A GENERALIZABLE METHODOLOGY FOR STABILITY ASSESSMENT OF WALKING AID USERS

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Abbreviations

Ad_1, Ad_2	Autocorrelation coefficients
ADL	Activity of Daily Living
AP	Anteroposterior
BMI	Body Mass Index
BoS	Base of Support
BoS_{PW}	Pick-up Walker Base of Support
BoS_{system}	combined (system = user + device) Base of Support
BoS_{User}	User's Base of Support
BW	Body Weight
CoP	Centre of pressure
CoP_{PW}	Pick-up Walker Centre of Pressure
CoP_{system}	combined (system = user + device) Centre of Pressure
CoP_{User}	User's Centre of Pressure
DL	Device Loading
FCI	Functional Comorbidity Index
FWW	Front Wheeled Walker
GRF	Ground Reaction Force(s)
IMU	Inertial Measurement Unit

LO	Lift-Off
ML	Mediolateral
MS	Multiple Sclerosis
PW	Pick-up Walker
PW1, PW2, …PW5	Pick-up Walker user 1, 2, …, 5
PWYA	Young Adult using a Pick-up Walker
R1, R2, …, R10	Rollator user 1, 2, …, 10
RMS	Root Mean Square
RYA	Young Adult using a rollator
S	Symmetry
SD	Standard Deviation
SM	combined (system = user + device) normalised Stability Margin
SM_p	Projected combined (system = user + device) Stability Margin
SM_{rate}	Rate of change of the combined (system = user + device) Stability Margin
SM_{system}	combined (system = user + device) Stability Margin
ST	Step Time
SUE	Simulated Urban Environment
SWAS	Salford Walking Aid System

TD	Touch-Down
WA	Walking Aid
YA	Young Adult
ZMP	Zero Moment Point

Abstract

Walking aids (WAs) aim to improve stability and are used by up to 50% of older Europeans. Paradoxically, their use has been linked to a 2-3-fold increase in the risk of falling. The reasons of this association are unknown, indeed WA use remains poorly understood as clinicians have no objective assessment method to identify how stable a person is with a particular WA. This gap in the knowledge base justifies further research into what constitutes stable/safe use of WAs.

This PhD presents the development and demonstration of a novel approach to the assessment of stability of WA users. The approach used introduces the concept of the combined Stability Margin, which considers the user and their walking aid as a single combined system and provides an indication of how close the system is to "tipping-over" and, hence, falling. To calculate the combined Stability Margin, the Salford Walking Aid System (SWAS) was developed, which comprises force sensors (one in each WA leg), two pressure-sensing insoles, infrared cameras, and custom-written software. The approach was implemented for three different WAs: a pick-up Zimmer frame, a rollator, and, towards the end of the PhD, a front-wheeled Zimmer frame.

The SWAS allow for investigation of the combined Stability Margin in relation to key factors such as movement patterns, activity type, device loading, and environment. Results show that stability is reduced during performance of complex tasks such as turning or stepping up a kerb as compared to straight line walking and that the strategy used to perform a given task also affects stability.

Furthermore, the combined Stability Margin depends on user-specific factors such as the amount of body weight transferred onto the device, suggesting that absolute values of the combined Stability Margin may not provide a comprehensive measure of stability. Hence, additional analyses are undertaken to explore how the combined Stability Margin can be used to distinguish between more and less stable users and inform on the most appropriate type of walking aid for a given user.

Longer term, this research provides the foundations for future prospective falls studies, focusing on the role of walking aids in falls and provides a basis for more informed WA prescription and user training.

1 Introduction

1.1 PhD rationale and overarching objective

Falls in older adults are a major global health problem due to their incidence, severity of consequences and associated costs. Indeed, more than 30% of older adults fall every year, and the percentage rises up to 50% for those aged 75 and over and those placed in permanent care (Tinetti, Speechley et al. 1988, Rubenstein and Josephson 2002, Organization 2007). As a result, those who have fallen, often suffer from serious consequences such as depressive syndromes and fear of falling (Tinetti, Mendes de Leon et al. 1994, Vellas, Wayne et al. 1997, Bloem, Steijns et al. 2003), loss of independence (Age UK 2011), hip and head fracture (Campbell, Borrie et al. 1990, Poór, Atkinson et al. 1995, Bloem, Steijns et al. 2003, Lisk and Yeong 2014), and even death (Barry, Galvin et al. 2014). Moreover, falls result in high medical and socioeconomic costs, which make them not only a threat to the health and quality of life of older adults, but also a matter of great concern for the government and society. For instance, it was estimated that, in 2013, the total cost to the UK Government of falls in the population aged over 60 was over £2.3 billions (NICE 2013).

Walking aids are designed to provide structural support for improved stability, to help their users remain mobile and independent as long as possible and reduce their falls-risk. Hence, older adults considered at increased risk of falling are often advised by their clinicians, family, and/or friends to use walking aids: to date, up to 50% of older people in Europe use some type of walking aid (Lofqvist, Nygren et al. 2005). However, rather counter-intuitively, walking aid use has been

associated with a 2-3 fold increased falls-risk (Deandrea, Lucenteforte et al. 2010), which is both surprising and extremely concerning considering the high prevalence of walking aid users among the oldest and most frail adults of the population.

The exact reasons underlying this association are unknown as walking aid use as a mean of fall prevention remains an under-researched area. Specifically, there are three major gaps in the current knowledge base, each of which need addressing in order to improve the effectiveness of walking aids.

First, the current understanding of walking aid use is very limited. For example, previous research in the area has characterised use of a walking aid as a simple "yes/no" based on either self-report or whether the person has been seen with one by a clinical professional during an appointment (Van der Esch, Heijmans et al. 2003, Hefflin, Gross et al. 2004, Andersen, Roos et al. 2007, Stevens, Thomas et al. 2009). Clearly, these approaches are extremely crude providing no details on when or where the device is used, nor for which activities. Patterns of WA use are highly likely to be very complex and influenced by both context and individual circumstances, (e.g., the user might or might not use their device to walk to the toilet during the night). Moreover, exactly *how* walking aids are used is also unknown, e.g., whether guidance (where provided) from clinicians on how to use a WA safely is adhered to.

Second, and partly a consequence of walking aid use being ill-defined, there is no understanding of the link (if any) between falls and walking aid use. Indeed, with many older adults denying having fallen (Campbell, Borrie et al. 1990) or being unable to recall how the fall happened (Stevens, Thomas et al. 2009), it has not yet been established whether walking aids were being used at the time of the fall,

and, if so, how (e.g. was the walking aid being used according to guidance? Did the fall result from a collision between the device and the surrounding environment or between the user and the device?).

Finally, clinicians have no objective way of quantifying stability of walking aid users other than their personal experience and they rely heavily on visual observation. Even though it has been reported that most falls occur during walking (Berg, Alessio et al. 1997), and that the oldest old, who are the most likely to fall and suffer from severe injuries (Tinetti, Speechley et al. 1988, Rubenstein and Josephson 2002, DH/SC 2009), (Scuffham, Chaplin et al. 2003), are also the most likely to use walking aids (Lofqvist, Nygren et al. 2005), research in the field of walking stability has focused almost entirely on unassisted walking; to date, no gold standard outcome measure of stability exists which adequately considers the user *and* their walking aid. Yet, we argue that to appropriately define "correct" and "incorrect" use of walking aids, usage patterns must first be assessed in relation to stability. Furthermore, quantification of stability may provide much needed insights into underlying mechanisms of the reported falls-risk of walking aid users. Hence, the aim of this PhD is to develop a novel, objective outcome measure of stability which can be used to narrow the following research question: "**What constitutes stable walking aid use?**".

Findings from this work have the potential to inform walking aid prescription and user training, and may therefore contribute to one of the key priorities for the devolved Greater Manchester Health and Social Care organisation: reducing the incidence of falls in older adults.

1.2 Thesis structure

This thesis includes 7 chapters.

Chapter 2 provides a comprehensive and critical review of the relevant existing literature; it aims to highlight the gap in the current knowledge base, leading into the overall objective of this PhD, and corresponding research questions, which, when answered individually, contribute to meeting the overall objective and narrowing the gap in the literature.

Chapter 3 describes the development of a novel, objective methodology for the assessment of walking aid user stability which is generalizable to different types of walking aids; specifically, it introduces the concept of the combined Stability Margin, which considers the user and their walking aid as a single combined system. It subsequently discusses the development of corresponding technology required to obtain the necessary measurements for the calculation of the combined Stability Margin, and establishes proof-of-concept for the example of a pick-up walker, highlighting why this approach is advantageous compared to previous methods which looked at either the user or the device alone. Finally, Chapter 3 demonstrates the application of the proposed methodology in one healthy young adult and one older user of a pick-up walker.

Chapter 4 presents the design, development, and validation phases of an instrumented rollator to be used to assess stability of rollator users. The objective of this chapter is to explain the design choices and selected instrumentation, to the degree of accuracy that can be considered fit for purpose (i.e., the suitability of the newly instrumented rollator to serve as a stability assessment tool).

Chapter 5 demonstrates the application of the general methodology and instrumented rollator developed in the previous chapters in a cohort of rollator users and aims to investigate how 1) the type of walking task 2) the amount of body weight supported by the walking aid, and 3) the strategy used to perform a particular task affect users' stability.

As it was observed in Chapter 5 that the Stability Margin is influenced by user-specific factors and, for this reason, may not provide a comprehensive measure of stability, Chapter 6 extends the work undertaken in previous chapters to investigate different approaches to interpreting the Stability Margin data. The approaches are evaluated on the basis of their ability to distinguish between more and less stable users (as judged using gait speed and visual observation).

Chapter 7 brings together all the outcome measures and analysis techniques introduced during this PhD in a final case study, and aims to explore how the type of device used and how the environment affect stability of the user-device system. For this, one participant who regularly uses 2 types of walking aids (a pick-up walker and a front wheeled walker) was tested in 2 different environments (a lab, which simulates the open space of a clinic, and a home environment).

Chapter 8 concludes the thesis as it summarises the novelty, key findings, and impact of the work undertaken during this PhD. It further discusses some of the issues encountered along the way and elaborates on the limitations of the work. Finally, it concludes with a recommendation for future research, to overcome limitations and progress towards the long-term aim of improving fall-prevention in users of walking aids.

2 Literature review

2.1 Falls literature

2.1.1 Prevalence, consequences, & associated costs of falls

The number of older adults in the world has been rapidly increasing during the last few decades and this ageing of the world population is set to continue in the future: the number of older adults has been estimated to increase by 56% in the next 15 years and by 100% by 2050 (United-Nations 2015). Moreover, the “oldest-old” group, comprised of those older than 85 years, is growing even faster and is projected to increase by 61% in the next 15 years (United-Nations 2015). Population estimates for the UK are perfectly in line with these global projections (Large 2015, ONS-Digital 2016).

It is well known that ageing has been associated with several health-related problems, including falls and fall-related injuries. More than 30% of community-dwelling people aged 65 and over fall every year, and the percentage rises up to 40-50% for those aged 75 and over and those placed in care (Tinetti, Speechley et al. 1988, Rubenstein and Josephson 2002, DH/SC 2009). In the United Kingdom as many as 700,000 calls for falls in older adults are reported annually by the ambulance services (which account for approximately 10% of total calls), and over 30% of these result in hospital admissions (Scuffham, Chaplin et al. 2003, DH/SC 2009).

Especially among older people falls lead to serious consequences. About 40% of all injury-related deaths occur due to a fall (Barry, Galvin et al. 2014); moreover, even if most falls do not cause death directly, their occurrence has been associated with significantly reduced survival even beyond the period of injury, especially for those fallers who sustained a severe injury such as head trauma or hip fracture (Campbell, Borrie et al. 1990, Poór, Atkinson et al. 1995, Bloem, Steijns et al. 2003, Lisk and Yeong 2014), which occur in five to ten percent of all falls (Deandrea, Lucenteforte et al. 2010). Indeed, 90% of hip fractures are caused by a fall (Baker and Harvey 1985, Zuckerman 1996). Subsequent to fracturing their hip, patients need complex surgical procedures followed by long and hard rehabilitation programmes, and they often develop delirium which increases the risk of institutionalisation (Schaafsma, Giladi et al. 2003, Ungar, Rafanelli et al. 2013).

Less serious fractures are common too: the number of all fall-related fractures is higher than the number of strokes/TIA and heart attacks and has increased over recent years (Age UK 2011). Furthermore, even without experiencing a physical trauma, those who have fallen are likely to develop depressive syndromes and fear of falling which may lead to reduced activity levels, loss of independency (50% of those who sustained hip fracture can no longer live independently (Age UK 2011)), and an increased risk of being institutionalised (Bloem, Steijns et al. 2003, Ungar, Rafanelli et al. 2013, Barry, Galvin et al. 2014). Recent studies have also established an association between fear of falling, as a negative consequence of previous falls, and abnormal protective responses and stiffening, which may consequently lead to the degeneration of postural control and loss of stability (Bloem, Steijns et al. 2003). In addition, reduced physical activity increases the risk of developing new pathologies and further deterioration of existing ones such as

cardiovascular diseases or osteoporosis, which increases the likelihood of fracturing again.

Interestingly, in agreement with several epidemiology studies which showed that the risk of falling increases with age (Campbell, Borrie et al. 1989, Campbell, Borrie et al. 1990, Deandrea, Lucenteforte et al. 2010), it was calculated that, in 1999, the rate of A&E attendences for fall related injuries of people aged 75 and older was three times higher than for those aged between 60 and 64 (Scuffham, Chaplin et al. 2003). However, the underlying reasons for this finding are unknown; it may be that more people over age 75 fell, or that those of age 75 and over are more likely to get injured, or a combination of both. It is known, however, that only 12.6% of A&E attendees in the age group 60-64 became in-patients in comparison to 39.0% of those in the older age group (Scuffham, Chaplin et al. 2003). One may therefore conclude that, similarly to fall risk, the risk of contracting severe injuries also increases with age.

Furthermore, because of the high medical and socioeconomic costs resulting from falls, falls are not only a threat to the health and quality of life of older adults, but also a matter of great concern for the government and society. It was estimated that the total cost to the UK Government of unintentional falls in the population aged over 60 was over £2.3 billions in 2013, 59% of which were incurred by the National Health Service (NHS) and the remaining 41% covering long term care costs (NICE 2013). The costs of falls are an issue in most developed countries. In 2009, for instance, costs related to falls accounted for the 0.85-1.5% of the total healthcare expenses in the UK, EU, USA, and Australia (Hamacher, Singh et al. 2011), and costs are expected to further rise by a factor of 1.6 in the next 20 years (Barry, Galvin et al. 2014).

Considering the costs of falls to the individual and society, it is not surprising that increasing efforts are being made to identity effective fall prevention strategies. For example, in Europe alone there are currently four EU funded projects focusing on fall prevention in older people, namely ProFouND, E-NO FALLS, the pilot European Innovation Partnership on Active and Healthy Ageing, and ProFaNE (Richardson 2013). However, despite these initiatives, no universally accepted fall prevention strategy exists to date.

2.1.2 Risk factors of falls

Falls are known to have a multifactorial aetiology (Tinetti 2003). Over 400 risk factors for falls have been reported (Hamacher, Singh et al. 2011), and those can be grouped into two categories: extrinsic and intrinsic factors.

Intrinsic factors can be quite complicated to identify. They depend on the person's physical abilities and include age, sex, cognitive impairment, chronic diseases, poor balance, muscle weakness, and gait disorders (Deandrea, Lucenteforte et al. 2010). Moreover, statistics proved that the risk of falling increases with age (Campbell, Borrie et al. 1989, Scuffham, Chaplin et al. 2003, Deandrea, Lucenteforte et al. 2010) and pathological conditions such as visual impairments, arthritis, and history of stroke (Campbell, Borrie et al. 1989).

Extrinsic factors, on the other hand, comprise environmental hazards both indoors (Campbell, Borrie et al. 1990) and outdoors (Li, Keegan et al. 2006, Kamp, Santos et al. 2014), use and number of medications (particularly sedatives, antihypertensives, antiepileptics, and antidepressants (Rubenstein 2006)), and activity-related factors such as dual-tasking (Shumway-Cook, Woollacott et al. 1997, Bloem, Steijns et al. 2003, Hyndman and Ashburn 2004, Bautmans, Jansen

et al. 2011, Baetens, De Kegel et al. 2013). Finally, and the motivation for this dissertation, the use of walking aids has been associated with increased falls-risk: in particular, it has been estimated that falls-risk is 2-3 times higher when using a walking aid (Deandrea, Lucenteforte et al. 2010). This association is surprising, considering that walking aids are designed to provide structural support for enhanced mobility and stability. Research yet needs to investigate possible reasons for this paradox.

2.2 Walking aids

This section is concerned with walking aids such as walking sticks, crutches, and walking frames (with and without wheels), which provide structural support and thereby assist a person to walk. Walking aids are also often referred to as “ambulatory assistive devices”, “mobility aids” or “mobility devices”, but walking aid will be used throughout this thesis to include all related work.

The main purpose of walking aids is to provide structural support for improved stability and mobility, to enable their user to better perform the principal activities of daily living, enhance independence and engagement with society, and consequently to postpone admission to a care home or hospital. This is achieved through the “legs” of walking aids providing additional contact points with the ground, thereby increasing the base of support “BoS” which is the area outlined by the feet in contact with the ground (Figure 2.1). In general, the larger the BoS is, the easier it is to maintain the vertical projection of one’s centre of mass “CoM” (the point where the entire mass of the body is concentrated) within the boundaries of the BoS, and in standing balance this is associated with good stability. Today, a wide range of walking aids are commercially available to meet different user needs

and preferences. This section discusses types of walking aids available and their prescription, as well as benefits and problems associated with their use.

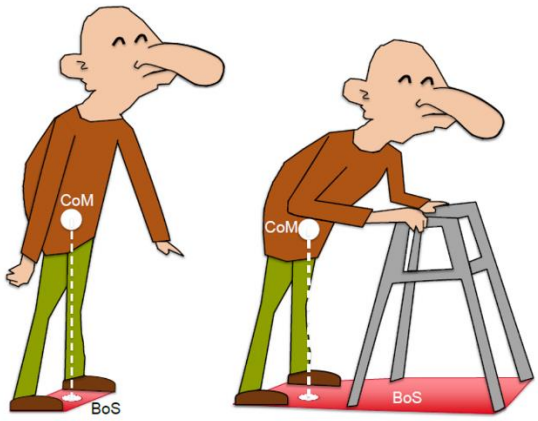


Figure 2.1: Base of support "BoS" shaded in red and vertical projection of the centre of mass "CoM" (dashed line) without and with an ambulatory assistive device.

2.2.1 Types of walking aids and their prevalence

In those of age 75-89, 12-25% use a walking aid indoors, exact numbers pending on the country of origin (Foley, Prax et al. 1996, Lofqvist, Nygren et al. 2007, Cetin, Muzembo et al. 2010). For walking outdoors, percentages of users have been reported as high as 47%, and over time numbers generally increase in this population, and with changes from less to more structurally supportive walking aids (Lofqvist, Nygren et al. 2005). The different types of walking aids available and their respective prevalence are discussed in the following sections.

2.2.1.1 Walking sticks

Walking sticks, sometimes referred to as 'canes', (Figure 2.2A-D), are used in European countries by 15-28% of community-dwelling adults aged over 75, and are the most common walking aid (Lofqvist, Nygren et al. 2005). In the United States, 10% of those age 65 and over have been reported to use a walking stick (Kaye,

Kang et al. 2000), with the total number of users approximately being 3,200,000. The proportion of users increases to about 27% in those age 85 and above (Kaye, Kang et al. 2000). Walking sticks are easy to use, manoeuvrable, suitable for indoor and outdoor environments, lightweight, and, equally important, socially well accepted (Lam 2007). Different types exist, including standard walking sticks (Figure 2.2A) and offset walking sticks (Figure 2.2B), the latter of which have a curved handle that helps distribute the weight directly over its shaft. Some have three or four feet and those are referred to as tripod (Figure 2.2D) and tetrapod/quadripod walking sticks, respectively. Multiple feet have the advantage that the walking stick can stand on its own, allowing the person to use his or her hands without having to find a stable support to lean the device on, thereby minimizing the chance of tripping and falling.

Figure 2.2: A) Standard walking stick, B) Offset walking stick with curved handle to distribute the weight over the shaft, C) Standard walking stick with an ergonomic Fisher handle, and D) Tripod walking stick with curved handle.

2.2.1.2 Crutches

A European study showed that, depending on country, 0.03% to 4% of those age 75 and older use crutches (Lofqvist, Nygren et al. 2007). In the United States, an

estimated 155,000 people age 65 and over report to use crutches, which is about 0.5% of this age group, and this percentage remains largely unaffected when looking at those age 85 and above (Kaye, Kang et al. 2000). As for walking sticks, there are different types of crutches available for purchase, including forearm, axillary, and platform crutches (Figure 2.3). In addition to the fact that they can be used both indoors and outdoors and can support the user to climb stairs, the main advantage of using these devices is that they can provide 100% weight bearing support if two of them are used, while one crutch is able to provide up to 80% weight bearing support (Joyce and Kirby 1991, Bradley and Hernandez 2011).

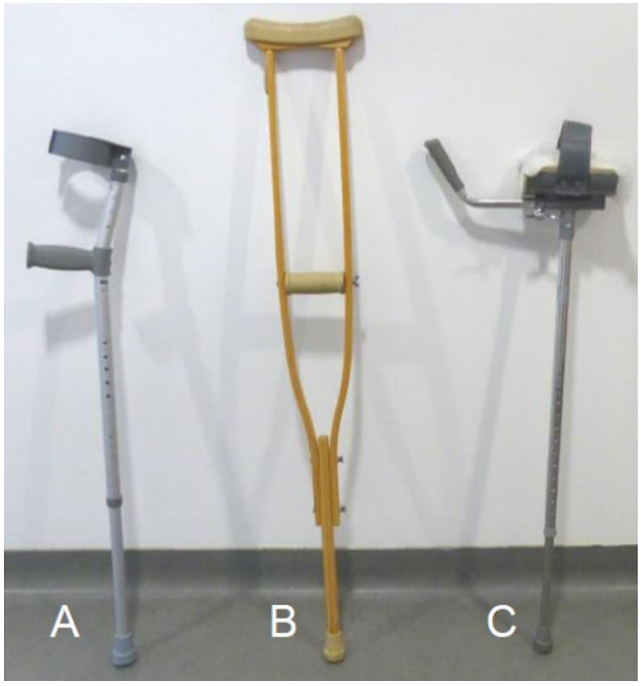


Figure 2.3: A) Forearm crutches, B) Axillary crutches, and C) Platform crutches.

2.2.1.3 Walking frames

Walking frames, also referred to as “walkers”, are increasingly owned by older adults as their age increases: it was estimated that only 2% of people aged under 75 own a walking frame, while up to 9% of those aged 75 and over (Edwards and Jones 1998, Lofqvist, Nygren et al. 2005) have one (with a peak of 26% in Sweden)

(Lofqvist, Nygren et al. 2005). Numbers are similar in the United States where walking frames, being the second most common walking aid after walking sticks, are used by approximately 4.6% of those age 65 and older (total number of users approximately being 1,421,000) (Kaye, Kang et al. 2000). Moreover, as for walking sticks, prevalence of walking frames in the United States increases with age, with approximately 17% of adults aged 85 and over reporting to use a walking frame (Kaye, Kang et al. 2000). In general, through their four, or, less commonly, three legs, walking frames offer a high degree of stability and provide the greatest base of support of all walking aids. As for the other devices described previously, different types can be purchased. Walking frames can be divided into two main categories: pick-up walkers and wheeled walking frames (Figure 2.4A-D). Pick-up walkers have no wheels and must be lifted forward by their user (Figure 2.4A), thereby significantly altering the gait cycle since the user has a prolonged stance phase during which the frame is lifted forward. Those with wheels can have two wheels in the front but none at the rear (front-wheeled walking frames, Figure 2.4B), or may have a total of three or four wheels, with a wheel at the end of each of their legs, and these are also referred to as “rollators” (Figure 2.4C & D). Since pick-up walkers do not have wheels they cannot roll away from their user, hence are providing greater structural support when grounded. Front-wheeled walkers with wheels attached only to the front legs of the frame, have also a reduced risk of rolling away as long as all four legs are on the ground. Pick-up walkers and front-wheeled walking frames are primarily designed for indoor use where it is less likely that their legs without wheels get caught on ground irregularities, whilst rollators with three or four wheels can be used indoors and outdoors and are able to overcome small bumps and cracks in the pavement. Rollators often include a seat, and furthermore

may contain a food tray or a basket for shopping bags and other items. Hand breaks allow the user to stop them from rolling away on slopes or when sitting down on the seat.

Figure 2.4: A) Pick-up Walker, B) Front wheeled walker, C) Three wheeled walker, and D) Four wheeled walker.

It must be noted that the reported prevalence of walking aids somewhat differs between countries and this may in part be due to the fact that walking aids can be purchased without a prescription, making gathering accurate data on ownership extremely difficult. In fact, self-purchase without medical consultation has been reported as high as 80% of the total number of users of rolling frames (Liu 2009). Finally, it is noteworthy that walking aid ownership has shown to be different in men and women: one study showed that in the UK 35% of older men own a walking stick, as compared to 27% of women, yet 1% of older men own a walking frame, as compared to 5% of women (Edwards and Jones 1998).

In summary, a range of walking aids exist, including different types of sticks, crutches and frames, and a generally increased use and use of more supportive devices can be observed over time (Lofqvist, Nygren et al. 2007). Prescription can

support device selection, i.e. matching walking aids to users, and user guidance may facilitate effective usage of the chosen walking aid.

2.2.2 Prescription of walking aids and user guidance

2.2.2.1 Device prescription

Prescription of walking aids is a complex issue: a range of walking aids exist, for diverse groups of users ranging from generally healthy older adults to stroke survivors and older adults with conditions such as dementia, multiple sclerosis, and similar.

Standard walking sticks (Figure 2.2 A) may improve stability in case of a moderate level of impairment such as mild sensory or coordination problems (Bateni and Maki 2005, Bradley and Hernandez 2011), however, they are generally not suitable for patients who need to transfer some of their weight through the walking aid (Bradley and Hernandez 2011). When more body weight support is required, then other types of walking sticks may be preferred. For example, for those who need to occasionally offload their lower limbs to get relief from pain due to knee or hip osteoarthritis, an offset cane (Figure 2.2 B) is considered appropriate (Lam 2007, Bradley and Hernandez 2011) as its handle helps distribute the weight directly over its shaft. Moreover, sticks with multiple feet allow for a wider base of support of the device, therefore providing greater stability to those people who require substantial weight bearing such as hemiplegic patients (Bradley and Hernandez 2011).

Crutches are suitable for patients who are only partially or not at all able to bear weight on one leg, often as a result of an injury, and who need to transfer considerable weight to their arms, generally to an extend above what is possible

with walking sticks. However, since crutches require substantial oxygen consumption and arm and shoulder strength, they are often inappropriate for frail older adults (Bradley and Hernandez 2011).

Perhaps with the exception of rollators, walking frames, and especially pick-up walkers, are predominantly for those that have a severe level of disability (Edwards and Jones 1998). Pick-up walkers (Figure 2.4 A) remain the most appropriate solution for those who need significant structural support when standing and walking. Examples of users include patients recovering from hip replacements or lower limb amputation, and older adults who have lower extremity weakness due to cardiovascular or musculoskeletal impairments (Pardo, Deathe et al. 1993, Pardo, Winter et al. 1993, Tsai, Kirby et al. 2003), severe myopathy, or neuropathy (Bradley and Hernandez 2011) - but who still have enough upper body strength to lift the pick-up walker up and move it forward (weight of which is approximately 2 Kg) before stepping. This movement pattern requires attention and also energy costs, as suggested by the increased heart rate of users compared to unassisted walking and/or wheeled walker use (Foley, Prax et al. 1996, Cetin, Muzembo et al. 2010), and further requires good coordination and balance control whilst the device is airborne: collisions with third objects may perturb the user's postural control, and the device itself may interfere with the user's limbs during balance recovery (Bateni, Heung et al. 2004, Bateni and Maki 2005). Front-wheeled walkers (Figure 2.4B), on the other hand, require that the user lifts the rear legs in time with their stepping, especially when turning (Kloos, Kegelmeyer et al. 2012); however, the reality is that often users let the rear legs slide along the floor (Nekoukar and Erfanian 2013) and this has been implemented in recent clinical guidance documents. Front-wheeled walkers stay steady when their rear legs are on the ground. Such walkers are

therefore appropriate for those who need substantial support but are unable to fully lift a pick-up walker (Bradley and Hernandez 2011). In addition, they are of particular benefit to patients with Parkinson Disease, as they may reduce “freezing” of gait induced by pick-up walkers (Bradley and Hernandez 2011). However, it is important that the user is able to control the distance of the device to their body, to stop it from “rolling away”.

Three or four wheeled walking frames (rollators) (Figure 2.4 C & D) are particularly suitable for those people with reduced balance but who do not need to transfer considerable weight, to have support and gain confidence, and potentially enable them to walk longer distances outdoors. People with respiratory diseases who often need to stop walking to rest are an example of patients for whom a rollator may be suitable (Bradley and Hernandez 2011), especially because most rollators include a seat on which the user may sit when a break is needed. However, rollator use increases attentional demands, especially when negotiating slopes or obstacles such as kerbs: if the brakes are not hit promptly due to a slowed reaction or hand weakness, or if the user does not remember to lock the brakes before sitting, a rollator may cause its owner to fall.

The purpose of all these walking aids is to provide structural support for enhanced mobility and stability when standing and walking throughout the day. Hence it seems logical that at the time of prescription the user’s general physical abilities and, quite critically, walking stability with a given walking aid should be considered, together with personal preferences and needs that, if ignored, may lead to device rejection/disuse. Some guidance is available that aims to support prescription of a single type of walking aid, for example (Lam 2007). Others have drawn up more comprehensive decision diagrams that consider various pathologies and a range of

devices (Van Hook, Demonbreun et al. 2003, Elmamoun and Mulley 2007). However, quantitative validation of any of these proposed guidelines in relation to improved walking stability and reduced falls-risk is lacking. At this time healthcare professionals' approach to prescription of WAs heavily relies on clinical experience and remains unsupported in terms of objective and established outcome measures (Martins, Santos et al. 2015). As a result, the prescription process can vary between different assessors and may, or not, include eyesight, hearing, cognition, grip strength, sitting balance, and leg strength to reach their decision. Moreover, prescription by a clinician is not the most common way of acquiring a WA; a sample of wheeled walker user residents in the US revealed that only 39% of them obtained their walker through a health care professional's prescription, while the remaining 61% based their decision on friends' or family's advice. Another study of rollators reported numbers of self-purchase without medical consultation being as high as 80% of the total number of users (Liu 2009).

2.2.2.2 User guidance

A vast amount of clinical and manufacturer leaflets exists that aim to provide guidance to users of walking aids. Guidance tends to be brief, although leaflets that inform on use of rollators are generally more comprehensive in comparison to those of other walking aids, and this may be due to their more versatile use, especially outdoors. A summary of the most common instructions found in leaflets from clinics and manufacturers is shown in Figure *2.5*, although the level of detail differs between clinical trusts and/or manufacturers.

Whilst these basic instructions appear sensible, they do not address everyday challenges such as avoidance of door frames/furniture or crossing of obstacles such as tree roots. Most importantly, their merit has to date not been validated in relation to user stability. Moreover, 81% of the total number of users, including those who received theirs following prescription, declared to never have received any instruction on how to use it (Liu 2009). At this time it is unknown whether the match between user and device as is presently achieved in clinical practice or through self-purchase, and current user guidance and training, do indeed facilitate frequent, stable device use in the real world. Nevertheless, a range of benefits of walking aids have been reported.

Common User Guidance for Ambulatory Assistive Devices

Walking Stick

- Rubber ferrules, adjustment pins and straightness of the stick are to be checked regularly.
- The height should be adjusted so that the handle of the stick is in line with the user's wrist crease during standing.
- Users are to use it on the opposite side to the weaker leg, if they have an affected side, and to place it slightly to the outside of their stance width to avoid tripping.
- The stick is to be moved at the same time as the opposite leg.
- Two sticks can be used together with the weaker leg, or, alternatively, each in turn with the opposite leg.
- To get up, push up from the chair/bed; hold the stick with one hand or place it on the side.
- To sit down, turn using the stick with one hand until the chair/bed is touching the back of the legs, then reach back with the free hand towards the armrest/bed and gently sit down.
- To go up steps hold the handrail with the free hand, then push on the stick with the other hand and step up with the stronger leg first, then with the weaker leg, and finally move the stick up. Repeat.
- To go down steps, move the stick one level down first, then take weight through the arms when moving the weaker leg, then move the stronger leg. Repeat.

Crutches

- Replace rubber ferrules if worn down.
- During walking keep your arms close to your side and the handles pointing forward. Place both crutches one step forward together with enough space in between them to step into.
- If not allowed to bare weight on one of the legs, slightly flex the knee, keeping the leg slightly behind or in front. Place both crutches forward together, then lean through the arms when hopping on the weight-baring leg up to the same level as the crutches.
- If allowed to bare some weight, place both crutches forward together, then step the affected leg up to just behind the crutches. Next lean through the arms and step with the intact leg forward to just beyond the crutches.

(Crutches continued)

- If allowed to bare full weight, stand on both feet when moving the crutches forward, then move the affected leg to just behind the crutches and the intact leg to just beyond the crutches. Try to fully stand on the affected leg whilst the intact leg is off the ground. Use crutches to support the limb.
- For standing up/sitting down take arms out of crutches and hold them in one hand.
- When sitting down, feel the furniture at the back of the legs and reach back to the armrest/bed with one hand whilst holding the crutches in the other hand, then gently sit down.
- To turn, step in a circle rather than turning on the spot.
- Use a banister or rail in one hand and a crutch in the other hand when walking stairs; the extra crutch may also be carried in this hand. Walk up with the sequence "good leg, bad leg, crutch"; walk down with the sequence "crutch, bad leg, good leg". If a handrail is not available use both crutches.

Pick-up Walker

- Regularly check for bent tubes, worn ferrules, and loose screws, pins, and handles.
- The width of the frame should be chosen based on the user's natural stance width.
- The handles of the frame should be in line with the client's wrist crease in standing, so that elbows are slightly bent when using the frame.
- When steady, place the walker one step ahead/a short distance forward, then walk towards it with the affected/weaker leg first, followed by the other leg. Repeat.
- To stand up push off the furniture, and to sit down turn until feeling the furniture at the back of the legs, then reach back with the hands to the armrest/bed and gently sit down.
- Do NOT walk too far into the frame area.
- Do NOT place the frame too far from the body.
- Do NOT use the walker on stairs or to pull oneself up from a chair, or outdoors.
- Do NOT exceed the maximum user weight.

Front-Wheeled Walker

- Similar to pick-up walker guidance, except that the frame is never airborne but instead pushed ahead of the body,
- Users are advised to set the rear legs one hole higher than the front legs in order to compensate for the size of the wheel.
- During turning and at door thresholds users are advised to lift the rear ferrules off the ground so they do not catch on the floor/threshold.

Rollator Guidance

- Check there are no loose bolts, wheels are secure on the axle, and brakes are fully functional, the seat pad is fully down and the rollator is fully opened.
- Adjust the handle height so you maintain an upright posture with elbows slightly flexed.
- Place the rollator in front of the body with the brake handles all the way down (until they click).
- Check if balanced, strong enough and ready to walk.
- When ready to walk, disengage the brakes until they click again.
- During walking, roll the rollator ahead yet not too far from the body: the feet must be in between the rear wheels after each step.
- Shorten longer step if steps are uneven.
- Engage the brakes to slow down on slopes or to come to a halt.
- Engage brakes to sit down on the seat; turn inside the rollator and lower down into its seat. Do not sit down on its seat on significant slopes.
- Brakes may be used during turning. Stay within the width of the rollator when turning and keep facing the front of the rollator; do not twist your back.
- When going up a kerb, first lift the front wheels then the back wheels onto the kerb, then engage brakes and step up.
- When going down a kerb, first lower the rollator down, then engage the brakes and step down.
- Do NOT use the rollator to pull up from a chair or bed; push up from the furniture instead.
- Do NOT exceed the maximum user weight.
- Do NOT overload the basket with heavy bags.
- Do NOT use rollator as a wheelchair.
- Do NOT use the rollator on stairs.

Figure 2.5: Common user guidance for walking aids as can be found in clinical and manufacturers' leaflets.

2.2.3 Benefits and effectiveness of walking aids

Walking aids such as walking sticks and walking frames have been designed to reduce falls-risk and enhance mobility (Bateni, Heung et al. 2004), yet only a few studies have investigated their benefits and effectiveness. Walking aids have shown to improve functional independence (Mann, Hurren et al. 1995), walking speed and confidence (Balash, Hadar-Frumer et al. 2007, Lucki, Bach et al. 2009), and performance of clinical mobility tests (Lucki, Bach et al. 2009).

One study assessed standing balance on a balance platform in patients with peripheral vestibular disorder with and without a walking stick, and found sway to be reduced with the stick (Nandapalan, Smith et al. 1995). Use of a walking stick has also shown to reduce muscular effort (Buurke, Hermens et al. 2005), and a simple walking stick with an ergonomic handle, as compared to a quadripod walking stick, has shown to be more beneficial in terms of walking velocity (Allet, Leemann et al. 2009). One study reported on the relationships among walking stick fitting, function and falls (Dean and Ross 1993), however, the authors relied on self-report regarding subjects' ability to perform standardized clinical assessment tests that characterize balance, and also relied on self-report of falls, despite self-report being often compromised in older adults (Levy, Holmes et al. 2003, Chase 2013). Nevertheless, they considered relationships between different factors, thereby recognizing the complexity of what contributes to effective walking aid use, i.e. recognizing it is a multifactorial issue.

More recently, it has been reported that rollator-usage during self-paced outdoor walking improved distance walked and time taken to walk that distance in individuals with chronic obstructive pulmonary disease (Vaes, Meijer et al. 2015). The same

patient group showed reduced disability (assessed using the Barthel Index) following rollator use (Yohannes and Connolly 2003). Moreover, rollators generally impact less on the user's gait pattern as they allow for a faster walking speed and require less energy (Tsai, Kirby et al. 2003, Bateni and Maki 2005). Yet it must be noted that these studies involved only a single type of assessment, or a single patient group or device (Nandapalan, Smith et al. 1995, Tsai, Kirby et al. 2003, Vaes, Meijer et al. 2015).

It seems reasonable to assume that walking aid effectiveness is reflected in frequent device usage, associated high levels of upright mobility, and a stable walking pattern with the device. However, to date these key factors of walking aid effectiveness are poorly understood.

Regarding frequent use of walking aids, it is largely unknown how often and for what tasks walking aids are used outside the clinic, and when they are not being used. Previous research defined walking aid use as a simple "yes/no" based on either self-report, hospital records (Van der Esch, Heijmans et al. 2003, Hefflin, Gross et al. 2004, Stevens, Thomas et al. 2009), whether the person attended a clinical appointment with a walking aid, or whether they had been previously seen using one (Andersen, Roos et al. 2007). However, such approaches are limited as they depend on the accuracy of users' self-report and hospital staff' note-taking or are based on observations made during a very narrow time window, which may or may not reflect everyday use. Indeed, self-report on general daily walking aid use provides, at best, a summary of patterns of use and may be compromised, especially among those in the most vulnerable and oldest-old groups who have difficulties with accurate recall (Chase 2013). Moreover, it is unknown to what extent user satisfaction influences frequent device use. Finally, at this time we do not

understand what constitutes stable walking with walking aids. Considering the scale of the health problem (an increase in walking aid users in our ageing population), this lack of understanding regarding the effectiveness of walking aids is a concern, as is the number of problems that have been reported in relation to usage of walking aids.

2.2.4 Problems with walking aids and falls-risk

2.2.4.1 Problems with walking aid use

Specific drawbacks are associated with each walking aid. For example, the increased width of multi-footed walking sticks represents a potential tripping hazard according to clinical experience (Independent-Living-Centre 2013), and also increases stance phase duration and gait asymmetry (Laufer 2003). Hence, although tri- and quadripod sticks enhance stability and safety through their free standing property, they also demand additional attention during walking and require good cognitive ability. Incorrect use of axillary crutches, on the other hand, may cause nerve or axillary artery compression (Faruqui and Jaeblon 2010), and generally crutches require substantial oxygen consumption and arm and shoulder strength (Bradley and Hernandez 2011). Furthermore, three-wheeled rollators have shown to increase step time as well as variability in the gait pattern, and it has been proposed that this may be due to their triangular shape which provides less mediolateral stability as compared to four-wheeled models (Kloos, Kegelmeyer et al. 2012). Finally, there is some evidence that walking aids may cause tripping, either over the device itself (Bateni, Heung et al. 2004) or through collision with other objects such as doorframes (Bateni and Maki 2005, Tung, Chee et al. 2015, Lindemann, Schwenk et al. 2016) which can compromise the user's postural control

(Andersen, Roos et al. 2007, Stevens, Thomas et al. 2009). Moreover, aspects of design have shown to increase the risk of collision of the lower limbs with the aid (Maki, Cheng et al. 2008).

Furthermore, a survey of walking frame users showed that 42 out of 69 users report problems related to their frame, and more than half of the problems were classified as “difficult and/or dangerous” (Mann, Hurren et al. 1995). Another study reported concerns such as “…could it [the walking frame] overturn when used; was it really stable?” (Skymne, Dahlin-Ivanoff et al. 2012). Moreover, walking frames are perceived to be heavy and tiring to use (Tsai, Kirby et al. 2003), and difficulties on slopes have been reported (Lindemann, Schwenk et al. 2016, Lindemann, Schwenk et al. 2017). It is noteworthy that a reported 30% to 50% of people abandon their device, some as soon as they receive it (Van der Esch, Heijmans et al. 2003, Bateni and Maki 2005), hence device rejection/disuse is a major problem that limits effectiveness of walking aids.

In summary, all walking aids have certain drawbacks associated with their use. Yet, to date problems with their use have received only little attention in the biomechanics and movement science literature, and what is known is primarily the result of clinical experience and users’ feedback. This gap in the knowledge base is of particular concern considering that use of walking aids has been linked to an increased falls-risk.

2.2.4.2 Falls-risk in users of walking aids

While walking aids can enhance mobility via provision of additional support through the upper extremities, their prescription alone does not eliminate risk of falling (Todd and Skelton 2004, Dionyssiotis 2012), in fact, for reasons unknown, use of a walking

aid has shown to be an indicator of increased falls-risk. Research in a group of 100 hospitalized patients found that those who fell were more likely to have used walking aids (Morse, Tylko et al. 1987), and a recent meta-analysis reported their use to be a risk factor for falls in community-dwelling older people (Deandrea, Lucenteforte et al. 2010). Interestingly, falls-risk of rollator users has been reported to be 7 times that of users of walking sticks (Stevens, Thomas et al. 2009). In agreement with these findings, adverse events such as lacerations, fractures, and contusions have been directly linked to falling with walking sticks, crutches and walkers (Hefflin, Gross et al. 2004). In the United States it has been estimated that 47,312 fall-related injuries treated annually in the emergency departments are associated with use of walking aids at the time of the fall, and of these 78.3% are related to walkers (Stevens, Thomas et al. 2009).

Only few circumstances leading to falls of users of walking aids have been reported, for example, whilst use of only one crutch makes it easier to manoeuvre around, doing so has been associated with an increased falls-risk (Gil-Agudo, Perez-Rizo et al. 2009). Unfortunately, regarding the reporting of walking aid-related falls, circumstances are often reported as “walking, not otherwise specified” (Stevens, Thomas et al. 2009), and, to date, no objective data exist on whether or not a walking aid was being used at the time when the fall occurred, preventing a thorough understanding of the underlying causes. At this time, we therefore cannot infer that walking aids are directly placing patients at increased falls-risk, however, their association with an elevated falls-risk does indicate that their effectiveness merits further study. As discussed above (Section 2.1.2), falls in general have a multi-factorial aetiology, involving a range of intrinsic (e.g. muscle weakness) and extrinsic (e.g. uneven ground) factors. Use of walking aids itself has been classified

as a “nonspecific” factor in relation to falls-risk, which cannot be prevented (Deandrea, Lucenteforte et al. 2010). Whilst users of walking aids are without doubt intrinsically vulnerable and hence likely to fall, this statement remains debatable considering that at this time it is unknown what influences stable use of walking aids. To improve current understanding of the relationship between use of walking aids and falls, specific factors that may play a unique role in the falls-risk of users yet require investigation: 1) bad design (Maki, Cheng et al. 2008), 2) ineffective (“incorrect”) match between user and device (Todd and Skelton 2004); 3) ineffective (“incorrect”) use of device (Morse, Tylko et al. 1987), for example use of walkers on steps and stairs (Stevens, Thomas et al. 2009), 4) device rejection/disuse (Morse, Tylko et al. 1987, Andersen, Roos et al. 2007), 5) defect devices, 6) increased activity following prescription (enhancing risk exposure), or any combination of these may limit their effectiveness. However, to which extend each of these factors contributes to occurrence of falls in walking aid users is presently unknown; there remains a need for additional research regarding walking aids to improve fall prevention (Kuan, Tsou et al. 1999, Tsai, Kirby et al. 2003, Bateni and Maki 2005, Gil-Agudo, Perez-Rizo et al. 2009, Stevens, Thomas et al. 2009, Kloos, Kegelmeyer et al. 2012, Wang, Merlet et al. 2016).

2.3 Characterizing stability for walking aid use

Prompted by the above reported links between walking aid use and falls, Section 2.3 will discuss the current knowledge base concerned with assessment of walking stability of both, the person and their walking aid.

From the manufacturers’ point of view, international ISO standards (ISO11199-1 for walking frames, ISO11199-2 for rollators, and ISO11334-4 for walking stick with three or more legs) specify requirements and methods to test static stability of

walking aids. The procedure, which is similar for all types of walking aids mentioned, requires to firmly place the walking aid on a plane that can be tilted, apply a static vertical force equal to 250 N through the handgrips, and increase the inclination of the plane until such point when the walking aid “tilts” (i.e., tips over). The tests are repeated in different directions (i.e., forward, backwards, and sideways) and the angle between the plane and the horizontal at which the walking aid tilts is recorded. The force applied to the walking aid, although not justified, seems reasonable based on recommended weight bearing ability of the individual walking aids (Disabled Living Foundation 2018), however, these tests involve static conditions only, and their relevance to everyday use or clinical practice is not discussed.

In contrast to simplistic manufacturers’ tests, most studies of assisted gait to date have largely focused on the gait parameters of the individual, assuming that the more the kinematics/kinetics resemble those of a healthy individual, the more stable the user is (Kuan, Tsou et al. 1999, Tsai, Kirby et al. 2003, Bateni and Maki 2005, Gil-Agudo, Perez-Rizo et al. 2009, Kloos, Kegelmeyer et al. 2012, Wang, Merlet et al. 2016). Comparisons of standard temporal and spatial gait parameters and walking speed obtained for walking with walking aids to values typically expected in unassisted walking are generally based on the underlying hypothesis that the walking aid which most successfully restores a natural gait pattern resembling unassisted, healthy walking is to be preferred (Hreljac 1993, Kuan, Tsou et al. 1999, Kloos, Kegelmeyer et al. 2012). However, these standard gait measures do not provide a clear link to stability. Walking at a slower speed may, for example, enhance stability when using a walking aid, as it allows the user more time to better control their own movements in combination with moving the device (Crosbie 1994, Yeung, Chow et al. 2012). The following sections will hence go beyond study of

basic gait parameters and discuss stability, specifically: 1) stability measures developed for assessment of the individual alone walking unassisted, 2) stability measures for assessment of the walking aid alone, and 3) stability measures developed for multi-legged robots, because the user and their walking aid may be considered a combined multi-legged system which, depending on the type of walking aid, has a minimum of 3 feet (user's two anatomic feet + the foot of a walking stick) and a maximum of 6 feet (user's two anatomic feet + four feet of a walking frame).

