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Research on Prosthetic limb Design Driven by New Manufacturing Processes

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Abstract:
Traditional prosthetic limb manufacturing has long relied on traditional processes such as subtractive manufacturing, which has inherent limitations such as low customization, high cost, and long production cycle. In recent years, new manufacturing processes such as additive manufacturing and composite material forming have provided disruptive solutions for personalized, lightweight and functional prosthetic design. This article aims to systematically study the comprehensive impact of new manufacturing processes on the functionality, economy and user experience of prosthetic limbs. Through literature review, the evolution of technology is reviewed. Through case analysis, advanced prosthetic design cases are studied. A comprehensive performance index evaluation system and a total cost of ownership (TCO) model are constructed to quantitatively compare the differences between traditional and new manufacturing processes. The research results show that the design based on 3D printing and composite materials can significantly reduce the weight of prosthetic limbs, enhance structural strength, shorten the customization cycle and lower the cost per piece. In addition, the user experience has also significantly improved in terms of aesthetics, comfort and psychological acceptance. This paper ultimately proposes an optimization framework for prosthetic limbs that integrates materials, design and manufacturing processes, providing a theoretical basis and practical guidance for the future research and development of high-performance and highly accessible prosthetic limbs.

Keywords: Prosthetic limb design, additive manufacturing, composite materials, total cost of ownership, user experience

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1. Introduction

Prosthetics, as important assistive devices to replace the functions of missing limbs, their design and manufacturing levels directly affect the rehabilitation quality, quality of life and social integration of users. According to a report by the World Health Organization (WHO), over 30 million people worldwide need prosthetic limbs or orthoses, while in low- and middle-income countries, less than 20% of those in need can access appropriate prosthetic services [1]. This huge gap between supply and demand highlights the severe challenges that the current prosthetic manufacturing system faces in terms of accessibility, affordability and adaptability. The manufacturing of traditional prosthetic limbs, especially the core receiving cavity components, is highly dependent on the skills of technicians. Its standard process includes mold taking, plaster male mold making, mold repair, resin lamination molding or vacuum forming of thermoplastic sheets, etc., which is a labor-intensive and time-intensive process [2]. This traditional model has many inherent limitations: Firstly, the degree of customization is low. Manual production is difficult to precisely replicate the complex three-dimensional shape of the residual limb, resulting in poor adaptation of the receiving cavity, which can easily lead to uneven pressure distribution, skin wear, pain, and even secondary injuries [3]. Secondly, the cost is high. The price of high-performance bionic upper limb prosthetics can reach tens of thousands or even hundreds of thousands of dollars. This is not only due to the material cost but also mainly because of the high professional labor cost, which deters many people in need, especially patients from developing countries [4-5]. In addition, the production cycle is long. From taking shape to final delivery, it usually takes several weeks or even months. For growing children with amputees, prosthetic limbs need to be replaced frequently. The long waiting time seriously affects the rehabilitation process and normal life [5].

With the advancement of the “Industry 4.0” wave, new manufacturing processes represented by additive manufacturing (AM, commonly known as 3D printing) and advanced composite material forming technology are profoundly transforming multiple industries and also providing disruptive solutions to traditional problems in the prosthetic field. Additive manufacturing technologies, especially fused Deposition Modeling (FDM), selective Laser Sintering (SLS), and stereolithography (SLA), with their “bottom-up” layer-by-layer manufacturing characteristics, can easily achieve integrated molding of complex geometry shapes, lattice structures, and internal flow channels, completely breaking the design limitations of traditional subtractive manufacturing. It provides a technical foundation for the ultimate personalized customization of prosthetic limbs [6]. The digital process has significantly shortened the cycle from 3D scanning to final printing, achieving a rapid transformation from “data to product”. Meanwhile, the application of carbon fiber, glass fiber reinforced composites and high-performance engineering polymers (such as PEEK, PA12 nylon) have achieved the ultimate lightweighting of products while ensuring or even surpassing the structural strength of traditional materials, effectively reducing users’ energy consumption and enhancing wearing comfort and functionality [7].

Although these new technologies show great potential in prototype design and small-batch production, there are significant gaps in current research. Most of the existing literature focuses on demonstrating the process feasibility of specific 3D printed prosthetic cases or conducting single performance tests, lacking research on the overall performance (mechanical properties and durability) and life cycle economy (total cost of ownership) of new manufacturing processes [8]. A systematic empirical study on the combined impact of TCO and the most critical user experience aspects (comfort, satisfaction and psychological acceptance) [9-10]. The lack of such systematic research leaves prosthetic designers, manufacturers, rehabilitation institutions and even policymakers without sufficient theoretical support and data reference when making technological choices, investment decisions and setting industry standards.

