



## Development of anatomical nasal protector for newborns using prongs\*

Desenvolvimento de protetor nasal anatômico para recém-nascidos em uso de pronga  
Desarrollo de protector nasal anatómico para recién nacidos utilizando prongs

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### ABSTRACT

**Objective:** To develop an anatomical nasal protector for newborns using prongs. **Method:** A descriptive study and technological production based on the Product Development Process, which involved informational design, conceptual design and detailed design phases, between March 2017 and February 2019. **Results:** The design and materialization of nasal protectors were achieved in hydrocolloid plates. These were reprocessed by five sterilization methods: ultraviolet and gamma radiation, gaseous formaldehyde, hydrogen peroxide plasma and saturated steam under pressure. Microbiological tests indicated bacterial growth after processing by formaldehyde and ultraviolet radiation. Gamma radiation guaranteed the sterility and stability of the material. **Conclusion:** Three classifications of nasal hydrocolloid protectors were achieved after the tests, with safe and promising characteristics to continue studies aiming at the clinical evaluation in newborns using prongs.

### DESCRIPTORS

Infant, Newborn; Wounds and Injuries; Nose; Neonatal Nursing; Technology.

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## INTRODUCTION

Science and technology in comprehensive care for the newborn (NB) are advancing and therefore are increasingly benefitting the field of neonatology. However, the appearance of lesions on the newborn's nasal skin, even when implementing measures and recommendations related to ventilatory assistance associated with prongs, and especially among those with an ever lower Gestational Age (GA), is still seen as a challenge for professionals who develop direct care in this area of knowledge and health.

Continuous Positive Airway Pressure (CPAP) has been widely used in many neonatal services as a non-invasive ventilatory mode for primary care in newborns with respiratory distress and after extubation<sup>(1)</sup>. It is characterized by the supply of a mixture of oxygen and compressed air by continuous positive pressure through different interfaces, with a short binasal prong being the most used<sup>(2)</sup>, made in different sizes and of flexible material<sup>(3)</sup>.

Despite the therapeutic advantages, the use of prongs during nasal CPAP therapy can result in injuries which can progress to deformities, nasal asymmetry and airway obstruction<sup>(4)</sup>. It is estimated that the prevalence of injury due to the use of nasal prongs can vary from 20 to 60% worldwide<sup>(5)</sup>, reaching percentages of 85 to 100% nationwide<sup>(6)</sup>.

The development of lesions on the newborn's nasal skin due to the pressure exerted by the prong associated with the length of stay in this ventilation therapy was highlighted in a study which indicates the need to adopt nursing practices emphasizing prevention for safe and quality care<sup>(7)</sup>. This injury is called a pressure ulcer, and its classification and concept were updated by the National Pressure Ulcer Advisory Panel in 2016<sup>(8)</sup>. Monitoring the incidence of pressure ulcers is an important indicator of the care quality provided with a view to patient safety.

The use of nasal protection is a national recommendation for preventing injury to the soft parts of the nostril and septum<sup>(9)</sup>. The use of nasal protectors as a practice to prevent nasal injury is observed in 88.4% of neonatal units in northeastern Brazil<sup>(10)</sup>. Hydrocolloid has been used and evaluated in national and international studies as a material for nasal protection in newborns on ventilatory support with prongs<sup>(7,11)</sup>.

Adoption of these protectors occurs in non-standardized formats, often being achieved through artisanal cuts in the service itself. Studies especially emphasize the use of "pieces" or even of the "pig snout" format to prevent nasal injury<sup>(6,10)</sup>. In this sense, there is a lack of nasal protectors with an anatomical shape made with safe material as a practical means for the care of newborns with prongs.

To this end, one sought to answer the following question with the objective of developing a nasal protector based on anatomical measures for newborns using prongs: What is the practical way to prevent or minimize nasal injuries in newborns with associated ventilatory support prongs?

## METHOD

### STUDY DESIGN

A descriptive and technological production study which used the Product Development Process (PDP) as a methodological reference<sup>(12)</sup>. It contemplated the macrophase of product development presenting the following phases: informational design, conceptual design and detailed design, executed from March 2017 to February 2019.

