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MOTOR ABILITY ASSESSMENT
IN LOWER-LIMB AMPUTEES

PhD Thesis

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Abstract

The modern clinical approach to the patient with motor disorders is identified in the functional evaluation that, coherently with the most recent documents of the World Health Organization, it would be better to call "assessment of motor ability" (WHO, 2001). Indeed, the formulation of a prognostic judgment, the appropriateness of a clinical care pathway or the outcome measures of a therapy, are based on the observation of the functional limitation both at the level of the whole person (disability or skill lacking) and at the level of the single organ or apparatus (damage). In the specific case of the lower-limb amputee patient, the evaluation can be articulated on two different levels: a first general, concerning the motor ability and quality of life as a function of that (level of independence), and a second local one, concerning the specificity of each single prosthetic module which composes the entire prosthetic chain in the relationship with the motor function of the person concerned.

This work investigates the necessary aspects for the motor ability assessment in persons with lower-limb amputations, following both the general and local evaluation approaches.

In the first chapter the theoretical background on the lower-limb amputation, the worldwide and Italian epidemiological overview, highlighting in particular the socio-economic impact on the NHS, are presented.

After reporting the etiological aspects of lower-limb amputations, especially attributable to peripheral arterial diseases, and the characterization of the main amputation levels as trans-tibial and trans-femoral ones, the chapter concerns the present scenario of prosthetic technology behind the traditional components of the modular prostheses such as feet, knees and sockets.

The second chapter covers the entire rehabilitation pathway after a lower-limb amputation, from the pre-surgical to the prosthetic phase until social reintegration, highlighting the main related issues such as post-surgical effects, changes in the residual limb volume and, above all the lack of guidelines for the patient's functional evaluation and the choice of prosthetic components to be used. It is furthermore presented a

literature review about the state of art on the motor ability assessment of lower-limb amputees, with the clinical and biomechanical parameters mainly investigated, underlining a clear lack of consensus within the scientific community.

Aim of the thesis is declared in the Chapter 3, in order to provide the cognitive and operational tools to both the identification of parameters of evaluation particularly sensitive to the motor ability changes in lower-limb amputees, and the definition of experimental methodological protocols ad hoc for the functional evaluation of the subject and for the appropriateness of the single prosthetic components.

The following chapters therefore concern six different experimental studies conducted during the PhD period, characterized according to the two levels of investigation general and local suggested by WHO.

In the fourth chapter is reported a study on the evaluation of peculiar gait parameters such as stability, harmony and symmetry in transfemoral (with free and locked knees), transtibial, and able-bodied subjects. The methodological approach included using of only one measurement tool based on inertial sensors, placed on the spinous process L2-L3 of each subject enrolled during the ambulatory task, allowing to identify a clear trend of the investigated indices depending both on the level of amputation and the type of prosthesis used.

Chapter 5 concerns an experimental study on the characterization of upper body accelerations in transtibial amputees using, unlike the previous chapter, a multi-sensory approach. Indeed, through this methodology is possible to identify the motor control strategy during walking, discerning indices as the RMS of the accelerations along the three anatominal axes and, in addition, the attenuation coefficients C_{ij} particularly useful in a clinical setting to monitor the attenuation of the accelerations among different parts of the upper body as pelvis, sternum and head.

The sixth and the seventh chapters report two studies on the comparison between different prosthetic feet, depending on the amputee's degree of mobility provided by the MCFL scale. In particular, in hypomobile amputees (K1-K2) the effects of the transition from a traditional non-articulated foot to a multiaxial one were evaluated, measuring the contribution of the DoFs increase by means of clinical outcomes and instrumental

measures. In amputees with greater degree of mobility (K3-K4), was compared instead a standard dynamic foot (carbon fiber, energy storing), with a new electronic ankle microprocessor controlled, that automatically adjust the dorsiflexion during the swing phase of gait: This study allowed, in addition to the evaluation of different clinical aspects, to quantify the energy cost of walking in several motor tasks with this new generation device.

Chapter 8 illustrates a study designed to evaluate the efficiency of suspension system passive vacuum based with 5 rings and a traditional urethane sealing suspension sleeve. Pistoning effect, that is the relative vertical movement between the socket and stump, was measured through a new methodological protocol. In order to optimized the proposal method, it was specifically designed and developed a system for the distal traction loads on the prosthesis, modular which allows to get closer to an ideal configuration in which the hip and knee joint centers are aligned with the barycenter of weight applied to the prosthesis. This experimental system was ad hoc clinically tested for the study.

In the ninth chapter a new methodological protocol for the functional assessment of the tranfemoral amputee and for clinical and technical evaluation of the prosthetic sockets is presented. This experimental design involves the use of the traditional instrumentation for kinematic and dynamic gait analysis (stereophotogrammetry and platforms of forces), wearable inertial sensors in performing stereotypical motor tasks as the sit-to-stand and walking on level ground, the metabolimeter and heart rate monitor for the physiological response and energy efficiency, as well as the traditional clinical approach based on scales and questionnaires. In particular, the ischial containement socket and the new generation Marlo Anatomical Socket were compared.

Finally, general conclusions and some directions for future researches are drafted in Chapter 10.

Sommario

L'approccio clinico moderno al paziente con disordini motori si identifica nella valutazione funzionale che, coerentemente con i più recenti documenti dell'Organizzazione Mondiale Della Sanità (OMS), è più opportuno denominare "valutazione dell'abilità motoria". In questo caso, la formulazione di un giudizio prognostico, la valutazione di appropriatezza di un dato progetto o percorso assistenziale, o la misura dell'esito di una terapia, si avvalgono della osservazione della limitazione funzionale a livello di persona (disabilità o carenza di abilità) piuttosto che a livello di organo o apparato (danno). Nello specifico caso del paziente amputato di arto inferiore, la valutazione può essere articolata su due livelli: un primo generale, riguardante l'abilità motoria e la qualità della vita in funzione della stessa (livello di indipendenza), ed un secondo a livello locale, riguardante la specificità dei singoli moduli protesici di cui sono costituite le protesi (ognuno dei quali può essere sostituito o modificato secondo le necessità) nella funzione e nel rapporto col soggetto portatore. Attualmente una delle principali problematiche associata alla riabilitazione della persona affetta da esiti di amputazione d'arto inferiore è associata al fatto che non esistono delle linee guida convenzionalmente riconosciute, sia per la valutazione funzionale ed il monitoraggio delle condizioni cliniche nel tempo del soggetto coinvolto, sia per la scelta del componente protesico più adatto per il soggetto stesso. Inoltre lo studio della letteratura denuncia una mancanza di consenso circa l'identificazione di parametri ed indici ritenuti maggiormente rilevanti per descrivere e valutare l'abilità motoria del paziente amputato, unitamente ad i vari protocolli metodologici di misura utilizzati. La diversità dei risultati può essere spiegata solo in relazione ai dissimili obiettivi specifici degli studi revisionati.

Gli obiettivi principali del presente lavoro di tesi sono quindi riassumibili:

1) Individuazione di parametri di valutazione sensibili alle variazioni di abilità motoria del soggetto amputato di arto inferiore

2) Definizione di protocolli metodologici sperimentali ad hoc per la valutazione funzionale del soggetto e per l'appropriatezza della componentistica protesica utilizzata

L'attività di ricerca oggetto del dottorato nasce dalla necessità di fornire risposte adeguate alle limitazioni sopracitate, fornendo gli strumenti conoscitivi ed operativi atti all'identificazione di una metodologia accurate ed affidabile per la valutazione della capacità e della prestazione motoria dell'amputato di arto inferiore.

La rilevanza della tematica è confermata dalla grande attenzione posta sull'invecchiamento attivo nel Programma Europeo Horizon 2020 e dall'alto impatto socio-economico che la riabilitazione del paziente amputato ha sul Sistema Sanitario Nazionale (SSN). Gli obiettivi sono stati perseguiti sia attraverso approcci clinico-tradizionali, che di tipo sperimentale.

Nel primo capitolo è illustrato il background teorico dell'amputazione di arto inferiore, il prospetto epidemiologico mondiale ed italiano, evidenziandone in particolare l'impatto socio-economico sul SSN. Dopo aver approfondito gli aspetti eziologici, nella maggior parte riconducibili ad arteriopatia obliterante periferica, e la caratterizzazione dei principali livelli di amputazione quali trans-tibiale e tran-femorale, è illustrato l'attuale scenario della tecnologia protesica alla base dei tradizionali componenti delle protesi modulari quali piedi, ginocchia ed invasature.

Il secondo capitolo percorre l'intero processo riabilitativo dell'amputato di arto inferiore, dalla fase pre-chirurgica, passando per quella protesica fino al suo reinserimento sociale, evidenziandone le principali problematiche connesse quali effetti post-chirurgici, variazioni di volume del moncone e, soprattutto, la mancanza di linee guide atte alla valutazione funzionale del paziente ed alla scelta delle componenti protesiche da utilizzare. E' presentata una revisione della letteratura circa lo stato dell'arte sulla valutazione dell'abilità motoria dell'amputato di arto inferiore, con i parametri clinici e biomeccanici maggiormente investigati, da cui emerge una chiara mancanza di consenso nell'ambito della comunità scientifica.

Nel terzo capitolo è quindi riportato l'obiettivo della tesi, con l'intento di fornire gli strumenti conoscitivi ed operativi atti all'identificazione di una metodologia, accurata e affidabile, per l'identificazione di parametri sensibili alla variazione dell'abilità motoria dell'amputato di arto inferiore.

I capitoli successivi riportano quindi sei studi sperimentali condotti durante il periodo di dottorato, caratterizzati a seconda dei due livelli di indagine suggeriti dall'OMS, ovvero generale e locale. I protocolli sperimentali sono stati disegnati ad hoc, attraverso metodologie e strumenti specifici per la valutazione dell'abilità motoria dell'amputato di arto inferiore, sia in funzione del suo livello di abilità che delle prestazioni dei vari moduli protesici utilizzati.

In particolare il quarto capitolo riguarda la valutazione di parametri caratteristici della deambulazione come stabilità, armonia e simmetria in soggetti transfemorali, con ginocchio libero e bloccato, e trans-tibiali, confrontati con un campione di controllo normodotato. L'approccio metodologico ha previsto l'uso di un solo sistema di misura basato su sensoristica inerziale posto sul processo spinoso L2-L3 di ogni soggetto durante il task deambulatorio, permettendo di identificare un chiaro trend delle caratteristiche investigate dipendentemente sia dal livello di amputazione che dal tipo di protesi indossata.

Nel quinto capitolo è riportato uno studio sperimentale circa la caratterizzazione delle accelerazioni della parte superiore del corpo in amputati transtibiali usando, a differenza del precedente capitolo, un approccio multi-sensoriale. Attraverso tale metodologia, infatti, è possibile identificare la particolare strategia di controllo motorio durante la deambulazione, discriminando indici quali RMS delle accelerazioni lungo i tre assi anatomici ed i coefficienti di attenuazione C_{ij}, particolarmente utili in un contesto clinico per monitorare l'attenuazione delle accelerazioni tra vari distretti corporei, nello specifico pelvi-manubrio sternale-testa.

Il sesto ed il settimo capitolo riportano due studi sul confronto di tra diversi piedi protesici, in relazione al grado di mobilità del soggetto amputato fornito dalla scala MCFL. In particolare negli amputati ipomobili (K1-K2) sono stati valutati gli effetti del passaggio da un piede tradizionale non-articolato ad uno multi assiale, misurando il

contributo dell'incremento dei DoFs all'articolazione protesica attraverso misure di outcome e strumentali. Nei soggetti con maggior grado di mobilità (K3-K4) è stata confrontata una caviglia elettronica di nuova generazione, controllata da un microprocessore interno che permette di regolare automaticamente la dorsiflessione del piede nella fase di oscillazione del passo, e un piede dinamico standard (fibra di carbonio a rilascio energetico), permettendo, oltre alla valutazione di diversi aspetti clinici, di quantificare il costo energetico del cammino in diversi task motori.

Il capitolo otto illustra uno studio atto a valutare l'efficienza di un sistema di sospensione a sottovuoto passivo a 5 anelli ed uno tradizionale a ginocchiera uretanica. Il livelllo di pistonamento, ovvero il movimento verticale relativo tra moncone ed invaso, è stato misurato attraverso una nuovo protocollo metodologico. Al fine di perfezionare il metodo è stato sviluppato e progettato un sistema per l'applicazione dei carichi di trazione distali alla protesi, modulabile, che permette di avvicinarsi ad una configurazione ideale, in cui i centri articolari di anca e ginocchio siano allineati col baricentro del peso applicato alla protesi stessa. Tale impianto sperimentale è stato testato clinicamente per lo studio descritto su un campione di soggetti transtibiali.

Nel nono capitolo è presentato un protocollo metodologico per la valutazione della valutazione funzionale dell'amputato tranfemorale, unitamente alla valutazione clinico-tecnica del modulo prrotescio invasatura. Tale disegno sperimentale prevede l'utilizzo della strumentazione atta alla tradizionale analisi cinematica e dinamica del cammino (stereofotogrammetria e piattaforme di forze), della sensoristica inerziale nell'esecuzione di task motori stereotipici quail sit-to-stand e deambulazione in piano, del metabolimetro e cardifrequenzimetro per la risposta fisiologica e l'efficienza energetica, oltre all'approccio clinico-tradizionale di scale e questionari specifici. In particolare sono state confrontare l'invasatura a contenimento ischiatico ed una di nuova generazione MAS.

Infine, nel capitolo dieci sono stilate le conclusioni generali e suggerite potenziali direzioni per future ricerche.

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To my wonderful family, my bearings

to Clarissa, my lifeblood

"If you can dream it, you can do it.
Always remember that this whole thing was started with a
dream and a mouse"

- Walt Disney -

Chapter 1

THE LOWER LIMB AMPUTATION

1.1 Theoretical background

Lower-extremity amputation is one of the oldest known surgically performed procedures (Murdoch et al., 1996; Tooms, 1987) and has been done since time immemorial. The first surgical description of a leg amputation was by Hippocrates (460-377 b.C.). Many different surgical techniques have been described through history, for instance the Guillotine amputation, the double circular incision or two cut technique, and the skin-muscle-flap method. The original surgical principles as described by Hippocrates remain true today. Refinements of surgical technique such as hemostasis, anesthesia, and improved perioperative conditions have occurred, but only relatively small technical improvements have been made. Amputation is still often viewed as a failure of treatment and the responsibility for performing it may even fall on the most junior member of the surgical team. Whatever, the reason for performing an extremity amputation should not be viewed as a failure of treatment. Amputation can be the treatment of choice for severe trauma, vascular disease, and tumors. Patients and family members must be aware of their options and have realistic expectations of surgical outcomes in order to make informed decisions regarding amputation (Eardley et al., 2010; Higgins et al., 2010). One of the greatest difficulties for a person undergoing amputation surgery is overcoming the psychological stigma that society associates with the loss of a limb. Indeed, persons who have undergone amputations are often viewed as incomplete individuals (Eartl et al., 2010). Following the removal of a diseased limb and the application of an appropriate prosthesis, the patient can resume being an active member of society and maintaining an independent lifestyle. Although a diseased limb can be removed quite readily, resolving the problem of the extremity, the care does not end there. The surgery must be performed well to ensure that the patient is able to wear prosthesis comfortably. Knee joint salvage enhances rehabilitative efforts and decreases the energy expenditure

required for ambulation. Till now, prostheseology gives better functional results than transplantation of the limb. Thus, patients still need to function with their amputated leg with or without prosthesis. Many aspects in amputation surgery, prostheseology, and the functional possibilities of patients with leg amputations have improved since Hippocrates. However, for the rehabilitation of amputee patients, treatment is still mainly based on clinical experience and only limited on evidence-based medicine. Knowledge of important aspects for the rehabilitation of patients with a leg amputation is limited. For example, prediction of functional outcome of amputee patients remains a very difficult problem, the relevance of vocational rehabilitation is just becoming evident, the effect of several therapies is uncertain, and the functional benefits of different types of prostheses are not proven yet. Different aspects of the functional outcome of amputee patients are the subjects of this thesis. The functional capacity consists of ADL (Activities of Daily Living) and HDL (Household activities of Daily Living) abilities as well as work ability. In the rehabilitation of amputee patients, goals are set to upgrade the functional capacity of the subject with the amputation, i.e. independence in self-care, and optimal participation in recreational and vocational activities. An amputation causes sustained restrictions in physical capacity but attempts should be made to minimalize the influence on the functional capacity of the person. Thus far, most studies have concentrated on the physical influences on functioning after an amputation. Social and mental influences have not very often been included in these studies.

1.1.1 Epidemiology

1.1.1.1 World

To this day, it is no easy to provide an unambiguous epidemiological prospectus focused on the world population relating to the causes of lower-limb amputation and their incidence. This picture indeed, is strongly influenced by many socioeconomic and geopolitical factors. Regarding the geopolitical picture at the global level, there are two principal world areas with opposite characteristics: an area corresponding to the western

countries, economically prosperous and technologically developed, and another one instead, corresponding to the poor and developing countries, often war zones or in which there are strong repercussions of a more or less recent conflict. The number of amputees varies in these two areas, but the most obvious differences do not concern the quantitative aspects, but the etiology of this disablement. Unfortunately, not many epidemiological data are available for a thorough study that could represent the real situation because in many developing countries there is not a health organization system that can classify the necessary interventions to assisting people in need of care. The average age of these populations is low, and vascular diseases have a significantly lower incidence because most people do not reach the age when they can weigh heavily on the individual life. The predominant cause is rather traumatic, usually because the presence of a war in action, and those of most affected are young people and children. In general, with reference to the industrialized countries, the major causes of lower-extremities amputation are ascribable to neoplastic diseases, especially vascular but also infective, to trauma and, for a minority, to the corrective surgery of congenital malformations. In recent years there has been, in these countries, an increase in the number of lower-limb amputations, probably due to a higher incidence of generalized chronic-degenerative diseases of the peripheral vascular apparatus of the population (bad habits as smoke and alcool, nutitional regimen fats and sugars based, generalized stress, etc.). Furthermore, in these countries has been gradually changed the weight of the causal factors of amputation. Indeed, it has decreased the number of traumatic amputees whereas it has increased that of geriatric amputees because of vascular causes. This clinical picture is due to several factors such as the increase of the average lifespan of the population and improved preventive surgery techniques (which has reduced the number of deaths due to arteriopathies), with a greater amputation survival rate, justified by an overall improvement of therapies and nursing in which undergoes this kind of patients. In countries with high socioeconomic level of the Western world, the atherosclerosis prevalence is about 2% in the sixth life decade and 7% in the seventh and eighth ones. Some studies focused on the arteriopathic patient follow-up reported that between six months and thirteen years from the onset of the clinical picture of a severe obstructive

arteriopathy, 6-15% of arteriopathic individuals undergoes amputation, as well as the critical ischemia involves 44% of amputation in one year. For instance, in the USA, 30-40K amputations are performed annually, and the numbers are rising. There were an estimated 1.6 million individuals living with the loss of a limb in 2005; these estimates are expected to more than double to 3.6 million such individuals by the year 2050 (Ziegler-Graham et al., 2008). Most amputations are performed for ischemic disease of the lower extremity. About dysvascular amputations, 15-28% of patients undergo contralateral limb amputations within 3 years. Regarding the elderly persons who undergo amputations, 50% survive the first 3 years. In 1965, the ratio of above-knee amputations to below-knee amputations was 70:30. A quarter century later, the value of retaining the knee joint and the greater success in doing so was appreciated, so the ratio became 30:70 (Flanagan et al., 2010).

1.1.1.2 Italy

As the international one, the Italian demographic trend observes an increase in the average life expectancy. Indeed, if the geriatric represents today the 20% of the entire population, it is expected that in 2030 will cover about the 30%. Presenting a brief epidemiological overview about the causes of amputation and their bearing on the Italian population, it can be said that until the 80s, there was a significant increase of this disablement of which the 96.5% concerned the lower extremities. The development of the many conserving surgery procedures, the anthiobiotic therapies advent, plastic, bone and skin surgery, and the continuous progress of the vascular surgery, have now greatly restricted the indications for amputation. Italian Board of Health (IBH) reports that the 70% of amputations in Italy are caused by vascular diseases and infectious (61-70 years), 22% by trauma (21-30 years) as road accidents or domestic, 5% by tumors (11-20 years) and 3% by congenital malformations (IBH, 2013). According to the Instituto Superiore di Sanità (ISS) data, over the last five years the total number of lower-extremities amputations has stabilized around 11000 cases per year (ISS, 2013). The main causes of lower-limb amputation in Italy are related to vascular pathologies as occlusive arteriopathies and diabetic vascular diseases. It is important to highlight that although in

Italy, according to ISTAT data processed by the ISS, diabetics represent about the 5% of the entire population, they represent 45% of all patients who undergo amputations because of their propensity for peripheral vascular disease. Therefore, the amputation's risk is strongly correlated with susceptibility of diabetes and trend in hospitalization rates (that is the ratio between the number of hospitalized diabetic patients per year and the resident population) has a strong positive derivative for people aged 50 to over. According to the demographic trend of the last 10 years, the Italian population of octogenarians is growing up of about 54%.

Generally, more than 98% of the surgical interventions of amputation is performed in ordinary hospitalization, 82% in public hospitals, 10% in accredited private clinics and about 7% in research institutes hospitals. For instance, the above-knee interventions require an average hospital stay of 23 days (which vary according to type and cause of amputation) and 60-90 days in rehabilitation centre. Finally, because of the greater survival probability of women, the lower-limb amputation incidence is higher in males than that of females. Therefore, it is conceivable that the number of limb amputees is going to increase.

In light of the foregoing is important to invest resources in this topic because the lower-limb amputee rehabilitation is significant from the social, economic and epidemiological standpoint and is very closely related to the Italian National Health Service.

1.1.2 Etiology

As mentioned previously, the most frequent causes that lead to lower-extremities amputation are Peripheral Vascular Diseases (PVD) and vasculopathies in general, trauma, tumors and congenital malformations (Smith et al., 2004). Despite is considered as the most common cause of amputation among adults, PVD is uncommon in the pediatric age group (Seymour, 2002). Any damage to the arteries and veins are referred to as PVD. Recent statistics show that vascular disease is the highest cause of amputation by 82%, followed by 22% of trauma, 4% of congenital and 4% of tumors in

the USA (Seymour, 2002). Furthermore, diabetic individuals are 15 times more likely to develop lower limb amputation compared with the healthy people.

1.1.2.1 Vasculopathies

Vasculopathies with ischemia not treatable with vascular reconstruction or other therapies, often lead to the amputation. Generally, the vascular pathology is also associated with other chronic-degenerative diseases as the cardiovascular system insufficiency (which can lead to heart attack), diabetes and its complications (diabetic retinopathy, peripheral nephropathy, etc). Vascular diseases that more frequently lead to the amputation's event are the following:

- *Peripheral vascular disease (PVD)*: atherosclerosis based, it consists in the vessel walls' thickening in response to a change in their structure linked to the deposit of minerals and fats, with a consequential reduction of the vessel lumen;

- *Diabetic vasculopathy*: diabetes is a metabolic disorder caused by a hyposecretion of insulin by the β pancreas cells. In the long term, it accelerates the atherosclerotic process at the great's vessels levels (eg. aorta) and creates damage to small arteries causing feet ulcers that tend not to heal but evolve in gangrene;

- *Burger's disease*: an inflammatory disease that mainly affects the peripheral arterial tree causing vascular occlusions. Etiology is unknown, but cigarette's smoke is a predisposing factor;

- *Aneurysm*: a wall-vessel dilatation wall that can both get broken with the consequent bleeding, and slow down the blood flow favoring stagnation and eventually the formation of thrombi. Thrombosis can downstream obliterate the arterial tree especially at the popliteal fossa level and the femoral triangle (of Scarpa);

- *Thromboembolism*: the formation in a blood vessel of clots that breaks loose and are carried by the blood stream to plug another vessel. Thrombi could get embolized causing ischemia in the sprayed zone of the arteria occluded.

1.1.2.2 Traumatisms

Generally the main causes may include crushing trauma (domestic, occupational, agricultural, car or motocycle crashes, etc.), firearms injuries or from war causes as antipersonnel mines that can lead to extensive bones and soft-tissues lesions with consequential very severe infections. Severe open fractures with popliteal artery and posterior tibial nerve injuries can be treated with current techniques; however, treatment is at a high cost, and multiple surgeries are required. The result is often a leg that ispainful, nonfunctional, and less efficient than a prosthesis (Tintle et al., 2010).

The amputation can be also "post-traumatic" if performed soon after the trauma or "post-surgical", after the failure of the reconstructive surgery. In the Western countries, the traumatic patient is generally a young adult with unilateral amputation and good general conditions that often needs high functional and aesthetic requirements for the prosthesis manufacturing.

1.1.2.3 Neoplasms

Neoplasms are diseases characterized by an uncontrolled cell proliferation. Tumors that inevitably lead to the amputation choice are primitive and malignant including bone, skin and vascular tumors coming from the peripheral nervous system. They predominantly affect the age group of young and male individuals.

There are also secondary tumors that are metastatis of primary tumors located in other anatomical parts such as in the prostate, breast, thyroid, lung, kidney or the bladder. Rarely, however, they require amputation or removal because of the already widespread metastatic process. Amputation is performed less frequently with the advent of advanced limb-salvage techniques.

1.1.2.4 Congenital malformations

Amputations for congenital limb deficiencies are performed primarily in the pediatric population because of failure of partial or complete formation of a portion of the limb. Congenital extremity deficiencies have been classified as longitudinal, transverse, or intercalary. Radial or tibial deficiencies are referred to as preaxial, and ulnar and fibular deficiencies are referred to as postaxial.

The more common malformations are the following:

- *Amelia*: total absence of a limb

- *Phocomelia*: absence of the proximal segment of a limb

- *Amimelia*: absence of the distal segment of a limb.

1.2 Traditional lower-limb amputation levels

For centuries, limb amputations were performed for the purpose of prognosis "quod vitam". Today, there are many recommendations, targeting the future functional and social reintegration of the person involved. The level of amputation is certainly one of major factors in determining the functional limitation level of the lower-limb amputee and the complexity associated with his rehabilitation. For example, a large body of literature reported that a higher amputation level is associated a greater energy cost of the walking and, consequently, a lower self-selected walking speed (Waters et al., 1976).

In general, the traditional lower-limb amputation levels can be summarized as follow:

- Amputation of digits;
- Partial foot amputation (i.e. Chopart, Lisfranc, Ray);
- Ankle disarticulation (i.e. Syme, Pyrogoff);
- Transtibial (or below-knee) amputation (i.e. Burgess and Kingsley Robinson technique);
- Knee disarticulation (i.e. Gritti or Gritti-Stokes);

- Tranfemoral (or above-knee) amputation;

- Rotationplasty (or Van-ness rotation). Foot is turned around and reattached to allow the ankle joint to be used as a knee;

- Hip disarticulation;

- Hemipelvectomy (or hindquarter) amputation.
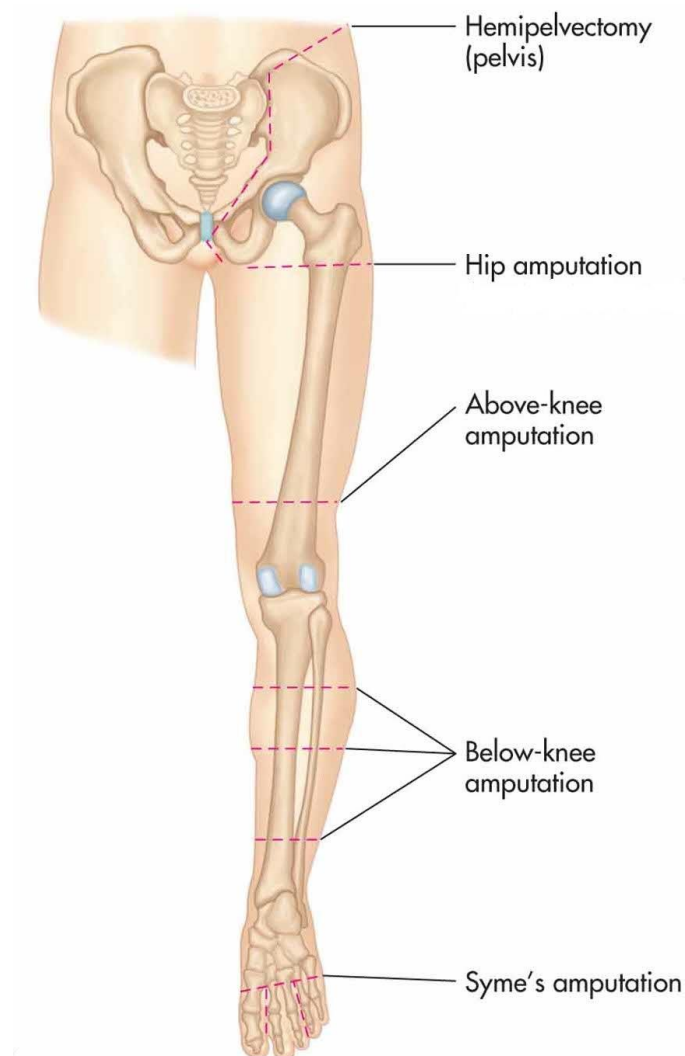
Figure 1.1 – Main lower-limb amputation levels.

The most prevalent amputation levels are transtibial (or below-knee) and tranfemoral (or above-knee) (Fig.1.2). It is not surprising that both these levels have attracted so much attention in rehabilitation, surgical literature and prosthetics. The transfemoral and transtibial amputee rehabilitation represent a very interesting field of potential innovations.

TRANSTIBIAL AMPUTATION   TRANSFEMORAL AMPUTATION
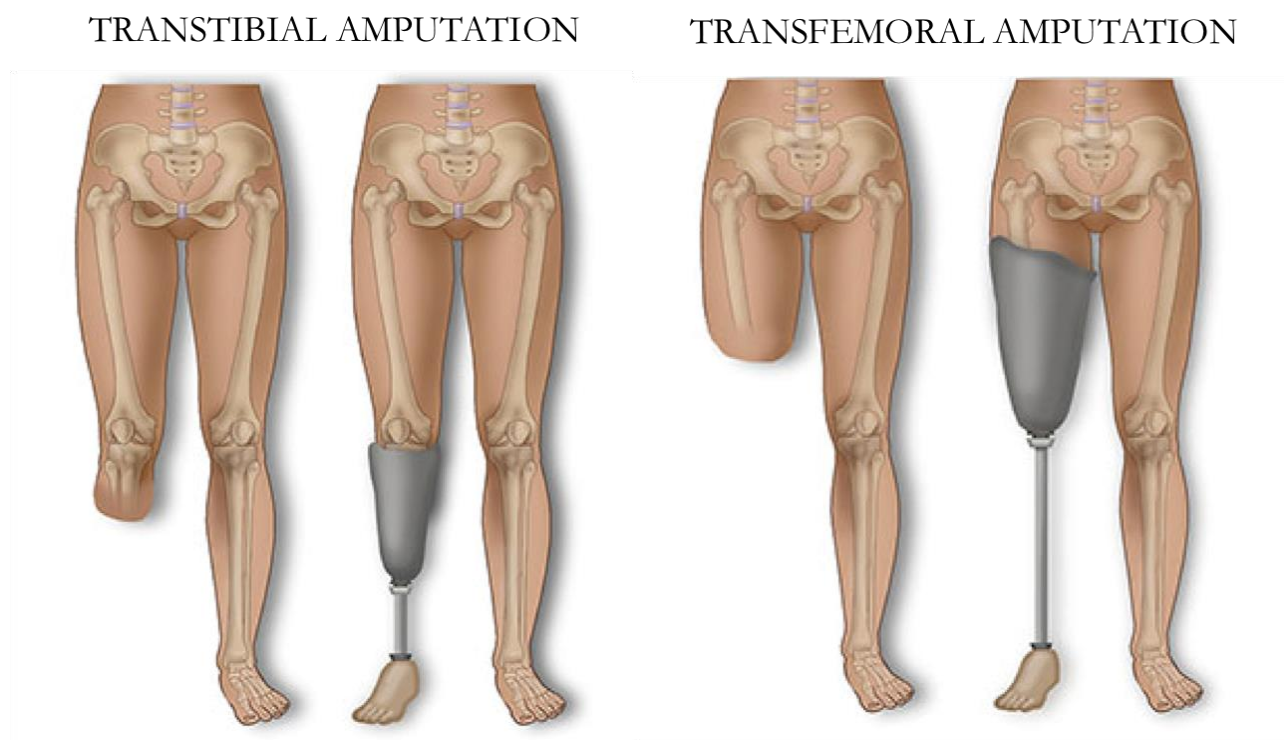
Figure 1.2 – Transtibial (below-knee) amputation and prosthesis example on the left side, transfmemoral (above-knee) amputation and prosthesis example on the right side.

1.2.1 Transtibial amputation

There are three main section levels for the transtibial amputation: upper, middle and lower, although the amputation involves the section between the upper and middle third of the tibia. The residual limb lends itself perfectly to the supply of prosthesis with good cosmetics. The section of the tibia and fibula must be at the same level. When this latter is longer, than is not possible to load and the stump get painful at first because the interosseous membrane tears, then because the higher tibial-fibular syndesmosis become

symptomatic. Generally, the upper limit of the tibial stump resection corresponds to the insertion of the patellar tendon, which is essential for the active extension: this type of amputation does not allow the direct loading on the stump. Whenever possible, the usual trend is to to carry out the transtibial amputation to preserve the knee joint that allows a good mechanical locomotion. Too short stumps, 6-7 cm, are difficult to prosthesize because it lacks the interosseous membrane, which causes a streching apart between the fibula and tibia for the biceps femoris action, causing a painful contact with the socket during the swing phase of the gait. On the other hand, even stumps too long have their contraindications due to difficulties in wound healing with risk of ischemia. From the surgical point of view, malleolous resection are often performed to remove the bulbosity of the anterior tibialis and of digitorum extensor to keep muscles fastened, the shell fixation with transosseous points to ensure a stable relationship with the prosthesis. The posterior myocutaneous flap, vee-shaped, is generally longer than the anterior one about 10 cm, so that it can fold on it. Its distal soft tissue is made up of the gemelli muscles; the soleus is removed because of the insufficient spraying and for the presence of a venous plexus that could lead to risk of post-operative thrombosis.

1.2.2 Tranfemoral amputation

The transfemoral amputation leads to a shortening (even considerable in some cases) of the femur, with a consequent reduction of the lever arm used to biomechanical control the prosthesis. Furthermore, the loss of two anatomical joints (ankle and knee) entails a decrease of the entire body mass approximately about 12-15% with consequent tranfer of the center of gravity towards the intact hemibody. The weight transfer on the prosthetic socket occurs primarily by the ischial tuberosity, causing elevated pressure gradients on it. Therefore, to reduce this load concentration, it is important to distribuite the weight both on the total stump surface and on his terminal part. The achievement of this goal is firstly related to the adopted surgical technique, thereafter to a suitable socket manufacturing. The optimal length of the transfemoral stump is obtained by the incision at the middle third of the thigh. At this level, it can get a stump with a good apex

covering and with a good lever arm, sufficiently balanced, referring to the adductors and abductors' work. However, longer stumps do not involve particular difficulties in the prosthesization, but rather allow lever arm increase. To apply the major part of prosthetic knees, without involving asymmetries in the sitting position in respect to the controlateral knee, it is suitable to provide at least a difference of 10-12 cm from the joint space of the knee. Tranfermoral stumps shorter than the middle third may entail increasing difficulty in the manufacturing and in the alignment of the socket in respect to the other prosthetic components, because of muscular imbalance between both adductors and abductors and between flexors and extensors of the thigh that causes a deviation of the stump:

- on the frontal plane, the stump assumes an attitude in abduction for the pelvis-trochanteric muscles action no longer opposed by adductors;

- on the sagittal plane, the iliopsoas prevail on extenders bringing in flexion the stump.

1.3 The prosthetic technology

The prostheses for lower-limb amputees consist of modules each of which can be replaced or modified according to the needs. To ensure the aim of bringing the amputee patient back to regain his autonomy and motor function, the technology represent an indispensable means. To this day, one of the hot spots of technological innovation lie in the osseointegration, which is a new method of direct stabilization of the amputation prostheses to the bone by means a threaded titanium pin inserted in: it can be attached, inducing an osseointegration process to fix and link the anatomical and prosthetic parts (Fig.1.3). The amputee could feel and perceive the prosthesis as own anatomical appendix. The Italian National Health Service can provide founds for the users but, at present, there is no the surgical competence and culture for this new method, that is evolving in USA and, especially, in Sweden.
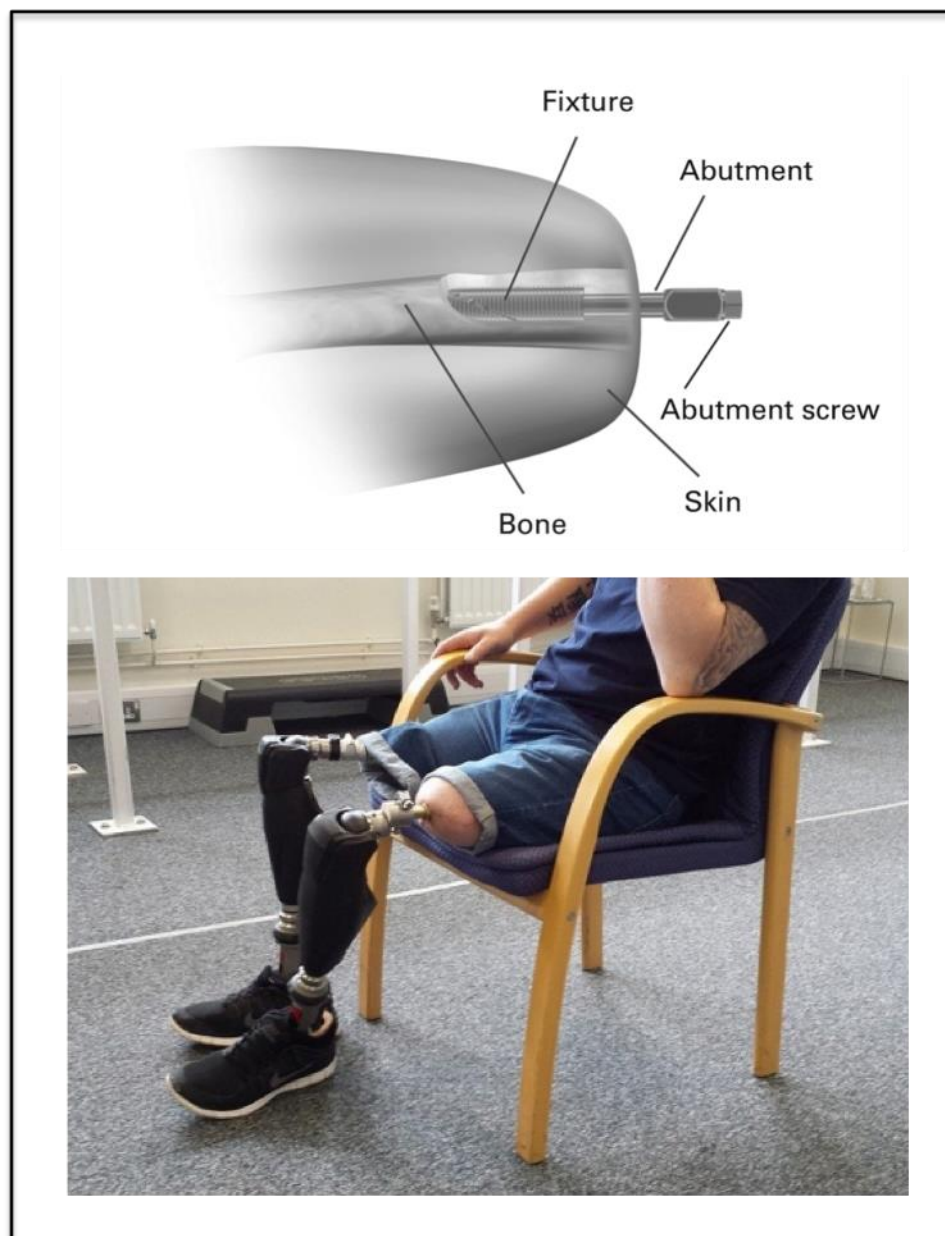
Figure 1.3 – Osseointegration schema (upper) and an example in a bilateral amputee (lower).

Another branch certainly fascinating is the neurosensory science, with the development of sensors technology able to collect the neural signals informations and transmit them to biomechatronic prosthetic devices such as artificial limbs, where the signals are processed, encoded and translated into a specific motor command. Through the brain control, the subject can be able to manage his artificial limbs in a natural manner (Fig.1.4). However, this type of research on very complex systems is till now still pure,

futuristic, and related to the academic world with just a few experiments in vivo and still at a mere prototypal and little tangible level.

Figure 1.4 - Neuroprosthesis: a thought-controlled bionic leg (Rehabilitation Institute of Chicago - Centre for Bionic Medicine).