2.3.1 Stability of the individual

Although falls with walking aids are reported, the biomechanics literature concerned with quantification of walking stability has largely focused on unassisted walking, i.e. measuring stability of the person. For example, research demonstrated that standing balance requires control of the position and velocity of the body's centre of mass within the stability limits, i.e. the boundaries of the base of support (Pai and Patton 1997) (see also Figure 2.1), while dynamic balance during walking is more complex since control of the momentum of the body mass occurs in relation to the continuously changing base of support (Lee and Chou 2006, Chen and Chou 2010). Studies of unassisted walking have reported that centre of mass movement characteristics are associated with balance impairments in older persons (Kaya, Krebs et al. 1998, Lee and Chou 2006, Chen and Chou 2010) and acceleration patterns of the head, torso & pelvis have shown to be indicative of falls-risk (Moe-Nilssen 1998, Menz, Lord et al. 2003, Marschollek, Wolf et al. 2008, Narayanan, Redmond et al. 2010). Furthermore, in unassisted walking, linear and non-linear variability of basic gait parameters such as stride, swing, and stance time have been

used to infer on stability as such measures have shown to discriminate between fallers and non-fallers (Hamacher, Singh et al. 2011). Critically, these methods assume periodicity of the gait cycle and large numbers of strides are generally required to calculate meaningful variability outcomes (Jordan, Challis et al. 2007, Toebes, Hoozemans et al. 2012, Bisi, Riva et al. 2014, Riva, Bisi et al. 2014). In contrast, Hof et al., have assessed stability in unassisted walking using the concept of the stability margin computed from the position and velocity of the centre of mass "CoM" (Hof, Gazendam et al. 2005). Such method, however, is only valid under the assumption that human walking can be described using inverted pendulum models (Hof, Gazendam et al. 2005, Hak, Houdijk et al. 2013).

In conclusion, basic gait measures such as walking speed do not inform on stability, whilst more complex measures are often based on the assumption that gait is periodic or that gait can be modelled as an inverted pendulum. Walking aids, however, impose a movement pattern that affects the periodicity of gait and generally invalidates the assumption of inverted pendulum balance, as two or more legs (of user and/or device) are in contact with the ground for parts of the movement cycle. Hence measures previously used to characterize stability of unassisted walking are not transferable to walking with a walking aid. For assessment of assisted walking stability, measures must consider the unique movement patterns walking aids impose upon their user as well as the dynamics of the walking aid itself: the interaction between the user and their device must be taken into account. The following sections discuss methodologies that have been specifically developed for stability assessment of walking aid users.

2.3.2 Stability of walking aids

In contrast to methods which focused entirely on the user, methodologies that were concerned with stable use of walking aids relied predominantly on interpreting movements and loading of the walking aid alone to infer on the user's stability (Pardo, Deathe et al. 1993, Pardo, Winter et al. 1993, Deathe, Pardo et al. 1996, Wu, Au et al. 2008, Ming, Bai et al. 2009). For example, the SmartCane is a modified walking stick that includes load cells, accelerometers and rate gyroscopes, and which informs on usage patterns with regard to weight dependence, hand grip force, and walking stick orientation (Au, Wu et al. 2008, Wu, Au et al. 2008), however, it does not directly measure stability. Similarly, different types of walking frames have been instrumented with force sensors to obtain the frame's vertical ground reaction force "Fz" and its location, the frame's centre of pressure "CoP", which together regulate device stability. Specifically, Pardo et al. were the first to integrate strain gauges into the legs of a frame, which, in combination with foot switches, allowed for labelling of walker-assisted gait phases and events and subsequent calculation of device loading and device CoP (Pardo, Winter et al. 1993). Stability can then be quantified by calculating the distance from the device's CoP to the nearest edge of the device's BoS, which is often referred to as the stability margin: the smaller this distance, the less stable the device is, and if zero, the device is at the point of tipping over. It is surmised that the user's overall stability is reduced at smaller device CoP-BoS distance values, and increasingly so for higher levels of device dependency, i.e. when the device supports substantial amounts of body weight. Subsequently, the authors derived the Walker User Risk Index which informs on the amount of support that the user would lose, should the device suddenly be removed (Pardo, Deathe et al. 1993) and their methodology has been further adapted since: Ming et

al. built on their approach and defined the Walker Tipping Index (WTI) that estimates the tendency of the device to tip over in both, anterior-posterior and mediolateral direction (Ming, Bai et al. 2009). Tung et al. then developed the iWalker (Tung, Chee et al. 2015), a rollator which contains load cells inside each leg and similarly measures the total vertical load applied to the device, from which the device CoP may be calculated. The iWalker additionally includes video cameras that record foot positioning as well as the environment, to inform on device collisions with the user's feet or environmental features such as door frames. In line with his predecessors, the iWalker evaluates stability based on excursions of the device's CoP and the user's reliance on their device in terms of body weight support. However, these approaches which measure only the forces on the device alone cannot inform on stability during those periods where the device is airborne, e.g., when crutches, a walking stick, or a pick-up walker are lifted up and forward by their user. Moreover, even when grounded, situations do exist where inference on stability based on the device's CoP-BoS relationship alone is misleading, as will be discussed in Chapter 3.

2.3.3 Characterizing stability of multi-legged robots

Building on approaches that focused on the device alone, the user and device can be treated as a multi-legged system, comparable to a multi-legged robot (Figure 2.6) which at any time can have between 1 or 6 feet in ground contact depending on the type of walking aid, whether the user is in single support or dual support, and whether their device is airborne or partially or fully grounded. For example, a walking stick user during the swing phase of their walking stick generally has only one anatomic foot in contact with the ground, but as soon as the walking stick and swing

leg are no longer airborne, a total of three feet are grounded: two anatomic feet plus the foot of the walking stick. A rollator user, on the other hand, has five feet in ground contact during the swing phase of gait: their stance foot plus the 4 wheeled “feet” of the rollator; once dual support begins, a total of six feet will be grounded: the two feet of the user plus the four wheeled “feet” of the device.

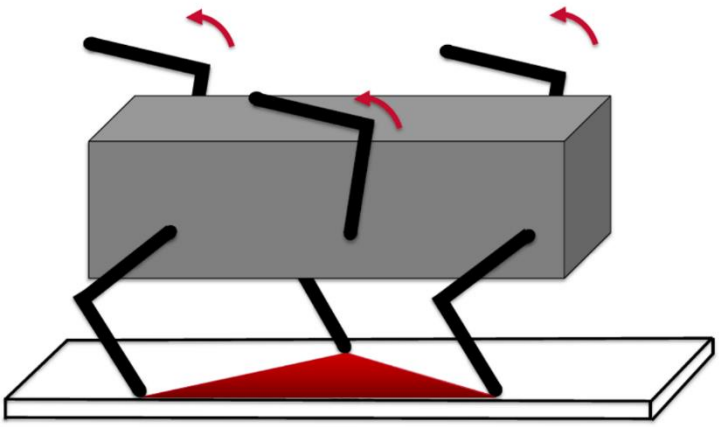


Figure 2.6: Simplified schematic of a multi-legged robot: the red shaded area represents the base of support for the 3 legs in ground contact.

Therefore, the principal outcome measures used to assess and control stability in walking robots have been explored to identify the ones, if any, that may be applied to walking with a walking aid. One common method used in robotics to assess and control walking stability utilizes the concept of the stability margin. Different definitions of the stability margin exist in the associated literature, some of which are described below:

1) The *stability margin* is defined as the shortest distance between the vertical projection of the Centre of Mass (CoM) and the edge of the Base of Support (BoS), defined as the convex polygon connecting all feet in the support phase, in any direction. A variation of such measure is the *per cent stability margin* which is the stability margin normalised by the maximum achievable

stability margin (Ting, Blickhan et al. 1994). For static stability to be verified, CoM must fall inside BoS (Kar 2003), and the closer it is to the edges of the BoS, the less stable the robot is, which means that the stability margin is directly proportional to the level of stability.

2) The *longitudinal stability margin* is defined as the shortest distance between the vertical projection of the Centre of Mass (CoM) and the edge of the Base of Support (BoS) in the walking direction (Kar 2003).
3) The *wide stability margin* is defined as the shortest distance between the Centre of Pressure (CoP) and the edge of the Base of Support (BoS), which, in turn, is defined as the convex polygon connecting all feet in the support phase and further including the vertical projection of those airborne (Hiroshi Kimura 2007). This adapted concept of the stability margin accounts for the fact that, during walking, any given leg could land immediately if needed to maintain stability and avoid a fall.

However, the most commonly used stability measure is the *zero-moment-point* (ZMP) which was firstly introduced by Vukobratović and Stepanenko in 1972. The authors defined the concept of ZMP as follows: in Figure 2.7 *"an example of force distribution across the foot is given. As the load has the same sign all over the surface, it can be reduced to the resultant force R, the point of attack of which will be in the boundaries of the foot. Let the point on the surface of the foot, where the resultant R passed, be denoted as the zero-moment point, or ZMP in short"* (Vukobratović and Stepanenko 1972). It appears evident from Figure 1.7 that the ZMP is equivalent to the Centre of Pressure (CoP).

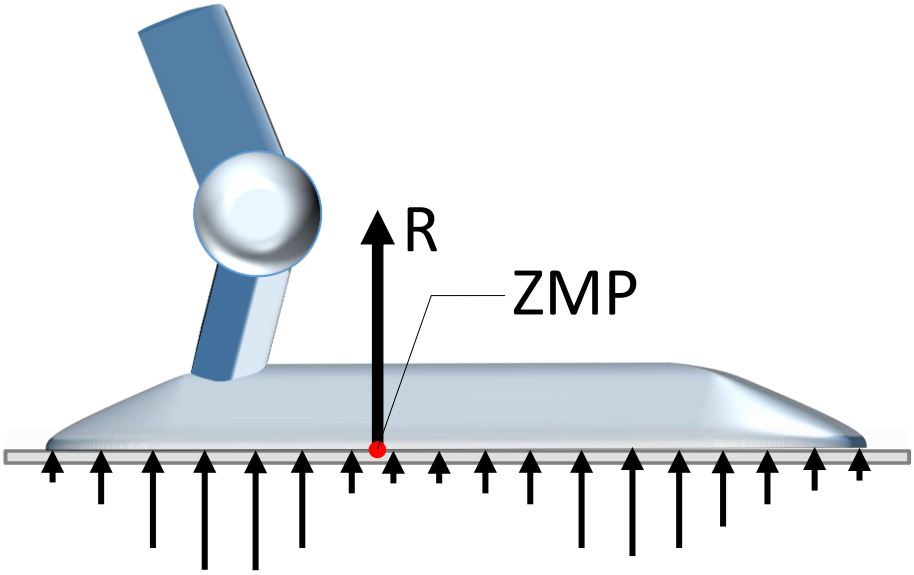


Figure 2.7 : Illustration of the ZMP adapted from Vukobratović and Stepanenko (Vukobratović and Stepanenko 1972). Individual arrows indicate the force distribution across the foot; R represents the resultant ground reaction force acting on the foot; and the zero-moment point 'ZMP' is the point of application of R.

Whilst the stability margin based on the CoM was originally proposed to describe static stability, for dynamic walking robots the stability margin can be defined as the shortest distance between ZMP and the edge of the BoS (Kajita and Espiau 2008). In addition, ZMP was used by Vukobratović and Stepanenko, and by many other groups since, to successfully control the gait of their recently developed biped robots, which establishes confidence in the validity of such method to assess the stability of the system.

Also, provided that CoP can be calculated, this method is of direct relevance to this problem as treating user and their device as a single multi-legged system allows for stability assessment of all user-device configurations, including when the walking aid is airborne, at which time the user may be particularly vulnerable to a loss of balance; moreover, with the CoP being a basic mechanical principle, it directly reflects stability and does not make assumptions on the nature of the walking system as done in those approaches that are based on a model-based approach,

such as the inverted pendulum (Hof, Gazendam et al. 2005) or which consider the gait cycle as strictly periodic (Hamacher, Singh et al. 2011). These assumptions may be valid in unassisted walking but not when walking with a walking aid as the gait pattern changes drastically and is much more complex.

2.4 Discussion and conclusions

In this chapter, we discussed how falls in older adults are a major global health problem for both the individual and the society due to their high incidence, severe consequences, and associated costs. Moreover, this problem is expected to become even more relevant in the next few decades due to the rapid increase of the older population, and especially of the oldest-old group, worldwide.

Older adults at risk of falling often use a walking aid to improve their balance and mobility; in Europe specifically, 29-49% of older adults use some type of walking aid either indoors and/or outdoors (Lofqvist, Nygren et al. 2005). Alarmingly, there is some evidence that use of walking aids is associated with 2-fold to 3-fold risk of falling (Deandrea, Lucenteforte et al. 2010).

This finding may be a result of non-use of the walking aid at the time of a fall, or the user interacting with the device in an unstable manner, but, at this stage, the exact causes of the relationship between walking aid use and increased risk of falling cannot be established due to several limitations in the current literature. First, everyday walking aid usage is still very poorly understood, and this is both surprising and concerning considering the high number of walking aid users in our population. Such lack of understanding concerns all aspects of walking aid use, i.e.: how often, if at all, is the walking aid used?; for which daily activities is the walking aid used/not

used?; specifically, how is the walking aid used? As mentioned in section 2.2.3, no objective data is available to date to help better understanding walking aid use. Second, the frequency and circumstances of falls are also often unclear as many older adults deny having fallen (Campbell, Borrie et al. 1990), are unable to recall how the fall happened (Stevens, Thomas et al. 2009), or even whether the walking aid was being used at the time of the fall. Finally, it seems surprising that, despite the high prevalence of walking aid users amongst the fall-prone older old, the majority of studies on walking stability focus on unassisted walking. Previous work concerned with walking aid stability has either focused on the walking aid alone or the person alone, without considering the frame and the person as a coupled system. Such approaches, as will be outlined in more detail in Chapter 3, can lead to incorrect conclusions. To date, no gold standard approach to the measurement of stability in either unassisted or assisted walking exists, and this is surprising and concerning, but also an indicator of the complexity of this research topic.

Considering the current gaps in the literature, we argue that being able to measure stability in assisted walking is one essential step towards the understanding of walking aid use and its alarming association with falls and, hence, is the motivation for this PhD. Specifically, this PhD aims to explore the following overarching research question: "**What constitutes stable walking aid use?**". To do so, the following objectives have been set:

Objective 1: To develop a novel, objective, and generalizable measure for the assessment of stability of walking aid users, which, in order to consider both the user and the walking aid, is inspired by methods from the robotics literature.

Objective 2: To design and develop corresponding technology and software necessary for the calculation of the selected outcome measure.

Objective 3: To establish confidence in the ability of the stability assessment methodology developed through objectives 1 and 2 to describe the stability of users of walking aids in relation to:

- the type of task performed (e.g., straight line walking task versus turning or stepping up a kerb);
- the environment (i.e., lab versus real-world representative environment);
- the type of walking aid used.
- To do so, three representative walking aids have been selected: a pick-up walker without wheels, a front wheeled walker (both of which are used by the least mobile users), and a rollator with four wheels (generally used by the most mobile users).

Objective 4: To investigate whether it is possible, using the methodology developed through objectives 1 and 2 and/or other associated metrics, to inform on relative stability of WA users

3 Design and validation of a new stability measure and associated technology

This chapter has been published in the Journal of Medical Engineering and Physics in 2017 with the title: “A generalizable methodology for stability assessment of walking aid users”.

3.1 Introduction

Falls in older adults are a major global health problem as more than 30% of community-dwelling people aged 65 and over fall every year (Rubenstein 2006), consequences of which range from reduced activity and fear of falling to injuries and death (Bloem, Steijns et al. 2003). Moreover, falls are also a matter of great concern for society as a whole: in 2013, for instance, it was estimated that falls cost the UK government over £2.3 billion (NICE 2013). Older frail people with an unstable gait are often advised by their clinician to use walking aids, which are designed to help them maintain their balance through an increase in the effective base of support area, and through provision of structural support and haptic sensory information (Jeka 1997, Maeda, Nakamura et al. 2001). Indeed, walking aids are used by 29-49% of older people (Lofqvist, Nygren et al. 2005). However, paradoxically, use of walking aids (versus non-use) has been associated with a 2-fold to 3-fold increase in risk of falling (Deandrea, Lucenteforte et al. 2010). There are a number of possible

explanations for this finding: one is that walking aids are prescribed to the most frail part of the population who, when falls occur, are most likely to suffer injury and, hence, appear in the statistics; another is that prescription of a walking aid increases the period spent upright or mobile and, hence, reduces time spent in a safer sitting or lying posture. However, in studies by Mann et al. (Mann, Hurren et al. 1995) and Skymne et al. (Skymne, Dahlin-Ivanoff et al. 2012), 60% of walker users reported problems with using their walker and quotations from users included “[the walker was] difficult and/or dangerous to use” and “…could it [the walker] overturn when used; was it really stable?”. Such concerns suggest that another possible explanation and the motivation for this work, is that incorrect device usage, as a result of inappropriate device selection and/or training, may be contributing to instability and falls in walker users.

Surprisingly, despite the large number of walking aid users amongst the older population, there are no objective, generalizable methods for assessing their stability. Previous work to date has often focused on the kinematics/kinetics of the user only, presuming that the more the gait pattern resembles that of a healthy subject, the more stable the user is (Kuan, Tsou et al. 1999, Tsai, Kirby et al. 2003, Bateni and Maki 2005, Gil-Agudo, Perez-Rizo et al. 2009, Kloos, Kegelmeyer et al. 2012, Wang, Merlet et al. 2016). Such an approach ignores any direct effects of the walking aid on the user’s stability, which is clearly incorrect (Yeung, Chow et al. 2012). Others focused on the device alone (Wu, Au et al. 2008, Sardini, Serpelloni et al. 2014): Pardo et al., for instance, developed an instrumented pick-up walker to detect lift-off/touch-down events of the device itself and to calculate device loading and device Centre of Pressure (CoP) (Pardo, Winter et al. 1993). They inferred stability by assuming that, if the device CoP approaches the boundaries of its Base

of Support (BoS) and, therefore, if the pick-up walker becomes unstable, then, the higher the loading on the device, the higher the risk of falling. To quantify stability, they derived the Walker Tipping Index (which gives an indication of how close the device is from tipping) from the horizontal and vertical forces applied to the pick-up walker, and then normalised such index to the percentage of body weight transferred onto the device (Pardo, Deathe et al. 1993). However, the walker and user are mechanically coupled and determining when tipping is imminent based on a measure of either the mechanics of the user alone, or their walker alone, is incorrect. For example, when the pick-up walker is being lifted, initially only two pick-up walker feet remain in contact with the ground, and the device CoP lies on the boundary of the device BoS, which is reduced to the line connecting the two grounded feet. A measure that only considers the pick-up walker would interpret this scenario as being unstable, whilst this is, in fact, a natural part of pick-up walker use. Therefore, although it is true that tipping of the walker might mean that the user has fallen, it is more likely to indicate that the user is beginning to lift the walker. Similarly, measures based on the walker alone cannot inform on stability when the device is fully airborne which is likely to constitute a particularly challenging situation to the user. Conversely, when the user is relying on the walker, it is likely that the CoP of the user alone is under the user's toes and, hence, very close to the edge of the user's BoS; however, this doesn't mean that the user is unstable, rather that they are leaning on the device. Only one study to date collected data on both user and their device (a rollator) (Tung, Chee et al. 2015). Whilst their approach is praiseworthy, stability of the overall system (defined as person and walking aid) was not adequately addressed because the mechanics of the user and their walking aid

were treated separately and stability was evaluated on the basis of reliance on the device and excursions of the device centre of pressure.

The whole system, comprising user and walking aid may be considered to be a configurable multi-legged device, similar to a multi-legged walking robot. Methods for the calculation of stability of multi-legged robots based on the CoP kinematics are well established (Vukobratović and Stepanenko 1972, Kar 2003, Kajita and Espiau 2008, Liu 2009) and are directly applicable to this problem. Yet stability methods from the robotics literature have not been previously reported in the context of walking aid usage. Considering user and device as a combined system has the advantage of allowing for the correct assessment of stability under all user-walker configurations, including when the device is airborne, which may be particularly critical.

This paper proposes an objective and generalizable method for the assessment of stability of walking aid users, based on methods from the robotics literature. Given that there are more walker users than users of crutches (Kaye, Kang et al. 2000) and since seven times as many injuries are associated with walkers compared with walking sticks (Stevens, Thomas et al. 2009), we here introduce our method for the assessment of stability of walker usage, specifically for a walker without wheels (a pick-up walker). We demonstrate the application of the methods for walking in a standardized home environment, the University of Salford Activities of Daily Living (ADL) flat.

3.2 Methods

3.2.1 Stability of the system

The novel methods proposed here consider the user and their four legged pick-up walker (PW) as a combined system. We define the combined centre of pressure (CoP_{system}) of user and PW to be the point through which the resultant ground reaction force for all feet of both the PW and user acts if the resultant moment acts only around an axis perpendicular to the ground plane.

The instantaneous position of the combined CoP is calculated as follows:

$$\boldsymbol{CoP_x = \frac{\sum_{i=1}^{n}(Fv_i x_i)}{\sum_{i=1}^{n} Fv_i}}, \qquad \boldsymbol{CoP_y = \frac{\sum_{i=1}^{n}(Fv_i y_i)}{\sum_{i=1}^{n} Fv_i}} \qquad \boldsymbol{Eq.}\ 3.1$$

where:

- $CoP_{x,y}$ are the coordinates of the CoP in the mediolateral and anteroposterior direction, respectively;
- Fv_i is the vertical load on the i_{th} supporting foot (either anatomical or of the PW);
- x_i, y_i are the coordinates of the i_{th} foot of the PW, or of the CoP for the i_{th} anatomical foot;
- n is the number of feet in contact with the ground. When all the feet are on the ground, n=6 (2 anatomic feet, 4 PW feet).

Therefore, according to $\boldsymbol{Eq.}\ 3.1$, at any instant in time, we must know the magnitude and position of the vertical load acting on each foot of the PW and acting on each anatomical foot of the person.

We also define the instantaneous combined BoS to be the convex polygon formed by the boundaries of the anatomical and PW feet in contact with the ground and interconnecting lines between them. Finally, in accordance with the walking robot

literature (Liu 2009), we define the instantaneous combined stability margin (SM_{system}) as the shortest distance between the combined CoP and the nearest edge of the combined BoS. It should be noted that, from the definition of CoP alone, it can be proven that, when the CoP reaches an edge of the BoS, the load under all feet, except those forming that edge, will be zero (i.e. when SM_{system} =0 tipping begins).

Furthermore, we also introduce into our analysis the rate of change of the stability margin. When the instantaneous SM_{system} is low, but the rate of change shows that SM_{system} is rapidly increasing, then it could be concluded that the user is unlikely to fall because they are becoming more stable. Conversely, if the rate of change shows a rapid decrease in the SM_{system}, then their risk of falling may be higher than SM_{system} suggests.

Finally, SM_{system} is likely to be misinterpreted when, for example, SM_{system} is close to zero because the user is in the process of transferring their body weight from one foot to another that has not yet touched the ground. Conversely, if a foot is in the process of taking off, the user may be less stable than SM_{system} suggests. Therefore, we also calculate the “projected” stability margin (SMp) which we define to be the shortest distance between the combined CoP and the nearest edge of the “projected” combined BoS. The “projected” combined BoS is calculated post-hoc to be the position of the combined BoS at a point in time *t* seconds later. The time *t* for each individual is the average duration of the terminal swing phase (or landing phase), calculated as 13% of the user’s own mean gait cycle duration (Merker, Hartmann et al. 2015).

3.2.2 Instrumentation development

To measure the required data, the Salford Walking Aid System (SWAS) was developed consisting of:

a) A purpose-designed instrumented pick-up walker (PW) to measure the vertical force acting through each of its “feet”;
b) Commercial in-shoe sensors (*medilogic®insole, T&T medilogic Medizintechnik GmbH,* Schönefeld, Germany) to measure the pressure distribution and hence the resultant vertical force and the corresponding CoP location for each anatomical foot;
c) An optoelectronic motion capture system to capture the position of both, the anatomical feet and walker feet. For this study, a mobile 6 camera system (Qualisys Oqus300, Qualisys AB, Göteborg, Sweden) was used.

The instrumented PW was modified to accommodate a single axis load cell (Futek LCM300, Futek Advanced Sensor Technology Inc., Irvine, CA, USA) in each leg of the device in order to measure the vertical ground reaction forces (Figure 3.1). The force data are sent to a laptop by wireless transmitters (Mantracourt T24-ACMi, Mantracourt Electronics Limited, Exeter, UK) fixed onto the walker.

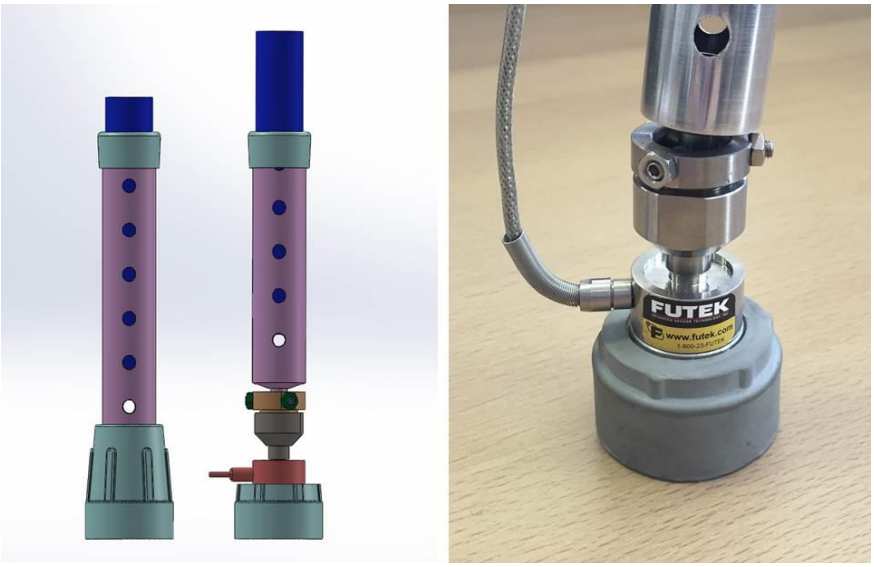


Figure 3.1: A) Model of an instrumented foot of the PW with integrated load cell. B) Instrumented foot with adjustable vertical axis of the load cell configuration, i.e., set to be perpendicular to the ground.

Design requirements included the necessity to be able to adjust the walker height for a range of users, to ensure that the axis of each load cell was perpendicular to the ground during the PW stance phase, and to minimise the weight added to the walker. Currently, the total weight of the instrumentation is 1 kg, which includes load cells, transmitters, batteries, and titanium connectors needed to integrate the load cells into the PW legs.

Equipment synchronisation

To obtain the selected outcome measures, PW load cells, pressure insoles, and optoelectronic camera data collection needed to be synchronised; this was done as follows:

- The Medilogic system was modified to receive a sync pulse through a trigger to allow for time alignment of foot pressure data with load cell data and position data;
- A reflective marker was attached to the top of a spare load cell;

- The Medilogic trigger was manually hit with the spare load cell with a fast, vertical movement: this action generates a trigger pulse in the Medilogic system, a force pulse in the load cell, and a minimum in the marker position data (Figure 3.2);
- Finally, the synchronisation pulses were used to align the data from the three systems in post-processing.

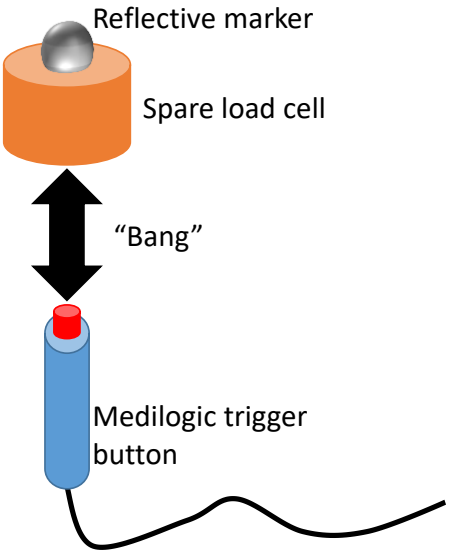


Figure 3.2: Manual synchronisation setup between 3D cameras, Futek load cells, and Medilogic pressure sensing insoles. The Medilogic trigger was manually hit with the spare load cell with a fast, vertical movement: this action generates a trigger pulse in the Medilogic system, a force pulse in the load cell, and a minimum in the marker position data allowing for time alignment of the synchronisation pulses and, therefore, of the three systems, in post-processing.

Load cell testing

The instrumented PW was first tested using a force-plate to verify the accuracy of the load cells as follows:

- Three of the four feet were each placed on a force plate (Figure 3.3), and a wooden board was placed across the lower crossbars of the PW;
- Force plates and load cells were then zeroed;

- Five trials were recorded during which the walker was first gradually loaded by adding known weights onto the board and subsequently gradually unloaded taking off the same weights;
- The same experiment was repeated rotating the walker to place the remaining foot onto a force plate which could not initially be fitted due to the arrangement of force plates in the gait lab.

Pressure insole system testing

To ensure that the sampling frequency of the insole system, which is a maximum s of 60 Hz, was suitable for the planned experiments, the frequency content of the centre of pressure of a healthy subject was analysed and compared to the frequency content of the CoP signal obtained using a force plate. A MATLAB script was written for this purpose.

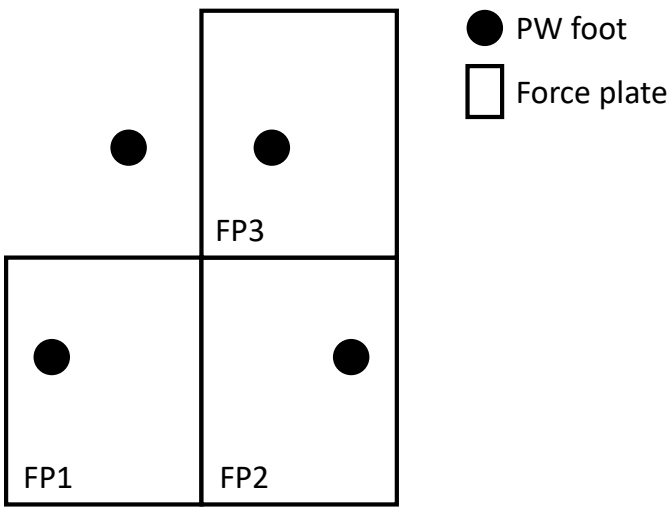


Figure 3.3: Configuration of force plates in the gait laboratory and positioning of the PW for validation of the load cells accuracy.

Next, the accuracy of the user's centre of pressure and the resultant vertical load acting on the user's feet as calculated from the insole data was determined as follows:

- A subject was asked to wear a standard pair of shoes (with 4 reflective markers on each shoe located in correspondence of the first, second, and fifth metatarsal head and on the heel) in which Medilogic pressure insoles had been previously placed;
- The subject was then asked to stand on a force plate;
    - Five trials we recorded during which the subject stepped on to the adjacent force plate and stood still;
    - Positon and force data were collected using a motion capture system, force plates, and pressure insoles data.

The trajectory of the centre of pressure and the total vertical ground reaction force were calculated from pressure insoles data as follows:

- First, the sensor map for each insole including sensor area and distance in anteroposterior and mediolateral direction between sensors was provided by the supplier;
- In order to obtain the resultant vertical load measured by the insoles, the pressure value in N/cm^2 of all sensors at a given time was summed and converted into N.
- The position and orientation of the insoles in space was estimated using the position data of the reflective markers attached to the shoes;
- Finally, knowing the pressure measured by all sensors and their relative position, the trajectory of the centre of pressure was calculated.

A recalibration of the insole system has also been attempted in order to improve its accuracy: the TRUBLU calibration device has been used to apply gradually increasing an equally distributed pressure to each insole. In this way, all sensors should, ideally, measure a pressure equal to that applied by the calibration device. The applied pressure ranged from 0.2 to 1 bar at 0.2 bar intervals and from 1 to 6 bar at 0.5 bar intervals. Successively, a 7^{th} order calibration equation (as this order allowed the best fitting of the experimental data) was created for each sensor in MATLAB using a linear regression method.

Combined Centre of Pressure accuracy testing

Finally, data from both the SWAS and force plate were recorded from a user picking up the walker, placing it forward onto the force plate, then stepping into it (a large 600 x 900 mm AMTI BP600900 force plate normally used for sprinting was used to allow for simultaneous contact with all 4 PW feet and both anatomical feet). This allowed the CoP_{system} calculated from load cell, insole and camera data to be compared against that calculated from force plate data.

3.2.3 Data processing

In order to process the force and position data, software written in MATLAB was developed to:

- Detect when each of the PW and user's feet are on the ground (supporting feet) through identification of individual touch-down (TD) and lift-off (LO) events of each foot of the device from load cell data, and TD (i.e. heel-strike) and LO (i.e. toe-off) events of the user's feet from force/insole data; load cell and insole signals were lowpass filtered at 6 Hz with a 4^{th} order Butterworth filter;

- Define the base of support at any time instant as the convex polygon formed by the boundaries of the anatomical and PW feet in contact with the ground and interconnecting lines between them;
- Calculate the resultant vertical force and the corresponding CoP location for each anatomical foot. This uses the individual pressure value from each sensor within each insole, together with the relative position of each sensor in each insole, and the global position of the insole itself;
- Apply (Eq 3.1) using 3D position data, load cell data of the PW feet, and the magnitude and coordinates of the resultant load that acts on each anatomical foot (calculated previously);
- Calculate the stability margin as the perpendicular distance from CoP_{system} to the nearest edge of BoS_{system};
- Calculate the rate of change of the stability margin by differentiating the stability margin curve;
- Calculate the projected stability margin as the perpendicular distance between CoP_{system} and the nearest edge of the projected combined BoS, at a participant-specific instant *t* seconds forward in time;
- Calculate device loading as the percentage of body weight transferred by the user onto the device;
- Determine the movement sequence of the walker in relation to the user's foot placements.

3.2.4 Subjects

One young adult (age=27) and one older PW user (age=83) were recruited to test the feasibility of the protocol and to establish proof-of-concept for the method. The

older subject met the inclusion criteria of being able to walk household distances with a walker but not being able to walk such distances unaided. A description of the participants' basic gait parameters is provided in Supplement A. Written informed consent was obtained and the experimental protocol was approved by the University of Salford Ethics Committee (HSCR13-48).

3.2.5 Protocol

To test our method, the young adult and the older PW user were asked to walk with the SWAS in a home-setting: the University of Salford Activities of Daily Living (ADL) flat (furnished, and equipped with 6 optoelectronic cameras). Here participants walked 3 times with the SWAS at their self-selected speed from the kitchen to the bathroom (6 metres). This pathway was selected as it included two consecutive 90 degree turns (through two doorways: kitchen to lounge, lounge to bathroom) and transitions between different flooring conditions (vinyl to carpet, carpet to vinyl), therefore representing real-world challenges seen in users' homes. For all trials, subjects were asked to walk with the PW as recommended by clinical guidance: to lift the device forward and, only once it is grounded, to then step into the device.

3.3 Results

3.3.1 Instrumentation development

Equipment synchronisation

Figure 3.4 shows an example of time alignment of position, load cell, and pressure insole data during post-processing.

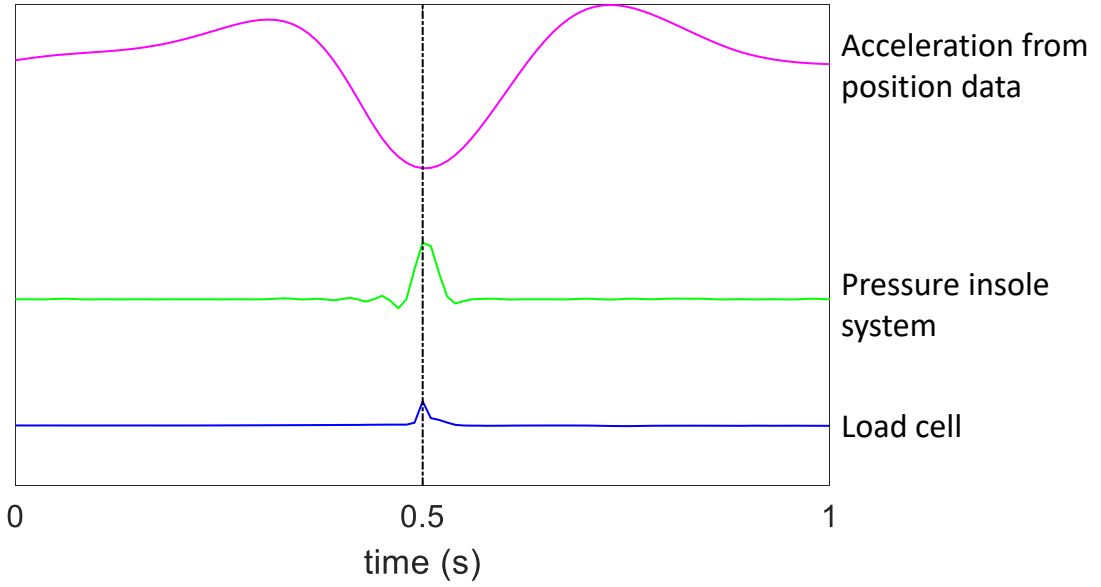


Figure 3.4: example of synchronisation pulses and time alignment of the three systems based on the manual synchronisation as shown in Figure 3.2. Units on the y axis are: m/s^2 for acceleration data (top), N/cm^2 for pressure insole data (middle), and N for load cell data (bottom).

Load cell testing

A Maximum error of 5% and Root Mean Square value of 0.46N were obtained when comparing the vertical force recorded by each load cell to the corresponding data recorded with a force plate (Figure 3.5).

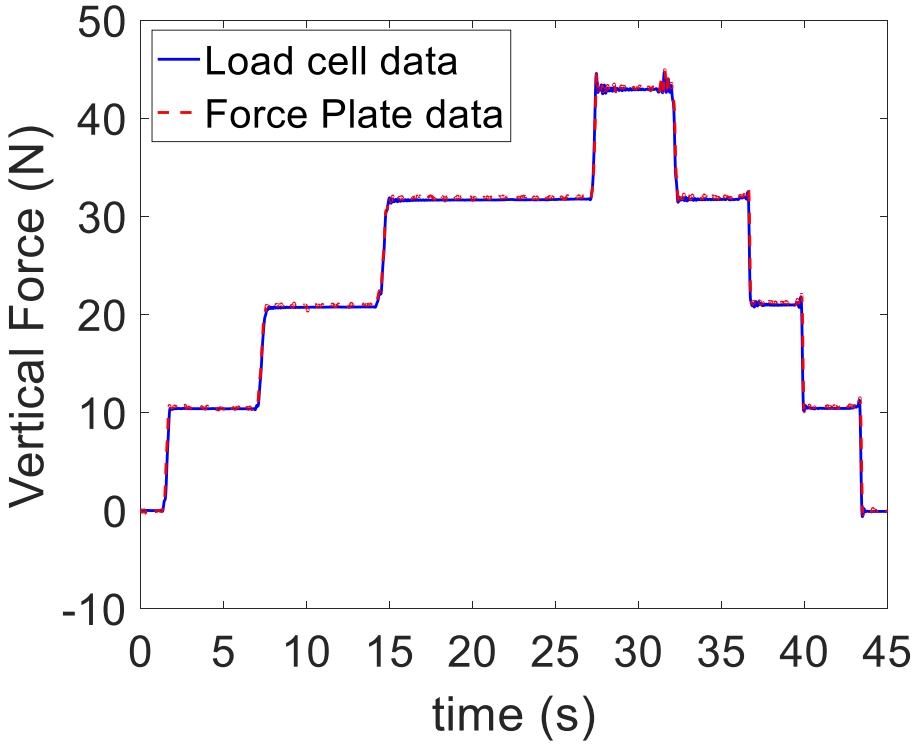


Figure 3.5: Example of comparison between the vertical force recorded by the load cell placed into one of the PW feet and the vertical force measured by the force plate.

Pressure insole system testing

With regard to the frequency content of the centre of pressure, based on the results of our analysis and in agreement with previous studies (Fitzpatrick, Gorman et al. 1992, Carpenter, Frank et al. 2001, Chiari, Rocchi et al. 2002, Vieira, Oliveira et al. 2009), it can be concluded that the CoP sway is restricted to low frequencies (<2.5 Hz), and that, therefore, a sampling frequency of 60 Hz is sufficiently high.

With regard to the total vertical load, the value measured by the insoles was approximately 4 times smaller than that measured by the force plate. It is believed that forces being transmitted through the gaps between sensors and the edges of the insoles may be the primary cause of this inaccuracy.

Figure 3.6 shows an example of the comparison between the trajectory of the centre of pressure calculated by the insoles and that calculated by the force plate. The

RMS value of the difference between force plate and insoles measurements was calculated: maximum RMS values of 20 mm in anteroposterior and 18 mm in mediolateral direction were found.

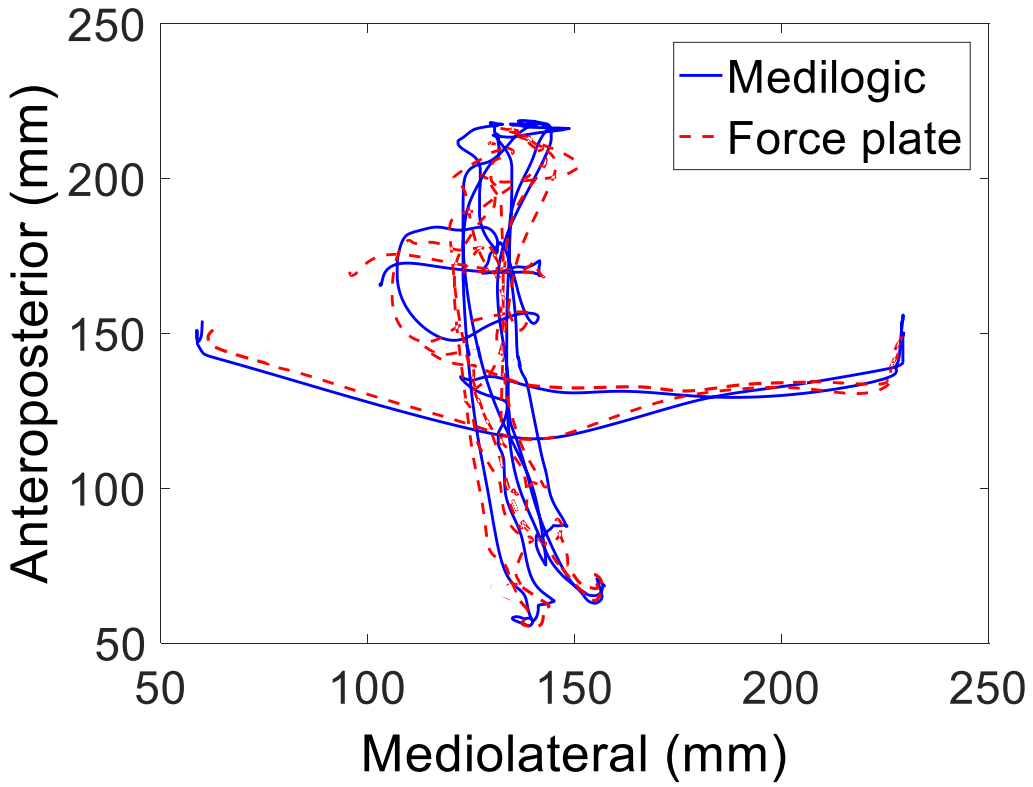


Figure 3.6: Comparison between the CoP trajectory calculated by the force plate and that calculated by the Medilogic pressure insole system. On the x and y axes are the coordinates of the CoP in mediolateral and anteroposterior direction, respectively.

After the recalibration of the insoles, the average error between sensed and applied pressure decreased from 60% to 6.6% at 0.2 bar and from 9.7% to 1.03% at 6 bar with the average error of all sensors across all applied pressures decreasing from 18% before the calibration to 3.1% after the calibration. Nevertheless, after applying the generated calibration curves to previously collected insoles data, and checking their accuracy again, it was found that the maximum RMS difference between insoles and force plate CoP position did not significantly decrease (Table 3.1 shows the RMS difference between insoles and force plate CoP position before and after

the calibration); there are several explanations for this: first, although the error at low pressures is very high (over 50%), it decreases considerably at higher pressures (comparable to those acting on the insoles while standing or walking); it was also observed that the error decreases when the average pressure measured by small groups of adjacent sensors are considered instead of the single sensors.

Table 3.1: Accuracy of the CoP calculated by Medilogic pressure insoles relative to that calculated by the force place before and after the calibration for four different trials (A-D).

	Before		***After***	
	RMS_x (mm)	**RMS_y (mm)**	**RMS_x (mm)**	**RMS_y (mm)**
A	6.02	10.09	5.21	7.88
B	18.33	20.56	18.51	19.38
C	10.35	9.72	8.68	8.75
D	17.77	13.09	16.4	12.53

Combined Centre of Pressure accuracy testing

Finally, with regard to the accuracy of the CoP_{system} calculated with our sensor system, a maximum error of 25 mm in mediolateral and 17 mm in anteroposterior direction was found, which we consider acceptable being equal, respectively, to 4.24% and 2.07% of the maximum width and length of the combined BoS in the testing conditions studied.

3.3.2 Characterization of Foot-Ground Contact Events and Movement Sequence

Walking with a pick-up walker differs significantly from unassisted walking in that the user needs to coordinate the movements of the device together with their own foot movements. Specifically, TD and LO gait events exist for the feet of both, the user as well as the PW, and the sequence in which they occur may vary greatly from one movement cycle to the next (see Figure 3.7).

