Universidad Rey Juan Carlos

DOCTORAL THESIS

A framework for the User-Centered Design of personalized hybrid wearable robots for gait rehabilitation

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“Anything you dream is fiction, and anything you accomplish is science,
the whole history of mankind is nothing but science fiction.”

Ray Bradbury

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Dedication

To my mother and my grandmother, the admirable women who raised me and inspired me to embark on this challenging journey, the goal of becoming a doctor is for you, for this is your dream.

A mis madres.

Porque este es su sueño. Porque ustedes me han permitido cumplir todos los míos, incluso aquellos que nunca soñé.

Summary

Wearable robotic devices (WRD) -either alone or combined with muscular electrical stimulation- for walking rehabilitation were supposed to provide higher clinical outcomes compared with traditional rehabilitation therapy, albeit the clinical evidence shows modest outcomes. One of the rationales of this lack of performance points towards the mismatch between user needs and the system's main features (mechatronic design, configuration, type of assistance). The state of the art highlights the limited evaluation of user satisfaction with WRD, the need to improve the usability of the devices, and the lack of reliable and valid instruments to assess the devices from the user's perspective. Consequently, it urges to involve people with neurological injuries in the design of WR to create devices that meet their needs, because users may only accept a technology if it is useful for their own purposes. User-centered design (UCD) is an approach that focuses on considering the users of a device as the center of an iterative design process. Despite its name can be misleading, it does not only consider design stages but rather all the stages involved throughout the design, development, and evaluation of technologies. In the case of robotic devices for gait rehabilitation, these stages involve different types of users and stakeholders such as people with gait impairments, their caregivers, clinicians in charge of their rehabilitation, developers of the technologies, healthcare providers, and insurance companies. Therefore, the implementation of UCD for these technologies ought to consider them in the stages where each is involved. As can be foreseen, this means that an interdisciplinary approach is needed to effectively communicate, involve, and ultimately provide tools for all these users. The literature shows some efforts conducted in this regard, yet focused mainly on the technical requirements and performance of the devices instead of considering all the dimensions that are important for users. This thesis comprises the research conducted to provide tools for various of the aforementioned stakeholders in all the stages related to the development and use of WRD for gait assistance. This research aimed to provide a comprehensive framework for the UCD of personalized hybrid wearable robots for gait rehabilitation. The proposed framework comprises device design, novel metrics to comprehensively assess gait function in neurological injuries that can be applied both during robot-assisted gait training (RAGT) and to assess gait improvement following rehabilitation –proposed based on studies exploring gait kinematic patterns of people with SCI–, creation and implementation of experimental protocols for personalizing devices and assistance, and lastly, a tool to facilitate and promote usability evaluation of the devices.

Resumen

Antecedentes

Se espera que los dispositivos robóticos portátiles (WRD) para la rehabilitación de la marcha, solos o combinados con estimulación eléctrica muscular, proporcionen mejores resultados clínicos que la terapia de rehabilitación tradicional, sin embargo, la evidencia clínica muestra resultados modestos. Una de las causas de este fenómeno es la diferencia entre las necesidades del usuario y las características del sistema (diseño mecatrónico, configuración, y tipo de asistencia). El estado del arte destaca la limitada evaluación de la satisfacción del usuario con WRD, la necesidad de mejorar la usabilidad de los dispositivos y la falta de instrumentos confiables y válidos para evaluar los dispositivos desde la perspectiva del usuario. En consecuencia, insta a involucrar a personas con lesiones neurológicas en el diseño de WRD para crear dispositivos que respondan a sus necesidades, porque los usuarios aceptan una tecnología solo si es útil para satisfacer sus necesidades. El diseño centrado en el usuario (UCD) es un enfoque que considera a los usuarios de un dispositivo como el centro de un proceso de diseño iterativo. El UCD no sólo considera las etapas de diseño sino también las etapas involucradas a de desarrollo y evaluación de tecnologías. En el caso de los dispositivos robóticos para la rehabilitación de la marcha, estas etapas involucran a diferentes tipos de usuarios y actores, que incluyen personas con afectación de la marcha, sus cuidadores, médicos a cargo de su rehabilitación, desarrolladores de tecnologías, proveedores de atención médica y compañías de seguros. Por lo tanto, la implementación de UCD para estas tecnologías debe considerarles en las etapas en las que cada uno esté involucrado. Para lograrlo se necesita un enfoque interdisciplinario que permita comunicarse con ellos, involucrarles y, en última instancia, proporcionar herramientas útiles para cada uno de estos actores. Algunos esfuerzos se han realizado en años recientes en este sentido, pero han estado centrados principalmente en los requisitos técnicos y el rendimiento de los dispositivos en lugar de considerar todas las dimensiones que son importantes para los usuarios.

Objetivos

Esta tesis comprende la investigación realizada para proporcionar herramientas a varios de los actores antes mencionados en todas las etapas relacionadas con el desarrollo y uso de WRD para rehabilitación de la marcha. En este sentido, el objetivo de esta tesis es proporcionar un marco integral para la implementación del UCD para robots vestibles híbridos y personalizables para la rehabilitación de la marcha.

Metodología

El marco propuesto comprende las etapas de: diseño del dispositivo (capítulo 3), métricas novedosas para evaluar de manera integral la función de la marcha en lesiones neurológicas que se pueden aplicar tanto durante el entrenamiento de la marcha asistido por robots (RAGT) como para evaluar la mejora de la marcha como consecuencia de la rehabilitación (capítulo 5), propuestas en base a estudios que exploran patrones cinemáticos de la marcha de personas con lesión medular (SCI) (capítulo 4), creación e implementación de protocolos experimentales para personalizar y evaluar los robots híbridos (capítulo 6) y, por último, una herramienta para facilitar y promover la evaluación de usabilidad de estos dispositivos (capítulo 7).

La metodología específica seguida para realizar las contribuciones en cada uno de estos campos tiene diferentes aproximaciones y aborda diferentes herramientas. Para el capítulo 3, se realizó un estudio cualitativo usando la metodología de análisis de contenido dirigido para definir los requisitos de los usuarios para el diseño de WRD para la rehabilitación de la marcha. Se recabaron los requisitos publicados en literatura previa con los que se crearon entrevistas semiestructuradas que fueron realizadas a personas con SCI con (6 personas) y sin experiencia (9 personas) en el uso de estas tecnologías y personal clínico a cargo de su rehabilitación (10 personas), con el objetivo de contrastar los requisitos expresados por esa población respecto a los disponibles en la literatura e indagar posibles códigos adicionales no reportados previamente. En el capítulo 4 se emplearon algoritmos de aprendizaje de máquina de agrupamiento y clasificación para indagar patrones de marcha dentro de la población con SCI e identificar los parámetros que permiten discriminar de forma óptima la cinemática de

esta población respecto a la de sujetos sin afectación de la marcha. El capítulo 5 presenta el desarrollo de una métrica de marcha clínicamente relevante que resume la cinemática de la población con SCI, que es computada a partir de datos de fotogrametría. Esta métrica, llamada *gait deviation index for spinal cord injury* (SCI-GDI), se obtiene a partir de la descomposición en valores singulares y la identificación de la cantidad mínima de componentes para formar una base ortonormal que permita reconstruir con fidelidad las curvas cinemáticas de una base de datos extensa de cinemática de personas con SCI. La base metodología matemática para la derivación de la métrica está inspirada en el *gait deviation index,* un índice que fue desarrollado originalmente con datos de población pediátrica con parálisis cerebral pero que ha sido ampliamente usada para valorar la marcha de diferentes poblaciones con afectaciones neurológicas. Una versión adaptada de esa misma métrica es desarrollada para ampliar su uso a sistemas de captura de movimiento más simples que la fotogrametría. Para ello, se suma el conocimiento clínico de la relevancia de los movimientos articulares contemplados para el cálculo de la métrica en la población específica de SCI, con la exploración matemática de los efectos de reducir las articulaciones requeridas para computar la métrica. Finalmente, para tener una valoración integral de la marcha, que contemple dimensiones relevantes y complementarias como son la cinemática, los parámetros espaciotemporales y las valoraciones funcionales, el último apartado del capítulo presenta la propuesta de una métrica integral para valoración de la marcha en el lesionado medular que comprende información clínicamente relevante y es intuitiva de interpretar. Para los estudios de los capítulos 4 y 5 se recabaron bases de datos retrospectivas de estudios de marcha realizados en el Hospital Nacional de Parapléjicos, en Toledo, España.

El capítulo 6 contiene el trabajo experimental de la tesis, en el que se presenta una estrategia de personalización para un exoesqueleto híbrido de rehabilitación de la marcha que se evalúa en un estudio piloto con 10 sujetos con SCI o ictus. La metodología de personalización fue definida para ser implementada rápidamente en el contexto clínico a partir del conocimiento de los profesionales de la salud involucrados en el proceso de rehabilitación de estos pacientes. Los resultados de la asistencia inmediata brindada por la tecnología personalizada se valoran a través de la cinemática y parámetros espaciotemporales de la marcha. El protocolo experimental también aborda la evaluación de usabilidad del sistema a través de escalas estandarizadas, dada la relevancia que tiene la usabilidad para los usuarios de estas tecnologías, como se evidenció en el capítulo 3. Finalmente, en línea con este último aspecto, el capítulo 7 presenta el proceso para definir un conjunto de atributos que abarcan la evaluación de usabilidad en WRD y la validación global de las definiciones construidas, de la relevancia de los atributos en el campo y de su aplicación en los desarrollos realizados por los desarrolladores que participaron en el estudio. Para ello, se realizó una encuesta online en la que participaron 70 desarrolladores de 17 países del mundo.

RESULTADOS

Para la fase de diseño de robots portátiles (WR) para la rehabilitación de la marcha se definió un conjunto de 78 requisitos, percepciones y expectativas que tienen las personas con SCI y los médicos a cargo de su rehabilitación. Los códigos fueron acordados por al menos el 20% de los usuarios entrevistados y se agruparon en 9 categorías. De las entrevistas del estudio surgieron de 16 códigos que no se identificaron en la literatura previa. Las estadísticas entre los códigos expresados por cada grupo muestran que existe un acuerdo limitado entre pacientes y médicos (50,00%) y entre ambos tipos de pacientes (55,77%). También se identificó que los pacientes y clínicos con experiencia en el uso de las tecnologías expresan requisitos de forma más puntual.

Respecto al trabajo del capítulo 4, los algoritmos de agrupamiento no encontraron patrones cinemáticos que tuviesen interpretación tomando como referencia las escalas clínicas disponibles claros en la base de datos usada. Se identificó una leve tendencia en la viabilidad de agrupar patrones con gran afectación de aquellos con afectación muy leve. Se evidenció que las variables espaciotemporales o cinemáticas permiten discriminar la marcha afecta de la no afecta al ser usados para entrenar algoritmos de clasificación.

En el capítulo 5 se evidenció la relevancia de desarrollar el SCI-GDI a partir de datos cinemáticos de población con SCI para obtener reconstrucciones que tengan alta fidelidad y que representen la alta variabilidad de

patrones propia de esta población. El índice se calcula con curvas de nueve articulaciones y segmentos de miembros inferiores y posteriormente se escala con respecto a una curva promedio de un grupo de sujetos control. La versión adaptada de la métrica que se desarrolla en la sección 5.2 usa información únicamente de 4 de estas articulaciones, que, además, son más fáciles de medir con precisión con sistemas de captura de movimiento alternativos a la fotogrametría. Los resultados muestran que la versión adaptada del índice es más generalizable que el SCI-GDI original, permitiendo reconstruir con más precisión curvas cinemáticas de datos que no fueron usados durante la derivación del índice. Además, el índice reducido muestra mejores correlaciones con múltiples escalas clínicas. Por último, la sección 5.3 muestra seis métricas de marcha representadas en un hexágono, para dar una visualización intuitiva al personal clínico. Las métricas seleccionadas muestran correlaciones moderadas o bajas, representando información completaría de la marcha.

En la ejecución experimental, se evidenció la viabilidad de la estrategia de personalización para ser usada en población con SCI e ictus con diferentes grados de afectación. Se encontró que la asistencia solo con estimulación eléctrica funcional (FES) es óptima para personas con baja afectación, mientras que la asistencia híbrida puede proveer beneficios cinemáticos para personas con afectación moderada o mayor. En población con ictus, la asistencia híbrida resulta interesante para trabajar la heminegligencia, aunque resulta más difícil para estos usuarios aprender a caminar con el exoesqueleto de miembro inferior. Los parámetros espacio temporales de la marcha empeoraron en todos los sujetos que usaron la asistencia híbrida, mientras que la mayoría de individuos que usaron solo FES, mejoraron tanto en estos parámetros como a nivel cinemático. En cada sujeto, la asistencia usada fue producto de un ajuste iterativo de la configuración planteada usando información observacional y perceptual de los clínicos y del paciente, lo que representa un proceso centrado en el usuario.

Finalmente, el capítulo 7 mostró consenso global alto o moderado en las definiciones de 42 de los 43 atributos comprendidos en el *Robotics Usability Glossary* (RUG). Para el atributo con consenso bajo, se propone una versión mejorada de la definición con base en los comentarios aportados por los participantes de la encuesta. La relevancia de 39 atributos fue considerada alta o moderada. En contraste, solo 25 atributos habían sido incluidos en los desarrollos previos de los participantes, lo que resalta la limitada implementación de la evaluación de usabilidad en WRD a pesar de su reconocida relevancia.

CONCLUSIONES

En general, esta tesis proporciona 1) criterios de diseño y asesoramiento a desarrolladores e investigadores para mejorar el diseño de los dispositivos a través de UCD (capítulo 3), 2) una estrategia para personalizar WRD híbridos para asistencia de la marcha junto con un protocolo experimental de asistencia personalizada con dichos dispositivos (capítulo 6), 3) una herramienta para ayudar a los desarrolladores de WRD a implementar la evaluación de usabilidad en sus desarrollos (capítulo 7), y 4) métodos para que investigadores y médicos evalúen de manera integral la marcha en lesiones neurológicas, con métricas desarrolladas específicamente para la población adulta con lesión medular (capítulo 5).

En cuanto a los requisitos para el diseño de WRD:

1. El conjunto integral de requisitos de los usuarios de exoesqueletos portátiles de miembros inferiores para la rehabilitación de la marcha se alinea parcialmente con los descritos anteriormente. Nuevos criterios surgieron de los datos recopilados en el estudio. Las personas con SCI y los médicos encargados de su rehabilitación tienen requisitos de diseño complementarios. Las diferencias en los requisitos de los usuarios primarios inexpertos y experimentados resaltan una brecha entre las ofertas tecnológicas actuales y las funcionalidades deseadas.

2. La baja participación de los usuarios durante el desarrollo de WRD para rehabilitación de la marcha se evidencia en los capítulos 3 y 7. Los médicos y las personas con lesión medular con experiencia con las tecnologías brindan retroalimentación enfocada y representativa de los requisitos de su grupo respectivo, por lo tanto, involucrar estos usuarios en los procesos de Diseño Centrado sería eficiente y útil para los desarrolladores.

Con respecto a la evaluación cuantitativa de la función de la marcha en lesión medular:

3. Diferenciar la variabilidad en el grado de deterioro de la marcha dentro de SCI sigue siendo un desafío para las métricas de evaluación.

4. El uso del GDI original en lesión medular puede llevar a una sobreestimación de la función de la marcha. El SCI-GDI desarrollado en esta tesis tiene mejores propiedades discriminativas con los niveles de WISCI II y es más sensible a mayores alteraciones de la marcha que el GDI, pero su sensibilidad disminuye con una función de la marcha menos deteriorada.

5. El SCI-GDI reducido permite ampliar el uso del SCI-GDI a tecnologías más simples que la fotogrametría sin perder precisión. Representa efectivamente la variabilidad de la marcha de adultos con SCI al igual que el SCI-GDI y se correlaciona mejor con otras escalas clínicas validadas en lesión medular.

6. Se proporciona una nueva métrica clínicamente significativa y fácil de entender para resumir de manera integral la marcha en pacientes con SCI. Abarca aspectos cinemáticos, espaciotemporales y funcionales de la marcha con pruebas validadas en la población con SCI.

7. Todas las metodologías usadas en este ámbito pueden aplicarse a poblaciones con otras lesiones neurológicas adaptando los datos y pruebas clínicas usadas, lo que resulta fundamental para adaptarse a las especificidades de la afectación motora propias de cada una de ellas.

En cuanto a la personalización de WRD:

8. La estrategia de personalización proporcionada para configurar tecnologías y sus parámetros de acuerdo con las necesidades del individuo demostró ser eficaz para grados de afectación heterogéneos. Se recomienda el uso de FES cuando en sujetos con discapacidad baja y el uso de asistencia híbrida para sujetos con discapacidad moderada a alta y para aquellos con marcada asimetría.

Con respecto a la evaluación de usabilidad de WRD:

9. El RUG proporciona un conjunto de atributos para evaluar la usabilidad de WRD. El consenso y la relevancia de estos UA fueron respaldados por las calificaciones de 70 desarrolladores de WRD de 17 países de todo el mundo. Es necesario considerar varios de estos atributos para realizar una evaluación integral de la usabilidad.

10. Falta énfasis en la usabilidad en el desarrollo de dispositivos, a pesar de su reconocida importancia. Integrar la evaluación de usabilidad para robots portátiles es crucial para alinear las percepciones de los desarrolladores con las necesidades de los usuarios. Se proporciona a los desarrolladores una herramienta para evaluar atributos de usabilidad con definiciones específicas consensuadas por la comunidad, lo que permite una evaluación y comparación sistemática de la usabilidad de diferentes dispositivos con contextos de uso común.

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ACRONYMS AND ABBREVIATURES

10MWT	10-meter Walking Test
3D	Three-dimensional
3DGA	Three-dimensional gait analysis
6MWT	Six-minute walking test
AIS	ASIA Impairment Scale
AITADIS	Asociación Iberoamericana de Tecnologías de Apoyo a la Discapacidad
ANOVA	Analysis of Variance
ASIA	American Spinal Injury Association
ASTM	American Society for Testing and Materials
BBS	Berg balance scale
BCI	Brain-computer interfaces
BSoD	Best Sum of Distances
CE	European Conformity
CEIC-CHTO	Institutional Review Board at the Ethics Committee of the Hospital Complex of Toledo, Spain
CG	Control group
COST	European Cooperation in Science and Technology
CP	Cerebral palsy
CPG	Central pattern generator
CREB	Research Centre for Biomedical Engineeering
e-SCI	Patients with SCI with previous experience with WR
ETH	Eidgenössische Technische Hochschule (Federal Institute of Technology)
FAC	Functional Ambulation Category
FES	Functional Electrical Stimulation
FLM	Fundación del Lesionado Medular, Madrid, Spain
GC	Gastrocnemius
GDI	Gait deviation index
GM	Gluteus Maximus
GPS	Gait Profile Score
GVS	Gait variable score
HNP	National Hospital for Paraplegics, Toledo, Spain
HR	Hybrid robots
HS	Hamstrings
HWR	Hybrid wearable robot
IBERDISCAP	Congreso Iberoamericano de Tecnologías de Apoyo a la Discapacidad
IG	Institut Guttmann
IMU	Inertial measurement units
iSCI	Incomplete spinal cord inujry
IUT	The Interactive Usability Toolbox
KAFOs	Knee-ankle-foot orthosis
KS	Kolmogórov-Smirnov
LEMS	Lower Extremity Motor Score
MAS	Modified Ashworth Scale
NP	Neuroprosthetics
NRG	Neural Rehabilitation Group
n-SCI	Patients with SCI without previous experience with WR

PCA	Principal component analysis
PM&R	Physical medicine and rehabilitation physician
PSR	Paretic step ratio
PT	Physiotherapists
QF	Quadriceps
QUEST	Quebec user evaluation of satisfaction with assistive technology
RAGT	Robot assisted gait training
RCT	Randomized control test
RELab	Rehabilitation Engineering Laboratory, ETH Zurich, Switzerland
RPE	Rate of Perceived Exertion
rSCI-GDI	Reduced gait deviation index for spinal cord injury
RUG	Robotics Usability Glossary
SCI	Spinal cord injury
SCI-GDI	Gait deviation index for spinal cord injury
SMS	Sensory-Motor Systems,ETH Zurich, Switzerland
SSD	Statistically significant differences
STD	Standard deviation
SUS	System Usability Scale
SVD	Singular Value Decomposition
TA	Tibialis Anterior
TAILOR	Personalized Robotic and Neuroprosthetic Modular Wearable Systems for Assistance of Impaired Walking
TD	Typically developing
TFL	Tensor Fasciae Latae
TRL	Technology Readiness Level
TUGT	Timed Up and Go test
UA	Usability attributes
UCD	User Centered Design
UPC	Universitat Politècninca de Catalunya
URJC	Universidad Rey Juan Carlos, Madrid, Spain
VAF	Variance accounted for
WISCI	Walking Index for Spinal Cord Injury
WR	Wearable robots
WRD	Wearable Robotic Devices

LIST OF ANNEXES

Annex 1. Full list of requirements of people with Spinal Cord Injury and clinicians for the design of lower limb wearable exoskeletons for gait rehabilitation (section 3.1).

Annex 2. Worksheet to compute the GDI-SCI (section 3.3.1).

Annex 3. Worksheet to compute the rGDI-SCI (section 3.3.2).

Annex 4. Individual ratings of the usability attributes included in the Robotics Usability Glossary obtained in both local and global validation stages. All the comments provided by the respondents and the improved definitions are also included (section 3.5).

Annex 5. Detailed comparison between the previous works in the field and the attributes of the Robotics Usability Glossary that encompass their definitions (section 3.5).

1. STATE OF THE ART

1.1. BACKGROUND

1.1.1. GAIT REHABILITATION AIDED BY ROBOTIC DEVICES AND FUNCTIONAL ELECTRICAL STIMULATION AFTER SPINAL CORD INJURY AND STROKE

Walking is an extraordinarily complex task requiring the integration of the entire nervous system, making gait susceptible to a variety of underlying neurologic abnormalities, such as Spinal Cord Injuries (SCI) and stroke. Mobility impairments affect the quality of life of people with neurological injuries, including their reintegration into social and productive activities [1]. Estimates of SCI prevalence widely vary across countries, with incidence rates from 52 to 56 cases per 1.000.000 inhabitants [2]. The average age of SCI is 33 years old, with men more affected than women with a 3.8:1 ratio [3]. From these, more than 95% experience mobility impairments [4], which can extend from complete paralysis to varying capacities of voluntary muscle activation and sensation [3]. Similarly, stroke is the third-leading cause of death and disability combined in the world, with an estimated incidence of 12 million cases each year, of whom 5 million become permanently disabled [5]. Despite both being injuries that affect the central nervous system, the structure affected by each of them is different, and thus, their clinical consequences. Specific scales and classification systems have been developed by international organizations to define the type of injury and degree of impairment that might arise after each of these neurological injuries.

SCI occurs when the nerves at any level of the spinal cord get damaged due to traumatic or non-traumatic events, affecting the functions of the organs innervated by the nerves at and below the injury. The spinal cord lies within the vertebral canal from the *medulla oblongata* to the L2 vertebral level, where it tapers off forming the *conus medullaris*, thus the level of the spinal cord is usually indicated by the vertebrae from which a spinal nerve root. This structure is the main route for information transmission linking the brain and peripheral nervous system because it contains both the sensitive (afferent) and the motor (efferent) fibers in the dorsal and ventral roots, respectively. Therefore, people with SCI experience alterations or lose of both sensory and motor functions [6]. The degree of impairment of each person depends on the location and extension of the damaged nerves of the spinal cord. In addition to motor impairments, individuals with SCI often experience neurogenic bowel or bladder dysfunction, potential respiratory complications, changes in sexual function, and psychological and emotional consequences, such as depression and anxiety [7]. The American Spinal Injury Association (ASIA) defined a set of guidelines to classify a SCI according to its severity and injury level [8] (see Figure 1). In this procedure, a physical medicine and rehabilitation (PM&R) physician assesses the muscular and sensory capacity of the patient in different parts of the body to identify the lowest preserved nerves and the severity of the injury. In this guideline, severity is classified following the ASIA Impairment Scale (AIS) into five levels depending on whether motor and sensory functions are partially or completely lost (see Table 1). It is common to refer to complete (AIS A or B) or incomplete (AIS C or D) spinal cord injuries. In some cases, this diagnosis is aided through medical imaging such as magnetic resonance to properly assess the extension of the damage and the persistence of inflammation in the spinal cord.

On the other hand, stroke occurs when blood flow to the brain is abruptly disrupted, leading to damage to brain tissue. This interruption can be ischemic, resulting from a blocked blood vessel, or hemorrhagic, caused by bleeding in the brain. The consequences after a stroke depend on the location and extent of the brain damage, which is also related to the amount of time the affected brain cells stood without blood flow. Nonetheless, a prominent consequence of stroke is hemiparetic motor impairment, affecting the contralateral side of the body to the brain hemisphere where the stroke occurred. In addition to motor deficits, approximately one-third of stroke survivors experience some degree of cognitive impairments, affecting memory, attention, and executive functions. Hypertension, cardiac arrhythmias, urinary incontinence, and respiratory issues are also prevalent among stroke survivors [9, 10]. Stroke is commonly

classified according to the etiology of the cerebrovascular accident and the name of the vessel that caused it.

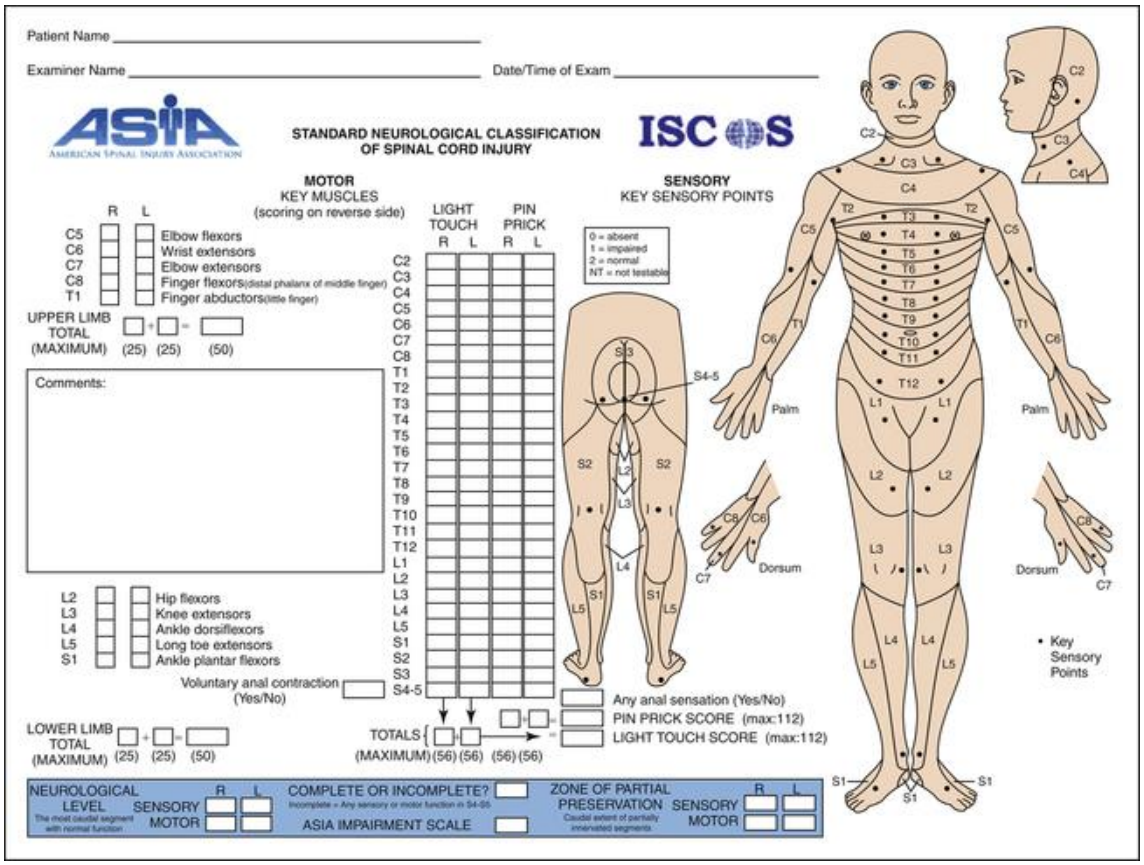

FIGURE 1. IMPAIRMENT SCALE SCORING SHEET FROM THE AMERICAN SPINAL INJURY ASSOCIATION **[8]**

TABLE 1. CLASSIFICATION OF THE SEVERITY OF A SPINAL CORD INJURY ACCORDING TO THE ASIA.

SCI severity level	Description
A	Injury is a complete spinal cord injury with no sensory or motor function preserved.
B	A sensory incomplete injury with complete motor function loss.
C	A motor incomplete injury, where there is some movement, but less than half the muscle groups are anti-gravity (can lift up against the force of gravity with a full range of motion).
D	A motor incomplete injury with more than half of the muscle groups are anti-gravity.
E	Normal

The overall objectives of rehabilitation after these neurological injuries are to increase personal independence and quality of life, minimizing the socio-economic burden [11]. Still, regardless of the severity of the SCI or stroke, the time after injury, or age at the time of injury, the restoration of walking is given high priority [12]. Gait rehabilitation includes therapeutic exercises for stretching and strengthening muscles, improving static and dynamic balance during standing and walking, improving coordination and motor control, and endurance training [13]. In the bigger picture, gait recovery starts with the ability to withstand standing, considering the cardiovascular, musculoskeletal, and proprioceptive requirements to achieve it; afterward, gait training starts aided by weight support systems whose assistance is gradually reduced until patients are capable of fully support themselves assisted by

the technical aids and orthoses, if needed. The process continues towards reaching a more independent gait ability, considering the reduction in the need for supervision or assistance from others, as well as the utilization of lighter technical aids and orthoses or their removal. The therapeutic process and goals of each patient are personalized according to the findings of the clinical, neurological, and functional assessments evaluated by the rehabilitation team at the moment of admission, and they are iteratively updated along the rehabilitation process [14].

Although there is no consensus on a unique gait rehabilitation paradigm or program, state-of-the art evidence shows that improvements in gait function are achieved by the exploitation of neuroplasticity, which plays a major role in training-induced recovery [15]. Intensive walking training is nowadays the basic strategy to enhance functional ambulation [11]. During training, the afferences to the spinal cord are stimulated, activating the neural circuits of the spinal cord responsible for the generation of rhythmic patterns of movement, in the central pattern generator (CPG). If the activation is maintained sufficiently over time, which is achieved through intensive locomotor training, it can induce plastic changes both at the level of the spinal cord and in the motor-sensory cortex in people with neurological injuries [16].

To provide intensive walking training, robotic devices were developed to allow longer training times in combination with monitoring changes in function. The first devices developed to this end were grounded exoskeletons over treadmill. During the last 25 years, many such devices have been developed and a few reached the market with the aim to achieve greater rehabilitation effects by inducing neuroplasticity through a higher number of movement repetitions. However, current clinical evidence claims that robotic-based rehabilitation interventions yield similar outcomes to traditional rehabilitation interventions [17] and that there is limited user acceptance and satisfaction with these technologies [18, 19]. The 10 randomized control test (RCT) studies that have been performed with the pioneer rehabilitation exoskeleton, the Lokomat [20], show no significant differences when comparing the therapeutic outcomes of using this device with the ones obtained through traditional rehabilitation. Moreover, the comparison between RAGT with grounded exoskeletons and traditional rehabilitation is still a matter of research due to the intrinsic difficulties in performing reliable and unbiased RCT with these technologies and the contrasting characteristics of each subject with neurological impairment [21].

Rationales for this lack of success are being discussed by the scientific community. The consensus is that the environmental context of training plays an important role in the motor learning process. Factors such as visual input, dynamic balance, and motor error induced by movement variability are eliminated within the restricted and controlled artificial training environment created by the robotic gait trainers [22]. In this sense, the field is experiencing a shift towards the use of ambulatory wearable robots (WR), which provide task-specific, contextually consistent, overground training. In contrast to non-portable robotic gait trainers, ambulatory WR optimally challenge the patient in the domains of balance and physical exercise, while providing visual and functional feedback consistent with the task. This provides an opportunity window for increasing rehabilitation outcomes, which is nowadays a subject of major research [15].

Nevertheless, quality clinical evidence of the outcomes attained with ambulatory WR is still limited and nonconclusive due to differences in interventions: robot type and control, treatment time and number of sessions [18]. According to the most recent systematic review on wearable lower-limb exoskeletons for gait training in neuromuscular impairments [21], there are only six RCT studies with lower limb exoskeletons for gait rehabilitation, five of them in post-stroke population. There is no RCT study with any of these technologies in SCI. Contrastingly, SCI is the neurological injury most often addressed among all the studies published with these technologies. Substantial improvements are found in this population in the observational and pilot studies found in the literature. Three studies have shown the benefits of these devices compared to passive knee-ankle-foot orthosis (KAFOs). Interestingly, most of the technologies available nowadays are developed for complete SCI, providing complete motor assistance to individuals,

but some devices in the field are working on including assist-as-needed controllers that can be used for the rehabilitation of incomplete SCI (iSCI). Despite SCI are the principal users of these technologies according to the literature, most of the clinical evidence and the most promising one attains the population with stroke. In light of this limited high-quality clinical evidence, the scientific community is questioning the basis of the design and application of rehabilitation robots. As a consequence, the field is recognizing the need to understand how to tune robot parameters depending on each patient's characteristics and therapeutic goals [19].

In parallel, researchers have combined rehabilitation robotics with other systems to add up their advantages and compensate for their drawbacks. An example of this are hybrid WRs (HWR), defined as the combination of a WR with functional electrical stimulation (FES) [23]. On its own, FES demonstrated to promote gait rehabilitation in incomplete SCI by promoting neuroplasticity during the acute and subacute periods after the injury, allowing motor relearning [24]. For people with iSCI or post-stroke, it has demonstrated to reduce motor impairments by increasing the participation of the subjects in voluntary activities [25]. It also provides secondary benefits derived from the artificial activation of the musculature [26] such as the improvement of force and prevention of atrophy [27]. However, the appearance of muscle fatigue and the non-linear response of the musculature make it difficult to use FES for gait assistance. Combining FES with an exoskeleton allows the compensation of muscle fatigue and improves movement control, increasing both the time of use and the quality of the movement generated [27]. This can be achieved through different approaches, for example, using electrical stimulation to aid some limbs' movement while the exoskeleton stabilizes, supports, and actuates other motions [28, 29], or implementing a cooperative control strategy, in which both assistances are realized on the same joint. The latter is more common in HWRs for lower limbs, mainly because the WRD can repeatably deliver power to allow fine control of joint movement that can compensate for the variable joint movement induced with the FES [30]. At the same time, neural plasticity and functional improvements are enhanced thanks to the intensive rehabilitation provided by the hybrid system and the integration of electric signaling of the nervous system induced by the FES. Nonetheless, there are several open challenges in the implementation of HWRs. The main one is the lack of strategies to optimally adapt the assistance provided by each system according to the specific functional need of each patient. Another one is the challenge of designing a hybrid control strategy that works harmonically for two systems with completely different actuation mechanisms that provide direct gait assistance by different means: musculoskeletal in the case of the WRD, and neurophysiological in the case of the FES. As indicated before, this is currently being studied in WRD, therefore, in hybrid systems the challenge of personalizing the FES and the interaction between both systems adds up.

To optimize the therapeutic assistance along the rehabilitation process, the evolution of gait rehabilitation needs to be measured to assess the effectiveness of the therapeutic approaches and technologies used. To this end, objective and observational measurements covering a wide range of measured outcomes and complexity are used. The gold standard for objective gait assessment is the three-dimensional gait analysis (3DGA), a technique used to capture the position and orientation of body parts using passive or active markers whose trajectory is recorded with cameras or sensors. After processing this data, the gait pattern of each subject can be objectively studied, allowing to quantify the disorders they present [31]. In addition, 3DGA provides a large amount of data describing the spatiotemporal gait parameters, together with three-dimensional (3D) pelvis, thigh, leg, and foot kinematics, as well as hip, knee, and ankle joint kinematics and kinetics during a gait cycle, along with specific values for each one of the gait phases and events [32]. This extensive information allows the exhaustive assessment of gait. It is usually presented with many graphs and tables, which are often both difficult and impractical to be understood by clinicians [33, 34]. Therefore, it is recognized that clinical interpretation of the 3DGA results needs to be facilitated to increase its usefulness in clinical settings. Simpler measures to assess spatiotemporal aspects of gait or

balance as well as categorical measures of ambulation are also available and are widely used in rehabilitation centers [35].

1.1.2. STATE OF THE ART IN THE USER-CENTERED DESIGN AND PERSONALIZATION OF LOWER LIMB WEARABLE ROBOTIC DEVICES FOR GAIT REHABILITATION

To date, user perspective of WRD devices for gait rehabilitation has been addressed by studying the perception of both patients and clinicians about the technologies after one session with a WRD through face-to-face interviews [36, 37], using online surveys with only patients [38, 39, 40] or clinicians [38, 40], or by assessing the number of developers that include users through the development of the technologies [41]. Longer studies have also been performed, where the authors evaluate patient's [42, 43, 44, 39, 45, 46, 47, 48, 49, 50] or clinician's [49, 51] perception after receiving training with a WRD, some of them with evolutive follow up throughout the study [46, 49, 39, 44]. Different stakeholders were approached in those studies, including patients with neuromusculoskeletal disorders, physiotherapists, occupational therapists, engineers developing the technologies, and salespersons. Increased awareness of the relevance of usability and acceptance of WRD devices for gait rehabilitation is evidenced in the growth of studies including these factors during technology evaluation [52]. Nonetheless, none of the studies available in the literature aims to identify comprehensive requirements that encompass the broader perspective of WR for gait rehabilitation. This involves a focus on understanding the needs and constraints of all stakeholders involved: subjects with neurological injuries as primary users, clinicians and caregivers as secondary users, and the real-life dynamics of rehabilitation centers. The findings of these studies demonstrate that, despite technical advances in the field, user acceptance and adoption of these technologies are still very limited [21]. They also highlight the limited evaluation of user satisfaction with WRD [53], the need to improve the usability of the devices [21], and the lack of reliable and valid instruments to assess the devices from the user's perspective [54]. Similarly, various authors underscore the urge to involve people with neurological injuries in the design of WR to develop devices that meet their needs [55, 56, 57] because users may only accept a technology if it is useful for their own purposes [58]. As a consequence, researchers in the field are starting to study the causes and the limiting factors of the user experience in human-robot interactions [52].

In this regard, widening the perspective of research and development teams beyond the engineering requirements is fundamental to promote the development of WRD that are usable, effectively respond to users' needs [52], and successfully reach end-users [21, 58, 59, 60]. The field currently predominantly relies on the use of three dimensions to describe usability (i.e. *effectiveness*, *satisfaction*, and *efficiency*) and usability evaluation is predominantly related to functional or performance-related outcomes [61, 62], followed by the evaluation *ease of use*, *safety* and *comfort* [63, 64]. Considering only these attributes of usability overlooks its multidimensionality, leaving out of assessment factors that affect usability. Increasing user acceptance of the technologies leads to better adherence to treatment [65], therefore potentially increasing the use of the technologies and rehabilitation outcomes, as well as the success of the devices in reaching their intended context of use.

At the same time, the scientific community is questioning the basis of the design and application of rehabilitation robots due to the limited high-quality clinical evidence of these devices [21]. Interaction-based controllers are becoming increasingly relevant in the field, pointing toward the need to understand how to tune robot parameters depending on each patient's physical characteristics and therapeutic goals [19]. Overall, the field of WRD is experiencing a paradigm shift towards UCD. According to a report published in 2020 [59], 66% of customers expect companies to understand their unique needs and expectations, and healthcare sector is the one in which customers are concerned the most about being the center of the products and services. Understanding this important expectation will be fundamental for developers and companies in the field to develop technologies that are successful in reaching end users. Most efforts are addressing two main dimensions of UCD: one is the importance of tailoring these

technologies to meet the specific needs and preferences of individuals undergoing gait rehabilitation, and the other is the improvement in usability and acceptance of WRD as a factor that strongly influences their effectiveness in gait rehabilitation.

Recent technological advancements have been devised to enhance personalization, exemplified by WRD controllers that enable the adjustment of assistance for specific subtasks, by setting specific assistance to joints and phases within the gait cycle associated with common impairments [66, 67]. Additionally, research with these subtask-based controllers has compared their performance and tuning time when applying automatically tuned robotic assistance to manually tuned robotic assistance (i.e., the current practice in the field). Different assistance levels were achieved through each method, demonstrating improved performance and shorter tuning times with the first approach. However, an exploration of the impact on clinical outcomes due to these differences in assistance levels remains to be conducted [68, 67]. These efforts represent advancements towards improved tuning of the assistance based on the user's individual performance performing the subtasks considered iteratively. Yet, none of the WRDs available in the market offers personalization comprising the hardware of the device [21], which still limits heterogeneous users to wear the same device despite their different functional requirements. Cyberdyne (Cyberdyne INC., Tsukuba, Japan) is the company that aligns the closest with this approach. However, they currently provide separate products rather than a modular WRD whose parts can be selected depending on the needs of individual users. As can be seen, solving the technical challenges to successfully provide personalized RAGT still remains an open challenge.

1.2. Thesis Outline

The thesis is written following an ordinal structure, but all the contents of this thesis are related to the others and as such, can be better understood as part of an iterative cycle, following the principles of UCD. Figure 2 summarizes the content and context of the thesis. Due to the transdisciplinary approach of the studies developed to build the framework presented in this thesis, independent studies with appropriate methodologies for each field were performed. These are detailed in subchapters 3.1 to 3.5 and a summary of their contents is outlined next.

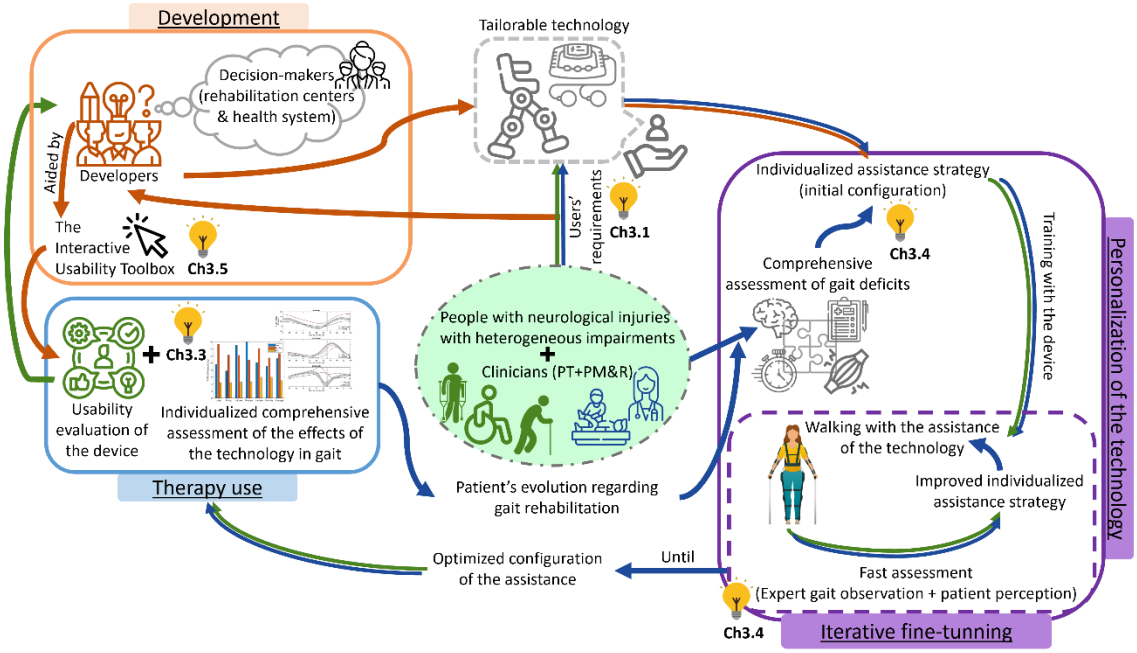

FIGURE 2. Summary of the content and context of the thesis. The diagram indicates the desired implementation of the framework presented in this thesis and the relationship of its subchapters. The colored circle represents the users of the technologies, who are the center of the process. The colored arrows indicate the stakeholders involved in each step of the framework presented in this

thesis: blue for clinicians, green for people with neurological injuries, and orange for the developers of the technologies. The bulbs indicate the subchapter of the thesis that contains the details of the stage or tool next to it.

The light bulbs in Figure 2 represent specific scientific contributions arising from this Thesis, detailed in subchapters 3.1 to 3.5.

The hypotheses and objectives of the thesis are outlined in chapter 2. Chapter 3.1 provides a qualitative study [1] aimed at retrieving design requirements of primary and secondary users of WRD for gait rehabilitation of people with SCI encompassing both data available in the literature and new requirements arising from the data gathered in the study. The set of criteria summarized is the most comprehensive one in the field and is meant to guide the design, development, and evaluation of these robotic devices to meet user's needs and allow them to be implemented in their intended context of use.

In chapter 3.2, a series of studies were conducted to explore kinematic patterns in the adult population with SCI aimed at ultimately creating a new metric to comprehensively assess gait in SCI. Chapter 3.3 presents the development, selection, and validation of a set of metrics to comprehensively evaluate gait in SCI. The methodologies followed to obtain the metrics are user centered. Section 3.2.1 shows an initial study conducted to explore possible types of patterns of gait that can be grouped among the SCI population. To this end, machine learning techniques for clustering were used[2]. Following upon the results of this study, section 3.2.2 shows a study exploring which parameters allow a better discrimination between gait in SCI compared to a healthy gait pattern and between subjects with different degrees of impairment. Machine learning classification algorithms were used for this task. Spatiotemporal features demonstrated to have more sensibility than kinematics to classify impaired from healthy gait [3]. Additionally, a specific metric for SCI was developed in section 3.3.1 to summarize the kinematic data registered during a 3DGA, the SCI gait deviation index (SCI-GDI)[4]. This index was developed to overcome the limitations of applying the original gait deviation index (GDI) to adult population with SCI found in a previous study[5]. Afterward, during the experimental study of this Thesis, presented in chapter 3.4, the limited applicability of using photogrammetry, and thus computing the SCI-GDI, during RAGT, was

[1] This study was partially developed in a Bachelor's Thesis [213] whose main advisor is the author of this PhD thesis and the complete study was published in a paper [52] that is part of the scientific production of this PhD thesis: **Herrera-Valenzuela, D.,** Díaz-Peña, L., Redondo-Galán, C. et al. A qualitative study to elicit user requirements for lower limb wearable exoskeletons for gait rehabilitation in spinal cord injury. J NeuroEngineering Rehabil 20, 138 (2023). https://doi.org/10.1186/s12984-023-01264-y

[2] This study was presented in an oral contribution in the XII Simposio CEA de Bioingeniería and is part of the scientific production of this PhD thesis: **Herrera-Valenzuela, DS**; Torrado-Carvajal, A; Moreno, JC; Sinovas-Alonso, I; de los Reyes, A; Gil-Agudo, A; del-Ama, AJ. "Exploración del uso de algoritmos de clustering para identificar patrones de marcha en lesión medular: resultados preliminares". XII Simposio CEA de Bioingeniería. Universidad Rey Juan Carlos. 2021. Spain.

[3] This study was presented in an oral contribution in the XI Congreso Iberoamericano de Tecnologías de Apoyo a la Discapacidad IBERDISCAP 2021 and is part of the scientific production of this PhD thesis: **Herrera-Valenzuela, DS**; Torrado-Carvajal, A; Moreno, JC; Sinovas-Alonso, I; de los Reyes, A; Gil-Agudo, A; del-Ama, AJ. "Clasificación de estudios de marcha de pacientes con lesión medular usando k-vecinos más cercanos". XI Congreso Iberoamericano de Tecnologías de Apoyo a la Discapacidad IBERDISCAP 2021. AITADIS. 2021. Spain.

[4] This study was published in a paper [177] that is part of the scientific production of this PhD thesis: **Herrera-Valenzuela, DS**; Sinovas-Alonso, I; Moreno, JC; Gil-Agudo, A; del-Ama, AJ. "Derivation of the Gait Deviation Index for Spinal Cord Injury". Frontiers in Bioengineering and Biotechnology, 10, (2022). https://doi.org/10.3389/fbioe.2022.874074.

[5] This study was published in a paper [165] that is **not** part of the part of the scientific production of this PhD. However, it was developed as part of a coordinated effort related to this thesis: Sinovas-Alonso I, **Herrera-Valenzuela D**, Cano-de-la-Cuerda R, Reyes-Guzmán AL, del-Ama AJ, Gil-Agudo Á. "Application of the Gait Deviation Index to Study Gait Impairment in Adult Population With Spinal Cord Injury: Comparison With the Walking Index for Spinal Cord Injury Levels." Front Hum Neurosci. 2022;16:826333. Published 2022 Apr 4. doi:10.3389/fnhum.2022.826333

identified. Consequently, section 3.3.2 presents the development of an adapted version of the SCI-GDI including kinematics of joints movements that can be acquired with precision with simpler and more versatile systems than 3DGA such as Inertial measurement units (IMU). A validation of a set of IMU with respect to a 3DGA system was performed to identify the joints movements that could be accurately measured with the IMU[6]. This validation added to the relevance of each joint movement included in the original GDI in the performance of the metric led to the selection of four movements for the reduced SCI-GDI: hip flexion/extension, hip abduction/adduction, knee flexion/extension and ankle dorsi/plantarflexion. Lastly, to combine all the findings of these studies, section 3.3.3 proposes a novel comprehensive metric for the assessment of gait function in SCI including three complementary aspects: kinematics, spatiotemporal features, and functional tests. All the metrics suggested can be used to assess patient's evolution throughout rehabilitation but they can also be used during RAGT, to evaluate the immediate effects of the technology in patients' gait.

Chapter 3.4 proposes a strategy for personalization of hybrid WRD based on clinical knowledge, which can be implemented on the fly in the clinical context. In addition, the experimental protocol designed and used to validate the efficacy and usability of the assistance provided when implementing the personalization strategy is provided.

Chapter 3.5 presents the creation and validation of a glossary of usability attributes that can be used to identify methods to evaluate specific attributes of usability[7]. The glossary is aimed at pushing the creation of benchmarks for usability evaluation that allow to further promote usability evaluation in the field of WRD.[8]

Last of all, chapter 4 covers the final discussion of the thesis, chapter 5 provides the conclusions of the document and outlines directions for future work and chapter 6 lists the scientific contributions developed along the thesis.

1.3. THESIS CONTEXT AND COLLABORATIONS

This thesis is framed within the project *Personalized Robotic and Neuroprosthetic Modular Wearable Systems for Assistance of Impaired Walking - TAILOR* (Ref.: RTI2018-097290-B-C31), which aims to advance the state of the art in robotics and neuroprosthetic devices for gait assistance. The project proposes an innovative approach to designing neurorobotic systems tailored to each patient, combining WRD, neuroprosthetics (NP), and modular WRD-NP hybrid robots (HR). The project aims to develop a new generation of these robotic technologies that can adapt to the functional requirements of each user, regardless of the etiology of their injury. This aims to provide a personalized robotic technology that is more efficient, offering a better user experience, longer usage time, increased user acceptance, and optimized support that can evolve along the rehabilitation process. The novelty of the TAILOR approach lies in developing technologies (NP, WRD, and HR) that can be configured according to the individual functional requirements of each patient. This approach considers the functional and usability requirements of technology users, including both patients and clinicians responsible for the rehabilitation process. Overall, the project is focused on the implementation of a UCD approach[9].

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[6] This study was developed as part of a Master's Thesis [180] whose main advisor is the author of this thesis.

[7] This study was published in a paper that is part of the scientific production of this PhD thesis:

Herrera-Valenzuela, D; Meyer, JT; del Ama-Espinosa, AJ; Moreno, JC; Gassert, R; Lambercy, O. "Towards a validated glossary of usability attributes for the evaluation of wearable robotic devices". J NeuroEngineering Rehabil. 21, 30 (2024). https://doi.org/10.1186/s12984-024-01312-1

[8] Improvements to the IUT were made during a 3-month research internship held at the RELab in ETH, Zurich.

[9] The Project was presented in an oral contribution in the XII Simposio CEA de Bioingeniería:

The participating institutions in the TAILOR project are the National Hospital for Paraplegics (HNP), the Neural Rehabilitation Group (NRG) at the Cajal Institute, the Biomedical Engineering Research Center (CREB) at the Universitat Politècnica de Catalunya (UPC), and the Institut Guttmann (IG). All of them have experience in the development and validation of robotic technologies to support the gait rehabilitation of patients with neurological injuries[10].