The more common technological innovation is that of the prosthetics out-and-out, with products modules that are already commercial realities. The amputation of a limb or a segment of this is a severe trauma, not only physically but also psychologically. It can be overcome in large part through the application of a suitable prosthesis from anatomical, biomechanical and aesthetic standpoint. The prosthetic personalization depends clearly on to various clinical and demographycal parameters (ie age, sex, weight, general physical and stump conditions, mobility, comorbidities, specific requests, etc.). Depending on the type of construction and composition are distinguished today two main prosthesis systems: the traditional type, mostly in wood and resin with only supporting function and in disuse today, and modular ones, composed by modules which can be changed and modified according to needs. These systems involve prosthetic modules as feet, tubular structures, suspensions systems, knees (i.e. for tranfemorals) and sockets (Fig. 1.5).

Materials as aluminum, steel, carbon or titanium, vary depending on the mobility and the clinical picture of the amputee user. A soft foam covering ensures the aesthetic and cosmetic appearance. Technological evolution has affected especially the prothetic feet and knees. For instance, the feet range from rigid, mono and multi-axes (ie. articulated joints that allows flexio-extention and prono-supination) to the most common elastic energy storage and return (ESAR). These latter have been developed that store and release elastic energy during stance (Hafner et al., 2002) and provide body support, forward propulsion and leg swing initiation (Zmitrewicz et al., 2006).

Figure 1.5 – Modular prostheses for the different amputation levels, from the right to the left: transtibial, knee-disarticulation, transfemoral and hip disarticulation.

Lastly, a very interesting field and in great expansion in recent years is certainly represented by the prosthetic bionics. The engineering principle at the base of the prosthetic bionics components is the perfect integration between the sensory components (accelerometers, load cells and gyroscopes), which detect the position and movement of the device in space, the processing algorithm, which processes the signals from the sensors and produces an adequate response and mechanical actuators (electrovalves, actuators and hydraulic pistons) that are engaged in this response. Based on these principles, is for instance the very common C-leg knee (Ottobock), which exploits load sensors, accelerometers and gyroscopes as sensors and electrovalves connected to hydraulic pistons as actuators. Another meaningful example is the Rheo Knee (Össur) with a similar sensorial network but a different implementation of the response, based on a magnetorheological fluid wich flows through parallel bars crating more or less fiction, depending on the need. Össur has also produced a bioinic prosthetic ankle-joint called Proprio Foot, equipped with load sensors, accelerometers

and gyroscopes, able to actively adapt by means of actuators with endless screw, the plantar-dorsal flexion to the events of the gait cylce during locomotion on all types of terrain, also those uneven. In recent years, has also been developed new bionic technology-based knees that allows overcoming the traditional limits to safely climb over an obstacle with the limb amputee, and ascend-descend stairs using different approaches. Indeed, Ottobock launched into the market the Genium knee, the natural evolution of the C-leg, whereas Össur developed the Power knee, the prosthetic knee joint embedded with a engine that allows of providing propulsive energy both in flexion and extension.
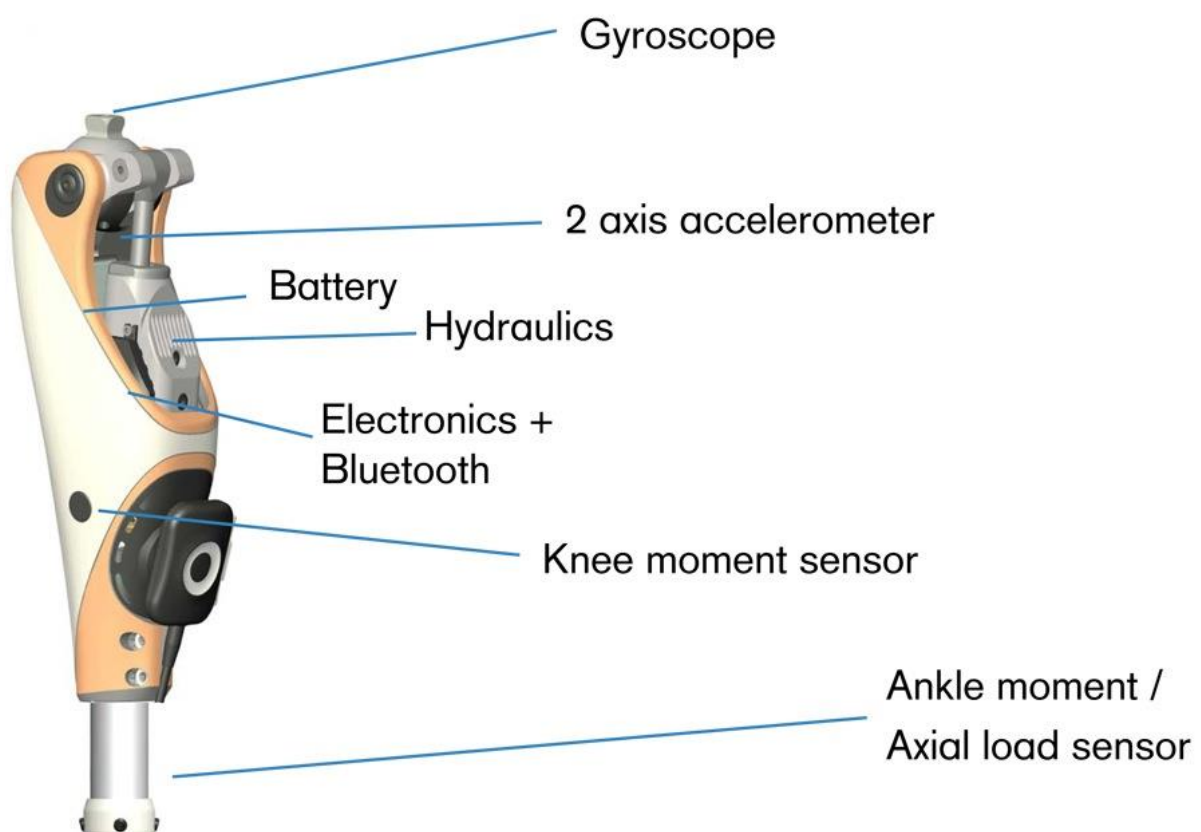
Figure 1.6 – The Genium knee (Ottobock), one of the commercial available prosthesis systems based on the bionic technology.

Figure 1.7 – The Simbionic Leg (Össur). This advanced prosthesis is the first to combine a bionic microprocessor knee and a powered bionic ankle with proactive ankle flexion into a single, integrated unit.

1.3.1 Traditional prosthetic feet

Foot classifications that have been used since the 1980s include:

- SACH

- Single axis

- Multi-axis

- Dynamic response

1.3.1.1 SACH foot

As biomechanical understanding and manufacturing capabilities evolved after World War II, component designers moved toward better simulating functions of the human foot and ankle complex. In the late 1950s, studies on the biomechanics of walking resulted in the creation of thepatellar tendon bearing (PTB) transtibial prosthesis including the concurrent development of the SACH foot. Functionally the SACH foot also helped to promote knee flexion that was important to PTB interface designs of the time. The heel cushion compressed under loading to simulate ankle plantarflexion and the eccentric contraction of the ankle dorsiflexors during loading response. The rigid keel simulated the stiffening effect of the ankle plantarflexors and forefoot dynamics during late stance. The SACH foot also addressed some of the maintenance and availability issues of the single axis foot by incorporating the functions of the single axis foot into an integrated design. Observational gait analysis typically reveals prolonged heel cushion compression of the prosthetic foot/ankle mechanism. Radcliffe advocated relative ankle plantarflexion alignment of the prosthetic foot/ankle mechanism in order to minimize heel cushion compression and to increase foot flat stability (Radcliffe, 1955). This was particularly emphasized for stabilizing the prosthetic knee in the alignment of prostheses for persons with transfemoral limb loss.

1.3.1.2 Single-Axis foot

Single-axis feet attempt to replace part of the anatomical ankle joint motion by incorporating a hinge at the approximate location of the transverse tarsal joint. The "single axis" of the foot/ankle mechanism mimics sagittal plane motion only. Variable-stiffness bumpers provide passive control of plantarflexion and dorsiflexion. Single-axis feet differ from solid-ankle designs in several ways. During loading response, single-axis feet plantarflex range of motion and timing vary depending on bumper properties. A soft bumper may result in premature foot flat. By contrast, when bumpers are too firm

the single axis foot may simply function as a solid-ankle foot. Historically, single axis feet were the first feet that were laboriously made for the patient with a toe break placed 6 mm posterior to the metatarsal heads. The forefoot rocker was positioned so as to augment the patient's movement. Today's single-axis designs are prefabricated and generally depend on the alignment capability of the prosthetist to optimize their rollover characteristics.

1.3.1.3 Multi-Axial foot

The multi-axial foot/ankle mechanism was designed to provide the ability to accommodate uneven terrain beyond that of the single axis foot/ankle mechanism by allowing motion in all planes, not just plantar and dorsiflexion in the sagittal plane. These foot/ankle mechanisms can be a simple split-keel variety, a carbon plate urethane overmolded sandwich, a hindfoot articulation or a combination of these designs. A split keel design allows for the forefoot of a foot/ankle mechanism to comply to the underlying surface as it is loaded. It behaves as two separate levers with a unified proximal junction. The carbon plate urethane sandwich allows the lower plate to accommodate ground surface contours while the urethane exhibits elastic properties to allow for ground compliance and reduction of ground reaction forces transferred proximally to the residual limb. Hindfoot articulations generally have elastic bumpers and bushings to allow for the plantar aspect of the foot/ankle mechanism to adapt to terrain through compression of these elastic members.

1.3.1.4 Dynamic Response foot

Dynamic Response foot/ankle mechanisms emerged in the 1980s with the objective of providing improved response over existing designs by simulating passive subtalar joint motion within the prosthetic foot. The SAFE foot (one of the first flexible keel feet) was introduced followed by the Seattle Foot, The Carbon Copy II and the Flex-Foot. A plethora of feet falling into the classification of dynamic response have since been developed. These designs employ a stiff anterior keel or leaf spring, made initially of

Delrin® (a nylon that can be easily machined and offers consistent spring function and toughness) and subsequently of phenolic and Fiberglas materials and high strength carbon plates. This was done theoretically to store spring potential energy through deformation of the keel in mid to late stance and return a portion of this energy for propulsion in the absence of active ankle plantarflexors.
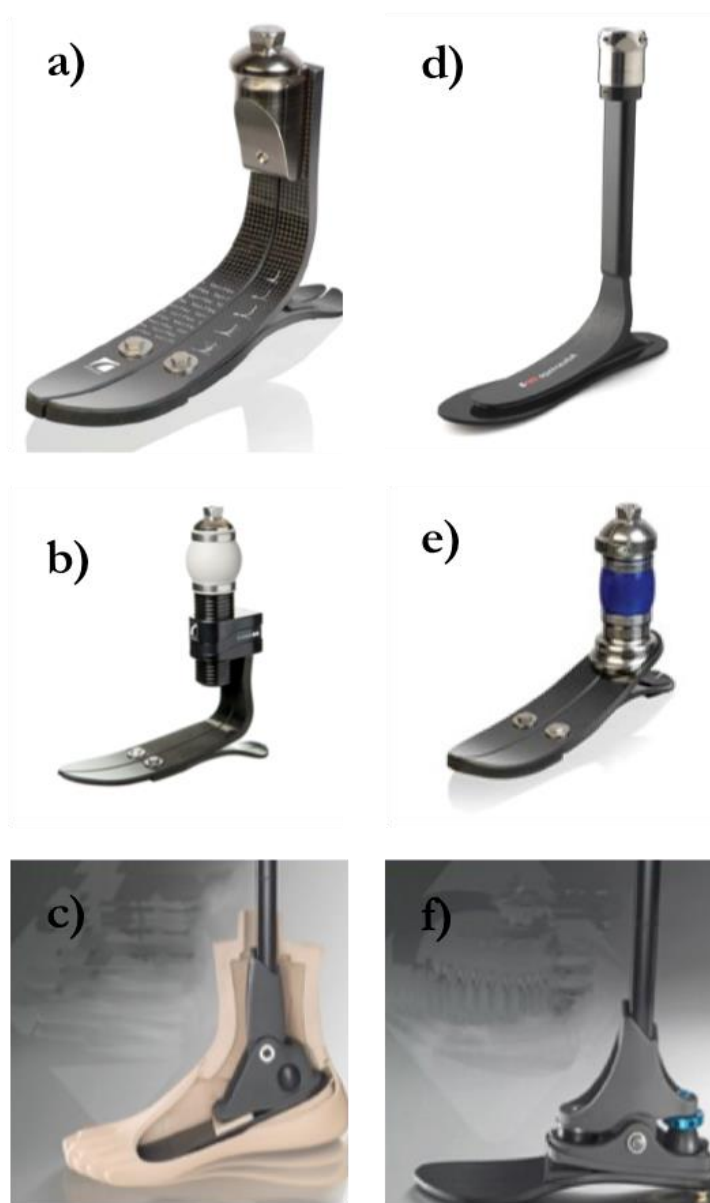
Figure 1.8 – Dynamic response feet. a: Vari-flex (Össur); b: Re-flex rotate (Össur); c: Accent (College Park); d: Springilite II (Ottobock); e: Ceterus (Össur); f: Onyx (College Park).

These designs were thought to also offer prolonged foot flat stability, better tibial progression, and more support distally when compared with SACH feet. Although this has not been verified with quantifiable data, many users report that dynamic response feet simply feel more lifelike when compared with other feet. Some report that although they like the springiness of the dynamic response feet, they may find themselves working against the action of the foot when walking at slower speeds, descending stairs, and even decelerating after running.

1.3.2 Traditional prosthetic knees

The type of knee used on an above knee prosthesis depends on the patient's activity level, the weight, strength and ability to control the knee, residual limb length, funding, and personal preferences. Friction is used in the knees in order to control the knee joint during walking. The friction controls how far and fast the knee bends and straightens during the gait. Some knees have mechanical friction while others have hydraulic resistance. Computerized knees are also available that control the knee speed based on the person's gait. Mechanical knees provide constant friction where the hydraulic knees and computerized knees change the knee speed depending on how fast the person is walking. The following are the principal knee typologies that are now available, exluding those based on the bionic technology.

1.3.2.1 Manual Locking Knee

The manual locking knee is the most stable knee used in prosthetics. The knee is locked during gait and the patient releases the lock mechanism in order to sit down. Manual locking knees are primarily used with patients who have very short residual limbs and/or poor hip strength and are unable to control the knee.

1.3.2.2 Single-Axis Constant Friction Knee

Single axis knees are basic knees that bend freely. The amputee must rely on his own muscle control for stability. The single axis constant friction knee is generally used by children who have a lower center of gravity or for patients with excellent musculature control that walk at a single speed. Friction in the knee can be adjusted by tightening a bolt. For exoskeletal knees, an extension strap made of elastic may be added to the front of the prosthesis to aid the knee in kicking forward. This knee is very durable and is easy to maintain and repair.

1.3.2.3 Weight Activated Stance Control Knee

The weight activated stance control knee is one of the most widely used knees in prosthetics. This knee is a single axis constant friction knee with a braking mechanism. When weight is put on the knee during gait, a braking mechanism is applied and the knee will not buckle. Using this knee, the patient must unload or take weight off of the prosthesis in order for the knee to bend. The wearer will need to unload the knee to sit or to initiate the swing phase of gait. This knee is sometimes referred to as the "safety" knee.

1.3.2.4 Polycentric Knees

The polycentric knee has a variable center of rotation allowing for stability at all phases of gait. The 4 bar linkage also allows the knee to collapse better during the swing phase of gait, essentially shortening the shin and allowing the foot to clear the ground easier. This collapsing feature also allows the knee to bend easier for sitting and is the ideal knee for knee disarticulation or long above knee amputees. The swing phase control can be either mechanical friction or hydraulic resistance. There are many manufacturers of polycentric knees.

1.3.2.5 Hydraulic Knees

Hydraulic knees allow adjustment of walking speed by the use of hydraulics (either liquid or air) within the knee. As a person's walking speed increases or decreases, the

hydraulics adjust to control the speed at which the shin of the prosthesis swings forward and bends backwards. This type of knee is often used for more active patients who vary their walking speeds and do not need assistive walking devices. Hydraulics can be used with single axis or polycentric knees.

1.3.3 Traditional prosthetic sockets

1.3.3.1 Patellar Tendon Bearing

The patellar tendon-bearing (PTB) socket consists of a laminated or thermoplastic socket that provides an intimate, total contact fit over the entire surface of the residual limb. The anterior wall of the socket extends proximally to encapsulate the distal third of the patella. Just below the patella, located at the middle of the patellar ligament, is an inward contour or bar that (via other biomechanical forces) converts the patellar tendon (ligament) of the residual limb into a weight-bearing surface. PTB is a misnomer, however, because the patellar tendon is not the only weight-bearing surface used by the PTB socket.

1.3.3.2 Total Surface Bearing

The total surface-bearing (TSB) socket design is commonly used when a gel liner is prescribed. The gel dissipates pressures throughout the socket and relieves bony prominences. Different from the PTB socket, pressure is intended for global distribution over the entire limb, as opposed to pressure-tolerant areas only. The gel liner cushions bone and other sensitive regions. Socket contours are smooth and without any obvious reliefs or undercuts lowering peak pressures. Similar to the PTB socket, this design also provides a total contact fit for comfort. The TSB socket significantly differs from PTB concepts in modification technique. In the PTB socket, plaster is removed over the patellar tendon, lateral pretibial group, the medial flare, and the popliteal region. Areas of plaster addition are the tibial tubercle, along the tibial crest, and the proximal and distal fibulae. TSB modification does not require buildups.

1.3.3.3 Ischial containment

One of the primary goals of the ischial containment socket is to provide medial-lateral stability by controlling the lateral shift of the femur during stance. This is accomplished by the narrow medial-lateral design and closely fitting socket that encases the medial aspect of the ischial tuberosity and ramus. As per its name, the ischial containment socket has the ischium within the socket itself. The socket is just wide enough at the level of the ischial tuberosity to allow the ischium to drop down inside the socket. The portion of the socket that extends proximally along the medial aspect of the ischial tuberosity and the ischial ramus is called the medial containment wall. This wall is angled to match the ischial ramus angle and does not follow the line of progression. Because the medial containment wall extends above the ischium, it will not allow the socket to migrate laterally.

1.3.3.4 Quadrilateral

The quadrilateral socket is designed for transfemoral amputees. The weight bearing in this socket is primarily on the ischium and the gluteal musculature (buttocks). This combination of bone and muscle rests on the posterior brim (back edge) of the socket, which creates a wide seat parallel to the ground. This socket can be held in place on the residual limb with suction, a Silesian or TES belt, or by the use of a soft insert with a suspension locking mechanism. This design aids in ease of sitting and, in comparison to the ischial containment socket, is more successful on long, firm residual limbs. This kind of prosthetic socket has fallen in disuse today.
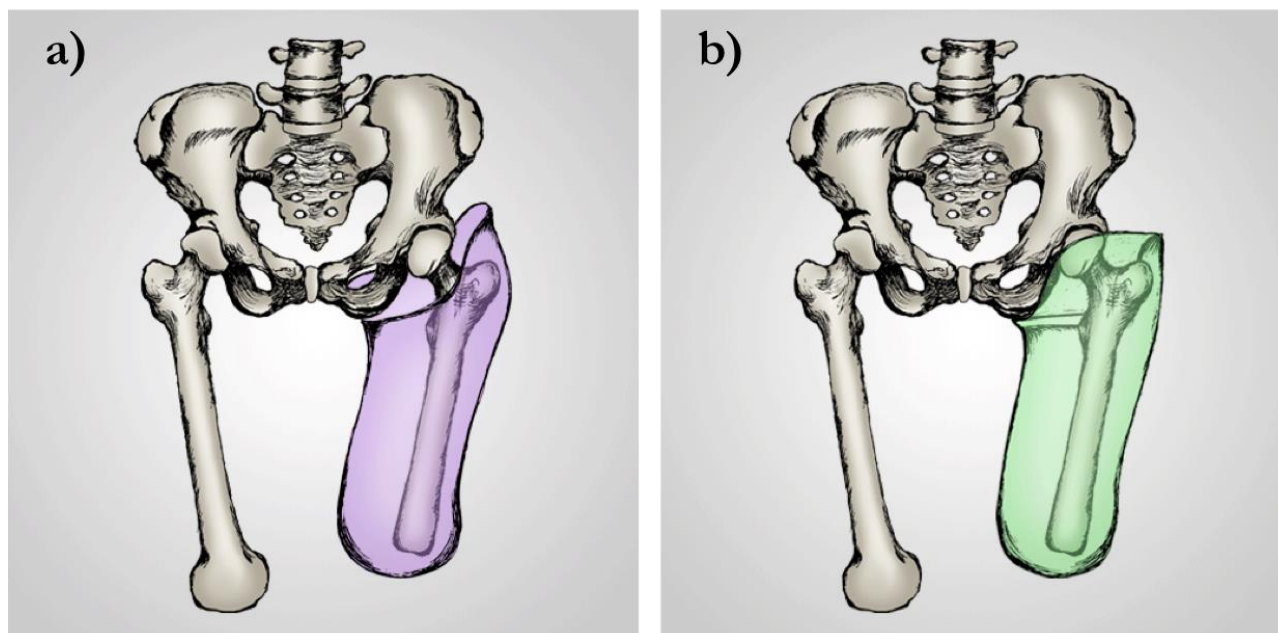
Figure 1.9 – a: Ischial containment prosthetic socket, b: Quadrilateral prosthetic socket.

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Chapter 2

THE AMPUTEE REHABILITATION PATHWAY

The physical rehabilitation pathway with a prosthesis or limb loss is often described as having several phases. While some phases include standardized milestones, not everyone has the same milestones or goes through the same phases. For example, individuals who lose a limb due to an accident usually do not have a pre-operative phase of physical rehabilitation because the limb is often sacrificed to save the person's life.

2.1 Amputee rehabilitation phases

The rehabilitation path generally involves different phases that can be summirezed as follow:

- Pre-operative phase
- Post-operative phase
- Pre-prosthetic phase
- Preparatory prosthetic training phase
- Definitive prosthetic training phase
- Reintegration phase
- Maintenance as needed

Several different physicians and physical therapists may be encountered during these phases. For example, the post-operative phase often occurs in the hospital, or sub-acute, setting. The pre-prosthetic and preparatory prosthetic phases will vary depending on the individual and situation. Some will go through these phases while in the hospital, others will visit an outpatient clinic, and some will have a combination. After the definitive prosthetic phase, services are commonly on an outpatient basis but some cases may

require an individual to be admitted for efficient coordination of services (Highsmith et al., 2008).

2.1.1 Pre-operative phase

In this stage, a person has often struggled with foot or leg problems for a long time (foot ulcers, fractures, infections, etc.) while providers try to prevent amputation. Often, ongoing therapy assists in coping with the existing level of function, but the goals of therapy change the day the decision is made to remove the limb. Therapists may encourage contracture prevention in residual joints, sound limb walking and balance activities, transfers and preservation strategies. This may be an ideal time to meet with a peer visitor, a support group and a prosthetist. This phase usually occurs in the outpatient setting.

2.1.2 Post-operative phase

The emphasis here is balancing recovery from the surgical amputation by protecting and beginning to shape the residual limb while encouraging mobility as soon as possible. There are no "easy" stages, but this is a particularly challenging time for all involved. The physical therapist is interested in encouraging mobility, but new amputees routinely have difficulty (psychologically and physically) accepting their present state of mobility. But mobility skills acquired in this phase are critical in terms of limb protection and shaping, the foundations set here can support the success of future prosthetic options, fitting and function. This phase commonly occurs in the hospital setting.

2.1.3 Pre-prosthetic phase

By now, mobility without prosthesis hopefully is progressing well. This phase focuses largely on strengthening, flexibility and final shaping of the residual limb for eventual fitting of the preparatory prosthesis. This phase, and the remaining phases, occurs in different settings, ranging from sub-acute, skilled-nursing, home health, outpatient and potentially others.

2.1.4 Preparatory prosthetic training phase

Many "firsts" are associated with the first prosthesis. Many basic prosthetic skills must be learned before and during early weight-bearing activities in the prosthesis. These include donning/doffing the various parts of the prosthesis, changing footwear, volume management techniques, getting dressed, maintaining the prosthesis, and, most importantly, inspecting and managing your skin/residual limb. Early weight-bearing accommodation, balance and sensory reintegration, and muscle re-education often precede and accompany gait activities. Finally, gait training on the prosthesis begins. It is crucial to understand that experienced prosthesis users "make it look easy." This is another example of why spending time with a peer is so important. Providers can tell the new amputee, but it means so much more coming from someone who has "been there". Being overly aggressive in this phase can reopen or create wounds, resulting in major setbacks.

2.1.5 Definitive prosthetic training phase

By now, the person no longer uses the preparatory prosthesis. Commonly, components have been changed to accommodate the walking style that the amputee will most likely adopt long-term. This does not mean that future changes are impossible, only that the healthcare team had to make an educated guess on how the amputee would progress when selecting preparatory components. Now, they have selected components based on those earlier experiences. If the person had major component changes, specific training may be needed. For example, if a flexible keel foot was previously used but now an energy-storing foot is used, the person should be taught to maximize the stride length and spend more time on the toe of the prosthesis. As the individual progresses into these later phases, the therapy becomes more individually tailored given individual circumstances, components and, above all, goals.

2.1.6 Reintegration phase

In this phase, the individual is preparing to return to specific activities such as work or recreation or may need help in training for new activities.

2.1.7 Maintenance as needed

This phase may occur if components, activities or goals are changed.

Figure 2.1 - The prosthetic training phase. Through stereotyped motors task and variable condition, patients are induced to internalize the prosthesis presence in their locomotor schema.

2.2 Main issues related to the amputee rehabilitation

The amputee patient must learn to manage his prosthesis in order to achieve a gait patten as much physiological as possible, in order to optimize his mobility. It needs to highlight that the expression "as much physiological as possible" does not means with trajectories proper of able-bodied people, but referes to the determining factors of the gait function as loads acting on the tissues, energy consumption or balance maintaining. Therefore, the main issues related to the amputee rehabilitation may macroscopically be attributable to three principal topics.

Firstly there are the post-surgical effects, unlikely reversibile because of the lack of standard surgical procedures of intervention relating to the muscles' role in relation to the portion of residual limb, with the consequence of a strong customization of the rehabilitative process. In fact, it is a priori decided which muscles to preserve and which make to prevail in length relating to the osteoplastic amputation. Consequently, patients may adopt postures unlikely to be removed to which compensating with compromises, most of the time, impairing the efficiency and gait comfort (Esquenazi, 2004).

An additional issue is represent by the stump volume fluctuactions and changes (Fig. 2.2), for various reasons (ie. environmental, humoral and psychological factors, cyclic mechanical stresses during gait, atmospheric changes, working hours etc.), which led to a redistribution of body fluids and, consequently, a redistribution of the loads acting on the stump, with the development of pressure gradients that cause pain and functional limitation (Tantua et al., 2014). These pressure gradients can also lead to developing the pistoning effect (one of the main causes of heat, sweating, dermatological disorders as ulcers, swelling and general discomfort and pain) between the residual limb and the socket (Sanders et al., 2011).
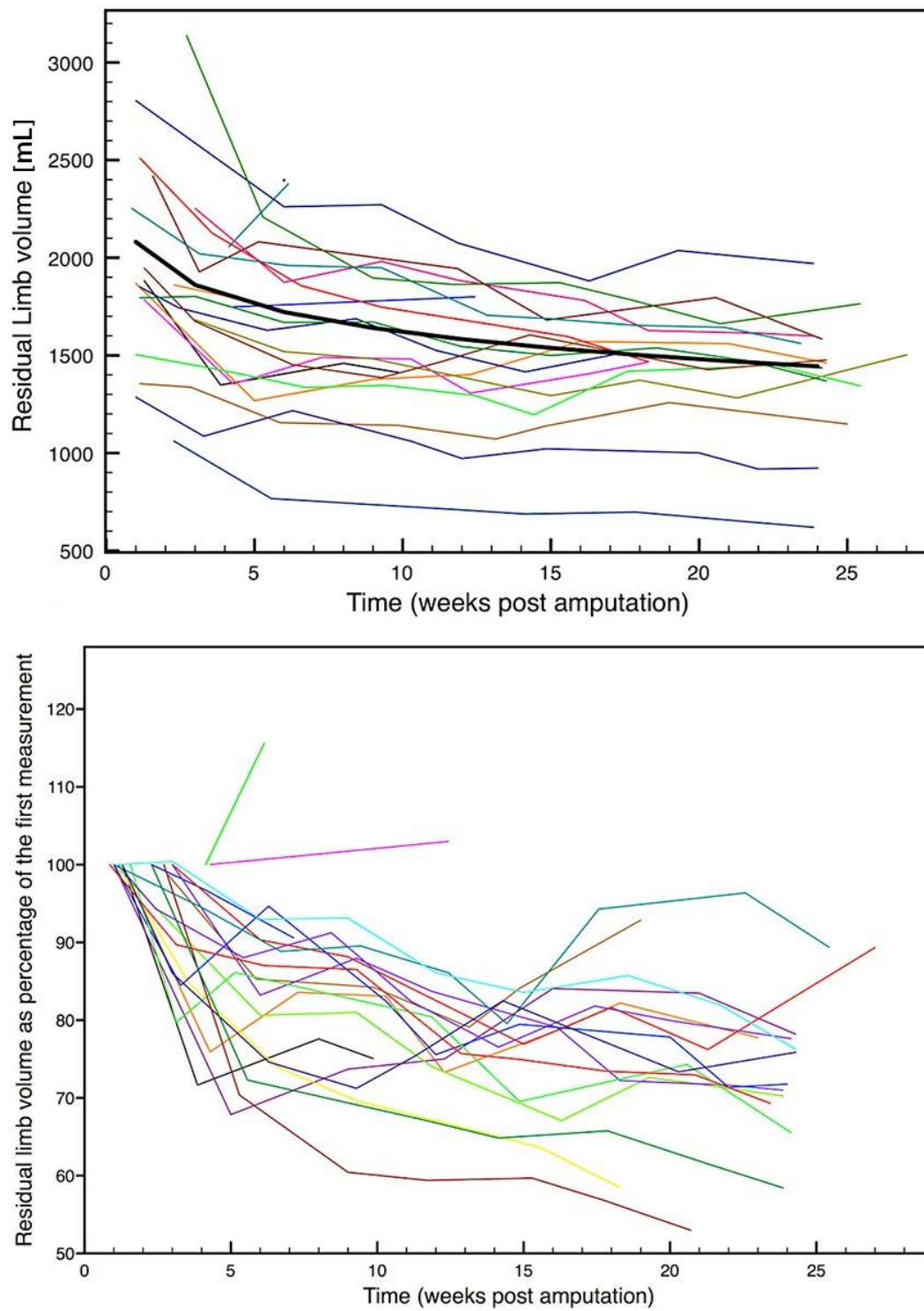
Figure 2.2 – Stump volume fluctuations over the time (Tantua et al., 2014)

Lastly, anectodal evidence indicates that both the prescription of optimal prosthetic components, and methods for functional evaluation and for the monitoring over time of the clinical conditions of the amputee patient to ensure successful rehabilitation are challenging, because there are no generally accepted clinical guidelines or standard protocols based on objective data (Zmitrewicz et al., 2006). Indeed, the proper choice is often derived from the particular clinical experience of the prosthetist and the rehabilitation team (Schaffalitzky et al., 2011).

2.3 Motor ability assessment: state of the art

In the clinical experience and scientific production, there are many studies on the assessment of the relationship among the amputee patient characteristics, the prosthesis and the environment. One of the most used indexes to describe the functional abilities of people with lower-limb amputation is certainly the Medicare Functional Classification Level (MFCL) (HCFA, 2001). The MFCL is a 5-level classification system that uses code modifiers (K-levels 0, 1, 2, 3, and 4) from the Health Care Financing Administration (Table 2.1). The patient's past medical history, current health, residual-limb status, associated medical problems, and personal motivation determines the classification levels. The MFCL has a wide range in function, from those who are bedbound (K0) to fully functioning people with amputation with the potential to participate in high-level activities (K4). The proper choice of prosthetic components and the development of a personalized rehabilitation process are strongly related to the K-level of the amputee patient, a synthetic index of his level of ability and mobility.

HCFA Modifier K Level	MFCL Description
K0	MFCL-0 Does not have the ability or potential to ambulate or transfer safety with or without assistance and prosthesis does not enhance qulity of life or mobility.
K1	MFCL-1 Has the ability or potential to use prosthesis for transfers or ambulation on level sufaces at fixed cadence. Typical of the limited and unlimited household ambulator.
K2	MFCL-2 has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulatory.
K3	MFCL-3 Has the ability or potential for ambulation with variable cadence. Typical of the community ambulatory who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
K4	MFCL-4 Has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult or athlete.

Table 2.1 – Medicare Functional Classification Level (MFCL) descriptions. HCFA = Health Care Financing Administration.

As for the functional tests, a number of outcome measures have been proposed in the field of prosthetics, but still there has not been reached a concordance among clinicians on when and which measurements to conduct. Some of these measures have proven validity and reliability, while others appear to be more critical regarding their sensitivity and repeatability (Condie et al., 2006). For these reasons, at present there is no consensus among the various rehabilitation specialists such as doctors, physiotherapists and prosthetists about the general criteria for the most proper choice of lower limb prosthesis that can respond to the needs and residual abilities of the amputee patient (Sagawa et al., 2011). Therefore, the various prosthetic modules are chosen based on the subjective empirical knowledge of the specific clinical rehabilitation team (Schaffalitzky et al., 2011). Standard measures for the assessment of the amputee's motor ability entail the self-selected walking speed (Boonstra et al., 1993; Nolan et al., 2003) and analysis the spatio-temporal parameters of the gait (Highsmith et al., 2010, Houdijk et al., 2008), functional assessments as the Six-minute walking (Lin t al., 2008) and the Timed Up & Go tests (Schoppen et al., 1999), as well as clinical and subjective approaches such as questionnaires and clininimetric scales (Rommers et al., 2001). These latter measures are simple to administer and does not require particular specialized equipment, are designed in order to evaluate the basal functional capacity, the quality of life and the general health conditions. As such, however, these can measure only limited aspects of mobility and motor ability (Rommers et al., 2001) and may thus have insufficient sensitivity to the higher levels of the function (Pasquina et al., 2006).

Mostly, gait analysis is used to assess the biomechanical and physiological aspects of gait, considered one of the most important factors for people's autonomy and self-sufficiency (Sansam et al., 2009). Gait analysis performed on amputees can have different aims: to provide an optimal adjustment of the prosthesis on the subject, the comparison between different solutions of prosthetic modules on the same subject (for example two different feet), the analysis of a new prosthetic component tested on different subjects. In addition, it can also be analyzed compensation strategies adopted by the patient to overcome the limitations of the prosthesis and the mechanical constraints, so that the

dysfunction sigs or negative secondary effects can be quickly recognized and avoided (Frigo et al., 1982; Rabuffetti et al., 1992; Frigo et al., 1994; Frittoli et al., 2009).
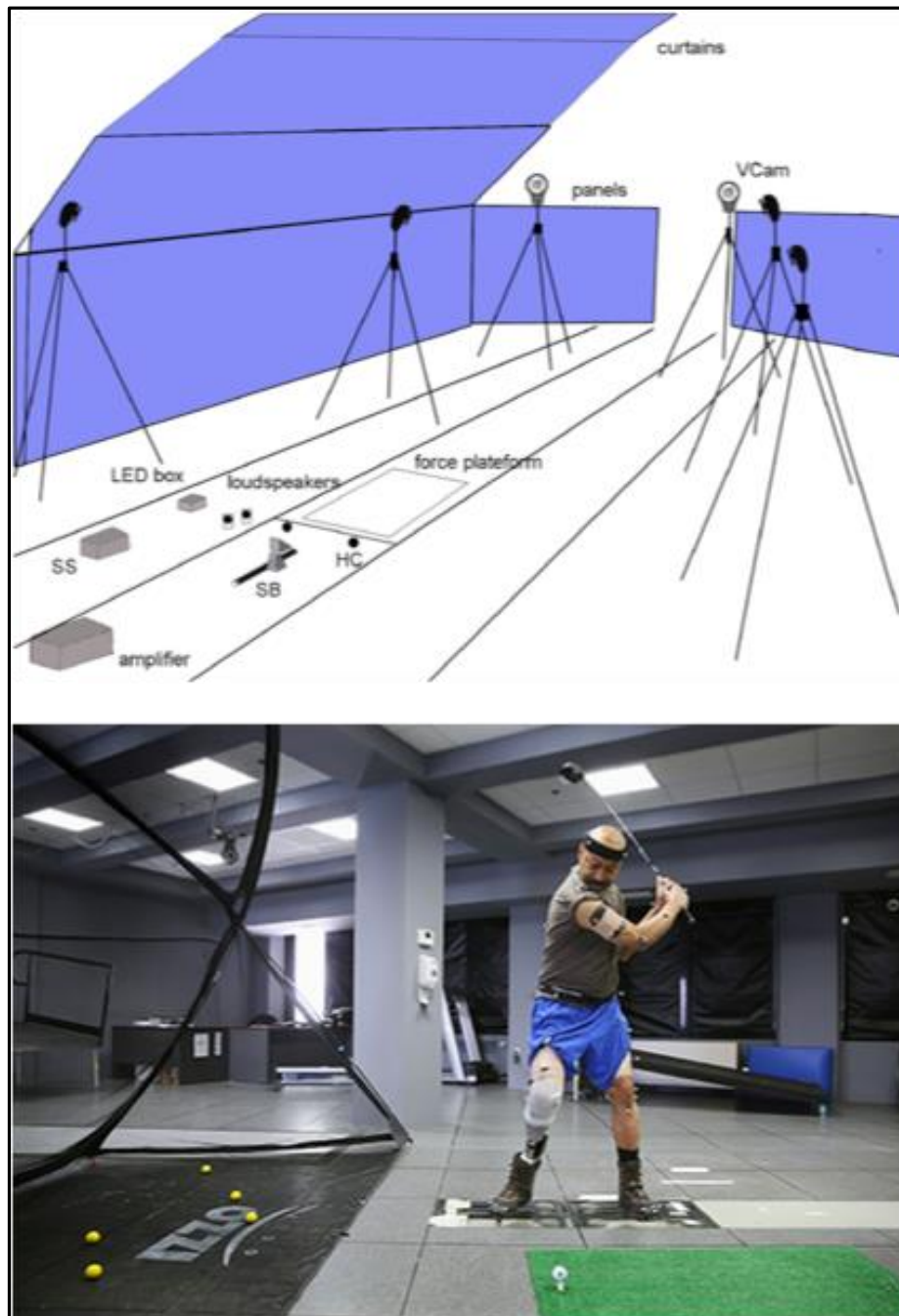
Figure 2.3 – Typical experimental setup of a motion analysis laboratory (top) and an application of the stereophotogrammetric measurements for the amputee sport gesture (bottom).

Among the dynamic and kinematic parameters most investigated in literature, emerge the self-selected walking speed, the knee joint angles and torques, the vertical component of the ground reaction force, the hip jointpower and the ankle joint angles (Sagawa et al., 2011). The prosthetic components most investigated are feet, followed by knees and, minimally, sockets.

Other parameters have been obtained from the ground reaction force and the pulse provided by the force platforms, mainly on the vertical and anteroposterior axes (Silverman et al., 2008).

These have been mainly used in studies focused on prosthetic feet as they can directly reflect the characteristics of propulsion and energy absorption. Intensity and duration of the EMG signal have been used to describe and quantify the muscle activity of the stump (Powers et al., 1998). This cannot be provided from informations of biomechanical parameters measurement, as muscle contractions are not activated to produce movement distally, but to compensate for the absence of the adjacent structures of the leg and to maintain the gait stability with the prosthesis. Additional spatio-temporal parameters may be relevant for the gait analysis on amputees, such as the stance phase duration, step lenght and width, step symmetry and frequency, ratio duration of the stance phase on entire gait cycle, etc. These parameters can be obtained with relative accuracy using a variety of tools (i.e. optoelectronic systems, inertial MEMS sensors, footswitches, etc.) and represent a global indicator of gait (Montero-Odasso et al., 2005). During the gait cycle, the stance phase on the prosthetic side is slightly shorter than the contralateral one: indeed, amputees walk with an asymmetrical gait, which may lead to future musculoskeletal degenerative changes (Van der Linden et al., 1999; Board et al., 2001). Subjects with unilateral amputation deeply entrust to their sound limb to compensate for the deficiencies associated with the disablement and the prosthesis'usage (Su et al., 2007). However, longer duration of the stance phase and an increased asimmetry may reveal development of complications on the sound limb joints (Pinzur et al., 1991). Instrumental gait analysis in amputees is currently limited to a few prosthetics and rehabilitation centers where there are available expensive motion capture laboratories. Moreover, in the laboratory the patient's gait generally may be strongly

affected by the stress imposed by operators and by the artificial environment. The magneto-inertial sensors can overcome these limitations, being a low-cost and a wearable technology, which allows measurements of significant duration also outside the lab, in daily life environment or, in the amputee's case, where he follows a rehabilitation program for restoring the gait function (Fig. 2.4). A poor body of literature reports the use of these systems and technology on amputees, but few developed protocols have been recently validated (Cutti et al., 2010).