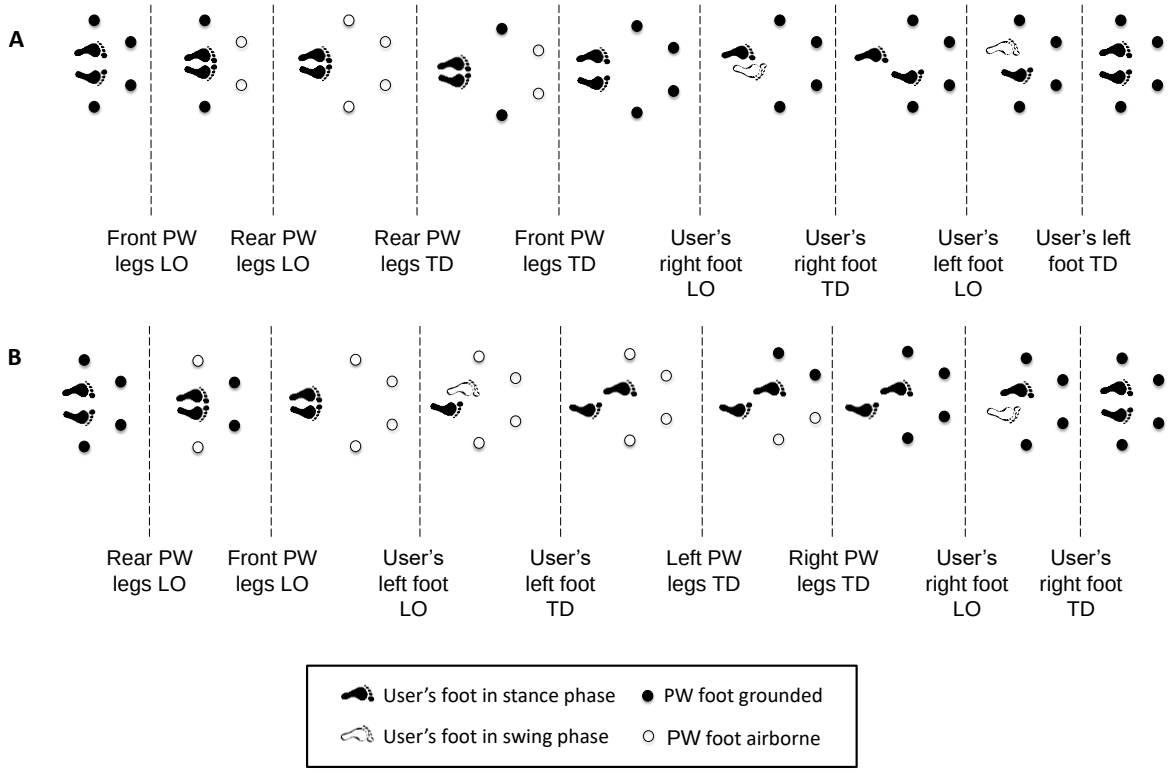
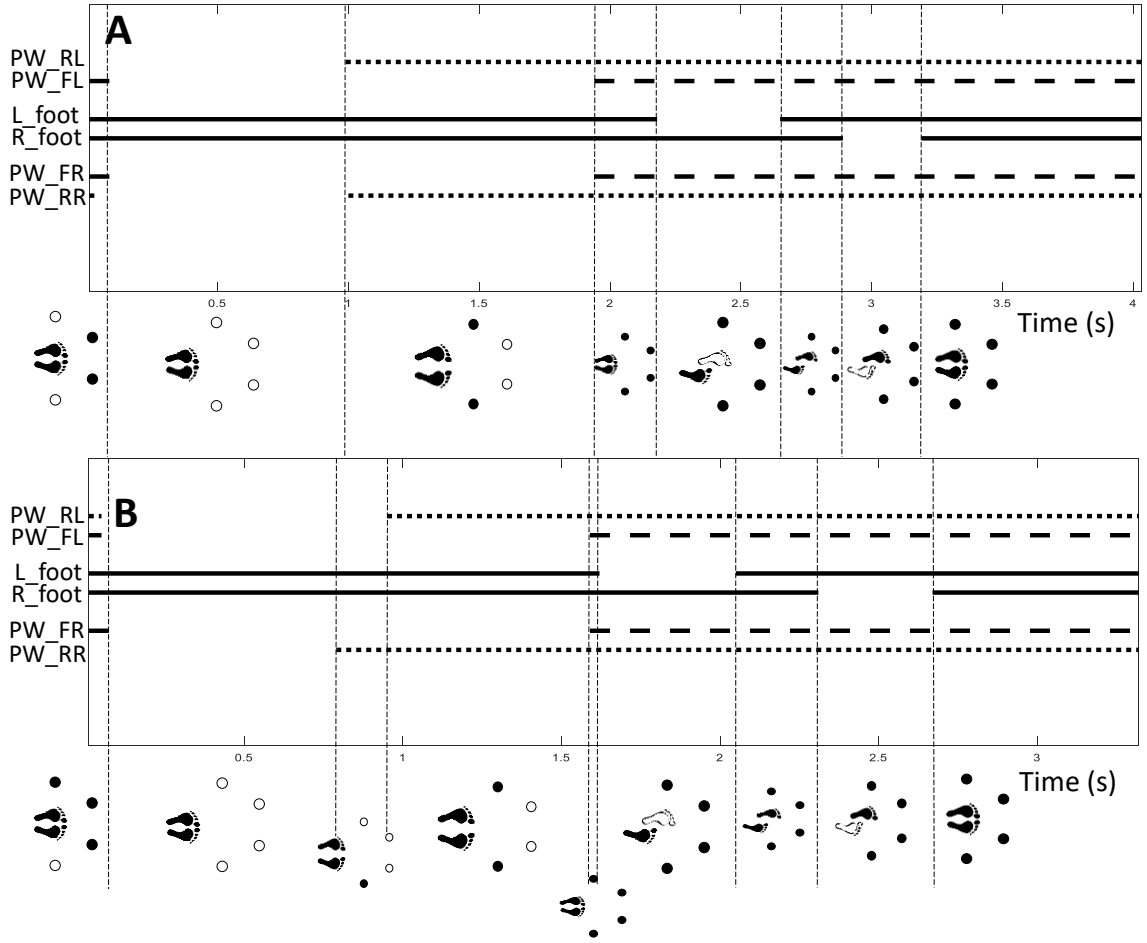


Figure 3.7: Examples of lift-off and touch-down sequence of user's and device feet for one movement cycle when walking with a PW in accordance with clinical guidance (A) and when walking with a phase of single support during which only one anatomical foot is on the ground, followed by a mediolateral rolling of the device at touch-down (B). Foot prints indicate gait phases (black foot prints indicate stance; white foot prints indicate swing), and dashed lines represent touch-down/lift-off events of anatomical and/or PW feet.

Figure 3.8 and Figure 3.9 show four examples of the timings of PW movements in relation to foot movements for one gait cycle obtained during straight line walking and one during turning for both the young adult (Figure 3.8) and the PW user (Figure 3.9). For the purpose of this study, the gait cycle is defined as the period starting when the first PW foot is lifted off the ground and finishing at the following first lift-off event of the PW. According to clinical guidance, Figure 3.8 represents an example of correct use as the young user only steps after the PW is firmly on the ground. Similarly, the older PW user demonstrates correct use of the device during

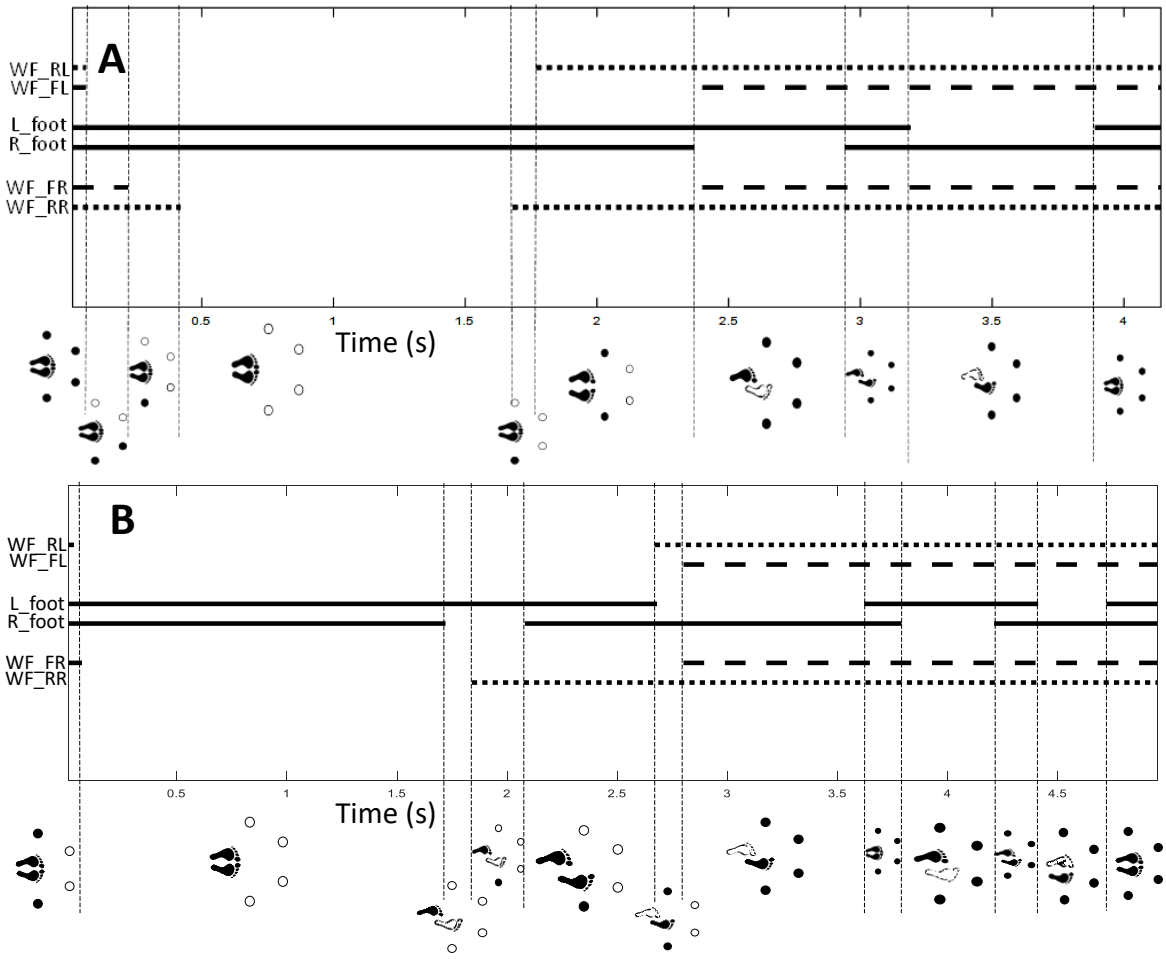
straight line walking (Figure 3.9 A), however, during turning (Figure 3.9 B) the older user steps while the PW is still airborne (creating a single support phase). This contradicts clinical guidance and Figure 3.13 B shows that stepping while the walker is airborne greatly decreases the stability margin during that phase.



PW_RL: walking frame rear left foot;
PW_FL: walking frame front left foot;
PW_FR: walking frame front right foot;
PW_RR: walking frame rear right foot;

L_foot: user's left foot;
R_foot: user's right foot;

Figure 3.8: Movement sequence: horizontal lines indicate times where feet of user and/or PW are grounded. Young adult following clinical guidance to only move themselves once the walker is solid on the ground for both, straight line walking (A) and turning (B). Dashed lines represent touch-down/lift-off events of anatomical and/or PW feet.



PW_RL: walking frame rear left foot;
PW_FL: walking frame front left foot;
PW_FR: walking frame front right foot;
PW_RR: walking frame rear right foot;

L_foot: user's left foot;
R_foot: user's right foot;

Figure 3.9: Movement sequence: lines indicate times where feet of user and/or device are grounded. Older PW user following clinical guidance to only move themselves once the walker is solid on the ground for straight line walking (A) but lifting and moving their right foot whilst the walker is still in the air during turning (B). Dashed lines represent touch-down/lift-off events of anatomical and/or PW feet.

3.3.3 Characterization of System Stability

Table 3.2 summarises the number of movement cycles for the young adult and the PW user in the ADL flat and presents terminal swing phase duration, minimum SM_{system}, and mean rate of change of SM_{system}, all averaged over the total number of gait cycles for both participants.

Table 3.2: Number of movement cycles and descriptive statistics for the Stability Margin and its rate of change.

	Total number of cycles	**Num. Straight line walking cycles**	**Num. Turning cycles**	**Average cycle duration (s)**	**Min SM_{system} (mm)**	**Pos. Mean rate of change of SM_{system} (m/s)**	**Neg. Mean rate of change of SM_{system} (m/s)**
YA	18	8	10	3.42	77.76	0.24	-0.37
PW user	16	10	6	4.82	64.9	0.15	-0.23

Figure 3.10 A-B and Figure 3.11 A-B illustrate the CoPs of the PW (CoP_{PW}), the user (CoP_{User}), and the combined system (CoP_{system}) – each in relation to their respective BoS for two different time instants of the overall movement cycle. Figure 3.10 A shows CoP_{PW} on the edge of BoS_{PW}, which, if viewed on its own, would indicate instability. However, this is because the PW is about to be lifted, which is part of the general movement cycle. When looking at CoP_{system} in Figure 3.10 B, it becomes clear that it is very close to CoP_{User} and well within BoS_{system} and, therefore, the system is stable even though the device alone appears unstable. Similarly, in Figure 3.11 A, CoP_{User} is near the outer edge of BoS_{User} (right foot single support) due to leaning onto the device, however, as the device is providing substantial support, CoP_{system} is well within BoS_{system} (Figure 3.11 B) and therefore one can conclude that the overall system is stable, even though the user alone appears unstable.

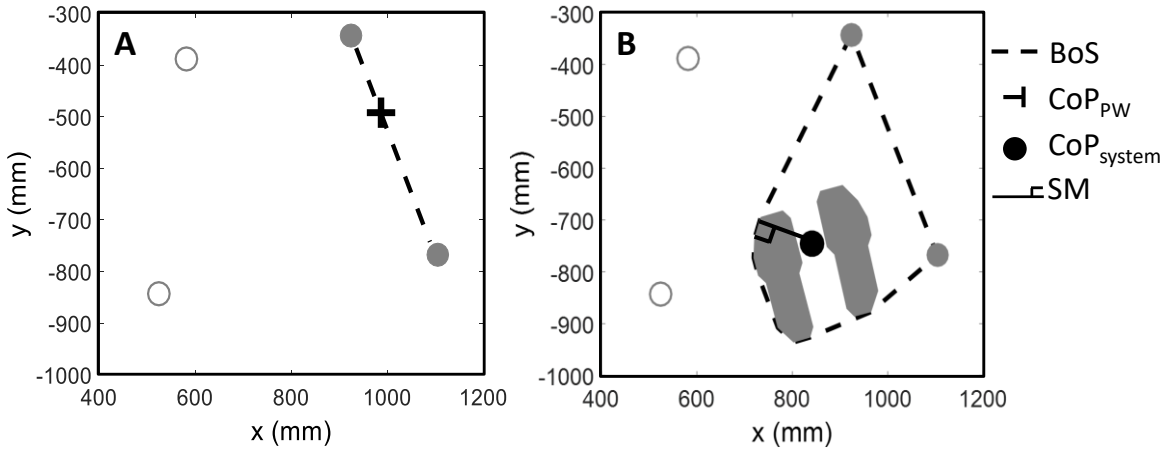


Figure 3.10: Illustration of (A) Pick-up walker centre of pressure (CoP_{PW}) alone in comparison to (B) combined centre of pressure (CoP_{system}) for an instant in time during which only two feet of the pick-up walker are on the ground, highlighting the importance of CoP_{system} in relation to the combined base of support (BoS_{system}) for accurate evaluation of the moving system's stability. Grey foot prints indicate stance; white foot prints indicate swing.

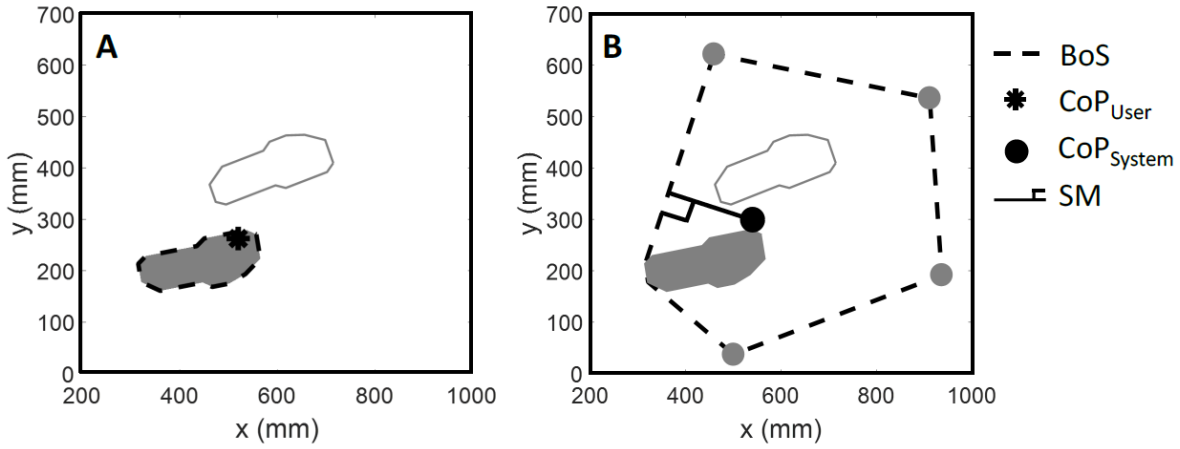


Figure 3.11: Illustration of (A) user's centre of pressure (CoP_{User}) alone in comparison to (B) combined centre of pressure (CoP_{system}) for an instant in time during which only the user's right foot is on the ground and the user is leaning forward onto the pick-up walker, highlighting the importance of CoP_{system} in relation to the combined base of support (BoS_{system}) for accurate evaluation of the moving system's stability. Grey foot prints indicate stance; white foot prints indicate swing.

By graphically representing the variation of the instantaneous stability margin (SM_{system}) over time, the user's overall stability in relation to different movement

patterns and walking conditions can be characterized. Figure 3.12 A-B respectively illustrate the SM_{system} for the same straight line walking and turning gait cycles represented in Figure 3.8 A-B for the young adult. Similarly, Figure 3.13 A-B illustrate the SM_{system} for the same straight line walking and turning gait cycles represented in Figure 3.9 A-B for the PW user. It is evident that, for both the young adult and the PW user, SM_{system} reaches its maximum when the PW is grounded. During turning however (Figure 3.13 B) the SM_{system} for the PW user drops to 12.7 mm and is approximately 5 times lower than during straight line walking (Figure 3.13 A) and 6.5 times lower than the minimum SM_{system} for the young adult during turning (Figure 3.12 B). It should also be noticed that, in Figure 3.13 B, the SM_{system} reaches its minimum when the PW user is in single support. Nevertheless, the rate of change of the SM_{system} indicates that, although the instantaneous Stability Margin value during single support appears to be low, it is increasing, suggesting that the CoP_{system} is moving towards a more stable position. Similarly, the projected stability margin predicts that an imminent change of BoS_{system} will cause the SM_{system} to increase, thereby improving the stability of the system (Figure 3.13 C). In contrast, in Figure 3.13 A, SM_{system} decreases drastically at the onset of the second step reaching the value of 66 mm (45 mm lower than that relative to the same event in Figure 3.13 B), thus suggesting increased instability probably due to the user's posture being excessively upright.

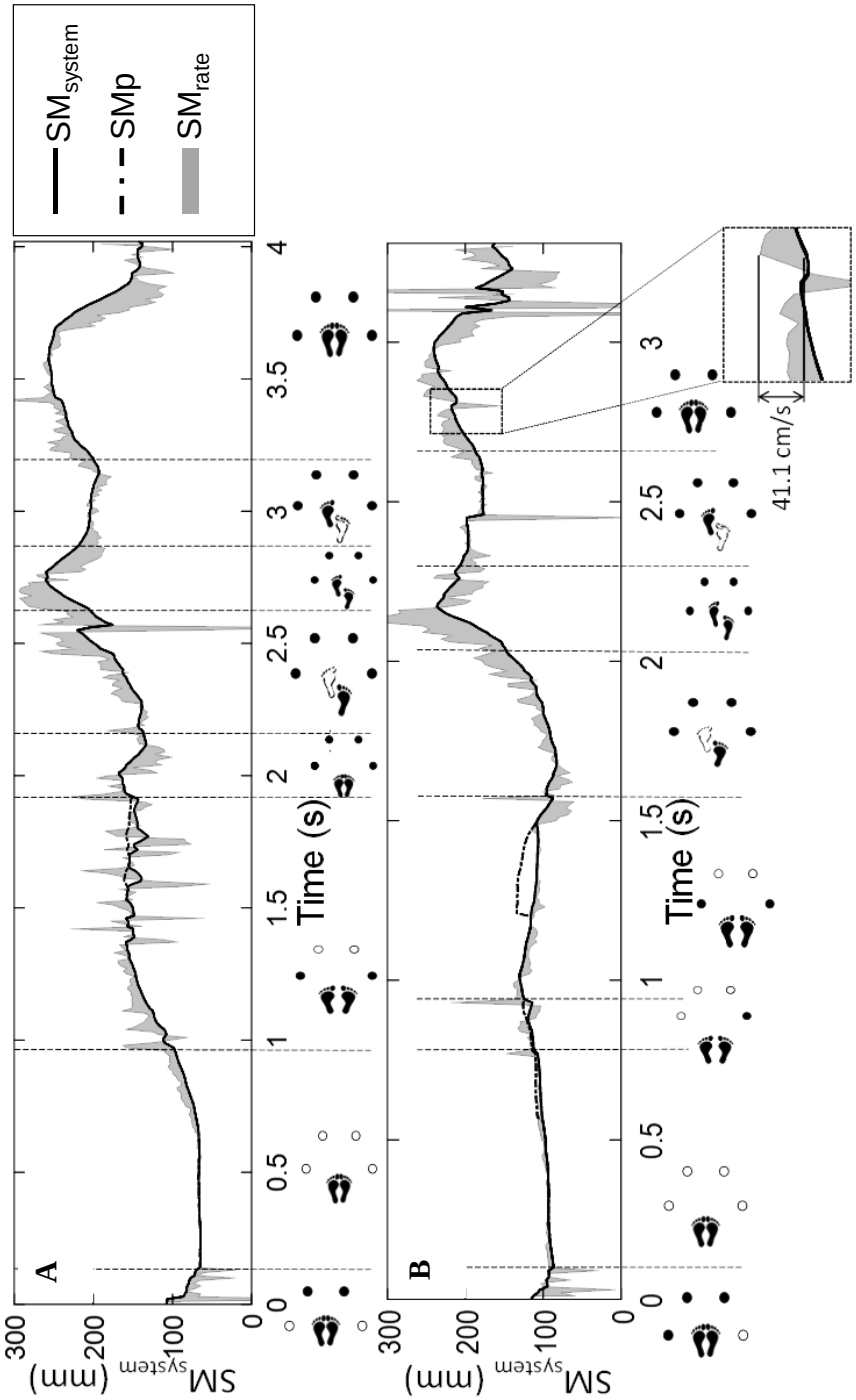


Figure 3.12: combined stability margin (SM_{system}) over a gait cycle for a young adult A) walking in a straight line in the ADL flat, and B) for a 90 degree turn in the ADL flat. The grey area shows SM_{rate} (i.e., the rate of change of SM_{system}) in units of cm/s (note that the 0 value has been shifted to lie on top of SM_{system}), whilst SM_p represents the projected Stability Margin in mm, which takes into account not just the feet already in contact with the ground, but also those where touch-down/lift-off is imminent. It can be observed that SM_{rate} presents very high peaks (low troughs) in correspondence to touch-down (lift-off) events of one or more feet: this is due to the instantaneous change in the BoS. For clarity of illustration, only phases that last longer than 0.1 s are represented by footprints.

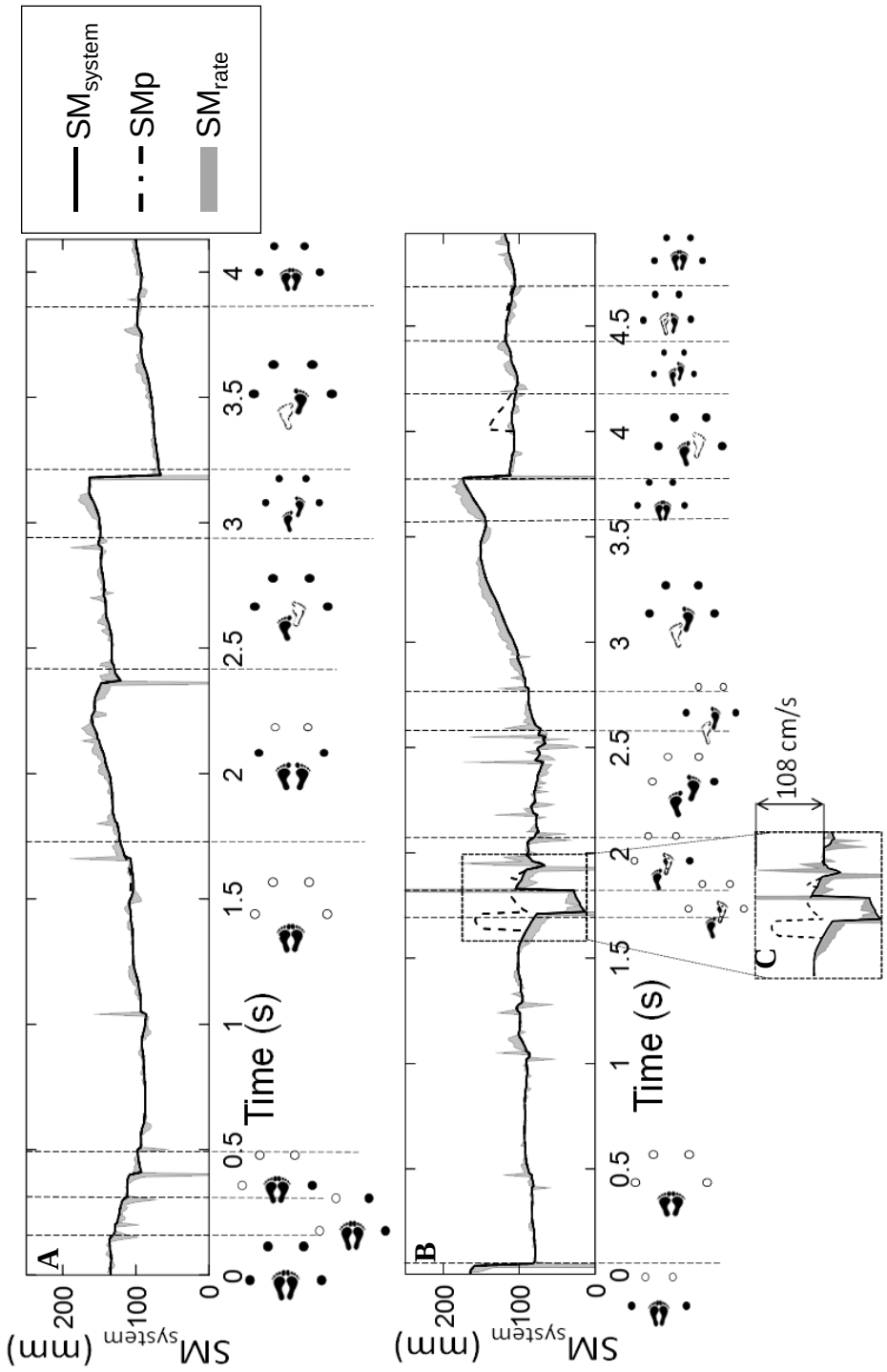


Figure 3.13: combined stability margin (SM_{system}) over a gait cycle for a PW user A) walking in a straight line in the ADL flat and B) performing a 90 degree turn in the ADL flat. C) The grey area shows SM_{rate} (i.e., the rate of change of SM_{system}) in units of cm/s (note that the 0 value has been shifted to lie on top of SM_{system}), whilst SMp represents the projected Stability Margin in mm, which takes into account not just the feet already in contact with the ground, but also those where touch-down/lift-off is imminent. It can be observed that SM_{rate} presents very high peaks (low troughs) in correspondence to touch-down (lift-off) events of one or more feet: this is due to the instantaneous change in the BoS. For clarity of illustration, only phases that last longer than 0.1 s are represented by footprints.

3.3.4 Characterization of Device Loading

Figure 3.14 shows a greater device loading for the PW user as compared to the young subject during straight line walking: whilst the young adult uses the device only for light touch support, the older PW user uses it for structural support.

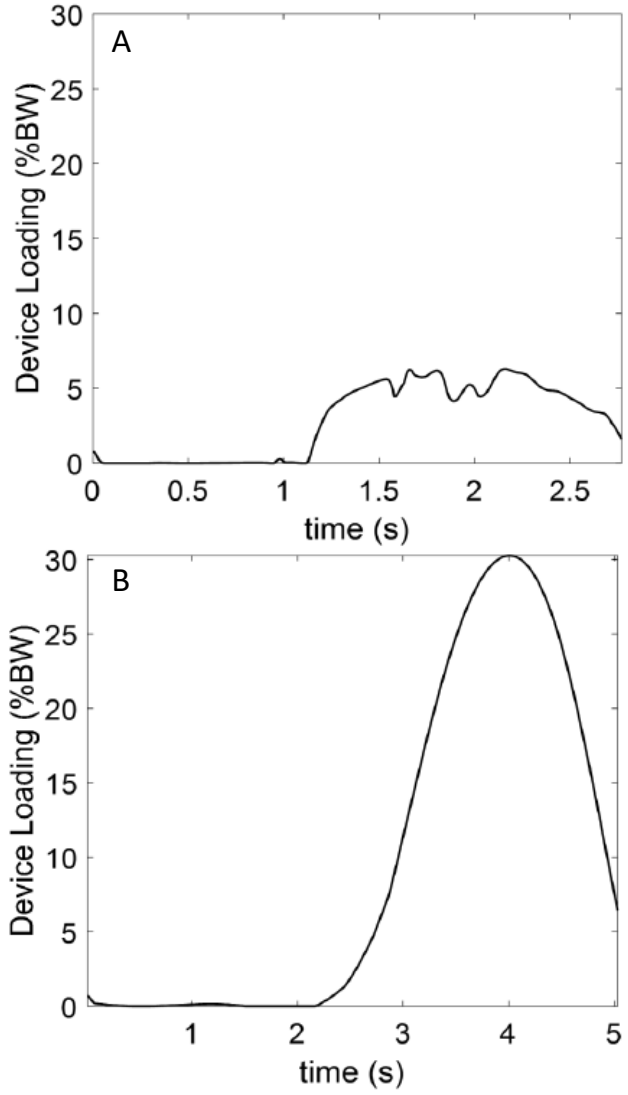


Figure 3.14: Device loading over a single gait cycle: A) using the device for light touch support (young adult) versus B) structural support (PW user) in the ADL flat when the device is grounded.

3.4 Discussion

We have developed and then demonstrated a novel method for the investigation of stability in walking aid users in a standardized home setting. Specifically, we have introduced a novel outcome measure which is generalizable to a range of walking aids, the stability margin of the combined system (user + device), and we have demonstrated that the stability margin of the combined system should be used for making inferences on PW user stability. Our stability margin was adapted from the walking robot literature (Vukobratović and Stepanenko 1972, Kar 2003, Kajita and Espiau 2008, Liu 2009) but, in order to take full account of weight, acceleration (linear and angular), and externally applied forces, the CoP was used instead of the vertical projection of the centre of mass. Indeed, although these two measures correspond when there is negligible acceleration and no external forces applied, in dynamic situations, tipping begins when the CoP, not the centre of mass, reaches the boundary of the base of support. Previous authors have investigated the kinematics of the CoP_{PW} and device loading for their inferences on stability and have concluded that, when the PW is on the ground, the user's loading of the device is directly proportional to the risk of falling (Pardo, Deathe et al. 1993, Tung, Chee et al. 2015). Their approach did not correctly quantify stability, relied on all four feet being on the ground making it inapplicable to cases when the PW was airborne or in the process of touching-down/lifting-off, and could not distinguish tipping from lifting of the device. Conversely, our approach is able to assess stability during all phases of gait, including when the PW is fully or partially grounded, but also when it is completely airborne (in which case BoS_{system} reverts automatically to BoS_{User}).

In this study, to calculate the stability margin, we recorded load cell, insole, and 3D position data of the device feet and anatomical feet. Moreover, although the stability margin is normally sufficient to describe PW use, in order to also take into account dynamic situations (e.g., when the user is in single support) or those situations in which a low SM_{system} does not indicate instability but is due to imminent touch-down of the PW or heel-strike of the next stance foot, the rate of change of the SM_{system} and the projected Stability Margin are also calculated. In addition, our system informs on the user's device loading based on the percentage of their body weight supported by the device. This information is expected to be particularly useful for clinicians who, especially during rehabilitation programmes, recommend their patients to transfer a specific amount of body weight onto the device as this is supposed to optimise the healing and recovery process. However, without any means of measurement, it is extremely difficult for the patient to follow such instructions and for the physiotherapist to evaluate the patient's compliance with these. Finally, the system further informs on the timings of user and device movements individually and in combination with one another to assess whether the movement sequence conforms with clinical guidance. Since our approach is generalizable to other walking aids, including crutches and walking sticks, it opens up significant opportunities to investigate stability in users of other devices.

However, it should be noted that, although the methodology introduced in this paper (i.e., the use of the combined stability margin) is generalizable, device-specific modifications to accommodate the load cells in such a way as to accurately measure vertical ground reaction forces may be required.

Moreover, at this stage, the SWAS is designed to report on stability only and cannot be utilized as a long-term monitoring or fall detection tool. Therefore,

although it is able to detect a reduction in stability, it cannot inform on the circumstances that caused such reduction. For this, additional instrumentation such as video cameras or inertial sensors would be needed to identify underlying causes such as collisions of the walker with either the user's feet or objects of the environment.

Finally, to calculate the stability margin, the SWAS system relies on knowing the location of the CoP of each anatomical foot with respect to the PW. At present, we use optoelectronic cameras to obtain the required position data of the anatomical and walking aid feet, but in future a more portable solution based on dedicated position sensing is required for home use.

Longer term, this method is expected to contribute to improved device prescription, user training & monitoring, and device design, all of which should impact positively on the quality and the frequency of use.

3.5 Supplement A

The table below shows the basic gait parameters for the pick-up walker user (PW user) and the young adult (YA). All parameters are presented as mean ± SD calculated over the total number of gait cycles (16 for the PW user and 18 for the young adult).

Walking speed has been derived from the displacement, in the walking direction, of a heel marker over time. Step time has been calculated as the time between two consecutive heel strikes, whilst swing time as the time between consecutive heel strike and toe off of the same foot.

As it can be seen, the standard deviation values of most parameters are large compared to their respective mean values. In addition, the young adult has considerably greater step length, walking speed, and foot clearance (mainly seen on the left foot) and considerably lower step time than the PW user.

When using a pick-up walker, the user generally moves the device forward, then steps with the “leading” foot, and, finally, with the “trailing” foot, ending the gait cycle with both feet parallel and on the ground. As expected, a slight difference in the swing time of left and right foot of both subjects was found which could be explained by the fact that the trailing foot only closes-in on the first foot, which is a quicker action then the initial step forward with the leading foot. In both participants, the step time of the left and right foot differ greatly: this is likely due to the characteristic movement of the user, which typically involves two steps towards the pick-up walker, followed by a pause in stepping, during which the walker is moved forward.

Table 3.3: Basic gait parameters for the pick-up walker user (PW user) and the young adult (YA). All parameters are presented as mean ± SD calculated over the total number of gait cycles (16 for the PW user and 18 for the young adult).

	Step Width (mm)	**Step Length left (mm)**	**Step Length right (mm)**	**Walking speed (m/s)**	**Foot clearance left (mm)**	**Foot clearance right (mm)**	**Swing time left (s)**	**Swing time right (s)**	**Step time left (s)**	**Step time right (s)**
PW user	135.88 ± 27.86	140.71 ± 88.7	138.04 ± 55.49	0.08 ± 0.39	47.90 ± 18.93	44.18 ± 11.97	0.47 ± 0.18	0.40 ± 0.13	2.05 ± 1.4	3.94 ± 1.81
YA	129.28 ±47.23	301.09 ± 108.28	301.14 ± 129.38	0.20 ± 0.77	59.59 ± 12.48	46.70 ± 33.26	0.41 ± 0.05	0.30 ± 0.06	0.57 ± 0.08	2.68 ± 0.96

4 Design and development of a smart rollator for the assessment of stability of rollator users

4.1 Introduction

As discussed in Chapter 3, we have developed and then demonstrated a novel method for the investigation of stability in walking aid users which is generalizable to a range of walking aids. The advantage of our method over current falls-risk tests and clinical interventions that almost entirely focus on unassisted walking is that it is designed to directly reflect stability of walking aid users. In addition, it is based on an objective mechanical principle, the concept of the centre of pressure, and does not rely on clinicians' subjective judgement.

Given that there are more walking frame users than users of crutches (Yeung, Chow et al. 2012) and since seven times as many injuries are associated with walking frames compared with walking sticks (Stevens, Thomas et al. 2009), this PhD had an initial focus on pick-up walkers. Moreover, the work started with pick-up walkers as they are used by extremely frail older adults who, in the event of a fall are likely to suffer severe consequences.

Nevertheless, to further demonstrate the generalizability of our novel methodology, we have instrumented a second type of walking aid, a 4-wheeled walker, also known as rollator. A rollator is a device with four wheeled legs, manual brakes, and often a seat and a basket to store personal belongings and/or shopping in (Figure 4.1). For these reasons, rollators are particularly convenient to use outdoors, and, although the exact number or rollator users is unknown, previous studies have found that, depending on the country, rollators are the most or second most used walking aid (Finkel, Fernie et al. 1997, Samuelsson and Wressle 2008). Instrumenting a rollator hence allows for any subsequent work to have an impact on a large proportion of walking aid users.

Figure 4.1: Typical rollator for outdoor use with bicycle-style brakes, a seat and a basket. Source: https://www.rollator-experts.nl/caremart-basic-rollator.

Furthermore, discussions with clinicians from various local organisations such as Pennine Acute Hospitals NHS Trust, Brain And Spinal Injury Centre (BASIC), or AgeUK revealed that, apart from extreme circumstances, they prefer to prescribe

wheeled walkers rather than pick-up walkers as such devices help the user maintain a more “fluid” walking pattern, thereby supporting the decision to develop an instrumented rollator.

The following sections present the work undertaken to design and validate an instrumented rollator to be used to characterize the biomechanics of rollator use and corresponding user stability. The work was planned in collaboration with the Geriatric Rehabilitation Clinic of the Robert-Bosch-Hospital in Stuttgart, Germany, which has been leading previous research concerned with effectiveness of rollators, has access to a wide range of rollator users, and offered us the opportunity to collect data on users’ stability with our instrumented rollator in their gait laboratory.

4.2 Design similarities with pick-up walker

This section outlines the design specifications based on the work outlined in Chapter 3. As our approach to stability of walking aid users is generalizable, the instrumentation requirements generally were common to both the pick-up walker and the rollator. Hence, the device must support:

1) Characterisation of device loading;
2) Characterisation of device and user movement;
3) Characterisation of system stability, where the system is defined as the combination of user and device.

4.2.1 Characterisation of device loading

In order to calculate device loading, the total load acting through the rollator needs to be known and can be calculated through use of suitable load cells. As is the

case for pick-up walker users, some may only use the rollator to help with their balance, whilst others may rely heavily on it for body weight support. We assume an average adult mass of 80 kg and that the total externally applied vertical load acting on the frame may vary from zero to 70% of body weight (550 N) as estimated in previous work (Ogden 2014). We also assume that this load is evenly distributed amongst the 4 legs. The estimated maximum vertical load (excluding the weight of the frame itself) through any given leg is therefore 137 N and the minimum is 0 N.

These considerations are the same previously made for the pick-up walker as the users are likely to be similar in terms of age, height, and body weight.

4.2.2 Characterisation of device and user movement

Although the movement of a rollator does not require the picking-up and moving forward of the device at every step as is the case for the pick-up walker, identification of associated events such as wheel lift-off and touch-down are relevant when characterising rollator use in specific circumstances such as when going up a step/kerb or walking on uneven ground. Consistent with the approach described in Chapter 3, detection of rollator wheel contact events can be achieved through use of suitable load cells, whilst infrared cameras will be used to detect the position of reflective markers on the rollator and person's feet, and therefore the capture of these position data is not considered part of the design specification.

4.2.3 Characterisation of system stability, where the system is defined as the combination of user and device.

As for the pick-up frame, to be able to infer on the system's stability, the load acting on each 'foot', either the anatomical foot or the rollator wheel, as well as the coordinates of all 'feet' need to be known for the calculation of the combined centre of pressure. The load acting on the rollator wheels can be measured through use of suitable load cells, whilst the same equipment as described in Chapter 3 will be used to capture the anatomical feet loads and locations of anatomical and rollator feet and, hence, is not considered part of the design specification.

Finally, all systems need to be battery-powered and able to transmit data wirelessly to guarantee freedom of movement whilst avoiding an increased risk of tripping.

4.3 Assessment of forces and moments acting on the device

It seems clear that the design requirements are similar to those previously identified for the pick-up walker. Therefore, the possibility of using the same load cells, which could be transferred between devices as required, hence avoiding the need to purchase new instrumentation, was explored. However, although only the vertical forces are of interest to calculate device loading and centre of pressure, given the necessity to locate any load sensing instrumentation above the wheels, the horizontal ground reaction forces must be also considered to estimate the resultant bending moments acting on the load cells, which, if too high, may cause damage (see Section 4.4 for details of the load cells).

To this end, Figure 4.2 shows the free body diagram of the rollator. To simplify the problem, we assume that the wheels are only in contact with smooth, level flooring.

This is a reasonable assumption for the lab work presented here, but further work would be needed before attempting to collect data in the real world. From the free body diagram, the sum of the vertical ground reaction forces equals the sum of the percentage of body weight transferred by the user onto the device through the handles plus the rollator weight ($Eq.4.1$).

$$F_z^{FL} + F_z^{FR} + F_z^{RL} + F_z^{RR} = BW_L + BW_R + W \qquad Eq.4.1$$

Where:

F_z^{FL} = Vertical ground reaction force through the front left leg;

F_z^{FR} = Vertical ground reaction force through the front right leg;

F_z^{RL} = Vertical ground reaction force through the rear left leg;

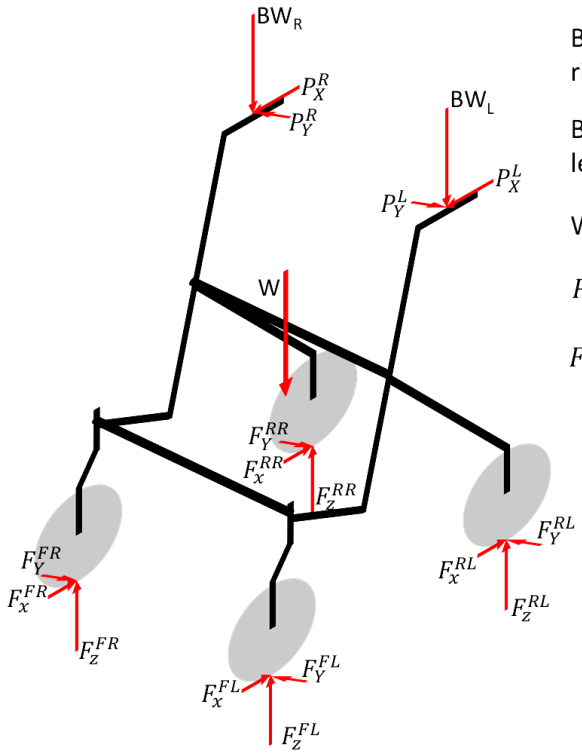
F_z^{RR} = Vertical ground reaction force through the rear right leg;

BW_L = load applied through the user's left hand;

BW_R = load applied through the user's right hand;

W = Rollator weight.

It should be noted that, as the rollator weight is known, the vertical ground reaction forces allow the total load applied by the user to the device to be calculated.



BW_R = Pushing force applied through user's right hand

BW_L = Pushing force applied through the user's left hand

W = Rollator weight

$P_{X,Y}^{R,L}$= horizontal forces applied by the user

$F_{X,Y,Z}^{FR,FL,RR,RL}$= ground reaction forces

Figure 4.2: Free body diagram of a rollator.

With regard to the horizontal ground reaction forces, these vary depending on whether or not the brakes are activated. If the rollator is accelerating/decelerating the resultant force in the walking direction is given by $Eq.4.2$ and $Eq.4.3$:

$$P_x^L + P_x^R - (F_x^{FL} + F_x^{FR} + F_x^{RL} + F_x^{RR}) = ma \qquad Eq.4.2$$

$$m = \frac{BW_L + BW_R + W}{9.81} \qquad Eq.4.3$$

Where:

$F_x^{FL,}$ = Horizontal ground reaction forces due to friction through the front left leg;

$F_x^{FR,}$ = Horizontal ground reaction forces due to friction through the front right leg;

$F_x^{RL,}$ = Horizontal ground reaction forces due to friction through the rear left leg;

$F_x^{RR,}$ = Horizontal ground reaction forces due to friction through the rear right leg;

m = mass of the loaded rollator;

a = acceleration of the centre of mass of the loaded rollator in the walking direction;

P_x^L = Pushing force applied by the user through the left handle;

P_x^R = Pushing force applied by the user through the right handle.

When the rollator is either moving at a constant velocity, or static, the acceleration of the rollator can be considered equal to zero ($Eq.4.4$).

$$F_x^{FL} + F_x^{FR} + F_x^{RL} + F_x^{RR} = (P_x^L + P_x^R) \qquad Eq.4.4$$

As there is no rolling or sliding in the mediolateral direction, then the horizontal lateral ground reaction forces equal the force applied by the user in this direction ($Eq.4.5$):

$$F_y^{FR} + F_y^{RR} - F_y^{FL} - F_y^{RL} = \left(P_y^L - P_y^R\right) \qquad Eq.4.5$$

4.4 Rollator design

4.4.1 Load cell tolerance of bending moments

The relevant specifications of the load cells currently used as provided by the manufacturer are summarised in Table 4.1.

Table 4.1: Load cell specifications as provided by the manufacturer.

Manufacturer	Device name	Number of axes	Capacity	Safe overload	Measuring range
Futek	LCM300	Single-axis	1112.5 N	1668 N (equal to 150% the load cell capacity	0 – 220 N

Furthermore, upon request, the manufacturer also provided a basic equation to determine if the total external stress applied to each load cell is acceptable ($Eq. 4.6$).

$$\sigma_{max} - (A)|F_x| + (B)|F_y| + (C)|F_z| + (D)|M_x| + (E)|M_y| + (F)|M_z| \geq 0 \quad Eq. 4.6$$

Where σ_{max} is a unitless number that the load cell can withstand and takes into consideration the maximum load that the load cells can withstand in each direction, the operation temperature and/or other factors. The value is supplied by the manufacturer for each model of load cell. $F_{x,y,z}$ and $M_{x,y,z}$ are, respectively, the forces and moments in lb and in-lb acting on the load cell in the x, y, and z direction, and the coefficients A,B,C,D,E,F are reported in Table 4.2. The coefficients A-F should be used as multiplication factors only as related units were not provided. The complete product datasheet can be found in Appendix B.

Table 4.2: Coefficients for the calculation of the maximum stress that the load cell can withstand and maximum external stress acceptable (σ_{max}) as provided by the manufacturer.

Device name	Capacity	A	B	C	D	E	F	σ_{max}
LCM300	250 lb	770	770	220	1955	1955	1380	87000

It is clear from $Eq.4.6$ that, in order to conclude on the suitability of the load cells, all forces and moments acting on each one of them need to be known.

For this purpose, a young healthy adult was asked to walk with a rollator of identical design to the one purchased-to-be-instrumented along 4 force plates transferring onto the device a percentage of body weight varying between 30% and 50%. Since previous data on rollator users is scarce, the choice of such percentage was based on typical values observed in pick-up walker users; however it is believed to be sufficient to represent this new population as a previous study by Tung et al. on 3 rollator users reported percentages of device loading not greater than 12% (Tung, Chee et al. 2015).

Two different walking conditions were tested:

1) Brakes OFF: the user walked continuously without ever activating the brakes;
2) Brakes ON: for each movement cycle, the user pushed the rollator forward by a small distance, activated the brakes, and then stepped twice towards the rollator. This usage pattern, although not common (according to clinicians), has been previously observed in some rollator users (Cheng, Kenney et al. 2016).

It should be noted that, in order to calculate the rollator GRF, the user walked in such a way that only the rollator wheels made contact with the force plates and not the user's feet. Also, periods during which more than one wheel was in contact with the same force plate were excluded.

After collection, force data were lowpass filtered at 6 Hz using a 4th order Butterworth filter, and Figure 4.3 shows the filtered ground reaction forces acting on one front and one rear wheel of the rollator with the brakes activated (A-B), and not activated (C-D).

