

User-Centered Design of a Wearable Gait Analysis Tool for Knee Endoprosthesis Rehabilitation

Katharina Lorenz¹, Hannah Friederike Fischer^{1,*} and Daniela Wittmann¹

¹German Research Center for Artificial Intelligence, Berlin, Germany

Abstract

With more than 193,000 cases in Germany in 2019, total knee endoprostheses (knee-TEP) are among the 20 most common surgeries performed on hospitalized patients [1]. A standard method for assessing post-operative mobility is the manual measurement of range of motion using a goniometer. This method is subjective, dependent on the clinician's experience, and provides only a snapshot of the patient's condition. Existing sensor-based systems for gait analysis are primarily designed for clinical use and research contexts, and are generally not intended for independent application by patients at home. To complement these solutions, we developed a mobile, wearable sensor system and a corresponding app that enables self-administered gait analysis and mobility assessment for patients with knee-TEPs in both clinical and home settings. This paper presents key insights gained from a user-centered design process employing participatory methods, highlighting implications for the development of patient centered rehabilitation technologies.

Keywords: User-centered design, Rehabilitation Tool for Patients with Knee Endoprostheses, IMU-Based Wearable for Gait Analysis.

Received on 15 September 2025, accepted on 30 October 2025, published on 18 December 2025

Copyright © 2025 Katharina Lorenz *et al.*, licensed to EAI. This is an open access article distributed under the terms of the [CC BY-NC-SA 4.0](#), which permits copying, redistributing, remixing, transformation, and building upon the material in any medium so long as the original work is properly cited.

doi: 10.4108/eetpht.11.11379

1. Introduction

With more than 193,000 cases in Germany in 2019, total knee endoprostheses (knee-TEP) is one of the 20 most common surgeries performed on hospitalized patients [1]. The most common cause of knee-TEP is a severe degeneration in the joint through osteoarthritis [2], which causes pain and limited mobility of the patient. Knee-TEP is a common orthopedic surgery that replaces the articular surfaces of the knee joint [3]. The orthopedic surgery aims to relieve pain, increase functionality and therefore improve the patients' quality of life [2].

A common post-operative recovery method to check the mobility of the patient, is the measurement of the range of motion using a goniometer, which is documented manually by hand. The measurement process is subjective and dependent on the experience of the person carrying it out

and only provides a snapshot of the overall circumstances. Although sensor-based systems for technically supported gait analysis already exist (e.g., from G-Walk from SinfoMed, Ultium Motion from NORAXON), they primarily focus on clinical use and research and are not designed for independent application by patients at home. With the OrthoSuPer project, we aim to develop a system that can be used not only in clinical settings but also by patients independently in their home environment. This approach enables patients to conduct gait analysis autonomously, facilitating continuous monitoring of their rehabilitation progress and potentially enhancing their engagement in the recovery process. Our system builds on the success of digital health applications (DiGAs), which have been scientifically shown to improve treatment outcomes and enhance patient motivation [4, 5]. The integrated system comprises a wearable sensor device, supported by a mobile application for patients and a digital

*Corresponding author. Email: hannah.fischer@dfki.de

platform for clinicians. It enables time-specific gait assessments throughout the rehabilitation process, both in clinics and at home, allowing for the early detection of poor healing processes. The wearable components include a strap-based sensor system for clinical settings and smart trousers designed for home use. Both are equipped with reliable, commercially available, inertial measurement units (IMU) (Movella DOT, El Segundo, CA, USA).

This paper provides an overview of the user centered design process and participatory methods employed in the development of the integrated rehabilitation system for patients with knee-TEP. We report key insights gained through participatory approaches, emphasizing their implications for the design of patient-centered rehabilitation technologies.

According to DIN EN ISO 62366, a user-centered design approach is essential in the development of healthcare technologies as it helps to avoid operating errors, increase the usability of medical devices, and thus improve the safety and effectiveness of clinical applications sustainably [6]. Furthermore, user-centered design is important because it results in better products, speeds up market launch and reduces the time and costs associated with manufacturing and evaluating unsuitable prototypes [7].

This paper presents the conceptualization and prototypical development of the demonstrator. A final user evaluation had not yet been conducted at the time of publication and is planned for the subsequent project phase. Accordingly, the aim of this paper is to document the development process and to provide insights that will inform the forthcoming validation.

2. Use Case, Wearable Design and System Overview

The system provides targeted and personalized support to patients undergoing knee replacement surgery during the treatment and rehabilitation process.

