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Strategic Design Framework for Personalized Assistive Products: Design tools for systemic orthosis co-creation

Ana Lya Moya Ferrari [a]* | **Luciana Ramos Baleotti** [b] | **Frode Eika Sandnes** [c] | **Fausto Orsi Medola** [a]

[a] São Paulo State University (UNESP), Graduate Program in Design, Faculty of Architecture, Arts, Communication and Design, Bauru, Brazil

[b] São Paulo State University (UNESP), Graduate Program in Human Development and Technologies, Institute of Biosciences, Rio Claro, Brazil

[c] Oslo Metropolitan University, Department of Computer Science, Oslo, Norway

* Corresponding author: analya_mf@hotmail.com

ABSTRACT

Assistive Technology (AT) orthoses pose socio-technical challenges, with high abandonment rates linked to poor aesthetics and conventional manufacturing limits. For users with motor impairment, specialized 3D scanning is often hindered by the critical technical barrier of maintaining limb position, restricting access to personalized design benefits. This study proposes a Strategic Design Framework centered on virtual limb repositioning, an intangible design artefact, to overcome this limitation. Showcased in a case study of a male teenager with spastic Cerebral Palsy, the methodology establishes an interdisciplinary-based approach where designer and occupational therapist collaboratively validate the limb's final functional pose using Blender software. This collaborative process, aligned with co-design principles, reconfigures the AT development process to prioritize user agency and aesthetic personalization, demonstrating a viable proposal for systemic intervention for AT provision, advancing sociotechnical innovation through the strategic alignment of clinical expertise and design tools.

Keywords: 3D scanning, 3D printing, Design, Interdisciplinarity, Orthotic Device, Upper Limb.

INTRODUCTION

Strategic design is defined as an evidence-based creative practice that bridges intangible design and social research, focusing on shaping strategies that enable organizations to achieve their goals (Caliskan & Wade, 2022). According to Torres (2018), strategic design is related to the pursuit of sociotechnical innovation, which entails fostering systemic change within the productive structure and among system actors. This expands the scope of design beyond products and services to encompass outcomes and impacts that originate from a clear understanding of user needs. In this context, all stakeholders are considered primary actors, and innovation emerges from understanding people's needs through co-design processes in which designers and non-designers collaborate in participatory settings (Torres, 2018).

Systemic design, in turn, is a strategic approach that integrates systems thinking and design thinking to address complex challenges. It applies human-centered design principles to large-scale systems characterized by social complexity and multiple interrelated subsystems (Smith & Kalantidou, 2023). This perspective within strategic design is particularly relevant to

projects in the healthcare domain, such as assistive technologies (AT) and medical devices (MDs). Due to their inherent complexity, these products may fail or be abandoned when human and environmental factors are not fully considered (Tsai et al. 2023; Zhang, Ma & Wang, 2023).

Within the development of AT and MDs, the frameworks of strategic design and systemic design become essential drivers of sociotechnical innovation (Torres, 2018). Strategic design guides the process by grounding it in users' needs, ensuring that development is user-driven and conducted through co-design principles that promote device acceptance (Tsai et al., 2023). Systemic design operates on a broader scale, ensuring that products not only meet immediate functional demands but also perform effectively within wider systems, accounting for the use environment, organizational structures, and the lifecycle processes of production, distribution, and maintenance (Tsai et al. 2023; Piaggio et al. 2021). Together, these two approaches have the potential to foster the systemic transformation required for healthcare innovations to evolve from the micro level to the sociotechnical regime, thereby advancing the goal of improving users' quality of life and autonomy.

Three-dimensional printing (3D printing) has revolutionized traditional manufacturing processes offering expanded possibilities for developing custom-made and personalized assistive technologies (AT) such as prosthetics (Manero et al. 2019), orthotics (Zheng et al. 2020; Chae et al. 2020; Choo, Boudier-Revéret & Chang, 2020) and wheelchair accessories (Jalal & Shaikh 2019). The key advantages include the efficient production of complex geometry and the ability for rehabilitation professionals to manufacture AT rapidly (Schwartz et al. 2020). However, successful AT development via 3D printing often requires advanced knowledge in modeling and technology. This highlights the critical role of interdisciplinarity and user participation, where the cooperation between occupational therapists (OTs), designers and engineers promotes innovations in orthosis development (Baleotti, Medola & Rodrigues 2018).

Occupational therapists are essential partners in working with designers, as they are specialists in biomechanical and functional analysis, as well as in the prescription and monitoring of orthoses (Ferrari, Medola & Baleotti 2020). In contrast, designers are trained in ideation, physical prototyping, and 3D modeling, skills needed to support the development of 3D-printed assistive products (Thorsen, Bortot & Caracciolo 2019). The combination of such expertise holds potential for significantly benefiting AT.