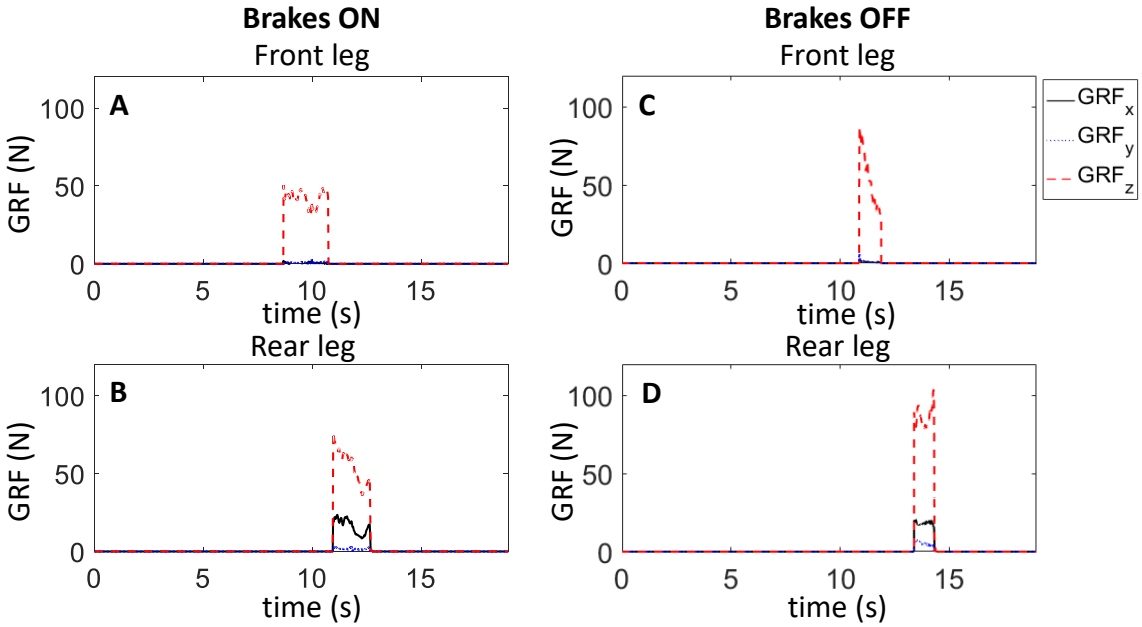


Figure 4.3: Ground reaction forces (GRF$_{x,y,z}$) acting on one front and one rear wheel of the rollator when the brakes are activated (A-B), and when the brakes are not activated (C-D). X, Y, Z indicate anteroposterior, mediolateral, and vertical direction, respectively. Force plate data have been placed equal to zero for those periods during which both (front and rear) feet are on the same force plate.

From these data, the maximum ground reaction forces acting on one front and one rear wheel of the rollator in both measuring conditions were recorded and are reported in Table 4.3.

Table 4.3: Maximum ground reaction forces acting on one front and one rear wheel of the rollator when the brakes are activated and when the brakes are not activated. X, Y, Z indicate anteroposterior, mediolateral, and vertical direction, respectively.

	Brakes ON		**Brakes OFF**	
	Front leg (N)	Rear leg (N)	Front leg (N)	Rear leg (N)
X	0.5	23.5	2.1	20.6
Y	0.2	3.8	5.8	7.4
Z	50.5	77	87.5	103.8

It is evident that the maximum vertical ground reaction force acting on one wheel of the rollator is well within the measuring range (0 - 220 N). Nevertheless, a safety factor of 3 has also been calculated to ensure that the load cells are not damaged by excessive load ($Eq.4.7$):

$$103N \times 3 = 309N \ll 1688\,N \qquad Eq.4.7$$

Where:

103 N = maximum vertical ground reaction force acting on one wheel of the rollator as measured by the force plate;

1668 N = safe overload equal to 1.5 x 1112.5 N, i.e., 1.5 times the capacity of the load cell (see Table 4.1).

Subsequently, the maximum ground reaction forces obtained above have been used to calculate the bending moments for different potential design configurations (see Section 4.4.2). Finally, $Eq.4.6$ has been calculated for each potential design configuration to determine suitability of a given design.

4.4.2 Rollator design

The original rollator required modification to accommodate the single axis load cells needed for the measurement of the vertical load acting on each wheel of the device. The rollator is shown in Figure 4.1 and, as the geometries of the front and rear legs of the rollator differ, the design of the load cell connectors had to be considered separately.

Front leg design

As the front leg is connected to the rest of the rollator through a vertical tube, it initially seemed reasonable to consider the possibility of simply screwing the load cell to each tube (Figure 4.4). To verify the suitability of such design, the moments that would act on the load cell have been calculated as shown in $Eq.4.8$:

$$\vec{M} = \vec{r} \times \vec{F} = \begin{bmatrix} \hat{\imath} & \hat{\jmath} & \hat{k} \\ 0.05 & 0 & 0.25 \\ 2.1 & 5.8 & 87.5 \end{bmatrix} = [1.45\ 3.85\ -0.29] \qquad Eq.4.8$$

Where $\vec{F}$ is the force vector representing the maximum ground reaction forces in the x, y, and z directions as reported in Table 4.3, and $\vec{r}$ is the position vector indicating the distance in space between the point of application of the ground reaction forces and the load cell in metres. After that, $\vec{F}$ and $\vec{M}$ have been converted into lb and in-lb to calculate calculated the total stress, σ, acting on the load cell ($Eq.4.9$):

$$\sigma = (A)|Fx| + (B)|Fy| + (C)|Fz| + (D)|Mx| + (E)|My| + (F)|Mz| =$$

$$= 770 \cdot 0.47 + 770 \cdot 1.30 + 220 \cdot 19.67 + 1955 \cdot 1.45 + 1955 \cdot 3.85 + 1380 \cdot 0.29 =$$

$$= 100940 \qquad Eq. 4.9$$

Considering that the maximum stress allowed (σ_{max}) is equal to 87000 (see Table 4.2), it became clear that the stress applied to the load cell due to the bending moments (100940) would exceed the maximum stress allowed, and this is due to the excessive distance between the point of application of the ground reaction forces, which is the point of contact between the wheel and the ground, and the load cell.

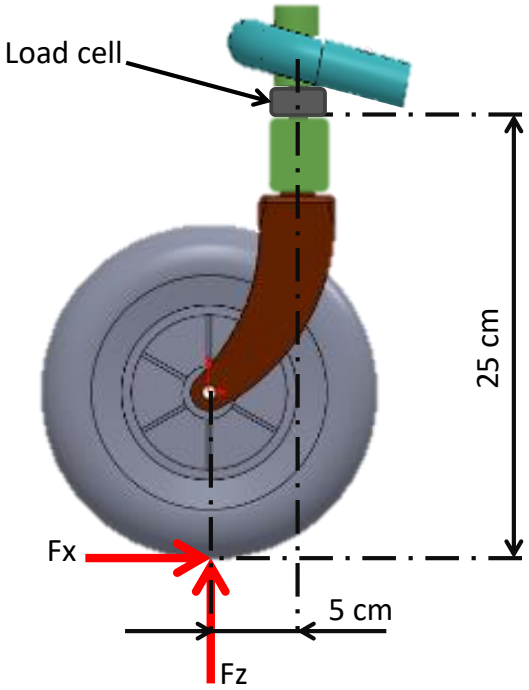


Figure 4.4: Geometry of the front wheel showing the distance in both vertical and horizontal direction between the point of application of the ground reaction forces F_x and F_z and the load cell for the case of a load cell screwed to the rollator leg. Note that the ground reaction force in the mediolateral direction, Fy, is not represented as it lies on the plane perpendicular to that shown in the figure.

Therefore, another solution was developed with the aim to reduce or, ideally, cancel the bending moments acting on the load cell. Figure 4.5A illustrates how, in the non-modified rollator, the wheel is connected to the rest of the device through

a steel piece (1) which is inserted into a sleeve (2) (to allow the wheel to swivel) and is constrained to it by a bolt (3).

Without modifying the original design, and in order to maintain the swivelling function of the wheel, a connector (4) was designed in collaboration with the Commercial Enterprise Unit to which the load cell could be fixated. In this configuration, the load cell (5) is in contact with (1) but is not screwed into it, which means that (1) restrains the load cell in the vertical direction only and is free to translate horizontally and rotate with respect to the load cell. Hence, only the vertical force is transmitted to the load cell but not any horizontal force or moment. A free body diagram of the front leg configuration is shown in Figure 4.5B.

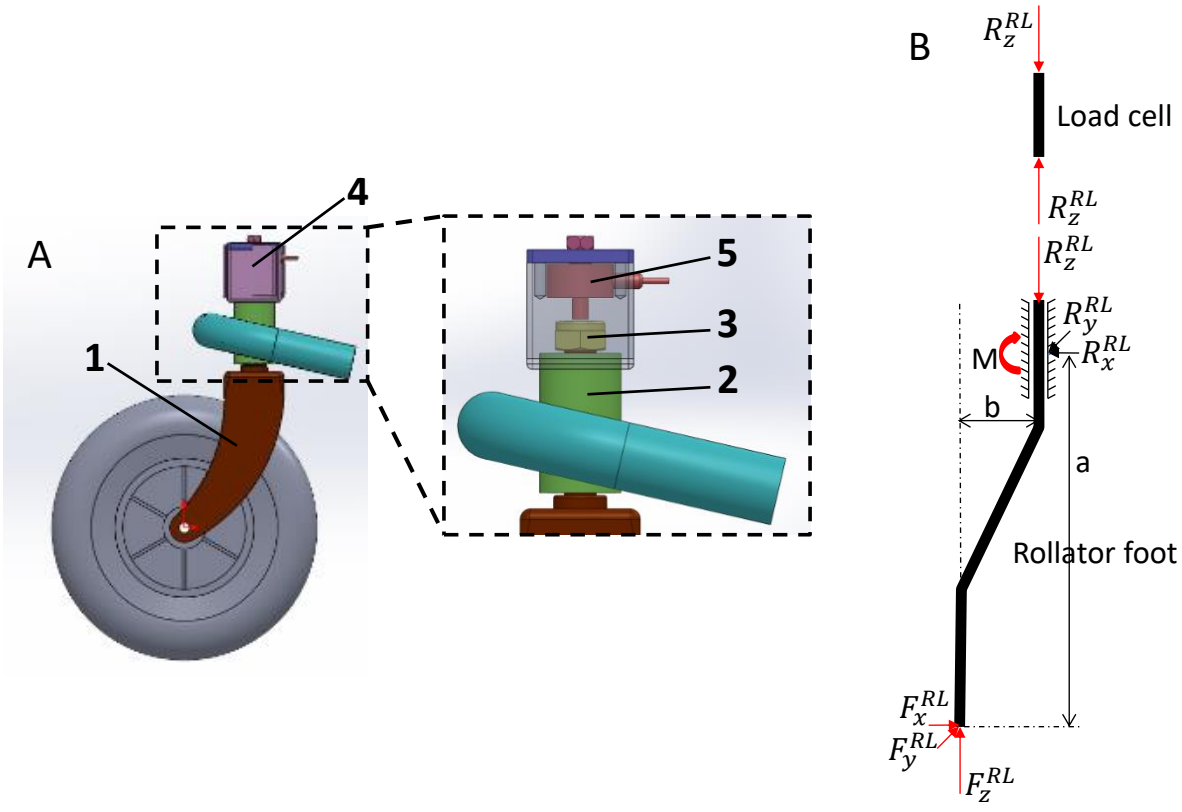


Figure 4.5: Side view and free body diagram of the design of the rollator front leg. In the free body diagram, x and z indicate the walking and vertical direction, respectively.

From the free body diagram, we have the following equations of equilibrium:

$$R_x^{FL} = F_x^{FL}$$

$$R_y^{FL} = F_y^{FL}$$

$$R_z^{FL} = F_z^{FL}$$

Finally, the moment about the point of contact between (1) and (2) is given by:

$$M = \left|\vec{r} \times \vec{F}\right| = \left\|\begin{bmatrix} \hat{\imath} & \hat{\jmath} & \hat{k} \\ 0.05 & 0 & 0.25 \\ 2.1 & 5.8 & 87.5 \end{bmatrix}\right\| = 4.12\ Nm \qquad Eq.4.10$$

Where $\vec{F}$ is the force vector representing the maximum ground reaction forces in the x, y, and z directions as reported in Table 4.3, and $\vec{r}$ is the position vector indicating the distance in space between the point of application of the ground reaction forces and the load cell in metres. However, according to the design configuration, M acts on the sleeve and not on the load cell, which therefore, is not at risk of damage.

It may be argued that with this design configuration, the amount of vertical load sensed by the load cell will be influenced by the friction between the rollator wheel bracket and the sleeve which are both made of steel. Considering a friction coefficient for lubricated steel-steel, μ, which ranges between 0.16 and 0.2, the amount of friction ($Eq.4.11$) is equal to approximately 1.23 N, which can introduce a maximum error of 1.4% on the measure of the vertical load.

$$F_f = \mu\sqrt{F_x^2 + F_y^2} = 1.23\ N \approx 0.014\ F_z \qquad Eq.4.11$$

$F_{x,y,z}$ are the ground reaction forces at the instant in time in which the horizontal forces, and therefore the friction, reach their maximum value.

Rear leg design

As with the front leg design, the bending moment due to the offset wheel precluded a simple solution. In addition, it was thought preferable to not modify the brake system that runs inside the tubing of the rear legs.

Therefore, a first design was proposed that would preserve the original leg configuration and would not affect the brake; corresponding drawing and free body diagrams of the proposed design are shown in Figure 4.6.

This design consists of placing the load cell in parallel to a connecting rod so that the load cell would be subject to axial force only, removing any risk of being damaged by bending moments. In order to calculate the axial load acting on the load cell, we can open the structure as shown in Figure 4.6C and calculate the moments around B:

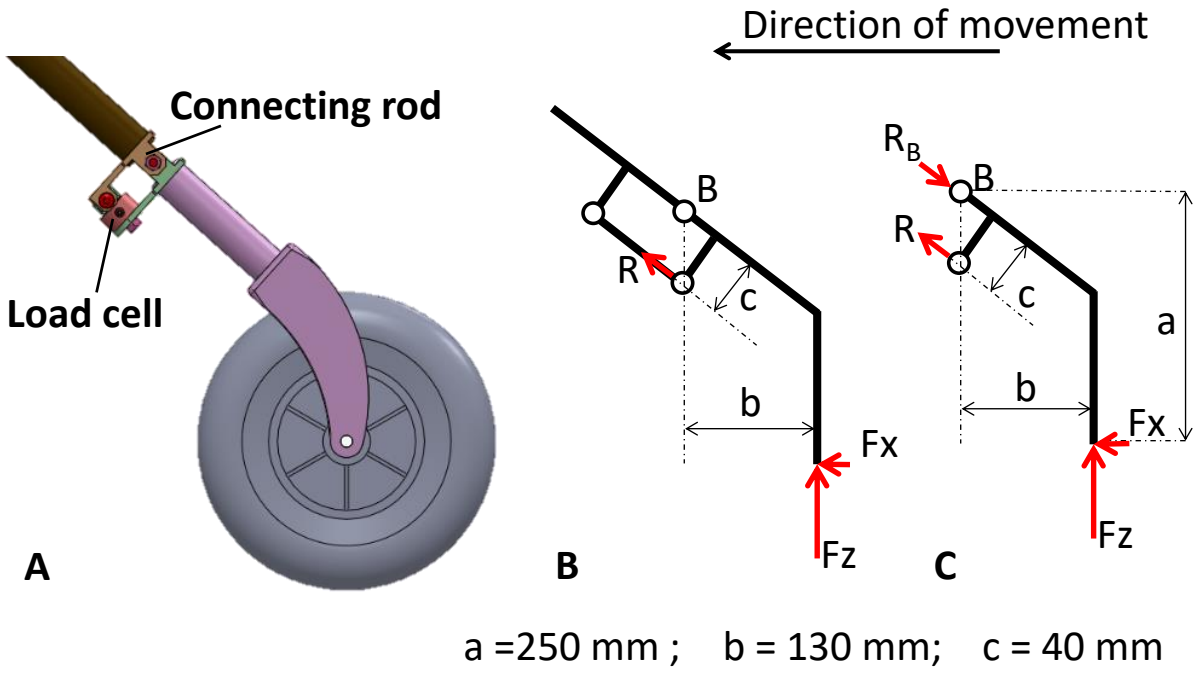


Figure 4.6: A) Side view and B) free body diagram of the first proposed design for the rollator rear leg.

$$R \cdot c + F_x \cdot a - F_z \cdot b = 0 \qquad Eq.4.12$$

$$R = \frac{Fz \cdot b - Fx \cdot a}{c} \qquad Eq.4.13$$

It should be noted that the horizontal forces acting in the mediolateral direction are not represented as they are significantly smaller compared to those in the vertical and anteroposterior direction; nevertheless, two complications emerged from $Eq.4.13$:

1) It became clear that, with this configuration, the load cell will sense not only the vertical load but also the horizontal ground reaction forces and, considering that, based on the values represented in Table 4.3, F_x can reach values equal to $\frac{1}{3} \cdot F_z = 23.5\ N$ when the brakes are activated, this would

lead to unacceptably inaccurate results (a maximum error in the measurement of the vertical load lower or as close as possible to 5% is desirable in order to achieve a level of accuracy comparable to that previously obtained for the instrumented pick-up walker, and which is known to lead to errors in the calculation of the combined centre of pressure of less than 5% (Section 3.3.1)).

2) Even if the horizontal forces were negligible, the load cell would sense an axial load equal to over 3 times the value of the vertical ground reaction force, which, considering a maximum vertical ground reaction force equal to approximately 100 N (Table 4.3, “brakes-off” condition), would be outside the measurement range.

Different design alternatives had to be considered: for example, in order to solve 2), the distance c between the load cell axis and the rollator leg could be increased, thereby reducing the axial load acting on the load cell. In addition, if it were possible to measure F_x, perhaps adding two extra load cells horizontally in the rollator handles, both the vertical and anteroposterior ground reaction forces could be determined providing information not only on device loading, but also on braking strategies. However, these options proved unfeasible in terms of bending moments and complications due to the presence of the brakes in the handles.

It was finally decided to adopt a solution similar to that for the front leg. Figure 4.7A-C shows 3D view, section view, and free body diagrams of the proposed design. It can be observed that the load cell (1) is fixated to the wheel bracket (2) and to the rollator leg (3) which, in turn, allows the rollator bracket to translate vertically but prevents it from rotating or translating horizontally. Hence, only the vertical load is transmitted axially to the load cell. Again, the interface between (2)

and (3) is lubricated steel-steel, which may introduce inaccuracy in the measurement of the vertical load due to friction. $Eq.4.11$ can be used to calculate the maximum friction force. Since, due to the brakes acting on the rear wheel, the horizontal ground reaction force in the anteroposterior direction is significantly higher than that experienced by the front leg, the error in the calculation of the vertical load due to friction can reach values equal to 6.2%. Use of linear ball bearings (which have a coefficient of static friction equal to 0.005) at the interface with the rollator wheel bracket were considered to decrease the friction, but this would have required modification or removal of the brake system. The former proved too expensive and time consuming whilst the latter would have removed a core function of the rollator, which would have compromised the user's safety. Hence the 6.2% error was accepted.

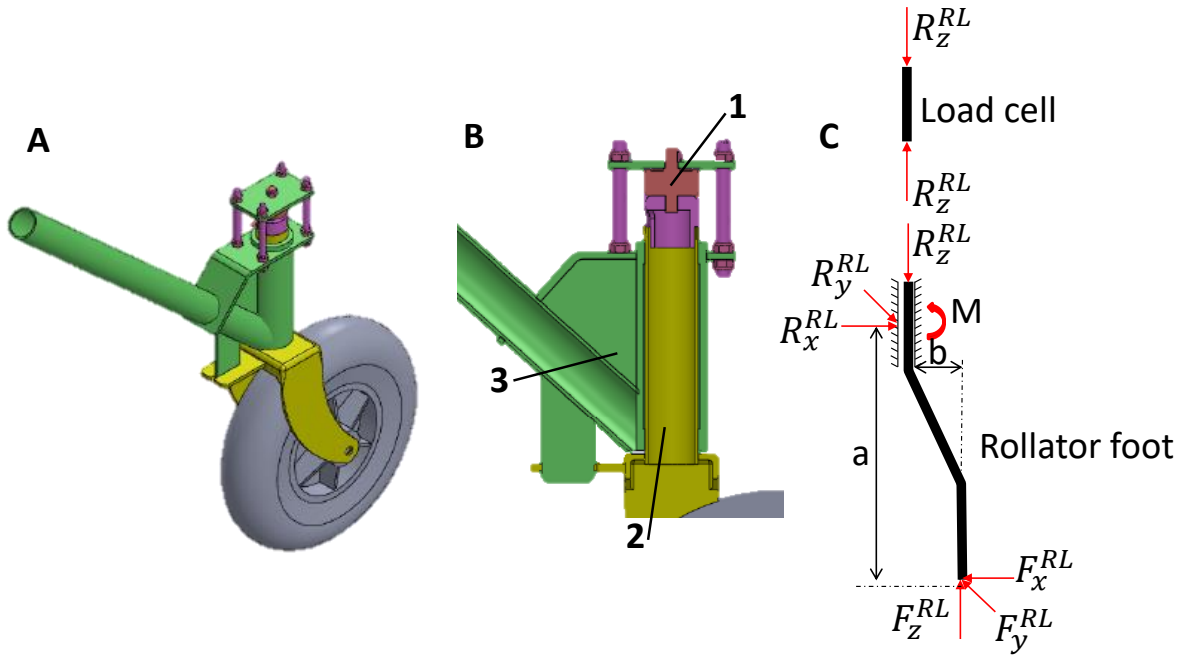


Figure 4.7: Rollator rear leg design. A) shows the 3D view, B) a section view from which it is possible to see how the load cell is connected to the rollator wheel, and C) the free body diagram.

4.5 Rollator development and manufacturing

The load cell connectors are made of steel and were manufactured by Ryder & Wallace Ltd. (Manchester, UK, http://www.ryderandwallace.co.uk/index.php), whilst the assembly of the modified rollator was carried out by the Commercial Enterprise Unit at the University of Salford.

Figure 4.8 shows a picture of the finished instrumented rollator.

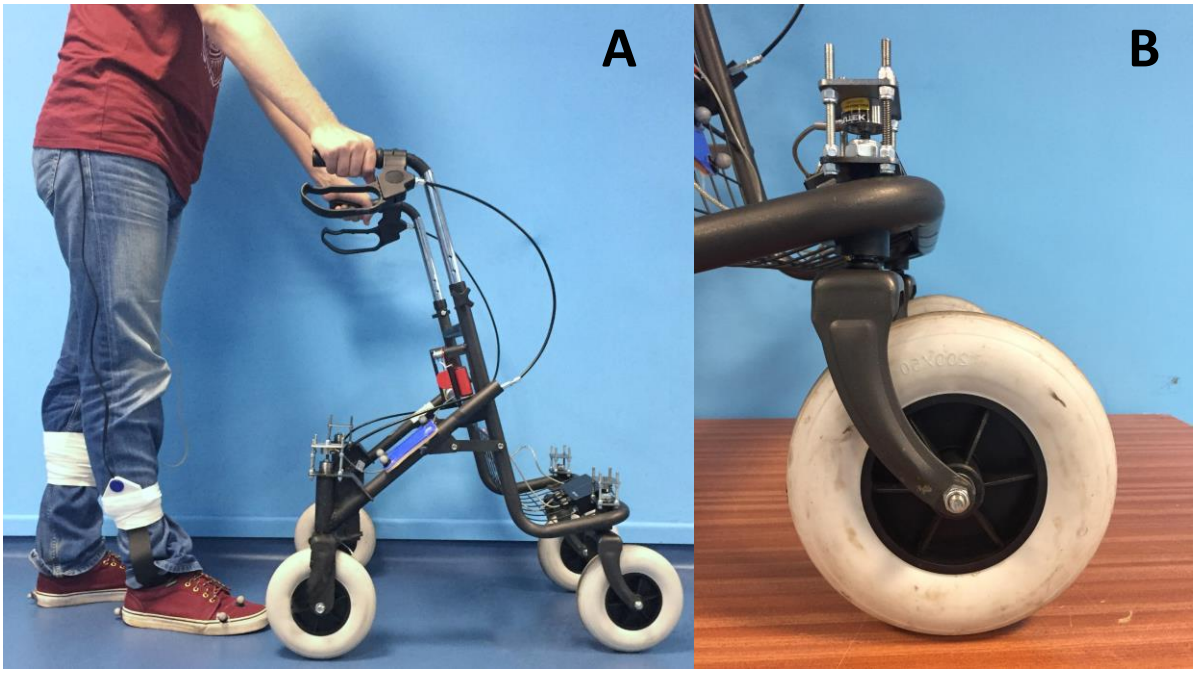


Figure 4.8: A) finished instrumented rollator. B) Detail of one instrumented 'leg'.

4.6 Validation of the instrumented rollator

Following the design phase, the accuracy of the vertical load and combined centre of pressure measured by the instrumented rollator was tested in the lab using a large 600 x 900 mm AMTI BP600900 force plate (normally used for sprinting) to allow for simultaneous contact with all 4 rollator wheels and both anatomical feet.

Methods and results of the validation of the instrumented rollator are described in the following paragraphs.

4.6.1 Accuracy of the total vertical load measured by the instrumented rollator

Methods

Data on the total vertical load measured by the load cells mounted on to the rollator and by the force plate were collected using the following procedure:

- With the rollator lifted off the floor, the 4 load cells were zeroed;
- The force plate was zeroed;
- The rollator was then placed with all 4 wheels onto the force plate;
- Instrumented rollator and force plate were synchronised using the synchronisation method described in Section 3.2.2;
- Five trials were recorded during which the rollator was gradually loaded by a young healthy adult standing outside the force plate. The load applied varied between 0% to approximately 40% of the subject's body weight (equal to 75 kg).

All data were processed and analysed in MATLAB R2016a as follows:

- The synchronisation pulses were used to time-align load cell and force plate data;
- Data were lowpass filtered at 6 Hz using a 4^{th} order Butterworth filter (the power spectrum of force plate signals was computed in order to choose the correct cutoff frequency; moreover, results were in agreement with Winter who found that, for normal walking, 99.7% of signal power is contained below 6 Hz (Winter) and other previous

studies (Fitzpatrick, Gorman et al. 1992, Carpenter, Frank et al. 2001, Chiari, Rocchi et al. 2002, Vieira, Oliveira et al. 2009));

- Maximum and Root Mean Square values of the difference between the vertical force recorded by each load cell and the corresponding data recorded with a force plate were calculated.

Results

A Maximum error of 5.8% and Root Mean Square value of 14.5 N were obtained when comparing the total vertical load recorded by the load cells to the corresponding data recorded with the force plate (Figure 4.9).

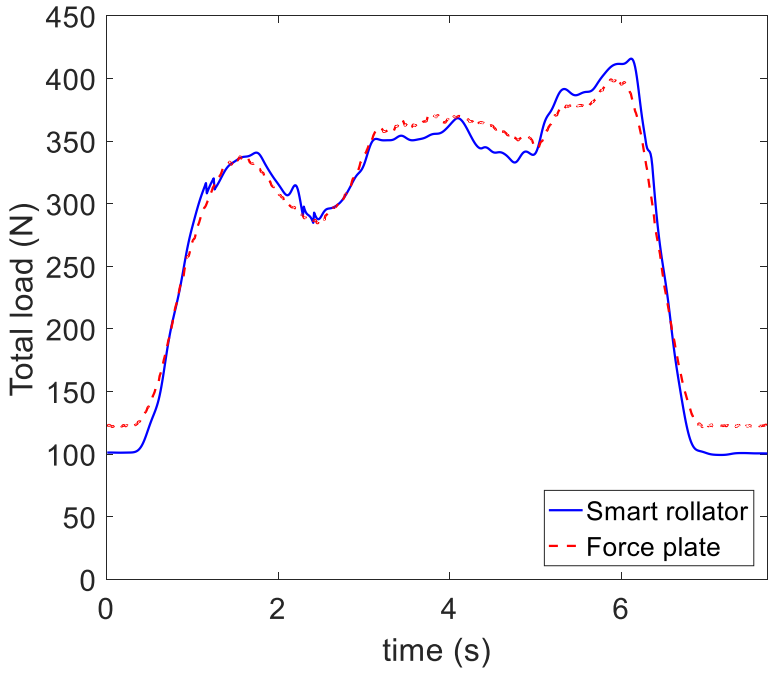


Figure 4.9: Example of comparison between the total vertical load recorded by the load cells placed into one of the rollator legs, and the corresponding force measured by the force plate.

4.6.2 Accuracy of combined centre of pressure

Methods

The data necessary for the calculation of the combined centre of pressure from both the instrumented rollator and the force plate were collected using the following procedure:

- A subject was asked to wear laboratory shoes (with attached reflective markers) in which Medilogic pressure insoles had been previously placed;
- Reflective markers were also attached to the rollator wheels;
- With the rollator lifted off the floor, the 4 load cells were zeroed;
- The force plate was zeroed;
- The rollator was then placed with all 4 wheels onto the force plate;
- The subject was asked to stand on the same force plate holding the rollator;
- Motion capture system, force plates, instrumented rollator and pressure insoles data were then synchronised using the synchronisation method described in Section 3.2.2;
- Five trials were recorded during which the young healthy adult leaned forward, backwards, left, and right while still holding the rollator. When leaning to the left/right, the subject was also asked to lift their right/left foot off the floor.

The trajectory of the combined centre of pressure was obtained from both the instrumented rollator (using the software developed in Chapter 3) and the force plate; after that, Maximum and Root Mean Square values of the difference between

the coordinates in AP and ML direction of the combined centre of pressure as calculated by the instrumented rollator, and the corresponding data recorded with a force plate, were calculated.

Results

A Root Mean Square difference equal to 10.18 mm in AP direction and 11.93 mm in ML direction were obtained when comparing the combined centre of pressure as calculated by the instrumented rollator to the corresponding data recorded with the force plate. With regard to the maximum difference, this was equal to 24.83 mm in AP direction and 19.8 mm in ML direction, which we considered acceptable being equal, respectively, to 3.67% and 3.36% of the width and length of the combined BoS in the testing conditions studied. An example of the comparison between the combined CoP calculated by the instrumented rollator and that calculated by the force plate is shown in Figure 4.10.

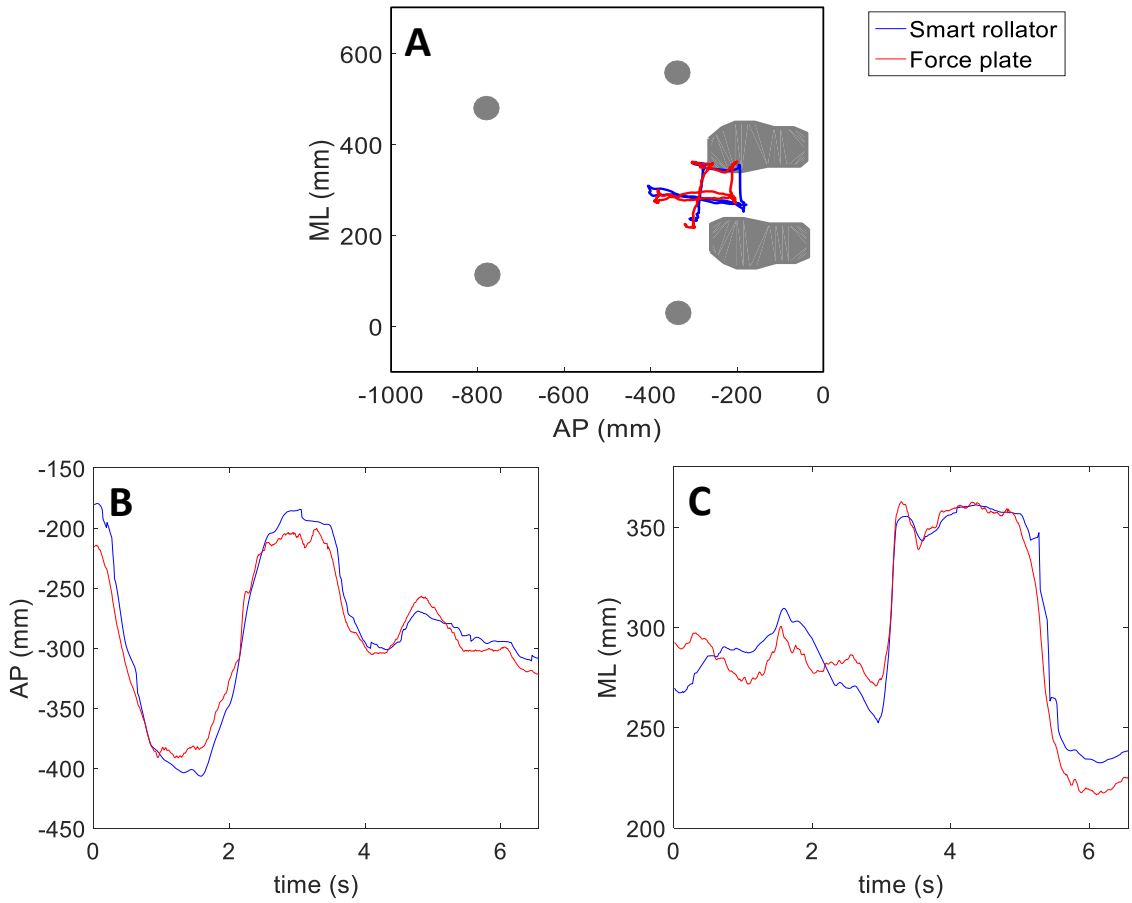


Figure 4.10: Comparison between the combined CoP calculated by the instrumented rollator and that calculated by the force plate. A) combined CoP trajectory; B) combined CoP coordinates in AP direction; C) combined CoP coordinates in ML direction.

4.7 Discussion and conclusions

This chapter presented the work undertaken to design, develop, and validate an instrumented rollator for the characterisation of stability of rollator users following the methodology developed in Chapter 3.

By modifying the design of the rollator legs it was possible, despite the substantial difference between the geometry of rollators and that of pick-up walkers, to re-use the same load cells, which was highly desirable in order to contain costs.

However, this also meant that a lower accuracy in the measurement of the vertical load acting through the rollator legs had to be accepted. A simple design such as

that used for the pick-up walker, which consisted of the load cell being screwed directly into the device's leg, would have damaged the load cell due to excessive bending moments, hence a design that avoids bending moments to be transferred to the load cell had to be adopted with the downside of introducing errors in the measurement due to friction. To overcome this issue, the use of linear ball bearings, which have a lower coefficient of friction compared to lubricated steel, at the interface with the rollator wheel bracket was also considered, but this would have required further expensive and risky (in terms of user's safety) modification or complete removal of the brake system. Therefore a 6.2% maximum error in the measurement of the total vertical load was accepted.

Moreover, we acknowledge that the current load cells only measure the load acting through the vertical axis and ignore horizontal forces, hence preventing a complete characterisation of the interaction between user and device. However, the vertical forces are sufficient for the calculation of the centre of pressure.

Finally, the tests performed to verify the accuracy of the total vertical load (needed for the calculation of both device loading and combined stability margin) as measured by the instrumented rollator confirmed that the difference between rollator and force plate measurements was consistent with and slightly lower than the maximum error estimated during the design phase. Regarding the accuracy of the combined centre of pressure, this was also acceptable (<4% in both AP and ML direction) and comparable to that previously found for the pick-up walker.

Hence, despite the several assumptions and limitations of the design, the newly developed instrumented rollator was considered suitable for assessing stability of rollator users in the lab.

5 Objective measures of rollator user stability and device loading during different walking scenarios.

This chapter is under review on PLOS ONE with the title: “Objective measures of rollator user stability and device loading during different walking scenarios”.

5.1 Introduction

Falls and fall-related injuries among older people are a major health problem; around 40% of the over 65s living at home are estimated to fall at least once a year, with around one in forty of the falls leading to hospitalisation (Rubenstein 2006). The incidence of falls and the severity of the consequences increase rapidly with age, and falls are leading causes of death in this age group (Rubenstein 2006, NHS 2014). Falls cost the NHS an estimated £2.3 billion per year (NICE 2013) and the social impact of falls on the individual and families can be overwhelming (Faes, Reelick et al. 2010). As the number of over 65s is due to double by 2050, without urgent action the number of fall-related injuries is certain to dramatically increase.

Regarding the circumstances of falls, ‘walking’ has been reported as the activity during which 48% of community-dwelling residents came to fall (Berg, Alessio et

al. 1997). Walking is an activity during which a walking aid such as a walking stick or walking frame can provide weight-bearing support. Indeed, 22% of older adults in the UK use a walking aid indoors, and 44% use one outdoors (Lofqvist, Nygren et al. 2007). However, rather counter-intuitively and the motivation for our research, general walking aid use (classified on a “yes”/”no” basis) has been shown to be a risk factor for falling (Deandrea, Lucenteforte et al. 2010), and injuries have been reported due to falling “whilst using” a walking aid (Hefflin, Gross et al. 2004). Unfortunately, this published data fails to capture any detail on how the devices may have been used, in general or at the time of the fall. To date, walking aid use as a means of fall prevention remains an under-researched area. Without doubt users of walking aids are intrinsically vulnerable and therefore likely to fall. For a walking aid to be effective in preventing a fall, it first and foremost must be used in a stable and safe manner. However, at this time it is unknown whether walking aids are used according to the user guidance and training currently provided, and whether that guidance/training indeed facilitates stable, and therefore safe, use of walking aids.

Nevertheless, a vast number of clinical and manufacturer leaflets exist that aim to provide straight-forward instructions to users of walking aids. Guidance is generally brief, with varying levels of detail between clinical trusts and/or manufacturers. Basic instructions appear sensible, however, they fail to address everyday tasks such as turning in confined spaces, opening doors, and negotiating obstacles and changes in flooring level, some of which have previously been reported to be problematic (Lindemann, Schwenk et al. 2016). Moreover, adherence to guidance is only judged via visual inspection, and the value of this is doubtful since “good use” is based entirely on subjective observation, often for only a small number of

steps taken in a straight line. To date, guidance has not been validated in relation to user stability when performing a range of everyday walking tasks, and this is of concern, especially considering the rise in numbers of walking aid users within the ageing population (Lofqvist, Nygren et al. 2007).

In this context, we recently developed a novel, objective measure of stability of walking aid users (Costamagna, Thies et al. 2017). The measure, termed the combined (or system) Stability Margin (SM_{system}), is calculated using force measurements taken from each of the walking aid legs and the user's shoes, together with the position of the anatomical feet relative to the walking aid. The smaller SM_{system}, the closer the system is to the point of tipping over, and the more susceptible it is to perturbations. To measure the required forces for calculation of SM_{system}, we initially instrumented a walking frame without wheels ("pick-up walker") with load cells, which together with pressure sensing insoles and optical motion tracking allow for calculation of SM_{system}. Our approach is novel in that it considers the person and their walking aid to be a single system. We proved that combining information of walking aid and person is vital to accurately evaluate overall stability (Costamagna, Thies et al. 2017), and our approach is generalizable to a range of walking aids, including wheeled rollator frames ('rollators'). Rollators are of particular interest because their general use has been shown to be ineffective in terms of preventing serious fall-related injuries (van Riel, Hartholt et al. 2014). Interestingly, and of direct relevance to this work, users of rollators have complained about lack of training (Brandt, Iwarsson et al. 2003), with as many as 80% having received no instructions or training at all regarding the use of their device (Liu 2009).

Our approach, which provides an objective measure of stability, has the potential to support current clinical practice through evidence-based training. In the work reported here, we adapted our approach for use with a 4-wheeled rollator frame and, in a cohort of 10 in-patients in a geriatric ward, assessed stability across a range of everyday tasks. The objectives were:

1. Investigate the effects of the task being undertaken on stability. *Hypothesis:* Stability is greatest for straight line walking as compared to more complex tasks such as turning or obstacle crossing.
2. Investigate the relationship between device loading (i.e. the amount of body weight supported by the rollator) and stability. *Hypothesis:* Increased leaning onto the rollator causes the centre of pressure of the system to move forward into the base of support, thereby increasing stability.
3. Investigate the effects of rollator use strategy on stability: *Hypothesis:* the strategy employed for performance of a single task may either facilitate or impede stability.

5.2 Methodology

5.2.1 Quantification of stability

Stability of rollator users was quantified using the methodology developed by Costamagna et al. (Costamagna, Thies et al. 2017), which, for the first time, looked at the user and their walking aid as a single combined system and quantified stability by calculating the combined (system) Stability Margin (SM_{system}) of user and device from wheel-force, insole-pressure, and position data using bespoke MATLAB algorithms. SM_{system} is defined as the shortest distance between the Centre of Pressure of the combined system (CoP_{system}) and the nearest edge of

the combined Base of Support (BoS_{system}) (Figure 5.1) and indicates how far the system is from tipping; hence, the higher SM_{system}, the more stable the system is. Figure 5.1 shows how the size of BoS_{system} can vary, including double support with the rollator grounded, single support with the rollator grounded, and double support with the rollator lifted (e.g. when the user is in the process of stepping up a kerb). It seems reasonable to think that when BoS_{system} is smaller, SM_{system} is also likely to be smaller; but this should not be confused with an unsafe gait as BoS_{system} may well be being sensibly utilised. For this reason, SM_{system} has been normalised by a parameter representative of the size of BoS_{system} ($Eq. 5.1$).

$$SM = \frac{SM_{system}}{\sqrt{Area(BoS_{system})}} \qquad Eq. 5.1$$

The normalised SM_{system} (which will replace SM_{system} in this and all the following chapters and will be referred to simply as SM in this thesis) is dimensionless as it is the ratio of two lengths.

Finally, to further characterise rollator use, we also present the movement pattern (foot placements in relation to rollator movements), and device loading (DL), defined as the percentage of body weight transferred to the device through the user's upper limbs.

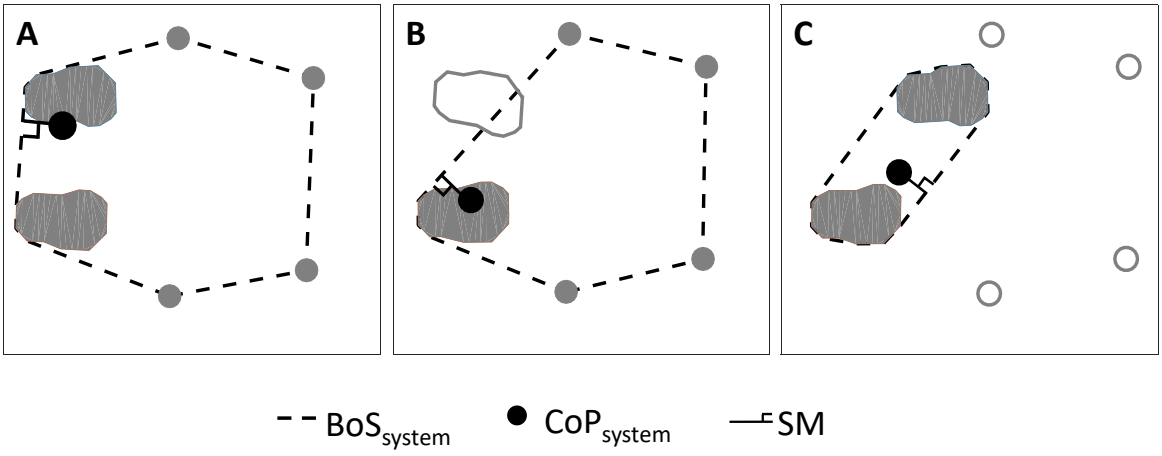


Figure 5.1: Examples of combined centre of pressure (CoP_{system}), combined base of support (BoS_{system}) and system Stability Margin (SM) for 3 cases: A) all 6 feet on the ground; B) 4 rollator feet on the ground and user in single support on their right foot; C) user in double support and rollator fully airborne (e.g. being lifted up a step). Grey foot prints indicate feet/wheels that are grounded; white foot prints indicate feet/wheels that are airborne.

5.2.2 Instrumentation

For the purpose of this study, the technology of our original instrumented pick-up walker (Costamagna, Thies et al. 2017) was adapted for a 4-wheeled rollator. The instrumentation includes 4 single axis load cells (Futek LCM300, FUTEK Advanced Sensor Technology Inc., Irvine, California) and corresponding transmitters (Mantracourt T24-ACMi, Mantracourt Electronics Ltd., Exeter, UK), a pressure-sensing insole system (medilogic®insole, T&T medilogic Medizintechnik GmbH, Schönefeld, Germany), and an 8-camera motion capture system (Vicon, Oxford, UK). Since the geometry and the characteristics of a rollator differ significantly from that of a pick-up walker, device-specific design modifications were necessary to integrate the load cells into the rollator legs in such a way that they accurately measure the vertical walker ground reaction forces; Figure 5.2 illustrates the modified rollator design.

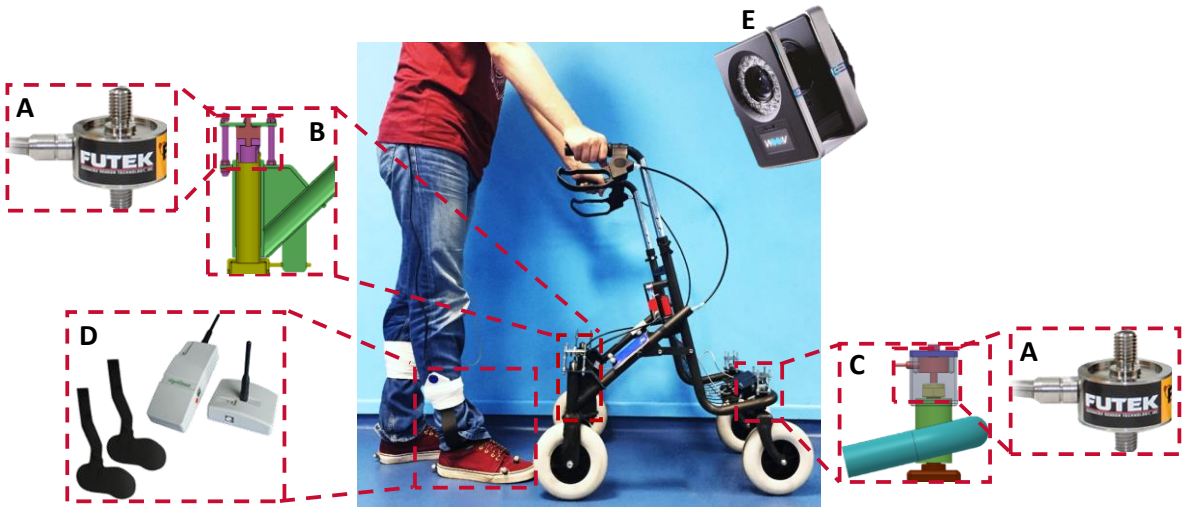


Figure 5.2: Instrumented rollator system with details of: A) load cell; B) rear leg design; C) front leg design; D) pressure-sensing insole system; E) infrared camera.

The accuracy of CoP_{system} as derived from the load cell and insole data was tested by placing the device onto a force plate (600 × 900 mm AMTI BP600900) and asking a user to step onto the same force plate while holding the rollator. Subsequently, CoP_{system} was calculated from "gold standard" force plate data and compared to CoP_{system} as calculated from instrumented rollator data. Results of this accuracy evaluation are shown in Section 4.5.

5.2.3 Participants

Ten rollator users aged 84.2 ± 5 years were recruited from the Geriatric Rehabilitation Clinic of the Robert-Bosch-Hospital Stuttgart, Germany. Inclusion criteria were: 1) age 65 years or older, 2) able to walk household distances with a rollator, but not able to walk such distances unaided. Exclusion criteria were: 1) history of head injury or concussion, 2) visual disorders not correctable by glasses, 3) diagnosed peripheral or central nerve dysfunction, 4) terminal disease, 5) inability to follow verbal instructions. Of the 10 participants, 8 were women, and 5 had a previous history of lower limb fracture. Moreover, 4 participants were new

users, 2 participants had had their rollator for less than 6 months, and the remaining 4 participants were experienced users (had used the rollator for more than 6 months). Additional descriptive parameters are presented in Table 5.1. Written informed consent was obtained from all participants, and the experimental protocol was approved by the University of Tuebingen Medical Faculty Ethics committee (678/2016BO1) and the University of Salford Ethics Committee (HSCR13-48).

Table 5.1: Descriptive parameters of study participants.

