

External Breast Prostheses After Mastectomy: A Systematic Review on Digital Manufacturing, Personalization, and User Experience

Próteses Mamárias Externas Pós-Mastectomia: Revisão Sistemática Sobre Manufatura Digital, Personalização e Experiência da Usuária

Prótesis Mamarias Externas Postmastectomía: Revisión Sistemática sobre Manufactura Digital, Personalización y Experiencia de la Usuaría

RESUMO

Objetivo: A mastectomia, frequentemente indicada no tratamento do câncer de mama, provoca alterações anatômicas e repercussões psicossociais que impactam a reabilitação e a qualidade de vida das mulheres. As próteses mamárias externas constituem uma alternativa não cirúrgica relevante, contribuindo para o equilíbrio corporal e a reconstrução da autoimagem. **Método:** Esta revisão sistemática analisou criticamente a literatura sobre próteses personalizadas, considerando aspectos tecnológicos, clínicos, psicossociais e institucionais. **Resultados:** 25 estudos foram incluídos e organizados em quatro eixos: tecnologias e processos de fabricação; experiência da usuária; desempenho biomecânico; e desafios de implementação. Foi identificada a consolidação de um fluxo digital envolvendo aquisição da geometria, modelagem tridimensional e manufatura, com diferentes abordagens produtivas. Peso e distribuição de massa destacam-se como fatores determinantes para conforto e alinhamento postural. Observam-se impactos positivos na autoestima e qualidade de vida. **Conclusão:** Persistem desafios de padronização, validação clínica e implementação, limitando a adoção em escala nos sistemas públicos de saúde.

DESCRIPTORIOS: Prótese mamária externa; Mastectomia; Manufatura aditiva; Experiência do paciente; Biomecânica; Saúde pública.

ABSTRACT

Objective: Mastectomy, frequently indicated in the treatment of breast cancer, causes anatomical changes and psychosocial repercussions that impact women's rehabilitation and quality of life. External breast prostheses constitute a relevant non-surgical alternative, contributing to body balance and the reconstruction of self-image. **Method:** This systematic review critically analyzed the literature on customized prostheses, considering technological, clinical, psychosocial, and institutional aspects. **Results:** Twenty-five studies were included and organized into four axes: technologies and manufacturing processes; user experience; biomechanical performance; and implementation challenges. The consolidation of a digital workflow involving geometry acquisition, three-dimensional modeling, and manufacturing was identified, with different production approaches. Weight and mass distribution stand out as determining factors for comfort and postural alignment. Positive impacts on self-esteem and quality of life were observed. **Conclusion:** Challenges related to standardization, clinical validation, and implementation persist, limiting large-scale adoption in public health systems.

DESCRIPTORS: External breast prosthesis; Mastectomy; Additive manufacturing; Patient experience; Biomechanics; Public health.

RESUMEN

Objetivo: La mastectomía, frecuentemente indicada en el tratamiento del cáncer de mama, provoca cambios anatómicos y repercusiones psicossociales que afectan la rehabilitación y la calidad de vida de las mujeres. Las prótesis mamarias externas constituyen una alternativa no quirúrgica relevante, contribuyendo al equilibrio corporal y a la reconstrucción de la autoimagen. **Método:** Esta revisión sistemática analizó críticamente la literatura sobre prótesis personalizadas, considerando aspectos tecnológicos, clínicos, psicossociales e institucionales. **Resultados:** Se incluyeron 25 estudios, organizados en cuatro ejes: tecnologías y procesos de fabricación; experiencia de la usuaria; desempeño biomecánico; y desafíos de implementación. Se identificó la consolidación de

un flujo digital que involucra la adquisición de la geometría, el modelado tridimensional y la manufactura, con diferentes enfoques productivos. El peso y la distribución de la masa se destacan como factores determinantes para la comodidad y la alineación postural. Se observaron impactos positivos en la autoestima y la calidad de vida. **Conclusión:** Persisten desafíos relacionados con la estandarización, la validación clínica y la implementación, lo que limita su adopción a gran escala en los sistemas públicos de salud.

DESCRIPTORES: Prótesis mamaria externa; Mastectomía; Manufactura aditiva; Experiencia del paciente; Bio-mecánica; Salud pública.

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INTRODUCTION

Breast cancer has a high global incidence and constitutes a major public health problem, with significant impacts on morbidity, mortality, and women's quality of life ⁽¹⁾. In Brazil, the National Cancer Institute estimates approximately 781,000 new cases of cancer per year for the 2026–2028 period, underscoring the need for comprehensive care strategies, including rehabilitation measures ⁽²⁾. Mastectomy, a procedure frequently indicated for the treatment of the disease, is associated with significant physical and psychosocial repercussions. The loss of a breast compromises not only anatomical integrity but also symbolic dimensions related to femininity, self-esteem, and body image ⁽³⁾. In this context, rehabilitation must be understood in a broader sense, incorporating functional, emotional, and social aspects of care.

