

# Reliability of the S-FLEX<sup>®</sup> device to measure non-nutritive sucking pressure in newborns

## Confiabilidade do equipamento S-FLEX<sup>®</sup> para verificação da pressão de sucção não nutritiva em recém-nascidos

Marlove Duarte Nascimento<sup>1</sup> , Daniela da Silva Gonçalves<sup>2</sup> , Geovana de Paula Bolzan<sup>3</sup> , Francine Pimentel Höher da Silveira<sup>1</sup> , Angela Regina Maciel Weinmann<sup>4</sup> , Marcus Vinícius de Moraes<sup>5</sup> 

### ABSTRACT

**Purpose:** to establish the reliability of the S-FLEX<sup>®</sup> to measure non-nutritive sucking pressure in full-term newborns. **Methods:** a cross-sectional and quantitative study was conducted in a tertiary hospital, on 30 one- to three-days-old infants born healthy and at term. Each newborn was evaluated twice, each time by a different examiner, at an interval of 4 hours. In each assessment, maximum and mean non-nutritive sucking pressure were measured three times consecutively. The reliability of the instrument was investigated by calculating the repeatability and reproducibility of these measurements. Repeatability was determined by analyzing the consecutive measures taken by each examiner using repeated-measures analysis of variance (ANOVA). **Results:** the maximum sucking pressure was found to be 10.44 ( $\pm$  2.25), 10.12 ( $\pm$  2.25) and 9.73 ( $\pm$  2.61) mmHg, ( $p$  = 0.120), in the first, second and third consecutive measurements, respectively. In the second evaluation, the values were 10.10 ( $\pm$  2.35), 9.98 ( $\pm$  2.02) and 10.37 ( $\pm$  2.29) mmHg, ( $p$  = 0.404). The measurements of mean sucking pressure taken by examiner A in the first evaluation were 3.64 ( $\pm$  1.04), 3.59 ( $\pm$  1.04) and 3.56 ( $\pm$  1.03) mmHg, ( $p$  = 0.852), respectively, and, in the second evaluation, 3.59 ( $\pm$  1.04), 3.51 ( $\pm$  0.92) and 3.63 ( $\pm$  1.04) mmHg, ( $p$  = 0.721). The correlation coefficients between measurements of maximum and mean sucking pressure were 0.708 ( $p$  = 0.001) and 0.828 ( $p$  < 0.001), which are indicative of good and excellent correlations, respectively. **Conclusion:** The S-FLEX<sup>®</sup> can provide reliable measurements of maximum and mean non-nutritive sucking pressure in healthy full-term newborns.

**Keywords:** Sucking behavior; Newborns; Reproducibility of results; Breast feeding; Pacifiers

### RESUMO

**Objetivo:** determinar a confiabilidade do equipamento S-FLEX<sup>®</sup> para verificar pressão de sucção não nutritiva em recém-nascidos a termo. **Métodos:** estudo transversal e quantitativo, com 30 recém-nascidos a termo, saudáveis, entre o primeiro e terceiro dia de vida, internados em um hospital terciário. Foram realizadas duas avaliações em cada recém-nascido, por dois examinadores distintos, com intervalo de quatro horas. Foram realizadas três determinações sucessivas da pressão máxima e a média de sucção não nutritiva, por meio do equipamento S-FLEX<sup>®</sup>. Para determinar a confiabilidade, avaliou-se a repetibilidade e a reprodutibilidade das medidas. Análise de variância e coeficiente de correlação intraclasse foram utilizados para análise dos resultados. **Resultados:** a pressão máxima de sucção, na 1ª avaliação, foi de 10,44 ( $\pm$  2,25), 10,12 ( $\pm$  2,25) e 9,73 ( $\pm$  2,61) mmHg, ( $p$  = 0,120), respectivamente para a 1ª, 2ª e 3ª medidas. Na 2ª avaliação, foi de 10,10 ( $\pm$  2,35), 9,98 ( $\pm$  2,02) e 10,37 ( $\pm$  2,29), ( $p$  = 0,404). A pressão média de sucção na 1ª avaliação foi de 3,64 ( $\pm$  1,04), 3,59 ( $\pm$  1,04) e 3,56 ( $\pm$  1,03), ( $p$  = 0,852) e, na 2ª avaliação, foi 3,59 ( $\pm$  1,04), 3,51 ( $\pm$  0,92) e 3,63 ( $\pm$  1,04), ( $p$  = 0,721). Para a pressão máxima de sucção, o coeficiente de correlação foi de 0,708 ( $p$  = 0,001); para a pressão média foi de 0,828 ( $p$  < 0,001), evidenciando boa e excelente correlação, respectivamente. **Conclusão:** o S-FLEX<sup>®</sup> mostrou-se um equipamento confiável para determinar a pressão de sucção não nutritiva em recém-nascidos a termo, saudáveis.