	AGE (years)	SEX (M/F)	WEIGHT (kg)	HEIGHT (cm)	BMI	FCI	FRACTURE	GAIT SPEED (m/s)	ROLLATOR USE (months)
P1	87	F	78	154	32.9	3	no	0.61	<0.5
P2	78	F	60	153	25.6	5	yes	0.65	0.5 - 6
P3	85	F	54	152	23.4	3	no	0.65	0.5 - 6
P4	83	F	71	160	27.7	4	no	0.51	<0.5
P5	79	M	71.5	168	25.3	6	yes	0.76	<0.5
P6	91	F	47	154	19.8	5	yes	0.48	>6
P7	82	F	60	153	25.6	3	no	0.37	>6
P8	77	F	80	161	30.8	4	yes	0.27	<0.5
P9	91	F	55	154	23.2	7	yes	0.71	>6
P10	89	M	79	158	31.6	3	no	0.50	>6

BMI: Body Mass Index; FCI: Functional Comorbidity Index (number of diseases and symptoms, from a maximum of 18);

5.2.4 Protocol

The experiments took place in the gait laboratory of the Robert-Bosch-Hospital in Stuttgart, Germany. All participants performed 6 tasks with the instrumented rollator representative of activities of daily living: straight line walk (5 m); 90° turn; 180° turn; obstacle crossing (involving pushing two wheels of the rollator over the end part of a long wooden beam, cross section 22 mm high and 62 mm wide, while the other two wheels remain on the level floor); backwards walk (2.5 m) as if to open a door; and negotiating a 50mm step up. Participants performed each task twice at their self-selected speed. As it was expected that some participants might

experience fatigue during the assessment, the order in which tasks 2-6 were performed was rotated.

5.2.5 Data analysis

5.2.5.1 Effects of task on stability margin

To test whether the task has an effect on stability and, if so, which tasks are more or less challenging to the user's stability, the minimum SM for each task (which corresponds to the instant during the whole task in which the user was the least stable) was compared to the minimum SM of all other tasks including straight line walking. For this, a Friedman test, which is robust to non-normality, followed by post-hoc one-sided Wilcoxon Signed-Rank Tests was run in R (R Core Team 2017) to analyse the effects of task on stability. Finally, to account for the fact that multiple conditions were tested in this study, all p-values were adjusted using a Bonferroni correction.

5.2.5.2 Relationship between stability margin and device loading

The relationship between SM and DL was investigated with a least-squares regression for each participant and for each task using a purpose-written FORTRAN program ($Eq.5.2$):

$$SM_{ij} = \alpha_{ij} + \beta_{ij} DL_{ij} \qquad Eq.5.2$$

where i = 1,2,…,10 indicates the i^{th} participant, j = 1,2,…, 6 the j^{th} task, and α and β are, respectively, the intercept and slope of the model.

However, since SM and DL are both time series, the assumption that observations are independent could not be made; therefore, the time series have been first differenced obtaining ΔSM_{ij} and ΔDL_{ij}, and then, since ΔSM_{ij} and ΔDL_{ij} showed

very low autocorrelation (<0.1), the least-squares regression without intercept was calculated ($\Delta SM_{ij} = \beta_{ij} \Delta DL_{ij}$). Finally, the overall regression coefficient, β, was obtained by calculating the weighted mean of all the β_{ij} with weights given by the computed inverse variance of β_{ij}.

To explore whether regression coefficients vary statistically between participants and tasks, a general linear model computed in SPSS was used, with tasks and patients as fixed effects.

5.2.5.3 Effects of step-up strategy on stability

To explore the effects of different strategies on stability, the strategy used spontaneously by each participant to get up the 50mm step was recorded, together with the corresponding minimum SM. How the adopted strategy influenced the corresponding minimum SM was then examined.

5.3 Results

5.3.1 Illustrative data on rollator use and user's stability

To illustrate the measures derived from our instrumented rollator system, Figure 5.3 shows the movement pattern, i.e. the times when wheels and feet are in contact with the ground, together with SM and DL data for straight line walking of two rollator users (P1 and P8). P8 was identified by the research team as a relatively frail user, who was limping due to history of hip fracture (right hip) and because he had the lowest gait speed (0.27 m/s) (Schoon, Bongers et al. 2014), whilst P1 was deemed fittest based on gait speed and functional comorbidity index. Surprisingly, it can be observed from the graphs that P8 has a generally higher SM (SM = 0.24 – 0.36) than P1 (SM = 0.15 – 0.30). However, P8 also shows a much greater DL (up to 37% BW) than P1 (up to 10% BW), and this may affect the observed absolute

values of SM. It is further notable that P1's DL remains approximately constant throughout the walking trial with a mean value of 6.8 ± 1.3% BW, whilst P8's DL is less regular, showing greater variability (25.1 ± 4.6% BW).

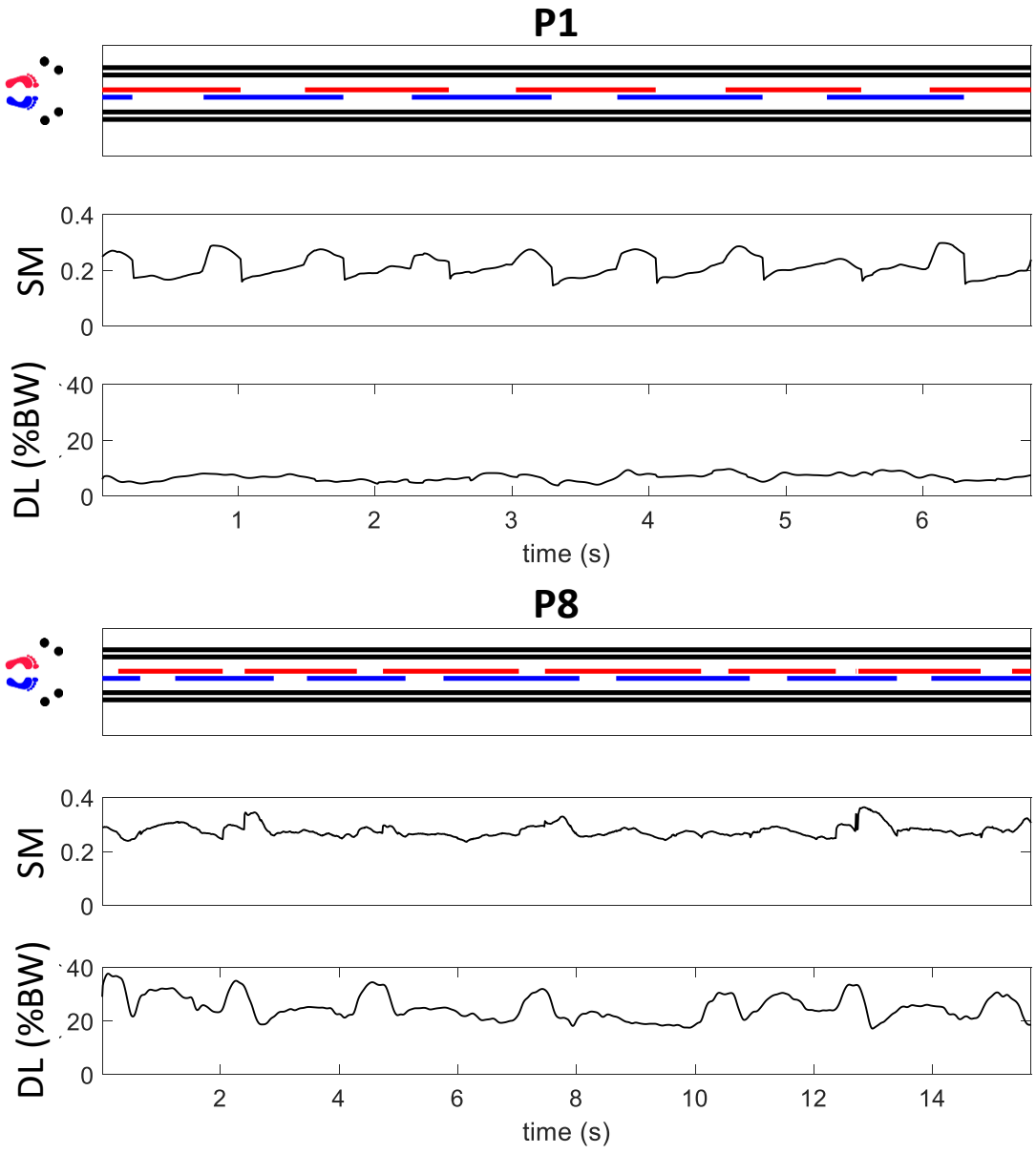


Figure 5.3: Example data sets for two rollator users (P1: fit, P8: frail) walking in a straight line for 5m. Top: movement pattern; red and blue lines indicate, respectively, times when the user's left and right foot are grounded, black lines represent the rollator wheels in continuous ground contact. Middle: stability margin 'SM' over time (non-dimensional as normalised by $\sqrt{Area(BoS_{system})}$). Bottom: device loading 'DL' defined as the percentage of body weight (%BW) transferred by the user onto the rollator. It can be seen that P8 shows greater task completion time, higher SM, and greater and more variable DL compared to P1.

Last but not least, it can be observed that DL considerably increases every time P8 is swinging the left foot forward, indicating a need for additional support from the rollator when standing in single support on the limb that was previously fractured.

5.3.2 Effects of task on stability

Figure 5.4 presents the distribution of the minimum SM for each task across the 10 participants, showing a visible difference between straight line walking and all other tasks. Corresponding results of the Friedman test showed that the task performed has a significant effect on stability ($\chi^2 = 20.2$, degrees of freedom = 5, $p = 0.001$), and the post-hoc Wilcoxon tests used to further investigate the effect of the individual tasks confirmed that that the minimum SM for each task is significantly lower than that during straight line walking (Table 5.2). Furthermore, the effect size $|r| > 0.5$ indicates that each task has a large effect on stability. Regarding the comparison between all other tasks, however, no further significant differences between the more complex tasks emerged from the Wilcoxon tests.

Table 5.2: Group median values of the minimum stability margin 'SMmin' (non-dimensional as normalised by $\sqrt{Area(BoS_{system})}$) for each task and results of the Wilcoxon Signed-Rank Test. "Straight": straight line walking, "Back": Backwards walking, "Obstacle": obstacle crossing, and "Step": stepping up a kerb.

	median	z-score	p value	effect size R
Straight	0.1665			
90° turn	0.1260	-2.8067	0.006	-0.8876
180° turn	0.1275	-2.8031	0.012	-0.8864
Back	0.1380	-2.6679	0.006	-0.8893
Obstacle	0.12	-2.8031	0.006	-0.8864
Step	0.1280	-2.8049	0.006	-0.8870

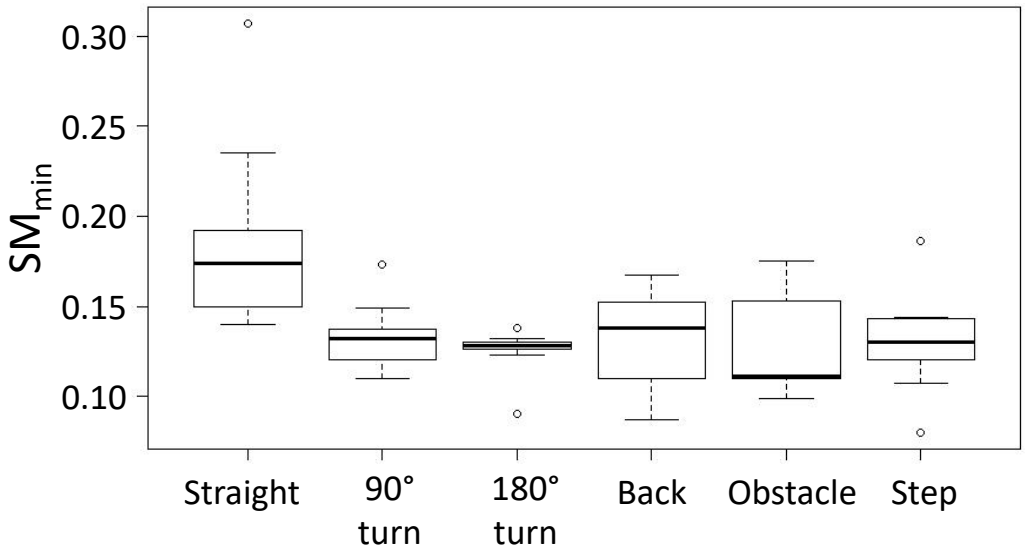


Figure 5.4: Box plot of the minimum SM (non-dimensional as normalised by $\sqrt{Area(BoS_{system})}$) for each task across the 10 participants. The bottom and top edge of the boxes indicate the first and third quartile, the thicker line inside the box represents the median, and the whiskers below and above the box show the minimum and maximum values respectively. Circles denote outliers as identified automatically by the software R. "Straight": straight line walking, "Back": Backwards walking, "Obstacle": obstacle crossing, and "Step": stepping up a kerb.

5.3.3 Relationship between stability margin and device loading

Results of the least-squares regression confirmed that the overall weighted regression coefficient, β, is significantly positive (β = 0.000695 ±0.000036, z-score = 18.51) and, hence, that SM increases with DL. Moreover, the general linear model showed that β varies significantly between participants ($p<0.001$) but not between tasks ($p = 0.69$). The mean (weighted) values of β for the 6 tasks and the 10 participants are shown in Figure 5.5.

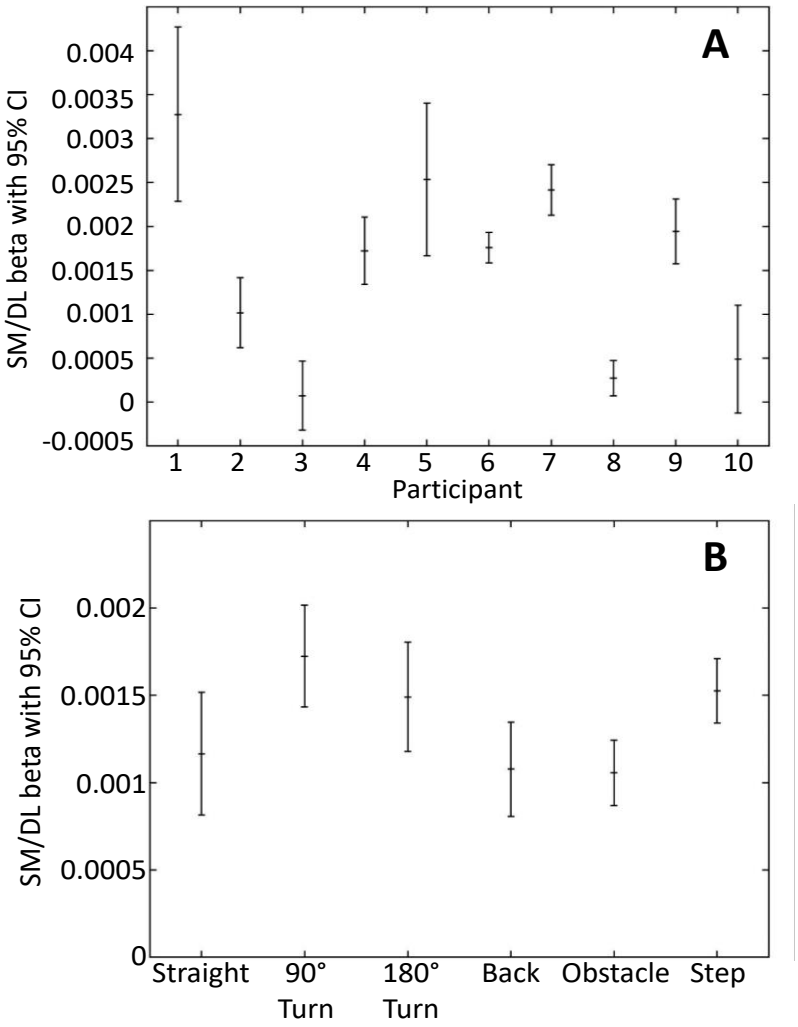


Figure 5.5: Mean (weighted) values of the regression coefficients β for A) the 10 participants and B) the 6 tasks.

5.3.4 Effects of strategy used on stability margin

Three different strategies to step onto a 50 mm-high platform were observed in the rollator users tested. Seven out of ten users adopted a lateral approach which consisted of:

- User lifts either the right or left side of the rollator first;
- User places the front wheel of the lifted side onto the platform;
- User lifts the rest of the rollator and places it onto the platform.

Two users adopted an “all together” approach (referred to as “All together V1”), using the handles to lift the rollator up completely in a single manoeuvre and

placing all 4 wheels simultaneously on top of the platform. Finally, 1 user adopted an alternative “all together” approach (referred to as “All together V2”) as follows:

- User leans forward and grabs the rollator horizontal bar with one hand while holding one handle with the other hand;
- User lifts the rollator up completely in a single manoeuvre.

Of the 3 different approaches adopted by the rollator users, the lateral approach was the one with the highest minimum SM (0.13 ± 0.03), followed by the “All together V1” approach (0.12 ± 0.01) and, lowest of all, the “All together V2” approach (0.11; since only 1 trial is available for this approach, standard deviation could not be calculated).

5.4 Discussion

This is the first study which, in a cohort of 10 in-patients in a geriatric ward, assessed stability with an instrumented rollator for six everyday walking tasks. Stability was investigated with an objective assessment methodology previously developed by the authors (Costamagna, Thies et al. 2017), which treats the user and their rollator as a single combined system and informs on the corresponding stability margin, i.e. how far the system is from the point of “tipping over”. It is noteworthy that since its initial development (Costamagna, Thies et al. 2017), the method has been further refined in that SM_{system} is now normalized to take into account the size of the BoS, because a smaller SM_{system} may simply be the consequence of a smaller BoS. However, despite this normalization, the sample data of two participants (one fit and one comparatively frail) indicate that, whilst SM is a direct measure of stability (nearness to tipping), a larger SM (as observed for the more frail user) does not necessarily mean a safer gait and lower risk of falling.

For instance, those users who need a rollator only as a balance aid, and which do not transfer substantial amounts of body weight onto the device, will likely have a lower SM than those who need it for weight-bearing support. In future, a measure representative of overall stability that does not depend on absolute values of SM would be more informative, especially when it is the aim to characterize relative stability of participants.

Investigating effects of task on SM, the data provide evidence that stability decreases substantially from straight line walking to all other tasks. Yet, no significant differences between the other tasks (90° turn, 180° turn, backwards walk, obstacle crossing, and step up/down) could be found, indicating that the level of challenge for each task may be similar or subjective. These findings provide initial evidence as to how safe use of a rollator may be facilitated: training should target daily activities other than straight line walking, and it should be customised to focus on those activities for which a user exhibits particularly low stability.

Investigating stability in relation to device loading, findings showed that SM generally increases significantly when DL increases, thereby supporting our hypothesis that as more weight is transferred onto the rollator, CoP_{system} moves forward towards the centre and away from the edges of BoS_{system}. Hence, advice to those who show generally low SM, and especially to those whose SM is often directed towards the rear of BoS_{system}, could include instruction to lean more onto the rollator. However, we acknowledge that this may not always be possible if users have weak upper limbs, and it may also lead to new pathologies such as tendonitis or osteoarthritis (Gelberman, Hergenroeder et al. 1981, Waring and Werner 1989). Furthermore, it must be considered that prolonged offloading of the lower limbs may induce lower limb weakness.

It must also be noted that, considering the different strategies used to stepping up a kerb, it may be that the relationship between SM and DL is influenced by the specific strategy used and this task may need to be treated separately from other tasks. Future work needs to investigate this further, however, at this time the authors did verify in a post-hoc analysis that the exclusion of the stepping-up task from the regression and general linear models did not change the significance of the models and neither the results for the remaining tasks.

Finally, for the first time, we have shown how stability data can inform rollator use strategies. Specifically, when going up a step the “lateral approach” appears to be the most stable strategy, because the rollator never leaves the ground completely and hence provides the user with continued support; the “All together” approaches, instead, require greater strength as the user has to lift the rollator in one manoeuvre and leave him/her with no support during the lifting-up phase. The authors note that none of the participants went up the step as stated in some guidance documents, i.e. lifting the front wheels first, then the rear, then squeezing the brakes before stepping up.

One limitation that emerges from the above discussion is that SM, despite its normalization by ($\sqrt{area(BoS)}$), appears to be further influenced by other factors. Therefore, future analysis should investigate additional factors such as DL and their effects on SM, and/or focus on analysis techniques that do not depend on absolute values of SM, for example, the regularity of the SM time series (e.g. as measured by autocorrelation).

5.5 Conclusions

In summary, our approach provides objective data on walking stability of the combined system (user and rollator) for a range of everyday tasks, and provides first insights into how to objectively assess alternative rollator use strategies to inform evidence-based training. The relevance of our approach lies in an increase in users of walking aids within our ageing population, and the associated costs arising from fall-related injuries. One key insight gained is that training should not be limited to straight line walking alone, but should include more complex tasks representative of daily walking activities. Within person, the stability margin SM can be used to identify which tasks need to be practiced, and which strategy facilitates stable performance of a given task. Indeed, in principle, the use of instrumented rollators as assessment tools in clinics could enable person-specific guidance and training. Longer-term, evidence-based training should increase the benefits of using rollators as a means of fall prevention.

5.6 Acknowledgements

The relationship between SM and DL was analysed with the support of Statistician Prof. Rose Baker who, recognising the complexity of the dataset, advised on the most suitable statistical method and offered support with its computation.

6 Stability of walking aid users: methods for the interpretation of combined stability margin data.

6.1 Introduction

Falls in older people are a major health problem due to their high incidence, severe consequences, and associated costs. Specifically, 30-50% of those aged over 65 fall every year (Tinetti, Speechley et al. 1988, Rubenstein and Josephson 2002, Organization 2007) and suffer from associated social and physical consequences such as fear of falling, loss of independence, hip fracture, and even death (Rubenstein 2006, Age UK 2011, NHS 2014). It was estimated that, in 2013, the total cost to the UK government of falls in the older population was over £2.3 billion (NICE 2013).

In order to improve balance and mobility and prevent falls, 29-49% of older Europeans use walking aids (WAs) (Lofqvist, Nygren et al. 2005); however, rather surprisingly, WA use has even been associated with a 2-3 fold increased falls-risk (Deandrea, Lucenteforte et al. 2010). At this stage, the reasons for this finding cannot be established, as there are few, if any objective studies of WA usage in the real world. Further, and of direct relevance to this chapter, there are no gold standard measures that objectively quantify stability in WA users. Indeed, the

majority of studies on walking stability focus on unassisted walking, which is both surprising and concerning considering that the most frail will often be users of WAs.

To address this problem, we previously developed a generalizable methodology for stability assessment of WA users (Costamagna, Thies et al. 2017), which calculates the combined Stability Margin (SM) for the user and WA. Specifically, SM is a non-dimensional measure, defined as the shortest distance between the combined centre of pressure and the nearest edge of the combined base of support (BoS), normalized by $\sqrt{area(BoS)}$ (Costamagna, Thies et al. 2017). In general, the smaller the SM, the less stable the system is, and, hence, we used the minimum (instantaneous) value of SM seen during the performance of a given activity to characterise stability.

To obtain SM, we need to measure the vertical load through each of the points of contact with the ground (both anatomical feet and feet of the WA), together with their relative location. To capture the vertical loads through the feet of the WA, load cells were integrated into the 'legs' of both a 4-wheeled walker (rollator) and also a Zimmer frame without wheels (pick-up walker 'PW'). To measure the loads through the anatomical feet, we use pressure sensing insoles inside the user's shoes, and, to measure the relative position of the user's feet in relation to the WA, we use 3D optoelectronic camera data (Costamagna E, Thies S.B. et al. 2017, Costamagna, Thies et al. 2017). In our previous work, we demonstrated that, within subject, the minimum value of SM is lower when subjects are performing intuitively more challenging tasks than straight line walking (e.g. such as obstacle crossing or turning) (Costamagna E, Thies S.B. et al. 2017).

Nevertheless, rather counter-intuitively, it was also observed that the minimum SM of a young healthy adult walking with a rollator is often considerably lower than that

of older users. Similarly, a relatively fit rollator user showed minimum values of SM much lower than that of a frailer user with previous history of lower limb fracture. This finding may partly be explained by considering the relationship between device loading and SM; as seen in Chapter 5, as device loading increases, SM also increases. Therefore, those users who only need a WA as a balance aid (such as a fit rollator user) and, for this reason, do not transfer significant amounts of body weight onto it, are likely to have lower SM than those who use their WA for structural support (e.g., a frail user with a history of lower limb fracture). As one might expect the user who relies on light touch support for balance to be less vulnerable to a fall than someone who relies on the WA for support, this finding suggests that the minimum value of SM alone may not provide a comprehensive measure of stability.

Indeed, looking at the minimum SM only is limiting as it considers a single instant across a whole task, while ignoring the behavior of SM over time. On the other hand, using differential values of SM, as compared to absolute values, may provide more useful insights as differential values remove the effect of user-specific factors (such as the amount of body weight transferred onto the walking aid) on absolute values of SM. Hence, additional analyses (e.g., time series analysis or differential measures) are needed to capture other parameters which may provide complementary information on stability.

In the literature there are a number of possible techniques that may be applied to SM time series in order to characterise the user's level of stability and indicate their proficiency in using their walking aid safely. For instance, as it is well known that healthy gait is highly periodic (Kobayashi, Kakihana et al. 2014), previous work concerned with unassisted walking used the autocorrelation technique to

demonstrate an association between decreased gait regularity and increased falls-risk in older people (van Schooten, Pijnappels et al. 2016). Although it is recognised that walking aids impose a movement pattern that may affect the periodicity of the user's gait, it seems reasonable to investigate whether, when considering the combined system (user + walking aid) instead of the user alone, SM regularity may also reflect stability. Another technique that has often been used to inform on stability is the root mean square (RMS) of measures such as centre of pressure deviation (Jeka, Easton et al. 1996, Jeka 1997, Jeka, Schoner et al. 1997, Tung, Gage et al. 2014) and postural sway (Fernie, Gryfe et al. 1982) under the assumption that greater stability leads to lower deviation. Since SM and centre of pressure are closely related, this technique could be directly applied to this work. Furthermore, calculating the difference in a given outcome measure for performance of a simpler and a more complex task has been suggested to differentiate between subjects (Ble, Volpato et al. 2005, Bridenbaugh, Beauchet et al. 2013). Similarly, the difference in SM between straight line walking and more complex walking tasks may guide decisions on users' level of stability based on the hypothesis that those who are more stable would show lower difference in SM between straight line walking and more complex walking tasks (e.g. turning a corner or stepping up a kerb) than those who are less stable. Finally, one may also argue that it is not just the instantaneous value of a stability measure that matters, but also the time over which the person is in a less stable situation. Hence those who spend more time further away from the tipping point (SM = 0) may be less likely to fall than those whose SM is consistently closer to 0; thus, the integral of SM over time may inform on users' stability.

With the long-term aim to support clinical decision making as to who is at greater risk of falling within the walking aid users population, a first step towards this aim, and the objective of this work, is to investigate the analysis techniques introduced above for their merit to characterise users' overall level of stability using an empirical approach.

6.2 Methods

6.2.1 Subjects

Fifteen (15) WA users aged 82 ± 6 years and one young healthy adult (for reference) aged 29 years were recruited for this study. Of the 15 WA users, 10 were rollator users and 5 were pick-up walker users. Inclusion criteria were: 1) age of 65 years or older, 2) able to walk household distances with a WA, however, not able to walk such distances unaided. Exclusion criteria were: 1) history of head injury or concussion, 2) visual disorders not correctable by glasses, 3) diagnosed peripheral or central nerve dysfunction, 5) inability to follow verbal instructions. Written informed consent was obtained from all participants, and the experimental protocols were approved by the University of Tuebingen Medical Faculty Ethics committee (678/2016BO1) and the University of Salford Ethics Committee (HSCR13-48).

6.2.2 Protocol

Since rollators are predominantly used outdoors and PWs indoors, and since PW users are generally considerably more frail than rollator users, two different experimental protocols were designed to reflect the everyday use of each device and the different physical conditions of the two populations. Rollator users

performed 6 tasks representative of everyday activities with the instrumented rollator developed in (Costamagna E, Thies S.B. et al. 2017): 1) straight line walk (5 m); 2) 90° turn; 3) 180° turn; 4) obstacle crossing (pushing the rollator over a wooden beam, 22 mm high and 62 mm wide, with 2 wheels of the same side); 5) backwards walk (2.5 m) as if to open a door; and 6) stepping up a 50 mm kerb. As it was expected that some users may experience fatigue, the order in which tasks 2-6 were performed was rotated.

PW users walked with the instrumented PW developed in (Costamagna, Thies et al. 2017) in a straight line (5 m) and along a path containing two 90° turns both in the lab (simulating an open space or clinic), and in the University of Salford Activities of Daily Living (ADL) flat: a fully furnished home-setting with doorways and transitions between different flooring conditions (carpet and vinyl flooring). Finally, the young healthy adult completed both protocols with both WAs. Participants performed all tasks at their self-selected speed.

6.2.3 Data analysis

SM for each participant has been analysed using bespoke code written in MATLAB R2016a using 4 different techniques, labelled ‘autocorrelation’, ‘RMS deviation’, ‘integral’, and ‘delta (difference in SM between tasks)’, as described below:

Autocorrelation

Autocorrelation coefficients were calculated in Matlab R2016a following the procedure presented by Moe-Nilssen (Moe-Nilssen and Helbostad 2004). In summary, the autocorrelation compares a time series of length N samples to the same time series delayed by n samples, where n ranges from 0 to N-1. When the delay is 0, the autocorrelation function is always equal to 1 as any time series is

identical to itself; as n increases, the autocorrelation function oscillates between 0 and 1 depending on how periodic the time series is: for a perfectly periodic signal such as a sine wave, for instance, the autocorrelation function will return peaks equal to 1 every $i \cdot T$ samples where T is the period of the sine wave and i = 1, 2, …, ∞, meaning that the sine wave is identical to a version of itself delayed by $i \cdot T$ samples. Thus, the more periodic a real time series is, the closer to 1 the peaks of the autocorrelation function will be. These peaks are called autocorrelation coefficients. In gait analysis, the first and second peak (A_{d1} and A_{d2}) are normally of interest as they indicate how similar two consecutive steps and two consecutive strides are, respectively. Knowing that healthy gait is highly periodic, it was expected that more stable users would show higher autocorrelation coefficients.

The autocorrelation function was calculated for straight line walking only since the nature of other tasks such as turning, crossing an obstacle, or going up a step will affect gait periodicity in a difficult-to-interpret way.

RMS deviation

RMS deviation of SM from the mean was calculated according to Eq. 6.1 with the assumption that lower deviation from the mean indicates higher stability.

$$\mathrm{d_{RMS}} = \sqrt{\frac{1}{\mathrm{N}}\sum_{\mathrm{n=1}}^{\mathrm{N}} |\mathrm{SM_n} - \overline{\mathrm{SM}}|^2} \qquad Eq.6.1$$

where d_{RMS} indicates the RMS deviation of SM, N the length of the SM time series, SM_n the value of the n-th sample of SM, and $\overline{SM}$ is the mean value of SM. Since previous work presented in Chapter 5 showed that the level of challenge for tasks other than straight line walking may vary between users (i.e., different users might

find a given task more or less challenging depending on their experience and abilities), RMS deviation was calculated for straight line walking only.

Integral

The integral of SM ($Eq. 6.2$) quantifies how far and for how long the system is away from the tipping point (SM = 0). The hypothesis is that the greater the integral, the further away the system is from the tipping point and for longer time, and, hence, the more stable the system is.

$$I = \int_0^T SM(t)dt \qquad Eq. 6.2$$

Where I is the integral and T equals 6 seconds for rollator users and 30 seconds for PW users. These values of T were chosen as they correspond to the maximum periods of time for which SM was available for all rollator and PW users respectively (e.g., the fastest rollator user performed the straight line walking task in 6 seconds). For similar reasons as stated for the RMS deviation, the integral of SM was calculated for straight line walking only.

Delta (difference in SM between tasks)

The delta (Δ) for each participant was calculated as the mean difference between the minimum SM during each complex task (i.e. turning, crossing an obstacle, etc.) and that during straight line walking ($Eq. 6.3$). This is based on the hypothesis that less vulnerable users will be more able to maintain stability across both, more and less difficult tasks, whilst less stable users would show a larger difference in stability between straight line walking and more difficult tasks (e.g. a young healthy

adult, for instance, might be almost as stable during turning as during straight line walking):

$$\Delta = \frac{1}{N}\sum_{i=1}^{N}\left|SMmin_i - SMmin_{straight}\right| \qquad Eq.6.3$$

where N is the total number of tasks excluding straight line walking (N=5 for rollator users and N=2 for PW users), $SMmin_i$ is the minimum SM for the ith task (i.e., 90° turn, 180° turn, backwards walking, obstacle crossing, and stepping up for rollator users, and turning in the lab and in the ADL flat for PW users), and $SMmin_{straight}$ is the minimum SM for straight line walking with either device.

Ranking of users

Users were ranked in order of decreasing stability as determined through each analysis technique. The ability of each technique to differentiate between more and less stable users was assessed based on how well they could classify the healthy young participant to be the most stable user, and the most frail participant (based on clinical observation and medical history) to be the least stable user. In addition, detailed rankings of all participants were investigated for their agreement with gait speed, which is commonly used in clinical practice as an indicator of walking ability (Barry, Galvin et al. 2014, Schoon, Bongers et al. 2014, van Schooten, Pijnappels et al. 2016). Since the type of walking aid used will affect SM values, as well as factors such as gait pattern and gait speed, which, in turn, would influence user rankings based on speed and autocorrelation, two separate rankings were made for rollator and PW users.

6.3 Results

Figure 6.1 A-B shows SM for straight line walking with the instrumented rollator for the healthy young adult (RYA) and one older user (R8) who was considered the least stable due to their visible frailty, previous history of hip fracture, and very low gait speed (0.2 m/s). Figure 6.2 A-B shows the equivalent data for straight line walking with the instrumented PW for the healthy young adult (PWYA) and one older user (PW1) who was one of the three slowest PW users tested (others being PW2 and PW5, see Table 6.2. For clarity, the young healthy adult will be referred to as RYA when walking with the rollator and as PWYA when using the PW. It should be noticed that, as it can be observed in Figures 6.1 and 6.2, despite being considered less stable, R8's SM was generally higher than that of RYA and SM for PWYA and PW1 were comparable.

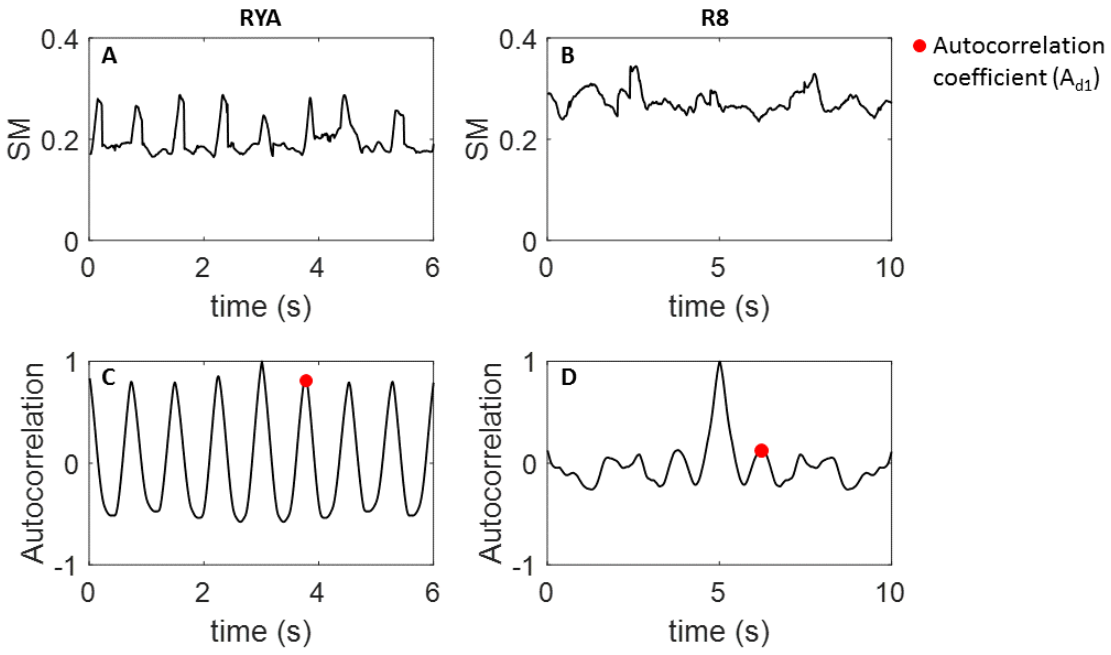


Figure 6.1: A) SM time series during straight line walking with the instrumented rollator for A) the young healthy adult (RYA) and B) one rollator user (R8). Autocorrelation function for straight line walking with the instrumented rollator for C) RYA, A_{d1} = 0.8 and D) R8, A_{d1} = 0.07. It can be seen that RYA, compared to R8, shows

lower SM but a much higher autocorrelation coefficient indicating greater regularity of SM.

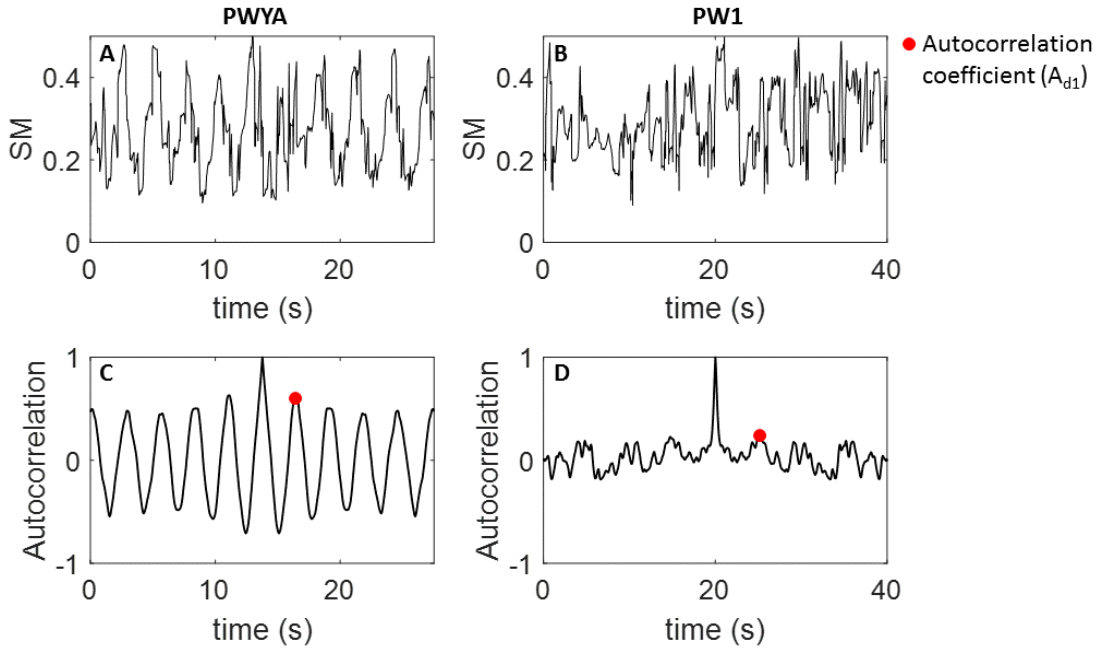


Figure 6.2: A) SM time series during straight line walking with the instrumented PW for A) the young healthy adult (PWYA) and B) one PW user (PW1). Autocorrelation function for straight line walking with the instrumented PW for C) PWYA, A_{d1} = 0.66 and D) PW1, A_{d1} = 0.06. It can be seen that PWYA, compared to PW1, shows similar SM but a much higher autocorrelation coefficient indicating greater regularity of SM.

Furthermore, it is noteworthy that SM of RYA and PWYA is visibly more periodic as compared to R8 and PW1, respectively, and this difference in periodicity is quantified by the autocorrelation function (Figure 6.1 C-D and Figure C-D) and, in particular, by higher values of the autocorrelation coefficient A_{d1}.

Table 6.1 and 6.2 show the results of all analysis techniques applied to SM for all participants.

Table 6.1: Results of the 4 analysis techniques for rollator users.

	Gait speed (m/s)	*Autocorrelation (A_{d1})*	*RMS deviation*	*Integral (ms)*	*Delta*
R1	0.59	0.73	0.037	0.87	0.037
R2	0.75	0.46	0.048	0.9	0.040
R3	0.66	0.55	0.046	0.74	0.015
R4	0.51	0.58	0.025	0.76	0.040
R5	0.76	0.1	0.031	0.83	0.041
R6	0.48	0.58	0.023	1.42	0.151
R7	0.36	0.34	0.029	0.89	0.031
R8	0.24	0.07	0.023	1.12	0.079
R9	0.67	0.76	0.055	1.28	0.070
R10	0.48	0.37	0.039	0.96	0.047
RYA	0.80	0.8	0.080	0.8	0.005

Table 6.2: Results of the 4 analysis techniques for PW users.

	Gait speed (m/s)	*Autocorrelation (A_{d1})*	*RMS deviation*	*Integral (ms)*	*Delta*
PW1	0.05	0.06	0.0811	5.37	0.033
PW2	0.04	0.39	0.0583	5.94	0.051
PW3	0.13	0.43	0.0566	5.87	0.015
PW4	0.15	0.54	0.0756	5.32	0.008
PW5	0.04	0.37	0.06	5.39	0.062
PWYA	0.16	0.66	0.086	5.39	0.005

Finally, based on the values reported in Tables 6.1 and 6.2, Table 6.3 and Table 6.4 rank, respectively, rollator and PW users in order of decreasing gait speed and

stability as obtained from each analysis technique. Referring to both tables, gait speed, autocorrelation, and delta place the young healthy adult at the top of both populations. Conversely, contrary to expectations, RMS deviation places the young adult at the very bottom, and the integral somewhere in the middle of the rankings. R8 was placed last in the rollator users ranking according to gait speed and autocorrelation and second to last according to delta. Among the PW users, gait speed, delta, and autocorrelation all placed the slower users PW1, PW2, and PW5 at the bottom of the rankings. Conversely, contrary to expectations, RMS deviation and the integral placed R8 and the group PW1, PW2, PW5 at the top or in the middle of the rankings for their respective populations.

Table 6.3: Ranking of rollator users in order of decreasing stability according to each analysis technique, and in relation to gait speed.

Gait speed	RYA	R5	R2	R9	R3	R1	R4	R10	R6	R7	R8
Autocorrelation (A_{d1})	RYA	R9	R1	R4	R6	R3	R2	R10	R7	R5	R8
RMS deviation	R8	R6	R4	R7	R5	R1	R10	R3	R2	R9	RYA
Integral	R6	R9	R8	R10	R2	R7	R1	R5	RYA	R4	R3
Delta	RYA	R3	R7	R1	R2	R4	R5	R10	R9	R8	R6

Table 6.4: Ranking of pick-up walker users in order of decreasing stability according to each analysis technique, and in relation to gait speed.

Gait speed	PWYA	PW4	PW3	PW1	PW2	PW5
Autocorrelation (A_{d1})	PWYA	PW4	PW3	PW2	PW5	PW1
RMS deviation	PW3	PW2	PW5	PW4	PW1	PWYA
Integral	PW2	PW3	PWYA	PW5	PW1	PW4
Delta	PWYA	PW4	PW3	PW1	PW2	PW5

6.4 Discussion

We have developed a novel methodology (Costamagna, Thies et al. 2017) for the assessment of stability of walking aid users which shows potential to inform user-specific training (Costamagna E, Thies S.B. et al. 2017). Here we build on our work by investigating the merit of different analysis techniques, applied to SM, to evaluate users' relative stability (i.e., autocorrelation, RMS deviation, integral, and delta). We have demonstrated graphically (Figure 1 A-B, Figure 2 A-B) that older WA users may show similar or even higher SM compared to a healthy young adult, indicating that absolute values of SM do not fully explain user's stability under all conditions and can produce counter-intuitive results. This observation supported our subsequent investigation of additional analysis techniques, which may provide a complementary, or better way of evaluating stability, based on the SM data.

Within the rollator users' population, autocorrelation of SM shows the greatest promise as its ranking of the most and least stable participant (RYA versus R8) agrees with clinical observation and gait speed. Delta also ranks RYA as the most stable and R8 among the least stable participants, which we argue makes it worthy of further investigation. Nevertheless, we acknowledge that, between the extremes, the agreement between autocorrelation, delta and gait speed is poor. RMS deviation and the integral, however, provide a very counter-intuitive ranking of participants with RYA and R8 being, respectively, last and first according to RMS deviation and third to last according to the integral.

Within the PW users' population, PWYA was, as expected, the fastest user, PW3 and PW4 were slightly slower than PWYA, whilst PW1, PW2, and PW5 were the slowest of the group. In this population, delta and autocorrelation both show full

agreement with gait speed as they classify PWYA as the most stable participant followed by PW4 and PW3, and PW1, PW2, and PW5 as the least stable ones. On the other hand, as for the rollator users, RMS deviation and the integral do not place the healthy participant at the top and the group of slow users (PW1/PW2/PW5) at the bottom.

We conclude that autocorrelation and delta show promise for distinguishing stable from unstable users in groups of rollator and pick-up walker users and, hence, should be investigated further. We also note that, of these two analysis techniques, autocorrelation quantifies a feature of SM which is also very evident upon observation (i.e., regularity) and has the advantage of reflecting the whole time series, whilst delta reflects a single instant, the one at which SM reaches its minimum.

A major limitation of this work is that the ability/inability of each technique to inform on users' relative stability was mainly judged based on its agreement with clinical observation and gait speed, which is commonly used as a proxy for gait performance (Barry, Galvin et al. 2014, Schoon, Bongers et al. 2014, van Schooten, Pijnappels et al. 2016). We did this because, to date, no gold standard measure of walking aid users' stability exists. However, although clinical observation could confidently identify the most and least stable users, it was often unable to rank those who showed a level of stability somewhere between the extremes. Furthermore, previous research has reported that gait speed does not necessarily inform on stability; indeed, walking at a slower speed may even improve stability as it allows the user more time to better control their movement and that of the WA (Crosbie 1994, Yeung, Chow et al. 2012). On the one hand, these considerations may explain the poor agreement between techniques such

as autocorrelation, delta and gait speed and, on the other hand, they may justify the need for measures that more directly and objectively reflect WA users' stability. Longer-term a prospective study on falls is needed to conclude on the merit of each analysis technique through correlations between stability measures, such as those investigated here, and the actual occurrence of falls.

Furthermore, future analyses should also consider additional factors that may impact on absolute values of SM and, in particular, device loading since previous work demonstrated that SM is strongly related to device loading (Chapter 5). However, when the WA is lifted - either as part of its movement cycle as is the case for a pick-up walker, or when going up/down a step, device loading will be 0, and, hence, SM/DL will approach infinity, thus rendering normalization by device loading inappropriate. Also, it must be considered that those who show generally low SM, and especially those whose SM is often directed towards the rear of the base of support, might benefit from leaning more onto the rollator (hence increasing DL); in such cases, removing the influence of DL through normalisation would limit insights gained.

In summary, absolute values of SM often produce counter-intuitive results when comparing users (due to SM being influenced by user-specific factors) and are hence not suitable to distinguish between more and less stable users. This work presents an initial investigation of alternative SM analysis techniques. Findings suggest that autocorrelation and delta of SM show the greatest potential to inform on the relative stability of walking aid users, whilst RMS deviation and the integral of SM proved unable to rank users' stability in an intuitive way. However, the need for a prospective falls study remains in order to confidently conclude on the merit

of different stability outcome measures and corresponding analysis techniques in relation to falls-risk.

Longer term, the quantification of stability in walking aid users may support the prescription of walking aids and training of users. The relevance of this work lies in the substantial costs, both social and financial, arising from falls and the increasing number of walking aid users.

7 Differences in usage and stability between two types of walking aids and two environments: a case study

7.1 Introduction

In Chapter 3, the development of a new methodology for the assessment of stability of walking aid users has been introduced. Subsequently, this methodology has been tested with a cohort of rollator and pick-up walker (PW) users, with the aim to investigate the user-device system's overall stability and task related changes in stability in order to inform clinical practice and user-specific training.

