Designing Customized Wearable Devices: A Novel AI-Based Framework for Product Development

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***Abstract*—The development of personalized wearable devices, including orthopedic products, requires individual customization to ensure user satisfaction and sustained usage over time. Recent advances in image-generative Artificial Intelligence (AI), such as DALL-E from ChatGPT, have shown promise for creating individualized designs tailored to user preferences. However, the structured integration of such AI tools into broader iterative product development workflows (including 3D-modeling, personalization, and physical manufacturing) remains largely unexplored in this application context. This work presents a user-centered design process that incorporates image-based generation into early design phases to address both functional and aesthetic user needs. A case study was conducted to demonstrate the process, resulting in the design and fabrication of a customized foot orthosis using additive manufacturing. To assess the design outcome, the prototype was evaluated through a subjective user questionnaire and supplemented by qualitative feedback from an orthopedic professional. The results highlight both strengths and limitations of AI-assisted workflows in personalized product design. Overall, the findings illustrate how AI can be effectively embedded in user-centered design processes and provide implications for applications beyond orthopedic footwear design.**

***Index Terms*—Additive Manufacturing, Artificial Intelligence, ChatGPT, Generative AI, Text-to-Image, Human-Centered Design, Personalized Foot Orthoses, Wearables**

I. Introduction

The development of wearable devices like personalized orthopedic products has to consider individual customization to ensure long-term use and therapeutic effectiveness. Therefore, their development needs to address both aesthetic and functional aspects to achieve high user satisfaction. Traditional design methods rely on manual customization, which is highly time-consuming and requires expert knowledge at every stage of the process. To make personalized solutions more accessible and efficient, new approaches are needed that streamline the design process while preserving individual adaptability.

Previous research has explored user-centered design approaches to improve product personalization [1, 2]. For example, Dabnichki and Pang [1] proposed a framework for personalized ankle-foot orthoses using additive manufacturing. However, this process still requires highly specific user input throughout the entire design process. Furthermore, Slegers et al. [2] compared three workflows for designing and manufacturing custom-made 3D-printed assistive devices, highlighting the value of interdisciplinary design teams consisting of clinicians, clients, and 3D printing experts. They further emphasized that 3D printing aligns well with a user-centered design approach, as it enables the creation of individual solutions tailored to specific user needs. Nevertheless, the process is always based on personal input for the design process.

Recent advancements in the field of artificial intelligence (AI), particularly in text-to-image generation, offer new opportunities to incorporate AI into the design process, for example to improve the personalization of footwear design [3, 4, 5]. A study by Resch et al. [6] demonstrated that AI-generated orthosis designs using DALL-E from OpenAI can significantly improve perceived social acceptability compared to conventionally designed devices. Additionally, they found that a customized Generative Pre-trained Transformer (GPT) trained with orthopedic data and specific prompting keywords further improved acceptance scores. These results highlight the potential for AI-driven design assistance in personalized medical device development. Moreover, a study by Popescu [7] highlighted the feasibility of AI-assisted hand orthosis design, where AI-generated 2D images were manually converted into 3D models for subsequent additive manufacturing.

Similarly, AI has been used in footwear design, where AI-generated shoe concepts rely on designers and specialized software to transform 2D outputs into functional 3D models [8]. While recent advancements enable direct text-to-3D generation, these outputs often lack the necessary quality and require manual refinement by experts to meet design and manufacturing standards. Taking this a step further, a study by Minaoglou et al. [9] demonstrated that integrating AI into the shoe design process can reduce design time by 59% compared to traditional methods, while also reducing costs. Furthermore, frameworks such as the proposed design process by Sengupta [10] highlight the potential of AI tools to accelerate conceptual design workflows in the fashion footwear domain. However, existing approaches focus predominantly on aesthetic aspects of shoe design, while functional and anatomical considerations, which are essential for orthopedic foot wearables, are not sufficiently addressed. In particular, the methodological integration of AI into the development of personalized orthopedic orthoses, which addresses both medical functionality and individual user needs, remains an open challenge.