**Palavras-chave:** Comportamento de sucção; Recém-nascido; Reprodutibilidade dos testes; Aleitamento materno; Chupetas

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<sup>1</sup>Hospital Universitário de Santa Maria, Universidade Federal de Santa Maria – UFSM – Santa Maria (RS), Brasil.

<sup>2</sup>Programa de Mestrado Profissional em Ciências da Saúde, Universidade Federal de Santa Maria – UFSM – Santa Maria (RS), Brasil.

<sup>3</sup>Departamento de Fonoaudiologia, Universidade Federal de Santa Maria – UFSM – Santa Maria (RS), Brasil.

<sup>4</sup>Departamento de Pediatria – Universidade Federal de Santa Maria – UFSM – Santa Maria (RS), Brasil.

<sup>5</sup>Departamento de Fisioterapia – Universidade Regional de Blumenau – Santa Catarina (SC), Brasil.

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**Authors' contributions:** MDN was involved in participant assessments, data collection, and all stages of manuscript drafting and revision; DSG, GPB, FPMS contributed to data collection and manuscript drafting; ARMW supervised the study, analyzed data and revised the manuscript; MVM contributed to study design, data analysis and manuscript drafting.

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**Corresponding author:** Geovana de Paula Bolzan. E-mail: gebolzan@gmail.com

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## INTRODUCTION

The sucking reflex is a simple motor response which is essential for feeding and, consequently, for the adequate growth and development of newborn infants. Unfortunately, the achievement of safe and efficient oral feeding has proved a constant challenge to multiprofessional teams in neonatal care units. As many as 30% of newborns who are hospitalized for preterm birth or other complex clinical conditions have difficulty achieving independent oral feeding<sup>(1-3)</sup>, leading to prolonged hospitalization and possibly childhood eating disorders<sup>(4,5)</sup>.

The assessment of oral skills has become an increasingly important part of routine clinical examinations of newborn infants, especially those born preterm<sup>(6-9)</sup>, since it allows for the implementation of oral motor interventions to optimize oral feeding.

Non-nutritive sucking represents an important indicator of nervous system function in the first weeks of life, and is therefore investigated in most oral assessment protocols. In routine clinical practice, the assessment of non-nutritive sucking is based on the visual and clinical analysis of a newborn's sucking behavior when in contact with an examiner's gloved finger. This evaluation is subjective and highly dependent on the examiner's experience. The search for a more precise assessment method which can quantify the different aspects of sucking behavior has prompted the development of several instruments<sup>(2,5,10-14)</sup>. However, currently available devices have proved impractical for routine hospital use, especially due to an inability to comply with hospital requirements and regulations such as the need for rigorous hygiene procedures<sup>(15)</sup>. Any equipment used in neonatal care units must also be practical, portable and adhere to biosafety standards.

In Brazil, one of the devices available for this purpose is the S-FLEX<sup>®</sup>, which measures the pressure of non-nutritive sucking in infants and expresses the results as physical quantities such as millimeters of mercury (mmHg), or grams of force per square centimeter (gf/cm<sup>2</sup>). The S-FLEX<sup>®</sup> has several features which make it ideal for use in hospital settings. It is easy to handle, portable and can be readily cleaned and sterilized, which is especially important for hospital use. It is also very safe, since it does not expose the infant to electrical currents or magnetic fields. These features are responsible for the practical, unique and innovative nature of the S-FLEX<sup>®</sup><sup>(16)</sup>. Though the equipment is commercially available, no studies to date have evaluated its use in neonatology.

