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Review

Exploring the Design for Wearability of Wearable Devices: A Scoping Review

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Abstract: Wearable smart devices have become ubiquitous in modern society, extensively researched for their health monitoring capabilities and convenience features. However, the "wearability" of these devices remains a relatively understudied area, particularly in terms of design informed by clinical trials. Wearable devices possess significant potential to enhance daily life, yet their success depends on understanding and validating the design factors that influence comfort, usability, and seamless integration into everyday routines. This review aimed to evaluate the "wearability" of smart devices through a mixed-methods scoping literature review. By analyzing studies on comfort, usability, and daily integration, it sought to identify design improvements and research gaps to enhance user experience and system design. From an initial pool of 130 publications (1998–2024), 19 studies met the inclusion criteria. The review identified three significant outcomes: (1) a lack of standardized assessment methods, (2) the predominance of qualitative over quantitative assessments, and (3) limited utility of findings for informing design. Although qualitative studies provide valuable insights, the absence of quantitative research hampers the development of validated, generalizable design criteria. This underscores the urgent need for future studies to adopt robust quantitative methodologies to better assess wearability and inform evidence-based design strategies.

Keywords: wearable devices; wearable comfort; comfort assessment; wearability design; wearability standards

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1. Introduction

Wearable devices, including smartwatches, fitness trackers, smart clothing, smart eyewear, wearable cameras, and physiological and biochemical monitors, are becoming increasingly integrated into daily life. There is a growing interest in utilizing these devices for clinical monitoring, recording, and decision making. However, this interest is accompanied by several operational, legal, and reimbursement challenges that must be addressed to facilitate their use in clinical care [1–5]. Significant research efforts are focused on improving the performance and user acceptance of wearable devices. This includes advancements in wireless communications, the optimization of operating systems, reduction in size, and enhancements in sensing capabilities. Improvements in sensing and transducer technologies will enable wearable devices to accurately monitor vital signs and other health metrics, providing valuable insights for healthcare and wellness applications. Wearable sensing technologies are poised to transform medical practice by offering the continuous real-time monitoring of biomarkers associated with various health conditions, including diabetes, stress, inflammation, heart disease, gout, and fertility [6]. Numerous research initiatives highlight the latest advancements in wearable biosensing technology development, healthcare applications, and manufacturing concerns [7–9].

The field of wearables is extensive, with at least one database listing over 430 devices and more than 250 companies involved in their manufacture. Including all the manufacturing companies and providing a review of sensor technology falls outside the intended scope of this review on human factors and would duplicate the existing published work. Several comprehensive reviews offer rigorous discussions on wearable sensors, covering their fundamentals, mechanisms, and various types used for numerous applications [10–13]. These references and several textbooks [14,15] provide a thorough overview of the wearables field.

Despite technological advancements, the comfort of wearable devices remains a crucial design consideration. For long-term monitoring applications, the devices must be comfortable enough for continuous wear: they must be "wearable to be worn." Therefore, a balanced approach that combines technological innovation with user-centric design principles is imperative for the successful development and adoption of wearable health devices [16].

Wearable comfort is directly related to the user acceptance of wearable devices and can potentially affect the performance of the products in a variety of aspects such as safety, sensing accuracy, reliability, user dependency, adherence, and compliance. The terms "adherence" and "compliance" are often used interchangeably, but they have distinct meanings. Compliance refers to the extent to which a patient follows the prescriber's advice [2], implying obedience to the physician's authority [3–5]. In contrast, adherence signifies a collaborative effort between the patient and physician to improve the patient's health, integrating the physician's medical opinion with the patient's lifestyle, values, and preferences for care [6–8]. Moreover, the comfort level of wearable devices can be subject to numerous factors: wearing methods and regions, supportive device materials, mechanical configurations, and product appearance. Therefore, the appropriate categorizations and definitions of wearable comfort are important for research on investigating comfort assessment. An extensive description has been given by Slater, defining comfort as a pleasant state of physiological, psychological, and physical harmony between a human being and the environment [17]. Although there is no comprehensive and widely accepted definition of wearable comfort, attempts have been made to define it from either a holistic perspective or based on specific devices. Among the various classifications of wearable comfort, physical comfort and psychological comfort are typically referred to as two major categories. As the names indicate, physical comfort mostly comes from physical contact between the human body and wearable devices, whereas psychological comfort is more about inner sensory perceptions such as emotional concerns about the safety and reliability of the devices. To assess the comfort levels of wearable devices, researchers have proposed various approaches in different application scenarios, which could be roughly categorized into subjective and objective assessment methods. Most of the subjective assessment methods are based on self-report scales including Visual Analog Scales (VASs), Numeric Rating Scales (NRSs), Verbal Rating Scales (VRSs), and Likert Scales, by which comfort levels of subjects are evaluated in a straightforward way based on the cognitive recognition of one's feeling and comprehension. By contrast, objective assessments focus on measurement methodologies using quantifiable physiological signals and only indirectly suggest wearability.

This study focuses on reviewing the literature to explore the relationship between wearability and the design of wearable devices. It aims to identify how wearability is conceptualized and to examine studies that provide insights into how devices can be designed to enhance wearability. The objective is to understand the factors influencing wearability and to identify design principles validated by clinical trials that optimize user experience, comfort, and usability. This review seeks to contribute to a deeper understanding of the interplay between wearability and design, offering valuable guidance for the development of future wearable technologies for clinical use.