### DATA COLLECTION

#### INFORMATIONAL DESIGN

The informational design phase involved surveying the scientific literature in the following Virtual Health Library (VHL) databases: *Base de Dados em Enfermagem (BDENF)*, Latin American and Caribbean Literature in Health Sciences (LILACS) and International Literature in Health Sciences (MEDLINE); in addition to the Public Medline (PubMed) and Scientific Electronic Library Online (SCIELO) databases; a search for patents was carried out in the National Institute of Industrial Property, Spacenet and Google Patent. Thus, the following descriptors were used: Newborn, Premature Newborn, Continuous Positive Airway Pressure, Wounds and Injuries, Skin; Nose; as well as the keywords: nasal protector and hydrocolloid. There was no delimitation as to time and language in this survey.

#### CONCEPTUAL DESIGN

The conceptual design phase started with improving the nasal protector models based on anatomical measurements of a sample of 300 newborns based on the columella width measurement averages, right and left nasal distance, right and left nasal introitus area, and nasal width<sup>(13)</sup>. Three classifications were proposed for the nasal protector, namely: 1 - for newborns with adequate weight for GA; 2 - for newborns with low weight for GA; and 3 - for newborns with very low weight for GA. These classifications were performed based on the chart in the child's handbook according to weight and GA<sup>(14)</sup>.

The design of each nasal protector was achieved using the CorelDraw, ImageJ and AutoCAD version 2017 programs. The patent for the final design of each nasal protector was filed with the National Institute of Industrial Property under registration number: BR10201807255; and title: "Nasal Protector Based on Anatomical Measurements of the Newborn".

It was then necessary to make a knife for the cutting and crease machine planned from the perfected drawings for the materialization of the nasal protectors. Next, the molds of each protector were laser cut on steel to guarantee the accuracy of the anatomical measurements. Hydrocolloid plates with 20x20cm dimensions were used, consisting of an external polyurethane film and an internal

layer of carboxymethylcellulose. This material is sold individually packaged and sterilized by gamma radiation. Thus, there was a need to choose an effective sterilization method for reprocessing after handling this material to cut the nasal protectors.

Five methods were considered for reprocessing the hydrocolloid nasal protectors: Saturated steam under pressure; Low Temperature Steam and Formaldehyde (LTSF); Hydrogen peroxide plasma; Ultraviolet radiation; and Gamma radiation, then individually wrapped in surgical grade paper and Tyvec, with this only for sterilization by hydrogen peroxide plasma, and thereafter heat sealed.

The methods Saturated steam under pressure and Hydrogen peroxide plasma were carried out in partnership with the material and sterilization center of a university hospital. LTSF reprocessing took place at a company specialized in sterilization services. Ultraviolet Radiation (UV) was used to evaluate its effectiveness in sterilizing this type of material based on availability in a laboratory linked to the Nursing and Pharmacy School of the Universidade Federal de Alagoas. The Gamma radiation method was carried out in partnership with the Center for Radiation Technologies of the Institute of Energy and Nuclear Research (CTR-IPEN) of the Universidade de São Paulo (USP) using a dose of 15kGy.

After reprocessing, hydrocolloid nasal protectors were subjected to macroscopic analysis on the following characteristics: 1) continuity - which refers to the absence of ruptures and fractures; 2) homogeneity - characterized by the absence of particles visible to the naked eye, areas of opacity or different colors; 3) handling - possibility of handling without risk of breakage; and 4) flexibility - the membrane's ability to fold without breaking<sup>(15)</sup>.

A microbiological and stability evaluation of the material was performed after macroscopic analysis. To do so, a sterility test was performed to check bacterial growth in Petri dishes and Mueller Hinton Agar samples from the three nasal protector classifications at the following storage times: 0, 7, 14, 28 days, after reprocessing. Therefore, Gram stain and microscopic analysis, Triple Sugar Iron Agar (TSI) and the MacConkey agar test were performed to complement this evaluation.

