TESIS DE LA UNIVERSIDAD DE ZARAGOZA
2021
229

Javier Marín Boné

Diseño en tres niveles en el ámbito de la salud. Captura de movimiento para análisis de la marcha en rehabilitación.

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ISSN 2254-7606

Prensas de la Universidad
Universidad Zaragoza

ISSN 2254-7606

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Escuela
Escuela de Ingeniería y Arquitectura (EINA)
Programa de Doctorado en Ingeniería de Diseño y Fabricación

Año
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| JAVIER MARÍN BONÉ | 2021 |

Tesis doctoral del Programa de Doctorado
en Ingeniería de Diseño y Fabricación

Directores:
Dr. José Javier Marín Zurdo
Dra.Teresa Blanco Bascuas

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Tesis doctoral

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Programa de Doctorado en Ingeniería de Diseño y
Fabricación de la Universidad de Zaragoza.

Zaragoza, febrero de 2021.

Esta tesis doctoral está compuesta por un compendio de cinco publicaciones científicas internacionales. El estudio 1 está indexado en *Scimago Journal & Country Rank* (SJR) y los estudios 2-5 están indexados en *Journal Citation Reports* (JCR).

- **Estudio 1:** Marín, J., Blanco, T., Marín, J.J. (2017). Research Lines to Improve Access to Health Instrumentation Design. *Procedia Computer Science*, 113, 641-646. https://doi.org/10.1016/j.procs.2017.08.323

- **Estudio 2:** Marín, J., Blanco, T., Marín, J.J. (2017). Octopus: A Design Methodology for Motion Capture Wearables. *Sensors*, 17, 1875. https://doi.org/10.3390/s17081875

- **Estudio 3:** Marín, J., Blanco, T., Marín, J.J., Moreno, A., Martitegui, E., Aragüés, J.C. (2019). Integrating a Gait Analysis Test in Hospital Rehabilitation: A Service Design Approach. *Plos One*, 14, e0224409. https://doi.org/10.1371/journal.pone.0224409

- **Estudio 4:** Marín, J., Blanco, T., de la Torre, J., Marín, J.J. (2020). Gait Analysis in a Box: A System Based on Magnetometer-Free IMUs or Clusters of Optical Markers with Automatic Event Detection. *Sensors*, 20, 3338. https://doi.org/10.3390/s20123338

- **Estudio 5:** Marín, J., Marín, J.J., Blanco, T., de la Torre, J., Salcedo I., Martitegui, E. (2020). Is My Patient Improving? Individualized Gait Analysis in Rehabilitation. *Applied Sciences*, 10, 8558. https://doi.org/10.3390/app10238558

Agradecimientos

En primer lugar, gracias a mis directores de investigación Teresa Blanco y José Javier Marín, sin ellos este trabajo no habría sido posible. Teresa, gracias por tu apoyo, consejos y sabiduría. Tu forma de trabajar y tu perspectiva han aportado un lado más humano a esta investigación. José Javier, esta tesis no existiría sin tu trabajo previo y tu perseverancia. Gracias por dejarme compartir contigo tantas experiencias en estos años.

Agradecer también a Nancy, mi tutora durante mi estancia en Malmö, así como a todas las personas que conocí en aquel lugar, donde se respiraba creatividad por todas partes. Me acogisteis e involucrasteis desde el primer día.

Gracias a los usuarios que participaron voluntariamente en los estudios, su disposición y experiencias fueron esenciales en esta investigación. De igual modo, gracias a los evaluadores internacionales, que valoraron los artículos, y de los que aprendí enormemente.

También mostrar mi agradecimiento a los compañeros del grupo de investigación, a Juan y Álex, que creyeron en el proyecto y con los que compartí retos y logros.

En especial, a mis padres María Jesús y José Javier, y a mi hermana Marta, por estar en todas las etapas de mi vida; agradezco sinceramente vuestro afecto, ánimo constante e interés en mi trabajo. Gracias al resto de mi familia y a las nuevas incorporaciones, siempre sois energía y un gran apoyo. Gracias a mis amigos de toda la vida, y a los que aparecisteis en el camino, que, a pesar de las agendas, y estos tiempos difíciles, siempre estáis y sé que me deseáis lo mejor.

Y, sobre todo, gracias a ti Belén, por ser, por estar siempre a mi lado, por apoyarme, y por afrontar la vida juntos.

"Al fin, la vida va enseñando que lo importante, lo verdaderamente importante, no es lo propio sino lo recibido, y solo una palabra es posible, Gracias"

Nacho Boné Pina SJ

Resumen

En el ámbito de la salud, tecnologías como la captura de movimiento, la dinamometría, o la electromiografía de superficie, entre otras, ofrecen amplias posibilidades para objetivar la capacidad musculoesquelética de los pacientes, favoreciendo el diagnóstico o el seguimiento del proceso de rehabilitación. No obstante, conseguir que estas tecnologías se adapten e integren adecuadamente en el contexto de los servicios sanitarios implica un reto complejo de abordar.

En esta tesis se presenta un compendio de publicaciones que dan respuesta a diferentes retos detectados durante el diseño, desarrollo y uso de tecnologías de evaluación del sistema musculoesquelético en el ámbito biosanitario. Particularmente, nos centramos en los sistemas de captura de movimiento; su complejidad a nivel operativo (colocación de diferentes elementos sobre el cuerpo), tecnológico (multitud de dispositivos electrónicos inalámbricos), y de análisis (generación de gran volumen de información) pone de manifiesto la necesidad de abordar esta investigación.

- La primera publicación presenta las necesidades que han motivado esta tesis, exponiendo las bases y objetivos de la misma, que se enmarcan en *healthcare*, *biomechanics*, y *usability*.
- La segunda introduce la metodología desarrollada Octopus, dirigida a apoyar el diseño de sistemas de captura de movimiento. Esta investigación clasifica y esquematiza los factores que deben considerarse durante el diseño y propone la idea de "Diseño en tres niveles": servicio, producto y software; que son las principales líneas de trabajo a la hora de desarrollar aplicaciones dirigidas a evaluar el sistema musculoesquelético.

Llegados a este punto, y fruto de diferentes colaboraciones del grupo de investigación con hospitales públicos de nuestra comunidad, así como una revisión exhaustiva del estado del arte, los trabajos de investigación se dirigieron hacia un nicho o caso de estudio enmarcado en el contexto de rehabilitación hospitalaria. En concreto, diseñar una prueba clínica de análisis de la marcha basada en captura de movimiento para monitorizar tratamientos de rehabilitación mediante sesiones de medición previas y posteriores a los tratamientos.

- Como resultado se elaboró una publicación encuadra en el primer nivel de Octopus, el diseño de servicios. Esta investigación estudia cómo integrar el test de análisis de la marcha en la rehabilitación hospitalaria. Incorporar un micro-servicio (test de análisis de la marcha) en un macro-servicio como es la rehabilitación, no es una tarea sencilla de abordar. Por ello, se propone un enfoque metodológico para evaluar cualitativamente el test de marcha en su contexto, cuya aplicación permitió obtener guías de diseño que proporcionan conocimiento multidisciplinar para integrar el test en la rehabilitación.
- Asimismo, se realizó una publicación que responde a otro de los niveles de Octopus, el diseño de producto. Este trabajo presenta un sistema de captura de movimiento llamado Move-Human Sensors (MH) que permite realizar pruebas de análisis de la marcha. Este sistema responde a las necesidades detectadas en el estudio del servicio, e incorpora dos funcionalidades clave: un procedimiento de calibración

anatómica que evita las perturbaciones magnéticas las cuales tienen efectos negativos en la captura de movimiento inercial; así como un algoritmo que detecta *gait events* a partir de los datos de movimiento sin requerir de instrumentación complementaria.

- Finalmente, se desarrolla una publicación enmarcada en el último nivel de Octopus, el diseño de software. Este estudio propone un método para gestionar los datos resultantes del test de análisis de la marcha. Dicho método permite comparar las capturas pre- y post-tratamiento para realizar el seguimiento de pacientes en rehabilitación, proporcionando información visual y específica al facultativo que puede apoyar la toma de decisiones clínicas.

Esta tesis contribuye al ámbito del diseño, aportando una perspectiva global basada en tres niveles: producto, servicio, y software. En esta línea, se presenta un sistema de captura de movimiento, cuyo diseño y desarrollo recorre los tres niveles y da solución a los retos clave detectados. Conforme se profundiza en el propio caso de estudio de análisis de la marcha, se avanza en *wearables*, biomecánica, tecnología de captura de movimiento, usabilidad y algoritmos de análisis de datos.

Las implicaciones que tiene esta investigación van más allá de las publicaciones descritas, ya que se enmarca en diferentes proyectos más amplios que dan sentido a la unidad temática de los capítulos abordados. En consecuencia, este trabajo está apoyado por otras comunicaciones científicas, desarrollos y colaboraciones que se han elaborado de manera paralela. Asimismo, los resultados de esta investigación están siendo extrapolados a otras áreas relacionadas; tanto en el propio sector sanitario -para la realización pruebas de valoración funcional- como en el sector industrial -para la realización de evaluación ergonómica de puestos de trabajo-, donde esta tecnología puede aportar valor.

Palabras clave

Diseño: Diseño de Producto, Servicio y Software, Metodología, Diseño Centrado en el Usuario, Experiencia de Usuario, Mapeo de Usuarios y Entornos, *Internet of Things* (Internet de las Cosas), Evaluación Cuantitativa y Cualitativa.

Captura de movimiento: Unidad de Medición Inercial (IMU), Captura de Movimiento Óptica, IMUs sin Magnetómetro, Sólidos Rígidos, Agrupaciones de Marcadores, *Wearables*, Fijación y Posicionamiento en el Cuerpo, Modelo Humano, Calibración Anatómica, *Sensor-to-Segment Alignment* (Alineación Sensor a Segmento).

Análisis de la marcha para rehabilitación: Sistema Musculoesquelético, Biomecánica, Análisis Clínico de la Marcha, *Gait Events* (Eventos de la Marcha), Espaciotemporal, Cinemática, Monitorización, Toma de Decisiones Médicas, Atención Centrada en el Paciente, Terapias Personalizadas, *Smart Health* (Salud Inteligente), Espasticidad Hemipléjica, Toxina Botulínica, Reproducibilidad, Mínimo Cambio Detectable (MDC), Decisiones Basadas en Magnitudes (MBD).

Abstract

In healthcare, technologies such as motion capture, dynamometry, or surface electromyography, among others, offer broad possibilities to objectify the patient musculoskeletal capacity, supporting the diagnosis and the rehabilitation process assessment. However, to adequately adapt and integrate these technologies in health services is a complex challenge.

This thesis presents a compendium of publications that face different challenges detected in the design, development and usage processes of technologies for the musculoskeletal system assessment in the healthcare field. Specifically, we focus on motion capture systems; its complexity at the procedure (numerous devices placed on the body), technological (multitude wireless electronic devices) and data analysis levels (massive volume of information), highlights the need to address this.

- The first publication presents the needs that motivate this thesis and exposes their research bases and objectives framed in healthcare, biomechanics, and usability.
- The following paper introduces the Octopus methodology, aimed at supporting the design of motion capture systems. This research classifies and outlines the factors to be considered in the design and poses the concept of "Three-Level Design": service, product and software; which are the main work lines to face the development of applications to assess the musculoskeletal system.

At this point, as a result of different collaborations of the research group with public hospitals, in addition to a review of state of the art, the research was focused on a niche or case study in the rehabilitation context. Specifically, to design a gait analysis clinical test based on motion capture to monitor rehabilitation treatments through pre- and post-treatment measurement sessions.

- As a result, a research paper was elaborated among the Octopus first level, service design. This research studies how to integrate the gait analysis test in hospital rehabilitation—incorporating a micro-service (gait analysis test) in a macro-service such as rehabilitation service is a complex challenge to face. For this reason, we propose a methodological approach to qualitatively assess the gait test, whose application provided design guidelines and multidisciplinary knowledge to integrate the test in rehabilitation.
- Likewise, a paper was made to answer another Octopus level, product design. This work presents a motion capture system called Move-Human Sensors (MH) that allows conducting these gait analysis tests. This system answers the needs detected in the service study and incorporates two important functionalities: an anatomical calibration procedure that avoids magnetic disturbances that significantly affect inertial technology; and an algorithm that detects gait events from kinematic data without requiring additional instrumentation.
- Finally, a paper was developed at the last Octopus level, software design. This study poses a method to manage the resulting data of the gait analysis test. This method allows comparing the pre- and post-treatment sessions to monitor patients in rehabilitation and provides visual and specific information to physician to improve clinical decision making.

This thesis contributes to design theory, providing a global perspective based on three levels: service, product, and software. In this line, we present a motion capture system, whom design and development cover the three levels and answer several associated challenges. Furthermore, as the research delves into the case study, progressions are made in wearables, biomechanics, motion capture technology, usability and data analysis algorithms.

This research's implications exceed the scope of the publications described since it is framed in different projects that provide sense and thematic unit to the various issues addressed. In consequence, this work is supported by other scientific communications, developments, and collaborations. Additionally, these research results are being extrapolated to other related areas, both in the healthcare context itself -to conduct functional biomechanical tests-, and in the industrial sector -to conduct workplace ergonomic assessments-, where this technology can add relevant value.

Keywords

Design: Product Design, Service Design, Software Design, Methodology, User-Centred-Design, User Experience, User and Environment Mapping, Internet of Things, Quantitative and Qualitative Assessment.

Motion Capture: Inertial Measurement Unit (IMU), Optical Motion Capture, Rigid body Magnetometer-Free IMUs, Full-Body, Cluster of Markers, Wearables, Body Attachment and Positioning, Human-model, Anatomical Calibration, Sensor-to-Segment Alignment.

Gait Analysis for Rehabilitation: Musculoskeletal System, Biomechanics, Clinical Gait Analysis, Gait Events, Spatiotemporal, Kinematics, Patient Monitoring, Medical Decision-Making, Patient-Centred Care, Personalised Therapies, Smart Health, Hemiplegic Spasticity, Botulinum Toxin, Reproducibility, Minimal Detectable Change (MDC), Magnitude-Based Decisions (MBD).

Tabla de contenido

1. Introducción

En esta sección se presenta el marco (1.1), retos (1.2) y objetivos (1.3) de la investigación. Asimismo, se presentan las publicaciones incluidas en el compendio (1.4), la perspectiva general de la metodología seguida (1.5) y la justificación de la unidad temática de las mismas (1.6).

1.1. Marco de la Investigación

Esta investigación se desarrolla en el marco del Grupo de Investigación IDERGO (Investigación y Desarrollo en Ergonomía) de la Universidad de Zaragoza, reconocido como Grupo de Referencia por el Departamento de Ciencia, Universidad y Sociedad del Conocimiento del Gobierno de Aragón, España.

1.1.1. Antecedentes

El Grupo IDERGO diseña y desarrolla sistemas de evaluación del sistema musculoesquelético dirigidos al ámbito de la ergonomía y prevención de riesgos laborales, así como al sector biosanitario. La línea de investigación relacionada con la ergonomía comenzó en el año 2004 con el objetivo de realizar evaluaciones ergonómicas de puestos de trabajo, de acuerdo con la Ley de Prevención de Riesgos Laborales, para evitar trastornos musculoesqueléticos de los trabajadores. En 2007 surgió la primera versión operativa del sistema Move-Human Sensors (MH) de captura de movimiento y simulación 3D con modelos humanos digitales. Esta versión se fundamentaba en un sistema portátil utilizable en los propios lugares de trabajo y basado en sensores inerciales de movimiento.

Desde entonces, y hasta la fecha, se han implementado mejoras y nuevas funcionalidades en el sistema MH como, por ejemplo, la integración con hardware complementario a la propia captura de movimiento. Asimismo, el sistema ha ampliado su campo de actuación al ámbito sanitario para la valoración de pacientes con trastornos musculoesqueléticos, tanto para la asistencia pericial o forense, como para guiar la rehabilitación o el entrenamiento deportivo.

Desde los inicios, el espíritu del grupo de investigación ha sido crear soluciones útiles y aplicables en distintos contextos sin requerir condiciones de laboratorio. Su objetivo ha sido dotar de herramientas de trabajo que resuelvan problemas y supongan una ayuda para trabajadores o pacientes. Todo ello sin interferir en la labor habitual e integrándose de manera natural en el entorno. De esta forma, los sistemas de IDERGO están actualmente en explotación por distintas entidades públicas y privadas, a través de proyectos y acuerdos firmados con la OTRI de la Universidad de Zaragoza.

Algunas de las empresas que están utilizando o han utilizado sistemas IDERGO para prevención de riesgos laborales son el Servicio de Prevención del Gobierno de Aragón, Premap (ahora Quirón-prevención), Mutua Universal, BSH electrodomésticos, Volkswagen-Navarra, Gesinor Servicio de Prevención; y en el sector asistencial o biosanitario, el Instituto de Medicina Legal de Aragón, Hospital Mutua de Accidentes MAZ (Servicio de Valoración Funcional) o el Hospital Miguel Servet de Zaragoza (Servicio de Rehabilitación).

1.1.2. Contexto

Esta tesis comienza en febrero del año 2017 con el objetivo de extender las tecnologías existentes en el Grupo IDERGO hacia pruebas de valoración funcional dirigidas al área asistencial y de rehabilitación. En este sentido, gracias la utilización continuada del sistema MH en distintos escenarios reales de uso, surgieron las diferentes necesidades

y preguntas de investigación que dieron lugar a esta tesis. Para ello, la colaboración con otras entidades y grupos de investigación ha sido clave.

Entre dichas colaboraciones, destaca la relación con el Grupo de Investigación Howlab (*Human Openware Research Lab*), cuyo apoyo metodológico ha sido esencial para dar respuesta a los retos de investigación establecidos. Howlab es grupo de investigación de la Universidad de Zaragoza reconocido como Grupo de Referencia por el Gobierno de Aragón. Se dedica al desarrollo de tecnologías centradas en las personas y sus entornos, a través de proyectos de *Internet of Things* (internet de las cosas), inteligencia artificial y diseño. Sus líneas de investigación se centran en metodologías de diseño, métodos de trabajo en entornos multidisciplinares y diseño de *wearables*. Esta colaboración ha facilitado identificar los factores de diseño que influyen en la implementación de aplicaciones para la valoración del sistema musculoesquelético, que ha sido uno de los ejes de investigación de esta tesis.

Asimismo, la relación con el Servicio de Rehabilitación del Hospital Miguel Servet permitió establecer una situación real donde aplicar la tecnología. Este servicio presta asistencia rehabilitadora para devolver el máximo grado de autonomía personal, y es un referente en la Comunidad Autónoma de Aragón. Está organizado en la Unidad de Lesionados Medulares y Neurorehabilitación, y en una zona de consultas externas y áreas terapéuticas (Fisioterapia, Electroterapia, Terapia Ocupacional y Logopedia). El proyecto colaborativo fue aprobado por el Comité de Bioética de Aragón el 20 junio de 2018, y se formalizó con el *"Acuerdo de Colaboración entre la Universidad de Zaragoza y la Fundación Instituto de Investigación Sanitaria Aragón"*, firmado el 1 de octubre de 2018.

Finalmente, destaca la colaboración con el Centro de Investigación *Internet of Things and People* (IOTAP) de la Universidad de Malmö, Suecia, donde se realizó una estancia de tres meses, desde septiembre hasta diciembre de 2017, en el departamento de Salud Inteligente, *Smart Health*. El centro IOTAP tiene como objetivo hacer que el contexto actual de dispositivos inteligentes interconectados y conectados a la nube en el *Internet of Things*, sea útil y beneficioso para las personas.

1.2. Retos de la Investigación

Los retos de esta investigación se derivan de los antecedentes y del contexto, así como de la revisión del estado del arte. Tal y como se desarrolla en este apartado, la instrumentación dirigida a la evaluación del sistema musculoesquelético, y particularmente la captura de movimiento, presenta barreras y dificultades que suponen un reto multidisciplinar.

1.2.1. Instrumentación para la Evaluación Musculoesquelética

Esta tesis se centra en el diseño de instrumentación dirigida a la valoración del sistema musculoesquelético en el ámbito sanitario. Definimos esta tecnología como aquella que mide la capacidad de un individuo, ya sea de movilidad, equilibrio, fuerza, actividad muscular u otras, con propósitos de diagnóstico, monitorización o asistencial (Marín *et al.*, 2017b; Shirmohammadi *et al.*, 2016). Este tipo de sistemas permiten conocer la situación funcional del paciente a través de información objetiva y estandarizada. Asimismo, pueden enmarcarse en la lógica *Smart Health*, *e-Health* y especialmente en filosofía de *Personalised Therapies* o Terapias Personalizadas (Varshney & Chang, 2016).

Como ejemplos de este tipo de instrumentación, podemos citar la captura de movimiento para medir la capacidad de movilidad de un sujeto, las plataformas estabilométricas, que permiten objetivar la capacidad para mantenerse estable o los dinamómetros, que permiten medir la fuerza ejercida por ciertos segmentos corporales. Dichas tecnologías se describirán con más detalle en los siguientes apartados. Asimismo, tal y como se justificará más adelante, se elige la captura de movimiento como paradigma o caso de estudio principal debido a su elevada complejidad y posibilidades de extrapolación hacia otras tecnologías menos complejas.

La figura 1 muestra un esquema de los elementos involucrados en un sistema de instrumentación *Smart Health* para evaluar el sistema musculoesquelético. Observamos que este tipo de ecosistemas contienen elementos tangibles, como los "*dispositivos*", que permiten medir las capacidades del paciente, o el "*punto de procesamiento de datos*", que gestiona la información recopilada; así como elementos intangibles, entre los que se encuentra la "*operativa de uso*", que establece los pasos a seguir por los distintos actores. Todo ello dirigido a los usuarios principales involucrados: facultativos y pacientes, y enmarcado en el entorno de uso biosanitario.

En esta línea, se considera que el desarrollo de dispositivos y punto de procesamiento de datos (instrumentación tangible) debe estar guiado por el contexto actual de objetos inteligentes interconectados a la nube en el *Internet of Things* (Blanco *et al.*, 2017; Blanco *et al.*, 2021; Perera *et al.*, 2014), así como por la necesidad de simplicidad, bajo coste, transparencia y privacidad (Blanco *et al.*, 2017). Adicionalmente, para lograr una experiencia de usuario satisfactoria, este tipo de sistemas requieren resolver la interacción usuario-usuario y usuario-máquina, por lo que es necesario responder a las cuestiones mostradas en los "*puntos de interacción*" de la figura 1 (Abras *et al.*, 2004; Tassi, 2009; Shneiderman, 2010; Uebbing, 2016).

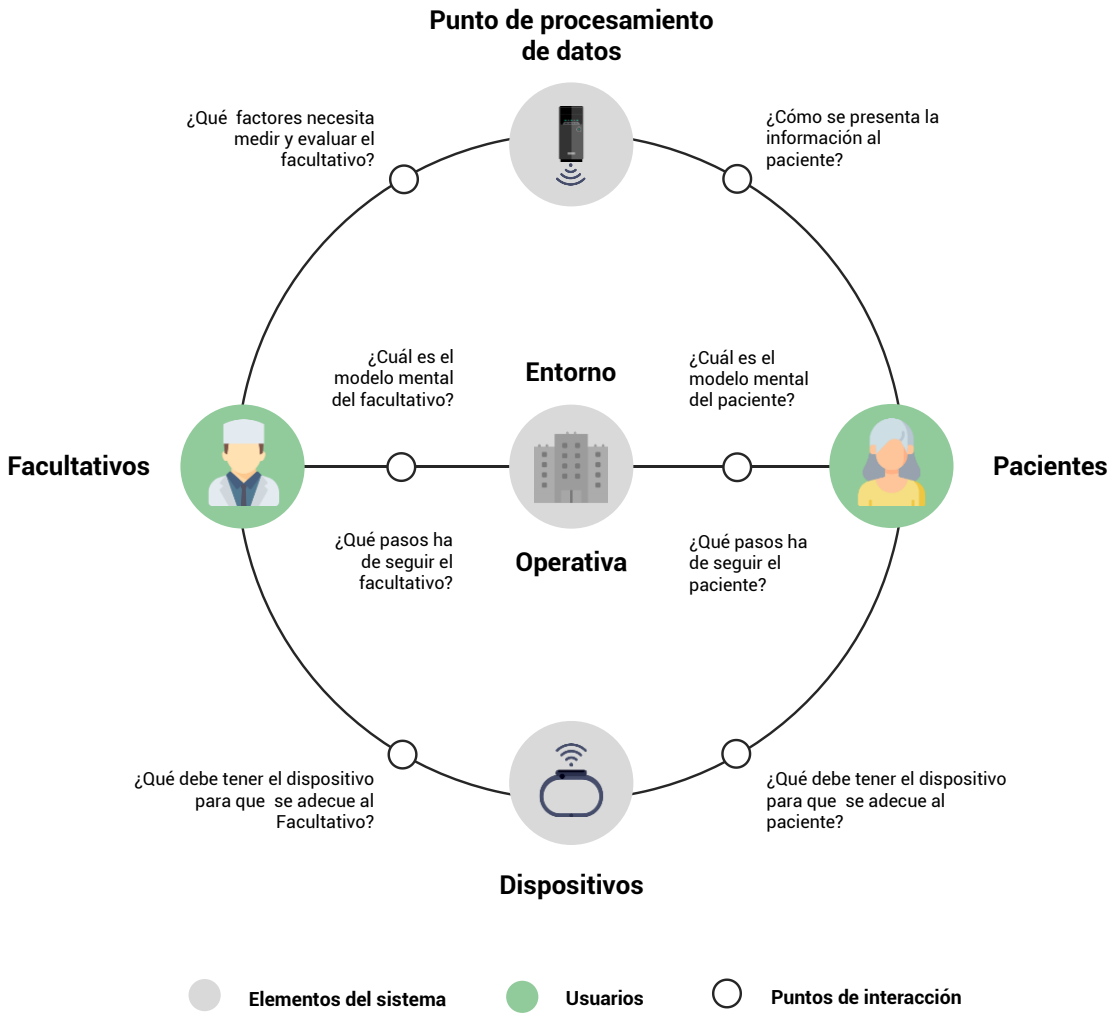


Fig 1. Instrumentación de salud y su ecosistema. Figura extraída de (Marín *et al.*, 2017b)*. Iconos por Freepik, Madebyoliver y Alfredo Hernandez de Flaticon*

En este sentido, Andersen *et al.* (2013) introduce el concepto de *"mejorar el acceso a la salud",* una necesidad que supone potenciar todo aquello que facilite el uso de los servicios de salud y superar aquellas barreras que lo impidan; mejorando la unión entre los sistemas o la tecnología sanitaria y la población.

Por tanto, es necesario desarrollar soluciones tecnológicas que acerquen la tecnología a la salud, haciéndola económica, sencilla y verdaderamente usable, es decir, acorde al contexto y a los usuarios. Sin embargo, alcanzar soluciones útiles y accesibles no es evidente; requiere combinar adecuadamente investigación, experimentación y creatividad. De esta reflexión surge el siguiente reto.

¿Cómo debe diseñarse la instrumentación dirigida a evaluar el sistema musculoesquelético? ¿Qué debemos considerar durante el diseño para que esta tecnología se adecúe a las necesidades de los usuarios y el contexto?

1.2.2. Diseño de Sistemas de Captura de Movimiento

Dentro de la instrumentación dirigida a la evaluación del sistema musculoesquelético, encontramos la tecnología de captura de movimiento. Estos sistemas son ampliamente reconocidos por su utilidad y aplicación en el ámbito de la salud (Ahmad *et al.*, 2013; Mayagoitia *et al.*, 2002). Ya sea por lesiones, enfermedades, o envejecimiento, todos estamos expuestos a perder capacidades de movilidad en alguna etapa de nuestra vida. Por tanto, disponer de tecnología que permita objetivar los patrones de movimiento, puede tener un papel esencial para el diagnóstico, la valoración de secuelas, o la rehabilitación.

La captura de movimiento se puede definir como una técnica de grabación de movimiento humano y el traslado de dicho movimiento a un modelo humano digital para su análisis (Cloete & Scheffer, 2008; Thewlis *et al.*, 2013). En cuanto a las tecnologías disponibles, algunas de las más utilizadas, y en las que nos centramos en esta investigación, son las basadas en marcadores superficiales. En concreto, las tecnologías que emplean cámaras y esferas reflectantes colocadas en el sujeto (en adelante, óptica) y las basadas en sensores inerciales o *Inertial Measurement Units* (IMUs). Estas técnicas consisten en la colocación sobre el cuerpo de diversos elementos que identifican los ángulos y/o las posiciones de los segmentos corporales a capturar. La figura 2 muestra ambas tecnologías.

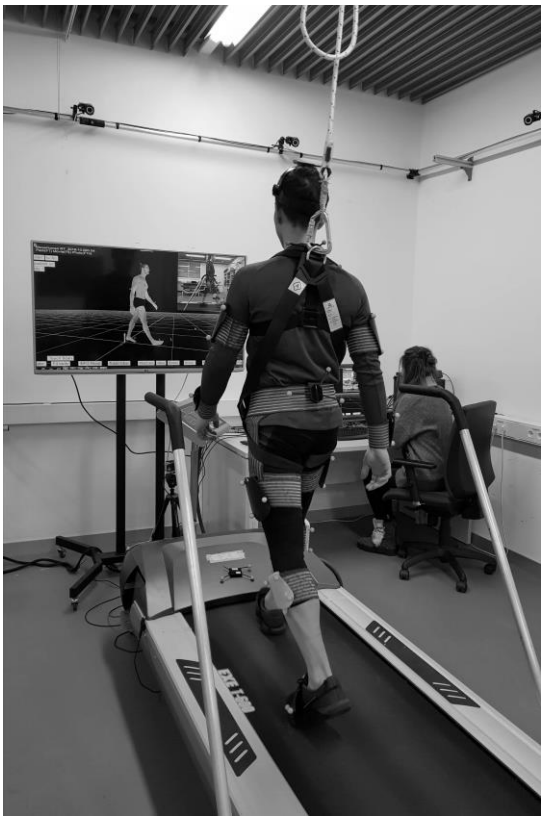
A  B 

Fig 2. Tecnologías de captura de movimiento. A: basada en marcadores reflectantes. B: basada en sensores inerciales.

La captura óptica se utiliza extensamente en la investigación biomédica y, debido a su elevada precisión, es considerada el *gold standard* (la referencia) en la comunidad científica. Esta tecnología utiliza cámaras situadas alrededor del área de captura que

emiten luz infrarroja e identifican la posición de marcadores esféricos reflectantes. Dichas esferas se sitúan directamente sobre la piel o ropa del participante, o bien en agrupaciones de tres o más marcadores llamados sólidos rígidos colocados en los segmentos corporales a capturar (Carse *et al.*, 2013; Mayagoitia *et al.*, 2002; Skogstad *et al.*, 2011). Para que un sólido rígido sea identificado unívocamente por el software, debe tener una distancia entre marcadores diferente al resto.

Los IMUs, por su parte, son dispositivos electrónicos que miden rotaciones a través del procesamiento de datos de tres tipos de sensores que tienen embebidos, acelerómetros, giróscopos y magnetómetros (Cloete & Scheffer, 2008; Cooper *et al.*, 2009; Mooney *et al.*, 2015). La tabla 1 muestra la comparativa entre ambas tecnologías.

Tabla 1. Comparativa entre tecnología de captura óptica e inercial.

	Óptica (sólidos rígidos)	**IMUs**
Medición	Desplazamientos y rotaciones	Rotaciones
Volumen captura	Limitado En interiores	Ilimitado En interiores o exteriores
Infraestructura	Cámaras fijas en la habitación conectadas a PC	Transmisión de datos inalámbrica con el PC
Precisión	Mayor Desplazamientos (≈0.4 mm) rotaciones (≈0.5º) [1]	Menor Rotaciones (<1º RMS pitch/roll, <2º RMS (heading)[1, 2]
Errores propios	Ocultación de marcadores reflectantes	Derivas de los giróscopos y perturbaciones en el campo magnético que afectan a magnetómetros
Coste	Mayor Desde ≈15.000€, 12 cámaras (sin incluir marcadores)[3]	Menor Sobre ≈350€/sensor[2]

[1]Marín et al. (2020), [2] X-io technologies (2020), [3] Natural Point (2020).

Es necesario destacar que los sistemas ópticos que utilizan sólidos rígidos presentan un gran paralelismo con los sistemas IMU, ya que, en ambos casos, la captura consiste en asociar un elemento - sólido rígido o IMU - a un segmento corporal (Marín *et al.*, 2017a). Así, en el caso de los sensores IMUs, cada elemento debe incorporar la electrónica necesaria; mientras que, en el caso de los ópticos, cada elemento requiere ubicar marcadores reflectantes con una disposición variable en su superficie. De esta forma, los elementos a colocar sobre el cuerpo pueden ser entendidos como *wearables* que miden movimiento, o más concretamente *MoCap-wearables* (Marín *et al.*, 2017a).

No obstante, capturar el movimiento con tecnologías basadas en marcadores superficiales requiere abordar exigencias no fáciles de satisfacer, tanto a nivel de precisión o calidad de medida, como a nivel de usuario. En este sentido, es importante considerar que el propio avance de la tecnología, con frecuencia más rápido que la investigación, da lugar a sistemas de captura de movimiento que no siempre se adecúan al contexto y a los usuarios, no aseguran un correcto posicionamiento de los dispositivos sobre el cuerpo, son incómodos o bien no proporcionan una suficiente precisión (Haratian *et al.*, 2014; Mooney *et al.*, 2015; Yang & Li, 2012). Todo ello justifica el siguiente reto.

¿Sería posible crear metodologías para diseñar productos de captura de movimiento *wearables* adecuados a los usuarios y al contexto?

1.2.3. Diseño de Sistemas de Equilibrio y Dinamometría

Existen otras tecnologías que pueden ser consideradas instrumentación de salud para evaluar el sistema musculoesquelético, como es el caso de las plataformas estabilométricas o los dinamómetros.

Las plataformas estabilométricas permiten objetivar la proyección del centro de gravedad o centro de presiones de un sujeto que se sitúa sobre ella (López & Calidonio, 2009; Postolache & Postolache, 2017; Zhu, 2017). Estos dispositivos también pueden denominarse plataformas posturográficas, estabilométricas, dinamométricas, de fuerza o de equilibrio. Aunque pueda parecer una tarea simple, mantener un correcto equilibrio en bipedestación representa una habilidad compleja para el ser humano. La estabilidad corporal implica la coordinación de múltiples componentes sensoriales, motores y biomecánicos, involucrando tres sistemas: visual, vestibular y somatosensorial (Guskiewicz & Perrin, 1996). Por ello, estas plataformas son reconocidas como una instrumentación de interés para evaluar la capacidad humana en lo relativo al control del equilibrio. Existen dos categorías de plataformas; plataformas monoaxiales, que miden la componente vertical de fuerza, y plataformas multiaxiales, que miden fuerza lineal y/o de torsión en más de una dirección espacial (Postolache & Postolache, 2017).

Los dinamómetros, por su parte, miden objetivamente la fuerza muscular de ciertos segmentos corporales al realizar un determinado ejercicio (Roy *et al.*, 2009). La objetivación de la fuerza muscular es un componente fundamental para evaluar el estado físico, ya que informa sobre la capacidad del sujeto para realizar actividades de la vida diaria que influyen en su autonomía personal (Holt *et al.*, 2016; Roy *et al.*, 2009). Pueden diferenciarse dos tipos de dinamómetro: los estacionarios y los isométricos. Los estacionarios permiten medir fuerza estática y dinámica a diferentes velocidades y, aunque son muy precisos (Wollin *et al.*, 2016), son equipos especialmente costosos, requieren un alto tiempo de preparación y, normalmente, son grandes y voluminosos (Holt *et al.*, 2016). La dinamometría isométrica, más simple y menos aparatosa, mide la fuerza muscular realizada en ejercicios en los cuales los músculos no varían de longitud, es decir, no precisan realizar un movimiento. Dentro de los isostáticos podemos distinguir varias tipologías: dinamómetros *hand-held*, sostenidos por el operador (Holt *et al.*, 2016; Roy *et al.*, 2009); dinamómetros para grupos musculares concretos, como los dinamómetros de mano o *hand-grip* (Bohannon, 2015); o la denominada dinamometría externa fija, que utilizan celdas de carga acopladas a un punto del entorno o el mobiliario y cinchas para que el sujeto tire de ellas (Wollin *et al.*, 2016).

A pesar del impacto positivo de estas tecnologías para la valoración de la capacidad funcional de un paciente, históricamente el uso de plataformas de equilibrio y dinamómetros ha estado limitado a laboratorios de investigación (Walsh *et al.*, 2006). Ello es debido a que requieren altas inversiones económicas y suelen disponer de un

software rígido con una configuración difícilmente adaptable a los sistemas informáticos clínicos, lo cual limita su extensión en el campo de la salud (Guskiewicz & Perrin, 1996; Postolache & Postolache, 2017; Zhu, Y., 2017).

En consecuencia, se requiere acercar estas tecnologías al ámbito de la salud, haciéndolas más usables, simples y flexibles; adecuándose, tal y como aseveran Postolache & Postolache (2017), al *situational context* y las *task demands,* es decir, al contexto y sus necesidades.

¿Cómo podrían diseñarse sistemas de equilibrio y dinamometría aplicables e integrados en el contexto?

1.2.4. Captura de Movimiento como Caso de Estudio Principal

Entre los posibles casos de estudio expuestos, esta tesis profundiza en el diseño de sistemas de captura de movimiento. Esta tecnología implica abordar retos de investigación a distintos niveles, que favorecen la extrapolación de los resultados a otros casos más favorables o menos complejos.

A nivel de producto, la captura de movimiento requiere diseñar numerosos elementos, los cuales deben acomodarse al cuerpo e interactuar con el paciente y el facultativo (Marín *et al.*, 2017a). Ello eleva la complejidad con respecto a los dispositivos de equilibrio o dinamometría que requieren diseñar un único producto.

Asimismo, a nivel de operativa, el clínico debe ser capaz de colocar los dispositivos correctamente e instruir al participante durante la calibración y movimientos a realizar (Ferber *et al.*, 2016; Karg *et al.*, 2015). Dichas instrucciones y participación activa por parte del paciente añaden complejidad respecto a otras tecnologías que precisan instrucciones al paciente más sencillas.

Adicionalmente, la interpretación de los resultados no es una labor simple (Prakash *et al.*, 2018; Simon, 2004). Para interpretar las curvas de movimiento se requiere un conocimiento extenso acerca de los patrones biomecánicos asociados a la patología a evaluar, lo cual añade dificultad al análisis (Marín *et al.*, 2020).

1.2.5. Oportunidades: *Wearables* y Metodologías de Diseño

Los avances relacionados con *wearables*, y las metodologías de diseño centradas en el usuario pueden suponer una oportunidad y una base de conocimiento esencial para dar respuesta a los retos descritos.

Los *wearables* se definen como dispositivos que permiten la interacción con el usuario mientras permanecen unidos al cuerpo, independientemente de la actividad realizada y sin requerir esfuerzo muscular para sujetarlos (Knight *et al.*, 2002; Knight *et al.*, 2006). Esta definición coincide con la descripción de los elementos a colocar en el paciente durante la captura de movimiento. En este contexto, conceptos como *Wearability* o *Dinamic wearability* pueden suponer un punto de partida para mejorar la experiencia de uso de los sistemas de captura. La *Wearability* estudia la interacción entre el cuerpo humano y el dispositivo, y la *Dinamic wearability* estudia la interacción incluyendo el movimiento del cuerpo humano (Gemperle *et al.*, 1998).

No obstante, como exponen Andreoni *et al.* (2016) o Motti & Caine (2014), los *wearables* implican un reto de investigación de carácter multidisciplinar. Es difícil considerar y priorizar adecuadamente las perspectivas de los usuarios en el diseño de *wearables*, de hecho, los factores humanos son a menudo descuidados. Desde la perspectiva de los usuarios, la estética y la comodidad son prioritarias; desde la perspectiva tecnológica, la funcionalidad y la duración de la batería son críticas; y desde el punto de vista clínico, la precisión, la privacidad y la accesibilidad son esenciales (Motti & Caine, 2014). Por tanto, el diseño debe asegurar un alto nivel de aceptación y su utilización mantenida en el tiempo. De hecho, la tecnología wearable, en ocasiones carece de dicha utilización perdurable, y ha adquirido el término *Engagement* para definir y establecer como objetivo el uso mantenido por parte de los usuarios (Lewis *et al.*, 2020).

En este sentido, Gemperle *et al.* (1998) exponen una metodología de diseño de *wearables* basada en trece puntos, que describe las características que deben satisfacer estos productos. Asimismo, Motti & Caine (2014) presentan una lista de veinte principios de diseño centrados en usuario para facilitar la consideración de los factores humanos en las fases iniciales de diseño de *wearables*. Finalmente, Andreoni *et al.* (2016) muestran diferentes conceptos y sus interrelaciones para ser considerados durante el diseño de este tipo de productos. Todo ello implica una base de conocimiento sólida para las etapas iniciales de esta investigación.

Más allá de la tecnología wearable, se considera que el estado del arte relacionado con las metodologías de diseño centradas en el usuario puede tener un papel fundamental para abordar las necesidades existentes en la captura de movimiento (Bouchachia *et al.*, 2016; Maguire, 2001; Marín, J. *et al.*, 2019). Los avances en la instrumentación de evaluación musculoesquelética suelen tener una perspectiva notoriamente tecnológica, y hay escasas contribuciones desde un punto de vista contextual y centrado en el usuario (Blanco, 2016; Blanco *et al.*, 2019).

Hay que destacar que no solo estamos ante el diseño de un producto tecnológico, sino que se trata de una combinación de actividades que dan servicio a varios usuarios. Y para proporcionar este servicio se hace uso de la propia tecnología, pero también de una serie de procedimientos que deben ser diseñados y planificados. En este contexto, las metodologías de diseño de servicios suponen una oportunidad, ya que permiten involucrar a los usuarios en el proceso de diseño. Entender las necesidades y expectativas de los usuarios permite conseguir la mejor experiencia de uso posible (Kujala, 2003; Tassi, 2009; Wetter-Edman *et al.*, 2018).

Dichas perspectivas de diseño (centrado en el usuario y de servicios) se alinean con la filosofía de atención centrada en el paciente, que es una prioridad de investigación biosanitaria (Blanco, 2016; Blanco *et al.*, 2019; McMurray *et al.*, 2016). Los métodos de diseño pueden reducir la incertidumbre que deben asumir los servicios de salud. Adicionalmente, estas técnicas son relevantes para que los profesionales involucrados en dichos servicios conozcan mejor sus roles y trabajen de manera óptima y ordenada; sobre todo cuando se pretende introducir mejoras tecnológicas como la captura de movimiento.

1.3. Definición de Objetivos de la Investigación

Esta tesis nace con el objetivo general de mejorar la usabilidad e integración de la instrumentación para evaluar el sistema musculoesquelético, centrándose en la captura de movimiento y el ámbito de la salud.

Derivado de los retos descritos anteriormente, se plantean los siguientes objetivos específicos de investigación. A cada objetivo se le ha asignado una abreviatura para relacionarlos con las publicaciones realizadas en esta investigación. Dicha relación se expone en los siguientes apartados.

(OB-1) Investigar las **necesidades** que presenta la instrumentación dirigida a evaluar el sistema musculoesquelético en el ámbito de la salud, para enmarcar esta investigación u otras relacionadas.

(OB-2) Crear una **metodología** para diseñar sistemas de captura de movimiento. Para ello, investigar el estado del arte de los sistemas de captura actuales, y estudiar la tecnología *wearable* y las metodologías de diseño como inspiración.

(OB-3) Aplicar la metodología desarrollada a un **caso de estudio** del ámbito de la salud.

- **(OB-3.1)** Analizar y diseñar la integración de un sistema de captura de movimiento en un servicio sanitario de rehabilitación.
- **(OB-3.2)** Adaptar el producto para su aplicación en el contexto sanitario, superando las barreras tecnológicas que presente.
- **(OB-3.3)** Desarrollar software para analizar los datos de movimiento y generar informes personalizados a cada paciente.

Los objetivos de esta tesis se alinean con las líneas estratégicas europeas concretadas en el *II Plan Aragonés de Investigación, Desarrollo y Transferencia de Conocimientos.* Especialmente con el punto *III Seguridad y Calidad de Vida Individual y Colectiv*a, donde se cita la creación de nuevas tecnologías de uso clínico, así como el desarrollo de herramientas informáticas que asistan al diagnóstico *e-health.*

Del mismo modo, los objetivos enlazan con *la Estrategia Aragonesa de Investigación e Innovación para una Especialización Inteligente, RIS3 Aragón*, que establece la prioridad estratégica de *Bienestar y Calidad de Vida* para promover desarrollos tecnológicos enmarcados en *Smart Health* e *Internet of Things*, que favorezcan el envejecimiento saludable *(Healthy Ageing)* y satisfagan las demandas sanitarias de la población dispersa y envejecida.

1.4. Presentación de los Estudios Publicados

Esta tesis doctoral está compuesta por un compendio de cinco publicaciones científicas internacionales. En adelante, estas publicaciones se presentan como estudios numerados del 1 al 5. Los estudios se enmarcan en los objetivos de investigación descritos; no obstante, cada uno de ellos responde a unas necesidades concretas y aporta conocimiento específico, por lo que pueden ser entendidos también de manera independiente. A continuación, se presentan cada uno de los estudios, incluyendo un resumen que lo contextualiza en la investigación global de esta tesis.

- **Estudio 1:** Marín, J., Blanco, T., Marín, J.J. (2017). Research Lines to Improve Access to Health Instrumentation Design. Procedia Computer Science, 113, 641-646. https:// doi.org/10.1016/j.procs.2017.08.323

  En el estudio 1 se presentan las necesidades de esta investigación. Este trabajo explora nuevas áreas de investigación en el desarrollo de instrumentación dirigida a evaluar el sistema musculoesquelético en el sector biosanitario. Bajo el contexto de la *Internet of Things*, analiza nuevas líneas de trabajo que mejoren la experiencia de usuario de los productos y servicios relacionados con el cuidado de la salud. Esta investigación incluye captura de movimiento, plataformas estabilométricas y dispositivos de dinamometría. Tras exponer el estado del arte, se propone desarrollar *Health Development Tools* (HDT), es decir, herramientas que asistan a los diseñadores para superar los retos que presenta esta tecnología y su contexto. Pueden existir HDT dirigidas al desarrollo de prototipos o productos físicos (HDT tangibles), como veremos en el estudio 4, o a la creación de metodologías o pautas de diseño (HDT intangibles), como puede observase en los estudios 2, 3 y 5.

- **Estudio 2:** Marín, J., Blanco, T., Marín, J.J. (2017). Octopus: A Design Methodology for Motion Capture Wearables. Sensors, 17, 1875. https://doi.org/10.3390/s17081875

  En el estudio 2 se propone la metodología de diseño Octopus. Esta metodología está dirigida a apoyar el diseño de sistemas de captura de movimiento denominados *MoCap-wearables*. La tecnología de captura de movimiento es útil y aplicable en diferentes campos, como la salud, el deporte o el ocio. Sin embargo, capturar el movimiento de manera adecuada requiere abordar requisitos que no son fáciles de satisfacer. Octopus clasifica y esquematiza los factores que se deben considerar en el proceso de diseño y proporciona una herramienta para que los equipos multidisciplinares definan los requisitos de diseño de este tipo de productos. Esta metodología puede ayudar a generar productos con mayor aceptabilidad e integración en los escenarios de uso.

- **Estudio 3:** Marín, J., Blanco, T., Marín, J.J., Moreno, A., Martitegui, E., Aragüés, J.C. (2019). Integrating a Gait Analysis Test in Hospital Rehabilitation: A Service Design Approach. Plos One, 14, e0224409. https://doi.org/10.1371/journal.pone.0224409

  El estudio 3 se centra en dar respuesta a la integración de la tecnología de captura de movimiento en la rehabilitación hospitalaria, detectando necesidades y planteando posibles soluciones. Se focaliza concretamente en el desarrollo de un test de análisis de la marcha, basado en captura de movimiento IMU, para monitorizar pacientes en rehabilitación mediante sesiones de medición breves, previas y posteriores a los tratamientos o terapias aplicados. Para asegurar la integración del test de marcha en el servicio hospitalario, realizamos una investigación cualitativa con 13 pacientes con espasticidad hemipléjica que recibieron tratamiento con toxina botulínica, 10 *proxies* (familiares, tutores o acompañantes del paciente) y 6 médicos. Se utilizaron técnicas de observación durante el uso del sistema, entrevistas semiestructuradas y talleres con profesionales de la salud. El análisis dio como resultado pautas de diseño, así como un esquema conceptual del servicio incluyendo la prueba de análisis de la marcha. Esta investigación puede favorecer la aplicabilidad y la utilidad de la tecnología de análisis de la marcha; además, el enfoque metodológico utilizado puede ayudar a integrar un micro-servicio en un macro-servicio.

- **Estudio 4:** Marín, J., Blanco, T., de la Torre, J., Marín, J.J. (2020). Gait Analysis in a Box: A System Based on Magnetometer-Free IMUs or Clusters of Optical Markers with Automatic Event Detection. Sensors, 20, 3338. https://doi.org/10.3390/s20123338

  El estudio 4 expone el sistema de captura de movimiento para análisis de la marcha llamado Move Human Sensors (MH). Este sistema se basa en la tecnología desarrollada por el Grupo de Investigación IDERGO, y sus especificaciones de diseño se fundamentan en las obtenidas en el estudio 2 (Octopus) y en el estudio 3 (diseño de servicios). El equipo MH se puede configurar con IMUs (MH-IMU) o con tecnología óptica basada en sólidos rígidos (MH-OPT). El estudio incorpora dos propuestas principales: por una parte, un procedimiento de calibración anatómica que permite la desactivación de los magnetómetros de los IMUs para evitar las perturbaciones magnéticas; y por otra, un algoritmo que detecta *gait events* a partir de datos cinemáticos y sin requerir instrumentación adicional. Estas propuestas superan ciertas limitaciones tecnológicas y mejoran la aplicabilidad del análisis de la marcha en la práctica clínica diaria para evaluar tratamientos y terapias. Mediante un experimento de reproducibilidad test-retest con 33 sujetos sanos (20 hombres y 13 mujeres, 21,7 ± 2,9 años), se determinó la reproducibilidad de ambas configuraciones. La evaluación y análisis confirmó que las propuestas funcionaron adecuadamente y permitió establecer consideraciones de uso.

- **Estudio 5:** Marín, J., Marín, J.J., Blanco, T., de la Torre, J., Salcedo I., Martitegui, E. (2020). Is My Patient Improving? Individualized Gait Analysis in Rehabilitation. Applied Sciences, 10, 8558. https://doi.org/10.3390/app10238558

  El estudio 5 recoge un método para gestionar los datos resultantes de la prueba de marcha basada en IMUs descrita en los estudios 3 y 4. La aplicación de este método en rehabilitación apoya la toma de decisiones relativas a los tratamientos ya que, permite comparar las capturas pre- y post-tratamiento mediante técnicas estadísticas basadas en magnitudes (*magnitude-based decisions*). Además, posibilita la detección de los cambios que superan las imprecisiones derivadas de la instrumentación y la operativa. El método se aplicó en 21 pacientes, que igual que en el estudio 3, tenían espasticidad hemipléjica y recibían tratamiento con toxina botulínica. A cada paciente se le realizó un test de marcha justo antes del tratamiento con infiltraciones de toxina botulínica y otro test después de un mes. El estudio demostró que era posible proveer de información simple y visual al clínico para inferir una conclusión acerca de la evolución experimentada por cada paciente.

1.5. Metodología

Desde una perspectiva general, esta investigación sigue una metodología basada en la corriente de investigación-acción. La investigación-acción implica llevar a cabo actividades estratégicas dirigidas tanto a mejorar la práctica, como a desarrollar planteamientos teóricos acerca de dicha práctica, y todo ello de manera iterativa o cíclica (Blanco, 2016). Este bucle fomenta el aprendizaje del investigador, mejora los productos o servicios analizados y favorece el avance conocimiento científico (Blanco, 2016).

Así, la investigación-acción encaja en el contexto de la tesis, ya que la naturaleza de los proyectos realizados conlleva requerimientos que es necesario materializar en la realidad. Por tanto, las contribuciones al conocimiento de esta investigación se basan en la observación y aprendizaje durante la práctica o acción, así como en la elaboración de estados del arte específicos para cada reto o acción a abordar, alcanzando un equilibrio entre *praxis* y avance científico.

La línea investigación-acción está conectada con las metodologías de diseño centradas en el usuario (Kujala, 2003; Tassi, 2009; Wetter-Edman *et al.*, 2018), ya que ambas se basan en procesos iterativos y flexibles (Blanco, 2016). De hecho, puede observase como las fases de diseño centrado en el usuario implican en sí mismas estos conceptos de investigación (comprender el problema, empatizar con el usuario, profundizar en el contexto, etc.) y acción (definir, idear, prototipar, testear, etc.).

Otra decisión metodológica importante es elegir la estrategia de diseño *inside-out* (desde adentro hacia afuera), frente a la perspectiva de *outside-in* (de fuera hacia dentro) (Franz, 2015). Es decir, utilizar los requerimientos del usuario y el contexto para mejorar los productos o la tecnología, involucrando al usuario desde las etapas iniciales de diseño (Kujala, 2003).

Por tanto, las publicaciones de la tesis pueden entenderse dentro de este bucle de investigación-acción y se fundamentan en el diseño centrado en el usuario. No obstante, cada una de ellas responde a un reto concreto y sigue una metodología específica. Por ello, el apartado 1.6. termina de definir la metodología de esta tesis, ya que materializa esta perspectiva general a través de las acciones específicas realizadas durante las investigaciones.

1.6. Justificación de la Unidad Temática de los Estudios

La relación entre los estudios de la tesis se recoge en la figura 3. El proyecto de investigación comienza con un plan de investigación que expone las necesidades y problemas detectados a partir de un primer estado del arte (estudio 1). Posteriormente, la investigación se focaliza en la tecnología de captura de movimiento, dando lugar a una propuesta metodológica denominada Octopus, la cual está dirigida a diseñar este tipo de sistemas de captura (estudio 2). Seguidamente, derivado de los proyectos y colaboraciones en curso, la investigación se centra en un caso de estudio dirigido al seguimiento de pacientes en rehabilitación mediante análisis de la marcha. De esta forma, la aplicación de la metodología Octopus se materializa en los estudios 3, 4 y 5, que se enmarcan en las líneas de trabajo de diseño de servicios, producto y software respectivamente.