1.1. Wearable Devices

The terms "wearable devices", "wearable technologies", or simply "wearables" refer to the smart electronic devices worn on the human body that can sense, record, transmit, and analyze physiological or biochemical signals in a real-time manner and/or assist users to perform desired tasks and/or actuate certain physical activities. Ideally, these functions should be executed effortlessly by the person who wears the devices. Because of their portability, intelligence, and convenience, wearable devices such as smartwatches, fitness trackers, smart clothing, smart eyewear, wearable cameras, and wearable medical devices are currently used in a variety of areas. They include medical health monitoring, human motion detection, interactive gaming, physical therapy and rehabilitation, sports performance monitoring, and so forth.

The wearability of biosensors remains unexplored and represents real-world usability. To align with the emerging definitions of terminology used for digital health and wearable products, we define "utility" as whether a product has the features that users need, and "usability" as how easy and pleasant those features are to use. Fundamentally, the more wearable a device is, the more people will wear and adhere to using it [18]. Conversely, poor adherence to using a wearable biosensor will limit the ability to predict adverse events [19]. Wearability is the concept describing the characteristics of an effective wearable biosensor, spanning sensor accuracy, comfort, battery life, aesthetics, form factor, method of attachment to the patient, and more [20–22]. User-centered design acknowledges the intimate relationship between the human body and wearable technology [23,24], and while critical to patient compliance, many devices are simply not designed for comfortable or long-term use, even for users who may be more tolerant of design flaws [25–27].

1.2. Design Perspective

The adoption of new technology in medical devices is primarily driven by its ability to address critical unmet patient or clinical needs [28]. For devices intended for medical use, the design process incorporates rigorous checkpoints, particularly verification and validation, to ensure safety, efficacy, and compliance. The FDA Waterfall model [29,30] plays a pivotal role in this process, clearly delineating the distinction between design validation—ensuring the device meets user needs and intended use—and clinical validation, which confirms its performance in real-world medical settings within a wearable system's development lifecycle [31]. Figure 1 illustrates the distinction between design validation and clinical validation within the overall design of a wearable medical device. A critical first step is the translation of clinical needs (T_1) into design input specifications, which guide the device design process. Subsequently, the design output is translated (T_2) into the presentation of the new wearable system. Verification testing ensures that the technology is designed correctly, addressing both functional requirements and wearability to meet the needs of users throughout the medical device lifecycle. However, if the design outcomes are not validated to meet clinical needs, they will have little impact on clinical decision making. The design process can be executed proficiently and thoroughly verified, ensuring the device meets technical and engineering specifications. However, biosensor technology may still fall short of addressing real-world clinical needs—including wearability—if it is not rigorously validated. Clinical validation ensures that the technology not only performs as intended but also delivers meaningful, reliable, and actionable outcomes in the context of patient care. Without this critical step, even well-designed biosensors risk failing to translate into effective medical solutions, underscoring the essential distinction between technical excellence and clinical relevance. Efforts to optimize the performance and quality improvement of emerging technology are necessary, but the translation into clinical practice is hindered if, at the outset, T_1 fails to convert a complete set of user functionality specifications into a comprehensive set of design input specifications.

In Figure 1, we propose that if the clinical requirement for wearability is not integrated into the user functional specifications (represented by step T_1), the design process will advance to an output design (represented by step T_2) that fails to fully address the comprehensive needs of the clinical lifecycle. Issues related to design considerations for longer-term wear need to be considered in the device design process [32,33]. If on-body comfort is missing in the set of functional specifications, the device's ability to meet both user and clinical demands effectively is compromised.

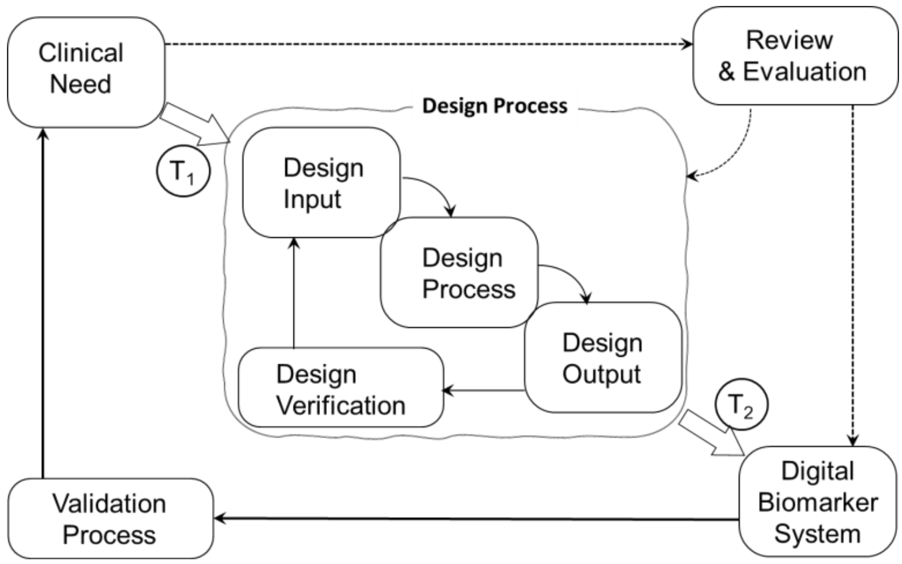

Figure 1. Distinction between design validation and clinical validation within the overall design of a wearable system. T_1 represents the translation of clinical needs into design input specifications, which guide the device design process. T_2 represents the translation of design output into the new wearable system.