External breast prostheses are an

important non-surgical alternative in this process, contributing to the restoration of body symmetry, physical comfort, and social reintegration for women ⁽⁴⁾. Beyond their aesthetic function, these devices play an important role in rebuilding self-image and the perception of bodily wholeness, especially when properly tailored to the individual needs of the users. However, the solutions available on the market are mostly standardized, with limitations regarding adaptation to individual anatomical and functional characteristics. This standardization can result in discomfort, poor fit, and low adherence to use, negatively impacting clinical and psychosocial outcomes ^(5–6).

Conventional standardized prostheses made of fabric, silicone, or other materials are often associated with discomfort, excessive weight, and poor anatomical fit—factors that compromise adherence to use and negatively impact users' quality of life ⁽⁶⁾. Advances

in digital manufacturing have expanded the possibilities for developing customized prostheses, with the potential to significantly improve the fit, comfort, and functionality of these devices ⁽⁷⁾. The use of three-dimensional (3D) scanning and additive manufacturing techniques allows for greater geometric precision and improved reproducibility of production processes, in addition to enabling weight reduction in prostheses and individualized adaptation to the wearer's body ^(8–10). Furthermore, biomimetic approaches are being explored as a strategy to replicate the structural and functional characteristics of breast tissue through the use of materials with adjustable properties and optimized internal structures ⁽¹¹⁾.

In Brazil, cancer care within the Unified Health System (SUS) includes rehabilitation as part of comprehensive care, in accordance with Ministry of Health guidelines ⁽¹²⁾. However, there is a lack of specific guidelines for the

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provision, selection, and distribution of external breast prostheses, which limits the organization of services and compromises equity in access. This systematic review aims to analyze the literature on custom-made external breast prostheses, with an emphasis on the integration of technological, clinical, psychosocial, and institutional aspects, with the goal of adopting a more comprehensive approach aligned with public health.

METHOD

The four thematic axes used in the methodology integrate technological, clinical, psychosocial, and institutional aspects (Fig. 1). 1) Technologies and manufacturing processes: Digital workflows employed in the manufacture of custom external breast prostheses, as well as the influence of material

and equipment choices on the final properties of the devices; 2. User experience and psychosocial impact: Effects of prosthesis use on quality of life, self-esteem, comfort, and body image, including limitations of conventional prostheses and proposed technological strategies to overcome them; 3. Biomechanical and functional performance: This section evaluates the impacts of external breast prostheses on posture and body biomechanics, considering recent clinical evidence and the potential of customization through additive manufacturing to reduce the weight and optimize the functionality of the devices; 4. Implementation challenges: This section discusses the main technical, economic, educational, and institutional obstacles to the large-scale adoption of customized external breast prostheses in the Unified Health System (SUS).

The population (P) included women who had undergone mastectomy; the phenomenon of interest (I) was the use of external breast prostheses, with an emphasis on customized and/or digitally manufactured devices; and the context (Co) encompassed clinical, biomechanical, and psychosocial aspects related to the user experience. These elements formed the basis for organizing the review into the four thematic areas adopted.

Search Strategy

Searches were conducted in the PubMed, Google Scholar, and SciELO databases. The search strategies were adapted to the specific characteristics of each database, taking into account language, search mechanisms, and indexing criteria. The search was conducted through February 2026. The search terms were organized into three conceptual themes:

- External breast prostheses: “external breast prosthesis”; “custom breast prosthesis”; “breast prosthesis”; “prótese mamária externa”; “prótese mamária personalizada”.
- Digital fabrication technologies: “3D printing”; “digital fabrication”; “additive manufacturing”; “impressão 3D”; “manufatura aditiva”.
- Context and user experience: “post-mastectomy”; “mastectomy”; “user experience”; “experiência do usuário”.

The terms were combined using the Boolean operators AND and OR in different arrangements across the defined axes to increase the search sensitivity and retrieve potentially relevant studies. The different strategies yielded partially overlapping results across the databases. Searches were conducted in the PubMed (2016–2026), Google Scholar (2016–2026), and SciELO (2006–2026) databases using combinations of terms in English and Portuguese related to 3D printing, digital fabrication, external breast prostheses, mastectomy, customization, and user

Figure 1. Methodological framework of the systematic review on customized external breast prostheses, organized by thematic areas.



Source: Authors

This systematic review was conducted in accordance with the *Preferred Reporting Items for Systematic Reviews and Meta-Analyses* (PRISMA) guidelines⁽¹³⁾ to identify and analyze studies on

external breast prostheses, with an emphasis on customization, digital manufacturing technologies, and aspects related to the user's experience following mastectomy. The research question was structured based on the PICO model:

experience. In PubMed, English terms showed greater sensitivity, while in Google Scholar, combinations focused on experience and customization were included. In SciELO, terms in both languages were used to broaden the scope of the results.

Eligibility Criteria

The inclusion and exclusion criteria were defined based on the review's objective. Studies were included that: addressed external breast prostheses in the post-mastectomy context, including conventional or customized models; investigated technological, clinical, biomechanical, functional, or experiential aspects related to the use of these prostheses; involved digital fabrication, 3D printing, or customization strategies, when applicable; had no language restrictions; provided access to the full text; and were published within the time frame applied to each database (2016–2026 for PubMed and Google Scholar; 2006–2026 for SciELO). The following were excluded: studies focused exclusively on surgical breast reconstruction or implantable prostheses; duplicate records due to variations in authors' spellings; studies not related to women who had undergone mastectomy; publications without access to the full text, such as conference abstracts, editorials, or short communications; and studies with substantial overlap in data or results from the same project, in which case the most complete version was retained. The use of different time frames reflects the specific coverage of each database, given the rapid evolution of technologies.

