

Original Article

Development of an Occipital Decompression Orthosis (ODO) for critically ill patients in intensive care units

Desenvolvimento da Órtese de Descompressão Occipital (ODO) para pacientes críticos em unidades de terapia intensiva

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Abstract

Introduction: Pressure ulcers (PU) are caused by prolonged contact of the skin with a surface, leading to significant damage that is difficult to recover from. Occupational therapists can play a role in preventing these injuries through the creation of assistive technology devices. **Objectives:** To present the development of a device to prevent and treat PU in the occipital region: the Occipital Decompression Orthosis (ODO). **Method:** This is an exploratory study applied using the project management method and developed in four stages. The device began to be developed in 2017 in a reference trauma hospital in the metropolitan region of Belém, state of Pará, Brazil. **Results:** A survey of devices available on the market was conducted, from which the ODO was developed. This orthosis uses the pyramidal mattress, a low-cost material that provides constant low pressure on the patient's occipital segment and was designed through an anthropometric assessment. Based on a literature review and a financial study, a model was created for decompression of the segment. This alternative model is low-cost and effective in preventing PU. **Conclusion:** The ODO is still under a refinement process. Although it is based on current literature addressing pressure injury prevention, it is still necessary to conduct a rigorous scientific study to verify its efficacy. The ODO presents limitations, especially regarding its approval for use by hospitals.

Keywords: Pressure Ulcer, Orthotic Devices, Occipital Bone, Ancillary Services; Hospital, Occupational Therapy.

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RESUMO

Introdução: Lesões por pressão são causadas por prolongado contato da pele com alguma superfície, levando a danos consideráveis de difícil recuperação. Terapeutas ocupacionais podem atuar na prevenção desses agravos por meio da confecção de dispositivos de tecnologia assistiva. **Objetivos:** Apresentar o desenvolvimento de um dispositivo para prevenir e tratar lesões por pressão na região occipital: a Órtese de Descompressão Occipital. **Método:** Esta é uma pesquisa exploratória aplicada através do método de gestão de projetos desenvolvida em quatro etapas. O dispositivo começou a ser desenvolvido em 2017 em um hospital de traumas referência na região metropolitana de Belém, PA, Brasil. **Resultado:** Foi realizado um levantamento dos dispositivos disponíveis no mercado e, a partir disso, desenvolvida a Órtese de Descompressão Occipital. Essa órtese utiliza o colchão piramidal, que é um material de baixo custo que promove a baixa pressão constante no segmento occipital do paciente, e foi confeccionada a partir de avaliação antropométrica. Com base na literatura e em um estudo financeiro, criou-se um modelo aplicável na descompressão do segmento. Esse modelo alternativo apresenta baixo custo e é eficiente para prevenir lesões por pressão. **Conclusão:** A Órtese de Descompressão Occipital segue em processo de aperfeiçoamento. Apesar de se embasar na literatura atual abordando a prevenção de lesões por pressão, ainda é necessário realizar um estudo científico criterioso para verificar sua eficácia. A Órtese de Descompressão Occipital apresenta limitações, principalmente quanto à aprovação de sua utilização por instituições hospitalares.

Palavras-chave: Lesão por Pressão, Aparelhos Ortopédicos, Osso Occipital, Serviços Técnicos Hospitalares, Terapia Ocupacional.

Introduction

The Intensive Care Unit (ICU) is the place designated for critically ill patients who require specific care and high-complexity life support. According to Branco et al. (2020), a critically ill patient is one whose life is “threatened”, is in a state of vital function failure, needs to be kept under constant surveillance, assisted by monitoring equipment, and often subjected to sedation, prolonged immobilization, mechanical ventilation, and the use of vasoactive drugs. The ICU aims to preserve and extend human life in the presence of life-threatening illness. Providing specialized rehabilitation is also part of the care for critically ill patients in ICUs (White et al., 2018).

Despite the use of high-tech services and products, the ICU is an environment that brings numerous complications to patients who do not receive adequate multidisciplinary care (Branco et al., 2020). One of these complications is the development of Pressure Ulcers (PU), also termed pressure injuries, decubitus ulcers, or bedsores. PU occur as a result of prolonged hospitalization, in scenarios of skin tissue perfusion impairment due to changes in blood flow at the pressure site, systemic inflammatory response syndrome, septic shock, hemorrhagic shock, medication use, and hemodynamic instability (Otto et al., 2019).

