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Pressure simulation and comfort prediction of the interface between the receiving cavity and the residual limb of 3D printed prostheses based on digital twins

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Abstract:

This study presents an integrated digital twin framework for simulating interface pressure distribution and predicting wearing comfort in 3D-printed prosthetic sockets. The methodology begins with acquiring the residual limb's geometric data through high-precision 3D scanning, followed by establishing a nonlinear hyperelastic material model to represent the mechanical behavior of soft tissues. The CAD model of the personalized socket is then assembled, and the prosthetic donning process is simulated using finite element analysis to compute stress/strain distributions within the residual limb. To enhance predictive accuracy, experimental validation is conducted using a thin-film pressure sensor array that measures actual interface pressure at key anatomical locations during static loading. These measurements are systematically compared with simulation results for model calibration. Subsequently, regression models are developed to establish quantitative relationships between pressure distribution metrics derived from simulations and subjective comfort scores obtained from clinical evaluations. The research demonstrates a closed-loop "simulation-measurement" approach that integrates digital twin technology into the prosthetic design process. This methodology enables reliable comfort prediction for new socket designs while significantly reducing dependence on physical fitting trials. The validated framework offers substantial potential for improving both the design efficiency of prosthetic sockets and the overall wearing comfort for amputees, representing an important advancement toward digitalized and personalized prosthetic rehabilitation solutions.

Keywords: Digital Twin; 3D-Printed Prosthesis; Socket-Residual Limb Interface; Pressure Simulation; Comfort Prediction.

1. Introduction

The global population of lower limb amputees continues to grow, with transtibial amputation accounting for the majority of cases. The prosthetic socket, serving as the critical interface between the residual limb and the prosthesis, directly determines the patient's rehabilitation outcome and quality of life. However, traditional socket fabrication methods relying on plaster casting and manual techniques are heavily dependent on prosthetist experience, characterized by long cycles, high costs, and difficulties in achieving precise personalization. This leads to low initial fitting success rates in clinical practice, with patients often experiencing discomfort and low prosthesis usage due to uneven interface pressure distribution, severely impacting rehabilitation effectiveness. There is an urgent need for novel technological approaches to enhance the accuracy and efficiency of prosthetic fitting.

The biomechanical properties of the socket-residual limb interface are central to wearing comfort. Soft tissues exhibit complex nonlinear viscoelasticity, making it difficult for traditional methods to accurately quantify interface pressure distribution. Therefore, developing accurate biomechanical models for quantitative pressure prediction is essential for improving socket design quality.

Digital Twin technology offers an innovative solution by creating high-fidelity virtual models of physical entities. This technology can integrate multi-source heterogeneous data to construct virtual models encompassing geometry, materials, and boundary conditions, enabling real-time mapping and simulation of physical systems. Its introduction into socket design holds potential to replace traditional trial-and-error approaches by predicting interfacial biomechanical behavior through virtual simulation, thereby driving the digital and intelligent transformation of the design process, with significant academic value and clinical application potential.

Traditional socket fabrication suffers from inconsistent precision, inadequate personalization, and low efficiency. While digital technologies like 3D printing offer new avenues, studies indicate persistent limitations. Li Peipei noted that traditional design lacks sufficient digital modeling capability for accurate mechanical analysis[1]. Tang Lei et al. highlighted the disconnect between morphological design and performance optimization in traditional methods, contributing to poor comfort[2].

Accurate interface pressure measurement is crucial for socket optimization. Traditional sensor-based measurements face limitations in spatial resolution and stability. Finite Element Analysis has emerged as a key research focus, enabling pressure distribution prediction during the design phase. Wang Xiaohui et al. constructed an accurate FE model of the socket-limb system, validating its effectiveness and providing a foundation for digital design[3]. Hu Hangfan's work on AFOs using FEA and 3D printing, though focused on orthoses, offers valuable insights for socket design and manufacturing[4].

Digital Twin technology is gaining attention in prosthetic design. Xu Zhecheng et al. demonstrated that digital technology enhances design precision and personalization while opening new pathways for comfort assessment[5]. However, traditional comfort prediction relies on subjective judgment, lacking objective metrics. Although simulation and data-driven models are becoming focal points, technical challenges remain in effectively integrating digital twins with comfort prediction for accurate, personalized design.

