Fibro Placa: Innovative 3D-Printed Product for Fibrosis Reduction in a Patient with Secondary Lymphedema after Breast Cancer

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Fibro Placa: Produto Inovador Impresso em 3D para Redução de Fibrose em Paciente com Linfedema Secundário ao Câncer de Mama

Fibro Placa: Producto Innovador Impreso en 3D para la Reducción de la Fibrosis en un Paciente con Linfedema Secundario al Cáncer de Mama

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ABSTRACT

Introduction: Lymphedema is one of the most common complications associated with breast cancer treatment, especially as a result of surgical interventions in the axillary region. This complication results in the accumulation of lymphatic fluid in the interstitial space, leading to edema. It is progressive in nature, and in more advanced stages, fibrosis develops, which compromises the function of the lymphatic system by reducing lymphatic drainage capacity and, consequently, decreasing the effectiveness of conservative treatments. **Objective:** To develop a 3D-printed product capable of optimizing conservative treatment in fibrotic areas of secondary lymphedema after breast cancer. **Method:** The product, named *Fibro Placa*, was developed through an interdisciplinary collaboration between the fields of Physiotherapy and Design and was printed using TPU filament on an Ender 5 Plus 3D printer. After fabrication, the product was placed within multilayer compression bandaging over the fibrotic area –posterolateral and proximal portion of the left forearm – of a patient with secondary lymphedema after breast cancer. The intervention lasted 12 weeks and was evaluated using left forearm perimetry, delineation of the fibrotic area, and ultrasonography of the same region. **Results:** There was a reduction in limb circumference, fibrotic area, and fibrous tissue thickness. **Conclusion:** The *Fibro Placa* was able to produce beneficial results for the treatment of this patient's fibrotic area and may contribute to fibrosis management in the conservative treatment of lymphedema.

Key words: Breast Neoplasms; Breast Cancer Lymphedema; Fibrosis; Printing, Three-Dimensional; Physical Therapy Services.

RESUMO

Introdução: O linfedema é uma das complicações mais comuns associadas ao tratamento do câncer de mama, especialmente em decorrência de intervenções cirúrgicas na região axilar. Esta complicação gera acúmulo de fluido linfático no espaço intersticial, ocasionando edema. Tem caráter progressivo e, em estágios mais avançados, há o desenvolvimento de fibrose, a qual compromete a função do sistema linfático, pois diminui a capacidade de drenagem linfática e, consequentemente, reduz a eficácia dos tratamentos conservadores. **Objetivo:** Desenvolver um produto impresso em 3D capaz de otimizar o tratamento conservador nas áreas de fibrose do linfedema secundário ao câncer de mama. **Método:** O produto, intitulado de Fibro Placa, foi desenvolvido de maneira interdisciplinar entre as áreas da Fisioterapia e do Design e impresso com o filamento de TPU na impressora 3D *Ender 5 Plus*. Após a confecção, o produto foi inserido dentro do enfaixamento compressivo multicamadas sobre a área de fibrose – porção posterolateral e proximal do antebraço esquerdo – de uma paciente com linfedema secundário ao câncer de mama. A intervenção durou 12 semanas e foi avaliada a partir da perimetria do antebraço esquerdo, delimitação da área da fibrose e ultrassonografia, dessa mesma área. **Resultados:** Houve redução da circunferência do membro, da área de fibrose e diminuição da espessura do tecido fibroso. **Conclusão:** A Fibro Placa foi capaz de gerar resultados benéficos para o tratamento da área de fibrose dessa paciente, podendo vir a contribuir com o manejo da fibrose no tratamento conservador de linfedema.

Palavras-chave: Neoplasias da Mama; Linfedema Relacionado a Câncer de Mama; Fibrose; Impressão Tridimensional; Serviços de Fisioterapia.