For the lower-limb amputee patient the loss of the normal gait cycle and of mechanisms with the purpose of transform and conserve energy during locomotion entails an increase in the energy cost of walking compared to able-bodied person (Waters et al., 1999). This parameter has a significant clinical relevance, as synthetic index of the subject's ability to use the prosthesis and motor skills involved in the ambulation. The level of amputation is also one of major factor in determining the level of functional limitation of the person involved and the complexity associated with his rehabilitation (Waters et al., 1976). For example, it is well known that higher is amputation level and the greater is the energy cost of walking (ECW), and conseguently lower the self-selected walking speed (Genin et al., 2008). In literature, the physiological parameters mostly investigated for the assessment of motor ability of amputees are the oxygen consumption in absolute values V'O2 [ml/min] and in relation to the body mass V'O2 [ml/min/kg], the carbon dioxide production V'CO2 [ml/min], the respiratory exchange ratio RER, ie V'CO2/V'O2, the energy cost of walking ECW V'O2 [ml/ kg/m], and the EMG signals for the muscle activity of the stump, as mentioned above (Sagawa et al., 2011).

The diversity of the selected results, methods and tools used to describe the motor ability of the lower-limb amputees can be only explained by the different research aims considered in the related literature. This picture of diversity reveals a lack of consensus (Sagawa et al., 2011) among researchers on the important aspects of motor ability in lower-limb amputees.

Therefore, more research is needed on which parameters could provide greater information content on the motor ability assessment in this special population.

Figure 2.4 – Wearable inertial measurement systems.

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Chapter 3
AIM OF THE THESIS

The modern clinical approach to the patient with motor disorders is identified in the functional evaluation that, coherently with the most recent documents of the World Health Organization, it would be better to call "assessment of motor ability" (WHO, 2001). Indeed, the formulation of a prognostic judgment, the appropriateness of a clinical care pathway or the outcome measures of a therapy, are based on the observation of the functional limitation both at the level of the whole person (disability or skill lacking) and at the level of the single organ or apparatus (damage).

In the specific case of the lower-limb amputee patient, the evaluation can be articulated on two different levels: a first general, concerning the motor ability and quality of life as a function of that (level of independence), and a second local one, concerning the specificity of each single prosthetic module which composes the entire prosthetic chain in the relationship with the motor function of the person concerned.

The main aims of the present thesis can be summarized in:

3) Identification of parameters of evaluation sensitive to the motor ability changes in lower-limb amputee subjects;

4) Definition of experimental methodological protocols ad hoc for the functional evaluation of the subject and for the appropriateness of the single prosthetic components

The general purpose is therefore to provide fact-finding and operational tools in order to identify an accurate and reliable methodology for the motor ability assessment of prosthetized lower-limb amputees, both during gait and stereotypic locomotor tasks. This methodology is intended to constitute a valid and conventionally recognized reference for the amputee rehabilitation team, both for the functional patient assessment

and for the techinal-clinical evaluation of the prosthetic modules used. The perspective purpose is to verify the extractability of parameters particulary sensitive to the variability of clinical aspects related to the the lower-limb amputee motor ability, that can therefore be measured by a simple, low cost, wearable instrumentation, making them intelligible and useful to the clinical team and exportable in a remote supervision context.

The research activity of the present thesis has been oriented on different works, each of which presents various peculiar aspects for the identification of specific indices for the assessment of the lower-limb amputee's motor ability.

The following chapters therefore concern six different experimental studies conducted during the PhD period, characterized according to the two levels of investigation general and local suggested by WHO.

In particular, chapters 4 and 5 are concerned to the study of the upper body accelerations in lower-limb amputees through the use of inertial systems, according respectively to an approach mono- and multi-sensory, highlighting different characteristics of the general motor ability. In the fourth chapter it has emphasized that not only the level of amputation conditions the gait stability of lower-limb amputees, but also the type of utilized prosthesis. In the fifth, with the use of a multi-sensory approach, it has highlighted the motor strategy differences in able-bodied and amputee subjects, objectified through a different management of the upper body accelerations during locomotion.

Switching over to a local level of investigation, the sixth and the seventh chapters report two studies on the comparison between different prosthetic feet, depending on the mobility level of the amputee subjects provided by MCFL scale. In particular, the effects of the transition from a traditional not-articulated to a multi-axial foot were evaluated in hypomobile amputees (Chapter 6), and in those with a greater mobility level from a dynamic energy storing foot to an electronic ankle microprocessor-controlled (Chapter 7). Chapter 8 collects a study on different suspension systems, traditional urethane sealing suspension sleeve and a passive vacuum one, proposing a new experimental methodology for the measurement of the relative movement between socket and stump (Pistoning Test). In Chapter 9 it is presented a methodological protocol covering a full

data collection for the motor ability assessment of transfemoral amputees and for the clinical and technical evaluation of prosthetic socket module. All the reported studies in this thesis have provided ad hoc experimental set-up protocols, with the use of specific instrumentation for the traditional kinematic and dynamic gait analysis (stereophotogrammetry and force platforms), the accelerometry with inertial sensors, energy cost and metabolic analysis about the physiological response and the energy efficiency in stereotypical motor tasks, and the traditional clinical approach of clinimetric scales and questionnaires.

Finally, general conclusions and some directions for future researches are drafted in Chapter 10.

Chapter 4

ASSESSMENT OF GAIT STABILITY, HARMONY, AND SYMMETRY IN LOWER LIMB AMPUTEES EVALUATED BY TRUNK ACCELERATIONS

4.1 Introduction

Walking with a lower-limb prosthesis is a challenging task because missing a part of a limb alters the motor system, sensory feedback (Lamoth et al., 2010), and locomotor body schema (Ivanenko et al., 2011). This commonly implies slower and less efficient walking in subjects with amputation than in healthy subjects (HSs) (Jaegers et al., 1993; Vitan et al., 2010). Thus, walking speed (WS) and oxygen consumption have been widely used as indicators of gait ability and to assess rehabilitation outcomes or prosthetic components (Chin et al., 2002; Delussu et al., 2013, Wezenberg et al., 2012; Mohanty et al., 2012). Conversely, little attention has been given to upright gait stability in the population with amputation (Lamoth et al., 2010; Vitan et al., 2010; Tura et al., 2010) and even less to gait harmony.

Upright gait stability has been defined as the capacity to minimize upper-body oscillations and absorb jerks, bumps, shakes, and fluctuations, despite the broad and fast movements of the lower limbs during locomotion (Cappozzo et al., 1982; Iosa et al., 2013). Hence, an upright gait is stable when upper-body accelerations are minimized and smoothed, whereas a distribution of accelerations in accordance with natural step-by-step repetition and bilateral evenness are signs of harmonic and symmetrical gait, respectively (Iosa et al., 2012). In the literature, the expression "gait stability" has been used with reference to the ability to walk with smoothed upper-body accelerations (Menz et al., 2003), as well as stride-to-stride kinematic variability (Dingwell et al., 2006)

and local dynamic stability related to the ability of the locomotor system to maintain continuous motion by accommodating natural, infinitesimally small perturbations (Terrier et al., 2011). Although mathematically and conceptually different, all of these parameters have been found related to balance and risk of falling (Dingwell et al., 2006, Toebes et al., 2012; Senden et al., 2012).

A large and growing body of literature has reported the successful use of accelerometers to investigate these gait features. In this study, gait stability was considered as the ability to walk by smoothing upper-body accelerations (Menz et al., 2003), in accordance with many previous studies in HSs (Kavanagh et al., 2004; Mazzà et al., 2008; Mazzà et al., 2009; Mazzà et al., 2010; Marigold et al., 2008), patients with stroke (Mizuike et al., 2009; Iosa et al., 2012), children with cerebral palsy (Iosa et al., 2013; Iosa et al., 2012), and people with lower-back pain (Lamoth et al., 2002) and cognitive impairments (Lamoth et al., 2011). In people with amputation, upper-body accelerations during walking were investigated in three recent studies.

Tura et al. compared the upper-body accelerations of 10 subjects with transfemoral amputation (TFA) with those of 10 healthy controls during walking at low, natural, and fast speeds (Tura et al., 2010). They found that a triaxial accelerometer (placed on the thorax at the xiphoid process) was adequate to assess gait features. They assessed symmetry and regularity of walking (using the autocorrelation coefficient of acceleration signals along the anteroposterior [AP] and craniocaudal [CC] axes, respectively), but not upright stability, as defined previously, or harmony of gait. In a more recent article, Tura et al. refined their analyses and identified the minimum number of strides (between 2 and 4) for a reliable computation of step symmetry based on accelerometric data (Tura et al., 2012).

Lamoth et al. not only focused their study on gait variability but also on upright gait stability in eight subjects with TFA compared with eight HSs during inside walking on smooth terrain, walking while performing a dual-task, and outside walking on even and uneven terrain (Lamoth et al., 2010). Data were collected using a triaxial wearable accelerometer fixed with an elastic belt close to the center of mass at the level of lumbar (L) segment 3.

These studies analyzed the walking of subjects with TFA by including subjects who had generally used prosthesis for many years and were able to walk without aids (Lamoth et al., 2010; Tura et al., 2010). It is conceivable that these subjects had already internalized into their locomotor body schema the mechanical characteristics of the prosthesis and the sensory feedback it provides at the residual limb level and had developed efficient locomotor patterns as demonstrated by their WS higher than 1 m/s. Stability, harmony, and symmetry are conceivably more impaired in people with amputation after a rehabilitation period using a new prosthesis. Indeed, it can increase their risk of falling and reduce fluidity of movements (Miller et al., 2001).

The aim of the present study was to assess upright gait stability, harmony, and symmetry in subjects with lower-limb amputation upon dismissal from a rehabilitative hospital after receipt of prosthesis compared with a control group consisting of age-matched HSs. The parameters of these gait features were obtained by measuring upper-body accelerations in different types of amputation: subjects with transtibial amputation (TTA) and subjects with TFA who walked with an unlocked knee (UK) or locked knee (LK) prosthesis. Then, to identify which parameter was directly related to severity of the impairment, the correlation between the accelerometric parameters and clinical score obtained by the subject after rehabilitation for level of independence was assessed.

4.2 Methods

4.2.1 Participants

Forty-four subjects were enrolled in this study: 22 with lower-limb amputation but no musculoskeletal or neurological comoborbities affecting gait not directly related to the amputation and 22 age-matched control HSs with no impairments. The amputation group included 14 subjects with TFA, 7 with an LK prosthesis (TFA-LK) and 7 with a UK prosthesis (TFA -UK), and 8 subjects with TTA. All were admitted to our rehabilitation hospital for a mean period of about 62 days, with a mean of 45 days of prosthesis use. Receipt of prosthesis (for the first time or for a change of prosthesis)

occurred on average 17 days after admission. Patients were assessed on 1 of the 3 days before dismissal from our rehabilitation hospital. The four groups of subjects (TFA-LK, TFA-UK, TTA, HS) were not statistically different in terms of age (analysis of variance [ANOVA]: F = 0.562, p = 0.64). Table 1 reports demographic and clinical data. The severity of impairment related to amputation was assessed in terms of the Barthel Index (BI); this is a clinical scale that evaluates independence in activities of daily living, ranging from 0 (completely dependent) to 100 (completely independent) (Mahoney et al., 1965).

Parameters	TFA-LK	TFA-UK	TTA	HS
No. of Subjects	7	7	8	22
Age yr (mean $\pm$ SD)	65.0 $\pm$ 5.8	58.1 $\pm$ 15.4	56.9 $\pm$5.3	59.2 $\pm$ 15.2
Sex (n)				
Female	3	3	1	10
Male	4	4	7	12
Barthel Index Score (mean $\pm$ SD)	87 $\pm$ 8	95 $\pm$ 7	99 $\pm$ 1	100 $\pm$ 0
Side of Amputation (n)				
Left	6	7	2	---
Right	1	0	6	
Cause of Amputation (n)				
Vascular Disease	4	3	5	---
Ischemic Event	2	---	---	---
Trauma	1	4	3	
Subjects Using Aids for Walking, n (%)	5 (71.4)	3 (42.9)	1 (12.5)	0 (0)
Aids Used (n)				
2 Crutches	4	3	1	---
2 Tetrapods	1	---	---	---
No Aids	2	4	7	22

Table 4.1 – Demographic and clinical features of four groups of enrolled subjects. SD = standard deviation, TFA-LK = subject with tranfemoral amputation with prosthesis with locked knee, TFA-UK = subject with transfemoral amputation with prosthesis with unlocked knee, TTA = subject with transtibial amputation, HS = healty subject.

4.2.2 Protocol

The last 3 days before dismissal from our hospital, subjects performed the following assessment protocol: they performed the 10 m walking test commonly used in clinical settings (Bohannon, 1992); then, they stood on a line marked on the floor and walked straight for 10 m at a self-selected speed until they arrived at another line on the floor in a 15 m-long rehabilitation gym. During the test, they wore an elastic belt with a wearable inertial sensor device (FreeSense, Sensorize; Rome, Italy [sampling frequency = 100 Hz, weight = 93 g]) containing a triaxial accelerometer to measure accelerations along the three body axes (AP, laterolateral [LL], and CC) and three gyroscopes to measure angular velocities around the axes. Similar to Lamoth et al., the device was located on an area of the back corresponding to the L2–L3 spinous processes, close to the body center of mass (Lamoth et al., 2010). During the test, subjects wore their commonly used shoes and subjects with amputation wore their prosthesis and used walking aids, if needed.

The time and number of steps needed to walk the 10 m were determined from the recorded peaks of AP acceleration (Iosa et al., 2013; Iosa et al., 2012). In fact, foot strikes (which defined the beginning and the end of each step) were identified, in agreement with previous studies (Iosa et al., 2012; Iosa et al. 2012), as the moment at which peak of AP acceleration occurred. Mean WS was computed as 10 m divided by the time spent to complete the test. Acceleration data of eight consecutive steps (four strides) performed in the central part of the walking pathway were analyzed. This approach has already been used and described in detail in previous studies in different populations of subjects (Iosa et al., 2012; Iosa et al. 2012) and is in agreement with Tura et al.'s observation that when initial and final strides are excluded from the analysis, the minimum number of strides needed for reliable computation of step symmetry and stride regularity is about 2.2 and 3.5 strides, respectively, in subjects with amputation (Tura et al., 2012). These signals were analyzed after their mean values were subtracted and after low-pass filtering at 20 Hz (Iosa et al., 2012; Mazzà et al., 2008; Zijlstra et al., 2003).

Figure 4.1 – The FreeSense (Sensorize) inertial system. This unit contains a 3-axial accelerometer (± 6g), a 3-axial gyroscope (± 500 deg/s), and a GPS module along with a wireless transmission module for sending data to a computer station and a memory card to store alternatively all data on board (sampling frequency = 100 Hz, weight = 93 g).

The following parameters were averaged for the four values of the four consecutive strides:

1. Root-mean-square (RMS) of acceleration, i.e., a measure of acceleration dispersion that coincides with the standard deviation because of signal mean subtraction (Menz et al., 2003).

$$RMS = \sqrt{\frac{\sum_{i}^{n} a_i^2}{n}}$$

Equation 4.1 – Root Mean Square (RMS) computed with acceleration signals (a_i with $i = 1 \ldots n$).

2. Harmonic ratio (HR), i.e., the ratio between the sum of the amplitudes of the two main even harmonics and the sum of the amplitudes of the two main odd harmonics for the AP and CC axes or the reverse (odd/even) for the LL axis calculated via the discrete Fourier transform, which is an indicator of the rhythmicity between acceleration patterns

and step repetition, with higher values corresponding to more harmonic gait (Menz et al., 2003; Figure 4.2).
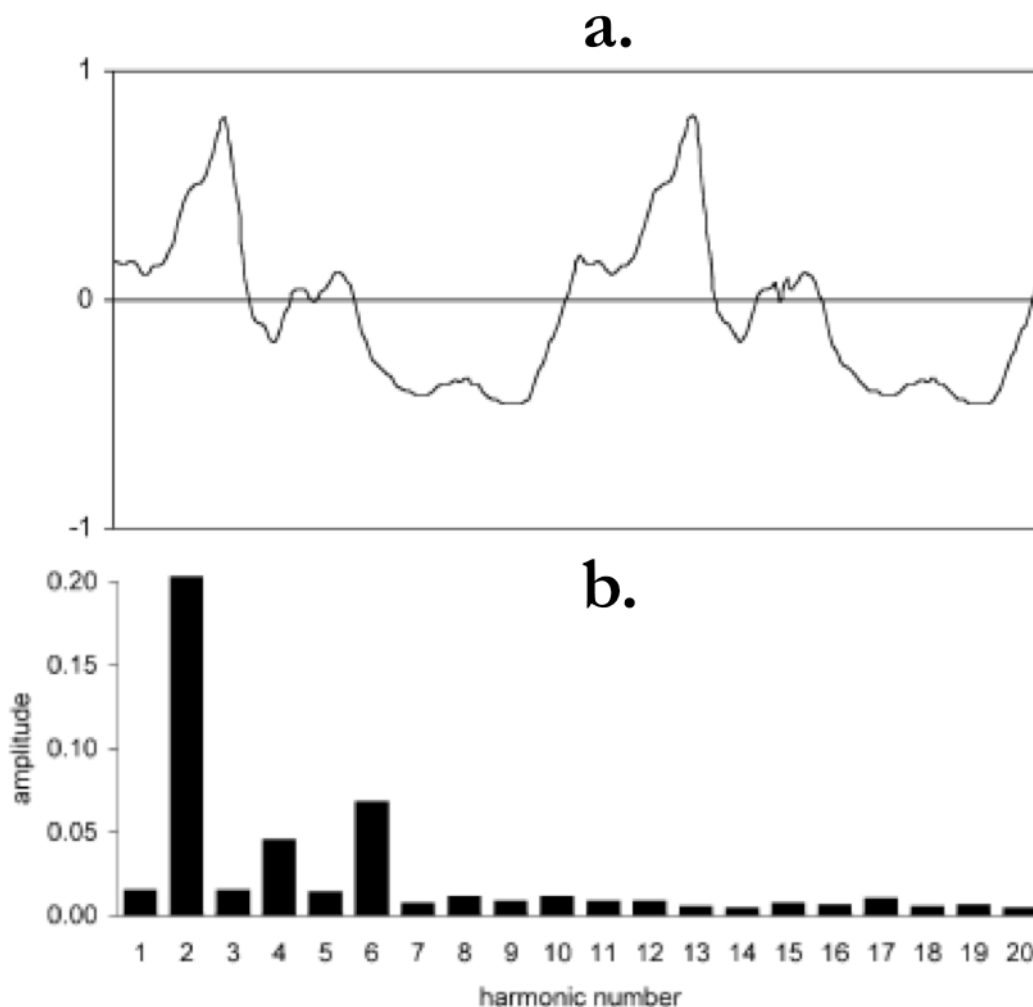
Figure 4.2 – Determination of the Harmonic Ratio. a. Vertical acceleration at the pelvis over the course of two steps (one stride). b. Amplitudes of the first twenty harmonics. Σ even harmonics = 0.37; Σ odd harmonics = 0.09; Harmonic Ratio = Σ even harmonics / Σ odd harmonics = 3.9.

3. Symmetry ratio index (SRI), i.e., the ratio between two consecutive minima of accelerations within each stride (a_{min}), corresponding to the accelerations at foot strikes. This is a measure of the steep decelerations affecting the conservation of momentum. SRI was computed as the percentage ratio between two consecutive amin relevant to two consecutive steps, each one performed by one leg (i.e., the ratio was computed between the lower a_{min} and the higher a_{min} absolute values). It provided values lower than

100 %or equal to 100 % (if the two consecutive steps had two equal values of a_{min}), representing an indicator of asymmetries in decelerations (Iosa et al., 2012; Seliktar et al., 1986).
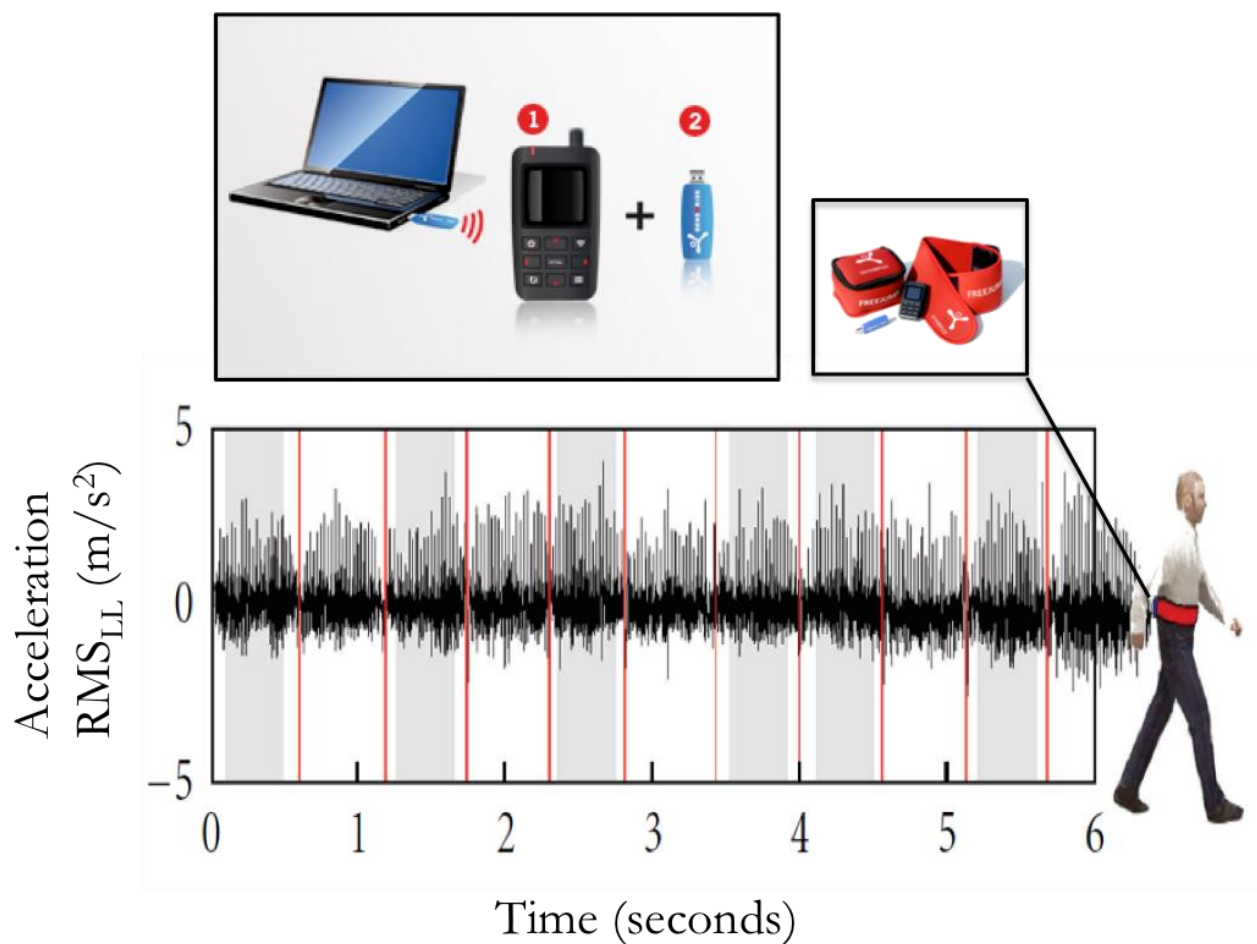
Figure 4.3 – Example of the acceleration signal along laterolateral direction of a patient enrolled, wearing an elastic belt at the pelvis level with the Freesense on board. Data recorded are trasmitted to a PC station by means of wireless trasmission.

Because the RMS of acceleration is strictly dependent on WS, the values of RMS-AP and RMS-LL were normalized with respect to those of RMS-CC by using the inverse of their percentage ratio as an indicator of stability. This approach was shown to be suitable for the analysis of trunk accelerations of patients with stroke (Iosa et al., 2012) based on the observation that CC accelerations were the least interesting from a locomotor control point of view (Iosa et al., 2010). In fact, Lamoth et al. also focused their study on AP and LL accelerations (Lamoth et al., 2010). In detail, because RMS-AP/ RMS-CC and RMS-LL/RMS-CC are two normalized parameters related to instabilities (Iosa et al., 2012), their inverses were used to quantitatively assess stability:

$$AP\_axis = \frac{RMS_{CC}}{RMS_{AP}} \cdot 100$$

$$LL\_axis = \frac{RMS_{CC}}{RMS_{LL}} \cdot 100$$

Equations 4.2 – Normalization of RMS$_{AP}$ and RMS$_{LL}$ with respect of those of RMS$_{CC}$.

Because it is conceivable that upright gait stability might be affected by alterations in prosthesis alignment, as is the case for postural standing stability (Kolarova et al., 2013), all prostheses were aligned by two highly experienced prosthetic technicians using L.A.S.A.R. Posture (Otto Bock Health-Care GmbH; Duderstadt, Germany), a system for the static alignment of prostheses that consists of a force-sensing platform and a projection system with laser and line optics.
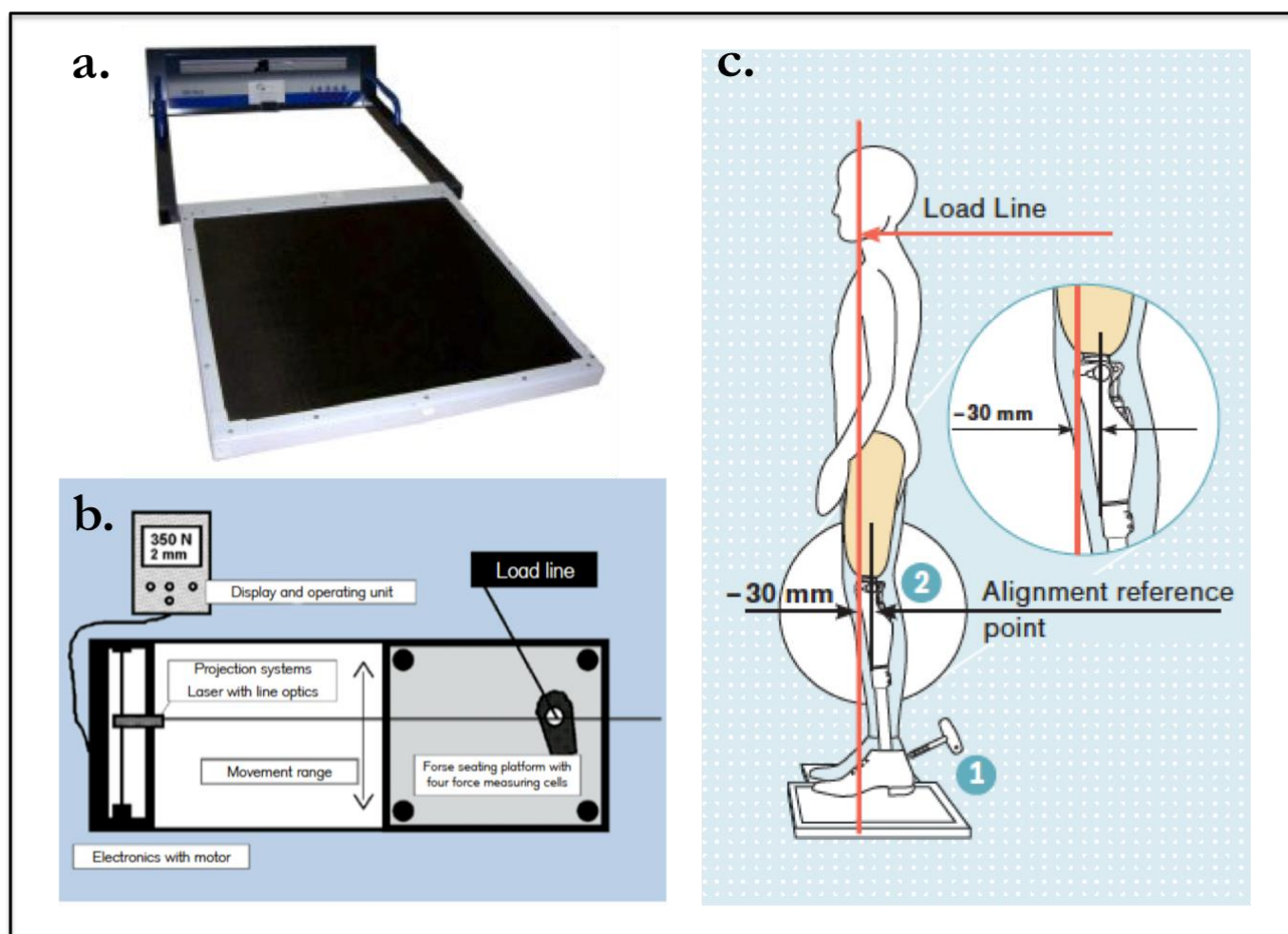
Figure 4.4 – a. The L.A.S.A.R. Posture system (Ottobock), is used to optimize the static alignment or to verificate the body posture during trial fit; **b.** L.A.S.A.R. consists in a force sensing platform with four integrated force measuring cells, a projection system with laser and line optins, a position system with electron ics and step motor, an operating and display unit and a leveling plate; **c.** Static knee alignment with L.A.S.A.R. example.

4.2.3 Statistical Analysis

ANOVA was performed to assess differences in terms of age or comfortable WS in the four groups of subjects. Repeated-measures ANOVA (RM-ANOVA) was performed on acceleration RMS, normalized RMS, HR, and SRI to analyze the main effect of group as a between-subject factor among the four groups, axis as a within-subject factor, and the effect of the interaction between group and axis. To take into account the possible effect of speed on the parameters extracted by acceleration signals, a similar RM-ANOVA was

also performed including WS as a possible covariate variable (Brach et al., 2011). Spearman correlation coefficient (r) was computed between the BI score and each accelerometric computed parameter.

The threshold of significance was set at 0.05 for all analyses with the exception of post hoc comparisons, for which Bonferroni correction was applied on this threshold.

4.3 Results

WS was found to be significantly lower in subjects with amputation than in HSs, especially for TFA-LK subjects (Table 4.2). Post hoc comparisons revealed that all three amputation groups walked significantly slower ($p < 0.001$) than HSs. All comparisons among amputation groups were statistically significant ($p < 0.009$), except for between TFA-UK and TTA subjects ($p = 0.69$).

Because of these differences in speed, accelerations also resulted in significant differences among groups (Figure 4.5). When accelerations were normalized to take into account their strict relationship with velocity, LL and AP stability were found to be lower in subjects with amputation than in HSs. Post hoc comparisons revealed higher instability in TFA-LK subjects along the CC and AP axes with respect to TFA-UK subjects ($p = 0.01$ and $p = 0.02$, respectively) and along the CC axis with respect to TTA subjects ($p = 0.01$). No statistically significant differences were noted in amputation subgroups along the LL axis. The main factor group affected stability as well as its interaction with axis, indicating that LL stability was more affected in subjects with amputation than AP stability.

Feature	Parameter	TFA-LK	TFA-UK	TTA	HS	Factors	F	p	ES
Ability	WS	0.35±0.19	0.62±0.14	0.72±0.24	1.08±0.17	Group	34.073	<0.001	0.719
Stability	RMS-CC	0.73±0.25	1.31±0.36	1.29±0.52	2.17±0.67	Group	8.273	<0.001	0.383
	RMS-LL	0.92±0.43	1.28±0.28	1.15±0.31	1.09±0.35	Axis	10.489	<0.001	0.208
	RMS-AP	0.75±0.18	1.27±0.35	1.18±0.45	1.46±0.30	Group*Axis	17.496	<0.001	0.567
	CC/LL	86.6±29.5	102.5±19.2	109.1±19.6	204.1±48.1	Group	34.353	<0.001	0.720
	CC/AP	95.6±17.0	103.7±11.9	110.2±17.1	146.9±25.5	Axis	3.147	0.084	0.073
						Group*Axis	9.318	<0.001	0.411
Harmony	HR-CC	1.42±0.69	1.52±0.63	2.73±0.99	9.00±3.38	Group	72.620	<0.001	0.845
	HR-LL	1.94±0.61	1.78±0.75	1.54±0.40	3.09±0.73	Axis	7.735	0.001	0.162
	HR-AP	0.73±0.38	0.89±0.21	1.98±1.17	7.59±2.13	Group*Axis	13.074	<0.001	0.495
Symmetry	SRI-CC	67.9±18.7	64.3±22.9	71.2±12.7	83.5±7.2	Group	12.028	<0.001	0.474
	SRI-LL	53.3±16.1	63.7±18.4	66.7±14.9	70.3±13.4	Axis	4.627	0.013	0.104
	SRI-AP	60.6±17.2	75.5±15.2	70.8±12.2	82.43±7.2	Group*Axis	0.897	0.502	0.063

Table 4.2 - Features of gait for the four group of subjects. Mean ± standard deviations for the computed values are reported. Results of Anova for walking speed (WS) and Repeated Measure Anova for transfemoral amputees with locked knee (TFA-LK), unlocked knee (TFA-UK) and transtibial amputees (TTA) in terms of F-value, p-value and effect size (ES, in terms of partial eta squared) are reported in the last columns.

Significant differences were found among groups and among axes for harmony, which was also affected by the interaction of these two factors. Post hoc comparisons revealed that subjects with amputation had lower harmony than HSs (p < 0.001) along all three axes. Specific differences among amputation subgroups were found along the AP axis between TFA-LK and TTA subjects (p = 0.02) and along the CC axis between TFA-LK and TTA subjects (p = 0.01) and TFA-UK and TTA subjects (p = 0.02).

It should be noted that the general trend highlighted in the Figure for WS, RMS, normalized RMS, and HR following the order of impairment of TFA-LK, TFA-UK, and TTA subjects and HSs was not strictly respected by RMS-LL and especially not by HR-LL. This was mainly due to two subjects with TTA whose WS was >1 m/s (mean: 1.07 m/s vs 0.61 m/s in other TTA subjects) but whose mean HR-LL was lower than that of the other subjects (1.16 vs 1.67), despite higher HR-AP (3.51 vs 1.46) and SRI-LL (80.6% vs 62.1%).

Symmetry was significantly different among groups and axes but did not depend on the interaction group × axis. Post hoc comparisons revealed that only TFA-LK subjects differed significantly from HSs along all three axes (AP: p < 0.001, LL: p = 0.01, CC: p = 0.01). TFA-UK subjects differed significantly from HSs only along CC (p = 0.01), and TTA subjects differed from HSs along CC (p = 0.01) and AP (p = 0.01) axes.

As reported in Table 4.2, the values of effect size for normalized RMS, HR, and SRI were higher for the factor group (about 0.7, 0.8, and 0.5, respectively) than for axis or interaction between group and axis.

According to the approach suggested by Branch et al., analyses similar to those reported in Table 2 were also performed, with WS as a covariate variable (Brach et al., 2011). With respect to the results reported in Table 4.2, the factor group continued to have a statistically significant effect on RMS (p < 0.001), normalized RMS (p = 0.01), and HR (p < 0.001) but not on SRI (p = 0.24). Furthermore, the interaction group × axis remained statistically signifi-cant for HR when WS was used as a covariate in the analyses.

Finally, the parameter values of the entire amputation group were found to be significantly correlated with BI score. Statistically significant correlations were found for

WS (r = 0.676, p = 0.01) and RMS-CC (r = 0.457, p = 0.03), and correlations close to statistical significance were also found for RMS-LL (r = 0.372, p = 0.09) and RMS-AP (r = 0.385, p = 0.08). This was mainly due to the relationship between RMS and WS and, as expected, confirmed by the strict relationship between RMS- CC and WS (r = 0.951, p < 0.001), which also supported its use in normalizing RMS-AP and RMS-LL. The BI score was also found to be significantly correlated with the sagittal harmony of walking HR-CC (r = 0.661, p = 0.01) and HR-AP (r = 0.604, p = 0.01).

4.4 Discussion

Results showed greater instability and asymmetry in subjects with amputation than in HSs during walking. Similar to previous studies (Lamoth et al., 2010, Tura et al., 2010), a triaxial accel-erometer was used to detect instability and asymmetry as well as loss of harmony. But differently from those studies, subjects with amputation were divided into three groups according to level of amputation and type of prosthesis. For most of the parameters investigated, a clear and significant trend related to the impairment (Figure 4.5) was found. In fact, the lowest values of stability, harmony, and symmetry in walking were found for subjects with TFA who walked using a prosthesis with an LK compared with those who walked with a UK. The values computed for subjects with TTA were closer to physiological ones. The latter values, collected in a sample of HSs (age-matched with enrolled subjects with amputation), were in line with those already reported in the literature (Lamoth et al., 2010; Iosa et al., 2012).

Regarding trunk accelerations, important difference with respect to previous results was found: in the present sample of subjects with amputation, trunk accelerations were lower than those of HSs; by contrast, Lamoth et al. found the reverse (Lamoth et al., 2010). As already reported (Iosa et al., 2012), trunk accelerations are strictly connected to speed and an increase in upper-body accelerations could be due to unsteady speed related to pathological instabilities as well as to an increase in WS related to better locomotor ability. In Lamoth et al. (Lamoth et al., 2010), the difference in speed between HSs and subjects with amputation during indoor level walking was only about 10 percent, which

allowed for a direct comparison of accelerations. At similar velocities, higher trunk accelerations are a sign of instability. In the present study, the difference in speeds was between 34% for TTA subjects and 68 percent for TFA-LK subjects with respect to HSs, implying the need to normalize accelerations. In fact, unlike subjects in previous studies (Lamoth et al., 2010; Tura et al., 2010), 20 out of 22 subjects with amputation enrolled for the present study walked at a speed lower than 1 m/s. There were two main reasons for this: the present sample included subjects with amputation being dismissed from a rehabilitative hospital after delivery of a first or a new prosthesis and they were 10 to 20 years older than those enrolled in the studies cited previously. On the other hand, control subjects enrolled were also older than those enrolled in previous studies (Lamoth et al., 2010; Tura et al., 2010, Tura et al., 2012) because they were age-matched with the present sample of subjects with amputation. Nevertheless, in subjects with amputation, older age has been shown to be a negative prognostic factor affecting walking recovery after amputation (Brunelli et al., 2006); indeed, it is probably stronger than the effect of aging on walking stability in HSs. It has also been suggested that reduced speed in severely impaired subjects may be a motor strategy to increase gait stability (Iosa et al., 2012). In fact, it was found that in subjects with amputation, the self-selected comfortable WS was lower than the most efficient one (whereas in HSs the two speeds coincided) (Jaegers et al., 1993). It is conceivable that subjects with amputation prefer slow walking to increase stability and not to optimize gait efficiency. This is supported by the fact that the only two subjects with amputation who walked faster than 1 m/s showed low harmony of gait along the LL axis. Less severely affected subjects with TTA probably use a compensation strategy to increase the speed and functionality of AP movements, based on LL compensation, indicating loss of stability and harmony. This could be why higher accelerations were found along the LL axis for TFA-UK and TTA subjects than HSs: the higher locomotor ability of TTA subjects (walking without aids and faster than TFA subjects) contributed to the LL harmony of walking. On the other hand, Lamoth et al. found that LL stability was most affected when the task difficulty was progressively increased, such as during walking on uneven terrain (Lamoth et al., 2010). The trend among groups was found for parameters evaluated along the AP

and CC axes, i.e., on the sagittal plane, but this trend, as well as correlation with the BI clinical score, was lost on the LL axis. This suggests that the LL accelerations of subjects with amputation do not depend directly on level of amputation, type of prosthesis, or clinical impairment (BI score). HSs are able to self-selected a speed that optimizes efficiency, comfort (Jaegers et al., 1993), and harmony (Menz et al. 2003) of walking. Probably at the end of the rehabilitation program, subjects with amputation should choose a speed and try to optimize one or more compensate for the effects of speed, significant reduction was found for stability along the AP and LL axes, especially the latter, with respect to HSs. Thus, only after that normalization did a result similar to the one reported by Lamoth et al. for TFA subjects was found (Lamoth et al., 2010), i.e., a larger difference between subjects with amputation and controls in LL trunk accelerations than in AP trunk accelerations.

Furthermore, with respect to previous studies, this study also analyzed harmony of walking in subjects with amputation. Two recent studies have highlighted the importance of this feature of gait. A low value of the HR of trunk acceleration has been highlighted as a prognostic factor for the risk of falling in the elderly (Doi et al., 2013). Moreover, harmony has recently been shown to be a fundamental feature of physiological human gait, with specific iterative proportions among repetitive gait phases related to the so-called golden ratio (Iosa et al., 2013).

Results showed very low values of HR for sub-jects with amputation: they were up to 90 percent lower than those of HSs for subjects with TFA walking with an LK prosthesis in the AP direction. These values were even lower than those observed in patients with stroke at dismissal from a rehabilitation hospital (Iosa et al., 2012) and in children with cerebral palsy (iosa et al., 2012). The biomechanical and sensory asymmetric changes that occur in subjects with amputation seemed to affect harmony of gait even more than neurological disorders. Conversely, stability (in terms of normalized RMS) was more impaired in the population with stroke (Iosa et al., 2012) than in the present sample of subjects with amputation. If there is a direct relationship between RMS and WS and increasing or decreasing gait velocity results in a corresponding increase or decrease in

acceleration amplitude (Iosa et al., 2012), the relationship between HR and speed seems more complicated.