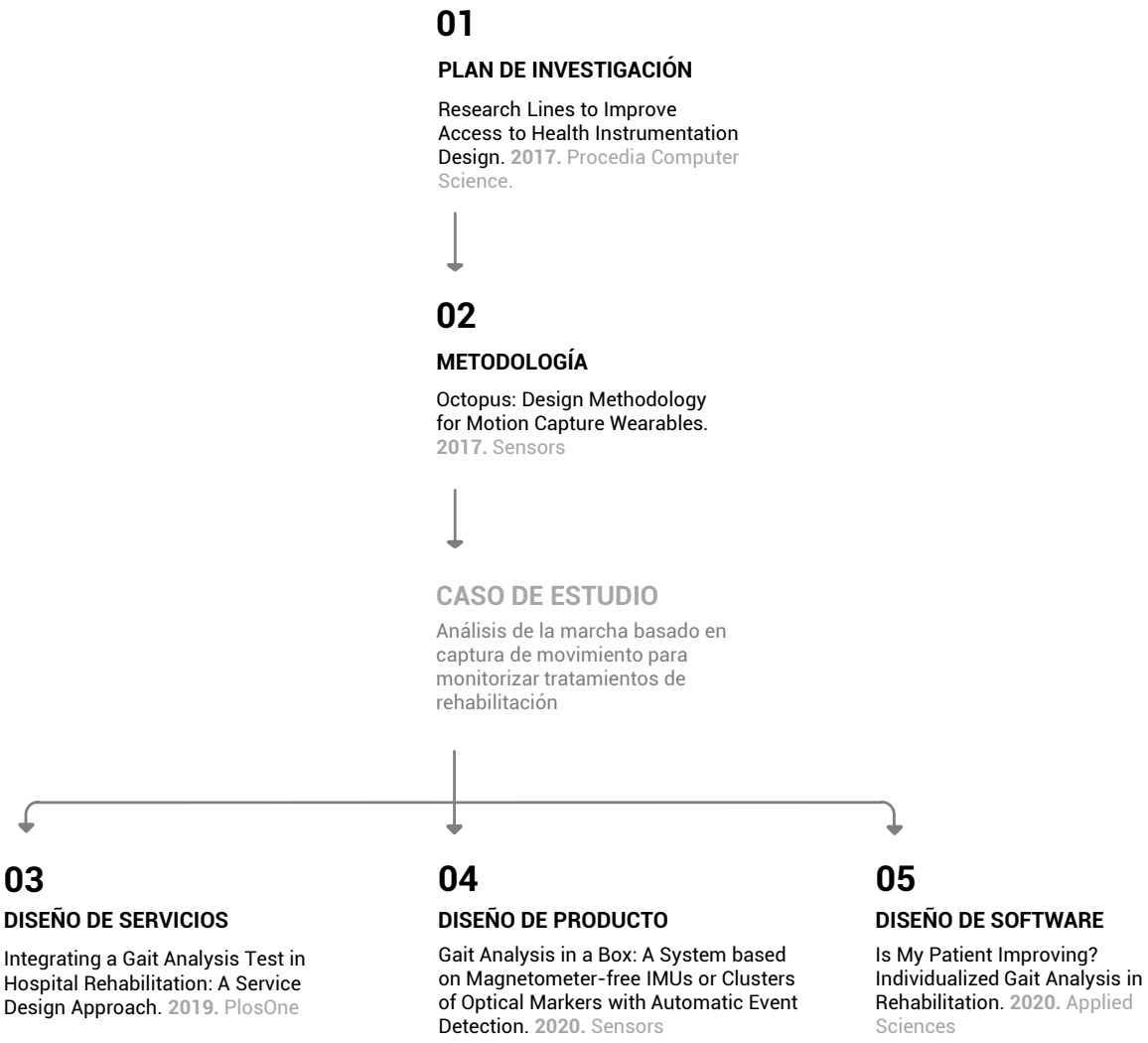


Fig 3. Relación entre los estudios de esta tesis.

Para desarrollar la ruta seguida por los artículos, es relevante conectarlos con los retos de investigación descritos. De esta forma, se puede afirmar que el estudio 1 responde al

OB-1, ya que se centra en la instrumentación sanitaria para evaluar el sistema musculoesquelético y permite enmarcar las necesidades generales del proyecto.

El estudio 2 se relaciona directamente con el OB-2 y presenta Octopus, dirigida a diseñar dispositivos de captura de movimiento, que identifica como *MoCap-wearables*. Esta metodología constituye una base teórica relevante para diseñar instrumentación de captura de movimiento y, por tanto, es la guía principal e hilo conductor que sigue el proyecto de investigación. El nombre de la metodología es una metáfora sobre cómo los dispositivos deberían adherirse al cuerpo y también hace referencia a los ocho pasos en los que se ordena la misma. La metodología propone abordar el diseño desde tres bloques o líneas de trabajo: diseño de servicios, producto y software. De esta manera, surge la idea de diseño en 3 niveles (servicios, producto y software), que son los tres conceptos que debería plantearse y abordar el diseñador a la hora de desarrollar soluciones dirigidas a evaluar el sistema musculoesquelético.

Bajo el paraguas de Octopus, se exploraron posibles casos de estudio reales donde aplicar la metodología, lo cual corresponde con el OB-3. El caso de estudio seleccionado se enmarca en la rehabilitación hospitalaria, y surgió gracias a la colaboración con el Servicio de Rehabilitación del Hospital Miguel Servet de Zaragoza.

Concretamente, el caso de estudio se centra en el diseño de una prueba clínica de análisis de la marcha basada en captura de movimiento para monitorizar pacientes que reciben tratamientos de rehabilitación. Dicha prueba puede aplicarse en sesiones de medición breves, previas y posteriores a los tratamientos y, con ello, generar informes de utilidad para los clínicos que permitan una evaluación individualizada de cada paciente. Este concepto se muestra en la figura 4. La iteración de este proceso es lo que permite llevar a cabo un proceso de monitorización individualizado para cada paciente.

Fig 4. Representación esquemática del caso de estudio.

La elección del análisis de la marcha como objeto de estudio fue una decisión combinada entre la experiencia del equipo médico y el equipo investigador, en base a las necesidades del servicio de rehabilitación. Aunque no somos conscientes de su complejidad, la marcha es una actividad compleja para el ser humano; requiere un alto control motor, y sus patologías tienen un efecto notable sobre la autonomía personal y las actividades de la vida diaria (Cimolin & Galli, 2014). Por ello, numerosos tratamientos e intervenciones de rehabilitación están dirigidos a mejorar el patrón de marcha (Baker, 2006; Chambers & Sutherland, 2002; Cook *et al.*, 2003; Duncan *et al.*, 1992; Prakash *et al.*, 2018; Simon, 2004; Zhou & Hu, 2008). En consecuencia, una prueba basada en captura de movimiento, con las características descritas e integrada en el proceso de rehabilitación, ayudaría a dirigir las decisiones sobre numerosos tratamientos e intervenciones.

De esta manera, la prueba de análisis de la marcha se aplicó en el citado servicio, concretamente en pacientes con espasticidad hemipléjica que recibían tratamiento con toxina botulínica. La elección de estos pacientes responde a los mismos criterios de necesidad real, y además proporciona un escenario desafiante que permite extrapolar los resultados y métodos a otros pacientes con condiciones físicas o cognitivas más favorables.

Para llevar a cabo el desarrollo de la prueba de marcha, al inicio de este proyecto de investigación se contaba con el sistema de captura de movimiento MH, desarrollado por el Grupo de Investigación IDERGO. Por tanto, tal y como muestran los siguientes puntos, los estudios 3, 4, y 5 recogen el análisis, diseño, validación y adaptación del sistema MH al caso específico de estudio.

- El estudio 3 responde al OB-3.1, y se enmarca en el bloque de diseño de servicios. Una de las primeras tareas necesarias relativas al caso de estudio, fue llevar a cabo una investigación cualitativa con la finalidad de generar especificaciones de diseño y pautas para integrar la tecnología de análisis de la marcha en un entorno de rehabilitación hospitalaria. Esta investigación se basó en observación, entrevistas y talleres con pacientes, *proxies* (familiares, tutores o cualquier acompañante del paciente) y profesionales del sector. La investigación permitió estudiar la integración del sistema MH en la rehabilitación y así fomentar la aplicabilidad de la tecnología.
- El estudio 4 da respuesta al OB-3.2, se encuadra en la rama de diseño de producto, y estudia el sistema MH en condiciones de laboratorio. Este estudio describe ampliamente la configuración del sistema MH basada en sensores inerciales (MH-IMU), así como la configuración basada en tecnología óptica (MH-OPT). El estudio incluye propuestas, tanto a nivel de captura de movimiento, como a nivel de análisis de la marcha, que pueden ser extrapolables a otros equipos y superan ciertas barreras tecnológicas que dificultaban su aplicación. Asimismo, estudia la reproducibilidad de ambas configuraciones con una muestra de 33 sujetos sanos; lo cual, permitió comprobar que el sistema y las propuestas que incorpora respondían adecuadamente a las exigencias planteadas, igualando e incluso superando la reproducibilidad de otros sistemas descritos en la literatura.
- Adicionalmente, se realizó el estudio 5, que se enmarca en el OB-3.2 relativo al diseño de software. Con el objetivo de comparar los resultados de dos capturas consecutivas de un paciente, se implementó un método que aplica técnicas estadísticas basadas en magnitudes, en inglés *magnitude-based decisions* (Batterham & Hopkins, 2006; Buchheit, 2018; Hopkins, 2019). El método presentado permite discernir si entre las dos capturas (pre- y post-tratamiento) han ocurrido cambios que superan a los propios errores derivados de la instrumentación, el protocolo o la variabilidad individual. El método se aplicó a 21 pacientes heterogéneos con espasticidad hemipléjica que recibieron tratamiento de toxina botulínica, 13 de los cuales coinciden con la muestra analizada cualitativamente en el estudio 3. A dichos pacientes se les capturó utilizando la configuración MH-IMU, y se demostró que era viable obtener conclusiones acerca de la naturaleza de los cambios (positivos, negativos o nulos) que habían experimentado tras un mes del tratamiento.

Se desprende de lo expuesto que los cinco estudios dan respuesta a los retos y preguntas inicialmente planteadas en esta investigación, proporcionado soluciones a la problemática de diseñar una prueba de análisis de la marcha para su aplicación en rehabilitación. En la sección de discusión, que se incluye posteriormente, se recoge de forma más detallada las contribuciones de los estudios descritos, así como consideraciones acerca de las decisiones y desarrollos necesarios durante el proceso de esta investigación.

2. Relación de Publicaciones

En esta sección se recogen los cinco estudios que conforman el cuerpo de esta tesis doctoral. El estudio 1 está indexado en *Scimago Journal & Country Rank* (SJR) y los estudios 2-5 están indexados en *Journal Citation Reports* (JCR). En relación con la revista científica de cada estudio, se indica la Base de Datos (BD) en la que está indexada, el Factor de Impacto (FI) y la categorías y cuartiles (Q) ordenadas según conexión temática con la tesis. Esta información corresponde al año de publicación, excepto en las publicadas en 2020 (estudios 4 y 5), que se toma la información del último año disponible, 2019.

2.1. Estudio 1

Marín, J., Blanco, T., Marín, J.J. (2017). Research Lines to Improve Access to Health Instrumentation Design. *Procedia Computer Science*, 113, 641-646. https://doi.org/10.1016/j.procs.2017.08.323

BD: SJR | FI: 0.258 | Q: *Computer Science: miscellaneous* (Q2 - 145/570)

Available online at www.sciencedirect.com

ScienceDirect

Procedia Computer Science 113 (2017) 641–646

Procedia Computer Science

www.elsevier.com/locate/procedia

International Workshop on Universal Design for IoT Smart Health (UDISH 2017)

Research Lines to Improve Access to Health Instrumentation Design

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Abstract

This document seeks new areas of research in musculoskeletal health instrumentation development, under the current context of the Internet of Things (IoT) and the design needs of achieving more efficient, profitable, and better user experience in healthcare-related products and services. Three health measurement instrumentation case studies are presented, which show latent barriers and needs as well as possible methods of solving these situations. The cases deal with instrumentation related to motion capture (MoCap), balance control measurement, and muscle strength measured by dynamometry. Using the cases, a scheme that includes the key elements involved in a health instrumentation system is proposed. The scheme is ideated to facilitate the creation of health development tools (HDT) that are intermediate tools that designers, developers, or researchers can use to implement health products and services in a more efficient, and accessible way.

Peer-review under responsibility of the Conference Program Chairs.

Keywords: Design Methodology; Multidisciplinarity; Smart Health; Wearable; MoCap; Human Balance; Dynamometry.

1. Introduction

The current context of intelligent objects interconnected with each other and the cloud in the Internet of Things (IoT),[1] has led to needs that transcend the mere profitability of technology products; issues such as usability, simplicity, intuitiveness, suitability to the user, or user experience improvement,[2] are increasingly essential for product success and to really improve people's lives. Therefore, it is necessary to consider how this context affects the development of health instrumentation, which refers to health measurement devices to obtain patient information. In this regard, Andersen et al.[3] described the concept of 'improving health care access', which means

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1877-0509 © 2017 The Authors. Published by Elsevier B.V.
Peer-review under responsibility of the Conference Program Chairs.
10.1016/j.procs.2017.08.323

enhancing everything that facilitates personal health service usage and overcoming barriers that hinder them, improving the alliance between health systems and the population by providing adequate services at the right time.

This concept leads to the development of the idea to 'improve access to health instrumentation design', with the same general objective as that of Andersen et al.[3] It focuses on facilitating health instrumentation development, considering the sector characteristics, requirements, limitations, and potentialities. Applying this approach will enable achieving technological solutions to specific health problems. The concept may have some parallelism and even contribute to the smart health field.[4] Consequently, it is understood that reaching and developing truly accessible technological solutions is not obvious and requires an adequate combination of research, experimentation, and creativity, which are issues that justify the inclusion of this concept in the scientific community.

The paper focuses on health instrumentation development aimed at assessing the musculoskeletal system by recording and analysing bio-signals related to movement, balance, and muscle effort, which respectively allows assessing personal functional capacity in terms of joint mobility, control of balance, and loss of muscle strength. These systems have a great impact on society as they imply a great user interaction opportunity, providing information to professionals, both directly (individual capacity, range of mobility of a joint, muscle strength, etc.) and indirectly (habits, physical inactivity, etc.).[5,6]

According to the above, the need to generate knowledge on the health instrumentation design field is justified. This would improve products and services aimed at professionals, such as doctors, physiotherapists, nurses, or occupational therapists. The tangible benefits and applications of this knowledge could be the following:

- Allowing the physicians to assess the musculoskeletal abilities of a patient at a certain point with different objectives, such as complementary diagnosis, job adaptation, treatment, or training objectives.
- Provide instrumentation that allows rehabilitation or training due to the 'biofeedback' in real time.[7]
- Establish a doctor-patient communication pathway, providing objective information about changes.
- Enable data collection outside the clinics or hospitals, promoting therapeutic activities in the home and improving personal autonomy.

These advantages combine with those described in *Strategic Research Lines of Horizon 2020* item 8, 'Health, demographic change and wellbeing',[8] supporting the development of information and communications technology (ICT) systems that fosters a high quality and economically sustainable healthcare system, responding to the strategic priority of 'Welfare and Quality of Life' ensuring 'healthy aging' and 'eHealth innovation in empowering the patient'. Additionally, note that systems designed within the framework described are not intended to replace the optional autonomous systems; they are expected to increase their knowledge and experience of tailoring treatment to each patient in line with the approach of 'personalised therapies'.

From the mentioned problem, it is expected that the scientific community will be aware of the problem and that this will transcend to other researchers and developers to improve the technological context of health. Therefore, three case studies of instrumentation are presented, showing some latent needs and pathways that can be oriented towards their solution. From these cases, a scheme is presented that includes the key elements of a health instrumentation system, and a future research line aims to facilitate access to this type of product development.

2. Case Studies

Three case studies that are related to monitoring and evaluating the musculoskeletal system are presented. They briefly describe the state of the art, the identified needs and barriers, and the possible factors and sources of inspiration that can improve access and determine their development. The cases focus on three types of systems: motion capture (MoCap), measurement of human balance, and measurement of muscle strength using dynamometry.

2.1. Case 1: Motion Capture (MoCap) Systems

MoCap systems that are used to analyse and study human motion are widely recognised for their usefulness and application in different fields, such as health, sports, or leisure.[9,10] MoCap technology usually uses elements that are placed in certain body points to identify movement, angles, and positions between them. Markers can have

embedded electronic sensors, inertial measurement units (IMU), or elements monitored by cameras located around the capture zone.

However, adequate MoCap requires addressing requirements that are difficult to satisfy; thus, the applications that are possible with this technology are stunted by several technological and usability barriers. These barriers are the result of the technology itself, which is often faster than research, and can generate MoCap systems that do not ensure correct positioning or attachment to the body or are uncomfortable and do not provide enough precision.[11,12] All this justifies the need to create methodologies to design products that are suitable to the context and users.
In this sense, wearable devices are a source of inspiration in scientific and market fields, as they can help overcome these barriers. Wearables have a parallelism with MoCap markers placed on the body, a key point for usability and accuracy. This is observed through the three main wearable characteristics:[13]

> (1) The device is attached to the body and does not require muscular effort to remain in contact with the body, (2) it remains attached to the body regardless of the body's orientation or activity, and (3) it does not have to be detached to be interacted with.[13]

Therefore, terms such as *wearability*, which defines the interaction between the human body and the device, or *dynamic wearability,* which includes the movement of the human body in the design,[14] can be a starting point to improve the MoCap system user experience.

In addition, as Andreoni et al.[15] and Motti and Caine[16] discussed, wearables are themselves a multidisciplinary research challenge, so this multidisciplinarity is an extensive and transversal need in MoCap and in any health instrumentation.

2.2. Case 2: Evaluating Human Balance Control

Human balance is important for healthy living and healthy ageing. Although it may seem a simple task, maintain standing balance is a complex skill; it involves coordinating multiple motor and biomechanical sensory components.[17] In this sense, stabilometric platforms are devices that allow an objective and precise quantification of the ability to remain stable; thus, they are considered a contrasting tool of evaluation.[18,19] However, in these type of devices, there are also barriers to design adequate products, among which cost and use flexibility are highlighted.

Cost is a key factor that largely impedes widespread access to stabilometric platform usage in different environments.[17] Platforms used for biomedical research can involve investments of over ten thousand US dollars.[18,19] In this line, some applications, such as gait analysis, require more than one platform, which aggravates this fact. This need is also contrasted by the growing number of articles destined to validate the Wii console platform that costs less than 100 €.[20,21]

The flexibility factor also plays a significant role. Historically, stabilometric platforms have been restricted to research laboratories.[22] The development of tools with flexible hardware and software can improve the integration between systems and allow experimentation in a variety of places and applications that previously were not considered practical.[19] In this way, Postolache and Postolache[18] added that balance-related technology must depend on the ‘situational context’ and the ‘task demands’, for which flexibility is required.

Consequently, and given the effects of balance health assessments and the barriers identified (cost and flexibility), the need to design new devices that overcome these barriers and extend their applications to other areas that are not yet explored is justified.

2.3. Case 3: Evaluating Muscle Strength

The assessment of muscular strength is a necessity of the healthcare community. Since the first manual muscle testing protocols were developed in the early 1900s, dynamometric devices have been implemented to objectively assess muscle strength.[23-26] Despite their great utility, they also have barriers and needs to overcome that can be added to those described in the previous cases (usability, multidisciplinary, cost, flexibility, etc.).

Among the dynamometry devices, two types can be differentiated: stationary dynamometers and isometric dynamometers. Stationary dynamometers allow measurement of static or dynamic force (at different speeds). They

are expensive equipment, require high preparation time, and are bulky.[23] However, they can be considered the dynamometric 'gold standard'.[26] Isometric dynamometers are simpler and less cumbersome; they measure static muscle strength while the subject performs exercises in which the muscles do not vary in length (isometric effort). In relation to the latter type, several product concepts have been detected: hand-held dynamometers,[23,24] externally fixed dynamometers,[26] and dynamometry for specific muscle groups.[25]

Hand-held devices that are sustained by the operator have been accepted as clinical evaluation methods because of their high reliability; however, they can accumulate errors related to reproducibility, operator strength, joint position, strength of application, or stabilisation of the patient. Externally fixed dynamometers use load cells connected by one of its sides to a fixed point and by the other to a grip; they have high interoperator reliability, but ad-hoc solutions are needed to affix the devices, either to room points or to furniture, which hinders its implementation. Solutions for specific muscle groups, such as hand dynamometry[25] can be a resource for creating more usable and commercial products.

According to the above, it would be beneficial to develop instrumentation or methodologies to design instrumentation that aims to overcome these barriers. Developed instrumentation could also include electromyography sensors, which record muscle electrical activity and could be added as an additional bio-signal. In this sense, commercial electromyography sensors that integrate with electronic development platforms have a moderate cost, which could be an opportunity to experiment with innovative solutions.

3. Research Methodology

The case studies, the detected needs, and the view of the authors in different areas (biomedical, mechanic, and design engineering) have allowed ideating a scheme of the elements that comprise a health product service and its ecosystem (Fig. 1). It is expected to help structure the projects carried out. In the scheme, several elements are observed: processing, devices, environment, and usage. Moreover, there are two users involved: health practitioners and patients. As seen in the scheme and its interrelations (Fig. 1), the different elements interact with the two users, which shows that the work is intrinsically related to different design branches: interaction design, user experience design, and service design, among others.[2,27-29]

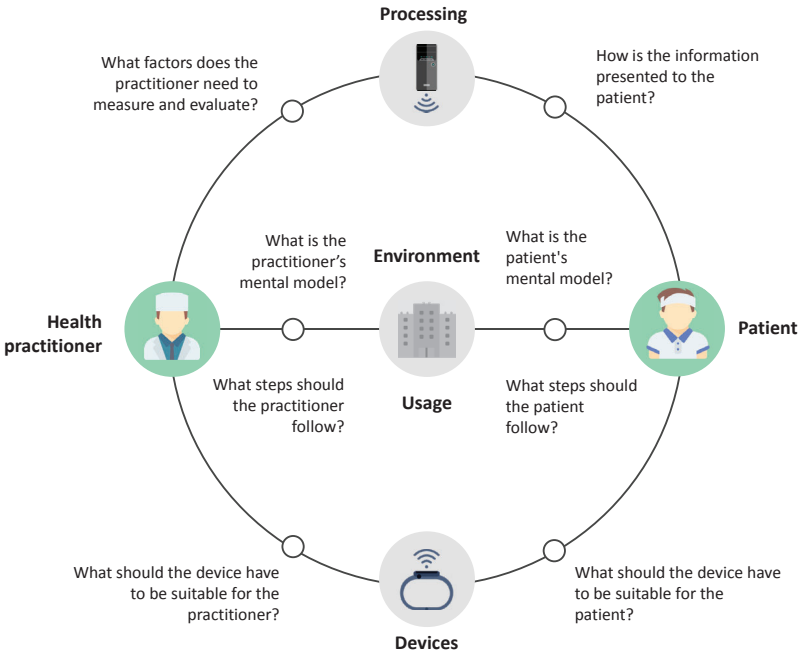

Fig. 1. Health Instrumentation and its ecosystem. Icons made by Freepik, Madebyoliver, and Alfredo Hernandez from www.flaticon.com

In view of the above, future research should focus on the creation of health development tools (HDT) that are intermediary tools that designers, developers, and researchers can use in a simpler and more efficient way to implement their projects and ideas, generating products and services that reach the final goal of improving access to health instrumentation. The creation of the HDT can be addressed using two approaches: development of physical prototypes or products (tangible HDT) and creating design methodologies or guidelines (intangible HDTs).

Tangible HDTs can be simply understood as an analogy to the Arduino product, an open development platform that facilitates the implementation of electronic projects. This philosophy could be extrapolated to develop solutions specifically targeted to health with its peculiarities and requirements. This could be useful in Case Studies 2 and 3, where the creation of simpler, more flexible, and economically balanced platforms or dynamometers could facilitate more optimal and accessible solutions. In this way, these HDT products could be easily reproducible by other researchers or acquired by them to experiment and to flexibly reach concrete solutions to the detected problems.

Moreover, intangible HDTs are a key point in the development of such complex instrumentation, which requires considering many aspects (Fig. 1). In fact, in Case Study 1, the requirements to be met in MoCap products could be addressed by a design methodology. These methodologies or guidelines could be useful in the phases of requirement extraction and/or the evaluation process. In any case, they should consider multidisciplinary factors in the entire process, ensuring joint work between technologists and users (patients and practitioners). This would help to extract realistic needs and generate solutions with greater acceptance,[30] promoting more efficient and useful health systems for society.

4. Conclusions

As a result of the current context of intelligent IoT objects, and with the goal of achieving quality health systems, this paper presents the need to improve access to health instrumentation development. This is discussed in the field of musculoskeletal monitoring and evaluation through three case studies. In them, it is detected that MoCap must overcome barriers mainly relating to usability and body attachment, balance, and dynamometry barriers relative to the cost or the flexibility of the systems – all this within a multidisciplinary approach. In this way, to achieve access to the development of this type of instrumentation, it is proposed to focus future research on HDT creation, developing tools specifically designed for the creation of health instrumentation.

The paper is expected to generate social and scientific benefits by approaching a specific problem from a general view. This motivates the PhD studies of one of the authors and is expected to raise interest in developing new products and services in the field of health, improving the user experience and the quality of people's lives.

Acknowledgements

The project was co-financed by the government of Aragon, the European Regional Development Fund, and the University of Zaragoza (Spain). The authors are thankful for the opportunity received from the IOTAP Centre of Malmö University to participate in the conference.

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2.2. Estudio 2

Marín, J., Blanco, T., Marín, J.J. (2017). Octopus: A Design Methodology for Motion Capture Wearables. *Sensors*, 17, 1875. https://doi.org/10.3390/s17081875

BD: JCR | FI: 2.475 | Q: *Instruments and Instrumentation* (Q2 - 16/61)

Chemistry Analytical (Q2 - 31/81)

Electrochemistry (Q3 – 15/28)

sensors

MDPI

Article

Octopus: A Design Methodology for Motion Capture Wearables

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Received: 3 July 2017; Accepted: 9 August 2017; Published: 15 August 2017

Abstract: Human motion capture (MoCap) is widely recognised for its usefulness and application in different fields, such as health, sports, and leisure; therefore, its inclusion in current wearables (MoCap-wearables) is increasing, and it may be very useful in a context of intelligent objects interconnected with each other and to the cloud in the Internet of Things (IoT). However, capturing human movement adequately requires addressing difficult-to-satisfy requirements, which means that the applications that are possible with this technology are held back by a series of accessibility barriers, some technological and some regarding usability. To overcome these barriers and generate products with greater wearability that are more efficient and accessible, factors are compiled through a review of publications and market research. The result of this analysis is a design methodology called Octopus, which ranks these factors and schematises them. Octopus provides a tool that can help define design requirements for multidisciplinary teams, generating a common framework and offering a new method of communication between them.

Keywords: design methodology; design requirements; wearables; MoCap; body positioning; body attachment; IMU; rigid bodies

1. Introduction

Movement is healthy, but whether from injury, illness, or ageing, we are all exposed to losing motor skills at some stage in our lives. In that case, we need to carry out a process of re-education, training, or rehabilitation that teaches us to move or exercise in a certain way. In this sense, motion capture (MoCap) is an opportunity that provides information, both directly (range of mobility of a joint) and indirectly (habits, physical inactivity, etc.) [1,2].

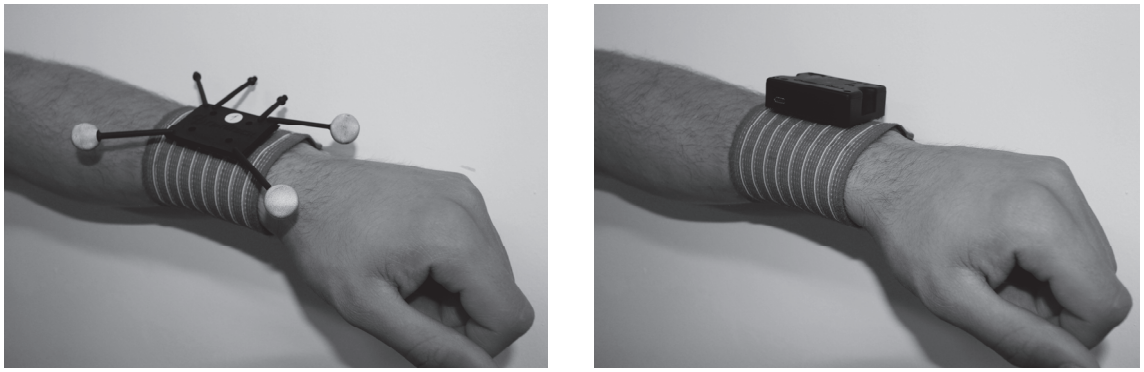
The exponential rate of technology development, and its extensive access through platforms, such as Arduino or Raspberry-Pi, has fostered a world of interconnected objects and connection to the cloud and the Internet of Things (IoT) [3]. In this context, existing objects take on new features, and new ones are inspired by the technology itself. In this way, the elements that we place in the body undergo this evolution, giving rise to a new generation of products, the wearables, whose appearance can be considered at the conceptual level as well as the user acceptance level, as one of the small revolutions within the IoT.

Based on the criteria proposed by Knight et al. [4], wearables can be defined as devices that allow user interaction and user data collection, while remaining attached to the body, regardless of the body's activity and without muscular effort required to hold them. Additionally, wearability describes the

interaction between the human body and the wearable device, and dynamic wearability includes the movement of the human body in the design [5].

For this text, the devices intended to capture human movement that meet the above-mentioned characteristics of wearability and dynamic wearability concepts will be referred to as motion capture wearables (MoCap-wearables). Specifically, we refer to MoCap systems based on the rigid bodies, concept defined by Skogstad et al. [6] as objects that will not deform and will simulate or monitor a body segment.

As shown in Figure 1, MoCap systems that are based on rigid bodies correspond to clusters of reflective spherical markers (Figure 1a) that can be univocally identified by infrared light emitting cameras [6,7], providing three rotations and three positions (one for each space axis). They can also be electronic devices—inertial measurement units (IMUs, Figure 1b)—that provide rotations (rotation matrix, euler angles, quaternions, etc.) through signal processing of the output data of different built-in sensors accelerometers, gyroscopes, and magnetometers) [8–10]. Furthermore by processing from the IMU acceleration data, more information can be extracted, such as speed and position [11,12] or even the moment of reaction on the ground [13]. For MoCap, the concept of a rigid body, in which we focus, matches for both cases, to associate a rigid body to a body segment.



(**a**) (**b**)

Figure 1. Motion capture (MoCap) rigid bodies: (**a**) optical rigid body [14]; (**b**) IMU rigid body [15].

Currently, MoCap applications are mainly restricted to research, medical rehabilitation, sports training, augmented reality systems, and 3D animation [7,16]. Unfortunately, the large numbers of applications that are possible with this technology are held back by many barriers related to various factors. Overcoming such barriers, we could improve existing applications through more usable, democratised, and higher quality technology. Alternatively, we can generate innovative methods of using MoCap through disruptive innovations based on its application in new fields.

There are barriers associated with errors of the technology itself (magnetic field disturbances, gyroscope drift, etc.) that have had a clear effect on the effectiveness of MoCap systems and therefore on the trust of the technology associated with them [17]. However, due to advances in technology, we observe that the errors directly linked to it are progressively diminishing, either through new or better signal processing or hardware upgrades [10,18–21].

Nevertheless, there are other barriers that are currently unavoidable, such as difficulty in measuring the skin, muscles, and soft tissue movements around the bones. This is one of the most problematic error sources in MoCap systems that use optical or IMU surface markers [20,22]. According to Capozzo et al. [23], isolated markers located directly on the skin at specific anatomical points (landmarks) may undergo relative displacements to the underlying bone in the range of 10–30 mm, which causes an error accumulation in the segment angle. Thus, it should be assumed that MoCap systems with surface markers do not represent bone movement [24].

On this basis, one of the main barrier in terms of error to overcome in MoCap applications is reproducibility [22,25]. Therefore, the accuracy of the body segment angle measurement does not matter, as the same results are obtained using a certain MoCap system with the same subject on different days with different operators in independent laboratories.

The reproducibility factor in a MoCap system is conditioned by the attachment of the markers or sensors to the body [20]. If the union is not constant, stable, and rigid, the measurement quality may worsen through the existence of relative movements between the devices and body [25–27]. Various authors have referred to errors derived for this reason in their research [6,8,11,28]. Although some authors consider the position of the IMUs in the body [29,30], positioning continues to be performed only by a visual check, by trying to align sensor axes with the segment [27,28,31]. Despite being decisive, union elements between the electronic device (IMU) and the body are usually one of the last issues considered in the design, when this should be a matter considered during product design.

We are therefore facing a design challenge, a problem that has been asserted by multiple authors and that transcends reproducibility and measurement accuracy. In this way, to offer products that expand the current sectorial limits (health, sports, 3D animation, etc.), factors such as body attachment, usability, device comfort [9], or accessible costs among others, should be considered, as these are the keys to an optimum MoCap-wearable design.

In view of these problems, this article collects design principles related to the physical aspects of MoCap-wearable systems. The challenge is to identify all those factors that affect the creation process to achieve a MoCap system design that includes both the most purely technical requirements and those that are more focused on the users and the environments. Collected factors are ranked and schematised in a design methodology for requirement definitions called Octopus. The aim of this tool is to facilitate and guide designers and other professionals involved in the development by generating knowledge that allows precisely considering, without omission, all factors from the initial stages of development. The tool is expected to improve existing applications or support the creation of new ones.

2. Materials and Methods

In the wake of the design needs detected, considering the high complexity of MoCap-wearable systems, this section presents a series of factors that are indispensable for study in the design process. These factors have been grouped by theme into five sub-sections: context (Section 2.1), technology (Section 2.2), body attachment (Section 2.3), physical properties (Section 2.4), and user interaction (Section 2.5).

A two-line research methodology has been carried out to identify the design factors. On one hand, a literature review has been conducted regarding wearables and MoCap, these articles are cited to describe the factors, and, on the other hand, an extensive study of the products currently available in the market has been done. Regarding this last point, Table 1 shows a selection of those studied products that will facilitate illustrating the factors proposed in this article since they have been considered representative of the different fields of application and/or provide innovative or unique solutions. Both full body MoCap systems and wearables products have interesting and prominent characteristics that have served as reference to find some of the following factors. Although not all selected wearable products are designed for MoCap purposes, we have used them as inspirational products, extrapolating the characteristics to the MoCap field.

For terminology in this document, *devices* will be understood as MoCap elements to be placed on the body and data processing points (DPPs) will be understood as elements to which they can be connected, such as computers, smartphones, tablets, consoles, etc. DPPs will carry out certain actions with the information collected from the devices. In this way, a set of devices, DPP, and the operation of use constitutes a system, which may refer to commercial systems (wearables or MoCap) or those that are intended to be designed (MoCap-wearables).

Table 1. Product and service market examples.

Full Body Systems MoCap				Wearable Products		
Wireless Inertial Products	**Wired Inertial Products** [1]	**Optical Products**	**Services**	**Head**	**Chest**	**Extremities**
Noraxon [32]	Perception Neuron [33]	Natural point [14]	MySwing [34]	Alex Posture [35]	Araig [36]	LEO Fitness Intelligence [37]
Notch [38]	Rokoko studios [39]	Vicon [40]	Run3D [41]	Google Glass [42]	MC10 [43]	Quell relief [44]
Perception Legacy [45]	Shadow [46]		Imaginarium Studios [47]	Jolt Sensor [48]	SenseOn [49]	Sensoria fitness [50]
Stt-Systems [51]	Technaid [52]			Melon Headband [53]	Tesla Suit [54]	Thalmic Labs [55]
Trivisio [15]	Xsens (suit) [56]			Reebok checklight [57]	UpRight [58]	
Xsens [56]				Thync [59]		

[1] Wired sensor to sensor products, but wireless communication with data processing point (DPP).

2.1. Contextual Factors

Contextual awareness addresses the study of scenarios in which the product is used [60] and allows developers to focus design decisions on the user's world, achieving greater acceptance and system usability. The contextual characteristics will translate into requirements and design opportunities, which allow cross-functional decisions that affect other factors. This section includes factors related to use, the user, and the environment of the product to be designed.

Environmental studies can provide information about available resources, protocols of use, level of hygiene required, etc., while user studies may allow considering both explicitly as latent needs related to psychological, physical, behavioural, or formative aspects.

Generally, and specifically in the case of MoCap-wearables systems, the environment defines the user. Table 2 lists the fields of existing applications—in line with Ahmad et al. [16] and Mayagoitia et al. [7]—and the users involved in each of them. Differentiation is made between two user profiles that can be identified in a MoCap-wearable system: the professional user, which is the person interested in obtaining the data and usually is the product purchaser or prescriber, and the actor user, which is the person captured by the system who may be interested in obtaining information. We assume that the concept of user profile may include one or more individuals as appropriate.

Table 2. Link between some MoCap environments and their users.

	Environment	**Professional User**	**Actor User**
Medicine	Diagnosis	Doctor	Patient
	Rehabilitation	Doctor, Physiotherapist	Patient
	Forensic	Forensic Doctor	Injured (may be uncooperative)
Sports	Performance	Coach, Physiotherapist	Athlete
	Rehabilitation	Coach, Physiotherapist	Athlete
Animation Simulation	Professional simulation	Coach, Technician, Others	Athlete, Military, Others
	Video game	Player	Player
	Cinema/theatre	Director, Technician, Others	Performer
Research	Laboratory	Developer, Researcher	Unknown

As seen in Table 2, in the medical and sports fields, the professional user may be a doctor, physiotherapist, or coach and the actor user a patient or athlete. In this area, patients are usually collaborators, except in the forensic environment, where expectations of a possible financial compensation for the damage or injury caused by an accident or other cause may call into question such collaboration. In 3D animation and simulation, user types depend on each application; for example, in video games, it is singular that the profiles of the professional and actor coincide in the same person:

the player. Finally, in the research sector, professional users are researchers or developers who are interested in obtaining information or implementing new applications.

It should be noted that, according to the mode of application or use of the system, the resulting niche can lead not only to a new commercial product development but also to a service or a product-service operation. Some manufacturers are already marketing MoCap systems as a service. This is the case of MySwing [34], where the customer has a personalised learning and analysis program of his or her golf practice. Likewise, a MoCap professional studio for the film industry or a gait analysis laboratory is intrinsically a service [41,47]. Figure 2 illustrates a real MoCap service with both described users involved.

Figure 2. MoCap service, biomechanics laboratory. System with simultaneous optical and IMU technology (optical full body MoCap and IMU upper body MoCap).

It is important to note that if a MoCap-wearable design is associated with a service, the system profitability and its purchase interest may depend on the developer or customer ability to perform an adequate servitisation of the product. In addition, the training, motivation, and resources available to the professional will be keys for the service to be adequate. In addition, the privacy and the required confidentiality level in each of the usage scenarios must be considered [60,61].

Therefore, assuming the business model as a service, defining the operational use from the initial development stages will allow applying specific design techniques to predict failures, extracting critical points and accompanying the physical design with the considerations related to the intangible part of the product.

2.2. User Interaction Factors

Achieving an appropriate interaction between users and the product is relevant to minimise the learning phase and avoid errors during use. In the literature review, it has been detected that, as a general rule, some adjectives that define a good user interaction with wearable devices are simplicity, subtlety, transparency, and intuitiveness [5,60].

The product-service system can interact with both the professional user and the actor user. Therefore, the information to be transmitted and its representation must be adequate to each profile mental model and to the context at the time of receiving the information [62]. Therefore, the user characterisation will greatly influence the interaction design, which will be a cross-functional theme for all product factors.

To classify the communication interfaces between users and technology, the two parts of the MoCap-wearable system can be used: devices and DPP. In Figure 3, the communication interfaces are illustrated: users with device and users with DPP. Note that there is also interaction between both types of users, but the definition of such interaction depends on the service design already discussed in Section 2.1.

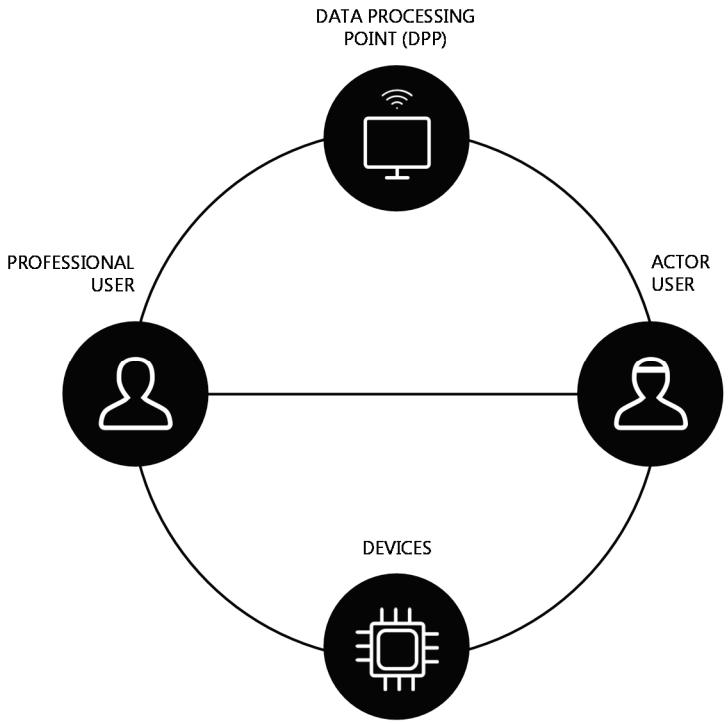


Figure 3. Communication interfaces scheme in a MoCap service. (Icons designed by Freepik and Alfredo Hernandez, from www.flaticon.com).

2.2.1. User Interface with MoCap-Wearable Device

MoCap-wearable devices require a user interface that should allow, facilitate, and optimise product usage, helping its cognitive interpretation. In the reviewed devices (Table 1), there are physical interaction components (power button, load connector, and light-emitting diodes (LEDs) to show the battery level and/or wireless connection status), and graphical components (X, Y, and Z axes on the surface to the device orientation in the body, and body segment labels). These interaction elements are generally aimed to the professional user; however, device designs should consider and take advantage of communication opportunities with the two types of users involved.

Through the interaction elements or other elements that can be incorporated in a bidirectional interaction process, the devices will be able to receive input stimuli (subject movements, change of configuration, etc.) and respond by feedback or output to the users. Such feedback can serve to communicate with the actor through biofeedback [63] (guide, correct movements, etc.) or to reach agreement with the professional (improper device positioning, wrong movements, low battery, etc.). The feedback types can be classified by human senses involved in communication:

- *Visual feedback*: Interaction with LEDs, images, or text. From the perspective of the user actor, an interesting point of interaction may be the upper face of the wrist, inspired by wearable wristwatch style designs or visible areas of the body, such as legs or arms.
- *Aural feedback*: Sounds, beeps, instructions, etc.
- *Haptic feedback*: Communication through non-visual and non-auditory sensations using vibration, temperature, or electrical impulses, which can be observed in some products, such as the Notch motion sensor [38], Araig jacket [36], or the Tesla suit [54].

2.2.2. User Interface with DPP

The DPP can also interact with both users at both hardware and software levels. From the hardware point of view, the most common design process is to select a smart device, such as a computer, smartphone, tablet, game console, etc. This can be recognised in most analysed products. Generally, in MoCap systems, a computer is employed, and in wearables, smartphone use is more frequent. The information input type (touch, voice, etc.) and the output characteristics (visual, sound, etc.) will depend on the selected DPP features to which the designer must adapt.

With this, the problem can be reduced to a software design issue and, from the standpoint of interaction, can be reduced to the screen interface or graphic user interface (GUI) design. Additionally, the software may be able to be supported in the cloud or even only operate on it; thus, the Internet communication will serve to store and download information or communicate with other systems.

2.3. Technological Factors

Technology, its possible configurations, and the main characteristics of the electronic components influence the device external parts that are in contact with the user [5]. Consequently, the technological requirement study includes the selection between optical or inertial systems, the electronic component structure that incorporates each capture device, and the possible configurations of interconnection between them.

2.3.1. Choice between Optical and Inertial MoCap Technology

The choice between inertial or optical MoCap technology depends on the application requirements, which should be contrasted with the characteristics of each technology features. In this paper, we focus on these products as they are the most common; however, it should be noted that these are not the only technologies used in MoCap systems [64].

Optical systems have a consolidated development and provide proven accuracy. However, they require a controlled space and environment, especially about lighting (preferably artificial), and a variable number of cameras that will depend on the area of the body to be monitored and the number of

simultaneous actors to capture. Normally, the technology is based on vision cameras that emit infrared light, which are capable of recording and processing the movement of reflective spherical markers placed at landmarks [6,7]. Its accuracy is high—on the order of 1% on the measurement taken [65] or 1 mm [22]. It is necessary to emphasise the problems derived from occlusions of the reflective markers by other body parts, other actors, or objects or devices that the actor handles or in the scene itself that may require a high number of cameras or important post-process work to recreate the actor's movement.

Moreover, inertial systems are generally more economical and require less infrastructure [7]. They can be used either in real time by a DPP signal-receiving device or autonomously with an internal memory storing the information. In contrast, integration errors and the presence of magnetic fields may reduce accuracy [8,10]. For MoCap commercial systems (Table 1), the IMU accuracy offered is in the following intervals: 0.2°–1° (roll/pitch), 0.4°–2° (yaw), and dynamic root mean square (RMS) 1°–2° RMS (roll/pitch/yaw).

2.3.2. Electronic Components (Building Blocks)

It is considered necessary to overcome the strict separation between design engineer and electronic engineer. Knowledge of electronics by the designer allows creation of more viable projects and, alternatively, generates more design opportunities due to the vision of possible technological options. It is true that, for an external device design, it is not necessary to know all the components in depth, but in line with [66], it is interesting to promote designers with minimal technological literacy that are aware and can collaborate in defining the main building blocks. This definition of blocks depends on the usage scenarios (context), especially regarding the times of use, the speed of movements, or the real-time capture needs.

The building blocks can be considered from the device, the DPP, or even the complete system point of view. In Figure 4, we see an example of the main blocks (building blocks) of a wireless IMU device. Under the scheme, the technological factors to consider for a wireless IMU are related to communication, storage, battery, intelligence, and interface.

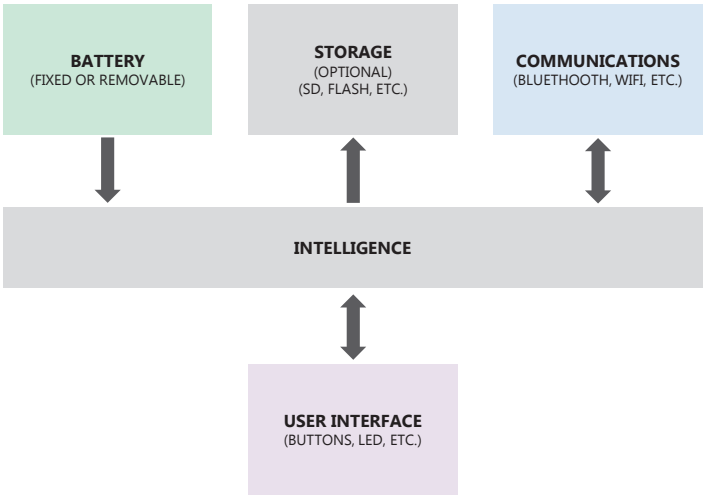


Figure 4. Building blocks example of a MoCap wireless IMU, created with the methodology of Blanco et al. [66].

In the case of revised IMUs for MoCap-based devices (Table 1), the following factors in relation to electronic components can be highlighted:

- *User interface*: Already mentioned in Section 2.2.
- *Battery*: MoCap wireless sensors typically have built-in non-removable batteries, recharging either in a charging socket or directly connecting to each sensor. The battery life (according to manufacturer's information) can vary between 3 h and 8 h. The battery selection has a special

interrelation with the other factors because it depends on the usage scenarios (life required), on the other components' consumption, on the DPP characteristics, and on the interconnection between the different components.

- *Storage*: With the option of including internal storage, it is not required to be in range of a wireless network, which increases versatility. In contrast, in this case, the ability to perform real-time processing is limited. Systems that work with internal storage usually have a secure digital (SD) card, such as Perception Neuron or Stt-Systems [33,51].
- *Communication*: The communication features between devices and the DPP depend on the selected wireless communication protocols and consequently on the selected DPP to process the data. However, sometimes, an external dongle communication is connected to the DPP, which relieves its selection requirements. Communication protocols are typically WiFi 2.4–5 GHz for local area networks (LANs), Bluetooth for personal area networks (PANs), or other proprietary protocols.
- *Intelligence*: All these actions are performed by the devices from raw measurement data and users' actions. In terms of intelligence, the quality of the measurements provided by the IMU, and therefore the restrictions for some applications, depends on the quality in the accelerometers, gyroscopes, and magnetometers and the quality of the signal processing. The IMU measurement ranges vary between ± 2 g and ± 50 g for accelerometers and between $\pm 150\,^{\circ}/s$ and $\pm 1000\,^{\circ}/s$ for gyroscopes [27]; however, the evolution of the technology is improving the quality of these aspects. In signal processing, Kalman filters are widely used [67]. Currently, this field is being improved by different authors. For example, Dejnabadi et al. (2006) and Favre et al. (2009) [19,20] have proposed other magnetic and compensation drift algorithms that have been shown to be effective.

2.3.3. Number of Devices and Interconnection of Them

A key factor in the technology definition is the number of devices be placed on the body areas, each application will require a varying number. The number of sensors influences and depends on the available computational resources and on how much the signal processing can be tailored to the application. In general, for full body MoCap, a total of 15 are required: three per each extremity, another to monitor the head, and two others for the chest. In addition, more sensors can be added in the phalanges or chest. We can see a MoCap application with fewer devices in Macard et al.'s paper [68]. In terms of interconnection and communication between devices, in the studied MoCap systems (Table 1), different possible configurations can be found:

- *Full body suits*: Typically made with Lycra, they contain devices in areas to be monitored. The sensors are wired to a hub placed on the waist or back. The hub communicates wirelessly with the DPP and includes a battery that powers the devices [39,56].
- *Wired independent elements*: These have the same operation and interconnection as the full body suit, but each sensor has an independent fixing support. The cables, sensors, and other devices are in sight [33,46,52].
- *Wireless devices*: Each sensor is placed with an individual fixing support, and each one has its own battery and communicates independently with the DPP [32,34,38,45,51,56].

2.4. Body Attachment Factors

Body attachment is one of the key factors in the MoCap-wearable device design, as it is a cross-functional concept. Thus, it directly affects system accuracy, reproducibility, user comfort, and, consequently, product market acceptance [9,25]. Although it could be analysed as a sub-point of the user study (ergonomics), it is considered that it goes further and is considered an independent issue, comprising the good characterisation of a considerable number of requirements.

Body attachment requires studying two sub-factors: positioning and the attachment method. The positioning refers to where the devices are located, that is, in which body segments and in which

zones within each segment. The attachment method defines how they are joined, that is, what elements are used to attach the devices to the body segments.

2.4.1. Device Positioning

Yang and Li [27] asserted that the effect of sensor location on measurement quality is not usually analysed; however, the collected data from acceleration and angular velocity are different in one location from another for the same body segment. Consequently, devices should be positioned so that they are oriented towards the body of a subject in the same way regardless of condition, context, or activity. Correct positioning should not depend mainly or exclusively on the professional user; in this sense, the product shape and the rules of use play a key role. Some authors have also detected this fact and have attempted to solve it through different software or hardware improvements [29,30,68,69], which is a complementary approach to the one presented here.

From the point of view of accuracy, to select the position of a body segment regarding where to affix the capture device, the potential effects of that place, and the quality of the movement measurement must be considered. In terms of comfort, devices should generally be non-intrusive and consider the body to be a dynamic structure in motion. Areas with relatively the same size should be selected in adults. Moreover, areas with the least movement, friction, and flexibility when the body is in motion should be selected. The anthropometry of the target users must be considered, and how the sections of each segment change according to age, morphology, and weight should be studied [5,26].

Following these rules and analysing the positioning areas of the commercial MoCap devices (Table 1), the most common placement areas for monitoring major segments of the body are shown in Figure 5.

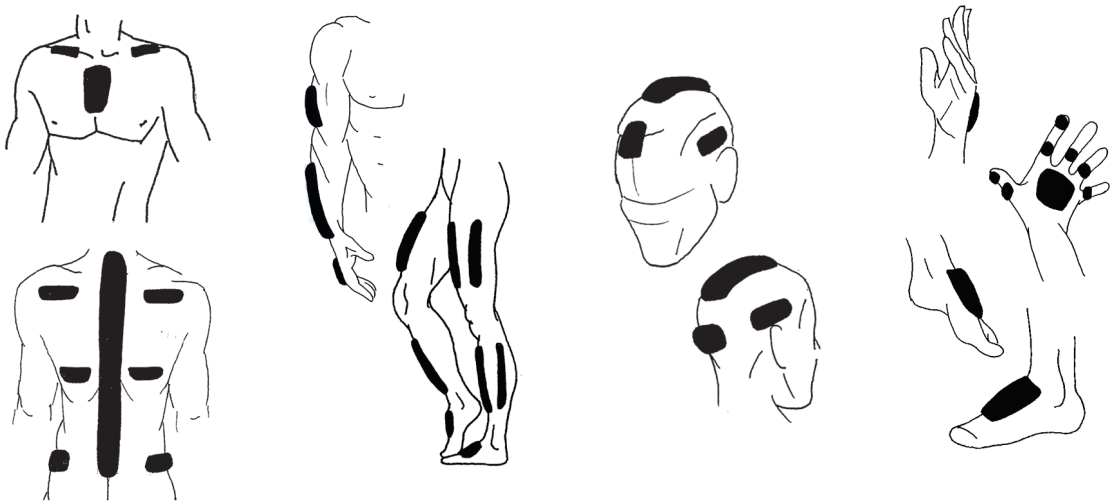


Figure 5. Main zones for positioning devices: (**a**) chest; (**b**) extremities; (**c**) head; (**d**) hands and feet.

In Figure 5a, areas of chest placement are seen. In this multi-segment zone, we can opt for different positioning alternatives: sternum, spine, hips, ribs, shoulder blades, or clavicles. Most systems place one sensor on the sacrum and another on a higher area of the torso, either the anterior or posterior part. To homogenise the stem analysis, Yu et al. [31] studied the movements of the vertebral column to determine the optimal placement of the sensor placed in the upper part. The results showed that the most representative points to monitor displacement of the medial or lateral trunk were the T7-T8 vertebrae. In these parts, the smallest error occurs (0.5°). However, using more sensors in this area may be beneficial, so some systems place a sensor in the mid-spine zone to improve the approximation of its curvature [32], others also add sensors on the sides (clavicles, shoulder blades,

or ribs), which allow monitoring the movements of the shoulders and/or the asymmetrical twists of the body [33,39,45,46,52,56].

Figure 5b shows the placement above the extremities. It should be noted that no consensus has been reached regarding the height at which to place the elements in each segment; nevertheless, there is more agreement about the segment faces used; the outermost zones that do not interfere with the movements are suggested. In the forearm, the upper surface of the wrist is used, just above the joint. In the legs, the frontal or outer zones are used. Sometimes, the same system combines both options, placing elements externally on the thigh and frontally on the shin. A resource that can help positioning the limbs is to take advantage of areas where muscles are inserted into the joint, such as the section between the calf muscle and the knee, which provides a curvature that prevents the device from slipping.

Figure 5c shows areas of head placement, with the most common placement being the front and the back of the head, and sometimes the sides or over the top. It is interesting how the head wearables show other positioning resources, using the natural supports that provide the upper part of the ears and the nasal septum [35,42,53,59].

