UNIVERSIDADE FEDERAL DO RIO GRANDE DO NORTE
FACULDADE DE CIÊNCIAS DA SAÚDE DO TRAIRI
PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS DA REABILITAÇÃO

FERNANDA DUTRA MIRANDA

DISPOSITIVO DE ALIMENTAÇÃO ADAPTATIVO 3D PARA PESSOAS COM DISTÚRBIOS NEUROLÓGICOS: UM ESTUDO PROVA DE CONCEITO

SANTA CRUZ – RN
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Área de Concentração: Saúde Funcional nos Diferentes Ciclos de Vida.

Linha de Pesquisa: Reabilitação Neurológica.

Orientador: Prof. Dr. Ênio Walker Azevedo Cacho.

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DEDICATÓRIA

Aos recomeços. Nunca é tarde para desistir da desistência, e retomar um sonho antigo.

AGRADECIMENTOS

Primeiramente, gostaria de agradecer as várias versões de mim mesma. A Fernanda que sonhou, a que idealizou, a que correu atrás, a que desistiu, a que recomeçou, e a que terminou essa etapa por todas elas. Em algum momento da minha trajetória esse título se tornou um sonho, que por muitas vezes pareceu inalcançável, mas cá estamos!

Aos que não me deixaram desistir e seguraram minha mão com palavras de apoio e incentivo. Especialmente meu orientador Enio. "Ainda dá tempo, se organize para cursar", se não fosse essa breve videochamada com o senhor eu não teria continuado.

À minha mãe, um exemplo de mulher e a quem devo muito do que me tornei. Obrigada por todo suporte e cuidado sempre. Às minhas irmãs por sempre me lembrarem do meu potencial. Ao meu pai que me enche de amor e risadas. Aos meus avós que carinhosamente me colocam em suas orações. Minha família é a minha força. Eu amo muito vocês!

Aos meus amigos de longa data e distância. São mais de 10 anos compartilhando infinitas versões de nós, sempre com muita cumplicidade e respeito, mesmo com muitos km me separando de vocês.

Aos meus amores potiguares que me acolheram e me deram uma família longe de casa, como é gostoso compartilhar a vida com vocês.

Aos meus professores da FACISA/UFRN e todos os colegas que fiz nessa jornada. Foi um prazer todos os aprendizados e trocas de conhecimento.

À minha psicóloga por me ajuda a manter a mente e o coração tranquilo apesar de todas as dificuldades do caminho.

A todos que estão lá de cima, cuidado e olhando por mim. Essa força maior que rege meus caminhos, me orienta em silencio, me ilumina e me guia.

Sou verdadeiramente grata por cada conexão, cada sorriso, cada lágrima, pelos encontros (e também pelos desencontros), por quem ficou, por tudo e todos que me ajudaram a construir essa história até aqui. E que continua...

RESUMO

Introdução: A autonomia na realização de atividades diárias, como conseguir se alimentar sozinho, é muito importante para manutenção da qualidade de vida. Porém, a independência na execução de tarefas pode ser afetada por limitações decorrentes de distúrbios neurológicos. Tecnologias assistivas, como dispositivos de alimentação adaptativos, podem ajudar a compensar essas limitações, mas a acessibilidade e os custos são desafios. **Objetivo:** Este estudo propõe o desenvolvimento e teste de viabilidade - prova de conceito, de um novo dispositivo de alimentação adaptativo fabricado com o uso de impressão 3D, buscando oferecer uma solução acessível, nacional, personalizada e de baixo custo, para melhorar a independência desses indivíduos. **Métodos:** Trata-se de um estudo observacional, clínico, transversal, de caráter quantitativo, que utilizou a abordagem de Design e Desenvolvimento de Produtos, junto a impressão 3D, para desenvolver um dispositivo de alimentação adaptativo. Para prova de conceito, o dispositivo foi avaliado por sete participantes com distúrbios neurológicos. Questionários clínicos foram aplicados para coletar dados. O desempenho e satisfação dos participantes foram avaliados pela COPM. A usabilidade e satisfação do dispositivo foram avaliadas pela SUS e B-QUEST 2.0. **Resultados:** O dispositivo de alimentação adaptativo foi desenvolvido para auxiliar indivíduos na tarefa de alimentação de forma autônoma e independente. Seu design universal e inovador pode contornar diferentes limitações decorrentes dos distúrbios, através de sete características chave. Além de personalizado, acessível e de baixo custo, o dispositivo resultou em melhor percepção do desempenho funcional e satisfação, apresentando uma boa usabilidade. A satisfação dos participantes com o dispositivo também foi positiva. **Conclusão:** O dispositivo de alimentação adaptativo 3D é recomendado para indivíduos com distúrbios neurológicos, proporcionando benefícios funcionais e a retomada da autonomia no processo de alimentação. A abordagem de desenvolvimento utilizada resultou em um dispositivo funcional, personalizado e de baixo custo, com boa usabilidade e satisfação, permitindo indicar a viabilidade do dispositivo.

Palavras-chave: Tecnologia Assistiva. Reabilitação. Utensílios de Alimentação. Satisfação do paciente. Impressão 3D. Distúrbios Neurológicos.

ABSTRACT

Introduction: Autonomy in performing daily activities, such as being able to feed oneself, is crucial for maintaining quality of life. However, neurological disorders can impose limitations that affect task independence. Assistive technologies, such as adaptive eating devices, can help compensate for these limitations. Nevertheless, accessibility and cost remain significant challenges. **Objective:** This study proposes the development and feasibility testing - proof of concept - of a novel adaptive eating device manufactured using 3D printing technology. The aim is to offer an accessible, national, personalized, and low-cost solution to improve the independence of individuals with neurological disorders who experience difficulties with self-feeding. **Methods:** This observational, clinical, cross-sectional, quantitative study, which utilized the Product Design and Development approach coupled with 3D printing to develop an adaptive eating device. For proof of concept, the device was evaluated by seven participants with neurological disorders. Clinical questionnaires were administered to collect data. Participant performance and satisfaction were evaluated using the COPM. Device usability and satisfaction were assessed using the SUS and B-QUEST 2.0. **Results:** The adaptive eating device was developed to assist individuals in the task of feeding autonomously and independently. Its universal and innovative design can overcome various limitations resulting from disorders, through seven key features. In addition to being personalized, accessible, and low-cost, the device resulted in improved perception of functional performance and satisfaction, exhibiting good usability. Participant satisfaction with the device was also positive. **Conclusion:** The 3D adaptive eating device is recommended for individuals with neurological disorders, providing functional benefits and restoring autonomy in the feeding process. The development approach yielded a functional, personalized, and low-cost device with good usability and satisfaction, allowing for the indication of device feasibility.

Keywords: Assistive Technology. Rehabilitation. Eating Utensils. Patient Satisfaction. 3D printing. Neurological Disorders.