Study Selection

The study selection process was conducted in accordance with the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020) flowchart, using Rayyan software⁽¹⁴⁾. Two independent reviewers performed a blind screening, evaluating titles, abstracts, and full-text

articles. Disagreements were resolved by consensus among the reviewers. This systematic review was not previously registered on platforms such as PROSPERO, since its scope includes, in addition to clinical outcomes, technological, psychosocial, and institutional dimensions related to the use of external breast prostheses. Given the interdisciplinary nature of the research and the absence of a formal registration requirement for this type of study, we chose to conduct the review based on the PRISMA guidelines, ensuring transparency, reproducibility, and methodological rigor.

Data Extraction and Analysis

After defining the studies included in the review, data extraction was performed using a structured spreadsheet. Information was collected regarding authors, year of publication, country of origin, study type, objectives, technologies employed, manufacturing processes, materials used, main results, and reported limitations. The team conducted the data extraction systematically and reviewed the data by consensus among the authors to ensure consistency and reliability in the characterization of the evidence. The data were organized and synthesized into a table, which allowed for comparison among the included studies. The analysis consisted of a thematic qualitative synthesis, conducted through an in-depth and comparative reading of the studies. The team performed coding based on the identification of recurring patterns, enabling the definition of analytical axes representative of the main dimensions addressed in the literature.

The four analytical axes are not mutually exclusive, allowing a single study to contribute to more than one category. This approach seeks to capture the complexity and interdisciplinary nature of the field under investigation. The graphical representations are derived from the analytical synthesis of the data and are descriptive and com-

parative in nature; they do not correspond to primary data from the included studies.

For the purposes of this review, a complete digital workflow is defined as the process that includes three-dimensional geometry acquisition, followed by digital modeling and additive manufacturing. In observational, experimental, or review studies, these stages were indicated in Table 1 as “–” (not applicable). Among the methodological limitations of this review are the heterogeneity of the study designs, the predominance of observational approaches, and the limited availability of robust clinical evidence. Additionally, variability in assessment methods and the outcomes analyzed may influence the comparability among studies and the generalizability of the results. Artificial intelligence tools were used to support the linguistic review and textual organization of the manuscript but did not participate in conducting the systematic review, analyzing the data, or interpreting the results.

RESULTS

During the identification phase, 622 records were retrieved (619 from databases and 3 identified through a manual search of reference lists). After removing duplicates ($n = 412$), 210 records were screened based on title and abstract. At this stage, 183 records were excluded because they were not related to the review's topic. During the eligibility assessment stage, 27 full-text reports were evaluated against the inclusion criteria. Of these, two were excluded: one due to an ineligible study population and the other due to data overlap with a previously included study. At the end of the process, 25 studies were included in the systematic review. The study selection process is presented in Figure 3, in accordance with the PRISMA 2020 guidelines (Fig. 2). The search strategies applied to the different databases yielded vary-

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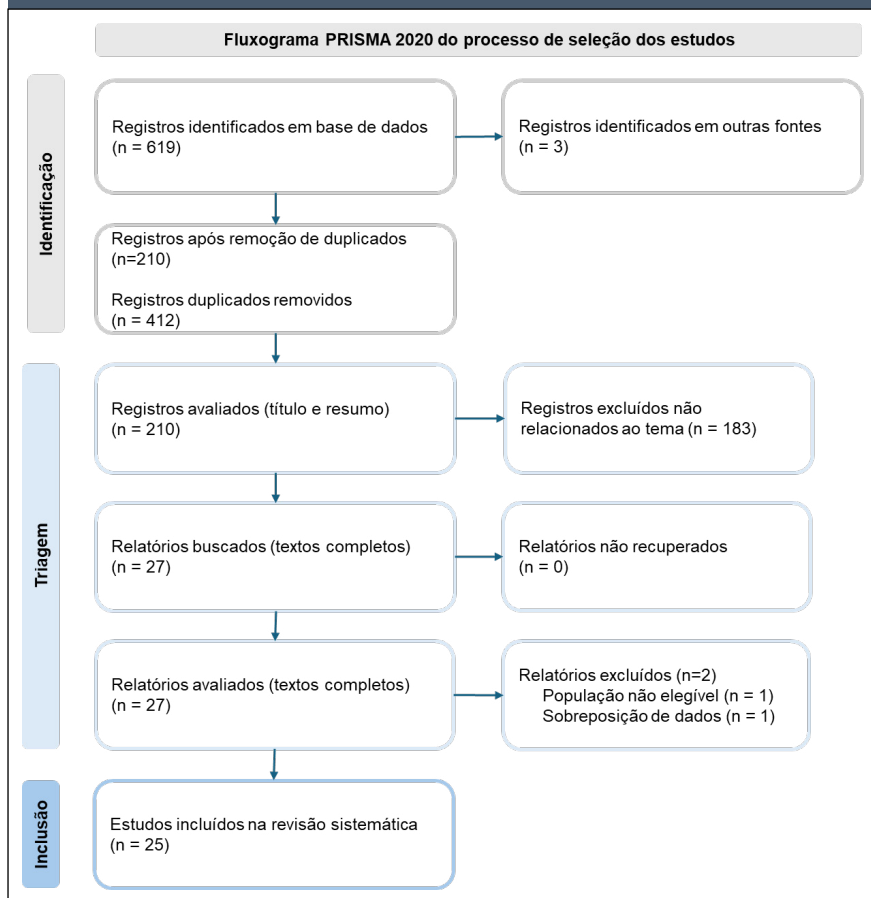
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ing numbers of records, reflecting the specific indexing practices, subject coverage, and sensitivity of each platform.

