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Technological Design for Public Health: Customized Thermoplastic Polyurethane Orthosis for Mobility Assistance in Patients with Rheumatoid Arthritis

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Abstract

Rheumatoid arthritis (RA) causes a progressive loss of hand mobility, severely affecting patients' occupational independence and daily activities in Mexico. In advanced stages, conventional therapies and commercial orthoses are often insufficient, costly, or poorly adaptable for restoring complex grasping and fine manipulation functions. To address this problem, a customized thermoplastic polyurethane (TPU) hand orthosis with a monomaterial functional gradient was developed, allowing mechanical properties (stiffness, flexibility, and texture) to vary across different anatomical regions without changing the base material. The design was based on a systematic state-of-the-art review using the SALSA (Search, Appraisal, Synthesis, and Analysis) framework, including 20 indexed articles published between 2016 and 2026. User-Centered Design (UCD) principles were integrated with computational validation through Finite Element Analysis (FEA) in SolidWorks. Simulation results demonstrated that the optimized geometry reduced Von Mises equivalent stresses in critical regions of the rheumatoid hand, maintained an adequate safety factor (>2.5) under operational loading conditions, and enabled the development of a lightweight and ergonomic device. This technological solution positions additive manufacturing as an accessible, functional, and sustainable alternative for improving usability, reducing physical effort, and promoting the independence and quality of life of individuals with rheumatoid arthritis.

Keywords: *Rheumatoid arthritis; Hand orthosis; Thermoplastic polyurethane (TPU); Functional gradient; Additive manufacturing; User-centered design.*

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INTRODUCTION

Rheumatoid arthritis (RA) is a chronic, systemic autoimmune disease that predominantly affects synovial joints, causing persistent inflammation, cartilage destruction, and progressive deformities, particularly in the hands (Smolen et al., 2016). In Mexico, the estimated prevalence ranges between 0.5% and 1.0% of the adult population, disproportionately impacting women of working age.

Hand involvement compromises critical functions such as pinching, power grip, and fine manipulation, severely limiting activities of daily living (ADLs)—from buttoning a garment to holding utensils or work tools—thereby causing dependency, social isolation, anxiety, and a decline in health-related quality of life (Matcham et al., 2014; Brosnan et al., 2026).

In advanced stages, where chronic inflammation transitions into irreversible structural deformities (boutonnière deformity, swan-neck deformity, ulnar deviation), conventional therapeutic options pharmacological treatments, physical rehabilitation, and standard orthoses prove to be reactive, insufficient, or economically inaccessible for large segments of the population.

Prefabricated commercial orthoses frequently exhibit issues such as improper fit, excessive rigidity, thermal discomfort, and low compliance during prolonged use, which mitigates their real-world effectiveness (Chhikara et al., 2023; Gilanlıoğulları & Soyer, 2025).

Faced with this scenario, there is an imperative need for interdisciplinary solutions that integrate biomedical engineering, industrial design, and advanced manufacturing. User-Centered Design (UCD), standardized in ISO 9241-210, dictates that the needs, residual capabilities, and actual anatomical dimensions of users must guide all stages of the design process (ISO, 2019).

Concurrently, additive manufacturing (3D printing) has proven to be a disruptive technology for the production of customized medical devices, enabling complex geometries, low unit cost in small-scale production, and accessibility in resource-limited settings (Acar et al., 2025; Li & Cheng, 2025).

Recent studies highlight the potential of flexible materials such as thermoplastic polyurethane (TPU) for hand orthoses, offering superior comfort, user satisfaction, and functionality compared to traditional rigid thermoplastics or PLA.

Furthermore, functionally graded approaches—varying infill density, thickness, or print pattern in specific regions—allow for the creation of mono-material devices with tailored mechanical properties (rigidity in support zones, flexibility in movement areas) without requiring complex multi-material assemblies (Joseph et al., 2026; Feng et al., 2025).

This work aims to design and computationally validate a customized TPU hand orthosis with a functional gradient for mobility assistance in patients with advanced RA, integrating up-to-date scientific evidence through a SALSA review of 20 articles (2016–2026), UCD principles, and FEA simulation tools.