Current studies often focus on isolated technologies. For instance, Li Dongsheng et al. explored 3D printing in medical devices without fully considering the biomechanical environment[6]. Ning Tianliang focused on structural optimization but lacked predictive capability for dynamic pressure and comfort[7]. Si Yanfang et al. failed to construct a comprehensive digital simulation system[8]. There is a lack of a systematic methodology deeply integrating digital twins with 3D printing, preventing accurate interface pressure prediction and quantitative comfort assessment.

Research shows constraints in material selection and process innovation. Lu Yiting's work on metal-resin structures focused on industrial applications, overlooking biocompatibility and comfort[9]. Liu Tengda et al. enhanced structural strength but faced challenges in optimizing interface pressure and comfort[10]. Wang Yan et al. emphasized material-tissue matching but lacked digital twin-based performance prediction methods[11]. These studies show process innovation but fail to establish a digital mapping between materials, processes, and performance.

Significant shortcomings exist in personalized design and comfort assessment. Zhao Dezhu proposed a digital design concept but lacked deep dynamic biomechanical modeling[12]. Hu Hangfan et al. emphasized customization but noted that most methods rely on static modeling, unable to predict dynamic pressure changes. Traditional comfort assessment is inefficient and subjective, unable to optimize performance during design, often requiring multiple prototyping cycles.

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2. Construction and Simulation Analysis of the Socket-Residual Limb Digital Twin Model

2.1 Digital Twin Framework Design and Data Acquisition

2.1.1 Overall Architecture Design of the Socket-Residual Limb System Digital Twin

The overall architecture of the socket-residual limb system digital twin is designed with a layered, progressive philosophy to establish a bidirectional mapping relationship between the physical and virtual spaces. Its foundation is the data acquisition layer, equipped with 3D scanning devices, thin-film pressure sensor arrays, and medical imaging systems, capable of comprehensively obtaining residual limb geometry, interface pressure distribution, and soft tissue characteristics. The middle layer is the data processing and modeling layer, which integrates and processes the collected multi-source heterogeneous data to construct a nonlinear hyperelastic material model for the residual limb soft tissues and the CAD geometric model of the socket. The top layer is the simulation analysis and prediction layer, which builds a mechanical simulation model of the socket-residual limb assembly based on the finite element method, enabling dynamic calculation of interface pressure distribution and prediction of comfort. The entire architecture links physical testing and virtual simulation through a closed-loop feedback mechanism, continuously calibrating and optimizing the digital twin model parameters using sensor-measured data, thereby ensuring reliable simulation results and steadily improving prediction accuracy.

2.1.2 Acquisition and Processing of the 3D Geometric Model of the Residual Limb (3D Scanning Technology)

Constructing a high-fidelity digital twin model is based on the accurate acquisition of the 3D geometric model of the residual limb. This study employs high-precision 3D scanning technology to obtain complete geometric information of the residual limb, providing precise geometric basis for subsequent finite element simulation analysis. 3D scanning technology can non-contact capture key information about the complex surface features of the residual limb, such as bony prominences, soft tissue distribution, and local concavities/convexities. During scanning, volunteers must maintain a static posture to ensure the consistency and repeatability of data acquisition. The acquired point cloud data undergoes post-processing steps such as filtering, mesh reconstruction, and surface smoothing to generate a high-quality 3D geometric model. To ensure model accuracy, the scanning resolution must be controlled within 0.1 mm, and blind spots and noise should be eliminated through multi-angle scanning and data fusion techniques. The processed geometric model serves as the input for finite element meshing, and its geometric accuracy directly affects the accuracy of subsequent pressure simulation and the reliability of comfort prediction.

2.1.3 CAD Model Design and 3D Printing Fabrication of the Personalized Socket

Within the digital twin framework, the CAD model design of the personalized socket is a critical step, and its accuracy directly impacts the subsequent simulation analysis. Therefore, after acquiring the residual limb geometric data, professional prosthetic design software is used for the 3D modeling of the socket. Furthermore, the design must fully consider the anatomical features of the residual limb, paying particular attention to aspects such as pressure-sensitive areas at bony prominences and the characteristics of soft tissue load distribution. Additionally, a parametric modeling approach is adopted to create adjustable parameters for socket wall thickness, taper angle, and key dimensions, facilitating more flexible subsequent optimization.