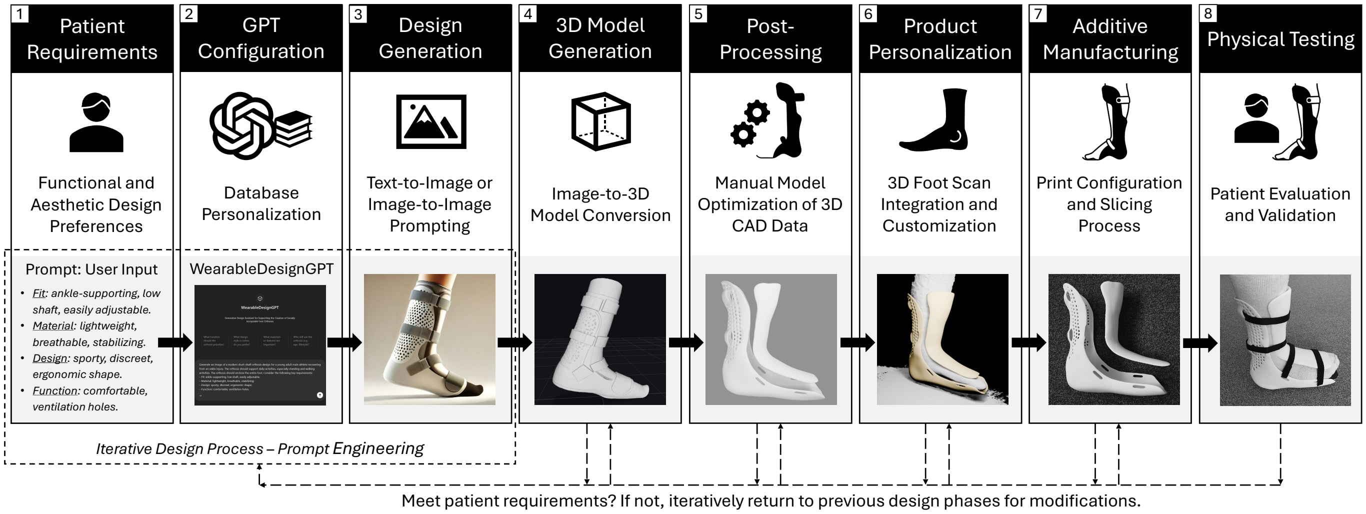

Fig. 1. Schematic overview of the eight-stage development process for personalized orthopedic devices using generative AI. The framework integrates patient-specific input, AI-assisted design generation, digital modeling, and additive manufacturing. It supports iterative refinement across all stages, from requirements analysis to physical testing.

This leads to the following research question: *How can a patient-centered AI-driven design framework for personalized foot orthoses be developed to meet both aesthetic and functional requirements while ensuring high user acceptance?*

Therefore, a new methodological approach is introduced that incorporates generative AI tools into the development of personalized wearable devices. The resulting framework aims to fulfill both aesthetic and functional requirements while enhancing patient acceptance.

II. Method

To implement the proposed framework, an iterative design process was developed and applied for the creation of a customized foot orthosis. The process is structured as an iterative eight-phase workflow that integrates image-based generative AI, digital 3D modeling, and additive manufacturing (see Figure 1). The iterative approach allows for modifications at any stage if requirements are not met or further improvements are necessary. Each step of this process is illustrated through a case study in which a personalized orthosis was developed based on patient-specific input.

Initially, individual user needs were systematically analyzed and the resulting requirements were translated into keyword-based prompts for generative design. These prompts were used to generate a visual design concept via a tailored GPT model. The generated concept served as input for 3D digital modeling, which was further refined using computer-aided design (CAD) software to meet functional and aesthetic criteria. Anatomical personalization was achieved by integrating 3D foot scan data, allowing the digital model to be precisely adapted to the patient's foot morphology. The finalized model was fabricated using 3D printing and the resulting prototype subsequently underwent a physical testing procedure.

The following subsections describe the technical implementation as well as the execution of the physical testing.