Searches were conducted in the PubMed, Google Scholar, and SciELO databases, focusing primarily on the last 10 years (and since 2006 in SciELO), using combinations of terms in English and Portuguese related to 3D printing, digital fabrication, external breast prostheses, mastectomy, customization, and user experience. In PubMed, the following terms stood out: “3D printing” AND “breast prosthesis” (n = 2), “3D printing” AND “post-mastectomy” (n = 4), “digital fabrication” OR “external breast prosthesis” (n = 200), “digital fabrication” (n = 183), “External Breast Prosthesis” (n = 105), and “mastectomy” AND “external breast prosthesis” (n = 15), with low sensitivity for terms in Portuguese. On Google Scholar, combinations such as “post-mastectomy” AND “user experience” (n = 84) and “external breast prosthesis” AND “3D printing” (n = 33) were used. In SciELO, the following stood out: “external breast prosthesis” OR “post-mastectomy” OR “3D printing” (n = 329) and “external breast prosthesis” OR “post-mastectomy” (n = 62).

Analysis of the 25 included studies revealed a diversity of methodological approaches, technologies employed, and analytical perspectives related to the development, evaluation, and use of external breast prostheses in the post-mastectomy context. Studies were identified involving conventional models, customized prostheses, and solutions based on additive manufacturing, highlighting an expanding field characterized by strong interdisciplinarity. The results were organized into four previously established thematic areas, allowing for a structured analysis of the different dimensions addressed in the literature (Table 1).

Figure 2. PRISMA 2020 flowchart of the process from study identification to inclusion.



Source: Authors

Table 1. Studies on the production of external breast prostheses for women who have undergone mastectomy

Study	Type	Process	Material	Dimension	Findings
15	Observational	—	Silicone	Psychosocial	Barriers to use
16	Experimental	Physical mold	Medical-grade silicone	Technological	Conventional manufacturing
17	Observational	—	Silicone	Psychosocial	Cultural experience
18	Observational	—	Silicone	Psychosocial	Quality of life
19	Observational	—	Silicone, cotton	Psychosocial	Adherence to use
20	Observational	—	Thermal silicone	Biomechanical	Thermal comfort
21	Observational	—	Silicone	Biomechanical	Postural impact
22	Experimental	CT, FDM	TPU Shore 82A	Biomechanical	Weight reduction
23	Observational	—	—	Psychosocial	Need for adaptation and professional guidance

24	Experimental	3D scanner, molding	Silicone, PLA	Technological	Weight reduction
25	Observational	—	—	Psychosocial	User experience
26	Observational	—	Silicone, cotton	Psychosocial	Comfort and adaptation
27	Experimental	3D scanner + molding	PLA, silicone	Technological	Digital workflow
28	Review	—	Polymers, metal, resin	Technological	General overview
29	Experimental	Kinect, FDM/LCD	PLA, resins	Technological	Low cost
30	Experimental	3D scanner, FDM mold	PLA, silicone	Technological	Hybrid process
31	Experimental	3D photogrammetry scanner	PU foam, silicone	Biomechanical	Postural impact
32	Experimental	PolyJet 3D scanner	Photopolymer	Technological	High realism
33	Experimental	3D scanner, FDM mold	PLA, silicone	Technological	Good anatomical fidelity
34	Experimental	Digital FDM model	TPU Shore 95A	Technological / Biomechanical	Significant weight reduction
35	Review	—	Silicone, foam	Technological / Implementation	Promising personalization
36	Review	—	Silicone, fabrics	Psychosocial / Implementation	Impact on self-esteem and access
37	Experimental	Parametric PolyJet	Elastomeric photopolymer	Technological / Biomechanical	Control of mechanical properties
38	Clinical trial	—	Cotton	Biomechanical	Equivalent weight with improved postural alignment
39	Experimental	3D scanner, FDM	TPU Shore 85A	Technological / Biomechanical	Direct manufacturing, low weight, and good adaptation

Biomechanics: Functional performance, mass distribution, and postural alignment; **FDM:** *Fused Deposition Modeling*; **Implementation:** Integration of technologies into health care services (organizational and institutional aspects); **LCD:** 3D printing via photopolymerization on a liquid crystal display (LCD); **FDM Mold:** Molds for filling with silicone; **PLA:** Polylactic Acid; **PolyJet:** Additive manufacturing via photopolymer jetting and ultraviolet light curing; **Psychosocial:** Dimension of the user's experience (self-esteem, quality of life, and body image); **PU:** Polyurethane; **CT:** Computed Tomography; **Technological:** Dimension of manufacturing processes, materials, and digital workflows; **TPU:** *Thermoplastic Polyurethane*.

