

Clinical and user perspectives in 3D-printed distal radius fracture orthosis: innovating through iterative Design

Rorato, Eduardo Keller^{*1}; Ganga, Thabata Alcantara Ferreira²;
Tacza, Yeni Varillas³; Kunkel, Maria Elizete⁴

1 – Instituto de Ciência e Tecnologia, UNIFESP, ek.rorato@unifesp.br

2 – Instituto de Ciência e Tecnologia, UNIFESP, thabata.ganga@unifesp.br

3 – Instituto de Ciência e Tecnologia, UNIFESP, yeni.varillas@unifesp.br

4 – Instituto de Ciência e Tecnologia, UNIFESP, elizete.kunkel@unifesp.br

* - Correspondência: Rua Talim, 330, Vila Nair, São José dos Campos, São Paulo, Brasil, 12231-280.

DOI 10.52050/9788579177149-14

ABSTRACT

Distal radius fractures require tailored immobilization solutions to promote bone healing and restore function. This study aims to document an iterative, practice-based workflow for developing a custom 3D-printed orthosis guided by clinical and user feedback. Methodology included an initial hybrid thermoforming prototype, followed by 3D limb scanning, Blender-based modeling, and four cycles of additive manufacturing using PLA and ABS variants. Results demonstrated improved anatomical fit, enhanced breathability, and user comfort, with optimized shell thickness, refined ventilation patterns, and anatomically informed adjustments. These findings offer a replicable protocol for integrating advanced digital fabrication into clinical practice, education, and assistive technology development.

Keywords: 3D printing, distal radius fracture, orthosis design.

1. INTRODUCTION

Distal radius fracture is the most common fracture affecting the upper extremity (Kong et al., 2025). Effective treatment focuses on restoring anatomical alignment and joint stability, controlling pain, promoting functional recovery, and preventing complications to ensure optimal rehabilitation outcomes (Kuloor & Shareef, 2019). While plaster casts are traditionally used due to their cost-effectiveness, newer thermoplastic orthoses offer improved

comfort, hygiene, and usability without compromising clinical outcomes (Klopfer et al., 2023; D'Amado et al., 2024).

An orthosis is an externally applied device designed to support or restrict movement of a body segment following injury, deformity, or surgery. Thermoplastic orthoses, while offering advantages over plaster casts, often suffer from poor ventilation, localized discomfort, and technical challenges during fabrication (Bakshi et al., 2023).

The fabrication of traditional thermoplastic orthoses for the upper limb starts with the creation of a flexible template, drawn onto a sheet of paper or fabric with the patient's hand positioned on top. This template is cut out and briefly tested on the patient to check the fit. Once adjusted, the final template is traced onto a thermoplastic sheet, which is then cut, heated, and molded over the patient's limb to achieve the correct shape. This process requires skill and experience to ensure comfort and proper function, as each patient's anatomy and clinical needs may present unique challenges (Savoldelli et al., 2024).

The integration of new materials and advanced manufacturing technologies, particularly computer-aided design (CAD), computer-aided engineering (CAE), and computer-aided manufacturing (CAM), significantly enhances the design and production of customized orthoses (Tobler-Ammann et al., 2025). These technologies facilitate the creation of lighter, more comfortable, accessible and personalized orthotic devices, which can lead to improved user acceptance and continuous use (Alqahtani et al., 2020; Barrios-Muriel et al., 2020). Structured digital workflows, integrating 3D scanning and additive manufacturing, now enable the in-hospital production of highly customized, anatomically compliant orthoses (Buonamici et al., 2018; Guida et al., 2019).

High-resolution anatomical scans are used in CAD to create detailed 3D models, allowing for precise visualization and customization tailored to each patient (Sala & Richert, 2025). These digital models can then be functionally validated and stress-tested in virtual biomechanical simulations using CAE, ensuring optimal performance and durability. Once validated, CAM software converts the designs into precise tool paths, supporting efficient and reproducible fabrication through additive manufacturing technologies (Choubey, 2025).