The stability of the material was verified by carrying out the absorption test and by infrared spectroscopy. In the absorption test, samples of the three classifications of nasal protectors in quadruplicates, together with standard commercialized material, were immersed in distilled water and 0.9% sodium chloride saline, totaling 16 samples in each medium. The dry weight ( $W_0$ ) was initially determined and then the wet weights ( $W_w$ ) of the samples were determined after predetermined periods of 1, 2, 4, 6, 8, 10, 24, 48, 72, 144 hours when they were dried twice with filter paper to remove the adsorbed water on the surface. The values were weighed on a scale and the absorption ratio (S) of the hydrocolloid protectors was calculated from the following equation:  $S (\%) = (W_w - W_0) * 100 / W_w^{(16)}$ .

## DATA ANALYSIS AND PROCESSING

Statistical analysis was performed from the absorption ratio calculation for each sample, as well as the mean and standard deviation. The ANOVA test and the Tukey test were used to perform multivariate comparisons to determine if there were statistically significant differences, considering significance  $< 0.05$  and 95% confidence interval.

The structural chemical analysis of the hydrocolloid was performed by Fourier-transform infrared spectroscopy (FTIR) in the medium. Thus, two samples were prepared prior to the analysis, with one sample referring to the commercialized hydrocolloid material called base gel (standard sample), and the other referring to the hydrocolloid material reprocessed by gamma radiation (gamma radiation gel). The samples were analyzed in tablet form from the mixture of KBr in the proportion of 99% to 1% on the optical path of the infrared beam in the region of 4000-400  $\text{cm}^{-1}$ .

The detailed design phase then took place with the technical specifications and definitions of the hydrocolloid nasal protector characteristics already achieved.

## ETHICAL ASPECTS

As this is a technological development study which did not involve human beings, it did not require an evaluation by the Research Ethics Committee.

## RESULTS

The results will be presented and organized according to the three phases considered for the development of the nasal protector according to the PDP, namely: Informational design, Conceptual design and Detailed design.

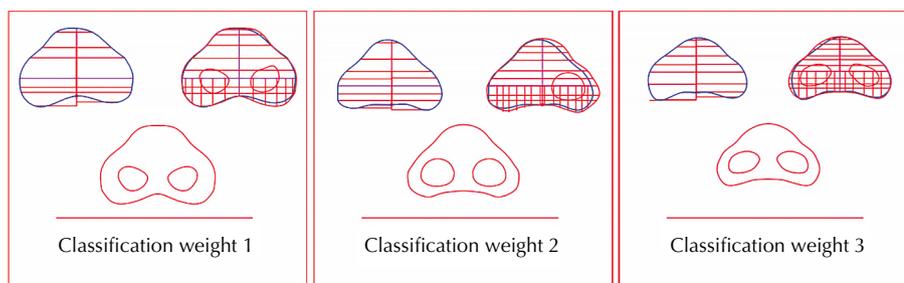
## INFORMATIONAL DESIGN

The scientific literature pointed out aspects which influence the identified problem. Protection of the newborn's nasal skin was verified through references about the use of different protective membranes during ventilatory therapy with prongs, such as: adhesive tape and disposable adhesive<sup>(6)</sup>, gas pad with sodium hyaluronate and polyurethane dressings<sup>(17)</sup>, hydrocolloid<sup>(7,11)</sup>, in addition to silicone gel<sup>(5)</sup>, in order to promote relief and prevent the friction of the prongs against the nasal wing and columella, especially in premature infants.

The search for the formation of patented nasal protectors resulted in five internationally registered patents, four of American origin<sup>(18-21)</sup> and one of Russian origin<sup>(22)</sup>; however, none of them had registered a nasal protector shape with anatomical characteristics of the newborn.

## CONCEPTUAL DESIGN

The results of the improved nasal protectors resulted in three weight classifications, anatomical shapes and different dimensions, as shown in Figure 1.



**Figure 1** – Nasal protectors in the three classifications by weight and gestational age – Maceió, AL, Brazil, 2019.

Samples from the three classifications were reprocessed after materialization with hydrocolloid, and then subjected to macroscopic evaluation as to its continuity, homogeneity, handling and flexibility characteristics. Only two methods corresponded to evaluating the material's excellence after reprocessing: ultraviolet radiation and gamma radiation. The saturated steam method under pressure was disregarded for the following evaluations due to significant macroscopic changes in the material.