A mobile, wearable sensor system and a corresponding app enable self-administered gait analysis and targeted mobility measurements in clinical and domestic contexts. The system consists of adjustable straps for clinical use and smart trousers that are easy to wear for home use (see Fig. 1). Both systems allow for the placement of seven small, lightweight, and wirelessly interconnected inertial measurement units (IMUs) with high reliability on the feet, lower legs, thighs, and hips to record pre- and postoperative data (see Fig. 2). Sensors can be removed, which guarantees hygiene and washability, as well as the possibility of repair. A color-coded system ensures the sensors are placed consistently and easily, which is crucial for reliable gait analysis.

The associated app provides patients with information tailored to their individual treatment needs throughout the entire treatment process and in subsequent phases. It can be used for documentation and self-reporting (e.g. pain levels), to provide feedback on gait analysis progress, and

serves as a motivational tool. An associated digital platform enables medical staff to monitor patients' rehabilitation progress in order to respond to potential complications early on.

The design of the wearable system, with particular emphasis on user-centered aspects, is presented in the following section.

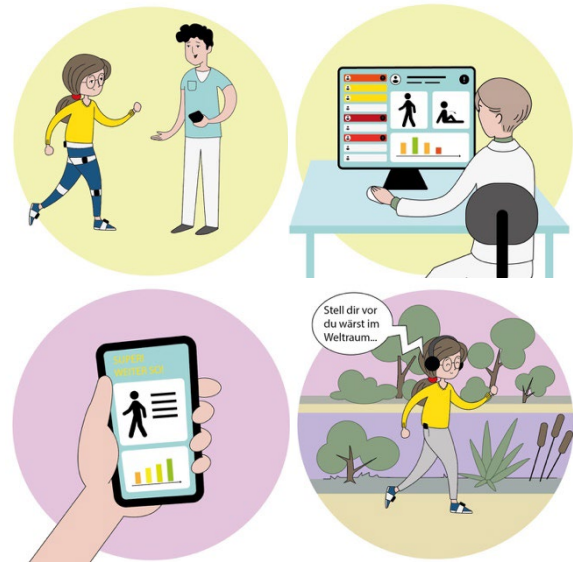


Figure 1. Illustrated use case of the system from right to left: (1) A strap-based wearable device to carry out gait analysis in clinical settings. (2) A digital platform that allows medical staff to monitor patients' rehabilitation progress. (3) A patient app providing individualized, targeted support throughout the treatment process. (4) Smart trousers to carry out gait analysis in domestic contexts

2.1. Mobile Sensor Strap system for clinical use by medical staff

The sensor strap system is specifically designed for clinical use, allowing medical staff to quickly fit sensors on patients of varying sizes through a highly customizable design (see Fig. 3). The system employs a unified design for foot sensors and body sensor straps, using narrow, non-slip, one-sided Velcro bands made of neoprene that are available in multiple sizes and can be adjusted for an optimal fit. Mushroom head Velcro fasteners ensure secure attachment in combination with 3D-printed sensor casings made from flexible material (Formlabs Inc., Flexible 80A Resin, Berlin, DE), whose geometry guarantees stable fixation of the sensors during movement. A color-coded system facilitates correct sensor placement by matching each sensor and its corresponding holder with a distinct color. A labeled, colored text indicates the anatomical location of the strap (e.g. "Right Leg"), thereby minimizing errors during setup.

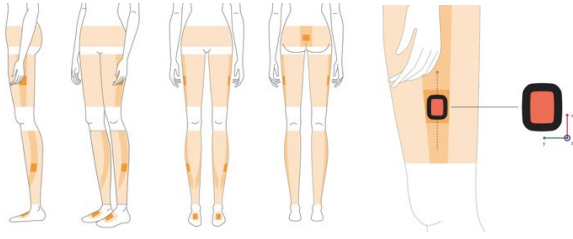


Figure 1. Placement of sensors



Figure 2. Design Sensor strap system: (1) Mushroom head Velcro fastener (2) One-sided Velcro bands made of neoprene with labeling (3) 3D-printed sensor case (4) Integrated opening in the sensor case serving as closure

2.2 Smart Trousers for personal use in home environment

A trouser design was developed to ensure the easy and reliable placement of sensors for patients when used in a home environment (see Fig. 4). This design enables independent gait analysis and allows the patient's rehabilitation progress to be monitored in a home environment. The sensors are integrated into the trousers via a pocket system: before being put on, the sensors are inserted into specially adapted pockets secured with zippers, which prevent them from slipping during movement and thus ensure constant signal quality of the IMU-Sensors. The color-coding for correct sensor placement is located inside the pockets, enhancing the handling and setup process without compromising the trousers' aesthetics.

The design is based on athletic, tight-fitting unisex leggings, that covers a wide range of body types. It provides a pocket for the smart phone and an additional opening with a large zipper closure at the calf, making them easier to put on and take off, especially for people with limited mobility. The trousers can optionally be combined with matching short over trousers. The material is a blue, lightweight, stretchable jersey knit fabric made of nylon and elastane.