The traditional method of upper limb orthosis production, usually involving the occupational therapist directly molding a heated low-temperature thermoplastic plate in the user's arm (Howell 2019), often results in limited aesthetics, usability problems like limb heating and difficulty cleaning (Cazon et al. 2017; Chu et al. 2022).Consequently, assistive products suffer from high abandonment rates, due factors such as product aesthetics that trigger stigma, discomfort, safety and usability issues (de Couvreur & Goossens 2015; Shinohara & Wobbrock 2016; Grüschke et al. 2019; Houwen-van Opstal et al. 2020; Asghar et al. 2020; Santos et al. 2020), and upper limb orthoses are among the assistive devices with the highest levels of abandonment (Sugawara et al. 2018). These persistent problems in orthosis design and manufacturing call for systemic changes in the way these products are conceived and manufactured.

While 3D printing is increasingly common in orthoses manufacturing (Barrios-Muriel et al. 2020), enabling products with superior aesthetic qualities, ventilation and clinical

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performance (Mohammed & Fey 2018; Zheng et al., 2020; Reis et al. 2022), its workflow frequently requires 3D scanning of the limb to obtain users' anatomy (Keller et al. 2021). Thus, 3D scanning techniques in patients with established deformities or motor control limitations, as cerebral palsy (CP), creating a significant barrier to including this user group in the benefits of modern AT production.

Current alternatives to direct scanning for patients with motor impairment, such as using external support (Volonghi, Baronio & Signoroni 2018), supportive devices (Baronio et al. 2017; Zheng et al. 2020; Štefanovič et al. 2020) or scanning a plaster cast (Schmitz 2019) are restrictive. Those methods can hinder the acquisition of the complete anatomy or add extra time-consuming steps to the manufacturing process, limiting the efficiency promises of 3D technologies. Furthermore, while virtual position correction has been described (Asanovic, Millward & Lewis, 2018), the complexity of clinical scenarios and patient limitations confirm the need for a strategically designed methodological framework to truly democratize personalized AT.

The complexity of socio-technical challenges in personalizing orthotic devices demands a strategic intervention that transcends incremental product improvement. This paper proposes a Strategic Design Framework for the co-creation of personalized orthosis. Our approach aims not only to overcome the technical limitation of 3D scanning for users with complex motor limitations but, to establish an interdisciplinary co-creation model (designer and occupational therapist) that reconfigures the AT process itself. Central to this contribution is the virtual limb repositioning methodology, which functions as an intangible design artifact fot the decentralization of agency and user-centered personalization. The framework is, therefore, a proposal for systemic intervention, demonstrating how digital tools can facilitate co-design and extend the aesthetic and usability benefits of 3D-printed orthoses to prescription historically underserved user group. To validate the process in operational terms, we present a descriptive case study.

1. MATERIALS AND METHODS

The participant was a teenager clinically diagnosed with right hemiparetic CP. This 13-year-old male was assisted by the occupational therapy service at a school clinic linked to a public university in Brazil (anonymized to preserve the privacy of the participant). The participant was selected following inclusion criteria: Prescription of static ventral wrist and finger positioning orthosis.

The participant and his mother were informed about the objectives and procedures of the study and the confidentiality of their personal data and, subsequently, signed an informed consent form, confirming participation, according to the ethical guidelines of the authors' University (Ethics and Research Committee of the XXXXXX). The participant's right forearm was pronated leading to wrist flexion and slight ulnar deviation. This condition made it difficult to position the limb for scanning. This section presents a detailed procedure involving five steps of the proposed framework, highlighting the first three stages (Figure 1). The last two steps will be covered in the results section.

Figure 1. Personalized orthosis development process.

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Before the production of the new personalized orthosis, a short unstructured interview was conducted with the participant and his mother to assess their perceptions about the participant's conventional device: a ventral resting orthosis made of low-temperature thermoplastic plate, and established aesthetic preferences, addressed during the interview. This initial engagement was crucial for grounding the subsequent technical modeling in co-design principles and ensuring user agency, transforming aesthetic requirements into design guidelines: ventilation holes, the color of the device and the presence of the emblem of user's favorite football team enhancing device acceptance and combating systemic abandonment.

1.1 . Acquisition of 3D geometry of the limb

The 3D scanning was made with the participant seated on a chair with the right elbow resting on an adapted school table made with tubular steel structure, table-top with body fit and adjustable inclination and height to the ground. This position allowed the wrist and fingers to be relaxed and stable for geometry acquisition (Figure 2). A portable scanner, (Structure Sensor, Occipital, Boulder, CO, USA) with the free software Scanner Structure SDK (Occipital, Inc), was used for this procedure.

Figure 2. Participant's limb resting in a stable position.

A researcher started the scanning process moving around the participant's right upper limb, approximately one meter to the front, left, and right. The top and bottom planes were also scanned to obtain the ventral and dorsal parts of the hand, including the fingers and fingertips. The geometry of the forearm, hand, and finger anatomy was then exported as OBJ 3D file format for mesh processing, excess data removal, surface smoothing and noise removal (Figure 3).