Indeed, as shown by Menz et al., HR peaks at self-selected speeds and decreases at both slower and faster speeds (Menz et al., 2003). This feature suggests changes in the spectrum content of acceleration signals at different speeds (Brach et al., 2011), probably involving aspects more related to motor control. Although all subjects involved in the present study were asked to walk at their self-selected comfortable speed, analysis was repeated on the HR also using WS as a covariate variable. The main results did not change and that HR values remained statistically different among groups. Two cases of subjects with TTA walking fast with a high HR-AP, but with a low HR-LL, confirmed that the dependence of HR on WS was not strictly linear (like that of RMS). In any case, further studies are needed to clarify the role of speed on the spectrum content of upper-body accelerations.

In terms of gait symmetry, despite the different parameters used to compute the symmetry index, in subjects with TFA symmetry values between 50% and 75% were found and in HSs between 70% and 85%, thus not far from those found by Tura et al. (Tura et al., 2010), which were between 40% and 60% for subjects with amputation and 80% and 90% for HSs. A general trend from TFA-LK to TFA-UK to TTA subjects was found also for symmetry. However, AP symmetry was signifi-cantly different from that of HSs in TTA subjects but not in TFA-UK subjects. Again, subjects with TTA are probably able to walk faster, but lose in terms of symmetry and harmony of gait. Furthermore, TFA-UK subjects probably need to adopt a locomotor strategy to exploit the inertia of the prosthesis along the progressive direction, hence favoring AP symmetry despite a slight reduction in CC symmetry. Once these analyses were adjusted for WS, the main group effect on SRI lost statistical significance. There may be two reasons for this. The first was methodological and related to the choice to assess SRI as the ratio between two consecutive minima of acceleration signals, which are strictly linked to and affected by WS; thus, when the WS effect was removed, the SRI values were more similar among groups. The second is more general: most impaired subjects

with amputation usually have asymmetric and slow gait; thus, considering speed as a covariate variable may reduce the effect of impairment on asymmetry.

Although symmetry was conceptually linked to harmony of gait, some differences were observed in terms of group effects between these two parameters. Perhaps this was because in the present study, symmetry was evaluated by comparing the accelerations of the two limbs at foot strikes, whereas harmony took into account the accelerometric signal along the entire gait cycle. Moreover, the higher differences were noted along the LL axis. As reported previously, symmetry was evaluated using a step-by-step comparison (such as harmony) in the AP and CC axes, whereas in the LL axis, harmony was more related to stride cycle (Menz et al., 2003; Mazzà et al., 2008).

The present study has some limits. A larger sample of subjects was enrolled with amputation with respect to previous studies investigating trunk accelerations during walking (N = 10 in Tura et al. 2010, N = 8 in Lamoth et al., 2010), but the division into three subgroups meant that there were only seven or eight subjects in each subgroup. This small subgroup size prevented us from further classifying sub-jects according to age, reason for amputation, or time since amputation (e.g., Hermodsson et al. demonstrated that postural standing sway was markedly different in patients with amputation of traumatic origin vs vascular origin (Hermodsson et al., 1994) and that some gait features were different depending on the cause of amputation (Hermodsson et al., 1994).
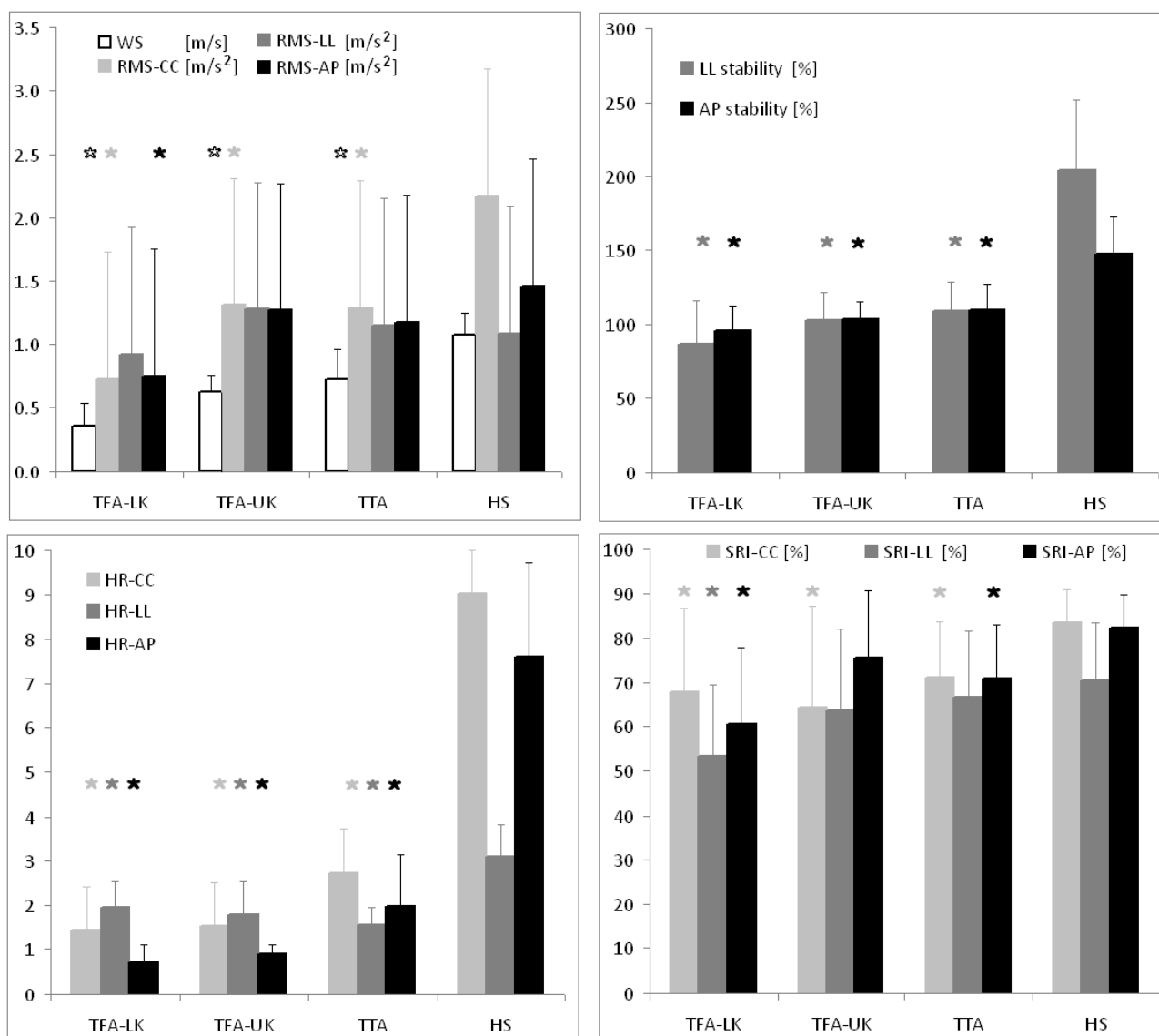
Figure 4.5 - Biomechanical gait features for four groups of subjects. **(a)** Mean ± standard deviation of walking speed (WS) and acceleration root- mean-square (RMS), **(b)** normalized RMS, **(c)** harmonic ratios (HRs), and **(d)** symmetry ratio index (SRI) of gait patterns along craniocaudal (CC), laterolateral (LL), and anteroposterior (AP) directions for subjects with transfemoral amputation with locked knee (TFA-LK), subjects with transfemoral amputation with unlocked knee (TFA-UK), subjects with transtibial amputation (TTA), and healthy subjects (HSs). *Indicates statistically significant difference for each parameter assessed between amputation group and HSs highlighted by post hoc comparisons.

Furthermore, the possible stabilizing effect of using crutches or tetrapods did not assessed, which could have influenced the results. For example, it has been shown that using supports has positive effects on WS and gait symmetry in patients with stroke (Beauchamp et al., 2009; Hesse et al., 1998). This aspect has not been investigated in subjects with amputation, but in the present study the only subject in the TFA-LK group who walked without aids showed higher stability in the AP direction (115.9% vs 92.2% for other subjects in the same group), but he also showed reduced stability in the LL direction (74.4% vs 88.6%). Conversely, only one of the subjects with TTA used crutches and his values of RMS and HR in the LL direction were close to those of other subjects with TTA. Obviously, the clinical decision process took into account observational assessment of subject stability, which generated a confounding factor between stabilization due to crutches and better internal control. The risk of falling was much too high in the present sample to ask subjects who needed crutches to walk without them, and this prevented us from designing a test-retest study with and without aids.

Another limit was that different prosthetic components were allowed in this study: they were differentiated only between subjects with TFA using prostheses with LKs and UKs. Nevertheless, the present study is the first one on upper-body acceleration during walking in subjects with amputation upon dismissal from a rehabilitation hospital including TTA and TFA subjects and dividing subjects according to type of prosthesis used (i.e., UK or LK).

4.5 Conclusion

With respect to previous studies investigating upper-body stability during gait in younger and long-time prosthesis users, lower stability, harmony, and symmetry in a sample of subjects with amputation upon dismissal from a rehabilitation hospital were found. A clear trend depending on level of amputation and type of prosthesis for the stability, harmony, and symmetry evaluated on the sagittal plane was also identified. Accelerations in the L direction seemed more related to motor control than biomechanical issues.

Rehabilitators should train subjects with amputation to progressively optimize gait features such as stability, efficiency, and functioning by making a safe choice about WS. The present study, together with previous ones (Lamoth et al., 2010; Tura et al., 2010; Tura e t al., 2012), also showed that the use of a single triaxial accelerometer (i.e., a low-cost, wearable, and easy-to-use device (Iosa et al., 2012) can provide useful quantitative and objective information about important gait features. The common walking tests performed in clinics on subjects with amputation, such as the 10 m walking test or the 6 min walking test (Tekin et al., 2009), just measure speed of walking without provid-ing information about the optimization of other important aspects of gait. The study also showed that fast speed may not be a safe choice, because it may lead to less harmonic gait, exposing subjects to a higher risk of falling (Senden et al., 2012, Doi et al., 2013).

In training people with amputation to use prostheses, researchers should focus interventions on the most impaired aspect of walking, i.e., harmony, a feature recently shown to be crucial for optimizing physiological gait (Doi et al., 2013; Iosa et al., 2013).

4.6 References

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Chapter 5

CONTROL OF THE UPPER BODY MOVEMENTS DURING LEVEL WALKING IN TRANSTIBIAL AMPUTEES

5.1 Introduction

Over recent years there has been a growing interest in the scientific community to the upper body mechanics during walking, both in healthy (Frigo et al., 2003; Kavanagh et al., 2004; Dingwell et al., 2006; Slavens et al., 2008; Mazzà et al., 2008) and in pathological subjects (Iosa et al., 2012; Conte et al., 2014; Iosa et al., 2014).

The most recent studies in this context have been conducted typically using a single body-worn inertial sensor to measure upper body accelerations on different types of individuals, as healthy, children, neurological patients, or elderly i.e. to prevent falls risk (Marschollek et al., 2008; Mazzà et al., 2008; Iosa et al. 2014; Weiss et al., 2014). Indeed, the accelerometric technique allows translating this type of evaluation to the clinic, where it is essential to perform analysis in a simple and inexpensive way, without the needs of involving complex laboratory assessments, warranting the minimum encumbrance for the patient under observation.

Regarding the role of the upper-body mechanics in gait stability, there is a focus in characterizing how these accelerations are transmitted from the pelvis to the head, where the vestibular receptors, primarily responsible for the ability to maintain the static and dynamic balance, are located. Indeed, the observation of the upper-body movements allow to better understand the motor strategy adopted during locomotion (Saunders et al., 1952; Cappozzo, 1982). Based on the literature (Henriksen et al., 2004; Kavanagh et al., 2008), linear accelerations of points distributed on the cranio-caudal axis, at level of lumbo-sacral and cervical-thoracic hinges and of the head, are considered as the most effective descriptors of the ambulatory task. Recent studies have shown how these

accelerations are transmitted in healthy people (Mazzà et al., 2008) and in some pathological subjects (Iosa et al., 2014; Buckley et al., 2015; Summa et al., 2016).

Gait stability has been referred to as the capacity to minimize oscillations during walking from the lower to the upper levels of the human body (Cappozzo, 1982).

In able-bodied individuals, both lumbar and cervical hinges play an important role in determining the attenuation of the mechanical perturbations transmitted from the hips to the pelvis and the spinal column, which eventually lead up to the head. This attenuation manifests itself in the decreased acceleration going from pelvis up to head level (Cappozzo, 1982; Winter, 1995). Acceleration data measured at different body levels in the three anatomical directions can provide insightful information about gait stability (Iosa et al., 2012). Using either Root Mean Square (RMS) values (Mazzà et al., 2008) or frequency domain measures (Kavanagh et al., 2005), upper body accelerations have been described in healthy subjects. Specifically, healthy subjects typically present a progressive reduction of acceleration from pelvis to sternum and from sternum to head, which reflects the adoption of postural control strategies

Conversely, it is conceivable that a different behaviour of these accelerations can be a symptom of difficulties in controlling the upper body movements, that have been reported to be associated with the fall risk (Marigold et al., 2008).

In particular, the lack of a limb and the functional asymmetry introduced by the use of prosthetic elements, may affect the stability of the movement during walking in the amputee subjects. It is conceivable that this kind of patients exhibit a different locomotor strategy compared to the able-bodied people, developing asymmetric compensation movements and altering the normal transmission of acceleration among the anatomical upper body segments. A recent study (Iosa et al., 2014) demonstrated indeed that the upper body accelerations and the gait stability change with different variations of prosthetic components, depending also on amputation levels. Therefore, the particular sensory feedback and the locomotive schema are not conditioned only by the impairment, but also by the physical presence of the prosthetic device. Moreover, using the same instrumental approach Howcroft identified three variables frequently related to clinical scores for dynamic stability, balance, and mobility, stating the need to

explore upper anatomical locations for accelerometers (Howcroft et al., 2014). At the state-of-the-art level, there are no studies available that describe how accelerations propagate through the upper body from the pelvis to the head of the amputee person.

Actually, limitation of these works relates to the adopted mono-sensor approach that does not allow appreciating the accelerations distribution among the upper-body hinges, whereby it is necessary a multi-sensors approach. To do that, the use of a multi-sensor approach should be taken into account.

Therefore, aim of the present study is to investigate upper body accelerations in transtibial amputees during gait and how they propagate from the pelvis up to the head. The importance of this analysis is in the possibility to find suitable quantitative indices to assess amputee persons' mobility and his/her gait stability which is strictly related to fall risk and the attainment of an adequate quality of life. Unlike the study presented in Chapter 4, where just one inertial unit on the L2–L3 spinous processes was adopted for the accelerometric gai analysis, in the present work a multi-sensors approach was made in order to investigate the trend of the measured accelerations measured at different levels of the upper body.

5.2 Methods

5.2.1 Subjects

A group of 20 people (19 male, 1 female; age: 51.1 ± 12.7 years old; height: 1.73 ± 0.06 m) with unilateral transtibial amputation (7 right side, 13 left side), definitive prosthesis users and able to walk without aids, and another one of 20 able-bodied (19 male, 1 female; age: 48,3 ± 8,7; height: 178,7 ± 0.06 m) were recruited for the study. Both groups were matched for gender and age. Table 5.1 shows the prosthetic components (foot, socket, and suspension system) of the amputee sample enrolled).

All subjects involved were physically active and had no neurological or motor disorders.

The Ethics Committee at the independent Saint Lucia Foundation in Rome approved experiments included in this work and information consent was obtained from all participants prior to start data acquisition.

Subjects	Foot	Socket	Suspension system
1	ÖSSUR Balance	TSB	Traditional vacuum with knee and valve
2	COLLEGE PARK Truestep	TSB	Harmony
3	ÖSSUR VariFlex LP	TSB	Harmony
4	COLLEGE PARK Truestep	TSB	Harmony
5	ÖSSUR VariFlex	TSB	Seal-In
6	ÖSSUR VariFlex LP	TSB	Harmony
7	OTTOBOCK 1C40	PTK	Traditional vacuum with knee and valve
8	ÖSSUR Flex Symes	TSB	Seal-In
9	ÖSSUR Balance	TSB	Traditional vacuum with knee and valve
10	ÖSSUR VariFlex	TSB	Traditional vacuum with knee and valve
11	ÖSSUR VariFlex	TSB	Seal-In
12	ÖSSUR Proprio Foot	TSB	Seal-In
13	ÖSSUR VariFlex	PTS	Traditional vacuum with knee and valve
14	ÖSSUR Proprio Foot	TSB	Seal-In
15	ÖSSUR VariFlex LP	TSB	Traditional vacuum with knee and valve
16	ÖSSUR VariFLex LP	TSB	Traditional vacuum with knee and valve
17	ÖSSUR VariFlex	TSB	Harmony
18	ÖSSUR Talux	TSB	Traditional vacuum with knee and valve
19	OTTOBOCK Springlite	TSB	PIN
20	ÖSSUR VariFlex	TSB	Seal-In

Table 5.1 – Prosthetic components of the 20 transtibial amputee subjects enrolled in the study. TSB = Total Surface Bearing; PTK = Prosthesis Tibiale Kegel; PTS = Patellar Tendon Supracondylar.

5.2.2 Equipment and data acquisition

Three magnetic inertial measurement units (Opal, APDM Inc., Oregon, USA) were used to collect 3D data of acceleration, angular velocity and magnetic field. Sample rate was set at 128 Hz, and full-range scale was set at +2g, with g = 9.81 m/s, ± 1500 °/s and ± 600 μT, respectively. The robust synchronized streaming mode configuration was used to synchronize the units and to avoid any loss of data even if there were interruptions in the wireless transmission.

Participants were dressed with swim cap, stretch top and stretch shorts, with specifically pockets for housing these measurement units, so that MIMUs were positioned at head (H), sternum (S) and pelvis (P) level, with the three sensible axes x, y and z aligned with the vertical (CC), medio-lateral (ML) and antero-posterior (AP) direction, respectively. Video recording were collected for each trial to control collected data using a commercial video camera (JVC GC-PX10 HD memory). The sensors location on the subject's body segments is shown in Fig. 5.1.
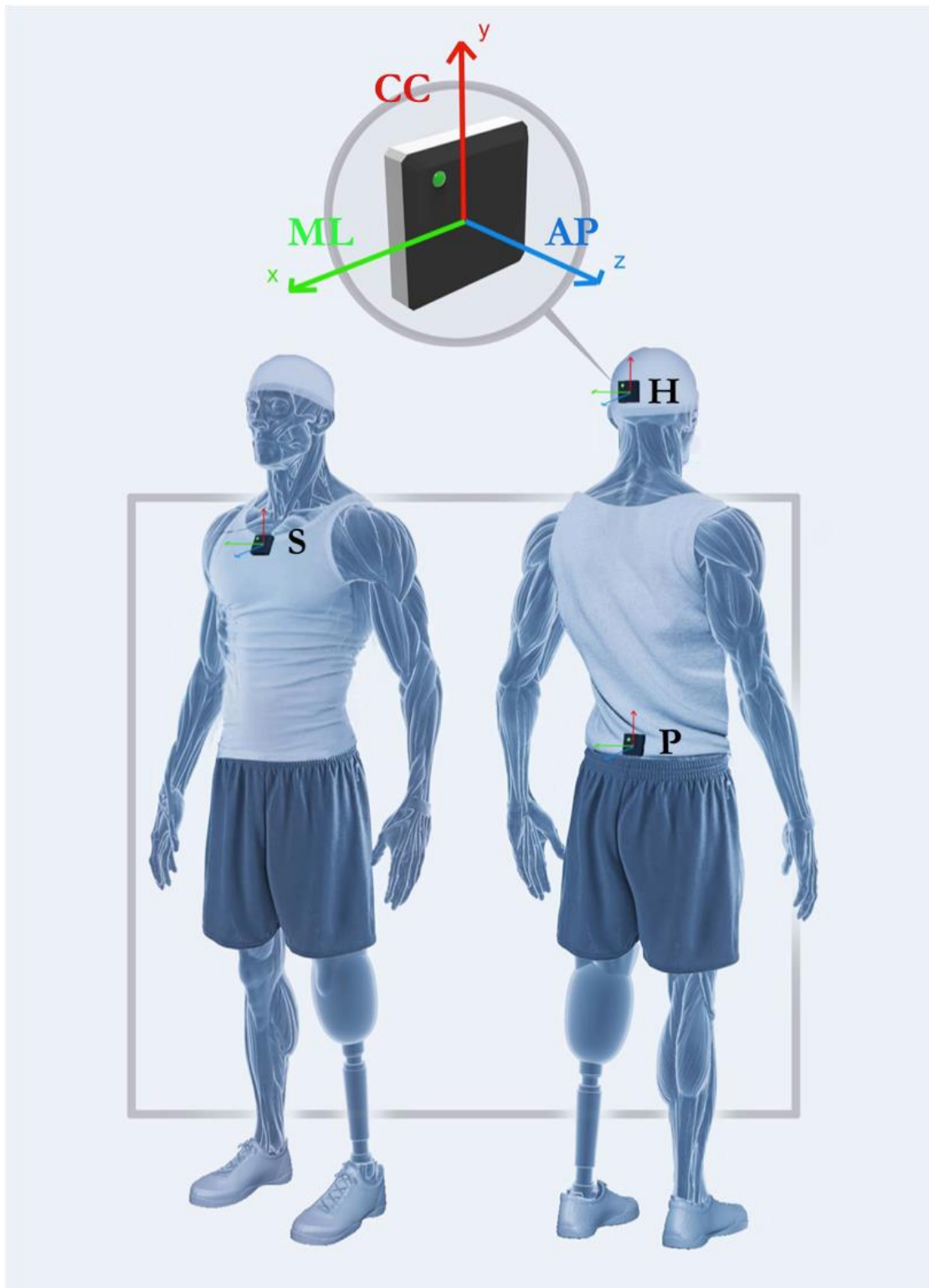
Figure 5.1 – Sensor location and axes orientation of the MIMUs (Opal, APDM Inc.) attached on the subject's body segments: Head (H), Sternum (S), Pelvis (P). MIMUs axes were aligned with the directions: Cranio-Caudal (CC), Medio-Lateral (ML), Antero-Posterior (AP).

5.2.3 Procedures

Each subject was asked to maintain the standing position for 10 s and then to walk in a 10 m linear pathway at his self-selected walking speed (Fig. 5.2). The start and the stop lines of the pathway were marked by two visible strips. Each subject performed three trials.

Figure 5.2 – Execution of the walking test. Note the pocket on the stretch top for housing the measurement unit on the sternum.

5.2.4 Data analysis

The data were processed using custom software written in MATLAB software (The MathWorks Inc., MA, US). A Local Anatomical (LA) frame was defined using a short acquisition of 2-3 s of orientation data recorded in the initial static part of the test, defined from the Inertial reference system (I) (Fig. 5.3). LA frame was characterized to have the CC axis aligned with gravity, while the subject stood erect and aligned with the progression direction, the AP axis aligned in the direction of progression and the ML axis obtained by vector product in a right-handed reference frame.
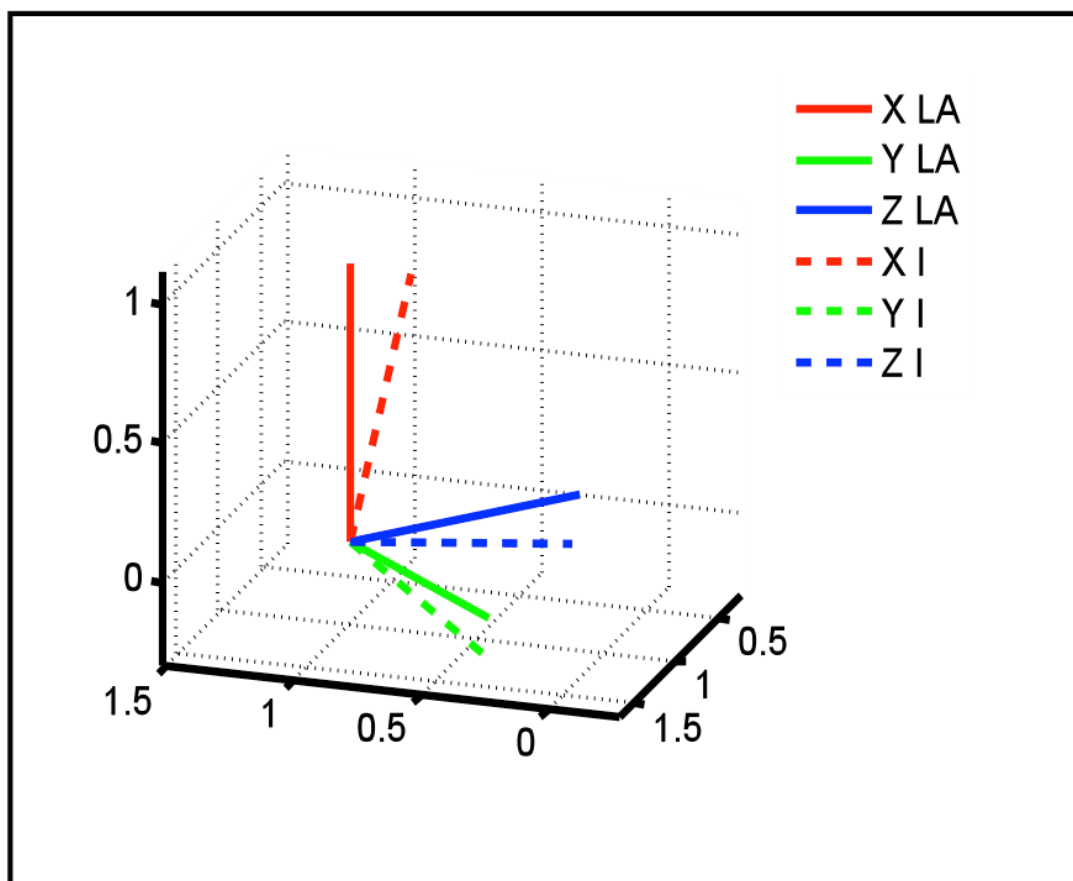
Figure 5.3 – Local Anatomical (LA) frame definition from the Inertial unit frame (I) reference system through MATLAB software.

The acceleration components were low-pass filtered using a 4th order Butterworth filter with a cut-off frequency of 20 Hz (Vaughan et al., 2003) and then expressed in LA frame. The gravitation acceleration component was subtracted from the recorded signal before data processing.

In accordance with Tura et al. (2010), the steady state phase was identified and four consecutive steps (two strides) for each trial were then selected for the analysis. After a bias removal on the acceleration signals, Root Mean Square of acceleration (RMSa) at the three levels of the upper body were computed in the LA frame in each stride, using both the resultant accelerations and their components.

$$RMSa = \sqrt{\frac{\sum_{i}^{n} a_i^2}{n}}$$

Equation 5.1 – Root Mean Square (RMS) of the acceleration signal

Variation of RMSa from a level i to an upper level j was taken into account computing the relevant attenuation coefficients C_{PS}, C_{SH}, C_{PH}:

$$C_{ij} = (1 - \frac{RMSa_j}{RMSa_i}) \cdot 100$$

Equation 5.2 – Computation of the attenuation coefficient C_{ij}

Both parameters, RMSa and Cij, proved to be effective to characterize how subjects attenuate upper body accelerations from the pelvis to the sternum and the head (Mazzà et al., 2008; Mazzà et al., 2010).

The average of the values obtained on the two selected strides were considered for each parameter. Moreover, the time and the number of steps performed walking for the 10 m

were estimated using peaks of the acceleration time histories (Brandes et al., 2006) and video data. From these measurements, step frequency (SF) [s^{-1}] and average step length (SL) [m] were thus estimated and the mean walking speed (WS) [m/s] was computed as the ratio between length of 2 strides and the relevant duration.

The correspondent normalized parameters, were computed scaling these three gait parameters with ML, as described by Hof (1996).

In particular to take into account for possible differences in the WS values due to stature differences, the Froude number (Vaughan et al., 2005) was also computed:

$$Fr = \frac{v^2}{gL}$$

Equation 5.3 – The Froude number, g = gravitational acceleration; L = leg length.

where g is the gravitational acceleration and L is the subject leg length.

Since WS affects all the RMSa values assessed along one of the three body axes (Iosa et al., 2012), the relationship among these three RMSa values were also evaluated in both groups, computing the two intra-subject ratios: RMSa value along ML axis on RMSa along CC axis (RMSa_ML/ RMSa_CC), RMSa value along AP axis on RMSa along CC axis (RMSa_AP/ RMSa_CC).

Differences between groups were evaluated using Independent Samples T-Tests ($\alpha=0.05$).

5.3 Results

The values of the spatio-temporal parameters computed for the two groups are reported in Table 5.2. Walking speed was found significantly lower in amputees group (AG) with respect of control group (CG) (AG: L = 0.88 ± 0.04 m; CG: L = 0.93 ± 0.05 m; p<0.001), whereas there are no significant differences for the normalized walking speed expressed by the Froude number. This result allowed for the use of RMSa for between-group comparisons (Menz et al., 2003).

	Walking Speed [m/s]	Step Frequency [step/s]	Step Lenght [m]	Froude number
AG	1.22 ± 0.14	1.85 ± 0.15	0.67 ± 0.07	0.18 ± 0.04
CG	1.35 ± 0.17	1.90 ± 0.17	0.72 ± 0.06	0.20 ± 0.05
p-value	**0.016**	0.316	0.302	0.068

Table 5.2 – Spatio-temporal parameters. Significant values of p are reported in bold ($p<0.05$).

RMSa parameters computed along CC, ML and AP directions at pelvis, sternum and head level are shown in Fig. 5.4 (left panel). RMSa were significantly larger in AG than in CG at pelvis level only along the ML direction ($p<0.05$), and at head level along AP and ML directions ($p<0.05$).

No significant differences were found between AG and CG groups in RMSa along all other directions at sternum level.

Concerning the attenuation coefficients (Fig. 5.4, right panel), CPS values were larger in AG than in CG group (C_{PS_AP}, C_{PS_ML}: $p<0.01$; C_{PS_CC}: $p<0.05$), whereas C_{SH} values have the opposite behavior along the three directions, larger in CG than AG (C_{SH_AP}, C_{SH_ML}: $p<0.01$; C_{SH_V}: $p<0.05$). No significant differences were found in C_{PH} values between AG and CG groups along AP, ML and CC directions.
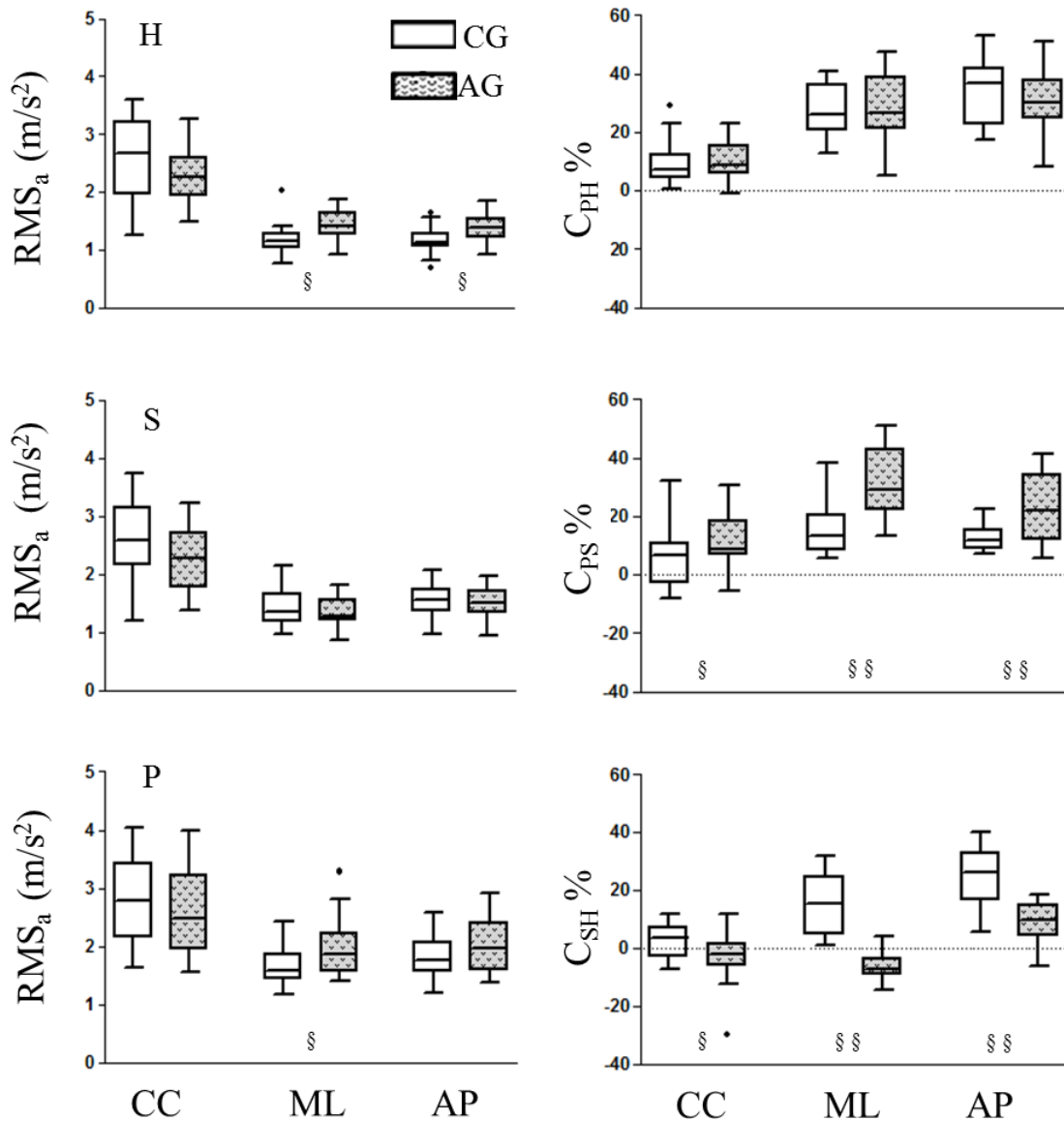
Figure 5.4 - On the left, RMS of the acceleration components at the three levels: Pelvis (P), Sternum (S) and Head (H). On the right, attenuation coefficients from pelvis to head (C_{PH}), from pelvis to sternum (C_{PS}), and from sternum to head (C_{SH}) along the three anatomical axes. Parameters computed for the CG and AG groups are represented with empty and filled box-plots, respectively. Significant between-groups differences ($p < 0.05$ or $p < 0.01$) are reported with the symbol § or §§, respectively.

When accelerations were normalized for taking into account their strict relationship with velocity, both AP- and ML-stability were found lower in amputees than in healthy subjects both at pelvis and head level. Accelerations on the transverse plane normalized for CC were slightly but not significantly lower in AG than CG at the sternum level (Table 5.3).

Level	Parameter	AG	CG	p-value
Pelvis	RMS_CC/RMS_AP	128.40 ± 21.56	152,28 ± 20.24	**0.0003**
	RMS_CC/RMS_ML	130.74 ± 25.99	167.16 ± 28.20	**0.0002**
Sternum	RMS_CC/RMS_AP	148.07 ± 30.12	164.32 ± 29.24	0.0592
	RMS_CC/RMS_ML	169.50 ± 36.20	186.18 ± 38.59	0.1966
Head	RMS_CC/RMS_AP	167.12 ± 32.32	216.61 ± 50.81	**0.0019**
	RMS_CC/RMS_ML	162.86 ± 29.57	214.53 ± 50.00	**0.0011**

Table 5.3 - Root Mean Square of acceleration (RMSa) along antero-posterior (RMSa_AP) and medio-lateral (RMSa_ML) axes normalized with respect to those of cranio-caudal (RMSa_CC) by using the inverse of their percentage ratio in AG and CG (mean ± SD). Significant values of p are reported in bold (p<0.05).

5.4 Discussion

In the present study, a multilevel inertial sensor set-up was proposed to characterize segmental accelerations of pelvis, sternum and head during gait, and to investigate how these accelerations are attenuated from the bottom to the top in transtibial amputees when compared to age-matched able-bodied subjects. Investigating accelerations and how they propagate through the upper body has a valuable physiological meaning and quantifies the role of upper body structures in reducing head accelerations: as a matter of facts, this role can be active, when looking at both trunk and arms movements during gait, as well as passive, when taking into account the contribution of the underlying anatomical structures (bones, muscles, tendons, cartilages) (Summa et al., 2016).

The analysis of the the cranio-caudal (CC), medio-lateral (ML) and antero-posterior (AP) components of acceleration measured at pelvis, sternum, and head levels was performed, which strongly confirmed differences in acceleration values between the two groups, a clear sign of a different control motor strategy adopted by the amputee subjects during gait.

The main consideration on the obtained results is related to the RMSa signal along the ML direction, at the pelvis level. This reflects a typical compensation of amputees that are unable to apply a plantar and dorsal flexion on the prosthetic foot, so they tend to overcome this enablement hyperextending hip and tilting pelvis forward, with consequent hyperlordosis of the lumbar spine during the rocker.

After a clinical evaluation, this particular behavior is generally easier to be found in the tranfemoral amputees than in the transtibial ones (being the degree of disability of lower-limb amputees often proportional to the height of amputation). These major pelvis oscillations may also explain the higher attenuation between the anatomical districts pelvis-sternum than those recorded between the sternum-head.

The larger pelvic oscillations along the ML direction recorded in the amputees sample, if on the one hand it contributes to the pelvis-sternum attenuation, on the other hand it involves oscillations in ML at the head that are not a result of biomechanical factors directly related to the prosthesis, but derive from the particular compensation strategy implemented at the pelvis segment level. Pelvic oscillations around the AP axis, more amplified in the amputees' sample compared with the control one, are not surprising and may be the expression of the sound limb support prevalence during the gait. Indeed, people with amputations have a high incidence of osteoarthritic joints degeneration on their sound limb (Eshraghi et al., 2014).

The larger accelerations recorded in AG at pelvis and head levels, may interfere with the normal processing of visual, vestibular, and somatosensory information regarding body position, thus inducing a vicious circle that potentially weakens the control of the upper body movement during gait, due to the altered sensory feedback (Summa et al., 2016).

The RMSa values obtained at the lower trunk were slightly higher than those previously reported in transtibial amputees (Iosa et al., 2014). In the cited study, subjects performed

the walking test the last week before dismissal from a rehabilitation hospital. It is conceivable that the mobility level of these subjects was lower than that of the sample enrolled in the present work, as shown by a lower WS. This study confirms that the high RMSa at pelvis level is an important clinical parameter justifying the reduced gait stability in the pathological group.

When accelerations were normalized for taking into account their strict relationship with gait velocity, both ML- and AP-stability were found lower in amputees than in healthy subjects. In particular, the inverse of the percentage ratios of RMSa_AP and RMSa_ML on RMSa_CC were significantly lower in AG group at pelvis and head levels, likely a sign of control issues and precarious balance. These normalized parameters were shown to be suitable for assessing the trunk stability during walking both in persons with stroke (Iosa et al., 2012) and amputation (Iosa et al., 2014), with higher values of normalized RMS representing higher instabilities.

It is revealed that even if subjects with a transtibial amputation apply an increased pelvis-to-sternum attenuation, this does not adequately reduce high acceleration values at the pelvis level, exhibiting an RMSa at sternum level that is still higher than healthy subjects.

Specifically, in AG group C_{PS} is positive and significantly larger than in the CG group, thus indicating that transtibial amputees attenuate more able-bodied from pelvis to sternum. Probably, the difference between pelvis-trunk AP accelerations is actually due to a different pattern of locomotion developed by amputees, as rightly pointed out by Iosa et al. 2014.

This circumstance could not be attributed to a deficit of the CG group, but potentially to the fact that for able-bodied, large attenuations are not strictly required to guarantee safe walking and an adequate dynamic stability of the trunk. Looking at the increased pelvis acceleration observed in AG group, it is conceivable that a physiotherapeutic intervention to stabilize the pelvis may also reduce accelerations at higher body levels.

Going upwards, the analysis of the sternum-to-head attenuation (C_{SH}) presented a behaviour in the AG group that was the opposite to that of the CG group. While the latter group reduced accelerations from the sternum to the head, guaranteeing protection of the head, the former presented a negative C_{SH}, meaning that acceleration increases

from the sternum to the head. This inefficiency in attenuating these accelerations could be related to a rigidity of the head-trunk system in this special population. It is conceivable that these higher accelerations in AG group could be a potential cause of the typical back and neck pains associated to the lower limb amputee's population (Ehde et al., 2000).

5.5 Conclusion

The present work focused on the quantitative assessment of upper body accelerations during gait and of their attenuation from the pelvis to the head, in transtibial amputees using wearable magneto-inertial sensors. The availability and accessibility of the inertial measurement equipment, in fact, does not limit its everyday use by clinicians. Moreover, characterizing how head stabilization is managed during gait in lower-limb amputees can be potentially useful to study gait patterns, including compensatory ones. In this respect, the potential role of trunk movements for compensating asymmetries in lower-limb patterns was highlighted, specifically involving decreasing/increasing accelerations at the different body levels. The adopted biomechanical parameters were fruitful in highlighting gait differences between amputee and able-bodied subjects and can be used to support therapists and physicians either to drive the design of innovative intervention protocols or to prescribe prosthetic devices, and to monitor their efficacy in terms of gait stability.