Additionally, Figure 5d depicts areas where devices are placed on the hands and feet, generally on the top of these body parts. These zones provide a relatively extensive and flat surface without movement impairments. When the fingers are monitored, sensors are placed on each of the proximal phalanges (first segment) and on the distal phalanx (last segment) of the thumb and forefinger.

In relation to the above and from a contextual point of view, a factor related to the positioning that is frequently not considered with the necessary detail is the device interaction with the garments. It is necessary to study what kind of clothes users will wear, the possibility of changing their clothes, and how it will affect their comfort and emotions as well as the intimacy and privacy feeling that may influence the individual acceptance and behaviour. For some applications, it may be necessary to design clothes that are compatible with the devices, either integrating the sensors in them or leaving space for the sensors to be positioned in the appropriate way, all respecting the requirements of hygiene and healthiness.

2.4.2. Device Attachment Methods

Multiple authors have stated the importance of using an appropriate attachment method; this is because union is a key factor in all wearables, but even so more in those that monitor movements [6,8,9,11,25–28]. In a research environment, the professional can use ad-hoc solutions (adhesive tape, dressings, medical plaster, etc.) that can ensure precise positioning and individual adjustment for each subject. However, in commercial applications, a proposal is required that ensures a constant, stable, rigid, comfortable attachment with minimal preparation requirements [9].

In the MoCap-wearable device body attachment design, it is advisable to try to keep the device as close as possible to the body and bones. In general, it is preferable to secure the device by completely or partially surrounding the body region involved, rather than using single-point fastening systems. Furthermore, the long-term effects of carrying the device should be considered, and its effects on the user from the psychological (comfort) and physical (sweating, tiredness, etc.) points should be analysed. In addition, the diversity of body size should be considered, allowing a certain size and shape customisation [5,60]. Thus, from the reviewed products (Table 1), the following types of body attachment or fixing supports can be distinguished:

- *Fabric fixing supports*: The union with fabric is made from different widths of bands or tape or tight garments. The elastic tape can be closed or open, and the latter will be closed with Velcro, clips, or buckles. The fabric characteristics will influence the union accuracy, perspiration, comfort, and wear resistance. The connection between the fabric and the device can be made with Velcro, pockets, dedicated housing (plastic base), or metal pressure clips that are used by some wearables [38,50]. In addition, it may be beneficial to use wide Velcro areas above the fabric, which allow certain variability at the point of attachment to suit each subject.

- *Disposable adhesive fixing supports*: This support type groups different types of unions: hypoallergenic double-sided adhesive, which is economical although relatively weak, bandage or kinesio-tape, which has high adhesion but with some preparation time required, and disposable electrodes, which are used in some wearables [43,49,58]. The latter can be standard or manufactured specifically for the product, being able to use one or several connection points and allowing measurement of biometric signals. Note that, if we choose disposable adhesive fixing supports, although hygiene is maximum, the cost is higher due to the material expenditure. In addition, body hair and sweating will significantly worsen the adhesion.
- *Semi-rigid fixing supports*: This union type is mainly found in wearable devices that, due to the flexibility of some of the parts, the product stands by itself, wrapping around the body or the garments that the subject wears. This solution is observed in the Thalmic Labs product [55] that has elastic zones to fit the arm, surrounding it as a bracelet, the Jolt Sensor wearable [48] that can be attached to clothing with flexible flaps, or others such as Alex Posture, Google Glass, Melon Headband, or Thync [35,42,53,59] that take advantage of their elasticity to hold onto the head as if they were hair headbands. Although it is a method that does not provide a strong union as others and it may be difficult to apply in all body segments, it must be considered to solve some problems, such as fungible expenditures or hygiene.

It should be noted that the different attachment methods can be combined. In fact, some wearables that use tape to surround body segments combine it with non-slip surfaces [37] or disposable electrodes that adhere the tape to the skin [44].

From these types of bindings, in Table 3, a weighting method for choosing the ideal type in a given application is proposed. It collects the body unions identified in the products and articles reviewed as well as a selection of seven factors that characterise each of them. Assuming that there is no better method of fixing than another, the selection will depend on the weight or value given to each of the seven factors, considering the particularities of each application and context.

The score of each factor varies from 1 to 3, with 1 being the worst and 3 being the best. The 'Result' column can be completed by applying Equation (1), whose highest value would correspond to the method of union most recommended for a given application and context:

$$R_j = \sum P_{ij} \times W_i \quad (1)$$

In Equation (1), R is the result obtained by each binding method, P is the score assigned to each element of the matrix (1, 2, 3), W is the weight assigned to each factor (from 1 to 10), while j is the rows and i is the columns.

In addition to Table 3 and the attachment methods described, we note that as device fixing support, elements that are already carried by the user in the application environment are a resource to consider. This is the case for some wearables that use everyday items, such as glasses, swimming caps, or jackets [36,42,57]. The use of these elements contains known interaction patterns, which is beneficial for all types of interaction, but it makes special sense when referring to the body attachment factor since it can favour technology learning and confidence. Thus, new union concepts require greater learning time and create a new interaction language; however, this does not mean a worse alternative, as long as the designer considers and plans how to transmit it and teach it to the users.

The most commonly used attachment methods in the reviewed products vary according to the anatomical area involved: on the torso (pelvis and thorax), disposable adhesives, harnesses, or adjustable and elastic tape is used; on extremities, elastic tape or disposable adhesive is used; on the head, hair headbands, elastic tape, helmets, hats, or semi-rigid elements that rest in the anatomical references, such as the ears, nasal septum, front, or nape, are used; on the hands, tape or gloves that surround the thumb and/or fingers to prevent the device slipping are used; and on the feet, disposable adhesive or elements attached to parts of the shoe (cords, tongue, or sole) are used.

Table 3. MoCap-wearable device body attachment methods valued by factors (1—worst, 3—best).

Attachment Method	Area Selection	Preparation Speed	Washing	Adapt-Ability	Fungible Restrictions	Union Distribution	Union Strength	Result (R)
Weight (W)	(5) [1]	(4) [1]	(9) [1]	(10) [1]	(2) [1]	(8) [1]	(8) [1]	-
Closed elastic tape [2]	3	1	1	2	3	3	3	(102) [1]
Open elastic tape [2]	3	2	1	3	3	3	3	(116) [1]
Garment (fixed pockets, clips) [2]	1	2	1	1	3	3	3	(86) [1]
Garment (Velcro areas) [2]	3	2	1	1	3	3	3	(96) [1]
Commercial electrode [3]	3	3	3	3	1	1	2	(110) [1]
Custom electrode [3]	3	3	3	3	1	2	2	(118) [1]
Double-sided tape [3]	3	2	3	3	1	1	2	(106) [1]
Bandage kinesiotape [3]	3	1	3	3	1	3	3	(126) [1]
Semi-rigid (bracelet, flaps) [4]	2	3	3	2	3	3	1	(107) [1]

[1] Example of scoring for a sanitary elderly rehabilitation application; [2] Fabric fixing supports; [3] Disposable adhesive fixing supports; [4] Semi-rigid fixing supports.

2.5. Physical Property Factors

The physical properties of the device, such as the shape, dimensions, or weight distribution, affect the user both physically and mentally. Therefore, the needs and restrictions of both user profiles in contact with the product are appreciated even more in this section. These factors have effects on the actor user in the aspects of energy expenditure, biomechanics, posture, movements, and perceived comfort [4]. From the professional user's point of view, they have effects on comfort, acceptance, use experience, and perceived accuracy.

2.5.1. Shape

The shape is one of the key product elements since it must be intimately linked to its function. The MoCap devices must have forms that facilitate positioning, which helps the professional find the proper fixation area and get and maintain its correct orientation, which are requirements that will vary according to each body part. Furthermore, a smooth and subtle transition must be ensured from the body surface to the device; this can be achieved with a concavity in the inner surface in contact with the body and with convexity in the outer surface to avoid blows and hooks [5]. The studied wearable products (Table 1) mostly follow these guidelines; however, the MoCap IMU devices do not. The latter are generally a rectangular box with slightly rounded corners or other polygonal shapes.

2.5.2. Dimensions

The device dimensions should be adequate to the areas to be monitored and should suit different morphologies, considering the diversity of body sizes [60]. Although the surface they occupy in each body segment is not a critical factor, the thickness is. According to Gemperle et al. [5] there is an intimate space or aura of 0 to 127 mm around the body for the devices, and as a rule, one should try to minimise the thickness as much as possible so that it feels like a part of the body.

2.5.3. Weight

The weight should be distributed so that the maximum load is placed near the body centre of mass [5,60]. In this way, if we have several elements to place, heavier ones should be in the torso, and the lighter ones in the extremities.

2.5.4. Flexibility

It is necessary to consider the flexibility of the MoCap-wearable device components. In this sense, the possibility of integrating flexible electronic-printed circuit boards would be the optimal solution for body adaptation, but this would possibly increase technical complexity and cost. Another option is to use rigid areas coupled with flexible areas. Thus, the flexible areas would be between the solid forms, extending it like wings [5]. This is shown in wearable market products, which integrate rigid areas combined with flexible ones in the same structure [35,43,48,55,59]. The MoCap devices are composed by the IMU zone, are completely rigid, and are near the fixing support area, which is usually more flexible and adaptable. The Shadow MoCap system [46] differs from the others because its sensors are embedded in fabric pads (neoprene type), which makes the entire system flexible.

2.5.5. Material

The material selection depends largely on the context of use, which determines different aspects to consider, such as weather resistance agents, abrasion, impacts, temperature, humidity, required maintenance, washing, hygiene, comfort, and breathability [5,26,60]. The most commonly used material in MoCap device housings is plastic. In wearables, however, we find other materials such as silicone or intelligent fabrics. It is important to note that the use of metallic (ferromagnetic) materials, that alter the magnetic field close to the IMU sensors can disorient its magnetometers, so some manufacturers use a shielded packaging [33].

2.5.6. Comfort

Comfort is not a tangible property by itself, but it depends on the physical aspects, and in MoCap-wearable device design, it is necessary to prioritise this factor [5,60,61] because it increases system usability and acceptance. According to Knight et al. [70], wearable comfort depends on several dimensions or factors: first, from the body attachment, the movement restriction, and the user concern about how the device moves in his or her body. Subsequently, the pain (itching, burning, pricking, heat, etc.), the perceived change (feeling physically different, strange, or uncoordinated), the anxiety that can be caused by the system, and the emotions that the device causes when it is worn; which are issues that link to the next point.

2.5.7. Psychological Aspects

The study of the emotional and psychological aspects that people have towards the products helps deepen understanding of the user and thus should also be present in the design process. According to Spagnolli et al. [61], the users should be characterised according to a series of psychological factors, among which we highlight the attitude towards technology, the perception about the product usefulness, the expected learning effort, the social influence for purchase, and the expected pleasure perception during use.

2.5.8. Aesthetics

In addition, in terms of user comfort, aesthetics can be considered one of the most relevant aspects in the MoCap-wearable device design [5,61]. Aesthetics is a more important issue than it may seem, even more so than in other technological products, because people consciously or unconsciously express themselves with the garments and objects worn, as they define us from the social and relational point of view [71]. In this sense, it may be beneficial to consider the user preferences, interests, and desires, and allow a certain personalisation, as Motti and Caine proposed [55]. Nevertheless, the options at this point are endless depending on the new applications.

3. Discussion

MoCap systems have been used for more than two decades, and their usefulness and application in various fields such as health, sports, or leisure are widely recognised; therefore, this is increasing its inclusion in current wearables. However, to adequately capture human motion requires addressing requirements that are difficult to satisfy. Among other issues to consider, devices must maintain their body position independently of the subject movements and not be invasive in order to facilitate natural body movements. With all this and because of its prohibitive costs in the past, MoCap expansion has slowed and unfortunately has been restricted to laboratories or specialised studies.

Today's society already has broad access to technology (cost reduction, free software development platforms, etc.). Therefore, in the context of interconnected objects (IoT) and constant technological development, it is also necessary to have greater access to the complete process of technology creation (design guidelines, methodologies, etc.). Thus, having tools that help the MoCap-wearables systems development process can introduce an entire range of possibilities and allow extending them to new areas where they are not present or not widespread, solving real problems of users and society.

Faced with this problem, a study of the factors that are critical to MoCap-wearable system designs has been conducted. Neglecting any of them may involve creating unprofitable products either because they are not viable or have low effectiveness or low acceptance. In this discussion, a specific design methodology called Octopus is proposed, which aims to manage all these factors and facilitate the requirement definitions of developers, designers, and multidisciplinary design teams. The Octopus is a metaphor for how the devices must be attached to the body, using the eight steps established below. Its scheme is shown in Figure 6.

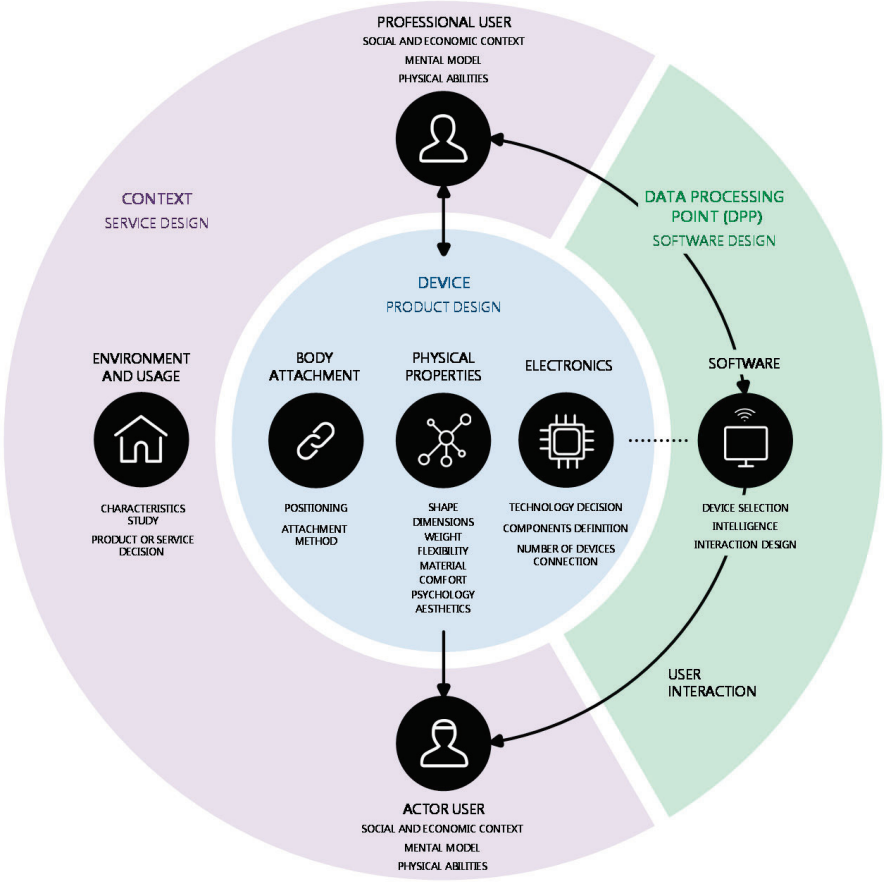


Figure 6. Octopus methodology for MoCap-wearable system designing. (Icons designed by Freepik, recep-kutuk, madebyoliver, gregor-cresnar, EleanorWang, cursor-creative, from www.flaticon.com).

The Octopus methodology is the result of ad-hoc research and analysis, of the different disciplinary author's views (mechanical engineering, biomedical, and design), and of the experience in MoCap systems use in the research group, which has conferred a lead user vision that, as Lilien et al. [72] indicated, benefits the design process.

In a general human-centred design methodology, the following iterative studies or stages can be identified: planning, context of use, requirements, design, and evaluation. For each, there are distinctive design methods [73]. The Octopus methodology approaches the first three steps: plan, contextualise, and extract requirements—in this case, the requirements of MoCap-wearable systems.

The scheme in Figure 6 is a representation of the MoCap-wearable product/service and its ecosystem. It is composed of three zones (context, device, and DPP), each of which houses a series of elements directly related to the factors described in the second section (materials and methods). The Octopus methodology proposes to approach the design sequentially, according to the following steps: (1) design goal; (2) context study; (3) service design; (4) user interaction; (5) technology; (6) body attachment; (7) physical properties; and (8) DPP. Although it is linearly represented in principle, it will usually be necessary to perform successive iterations and made a sequence accommodation to each situation.

3.1. Step 1: Design Goal

The initial methodology hypothesis starts from the design goal definition. Obviously, the design process evolution—even more in iterative orientations—can slightly or substantially modify this initial objective, especially when one of the main aspirations of the present methodology is linked to the latent need to search for new applications, a necessity for MoCap and wearable evolution. As mentioned, the methodology is flexible enough to adapt to the project imponderables, in line with the iterative design methods, returning to the needed point and taking advantage of the experience gained. In this sense, establishing an abstract character of the design goal will depend on the project philosophy. That is, the challenge can be placed in a concrete improvement (e.g., creating a MoCap system for older people for rehabilitation in their homes) or placing it in more intangible horizons (e.g., look for application fields using new materials). The goal level of abstraction will also influence the starting point, the number of iterations required, and the linear character of the process.

3.2. Step 2: Context Study

Once the objective has been established, the next stage is context characterisation, definition and modelling of user types, and use of the product (use, user, and environment analysis). Figure 6 includes the two most common user profiles in MoCap, the professional user and actor user; nevertheless, as many user profiles or sub-types as necessary may be added. Observational methods, interviews, focus groups, and role play among others can be used for this study [73]. Due to these, context characteristics, opportunities, and problems as well as user qualities, capacities, behaviour models, and desires can be extracted. To synthesise the information collected, some tools such as the 'person-method', user targets, or archetypes can be applied [74]. Moreover, in terms of use, developers can establish analogies with related products to approach the user's base knowledge.

3.3. Step 3: Service Design

This step will be included if the product is considered a service, a growing area for MoCap; in this case, service design tools [75,76] would be an indispensable basis for the project. One of the most interesting methods is 'Blueprint' [77], a design tool and dialogue and training media for professional users, because it marks the necessary key moments in the service for each of the users involved through a temporary schematisation.

In a MoCap-wearable service, the key moments or actions that are usually carried out are the following: (1) explanation to the actor user; (2) device body placement; (3) anatomical calibration; (4) capture; (5) data and result generation; (6) data processing (by software and/or by user); and (7) final

actions (e.g., medical reports, real-time feedback, etc.). This generic use protocol must be considered in the physical device design and if applicable, in the service definition. It will influence both users experience and, consequently, the final solution success.

3.4. Step 4: User Interaction

User interaction flows are defined in the Figure 6 diagram by arrows for all items that relate to users. These interaction lines can be unidirectional (feedback or biofeedback) or bidirectional (information exchange), which may vary depending on the device, the user, and the context.

In the early design iterations, these lines can be used to define some needs and specifications, based on the work already done; thus, a relational needs methodology can be followed. This tool is applied in cases like ours, where it is intended to design solutions that involve relationships between several users to detect those needs that each specific user has with respect to the others [78]. Here, it can be proposed to apply in the rest of the items, contemplating the human-machine and machine-machine relations.

With respect to human-machine interactions, as detailed in Section 2.2, the system interaction with the professional user can be bidirectional, from devices and from DPP, including interaction with devices regarding proper placement, maintenance, or connection and with DPP regarding capture configuration of possible incidents, annotation, or result study, analysis, and interpretation.

The human-machine interaction with the actor user are typically unidirectional, from the device and/or the DPP; it can be either as feedback or as biofeedback [63] and in a visual, auditory, or haptic way, showing different events like movement changes on a screen with a virtual scene, or the start and end sounds, among others. In design, it will be important to consider the elements that are necessary to allow and favour the mentioned user interaction.

3.5. Step 5: Technology

It is necessary to study the technological content, as it affects the physical product conception. To do this, it is proposed to approach it through some points, which, despite being presented sequentially, will require iterations due to their strong interrelation between them and with the rest of the sections:

- Make decisions about the technology type to be used (described in Section 2.3.1): optical, inertial, or even other MoCap technologies depending on the application. Thus, we can find solutions such as the one proposed by Shiratori et al. [64], which uses cameras fixed on the body.
- Define the main electronics that are needed, for which the electronic building blocks can be made and apply electronic design methodologies focused on designers or multidisciplinary teams, as Blanco et al. proposed [66]. Defining the building blocks (Figure 4) is necessary to ensure product viability, and to anticipate factors like the space that can occupy the electronics or the associated requirements and restrictions; for example, for IMU design, zones free of ferromagnetic materials and a minimum distance from the human body are required to not alter the magnetic fields and facilitate radiofrequency communications. The main blocks in the case of MoCap-wearables devices would be (Section 2.3.2) communication (dashed line of the schematic), storage, battery, intelligence, and interface (defined in Step 4). Note that, to be able to define some points of the electronics, it will be necessary to at least have selected the DPP that will process and register the data (Step 8) because the DPP will also influence the communications, functionalities, size of components, etc.
- Select the required number of MoCap-wearable devices to be placed on the body and the most appropriate interconnection between them (Section 2.3.3): full body suits, wired independent elements, or wireless devices.

3.6. Step 6: Body Attachment

It is necessary to consider the body attachment, a key factor in the design of wearables. At this point, the positioning and the attachment method must be determined. In relation to the positioning, the exact area must be determined, explaining the reasons for its selection, and investigating and testing the best rules to help the professional user determine its correct location. Regarding the attachment method, the proposed decision table can be used (Table 3), in which more attachment methods can be included as this scope progresses. In any case, prototyping at this stage will be crucial.

3.7. Step 7: Device Physical Properties

It is also required to define the physical MoCap-wearable device properties. For this purpose, criteria are presented in Section 2.5 related to shape, dimensions, weight, flexibility, material, comfort, psychological aspects, and aesthetics, which are crucial factors to achieve the necessary precision measurement for good user adaptation.

3.8. Step 8: DPP

Having selected the DPP product to perform processing, at this stage, it is not necessary to define the interaction elements because they are given by the product. Thus, this stage requires the software design, which, according to the purposes of each MoCap application, will utilise data processing and will communicate the appropriate and accurate information to carry out the user interaction. For this design, software development and interaction methodologies [62] can be followed. The development of this point depends on the system purpose, which, due to Octopus, is expected to extend to other areas not yet explored.

3.9. Case Study, Methodology Assessment

To illustrate the methodology and assess its applicability, a case study is included in Table 4, where the basic requirements of a shoulder rehabilitation service for elderly individuals are defined.

Table 4. Case study, shoulder rehabilitation service for elderly individuals.

Step 1: Design Goal
Shoulder rehabilitation service for elderly in private clinics.
Step 2: Context Study
Professional User Target: Occupation: Physiotherapist. Age: 35. Technology level: Medium—High. Verbatim: 'I am a person who wants to improve and learn every day in my work. I have little time since I attend about six patients a day in 45-min sessions'. **Actor User Target (patient):** Occupation: Retired. Age: 78. Technology level: Low. Verbatim: 'At my age, I appreciate tranquillity and patience; it makes me feel safer'. **Environmental Characteristics:** Indoor, bright, hygienic, and clean. Furniture: work tables, chairs, and stretchers.
Step 3: Service Design
1. Explain the test to the patient. 2. Place the devices on the patient and warm up. 3. Record the target movement cyclically (e.g., flexor-extension or internal-external rotation), while the physiotherapist mobilises the patient's shoulder according to the appropriate rehabilitation schedule. 4. The patient repeats the movement alone while receiving biofeedback from the recorded motion. 5. Report of the results (success or failure regarding the recorded movement cycle).

Table 4. *Cont.*

Step 4: User Interaction
DPP—Professional Interaction: Allow to start and pause motion recording (possibility to do it remotely). Set the number of repetitions of the exercise and grade the threshold to consider whether the movement is correct for rehabilitation purposes in the session. Observe the results. **DPP—Patient Interaction:** Display an avatar that moves in real time according to the patient's movement. Display a superimposed avatar that plays the pre-recorded motions during the professional's mobilisation. Use gamification techniques to facilitate tracking of target movement. **Device—Professional Interaction:** During the recording period, the user interacts with the devices through the visual sense: green LED—transmitting and no movement recorded, red LED—recording, and blue LED—there is movement recorded. **Device—Patient Interaction:** During the task of repetitive movements, the patient interacts with the haptic sense (vibration) to indicate breaks, repetitive failures, phase changes, etc.
Step 5: Technology
Technology Selection: IMU devices are used. No special lighting or space requirements are necessary. During the physiotherapist manipulation, there are no problems with marker occultations. **Building Blocks:** Shown in Figure 7. **Number of Sensors:** Five are placed if a single upper extremity is examined and seven for both. **Connection:** The sensors are wireless and connect to the DPP via Wi-Fi.
Step 6: Body Attachment
Placement: Sacrum, on vertebra D2, the upper area of the head, outside of the arm just above the elbow, and on the forearm on the upper face of the wrist. **Attachment Method:** Device on the skin, attached to the body by pre-cut kinesio-tape bands with hole to protrude the device and leave the LED visible. (In case of excessive hair, this would be removed. The area is cleaned with disinfectant). The choice of this attachment method is justified in the Table 3 example.
Step 7: Device Physical Properties
Shape: Oval, rounded edges with wings in the skin contact area, where the tape is fixed. **Dimensions:** 4 × 3 cm. **Weight:** 40 grams per sensor. **Housing material:** Rigid plastic and resistant to humidity. It is painted with silicone texture for easy sanitising. **Colour:** It is white, adapts to the environment, and transmits appropriate values.
Step 8: DPP
Elements: Computer, Wi-Fi dongle for communications, and an external monitor. **Basic software operation:** It has two modes, the configuration for the professional user and the display for the patient user. It calculates the hits and misses regarding the target movement and displays them in real time. It connects to the Internet to store data in the cloud at the end of the session.

The example summarised in Table 4 and shown in the building-block scheme (Figure 7) considers the main requirements for the case of a rehabilitation service. It has been observed that the structuring carried out systematises the development process from the design goal. In the absence of being applied in more cases, it is considered to be a useful tool for new or improved product development.

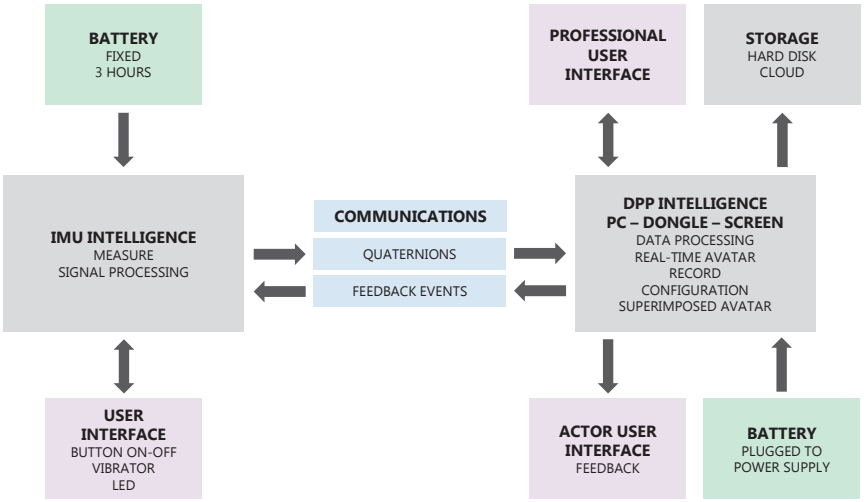


Figure 7. Case study building blocks.

4. Conclusions

This article presents a problem about the MoCap-wearable systems that affects product and service designers and electronics developers. This problem is related to the difficulty of considering all human, ergonomic, technological, or material factors, among others. Thus, MoCap-wearable designs require studying the following critical aspects that have been identified: context, user interaction, technology, body attachment, and physical property factors.

In response to this problem, a bibliographical and representative commercial product review has been carried out, which allowed extracting the factors directly related to design requirements, which have been collected and ranked. As a result, the Octopus methodology is proposed, which aims to help the MoCap-wearable system requirement extraction process, due to the factor schematisation and a visual representation that allow this to be studied and evaluated sequentially.

Octopus begins by studying the context to later develop the product or service. The method allows the creation of systems aimed towards MoCap from one, several, or all parts of the body. It has several characteristics that imply an improvement in this type of product design process, as follows:

- It is flexible and adaptable. Without a closed and immovable scheme that limits creativity, the design team, which is necessarily multidisciplinary, can eliminate or add factors and elements according to each case.
- The tool makes the job easier. Due to the visual representation of Figure 6 and the different steps proposed, it is expected to improve organisation, structuring, synthesis, and facilitate decision making, providing a global view of all the necessary factors.
- Due to the case study, it has been observed that the tool allows us to generate innovative ideas in an effortless way and to consider the main specifications and design problems.
- It is a communication tool between professionals or researchers from different disciplines involved in the design team, illustrating the common objectives to be fulfilled, mapping the status of the project, and allowing the assessment and recognition of the contributions of each of the team members.

Due to the simplification of the MoCap-wearable system creation process, this article introduces different fields and possibilities:

- In the current context of the technological progress, electronics miniaturisation, cost reduction, and the IoT, Octopus can contribute to facilitating the success of new products aimed at the MoCap area. It is expected that developed MoCap-wearable systems will be more suited to users

and environments, so that MoCap can be used more extensively solving current problems in existing applications and allowing its implementation in more and new ones.

- In relation to this search for new applications, it is observed that the assumption of the MoCap as a service can be an improvement and an opportunity to cover real needs.
- It is expected that the study increases knowledge of optical rigid body MoCap systems that, according to Baker et al. [22], have been largely ignored in the literature as of 2006, and it has been verified in further review that it has not increased in the last years.
- MoCap-wearables devices can be considered products of high or very high complexity in relation to the design requirements, so the study can also be extrapolated to other wearables and to other areas with less complexity. In fact, the described factors can be used not only for advanced technological devices but also for other, more basic products that need to be precisely and comfortably placed on the body.

As future work, the methodology should be implemented in more cases to improve it. Additionally, it is proposed to create objective methods to adequately evaluate the prototypes developed by operating in real situations, mainly in relation to the union attachment. In this way, it is proposed to investigate new types of body attachment. This may be interesting to study regarding the behaviour of the skin with the body movement and the design of the contact surfaces, considering anthropometric and morphological factors of the subject under study. In addition, there is no doubt that there is a latent need to look for new MoCap applications and areas, improving the movement and consequently the quality of life of more sectors of the population.

Acknowledgments: The project was co-financed by the Government of Aragon, the European Regional Development Fund, and the University of Zaragoza (Spain). The authors are thankful for the media and materials provided by University of Zaragoza Research Institute I3A.

Author Contributions: J.J.M.: literature review, synthesis, ideation, and paper writing; J.M.: planning, ideation, and critical review of the article with special attention to motion capture technology and ergonomics; T.B.: planning, ideation, and critical review of the article with special attention to product design and design methodology aspects.

Conflicts of Interest: The authors declare no conflict of interest.

Abbreviations

MoCap	Motion Capture
IoT	Internet of Things
IMU	Inertial Measurement Unit
DPP	Data Processing Point
LED	Light-Emitting Diode
GUI	Graphic User Interface
RMS	Root Mean Square
SD	Secure Digital
LAN	Local Area Network
PAN	Personal Area Network

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2.3. Estudio 3

Marín, J., Blanco, T., Marín, J.J., Moreno, A., Martitegui, E., Aragüés, J.C. (2019). Integrating a Gait Analysis Test in Hospital Rehabilitation: A Service Design Approach. *Plos One*, 14, e0224409. https://doi.org/10.1371/journal.pone.0224409

BD: JCR | FI: 2.740 | Q: *Multidisciplinary sciences* (Q2 – 27/71)

PLOS ONE

RESEARCH ARTICLE

Integrating a gait analysis test in hospital rehabilitation: A service design approach

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Citation: Marín J, Blanco T, Marín JJ, Moreno A, Martitegui E, Aragüés JC (2019) Integrating a gait analysis test in hospital rehabilitation: A service design approach. PLoS ONE 14(10): e0224409. https://doi.org/10.1371/journal.pone.0224409

Editor: Andrew Soundy, University of Birmingham, UNITED KINGDOM

Received: July 9, 2019

Accepted: October 11, 2019

Published: October 30, 2019

Data Availability Statement: All relevant data are within the manuscript and its Supporting Information files.

Funding: The authors received no specific funding for this work.

Competing interests: The authors have declared that no competing interests exist.

Abstract

Background

Gait analysis with motion capture (MoCap) during rehabilitation can provide objective information to facilitate treatment decision making. However, designing a test to be integrated into healthcare services requires considering multiple design factors. The difficulty of integrating a 'micro-service' (gait test) within a 'macro-service' (healthcare service) has received little attention in the gait analysis literature. It is a challenge that goes beyond the gait analysis case study because service design methods commonly focus on the entire service design (macro-level).

Objective

This study aims to extract design considerations and generate guidelines to integrate MoCap technology for gait analysis in the hospital rehabilitation setting. Specifically, the aim is to design a gait test to assess the response of the applied treatments through pre- and post-measurement sessions.

Methods

We focused on patients with spasticity who received botulinum toxin treatment. A qualitative research design was used to investigate the integration of a gait analysis system based on inertial measurement units in a rehabilitation service at a reference hospital. The methodological approach was based on contrasted methodologies from the service design field, which materialise through observation techniques (during system use), semi-structured interviews, and workshops with healthcare professionals (13 patients, 10 'proxies', and 6 doctors).

Results

The analysis resulted in six themes: (1) patients' understanding, (2) guiding the gait tests, (3) which professionals guide the gait tests, (4) gait test reports, (5) requesting gait tests (doctors and test guide communication), and the (6) conceptual design of the service with the gait test.

Conclusions

The extracted design considerations and guidelines increase the applicability and usefulness of the gait analysis technology, improving the link between technologists and healthcare professionals. The proposed methodological approach can also be useful for service design teams that deal with the integration of one service into another.

Background

Although we are not conscious of its complexity, gait is a complex activity for human beings. It requires high motor control, and its pathologies have a harmful effect on personal autonomy and daily life activities [1]. Gait analysis with motion capture (MoCap) technology in the usual clinical practice is called 'clinical gait analysis' [2]; it is considered an important measurement in the rehabilitation field, where decision making on numerous treatments and interventions can benefit from objective information on the patient's walking pattern [3–7]. Clinical gait analysis is especially important in the treatment of hemiparetic individuals after a stroke (or other causes), because they experience numerous impairments in walking skills that are reflected in the gait pattern [8].

In this regard, clinical gait analysis based on MoCap technology can be defined as the instrumented measurement of movement patterns that comprise walking and the associated interpretation of these patterns[2]. A MoCap instrumentation that is extensively used in biomedical research is optical technology (gold standard), which tracks the position of reflective surface markers with infrared cameras. Another instrumentation is technology based on inertial measurement units (IMU), which are electronic devices that measure rotations (rotation matrices, Euler angles, quaternions, etc.) by processing the signal of embedded sensors (accelerometers, gyroscopes, and magnetometers) [9–13]. Regarding their differences, optical technology is more accurate than IMU technology, which could present drift errors. However, it requires a camera infrastructure and sometimes presents shadowing problems [14]. In contrast, the IMU technology is more economical and portable and has been recently used in wearable technology [15], which could encourage cloud data processing and information exchange in the context of the Internet of things [16].

MoCap gait analysis is widely used in clinical research; however, certain factors have prevented the spread of this technology in hospital rehabilitation [17,18]. Nowadays, gait evaluation relies mostly on observational criteria. These systems involve high technical complexity, requiring the application of a strict protocol for accurate and repeatable measurements [2,19,20]. The massive amount of information they provide requires complex processing methods [8,21,22]. Currently, the professionals involved in this type of analysis must be highly qualified [2], which conflicts with the present needs for simplicity, usability, and intuitiveness [23].

Many of these factors have been identified by the cited researchers; however, despite being relevant, the difficulty of the 'servitisation' of gait analysis has received little attention in the literature [15]. Because of the challenges that servitisation poses, it should be added as an additional research objective.

Designing an integrated test in the biomedical field is particularly complex because multiple stakeholders have different needs. Solutions that involve all users (patients, doctors, therapists, etc.) in the context of the technology are required to make it useful, cost-effective, and truly usable [24]. This includes family members and people close to patients (proxies), who are especially affected by the situation that the patient experiences [25,26]. Therefore, we address a problem that goes beyond the development of the technology by investigating how to apply a certain technology (gait analysis) to a specific context (hospital rehabilitation services).

If we assume that the design object is a service and not only the technology that measures movement, the use of specific service design techniques [27,28] will allow us to predict failures, extract critical points, and consider the intangible and contextual part of the product [15]. These methods are aligned with the patient-centred care (PCC) philosophy, which is a priority in the healthcare field [29] and shares its philosophy with human-centred design (HCD) [30]. Despite the uncertainty in health services (timing, diagnoses, resources per patient, etc.), these methods are relevant for professionals to know exactly what their roles are and to work in a more optimal and orderly manner. To achieve this, the involvement of users in the design process is key [31].

However, these methods, although highly flexible, are commonly focused on the entire service design [27,30]. Service design methods and the theoretical basis of service-dominant logic [32] aim to guide service innovations and are focused on the perspective of the whole company. Wetter et al. [33] identified this situation as a 'macro-level' approach and asserted that, in some cases, it is not clear how to act at a more operational level with a 'micro-level' approach or how to guide specific actions and projects to favour service innovations. Thus, contributions are needed to connect design methods with real situations and problems, producing pragmatic, empirical, and micro-level approaches.

Based on this terminology, we face a scenario in which we incorporate what we call a 'micro-service' (a gait analysis test) within a more complex 'macro-service' (rehabilitation services). In terms of service design, this situation has particularities and implications that are essential to consider. How can the gait test be included in the hospital as an additional medical test? What additional materials must be designed, developed, or adapted for the gait test? How do the patient's capabilities influence the design and guidance of the gait test? Which professionals will guide it? Is there a lack of certain professionals in the macro-service? In this regard, qualitative studies can provide a meaningful view of the perspectives, opinions, and priorities of the users (patients, healthcare professionals, and proxies) and reveal the underlying conceptual structure of their existing and/or desired interactions [34–36].

This article qualitatively evaluates a MoCap gait analysis system during its integration in a hospital rehabilitation environment, constructing the research through design methods. We focus on a specific case study of neurological patients with spasticity in the lower limbs who are treated with botulinum toxin. Thus, we present design considerations and guidelines for the improvement and adaptation of the system, which can be extrapolated to other scenarios at both the service design and hospital environment levels. In the results section, the guidelines are structured into six main themes. Finally, in the discussion section, we discuss the advantages and benefits that an integrated gait analysis test would introduce in rehabilitation services.

Methods

A qualitative research design was used to provide design considerations and guidelines to integrate the MoCap technology for gait analysis in a hospital rehabilitation service. The methodological approach was based on contrasted methodologies from the field of service design, which were materialised through observation techniques (during system use), semi-structured interviews, and workshops with healthcare professionals. A sample of 29 participants was analysed (13 patients, 10 'proxies', and 6 doctors). The reporting of the results follows the Consolidated Criteria for Reporting Qualitative Research (COREQ) statement [37] (S1 Table).

Paradigmatic position

Within the paradigms 'that guide disciplined research' [38], the paradigmatic position of this research is in the field of interpretivism (aligned with qualitative research). In interpretivism, 'reality' is constructed in people's minds and can be clearly understood through an interactive dialogue between the researcher and participant [39]. The interpretivism paradigm and the qualitative methods are naturally closer than quantitative methods to design practice [RW. ERROR—Unable to find reference:453]. According to Blanco et al. [40], not considering the qualitative perspective of end users could lead to suboptimal solutions in product and service designs. In our case, the research question of this study is concerned with providing an understanding of how to integrate MoCap gait analysis technology into the rehabilitation field according to the end user's knowledge, experience, and expectations.

Ethics

The experimental study was conducted after the formal approval of the local ethical committee (Bioethics Committee of Aragón Spain, CEICA; Act No. 12/2018). The study was conducted in accordance with relevant ethical guidelines, including a verbal explanation and written informed consent from the participants.

The gait analysis system

The MoCap system used in this study was the Move-Human Sensors system developed by the IDERGO research group, which includes a module for gait cycle analysis [15,41]. The first version of the system was implemented in 2007. Since then, it has been used in numerous public and private projects both in hospitals (healthcare field) and companies (ergonomics field). The system has been incorporating the concerns of the professionals involved in the projects (engineers, doctors, ergonomists, prevention technicians, etc.).

The measurement validity of the MoCap system is largely determined by the accuracy of the sensors it uses. In this case, it is based on wireless IMUs, specifically, the NGIMUs devices [42], which are placed on the patient's body with elastic bands. The NGIMU sensors are calibrated by the manufacturer. They filter and process the signal internally to directly send the rotation information. The NGIMU sensors have been used and assessed in numerous publications, which have guaranteed their accuracy, as can be found on the manufacturer's website [43].

The gait test of this study is aimed to be used as a medical test based on pre- and post-measurement sessions for the applied rehabilitation treatments. The generated reports show the changes that have occurred in each patient's gait between the pre- and post-sessions. These reports can be used to make decisions about the treatments (continue treatment, change to another, increase the intensity, etc.). In this regard, it should be noted that this study does not focus on the gait report, how it is designed, or what information it contains. Instead, we

present a more global perspective of the service design. However, because the gait report design is a relevant research issue, we have considered it in the fieldwork to extract participants' expectations and research opportunities.

Hospital setting

The research setting was the Rehabilitation and Physical Medicine Service of the Miguel Servet University Hospital (HUMS) of Zaragoza, Spain, a reference hospital in the country. This service provides rehabilitative assistance to return the highest degree of functional capacity and independence to the patient as possible, favouring family, social, and work reinsertion. It is organised into areas of hospitalisation, outpatient consultation, and therapy (physiotherapy, occupational therapy, hydrotherapy, electrotherapy, and speech therapy).

Pathology and treatment

We were focused on evaluating the gait of patients with spasticity when they receive treatment with botulinum toxin. The choice of these patients makes it possible to extrapolate the results to other patients with more favourable physical or cognitive conditions. Spasticity is a symptom that affects a large group of patients after suffering from neurological damage. Negative effects include pain, decreased mobility, contractures, and muscle spasms, which can interfere with daily life activities and sleep to a greater or lesser degree. The causes are diverse; some of the best-known causes are stroke [44], multiple sclerosis [45], post-traumatic brain damage [44], spinal cord injury [46], cerebral palsy, amyotrophic lateral sclerosis, and polyradiculitis. In HUMS, more than 850 patients were admitted with stroke pathology in 2017, and 75% of these cases required attention and subsequent follow-up.

The botulinum toxin treatment aims to treat focal spasticity via muscle infiltration with reversible paralytic action after 4 to 6 months [44,47,48]. Although there are other possible treatments for spasticity, for this study, the observed efficacy, personalised patient needs (dose, muscles to be inoculated, etc.), relatively high cost, and widespread use of the treatment justify the treatment choice. The gait test can aid the doctor in decisions [49] regarding (1) continuing to apply the treatment, (2) detecting whether the infiltrated muscles are adequate, and (3) maintaining or modifying the dose.

Study design

Discover, define, design, and develop are the most common phases of service model development [28], constituting the global structure and philosophy that we follow. However, in this paper, as claimed in the literature [33], we delved into the specific methods related to our case study, providing the methodology design, reasoning, and how the specific methods were used and applied. Consistently, we contextualised the study design through a theoretical framework based on methods endorsed by the scientific community.

Our scenario started from an existing gait test based on IMU technology. In this context, we proposed a methodological approach to qualitatively assess three dimensions of the test, which gave rise to our research phases: (1) the user-product proximity effect, (2) the effect on and value in the service, and (3) user interactions. The theoretical framework of this approach was based on the following contrasted methodologies from the field of service design and HCD (which, as we have seen, is related to the PCC philosophy):

- The general vision was based on the Octopus methodology by Marin et al. [15], which aims to define design specifications to create MoCap devices from three points of view: product,

software (information analysis), and service. As the design object is a service, this study focused on this approach.

- The phases within the methodological sequence were based on the Xassess evaluation methodology by Blanco et al. [40]. Because the starting point was an existing product (a gait analysis system), we inevitably faced the evaluation of the system. In this regard, Xassess proposed three evaluation strategies: (1) 'complementation' (each product dimension is evaluated with one qualitative or quantitative technique), (2) 'triangulation' (each dimension is evaluated with two or more parallel techniques), and (3) 'combination' (each dimension is evaluated with two or more successive techniques). As shown in Fig 1, the methodological proposal followed a general strategy of triangulation (three parallel phases). Examining each phase separately, Phase 1 followed a triangulation strategy, and Phases 2 and 3 followed a combination strategy. Combination strategies offer advantages because each evaluation illuminates the following steps or techniques strategies, avoiding overlap and favouring the construction of knowledge on a solid basis.
- Finally, Phase 3 was based on Community, which Blanco [26] proposed as a methodology for the design of complex services with interrelationships between multiple users. Here, it was adapted to a workshop format for professionals from the health sector.

Table 1 shows the construction of the research methodology. Three assessment dimensions (phases) led to concrete research questions, which were answered with different user profiles (participants) through observation techniques, semi-structured interviews, and workshops.

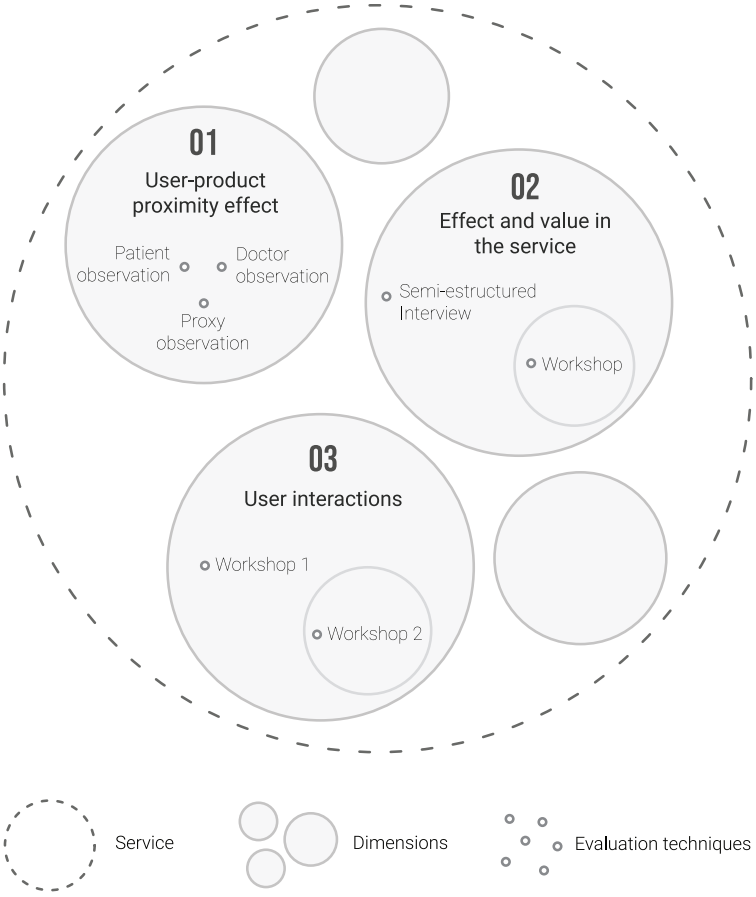

Fig 1. Product evaluation strategies in our case study, based on Blanco et al. [40].

https://doi.org/10.1371/journal.pone.0224409.g001

Regarding the participants mentioned in Table 1, the relationship established with the doctors was possibly due to previous meetings in which they showed a shared interest in integrating a gait analysis system into their service. A relationship was established with the patients with the six doctors in Table 1, who conducted the patient rehabilitation and recruited them face-to-face during the consultation. The interest in improving rehabilitation through gait analysis was communicated to the patients and proxies. No one refused to participate in the study.

The sample size of patients and proxies (phase 1) was determined by the concept of *saturation*, which was defined by Glaser and Strauss [50] and has been widely used in qualitative research. Saturation has been reached when adding more participants to the study does not generate additional insight or information. In this way, the measurement sessions were repeated until saturation was reached with 13 patients and 10 proxies. The sample size of doctors was six (Phases 1, 2, and 3), which corresponds to the number of physicians involved in the analysed rehabilitation service and the applied treatment.

In the following sections, each phase of the methodology is explained in depth, including the specific research objectives, participants, and study design.

Phase 1: User-product proximity effect

Phase 1 aims to learn from observing the use of the MoCap system in its context. The strategy in this step was to perform the gait test in the rehabilitation service, carrying out an observation focused on understanding the effect on the involved actors (patients, proxies, and professionals).

There were 26 observation sessions carried out with 29 users of different profiles: the patients (n = 13) who performed the test, the proxies (n = 10) who (in some cases) accompanied the patients and observed the test from nearby, and the doctors of the service (n = 5 rehabilitation specialist doctors and 1 resident doctor) who were free to observe the gait test and talk with the patients or proxies. Each of the 13 patients with spasticity (7 men and 6 women; average age = 45.9 ± 19.8 years) underwent the gait test twice. The first test was performed a few minutes before receiving the botulinum toxin treatment, and a follow-up was performed a month later.

The patients had been diagnosed by the rehabilitation service of the hospital in the evaluation consultation and were selected for the study by meeting the following inclusion criteria:

- The patient can walk autonomously.
- The patient presents a dynamic or reducible contracture that alters motor function.

Table 1. Research methodology.

	Dimensions to evaluate	Research questions	Research techniques	Participants	Main output results section
Phase 1	User-product proximity effect	How do the actors involved react to the test? How can we consider their experience for the gait test design?	Gait test Observation: 26 sessions	13 patients, 10 proxies, 6 doctors of the service (head of the service, head of the neurological section, 3 specialists, and 1 resident)	First 5 subsections
Phase 2	Effect and value in the service	How can the test be integrated into the service? What route will patients follow in the service?	Semi-structured interview: 1 session Workshop: 1 session	2 doctors of the service (head of the service and head of the neurological section)	Diagram 1 of the 6th section
Phase 3	User interactions	Which actors are involved directly or indirectly with the test? What information flows exist or should exist between them?	Workshop: 2 sessions	The 6 doctors from Phase 1	Diagram 2 of the 6th section

https://doi.org/10.1371/journal.pone.0224409.t001

Table 2. Patient's characteristics.

ID	Affected side	Gender	Age	Height [cm]	Abdominal Perimeter [cm]	Initial Gait speed [m/s]	Proxy
P001	L	M	36	177	108	0.36	Yes
P002	R	M	19	170	85	0.86	Yes
P003	R	M	44	172	85	0.79	Yes
P004	R	F	55	161	115	0.30	Yes
P005	L	M	18	164	64	0.66	Yes
P006	R	F	32	164	90	0.77	Yes
P007	L	F	69	148	83	0.19	Yes
P008	L	F	63	154	106	0.37	Yes
P009	L	M	70	176	102	0.34	Yes
P010	L	M	19	173	96	0.68	Yes
P011	R	M	60	164	92	0.33	No
P012	R	F	44	170	98	0.34	No
P013	R	F	68	165	92	0.32	No
13 patients	7 (R), 6 (L)	6 (F), 7 (M)	45.9 (19.8)	166 (8.4)	93.5 (13.1)	0.49 (0.23)	10 proxies

https://doi.org/10.1371/journal.pone.0224409.t002

- A reduction in spasticity is expected to lead to a functional improvement with the treatment, according to the doctor's previous experience.
- The patient has the possibility of receiving periodic controls to learn patterns of movement at home or complementary physiotherapy treatment.
- The patient is included in the indications of the technical sheet approved by the Spanish Agency of Medicines.

Table 2 includes the patient's characteristics. The gait speed at the beginning of the patient's evaluation has been included because it is an important indicator to represent the general state of health and is related to impairment, functionality, mobility, independence, autonomy, and comorbidity levels [51,52].

According to the statement terminology of the COREQ [37], the sampling method was purposive in the case of the patients because they met the inclusion criteria and were of diverse ages and disease levels, according to the doctor's criteria. Proxies were recruited through the snowball method because they were dependent on the patient section. Doctors were also purposively sampled because they represented different profiles (two heads, three specialists, and a resident doctor).

The gait test was carried out using two 'test guides', one engineer (JM), who managed the computer, and a physiotherapist (AM), who guided the patients and interacted with them. In each measurement session, the patients were instrumented with the MoCap sensors (Fig 2) and walked naturally 6 m in a straight line at a self-selected speed. When the distance was completed, the patient turned around and walked back in the opposite direction. This operation was repeated to measure up to 25 strides. Only strides in a straight line were used, discarding any turns and start and stop zones. The duration of each test was 20 to 25 minutes.

The observations during the test were carried out by the test guides. It was established that observers should focus on the following factors or dimensions: (1) physical and cognitive abilities (patients), (2) motivation (patients), (3) concentration (patients), (4) reactions to the test and technology including what they said, what they did, and how they responded (patients, relatives, and doctors), and (5) operational and technical problems (test guides). Field notes were

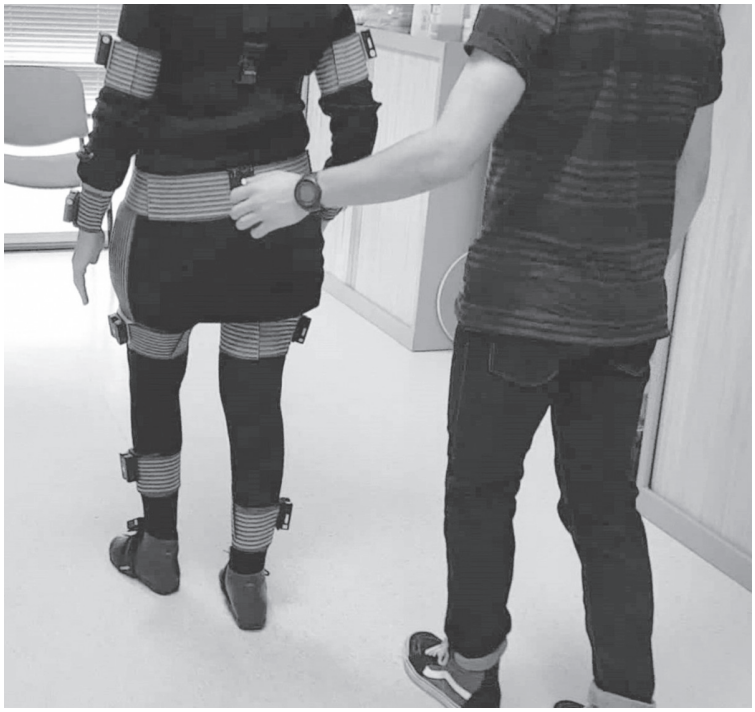

Fig 2. Gait test in hospital. The individual in this picture has given written informed consent (as outlined in the *PloS* consent form) to publish these case details.

https://doi.org/10.1371/journal.pone.0224409.g002

made during the observation. Audio and visual recordings were not used because the predefined observation dimensions were considered enough to address the research objectives.

Phase 2: Effect and value in the service

Designing a system that aims to advise professionals in the rehabilitation process requires going beyond what happens only in the test session. Phase 2 evaluates the effect and value of the micro-service within the HUMS macro-service, seeking to obtain an overview of the general path followed by the patient according to the diagnostic and care decisions.