Within the development of the project TAILOR, the limited knowledge and tools available for developers to evaluate the usability of their devices was identified. Therefore, the researcher did a 3-month research internship at the Rehabilitation Engineering Laboratory (RELab) of ETH Zürich[11], a group with expertise and an active research line in usability evaluation of WRD. This institution created The Interactive Usability Toolbox (IUT), a tool aimed at aiding developers of WRD to implement usability evaluation of their devices. Due to the shared interest in the user-centered approach in the TAILOR project and the efforts in pushing usability evaluation of WRD, the researcher further developed the Toolbox during her internship, as indicated in chapter 3.5 of this thesis.

Herrera-Valenzuela, D; Gil-Castillo, J; Pina, J; et al; del Ama, AJ. "Desarrollo de sistemas modulares robóticos y neuroprotésicos personalizables para la asistencia de la marcha patológica a través del diseño centrado en el usuario: PROYECTO TAILOR". XII Simposio CEA de Bioingeniería. Universidad Rey Juan Carlos. 2021. Spain.

[10] The institutions belonging to the TAILOR consortium appreciate the funding granted by the State Research Agency in the 2018 call, with reference RTI2018-097290-B-C31.

[11] https://relab.ethz.ch/

2. OBJECTIVES

2.1 MAIN HYPOTHESIS

There is a lack of a) tools for the comprehensive identification of design requirements for WRD for gait rehabilitation and b) experimental procedures specific to personalize and evaluate these technologies, including the identification of the usability requirements that ought to be included in the evaluation.

2.2 MAIN OBJECTIVE

The objective of this thesis is to develop a comprehensive framework for the User-Centered Design of personalized hybrid wearable robots for gait rehabilitation including tools and methodologies for 1) the design of devices, 2) the quantitative evaluation of the effects of the devices on gait, 3) the personalization of such technologies according to individual functional needs, including the design of experimental protocols involving personalized technologies, and 4) their usability evaluation.

2.2 SECONDARY OBJECTIVES AND HYPOTHESES

1. Hypothesis 1: The requirements for the design of lower limb WRD for gait rehabilitation of primary and secondary end-users could be complimentary and ought to be comprehensively considered to guide future design and development processes for these devices to properly address end-users needs.
   Objective 1: To elicit and assess the set of requirements, perceptions, and expectations that people with spinal cord injury and the clinicians in charge of their rehabilitation have regarding the use of WR for walking rehabilitation.
2. Hypothesis 2: The absence of a specifically developed and validated metric for studying gait kinematics in the population with SCI may result in limitations in accurately assessing and understanding their gait patterns.
   Objective 2: To develop a metric to evaluate gait kinematics of people with SCI.
3. Hypothesis 3: The evaluation of gait rehabilitation should comprehensively include both functional and biomechanical aspects of gait adapted to the specific characteristics of different neurological injuries.
   Objective 3: To develop a methodology to propose comprehensive metrics for gait assessment tailored to specific neurological injuries.
4. Hypothesis 4: Hybrid WRD for gait rehabilitation that can be personalized to individual functional requirements provide effective gait assistance and a positive user experience for people with neurological injuries.
   Objective 4: To propose a personalization strategy for modular hybrid systems for gait rehabilitation that can be applied in clinical rehabilitation settings.
5. Hypothesis 5: The lack of a defined scope and specific definitions to identify the usability of WRD may limit the inclusion of usability attributes in the design and evaluation of these devices.
   Objective 5: To provide a validated glossary of usability attributes with consensus-based definitions that are easily accessible and implementable by developers to recommend context-specific outcome measures and usability research methods.

3. EXPERIMENTAL METHODOLOGY

3.1 STUDY 1: A QUALITATIVE STUDY TO ELICIT USER REQUIREMENTS FOR LOWER LIMB WEARABLE EXOSKELETONS FOR GAIT REHABILITATION IN SPINAL CORD INJURY[12]

INTRODUCTION

During the last 30 years, there has been an increase in the development and testing of robotic wearable exoskeletons for walking rehabilitation following SCI. The intended effect of these devices is to induce neuroplastic changes through intensive walking training [69], while also providing task-related visual and functional feedback [15]. Besides, WR provide a richer walking experience compared to traditional therapy, allowing independent ambulation while maintaining postural stability [22]. However, clinical evidence is still limited and nonconclusive [18], thus, the scientific community is questioning the design and application principles of WR, as well as pointing towards the actual understanding of how to tune WR control parameters depending on the patient's characteristics and therapeutic goals [19].

In parallel, the scientific community is also becoming interested in the limitations related to users' acceptance of WR and their interactions. Qualitative research allows exploring this phenomenon from the user's point of view. Researchers have studied the perception of both patients and clinicians about the technologies after one session with a WR through face-to-face interviews [36, 37], using online surveys with only patients [38, 39, 40] or clinicians [38, 40], or to assess the number of developers that include users through the development of the technologies [41]. Longer studies have also been performed, where the authors evaluate patient's [42, 43, 44, 39, 45, 46, 47, 48, 49, 50] or clinician's [49, 51] perception after receiving training with a WR, some of them with evolutive follow up throughout the study [46, 49, 39, 44]. Overall, the authors highlight the limited evaluation of user satisfaction with WR [70], the need to improve the usability of the devices [21], and the lack of reliable and valid instruments to assess the devices from the user's perspective [54]. As a consequence, authors highlight the urge to involve people with neurological injuries in the design of WR, to develop devices that meet their needs [55, 57, 56], because users may only accept a technology if it is useful for their own purposes [58].

Therefore, the limited clinical evidence regarding WR for gait rehabilitation, their lack of customization, and the constraints in user acceptance, arise doubts as to whether it is worth investing in these pricey technologies [21], since there is no clear sustainable economic model to effectively deploy them. Therefore, developers need to study the bigger picture regarding WR for gait rehabilitation, emphasizing the understanding of the needs and constraints of all stakeholders involved: subjects with neurological injuries as primary users, clinicians and caregivers as secondary users, and the real-life dynamics of rehabilitation centers. This study aimed at determining a comprehensive set of requirements, perceptions, and expectations that people with spinal cord injury and the clinicians in charge of their rehabilitation have regarding the use of WR for walking rehabilitation, by using a directed content analysis approach. This qualitative research methodology allows focusing criteria elicitation from the user's point of view, encompassing both the knowledge available in the literature, and allowing new criteria to emerge from the new data collected through interviews. It is expected that the complete set of criteria summarized in this study will be useful to guide the design, development and evaluation of WR for gait rehabilitation to make sure the efforts invested in the field lead to technologies that respond to the needs

[12] This chapter is based in [52], a paper that is part of the scientific production of this Ph.D. thesis: **Herrera-Valenzuela, D.**, Díaz-Peña, L., Redondo-Galán, C. et al. A qualitative study to elicit user requirements for lower limb wearable exoskeletons for gait rehabilitation in spinal cord injury. J NeuroEngineering Rehabil 20, 138 (2023). https://doi.org/10.1186/s12984-023-01264-y

and expectations of their primary and secondary end users and are feasible to implement in their intended context of use.

METHODS

STUDY DESIGN

A qualitative study using directed content analysis was conducted [71], following the Standards for Reporting Qualitative Research [72] and Consolidated Criteria for Reporting Qualitative Research [73]. This design was chosen to state a set of requirements for the design and development of these technologies, taking as a starting point the requirements found in the literature [74, 75]. Criteria proposed in [76, 77] were followed to establish trustworthiness and credibility in line with similar qualitative research studies [78, 79]. The procedures used regarding data credibility, transferability, dependability, and confirmability are shown in Table 2 [80].

TABLE 2. Criteria and strategies used to establish trustworthiness.

Criteria	Strategies used
Credibility	Investigator triangulation: the analysis of each interview was checked by two researchers. Additionally, both authors discussed all the analyses to reach consensus about the differences in coding and identified categories together. Participant triangulation: the study included participants with different: degrees of experience with lower limb wearable exoskeletons, backgrounds, SCI classification, mobility impairment, ages, sex and related to different institutions. Therefore, multiple perspectives were acquired about a common topic: the requirements, expectations and needs of people with SCI for a wearable lower limb exoskeleton. Triangulation of methods of data collection: semi structured interviews as well as researcher field notes were gathered. Researcher reflexivity was reinforced by discussing researchers' positionality in reference to the topic studied and the population included in the study, and by clarifying the rationale behind the study.
Transferability	The methodology used in this study is described in-depth, including characteristics of researchers, participants, contexts and sampling strategies, as well as the procedures used for data collection and analysis.
Dependability	Audit trail: the researchers kept record of all the steps taken during the process from the conception of the study to the reporting of the results. This register of the research path guarantees the study conform to the standards for qualitative research using content analysis.
Confirmability	Triangulations of researchers, participants, and methods of data collection were performed. Researcher reflexivity was reinforced by discussing researchers' positionality in reference to the topic studied and the population included in the study, and by clarifying the rationale behind the study. Relevant issues regarding the positioning of the researchers are: (a) the study is part of a larger project called TAILOR (RTI2018-097290-B-C31), aimed at developing "Personalized Robotic and Neuroprosthetic Modular Wearable Systems for Assistance of Impaired Walking", (b) none of the researchers has a SCI, (c) none of the interviewers had ever developed a robotic technology or is in charge of developing the exoskeleton in TAILOR, and (d) the interviewers did not and will not provide any type of clinical assistance to the subjects recruited.

LITERATURE SURVEY

The initial codes and categories to implement the directed content analysis methodology were established based on a literature survey. An advanced search in the Scopus database was performed comprising the period until December 31st, 2020, using the query string "(exoskeleton) AND (user AND center* AND design) OR (perception) OR (experience) OR (perspective*)", only research articles and reviews written in English were considered. Further selection was performed by reading the title and abstract, when necessary, to guarantee that the included articles assessed lower limb exoskeletons for gait rehabilitation in terms of the user's perspective or experience.

CONTEXT

The National Hospital for Paraplegics (HNP) is the main monographic public hospital for intensive rehabilitation of SCI in Spain. Institut Guttmann (IG) is the main private foundation for rehabilitation of neurological injuries in the region of Catalonia. Both have vast experience in cooperating in research projects devoted to the development and evaluation of rehabilitation technologies, including lower limb exoskeletons. Spinal Cord Injury Foundation (FLM) is a private neurorehabilitation center located in Madrid, Spain, that provides integral rehabilitation, including therapy with lower limb WR, for people with SCI after their discharge from rehabilitation hospitals.

PARTICIPANTS

Both people with SCI and clinicians were separately considered as end-users, as they might have different perspectives and requirements. In addition, and to better understand the impact of the technology on patient's expectancies, the SCI group was split within patients with and without previous experience with WR (e-SCI and n-SCI respectively). The objective was to assess different perspectives: feedback about actual technologies and requirements that arose from experience (e-SCI and clinicians), expectations and unbiased requirements for the technologies (n-SCI), and expert advice on the requirements for the technologies to be effective as a gait rehabilitation tool (clinicians). The common exclusion criteria were inability to communicate in Spanish, inability to use to use crutches or a walker to walk with the WR, difficulties in comprehension and communication, and refusal to participate in the study. This research complied with the Declaration of Helsinki and was approved by the Institutional Review Board at the Ethics Committee of the Hospital Complex of Toledo, Spain (CEIC-CHTO, no. 2541 17/02/2021). Informed consent was obtained from each participant.

PARTICIPANT RECRUITMENT

The sample size was determined following the estimates presented in [81], where it is reported that 15 to 20 interviews are required for content analysis to reach data saturation. Data saturation was confirmed within each group after completing the sample. Besides, sample size is consistent with previous similar studies using semi-structured interviews (3 to 17 subjects, median: 10) [82, 36, 83, 43, 53, 47, 51, 84, 49]. SCI participants were recruited between March 30, 2021, and March 11, 2022 through criterion and convenience sampling techniques [81]: 9 from HNP (n-SCI) and 6 from FLM (e-SCI), aged from 20 to 65 years (see Table 3). No participants withdrew from the study. The sampling techniques helped to guarantee that participants recruited are either potential users or experienced users of rehabilitation wearable lower limb exoskeletons and that they could be interviewed despite of the restrictions due to the COVID-19 pandemic.

TABLE 3. Demographic and clinical characteristics of the subjects with SCI recruited.

Characteristic	Type	HNP (n=9)	FLM (n=6)
Sex	Female	2 (22.2%)	2 (33.3%)

Age	20-30	1 (11.1%)	1 (16.7%)
	31-40	1 (11.1%)	1 (16.7%)
	41-50	3 (33.3%)	2 (33.3%)
	51-60	3 (33.3%)	1 (16.7%)
	>60	1 (11.1%)	1 (16.7%)
AIS	A	1 (11.1%)	3 (50.0%)
	B	0 (0.0%)	1 (16.7%)
	C	3 (33.3%)	2 (33.3%)
	D	5 (55.6%)	0 (0.0%)
Time since injury	Mean ± STD Range (min - max)	5.9 ± 3.0 months (2.5 - 11) months	17.1 ± 12.2 years (2.7 - 30) years
Injury level	C1-C8	3 (33.3%)	1 (16.7%)
	T1-T6	3 (33.3%)	0
	T7-T12	2 (22.2%)	4 (66.7%)
	L1-L5	1 (11.1%)	1 (16.7%)
WISCI II level	Level Nº subjects	0 | 9 | 12 | 16 | 19 | 20 1 | 1 | 1 | 1 | 2 | 3	0 | 6 | 9 | 20 2 | 1 | 2 | 1
Etiology	Trauma	6 (66.7%)	5 (83.3%)
	Others (Spinal sugery or spinal cord affections)	3 (33.3%)	1 (16.7%)
Intervew time (min)	Mean ± STD	34.0 ± 24.4	22.5 ± 12.6
	Total recorded time	306.4	134.8

Similarly, for the clinicians user group, PM&R physicians and physiotherapists (PT) involved with the rehabilitation of people with SCI and/or with experience in research with WR were recruited through convenience and snowball sampling techniques [81] between April 25th and May 19th, 2021: 6 from HNP and 4 from IG (see Table 4). No participants withdrew from the study. These sampling methods helped to guarantee that clinicians recruited had valuable knowledge for the design of lower limb wearable exoskeletons for gait rehabilitation, especially for SCI patients.

TABLE 4. Demographic and professional characteristics of the clinicians recruited.

Characteristic	**Type**	**Total (n=10)**	**HNP (n=6)**	**IG (n=4)**
Sex	Female	5 (50.0%)	4 (66.7%)	1 (50.0%)
Profession	PT&R	5 (50.0%)	2 (33.3%)	3 (75.0%)

	Physiotherapist	5 (50.0%)	4 (66.7%)	1 (25.0%)
Age	Mean ± STD	41.8 ± 12.7	35.2 ± 10.6	51.8 ± 8.6
	Range (min - max)	(26 to 62 y.o.)	(26 to 56 y.o.)	(41 to 62 y.o.)
Years working with SCI people	Mean ± STD	12.2 ± 10.6	5.9 ± 5.2	21.5 ± 10.0
Self-percieved knowledge about lower limb exoskeletons	Mean ± STD (1 to 4 scale)	2.8 ± 0.6	2.5 ± 0.6	3.25 ± 0.5
Intervew time (min)	Mean ± STD	21.2 ± 7.3	19.1 ± 8.8	24.3 ± 2.8
	Total recorded time	212.2	114.8	97.4

DATA COLLECTION

Individual, semi-structured interviews led by a theme-based interview guide with open-ended questions were used to obtain detailed descriptions of the themes previously identified in the literature [85, 81]. The interviews were audio-recorded with written permission of the participants. When needed, follow-up questions to enhance the depth of the description of a specific topic were made. All the interviews were individual and conducted by one researcher in Spanish, they were scheduled according to participants availability. A total of 653.4 minutes were recorded, with an average of 26.1±17.0 minutes per interview (see Table 3 and Table 4).

DATA ANALYSIS

Verbatim transcriptions of all interviews were made using the semi-automated transcription software Amberscript (www.amberscript.com, Amsterdam, The Netherlands), these were reviewed and corrected manually. Two researchers analyzed each transcription performing deductive content analysis, following the directive content analysis approach [86]. To this end the authors used a formative categorization matrix of the main categories and related subcategories, built based on the available literature [87, 71]. Afterwards, researchers performed an inductive analysis of the data based on the participants' narratives to allow new codes and categories to emerge, thus extending and validating a conceptual framework [86]. Coding was conducted by both authors until a consensus was reached. The relative frequency of participants from each one of the three groups that referred to each code was calculated. The final list of requirements comprises only the codes with at least 20% of agreement within each group. Likewise, the intra and inter group agreement rate was calculated. Lastly, the authors identified categories and created a codebook. Data was organized and visualized using Microsoft Excel (www.microsoft.com/microsoft-365/excel, Redmond, WA, USA). The whole codification process is shown in Figure 3.

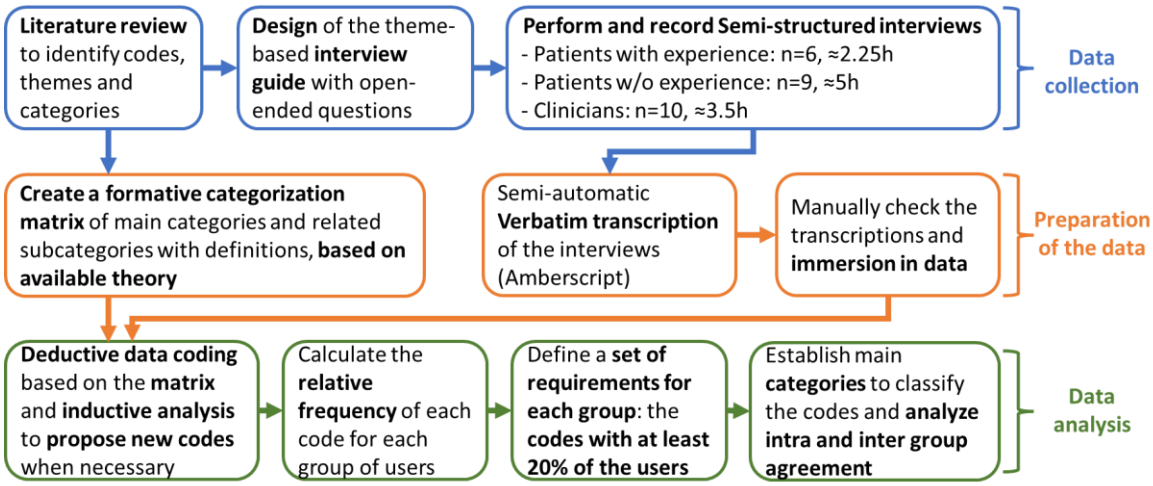


FIGURE 3. Details of the directive content analysis methodology implemented in the study.

RESULTS

LITERATURE SURVEY

The initial search yielded 53 results, of whom 32 studies were excluded after reading the title and abstract. The 21 articles included were analyzed in detail to compile the codes available in the literature regarding the design of lower limb exoskeletons for rehabilitation from a user-centered perspective [38, 43, 53, 42, 45, 47, 51, 82, 36, 83] [88, 40, 89, 90, 91, 92, 93, 94, 95, 96] [97]. From the references of these articles, other 14 studies were identified as relevant and included in the analysis (see Figure 4) [41, 44, 37, 98, 46, 49, 39, 48, 50, 54] [55, 99, 100, 101].

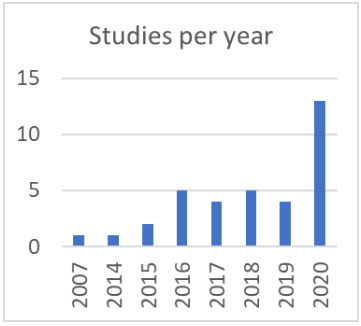


FIGURE 4. Number of articles published each year assessing lower limb exoskeletons for gait rehabilitation in terms of the user's perspective or experience.

The set of reviewed articles included diverse qualitative and quantitative methodologies to assess the perception or experience of users about lower limb exoskeletons. To create the categorization matrix, all the codes and themes that arose from qualitative methods such as content or thematic analysis, as well as the items of standardized questionnaires used in the studies were listed and grouped. In total, 98 codes were identified and grouped into 9 categories: physical results (21), usability (17), psychology related codes (15), technical characteristics (14), activities (12), acquisition issues (4), and context of use (3). The full list is available in Annex 1. These requirements arose from the following stakeholders: patients, physiotherapists, occupational therapists, engineers, and salespersons.

PARTICIPANT RECRUITMENT AND DATA COLLECTION

The sample of primary users consisted of 15 adults with spinal cord injury (4 women, 26.67%), aged 45.5±13.2 years (range 20 to 65 years), and with a median of 7.1 months since injury onset (min. 2.5 months, max. 30 years). All participants had a diagnosis of SCI with various degrees of impairment to walk, different etiologies of the injury (mostly traumatic, 73.3%), and a variety of injury classification (see Table

3). Subjects recruited had a wide variety of occupations and educational levels. Heterogeneity of the subjects was desirable to gather narratives from different perspectives.

As secondary users, 10 clinicians were recruited (5 women, 50.0%): five PM&R and five PT. Average age was 41.8±12.7 y.o. (range 26 to 62 years) and had on average 12.2±10.6 years of experience working with SCI (range 2 to 30 years) (see Table 4). Most of the subjects recruited had experience in clinical research of lower limb wearable robots for rehabilitation (n=7, 70 %), of whom three were also actively involved in clinical activity at the time of the study. The remaining three subjects had used the technologies in rehabilitation settings and were actively involved in clinical rehabilitation when interviewed. Experience and deep knowledge about lower limb exoskeletons for rehabilitation of spinal cord injury subjects was desirable to identify requirements that these devices must have to be a useful tool for gait rehabilitation.

CODES AND CATEGORIES

In total, 78 codes were retrieved from the interviews with at least 20% of agreement of the users. From these, 16 codes (20,25%) were not previously identified in the literature (see Table 5). In parallel, some codes available in the literature were merged during the analysis. All codes were classified in the previously stated categories: Physical results (16), Technical characteristics (15), Usability (12), Psychology related codes (10), Activities (7), Development of the technologies (6), Clinical rehabilitation context (6), Context of use (4), and Acquisition issues (2). The narratives of the participants to describe each code were extracted directly from the interviews [71]. Annex 1 includes a detailed summary of the categories and the new codes retrieved in this study. Figure 5 shows the intragroup agreement rates.

TABLE 5. Number of codes that each group and subgroup of users talked about.

Group	**All users**	**Clinicians (n=10)**	**People with SCI (n=15)**	**e-SCI (n=6)**	**n-SCI (n=9)**
Total nº of codes expressed	118	100	82	59	72
Nº Codes agreed by ≥20% of the group	78 (66,10%)	82 (82,00%)	52 (63,41%)	38 (64,41%)	44 (61,11%)
New Codes agreed by ≥20% of the group	16	11	10	8	8

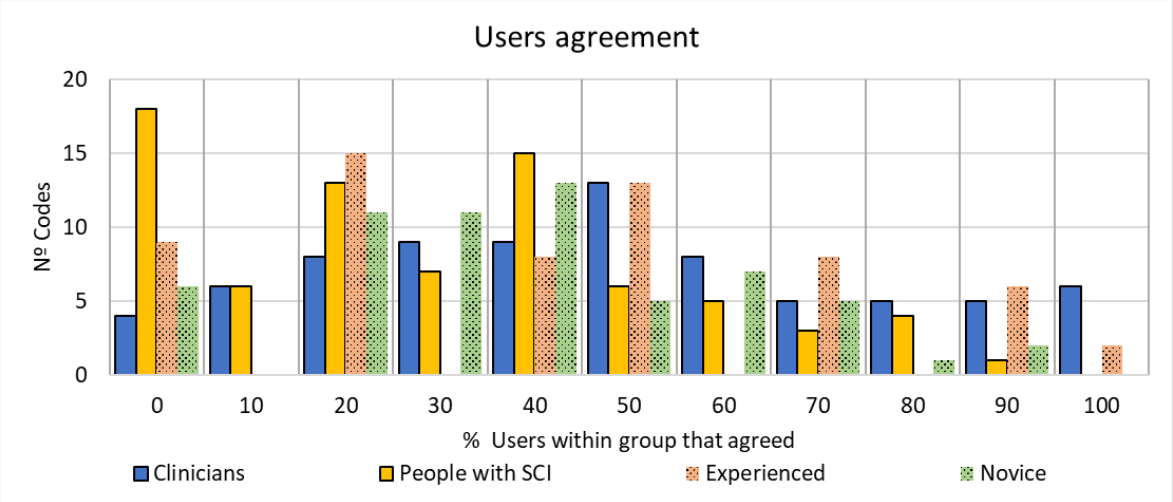


FIGURE 5. Intragroup agreement assessed as the number of codes (y-axis) that certain percentage of users of each group talked about (x-axis).

The agreement percentage between each group and subgroup included in the study was also assessed, calculated as the number of codes that more than 20% of both groups expressed, divided over the total amount of codes any of those two groups agreed on (≥20%). This analysis showed that patients and

clinicians agreed on 50.00% of the codes, n-SCI and e-SCI agreed on 55.77% of the codes, clinicians and e-SCI agreed on 45.83% of the codes and lastly, clinicians and n-SCI agreed on 45.45% of the codes.

To visualize the codes expressed by at least 20% of clinicians or people with SCI, column charts were designed showing the relative frequency of each group that referred to each code. Figures for each category are comprised within Figure 6 to Figure 14. In all graphs, the codes on the left side correspond to the ones expressed by more e-SCI than n-SCI, and the ones in the right to codes expressed by more n-SCI. The new codes that arose from the data of the study are marked with the symbol (^{N}). Some codes in the figures have a sign (*) at the end, representing that some users that talked about the same code but with a different perspective from the other users; these cases are detailed in the description of the corresponding figure.

CATEGORY 1: PHYSICAL RESULTS (16 CODES)

This is the category with more codes, most likely because the main goal of WR for gait rehabilitation is providing physical benefits. Firstly, it is observed that the agreement of patients in these codes is low, especially in e-SCI. Clinicians have higher agreements and refer to more codes than patients, since physical benefits are the reason why they would use the technologies. Interestingly, this is the only category where n-SCI referred to more codes than e-SCI. Among patients, only e-SCI expressed the importance of having devices that do not cause skin abrasions, one of the most common adverse events related to the use of exoskeletons [21]. Users expect improvements not only related to walking and standing but also regarding other body systems that are benefited by walking, standing and in general, by avoiding long-lasting wheelchair sitting. One patient expressed that he did not expect the technologies to improve his endurance for daily activities, whereas more than 30% of all the patients did expect this. Three (3) new codes arose in this category: reduce complications due to wheelchair sitting, improvements in respiratory system, and overall physiological improvement.

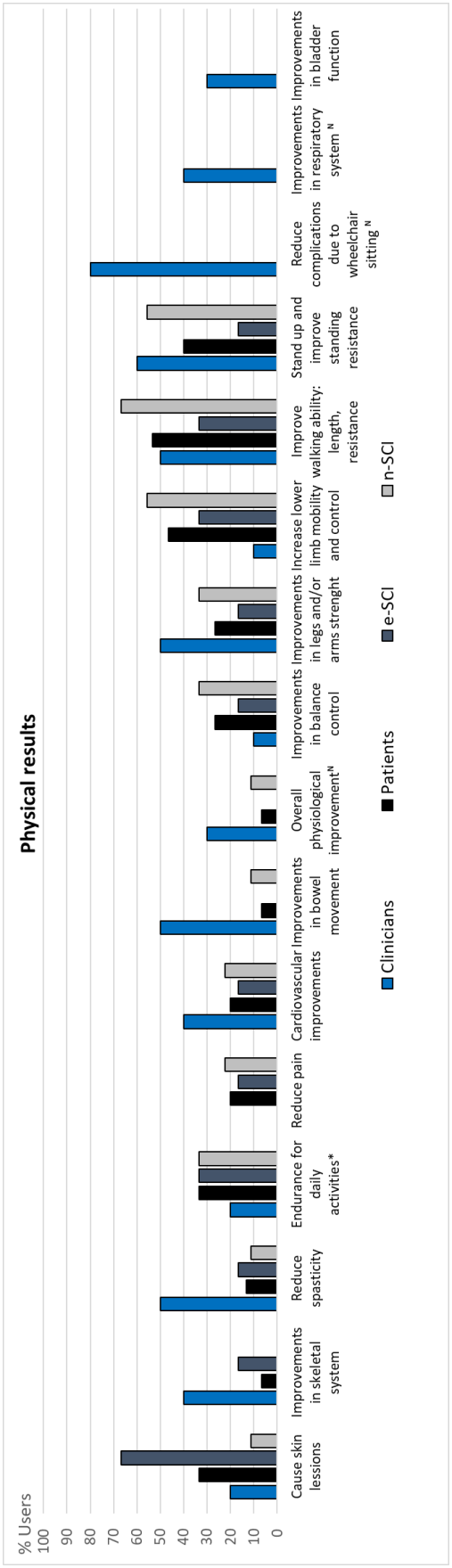


FIGURE 6. Codes of the category physical results.

CATEGORY 2: TECHNICAL CHARACTERISTICS (15 CODES)

This category comprises requirements that can translate directly into technical characteristics of the device and is the second largest one. Most of the codes within this category are expressed by at least 30% of the clinicians and two codes were only expressed by these users: 1) the possibility to adjust the device to each patient for rehabilitation and 2) to record and use the data gathered by the exoskeleton as feedback of the rehabilitation. Other codes with high agreement, expressed mostly by e-SCI and clinicians include: lowering the weight of the device and making it less cumbersome, easy donning and doffing (with the highest agreement among clinicians, given that this is essential to make the use of technologies viable during rehabilitation), and having a device that can be fitted to the body of each patient and able to adapt to the changing needs during the rehabilitation process. This is a new code and is the one with the highest agreement among all groups in this category. Additionally, mostly clinicians referred to the need to increase the duration of the battery of the device and of improving the interaction of the devices with the surroundings by adding feedback in the control loop to allow the device to adapt. Almost one third of n-SCI considered important the device's aesthetics, whereas no e-SCI talked about this. Interestingly, one code in this category is the mistaken expectation of some patients that exoskeletons will be embedded inside their bodies, an inconsistency with the definition of these devices showing that some patients expect long-lasting surgical aids or treatments for their rehabilitation instead of external tools for occasional use. Six (6) new codes emerged in this category, only two of them have not been addressed in this section: some users expect exoskeletons to provide trunk support and assist trunk movement, and some clinicians and e-SCI consider that combining exoskeletons with other technologies such as FES or brain-computer interfaces (BCI) has advantages for users.

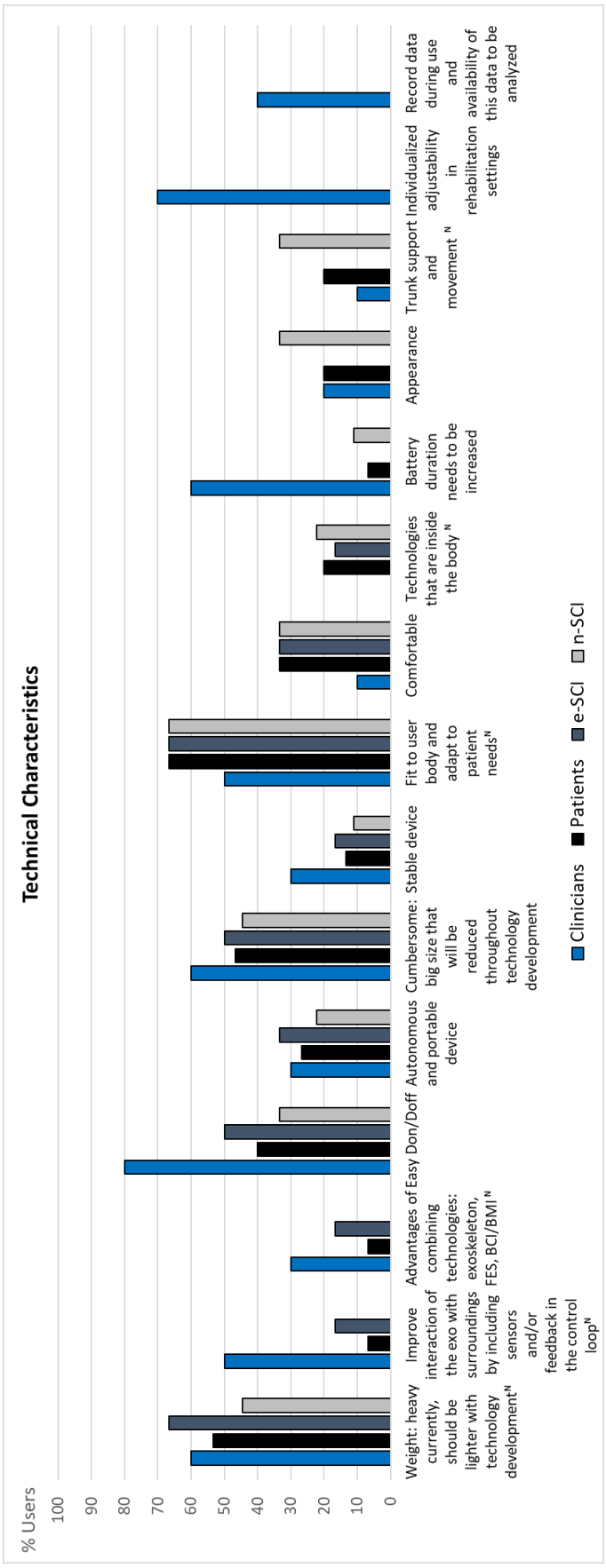


FIGURE 7. Codes of the category technical characteristics.

CATEGORY 3: USABILITY (12 CODES)

Although usability is not well defined in the field of WR [102][13], codes related to the interaction between the users and the technology that determine the outcome of its use were grouped within this category. All but one e-SCI (83,33%) expressed their desire to use these devices more frequently, which is directly related to the limited accessibility that exoskeletons currently have. This was not mentioned by clinicians or n-SCI, most likely because the latter have not experienced this issue, since they have never used the technologies. Both e-SCI and clinicians agreed on the importance of the training process, which few n-SCI thought about during the interview. Likewise, patients and clinicians agreed on the relevance of having technologies that are compatible with all the clinical symptoms of the neurological injuries they are aimed for, and on having devices with gait patterns that avoid functional compensations, are natural, and allow the users to feel the connection with the machine. Some codes are related to the safety of the device: having the fall risk and device failure under control and providing a safety perception. The clinicians also highlighted the importance of the devices being easy to use by them and of allowing patients to use their hands while walking or standing. Regarding this last code, even though patients did not explicitly say it, various of the activities they expect to do with exoskeletons imply being able to use their hands freely. About the physical exertion caused by the devices, patients expressed that the energy needed to use the device at the beginning is very high but that after learning to use it, they expect to (n-SCI) and actually require (e-SCI) less effort to walk when compared to non-assisted walking. No new codes arose regarding usability.

[13] To fill this gap, the research presented in section 3.5 was developed in collaboration with the RELab of ETH, Zurich.

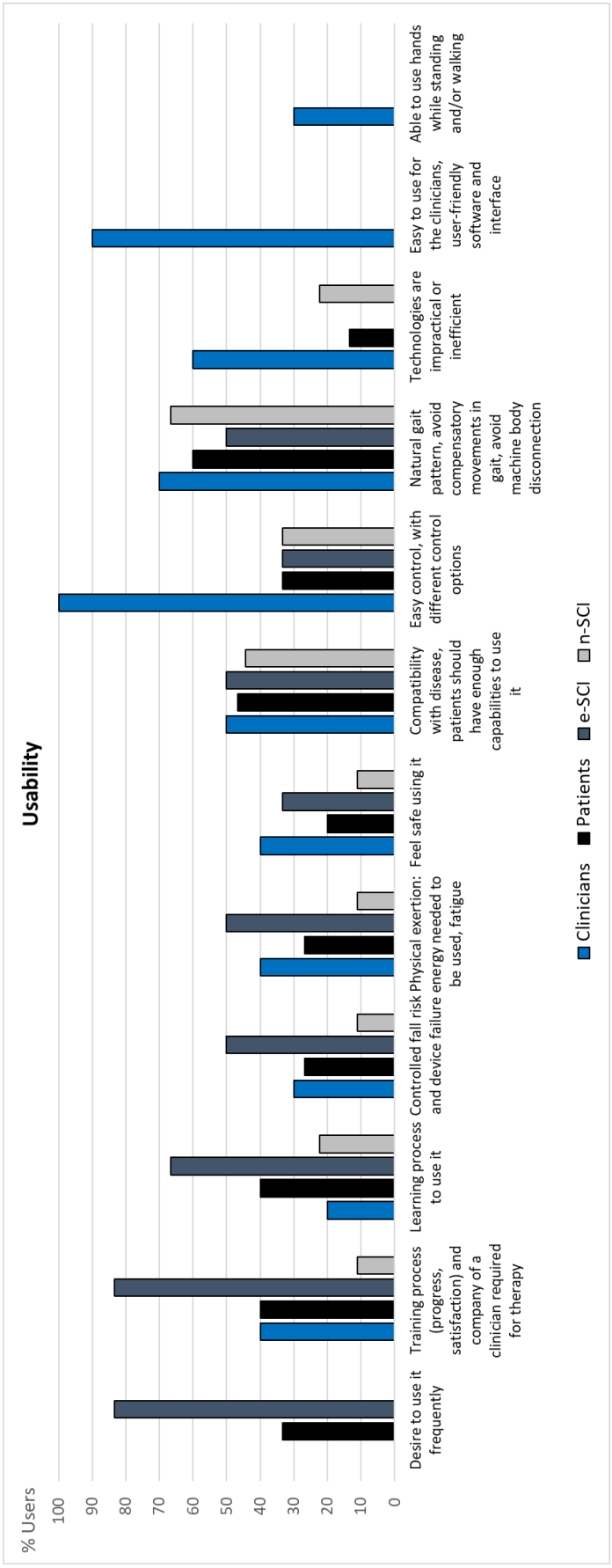


FIGURE 8. Codes of the category usability.

CATEGORY 4: PSYCHOLOGY RELATED CODES (10 CODES)

The number of codes in this category demonstrates that the benefits expected from the use of WR for gait rehabilitation of SCI patients do not only concern physical benefits but also psychological benefits. In this category, patients overall showed high agreements in most codes. Almost half of both patients and clinicians have a positive perception about the technologies, about the feeling of being able to walk and stand up again even if their loss is permanent, and they expect improvements in the mental health and psychological well-being of patients thanks to the use of these devices. These are mostly expressed by e-SCI, showing the opportunities of the technologies in cases of people who have already used them. This should be an incentive to make these devices more accessible to their intended users. Additionally, n-SCI expressed they felt motivated to support the development of the technologies to benefit their community in the future, showing that patients are willing and eager to be included in the design and development processes. Four patients said the use of the technologies gave them a physical and/or psychological sense of wellness, but one n-SCI was more skeptical about this effect.

In this category, two out of the four new codes that emerged were related to negative aspects such as 40% of the patients having fears about using exoskeletons or 50% of the clinicians and 22,20% of n-SCI having reasons to reject their use. Examples of the fears are: falling, damaging the device, “doing it wrong”, and hurting one-self and affecting body parts that are currently healthy. Patients’ reason not to use the technologies is that for their recovery and independence it is better to do all the activities they can without the exoskeleton, and they need to know their capabilities at the end of their sub-acute rehabilitation to assess if an exoskeleton is needed. For clinicians the reasons include: the need to adapt to a new technology that could be complex to use, lack of trust towards technologies due to the fear that they will replace physiotherapists in their workplace, having to lift and move heavy devices, and believing that traditional therapy is better than robot-assisted therapy.

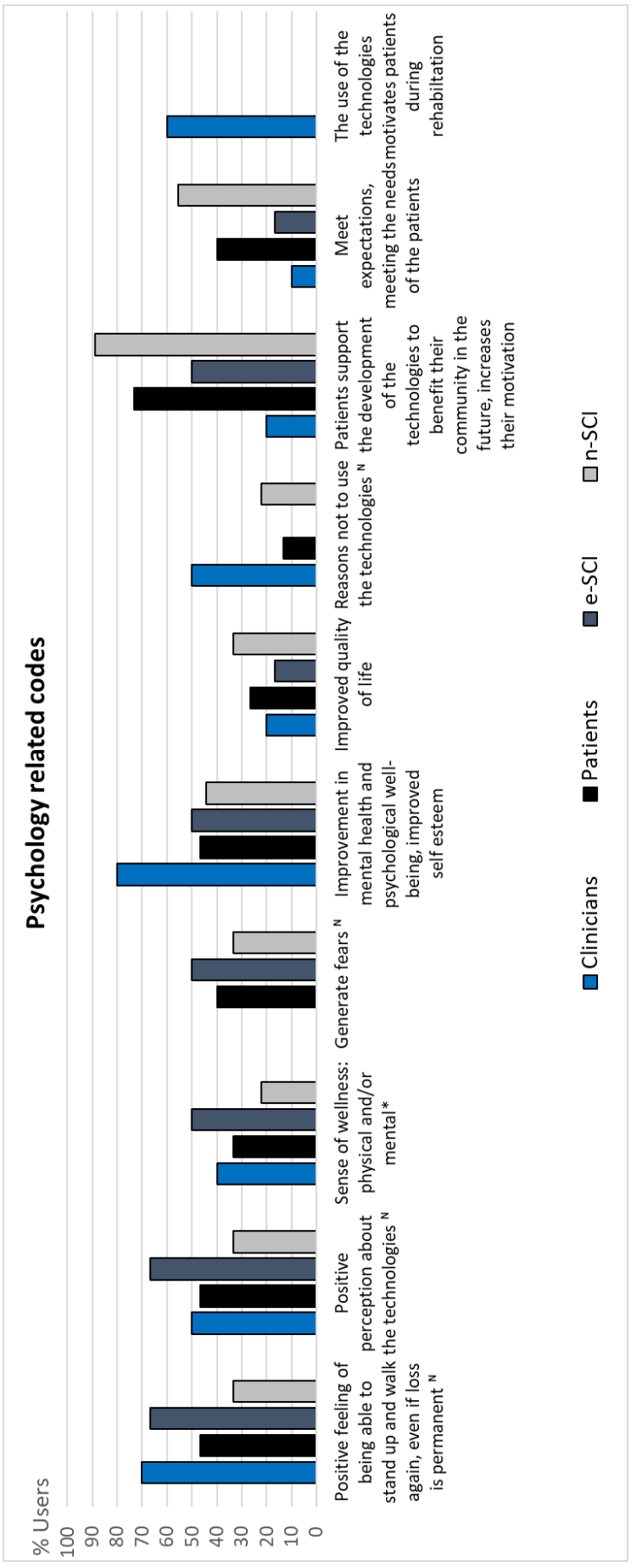


FIGURE 9. Codes related to psychology.

CATEGORY 5: ACTIVITIES (7 CODES)

This category comprises the activities that users would like to do with the technologies. All groups mostly highlighted that they expect the devices to allow them to walk independently and to allow them to do self-care and daily activities with independence. Interestingly, one e-SCI explicitly mentioned that the technology he tried was not ready to be used independently by him at home. Only n-SCI expect the device to enable them to do sports or recreational activities, perhaps because e-SCI have met the actual capabilities and limitations of currently available technologies whereas n-SCI have not. Lastly, clinicians expressed interest in the possibility to climb steps or stairs with the technology, since this is a rehabilitation task. No activities besides the ones found in the literature were expressed by the users interviewed.

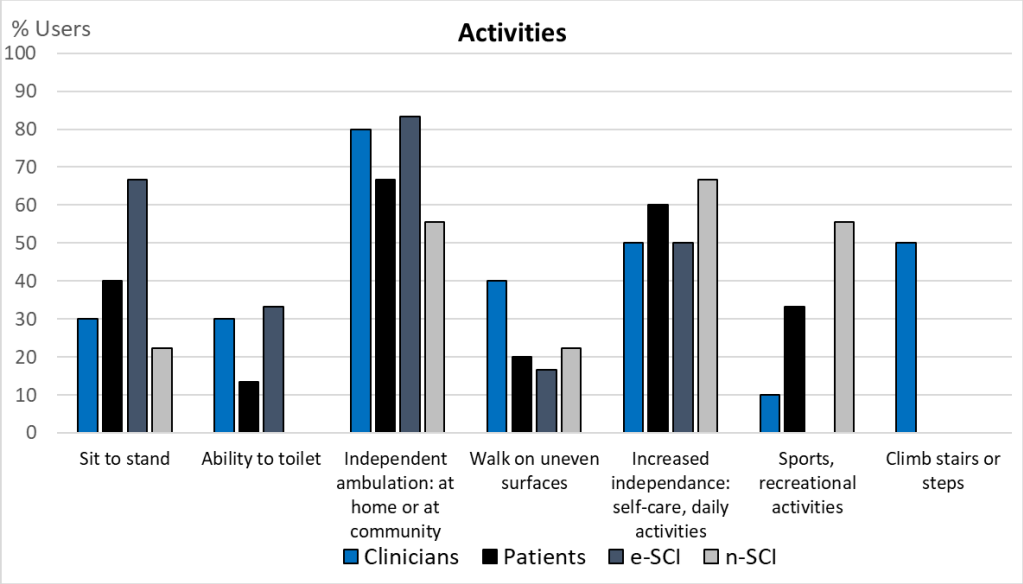


FIGURE 10. Codes of the category activities.

CATEGORY 6: DEVELOPMENT OF THE TECHNOLOGIES (6 CODES)

The codes related to the opinions of the users regarding the future development of the technologies were grouped within this category. There is high agreement among users in the need to further develop the technologies but also in the urge to involve patients in the development of the technologies. Users say patients are the ones who know what they need and the requirements that they have as primary users of exoskeletons. At the same time, both groups of users recognize that patients feel motivated about the possibility of supporting the research and development of the technologies. Therefore, it is a win-win situation for developers and users to involve patients within the technology development cycle. The only new code that arose in this category was the call to increase the funding for the development of exoskeletons, and they expressed this is relation to governmental institutions. All clinicians said it is important to involve them in the developments as well, since they are the ones who know the rehabilitation needs of the patients, and the needs of the PT and PM&R within the real constraints of the health system. Most of them also talked about the lack of clinical evidence to support the use of the technologies, which is still matter of research, given the difficulties of performing randomized case-controlled trials in the field [21].

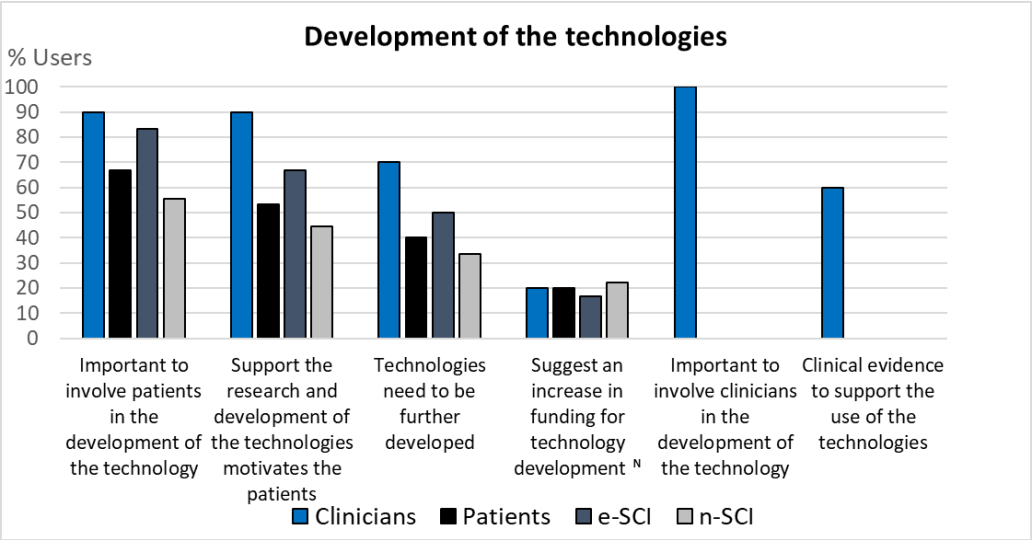


FIGURE 11. Codes related to the development of the technologies.

CATEGORY 7: CLINICAL REHABILITATION CONTEXT (6 CODES)

This category has codes related to constraints of the clinical rehabilitation context that must be considered to ensure the feasibility of deploying exoskeletons within the health care facilities. Clinicians identify challenges related to the organizational capacity of hospitals to implement exoskeletons in rehabilitation such as space availability, high purchase cost and an increase in workload. Most clinicians (70,0%) consider that the use of exoskeletons will result in an increase in the physical and/or cognitive workload of the PT. However, 50% consider that the workload will not increase after they get adapted to exoskeletons as a new tool for therapy. In this regard, the only new code in this category is precisely clinicians seeing exoskeletons as a new tool to assist them for physical therapy. Likewise, this is related to the importance of training health professionals to use the devices, a topic that 90% of them expressed. Most of the clinicians (80,0%) were concerned about the ethical issues regarding the selection of the patients that are prescribed to use the technologies, i.e. prescribing them only to patients that can benefit the most with the use of the exoskeletons but leaving out other patients that could still benefit from them, due to the limited devices available and their limited accessibility.

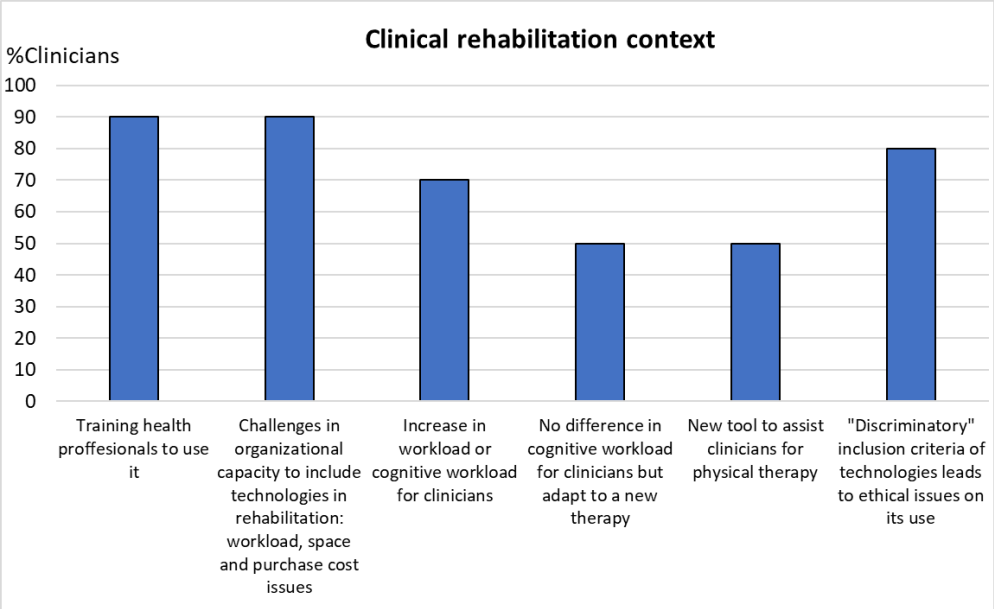


FIGURE 12. Codes related to the clinical rehabilitation context.

CATEGORY 8: CONTEXT OF USE (4 CODES)

Most participants would like to use the technologies in rehabilitation settings, in their communities (e.g. public space or at work), and also in a daily basis at home. However, two patients said these technologies, in their current state, are not ready to be used at home. Similarly, one e-SCI said he would not "dare go outside wearing [an exoskeleton] and go for a beer two blocks away". Clinicians (60%) also expect the technologies can assist complete SCI patients in their daily life. The latter is the only new code in this category.

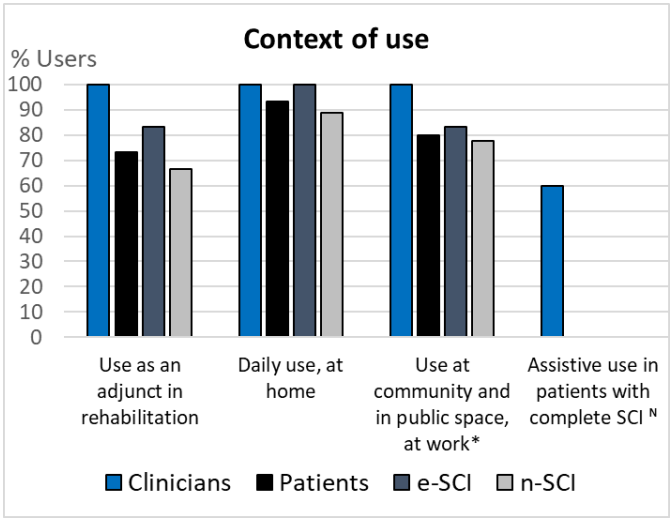


FIGURE 13. Codes related to the context of use.

CATEGORY 9: ACQUISITION ISSUES (2 CODES)

The main acquisition issue expressed by all experienced users (clinicians and e-SCI) and most n-SCI (55,6%) is the purchase cost, a well-known limitation of exoskeletons currently [21]. Some of the users, mostly e-SCI, also talked about the limited access to the technologies that are in hospitals or rehabilitation centers, both because there are few devices available and because they are busy most of the time, given that several users are assigned to each available device. No new codes emerged in this field.