A. GPT Configuration

A custom GPT, named "WearableDesignGPT", was created using the ChatGPT-4 Pro interface from OpenAI (version as of March 2025), to support the generation of image outputs that align with orthopedic design requirements. As part of this configuration, the integrated image generation function (DALL-E) was activated to create visual design concepts. DALL-E utilizes a transformer-based diffusion architecture to generate images based on natural language prompts.

The knowledge base of "WearableDesignGPT" was filled with domain-specific documents, including orthosis design guidelines, manufacturer manuals, product specifications (e.g., materials, mechanical properties), and reference images of existing products, as recommended by related works [6, 7]. These resources were provided in PDF and text format, reflecting both clinical standards and commercially available solutions.

B. Patient Requirements and Design Generation

Medical and aesthetic requirements were previously recorded and documented to address patient needs. Aesthetic preferences include color, design style (whether traditional, sporty, or casual), as well as other aspects of visibility. These requirements are then summarized in the prompt as keywords to achieve suitable design outcomes. Following this, an iterative prompt engineering process is essential to refine the generated results.

While earlier versions of ChatGPT generated entirely new image variations upon re-prompting, the latest version enables manual selection of specific areas within an image to modify them based on an updated prompt, preserving the overall concept. This iterative re-prompting approach enables targeted modifications to achieve the desired design solution. Alternatively, image-to-image prompting based on desired product designs or sketches can be used in combination with text-based prompts to guide the creation process.

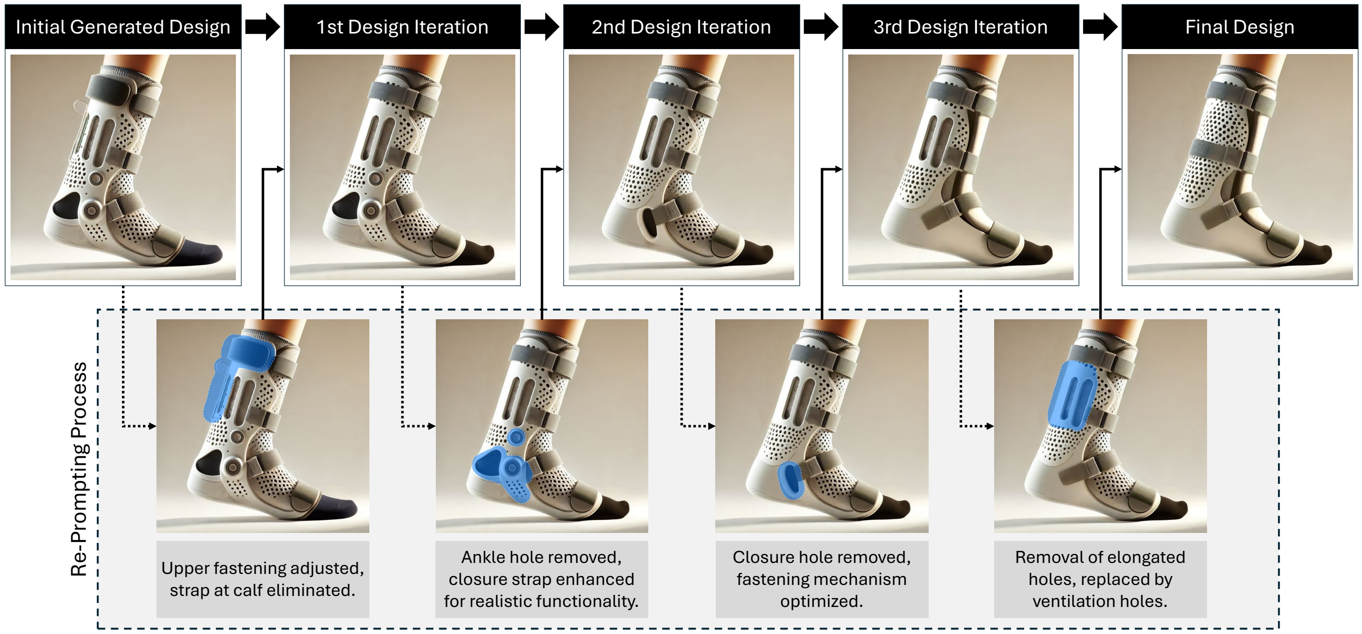

Fig. 2. Iterative design process of the orthosis using WearableDesignGPT. From left to right: initial design, three targeted modifications, and final design. The lower row illustrates the four-step re-prompting process, involving manual selection of orthosis components for targeted refinement.