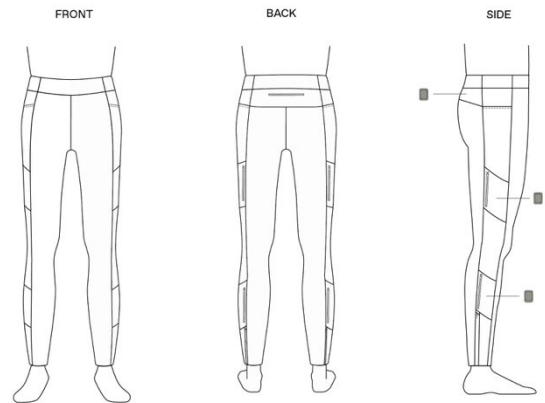


Figure 3. Design of trousers with integrated sensor pockets

3. Participatory design process and applied methods

This project follows a participatory design process to develop a wearable system with highest user acceptance. Potential users and relevant stakeholders were involved in the entire design process to ensure acceptance and usability (see Fig. 5). The participative activities, including methods employed as well as relevant results are presented below. The reported results should be regarded as interim findings within the ongoing development process, as a final evaluation had not yet been conducted at the time of publication.

All collected data were pseudonymized and processed in compliance with the GDPR; storage was secured and access was restricted to authorized personnel. Participants provided their informed consent prior to inclusion.



Figure 4. Overview of the participatory design process.

3.1 Interdisciplinary workshop with experts to develop an initial use case

At the beginning of the project, an interdisciplinary workshop was conducted with 11 experts from diverse domains, including medicine (surgery), orthopedic technology, design and engineering. The aim was to

develop a shared project vision and to define a user journey that informs the development of an initial use case. During the workshop, methods such as personas and storyboards were employed to foster the participants' empathy with potential users and to develop a user journey that illustrates how different stakeholders use the system (see Fig 6).

The workshop's key findings included identifying central treatment phases (preparation phase, surgery, stationary rehabilitation, outpatient rehab at home, check-up appointment in the surgical clinic) and key stakeholders (patients, surgeons and rehabilitation physicians), which were then applied to an initial use case. The workshop results formed the basis for the development of further participatory formats, specifically designed to capture the perspectives and requirements of other stakeholders.



Figure 5. Storyboards developed by workshop participants

3.2 Expert interview on rehabilitation after knee TEP

As part of the requirement analysis a two-hour guided interview was conducted with a senior physician at a rehabilitation clinic as well as an observation during a clinical examination in aftercare. The observation and interview were conducted in a rehabilitation clinic that treats patients after knee surgery from a partner hospital within the consortium. The aim was to record the perspectives of doctors on the rehabilitation processes as well as to identify critical phases, and challenges in the rehabilitation and everyday lives of patients with knee TEPs. Additionally, the requirements for the technical system were determined. The findings of the interview and observation were used to improve the overall understanding of the potential users and application context and to derive system requirements and ideas for potential applications. The findings of the interview and observation relevant to the subsequent development of the use case are presented below.

Rehabilitation process and objectives. Inpatient rehabilitation usually starts between the third and tenth postoperative day. During the patient's three-week stay a standardized therapy program is adapted to each patient's

needs, including individual and group therapy, gait training, and manual lymphatic drainage, among other treatments. The aim of rehabilitation is to regain physical function to the greatest extent possible. Milestones include (1) achieving wound healing, (2) regaining mobility, (3) strengthening the muscle tissue, (4) reducing swelling, and (5) restoring an unimpeded gait. As the entire rehabilitation process usually extends beyond the clinical stay, the technical system must be adapted and configured for long-term use, thus extending monitoring and evaluation to the home environment. Thus, as the patient proceeds from one environment to another, and as the care level moves from expert care giver to patient, a user-friendly design of the wearable device and patient app is required.

Parameters for assessing the progress of rehabilitation. The range of motion of the knee angle is an important criterion for measuring the progress of a patient's rehabilitation. However, the quality of movement within the functionally relevant limit range is more important than the absolute measurement of the knee angle. Thus, providing automatic feedback through the system in the event of critical deviations could improve therapeutic treatment.

The system also includes the development of an automated gait analysis tool. At present, gait patterns are assessed through visual observation by medical practitioners. Medical practitioners monitor for asymmetries, such as differences in the duration of the stance or swing phases of the two legs. Utilizing data-supported gait analysis could facilitate the early detection of abnormalities after clinical discharge and enable timely intervention.

Motivation and customization. Most patients demonstrate a high level of intrinsic motivation due to the extensive preparation for the procedure. To achieve a balanced rehabilitation process and avoid over- or underchallenging the patient, therapeutic care in rehabilitation requires a high degree of individualization: Anxious patients require motivational support, while over-motivated patients need to be slowed down to prevent overload and regression.