Nevertheless, there are still several aspects of walking aid use which have not been explored. For example, it is known that walking aid prescription guidelines are often very generic and are based on observation, pre-existing conditions, and upper and lower limb strength, but they are not supported by objective stability outcomes (see section 2.2.2.1 for additional details on prescription guidelines). Moreover, previous conversations with clinicians revealed that prescription of walking aids is often based on clinicians' personal experience and preferences. Based on the inherent variation in approaches, current pairings of user and walking aid are highly unlikely to be optimal, with regard to supporting stable walking.

However, until now, no research has demonstrated the scale of the difference in stability metrics which might be seen between different Was, and hence the importance of prescribing the 'right' device.

Moreover, there are also some alarming findings with regard to user training: for example, it has been reported that walking aid users often do not receive training (Liu 2009) or that they are only shown how to use their device in a hospital corridor or in a clinic. However, even in cases where people are able to use their WA according to guidelines in a corridor with smooth, flat flooring, it is not known whether the same usage pattern is adhered to at home.

Hence, the aim of this chapter is to provide preliminary insights into how people use different walking aids in different environments, a lab, which simulates the open space of a clinic, and a home environment, the ADL flat, and to observe any associated changes in stability metrics. To achieve this, the stability assessment methodology developed in Chapter 3, together with the analysis techniques of SM from Chapter 6, have been brought together in this case study of one user who regularly uses 2 different walking aids (a PW and a FWW).

7.2 Methods

7.2.1 Participant's details

One older walking aid user (male, age=78) who regularly uses 2 different types of indoor walking frames (a PW and a FWW) was recruited for this case study. Additional inclusion criteria were: 1) age of 65 years or older, 2) able to walk household distances with a WA, however, not able to walk such distances unaided. Exclusion criteria were: 1) history of head injury or concussion, 2) visual disorders

not correctable by glasses, 3) diagnosed peripheral or central nerve dysfunction, 5) inability to follow verbal instructions. Written informed consent was obtained and the experimental protocol was approved by the University of Salford Ethics Committee (HSCR13-48).

7.2.2 Instrumentation

In order to assess walking aid use and the system's stability, the participant was required to use the instrumented PW and FWW described in Chapters 3 and in Appendix D, respectively. Since the participant was tested in two different environments, two different camera systems had to be used: a ceiling-mounted 10 camera Vicon system was used for the lab assessment and a mobile 6 camera Qualisys system was used for assessment in the University of Salford Activities of Daily Living flat, which is described below. Details of marker setup and camera positions can be found in Appendix C.

7.2.3 Protocol

The user walked with both the instrumented PW and the instrumented FWW in two different environments at the University of Salford: a gait laboratory (representing an open space such as a clinic or hospital corridor) and the Activities of Daily Living (ADL) flat, a fully furnished home-setting with doorways and transitions between different flooring conditions (carpet and vinyl flooring). The experimental protocol was the same for both devices. Laboratory and ADL flat assessment with each device took place on the same day, but the participant was tested with the PW and with the FWW on two separate occasions.

7.2.3.1 Laboratory assessment

After having adjusted the height of the two instrumented walking frames to match the participant's own ones, the following tasks were performed:

1) Static trial (1 trial): the participant was asked to stand still with the PW and the FWW for approximately 20 seconds. Position camera data were collected during this trial to allow our software to create a 3D map of the sensors for each insole.

2) 5m straight line walk (2 trials): the participant walked with the PW/FWW at a self-selected speed for 5m (approximately the length of the lab area visible by the cameras); no instructions were given on how to use the device.

3) Simulated "Kitchen to bathroom" walk (2 trials): the participant walked with the PW/FWW at a self-selected speed along a pathway marked on the lab floor using masking tape which accurately reproduced the dimensions of the ADL flat but without any furnishings or changes in flooring. The pathway included two consecutive 90 degrees turns (left and right).

7.2.3.2 ADL flat assessment

As for the lab assessment, the ADL flat assessment included the static trial and the “kitchen-to-bathroom” walk, which then went around furnishings and passed through two door frames (kitchen-to-lounge and lounge-to bathroom). The straight line walk was not performed in the ADL flat.

7.2.4 Data analysis

Similar to previous biomechanical studies (Tsai, Kirby et al. 2003, Kloos, Kegelmeyer et al. 2012), the user's gait with the two different walking aids and in the two environments was described calculating the following basic gait parameters:

- Gait speed and mean ± SD of the following temporal gait parameters: stride time, step time, stance phase, swing phase, and step time symmetry "S", which has been quantified according to $Eq.7.1$ (Portnoy and Schwartz 2013):

$$S\,[\%] = \frac{(ST_l - ST_r)}{\frac{1}{2}(ST_l + ST_r)} \cdot 100 \qquad Eq.7.1$$

where ST_l and ST_r indicate the step time, in seconds, of the left and right foot, respectively. S ranges from 0% to 200% with 0% representing perfect symmetry and 200% complete asymmetry.

After that, walking aid use and the system's stability were characterised using the custom-written MATLAB software developed in Chapter 3, which calculates the following outcome measures for each task, device and environment:

- Movement pattern (i.e., user's and walking frame's foot-ground contact events and the sequence in which they occur);
- Device loading (DL) (instantaneous values and Mean ± SD);
- Stability margin (SM) (instantaneous and minimum values):

Finally, to characterize relative stability of the two walking aids and, hence, to conclude on which device is more suitable for the specific user tested, autocorrelation of SM during straight line walking in the lab and delta of SM have also been calculated using the methodology introduced in Chapter 6.

7.3 Results

7.3.1 Gait speed and temporal gait parameters

Figure 7.1 shows stride time, step time, stance phase, swing phase, and step time symmetry of the anatomical feet for each task/environment for the PW and the FWW.

Regarding changes in gait parameters between the 2 devices, it can be noticed that PW use leads to greater stance phase duration across all tasks (Figure 7.1 C), which, in turn, also results in an increase in stride (Figure 7.1 A) and step (Figure 7.1 B) time and translates into reduced gait speed (0.15 m/s with the PW versus 0.4 m/s with the FWW). Moreover, PW use is also characterised by greater asymmetry between left and right step than FWW use across all tasks (Figure 7.1 E).

When comparing the 2 environments, on the other hand, no considerable differences can be observed in stride time, step time, stance, and swing phase between the same task (“kitchen to bathroom”) in the lab and in the ADL flat, although the user tends to spend slightly more time in the stance phase and less in the swing phase with both devices in the ADL flat as compared to the lab. With regard to step time symmetry, it can be observed that this decreases for both

devices from the lab to the ADL flat, although the difference is much more evident for the PW.

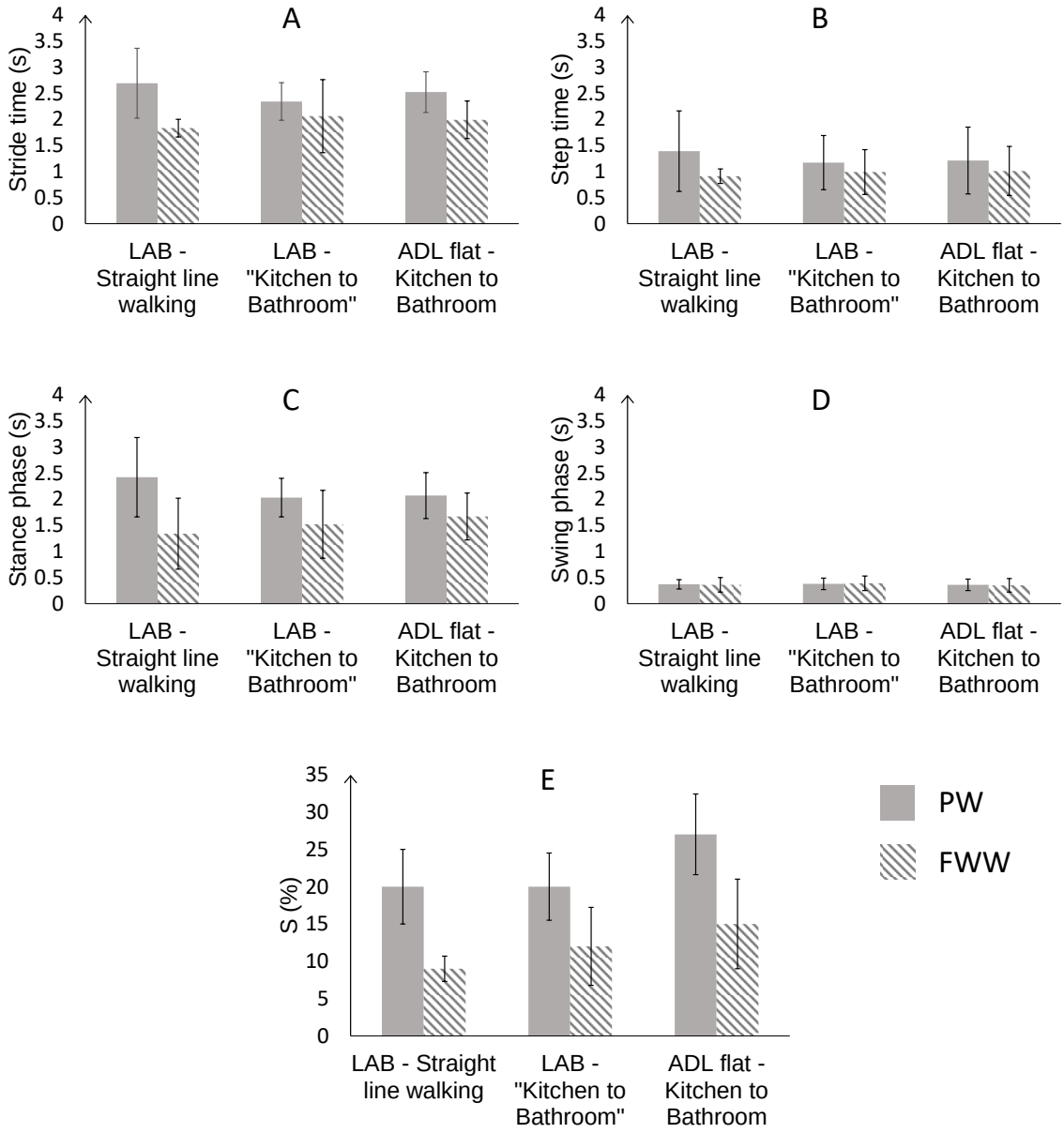


Figure 7.1: Mean ± SD of A) stride time, B) step time, C) stance phase, D) swing phase, and E) step time symmetry "S" for each task/environment for both the PW and the FWW. S can range between 0% and 200% with 0% indicating perfect symmetry and 200% indicating complete asymmetry.

7.3.2 Movement pattern

Figure 7.2 shows the movement pattern of user and device while using the PW (A) and the FWW (B) for straight line walking in the lab. It is evident that, during PW use, the user only steps when all 4 feet of the device are in contact with the ground, and this is in accordance with guidance. During FWW use, however, the device's front wheels remain constantly on the ground, whilst the rear rubber feet are mostly airborne and only get in contact with the ground occasionally and without a regular pattern. Whilst keeping the walking frame only on its front-wheels seems risky in terms of it running away, typical guidance does not comment on this aspect of the usage pattern as it only states: *"Glide the frame forwards to approximately one step ahead. Walk towards the frame stepping one foot in front of the other"* (Oxford Health NHS Foundation Trust).

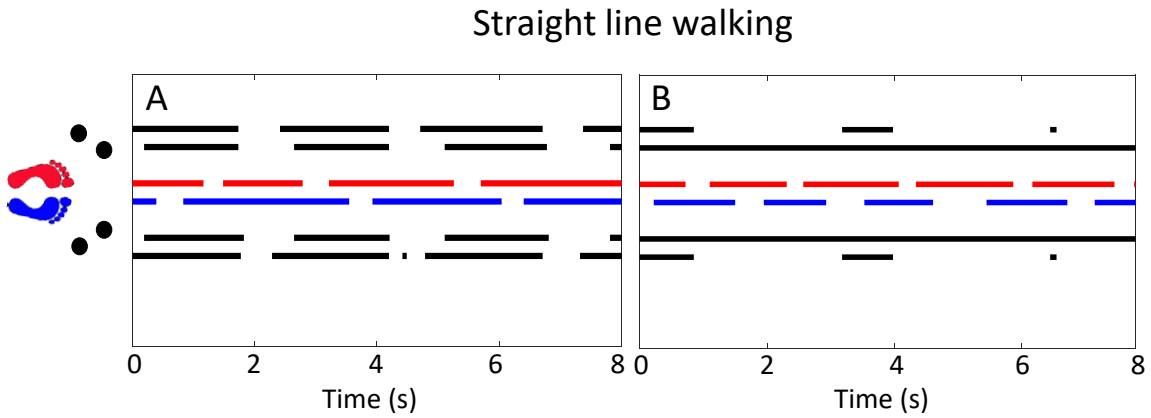


Figure 7.2: Movement pattern during straight line walking in the lab with A) the PW and B) the FWW. Solid lines indicate when the walking frame feet and the user's feet are on the ground (whilst gaps indicate that a foot/wheel is airborne). For the PW, it can be seen that the user steps only when all feet of the PW are well-grounded; for the FWW, it can be seen that the 2 front-wheels remain constantly grounded whilst the rear feet are frequently airborne. Both movement patterns appear in agreement with clinical guidance for the corresponding walking frame, although it must be noted that rear-legs lifting-off in case of the FWW is not explicitly discussed in clinical leaflets.

In the ADL flat, on the other hand, the user does not adhere to the same movement patterns; indeed, he repeatedly steps before the PW is firmly grounded (Figure 7.3 A) and with the FWW keeps the device periodically completely airborne or with only one front wheel in contact with the ground (Figure 7.3 B).

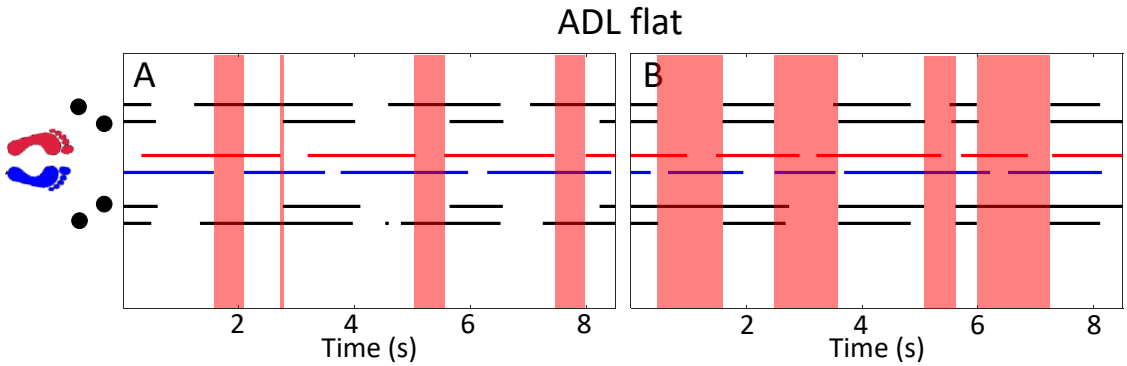


Figure 7.3: Movement pattern of user and device in the ADL flat with A) the PW and B) the FWW. Solid lines indicate when the walking frame feet and the user's feet are on the ground (whilst gaps indicate a foot/wheel is airborne). For the PW the user here repeatedly steps while the device is still partially airborne, although this is against clinical guidance; similarly, for the FWW, the user often steps while the device is fully airborne or in contact with ground with only one wheel. Red areas indicate these risky periods of the observed movement pattern.

7.3.3 Device loading

Figure 7.4 presents data on DL for the PW and the FWW during straight line walking in the lab (A) and during walking in the ADL flat (B).

It can be seen that average DL is generally considerably higher for the PW than for the FWW (12.3% versus 3.6% in the lab and 9.4% versus 2.2% in the ADL flat, respectively).

In addition, it should be noticed that, for both devices, DL is lower in the ADL flat than during straight line walking in the lab (9.4% versus 12.3% for the PW walker and 2.2% versus 3.6% for the FWW), indicating that the user transfers less body

weight onto the device when they have to turn corners and/or walk across different types of flooring.

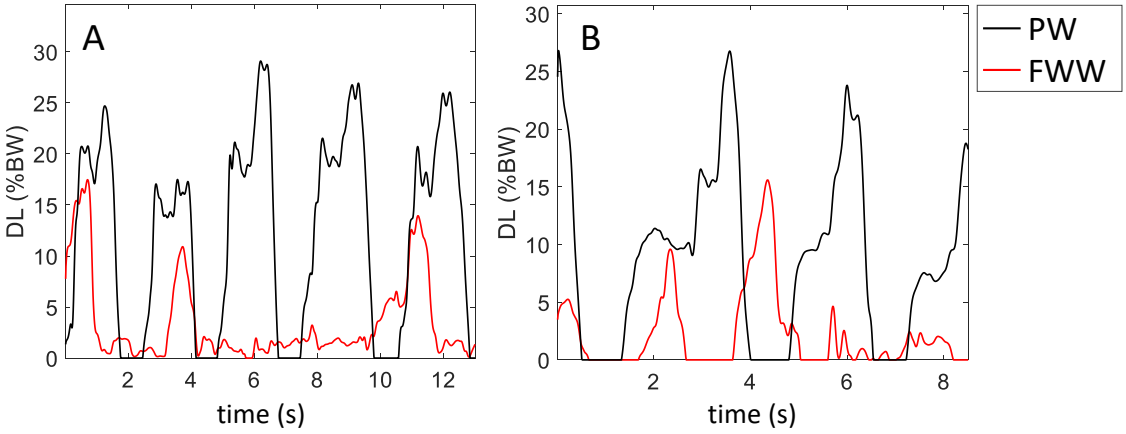


Figure 7.4: Device loading 'DL' in % body weight (%BW) over time for the pick-up walker 'PW' (black line) and the front wheeled walker 'FWW' (red line). Data are shown for (A) straight line walking in the lab and (B) for walking in the ADL flat. It can be seen that, in both environments, DL is greater when using the PW than when using the FWW.

7.3.4 Stability of the system

The SM over time for each device and for each environment is illustrated in Figure 7.5 (PW) and Figure 7.6 (FWW).

When comparing the 2 walking frames, it appears clear that the minimum SM is considerably greater when using the PW than when using the FWW both in the lab and in the ADL flat.

When comparing the two environments, from the figures it is possible to see that the user exhibits lower SM in the ADL flat than in the lab, and this can be observed for both devices.

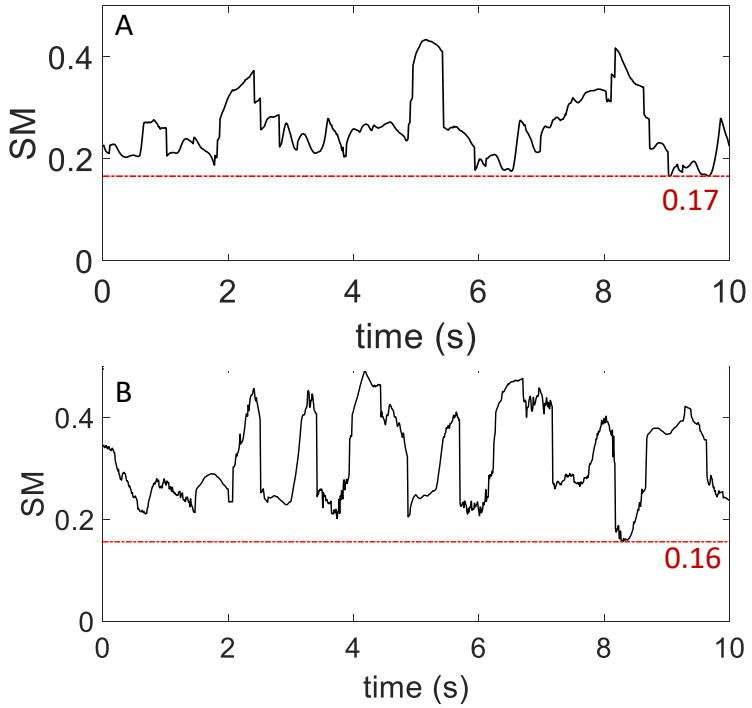


Figure 7.5: PW SM for A) straight line walking in the lab and B) walking in the ADL flat. In the ADL flat the minimum SM is slightly lower than that in the lab.

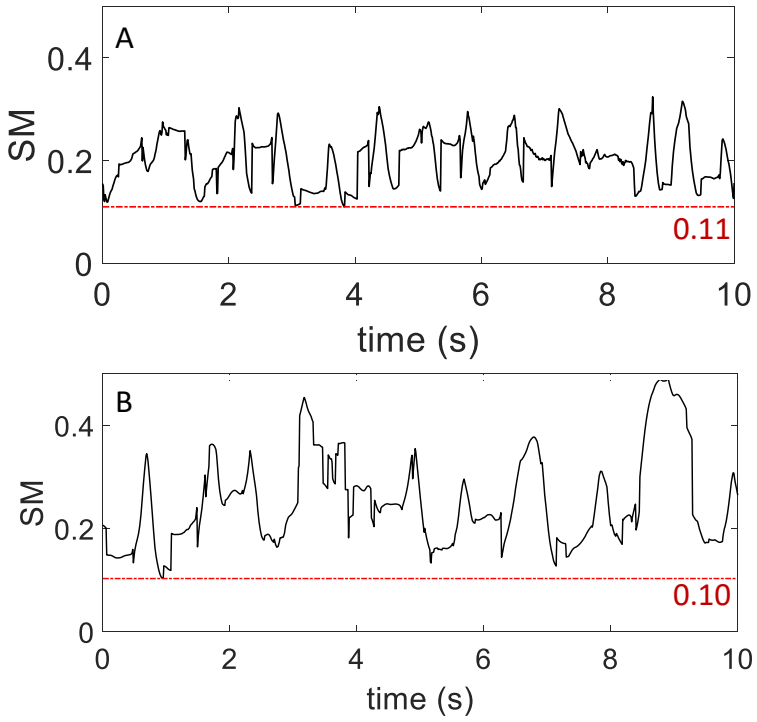


Figure 7.6: FWW SM for A) straight line walking in the lab and B) walking in the ADL flat. In the ADL flat, the minimum SM is lower than that in the lab.

7.3.5 Autocorrelation of SM

Results of the autocorrelation technique show that, during straight line walking, PW use is characterised by greater SM regularity (PW_{Ad1}=0.54 versus FWW_{Ad1} = 0.1) indicating that, based on the hypothesis formulated in Chapter 6, the user is more stable with the PW than with the FWW. Moreover it was also noted that SM during PW use presents identical Ad1 and Ad2, whilst, during FWW use, Ad2 is more than twice the value of Ad1 (FWW_{Ad2} = 0.23). This scale of difference between the two coefficients for the FWW suggests significant step asymmetry (Moe-Nilssen and Helbostad 2004). However, for the PW, equal Ad1 and Ad2 should not be interpreted as equal step and stride symmetry: indeed, when using a PW, the movement cycle differs significantly from that of normal walking as the user, at each gait cycle, lifts the device, moves it forward by a small distance, puts it on the ground and then steps into it; thus, the autocorrelation coefficients for the PW are likely to be related to consecutive pick-up walker movement cycles (one cycle including the lift-off & touch-down of the device as well as the stepping into the frame), rather than to user's steps and strides.

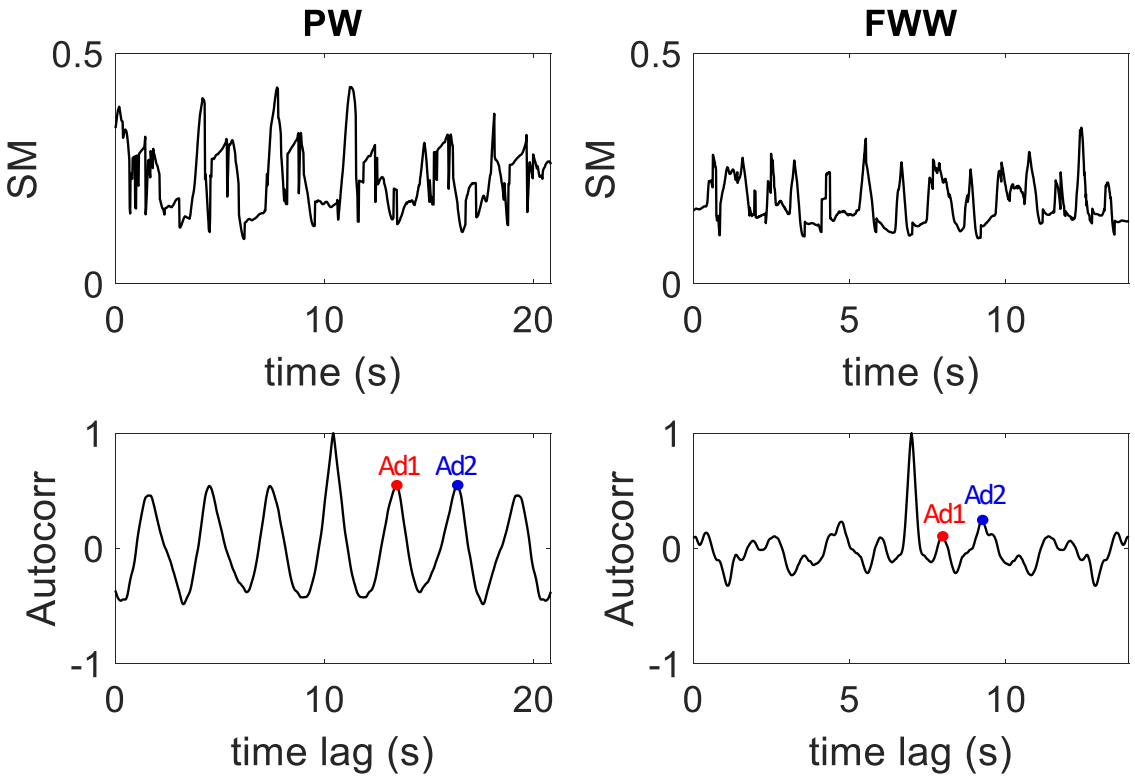


Figure 7.7: Autocorrelation functions and autocorrelation coefficients of SM time series for both the PW and the FWW during straight line walking in the lab. For the PW, Ad1 = Ad2 = 0.54. For the FWW, Ad1 = 0.1 and Ad2 = 0.23.

7.3.6 Delta SM

It was found that the mean difference (i.e. Delta SM 'Δ') between the minimum SM during each complex task (i.e. the "kitchen to bathroom" task in the lab and in the ADL flat) and that during straight line walking for the FWW is almost twice that observed for the PW (Δ_{PW}= 0.009, Δ_{FWW}= 0.016). Based on the hypothesis formulated in Chapter 6, this may suggest that the user is more stable with the PW than with the FWW.

7.4 Discussion

The objective of this chapter was to bring together the methodology, corresponding technology, and analysis techniques developed during the course of this PhD to compare walking aid use and stability for two different devices (PW, FWW), and for two different environments (the lab, which is comparable to the open space of a clinic or hospital corridor, and the ADL flat, representative of a home environment in which walking aids are commonly used).

When comparing the two devices, findings are in agreement with previous basic biomechanical studies (Tsai, Kirby et al. 2003, Kloos, Kegelmeyer et al. 2012) and indicate that PW use leads to lower gait speed and greater time asymmetry between consecutive steps. This was expected as walking with a PW introduces an altered walking pattern. For instance, the movement cycle includes additional gait phases as compared to a normal gait cycle (i.e., PW lift-off, forward movement of the PW, PW touch-down, and, finally, stepping forward of the user). Also, if the PW is used according to clinical guidance, during each movement cycle, one of the user's steps is followed by device lift-off and not by a step with the opposite leg like in unassisted walking, hence explaining step asymmetry. On the other hand, when grounded, the PW provides much greater structural support than the FWW, probably because its rubber feet prevent it from "rolling away". In terms of stability, PW use is characterised by higher minimum SM both in the lab and in the ADL flat. Since it was demonstrated, in Chapter 5, that there is a positive correlation between DL and SM, a simple explanation for this result could be found in the greater DL observed in PW use compared to FWW use. However, another reason could be the greater steadiness of the PW during the times in which it is grounded

as opposite to the constant movement and, possibly, side-to-side wobbling of the FWW. In support of this second hypothesis, both the autocorrelation and the delta analyses suggest that the user is more stable with the PW than with the FWW. This finding is rather surprising as, according to previous conversations, clinicians prefer to prescribe wheeled walkers based on the fact that they allow the user to maintain a more “normal” walking pattern (although such statements do somewhat contradict the guidance, which suggests that the FWW should glide forward first, then the user should step, hence being similar to the PW in terms of lengthening the movement cycle). Finally, in agreement with previous research (Crosbie 1994, Yeung, Chow et al. 2012), these results also support the hypothesis that greater gait speed does not necessarily translate into greater stability and, thus, that gait speed may not be a good indicator of stability.

When exploring how walking aid use changes from one environment to another, data show that the user is unable to adhere to clinical guidance with regard to movement patterns in the ADL flat, and also that device loading decreases when walking in the ADL flat as compared to the open lab with smooth flooring. Moreover, changes in walking aid use are also associated with changes in stability: in this context, decreased minimum SM in the ADL flat, as compared to the lab, are evident for both devices. These results suggest that the home environment may pose a challenge to the user due to the presence of narrow corridors and doorways, furniture, and transitions between different types of flooring (specifically, transition trims are thought to potentially destabilise the system as they represent a change in floor level that the user has to cross with their device). As a result, the user does not use their device for structural support as much as he did in the open lab environment with smooth flooring, and correspondingly shows reduced stability in

the ADL flat. Hence, since walking aids such as PW and FWW are mostly used at home, it is important that clinical training is not limited to the clinic but is also done in users' homes.

It is important to remember that, since this study is based on one user only, results should be interpreted user-specific. For example, a different person may show better adherence to clinical guidance and/or greater stability with the FWW than with the PW.

Most importantly, a major limitation of this study is that its conclusions on stability are made according to the methodology developed in this work, which has not been validated against gold standard measures. This is due to the fact that, to date, no gold standard measures of stability for walking aid users exist. However, the agreement between all SM metrics (minimum SM, autocorrelation, and delta), in addition to SM reflecting the expected reduced stability in the ADL flat compared to the lab, establish confidence in this novel approach. In future, a prospective study of stability outcomes in relation to occurrence of falls is needed.

In summary, this case study highlights several differences in walking aid use between different devices and environments and contributes to build confidence that the methodology developed during this PhD is reflective of user's stability. Since the same user has been tested in a multi-factorial design, and since he was experienced with both walking aids, it seems sensible to conclude that the changes observed were directly related to the type of device used (PW, FWW) and/or the type of environment he walked in (lab, ADL flat). This is of clinical relevance as it highlights the need for both, user-specific prescription and training based on

objective stability outcome measures, and moreover, that training of users should also take place at home rather than in a clinic or hospital alone.

8 Discussion, conclusions, and future work

8.1 PhD aims

Falls in older adults are a major global health problem, with those in the oldest old group being the most likely to fall (Tinetti, Speechley et al. 1988, Rubenstein and Josephson 2002, DH/SC 2009) and to suffer from severe injuries (Scuffham, Chaplin et al. 2003). Moreover, it is known that, in order to improve stability and prevent falls, those in the oldest old group are also the most likely to use walking aids. However, walking aid use has been associated with an increased falls-risk (Deandrea, Lucenteforte et al. 2010). Surprisingly, given this evidence, walking aid use as a mean of fall prevention is an extremely under-researched area. Indeed, in the clinic, mobility of walking aid users is generally assessed using methods based simply on observation and gait speed and which are not specifically designed for walking aid users. This is likely due to the fact that no gold standard measures of stability exist (in either unassisted or assisted walking) as stability is an extremely complex topic, and previous research on walking stability has almost entirely focused on unassisted walking.

Hence, the overall aim of this PhD was to narrow the gap in the existing literature with regard to the research question: "**What constitutes stable walking aid use?**". To achieve this, the following objectives were set:

1. To develop a novel, objective, and generalizable methodology for the assessment of stability of walking aid users.

Chapter 3 described in detail the development of a new methodology, which directly reflects stability of walking aid users by estimating how far user and walking aid are from tipping over and falling. The method is novel in that it considers the user and the walking aid as a coupled system. Furthermore, it is objective as it is based on a basic mechanical principle (the centre of pressure) and does not rely on clinicians' visual observation and experience. Finally, although it was originally developed for pick-up walker users, it has been successfully applied to characterize rollator and front wheeled walker use, demonstrating its generalisability.

2. To design and develop corresponding technology and software necessary for the calculation of the proposed outcome measure.

Three (3) instrumented walking aid systems were designed during this PhD: a pick-up walker (Chapter 3), a rollator (Chapter 4), and a front wheeled walker (Appendix D), all including the same set of sensors which can be swapped between systems as needed. Furthermore, custom-written MATLAB software was developed that uses the data collected with the instrumented walking aid systems to calculate the outcome measure of stability introduced in this work (the combined Stability Margin), and the parameters necessary for its interpretation (movement pattern of user and walking aid device loading).

3. To establish confidence in the ability of the stability assessment methodology developed through objectives 1 and 2 to describe the stability of walking aid

users in relation to the type of walking task performed, the environment, and the type of walking aid used.

The methodology and associated instrumentation developed during the course of this PhD were used to collect data from: 1) a cohort of 10 rollator users in a gait laboratory who performed several tasks representative of daily activities; 2) a group of 5 pick-up walker users who walked with the instrumented pick-up walker both in the lab and in a simulated home environment (the Activities of Daily Living flat at the University of Salford); and 3) a case study of 1 user walking with 2 types of walking aids (a pick-up walker and a front wheeled walker) in 2 environments (lab and ADL flat). The data collected were then analysed according to the methodology developed through Objective 1, and used to evaluate the ability of the combined Stability Margin to recognise the following:

- a decrease in stability between a simple task (i.e., straight line walking) and more complex ones (e.g., turning, stepping up a kerb);
- a decrease in stability between an open space with smooth level flooring (the lab) and a home environment with narrow corridors, doorways, and transitions between different types of flooring;
- differences in walking aid use and corresponding stability between different walking aids.

4. To investigate whether it is possible, using the methodology developed through Objectives 1 & 2 and/or other associated metrics, to inform on relative stability of WA users.

In chapter 6, absolute values and other metrics of the combined Stability Margin (autocorrelation, delta, integral and RMS deviation) were investigated with regard to their potential to differentiate between more and less stable users, as identified based on history of fracture, gait speed, and clinical observation.

8.2 Novelty

The main novelty of this work lies in the introduction of a new outcome measure of stability, the combined stability margin “SM”, which, for the first time, considers the user and their walking aid as a single system. Previous authors investigated stability of walkers by exploring the kinematics of the device’s centre of pressure and concluded that, when the device is on the ground, the user’s loading of the device is directly proportional to their risk of falling (Pardo, Deathe et al. 1993, Tung, Chee et al. 2015). Their approach, however, did not adequately quantify stability as it considered the device only and relied on the device being grounded with all 4 feet; hence it could not be applied at times when the walking aid was airborne and could not distinguish tipping from the onset of lifting/touching down of the device. In contrast, the method developed in this work is able to assess stability during all phases of gait, including when the walking aid is airborne or partially grounded.

Furthermore, another advantage of SM is that it is based on a simple and basic mechanical principle, the centre of pressure. Whilst previous measures of stability were based on the hypothesis that human gait is highly periodic (Jordan, Challis et al. 2007, Toebes, Hoozemans et al. 2012, Bisi, Riva et al. 2014, Riva, Bisi et al. 2014) or that it can be assimilated to an inverted pendulum (Hof, Gazendam et al. 2005, Hak, Houdijk et al. 2013), SM does not make any assumption and, therefore,

its applicability is not limited by the configuration of the walking system of interest. Finally, in contrast to previous research which focused on one specific type of device (Pardo, Deathe et al. 1993, Tung 2010), the methodology developed during this PhD is generalizable to a range of walking aids, as has been demonstrated by applying it to rollator and front wheeled walker users in addition to pick-up walker users for which it was initially designed. Of course, device-specific modifications were necessary to accommodate the load cells in such a way as to accurately measure the forces through the ground contact points, however, given suitable instrumentation, the measure SM itself is generalizable.

8.3 Key findings and contribution to knowledge

Results of the assessment of rollator users presented in Chapter 5 showed that stability decreases substantially from straight line walking to more complex tasks. Yet, no significant differences between the other tasks (90° turn, 180° turn, backwards walk, obstacle crossing, and step up/down) could be found, indicating that the level of challenge for each task may be either similar or subjective. Moreover, findings of this study also suggest that stability may be influenced not just by the type of task, but also by the specific strategy used to perform a given task.

In addition, data from the case study suggest that stability is reduced in the ADL flat compared to the lab, indicating that the home environment may pose a challenge to the user due to the presence of narrow corridors and doorways, furniture, and transitions between different types of flooring (specifically, transition trims are thought to potentially destabilise the system as they represent a change in floor level that the user has to cross with their device).

With regard to user-specific factors, it was found that both the size of the system's base of support and the amount of the user's body weight transferred onto the walking aid (device loading) affect stability outcome measures. With regard to the base of support, although it is reasonable to assume that the greater the base of support, the further the centre of pressure can travel before reaching the tipping point, it is also true that a smaller SM simply due to a smaller base of support should not be confused with an unsafe gait, as the base of support may well be sensibly utilised. Hence, it was decided to normalise SM by a parameter representative of the size of the base of support. With regard to device loading it must be noted that when the walking aid is lifted its load is 0, and hence SM/DL would approach infinity, thus rendering normalization by device loading inappropriate. Moreover, in certain circumstances, advice to those who show generally low SM, and especially to those whose SM is often directed towards the rear of the base of support, could include instruction to lean more onto the rollator; in such cases, removing the influence of DL through normalisation would limit insights gained.

Finally, in Chapter 6, it was found that some analysis techniques of SM such as the autocorrelation and delta show promise to distinguish between more and less stable user-device systems. Analysis techniques were first applied to rollator and pick-up walker users to rank them in order of stability, and then to a single user of two devices (pick-up walker and front wheeled walker), the latter to indicate which system (user + pick-up walker or user + front wheeled walker) was more stable, and hence which walking aid was more suitable. Specifically, all the stability metrics used (minimum SM, autocorrelation, and delta) were consistent and suggested that the user may be more stable with the pick-up walker, which was

surprising as it is known from previous conversations that clinicians prefer to prescribe wheeled walkers based on the fact that they allow the user to maintain a more “fluid” walking pattern.

Overall, SM proved able to reflect the expected decrease in stability between simpler and more complex walking tasks representative of daily activities, and between an open space and a home environment, building confidence that the stability assessment methodology developed during this PhD is able to characterise walking aid users’ stability.

Furthermore, these findings provide initial evidence as to how the proposed methodology and associated instrumentation may facilitate safe use of walking aids. Firstly, device selection and prescription should be informed by objective stability measures and not exclusively be based on clinicians’ observation & experience or recommendations from family and friends. Second, training should target daily activities other than straight line walking, and should be customised to focus on those activities for which a user exhibits particularly low stability, and should not be limited to the clinic but should also be done in users’ homes.

Finally, the instrumented walking aids developed during this PhD also offer the possibility to calculate parameters such as walking pattern and device loading, which were proven to influence SM and can be controlled. Thus, in future, clinicians may use this parameters to train users suggesting, for example, to change their walking pattern and/or regulate device loading in order to increase SM.

8.4 Challenges, limitations and recommended future work

Some important limitations must be discussed which prevent this work from having a direct impact on clinical practice and, in particular, on prescription and training or walking aid users. First of all, it must be acknowledged that the number of users

tested (10 rollator users, 5 pick-up walker users, and 1 user of two different types of walking aids) is too small to generalize findings. Nevertheless, these numbers are in line with previous lab-based biomechanical studies that involved older frail adults (Deathe, Pardo et al. 1996, Bateni, Heung et al. 2004, Tung 2010, Tung, Chee et al. 2015), and participation has been limited by frailty, reduced mobility, and cognitive decline which are common among this population. In fact, although several organisations including community centres, care homes, falls-clinics and intermediate care units were approached to identify participants, the recruitment rate remained low throughout the study as many eligible participants refused to participate as they felt uncomfortable or unable to travel to the lab.

Moreover, the outcome measures and techniques introduced during this PhD have not yet been validated. However, to date, no gold standard measures of stability of walking aid users exist, and previous research reported that even measures commonly used in clinical practice such as gait speed do not necessarily inform on stability; indeed, walking at a slower speed may even improve stability as it allows the user more time to better control their movement and that of the WA (Crosbie 1994, Yeung, Chow et al. 2012). Hence, longer-term, a prospective study on falls is needed to conclude on the merit of SM and associated analysis techniques of SM in relation to occurrence of falls.

Finally, to facilitate clinical adoption of the stability assessment methodology and corresponding technology developed here, substantial improvements need to be made to the current instrumented walking aid systems. Indeed, at present, the methodology relies on the use of optoelectronic cameras to obtain position data of the anatomical and walking aid feet, which are necessary for the calculation of SM.

In future, a more portable solution based on dedicated position sensing is required. There are several technologies on the market that may be suitable for this purpose such as inertial measurement units (IMUs), ultrasound sensors, magnetic sensors, RGB cameras, and infrared cameras. Previous related work at the University of Salford (Voltzenlogel 2017), for example, investigated the ability of a single Kinect unit to track the position of the user's feet while walking with a walking aid in the lab. Kinect cameras have the advantage of being considerably cheaper than optoelectronic cameras (£200 versus several hundred thousand Pounds); furthermore, they do not require markers on the user's feet, and include both RGB and infrared cameras providing information on feet positions as well as on the surrounding environment. However, the Kinect unit used proved to be very sensitive to lighting conditions (making it unsuitable for use outside a controlled environment), and it has considerable weight and required several cables, which prevents it from ever being mounted onto a walking aid. Most importantly, the error in the measurement of feet positions (several centimetres) was too large for this technology to be used for the calculation of the centre of pressure. Nevertheless, with technology continuously getting more accurate, smaller, and wireless, future work should focus on improving the suitability of infrared and/or RGB cameras for this type of application.

Furthermore, costs for the development of the instrumented walking aids are currently very high as approximately £2000 were spent to manufacture each device and £5000 for the purchase of the load cells and corresponding transmitters. For this PhD, load cells were swapped between devices as needed, to contain costs, but their transfer is time consuming and accelerates wear and tear of the load cell connectors. Hence, especially considering that clinics would need to purchase a

set of fully instrumented walking aids, reducing costs is essential. To this end, mass production would probably make the manufacturing process more cost effective, whilst load cells could be replaced with less expensive strain gages.

8.5 Conclusions

In summary, this PhD developed a novel methodology for stability assessment of walking aid users which is objective and generalizable to a range of walking aids. Furthermore, corresponding instrumentation was designed and tested, providing the first objective data on stability of users of 3 different walking aids during performance of several tasks representative of daily activities, and in 2 different environments (the lab and a simulated home environment). Hence, this PhD unlocked the potential of a novel approach to address the three major gaps in the knowledge base, identified in the introduction of this thesis: 1) a limited understanding of walking aid use, 2) lack of measures/methods that adequately quantify stability of walking aid users, and 3) limited understanding of potential mechanisms underlying the reported falls-rate in users of walking aids. Narrowing these gaps in the knowledge base may longer-term have a positive impact on clinical practice and fall prevention in this population.

Appendices

A. Characterisation of rollator use using inertial sensors

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The use of walking aids is prevalent among older people and people with mobility impairment. Rollators are designed to support outdoor mobility and require the user to negotiate curbs and slopes in the urban environment. Despite the prevalence of rollators, analysis of their use outside of controlled environments has received relatively little attention. This Letter reports on an initial study to characterise rollator movement. An inertial measurement unit (IMU) was used to measure the motion of the rollator and analytical approaches were developed to extract features characterising the rollator movement, properties of the surface and push events. The analytics were tested in two situations: first, a healthy participant used a rollator in a laboratory using a motion capture system to obtain ground truth. Second, the IMU was used to measure the movement of a rollator being used by a user with multiple sclerosis on a flat surface, cross-slope, up and down slopes and up and down a step.

The results showed that surface inclination and distance travelled measured by the IMU have close approximation to the results from ground truth; therefore, demonstrating the potential for IMU-derived metrics to characterise rollator movement and user's pushing style in the outdoor environment.

1. Introduction

In the United States ~4.2 million older adults use at least one walking aid, with a view to reducing fall risk and/or enhancing mobility [1]. A European study that included the UK found that walking aids were reported to be used by 29–49% of older people [2]. However, as will be discussed in more detail below, we have surprisingly little objective data on the extent to which such devices are actually used, how they enhance mobility or reduce fall risk. Indeed, a rather surprising finding from a number of studies is that their reported use has been associated with falls. Research found that hospitalised patients who fell were more likely to be users of walking aids [3], and a meta-analysis associated walking aid use with a two–three-fold risk of falling [4]. Whilst correlation cannot be assumed to indicate causation, this is certainly of serious concern and justifies further research.

Rollators are the most and second most common walking aids in Sweden [5] and Canada [6], respectively, due to the greater provision of stability support than walking sticks. Rollators are often fitted with seats and/or baskets to allow users to travel longer distances and run errands outdoors. Rollators typically have manual brakes installed on the rear wheels to prevent the rollator running away from the user while the user is moving and also to allow the user to adjust the movement of rollator in relation to their gait pattern.

A small number of studies have reported on user views on rollators. Brandt et al. [7] carried out a longitudinal study using the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST version 1) to understand the satisfaction with rollators among community-dwelling users (mean age of 76) in Denmark. The overall satisfaction with rollators was above 90%, particularly with the effectiveness, durability and safety of rollators. More than two-thirds of the users reported using their rollators at least once a day. However, rollators were reported to be too heavy to handle when getting over curbs and steps. A study by Lindemann et al. [8] found that rollator users reported walking downhill, uphill, over uneven surfaces outdoors and obstacle crossing to be major concerns with regard to safety. Rollator users in Denmark [7] and Japan [9] were found to be less satisfied with the professional and follow-up services including the provision of training by the physiotherapists, repairs and visits. This left them without enough knowledge of basic instructions, adjustments to and repairs of their rollator. In addition, there was a lack of channels to feedback or report problems with their rollator.

From a biomechanics perspective, despite their prevalence amongst the older population, the literature on characterisation of rollator–user interaction is very limited. Kegelmeyer et al. [10] studied 27 individuals with Parkinson's disease, finding that rollator use led to less variability in gait measures of velocity, stride length, per cent swing and double support time compared with walking sticks, walking frames, two-wheeled walkers and U-Step walkers. Lindemann et al. [8] studied the gait of 22 rollator users (median age of 82) in a geriatric rehabilitation clinic in Germany. The results showed that with rollators, users walked faster with smaller step width and higher walk ratio (i.e. step length divided by step frequency) than without rollators in both forward and backward walking, indicating an improved walking performance. However,

complex walking tasks such as opening a door were found to lead to the impossibility to open and pass through a door with a rollator, because of the rigid rear wheels. Chee et al. [11] investigated the step width, the variability of step width and velocity of two community-dwelling rollator users with multiple sclerosis (MS) by comparing their performance in the laboratory and outdoor walking environment including an urban pavement, a ramp and pedestrian crossing, using an instrumented rollator. The results suggest that the outdoor walking environment may affect foot placement patterns, and hence potentially, trip risk. The step width variability of up-ramp walking had greater step-width variability than laboratory walking and down-ramp walking, indicating an unstable mediolateral movement which could lead to falls. Moreover, the walking velocity significantly increased at the pedestrian crossing as compared with walking in the laboratory.

In one of the most recent papers, Tung et al. [12] studied three stroke or traumatic brain injury users of rollators in the laboratory and on a walking course inside a rehabilitation hospital containing hallways, turns, ramps, doors and lifts. A single-axis load cell was mounted into each leg and a three-axis accelerometer was mounted under the seat of the rollator to capture the performance of rollator use. High fall risk behaviours such as collisions with door frames and between the foot and the rollator, as well as stumbling and lifting the rollator, were observed in the walking course.