Regarding the participants involved in this phase, owing to their deep understanding of service performance, the participants were two doctors who were familiar with the gait test: (1) the head of the neurological rehabilitation section and (2) the head of the rehabilitation service.

First, a face-to-face semi-structured interview with the user (1) was conducted, addressing the issues collected in Table 3. This allowed us to develop the first version of a graphic map that represents the flow of clinical decisions of the service with the new test introduced in it.

Table 3. Semi-structured interview questions.

How is the service structured?
What steps do patients follow when they receive the service?
What are the logistics, periodicity of the reviews, and communication pathways between patients and healthcare professionals?
What decisions do physicians have to make regarding patients?
What is the parallelism of the test with other existing medical tests?
Which healthcare professional should perform the test?

https://doi.org/10.1371/journal.pone.0224409.t003

Following a 'combination' strategy [40], in the second session, a workshop was held with both users (1 and 2) to evaluate the map of the service proposed after the first interview. The users had the opportunity to redefine and improve it to ensure that it reflected the entire process. The duration of each session was 40 minutes. They were pilot tested and conducted by JM and AM who recorded the audio.

Phase 3: User interactions

We assume that we are facing a complex and multi-user information network. For this reason, Phase 3 aims to define the information flows (connections) that must exist between the macro-service users for an adequate implementation of the gait test. These connections should allow the test implementation and should cover the relational needs of the Community methodology [17], improving the user experience, acceptance, and clinical effectiveness of the new gait test.

A workshop was held twice in succession with six doctors from the rehabilitation service, as shown in Table 1, first with three doctors and later with another three others. They were pilot tested and conducted by JM and AM. The duration of each workshop was 100 minutes, and the audio was recorded.

The workshop challenge was 'How could we develop a useful gait test for the rehabilitation service?'. The main task involved collaboratively drawing the users' relational needs by connecting user groups using arrows (unidirectional or bidirectional) that represent information exchanges and/or interactions. To facilitate the process, pre-designed cards with icons of the involved professionals had been prepared. Initially, the organisers structured some user groups and connections as an example. The schemes created by the doctors during the sessions are shown in Fig 3. In the second workshop, to reach a consensus between both workshops, following a 'combination' strategy [40], the researchers inquired about the differences from the map developed in the first session.

Data analysis

Observational notes of Phase 1 and the audios of Phases 2 and 3 were transcribed and coded using the thematic analysis approach [53]. The full transcription was read several times separately by JM, JJM, and TB to identify differences and similarities of the content. Similar content was underlined in the same colour, and a descriptive concept (category) was assigned to each colour. Afterwards, the researchers discussed their reflections. Once a consensus was reached, the latent content and implicit messages of each category were described in the results section. According to the COREQ statement [37], the identified categories were derived from the data (i.e. they are inductive). To improve the understanding of the maps from Phases 2 and 3, they were laid out as simply and perceptibly as possible. It was necessary to hear the audios repeatedly to include all the comments in the maps, not just the handwritten information. Microsoft Word and Excel were used to manage the data, and Illustrator was used to create the figures.

Trustworthiness

To achieve scientific rigour in qualitative research, Guba and Lincoln [38] proposed including a section about the trustworthiness of the interpretations. An integral aspect of trustworthiness is maintaining a detailed audit trail. Thus, we recorded our reflective memos and analysis decisions throughout the study. Additionally, in this paper, we provide clear and thick descriptions of the context, data collection, and analysis process, which favour the reproducibility of the study. To consider different perspectives and avoid bias, members of the research team

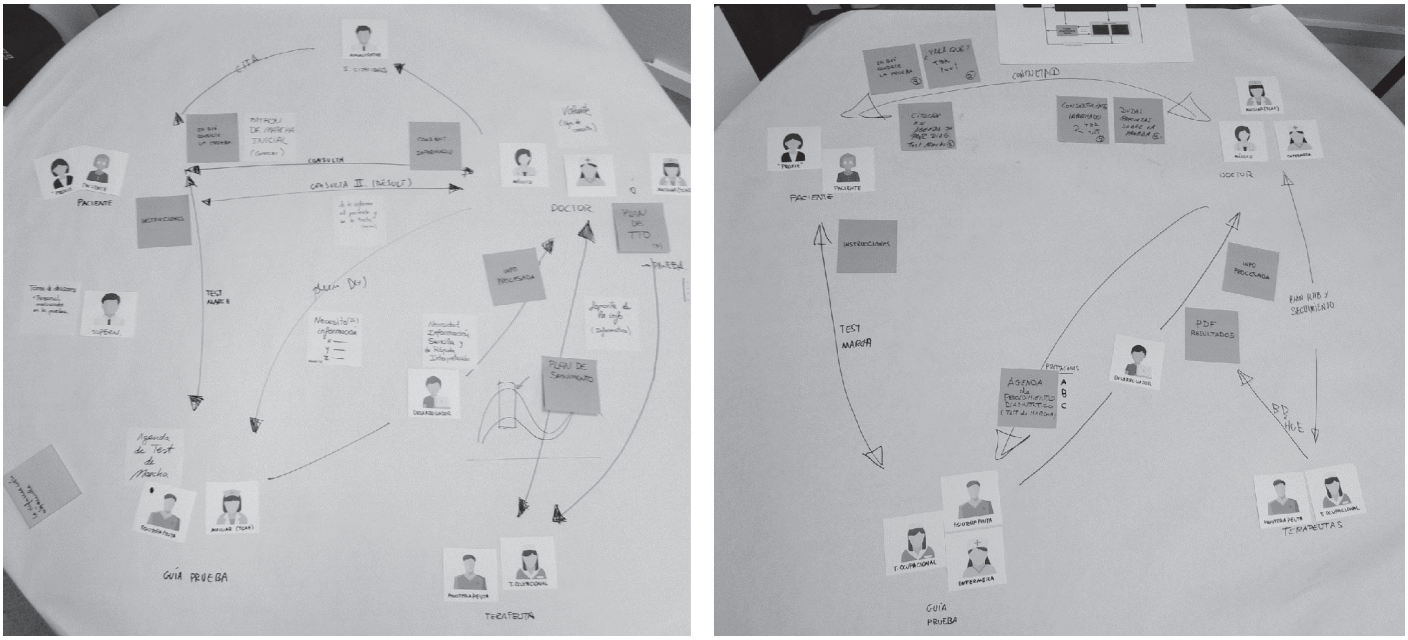

Fig 3. The maps of relational needs from the workshops with the doctors.

https://doi.org/10.1371/journal.pone.0224409.g003

represented different professions, and three of them independently identified and agreed on the categories presented in the results section. Finally, the resulting maps from Phases 2 and 3 reduced the subjective nature of the paper because they are tangible and factual objects proposed by the participants, who constitute an additional perspective as experts on their own experience in the environment [31].

Results

From the field research, design considerations and guidelines have been obtained and grouped in the following sections: (1) patients' understanding, (2) guiding the gait test, (3) which professionals guide the gait tests, (4) gait test reports, (5) requesting gait tests (doctors and test guide communication), and the (6) conceptual design of the service with the gait test.

Patients' understanding

The extreme diversity of the patients is evidenced. One of the most repeated phrases among doctors is 'each patient is a whole world' on a physical and cognitive level and in terms of the care that each one requires.

- **The accessibility level of the gait test should be maximised**.

Most patients receive other types of therapy than just those received in the hospital, such as therapies in elderly centres, associations, or private centres: 'I've been going to rehabilitation since I can remember'. They are aware of their limitations and are realistic about their situation: 'You can notice evolution for a while, but then you stabilise at a certain level'. 'In winter, I can feel my muscles [are] more contracted'. However, we also observe how doctors try to lower the expectations that the proxies sometimes have with botulinum toxin therapy. They indicated that rehabilitation objectives that are too high or optimistic can lead to frustration and disinterest in the rehabilitation process.

- **It should be assumed that not all patients will be able to recover their previous functional capacity. They usually know their own limitations. We should take this into account and be honest in relation to their chances of recovery**.

Those who have decided to participate in this study go to rehabilitation voluntarily and have a clear motivation to recover; however, the degree and origin of this motivation are very diverse. Some of them transmit their willpower with their daily habits, 'every morning I walk around the block'. 'I am always trying to improve, stretching and moving, for example, while I cook or while I dress'. Those who are older show that they have recovered the motivation they had lost: 'Recently, we went to the neurologist, and he explained the treatment to us. We have been encouraged to try. We had been disconnected from this world for many years'. In the youngest patients, motivation, strength, and interest usually come from family members, who are the protagonists in the interactions with the test guides and express their curiosity regarding new treatments and techniques.

- **The motivation of the patients and proxies should be exploited and maximised as much as possible. The gait test should become a motivating and engaging element whether the results are positive or negative**.

Guiding the gait test

How and who performs the test can be keys to its success. The test guides should ensure that patients walk with their usual pattern. In Fig 4, we see the movement curve irregularities of (a) a patient who is not accustomed to walking in the test and (b) those of the same patient who became accustomed to walking in the test after crossing the corridor two or three times.

As a general rule, the concentration level of the patients during the test was high. They were previously silent, struggling, and looking at the ground as they walked. Even those with limited cognitive and communicative ability understood the explanations and satisfactorily executed the test guide instructions. However, there are factors that affect the concentration and are

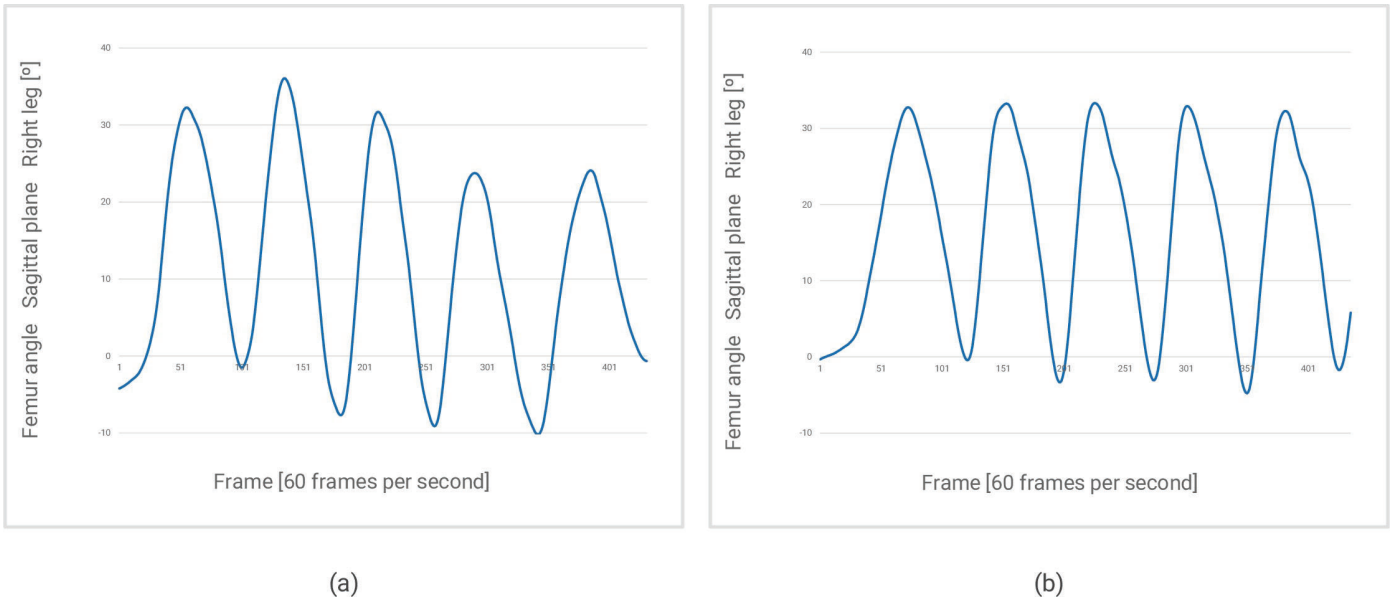

Fig 4. Femur angle with respect to the hip in the sagittal plane. (a) Before and (b) after the patient adapted to walking using the usual pattern.

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necessary to consider to accelerate the tests and avoid incidents that would require discarding the results.

The patient's concentration is improved with a calm and constant environment without sudden noises, foot traffic, or conversations. Patients can sometimes lose concentration, become scared, and even stop walking when someone suddenly enters the room, when there is a slam, or when staff or family members converse, more so if the conversation deals with issues related to the patient. To create this environment, the test guides must empathise with the patient and their relatives, using appropriate language with clear, concrete, and predictable instructions, while avoiding technical terminology (e.g. using anatomical calibration functions: 'Now I need you to be very still, like in a picture').

- **The role of the test guides is especially relevant. They should be able to extract the usual walking pattern of the patients. Access should be restricted to the room to achieve a calm and favourable environment during the performance of the test**.

During the tests, the patients displayed different emotions and reactions from showing fear of pain to satisfaction or gratitude. Considering these reactions can provide value from the user-experience point of view. Below, the reactions are sorted in the order of appearance along the process.

- **Mistrust, does it hurt?** One of the first reactions and doubts that arose in both patients and family members was regarding whether the test was painful. They worried about whether the devices give electric shocks or punctures. Many of them had suffered from various painful treatments, and these doubts could be a reason for the initial rejection.
- **Arriving late, anxiety**. Some were nervous about being late for the tests, either due to not finding the room, transportation difficulties, or the schedules of the relatives who accompanied them. The doctors indicated that sometimes patients present anxiety for these reasons, and they must spend the first minutes of the consultation session reassuring them. Nonetheless, this was not the case in this study.
- **Fatigue**. Some patients, owing to their physical condition and especially their age, asked to rest as soon as they reached the room. In these cases, the sensors were placed and removed while they were sitting.
- **Feeling observed**. Once we placed the sensors, we saw how the patients joked with their relatives. Others, especially the younger ones, presented a certain shyness and appeared to feel uncomfortable, exposed, and observed.
- **Gratitude**. At the end of the test, gratitude reactions often arose: 'It is a very difficult disease. It is comforting to see how people are working on this. We will help with everything that we can'. It is important that they feel they are part of the technological evolution in this field.
- **Bond of trust in the second session**. As a general rule, on the second day, the patients were more confident. They interacted more and had a greater link with the test guides. The most noticeable effect occurred in the young patients, who, as mentioned, were uncomfortable and shy on the first day.
- **The test guides should explain the test properly and act effectively towards the different reactions that patients may present. Behaviour guidelines for test guides should be established**.

Which professionals should guide the gait tests?

Due to the test characteristics, doctors concluded that two people are needed to run the test: one to guide the patient (place and remove sensors and give instructions to the patient) and another to operate the computer. Different health professionals have adequate training and capacity (doctors, nurses, physiotherapists, occupational therapists, etc.). According to health-care professionals, in our environment, the test would be carried out by the nursing section: 'Nursing is accustomed to doing this type of test; it falls within their competence'. 'Certainly, there are tests performed by a doctor, for example, an endoscopy, but in that case, you are getting inside a human being. This test has nothing to do with that'.

Likewise, tests could also be performed by physiotherapists. These professionals are the most interested (along with doctors) in obtaining objective information on the gait pattern because they also apply therapies aimed at rehabilitating walking; however, the availability of these professionals is reduced, at least at HUMS. The final decision rests on the service head, on the professional availability of each hospital, and on the derived costs.

- **The test should be conducted by two trained healthcare professionals. It would be feasible for nurses or physiotherapists to conduct the test. The decision depends on each service**.

Gait test reports

Doctors have a negative perception of the results provided by the test. They consider the test to be far from their area of knowledge and difficult to interpret, requiring a high learning curve. They called it 'the test of the engineers', in some cases, showing concern and anxiety regarding who would interpret the data and how much time would be necessary to do so.

- **The gait analysis test should provide a brief and easily interpreted report. Results must be communicated to patients in an understandable and personalised way to make more consensual decisions**.

Defining the content and design of the test report is one of the challenges that must be addressed. According to the doctors' opinion, the first test should serve to assess the functional state of the patient and, together with the rest of the information and inputs (clinical exploration, interview with the patient, clinical history, etc.), establish the rehabilitation objectives. Regarding the second test, they affirm that it should measure the treatment effects and allow the assessment of the achievement of the initial objectives: 'We could try to assess if the patient has improved above what is expected, at what is expected, or below what is expected'.

- **Future research should serve to detect the most representative and useful information for clinical decision making**.
- **With the first test, the rehabilitation objectives are established. With the second test, whether the treatment effects were as expected is assessed**.

A general statement was made that the test report results should be available in digital format for consultation between the professionals involved in a patient's rehabilitation. Consequently, the report should be uploaded and incorporated into the patient's electronic medical record. In this regard, HUMS has its own intranet and another at the regional level. In our research, we refer to the electronic medical record without differentiating between these two. In this sense, the communication vehicle between doctors and therapists is the electronic rehabilitation plan, which allows prescribing treatments and tracking the patient by the involved physicians (renamed the electronic monitoring plan once the treatment begins). Uploading

the gait test report to the electronic medical record would improve the doctor-therapist communication so they could share considerations about the results through the electronic rehabilitation plan and take more consensual decisions based on objective information.

- **The doctor should be able to upload the gait test report in digital format to the electronic medical record**.

Requesting gait tests: Doctors and test guide communication

Doctors agreed that it is not possible to run the test during consultation time. According to them, 'it is the same as an X-ray or a blood test; I prescribe it, and I get the results back'. One of the questions that emerged in the workshops was how a doctor could request a test from the consultation. In this regard, doctors proposed the creation of a new agenda called the 'gait test agenda' with specific schedules and professionals assigned that would be shared between doctors and test guides and completed in the consultation.

- **To cite prescribe patients to perform the test, it is proposed to create an electronic 'gait test agenda' shared between doctors and test guides**.

Conceptual design of the service with the gait test

Based on the specifications obtained in the previous sections and according to the specific outputs of Phases 2 and 3 of the methodology (Table 1), two schemes are presented that represent a conceptual proposal of the rehabilitation service that includes the new gait test in its operation. The first scheme, called the actuation flowchart (Fig 5), shows the circuit of decisions that physicians must face during the spasticity rehabilitation process. The figure shows two different areas shaded in grey: consultation and intervention. A patient will go through both areas iteratively as many times as necessary. It also shows the gait test, which is accessed through two entryways:

- **First gait entry**. The test can be prescribed from a consultation in which the doctor considers that further information is needed. In this case, the test would have a diagnostic purpose. This option is parallel to the current possibility of requesting information from other services (e.g. an interconsultation request to obtain a psychological report).
- **Second gait entry**. It is possible to incorporate the gait tests during the intervention process, as long as it is planned from the consultation. In this case, the test would have a monitoring function. This option, based on pre- and post-treatment measurement sessions, is the one planned (methods section) to assist clinicians during the rehabilitation process.

Note that an item drawn with an empty circle indicates that the patient will undergo the process only if it is prescribed by the responsible physician (e.g. a patient may receive therapy sessions but not receive medical and nursing treatment sessions).

The second scheme, developed following Community [26], represents the connections between the user profiles that interact with the gait test and its results (Fig 6; arrows from 1 to 7). Dark arrows represent the information flows that need to be designed and implemented. Light coloured lines represent the macro-service connections, which our design will not influence, but it will have a certain influence on the gait test integration. The represented users are grouped according to the 'network spaces', areas of conceptual interaction with different objectives and themes where users communicate and interactions can take place (e.g. gait test session, management, etc.). We see how a user can be present in several 'network spaces'.

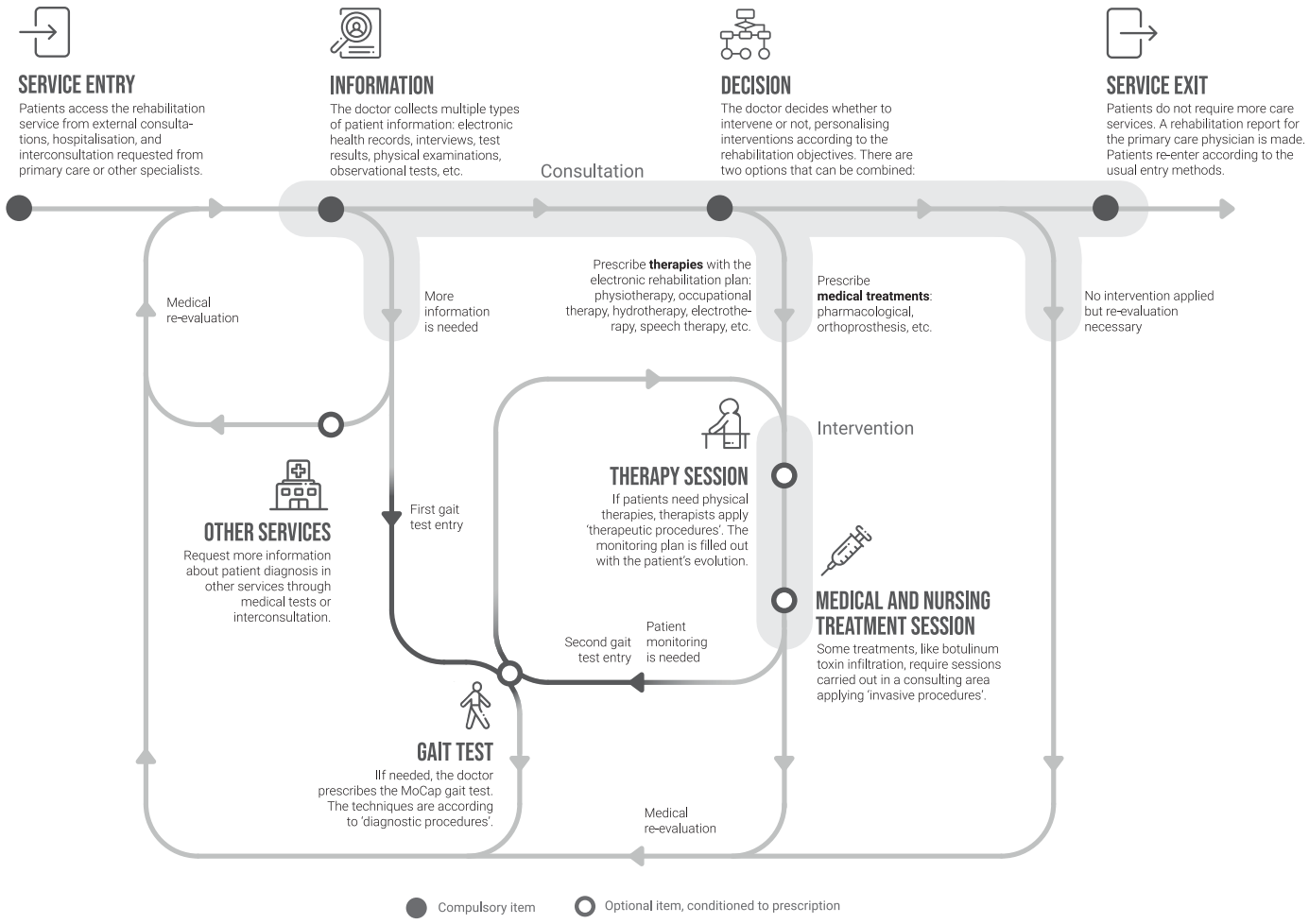

Fig 5. Actuation flowchart decision making of the rehabilitation service. Figure elaborated by authors. Icons made by Freepick, Pause08, Pixel perfect and Srip from www.flaticon.com.

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Likewise, in the scheme, the materials to be developed are established (graphic documents, electronic agenda, cloud, etc.), which are also called 'touch points', that is, tangible or intangible elements that are in contact with the users. In line with the theory of service design, two conceptual interaction areas are also included, 'backstage' and 'onstage' [54]. Backstage is the invisible part for the user, where the processes that articulate the services take place. Onstage is the visible part that encompasses the target users.

Note that 'developers' have been included as temporary participants in the process because, although their permanent presence could be useful, their role during the first stages will be to process the information manually. Once the project evolves, and it is decided which information is the most adequate to facilitate the clinical evaluation, this process can be automated, and these users can be eliminated.

Discussion

This study highlights an underlying need for MoCap gait analysis technology. Although it can generate individual objective outcome measures in usual clinical practice [55], further research is required for its effective and useful clinical application. In this framework, we apply a

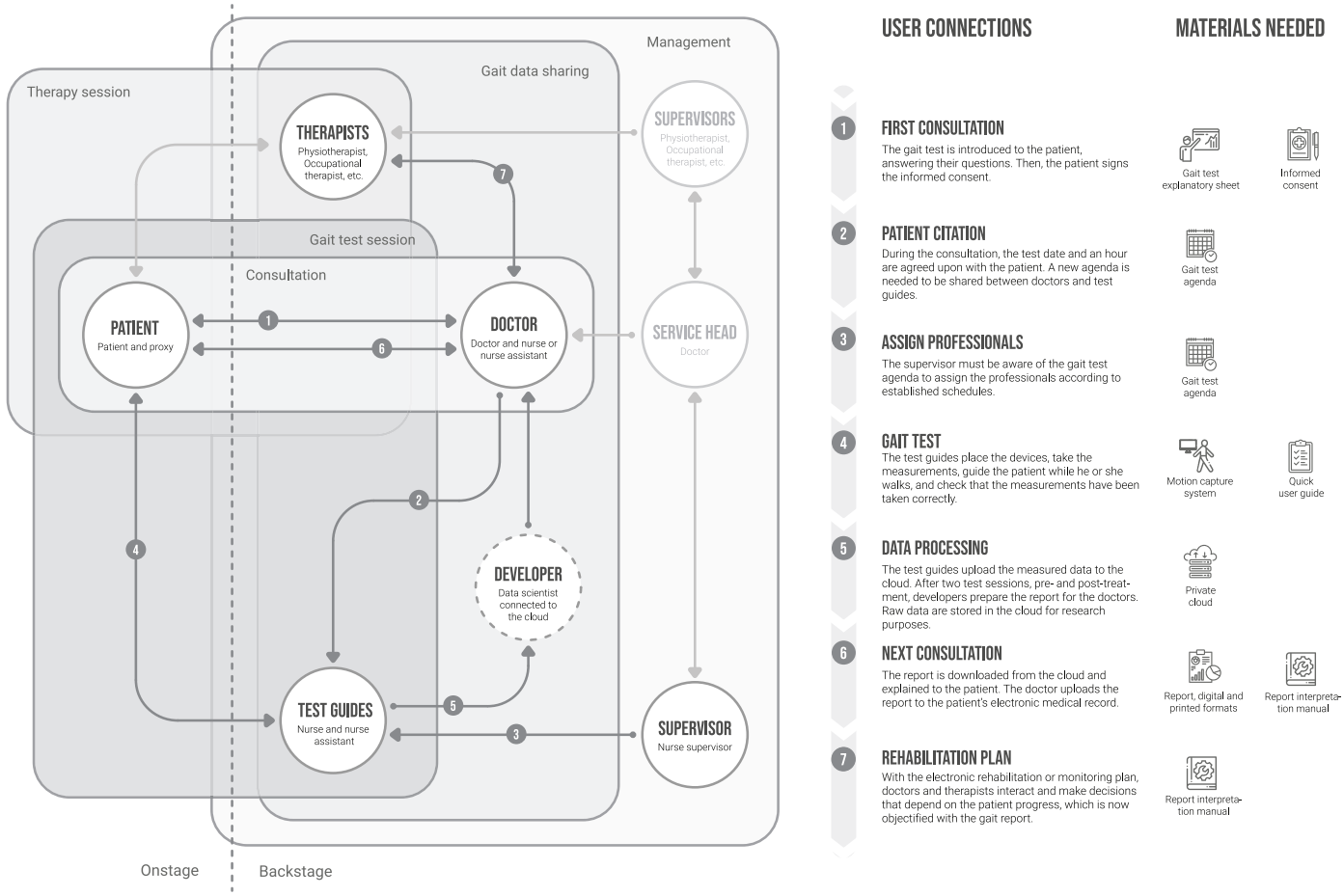

Fig 6. Community scheme based on [26] with new or improved information flows to include the gait test in the service. Figure elaborated by authors. Icons made by Freepik, Smartline, Mynamepong, Pause08 and dDara from www.flaticon.com.

https://doi.org/10.1371/journal.pone.0224409.g006

research methodology that starts from a specific concept: to design a gait test integrated into the hospital setting that provides objective information to support decision making regarding the rehabilitation process. We focus on the case study of neurological patients with disorders derived from spasticity who receive treatment with botulinum toxin. We have conducted a field investigation introducing a gait analysis system into the HUMS environment and evaluated it through observation, interviews, and workshops. As a result, design considerations have been obtained that can be useful for design teams that face these types of challenges in the future. Among these considerations, the micro-service (gait test) integrated into the macro-service (hospital rehabilitation service) has been conceptually defined through two infographics.

We assume that the proposed concept involves an extra effort for hospitals (economic and resource investment), for professionals (more workload and learning), and for patients and proxies (more visits to the hospital). However, the gait test would provide a substantial improvement in the quality of care, encouraging professional development and collaborative research among physicians. Likewise, the system requirements are relatively simple. With a short test duration and a short preparation time (20–25 min per patient), it does not require an exclusively dedicated room. For patients, it is not an invasive test, and it does not entail

visiting centres other than the hospital where they usually receive treatments. The advantages and benefits that it would bring in rehabilitation services are described below:

- **Sustain decisions at a clinical level**. Having a test that provides objective data on the patient therapy response allows more precision in the decision-making process, including the option of not further intervening.
- **Sustain decisions at the administrative and social levels**. Inevitably, physicians are under pressure that comes with human responsibility, schedules, efficiency requirements, legal disputes, or limitations in resources.
- **Improve treatment profitability**. Some treatments entail significant costs to the public or private health entities involved, as in the case of treatment with botulinum toxin. The gait test can avoid applying those treatments that do not provide positive effects to certain patients.
- **Facilitate communication between physicians**. The test could unify gait evaluation and enhance the transmission of knowledge among health professionals.
- **Positive feedback for the therapist**. Objective information allows the clinical plan to be personalised for each patient, establishing more realistic objectives and generating a theoretical basis that could improve their evolution.
- **Positive feedback for the patient**. It may involve extra motivation for patients, encouraging confidence in the treatments and a greater perception of healthcare safety and trust.
- **Improve medical and patient communication**. Properly presented information can establish a doctor-patient communication pathway, improving the reasoning of patients (and relatives) and improving treatment decision making.
- **Feed databases**. Collecting gait information may have a practical effect to create predictions for new patients and facilitate diagnoses through machine-learning techniques.
- **Enhance research among physicians**. It can improve the collaborative research work among physicians, allowing the validation of new or modified treatments. Data from the database can be filtered for each investigation.

The mentioned benefits coincide with some concepts that McHorney and Tarlov [56] generically described for the healthcare field sector. They provide ways in which data from individual people in healthcare can be used, including to describe a patient's health state, to monitor disease progression, or to standardize interactions between health care practitioners and patients [56]. In this regard, Cella et al. [57] summarised the concepts from McHorney and Tarlov [56] into two possible perspectives or uses that have similarities with the two gait test entries that we propose in Fig 5. The first use (similar to the first gait entry) is clinical decision making under uncertainty: 'estimating the likelihood that a patient will profit from a given intervention'. The second use (similar to the second gait entry) is clinical evaluation: 'examining whether a given treatment makes a meaningful difference for an individual patient'.

Beyond the benefits that MoCap gait analysis would bring in rehabilitation services, this paper has two main strengths or contributions. First, it provides design considerations and guidelines to integrate a gait analysis test based on MoCap technology in the rehabilitation hospital setting, which is a novel contribution and can encourage the use of this technology in this field. In this regard, Martin et al. [58] encouraged researchers to realise studies that propose design recommendations based on HCD, especially in scenarios where users (in our case

patients) are heterogeneous (as we see in patients with hemiplegia). This reasoning supports the presented results.

The second strength is proposing a reproducible methodological approach to integrate a 'micro-service' (gait test) within a 'macro-service' (rehabilitation service), which advances service design knowledge and may be applied to other case studies or other technologies. This methodological approach had great acceptance among physicians. They ensured that the sessions where they participated were useful, practical, and different from the usual way of working: 'I see these types of sessions and workshops as essential. It is useful to clean up many useless connections and make them simpler. I like it [the map]; it's clean and illustrative'.

The importance of properly designing the rehabilitation service is manifested in numerous investigations that seek to assess the patient's experience (e.g. [59,60]). In this context, service design and the theoretical basis of service-dominant logic [32] have great importance. They allow one to address stakeholder's needs and strengthen professional relationships. However, as Han et al. [28] indicated, it is necessary to consider the specific needs of the clinical environment when applying service design techniques. This is translated to our specific case study in the necessity of integrating a 'micro-service' (gait test) within a more complex 'macro-service' (rehabilitation service). The scenario of the micro-service integration has particularities that differentiate it from a mere application of service design methods, which concern the design of the service as a whole. In return, we focus our design on 'one link in the chain', a new gait test in a hospital rehabilitation service. According to Wetter et al. [33], this contributes to improving the theoretical framework of the service design because it is not actually clear how to act at a 'micro-level' approach to connect design methods with real situations and favour service innovations.

Additionally, certain weaknesses or limitations have been identified in this study. It should be noted that we focus on a relatively specific case (gait tests for patients with spasticity in a particular rehabilitation service) and on a limited sample of professionals who know the service and the treatment used. Thus, if one intends to integrate this or another similar system into another hospital, it should be considered that other centres may be different at the organisational level. Some concepts (mentioned throughout the results section), such as agendas, the involved personnel, the rehabilitation plan, or the patients under study, may be different; thus, certain sections may be adapted to the particular case. In this regard, it may be useful to rely on the research methodology presented, especially in Phases 2 and 3.

Another limitation concerns the (1) gait report (including processing backwards) and the (2) measurement validity of the MoCap system. Although they are not part of the objectives of this study, they are key questions for the system design to achieve successful integration in a hospital. Both topics have been extensively discussed in the literature, and we encourage further investigation. In this sense, this paper is focused on the service design, which complements and strengthens this area of research.

Additionally, it should be noted that this study is interpretivist and the research techniques used are qualitative. This intrinsically implies that the participants are those who experience, process, and label the 'reality' under investigation and transmit it to the researcher [39]. To do this, the participants rely on their individual experience, memories, and expectations [38]. This prevents the total objectivity of the study and complete neutrality.

In summary, although we focused on a relatively specific case (gait tests for patients with spasticity in a particular rehabilitation service), the proposed design recommendations are partially generalisable to other treatments or health centres. Additionally, the proposed methodology can be useful and reproducible to obtain design considerations to integrate a micro-service into a macro-service.

Nowadays, healthcare technology is developing more rapidly and efficiently and requires fewer resources. This research contributes to improving the application of this type of system and other Internet of things devices [16] that can be developed in the healthcare field of 'smart health' [61,62]. It is expected that future health devices (micro-services) could be more useful to hospital services (macro-services) by maintaining their use over time and improving their acceptance.

Conclusions

We conducted a field investigation introducing a gait analysis system into a hospital rehabilitation environment and evaluated it through observation, interviews, and workshops. We focused on patients with spasticity who received treatment with botulinum toxin. The main conclusion is that integrating a gait test into hospital rehabilitation services is beneficial for physicians, patients, and proxies, but to make it really applicable and useful, some design specifications should be considered. The design specifications and the methods applied to obtain them can be useful for both technology developers and healthcare professionals who seek to improve the quality of healthcare services.

Supporting information

S1 Table. Reporting according to the COREQ criteria.
(DOCX)

Acknowledgments

The authors would like to acknowledge and thank Dr Nicolas Rivas, Dr Ricardo Jariod, Dr Inmaculada Salcedo, and Dr M. Teresa Zarraluqui for their suggestions, involvement in the project, and their interest. Likewise, the authors would like to thank all participants who voluntarily participated in this study.

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2.4. Estudio 4

Marín, J., Blanco, T., de la Torre, J., Marín, J.J. (2020). Gait Analysis in a Box: A System Based on Magnetometer-Free IMUs or Clusters of Optical Markers with Automatic Event Detection. *Sensors*, 20, 3338. https://doi.org/10.3390/s20123338

BD: JCR | FI: 3.275 | Q: *Instruments and Instrumentation* (Q1 – 15/64)

Engineering, Electrical and Electronic (Q2 – 77/266)

Chemistry analytical (Q2 - 22/86)

sensors

MDPI

Article

Gait Analysis in a Box: A System Based on Magnetometer-Free IMUs or Clusters of Optical Markers with Automatic Event Detection

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Received: 29 April 2020; Accepted: 10 June 2020; Published: 12 June 2020

Abstract: Gait analysis based on full-body motion capture technology (MoCap) can be used in rehabilitation to aid in decision making during treatments or therapies. In order to promote the use of MoCap gait analysis based on inertial measurement units (IMUs) or optical technology, it is necessary to overcome certain limitations, such as the need for magnetically controlled environments, which affect IMU systems, or the need for additional instrumentation to detect gait events, which affects IMUs and optical systems. We present a MoCap gait analysis system called Move Human Sensors (MH), which incorporates proposals to overcome both limitations and can be configured via magnetometer-free IMUs (MH-IMU) or clusters of optical markers (MH-OPT). Using a test–retest reliability experiment with thirty-three healthy subjects (20 men and 13 women, 21.7 ± 2.9 years), we determined the reproducibility of both configurations. The assessment confirmed that the proposals performed adequately and allowed us to establish usage considerations. This study aims to enhance gait analysis in daily clinical practice.

Keywords: biomechanics; gait analysis; design; algorithm; gait events; applicability; reproducibility; minimal detectable change (MDC)

1. Introduction

Gait analysis based on full-body motion capture (MoCap) provides spatio-temporal and kinematic variables [1]. These variables are particularly useful for monitoring the progress of patients with musculoskeletal pathologies, and can offer ample possibilities in the rehabilitation field by assisting in decision making through measurement sessions before and after treatments, interventions, or therapies [2–5].

Gait analysis can be conducted using various types of MoCap technologies; two of the most common are optic-based and inertial measurement unit (IMU)-based technologies. Optical MoCap uses infrared light-emitting cameras situated in the room that can identify the position of spherical

reflective markers placed on the subject. The reflective markers can be placed on the body either individually or grouped in clusters called rigid bodies (RBs) [6–8]. The IMUs are electronic devices that capture movement through signal processing of the output data of different built-in sensors (accelerometers, gyroscopes, and magnetometers) [9–11]. When optical systems use RBs, they have significant parallels with IMU systems, since the capture consists of associating an element (an RB or an IMU) with a body segment in both cases [12].

There are many systems for capturing human motion [13,14]; Marin et al. [12] reviewed commercially available IMU- and optic-based systems and analysed factors such as the devices used or their placement on the body. Other researchers, such as Tao et al. [15] and Muro-de-la-Herran et al. [16], reviewed existing approaches to analysing gait, including the use of algorithms to analyse gait patterns. These and other authors have discussed the potentialities and limitations of both technologies [6–18]. With regard to the potentialities, optical technology is characterised by its precise measurements; for this reason, it is considered the gold standard for MoCap systems. IMU technology is characterised by portability; as it does not require a fixed camera infrastructure, it can be used in different spaces in a relatively straightforward manner.

With regard to the limitations, some factors prevent the use and application of these technologies in daily clinical practice [12,19,20]. Amongst these factors, the measurement errors or inaccuracies that arise due to the following causes are important issues:

1. **Intrinsic variation:** Although the gait pattern is highly internalised in the brain, it is impossible to repeat the gait or any other movement in precisely the same way each time; there are always minimal individual variations, which are called intrinsic variations [21]. Intrinsic variation can be exacerbated if the experiment does not take place in a suitable environment that allows the subject to walk using his or her habitual gait pattern [22] or if the subject does not feel comfortable with the devices placed on the body. These situations can cause alterations in the movements [10] and can make the subject feel physically different, or uncoordinated [23].
2. **Soft tissue movements:** The movements of the skin, muscles, and other tissues around the bones are an artefact that occurs persistently in surface-marker MoCap systems [19]. The soft tissue effect is particularly notable on the thighs since the femur is covered by a considerable amount of tissue [24,25]. To avoid these effects, the optical systems based on individual markers often place the markers on bony structures, or "landmarks" [24]. However, it should be assumed that surface-marker MoCap systems do not represent the real movement of the bones [26].
3. **Relative movements between the device and the skin:** These relative movements are related to the adjustment of the fastenings that hold the devices on the body [25,27,28].
4. **Positioning:** It is difficult to position the devices in the same manner each time. The data obtained from acceleration and angular velocity differ from one location to another for the same body segment [27,29,30]. Differences in acceleration and angular velocity can be minimised by calibrating before the measurements are taken (see factor 7).
5. **Instrument accuracy:** The optical system's accuracy is in the order of 1% [31] or 1 mm [19] for the measurement. IMUs use a sensor fusion algorithm to provide rotations from the signal of the built-in sensors [18,32]. IMUs are highly sensitive to disturbances in the Earth's magnetic field, which disorients magnetometers, especially in indoor environments. In addition, a drift artefact is caused by cumulative gyro integration errors [33]. Thus, these types of sensors have accuracy ranges of 0.2°–1° (roll/pitch), 0.4°–2° (yaw) and a dynamic root mean square (RMS) of 1°–2° RMS, depending on the manufacturer [12].
6. **Gait event detection:** Gait events are relevant moments throughout the gait cycle, such as the initial or the final contact of each stride, which allow for the normalisation, superimposition, and analysis of the strides captured [15]. Events can be estimated using additional instrumentation (e.g., pressure platforms or instrumented templates), or using the movement data itself. In either case, there may be inaccuracies of a few milliseconds in the detection. In IMU-based systems,

these errors in parameters such as the step length may be cumulative and translated as a few centimetres [34–36].

7. **Anatomical calibration:** When the devices are placed on the body, their coordinate systems always differ according to the anatomical segment on which they are fixed [18,37]. The anatomical calibration, also called sensor-to-segment alignment [38,39], is used to calculate the relative rotation between the device and the bone, which is assumed to be time-invariant once the sensor is mounted on the body [18,40]. The calibration allows for the calculation of the joints' angles and the establishment of the participant's neutral position, which corresponds to the zero rotation of all the body segments. Two main approaches [18,37] are used to accomplish the calibration: (1) Anatomical approaches, in which the user is asked to stay still in one or more body positions while the sensors are oriented to those expected in the static pose [41,42], and (2) functional approaches, in which the subject is asked to perform mono-dimensional or arbitrary motions to estimate the anatomical axes [39,43–45]. As it is not possible to adopt precisely the same position or to execute exactly the same movements in each measurement session, there is always intrinsic variation [21]. Similarly, anthropometric measurements of the participant are usually introduced during the anatomical calibration, which adds errors to those mentioned previously [40,41,44].

Given the errors and measurement inaccuracies exposed, it can be deduced that factors 1 and 2 are circumstantial and inherent in human biomechanics. However, factors 3–6 are related directly to the design of the product, the design of the experiment, or the design of the data processing. Factor 7—anatomical calibration—is a combination of both perspectives in that must be designed, but, at the same time, is related to intrinsic variation (factor 1). Therefore, it is relevant and necessary to make design proposals to improve factors 3 to 7, since such improvements will encourage the application of these technologies in daily clinical practice.

As a result of this reflection, we focused on two issues that have previously attracted interest in the literature; one is the development of IMU MoCap systems that are not affected or are less affected by alterations in the magnetic field, while the other is the development of MoCap systems (both optical and IMU) that detect gait events automatically using kinematic data without the need for additional instrumentation.

With regard to issue of the magnetic field, many studies have shown that it is possible to omit the magnetometer information [32,43,46–48]; however, there are two main drawbacks to the omission of magnetometers. The first is that there is no common horizontal reference (heading). The exposed anatomical calibration plays a key role in overcoming this problem, because this process deduces the heading direction [18,37]. In addition, recent research has revealed that the exploitation of kinematic constraints (such as boundary conditions in the degrees of freedom or the range of motion of the joints) can improve the heading calculation [45,46,49–52]. The second drawback is that, when the magnetometer information is omitted, the cumulative gyro integration errors are not corrected, which results in drift errors that increase with the capture time [33,53]. The most straightforward approach for resolving the drift errors is to limit the capture time, which is appropriate when only a short period is required to execute the movements being investigated [38]. For long-term captures, one approach is to use the aforementioned kinematic constraints, since they limit the drift artefact [45,46,49–52]; another possible method is to use zero-velocity updates [54] or dead reckoning [55] algorithms, which reset integration and acceleration errors when detecting zero-velocity periods during the gait.

With regard to detecting the gait events, numerous studies have proposed algorithms to detect gait events using kinematic data, both in IMU and in optic systems [34–36,56–60]. Algorithms usually search for events in the motion curves, such as the orientation, displacement, linear/angular velocity, or acceleration curves. Many computational methods have been used to search for these events, ranging from peak searching algorithms (e.g., [58]) to hidden Markov models (e.g., [61]).

Although there have been substantial contributions and achievements along these lines, it is necessary to discuss and propose complete solutions that overcome magnetic field alterations and

detect gait events automatically [37]. The combination of these characteristics could enhance IMU and optical technologies in daily clinical practice.

When proposals are made along these lines—or along any others related to the errors collected—indicators and metrics are required to assess the quality and validity. In this regard, although each proposal may have individual indicators and metrics, reproducibility is the most general and important indicator that a MoCap gait analysis system should consider [19,28]. Satisfactory reproducibility results show that, under the same conditions, the system produces similar data every time it is used, and indicate that the system has sufficient precision to compare results, both within a subject over time and within groups of subjects, which is highly relevant for monitoring the progress of rehabilitation [62].

Moreover, reproducibility is an index that has value in itself. Reproducibility values can be used as a threshold in a capture comparison, allowing researchers to identify whether the change between two sessions is due simply to measurement errors and is thus not attributable to real changes in the subject [63]. In this regard, the minimal detectable change (MDC) index has been identified as one of the most relevant reproducibility indexes to judge the likelihood of real improvement (or impairment) in a subject [64–68].

In this study, we present a MoCap gait analysis system called Move Human Sensors (MH). This system can be configured using IMU technology (MH-IMU henceforth), or using optical technology (MH-OPT henceforth). The MH system includes two proposals: (1) an anatomical calibration procedure that allows for the deactivation of the IMUs' magnetometers to avoid the magnetic influence, and (2) an algorithm that detects gait events from kinematic data without additional instrumentation.

We determined the reproducibility of both configurations via a test–retest reliability experiment with thirty-three healthy subjects. The study allowed us to evaluate the proposals of the MH system, to establish the usage considerations, and to compare the reproducibility of both configurations to each other and to similar studies. The concept of "gait analysis in a box", which was inspired by Najafi et al. [69], appears in the title of the article to highlight the potential of these technologies, particularly IMU, to enhance the application of gait analysis in daily clinical practice.

2. Materials and Methods

In this study, we introduce the MH MoCap gait analysis system, which has two configurations, namely MH-IMU and MH-OPT. This section describes the MH system (Section 2.1), as well as the design of the experiment that we conducted to evaluate reproducibility (Section 2.2).

2.1. The Move Human Sensors (MH) System

The MH-IMU configuration uses up to 15 inertial sensors, specifically the NGIMU devices from x-io Technologies [70], which are calibrated by the manufacturer, and filters and processes the signal internally to transmit the rotations: in our case, quaternions.

The MH-OPT configuration uses up to 15 ad-hoc-designed rigid bodies (RBs), and a set of 12 cameras to capture the position and orientation of the RBs (OptiTrack Flex 13 cameras using Motive software [71]). Each RB is a cluster of three reflective markers (diameter 14 mm) placed on a rigid 3D-printed surface [6–8]. The markers for each RB have a unique spatial relationship (i.e., a unique marker distribution and a unique marker-to-marker distance) because this allows the software to differentiate one RB from another.

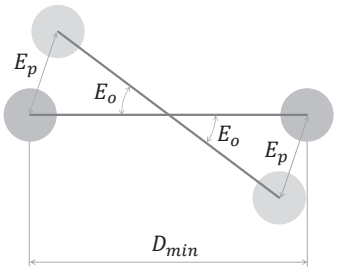
In the following sections, the MH system is presented in its full-body configuration (15 IMUs or RBs), although the system can be configured with fewer devices. In fact, in our reproducibility study, we configured the system with fewer devices because only the information from eight devices (IMUs or RBs) were needed (the feet, calves, thighs, pelvis, and chest) to analyse gait.

With regard to the accuracy of both configurations, according to the manufacturer's webpage, the NGIMU has an orientation accuracy of <1° RMS (pitch/roll) and <2° RMS (heading) [70]. The maximum orientation error (E_o) of each RB is shown in Table 1. This error was calculated using the minimum

marker-to-marker distance (D_{min}) and the mean positioning error $\left(E_p = 0.34 \text{ mm}\right)$ of each marker provided by the Motive [71] software when the 12 cameras were calibrated.

Table 1. Marker-to-marker distance (D) and maximum orientation error (E_o) of each rigid body (RB). Positioning error in our camera configuration ($E_p = 0.34$ mm).

Body Part	Side	D_{1-2}[mm]	D_{1-3}[mm]	D_{2-3}[mm]	E_o[°]
Head	-	132.2	116.0	151.4	0.34
Arm	R	99.0	92.1	134.0	0.42
Arm	L	113.7	91.6	117.1	0.43
Forearm	R	104.4	81.3	95.6	0.48
Forearm	L	116.3	75.3	85.7	0.52
Hand	R	128.2	69.4	146.3	0.56
Hand	L	70.3	120.3	135.6	0.55
Chest	-	140.1	108.7	169.9	0.36
Pelvic	-	180.6	105.3	163.0	0.37
Thigh	R	126.2	114.8	99.6	0.39
Thigh	L	95.4	105.2	122.3	0.41
Calf	R	95.5	109.7	75.7	0.51
Calf	L	126.3	70.1	82.4	0.56
Foot	R	63.9	107.0	83.1	0.61
Foot	L	114.0	64.1	94.1	0.61
Mean (SD)	-	-	-	-	0.47 (0.09)



R: right-hand side; L: left-hand side.

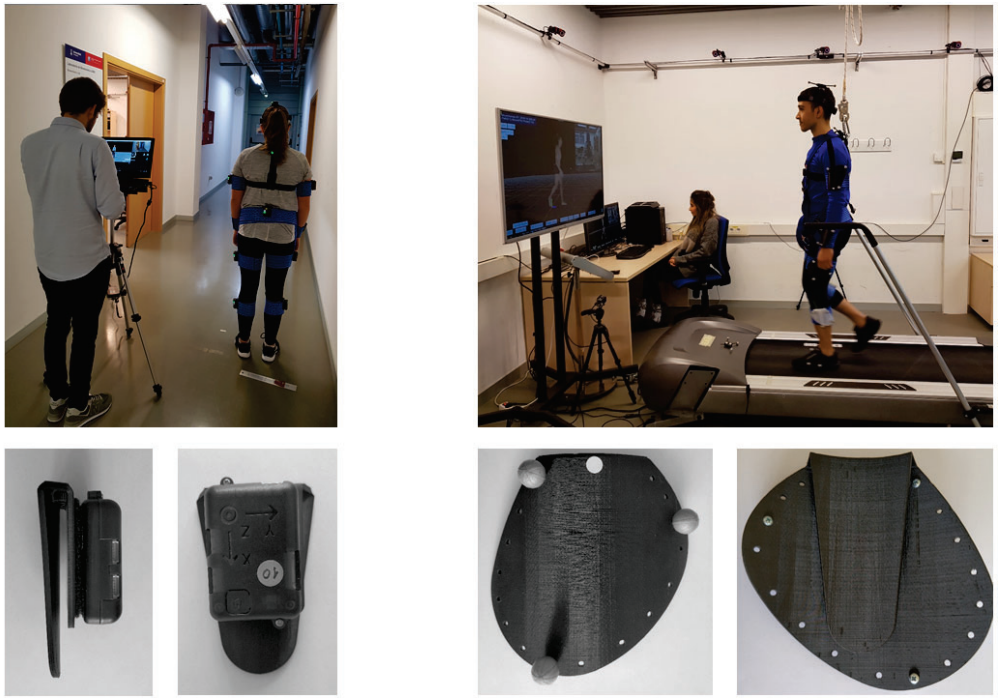
IMUs or RBs are placed on the body with elastic bands. We developed U-shaped, 3D-printed bases, one to place on one side of the U below the band, and the other to hold the IMU or the RB (Figure 1). Each base was designed individually to fit each body segment (adult's anthropometry), and has small ribs on the inside of the U to guarantee rigidity and stability. The U-shape was chosen to facilitate the placement and decrease the preparation time. In this manner, the elastic bands are adjusted on the participant first to then position the bases with the IMUs or RBs; therefore, before completing a capture with one participant, the next participant may already have had another set of elastic bands put in place.

Figure 1 shows the MH-IMU configuration in which the subject walks on the floor and the MH-OPT configuration in which the subject walks on a treadmill (EXE T800 modified with the control panel placed independently). The MH system does not specify the use of the floor or a treadmill; however, we chose this disposition for either enhancing a specific advantage or for reducing a particular limitation of each configuration. The use of the floor in the MH-IMU configuration ensures its portability and makes measuring a realistic pattern possible. The treadmill in the MH-OPT configuration decreases the capture area and thus the number of cameras required; in addition, it allows for capturing numerous strides in standardised conditions (constant gait speed) without the subject needing to turn around [72–74].

It can be assured that the gait pattern will not be identical on the floor and on the treadmill. Although other studies have shown that the differences between both situations are small [74], we assumed that the gait pattern on the floor is one phenomenon and that the gait pattern on the treadmill is another. Therefore, in this study, we compared them solely in terms of reproducibility because this indicator is independent of the phenomenon being measured.

If required, the MH system can be configured to record live video with up to two Logitech C920 webcam cameras synchronised with the MoCap. Two cameras are used in the MH-OPT configuration,

one in front of the subject in the direction in which he/she is walking, and the other at the side of the treadmill; the MH-IMU configuration uses one camera placed on the tripod that holds the computer.



(**a**) (**b**)

Figure 1. (**a**) Move Human Sensors (MH) system configured with inertial measurement units (IMUs) (MH-IMU); (**b**) MH system configured with optical technology (MH-OPT).

With regard to communications, in the MH-IMU configuration, the devices are connected to the computer via Wi-Fi using the open sound control (OSC) communication protocol, and send the quaternions at a frequency of 60 Hz, which is sufficient to capture human movement at walking speed [75]. A portable router (Netgear Nighthawk M1) establishes the Wi-Fi network to which the computer and IMUs are connected at 5 GHz. In the MH-OPT configuration, the MH software is connected in real time via a virtual-reality peripheral network (VRPN) protocol to the Motive software [71], which transmits the transformation matrix of each RB at a frequency of 120 Hz.

The MH software, which integrates the mentioned features, was implemented using WorldViz-Vizard 6.2 (Python 2.7). As detailed in the following sections, the software captures the motion, transmits it to a human model in real time, and processes the information to detect the gait cycle and to generate variables.

2.1.1. Human Model

The MH system uses the real-time motion information provided by the IMUs or RBs to animate a human model or avatar adjusted to the anthropometric dimensions of the participant. The human model was created using the 'Genesis 2' model of DAZ Studio 4.10 software [76]. In order to achieve a smooth real-time visual representation, the avatar mesh was reduced from 40,000 polygons in the original model to 7000 in our version. The resulting human model is a 20-bone skeleton, of which 15 bones are associated with the IMUs or RBs placed on the body. Figure 2 shows the human model in a neutral position and the local coordinate system for each bone. These coordinate systems are situated on the centres of the joints at the beginning of each bone (e.g., the centre of the femur bone is situated on the centre of the hip joint), except for the pelvic bone, where the centre is located at the geometric

centre of the pelvis. The coordinate systems of the bones follow the right-hand rule for interpreting the directions of the bone rotation as positive or negative.