Therefore, in order to confirm the hypothesis that the equipment can provide objective and reliable measurements to complement existing protocols for the assessment of oral skills in newborns, the aim of this study was to determine the reliability of the S-FLEX<sup>®</sup> for measuring the pressure of non-nutritive sucking in healthy full-term newborns.

## METHOD

This cross-sectional study was conducted at a tertiary university hospital from February to March 2018. The study was approved by the UFSM Research Ethics Committee under project number 1.971.069. The mothers of eligible infants were

informed of the goals and procedures of the study and provided written consent to the participation of their children.

Sample size was calculated based on a pilot study of five healthy full-term neonates. Measurements were conducted by two examiners. Variability was quantified as the standard deviation of mean non-nutritive sucking pressure, as measured by each of the examiners (examiner A, standard deviation: 0.396 mmHg; examiner B, standard deviation: 0.309 mmHg). Considering a sampling error of 0.20 mmHg and a significance level of 5%, the sample size was calculated at 24 participants.

The sample for this study consisted of 30 healthy full-term newborns admitted to the Combined Accommodation Unit of the HUSM/UFSM/RS. Infants who met eligibility criteria were identified through hospital records.

The inclusion criteria for the present study were as follows: gestational age of at least 37 weeks, adequate weight for gestational age at birth and a postnatal age of 24 to 72 hours. Exclusion criteria included congenital malformations of the head and neck or central nervous system, chromosomal syndromes and clinical and/or respiratory instability. After informed consent was obtained from the mothers of all participants, the following data were collected: identification details, date and time of birth, gestational age and weight at birth, Apgar score and type of delivery.

Non-nutritive sucking pressure was measured by two different examiners (M.N.D. and D.S.G) on two occasions separated by a 4-hour interval. The examiners were assisted by another professional who helped record the measurements. To facilitate data collection, assessments were conducted at least one hour after infants had been breastfed, and with all infants in an alert or somnolent state. Those in deep sleep were only evaluated after a change in behavioral state. All assessments were conducted under the same conditions, in a quiet and temperature-controlled environment. Mothers were asked to be present during the assessments, and instructed to express a small amount of breast milk to moisten the pacifier attached to the equipment and act as a gustatory stimulus to encourage the sucking reflex. Newborns were then placed on the examiner's lap, with the head and trunk elevated and in midline position, with a slight flexion. The tip of the pacifier was coated in breast milk and placed near the infant's mouth, inducing a seeking reflex. The pacifier was then immediately introduced into the oral cavity. To increase stability, the examiner held the pacifier in place using their thumb and index finger, but did not offer any resistant to the movement of the newborn, who could easily release the pacifier at any point in the assessment. Infants were allowed to suck freely, and the research assistant only started recording the measurements of non-nutritive sucking pressure once the infant had adapted to the pacifier and demonstrated effective sucking behaviors. The evaluation lasted approximately ten minutes. At each of the two assessment points, three successive measurements of non-nutritive sucking pressure were recorded. Whenever infants showed any signs of distress, the assessment was interrupted, and the examiners waited for ideal conditions to restart the procedure.

The variables analyzed in this study were the maximum and mean pressure of non-nutritive sucking, as determined by the pressure exerted on the pacifier attached to the S-FLEX<sup>®</sup> equipment by each of the infants examined.

The three measurements collected in the same evaluation by a single examiner, under the same assessment conditions, were used to determine the repeatability of measures of non-nutritive sucking pressure provided by the S-FLEX®.

The comparison of measures obtained by different examiners allowed for an assessment of the reproducibility of these measurements.