Despite the recent advances in low-cost computing and sensing, there is no data on the patterns of use of rollator devices outside of controlled environments, whereas in other areas of mobility aids research such as wheelchairs the usage and activity levels can be measured by accelerometers and inertial measurement units (IMUs) [13–15]. This is very surprising, particularly given the high prevalence of rollators amongst older people and recent studies that indicate the potential for increased trip or fall risk

outside of the laboratory [11, 12]. Indeed, even basic information on the extent to which prescription of such devices leads to increased mobility is absent.

In the light of this, this Letter reports on a feasibility study to characterise rollator use in the laboratory using real-world surfaces. Two experiments are presented, first an experiment with a healthy user, and second an experiment with a user who has MS. The first experiment demonstrates how a single IMU mounted on the rollator frame together with sensors on the user's feet can be used to characterise basic features of rollator use. These features are number of push events, distance travelled, average distance and duration of each push, and the push events in relation to the foot movements. The second experiment applies this technique to one rollator user with MS in a simulated urban environment (SUE) and demonstrates the potential to obtain information on the environment including surface slope and curb crossing events from a rollator-mounted sensor, in addition to the basic gait features.

2. **Methods**

The aim of the feasibility study was to establish the capability of the IMU to capture the interaction between the rollator, the user and the walking environment. To evaluate the capability of the IMU, the experiment was two-fold, containing (i) testing of protocols and software algorithm using a gold standard motion capture system and (ii) testing of the protocols and algorithm in an SUE.

2.1 Participants

A healthy participant was recruited for understanding baseline performance. Subsequently, a participant with 3 years of MS participated in tasks in the SUE. Ethical approval was obtained from the University College London Research Ethics Committee (4721/002).

2.2 Gold standard testing in the laboratory

The gold standard test comprised a 6 m straight-line walking assessment with a rollator. The healthy participant had IMUs of Xsens MTw2 Awinda (Xsens Technologies Besloten Vennootschap, the Netherlands) attached to the pelvis and both feet, operating at a sampling frequency of 100 Hz. To obtain ground truth, the three-dimensional coordinate data of the pelvis and both feet were captured using an eight-camera VICON Motion Capture System at a sampling frequency of 100 Hz. On the rollator, there were an IMU horizontally attached to the frame and a cluster of markers to each of the left, right and front side of the frame as shown in Fig. 1. The orientation of the IMU on the rollator is the Y-axis for anterior–posterior movements, the X-axis for mediolateral movements and Z-axis for vertical movements. The IMU is oriented such that a negative value in the Y-axis corresponds to forward movement. The rollator was banged onto the force plates by the participant before the start of each trial to get a peak force in both VICON and Xsens to synchronise the two datasets.

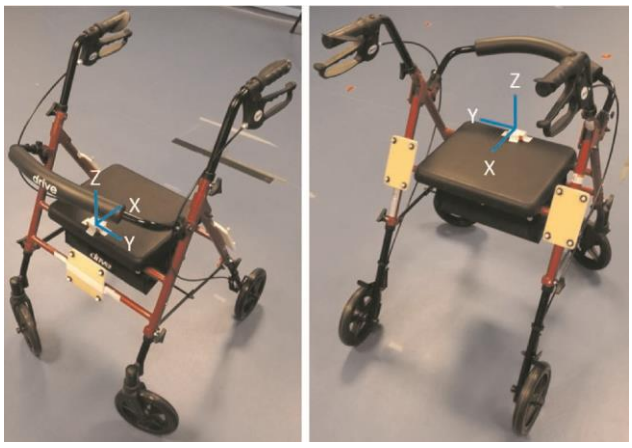

Figure A.1: Placement of the IMU, taped in white and on top of the seat and cluster markers, on the left, right and front side of the rollator

2.3 Testing in the SUE

The tests in the simulated environment used the same IMU placement as the gold standard testing, but did not use the motion capture system. The tests consisted of a participant moving along four straight lanes including an 8.4 m flat path, an 8.4 m 4% cross-slope (2.29° elevation across the distance of travel), a 4.8 m 6% slope (3.44° elevation in the distance of travel) and a step of 80 mm, which were set up at the Pedestrian Accessibility Movement Environment Laboratory at University College London as shown in Fig. 2. The participant with MS was asked to move along each lane at a self-selected speed and in a way they normally moved in their everyday environment. In each lane, the participant performed one to three trials, depending on their physical capability, with a pre-experiment in which several trials were conducted to familiarise the user with the laboratory settings.

3. Data analysis:

The results of the gold standard testing from the motion capture system served as the ground truth to examine the analysis of the IMU data for distance travelled, whilst the known characteristics of the surface of the SUE served as ground truth for surface detection. Gait phase data was obtained from the foot-worn IMU, which was measured alongside the push events of the rollator. The analysis was utilised to measure the characteristics of rollator usage in the laboratory and SUE.

3.1 Raw data and filtering

The raw data in the X, Y and Z axes are vectors with length n of the form

$$X = (x_1, x_2, x_3, ..., x_n).$$

$$Y = (y_1, y_2, y_3, ..., y_n).$$

$$Z = (z_1, z_2, z_3, ..., z_n).$$

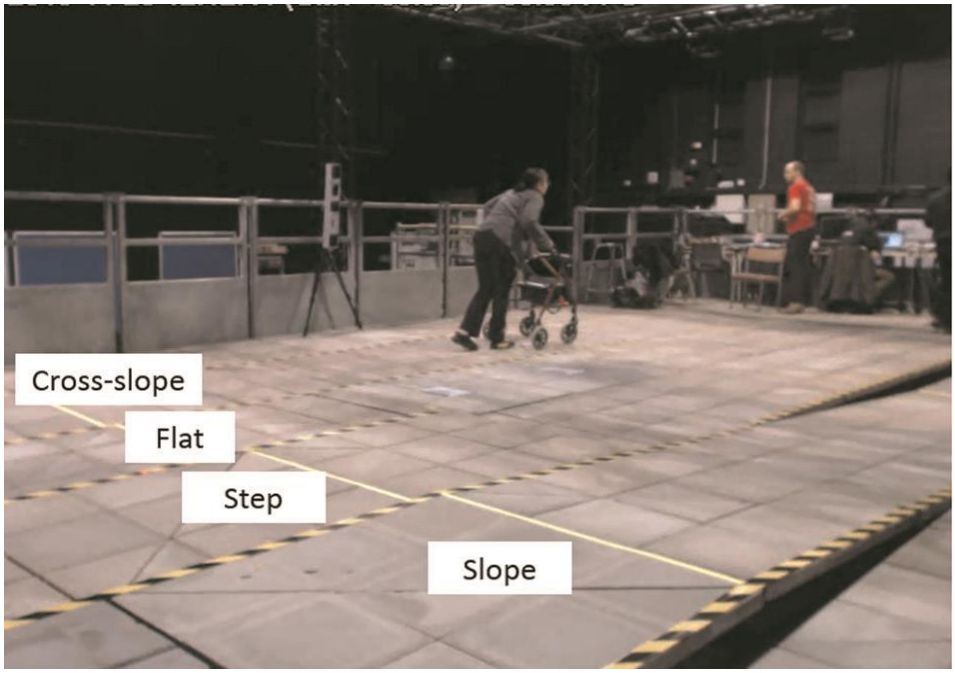

Figure A.2: ***Experiment set-up for the SUE and the property of surfaces.***

Two different filtering operations are applied to the data prior to subsequent processing, a low-pass filter and a band-pass filter, to give two differently filtered versions of the raw data. A fourth-order Butterworth low-pass filter at 0.2 Hz is used to extract the baseline from the data, as X^b, Y^b and Z^b, with components x^b_i, y^b_i and z^b_i. A second-order Butterworth band-pass filter between 0.2 and 3 Hz is used to extract the motion-related component of the signal as X^m, Y^m and Z^m, with components x^m_i, y^m_i and z^m_i.

3.2 Surface detection

The acceleration of the Y-axis is used to calculate the longitudinal tilt of the rollator on the flat surface, slope and step; the acceleration of the X-axis is used to calculate the cross-sectional tilt of the rollator on the cross-slope.

The low-pass data are used for surface detection. From these data, the orientation of the rollator with respect to the gravitational pull of the earth is estimated, which

provides the angle of the horizontal plane of the rollator to the earth. From this angle the direction of the surface slope, if any, can be determined. Orientation is calculated as:

Equation 1

$$\theta_i^Y = cos^{-1}\left(\frac{y_i^b}{\sqrt{x_i^{b^2} + y_i^{b^2} + z_i^{b^2}}}\right),$$

Equation 2

$$\theta_i^X = cos^{-1}\left(\frac{x_i^b}{\sqrt{x_i^{b^2} + y_i^{b^2} + z_i^{b^2}}}\right).$$

3.3 Distance travelled

Distance travelled is obtained principally from a double integration of the accelerometer signal in the direction of travel. For this work, only the Y-axis (corresponding to the anterior–posterior orientation of the rollator) has been used. This axis is oriented approximately parallel to the ground in the direction of movement and thus captures the majority of the motion of interest.

The band-pass filtered data were used to calculate distance travelled. After filtering, the signal was cumulatively, numerically integrated to obtain velocity over time, $\mathbf{Y}^v$. This is achieved using the trapezoidal rule for integration, given in this case as

Equation 3

$$f(\boldsymbol{Y}, a, b) = \int_a^b \boldsymbol{Y} = \frac{b-a}{2(b-a)} \sum_{i=a}^{b-a} y_i + y_{i+1}$$

where a and b are the indices of Y between which an integral is required. Equation 3 is then used cumulatively to provide the cumulative numeric integration as

Equation 4

$$g(\boldsymbol{Y}, \alpha, \beta) = (f(\boldsymbol{Y}, \alpha, \alpha), f(\boldsymbol{Y}, \alpha, \alpha + 1), f(\boldsymbol{Y}, \alpha, \alpha + 2), \dots, f(\boldsymbol{Y}, \alpha, \beta))$$

Owing to the high-pass filtering removing the DC component, the velocity oscillated around zero, which transposed the velocity downwards, which when integrated to get distance results in error building up cumulatively. To counteract this, an adjustment was made to the velocity signal based on the assumption that a person pushing a rollator will not maintain a constant velocity unless the rollator is stationary. Therefore, if the stationary periods are identified, the velocity signal can be zeroed around these points to get back to true velocity.

To achieve this, a baseline signal is created by interpolating between velocity points where the gradient is below 0.5×10^{-3}. The set of zero-points and their associated timestamps are interpolated to get a baseline signal with the same timestamps as the velocity signal using MATLAB's pchip interpolation, which is based on work by Fritsch and Carlson [16] and Kahaner et al. [17]. Pchip interpolation was chosen as it is only based on points close to the interpolation target and is robust to local changes in signal.

Once a baseline signal is created, it is added to the velocity signal to correct the offset. The adjusted velocity signal is then cumulatively integrated a second time, using Equation 4, to get distance travelled. Other parameters of interest such as push identification can be obtained from a simple analysis of the adjusted velocity signal or the cumulative distance travelled.

4. Results

4.1 Gold standard testing in the laboratory

Results from the ground truth test with the healthy participant showed that calculated distance travelled is a very close approximation to ground truth for both tests. Figure 3 shows this for one of the two tests. Furthermore, a distinct push pattern, as shown in Figure 3, can be identified. Figure 4 shows the derived velocity signal, cumulative distance and orientation of the rollator over time.

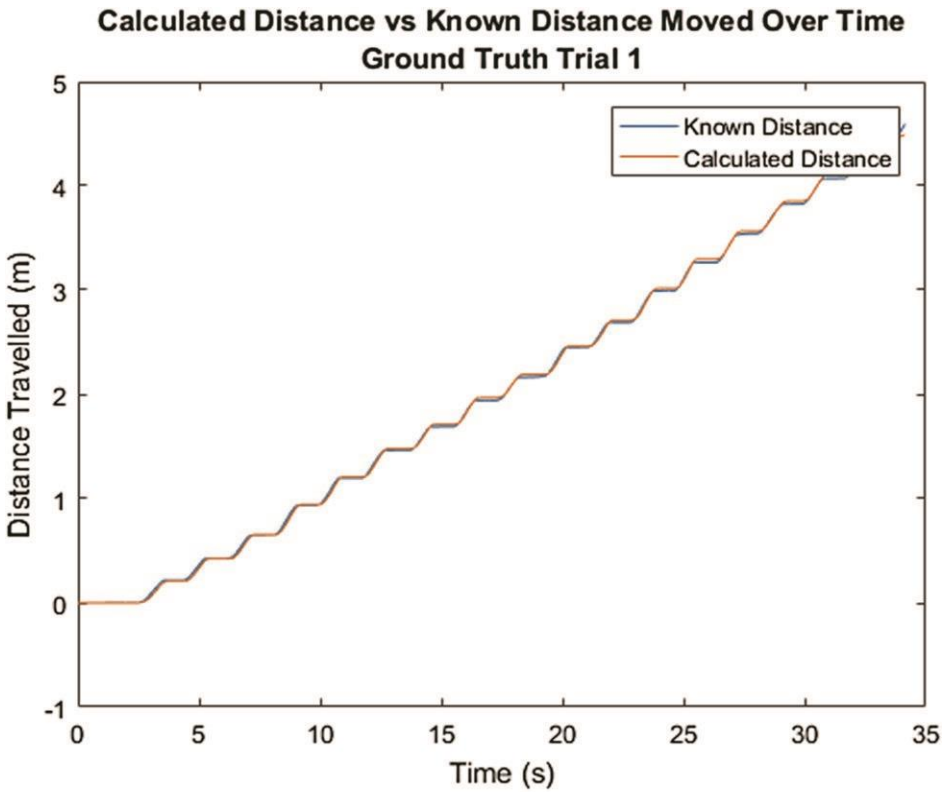

Figure A.3: comparison between distance calculated by IMU and known distance from motor capture system in the gold standard testing with the healthy participant.

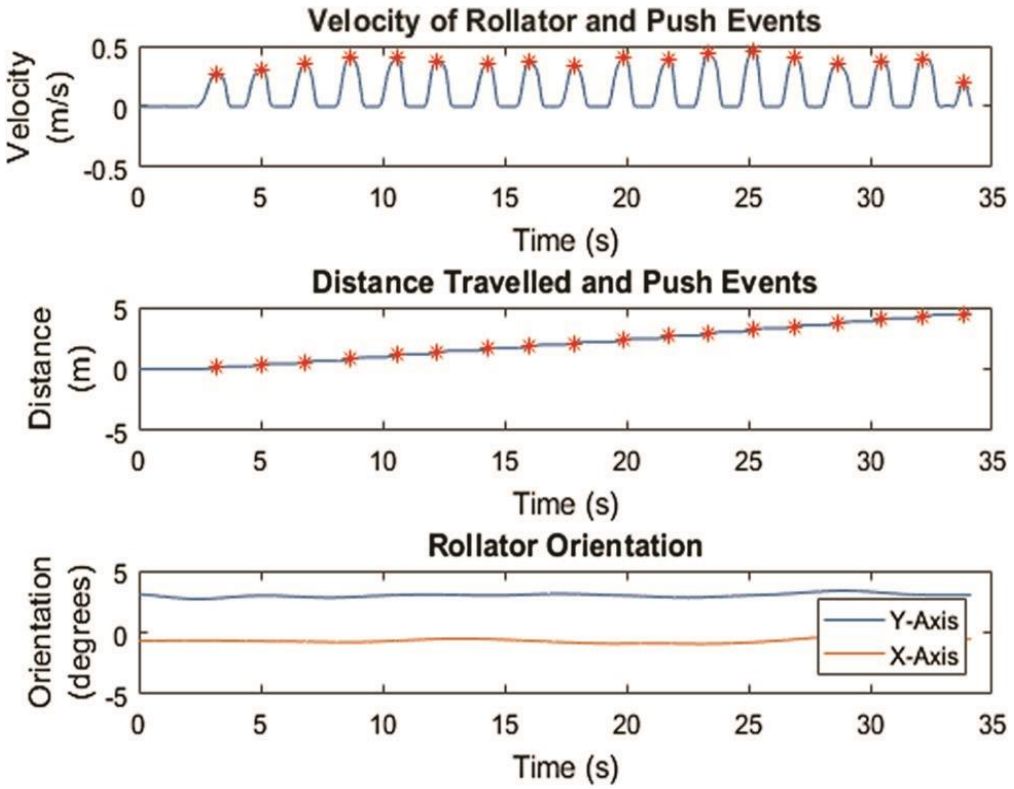

Figure A.4: IMU data shows velocity (top) and distance travelled (middle) in relation to push events (red stars); and the orientation of the rollator over time (bottom) in the gold standard testing with the healthy participant.

Pushes, identified as moments of peak positive velocity, are identified with red stars. The orientation of the rollator shows a constant orientation over the walk, indicating no change in orientation occurred.

The basic features of rollator use of the healthy participant including the number of push events, average distance and distance of each push, and mean velocity of rollator movement are shown in Table 1. Fig. 5 shows a distinctive pattern of a push event happening around the start of a stance phase of either of the feet, demonstrating the healthy participant's pushing style.

Table 1 Basic features of rollator use including number of push events, average distance and distance of each push, and mean velocity of rollator movement.

Surface types	*Number of push events*	*Average distance per push, m*	*Average duration per push, s*	*Mean velocity, m/s*

gold standard with the healthy participant	–	–	–	–
4.6 m flat surface	18	0.2623	1.8062	0.1459
SUE with the MS participant	–	–	–	–
8.4 m flat surface	36	0.2344	1.7118	0.1367
4% 8.4 m cross-slope (right)	39	0.2311	1.3989	0.1516
4% 8.4 m cross-slope (left)	19	0.3105	1.6447	0.1904
6% 6 m up-slope	38	0.1904	1.4522	0.1283
6% 6 m down-slope	19	0.3248	1.6765	0.1952
80 mm step-up on 8.4 m path	45	0.1973	1.5656	0.1284
80 mm step-down on 8.4 m path	43	0.2154	1.5546	0.1423

4.2 *Testing in the SUE*

The basic features of rollator use of the MS participant measured by the analysis of IMU data developed in the gold standard testing and applied to the SUE data are presented in Table 1.

Similar to the results in the gold standard testing, the characteristics of the rollator movement of the MS participant along the flat surface are comparatively steady, as shown in Figure 6, as opposed to other surfaces as shown in Figures 8–11. Results from the simulated surface testing on the flat surface, as shown in Figure 6, are encouraging with total distance travelled from IMU data being approximately equal to the known distance measured by the motion capture system. The push pattern is harder to identify in this data, but is likely to be the result of the MS participant's particular gait pattern. The pushing style also demonstrates a similar pattern to the gold standard testing in which a push event happened around the start of a stance phase, as shown in Figure 7.

The mediolateral inclination of the rollator movement along the 6% cross-slope is identified by the degrees elevation across the distance of travel, around −2° to −3° on the X-axis, as shown in Figs. 8 and 9. The start and end of the 6% slope is identified by the change in degree elevation from around −2 to +5 on the Y-axis (Figures 10 and 11).

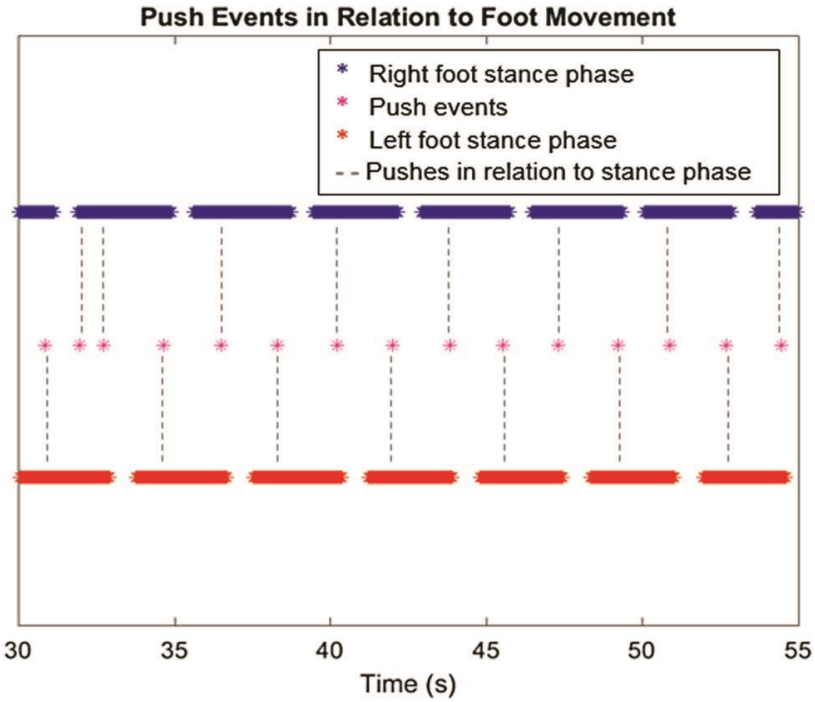

Figure A.5: Push events from IMU data in relation to foot movement in the 25 s segment in the gold standard testing with the healthy participant.

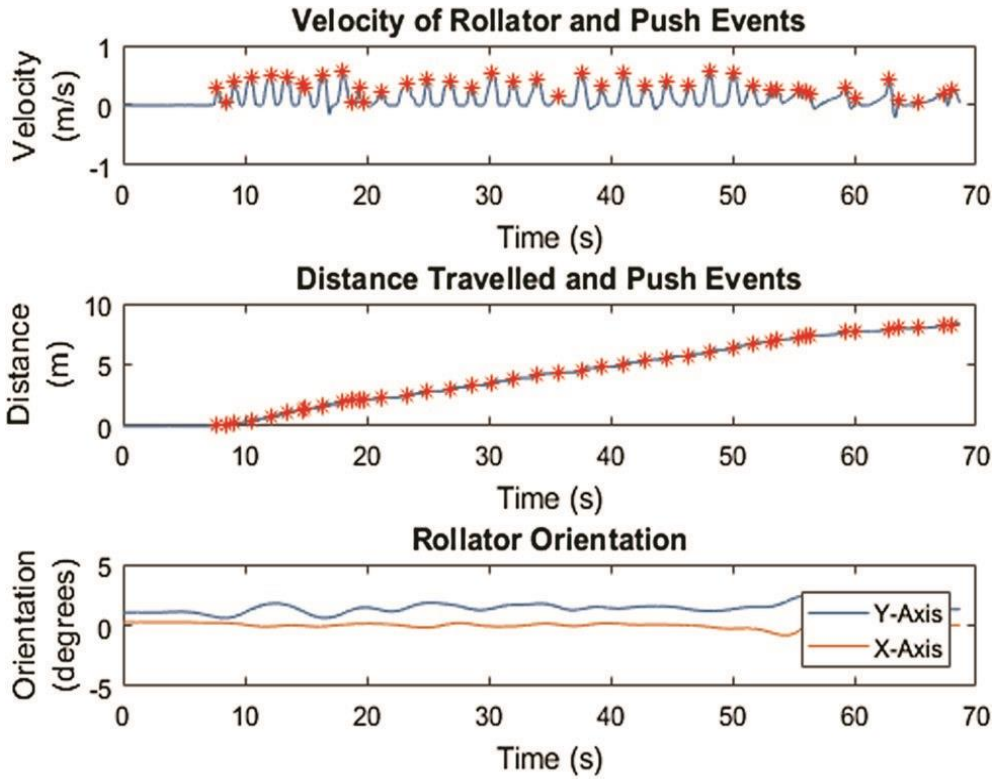

Figure A.6: IMU data shows velocity (top) and distance travelled (middle) relating to push events; the orientation of the rollator (bottom) along the flat surface with the MS participant in the SUE.

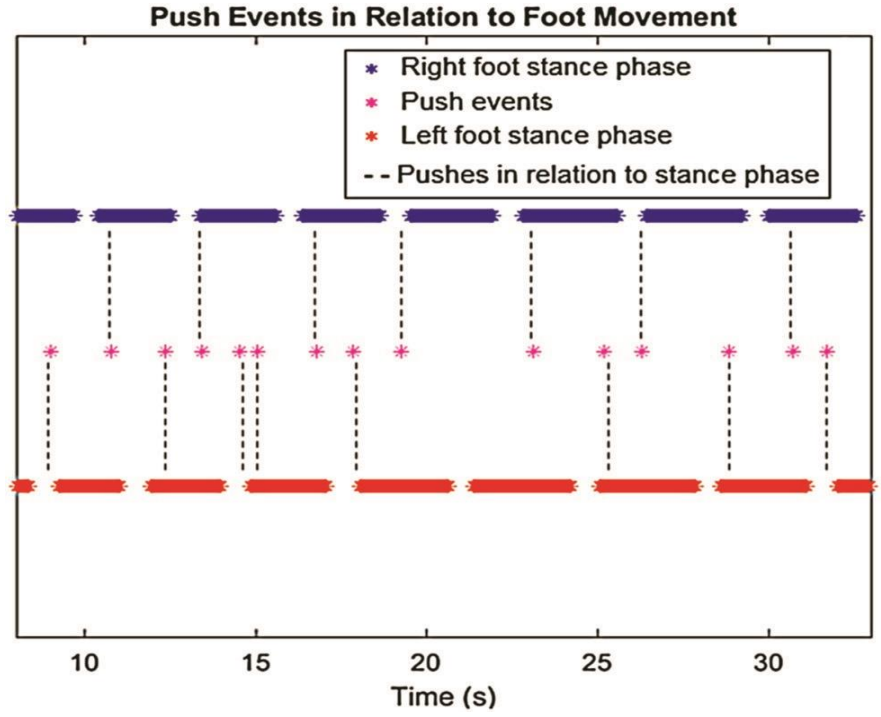

Figure A.7: Push events from IMU data relating to foot movement in the 25 s segment along the flat surface with the MS participant in the SUE.

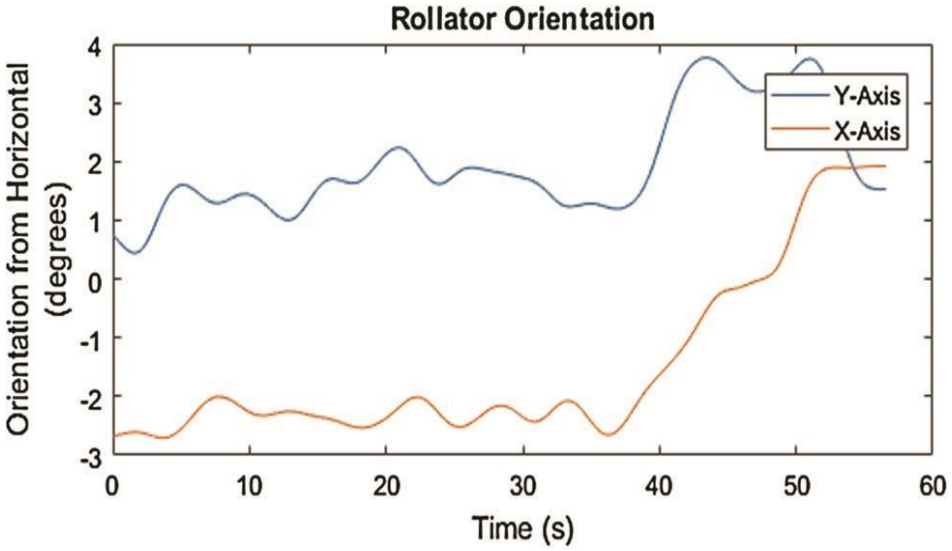

Figure A.8: Orientation from IMU data, between 0 and 37 s, of the rollator along the 4% (2.29°) cross-slope with the elevation on the right with respect to the MS participant in the SUE.

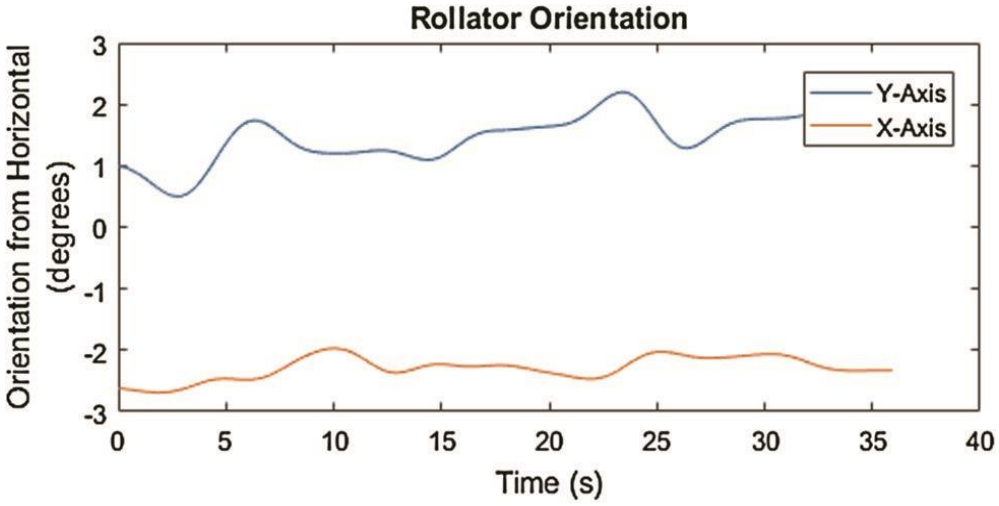

Figure A.9: Orientation from IMU data of the rollator along the 4% (2.29°) cross-slope with the elevation on the left with respect to the MS participant in the SUE.

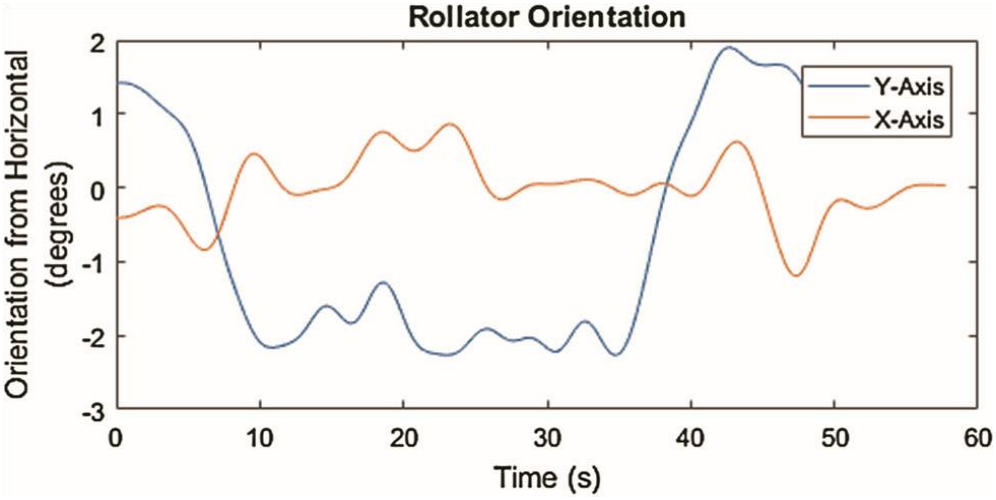

Figure A.10: Orientation of the rollator along the 6% (3.44°) up-slope with the MS user in the SUE.

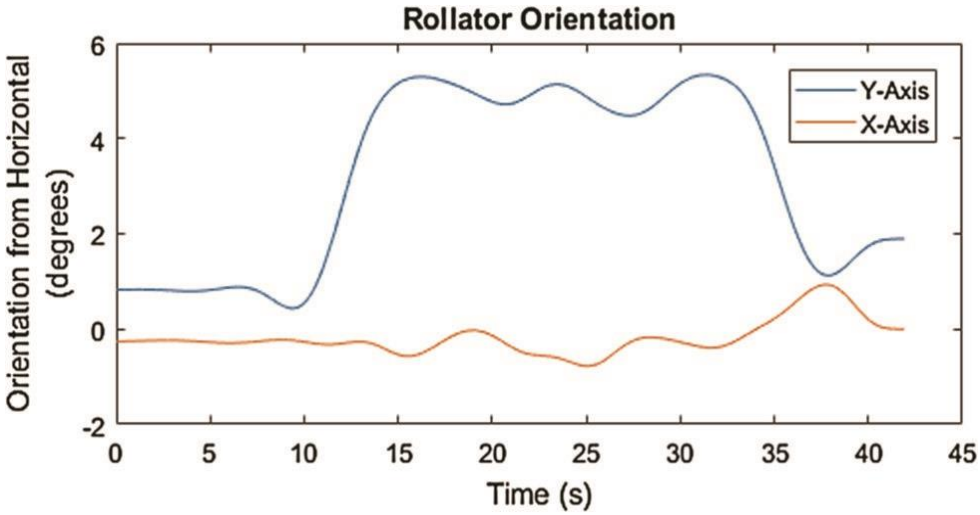

Figure A.11: Orientation of the rollator along the 6% (3.44°) down-slope with the MS user in the SUE.

During the step-up and step-down, the regular movement of the rollator is shown to have been interfered with the step. Figures 12 and 13 show an increase of push events when the MS participant was encountering the step-up. The orientation data in Figures 12 suggests that the rollator might be initially pulled close to the MS participant and then lifted up to the raised step, hence a dip in the orientation in the Y-axis.

Figures 14 and 15 show an increased interval between pushes when the MS participant was encountering the step-down. The orientation data in Figure 14 suggest that the rollator might be pushed away from the MS participant and then land on the lowered step, hence the peak in the orientation of the Y-axis.

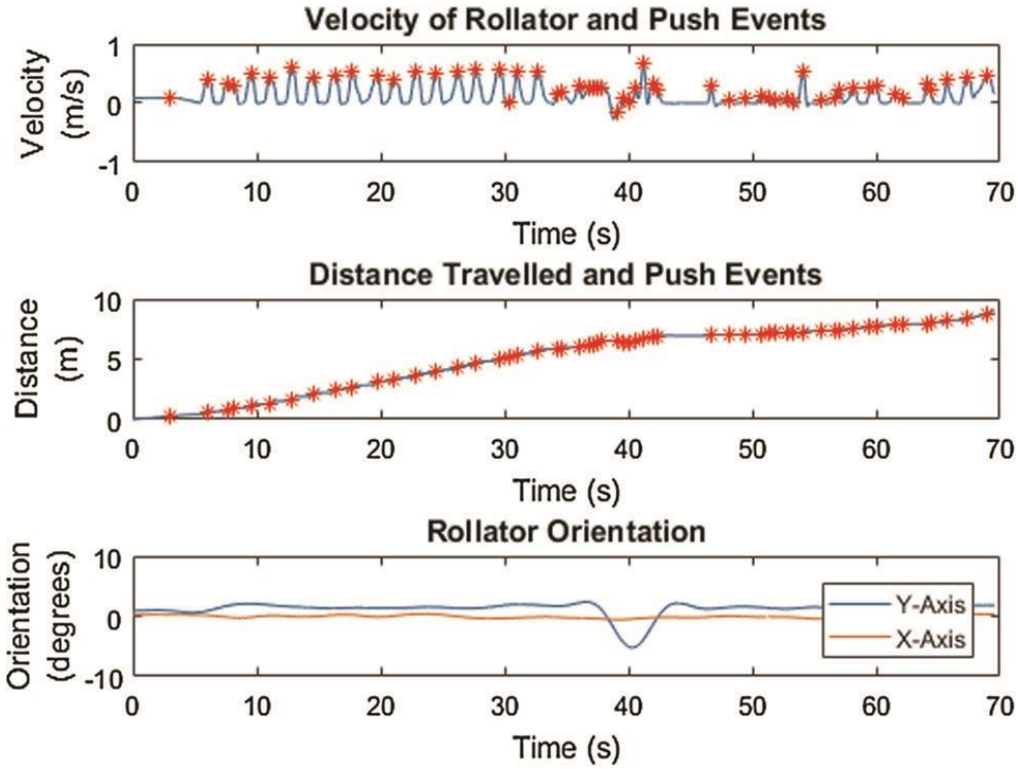

Figure A.12: IMU data shows velocity (top) and distance travelled (middle) in relation to push events; the orientation of the rollator over time (bottom) during the step-up with the MS participant in the SUE.

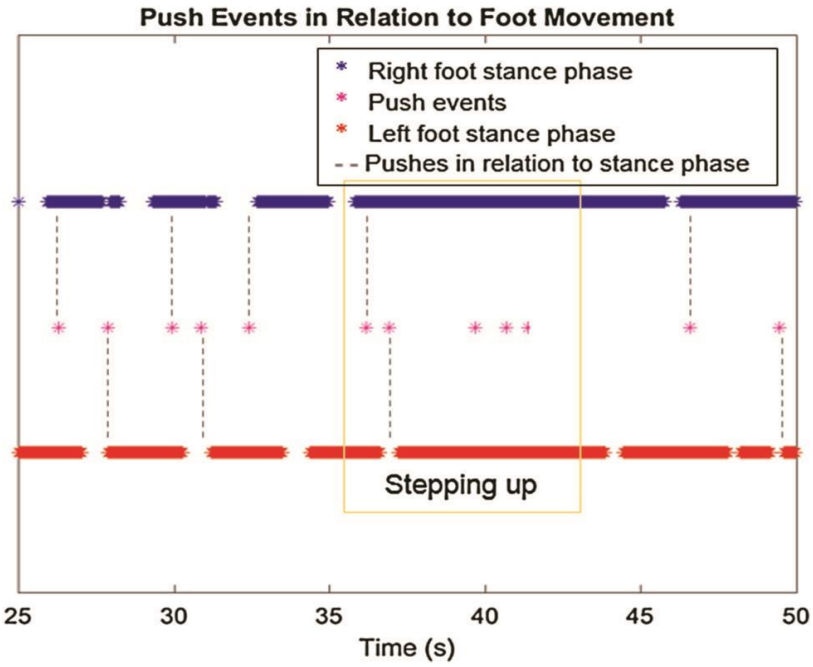

Figure A.13: Push events from IMU data for foot movement in the 25 s segment during the step-up with the MS participant in the SUE.

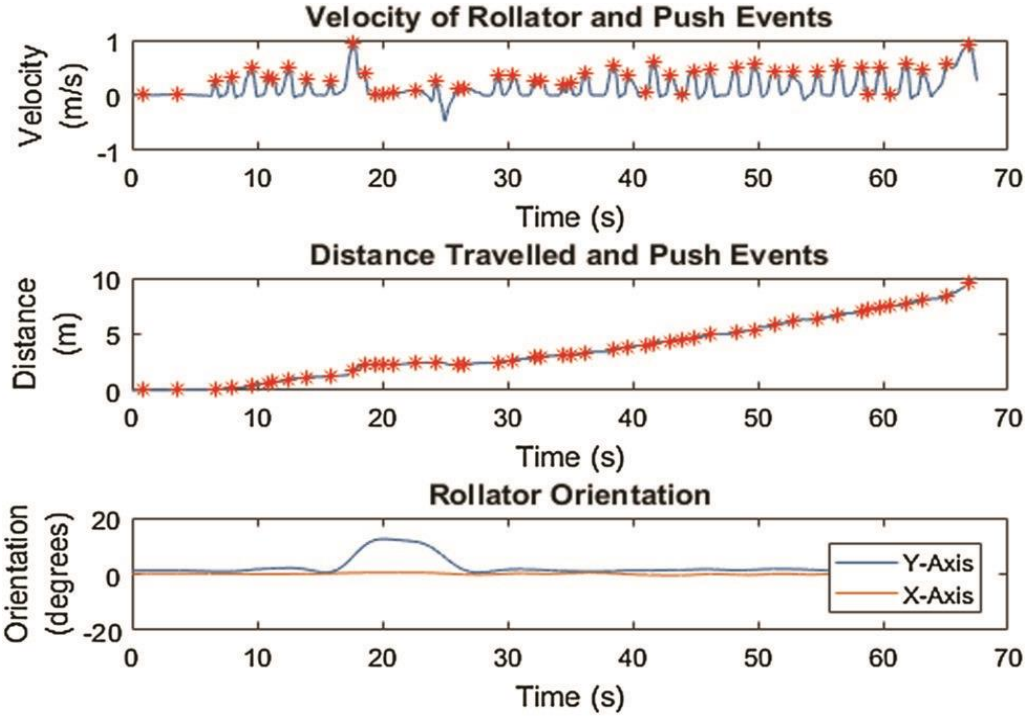

Figure A.14: IMU data shows velocity (top) and distance travelled (middle) in relation to push events; the orientation of the rollator over time (bottom) during the step-down with the MS participant in the SUE.

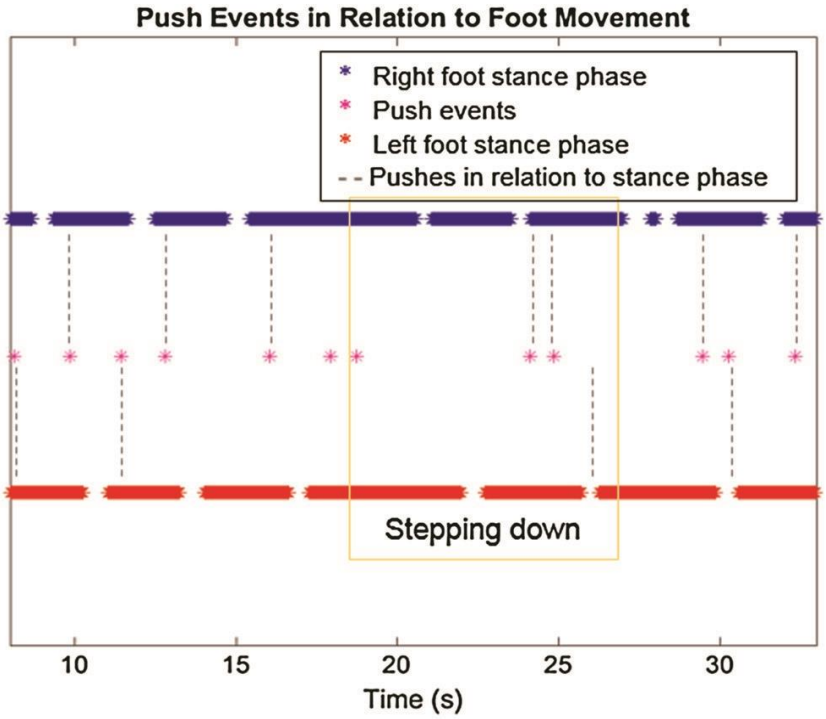

Figure A.15: Push events from IMU data relating to foot movement in the 25 s segment during the step-down with the MS participant in the SUE.

5. Discussion:

The results of the tests in the laboratory and SUE show that it is feasible to use an IMU to characterise the rollator movement and measure the interaction between the rollator, the user and the urban environment. The results also show that by using an IMU alone, the travel pattern can be reconstructed offline, which can provide researchers and physiotherapists with insight into a user's performance while walking and using a rollator.

Past studies have demonstrated the difference in the movement behaviour between laboratory assessments and real environment and call for a better understanding of the interaction [11, 12]. This Letter clearly demonstrates, the healthy participant's pushes, distance travelled, average distance and duration of each push, and the push events in relation to the foot movement in the laboratory through the motion capture

system and IMU. When the IMU and protocol were then brought to the SUE, the MS participant can be seen to tend to consistently initiate the push of the rollator around the heel strike of each foot. The MS participant demonstrates a smooth and less interfered gait with the help of the rollator, which has also been shown in past studies [8, 10]. However, the MS participant's movement was interfered while walking up the step due in part to the physical constraint of lifting the rollator up or down the step. This is also a type of collision in the urban environment that past studies [11, 12] indicated and this Letter has demonstrated the capability of IMUs to record and measure the foot and rollator movements during these collisions.

The property of the surface and distance travelled can be detected by the IMU by the degree of the inclination of the rollator and integration of the acceleration of the rollator movement. Along with the push events in relation to the foot movement and average distance and duration of each push, the user's balance mechanism and coping strategy used to deal with the uneven surface in the urban environment can be further understood.

Investigating the characterisation of rollator use has helped shed some light on the understanding of the quality, difficulty and risk of the use of rollators in the urban environment. Furthermore, studies need to investigate how the understanding of this interaction between the rollator, the user and the urban environment can help physiotherapists provide training, rehabilitation and assessments for rollator users of different physical, cognitive and sensory capabilities.

We do, however, acknowledge several limitations of this Letter. As a pilot study exploring the interaction between the rollator, the user and the environment, only one participant was measured in each of the laboratory and SUE. This Letter does not

intend to demonstrate the generalisability of findings, but explore the potential and validation of using low cost, portable IMUs to characterise rollator use outside the laboratory setting. This Letter provides initial evidence to conduct future research with larger sample sizes, more types of surfaces and longer walking distances. Furthermore, work will focus on creating a generalised set of algorithms to extract rollator characterisation data from IMUs and the applications of this approach to different user groups.

6. Conclusions:

The work presented in this Letter provides a first examination of the interaction between the rollator, the user and the environment using potable IMUs to characterise the rollator movements. A healthy participant performed walking tests using a rollator on a flat surface in the laboratory to examine the IMU measures with the gold standard ground truth from a motion capture system. Subsequently, a participant with MS performed walking tests using a rollator on a flat surface, cross-slope, up and down-slope and up and down a step in an SUE with an IMU alone attached. The use of IMUs to measure the pushing style, property of surface and travel distance has been examined by the motion capture system and can be utilised to detect these movement characteristics of a rollator user with MS on different surfaces. The results of this Letter show the potential to provide insight into the quality of the use of rollators, fall risks associated to rollators and quality of the provision of rehabilitation for rollator users.

7. Acknowledgments

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Sciences of Oxford Brookes University and the School of Engineering of Cardiff University for protocol designs, data collection and technical support. All data supporting this study are openly available from the University of Salford Data Repository https://dx. doi.org/10.17866/rd.salford.c.3516993.v1.