An adaptive technical system could recognize these different behavioral patterns and address them in a targeted manner, for example by providing personalized instructions, exercise recommendations and educational content.

3.3 Patient survey

14 patients (8 female, 6 males; aged 55–75) with knee-TEP were interviewed around six weeks after surgery at an orthopedic hospital. Participants were recruited through the orthopedic hospital and took part in the project on a voluntary basis, motivated by their own interest. The aim was to gain insights into the patients' experiences of the rehabilitation process, as well as their needs, expectations, and wishes with regard to the planned system. Data was collected using a questionnaire (14 participants) and guided

interviews (10 participants). The results served as a basis for the subsequent development of the use case and design decisions. Selected results are presented below.

Assessment of system functions. Eight potential system functions were presented to the patient and they were asked to indicate those that they found to be beneficial (see Fig. 7). The vast majority rated feedback on their individual therapy progress as particularly relevant (9 out of 10 people). Personalized training plans and motivational elements to encourage exercise were frequently requested (7 out of 10 people). Five out of ten people indicated a preference for assistance with independent training in domestic environment and access to their exercise data.



Figure 6. Patients' assessment of the benefits of potential system functions – Evaluation of the planned functions of a digital measurement system in a rehabilitation context

Application context. As rehabilitation after knee-TEP comprises various treatment phases (surgery clinic, rehabilitation clinic and home context), participants were asked to assess the system's relevance in each of these phases (see Fig. 8). The majority (11–13 participants) stated that they were to likely use the system at home. Many (7–11 participants) considered it beneficial to use the system during a rehabilitation stay. Only a few respondents referred to using the device post-surgery in the surgery clinic as an ancillary benefit, as pain management and recovery are main concerns during this phase (4 to 5 participants answered 'yes' or 'rather yes').

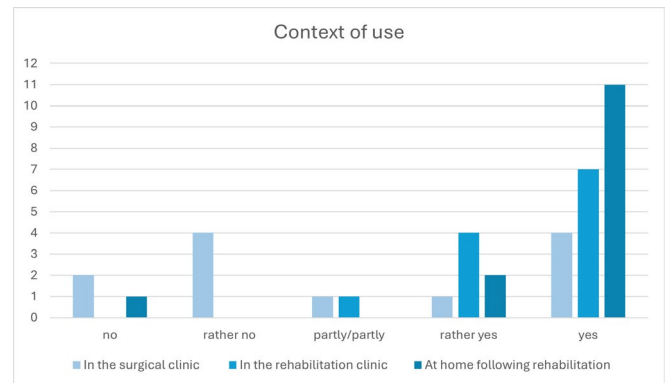


Figure 7. Assessment of the system's relevance in different rehabilitation phases (surgery clinic, rehabilitation clinic, home context) on a scale from 1 (not useful) to 5 (very useful)

Design of the wearable. Patients were surveyed about their design preferences about the wearable system. Developing a comfortable and intuitive system is central to ensure optimal usability (multiple responses possible) (see Fig. 9). The majority of the participants (7 out of 10) preferred integrating the sensor system into trousers, citing the design practical and comfortable due to sensor placement on the hip and lateral regions, thus avoiding interference with surgical scars. In comparison to existing systems with multiple fastening straps, trousers were considered to be more user-friendly and reliable in terms of sensor placement.

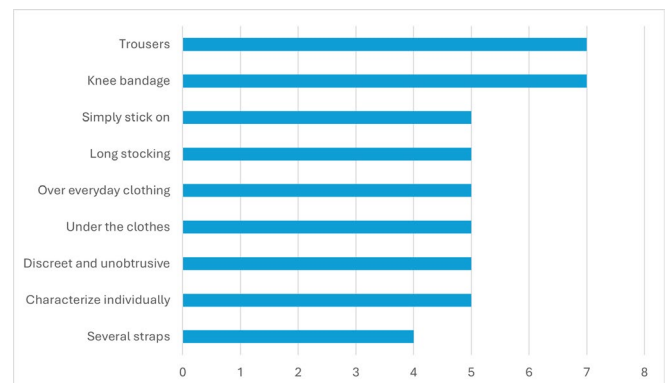


Figure 8. Preferred design variants of the wearable, as identified by the surveyed patients

Willingness to use. In terms of willingness to use the system, the majority of participants (6 to 11 participants) stated that they were to likely use the system and rated it as potentially helpful for their personal rehabilitation (see Fig. 10).