RESUMEN

Introducción: El linfedema es una de las complicaciones más comunes asociadas al tratamiento del cáncer de mama, especialmente como consecuencia de intervenciones quirúrgicas en la región axilar. Esta complicación provoca la acumulación de líquido linfático en el espacio intersticial, ocasionando edema. Tiene carácter progresivo y, en etapas más avanzadas, se desarrolla fibrosis, la cual compromete la función del sistema linfático al disminuir la capacidad de drenaje linfático y, en consecuencia, reducir la eficacia de los tratamientos conservadores. **Objetivo:** Desarrollar un producto impreso en 3D capaz de optimizar el tratamiento conservador en las áreas de fibrosis del linfedema secundario al cáncer de mama. **Método:** El producto, denominado Fibro Placa, fue desarrollado de manera interdisciplinaria entre las áreas de Fisioterapia y Diseño, y se imprimió con filamento de TPU en la impresora 3D Ender 5 Plus. Tras su confección, el producto se colocó dentro de un vendaje compresivo multicapa sobre el área de fibrosis –porción posterolateral y proximal del antebrazo izquierdo– de una paciente con linfedema secundario al cáncer de mama. La intervención tuvo una duración de 12 semanas y fue evaluada mediante perimetría del antebrazo izquierdo, delimitación del área de fibrosis y ecografía de la misma región. **Resultados:** Se observó una reducción en la circunferencia del miembro, en el área de fibrosis y en el espesor del tejido fibroso. **Conclusión:** La Fibro Placa fue capaz de generar resultados beneficiosos en el tratamiento del área de fibrosis de esta paciente y podría contribuir al manejo de la fibrosis en el tratamiento conservador del linfedema.

Palabras clave: Neoplasias de la Mama; Linfedema del Cáncer de Mama; Fibrosis; Impresión Tridimensional; Servicios de Fisioterapia.

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INTRODUCTION

Lymphedema is a condition resulting from lymphatic system insufficiency, characterized by a blockage in lymph transportation. This dysfunction leads to lymphatic fluid accumulating in the interstitial space, causing edema, predominantly in the extremities[1]. Lymphedema is one of the most common complications associated with breast cancer treatment, especially as a result of surgical interventions in the axillary region. The incidence of lymphedema in the upper limbs tends to progressively increase up to two years after diagnosis or surgical intervention for breast cancer treatment[2].

Lymphedema is clinically classified in three progressive stages: I – light edema, reversible, especially in a resting position; II – irreversible edema and presence of initial fibrosis; and III, or elephantiasis, – significant changes in tissue architecture, such as cutaneous thickening and dense fibrosis[3].

Complex Physical Therapy (CPT) is considered the gold-standard treatment for lymphedema control. It is divided into two phases: an intensive phase, which includes manual lymphatic drainage, multilayer compressive banding, lymphokinetic exercises, and skin care; and a maintenance phase, focused on maintaining treatment continuity with the use of compression garments, self-massage, and guided exercises[1].

Fibrosis plays a central role in regulating lymphatic function in both the short and long term, directly related to the worsening of lymphedema, characterized by a blockage in lymphatic drainage and suppression of lymphangiogenesis[4]. Lymphostatic fibrosis differs from post-surgical scar fibrosis, as it results from the accumulation of lymphatic fluid over time and persistent inflammation, leading to abnormal collagen deposition and changes to the extracellular matrix[4]. Literature has shown that, in more advanced stages of lymphedema, CPT can present a limited response in the fibrosed areas, requiring complementary therapeutic strategies[3].

The interaction between design and health fields, facilitated by digital manufacturing, has grown during the pandemic as a solution for producing individual protective equipment that was in short supply[5,6]. Digital manufacturing is understood as a set of diverse manufacturing technologies for the production of limited products, which allows the production to be locally sourced from digital 3D models[7]. Digital manufacturing from 3D digital models has been present in the health field, mainly in the elaboration of new therapeutic approaches, like the development of individualized prosthetics and orthoses[8], and in making surgical procedures more dynamic, improving prognoses and quality of life[9].

Therefore, the objective of this study was to employ digital manufacturing, joining knowledge from the Physiotherapy and Design fields to elaborate a 3D-printed innovative product that complements CPT conservative treatment, directly acting on the fibrosis area of a patient with lymphedema secondary to breast cancer.