Indeed, the evaluation of upper body accelerations can be related not only to the monitoring and assessment of the amputees rehabilitation training, but also to the assessment and the design of prosthetic components. In the first case this approach might represent an analysis tool for stability in order to quantify compensation movements during walking. In fact the lower-limb amputees presents gait deviations and postural asymmetries as trunk forward inclination (due to i.e. weakness of hip extensors). Angles values provide the magnitude of compensation movements but not the dynamics with which these occur. Regarding the second field of application, the knowledge of the upper body accelerations distribution can be represent a useful tool for verifying the

goodness of prosthesis design characteristics. Indeed, all the prosthetic elements that act as "shock absorbers" (i.e. carbon fiber feet, type of suspension system, etc.) affect in a direct manner the accelerations at the pelvis and trunk level. For instance, the damping time of the oscillations could be a parameter discriminating the goodness of the prosthetic components used.

In this context, the attenuation coefficients Cij may represent a useful synthetic index for the objective assessment of the mobility of the amputee person associated with the traditional clinical approach.

Further studies may test the ability of these indices to assess and monitor the outcomes of different therapeutic interventions.

5.6 References

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Chapter 6

A CLINICAL COMPARISON BETWEEN THE CONVENTIONAL NON-ARTICULATED SACH AND A MULTI-AXIAL PROSTHETIC FOOT FOR HYPOMOBILE TRANSTIBIAL AMPUTEES

6.1 Introduction

Prosthetic feet are devices designed to replace one or more function of the biological human ankle-foot system. Over the past few years developers have released to the market a large variety of technologically advanced prosthetic feet, broadening the range of available devices.

Despite the technological progress, the selection of the most appropriate foot for each person with amputation is still difficult. Anecdotal evidence indicates that prescription of optimal prosthetic feet to ensure successful rehabilitation is challenging because there are no generally accepted clinical guidelines based on objective data (Zmitrewicz et al., 2006). Indeed, although depends on the patient's Medicare Functional Classification Level (MFCL) (HCFA, 2001), the proper choice is often derived from the particular clinical experience of the prosthetist and the rehabilitation team (Schaffalitzky et al., 2011). Translational research in this field could provide the scientific evidence required to improve and make more objective the prescriptions of prosthetic feet to persons with lower-limb amputation.

Most studies concerning the influence of prosthetic feet in transtibial amputees (TTAs) on gait compared one or more energy storing and return (ESAR) devices and the conventional and most frequently studied Solid Ankle Cushioned Heel (SACH) foot (Turcot et al., 2013). ESAR feet used by active TTAs were shown to provide better

clinical effects than the SACH foot, in terms of energy cost of walking (Hsu et al., 1999), gait symmetry in ascending stairs (Torburn et al., 1994) and biomechanical parameters such as increased ankle range of motion (RoM) and power absorption in prosthetic ankle during weight bearing (Underwood et al., 2004). Conversely, the SACH is considered to be the most appropriate foot for hypomobile TTAs and also the most prescribed, as it is inexpensive, easy to use, and perceived as stable and safe by hypomobile amputees (Andrews et al., 1996; Dudkiewicz et al., 2011; Bonnet et al., 2014). However, the SACH has many disadvantages; for instance the time between heel strike and foot flat is twice as long as in normal gait (Goh et al., 1984), it almost never remains flat during the stance phase and the heel rises very early, which makes it less versatile on uneven terrain (Bonnet et al., 2014). Moreover walking on inclines with the SACH is particularly demanding, especially in descending ramps (Sin et al., 2001). As ESAR feet are not recommended for hypomobile TTA (Bonnet et al., 2014) due to the perceived instability of energy return, an alternative to the conventional SACH could be represented by multi-axial feet. Indeed, multi-axial feet have no energy returning capacity while allowing higher degrees of freedom (DoFs) and RoM at the joint, therefore providing a closer representation of a natural foot-ankle system than the SACH. Despite its potential, this type of foot has not been studied thoroughly yet.

Actually only two studies have compared the SACH with a multi-axial foot (Zmitrewicz et al., 2006; Marinakis et al., 2004). Marinakis found significant improvement in spatial-temporal parameters, symmetry index of the hip and ankle RoM when SACH was replaced by the Greissenger Plus foot, composed of a rigid longitudinal keel and a multi-axial ankle (Marinakis et al., 2004). However, participants were not confident prosthetic users but only in the early stages of rehabilitation. Moreover the study did not include structured questionnaires that cover major aspects of everyday life that might be affected by living with prosthesis. The second study (Zmitrewicz et al., 2006) presents a comparison between ESAR and SACH feet, both with and without a multi-axial joint. The authors showed that older low-mobility TTAs did not benefit from the ESAR but did benefit from the increased flexibility provided by multi-axial ankles. In fact, the majority of participants (11 of 15) preferred the SACH foot integrated with the multi-

axial joint (called "SACH-MA"), designed specifically for the study but not available commercially. However, the authors concluded that the results could provide a scientific rationale for prescribing a multi-axial ankle to improve TTAs gait performance.

In the light of the above, a clinical comparison between SACH and a multi-axial prosthetic foot for low-mobility TTAs is both useful and necessary in order to allow practitioners to prescribe the most adequate device. The hypothesis underlying this study is that the use of a multi-axial foot allows an improved performance in confident SACH users TTAs, as it presents more DoFs without introducing other elements that may jeopardise the user's perceived safety.

Thus the main aim of this study is to compare the clinical effects of SACH and multi-axial prosthetic feet on mobility, balance performances and prosthesis-related quality of life in hypomobile unilateral TTAs.

6.2 Methods

6.2.1 Subjects

All of the consecutive TTAs treated in the outpatients department of our rehabilitation hospital were screened for the following enrolling criteria: (a) body mass < 125 kg, (b) functional mobility K-level 1 (the patient has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence: this is typical of a household ambulator or a person who only walks about in their own home) or K-level 2 (the patient has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces: this is typical of the limited community ambulator.) (HCFA, 2001), (c) SACH foot users for at least 6 months and for a minimum of 4 hours per day, (d) absence of severe comorbidities or clinical residual limb complications.

6.2.2 Prosthetic feet

Two types of prosthetic feet were used (Figure 6.1), the SACH and the 1M10 Adjust® (1M10), both manufactured by Otto Bock HealthCare GmbH (Duderstadt, Germany).
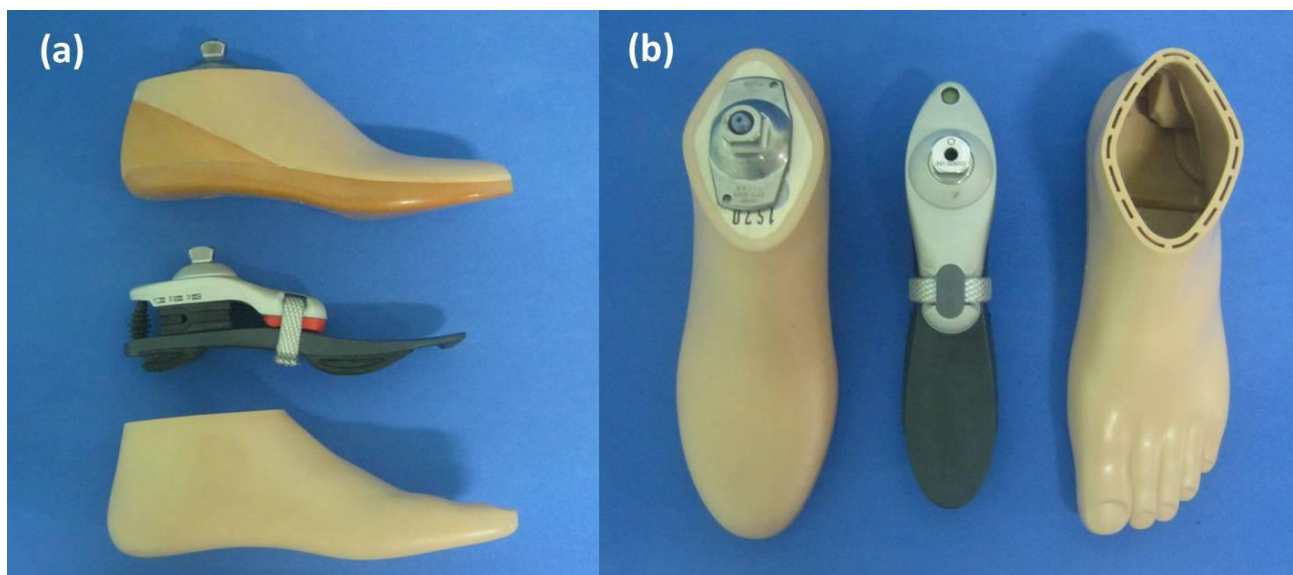
Figure 6.1 - The SACH and the 1M10 Adjust prosthetic feet on the sagittal (a) and the trasversal (b) plane. The SACH foot is placed on the top in (a) and on the left in (b), while the 1M10 Adjust® is depicted with the respective cosmetic cover.

SACH has no ankle joint mechanism. It is composed of a rigid wooden keel that provides midstance stability and forms the internal component. The keel is covered by plastic polymers with different densities that supply the function of cushioning the heel strike (Cushioned Heel) and facilitating the forefoot rocker, while maintaining the ankle stiffness (Solid Ankle).

1M10 is a prosthetic foot with multi-axial joint positioned at load line, made up of a flexible functional module and a forefoot ball-pad that could help the users' stability during walking and standing, as claimed by the manufacturer. Multi-axial behaviour permits inversion-eversion on the frontal and dorsi-plantar flexion on the sagittal plane.

Figure 6.2 – The SACH (top) has no ankle joint mechanism, whereas the 1M10 Adjust (bottom) has a multi-axial joint positioned at load line.

6.2.3 Outcome measures and tools

To thoroughly investigate the three clinical aspects of interest we chose the following outcome measures. Mobility was assessed by the patient's ambulatory skills on floor, ramps and stairs by means of the Locomotor Capability Index-5 (LCI-5) (Franchignoni et al., 2004), Six-Minute Walking Test (6MWT) (ATS, 2002) Hill Assessment Index (HAI) (Buell et al., 2004) and Stairs assessment Index (SAI) (Buell et al., 2004). Balance was assessed by means of the Berg Balance Scale (BBS) (Berg et al., 1995) and gait stability through analysis of upper-body accelerations. Finally we took into consideration the feedback of participants concerning quality of life and general comfort perceived with each foot by means the self-report Prosthesis Evaluation Questionnaire (PEQ) (Legro et al., 1998).

6.2.3.1 Locomotor Capability Index-5 (LCI-5)

The LCI-5 (Franchignoni et al., 2004) evaluates the subject's ambulatory skills through the assessment of the subject's capability performing 14 different activities while wearing prosthesis, rated with a 5-point ordinal scale ranging from 0-4. The maximum total score of the index is 56. The self-report measure of LCI-5 has demonstrated good test-retest reliability and internal construct validity in elderly and middle-aged persons with amputation (Franchignoni et al., 2004).

6.2.3.2 Six-Minute Walking Test (6MWT)

The 6MWT (ATS, 2002) consists of walking for 6 minutes at one's own self-selected walking speed (SSWS). It is a reliable and useful measure of functional mobility especially for people with impairment (Enright et al., 2003), TTAs included (Lin et al., 2008). In studies of prosthetic components SSWS has often been used as a parameter for the quality of performance (Boonstra et al., 1993; Sagawa et al., 2011) also when different prosthetic feet were compared (Snyder et al., 1995). According to other studies (Steffen et al., 2002) the average SSWS [m/s] for each participant was computed dividing the covered distance by 360 seconds.

6.2.3.3 Hill Assessment Index (HAI) and Stair Assessment Index (SAI)

The HAI (Buell et al., 2004) and the SAI (Buell et al., 2004) evaluate the ability to walk up/down on an inclined surface and to ascend/descend a certain number of stair steps, respectively. Both these performance-based test were used in previous works to evaluate or compare different prosthetic components and feet (Hafner et al., 2007; Delussu et al., 2013). Also the time [s] required in HAI going uphill/downhill and SAI walking up/down at self-selected speeds was recorded as previously reported by Highsmith (Highsmith et al., 2013). The stair used for SAI was 2 meters wide and had 12 steps, 31 centimeters deep and 18 centimeters high, with a handrail on the right side. The ramp used for HAI was 28 meters long and paved with a slope of 10 degrees.

6.2.3.4 Berg Balance Scale (BBS)

The BBS (Berg et al., 1995) is composed of 14 functional tasks, each of them ranking 0-4; the maximum total score of the index is 56. Major demonstrated the high BBS validity and reliability for assessing balance in lower-limb amputees (Major et al., 2013).

6.2.3.5 Upright Gait Stability (UGS)

The UGS has been defined as the capacity to minimize upper body oscillations and absorb jerks, bumps, shakes, and fluctuations, despite the broad and fast movements of the lower-limbs during locomotion (Cappozzo et al., 1982; Iosa et al., 2013). Hence, an upright gait is stable when upper body accelerations are minimized and smoothed (Iosa et al., 2012). The methodological approach followed in this work was similar to many previous studies concerning other pathological populations, and already used also in amputees (Iosa et al., 2014). In detail, each person was equipped with an Inertial Measurement Unit (IMU) [FreeSense®, Sensorize srl; Rome, Italy] during the 6MWT (Figure 6.3). This small and lightweight device was placed within an elastic belt worn by patients and located on an area of their back corresponding to the L2-L3 spinous processes (Horner et al., 2013). The considered IMU contains a tri-axial accelerometer and two bi-axial gyroscopes and provides data with respect to a local sensor-embedded frame coinciding with the geometrical axis of the IMU case. The device allows expressing both acceleration and angular velocity signals along the three anatomical axes: antero-posterior (AP), latero-lateral (LL), cranio-caudal (CC). Sampling frequency at 100 frames/s was used. The IMU data extraction and analysis were performed with MATLAB [version 8.2].
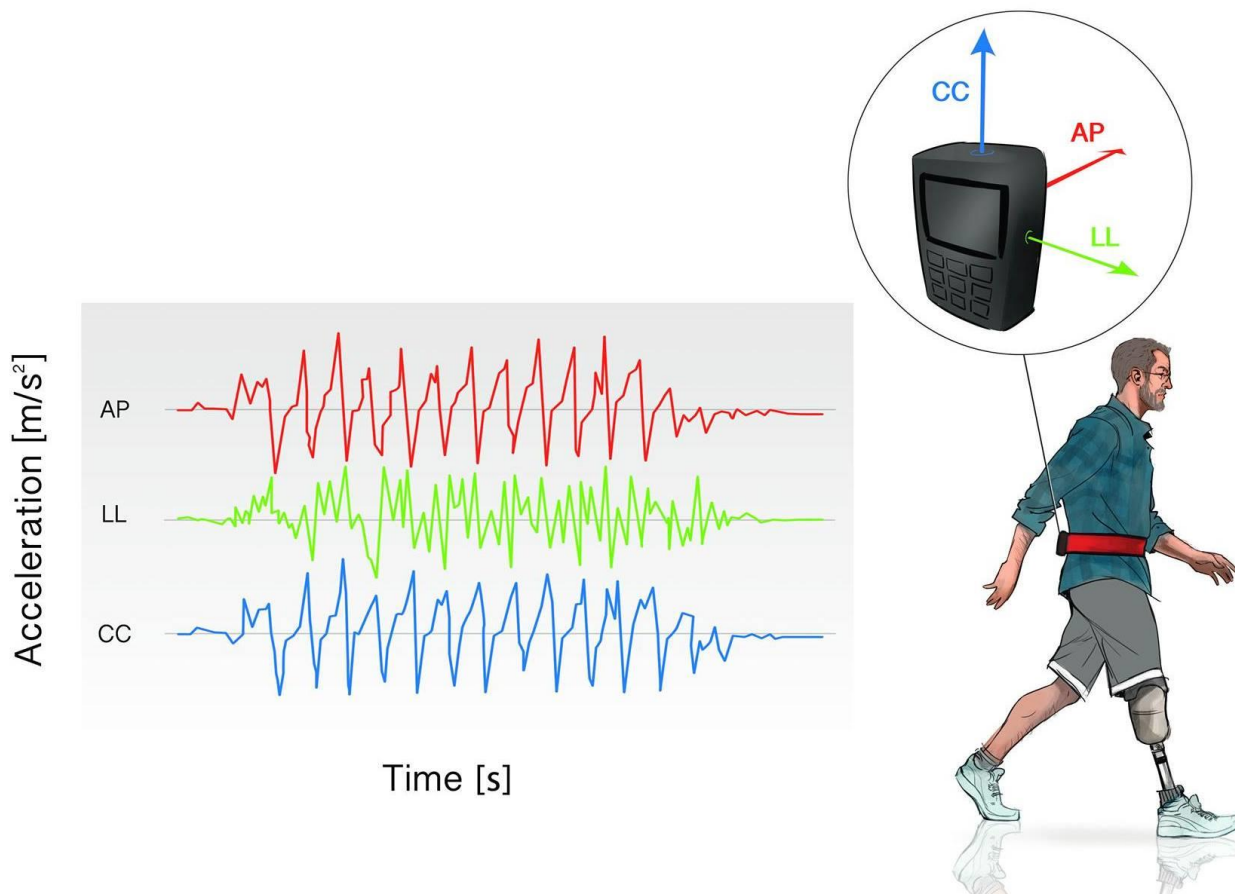
Figure 6.3 - The Upright Gait Stability assessment during walking. The triaxial accelerometer placed on the back area (L2-L3) of each subject allows to express the acceleration's signals along the three anatomical axes: Antero-Posterior (AP, red line), Latero-Lateral (LL, green line) and Cranio-Caudal (CC, blue line).

The three accelerometric signals were low-pass filtered using a 20 Hz low-pass 2nd order Butterworth filter applied to the signals after their mean value subtraction. The Root Mean Square (RMS) of acceleration was then computed, as measure of acceleration dispersion that coincides with the standard deviation because of the signal mean subtraction. As the RMS of acceleration is strictly dependent on walking speed, the values of RMS-AP and RMS-LL were normalized with respect to those of RMS-CC by using the inverse of their percentage ratio as an indicator of UGS. These normalized parameters were shown to be suitable for assessing the trunk stability during walking both in persons with stroke (Iosa et al., 2012) and amputation (Iosa et al., 2014), with higher values of normalized RMS representing higher instabilities.

6.2.3.6 Prosthesis Evaluation Questionnaire (PEQ)

Users' satisfaction with the prosthesis was assessed by means of the PEQ (Legro et al., 1998). The questionnaire consists of a series of items with a linear analogical scale response format, organized into nine functional domain scales, widely used to evaluate the effects on TTAs prosthesis-related quality of life with different prosthetic feet (Delussu et al., 2013, Brunelli et al., 2013). The functional scales are: Ambulation, Appearance, Frustration, Perceived response, Residual limb health, Social burden, Sounds, Utility, and Well-being. The reliability and validity of this survey have previously been assessed and approved (Miller et al., 2001; Resnik et al., 2011).

6.2.4 Data collection

The study was organized into two main phases of evaluation. During the first phase (P1) fulfillment of inclusion criteria was verified; anthropometric, anamnestic and demographical information were also collected. The same physiatrist, experienced in amputee rehabilitation, classified each person enrolled according to his or her functional level with the MFCL system. Then a certified prosthetist verified the proper SACH

alignment with respect to a reference line by means of a posture system [L.A.S.A.R. Posture, Otto Bock HealthCare GmbH; Duderstadt, Germany]. If the alignment did not appear to be correct, the patient was automatically excluded from the study. Later all self-report and performed-based test described above were administrated. Participants carry out the performed tests (i.e. 6MWT, UGS, BBS, HAI, SAI) during a morning session, allowing enough recovery time between each test in order to avoid effect of fatigue on measurements. Note that UGS data are recorded simultaneously to 6MWT. At the end of P1 the same prosthetist changed the SACH with the 1M10 without changing the socket. A correct alignment was enured with the same posture system. Participants continuously used 1M10 for 4 weeks to ensure adequate prosthesis acclimation (English et al., 1995) and were required to maintain their lifestyle unchanged (i.e. physical activity, nutritional regimen, etc.) for the entire time of the study. In the second phase of evaluation (P2) all participants performed the same tests as P1 fitting the multi-axial foot. The same researcher administered each outcome measure in both data collection sessions. Each performed based test was carried out once to avoid learning effects. The experimental tests in P1 and P2 were conducted with the same pair of shoes and at the same hour of the morning to avoid inaccurate data due to eventual fluctuations in residual limb volume. A flowchart of the study design is shown in Figure 6.4. All the physiological responses recorded through a portable metabolimeter and the functional assessment on the perceived exertion (Borg scale) and satisfaction (SATPRO) are not reported in this thesis, but are available in the following paper: "Comparison between SACH foot and a new multi axial foot during walking in hypomobile transtibial amputees: physiological responses and functional assessment. Delussu AS, Paradisi F, Brunelli S, Pellegrini R, Zenardi D, Traballesi M. Eur J Phys Rehabil Med. 2016 Mar 18".
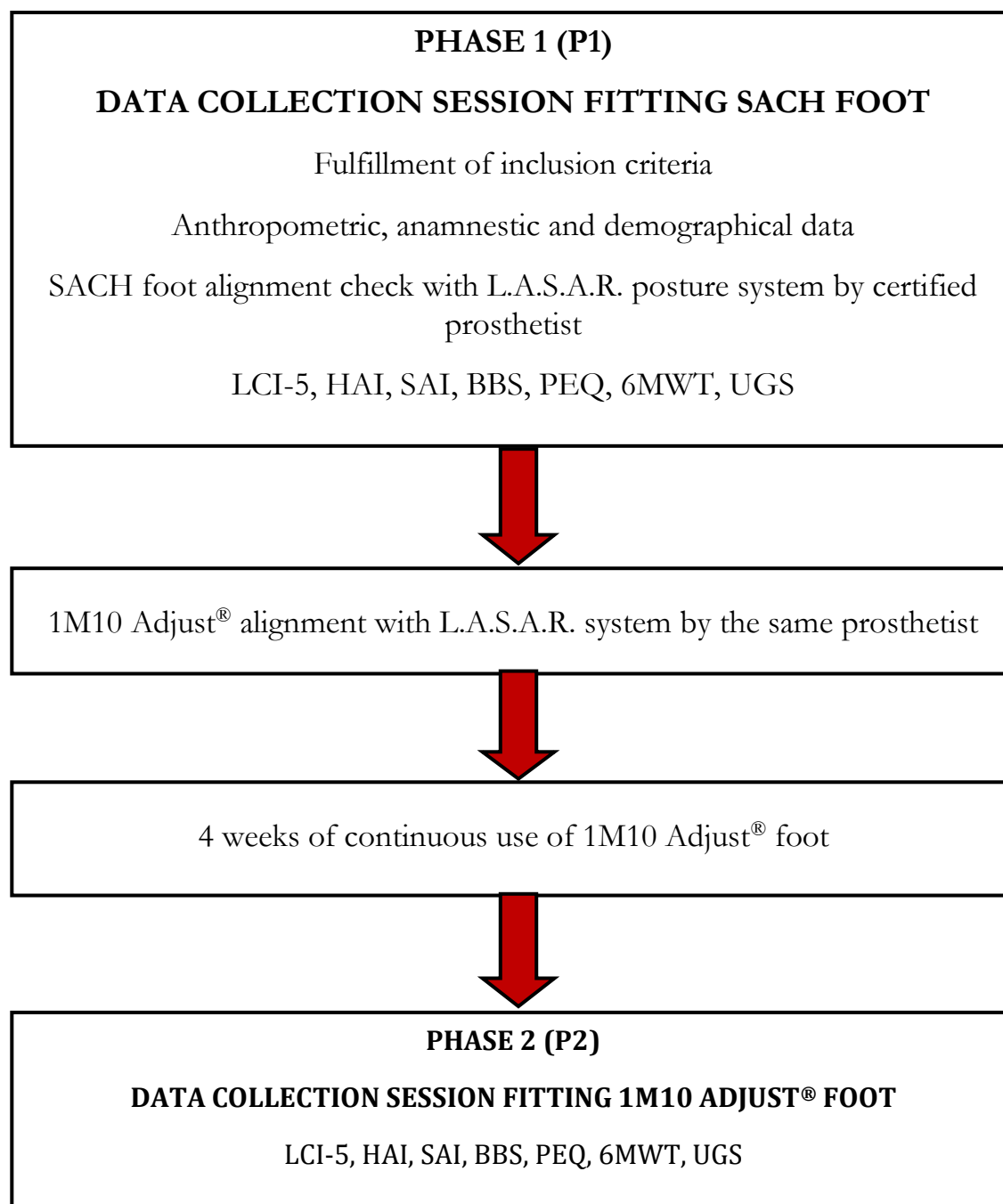
Figure 6.4 - Study design and timing. The L.A.S.A.R. posture system was used to check the alignment of SACH and to optimize that of the 1M10 Adjust® by the same certified prosthesist. Outcome measures of Locomotor Capability Index-5 (LCI-5), Hill Assessment Index (HAI), Stair Assessment Index (SAI), Berg Balance Scale (BBS), Prosthesis Evaluation Questionnaire (PEQ), Six-Minute Walking Test (6MWT), Upright Gait Stability (UGS) were collected fitting SACH during the first phase of evaluation (P1) and 1M10 Adjust® foot after one month of acclimation (P2).
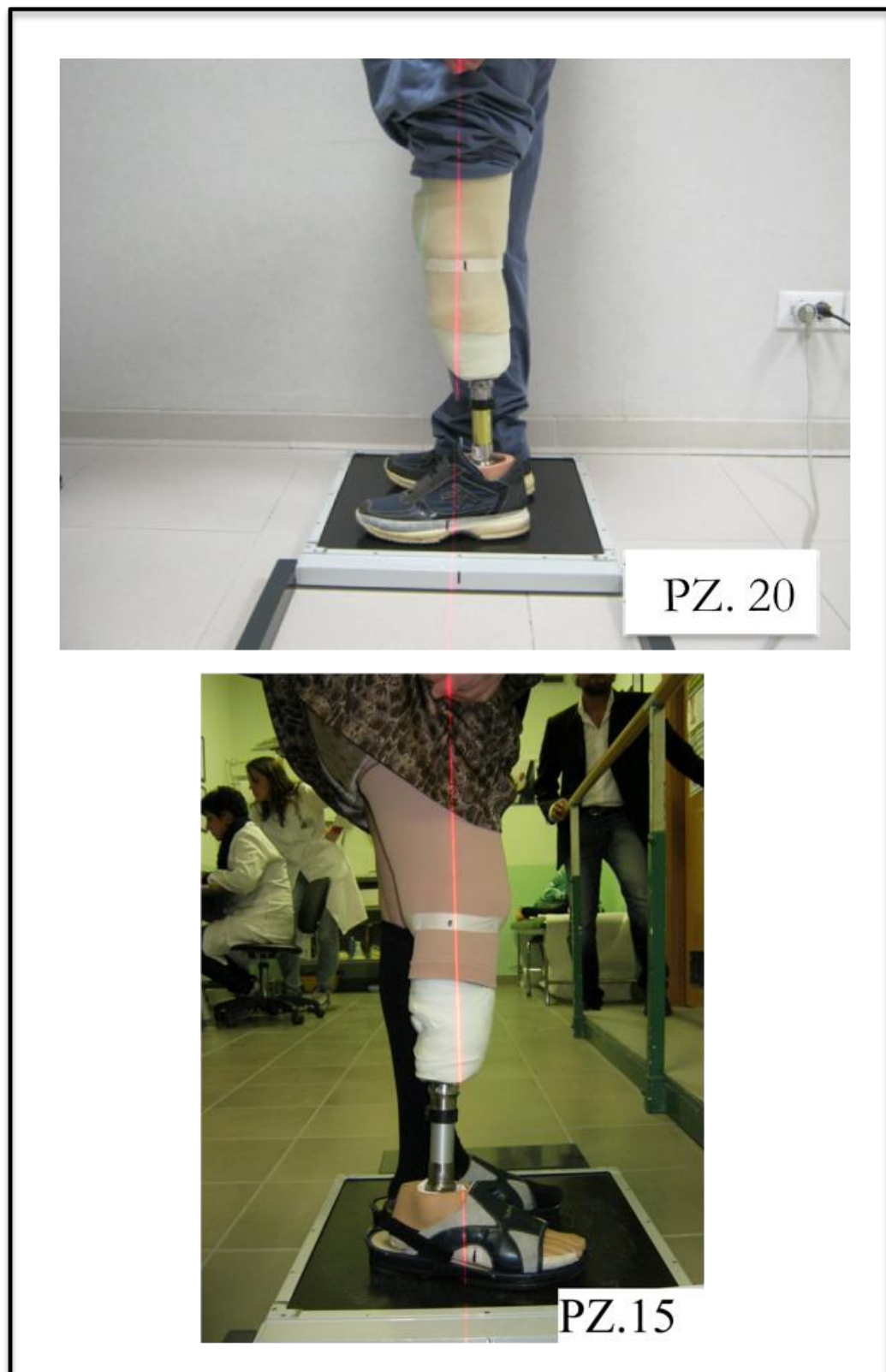
Figure 6.5 – Alignment of 1M10 Adjust® by means of the L.A.S.A.R. posture system, example in two patients enrolled

The local Ethics Committee approved the study procedures that adhered to the Declaration of Helsinki for medical research involving human subjects for the study, and informed consent was obtained from all subjects prior to their participation on a voluntary basis.

6.2.5 Statistical Analysis

Statistical analyses were conducted using SPSS [version 17.0 for Windows]. Non-parametric statistics was used for ordinal scores of clinical scales (BBS, LCI-5, HAI, SAI) and questionnaire (PEQ). In particular these ordinal data have been described using median, quartiles, and interquartile range (i.e. the difference between third and first quartiles) and compared between P1 and P2 using Wilcoxon signed ranks test. Parametric statistics was used for continuous quantitative measures such as the measured time of HAI and SAI tests, the self-selected walking speed in 6MWT, and the root mean squares of trunk accelerations. These continuous data have been reported in terms of means and standard deviations, and compared between P1 and P2 using Student's t-test. As the RMS of acceleration is strictly dependent on the walking speed, the values of RMS-AP and RMS-LL were normalized with respect to those of RMS-CC, analogously to previous studies (Iosa et al., 2013; Iosa et al., 2012). The critical alpha was set at 0.05 for all data analyses.

6.3 Results

Twenty-one subjects were enrolled in this study, of those, one dropped out for heart disease. Clinical and demographical data are reported in Table 6.1.

Subject	Sex	MFCL level	Age [years]	Body mass [kg]	Height [cm]	Time since amputation [years]	Type	Etiology
1	M	K2	66	100	171	2	TSB	Vascular
2	M	K2	71	60	172	5	TSB	Neoplasia
3	F	K2	65	100	159	24	PTK	Trauma
4	M	K2	51	82	182	34	PTK	Trauma
5	M	K2	59	80	168	5	TSB	Trauma
6	M	K2	74	75	165	56	PTK	Trauma
7	M	K2	68	72	172	8	TSB	Vascular
8	M	K2	74	81	165	8	TSB	Vascular
9	M	K2	67	77	180	5	TSB	Vascular
10	M	K2	65	77	163	5	TSB	Vascular
11	M	K2	68	88	178	4	TSB	Vascular
12	M	K2	58	100	180	4	TSB	Vascular
13	M	K2	63	69	163	5	TSB	Vascular
14	F	K2	74	80	160	7	TSB	Vascular
15	M	K2	63	97	171	3	TSB	Trauma
16	M	K2	78	56	161	2	TSB	Vascular
17	M	K1	71	70	160	11	TSB	Vascular
18	F	K2	64	60	159	1	TSB	Vascular
19	M	K2	74	74	173	6	TSB	Vascular
20	M	K2	60	72	167	1	TSB	Trauma
Mean			66.7	78.7	168.6	9.8		
SD			6.7	13.2	7.6	13.5		

Table 6.1 - Demographic features of study subjects with different Medical Functional Classification Level (MFCL) fitting two main prosthesis' type: Total Surface Bearing (TSB) and Prosthese Tibiale Kegel (PTK).

For what concerns the score results of functional tests, statistically significant improvements were found at P2 in the LCI-5, BBS, HAI and SAI scores (Table 6.2).

Outcome	Score P1	Score P2	Z	p
BBS	50.5 (7.5)	54.5 (3.0)	-3.281	**0.001**
LCI-5	45 (18)	49 (16)	-2.521	**0.012**
HAI	7 (4.25)	7 (4.0)	-2.041	**0.041**
SAI	11 (4.25)	11.5 (4.25)	-2.251	**0.024**

Table 6.2 - Score results of Berg Balance Scale (BBS), Locomotor Capability Index-5 (LCI-5), Stair Assessment Index (SAI), Hill Assessment Index (HAI) during data collection sessions fitting the SACH (P1) and the multi-axial foot (P2) compared by means of a nonparametric Wilcoxon signed rank test. Data shown in this table are expressed as median (interquartile range), Z and p values (significant in bold) are reported.

Significant differences were found both in SAI going up and down times, whereas none were found in HAI uphill and downhill times (Table 6.3).

Outcome	Time [s] P1	Time [s] P2	t	p
HAI Walking up	43.6 ± 28.4	40.3 ± 33.0	2.064	0.276
HAI Walking down	40.8 ± 25.4	34.5 ± 17.2	1.121	0.053
SAI Ascending	32.0 ± 16.4	27.9 ± 16.4	2.522	**0.021**
SAI Descending	37.1 ± 23.4	31.8 ± 19.9	3.912	**0.001**

Table 6.3 - Uphill and downhill times in Hill Assessment Index (HAI) and going up and down times in Stairs Assessment Index (SAI) during the first (P1) and the second (P2) phase of evaluation, compared using two-tailed paired t-test. Value expressed as mean ± standard deviation (SD), t and p values (significant in bold) are reported.

The PEQ values showed significant improvements in these domains: Ambulation, Residual limb health, Utility and Well-being (Figure 6.6).
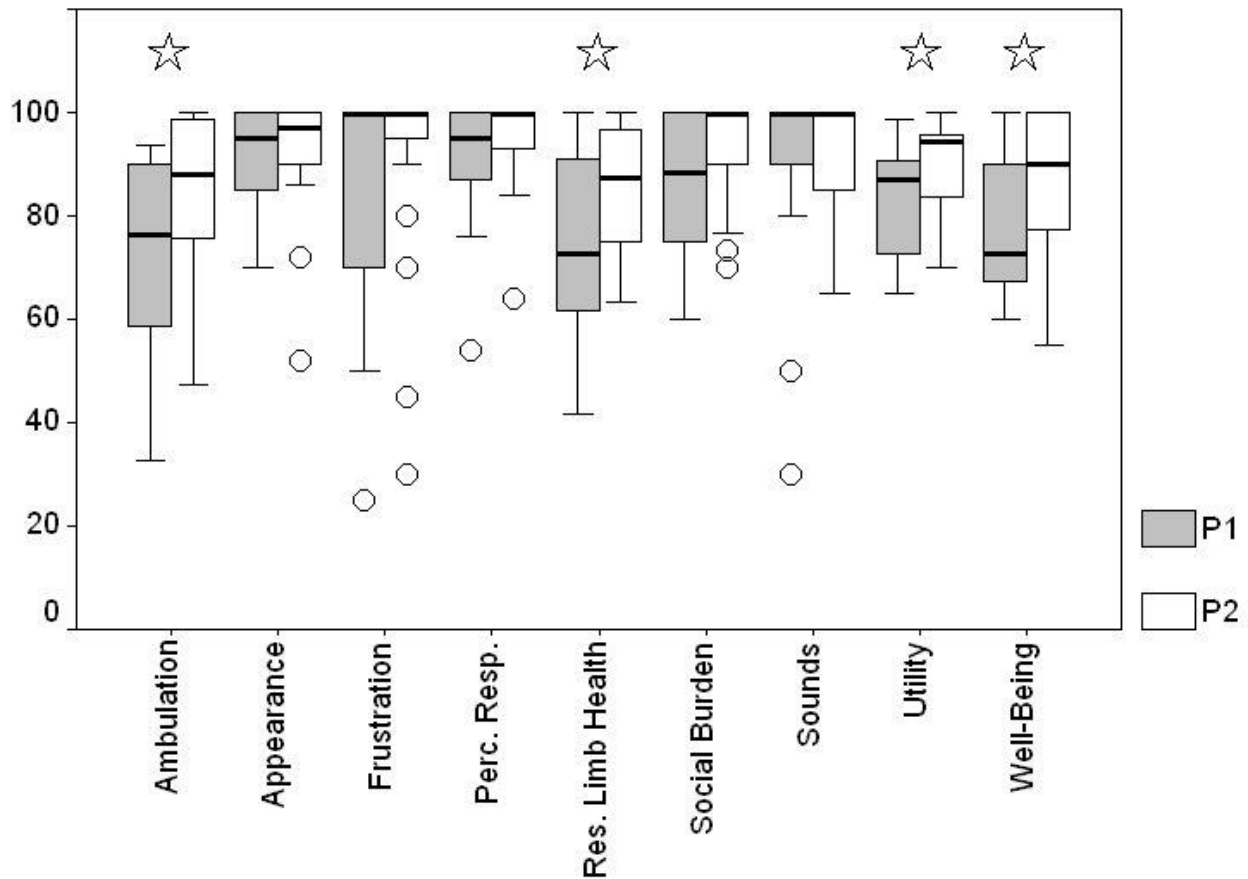
Figure 6.6 - Box-plots for the nine subscales scores of the Prosthesis Evaluation Questionnaire (PEQ). The boxes show the lower quartile, median (bold line), and upper quartile values, the whiskers represent the most extreme values within 1.5 times the interquartile range from the ends of the box, the circles represent the outliers (data with values beyond the ends of the whiskers). The ordinal data of the nine fuctional scales of PEQ have been compared between P1 and P2 using Wilcoxon signed ranks test. Stars show statistically significant differences between P1 and P2.

The mean SSWS during 6MWT was significantly higher (p=0.034) when participants used the 1M10 (0.71±0.27 m/s) compared to SACH (0.67±0.30 m/s).

The UGS results are shown in Figure 6.7. Despite the higher speed, accelerations on the transverse plane normalized for CC, resulted slightly but not significantly lower, with the 1M10 compared to the SACH foot (LL: 86.94±19.56% vs. 92.44±19.26%, p=0.056; AP: 94.67±20.05 vs. 95.62±18.00, p=0.785).
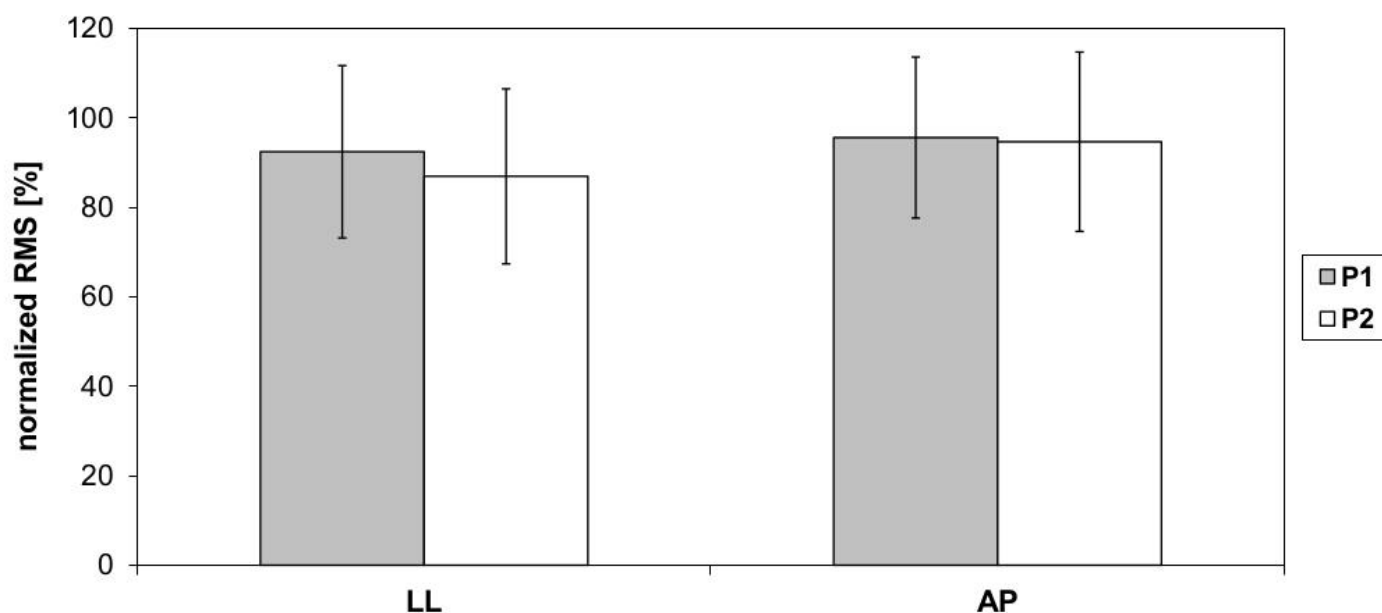
Figure 6.7. Root Mean Square (RMS) of acceleration along antero-posterior (AP) and latero-lateral (LL) axes normalized in respect to those of cranio-caudal (RMS-CC) by using the inverse of their percentage ratio in P1 and P2 (mean ± SD).