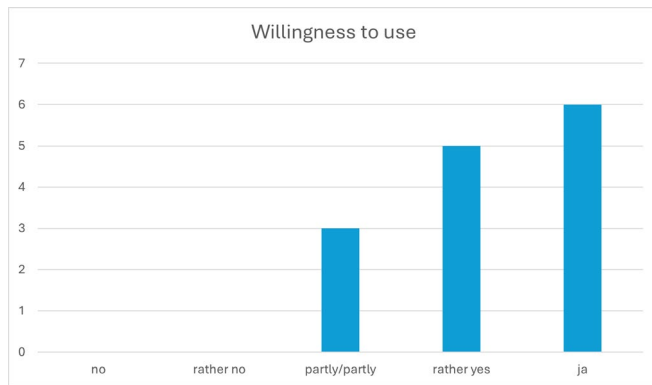


Figure 9. Willingness of patients surveyed to use the system

3.4 Ideation and Prototyping: First prototypes for the wearables

Based on the results of the use case workshop as well as expert and patient interviews, initial prototypes and design concepts for sensor integration were developed for both clinical and home use. A key challenge was the large number of sensors (7) that need to be placed on different parts of the body with varying ergonomic requirements – such as the legs, upper feet, and pelvic region. Although the sensors are identical in appearance, each one must be placed in a precise, predefined location to ensure reliable gait analysis. Furthermore, the sensors need to remain securely in place during movement to maintain strong and stable signal quality.

The differing application contexts – clinical vs. home – require fundamentally different design approaches due to distinct handling needs. In the home setting, the system must be easy to use by patients, enabling correct placement of the sensors without technical knowledge. The system must also be comfortable to wear for longer periods of time such as during gait analysis walks. In contrast, within the clinical context, the system demands configuration for quick handling due to time constraints in everyday clinical routines, must comply with hygiene standards, and must be adaptable to different body sizes.

For the co-design workshops with physiotherapists, four different prototypes of a strap-based sensor attachment system were developed (see Fig. 11). These prototypes explored various techniques and materials for sensor housings, closure mechanisms, size adjustability, and strap configurations.

For the workshop with patients, a series of pocket-based attachment methods for sensor integration were developed that could potentially be integrated into trousers. These pocket variants were created as 10x10 cm prototypes that can be attached to commercially available leggings with Velcro. Two pocket designs were rated best in terms of

usability and handling with 4 participants in an initial user test: one with a zipper and one with a simple slide-in pocket. These designs were compiled for the patient workshops (see Fig. 15).

3.5 Co-Design Workshop with physiotherapists

A co-design workshop with 11 physiotherapists (8 female, 3 male) was held to review the usability and user acceptance of the strap-based sensor system as well as to generate ideas for an expert software and a patient app. The 2.5-hour workshop was conducted in groups of three to four participants. Participants were recruited through the rehabilitation clinic and took part in the project on a voluntary basis, motivated by their own interest.

During the first part of the workshop, participants tested four different mock-up attachment variants by attaching sensors to each other (see Fig. 11). A color code was used to find the correct positioning of the sensors on the body. While testing the mock-ups, the participants were observed by the experimenters and shared their thoughts by using the thinking-aloud method. Participants evaluated each mock-up using a questionnaire. The favorite mock-up of each participant, along with the positive and negative aspects, were compiled in a final discussion.



Figure 10. Four different prototypes of a strap-based sensor attachment system to explore various techniques and materials for sensor housings, closure mechanisms, size adjustability, and strap configurations

In a subsequent paper prototyping session, the participants developed ideas for software interfaces aimed at medical staff and for an app aimed at patients using prepared visual materials such as interface elements (e.g. buttons, symbols, gait analysis feedback options) (see Fig. 12). In a plenary session, each group presented their ideas for the app concepts and the following questions were discussed: What information or parameters should be displayed and in what form? What anomalies or situations would you like the system to inform you about?



Figure 11. Paper prototyping material

Results regarding the design of the strap-based wearables. The results of the questionnaires indicate that mock-ups B, C and D were predominantly rated positively. Mock-up A received rather negative ratings for most items. Mock-ups B and D were rated the best (see Fig 13).

Three groups identified mock-up B (see Fig. 11, first picture) as their favorite due to the magnetic closure. However, there were handling issues: one group reported that the sensor fell out of the case, while another found it difficult to remove it, presumably due to incorrect insertion. One group named mock-up D as their favorite in terms of closure and textile sensor pocket. The following results and design decisions for the strap-based system were derived from the findings of the workshop:

Closure: Velcro fasteners were predominantly rejected due to snagging on clothing or other Velcro surfaces. The magnetic closure was preferred for its simple and intuitive handling. Alternative Velcro systems (e.g. mushroom head Velcro with flexible loop tape) and the suitability of the magnetic closure with regard to possible interference with the sensor system are being tested for further development.

Sensor case: In terms of stability, safety and ease of use, the textile pocket was sometimes preferred to the 3D-printed versions. It reliably secures the sensor in place and is easy to handle. The 3D-printed sensor cases were rated more positively in terms of aesthetics. Further developments include a 3D-printed sensor case made from a more flexible, robust material with optimized geometry to ensure the sensor is fixed securely in place.