PU are of significant concern, as their incidence impacts not only the patient and their family, but also the health system, increasing the risks of infection and the costs of supplies and medications, and causing other complications (Brasil, 2017).

Because of their iatrogenic nature, meaning their occurrence is preventable, PU are multifactorial and considered a global public health problem (Pinto, 2011).

The main clause of art. 129 of the Brazilian Penal Code states that bodily injury is characterized by offense to the physical integrity or health of another, targeting both the physical and psychological integrity of the victim. Therefore, any harmful anatomical change to the human body, such as fractures, cuts, abrasions, dislocations, and burns, among others, is understood as physical harm (Brasil, 1940).

According to the Jusbrasil (2014) official website, the crime of bodily injury, as previously described, can be committed by action or omission, such as not providing adequate health care. In any case, the proper forms of punishment for those responsible should be applied when appropriate.

Because it is an iatrogenic event, the care provided to critically ill patients should consider different situations, in which potential risks for the occurrence of PU must be identified, and different initiatives be taken that help minimize their occurrence in ICUs. In this context, occupational therapists play a crucial role in planning and implementing strategies aimed at increasing the functionality of critically ill or potentially critically ill patients, as well as actions directed at preventing complications.

Therefore, the purpose of this study is to present the development of an innovative device, created from alternative and economically accessible materials, to prevent and treat PU in the occipital region of critically ill patients: the Occipital Decompression Orthosis (ODO). Additionally, it aims to introduce to the academic community the use of this assistive technology (AT) device as a resource for pressure injury prevention.

Method

The present study, in its nature, is classified as applied or technological research. Applied research uses the scientific method to solve specific questions and problems, seeking solutions to barriers encountered in everyday practice. According to Silva & Zambalde (2008), this method can be applied to generate new products, patents, or services.

Regarding its objectives, the study is exploratory. As per Gil (2017), exploratory research provides the researcher with refined ideas and greater familiarity with the subject studied. Such research involves literature reviews, interviews, and analyses of examples and/or facts.

Furthermore, the study uses a project management, development, and innovation method aimed at obtaining a product, in this case, the ODO. This is an innovative device developed to meet the locoregional specificities in assisting critically ill patients and individuals bedridden for extended periods.

The ODO began to be developed in 2017 by the first author of this article, while he was still a resident at the Metropolitan Hospital of Urgency and Emergency (HMUE), located in the city of Ananindeua, state of Pará, Brazil. A literature review was carried out on orthoses, especially those of the decompression type used by ICU patients, aiming to prevent PU.

This study was divided into four stages: 1. Literature review and market survey on decompression orthoses; 2. Description of the ODO development; 3. Financial study of the ODO; 4. Current product. These stages are further explored in the following section.

Results and Discussion

Stage 1: Literature review and market survey on decompression orthoses

A literature search and a market survey were conducted on products aimed at decompressing the occipital region. The survey was aimed at products widely marketed by specialized companies and served as a foundation for the authors in the development and elaboration of the ODO.

Products were searched using keywords in both Portuguese and English. In Portuguese, the best results were obtained using the descriptors: “órteses para occipital”; “coxins para occipital”; “coxins para cabeça”; “descanso para cabeça”, whereas for English the best results were found with the terms: “head cradle”; “headrest”; “occipital cushion”.

The aforementioned keywords were used separately. The survey was carried out through Internet search engines, which led to the websites of the manufacturing and/or distributing companies. Additionally, searches were conducted at the SciELO and BVSalud databases. These searches were carried out between September 2022 and February 2023.

Devices developed and/or that received a design update, documented on various platforms between 2018 and 2023, were considered. The choice of this time frame was due to the need to find up-to-date devices that follow scientific recommendations and are effective in preventing/reducing PU.

The following inclusion criteria were applied: be a device for the prevention of PU in the occipital region; present an image or visual representation; be described as a product that can be used to prevent injuries in the occipital region.

After the initial selection through the inclusion criteria, the following exclusion criteria were applied: products whose representative website requested a quote to view the technical specifications; products that displayed images of use in the occipital region but did not describe the goal of injury prevention in that segment. The latter was a key criterion for the research because even if the product showed an image of use in the occipital area, there was no description of how to use it. Thus, possible inference errors by the authors were minimized.