Axis 1 – Technologies and Manufacturing Processes

The studies analyzed demonstrate the consolidation of a digital workflow for the production of customized

external breast prostheses (28,35–36). This workflow is typically structured into three main stages: acquisition of breast geometry, digital modeling, and manufacturing, which can occur indirectly—through the production of molds subsequently filled with silicone—or directly, through the fabrication of the final prosthesis. Different manufacturing strategies have been employed, notably direct manufacturing—based on 3D printing of flexible materials—with reports of development and initial clinical validation based on functional and experiential evaluations (22,34,39), and indirect manufacturing, which uses custom molds produced by ad-

ditive manufacturing for subsequent filling with silicone (24,27,30,33). These approaches have advantages and limitations related to anatomical fidelity, mechanical properties, production time, and cost (22,33,34,37), highlighting the existence of technical trade-offs between lightness, tactile realism, production time, and process replicability (22,33–34). There was variability in the tools used and in the level of technical detail reported, especially regarding geometric accuracy, production time, and the reproducibility of the processes (24,27,39). This heterogeneity points to the absence of standardized protocols, which may limit comparability between studies and the incorporation of these technologies into clinical practice.

Geometric data acquisition is predominantly performed via 3D scanning of the user's torso (27), using structured light technologies such as Artec Eva™ (33,29) and EinScan (24). This approach offers advantages because it is noninvasive and easy to apply in clinical settings. Alternatively, some studies use medical imaging, such as computed tomography (CT), especially in situations requiring greater anatomical detail, although this involves higher costs and a greater reliance on infrastructure (22,32). In general, 3D scanning is the primary solution for clinical applications and custom production, due to its accessibility and practical applicability.

During the digital modeling stage, the prosthesis is customized based on the user's body symmetry and fit to her chest (27). Tools such as Meshmixer are used for initial data processing (24,30), and software such as Blender and Geomagic enable more advanced operations (27,29), including mirroring the contralateral breast and final adjustments (29,33). However, there is a lack of standardized performance metrics, such as geometric error and modeling time, highlighting signifi-

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cant methodological gaps. ZHANG et al.⁽³⁷⁾ incorporate parametric modeling and optimized internal structures, expanding the concept of customization beyond the external shape.

In the manufacturing stage, the PolyJet process and Fused Deposition Modeling (FDM) or Fused Filament Fabrication (FFF) stand out^(37,39). The PolyJet process, based on the jetting of photopolymer resin cured by ultraviolet light, offers high precision and surface finish quality; it is recommended when geometric and aesthetic fidelity is a priority, though it comes with higher costs and is less accessible⁽³⁷⁾. The FDM/FFF process stands out for its greater cost-effectiveness and potential for use in decentralized settings, although it has limitations in terms of resolution and surface finish^(34,39). This duality highlights a necessary balance between technical performance and feasibility of implementation, which is particularly relevant in public health systems.

Recent advances include the use of designed internal structures, such as gyroid geometries, which allow

for the control of the mechanical and thermal properties of prostheses⁽³⁷⁾. The evaluation of these structures through mechanical testing and computational simulations indicates progress in geometric customization for approaches aimed at functional performance.

The data indicate significant reductions in mass for prostheses produced by additive manufacturing, especially those made of thermoplastic polyurethane (TPU), when compared to conventional solutions^(22,34), as well as reductions in silicone molding⁽²⁴⁾. The heterogeneity of the metrics limits direct comparability between studies. An analysis of replicability shows greater consistency in the Polyjet and FDM/FFF processes, attributed to the standardization of digital files and the repeatability of the processes. In contrast, 3D scanning and FDM/FFF processes exhibit greater variability, influenced by operational factors, equipment calibration, and local production conditions. Technologies with greater replicability, such as PolyJet, have limitations in terms of access and cost, while

more accessible approaches, such as FDM/FFF, exhibit greater operational variability, striking a balance between standardization and implementation.

The choice of materials has a direct influence on the final properties of the prostheses. TPU combines lightwe , flexibility, and low cost, and is widely used in direct printing, although it still has limitations regarding tactile realism^(22,34,39). Baron⁽³⁴⁾ reports weight reductions of up to 78% in prostheses made of TPU compared to conventional silicone prostheses. However, limitations remain regarding the surface texture and mechanical consistency of the prosthesis^(22,24).

On the other hand, silicone remains the gold standard in terms of appearance and consistency, being applied primarily through indirect molding, although this involves longer production times and greater relative weight. Alternatives such as silicone foam and photopolymer resins allow for advances in lightness and property control, but with limitations related to cost and scalability^(24,27,33).