In this case study, the following prompt was used to design a short-shaft orthosis for a sporty 28-year-old male participant: *"Generate an image of a modern short-shaft orthosis design for a young adult male athlete recovering from an ankle injury. The orthosis should support daily activities, especially standing and walking activities. The orthosis should enclose the entire foot. Consider the following key requirements:*

- *Fit: ankle-supporting, low shaft, easily adjustable;*
- *Material: lightweight, breathable, stabilizing;*
- *Design: sporty, discreet, ergonomic shape;*
- *Function: comfortable, ventilation holes."*

The initial design concept was iteratively refined through four re-prompting steps, resulting in a final design that aligned with the required technical functionalities (confirmed by one expert) and matched participants' preferences. The design process is documented in Figure 2.

C. 3D-Model Generation

The transformation from the 2D-generated image to a virtual 3D model can be achieved through various approaches. Traditionally, this process requires a manual redesign by a designer, which can be time-consuming. Recent advancements in AI have introduced tools that can generate simple 3D objects directly from text prompts or images. However, text-to-3D output is still primarily applied in simple 3D modeling or avatar creation, rather than in the design of functional CAD components. To obtain a suitable 3D representation of the generated image, an image-to-3D reconstruction method was used. This method allows for a rapid transformation of the outer orthosis contour, similar to a 3D scan of an object. Backflip.ai [1] was applied, which converts the image into a 3D mesh model and enables subsequent modifications. The generated part of the orthosis was exported in Stereolithography (STL) format, commonly used in CAD software and 3D printing, containing only surface geometry without texture or color information. This approach enables rapid 3D model generation for subsequent post-processing and personalization.

D. Post-Processing and Product Personalization

For manual post-processing, the 3D model was imported into Blender [2] (software version 4.1). The outer contour of the orthosis was adjusted using an offset operation to separate key components, such as the posterior and anterior corpus, straps, and inner padding. The surfaces were further refined to ensure that all components had the desired shape and contour. For the personalization of the orthosis, a 3D scan of the participant's leg was used. The scan data were obtained using the "Heges 3D Scanner" app [3] on an iPhone 13 (iOS 18.3.2), utilizing the TrueDepth camera for depth sensing. To ensure that the scan captured the entire foot geometry, the foot was placed on a small rectangular object positioned at midfoot level, simulating a stance-phase scan. This method enables a rapid scan of the outer leg contour in approximately 30 seconds, requiring only minor post-processing adjustments. Although this freely available app offers only moderate scan quality, it is sufficient to capture the outer leg contour and dimensions. The scanned STL data were imported into Blender, where the orthosis model was scaled to match the participant's foot size. Further refinements were applied to adapt the shape to

[1]https://www.backflip.ai/
[2]https://www.blender.org/
[3]https://apps.apple.com/app/id1382310112

the individual's foot morphology, ensuring an optimal fit and providing targeted support in key areas. After finalizing the personalization and manual adjustments, the 3D model was prepared for subsequent additive manufacturing.

E. Additive Manufacturing

For rapid prototyping, the Fused Deposition Modeling (FFF) process was used. The final 3D model was imported into FlashPrint [4] slicer software (version 5.8.7) to prepare the parts for 3D printing. A Creator 4A printer (Flashforge) equipped with an HT extruder was used to print with white acrylonitrile butadiene styrene (ABS) thermoplastic material. Printing settings followed recommended ABS material specifications: 0.4 mm nozzle, 1.75 mm filament diameter, and 230°C extruder temperature. A 0.3 mm layer height, 30% infill density, and a treelike support structure were applied. The total print duration for the main corpus and the front shell was 40 hours. After printing, manual post-processing steps were performed, including the removal of support material and surface finishing. The printed prototype (see Figure 1), was prepared with Velcro strips for fixation and attachment. The total weight of the assembled parts was 375 grams.