Twenty-five products were selected, all with visual representation and a description of the objective to decompress the occipital region to prevent PU. However, two main limitations were observed: the first was the purchase price – the lowest cost of one of the found products was BRL 214.99, while the highest was BRL 1,881.00. Moreover, none of these products were available in branch stores or through resellers in Brazil, let alone in the North region, thus also increasing the cost of transportation or import. The second limitation was the fact that some products had a design similar to a kneepad or a donut, which could cause PU. Levy et al. (2017) demonstrated that decompression device designs with a central depression can worsen pressure distribution, reducing the contact area of the occipital region and increasing the risks of injuries.

Based on these findings, there was a lack of economically viable products that are suitable for the context of the hospital in question, where there are critical, polytraumatized patients, confined to bed with limited mobility, increasing the risk of developing/worsening PU.

Thus, the ODO emerged as a product to minimize the occurrence and damages caused by PU in patients admitted to the ICU of the said hospital.

Stage 2: Description of the ODO development

The ODO was developed throughout the following phases: patient evaluation, prescription, manufacture, dispensation, and ongoing assessment, adopting strict sanitation protocols to minimize infection risks to the patient.

To produce the ODO, minimal infrastructure is required: an air-conditioned room, a table, ergonomic chairs for the professionals, and personal protective equipment. Common scissors and a utility knife are used as working tools.

The initial versions of the ODO were made using polyvinyl chloride (PVC) as a rigid base, covered with a pyramid-shaped foam mattress, also known as an egg crate mattress. As the production evolved, ethylene-vinyl acetate (EVA) began to be used for constructing the base, enabling better replication, simplifying the manufacturing process, and providing a better anatomical fit to the patient's occipital region. The materials currently used to create the ODO are accessible and low-cost; therefore, this device is easy to handle and can be replicated in various settings.

Initially, the ODO mold was drawn and cut out on an EVA sheet. Subsequently, portions of the pyramid-shaped mattress for attachment to the front and side flaps and to the back part were cut out. The mold measures approximately 32 cm in width and 24 cm in length, serving as a base for standardizing the devices in use, with a pyramid-shaped D28 foam mattress and regular white adhesive tape. To create the mold, anatomical points of the occipital region were considered, using vertical and horizontal lines. The vertical line runs from the external occipital protuberance to, approximately, the lambdoid suture. For the horizontal line, the distance between the ear tubercles is considered (Figure 1).

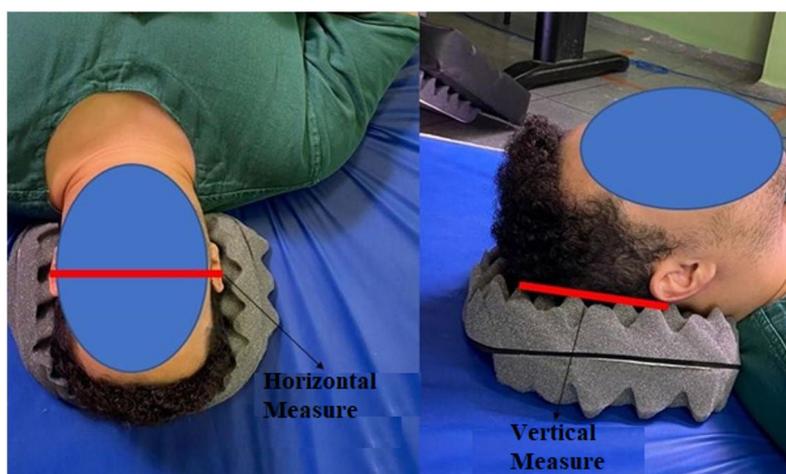


Figure 1. Anatomical considerations of the device.

Source: Prepared by the authors, 2023.

With the molds cut out, the next step was to prepare the adhesive tape strips to secure the structure, with four strips for the anterior region, distributed uniformly and horizontally from the distal to the central area, and four more strips for the posterior region, attached vertically to the side flaps – two on the left side and two on the right side. All portions of the egg crate mattress are secured. Figure 2 shows a detail of the finished device.