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LISTA DE ABREVIAÇÕES

3DAED: 3D Adaptive Eating Device

3D printing: Three-dimensional printing

ADLs: Activities of Daily Living

AD: Assitive Device

AED: Adaptive Eating Device

AT: Assistive Technology

B-QUEST 2.0: Quebec User Evaluation of Satisfaction with Assistive Technology (Version 2.0)

CAD: Computer-Aided Design

COPM: Canadian Occupational Performance Measure

CP: Cerebral Palsy

EHI: Edinburgh Handedness Inventory

FIM: Functional Independence Measure

MMSE: Mini-Mental State Examination

MVP: Minimum Viable Product

ND: Neurological Disorders

PD: Parkinson's Disease

PDD: Product Design and Development

PWD: People with Disabilities

RN: Rio Grande do Norte

SMA: Spinal Muscular Atrophy

SUS: System Usability Scale

TBI: Traumatic Brain Injury

SUMÁRIO

1 INTRODUÇÃO E JUSTIFICATIVA

Estima-se que cerca de 1,3 bilhões de pessoas vivam com algum tipo de deficiência, o que representa 16% da população do mundo (WHO, 2023). No Brasil, segundo os dados publicados na Pesquisa Nacional por Amostra de Domicílios Contínua (PNAD), a população com deficiência corresponde a aproximadamente 18,6 milhões de pessoas, com a região Nordeste destacando-se com o maior percentual de PCD, estimado em 5,8 milhões de pessoas (IBGE, 2023).

O conceito de deficiência foi amplamente discutido ao longo dos anos, sendo alterado de uma visão clínica e individual, para uma perspectiva sócio estrutural, entendendo, a deficiência e a funcionalidade como fruto da interação dinâmica das questões de saúde com os fatores contextuais, pessoais e ambientais (WHO, 2011).

Diante desse conceito, as Pessoas com Deficiência (PCD), segundo a Lei 13146/15 (Estatuto da Pessoa com Deficiência), que concretiza o compromisso firmado pelo Brasil na Convenção Internacional sobre os Direitos das Pessoas com Deficiência, são aquelas que “têm impedimentos de longo prazo de natureza física, mental, intelectual ou sensorial, os quais, em interação com diversas barreiras, podem obstruir sua participação plena e efetiva na sociedade em igualdades de condições com as demais pessoas” (BRASIL, 2015).

Ainda segundo os dados da PNAD, cerca de 1,2% da população com deficiência no Brasil apresenta alguma dificuldade para realização de atividades relacionadas ao cuidado pessoal (IBGE, 2023). Essas atividades também podem ser chamadas de Atividades da Vida Diária (AVDs), que são tarefas desempenhadas para manutenção pessoal, como, no caso do autocuidado, banhar-se, vestir-se ou alimentar-se (TROMBLY, et al., 2005).

A capacidade de conseguir realizar as AVDs sem a ajuda de outras pessoas, como conseguir comer sozinho, é muito importante para manutenção da independência na vida diária (TURGEON et al., 2022). Porém, o indivíduo pode ter essa autonomia afetada decorrente de distúrbios neurológicos, que afetam de alguma forma o sistema nervoso central e periférico, por diversas causas, como doenças genéticas, lesões cerebrais, doenças neurodegenerativas ou paralisia cerebral (VICENTE-SAMPER et al., 2021).

Uma forma de retomar a execução dessas tarefas e de melhorar a qualidade de vida dessas pessoas pode ser feita através do uso de Tecnologias Assistivas (TA), que incluem produtos, serviços, equipamentos ou tecnologias adaptadas, que visam a manutenção ou melhoria do funcionamento e independência dos indivíduos

(BHIDAYASIRI et al. 2022; HOLLOWAY et al., 2021). Desenhadas e construídas para atender a uma necessidade específica, as TA não melhoram a função em si, mas compensam a função prejudicada, otimizando as execuções das tarefas diárias dos indivíduos, tornando-os mais autoconfiantes, autossuficientes e independentes. Os dispositivos assistivos podem, portanto, auxiliar essas pessoas em atividades como no processo de alimentação, proporcionando que consigam comer de forma eficaz e sozinhas (NAZRIN; ABDULLA; SAN, 2021; WÄCKERLIN et al., 2020).

Entretanto, é estimado que a cada dez pessoas, nove não conseguem ter acesso a esses dispositivos, por fatores limitantes como a disponibilidade e principalmente o custo (HOLLOWAY et al., 2021). Além de caro, os dispositivos comerciais podem não ser personalizáveis, não atendendo às necessidades específicas dos indivíduos. Para contornar essas problemáticas, uma alternativa que pode ser empregada é o uso da tecnologia de impressão 3D, que permite a fabricação de dispositivos adaptativos de baixo custo, com design personalizados, com tempo de produção otimizado, permitindo replicabilidade em escala, melhorando a adaptabilidade e incorporando funcionalidade (HUNZEKER; OZELIE, 2021; SILVA et al., 2024).

Diante do exposto, e tendo em vista as implicações dos distúrbios neurológicos na vida dos indivíduos acometidos, principalmente no que se refere às questões de autocuidado, impossibilitando processos simples e importantes, como o processo de alimentação de forma autônoma, e considerando também a baixa acessibilidade e altos custos dos dispositivos de alimentação adaptativos, este estudo propõe o desenvolvimento e teste de viabilidade - prova de conceito, de um novo dispositivo de alimentação adaptativo 3D para indivíduos com distúrbio neurológicos, com o intuito de oferecer uma nova tecnologia acessível, nacional e de baixo custo.

2 OBJETIVOS

2.1 Objetivo geral

- Desenvolver e testar a viabilidade de um dispositivo de alimentação adaptativo 3D para indivíduos com distúrbios neurológicos.

2.2 Objetivos específicos

- Desenvolver e validar o design de um dispositivo de alimentação adaptativo de baixo custo utilizando a abordagem de Design e Desenvolvimento de Produto e a impressão 3D (Artigo 1).
- Avaliar e verificar a viabilidade do dispositivo de alimentação adaptativo 3D no processo alimentar de indivíduos com distúrbios neurológicos (Artigo 2).

3 ARTIGOS

3.1 Artigo 1

Design and Fabrication of a 3D adaptive eating device based on a PDD approach

Fernanda Dutra Miranda and Enio Walker Azevedo Cacho

Abstract

Background: Assistive Technology (AT) can aid individuals with disabilities or limitations, result from neurological disorders, enhancing functionality and independence in Activities of Daily Living using personalized products. While AT solutions for feeding tasks exist, reducing costs and promoting autonomy, there's a gap in low-cost options in Brazil. This study aimed to fill this gap by developing and validating a low-cost adaptive eating device using the Product Design and Development (PDD) approach and 3D printing.

Methods: The 3D adaptive eating device was developed and manufactured using the PDD approach and 3D printing. Testing and validation of the device were performed by seven individuals with neurological disorders to determine the usability and final design of the 3D adaptive eating device using a questionnaire and open-ended feedback.

Results: Developed to assist patients with eating tasks, the 3D adaptive eating device presents a universal design to overcome various limitations, through seven key features. The innovative design of the device improves usability and offers affordability and replicability. Evaluation by patients confirmed its practicality and user-friendly, with most expressing willingness to purchase. No design changes were suggested, affirming its potential market viability.

Conclusion: The 3D adaptive eating device is recommended for patients with neurological disorders, providing autonomy in feeding tasks. Utilizing the PDD approach and 3D printing enhanced the development process, optimizing time and costs, and promoting stakeholder integration. This approach resulted in a functional and innovative product, addressing market gaps.

Keywords: Assistive Technology; Product Design; Product Development; 3D printing; Neurological Disorders.