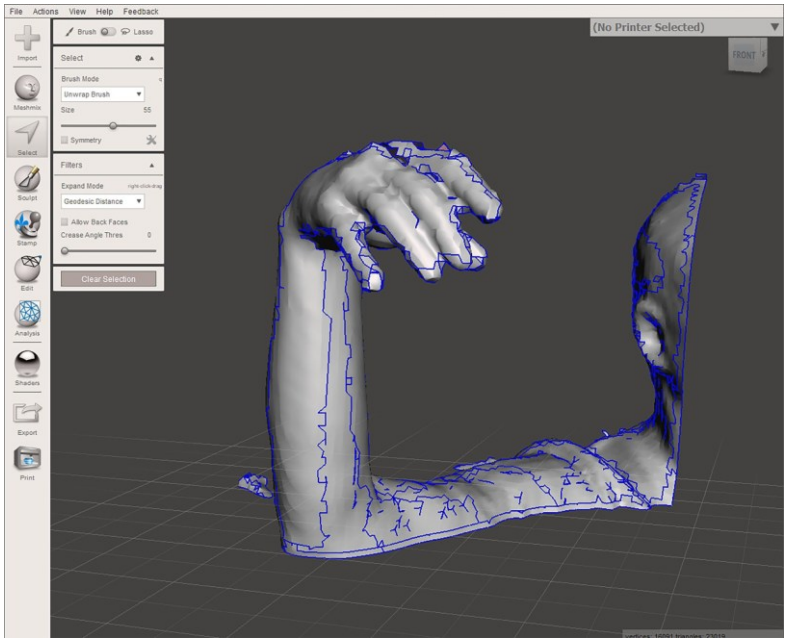

Figure 3. Raw mesh of the 3D model.

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1.2 . Preparation of the virtual mesh and limb repositioning

The raw triangular mesh was post processed with Autodesk Meshmixer (version 3.5.474. The process of repairing and cleaning the mesh was conducted manually. In Meshmixer, excess data that appeared in the obtained geometry of the arm, shoulder, and part of the participant's head was removed. The holes and noise resulting from the scanning process were repaired and cleaned and the surface was manually smoothed (Figure 4). The mesh was exported as STL 3D file format for limb repositioning.

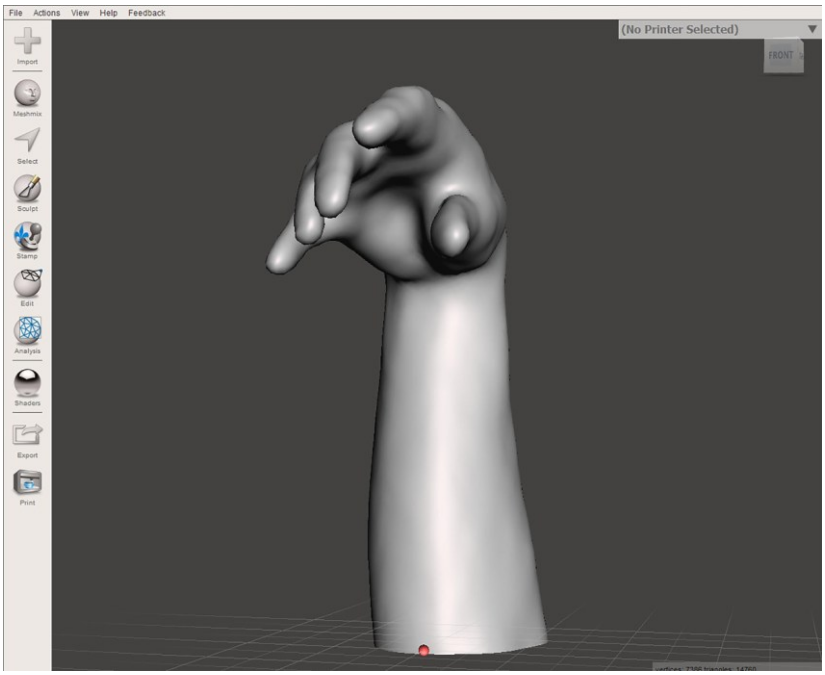

Figure 4. Limb mesh after the processing.

For the virtual repositioning of the limb, the open-source software Blender version 2.90.1 was used (https://www.blender.org/). The choice of open-source software facilitates the scalability of this framework in low-resource and clinical contexts, supporting its adoption as a systemic intervention model. The repositioning limb process can be summarized in five steps as presented in Figure 5.

Figure 5. Limb repositioning process.

We worked with a set of animation tools, namely rigging and armature. Rigging refers to the addition of rules and restrictions that help control the movements of an object. Armature includes several tools that produce virtual skeletons, helping in the repositioning and movement of the limb, with the creation of flexible joints.

The first step in repositioning the limb was the creation of a skeleton following the anatomy and pose of the scanned limb. For the fingers, the bones were built in the place of the phalanges and metacarpal bones of a human hand. For wrist movement, a single bone was created in the forearm, replacing the radio and ulna. A single bone connected to the forearm bone was built to represent the carpal bones and create the joint, allowing flexion, extension, adduction and abduction movements (Figure 6).