6.4 Discussion

The topic of this study, comparing the clinical effects of non-articulated and multi-axial foot-ankle mechanism on performance of low-activity users, addresses a concept that historically has received little attention in prosthetics research and is of clear interest to the clinical community involved in amputee rehabilitation.

Lower-limb amputees must learn to manage their own prosthesis in order to optimize mobility not only relating to the walking performance but also to negotiating ramps and stairs, balance performances, gait stability and general comfort. The prosthetic componentry may significantly affect these aspects, which are key indicators of the amputee's autonomy in activities of daily living. The collected outcomes measures were selected in order to investigate these important clinical aspects related to the use of prosthesis, addressing the working hypotesis and the central objective of this study. We have investigated more aspects of the prosthesis' usage as overall mobility, balance and general satisfaction in a group of low-mobility TTAs fitting the conventional SACH foot and, after an adequate acclimation period, a multi-axial one. 1M10 is endowed with a multi-axiality feature without dynamic elements on board and was supposed to yield a comparable or more adaptable gait with respect to the conventional SACH foot in the selected sample.

Comparisons between the two considered prosthetic feet showed that when using the multi-axial foot there were significant improvements in the overall SSWS, HAI, SAI, LCI-5, BBS and in some PEQ scales.

No significant differences were detected in the UGS, showing a similar clinical response with both prosthetic devices during walking. So, the increased number of DoFs in the multi-axial joint, appears to not jeopardize the subjects' stability during locomotion but to improve the perceived safety, as confirmed by the PEQ results (Ambulation) and by an improved walking performance during the 6MWT. Indeed the SSWS resulted significantly higher in our sample when participants used 1M10. Overall the SSWS value obtained in our study with SACH is considerably lower than that of Torburn (1.12±0.26 m/s), Snyder (1.06±0.16 m/s) and Nielsen (1.19±0.28 m/s), but all these authors have

enrolled unilateral TTAs with higher level of mobility than our patients (Torburn et al., 1994; Snyder et al., 1995; Nielsen et al., 1988). Zmitrewicz did not find significant differences in SSWS, almost equal with SACH and SACH-MA (SACH: 1.04±0.15 m/s; SACH-MA: 1.03±0.15 m/s) and however higher than our values, but also their study included only active TTAs (Zmitrewicz et al., 2006). Moreover the SACH-MA, although it has multi-axial properties, was a prototype designed specifically for the study and not commercially available.

It was not possible to compare our data with those of Marinakis, that reported the comparison between SACH and the Greissenger Plus foot, because their study did not report the overall SSWS but only walking speed of the limb involved, obtained by dividing the step length over the step time (Marinakis et al., 2004).

The LCI-5 did significantly improve fitting the multi-axial foot. This result was in contrast with those reported by Gailey who stated that the LCI-5 is unable to detect differences in participants' perception of mobility after fitting with four categories of prosthetic feet (Gailey et al., 2012). It must be considered, however, that the LCI-5 score of SACH users in the study of Gailey was on average above 54 points, which is considerably higher than that of our sample. We have found a median LCI-5 score of 45 with the SACH foot and a score of 49 with the multi-axial one, without any "ceiling effect" but with a significant increase (p=0.012).

SAI and HAI scores and SAI times results showed a significantly improved ability in walking up and down on inclined surfaces and ascending/descending stairs exploiting the multi-axial behavior of the 1M10, as shown in **Table 3**. SAI and HAI scores improved in P2 by a small but statistically significant quantity. This result was due to the fact that the SAI score was higher using the 1M10 in 6 subjects, equal in the two feet in 14 subjects, but none of them did the SAI-score result higher using the SACH. Similarly the HAI score was equal in 15 participants and higher in 5 between P1 and P2. Therefore the statistical significance observed in HAI and SAI score results probably derives from the fact that the increase, although very small, is highly systematic. Although they have shown a better gait pattern, confirmed by a systematic improvement in HAI score, participants exhibited a similar duration in walking up and down the ramp.

As expected, indeed, the ascent and descent HAI times showed only a slightly improving trend in P2. This result is not surprising, because persons with lower-limb amputation usually feel insecure on ramps especially walking downhill for fear of their body weight puling forward, unbalancing them and subsequently, leading to a fall. The HAI score measure persons' overall ability and quality of performance during hill negotiation. It is conceivable that subjects in P2 systematically improved the quality of the motor task execution, without affecting the measured HAI uphill/downhill time. In addition, it should be considered that both the feet tested have no active dorsi-flexion or dynamic components for greater uphill propulsion.

As shown in Table 6.2, all TTAs tested had a low risk of falling, both with the SACH and the 1M10. Indeed a BBS score of 0-20 indicates a high risk, 21-40 a medium risk, and 41-56 a low risk of falling (Berg et al., 1995). Differences in BBS have been said to be statistically significant, with a score improvement of nearly 10% with the multi-axial foot. However, the 4 points score increase value is very close to the minimum detectable change of this instrument for other pathological groups (e.g. for people with stroke is about 5 points (Hiengkaew et al., 2012).

Usally, higher velocity intrinsically implied higher accelerations. Both raw RMS and normalized ones were investigated during UGS. The RMS along the CC axis is usually more dependent on speed, and in fact it was higher when subjects walked faster using the 1M10. Conversely, when this parameter was used to normalize accelerations along the other two axes, no significant differences were detected. So, according to previous studies on upper body accelerations during gait (Iosa et al., 2014) it is conceivable to assert that subjects walked faster when they used 1M10 compared to when they used the SACH, with similar upright stability between the two feet. This means that stability is not jeopardized by 1M10 use, despite leading to faster SSWS.

Relating to the PEQ results, participants rated abilities to ambulate better when using the 1M10 ("Ambulation" scale), with an improvement of nearly 16% in the score. This fact confirms the results obtained in the outcome measures related to mobility presented above. Also the perceived residual limb health improved in P2 with statistical evidence ($p<0.05$). One might speculate that this result may be due to lower share and stress

forces perceived on the residual limb when the multi-axial foot was used but this study does not provide any scientific evidence to support this hypothesis. The other scales of the PEQ that were significantly improved, passing from the SACH to the 1M10 foot, were "Utility" and "Well Being" ($p < 0.05$) of the general comfort and self-rated quality of life. The score of the remaining 5 scales of PEQ showed small improvements, which were not statistically significant. PEQ data are coherent with those of SSWS, LCI-5 and SAI, with greater perceived mobility using the multi-axial foot.

Previous studies that compared two feet did not detect such evident differences (Hiengkaew et al., 2012) but this could be due to the heterogeneous or small samples of the participants involved. In fact studies indicate a lack of consistency in quantitative gait measures in prosthesis users, even with similar populations walking with comparable prosthetic configurations (Gailey et al., 2012). The biomechanical analysis of the two previous studies on the comparison between SACH and multi-axial foot (Zmitrewicz et al., 2006; Marinakis et al., 2004), showed that hypomobile TTAs do benefit from the flexibility provided by multi-axial ankles, improving the spatio-temporal time parameters and the ability to generate impulses with the residual leg, thus the loading symmetry between the residual and sound limb. As reported by the authors (Zmitrewicz et al., 2006; Marinakis et al., 2004), their study limitations refer to the the fact that they enrolled solely vascular (Zmitrewicz et al., 2006) or traumatic (in the early stages of rehabilitation and without the definitive prosthesis) (Marinakis et al., 2004) TTAs, focusing exclusively on the biomechanical analysis and not covering major aspects of life that can be affected while living with the prosthesis. Indeed, as highlighted by Marinakis, prescribing a prosthetic component as foot only on the basis of gait analysis data is unwise (Marinakis et al., 2004). In the present study we enrolled a sample of 20 K1-K2 TTAs, both vascular and traumatic, definitive prosthesis users: so, it is conceivable that these subjects had already internalized the presence of the prosthesis into their locomotor body schema. The contribution of this work provides useful evidence that could help practitioners in the amputee rehabilitation to select the more appropriate prosthetic foot for hypomobile TTAs through the data integration derived from experimental outcome measurements, such as mobility and stability, and clinical self-

reported scales, testing the same patients with two different types of feet and overcoming some limitations of previous studies (Zmitrewicz et al., 2006; Marinakis et al., 2004). Our results may be closely correlated with the findings of Zmitrewicz et al (2006). Indeed, they assert that SACH-MA produced the best combination of residual-to-intact leg braking and propulsive ratios: the clinical improvements can be related to loading symmetry and the ability to generate increased propulsion with the residual leg with the multi-axial feet. Therefore, to have a prosthetic joint that better reproduce the DoFs of the natural ankle (without dynamic and elastic elements that, as is well known, could destabilize the hypomobile amputees' gait) can improve quality of walking, balance and satisfaction perceived. In light of the results, significant improvements were observed in most of the outcome measures collected using the multi-axial foot. Thus, the working hypothesis was confirmed. Nevertheless, such improvements can be considered more or less clinically relevant. However, it can be argued that the increased number of DoFs in the multi-axial joint can provide a better, comparable but certainly not worse clinical response with respect of the traditional SACH.

6.4.1 Study limitations and future research

The study protocol, despite including walking on slopes, did not use specific functional tests focused on the comparison of the two feet on uneven terrain on which benefits of a multi-axial foot may be still greater than the rigid one on the basis of its design features.

Although the biomechanical analysis on the comparison between SACH and multi-axial foot has already been conducted (Zmitrewicz et al., 2006; Marinakis et al., 2004), further studies could thoroughly examine the biomechanical aspects of the 1M10 involving energy cost, kinetic and kinematic analysis and investigating the underlying mechanisms of the relationship between user performance/perception and prosthetic mechanical properties to more definitively explain the clinical effects that we have observed. Without actually quantifying differences in the mechanical function of each prosthesis, it may be argued that the 1M10 behaves similarly to the SACH foot when participants are subjected to the conditions associated with the battery of outcome measures collected.

Moreover it may be interesting to conduct an EMG analysis to understand how the change of foot could affect the residual muscle activities and therefore explain the significant improvement between P1 and P2 in the "Residual limb health" domain of PEQ. In addition a multi-axial foot could be compared with ESAR feet on the same category of patients or, alternatively, on the TTAs with higher mobility level to provide, more accurately, the applicable limit of this device.

6.5 Conclusion

To identify the most proper prosthesis and improve user efficiency and safety, it is important to study the effect of different feet on a specific category of amputees.

This paper fills an important gap in the literature as, to the best of our knowledge, there are no similar studies about the considered prosthetic feet for low-activity users with so wide a range of clinical evaluations. After the replacement of the SACH with a multi-axial foot, patients have maintained the same level of stability and perceived safety, while presenting a significant albeit slight improvement in some important clinical aspects of TTAs' daily living, as overall mobility, balance, general comfort and the perceived satisfaction with their own prosthesis.
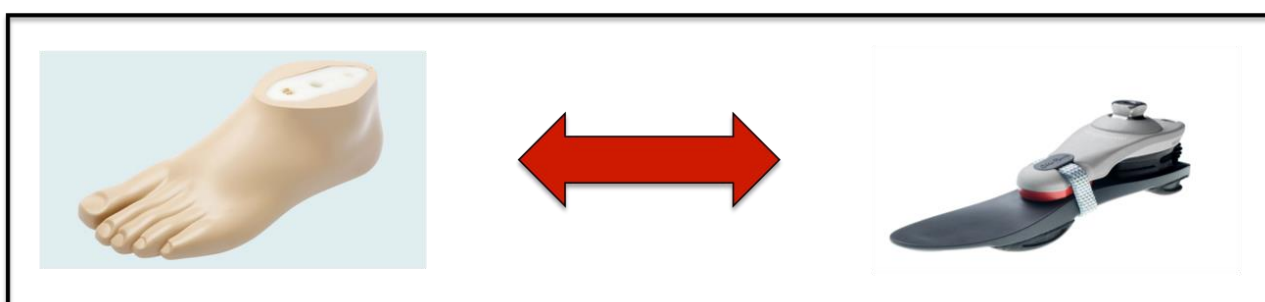
Figure 6.8 – The multi-axial foot has the potential to represent an effective alternative to the SACH. It can produce a better quality of life without great increase in prosthesis cost.

Our findings demonstrate that a multi-axial foot represents an alternative solution with respect to the conventional SACH in the prescription of prosthetic feet for hypomobile TTAs. Thus, the range of prosthetic devices available to practitioners involved in

amputee rehabilitation is increased, therefore allowing them to select the most appropriate solution for each specific subject based on their clinical experience.

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Chapter 7

ASSESSMENT OF THE EFFECTS ON CARBON FIBER AND BIONIC FOOT DURING OVERGROUND AND TREADMILL WALKING IN TRANSTIBIAL AMPUTEES

7.1 Introduction

As the ability to walk is one of the most important activities of daily living, transtibial amputees (TTAs) experience discomfort in their everyday life. Prosthesis feet design development has lead to more complex feet, thanks to the use of carbon fiber and of microprocessor driven motors or actuators.

Recently, a new microprocessor-controlled adaptive prosthetic ankle (i.e. Proprio Foot, Össur) was designed to improve the prosthetic technology for lower-limb amputees. As claimed by the producer, the Proprio Foot has a wide and automated range of ankle flexion that responds to the underlying terrain. The microprocessor allows the Proprio Foot to automatically increase dorsiflexion during the unloaded swing phase in ambulation, on level ground, stairs and ramps (Fig. 7.1). Some studies have reported benefits deriving from Proprio Foot use. Alimusaj reported that walking with Proprio Foot results in kinematics and kinetics that are closer to physiological patterns for the involved side (Alimusaj et al., 2009). This could reasonably produce a more energy efficient-walking pattern. Wolf reported that adapting the ankle angle of the Proprio Foot on stairs and ramps modified the pressure data registered at the stump making them more similar to those in level walking (Wolf et al., 2009). Agrawal reported that Proprio Foot resulted to have the highest degree of symmetry between the intact and the prosthetic limb (94.5%; a symmetry index of 100% means that an equal amount of work is done by the two legs) indicating that the vertical kinetic and potential energy changes

in the body center of mass caused by the Proprio Foot were similar to those produced by the intact foot (Agrawal et al., 2009).

Figure 7.1 - The electronic ankle Proprio Foot microcontrolling based (Össur, Reykjavik). It is is an adaptive prosthetic device for low to moderately active below-knee amputees that mimics natural foot motion. It has a rechargeable lithium-ion battery (1800 mAh) with output voltage = 14.8 V.

Figure 7.2 - The Proprio Foot during the swing phase automatically lifts the toe to reduce the risk of trips. Note the battery on the rear side of the socket and the Seal-In X5 liner under the test socket.

On the other hand, it has to be taken into account that the Proprio Foot has an additional weight, compared to a conventional prosthetic ankle (about 2-fold), that raises the importance of a good socket fitting since for "heavy" prosthetic device pistoning effects have been reported occasionally (Alimusaj et al., 2009). Pistoning is the vertical movement of the stump within the socket (Commean et al., 1997; Michael et al., 2004). It is minimized by an appropriate suspension system that secures the socket to the amputee's stump, guaranteeing prosthesis efficiency (Newton et al., 1988; Gholiadzeh et al., 2012). When pistoning occurs, the prosthesis fit is deteriorated and as a consequence occur the reduction of amputee's mobility and autonomy (Newton et al., 1998; Board et

al., 2001). Gholizadeh et al. reported that Seal In X5, Össur, provided less pistoning than the pin lock system, also when additional overload was applied to the prosthetic foot (Gholiadzeh et al., 2012). Seal In X5 is a prosthetic liner that holds five silicone hypobaric seals that are able to adapt to the internal surface of the socket (Fig. 7.2).

It guarantees vacuum socket suspension creating negative pressure between the liner and the socket by means of a one-way valve positioned in the distal part of the socket.

Although several studies have reported the benefits or otherwise of the Proprio Foot (Alimusaj et al., 2009; Wolf et al., 2009; Agrawal et al., 2009), to the authors' knowledge there are no studies on the energy cost of walking (ECW) using the Proprio Foot.

The main aim of the present study was to quantify ECW using the Proprio Foot in four different conditions: on the floor and on treadmill with three slopes (0%, 5% and 12%) in TTAs who use the dynamic carbon fiber foot (DCF). Considering the added weight of the Proprio Foot and the reduced pistoning of the Seal In X5, as reported by Gholizadeh et al. (2009), the Proprio Foot evaluations were carried out together with Seal In X5.

Other aims were: to compare ECW using the Proprio Foot and the DCF; to determine the length of the acclimation period needed to become accustomed to the Proprio Foot; to evaluate the effects of using the Proprio Foot on perceived mobility and ability to walk on stairs and ramps.

7.2 Methods

7.2.1 Inclusion criteria

(a) Unilateral transtibial amputation.
(b) Prosthesis user for at least 1 year.
(c) A mobility K level of 2 or more (DMEPOS, 2005).
(d) DCF user.
(e) Absence of pathological stump conditions counteracting prosthesis use.
(f) Absence of mental/clinical disorders.

10 transtibial amputees, Standard Suction Socket (SSS) and dynamic carbon fibre foot users.

Phase 0 (P0)
Evaluation session with SSS and dynamic carbon fibre foot
(ECW tests on floor and on treadmill; HS, HAI, SAI, TUGT and LCI-5)

Construction of the new socket for the Seal In X5 by an experienced prosthetist who kept all other prosthesis components unchanged.

Phase 1 (P1)
Intermediate evaluation (ECW tests, HS, HAI, SAI, TUGT and LCI-5) after 7 weeks of Seal In X5 use

Fitting and alignment of each prosthesis was performed by the same board certified prosthetist.

Phase 2 (P2)
Intermediate evaluation (ECW tests). The same prosthetist replaced the carbon fibre foot with the Proprio-Foot®and again checked the alignment and fit of the prosthesis (the other prosthesis components upstream remained unchanged). The TTAs were given instructions and directions on the use of Proprio-Foot ®, according to the manufacturer's indications. Then immediately after Proprio-Foot® delivery and use training (about 1 hour of use training) the TTAs performed ECW tests

Phase 3 and 4 (P3, P4)
Intermediate evaluation (ECW tests) after 30 and 60 days of Proprio-Foot® use

Phase 5 (P5)
Final evaluation after 90 days of Proprio-Foot® use
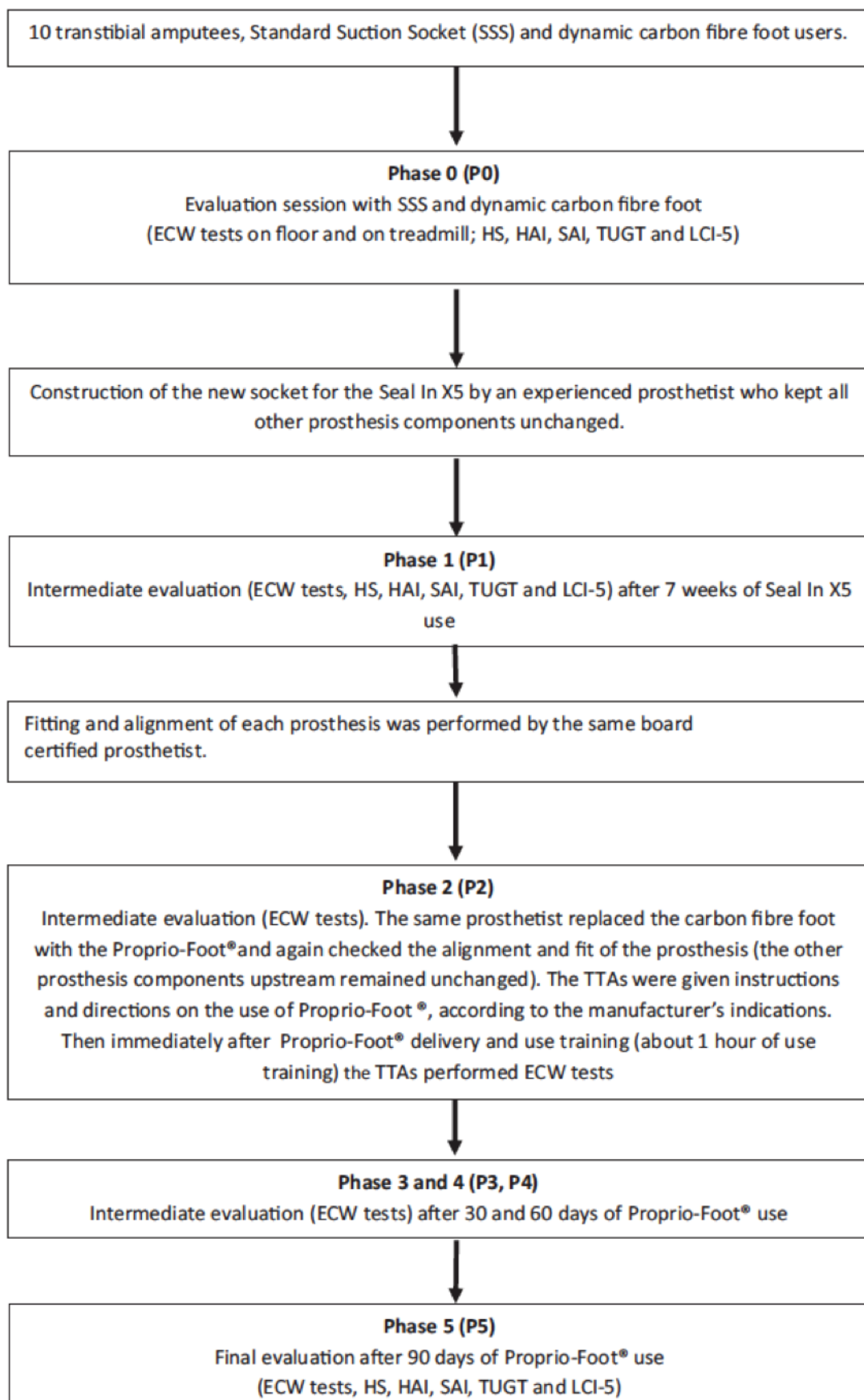(ECW tests, HS, HAI, SAI, TUGT and LCI-5)

Figure 7.3 - Study flow-chart diagram

The TTAs gave their informed consent and they received no payment. The local ethics committee approved the study. TTAs underwent several evaluation sessions (see Fig. 7.3). Before the first evaluation session, TTAs performed at least 2 trials on the treadmill with the slopes needed for the study to avoid possible learning effects of walking on the treadmill.

7.2.2 ECW data collection

The ECW tests were performed in the following conditions: on the floor (floor walking test: FWT), in a hallway with a regular surface, and on a treadmill at three different slopes, 0%, 5% and 12% (treadmill walking test: TWT0%, TWT-5% and TWT12%, respectively). During the walking tests, TTAs wore the portable metabolimeter K4b2 (Cosmed, Italy, Fig. 7.4) to collect metabolic data (oxygen consumption – V'O2; carbon dioxide – V'CO2; respiratory exchange ratio – RER, V'CO2/V'O2) and a heart rate (HR) monitor.

Figure 7.4 – The K4b² portable metabolimeter (Cosmed, Italy) used for ECW data collection.

In both the FWT and the TWT, TTAs were requested to walk at their own self-selected comfortable walking speed (SSWS).

Figure 7.5 – Patient preparation and floor walking test (FWT) performing instrumented with the K4b².

The TWTs were conducted on a RUNRACE model treadmill (Technogym, Italy), with the speed indicator covered; the TTAs chose their SSWS without knowing the speed indicated on the treadmill. The duration of each test was at least 7 min to allow participants to reach and maintain the steady state (SS) condition of HR and metabolic parameters. The ECW at SS, (ml/m/kg) was calculated as "oxygen consumption/speed". For FWT, mean walking speed was calculated as the ratio of distance to time. The trials were performed in a random sequence. The time interval between each trial was approximately 30 min (Schmalz et al., 2002).

Figure 7.6 – Treadmill walking test (TWT) at different slopes: level 0%; downhill -5% (-2.9°); uphill + 12% (6.8°).

7.2.3 Functional tests

7.2.3.1 Houghton Scale (HS)

The HS was used to measure time spent wearing the prosthesis and its functional use (Houghton et al., 1992). The HS consists of four items: time spent using the prosthesis, how the prosthesis is used, the need for an assistive device, and the individual's perception of stability while walking outside on a variety of terrains. The maximum score is 12.

7.2.3.2 Hill Assessment Index (HAI) and Stair Assessment Index (SAI)

The HAI (Buell et al., 2004) evaluates the ability to walk down a ramp. It is measured with an ordinal rating (ranging from 1 to 11) depending on subjects' quality of gait. The

SAI (Buell et al., 2004) evaluates quality of gait by observing TTAs' use of the handrail (or other assistive device) and foot placement while they descend 12 steps. It rates on 14-level items.

7.2.3.3 The Timed "UP&GO" Test (TUGT)

The TUGT, even if not specific for TTAs, was used to assess TTAs motor ability while wearing the prosthesis (Podsiadlo et al., 1991). The test measures the time (in seconds) needed by a subject to stand up from a standard armchair, walk 3 m, turn, walk back to the chair and sit down again.

7.2.3.4 Locomotor Capability Index-5 (LCI-5)

The LCI-5 was used to evaluate lower-limb amputees' ambulatory skills using the prosthesis (Grisè et al., 1993). The LCI, which includes 14 items, measures the ability to perform a number of motor tasks. The maximum total score of the index is 56.

7.2.4 Statistical Analysis

All data were reported as mean and standard deviation. A repeated measure ANOVA was carried out to evaluate differences among conditions and along the study length. When ANOVA analyses were significant at the 0.05 p level, post hoc analysis was carried out. For ordinal parameters, non-parametric analysis was conducted. For the comparison among phases (i.e., each phase from P0 to P5) Friedman's test was used. When the latter was statistically significant, a non-parametric post hoc multiple comparison was performed using Wilcoxon's test.

7.3 Results

Ten TTAs were enrolled. Their characteristics are reported in Table 7.1. At the time of enrollment all subjects had been using a standard suspension system (i.e., a total surface bearing socket, with a one-way valve that creates a passive vacuum between the liner and the socket) and a dynamic carbon fiber foot daily for at least 18 months. All participants were able to walk without aids and had been using the prosthesis continuously for 5–9 h a day. All subjects completed the study protocol. Table 7.2 reports functional data for walking tests. The RM ANOVA showed statistically significant differences during the observational period (i.e. P0–P5). As shown in Fig. 7.7, significant differences were found in ECW tests conducted on the floor between P1 and P5 ($p = 0.002$) and also between P0 and P5, p 0.0051, and also between P2 and P5, $p = 0.01$.

Subjects	Gender	Age [y]	Body Mass [kg]	Height [cm]	Time since amputation [months]	Functional level	Etiology	Liner	Foot
1	M	38	70	182	96	K4	Traumatic	Styrene Gel	Spiligite
2	M	41	91	179	96	K4	Traumatic	Styrene Gel	Truestep
3	M	35	76	175	228	K4	Traumatic	Styrene Gel	Variflex LP
4	M	23	50	160	84	K4	Traumatic	Styrene Gel	Truestep
5	M	44	98	173	288	K4	Traumatic	Polyurethane	Modular III
6	M	51	74	172	36	K3	Infection	Styrene Gel	Truestep
7	M	53	83	182	28	K3	Traumatic	Styrene Gel	Variflex LP
8	M	50	101	167	25	K3	Vascular	Styrene Gel	Variflex LP
9	M	54	96	180	144	K4	Traumatic	Polyurethane	Modular III
10	M	53	73	168	22	K3	Traumatic	Styrene Gel	Variflex LP
Mean		44.2	81	173.8	104.7				
SD		10.1	16	7.3	91.1				

Table 7.1 - Participants' demographic characteristics

Regarding the TWT, as reported in Fig. 7.7, ECW in the three TWTs showed a trend toward improvement. The changes in ECW (ml/kg/ m) in the evaluations were as follows: from P0 (0.33 0.09) and P1 (0.28 0.08) to P5 (0.26 0.1) on average 18% and 8% respectively in TWT 5% slope; from P0 (0.35 0.08) and P1 (0.35 0.14) to P5 (0.27 0.06) on average 18% and 13% respectively in TWT 0% slope; from P0 (0.57 0.13) and P1 (0.480 0.16) to P5 (0.481 0.11) on average 13% and +1% respectively in TWT 12% slope.
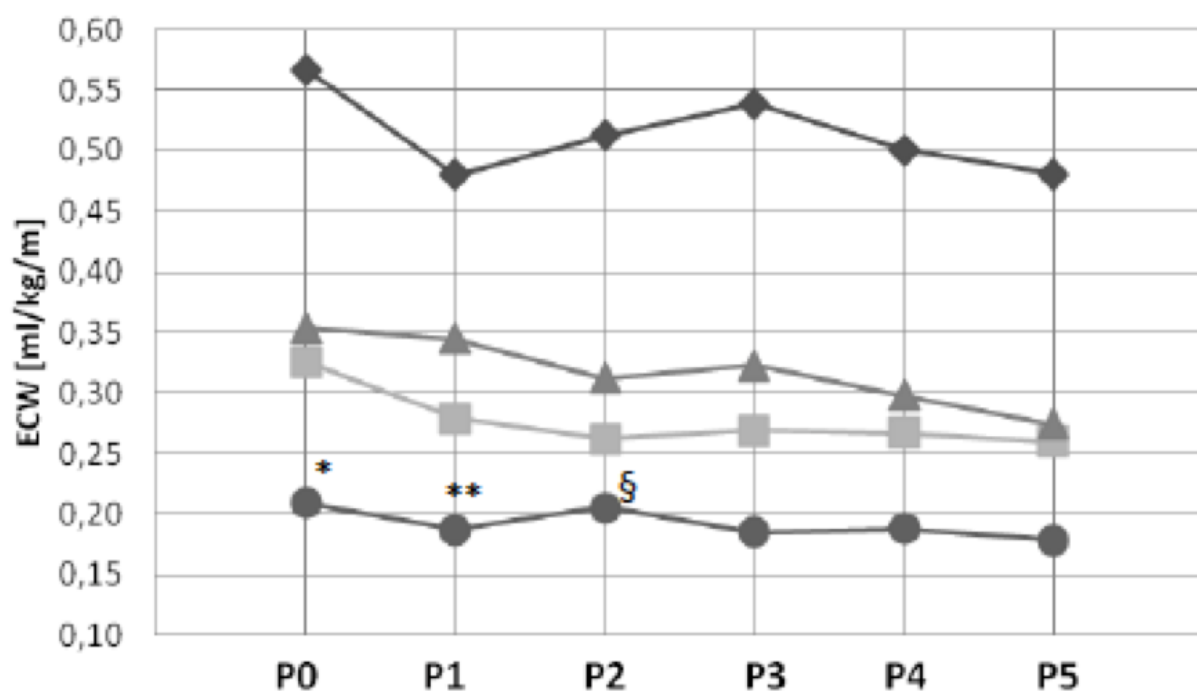

Figure 7.7 - ECW in the six phases and the four conditions. Legend: circle: floor; square: treadmill -5% slope; triangle: treadmill 0% slope; diamond: treadmill 12% slope. P0: phase 0 (subjects fit with standard suction system socket and dynamic carbon fiber foot); P1: phase 1 (subjects fit with dynamic carbon fiber foot an Seal In X5 for 7 weeks); P2: phase 2 (subjects fit with Seal In X5 and Proprio Foot, 1 h after delivery to the subjects); P3: phase 3 (after 30 days of Proprio Foot use); P4: phase 4 (after 60 days of Proprio Foot use); P5: phase 5 (after 90 days of Proprio Foot use). *P0 vs P5, p = 0.0051; **P1 vs P5, p = 0.002; §P2 vs P5, p = 0.01.

As shown in Table 7.2, walking speed remained substantially unchanged in the four conditions (FWT and TWT); also the fastest speeds were recorded on the floor and were always significantly higher than those on the treadmill ($p < 0.001$).

Regarding the acclimation period, as can be seen in Fig. 7.7, significant ECW improvement was observed on the floor after 90 days of Proprio Foot use. This amount of time was needed for the TTAs to become accustomed to the new ankle.

Table 7.3 shows the results of the HS, HAI, SAI, TUGT and LCI-5. As it can be noted for these parameters, that are very near to their own maximum achievable value, a trend of improvement without statistical significance was registered.

7.4 Discussion

The main aim of this study was to assess the ECW of TTAs when they walked on the floor and on a treadmill with different slopes. FWT has been widely used to assess ECW in lower-limb amputees (Traballesi et al., 2008; Chin et al., 2006; Traballesi et al., 2011; Genin et al., 2008). TWT was also used to evaluate the effects of prosthetic components on walking energy expenditure (Schmalz et al., 2002; Datta et al., 2004; Hsu et al., 2006). Although the FWT is preferable to the TWT (because the latter produces an overestimation of ECW (Dal et al., 2010) and does not indicate the individual's real walking capability (Traballesi et al., 2008) the treadmill tests were conducted to test the effects of the Proprio Foot on ECW while the participants walked on slopes, because the Proprio Foot is able to adapt ankle angle during ramp walking (Alimusaj et al., 2009). Slopes use in TWT on amputees was reported by Göktepe (Göktepe et al., 2010) and Huang (Huang et al., 2001). SSWS was used in all walking tests because at a natural walking cadence the lower-limb muscles work at a lower percentage of their maximum capacity (Teixeira-Salmela et al., 2008).

The potential benefits of the Proprio Foot on ECW might be affected by the increased weight (about twice that of the DCF), with negative effects on gait efficiency. Also, this added load could produce pistoning, affect the fit of the prosthesis and cause discomfort and/or greater energy expenditure, with less gait efficiency than with the DCF.

To reduce pistoning while using the Proprio Foot a new suspension system (Seal In X5, Össur) was given to all participants. According to Gholizadeh, it provides more efficient prosthesis fitting and significantly reduces pistoning (Gholiadzeh et al., 2012). All participants used Seal In X5 for 7 weeks, which is a suitable time period to be acclimated to a new suspension system (Datta et al., 2004), and were then given the Proprio Foot.

FWT results showed a significant reduction in ECW after 90 days of using the Proprio Foot compared with DCF in association with Seal In X5 (P1 vs P5: $p = 0.002$) and compared to P0 (P0 vs P5: $p = 0.005$). As stated before, ECW (ml/kg/m) is derived from the ratio between oxygen consumption (V'O2, ml/kg/min) and walking speed (m/min); in the FWTs, the SSWS (see Table 7.2) remained about the same in the study phases, but there was a 12% reduction of V'O2 between P1 and P5.

As expected, ECW on the floor was always lower than ECW on the treadmill (i.e. TWT 5%, 0% and 12%), $p < 0.005$. Similar results regarding the comparison between walking tests on the floor and the treadmill with a 0% slope were also reported by Traballesi (traballesi et al., 2008). The reason for the higher ECW on the treadmill may relay on the lower SSWS on the floor. The treadmill is an unnatural condition leading to a lower SSWS, even in people accustomed to using the treadmill, as the TTAs enrolled were.

	V'O$_2$ SS [ml/kg/min]				SSWS [m/min]				EI (%)				RER SS			
	FWT	TWT -5%	TWT 0%	TWT 12%	FWT	TWT -5%	TWT 0%	TWT 12%	FWT	TWT -5%	TWT 0%	TWT 12%	FWT	TWT -5%	TWT 0%	TWT 12%
P0	14.7±3.5	12.2±2.8	13.9±3.0	21.8±5.5	70.3±8.0	39.2±11.3	40.8±11.3	40.2±12.4	64±14	57±9	57±10	71±14	0.82±0.07	0.76±0.05	0.75±0.05	0.83±0.08
P1	15.1±4.2	10.9±2.4	12.7±3.3	19.7±7.3	74.2±6.7	41.5±14.7	43.0±14.7	42.8±11.9	61±12	53±7	55±7	65±10	0.79±0.15	0.81±0.04	0.78±0.06	0.86±0.07
P2	14.4±2.9	10.9±2.0	13.3±2.4	21.6±6.0	71.4±7.6	42.4±9.9	46.5±9.9	43.5±9.8	61±6	56±7	58±8	71±11	0.86±0.07	0.79±0.04	0.77±0.06	0.85±0.04
P3	13.4±3.1	10.7±3.2	12.6±2.3	19.7±5.8	71.5±5.3	41.5±11.2	41.3±11.2	37.2±13.3	58±8	52±6	53±7	63±13	0.81±0.06	0.78±0.08	0.77±0.06	0.84±0.05
P4	13.9±4.4	9.8±2.5	11.8±1.8	19.9±4.9	72.7±5.7	38.1±12.1	43.2±12.1	40.5±8.5	57±8	50±6	54±9	65±11	0.79±0.09	0.76±0.07	0.76±0.08	0.82±0.10
P5	12.8±2.6	9.7±1.8	11.8±2.1	19.8±5.5	71.1±5.1	41.7±12.9	45.0±12.9	42.5±11.8	60±6	54±6	56±6	68±11	0.83±0.06	0.81±0.08	0.79±0.06	0.87±0.06

Table 7.2 – FWT: floor walking test; TWT -5%: treadmill walking test with a -5% slope; TWT 0%: treadmill walking test with 0% slope; TWT 12%: treadmill walking test with a 12% slope. P0: phase 0 (subjects fit with standard suction system socket and dynamic carbon fiber foot); P1: phase 1 (subjects fit with dynamic carbon fiber foot an Seal In X5 for 7 weeks); P2: phase 2 (subjects fit with Seal In X5 and Proprio Foot, 1 h after delivery to the subjects); P3: phase 3 (after 30 days of Proprio Foot use); P4: phase 4 (after 60 days of Proprio Foot use); P5: phase 5 (after 90 days of Proprio Foot use). V'O$_2$: oxygen consumption; SS: steady state; SSWS: self-selected walking speed; EI: exercise intensity (percentage of age predicted maximum heart rate); RER: respiratory exchange ratio. * P1 vs P5 (p=0.006)

In any case, at all TWTs slopes, the ECW results showed a trend toward improvement (see Fig. 7.7). Considering that the SSWS remained substantially unchanged during the study phases (no significant differences were observed), the ECW improvements in TWTs can be ascribable to a reduction in V'O2, which on average was 7% in the three TWTs (5%, 0% and 12%) between P5 and P1. It was found a reduction of V'O2 lower than 5% in only 2 TTAs, whereas the average change was higher than 10% for the other 8 TTAs.

For submaximal effort, Armstrong reported that variations of less than 5% have to be considered normal (i.e., without clinical relevance) (Armstrong et al., 1985). Thus, although the variations observed in the present study are not statistically significant, they might be clinically relevant. It has also been reported that for submaximal effort (as in the present study, see Table 2), V'O2 increases with the addition of mass to the lower-limb.

Catlin reported that adding 0.1 kg per shoe resulted in a 1.9% increase in running submaximal V'O2 (Catiln et al., 1979). Furthermore, Martin reported an increase of 3.5% and 7%, respectively, with the addition of 0.5 kg mass to a runner's thigh or foot (Martin et al., 1985).

As the Proprio Foot mass was 0.4-0.5 kg more than the DCF mass, the reduction of ECW in all trials (secondary to a V'O2 reduction) using the Proprio Foot seems to indicate that the expected limitation deriving from the increased weight of the Proprio Foot is largely negated by its functional benefits. These findings suggest that if the weight of the Proprio Foot was the same as the DCF, then a greater reduction in V'O2 (and consequently of the ECW) would be found. Anyway, the hypothesis that a lighter weight could reduce V'O2 needs further investigation.

Regarding the acclimation period, considering that FWT indicates the individual's real daily walking capability with respect to TWTs (Traballesi et al., 2008), on the basis of the FWT ECW improvement, it can be assumed that 90 days are enough to become accustomed to the Proprio Foot.

The results regarding the subjective prosthesis evaluation (by means of the HS) showed a trend towards improvement, which suggests a more intensive and safe use of the

prosthesis. Regarding the functional tests, despite a significant improvement in FWT ECW, no motor capability tests showed significant improvement. Both HAI and SAI have been used in previous studies to compare and evaluate different prosthetic components (Hafner et al., 2007; Hafner et al., 2009).

	P0	P1	P5
HS (score)	10.4 ± 1.8	11.0 ± 1.3	10.7 ± 1.7
HAI (score)	10.7 ± 0.9	11.0 ± 0.0	11.0 ± 0.0
SAI (score)	12.4 ± 3.10	12.4 ± 3.10	13.4 ± 0.9
TUGT (s)	7.9 ± 1.6	7.4 ± 1.3	7.4 ± 1.4
LCI-5 (score)	51.8 ± 10.9	53.9 ± 4.3	52.4 ± 6.1

Table 7.3 – Results of the functional tests. P0: phase 0 (subjects fit with standard suction system socket and dynamic carbon fiber foot); P1: phase 1 (subjects fit with dynamic carbon fiber foot an Seal In X5 for 7 weeks); P5: phase 5 (after 90 days of Proprio Foot use).