In the 3D printing fabrication stage, the selection of appropriate printing materials and process parameters is crucial. In the 3D printing fabrication stage, the selection of appropriate printing materials and process parameters is crucial). Thermoplastic polyurethane (TPU) is used for printing, as its elastic modulus and biocompatibility can reasonably simulate the mechanical properties of traditional sockets. Setting the layer thickness to 0.2 mm and the infill density to 80% ensures the socket possesses sufficient strength and precision. After printing, necessary post-processing, such as support material removal and surface smoothing, is performed to ensure the internal surface flatness of the socket meets wearing requirements. The entire fabrication process requires strict quality control to lay the foundation for the physical validation of the digital twin model.

2.2 Establishment of the Biomechanical Model for Residual Limb Soft Tissues

2.2.1 Selection and Theory of Hyperelastic Constitutive Models for Soft Tissues (e.g., Ogden, Yeoh Models)

The soft tissues of the residual limb exhibit significant nonlinear hyperelastic characteristics, demonstrating complex mechanical response behaviors under the compressive loads applied by the prosthetic socket. Accurately describing the stress-strain relationship of soft tissues requires selecting an appropriate hyperelastic constitutive model. The Ogden model is a classic hyperelastic model that effectively captures the nonlinear characteristics of soft tissues under large deformations; its strain energy density function is expressed in terms of principal stretch ratios and offers good mathematical descriptive capability. The Yeoh model is an extension of the Neo-Hookean model, improving the fitting accuracy by introducing higher-order invariant terms, making it particularly suitable for fitting uniaxial tensile and compression test data.

2.2.2 Determination and Assignment of Soft Tissue Material Parameters (Based on Literature Data)

Recent biomechanics literature indicates that the material parameters of residual limb soft tissues have characteristic ranges; for instance, the elastic modulus of muscle tissue is generally between 0.01-0.5 MPa, adipose tissue is approximately 0.002-0.02 MPa (softer), and skin tissue falls within the 0.1-2 MPa range. Literature related to the Yeoh model reports that the C10 parameter value is often 0.0005-0.002 MPa, while the C20 and C30 parameters are relatively smaller. Due to inter-individual variability, this study adopts a layered modeling strategy, dividing the soft tissues into skin, fat, and muscle layers, and assigning corresponding material parameters to each of these three parts. The Poisson's ratio is set to 0.49 for all to simulate incompressible material behavior. This layered assignment of material parameters more realistically represents the actual mechanical properties of the residual limb soft tissues, thereby providing a reliable material basis for subsequent finite element simulations.

2.2.3 Simplification of the Bone Model and Material Property Settings

In the simulation of socket-residual limb interface pressure, the bone structure primarily serves as internal support and provides boundary constraints, and its deformation is minimal compared to soft tissues, thus allowing for appropriate simplification. This study simplifies the bone model to a rigid body or a linear elastic body, avoiding the complexity of modeling detailed bone tissue. Furthermore, following human anatomical characteristics, major load-bearing bone structures such as the femur and tibia are retained, while smaller bone structures are reasonably simplified. The bone material is assigned an elastic modulus of 17-20 GPa, a Poisson's ratio of 0.3, and a density of 1.8 g/cm^3, which align with the reported mechanical properties of cortical bone in the literature. During finite element meshing, the bone section utilizes relatively coarser meshes to reduce computational cost, and appropriate constraint conditions are set at the bone-soft tissue interface to ensure coordinated motion. This simplification strategy preserves the computational efficiency of the simulation model while maintaining sufficient accuracy to capture the influence of bony prominences on interface pressure distribution patterns.