In order to adjust the length of the segments of the human model to the participant's dimensions and to locate the centres of the joints, as shown in Figure 2, the rater needs to take specific anthropometric measurements. In the MH-IMU configuration, the rater must measure the height of the subject from which the human model is scaled, the distance between the elbows, from which the shoulder width is calculated and adjusted by projecting the angle of the arms in the frontal plane, and the distance between the iliac crests, from which the width of the hips is determined and adjusted (see Bell et al. [77]). In the MH-OPT configuration, the RB located on the head measures the height of the subject automatically; in addition, using an instrumented pointer synchronised with the MH software, the rater must measure the anatomical points (landmarks) of the acromions, greater trochanters, external malleolus, and iliac crests [78,79].

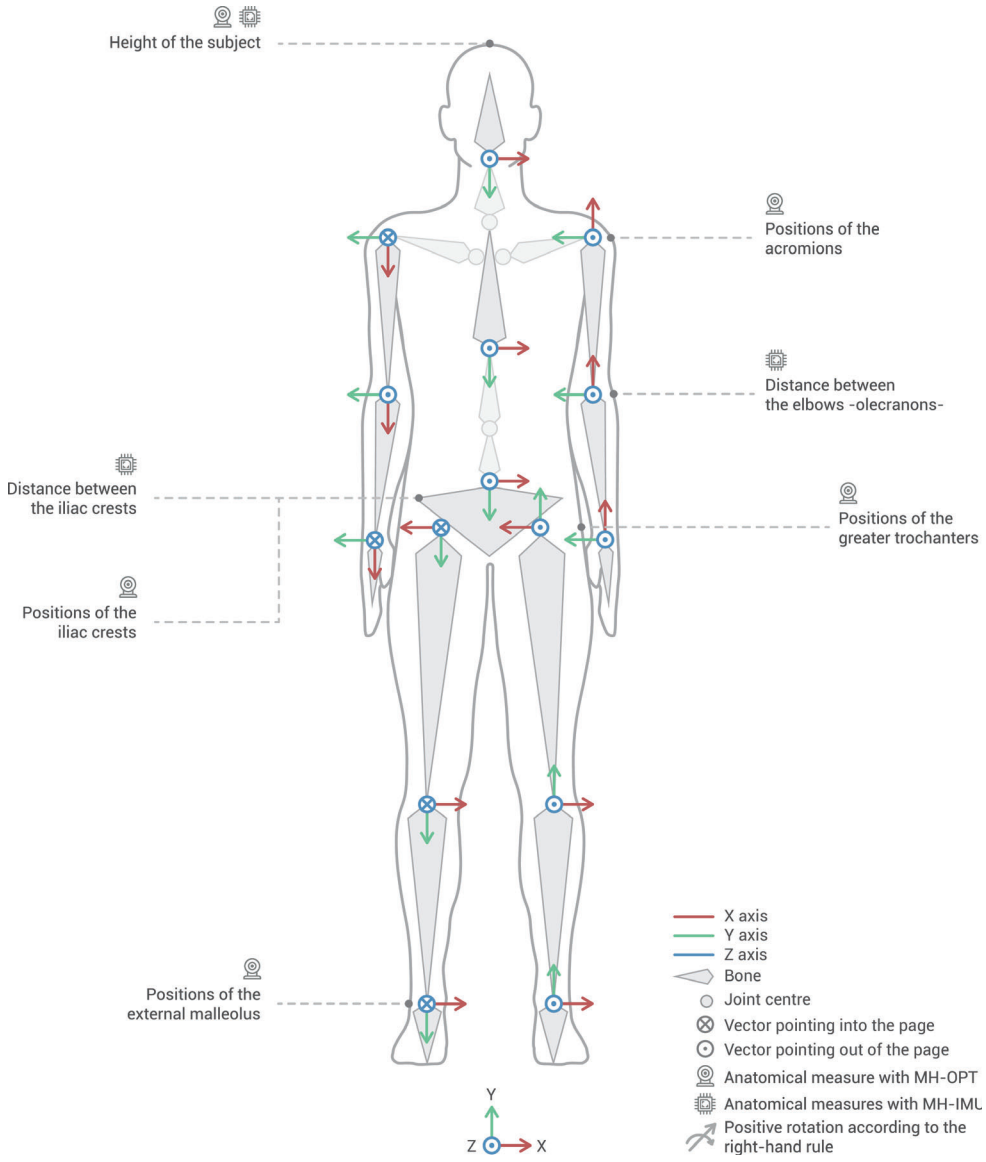


Figure 2. Human model in a neutral position, the local coordinate system for each bone, and the anatomical measurements needed. The positive rotation directions are interpreted according to the right-hand rule. Source: figure by the authors, icons (chip and camera) by Darius Dan and Vitaly Gorvachev from Flaticon [80].

2.1.2. Fitbody Calibration Process

Before conducting the gait capture, it is necessary to perform an ad-hoc calibration process, which we call Fitbody. This procedure includes a correction for magnetic north [81] (applied to MH-IMU) and an anatomical calibration [40,41,44] (applied to both MH-IMU and MH-OPT). As a result, this process establishes the participant's neutral position and saves it for future reference. This position corresponds to the zero rotation of all the body segments, based on which each rotation will be positive or negative according to the established sign convention (Figure 2). Conceptually, the anatomical calibration is similar to the taring process of a scale in which we subtract the weight of a container, except that, in this case, we subtract the angles that the devices register on the surface of the musculature when the participant is in the neutral position. This process links IMUs or RBs to the human model's bones virtually; in other words, it links the coordinate systems of the bones of the human model (Figure 2) to the coordinate system of each IMU or RB (Figure 3).

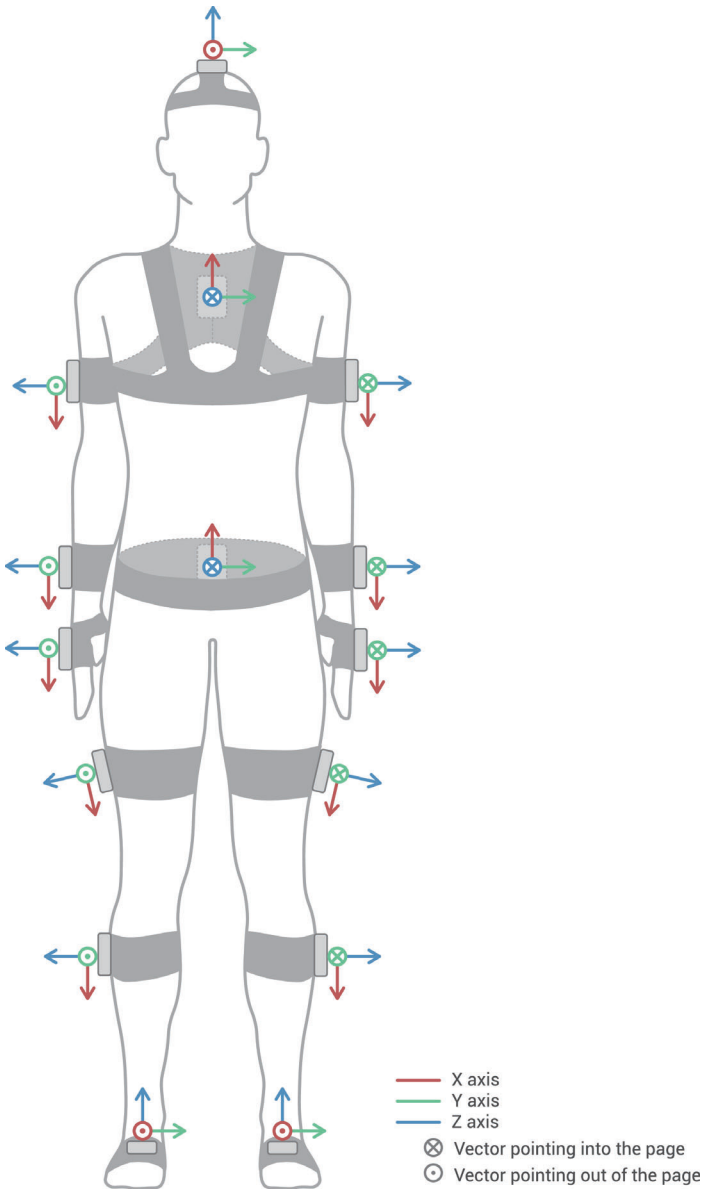
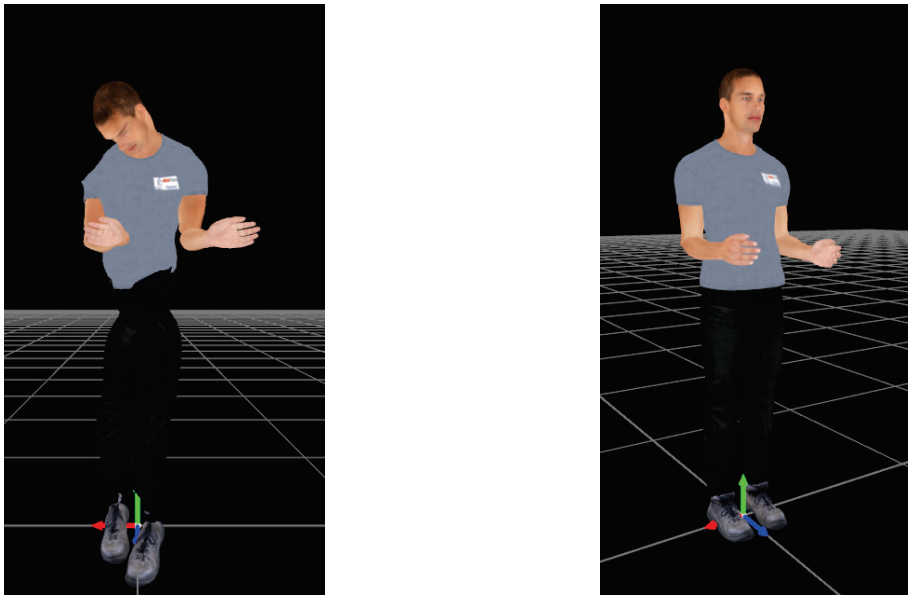


Figure 3. Placement of the devices on the body and the coordinate system for the devices. The IMUs and RBs are placed in the same positions because the surfaces that rest on the body are similar in size and shape.

The Fitbody is required in both the MH-IMU and MH-OPT configurations. However, in the MH-IMU configuration, the magnetometers can be disabled as the Fitbody process infers the heading of the IMUs, thus avoiding the adverse effects that disturbances in the magnetic field may cause. In addition, as Lebleu et al. [38] explained, only a short time is required to capture the gait, and it is possible to repeat the Fitbody process before each capture, which is a sufficient procedure to overcome drift errors [33,53]. Figure 4 shows the Fitbody's effect on the human model.



(**a**) (**b**)

Figure 4. Human model (**a**) before and (**b**) after the Fitbody process in the MH-IMU configuration with the magnetometers disabled.

At the operational level, the calibration process requires the participant to adopt a specific static body position (Figure 5); at the same time, the rater needs to execute the Fitbody function implemented in the MH software. As mentioned, there are also "functional calibration" approaches in which the participants have to move the segments to determine the sensor-to-segment orientation. Although these functional procedures could be more precise than when remaining in a static pose [82], they are too demanding, particularly when several segments are considered, or when the system is intended to be used in pathological populations that may have substantial motion limitations [37].

The Fitbody calculation process is based on the scheme in Figure 6, in which we call the moment at which the rater launches the process instant 0. In the MH-IMU configuration, the quaternions read from the sensors are transformed into 3×3 rotation matrices (see "transformations"; Python library [83]); these matrices rotate the bones around the joints. In the MH-OPT configuration, the movements characterised by 4×4 transformation matrices read directly from the Motive software [71], including the rotations and displacements of the RBs. Therefore, RBs rotate the bones and displace them according to their centres of instantaneous rotation. Nevertheless, the term "rotation matrix" will be used in the explanation for both cases.

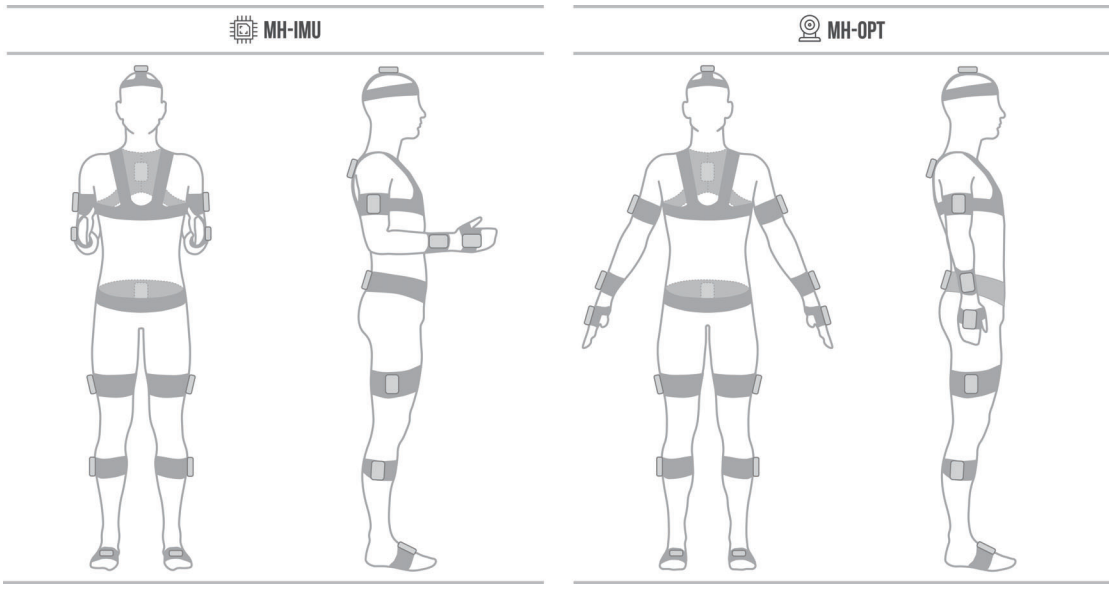


Figure 5. Fitbody position in the MH-IMU and MH-OPT configurations.

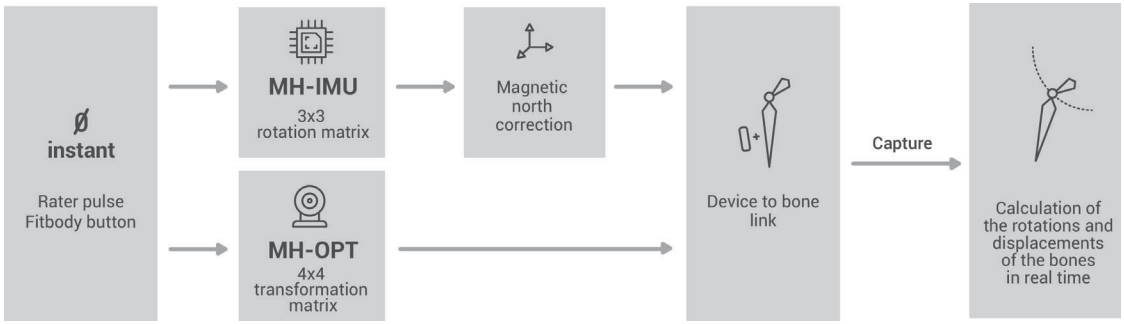


Figure 6. Fitbody calculation process.

The first step in the MH-IMU configuration is to correct the magnetic north (heading) of each sensor. At instant 0, each IMU sensor has its own global coordinate system, which is called Gs (see Figure 7). In Gs, the *Z*-axis is perpendicular to the ground and coincides in all sensors, since the data are taken from the gravity measurement. The *X*-axis is at a right angle to the *Z*-axis (i.e., parallel to the ground). It corresponds to magnetic north when the magnetometer is activated, and to a random direction when the magnetometer is disabled. The *X*-axis is different in each sensor; there are significant differences in the absence of magnetometers and a few differences when magnetometers are present since, even when sensors are placed on the body (i.e., all the sensors are within <2 m), the measure of magnetic north is different in each location [81]. Finally, the Y-axis is at right angles to the X- and Z-axes in accordance with the right-hand rule.

Either with or without magnetometers, due to the *X*-axis disposition, it is necessary to establish a global coordinate system that is shared by all the IMUs, which is called G. The MH application establishes the Gs of the sensor located on the pelvis as G because it is the first element in the kinematic chain; in other words, MH copies the magnetic north of the sensor located on the pelvis to all the sensors.

The magnetic north correction is based on the assumption that, at instant 0, one of the axes of each sensor is placed on the body in a particular manner. This assumption is detailed in Table 2. The criterion for choosing the axis of each sensor is to identify the axes that is most parallel to the ground considering the natural inclination of the sensor when placed on the body. Note that the orientation of the sensors in other axes or their height on the body segment do not influence the process

(e.g., the fact that the chest sensor has an inclination around the *Y*-axis due to the inclination of the area in which it is placed, vertebra D2–D3, has no effect).

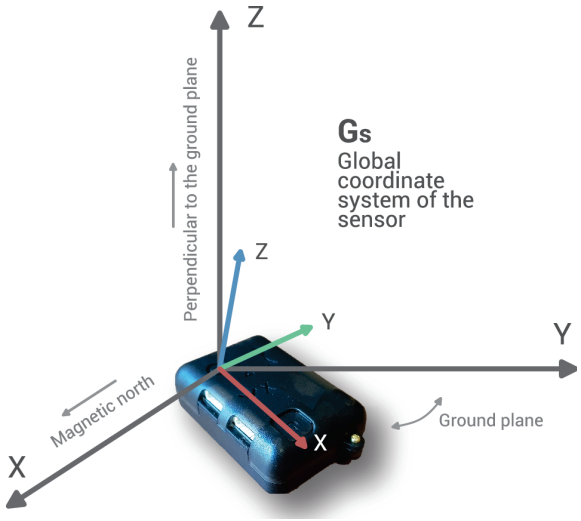


Figure 7. The global coordinate system of an IMU (Gs).

Table 2. Assumptions made for each body part to correct the magnetic north in the MH-IMU configuration.

IMU Sensor	Axis Projected on the Ground	Angle with the *Y*-Axis of the Pelvis Projected on the Ground [°]
Head	X	90
Arm	Y	90
Forearm	X	90
Hand	X	90
Chest	Y	0
Thigh	Y	90
Calf	Y	90
Foot	Y	0

The axes mentioned are those represented in Figure 3, considering that the participants had adopted the Fitbody position for the MH-IMU configuration represented in Figure 5.

Given this assumption, the next step is to calculate the relative angle (α) on the ground plane between the axes mentioned in Table 2. For example, if we consider the thigh sensor that is placed on the outer face of the thigh, the *Y*-axis projected onto the floor should be at 90° to the *Y*-axis projected from the pelvic sensor, which is placed on the sacrum. Thus, if the relative rotation were 83°, the angle to be corrected would be $\alpha = 7°$. This α angle is transformed into the ${}^{G}R^{0}_{Gs}$ rotation matrix via Equation (1). According to the notation used in this study, ${}^{G}R^{0}_{Gs}$ is read as the rotation of Gs with regard to G at instant 0.

$$ {}^{G}R^{0}_{Gs} = \begin{pmatrix} \cos(\alpha) & 0 & sin(\alpha) \\ 0 & 1 & 0 \\ -\sin(\alpha) & 0 & cos(\alpha) \end{pmatrix} \quad (1) $$

Subsequently, this matrix is multiplied by ${}^{Gs}R^{0}_{s}$, the rotation read from the sensor (to be corrected) at instant 0 (Equation (2)), resulting in ${}^{G}R^{0}_{s}$, the rotation of the sensor with respect to G at instant 0.

$$ {}^{G}R^{0}_{s} = {}^{G}R^{0}_{Gs} \cdot {}^{Gs}R^{0}_{s} \quad (2) $$

Note that the magnetic north correction does not need to be applied in the MH-OPT configuration because the global coordinate system of each RB coincides with the global coordinate system of the world (G) and the rotation ${}^{G}R_{s}^{0}$ of each RB is known.

The next step in the Fitbody process is performed in both the MH-IMU and MH-OPT configurations, and consists of linking the coordinate system of each bone in the human model (Figure 2) to the coordinate system of each device (IMU or RB) placed on the body (Figure 3). Equation (3) must be applied to link these parts:

$$ {}^{b}R_{s}^{0} = \left[{}^{G}R_{b}^{0}\right]^{T} \cdot {}^{G}R_{s}^{0}, \tag{3} $$

where ${}^{b}R_{s}^{0}$ is the sensor rotation with respect to the bone at instant 0; ${}^{G}R_{b}^{0}$ is the bone rotation in the Fitbody position, which is a known orientation; and ${}^{G}R_{s}^{0}$ is either obtained from Equation (2) (MH-IMU) or is read directly from RB (MH-OPT). It should be noted that ${}^{b}R_{s}^{0}$ is considered constant throughout the capture, since it is assumed that the sensor does not move from the segment to which it is attached, a hypothesis that, as explained in the discussion, is necessary to ensure sufficient attachments to the body.

After these steps, it is possible to calculate, in both configurations, the absolute or relative bone rotations during the rest of instant i of the capture. The rotation of each bone with respect to G (namely absolute rotation) can be identified using Equation (4).

$$ {}^{G}R_{b}^{i} = {}^{G}R_{s}^{i} \cdot \left[{}^{b}R_{s}^{0}\right]^{T} \tag{4} $$

Similarly, Equation (5) enables the identification of the relative rotation of the joints; that is, the rotation of each bone relative to its parent bone (p). In our case, the hierarchy of the bones of the kinematic chain begins in the pelvis, which is the main bone; the pelvis is the parent of the thorax and thighs, the thighs are the parents of the calves, the calves are the parents of the feet, and so on.

$$ {}^{p}R_{b}^{i} = \left[{}^{G}R_{p}^{i}\right]^{T} \cdot {}^{G}R_{b}^{i} \tag{5} $$

To identify the rotations in each plane, the rotation/transformation matrix of each bone is transformed into Euler angles, with the order of X-, Z-, and Y-axis of the human model (Figure 2). To accomplish this, we use the transformations Python library [83] with the "rxzy" order, where r means "rotating frame". Thus, in the femur bone, the X-axis rotation represents the flexion–extension, the Z-axis rotation the abduction–adduction, and the Y-axis rotation the internal–external rotation.

In the MM-OPT configuration, each bone's ${}^{G}R_{b}^{i}$ transformation matrix includes the displacement of the bone's centre with respect to G (i.e., the centre of the bone moves according to the movement of the RB to which it is linked). In the MH-IMU configuration, the displacement of each bone's centre is calculated by direct kinematics [84] by using the joint rotations (i.e., ${}^{p}R_{b}^{i}$) and the length of each bone [84,85]. As mentioned, and as can be seen in Figure 2, each bone's centre is located at the beginning of the bone, just on the joint with the previous bone of the kinematic chain. Thus, the displacements of the bones' centres coincide with the displacements of the joints' centres.

2.1.3. Gait Event Detection Algorithm

Once the gait capture has been completed, the walking pattern is analysed throughout the gait cycle, which is characterised by several key moments called gait events. These events delimit the start and end of each stride, identify the gait phases, and allow for the overlap and normalisation of movement curves from 0% to 100% [15,34–36]. The MH system identifies six gait events (T1–T6; see Figure 8). At this point, we differentiate between two important terms related to the gait cycle: the step length (of a specific leg), which is the distance between the centres of both ankle joints in the sagittal plane at T1, and stride length (of a specific leg), which is the distance between the position of the centre of the ankle joint at T1 and its position at T6 in the sagittal plane (in other words, the entire path of the centre of the ankle joint during the gait cycle).

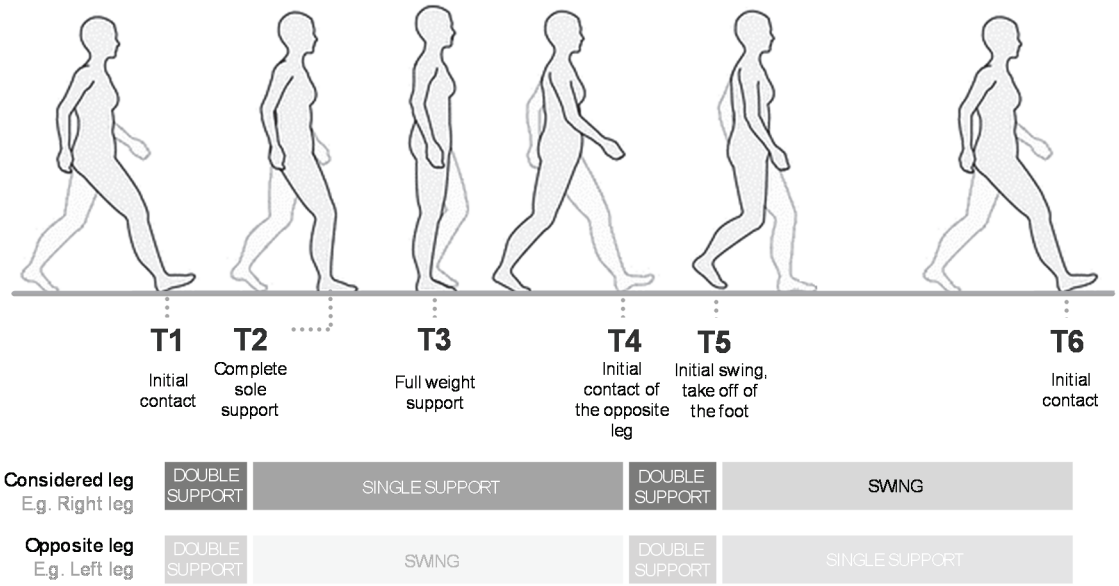


Figure 8. The gait events considered.

The MH system uses specific movement curves and rules to detect gait events. Figure 9 shows the curves and rules established for each configuration. The algorithm was initially developed based on the researchers' experience, and was then tested and improved iteratively using different gait captures from previous, unpublished experiments. These gait captures were of diverse participants, ranging from healthy subjects to individuals with valgus foot, osteoarthritis of the hip, ankle injuries, knee injuries, and non-severe spasticity. This iterative process was possible because the MH system allows for the visualisation of the human model's movements and live video images from the synchronised cameras, and because the software can be configured to illuminate a sphere each time an event is detected.

The detection of gait events in the MH-IMU configuration is based on the hip flexion–extension curve and the same curve in the opposite leg. In the MH-OPT configuration, the detection is based on the curve of the absolute displacement of the centre of the ankle joint on the *Z*-axis, and the same curve in the opposite foot. In order to detect events in the MH-IMU configuration, the rater must select the sections to analyse; that is, the sections in which the patient walks in a straight line, excluding turns, starts, and stops. This operation is not required in the MH-OPT configuration because the gait capture is continuous, and does not entail stops or changes in direction.

As seen in Figure 9, the rules for detecting gait events are based on search maximums and minimums of the mentioned curves. To avoid detecting false maximums or minimums, we used a process to smooth these curves, specifically a "sliding window" method based on the convolution function in NumPy (see "smoothing of a 1D signal" in the SciPy library [86]), with a window size of 0.2 s.

To justify the use of the hip flexion–extension in the MH-IMU configuration, it should be noted that the rotation matrices of the IMUs rotate the bones in relation to the joints, and their displacements depend on the lengths and angles in the kinematic chain. If it were to use the displacement of the ankles' centres on the *Z*-axis (as in the MH-OPT configuration), this measurement would be obtained from the sum of the angles in the kinematic chain, and would involve the accumulation of errors from different sensors and different anthropometric measurements. Therefore, it is more reasonable to estimate the gait events using the hip flexion–extension curves, which are only influenced by the pelvic and the thigh sensor errors, and not by the entire kinematic chain. Conversely, in the MH-OPT configuration, the use of the displacement of the ankle joints' centres on the *Z*-axis is justified because each bone moves and rotates driven by the RBs transformation matrices; therefore, each RB has independent precision. This independence makes the use of the ankles' centres to estimate gait events, whereby the entire path of the feet can be appreciated, a reasonable choice.

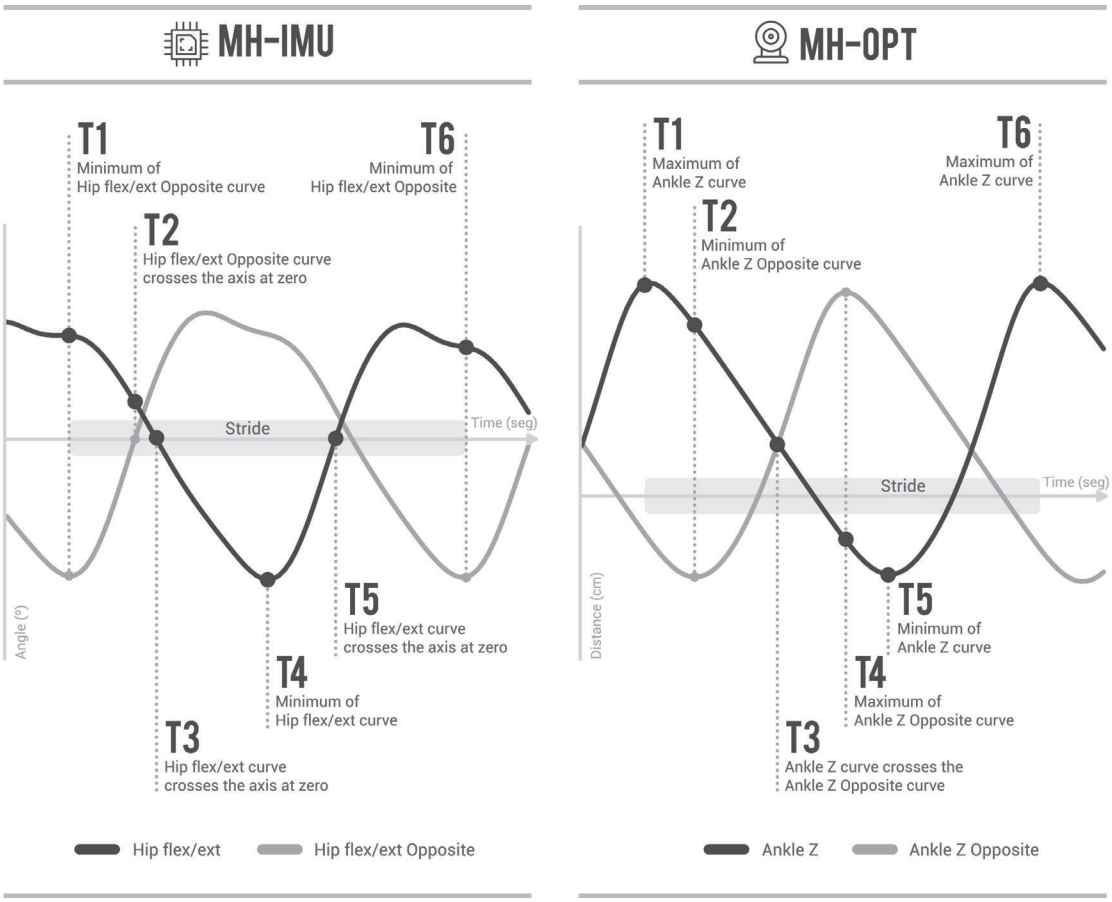


Figure 9. Logical rules for the detection of gait events in MH-IMU and MH-OPT configurations. To detect gait events, the MH-IMU uses the hip flexo-extension curve of both legs, and the MH-OPT uses the displacement of the centres of the ankle joints on the *Z*-axis.

2.2. Test–Retest Study Design

The reproducibility of the MH-IMU and MH-OPT configurations was studied via a test–retest reliability study with thirty-three healthy subjects (20 men and 13 women; 21.7 ± 2.9 years of age; height 173.1 ± 9.1 cm; weight 66.9 ± 11.0 kg). All participants met the inclusion criteria of being over eighteen years of age, being able to walk unaided, not having injuries or having undergone recent surgeries that limited the mobility of the lower limbs, not having received recent pharmacological treatments, and not having had regular incidents of vertigo or dizziness. The study was approved by the Bioethics Committee of Aragón, Spain (N° 12/2018), and informed consent was obtained from all the participants.

The test–retest reliability study consisted of repeating the gait test under the same conditions following the process in Figure 10. The devices placed on the body were removed between the tests, the rater did not change, and the MH-IMU or MH-OPT tests started randomly. Three hours elapsed between the test and the retest; during this time, we ensured that the participants did not perform any activity that could influence the retest (e.g., physical exercise, eating a big meal, and so forth); they remained in the laboratory participating in other nonphysical tests and/or sat in an adjoining study room. The three-hour period was chosen because these reproducibility results can be particularly useful for assessing changes in the interventions applied during the same session or on the same day.

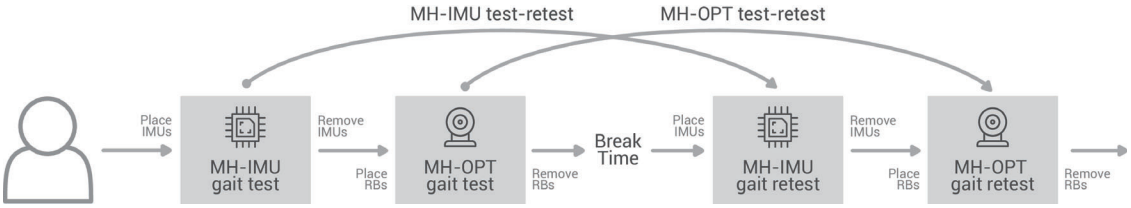


Figure 10. Sequence followed by the participants in the test–retest reliability experiment (begun randomly with MH-IMU or MH-OPT).

In the MH-IMU configuration, the participant walked naturally in a straight line at a self-selected speed for six metres, then turned around and walked back multiple times. To become familiar with the instrumentation, the subjects walked along the path for five minutes; they then stopped to conduct the Fitbody process. This stop was necessary due to the aforementioned limited duration of the Fitbody process without magnetometers. Subsequently, the participants continued to walk until they had reached 25 strides (i.e., 25 complete gait cycles, or 50 steps). To count the 25 strides, only those performed in a straight line were considered, and turns, starts, and stops were excluded. The rater observed the participants and questioned them to confirm that there were no signs of fatigue.

In the MH-OPT configuration, the participants first conducted the Fitbody; then, they became familiar with the instrumentation by walking on a treadmill for five to ten minutes [72]; finally, we measured the 25 strides. The treadmill speed was stipulated, as described by England and Granata [87], according to the theoretical natural gait speed calculated using the leg length (distance from the centre of the hip to the centre of the ankle) of each subject. England and Granata's [87] formulation is included in the MH software, and the mean of the length of both legs is computed automatically from the anthropometric measurements. The same speed was used in the test and in the retest. The rater asked each participant to confirm that it was a comfortable speed, and that he/she did not experience fatigue; this procedure meant that it was not necessary to modify the theoretical natural gait speed, and any participant reported or showed fatigue in any configuration.

The 25 straight strides measured in each test were chosen according to Kribus-Shmiel et al. [22], who assured that statistical stability and normality were achieved within 23 strides, and that this number of strides was sufficient to represent the mean behaviour in gait analysis.

The data analysis was integrated into the MH software to obtain the spatio-temporal and kinematic variables (Table 3). The kinematic variables were the ranges of movement between two gait events, and their sign of rotation (positive or negative) was interpreted according to the right-hand rule, as shown in Figure 2.

The values of the 25 strides in each test were averaged to consider the variability of the gait [21]. Once the data from the thirty-three subjects had been collected, the MDC index at 95% confidence (MDC95) was calculated using Equation (6) [64–68],

$$\text{MDC95} = 1.96\ \sqrt{2}\,\text{SEM};\ \text{SEM} = \text{SD}_{pooled}\ \sqrt{1-\text{ICC}}\,, \tag{6}$$

where SD is the *pooled* average of the standard deviation in the test and the retest, ICC is the intraclass correlation coefficient, and the SEM is the standard error of the measurement.

The effect size of the MDC95 index was calculated as dimensionless using Equation (7), resulting in MDCes95, which indicates the number of standard deviations the experiment is capable of detecting [88],

$$\text{MDCes95} = \text{MDC95}/SDtst\,, \tag{7}$$

where *SDtst* is the standard deviation of the initial test.

Table 3. Variables considered in the study.

	Name	Description
Spatio-temporal Variables Dimensions that are based on whole-body movement	*Step length [cm]*	Distance between the centres of both ankle joints in the sagittal plane at T1.
	Step width [cm]	Distance between the centres of both ankle joints in the frontal plane at T1.
	Single support [%]	Percentage of mono-pedal support during the stride time. Percentage of T2 to T4 time with respect to the entire stride time.
	Double support [%]	Percentage of bipedal support during the stride time. Percentage of T1 to T2 time and T4 to T5 with respect to the entire stride time.
	Gait speed [cm/s]	Mean of the gait speed during the stride. Stride length divided by stride time.
Kinematic Variables [°] Dimensions that are based on the movement of each body segment	*Range of the trunk tilt. T2 to T5*	Chest rotation around the *Z*-axis with regard to the pelvic bone. Range from T2 to T5.
	Range of the pelvic tilt. T1 to T4	Pelvic bone rotation around the *Z*-axis. Range from T1 to T4.
	Range of the hip flexion/extension. T1 to T4	Hip joint rotation around the *X*-axis. Range from T1 to T4.
	Range of the hip adduction/abduction. T4 to T5	Hip joint rotation around the *Z*-axis. Range from T4 to T5.
	Range of the knee flexion/extension. T4 to T5	Knee joint rotation around the *X*-axis. Range from T4 to T5.
	Range of the ankle dorsi/plantar flexion. T4 to T5	Ankle joint rotation around the *X*-axis. Range from T4 to T5.
	Range of the ankle inversion/eversion. T1 to T3	Ankle joint rotation around the *Z*-axis. Range from T1 to T3.

3. Results

Table 4 shows the results obtained in the test–retest reliability study using MH-IMU and MH-OPT configurations. This table includes the mean differences between the subject's tests (i.e., the mean of the differences between the test and retest of each subject) and the reproducibility, which is represented by ICC, MDC95, and MDCes95 indices. The variables described previously in Table 3 were calculated for the right-hand (R) and for the left-hand (L) sides.

The gait of healthy subjects is usually symmetrical, with minor deviations [89]; in our case, the average difference between the right- and left-hand sides was 1.0 cm for step measures (*step length* and, 0.3% for support percentages (and *double support)*, and 0.5° for kinematic measures. These results were notably less than the MDC95 magnitudes; therefore, the right- and left-hand sides were averaged, and the results are shown in Figure 11.

Table 4. Test–retest reliability results.

		MH-IMU						MH-OPT					
		Test μ (SD)	**Retest μ (SD)**	**Dif. μ (SD)**	**ICC**	**MCD es95**	**MCD 95**	**Test μ (SD)**	**Retest μ (SD)**	**Dif. μ (SD)**	**ICC**	**MCD es95**	**MCD 95**
Step length [cm]	R	58.8 (4.6)	58.7 (4.8)	−0.1 (2.4)	0.93	0.8	3.5	59.5 (4.2)	59.5 (3.9)	0.0 (1.6)	0.96	0.5	2.3
	L	58.0 (5.0)	58.6 (5.0)	0.7 (2.1)	0.95	0.6	3.0	58.2 (4.0)	58.4 (4.3)	0.2 (1.4)	0.97	0.5	2.0
Step width [cm]	R	8.9 (3.5)	8.1 (4.0)	−0.8 (3.5)	0.72	1.6	5.5	12.8 (2.3)	12.6 (2.6)	−0.3 (1.2)	0.94	0.7	1.7
	L	10.1 (4.4)	9.9 (3.6)	−0.1 (4.1)	0.64	1.5	6.6	12.0 (2.1)	11.8 (2.5)	−0.2 (1.1)	0.94	0.8	1.6
Single support [%]	R	35.2 (2.3)	35.6 (2.2)	0.4 (1.1)	0.93	0.7	1.6	39.9 (0.9)	39.8 (0.9)	0.0 (0.5)	0.89	0.9	0.8
	L	36.0 (2.1)	36.4 (2.6)	0.4 (1.3)	0.91	0.9	1.9	39.8 (0.8)	39.7 (0.7)	0.0 (0.3)	0.95	0.6	0.5
Double support [%]	R	29.0 (3.9)	28.2 (4.2)	−0.8 (1.9)	0.94	0.7	2.7	20.4 (1.5)	20.4 (1.5)	0.1 (0.7)	0.95	0.6	1.0
	L	29.0 (4.0)	28.1 (4.4)	−0.8 (2.0)	0.94	0.7	2.8	20.4 (1.5)	20.4 (1.5)	0.0 (0.7)	0.95	0.6	0.9
Gait speed [cm/s]		121.8 (12.4)	123.3 (12.9)	0.1 (0.2)	0.97	0.5	6.5	114.2 (3.7)	114.3 (3.8)	0.0 (0.0)	1.00	0.2	0.7
Range of trunk tilt T2 to T5 [°]	R	10.0 (2.4)	9.8 (2.8)	−0.2 (1.2)	0.94	0.7	1.7	3.3 (2.1)	3.5 (1.9)	0.2 (1.4)	0.87	1.0	2.0
	L	10.0 (2.4)	9.8 (2.7)	−0.2 (1.2)	0.94	0.7	1.7	3.3 (2.1)	3.5 (1.9)	0.2 (1.3)	0.88	0.9	1.9
Range of pelvic tilt T1 to T4 [°]	R	4.8 (2.6)	4.6 (2.3)	−0.2 (1.1)	0.95	0.6	1.5	5.2 (2.1)	5.1 (2.0)	−0.1 (1.0)	0.94	0.7	1.4
	L	4.7 (2.5)	4.5 (2.3)	−0.2 (1.1)	0.95	0.6	1.5	5.2 (2.1)	5.1 (2.0)	−0.1 (1.0)	0.94	0.7	1.4
Range of hip flexion-extension T1 to T4 [°]	R	35.0 (3.5)	35.3 (4)	0.4 (1.9)	0.93	0.8	2.8	32.9 (3.3)	33.2 (3.6)	0.3 (1.6)	0.95	0.7	2.3
	L	35.3 (4.0)	35.6 (3.8)	0.3 (2.5)	0.89	0.9	3.6	33.4 (3.6)	33.1 (3.6)	−0.3 (1.8)	0.93	0.7	2.6
Range of hip adduction-abduction T4 to T5 [°]	R	7.7 (2.3)	7.7 (2.4)	0.0 (1.8)	0.83	1.2	2.7	5.1 (1.0)	5.2 (1.1)	0.2 (0.5)	0.93	0.8	0.8
	L	8.6 (2.4)	8.9 (2.8)	0.3 (1.9)	0.85	1.2	2.8	4.9 (1.0)	4.9 (1.1)	0.0 (0.6)	0.92	0.8	0.8
Range of knee flexion-extension T4 to T5 [°]	R	34.9 (6.2)	34.2 (7.1)	−0.8 (3.0)	0.95	0.7	4.2	22.4 (2.6)	22.9 (2.6)	0.5 (1.2)	0.94	0.7	1.7
	L	37.3 (6.4)	36.2 (6.5)	−1.0 (2.6)	0.96	0.6	3.7	22.0 (2.6)	22.2 (3.1)	0.1 (1.6)	0.91	0.9	2.4
Range of ankle dorsi flexion. T4 to T5 [°]	R	23.2 (4.0)	22.6 (4.0)	−0.6 (2.1)	0.92	0.8	3.1	15.6 (1.6)	15.4 (2.0)	−0.2 (1.6)	0.77	1.5	2.4
	L	22.6 (3.5)	23.2 (3.3)	0.5 (2.1)	0.89	0.9	3.1	14.9 (1.6)	15.1 (1.9)	0.2 (1.2)	0.87	1.1	1.7
Range of ankle inv.-ev. T1 to T3 [°]	R	8.1 (4.2)	9.5 (5.2)	1.4 (3.3)	0.86	1.1	4.8	9.1 (3.7)	9.3 (3.9)	0.2 (1.6)	0.95	0.6	2.3
	L	8.5 (3.9)	9.2 (4.3)	0.7 (3.0)	0.84	1.2	4.5	8.8 (3.8)	8.8 (4.2)	0.0 (1.3)	0.97	0.5	1.8

μ: Average; SD: Standard deviation; Dif.: Mean difference between a subject's tests; ICC: Intraclass correlation coefficient; MDC95: Minimal detectable change at 95%; MDCes95: Effect size of the minimal detectable change at 95%; R: right-hand side; L: left-hand side.

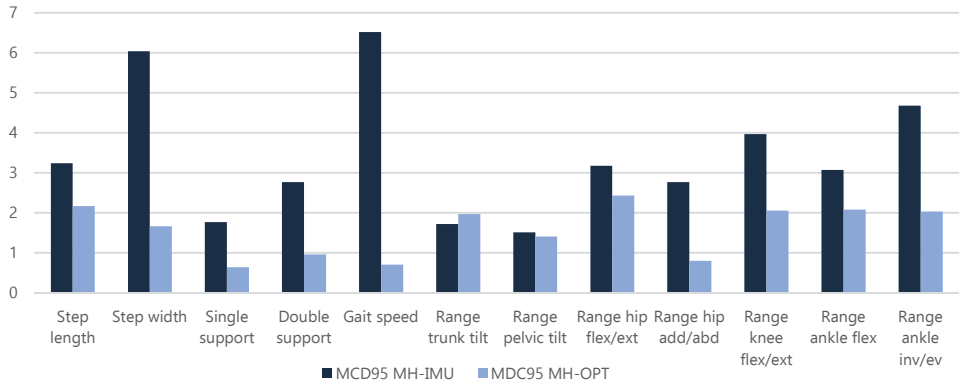


Figure 11. MDC95 results for both configurations averaging the right- and left-hand sides.

4. Discussion

In this study, we presented the MH MoCap gait analysis system, which has two configurations—MH-IMU and MH-OPT. The MH system includes two key proposals, which are (1) an anatomical calibration procedure that permits the deactivation of the IMUs' magnetometers to avoid magnetic influence, and (2) an algorithm that detects gait events from kinematic data without additional instrumentation.

These proposals add value to the field of gait analysis, are applicable to other systems, and overcome specific barriers, such as the need for a magnetically controlled environment, which affects the operation of IMU technology, and the need for additional instrumentation or a laborious data analysis process to detect gait events, which affects the IMU and optic technology operations. This study posits a reduction in the time and resources dedicated to each patient during gait analysis, and promotes the application of both technologies in daily clinical practice.

In this section, we discuss the reproducibility of the results obtained in the experiment (Section 4.1), as well as the considerations and limitations of the MH system, particularly those related to the proposals that the system incorporates (Section 4.2).

4.1. Discussion of the Test–Retest Results

The test–retest reliability experiment verified the general operation of the proposals described. This experiment proved the reproducibility of both configurations. Reproducibility is known as the most general and important indicator that MoCap gait analysis applications should consider [19,28]. The average MDC95 results for the MH-IMU configuration were 4.6 cm for the step measures, 2.3% for the support percentages, 6.5 cm/s for the gait speed, and 3.0° for the kinematic variables. The results for the MH-OPT configuration were 1.9 cm, 0.8%, 0.7 cm/s, and 1.8°, respectively. The results were similar for both configurations, although they were slightly better for the MH-OPT configuration, which could be justified by the greater precision of this technology [6,7]. A greater difference was observed in the gait speed; this was expected because the speed on the treadmill did not change between the test and the retest [72,73].

Furthermore, in the MH-IMU configuration, the average MDCes95 was 0.86, and was 0.74 in the MH-OPT configuration; thus, according to Hopkins et al.'s [90] classification, it can be confirmed that both configurations can detect between "moderate" and "large" changes. In terms of ICC, the MH-IMU had an average of 0.90 and the MH-OPT of 0.93; according to Koo and Li's [91] classification, these results show "excellent" reproducibility. Therefore, we can assert that the reproducibility was satisfactory; thus, the proposals performed adequately at a global level.

With regard to the application of the results, it should be mentioned that the MDC95 is usually defined as the minimal amount of change within a subject that is not due to a random variation or an error in measurement [65]. This definition establishes an interesting framework in which to apply the MH system in daily clinical practice. As described by Marin et al. [20], the gait test could be used as a

medical test based on pre- and post-measurement sessions of the rehabilitation treatments applied. The reports generated would show the changes that occurred in each patient's gait between the pre- and post-sessions. These reports could be used to make decisions about treatment (such as to continue treatment, to change treatments, to increase the intensity of treatment, and so on). In this context, it is necessary to consider the approximate magnitude of the expected changes. For example, if the intention is to evaluate a plantar orthosis for a slightly valgus foot, the changes in the subject's gait pattern are expected to be small; moreover, these changes will be highly concentrated in the foot, possibly with minor effects in the knee and hip; therefore, an accurate MDC95 will be necessary. Conversely, if the aim is to evaluate the impact of a drug designed to treat a severe vertiginous pathology, it is expected that pronounced changes to the entire body will be seen; therefore, a less accurate MDC95 will be sufficient.

In addition, it is relevant to mention that the MDC95 was conducted following a three-hour break between the test and the retest, which can be particularly useful for assessing changes in the interventions employed during the same session. For example, two successive gait analysis tests could be used to select the optimum torque to be exerted by the mechanical knee joint of a transfemoral prosthesis; the first test could be conducted using the pre-established or usual torque configuration, and the second using a configuration that is predicted to be superior. Such an experiment could confirm or reject an orthopaedic technician's hypothesis regarding the optimal torque for a specific patient.

Continuing with the application of the MDC95 results, if changes in groups of subjects need to be evaluated, the revealed MDC95 values should be modified according to Equation (8), in which n is the sample of subjects to be evaluated [68,92].

$$MDC95_{group} = \frac{MDC95}{\sqrt{n}} \tag{8}$$

In addition, it is important to compare the results to those in other studies (see Table 5). The following criteria were used to select similar studies: (1) experiments that involved the subjects walking either on the floor or on a treadmill, (2) healthy subjects, (3) young subjects, and (4) studies that provided the MDC value. It should be noted that it was necessary to average some of the values in our study and in the other studies (see the row of "notes" for Table 5) in order to provide comparable values.

The results of the other studies can be grouped according to different criteria; for example, according to the technology used (optical/IMU), or according to the experimental conditions (floor/treadmill). However, to obtain a general conclusion regarding reproducibility, and due to the limited number of studies, it can be summarised that the average MDCs in other studies were 5 cm for the step measures, 1.7% for the support percentages, 12.7 cm/s for the *gait speed*, and 4.6° for the kinematic variables. Thus, from a general perspective, we can confirm that the reproducibility of both configurations was better than the average found in the literature. Nevertheless, as presented in Table 3, certain values in our study showed worse MDCs than were found in other studies (see asterisks in Table 5); of these values, the only one with a reasonable difference in magnitude was the *step width* in the MH-IMU configuration. We consider that this result is justified because the data for this variable in other studies were derived from optical systems and, as described, these systems achieve more precision than do IMU-based systems in a bone as distal as the foot, where the *step width* is computed.

Nonetheless, we compared the results with caution. We attempted to find the maximum similarity to other studies by using the aforementioned criteria. However, these studies used different anatomical calibration procedures, different parameters and, in particular, different times between the test and the retest, which were longer in the collected studies than in this study. All these differences may explain our superior results.

Table 5. Comparison of the MDC results to those in other studies.

	MDCs in the Literature						MDCs in This Study		
	[93]	[94]	[95]	[96]	[97]		[92]	MH-IMU	MH OPT
Spatio-temporal variables									
Step/Stride length [cm]	8.0	8.0	-	4.0	5.4	11.0	10.0	3.2	2.2
Step width [cm]	3.0	2.0	-	2.0	2.3	-	-	6.0*	1.7
Average of gait phases [%]	1.9	-	-	-	-	1.5	1.7	2.3*	0.8
Gait speed [cm/s]	17.0	12.0	-	9.0	15.0	12.0	7.0	6.5	0.7
Kinematic variables [°]									
Range of trunk tilt	-	2.5	1.1	-	-	-	-	1.7	2.0*
Range of pelvic tilt	1.9	4.4	2.5	-	-	-	-	1.5	1.4
Range of hip flexion/extension	4.4	8.3	2.7	3.0	3.3	-	-	3.2	2.4
Range of hip adduction/abduction	3.0	5.1	2.6	2.0	5.5	-	-	2.8	0.8
Range of knee flexion/extension	4.0	4.5	5.1	3.0	3.5	-	-	4.0	2.1
Range of ankle dorsi/plantar flexion	8.7	4.1	3.5	-	8.5	-	-	3. 1	2.1
Range of ankle inversion eversion	-	9.6	-	-	-	-	-	4.7	2.0
Study details									
Experimental conditions	Floor	Floor	Floor	Treadmill	Treadmill	Floor	Treadmill	Floor	Treadmill
MoCap technology	Full body optical	Full body optical	Full body optical	Full body optical	Lower body optical	Feet placement IMU		Full body IMU	Full body optical
Sample	30 (18F, 12M)	23 (12F, 11M)	29 (15F, 14M)	20 (10F, 10M)	23 (23M)	39 (14F, 25M)		33 (13F, 20M)	
Age	30 ± 6.8	35 ± 7.3	24 ± 5.7	25 ± 4.0	35 ± 5.1	23 ± 6.2		22 ± 2.9	
Rater	Same	Same	Same	Same	Same (except for anatomical measures)	Not found		Same	
Time	1 to 14 days	One week	5.6 ± 2.2 days	One week	5 ± 3.0 days	More than one day		Three hours	
Notes	Gait phases averaged: Foot off, Opposite foot contact, and Opposite foot off. MDC from stride length.	They do not provide ranges of movement. We have averaged the MDC of the peaks. MDC from stride length.	Data from 'intrarater intersession' at 'FR3' speed.	Some ranges are from max. to min. and others from one gait event to another. MDC from step length.	Right and left sides averaged. MDC from step length.	Gait phases averaged: Stance and Swing. Feet IMU placement selected; this was preferred by the authors. MDC from stride length.		Gait phases averaged: Single and double support. Right and left sides averaged. The ranges are from one gait event to another. MDC from step length.	

* Values with worse MDCs than the average in other studies.

To discuss the time between captures, we should return to the factors mentioned in the introduction. It can be stated that 1—intrinsic variation and 7—anatomical calibration factors depended on the time that had elapsed between captures. However, as long as the devices were removed from the subject between the tests, the experiment fully considered the errors derived from factor 2—soft tissue movements, 3—relative movements between the device and the skin, 4—positioning, 5—instrument accuracy, and 6—gait event precision. The time dependency of factors 1 and 7 is related to the limited human ability to remember unconscious body control sensations. Although the instructions given to participants were relatively simple (walk at a natural pace in a straight line, or on the treadmill), when a long time has elapsed, one cannot remember these unconscious body control sensations accurately, such as the exact placement of the body for the Fitbody position (such as how stretched one was,

whether the muscles were relaxed or not, and so on) or, for example, the level of control or strength applied in the impulse of each step. Thus, time has an influence and may have contributed to our superior results, but we could not determine the precise extent of this contribution.