Introduction

Assistive Technology (AT) is a term used to identify products and services designed to compensate for a difficulty, maintaining or improving functionality, functional independence, social participation, and well-being of an individual, especially People with Disabilities (PWD), elderly people, or individuals with long-term limitations [1, 2]. AT is prescribed to individuals, as a strategy in a rehabilitation context, to act as facilitators, removing barriers and functional limitations, and supporting the execution of Activities of Daily Living (ADLs) [3].

Limitations in performing ADLs autonomously may result from physical disabilities or movement disorders, stemming from various causes such as Neurological Disorders (ND), which often lead to progressive or permanent sequelae [4, 5]. NDs represent one of the world's major health issues [6], being one of the leading causes of disability and the second most common cause of death [7]. However, as it includes different pathologies, such as Cerebral Palsy (CP), Traumatic Brain Injury (TBI), Parkinson's Disease (PD), or neuromuscular diseases, such as Spinal Muscular Atrophy (SMA), limitations and disabilities present themselves in different ways, requiring different care, services, and assistive devices [4, 7, 8].

Understanding the context and needs of individuals with ND, the inclusion of AT into the Rehabilitation process, besides the advantages of supporting active participation and promoting functional autonomy, has the potential to reduce social and healthcare costs [2, 5, 9]. Furthermore, access to AT is an international human right, legislatively protected, where the state should assume the role of facilitator to promote such access to AT [3].

The first device, within the scope of AT, aimed at assisting individuals with limitations in feeding tasks, available on a large scale commercially, was registered in the 1990s [8]. In recent years, new device solutions to assist in feeding tasks have been proposed, such as smart spoons, active and passive stabilization devices, and weighted spoons, with the majority focused on patients with PD [8, 10-15].

Some of these studies have been conducted in Brazil; however, the national demand for adaptive eating devices is still not met because there is insufficient development of local technologies, leading to imports. This scenario complicates the acquisition process, making access private, due to high costs [3, 8].

Product design can be focused on novelty or efficiency [16], but generally, the Product Design and Development (PDD) process is summarized by the logical systematization of activities that translate the individual's needs into a final product [17].

The development of AT must combine technical and social knowledge in a user-centered approach [18], making collaboration among professionals from different rehabilitation fields essential in this process [19], aiming to meet the individual's real needs with low-cost, lightweight, user-friendly, and personalized solutions [20]. To meet these requirements, the use of 3D printing has been increasingly used in the healthcare sector, as it allows not only individual customization, but also accessible replicability [21].

Most studies that use 3D printing in rehabilitation focus on the development of orthoses and prosthetics. However, both process, systematization and 3D printing, can be used in the development of adaptive eating devices [13, 22], given that 3D printing reduces costs and acquisition time compared to the average price and wait time to purchase and receive a commercial device [21].

Due to the scarcity of low-cost national supply of adaptive eating devices, it is necessary to improve studies involving the design and development of new devices that effectively assist individuals with ND in feeding tasks. Therefore, the aim of this study was to develop and validate a low-cost adaptive eating device that meets the various needs of individuals with ND, through the application of the PDD approach along with 3D printing.

Methods

The PDD approach [23] was used to develop and manufacture a 3D adaptive eating device. This approach, which takes a more commercial vision, incorporates market issues into the process of ideation and development of new solutions. The use of PDD aimed to overcome the challenge of creating a new innovative, scalable, and low-cost adapted device.

The process of the 3D adaptive eating device followed the first seven stages of PDD: Analyzing market and customers' needs, (2) Product concept generation, (3) Product design specifications, (4) Design for manufacturing, (5) Development of concept and prototype, (6) Detailed design, (7) Design evaluation and review. The specific tasks are described in Fig. 1. The last step, Product launch, was not covered in this study.

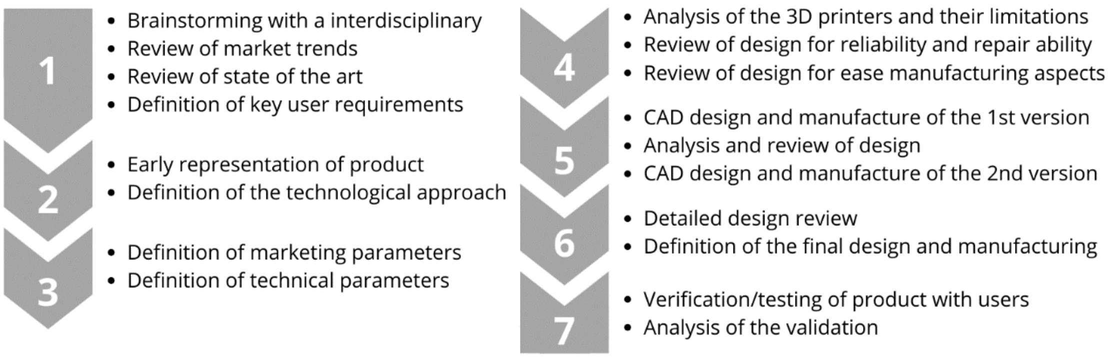

Fig. 1 PDD specifics tasks

Analyzing market and customers' needs

The first step consisted of identifying and analyzing the opportunity for the new product in the market, as well as understanding and defining the users' needs to establish the main requirements of the adaptive eating device. The study began with brainstorming rounds among an interdisciplinary group composed of professionals related to the area of rehabilitation (Biomedical Engineer, Physiotherapist, and Occupational Therapist) to identify the primary issues and limitations experienced by patients with ND when performing feeding tasks.

In the discussion, professional experiences were considered through case reports, taking into account the reality of the population in the Brazilian Northeast, more specifically of patients from the interior of the state of Rio Grande do Norte (RN). Socioeconomic, cultural, and access issues to AT devices for this population were included in the debate. The analysis of models and availability of adaptive eating devices was carried out in two ways: market analysis and state-of-the-art analysis. The market review was carried out through research using the online search tool Google. The existing adapted device options were identified and evaluated according to the level of complexity of the product, target audience, price, nationality, and sales locations, as well as the level of competitiveness in the market.

Once the market was understood, the research was expanded to scientific analysis, with literature searches using electronic database tools, such as PubMed, Web of Science and LILACS. Studies involving the development of adaptive eating devices were evaluated based on their level of complexity and scalability, publication year and country, impact factor, and target audience.

With the information and analyses obtained up to this stage, the main characteristics to be used as inspiration for the design were listed. The main requirements of the adaptive eating device were defined as: a shell-shaped tip to prevent spillage; a thickened, textured, and rubberized handle; the possibility of adjusting the weight; and the inclusion of a strap for optional attachment.

The definition of requirements was made not only to propose an improvement over the identified products, including an innovative differential, but also to propose a design that would make the new adaptive eating device as universal as possible, catering to a wider range of neurological conditions.

Product concept generation

Understanding the available market reality and the needs of users, patients with ND living in the Brazilian Northeast, the concept of the device began to be developed. The initial representation of the product was made through freehand sketches to refine its design and details in line with the desired characteristics and requirements. Once the concept was defined, the next task was to determine the technological approach, that is, how the idea for the device would come from paper to become a physical product. The additive manufacturing process, through 3D printing, was selected as the means of manufacturing the adaptive eating device.

Product design specifications

The objective of this stage is to document how the product should be and its performance, specifying all the characteristics and requirements of the product based on the defined design and selected manufacturing method, also considering the materials and inputs. In this step, market parameters were also determined, such as potential customers, competitors, average price, and possible distribution methods; as well as technical parameters, including quality standards, weight and size limitations, safety and maintenance requirements, material specifications, and manufacturing constraints.