Straps and size adjustability: Due to the high variance in body dimensions, several strap sizes are required. A non-slip material such as uncoated neoprene should be used for stable fixation.

Color code: A clear color differentiation is required for clear visual differentiation of the various sensor positions.

Hip sensor: The hip sensor tends to slip when walking and moving, potentially compromising measurement accuracy. A narrower, non-slip strap is being evaluated.

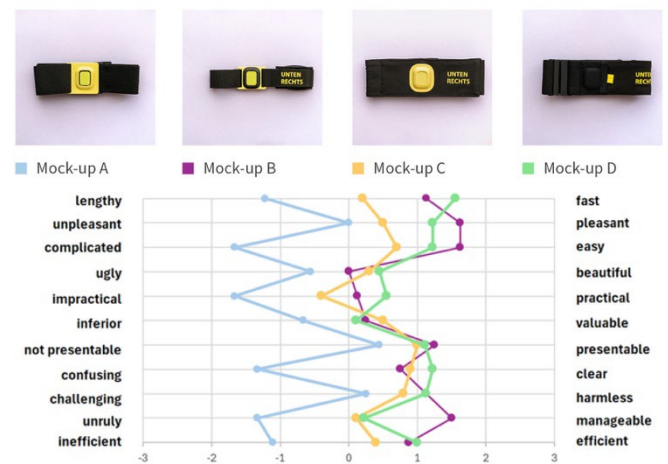


Figure 12. Results of the patient questionnaire evaluating the mock-up

Results regarding the clinical software. The most important requirement for all groups is to consistently reduce the software to its essentials. This involves avoiding information overload and focusing on two or three clearly defined and valid measurement parameters, while ensuring seamless integration into existing practice systems. The most important parameters include knee flexion and extension, ankle joint flexion and extension, roll-off phase and pain intensity via self-reporting by patients as well as pelvic tilt (flexion/extension). The aim is to enable intuitive, practical use without overburdening users with excessive complexity. The following basic functions were derived for the software: (1) an overview of all patients in the form of a list and a search function, (2) a patient dashboard for each patient with an overview of relevant patient information (e.g. surgical reports, previous illness, surgical history, etc.), possibility to conduct a gait analysis and a clear presentation of the gait analysis results (e.g. in the form of a comparison of parameters over the course of treatment), as well as a comment function for therapists and doctors to display and enter relevant additional information, (3) a “traffic light system” (e.g., red, yellow, green ratings) to display patients with conspicuous gait analysis results, (4) option to configure the gait analysis parameters individually for each patient.

Results regarding the patient app. The app for patients should be easy to use, low-threshold, and reduced to essential functions, as it is primarily intended for older users. Instead of standardized feedback mechanisms such as traffic light systems which could potentially have a demotivating effect, the focus should be on individual progress. A high degree of customizability in terms of goals, levels, functionality and complexity of the app is essential. The utilization of the wearable sensor system should be independent of an app, thereby ensuring accessibility to patients with limited technical skills or without access to smartphones. As shown in Fig. 14 the

therapists developed four concepts for providing feedback on gait analysis to patients.



Figure 13. Feedback concepts with potential feedback options on gait and rehab progress from right to left: (1) Video animation using avatars to visualize the patients gait and atypical movement patterns. (2) Feedback and information on gait quality in the form of voice output or text. (3) Motivational visualization of the patients' progress in the form of self-selected goals. (4) Diagrams to illustrate parameters across several time points to indicate progress

3.6 Workshops with patients

Three separate one-person workshops were conducted with knee-TEP patients (2 female, 1 male, aged 69–71 years) to test the design, usability and acceptance of the initial prototypes of a sensor system integrated into a pair of trousers. The aim was to identify operating and application errors in handling and positioning of the sensors and to obtain feedback on the design concept of the trousers and the design of the patient app's gait analysis feedback. Recruitment was conducted via the rehabilitation clinic; participants joined voluntarily and were deemed suitable for the project given their stage of recovery.

As part of a task-based usability test, participants tested two mock-ups verbalizing their thoughts by using the thinking aloud method (see Fig. 15). The test subjects were observed, and the mock-ups were evaluated using a questionnaire and semi-structured interviews regarding design aspects and the implementation of a color code for sensor assignment.



Figure 14. Two prototypes for pocket-based attachment methods for sensor integration: (1) the slide-in pocket, (2) zipper pocket

In the second part of the workshop, design proposals for material, color and style categories were discussed using a mood board with prepared design elements (see Fig. 16).

In the final task, the participants evaluated four concepts of potential feedback options on gait analysis, which were developed by the therapists in the expert workshop.