The sterility test was carried out to microbiologically evaluate the nasal protectors submitted to sterilization by low temperature methods: LTSF and hydrogen peroxide plasma; and by radiation: UV and gamma. The results showed that the methods by LTSF and ultraviolet radiation were not effective for sterilizing the protectors against the material used. However, the other methods achieved sterilization for the three protector classifications in the four storage times. It is worth mentioning that a bacterial growth evaluation was considered on both the external and internal (adhesive) faces of the protectors.

The Gram stain test mainly pointed to the growth of Gram positive cocci and bacilli in methods with proven sterilization inefficiency. However, Gram negative bacilli were only found in the UV radiation method in the classification

3 nasal protector samples stored at different times of 7 and 28 days. Gram negative bacteria were exposed to differential media for enterobacteria, and such characterization was not found after results obtained by the TSI and MacConkey tests.

The stability of the material was evaluated by the absorption test in order to verify the maintenance of the hydrocolloid property after reprocessing by gamma radiation. Similar absorption behavior was observed in the hydrocolloid nasal protector samples in relation to the comparative sample of the same material processed only once (standard sample). However, the swelling rate was higher for all classifications of nasal protectors submitted to the sterilizing solution when compared to the aqueous medium.

There was a statistically significant difference ( $p < 0.05$ ) for the low weight and very low weight nasal protector samples in the aqueous medium during the 24-hour evaluation. There was a statistical difference ( $p < 0.05$ ) for the nasal protector sample with adequate weight and the standard sample in the 48-hour evaluation. There was also a statistically significant difference ( $p < 0.05$ ) for low weight and very low weight samples in the physiological solution medium in the 24h evaluation, and in the 72h and 48h evaluations ( $p < 0.05$ ) for standard samples and adequate weight, respectively, as can be seen in Table 1.

**Table 1** – Synthesis of the absorption test results with nasal protector samples submitted in aqueous medium and saline – Maceió, AL, Brazil, 2019.

| Medium               | Sample          | Max. absorption % (time) | Standard deviation | <i>p</i> -value* (time) |
|----------------------|-----------------|--------------------------|--------------------|-------------------------|
| Distilled water      | Standard        | 78.049 (72h)             | ± 05.015           | 0.00018 (48h)           |
|                      | Adequate weight | 90.972 (48h)             | ± 15.731           | 0.00017 (48h)           |
|                      | Low weight      | 57.813 (24h)             | ± 15.998           | 0.0011 (24h)            |
|                      | Very low weight | 70.760 (48h)             | ± 04.363           | 0.00019 (24h)           |
| Sterilizing solution | Standard        | 153.364 (144h)           | ± 13.305           | 0.00018 (72h)           |
|                      | Adequate weight | 131.190 (72h)            | ± 09.098           | 0.00018 (48h)           |
|                      | Low weight      | 109.217 (48h)            | ± 08.008           | 0.00019 (24h)           |
|                      | Very low weight | 99.363 (48h)             | ± 18.290           | 0.00020 (24h)           |

\*: *P*-value corresponding to the result of Tukey's pairwise comparisons between the times of the absorption test.

The evaluation by infrared spectroscopy of the chemical structure of the developed nasal protective material did not indicate structural changes resulting from the reprocessing by gamma radiation when compared with the chemical structure of the commercialized hydrocolloid submitted to a single sterilization process.

#### DETAILED PROJECT

Three anatomical nasal protectors made of hydrocolloid were produced with the following dimensions:

*Classification 1* - 0.411 cm columella width, and 1.152 cm in distance from the columellar midline to the right or left

nose wing, with nasal width of 2.304 cm, and right and left nasal introitus area measuring 0.20 cm (Figure 2a);

*Classification 2* - 0.37 cm columella width, and 1.11 cm in distance from the columellar midline to the right or left nose wing, with a nasal width of 2.23 cm, and right and left nasal introitus area measuring 0.20 cm (Figure 2b);

*Classification 3* - 0.35 cm columella width, and 1.03 cm in distance from the columellar midline to the right or left nose wing, with a nasal width of 2.06 cm, and right and left nasal introitus area measuring 0.14 cm (Figure 2c).