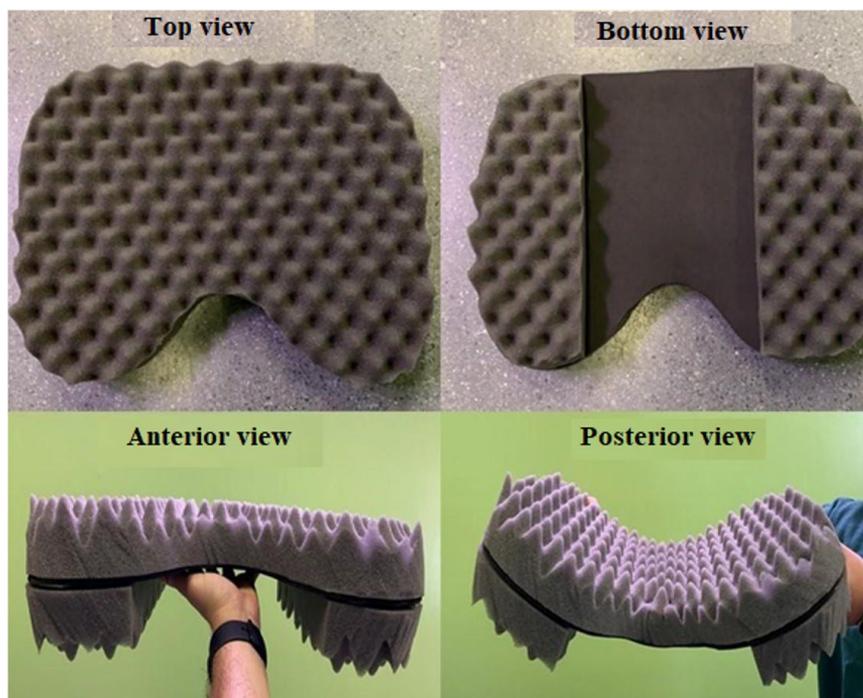


Figure 2. Completed ODO. Source: Prepared by the authors, 2023.

Stage 3: Financial study of the ODO

From a thorough dimensional analysis of the ODO highlights the following: with a main mold of approximately 344.45 ft^2 in width and 258.34 ft^2 in length, this device has an area of about 0.8269 ft^2 . The molds of its two side flaps, with a width of about 53.82 ft^2 and a height of 258.34 ft^2 , have a combined area of $\sim 0.2583 \text{ ft}^2$. Adding the area of the main mold to that of the two side flap molds, a total area of $\sim 1.0852 \text{ ft}^2$ is obtained.

For an accurate financial analysis, one can calculate the value per unit of measurement (ft^2 or ft) of each material (pyramid-shaped D28-foam mattress and adhesive tape) from the ratio between the total value of the material and the total measure of the material in square or linear feet. With this value per unit, it is possible to calculate the cost of each material per piece manufactured by multiplying this value and the specific material measure used in one ODO.

Regarding the D28-foam pyramid-shaped mattress, there is a product on the market with dimensions of about $20.236 \text{ ft} \times 9.4728 \text{ ft}$, resulting in a total area of $\sim 17.7982 \text{ ft}^2$. This mattress was priced at BRL 78.00 at the time of this project's construction. Based on these data, the price per square foot of material is approximately BRL 4.384.

By multiplying this by the amount of material used in one ODO, a cost of about BRL 4.75 is obtained. Note that from a single D28-foam pyramid-shaped mattress it is possible to produce about 16 orthoses.

The EVA roll measuring about 484.38 ft x 107.639 ft (area of ~48.438 ft²) and 0.0164 ft thick is priced at BRL 229.90. From this, the cost per square foot is about BRL 4.744. Given the area used in a single ODO is about 0.8269 ft², the cost is BRL 3.92. Using a single EVA roll, 58 ODOs can be produced.

The adhesive tape roll, with a length of about 14.7639 ft, is priced at BRL 15.90. Considering the use of about 5.0518 ft of tape per device, a cost of BRL 5.44 is reached for each orthosis, allowing for approximately 3 ODOs to be made from a regular adhesive tape roll.