Additive manufacturing, particularly Fused Deposition Modeling (FDM), has transformed orthosis fabrication by enabling fast, customized production of complex devices. FDM involves the layer-by-layer extrusion of various thermoplastics, selected according to their specific mechanical or thermal properties. For instance, polylactic acid (PLA) is known for rigidity and minimal deformation, acrylonitrile butadiene styrene (ABS) and polyethylene

terephthalate glycol (PETG) offer better impact resistance, and thermoplastic polyurethane (TPU) provides flexibility. Recent studies highlight how appropriate material choice and geometric design significantly influence the stiffness, flexibility, and comfort of orthoses, allowing tailored solutions for different neuromusculoskeletal conditions (Serrano et al., 2024).

Despite recent advances in digital fabrication and materials, integrating these technologies into routine clinical practice remains challenging, especially within the Brazilian healthcare system, where solutions must be accessible, efficient, and adaptable to local conditions. Motivated by a personal experience of sustaining a distal radius fracture, this work documents the iterative design and advanced manufacturing process of a custom orthosis, aiming not only at technical refinement but also at building essential expertise for future training programs, knowledge dissemination, and broader implementation of personalized orthotic solutions within the Brazilian public health system (SUS).

2. DEVELOPMENT

The development of the custom distal radius fracture orthosis was carried out in two major phases. Phase 1 established a hybrid workflow that combined traditional thermoforming with additive manufacturing to produce an initial functional prototype. Phase 2 transitioned to a fully digital process—beginning with 3D limb scanning and unfolding across four iterative design cycles of biomodel manipulation, orthosis sculpting, slicing, and FDM printing.

Phase 1 – Integrated Prototype: Additive Manufacturing Integrated with Traditional Thermoforming

The first prototype was developed collaboratively with an occupational therapist experienced in traditional thermoplastic orthoses. Key steps included manual template creation, limb fit testing, and digital modeling of the orthosis shape using Blender software (version 3.6 LTS). The orthosis featured a 2.5 mm wall thickness, small ventilation holes, Velcro strap slots, and an ouroboros aesthetic feature. It was fabricated in PLA using a Creality Ender 3 printer, with slicing performed in Ultimaker Cura. Post-printing adjustments involved gradual thermoforming directly onto the patient's limb, with continuous assessment by the occupational therapist to identify and document areas requiring refinement. Figure 1 illustrates the step-by-step process of the first prototype's development, from manual template creation to digital modeling, 3D printing, and thermoforming for clinical fitting.

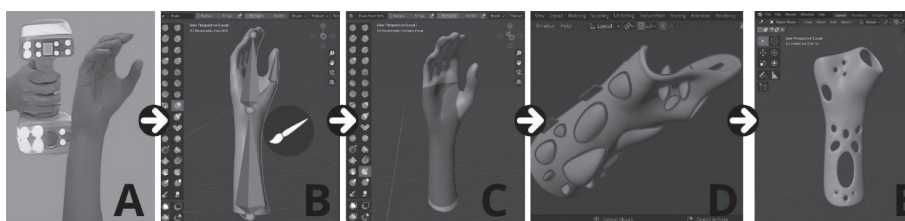
Figure 01 - Paper mold of the orthosis (A); 3D model in Blender (B); Orthosis during printing (C); Orthosis thermoforming (D).



Phase 2 – Transition to Fully Digital Workflow: 3D Scanning and Iterative Modeling

The transition to a fully digital workflow began with the acquisition of a high-resolution 3D scan of the affected limb using a Shining H2 scanner (Figure 2A). The resulting mesh was then imported into Blender (version 3.6 LTS), where it was manipulated and optimized for orthotic modeling (Figure 2B). In Blender's sculpt mode, a custom mask was outlined on the biomodel to define the orthosis coverage (Figure 2C); this outline was then used to generate the orthosis shell with offset and a uniform wall thickness. Ventilation holes were integrated into the design (Figure 2D), and the final 3D model was exported for fabrication (Figure 2E).

Figure 02 - 3D limb scanning with Shining H2 (A); Refined biomodel (B); Custom orthosis mask outline (C); Integrated ventilation holes (D); Orthosis model exported for fabrication (E).



The digital workflow was applied in four prototyping cycles, each using a 1 mm offset from the scanned biomodel. In the first iteration, a 3 mm shell was created with ventilation holes Boolean-cut directly into the orthosis mesh. The second iteration maintained the 3 mm thickness but moved hole placement into the mask outline before printing. In the third and fourth iterations, the biomodel underwent additional refinement, the shell thickness was raised to 4 mm, and the mask-based ventilation pattern was maintained.