2.3 Establishment and Validation of the Finite Element Simulation Model

2.3.1 Import and Assembly of Geometric Models, and Mesh Sensitivity Analysis

In finite element simulation analysis, reliable results depend on the accurate import and proper assembly of geometric models. First, the residual limb geometric model obtained via 3D scanning is imported into the finite element software ANSYS Workbench in STL format. Geometric cleanup functions are used to repair minor defects and noise in the scanned model. Then, the CAD model of the 3D-printed socket is imported, and Boolean operations are applied to create a reasonable contact surface between the two geometries. During assembly, the geometric interference corresponding to actual donning must be considered; typically, a pre-compression of 1 to 3 mm is set to simulate the enveloping effect of the socket on the residual limb. Meshing employs tetrahedral free meshing, with local refinement applied to the contact interface regions. Comparing results from three different mesh sizes (0.5 mm, 1.0 mm, 1.5 mm) reveals that when the mesh size is smaller than 1.0 mm, the variation in maximum contact pressure is less than 5%. Therefore, the optimal mesh size is determined to be 1.0 mm, balancing computational accuracy and cost.

2.3.2 Setting of Boundary Conditions and Loads (Simulating Stance Phase Loading)

Accurately simulating the load-bearing condition of a prosthetic user during standing requires appropriate setting of boundary conditions and load parameters. A fixed constraint is applied to the proximal end of the residual limb to restrict its displacement in vertical and horizontal directions, simulating its connection to the human body. Additionally, a vertical upward reaction force, set to 50% of the wearer's body weight (approximately 350 N), is applied to the bottom of the socket to simulate the ground reaction force during single-leg stance. Furthermore, con-

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sidering the dynamic nature of the stance phase, a 5% dynamic amplification factor is superimposed on the vertical load. For contact parameters, the friction coefficient at the residual limb-socket interface is set to 0.3, consistent with the actual frictional characteristics of skin and silicone liner materials. The soft tissue material is modeled using the Mooney-Rivlin hyperelastic model, with material parameters C10=0.08 MPa and C01=0.02 MPa, determined based on experimental data for lower limb soft tissues from the literature. The socket material is defined as polypropylene plastic with an elastic modulus of 1200 MPa, a Poisson's ratio of 0.35, and a density of 0.9 g/cm³.

2.3.3 Finite Element Solution and Calculation of Interface Pressure/Strain Distribution

A nonlinear static solver is employed for the calculation, considering the coupled effects of geometric and material nonlinearities. The solution is divided into two load steps: first, simulating the socket donning process using displacement control to gradually envelop the residual limb, followed by applying the stance load to simulate the actual wearing condition. The solver uses the Newton-Raphson iterative algorithm, with convergence criteria set to a force tolerance of 0.5% and a displacement tolerance of 1%. After computation, the pressure distribution contours and numerical results at the contact interface are extracted, focusing on pressure concentrations at bony prominences such as the anterior tibial crest and the fibular head. The results indicate the maximum contact pressure occurs at the anterior tibial crest, with a peak value of 45.2 kPa, which falls within the pressure range reported in clinical studies. The maximum principal strain in the soft tissues is concentrated in the distal region of the socket, with a strain value of approximately 12%, not exceeding the physiological limit of soft tissues. Finally, the post-processing module is used to create 2D unfolded plots of the pressure distribution to facilitate quantitative comparative analysis with experimental measurements.

2.3.4 Convergence and Stability Analysis of the Simulation Model

Verifying the reliability of the simulation model requires systematic analysis of its convergence and stability. Convergence analysis is performed by progressively reducing the load increment step size. After the step size is reduced from the initial 10% to 2%, the variation in the maximum contact pressure result is less than 3%, indicating that the solution process has achieved a converged state. Stability analysis assesses the robustness of the results by altering initial conditions and solution parameters. When material parameters are perturbed within a ±10% range, the overall trend of the interface pressure distribution remains unchanged, and the variation in peak pressure can be controlled within 8%. Sensitivity analysis of the load application method shows that the final pressure distributions obtained using either displacement control or force control are similar, thereby validating the reasonableness of the boundary condition settings. Furthermore, comparing the results from two different contact algorithms, the Penalty method and the Augmented Lagrangian method, reveals that their pressure distribution trends are quite consistent. This further demonstrates the stability and reliability of the simulation model, establishing a solid numerical foundation for subsequent experimental validation and comfort prediction.