Design for manufacturing

In the Design for Manufacturing step, consideration was given to how the parts and components of the product would be produced and assembled. After all, the goal was to design a product that could be easily and economically manufactured. The choice of using 3D printing was made because it brings benefits such as cost reduction, good quality, and minimizing environmental impact by reducing waste generated during production.

However, the 3D printing production technique has limitations, as 3D printers have different characteristics, requiring an analysis of the models to define the most suitable one. The selected printer was capable of printing all parts of the device simultaneously, in a timely manner, with little material consumption and good quality, eliminating the need for post-processing to finish the product.

At this step, the design was reviewed in terms of reliability and repair ability, which involved checking potential product failures, such as where and how it could break; determining if parts can be replaced; and other maintenance aspects such as cleaning. A review of manufacturing aspects was also conducted to ensure that the product does not require extensive assembly and handling instructions.

Development of concept and prototype

After establishing and finalizing the entire product design and manufacturing issues, the product development step began. The first version of the adaptive eating device was represented by a virtual model (Fig. 2a), using Computer-Aided Design (CAD) software, Autodesk Fusion 360, and then manufactured through 3D printing.

After manufacturing, the first mock-up underwent analyses where positive aspects were identified, but also improvement points were listed, such as dividing the device into two parts, aiming for a more effective and efficient manufacturing process. The design was refined, and new CAD versions were created.

A second version was modeled (Fig. 2b) and manufactured, then submitted for analysis again. The device remained as a single final piece, however, for manufacturing it was sectioned, and the parts were later joined together (Fig. 2c). In addition to product quality parameters and manufacturing parameters, this version underwent preliminary laboratory tests. Although the second version proved to be more functional, new design refinements were proposed, aiming for structural improvements for scale production, as well as considering aesthetic adjustments.

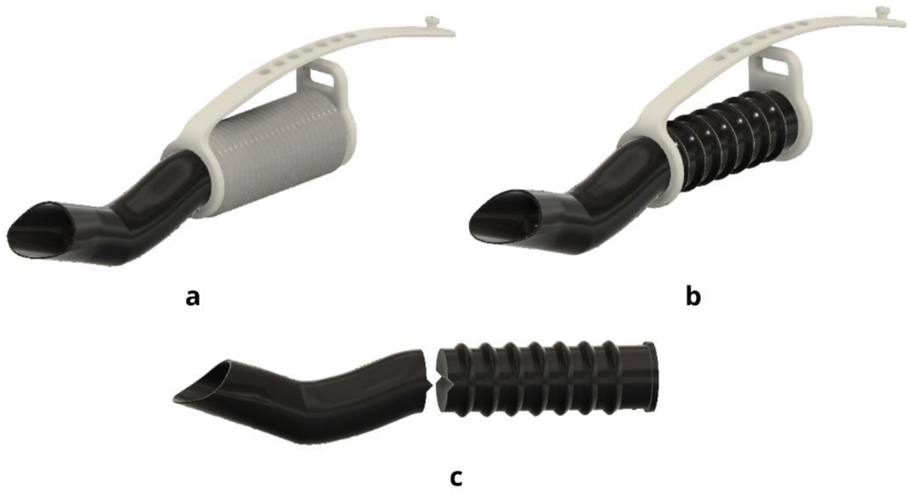

Fig. 2 CAD representations. (**a**) Virtual model of the first version. (**b**) Virtual model of the second version. (**c**) Second version in two parts.

Detailed design

In the previous steps, assumptions and predictions of potential errors and product failures were introduced, in order to reassess and refine the design. This process aims to reduce uncertainties until reaching a solid conception of the final product.

A thorough review of the entire project was used to confirm whether the developed adaptive device met the intended purpose, taking into account both design and manufacturing requirements. However, market assessments were also included, detailing the expected reliability of the product, its maintenance, safety, including considerations of locality and social, cultural, and economic characteristics. Environmental and sustainability issues were established, detailing the use and availability of raw materials, waste generation, and ways to reduce environmental impacts.

Based on this review, the Detailed Design ensures that the physical manifestation of the product meets all desired specifications. The functional composition of the device, its components, and all design and manufacturing properties of the product were defined in detail. The shape, dimensions, weight, types of materials, mechanical tolerances, assembly, manufacturing time, and average cost were established and documented. The flow and stages of the manufacturing process were also described for the development of the Minimum Viable Product (MVP).

Finally, the third version of the adaptive eating device was modeled, as seen in Fig. 3, and the MVP was manufactured for use in validation tests. Among the changes, the final model was redesigned to be composed of two parts for assembly, allowing for the interchangeability of the device tip with variations of shapes. The fixing handle was made of a rubberized material.

Fig. 3 CAD MVP representation. (**a**) Virtual model of the third version. (**b**) Fit between the parts.

Design evaluation and review

To ensure that the product complied with the original objectives, in addition to mechanical tests for validating the manufacturing method, it underwent an evaluation of its functionality and usability. For this purpose, the validation process was conducted with patients with physical disabilities and/or movement disorders that impair feeding, resulting from some underlying neurological condition, and who receive therapeutic follow-up at the institution in Santa Cruz - RN - Brazil. The study was approved by the local ethics committee (CAAE: 70240123.9.0000.5568), and participants signed the consent form.

After conducting the validation tests, the patients responded to a questionnaire regarding the adaptive device, evaluating the five statements using a Likert scale from 1 to 5 (1 - Strongly Disagree and 5 - Strongly Agree) to verify if the developed product was validated. The results and feedback were analyzed, and a final review of the project was conducted to define the ultimate model of the low-cost 3D adaptive eating device.

Results

3D adaptive eating device

The 3D adaptive eating device was developed to enable patients with ND to perform feeding tasks more independently, aiming to offer the market an adapted device with a more universal character. The product design mixes different elements and characteristics, to overcome different limitations, such as grip difficulties, tremors, weakness, and sensory deficits.

The ideation process of the device was based on the PDD approach, and took as a reference the products available on the market as well as proposals found in the literature, while also considering the socioeconomic and environmental context of patients with ND. Seeking to offer a practical, low-cost alternative to this audience, the adaptive eating device was designed to be manufactured using 3D printing. Through this manufacturing method, components can be produced simultaneously, making their cost more affordable, with an average cost of approximately $10, and also making it easier to replicate on a larger scale.

The innovative design of the device has seven key features: the first two at the tip, which is shell-shaped, to prevent food spillage, and is also removable and can be exchanged for other tip shapes; the remaining features are in the handle region, which is not only thickened and textured but also hollow, allowing for the insertion of weights to provide added heft to the utensil; it also offers the possibility of being externally coated with rubberized material for enhanced grip. The cutlery also has a securing strap that can be attached to the handle.

Furthermore, the product features an essentially mechanical system, allowing it to be easily assembled/disassembled and transported, making it user-friendly and intuitive to use. The device also offers good maintainability, as its parts are simple to exchange or replace, as well as being easy to clean. The MVP of the 3D adaptive eating device is shown in Fig. 4.

Fig. 4 3D adaptive eating device MVP

Design validation

The 3D adaptive eating device was evaluated by seven patients (Table 1) who had physical disabilities or movement disorders compromising their ability to perform feeding tasks, stemming from five different clinical diagnoses.