F. Physical Testing

To evaluate the proposed framework from an end-user perspective, a short-duration physical test was conducted with one 28-year-old male participant. Additionally, the development process was validated through a semi-structured interview with an orthopedic technician (29, male) from a medical supply store, who has practical experience in the production of foot and hand orthoses and insoles. He reported no prior experience with AI-based tools in this context. The expert was recruited via personal contacts and the participant through institutional mailing lists. The study received ethical clearance and was conducted in accordance with the privacy regulations of our institution. Informed consent was obtained from both the participant and the expert.

The test was conducted in a controlled laboratory setting, following the described procedure. First, the participant was introduced to the orthosis, followed by a visual inspection and a fitting process. Following this, the participant performed representative daily activities, including walking, climbing stairs, sitting, and standing. Afterwards, the participant completed the AttrakDiff Mini [11] questionnaire. This standardized questionnaire is commonly used in user experience (UX) research to assess the subjective perception of usability and visual appeal. The questionnaire was used to assess whether the final design met the participant's visual expectations. Descriptive statistics were performed to analyze the results.

After physical testing, a semi-structured expert interview was conducted in person to validate the overall design framework and final prototype from a professional perspective. The interview was guided by open-ended questions focusing on general feasibility, suitability, and clinical integration. A semi-structured approach was applied to address key themes while allowing for additional inquiries to gain deeper insights into the expert's perspective. The interview was documented with manual notes, which were transcribed and thematically coded sentence-wise by one researcher and analyzed using an inductive thematic analysis [12].

[4]https://enterprise.flashforge.com/pages/flashprint

III. Results

The results section presents findings from quantitative patient feedback (see Subsection III-A) and qualitative expert feedback obtained through a semi-structured interview (see Subsection III-B).

A. Quantitative Patient Evaluation

The AttrakDiff mini questionnaire consists of ten items (five reversed scored), which were rated on a 7-point Likert scale, and covers four dimensions: Attractiveness (ATT), Pragmatic Quality (PQ), Hedonic Quality (HQ), which is categorized into Hedonic Quality Identity (HQ-I) and Hedonic Quality Stimulation (HQ-S). ATT describes the product's overall appeal, PQ refers to perceived usability and functionality, HQ-I captures aspects of self-expression; and HQ-S reflects perceived novelty and stimulation.

The scale ranges from +3 (positive rating) to –3 (negative rating), with 0 representing a neutral midpoint. The results show positive ratings across all four dimensions, indicating high user satisfaction. Based on the participant's responses, PQ and HQ-I received the highest rating (1.5), followed by ATT (1.0), and HQ-S (0.5).

Figure 3 summarizes the ratings of the four dimensions. Furthermore, Figure 4 presents the PQ-HQ portfolio visualization. The rating ($PQ = 1.5$ and $HQ = 1.0$) placed the product between the "desired" and "task-oriented" quadrant of the PQ-HQ matrix.

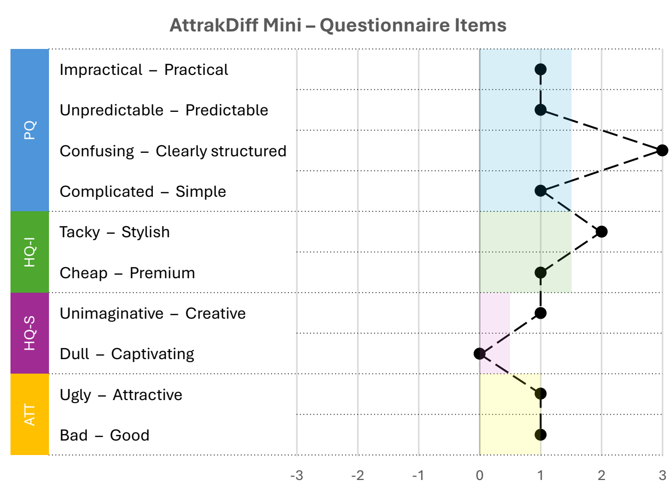

Fig. 3. Vertical line chart showing participant ratings of the ten AttrakDiff Mini items. Colored bars represent the mean values of each dimension: PQ (1.5), HQ-I (1.5), HQ-S (0.5), ATT (1.0).