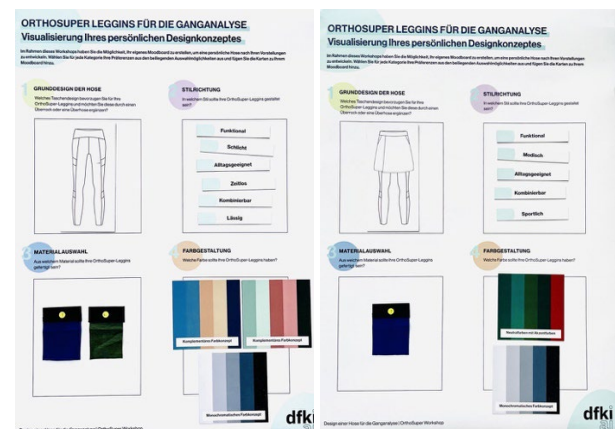


Figure 15. Mood board created by patients

Results regarding the design of the trousers. The results of the questionnaires indicate that both variants – the slide-in pocket and the zipper pocket – were rated positively overall (see Fig. 17). The slide-in pocket received above-average ratings in most of the items, particularly with regard to the characteristics 'quick', 'comfortable', 'simple', 'clear' and 'easy to use', which indicates a high level of usability and ease of use. An exception was observed for the item 'ugly/beautiful': The slide-in pocket received lower ratings, likely due to the visibility of colored markings on the exterior. Two participants preferred the

zipper pocket citing enhanced safety and reliability, as it prevents the sensors from falling out.

All participants coped well with the color-coded assignment of the sensors. There was a clear preference for unobtrusive design variants and discreet markings, such as arrows or dots, which were preferred due to their additional orientation aid.

The evaluation of the mood board task indicates that the sensor system for the patient, in the form of a pair of trousers, is generally accepted by the participants. One male participant noted that male users may be reluctant to wear body-hugging clothing. However, the participant himself would accept the leggings for functional purposes such as for gait analysis. Key aspects for the design are suitability for everyday use and functionality, particularly with regard to ease of use and independence when putting them on and taking them off, and when interacting with the sensors. For most users, they thought the trousers should be sporty and versatile and while for some users they prefer the design to be simple, timeless and fashionable. The choice of color varies and has a strong influence on aesthetic perception. It is therefore recommended that a design concept is developed which allows for individual color choices. Overall, the design of the trousers should be subtle and restrained to ensure broad acceptance. Based on the findings of the workshop, the following design recommendations were made:

Zipper pocket integration. Given the sensor's positioning on the hip, which is difficult to access once the trousers are worn, sensor integration should occur beforehand. To ensure secure fixation, the zipper closure was selected.

Larger zipper with pendant. It is recommended to use large zippers with a removable pendant to enhance handling, particularly for older people or those with limited fine motor skills.

The sensor is positioned at the front of the thigh. The pockets should be placed on the front instead of the sides, to improve the handling of sensor placement. Directional marking with arrows. Sensors should be labelled with arrows to improve orientation and ensure correct alignment.

High-contrast color coding. Strong color contrasts are recommended to improve visual recognition, particularly for those with visual impairments.

Smartphone pocket integration. For gait analysis and everyday use of the system, an additional smartphone pocket should be integrated into the trousers.

Calf zipper. A zipper opening in the calf region should be integrated to facilitate the donning process, particularly for older people, and to enable enhanced adjustability.

Revision of the foot sensor. The two-part foot sensor was considered difficult in handling. It is recommended to combine the sensor case with the elastic band.

Creation of a tutorial. A tutorial should be provided to guide users through the process of putting on and preparing the trousers.

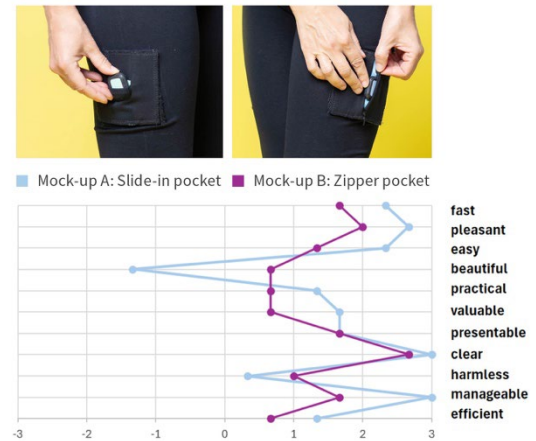


Figure 16. Results of the patient questionnaire evaluating the mock-up

Results regarding the design of the app and gait analysis feedback. The app should be designed user-friendly and straightforward to use, to avoid overwhelming users with excessive functionality: A modular structure is recommended to adjust the range of functions and the degree of complexity to different usage requirements and digital experience. The wearable sensor system should function without the patient's active interaction with the app, e.g. data should be transferred automatically to healthcare professionals.