As reported in Table 7.3, the investigated sample showed no significant improvement in walking down an inclined surface or descending stairs HAI and SAI, respectively. Further, the TUGT data also showed the high level of physical mobility of the present sample; the time to perform the test was always less than 8 s.

The high functional level of the sample investigated (mean LCI 52, K-level 3-4) was responsible for the difficulty in improving efficiency. Specifically, HS and functional tests were prone to high ceiling effects, which limited their ability to detect improvements.

On the basis of data obtained and results reported by other authors (Alimusaj et al., 2009; Agrawal et al., 2009; Commean et al., 1997), one may speculate that the improvement in the ECW produced by the Proprio Foot may be due to kinematics and

kinetics that are closer to the physiological patterns of the involved side. Human locomotion depends on several biomechanical factors: step length, cadence, walking speed, stance and swing time, which influence energy expenditure. Knowing which of these factors is most influenced by ankle properties is crucial to develop a more effective prosthetic component. Therefore, further studies are needed to deepen our understanding of how to improve prosthetic functioning and transfer the results to a wider population.

7.4.1 Study limitations

The first limitation of this study is the small sample size. It should be noted, however, that is very difficult to recruit amputees willing to change their prosthesis components and take part in a long-term study. The authors are also aware that to achieve the secondary aim, i.e., to compare the effects of the Proprio Foot on ECW with those of the DCF, the same data collection should have been carried out in TTAs using the Proprio Foot in association with their usual standard suction socket. Also, in this case the choice was secondary to the difficulty of enrolling TTAs.

Moreover, the study participants included TTAs with high functional status who had a young mean age. Thus, the results cannot be generalized across a wider population.

7.5 Conclusion

The results of this study indicate that the Proprio Foot is capable of reducing energy cost of walking in all the studied conditions, and with statistical significance on floor, despite its extra weight. Lastly, further studies are needed to investigate ECW, quality of life, perceived mobility and motor capability in older and/or less active TTAs.

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Chapter 8

A COMPARISON BETWEEN THE SUCTION SUSPENSION SYSTEM AND HYPOBARIC ICEROSS SEAL-IN X5 IN TRANSTIBIAL AMPUTEES

8.1 Introduction

The efficiency of the prosthesis is mainly guaranteed by its suspension method for securing the socket to the stump (Gholiadzeh et al., 2012). A proper method of prosthetic suspension ensures a well functioning and safe prosthesis (Kapp, 2004). Transtibial amputees (TTA) reduce their activity and limit prosthetic use because of residual limb problems and discomfort experienced at the socket interface (Astrom et al., 2004). In fact, the socket is the critical interface between the stump and the prosthesis (Laing et al., 2011). Residual limb volume and shape changes lead to gait instability, which causes poor adaptation to the socket by altering limb-socket interface pressure and increasing shear stress (Sanders et al., 2005). These events occur even in a "mature" residual limb (defined by Berke et al., 2004 as >18 months post amputation); in fact, unpredictable individual daily fluctuations of residual limbs were observed in transtibial prosthetic users (Zachariah et al., 2004). Board reported an average 6.5% residual limb volume reduction after only 30 min of walking with a standard Total Surface Bearing (TSB) socket with a one-way valve (Board et al., 2001).

Residual limb volume loss due to prosthetic use leads to increased vertical movement of the stump in the socket, called "pistoning" (Commean et al., 1997; Michael et al., 2004). This phenomenon is minimized by a good suspension system that secures the socket to the amputee's stump, guaranteeing prosthesis efficiency (Gholiadzeh et al., 2012; Newton et al., 1988). As pistoning increases, fit deteriorates, interface pressure and shear

stresses increase, and skin ulcerations may appear and limit the amputee's mobility and autonomy (Board et al., 2001; Newton et al., 1988).

The range of pistoning in the TSB socket of TTA has been studied using various methods. Board adopted a roentgen approach and applied different loads and found a mean tibia bone displacement relative to the end of the socket of 4 and 3.3 cm for the socket with electric vacuum pump and suction suspension system (SSS), respectively (Board et al., 2001). With the static photographic method, a mean displacement of 0.9 and 1.3 cm was found in the shuttle lock prosthesis duringn non-weight-bearing and when 30 N was applied, respectively (Gholizadeh et al., 2011). Using a motion analysis system to investigate the Seal-In X5 liners, Gholizadeh reported 0.0, 0.1, 0.1, and 0.2 cm of pistoning in non-weight-bearing, 30, 60, and 90 N conditions, respectively Gholizadeh et al., 2012).

Many studies have compared different suspension systems (Gholiadzeh et al., 2012; Zachariah et al., 2004; Board et al., 2001; Klute et al., 2011; Beil et al., 2002; Dumbleton et al., 2009; Sellers et al., 2005; Hachisuka et al., 1998). As far as it is known, however, no articles have been published to date that compare the two passive vacuum suspension systems currently available in TSB sockets, that is, the hypobaric Iceross Seal-In® (HIS) and the SSS. TSB suction sockets are widely used in clinical practice because of their better fit and suspension.

The passive vacuum system is obtained in both systems by means of a one-way valve positioned in the distal part of the socket. This valve creates negative pressure between the liner and the socket. In Össur's hypobaric Iceross Seal-In® (HIS) prosthetic liner, the liner holds five silicone hypobaric seals that are able to adapt to the internal surface of the socket, guaranteeing vacuum socket suspension without an external sleeve (Figure 8.1) (Gholiadzeh et al., 2012). In the SSS, the vacuum is obtained by placing a urethane knee sleeve over the proximal one- half of the exterior socket wall and the distal three-quartersof the thigh (Figure 8.1) (Board et al., 2001).

This study aimed to evaluate the influence of the HIS suction system on pistoning, quality of life, and efficiency compared with SSS in unilateral TTA. To achieve the goals above, the following tests and questionnaires were used: the pistoning test (PT) to

compare vertical movement of the stump within the socket, energy cost of walking (ECW) to check prosthesis efficiency, the Prosthesis Evaluation Questionnaire (PEQ) and the Houghton Scale Questionnaire (HSQ) to evaluate perceived mobility and quality of life with the prosthesis, and the Timed Up&Go Test (TUGT) and the Locomotor Capability Index (LCI) for functional mobility.

The determination of time needed by a new HIS Seal-In X5 user to reach or surpass the same suspension stability and ECW they had obtained using the SSS were also considered. It was concevable the vacuum obtained with the hypobaric seals would provide better socket suspension than that obtained with the external sleeve, and that this would result in less pistoning, and better user satisfaction and performance with the prosthesis

Figure 8.1 – Transtibial suspension system used in the study. Suction suspension system socket components on the left side, and hypobaric Iceross – Seal In X5 on the right.

8.2 Methods

To participate in the study, subjects had to meet the following inclusion criteria: (a) unilateral amputation of lower-limb atbelow-knee level, (b) age 20-65 years, (c) body mass <116 kg and stump at least 11 cm long (to allow using Seal-In), (d) TSB SSS prosthesis user for at least 18 months and for a minimum of 4 h per day, (e) K-level of 3 or 4 (HCFA, 2001), (f) ability to walk and perform ramp descending and ascending without aids, and (g) absence of significant clinical disorders.

10 TTAs were enrolled to participate in the study. They were selected from those who were already SSS and carbon fiber foot users in the amputee department database of Santa Lucia Foundation; they had never used a Seal-In liner and wore a prosthesis that was made in the last 18 months by the same expert prosthetist on our team.

The enrolled TTAs gave their informed consent to participate in the study, according to the guidelines of the local ethics committee that approved the study. Each participant was fully informed about the research and understood that participation in the study was voluntary. No fee was paid to participants in the research.

8.2.1 Pistoning Test

To measure differences between the SSS and the HIS, several PTs were carried out in each evaluation session as follows: first, to obtain a baseline measure, the patient was requested to stand only on the prosthetic limb and second, two measures were obtained when 0 and 30 N forces were applied to the prosthesis in the longitudinal direction while the TTA held the prosthetic leg straight in the air.

Figure 8.2 - The system specifically designed and developed for the study. It allows the modular application of loads distally, minimizing measurement errors due to the knee flexion. Each weight is 1 kg ($\approx$ 1N), with a mobile guide a the bottom.

The displacements (in mm) of the markers located on the greater trochanter (GT), proximal lateral end of the liner (PL), proximal lateral end of the socket (PS), and distal end of the socket (DS), as in the procedure described by Gholizadeh (Gholizadeh et al., 2011) were calculated. To minimize measurement errors, the means of the following displacements in each measure were calcualted: GT-PS, GT-DS, and PL-DS. The amount of displacement from the baseline identifies the pistoning movement: lesser the displacement, lesser is the pistoning.

Data were collected by photos acquired by high-resolution camera (Figure 8.3).

Figure 8.3 - The three conditions of the pistoning test on the hypobaric Iceross Seal-In X5. The baseline evaluation is on the left, 0 N applied to the prosthesis is in the middle, and 30 N applied is on the right. Note the markers on the thigh and on the socket.
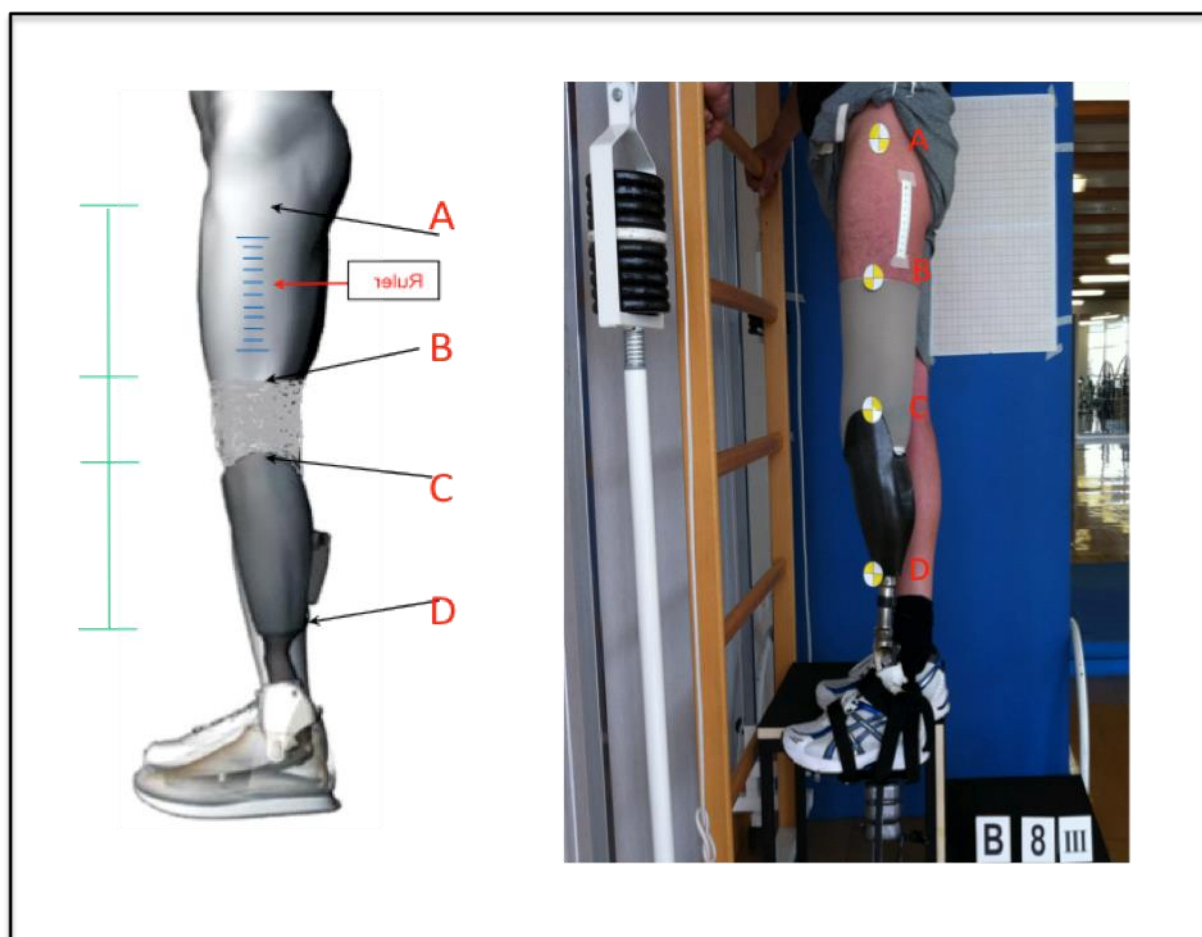
Figure 8.4 – Pistoning Test marker set. A = greater trocanter; B = external/upper edge of the liner; C = external/upper edge of the socket; D = lower edge of the socket.

Due to the presence of the sleeve in the SSS, the PS and the PL markers were positioned at the same level as the HIS but above the sleeve (Figure 8.4).

Compared with Gholizadeh et al.'s procedure, we did not test pistoning by adding 60 and 90 N because we noticed excessive knee flexion on the prosthetic side due to a load reflex of the knee muscles, which affected the pistoning measurements.

8.2.2 ECW Test

ECW tests were performed on the floor (floor walking test (FWT)) and on a treadmill (treadmill walking test (TWT)).

During the walking tests, metabolic data were collected using a portable metabolimeter K4b2 (Cosmed, Italy). This device guarantees breath-by-breath collection of oxygen consumption data. TWT were performed with ascendant slope (12%), descendent slope (5%), and without slope (0%). Slopes used in a treadmill test in amputees were reported by Göktepe (Göktepe et al., 2010) and Huang (Huang et al., 2001). In previous studies, TWTs were widely used to compare the effect of different prosthetic components on energy expenditure during ambulation (Datta et al., 2005; Schmalz et al., 2002). FWT is also widely used in amputee ECW evaluation (Chin et al., 2006; Traballesi et al., 2011; Genin et al., 2008). In both TWT and FWT, amputees were requested to walk at their own self-selected speed wearing the portable metabolimeter.

ECW at steady state was calculated using the formula: oxygen consumption/speed" (mL/kg/m). Trials were performed in a random sequence. The interval time between each trial was 30 min for recovery to baseline, as used by Schmalz (Schmalz et al., 2002).

8.2.3 Functional Tests

8.2.3.1 Timed Up & Go Test (TUGT)

TUGT was used to assess participants' motor ability when they were wearing the prosthesis (Podsiadlo et al., 1991). The test measures the time (in seconds) needed to

stand up from a standard armchair, walk 3 m, turn, walk back to the chair, and sit down again.

8.2.3.2 Locomotor Capability Index-5 (LCI-5)

The LCI-5 was used to evaluate lower-limb amputees' ambulatory skills with the prosthesis (Franchignoni et al., 2004). The LCI tests the ability to perform a number of motor tasks. It provides an aggregated score for 14 items. The maximum total score of the index was 56.

8.2.4 Clinimetric Scales

8.2.4.1 Prosthesis Evaluation Questionnaire (PEQ)

The PEQ is a self-report questionnaire that measures prosthesis-related quality of life and functional outcomes. It consists of nine independent functional domain scales: appearance, ambulation, frustration, perceived response, residual limb health, social burden, sounds, utility, and well-being (Legro et al., 1998).

8.2.4.2 Houghton Scale (HS)

The HSQ was used to measures time spent wearing the prosthesis and its functional use (Hiughton et al., 1989). It consists of four items: amount of time the prosthesis is used, manner in which it is used, individual's perception of stability, and whether walking aids are used while walking outside on a variety of terrains. Each item is scored on a 4-point ordinal scale, and the perception of stability questions is binary yes/no answers. The maximum score is 12.

8.2.5 Timing

In a pretest morning session, the same prosthetist on our team who had previously designed the SSS, checked the alignment and adequacy of each participant's prosthesis. Then each participant was administered the PEQ and the HSQ. Anthropometric (body mass, height) and anamnestic data were also collected. In the afternoon, the participants performed the PT with SSS. Preliminary walking tests on the treadmill (at three different slopes) were also conducted to allow TTAs to become familiar with the equipment and to avoid a learning effect. Two days later, TTAs were administered the ECW tests, LCI-5, and TUGT.

Meanwhile, the same experienced prosthetist began to construct the HIS starting from the plaster cast of the new socket, which is necessary for the Seal-In system. During the 2 weeks or so required manufacturing the HIS, the amputees met with the prosthetist three times. All other prosthesis components remained unchanged.

After 2, 5, and 7 weeks of HIS use, the participants performed the ECW tests and the PT at the same time as the SSS tests and wearing the same shoes. Before each session, body mass was measured to avoid erroneous comparisons between tests. The length of the acclimation periods was established on the basis of Datta's results (Datta et al., 2005). These authors reported that TTAs needed a minimum of 6 weeks to become accustomed to a new socket. LCI-5, TUGT, PEQ, and HSQ were administered after 7 weeks of HIS use. Figure 8.5 presents a flow chart of the study.
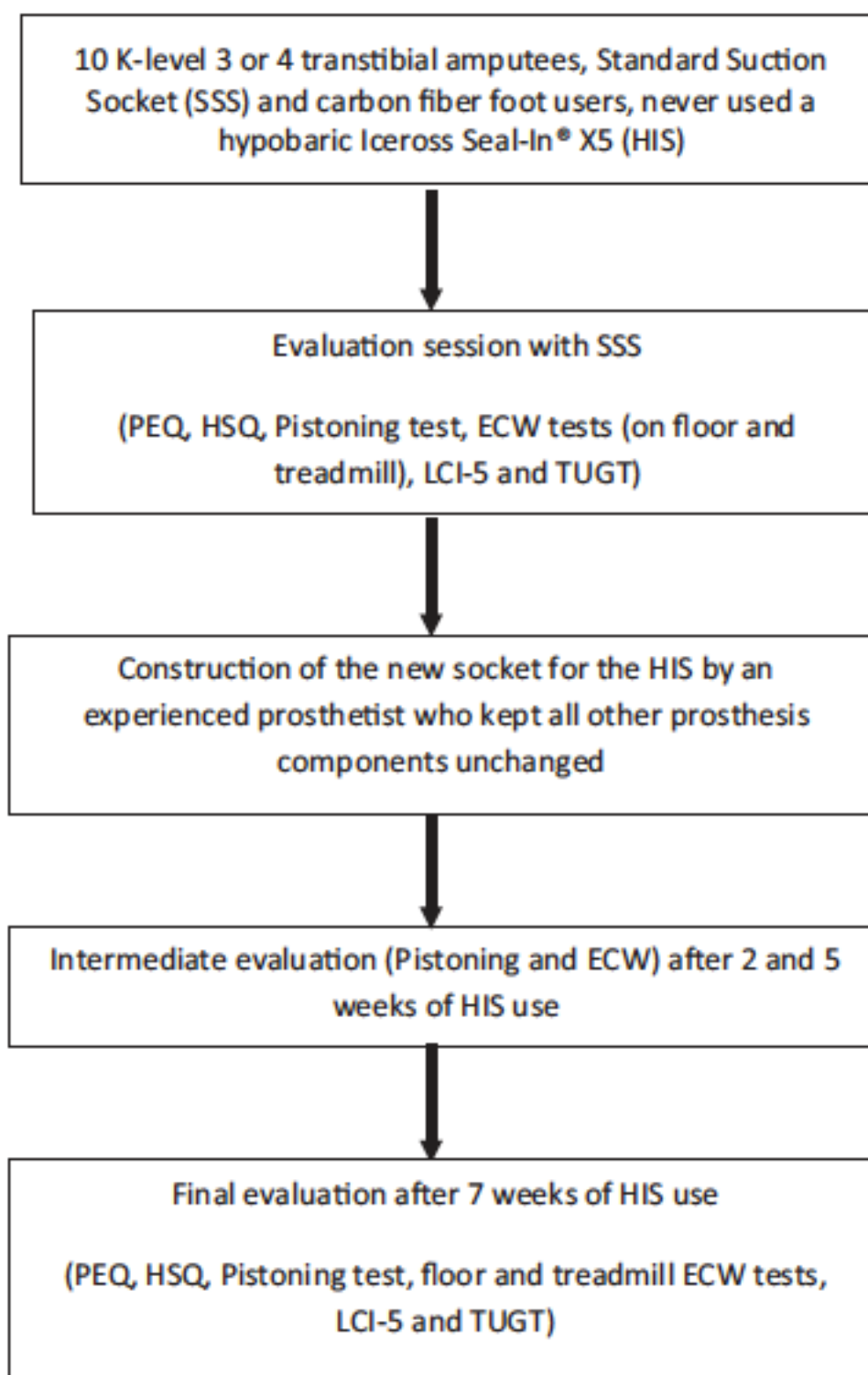
Figure 8.5 – Study flow chart diagram

8.2.6 Statistical Analysis

Statistical analyses were performed using Statistical Package for Social Sciences (SPSS) version 17.0 for Windows. All data were reported as means and standard deviations (SDs). A repeated-measures analysis of variance (ANOVA) was performed on continuous measures (TUGT, PT, and ECW tests) as within-subject factor along the observation period. Where ANOVAs were significant at a $p = 0.05$ level, a post hoc analysis was performed, setting the critical adjusted α-value by using Bonferroni's inequality. For non-parametric variables (PEQ, HSQ, and LCI), the Wilcoxon signed-ranktest analysis was performed.

8.3 Results

Ten male TTAs were recruited to participate in the trial. Their mean age was 44.9 years (SD = 9.5 years). All had been using a SSS prosthesis daily for at least 18 months and continuously for at least 6 h a day. All participants were able to walk without aids, and were active and employed. Demographic data are summarized in Table 8.1.

Subjects	Sex	Age [y]	Body mass [kg]	Height [cm]	Time since amputation [months]	Functional level	Etiology	Foot	Liner
1	M	40	68.6	182	96	K4	Traumatic	Sprilgite	Styrene gel
2	M	43	90.2	179	96	K4	Traumatic	Truestep	Styrene gel
3	M	37	76.6	175	228	K4	Traumatic	Vari-Flex LP	Styrene gel
4	M	24	50.0	160	84	K4	Traumatic	Truestep	Styrene gel
5	M	44	98.2	173	288	K4	Traumatic	Modular III	Polyurethane
6	M	51	74.6	172	36	K3	Infection	Truestep	Styrene gel
7	M	53	82.8	182	28	K3	Traumatic	Vari-Flex LP	Styrene gel
8	M	50	101.0	167	25	K3	Vascular	Vari-Flex LP	Styrene gel
9	M	54	95.8	180	144	K4	Traumatic	Modular III	Polyurethane
10	M	53	73.2	168	22	K3	Traumatic	Vari-Flex LP	Styrene gel
Mean		44.9	81.1	173.8	104.7				
SD		9.5	15.8	7.3	91.1				

Table 8.1 – Participants' demographic information and components of their standard suction socket. SD = standard deviation.

All participants completed the trial. The results of the PEQ are summarized in Table 8.2.

	Appearance	Ambulation	Frustration	Perceived response	Residual limb heatlh	Social burden	Sounds	Utility	Well-being
SSS	79 ± 21	71 ± 13	93 ± 0	95 ± 4	73 ± 26	87 ± 10	87 ± 10	68 ± 19	76 ± 8
HIS	88 ± 11**	84 ± 9**	90 ± 1	92 ± 9	76 ± 22	90 ± 8	90 ± 8	78 ± 14	87 ± 8**

Table 8.2 – Results of the PEQ (means ± SDs) administered with the SSS and after 7 weeks of the HIS use. PEQ: Prosthesis Evaluation Questionnaire; SD: standard deviaion; SSS: suction suspension system; HIS: hypobaric Iceross Seal-In X5

Significant improvement can be observed in the "Appearance", "Ambulation", and "Well-being" domains, as reported by participants when utilizing the HIS compared to their answers when they were using SSS.

With no additional weight, the vertical mean displacement with SSS was 7.5 ± 4.7 mm; with HIS, it was 4.7 ± 3.1, 4.6 ± 2.9, and 3.6 ± 3.1 mm after 2, 5, and 7 weeks of HIS use, respectively. As can be seen in Figure 5, use of the HIS led to reduced pistoning, with a statistically significant differ- ence between the first and the last assessment ($p = 0.016$), in which the mean difference between SSS and HIS displacement was 3.9 mm.

When an additional 30 N weight was applied to the prosthesis prior to the PT, HIS use produced a significant improvement after only 2 weeks ($p = 0.025$); and after 5 and 7 weeks of HIS use, the statistical difference could still be observed, with p values of 0.010 and 0.006, respectively (Figure 8.6).
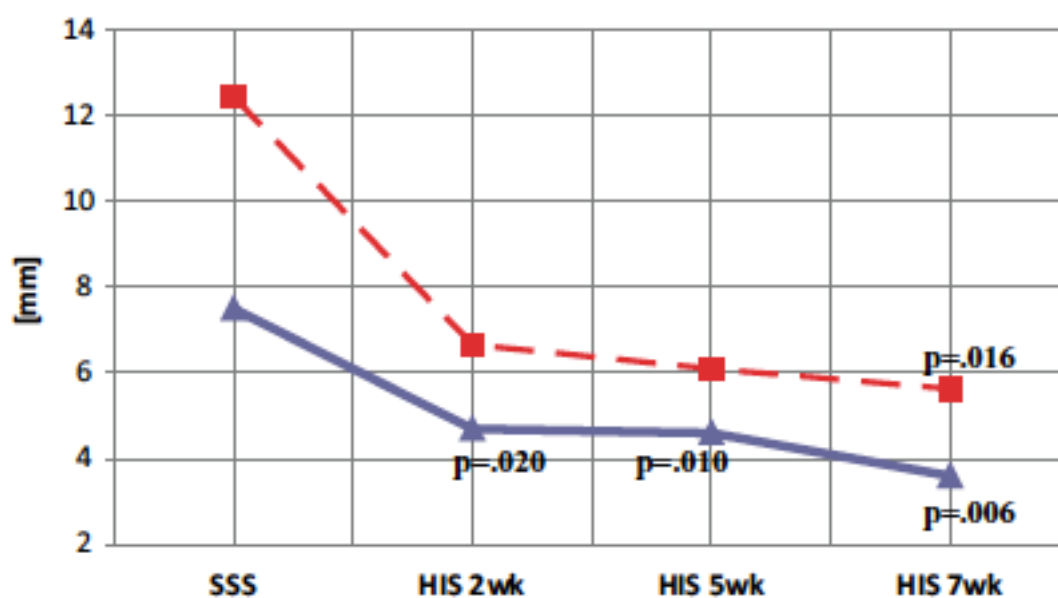

Figure 8.6 – Prosthesis displacement with no weight on the prosthesis (continous line) and with 30 N applied (dotted line). HIS: hypobaric Iceross Seal-In; SSS refers to evaluation with standard suspension system. HIS 2wk, HIS 5wk, HIS 7wk refers to evaluations after 2,5 and 7 weeks of hypobaric Iceross Seal-In use, respectively.

The mean vertical displacement with SSS was 12.4 ± 5.6 mm; with HIS, it was 6.7 ± 4.1, 6.1 ± 3.1, and 5.6 ± 3.1 mm after 2, 5, and 7 weeks of HIS use, respectively. In this test, the difference between the displacements with SSS and after 7 weeks of HIS was 6.8 mm. In both pistoning conditions (i.e. no weight and 30 N applied), no statistical differences were found in the data at 2 versus 5 weeks, 2 versus 7 weeks, and 5 versus 7 weeks of HIS use.
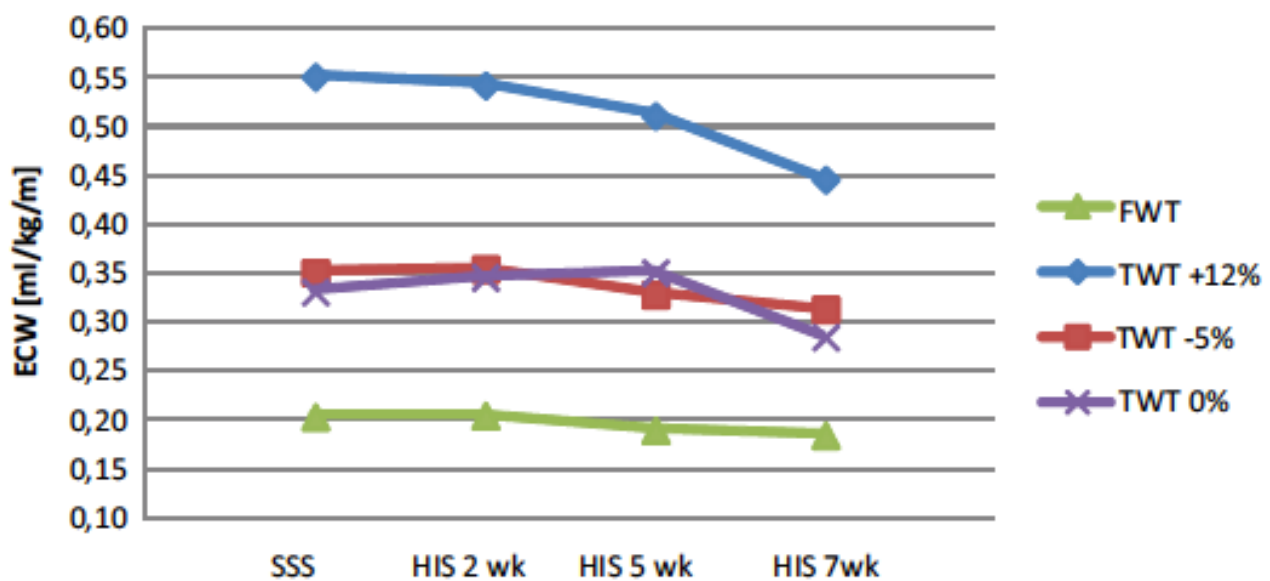

Figure 8.7 – ECW in the four evaluation sessions on floor and on treadmill at different scope. ECW: Energy costo f walking; FWT: floor walking test; TWT: treadmill walking test. SSS here refers to evaluation with standard suction system. HIS 2 wk, HIS 5wk and HIS 7 wk: evaluations after 2,5,and 7 weeks of hypobaric Iceross Seal-In X% use, respectively.

As shown in Figure 8.7, use of the HIS produced a reduction in ECW, which was more marked on the treadmill with the +12% slope. Improvement (mL/kg/m) in the evaluation with SSS and after 7 weeks of HIS use ranged from 0.20 ± 0.21 to 0.18 ± 0.03 (+10%) in FWT, from 0.35 ± 0.1 to 0.31± 0.04 (+11.5%) in TWT 0%, from 0.55 ± 0.1 to 0.44 ± 0.13 (+20%) in TWT +12%, and from 0.33 ± 0.11 to 0.28 ± 0.01 (+14.8%) in TWT -5%.

Nevertheless, no statistical significance was observed between the two systems in the four conditions. Although walking speed showed a trend toward improvement, it did

not reach statistical significance. When evaluated with the SSS, the mean FWT speed was 70.34 ± 11.11 m/min, and after 7 weeks of HIS use the mean speed was 74.21 ± 5.9 m/min, thus showing an increase of 5.5%.

LCI and TUGT data show a trend toward improvement using the HIS (Table 8.3). Statistically significant improve- ment was observed in HSQ (Table 8.3).

Evaluation methods		SSS (N = 10)	HIS (N = 10)
TUGT	Time (s)	7.9 ± 1.6	7.4 ± 1.3
HSQ	Score	10.6 ± 1.8	11.1 ± 1.3*
LCI	Score	52 ± 11	54 ± 4

Table 8.3 – TUGT, HSQ and LCI results (mean ± SD). SD: standard deviation; TUGT: Timed Up&Go Test, HSQ: Houghton Scale Questionnaire; LCI: Locomotor Capability Index; SSS: suction suspension system; HIS: hypobaric Iceross Seal-In X5. SSS subjects used their own habitual SSS prosthesis, and HIS subjects used the HIS for 7 weeks. *p = 0.005.

8.4 Discussion

This study investigated two of the most used passive vacuum suspension systems: the HIS system and the SSS. To ensure suspension of the prosthesis, both systems have a one-way valve that creates a vacuum between the liner and the socket, but the HIS needs a seal that adheres to the liner, not a sleeve. Gholizadeh (Gholizadeh et al., 2012) investigated the HIS and reported a 71% pistoning decrease with its use compared with a Dermo® liner (shuttle lock system), but their study was limited to the PT. In this study, a wide range of evaluations (PEQ, PT, HSQ, ECW, TUGT, and LCI) was used to explore a wider range of prosthetic function.

The PEQ data showed a statistically significant improvement in the Appearance domain, that is, the amputees thought the HIS prosthesis had a more pleasing appearance than the SSS prosthesis. Moreover, participants rated their abilities to ambulate higher when wearing the HIS ("Ambulation" domain). After 7 weeks of HIS use, participants also reported significant improvement in the "Well Being" domain. The PEQ improvements may also explain the significant improvement in the HSQ. In fact, the HSQ asks amputees whether they feel unstable when walking outside on slopes with the prosthesis and for how long and when they wear the prosthesis. In light of these results, it was also expected a significant improvement in "Utility", but, despite an improvement of 12.8%, the p level of significance in this domain was 0.057. Perhaps subjects were influenced by difficulty in donning the Seal-In X5 because it takes some effort to reverse the liner and roll it over the residual limb.

The importance of a proper suspension system to guarantee amputees' comfort and prosthetic function has been widely indicated in the literature, and vertical displacement or pistoning within the socket has been suggested to be one of the main indicators of suspension system efficacy in lower-limb prostheses (Gholiadzeh et al., 2012; Laing et al., 2011; Gholiadzeh et al., 2011; Beil et al., 2002; Eshraghi et al., 2012). A statistically significant reduction of pistoning with HIS use was found. This effect may be related to the vacuum provided by the hypobaric seals of the Seal-In® X5. By contrast, in the SSS, the sleeve provides the vacuum. Moreover, the values recorded with the SSS may be underestimated because the proximal marker (PL), which should be fixed, is placed above the sleeve and may be slightly dragged down by gravity and applied weight. The vertical displacements found by Gholizadeh (Gholizadeh et al., 2012) investigating the same Seal-In® X5 liner, were 0 mm in the non-weight-bearing (0 N) and 1 ± 0.8 mm in the 30 N applied condition after 4 weeks of HIS use. These values are lower than ours, that is, the mean displacement with HIS was 4.6 ± 2.9 mm in the 0 N condition and 6.1 ± 3.1 in the 30 N condition after 5 weeks of HIS use. These differences may be due to marker positioning and different measuring systems. Gholizadeh used the Vicon motion system and the transparent socket to check vertical movement in the socket (Gholizadeh et al., 2012). Comparing the results with those of Gholizadeh et al. (2012) using the same

PT methodology, the displacement observed in the 0 N and 30 N condition with a shuttle lock system (10 ± 9.2 mm and 14 mm, respectively) was found more than that obtained in the present study with the SSS (7.5 ± 4.7 mm and 12.4 ± 5.6 mm). Klute reported similar results in pin lock suspension pistoning at 0 N (6 ± 4 mm) (Klute et al., 2011).

To authors' knowledge, there are no studies comparing ECW with two different suspension systems in the recent literature (Sagawa et al., 2011). The energy cost on floor data with HIS (0.18 mL/kg/m) is similar to those reported in the literature for a comparable sample (0.16 mL/kg/m) and closer to those of healthy adults (0.15 mL/kg/m) (Waters et al., 1999) ECW was higher with SSS (0.20 mL/kg/m). The ECW data analysis showed that HIS might allow for more efficient gait, as reflected by the lower ECW and higher walking speed (not statistically significant) in all conditions.

The TUGT data show the high level of physical mobility of sample enrolled. Time needed to perform the test was less than 8 s with both suspension systems. These data are similar to those reported in an analogous sample (Lin et al., 208).

This study showed that HIS use decreases pistoning significantly, improves some aspects (appearance, ambulation, and well-being) of amputees' perception of their prosthesis and prosthesis function, and increases prosthesis use when compared with a standard suction socket. Patients' improved perception of mobility and functional outcome is not captured with objective functional tests (i.e. ECW and TUGT). The less pistoning experienced with HIS could be the main factor determining amputees' satisfaction because they felt more stable in the socket. It must be emphasized that the PEQ is sensitive to changes specific to prosthesis function and allows investigating important effects that probably would not be detected by any of the existing rehabilitation outcome measurements (Boone et el., 2006).

Despite a significant reduction of vertical displacement within the socket, neither motor capability test results nor ECW improved. However, it have to considered that the high functional level of the sample (mean LCI score of 52; K-level of 3 and 4) whose efficiency was hard to improve. In particular, LCI is prone to ceiling effects that would limit its ability to detect improvement (Miller et al., 2001). Moreover, the ECW test

results showed a non-significant trend toward improvement while using HIS. Regarding the aim to determine the time needed to become acclimated to the HIS, one may speculate that 2 weeks are enough to reach the same performance as that with the SSS. In fact, the ECW and the PT with no additional weight remained statistically the same with the two suspension systems after 2 weeks of HIS use. Moreover, PT with 30 N significantly improved after 2 weeks, but no further significant improvements were observed in the values after 5 and 7 weeks of HIS use. Significant improvement in both conditions (PT with no additional weight and 30 N) was observed after 7 weeks of HIS use. It can be speculated that this is the time necessary for new HIS users to fully adapt their sensations and residual limb muscles to the new proprioception provided by the different suspension socket.

8.4.1 Study limitations

The experimental sample was relatively small (10 subjects) because of difficulty in recruiting subjects willing to change their usual suspension system and take part in a study requiring many days of commitment. These difficulties have also been observed in previous studies: for example, Prince enrolled 5 TT amputees for a comparison between different prosthetic feet (Prince et al., 1998), and Klute analyzed the outcome of only 5 TT amputees when comparing PIN and a vacuum-assisted system because 15 patients dropped out (Klute et al., 2011). Indeed, the study population included only amputees of a given functional status who were active and had defined prosthetic components. Therefore, the results cannot be generalized across a broader population. In fact, the HIS produced insignificant reduction on the floor and treadmill ECW and on TUGT time; this may have been due to the high functional level of the present small sample. Future studies should recruit larger patient samples with broader functional levels.

8.5 Conclusions

Using the hypobaric Iceross Seal-In X5, there were fewer pistoning movements in the socket. This was associated with a statistically significant improvement in quality of life,

as reported by users. Moreover, HIS use led to improvement on the HSQ, which indicates more intensive and safe use of the prosthesis. In conclusion, this study shows that in unilateral TTAs, the HIS suction system (compared with that of the SSS) reduces pistoning and improves quality of life.

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Chapter 9

DESIGN OF AN EXPERIMENTAL PROTOCOL FOR THE MOTOR ABILITY ASSESSMENT IN TRANFERMORAL AMPUTEES: EVALUATION OF THE CAT CAM AND MAS PROSTHETIC SOCKETS

9.1 Introduction

Despite technological innovation in prosthetics has led to the manufacturing of ever more efficient modules, increasingly comfortable and performing, one of the most critical problems that the amputee patient found in his relationship with the prosthesis concerns the socket (Fig.9.1).

Figure 9.1 – Prosthetic socket for the transfemoral amputee, sagittal and frontal views.

Socket is perhaps the most low-tech prosthetic module but certainly, the most essential because, through it, the user can transfer his/her own body weight to the ground, allowing the residual limb muscles action for the dynamic and control strategy. In particular, socket shape is important for a good comfort in static conditions and during the stance, while the particular suspension system adopted is fundamental during the swing phase.

Altought its key role, the socket has been the least studied prosthetic component.

As transfemoral (TF) amputees have a greater energy cost of walking (ECW) than intact individuals and individuals with a lower amputation level (Waters et al., 1976), prosthesis design is typically aimed at improving their walking efficiency. The most used socket shape among TF amputees is the Ischial Containment (IC) Socket. It has an elliptical-shaped brim, a wide antero-posterior and a narrow medio-lateral size with a high lateral brim (Fig. 9.2, a-b). It is also known as CAT CAM (Contoured Adducted Trochanteric Controlled Alignment Method) or "ischial ramal weight bearing socket", because it encloses the ischial tuberosity and the ramus within the socket. For more than two decades, the CAT CAM socket supplanted the quadrilateral socket, also because it reduces the energy cost of walking (Gailey et al., 1993). More recently, about ten years ago, Marlo Ortiz Vasquez developed the Marlo Anatomical Socket (MAS) for TF amputees (Fig. 9.2, c-d). According to Trower (Trower et al., 2006), the MAS seems to provide greater ischial containment and mediolateral stability than other sockets; it also reduces trim lines and improves hip range of motion (ROM).