Of particular interest in this study are the contemporary commercial wearable devices, particularly those popularized by the "quantified self" movement for health monitoring; many of these consumer devices are perceived as medical devices but are not, in fact, validated as medical grade. Despite their growing adoption, consumer devices often prioritize functionality over critical aspects like on-body comfort and long-term wearability. The current work seeks to identify research that addresses the interplay between ergonomic design, material innovation, and user compliance in wearable technology. Such a review can guide the development of devices that better meet both consumer and clinical demands for comfort and sustained usability. The current work distinguishes itself from conventional reviews that address wearability only in broad terms by delving into the critical nexus of design specifications and validation efforts, thus providing design guidance that can inform standards [23,34,35], leading to devices designed to meet the needs of users. Through an analysis of the existing literature, the study aims to uncover manuscripts rooted in empirical research, and directly connect device design with wearability outcomes that can inform the design and development of future wearable devices for health monitoring and beyond.

1.3. Research Questions

In this scoping review, the objective is to identify key concepts and determine the scope or coverage of the literature. While specific research questions are not required, having a set of general research questions helps guide the review process. Here are three general research questions for exploring the "wearability" of wearable devices in our scoping review:

1. What are the key factors influencing the wearability of wearable devices?
2. What methodologies and measures are used to assess the wearability of wearable devices?
3. What are the reported user experiences and satisfaction levels regarding the wearability of different types of wearable devices?

1.4. Design Considerations

Translating functional specifications into design specifications is a well-known challenge in design [36,37] and for the present work, Table 1 highlights 12 key parameters that assist in understanding the landscape of potential user needs and the related design criteria. Our scoping survey aligns with the Stanford Biodesign process by defining the problem space broadly to capture a wide range of user needs, not constrained by well-defined pre-existing functional specifications [31]. The parameters in Table 1 collectively ensure that the wearable device is practical, comfortable, and effective for use in a clinical trial setting. These design considerations are central to the critical appraisal of research studies.

Table 1. User needs and potential design specifications to consider in the design of a wearable device.

	User Need	Design Considerations
A.	Comfort	Evaluate the comfort of the device when worn for extended periods. This includes assessing the materials used, fit, weight, and overall ergonomic design.
B.	Fit and Adjustability	Ensure that the device can fit various body types and sizes. This includes the design of adjustable straps, bands, or other mechanisms to secure the device properly.
C.	Battery Life	Assess the duration the device can operate before needing a recharge. Longer battery life is preferable to reduce the frequency of recharging, which can affect wearability and user compliance.
D.	Durability and Robustness	The device should withstand daily wear and tear, including exposure to different environmental conditions like moisture, dust, and physical impact.
E.	Ease of Use	Evaluate how easy it is for users to operate the device. This includes the simplicity of putting it on and taking it off, as well as the user interface for any necessary interactions.
F.	Data Accuracy and Reliability	Assess the precision and consistency of the data collected by the device. Reliable sensors and accurate data collection are crucial for clinical trial validity.
G.	Mobility and Range of Motion	Determine how the device affects natural movement and range of motion. Assess whether it restricts movement during various activities.
H.	Integration with Clothing and Accessories	Determine how well the device integrates with different types of clothing and accessories. Assess whether it can be worn discreetly or if it interferes with other wearable items.
I.	Aesthetic Appeal	Consider the visual design of the device. It should be appealing or at least unobtrusive to encourage regular wear.
J.	Skin Compatibility	Ensure that the materials used do not cause skin irritation or allergies. This includes testing for hypoallergenic properties and the breathability of materials in contact with the skin.
K.	Connectivity and Data Transfer	Evaluate how the device connects to other systems or devices for data transfer (including the reliability and security of connections).
L.	Regulatory Compliance	Ensure that the device meets all the necessary regulatory standards and guidelines for medical devices. This includes certifications and compliance with the relevant health and safety standards.

Table 2 offers a rubric for evaluating papers based on their relevance to the user needs outlined in Table 1. Scores range from 1 to 10, where 10 indicates that the paper provides extensive data, examples, and critical analysis, making it highly relevant. Conversely, a score of 1 signifies that the paper either does not mention or only briefly touches on the topic without detail. This scoring system helps in assessing how well a paper meets the specified user requirements.

Table 2. Assessment rubric for evaluating references.

Assessment of User Need	Score
Reference does not mention or only briefly mentions, without detail.	1–2
Reference mentions with some detail.	3–4
Reference discusses with moderate detail and some context.	5–6
Reference provides detailed discussion w/ relevant data/examples.	7–8
Reference extensively provides comprehensive data, examples, and critical analysis.	9–10

2. Materials and Methods

A scoping approach was taken when collecting all the relevant papers for the literature review. Pilot testing of literature searches across multiple databases revealed a limited number of studies examining design guidance derived from wearable validation studies. Given the lack of specific questions and concepts for critical appraisal, a mixed-methods (qualitative and quantitative data) scoping review was deemed more appropriate than a systematic review. While a systematic review allows for the examination of practice based on the quality of evidence, specific deficiencies, and gaps in evidence to inform future research, the scoping review approach was chosen to better map the breadth and scope of the existing literature. A scoping review aligns with the current work in which we seek to identify evolving or emerging topics prior to undertaking a systematic review, the latter of which could meet the criteria for registration with Cochrane [38,39].

2.1. Search Strategy

Our mixed-methods scoping literature review search strategy employed PubMed, Scopus, Google Scholar, ScienceDirect, Cochrane, and ClinicalTrial.gov to identify scholarly works linking the concept of wearability with specific device design features and guidance. Preliminary work focused on articles, papers, reviews, and studies that explored the relationship between wearability and the design characteristics of wearable devices. By utilizing these comprehensive databases, we aimed to gather a diverse range of academic perspectives and findings on how design features influence the wearability of such devices.