METHOD

Development and viability study of an individualized therapeutic 3D-printed plaque for fibrosis control in the conservative treatment of lymphedema secondary to breast cancer. Design Thinking was the guiding approach for the whole product development process. It is an iterative model for thinking, problem-solving, opportunity exploration, and value creation[10-13] that makes the innovation process viable[14-17].

Considering this approach, the product elaboration process followed four main steps: 1) problem immersion by talking with a specialist, followed by research on similar themes and a related literature review; 2) ideation of the prototype using manual sketches and team discussions; 3) experimenting through digital 3D modeling and 3D-printed prototypes; 4) physiotherapist-supervised prototype test on the patient, followed by discussion and remodeling for improvement.

Each step was conducted in an interdisciplinary manner, combining knowledge in Design (such as development and construction of a 3D virtual model) and Physiotherapy (with the necessary applications for clinical practice). These activities were developed in the Londrina University Hospital digital manufacturing lab *(Laboratório de P&D e Fabricação Digital do Hospital Universitário de Londrina* – Fab.i®HU), a supplementary organ of the State University of Londrina (*Universidade Estadual de Londrina – UEL*), which has a 3D product printing facility that uses two distinct processes: Digital Light Processing (DLP) for photosensitive liquid resin pieces from the strong light projection, and Fused Deposition Modeling (FDM), which produces pieces from the deposition of molten thermoplastic filament. Both processes allow the construction of objects layer by layer. The process used in this study was FDM. Two prototype versions were produced before reaching the end product. Both prototypes used the same materials, the Rhinoceros® 7 software for 3D digital building and the thermoplastic polyurethane (TPU) filament for 3D printing in the Ender 5 Plus equipment by Creality®.

It is worth mentioning that previously determining the design requirements (what the product should achieve) and design attributes (what features it should have) is essential to guide product development. These requirements and attributes are derived directly from Step 1 (Immersion). Thus, in Step 1, it was determined that the product should have enough malleability to adapt to the shape of the limb, without compromising the necessary superficial endurance to generate pressure points on the fibrosis. The first prototype conceptualization (Step 2) and its modeling and impression (Step 3) incorporated the following requirements and attributes, enabling advancement to Step 4, in which the model was confirmed to meet the malleability and endurance requirements.

After the first prototype materialized, its design was observed to have too many sharp angles, due to its hexagonal shape, which could cause cutaneous lesions. Moreover, regarding the contact area, there were more hollow spaces than high-relief surfaces, which would not generate the necessary pressure and decrease product efficiency. Based on these observations, the first prototype went through formal and structural modifications to optimize its function and reduce the risk of cutaneous lesions. Prototype 2 had its structure inspired by the "S" maneuver. This manual lymphatic drainage technique consists of sliding both thumbs, applying a certain pressure, and moving simultaneously from the outside to the inside in the same direction, as if each thumb were a "leg" of the letter S, meeting in the middle, to mobilize the fibrosis subcutaneous rigidity[18,19]. The arrangement of reliefs aimed to reproduce the position of the thumbs. Moreover, the hexagonal shape was replaced with a spherical shape to eliminate angles and improve product safety. These changes resulted in the product's final version: a rectangular plaque with reliefs in rounded finishing, interleaved with hollow areas in its surface (Figure 1).

After product development, the final version was tested on a patient. Inclusion criteria were patients in advanced lymphedema stage (≥II) secondary to breast cancer, with the presence of fibrosis. Exclusion criteria were patients in the initial lymphedema stage (stage I) with no presence of fibrosis. The classification of the lymphedema stage followed Grada and Phillips[3]. Patient H. F. M., selected by convenience, who was already being followed up in the physiotherapy outpatient clinic and met the criteria, female, elderly, 75 years, presented stage II lymphedema in the left upper limb and an extensive fibrosis area in the forearm postolateral and proximal region, developed secondarily and progressively to a radical mastectomy with removal of left lymph nodes in 2019.