Participants generally rated the proposed concepts for gait feedback as beneficial for self-assessment of rehabilitation progress. The feedback variants should be made individually selectable to account for user preferences. All participants expressed a preference for feedback on their gait pattern in form of a video animation. Two out of three participants would also like to receive feedback in form of diagrams.

4. Conclusion

This paper illustrates the effective use of participatory design methods within a user-centered development process for a medical rehabilitation technology. Engaging potential user groups and relevant stakeholders supported the design of products that align more closely with the users' actual needs, thereby enhancing usability and acceptance. A mixed-methods approach was employed to evaluate the developed prototypes with potential users and experts. This approach combined qualitative and quantitative methods, including interviews, questionnaires, observations and think-aloud sessions. Although number of participants in some workshop formats were limited, the findings indicate that individual user feedback can be sufficient to uncover key usability issues and provide valuable insights for design decisions.

An interdisciplinary workshop with all project partners at the beginning of the project, facilitated the development of a shared vision, sharpened the project objectives and helped to identify key issues and relevant user groups at an early stage. The insights gained from that workshop served as the foundation for subsequent participatory design approach. The use of participatory formats not only enabled the identification of specific requirements and needs of the user groups but also facilitated the generation of comprehensive ideas for the overall system. Based on the insights gained through the participatory design process, the prototypes were refined and subsequently evaluated with patients and medical professionals.

The success of participatory formats depends on the selection and adaptation of methods to the specific target group and application context. To encourage both patients and experts to share their perspectives, needs, concerns and ideas – and to actively participate in the design process – materials should be diverse, tangible and visually engaging. In the initial use case workshop with the interdisciplinary project team, various templates were employed to collaboratively develop personas and storyboards illustrating the user journey. In workshops with medical experts, paper prototypes and pre-prepared graphic image elements supported the joint development and reflection of concepts for the expert platform and the patient app. In a workshop with patients, mood boards with diverse visual design elements facilitated the discussion of design concepts and promoted the patients' active participation in the dialogue.

In conclusion, this study demonstrates the successful conceptualization and prototypical development of the demonstrator, thereby providing an important foundation for its further application and refinement. At the time of publication, a final user evaluation had not yet been conducted; this is planned for the subsequent project phase. The results of this evaluation will serve as the basis for final validation and the potential transfer into practice.

Acknowledgements.

We would like to thank our project partners, our student assistant and all workshop participants for their great support and cooperation. The project is supported by the Federal Ministry of Research, Technology and Space (funding codes: 13 GW0564 A-F). It has been approved by a local ethics committee of German Research Center for Artificial Intelligence Ethics Board. Large Language Models (LLMs) were used as a tool for editing the authors' own text in this paper.

References

- [1] Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG). Mindestmengen an Knie-TEP: Höhere Fallzahlen bringen mehr Behandlungsqualität [Internet]. 2022 [cited 2025 Jul 08]. Available from: https://www.iqwig.de/presse/pressemitteilungen/pressemitteilungen-detailseite_62336.html
- [2] Evans, J.T., Walker, R.W., Evans, J.P., Blom, A.W., Sayers, A., Whitehouse, M.R.: How long does a knee replacement last? A systematic review and meta-analysis of case series and national registry reports with more than 15 years of follow-up. *The Lancet*, 393, 655–663 (2019).
- [3] Palmer S. Total Knee Arthroplasty (TKA) [Internet]. Medscape; 2020 [cited 2022 Jul 08]. Available from: <https://emedicine.medscape.com/article/1250275-overview>
- [4] Bretschneider, M., Kolasińska, A., Šomvárska, L., Klásek, J., Mareš, J., Schwarz, P. Evaluation of the Impact of Mobile Health App Vitadio in Patients With Type 2 Diabetes: Randomized Controlled Trial. *J. Med. Internet Res.* 2025;27:e68648. <https://doi.org/10.2196/68648>
- [5] Heidel, A., Hagist, C. Potential Benefits and Risks Resulting from the Introduction of Health Apps and Wearables Into the German Statutory Health Care System: Scoping Review. *JMIR Mhealth Uhealth.* 2020;8(9):e16444. <https://doi.org/10.2196/16444>
- [6] DIN. DIN EN ISO 62366-1:2021-08 – Medizinprodukte – Teil 1: Anwendung der Gebrauchstauglichkeit auf Medizinprodukte (ISO 62366-1:2015 + Amd 1:2020). Berlin: Beuth Verlag; 2021.
- [7] Martin JL, Clark DJ, Morgan SP, Crowe JA, Murphy E. A user-centered approach to requirements elicitation in medical device development: a case study from an industry perspective. *Applied Ergonomics.* 2012; 43(1):184-190.