Alongside these design refinements, each iteration also employed specific printer, material, and slicing software combinations (Table 1). The first digital prototype used ABS on a Creality CR200B with Ultimaker Cura. The second iteration printed carbon fiber– reinforced PLA (PLA–CF) on a Bambu Lab X1 Carbon using Bambu Studio. Both the third and fourth cycles returned to ABS on a Creality K1 Max, also sliced in Bambu Studio. In every cycle, printing parameters were initially set to the slicing software’s recommended presets and then fine-tuned as needed; these adjustments are detailed in the Results section.

Table 01 - Printer, material, and slicing software used in each Phase 2 prototyping cycle.

ITERATION	1	2	3 and 4
PRINTER	 CR200b	 X1C	 K1 Max
MATERIAL	ABS	PLA-CF	ABS
SLICER	Cura	Bambu Studio	Bambu Studio

3. RESULTS

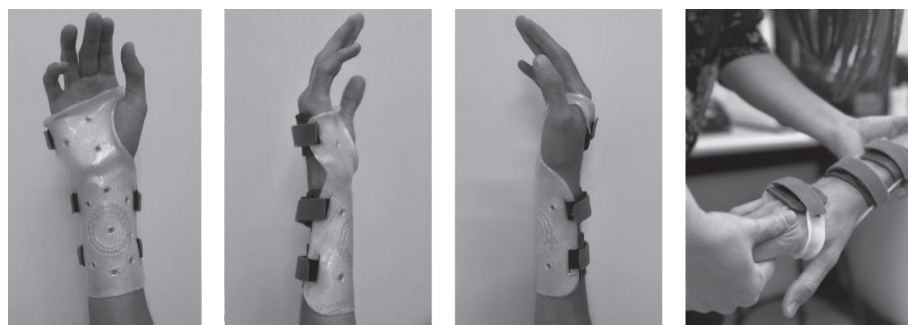
This section presents results related to the manufacturing process—covering material selection, printer limitations, and slicing strategies—followed by outcomes from each phase of iterative prototyping and design.

Phase 1 – Integrated Prototype: Additive Manufacturing Integrated with Traditional Thermoforming

Under the occupational therapist’s guidance, the final orthosis configuration positioned the wrist in slight ulnar deviation with three-point fixation (hand, wrist, and forearm) and incorporated palm support for optimal stability (Figure 3). Shaping the PLA device directly on the patient’s limb proved more demanding than conventional methods, necessitating multiple heat-and-fit cycles to achieve a satisfactory fit. After one week of wear, a targeted modification relieved

pressure over the bony prominence at the thumb base, further enhancing comfort.

Figure 03 - Phase 1 orthosis prototype.



PLA was selected for its well-established thermoforming properties, and the shell's 2.5 mm wall thickness replicated conventional thermoplastic sheets—ensuring both formability and structural integrity. Printing on the entry-level Creality Ender 3 revealed a limited build area that constrained the wrist-to-elbow span. Reducing the extrusion temperature to 180–190 °C—particularly when using older PLA spools—significantly improved surface quality.

Phase 2 – Transition to Fully Digital Workflow: 3D Scanning and Iterative Modeling

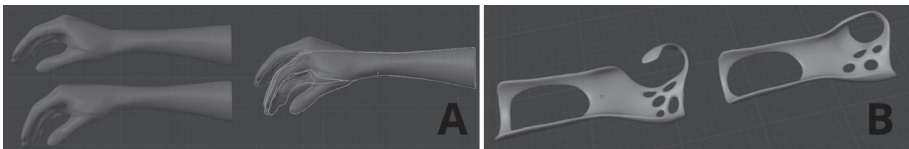
The first fully digital prototype introduced a thumb-wrapping design, smooth organic borders, and added padding over the wrist's bony prominence. It used off-the-shelf, auto-attachable Velcro straps inserted through Boolean-cut slots, but the Boolean modifier caused occasional mesh errors. Moreover, the excessive number and size of holes revealed minor structural weaknesses in the 3 mm shell. In the second iteration, those straps were bonded directly to the shell, allowing the lateral walls to be lowered for enhanced comfort and mobility. Ventilation holes were then outlined on the mask itself—streamlining the modeling process and optimizing breathability, surface aesthetics, and mechanical strength. Figure 4 presents the two first prototypes of Phase 2.