Table 1 Demographics and clinical characteristics of participants (n=7)

	Count (%) or Mean (SD)
Gender	
Female	3 (43%)
Male	4 (57%)
Age (years)	36 (24.97)
Neurological Disorder	
Cerebellar Ataxia	1 (14%)
Cerebral Palsy	1 (14%)
Parkinson's Disease	2 (29%)
Spinal Muscular Atrophy	1 (14%)
Traumatic Brain Injury	2 (29%)
Disease duration (years)	12 (9.34)

The result of the device evaluation questionnaire is described in Figure 5 by the average of the obtained responses. Regarding the device's characteristics, the average responses (2.57 ± 1.39) indicate that patients disagreed that it should present other variations besides the presented design. The average score for the device being discreet (3.14 ± 1.46) or coming with a case for storage (3.57 ± 1.51) indicating that patients were indifferent, neither agreeing nor disagreeing. However, it can be inferred that patients agreed that the device should be easy to clean (4.43 ± 0.79), as well as agreed that they would buy the 3D adaptive eating device (4.43 ± 1.13).

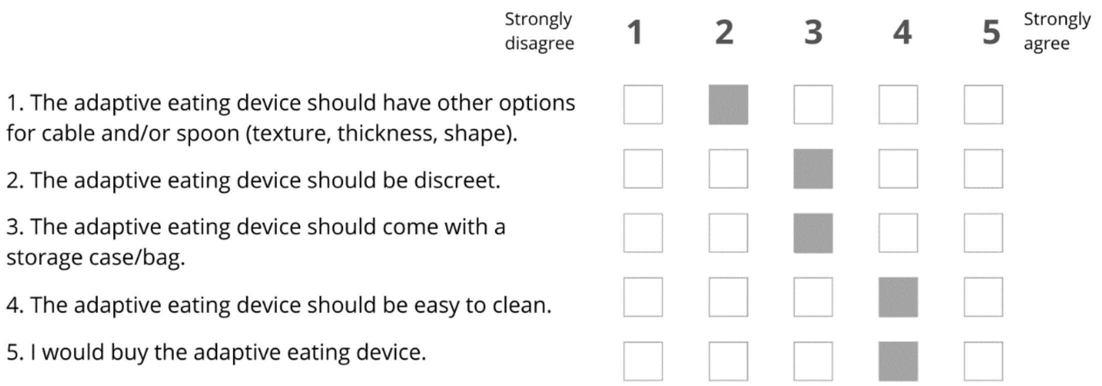

Fig. 5 Device validation

Through an open-ended question, feedback from patients was collected after using the 3D adaptive eating device, and most responses were positive. Answers to the question "Do you have any comments, complaints, compliments, or suggestions about the utensil?" included "the weight is too good," "it's too easy to adjust in the hand and use," "I feel it spills less (food) because it's more closed. People have more difficulty spilling (food). I spill a lot when I'm feeding. With this one (product), you can tremble, and it won't spill", "I found it very positive that it's easy to assemble for people with not much muscle strength. It's something I can do on my own," and "I'd buy it right away."

The majority of patients reiterated their intention to purchase and use the 3D adaptive eating device if it were already available on the market. No improvements or changes to the model were suggested. The final design of the model is presented in Fig. 6.

Fig. 6 3D adaptive eating device. (**a**) Final design. (**b**) Exploded view.

Discussion

This study proposed the development and validation of a new 3D adaptive eating device, using the PDD approach. The systematization of the product development process, from ideation through design and development to validation, had already been proposed in the literature [13]. The use of the PDD approach, with its well-defined steps, resulted in an effective and efficient design and manufacturing process. Through the initial stage of this approach, it was possible to better identify windows of opportunities and innovative possibilities before starting the concept and design of the model, which occurred in a more fluid and conscious manner.

The final design of the 3D adaptive eating device incorporates various features aimed at overcoming different difficulties caused by movement disorders and physical disabilities present in neurological patients. ND manifests itself in different ways and can lead to multiple functional interferences and significant restrictions in involvement and participation in ADLs.

In patients who may exhibit some degree of tremor, common in patients with PD, for example, various devices have already been developed to minimize the tremor effect, aiming to regain autonomy in tasks such as feeding [24]. The shape of the tip of the 3D adaptive eating device was designed with a slight cavity, making food spillage more difficult. This feature reduces the negative impact of tremors on the feeding process, as validated by the feedback of one patient who felt greater security with the developed device.

Patients with SMA experience progressive degeneration of motor neurons and muscle weakness, and they typically receive the diagnosis by 18 months of age [25]. Even though they may exhibit good motor development and be able to perform feeding tasks, the progression of the disease can lead to a regression in functional independence. The design of the 3D adaptive eating device appears to be a good option for these patients, as it allows for easy replacement of the tip shape, accommodating changes in the patient's limitations. Additionally, it does not require much force for assembly, maintaining good usability even with loss of muscle strength.

In line with other studies that highlight the benefits of using 3D printing for adapted devices [13, 15], the production cost of the product was reduced by using only the material necessary for the device, in addition to reducing labor costs since the printer performs the entire manufacturing process. It is worth noting that this advantage extends to the possibility of local-scale production since there are few parts to assemble, and they can be manufactured simultaneously, reducing the waiting time for receiving the device.

As the main features of the 3D adaptive eating device have been validated, any potential design adjustments are merely proposals to add value to the product in case of commercialization, such as the inclusion of accessories like a storage case, or even the conceptualization of a brush to facilitate cleaning, given that the requirement for ease of cleaning was valued.

The results of this study also indicate the desire of patients to have access to affordable options for adaptive eating devices in the market. Even though some patients may experience mild to moderate difficulty, there is an understanding that others in similar clinical situations may face more severe difficulties, or they may experience an increase in long-term limitations. This reinforces the desire to purchase the 3D adaptive eating device, whether for immediate or future use. Furthermore, patients expressed their intention to purchase without even questioning the value of the device. This demonstrates the importance of the study and the willingness of patients to find effective strategies to preserve their autonomy.

Limitations and future research

Although the 3D adaptive eating device offers good cost-effectiveness with satisfactory results, this study has limitations due to the low number of patients for validation. Since the device was designed for patients with neurological disorders, which encompass a wide range of pathologies, and the manifestations of limitations and difficulties vary among each patient, it would be beneficial to conduct a second validation with a larger sample, including more diverse pathologies, with a good representation of patients for each one. Additionally, the validation process of the utensil, included in the PDD process, was based on the patients' initial contact with the solution. In the long term, with continuous use of the device, adjustments to the design may be suggested, even though the preliminary results do not indicate this.

Conclusion

The results of this study allow us to indicate the developed 3D adaptive eating device as a good option for regaining autonomy in feeding tasks for patients with neurological disorders. The use of the PDD approach for the design and manufacturing of the device facilitated the clear identification of demand, enhancing the understanding of opportunities, needs, and innovative possibilities, thereby making the final outcome more effective and efficient.

The incorporation of 3D printing into the process, in addition to achieving the objective of delivering a low-cost product, brought about a significant optimization and integration of stages. The PDD combined with 3D printing optimized both the development and manufacturing time, while also fostering greater integration among stakeholders (Biomedical Engineers, Physiotherapists, Occupational Therapists, and patients) through active participation in product testing and validation. Furthermore, they enabled the development of a new, functional, and innovative product, proving to be a successful combination for the development of products with few similar options available in the market.