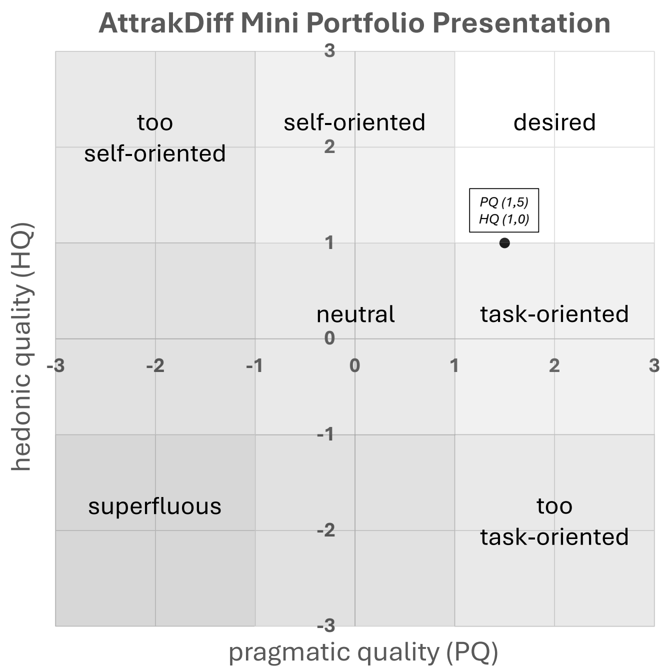

Fig. 4. Portfolio presentation of HQ and PQ dimensions, placing the product between the "desired" and "task-oriented" quadrant of the PQ-HQ matrix ($PQ = 1.5$, $HQ = 1.0$).

B. *Qualitative Expert Evaluation*

An inductive thematic analysis revealed three key themes: *alignment with patient needs*, *perceived innovativeness*, and *challenges for practical use*. In the following paragraphs each theme is documented.

Alignment with patient needs

In general, the expert stated that the exemplified process is *"targeting patient needs."* He reported an example of how aesthetic appearance can negatively influence the willingness to wear the device, aligning with existing literature [13, 14]. Therefore, he concluded that *"if it looks appealing, the patient will wear it ... as it goes hand in hand with increasing user acceptance."* However, it was also emphasized that the workflow requires a technical expert to ensure optimal alignment with the patient's needs, as *"a technician must take over the adjustment step regarding technical specifications (e.g., ideal force absorption)."*

Perceived innovativeness

The presented workflow of an AI-assisted design process was generally perceived as *"innovative,"* because conventional approaches lack a systematic method for incorporating patient preferences. Currently, products are typically adapted only to anatomical shape, and in some cases, basic color preferences are considered for personalization. However, patients are usually not involved in the design process itself. The expert noted that the new approach is *"extremely practical for medical supply facilities, as the process can begin without the technician having to be present."*

Furthermore, he suggested that a standardized form could be envisioned in which patients indicate their preferences, enabling rapid generation and adaptation of design solutions through automation. From his point of view, this approach targets patient needs and is *"valuable for future development."* Additionally, *"time savings could play a role."*

Challenges for practical use

In addition to the perceived innovativeness and future potential, the expert raised several concerns regarding current challenges, limitations, and risks associated with the integration of AI into orthopedic product development workflows. One central point was the issue of regulatory compliance:
"Regulatory hurdles and medical approvals need to be considered, as there are strict certification procedures for medical products, and orthotic boots are commonly certified."