**Figure 2** – Hydrocolloid nasal protectors after gamma radiation reprocessing in classifications 1, 2 and 3, respectively – Maceió, AL, Brazil, 2019.

The most appropriate sterilization method for reprocessing was gamma radiation, which enabled the macroscopic characteristics of the hydrocolloid to be maintained while also maintaining its constituents intact and preserving its absorption property.

#### DISCUSSION

The nasal protectors developed with biometric measures have dimensional and shape characteristics according to the classification by weight of the newborns. Hydrocolloid material was adopted for producing the nasal protectors in this study. Its benefits are known to prevent<sup>(11)</sup> and minimize the severity of nasal lesions<sup>(23)</sup>. However, its use should be avoided in those who are infected or colonized with the presence of devitalized tissue<sup>(24)</sup>.

Handling the material to cut it decontaminated it and consequently possibly contaminated it, which would limit its use after cutting the nasal protectors. It is noteworthy that the manufactured nasal protectors were only handled during cutting and never used. This situation could generate greater risk due to the vulnerability of newborns to infections, especially preterm infants who have immature immunological and skin conditions<sup>(25)</sup>.

As a result, it was necessary to choose a safe and effective sterilization method which would preserve the quality of the hydrocolloid after reprocessing. Using methods under the influence of temperature resulted in changes in the hydrocolloid material with the naked eye. The analysis of the macroscopic characteristics pointed to alterations which may be related to the thermal action in the bonds of the

material constituents with impaired homogeneity, characterized by alteration in the color and formation of microbubbles. LTSF sterilization was also compromised among the low-temperature methods, possibly due to hydrocolloid penetration failures, as there are no studies to prove its action on this type of material.

There was ineffectiveness in the ultraviolet radiation process among the radiation sterilization methods, possibly related to the extent of wave penetration in the material used (hydrocolloid) and the influence of surgical grade paper packaging. In contrast, the results after gamma radiation reprocessing demonstrated effectiveness, in particular due to the greater penetrating power of gamma-type electromagnetic waves<sup>(26)</sup>, which even reach products packaged in surgical grade paper (to which the nasal protectors were subjected).

The dose used for reprocessing nasal protectors by gamma radiation was 15kGy, being defined based on the type of material and aspects of possible contamination. It was found to be a sufficient dose for the sterility of this material, as there was no growth of bacterial colonies in any of the nasal protector samples, nor on the external or internal surfaces.

The contamination present in the nasal protector samples reprocessed by LTSF and UV radiation, is possibly linked to microbiota on the hands, which is the main transmission route, as the skin is a reservoir which houses several microorganisms such as staphylococci and micrococci, and transient agents such as spore-forming fungi and aerobic bacteria. Some of these microorganisms may also be present in the nasal cavity<sup>(27)</sup>.

The Gram positive cocci and bacilli stood out among the microorganisms identified in the plates which were positive after reprocessing by UV radiation; however, there was also a growth of two colony-forming units in different plates which were positive for Gram negative bacilli, both in classification 3 protectors. Despite being identified in a smaller quantity, Gram negative bacteria present a special alert on the transmission of neonatal sepsis, since contamination by these microorganisms is more related to cases of neonatal sepsis with the evolution to death.

This association was found in the study, which indicated a 43% mortality rate among the 84 newborns with diagnosed sepsis. Of these deaths, blood cultures showed that 67% occurred due to Gram-negative contamination<sup>(28)</sup>. It is inferred that the presence of Gram positive and negative microorganisms present in nasal protectors may represent infection sources for the newborn, which demonstrates the need for sterility of the devices.

Maintenance of the chemical structure of the hydrocolloid was observed in the stability evaluation by infrared spectroscopy after gamma radiation reprocessing. A similar study which evaluated the effects on the chemical structure of different types of hydrogel-based systems submitted to the same sterilization method also found preservation of functional groups<sup>(29)</sup>. This signals the possibility of developing new studies which can verify gamma radiation reprocessing of other hydrocolloid-based health products which have not yet been used, such as those where the wrapper has broken.