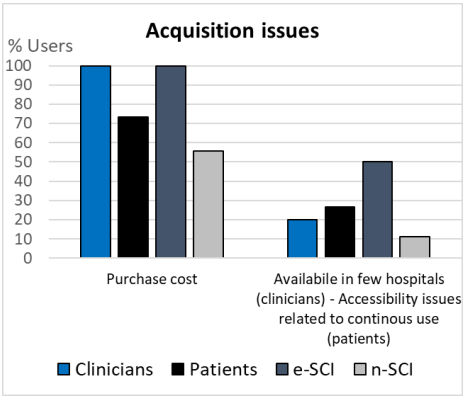


FIGURE 14. Codes related to acquisition issues.

DISCUSSION

Through qualitative research, this study managed to determine a comprehensive set of requirements, perceptions, and expectations that people with spinal cord injury and the clinicians in charge of their rehabilitation have for the design of lower limb wearable exoskeletons for gait rehabilitation. To the authors' knowledge, this is the first research comparing the expectations of people with SCI without experience in the use of exoskeletons versus the requirements of experienced users, and most

importantly, the first study that aims to summarize a comprehensive list of criteria for the design of these technologies, encompassing the knowledge available in the literature and allowing new criteria to emerge from the data collected for this study. The combined set of criteria summarized in the study (see Annex 1), ought to guide developers of these technologies to make sure the efforts invested in the field lead to technologies that respond to the needs and expectations of their end users, comprising people with SCI as well as clinicians as secondary users. This will improve the availability and accessibility of the technologies, by designing devices that are feasible to be implemented in their intended contexts.

The motivation to conduct this comprehensive study is also consequence of the increasing interest shown by developers and researchers in the field in understanding user perception and experience with lower-limb wearable exoskeletons, as seen by a steep increment in studies published in 2020 regarding the topic, performed with smaller samples and specific devices. The comprehensive and in-depth study presented here was possible thanks to the use of directed content analysis approach, a qualitative research methodology that allows to focus criteria elicitation from the user's point of view.

Regarding the data collected in this study, the ratio between the average length of the interviews for each group and the number of codes that emerged (n-SCI: 34.0 min, 44 codes; e-SCI: 22.5 min, 38 codes; Clinicians: 21.2 min, 82 codes), shows even though less clinicians than patients were interviewed, they agreed on more codes in interviews that were almost 1/3rd shorter. On the contrary, n-SCI are less accurate in expressing their requirements and have a wider imaginary about exoskeletons. This is a result of the limited knowledge and information that people out of the field have about these technologies. When interviewed, all n-SCI but one said they did not have any previous knowledge about exoskeletons before being admitted to the hospital. Of these, four patients did not have information about the technologies even after being in the hospital. When asked about what an exoskeleton for them was, they recalled movies or news as their only source of information to make a guess. The remaining four patients recognized the Lokomat as an exoskeleton for gait rehabilitation, available in the gym at the hospital. Only two n-SCI had seen a portable exoskeleton before.

In relation to intergroup agreement rates, the agreement percentage among both types of patients (55.77%) demonstrates the contrast between the expectations from n-SCI and the "down-to-earth" requirements from e-SCI, and therefore, the complementarity of their requirements. Indeed, including both types of patients in this study and people with injuries of different severity was aimed at seeking requirements representative of the heterogeneous SCI population. Similarly, the intergroup agreement percentage of 50.0% between patients and clinicians indicates that including both types of users in the design process of these technologies is a must, given that their requirements are complementary. As shown in the results, both patients and clinicians agree on the importance of involving both types of users in the design and development of lower limb wearable exoskeletons, and they are motivated and willing to participate in these processes [99, 55]. They are stakeholders of exoskeletons in different ways; thus, both must be considered to design technologies that are usable, respond to users' needs and that are feasible to implement in their intended contexts. For most customers (i.e. individuals, hospitals, healthcare systems, or private rehabilitation institutions) the overall experience with a company, and not only the product itself (i.e. the exoskeleton), is fundamental to engage in business [59]. In fact, according to a report published in 2020 [59], 66% of customers expect companies to understand their unique needs and expectations, and healthcare sector is the one in which customers are concerned the most about being the center of the products and services. Understanding this important expectation will be fundamental for developers and companies in the field to develop technologies that are successful in reaching end users.

With respect to the agreement intragroup (see Figure 5), clinicians show higher agreement percentages for more codes, with the whole group agreeing on six (6) codes (high purchase cost, use at community and in public space or at work, daily use at home, use as an adjunct in rehabilitation, easy control with

different control options, important to involve clinicians in the development of the technologies). On the contrary, all the group of patients or n-SCI patients do not agree on any code, but all e-SCI patients interviewed did agree on two (2) codes (daily use at home, high purchase cost). In total, 18 codes expressed by clinicians were not mentioned by the patients (23,1% of all the codes). In general, for all the agreement deciles over 40%, more codes were agreed on by clinicians than patients. This demonstrates that having experience with the technologies (clinicians and e-SCI) result in higher agreements and in having focused requirements within a group. In this regard, the experience with the technologies makes the e-SCI group similar to the clinicians in terms of expressing more requirements in shorter interviews and in higher agreement rates between both groups when compared to n-SCI. Therefore, involving clinicians and e-SCI in UCD processes, even if they are few people, would be efficient and useful for developers because they give focused feedback representative of their respective requirements.

The new codes found in the data acquired in the study are one the most important contributions of this research. Considering the use of lower limb exoskeletons in rehabilitation settings, it is very important for PT that the devices have manageable weights and are easy to handle and move around, to not to increase the physical burden during therapy due to the manipulation of the device. All three groups agreed on the relevance of having devices that can be fit to different bodies and functionally adapted according to the patient needs, since these needs differ from user to user due to their specific impairment, and also evolve along therapy. Overall, there is a lack of scientific evidence to identify the specific population that can benefit from each technology depending on its features, as well as regarding the specific protocols that allow to optimize their use as rehabilitation devices [21].

Mostly clinicians and some e-SCI demand an improvement in the interaction of the device with the surroundings through sensors that help the device to automatically adapt to different scenarios, and an improvement in the interaction of the device with the person wearing it by closing the control loop through biofeedback and intention detection to move the exoskeleton. The latter is key to enhance neuroplasticity in robotic-assisted gait rehabilitation [69]. To these ends, both groups also referred to the advantages of combining lower limb exoskeletons with BCI or FES. Hybrid exoskeletons for gait rehabilitation are currently being explored due to the potential of adding the benefits of both types of technologies [23].

It is also very important to understand the fears that SCI people have regarding the use of these devices, because they ought to be addressed during the design of the technologies and when training the users, to allow them to trust the device and have a smooth interaction. Similarly, it is imperative to address clinicians' concerns regarding the perceived threat of exoskeletons for walking rehabilitation through education and divulgation. Exoskeletons for gait rehabilitation are not meant to replace physiotherapists, instead, they are meant to be a new tool to assist clinicians for physical therapy, exactly like the healthcare workers of this study expressed. Previous experiences with similar technologies, including for example the Lokomat, can show clinicians that these devices allow to provide intensive rehabilitation reducing the physical burden that PT have in traditional therapy, allowing them to 1) invest the time in more observation and evaluation of the progress of patients, 2) have more time available to design better therapy plans for patients and 3) have objective data regarding the patient movement and evolution, provided by the devices.

All types of users interviewed in this study suggest an increase in funding for lower limb exoskeletons, mostly because they consider these technologies are still under development. Nonetheless, currently there are six (6) devices with the European conformity (CE) mark, and there are at least four times more devices in different development stages [21], most of whom have been developed thanks to funding provided by public and private institutions. Then, why is it that at least 30 years of research, funding and dozens of developments aimed at the same goals have not provided at least a couple of devices that are not perceived by users as "still under development"? Perhaps the community of developers are not

focusing enough in investing the funding available to develop technologies that are usable by their end users and perceived by them as close to be realistically available in their intended contexts. In fact, the limited accessibility and availability of lower limb exoskeletons for gait rehabilitation is a topic that arose in most of the interviews, demonstrating the limited devices that have successfully reached end users when compared to the demand for exoskeletons. To overcome this issue, researchers and developers ought to 1) improve the usability of their devices including usability evaluations of their devices following benchmarks [102, 103] and 2) implement UCD: people with SCI and clinicians expressed they are motivated to participate in the developments and that their involvement is fundamental, because, in their own words, "they are the ones who know what they need". Even though they perceive the technologies still need years of development, almost half of the users interviewed have a positive perception about the technologies, especially e-SCI. They, together with clinicians, highlight the positive feeling of being able to stand up and walk again, even if the loss is permanent. This demonstrates it is worthy to keep working on improving the devices, since experienced users see the potential they have, but developers must focus on meeting the actual needs of their end users and on addressing the constraints of their intended context of use.

The complete set of criteria summarized in this chapter, encompassing both the knowledge available in the literature and the new criteria that emerged from the acquired data, will be useful to guide developers of WR for gait rehabilitation in the design, development and evaluation of their technologies, to make sure the efforts invested in the field lead to technologies that respond to the needs and expectations of their end users and are feasible to implement in their intended context of use. Additionally, the results emphasize the need to implement User-Centered Design and usability evaluation in the field, in line with the framework proposed in this Thesis.

LIMITATIONS AND FUTURE DIRECTIONS

Qualitative research does not allow to draw conclusions representative of the population studied. Nevertheless, the sample recruited for this research has similar gender distribution to the incidence of SCI [3], conforms to the sample characteristics suggested in the literature to implement qualitative methodologies through content analysis of semi-structured interviews [81] and allowed to reach data saturation thanks to performing comprehensive semi-structured interviews regarding a specific topic. Moreover, it is larger than the samples of most other studies available in the literature implementing similar methodologies and related to the same topic. The only study with similar methodology but a larger sample [100] focuses in identifying only functional and design requirements for a soft exoskeleton, whereas this study aimed at identifying a more comprehensive set of requirements in different dimensions for the design of lower limb exoskeletons.

On this behalf, it would be interesting to hold comparable studies in other countries to evaluate if similar requirements arise and similar agreement rates prevail despite the differences in contexts. It would be of special interest to analyze contrasts between countries with public health systems with respect to those that only rely on private health. In addition, there is limited interpretability about the relative relevance of each requirement due to the methodology used. Currently, it could be inferred that the more users expressing a requirement, the more important it is, but it is necessary to run a specific study focused in evaluating users' priorities among the comprehensive list of requirements presented in this study. For specific technology developments, such a study to identify users' design priorities could be optimal to focus efforts depending on the specific population(s), context of use, and type of technology to be developed.

CONCLUSIONS

People with spinal cord injury and the clinicians in charge of their rehabilitation are stakeholders of exoskeletons with complimentary design requirements. Therefore, it is essential to engage both types of

users in the design process to create technologies that are responsive to users' needs, usable and feasible to implement in their intended contexts. This engagement is relevant due to the current limitations in accessibility and availability of lower limb exoskeletons for gait rehabilitation. This can be achieved through implementing User-centered design during the development of these technologies: users interviewed are motivated to participate in the developments and they agreed on the relevance of being involved. The criteria elicited in the research confirms previously reported requirements and adds up new ones, providing a comprehensive set of requirements, perceptions, and expectations of users of lower limb wearable exoskeletons for gait rehabilitation. They can guide developers in future technology developments.

3.2 Study 2: Exploring gait patterns in Spinal Cord Injury

3.2.1 Exploring the use of clustering algorithms to identify gait patterns in spinal cord injury[14]

INTRODUCTION

In recent years, robot-assisted gait rehabilitation has attracted interest, as it shows similar results to those of traditional rehabilitation [104]. Its evolution has resulted in the use of overground wearable exoskeletons that allow a wider range of possibilities for use in rehabilitation compared to more traditional robotic support technologies like treadmill exoskeletons [105, 106]. Although there are some alternatives available in the market, these have limited efficacy because they are developed as generic solutions for a wide spectrum of conditions, and therefore lack customization possibilities for the individual requirements of each patient.

In cases such as SCI, where loss of motor function is a common consequence and one of the main goals of rehabilitation is walking [107], rehabilitation ought to be adapted according to the requirements of each patient in order to be efficient and effective [89], given the high variability in gait patterns between subjects. One way to identify these requirements is through 3DGA, since these allow to objectively study and quantify individual gait disorders they present [31].

Given the large amount of kinematic, kinetic, and spatiotemporal information that a 3DGA provides [31], machine learning tools are useful for looking for patterns in the data [7-11]. In this field, unsupervised learning algorithms that group data from gait studies based on their similarity, also called clustering methods, could identify groups of patients with similar requirements in terms of gait functionality. This could be translated into specific functional requirements for assisting the gait of each patient, which could be used in the development of rehabilitation exoskeletons that are useful for groups of patients with similar functional requirements. These algorithms have been used successfully to pool gait studies of patients with cerebral palsy for diagnostic purposes [108, 109, 110, 111, 112]. However, to the authors' knowledge, no studies have been conducted exploring their use in gait data from SCI patients.

The aim of this paper is to explore the use of traditional clustering methods (k-means and hierarchical) with kinematic and spatiotemporal variables obtained from 3DGA of patients with SCI, in relation to the Walking Index for Spinal Cord Injury (WISCI) II scale [113] and with the combination between the AIS and the level of injury. The algorithms are expected to group the data in relation to the functionality of the gait of the patients.

METHODOLOGY

Spatiotemporal and kinematic variables were retrospectively collected from patients diagnosed with SCI who underwent a 3DGA at the National Hospital for Paraplegics in Toledo, Spain, between August 2019 and February 2021. Only the studies performed without using any technical assistance or orthotics were used. The gait studies were recorded with the CODA motion analysis system and were processed with ODIN v. 2.02 software (Codamotion Ltd., England, UK). In total, records of 413 strides were collected, corresponding to 50 gait studies of 43 patients aged between 5 and 70 years (median: 15 years, mean: 20.14 years ±16.16 years). The sample includes AIS B, C, D and E injuries in levels between C1 to L4. All patients signed the informed consent to perform the 3DGA.

[14] This subchapter is based in an oral contribution that is part of the scientific production of this PhD thesis:

Herrera-Valenzuela, DS; Torrado-Carvajal, A; Moreno, JC; Sinovas-Alonso, I; de los Reyes, A; Gil-Agudo, A; del Ama-Espinosa, AJ. "Exploración del uso de algoritmos de clustering para identificar patrones de marcha en lesión medular: resultados preliminares". XII Simposio CEA de Bioingeniería. Universidad Rey Juan Carlos. 2021. Spain.

Data were normalized with the z-score method and used in hierarchical clustering algorithms and k-means to explore patterns between records. Pearson's correlation coefficient was used due to the unbalanced nature of the database. The number of groups (k) was established at six for the WISCI II scale, corresponding to the number of values of this scale present in the population, and at nine for the combination between AIS and injury level, since there are 9 possible combinations in the available data. Ten replicates were performed using parallel computing to identify the smallest value of sum of distances (BSoD) when using k-means. For the hierarchical classification, a quantile of 0.95 of inconsistency was determined to define the groups and the Cophenet correlation coefficient was calculated as an indicator of the correlation between the linking of objects in the tree with the distances between the objects.

The resulting clusters were studied with respect to the WISCI II scale using one-way analysis of variance (ANOVA), previous verification the normality of the data with Kolmogorov-Smirnov tests. The WISCI II is a scale of gait independence in 10 meters previously validated in SCI [113]. Consequently, the assessment of the clusters with respect to the WISCI II is aimed at exploring if the clusters are grouped according to gait independence. The relationship of the clusters with the combination between AIS and injury level was studied descriptively, through the percentages of data for each combination classified in each cluster For this assessment, five subgroups were defined within injury levels: equal to or above T2 (<=T2), below T2 and above or equal to T12 (<=T12), below T12 and above or equal to L3 (<=L3), below L3 (>L3), and injuries with etiologies that do not allow defining a level of injury (occult spina bifida, achondroplasia and incomplete myelopathy due to lumbar stenosis, tethered spinal cord and epidermoid tumor). The distribution of records for each level of WISCI II, AIS, and injury level is shown in Table 6.

For all the tests, the MATLAB R2019a software was used (The MathWorks Inc., Natickle, Massachusetts, USA).

TABLE 6. Number of records for each level of WISCI II, AIS and group of injury level.

WISCI II	12	15	16	18	19	20	TOTAL
n	6	16	20	93	40	238	413
AIS	B	C	D	E	N/A	TOTAL	
n	20	119	225	9	40	413	
Injury level	<=T2	<=T12	<=L3	>L3	N/A	TOTAL	
n	109	105	139	32	28	413	

RESULTS

When exploring the relationship between the WISCI II scale and the clusters obtained using k-means (k=6) with the correlation distance, among the 16 combinations between the clusters formed, statistically significant differences between 10 of them (2 vs 1,3,5,6; 1 vs 3.5; 3 vs 4; 4 vs 5.6; 5 vs 6) were found. For hierarchical clustering, statistically significant differences were found between 4 combinations (4 vs 2,5,6; 5 vs 6) (see Figure 15). However, the sets of data within each cluster do not meet the normality assumption.

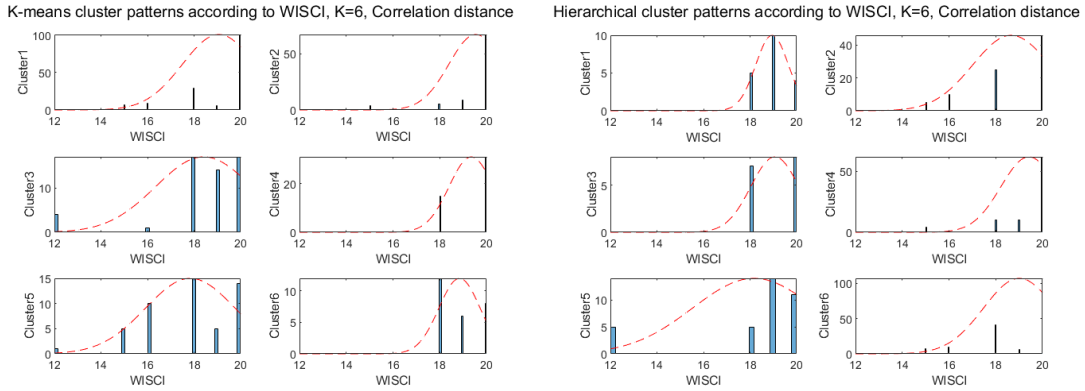


FIGURE 15. Relationship between the clusters and the WISCI II scale. Statistically significant differences were found between clusters 2 vs 1,3,5,6; 1 vs 3.5; 3 vs 4; 4 vs 5.6; 5 vs 6 when applying k-means (left), and between the clusters 4 vs 2,5,6; 5 vs 6 with the hierarchical method (right). Not all the sets of data within each cluster meet the normality assumption.

Figure 16 shows a descriptive representation of the percentage of data from each level of the WISCI II that were assigned to each cluster.

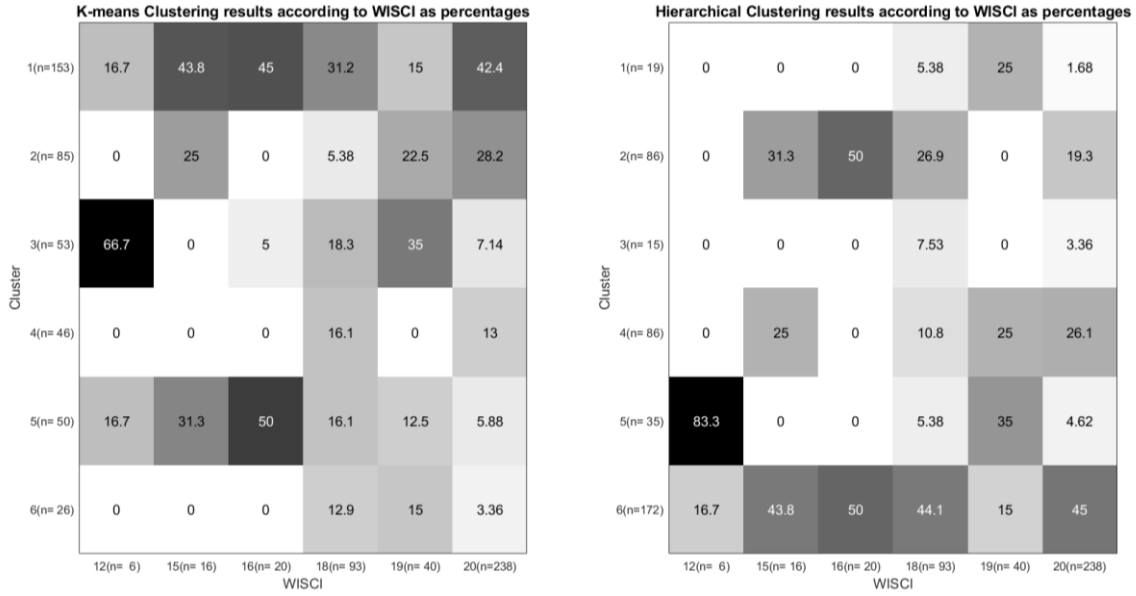


FIGURE 16. Distribution of the records in terms of the percentage of data from each level of the WISCI II (columns) that were assigned to each cluster (rows). On the left the results when using the k-means algorithm and on the right those of hierarchical grouping. The numbers in parentheses for each label indicate the number of records that were grouped into each cluster or the number of records the database has for each WISCI II level.

Finally, Figure 17 contains the descriptive representation of the percentage of data from each combination between AIS and injury level that were assigned to each cluster. In this experiment, k=9 was used, since it is the number of combinations between both categories.

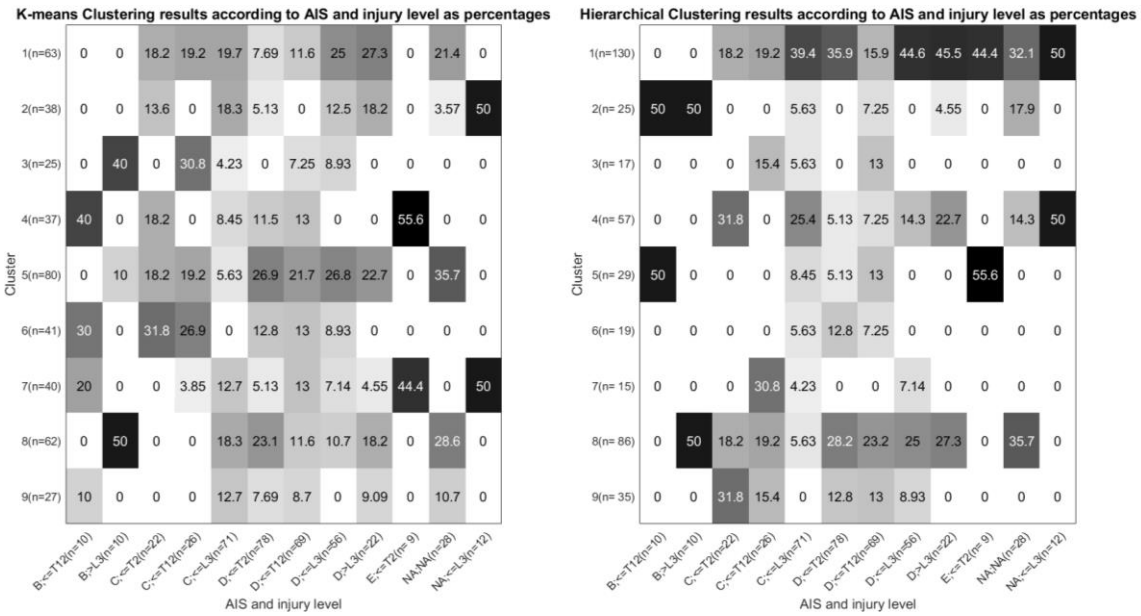


FIGURE 17. Distribution of records in terms of the percentage of data from each combination between AIS and injury level (columns) that were assigned to each cluster (rows). Darker colors indicate a higher percentage. On the left are the results when using the k-means algorithm and on the right those of hierarchical clustering. The numbers in parentheses for each label indicate the number of records that were grouped into each cluster or the number of records that the database has for each combination between AIS and injury level.

ANALYSIS

In Figure 15 there is no clear pattern between the distribution or the mean of the clusters, since for all of them, the value oscillates between 18 and 20. Since not all the data within each cluster fulfilled the assumption of normality, the differences identified between the groups with the ANOVAs are considered non-conclusive. It is worth noting that for both methods, one or two clusters group almost all the records of levels 12, 15 and 16 of the WISCI II, corresponding to the lowest values available in the dataset. The same pattern can be seen in Figure 16 and Figure 17.

It is important to highlight the disproportion between the number of records grouped in each cluster, especially when using the hierarchical method, where a single cluster comprises more than a third of the data and others have less than 20 records. This is due to the use of an imbalanced database, especially in relation to the values of the WISCI II scale, where more than half of the data correspond to a level of 20. According to the literature, the consequence of an unequal distribution is that the algorithm learns to group better the data of levels with the largest number of samples, because they have more impact on the result of the data grouping. Therefore, the less represented levels do not converge [114]. However, an opposite result is evident, since the three lowest levels of WISCI II, which are also the ones with the least data, are entirely grouped into two or three clusters, while the records of the three highest levels of the scale they are scattered among almost all clusters (see Figure 16). Similar result can be seen in Figure 17, where the combinations with less data are grouped into few clusters. For the WISCI II, this can be explained because the level of gait impairment is higher for subjects with lower values on the scale, which up to level 16 corresponds to the use of two crutches. For the combination between AIS and injury level, most of the combinations that are grouped between two to four clusters correspond to an AIS B, that is, the most severe injuries available in the dataset. In general, the categories grouped into fewer clusters also coincide with those with fewer records in the database. A possible explanation for this is that data of categories with many records are more difficult to group because they comprise a greater variability between gait patterns.

Finally, it is interesting to observe that for both values of k used, the hierarchical method clusters both the low values of WISCI II (12, 15 and 16) and the combinations with AIS B into fewer clusters. This finding makes sense because the hierarchical clustering algorithms are not sensitive to imbalance in the databases, unlike k-means.

CONCLUSIONS

No conclusive relationship was found between the SCI gait independence assessment scale, WISCI II, and the groups obtained by applying k-means and hierarchical clustering algorithms in the database of 3DGA of subjects with SCI. At a descriptive level, the results seem to indicate that these algorithms more accurately group the records of subjects with greater and no level of gait impairment, reflected in low values on the WISCI II scale and in spinal cord injuries corresponding to AIS B or E. Hierarchical clustering methods perform better, probably because it is robust against unbalanced databases, unlike k-means. To lessen the impact of database imbalance, the use of modified versions of clustering algorithms developed specifically for this data can be explored. Another alternative is carrying out a subsampling of the categories with more data to balance the sample, or to explore the clusters in relation to variables other than WISCI II, AIS and level of injury.

3.2.2 CLASSIFICATION OF 3D GAIT ANALYSES OF PEOPLE WITH SPINAL CORD INJURY USING K-NEAREST NEIGHBORS[15]

INTRODUCTION

Loss of motor function is a common consequence of SCI, usually affecting gait. Given the close relationship between gait and quality of life, walking is one of the main rehabilitation objectives for people with SCI [107]. To achieve efficient and effective rehabilitation, it must be adapted according to the functional state and the characteristics of the injury of each subject [89], since the variability in gait patterns and in the compensatory strategies between patients is very high. One way to identify these requirements is through 3DGA, since these allow an objective analysis of individual disorders [31].

Given the large amount of kinematic, kinetic, and spatiotemporal information provided by a gait study [31], machine learning tools are useful for identifying the most important variables that represent a given population and that allow to differentiate it from others [109, 112]. In this sense, classification algorithms can be used to differentiate pathological from non-pathological gait, and even to identify the main variables that represent gait variability in a population. These could be translated into specific functional needs for the gait of each patient, which allow the development of personalized strategies and tools for gait rehabilitation.

Various supervised and unsupervised machine learning algorithms have been used successfully to pool gait studies of patients with cerebral palsy for diagnostic purposes [108, 110, 111, 112]. In spinal cord injury, work has been carried out to identify the spatiotemporal parameters of gait that allow better discrimination between a group of rats with incomplete injury and a control group [115], and unsupervised learning algorithms have been implemented for the prognosis of gait rehabilitation outcomes in patients with spinal cord injury [116].

To the authors' knowledge, there have been no studies exploring the use of machine learning-based classification algorithms to discriminate non-pathological gait from that of SCI patients. Therefore, the aim of this work is to implement a classic classification model, known as k-nearest neighbors, to classify

[15] This subchapter is based in an oral contribution that is part of the scientific production of this PhD thesis:

Herrera-Valenzuela, DS; Torrado-Carvajal, A; Moreno, JC; Sinovas-Alonso, I; de los Reyes, A; Gil-Agudo, A; del Ama-Espinosa, AJ. “Clasificación de estudios de marcha de pacientes con lesión medular usando k-vecinos más cercanos”. XI Congreso Iberoamericano de Tecnologías de Apoyo a la Discapacidad IBERDISCAP 2021. AITADIS. 2021. Spain.

the gait of patients with SCI and the gait of healthy subjects, using kinematic and spatiotemporal variables obtained from 3DGA. The components that contribute to a greater extent to the favorable performance of the classifier are also identified.

METHODOLOGY

Spatiotemporal and kinematic variables were retrospectively collected from patients diagnosed with SCI who underwent a 3DGA at the National Hospital for Paraplegics in Toledo, Spain, between August 2019 and June 2021. The gait studies were recorded with the CODA motion analysis system and were processed with ODIN v. 2.02 software (Codamotion Ltd., England, UK). All the subjects or their guardians signed the informed consent prior to conducting the study. In total, records of 776 steps were collected, corresponding to 96 gait studies of 81 patients, aged between 5 and 70 years (median: 15 years, mean: 20.84 ±16.51 years). The records of the control group (CG) were collected in the same way and consisted of 496 steps of 50 subjects, aged between 18 and 63 years (median: 28 years, mean: 34.54 ±15.02 years).

To train the classifier 18 variables were used, nine from kinematics (maximum, minimum, and joint range values in the sagittal plane of the hip, knee, and ankle), and nine spatiotemporal parameters (speed, cadence, strides per minute, percentage of stance phase, step time, stride time, and the values of step width, step length, and stride length normalized by the height of each patient).

Regarding the training of the model, four experiments were carried out in which the data used to train and evaluate the k-nearest neighbors model were modified. In the first one, all the 18 available variables were used. In the second, principal component analysis (PCA) was applied before training the model, so that the PCA indicated the minimum number of principal components required to describe the differences between the data. Subsequently, the classifier was trained only with the nine kinematic variables and finally, it was trained only with the nine spatiotemporal variables. The purpose of these last tests was to identify if one of the two types of variables had more influence in the performance of the classifier to properly discriminate between the groups (SCI or CG).

For all the experiments, each variable was normalized with the z-score method and the data was randomly divided into two groups for the training (70%) and test (30%) of the classifier, i.e. 899 training steps and 383 test steps. A classifier based on the k-nearest neighbors algorithm was trained with five cross-validation iterations. The performance of the classifier was evaluated with a confusion matrix, considering accuracy and precision as the main evaluation metrics, calculated as follows:

$$Accuracy = (True\ Positives + True\ Negatives) / Total\ Data$$

$$Precision = True\ Positives / (True\ Positives + False\ Positives)$$

All tests were performed using MATLAB R2019a software (The MathWorks Inc., Natick, Massachusetts, USA).

RESULTS

Table 7 shows the results obtained in the training and test datasets for the four experimental conditions evaluated. By including the PCA, it was found that six components are sufficient to represent 95% of the variability of the database.

TABLE 7. Results of the classification using k-nearest neighbors in four different experiments.

Database	**Training** (899 steps)		**Evaluation** (383 steps)	
Data Used	*Accuracy*	*Precision*	*Accuracy*	*Precision*
18 variables	97.9%	98.9%	100%	100%

PCA (6 components)	94.2%	95.4%	96.6%	98.7%
9 kinematic variables	93.7%	95.4%	92.1%	94.7%
9 spatiotemporal variables	94.2%	96.1%	96.8%	98.2%

DISCUSSION

The accuracy and precision obtained by using a basic classification algorithm, such as k-nearest neighbors, are high. This indicates that the 18 kinematic and spatiotemporal variables used are sufficient to discriminate the gait of subjects with SCI from that of control subjects. In fact, when training the classifier with the first 6 principal components of the database, the performance of the algorithm decreases by less than 4% in both sets and metrics, demonstrating a high correlation between the original variables.

When training the same algorithm only with the spatiotemporal or kinematic information, the results obtained are slightly lower than those of obtained using the whole set of variables, but all of them are above 92%, which can be considered as a satisfactory performance. This indicates that, independently, any of the two types of information makes it possible to discriminate pathological from non-pathological gait, although the remaining variables provide some additional information that does not reflect just one of the sets individually. However, given that the result obtained using only spatiotemporal information is slightly higher than that obtained using only kinematic information and even better than the results obtained when training the classifier with the output of the PCA, it can be suggested that the former are more effective for discriminating the gait of both groups. This can be attributed to the fact that it is at the functional level where the greatest difference is observed between both groups [117, 118]. The improvement of spatiotemporal indicators such as cadence, stride length and speed are associated with common rehabilitation objectives directly related to gait assessment tests used in clinical practice, such as the Timed Up and Go test (TUGT), the 10-meter Walking Test (10MWT) or the six-minute walking test (6MWT). These reflect changes at the physiological level such as improvements in balance, a more efficient use of the energy invested in walking, or reductions in the risk of falling [119, 120, 121]. In everyday life, these indicators are related to factors that affect the quality of life of patients [122].

CONCLUSIONS

The kinematic and spatiotemporal information collected in 3DGA allows discriminating the gait of SCI patients from that of control subjects with accuracy and precision when used to train a k-nearest neighbor model. Similar performance is achieved by using only the spatiotemporal or kinematic variables to train the same algorithm, providing slightly better results with the former than the latter.

Advances in the use of machine learning techniques in gait analysis could allow them to become useful tools to support the diagnostic process of gait pathologies. Additionally, these tools make it possible to accurately identify the aspects in which there is the greatest difference between pathological and non-pathological gait, which could be useful in the development of rehabilitation tools and strategies, as well as in metrics oriented towards a comprehensive gait evaluation.

3.3 STUDY 3: DEVELOPMENT OF NEW COMPREHENSIVE METRICS FOR INDIVIDUAL GAIT ASSESSMENT

3.3.1 DERIVATION OF THE GAIT DEVIATION INDEX FOR SPINAL CORD INJURY[16]

INTRODUCTION

Walking is an extraordinarily complex task requiring integration of the entire nervous system, making gait susceptible to a variety of underlying neurologic abnormalities, such as SCI. Incidence rates of SCI vary across countries between 10.4 and 83 new cases per million inhabitants per year [3], with a global prevalence between 236 and 1,009 per million [123]. From these, more than 95% experience mobility impairments resulting from the injury [124], which affects their quality of life. The average age when subjects experience an SCI is 33 years and men are more affected than women with a 3.8:1 ratio [3]. Therefore, although the incidence is considered low, the personal, social and economic consequences of spinal cord damage can be severe.

The overall objectives of rehabilitation in SCI are to increase personal independence and quality of life minimizing the socio-economic burden. Still, regardless of the severity of the SCI, the time after lesion, or age at the time of injury, the restoration of walking is given high priority [12].Gait improvement in SCI following rehabilitation is assessed using different procedures, metrics and tools: on the one hand, validated clinical tests on overall gait function, such as categorical and spatiotemporal-related walking and balance assessment measures like the WISCI II [125], the 10MWT [126], the TUGT [127], the 6MWT [128], and the Berg balance scale (BBS) [129], among others [3]; on the other hand, tests of motor function and spasticity assessment, such as the Lower Extremity Motor Score (LEMS) and the Modified Ashworth Scale (MAS), respectively; and finally, instrumental techniques including dynamometry and 3DGA. The latter is the most comprehensive and precise technology to analyze gait that allows to objectively assess lower limb kinematics and kinetics, thus providing a powerful tool for quantifying gait impairment and, therefore, to assist decision-making for clinicians [33, 35, 130, 131].

The main feature of 3DGA is that it provides a large amount of data describing the spatiotemporal gait parameters, together with 3D pelvis, thigh, leg, and foot kinematics, as well as hip, knee, and ankle joint kinematics and kinetics during a gait cycle, along with specific values for each one of the gait phases and events [32]. This extensive information, usually presented with many graphs and tables, is often both difficult and impractical to be understood by clinicians [33, 34]. Therefore, it is recognized that clinical interpretation of the 3DGA results needs to be facilitated to increase its usefulness in clinical settings. One way to achieve this goal is to develop and implement straight-forward, easy to interpret metrics that merge data from 3DGA and yield a metric -or set of metrics- that describe overall gait deficits. One such metric is the gait deviation index (GDI), which is a dimensionless multivariate measure of overall gait pathology represented as a single score that indicates the gait deviation from a normal gait pattern average [132]. It is calculated upon the kinematics of pelvis and hip in the three planes in space, knee and ankle in the sagittal plane, and foot progression angle.

Originally, a dataset with more than 6000 strides of children with Cerebral Palsy (CP) was built to develop the GDI [132]. Based on these data, the authors derived a set of independent joint rotation patterns, referred to as gait features, so that, when combined linearly, high-quality reconstructions of gait curves can be obtained. In order to select the least number of features needed to represent the whole CP gait

[16] This chapter is based in a paper [177] that is part of the scientific production of this PhD thesis:

Herrera-Valenzuela, DS; Sinovas-Alonso, I; Moreno, JC; Gil-Agudo, A; del Ama-Espinosa, AJ. "Derivation of the Gait Deviation Index for Spinal Cord Injury". Frontiers in Bioengineering and Biotechnology, 10, (2022). https://doi.org/10.3389/fbioe.2022.874074.

profile dataset, they considered two criteria: 1) the set of features selected must account for at least 95% of the overall variance of the whole dataset, and 2) they must provide high-fidelity reconstructions of any gait curve with respect to the original curve. Applying these criteria, the authors found that 15 features out of 459 were enough to account for 98% of the total variance of the whole dataset and allowed to reconstruct the gait curves with a 98% fidelity on average. These 15 features were organized into a matrix used as an orthonormal basis to calculate the representation of any gait curve. Afterwards, to obtain the GDI, the Euclidean distance between this representation and the average of a set of control strides that may be introduced by the user, is calculated, representing the deviation of a gait pattern from a control group of typically developing (TD) children. Lastly, this value is scaled to improve the interpretability of the index, so that every 10 points of GDI below 100 correspond to one standard deviation away from the control pattern, whereas a score ≥100 represents a gait without any pathology [132].

Ever since, that 15-feature basis originally developed from data of children with CP has been widely used to calculate the GDI across different conditions, including post-stroke hemiparetic gait [133, 134], Duchenne muscular dystrophy [135], Parkinson's disease [136, 137], arthritis [138, 139, 140, 141], lower limb amputations [142, 143], degenerative spinal pathologies [144, 145, 146], genetic disorders [147, 148], congenital disorders [149, 150], the effect of the Covid-19 on physical function [151], and mostly in CP [152, 132, 153, 154, 155, 156, 157, 158, 159].

The GDI has therefore become a clinically relevant score, partly because it is easy to interpret and compute. Nevertheless, the basis provided in [132] has proved to account for the variance in gait patterns, and to reconstruct gait vectors with high fidelity, only in pediatric CP population. Significant differences in gait patterns among pediatric and adult population have been described [160, 161, 162], as well as both clinical and biomechanical differences among the different neurological disorders. Furthermore, when applied only to CP, differences in GDI were found between adult and pediatric population [163]. Actually, the authors in the original work of the development of the index suggested that the methodology could be used in other sets of data [132] but instead of developing a new basis for each condition, the articles found in the literature implement the GDI using the original basis regardless of the population. Therefore, straightforward application of the GDI derived in [132] in other populations than pediatric CP can lead to a misleading interpretation of the gait data.

To date, no studies have attempted to validate the GDI in SCI. Only two articles have investigated its application in this condition [164, 165]. One of them uses the index to quantify and characterize gait patterns in ambulatory children and adolescents with transverse myelitis with respect to a normal gait pattern [164]. In this work, the difference in gait between patients and TD children was assessed with the GDI, without addressing the discriminative validity of the scale within different levels of impairment. The work presented in [165] compared the GDI and the WISCI II, showing limited discriminative properties of the GDI in SCI because there were statistically significant differences in the GDI values only between levels 13, 19, 20 and the control group. Therefore, the applicability of the GDI to SCI population that leads to discriminate the heterogeneity of gait impairment is still an open question calling for investigation.

The main objective of this article is to investigate the application of the mathematical methodology behind the GDI [132] to a dataset of adults with SCI, resulting in the new SCI-GDI. Then, an evaluation of the differences between new SCI-GDI with the original GDI is presented, assessing the need for a specific GDI for SCI. Lastly, the relationship between the SCI-GDI and the WISCI II, the most validated scale in SCI developed specifically for this population [35], is further presented to investigate the differences between the GDI and the novel SCI-GDI in terms of stratification and sensitivity to walking impairment with respect to a validated scale.

MATERIALS AND METHODS

PARTICIPANTS

A dataset containing kinematic data from 3D gait analysis of patients with SCI was used in this study. The 3DGA were conducted between August 2019 and July 2021 at the Biomechanics and Technical Aids Unit of the National Hospital for Paraplegics of Toledo, Spain. Patients aged ≥16 years old with diagnosis of SCI, regardless of the etiology, time since injury, injury level or injury severity were included. A total of 302 strides from patients aged between 16 and 70 y.o. (33.91±17.86), with injury levels between C1 and L5 and AIS C to D were gathered. The ratio of males to females of the dataset is 3.25:1. The detailed demographic and clinical characteristics of the sample are presented in Table 8. Additionally, a control group with the 3D kinematic gait data of 446 strides from adults without gait pathologies was collected. These HV were between 18 and 63 y.o. (35.10±15.41) and the ratio females to males was 1.63:1.

All patients and HV signed an informed consent to perform the gait analysis. The study protocol was approved by the local bioethics committee (CEIC-CHTO, no. 823) and conformed to the Declaration of Helsinki.

TABLE 8. Demographic and clinical characteristics of the samples in the train and validation datasets.

Characteristic	Type	Train (n=302)	Validation (n=72)
Age	16-25	156	52
	26-40	32	0
	41-60	79	10
	>60	35	10
AIS	A	0	10
	C	36	10
	D	256	36
	Cauda equina	10	10
	N.A. (Congenital)	0	6
Time since injury	6 months (incl.) or less	58	10
	6 months (excl.) to 1 year (incl.)	40	0
	1 (excl.) to 5 years (incl.)	86	26
	More than 5 years	92	30
	Congenital	26	6
Injury level	C1-C8	153	0
	T1-T6	12	26
	T7-T12	68	20
	L1-L5	69	20
	N.A. (Congenital)	0	6
WISCI II level	12	2	0
	13	6	0
	15	18	10
	16	65	26
	18	12	6
	19	87	0
	20	112	30

EXPERIMENTAL PROCEDURE

A Codamotion® motion capture system (Charnwood Dynamics, Ltd, UK) was used to capture 3D kinematic gait data. The standard protocol with 22 active markers placed on the lower limbs [166], three scanners, and two force platforms Kistler 9286A (Kistler Group, Switzerland) in the center of a 10-meter walkway were used. Post-processing was performed using the software ODIN v. 2.02 (Codamotion Ltd., England,

United Kingdom). Subjects were asked to walk barefoot at a comfortable speed with the minimum external assistance required. Five complete gait cycles were recorded and time normalized. For patients who were not able to complete five trials, at least three cycles were gathered.

OVERVIEW OF THE CALCULATION OF THE GDI

The GDI derivation procedure was described in detail in [132]. The calculation is based on a matrix with kinematic data from several walking strides where each column vector is a stride represented by nine joint angles of a whole gait cycle extracted at 2% increments: three planes for the pelvis and hip, knee flex/extension, ankle dorsi/plantarflexion and foot progression angle. Singular Value Decomposition (SVD) of the matrix is computed to obtain its singular values and singular vectors. Using the latter, referred herein as gait features, the authors build an orthonormal basis that is both optimal to maximize the Variance Accounted For (VAF) of the whole dataset, and useful to reconstruct gait data. When multiplying the first *m*-vectors of this basis by any gait vector, an m^{th} order approximation of the vector is obtained, forming therefore a vectorial basis. The accuracy of this reconstruction is calculated with its projection onto the original vector, normalized by the original gait curve. Two criteria were used to find out the minimum *m* features needed to form a reduced order basis such that it represented the whole CP dataset; firstly, these first *m* features accounted for 98% of the total variance of the original dataset, and secondly, the accuracy of the m^{th} order reconstructed curves was 98% on average. The authors in [132] found that 15 features were sufficient to form the reduced order basis. Lastly, using the approximation of a gait vector obtained with this basis, its Euclidean distance with an average gait vector from a control group is calculated and scaled to obtain the GDI.

DATA ANALYSIS

An overview of the data analysis performed is presented in this section. The detailed description of each step is found in the following subsections. Henceforth, all data analysis was performed with Matlab R2019a (The MathWorks, Inc., Natick, Massachusetts, USA).

Using the dataset described previously, the first step of the data analysis was the computation of the SCI-GDI basis, that is, the optimal reduced order orthonormal basis to reconstruct gait data of SCI with high fidelity and to account for most of the variance of the SCI dataset. Once the SCI basis is formed with the sufficient amount of gait features *m*, in order to assess the appropriateness of computing the GDI in adult population with SCI using the original GDI basis, developed using a dataset of pediatric patients with CP [132], a comparison of the quality of the reconstructions of the whole SCI dataset obtained with three bases –the SCI-GDI basis, the original GDI basis that comprises 15 gait features [132], and the first 15 features of the SCI-GDI basis– was held. From the three bases, the latter was used to compare the fidelity of the reconstructions of the same order as those obtained with the original GDI basis. Figure 18 shows a diagram of the steps followed to obtain these three bases. Additionally, to assess the generalizability of the new SCI basis in foreign data, the quality of reconstruction in a set of strides not used during the computation of the SCI basis was computed.

Afterwards, the SCI-GDI of the dataset was calculated and it was compared with the WISCI II scale to assess the stratification of gait impairment and discriminative properties of the new index. Only one work has studied the relationship of the GDI with a scale developed specifically for SCI and validated in this population, which is the WISCI II [165]. No comparisons with other validated metrics in SCI, such as the 10MWT, the 6MWT, the TUGT or the BBS were conducted because these were not available. Lastly, the comparison and correlation of the GDI and the SCI-GDI in the dataset of this study was evaluated to find out whether there is an actual difference between both indexes when computed in the same set of SCI subjects, to recommend one index over the other in this specific population of adults with SCI. Data analysis details are described below.

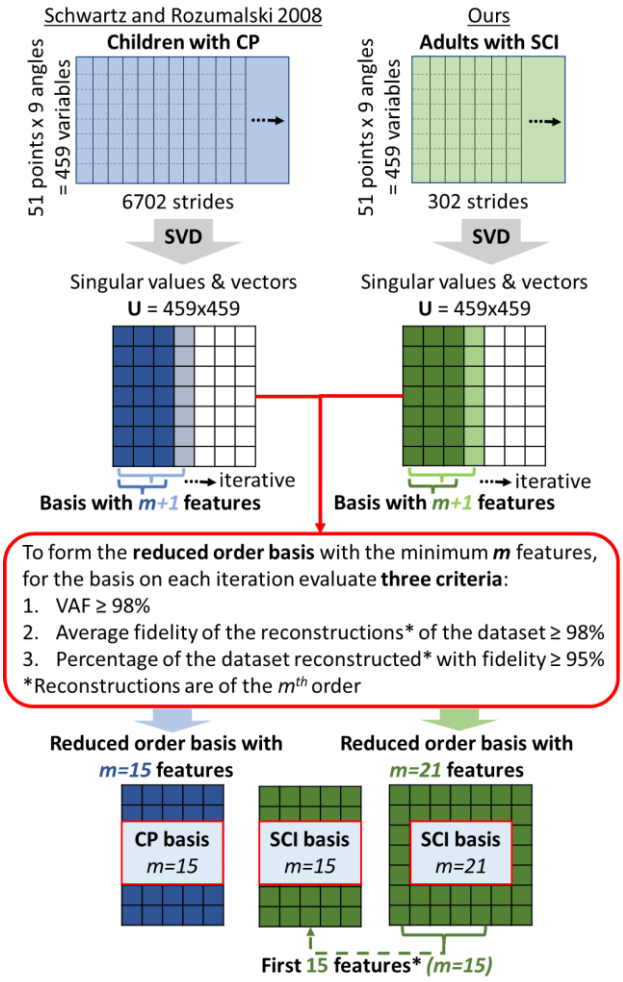


FIGURE 18. Diagram showing the steps followed to obtain the three reduced order bases compared in this study. The column on the left, with matrices in blue, represents the process followed in the original article by **[132]**, whereas the green matrices on the right correspond to the steps performed in this work, using SCI gait data. Note that the reduced order SCI basis with 15 features, located in the middle at the bottom of the diagram, is merely the set of the first 15 features of the 21-feature reduced order SCI basis. The three criteria contained in the red square were evaluated with the three bases on the bottom of the figure because the number of features in the basis determines the order of the reconstructions of the gait curves. Thus, it is fair to compare the quality of the reconstructions of the same order.

COMPUTATION OF THE SCI-GDI BASIS

In this work, 302 strides from SCI patients form the train dataset. These were used to form a matrix to compute the reduced order optimal basis. A grid search considering values of *m* between 10 to 30 was performed to find the minimum features needed to form the optimal reduced order SCI basis with the two criteria explained at the end of section "Overview of the calculation of the GDI". Another criterion considered was the percentage of gait vectors of the whole dataset reconstructed with a fidelity ≥95%, a parameter reported in the original work of the derivation of the GDI [132]. Although the dataset used in this study could be considered small to perform Feature Analysis, especially when compared to the 6000-stride dataset of the original GDI work, it is possible to obtain reliable, high-quality solutions with small datasets if the communalities between the features are high, because accurate recovery of population structure may be obtained with a small sample; thus, the size of the dataset will have little impact on the quality of the result [167]. Communality is related to the VAF criteria previously defined in this work, because it is defined as the proportion of the variance of the variable that is accounted for by the features [168]. Therefore, to consider the validity of the dataset used in this task, a Monte Carlo cross-validation with 10 iterations to assess the stability of the result was performed. On each iteration, five percent of the data was randomly removed before computing the SVD and a surrogate model was built. With each

model, the three criteria were assessed to find the minimum *m* features that allowed to fulfill each criterion: VAF≥98%, average fidelity of the reconstructions ≥98%, and percentage of the dataset reconstructed with fidelity ≥95%. Small differences between the *m* values found on each run, indicated similarity between the models and stable results [167].

Moreover, these results were compared with the quality of the 15^{th} order reconstructions of all the gait vectors in the dataset using the basis provided in [132], built with 15 features from CP patients, and also with the reconstructions obtained with the first 15 features of the basis calculated with the SCI dataset. Furthermore, to validate the generalizability of the new basis built from SCI gait data, a validation set was built with 72 additional strides that were not used to calculate the basis. These were reconstructed and compared using the three bases, and the reconstruction fidelity was assessed with the same criteria used in the train set, allowing to compare the quality of the reconstructions in foreign data.

COMPARISON BETWEEN THE SCI-GDI AND THE WISCI II SCALE

The SCI-GDI was calculated for each stride of both patients and HV using the reduced order orthonormal basis built in this work. Control group data, used as the reference gait pattern to compute the gait deviation, was collected at National Hospital for Paraplegics, as described in section "Data Collection", following the same procedure used with the patients. Each gait analysis study had an associated WISCI II level according to the walking impairment of the patient when recording the study. SCI-GDI data was grouped according to the corresponding WISCI II level and HV data was considered as an additional set. The dataset included WISCI II levels 12, 13, 15, 16, 18, 19 and 20. Normal distribution for each group was assessed with Kolmogorov-Smirnov tests ($p<0.05$).

To facilitate data interpretation, a histogram of the SCI-GDI data comprised within each WISCI II level was calculated with a normal distribution curve fitted to its mean and standard deviation. A stratified result of the histograms was expected, in accordance with the ordinal nature of the WISCI II scale. Afterwards, one-way ANOVA tests were performed between the SCI-GDI values of each pair of WISCI II levels to identify differences among groups ($p<0.05$). Additionally, a Kendall's Tau-B correlation was run between both scales to assess their relationship.

COMPARISON AND CORRELATION BETWEEN THE SCI-GDI AND THE GDI

To seek differences between the original GDI, calculated from a basis derived from a CP pediatric population [132], and the SCI-GDI, both indexes were calculated for each stride of the dataset using the HV data gathered at HNP. Results were grouped according to the WISCI II level of the sample. Normal distribution for each group was assessed with Kolmogorov-Smirnov tests ($p<0.05$). Consequently, one-way ANOVA tests were performed between each pair of equivalent WISCI II levels to identify differences among groups ($p<0.05$). Additionally, to study the relationship between both indexes, Pearson's correlation and linear regression were calculated between both GDI values using the whole dataset.