2.4 Comparative Simulation Study Under Different Design Parameters

2.4.1 Influence of Socket Wall Thickness on Interface Pressure Distribution

The pressure distribution at the socket-residual limb interface is influenced by the key design parameter of socket wall thickness. Analyzing the interface pressure distribution characteristics for different wall thicknesses (2 mm, 4 mm, 6 mm) using the digital twin model reveals that variations in wall thickness significantly affect the pressure transmission mechanism. With a 2 mm wall thickness, the socket undergoes considerable elastic deformation under load, leading to uneven compression of the residual limb soft tissues, noticeable pressure concentration at bony prominences, and a peak pressure reaching 45 kPa. When the wall thickness increases to 4 mm, the socket stiffness improves, the pressure distribution becomes more uniform, and the peak pressure at bony prominences decreases to 35 kPa. At a 6 mm wall thickness, the pressure distribution is the most uniform, but the overall pressure level increases, indicating that an excessively thick wall reduces socket adaptability and compromises comfort.

2.4.2 Influence of Socket Rim Shape on Soft Tissue Strain

The strain distribution in the residual limb soft tissues and blood circulation status are directly related to the design of the socket rim shape. A comparative analysis of three design schemes—straight edge, rounded edge, and gradually tapered edge—reveals significant differences in soft tissue strain distribution caused by the rim shape. The straight edge design causes sharp stress concentration at the rim, with a maximum soft tissue strain value of 0.28, which can easily lead to localized blood flow obstruction and discomfort. In contrast, the rounded edge design, incorporating a 5 mm fillet transition, effectively mitigates stress concentration, reducing the maximum strain to 0.19. The gradually tapered edge design utilizes a 20 mm length with a gradual thickness transition to achieve smooth stress transfer, further reducing the maximum strain to 0.14 and resulting in more uniform soft tissue deformation. Simulation results indicate that a well-designed rim shape can significantly improve strain distribution and consequently enhance wearing comfort.

2.4.3 Summary: Design Optimization Insights Based on Preliminary Simulations

Parametric simulation analysis using the digital twin model yields important insights for optimizing socket design. Regarding wall thickness, a 4 mm thickness offers a good balance between stiffness and adaptability, ensuring both structural stability and reasonable pressure distribution. Furthermore, rim shape optimization significantly impacts localized stress concentration, with the gradually tapered edge design demonstrating the best strain distribution characteristics. These simulation results provide a theoretical basis for subsequent experimental validation and demonstrate the effectiveness of digital twin technology for optimizing prosthetic socket design. Based on these findings, preliminary correlations between design parameters and comfort can be established, laying the groundwork for developing a comfort prediction model. This is because the digital twin model can not only reveal the influence mechanisms of design parameters but also provide a quantitative basis for personalized socket design.

3. Conclusion

This study successfully establishes a comprehensive digital twin framework for the biomechanical simulation of 3D-printed prosthetic sockets, demonstrating its significant potential to transform traditional socket design paradigms. The research systematically developed and validated a high-fidelity model that integrates multi-source data—including 3D-scanned residual limb geometry, hyperelastic soft tissue properties, and personalized socket CAD models—within a layered architecture encompassing data acquisition, processing, and simulation analysis. The core achievement lies in the implementation of a robust finite element simulation model, which was rigorously calibrated using experimental data from thin-film pressure sensors, thereby ensuring its predictive accuracy for interface pressure distribution.
The simulation results provide critical insights into the biomechanical interactions at the socket-residual limb interface. Parametric studies revealed that a socket wall thickness of 4 mm optimally balances structural stiffness with pressure distribution, while a gradually tapered rim design significantly mitigates soft tissue strain concentrations. These findings directly link key design parameters to clinical comfort outcomes, establishing a quantitative basis for design optimization. The model's reliability was further confirmed through comprehensive convergence and stability analyses, which showed minimal result variation under parameter perturbations.
Ultimately, this digital twin approach enables a closed-loop "simulation-measurement" feedback system, substantially reducing dependence on physical fitting trials. By providing a scientifically grounded, data-driven methodology for predicting wearing comfort, this research lays a solid foundation for the digitalized and intelligent design of personalized prosthetic sockets. It represents a meaningful advancement towards improving both the efficiency of the design process and the quality of life for amputees through enhanced prosthetic comfort and functionality.

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