8. Funding and declaration of interests

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B. Futek LCM300 load cell product datasheet and extraneous datasheet

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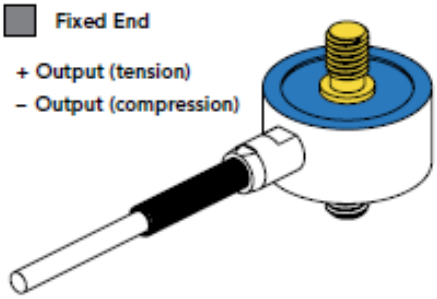
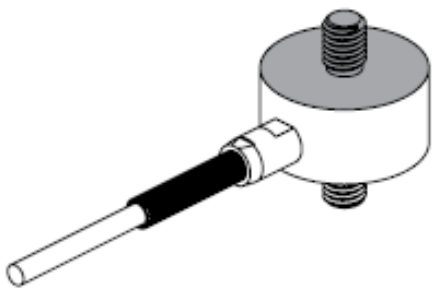
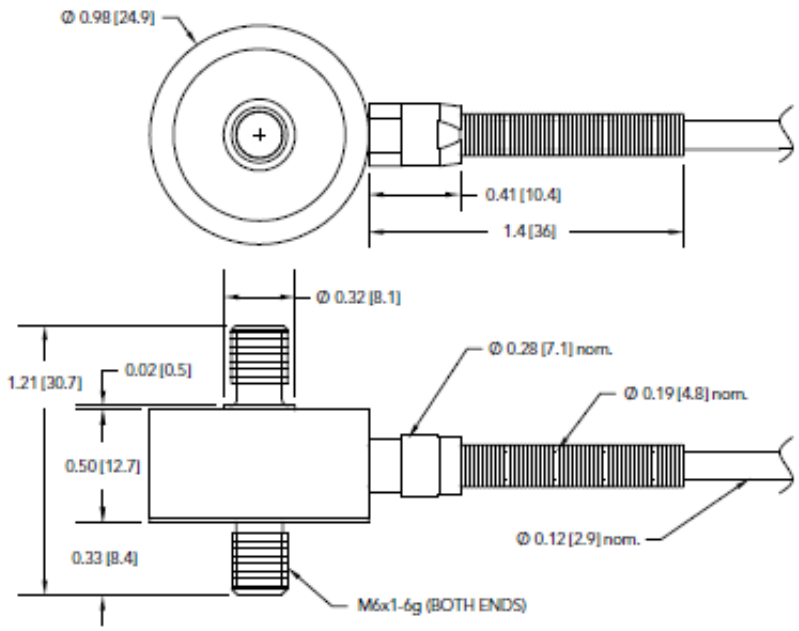




SPECIFICATIONS	
PERFORMANCE	
Nonlinearity	±0.25% of RO
Hysteresis	±0.25% of RO
Nonrepeatability	±0.1% of RO
ELECTRICAL	
Rated Output (RO)	2 mV/V nom
Excitation (VDC or VAC)	15 max
Bridge Resistance	740 Ohm nom
Insulation Resistance	≥500 MOhm @ 50 VDC
Connection	#28 AWG, 4 conductor braided-shielded PVC cable 10 ft (3 m) long
Wiring/Connector Code	WC1
MECHANICAL	
Weight (minus cable)	1.5 oz [42.5 g]
Safe Overload	150% of RO
Deflection	0.001 in [0.03 mm] nom
Material (flexure)	17-4 PH stainless-steel
IP Rating	IP64
TEMPERATURE	
Operating Temperature	–45 to 200°F (–42 to 93°C)
Compensated Temperature	60 to 160°F (15 to 72°C)
Temperature Shift Zero	±0.005% of RO/°F (±0.01 of RO/°C)
Temperature Shift Span	±0.02% of load/°F (±0.036 of load/°C)
CALIBRATION	
Calibration Test Excitation	10 VDC
Calibration (standard)	5-pt Tension
Calibration (available)	Compression
Shunt Calibration Value	100 kOhm
CONFORMITY	
RoHS	2011/65/EU
CE	EN55011:2009; EN61326-1:2006

DIMENSIONS Inches [mm]



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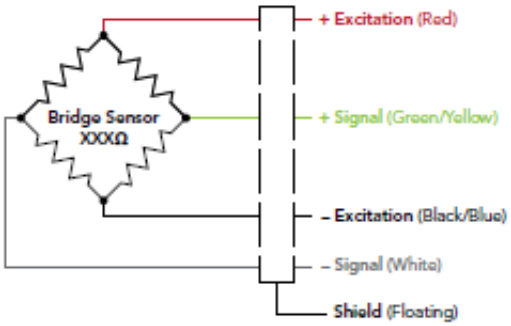
BLACK	– EXCITATION
GREEN	+ SIGNAL
WHITE	– SIGNAL
SHIELD	FLOATING



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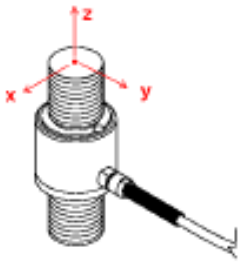
Model # LCM300 (L1650) Series

Extraneous Load Factors



Equation: $\sigma_{max} \geq$ (A)Fx +(B)Fy +(C)Fz +(D)Mx +(E)My +(F)Mz

Material: 2024-T4 Aluminum (AL) ; 17-4 P.H. Stainless Steel (S.S.)

Material	Model #	Capacity (lb)	A	B	C	D	E	F
(AL)	LCM300	25	1200	1200	560	3500	3500	1040
(S.S.)		50	3500	3500	870	8955	8955	7225
		100	3336	3336	530	9050	9050	8345
		250	770	770	220	1955	1955	1380
		500	665	665	150	1420	1420	1250
		1,000	475	475	86	1405	1405	1190
	LCM325	2,000	660	660	30	775	775	610
		3,000	400	400	20	420	420	345
	LCM350	4,000	480	480	16	305	305	225
		5,000	330	330	13	206	206	170
	LCM375	7,500	180	180	10	105	105	78
		10,000	120	120	8	75	75	55

All force and moments to be calculated using lb & in-lb units

σ_{max} Table

Material	Static Load (=60% Y.S.)	Fatigue (Non Reversing Loads)	Fatigue (Full Reversing Loads)
2024-T4 AL	28,000	18,000	15,000*
17-4PH S.S	87,000	78,000	62,000*

*Value is 75% of Fatigue Strength based on 10-20 x 10^6 cycles and allow for factors that influence Fatigue such as surface finish, stress concentrations, corrosion, temperature and other variables for the production of the transducer, for infinite Fatigue Life (100 x 10^6) use 75% of values shown.

Deflection & Natural Frequency

Model #	Capacity (lb)	Deflection (in.)	Natural Frequency (Hz)	β
LCM300	25	0.0008	8,750	0.004
	50	0.0012	7,500	0.0072
	100	0.0013	10,200	0.0072
	250	0.0013	16,200	0.0072
	500	0.0013	22,900	0.0072
	1,000	0.0015	30,100	0.0072
LCM325	2,000	0.0013	20,100	0.0443
	3,000	0.0014	21,600	0.0443
LCM350	4,000	0.0018	14,200	0.1075
	5,000	0.0021	14,700	0.1075
LCM375	7,500	0.0021	14,100	0.1769
	10,000	0.0025	14,900	0.1769

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Natural Frequency & Frequency Response Equation's:

$$\text{Natural Frequency (FN)} = 3.13 \sqrt{\frac{1}{\frac{\beta}{Capacity} \bullet Deflection}} \text{ (Hz)}$$

$$\text{Frequency Response with load (FR)} = 3.13 \sqrt{\frac{1}{\frac{\beta + AppliedLoad}{Capacity} \bullet Deflection}} \text{ (Hz)}$$

*Where β values are obtained by Futek Engineers

C. Marker and equipment setup

C.1 Marker setup

In order to determine the combined base of support and calculate the position of the combined centre of pressure needed to assess system's stability, the relative position of all feet of both user and walking aid at any given time must to be known, and this is achieved through the use of a 3D camera system (either Vicon in the lab or Qualisys in the ADL flat) and corresponding reflective markers.

Positions of reflective markers on the user are shown in Figure C.1. The same marker setup was used for static and dynamic trials, however, , the exact marker placements differed for lab and ADL flat assessments. In the ADL flat, there are 3 markers attached to each heel in order to enhance capture as, in this environment, only the front or the back of the user is likely to be visible by the cameras at any given time (Section C.2).

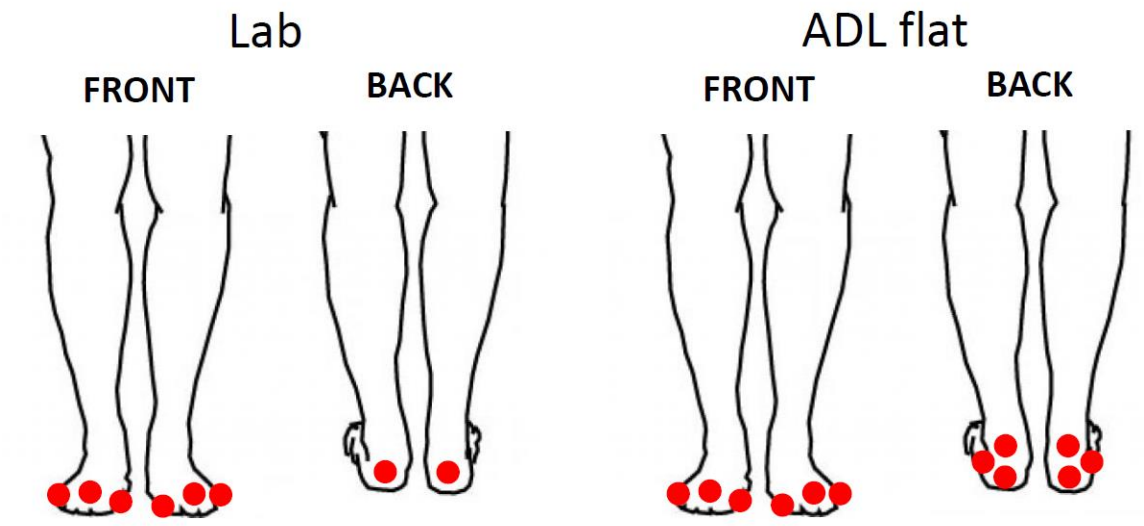


Figure C.1: Marker setup for the user in the lab and ADL flat. Red dots represent markers.

Figure C.2 shows the position of the reflective markers on the walking aid: here two different marker setups are needed for static and dynamic trials as markers on the feet of the device would likely detach during use; however, since the device is a rigid body, their position can be easily reconstructed from the clusters on the device's legs. For convenience, such clusters have been permanently glued to the device so that a static trial of the walking aid had to be recorded only once, and the position of the feet could then be estimated after every testing session without the need of recording a new static trial each time. As there are clusters on the front and back of the device, the same setup could be used in both the lab and the ADL flat. For illustrative purposes, only the pick-up walker is shown in the figure, but the same setup is used for the other two walking frames.

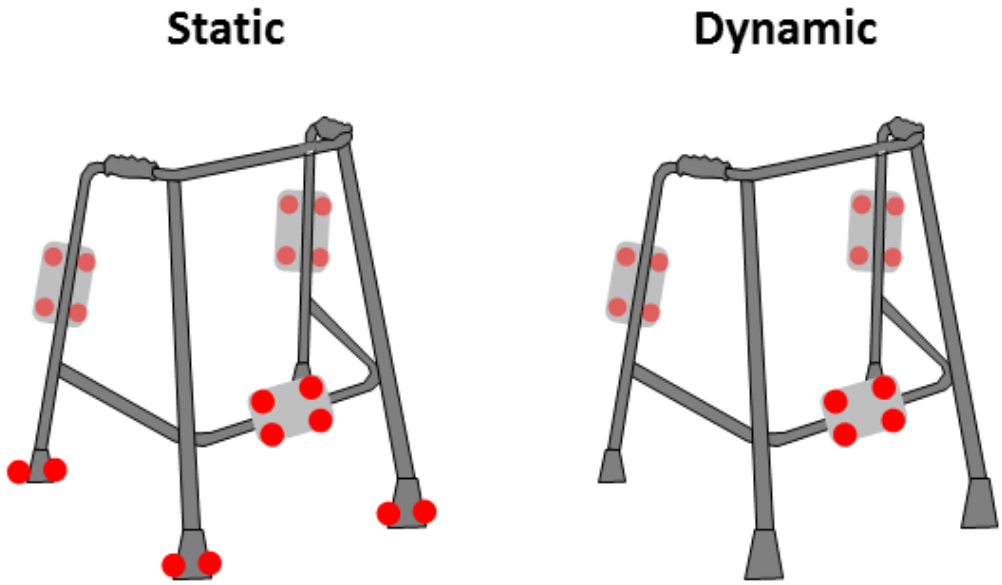


Figure C.2: Static and dynamic marker setup for the walking aid. Red dots represent markers. The same marker configuration is used for all 4 feet of the device, although, in the drawing, the rear left foot is not visible.

C.2 Camera positioning in the ADL flat

Figure C.3 illustrates the floor plan of the ADL flat, the position of the optoelectronic cameras, and the walking path. It should be noted that the presence of walls creates occlusion problems, hence the cameras had to be positioned extremely carefully in order to guarantee sufficient visibility of the markers.

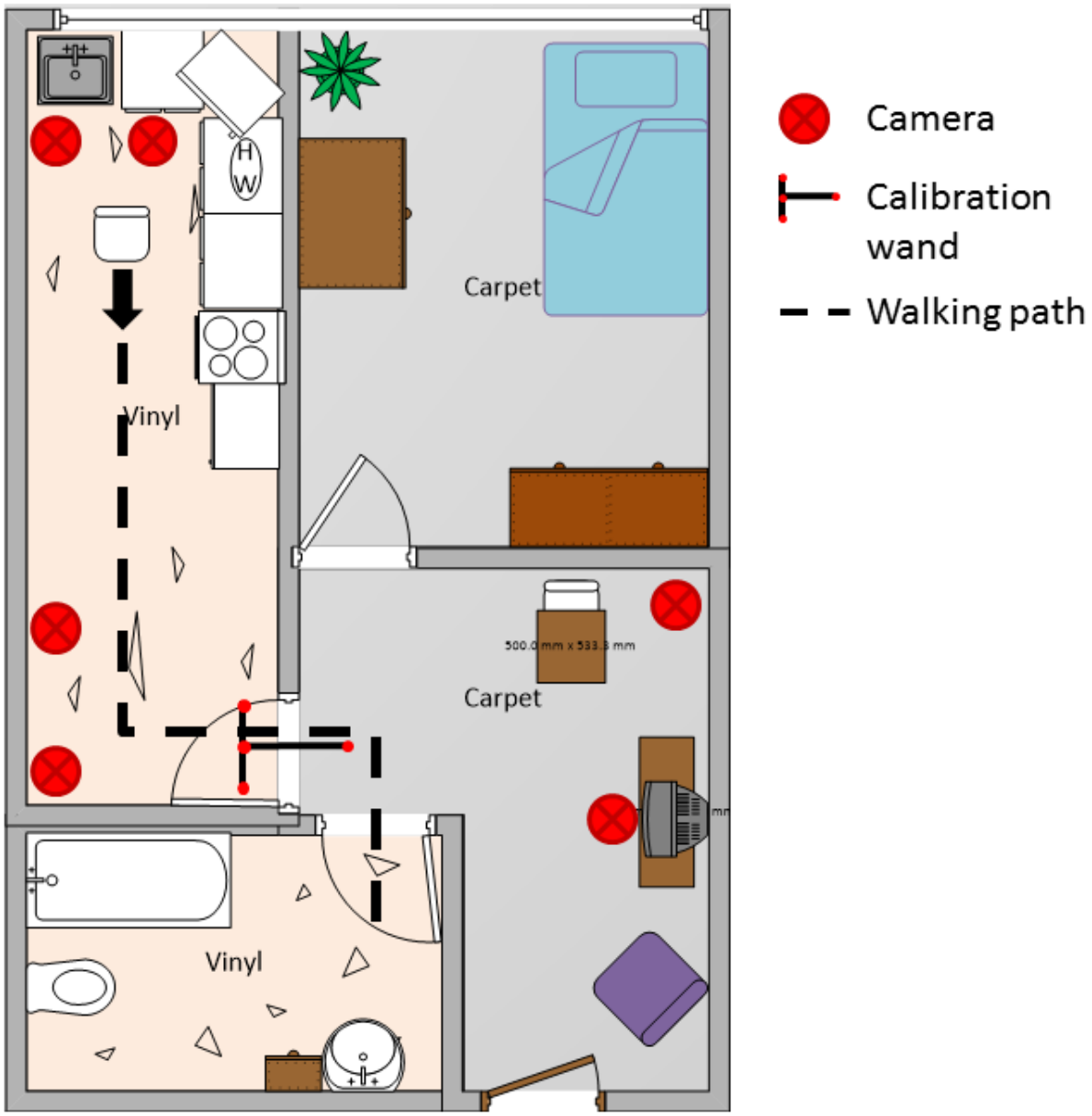


Figure C.3: Floor plan, camera position, and walking path in the ADL flat.

D. Design and development of an instrumented front wheeled walker

D.1 Introduction

Chapters 3 and 4 discussed the development and demonstration of a novel generalizable methodology (and corresponding technology) for stability assessment of walking aid users. Such methodology was initially applied to a cohort of rollator and pick-up walker users (Chapters 3 and 4) for the following reasons: firstly, rollators are one of the most commonly used walking aids and hence their study is of relevance to a large proportion of walking aid users, (Finkel, Fernie et al. 1997, Samuelsson and Wressle 2008), and secondly because pick-up walker users are very frail people and a thorough understanding of walking aid use for improved fall prevention would be of great benefit to them.

Nevertheless, it became clear through frequent conversations with clinicians that pick-up walkers are only prescribed in exceptional circumstances and that, whenever possible, clinicians recommend front wheeled walkers (FWW) (Figure D.1) even to their most frail patients. FWW are similar in design, size, and function to a pick-up walker, but have the benefit that they do not need to be lifted and allow for a more "fluid" walking pattern which better resembles that of unassisted walking.

Figure D.1: Front wheeled walker. Source: http://www.simplymed.co.uk/all-products/page/3/.

Hence, in order to be able to apply the stability assessment methodology developed in Chapter 3 to a greater number of frail users, an instrumented FWW was also developed towards the end of this PhD, as described in this Appendix.

D.2 Design requirements

The same design requirements previously identified for the rollator and pick-up walker also apply to the FWW, as the new instrumented device must support:

- The characterisation of device loading;
- The characterisation of device and user movement;
- The characterisation of system stability, where the system is defined as the combination of user and device;

- Wireless data collection, and therefore the instrumentation must be battery powered.

Hence, it seemed reasonable to use the same set of instrumentation previously used for the rollator and the pick-up walker, which consists of:

- Pressure sensing insoles (medilogic®insole, T&T medilogic Medizintechnik GmbH, Schönefeld, Germany) to measure the pressure distribution and hence the corresponding CoP location for each anatomical foot;
- An optoelectronic motion capture system (either 6 Qualisys Oqus300 cameras, Qualisys AB, Göteborg, Sweden or 10 Vicon T-series cameras, Vicon Motion Systems Ltd, Oxford, UK) to capture the position of both, the anatomical feet and walking frame feet.
- Four single axis load cells (Futek LCM300, FUTEK Advanced Sensor Technology, Inc., Irvine, California) in each leg of the frame, to measure the vertical walker ground reaction forces, and corresponding transmitters (Mantracourt T24-ACMi, Mantracourt Electronics Ltd., Exeter, UK).

D.3 Front wheeled walker design

As it is possible to see from Figure D.1, the rear feet of a FWW are identical to that of a pick-up walker; in fact, pick-up walkers are usually sold with interchangeable front feet so that the same device could be used as a pick-up walker or as a FWW. Hence, it was thought to use the previously developed instrumented pick-up walker and to

simply re-design the front wheels, which could then be swapped with the front feet of the pick-up walker.

Following the same process adopted for the rollator, the design phase started by assessing all forces acting on the front wheels of the device to ensure that the stress applied to the load cells for a given design configuration would not exceed the maximum stress acceptable. For this purpose, a healthy young adult was asked to walk with a FWW (of identical design to the one purchased to be instrumented) along 4 force plates and on two types of flooring which can be commonly found in users' homes, vinyl flooring and carpet, as it was expected that the ground reaction forces when walking on carpet would be higher due to greater friction between the wheels and the carpet. The participant was also instructed to transfer onto the device a percentage of body weight varying between 30% and 50%. Since previous data on FWW users is scarce, the choice of such percentages was based on typical values observed in pick-up walker users; however, these values are believed to be realistic as the two populations are similar in terms of their physical condition and amount of structural support needed from the device.

From the analysis of the data collected, it was found, once again, that simply screwing the load cell to the FWW legs was not possible as this would have resulted in excessive bending moments and subsequent breakage of the load cell. Thus, a design configuration similar to that of the instrumented rollator was adopted, which allows for only the vertical load to be transmitted axially to the load cell, but not any bending moment. Figure D.2 and Figure D.3 show, respectively, the FWW front wheel and rear foot design and a picture of the final instrumented FWW.

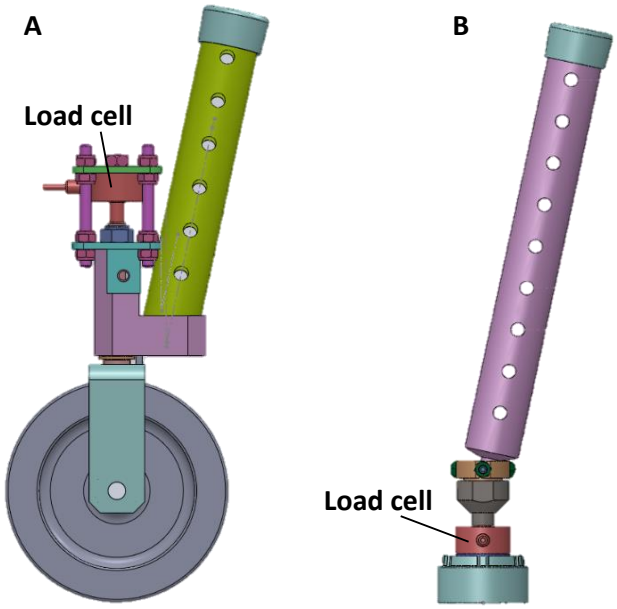


Figure D.2: Side view of FWW feet design. A) Front wheel design, B) Rear foot design (same as pick-up walker).

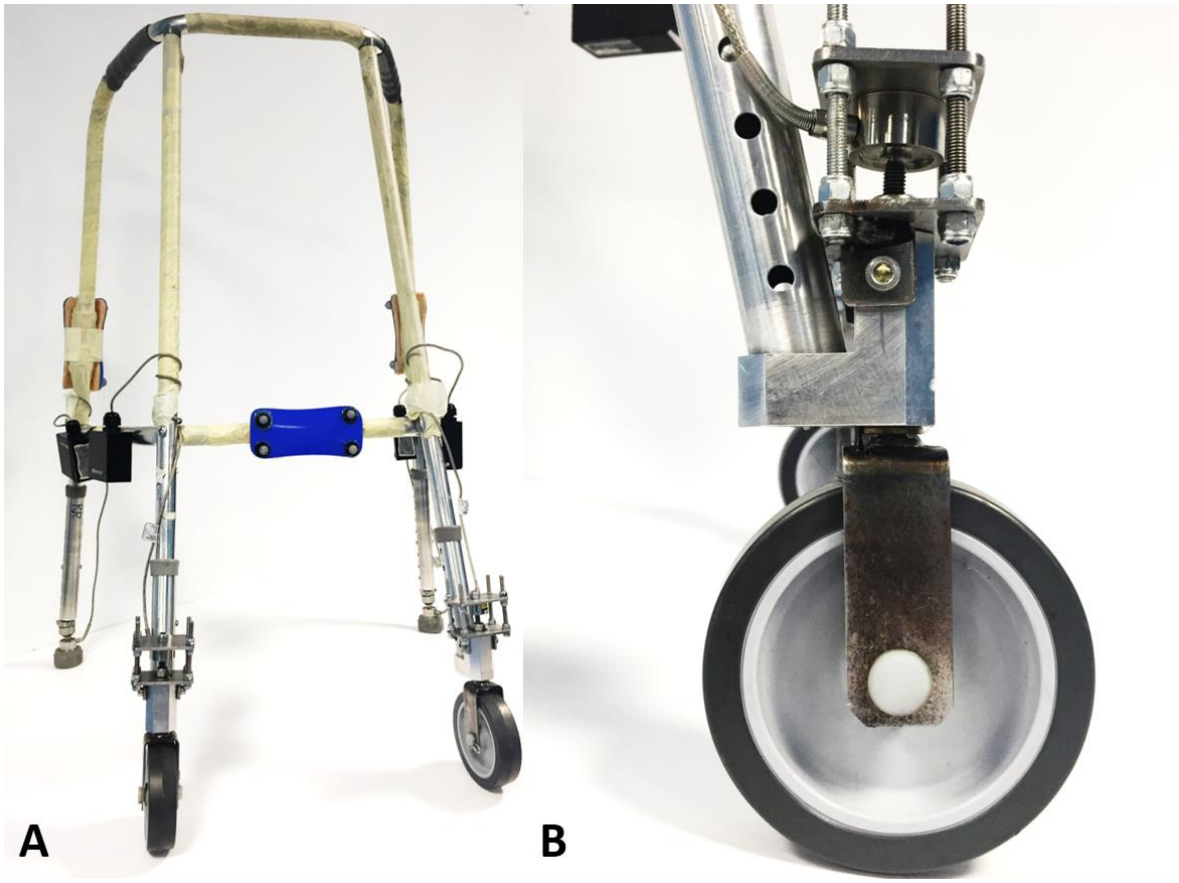


Figure D.3: A) Final instrumented FWW; B) the FWW's front wheel.

D.4 Validation of the instrumented FWW

Following the design phase, the accuracy of the vertical load and combined centre of pressure measured by the instrumented FWW were tested in the lab following the same procedure previously adopted for the rollator (Section 4.5).

As a result, a maximum error equal to 5.2% and Root Mean Square value of 12.04 N were obtained when comparing the total vertical load recorded by the load cells to the corresponding data recorded with the force plate.

Also, a maximum error equal to 18.09 mm in AP direction and 19.61 mm in ML direction were obtained when comparing the combined centre of pressure, which we consider acceptable being equal, respectively, to 3.7% and 4.1% of the maximum width and length of the combined BoS in the testing conditions studied.

E. Determination of limits of stability

E.1 Introduction

Previous work has developed a novel methodology that allows for the characterisation of stability of walking aid users (Costamagna E 2016). Specifically, this approach considers the user and their walking aid as a single combined system and calculates the margin of stability “SM”. Subsequently, data from two groups of walking aid users (PW users and rollator users) have been collected and analysed in relation to task type and device loading. However, although valuable insights were gained from such data, to be able to interpret stability outcome measures in relation to falls-risk, the question “how small of a stability margin is too small?” (i.e. at what values of SM will the user either need to take a compensatory recovery step or experience a fall?) needs to be answered. This is of particular importance because recovery steps may lead to foot-frame collisions [REF Make/Bateni] and may thereby induce a fall. Previous research investigated limits of stability and balance recovery through experiments that involved leaning from standing unassisted in anteroposterior and mediolateral direction (Thelen, Wojcik et al. 1997, Wojcik, Thelen et al. 1999, Thelen, Muriuki et al. 2000, Hsiao-Wecksler 2008, Carbonneau and Smeesters 2014).

Moreover, in the special case of wheeled walkers, it is important to understand at what point the base of support of the system is becoming so large in the anterior-posterior

direction that a fall of the user is imminent due to the device “rolling away” from its user.

To explore the above, a study was designed that involved older healthy adults in a safety harness using the two instrumented walking aids previously developed (PW; rollator) under circumstances that challenged their stability up to the point of either needing a recovery step or experiencing a fall. Only healthy adults have been tested because it would have been unethical to test a sample of actual walking frame users who could have suffered serious consequences such as developing fear of falling through participation in this experiment.

E.2 Methods

E.2.1 Subjects

Ten (10) healthy older adults aged 67.8 ± 5 years were recruited for this study. Inclusion criteria were: 1) being able to walk unaided; 2) not having mobility impairments. Exclusion criteria were: 1) a history of head injury, concussion, stroke/TIA, or diabetes; 2) visual disorders not correctable by glasses; 3) amputation of upper or lower limbs; 4) using a walking aid; 5) having chronic ankle instability. Written informed consent was obtained from all participants, and the experimental protocol was approved by the University of Salford Ethics Committee (HSR1617-105).

E.2.2 Protocol

The experiments took place in the Human Performance Lab at the University of Salford. All participants wore a safety harness and performed 20 leaning tasks with two instrumented walking aids (8 tasks with the instrumented rollator and 12 with the

instrumented PW). For each device, the individual tasks were designed to replicate the different foot-frame configurations that are likely to occur during normal walking. For example, while walking with a rollator, the user is likely to always have one anatomical foot in front of the other (continuous stepping) and the device should be grounded at all times.

Hence, with the rollator, participants performed the following tasks:

1) **a.** Right foot forward of the rollator's rear wheels, left foot immediately behind right foot (toe-to-heel) (Figure E.1 A), with a comfortable stance width, and hips in line with handles. The participant leans to their **right** keeping their torso in line with their hips (as a tower) as much as they can until they need to step to recover balance.

   b. The participant then repeats the same task leaning to the **left.**

2) **a.** Right foot in between the rollator's rear wheels, left foot immediately behind right foot (toe-to-heel), and with a comfortable stance width (Figure E.1 B). The participant leans to their **right** keeping their torso in line with their hips (as a tower) as much as they can until they need to step to recover balance.

b. The participant then repeats the same task leaning to the **left.**

3) **a.** Right foot behind the rollator's rear wheels, left foot immediately behind right foot (toe-to-heel), and with a comfortable stance width (Figure E.1 C). The subject leans to their **right** keeping their torso in line with their hips (as a tower) as much as they can until they need to step to recover balance.

   b. The participant then repeats the same task leaning to the **left.**

4) Right foot in line with the rollator's rear wheels, left foot immediately behind right foot (toe-to-heel), and with a comfortable stance width (Figure E.1 B). The subject leans **backwards** keeping their torso in line with their hips (as a tower) as much as they can until they need to step to recover balance.
5) Right foot in line with the rollator's rear wheels, left foot immediately behind right foot (toe-to-heel), and comfortable stance width (Figure E.1 B). The subject **pushes the rollator forward** keeping their torso in line with their hips (as a tower) as much as they can until they need to step to recover balance.

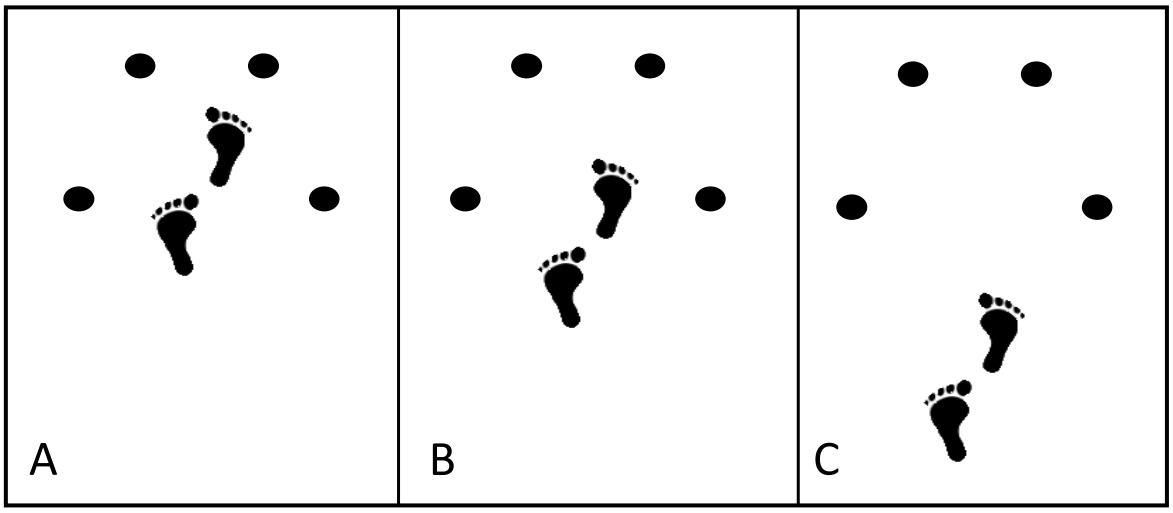


Figure E.1: Different foot-frame distance configurations illustrating the different starting positions of the anatomic feet in relation to the rollator's wheels.

While using a PW, on the other hand, the user will find themselves with a foot in front of the other during stepping (walker being grounded), yet with their feet approximately parallel when moving the device forward; the PW can be either grounded or airborne.

Therefore, with the PW, participants performed the following tasks:

1) Both feet in **parallel** in front of the PW's rear feet and with a comfortable stance width (Figure E.1 A). The subject leans to their **right** keeping their torso in line

with their hips and legs (as a tower) as much as they can until they need to step to recover balance.

2) Both feet in **parallel** in line with the PW's rear feet and with a comfortable stance width (Figure E.1 B). The subject leans to their **right** keeping their torso in line with their hips and legs (as a tower) as much as they can until they need to step to recover balance.
3) Both feet in **parallel** behind the PW's rear feet (one user's foot distance between user's toes and PW's rear feet to simulate position after PW touch-down) and with a comfortable stance width (Figure E.1 C). The subject leans to their **right** keeping their torso in line with their hips and legs (as a tower) as much as they can until they need to step to recover balance.
4) **a.** Right foot in front of the PW's rear feet, hips between the handles, left foot immediately behind right foot (**toe-to-heel**), and with a comfortable stance width (Figure E.1 D). The subject leans to their **right** keeping their torso in line with their hips (as a tower) as much as they can until they need to step to recover balance.

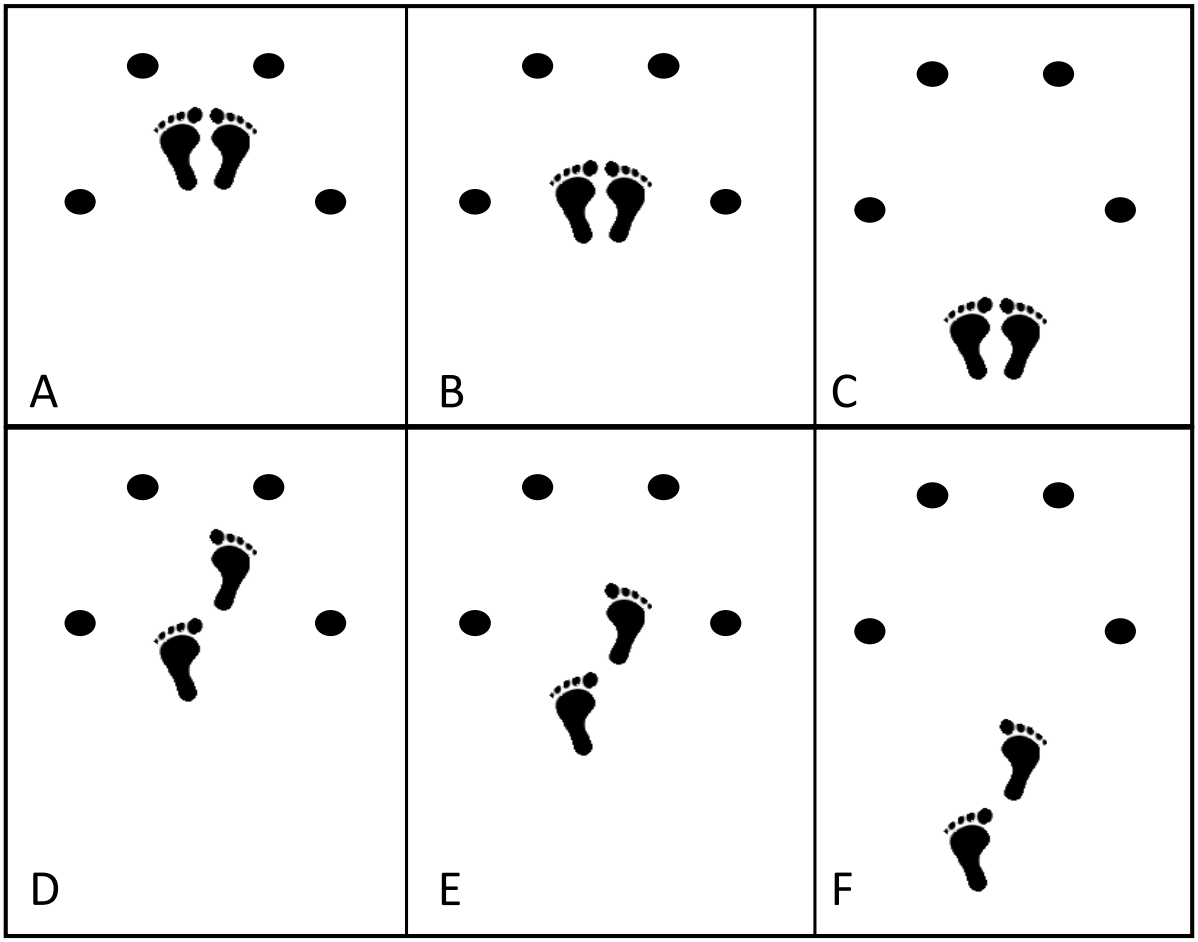
   b. The participant then repeats the same task leaning to the **left.**
5) **a.** Right foot in line with the PW's rear feet, left foot immediately behind right foot (**toe-to-heel**), and with a comfortable stance width (Figure E.1 E). The subject leans to their **right** keeping their torso in line with their hips (as a tower) as much as they can until they need to step to recover balance.

   b. The participant then repeats the same task leaning to the **left.**
6) **a.** Right foot behind the PW's rear feet, left foot immediately behind right foot (**toe-to-heel**), and with a comfortable stance width (Figure E.1 F). The subject

leans to their **right** keeping their torso in line with their hips (as a tower) as much as they can until they need to step to recover balance.

b) The participant then repeats the same task leaning to the **left.**

7) Both feet in parallel, **PW airborne** (to simulate swing phase of the walker), and with a comfortable stance width. The subject leans to their **right** keeping their torso in line with their hips and legs (as a tower) as much as they can until they need to step to recover balance
8) Both feet in **parallel**, **PW airborne** (to simulate swing phase of the PW), and with a comfortable stance width. The subject leans **backwards** keeping their torso in line with their hips and legs (as a tower) as much as they can until they need to step to recover balance.
9) Right foot in front, left foot immediately behind right foot (**toe-to-heel**), and with a comfortable stance width, **PW airborne** (to simulate swing phase of the PW). The subject leans **backwards** keeping their torso in line with their hips and legs (as a tower) as much as they can until they need to step to recover balance.



Each task was performed once. Only if data collection of the first trial was unsuccessful, a second trial was recorded.

Finally, presentation of device to each participant was alternated (i.e. participants 1, 3, 5, 7, 9 were tested with the PW first and with the rollator after, and vice versa for participants 2, 4, 6, 8, 10), and presentation of tasks within device (i.e. tasks 1-5 for the rollator, and tasks 1-9 for the PW) was randomized.

E.2.3 Data analysis

For each trial, SM at the onset (lift-off) of the recovery step was calculated using the software developed in Chapter 3, and this value of SM was recorded as the Limit of Stability (LoS) in a given direction and for a given foot-frame configuration for these

experiments from standing. Subsequently, mean and standard deviation (SD) of the LoS for each task across all participants were obtained.

With regard to the maximum safe length of the base of support for the rollator, mean and SD of the base of support length at the onset of the recovery step during forward leaning with the rollator were calculated.

Finally, the SM values observed in rollator and PW users previously in this PhD were compared to their corresponding LoS as follows:

1) the minimum SM for a given participant performing a given walking task (i.e. straight line walking, 90° turn, 180° turn, backward walking, obstacle crossing, and step up for the rollator and straight line walking, turning in the lab, and turning in the ADL flat for the PW) was recorded;
2) the foot-frame configuration at the instant in time during which the minimum SM occurred was analysed to identify the distance between user's feet and device, and, for the PW only, whether the user's feet were parallel or toe-to-heel, and whether the device was grounded or airborne;
3) the edge of the combined base of support which was closest to the combined centre of pressure at the instant in time during which the minimum SM occurred (i.e. the edge used for the calculation of SM) was identified;
4) based on the information obtained in 2) and 3), the value of the minimum SM was compared to the LoS which most closely represented the conditions in which the minimum SM occurred (e.g. in the case illustrated in Figure E.2, assuming that the user was using the rollator,

the minimum SM would be compared to LoS relative to task 2b, that is leaning to the left with the right foot in line with the rollator's rear wheels and the left foot immediately behind the right foot (toe-to-heel)). If SM is greater than the corresponding LoS, then the user is stable, otherwise it would be concluded that a recovery step is imminent.

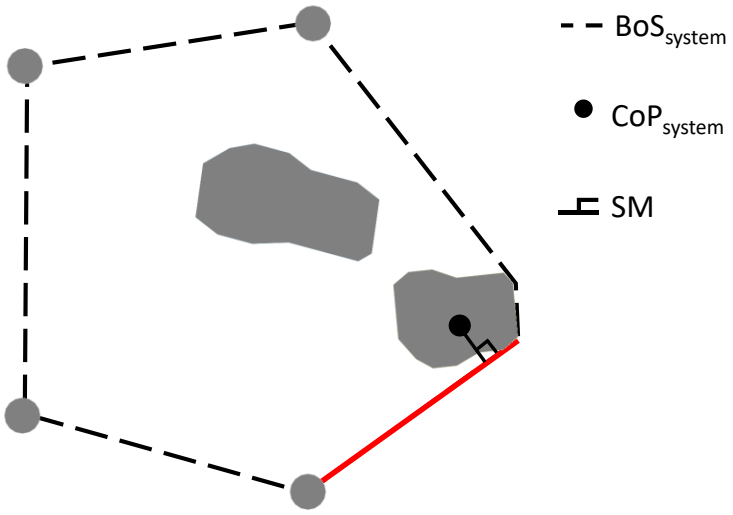


Figure E.2: Example of foot-frame configuration. BoS_{system} indicates the combined base of support, CoP_{system} indicates the combined centre of pressure, and the red line represents the edge of the combined base of support which is closest to the combined centre of pressure (i.e. the edge used for the calculation of SM).

E.3 Results

Tables E.1 and E.2 report the mean ± SD values of the LoS for each task for the rollator and PW, respectively. It should be noticed that, for the same foot-frame configuration, LoS values relative to left and right leaning are often identical when rounded to the second decimal place. Also, both mean and SD values of LoS for rollator and PW are comparable and no considerable differences were noted.

Table E.1: LoS for the rollator. Tasks are labelled as listed in Section E.2.2.

Task	*Mean ± SD*

1a	0.18 ± 0.07
1b	0.18 ± 0.07
2a	0.20 ± 0.07
2b	0.20 ± 0.07
3a	0.16 ± 0.05
3b	0.17 ± 0.04
4	0.20 ± 0.11
5	0.16 ± 0.03

Table E.2: LoS for the PW. Tasks are labelled as listed in Section E.2.2.

Task	*Mean ± SD*
1	0.20 ± 0.04
2	0.18 ± 0.12
3	0.17 ± 0.05
4a	0.17 ± 0.06
4b	0.17 ± 0.06
5a	0.16 ± 0.08
5b	0.15 ± 0.07
6a	0.20 ± 0.06
6b	0.20 ± 0.05
7	0.19 ± 0.11
8	0.14 ± 0.1
9	0.22 ± 0.06

However, looking at the minimum values of SM observed in walking aid users during performance of several walking tasks representative of daily activities, it was found that these values are often considerably lower than their corresponding LoS, and this is true for both older users and the healthy young adult walking with either device. As an example, Table E.3Table E.4 report the minimum SM during straight line walking for all rollator and PW users and for the healthy young adult.

Table E.3: Minimum SM during straight line walking for all rollator users tested and the young healthy adult (RYA).

	SM_{min}
R1	0.15
R2	0.15
R3	0.14
R4	0.14
R5	0.16
R6	0.31
R7	0.17
R8	0.24
R9	0.19
R10	0.18
RYA	0.15

Table E.4: Minimum SM during straight line walking for all PW users tested and the young healthy adult (PWYA).

	SM_{min}
PW1	0.08
PW2	0.16
PW3	0.14
PW4	0.10
PW5	0.13
PWYA	0.08

Regarding the maximum safe length of the base of support, this was found to be equal to 1459.67 ± 351.34 mm, which is much greater than that observed in the rollator users tested.

E.4 Discussion

The main aim of this study was to identify threshold values of SM that discriminate between stability and instability (e.g., how small of a stability margin is too small) in order to inform device selection and prescription: for instance, at the time of

prescription, older adults may be asked to try out different walking aids and their minimum SM could be compared to the LoS of each device; if the system's (person + given walking aid) stability margin approaches the limit when using a certain device, then it is probable that such device is not appropriate for that particular person. However, it is evident that minimum SM values of rollator and PW users and even those of the healthy young adult were often considerably lower than their corresponding LoS, which would have suggested that most users were highly unstable and likely to fall, but this is, clearly, incorrect as none of them fell during testing.

Several reasons could be identified that explain why the results of this study are not informative as initially hoped. First, it must be observed that LoS were calculated from standing in double support of the anatomical feet, whilst minimum values of SM often occur while the user in single support. For this reason, it was thought to repeat this LoS study with users in single support. Nevertheless, measurement of the onset of the recovery step would have not been trivial, especially because the equipment (force plate) used relies on foot lift-off to detect the onset of the recovery step.

Furthermore, the minimum values of SM observed in rollator and PW users during walking were compared to a specific LoS, which was selected based on similarities in the foot-frame configuration (i.e. the distance between the user's feet and the device, the position of the user's feet relative to each other, and the device being grounded or airborne). Although this was originally believed to be a sufficient approximation, it is also true that there are unlimited possible foot-frame configurations: for instance, the device may be only partially grounded or, especially during tasks other than straight line walking (e.g. 90 and 180 degree turning), the anatomical feet may be oriented differently in relation to the device than during the LoS testing, affecting the shape of the combined base of support and, hence, SM values.

Most importantly, it must be acknowledged that the conditions tested in this study (i.e. leaning from standing) ignored a fundamental part of walking, which is the momentum that keeps a person balanced whilst moving forward. As a result of this momentum, a (older) person is able to balance on one foot during walking, even though they would not be able to balance on one foot during standing. Hence, the lack of forward momentum could explain, at least in part, the low SM values observed in walking aid users during walking.

Finally, another factor that was not controlled during this study is device loading “DL”, which, as detailed in Chapter 5, is known to have a positive effect on SM. Indeed, post-hoc analysis revealed that participants of the LoS study generally showed higher DL than most rollator users. Nevertheless, neither controlling for DL, nor grouping participants based on DL was possible, the former due to the lack of real time DL feedback and the fact that DL inevitably changes during leaning, and the latter because of the small number of participants tested.

In conclusion, finding threshold values of SM able to discriminate between stability and instability resulted to be extremely challenging due to several equipment and experimental limitations. Nevertheless, defining limits of stability remains essential to confidently conclude on stability and inform device selection and prescription. Hence, future work should look at alternative and more valid ways to explore this important gap in the current knowledge base.

F. Ethical approval letters

NHS
Health Research Authority

Miss Eleonora Costamagna
Room PO34
Brian Blatchford Building
University of Salford
M6 6PU

Email: hra.approval@nhs.net

11 August 2016

Dear Miss Costamagna,

Letter of HRA Approval

Study title:	**A clinical assessment tool for safe walking frame use to improve fall prevention by informing frame selection, training and monitoring.**
IRAS project ID:	**196275**
REC reference:	**16/LO/0986**
Sponsor	**University of Salford**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

University of Salford MANCHESTER

Research, Innovation and Academic Engagement Ethical Approval Panel

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T +44(0)161 295 2280

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5 October 2016

Dear Eleonora,

RE: ETHICS APPLICATION– HSCR13-48 - A clinical assessment tool for safe walking frame use to improve fall prevention by informing frame selection, training and monitoring

Based on the information you provided, I am pleased to inform you that your amendments to application HSCR13-48 have been approved.

If there are any changes to the project and/ or its methodology, please inform the Panel as soon as possible by contacting Health-ResearchEthics@salford.ac.uk

Yours sincerely,

Sue McAndrew
Chair of the Research Ethics Panel

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TÜBINGEN

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Auerbachstraße 110
70376 Stuttgart

nachrichtlich:
Herrn Prof. Dr. med. Clemens Becker

678/2016BO1	05.10.2016	19.10.2016
unsere Projekt-Nummer	eingegangen am	Datum

Klinische Untersuchung zum sicheren Gebrauch von Rollatoren. Clinical assessment tool for safe walking frame use.
Auflistung der eingereichten Unterlagen siehe Seite 2

Sehr geehrter Herr Kollege,

die Unterlagen zur o.g. Studie haben den Mitgliedern der Ethik-Kommission an der Medizinischen Fakultät und am Universitätsklinikum Tübingen in der Sitzung am 17.10.2016 zur Beratung vorgelegen.

Danach bestehen gegen die geplante Studie seitens der Kommission keine Bedenken.

Die Ethik-Kommission empfiehlt Klarstellungen im Prüfplan sowie Ergänzungen im Informationstext. Einzelheiten finden Sie im Folgenden aufgelistet:
Prüfplan:
Abschnitt 5: Die Ethik-Kommission geht bei ihrer berufsrechtlichen Beratung davon aus, dass sämtliche an der Studie teilnehmenden geriatrischen Patienten einwilligungsfähig sind.
Informationstext:
Persönliche Risiken und Nutzen durch die Studienteilnahme sollten im Informationstext ausdrücklich erwähnt werden.

Für die Durchführung der Studie wünschen wir Ihnen viel Erfolg.
Mit freundlichen Grüßen

Prof. Dr. med. Dieter Luft
Vorsitzender der Ethik-Kommission

ALLGEMEINE HINWEISE SIEHE SEITE 2

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27 March 2017

Dear Eleonora,

RE: ETHICS APPLICATION–HSR1617-105–'An investigation of compensatory stepping from standing in healthy individuals with a walking frame.'

Based on the information you provided I am pleased to inform you that application HSR1617-105 has been approved.

If there are any changes to the project and/or its methodology, then please inform the Panel as soon as possible by contacting Health-ResearchEthics@salford.ac.uk

Yours sincerely,

Sue McAndrew
Chair of the Research Ethics Panel

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