RESULTS

COMPUTATION OF THE SCI-GDI

The Monte Carlo cross-validation demonstrated stable results in terms of differences no larger than one in the minimum number of features necessary to build the basis, according to the criteria defined. On average, 19.3±0.5 features were sufficient to account for 98% of variance of the dataset. Nevertheless, 21.0±0.0 features were necessary to reconstruct the vectors of the dataset with an average fidelity of 98%. At m=21, 97.9±0.4% of the whole dataset was reconstructed with a fidelity of at least 95%. Therefore, m=21 was set as the minimum number of features to build the basis to represent the whole SCI gait dataset.

The comparison of the quality of reconstruction of the whole dataset when using the SCI basis with m=21, the SCI basis with m=15 and the basis of the original GDI derived for children with CP with m=15 is

presented in Table 9. The best results in terms of average fidelity of the reconstructions and percentage of vectors reconstructed with a fidelity ≥95% were obtained with the *m*=21 basis, followed by the basis built using only the first 15 features. Less than 50% of the dataset was reconstructed with a quality of at least 95% when using the basis provided in [132]. Note that it was not possible to calculate the VAF with the original GDI basis because the singular values of the original dataset are not publicly available. In the validation set, the results for all criteria followed the same pattern when using each type of basis but all scores were lower than those obtained in the train dataset. Figure 19 presents the reconstructions obtained with the three bases on a sample of the validation dataset with a SCI-GDI of 55.59 and a GDI of 60.03.

TABLE 9. Comparison of the quality of reconstruction of the whole dataset when using the SCI basis with *m*=21, the SCI basis with *m*=15 and the basis of the original GDI derived for children with CP with *m*=15 **[132]**. The best results in terms of average fidelity of the reconstructions and percentage of vectors reconstructed with a fidelity ≥95% are obtained with the m=21 basis, followed by the basis built using only the first 15 features.

Basis (nº of features)	Set	VAF	Average fidelity of reconstruction	% of gait vectors reconstructed with average fidelity ≥95%
SCI basis (*m*=21)	Train	98.27%	97.99%±1.54%	97.86%
	Validation		94.74%±4.88%	72.22%
SCI basis (*m*=15)	Train	97.11%	96.58%±2.49%	83.11%
	Validation		92.40%±6.64%	52.78%
CP basis (*m*=15) (10)	Train	N/A	93.13%±5.51%	44.70%
	Validation		90.73%±7.81%	40.28%

VAF, Variance accounted for; SCI, Spinal cord injury; CP, Cerebral Palsy; N/A, Not applicable.

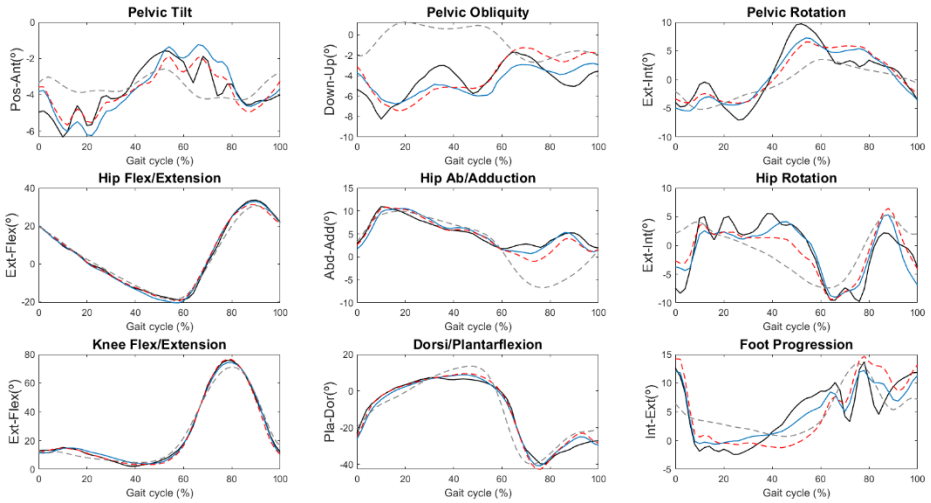


FIGURE 19. Kinematic reconstructions of a validation stride using the three bases. The black line is the original curve, the blue line the result when using the SCI basis with *m*=21, the red dashed line corresponds to the reconstruction with the SCI basis with *m*=15 and the grey dashed line is the reconstruction with the CP basis **[132]**. For all nine angles, the reconstructions with the original CP basis provide the largest deviation from the original curve.

COMPARISON BETWEEN THE SCI-GDI AND THE WISCI II SCALE

The results showed that the SCI-GDI is normally distributed across all WISCI II levels and in the HV group. Table 10 presents the distribution of the data, the mean and the standard deviation of the SCI-GDI values comprised in each WISCI II level. There is a trend of increasing SCI-GDI with decreasing level of functional limitation in WISCI II levels 13 to 20 and in the control group, except in level 18, with an average SCI-GDI lower than the average on level 16. This can be seen in Figure 20, that shows the histograms of the SCI-GDI stratified by WISCI II level. Statistically significant differences were found between the control group,

levels 13, 19 and 20 with all other groups, and additionally, between levels 15 and 16. In essence, all the levels had statistically significant differences except from 12 and 18 (see Table 10). Furthermore, both SCI-GDI and WISCI II have a strong, positive correlation of 0.460 which is statistically significant, according to Kendall's coefficient of rank correlation (*p*=1.63e-26) [169].

TABLE 10. Descriptive statistics of the SCI-GDI values within each WISCI II level. Numbers in parentheses indicate statistically significant differences found with an ANOVA ($p < 0.05$). The values marked with * indicate statistically significant differences found only in the SCI-GDI but not with the original GDI **[165]**.

WISCI II	Nº. Strides	Mean ± S.D. SCI-GDI	Minimum SCI-GDI	Maximum SCI-GDI	K-S test
C (12, 13, 15, 16, 18, 19, 20)	446	100.0 ± 10.0	72.2	126.5	True
20 (12, 13, 15, 16, 18, 19, C)	112	77.7 ± 15.8	53.8	120.8	True
19 (12, 13, 15, 16, 18, 20, C)	87	67.0 ± 8.4	51.7	95.0	True
18 (13, 19, 20, C)	12	54.7 ± 5.1	42.0	59.2	True
16 (13, 15*, 19, 20, C)	65	59.3 ± 10.8	41.0	80.2	True
15 (13, 16*, 19, 20, C)	18	52.6 ± 6.6	44.8	66.2	True
13 (12, 15, 16, 18, 19, 20, C)	6	42.7 ± 1.9	40.7	44.9	True
12 (13, 19, 20, C)	2	52.4 ± 3.5	49.9	54.8	True

WISCI II, Walking Index for Spinal Cord Injury II; SCI-GDI, Gait Deviation Index for Spinal Cord Injury; S.D., Standard Deviation; C, control; K-S Test, Kolmogórov-Smirnov test.

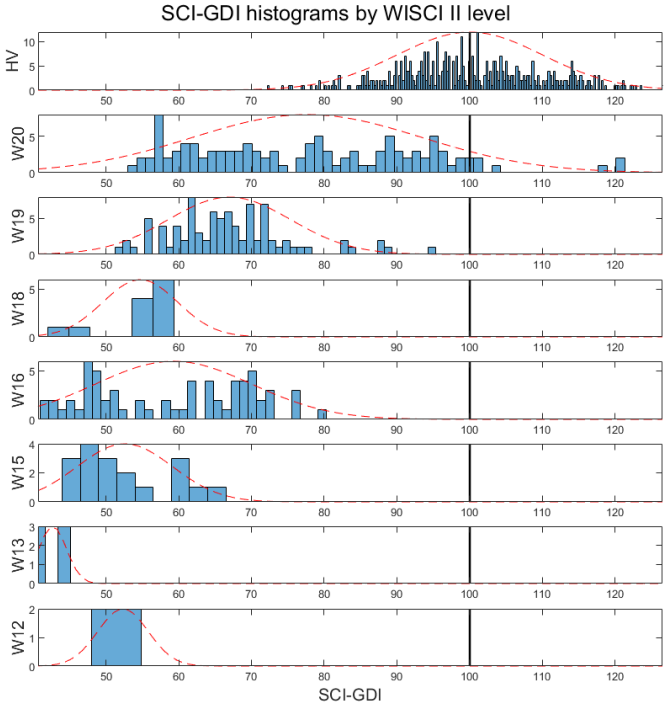


FIGURE 20. Histograms of the SCI-GDI stratified by WISCI II level (12 to 20 and control). The dotted line represents the normal distribution curve fitted to the data within each level. The vertical black line indicates the control mean.

COMPARISON AND CORRELATION BETWEEN THE SCI-GDI AND THE GDI

Both SCI-GDI and GDI are normally distributed across all WISCI II levels and in the control group according to the KS tests. When comparing the GDI and SCI-GDI values within each WISCI II level (Figure 21), statistically significant differences were found between all levels except for 12, 20 and the control group. For all levels, average GDI was greater than average SCI-GDI and followed the same pattern among

adjacent WISCI levels (Figure 21). Furthermore, a strong linear correlation between both GDI and SCI-GDI was found (*r*=0.993) (Figure 22), although both deviate at lower values.

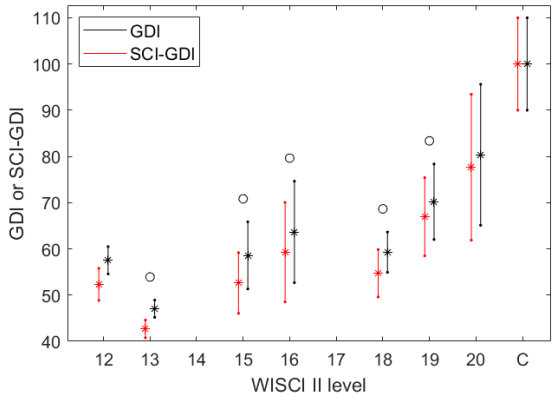


FIGURE 21. Average ± one standard deviation for GDI (black) and SCI-GDI (red) for each WISCI II level. In all levels, GDI values are greater than SCI-GDI values. WISCI II levels with a statistically significant difference between both indexes are marked with a circle.

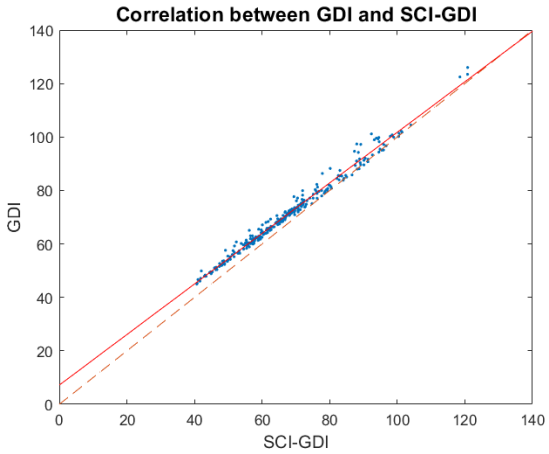


FIGURE 22. A strong linear correlation was found between the GDI and SCI-GDI (*r*=0.993). The linear regression between both indexes, represented by the continuous line, is given by the equation $\boldsymbol{SCI\_GDI = 1.0573 * GDI - 7.5915}$ the dashed line indicates the 1:1 axis. For all the samples, GDI values are larger than SCI-GDI values. The difference between both indexes is larger in data with greater impairment and it reduces progressively towards a normal gait pattern.

DISCUSSION

The main objective of this article was to derive a specific GDI applicable to SCI (SCI-GDI). The hypothesis of this research was that, since the GDI was obtained from a database of children with CP, the application to SCI would not correctly represent the gait impairments of this population. To this extent, a GDI was computed following the methodology originally proposed in [132] with a gait database of adults with SCI, to obtain the SCI-GDI. The correlation of the SCI-GDI with the WISCI-II, and its comparison with the GDI were evaluated.

Although the dataset to compute the reduced order SCI basis contained fewer number of steps than the original one, there is no rule of thumb to define the minimum size that a dataset should have to perform SVD and feature selection given an initial number of features [170]. Different recommendations stated in the literature and some studies demonstrate that it is feasible to obtain quality solutions with small datasets if certain conditions are met, like having data with high communalities [167, 168, 171]. During the process of finding the number of gait features necessary to form the optimal reduced order SCI basis, a high variables-to-factors ratio and stable results with variations of at most one feature in the Monte Carlo cross-validation, suggested that the dataset is large enough to represent robustly the variety of gait

patterns within the population of SCI comprised in the data, by using linear combinations of the information. Nevertheless, a larger dataset would be recommendable, given the number of features of the original matrix in which SVD is performed.

Regarding the process of defining the minimum number of features to form the reduced order basis, the results showed that *m*=19 was enough to account for at least 98% of the variance comprised in the dataset, indicating high communalities in the data, and suggesting that the size of the dataset is acceptable to be used in this study. Two more features are necessary (*m*=21) to reconstruct the curves within the dataset with an average fidelity of 98%. This difference is understandable because the first criterion was calculated with the singular values of the PCA while the second one depended on the singular vectors. Additionally, at *m*=21 almost 98% of the whole dataset was reconstructed with a fidelity of at least 95%, only 1% less than the results presented by [132] in the original derivation of the GDI in CP. Therefore, the 21st features were selected (*m*=21) to build the SCI basis, because both criteria must be fulfilled to build a basis that represents the whole dataset. It is important to note that these results indicate that six features more are necessary to represent the variety of gait in SCI when compared to the 15 features that were sufficient in CP [132]. These results suggest a larger variance in the kinematics of gait in SCI when compared to CP, which may be related to the heterogeneity of the clinical forms of incomplete SCI depending on the level of injury and AIS. Hence, the original 15-feature basis of the GDI may not account for the variety nor reconstruct with enough precision gait vectors in SCI.

In this regard, the results presented in Table 9 show that when calculating the quality of the reconstructions obtained with the original basis of the GDI [132] on the train dataset, fidelity drops from an “ideal” value reported in [132] of 98% to 93% and most importantly, only 44.70% of the dataset is reconstructed with a fidelity of at least 95%. These findings support the fact that the implementation of the GDI in SCI is not recommended, because the dataset used to derive the GDI basis was a pediatric CP population and there are differences in the etiology of the neurological impairment, clinical consequences related to function and maturity of gait between adults and children, that cause differences in gait patterns among populations. Indeed, even when using only the first 15 features of the SCI basis, the average fidelity of reconstruction is 1.41% lower when compared to the SCI basis with 21 features, but only 83.11% of the dataset is reconstructed with high quality. Still, this percentage is almost twice the value obtained with the CP basis, meaning that using a basis built with data of adults with SCI, 15 features are not enough to represent and reconstruct with accuracy the whole dataset but are better than using the 15 features from the original CP basis.

The results obtained using the validation dataset follow the same pattern, supporting the previous findings and indicating that results are not due to an overfitting to the dataset. Nevertheless, it is important to highlight the fact that all the values obtained when using the validation dataset are lower than the corresponding results in the train dataset, suggesting that using more train data would be recommended to obtain a SCI basis that provides more generalizable results, as reflected by smaller differences in performance when evaluating the criteria in both sets.

Moreover, the reconstruction of a single sample of the validation set with a large level of gait deviation (WISCI II=18, SCI-GDI=53.47 and GDI=60.43) in Figure 19, shows that the reconstructions obtained with the CP basis are poorly related to the original vector, whereas reconstructions with the SCI basis with 15 features have a better quality and the most accurate results are obtained with the 21st order reconstructions. It is also noteworthy that pelvic movement in the three axis is poorly reconstructed in all cases. This might be because the pelvis is the most complicated segment to model accurately and with reliability during a 3DGA [172]. The anatomical landmarks used to place or align the pelvic markers on most motion capture systems, including the CODA motion, are the anterior and posterior superior Iliac spines. These are bony protuberances in the pelvis covered with adipose tissue, therefore, the markers cannot be placed accurately on the subjects [173] and are prone to soft tissue artefacts [174]. Based on

these markers, the position of the pelvis is estimated, thus, the sources of error propagate from marker positioning to the computation of the kinematics of the segment. The improvement of the register of the pelvis during 3DGA is out of the scope of this article, but the issues for precisely estimating the position of the pelvis during a 3DGA are common to any capture, and therefore it is a limitation present in any 3DGA, and not only applicable to the calculation of the GDI or the SCI-GDI. Although it is not stated in the work by [132], in their Figure 2 it seems they identified similar difficulties in achieving precise pelvic representations. On the contrary, kinematics in the sagittal plane for the knee, hip and ankle have more precise reconstructions in the three examples. The angles that are better reconstructed might be more useful in attempts to derive indexes that use less variables than the nine used in the GDI.

In other respects, the comparison between the SCI-GDI and the WISCI II scale showed the stratification expected in levels 13 to 20 and in the control group, except in level 18 (see Figure 20), similarly to the results obtained when using the GDI [165]. Nevertheless, an important difference is that only in the SCI-GDI, levels 15 and 16 showed a statistically difference, unlike in GDI (see Table 10). Therefore, the SCI-GDI provides a better discrimination of more WISCI II levels when compared to the GDI. The new index managed to discriminate all the levels comprised in the dataset except for 12 and 18, that have few data, especially level 12. Therefore, the SCI-GDI provides a good discrimination of most WISCI II levels between 13 and 20. It is likely that level 18 is hard to discriminate firstly because there are few data in this level, and secondly because it indicates the use of braces to improve functionality, which blocks differently hip, knee and ankle joints, depending on the nature of the orthosis, imposing a less-physiological gait pattern. Asking a patient that usually uses braces to walk without them, even in short distances like during a 3DGA, increases considerably the difficulty of the task, highlighting the impairment of gait with respect to the normal pattern. That might be why impairment as measured by the GDI is increased in level 18 with respect to level 16, that does not include the use braces but the use of crutches, that affect mostly gait kinetics instead of kinematics. Moreover, the strong, positive correlation found between both scales (τ_B = 0.460) show that they are related and measure gait impairment while at the same time, with a τ_B value far from a perfect correlation, representing different aspects of gait pathology. Furthermore, the comparison between the GDI and SCI-GDI demonstrated that both indexes are statistically different (see Figure 21) for all the WISCI II levels analyzed that include any type of walking assistance, supporting the importance of using a gait deviation index derived from a proper sample, in essence, a SCI adult population. Level 12 is not analyzed in detail because it is poorly represented with only two samples.

Results shown in Figure 21 indicate that lower SCI-GDI values are given to walking impairment when compared with the corresponding GDI values. This is congruent with the findings stated previously in this work because if the CP basis covers a smaller variance on gait patterns and provides low quality reconstructions on SCI, the GDI calculated from a SCI gait vector using this basis might be based on a poorer representation of the original SCI vector and therefore, less penalized than when the vector is better reconstructed and includes the alterations present in the gait curves. Furthermore, the similar patterns between both deviation indexes across all WISCI II levels presented in Figure 21 and the strong linear correlation (r=0.993) support that the SCI-GDI represents the same aspects of gait impairment as the GDI. The linear relationship between both indexes presented in Figure 22 clearly show that in higher values of GDI, the differences between GDI and SCI-GDI reduce. Thus, the application of the GDI in SCI could provide misleading information about the dimension of gait impairment, especially in patients with greater neurological damage. Therefore, the SCI-GDI is more sensitive to larger gait impairment than the GDI, but the difference between both indexes reduces progressively towards normal gait. These findings are congruent with the statistical differences found between both indexes for all WISCI II levels except for level 20 (see Figure 21), corresponding to individuals that do not require any assistance to walk. This makes sense because no difference in the degree of gait impairment is identified in subjects that do not need assistance to walk.

This study had several limitations. Firstly, as mentioned before, even though the computation of the SCI-GDI basis showed stable results, using a larger dataset would allow us to verify that the results (number of features *m*, VAF and reconstruction percentages) indeed remain independently of the number of strides in the database. Other of the limitations inherent to the SCI pathology is that, due to the high variability of gait impairment in SCI -which depends on several factors such as the neurological level of injury (NLI), the severity of the injury according to the AIS and the time since onset of injury- there is no topographic classification of SCI to assess an ordinal level of gait impairment, unlike other neurological pathologies such as CP [32]. Therefore, it is not possible to compare or validate the SCI-GDI with neither the AIS nor the NLI. Even though the SCI-GDI was only compared with the WISCI II due to data availability, a more balanced distribution of the data within the WISCI II levels was desirable. In this regard, this study lacks data of other gait tests or scales validated in SCI, like the 6MWT, TUGT, 10MWT or the BBS, to further validate the SCI-GDI. Such validation will also reinforce the need of developing specific GDIs for each condition instead of implementing the pediatric CP-based GDI to several populations without sufficient validation. Centers with gait datasets from other pathologies than CP [132] and SCI (this work) can reproduce this methodology to develop specific gait deviation indexes for their specific pathologies.

In spite of these limitations, the SCI-GDI can be applied in any person with a SCI regardless of the severity or neurological level of injury, from 16 to 70 years old in both men and women. The most important changes in gait kinematics occur during adolescence, and gait is considered mature and steady afterwards, with few changes [161]. Children have different gait kinematics than adults [162], that are constantly changing through the ages, and in elderly, around the age of 60 to 70, significant changes in gait are also reported [175]. Additionally, after a SCI is chronic, changes in gait are reduced mostly to those related to rehabilitation outcomes and are covered by the data included in the dataset. Likewise, the small differences in gait kinematics between men and women, that are mostly present in the frontal plane of the pelvis and hip [176], are not as conditioning as the gait limitations after a SCI, allowing the application of the SCI-GDI regardless of sex. The dataset intentionally captures a wide variety of gait data of SCI with different severity, neurological level of injury, time since injury onset, sex and age. The rationale behind is to capture the largest possible variety in gait patterns available at the HNP, to guarantee that the SCI-GDI could properly represent any of these patterns. Therefore, the results obtained allow to suggest the implementation of the SCI-GDI in adults with SCI from 16 to 70 y.o. using the electronic addendum provided in Annex 2. Detailed instructions to compute the index are provided in the same file. The novelty of this study with respect to the original development of the GDI [132] is the 21st feature SCI basis calculated. Therefore, the addendum provided has the same structure as the one provided to compute the GDI, but with the SCI basis.

CONCLUSION

The SCI-GDI is calculated using a 21-feature vectorial basis derived from gait data of adult population with SCI, instead of the 15-feature basis used for the original GDI. This index has better discriminative properties of more WISCI II levels than the original GDI when applied to adults with SCI and conforms to the stratification of gait impairment of the WISCI II scale. Additionally, the SCI-GDI is more sensitive to larger gait impairment than the GDI, but its sensitivity decreases with less impaired gait function. Indeed, the implementation of the original GDI in SCI may lead to overestimation of gait function. The SCI basis also allows to build higher-quality reconstructions of gait curves when compared to the original GDI basis. Although further validation of the index with other scales used in SCI would be of interest, its implementation in adults with SCI is recommended. It can be easily computed using the electronic addendum provided in the published article (also available in Annex 2).

3.3.2 IMPROVEMENT OF THE GAIT DEVIATION INDEX FOR SPINAL CORD INJURY TO BROADEN ITS APPLICABILITY: THE REDUCED GAIT DEVIATION INDEX FOR SPINAL CORD INJURY (RSCI-GDI)

INTRODUCTION

The SCI-GDI is an accurate and effective metric to summarize gait kinematics in adults with SCI. The GDI and the SCI-GDI are usually computed with information retrieved from a 3DGA performed using a photogrammetry system, requiring accurate information of pelvic and hip movement in the three anatomic planes, which is challenging to accurately register. Additionally, due to being developed from the GDI, the SCI-GDI is built upon nine joint movements selected for a pediatric population with cerebral palsy, for which the GDI was originally developed [132], but those nine movements are not as representative for adults with SCI. These are important limitations for various reasons. Firstly, pelvic movement has been proven to have low reliability even with gold-standard photogrammetry systems due to anatomic constraints for accurately mark the ideal anatomical landmarks [177, 172, 174]. Similarly, hip rotation in the transversal plane has been shown to have low reliability even when acquired with photogrammetry systems [178]. Additionally, the use of photogrammetry is limited in real-life scenarios because it requires a constrained scenario to work properly. This limits the use of the SCI-GDI to evaluate gait in alternative scenarios to gait laboratories. Besides, the instrumentation required for photogrammetry turns complicated to implement when used with WRD, limiting the possibility of using the SCI-GDI to evaluate technologies for gait assistance due to the likelihood of having a high rate of marker occlusion and the need to adapt the models to compute kinematics, which reduce its accuracy.

In consequence, this research aimed to improve the SCI-GDI to broaden its applicability beyond the use of photogrammetry in laboratory settings. To this end, an adapted version of the SCI-GDI including kinematics of less joints movements than the ones used to compute it was developed. The same dataset used in the derivation of the SCI-GDI [177] was used in this exploration to compare the effects of reducing the input kinematics of the index in the same sample of adults with SCI. Priority was given to the most relevant joint movements for the population with SCI that can be acquired with precision with simpler and more versatile systems than photogrammetry. An example of such systems are IMU, sensors that are easier to use, less time consuming and cheaper than photogrammetry, but also offer lower precision [179]. A previous study validated that hip flexion/extension, hip abduction/adduction, knee flexion/extension and ankle dorsi/plantarflexion can be assessed with equivalent precision using a set of IMU (Tech-MCS V3, Technaid, Spain) versus a VICON motion capture system [180]. Considering the clinical relevance of each of these joints in gait patterns in the SCI population and exploring mathematically the relevance of each joint movement included in the original GDI in the performance of the metric, the reduced SCI-GDI was computed with those four movements. This subchapter presents the derivation of this index, its statistical comparison with the SCI-GDI, and its validation with the WISCI II and other clinical tests validated in SCI.

METHDOLOGY

PARTICIPANTS AND EXPERIMENTAL PROCEDURE

The same dataset used in section 3.3.1 was used in this study. It contains the kinematics of 302 and 446 strides retrieved from 3DGA conducted with patients with SCI and healthy volunteers, respectively.

DATA ANALYSIS

The data analysis is the same used in section 3.3.1 with minor changes that are described below. For details about each step, please refer to the detailed descriptions in the data analysis of section 3.3.1. All data analysis was performed with Matlab R2019a (The MathWorks, Inc., Natick, Massachusetts, USA).

MATHEMATICAL EXPLORATION OF THE RELEVANCE OF THE 9 JOINT MOVEMENTS USED IN THE GDI-SCI

The complete dataset with nine kinematic curves was modified by removing the three pelvic curves from the 302 strides. A leave-one-out experiment with the six kinematic curves (three planes for the hip, knee flexion and ankle dorsi/plantarflexion and foot progression angle) was performed through a factorial analysis to identify the joints that introduce more variability of the dataset (i.e. the ones that, when left

out, allow to successfully represent the dataset with an orthonormal basis of lower order). Each joint curve was removed from the dataset before computing the reduced order (m^{th} order) orthonormal basis. A grid search considering values of *m* between 15 to 35 was used. In each case, an analysis of the order of the basis required to fulfill the three criteria defined in [177] to select the least possible features to effectively represent the variability of the dataset and to allow high fidelity reconstructions was performed. These are: to account for at least 98.0% of the variance of the dataset (VAF≥98.0%), allow to obtain a mean accuracy of 98% of the m^{th} order reconstructed curves, and to reconstruct most of the curves of the dataset with fidelity ≥95.0%.

COMPUTATION OF THE REDUCED SCI-GDI BASIS

Based on the results obtained in combination with the clinical experience and scientific evidence regarding the accuracy of the register of specific joint movements during 3DGA [178], a reduced SCI-GDI comprising only hip flexion/extension, hip abduction/adduction, knee flexion/extension and ankle dorsi/plantarflexion was computed and assessed. Compared to the 9 joints used in the complete SCI-GDI, pelvic movements were removed due to the low reliability in capturing them even with gold-standard photogrammetry systems due to anatomic constraints for accurately mark the ideal anatomical landmarks [177, 172, 174, 178]. Similarly, hip rotation was removed due to the poor inter-evaluator and moderate inter-trial and intra-evaluator reliability reported in 3DGA [178]. Lastly, foot progression angle presents moderate reliability for these three aspects [178] but was removed mainly because it has little relevance in SCI.

A matrix to compute the reduced order optimal basis was formed with the 302 strides from SCI patients. This data is named as train dataset. A grid search considering values of *m* between 10 to 25 was performed to find the minimum features needed to form the optimal reduced order SCI basis to fulfill the three criteria explained at the end of the previous section.

Furthermore, to validate the generalizability of the reduced SCI-GDI basis, a validation set was built with 72 additional strides that were not used to calculate the basis. These were reconstructed and the reconstruction fidelity was assessed with the same criteria used in the train set, allowing to compare the quality of the reconstructions in foreign data.

COMPARISON BETWEEN THE SCI-GDI AND THE RSCI-GDI WITH RESPECT TO THE WISCI II SCALE

The rSCI-GDI was calculated for each stride of the dataset using the control group data gathered at HNP. Each gait analysis study had an associated WISCI II level according to the walking impairment of the patient when recording the study. rSCI-GDI data was grouped according to the corresponding WISCI II level. The dataset included WISCI II levels 12, 13, 15, 16, 18, 19 and 20. Normal distribution for each group was assessed with Kolmogorov-Smirnov tests ($p<0.05$).

To facilitate the analysis, a histogram of the rSCI-GDI data comprised within each WISCI II level was calculated with a normal distribution curve fitted to its mean and standard deviation. A stratified result of the histograms was expected, in accordance with the ordinal nature of the WISCI II scale. Afterwards, one-way ANOVA tests were performed between the rSCI-GDI values of each pair of WISCI II levels to identify differences among groups ($p<0.05$).

To seek differences between the original SCI-GDI [177] and the rSCI-GDI, both indexes were calculated for each stride of the dataset using the HV data gathered at HNP. Consequently, one-way ANOVA tests were performed between each pair of equivalent WISCI II levels to identify differences among groups ($p<0.05$).

Additionally, to study the relationship between both indexes, Pearson's correlation and linear regression were calculated between both GDI values using the whole dataset.

VALIDATION OF THE RSCI-GDI WITH RESPECT TO OTHER CLINICAL MEASURES VALIDATED FOR THE POPULATION WITH SCI

The construct validity of the rSCI-GDI was evaluated with the validated clinical tests contained in the dataset used in the equivalent study done for the SCI-GDI [181]. It contains data from 35 adults with a diagnosis of SCI who underwent 3DGA at the HNP, in Toledo, Spain. During the 3DGA sessions the 10MWT in both self-selected and maximum speeds, the TUGT, and the LEMS were gathered. The 10MWT and TUGT were recorded three times and averaged for each subject. With the data collected, calculations for cadence, gait speed, stance percentage, step width, stride and step length, and the rGDI-SCI were performed. The Spearman correlation coefficient between the rGDI-SCI and all the tests and spatiotemporal parameters was calculated. The normal distribution of all variables was evaluated with a Kolmogorov-Smirnov (KS) test. Descriptive statistics for each of these scales and the subjects' demographics are summarized in Table 11.

TABLE 11. Demographic and clinical characteristics of subjects in the dataset with clinical tests validated in SCI.

Characteristic	Type	Number of subjects (n=35)
Age	16-25	16
	26-40	4
	41-60	11
	>60	4
AIS	C	4
	D	29
	E	2
Etiology	Traumatic	17
	Non-traumatic	18
Time since injury	6 months (incl.) or less	16
	6 months (excl.) to 1 year (incl.)	2
	1 (excl.) to 5 years (incl.)	8
	More than 5 years	8
	Congenital	1
Injury level	C1-C8	9
	T1-T6	6
	T7-T12	10
	L1-L5	10
WISCI II level	12	3
	13	1
	15	4
	16	9
	18	2
	19	3
	20	13
TUGT	Mean ± STD	12.01 ± 4.89
	Min – Max (Q1-Q3)	5.61 – 23.23 (8.38 – 14.66)
10MWT	Mean ± STD (Self-selected speed)	12.32 ± 4.44
	Min – Max (IQR) (Self-selected speed)	6.48 – 23.15 (8.11 – 14-63)
	Mean ± STD (Max. speed)	9.63 ± 3.77
	Min – Max (Q1-Q3) (Max. speed)	4.47 – 19.61 (5.98 – 11.76)
LEMS	Mean ± STD	37.20 ± 7.71

	Min – Max (Q1-Q3)	18.00 – 48.00 (33.00 – 42.50)
GDI-SCI	Mean ± STD	70.49 ± 14.58
	Min – Max (Q1-Q3)	36.33 – 104.39 (62.66 – 77.99)
	Min – Max (Q1-Q3)	41.64 – 99.99 (61.14 – 81.03)

RESULTS

MATHEMATICAL EXPLORATION OF THE RELEVANCE OF THE 9 JOINT MOVEMENTS USED IN THE GDI-SCI

Results of the factorial analysis are shown in Figure 23. The dataset is successfully represented requiring a lower order basis when removing hip internal/external rotation or the ankle foot progression angle.

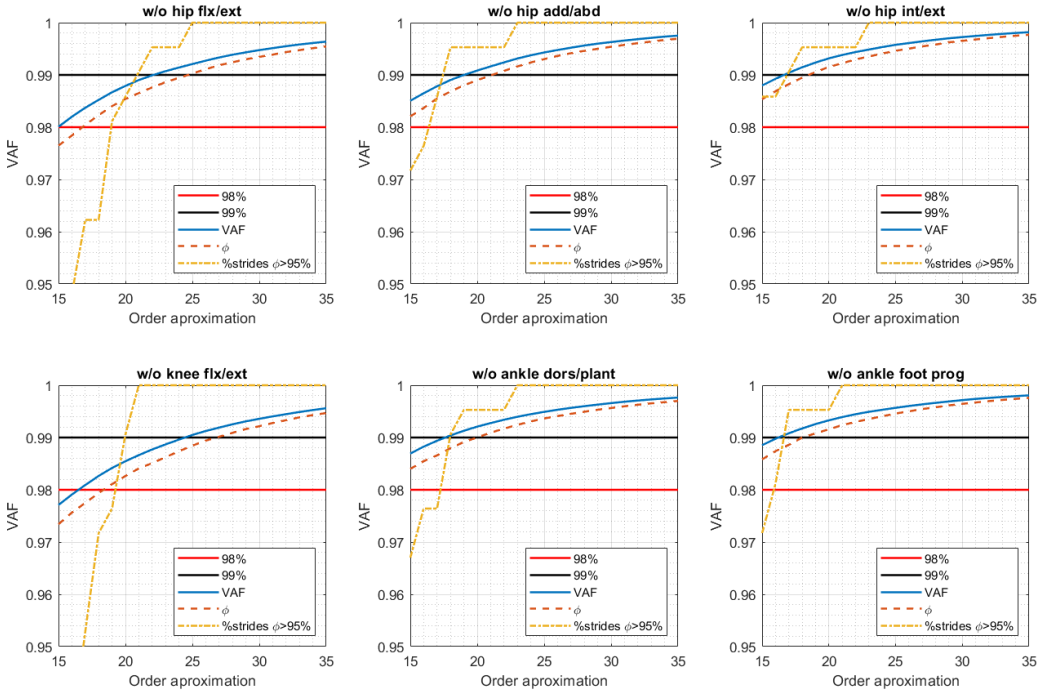


FIGURE 23. Results of the grid search exploration to find the reduced order basis required to fulfill the criteria required to have quality reconstructions when leaving out each one of the six joints of the dataset. For each order approximation, the blue lines indicate the VAF, the orange dotted line the average fidelity of the reconstructions and the yellow dotted line the percentage of the dataset reconstructed with fidelity over 95%. The red line indicates the threshold for the VAF, stated at 98%. The black line indicates the threshold of the percentage of the dataset reconstructed with fidelity over 95%, reported in 99% in the article of the original derivation of SCI **[132]**.

COMPUTATION OF THE REDUCED SCI-GDI BASIS

Figure 24 contains the results obtained in both train and validation datasets with the 4-joint reduced SCI-GDI basis. Results in both the train and validation set show that 14 features are enough to fulfill the three criteria considered for the creation of the GDI (VAF≥98.0%, accuracy of the m^{th} order reconstructed curves is 98% on average, percentage of the dataset reconstructed with accuracy ≥95.0%) [177]. In consequence, the orthonormal basis for the reduced SCI-GDI is built with the first 14 features of the basis built comprising kinematic data of only hip flexion/extension, hip abduction/adduction, knee flexion/extension and ankle dorsi/plantarflexion.

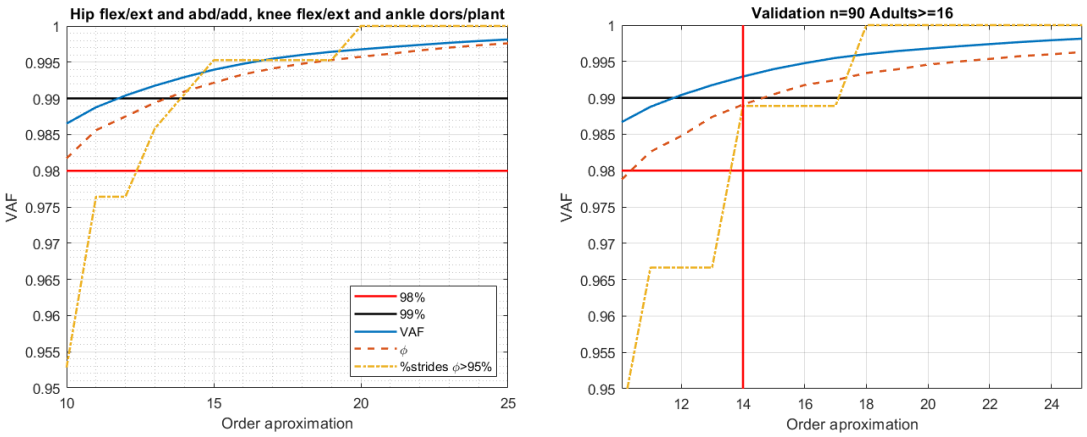


FIGURE 24. Results of the grid search exploration with the 4-joint dataset. The first 14 components of the reduced order basis allow to fulfill the criteria required to have quality reconstructions in both the train (left) and validation (right) datasets. For each order approximation, the blue lines indicate the VAF, the orange dotted line the average fidelity of the reconstructions and the yellow dotted line the percentage of the dataset reconstructed with fidelity over 95%. The red line indicates the threshold for the VAF, stated at 98%. The black line indicates the threshold of the percentage of the dataset reconstructed with fidelity over 95%, reported in 99% in the article of the original derivation of SCI **[132]**.

The summary of the results obtained for each criterion with this 14-feature reduced SCI-GDI basis in comparison to the ones obtained with the 21-feature SCI-GDI basis are summarized in Table 12. A strong correlation between both indexes was found (r=0.9118) and can be seen in Figure 25.

TABLE 12. Comparison of the quality of reconstruction of the whole dataset when using the reduced SCI-GDI basis with *m*=14 and the SCI-GDI basis with *m*=21 **[177]**. Better results are obtained with the reduced SCI-GDI basis in the train and validation sets.

Basis (nº of features)	Set	VAF	Average fidelity of reconstruction	% of gait vectors reconstructed with average fidelity ≥95%
SCI-GDI basis (*m*=21)	Train	98.27%	97.99%	97.86%
	Validation		94.74%	72.22%
Reduced SCI-GDI basis (*m*=14)	Train	99.29%	99.09%	99.06%
	Validation		98.91%	98.89%

VAF, Variance accounted for; SCI, Spinal cord injury; CP, Cerebral Palsy; N/A, Not applicable.

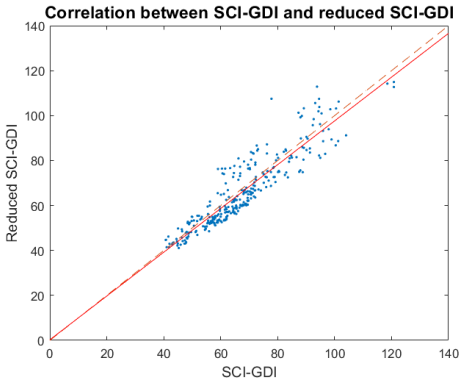


FIGURE 25. A strong linear correlation was found between the reduced SCI-GDI and SCI-GDI (*r*=0.9118). The linear regression between both indexes is represented by the continuous line, whereas the dashed line indicates the 1:1 axis. For less impaired subjects, lower reduced SCI-GDI can be assigned with respect to SCI-GDI values. The difference between both indexes is larger in data with less impairment and it reduces progressively towards more impaired gait patterns.

COMPARISON BETWEEN THE SCI-GDI AND THE RSCI-GDI WITH RESPECT TO THE WISCI II SCALE

The stratification of the reduced SCI-GDI with respect to the WISCI II levels comprised in the dataset used was confirmed, except for levels 18 and 13 (see Figure 26). The reduced SCI-GDI presents a more limited sensibility with respect to WISCI II levels than the original SCI-GDI. Statistically significant differences were found between all levels but between level 19 and level 12; between level 18 and levels 12, 15 and 16; between level 16 and levels 18, 15 and 12; and between level 15 and levels 18, 16 and 12. The only difference in the sensibility of both indexes is that the SCI-GDI can differentiate WISCI levels 15 and 16, unlike the reduced SCI-GDI. Additionally, statistically significant differences were only found between both indexes for the data of the WISCI level 19 (p=0.0036).

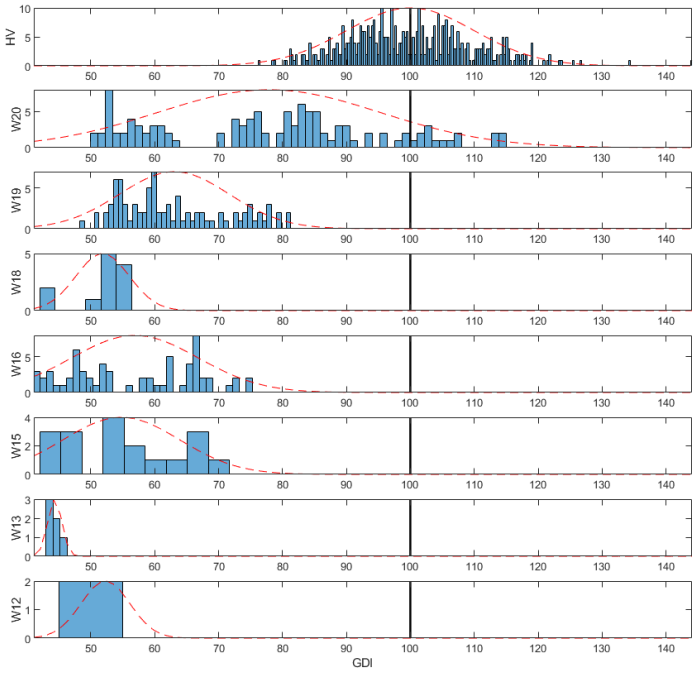


FIGURE 26. Histograms of the reduced SCI-GDI stratified by WISCI II level (12 to 20 and healthy volunteers). The dotted line represents the normal distribution curve fitted to the data within each level. The vertical black line indicates the control mean.

VALIDATION OF THE RSCI-GDI WITH RESPECT TO OTHER CLINICAL MEASURES VALIDATED FOR THE POPULATION WITH SCI

The rSCI-GDI presents very strong correlation with the SCI-GDI, similar to the one obtained with the dataset used for the derivation of the rSCI-GDI. Moderate correlations were found between the index and the LEMS, TUGT, the 10MWT for both self-selected and maximum speed, cadence, walking speed, stance percentage, and stride and step length. Fair correlations were found with the WISCI II scale and step width[17]. Overall, equivalent or stronger correlation coefficients were found with most of the clinical tests evaluated when compared to the SCI-GDI. Correlations with the TUGT, cadence, and stance percentage improve from fair (SCI-GDI) to moderate (rSCI-GDI), whereas the correlation with step width improves from poor to fair. Only the correlation with the LEMS decreased with the rSCI-GDI. The full set of correlations is presented in Table 13.

[17] The interpretation of the strength of the coefficients follow the guidelines in [182].

TABLE 13. Spearman correlation coefficients of the GDI-SCI and the rGDI-SCI with spatiotemporal features of gait and clinical tests validated in SCI. Correlation strength is classified following the guidelines in **[182]**: very strong ≥0.8 (green), moderate ≥0.6 (light green), fair ≥0.3 and poor <0.3. Arrows indicate larger or smaller correlation coefficient of the rSCI-GDI with respect to the SCI-GDI.

Measurement	Rho (rSCI-GDI)	P value (rSCI-GDI)	Rho (SCI-GDI)	P value (SCI-GDI)
GDI-SCI	0,901	<0,001	1,000	<0,001
WISCI ss	↑ 0,566	<0,001	0,521	<0,01
LEMS	↓ 0,612	<0,001	0,638	<0,001
TUGT	↑ -0,669	<0,001	-0,582	<0,001
10MWT pref	↑ -0,769	<0,001	-0,711	<0,001
10MWT max	↑ -0,791	<0,001	-0,716	<0,001
Cadence	↑ 0,611	<0,001	0,522	<0,01
Speed	↑ 0,790	<0,001	0,723	<0,001
Stance %	↑ -0,684	<0,001	-0,579	<0,001
Stride length	↑ 0,749	<0,001	0,684	<0,001
Step width	↑ -0,373	0,027	-0,279	0,104
Step length	↑ 0,760	<0,001	0,698	<0,001

DISCUSSION

The main objective of this study was to improve the SCI-GDI to broaden its applicability beyond the use of photogrammetry. To this end, the derivation and validation of the reduced SCI-GDI was performed. This study demonstrates that the reduced SCI-GDI (rSCI-GDI) effectively represents the variability of gait patterns among the population of SCI, provides more generalizable results than the SCI-GDI and has equivalent or better correlations with clinical tests validated in the population. The rSCI-GDI is computed with a 14^{th} order orthonormal basis derived from a dataset with four joint movements: hip flexion/extension, hip abduction/adduction, knee flexion/extension and ankle dorsi/plantarflexion.

The dataset of gait kinematics of adult population with SCI can be successfully represented requiring a lower order basis when removing hip internal/external rotation or the ankle foot progression angle (see Figure 23). Therefore, these kinematics are the ones that introduce most variability to the dataset due to the intrinsic limitations to be accurately measured. Hip rotation in the transversal plane has been shown to have low reliability even when acquired with photogrammetry systems [183], thereby, the variability introduced to the dataset of adult population with SCI is not due to intrinsic gait characteristics of this neurological population but due to the intrinsic limitations of the acquisition system. Therefore, this plane was removed from the ones used in the reduced SCI-GDI. Similarly, foot progression angle is the second joint with more variability when computing the Gait Variable Score (GVS) [183], a prior of the GDI. Moreover, this movement is representative of children with Cerebral Palsy, the population for which the GDI was originally computed [132], but it has not been described as a relevant joint movement in the gait kinematics of people with SCI. Consequently, supported in the clinical knowledge, in the results of the mathematical exploration of the impact of removing these joints, and in the technical viability for measuring each joint movement with commonly used systems, a reduced SCI-GDI using only the movements of hip flexion/extension, hip abduction/adduction, knee flexion/extension and ankle dorsi/plantarflexion was developed.

The reduced SCI-GDI shows a slightly better performance than the SCI-GDI in their respective training sets (containing the same subjects) for the three criteria evaluated: variance accounted for, similar average fidelity of reconstruction and similar percentage of gait vectors reconstructed with average fidelity ≥95% (see Table 12). Moreover, the reduced SCI-GDI shows better performance in the validation set and a negligible difference between both sets in the three criteria measured, indicating that it is a more robust index with high generalizability. These findings demonstrate that kinematics of pelvic movements in the

three planes, hip rotation in the transversal plane, and the ankle foot progression angle, increment the variability of the gait kinematics within the adult population with SCI due to difficulties in accurately measuring them, introducing noise in the captured data. When removed, consistent kinematic patterns of individuals with SCI can be reconstructed with more precision, demonstrating that the remaining joint kinematics included in the calculation of the GDI (i.e. ankle, knee and hip flexion/extension and hip abduction/adduction) are more representative of this population. Strong evidence to support this fact is the almost equivalent performance of the rSCI-GDI in the validation dataset compared to the train dataset, because it demonstrates that the orthonormal basis derived from the reduced dataset allows to recover with high precision gait kinematics from foreign data. Unlike the SCI-GDI, whose orthonormal basis reconstructs less than 73% of the validation vectors with high fidelity (≥95%), more than 98% of the validation vectors of the reduced data fulfill the same criterion. The reduction from 21 to 14 eigenvectors to form the reduced order orthonormal basis from the SCI-GDI and the rSCI-GDI (respectively), could be explained because the less joint movements included, the less variability must be covered in the projections of the vectorial space covered by the orthonormal basis.

Both indexes have a strong linear correlation (r=0.912), indicating they are effectively measuring similar aspects of gait of the SCI population. Bigger differences between both indexes can be observed in subjects with little gait impairment (see Figure 25), but statistically significant differences between both indexes were only observed in subjects in WISCI II level 19. Additionally, the only difference when assessing the sensibility of these indexes with respect to the WISCI II levels is that the SCI-GDI is sensible enough to differentiate levels 15 and 16, unlike the reduced version of the metric. This could be explained because the joint movements removed from the index (pelvic tilt, obliquity and rotation, hip rotation, and foot progression angle) have smaller angular variations between different functional levels (from 0.4º to 1.2º) compared to the variations of the remaining joints that are included in the rSCI-GDI (from 0.6º to 3.4º) [183]. Therefore, while the reduced index manages to have enough sensibility to detect movements showing bigger differences, the reduction in joint movements used as an input compromise the index ability to detect the smaller differences of the removed joints that are related to the functionality of gait described by the WISCI II. In this regard, finding a limited relationship of the index with the WISCI II is expected due to the contrasting aspects of gait that they describe [165]. While the GDI describes gait kinematics, the WISCI II describes the ability to perform independent gait, measured by the number and type of technical aids and human support required to walk, which can be acquired with alternative gait patterns than the ones described by healthy controls.

Instead, the results of the validation of the rSCI-GDI against a broader set of clinically validated tests and spatiotemporal features of gait demonstrate the advantages of this reduced index with respect to the SCI-GDI [181]. The generalizability of the rSCI-GDI is confirmed by the very strong correlation found with the SCI-GDI calculated in this dataset, comprising foreign data that was not used during the derivation of the reduced index. All correlations with the clinical scales are higher with the rSCI-GDI, being the only exception the LEMS, whose correlation decreased. Nonetheless, most of them remain in the same ranges of correlation strength. Interestingly, correlations with the TUGT, cadence, and stance percentage improve from fair to moderate, whereas the correlation with step width improves from poor to fair. Among these, the TUGT, the stance percentage and the step width are related to dynamic balance [184], indicating that although kinematics of the pelvic movement, hip rotation and foot progression are removed, the reduced index successfully conveys information related to the displacement and projection of the center of mass within the base of support, determinant of dynamic balance. The non-significant reduction in the correlation with the LEMS can be explained because this muscular balance evaluates hip flexors and knee extensors, which are also related to pelvic movement [185], thus, probably the SCI-GDI correlates better with the LEMS because it includes pelvic movement, unlike the rSCI-GDI.

LIMITATIONS AND FUTURE DIRECTIONS

Despite being developed to be feasible to compute using the kinematics registered with simpler systems than photogrammetry, it is necessary to develop future studies that assess the concurrent validity of computing the rSCI-GDI with photogrammetry and with other more versatile systems such as IMUs, goniometers, 2-D video-based analysis, among others. This is fundamental due to the differences in accuracy that each of them may have and to the intrinsic registration variability of each specific device. The latter could be affected by instrumentation protocols, the hardware used, the version of the software due to raw data processing, and even environmental aspects. In case other centers with gait datasets from other neurological injuries are interested in developing an injury-specific gait deviation index, it is worth to explore mathematically the reduction of the 9 joints originally considered for the GDI [132] to use only the joints considered relevant for each specific population. Adding other joint movements that are considered relevant can also be explored. By doing so, a more generalizable index could be obtained by focusing on the kinematic movements that characterize the kinematic patterns of each specific population and reducing the variability generated by external factors that are not related to the impairment caused by the injury.

CONCLUSIONS

The reduced SCI-GDI effectively represents gait variability of adults with SCI as does the SCI-GDI, while providing more generalizable results and stronger correlations with clinical tests validated in the population. It can be computed only with gait kinematics of the sagittal planes of hip, knee and ankle and hip abduction/adduction. These kinematic data can be reliably registered with simpler systems than photogrammetry and/or outside of laboratory settings. The rSCI-GDI can be calculated using the 14-feature vectorial basis provided in annex 3. During the derivation of the improved index, it was demonstrated that pelvic movements, hip rotation, and foot progression angle introduce high variability to the dataset of gait patterns of adult population with SCI, but they have low relevance to characterize gait kinematics of this population.