Figure 04 - Prototype 1 and 2 of Phase 2



Building on clinical feedback, advanced rigging techniques in Blender allowed precise anatomical adjustments to the biomodel. At an orthopedist's recommendation, the wrist was repositioned into increased dorsal extension (Figure 5A), beneficial for conditions like carpal tunnel syndrome and post-operative immobilization. Two final prototypes were then produced: one retaining the thumb-wrapping design for maximal stability, and the other reverting to the original thumb-free configuration from Phase 1 to maximize hand mobility (Figure 5B). Both configurations demonstrated improved palmar and lateral movement, and are being presented to orthopedic specialists for comparative validation, with the goal of identifying the optimal design for specific clinical scenarios.

Figure 05 - Anatomical rigging adjustment showing increased dorsal wrist extension (A); Comparison of the two final prototype configurations: thumb-wrapping design (right) and thumb-free design (left) (B).



Printing the first digital prototype on the Creality CR200B demanded angled orientation and substantial support structures due to its limited build area, resulting in increased material waste (Figure 6A). Consistent ABS prints were obtained by reducing the first-layer speed to 40 mm/s and adding a brim to enhance bed adhesion. The Bambu Lab X1 Carbon, using PLA-CF, produced rigid, matte-finished orthoses; print orientation was adjusted to minimize support usage, though at the expense of ideal mechanical strength (Figure 6B). Finally, the Creality K1 Max delivered both high print quality and cost-effectiveness. In this phase, the optimal orientation for mechanical strength was employed (Figure 6C), combined with a high support-interface density and a one-layer gap to ensure easy support removal and an excellent surface finish.

Figure 06 - Angled ABS print on Creality CR200B with extensive supports (A); Support oriented matte-finished PLA-CF prototype (B); ABS orthosis on Creality K1 Max using optimal orientation and high-density support interface (C).



4. DISCUSSION AND CONCLUSION

Addressing the challenges of implementing advanced fabrication in the Brazilian healthcare system—where accessibility, efficiency, and adaptability are paramount—this work documented a practice-based, iterative methodology for creating a custom 3D-printed orthosis for distal radius fractures. Inspired by the author’s personal injury experience, the study confirmed that combining hybrid thermoforming and fully digital workflows can yield patient-specific devices that meet clinical requirements and support local resource constraints.

Practically, the project established a streamlined protocol encompassing 3D limb scanning, Blender-based modeling, and FDM production; identified optimal shell thicknesses (3–4 mm) and ventilation strategies; and validated material-printer pairings that balance strength, aesthetics, and comfort. The resulting orthoses demonstrated improved fit, breathability, and user satisfaction compared to traditional methods, while reducing manual molding effort and patient discomfort.

Looking ahead, we recommend integrating finite element analysis to anticipate stress points, evaluating new biocompatible and sustainable materials, and conducting formal clinical trials—particularly to compare thumb-wrapping versus thumb-free configurations across diverse patient groups. These steps will support the development of training programs and knowledge-sharing initiatives, furthering the adoption of personalized orthotic solutions within the SUS and similar healthcare environments.

ACKNOWLEDGMENT

The authors gratefully acknowledge the support of the Secretária da Informação e Saúde Digital do Ministério da Saúde (SEIDIGI), the Programa de Educação pelo Trabalho para a Saúde – PET Saúde Digital, the Conselho Nacional

de Desenvolvimento Científico e Tecnológico (CNPq), and the Financiadora de Estudos e Projetos (FINEP) for their funding and technical assistance in this project.

REFERENCES

ALQAHTANI, Mohammed; ALQAHTANI, Mohammed; AL-TAMIMI, Abdulsalam Abdulaziz; AL-TAMIMI, Abdulsalam Abdulaziz; ALMEIDA, Henrique A.; COOPER, Glen; BARTOLO, Paulo Jorge da Silva. A review on the use of additive manufacturing to produce lower limb orthoses. v. 5, n. 2, p. 85–94, 2020. DOI: 10.1007/S40964-019-00104-7.