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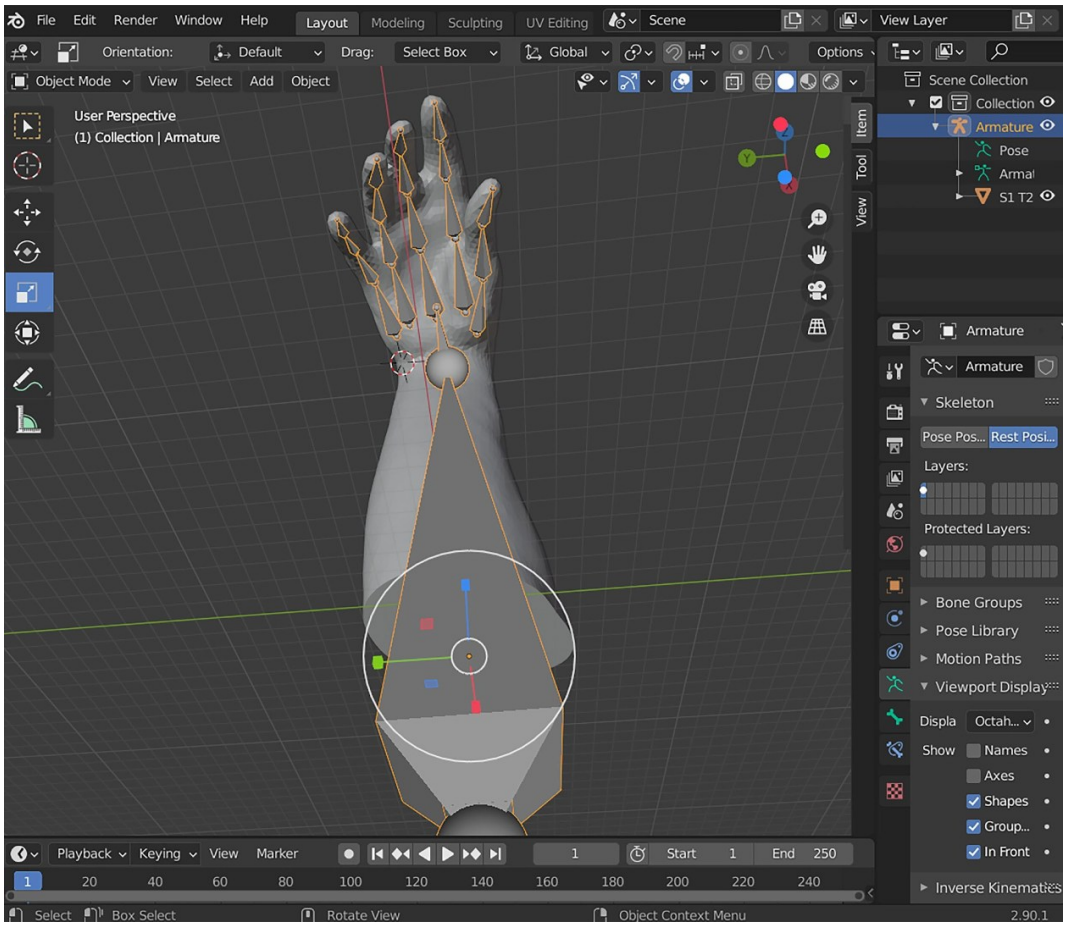

Figure 6. The mesh of the scanned limb with armature in Blender.

Relations in bone properties menu were established to control bones movements: (1) all the bones on each finger were connected to each other through the joints formed by the head of the bone with the tile of the subsequent bone; (2) all the metacarpal bones had a parent relation with the carpal bone to guarantee that fingers and metacarpal bones follow the movements of the wrist joint; (3) the carpal bone had a parent relation with the forearm bone.

To simulate the muscular movements that follow the pronation and supination of the wrist, three bones were built in the interior of the forearm bone, positioned aligned and parented to the forearm bone (Figure 7).