The complexity of this topic became apparent in the need to identify slightly different sets of keywords when searching a specific domain. In a way, this slightly decomposes the original topic question into more focused searches to enable capturing the relevant literature from each domain. This is especially relevant in interdisciplinary topics where different fields may approach the topic from distinct perspectives. This approach allowed us to access a breadth of the relevant literature and insights, facilitating a thorough analysis of the interplay between wearability and device design. However, it is important to maintain coherence and relevance across the different search outcomes to ensure that the overall objectives of the review are met.

In this scoping review, we included references that were systematic reviews or mini-reviews, as these sources typically encompass citations that could be informative of experimental data or clinical trials. These references were explored with the belief that they may provide valuable insights into the scope of design criteria used in wearable device design. Additionally, we included references that described experiments with the potential to include or lead to clinical trial work, further enriching our understanding of the design and application of wearable devices.

Figure 2 illustrates word search results from six databases, yielding 130 manuscripts as the foundation for further scrutiny in the current work. Including the search keyword algorithm arguments in a scoping review is critical for ensuring transparency, reproducibility, and scientific rigor. These arguments offer a comprehensive account of our literature search process, which is fundamental to the integrity of any systematic or scoping review. By detailing the exact search terms, Boolean operators, truncations, and database-specific syntax, we provide a clear framework that allows other researchers to replicate the search.

This reproducibility is essential for verifying the findings and conducting subsequent studies. Furthermore, explicitly documenting the search strategy helps minimize selection bias, demonstrating that the review's scope is guided by predefined, systematic criteria rather than arbitrary decisions. Figure 3 illustrates the manuscript review process in a PRISMA flow diagram, identifying the final number of manuscripts from the database search and other sources that were subjected to detailed review.

PubMed Search A: Search returned 52 papers: ((((“wearability”[Title/Abstract])) AND ((“wearable”[All Fields] OR “wearable electronic devices”[All Fields] OR “wireless technology”[All Fields] OR “watch”[All Fields] OR “smartwatch” [All Fields] OR “Fitness Trackers”[All Fields]))) AND (review[Filter]))
PubMed Search B: Search returned 35 papers: ((((“wearability”[Title/Abstract])) AND ("validity"[all fields] OR "cardiovascular"[all fields] OR "reliability"[all fields] OR "wearability" [all fields]) AND ("monitoring" [all fields]) AND ("wireless technology"[all fields]))
PubMed Search C: Search returned 28 papers: (“wearability”[Title/Abstract]) AND (“design”[Title/Abstract])
Google Scholar: Returned 6 papers intitle:wearability AND intitle:design AND intitle:wearables
ScienceDirect: Returned 19 papers: Title (wearability AND design AND wearables)
Scopus: Returned 12 papers wearability AND design
Cochrane: Returned 18 papers (“wearability” OR “design”) AND ”wearables” [in Title/Abstract]
ClinicalTrials.gov: Returned 1 study: (wearability OR design) AND wearables

Figure 2. Keyword search results from a mixed-methods scoping review conducted across six databases, yielding 130 manuscripts as the foundation for further scrutiny in the current work.

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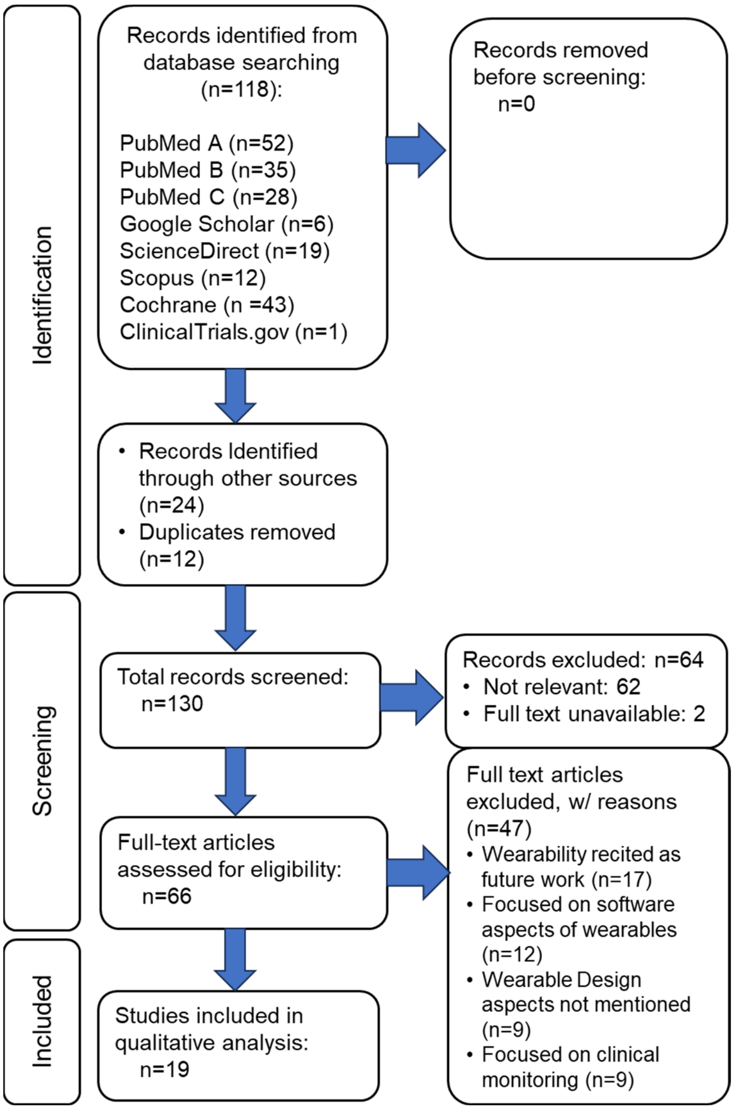

Figure 3. PRISMA flow diagram of the wearability literature review process for studies on the wearability of wearables.