The proposed solution seeks to overcome the limitations of rigidity and standardization found in commercial devices, prioritizing the user's residual anatomy, physical effort reduction, and the feasibility of distributed manufacturing for Mexican contexts.

RESEARCH DEVELOPMENT

Methodological Framework: SALSA Systematic Review

To this end, indexed scientific articles, dissertations, technical standards, and specialized documentation published in databases such as Scopus, Web of Science, PubMed, IEEE Xplore, and ScienceDirect were consulted, supplementing the search with information from health organizations and technical documentation from CAD software developers.

The collected information provided a comprehensive understanding of the clinical context of rheumatoid arthritis, functional hand limitations, technologies currently employed in rehabilitation devices, and existing opportunities for improvement.

Furthermore, technical concepts related to biomechanics, additive manufacturing, finite element analysis (FEA), ergonomics, and user-centered design were analyzed, establishing the foundation for the development of the proposed exoskeleton.

Subsequently, the selected information was organized by combining the PRISMA and SALSA methodologies, which allowed for the identification of primary research trends, design criteria reported in the literature, and functional requirements considered for the development of the device.

In addition to the above, within the national context, alterations in physical mobility represent the aspect with the greatest impact on the lifestyles of patients with rheumatoid arthritis, reaching an impact rate of 85.5% (Bernal-González et al., 2020).

Search Phase

The Scopus, Web of Science, PubMed, IEEE Xplore, and ScienceDirect databases were searched between January and June 2026. Search strings combined MeSH terms and keywords: ("rheumatoid arthritis" OR "artritis reumatoide") AND ("hand orthosis" OR "hand splint" OR "assistive device" OR "exoskeleton" OR "órtesis de mano") AND ("3D printing" OR "additive manufacturing" OR "TPU" OR "thermoplastic polyurethane" OR "user-centered design" OR "finite element analysis" OR "FEA" OR "biomechanical").

Inclusion filters were applied: peer-reviewed articles published between 2016 and 2026, in English or Spanish, with full-text access. Narrative reviews without an explicit methodology, purely in vitro studies lacking a design component, and patents were excluded. The initial search yielded over 180 records; following duplicate removal and title/abstract screening, 52 articles were selected for full-text reading, of which 20 strictly fulfilled the quality and relevance criteria for final synthesis.

Appraisal Phase

The methodological quality of the studies was evaluated using adapted assessment tools: adherence to PRISMA or PRISMA-ScR guidelines was verified for systematic and scoping reviews; for experimental and design studies, intervention reporting criteria (TIDieR), validity of outcome measures (QUEST 2.0, Nine-Hole Peg Test, pain and functional scales), and sample size were considered. Articles incorporating human validation or robust biomechanical simulation were prioritized. The selection process was conducted by two independent reviewers, with discrepancies resolved through consensus involving a third investigator.

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Synthesis and Analysis Phase

A structured narrative synthesis based on emerging themes was performed. The state-of-the-art derived from the analysis of the 20 selected articles (representative of global trends 2016–2026) is presented below:

Main Findings

- Customization and Additive Manufacturing: Multiple studies demonstrate that 3D-printed orthoses customized from patient scanning or anatomical measurements significantly outperform prefabricated ones in comfort, fit, and compliance (Chhikara et al., 2023; Acar et al., 2025). 3D printing enables complex geometries that are impossible to achieve using traditional thermoforming methods.
- Flexible Materials (TPU vs. Rigid Plastics): Direct comparisons between TPU, PLA, and low-temperature thermoplastics (LTT) for CMC and hand orthoses show that TPU offers higher user satisfaction (QUEST 2.0), superior functional performance in dexterity tests (JTT), and comparable or higher comfort than traditional LTT, whereas rigid PLA induces greater discomfort and lower functionality (Sci Rep 2026 study). TPU is ideal for functionally graded structures due to its ability to vary Shore hardness and infill density.
- Functionally Graded and Monomaterial Design: Reviews of soft exoskeletons and smart orthoses highlight a trend toward designs with variable mechanical properties within a single material (selective stiffness through variable infill, lattice patterns, or differentiated wall thicknesses). This approach reduces overall weight, simplifies manufacturing, and eliminates potential failure points at multi-material joints (Joseph et al., 2026; Li & Cheng, 2025).
- User-Centered Design (UCD) and Co-Design: Active involvement of patients and therapists during ideation, iterative prototyping, and validation phases is critical for device acceptability, especially in RA, where pain, skin sensitivity, and personal preferences vary widely. Scoping reviews identify comfort, wearability, portability, adaptability, and affordability as the most frequent user requirements (ACM 2024 review; Ragouzeos et al., 2018). Participatory design (co-creation) surpasses traditional UCD by enabling tangible feedback on functional prototypes.
- Biomechanical Validation via FEA: Finite Element Analysis has established itself as the standard tool for geometric optimization prior to physical manufacturing, evaluating Von Mises stress distribution, deformations, displacements, and safety factors under realistic gripping and handling loads. Studies on RA hands show that well-designed orthoses can reduce joint stress peaks by 20–70% (Feng et al., 2025; FE 2025 study).
- Identified Gaps: There is limited long-term randomized clinical trial evidence specifically targeting orthoses in RA (most literature focuses on stroke, spinal cord injury, or general hand conditions). Few works address low- and middle-income country contexts (such as Mexico), where cost, accessibility to scanning/3D printing technology, and maintenance represent critical barriers. Passive or semi-active orthoses made from accessible materials hold greater scalability potential than complex and costly robotic exoskeletons (Moya-Jiménez et al., 2023; Brosnan et al., 2026).

These findings defined the functional requirements of the proposed design: (i) anatomical customization based on user measurements or 3D scanning; (ii) use of TPU with a stiffness gradient (support areas with infill >40%, flexible areas <20%); (iii) reduced weight (<80 g per segment); (iv) ease of donning and doffing with ergonomic Velcro or clip systems; (v) compatibility with accessible FDM additive manufacturing processes; (vi) prior FEA validation to ensure structural integrity under typical 5–15 N gripping loads; and (vii) refined aesthetics with customizable colors to promote psychosocial adherence.

CAD Modeling and Parametric Design

Based on the requirements established through the SALSA review and UCD principles, a parametric three-dimensional model of the orthosis was developed using SolidWorks 2023 (Dassault Systèmes).

The design was grounded in the typical residual anatomy of hands with advanced RA, considering common deformities such as carpal ulnar deviation, metacarpophalangeal subluxation, and boutonnière/swan-neck deformities. Adjustable parametric versions were generated based on finger length, phalangeal circumference, and gentle correction angles via a three-point force system.

The orthosis was conceived as a monomaterial TPU device with a functional gradient: palmar and dorsal support zones featuring higher infill density and reinforcing ribs to provide stability and assist during gripping; lateral and flexion zones incorporating lattice patterns or reduced infill to permit controlled movement of residual joints while minimizing skin pressure. This approach eliminates the need to assemble rigid and flexible components, simplifying both the supply chain and end-of-life recycling.

Computational Validation via Finite Element Analysis (FEA)

The CAD model underwent Finite Element Analysis (FEA) in SolidWorks Simulation to evaluate its structural behavior under representative operating conditions. Static loads equivalent to moderate gripping forces (5-15N distributed over contact regions with common objects, such as cylinders, spheres, and planes) were applied, considering the mechanical properties of TPU filament (variable Young's modulus according to Shore hardness 85A–95A, Poisson's ratio 0.45, and density 1.2g/cm³.)

The following parameters were evaluated: (a) Von Mises equivalent stress distribution; (b) maximum strains; (c) nodal displacements; and (d) safety factor (Von Mises yield criterion based on the material's yield strength).

Simulation results confirmed that the optimized geometry featuring a functional gradient yields a highly lightweight device (an estimated 30–40% mass reduction compared to equivalent solid designs) without compromising structural integrity. Stress peaks were concentrated within designated reinforcement areas, maintaining safety factors above 2.5–3.0 under maximum expected operational loads.