Abbreviations

3D printing: Three-dimensional printing

ADLs: Activities of Daily Living

AT: Assistive Technology

CAD: Computer-Aided Design

CP: Cerebral Palsy

MVP: Minimum Viable Product

ND: Neurological Disorders

PD: Parkinson's Disease

PDD: Product Design and Development

PWD: People with Disabilities

RN: Rio Grande do Norte

SMA: Spinal Muscular Atrophy

TBI: Traumatic Brain Injury

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3.2 Artigo 2

3D adaptive eating device for people with neurological disorders: a proof of concept study

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Abstract

Purpose: Evaluate and verify the feasibility of a 3D Adaptive Eating Device (3D AED) in the feeding process for individuals with Neurological Disorders.

Methods: A 3D AED was developed and evaluated in the short term with seven participants with different neurological disorders. Data were collected through observation and recording of device usage tests, as well as through the administration of clinical questionnaires. Participant performance and satisfaction were assessed using COPM. Device usability and satisfaction were evaluated using SUS and B-QUEST 2.0.

Results: The use of the 3D AED resulted in a better perception of functional performance and satisfaction, as it improved task execution times. However, there was no significant difference between the device and a tablespoon. The average SUS score of 73.21 indicates good usability of the 3D AED. Participants' satisfaction with the device was positive, with an average score of 4.2. "Ease of use" was the requirement with the worst evaluation, which may be due to the short time of contact with the technology, requiring a longer period of familiarization.

Conclusion: The results demonstrate that the personalized and low-cost 3D AED was validated for promoting functional benefits and autonomy to the participants, with good usability and satisfaction, thereby indicating the feasibility of the device.

Implications for rehabilitation:

- Propose a new adapted and low-cost device solution for individuals with neurological disorders.

- The use of the adapted device can benefit individuals with neurological disorders during the feeding task.
- Encourage individuals with movement disorders to adopt Assistive Technologies to improve quality of life and autonomy.

Key words: Assistive Technology; Rehabilitation; Patient Satisfaction; Eating Utensils; Neurological Disorders.

Introduction

The upper limb exhibits extensive refined and specific functionality, contributing to individuals' social interaction and playing a fundamental role in Activities of Daily Living (ADLs), such as self-care activities [1]. However, if the upper limb is affected by a neuromuscular disorder that involves sensory-motor alterations, the individual's functional performance is also affected, reflecting in the execution of these ADLs [1, 2].

According to data from the World Health Organization, it is estimated that 1.3 billion people worldwide have some form of disability [3]. In Brazil, the population with disabilities amounts to 18.6 million people, with 1.2% of this population experiencing difficulty in performing activities related to personal care [4].

Neurological disorders, such as Parkinson's Disease (PD), Cerebral Palsy (CP), Traumatic Brain Injury (TBI), or Spinal Muscular Atrophy (SMA), result in permanent functional limitations that prevent the performance of ADLs such as bathing, dressing, and feeding [2, 5-7].

The ability to independently perform the feeding task, without the assistance of others, is crucial for maintaining autonomy and functional independence in individuals [2]. To achieve this, individuals affected by neurological disorders can use Assistive Devices (AD), which are developed with the aim of maintaining or improving an individual's functionality, thereby facilitating their social participation [8]. Furthermore, access to these devices is legislatively guaranteed throughout the world, and therefore denying their access constitutes a violation of a basic human right [8, 9].

However, finding a device that meets the needs of each individual is a challenge, and although there are different options of AD available to assist with the feeding task, both in the market and in the literature, most were developed for a very specific audience [10]. In addition to the difficulty of finding an Adaptive Eating Device (AED) that functionally meets a wide range of characteristics, other issues include usability challenges, lack of information or technical support, or the device performing below expectations due to inefficient adaptation. Another major challenge faced by individuals with neurological disorders in accessing these devices is the high costs [2, 11, 12].

An innovative way to democratize access to AD, which has increased in the rehabilitation field, allowing better attention to the needs of individuals in a personalized way, can be achieved through the use of 3D printing [11, 13]. This technology enables the production of low-cost AD as it requires minimal resources, materials, and time in the manufacturing process [1, 14]. 3D-printed AD are designed to be easy to manufacture, replicate on a large scale, assemble and use, while also being comfortable and functional [15].

In this context this study aims to investigate and verify the feasibility of a new 3D Adaptive Eating Device (3D AED) developed in the feeding process of individuals with neurological disorders through evaluating the use of the device, contributing to the validation of a new solution for this population.

Methods

This feasibility study describes the usability and satisfaction results of using a low-cost 3D AED by individuals with neurological disorders undergoing therapeutic monitoring at the institution. Furthermore, the study addresses the design and development process of the Minimum Viable Product (MVP) of the device and its manufacturing using a 3D printer.

Ethical Approval

The study was approved by the ethics committee of the Federal University of Rio Grande do Norte (CAAE: 70240123.9.0000.5568). All participants signed the informed consent form to participate in the research.

Participants Recruitment

Participants were recruited through non-probabilistic, convenience, and intentional sampling methods, being contacted by phone, and invited to participate in the study. Participants diagnosed with any neurological disorder who expressed interest in the study were selected for initial eligibility. Inclusion criteria were (1) being over 18 years old, (2) having some sensory-motor alteration that causes feeding difficulties, and (3) having preserved swallowing capacity to ingest food. Participants were assessed regarding their ability to understand commands, using the Mini Mental State Examination (MMSE) [16], dominant hand through evaluation of hand dominance using the Edinburgh Handedness

Inventory (EHI) [17], and their level of functional independence in feeding using the subsection “Eating” of the Functional Independence Measure (FIM) [18].

Description of the 3D Adaptive Eating Device

The 3D AED was developed to assist individuals diagnosed with sensory-motor alterations resulting from a neurological disorder. The motivation behind its development was not only to help individuals who have difficulty with the feeding task but also to offer a national, low-cost, and universal option, not focused on addressing a specific condition. After all, each person is unique and, may not necessarily, have the same needs at the same level.

Thus, using the Product Design and Development (PDD) approach [19], market considerations, references described in the literature, insights and professional experiences from an interdisciplinary team composed of Biomedical Engineering, Physiotherapy, and Occupational Therapy experts, as well as the socioeconomic and environmental context of the Northeast region of Brazil were taken into account for the design proposal of the device. Manufacturing was carried out through 3D printing, allowing for scalability with low production costs.

The developed 3D AED proposes a new commercial solution that allows for personalization for each individual, offering greater comfort and autonomy due to its assembly options and ways of use. The device has two tip options, both in a shell shape, but with differences in opening and depth, which minimizes food spillage. It also has a customized handle that allows for the addition of weight, with the possibility of being externally coated with rubber material to provide greater grip. The 3D AD also features a fixation strap that can be attached to the handle. The use of weight, rubber coating, and fixation strap are optional.

The device is composed of a purely mechanical system, allowing for easy assembly and exchange of tips, as the attachment of the tip to the handle is done through a simple fitting. The MVP is shown in Figure 1.