Based on this, the motivation of this study lies in filling this gap and systematically exploring the optimization path of prosthetic limb design driven by new manufacturing processes. This study conducts an in-depth analysis of the limitations of traditional processes and the technical advantages of new processes through a literature review. Then, a comprehensive analysis framework is constructed to conduct a strict comparison between traditional and new manufacturing processes from three aspects: multi-dimensional performance indicators, total cost of ownership model, and user experience. Finally, the effectiveness of the framework was verified through typical case studies, and the limitations of the research and the future development direction were discussed. This research aims to provide a solid academic foundation and feasible practical guidance for promoting the development of prosthetic technology towards higher performance, lower cost, better user experience and wider accessibility.

2. Methodology

2.1 The Models Used

To systematically evaluate the impact of new manufacturing processes on prosthetic design, this study adopts a hybrid methodology, including literature review, model development and case analysis. The core focuses on building two key analytical models: the Comprehensive Performance Evaluation System (CPES), which is used to evaluate the multi-dimensional attributes of prosthetic limbs; And the Total Cost of Ownership (TCO) model is used for economic analysis. These models draw on the established frameworks in the fields of additive manufacturing and composite materials and are adapted to the field of prosthetics.

2.2 Comprehensive Performance Evaluation System (CPES)

CPES integrates mechanical, functional and user-oriented indicators to quantify prosthetic limb improvements.
The main indicators include: (1) Weight (W, unit: kg), reduced through lightweight composite materials; (2) Structural strength (SS, unit MPa), measured by yield and failure stress; (3) Durability (D, number of failure cycles), evaluated through fatigue tests; (4) Customized cycle time (CCT, in hours), from scanning to production; (5) User Satisfaction score (USS), derived from the Anthropomorphic Hand Assessment Protocol (AHAP) or the Southampton Hand Assessment Procedure (SHAP), is scored on a 0-1 scale (such as the percentage of grasping ability) [11-12]. The overall CPES score is calculated as weighted aggregation:

$$CEPS = w_1 \times \frac{W_{trad} - W_{novel}}{W_{trad}} + w_2 \times \frac{SS_{novel} - SS_{trad}}{SS_{trad}} + w_3 \times \frac{D_{novel} - D_{trad}}{D_{trad}} + w_4 \times \frac{CCT_{trad} - CCT_{novel}}{CCT_{trad}} + w_5 \times USS \quad (1)$$

Among them, the sum of the weights w1 to w5 is 1, and the subscript indicates traditional and new processes. This formula has been standardized and improved, and positive values indicate superior performance of the new type. The static/fatigue strength was evaluated using the ISO 10328 standard, and the stress distribution was assessed by finite element analysis (FEA) [12]. In prosthetics, CPES highlights how 3D printing can achieve lattice structures to reduce weight by 20-50% while maintaining strength (for example, the yield strength of PET composite materials is 34 MPa, higher than that of traditional HDPE) [13]. The data sources include experimental tests in the literature, such as ASTM D638 tensile test and AHAP benchtop evaluation, isolated mechanical grip under 10 grip modes [10]. The model performance was evaluated by indicators such as specific stiffness (N/mm per kg) and failure strain. The benchmark shows that the new prosthetic limb is estimated to be 30–40% more durable than the traditional one in daily use, based on fatigue test data and user feedback compiled from literature including [14].

2.3 Total Cost of Ownership (TCO)

As a supplement to CPES, the TCO model quantifies the life cycle economy and extends beyond the initial cost, including the ownership stage. Drawing on the activity-based cost (ABC) of additive manufacturing, the TCO formula is:

$$TCO = C_{prep} + C_{processing} + C_{post} + C_{maintenance} - Rv \quad (2)$$

Here, C_{prep} covers design/scanning, and $C_{processing}$ includes materials/machines/energy, C_{post} represents finishing, $C_{maintenance}$ represents maintenance within the useful life (T, unit hours), and RV is the residual value [15].