To conclude the discussion of the results, it should be mentioned that we compared the MH-IMU and MH-OPT configurations solely in terms of reproducibility. Nevertheless, the results in Table 4 show that there are variables that exhibit notable differences between walking on a treadmill (MH-OPT) and walking on the floor (MH-IMU) that are even higher than the MDC values (step width, double support, range of trunk tilt, range of knee flexo-extension, and range of ankle dorsi/plantar flexion). Although other studies have found that there were small differences between walking on a treadmill and walking on the floor [74], our results suggest that we cannot consider both situations to constitute exactly the same phenomenon.

4.2. Usage Considerations and Limitations of the MH System

After discussing the results of the test–retest reliability experiment, it is necessary to identify and discuss the usage considerations, or precautions, and the limitations of the MH system, particularly the main proposals that the system includes.

Firstly, it is important to note that a full-body MoCap of 15 IMUs or RBs was presented. However, the system can be configured with fewer sensors depending on which kinematics are needed. The pelvis is always required, and IMUs or RBs must be added following the kinematic chain towards the upper and/or the lower body. In our case, only eight elements were necessary to analyse the gait. This number of devices decreases the preparation time and, in the MH-IMU configuration, reduces the cost considerably. At this point, it should also be noted that the main difference in the MH-IMU configuration from systems based on a single IMU (usually situated on the pelvis; e.g., [98]) or two IMUs (usually located on the feet; e.g., [92]) is that the angle of each joint is calculated in addition to the calculation of the spatio-temporal variables, which is relevant information for analysing gait patterns. With regard to reducing the number of devices, recent research has revealed that it is possible to apply inverse kinematics to calculate the movement of unequipped body segments (e.g., using the IMUs on the thigh and the foot to calculate the movements of the calf); this approach has been called "sparse inertial motion tracking" [45].

With reference to the Fitbody calibration process, we should discuss the north correction of the IMU sensors. The magnetic north correction should be applied either with or without magnetometers. Nevertheless, it should be noted that, if magnetometers are used, the correction has an important limitation. The corrected angle is based on the between-sensor differences in the measurement of magnetic north at the initial instant, but these between-sensor differences rarely remain constant when the subject is walking, and the IMUs can become disoriented. Conversely, when the magnetometers are disabled (as in our experiment), the between-sensor differences remain constant, which is an important advantage that allows for the use of the system in any environment.

However, disabling the magnetometers is not without limitations; due to the internal IMU sensor fusion algorithm, there is a drift error that increases with time in the absence of magnetic information, and the duration of the calibration depends on the integration of the drift of the gyros [33]. In our case, conducting a Fitbody process before each gait test allowed for sufficient time to obtain results that had satisfactory reproducibility. Thus, we conclude that the Fitbody process in the MH-IMU configuration with magnetometers disabled can be used to capture data for short-term gait analysis, but could lose precision in longer captures. The average duration of the 33 × 2 captures with the MH-IMU configuration was 39.4 ± 6.7 s. It would be useful to conduct future studies to evaluate the loss of precision over time.

Different approaches could be used to extend the capture time in the MH-IMU configuration. One is the exploitation of kinematic constraints; for example, using the knowledge that the elbow joint does not permit abduction/adduction, or that the shoulder cannot attain more than 180 degrees of abduction or flexion [45,46,49–52]. Another approach could be to use zero-velocity updates [54] or

dead reckoning [55] algorithms that reset the errors when detecting zero-velocity periods during the gait. If the capture time were prolonged, both the MH-IMU and the MH-OPT configurations could be used for the for rehabilitation itself. As Georgiou [99] and Braga et al. [100] demonstrated, these types of systems can provide visual, auditory, and haptic feedback to improve gait patterns.

Continuing with the Fitbody process, it should be noted that, in both the MH-IMU and MH-OPT configurations, the position adopted by the participant (Figure 5) at the moment of executing the Fitbody function is an important issue. Due to the second step in the Fitbody process (the device-to-bone link), this position will be the neutral reference for the data capture, and the recorded angles will rely on this position. If a back flexion position were adopted by the subject in the Fitbody, when the subject adopted his or her neutral position, the human model would show an excessive back extension that would not represent reality. Therefore, the quality of the data captured is conditional upon the rater's ability to instruct the participant to adopt the correct body position.

The rater has to memorise specific instructions and must be able to determine the participant's neutral position, which depends on the participant's anatomy and pathology. In our study, standing directly in front of the participant in the Fitbody posture and asking the participant to copy the pose was useful. Moreover, specific phrases such as "Now I need you to be very still, as in a picture", "Place yourself in a neutral position", "Face forward", and "Place your feet parallel and at the width of your hips" were useful. In the MH-IMU configuration, "Place your arms at ninety degrees of flexion with the palms facing each other" was required, while "Place your arms outstretched at an intermediate height with the palms facing the body" was the requirement in the MH-OPT configuration.

Another important concern in the Fitbody function is the assumption that the devices are fixed securely [10] and positioned appropriately on the body [30], which is not a simple task [12].

With regard to fixing the devices to the body, the following guidelines assisted us to improve the process of attaching the devices. The straps that connect the devices to the body need to be sufficiently tight to prevent them from moving during the capture, they must respect the joint mobility space, and the participants must be able to reach their maximum ranges without discomfort or impediments [23]. It is necessary to ask the participant if he or she is comfortable and to modify the positioning or tighten the straps if necessary. If the subject is not comfortable wearing the devices, he or she may not move naturally [10], and may feel physically different, awkward, or uncoordinated [23]. Thus, the participant should walk and move around several times while employing wide ranges of movement; this ensures that the devices do not move significantly on the body.

With regard to the positioning of the devices on the body, certain considerations were particularly relevant. In the MH-IMU configuration, as shown in Table 2, the general criterion was to place one of the sensor's axes in a particular direction on the body. Useful ways of accomplishing this were to verify that the leg and arm sensors were situated on the lateral surfaces of these extremities, that the *X*-axes of the chest and the pelvic sensors were aligned with the spine, and that the X-axes of the head sensor and the feet sensors were aligned with the direction in which the subject was pointing. In the verification process, the height of the sensor along the body segment to which it is attached and its direction with regard to other axes are irrelevant; these parameters depend on the subject's anatomy and do not affect the Fitbody process.

If these positioning guides are not applied, the human model's movements will not represent the real movement of the subject. For example, if we were to place the tight-fitting sensor on the lateral surface of the leg, but the *Y*-axis was not orthogonal to the *Y*-axis of the pelvis (20 degrees), the magnetic north correction made on the Fitbody would be incorrect; therefore, when the participant moved the hip on the sagittal plane, the leg of the human model would move on a plane rotated from the sagittal plane (i.e., 20 degrees).

The positioning guidelines in the MH-OPT configuration were derived from the adjustment of the human model's joint centres. The pelvis and thorax RBs must be centred on the spine, the first in the sacrum area and the second on the D2 vertebra. The leg and arm RBs have to be fixed on the lateral surfaces of these extremities to make them more visible to the cameras. Finally, the feet RBs have to be

fixed to the centre of the upper surface of the foot, aligning the sensor's *X*-axis with the bone's *Z*-axis. If the positioning is inadequate, the main implication will be that the human model's joint centres will be positioned imprecisely, and the model will adopt a shape that will not correspond to the shape and dimensions of the subject.

With regard to the detection of the gait event, it should be noted that, as described, the proposed algorithm is reproducible. Nevertheless, further studies could be conducted to calculate the absolute accuracy of this algorithm in frame units. Absolute accuracy is usually obtained by matching the gait events detected by the algorithm to the events detected by one or more raters observing the live video recordings [34–36,56–60].

Similarly, it should be noted that the algorithm could be used for pathological gaits if the movement fulfils certain conditions. As described in Section 2.1.3, the event detection is based on the hip flexo/extension curves (MH-IMU configuration) and the displacement of the centres of the ankle joints on the sagittal plane (MH-OPT configuration). For this reason, it is necessary that the gait pattern shows a minimum of leg extension and flexion. If one of the legs were not to have any flexion or extension due to a pathology, it would not be possible to detect the events. Based on the same rationale, another factor that can have a negative effect is the analysis of a gait with considerable leg tremors in the sagittal plane; that is, forward and backward leg movements. As described, the signal is smoothed, but the algorithm may not detect the peaks correctly if such tremors are too great. Therefore, further research is required to test this algorithm in pathological populations.

To conclude the discussion section, it can be stated that this study presents a complete solution for gait analysis that can be used with satisfactory reproducibility, and which includes valuable proposals to enhance gait analysis in daily clinical practice. However, the MH system and the proposals that it includes are not without limitations; thus, the reflections provided in this section can be useful to improve applicability and to establish avenues for future research.

5. Conclusions

In this study, we presented the MH MoCap gait analysis system, which can be configured with magnetometer-free IMUs (MH-IMU) or with clusters of optical markers (MH-OPT). The MH system incorporates an anatomical calibration procedure that allows for the deactivation of the IMUs' magnetometers to avoid the magnetic influence, and an algorithm that detects gait events from kinematic data without additional instrumentation. We determined the reproducibility of both configurations via a test–retest reliability experiment with 33 healthy subjects. The experiment confirmed that the proposals performed adequately, and allowed us to establish usage considerations. The MH-IMU configuration showed slightly less reproducibility than did the MH-OPT, but it still provided results that were equal to or even better than those in other studies. The MH system adds value to the field of gait analysis, and aims to improve the applicability of optical and IMU technologies in daily clinical practice. In this sense, if the MH system were used to conduct pre- and post-measurement sessions for the rehabilitation treatments or therapies applied, the MDC results would assist clinicians to assess the changes and to make better decisions for each individual patient.

Author Contributions: J.M.: conceptualisation, data curation, investigation, methodology, software, visualisation, writing—original draft, writing—review and editing; T.B.: methodology, supervision, writing—review and editing; J.d.l.T.: data curation, writing—review and editing. J.J.M.: conceptualisation, funding acquisition, methodology, project administration, software, supervision, writing—review and editing. All authors have read and agreed to the published version of the manuscript.

Funding: The project was co-financed by the Government of Aragon, the European Regional Development Fund, and the University of Zaragoza (Spain). The Government of Spain co-financed Teresa Blanco's work through grant PTQ2018-010045.

Acknowledgments: We would like to thank all the participants who participated voluntarily in this study, and the I3A—University Institute of Engineering Research of Aragon, University of Zaragoza, Zaragoza, Spain, for the materials they provided.

Conflicts of Interest: The authors declare no conflict of interest.

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2.5. Estudio 5

Marín, J., Marín, J.J., Blanco, T., de la Torre, J., Salcedo I., Martitegui, E. (2020). Is My Patient Improving? Individualized Gait Analysis in Rehabilitation. *Applied Sciences*, 10, 8558. https://doi.org/10.3390/app10238558

BD: JCR | FI: 2.474 | Q: *Multidisciplinary Engineering* (Q2 – 32/91)
Applied Physics (Q2 – 63/155)
Multidisciplinary Materials Science (Q3 -161/314)
Multidisciplinary Chemistry (Q2 – 88/177)

applied sciences

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Is My Patient Improving? Individualized Gait Analysis in Rehabilitation

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Received: 9 November 2020; Accepted: 28 November 2020; Published: 29 November 2020

Abstract: In the rehabilitation field, clinicians are continually struggling to assess improvements in patients following interventions. In this paper, we propose an approach to use gait analysis based on inertial motion capture (MoCap) to monitor individuals during rehabilitation. Gait is a cyclical movement that generates a sufficiently large data sample in each capture session to statistically compare two different sessions from a single patient. Using this crucial idea, 21 heterogeneous patients with hemiplegic spasticity were assessed using gait analysis before and after receiving treatment with botulinum toxin injections. Afterwards, the two sessions for each patient were compared using the magnitude-based decision statistical method. Due to the challenge of classifying changes in gait variables such as improvements or impairments, assessing each patient's progress required an interpretative process. After completing this process, we determined that 10 patients showed overall improvement, five patients showed overall impairment, and six patients did not show any overall change. Finally, the interpretation process was summarized by developing guidelines to aid in future assessments. In this manner, our approach provides graphical information about the patients' progress to assess improvement following intervention and to support decision-making. This research contributes to integrating MoCap-based gait analysis into rehabilitation.

Keywords: motion capture (MoCap); inertial measurement unit (IMU); clinical applicability; motion data analysis; patient-specific; patient-level; spasticity; hemiparesis

1. Introduction

In the field of rehabilitation, clinicians continuously assess the improvement of patients to verify that treatments or therapies are achieving satisfactory results. In this context, numerous treatments are aimed at improving the ability to walk because this activity is essential to quality of life and personal

autonomy. One clear example of this is the importance of rehabilitation treatments in the recovery of an individual with hemiplegic spasticity following a stroke who experiences walking impairment [1–6].

Currently, assessing gait improvements after treatment is normally conducted through qualitative techniques, either by observation or through interviews with the patient [7]. However, these existing techniques could incorporate technology providing objective information regarding the patient's progress without requiring excessive time or advanced technological knowledge on the part of clinicians.

In this regard, gait analysis based on motion capture (MoCap) involves the measurement, analysis, and interpretation of human locomotion [8]. In the rehabilitation field, the information this analysis provides offers a wide variety of applications, including supporting decision-making for treatments and interventions [9–14]. It can support decisions regarding changing; adjusting (e.g., dosage) or discontinuing treatment [15]. Among the existing MoCap technologies, those based on inertial measurement units (IMUs) have been gaining particular relevance because they do not require external cameras and can be embedded into wearable technology [16,17].

Marin et al. [7] demonstrated that it is possible to integrate an IMU gait analysis test into a rehabilitation service such as a medical test. In the same manner, Marin et al. [17] proposed a gait analysis system based on IMUs free of magnetic disturbances, overcoming a limitation of this technology. Additionally, they demonstrated that this technology was reproducible and that the duration of the gait test was compatible with the daily practice of a rehabilitation service.

However, despite the great utility of clinical gait analysis [15,18] and the described advances, for its complete integration into the clinical setting, this technology must still overcome various challenges. One of these is the data analysis resulting from measuring an individual's gait. Methods must be developed to automatically and repeatedly process the generated spatiotemporal and kinematic variables [8]. More specifically, it is necessary to standardize methods in order to compare the variables generated in two different measurement sessions, between which the patient may have changed his or her gait pattern. For example, this could happen before and after a treatment or intervention or at the beginning of and during the rehabilitation process. Since this comparison of individual gait analysis data is not yet standardized or automated, the time required for data processing, the need for highly qualified professionals to interpret the results, and the handling of massive amounts of data hinder the use of gait analysis as standard practice [8,11,16,19,20].

The comparison of gait variables from two different measurement sessions has been executed among groups of patients in clinical trials studies. Such studies are widespread in clinical research, and many of them have used gait analysis for this purpose [21–24]. This type of study selects a homogeneous group of patients with a specific pathology and applies a pre- and post-treatment gait test to compare the results between both measurements.

However, this study did not focus on assessing a group of patients. Instead, we deal with the heterogeneity among rehabilitation patients in daily clinical practice. We face the challenge of assessing each patient, comparing the data in one session with the corresponding data of the patient in another session. Concerning this issue, little research has been conducted in biomedical studies [18].

In this regard, gait is a cyclical movement that generates a sufficiently large data sample in each capture session to statistically compare two different sessions (i.e., pre-treatment and post-treatment sessions) from a single patient. Using this essential feature, this paper illustrates how to assess individuals undergoing rehabilitation using the MoCap gait analysis based on IMUs. For this purpose, 21 heterogeneous patients with hemiplegic spasticity were assessed before and after treatment with botulinum toxin injections. To make the statistical comparisons between the two sessions, we used the magnitude-based decision (MBD) method [25]. The information that these comparatives provide can be useful in understanding the evolution of a patient between the two stages, but due to the challenge of classifying changes in gait variables as improvements or impairments, it requires clinical interpretation. Thus, using the information from the 21 individual assessments, we classified the patients according to their overall progress. As a result of this process, we propose interpretation guidelines to improve the applicability of this type of analysis in the clinical environment. This paper

seeks to contribute to a data management option for gait analysis that could enhance the integration of MoCap-based gait analysis into rehabilitation.

2. Materials and Methods

2.1. Study Design

Twenty-one patients with hemiplegic spasticity in their lower limbs underwent two MoCap gait tests; the first took place a few minutes before treatment with botulinum toxin (pre-treatment), and the second took place approximately one month later (post-treatment).

In the pre- and post-treatment measurement sessions, we instrumented the patient as shown in Figure 1. Afterwards, he or she walked naturally for six meters in a straight line at a self-selected speed and then turned around and walked back to the starting position multiple times. As we studied the gait cycle, only strides in a straight line were considered for analysis, and turns, starts, and stops were excluded. We measured 25 strides per patient per session.

Figure 1. Gait test in hospital. The sensor placement is shown on a patient with spasticity.

2.2. Ethical Statement

The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Bioethics Committee of Aragón, Spain (N° 12/2018). A written informed consent was obtained from each participant.

2.3. Technology and Instrumentation

We used the Move Human Sensors MoCap system developed by the IDERGO Research Group, selecting the system's MH-IMU configuration, which was recently described and assessed by Marin et al. [17]. This system is based on next-generation IMU (NGIMU) devices [26], which measure the rotations via signal processing in embedded sensors (accelerometers, gyroscopes, and magnetometers) and are placed on the body with elastic bands. In our experiment, we used the information from eight IMUs configured at 60 Hz (placed on the feet, calves, thighs, pelvis, and chest) to analyze the gait, as Marin et al. [17] described. Nevertheless, we placed the full-body configuration (15 IMUs) on the participant for possible further investigation. This system incorporates an anatomical calibration procedure that allows for the deactivation of the IMUs' magnetometers, avoiding the

adverse effects that disturbances in the magnetic field may cause. These magnetic disturbances are expected when the participant moves along a few meters especially in a hospital environment, which is filled with different equipment, wiring, and electromagnetic signals. Beyond this, the Move Human Sensors MoCap system includes an algorithm that detects gait events from kinematic data without additional instrumentation. These features justified the selection of this system and may favor the applicability of this technology in the clinical environment.

2.4. Participants

The choice of neurological patients with hemiplegic spasticity provides a challenging environment that enables the extrapolation of the results and methods to other patients with less severe physical or cognitive conditions. Spasticity is a symptom that affects numerous patients. Its adverse effects include pain, decreased mobility, contractures, and muscle spasms, which can interfere with daily activities and sleep to a greater or lesser degree [27–29]. In this regard, the botulinum toxin treats focal spasticity via muscle injection with a reversible paralytic action [27,30,31]. Although other treatments for spasticity exist, the observed efficacy; required personalization for each patient (dose, muscles to be inoculated, etc.); and widespread use justify the choice in this study.

We analyzed 21 heterogeneous patients (shown in Table 1), 11 women and 10 men (46 ± 16 y, mean ± SD). They met the general inclusion criterion, which was that the disease allowed them to walk autonomously. The sample of participants corresponds with the circumstances of patients who receive rehabilitation services from public hospitals.

Table 1. Patient characteristics.

Patient	Affected Side	Gender	Days Between	Age	Height (cm)	Abdominal Perimeter (cm)
S001	L	M	28	36	177	108
S002	R	M	28	19	170	85
S003	R	M	28	44	172	85
S004	R	F	26	55	161	115
S005	L	M	26	18	164	64
S006	R	F	26	32	164	90
S007	L	F	33	63	154	106
S008	L	M	29	19	173	96
S009	R	M	36	60	164	92
S010	R	F	50	68	165	92
S011	R	F	25	66	157	97
S012	R	F	25	57	157	100
S013	R	M	25	26	176	79
S014	R	M	28	40	187	128
S015	L	M	28	59	173	55
S016	L	F	28	58	147	79
S017	L	M	28	49	174	106
S018	L	F	35	49	164	91
S019	R	F	28	55	162	82
S020	L	F	28	61	154	109
S021	L	F	28	48	167	81

L: Left. R: Right. F: Female. M: Male.

2.5. Variables

We obtained the spatiotemporal and kinematic variables [8,32] shown in Table 2. Each variable, except for *GaitSpeed*, was calculated for the pathological or affected side (A) and the non-affected or healthy side (H).

Table 2. Variables considered in the study.

	Variable	Description
Spatiotemporal Variables	*StepLgth* (cm)	Distance between feet in the sagittal plane at initial contact
	StepWdth (cm)	Distance between feet in the frontal plane at initial contact
	FullSupp (%)	Percentage of support throughout the stride length
	Double.Supp (%)	Percentage of bipedal support throughout the stride length
	GaitSpeed (cm/s)	Mean of the gait speed throughout the stride length
Kinematic Variables (°)	*Pelvic.Tilt*	Range of Pelvic tilt
	Hip.FlexExt	Range of Hip flexo-extension
	Hip.AbdAdd	Range of Hip adduction-abduction
	Knee.FlexExt	Range of Knee flexo-extension
	Ankle.FlexExt	Range of Ankle flexo-extension
	Ankle.InvEv	Range of Ankle inversion-eversion
	Chest.Tilt	Range of chest tilt

Spatiotemporal Variables: Dimensions that depend on whole-body movement. Kinematic Variables: Dimensions that depend on the movement of each body segment.

2.6. Magnitude-Based Decision (MBD) to Monitor Individuals with Gait Analysis

Concerning individual monitoring, the human gait is a repetitive cyclical movement; thus, in a measurement session, a variable produces a multitude of samples (e.g., 25 samples of the *StepLght* variable for Patient S001 in a measurement session). Therefore, to monitor an individual, it is possible to compare two groups of measurements, namely the group of measurements from a pre-treatment session (n_1 samples, X_1 mean, and SD_1 standard deviation) and the group of measurements from a post-treatment session (n_2 samples, X_2 mean, and SD_2 standard deviation). Thus, according to traditional statistical theory, this approach is a two-mean comparison of independent samples because gait cycles, despite being obtained from the same patient, are not pair related.

Regarding the sample of strides recorded in each session, more strides would obviously provide better statistical normality and better precision. However, it was necessary to balance the number of steps to be recorded, the time that the test would take in the daily clinic, and the fatigue that the test could cause in certain patients if they walked for a long time. Thus, we decided to record 25 strides per patient per session. We did this to satisfy the central limit theorem and especially because Kribus-Shmiel et al. [33] ensured that 23 strides usually achieve statistical normality and stability. As will be explained later in this sub-section, to prove that the stride sample was sufficient, we calculated the power of each statistical comparison.

To conduct the comparison between the pre- and post-sessions, applying a student's *t*-test of the independent samples to each specific variable could be valid. Applying this test, a *p*-value lower than 0.05 would indicate that a difference existed between the pre- and pot-sessions. Nevertheless, as Amrhein et al. [34] stated, although it is currently accepted that an effect is significant if the *p*-value does not exceed a value of 0.05, this generates a dichotomy that is far from reality. According to the *Nature Research Journal* this statement about the *p*-value has been supported by more than 800 researchers [34]. Thus, to infer a conclusion, researchers must delve deeper into the results. For this purpose, the magnitude-based inference method, which has recently been rebranded as the MBD method, addresses this need by using a more realistic threshold than a *p*-value of 0.05. Information about the MBD approach can be found in Excel spreadsheets, presentations, notes, and articles, all of

which are available from sportsci.org [35]. The MBD method provides the probability that a change (defined by the confidence interval of the difference, *CIdif*) exceeds a specific threshold ($-\delta$, $+\delta$) selected by researchers in accordance with their objectives [36,37].

This method is not exempt from controversy; thus, some authors support [38–41] and others oppose [42,43] its application. However, we assumed this method to transmit a simple and interesting idea, considering a change 'relevant' if it exceeds a specific threshold. This idea may not be applicable in all fields but it makes sense in individual patient monitoring. The MBD method has, for example, been applied to elite athletes (e.g., [44]). We found similarities between elite athletes and the patients with spasticity because, in both cases, an individualized evaluation is required due to the uniqueness or heterogeneity of each participant, and it is difficult to compare a participant with a reference database. This idea has also been illustrated by de la Torre et al. [45], who applied MBD to the individual evaluation of patients with vertiginous pathologies.

Therefore, the application of the MBD method requires facing the challenge of establishing an adequate threshold δ. According to the MBD basis, the ideal or optimal solution would be to use as the threshold δ the minimal important difference (MID) [46], the smallest worthwhile change [47], the smallest clinically important value [37], or any other combination of the terms used in the literature to identify changes that have clinical or practical relevance (i.e., changes that have an effect on quality of life). Nevertheless, to the best of our knowledge, no one has proposed MID indexes for gait variables resulting from a MoCap system for the same population or treatment. This would be a challenge requiring in-depth further research beyond the scope of this study.

Thus, until further research provides these MID values, it will be reasonable to affirm that a change is significant if it overcomes at least the errors inherent in the test. In this regard, it will not be known if a change influenced a participant's quality of life, but at least, it will be known that the change existed and was not the result of a measurement error. This conclusion could be useful for clinicians, especially if they combine it with the rest of the clinical information.

In this regard, Marin et al. [17] recently summarized the error sources of a gait analysis test in the following groups: participant intrinsic variation, soft tissue movement, relative movement between the device and skin, positioning, instrument accuracy, gait event detection, and anatomical calibration. As shown in other studies [2,48–50], the magnitude of these errors in our experiment could be estimated for each participant using Bland and Altman's limits of agreement [51] (see Equation (1)). Using these errors as threshold δ, the MBD method provides the probability that a change had been more than zero. This is the probability that a patient had undergone 'real' changes. Reflections about the implication of using this threshold δ will be explored in the Discussion section. In this manner, the threshold δ was calculated using Equation (1):

$$\delta = Z_{1-\alpha/2}\ \sqrt{2}\ SE_{dif};\ SE_{dif} = \sqrt{\frac{SD_1^2}{n_1} + \frac{SD_2^2}{n_2}}, \quad (1)$$

where $Z_{1-\alpha/2}$ is the value of the normal distribution at $1-\alpha/2$ (as we stabilized a confidence level of 95%, α was 0.05 and the $Z_{1-\alpha/2}$ value was 1.96), $\sqrt{2}$ accounts for errors between two measurements [51–54], *SEdif* is the standard error of the difference between the means, n_1 and n_2 are the respective samples of the pre- and post-tests, and SD_1 and SD_2 are the respective standard deviations of the pre- and post-tests.

Moving from the threshold δ, another important issue in individualized gait analysis monitoring is that most of the changes in gait variables are not clearly either beneficial or harmful (see the terminology used by Hopkins and Batterham [55]). An increment or decrement in the magnitude of a specific gait variable could be beneficial for one patient but harmful for another. Spasticity causes such alterations to gait that, even if a particular gait variable changes to a value closer to normal, this will not necessarily indicate a beneficial change. In the rehabilitation process of patients with spasticity, the goal is usually to develop, learn, or internalize a gait pattern that is as functional and harmless as possible considering anthropometric, muscular, or cognitive conditions, regardless of the

normality of the pattern itself [7,56–58]. Therefore, in an experiment like this one, it is necessary to interpret the results for each patient independently.

For this reason, we used the 'real' changes provided by the MBD method to conduct a process that we called biomechanical interpretation. Three researchers—J.M. (an engineer), I.S. (a medical doctor), and E.M. (a medical doctor)—independently studied the same results (tables and graphs). They only considered changes that were at least 'very likely' (>95% chance). Following a discussion of their reflections and once a consensus had been reached, the conclusions for each patient were listed in detail (see the Supplementary Materials). These researchers later classified the patients into the following three groups: patients with overall improvement, those with overall impairment, and those without overall change. Finally, based on the information acquired during the interpretation process, the researchers wrote interpretation guidelines applicable to other assessments (see Section 4).

After outlining the decisions made in this study regarding the threshold δ and the interpretations of the results, we will introduce how we compared the two groups of measurements using the MBD approach. Hopkins [59] developed a spreadsheet to compare 'means of two groups'. Based on this spreadsheet, we developed a script applying the MBD method by using as input the threshold δ selected by the researcher, and the measurements taken from the pre- and post-tests of one specific patient. This script was developed using Vizard (6.2 version, WorldViz, Santa Barbara, CA, USA, 2020), which is based on Python 2.7, and the Pandas and Matplotlib libraries. The sequence that this program follows for a two-mean comparison begins with the calculation of the interval of the difference *CIdif*, which defines the lower and upper limits (*Li*, *Ls*) of the change (Equation (2)) [59]:

$$CIdif = t_{\alpha,\, DoF}\, SE_{dif};\, [Li,\, Ls] = \left[X_{dif} - CIdif,\; X_{dif} + CIdif\right], \tag{2}$$

$$DoF = \frac{\left(\frac{SD_1^2}{n_1} + \frac{SD_2^2}{n_2}\right)^2}{\frac{SD_1^4}{n_1^2(n_1-1)} + \frac{SD_2^4}{n_2^2(n_2-1)}}, \tag{3}$$

$$X_{dif} = X_2 - X_1. \tag{4}$$

In Equation (2), $t_{\alpha,DoF}$ is the value of the t distribution for a specific α selected by the researchers, (we defined α as 0.05 to achieve a confidence level of 95%) and a specific degree of freedom (*DoF*), which is computed with Equation (3) using Welch–Satterthwaite's approximation [60], where n and SD are the stride sample size and standard deviation, respectively; *SEdif* is calculated as explained with Equation (1); and the difference between means (*Xdif)* is computed with Equation (4), where X_2 is the post-test mean, and X_1 is the pre-test mean.

Exposed calculations assume independent samples, non-equal variances, and data that have approximately normal distribution. This data normality assumption is based on work by Kribus-Shmiel et al. [33], who ensured that statistical stability and normality could be achieved with 23 strides or more and that this number of cycles was sufficient to represent the mean behavior.

After δ and *CIdif* have been defined, it is possible to develop a graph for each variable, such as the one in Figure 2, representing the threshold ($-\delta$, $+\delta$) and the t-distribution of the change between the pre- and post-series. This representation facilitates analysis where the change falls in relation to the threshold δ. To accomplish this analysis numerically, the percentage of the t area that falls within the 'negative' region ($-\infty$, $-\delta$), within the 'trivial' region ($-\delta$, $+\delta$), and within a 'positive' region ($+\delta$, $+\infty$) must be computed. These areas are respectively labelled as follows: probabilities of negative change (N), trivial change (T), and positive change (P) [37].

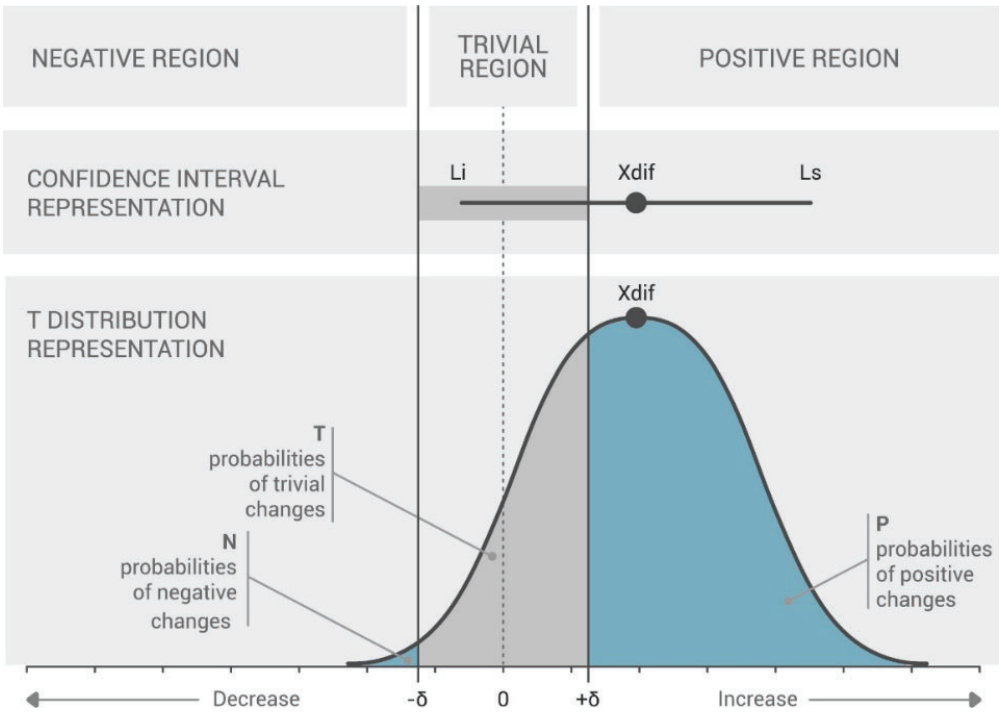

Figure 2. Representation of the change between the pre- and post-series of one variable; δ: magnitude-based decisions (MBD) threshold. *Xdif*: change within a subject (difference of means between pre- and post-series). *Li*: lower limit of the change. *Ls*: upper limit of the change. Note: δ, *Xdif*, *Li*, and *Ls* were computed using Equations (1)–(4).

In this manner, if the percentages of P and N are both less than 5%, ($N < 5\%$ and $P < 5\%$), the change is considered null or trivial because it does not exceed the threshold δ in any direction. If P and N are both higher than 5% ($N > 5\%$ and $P > 5\%$), the change is categorized as unclear because it simultaneously exceeds the threshold δ in both directions. Any other disposal of *CIdif* can be categorized as positive (increment) or negative (decrement) with a determined probability of change. If the change is an increment, the probability of change is P, and if the change is a decrement, the probability of change is N. The probability of change is classified as follows: 5 to 25% is 'unlikely', 25 to 75% is 'possibly', 75 to 95% is 'likely', 95 to 99% is 'very likely', and greater than 99% is 'most likely' [37,61].

Equations (5)–(9) show how to calculate N, T, and P using Excel formulas [59]. These expressions include values computed using the previous equations. Additionally, the choice of the formula used to compute N, T, and P depends on where the *Xdif* falls in relation to the threshold ($-\delta$, $+\delta$):

$$if\ X_{dif} \leq \delta\text{: } P = DSTR.T\left[\frac{\delta - X_{dif}}{SE_{dif}}; DoF; 1\right], \tag{5}$$

$$else: P = 1 - \ DSTR.T\left[\frac{X_{dif} - \delta}{SE_{dif}}; DoF; 1\right], \tag{6}$$

$$if\ X_{dif} \geq -\delta\text{: } N = DSTR.T\left[\frac{X_{dif} + \delta}{SE_{dif}}; DoF; 1\right], \tag{7}$$

$$else\text{: } N = 1 - \ DSTR.T\left[\frac{-\delta - X_{dif}}{SE_{dif}}; DoF; 1\right], \tag{8}$$

$$T = 1 - P - N. \tag{9}$$

The last step of our analysis was to examine whether the sample size of 25 strides was adequate. As described at the beginning of this subsection, we decided to capture 25 strides per patient per session because this number of strides seemed to be adequate according to the literature and provided a reasonable test duration. In this sense, Equation (10) relates the sample size (n) of strides (i.e., 25) to the threshold δ described; the statistical power ($1 - \beta$), which is the probability of detecting effects without committing Type II errors (false negatives); the α selected, which is the probability of committing Type I errors (false positive); and the *SDpool*, which is the pooled standard deviation of the pre- and post-tests:

$$Z_{1-\beta} = \sqrt{\frac{n}{2}} \frac{\delta}{SD_{pool}} - Z_{1-\alpha/2}. \quad (10)$$

Equation (10) is a formula based on the normal distribution and is applied for the two mean comparisons [62]. In this equation, $Z_{1-\alpha/2}$ is the value of the normal distribution at *1-α/2* (as we stabilized a confidence level of 95%, α was 0.05, and the $Z_{1-\alpha/2}$ value was 1.96), and $Z_{1-\beta}$ is the value of the normal distribution at $1 - \beta$ (e.g., for a power of 80%, the $Z_{1-\beta}$ value would be 0.84).

Using this equation, we first calculated the power for each statistical comparison using the sample of 25 strides for each variable, patient, and session. Second, from another perspective, we calculated the sample size (n) needed if we fixed the power at 80%, which is the typical stabilized power in research.

3. Results

The results of this study involved 21 separate patient-level analyses. After the interpretation of the MBD results of all the individual patients, it can be said that 10 patients showed overall improvement, five patients showed overall impairment, and six patients did not show overall change. In this section, we present one example of the patient-level analysis (Patient S014) in Table 3 and Figure 3. The numerical results and biomechanical interpretation of all participants are presented as Supplementary Materials in an Excel file.

Table 3. Results of one patient-level study, patient S014.

Variables	Mean Pre (*SD*)	Mean Post (*SD*)	*Xdif* (*CIdif*)	±*δ*	*N/T/P* (%)
StepLgth.H (cm)	24.7 (6.0)	38.1 (3.1)	13.4 (2.4)	2.8	0/0/100
StepLgth.A (cm)	32.1 (4.1)	44.0 (2.9)	11.9 (1.8)	1.9	0/0/100
StepWdth.H (cm)	23.3 (2.5)	22.7 (2.2)	−0.7 (1.2)	1.1	22/78/0
StepWdth.A (cm)	27.9 (2.8)	23.2 (1.5)	−4.7 (1.1)	1.3	100/0/0
FullSupp.H (%)	66.8 (2.8)	60.6 (4.2)	−6.2 (2.0)	1.3	100/0/0
FullSupp.A (%)	64.9 (4.7)	64.1 (2.2)	−0.8 (1.8)	2.2	7/93/0
DoubleSupp.H (%)	32.0 (3.3)	24.0 (2.1)	−8.0 (1.4)	1.5	100/0/0
DoubleSupp.A (%)	31.9 (3.3)	23.7 (1.8)	−8.3 (1.3)	1.5	100/0/0
GaitSpeed (cm/s)	38.5 (4.4)	61.8 (11.2)	23.2 (4.9)	2.1	0/0/100
Pelvic.Tilt.H (°)	5.9 (0.9)	3.4 (0.6)	−2.5 (0.4)	0.4	100/0/0
Pelvic.Tilt.A (°)	5.7 (0.8)	3.4 (0.7)	−2.3 (0.4)	0.4	100/0/0
Hip.FlexExt.H (°)	34.4 (1.8)	43.6 (1.5)	9.2 (0.9)	0.8	0/0/100
Hip.FlexExt.A (°)	21.1 (4.5)	25.9 (2.1)	4.9 (1.7)	2.1	0/0/100
Hip.AbdAdd.H (°)	10.8 (1.4)	8.5 (1.3)	−2.2 (0.7)	0.6	100/0/0
Hip.AbdAdd.A (°)	10.9 (2.4)	9.2 (0.9)	−1.7 (0.9)	1.1	92/8/0
Knee.FlexExt.H (°)	32.2 (4.8)	26.9 (4.1)	−5.3 (2.3)	2.2	100/0/0
Knee.FlexExt.A (°)	29.0 (6.0)	27.9 (2.1)	−1.1 (2.2)	2.8	6/94/0
Ankle.FlexExt.H (°)	6.9 (5.4)	7.7 (4.3)	0.8 (2.5)	2.5	1/91/9
Ankle.FlexExt.A (°)	1.6 (1.1)	3.7 (0.8)	2.1 (0.5)	0.5	0/0/100
Ankle.InvEv.H (°)	3.5 (1.8)	3.8 (2.0)	0.2 (1.0)	0.8	2/84/14
Ankle.InvEv.A (°)	3.6 (1.3)	1.0 (0.9)	−2.6 (0.6)	0.6	100/0/0
Chest.Tilt.H (°)	2.8 (1.5)	1.9 (1.0)	−0.9 (0.7)	0.7	68/32/0
Chest.Tilt.A (°)	2.7 (1.3)	1.5 (1.1)	−1.2 (0.6)	0.6	96/4/0

SD: Standard deviation. *δ*: MBD threshold. *Xdif:* difference of means. *CIdif*: Confidence interval of the differences at a 95% confidence interval. *A*: pathological or affected side. *H*: healthy or non-affected side. *N*: Probabilities of negative changes. *T*: Probabilities of trivial changes. *P*: Probabilities of positive changes.

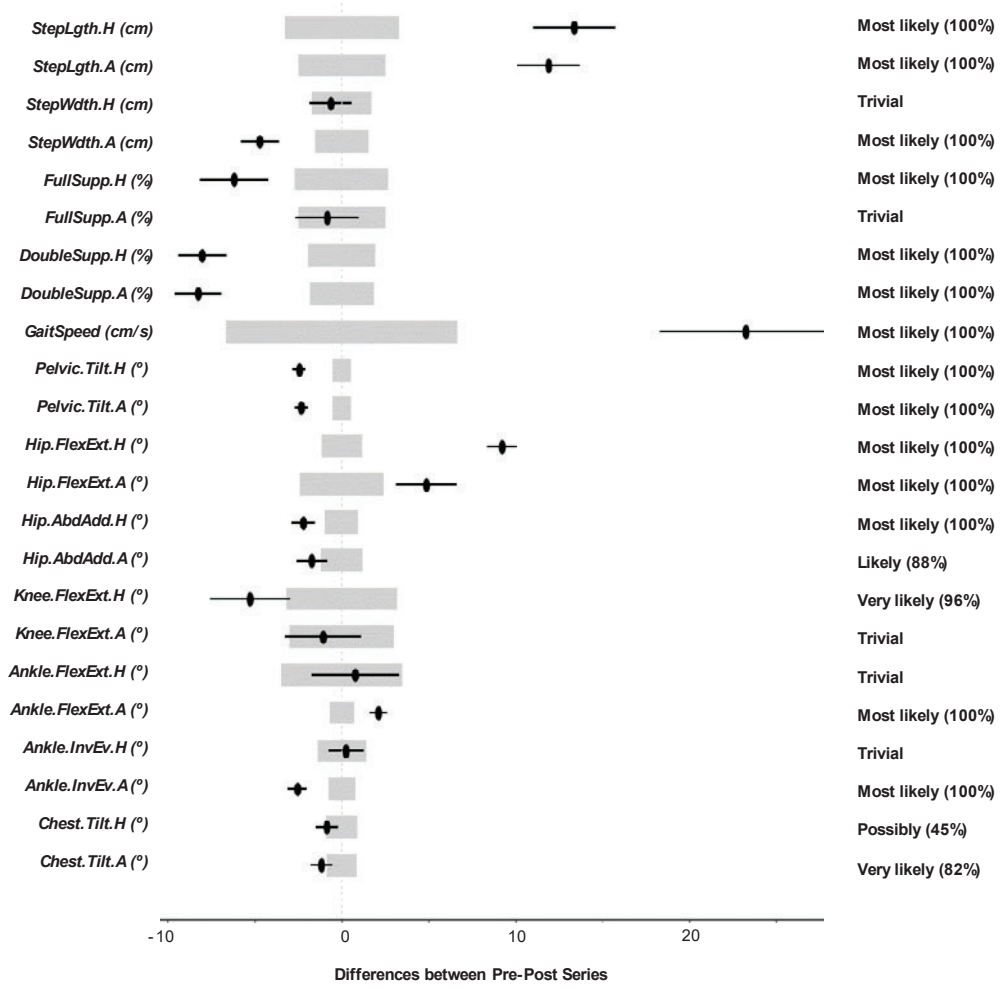

Figure 3. Patient-level analysis and confidence interval representation for Patient S014. Wide light grey bars: MBD threshold. Thin black bars: Confidence interval of the difference (*CIdif*).

Note that the *N*, *T*, and *P* terms shown in Table 3 were the result of the statistical comparison using the MBD approach, and their meanings were included in Figure 2 and the related paragraphs in the previous section.

Table 3 includes the change between the pre- and post-series of the analyzed variables in one single patient (patient S014), the threshold δ, and the MBD numerical results (i.e., the *N*, *T*, and *P* values). Figure 3 uses the confidence interval representation (see terminology used in Figure 2) to show the information included in Table 3. The grey areas represent the threshold ($-\delta$, $+\delta$), and the black lines illustrate the change. The information showed in the right margin includes the probability of change (i.e., one of the values *N*, *T*, or *P* depending on the result) and the qualitative classifications of the change.

The biomechanical interpretation of the results for Patient S014 (a 40-year-old man with the right side affected) demonstrates that the patient experienced an overall improvement, improving some key aspects of his gait pattern.

- He increased the *StepLgth* of both legs (positive).
- The percentage of *Double.Supp* of both legs decreased considerably. He can now spend more time in mono-pedal support. This could mean more confidence and security (positive).
- He increased his *GaitSpeed* (positive).
- He decreased his Pelvic.Tilt, resulting in lower energy cost and greater security (positive).
- He increased the *Hip.FlexExt* of both legs. The asymmetry that already existed increased (negative).

- He reduced the *Hip.AbdAdd* of both legs. He reduced the movement of the legs in the frontal plane (positive).

The analysis conducted to verify the sample size (25 strides) can be found in the last two sheets of the Excel file of the Supplementary Materials. The first sheet shows the power for each statistical comparison (i.e., 23 variables compared in each of the 21 patients, producing 483 comparisons). The second sheet shows the number of strides (sample size) that would be required to ensure a power of 80%. The summary of these results shows that the mean power of the statistical comparisons was 89.8 ± 8.4%, and, fixing the power to 80%, the mean sample size required was 18 ± 6.5 strides.

4. Discussion

In this study, we present an approach based on the MBD method to monitor individuals using gait analysis. This approach was applied to 21 heterogeneous patients with hemiplegic spasticity who had received treatment with botulinum toxin. The results for each patient were interpreted considering 'real' changes (i.e., considering those changes that exceeded the threshold δ by degrees of 'very likely' or above (>95%) probability). Finally, the patients were classified according to their overall progress, and 10 patients showed overall improvement, five patients showed overall impairment and six patients did not show any overall change.

Generating objective information for each individual patient was crucial [63]. The MBD approach provided useful, graphic information to improve the clinical decision-making process. When the investigated population displays a wide range of mobilities and clinical statuses, the importance of personalizing treatment and assessment become clear. These conclusions coincide with the Marin et al. [7] statement, who ensured that individual gait analysis monitoring has key advantages in daily clinical practice in the treatment of pathologies such as spasticity.

Comparing the approach here with others in the field, we did not find any other study that used the idea of gait as a cyclical movement to analyze individual patients. This feature has generally been applied only to average these cycles to achieve a more stable or representative cycle. However, we did find other studies sharing the objective of assessing individuals [18]. For instance, studies by Cloete and Scheffer [64], Bolink et al. [65], and Marin et al. [17] assessed MoCap systems to discover whether they could adequately monitor patients, which was our intention as well.

It is important to highlight that the approach does not determine whether improvement or impairment of a patient has occurred; that is the ultimate responsibility of a physician. The judgement of a specialist is always necessary to evaluate the results of this method, and one cannot separate the specialist from the method. The full name of the statistical method employed in this study, MBD, includes the word 'decisions', but this does not imply that the method alone facilitates decision-making.

In addition, we found the technology based on wireless IMUs to be a valid alternative to the gold-standard optical MoCap technology [66–70]. Although IMUs are slightly less accurate than optical MoCap systems due to drift errors, they are more economical and portable, do not require a camera infrastructure and do not present shadowing problems. Therefore, they are a suitable choice in a hospital environment in which substantial limitations exist in terms of the dedicated spaces required for optical systems [7,17].

On this subject, we highlight the operation of the MH-IMU system used in this study [17]. This instrumentation performed adequately in patients with hemiplegic spasticity. The deactivation of the IMUs' magnetometers had significant implications since it eliminated the need for a magnetically controlled environment. Additionally, the algorithm that the system incorporates to detect gait events performed adequately in the patients of our study, which was an important challenge due to the random nature of their gait patterns.

It can be assured that the MBD approach is a more realistic method than null-hypothesis significance tests [71], but it requires the making of important, logical decisions regarding the threshold δ during the application process [37]. Our threshold δ comprised Bland and Altman's limits of agreement [51].

These limits depend on patient variability, which is one of the most important sources of error when assessing changes in this population, and which make this method realistic.

The MBD approach requires the making of important, logical decisions regarding the threshold δ during the application process [37]. We decided to use as threshold δ the Bland and Altman's limits of agreement [51]. These limits depend on patient variability, which is one of the most important sources of error when assessing changes in this population. Spasticity affects muscle tone and motor skills and induces considerable fluctuations in gait patterns [66,72]. Thus, this convention brought realism to the data analysis, as it allowed for the personalization of the MBD process according to the specific movement pattern of each individual patient.

Nevertheless, using the limits of agreement as threshold δ partially deviates from the nature of the MBD method, which was created to calculate the probability that a change will have a practical effect on an individual using MIDs. In addition, it could be said that our approach was closer to the null-hypothesis significance test [37,71] which searches for non-zero (not null) changes. For this reason, we do not consider the limits of agreement the definitive solution. Instead, we consider these limits to be an instrument introducing the MBD method to assess individual patients. We hope that our study will expand the debate regarding which threshold δ to use in gait analysis to assess an individual patient's changes.

An alternative option regarding threshold δ is to use the minimal detectable change (MDC). This figure could be calculated by conducting a reliability study with a month between trials among a group of patients with spasticity similar to the patient being studied [2,46,52,53]. Nevertheless, there is a key difficulty in finding a homogeneous sample of patients such as these [15,63]. Furthermore, this threshold δ shares limitations with the Bland and Altman's limits of agreement used in this study, since it is also used to seek non-zero (not null) changes but not for practical changes.

For this reason, we agree with Batterham and Hopkins [37] and Buchheit [47], who explained that the optimal choice for the threshold δ is to use the MID value [46]. To the best of our knowledge, no previous studies have calculated MID values of spatiotemporal or kinematic variables resulting from a MoCap gait analysis system for patients with spasticity. MDI was calculated for the *GaitSpeed* variable, and though this measure can be taken readily with a chronometer; it was examined in patients experiencing stroke [72–74] or other pathologies [75] than the one in this study. Thus, we propose that studies be conducted to calculate MID indexes for gait variables using anchor-based methods [76].

Determining MID values in this area is complex due to the aforementioned difficulty of finding homogenous samples, as well as the numerous variables generated by a MoCap gait analysis system and the combined biomechanical interpretation it requires. However, such complexity should not hinder investigations to generate MID values for gait variables or for gait indexes that combine them [77]. Studies of this kind would reinforce clinical decision-making and the individual analysis approach described here.

As previously mentioned, based on the interpretation process, which is included as Supplementary Materials, a series of interpretation guidelines to classify changes as either improvements or impairments have been proposed. These guidelines are ordered from the most general, which affect all of the variables, to the most variable-specific guidelines, as listed below:

- Improving symmetry is beneficial. A change is positive when the values for the healthy and affected legs are closer in the second session [78].
- Increasing *GaitSpeed* is a highly positive change, as it is associated with functional improvement [72–74].
- Decreasing the *Pelvic.Tilt* or *Chest.Tilt* is interpreted as a positive change, as it implies lower energy cost and greater stability [56].
- Increasing the *StepLgth* is considered to be positive, except if it is due to uncontrolled or involuntary movement [56] (noticeable when *StepLgth* presents high variability). In this regard, increasing the *StepLgth* of the healthy leg is particularly positive. In the patients in this study, the *StepLgth* was usually greater in the affected leg because the affected leg moves to its maximum range when the

healthy leg supports the full body weight. Thus, increasing the *StepLgth* of the healthy leg means that the affected leg is capable of supporting the full body weight over a more extended range.

- Decreasing the percentage of *Double.Supp* implies that the patient can spend more time in mono-pedal support, which results in increased confidence and security.
- Reducing the *Step.Wdth* means reducing the base of support, which can be associated with improvement in terms of stability and confidence [56]. However, it is necessary to check whether the change is causing instabilities (i.e., increase in the *Pelvic.Tilt* or *Chest.Tilt*).
- Reducing the *Ankle.InvEv* is a positive change, as it can imply a reduction of the equinovarus foot effect, which hemiplegic spasticity usually produces [27–29].

Notably, in some cases, it is impossible to determine the nature of one change in isolation. Instead, it is necessary to consider a change in combination with other changes and with the increase or decrease in variability. These guidelines were explored during the study of a limited and specific sample; thus, we encourage improvements to them or the addition of more guidelines based on further research.

In addition to the proposed analysis and guidelines, we examined whether the samples (25 strides) recorded per patient per session were sufficient. With this sample size, the statistical comparison achieved a mean power of 89.8 ± 8.4%, indicating a high probability of detecting effects and avoiding Type II errors (false negatives). Additionally, the 25 strides recorded were higher than the 18 ± 6.5 strides that would be necessary to achieve a power of 80%. Both of these conclusions affirmed that the selected number of strides was reasonable.

In relation to these results, the number of statistical tests per patient was high (23 variables were statistically compared for each patient), which increased the risk of making a Type I error (see the section on multiple inferences in Hopkins [61]). As established in the Methods section, this probability was 5%, since we defined a confidence level of 95%. This scenario suggested the need for a more conservative approach to evaluating the statistical tests, such as the Bonferroni [79] adjustment. However, we agreed with others (e.g., Perneger [80]) who have advised against using the Bonferroni adjustment, instead asserting that each variable must be assessed in its own right. 'Evidence in data is what the data say—other considerations, such as how many other tests were performed, are irrelevant' [80], and the probability to commit an error with each inference must be assumed by the data interpreter. In any event, the MBD approach does not prevent including such adjustments if they are needed. To accomplish this, the α variable of the *CIdif* can be adjusted.

In light of the goal of this study, we must mention that in recent years, data management options based on machine learning have been gaining special relevance. In gait analysis, machine learning techniques are usually applied to classify types of gait, identify human physical activity, or detect gait events [8,81,82]. In other healthcare fields, these techniques are also being used to monitor individual characteristics [83,84]. Thus, future research could focus on feed machine learning models with the results that our approach would provide. This could lend insight to both the exposed interpretation process and to clinicians' decisions.

In summary, the MBD approach to monitoring individuals allowed us to assess the progression of 21 patients with hemiplegic spasticity. This approach necessitates thoughtful decisions, but it can also provide a standardized, automated, realistic option for data processing. Furthermore, it could be used in other gait analysis systems or even in other MoCap measures of repetitive movements that yield datasets with each repetition (e.g., the range of movement assessment). We hope that this approach will generate more efficient medical reports illustrating whether real changes have occurred in an individual patient during rehabilitation.

5. Conclusions

In this article, we propose an approach to compare the IMU gait analysis data resulting from two measurement sessions to monitor individuals in rehabilitation. The approach, which is based on the MBD method, is applied to 21 patients with hemiplegic spasticity who received treatment with botulinum toxin injections and who participated in two gait analysis sessions, spaced one month apart.

After the interpretation of the MBD results of all the individual patients, 10 patients showed overall improvement, five patients showed overall impairment, and six patients did not show overall change. As a result of the interpretation process, we propose guidelines to classify changes in the measures of gait as improvements or impairments, which can be used in future assessments. We conclude that our data analysis approach could enhance the application of clinical gait analysis based on IMU technology in rehabilitation. In addition, it has provided a useful, graphic tool for monitoring individuals and supporting personalized treatment decisions. Finally, this approach may aid clinicians in daily clinical practices, improving the rehabilitative process of patients with pathologies that affect gait biomechanics.

Supplementary Materials: The following are available online at http://www.mdpi.com/2076-3417/10/23/8558/s1, Table S1: Results and interpretation. This file includes the results of the individual analysis made on 21 patients and the results of the statistical power study.