3.3.3 NOVEL COMPREHENSIVE METRIC FOR GAIT ASSESSMENT IN SPINAL CORD INJURY

INTRODUCTION

The etiology and clinical consequences of each type of neurological injury are different, and as such, metrics to assess gait rehabilitation ought to consider these specificities [186]. Functional recovery during gait rehabilitation after a neurological injury can occur through compensation and through resolution of impairment [187, 188]. Some approaches of widely used assessments (e.g. 3DGA) and patterns followed by most technologies (e.g. robotic technologies) are based on the comparison of pathological gait patterns against a normative pattern, pursuing the second mechanism. Other approaches focus rehabilitation recovering the most functional gait each subject can achieve, regardless of the compensations required and of the quality of the pattern followed. Both alternatives have funded arguments. Pursuing a normative gait pattern is important because it reduces the compensations and the consequent complications these may cause in the mid and long-term, especially in the musculoskeletal system. Additionally, training gait following a normative pattern is the most metabolically efficient way of moving, which allows subjects to increase resistance and to perform activities that require longer displacements [187, 188]. On the other hand, focusing rehabilitation on achieving a functional gait as soon as possible is reasonable because it allows subjects to increase their independence in daily-life activities. Moreover, depending on the impairment and clinical onset of each case, neurologically impaired subjects will not be able to recover a healthy gait pattern, thus, compensated strategies are their only realistic way for recovering ambulation [187, 189].

Gait improvement following rehabilitation is assessed using different procedures, metrics and tools. 3DGA is the most comprehensive and precise technology to analyze gait that allows to objectively assess lower limb kinematics and kinetics, thus providing a powerful tool for quantifying gait impairment and, therefore, to assist decision-making for clinicians [33, 35, 130, 131]. On the other hand, there are validated

clinical tests to assess overall gait function. Validation of such tests must be done in specific neurological populations. In the case of SCI these can be categorical, like the WISCI II [125]; spatiotemporal-related, such as the 10MWT [126], the TUGT [127] and the 6MWT [128]; and to assess balance, in the case of the BBS [129], among others [3]. Besides, tests of motor function and spasticity assessment are often performed, such as the LEMS and the MAS.

Considering the large clinical expertise of the clinical centers involved in the research shown in this thesis, this section proposes a novel comprehensive metric for the assessment of gait function in SCI including three complementary aspects: kinematics, spatiotemporal features and functional tests.

METHODOLOGY

Metric design

The new comprehensive metric for gait assessment in SCI is an easy-to-interpret polygon that includes clinically relevant measures and tests that relate to different aspects affecting gait function. All tests considered have been previously validated for SCI. The new metric is based on a hexagon whose vertices correspond to tests and measurements representing gait kinematics, spatiotemporal features of gait, or validated functional tests. Two measurements corresponding to each of those fields are included in the hexagon. They are displayed in a figure that is straightforward to interpret. The alternatives considered for each are the following: right and left SCI-GDI to summarize gait kinematics; cadence, step width and gait velocity as spatiotemporal features of gait; and the 10MWT, TUGT, or the WISCI II as validated assessments of gait function.

An assessment of the correlation between the tests and measurements available in the database was performed to select six to be included in the hexagon reducing data redundancy. The normal distribution of all variables was evaluated with a Shapiro-Wilk test to select an appropriate correlation coefficient. To be consistent in maximizing the axes values as a sign of better walking function, values for the TUGT, 10MWT, and step width were inverted. Given that the polygon is formed with validated measurements that represent comprehensively gait, it is of interest to study whether the area of the polygon provides valid information as a single-number comprehensive new metric to assess gait function in SCI. Therefore, after selecting the measurements selected to form the hexagon, the area of the polygon was calculated and the concurrent validity of the resulting number was evaluated with respect to the WISCI II, the LEMS, and the combination between the AIS and the injury level of the subjects in the dataset.

Understanding the relevance of implementing a UCD in the development of this new metric that aims to be clinically meaningful, the polygon was developed with the participation of a physiotherapist with vast experience in the gait rehabilitation of people with SCI, who provided knowledge regarding metric selection to create the hexagon and to guarantee its clinical interpretability.

Data description

The data employed to build and validate the metric presented in this study was not originally gathered for this research but is data previously collected at the Biomechanics Unit of the HNP, in Toledo, Spain. All the data corresponds to the subjects indicated for 3DGA as part of the assessment of the evolution of their SCI between March 2021 and July 2022. They all were inpatients or outpatients of the Hospital. All subjects and their legal tutors (when needed) provided their written informed consent to do the 3DGA. In total, data from 35 subjects was collected (11 females). Subjects participating were aged at least 16 y.o. with a diagnosis of incomplete spinal cord injury, regardless of the etiology or time since injury, with the ability to walk 10 meters with technical aids, if needed, but without physical support, and with the ability to provide consent to participate in the study.

The data gathered during the sessions included the measures for the 10MWT in both self-selected and maximum speeds, the TUGT, the assessment of the LEMS, and kinematics recorded with a Codamotion motion capture system (Charnwood Dynamics, Ltd, UK) in a 10-meter walkway with two Kistler force platforms (Kistler Group, Switzerland) embedded. All the tests with all subjects were performed by an experienced PT. The 10MWT and TUGT were recorded three times and averaged for each subject. With the data collected, calculations for cadence, gait velocity, and the Gait Deviation Index for SCI (SCI-GDI) for each leg were performed. Descriptive statistics for each of these scales and the subjects' demographics are summarized in Table 11.

Validity of the area of the polygon

With the data available, the following types of validations were performed:

1. Content validity of the polygon: assesses whether the metric adequately covers all aspects of the construct or concept it is meant to measure. Given that the measures and tests contained in the polygon are previously validated in adults with SCI, content validity is assured. Additionally, expert advice in the field indicates these measures represent comprehensively some of the most relevant dimensions to describe gait rehabilitation.
2. Concurrent validity of the area of the polygon: this validity assesses how well a measure predicts an external criterion, such as a specific outcome or behavior. It is computed as the measure of the correlation between the measure and the criterion at the same time. There is no way to perform this validation for the full polygon, which is the actual metric. Instead, the validation was run only for the area of the polygon, to explore if it provides valid information as a summary of the metric. In this way, the area was validated with respect to the WISCI II, the LEMS, and the combination between the AIS and the injury level of the subjects. The LEMS was divided into subgroups every 10 points in the scale. Factorial analysis was also performed to study the variability covered by the area of the polygon. To this end, PCA was calculated and the variability explained by the components with respect to the LEMS was assessed.

RESULTS

Selection of measurements for the metric

It is important to note that only the tests and measurements included in the dataset could be considered to form the new metric. Spearman correlation was selected because normality was not confirmed for the TUGT (p-value=0.027), the 10MWT (p-value=0.014), the WISCI II scale (p-value=0.000), the LEMS (p-value=0.004) and walking speed (0.009). Correlation coefficients are shown in Figure 27. According to these results, two sets of metrics were tested for the hexagon. Alternative one comprises the SCI-GDI for both legs, gait speed, cadence, the TUGT and the WISCI II scale whereas alternative two considers step width instead of gait speed. Examples of the two alternatives are displayed in Figure 28.

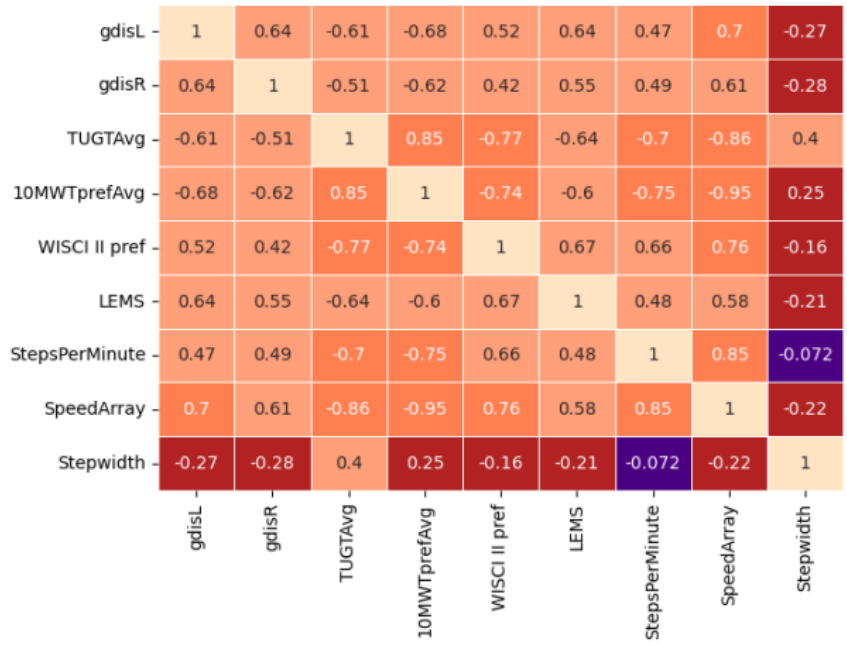


FIGURE 27. Spearman correlation coefficients between the measures and tests considered to create the polygon. Coefficients ≥ 0.1 and < 0.3 are considered weak, between ≥ 0.4 and <0.7 moderate, and between ≥ 0.7 and <1.0 strong.

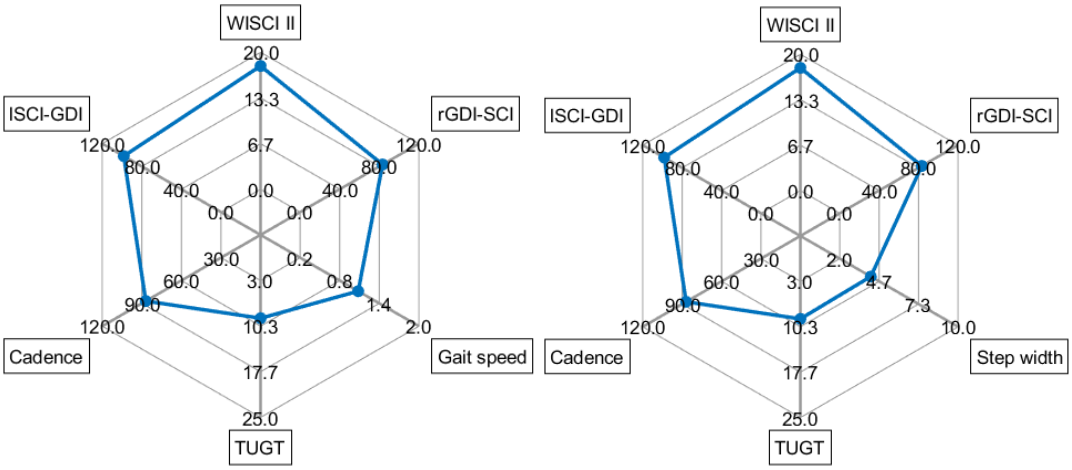


FIGURE 28. Two alternative sets of measures are shown to form the comprehensive metric for the assessment of gait in SCI. The alternative on the left comprises gait speed instead of the step width, included in the alternative displayed in the right.

Concurrent validity of the polygon area

Alternative one

In the assessment of the sensibility of the hexagon area with respect to levels of the WISCI II scale, statistically significant differences were found only between the subjects with WISCI II level of 20 and subjects in all the other levels in the dataset, but not between lower levels ($p < 0.05$). Similarly, the sensibility analysis of the hexagon area concerning the LEMS showed statistically significant differences only between subjects with the highest scores (41 to 50 points) and the other three subgroups (see Table 14). Lastly, the same analysis with the combination between AIS and injury level showed no statistically significant differences between any groups. In the factorial analysis, five of the principal components were necessary to explain at least 95% of the variability of the LEMS data variability (see Figure 29).

TABLE 14. Statistically significant differences (SSD) found between different WISCI II levels and LEMS groups with the area of the hexagon of the first alternative.

WISCI II	**20**	**19**	**18**	**16**	**15**	**13**	**12**
SSD	19,18,16,15,13,12	None	None	None	None	None	None
LEMS	**(A) 50-41**	**(B) 40-31**	**(C) 30-21**	**(D) 20-11**			
SSD	B, C, D	None	None	None			

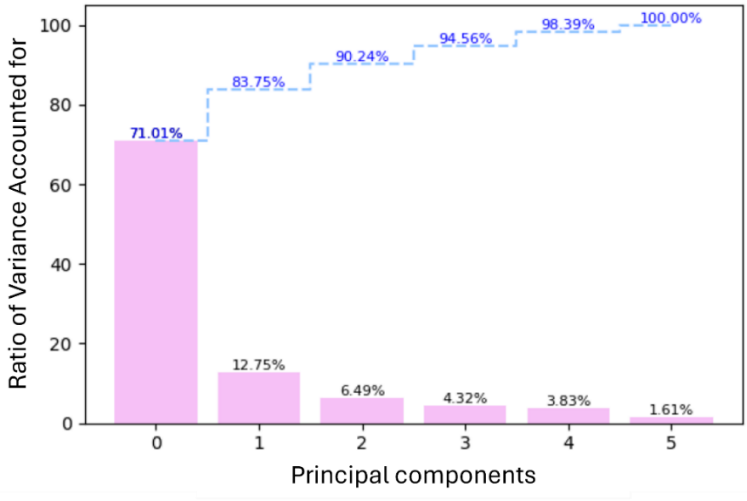


FIGURE 29. Principal component analysis of the metric formed in alternative one. The dotted line indicates the cumulative explained variance and the columns the individual explained variance.

Alternative two

The hexagon area with respect to levels of the WISCI II scale showed statistically significant differences between the subjects with WISCI II level of 20 and subjects in levels 12, 13, 15 and 16, but not between other levels ($p < 0.05$). This indicates a lower sensibility with respect to alternative one regarding the WISCI II scale. Similarly, the sensibility analysis of the hexagon area concerning the LEMS showed statistically significant differences only between subjects with the highest scores (41 to 50 points) and the other three subgroups (see Table 15). Lastly, the same analysis with the combination between AIS and injury level showed no statistically significant differences between any groups. In the factorial analysis, five of the principal components were necessary to explain at least 95% of the variability of both the LEMS data variability (see Figure 30) .

TABLE 15. Statistically significant differences (SSD) found between different WISCI II levels and LEMS groups with the area of the hexagon of the second alternative. Less WISCI II levels are discriminated compared to the first alternative.

WISCI II	**20**	**19**	**18**	**16**	**15**	**13**	**12**
SSD	16,15,13,12	None	None	None	None	None	None
LEMS	**(A) 50-41**	**(B) 40-31**	**(C) 30-21**	**(D) 20-11**			
SSD	B,C,D	None	None	None			

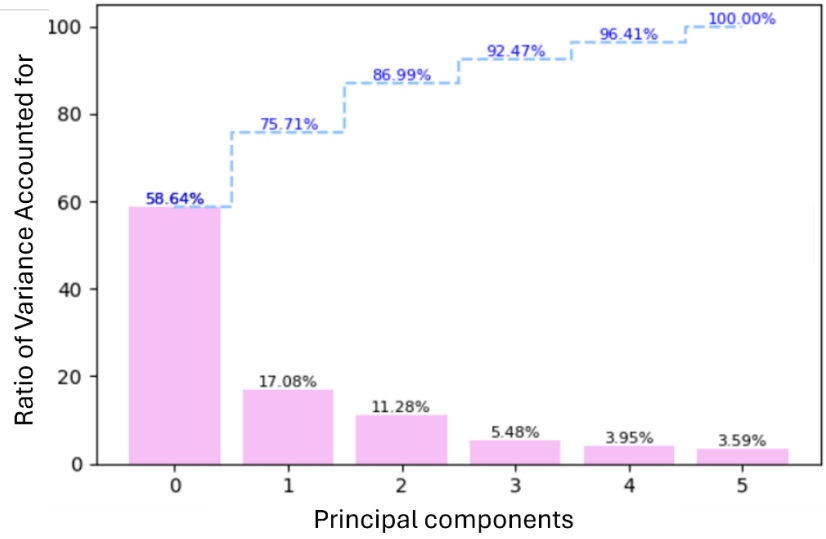


FIGURE 30. Principal component analysis of the metric formed in alternative two. The dotted line indicates the cumulative explained variance and the columns the individual explained variance.

DISCUSSION

A new easy-to-understand and clinically meaningful metric to comprehensively summarize gait in SCI in presented. It is formed using the SCI-GDI for both legs, step width, cadence, the TUGT and the WISCI II as vertices of a hexagon. Following a UCD approach, the measurements evaluated to be included in this new metric were identified as relevant to describe gait by a physiotherapist with vast experience in the gait rehabilitation of people with SCI. Asides from being validated specifically for SCI, the tests were selected due to being clinically meaningful and feasible to collect in the time available to perform a 3DGA, thus considering the constraints of the public healthcare context. From the pool of measurements identified by an expert in the field, statistics were used to select six that reduce data redundancy and emphasize the most important aspects of gait. In this way, the clinical interpretability and quality of the information conveyed in the metric are guaranteed.

From the results obtained, the second alternative was selected because it presents less data redundancy. Step width provides complimentary information to all the other scales as shown by the reduced correlation coefficients. According to literature, it relates to the stability, dynamic balance and optimal metabolic cost of gait [184]. All the metrics suggested can also be assessed during RAGT, therefore, the hexagon can be used to assess the immediate effects of the technology in patients' gait and their evolution throughout rehabilitation. The measurements used were carefully selected specifically for SCI but other polygons whose metrics and tests are validated in other neurological injuries can also be proposed. Thus, this concept is transversally applicable to other neurological injuries but considers the particularities of each type of injury.

The area of the polygon was not validated as a measurement with sensibility to summarize the scales contained in it. This could be because not all the metrics contained in the hexagon are meant to be maximized or minimized during gait rehabilitation (i.e. step width or cadence), but they rather have ranges of values that are considered normal. This limits the feasibility of using the area of the polygon to summarize all the aspects contained in it. Alternative representations of the set of measures identified in this research or other metrics from the polygon such as symmetry or perimeter can be explored as prompts to summarize the information it contains. Nonetheless, it is important to preserve a straightforward visual representation of the metric to guarantee its clinical interpretability. A sensitivity validation study of the hexagon is suggested to verify if the metric can accurately detect changes in gait over time and to assess the impact of interventions, treatments, or other factors.

3.4 STUDY 4: EVALUATION OF A PERSONALIZED LOWER LIMB ROBOTIC DEVICE FOR GAIT REHABILITATION[18]

INTRODUCTION

Rehabilitation robotic devices were developed to allow intensive locomotor training, longer training times, and monitoring changes in function [15, 11] in people with walking impairments due to a variety of underlying neurologic abnormalities, such as SCI and stroke [3, 5]. During the last 25 years, many such devices have been developed and a few reached the market with the aim to achieve greater rehabilitation effects by inducing neuroplasticity through a higher number of movement repetitions. However, current clinical evidence claims that robotic-based rehabilitation interventions yield similar outcomes to traditional rehabilitation interventions [22] and that there is limited user acceptance and satisfaction with these technologies [6, 7].

Rationales for this lack of success have been discussed by the scientific community. The consensus is that the environmental context of training plays an important role in the motor learning process. Factors such as visual input, dynamic balance, and motor error induced by movement variability are eliminated within the restricted and controlled artificial training environment created by the robotic gait trainers [22]. In this sense, the field has broadened towards the use of ambulatory WRD, which provide task-specific, contextually consistent, overground training. In contrast to robotic treadmill trainers, ambulatory WRD optimally challenge the patient in the domains of balance and physical exercise, while providing visual and functional feedback consistent with the task. This provides an opportunity window for increasing rehabilitation outcomes, which is nowadays a subject of major research [15]. Nevertheless, the clinical evidence of the outcomes attained with ambulatory WRD is still limited and nonconclusive due to differences in interventions: robot type and control, treatment time, and number of sessions [18]. In light of such results, the scientific community is questioning the basis of the design and application of rehabilitation robots, pointing towards the need to understand how to tune robot parameters depending on each patient's characteristics and therapeutic goals [19].

To this aim, recent advancements have led to the development of WRD controllers that enable the adjustment of assistance for specific subtasks, by setting specific assistance to joints and phases within the gait cycle associated with common impairments [66, 67]. Additionally, research with these subtask-based controllers has compared their performance and tuning time when applying automatically-tuned robotic assistance to manually-tuned robotic assistance (i.e., the current practice in the field). Different assistance levels were achieved through each method, demonstrating improved performance and shorter tuning times with the first approach. However, an exploration of the impact on clinical outcomes due to these differences in assistance levels remains to be conducted [68, 67]. These efforts represent advancements towards improved tuning of the assistance based on the user's individual performance performing the subtasks considered iteratively. Yet, none of the WRDs available in the market offers personalization comprising the hardware of the device [21], which still limits heterogeneous users to wear the same device despite their different functional requirements. Cyberdyne (Cyberdyne INC., Tsukuba, Japan) is the company that aligns the closest with this approach. However, they currently provide separate products rather than a modular WRD whose parts can be selected depending on the needs of individual users.

[18] *The results of the research conducted for this chapter were disseminated in the following:*

Oral contribution in the XL Congreso Anual de la Sociedad Española de Ingeniería Biomédica (CASEIB 2022): ***Herrera-Valenzuela, D****; Gil-Castillo, J; Pina, J; et al; del Ama, AJ. "Rehabilitación de la marcha asistida por un sistema híbrido personalizable en dos casos de lesión medular incompleta". CASEIB 2022. Sociedad española de ingeniería biomédica. 2022. Spain.*

In parallel, researchers have combined rehabilitation robotics with other systems to add up their advantages and compensate for their drawbacks. An example of this are hybrid WRs (HWR), defined as the combination of a WRD with FES [23]. On its own, FES demonstrated to enhance gait rehabilitation in incomplete SCI by promoting neuroplasticity during the acute and subacute periods after the injury, allowing motor relearning [24]. It also provides secondary benefits derived from the artificial activation of the musculature such as the improvement of force and prevention of atrophy [27, 26]. However, the appearance of muscle fatigue and the non-linear response of the musculature make it difficult to use FES for gait assistance. The combination of a FES system with a robotic exoskeleton allows compensation of muscle fatigue and improves movement control, increasing both the time of use and the quality of the movement generated [27]. This can be achieved through different approaches, for example, using electrical stimulation to aid some limbs' movement while the exoskeleton stabilizes, supports, and actuates other motions [28, 29], or implementing a cooperative control strategy, in which both assistances are realized on the same joint. The latter is more common in HWRs for lower limbs, mainly because the WRD can repeatably deliver power to allow fine control of joint movement that can compensate for the variable joint movement induced with the FES [30]. At the same time, neural plasticity and functional improvements are enhanced thanks to the intensive rehabilitation provided by the hybrid system and the integration of electric signaling of the nervous system induced by the FES.

Understanding the current trends in the field, a proof-of-concept study of a personalization strategy for hybrid robotic technologies that can be tailored for gait rehabilitation of neurological injuries was performed. The main goals of the study were 1) to propose a personalization strategy for modular hybrid systems for gait rehabilitation that can be applied in clinical rehabilitation settings, providing results of a feasibility study conducted with patients, and 2) to demonstrate that tailoring a modular hybrid system to the specific functional requirements of individuals with neurological pathologies provides effective gait assistance and positive user perception. To this end, a case series of 10 subjects with either iSCI or post-stroke using the hybrid system tailored according to their individual functional requirements is presented. Both populations are included to study the degree of personalization of the hybrid system and its effects on gait biomechanics in a heterogeneous sample. The immediate impact of the wearable system on gait function is assessed by means of kinematics and spatiotemporal metrics; the usability of the device is also assessed.

METHODOLOGY

SAMPLE

The study was held with a series of ten cases of subjects from two neurological injury populations, SCI and stroke survivors. The four SCI cases were recruited at the National Hospital for Paraplegics, the main monographic public hospital for intensive rehabilitation of SCI in Spain, whereas the six stroke cases were recruited at Institut Guttmann, the main private hospital for neurorehabilitation in the region of Catalonia, also in Spain. Inclusion criteria for both groups comprised ability to withstand standing and ability to walk, regardless the assistance required and overall physical condition to use FES and the WRD. Exclusion criteria for both groups included spasticity over 3 in the MAS or significant contractures in the lower limbs. All subjects were inpatients ongoing rehabilitation in their respective centers and participating in this study did not affect their scheduled activities. Three participants were women, of whom two were stroke survivors. Subjects had an average age of 48.7±10.8 y.o. Detailed demographics and clinics of each case are presented in the results section.

This research complied with the Declaration of Helsinki and was approved by the Institutional Review Board at the Ethics Committee of the Hospital Complex of Toledo, Spain (CEIC-CHTO, no. 716 26/05/2021). Informed consent was obtained from each participant.

DESCRIPTION OF THE MODULAR HYBRID SYSTEM

The hybrid exoskeleton used in this study combines the ABLE Exoskeleton (ABLE Human Motion SL, Barcelona, Spain) with a modular system for FES developed for this study. The version of the ABLE Exoskeleton comprised hip, knee, and ankle joints, with active actuation only in the knee joints. Hip and ankle joints were articulated within anatomic limits. The exoskeleton allowed to assist sit-to-stand and stand-to-sit transitions, as well as walking while setting the following parameters in a mobile app controlled by a trained PT: maximum knee flexion angle during the swing phase of the gait cycle, knee flexion/extension ratio during swing, knee flexion angle for sit-to-stand, and the sensibility of the intention detection to trigger the steps. The intention detection of the device is based on the acceleration measured by sensors located in the thigh of the device: when the acceleration exceeds a certain threshold, the step is generated. This WRD is meant to be combined with a traditional aid to guarantee the user's safety (e.g., walker, crutches, or cane). The device had three control options, i) manual, where the PT triggers each step and postural transitions with buttons located in the lumbar area of the device, ii) automatic, when each step is triggered by the devices' detection of the intention of movement, while postural transitions are triggered by the PT with the buttons, and iii) user-controlled, where the user has a control to select the activity to be performed while using the intention detection algorithm during gait. Only the first two were used in this study.

The modular FES system developed for this study was designed to provide tailored assistance during gait [190]. Up to four (4) peripheral stimulation nodes can be used in the system with up to four (4) stimulation channels each, allowing to set a total of 16 stimulation channels. The unique functional requirements of each subject guided the selection of the targeted muscle groups for stimulation, as well as the customization of their individual stimulation parameters. These parameters, including stimulation amplitude and the utilization and timing of both upward and downward ramps, were configured in dedicated individual channels. The rationale of this process is described in detail in section "Personalization of the system". All pulse trains applied were symmetric biphasic at 40 Hz [191], although the system allowed to modify their frequency, pulse width, and pulse type (i.e., symmetrical or asymmetrical and monophasic or biphasic). Following the healthy pattern of activation of the main muscle groups of the lower limb during the gait cycle, the stimulation strategy was designed by using a state machine where the following muscular groups can be selected: gluteus maximus (GM), tensor fasciae latae (TFL), quadriceps (QF), hamstrings (HS), gastrocnemius (GC) and tibialis anterior (TA) (see Figure 31). The GM had two alternative stimulation strategies, cross-assisted or unilateral-assisted, depending on whether the events detected to trigger the stimulation were done in the contralateral or unilateral limb, respectively. The event detection control strategy to trigger the stimulation was based on gait kinematics, measured with a sensor network of six (6) W110 or W150 wireless twin-axis electrogoniometers (Biometrics Ltd, Newport, United Kingdom) located in both hips, knees, and ankles.

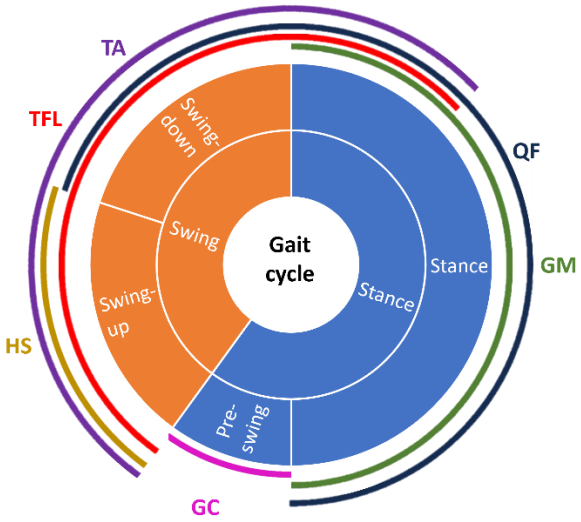


FIGURE 31. Muscles (left) and control strategy (right) for the FES. Adapted from **[190]**.

The modular hybrid system aimed to be versatile, therefore, the FES system was designed to be used independently or easily attached to the exoskeleton with a set of 3D printed pieces specially designed to this end [190]. In this way, patients could be assisted only with FES and/or with the hybrid robot using an open loop control strategy, depending on the configuration chosen for each subject according to their functional requirements.

PROOF OF CONCEPT STUDY OF THE PERSONALIZATION STRATEGY FOR THE HYBRID SYSTEM

Two sessions were performed for each subject, a first training session, aimed at teaching patients how to walk with the exoskeleton and run the clinical assessments required to personalize the technologies, and a second session to fine-tune the parameters of the assistance selected for each subject and quantitatively assess its impact on walking function. Details of each are presented below.

A. PERSONALIZATION OF THE SYSTEM

The personalization protocol of the hybrid system is one of the main contributions of this study to the field. The initial setup is defined based on clinical and functional assessments. Firstly, the LEMS assessment was performed to identify the muscles that required assistance through FES. In the first setup of the assistance, all these muscles were targeted and attempted to be assisted with FES. Spasticity assessment through the MAS was also performed to identify joints that could either potentially limit the movements assisted by the WRD or those that could be negatively affected by FES. In addition, the assistance required by the subjects to walk was considered, scored with the WISCI II or with the Functional Ambulation Category (FAC) in stroke. These scales allow the team to decide if the structural assistance provided by the WRD was needed by each subject and was the main indicator to measure the degree of impairment of the subjects. Lastly, additional information on the functional requirements of the gait pattern of each patient was gathered through the observation performed by a PT with experience in gait rehabilitation of the corresponding neurological injury. The clinical assessments required for personalization, the visual analysis of the gait pattern, and the resulting initial personalization strategy were performed during the training session. This initial configuration was modified, when needed, upon feedback from the patient and observation from the PT in both the training and fine-tuning and assessment sessions until an efficient setup was reached. The iterative process followed to reach an optimal personalized stimulation strategy is inspired by the iterative nature of User-centered design. The proposed strategy is feasible to implement on the fly thanks to the modular design of the hybrid system. Figure 32 summarizes the personalization protocol.

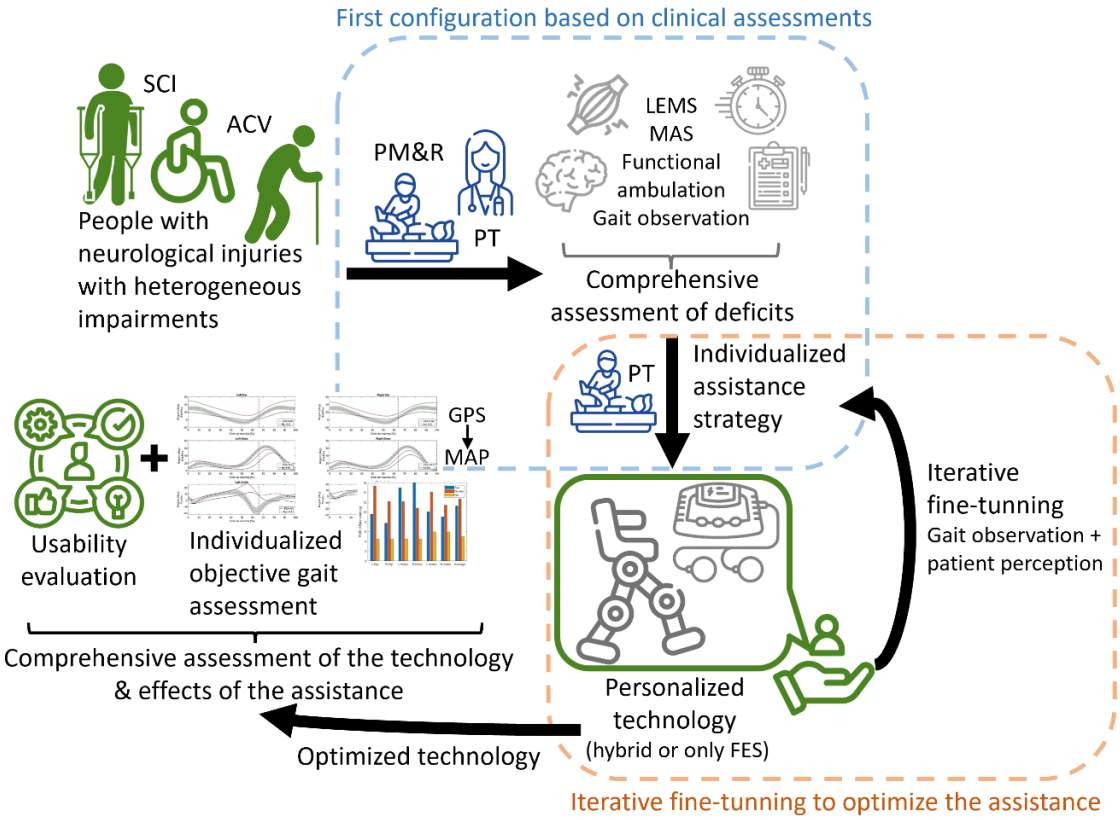


FIGURE 32. Personalization protocol for the modular tailorable FES and hybrid systems.

B. TRAINING SESSION

The first session was aimed at performing the clinical assessments required to personalize the technologies and at teaching patients how to use the exoskeleton. The latter includes weight shifting between both legs, get adapted to the sensation of wearing the device, trusting on it, and going from the manual control of the WRD driven by the PT to the automatic control mode, in which the patients' intent of performing each step triggers the steps of the device. Additionally, the research team identified the optimal parameters of the exoskeleton for each subject, i.e., anatomical fit and knee assistance settings. When there was time availability in the training sessions and the subject's exertion levels were minimal, either tuning of the FES thresholds and/or hybrid assistance training were also performed. In all cases, the first personalized configuration of the technologies was defined during this session.

In both hospitals, the training session was performed in large areas. During this session, kinematic information was gathered with the electrogoniometers used with the hybrid system. These were placed on the exoskeleton joints. Donning, doffing, and walking times were registered whereas spatiotemporal metrics of gait were retrieved from the mobile app of the ABLE Exoskeleton. At the end of the session, the Rate of Perceived Exertion (RPE) was measured with the Modified Borg scale.

C. FINE-TUNING AND ASSESSMENT SESSION

The second session was performed at most one week after the training session, depending on the availability of each subject. It was aimed at registering gait with a three-dimensional motion capture system in two or three conditions for each subject: without the assistance of the technology, with FES assistance and/or with the hybrid system personalized according to the strategy designed during the training session. To this end, the electrogoniometers, 5x5 cm electrodes for FES and passive markers for 3DGA were placed in lower limbs and torso. For the latter, either the PlugInGait Full Body protocol without head markers for a VICON system (Vicon Motion Systems Ltd, UK) at HNP or the Davis protocol for a BTS

system (BTS S.p.A., Italy) at IG was followed. In both hospitals, systems had 8 cameras around a 10-meter walkway, with two (Kistler 9286A, Kistler Group, Switzerland) and four force platforms BTS P-6000 (BTS S.p.A., Italy) embedded at HNP and IG, respectively. If able, subjects were asked to walk barefoot for the non-assisted records. They walked with the least assistive and orthotic devices possible. At least three walking trials were recorded for each subject.

After recording the non-assisted gait of subjects (register 1), calibration for each channel of the FES device was performed by looking for the motor threshold of the corresponding muscular group. The comfort threshold was set as the upper limit for stimulation, even if it was lower than the motor threshold. Next, the whole FES system was worn on the patient. Records of the user were taken while the configuration of the stimulation was iteratively modified according to the gait pattern seen in the user, until reaching an optimal FES assistance according to the PT perspective and subjects' comfort. At least three walking trials were registered with this stimulation (register 2).

Lastly, the setup of the FES system with the exoskeleton was done. Markers for 3DGA were relocated over the exoskeleton when needed. The hybrid WRD was worn on the subject and several walking trials were recorded with the optimized hybrid assistance (register 3). Records were stopped when the time available for the session was over or when patients expressed physical or cognitive exertion. The hybrid robot was used with a walker, for SCI subjects, and with a 4-point cane in the case of stroke subjects. As a safety measure for all subjects, the PT was always holding the exoskeleton from behind and aiding weight shifting when needed.

Most SCI subjects who were able to walk without any assistive device (i.e., WISCI II of 20) did not perform a training session, given that the optimal assistance for them was considered to be only using FES. Thus, only the second session was performed to gather registers of no assisted walking and FES-assisted walking. On the other hand, stroke patients that did not manage to use the exoskeleton during the training session due to balance problems or spasticity only received FES assistance during the second session.

D. USABILITY EVALUATION

At the end of the assessment session, the Borg scale, the System Usability Scale (SUS) and the Quebec User Evaluation of Satisfaction with Assistive Technology v2 (QUEST) were recorded to evaluate user satisfaction and usability of the technology, asking the patients to rate independently the configurations they tested during session two. Observation during usability testing [192] was performed throughout the whole session, and Time for task registers were collected. In the end, subjects were asked what they thought about the device they used, and their responses were voice-recorded. Recordings were analyzed using content analysis to identify specific attributes of the devices that patients evaluated positively or negatively.

DATA ANALYSIS

Gait kinematics from both sessions were analyzed qualitatively through comparison with the average pattern of healthy volunteers and quantitatively by using the Gait Profile Score (GPS) [193]. The score was calculated individually for each type of assistance tested during the fine-tuning and assessment session and for the non-assisted gait of each user, taking as a reference an average healthy gait pattern for the adult population. Spatiotemporal parameters of gait are computed as the average between the collected gait cycles for each configuration. The paretic step ratio (PSR) was computed as a measure of spatial symmetry of gait, calculated as the paretic step length divided by the sum of paretic and nonparetic step lengths. The same rationale was used with the oscillation times of the subjects to compute an index as a cue to the temporal symmetry of gait. Both indexes are interpreted as symmetrical ($0.475 \leq \text{index} \leq 0.525$), paretic shorter than nonparetic (index < 0.475), and nonparetic shorter than paretic (> 0.525) [194]. Usability questionnaires are presented with descriptive statistics for the whole case series and for each

type of population. Attributes identified through the observation and interview process are presented including the frequency of appearance in terms of the number of users.

RESULTS

CASE SERIES:

TABLE 16 SUMMARIZES EACH SUBJECT'S DEMOGRAPHICS AND CLINICAL DATA WHEREAS

Table 17 presents the measures of gait achieved with the different types of assistance tested for each case. All subjects but one tested the FES assistance and four subjects received hybrid assistance. Details about the clinical assessments, gait pattern and the consequent optimal assistance selected for each case are explained below.

TABLE 16. Demographics and clinical data of each subject of the case series. The WISCI II level is shown for subjects with a SCI whereas the FAC level is shown for post-stroke subjects.

Subject	Sex	Age	Injury	Type	Etiology	WISCI II or FAC	Months since injury
C1	M	32	SCI	AIS D – L1	Traumatic	16	3,3
C2	M	51	SCI	AIS C – T4	Non-traumatic	8	3,0
C3	F	67	SCI	AIS D – L2	Non-traumatic	19	5,0
C4	M	44	SCI	AIS D – T12	Non-traumatic	16	6,0
C5	F	56	Stroke	Right	Ischemic	3	1,8
C6	M	34	Stroke	Right	Infarction	4	2,8
C7	F	47	Stroke	Right	Ischemic	3	1,5
C8	M	43	Stroke	Right	Hemorrhagic	4	3,0
C9	M	59	Stroke	Right	Hemorrhagic	4	0,8
C10	M	48	Stroke	Right	Ischemic	3	1,5

TABLE 17. Spatiotemporal parameters of gait for each type of assistance tested by each subject. The muscular groups assisted with FES are indicated next to the type of assistance selected, subscripts indicate the leg(s) in which the muscle was assisted. The best results achieved by each subject are bolded. SCI subjects are shaded in pink whereas post-stroke subjects are in yellow. Heuristic value for moderate cadence is 100 steps/min **[195]** whereas a moderate speed range is considered between 1.13 and 1.36 m/s **[196]**. Normative foot off is 60% of the gait cycle. Symmetry indexes are interpreted as symmetrical (0.475 ≤ index ≤ 0.525), paretic shorter than nonparetic (index < 0.475), and nonparetic shorter than paretic (> 0.525) **[194]**.

Subject	Assistance	Measure										
		Cadence (steps/min)		Walking speed (m/s)		Foot Off (%)		Symmetry		GPS (deg)		
		Left	Right	Left	Right	Left	Right	Spatial	Temporal	Left	Right	Average
C1	None	103,45	104,10	0,80	0,80	64,50	69,00	**0,49**	0,50	12,62	10,93	11,78
	FES: $_{L/R}$TS	**106,20**	**105,30**	0,80	0,80	**64,40**	**68,40**	0,53	0,50	**11,22**	**10,73**	**10,98**
C2	None	**43,80**	**43,00**	**0,31**	**0,31**	81,02	78,85	0,41	**0,47**	20,60	**17,30**	18,95
	HR: $_{L/R}$ HS	35,71	39,60	0,22	0,22	**75,30**	**70,96**	0,61	0,46	**18,03**	19,60	**18,82**
C3	None	80,90	**83,30**	0,30	**0,40**	66,40	**76,10**	**0,46**	**0,58**	14,63	**14,67**	**14,65**
	FES: $_{L}$HS, $_{L}$TA	**85,11**	82,76	**0,33**	0,36	**61,70**	81,38	0,40	0,67	**14,50**	17,67	16,08
C4	None	**80,90**	**83,50**	**0,70**	**0,70**	**67,50**	**69,20**	0,54	0,51	11,36	13,40	12,38
	FES: $_{L/R}$ GC	69,90	71,00	0,60	0,60	68,90	70,10	**0,49**	0,51	**9,70**	**13,29**	**11,50**
C5	None	38,31	38,66	**0,20**	0,15	71,52	86,73	**0,61**	0,68	15,27	20,33	17,80
	FES: $_{L}$HS, $_{L}$TA, $_{L}$GC	**43,17**	**44,38**	0,17	**0,17**	**60,22**	86,83	0,63	0,75	**14,17**	20,10	**17,13**
	HR: $_{L}$HS, $_{L}$TA, $_{L}$GC	27,47	24,31	0,01	0,07	90,02	**83,14**	0,26	**0,37**	20,83	**18,94**	19,89
C6	None	49,71	51,81	0,28	0,28	63,55	80,22	0,38	0,65	14,02	**15,63**	14,83
	FES: $_{L}$TA, $_{L}$GC	**67,95**	**67,19**	**0,49**	**0,50**	**61,04**	**76,93**	**0,40**	**0,63**	**12,37**	16,07	**14,22**
C7	None	67,95	67,72	0,34	0,32	67,61	**69,75**	**0,61**	**0,52**	**14,25**	**12,48**	**13,36**
	FES: $_{L}$HS, $_{L}$GM, $_{L}$GC	**73,53**	**71,26**	**0,38**	0,32	**58,58**	74,11	0,63	0,62	17,47	15,55	16,51
C8	None	**45,08**	**43,48**	**0,24**	0,21	74,00	86,45	0,46	0,66	19,37	**15,80**	17,58
	FES: $_{L}$HS, $_{L}$TA, $_{L}$GC	44,51	42,40	0,23	**0,23**	**64,54**	82,76	0,38	0,67	**16,57**	15,93	**16,25**
	HR: $_{L}$HS, $_{L}$TA, $_{L}$GC	30,12	31,30	0,17	0,18	80,62	**74,75**	**0,47**	**0,43**	21,10	18,00	19,55
C9	None	57,91	59,29	0,47	0,49	**63,42**	76,38	**0,50**	0,61	15,58	20,17	17,87
	FES: $_{L}$HS, $_{L}$TA, $_{L}$GC	**71,26**	**72,38**	**0,59**	**0,61**	53,33	**75,39**	0,53	0,66	**14,07**	**19,60**	**16,83**
	HR: $_{L}$HS, $_{L}$TA, $_{L}$GC	38,39	37,95	0,31	0,30	69,42	75,46	0,55	**0,56**	16,69	19,97	18,33
C10	None	43,48	42,31	0,19	0,18	65,36	82,86	**0,56**	0,67	14,70	17,63	16,17
	FES: $_{L}$HS, $_{L}$TA, $_{L}$GM	**47,62**	**46,80**	**0,23**	**0,25**	**55,79**	**78,55**	0,61	0,67	**14,07**	**15,30**	**14,68**

CASE 1:

32 y.o. male with a spinal cord injury AIS D, level of injury L1, of traumatic etiology with 3.3 months of evolution. Preference to walk short distances using two crutches (preferent WISCI II = 16) but capable of walking without crutches with a lower cadence and greater instability (maximum WISCI II = 20). Wheelchair user for long distances. At exploration with the LEMS, he scored 5 for all the muscles except for hip flexors, scored with 4. When observing his gait pattern, the subject shows a fixed ankle trajectory in the whole gait cycle, compromising push-off and, therefore, reduced ankle dorsiflexion, especially during the swing phase. Consequently, to improve push-off, this subject was assisted only with FES in both triceps surae with 20 and 21 mA in his right and left legs, respectively. At the end of the 75 min assessment session, the subject expressed a RPE of 6.

The assistance showed a slight improvement in bilateral kinematics and spatiotemporal measures of gait. Plantar flexion increased, accordingly to what was expected with the stimulation, nevertheless, the oscillation phase was not increased, probably because knee flexion was slightly reduced. Greater bilateral hip extension is seen throughout the cycle presumably because of the improvement in the ankle plantar flexion. He said he would like to go for a walk with the FES, he felt it helped him. He expressed his desire to count on the system as an additional tool for his ongoing rehabilitation.

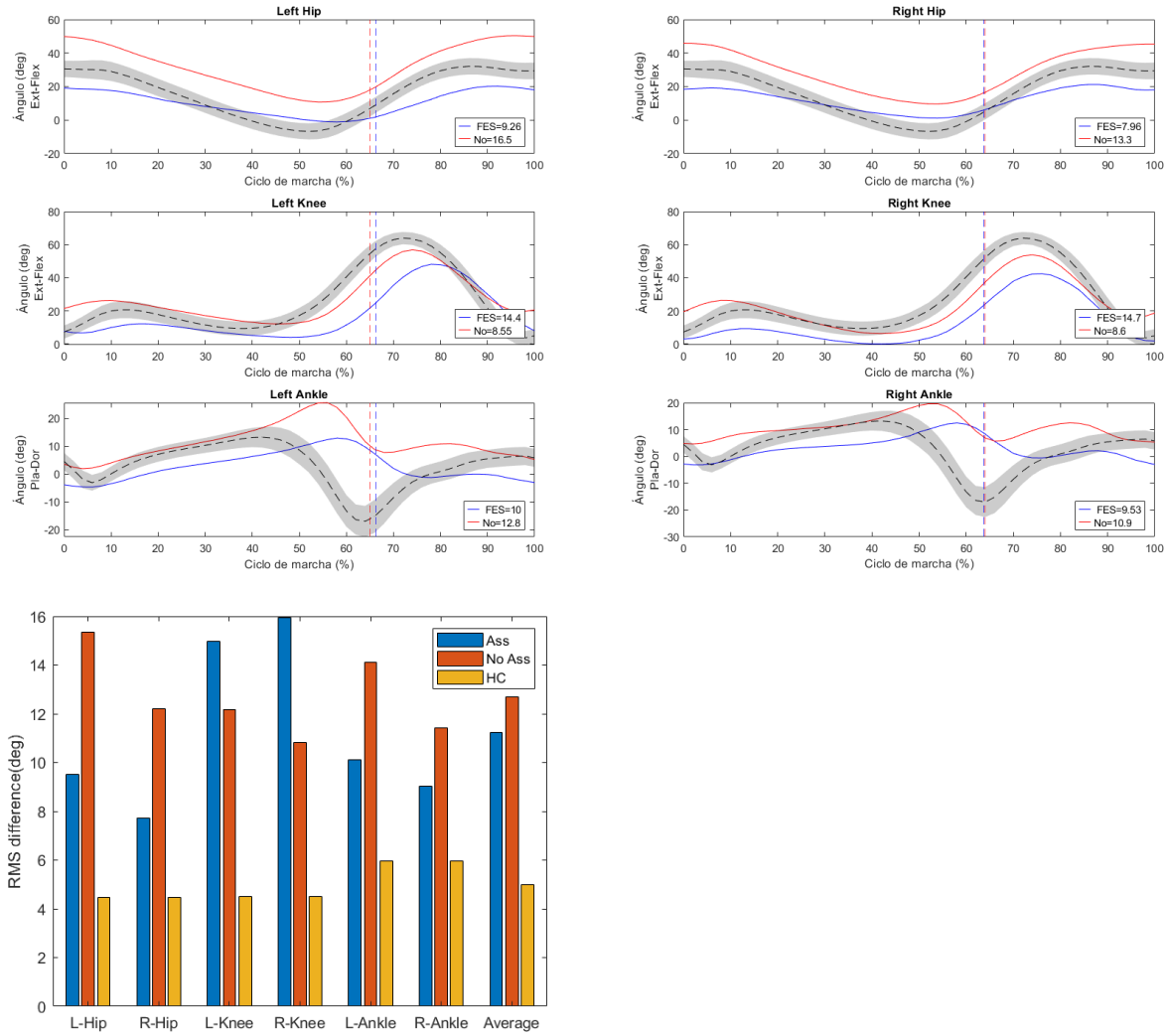


FIGURE 33. Kinematic curves of the FES-assisted and unassisted gait (top) of case 1 and the MAP summarizing the GVS of each joint (bottom).

CASE 2:

51 y.o. male with a spinal cord injury AIS C, level of injury T4, of non-traumatic etiology (herniated disc surgery) with 3.0 months of evolution. When performing the training session, the subject was capable of walking only in parallel bars without supervision for short periods of time (maximum WISCI II = 5). Nine days later, in the assessment session, he was able to walk short distances with a walker and physical assistance of one person (maximum WISCI II = 8). For daily activities and displacements, the subject used a wheelchair. At exploration with the LEMS, he scored 5 for all the muscles except for hip flexors, which scored 4. Despite these results, when performing gait observation, the subject was in an early rehabilitation stage and showed a reduced ability to resist bodyweight during stance and when walking. Due to this, his whole gait pattern was compromised in dynamic loading.

Consequently, the subject required the mechanical support provided by the exoskeleton as an orthotic device, thus, he was only assisted with the hybrid robot. The optimal stimulation profile achieved for this case was the assistance of both HS to coordinate the muscle contraction provided by FES, with the joint movement provided by both the WRD and FES during knee flexion in the swing phase. To this end, 47 and 50 mA were applied in the left and right legs, respectively. Additionally, FES was applied in both tibialis anterior with 32 and 35 mA in the left and right legs, respectively, to improve ankle dorsi flexion and foot clearance during the swing phase, a movement that is not actively assisted by the exoskeleton. Support during stance was effectively provided by the structure of the exoskeleton. Stimulating the GM in this

subject to aid stabilization during stance was also explored, but the amplitude of the stimulation required to elicit muscle contraction was beyond the comfort threshold of the patient, thus, the patient expressed discomfort before the motor response was elicited and stimulation was removed. At the end of the 2h assessment session, the subject expressed a RPE of 3.

The effect of the assistance revealed an improvement in bilateral kinematics and in the duration of the swing phase, but a reduction in cadence and walking speed. Hip flexion is increased almost throughout the gait cycle due to the loading of the subject on the walker. Maximum knee flexion is slightly reduced due to the imposition of the WRD over the FES of the HS, aimed at increasing it, nevertheless, the oscillation phase is increased, because the hybrid assistance allowed the flexion of the hip and knee to last longer. Ankle kinematics have major changes. Dorsiflexion is increased in the whole gait cycle due to the mechanical constraint of the WRD, and an improved pattern during push-off is seen in the ankle thanks to the hybrid assistance. In this way, the hybrid assistance allows for improving foot clearance and increasing swing. The immediate kinematic changes reflect an improved dynamic balance of assisted gait compared to unassisted gait.