Table 2. Quantitative parameters associated with external breast prosthesis manufacturing processes

Study	Material	Process	Outcome	Advantages	Limitations
22, 29, 34, 39	TPU Shore 82A or 95A, PLA, resins	Direct (FDM/FFF/ LCD)	Weight reduction (g): 33 → 90 (22); 1,200 → 150 (34)	Low weight and cost; rapid manufacturing; flexibility	Low tactile and surface fidelity; limited finishing
24, 27, 30, 33	Silicone Shore A	Indirect (FDM Mold)	Weight reduction (g): 317%	High tactile and aesthetic realism; wide clinical acceptance	Higher relative weight; longer production time
31	PU Foam and Silicone	Process not described	–	Weight reduction; good fit	Limitations in aesthetic finishing and painting
28, 32, 36	Photopolymer (Rigid and Flexible)	Direct (PolyJet)	–	Realism; hardness gradients	High cost; low feasibility for large-scale production
37	Architected Materials	Parametric modeling with direct 3D printing	Compression test, FEA	Rigidity control; optimized lightness; thermal dissipation	High cost; low scalability

FDM: Fused Deposition Modeling; **FEA:** Finite Element Analysis; **FFF:** Fused Filament Fabrication; **PolyJet:** Additive manufacturing technology based on the jetting of photopolymers cured by ultraviolet light; **T1/T2:** Types of internal structure evaluated in the study; **TPU:** Thermoplastic Polyurethane; λ/λ_s : Ratio of the material's thermal conductivity to that of the reference solid;

In addition, recent studies have explored the use of photopolymers in PolyJet processes, enabling the creation of internal hardness gradients and highly realistic textures. However, the high cost of equipment and materials limits the large-scale adoption of this approach, especially in public health settings^(28,32).

Overall, the findings indicate that the development of customized external breast prostheses through digital manufacturing involves striking a balance between geometric precision, functional properties, cost, and production feasibility. Despite technical advances, significant limitations persist, particularly regarding surface texture, sensory fidelity, and thermal control, which directly impact the user's experience and limit the complete replacement of conventional prostheses.

Axis 2 – User Experience and Psychosocial Impact

Of the 25 studies included in this systematic review, nine directly investigated the user experience with external breast prostheses in the post-mastectomy context (Fig. 3A). These studies addressed psychosocial dimensions related to body image, self-esteem, feminine identity, and quality of life^(15–25). The proportions were estimated based on the frequency of occurrence of the categories in the studies included in this axis, totaling 13 thematic occurrences. Physical comfort was the most frequently reported dimension, accounting for 30.8% of the occurrences. The other dimensions (self-esteem, quality of life, and body image) had equivalent frequencies, each accounting for 23.1%. Physical comfort predominated as the main dimension reported, while the other dimensions were distributed equally, indicating the multifactorial nature of the user's experience.

Among these nine studies, physical comfort was the most frequently reported aspect, being associated pri-

marily with the anatomical fit of the prosthesis, weight distribution, and reduced discomfort during prolonged use^(15,19–21). Increased self-esteem was also widely reported, particularly in relation to the restoration of body symmetry and the ability to wear clothing without feeling self-conscious^(20–21, 25).

Quality of life was described as resulting from the resumption of social activities, a reduction in the emotional impact associated with the absence of the breast, and a sense of greater security and body confidence^(15,18,23). Body image, on the other hand, was related to the aesthetic and tactile realism of the prosthesis, influencing the perception of wholeness and belonging to one's own body^(16,18,25). In addition to these dimensions, six of the nine studies analyzed^(15; 17, 19–21, 23) highlighted the excessive weight of conventional prostheses as a critical factor contributing to discomfort, associated with musculoskeletal pain, postural changes, and discontinuation of use over time. In five studies^(18,20–21,24–25), the user's active participation in the process of selecting and fitting the prosthesis was identified as a central element for a positive experience, while the lack of qualified consultation was linked to the device's unsuitability and reduced adherence to use.

The findings indicate that the user's experience goes beyond exclusively technical criteria, involving subjective, functional, and contextual dimensions of care. The studies in this category reinforce the need for woman-centered approaches that integrate physical comfort, aesthetics, symbolic meaning, and life context into post-mastectomy care. These findings underscore the importance of incorporating user-centered care practices within the context of health services, especially in the SUS, given the diversity of women's experiences and needs following mastectomy.

Axis 3 – Clinical and Biomechanical

Outcomes

The clinical and biomechanical impacts associated with the use of prostheses were investigated in nine of the 25 studies included in this systematic review. These studies primarily analyzed the effects of the device's weight, its influence on postural alignment, and functional outcomes during use in the post-mastectomy period. Among the studies analyzed, weight reduction was the most frequently reported finding. Studies based on additive manufacturing demonstrated significant reductions in mass compared to conventional commercial prostheses, which are often associated with musculoskeletal discomfort, strain on bra straps, and compensatory postural changes^(21–22, 31, 34). In general, lighter prostheses were associated with greater functional comfort and better tolerance for prolonged use.

However, the findings indicate that the clinical benefit does not stem exclusively from the absolute reduction in weight, but rather from the biomechanical balance between the two sides of the body. The randomized clinical trial conducted by XIE et al. (2025) demonstrated a statistically significant improvement in cervical and scapular alignment when a device with a weight equivalent to that of the contralateral breast was used. These results suggest that the ideal weight should take into account body symmetry and postural compensation, and not merely the device's weight alone^(31,38). In this regard, the literature points to the need for a more precise approach in defining prosthesis design parameters, incorporating biomechanical criteria that account for mass distribution, the center of gravity, and interaction with the musculoskeletal system.