2.2. *Eligibility Criteria and Screening*

The inclusion criteria for our scoping review required a focus on the qualitative aspects of wearability concerning wearable devices. This was to ensure the inclusion of studies examining user experiences, perceptions, and subjective evaluations of device comfort, usability, and overall satisfaction. Papers meeting this criterion provide valuable insights into the qualitative dimensions of wearability, highlighting the factors influencing user acceptance and adoption.

Additionally, our review targeted papers reporting on quantitative pilot studies or clinical trials that specifically examined the device wearability-related outcomes described in Table 1. Such studies employ quantitative methodologies to assess the objective measures of wearability, such as ergonomic design features, physiological impacts, and usability metrics.

By incorporating quantitative data, these papers contribute to a more comprehensive understanding of the effectiveness and efficacy of wearable device designs in enhancing user experience and usability. Furthermore, manuscripts intended for inclusion had to report a link between wearability and device design. These papers elucidated how specific design features or interventions influence the wearability of wearable devices, providing empirical evidence of the relationship between design and user experience. By examining this link, these manuscripts offer valuable insights for designers, engineers, and researchers seeking to optimize wearable device design to maximize user comfort, usability, and overall wearability.

Manuscripts that did not meet these eligibility criteria were excluded from the pool of candidate studies for detailed review.

3. Results

Table 3 lists the 19 literature search outcomes. Although this is a fairly small subset of papers for further study, it, nonetheless, represents the current state-of-the-art in research related to wearable device design for comfort and wearability. Despite the extensive body of literature on wearable technology, our specific criteria—focusing on qualitative wearability assessments, quantitative evaluations, and the relationship between design features and user experience—resulted in a significantly narrowed pool.

Table 3. Publications selected for a detailed content review as the potential sources of relevant user need and human factor data.

	Author	Year	Type	Title
1.	Canali et al. [40]	2022	R	Challenges and recommendations for wearable devices in digital health: Data quality, interoperability, health equity, fairness
2.	Cho et al. [41]	2022	R	Smart electronic textiles for wearable sensing and display
3.	Ferguson et al. [16]	2021	R	Wearables only work on patients that wear them: Barriers and facilitators to the adoption of wearable cardiac monitoring technologies
4.	Ferraro and Yavuz [24]	2011	D	Designing wearable technologies through a user centered approach
5.	Frances-Morcillo et al. [23]	2020	D	Wearable design requirements identification and evaluation.
6.	Friend et al. [3]	2023	R	Wearable digital health technology.
7.	Ginsburg et al. [4]	2024	D	Key Issues as Wearable Digital Health Technologies Enter Clinical Care
8.	Gemperle et al. [42]	1998	D	Design for wearability
9.	Haghi et al. [43]	2021	R	Wearable Devices in Health Monitoring from the Environmental towards Multiple Domains: A Survey
10.	Jamshidi et al. [44]	2024	E	The design and fabrication of a wearable lattice-patterned 3D sensing skin
11.	Kim et al. [45]	2019	R	Wearable biosensors for healthcare monitoring
12.	Lee et al. [46]	2021	R	Evidence for the Effectiveness of Feedback from Wearable Inertial Sensors during Work-Related Activities: A Scoping Review
13.	Lind et al. [47]	2023	D	Wearable Motion Capture Devices for the Prevention of Work-Related Musculoskeletal Disorders in Ergonomics
14.	Liu et al. [48]	2023	R	Recent Advancements in Physiological, Biochemical, and Multimodal Sensors Based on Flexible Substances: Strategies, Technologies, and Integrations.
15.	Shah et al. [49]	2022	R	Applications of nanotechnology in smart textile industry: A critical review.
16.	Tandon et al. [50]	2024	R	A systematic scoping review of studies describing human factors, human-centered design, and usability of sensor-based digital health technologies
17.	Uchitel et al. [51]	2021	R	Wearable, integrated EEG-fNIRS technologies: A review
18.	Zhao et al. [52]	2022	R	Recent advances in flexible and wearable sensors for monitoring chemical molecules
19.	Zhao et al. [53]	2023	D	Emerging sensing and modeling technologies for wearable and cuffless blood pressure monitoring

Legend: R—systematic, umbrella, scoping, or short review paper; D—paper describing the design of a system or subsystem; E—report on the outcome of an experimental or non-clinical test.

Many of the papers identified during our review did not meet our inclusion criteria due to their primary focus on sensing materials, new sensor designs, or data analytics. While these papers contribute valuable insights into the broader field of wearable technology, they did not directly address wearability aspects or the impact of design features on user experience—the central themes of our study.

Despite the limited quantity of qualified papers, the selected subset exhibits diversity in methodologies, perspectives, and findings. These papers frequently represent cutting-edge research efforts aimed at enhancing wearable device comfort and wearability, showcasing innovative approaches, emerging trends, and relevant challenges. Although the literature search outcomes featured specific design data, our focused analysis in the next section aims to uncover key insights and implications that can inform future research and contribute to the ongoing evolution of wearable technology, ultimately optimizing user experience and satisfaction.