The absorption test demonstrated that there was no change in the hydrocolloid absorption property after reprocessing the nasal protectors by gamma radiation in both aqueous and saline media. However, there was greater maximum absorption by samples submitted to saline. This can be explained by the presence of salts which favor greater water absorption by osmolarity.

The beginning of the absorption time can be related to the low wettability characteristic of carboxymethylcellulose, despite

having a high affinity for water and being highly hygroscopic, which resulted in the beginning of absorption for all samples only after 10 hours, and gradually from the peripheral to the central area. Wettability refers to the interaction property that a given liquid has to spread on the surface of some material<sup>(29)</sup>.

The gradual increase in water absorption by hydrocolloid nasal protectors enabled evaluating an important parameter regarding its use on the skin to prevent or even delay the severity of injuries. Swelling is evaluated in order to verify the maintenance of the material properties considering the lost functions of the injured skin, as well as to avoid liquid accumulation which can favor developing an infection<sup>(30)</sup>.

This issue emphasizes the need for observance by professionals, especially nurses, regarding the solutions used for providing care to newborns using prongs. The hydrocolloid in saline solution showed a higher swelling rate and a longer time for absorption saturation, which may consequently indicate a longer time to exchange nasal protectors produced with this material.

## CONCLUSION

The developed hydrocolloid nasal protectors are revealed as practical means for the prevention and minimization of nasal lesions in newborns with adequate weight, low weight and very low weight for GA, who are on ventilatory support and using prongs.

The microbiological, absorption and chemical characterization tests indicate that the hydrocolloid nasal protector reprocessed by gamma radiation is safe to be used with newborns using nasal prongs during ventilatory therapy.

For future studies, it is suggested to carry out adequacy tests of the nasal protector by weight classification of the newborn, as well as a clinical trial which assesses the effectiveness of hydrocolloid protectors for preventing nasal injuries in newborns using prongs.

## RESUMO

**Objetivo:** Desenvolver protetor nasal anatômico para recém-nascidos em uso de pronga. **Método:** Estudo descritivo e de produção tecnológica baseado no Processo de Desenvolvimento de Produto, que envolveu as fases de projeto informacional, projeto conceitual e projeto detalhado, entre março de 2017 e fevereiro de 2019. **Resultados:** Alcançou-se o desenho e materialização dos protetores nasais em placas de hidrocoloide. Estes foram reprocessados por cinco métodos de esterilização: radiação ultravioleta e gama, formaldeído gasoso, plasma de peróxido de hidrogênio e vapor saturado sob pressão. Os testes microbiológicos indicaram crescimento bacteriano após processamento por formaldeído e radiação ultravioleta. A radiação gama garantiu a esterilidade e estabilidade do material. **Conclusão:** Após os testes, foram alcançadas três classificações de protetores nasais de hidrocoloide com características seguras e promissoras para a continuação de estudos, visando à avaliação clínica em recém-nascidos em uso de pronga.

## DESCRITORES

Recém-Nascido; Ferimentos e Lesões; Nariz; Enfermagem Neonatal; Tecnologia.

## RESUMEN

**Objetivo:** Desarrollar un protector nasal anatómico para los recién nacidos usando prongs. **Método:** Estudio descriptivo y tecnológico de producción basado en el Proceso de Desarrollo de Productos, que incluyó las fases de diseño informativo, diseño conceptual y diseño detallado, entre marzo de 2017 y febrero de 2019. **Resultados:** Se logró el diseño y la materialización de protectores nasales en placas hidrocoloides. Estos fueron reprocesados por cinco métodos de esterilización: radiación ultravioleta y gamma, formaldehído gaseoso, plasma de peróxido de hidrógeno y vapor saturado a presión. Las pruebas microbiológicas indicaron un crecimiento bacteriano después del procesamiento por medio de formaldehído y radiación ultravioleta. La radiación gamma aseguró la esterilidad y la estabilidad del material. **Conclusión:** Después de las pruebas, se lograron tres clasificaciones de protectores nasales hidrocoloides con características seguras y prometedoras para la continuación de los estudios, con el objetivo de la evaluación clínica en los recién nacidos utilizando prongs.

## DESCRIPTORES

Recién Nacido; Heridas y Traumatismos; Nariz; Enfermería Neonatal; Tecnología.

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