Adding all the unit values corresponding to each material, the total cost for the ODO is BRL 14.12. This is economically attractive for the Brazilian public health reality, allowing for a substantial return on benefits for patients needing to prevent the onset of PU in the occipital region. It is worth noting that this cost only accounts for the materials used, not including labor or permanent materials. This exposition only includes the material's cost since the product is not intended for market sale but for presentation to the scientific community for replication in other services similar to the environment where the ODO was conceived. Table 1 organizes the data for easier visualization. The reference materials used in the device's construction are shown in Table 2.

Table 1. Values for the manufacture of the ODO.

Material	Total measure	Total material cost	Cost per unit of measurement	Measure used for ODO manufacture	Cost for ODO material used
D28-foam pyramid-shaped mattress	17.7982 ft ²	BRL 78.00	BRL 4.384/ft ²	1.0852 ft ²	BRL 4.75
EVA roll	48.438 ft ²	BRL 229.90	BRL 4.744/ft ²	0.8269 ft ²	BRL 3.92
Adhesive tape roll	14.7639 ft	BRL 15.90	BRL 1.077/ft	5.0518 ft	BRL 5.44
Total					BRL 14.12

Source: Compiled by the authors, 2023.

Table 2. Reference materials for the ODO cost calculation.

Material	Value reference
Pyramid-shaped D28-foam mattress	Mercado Livre (2022a)
EVA	Mercado Livre (2022b)
Adhesive tape	Casa e Vídeo (2022)

Source: Compiled by the authors, 2023.

Stage 4: Current product

The described device is configured as an AT resource, more specifically, an orthosis. AT is an area of knowledge that encompasses resources, services, strategies, and techniques aimed at providing a better quality of life for individuals with transient or permanent functional losses (Pelosi & Gomes, 2018).

This device was named an orthosis based on the concepts described by Ramos et al. (2021). Orthoses are AT devices applied externally to the body segment to aid in the prevention of injuries and deformities, maintain joint motion range and muscle strength, and enhance the function of the limb, as per the patient's need. The crafting of an orthosis requires comprehensive knowledge, from the selection and understanding of materials to anatomical, functional, and individual need analyses of each pathology and subject, so that the model meets all necessary aspects to be effective in the therapeutic process (Ramos et al., 2021).

In the hospital and intensive therapy context, it is observed how the occupational therapist, once qualified for this, plays a crucial role in the prescription and creation of this AT resource, planning and executing adaptation, orientation, and training strategies aimed at greater functionality of critically ill or potentially critically ill patients, as well as actions focused on preventing complications (Brasil, 2013).

The literature reports measures used by care teams to prevent the appearance of PU. Feitosa et al. (2020) conducted a literature review and found 10 Brazilian studies addressing strategies used to prevent and treat PU. These strategies include constant skin integrity checks, skin cleansing and moisturizing, the use of plates and covers, position changes every two hours, early patient mobilization, and ensuring a good nutrient intake. Also, the protection strategy for bony prominences is highlighted.

The strategy of protecting bony prominences is corroborated by Mervis & Phillips (2019), who indicate various methods to protect bony prominences, among them, the use of support surfaces, specifically those classified by these authors as constant low pressure (CLP). This pressure refers to the amount of force applied at the contact of the bony prominence with some surface. This force can be reduced by using materials that redistribute it and, consequently, protect the segment.

A material that fits the CLP characteristic is the pyramid-shaped mattress (Barreto, 2016), which is the main raw material for crafting the ODO. This mattress features a slender structure, with varying heights across its length, increasing the contact area, and thus decreasing pressure. Positive points of using the pyramid-shaped mattress for crafting the ODO include easy use and handling due to its lightness and a lower production cost compared with other researched products, in addition to not requiring electricity and presenting low maintenance. A downside to this material is the existence of low-quality products in the market, which have low durability and exhibit inappropriate use, affecting the quality of the orthoses crafted (Barreto, 2016).

In a 2016 experimental study, Barreto, following a team with technical expertise for assistance, reported no significant difference in the prevention of PU between the use of pyramid-shaped mattresses and other types of surfaces. This finding suggests that both the pyramid-shaped mattress and other mattresses are effective in preventing PU. However, the preference for the pyramid-shaped mattress was due to its ease of purchase.

Additionally, this material allows for cuts, molding, and handling for transformations and specifically for crafting orthoses that protect body segments when evaluated by a professional skilled in AT, such as an occupational therapist.