Figure 1. 3D Adaptive Eating Device MVP

Instruments

For the feasibility analysis of the 3D AED, different assessments were utilized to gain an overall perception of the participants regarding the developed technology. The perception of occupational performance and satisfaction were measured using the Canadian Occupational Performance Measure (COPM) [20]. The device's usability was evaluated using the System Usability Scale (SUS) [21]. Participant satisfaction with the device was assessed through the application of the Quebec User Evaluation of Satisfaction with Assistive Technology (B-QUEST 2.0) [22], disregarding the four items referring to “services”. The tests were filmed with participants' written consent and the images were also analyzed for comparison.

Procedure

Before starting the study, a round of mechanical tests was conducted with the developed device, aiming to test it for its characteristics and its compliance with the idealized design requirements, confirming that it would be suitable for use.

The study was carried out at the institution's clinic and began after the participants provided written informed consent. The tests were conducted individually in a closed space and started with the application of clinical assessments, including MMSE, EHI, and COPM (initial assessment). Clinical and demographic data of the participants were collected from their medical records.

The feeding tests were conducted in two stages: (1) using a regular all-metal tablespoon and (2) using the 3D AED. In each stage, three foods with different consistencies were used: brazilian couscous, banana, and soup, respectively. The foods were selected considering the local cultural context, as they are part of the staple diet of the study population and are simple and accessible.

During the tests, participants were seated in a chair with a backrest, with their feet supported on the floor, or seated in their wheelchair, also with their backs supported and feet supported. A table was positioned in front of the participants, on which a bowl with one of the foods and one of the utensils would be placed. To perform the feeding task, participants were instructed to pick up the utensil from the table, take the food from the bowl, bring it to their mouth, and return the utensil to the table. This task was performed at least three times for each food in each stage.

At the end of the first stage, the assessment of the "Eating" subsection of the FIM was conducted. At the end of the second stage, the B-QUEST 2.0 and SUS were administered. The COPM was reapplied at the end of each stage (after using the tablespoon and after using the 3D AED), reassessing the perception of performance and satisfaction in performing the task.

A dialogue space was created at the end of the tests for participants to express their opinions and perceptions about the tests and usage experience of the device. They were encouraged to provide both positive and negative feedback, as well as suggestions regarding the 3D AED.

Data Analysis

For statistical analysis, the JASP software, version 0.18.3.0, was used. Demographic, clinical (MMSE, EHI, FIM), usability (SUS), and satisfaction (B-QUEST 2.0) data were analyzed descriptively. Central tendency measures (mean) and dispersion (standard deviation), as well as absolute and relative frequencies, were observed according to the type of variable.

The Shapiro-Wilk test was used to analyze the normality of the sample data related to COPM and the average task execution times. Considering the parametric values of the task execution times (average of three attempts for each food), the t-test was used to compare the times between the tablespoon and the 3D AED, with the three foods. To evaluate performance and satisfaction in the three conditions (initial assessment, after using the tablespoon, and after using the 3D AED), a non-parametric test, the Friedman Test, was used. For both tests, $p<0.05$ was observed to establish significance between the analyzed parameters.

Results

Participant demographics and clinical

This study involved seven individuals diagnosed clinically with Traumatic Brain Injury (TBI) (two participants), Parkinson's Disease (PD) (two participants), Cerebral Palsy (CP), Spinal Muscular Atrophy type II (SMA II), and Cerebellar Ataxia (the latter three with one participant each), of both sexes, and aged between 18 and 73 years.

The participants with the same clinical diagnosis exhibited varying degrees of movement difficulty. Among the participants with PD, participant 1 had a much more pronounced tremor, with episodes of freezing. Participants 2 and 4 were right-handed but had their right limbs more affected after the TBI. Participant 2 completely lost the movements of the right limb, having to relearn tasks with the left hand (evaluated hand). The other participant (4) had only partial loss of active movement in the right limb, using it during the tests. The characterization of the participants is described in Table 1.

Table 1 Clinical and demographic characteristics of participants

Participant	Gender	Age (y)	Neurological disorder	Disease duration (y)	MMSE	EHI	Evaluated hand
1	M	71	PD	17	21	R	R
2	M	25	TBI	2	20	L	R
3	M	73	PD	15	30	R	R
4	F	18	TBI	1	18	L	L
5	F	20	SMA II	18	29	R	R
6	M	25	CP	25	16	L	L
7	F	18	CA	4	24	R	R
Nº (%) or Mean (DP)	3 (43%) F 4 (57%) M	36 (24.07)	2 (29%) DP/TBI 1 (14%) SMA II/CP/CA	12 (9.34)	23 (5.35)	4 (57%) R 3 (43%) L	5 (71%) R 2 (29%) L

F= Female; M= Male; PD= Parkinson's Disease; TBI= Traumatic Brain Injury; SMA= Spinal Muscular Atrophy type II; CP = Cerebral Palsy; CA = Cerebellar Ataxia; R= Right; L= Left.

Comparison between a tablespoon and the 3D adaptive eating device

The result of the comparison of performance and satisfaction in the three conditions (initial assessment, after using the tablespoon, and after using the 3D AED) is presented in Table 2, and the average task execution time with the tablespoon and the 3D AED is described in Table 3.

Table 2 Comparison between participants' performance and satisfaction (COPM) in the three feeding conditions.

Participant	Performance			Satisfaction		
	Initial	**Spoon**	**3D DEA**	**Initial**	**Spoon**	**3D DEA**
1	8	10	10	9	10	8
2	10	4	7	10	10	10
3	8	6	10	8	7	10
4	5	10	10	5	5	7
5	9	10	10	10	10	10
6	1	10	10	1	10	10
7	5	10	6	10	10	10
Mean (DP)	6.57 (3.1)	8.57 (2.51)	9 (1.73)	7.57 (3.41)	8.86 (2.04)	9.29 (1.25)

Table 3 Comparison of average task execution times per food item with the tablespoon and the 3D AED.

Participant	Couscous		Banana		Soup	
	Spoon	**3D DEA**	**Spoon**	**3D DEA**	**Spoon**	**3D DEA**
1	12.3	8	11.3	9.7	7.3	5.3
2	23	20.7	39.7	15.3	20	23.3
3	9	9.7	9	10.3	6	8
4	18.7	15.7	26.3	12.3	14.3	18.7
5	13.7	13	14.3	11	13.3	13
6	24	8	22.3	14.7	13	11
7	14.3	11.3	12	12.7	17.3	12.3
Mean (DP)	16.43 (5.63)	12.34 (4.61)	19.27 (10.97)	12.29 (2.14)	13.03 (5.01)	13.09 (6.16)

The level of performance and satisfaction with the task was higher with the 3D AED than with the tablespoon. However, statistically, there is no significant difference between the values presented. The average time for feeding using the tablespoon was longer than the average time spent eating with the device, both for couscous and banana. However, there is also no significant difference between the times.

Usability

The usability of the device was measured using the System Usability Scale (SUS), obtaining an average score of 73.21 (± 16.88), classified as "Good." The assessments made by each participant are described in Table 4.

Table 4 Device usability evaluation

Participant	Score	Classificação*
1	37.5	Poor
2	75	Excellent
3	77.5	Excellent
4	77.5	Excellent
5	92.5	Best imaginable
6	75	Excellent
7	77.5	Excellent

*20,5 (worst imaginable); 21 a 38,5 (poor); 39 a 52,5 (ok); 53 a 73,5 (good); 74 a 85,5 (excellent); e 86 a 100 (best imaginable).