Each of the 19 papers was reviewed to determine whether it included one or more of the user need design criteria. The scores presented in Table 4 are based on the scoring rubric outlined in Table 2. After evaluating each paper's ability to address the user need design criteria, an average score was calculated based on an unweighted average of the 12 design criteria; this is shown in Table 4 as the "average score."

Table 4. User need design criteria scores for the publications selected for detailed review. The assessment criteria for each user need is provided in Table 2. The average score is computed as an unweighted average of the twelve criteria A–L.

		User Need Design Criteria												Average
	Reference	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	**L**	**Score**
1.	Canali et al. [40]	2	2	1	3	2	4	2	1	2	2	2	1	2.0
2.	Cho et al. [41]	2	2	1	1	5	7	3	1	1	1	3	1	2.3
3.	Ferguson et al. [16]	4	4	4	4	8	5	1	3	7	1	3	1	3.8
4.	Ferraro and Yavuz [24]	6	6	2	2	6	3	6	5	4	3	2	2	3.9
5.	Frances-Morcillo et al. [23]	7	7	5	8	8	5	5	5	5	3	3	1	5.2
6.	Friend et al. [3]	3	5	5	6	5	7	2	2	2	6	8	7	4.8
7.	Ginsburg et al. [4]	1	1	5	3	7	9	5	3	3	6	9	9	5.1
8.	Gemperle et al. [42]	3	8	1	7	1	1	9	2	2	6	1	1	3.5
9.	Haghi et al. [43]	2	2	8	6	4	9	2	2	2	4	9	4	4.5
10.	Jamshidi et al. [44]	1	1	1	4	4	6	1	1	5	10	5	1	3.3
11.	Kim et al. [45]	2	2	5	4	4	7	4	4	4	10	10	1	4.8
12.	Lee et al. [46]	3	5	5	6	5	6	10	7	2	4	7	1	5.1
13.	Lind et al. [47]	1	3	1	3	1	6	9	9	2	2	3	2	3.5
14.	Liu et al. [48]	2	2	6	6	1	3	1	1	2	6	5	1	3.0
15.	Shah et al. [49]	1	1	4	4	4	4	1	9	6	4	5	1	3.7
16.	Tandon et al. [50]	5	5	1	1	5	6	5	1	2	2	2	2	3.1
17.	Uchitel et al. [51]	2	2	3	5	1	5	1	1	1	6	5	1	2.8
18.	Zhao et al. [52]	1	2	2	2	1	7	1	1	2	5	5	1	2.5
19.	Zhao et al. [53]	2	2	2	3	2	4	1	1	1	3	3	1	2.1

Legend: A. Comfort; B. Fit and Adjustability; C. Battery Life; D. Durability and Robustness; E. Ease of Use; F. Data Accuracy and Reliability; G. Mobility and Range of Motion; H. Integration with Clothing and Accessories; I. Aesthetic Appeal; J. Skin Compatibility; K. Connectivity and Data Transfer; L. Regulatory Compliance.

Table 5 was then used to make an approximate assessment of the cross-reference for the evaluation of the potential impact a reviewed manuscript may have as a data source for the "design for wearability" process. This created three categories of papers as a way to summarize the abundance or absence of design data that would have an impact on an effort to design for wearability.

Table 5 enables the results of Table 4 to be prioritized for the potential impact a reviewed manuscript may have as a data source for the "design for wearability" process. Table 6 provides the impact scale along with a brief summary description of each of the papers reviewed.

Table 5. Cross-reference for the evaluation of the potential impact a reviewed manuscript may have as a data source for the "design for wearability" process.

Assessment	Average Score	Impact
Minimal value as a data source for design	Under 3	Low
Provides indirect linkage to studies or reviews with data	3–5	Medium
Recites data that has potential support for device design	Over 5	High

Table 6. Summary description for each of the publications selected for detailed review. The scale of impact as a potential data source for the "design for wearability" process is provided in Table 5.

Paper	Author	Scale	Summary Description
1	Canali et al. [40]	L	The paper maps out the principles for which wearable devices can be measured and the ethical problems they present. The paper recognized the gap in equity and medical literacy when it comes to wearable devices. Though the paper recognizes and comments on ethical topics/issues, it does not touch on the design and engineering process of them.
2	Cho et al. [41]	L	The paper focuses on the aspects of the design and use of e-textiles. Though the paper mentions many issues related to the use of textiles for wearable technology, specific links to device design are absent.
3	Ferguson et al. [16]	M	This paper focuses not only on the developmental and design aspects of wearable technology, but it also addresses the ethical and social barriers that are presented that may hinder the use of them. Cardiac devices are used as an example and design for specific end-users is discussed, such as the elderly.
4	Ferraro and Yavuz [24]	M	The paper is directed towards designers who are responsible for upcoming wearable technology to consider the human aspects in the design. The paper has a portion focused on the wearability of products and suggests a user-adjustable approach to this issue. The paper also mentions how devices affect human life and what the body "senses" from these new technologies. The paper informs on psychological aspects of rejection reactions that might occur by patients of older age.
5	Frances-Morcillo et al. [23]	H	The paper is directed towards identifying the design features of the wearability of wearables. The paper includes surveys from experts who are developing wearable technology and presents the results of questionnaires.
6	Friend et al. [3]	M	The paper focuses on clinical insight that could result from the clinical trials of wearable devices. Although the paper identifies challenges in the field of wearables, no specific data are provided.
7	Ginsburg et al. [4]	H	The paper successfully mentions the challenges encountered while pursuing the application of wearable technologies to healthcare. It is ranked high due to the inclusion of regulatory issues and the need for design standards.
8	Gemperle et al. [42]	M	The paper is directed toward identifying specific design considerations that prevail when wearables are used in high-activity scenarios. The paper does not include design data but addresses device detachment during motion.
9	Haghi et al. [43]	M	The paper highlights the psychological aspect of utilizing wearability and the patient's responses towards implanting or using or wearing wearables. Although the design specifications are not discussed, the specifications to be considered when applying wearable sensors to clinical settings are presented.
10	Jamshidi et al. [44]	M	With a focus on the interaction between wearable devices and body location, the paper provides ideas to consider when studying the interaction itself. The paper focuses on the joints and appropriate location of wearables.
11	Kim et al. [45]	M	The paper provides a comprehensive study of the different types of wearable sensor technology and the nature of the data that can be collected. This is an ideal manuscript to identify wearability relative to sensor data.