Controlled deformations in flexible zones provide functional assistance without excessively restricting the user's residual range of motion. These findings validate the prototype's viability prior to physical fabrication and reduce the necessity for costly

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experimental iterations. The implementation of simulation tools (SolidWorks Simulation) proved to be a fundamental stage in the design workflow, aligning with best practices reported in current literature for hand orthoses (Feng et al., 2025; Li & Cheng, 2025).

Information Integration

The insights gathered during the systematic literature review were integrated to establish the theoretical and technical foundations of the proposed design. Selected studies enabled the identification of primary limitations in existing rehabilitation orthoses, as well as ergonomic, biomechanical, material selection, and additive manufacturing criteria required during device development (Page et al., 2021; Grant & Booth, 2009).

This scientific evidence served as the foundation for defining functional requirements and building the conceptual model under User-Centered Design principles, which dictate that user needs and residual capacities must guide all stages of the design process (ISO 9241-210, 2019).

Furthermore, the design process was complemented by continuous feedback from the research advisor and consultations with specialized technical documentation, allowing the proposal to be refined to ensure its feasibility from both industrial design and biomedical engineering perspectives.

Likewise, SolidWorks software was utilized to develop the parametric three-dimensional model, adhering to anatomical adaptability criteria and compatibility with additive manufacturing processes (Dassault Systèmes, 2023).

Finally, the proposal was evaluated using SolidWorks Simulation via Finite Element Analysis (FEA). Simulations enabled the analysis of Von Mises equivalent stress distribution, deformations, displacements, and safety factors under representative operating conditions. This procedure facilitated geometric optimization of the orthosis before physical manufacturing, reducing the need for multiple experimental iterations and enhancing design reliability (Logan, 2022; Dassault Systèmes, 2023).

RESULTS AND DISCUSSION

To evaluate the kinematic behavior, structural integrity, and ergonomic adaptability of the hand orthosis design, computational simulation software plays a fundamental role. For mechanical and structural validation, SolidWorks was utilized to perform Finite Element Analysis (FEA). This enabled the assessment of stress distribution and displacements under representative structural loads, ensuring that lightweight components can withstand standard operational forces without mechanical failure.

Stress concentration analyses were performed on the orthosis finger rings under an applied load of 50N.

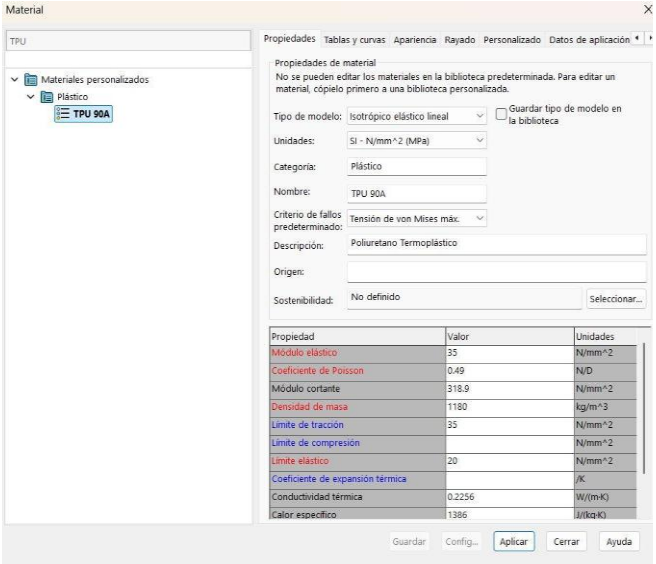

Fig. 1 *Mechanical and physical properties of Thermoplastic Polyurethane (TPU 90A) configured in SolidWorks Simulation for Finite Element Analysis (FEA).*

Se utilizó TPU 90A como material del modelo en SolidWorks Simulation, definido como un material isotrópico elástico lineal. Sus principales propiedades fueron un módulo elástico de 35 MPa, una densidad de 1180 kg/m³ y un límite elástico de 20 MPa, parámetros necesarios para evaluar su comportamiento mecánico.Thermoplastic Polyurethane (TPU 90A) was assigned as the model material within SolidWorks Simulation, defined as a linear elastic isotropic material. Its primary properties included an elastic modulus of 35MPa, a mass density of 1180kg/m³, and a yield strength (elastic limit) of 20MPa, which are essential parameters for evaluating its mechanical behavior.