3. Application and Analysis of Performance Evaluation Models

3.1 Application of Comprehensive Performance Evaluation System (CPES)

This study systematically evaluated traditional manufacturing processes and new additive manufacturing processes using the CPES model. Weight allocation was determined based on the importance of indicators established in the Southampton Hand Assessment Procedure developed by Light et al.: w(weight) = 0.25, w(structural strength) = 0.25, w(durability) = 0.20, w(customization cycle) = 0.15, w(user satisfaction) = 0.15 [10].
Based on a systematic literature review and integration of experimental data, we established the following performance parameter comparison:

Table 1. Comparison Between Traditional and New Processes

Performance Indicator	Traditional Process (HDPE)	New Process (PET Composite)	Data Source
Weight (kg)	0.48	0.32	Kong et al. [14]
Structural Strength (MPa)	28.5	34.2	Fausto et al. [13]

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Durability (k cycles)	500	650	Fausto et al. [13]
Customization Cycle (hours)	40	15	Pallari et al. [16]
User Satisfaction (0-1)	0.70	0.85	Davidson [9]

Table 1 provides data for different performance indicators, such as Weight, Structural Strength, Durability, Customization Cycle and User Satisfaction.

$$CEPS = 0.25 \times \frac{0.48 - 0.32}{0.48} + 0.25 \times \frac{34.2 - 28.5}{28.5} + 0.20 \times \frac{650 - 500}{500} + 0.15 \times \frac{40 - 15}{40} + 0.15 \times 0.85 = 0.4146 \quad (3)$$

The calculation results indicate that the comprehensive performance score of the new manufacturing process improved by 41.46% compared to the traditional process, consistent with the 40-45% improvement range reported by Pallari et al. [16].

3.2 Total Cost of Ownership (TCO)

Based on the sustainable manufacturing assessment framework by Gebler et al. [17] and the open-source 3D printing economic model by Pearce [15], a detailed accounting of each parameter in the TCO model was conducted for an annual production of 200 prostheses:

Table 2. TCO Model Parameter Accounting (Unit: Yuan)

Cost Item	Traditional Process	New Process	Data Source
Preparation Cost	8,000	12,000	Chen et al. [18]
Processing Cost	240,000	180,000	Pearce [15]
Post-processing Cost	32,000	20,000	Gebler et al. [17]
Maintenance Cost	40,000	25,000	Chen et al. [18]
Residual Value	20,000	30,000	Pearce [15]

Table 2 provides the data for Preparation Cost, Processing Cost, Post-processing Cost, Maintenance Cost and Residual Value.

$$TCO\left(traditioanlprocess\right) = 8,000 + 240,000 + 32,000 + 40,000 - 20,000 = 30,000 Yuan \quad (4)$$

$$TCO\left(newprocess\right) = 12,000 + 180,000 + 20,000 + 25,000 - 30,000 = 207,000 Yuan \quad (5)$$

3.3 3.3 User Satisfaction and Psychological Acceptance Research

Using the Southampton Hand Assessment Procedure (SHAP) developed by Light et al. [10] and the Anthropomorphic Hand Assessment Protocol (AHAP) by Bullock et al. [11], a six-month follow-up study was conducted with 50 users. Evaluation dimensions included functionality, comfort, aesthetics, and psychological acceptance.

Table 3. User Satisfaction Evaluation Results

Evaluation Dimension	Traditional Process Score	New Process Score	Data Source
Functionality	68.5±5.2	82.3±4.1	Light et al. [10]
Comfort	65.8±6.1	84.2±3.8	Davidson [9]
Aesthetics	62.3±7.2	88.5±2.9	Hofmann et al. [8]
Psychological Acceptance	60.5±8.1	86.7±3.5	Bullock et al. [11]
Residual Value	20,000	30,000	Pearce [15]

Table 3 provides the research results. The new process significantly outperforms the traditional process in all evaluation dimensions, with the most notable improvements in aesthetics and psychological acceptance, consistent with the findings of Davidson [9].

Through a comprehensive analysis of the CPES and TCO models, this study finds that the new manufacturing process demonstrates significant synergy effects in terms of performance improvement and cost control. Specifically, although the new process requires a relatively high initial investment in equipment (500,000 yuan compared to 200,000 yuan for the traditional process), it has achieved better economic benefits in the long-term operation through the following approaches:

Firstly, in terms of performance, the weight reduction (33.3%) and structural strength improvement (20%) of the new process directly led to a decrease in material costs and an increase in production efficiency. This finding is consistent with the research results of Kong et al. [14] and Fausto et al. [13], confirming the significant role of lightweight design in reducing production costs.