The product was inserted in the multilayer compressive banding, according to the order of the following steps: (1) applying body lotion on the skin; (2) putting on the cotton tubular mesh; (3) inserting the *Fibro Placa* directly on the fibrosis area, with reliefs facing down; and (4) applying low elasticity banding as a final compressive layer (Figure 2). This application was to generate sustained pressure on several fibrosis points for an extended period. The option not to use a concentric compression with a foam banding was due to the patient's previously identified allergy to the material, which could cause discomfort, cutaneous reactions, and compromise treatment adherence. This adaptation aimed to ensure patient safety and well-being. The rest of the protocol was maintained.

The intervention lasted 12 weeks, from August to October 2023, with two sessions a week. These were

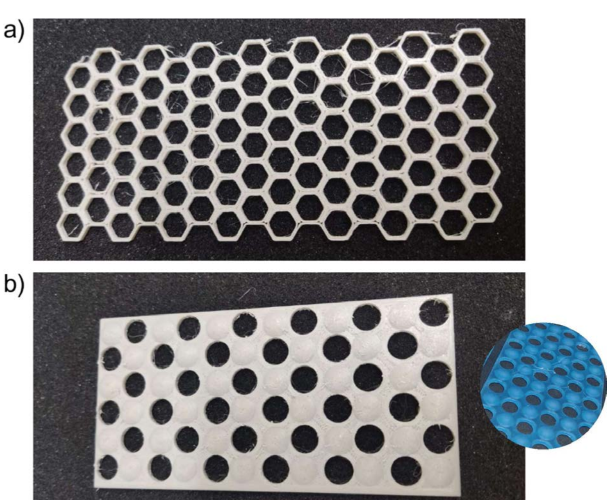

Figure 1. Prototypes printed during product development: a) prototype 1 and b) prototype 2, final version

Figure 2. How to use the *Fibro Placa*. Inserted inside the multilayer compressive banding in the following order: (1) skin hydration; (2) cotton tubular mesh; (3) *Fibro Placa* directly on the fibrosis area, with reliefs facing down; (4) low elasticity banding applied as a final compressive layer

performed in the physiotherapy outpatient clinic of the Gynecology and Obstetrics ward of HU – UEL.

To assess the intervention response on the fibrosis area, the following variables were analyzed: delimitation of the fibrosis area through palpation and measurement of its length and width; perimetry of the left forearm in three specific points – 5, 10, and 15 centimeters below the cubital fossa (CF), and ultrasound on the delimited area to assess the respective outcomes: perception of rigidity during palpation; forearm circumference, and thickness/features of the subcutaneous tissue. Two analyses were conducted: before the use of the product and immediately 12 weeks after treatment, which allowed for a comparative analysis of the condition's evolution.

Perimetry and delimitation were measured in each session, throughout its use, by the same examiner, experienced in applying the technique. Houwen et al.[20] stated that perimetry is a reliable tool for lymphedema follow-up, especially when standardized: all the measurements were taken by the same evaluator, skilled in the technique. According to Rezende et al.[21], the diagnostic ultrasound has been demonstrated to be a safe, minimally invasive, and low-cost method, useful for assessing the efficacy of therapies for lymphedema treatment, monitoring changes, and progression of the condition by assessing aspects like tissue thickness and rigidity.

This article has been approved by the Research Ethics Committee, report number 5,993,830 (CAAE (submission for ethical review): 67725423,5,0000,5231), in compliance with Resolution No. 466/12[22] of the National Health Council, which regulates scientific research in human beings. The patient agreed to participate by signing an Informed Consent Form.

RESULTS

Perimetry revealed a volume reduction throughout the whole extension of the patient's left forearm, including the fibrosis area (Figure 3). This reduction corresponded to approximately 2 cm in each of the recorded margins. Delimitation of the fibrosis area revealed a significant reduction in its dimensions, both in width and length (Figure 4), corresponding to a reduction of approximately 4 cm in both measurements. The values presented in session 1 reflect the measures taken before using the therapeutic compression product.