Thus, studies converge on the understanding that a prosthesis's clinical performance depends on proper mass distribution and individual anatomical adaptation. Excessively heavy pros-

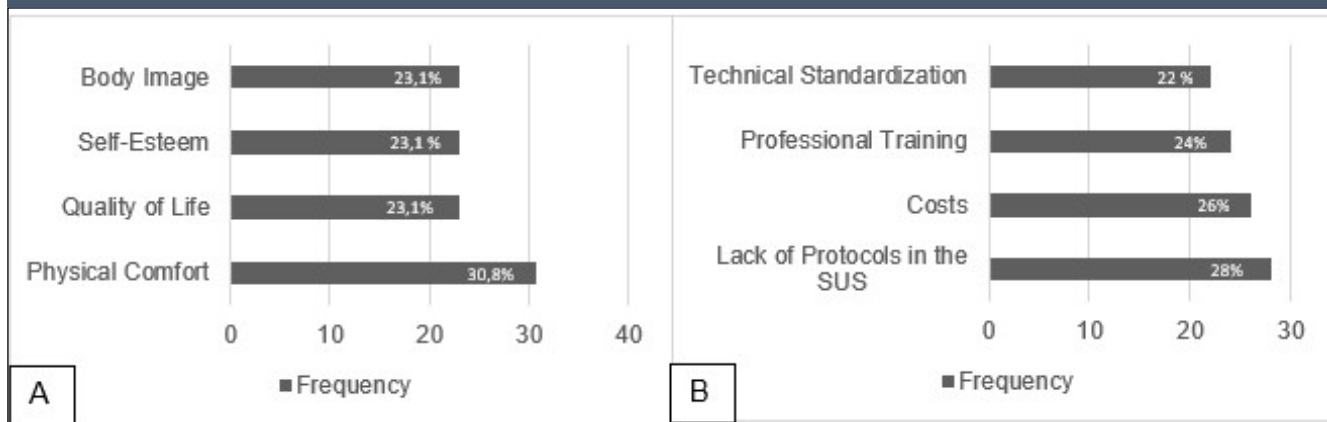
theses can increase musculoskeletal overload, while devices that are too light may not adequately compensate for body asymmetry. These findings reinforce that customization based on objective biomechanical criteria is central to the development of external prostheses with improved clinical performance. Taken together, these findings underscore that customization based on objective biomechanical criteria is central to the development of external prostheses with improved clinical performance and greater potential for user adherence.

Axis 4 – Implementation Challenges

Challenges related to the implementation of customized external breast prostheses constitute a specific theme in the analyzed literature. Among the 25 studies included in this systematic review, eight articles directly addressed issues related to the incorporation of these technologies into health care services, with an emphasis on institutional, organizational, and structural barriers, especially in the context of public health systems ^(15,19,23,26–28,35–36). Figure 3B

presents the relative distribution of the main challenges identified in this area, based on the thematic coding of the included studies. The graph organizes the findings into four subcategories: lack of protocols in the public health system, equipment costs, professional training, and technical standardization. The percentages reflect the relative frequency of these themes within the set of thematic records for this axis, not the proportion of articles relative to the review's total corpus.

Figure 3. User experience with customized external breast prostheses (A). Distribution of the main challenges for implementing the prostheses (B).



Source: Authors

Institutional barriers predominate, particularly the lack of protocols in the SUS, followed by economic and professional training challenges, highlighting that the implementation of these technologies depends on structural factors beyond technical development. The lack of protocols in the public health system represents the most recurrent challenge, accounting for 28% of the coded mentions. Studies indicate a lack of clear clinical guidelines and institutional workflows for the prescription, fabrication, and distribution of custom external breast prostheses. This gap hinders the incorporation of these technologies into the routine of public health services and

compromises equity in access to assistive technologies ^(15,27–28,36).

Approximately 26% of the mentions refer to cost-related access difficulties. The literature highlights limitations in measuring these costs, as studies rarely present detailed quantitative data. The findings suggest that the main barrier is associated with the integration of these technologies in contexts of budgetary constraints, especially in public systems ^(19,26,36). Additionally, emerging technologies present challenges related to scalability and the cost of specialized supplies ⁽³⁵⁾.

Professional training was identified in 24% of the mentions. The studies highlight the need for technical training, professional guidance, and

interdisciplinary coordination to integrate clinical, technological, and psychosocial aspects into patient care. The lack of adequate training limits the adoption of these technologies, even when infrastructure and material resources are available ^(23,27). Technical standardization accounts for 22% of the identified mentions. The literature points to heterogeneity in workflows, the materials used, and the criteria for the evaluation of prostheses. This lack of standardization hinders comparisons between studies, the replication of processes, and the consolidation of evidence for the formulation of public policies ^(27–28).

The obstacles to the implementation of customized external breast

prostheses do not stem exclusively from technological limitations, but from a set of structural and organizational factors. Institutional, organizational, and training barriers play a central role in the incorporation of these innovations into the public health system, reinforcing the need for integrated strategies that link technological development, professional training, process standardization, and service organization.