Table 6. *Cont.*

Paper	Author	Scale	Summary Description
12	Lee et al. [46]	H	The paper highlights the influences of wearability on the biosensor field. Although the paper does not discuss the "design aspects" of wearability directly, it does discuss the guidelines of wearability. They introduce a "Technological and Design Checklist" of wearable inertial sensors and also underline the importance of personalized designs to enhance the wearability experience for patients
13	Lind et al. [47]	M	The paper highlights human movements in the context of typical work-related musculoskeletal activities. The paper recites issues in current use-case applications, challenges, and detailed future opportunities. The paper is focused on muscular data collection.
14	Liu et al. [48]	M	The paper is directed towards materials that can enhance the wearability experience of the patient. The paper then focuses highly on the improvements that should be made to utilize the fiber-contained devices to become practical in the field.
15	Shah et al. [49]	M	The paper focuses on the different smart textiles that can be utilized to enhance the wearability of sensor clothes. Additionally, it categorized different textiles for different usage of clothing sensors such as electrically conductive textiles and energy-storing textiles.
16	Tandon et al. [50].	M	The paper offers a comprehensive review of digital health technologies relative to approaches to evaluating sensor wearability, with a special focus on human factors, human-centered design, and usability. Suggestions are included on how to improve the digital health technologies field, but no data are provided.
17	Uchitel et al. [51]	L	The paper emphasizes the integration of EEG and fNIRS for portable, affordable, and appropriate long-term monitoring. The paper highlights the evaluation of the types of EEG electrodes and amplifiers though only peripherally mentions device design aspects of the technologies.
18	Zhao et al. [52]	L	The paper emphasizes flexible wearable devices for real-time health monitoring based on small, soft, and low-cost materials. The paper focuses on the wearability of chemical sensors for various biomarkers, commenting on the advantages and disadvantages.
19	Zhao et al. [53]	L	The paper emphasizes the challenges of monitoring blood pressure and focuses on topics such as flexible sensing, signal collecting and processing, noise reduction, and estimation models for blood pressure extraction. The accuracy of continuous data collection is discussed.

In summary, nineteen papers were reviewed to determine if they met the user need design criteria. The scores were calculated based on a rubric and averaged across the 12 design criteria, as shown in Table 4. Table 5 was used to assess the potential impact of each paper on the "design for wearability" process, categorizing them into three groups based on the abundance or absence of relevant design data. This prioritization helps identify which papers are most valuable as data sources for designing wearable products. Table 6 provides an impact scale and brief summaries of each reviewed paper.

4. Discussion

It seems logical that the greater the wearability of a device, the more likely people are to consistently use it or comply with long-term usage recommendations. The current work finds that while numerous wearable technologies have been proposed and some have entered the commercial market, very little scholarship prevails on how to design for wearability. While the dominant use of wearables is for fitness applications, comprehensive studies on wearability and its impact on usage and accuracy in clinical contexts remain scarce. Validated design standards and recommendations for designing for wearability are virtually absent.

In our review of 19 research papers related to wearable devices, Tables 3, 4 and 6 succinctly present a summary description for each of these papers, capturing their key findings, methodologies, and contributions. However, mere summaries do not suffice; we sought to distill their relevance further.

To achieve this, we devised a ranking system that led to a cross-reference for the potential impact a reviewed manuscript may have as a data source for the "design for wearability" process. This assessment considered factors such as alignment with our research focus, methodological rigor, and impact on the field. Approximately 90% of the papers were ranked as providing low or medium impact in terms of the ability to inform the design for the wearability process.

Although some studies emphasize user-centered design, objective metrics are often missing, and the concept of long-term wearability does not always align with patient needs. Notably, compliance with wearables tends to decline over time during research studies. For instance, in an adult study involving wristwatch-style wearable biosensors, mean daily data collection hours decreased from 13.3 to 6.3 h over a 6-month period [54]. In another study, workers were asked how comfortable they found a temperature measurement sensor worn for an 8 h work shift, though data on the impact of design on wearability was not collected [55]. Wearable devices that study self-powered systems [24,56] center on the technology to power a device but not on specific design elements for long-term wear. Recent research studying the continuous monitoring of fall detection utilizing machine learning has the potential to tease out wearability classification, but the study design did not explore wearability [57].