The ultrasound exam presented an image with a more diffuse fibrosis area after the intervention (Figure 5), representing an improvement in the rigidity pattern. Moreover, the patient reported feedback with the following impressions: "feeling of reduced weight on the member, less tightened skin, and softer to the touch".

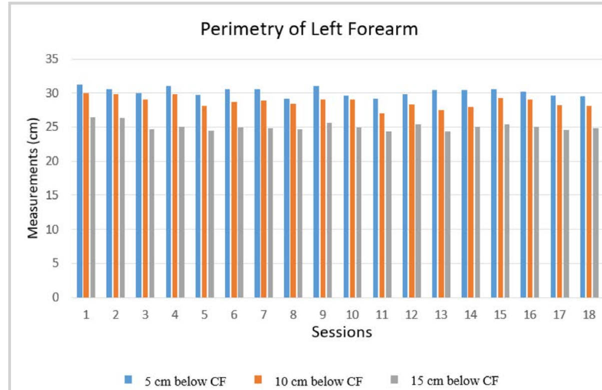

Figure 3. Left forearm perimetry measurements recorded before each treatment session
Caption: CF = cubital fossa.

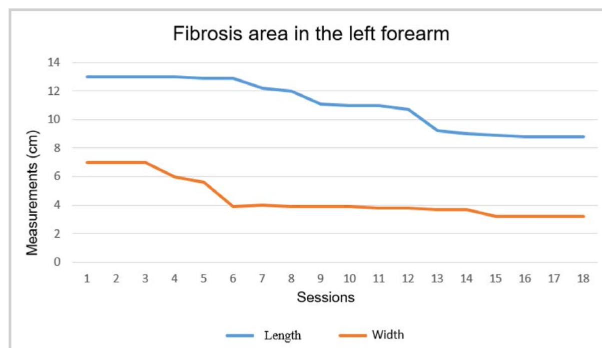

Figure 4. Left forearm fibrosis delimitation area measurement values recorded before each treatment session

a)
b)

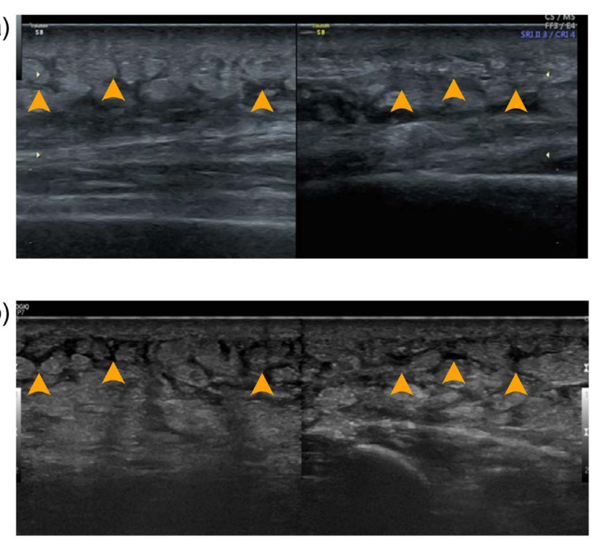

Figure 5. Comparison between ultrasound images of the patient's left forearm fibrosis area: a) pre-intervention (before using the *Fibro Placa*) and b) post-intervention (immediately after the 18 treatment sessions). Image a): well-delimited fibrotic plaque, followed by a localized accumulation of anechoic fluid adjacent to the fibrotic area. Image b): Partial fragmentation of fibrotic plaque, demonstrated by discontinuity in the hyperechoic echoes that compose fibrosis and better distribution of the interstitial liquid: reduction of local accumulation and more homogeneous dispersion of fluid in the subcutaneous tissue. Yellow arrows: comparative indication between the same regions in images a) and b)

DISCUSSION

This study aimed to develop and apply a 3D-printed product that could act as a complementary resource to CPT, inserted within one of its steps: multilayer compressive banding, more specifically, between the tubular mesh and the elastic band, positioned with reliefs facing downwards on the fibrosis area. The application was done on the fibrosis area of a patient with stage II lymphedema, secondary to breast cancer.