BAKSHI, Priya; CASTILLO, Daisy; MITCHENER, Heidi; LAGERHAUSEN, Zoe; PAISLEY, Lauren; QUINLIVAN, Amanda; ANDREA, Brandi. Thermoplastic material selection and barriers to custom orthotic fabrication: A survey of occupational and physical therapists. *The Open Journal of Occupational Therapy*, v. 11, n. 4, p. 1–13, 2023. DOI: 10.15453/2168-6408.2143.

BARRIOS-MURIEL, Jorge; ROMERO-SÁNCHEZ, Francisco; ALONSO-SÁNCHEZ, Francisco Javier; RODRÍGUEZ SALGADO, David. Advances in Orthotic and Prosthetic Manufacturing: A Technology Review. *Materials*, v. 13, n. 2, p. 295, 2020. DOI: 10.3390/MA13020295.

BUONAMICI, Francesco; FURFERI, Rocco; GOVERNI, Lapo; LAZZERI, Simone; MCGREEVY, Kathleen S.; SERVI, Michaela; EMILIANO, Talanti; UCCHEDDU, Maria Francesca; VOLPE, Yary. A CAD-based procedure for designing 3D printable arm-wrist-hand cast. *Computer-Aided Design and Applications*, v. 16, n. 1, p. 25–34, 2018. DOI: 10.14733/CADAPS.2019.25-34.

D'AMADO, Marcelo P.; ALBUQUERQUE, João Bourbon de; BEZOLD, Will A.; CRIST, Brett D.; COOK, James L. Biomechanical comparison of traditional plaster cast and 3D-printed orthosis for external coaptation of distal radius fractures. *Annals of 3D Printed Medicine*, v. 10, p. 100146, 2024. DOI: 10.1016/j.stlm.2024.100146.

GUIDA, P.; CASABURI, A.; BUSIELLO, T.; LAM BERTI, D.; SORRENTINO, A.; IUPPARELLO, L.; D'ALBORE, M.; COLELLA, F.; CLEMENTE, F. An alternative to plaster cast treatment in a pediatric trauma center using CAD/CAM technology to manufacture customized three-dimensional-printed orthoses in a totally hospital context: a feasibility study. *Journal of Pediatric Orthopaedics B*, v. 28, n. 3, p. 248–255, 2019. DOI: 10.1097/BPB.0000000000000589.

KONG, Mingdong; FANG, Christian; YUNG, Colin Shing-Yat; KWOK, Theresa; LEUNG, Keith Sai Kit; LEUNG, Frankie. Evaluation of using grip strength and hand muscle cross-sectional area to predict secondary fractures post distal radius fracture. *Archives of Osteoporosis*, v. 20, n. 1, p. 1–12, 2025. DOI: 10.1007/s11657-024-01465-5.

KLOPFER, Tim; HEMMANN, Philipp; RUPPRECHT, Verena; STUBY, Fabian; STÖCKLE, Ulrich; MEDER, Adrian. Outcome analysis of distal radius fracture with orthosis versus cast immobilization after palmar plate osteosynthesis: A randomized controlled study. *Journal of Personalized Medicine*, v. 13, n. 1, p. 130, 2023. DOI: 10.3390/jpm13010130.

KULOOR, Subraya Bhat; SHAREEF, Abdul Jameel. Distal radius fractures with unstable distal radioulnar joint treated by volar plate: a comparative study of immobilization versus early mobilization. *Journal of Orthopaedic Association of South India*, v. 16, n. 3, p. 45–50, 2019. DOI: 10.4103/JOAS.JOAS_6_19.

SAVOLDELLI, Veruschka; POZZI, Jaqueline; TREVELIN, Marília; OLIVEIRA, Rosana. Curso Mãos à Órtese. [híbrido], Santos (SP): Hamato Reabilitação, maio 2024. 20h.

SERRANO, Katherine Dayana Alberto; SILVA, Jorge Vicente Lopes da; LEIVA, Karla Miriam Reyes. Finite element analysis on solid ankle-foot orthosis with additive manufacturing materials. 2024. DOI: 10.1109/ehb64556.2024.10805597.