DISCUSSION

This systematic review, comprising 25 studies, identifies the consolidation of a digital workflow consisting of geometry acquisition, digital modeling, and manufacturing as a technical benchmark in the development of customized external breast prostheses. The recurrence of this model in the literature reinforces its operational feasibility and its ability to accommodate the individual anatomical characteristics of users. Recent studies describe complete digital workflows that integrate 3D scanning, digital modeling, and direct additive manufacturing⁽³⁹⁾, indicating advances in the technical standardization of these processes. Overall, the studies point to a consensus regarding improvements in the anatomical fit and comfort of customized prostheses, especially those produced through digital manufacturing. However, limitations persist regarding clinical validation, process standardization, and the economic accessibility of these technologies.

Despite these advances, the analysis indicates a balance still in the making between technological performance, sensory realism, and production feasibility. Indirect manufacturing based on silicone molding remains the gold standard for sensory realism, offering greater tactile and aesthetic fidelity^(24,27). This process, however, requires a longer production time and includes additional steps, such as mold mak-

ing and silicone curing. In contrast, direct manufacturing via 3D printing with thermoplastic polyurethane offers lightness, production agility, and greater potential for replicability^(22,34), although it still has limitations in reproducing the texture and consistency of breast tissue.

More recent technologies expand this technical repertoire by exploring photopolymer materials and engineered structures with controlled mechanical properties. PolyJet printing allows for the creation of internal hardness gradients and greater geometric control⁽³²⁾. Studies based on engineered materials demonstrate the possibility of adjusting mechanical and thermal properties through parameterized internal geometries, such as gyroid-type structures⁽³⁷⁾. These approaches expand the concept of customization by integrating functional materials engineering, going beyond the purely geometric adaptation of the prosthesis. The high cost of specialized equipment and supplies limits the large-scale adoption of these technologies, especially in public health systems.

From a clinical and biomechanical perspective, the studies analyzed indicate that the weight and mass distribution of the prosthesis are key factors for functional comfort and postural alignment in women. Research based on additive manufacturing reports significant reductions in mass compared to conventional commercial prostheses, which are often associated with musculoskeletal discomfort and strain on bra straps^(21–22, 31, 34). Recent clinical evidence reinforces this association: a randomized clinical trial demonstrated significant improvement in cervical and scapular alignment with the use of a device weighing the same as the contralateral breast⁽³⁸⁾. These results indicate that the biomechanical performance of prostheses depends not only on absolute weight reduction but also on body balance and individual

postural compensation.

Biomechanical factors are directly related to the psychosocial aspects of the user's experience. Physical comfort, self-esteem, quality of life, and body image are interdependent factors in the post-mastectomy rehabilitation process. Weight reduction and anatomical adaptation contribute to the acceptance of the device, while the impact of these prostheses also involves symbolic and identity-related aspects tied to the perception of bodily wholeness and social reintegration. Studies conducted in different cultural contexts indicate that social factors, access to information, and professional support influence users' experiences and adherence to prosthesis use^(16–19).

Despite the technological advances observed over the past two decades, the large-scale implementation of these innovations remains limited. The studies included in this review point to the absence of standardized clinical protocols, gaps in professional training, funding difficulties, and technical heterogeneity as barriers to the incorporation of these technologies into public health systems^(15,19,23,26–28,35–36). Although cost is frequently cited as a barrier, the studies do not present standardized quantitative data. This aspect is addressed predominantly from a qualitative perspective, based on the characteristics of the materials, processes, and manufacturing time, which limits comparisons between approaches and the assessment of large-scale economic feasibility.

The findings of this review indicate that the development of customized external breast prostheses requires coordination between technological innovation, clinical evidence, user experience, and institutional feasibility. The advancement of these solutions depends on the development of clinical protocols, funding strategies, and interdisciplinary training capable of supporting their integration into healthcare. In this regard, the results

show that the implementation of personalized assistive technologies within the SUS context depends less on technological maturity and more on the organizational capacity of services, professional training, and the development of structured guidelines.

CONCLUSION

This systematic review mapped and critically analyzed the literature on customized external breast prostheses, highlighting the consolidation of a structured digital workflow involving geometry acquisition, modeling, and manufacturing as a technical framework for the development of these devices. From a technological perspective, the development of customized external breast prostheses involves complementary production approaches,

in which indirect silicone manufacturing maintains superiority in sensory realism, while additive manufacturing expands possibilities for lightness and replicability. Emerging technologies incorporate functional materials engineering, expanding the concept of customization beyond geometric adaptation. In clinical and biomechanical aspects, the weight and mass distribution of the prosthesis are determining factors for functional comfort and postural alignment, indicating that the performance of these devices depends on biomechanical balance and individual adaptation. In the psychosocial realm, the user's experience integrates interdependent dimensions of comfort, self-esteem, quality of life, and body image, reinforcing the multifactorial nature of the post-mastectomy rehabilitation process. At the institu-

tional level, the analyzed studies identify challenges related to technical standardization, professional training, and process organization, highlighting that the incorporation of these technologies depends on structural conditions that go beyond technical development. Advances in the development and application of customized external breast prostheses require the integration of technological innovation, clinical evidence, user experience, and institutional feasibility. In this context, expanding access to these technologies—especially in public health systems such as the SUS—depends on the development of clinical protocols, professional training strategies, and implementation models that integrate technology with user-centered care.

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