Author Contributions: Conceptualization, J.M., J.J.M. and T.B.; Data curation, J.M., J.d.l.T., I.S. and E.M.; Funding acquisition, J.J.M; Investigation, J.M., J.J.M.; Methodology, J.M., J.J.M. and T.B.; Project administration, J.J.M.; Resources, J.J.M., I.S. and E.M.; Software, J.M. and J.J.M.; Visualization, J.M.; Writing—original draft, J.M.; Writing—review & editing, J.M., J.J.M., T.B., J.d.l.T., I.S. and E.M. All authors have read and agreed to the published version of the manuscript.

Funding: The project was co-financed by the Government of Aragon, the European Regional Development Fund, and the University of Zaragoza (Spain). The Government of Spain co-financed Teresa Blanco's work through grant PTQ2018-010045.

Acknowledgments: The authors would like to acknowledge and thank Juan C. Aragüés, Nicolas Rivas, Ricardo Jariod, M. Teresa Zarraluqui, and Alejandro Moreno for their suggestions, involvement in the project, and interest. We also thank the I3A—University Institute of Research of Engineering of Aragon, University of Zaragoza, Zaragoza, Spain, for the materials they provided.

Conflicts of Interest: The authors declare no conflict of interest.

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3. Discusión

Esta tesis nace con el objetivo de mejorar la usabilidad e integración de la tecnología de captura de movimiento en el ámbito de la salud; para los cual se establecieron 3 objetivos específicos dirigidos a detectar necesidades (OB-1), realizar propuestas metodológicas (OB-2) y profundizar en un caso de estudio concreto (OB-3).

La consecución de la investigación y los objetivos mencionados proporcionan una serie de contribuciones al conocimiento que se sintetizan en esta sección. Dichas contribuciones se estructuran desde las más generales, relativas al ámbito del diseño (3.1), hasta las más específicas, relacionadas al caso de estudio de la captura de movimiento (3.2) y al análisis de la marcha en rehabilitación (3.3). Adicionalmente, esta sección recopila las limitaciones identificadas de los estudios realizados e incluye propuestas de posibles futuras investigaciones (3.4).

3.1. Contribuciones en Metodologías de Diseño en el Contexto *Smart Health*

Este primer bloque de contribuciones ordena las aportaciones de esta investigación a la teoría de diseño centrado en el usuario. Para ello, se exponen los aportes de la metodología Octopus, el mapeo de usuarios y entornos y los avances en diseño de servicios para la integración de un micro-servicio en un macro-servicio.

En este marco, hay que destacar que, al inicio de esta investigación, se contaba con el sistema de captura de movimiento MH desarrollado por el Grupo de Investigación IDERGO. Desde la perspectiva de diseño, este sistema establece un punto de partida avanzado, con la suficiente flexibilidad para poder controlar la mayoría de los factores involucrados en el desarrollo.

3.1.1. Metodología de Diseño Octopus y su Aplicación

Octopus (estudio 2) contribuye al diseño de sistemas de captura de movimiento (OB-2) y da respuesta a las necesidades relacionadas con la instrumentación de evaluación musculoesquelética detectadas en el estudio 1 (OB-1).

Esta metodología establece la premisa de diseñar *MoCap-wearables*, es decir, elementos a colocar en cada segmento corporal, ya sean basados en IMUs o sólidos rígidos. Esta metodología es el resultado del conocimiento adquirido por las distintas experiencias, junto con una revisión profunda del estado del arte y un análisis de mercado. Estas tres líneas (experiencia, estado del arte y mercado) constituyen una combinación adecuada para obtener metodologías que se acerquen a los problemas reales que deben afrontar los equipos de diseño al desarrollar este tipo de productos.

Los aportes en diseño de Octopus se concretan a través de una serie de pautas de claves para desarrollar tecnologías de captura de movimiento, que como se ha descrito, son sistemas que presentan una elevada complejidad a nivel tecnológico y de usabilidad. De esta forma, Octopus propone afrontar el diseño considerando factores como el contexto, la interacción entre usuarios, la tecnología, la unión al cuerpo, el posicionamiento y las propiedades físicas. Valorar dichos factores desde las etapas iniciales del diseño puede encaminar a diseñadores y demás profesionales involucrados hacia soluciones con mayor aceptación por parte de los usuarios.

Adicionalmente, la metodología propone agrupar los factores en tres bloques principales: diseño de servicio, producto y software que, tal y como recoge el título de esta tesis, responden a los tres niveles de diseño que deben abordarse para el desarrollo de este tipo de productos. Finalmente, introduce ocho pasos para considerar los factores que, si bien se presentan en orden, la metodología no obliga a recorrerlos de manera lineal. La ordenación debe adaptarse a cada caso, y seguir un proceso iterativo, retrocediendo a la etapa que corresponda siempre que sea necesario.

Tras la publicación de Octopus (estudio 2), y gracias a la colaboración con el Servicio de Rehabilitación del Hospital Miguel Servet, se definió el caso de estudio donde aplicar dicha metodología (OB-3). Después de varias sesiones con el equipo médico del citado servicio, se dio forma al propósito de la investigación: diseñar una prueba clínica de

análisis de la marcha para monitorizar tratamientos de rehabilitación mediante sesiones de medición breves, previas y posteriores a los tratamientos.

Como resultado del caso de estudio, se elaboró el mapa que se muestra en la figura 5, el cual incluye los ocho pasos de Octopus en formato cíclico, y su relación con los bloques de diseño de servicio, producto y software. Este mapa contribuye a la aplicabilidad de Octopus, especialmente cuando se desea aplicar en equipos de trabajo multidisciplinares.

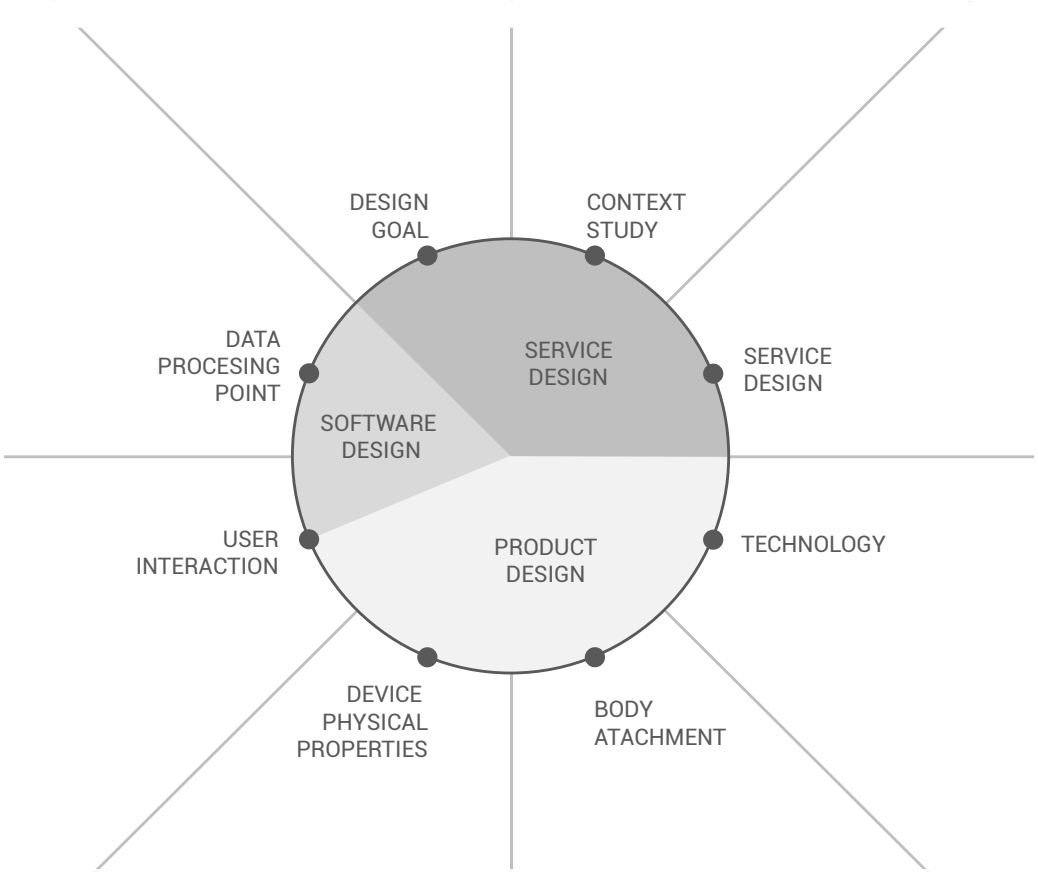


Fig 5. Octopus adaptado al desarrollo colaborativo de productos de captura de movimiento.

El mapa de la figura 5 se utilizó para definir las líneas de trabajo. Este esquema se colocó sobre una pizarra con la finalidad de que los miembros del equipo colocaran pósits en cada una de las secciones del mapa. Estas notas contenían ideas, restricciones, retos, preguntas o acciones a realizar. Todo ello, considerando el objetivo de diseño (prueba de análisis de marcha para rehabilitación) y las posibilidades de adaptación y mejora del sistema de captura de movimiento MH. Tras observar la utilidad de este proceso, se considera que este tipo de ejercicios pueden favorecer la organización del diseño de sistemas complejos y multifactoriales.

Mediante la agrupación y el análisis del contenido de estos pósits, surgieron las líneas de trabajo que se muestran en la figura 6, que definen la necesidad de realizar los estudios 3, 4 y 5, correspondientes a los tres niveles de diseño, servicio, producto y software respectivamente. En este marco de tres niveles, también se requirió llevar a cabo otras actividades complementarias, como posteriormente se expone.

Fig 6. Líneas de trabajo para el desarrollo del caso de estudio.

3.1.2. Mapeado de Usuarios y Entornos

La primera acción de investigación del caso de estudio fue afrontar el análisis del sistema de captura de movimiento MH desde el punto de vista de los usuarios y entornos implicados. Conocer las necesidades, expectativas, opiniones y modelo mental de los usuarios, así como las oportunidades y restricciones del entorno, favorece la aceptación de los productos y servicios (Kujala, 2003).

El mapa de usuarios y entornos analizados en esta investigación se muestra en la figura 7, el cual se estructura según las líneas de trabajo definidas de servicio, producto y software. La figura 7 incluye a los pacientes, *proxies*, profesionales, voluntarios sanos, y también a los desarrolladores y/o diseñadores (perfil del autor y directores de la tesis), ya que la perspectiva de este último perfil está presente a lo largo de la toda la investigación por ser quien organiza, interpreta, etiqueta y expone la información recopilada.

En relación con el usuario paciente, el equipo médico eligió analizar personas con espasticidad hemipléjica a los que se les aplicaba tratamiento con infiltraciones de toxina botulínica. Este tipo de pacientes presentan alteraciones significativas del patrón de marcha, lo cual eleva la incertidumbre para evaluar el sistema MH y brinda la posibilidad de que los resultados de la investigación sean aplicables a pacientes con condiciones físicas o cognitivas más favorables.

Los efectos negativos de la espasticidad incluyen dolor, disminución de la movilidad, contracturas y espasmos musculares, que pueden interferir con las actividades de la vida diaria o el sueño. Las causas son diversas; algunas de las más conocidas son ictus, daño cerebral postraumático, esclerosis múltiple, lesión de la médula espinal, parálisis cerebral, esclerosis lateral amiotrófica y polirradiculitis (Maynard *et al.*, 1990; Rizzo *et al.*, 2004; Thibaut *et al.*, 2013).

Los pacientes que participaron fueron seleccionados por el servicio de rehabilitación del hospital, tratando de buscar una muestra lo más heterogénea posible, en cuanto a edad, situación física y/o cognitiva, que representara la amplia variedad de pacientes con espasticidad que recibe el hospital (ver criterios de inclusión/exclusión del estudio

3). Así, en el estudio 5, de carácter cuantitativo, se analizaron 21 pacientes (46 ± 16 años), de los cuales 13 (46 ± 20 años) se evaluaron en el estudio 3, de perspectiva cualitativa. La muestra de pacientes es menor en el estudio 3 debido al concepto de "saturación" definido por Glaser & Strauss (1967). La saturación se alcanza cuando incluir más participantes al estudio no genera nuevos conocimientos o aporta información adicional.

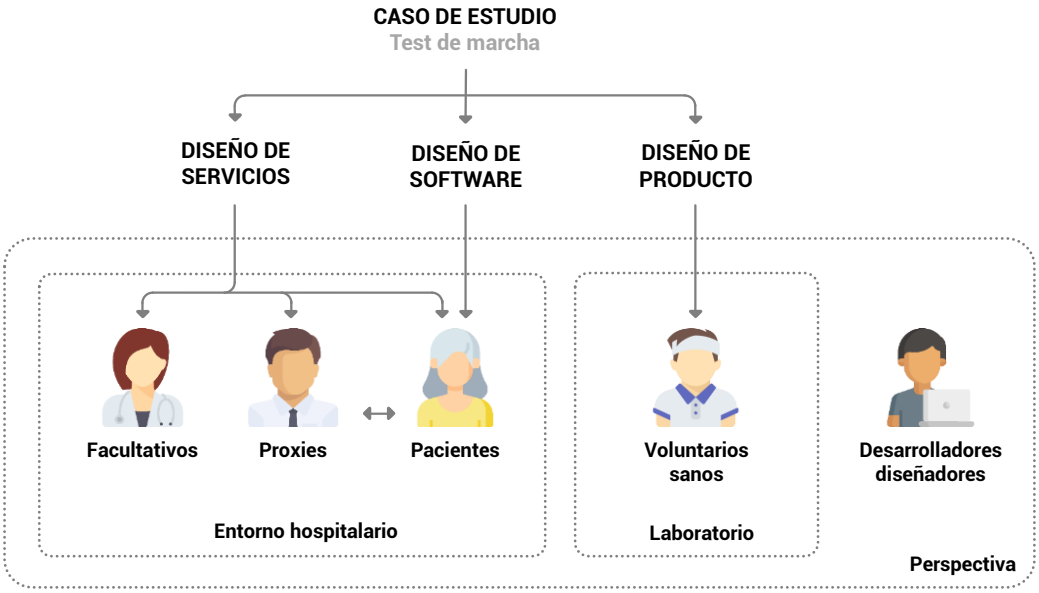


Fig 7. Mapa de usuarios y entornos considerados en la investigación. Iconos por Freepik de Flaticon.

Además de analizar a los pacientes, también se consideró la visión de los denominados *proxies*, es decir, familiares tutores o cualquier acompañante del paciente durante la prueba de marcha. Estos usuarios observaban el test desde una posición cercana y tenían libertad para interactuar con los clínicos y los investigadores que guiaban la prueba. Concretamente se analizaron 10 *proxies*.

Otra perspectiva analizada en esta investigación fue la de los 6 facultativos implicados en el tratamiento con toxina botulínica y seguimiento a este tipo de pacientes en el servicio de rehabilitación. En total, cinco médicos especialistas y un médico residente, que se turnaban según su disponibilidad para explicar verbalmente la prueba de marcha al participante, así como interactuar con él y con los *proxies* durante la ejecución. Además, como se explica en el estudio 3, participaron en una serie de talleres para definir las especificaciones a nivel de servicio.

Por otra parte, para poder validar y comprobar la precisión del sistema, se requirió llevar a cabo un estudio experimental con sujetos sanos. En total, 33 participantes, 20 hombres y 13 mujeres (21.7 ± 2.9 años). La realización de este estudio fue clave para comprobar el funcionamiento del producto y de los algoritmos de cálculo.

En relación con los entornos que muestra la figura 7, se debe destacar que el contexto hospitalario es el que tiene mayor relevancia a nivel de diseño por ser donde se pretende utilizar el sistema. Como se ha descrito, este entono corresponde al Servicio de Rehabilitación del Hospital Miguel Servet; concretamente, a uno de los gimnasios de

los que dispone el servicio para aplicar las distintas terapias. En la figura 1 del estudio 3 se puede observar esta sala.

Para llevar a cabo la experimentación con sujetos sanos se hizo uso del laboratorio de biomecánica del edificio I3A de la Universidad de Zaragoza. Este espacio dispone de una estructura de tubos que soporta un conjunto de 12 cámaras (OptiTrack Flex 13) y un tapiz rodante (EXE T800) modificado con el panel de control colocado de forma independiente. Para realizar la prueba de marcha sobre suelo con IMUs, se utilizó el pasillo que da acceso al laboratorio; este pasillo cuenta con una longitud útil superior a los 10 metros. En la figura 1 del estudio 4 se pueden apreciar tanto el laboratorio como el pasillo de acceso.

3.1.3. Integración de un Micro-Servicio en un Macro-Servicio

Siguiendo con las contribuciones relacionadas con la teoría de diseño, destaca el estudio 3. Este estudio responde al OB-3.1, y afronta la implantación del test de análisis de la marcha en un servicio de rehabilitación desde la perspectiva de diseño de servicios, lo cual ha recibido escasa atención en la literatura (Marín *et al.*, 2017a).

El reto fue adaptar un *micro-servicio* (el test de marcha) a un *macro-servicio* más complejo (servicio de rehabilitación). Tal y como muestran los estudios 2 y 3, el análisis de las necesidades, oportunidades y restricciones del servicio es clave para guiar las especificaciones de diseño del sistema completo.

No obstante, extraer dichas especificaciones en el ámbito biomédico es particularmente complejo, por la existencia de múltiples *stakeholders* (partes interesadas), cada una de las cuales cuenta con diferentes, expectativas y necesidades (Blanco *et al.*, 2016; Blanco *et al.*, 2019). Como se muestra el mapa de la figura 6 del estudio 3, para que la tecnología sea útil, rentable y realmente utilizable, se requieren soluciones que involucren a todos los usuarios: pacientes, médicos, terapeutas, etc. (Andersen *et al.*, 2013; Blanco *et al.*, 2016; Uebbing, 2016). Esto incluye, como se ha constatado, a familiares y personas cercanas a los pacientes (*proxies*), que se ven especialmente afectados por la situación que vive el paciente (Blanco, 2016; Jones & Vetter, 1984).

Por todo ello, el estudio 3 contribuye aportando una metodológica aplicable a otros casos donde se requiera integrar un servicio en otro de mayores dimensiones. Asimismo, se observa que, dentro de los tres niveles de diseño a considerar (servicio, producto y software), el nivel servicio tiene una relevancia superior para la toma de decisiones.

3.2. Contribuciones en captura de movimiento

Las contribuciones relacionadas con la captura de movimiento son otro resultado relevante de esta investigación. En este sentido, el estudio 4 presenta los avances más significativos que se han logrado en los últimos años en el diseño y aplicación del sistema MH, los cuales responden al OB-3.2. Los avances descritos en esa sección han sido materializados gracias al trabajo realizado durante esta tesis doctoral, donde Octopus y sus tres niveles (servicio, producto y software) han tenido un papel esencial para considerar las especificaciones de diseño del caso de estudio.

Las mejoras implementadas son relativas, por un lado, a los elementos físicos del sistema (elementos/sensores a colocar sobre el cuerpo) y, por otro, al software (modelos humanos y calibración anatómica). Dichas mejoras han sido llevadas a cabo en ambas configuraciones del sistema: MH-IMU (basada en sensores inerciales) y MH-OPT (basada en tecnología óptica).

3.2.1. Diseño de Wearables de Captura de Movimiento

La unión de los elementos al cuerpo y su adecuado posicionamiento es un aspecto singularmente relevante en un sistema como el que nos ocupa y, en general, es un concepto pobremente tratado en la literatura y también en muchos de los productos comerciales actuales (Dejnabadi *et al.*, 2006; Haratian *et al.*, 2014; Yang & Li, 2012). Llegar a la solución que se muestra en el estudio 4 requirió testar múltiples soluciones de forma iterativa.

En la configuración MH-OPT se utiliza un conjunto de 12 cámaras (OptiTrack Flex 13 y el software Motive) para capturar la posición y orientación de hasta 15 sólidos rígidos situados sobre cuerpo. Cada uno de estos sólidos está compuesto por un grupo de tres o más marcadores reflectantes (diámetro 14 mm) colocados en una superficie rígida (Carse *et al.*, 2013; Mayagoitia *et al.*, 2002; Skogstad *et al.*, 2011), en nuestro caso impresa en 3D. Los marcadores de cada sólido rígido tienen una relación espacial única, es decir, una distancia entre marcadores diferente, lo cual le permite al software diferenciar uno de otro. La tabla 1 del estudio 4 muestra las distancias relativas entre las esferas de cada marcador.

Al comienzo de esta tesis, los sólidos rígidos se realizaban de manera manual con material termoconformable (ver figura 8). Esta operación requería un tiempo considerable; se debía recortar cada silueta (diferente para cada parte del cuerpo), darle la forma deseada aplicando calor y después colocar las esferas reflectantes. En algunos casos se utilizaban peanas o varillas para separar las esferas de las placas de termoconformable y hacerlas más visibles por las cámaras.

El problema de esta forma de operar, además del tiempo fabricación y montaje, era la dificultad para distribuir las esferas de manera única para cada sólido rígido. Las distancias entre las esferas deben tener una diferencia mayor a la precisión del sistema (≈0.4mm, ver tabla 1), y además no pueden generar triángulos equiláteros o isósceles, ya que, en ese caso, el algoritmo de detección de los sólidos rígidos puede confundir su orientación espacial, al no reconocer si se trata de la cara interna o externa. Estos requerimientos dificultaban la elaboración manual ya que, aunque se disponía de plantillas para recortar las siluetas y las distancias entre marcadores se comprobaban

con un calibre, hasta que los sólidos rígidos no se daban de alta en la aplicación, no se podía validar que la detección de cada uno era correcta.

Fig 8. Solidos rígidos al comienzo de la investigación. Realizados manualmente con material termoconformable.

Al objeto de superar estas limitaciones, se diseñaron formas en 3D para cada segmento corporal, las cuales se imprimieron por prototipado rápido (ver figura 9). Para ello, estas piezas se modelizaron con el software Solidworks y se fabricaron utilizando la impresora Ultimaker 2+ Extended con material PLA 3D850 de SmartMaterials 3D. Estas formas se muestran en la figura 8. Gracias a ello, una vez comprobado el correcto funcionamiento de un conjunto de sólidos rígidos, se puede replicar para el resto de instalaciones. Además, reponer un sólido rígido deteriorado no precisa un procedimiento de recalibración en la aplicación, ya que la distribución de marcadores es siempre idéntica a la original.

Los sólidos rígidos que se muestran en la figura 9 disponen de orificios donde se colocan las esferas reflectantes mediante un tornillo pasante. Estos elementos, se diseñaron para adaptarse a cada uno de los segmentos corporales de un adulto. Para unir las fijaciones al cuerpo se utilizan bandas elásticas con velcro, las cuales son de uso médico, lavables y están disponibles comercialmente.

Asimismo, los sólidos rígidos se idearon con forma de U y con nervios en el interior para garantizar rigidez y estabilidad; de manera que un lado de la U se coloca debajo de la banda, y el otro lado sostiene los marcadores reflectantes. De esta forma, los sólidos no requieren estar en contacto con la piel, ya que se introducen entre dos de las vueltas que dan las bandas elásticas alrededor de cada segmento corporal. La forma de U facilita la colocación y disminuye el tiempo de preparación: primero se colocan las bandas elásticas y después se posicionan los sólidos rígidos. Así, antes de finalizar la captura

con un paciente, es posible colocar otro juego de cintas al siguiente y sólo requerir mover los marcadores de un participante a otro.

Fig 9. Solidos rígidos a colocar en muñeca, brazo, pie, muslo y pantorrilla (orden de lectura). No incluyen esferas. Ver impresión 3D en figura 1 de estudio 4.

Cabe destacar que, para los sólidos rígidos de cabeza, tórax, y pelvis se realizó un diseño específico que se muestra en la figura 10. Este diseño no se incluyó en el estudio 4 para no sumar complejidad a la publicación, pero puede tener implicaciones relevantes para la captura de movimiento por permitir construir marcadores ópticos modulares. Es decir, con un único diseño se pueden construir multitud de patrones únicos.

Los conjuntos mostrados en la figura 10 permiten colocar esferas reflectantes en varillas de distintas longitudes o tallas (comprendidas entre 40 y 90mm). Estas varillas se sujetan mediante dos placas con forma hexagonal que se fijan mediante tornillo y tuerca. Según las pruebas realizadas, la sujeción de esferas mediante varillas mejora notablemente la visibilidad por parte de las cámaras. El uso de varillas para la cabeza, tórax y pelvis resulta especialmente útil en comparación con las extremidades donde se ha observado mayor riesgo de sufrir choques con los elementos del entorno.

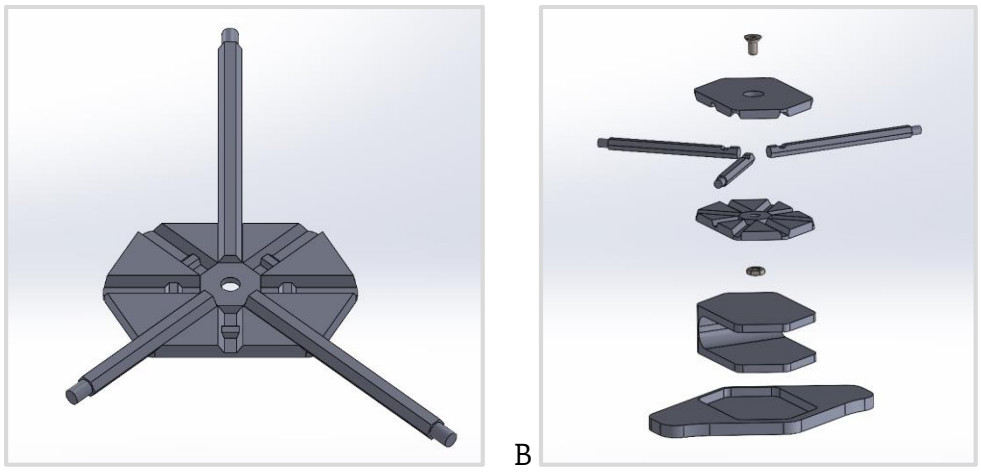


Fig 10. Diseño modular para marcadores ópticos. Vista parcial de base y varillas (A). Vista completa explosionada (B).

En relación con los sensores inerciales, fruto de esta tesis, el sistema MH utiliza dispositivos NGIMUS que presentan ciertas ventajas con respecto a los anteriores Trivisio-Colibri. En primer lugar, estos sensores disponen de comandos que pueden ejecutarse directamente desde una aplicación realizada en Python (como es el caso del sistema MH) y sin necesidad de una aplicación externa. Adicionalmente, permiten desactivar los magnetómetros y proporcionar una orientación correcta durante un tiempo suficiente (alrededor de 2 o 3 minutos), y su conexión vía wifi aporta mayor flexibilidad para su integración.

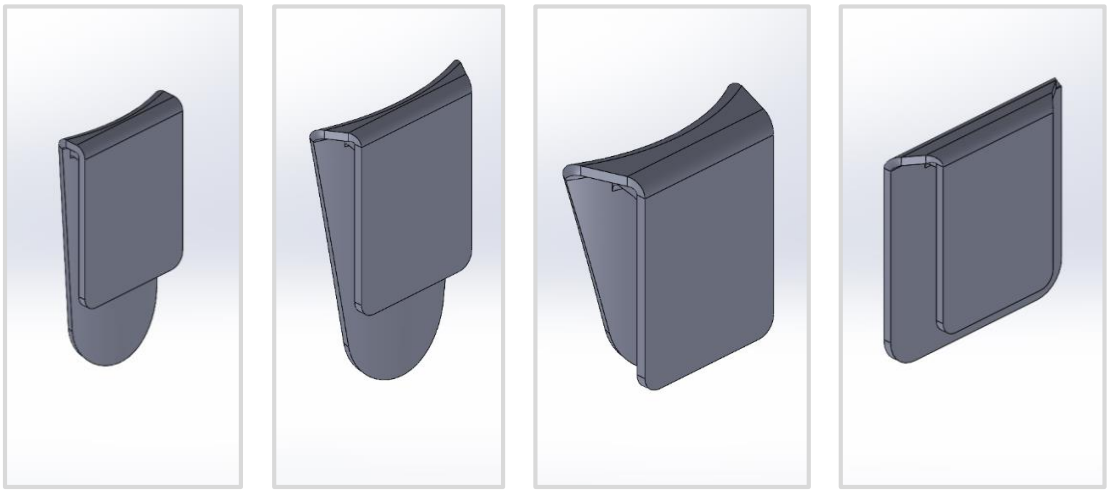


Fig 11. Soportes de sensores inerciales para colocar en muñecas, brazos y piernas, pies y pelvis (orden de lectura). Ver impresión 3D en figura 1 de estudio 4.

La evolución de los soportes para los sensores IMUs han experimentado una mejora similar a la configuración óptica; al inicio estos soportes se realizaban con material termoconformable, y actualmente se basan en elementos con forma de U realizadas con impresión 3D (ver figura 11). No obstante, en este caso, el lado externo de la U es una superficie rectangular plana a la cual se adhiere el IMU mediante velcro.

El resultado final de la mejora de los wearables, tanto para tecnología óptica como inercial, se muestra en la figura 12, donde se puede observar su colocación en el cuerpo.

Gracias a las mejoras implementadas, las formas se adaptan mejor a cada una de las zonas anatómicas, y son más perceptibles e intuitivas para su correcta fijación al cuerpo por parte del operador.

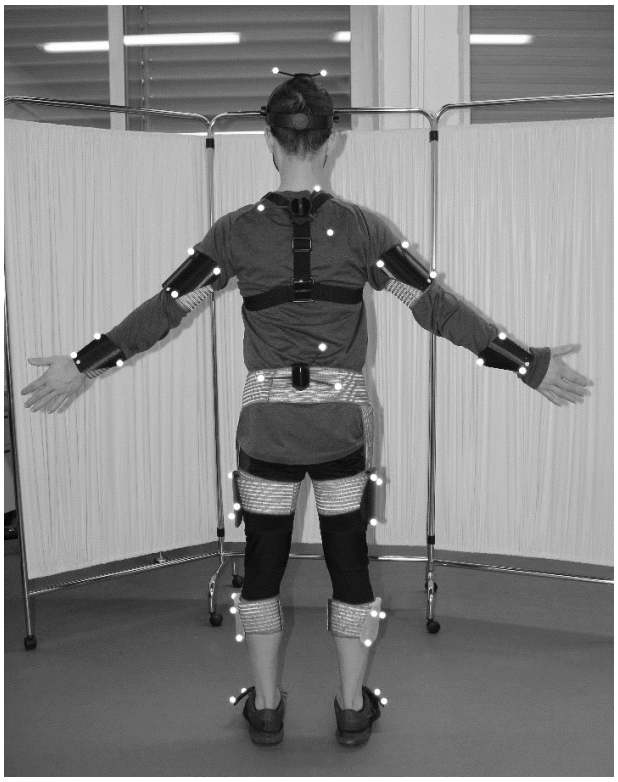
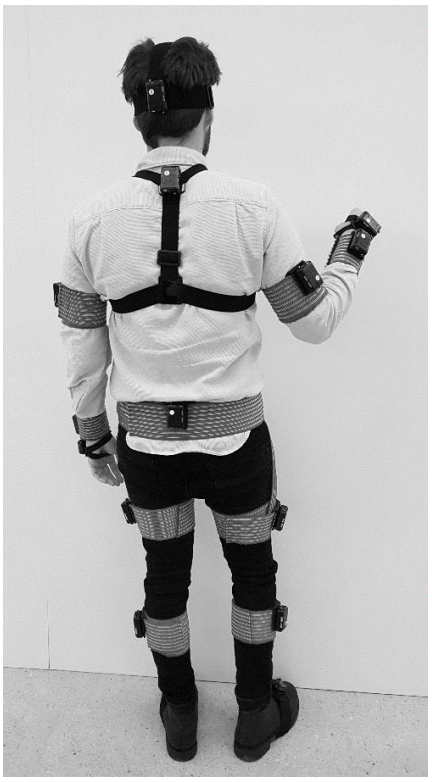
A  B 

Fig 12. Colocación de sólidos rígidos ópticos (A) y sensores inerciales en el usuario (B).

3.2.2. Modelos Humanos y Calibración Anatómica

Otra contribución al ámbito de la captura de movimiento es lo relativo al modelo humano descrito en el apartado 2.1.1 del estudio 4. Este modelo establece el sistema de coordenadas definido en cada hueso y las medidas que es necesario tomar para ajustarlo a la antropometría del participante. El convenio de signos establecido permite identificar el signo de las rotaciones como positivas o negativas para facilitar la interpretación y es el resultado de la colaboración con investigadores clínicos a lo largo de los últimos años. Este modelo puede extrapolarse a otros sistemas de captura de movimiento.

Adicionalmente, la calibración anatómica introducida denominada *FitBody* supone una contribución fundamental tanto para los sistemas ópticos como inerciales. Los fundamentos de esta calibración son similares en ambas configuraciones (ver sección 2.1.2 del estudio 4); si bien, en el caso de la versión MH-IMU introduce ciertas correcciones para permitir desactivar los magnetómetros y así lograr que los sensores no se vean alterados por perturbaciones en el campo magnético, que son frecuentes y afectan notablemente a la orientación espacial (Cloete & Scheffer, 2010).

A nivel operativo, el proceso de calibración requiere que el participante adopte una posición corporal estática específica (figura 5 del estudio 4) y, seguidamente, el evaluador ejecute la función *Fitbody*, asegurándose que la posición del participante es la adecuada. Con ello, se activan dos procesos: la corrección para el norte magnético

(Zhu *et al.*, 2020), aplicada únicamente a los sensores inerciales, y la calibración anatómica propiamente dicha, también llamada *sensor-to segment aligment,* aplicada a inerciales y ópticos (Bonnet *et al.*, 2009; Palermo *et al.*, 2014; Vargas-Valencia *et al.*, 2016).

Para que el proceso completo de calibración se realice de forma correcta, se establecieron una serie de pautas (ver apartado 4.2 del estudio 4) a tener en cuenta para lograr que el participante adopte una posición neutra o de calibración correcta. Esta posición está condicionada por la anatomía y patología de cada participante, por lo que el operador debe adecuar estas instrucciones a cada caso. En la experimentación, fue útil que el operador se colocara en la postura calibración y le pidiera al participante que tratara de copiar su postura.

En consecuencia, el proceso de *Fitbody* propuesto en esta investigación es un procedimiento de calibración que tiene características relevantes para ser utilizado en sistemas de captura de movimiento. Permite la desactivación de magnetómetros, puede realizarse en pocos segundos, la postura de calibración puede transmitirse eficazmente a los participantes y, derivado de la investigación realizada en el estudio 4, se ha demostrado que permite obtener una reproducibilidad adecuada. Asimismo, la calibración ha evidenciado poder aplicarse de manera satisfactoria en una muestra heterogénea pacientes con espasticidad hemipléjica (ver estudio 5), que tienen limitaciones físicas y, en algunos casos, también cognitivas.

3.3. Contribuciones en Análisis de la Marcha para Rehabilitación

Las contribuciones en el ámbito de análisis de la marcha han sido el resultado del desarrollo del caso de estudio, y se recogen en los estudios 3, 4, y 5. Como se ha descrito, el objetivo del caso de estudio es diseñar una prueba de análisis de la marcha para ser utilizada como prueba médica complementaria, basada en sesiones breves de medición, previas y posteriores a los tratamientos de rehabilitación aplicados. La finalidad última es generar un informe que muestre los cambios que se han producido en el paciente y favorezca la toma decisiones por parte del personal sanitario involucrado.

3.3.1. Prueba de Marcha desde el Diseño de Servicios

En Octopus (estudio 2) se define la captura de movimiento como un servicio, es decir un conjunto de actividades que satisface las necesidades de varios usuarios (en este caso, facultativos y pacientes) a través de diferentes materiales y procedimientos. Este concepto de "servitización" se materializa en su sentido más amplio en el estudio 3.

Dicho estudio muestra un enfoque metodológico cualitativo basado en tres fases, que puede ser de utilidad para mejorar la aplicabilidad de este tipo de pruebas en el sector hospitalario. La primera fase de la metodología estudia el efecto de proximidad usuario-producto, y consiste en la observación del uso del sistema de captura de movimiento en su contexto y con los usuarios implicados (médicos, pacientes y *proxies*). La segunda fase va más allá de lo que ocurre en la sesión de prueba, evaluando el efecto y valor del micro-servicio dentro del macro-servicio, para obtener una visión general de la ruta seguida por el paciente a lo largo del servicio. Finalmente, la tercera fase, estudia las interacciones entre usuarios para definir los flujos de información que deben existir entre los mismos. Este enfoque se recopiló en la tabla normalizada COREQ adjuntada al estudio 3, que facilita la descripción de la metodología.

La aplicación de las tres fases dio como resultado ciertas conclusiones que se agruparon en distintos temas, desde la comprensión del arquetipo paciente, a la definición de los profesionales que realizan la prueba (ver sección de resultados del estudio 3). Adicionalmente, se propusieron dos esquemas (figura 5 y 6 del estudio 3) que definen conceptualmente el servicio de rehabilitación en el cual se integra el test de marcha. Dichos esquemas fueron especialmente relevantes para mostrar el rol del nuevo test de marcha en el servicio.

Todo ello, generó la necesidad de desarrollar ciertos materiales o *touch points*. En concreto, fue necesario diseñar: (1) un documento de consentimiento informado a firmar por el paciente, cuya redacción fue supervisada por el equipo investigador y validada por el Comité de Bioética de Aragón; (2) un módulo de software integrado en el sistema MH que, tras terminar la segunda captura, procesa los resultados automáticamente y genera un informe que muestra de forma gráfica la evolución del participante; así como (3) un manual visual de interpretación y una guía para el uso del software y la instrumentación.

Derivado de todo ello, se extrajeron las siguientes ventajas resultantes de integrar una prueba de marcha en un servicio de rehabilitación.

- Apoya decisiones a nivel clínico. Tener una prueba que proporcione datos objetivos sobre la respuesta a la terapia favorece la toma de decisiones clínicas.
- Facilita las decisiones a nivel social y administrativo. Los datos objetivos, disminuyen la incertidumbre y descargan de cierta presión psicológica derivada de la responsabilidad humana que conlleva la labor del clínico. Asimismo, también reduce cierta presión de carácter administrativa, como los horarios, requisitos de eficiencia, disputas legales o la limitación de recursos.
- Mejora la rentabilidad del tratamiento. Algunos tratamientos conllevan costes importantes para las entidades sanitarias públicas o privadas implicadas. La prueba de la marcha permite ajustar mejor las características de los tratamientos según resultados específicos obtenidos por cada paciente.
- Facilita la comunicación entre clínicos. La prueba puede unificar la evaluación de la marcha y mejorar la transmisión de conocimientos entre profesionales.
- Mejora la comunicación entre clínico y paciente. Los resultados pueden establecer una vía de comunicación médico-paciente, mejorando los razonamientos (y familiares) al tomar las decisiones relativas a sus tratamientos.
- Proporciona *feedback* positivo para el terapeuta. La prueba puede generar bases teóricas basadas en las experiencias previas que favorezcan la creación de nuevas terapias o la mejora de las existentes.
- Provee *feedback* positivo para el paciente. El test puede implicar una motivación adicional para los pacientes, fomentando la confianza en los tratamientos y una mayor percepción de seguridad y confianza en la asistencia sanitaria.
- Genera información para crear bases de datos. La recopilación de información sobre la marcha puede tener un efecto práctico para diagnosticar a nuevos pacientes.
- Facilita la investigación de tratamientos en el propio el servicio. Las bases de datos recopiladas pueden ser de utilidad para llevar a cabo investigación sin requerir de experimentación adicional.

3.3.2. Validación del Sistema MH: Estudio de Reproducibilidad

La configuración del sistema MH con sensores inerciales MH-IMU es la versión a aplicar en el ámbito biosanitario de rehabilitación. No obstante, se dispone también de la configuración óptica basada en marcadores ópticos MH-OPT. Dadas las similitudes existentes entre ambas, se consideró oportuno abordar la validación en paralelo de ambas configuraciones, a través de un estudio experimental sobre una misma muestra de participantes voluntarios sanos (estudio 4).

Al respecto, es necesario destacar la decisión de realizar la captura de la marcha sobre suelo con la configuración MH-IMU y sobre tapiz rodante con la configuración MH-OPT. Esta decisión fue motivada en cierto modo, para potenciar ciertas ventajas y mitigar algunas limitaciones de cada tecnología. En la configuración MH-IMU caminar sobre el suelo asegura la portabilidad y permite medir un patrón realista. Por contra, en la versión MH-OPT, caminar sobre tapiz rodante reduce el área de captura y, por lo

tanto, el número de cámaras y coste asociado; además, permite capturar numerosos pasos con una velocidad de marcha constante y sin que el sujeto tenga que dar la vuelta al final del área de captura (Faude *et al.*, 2012; Papegaaij & Steenbrink, 2017; Van de Putte *et al.*, 2006). Estas observaciones pueden ser de utilidad para el uso de otros sistemas basados en IMUs o marcadores ópticos.

Con estas configuraciones, el funcionamiento del Sistema MH se evaluó mediante un experimento de reproducibilidad test-retest con 33 sujetos sanos. En el estudio 4, el protocolo del este experimento se explica en detalle, y sus resultados se contrastaron con los de otros estudios de la literatura, lo cual permitió corroborar el adecuado funcionamiento de ambas configuraciones.

Hay que considerar que la reproducibilidad es el indicador más general e importante para asegurar el adecuado funcionamiento de un sistema de análisis de la marcha (Baker, 2006; Haratian *et al.*, 2014). Una elevada reproducibilidad asegura que, en las mismas condiciones, el sistema produce datos similares y, por tanto, tiene la precisión suficiente para comparar resultados, ya sean los de un paciente a lo largo del tiempo o los de grupos de pacientes.

En relación con los resultados de reproducibilidad, destaca el índice de Mínimo Cambio Detectable (MDC), que fue calculado para todas las variables resultantes de la prueba. Este índice se define como la cantidad de cambio en un sujeto que puede deberse a una variación aleatoria o errores en la medición (Steffen & Seney, 2008); de forma que un cambio superior a dicha magnitud implica un cambio real en el sujeto. Esta definición, conlleva que el MDC sea un índice relevante para aplicar este tipo de sistemas en la clínica diaria, ya que permite al facultativo valorar la relevancia de los cambios producidos en cada uno de los pacientes, teniendo visibilidad de la variabilidad del propio sistema de medida (Kovacs *et al.*, 2008; Lee *et al.*, 2013; Marchetti *et al.*, 2014; Schuck & Zwingmann, 2003; Steffen & Seney, 2008).

3.3.3. Detección de *Gait Events*

Otra contribución relevante en esta investigación es el algoritmo propuesto en el estudio 4 para la detección de *gait events*, que puede aplicarse tanto en el análisis de la marcha sobre suelo, como sobre tapiz rodante. Los *gait events* delimitan el inicio y final del ciclo de la marcha e identifican sus fases (apoyo, doble apoyo, vuelo, etc.). Asimismo, permiten la superposición y normalización de las curvas de movimiento entre 0% y el 100%, y, por tanto, el estudio conjunto de los ciclos independientemente de la duración exacta de cada uno (Bejarano *et al.*, 2015; Marín *et al.*, 2020; O'Connor *et al.*, 2007; Tao *et al.*, 2012; Trojaniello *et al.*, 2014).

La detección de eventos de la marcha generalmente se realiza con instrumentación adicional (por ejemplo, plataformas de presión o plantillas instrumentadas), o bien de manera visual seleccionando los instantes sobre el video capturado. Ambas opciones complican el estudio respecto al algoritmo presentado, bien por requerir más tecnología o bien por requerir un post-proceso tedioso por parte del operador.

Para detectar los eventos de la marcha, definidos entre T1 y T6, el algoritmo utiliza curvas de movimiento específicas sobre las que se aplican reglas o condiciones para buscar máximos y mínimos que coinciden con los eventos. En la configuración MH-IMU, se utiliza la curva de flexión-extensión de la cadera y la misma curva en la pierna

opuesta. En la configuración MH-OPT, la detección se basa en la curva del desplazamiento de la articulación del tobillo en el eje sagital y la misma curva en el pie opuesto. Tal y como se expone en la sección 2.1.3. del estudio 4, la elección de estas curvas se basa en las características de cada tecnología.

En este punto, debemos indicar que ya existía una versión inicial del algoritmo de detección de eventos, previo al inicio de esta tesis. En esta investigación, dicho cálculo ha sido mejorado de forma iterativa a partir de diferentes capturas en las que participaban sujetos voluntarios sanos y patológicos. Tras este proceso, el algoritmo final se sintetizó en la figura 9 del estudio 4, donde se muestra de manera visual.

Finalmente, cabe subrayar que, tal y como muestra el estudio 4, este algoritmo demostró una reproducibilidad adecuada, y puede ser utilizado con participantes sanos, así como con pacientes con espasticidad hemipléjica con un grado de afección física y/o cognitiva diversa. Esto último se demostró en el estudio 5. Por tanto, puede aseverarse que el algoritmo cumple con su propósito y puede extrapolarse a otros sistemas.

3.3.4. Selección de Variables Representativas

Para analizar la marcha, se dispone las curvas de movimiento normalizadas, que son especialmente útiles para interpretar los patrones de movimiento de forma visual, así como de variables cinemáticas y temporoespaciales, que permiten objetivar numéricamente dichos patrones (Cimolin & Galli, 2014; Prakash *et al.*, 2018). No obstante, la cantidad de parámetros que proveen este tipo de sistemas puede ser abrumador, lo cual hace necesario seleccionar aquellas variables más relevantes.

En nuestro caso, la selección se realizó conjuntamente entre desarrolladores y facultativos del hospital, con el objetivo de valorar la espasticidad hemipléjica. Para tal propósito se utilizó colaborativamente la ficha mostrada en la tabla 2, acompañada del diagrama que muestra los *gait events* que puede detectar el sistema MH (figura 8 del estudio 4).

Como se puede observar en la tabla 2, es posible seleccionar tanto variables cinemáticas como temporoespaciales (Cimolin & Galli, 2014; Prakash *et al.*, 2018). Para ello, hay que considerar que se dispone para cada *gait event,* de la rotación en cada plano (RX, RY, RZ); del desplazamiento respecto a la pelvis en cada eje (X, Y, Z); y de la duración entre los propios *gait events*. De esta forma, con un círculo se selecciona la rotación o desplazamiento en un *gait event* concreto, y con una línea horizontal, el rango de rotación, desplazamiento o duración entre dos *gait events*.

De esta forma, según el criterio del equipo médico, para las variables cinemáticas se seleccionaron los rangos de rotación entre dos *gait events*. Adicionalmente, para las variables temporoespaciales, se seleccionó, por una parte, la longitud y anchura de paso, y por otra, el porcentaje del ciclo de la marcha con apoyo doble y total. Finalmente, para el cálculo de la velocidad de marcha se realizó el cociente entre la longitud y el tiempo invertido en cada zancada. Como se puede deducir, estas variables tienen un valor para en cada zancada capturada, lo cual es relevante para introducir el apartado 3.5.5.

Tabla 2. Ficha para elegir variables de marcha cumplimentada con las del estudio 5.

Articulación	Rotación	T1	T2	T3	T4	T5	T6	Nombre de Variable (estudio 5)
Tobillo	RX				●	●		*Ankle flexo-extension from T4 to T5*
	RZ	●	●	●				*Ankle inversion-eversion from T1 to T3*
	RY							
Rodilla	RX				●	●		*Knee flexo-extension from T4 to T5*
	RZ							
	RY							
Cadera	RX	●	●	●	●			*Hip flexo-extension from T1 to T4*
	RZ				●	●		*Hip adduction-abduction from T4 to T5*
	RY							
Pelvis	RX							
	RZ	●	●	●	●			*Pelvic tilt from T1 to T2*
	RY							
Tórax	RX							
	RZ		●	●	●	●		*Chest tilt from T2 to T5*
	RY							
	Desplazamiento	**T1**	**T2**	**T3**	**T4**	**T5**	**T6**	
Tobillo	X	●	●	●	●	●	●	*Step length at T1 and gait speed calculation*
	Z	●						*Step widht at T1*
	Y							
Rodilla	X							
	Z							
	Y							
Cadera	X							
	Z							
	Y							
Tórax	X							
	Z							
	Y							
Pelvis	X							
	Z							
	Y							
	Tiempo	**T1**	**T2**	**T3**	**T4**	**T5**	**T6**	
Duración de los eventos		●	●		●	●		*Percentage of double support*
		●	●	●	●	●		*Percentage of full support*
		●	●	●	●	●	●	*Gait speed calculation*

RX: Rotación en plano sagital. X: Desplazamiento en el eje sagital, RZ: Rotación en plano frontal, Z: Desplazamiento en el eje frontal. RY: Rotación en plano transversal. Y: Desplazamiento en el eje vertical.

Derivado de la expuesto, puede resumirse que esta investigación incluye una propuesta de variables para analizar la marcha y también una herramienta para seleccionar colaborativamente aquellas más relevantes. Ambas cuestiones aportan conocimiento al contexto de análisis de la marcha y pueden ser de utilidad para otros investigadores.

3.3.5. Método para Monitorizar Pacientes en Rehabilitación

Otra contribución que podemos destacar de esta investigación es relativa al método propuesto en el estudio 5, que da respuesta al OBJ-3.3. Este método permite analizar la evolución de pacientes de rehabilitación para proveer información objetiva al clínico.

Más concretamente, permite realizar comparaciones estadísticas con las variables resultantes de dos sesiones de un mismo paciente, esto es, comparar a cada paciente consigo mismo.

Este método constituye una aportación de interés para aplicar el test de marcha en la práctica clínica habitual, especialmente cuando los pacientes presentan trastornos singulares difíciles de caracterizar respecto a la población normal. Adicionalmente, según refieren otros investigadores, mientras no se estandarice y automatice el procesamiento de datos, el tiempo requerido para gestionar la cantidad masiva de datos resultante unido a la necesidad de profesionales altamente cualificados para interpretarlos, dificultan considerablemente el uso de este tipo de sistemas (Ferber *et al.*, 2016; Karg *et al.*, 2015; Marín *et al.*, 2017a; Prakash *et al.*, 2018; Simon, 2004).

El método expuesto se basa en una idea simple que se apoya en el siguiente razonamiento: la marcha genera un registro de datos en cada ciclo de movimiento y, como en cada sesión se registran multitud de ciclos, es posible comparar dos grupos de mediciones - el grupo de datos de la sesión pre-tratamiento y el grupo de la sesión post-tratamiento – y en consecuencia es posible estudiar la evolución del paciente entre ambas sesiones.

Si esta idea la traducimos al ejemplo de una variable, como puede ser la longitud de paso, estamos comparando n longitudes de paso de la sesión pre-tratamiento con n longitudes de paso de la sesión post-tratamiento, siendo n el número de ciclos medidos en cada sesión. Según la teoría estadística tradicional, estamos ante una comparación de dos muestras independientes, ya que los ciclos de la marcha, a pesar de ser obtenidos del mismo paciente, no están relacionados por pares.

De esta forma, para realizar la comparación, podría ser válido aplicar una prueba t de *Student* de muestras independientes. No obstante, esta investigación apoya las técnicas estadísticas basada en magnitudes (Batterham & Hopkins, 2006). Para justificar el uso de estas técnicas, en el estudio 5 recurrimos al texto de Amrhein *et al.* (2019). Estos autores publicaron una comunicación en la prestigiosa revista *Nature*, la cual fue apoyada por más de 800 investigadores, en la que instaban buscar alternativas a los estudios de significancia estadística basados en hipótesis nula (como prueba t de *Student*), en la que un cambio es significativo si supera un p-valor de 0.05, cuestionándose por qué este valor y no otro. La estadística basada en magnitudes no está exenta de controversias, pero aborda la necesidad descrita mediante el uso de un umbral más realista que el p-valor de 0.05, y considera un cambio relevante si excede un umbral elegido por los investigadores (Batterham & Hopkins, 2006; Buchheit, 2018; Hopkins, 2019). En nuestro caso, dedicamos gran parte del estudio 5 a justificar la elección del umbral idóneo en nuestra investigación.

El método de cálculo basado en magnitudes fue integrado en el sistema MH y testeado con una muestra de 21 pacientes con espasticidad, de forma que se generó, para cada participante, una tabla y un gráfico como los que se muestran en la figura 13 y tabla 3. El resto puede consultarse en el material suplementario que incorpora el estudio 5.

La figura 13 y la tabla 3 muestran los resultados relativos al paciente S014 de forma gráfica y numérica respectivamente (hombre de 40 años con el lado derecho afectado por espasticidad). El gráfico de la figura 13 es una de las contribuciones clave de este método, ya que permite interpretar los cambios de manera visual. Este gráfico incluye:

en el margen izquierdo, las variables analizadas; en el área central, el umbral seleccionado por los investigadores (área en gris) y el intervalo de confianza de la diferencia entre las sesiones pre y post (líneas negras); y finalmente, en el margen derecho, la probabilidad de que el cambio haya ocurrido realmente y la clasificación cualitativa asociada a dicho cambio según Batterham & Hopkins (2006).

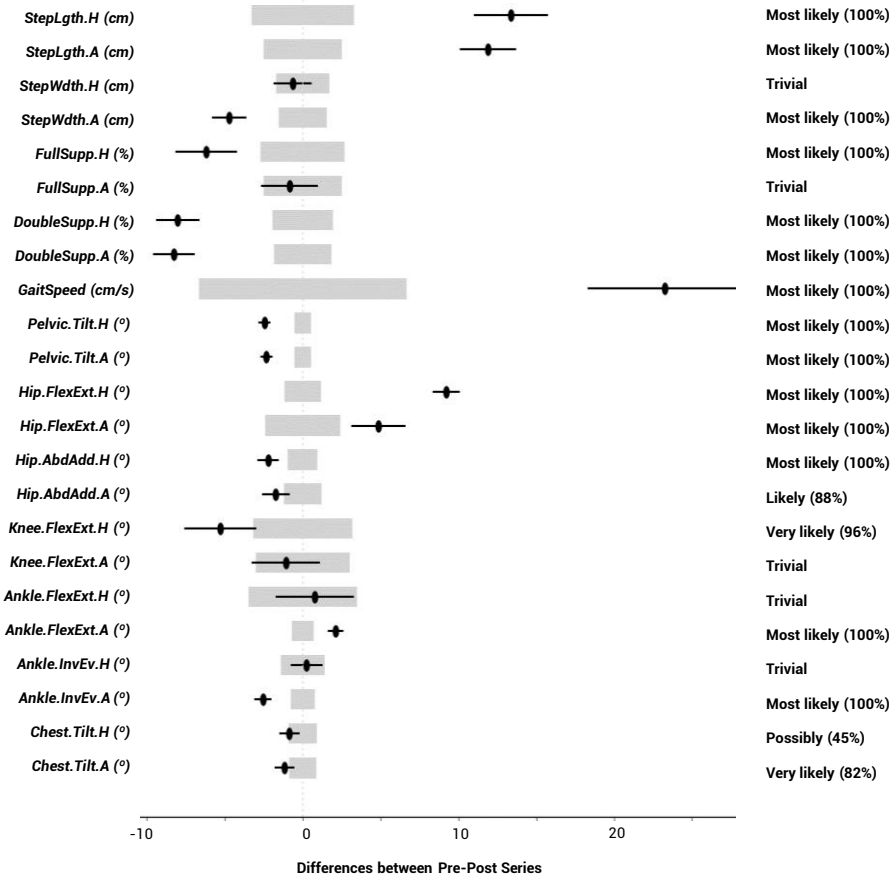


Fig 13. Resultados gráficos del paciente So14. A: Lado afecto. H: Lado no afecto

Si nos fijamos en la variable Step.Lgth.A de la figura 13, observamos que el intervalo de la diferencia se encuentra en la zona positiva, por lo que se puede concluir que la longitud de paso de la pierna afecta ha aumentado (concretamente 11.9 ± 1.8 cm según la tabla 3). Además, el gráfico aporta una información esencial: el intervalo de la diferencia no se superpone con el intervalo del umbral sombreado en gris, por lo que la probabilidad de que este cambio sea real, y no fruto de errores de medición, es del 100%.