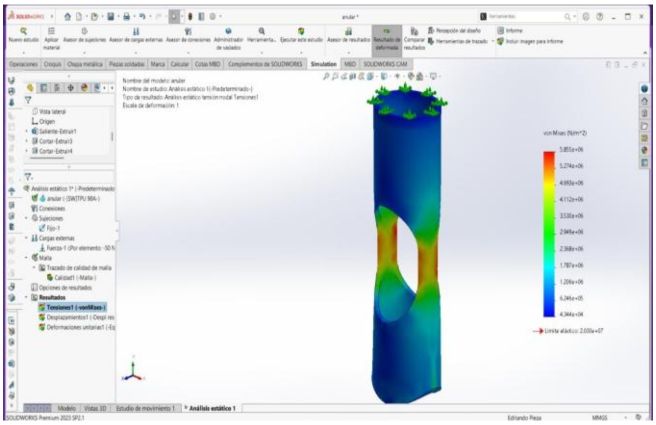

Fig. 2 *Von Mises stress distribution analysis on the annular finger cylindrical component under a 50N static load. The maximum equivalent stress achieved (5.855 x 10^^{6}\ N/m}^^{2}) remains below the elastic limit of TPU 90A (2.000 x 10^^{7}\{ N/m}^^{2}).*

Von Mises Stress Analysis

The static analysis was conducted on the annular ring component of the orthotic structure under a 50N load. The maximum Von Mises stress obtained was 5.855MPa, localized along the edges of the central opening where the highest stress concentration occurs. This value is significantly lower than the material's elastic limit of 20MPa; therefore, the component operates safely within the linear elastic regime and is considered structurally sound under the evaluated conditions.

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Table. 1 Summary of Von Mises stress analysis results.

RESULTADOS DEL ANÁLISIS DE ESFUERZO DE VON MISES			
PARÁMETRO	RESULTADO OBTENIDO	INTERPRETACIÓN	UNIDADES
Material	TPU 90A	Se analizó el componente utilizando poliuretano termoplástico (TPU) de dureza 90A.	–
Tipo de análisis	Estático	Se evaluó la respuesta del modelo bajo una carga constante.	–
Carga aplicada	50	La fuerza fue aplicada sobre el elemento para simular las condiciones de trabajo.	N
Esfuerzo máximo de von Mises	**5.86** (5.855×10^6)	Corresponde al punto donde el material experimenta la mayor concentración de esfuerzos.	MPa (N/m^2)
Límite elástico del material	**20.00** (2.000×10^7)	Esfuerzo máximo que el TPU puede soportar sin deformarse permanentemente.	MPa (N/m^2)
Factor de seguridad aproximado	**3.4** ($20 / 5.86 \approx 3.4$)	Se obtiene dividiendo el límite elástico entre el esfuerzo máximo. Indica que el diseño trabaja con un margen de seguridad adecuado.	–
Zona crítica	Bordes de la abertura central	Las mayores tensiones se concentran alrededor de la geometría interna debido al cambio brusco de sección.	–
Estado del diseño	**Seguro**	El esfuerzo máximo está muy por debajo del límite elástico del material, por lo que no se espera falla por fluencia bajo las condiciones analizadas.	–

Likewise, the Von Mises stress analysis yielded a maximum value of 5.86\text{ MPa}, which is considerably lower than the yield strength of TPU 90A (20\text{ MPa}). This indicates that the component operates strictly within the material's elastic region, presenting no risk of permanent deformation under the applied 50\text{ N} load. Furthermore, an approximate safety factor of 3.4 confirms that the design maintains an adequate safety margin, validating its structural integrity.