As previously mentioned, there are materials in the literature that propose pressure relief in the occipital region. However, to utilize these devices, the care team must first understand the decompression process. Katzengold & Gefen (2018) list some criteria that decompression devices for the occipital region should follow to be suitable for use, such as design specifically customized for each patient, maintenance of body alignment/positioning, and adaptation or adjustment to anatomical curves.

It is worth noting that, for better effectiveness, the device should not be covered with thick materials like synthetic leather or comforter, as these can promote the warming of the occipital segment, leading to a breach in tissue protection. Based on the authors' experience, it is recommended to use only simple pillowcases, like those for cushions or pillows, to maintain the CLP provided by the pyramid-shaped mattress.

Another point to highlight is devices that have a kneepad or donut shape with a central opening in their design. Although these devices aim to reduce pressure, some studies have shown that their use can have the opposite effect, impairing the redistribution of pressure in the occipital region and potentially causing permanent deformities in the bone structure (Katzengold & Gefen, 2018; Levy et al., 2017).

Furthermore, it is advised that decompression devices for the occipital region should not be crafted using makeshift strategies, such as the use of rolls, towels, blankets, or bandages, as commonly observed in ICUs. This is because their use might not maintain positioning and could breach tissue integrity, increasing the risk of injuries (Waters et al., 2011).

The ODOs were crafted using affordable and low-cost materials: egg crate mattresses, EVA, and adhesive tape. The model considers the anatomical position and is intended for continuous use.

One point to emphasize is that each orthosis can be used for approximately seven days, with variations depending on the loss of density. Thus, if the patient requires continuous use for an extended period, there may be a need for replacement to maintain CLP and minimize the occurrence of PU. The usage duration is a point of comparison between the ODO and pre-fabricated orthoses, given that those available on the market tend to have a slightly longer lifespan.

Thus, the strategy of using the ODO, to prevent PU, supports some findings in the literature. This device employs a material that facilitates pressure redistribution – the pyramid-shaped D28-foam mattress, as long as recommendations are followed to maintain body alignment, have a design based on patient anthropometry, and adapt to users' anatomical curves. Moreover, the device does not have a central depression, allowing it to maintain positioning without increasing the risk of developing PU.

Conclusion

Currently, the ODO is undergoing refinement to become a therapeutic device incorporated into the standard institutional protocol of the ICU in a private hospital in Belém, state of Pará, Brazil. Thus, the aim of this study was, first and foremost, to introduce the ODO in academic literature as a device that can assist in reducing the occurrence of PU in critically ill patients during extended hospital stays and bed restrictions.

While the ODO is based on current literature addressing the prevention of PU, there is still a need for a rigorous scientific study to determine its efficacy, through studies that include control and randomized groups conducted with trauma patients in an ICU setting, where the device was initially designed and applied.

The ODO presents limitations, especially regarding its approval for use by hospitals, the need for training to prepare professionals for its evaluation, prescription, manufacture, and dispensation, and the motor skills required for crafting it, among other points.

Another limitation, which can also be seen as a strength, is the novelty of this device, which uses materials that were originally not intended to be transformed into decompression orthoses. This restricts findings in databases regarding prior experiences.

However, the aim of introducing the ODO to the scientific community will continue in future publications by the authors discussing the results from the ongoing research about the actual efficacy of the product.

Noteworthy is the relevance of developing and continuing studies with this innovative device, given the broadening range of possibilities it provides to occupational therapists in the ICU setting, as well as the reduced hospital costs in providing care to critically ill patients.

The creation of this device by the occupational therapy team has gained recognition, enabling the establishment and expansion of an Assistive Technology Laboratory within the HMUE, as well as in other hospitals in the region, where the devices are currently crafted under the management of occupational therapists.

In conclusion, it is essential to emphasize that the ODO is continuously updated to prevent and treat PU in the occipital segment of patients. New models may emerge, as well as models that aim at decompression in other parts of the body, based on the principles used in the ODO.

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Lucas da Silva Muniz: study design, data organization, writing, and proofreading of the manuscript. Nonato Márcio Custódio Maia Sá: study advising, data organization, and manuscript proofreading. Carlos Roberto Monteiro de Vasconcelos Filho: study design, data organization, writing, and proofreading of the manuscript. All authors approved the final version of the text.

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