With the Stanford Biodesign process in mind, user need is a critical starting point in design, and demographics matter [31]. For instance, consider the unique case of wearables for children. For applications in children, sensing modalities are limited due to size and sensitivity requirements. Currently, studies are limited to the recordings of ECG, audio, and accelerometer signals. There have been no studies of pO2, blood pressure, respiration, or other important biological signals. Assessments examine (a) increased compliance due to good comfort and interesting features [48] and (b) decreased compliance related to devices being uncomfortable [58,59], embarrassing, noisy, or falling off a lot [60].

Ensuring wearability is crucial for the real-world adoption of wearable devices. However, despite the growing interest in wearable biosensors, many studies fail to address wearability [21,61]. Unfortunately, our understanding of wearability has seen limited progress over the past several years [62]. Enhancing wearability assessment is essential for advancing translational research and promoting the wider adoption of well-designed wearable biosensors.

Limitations

Our review has two main limitations:

1. Despite providing insight into the limited data available to support design for wearability, the sample size for the scoping review was small and the search terms may not have been adequate to tease out design data. The field of digital medicine continues to evolve rapidly, and investigators may use terms in their studies that we did not use in our search.
2. Our search was limited to the peer-reviewed literature. It seems reasonable that we are unaware of many usability studies undertaken by technology manufacturers—the clinical trials we reviewed that were sponsored by the industry appeared to be more for the goal of collecting marketing data, not providing design insight.

Given that our comprehensive scoping effort yielded few relevant manuscripts from the research pool, it may be worth considering whether a shift in the research question should have been explored. Our primary research questions, outlined in Section 1.3, focused on identifying the data-driven studies that specifically examined clinical trials on factors influencing wearability, methods to assess wearability, and reported user experiences and satisfaction with wearability.

A strategic shift in our approach could potentially yield new insights. For example, employing a search algorithm with keywords aimed at identifying studies designed to enhance wearable device comfort and wearability—integrating both innovative and established design approaches—could indirectly highlight specific design features that improve wearability. While such a shift could address the current study limitations by incorporating a broader range of research and methodologies, this indirect approach to discussing data-driven clinical trials on wearability might only underscore the notable absence of intentional design for wearability in the existing literature.

5. Conclusions

In this scoping review, we conducted a methodical examination of the open-access literature within the wearable technology domain. Scoping reviews are known for their ability to provide a broad overview of the existing research, and the current work enabled us to identify three significant limitations in prior studies. These limitations highlight fundamental gaps in the current body of knowledge, particularly in areas where evidence is sparse or fragmented. We have systematically approached identifying critical gaps in the functional specifications of on-body device wearability, emphasizing the urgent need for novel, targeted research to address three fundamental challenges. This research holds the potential to advance both the theoretical foundations of the field and its practical applications, ultimately driving innovation in design and enhancing user experience. We conclude that targeted research is needed to address the following three research gaps to enable advancements in both the field's theoretical foundations and its practical applications:

1. Lack of Standardized Assessment Methods: The absence of an accepted and standardized method for assessing wearability has resulted in inconsistent evaluations across studies. Researchers often rely on subjective criteria, leading to variability in how wearability is measured and reported.
2. Qualitative Nature of Assessments: Most existing assessments of wearability remain qualitative, lacking objective metrics for rigorous analysis. While self-report scales provide valuable insights, they fall short of quantifying wearability in a consistent and comparable manner.
3. Limited Utility for Design: Despite the wealth of existing studies, their qualitative nature and lack of quantifiable data hinder their practical utility in designing wearable devices. Insights gleaned from these studies do not directly inform design decisions or address the specific needs of users.

To advance the field, it is imperative to address the three limitations outlined above. Researchers must collaborate to establish robust methodologies for assessing wearability objectively. By doing so, we can enhance the design, usability, and overall impact of wearable technologies, ultimately benefiting users and advancing the field.

To evaluate the integration of "wearability" in medical devices, it is essential to consider a comprehensive framework that examines both the subjective and objective aspects of wearable comfort. Wearability should be assessed in terms of physical and psychological comfort, with physical comfort relating to the device's physical contact with the body, such as wearing methods, regions, materials, and design configurations. Psychological comfort focuses on the user's sensory and emotional perceptions, including concerns about safety, reliability, and overall user confidence in the device. Metrics for evaluation can include adherence and compliance rates, as these reflect user engagement and alignment with prescribed usage. Subjective assessment tools, such as Visual Analog Scales (VAS) or Likert Scales, allow users to report their perceptions of comfort, while objective methods employ physiological measurements to infer wearability indirectly. By integrating these approaches, researchers can effectively evaluate factors influencing user acceptance and device performance, ensuring that medical devices meet standards for safety, accuracy, reliability, and user-centered design.

Future Directions

Future research in the wearable technology domain must prioritize addressing the three critical gaps identified in this scoping review. First, there is a pressing need to develop standardized methods for assessing wearability. The current reliance on subjective and inconsistent criteria has led to variability in evaluations, making it difficult to compare findings across studies. Establishing universally accepted protocols will enhance reliability and reproducibility in wearability research.

Second, transitioning from predominantly qualitative assessments to the inclusion of objective metrics is essential. While qualitative insights are valuable for understanding user experiences, the lack of quantifiable data limits the rigor and comparability of current research. Developing comprehensive, objective tools for evaluating wearability will strengthen the field's analytical foundation.

Lastly, researchers must bridge the gap between assessment and application. The existing studies often fail to translate findings into actionable insights for device design, leaving user needs unaddressed. Future work should integrate usability-focused methodologies that directly inform the creation of innovative, user-centered wearable devices.

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