Satisfaction

The participants' satisfaction level with the 3D AED was evaluated using the B-QUEST 2.0, obtaining a final average score of 4.2 (± 0.46), classified as "Quite satisfied." Among the seven participants, four rated their satisfaction level as 4.5. Table 5 presents the satisfaction averages per evaluated item. The assessment includes selecting the three most important items in the participant's perception. The most chosen items were "Ease of use," "Weight," and "Comfort."

Tabela 5 Evaluation of the device by item of the B-QUEST 2.0

Variável	Mean (DP)	Classificação
Dimensions	4,14 (0,9)	Quite satisfied
Weight	4,57 (0,54)	Very satisfied
Adjustments	4,57 (0,79)	Very satisfied
Safety	3,57 (1,4)	Quite satisfied
Durability	4,71 (0,49)	Very satisfied
Ease of use	3,43 (1,72)	More or less satisfied
Confort	4,29 (0,76)	Quite satisfied
Effectiveness	4,29 (0,76)	Quite satisfied

Open-ended feedback

At the end of the tests, a space was opened for participants to provide feedback on the 3D AED and their usage experience. Among the comments made, transcribed from the recordings, the following statements stand out: "I am very satisfied. It's a ten. I can't eat with this hand here (right). I never could after the accident. I'm eating now", "I think the idea is great and it will help many people like me who need this kind of help.", "Is it by pulling? (to change the tip) I found it accessible.", "I'm thinking in long term, because, for example, in the future, I would like to use it frequently, since my illness is progressive and muscular, and eventually I will have less muscular strength and ability to perform some movements", "I found it very interesting because the device is also accessible in assembly. And that's important because it's about autonomy too. For example, I go to a restaurant and alone I can pick up the device, assemble it, and use it. So it has that accessibility and that's very important. I really liked it."

Discussion

This study aimed to test the feasibility of a new 3D AED in the feeding process of individuals with neurological disorders for technology validation. To achieve this, an MVP was developed through a systematic and interdisciplinary process to be used and evaluated by seven individuals with neurological disorders, who had different clinical diagnoses.

During the feeding tests, the execution times of each attempt with different utensils and foods were recorded, and the COPM was applied after attempts with both a tablespoon and the 3D AED for comparative analysis. The results indicate that statistically, there is no significant difference between the tablespoon and the 3D AED. However, observing the data on participants' performance and satisfaction levels, it is noted that both the average performance and satisfaction were higher for the 3D AED than for the tablespoon. Regarding the average task execution time, it was observed to be shorter with the device for couscous and banana. These findings may suggest a benefit in using the device, as it optimizes the feeding process and is more pleasurable for the individual.

Analyzing the technology itself, the 3D AED was validated for its usability and the participants' level of satisfaction with the device, considering its design and characteristics, through two distinct and specific evaluations, the SUS and B-QUEST 2.0. Considering that the tests were conducted using an MVP, the results were valuable and encouraging.

Although few participants took part in the tests, which is one of the study's limitations, this number is sufficient for preliminary assessments of the AD's usability. With at least five evaluations, the main issues of the device will already be highlighted, indicating its level of usability. Reducing the number of participants becomes a study strategy, as it reduces time and costs associated with testing while obtaining significant results about the technology's design [23].

Among usability questionnaires, the SUS is the most recommended and widely used because it is free of copyrights (open for use), quick and simple to apply, and can be used to evaluate different technologies, such as products or services. Additionally, its assessment includes the user's perception of satisfaction, presenting good reliability of data. The SUS score ranges from "Worst Imaginable" to "Best Imaginable."

The average usability score of the device classified it as "Good," with 85.7% of the participants rating it as "Excellent" or higher. This result, coupled with the definition of usability according to ISO 9241-11 [26], allows us to infer that the use of the 3D AED, in a specific context and with a specific audience, fulfills its purpose of assisting in the feeding process effectively, efficiently, and with satisfaction.

In line with the usability results, the direct assessment of participants' satisfaction with the device was positive. However, of the three characteristics selected as most important, "Ease of use" obtained the lowest average score compared to other characteristics of the 3D AED. This low score may reflect another limitation of this study, the short duration of the tests.

The satisfaction assessment was based on the perception of use during initial contact with the device, without disregarding the familiarization time. In a scenario of daily use of the device, participants would have time to understand and establish the best way to use it, grip it, and transfer food from the bowl to the mouth, which could change their perception of its use.

Another characteristic rated as important was the weight of the device. Some studies, such as a similar research with AD [27], indicate the use of weighted utensils for individuals with PD to improve performance by promoting greater stability. The 3D AED, although allowing the addition of weight to its handle, was tested without this modification by all participants, including those with PD, and still obtained one of the highest average satisfaction score, along with "Adjustments" and “Durability”.

However, even though participants considered the weight of the AD as positive, performing the task with the addition of weight to the handle could provide an even better user experience and satisfaction for some individuals, enhancing their perception of the device's stability and safety.

The developed device is entirely mechanical, which aids in its manufacturing process, as well as in its assembly/disassembly, assisting individuals in its use, being an advantage of the design of the 3D AED by promoting accessibility. As stated by the participants in the open feedback, this characteristic also brings autonomy to the individual, who can resume the task of feeding with the affected limb and can also use the device without needing assistance from others.

The results of the open feedback reinforce the other findings obtained in this validation process of the 3D AED, demonstrating that this new solution not only has good usability, satisfaction, and performance but also has good acceptance among individuals with neurological disorders.

Conclusion

This study aimed to validate a new solution for individuals with neurological disorders by evaluating the use of the 3D AED in the feeding process. The 3D-printed version of the device was proposed to offer a low-cost alternative, being accessible, personalized, and functional, ensuring standardization and scalability.

The design of the MVP of the 3D AED, featuring a purely mechanical system, was validated in tests with participants presenting different neurological disorders, promoting benefits during the feeding process, assisting them in executing the task in a skilled, simple, and independent manner.

Although the study has some limitations, its results suggest the feasibility of the device for this population, given the positive evaluation of the device, which demonstrates good performance and usability, along with a high level of satisfaction with the technology.

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4 CONSIDERAÇÕES FINAIS

Este estudo propôs o desenvolvimento e validação da viabilidade – prova de conceito, de um novo modelo de dispositivo de alimentação adaptativo de baixo custo para pessoas com distúrbios neurológicos. A utilização da abordagem de Desing e Desenvolvimento de Produtos (PDD) em conjunto com a tecnologia de impressão 3D para projetar e fabricar o dispositivo permitiu a identificação clara das demandas, oportunidades e possibilidades de inovação, além de otimizar o tempo de desenvolvimento e fabricação, entregando uma solução acessível e de baixo custo.

O teste e avaliação da versão fabricada do dispositivo foi feita por um grupo de sete participantes com diagnóstico clínico de algum distúrbio neurológico, e os resultados indicam que o dispositivo de alimentação adaptativo 3D é uma boa opção personalizada, acessível e funcional, podendo promover a autonomia e facilitar a execução das tarefas de alimentação de forma eficiente e independente, em indivíduos com distúrbios neurológicos.

Embora o estudo apresente algumas limitações, como tamanho da amostra e tempo curto de familiarização com o dispositivo para os testes, os resultados indicam a viabilidade, pela boa usabilidade e pela satisfação dos participantes com o dispositivo, sugerindo, dessa forma, seu potencial para melhorar a qualidade de vida desses indivíduos.

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