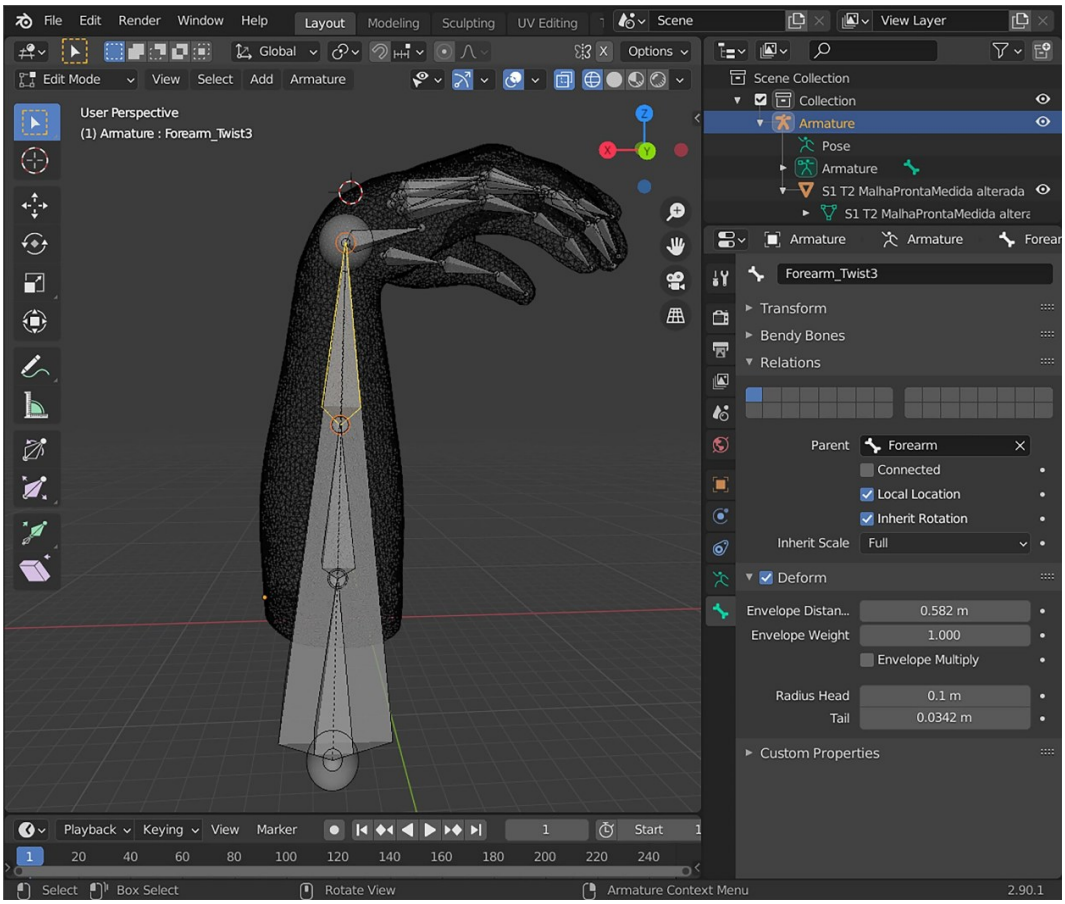

Figure 7. Parent relations menu of the twist arm system.

The next step was to establish a relation between the skeleton and the mesh of the limb. With both, armature and mesh selected, we applied another parent relation using the commands *armature deform* and *with automatic weight* at the *object menu*. This parent relation allows mesh deformation to follow the movements of the skeleton.

Next, movement configurations were adjusted in the software's *pose mode*. At the *bones constraint properties menu*, a copy rotation constraint was added for each interior forearm bones. Consequently, the mesh simulates the movement of the skin and muscles of the forearm, following the rotation of the wrist joint.

After establishing the movement configurations, we began the process of repositioning the limb. This procedure was made in the Blender *pose mode* and involved the designer and the occupational therapist to collaboratively validate the final functional pose. This co-creation step is a key strategic element of the framework, ensuring he translation of clinical expertise into the digital artefact and confirming the clinical fidelity of the orthosis prescription. The repositioning started with the extension of the wrist. The wrist joint, that was originally flexed, was extended at an angle of approximately 20°. In addition, the ulnar deviation of the wrist was reduced and adjusted to a functional position. Each finger was adjusted to increase the flexion of the proximal phalanges. The thumb was also adjusted, positioning the hand in the functional position suitable for grip movement and decreasing the extension of the distal phalanx and reducing the extension of the distal phalange (Figure 8). Repositioning the wrist, a deformity has formed on the back of the wrist. This deformity was manually smooth. With the mesh selected, the *smooth tool* was selected in the *sculpt mode*. Since the orthosis doesn't have contact with the dorse of the hand, this process does not interfere with the shape of the device. At the end of the repositioning process, the mesh of the repositioned limb was exported to STL format for personalized orthosis modeling.

Figure 8. Repositioned limb in Blender.

2. RESULTS

2.1 Personalized orthosis modeling

The new orthosis was imported and designed in Meshmixer. To assist the design of the orthosis, the repositioned mesh was modified again. The areas between the fingers were filled, thus making the resting surface for the fingers stable and secure. With the repositioned limb as a reference, a segment corresponding to the region that the orthosis should cover was selected (Figure 9).

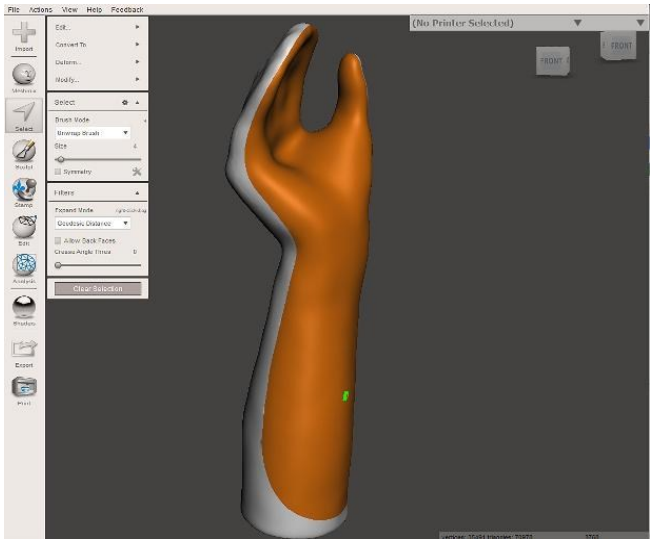

Figure 9. The selected segment covered by the orthosis is marked in orange.

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Ventilation holes were added to the new surface. We made another offset of 3.2 mm of the selected surface with the ventilation holes to create the thickness of the orthosis (Figure 10).