Estos resultados demuestran que es posible proveer a los clínicos datos sencillos y visuales acerca de los cambios experimentados por un paciente y sin requerir un tiempo adicional de post-proceso o análisis.

Desafortunadamente, en el caso de análisis de la marcha, disponer de esta información visual y numérica no es suficiente para inferir una conclusión acerca de la naturaleza de los cambios en el paciente como positivos o negativos. Esto es debido a que muchas de las variables resultantes de la marcha no tienen una dirección beneficiosa o perjudicial clara, y un aumento o disminución en la magnitud de una variable podría ser beneficioso para un paciente, pero perjudicial para otro (ver terminología Hopkins & Batterham (2016) sobre la dirección beneficiosa o perjudicial de una variable).

Tabla 3. Resultados numéricos del paciente S014

Variables	***Media Pre (SD)***	***Media Post (SD)***	***Xdif (CIdif)***	***± δ***	***N/T/P (%)***
StepLgth.H (cm)	24.7 (6.0)	38.1 (3.1)	13.4 (2.4)	2.8	0/0/100
StepLgth.A (cm)	32.1 (4.1)	44.0 (2.9)	11.9 (1.8)	1.9	0/0/100
StepWdth.H (cm)	23.3 (2.5)	22.7 (2.2)	−0.7 (1.2)	1.1	22/78/0
StepWdth.A (cm)	27.9 (2.8)	23.2 (1.5)	−4.7 (1.1)	1.3	100/0/0
FullSupp.H (%)	66.8 (2.8)	60.6 (4.2)	−6.2 (2.0)	1.3	100/0/0
FullSupp.A (%)	64.9 (4.7)	64.1 (2.2)	−0.8 (1.8)	2.2	7/93/0
DoubleSupp.H (%)	32.0 (3.3)	24.0 (2.1)	−8.0 (1.4)	1.5	100/0/0
DoubleSupp.A (%)	31.9 (3.3)	23.7 (1.8)	−8.3 (1.3)	1.5	100/0/0
GaitSpeed (cm/s)	38.5 (4.4)	61.8 (11.2)	23.2 (4.9)	2.1	0/0/100
Pelvic.Tilt.H (º)	5.9 (0.9)	3.4 (0.6)	−2.5 (0.4)	0.4	100/0/0
Pelvic.Tilt.A (º)	5.7 (0.8)	3.4 (0.7)	−2.3 (0.4)	0.4	100/0/0
Hip.FlexExt.H (º)	34.4 (1.8)	43.6 (1.5)	9.2 (0.9)	0.8	0/0/100
Hip.FlexExt.A (º)	21.1 (4.5)	25.9 (2.1)	4.9 (1.7)	2.1	0/0/100
Hip.AbdAdd.H (º)	10.8 (1.4)	8.5 (1.3)	−2.2 (0.7)	0.6	100/0/0
Hip.AbdAdd.A (º)	10.9 (2.4)	9.2 (0.9)	−1.7 (0.9)	1.1	92/8/0
Knee.FlexExt.H (º)	32.2 (4.8)	26.9 (4.1)	−5.3 (2.3)	2.2	100/0/0
Knee.FlexExt.A (º)	29.0 (6.0)	27.9 (2.1)	−1.1 (2.2)	2.8	6/94/0
Ankle.FlexExt.H (º)	6.9 (5.4)	7.7 (4.3)	0.8 (2.5)	2.5	1/91/9
Ankle.FlexExt.A (º)	1.6 (1.1)	3.7 (0.8)	2.1 (0.5)	0.5	0/0/100
Ankle.InvEv.H (º)	3.5 (1.8)	3.8 (2.0)	0.2 (1.0)	0.8	2/84/14
Ankle.InvEv.A (º)	3.6 (1.3)	1.0 (0.9)	−2.6 (0.6)	0.6	100/0/0
Chest.Tilt.H (º)	2.8 (1.5)	1.9 (1.0)	−0.9 (0.7)	0.7	68/32/0
Chest.Tilt.A (º)	2.7 (1.3)	1.5 (1.1)	−1.2 (0.6)	0.6	96/4/0

SD: desviación estándar. δ: umbral seleccionado. Xdif: diferencia de medias. CIdif: intervalo de confianza de las diferencias con confianza del 95%. A: lado afecto. H: lado no afecto. N: Probabilidades de cambios negativos. T: Probabilidades de cambios triviales o nulos. P: Probabilidades de cambios positivos.

Por ello, se consideró necesario llevar a cabo un proceso de interpretación entre el equipo investigador acerca de los resultados de cada paciente. Con ello se demostró que era posible clasificar a los pacientes participantes en el estudio en tres grupos: pacientes con cambios generales positivos, negativos y nulos. Finalmente, a partir de la información obtenida durante el proceso de interpretación, se redactaron pautas de interpretación aplicables a otras valoraciones que pueden consultarse en la sección 4 del estudio 5.

3.4. Limitaciones y Trabajo Futuro

En esta sección se presentan las limitaciones de las investigaciones llevadas a cabo, así como posibles líneas futuras de trabajo que pueden derivarse de esta tesis.

El primer bloque de limitaciones y posibles acciones futuras de investigación se relaciona con las metodologías desarrolladas y aplicadas durante la investigación en cada uno de los estudios realizados.

- El estudio 1 revisa las necesidades detectadas relacionadas con la tecnología de evaluación del sistema musculoesquelético; no obstante, probablemente existan otras necesidades y requerimientos no detectados, así como otras tecnologías no valoradas en esta investigación. Por ejemplo, durante esta tesis ha surgido la necesidad de mantener una higiene exhaustiva de toda la instrumentación utilizada debido a la COVID-19.
- Paralelamente, la metodología Octopus (estudio 2) se desarrolló en base a la experiencia y a la literatura, así como a una revisión de los productos comerciales en el momento del estudio. No obstante, es posible que surjan nuevas áreas de aplicación de la captura de movimiento; lo cual, unido a los avances tecnológicos que se sucedan, hace necesario que la metodología requiera ampliarse o ajustarse para contemplar otros escenarios. Al respecto, el esquema propuesto en la figura 5 puede favorecer su uso colaborativo de cara a incorporar mejoras de la metodología, y su utilización en más casos de estudio podría perfeccionar su aplicabilidad.
- Relacionado con el contexto y muestra analizada en el estudio cualitativo (estudio 3), cabe destacar que nos centramos en un caso relativamente específico (pruebas de marcha para pacientes con espasticidad en un servicio de rehabilitación particular) y se analizan un número limitado de profesionales que conocen el servicio y el tratamiento utilizado. Por tanto, si se pretende integrar este u otro sistema similar en un hospital, se debe considerar que su organización y procesos pueden ser diferentes. En ese caso, deben primar las contribuciones a nivel metodológico frente a los resultados específicos de dicho estudio, ya que el enfoque metodológico está ideado para integrar un micro-servicio de este tipo en un macro-servicio.
- Adicionalmente, es importante aclarar que el estudio 3 tiene una perspectiva interpretativa y, por tanto, las técnicas de investigación empleadas son cualitativas. Esto implica que los participantes del estudio son quienes experimentan, procesan y etiquetan la realidad y transmiten su experiencia, recuerdos y expectativas individuales a los investigadores (Guba & Lincoln, 2005; Ponterotto, 2005). Esto evita la total objetividad y neutralidad del estudio.
- En relación con la metodología de investigación del estudio 4, en el que se analizó la reproducibilidad del test de marcha, cabe destacar que, si bien participaron un número suficiente de sujetos; y el tamaño de la muestra es equiparable a otros estudios a efecto de potencia estadística, se podría estudiar en el futuro otros grupos con edad avanzada o con algún tipo de patología para comprobar si la reproducibilidad varía.

- La metodología propuesta en estudio 5 provee información visual y directa al clínico para facilitar la toma de decisiones. Sin embargo, no es sencillo elegir las variables útiles a efectos clínicos, seleccionar el umbral más adecuado para el cálculo, así como la interpretación de los resultados por parte del facultativo. Por ello, la aplicación del método en otros pacientes y tratamientos sería positivo para aumentar el conocimiento relacionado con estas incertidumbres. Al respecto, como futura investigación se propone el uso de este método para evaluar pacientes que requieran prótesis en extremidades inferiores; en este caso, los resultados de la monitorización podrían favorecen la selección de la prótesis idónea al paciente y su posterior ajuste para lograr resultados satisfactorios.

El segundo bloque de limitaciones y líneas futuras de investigación está relacionado los desarrollos tecnológicos y de software implementados que se integran en el sistema MH.

- En la captura de movimiento hay ciertos errores o imprecisiones de medición que se identifican y detallan en el estudio 4. Estas imprecisiones son, en cierta medida, intrínsecas a la tecnología y a la operativa. No obstante, la experimentación test-retest realizada en este estudio ha permitido cuantificar la magnitud de las mismas. Acotar estas imprecisiones es esencial de cara a diferenciar entre cambios reales en el participante y errores instrumentales u operacionales. Por tanto, es necesario llevar a cabo estudios de reproducibilidad en futuros sistemas desarrollados.
- En la tecnología inercial, se ha observado la limitación de los IMUs inalámbricos relativa al consumo de batería. Los NGIMUS integrados en el sistema MH tienen una duración de aproximadamente 2 horas y 30 minutos. Esta duración es suficiente para nuestro caso de estudio, pero puede ser insuficiente en algunas aplicaciones. Para superar esta limitación, pueden implementarse mejoras a nivel de software para reducir el consumo cuando no se requiera medir el movimiento (por ejemplo, al colocar los sensores, o entre captura y captura); y a nivel de hardware, pueden desarrollarse estaciones de carga donde colocar los sensores entre captura y captura (por ejemplo, con tecnología de carga inalámbrica) o bien independizar la batería del sensor, para disponer de baterías intercambiables.
- Con respecto a la corrección del norte magnético propuesta para la tecnología de sensores inerciales, hay que considerar no está exenta de ciertas limitaciones, tanto si se aplica con o sin magnetómetros. Si se utilizan magnetómetros, el algoritmo corrige las diferencias del norte magnético que mide cada sensor en el instante inicial, pero estas diferencias entre sensores rara vez permanecen constantes cuando el sujeto está caminando, lo cual desorienta los IMUs. Por otra parte, cuando los magnetómetros están desactivados, las diferencias entre sensores permanecen constantes, lo cual es una ventaja importante. Sin embargo, debido algoritmo de fusión que incorpora el IMU internamente, existe un error de deriva provocado por los giróscopos que aumenta con el tiempo en ausencia de información magnética (Cloete & Scheffer, 2010). La realización de un proceso Fitbody antes de cada prueba de marcha, posibilitó desactivar los magnetómetros y alcanzar una reproducibilidad satisfactoria, si bien con la limitación de no superar los 3 minutos de captura.

- Con relación a este último punto, se podrían utilizar diferentes metodologías para extender el tiempo de captura. Esta línea de trabajo es especialmente relevante, ya que, tal y como demostraron Georgiou (2018) o Braga-Rodrigues *et al.* (2020), la captura de movimiento, además de ser útil para la evaluación, pueden también aplicarse en la propia rehabilitación de la marcha, proporcionando *feedback* visual, auditivo o háptico, para lo cual la duración de las capturas requeriría ser mayor. La primera actuación para alargar la duración, y también la más directa, es activar los magnetómetros y buscar áreas de captura sin perturbaciones magnéticas. Si esto no es posible, el modelo humano puede incorporar restricciones cinemáticas; por ejemplo, no permitir la abducción o aducción de codo (Eckhoff *et al.*, 2020; El-Gohary & McNames, 2015; Laidig *et al.*, 2017; Laidig *et al.*, 2019; Lee & Jeon, 2018; Lehmann *et al.*, 2020). Otro enfoque podría ser utilizar algoritmos denominados *zero-velocity update* (Cardarelli *et al.*, 2019) o *dead reckoning* (Visi *et al.*, 2017) que restablecen los errores al detectar períodos de velocidad cero.
- Continuando con el algoritmo de calibración anatómica o *Fitbody*, debe destacarse que la posición adoptada por el participante (figura 5 del estudio 4) y el posicionamiento de los dispositivos en el cuerpo en el instante de calibración son factores esenciales. Si un factor u otro no se ejecuta adecuadamente, la calidad de la captura se verá mermada considerablemente, y el movimiento del modelo humano no coincidirá con el movimiento real del participante. Para afrontar esta limitación se han provisto de instrucciones dirigidas a facilitar la correcta ejecución de postura la calibración y el adecuado posicionamiento de los dispositivos (ver apartado 4.2 del estudio 4). Estas pautas se han materializado en una guía de usuario.
- Con respecto al algoritmo de detección *gait events*, cabe indicar que no conocemos su precisión exacta. Aunque la reproducibilidad demostrada es suficiente para que el algoritmo sea aplicable (Baker et al. 2006), se podrían realizar más estudios para calcular la precisión de este algoritmo. Para ello se deben contrastar los *gait events* detectados por el algoritmo con los detectados por uno o más evaluadores que observan las grabaciones de vídeo en vivo de las mismas capturas (Bejarano *et al.*, 2015; Mariani *et al.*, 2012; Mariani *et al.*, 2013; O'Connor *et al.*, 2007; Olsen *et al.*, 2012; Teufl *et al.*, 2019; Trojaniello *et al.*, 2014; Zeni *et al.*, 2008).
- Profundizando en el método para comparar capturas del estudio 5, destaca la dificultad mencionada de seleccionar el umbral para determinar si los cambios son relevantes. La solución ideal u óptima sería usar como umbral el *minimal important difference* (de Vet & Terwee, 2010), que ha recibido muchos otros nombres en la literatura, como *smallest worthwhile change* (Buchheit, 2016) o *smallest clinically important value* (Batterham & Hopkins, 2006). Este tipo de umbrales permite identificar cambios que tienen efectos tangibles sobre la calidad de vida del paciente. Sin embargo, hasta donde sabemos, nadie ha propuesto índices de este tipo para variables de la marcha medidas con captura de movimiento, por lo que sería necesario realizar investigaciones en esta dirección. Hasta entonces, es razonable afirmar que un cambio existe si supera, al menos, los errores inherentes a la prueba. En este sentido, no se sabrá si un cambio influye en la calidad de vida de un participante, pero al menos se sabrá que el cambio no fue

el resultado de un error de medición. Esta conclusión tiene utilidad para los facultativos, especialmente si se combina con el resto de la información clínica.

- Otro aspecto a destacar en la monitorización de pacientes individualizada es la dificultad de interpretar los cambios en el patrón de marcha. Como se ha descrito, la mayoría de los cambios en las variables de la marcha no tienen direcciones claramente beneficiosos ni perjudiciales. Para mejorar este aspecto, se han propuesto guías de interpretación y la ficha mostrada en la tabla 2 para la selección de variables. No obstante, se requiere desarrollar una base teórica extensa basada en casos previos que facilite tanto la interpretación como la selección de variables para cada caso, e incluso la creación de índices con un mayor significado clínico (Cimolin & Galli, 2014). Para ambas acciones se requiere un trabajo conjunto entre tecnólogos y clínicos.

4. Investigaciones Relacionadas

El desarrollo de esta tesis se enmarca en proyectos y acciones de investigación relacionados (4.1) que han favorecido la detección de necesidades y problemas, así como el análisis de los desarrollos realizados. Adicionalmente, la participación en otras acciones de investigación, han generado una serie de publicaciones científicas relacionadas (4.2).

4.1. Proyectos y Acciones de Investigación Relacionados

Adicionalmente a las actividades de investigación expuestas en los capítulos previos, cabe destacar ciertos proyectos y tareas que se relacionan y contextualizan esta tesis doctoral. A continuación, se describen los hitos clave de cada uno de ellos.

4.1.1. Colaboración con el Servicio de Rehabilitación Hospitalario

En primer lugar, subrayamos la colaboración con el Servicio de Rehabilitación del Hospital Miguel Servet, que ha hecho posible el desarrollo del caso de estudio principal de esta investigación. Los resultados de esta colaboración se han expuesto a lo largo de la sección 3 de este documento, no obstante, es relevante destacar ciertos hitos acontecidos a lo largo de esta colaboración:

- Redacción del proyecto para el Comité de Bioética de Aragón, y su aprobación el 20 de junio de 2018.
- Firma del Acuerdo de Colaboración entre la Universidad de Zaragoza y la Fundación instituto de Investigación Sanitaria de Aragón, para desarrollar conjuntamente el proyecto: "*Pruebas Médicas Complementarias basadas en Tecnologías Smart Health para evaluar Tratamientos Personalizados de Rehabilitación*", el 1 de octubre de 2018.
- Realización de capturas de movimiento en pacientes con espasticidad en las dependencias del Hospital Miguel Servet de Zaragoza, así como talleres y reuniones con facultativos adscritos al servicio de rehabilitación; desde mitad de 2018 a finales de 2019.
- Participación en el proyecto Zinkinn, dirigido a promover y difundir proyectos de investigación y desarrollo a través de videos y artículos web divulgativos. El artículo y video divulgativo se tituló *"Dispositivos Smart Health: Innovación para su Aplicación Efectiva en Clínica"* y fue publicado el 9 mayo de 2019.
- Presentación y debate con los médicos especialistas y residentes del servicio de rehabilitación del citado hospital acerca de los avances y resultados del proyecto de investigación. El 13 de noviembre de 2019.

4.1.2. Estancia de Investigación

En septiembre de 2017 se realizó una estancia en el centro IOTAP en la universidad de Malmö, Suecia, de una duración de tres meses, en concreto, en el departamento de S*mart Health*. La profesora Nancy L. Russo, coordinadora de dicho departamento, fue la tutora de las actividades realizadas. Durante la estancia, se tuvo la oportunidad de colaborar en tareas de investigación relacionadas con la temática de la tesis de *Internet of Things*, interacción con el usuario, *wearables* o diseño de producto para *Smart Health*. Al respecto, destacan las siguientes actividades:

- Participación en el seminario de doctorado organizado por el citado departamento de Smart Health, donde se presentó el trabajo de investigación realizado hasta la

fecha, que resumía el estudio 2 (Octopus). El seminario tuvo lugar el 11 de septiembre de 2017.

- Exposición oral del estudio 1 de esta tesis, en la *7th International Conference on Current and Future Trends of Information and Communication Technologies in Healthcare* (ICTH 2017), celebrado en del Lund, Suecia, desde el 18 al 20 de septiembre de 2017.
- Colaboración en el proyecto *Walk the Ward*, expuesto en el estudio 15 (ver sección 4.2). Este proyecto tenía como objetivo mejorar la movilidad y sociabilización de pacientes de la tercera edad hospitalizados, mediante un juego interactivo. Por medio de *tablets,* los pacientes debían recorrer la planta (*Ward* en inglés) y escanear códigos QR, situados junto a cuadros decorativos. Tras el escaneo, la aplicación proponía preguntas y retos que los pacientes debían realizar individualmente o bien junto a otros pacientes, facultativos o familiares. Durante la participación se realizaron sesiones creativas con alumnos y personal del hospital.
- Participación en el estudio 14 (ver sección 4.2) que investigaba cómo diseñar aplicaciones que monitorizaran y favorecieran la salud emocional
- Realización de actividades en el laboratorio de IOTAP para el desarrollo de varios prototipos electrónicos. El conocimiento adquirido en estos desarrollos, permitió posteriormente trasladarlo a los sensores inerciales NGIMUS en el sistema MH. En concreto, la posibilidad de desactivar los magnetómetros, que fue una característica decisiva para llevar a cabo el caso de estudio de esta tesis.
- Asistencia a talleres y conferencias. Taller sobre el fomento de la creatividad en la empresa LEGO por Daniel Spikol (23 de octubre de 2017). Conferencia sobre *Smart Health* titulada "*Digital Health Now and in the Future: Some Perspectives from Social Research*", cuya ponente principal fue Deborah Lupton (6 de noviembre de 2017). Participación en el taller sobre *Smart Health* titulado "*A Smart Health Check Up: Current State and Potential Futures"* (1 de diciembre de 2017). Asistencia como oyente a clases de las asignaturas "*Designing Wearables*" impartida por David Cuartielles, e *"Interactivity*" impartida por Clint Heyer.

4.1.3. Implantación del Sistema MH en Clínica de Podología.

Desde el comienzo de esta tesis se participó en la implantación, personalización y adaptación del sistema MH en su configuración óptica (MH-OPT) para análisis de la marcha sobre tapiz rodante, en la Clínica del Pie de Moisés Pardos, ubicada en la ciudad de Zaragoza, España. La participación consistió en el montaje de las cámaras de visión, ajuste del tapiz rodante, diseño y fabricación de marcadores ópticos, adaptación del software, y diseño del informe adaptado a las necesidades del centro. Además, tras la instalación y el testeo se proporciona un soporte y colaboración que continúa actualmente.

4.1.4. Desarrollo de Instrumentación Complementaria

Durante el desarrollo de esta tesis doctoral, y enmarcado en el plan de investigación (estudio 1), se ha desarrollado tecnología para evaluar el sistema músculoesquelético,

que complementa la captura de movimiento y permite capturar bioseñales adicionales. En concreto, tal y como se expone en los siguientes puntos, se ha desarrollado una plataforma de equilibrio mono-axial, un dispositivo de dinamometría de manos, y un conjunto de sensores de electromiografía de superficie.

- **Plataforma de equilibrio.** La plataforma permite capturar y visualizar en tiempo real la proyección del centro de gravedad del sujeto en posición de bipedestación. La medición se realiza a través de cuatro celdas de carga situadas entre dos placas de aluminio. Esta plataforma permite aplicar el test de Romberg sobre superficie rígida, blanda, con ojos abiertos o cerrados, así como los test dinámicos de límites de estabilidad o el control rítmico direccional. Adicionalmente, permite medir el esfuerzo isométrico de elevación agarrando dos cinchas con las manos, las cuales están fijas a la base de la plataforma.
- **Dinamometría de mano.** Se trata de un dispositivo diseñado para objetivar la fuerza de prensión realizada con las manos, permitiendo visualizar y registrar la curva de fuerza en tiempo real. El equipo dispone de un agarre para cada mano y un mecanismo para seleccionar varios grados de apertura.
- **Sensores de electromiografía de superficie.** Se han llevado a cabo la integración de sensores de electromiografía de superficie en el software MH para la medida de la actividad muscular. Para ello, se han utilizado sensores *MyoWare Mucle Sensor* y la plataforma *Arduino*. Cada sensor se aloja en una carcasa fabricada con impresión 3D con material PLA 3D850. Los sensores se conectan mediante un cable con conexión tipo Jack de cuatro canales hasta una caja, donde se encuentra el dispositivo *Arduino* que se conecta por *Bluethooth* al ordenador. La solución implementada permite capturar y visualizar el tiempo real la señal electromiografía de hasta ocho canales simultáneos debidamente rectificada, integrada y sincronizada con el resto de las señales, ya sean de dinamometría o de movimiento.

Estas tecnologías se están utilizando en los distintos proyectos del grupo de investigación, especialmente en el proyecto con el Hospital MAZ de Zaragoza (apartado 4.1.5). Asimismo, la dinamometría se utiliza en la evaluación de puestos de trabajo apartado 4.1.6), para objetivar fuerzas que realizan los trabajadores.

4.1.5. Colaboración con el Servicio de Valoración Hospitalario

Desde principios del año 2019, se colabora con el Servicio de Valoración del Hospital MAZ Zaragoza para la realización de pruebas diagnósticas complementarias en el ámbito pericial y el seguimiento y control evolutivo de tratamientos de rehabilitación. Dicho proyecto, titulado *"Unidades móviles para Valoración Funcional del Sistema Musculoesquelético"*, se formalizó mediante un convenio de colaboración entre la Universidad de Zaragoza y MAZ. En este proyecto, las pruebas basadas en el sistema MH permiten valorar la capacidad funcional del paciente mientras ejecuta determinados movimientos o acciones, tomando medidas con captura de movimiento, dinamómetro de mano, plataforma de equilibrio o electromiografía. Podemos destacar las siguientes actividades donde se ha participado:

- Implantación de pruebas y formación para el uso del sistema.

- Sesiones de trabajo, talleres, y reuniones colaborativas con médicos y personal clínico asociado al proyecto, así como personal del departamento de Tecnologías de la Información y la Comunicación.
- Validación de protocolos para cada prueba, diseño colaborativo de informes y de guías uso e interpretación de resultados.
- Parametrización del software MH para la adecuación al servicio hospitalario y su integración en la red informática de MAZ.
- Asistencia en la realización de las pruebas y colaboración en recopilación de bases de datos de normalidad.
- Realización de pruebas en otros centros o ambulatorios de MAZ, con asistencia remota desde su laboratorio de biomecánica de Zaragoza.

4.1.6. Evaluación Ergonómica de Puestos de Trabajo.

Durante el desarrollo de la tesis, se ha colaborado en la evaluación ergonómica de puestos de trabajo. Al respecto, podemos destacar las colaboraciones con el Laboratorio de Ergonomía de Mutua Universal, Quirón Prevención, ASIME (Asociación de Industrias del Metal de Galicia) o Gesinor (Servicio de Prevención de Navarra) así como, la implantación del sistema MH-Sensors y métodos propios para evaluación ergonómica en empresas como BSH-Electrodomésticos, Volkswagen-Navarra o Magna Automotive Spain.

El Grupo de Investigación IDERGO lleva desarrollando durante más de 10 años el método ergonómico MH-Forces, que permite obtener el riesgo musculo esquelético en cada articulación a partir de una captura de movimiento en el propio puesto de trabajo (configuración MH-IMU). Como resultado, se puede elaborar un mapa de riesgos en el cual se identifican el nivel de riesgo por zonas anatómicas en cada uno de los puestos de trabajo de la empresa.

Estos resultados permiten realizar acciones de mejora ergonómicas en los puestos de trabajo. Asimismo, pueden favorecer la organización de rotaciones de los trabajadores entre distintos puestos, la reubicación de trabajadores sensibles con trastornos en determinadas articulaciones, así como promover una educación postural de buenas prácticas.

En este sentido, ciertos resultados de esta tesis han sido extrapolados al ámbito de la evaluación ergonómica. La posibilidad de desactivar los magnetómetros en los sensores inerciales ha sido un factor esencial para aplicar esta tecnología en el entorno industrial, donde las perturbaciones magnéticas son significativas y afectan negativamente al rendimiento de los sensores. Asimismo, el estudio 4 de esta investigación, ha supuesto un respaldo metodológico y científico en la validación del sistema MH para su aplicación en las evaluaciones ergonómicas, dado que la experimentación realizada para determinar la reproducibilidad del sistema también es un indicador clave para la realización de este tipo de mediciones.

4.2. Publicaciones Científicas Relacionadas

La figura 14 muestra en sombreado la línea argumental descrita en esta tesis (estudios 1-5), y su relación con ciertas publicaciones o comunicaciones científicas en las que se ha participado como coautor, junto a otros investigadores y doctorandos. Cabe destacar, que para la identificación de las comunicaciones se ha continuado con el sistema de numeración (estudios 6-19); asimismo, a lo largo de esta sección se indica la referencia completa a cada artículo, y la información relativa a la revista, siguiendo los criterios indicados al inicio del apartado 2 de este documento.

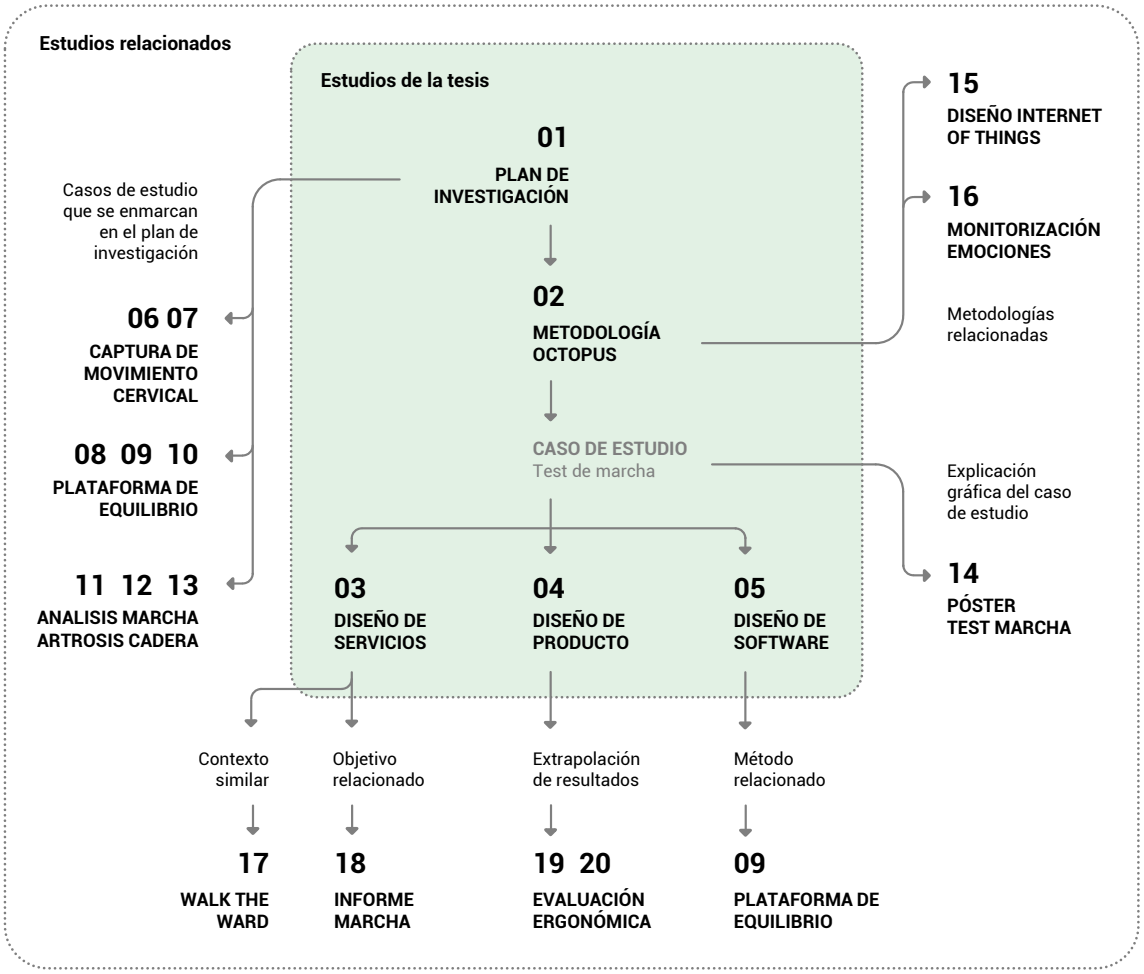


Fig 14. Publicaciones relacionadas.

Los estudios 6-10 fueron posibles gracias a la colaboración con otros miembros del Grupo de Investigación IDERGO. En ellas se participó en la conceptualización, revisión bibliográfica, y redacción de las mismas. Dichas publicaciones tal y como muestra la figura 14, se enmarcan en el plan de esta investigación.

Las dos primeras están relacionadas con la captura de movimiento del rango de movimiento cervical; una desarrolla el protocolo y validación de la medición del rango cervical aplicando movilización pasiva y activa con sistema de captura de movimiento óptico; y otra, muestra una metodología para aplicar técnicas de *Machine Learning* a los datos proporcionados por el sistema de captura en el ámbito de la salud. Las tres siguientes son relativas a las pruebas con plataforma de equilibrio. La primera valida el

equipo, el protocolo y selecciona aquellas variables más representativas para el análisis. La siguiente expone cómo monitorizar individuos en rehabilitación con posturografía comparando entre dos capturas, y utiliza un método similar al del estudio 5. La última, muestra un método que permite interpretar la comparativa entre dos capturas y proporciona resultados en lenguaje natural dirigido a facilitar la interpretación clínica de los resultados.

- **Estudio 6:** Moreno, A.J., Utrilla, G., Marín, J., Marín, J.J., Sánchez-Valverde, M.B., Royo, A.C. (2017). Cervical Spine Assessment using Passive and Active Mobilization Recorded through an Optical Motion Capture. *Journal of chiropractic medicine, 17*, 167-181. https://doi.org/10.1016/j.jcm.2017.12.004

  BD: SJR | FI: 0.337 | Q: *Health Professions: Chiropractics* (Q2 – 4/9)

- **Estudio 7:** De la Torre, J., Marín, J., Ilarri, S., Marín, J.J. (2020). Applying Machine Learning for Healthcare: A Case Study on Cervical Pain Assessment with Motion Capture. *Applied Sciences, 10*, 5942. https://doi.org/10.3390/app10175942

  BD: JCR | FI: 2.474 | Q: *Multidisciplinary Engineering* (Q2 – 32/91)

  Applied Physics (Q2 – 63/155)

  Multidisciplinary Materials Science (Q3 -161/314)

  Multidisciplinary Chemistry (Q2 – 88/177)

- **Estudio 8:** De la Torre, J., Marín, J., Marín, J.J., Auría, J.M., Sánchez-Valverde, M.B. (2017). Balance Study in Asymptomatic Subjects: Determination of Significant Variables and Reference Patterns to Improve Clinical Application. *Journal of Biomechanics, 8, 161-168.* https://doi.org/10.1016/j.jbiomech.2017.10.013

  BD: JCR | FI: 2.730 | Q: *Biomedical Engineering"* (Q2 – 31/78)

  Biophysics" (Q3 – 39/72)

- **Estudio 9:** De la Torre, J., Marín, J., Polo, M., Marín, J.J. (2020). Applying the Minimal Detectable Change of a Static and Dynamic Balance Test using a Portable Stabilometric Platform to Individually Assess Patients with Balance Disorders. *Healthcare*, 8, 4, 402. https://doi.org/10.3390/healthcare8040402

  BD: JCR | FI: 1.916 | Q: *Health Care Sciences and Services* (Q3 – 62/102)

  Health Policy and Services" (Q3 – 45/87)

- **Estudio 10:** De la Torre, J., Marín, J., Polo, M., Gómez-Trullen E.M., Marín, J.J. (2021). MCQ-Balance: A method to monitor patients with balance disorders and improve clinical interpretation of posturography. *PeerJ.* Accepted for publication.

  BD: JCR | FI: 2.379 | Q: *Multidisciplinary Sciences* (Q2 – 32/71).

Los estudios 11-13 también se encuadran en el plan de esta investigación (ver figura 14). Este caso de estudio relacionado fue liderado por colaboradores del ámbito de la fisioterapia, quienes llevaron a cabo una experimentación con pacientes con artrosis unilateral de cadera, a los cuales se les aplicó tratamiento con punción seca. En estos

estudios se participó en la configuración del equipo para la toma de datos, concretamente se utilizó la configuración MH-OPT sobre tapiz rodante.

- **Estudio 11:** Ceballos-Laita, L., Jiménez-del-Barrio, S., Marín-Zurdo, J., Moreno-Calvo, A., Marín-Boné, J., Albarova-Corral, M.I., Estébanez-de-Miguel, E. (2021). Effectiveness of dry needling therapy on pain, hip muscle strength and physical function in patients with hip osteoarthritis: a randomized controlled trial. *Archives of Physical Medicine and Rehabilitation*. Accepted for publication.

  BD: JCR | FI: 3.098 | Q: *Rehabiltiation* (Q1 – 9/68)

  Sports Sciences (Q1 – 17/84)

- **Estudio 12**: Ceballos-Laita, L., Jiménez-del-Barrio, S., Marín-Zurdo, J., Moreno-Calvo, A., Marín-Boné, J., Albarova-Corral, M.I., Estébanez-de-Miguel, E. (2020). Effects of Dry Needling on Pain, Pressure Pain Threshold and Psychological Distress in Patients with Mild to Moderate Hip Osteoarthritis: Secondary Analysis of a Randomized Controlled Trial. *Complementary Therapies in Medicine, 51*, 102443. https://doi.org/10.1016/j.ctim.2020.102443

  BD: JCR | FI: 2.063 | Q: *Integrative and Complementary Medicine* (Q2 – 14/28)

- **Estudio 13:** Ceballos-Laita, L., Jiménez-del-Barrio, S., Marín-Zurdo, J., Moreno-Calvo, A., Marín-Boné, J., Albarova-Corral, M.I., Estébanez-de-Miguel, E. (2019) Effects of Dry Needling in HIP Muscles in Patients with HIP Osteoarthritis: A Randomized Controlled Trial. *Musculoskeletal Science and Practice, 43*, 76-82. https:// doi.org/10.1016/j.msksp.2019.07.006

  BD: JCR | FI: 1.911 | Q: *Rehabilitation* (Q2 – 23/68).

Enmarcado en el caso de estudio, se elaboró un poster (estudio 14) que resumía el el test de análisis de la martcha aplicable a rehabilitación en colaboración el Hospital Miguel Servet de Zaragoza. El póster se presentó en una ponencia oral en las Jornadas Doctorales del Campus Iberús.

- **Estudio 14:** Marín, J., Blanco, T., Marín, J.J. (2018). Diseño de Dispositivos Smart Health, Innovación Para su Aplicación Efectiva en Clínica. *V Jornadas Doctorales de Campus Iberus*, Jaca, España.

A partir de la colaboración con el Grupo de Investigación Howlab se participó en la conceptualización, redacción y elaboración de material visual del estudio 15. Este trabajo presenta una metodología denominada Cosica, que de forma similar al estudio 2 (Octopus), proporciona especificaciones y técnicas para diseñar productos enmarcados en el *Internet of Things*. Este estudio se encuentra en su versión *preprint*.

- **Estudio 15:** Blanco, T., Casas, R., Marín, J., & Marco, Á. (2021). Designing on the Internet of Things. A multidisciplinar instructional methodology. *Preprint*. Contact: Blanco, T., tblanco@unizar.es, Univesity of Zaragoza.

Gracias a la estancia de investigación realizada en Malmö, se participó en la recopilación del estado del arte del estudio 16, que de forma análoga a los estudios 2 y 15, proporciona guías, factores, o pautas para diseñar un tipo de producto concreto; en este caso, aplicaciones que monitoricen y favorezcan la salud emocional. En esta

publicación se analizan las limitaciones que presentan este tipo de aplicaciones y, se aporta una recopilación de los factores que deberían considerarse para su diseño.

- **Estudio 16:** Eriksson, J., Russo, N.L., Marín, J. (2018). Using the Internet of Things to Support Emotional Health. *EAI Endorsed Transactions on Ambient Systems*, 17. https://doi.org/10.4108/eai.23-3-2018.154372

Asimismo, la estancia de investigación también permitió la participación en el estudio 17. Este documento recoge el proyecto Walk the Ward, que se describe en el apartado 4.1. La profesora, Nancy L. Russo, expuso los avances de dicho proyecto en el congreso *Academy for Information Systems* en el Reino Unido. Tal y como muestra la figura 14, se trata de un trabajo, que por su temática, se relaciona con el estudio realizado para la integración de un micro-servicio en un macro-servicio hospitalario.

- **Estudio 17:** Russo, N.L., Eriksson, J., Harden Mugelli, S., Marín, J. (2018). Small Steps: Improving Healthcare with Local Innovation. *UK Academy for Information Systems (UKAIS) 23rd Annual Conference*, Oxford, UK.

El estudio 18 se realizó de manera paralela al estudio 3. Esta investigación permitió reflexionar sobre posibles métodos de trabajo colaborativos para diseñar informes de análisis de la marcha. El estudio 18 se presentó en una ponencia en la VIII Reunión del Capítulo Español de la Sociedad Europea de Biomecánica.

- **Estudio 18:** Marín, J., De la Torre, J., Moreno A, Aragüés J.C., Marín, J.J. (2018). Análisis de la Marcha en Rehabilitación. Diseñando Informes con Mayor Utilidad Clínica. *VIII Reunión del Capítulo Español de la Sociedad Europea de Biomecánica (ESB)*, Castellón, España.

Finalmente, motivado por las evaluaciones ergonómicas que se realizan en el grupo de investigación, se redactaron los estudios 19 y 20; contando en este último con la colaboración de técnicos ergónomos de Mutua-Universal. Ambos fueron expuestos en el congreso *WeRob* en formato virtual. En ellos, se describe el desarrollo realizado para evaluar, de manera predictiva, los efectos de un exoesqueleto para asistencia lumbar en puestos de trabajo de manipulación de cargas. Estos trabajos se relacionan con el estudio 4, ya que las contribuciones realizadas a la captura de movimiento, en relación a la desactivación de magnetómetros, aportaron un avance fundamental en las evaluaciones ergonómicas realizadas por el grupo de investigación.

- **Estudio 19:** Marín, J., De la Torre, J., Marín, J.J. (2020). MH-Forces, a Motion-Capture Based Method to Evaluate Workplace Ergonomics: Simulating Exoskeleton Effects. *International Symposium on Wearable Robotics (WeRob)*, Virtual and Vigo, Spain.
- **Estudio 20:** Planas-Lara, A.E., Ducun-Lecumberri, M., Tomás-Royo, J.A., Marín, J., Marín, J.J. (2020). Objective Techniques to Measure the Effect of an Exoskeleton. *International Symposium on Wearable Robotics (WeRob)*, Virtual and Vigo, Spain.

5. Conclusiones

5.1. Conclusiones de la Investigación

Como resultado de esta investigación basada en cinco publicaciones internacionales, se derivan tres bloques de conclusiones. El primer bloque responde al OB-1 y se relaciona con el diseño de instrumentación dirigida a evaluar el sistema musculoesquelético, como la captura de movimiento, la dinamometría, o las plataformas de equilibrio.

- Es necesario y factible diseñar instrumentación orientada a evaluar el sistema musculoesquelético desde la perspectiva de diseño centrado en el usuario.
- El diseño de esta instrumentación debe abordarse desde los tres niveles de la metodología Octopus: diseño de servicio, producto y software; los cuales están relacionados y deben retroalimentarse.
- Las especificaciones de diseño de los tres niveles deben nacer del servicio, es decir, del conjunto de actividades que satisface las necesidades de los usuarios a través de los diferentes materiales y procedimientos. Por tanto, la perspectiva de diseño de servicios debe prevalecer sobre el resto y guiar los requerimientos de todo el conjunto.

Las siguientes conclusiones abordan el OB-2 y se centran en la metodología propuesta Octopus, cuyo propósito es facilitar el diseño de sistemas de captura de movimiento.

- La metodología Octopus establece un hilo conductor en el proceso de diseño de sistemas de captura de movimiento desde un punto de vista multidisciplinar, y promueve el desarrollo de productos con alta aceptabilidad e integración en el contexto.
- Octopus acuña el concepto de *MoCap-wearables*, que defiende que los sistemas de captura basados en IMUs, y los sistemas ópticos basados en sólidos rígidos, comparten el objetivo de desarrollar *wearables* para cada segmento corporal a capturar.
- Para abordar el diseño, esta metodología propone el estudio y análisis de los siguientes factores: contexto, interacción entre usuarios, características de la tecnología a utilizar, propiedades físicas de los *wearables*, métodos de unión y posicionamiento en el cuerpo, así como gestión de datos.

Finalmente, el último bloque de conclusiones da respuesta al OB-3. La aplicación de Octopus en el ámbito biosanitario y en el contexto de *Smart Health*, se materializó en el diseño de un sistema de captura de movimiento para análisis de la marcha en rehabilitación. Del diseño de este sistema se derivan las siguientes conclusiones.

- Un sistema de análisis de la marcha que permita realizar sesiones de medida pre- y post-tratamiento para el seguimiento de la rehabilitación apoya las decisiones clínicas, mejora la eficacia y personalización de los tratamientos, facilita la comunicación con el paciente y entre facultativos, retroalimenta positivamente a pacientes y terapeutas, y crea bases de datos útiles para el diagnóstico y la investigación.
- Para integrar un micro-servicio, como el test de marcha, en un macro-servicio, como el servicio de rehabilitación, es necesario estudiar el efecto del producto en el usuario, el valor del micro-servicio en el macro-servicio, y las interacciones entre

usuarios. Para ello, es útil aplicar métodos cualitativos como la observación in situ del test de marcha con los pacientes, así como talleres y entrevistas con clínicos.

- Se ha demostrado que es posible ofrecer una solución tecnológica completa de captura de movimiento que permita realizar un test de marcha en un corto periodo de tiempo (sistema MH). El protocolo asociado a este test, así como los algoritmos de cálculo diseñados, tanto en su versión inercial (MH-IMU) como óptica (MH-OPT), han alcanzado una reproducibilidad clasificada como "excelente" (en las variables seleccionadas un ICC promedio de 0.90 para configuración inercial y 0.93 para la configuración óptica), que iguala e incluso mejora los resultados descritos en la literatura.
- Respecto a los algoritmos de cálculo propuestos para el sistema MH, cabe destacar que la calibración anatómica presentada se puede realizar ágilmente, se transmite de forma sencilla al paciente y, cuando se aplica a la configuración inercial, permite desactivar los magnetómetros, lo cual supera una limitación significativa de esta tecnología. Por su parte, la detección de *gait events* no requiere de un tiempo de post-proceso adicional ni de instrumentación complementaria durante la prueba.
- Finalmente, podemos afirmar que el método propuesto para comparar las sesiones pre- y post-tratamiento es útil para realizar el seguimiento de pacientes en rehabilitación. Este método identifica aquellos cambios que superan los errores propios de la instrumentación y la variabilidad del participante, por lo que además de ser una opción de procesado de datos automatizada, es una opción realista, que puede favorecer la creación de informes eficientes y visuales para ayudar en la toma de decisiones clínicas.

5.2. Research Conclusions

As a result of this research based on five international papers, three sections of conclusions are derived. The first section answers the OB-1 and is related to the instrumentation design for the musculoskeletal system assessment, like motion capture, dynamometry, or balance platforms.

- It is necessary and feasible to design instrumentation to evaluate the musculoskeletal system from a user-centred design perspective.
- This instrumentation design must be addressed from the three levels of the Octopus methodology: service, product and software design; which are related and should feedback each other.
- The design specifications of the three levels must arise from the service; that is, from the activities that satisfy the users' needs through different materials and procedures. Therefore, the service design perspective must prevail over the rest and guide the whole system's requirements.

The following conclusions face the OB-2 and are focused on the proposed Octopus methodology, aimed to favour the design process of motion capture systems.

- The Octopus methodology establishes guidelines to design motion capture systems from a multidisciplinary perspective promoting the development of products with higher acceptability and context integration.
- This methodology poses the concept of MoCap-wearables, which defends that capture systems based on IMUs and optical systems based on rigid bodies, share the objective of developing wearables for each body segment to be captured.
- To address the design, the methodology proposes the study and analysis of the following factors: context, users' interaction, technology characteristics, physical properties of wearables, methods of body attachment and positioning, as well as data management.

Finally, the last section of conclusions answers the OB-3. The application of Octopus in the healthcare field and the Smart Health context resulted in designing a motion capture system for gait analysis in rehabilitation. From the design of this system, the following conclusions arise.

- A gait analysis system that allows conducting pre- and post-treatment measurement sessions to monitor patients in rehabilitation supports clinical decisions, improves personalisation and efficiency of treatments, facilitates communication between clinicians and with the patient, provides positive feedback to patients and therapists, and creates useful databases for diagnosis and research purposes.
- To integrate a micro-service, such as a gait test, into a macro-service, such as the rehabilitation service, it is necessary to study the proximity effect of the product on the user, the value of the micro-service in the macro-service, and interactions between users. For this purpose, it is useful to apply qualitative methods such as observation of the gait test with patients, or workshops and interviews with clinicians.

- It has been shown that it is possible to offer a complete motion capture technology solution that allows conducting the gait test in a short time (MH system). The protocol associated with this test, as well as the designed algorithms for the inertial (MH-IMU) and optical (MH-OPT) configurations, have achieved a reproducibility that can be classified as "excellent" (an average ICC 0.90 for inertial configuration and 0.93 for optical configuration in the selected variables), which equals and even improves the results described in the literature.
- Regarding the calculation algorithms proposed for the MH system, it should be noted that the anatomical calibration presented can be performed rapidly, can be easily transmitted to the patient and, when it is applied to the inertial configuration, it allows the magnetometers to be deactivated, which overcomes a significant limitation of this technology. For its part, the gait events detection algorithm does not require additional post-processing time or additional instrumentation during the test, which implies a notable advantage.
- Finally, we highlight that the proposed method for comparing pre- and post-treatment sessions is a useful tool for monitoring rehabilitation patients. This method identifies those changes that exceed the instrumentation errors and the participant's variability; therefore, in addition to being an automated data management option, it is a realistic option, favouring the development of efficient and visual reports to aid in clinical decision making.

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7. Anexos

Como información complementaria, se incluyen las contribuciones del doctorado a cada uno de las publicaciones (7.1) y el factor de impacto y categoría de las resistas en las que se publicaron los estudios que conforman esta investigación (7.2).

7.1. Contribución del Doctorado a los Artículos

Definir las contribuciones específicas ha sido una inquietud presente a lo largo de todos los capítulos de esta investigación, ya que esta tesis nace con una tecnología en un estado de desarrollo avanzado. A largo del documento se ha especificado los puntos de partida y aquellas acciones concretas llevadas a cabo. En cualquier caso, a continuación, se detallan las contribuciones específicas del doctorando a cada uno de los artículos realizados en coautoría.

Estudio 1: Marín, J., Blanco, T., Marín, J.J. (2017). Research Lines to Improve Access to Health Instrumentation Design. *Procedia Computer Science*, 113, 641-646. https://doi.org/ 10.1016/j.procs.2017.08.323

- Conceptualización e ideación.
- Revisión de literatura.
- Redacción del paper.
- Maquetación y arte gráfico.
- Redacción de carta al editor y gestión de envío a revista.
- Mejoras del paper según revisión de expertos.

Estudio 2: Marín, J., Blanco, T., Marín, J.J. (2017). Octopus: A Design Methodology for Motion Capture Wearables. *Sensors*, 17, 1875. https://doi.org/10.3390/s17081875

- Conceptualización e ideación.
- Revisión de literatura y mercado.
- Redacción del paper.
- Maquetación y arte gráfico.
- Redacción de carta al editor y gestión de envío a revista.
- Mejoras del paper según revisión de expertos.

Estudio 3: Marín, J., Blanco, T., Marín, J.J., Moreno, A., Martitegui, E., Aragüés, J.C. (2019). Integrating a Gait Analysis Test in Hospital Rehabilitation: A Service Design Approach. *Plos One*, 14, e0224409. https://doi.org/10.1371/journal.pone.0224409

- Conceptualización e ideación.
- Revisión de literatura.
- Ejecución de capturas de movimiento con pacientes.
- Planificación y ejecución de talleres con facultativos.
- Análisis de resultados.
- Redacción del paper y material complementario.
- Maquetación y arte gráfico.
- Redacción de carta al editor y gestión de envío a revista.

- Mejoras del paper según revisión de expertos.

Estudio 4: Marín, J., Blanco, T., de la Torre, J., Marín, J.J. (2020). Gait Analysis in a Box: A System Based on Magnetometer-Free IMUs or Clusters of Optical Markers with Automatic Event Detection. *Sensors*, 20, 3338. https://doi.org/10.3390/s20123338

- Conceptualización e ideación.
- Revisión de literatura y desarrollos previos del software MH.
- Ejecución de capturas de movimiento con voluntarios sanos.
- Desarrollo de software.
- Análisis de resultados.
- Redacción del paper y material complementario.
- Maquetación y arte gráfico.
- Redacción de carta al editor y gestión de envío a revista.
- Mejoras del paper según revisión de expertos.

Estudio 5: Marín, J., Marín, J.J., Blanco, T., de la Torre, J., Salcedo I., Martitegui, E. (2020). Is My Patient Improving? Individualized Gait Analysis in Rehabilitation. *Applied Sciences*, 10, 8558. https://doi.org/10.3390/app10238558

- Conceptualización e ideación.
- Revisión de literatura.
- Ejecución de capturas de movimiento con pacientes.
- Desarrollo de software.
- Análisis de resultados.
- Redacción del paper y material complementario.
- Maquetación y arte gráfico.
- Redacción de carta al editor y gestión de envío a revista.
- Mejoras del paper según revisión de expertos.

7.2. Factor de Impacto y Categorías de Revistas

A continuación, se describe la Base de Datos (BD) en la que está indexada cada revista, el Factor de Impacto (FI) y la categorías y cuartiles (Q) ordenadas según conexión temática con la tesis. Estos datos corresponden al año de publicación, excepto en las publicadas en 2020 (estudios 4 y 5), que se toma la información del último año disponible, 2019

Estudio 1: Marín, J., Blanco, T., Marín, J.J. (2017). Research Lines to Improve Access to Health Instrumentation Design. *Procedia Computer Science*, 113, 641-646. https://doi.org/ 10.1016/j.procs.2017.08.323

BD: SJR | FI: 0.258 | Q: *Computer Science: miscellaneous* (Q2 - 145/570)

Estudio 2: Marín, J., Blanco, T., Marín, J.J. (2017). Octopus: A Design Methodology for Motion Capture Wearables. *Sensors*, 17, 1875. https://doi.org/10.3390/s17081875

BD: JCR | FI: 2.475 | Q: *Instruments and Instrumentation* (Q2 - 16/61)
Chemistry Analytical (Q2 - 31/81)
Electrochemistry (Q3 – 15/28)

Estudio 3: Marín, J., Blanco, T., Marín, J.J., Moreno, A., Martitegui, E., Aragüés, J.C. (2019). Integrating a Gait Analysis Test in Hospital Rehabilitation: A Service Design Approach. *Plos One*, 14, e0224409. https://doi.org/10.1371/journal.pone.0224409

BD: JCR | FI: 2.740 | Q: *Multidisciplinary sciences* (Q2 – 27/71)

Estudio 4: Marín, J., Blanco, T., de la Torre, J., Marín, J.J. (2020). Gait Analysis in a Box: A System Based on Magnetometer-Free IMUs or Clusters of Optical Markers with Automatic Event Detection. *Sensors,* 20, 3338. https://doi.org/10.3390/s20123338

BD: JCR | FI: 3.275 | Q: *Instruments and Instrumentation* (Q1 – 15/64)
Engineering, Electrical and Electronic (Q2 – 77/266)
Chemistry analytical (Q2 - 22/86)

Estudio 5: Marín, J., Marín, J.J., Blanco, T., de la Torre, J., Salcedo I., Martitegui, E. (2020). Is My Patient Improving? Individualized Gait Analysis in Rehabilitation. *Applied Sciences*, 10, 8558. https://doi.org/10.3390/app10238558

BD: JCR | FI: 2.474 | Q: *Multidisciplinary Engineering* (Q2 – 32/91)
Applied Physics (Q2 – 63/155)
Multidisciplinary Materials Science (Q3 -161/314)
Multidisciplinary Chemistry (Q2 – 88/177)

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