### The S-FLEX® device

The S-FLEX® (Figure 1) is manufactured by the TODMED company (Blumenau, SC). It registers the non-nutritive sucking pressure of newborns and provides both numeral and graphical output. It contains a pacifier with an orifice at one of its extremities, attached to a concave anatomical ring and a pressure sensor. The pacifier is connected to the equipment by a 1.5m extension tube with a 1.25mm diameter. The S-FLEX® can be attached to different types of pacifier. The one used in the present study was a size 1 orthodontic silicone pacifier, extracted from the *oral fit* model from the NUK® brand, and recommended for breastfeeding infants aged 0 to 6 months. A small hole was made on the tip of the pacifier using a 1014 diamond bur (KGS). The physical characteristics of the



Figure 1. The S-FLEX® equipment

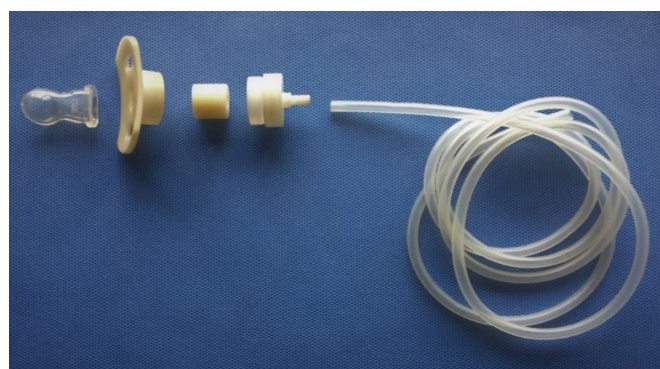


Figure 2. Removable and sterilizable components of the S-FLEX®

S-FLEX® equipment allow for data to be collected in different environments, facilitating the investigation of the interaction between the infant and their surroundings while maintaining ecological validity. The materials and components which come into direct contact with the infant during the use of the equipment meet biocompatibility and electrical safety requirements. They are also made for individual use and can be easily disassembled, cleaned and sterilized by autoclaving (Figure 2).

Results were entered into Microsoft Excel and analyzed using the STATA 10 software. Data normality was tested using the Shapiro-Wilk test. Continuous variables were expressed as mean and standard deviation, while categorical variables were expressed as percentages. Comparisons of measures of non-nutritive sucking pressure obtained by the same examiner (repeatability) were examined using analysis of variance (ANOVA). The comparison of measurements made by different examiners (reproducibility) was carried out using intraclass correlation coefficients (ICC). Results were considered significant at  $p < 0.05$ .

### RESULTS

The mean gestational age and weight at birth were  $39 \pm 1.10$  weeks and  $3141 \pm 262$  grams, respectively. Girls comprised 53.33% of the sample, while the remaining 46.67% were boys. Slightly over half the sample (53.33%) was born through vaginal delivery, and participants as a whole had normal Apgar scores at birth. Sucking pressure was evaluated  $35.04 \pm 0.68$  hours after birth. The characteristics of the infants are shown in Table 1.

The maximum and mean pressure of non-nutritive sucking obtained in three consecutive measurements were very similar between examiners A and B ( $p=0.120$  and  $p=0.404$  for maximum pressure;  $p = 0.852$  and  $p=0.721$  for mean pressure). These results support the repeatability of measurements made using the S-FLEX®. The measurements of maximum and mean pressure of non-nutritive sucking obtained by the two examiners are shown in Tables 2 and 3, respectively.

The analysis of reproducibility was based on the intraclass correlation coefficient between measures of maximum and mean pressure obtained by each examiner separately. Correlations between these values were classified as good and excellent, respectively (Table 4).