In general, certified professionals at medical supply stores are able to individually adapt solutions for personalized products such as insoles. However, implementing a user-centered design process with AI tools *"requires AI expertise, which is currently lacking."* Furthermore, a limiting factor is that *"healthcare insurers typically do not cover additional costs."* Therefore, it can be challenging to integrate such solutions into traditional workflows, as facilities must be prepared accordingly and *"require the necessary software and an established 3D printing process."*

From an ethical perspective, the expert expressed no fundamental concerns. However, data privacy remains an important issue, as *"the protection of patient data (e.g., anatomically recorded data) must be strictly ensured to comply with data protection regulations."* Finally, regarding potential limitations of AI it was noted that *"AI data set filtering (one-sided feeding) could potentially limit creativity."*

IV. Discussion

A single-participant case study was conducted to evaluate the proposed generative AI workflow for orthosis design. Following the framework, a foot orthosis was generated, modeled, and 3D-printed for short-term testing and expert validation.

Overall, the participant's ratings of the AttrakDiff mini questionnaire suggest that PQ was successfully addressed, indicating sufficient usability, clarity, and efficiency, while HQ scores reflected positive perceptions of attractiveness, stimulation, and identification. However, the results lack comparability, as they are based on a single, subjective short-term evaluation. The design was positioned between the desired and task-oriented quadrants, showing that the workflow balances functional and preference-oriented aspects. The trend toward the task-oriented side likely reflects the medical context, as such products are primarily designed for functionality and utility rather than self-expression. By contrast, more fashion-oriented items could shift the evaluation toward the self-oriented quadrant.

Qualitative expert feedback emphasized the potential of this workflow as an innovative alternative to traditional methods by directly involving patients in the design process. However, several challenges remain, including the reliance on specialized orthopedic software, limited transparency and data privacy in current AI solutions, and the integration of AI expertise into clinical workflows. A promising future direction is the integration of prompt-to-3D-model functionality in professional CAD software, supported by custom AI modules, for a seamless workflow from user input to 3D modeling and printing.

A. Implications

This case study demonstrates the integration of AI-assisted design processes in the medical domain, particularly for the development of personalized orthopedic devices. The proposed framework illustrates how generative AI can be embedded in early design phases to support patient-centered development. Although exemplified for the foot, the applied approach is not limited to this body region and can be extended to other types of wearable devices. The evaluation with a user and an expert highlights both the potential and challenges of such workflows in addressing individual user needs while streamlining the customization process. Building on previous work that demonstrated the benefits of AI-integrated workflows [15, 16], the findings suggest that AI can support the aesthetic dimension of product development, but functional validation must remain under the supervision of qualified professionals. This opens new perspectives for future applications, especially in environments where expert time and resources are limited. Moreover, the approach could be extended by integrating diagnostic data to inform the design process, as shown by Rajagopal et al. [17], who used machine learning for foot condition classification and personalized footwear recommendation. Therefore, future research could use this framework as a basis to develop and evaluate AI-assisted workflows in other domains of wearable device design.

B. Limitations and Future Work

This study is subject to several limitations, including the AI software used, as the training data is non-public which reduces transparency and adaptability. Furthermore, the validation is based on a single use case with short-term testing, which limits the generalizability and representativeness of the results for broader user groups. To address these limitations, future research should validate the approach using larger samples and extended testing periods. In addition, future implementations of AI-assisted workflows could help overcome the limitations of isolated AI tools and improve overall efficiency and applicability. Future work could adapt the design process beyond orthoses and footwear, extending it to consumer products where personalization and adaptability are essential.

V. Conclusion

A novel framework for human-AI-driven product development was introduced and exemplified through a case study. Our workflow demonstrates the potential of AI in rapid design generation for the development of personalized foot orthoses. The results highlighted both the strengths and current limitations of the proposed approach. While challenges remain, the proposed approach provides a foundation for future research and can be adapted to application areas beyond orthotic and footwear design. Overall, this work demonstrates the broader potential of integrating AI into user-centered design processes, particularly for addressing individual user needs.

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