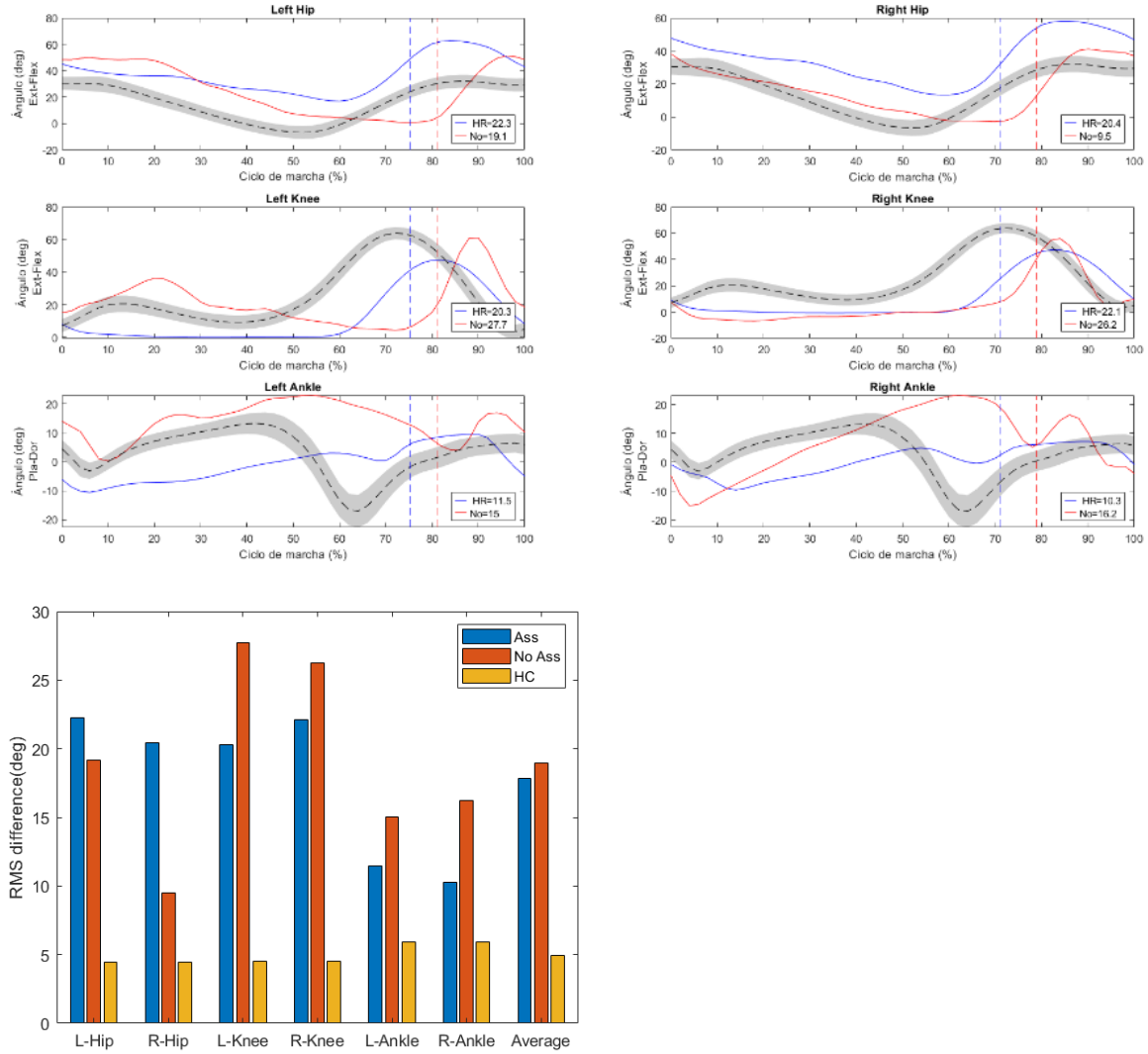
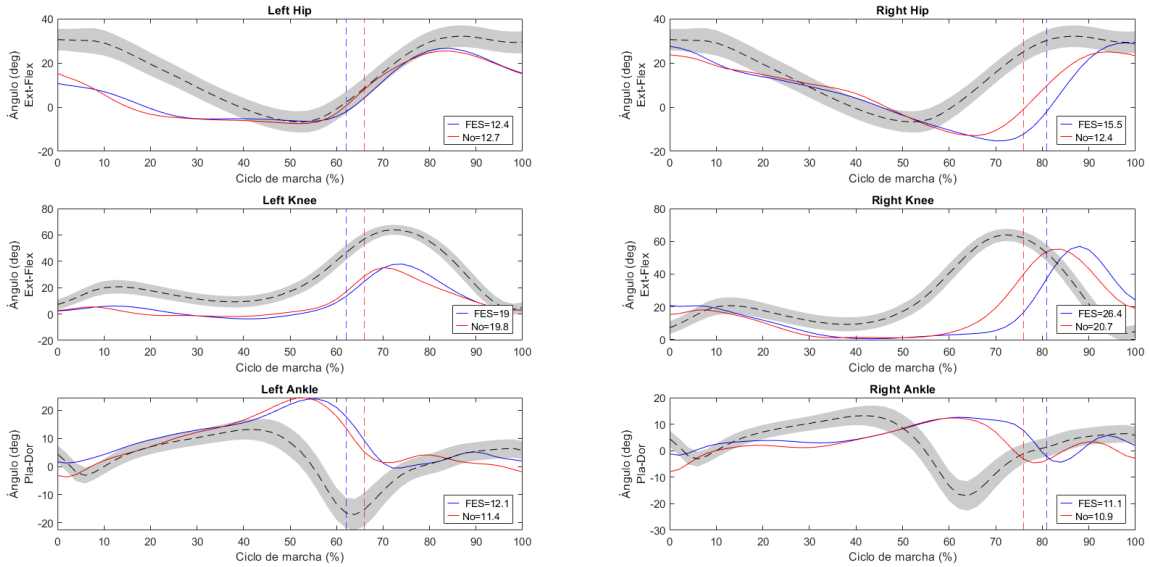


FIGURE 34. Kinematic curves of the HWR-assisted and unassisted gait (top) of case 2 and the MAP summarizing the GVS of each joint (bottom).

CASE 3:

67 y.o. female with a spinal cord injury AIS D, level of injury L2, of non-traumatic etiology (transverse myelitis) with 5.0 months of evolution. The subject used one crutch to walk short distances (maximum and preferent WISCI II = 19) and two crutches for longer distances. Only the left lower limb showed impairment. At exploration with the LEMS, she scored 5 for all the muscles on the right lower limb except for hip abductors, which scored 4. The left lower limb scored 2 for the thumb flexor, 3 for plantar flexors and hip extensors, 5 for the hip adductors and knee extensors, and 4 for the remaining muscles. When performing gait observation, the subject showed compromised foot clearance due to reduced ankle dorsi flexion and poor push-off as well as reduced knee flexion during swing. Since these impairments were only in the left lower limb, this subject was assisted only in this leg with FES and the optimized stimulation strategy achieved was applying 65 mA in the HS to aid knee flexion during swing and 55 mA to the TA to improve ankle dorsi flexion and foot clearance during swing. Stimulation of the GC with 45 mA was also tested but the timing between the unilateral-assisted stimulation of the antagonist muscles (triceps surae and TA) compromised the proper coordination of the ankle movement required between push-off and during swing, and better results were observable with stimulation only in the TA. At the end of the 105 min assessment session, the subject expressed a RPE of 3.

The assistance showed a small improvement in the kinematics and spatiotemporal measures of gait of the assisted leg. Temporal symmetry worsened towards a shorter swing of the non-affected limb. There are few changes at the biomechanical level. The main one, although small, is that the take-off of the right foot is delayed, reducing the oscillation non-affected limb, and increasing that of the contralateral limb (≤5% of the gait cycle for both limbs). This represents a reduction in the stability of the subject because of the stimulation. There is no change in the range of motion of the left ankle, but in general, the left ankle is more dorsiflexed than the right, according to what was aimed with the FES. She felt the assistance was helpful in improving foot clearance and provided positive feedback while completing the usability questionnaires. She also expressed reduced numbness of the stimulated foot that lasted days after the session, the desire to do more sessions with the technology, and the perception that the system “could help many people”.



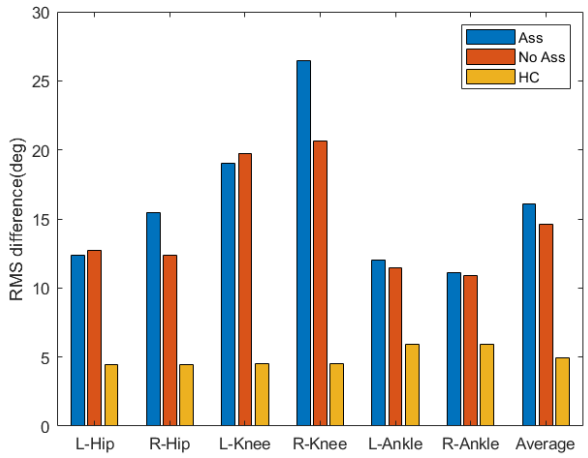
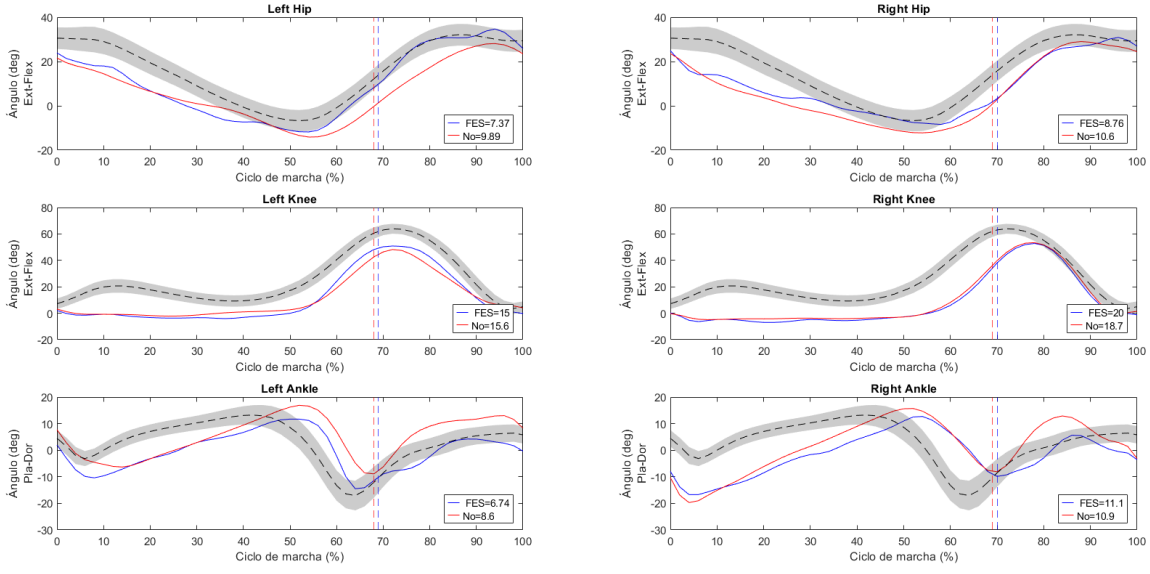


FIGURE 35. Kinematic curves of the FES-assisted and unassisted gait (top) of case 3 and the MAP summarizing the GVS of each joint (bottom).

CASE 4:

44 y.o. male with a spinal cord injury AIS D, level of injury T12, of non-traumatic etiology (spinal cord ischemia) with 6.0 months of evolution. Preference to walk short distances using two crutches (preferent WISCI II = 16) but capable of walking without crutches with a lower cadence and greater instability (maximum WISCI II = 20). For long distances, the subject uses two crutches. The subject has proprioceptive impairment with reduced sensibility at the distal left lower extremity. At exploration with the LEMS, he scored 5 for all the muscles except for plantar flexors, which scored 4. When performing gait observation, the subject shows poor push-off and, consequently, reduced ankle dorsi flexion during swing. To improve his gait pattern during swing, the subject was assisted only with FES in both GC with 35 and 40 mA, for the right and left legs, respectively. Stimulation of both TA was also tested but the timing between the unilateral-assisted stimulation of the antagonist muscles compromised the proper coordination of the ankle movement required between push-off and during swing, and better results were observable with stimulation only in the GC. At the end of the 75 min assessment session, the subject expressed a RPE of 3.

The assistance showed a small improvement in bilateral kinematics and spatial symmetry and a worsening in bilateral cadence. Kinematic improvement is a consequence of the increased plantar flexion generated by the FES.



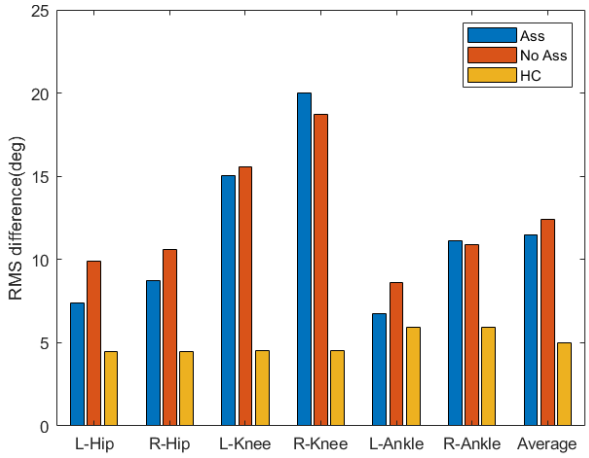


FIGURE 36. Kinematic curves of the FES-assisted and unassisted gait (top) of case 4 and the MAP summarizing the GVS of each joint (bottom).

CASE 5:

Female ischemic stroke survivor of 56 y.o. with 1.75 months of evolution and left hemiparesis. Use of an ankle-foot orthosis for foot drop and a 4-point cane to walk short distances (FAC=3). At exploration with the LEMS, she scored 5 for all the muscles on the right lower limb, and in the left lower limb 3+ for hip adductors and knee extensors, 3 for hip flexors, 1 for plantar and dorsiflexors and 2 for the remaining muscle groups. Shows slight spasticity (MAS 1+) on the hemiparetic limb. When performing gait observation, the subject shows left hemineglect, gait with the trunk leaning to the right, and avoids stance on the left leg in the middle stance phase with slight claudication.

Hybrid assistance was selected for this case, but the WRD was used with the manual control driven by the PT due to the high degree of left hemineglect of the subject, which limited her ability to shift the weight towards the hemiparetic side, required to use the exoskeleton in the automatic control mode. FES was applied in the left leg in the TA with 45 mA, GC with 35 mA, and HS with 39 mA. This strategy was aimed at improving the pattern of the ankle during push-off and swing, improving bilateral foot clearance by increasing knee flexion during swing with the exoskeleton while coordinating the movement with the muscle contraction of the left HS, and providing stability in the hemiparetic limb during stance by activating the left GM and with the orthotic support of the WRD. At the end of the 1h 40 min assessment session, the subject expressed a RPE of 2.

The FES assistance showed an improvement in bilateral kinematics, cadence, and left foot off, but increased temporal and spatial asymmetry towards increased paretic activity. Stimulation in the GC allows ankle plantar flexion of the foot at the beginning of the stance phase, which the patient cannot do without assistance due to the spasticity and atrophy that she presents, which is seen bilaterally. However, the stimulation in the GC does not assist the plantar flexion that is needed for the push-off, which aids foot clearance during swing. This could be due to the difficulty in properly coordinating their stimulation with the assistance of the TA. The latter helps to maintain dorsiflexion until the end of the cycle, improving foot clearance, especially at the end of the swing phase, where, without assistance, the patient has plantarflexion that could compromise foot clearance and cause falls. The stimulation of the hamstrings does not show alterations in the kinematic curves, but the stimulation set allows the duration of the oscillation phase to be increased to a value close to normal, reflecting better balance compared to unassisted walking.

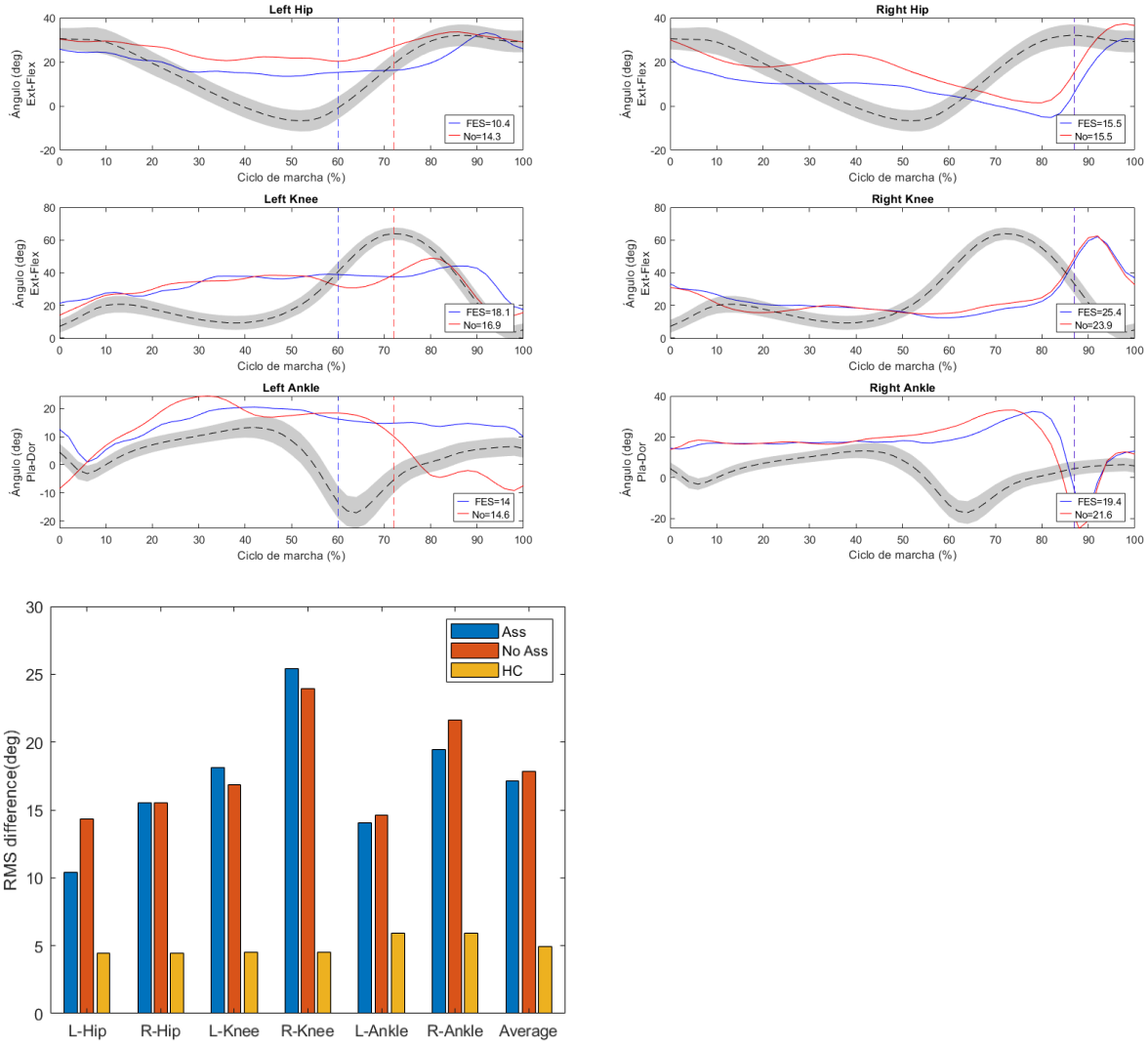


FIGURE 37. Kinematic curves of the FES-assisted and unassisted gait (top) of case 5 and the MAP summarizing the GVS of each joint (bottom).

On the other hand, the hybrid assistance showed a slight improvement in bilateral kinematics and in right foot off, but a worsening in the other spatiotemporal measures of gait and in spatial and temporal asymmetry of reduced activity of the paretic limb. Knee kinematics are totally imposed by the WRD, compromising knee flexion during the stance phase and avoiding the stimulation in the left HS to generate any difference in the knee pattern. This can be seen when comparing bilaterally both knees. While the exoskeleton is not providing assistance at ankle level, the ankle remains in a neutral position for almost the entire trajectory, with a greater range of dorsiflexion in the left foot compared to the right foot, which is attributed to stimulation of the TA. There is also a peak in hip flexion, consistent with the movement that patients must make for the WRD to recognize the intention to make step. This subject expressed that she liked the hybrid system and that she thinks it is not cumbersome; she felt well and safe.

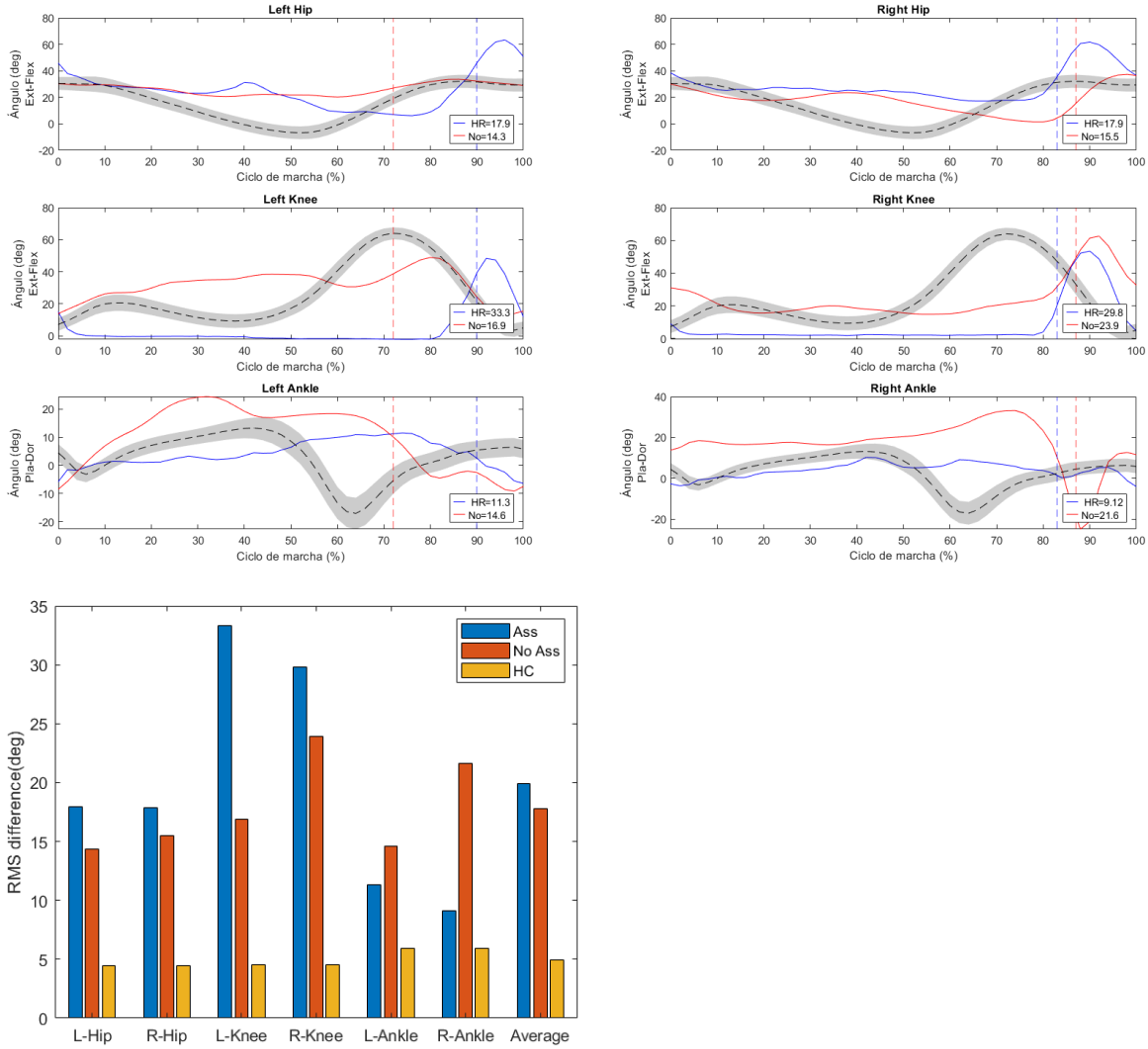


FIGURE 38. Kinematic curves of the HWR-assisted and unassisted gait (top) of case 5 and the MAP summarizing the GVS of each joint (bottom).

CASE 6:

Male infarction stroke survivor of 34 y.o. with 2.75 months of evolution and left hemiparesis. Use of an ankle-foot orthosis for foot drop to walk (FAC=4). At exploration with the LEMS, he scored 5 for all the muscles on the right lower limb, and in the left lower limb 4 for hip flexors and knee extensors, 3 for hip abductors and adductors, 2 for hip extensors and knee flexors and 1 for ankle plantar and dorsi flexors. Shows mild spasticity (MAS 2) on the hemiparetic limb. When performing gait observation, the subject shows a gait pattern with reduced knee flexion and ankle dorsiflexion during the swing phase, as well as a poor push-off due to limited activity of ankle plantar flexors.

This subject did not manage to use the exoskeleton in the training session mostly due to a poor weight shift towards the hemiparetic limb. Therefore, the strategy designed for him was assisting only with FES in the left TA, GC, HS and QF. The stimulation was aimed at improving the pattern of the ankle during push-off and swing, improving at the same time foot clearance, accompanied by increasing knee flexion during swing and aiding knee extension prior to and during foot contact. However, due to spasticity and weakness in the muscles, the event detection algorithm to control the FES was not reliable to provide stimulation of the HS and QF with suitable timing throughout the gait cycle for this patient. Therefore, the final stimulation set for the patient was only in TA and GC with 26 mA and 38 mA, respectively. At the end of the 91 min assessment session, the subject expressed a RPE of 6.

The assistance showed an improvement in bilateral kinematics, in spatiotemporal measures of gait and in spatial and temporal symmetry. Few differences are observable in the left ankle kinematics. The most marked is a dorsiflexion in the swing phase thanks to the assistance in TA that allows foot clearance, in contrast to the plantar flexion that the patient presents without assistance. Left knee flexion during mid stance is allowed with the stimulation and maximum knee flexion is increased during swing, although a sudden knee extension is performed by the subject during oscillation probably as a response to the stimulation of the TA. The oscillation phase increases slightly bilaterally, reflecting an improvement in the subject's dynamic balance.

Even though this subject did not manage to learn to use the WRD in automatic mode, he said that the training with the WRD allowed him to learn the sequence of movements required to walk, i.e. the need to load the weight in one leg to allow the other to advance in the oscillation phase. By learning this, days after the training session he expressed he does “better” during traditional gait rehabilitation because he consciously attempts to follow the required sequence of movements.

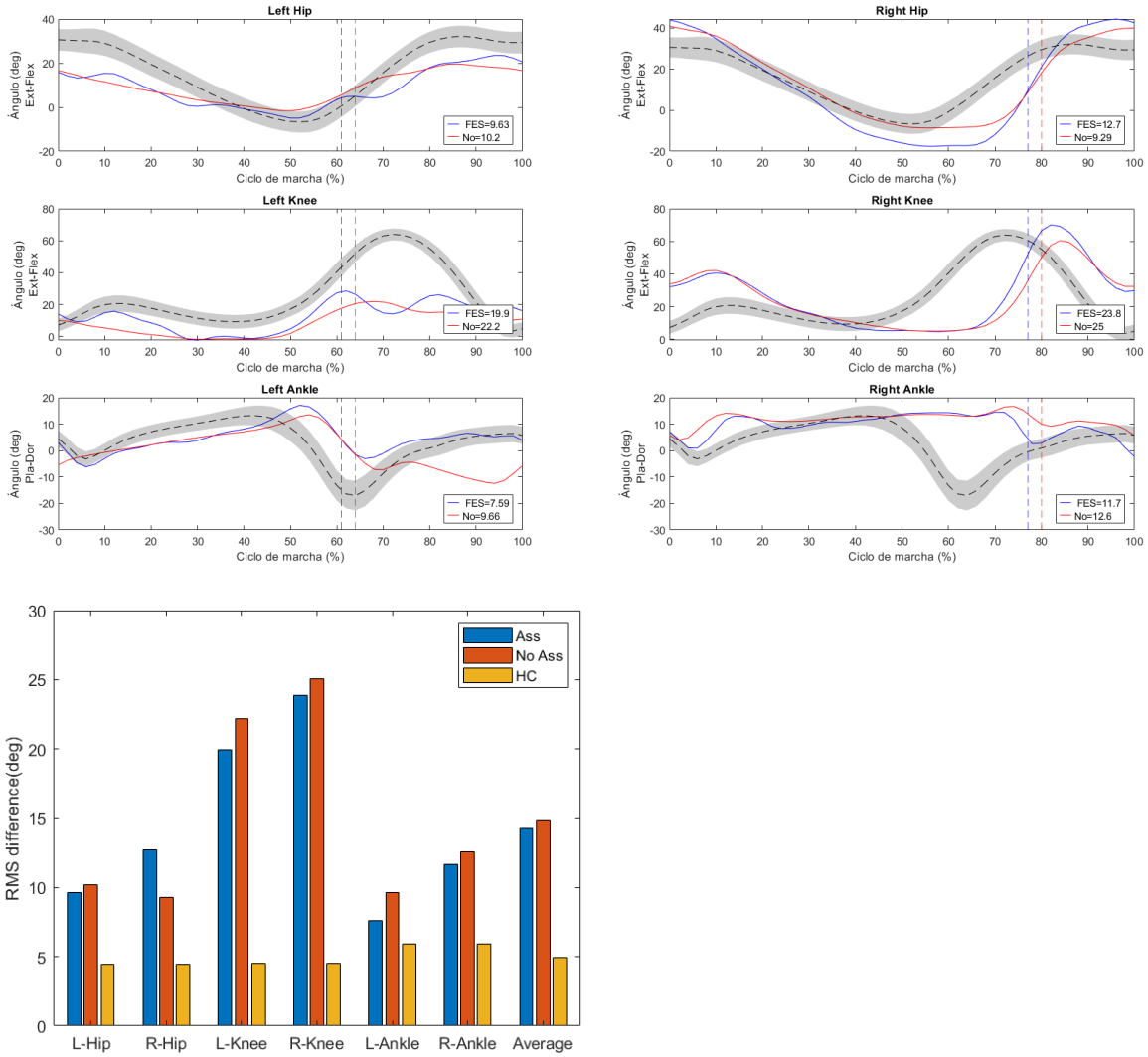


FIGURE 39. Kinematic curves of the FES-assisted and unassisted gait (top) of case 6 and the MAP summarizing the GVS of each joint (bottom).

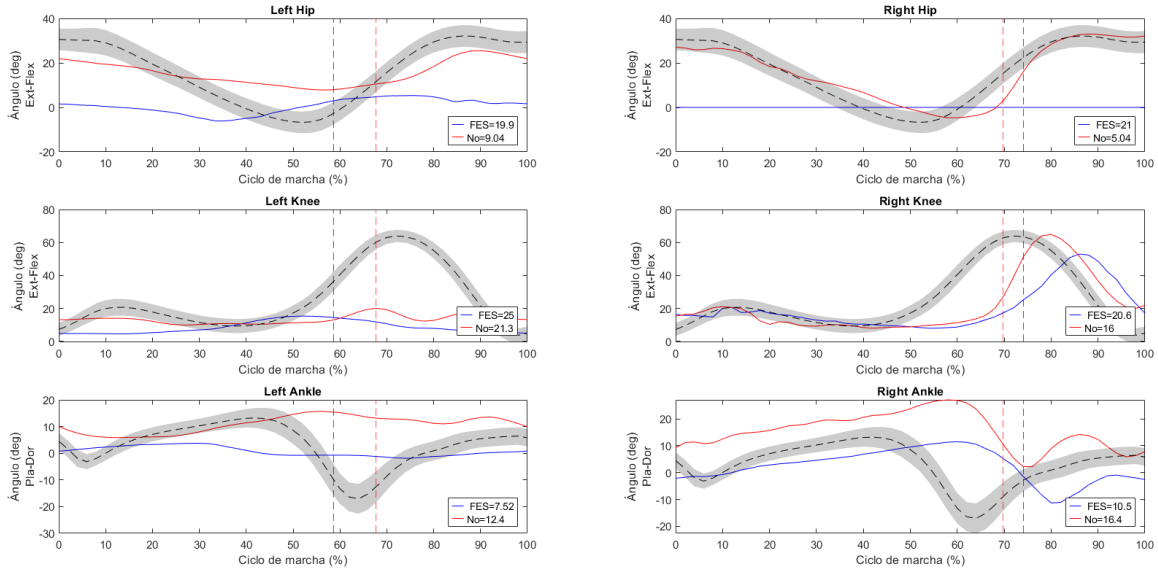
CASE 7:

Female ischemic stroke survivor of 47 y.o. with 1.5 months of evolution and left hemiparesis. Use of a foot drop brace and one crutch to walk (FAC=3). At exploration with the LEMS, she scored 5 for all the muscles

on the right lower limb, and in the left lower limb 4 for hip adductors, 3+ for hip flexors and knee extensors, 3 for knee flexors, 2 for hip extensors and abductors, and 1 for ankle plantar and dorsi flexors. Shows considerable spasticity (MAS 3) on the hemiparetic limb. When performing gait observation, the subject shows poor motor control, plantar hyperreflexia with flexed toes during the stance phase, fixed ankle dorsi flexion throughout the whole gait cycle, and thus no power during push-off, and no knee flexion during the swing phase.

This patient did not manage to use the exoskeleton in the training session due to a flexor pattern and spasticity in the hemiparetic limb that did not allow the WRD to extend her leg. Consequently, the selected strategy was assisting only with FES in the left TA, GC, HS, and GM. The priority of the stimulation was generating ankle dorsiflexion during swing, but it was also designed to improve push-off and foot clearance by increasing knee flexion during swing, and to provide stability in the hemiparetic limb during stance by assisting the left GM. However, due to the spasticity of this patient, the event detection algorithm to control the FES was not reliable to provide stimulation of the TA with suitable timing throughout the gait cycle due to inaccurate detection of the foot-off event. Therefore, TA was removed from the final stimulation set for the patient. Stimulation values were 41 mA for the GC, 49 mA for the HS, and 54 mA for the GM. At the end of the 80 min assessment session, the subject expressed a RPE of 2.

Due to high marker occlusion throughout the second session, right hip kinematics were not feasible to be retrieved from this register. The assistance improved spatiotemporal parameters of gait, except for the right foot off, but temporal symmetry worsened as a result of reduced swing of the non-paretic limb. Left hip kinematics worsened importantly due to a maintained hip extension caused by the stimulation of the HS. Nevertheless, this stimulation did not manage to improve knee flexion of the impaired leg due to the considerable spasticity of the subject. As a consequence, knee flexion of the right leg decreased and delayed, reducing the oscillation phase to preserve balance by increasing stance on the non-paretic limb. On the contrary, both ankles show improvement in kinematics through reducing the increased dorsiflexion caused by the spasticity thanks to the stimulation of the GC, which allowed to increase oscillation of the impaired limb by improving foot clearance.



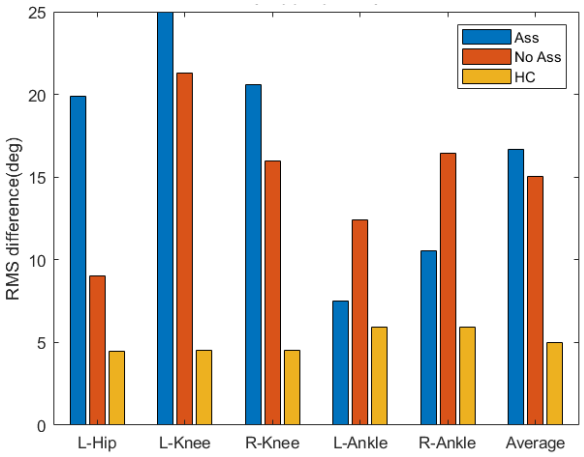


FIGURE 40. Kinematic curves of the FES-assisted and unassisted gait (top) of case 7 and the MAP summarizing the GVS of each joint (bottom).

CASE 8:

Male hemorrhagic stroke survivor of 43 y.o. with 3.0 months of evolution and left hemiparesis. Use of dyna ankle brace and one crutch to walk (FAC=4). At exploration with the LEMS, he scored 5 for all the muscles on the right lower limb, and in the left lower limb 3 for ankle plantar flexors, 3+ for knee flexors, 4 for ankle dorsi flexors, hip flexors and abductors, and 5 for the remaining muscle groups. Shows slight spasticity (MAS 1) on the hemiparetic limb. When performing gait observation, the subject shows compromised foot clearance due to increased ankle plantar flexion and ankle inversion during the swing phase.

Both FES assistance and hybrid assistance were successfully implemented and explored in this case, because the patient was able to learn to control and walk with the WRD in the automatic control mode. FES was applied in the left leg in the TA with 30 mA, GC with 40 mA, and HS with 40 mA. The stimulation strategy was aimed at improving foot clearance of the hemiparetic limb by generating ankle dorsiflexion and knee flexion during swing, as well as increasing step length by aiding push-off. In addition, it was aimed at reducing compensatory movements in the non-hemiparetic limb thanks to the assistance of the impaired limb. The latter was also sought by providing hybrid assistance since it was expected to improve gait symmetry by providing stability to the non-hemiparetic limb with the orthotic support of the WRD, reducing compensatory movements. At the end of the 2 h 13 min assessment session, the subject expressed a RPE of 2.

The FES assistance showed a slight improvement in bilateral kinematics and duration of the swing phase with respect to the unassisted gait of this subject. Spatial symmetry worsened due to a reduction in the step length of the impaired limb w.r.t. the non-impaired leg, although swing time of the impaired limb improved. The assistance does not generate kinematic changes in the non-paretic limb. In the left ankle, dorsiflexion during oscillation improves thanks to the stimulation in TA, given that he presents permanent plantar flexion as a base pattern, which detriments foot clearance. However, the assistance ought to be lowered, because the range of dorsiflexion during oscillation significantly exceeds the control pattern. Enhanced take-off is also generated thanks to the stimulation in the GC, that generates a faster transition from ankle plantar to dorsiflexion, increasing the power for take-off, thus increasing swing, and improving foot clearance. The latter is also improved thanks to generating knee flexion earlier during the gait cycle through the stimulation in HS. Overall, the kinematic changes of the paretic limb and the lack of compensatory changes in the non-paretic indicate better dynamic balance during gait.

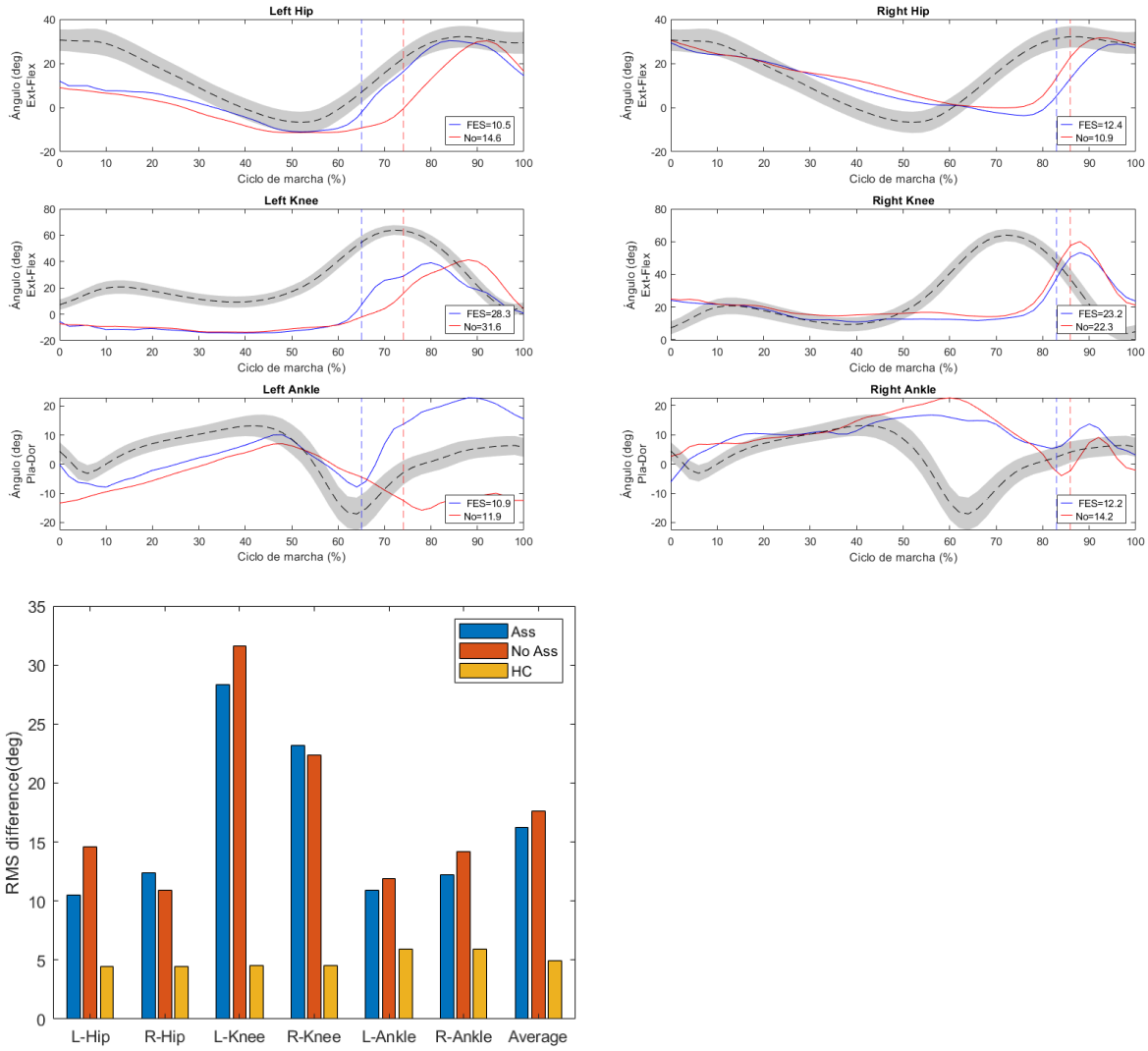


FIGURE 41. Kinematic curves of the FES-assisted and unassisted gait (top) of case 8 and the MAP summarizing the GVS of each joint (bottom).

On the other hand, the hybrid WRD assistance showed a slight worsening in bilateral kinematics and worsening in the spatiotemporal measures of gait, with improvement only in the duration of the swing phase of the right leg. Spatial symmetry improved, reaching the symmetry range, whereas temporal asymmetry shifted from a reduced swing of the non-impaired leg towards a reduced swing of the impaired leg. With hybrid assistance, the hip kinematic pattern is similar to the unassisted condition, but with a greater degree of flexion throughout the cycle. This happens because usually, when using the exoskeleton, the subjects support their weight on the cane by leaning the trunk forward. The knee joint in sagittal plane maintains a similar pattern in both conditions, but imposition of the actuated joint of the WRD is evident, without the stimulation in the left IQ generating any alteration on the flexion of the left knee. When comparing both ankles, the dorsiflexion caused by the stimulation in the TA during oscillation is visible, but this flexion lasts shorter than desired. Therefore, although it helps to improve foot clearance, it is not enough to impact importantly the stride length. Nevertheless, generating dorsiflexion is an improvement to guarantee foot clearance, since the subject presents no dorsiflexion in the unassisted pattern. Actually, both curves show a pattern of plantar flexion throughout the entire cycle, which may be due to the difficulty of moving the WRD insole using only the ankle force.

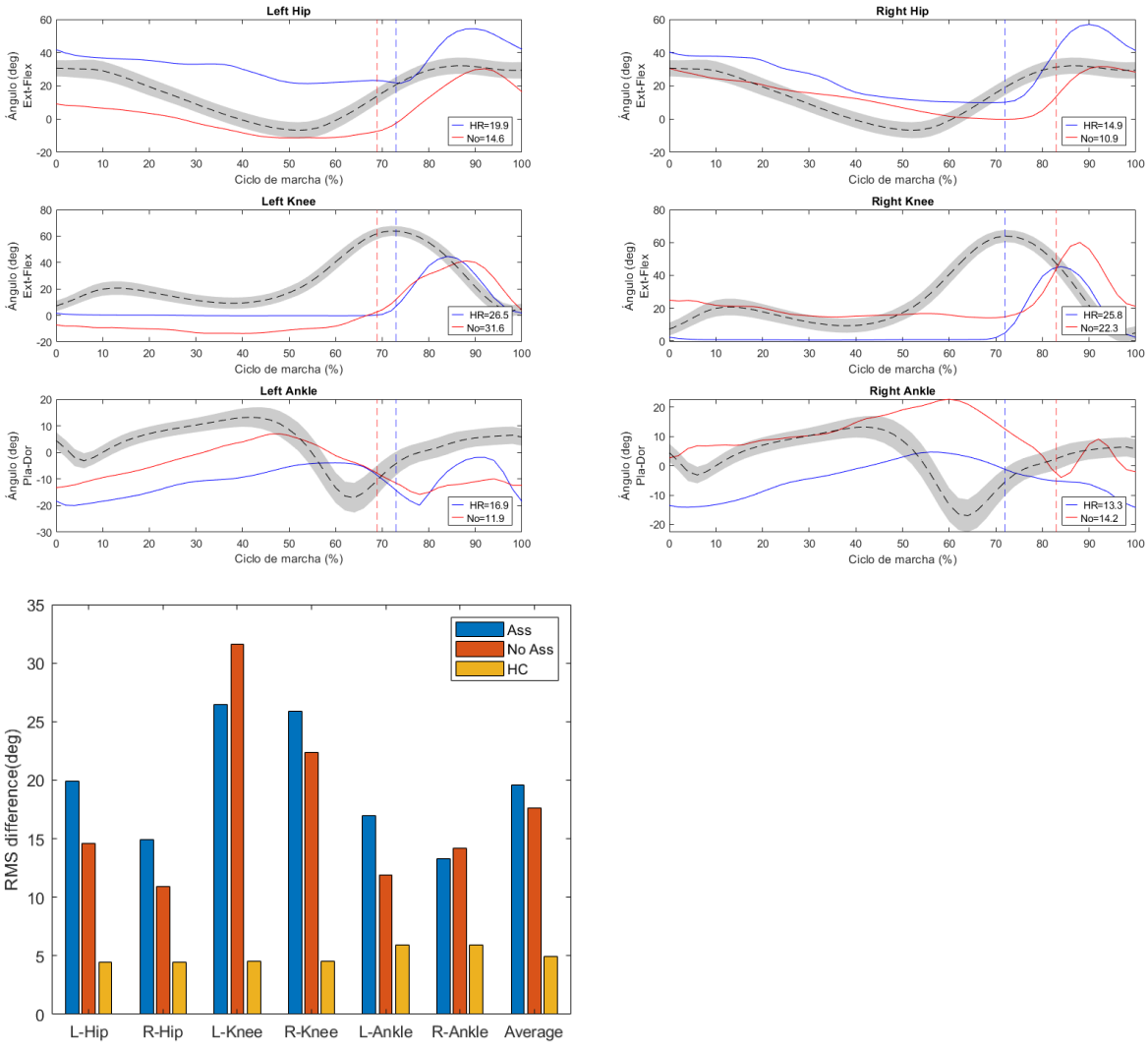


FIGURE 42. Kinematic curves of the HWR-assisted and unassisted gait (top) of case 8 and the MAP summarizing the GVS of each joint (bottom).

CASE 9:

Male hemorrhagic stroke survivor of 59 y.o. with 0.75 months of evolution and left hemiparesis. Use of an ankle-foot orthosis for foot drop and one crutch to walk (FAC=4). At exploration with the LEMS, he scored 5 for all the muscles on the right lower limb, and in the left lower limb 5 for knee extensors, 3 for ankle plantar and dorsi flexors, and 4 for the remaining muscle groups. Shows mild spasticity (MAS 2) on the hemiparetic limb. When performing gait observation, the subject shows compromised foot clearance due to increased ankle plantar flexion during the swing phase.

Both FES assistance and hybrid assistance were successfully implemented and explored in this case, because the patient was able to learn to control and walk with the WRD in the automatic control mode. FES was applied in the left leg in the TA with 60 mA, GC with 60 mA, and HS with 77 mA. The stimulation strategy was aimed at improving foot clearance of the hemiparetic limb by increasing ankle dorsiflexion and knee flexion during swing, as well as increasing step length by aiding push-off. Providing hybrid assistance was aimed at improving gait symmetry by reducing compensatory movements in the non-hemiparetic limb, thanks to the assistance of the impaired limb. At the end of the 95 min assessment session, the subject expressed a RPE of 6.

The FES assistance showed a slight improvement in the kinematics of the non-assisted limb and in the spatiotemporal measures of gait. Temporal asymmetry increased due to an increase in the swing of the impaired leg. The right kinematic curves do not show significant changes in the assisted and unassisted patterns, only a reduction in the range of motion of the ankle. The left ankle remains in permanent dorsiflexion, indicating permanent stimulation in the tibialis anterior due to false positive detections in the event detection algorithm. The assistance in the GC is counteracted by the effect of permanent stimulation in TA. The lack of dorsiflexion immediately following foot contact seen in the unassisted pattern of the patient is improved with the stimulation of the TA. Stimulation in the HS, which aids knee flexion in toe-off and swing, occurs too early in the gait cycle, extending the duration of the swing phase of the left leg to 50% of the cycle and increasing the temporal asymmetry of gait. The knee range of motion is equal with assistance and without assistance, but greater flexion during the stance phase is generated thanks to the stimulation of the impaired leg. Finally, the left hip remains in a greater degree of flexion throughout the entire cycle, getting closer to the control pattern. This may be due to assisted ankle dorsiflexion and knee flexion, which facilitate foot clearance and eliminate the need to compensate with hip extension to complete the swing in the subject's unassisted gait.

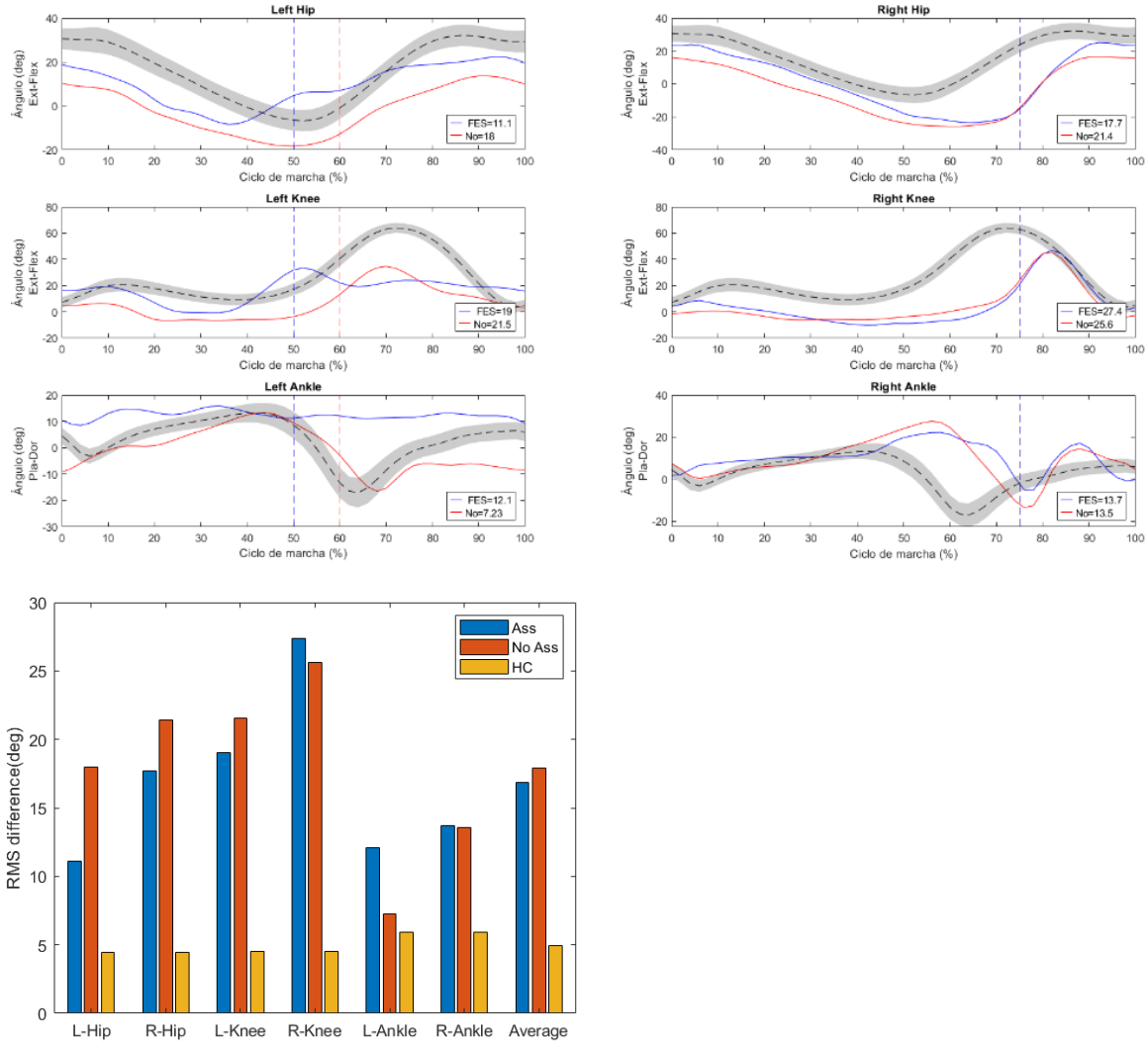


FIGURE 43. Kinematic curves of the FES-assisted and unassisted gait (top) of case 9 and the MAP summarizing the GVS of each joint (bottom).