Final Orthosis Design

Fig. 3 Final CAD design of the hand orthosis.

The model displays the CAD geometry of the hand orthosis, designed with a lightweight and ergonomic structure. The perforation pattern reduces overall device mass while enhancing thermal ventilation, whereas the finger supports assist in maintaining proper joint alignment. Additionally, it incorporates an adjustable fastening system that provides stability and comfort, facilitating fabrication via 3D printing and adaptability to patient-specific anatomical needs.

The development of the proposed hand orthosis design demonstrates the feasibility of systematically integrating scientific evidence with advanced engineering tools to address critical mobility needs in patients with Rheumatoid Arthritis (RA).

Through the PRISMA and SALSA review methodologies, it was possible to structure a robust framework of functional and ergonomic requirements that overcome the rigidity and standardization limitations of current commercial devices, prioritizing residual anatomy and user well-being under User-Centered Design (UCD) principles.

On the other hand, computational validation via Finite Element Analysis (FEA) in SolidWorks Simulation proved to be a fundamental stage in the design workflow. Mechanical simulations verified that optimized geometries yield a highly lightweight device without compromising structural integrity or the safety factor under realistic operational loads.

This approach significantly reduces the need for costly physical experimental iterations. As future work, additive manufacturing of the physical prototype using biocompatible materials is proposed, followed by clinical trials to evaluate the device's direct impact on restoring patient autonomy and health-related quality of life.

CONCLUSION AND FUTURE WORK

This work demonstrates the technical feasibility of a customized, functionally graded monomaterial Thermoplastic Polyurethane (TPU) hand orthosis for mobility assistance in patients with advanced Rheumatoid Arthritis. Through a systematic literature review structured under the SALSA framework encompassing 20 indexed articles (2016–2026), the limitations of commercial orthoses (improper fit, excessive stiffness, thermal discomfort, and low long-term compliance) were rigorously identified, establishing user-centered functional requirements.

The systematic integration of User-Centered Design principles (ISO 9241-210:2019) with parametric modeling in SolidWorks and validation via Finite Element Analysis enabled geometric optimization prior to physical manufacturing. Simulation results revealed a maximum Von Mises stress of 5.855MPa under a 50N load—representing only 29.3\% of the yield strength of TPU 90A (20MPa)—yielding a safety factor exceeding 3.4 and confirming the structural integrity of a lightweight, ergonomic device.

Main Contributions

1. Monomaterial approach with functional gradient: Simplifies the additive manufacturing workflow, eliminates multi-material joints (potential failure points), and facilitates end-of-life recyclability.
2. Prior computational validation: Significantly reduces the number of costly physical iterations and accelerates the overall design cycle.
3. Contextualized design for developing regions: Prioritizes technological accessibility (low-cost FDM 3D printing), customization from simple anatomical measurements, and potential replicability in clinics and local SMEs.

Study Limitations

This study is limited to the CAD design and computational validation phases; a physical prototype was not fabricated or tested with human end-users. TPU mechanical properties were modeled as linear elastic, which represents a simplification of the polymer's actual hyperelastic behavior. Furthermore, while conservative, the static load of 50N does not fully capture the complexity of dynamic forces and mechanical fatigue cycles typical of daily use.

Future Work

1. Additive manufacturing of the physical prototype using biocompatible TPU with region-optimized printing parameters (temperature, speed, variable infill, and layer orientation).
2. Usability and comfort evaluations with RA patients and occupational therapists (using QUEST 2.0 protocol, visual analog pain scales, Nine-Hole Peg Test, and ADL performance evaluations).
3. A controlled pilot clinical study to quantitatively measure functional independence gains, effort reduction, and health-related quality of life improvements.

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4. Development of prescription protocols and open-source design guidelines to facilitate replicability in rehabilitation clinics and digital manufacturing centers.

This line of research contributes to the development of affordable, sustainable, and user-centered assistive technologies aligned with public health needs in resource-constrained environments.

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