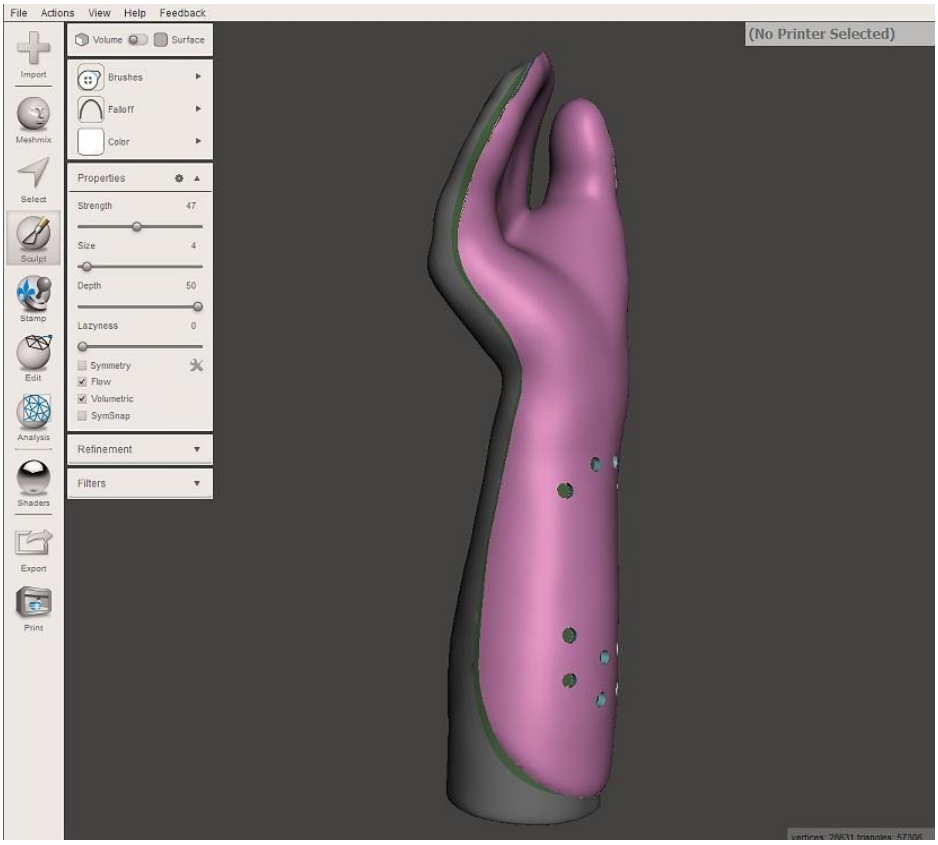

Figure 10. Offset test to provide thickness to the orthosis surface.

The surface and edges of the orthosis were smoothed for greater comfort. The last stage of the orthosis design was the modelling of the emblem of the user's favorite football team. The emblem was modelled in the external part of the orthosis, about the region of the forearm (Figure 11). These features (custom emblem and ventilation) represent the successful incorporation of user agency obtained during the co-creation phase. By transforming the orthosis into an expression of personal identity, the design addresses socio-technical issues related to device stigma and abandonment.

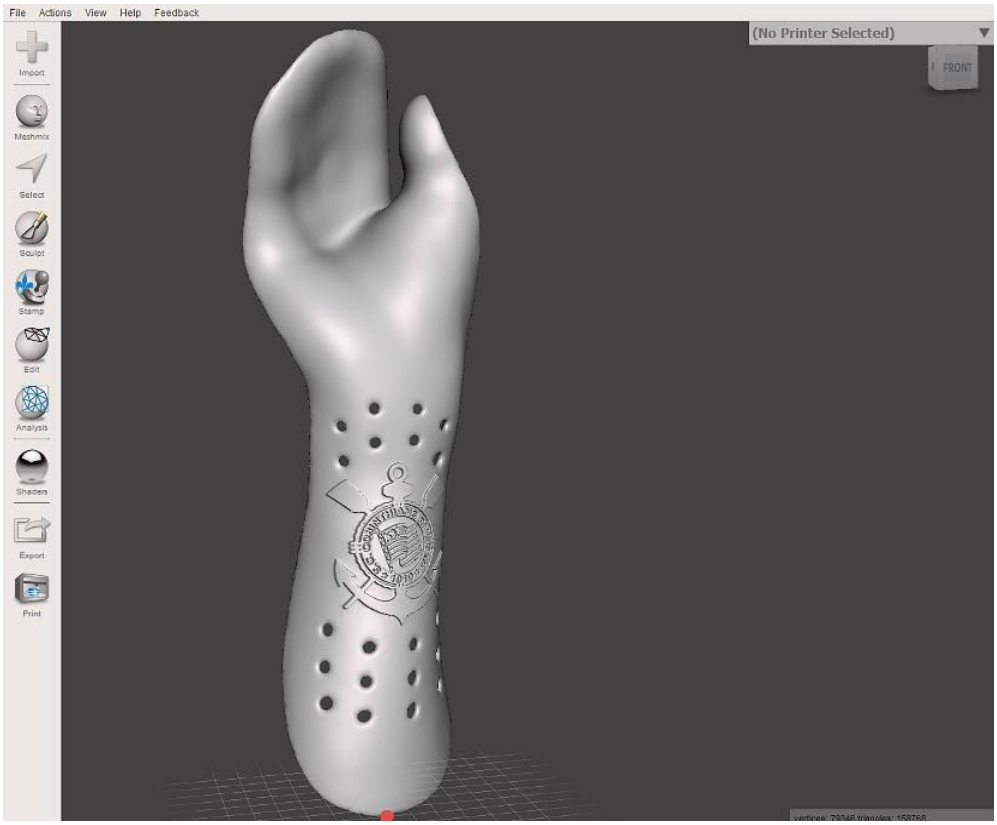

Figure 11. The personalized orthosis in Meshmixer software.