Table 1. General characteristics of the sample of 30 newborns

Variables	Mean ± SD	% (n = 30)
Weight at birth (grams)	3141 ± 262	
GA at birth (weeks)	39 ± 1.10	
Apgar		
1 Minute	8.57 ± 1.33	
5 Minute	9.73 ± 0.52	
Type of delivery		
Vaginal		53.33 (16)
Cesarean		46.67 (14)
Gender		
Male		46.67 (14)
Female		53.33 (16)
Postnatal age at assessment (hours)	35.04 ± 0.68	

Subtitle: GA = Gestational Age; n = Number of infants; SD = Standard Deviation



**Table 2.** Maximum non-nutritive sucking pressure (mmHg) of 30 newborns as measured by examiners A and B using the S-FLEX®

	Maximum NNS pressure (mmHg)	p-value
1st assessment	Examiner A	
1st measurement	10.44 (± 2.25)	
2nd measurement	10.12 (± 2.25)	
3rd measurement	9.73 (± 2.61)	0.120
2nd assessment	Examiner B	
1st measurement	10.10 (2.35)	
2nd measurement	9.98 (2.02)	
3rd measurement	10.37 (2.29)	0.404

p = Repeated measures analysis of variance (ANOVA)

Subtitle: NNS = Non-nutritive sucking

**Table 3.** Mean non-nutritive sucking pressure (mmHg) of 30 newborns as measured by examiners A and B using the S-FLEX®

	Mean NNS Pressure (mmHg)	p-value
1st assessment	Examiner A	
1st measurement	3.64 (± 1.04)	
2nd measurement	3.59 (± 1.03)	
3rd measurement	3.56 (± 1.03)	0.852
2nd assessment	Examiner B	
1st measurement	3.59 (± 1.04)	
2nd measurement	3.51 (± 0.92)	
3rd measurement	3.63 (± 1.04)	0.721

p = repeated measures analysis of variance (ANOVA)

Subtitle: NNS = Non-nutritive sucking p=repeated measures analysis of variance (ANOVA)

**Table 4.** Reproducibility of measurements of mean and maximum non-nutritive sucking pressure as determined by the S-FLEX®.

	Maximum NNS Pressure (mmHg)	p value
1st assessment	10.10 (± 2.37)	
2nd assessment	10.15 (± 2.21)	
ICC (95%CI)	0.708 (0.387 – 0.861)	0.001
	Mean NNS Pressure (mmHg)	p value
1st assessment	3.59 (± 0.91)	
2nd assessment	3.55 (± 0.94)	
ICC (95%CI)	0.828 (0.638 – 0.918)	<0.001

p = repeated measures analysis of variance (ANOVA)

Subtitle: NNS = Non-nutritive sucking; ICC = Intraclass Correlation Coefficient; 95%; CI = 95% Confidence interval

## DISCUSSION

This study aimed to investigate the reliability of the S-FLEX® for the measurement of non-nutritive sucking pressure. The results confirmed the reproducibility and repeatability of measurements of maximum and mean pressure of non-nutritive sucking in healthy full-term newborns. The S-FLEX® is an innovative assessment tool and the first of its kind in the field of speech pathology. Not only could the instrument contribute to the care of newborns with feeding problems, but also obtain diagnostic information for different clinical conditions based on variations in sucking patterns.

The achievement of efficient oral feeding is an essential criterion for hospital discharge in newborns, especially those

born preterm<sup>(17)</sup>. In these infants, it may be particularly difficult to identify the ideal moment to initiate the transition from gavage to oral feeding. Though this decision is always based on parameters such as corrected gestational age, weight and clinical condition, this may not be sufficient to ensure the safety of oral feeding. As such, a comprehensive assessment of oral skills may make a significant contribution to this process.

The evaluation of non-nutritive sucking is particularly important, as it provides a marker of nervous system function in the first weeks of life; however, it may not be able to predict the coordination between sucking, swallowing and breathing<sup>(5)</sup>. In clinical practice, the assessment of non-nutritive sucking is usually based on the examiner's observation and perception of the infant's interaction with a gloved finger. This method is inherently subjective. This has led several authors to stress the need for instruments which generate more objective, and therefore, precise measures of non-nutritive sucking pressure<sup>(2,5,10,12)</sup>.

This is precisely the goal of the S-FLEX®, an equipment created in Brazil and developed using national technological resources (TODMED/SC). It is an innovative product with several advantageous features: it is practical, portable and the parts that come into contact with the newborn are easy to clean and sterilize, which is an important prerequisite for hospital use. As a result of these characteristics, the S-FLEX® may be a promising addition to routine hospital care, but no studies to date have confirmed its reliability for use in newborn infants. The aim of the present study was therefore to investigate the repeatability and reproducibility of measures of non-nutritive sucking pressure taken using the S-FLEX® in healthy, full-term newborns.

