressure criteria. The NTrainer® [11,22,23] helps develop and monitor progress of NNS ability in newborns. It is a silicone pacifier with a computer-controlled air pump used to make the nipple pulsate and stimulate the infant's lips and tongue.

These three devices allow for quantify the burst-pause cycles, but the rhythmicity between suction and expression phases was not explored.

Drawing inspiration from clinical practice based on the use of a gloved finger, Lau and Kusnierczyk [24] proposed a finger pressure device to monitor infants' NNS suction and expression pressures. Two catheters were inserted into the index finger of a disposable glove; one was connected to a Micro-tip sensor transducer on the tip and the other to a separate sensor. However, the main drawbacks of this device are the low accuracy, repeatability and reproducibility of measurements; moreover, it is more invasive for the newborn compared to a common teat.

Our solution, to go beyond the limitations of the works previously described, is a sensorized pacifier. The innovative aspect is the possibility to monitor not only the expression pressure but the whole NNS pattern and to differentiate the two NNS components in a non-intrusive way. In addition to our previous related work [25], we identified key parameters to quantify the suction/expression rhythmicity. The idea is to evaluate the functional aspect of these alternating phases and consequently to discover new knowledge about NNS and its development.

2. Methods

2.1. Clinical and technical specifications

On the basis of literature and clinicians' guidelines, we selected the parameters to detect. In order to measure suction and expression during the NNS of infants, the trend of the expression pressure on the teat, and the intraoral negative pressure should be acquired.

Another important aspect that must be taken into consideration when drawing up the specifications is to allow for measurement of the natural movement in an ecological setting, so as not to affect the infant's normal type of sucking. The key features taken into account during the technical design of the device are the followings:

- The material and the components of the device must fulfill the requirements of biocompatibility and electrical safety, in terms of internal voltages, electrical insulation and reached temperature.
- The sensory system should be embedded into the pacifier, so the size should not exceed (3 mm × 3 mm × 1 mm).
- The weight of the sensory system should be less than 15 g in order not to affect the infants' NNS ability and to avoid the pacifier to fall out from the infant's mouth.
- The sensor should be sensitive in the range 110–50 kPa [26] in order to be able to detect NNS pressures in newborns.
- The device should be robust so as to allow reusability.

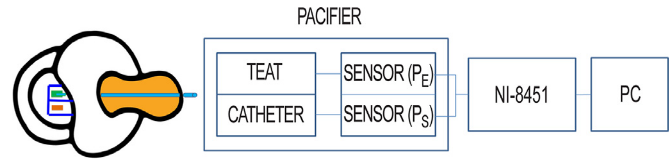

Fig. 1. Design of the device. Left: catheter and sensors placement. The two pressure sensors (red and green boxes) allow to measure both the pacifier pressure and the intra-oral pressure. Right: general scheme of the acquisition system of the sensorized pacifier. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article).

The complete system of data acquisition should be easy to manage, in order make it adaptable to a clinical environment.

2.2. Device design

The device was made by integrating two pressure sensors inside a commercial teat. The general scheme of the device is reported in Fig. 1 and the relative components are described in the following paragraph.

The teat adopted for this application is commercially available (NUK®), suitable for 1–6 month old babies (size 1) and it has a specially designed orthodontic shape, which adapts to the baby's mouth and allows for healthy development of both teeth and jaws [27]. There are both silicone and latex soothers; for this application we chose latex because it is softer and more flexible.

After careful analysis of commercially available sensors, a digital absolute piezoresistive sensor, the LPS331AP (STMicroelectronics®) has been selected. It fits the present application thanks to: (i) the small size (3 mm × 3 mm × 1 mm), (ii) the working range (26–126 kPa), (iii) the sensitivity (4096 LSB/mbar), iv) the low cost and (v) the signal conditioning not required.

The solution proposed is non-invasive, since the two sensors are embedded into an acrylic resin case purposively designed by a 3D-printer and connected to the outer part of the pacifier.

The first sensor is required in order to measure the expression pressure, but size constraints require the pressure sensor to be placed outside the teat, connected to the electronic unit. The inner pressure variations are detected through a hole along the rigid case. This solution ensures a hermetical coupling between the teat and the sensor: while squeezing the latex part of the pacifier, the pressure measured by the sensor reveals the pressure exerted by the infant's tongue, otherwise the pressure value equals the atmospheric pressure. Suction, the negative intraoral pressure, is recorded via a catheter (Medicoplast International GmbH, $\emptyset = 6$ Fr). This small tube from one side is directly connected to the sensor, and on the other it is inserted through an incision of the teat, and it protrudes approximately 2 mm from its tip into the middle of the infant's oral cavity [24,28]. The catheter is made airtight against the nipple with natural latex.

The pressure data can be accessed through an Inter-Integrated Circuit (I^2C) interface. For this application of the I^2C communication protocol, the master is the data acquisition hardware (NI-845, National Instruments®) and the slaves are the two sensors from which the digital pressures are extracted using a single communication bus. The analog to digital converter and the digital filter are embedded in the LPS331AP sensor; it stores the pressure values in two's complement registers that can be read via the I^2C host interface. The software package that is adopted for the proposed measurement system is based on the graphical programming language (LabVIEW®) that provides several advantages, namely flexibility, debugging facilities and friendly user interface. The acquisition period and consequently the duration of a single test can be set by the user while the sampling frequency of the signal is set at 12.5 Hz. The recordings, saved through the LabVIEW® interface,