On the other hand, the hybrid WRD assistance showed slight improvement in the kinematics of the non-assisted limb and a worsening in bilateral cadence and walking speed. Spatial asymmetry increased due

to an increase in the hemiparetic limb step length whereas temporal asymmetry improved due to a reduction in the swing time of the impaired limb. With the hybrid assistance a bilateral greater degree of hip flexion is seen throughout the entire cycle due to the posture with which patients walk with the WRD, in which they support all their weight on the cane and lean forward. There is also evidence of a bilateral flexion peak in the swing phase that corresponds to the movement that users must do to trigger the intention detection algorithm to perform each step with the WRD. In the knee, flexion is enhanced thanks to the active knee assistance of the WRD both in magnitude and duration, when compared to the unassisted pattern. Increased knee flexion throughout oscillation improves foot clearance, which is compromised in the subject's unassisted pattern of the impaired limb due to the reduced knee flexion and increased plantarflexion. The pattern of the knee is imposed by the WRD, eliminating the knee flexion that should be in the middle support phase. Finally, the assistance in the left TA successfully enhances ankle dorsiflexion during loading response and swing. The increased plantarflexion of the subjects' hemiparetic limb in non-assisted gait during swing and until loading response hinders foot clearance. Reduction of ankle plantar flexion is observed to initiate the swing, which is consistent with an increase in knee flexion in the swing phase, to compensate for the hindered power of the push-off phase.

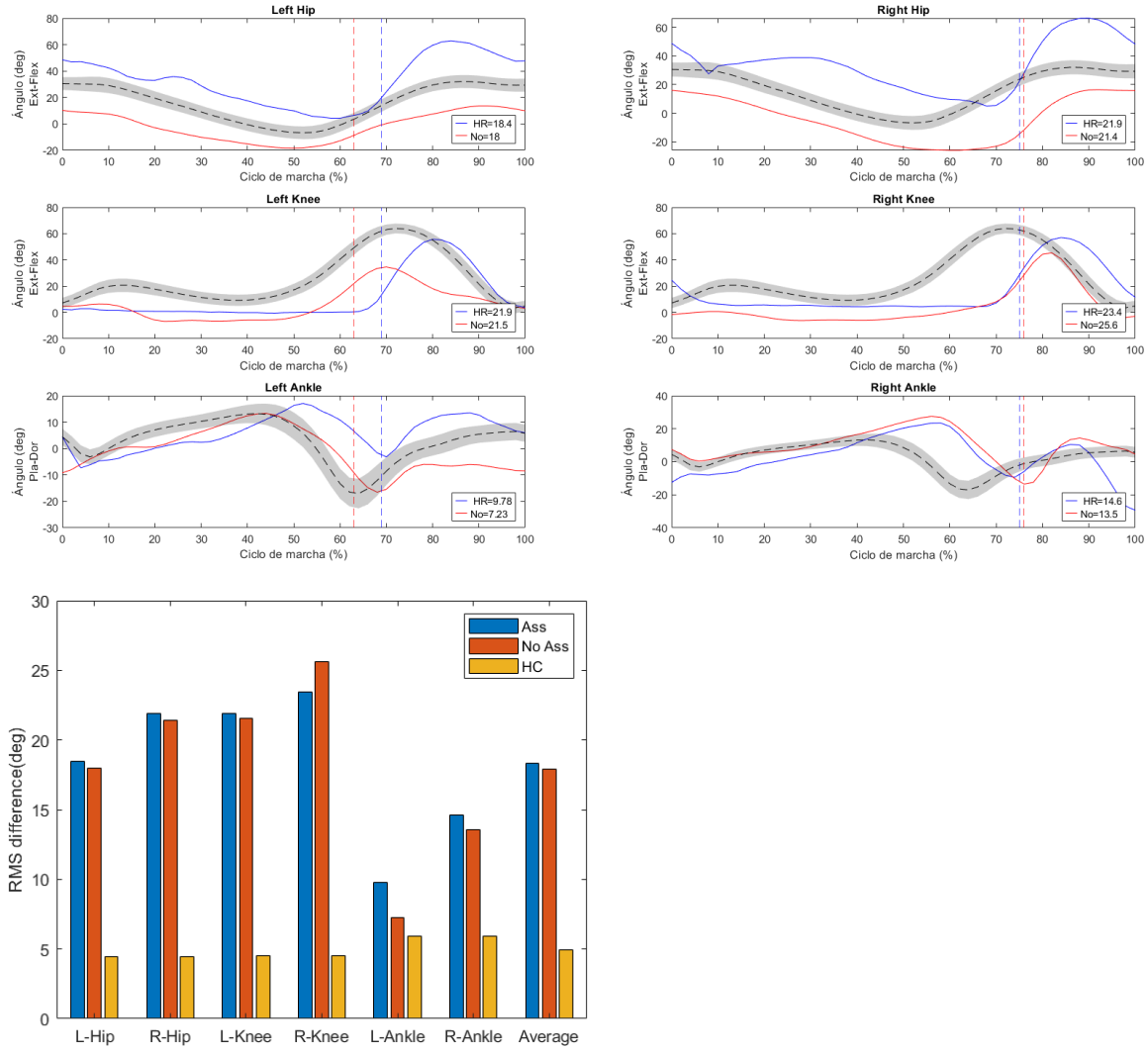


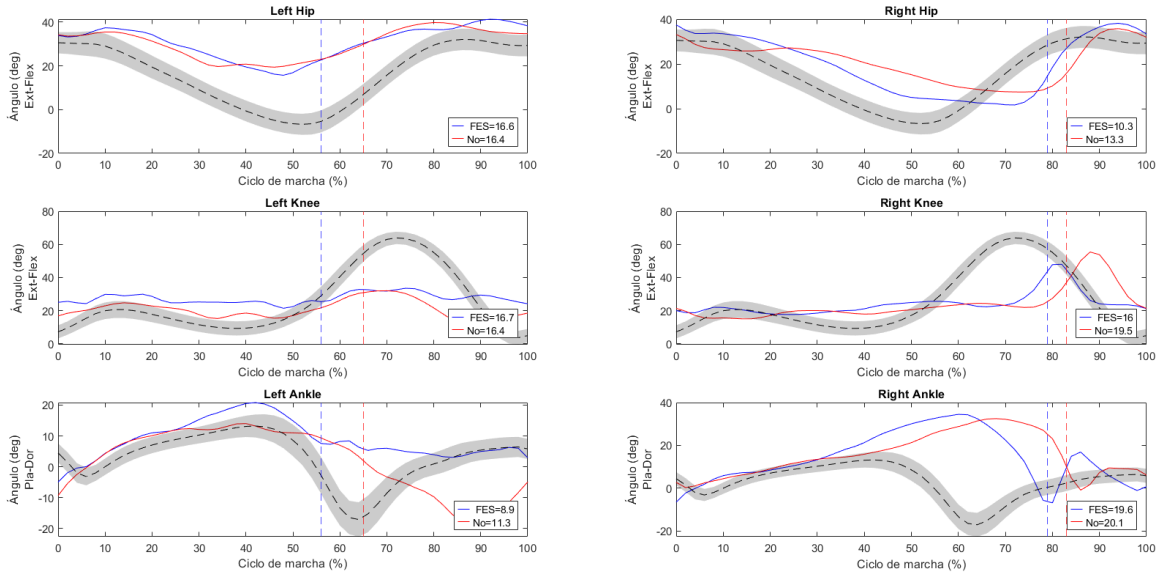
FIGURE 44. Kinematic curves of the HWR-assisted and unassisted gait (top) of case 9 and the MAP summarizing the GVS of each joint (bottom).

CASE 10:

Male ischemic stroke survivor of 48 y.o. with 1.5 months of evolution and left hemiparesis. Use of a foot drop brace and one crutch to walk (FAC=3). At exploration with the LEMS, he scored 5 for all the muscles on the right lower limb, and in the left lower limb 1 for hip extensors and knee flexors, 2 for hip abductors and ankle plantar and dorsi flexors, and 4 for the remaining muscle groups. Shows slight spasticity (MAS 1+) on the hemiparetic limb. When performing gait observation, the subject shows compromised foot clearance due to increased ankle plantar flexion and ankle inversion during the swing phase, as well as left hemineglect, gait with the trunk leaning to the right, and reduction of the loading on the left leg in the middle phase of support with slight claudication.

This patient did not manage to use the exoskeleton in the training session due to a poor weight shift towards the hemiparetic limb caused by having left hemineglect, considerable instability, and loss of muscle strength. The assistance strategy designed for him was applying FES in the left TA, GC, HS, and GM. This strategy was aimed at improving foot clearance by increasing knee flexion and ankle dorsiflexion during swing, while reducing ankle inversion and improving push-off through the stimulation of the GC. To provide stability in the hemiparetic limb during stance, assistance to the QF and the GM were also provided. Nevertheless, due to the considerable left hemineglect of the subject, the event detection algorithm to control the FES did not work properly and stimulation of the GC and QF was removed, due to permanent activation. Thus, FES was applied in the left leg in the TA with 31 mA, HS with 42 mA, and GM with 55 mA. At the end of the 81 min assessment session, the subject expressed a RPE of 2.

The FES assistance showed a slight improvement in the kinematics of the non-assisted limb and in the spatiotemporal measures of gait. Spatial and temporal asymmetry increased due to reduced contribution of the non-impaired limb. Despite the stimulation applied in the HS, no differences were observed between the assisted and unassisted kinematics of the hip or knee. A slight increase in the duration of the oscillation is observed, which reflects a better dynamic balance of the patient thanks to the stimulation of the GM and HS, which allow stability during support. In the ankle, greater ankle dorsiflexion is noticeable in the swing phase, in contrast to the marked plantarflexion of the unassisted curve, thus improving foot clearance thanks to the assistance provided.



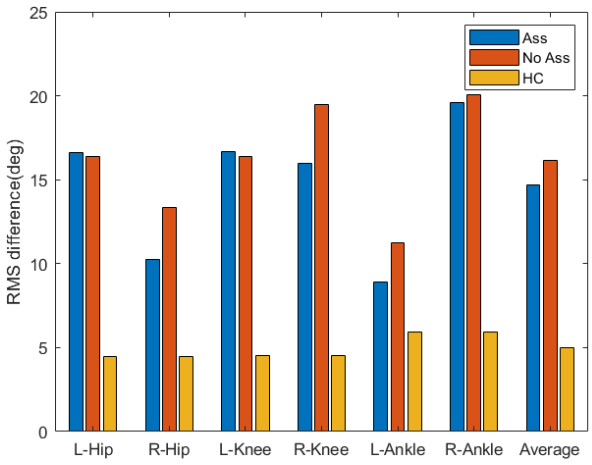


FIGURE 45. Kinematic curves of the FES-assisted and unassisted gait (top) of case 10 and the MAP summarizing the GVS of each joint (bottom).

USABILITY EVALUATION

Scores of the questionnaires completed to assess the usability of the systems tested by each subject are shown in Table 18 and Table 19. Scores of the SUS above 68 are considered above average [197]. No such threshold has been reported for the QUEST. For the latter, when asked to choose the three more important dimensions among the eight included in the questionnaire, the most frequent ones chose by the users who tested the FES modular system were effectiveness and comfort (71,4%), followed by weight, safety and easy to use, chosen by 57,1% of the subjects. The dimensions chosen most often by the users who tested the hybrid assistance were effectiveness (75,0%), followed by safety, durability, and adjustments, chosen by 50,0% of the subjects.

TABLE 18. Scores of the System Usability Scale for the FES system (top) and the hybrid system (bottom). Cells in pink correspond to SCI subjects whereas yellow cells correspond to post-stroke subjects. Cells in green show the SUS scores that are above average (>68).

FES system - SYSTEM USABILITY SCALE (SUS) SCORES											
Subject	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**SCORE**
Case 1	4	2	5	5	4	2	5	2	5	4	70,00
Case 3	5	5	5	5	5	1	5	5	5	4	62,50
Case 4	4	2	3	4	3	3	4	2	4	2	62,50
Case 6	5	1	4	5	4	1	4	3	5	3	72,50
Case 7	5	1	1	5	5	1	5	1	5	1	80,00
Case 9	2	3	4	4	3	2	3	1	3	2	57,50
Case 10	5	1	5	5	4	1	1	2	1	1	65,00
Avg SCI	4,33	3,00	4,33	4,67	4,00	2,00	4,67	3,00	4,67	3,33	65,00
Avg Stroke	4,25	1,50	3,50	4,75	4,00	1,25	3,25	1,75	3,50	1,75	68,75
Avg TOTAL	4,29	2,14	3,86	4,71	4,00	1,57	3,86	2,29	4,00	2,43	67,14
Hybrid system - SYSTEM USABILITY SCALE (SUS) SCORES											
Subject	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**SCORE**
Case 2	4	3	3	4	4	3	3	3	3	2	55,00
Case 5	1	5	5	5	5	1	4	2	5	2	62,50
Case 8	4	3	4	5	3	2	5	3	5	3	62,50
Case 9	3	3	4	4	3	2	3	1	3	2	60,00
Avg SCI	4,00	3,00	3,00	4,00	4,00	3,00	3,00	3,00	3,00	2,00	55,00
Avg Stroke	2,67	3,67	4,33	4,67	3,67	1,67	4,00	2,00	4,33	2,33	61,67
Avg TOTAL	3,00	3,50	4,00	4,50	3,75	2,00	3,75	2,25	4,00	2,25	60,00

TABLE 19. Scores of the QUEST scale for the FES system (top) and the hybrid system (bottom). Cells in pink correspond to SCI subjects whereas yellow cells correspond to post-stroke subjects. Cells in green show the high QUEST scores (>4,00).

FES system - QUEST SCORES									
Subject	**Dimensions**	**Weight**	**Ease in adjusting**	**Safe and secure**	**Durability**	**Easy to use**	**Comfortable**	**Effective**	**MEAN**
Case 1	4	5	4	5	4	5	4	5	4,50
Case 3	5	5	5	5	5	5	5	5	5,00
Case 4	2	4	2	3	3	2	2	4	2,75
Case 6	5	5	3	5	4	3	3	5	4,13
Case 7	3	2	1	5	2	1	1	5	2,50
Case 9	3	3	3	4	3	4	3	2	3,13
Case 10	4	4	2	2	2	3	3	3	2,88
Avg SCI	3,67	4,67	3,67	4,33	4,00	4,00	3,67	4,67	4,08
Avg Stroke	3,75	3,50	2,25	4,00	2,75	2,75	2,50	3,75	3,16
Avg TOTAL	3,71	4,00	2,86	4,14	3,29	3,29	3,00	4,14	3,55
Hybrid system - QUEST SCORES									
Subject	**Dimensions**	**Weight**	**Ease in adjusting**	**Safe and secure**	**Durability**	**Easy to use**	**Comfortable**	**Effective**	**MEAN**
Case 2	4	3	3	3	4	3	3	4	3,38
Case 5	5	1	5	5	5	4	5	5	4,38
Case 8	4	4	3	4	4	4	4	4	3,88
Case 9	3	3	3	4	3	4	3	2	3,13
Avg SCI	4,00	3,00	3,00	3,00	4,00	3,00	3,00	4,00	3,38
Avg Stroke	4,00	2,67	3,67	4,33	4,00	4,00	4,00	3,67	3,79
Avg TOTAL	4,00	2,75	3,50	4,00	4,00	3,75	3,75	3,75	3,69

Time for task registers showed the average time for the training sessions were 26.27±6.09 min when subjects were trained only to use the FES, 36.80±10.41 min when being taught to walk with the exoskeleton and 67.69±10.44 min when trained with the hybrid system. In the fine-tuning and assessment session, average donning times for the FES system were 17.35±8.99 min, including the calibration of the stimulation (10.62±7.37 min). Additional 21.80±12.58 min were required to setup and Donn the exoskeleton when assisting with the hybrid system. Subjects used the FES system for 25.43±9.13 min and the hybrid WRD for 34.19±19.86 min, and their doffing times were 4.63±1.78 min and 5.41±2.45 min, respectively. The average total session time was 84.64±11.58 min for those who were assisted only with FES, and 126.95±27.06 min for subjects who walked with the assistance of both systems. Note that the total session time comprises also the register of non-assisted gait (10.96±3.68 min) and its respective instrumentation time (22.70±7.16 min).

Lastly, the content analysis of the thoughts expressed by the users about the device(s) they used, showed that six out of ten enjoyed the experience of being assisted by the system(s), of whom three out of six received hybrid assistance and the other received only FES assistance; the latter also felt the assistance was adequate according to the phase of gait intended to help and was therefore, helpful. Interestingly, one of them (case 6) did not manage to use the exoskeleton fluently but he said the learning process to use the WRD was helpful to learn to be conscient about the sequence of movements required to walk, especially regarding the need to shift the weight, which helped him in the following days when doing gait rehabilitation. Similarly, the subject of case 3 indicated a sense of improvement in her left foot after receiving FES and a reduction of its numbness. She also indicated the FES system was not heavy or uncomfortable. Two subjects said they felt safe (C1 and C5) when using the systems and that they were not cumbersome, whereas two post-stroke subjects felt risky situations when using the exoskeleton (C6 and C7). On the other hand, two SCI subjects (C1 and C2) felt the FES system was too big and heavy. Two subjects who used the HWR (C2 and C9) felt the system forced them to follow imposed or compensatory movements. Lastly, two subjects (C1 and C9) expressed they knew that the systems used were prototypes and required further development to be improved.

DISCUSSION

The results of the proof-of-concept study demonstrate that the personalization strategy for modular hybrid systems for gait rehabilitation can be applied on the fly in clinical rehabilitation settings using as input traditional clinical assessments, like the LEMS and MAS and the expertise of PTs, and then fine-

tuning the configuration and assistance following functional observation and self-reported user perception. The approach is therefore funded on adding up the irreplaceable value of involving experienced PTs to plan and follow the rehabilitation process for each patient, with the advantages of providing tailored technology for gait assistance, meeting the specific functional user needs while positively affecting user perception. It is likely that improvements in both aspects will positively impact the therapy outcomes and acceptance of rehabilitation technologies. In the proof-of-concept study, it was feasible to readily tailor the systems thanks to their user-friendly interfaces that allowed the PT to easily modify the assistance of the systems iteratively until effective assistance was reached.

The proposed personalization strategy allowed for successful tailoring of the hybrid platform according to the individual functional requirements of 10 subjects with either iSCI or post-stroke. Subjects had heterogeneous degrees of impairment due to the type and severity of their injuries. All cases were effectively assisted, as shown by improvements in one or more of the measured variables (i.e., kinematics, spatiotemporal parameters of gait, or gait symmetry). The assistance strategy provided was mostly addressed towards improving knee extension and ankle plantar and dorsi flexion because these are the most important movements to achieve functional gait; a lack of them compromises the inertia of movement. As expected, the heterogeneity of the sample regarding the type and degree of impairment yielded contrasting results among cases. Overall, tailored FES assistance improved gait kinematics and spatiotemporal parameters of gait in all but one of the subjects that tested it. In this case (case 7), high spasticity affected the performance of the event detector that controls the stimulation, limiting the possibility of assisting with the proper coordination all the desired muscles in the subjects.

Contrastingly, only the two subjects with mild to high impairment (cases 2 and 5) that received hybrid assistance improved their gait kinematics, and the other two, with little impairment, improved the spatial and temporal symmetry of gait. Nevertheless, in all four cases assisted with the hybrid system, none of them improved the spatiotemporal parameters of gait. As the experience in the HNP of using WRD for gait rehabilitation dictates, the use of the WRD for gait assistance by people with SCI with low impairment does not seem to provide useful assistance but rather forces them to perform compensatory movements to trigger the step intention of the device. Nevertheless, subjects with low impairment participating in the study showed improvements in gait symmetry when using hybrid assistance. This can be explained because, during gait training, the afferences to the spinal cord are stimulated, activating the neural circuits of the spinal cord responsible for the generation of rhythmic patterns of movement in the central pattern generator. If the activation is maintained sufficiently over time, which is achieved through intensive locomotor training, it can induce plastic changes both at the level of the spinal cord and in the motor-sensory cortex in people with neurological injuries [16]. This is nowadays the basic strategy to enhance functional ambulation [11]. Consequently, further studies are required to include the evaluation of muscular activity through electromyography to evaluate possible improvements in the rhythmic coordinated activation of muscular activity when doing hybrid or robot-assisted gait training.

Based on the results of this study different opportunities to improve the modular systems used were identified. As mentioned above, the FES assistance in post-stroke patients with spasticity was challenging due to the difficulty in accurately identifying gait events to trigger the stimulation in the appropriate phase of gait for each muscular group. It is necessary to develop control algorithms and specific technologies that support accurate automated gait event detection designed for specific neurological populations because gait kinematics change importantly between them and have large variability among subjects with the same type of neurological injury [177]. Another area for improvement is that the requirements for FES assistance vary depending on the type and severity of neurological injury since their clinical and functional consequences are different. In post-stroke patients who did not manage to use the exoskeleton and could be assisted only using FES, it was identified the need to provide FES assistance not only to generate movement along the gait cycle but also to provide stability during the stance phase in muscles

with reduced strength. Therefore, an opportunity for further improvement of the modular FES system is that it allows to select specific muscles to stimulate with individual stimulation profiles and to select the specific subphases of the gait cycle to assist each of them. In this way, the stimulation strategy would be fully tailorable muscle-wise, and thus, the assistance optimized. These features ought to be added to the easy-to-use interface of the system. Overall, having a control system that allows tailoring the assistance depending on the type of neurological injury and specific functional requirements of each subject, would provide effective FES assistance for gait rehabilitation of subjects with low impairment and effective hybrid assistance for subjects with mild to high impairment.

Additionally, opportunities to improve the experimental protocol of the study were also identified. Despite having only one training session to learn to use the WRD, all iSCI subjects and half post-stroke subjects that performed the training session learned to use the device and could be assisted with the hybrid system. For the post-stroke patients who did not manage to learn to use the exoskeleton in one session due to their marked left hemineglect and high impairment, more training sessions would have allowed them to be able to use the device, as indicated in the training programs of WRD developed for gait rehabilitation. Therefore, some patients who could benefit from using the hybrid assistance but did not learn how to use the WRD were not assisted with the optimum assistance. This study showed that providing assistance to post-stroke patients with mild to high impairment using the hybrid system was beneficial. This assistance led to a more symmetrical gait pattern by reducing compensatory movements in the non-paretic limb. This was achieved by enabling the use of the paretic limb during gait and providing mechanical support and stability during the single stance phase of gait. In turn, this allowed to increase the step length and walking speed, important goals of gait rehabilitation programs for populations with neurological injuries. Overall, it was challenging for subjects ongoing in an early rehabilitation stage to learn to use the WRD in automatic mode in one session, but the motivation that all subjects involved in the study showed and the experience of the research team to perform a progressive, safe training, allowed most of them to learn the necessary skills in just one session.

In addition to evaluating the effects of the technologies in gait biomechanics, usability evaluation was included as part of the experimental protocol. It is imperative to take this dimension into account because despite the technical advances in the field, users' acceptance of the technologies is still limited as a consequence of limited evaluation of user satisfaction with WRD [70, 48], the lack of validated tools to assess the devices from the user's perspective [54], and the need to improve their usability [21]. Moreover, increasing user acceptance of the technologies leads to better adherence to treatment [65], therefore potentially increasing the use of the technologies and rehabilitation outcomes, as well as the success of the devices in reaching their intended context of use. The usability of the FES system and the hybrid system were assessed separately. Three out of the seven subjects that rated the former gave it a score above average in the SUS, indicating they consider it easy to use and have global system satisfaction. The average SUS score for the FES system was 10 points higher than the one scored by the users of the hybrid WRD. None of these subjects gave the hybrid system a score above average. Interestingly, all post-stroke patients rated higher than the iSCI subject the ease-of-use of the hybrid system. The SUS also provides a measure of learnability in items 4 and 10 and of usability with the other 8 items [25]. In this regard, both systems received moderate scores for usability and low scores for learnability, because they needed to be set up by the research team, since they were prototypes aimed to be used in a pilot study. For both sub-dimensions, scores were higher for the FES system.

The QUEST scores show similar results. Three out of seven subjects that rated the FES system gave scores over 4,5. The average score of the iSCI subjects was higher than the score given by post-stroke patients, probably because the performance of the event detection algorithm of the system was worse in the latter. Only one post-stroke subject rated with more than 4.5 the hybrid system, and all the scores given by this population were higher than the one given by the iSCI subject. Items with the highest satisfaction rates

were safety (FES = 4.14, HWR = 4.0), effectiveness (FES = 4.14), weight (FES = 4.0), dimensions (HWR = 4.0), and durability (HWR=4.0). Comparing these dimensions with the ones chosen by the users as the most important ones, it can be seen that users' expectations regarding the effectiveness, weight, and safety of the FES system and expectations about the safety and durability of the HWR are successfully met. Based on the content analysis of the comments expressed by the subjects regarding the technologies and the time for task recorded, the technologies need to be improved to decrease donning times, size, and weight when moving on from prototypes to final products to be feasible to implement as part of daily therapy. Most subjects expressed that the belt to attach the FES system was uncomfortable and needed improvement, highlighting the need to invest effort in the wearability and comfort of these technologies. Nevertheless, despite being prototypes used in a pilot study and thus not reaching desirable usability scores, most subjects expressed positive comments regarding the experience and the assistance provided by the FES system and the HWR. It is very important that developers implement a UCD approach along their developments to iteratively improve their devices, so that they satisfy the needs and requirements of the end-users. This will largely impact the usability and thus, the acceptance of their technologies.

Lastly, based on the results and on the observation during usability testing [192] performed throughout the whole session, a summary of the type of assistance the research team suggests for the populations studied considering their degree of impairment is presented. For iSCI subjects with mild to high impairment, such as the subject of case 2, the hybrid assistance provides mechanical support that provides stability and allows more independent and longer walking training. During the training session, this subject was training gait in parallel bars. Therefore, he took his first rehabilitation steps with a walker during this study's first session, which means that having the support of the hybrid system represented training a more independent gait (i.e., move from WISCI II 5 to 6) sooner during the sub-acute rehabilitation period. A similar situation was seen in this case when performing the fine-tuning and assessment session. By that time, he was starting training using a walker with the assistance of a PT, but with us, he managed to walk with hybrid assistance and without physical assistance. This means that providing the hybrid support represented a progress of at least 9 days in independent walking training for this subject, which would allow him to benefit further from the enhanced neuroplasticity after a spinal cord injury [198]. For the remaining iSCI cases with low impairment, providing assistance only with FES demonstrated to be useful, positively appreciated, and desirable. Similarly, post-stroke patients with mild to high impairment (i.e., cases 5, 6, 7, and 10) would largely benefit from the hybrid assistance thanks to the mechanical support provided by the WRD that allows them to load their paretic limb and thus, improve gait symmetry and reduce compensatory movements of their non-paretic limb. Nevertheless, in these cases, it is necessary to provide more than one training session or to use a hands-free WRD, due to the difficulty in using the paretic upper limb and to the hemineglect caused by the stroke.

LIMITATIONS AND FUTURE WORK

Only the sagittal plane was analyzed due to issues during data acquisition that compromised marker visibility in several cases. Thus, some registers of the assisted walk were analyzed based on the data of the electrogoniometers instead of using the data recorded with VICON. In this regard, only hip, knee and ankle joints were analyzed because pelvic markers had to be relocated when using the assistive systems, leading to a low fidelity representation of pelvic kinematics. Likewise, hip rotation was also discarded since it has poor reliability when computing the GPS [193].

Regarding the difficulty of post-stroke patients learning to use the WRD after only one session, for future research in the field, it is recommended to involve post-stroke subjects with both left and right hemiparesis, given that, in this case series, patients who presented a marked left hemineglect were the ones with more difficulty in learning to use the WRD. This could be because subjects with right-hemisphere stroke are 80% more prompt to have left hemineglect when compared to left brain stroke [199]. In this pilot study, the inclusion criteria considered recruiting only right-hemisphere stroke subjects

due to time availability and to avoid any cognitive impairment that would undermine users' ability to follow instructions and provide clear feedback on the use of the technologies.

It is a remaining challenge in the field to optimally calibrate stimulation intensities, given that nociception and stimulation required to reach the motor threshold change between the static positions in which calibration is performed and dynamic walking, when legs are loaded. For example, case 3, expressed discomfort when started walking due to stimulation, but after optimizing the stimulation, the foot clearance of the subject improved. During the iterative setup of the assistance, it is imperative to take as the top priority the patient's comfort and listen to their perception.

Lastly, to count with a fully modular and tailorable hybrid system, it would be ideal to use a modular WRD that allows selecting specific modules to be mounted up and assisting separately each lower limb joint. Using the FES system with such a WRD device and closing the control loop between both devices is ideal for potentiating all the advantages of a fully tailorable hybrid system in gait rehabilitation.

CONCLUSIONS

This study presents a personalization strategy for modular hybrid systems for gait rehabilitation that can be applied on the fly in clinical rehabilitation settings using as input traditional clinical assessments and the expertise of PTs who work in the rehabilitation of subjects with neurological injuries. The approach presented, which offers personalized assistance by configuring technologies and their parameters according to the individual's needs, allows to deliver effective gait assistance and aims to create a positive user experience. The configuration of the personalized optimal assistance begins with an evaluation of the patient's functional deficits through traditional clinical assessments and is subsequently fine-tuned based on functional observations and the user's self-reported perceptions. The rehabilitation technologies used in this pilot study were feasible to readily tailor thanks to the user-friendly interfaces that allowed the PT to easily modify the assistance and the modular design of the FES system. Through the implementation of the personalization strategy, the hybrid platform was successfully tailored according to the individual functional requirements of 10 subjects with either iSCI or post-stroke. Four of them received hybrid assistance and 9 of them tested the FES assistance. Due to the heterogeneity of the sample regarding the type and degree of impairment, contrasting results were obtained in the cases. Overall, the tailored FES assistance improved gait kinematics and spatiotemporal parameters of gait in all but one of the subjects that tested it. Nevertheless, further improvements to the event detector algorithm and the control system of the FES must be made to adapt to the constraints and requirements of different neurological injuries. Contrastingly, only the two subjects with mild to high impairment that received hybrid assistance improved their gait kinematics, and the other two, with little impairment, improved the spatial and temporal symmetry of gait. Nevertheless, in all four cases assisted with the hybrid system, none of them improved the spatiotemporal parameters of gait.

3.5 STUDY 5: IMPROVING THE USABILITY EVALUATION OF WEARABLE ROBOTS[19]

INTRODUCTION

Over the last decades, there has been an outstanding evolution in the field of wearable robotic devices WRD for rehabilitation and assistance. However, despite technical advances, user acceptance and adoption of these technologies is still very limited [21]. This fact is increasingly attracting the interest of researchers in the WRD field with the aim of better understanding its causes and the limiting factors of the user experience in human-robot interactions [52]. Of particular importance, studies have shown the limited evaluation of user satisfaction with WRD [70], the lack of validated tools to assess devices from the user's perspective [54], and the need to improve their usability [21].

When it comes to usability, there is a scattered landscape of definitions and scopes for the term. The best-known standard related to usability of human-robot interactions is ISO 9241-11, which defines usability as "the extent to which the user's physical, cognitive and emotional responses that result from the use of a system, product, or service meet the user's needs and expectation" [200]. However, only a few WRD studies end up using the exact terminology the standard provides, underlining the difficulty in capturing the complex construct of usability by the means of only three dimensions: effectiveness, efficiency, and satisfaction. As a consequence, other models including further dimensions have been proposed to evaluate usability in assistive technologies [98, 201, 202, 203], demonstrating that technology developers more often refer to usability using a broader scope of terms, hereinafter called "usability attributes" (UA). The definition of such UA is often blurry, offering the possibility for different interpretations based on the educational background, the language, as well as application context. Consequently, as of now, there exist no validated definitions of UA that are easily accessible and, more importantly, that were agreed upon by WRD developers. Only once the field establishes an agreement upon specific UA with their respective definitions, the WRD community can evaluate the same things and provide data that can be more easily compared across devices and studies.

In this regard, open-source benchmarks for the evaluation of WRD have been developed recently in two coordinated European efforts: Eurobench [103] and the European Cooperation in Science and Technology (COST) action for Wearable Robotics [204]. Eurobench aimed to create a framework for applying benchmarking methodology on bipedal robotic systems, including lower limb WRD and robotic humanoids. To run the evaluations proposed in their framework, two facilities with standardized equipment and settings to evaluate lower limb WRD were set up in Europe. Only one of the 75 protocols developed in the Eurobench framework addresses the usability of WRD. This evaluation is conducted through a questionnaire including the attributes acceptability, perceptibility, and functionality. The questionnaire evaluates usability by asking if the device is useful to the user and provides a scoring system based on the three dimensions stated by ISO 9241-11 [205]. Additionally, the protocol is limited only to lower limb WRD, has limited accessibility for developers around the world due to the specialized setups required to evaluate the technologies, and is only applicable to devices in advanced development stages with Technology Readiness Levels (TRL) ≥ 7. On the other hand, the first objective of the COST action for wearable robotics was to create a common understanding of terms and concepts related to wearable

[19] *The results of the research conducted for this chapter were disseminated in the following:*

***Herrera-Valenzuela, D**; Meyer, JT; del Ama-Espinosa, AJ; Moreno, JC; Gassert, R; Lambercy, O. "Towards a validated glossary of usability attributes for the evaluation of wearable robotic devices". J NeuroEngineering Rehabil. 21, 30 (2024). https://doi.org/10.1186/s12984-024-01312-1*

*Oral contribution in ExoBerlin 2022: **Herrera-Valenzuela, DS**; Meyer, JT; Moreno, JC; del-Ama, AJ; Lambercy, O. "Benchmarking usability in wearable robotics: Effort towards a shared and applicable terminology". International Exhibition & Conference for Exoskeleton & Human Augmentation Systems - ExoBerlín 2022. ExoBerlin. 2022. Germany.*

robotics among fields of expertise in general. Nevertheless, their vocabulary is not specific to usability or user experience. As such, the term usability itself was not included, but the UA *cognitive load*, *mental fatigue*, *robustness*, and *wearability* were separately considered [204]. This further highlights the need for a more comprehensive, usability-focused framework to define and evaluate the usability of WRD at any TRL.

With a similar motivation, the committee F48 on Exoskeletons and Exosuits formed by the American Society for Testing and Materials (ASTM) has been working to develop voluntary consensus standards for WRD since 2017. They have a subcommittee specifically devoted to defining a Standard Terminology for these WRD, which published the standard F3323-21 with the proposed terms and definitions [206]. Nonetheless, this standard is not related to usability, is not open-access, and was not externally validated, thus having limited accessibility and applicability among WRD developers.

To push usability evaluation and integrate usability features as design requirements during technology development, having benchmarks and shared terminology that can be unequivocally understood, are easily accessible, and implementable by WRD researchers and developers is necessary. To this end, the Interactive Usability Toolbox (IUT) was developed at ETH Zurich [207]. It takes the form of an online platform aimed at increasing and improving usability evaluation practices during the development of WRD [102]. The Toolbox facilitates the search and selection of context-specific outcome measures and usability research methods, including the option to select specific UA as part of the intended context. To guarantee the comprehensiveness, generalizability, and validity of the UA, which are the starting point to recommend specific usability evaluation methods, an internationally validated glossary of UA was developed as part of the IUT. The objective of this paper is to describe the process of building and externally validating the Robotics Usability Glossary (RUG), a glossary with consensus-based definitions for each commonly used UA. Specifically, this study provides the results of a two-step validation consisting first of a local evaluation with usability experts, followed by an online survey administered to developers of WRD around the world to assess the external validity of this glossary. These agreed UA should then become the basis to find and create more widely accepted benchmarks for the usability evaluation of WRD.

METHODOLOGY

STUDY DESIGN

An initial set of UA was extracted from a literature survey on usability evaluation in WRD. The initial set of attributes was enriched and locally validated with seven developers of WRD through an online survey and a focus group, leading to a reasonable consensus. The locally validated glossary was then externally validated through a globally distributed online survey. The current study purposely targeted only technology developers because they are mostly the ones conducting and designing usability evaluations or WRD. Therefore, the aim was to reach a consensus among them. Figure 46 summarizes the overall methodology. The details of the process of building the glossary and of the two-step validation are described in the following sections.

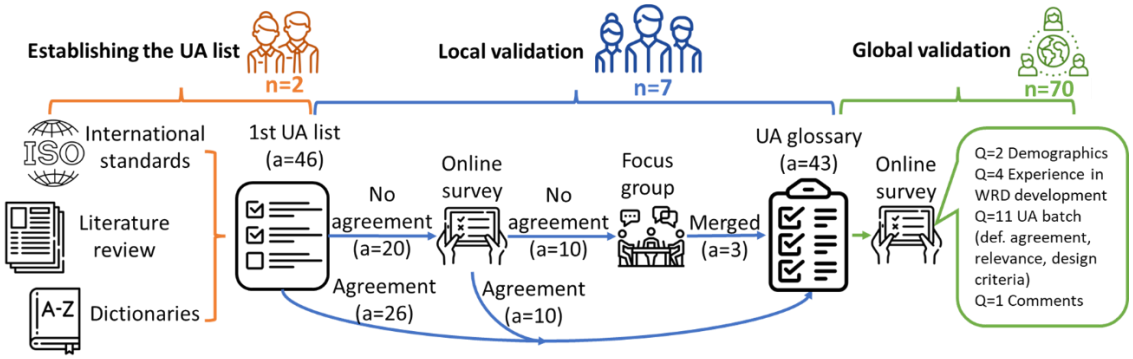


FIGURE 46. Schematics of the methodology followed to build the UA glossary, validate it locally and launch an online survey to validate it worldwide. The acronyms correspond to the number of developers (n), the number of usability attributes (a), and the number of questions (Q).

ESTABLISHING THE UA LIST

The first set of UA was gathered based on a literature survey on how usability is assessed in the field of WRD, mostly from other models proposed for usability evaluation [98, 201, 203, 202]. The resulting data was summarized in 46 UA that encompass the overall usability of WRD. Previously available definitions were retrieved from their respective papers when available, from standardized guidelines such as ISO 9241-11, from international health organizations like the World Health Organization and the Agency for Healthcare Research and Quality, or from English dictionaries (e.g. Cambridge Dictionary, Oxford English Dictionary). The definition that best fit the attribute with respect to WRD was selected, based on the agreement of the two main study coordinators.

LOCAL VALIDATION

UA definitions for which the two study coordinators did not reach a consensus were discussed with a group of seven local WRD developers through an online questionnaire, where the respondents rated with a 5-point Likert scale their agreement with the provided definition(s) of each UA, as well as the applicability of each attribute for the development of WRD. The definitions with average agreement scores of at least 4.0 were thus considered locally validated and not further discussed. The remaining UA were discussed with four of the respondents of the survey during a focus group aimed at i) improving the definitions based on the available ones and ii) deciding to potentially merge UA with similar definitions. Despite all seven local developers being invited to participate in the focus group, only 4 of them could participate due to time availability. The session was moderated by the study coordinators. All the descriptions built during this session were scored once again by six of the respondents from the initial local survey in a second online survey.

Both surveys were reviewed and tested before being distributed to guarantee the understandability of the questions and face validity of the survey. Comment boxes were always included to gather further insights from the respondents about the definition of each UA. Before starting the study, the research aims and methods were discussed and approved among the authors, assuring that face validity was established.

GLOBAL VALIDATION

With the locally validated glossary, a second online survey was designed and launched to validate the glossary in the international community of WRD developers. The intended sample size for this study was set at 91 respondents, determined based on an estimated total target population size of N=1000, a 95% confidence interval and 10% accepted margin of error [63, 208]. The full set of UA was divided into four batches so that respondents rated at least one of the batches. The division of the set was done to reduce the time required to complete the survey to under 15 minutes, aimed at increasing the completion rate.

The UA in each batch were strategically distributed to balance the ones that had lower agreement scores from the local validation. The survey contained initial questions on demographics, and respondent's experience in device development and usability evaluation, followed by the selection of one of the batches to rate (a) the respondent's agreement with the proposed definition for each UA, (b) the relevance of the UA for the development of WRD and (c) the inclusion of the UA as a design criterion in the developments that the respondent was involved in. For all the ratings, a 5-point Likert scale was used. If the agreement rate for any UA definition was below 3, a text box was displayed giving the option to describe how they would improve or change the proposed definition. At the end of the survey, respondents could write down further comments in a text box and they could also choose to complete other attribute batches. The survey was reviewed and tested by four researchers with three different native languages (all proficient in the English language) to guarantee the understandability of the questions and face validity of the survey.

All surveys were administered using the QuestionPro Survey Software (QuestionPro Inc., Austin, TX, USA). On the landing page of each survey, the study aims were presented, and informed consent was collected from the participants. Once the participants agreed with the stated terms and conditions, the surveys started. Data was collected from August 2022 to February 2023.

SAMPLE

The participants for the local validation were recruited through purposive and convenience sampling techniques, to guarantee valuable knowledge on the aspects studied and to allow performing on-site activities like the focus group in a timely manner, since they all were familiar with the IUT beforehand. An email was sent to the experts explaining the aim of the study, both the online survey and the focus group, and inviting them to participate in both or at least in the online survey. Inclusion criteria included experience in the development and usability evaluation of WRD, previous knowledge of the IUT, and a legally valid signature of the informed consent.

For the global validation stage purposive and snowball sampling techniques were used to obtain survey responses. Recruitment was made from the authors' wider network via email, social media, the IUT website, and as well as at international conferences related to the field of WRD. Developers contacted through these channels were encouraged to take part in the survey emphasizing the importance of reaching a consensus regarding the definitions of usability attributes within the field. Their participation was underscored as vital for the validation of the glossary, ensuring a diverse range of respondents contributed to the process. Inclusion criteria included an agreement to participate in the survey and share the results (obtained at the beginning of the survey), and experience in the development and usability evaluation of WRD, assessed through four questions regarding this matter in the questionnaire. Additionally, there was a highlighted note in the introduction of the survey indicating that only WRD developers should complete it.

DATA ANALYSIS

All demographic variables and ratings are presented using descriptive statistics, either with their mean and standard deviation (mean ± STD) or with their median and quartiles first and third, Mdn (Q1-Q3), in case of high data dispersion. Categorical variables are analyzed with absolute frequency. Kolmogórov-Smirnov (KS) tests were performed for each demographic variable and rating to test for normal distribution. To further investigate whether professional experience influences the agreement, relevance or previous implementation of the UA included in the RUG, Spearman rank correlation tests were performed to assess possible correlations between each of the three ratings asked in the surveys and the professional data collected from the subjects: i) years of experience as a developer, ii) highest TRL achieved, iii) the number of dedicated usability studies performed, and iv) number of users they had

previously interacted with. Lastly, the kurtosis and Pearson's 2nd coefficient of skewness were calculated to study the distribution of the three ratings evaluated.

RESULTS

The local validation was performed with 7 WRD experts from ETH Zurich. In the global validation, 70 respondents from 17 countries around the globe participated. The participants' demographics and WRD experiences are summarized in Table 20. Only 20 UA were assessed during the local validation, since those were the ones for which the study coordinators did not reach a consensus. Of these, only the 10 attributes that were not rated with an average agreement score of at least 4.0 were further discussed during the focus group. The participants of the focus group agreed on merging three out of five pairs of UA with similar definitions, preserving only the attribute that best encompassed both definitions. Therefore, by the end of the local validation, the glossary contained 43 UA to be externally validated. The list of the individual UA, their definitions and the ratings obtained in the global validation are available in Table 21. The full individual ratings obtained in both local and global validation stages are additionally included in Annex 4. A summary of these ratings is shown in Table 22 Box plots showing the distribution of each type of rate among the 43 attributes are shown in Figure 47. The average response time for this survey was 2.74 (2.05-4.02) min for the introductory part and 6.85 (4.80-11.85) min for the UA batches. The survey reached 713 viewers worldwide, of whom 150 started the survey and 70 fully completed it (completion rate = 46.67%). The geographical distribution of the respondents of the globally distributed survey is displayed in Figure 48.

TABLE 20. Demographics and experience in the development of WRD of the respondents involved in the local and global validation of the UA glossary.

Characteristic	**Data**	**Local (n=7)**	**Global (n=70)**
Age	Mean ± STD	29.7 ± 5.3	38.0 ± 11.0
Sex	Female	3	16
	Male	4	53
	Other	0	1
Countries	Total (Total)	4	17
Years involved in the development of WRD	Median (Q1-Q3)	3.0 (2.3-7.0)	7.0 (3.0-10.0)
No. of dedicated usability evaluation studies	Median (Q1-Q3)	2.0 (1.0-7.0)	2.0 (1.0-3.75)
No. of target users personally interacted with	Median (Q1-Q3)	15.0 (7.0-25.0)	15.0 (5.0-50.0)
Maximum TRL achieved	1 Basic research	0	2
	2 Technology formulation	0	1
	3 Needs validation	0	2
	4 Small-scale prototype	3	7
	5 Large-scale prototype	1	11
	6 Prototype system	1	8

	7 Demonstration system	1	12
	8 Initial commercialization	0	2
	9 Full commercial application	1	17

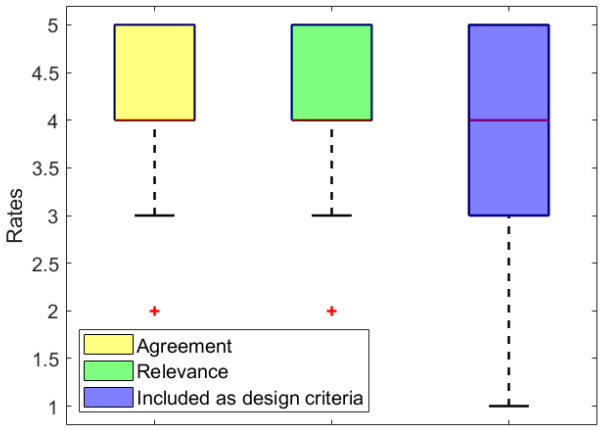


FIGURE 47. Box plots for each one of the three ratings assessed in the global validation stages for all the attributes.

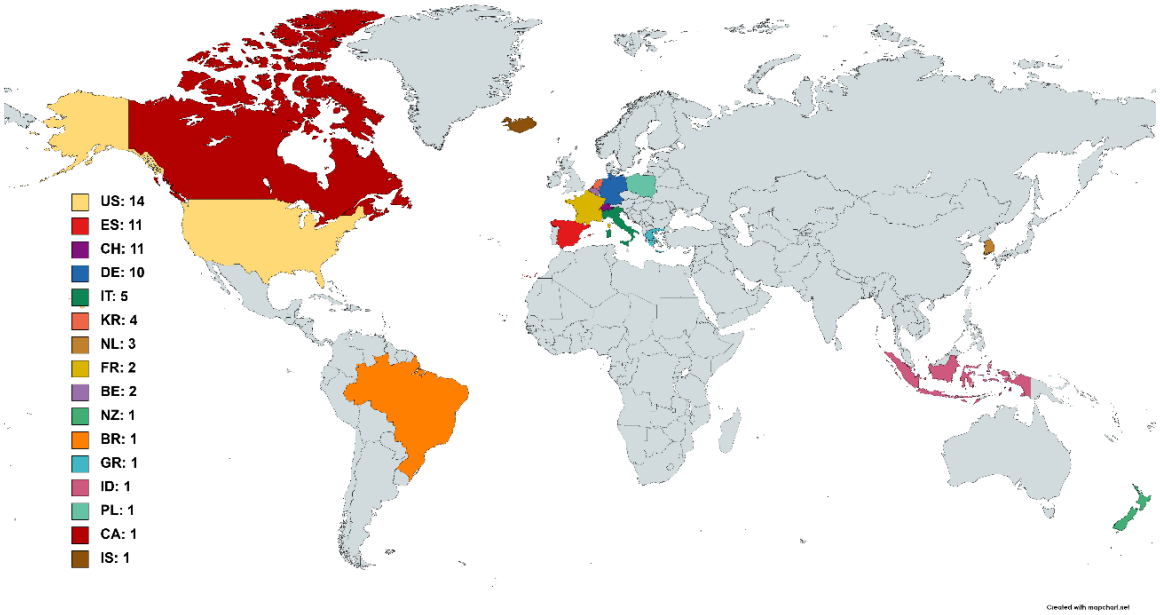


FIGURE 48. Respondents per country of the global validation stage. the acronyms used are United States (US), Spain (ES), Switzerland (CH), Germany (DE), Italy (IT), Korea (KR), Netherlands (NL), France (FR), Belgium (BE), India (IN), New Zealand (NZ), Brazil (BR), Greece (GR), Indonesia (ID), Poland (PL), Canada (CA) and Iceland (IS).

TABLE 21. Usability attributes of the glossary with their proposed definitions and the average ± STD ratings obtained in the global validation. The * indicates the attributes that were evaluated with the survey of the local validation stage whereas the ones marked with º indicate those that were discussed within the focus group. Attributes marked with ** were initially considered for merging due to similarities in their definitions with other UA in the set. However, they were not merged as per the focus group's decision.

Attribute	Proposed definition in the global validation survey	Agreement with the definition	Relevance in the field	Included as design criteria
Accessibility	The quality of being easily obtainable or reachable.	4,00±0,82	3,71±1,21	2,71±1,45
Adaptability	The ability of a system to change in order to suit different conditions.	3,88±1,45	4,13±1,02	3,31±1,35
Aesthetics	The extent to which a system's design is (visually) pleasing to the user.	4,20±0,95	3,45±1,10	2,95±1,15
Autonomy**	The capability of achieving a set goal within a defined scope without human interventions while adapting to operational and environmental conditions.	3,83±0,92	3,56±1,20	2,94±1,47
Cognitive load	The amount of mental effort required to perform a task.	4,06±1,34	4,12±0,78	3,06±1,14
Comfort*º	The extent to which the use of a system does not induce pain, unnecessary constraint or unpleasant feelings.	4,33±0,9	4,75±0,58	4,31±1,01
Compatibility *	The ability to work with other specific systems or environments without problems or conflict.	4,20±0,86	4,00±1,03	3,00±1,46
Complexity	The amount of effort needed to describe or use a system.	3,71±1,10	4,00±1,00	3,56±1,15
Cost-effectiveness	The degree to which something is effective or productive in relation to its cost.	4,00±1,32	3,65±1,06	3,29±1,26
Customizability	The ability to be modified to suit a particular individual, task, or environment.	4,44±1,03	4,13±1,02	3,87±1,19
Desirability*	The degree of how much a product is wanted by a user.	4,27±0,88	3,50±1,21	2,69±1,35
Durability	The ability to withstand wear, pressure, or damage.	4,07±1,00	3,93±1,16	3,53±1,60
Ease of use	The degree to which using a system is free of unnecessary effort.	3,63±1,15	4,33±0,90	4,13±0,99
Effectiveness	The accuracy and completeness with which users achieve specified goals.	4,13±1,15	4,63±0,50	4,44±0,81
Efficiency	The resources used in relation to the results achieved.	4,26±0,99	4,35±0,81	3,95±1,19
Embodiment	The perception of a beign part of the body-image as a feeling of ownership and agency.	4,13±1,15	3,44±0,96	2,50±0,82
Ergonomics	The degree of, or design for kinematic compatibility in a human-robot interface.	3,06±1,53	4,35±1,06	3,76±1,30
Error recovery	The quality of a system to allow the user to exit from a situation that the user did not intend to be in.	4,24±0,83	3,94±1,20	2,63±1,15
Feasibility	The determination as to whether assigned tasks could be accomplished by using the given resources.	4,18±0,88	3,94±1,09	3,53±1,37
Frustration	The feeling of being upset or annoyed as a result of being unable to change or achieve something.	4,35±0,79	3,59±1,12	2,71±1,53
Functionality*º	The extent to which the range of functions offered by a system can be used to perform the intended tasks.	4,12±0,86	4,56±0,70	4,28±0,89
Health benefit	The positive effect on a person's health gained from a system.	4,53±1,01	4,13±1,26	3,44±1,50
Helpfulness**	The ability of providing useful assistance.	3,87±1,3	4,00±1,46	3,56±1,63
Independence**	The ability to perform an activity with no or little help from others.	4,53±0,72	4,28±1,07	3,72±1,53
Intuitiveness*º	The extent to which a system is easy and natural to use, learnable and understandable.	4,15±0,93	4,30±0,80	3,84±0,90
Learnability	The ease and speed with which the users get familiar with the use of a system and retain these skills and knowledge.	4,27±0,88	4,14±0,53	3,79±0,97
Meet user needs*	The extent to which a system fulfills the design criteria given by the target user group.	3,75±1,18	4,63±1,02	4,38±0,96
Mobility*º	The ability to move in one's environment with ease and without restriction.	4,47±0,72	4,44±0,70	4,17±0,71
Motivation	The desire, or enthusiasm to do something (e.g. use a system or complete a task).	4,25±0,85	3,75±0,91	3,11±1,10
Performance	The level of success in completing a task.	4,24±1,03	4,41±0,62	4,35±0,79
Physical workload	The amount and intensity of physical activity required to complete a task.	4,16±1,01	3,70±1,08	3,60±1,05
Pleasure*	A feeling of enjoyment or satisfaction, or something that produces this feeling.	4,00±0,69	2,94±1,30	2,00±1,08
Practicality*	The extent to being suitable for a particular occasion or use, or of being able to provide effective solutions to problems.	3,61±1,20	3,82±0,88	3,41±1,46
Quality of life	An individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.	4,25±1,07	4,10±0,85	3,15±1,14
Reliability*º	The extent to which a system will consistently perform its intended function adequately over time in a specific context of use.	4,40±0,75	4,70±0,73	4,05±1,00
Robustness	The quality of being strong and unlikely to break or fail.	3,95±1,32	4,25±0,97	3,95±0,91
Safety*º	The extent to which the use of a system is free from danger or risk of injury.	4,53±0,51	4,76±0,44	4,53±1,01
Satisfaction	The extent to which the user's physical, cognitive and emotional responses that result from the use of a system meet the user's needs and expectations.	4,16±1,01	4,50±0,69	3,80±1,06
Technical requirements*º	The set of technical design criteria required to deliver a desired function or behavior from a system to satisfy a user's standards and needs.	3,50±1,51	3,13±1,85	3,44±1,50
Temporal demand	The amount of time required to complete a specific task using the system or in setting it up to be used.	4,26±0,99	4,21±0,92	3,55±1,05
Understandability**	The extent to which a system's functions and provided information are comprehensible.	4,15±0,99	3,79±1,08	3,37±1,30
Usefulness*º	The extent to which a system is effective in helping the user to do or achieve something in a practical way.	4,47±0,62	4,76±0,56	4,24±1,03
Wearability*º	The extent to which a WR can be mounted on the body and used without unnecessary movement restriction.	3,88±1,31 3,94±0,97	4,69±0,60 4,59±0,87	4,13±0,96 4,12±1,17

TABLE 22. Number of usability attributes of the glossary within a given range of ratings for each of the three questions included in the global survey. Specific attributes are shown for the lower scores. The thresholds stated in this table will be hereafter referred to as the following categories: high rates ≥ 4.0, moderate rates [3.5 – 4.0), low rates [3.0 – 3.5) and very low rates <3.0.