2.2 . 3D printing

The orthosis was printed by fused deposition modeling (FDM) process. Because of the need for support during the printing, we chose to print the orthosis in the vertically, with an inclination of 5 degrees, allowing a lower surface contact between the orthosis and the support. The supports were generated concentrated on the internal surface of the orthosis, which is covered by the user's hand (Figure 12). The excess material left by the supports should be removed after printing. This way, the sanded surface resulting from the removal of the supports would not be visible.

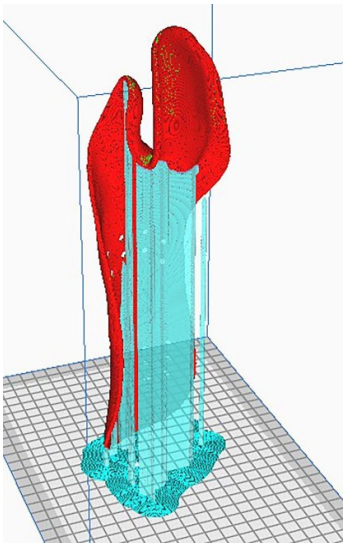
Figure 12. Printed orthosis position and supports in Cura software.

The orthosis was printed with a layer height of 0.2mm, with 3 shells and 20% of infill in an octet configuration. These configurations were chosen to guarantee a balance between printing time, amount of material, resistance and finishing of the orthosis. The 3D printer Builder Mega 2 (Mousta Impressoras 3D, Bauru, Brazil) was used to print the orthosis with

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polylactic acid (PLA) filament. In addition to its mechanical characteristics, the thermoformable properties of PLA provide flexibility, allowing or conventional post-printing clinical adjustments. This feature enhances the orthosis's resilience within the clinical service system, supporting the practical implementation of this Strategic Design Framework. After the first test with the user, we adjusted the ventilation holes by reducing their size to help the printing process and increased the number of holes. The process to print the final orthosis took approximately 10 hours and 30 minutes, with material consumption estimated at 146g (Figure 13).

Figure 13. Orthosis with supports (left) and orthosis finished without supports (right).

3. DISCUSSION

The acquisition of anthropometric data using 3D scanning during the orthoses development process is complex and depends on the patient's cooperation as well as the limb's condition in terms of posture, muscular tonus (hypotonia or spasticity) and deformities. Ideally, minimal mesh adjustments are preferred for anatomical fidelity (Palousek et al. 2014; Li & Tanaka, 2018a). However, this direct scanning approach is not feasible for users with musculoskeletal issues, such spasticity and contractures, who cannot maintain a stable, ideal position. Conventional alternatives, such as providing manual support (Asanovic, Millward & Lewis 2019) or support device (Baronio, Volonghi, & Signoroni 2017; Štefanovič et al. 2020) or scanning a plaster mold (Schmitz et al. 2019) add extra time and cost to the production process and are often restrictive in cases of variation in anatomy, as the method of scanning and mirror the unaffected limb (Lee et al. 2019), thus falling to address the systemic barrier of user compliance and the potential efficiency of 3D printing. The proposed framework presents an alternative by adopting 3D scanning of the limb followed by virtual repositioning, which is less physically demanding for the user and strategically focuses clinical expertise on the digital validation stage.

However, it is important to highlight that the development of orthosis for people with CP and other musculoskeletal disorders is complex and depends on an evaluation of each case. This procedure was possible thanks to the clinical characteristics of the participant in this study and the need for a static ventral wrist and finger positioning orthosis. The procedure is

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therefore a viable alternative for the production of orthoses in patients who can maintain the stability of the limb in a position that does not compromise the scanning of the surface with which the orthosis will be in direct contact.

The methodology of virtual limb repositioning, based on Blender's rigging and armature tools, constitutes an intangible design artifact in the context of Strategic Design (Caliskan & Wade, 2022). Unlike previous methods that required in vivo limb positioning (Asanovic, Millward & Lewis 2018), our approach allows for the digital manipulation of the anatomy. While greater freedom of movement can, theoretically, lead to distortions in anatomy, the methodology strategically leverages interdisciplinary co-creation, involving the designer's digital skills and the health professional's clinical expertise, to manage this risk. This shifts the focus from achieving anatomical fidelity at the time of scanning to ensuring clinical fidelity during virtual validation. By decoupling the physical compliance from the technical scanning process, the framework addresses a critical technical barrier and expands the accessibility of personalized 3D orthoses to complex clinical scenarios.