The *Fibro Placa* application has proved promising for localized fibrosis compression, contributing to a reduction in limb circumference, extension of the fibrosis area, and modification of the tissue texture of the afflicted area. Similar results have been described in the literature, indicating that localized compression can help reshape the fibrotic tissue when associated with conventional therapies[23]. Recent studies have shown that changes to the subcutaneous tissue, such as increased thickness and echogenicity, detectable by ultrasound, are associated with fibrosis progression in patients with post-breast cancer lymphedema. Likewise, structural complexity technique analyses have identified patterns related to fluid accumulation and reorganization of the tissue matrix, which suggests that targeted compressive interventions can modulate these tissue alterations[24].

It is important to highlight that the device was integrated into an already validated conservative protocol and not used in isolation. Thus, the observed effects cannot be exclusively attributed to the *Fibro Placa*. However, its localized action, associated with anatomic conformity and customized design, may have potentiated the therapeutic effects, especially in areas of dense fibrosis, where conventional techniques often present a limited response[24].

The *Fibro Placa* does not replace conventional techniques, but represents a complementary innovation based on Design Thinking, which enabled the meeting of a specific clinical demand. The device was conceived to mimic the lymphatic drainage "S" maneuver, promoting continuous and controlled compression on the fibrosis during compressive banding[18,19].

Interdisciplinary collaboration between Physiotherapy and Design was fundamental in every step of development, enabling the creation of an innovative product guided by Design Thinking, a broad challenge solution approach[10-13,25,26] that fostered innovation, culminating in a patent registration titled *Fibro Placa*. The result of this process was a singular artifact, adapted to the morphological needs of the patient, which represents a novelty in relation to conventional compressive devices. Moreover, it proved to be safe since it did not cause lesions or discomfort to the patient.

Among the main benefits of digital manufacturing are the ability to produce single pieces in small quantities[7]. In this context, it was possible to produce a highly individualized device, precisely adjusted to the patient's fibrosis area, comfortably achieving its therapeutic function. Biological variability is inherent to patient individuality, capable of making even the same pathological manifestations different from one another. Digital manufacturing can be explored to meet this singularity, offering customized and adaptable solutions to the needs of each individual.

Currently, the main application of 3D printing in the health care field is for developing customized prosthetics and orthoses[8] and optimizing surgical procedures[9]. This customization is acknowledged as a promising trend in custom medicine, especially in extended treatment or chronic conditions[25,26].

Despite the positive results, the present study presents some limitations: it is not possible to attest the efficacy of the product for managing fibrosis, nor the prolonged tolerability of its use and secondary effects. For that end, further studies are needed, with larger samples and methodological rigor, a control group, and a longer follow-up period. Moreover, the protocol applied in this study does not include a concentric compressive layer with a foam band, due to the patient's allergy to this material. This decision was necessary to ensure patient safety and comfort, but it may have altered the banding pressure and general dynamic.

CONCLUSION

The *Fibro Placa*, developed through 3D-printing and used as a complement to CPT, has proved to be a promising strategy for managing fibrosis in a patient with lymphedema secondary to breast cancer treatment. The product contributed to perimetrical measurement reduction and clinical improvement of the tissue texture, as observed in an imaging test and a subjective patient report. However, it is not possible to confirm its efficacy in isolation, considering that the device was integrated into a consolidated therapeutic protocol. Further studies with a larger number of participants, longer follow-up time, and variable control are needed to validate the efficacy and safety of *Fibro Placa* as a complementary resource in the treatment of lymphedema with fibrosis. The Design Thinking-based development methodology proved efficient in generating innovative solutions focused on the patient, pointing to a viable path for integrating Design and Physiotherapy in the health field.

CONTRIBUTIONS

All the authors have substantially contributed to the study design, data acquisition, analysis, interpretation, wording, and critical review. They approved the final version for publication.

DECLARATION OF CONFLICT OF INTERESTS

There is no conflict of interest to declare.

DATA AVAILABILITY STATEMENT

All the contents associated with the article are included in the manuscript.

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