Rate	≥ 4.0	[3.5 – 4.0)	[3.0 – 3.5)	<3.0
Agreement	32 UA	10 UA	1 UA (Ergonomics)	0 UA
Relevance	27 UA	12 UA	3 UA (Aesthetics> Embodyment> Technical Requirements)	1 UA (Pleasure)
Incl. Design	11 UA	14 UA	10 UA	8 UA

KS tests indicated neither the demographic data nor the ratings followed a normal distribution, as can be confirmed with the skewness and kurtosis values. Poor Spearman rank correlations ($|\rho| < 0.3$) [209] were found between all the ratings and professional data from the respondents. These values are presented in Table 23.

TABLE 23. Spearman rank correlations for all three ratings and professional experience variables. Correlation coefficients are considered very strong ($|\rho| > 0.7$), moderate ($0.7 \leq |\rho| < 0.5$), fair ($0.5 \leq |\rho| \leq 0.3$), or poor ($|\rho| < 0.3$) **[209]**. Moderate correlations are highlighted in bold.

Coefficient (ρ)	**Agreement**	**Relevance**	**Incl. design**
Years of experience	-0.20	-0.05	-0.02
Max. TRL	-0.11	0.03	0.14
Nº usability studies	-0.10	0.11	0.27
Nº users interacted	-0.17	0.04	0.18
Coefficient (ρ)	**Years exp.**	**Max. TRL**	**Nº usability studies**
Years of experience	N/A	**0.51**	0.28
Max. TRL	**0.51**	N/A	**0.54**
Nº usability studies	0.28	**0.54**	N/A
Nº users interacted	0.34	**0.52**	**0.55**
Coefficient (ρ)	**Agreement**	**Relevance**	**Incl. design**
Agreement	N/A	0.26	0.16
Relevance	0.26	N/A	**0.62**

DISCUSSION

The objective of this work was to establish and validate a glossary of usability attributes aimed at improving usability evaluation practices to support the user-centered design of WRD. The established glossary, the RUG, provides a shared and validated terminology that is easily accessible and implementable by developers. To this end, the glossary facilitates the search and selection of context-specific outcome measures and usability research methods within the online IUT of ETH Zurich [207]. The generalizability and validity of the UA definitions comprised in the glossary were supported by the ratings of 70 developers of WRD from 17 countries around the world, who showed high agreement (≥4.0) on 32 of the 43 UA, and moderate agreement (4.0>agreement≥3.5) on other 10 UA. Likewise, developers agreed on the relevance of most of these attributes in the field of WRD, with 27 UA considered as highly relevant (≥4.0) and other 12 as moderately relevant (4.0>relevance≥3.5). Improved definitions for the attributes considered relevant but with moderate or low agreement ratings are also proposed based on the feedback provided by the respondents. All the comments provided by the respondents and the improved definitions are included in Annex 4.

The high agreement ratings for most of the UA included in the glossary underline that, despite the wide interpretation of UA in the literature [98, 201, 202, 203] the definitions are in general adequate and could serve as reference for future studies or for people interested in comprehensive usability evaluation of WRD. It is interesting to highlight that most UA with moderate or high-to-moderate agreement ratings are terms usually found within the field of engineering, e.g. *autonomy*, *complexity*, *robustness*, *technical requirements* and *wearability* [204]. A hypothesis is that most developers possess an engineering background, which may lead them to interpret these terms in alignment with engineering-based definitions. Consequently, when prompted to provide a perspective on these terms from a different field, such as usability, discrepancies may arise. Widening the perspective of research and development teams beyond the engineering requirements is fundamental to promote the development of WRD that are usable and effectively respond to users' needs [52].

A special case is that of *ergonomics*, the only attribute with low agreement but with high relevance. *Ergonomics* is a very wide umbrella term used differently across different fields and, thus, can be understood in different ways. In fact, this was the attribute that received the most comments. Instead of considering it as part of usability, *ergonomics* has long been studied as a separate field of research interacting with usability [210] and there are longstanding international efforts such as the Ergonomics Research Society or the International Ergonomics Association [211], that have stated definitions of the term *ergonomics* that can be adapted to suit specific fields. Consequently, several of the aspects regarding *ergonomics* relate also to usability, including other UA of the glossary such as *comfort* or *wearability*, and therefore, some WRD developers might consider that the whole field of *ergonomics* cannot be synthesized as a single, specific UA. Due to its high relevance, it is crucial to integrate *ergonomics* into the IUT, enabling developers to access the available tools for assessing the *ergonomics* of WRD, even though simplifying the entire field as a UA may be an oversimplification. Based on the feedback provided by the respondents and the definitions stated by the aforementioned organizations, the improved definition for *ergonomics* in the RUG is "the degree to which the interactions among users and elements of a WRD are optimized to increase human well-being and overall system performance including anatomical, anthropometric, physiological and biomechanical characteristics that relate to the intended use of a WRD".

Complementary to the high agreement ratings obtained, the high (27 out of 43) and moderate (12 out of 43) relevance ratings of most UA underscore the multifaceted nature of usability. This observation highlights that usability is not a singular, simplistic concept but rather a complex interplay of various dimensions and attributes [63]. Consequently, to conduct a comprehensive assessment of usability, it becomes evident that multiple attributes of usability must be taken into consideration, highlighting the necessity for a holistic evaluation approach that transcends the prevalent trend in the field. Currently, the field predominantly relies on the use of three dimensions to describe usability (i.e. *effectiveness*, *satisfaction*, and *efficiency*) and usability evaluation is predominantly related to functional or performance-related outcomes [61, 62], followed by the evaluation *ease of use*, *safety* and *comfort* [63, 64], which may overlook the richness of usability. As expected, in the survey, many of the most widespread attributes related to the usability of WRD received very high relevance ratings (≥4.5): *safety*, *usefulness*, *comfort*, *reliability*, *wearability*, *effectiveness*, *functionality*, *meet user needs*, and *satisfaction*. However, *efficiency* received a high but not very high rate, indicating that other attributes are more relevant to the developers than only the three stated by ISO 9241-11. The glossary provided within this study, which deems most UA as relevant, signifies that the UA summarized and validated therein serve as pivotal elements that effectively encapsulate and represent the entirety of usability. A detailed analysis of the individual ratings (see Annex 4) raises the need to debate whether the four attributes with relevance scores below 3.5 should be included in the glossary. *Aesthetics* and *embodiment* have borderline low-to-moderate relevance. Since they have been previously found to be design criteria important for the primary users of WRD under comparable terms such as "appearance" and "avoid

machine body disconnection" [52], respectively, they should be included in the list of UA of the IUT. Both definitions stated for these UA have high agreement, therefore, they do not need improved descriptions but rather more awareness from developers to be included as part of their design criteria, because both have poor scores in this regard. On the other hand, the UA *technical requirements* received a low relevance score and exhibited borderline moderate-to-low agreement among respondents. Comments associated with this attribute suggest that developers do not necessarily perceive it as an integral component of usability but rather believe that *technical requirements* and usability requirements are complementary in technology developments. Considering this valuable feedback, it is prudent to consider removing this attribute from the glossary. On the other hand, *pleasure* stands as the only UA marked with a low relevance score, albeit displaying high agreement in its definition. A detailed examination of the definition provided for this UA shows that it could be closely intertwined with the attribute of *satisfaction*, which holds very high relevance in the field. Hence, it may be reasonable to also consider omitting *pleasure* from the set of UA. Both UA are closely related to two psychology-related codes expressed by end-users of lower limb robotic devices for gait rehabilitation, including "positive feeling of being able to stand up and walk again" and "sense of wellness (physical and/or mental)" [52], underlining their relevance for end-users.

From the remaining 41 attributes, improved definitions were proposed for eight UA considered highly relevant (≥4.0) but with moderate (*adaptability*, *complexity*, *ease of use*, *helpfulness*, *meet user needs*, *robustness*, and *wearability*) or low (*ergonomics*) agreement ratings. In fact, most of these UA were the ones that more respondents commented on: *ergonomics* (10 comments), *adaptability*, *helpfulness*, *wearability*, and *technical requirements* with 4 comments each, and *robustness* and *durability* with 3 comments each. Three of these attributes (*ease of use*, *meet user needs*, and *wearability*) are also often included as design criteria (ratings ≥4.0), underpinning the importance of providing definitions that are agreed upon by developers in the field.

Moreover, a detailed analysis of the boxplots in Figure 47 and the summary of the ratings in Table 22, show that while most of the attributes of the glossary are considered relevant in the field of WRD and that there is a high agreement with their proposed definitions, they have not been often included as design criteria in previous developments [63]. This can be confirmed by comparing the respondents' years of experience in the field (mdn=7) and the number of dedicated usability studies performed (mdn=2). Therefore, this study underlines that usability is still poorly considered as part of the design criteria during device development, even if developers recognize its relevance. Actually, 10 respondents (17.14%) indicated that they had not performed any dedicated usability study in their career and two respondents (2.86%) reported they had never had contact with end-users of their devices. There must be a paradigm shift in WRD development towards implementing user-centered design to properly address users' needs during device developments [55, 57, 56], since it is unlikely that developments done without both involving users [99] and considering usability issues will be successful in reaching end-users [21, 58, 59].

It is worth noting that the highest correlation among all the studied combinations was found between the ratings of "relevance in the field" and "previously included as design criteria in technology developments" (moderate correlation, ρ=0.62, p-value≈0.00). This could be explained by the fact that developers may only include as design criteria the attributes that they consider relevant and overlook the ones that they do not consider important. In fact, the eight UA seldomly included as design criteria (ratings <3.00) are not considered highly relevant in the field (relevance <4.0). These are *accessibility*, *aesthetics*, *autonomy*, *desirability*, *embodiment*, *error recovery*, *frustration*, and *pleasure*. All of these UA exhibit high or moderate (only in the case of *autonomy*) agreement in their respective definitions. Therefore, their infrequent inclusion as design criteria, despite their moderate relevance scores, cannot be attributed to having ambiguous definitions. Instead, this pattern illustrates that some UA are potentially less relevant in specific application cases of WRD or could arise from a potential lack of awareness regarding their

significance from the perspective of end-users. It's important to note that all the listed UA originally emerged as design criteria demanded by primary or secondary end-users in a prior study on lower limb WRD [52].

A moderate correlation between the professional experience related to the "number of dedicated usability studies performed" and the "number of users personally interacted" was found (ρ=0.55, p-value≈0.00). This can be easily understood because the more usability studies performed, the more users are involved in these studies. Similarly, more users must be involved in usability evaluation as technology becomes more mature, which explains the positive correlation between higher TRLs and both the "number of usability studies performed" (ρ=0.54, p-value≈0.00) and "number of users personally interacted" (ρ=0.52, p-value≈0.00). In this regard, results show that the peak values for both user involvement and usability studies are in late TRLs (i.e. 6, 8 and 9), corresponding to the stages of prototypes validated and product. Similar results were found in a previous study [63], highlighting the relevance of user involvement to develop technologies that go beyond the prototype phase and successfully reach end-users [60].

Previous efforts to define usability in WRD [201, 202] contained 17 attributes each and agreed on seven of them. Nonetheless, some of them are related to services that must be provided by the distributors of the WRD or are entirely device centered. Moreover, in contrast to this work, none of these models validated the attributes and their definition within the local or global community of WRD developers, limiting the diffusion, impact, and generalizability of the proposed glossaries. Therefore, their selection of terms for what is considered usability was arbitrary, and some of the proposed definitions are not specifically related to usability. The RUG comprises all the UA included in previous efforts and provides definitions specifically related to usability, including the four UA included in the COST action dictionary and the factors and subfactors in the EXPERIENCE questionnaire from Eurobench [204, 205]. The detailed comparison between these previous works in the field and the attributes of the RUG that encompass their definitions are presented in Annex 5.

Therefore, the RUG is the most comprehensive set of UA available in the field of WRD to evaluate usability and has been externally assessed and improved by developers from most of the active countries working in the field of WRD, thus enhancing its generalizability. It can be readily accessed through the IUT website (www.usabilitytoolbox.ch), enabling developers to have immediate open access to the definitions of each UA and to identify context-specific outcome measures and usability evaluation methods related to each attribute. Three examples are presented in Table 24. The results of this study do not aim to point to specific attributes as being more important than others, but rather underline that all attributes should ideally be considered for a holistic usability evaluation. Despite the glossary being built entirely in English, it was mostly agreed upon by both native and non-native English speakers. In fact, all the definitions within the glossary are not aimed exclusively at the field of WRD but were rather built from a usability perspective. This means that they could possibly be useful to be implemented in other fields related to wearables, robotics, and health technologies overall. In case such interest arises, it is recommended to engage developers from each specialized field to evaluate the significance of the attributes included in the RUG and the appropriateness of the proposed definitions within their respective domains. This evaluation is advised before directly implementing the current glossary.

TABLE 24. Examples of measurement tools selected using the IUT to evaluate specific usability attributes of three different WRD for different target users: an upper limb WRD for amputated children, an augmentation lower limb WRD for adults, and a lower limb WRD for gait rehabilitation of post-stroke adults.

Upper limb WRD for amputated children	Augmentation lower limb WRD for adults	Lower limb WRD for stroke therapy of adult population
COMFORT	EFFECTIVENESS	EFFECTIVENESS
• Assistive Technology Device Predisposition Assessment (ATD-PA) • Michigan Hand Outcomes Questionnaire • Product Emotion Measurement Tool • Visual Analog Scale • Evaluation grid • Numeric Rating Scale	• Kinetic and kinematic analysis • Physiological measures • Task analysis	• Kinetic and kinematic analysis • Physiological measures • Task analysis • Fugl-Meyer Assessment • Foot and Ankle Ability Measures • Mini Balance Evaluation Systems Test • Short Physical Performance Battery
DURABILITY	EFFICIENCY	EFFICIENCY
• Visual Analogue Scale • 3D models and simulations • Evaluation grid • Failure Mode and Effect Analysis	• Subjective Workload Assessment Technique • Time for Task • Task Analysis • Perlman's Practical Heuristics for Usability Evaluation	• Subjective Workload Assessment Technique • Time for Task • Task Analysis • Perlman's Practical Heuristics for Usability Evaluation
FUNCTIONALITY	SATISFACTION	SATISFACTION
• Canadian Occupational Performance Measure • Children Amputee Prosthetics Projects - Prosthesis Satisfaction Inventory • Assistive Technology Device Predisposition Assessment • Upper Extremity Function Test • Action Research Arm Test • Physiological measures • Kinetic and/or kinematic analysis • Evaluation grid • Accessible Usability Scale • Box and block test • Hand-held dynamometer	• System Usability Scale • Self-Assessment Manikin • Net Promoter Score	• System Usability Scale • Self-Assessment Manikin • Net Promoter Score • Short Form-36 Health Survey Questionnaire • Utrecht Scale for Evaluation of Rehabilitation-Participation • Stroke Specific Quality of Life Scale

LIMITATIONS AND FUTURE WORK

The estimated target sample size of the global validation stage was not fully met. Nevertheless, in line with the previous online survey experience of the research team [63], all measures to reach the largest possible sample were taken. The survey was widely shared through several channels (e.g. social media, conferences, email lists, research centers and companies, the IUT website, and Exoskeleton Report) to reach WRD developers from different countries and from both academia and industry. Additionally, the data collection period was extended until there was no increase in the responses gathered. To increase the completion rate, the survey was designed dividing the glossary into the UA batches to guarantee a reasonable response time (below 10 min.). Nevertheless, this raises an additional limitation to the study, since not all respondents rated all UA, representing a possible confounding variable. The authors gave priority to increasing the number of responses collected, since the main objective of the study was to obtain an external validation of the glossary with the participation of a wide sample of respondents.

Collecting the professional background information of the respondents in the global survey would have enabled us to explore potential correlations between each rating and the respondents' profiles. This is important because some respondents may have a technical development-oriented perspective, while others might have professional backgrounds more closely aligned with being end-users of the technologies (e.g. clinicians or people with neurological injuries), thereby reflecting perspectives from real-life scenarios. The current study purposely targeted only technology developers because they are mostly the ones conducting and designing usability evaluations or WRD. Therefore, the aim was to reach a consensus among them. Nevertheless, understanding that there might be differences between end-users and developers regarding the perception and relevance of the usability attributes, it would be interesting to perform another study targeting only end-users. The study would be aimed at comparing

the understanding and relevance of the UA included in the RUG and to check if end-users identify additional usability attributes that ought to be added to the glossary. Such an effort would require a different survey and different distribution channels to the ones used in this work. It is strongly suggested to include a question to identify the background of the respondents in the survey and assess possible differences in their responses. As indicated before, this is an important limitation of this study.

Another limitation of this effort is that the proposed methodology was aimed at reaching an external validation of the glossary but could instead be considered a participative assessment and improvement of the proposed definitions. Therefore, it remains as a somewhat subjective methodology, because the global validation stage was not implemented as a truly iterative process with multiple rounds of evaluation where participants could reach a consensus. Ideally, the global validation could have taken the form of an e-Delphi study [212], but such an approach is highly resource and effort demanding, which might have further limited the participation of developers. The participation of developers from several countries and with different native languages was fundamental to making the glossary generalizable, understandable, and representative to developers from all continents. For developers interested in translating the RUG to other languages, such translation ought to be performed carefully by native speakers with knowledge of the field, to make sure the specificity of the terms is preserved.

Lastly, it might be worth to regularly updating the RUG based on the potential emergence of new disruptive technologies, because WRD is still a developing field. Doing it is important to assess if new attributes are needed when such devices appear in the field. A new survey can be carried out to this end. If performed, it is strongly suggested also considering the application(s) of the WRD with whom respondents have experience. This is important because the relevance of certain usability attributes can depend on the application of a given WRD, as discussed before. Alternatively, any other type of global coordinated effort between leading organizations in the field or WRD can lead to an updated version of the RUG when considered necessary by the demands of the people working in the field.

CONCLUSIONS

The RUG provides a comprehensive set of UA in the field of WRD to evaluate usability. The generalizability and relevance of these UA were supported by the ratings of 70 developers of WRD from 17 countries around the world. These results signify that the UA summarized and validated in the RUG serve as pivotal elements that effectively encapsulate and represent the entirety of usability. To conduct a comprehensive assessment of usability, multiple attributes of usability must be taken into consideration, in contrast to the prevalent trend in the field. This study underlines that usability is still poorly considered part of the design criteria during device development, even if developers recognize its relevance. In this regard, there seems to be a lack of awareness regarding the significance from the perspective of end-users of some UA considered moderately relevant but seldom included during device development.

Overall, this effort is aimed at improving usability evaluation practices during the development of WRD by providing a shared and validated terminology that is easily accessible and implementable by developers, and that can lead to the definition of benchmarks for usability evaluation to promote the acceptance of WRD.

4. RESULTS AND DISCUSSION

WRD for gait rehabilitation address important limitations to effectively fulfill the requirements of end-users within the intended contexts of use. After more than 20 years of remarkable technological advances in the field that have led to six (6) devices CE marked, and at least four times more devices in different development stages [21], users interviewed in chapter 3.1 unanimously agreed on the limited accessibility and availability of lower limb exoskeletons for gait rehabilitation, demonstrating the limited number of devices that have successfully reached end users when compared to the demand for exoskeletons. These users also consider that these devices are still under development, suggesting an increase in funding for their development, as reported. But why is it that at least 30 years of research, funding and dozens of developments aimed at the same goals have not provided at least a couple of devices that are not perceived by users as "still under development"? The data obtained in chapter 3.1 and the findings reported in the literature indicate that a key factor that is still hindering the success of these technologies is the limited user acceptance [21] because the demands of the users are yet to be met [55, 57, 56].

There is increasing interest shown by developers and researchers in the field in understanding user perception and experience with lower-limb wearable exoskeletons, as seen by a steep increment in studies published in 2020 regarding the topic (see Figure 4). The state-of-the-art of WRD for gait rehabilitation highlights the limited evaluation of user satisfaction with WRD [70, 54] and the need to improve the usability of the devices [21]. A possible cause, in line with the findings of chapter 3.5, is that not all the research and development teams of these devices involve end-users during their technology developments, as shown in the ratio of years of experience and users approached of the respondents. Even those who do involve them, often focus solely on technical requirements and performance, underestimating the relevance of other dimensions that are relevant for end-users. Currently, the field predominantly relies on the use of three dimensions to describe usability (i.e. *effectiveness*, *satisfaction*, and *efficiency*) and usability evaluation is predominantly related to functional or performance-related outcomes [61, 62], followed by the evaluation *ease of use*, *safety* and *comfort* [63, 64], which may overlook the richness of usability. The intersections between the findings of chapter 3.1 and chapter 3.5 of this thesis support this affirmation. Three UA scored with moderate or low relevance by developers participating in the study presented in chapter 3.5 arose in the study shown in chapter 3.1 as requirements expressed by users, indicating that, developers underestimate the relevance that aspects such as *aesthetics*, *embodiment* and *pleasure* have for technology users. On the contrary, some of the new codes that arose in chapter 3 also correspond to UA included in the RUG scored as relevant by developers. These are related to the usability attributes *mobility* of the WRD and *physical exertion* required by the PT to use them, and to the *adaptability*, *practicality*, *intuitiveness*, and *customizability* of the devices.

Furthermore, the collective agreement of users approached in chapter 3.1 highlighted the urge to involve end-users in the developments of the technologies and to considering their global requirements, this is, implementing a UCD approach. In line with the literature, authors working in the field already insisted on the urge of engaging individuals with neurological injuries in the design of WRD to ensure the development of devices that align with their specific needs. Users may only accept a technology if it is useful for their own purposes. This is paramount because the people with neurological injuries, as the primary users of the devices, are the ones who can tell what they want, what they are willing to use and what they can use depending on their impairments. Similarly, clinicians in charge of the rehabilitation of subjects with neurological injuries are the ones who know the rehabilitation goals that must be pursued and the exercises or activities that are useful to reach them, as well as the limitations of the primary users that must be considered to develop technologies that are feasible to be used. As secondary users of the devices, their experience is fundamental also because they know the daily dynamics of the rehabilitation centers where these WRD are meant to be used, which must be considered to develop strategies for

technology deployments that are realistic to be implemented in the clinical setting. The intergroup agreement percentage of 50.0% between patients and clinicians reported in the study presented in chapter 3.1 indicates that their requirements are complementary, and therefore including both type of users in the design process of these technologies should be considered. As shown in the same chapter, both patients and clinicians agree on the importance of involving both types of users in the design and development of lower limb wearable exoskeletons, and they are motivated and willing to participate in these processes [99, 55]. They are stakeholders of exoskeletons in different ways; thus, both must be taken into account to design technologies that are usable, respond to users' needs and that are feasible to implement in their intended contexts. For most customers (i.e. individuals, hospitals, healthcare systems, or private rehabilitation institutions) the overall experience with a company, and not only the product itself (i.e. the exoskeleton), is fundamental to engage in business [59]. Actually, according to a report published in 2020 [59], 66% of customers expect companies to understand their unique needs and expectations, and healthcare sector is the one in which customers are concerned the most about being the center of the products and services. Understanding this important expectation will be fundamental for developers and companies in the field to develop technologies that are successful in reaching end users and that meet their individual needs along rehabilitation [186].

Hereby, two contributions are comprised within this thesis to provide tools for researchers involved in the field to fill these gaps. Chapter 3.1 provides the most comprehensive study in the field aimed at retrieving design requirements of primary and secondary users of WRD for gait rehabilitation of people with SCI encompassing both data available in the literature and new complimentary requirements arising from the data of the study. The criteria summarized can be useful to guide current developments to make sure the devices created effectively respond to users' needs and expectations and are feasible to be used in their intended contexts. The successful consideration of several of these requirements can be evaluated with the tools provided by the IUT, which provides specific advice for the usability evaluation of WRD devices related to specific UA. Given that there were no specific consensus-based definitions for these UA, these were gathered in the RUG and validated in the study presented in chapter 3.5. Moreover, given the interesting contrasts found between the expectations and requirements of both types of users approached in chapter 3.1, with differences also depending on users' previous experience with these devices, advice is provided to involve clinicians and people with SCI with experience with the technologies to give focused feedback representative of the requirements of their respective group. In this way, involving these experienced users in UCD processes, even if their number is limited, would be efficient and useful for developers.

Furthermore, a major claim of subjects with SCI included in the study of chapter 3.1 is that they need technologies capable of adapt to their specific needs, with most clinicians interviewed agreeing on the need to have technologies that can be adjustable to each individual in rehabilitation settings [186]. As a consequence, there is a trend in the field towards developing technologies that can be personalized. The first challenge in this regard is the technical development of such devices, which comprises modular systems that allow the use of only the modules necessary to assist the specific function(s) required by the individual, and adjustable parameters to allow setting up the assistance required by each individual along the different stages of the ongoing rehabilitation. With such devices available, a strategy to personalize them is required. The study presented in chapter 3.4 proposes a strategy for personalization of a modular NP that can be combined with an WRD based on clinical knowledge, which can be implemented on the fly in the clinical context. The feasibility of the personalization strategy is investigated in a case series of people with SCI and post-stroke survivors with different functional needs, analyzing the assistance provided along with the user acceptance, showcasing the feasibility of the personalization strategy. The metrics introduced in chapter 3.3 were specifically designed for practical applicability during this evaluation process.

The experimental protocol to personalize and evaluate these devices in a real clinical setting is a core contribution for healthcare workers related to the field. For these users, exoskeletons for gait rehabilitation are meant to be a new tool to assist them with physical therapy, exactly like the they expressed in chapter 3.1. Despite some PT expressed fear in being replaced by these technologies, previous experiences with similar robotic technologies (i.e. the Lokomat), can show clinicians that these devices allow to provide intensive rehabilitation reducing the physical burden that PT have in traditional therapy, allowing them to invest more time in observation and evaluation of the progress of patients, as well as in defining better therapy plans for patients [20]. In this regard, an advantage of using WRD for RAGT is their ability to provide objective data related to patient movement using their integrated components and sensors. Such devices provide massive amounts of information that need to be summarized in understandable metrics representing the most important aspects related to gait. Therefore, there is a need to provide these users with metrics that allow for accurate and straightforward analysis of the patient's gait function during RAGT and along the rehabilitation process. These will aid clinicians in making informed decisions to guide the rehabilitation process and to personalize the assistance of the technologies used. The study presented in chapter 3.4 includes an evaluation protocol that can be implemented to this end, the metrics developed in sections 3.3.2 and 3.3.3 can be evaluated during RAGT using the data captured by the WRD.

Similarly, 3DGA, which is the gold-standard to quantify gait impairment and to assist decision-making for clinicians [33, 35, 130, 131] provides a large amount of data [32] that is often both difficult and impractical to be understood by clinicians [33, 34]. Chapters 4 and 5 of this thesis comprises studies conducted to increase the clinical usefulness of the data obtained from 3DGA or sources that allow to capture gait kinematics. An initial study with data acquired through 3DGA was held to explore possible types of patterns of gait that can be grouped among the SCI population. To this end, machine learning techniques for clustering were used (study in section 3.2.1). Other than the extremes of subjects with high and very low impairments, no intrinsic patterns were found through this method. Consequently, an exploration of which parameters allow a better discrimination between gait in SCI compared to a healthy gait pattern and between subjects with different degrees of impairment was conducted. To this extent, machine learning classification algorithms were used for this task (study in section 3.2.2). Spatiotemporal features demonstrated to have more sensibility than kinematics to classify impaired from healthy gait. This can be attributed to the fact that it is at the functional level where the greatest difference is observed between both groups [117, 118]. The improvement of spatiotemporal indicators such as cadence, stride length, and speed are associated with common rehabilitation objectives directly related to gait assessment tests used in clinical practice, such as the TUGT, the 10MWT or the 6MWT. These reflect changes at the physiological level such as improvements in balance, a more efficient use of the energy invested in walking, or reductions in the risk of falling [119, 120, 121]. In everyday life, these indicators are related to factors that affect the quality of life of patients [122].

In fact, the aforementioned tests are the majority of the walking assessments validated in the SCI population and most of them are focused on gait function. On the contrary, there is no metric considering gait kinematics thoroughly validated within this population. With this motivation, chapter 3.3.1 presents the study developed to create the SCI-GDI, an index that comprehensively summarizes gait kinematics preserving particularities and representing the heterogeneity of gait patterns in the adult population with SCI.

As an evolution of the work developed in chapter 3.3.1 and in line with the experience acquired during the experiments developed in chapter 3.4, the reduced SCI-GDI was computed and assessed as an alternative to the SCI-GDI feasible to be measured with simpler systems than photogrammetry. The use of photogrammetry during RAGT is hindered due to the constrained scenario required for these tests, a high rate of marker occlusion and the need to adapt the models to compute kinematics. The identification

of the joint movements removed from the index was based on their intrinsic limitations to be precisely measured, supported with evidence found in the literature, and verified during the mathematical derivation of the reduced SCI-GDI (see chapter 3.3.2). This reduced index proved to be more generalizable than the SCI-GDI, better correlated to other clinical tests validated in SCI, but slightly less sensitive with respect to the WISCI II levels. In this regard, the results of this section show that the kinematics removed from the index (i.e. pelvic movements, hip rotation and foot progression angle) introduce variability to the gait patterns of adults with SCI that are not representative of the population. Improvements in the acquisition protocols to precisely measure them with gold-standard systems or simpler alternatives are needed because hip and pelvic movement is strongly related to an optimal gait in terms of energy expenditure [178].

The metrics developed to represent gait kinematics showed limited correlation with the other clinically meaningful tests, because evaluating only gait kinematics does not consider other factors that relate to gait function (e.g. compensatory movements, technical aids required to walk, independance). Therefore, in line with the holistic approach considered in gait rehabilitation, chapter 3.3.3 proposes a novel comprehensive metric for the assessment of gait function in SCI including three complementary aspects: kinematics, spatiotemporal features and validated functional tests. All the metrics suggested can be assessed during RAGT, so that they can be used to assess the immediate effects of the technology in patients' gait but also their evolution throughout rehabilitation.

During the process of development of the SCI-GDI (see chapter 3.3.1), the limitations of applying the original GDI to adult population with SCI were demonstrated, highlighting the relevance of adapting metrics to functional specificities of different populations through the implementation of transversal methodologies with specific datasets for each population. This is imperative due to the differences in etiology and clinical consequences of each type of neurological injury. For the comprehensive metric, the measurements selected to form the polygon should be adapted for each specific neurological injury. They can be adapted by integrating the clinical knowledge of experts for the selection of appropriate tests and metrics validated and clinically relevant for each population.

In this way, the methodologies proposed in chapter 3.3 to design metrics to comprehensively evaluate gait in SCI end were carefully thought to be adaptable to other neurological injuries, thus being transversally applicable but recognizing the importance of the particularities of each type of injury. The latter is paramount to consider the specificities of specific types of injuries. On this wise, the methodologies presented to obtain the metrics are user centered.

Returning to the experimental protocol of chapter 3.4, it is interesting to highlight that it also aligns with the awareness shown by the users who participated in the study of chapter 3.1 regarding the advantages of combining lower limb exoskeletons with BCI or FES. Hybrid exoskeletons for gait rehabilitation have been explored the last decade due to the potential of adding the benefits of both types of technologies while mitigating their respective challenges [23]. There is little research performed with hybrid technologies and the study conducted in chapter 3.4 led to useful conclusions and learning opportunities for future experiments. For iSCI subjects with mild to high impairment, the hybrid assistance provides mechanical support that provides stability and allows more independent and longer walking training. On the contrary, providing assistance only with FES to the iSCI cases with low impairment demonstrated to be useful, positively appreciated, and desirable. Post-stroke patients with mild to high impairment would largely benefit from the hybrid assistance thanks to the mechanical support provided by the WRD. It allows them to load their paretic limb and thus, improve gait symmetry and reduce compensatory movements of their non-paretic limb. Nevertheless, in these cases, it is necessary to provide more than one training session or to use a hands-free WRD, due to the difficulty in using the paretic upper limb and to the hemineglect caused by the stroke. Researchers can design their protocols with the take-home messages of the experimental execution as well as these conclusions regarding which type of assistance

is effective for subjects with two types of neurological injuries with different degrees of impairment. The protocol and personalization strategy presented are not dependent on time or resource consuming tests, and as such, can be easily applied in rehabilitation centers, as can be seen by the time for task registers collected in the study and the resources used to implement it.

Furthermore, usability evaluation is included in the research protocol, following the findings of chapter 3.1. Several of the design criteria expressed by users are related to usability of rehabilitation technologies, and as such, they are deemed fundamental to increase technology acceptance and success in reaching end users. In consequence, usability evaluation should be part of the protocols for the validation of WRD for gait rehabilitation. Currently, as outlined in chapter 3.5, the evaluation of these technologies is mainly focused on the functional dimension. Therefore, due to the relevance of usability identified in chapter 3.1 and the limited methods to implement usability evaluation of WRD for gait rehabilitation encountered when designing the experimental protocol presented in chapter 3.4, part of this thesis was devoted to improving the Interactive Usability Toolbox (https://www.usabilitytoolbox.ch/), a tool developed to promote usability evaluation of WRD. This platform seeks to aid developers and researchers in the field in including usability evaluation during their developments. It allows to identify methods to evaluate specific attributes of usability for context specific WRD. Features were implemented in the platform to improve user experience and enrich the suggestions of the platform by developing a system to allow developers to include the methodologies they have used for usability evaluation. In addition, the study presented in chapter 3.4 was aimed at defining the scope of usability within the field of WRD and at reaching consensus-based definitions for the usability attributes identified. These are comprised in the RUG, developed and validated by developers from different countries. In the bigger picture, the RUG is aimed at pushing the creation of benchmarks for usability evaluation that allow to further promote usability evaluation in the field of WRD. As a practical example, the IUT could be used to create the usability evaluation part of the protocol presented in chapter 3.4 by selecting the context of the technology –a lower limb WRD in prototype phase for therapy of adults with a SCI and post-stroke survivors– and the usability attributes to evaluate. Being a pilot study to validate a tailorable hybrid WRD, attributes such as *safety, customizability, compatibility, effectiveness* and *feasibility* would be prioritized. Among the suggested methods to evaluate usability, quantitative rapid-to-assess alternatives would be selected to prevent further lengthening of an already extended session, and at least a qualitative approach would be included to gather insights from the users that could guide the subsequent iterative improvements of the device tested. The quantitative measurements can be compared along these iterations to assess if the modifications are serving their purpose or not. They can also be useful to objectively compare the device tested with other alternatives addressing the same need in an equivalent context.

On the whole, this thesis provides 1) design criteria and advice to developers and researchers to improve the design of the devices through UCD, 2) a strategy to personalize hybrid WRD for gait assistance for clinicians working in the field together with an experimental protocol for personalized assistance with such devices, which can also be useful for researches in the field, 3) a tool for the latter to aid them in implementing usability evaluation in their developments, and 4) methods for researchers and clinicians to comprehensively assess gait in neurological injuries, with metrics specifically developed for adult population with SCI. All these efforts are focused on subjects with neurological injuries, considering them the center of the development of hybrid WRD for gait rehabilitation. They are solely aimed at improving the acceptability, efficacy, and accessibility of these devices through the implementation of UCD. The tools and conclusions presented in this thesis are meant to be applicable by researchers, developers and clinicians working in the field to increase the success of the technologies in reaching their end users in their intended contexts of use, ultimately improving their gait rehabilitation and thus, hopefully, their quality of life.

5. CONCLUSIONS AND FUTURE WORK

This chapter presents the main conclusions and future work of the thesis. A summary of the contributions of the thesis to the state of the art is also outlined. Detailed conclusions and future work of the specific studies presented in chapter 3 can be found in their corresponding sections.

a. CONCLUSIONS

1. A comprehensive framework to implement a UCD approach to design, develop and evaluate personalized hybrid WR for gait rehabilitation is provided, including 1) user-centered design criteria, 2) a protocol to personalize hybrid WRD for gait assistance, 3) a tool to implement usability evaluation of WRD, and 4) methods to comprehensively assess gait in neurological injuries, specifically developed for SCI.

With regards to the requirements for design WRD:

2. The comprehensive set of requirements of users of lower limb wearable exoskeletons for gait rehabilitation partially aligns with the ones described previously; new criteria emerged from the data collected in the study. People with spinal cord injury and the clinicians in charge of their rehabilitation have complimentary design requirements. The differences in the requirements of inexperienced and experienced primary users highlight a gap between current technological offerings and desired functionalities.
3. Low user involvement during development of WRD for RAGT is evidenced in chapter 3.1 and chapter 3.5. Clinicians and people with SCI with experience with the technologies give focused feedback representative of the requirements of their respective group, therefore, involving experienced users in User-Centered Design processes would be efficient and useful for developers.

With regards to the quantitative evaluation of gait function in SCI:

4. No conclusive relationship was found between the SCI gait independence assessment scale, WISCI II, and the clusters grouped according to kinematic data. On the contrary, a k-nearest neighbor model trained with kinematic and spatiotemporal information collected in 3DGA managed to discriminate the gait of SCI patients from control subjects. Differentiating the variability in the degree of gait impairment within SCI remains a challenge for evaluation metrics.
5. The use of the original GDI in SCI may lead to overestimation of gait function. The SCI-GDI developed in this thesis has better discriminative properties with the WISCI II levels and is more sensitive to larger gait impairment than the GDI, but its sensitivity decreases with less impaired gait function.
6. The reduced SCI-GDI allows to broaden the use of the SCI-GDI to simpler and cheaper technologies than photogrammetry without losing accuracy. It effectively represents gait variability of adults with SCI as does the SCI-GDI and correlates better with other clinical scales validated in SCI.
7. A new easy-to-understand and clinically meaningful metric to comprehensively summarize gait in SCI is provided. It conveys kinematic, spatiotemporal, and functional aspects of gait with tests validated in the population with SCI.

With regards to the personalization of WRD:

8. The personalization strategy provided for configuring technologies and their parameters according to the individual's needs can be applied on the fly in clinical rehabilitation settings using as input traditional clinical assessments and clinical expertise. Personalized assistance proved to be effective for cases with heterogeneous types and degrees of impairment. The use of FES is recommended when effective to generate muscle contraction in subjects with low impairment, due to its wearability and capability to setup to assist specific movements, whereas the use of hybrid assistance is recommended for subjects with moderate to high impairment and for those with marked asymmetry.

With regards to the usability evaluation of WRD:

9. The RUG provides a set of UA to evaluate usability of WRD. The generalizability and relevance of these UA were supported by the ratings of 70 developers of WRD from 17 countries around the world. Multiple of these attributes need to be considered for a comprehensive assessment of usability.
10. Usability in device development lacks emphasis, despite its recognized importance. Integrating usability evaluation into UCD for wearable robots is crucial to align developer perceptions with user needs. Presently, technologies prioritize developer-defined needs over user requirements, highlighting communication and user involvement deficits in UCD. A tool to evaluate usability attributes with specific consensus-based definitions is provided for developers, enabling systematic evaluation and comparison of the usability of different devices with common use contexts.

b. Contributions to the State of the Art

On the whole, this thesis provides 1) design criteria and advice to developers and researchers to improve the design of the devices through UCD (chapter 3.1), 2) a strategy to personalize hybrid WRD for gait assistance for clinicians working in the field together with an experimental protocol for personalized assistance with such devices, which can also be useful for researchers in the field (chapter 3.4), 3) a tool for the latter to aid them in implementing usability evaluation in their developments (chapter 3.5), and 4) methods for researchers and clinicians to comprehensively assess gait in neurological injuries, with metrics specifically developed for adult population with SCI (chapter 3.3).

c. Future Work

With regards to the requirements for design WRD:

1. It would be interesting to hold comparable studies to the one presented in chapter 3.1 in countries with different contexts to evaluate if similar requirements arise and similar agreement rates prevail. It would be of special interest to analyze contrasts between countries with public health systems with respect to those that only rely on private health.
2. There is limited interpretability about the relative relevance of each requirement identified in chapter 3.1 due to the methodology used. Currently, it could be inferred that the more users expressing a requirement, the more important it is, but it is necessary to run a specific study focused on evaluating users' priorities among the comprehensive list of requirements presented in the chapter. For specific technology developments, such a study to identify users' design priorities could be optimal to focus efforts depending on the specific population(s), context of use, and type of technology to be developed.

With regards to the quantitative evaluation of gait function in SCI:

3. Despite being developed to be feasible to compute using the kinematics registered with simpler systems than photogrammetry, it is necessary to develop future studies that assess the concurrent validity of computing the rSCI-GDI with photogrammetry and with other more versatile systems such as IMUs, goniometers, 2-D video-based analysis, among others. This is fundamental due to the differences in accuracy that each of them may have and to the intrinsic registration variability of each specific device. The latter could be affected by instrumentation protocols, the hardware used, the version of the software due to raw data processing, and even environmental aspects.
4. Centers with gait datasets from other neurological injuries than CP and SCI can reproduce the methodology presented in chapters 5.1 and 5.2 to develop injury-specific gait deviation indexes. In case they are interested in performing such endeavor, it is worth exploring mathematically the reduction of the 9 joints originally considered for the GDI to use only the joints considered relevant for each specific population. Adding other joint movements that are considered relevant can also be explored. By doing so, a more generalizable index could be obtained by focusing on

the kinematic movements that characterize the kinematic patterns of each specific population and reducing the variability generated by external factors that are not related to the impairment caused by the injury.

5. Alternative representations of the set of measures identified in the research of chapter 3.3.3 or different metrics from the polygon such as symmetry or perimeter can be explored as prompts to summarize the information it contains. Nonetheless, it is important to preserve a straightforward visual representation of the metric to guarantee its clinical interpretability. A sensitivity validation study of the hexagon is suggested to verify if the metric can accurately detect changes in gait over time and to assess the impact of interventions, treatments, or other factors.

With regards to the personalization of WRD:

6. Regarding the difficulty of post-stroke patients learning to use the WRD after only one session, for future research in the field, it is recommended to involve post-stroke subjects with both left and right hemiparesis, given that, in the case series presented in chapter 3.4, patients who presented a marked left hemineglect were the ones with more difficulty in learning to use the WRD. Evaluating the users' ability to follow instructions and provide clear feedback on the use of the technologies during recruitment would be necessary when adding left-hemisphere stroke to the inclusion criteria to make sure there is no cognitive impairment that would bias the user experience.
7. To count with a fully modular and tailorable hybrid system, it would be ideal to use a modular WRD that allows selecting specific modules to be mounted up and assisting separately each lower limb joint. Using the FES system with such a WRD device and closing the control loop between both devices is ideal for potentiating all the advantages of a fully tailorable hybrid system in gait rehabilitation. Additionally, an ongoing challenge in the field is to optimally calibrate stimulation intensities, given that nociception and stimulation required to reach the motor threshold change between the static positions in which calibration is performed and dynamic walking, when legs are loaded.

With regards to the usability evaluation of WRD:

8. Understanding that there might be differences between end-users and developers regarding the perception and relevance of the usability attributes included in the RUG, it would be interesting to conduct another study targeting only end-users. It would be aimed at comparing the understanding and relevance of the UA and to check if end-users identify additional usability attributes that ought to be added to the glossary. Such an effort would require a different survey and other distribution channels to the ones used in this work. It is strongly suggested to include a question to identify the background of the respondents in the survey and assess possible differences in their responses.
9. For developers interested in translating the RUG to other languages, such translation ought to be performed carefully by native speakers with knowledge of the field, to make sure the specificity of the terms is preserved. When possible, results of usability evaluation studies should be shared using the original RUG so that it is feasible to compare them worldwide, pushing further usability as a core factor in the development of WRD. Besides, it might be worth to regularly updating the RUG based on the potential emergence of new disruptive technologies, because WRD is still a developing field. Doing it is important to assess if new attributes are needed when such devices appear in the field.

6. Scientific Contributions

a. Research Articles

1. (Chapter 3.1) **Herrera-Valenzuela, D.**, Díaz-Peña, L., Redondo-Galán, C., Arroyo, M.J., Cascante-Gutiérrez, L., Gil-Agudo, Á., Moreno, J.C., del-Ama, A.J. "A qualitative study to elicit user requirements for lower limb wearable exoskeletons for gait rehabilitation in spinal cord injury". Journal of NeuroEngineering and Rehabilitation, 20, 138 (2023). https://doi.org/10.1186/s12984-023-01264-y
2. (Chapter 3.3) **Herrera-Valenzuela, DS**; Sinovas-Alonso, I; Moreno, JC; Gil-Agudo, A; del Ama-Espinosa, AJ. "Derivation of the Gait Deviation Index for Spinal Cord Injury". Frontiers in Bioengineering and Biotechnology, 10, (2022). https://doi.org/10.3389/fbioe.2022.874074.
3. (Chapter 3.5) **Herrera-Valenzuela, D**; Meyer, JT; del Ama-Espinosa, AJ; Moreno, JC; Gassert, R; Lambercy, O. "Towards a validated glossary of usability attributes for the evaluation of wearable robotic devices". Journal of NeuroEngineering and Rehabilitation, 21, 30 (2024). https://doi.org/10.1186/s12984-024-01312-1

3.2 Conferences, Seminars and Courses

1. (Chapter 4) Oral contribution in the XII Simposio CEA de Bioingeniería: **Herrera-Valenzuela, DS**; Torrado-Carvajal, A; Moreno, JC; Sinovas-Alonso, I; de los Reyes, A; Gil-Agudo, A; del Ama-Espinosa, AJ. "Exploración del uso de algoritmos de clustering para identificar patrones de marcha en lesión medular: resultados preliminares". XII Simposio CEA de Bioingeniería. Universidad Rey Juan Carlos. 2021. Spain.
2. (Chapter 4) Oral contribution in the XII Congreso Iberoamericano de Tecnologías de Apoyo a la Discapacidad IBERDISCAP 2021: **Herrera-Valenzuela, DS**; Torrado-Carvajal, A; Moreno, JC; Sinovas-Alonso, I; de los Reyes, A; Gil-Agudo, A; del Ama-Espinosa, AJ. "Clasificación de estudios de marcha de pacientes con lesión medular usando k-vecinos más cercanos". XI Congreso Iberoamericano de Tecnologías de Apoyo a la Discapacidad IBERDISCAP 2021. AITADIS. 2021. Spain.
3. (Chapter 3.4) Oral contribution in the XL Congreso Anual de la Sociedad Española de Ingeniería Biomédica (CASEIB 2022): **Herrera-Valenzuela, D**; Gil-Castillo, J; Pina, J; Megía-García, Á; Gil-Agudo, A; Moreno, JC; del Ama, AJ. "Rehabilitación de la marcha asistida por un sistema híbrido personalizable en dos casos de lesión medular incompleta". CASEIB 2022. Sociedad española de ingeniería biomédica. 2022. Spain.
4. (Chapter 3.5) Oral contribution in ExoBerlin 2022: **Herrera-Valenzuela, DS**; Meyer, JT; Moreno, JC; del-Ama, AJ; Lambercy, O. "Benchmarking usability in wearable robotics: Effort towards a shared and applicable terminology". International Exhibition & Conference for Exoskeleton & Human Augmentation Systems - ExoBerlín 2022. ExoBerlin. 2022. Germany.
5. (Full thesis) Speaker at the Second Summer School on Neuroengineering organized in the context of the Horizon 2020 project "BrainTwin: Development of a World-Level Neuroengineering Research Centre by European Twinning" (H2020-WIDESPREAD-2020-5, grant agreement ID: 952378), held online on September 5-9, 2022: **Herrera-Valenzuela, D.** "An experience in the User-centered design of a hybrid wearable robot for spinal cord injury". Second Summer School on Neuroengineering. BrainTwin: Development of a World-Level Neuroengineering Research Centre by European Twinning. 2022. Germany and Rumania [online].
6. (Full thesis) Oral presentation at the course "Experiencias Clínicas con Tecnologías en Neurorrehabilitación", held at the National Hospital for Paraplegics in Toledo, Spain from February 27th to March 3rd, 2023: **Herrera-Valenzuela, D.** "El ciclo de la evaluación al diseño de

tecnologías robóticas para rehabilitación de la marcha". Experiencias Clínicas con Tecnologías en Neurorrehabilitación. AITADIS. 2023. Spain.

7. (Full thesis) Oral presentation at the "II Jornadas Nuevas Realidades de la Ingeniería Biomédica: de la Ingeniería para la Discapacidad a la Imagen Médica", held at Universidad Rey Juan Carlos, on Aptil 20th, 2023: **Herrera-Valenzuela, D.** "El ciclo de la evaluación al diseño de tecnologías robóticas para rehabilitación de la marcha". II Jornadas Nuevas Realidades de la Ingeniería Biomédica: de la Ingeniería para la Discapacidad a la Imagen Médica. Universidad Rey Juan Carlos. 2023. Spain.
8. (Full thesis) Oral presentation at the "I Jornada IDISCAM Comunidades del Instituto de Investigación Sanitaria de Castilla - La Mancha", held on September 27th, 2023: **Herrera-Valenzuela, D.**, Blanco-Coloma, L.; García-González, L.; Torío, S.; Gil-Agudo, Á. "Protocolo de investigación para evaluar robots portables combinados con estimulación espinal transcutánea para rehabilitación de la marcha". I Jornada IDISCAM Comunidades del Instituto de Investigación Sanitaria de Castilla - La Mancha. IDISCAM. 2023. Spain.
9. (Full thesis) Poster at the Summer School on Neurorehabilitation 2023, held on June 11th to 16th, 2023: **Herrera-Valenzuela, D.**, Blanco-Coloma, L.; García-González, L. "A Research Protocol to Evaluate Wearable Robotics for Gait Rehabilitation Combined with Transcutaneous Spinal Cord Stimulation and a Neural-Machine Interface". Summer School on Neurorehabilitation 2023. Spain.

3.3 Teaching Activity

1. (Chapter 3.1) Main advisor of the Bachelor's Thesis of Laura Díaz Peña, entitled "Requerimientos para el diseño de exoesqueletos portables en base al diseño centrado en el usuario". Bachelor in Biomedical Engineering, Escuela Técnica Superior de Ingeniería de Telecomunicación, Universidad Rey Juan Carlos. Dissertation date: July 22nd 2022.
2. (Chapter 3.4) Main advisor of the Master's Thesis of Laura Blanco Coloma, entitled "Design of a new approach to register biomechanical gait data, when combining lower limb powered exoskeletons controlled by neural machine interfaces and transcutaneous spinal current stimulation". Master in Neuroengineering and Rehabilitation, Universitat Politècnica de Catalunya. Dissertation date: May 15th 2023.
3. (Chapters 3 and 6) Main advisor of the undergraduate curricular internship of two students of biomedical engineering at Universidad Rey Juan Carlos.
4. (Chapter 3.4) Main advisor of the master's curricular internship of a student enrolled in the Master in Neuroengineering and Rehabilitation at Universitat Politècnica de Catalunya.

3.4 Research Internship

1. 3-month research internship at the Rehabilitation Engineering Laboratory (RELab) in ETH Zurich.

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