The three measurements taken with the S-FLEX® in each of the assessment sessions did not significantly differ from one another. The similarity across multiple measurements made by an examiner over a short period of time (intratest) confirms the repeatability of test results<sup>(18)</sup>.

Reproducibility, which corresponds to the similarity between results obtained under different measurement conditions, was determined by comparing the measurements taken by two examiners at different time points<sup>(18)</sup>. The agreement rates for mean (p = 0.825) and maximum suction pressure (p = 0.702) (p<0.001) were classified as excellent and good, respectively, and confirmed the reproducibility of measurements obtained using the S-FLEX® in this participant group.

The use of specialized equipment has long been recognized as a promising method of obtaining objective measurements of sucking in newborns. However, most of the devices used for this purpose lack the distinct characteristics of the S-FLEX®. Additionally, the reliability of measurements obtained using other instruments has not been evaluated by empirical studies.

The first attempt to study non-nutritive sucking behavior in healthy full-term infants was made by Wolff<sup>(19)</sup>. The author collected basic measurements using a commercially available pacifier attached to a pressure transducer. The study found an average sucking frequency of two sucks per second, a range of four to 19 sucks per burst, and rest periods of three to ten seconds between bursts. However, the author did not measure sucking pressure.

In an attempt to quantify the sucking pressure of newborn infants, Lau and Kusnierczyk<sup>(11)</sup> created a device containing

a pressure sensor which could be attached to a gloved finger. This system was tested in four preterm newborns and provided measurements which were more reliable than those involving a gloved finger alone. The pressure readings were only provided for two of the newborns, and ranged from 15 to 35 mmHg. These figures are slightly higher than the maximum pressure observed in the present study, whose average values ranged from 9.73 to 10.44 mmHg.

Simbrón et al.<sup>(13)</sup> calibrated pressure sensors according to the capacity of newborn infants in order to evaluate cyclical patterns of non-nutritive sucking in 34 healthy preterm newborns. The authors reported maximum values of 16 to 20 mmH<sub>2</sub>O, or 11.76 to 14.71 mmHg, which is very similar to the values obtained in the present study.

The equipment used in more recent studies is mostly in prototype and test phase, and not expected to be commercialized in the near future. One example is the system developed by Grassi et al.<sup>(10)</sup>, consisting of a pacifier with two pressure sensors which can differentiate between the components of sucking (suction and expression). The equipment was used to measure parameters such as frequency of sucks per second (Hz) and duration of suction and expression phases in 9 one- to three-day-old infants with gestational age ranging from 33 to 40 weeks. Though experimental results were promising, the sample was small, and the authors acknowledged the need to improve their equipment in order to increase acceptability and facilitate sterilization.

In Brazil, Motta et al.<sup>(12)</sup> developed a device which can use variables such as number of sucking bursts, suction pressure and number of isolated sucks to create a profile of non-nutritive sucking in newborns. According to the authors, preliminary findings suggest that the device may be a promising measuring tool for the assessment of non-nutritive sucking.

The present study represents only a first step toward the development of more objective evaluation methods to assess non-nutritive sucking in the neonatal period. There is still a need to determine the reliability of this equipment in preterm newborns. Feeding difficulties are common in this population as a result of impaired oral motor skills due to interventions performed during the neonatal period. These infants would certainly benefit from assessments conducted with equipment such as the S-FLEX<sup>®</sup>, which provides objective, quantitative and reliable information on non-nutritive sucking. The equipment also has several advantageous features, including its practicality, portability and the ease of use and sterilization, which make it a valuable addition to routine assessments in neonatal care.

## CONCLUSION

The study of equipment reliability is crucial to determine the quality of measurement tools. The results of the present study demonstrate that the S-FLEX<sup>®</sup> is reliable and can be recommended for use in full-term newborns.

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