The success of the virtual repositioning process is intrinsically linked to interdisciplinary collaboration, which may be considered as a strategic imperative for socio-technical innovation (Torres, 2018). The designer manages the digital modeling tools, while the occupational therapist applies specialized clinical knowledge to validate the correct functional position of the virtual limb. This collaborative work establishes a co-creation model that is central to Systemic Design: it allows the service delivery process to be reconfigured (Tsai et al., 2023). By integrating specialized knowledge at the point of decision, the framework promotes systemic change by transforming the clinical service structure. This approach transcends merely improving a product; it designs the organizational capability, or the socio-technical assemblage, necessary to deliver highly personalized AT resilient to clinical complexity (Caliskan & Wade, 2022).

Beyond functional fit, the framework directly addresses the systemic problem of AT abandonment caused by stigma and poor aesthetics (Shinohara & Wobbrock 2016). The ability to incorporate user aesthetic preferences, such as the football team emblem and customized ventilation holes, transforms the orthosis from a purely functional object into an expression of personal identity (Ravneberg & Söderström 2017). This process of incorporating user agency into the design through co-creation is a core element of Strategic Design aimed at fostering social innovation and improving users' quality of life (Zhang, Ma & Wang, 2023). By facilitating this level of personalization for complex cases, the framework enables innovations to move from the clinical micro level to a sociotechnical regime that prioritizes human and environmental factors (Piaggio et al., 2021). The outcome is not just a better product, but an intervention in the social perception of the device, which is key to long-term adoption (Tsai et al., 2023).

Besides the rigging process, orthosis design for 3D printing also can be performed with different 3D modeling techniques and software, such as Rhinoceros (Li & Tanaka 2018b) and Autodesk Inventor (Górski et al. 2019). Regarding the implementation methodology, the choice of open-source software like Blender and Meshmixer makes this methodology more accessible and viable in low-budget contexts, supporting the scalability of this strategic innovation. The post-processing of the mesh can be performed using specific algorithms in CAD software or even available in some scanning software. In Meshmixer, the post-processing can be conducted using the software's inspector tool, an automatic tool for correcting the

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mesh, as performed by Fernandez-Vicente, Chust and Conejero (2017); or through visual inspection, in Olsen et al. (2021), and as performed here to maintain the originality of the scanned model as much as possible.

The choice of Polylactic Acid (PLA) for printing is consistent with current orthopedic contexts (Li et al, 2020; (Morimoto et al, 2021) and the production of orthosis and prosthesis through 3D printing, and provides the added strategic benefit of thermoformable properties, allowing for conventional post-printing clinical adjustments, thus increasing the orthosis's adaptability in the clinical setting (Piaggio et al., 2021). Methodological developments, such as applying joint movement restrictions in the armature, should be explored in future work to reduce potential anatomical distortions further.

The development of this framework must be contextualized within the domain of Assistive Technology (AT), which, unlike regulated medical devices, often has greater flexibility for rapid design and user-centered adaptation. While our methodology introduces a systemically innovative co-creation model, as a single-case study focused on a specific diagnosis, the findings primarily validate the concept of strategic and technical feasibility, demonstrating how a systemic barrier can be overcome, rather than providing generalizable clinical outcomes. Therefore, future work must focus on scaling the framework to larger, diverse user populations and formally evaluating its efficiency and user acceptance across various contexts to advance its impact from a niche innovation to a scalable, systemic solution in the broader AT provision ecosystem (Piaggio et al., 2021). This includes exploring how emerging how emerging Artificial Intelligence (AI) models could be integrated to streamline data acquisition and simplify co-design processes by automatically extracting key patient-specific parameters, accelerating the scaling of the framework, thereby fully realizing the strategic objectives of design-driven AT development.

4. CONCLUSIONS

This paper reported on the development of a Strategic Design Framework for the personalization of wrist orthosis using 3D technologies. The primary contribution of this work is the Strategic Design Framework itself, which establishes a viable interdisciplinary co-creation model, demonstrated in a descriptive case study, to overcome systemic barriers in the provision of AT. The core of this framework is the virtual limb repositioning methodology, which functions as the enabling artifact for personalized geometry acquisition in users with complex motor limitations, ensuring proper fit and correct therapeutic positioning.

By reconfiguring the AT development process, this methodology transcends a mere technical fix. It stands as a proposal for systemic intervention that utilizes an intangible design artifact (the virtual repositioning) to promote user agency and directly address the systemic issues of device abandonment and stigma. This approach exemplifies how Design can elevate an innovation from the niche level to a strategic solution for sociotechnical innovation. As a single-case study, the findings validate the strategic and technical feasibility of the proposed framework but do not offer generalizable clinical outcomes. Methodologically, the work advances Strategic Design research by providing a proven model for how intangible design artifacts (the virtual repositioning methodology) can be employed to reconfigure service delivery and foster socio-technical assemblages in the highly interdisciplinary Assistive Technology domain. Future research should prioritize scaling the framework to diverse user populations, focusing on its formal evaluation as a replicable systemic intervention model,

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moving the emphasis from product innovation to the design of resilient, user-centered service systems in healthcare.

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