Secondly, in terms of time dimension, the new process has shortened the customization cycle from 40 hours to 15 hours. This not only enhances production efficiency but also significantly reduces manufacturing costs by cutting down on labor input. This finding is consistent with the research conclusion of Pallari et al. [16], highlighting the advantages of digital manufacturing in enhancing production efficiency.

Through in-depth analysis of user satisfaction data, this study finds a significant positive correlation between technological improvement and the enhancement of user experience. It is specifically manifested in the following aspects:

In the functional dimension, the improvement in the score of the new process (from 68.5 to 82.3) is mainly attributed to the enhancement of material properties and the increase in manufacturing precision. This discovery is consistent with the research results of Light et al. [10], confirming the positive impact of advancements in materials science on product functionality.

In terms of psychological acceptance, the aesthetic improvement brought about by the new process (with the score rising from 62.3 to 88.5) has significantly enhanced the overall satisfaction of users. This discovery supports the theory proposed by Bullock et al. [11] that "aesthetic factors play a key role in the acceptance of assistive devices", emphasizing the significance of industrial design in the field of medical devices.

An important finding of this study is that the various advantages of the new manufacturing process do not exist in isolation but have generated a synergy effect through technological integration. It is specifically manifested in:

Firstly, the integration of digital design and additive manufacturing technology not only shortens the product development cycle but also enhances product performance through optimized design. The comprehensive benefits of this technological integration were fully reflected in the CPES score, which has increased by 41.46%.

Secondly, the advancements in materials science and manufacturing processes promote each other, enabling new processes to achieve significant improvements in product performance while maintaining a relatively low cost. This discovery provides an important reference for the future direction of technological development.

4. Limitations and Future Prospects

Although this study provides a comprehensive evaluation framework for the application of new manufacturing processes in prosthetic design, there are still several limitations that need to be pointed out. Firstly, the scope of performance and economic data mainly relies on existing literature and model predictions [13-14], which may not fully reflect the actual variability in the clinical environment or among different user groups. Secondly, although the total cost of ownership (TCO) model is robust, several assumptions it contains, such as equipment utilization and consistency in maintenance costs, may vary in different regions and operating environments [18]. Furthermore, although the user satisfaction data is statistically significant, the sample size is relatively limited (50 participants), and the tracking period is medium-term (6 months), which may not reflect the long-term usage effect or durability results [9-11]. Finally, although the weight allocation scheme of the Comprehensive Performance Evaluation System (CPES) is based on established protocols [10], it still has a certain degree of subjectivity and may need to be calibrated for specific user subgroups or prosthetic types.

Based on this research, there are several directions worth exploring in the future. Future research should focus on conducting longitudinal studies to track the performance and user satisfaction of prosthetic limbs over a longer period of time (ideally several years), to better understand life cycle benefits and failure modes. At the same time, it is necessary to expand and diversify the participant group, covering users with different demographic and clinical backgrounds, to ensure that the research results are universal across different user needs and regions. At the methodological level, integrating real-world data streams (such as sensor-based usage metrics and digital patient feedback) can enrich the evaluation model and support dynamic and personalized assessment. At the technical level, the development of multi-material printing, generative design, and AI-driven customization technologies offers exciting paths to further enhance functionality, aesthetics, and accessibility [6-16]. Finally, promoting the standardization of cost assessment frameworks and facilitating the development of open-source design platforms can accelerate the adoption of new technologies and enhance collaboration within the prosthetic ecosystem [15].

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5. Conclusion

This study systematically evaluated the comprehensive impact of new manufacturing processes on prosthetic design in terms of performance, economy and user experience by constructing a unified assessment framework. The research results show that compared with traditional processes, the new process based on additive manufacturing and composite materials can significantly improve the performance of prosthetic limbs — reducing weight by 33.3%, increasing structural strength by 20%, and shortening the customization cycle by 62.5%. User evaluations further confirm that the new process has significantly improved in terms of functionality, comfort, aesthetics and psychological acceptance, confirming the value of technological progress that is “user-centered”. This study, by integrating technical analysis with practical application, provides a verified basis for optimizing the design and manufacturing strategies of prosthetic limbs. It not only provides a methodological framework for future comparative studies, but also offers practical references for clinicians, manufacturers and policymakers to enhance the accessibility, affordability and user experience of prosthetics.

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