The main feature of the MAS design is that the ischium and gluteus maximum are not included in the socket because of the lowered posterior shelf. In TF amputees, CAT CAM socket interference limits the physiological ROM (Rabuffetti et al., 2005). Michaud (Michaud et al., 2000) found that at self-selected speeds TF amputees lift the pelvis on the swing side while walking. This compensatory motion, known as hip hiking, may require additional metabolic energy to lift body mass against gravity, thus reducing gait efficiency. Due to its characteristics, the MAS should reduce ECW and improve prosthesis-related perceived mobility compared with the CAT CAM socket. Assessing ECW is a functional evaluation method used to investigate the physiological response to

exercise. In the field of rehabilitation, this method is used to quantify the influence of disability on walking capacity (Waters et al., 1999). The ECW is commonly used to quantify the actual energy demand during walking (Waters et al., 1976; Traugh et al., 1975; Gonzalez et al., 1974; Gailey et al., 1994; Pagliarulo et al., 1979), and to compare the efficiency of different types of prostheses (Boonstra et al., 1995; Datta et al., 2005; Torburn et al., 1995; Schmalz et al., 2002; Casillas et al., 1995; James et al., 1986).
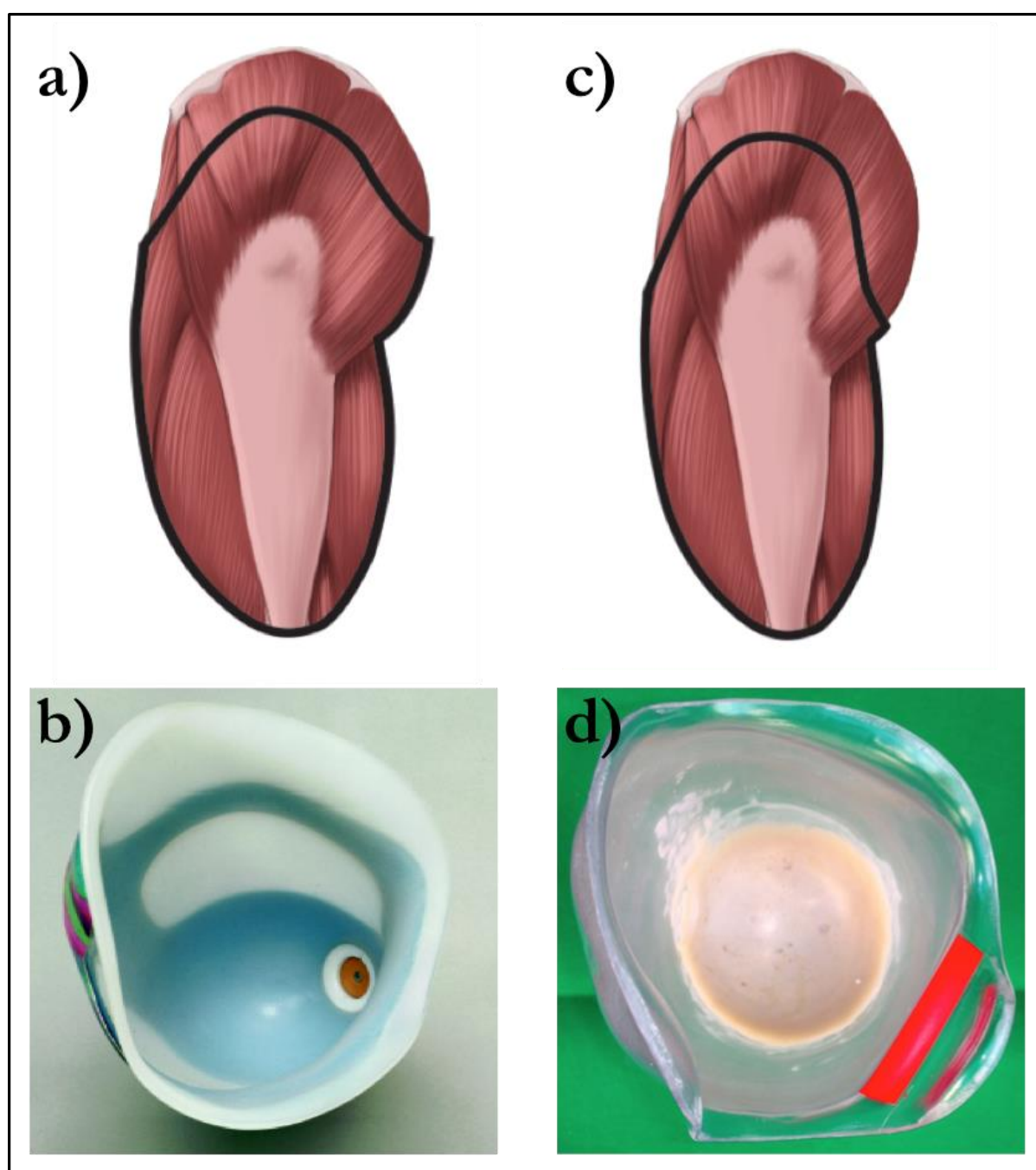

Figure 9.2 - Contoured Adducted Trochanteric Controlled Alignment Method (CAT CAM) socket: a) trim lines, b) view from above; Marlo Anatomical Socket (MAS): c) trim lines, d) view from above.

ECW evaluation is an important clinical outcome measure. In fact, ECW greatly influences the individual's ability to use the prosthesis and to walk, thus affecting autonomy level and quality of life. A recent study has found that the use of the MAS socket, compared with the CAT CAM, improves the gait efficiency in TF amputees, with a significant ECW decrease after 60 days of continous use (Traballesi et al., 2011). However, the main limitation of this study is to have investigated the impact of this new generation device only from the ECW point, not deepening the kinematic and dynamic aspects and reasons behind the reported improvement compared to the traditional CAT CAM socket.

Therefore, an ad-hoc experimental protocol for the motor ability assessment in TF was designed, aiming at investigating several biomechanical aspects related to the prosthetic sockets' use. In particular, the study focused on the comparison between the traditional CAT CAM socket and the new generation MAS (Traballesi et al., 2011). The main aim was to propose a methodological reference point to approach a clinical evaluation of the socket's impact on users for the rehabilitation team, discriminating those parameters that may be more clinically meaningful and easy to interpret.

This experimental protocol is meant to represent an all-round instrument for the assessment of the various aspects of TF patient's motor ability, using all available relevant tools (Fig. 9.3).
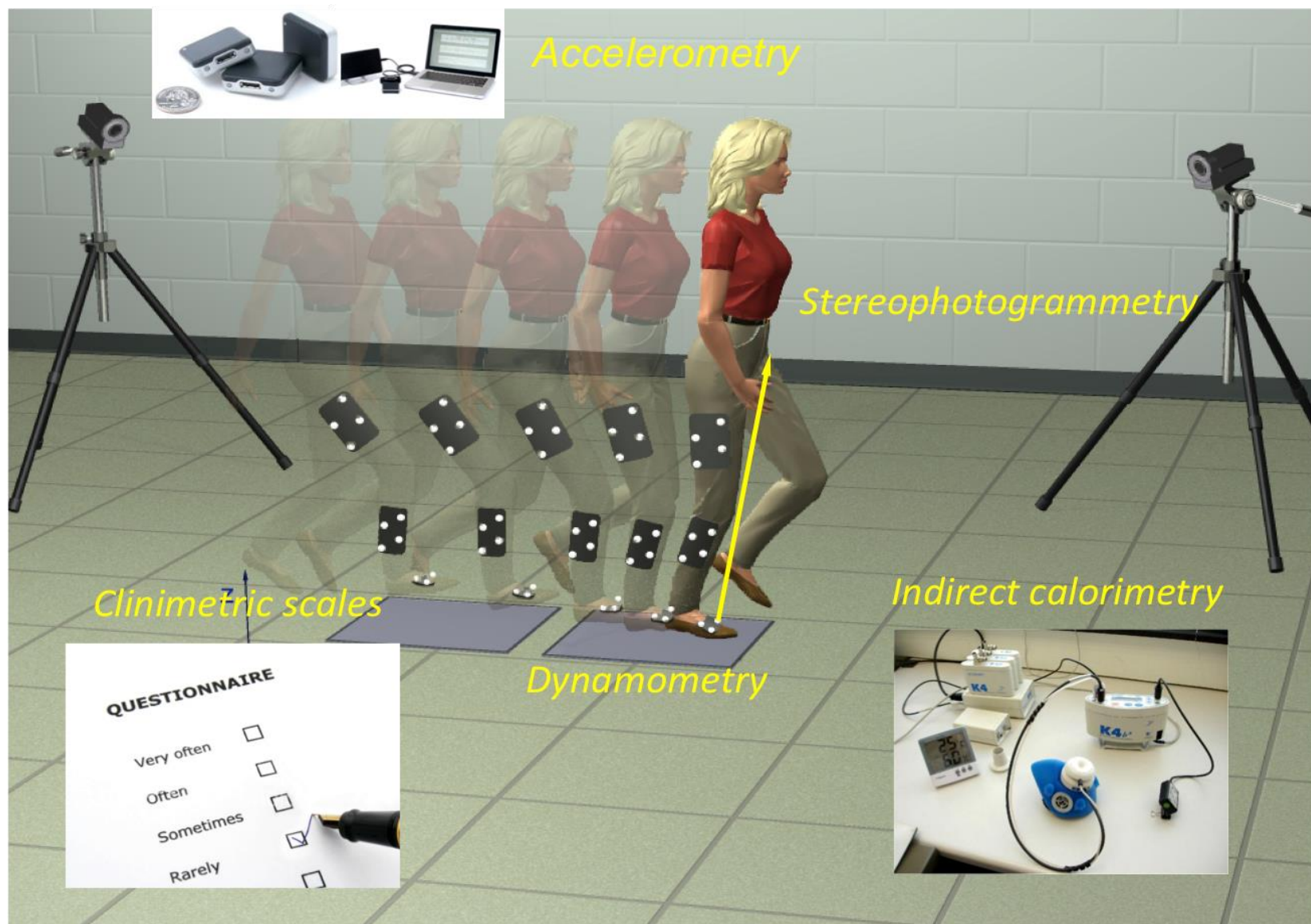
Figure 9.3 – The instrumental measurements tools involved in the experimental protocol proposed.

9.2 Methods

To participate in the study, subjects had to meet the following inclusion criteria: (a) unilateral amputation of lower-limb at above-knee level, (b) age 18 to 75 years (c) body mass <120 kg and stump at least 11 cm long; (d) CAT CAM socket user for at least 18 months and for a minimum of 4 hours per day; (e) K-level of 3 or 4; (f) ability to perform motor tasks besides walking at level without aids; (g) absence of significant clinical disorders or comorbidities. We enrolled 4 TFs to participate in the study. They were selected from those who were already CAT CAM users in database of ITOP Officine Ortopediche (Palestrina, Rome); they had never used a MAS socket and wore a prosthesis that was made at least form 18 months by the same expert prosthetist on our team. The enrolled TFs gave their informed consent to participate in the study, according to the guidelines of the local ethics committee that approved the study. Each subject was fully informed about the research and understood that participation in the study was voluntary. No fee was paid to patients who participated in the research.

A pilot test was preliminary conducted on a unilateral transfemoral amputee in order to assess the feasibility of the experimental protocol designed: this protocol was resulted applicable. It was carried out a preliminary study through pilot evaluations on people with different levels of amputation and, on the basis of type of subjects identified in the eligibility criteria of the protocol, the experimental activities has been starded in collaboration between the Locomotor Apparatus Bioengineering Laboratory (LABLAB) of University of Rome "Foro Italico" and the Applied Research on Amputees and Human performanceS laboratory (ARAHS lab) of IRCCS Santa Lucia Foundation of Rome.

The study consisted of three data acquisition sessions in which the same testing protocol was applied. After the first meeting with CAT CAM (P0) socket, a MAS socket was ad-hoc manufactured by the same expert prosthetist, and assessed after 30 (P1) and 60 days of continuous use (P2).

The length of the acclimation periods was established on the basis of Datta's results (Datta et al., 2005); these authors reported that transtibial amputees needed a minimum

of 6 weeks to become accustomed to a socket. As there are no data in the literature on the acclimation period needed by TF amputees following a change of socket (i.e. to one with a different shape), it was chosen 30-day and 60-day acclimation periods in according with Traballesi et al. (2011). The experimental tests were conducted with the same pair of shoes and at the same hour of the morning to avoid inaccurate data due to eventual fluctuations in residual limb volume. Participants carry out the following performed tests, allowing enough recovery time between each test in order to avoid effect of fatigue on measurements. The protocol firstly provided the recording of anamnestic and anthropometric data (age, time elapsed since amputation, body mass [kg], height [cm], stump length and the distal circumference [cm], sound limb length [cm], body mass index [kg/m^2], the MFCL classification level (HCFA, 2001) and the type of prosthetic modules in use.

Then, the following clinical scales, already described in previous chapters, were administered: Locomotor Capability Index-5 (LCI-5) (Franchignoni et al., 2004), Prosthesis Evaluation questionnaire (PEQ) (Legro et al., 1998) and Satisfaction with Prosthesis (SATPRO) (Bilodeau et al., 1999).

Following, tests for the kinematic, dynamic and metabolic characterization were performed.

A 9-camera stereophotogrammetric system (VICON MX13, sampling rate at 120 frames/second) was used to measure the three-dimensional trajectories of the 36 reflective markers placed on the body of the each subject, according to CAST (Calibration Anatomical System Technique) protocol (Cappozzo et al., 1995).

In detail, 2 markers were placed on the right and the left acromions, 4 on the trunk, 4 on the pelvis (anterior-posterior iliac spines), 4 on the sound limb thigh and 4 on the socket, 4 on tibia and 4 on tibial aesthetic cover of prosthesis, 3 on each foot and 4 on the head. The full marker set is shown in Fig. 9.4.
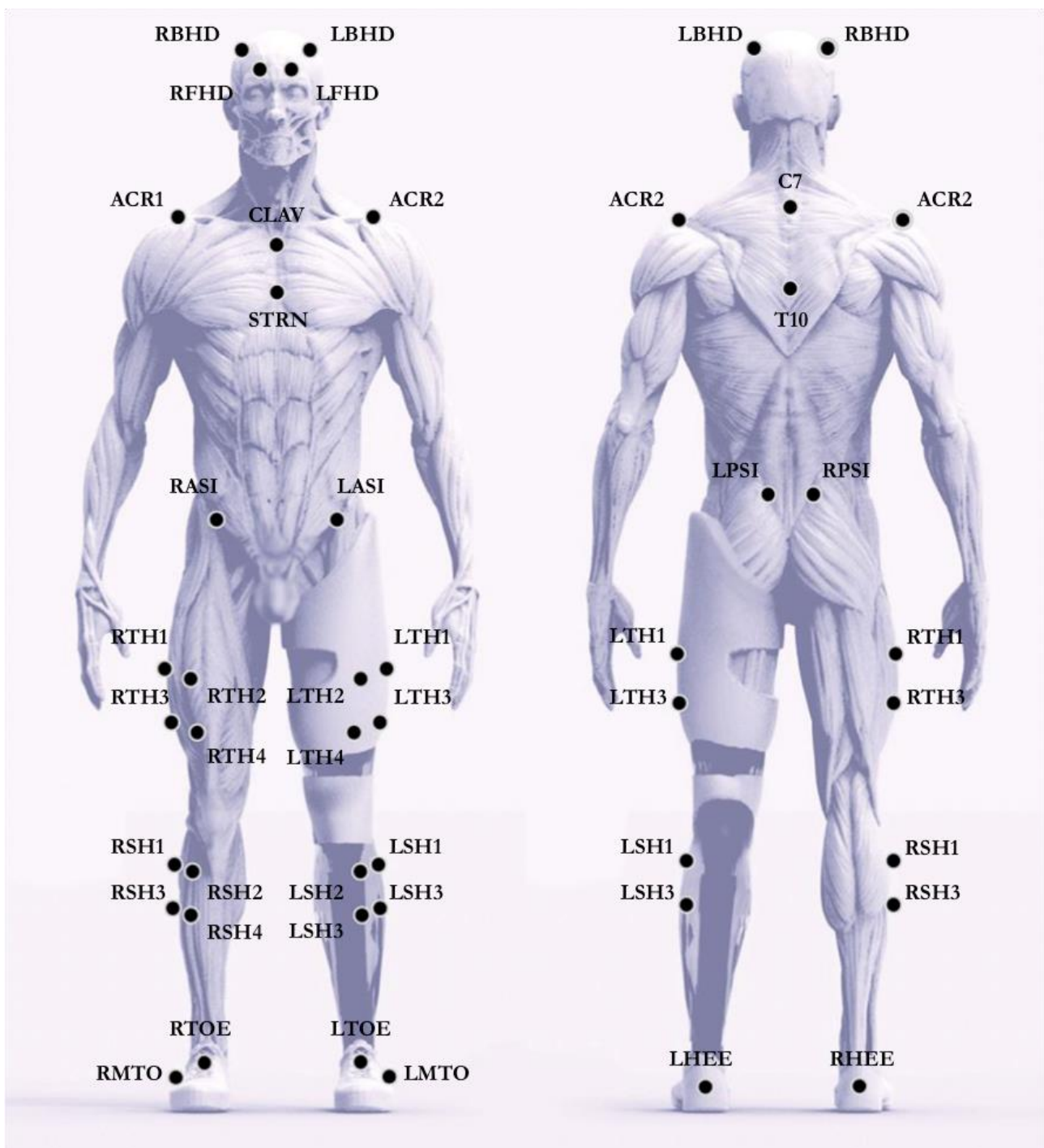
Figure 9.4 – Location of the passive retro-reflective spherical body markers arranged on the enrolled subject's body in relation to the human skeletal system. This marker set was specifically designed fot the present study.
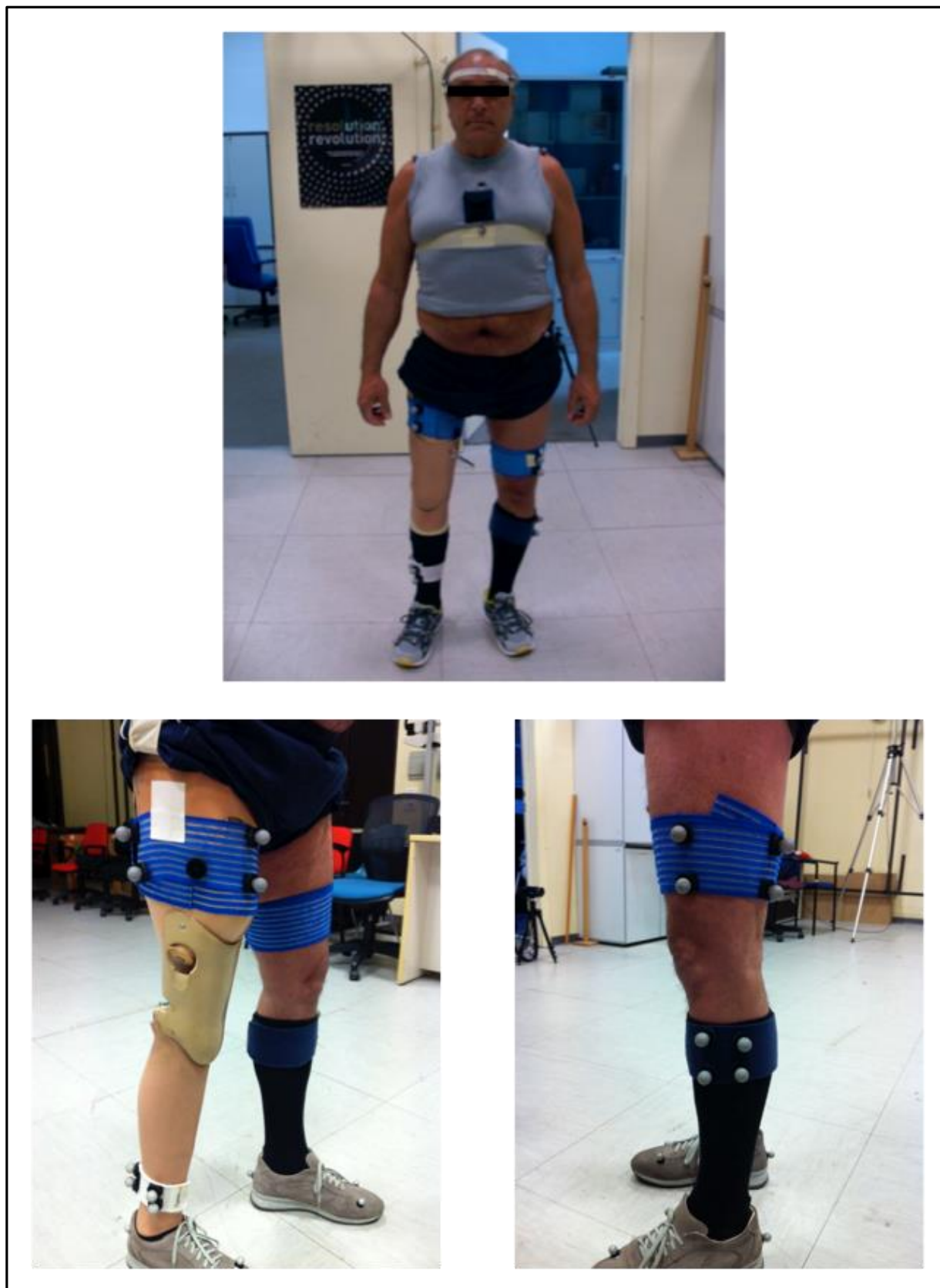
Figure 9.5 – Subject preparation to the functional test, particulars on the prosthetic (left) and sound (right) limbs. Note the black pocket at the sternal manubrium level with one MIMU inside (above).

SEGMENT	MARKER	CAST CALIBRATION
Head	RFHD, RBHD; LFHD, LBHD	
Upper Thorax	C7, CLAV	
Torso	STRN, T10	
Shoulder Joint	ACR1, ACR2	
Pelvis	RASI,RPSI; LASI, LPSI	
Thigh	RTH1, RTH2, RTH3, RTH4; LTH1, LTH2, LTH3, LTH4 (*Clusters*)	HJC movement, LE, ME
Shank	RSH1, RSH2, RSH3, RSH4; LSH1, LSH2, LSH3, LSH4 (*Clusters*)	LM, MM, HF, TT
Foot	RTOE, RMTO, RHEE; LTOE, LMTO, LHEE	
TOTAL markers	36	

Table 9.1 - Markers set landmarks. Head: left and right, anterior and posterior; Upper thorax: 7th cervical vertebra and clavicle; Torso: sternum and 10th thoracic vertebra; Torso: left and right acromion; Pelvis: left and right, anterior and posterior superior iliac spines; Thigh: clusters of 4, left and right, anterior and posterior (sound limb and socket); Shank: clusters of 4, left and right, anterior and posterior (sound limb and cosmetic cover); Foot: left and right, head of 2nd and 5th metatarsus, heel. HJC = hip joint center, LE and ME = lateral and medial femoral epicondyles; LM and MM = lateral and medial malleoli; HF = head of fibula; TT = tibial tuberosity.

A wand equipped with four markers was used for the anatomical calibration to identify the lower extremity anatomical landmarks of interest, while the subject maintained the upright posture. The wand containing markers of known distance separation, placed at

an anatomical landmark, indicates the global coordinates of this landmark once the orientation of the wand is known. Pointing the wand tip at specific anatomical landmarks, may be used to provide a high degree of accuracy without the limitation of soft tissue artefact or marker placement inaccuracy. This calibration method using the wand has been reported to have very high accuracy with error of less than 1 mm (Donati et al., 2008). The hip joint centre (HJC) and the mechanical axis of the knees were identified through the functional approach (Camomilla et al., 2006). The functional calibration was performed using a star-arc-movement (flexion/extension-abduction/adduction of the hip in different planes followed by a half circumduction), on both sound and prosthetic sides. Besides kinematic analysis for the data acquisition, the ground reaction forces for each weight bearing were measured through three Bertec force platforms. Subjects wore also three Magneto-Inertial Measurement Units (MIMU) (Opal, APDM Inc., Oregon, USA), which incorporate 3D accelerometer, gyroscope and magnetometer. Sample rate was set at 128 Hz, and full-range scale was set at +2g, with g = 9.81 m/s, ± 1500 °/s and ± 600 μT, respectively. The Opal MIMU (Fig. 9.6) can be used in the robust synchronized streaming mode, thus, data are directly streamed on multiple and synchronized monitors without the risk of losing data in case of interruptions during the wireless signal transmission.

Figure 9.6 - The Opal (APDM) Magneto-Inertial Measurement

Participants wore stretch clothes and swim cap with pockets in which were placed the sensors at the level of the sternum, the pelvis and the head for the measurement of linear accelerations and angular velocities along/around the three anatomical axes, according to the study described in Chapter 5 (Fig. 9.5).

Recorded acceleration signals were low-pass filtered with a 4th order Butterworth filter with a cut-off frequency of 20 Hz. The instantaneous linear acceleration vector components were measured as represented in the inertial frames embedded in each sensor case, defined by gravity and local magnetic North. The system output includes the instantaneous orientation of each sensor case with respect to the respective inertial frame. Using this information, the local acceleration local components measured by the different units were expressed in a global reference frame where the vertical (V) axis was defined by gravity, the antero-posterior (AP) axis by the direction of the walk path and the medio-lateral (ML) axis according to a right-handed reference frame. Bias removal was also carried out to improve the quality of the signal (Bergamini et al, 2014). Further, a commercial video-camera (JVC GC-PX10) was used to record each test to facilitate the clinical data interpretation.

9.2.1 Level walking test

Subjects were asked to walk in straight line at their self-selected walking speed, turn 180° at the end of a 10 m pathway and return to the starting position (Fig. 9.7). The kinematic data were recorded by the stereophotogrammetric system and the three MIMU, the ground reaction forces by the three force platforms hidden in the middle portion of the walkway pathway, positioned in series. Each subject performed 3 trials in each phase of the data acquisition (P0-P1-P2), in order to have a minimum of 5 foot rests on the force platforms for each limb.
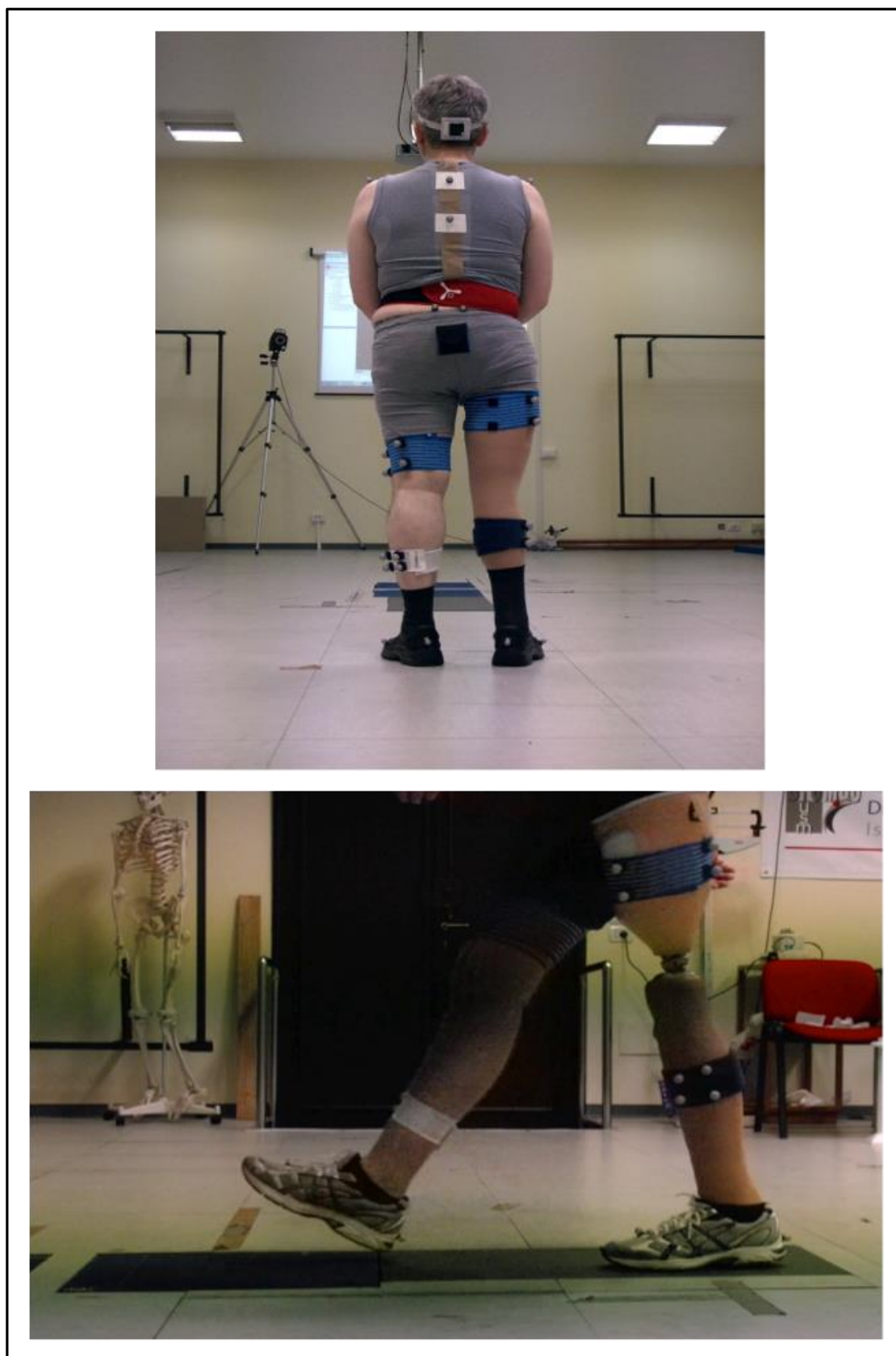
Figure 9.7 – The level walking test. Starting position (upper) and the foot prosthetic flat moment on the first force platform (lower).

9.2.2 Sit to Stand test (STS)

Each subject was asked to start in sitting position with both feet (natural and prosthetic) resting on the two separate force platforms (with a standard chair positioned off of them), to perform a chair rising with arms free, and to maintain the upright position for about 10 seconds before returning seated (Fig. 9.8). This functional test was carried out to measure the ground reaction forces both of the sound and the prosthetic limb, to objectify any load distribution asymmetries and to check the differences between the CAT CAM socket (P0) and the MAS one (P1-P2). The kinematic data were recorded by the stereophotogrammetric system and the three MIMU, the ground reaction forces by the three force platforms hidden in the middle portion of the walkway pathway, positioned in series. 3 trials of the STS in each phase of the data acquisition were performed.
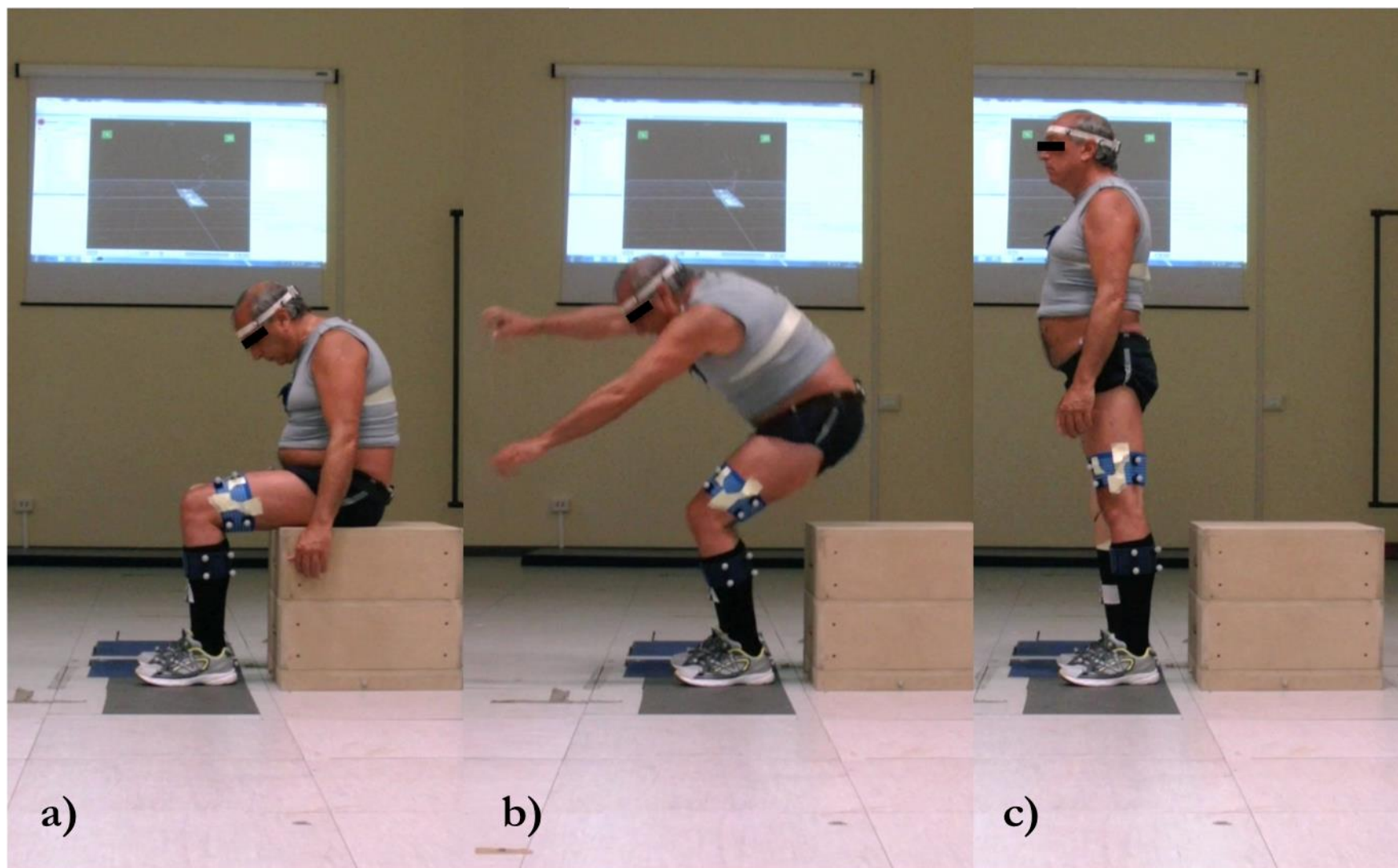
Figure 9.8 – The Sit To Stand test. a) starting from sitting position; b) rising up; c) upright posture mainteinance. Note that both the feet are on the two separate force plateforms.

9.2.3 Timed Up & Go test (TUGT)

Each subject was asked to stand up from a standard stool, walk for 3 m and come back to the stool, and sit down again (Fig. 9.9). The test is measured in time (seconds), the stopwatch should start when the assessor say "go!" and should be stopped with the subject's buttocks touch the seat. The kinematic data were recorded by the stereophotogrammetric system and the three MIMU, the ground reaction forces by the three force platforms hidden in the middle portion of the walkway pathway, positioned in series. 3 trials of the TUGT in each phase of the data acquisition (P0-P1-P2) were performed.

Figure 9.9 – The Timed Up & Go Test.

9.2.4 Six-Minute Walking Test (6MWT)

Each subject was requested to walk at his own self-selected walking speed up and down a 30 m linear course in a hallway with a regular floor surface, wearing a a breath-by-breath portable gas analyzer (K4b^2, Cosmed) and a heart rate monitor (Polar Electro Oy) (Fig. 9.10). The K4b^2 was calibrated before every test according to the manufacturer's procedures. This device guarantees breath-by-breath collection of oxygen consumption data. The 6MWT was instrumented also with the MIMU. At the end of 6MWT, the 0-10 Borg scale (Borg et al., 1982) for the rated perceived exertion was administered. This rating indicates how hard a subject feels a motor task. This is a subjective measure but a person's exertion rating may provide a fairly good estimate of the actual heart rate during physical activity.

Figure 9.10 - The Six-Minute Walking Test instrumented with a gas analyzer, an heart rate monitor and three MIMU.

9.3 Preliminary results

A sample of four TF amputees (3 right and 1 left), age: 41 $\pm$ 9 years, height: 173 $\pm$ 15 cm, body mass: 75 $\pm$ 13 kg, leg length: 82 $\pm$ 18 cm, body mass index 24.9 $\pm$ 0.3 kg/m^2, stump length: 52 $\pm$ 10 cm, stump width 41 $\pm$ 5 cm, ischial containment socket CAT CAM user at least since 4 years, participated in the study.

The entire sample enrolled has completed all three phases of acquisition provided by the study (P0-P1-P2). Preliminary results are related to the analysis of the STS through force platforms signals and metabolic cost measurements during the 6MWT.

During the 6MWT the following parameters were recorded: hearth rate (HR), self-selected walking speed (SSWS), oxygen consumption (VO$_2$), respiratory exchange ratio (RER), total distance covered (6MWD), energy cost of walking (ECW). Steady state data was calculated as the mean value of data collected in the last 2 minutes of data recording. ECW was calculated as follows: V'O2 (ml/kg/min) / SSWS (m/min).

Regarding the STS test, following parameters were taken into consideration:

1) The duration of the STS: times of the rising up from the chair, (acquired through MATLAB) taking as reference points the previous instant to the stage of "Counter" and the end of the stabilization phase "Rebound" (Entyre et al., 2007).

2) The peak value of the vertical force (Fv) generated during the rising phase, both of the sound limb and residual limb. These values were also normalized to the subject's body weight.

3) The ratio of the area under the force Fv curve: the force curves trend does not generate, as in able-bodied subjects, two patterns substantially overlapping, but two well distinct curves due to the typical asymmetry of amputee subjects. These curves have been evaluated in the different tests and retest phases of the study.

The statistical analysis was carried out using the SPSS software (SPSS 21.0, SPSS Inc.), with alpha level set at 0.05. As first, test Shapiro – Wilk was performed to verify the normality of data, then a repeated measurements ANOVA (for all variables was verified

the normality assumption, p>0.05) in order to investigate the new socket effects during the three acquisition sessions P0, P1 and P2. When ANOVA showed significant differences among the variuos sessions, post-doc Bonferroni multiple comparisons was performer to identify in which session each variable showed those differences. For the parametric analysis, comparisons were carried out using paired t-tests, while for data non normally distributed a Mann-Whitney U test was performed. Correlation analysis was carried out using the Spearman correlation coefficient between the parameters of interest.

In Table 9.2, times spent by each subject enrolled to perform the STS test in the three evaluation phases are reported. All participants improved their STS times with a statistical significance in retests P1-P2 with the MAS compared to those of P0 with the CAT CAM socket. Demographic sample data are shown in Table 9.3, the prosthetic components in Table 9.4.
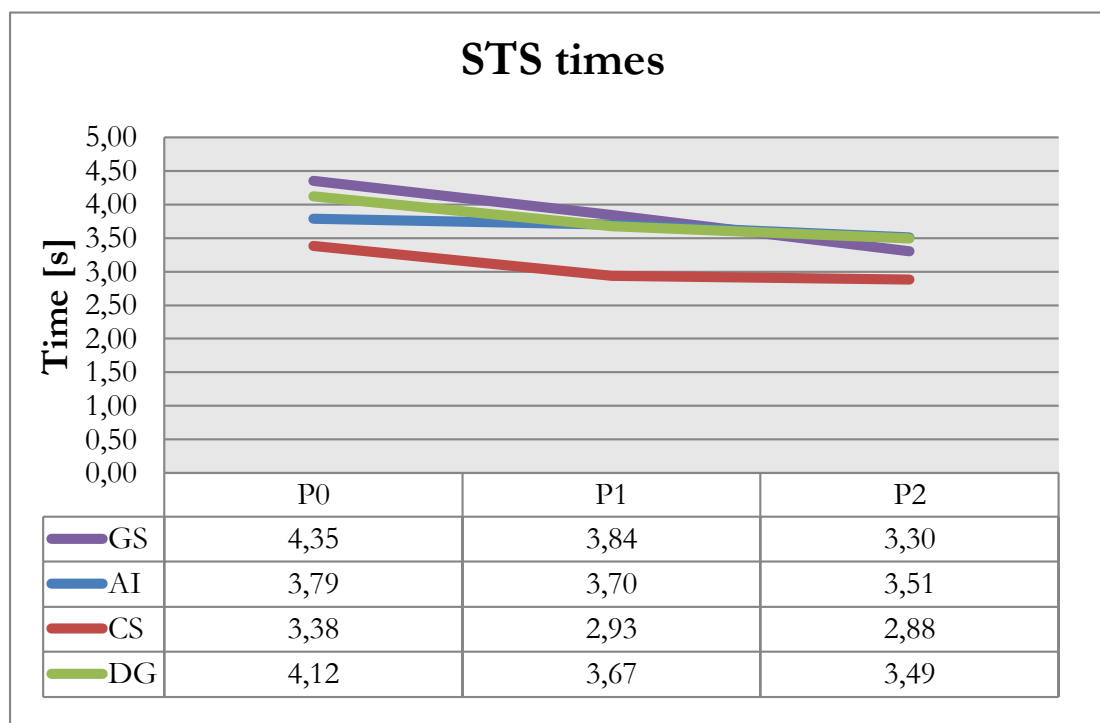
STS times

	P0	P1	P2
GS	4,35	3,84	3,30
AI	3,79	3,70	3,51
CS	3,38	2,93	2,88
DG	4,12	3,67	3,49

Table 9.2 – Sit to Stand test times of the four subjects enrolled.

Subject	Age (years)	Body mass (kg)	Height (cm)	Amputation side	K Level	BMI (kg/m²)	Stump length (cm)	Stump width (cm)	Controlateral length (cm)	Time since amputation (years)
AI	40	89.3	165	Left	3	24.67	64	47	70	6
CS	35	69.6	165	Right	3	25.34	48	38	58	13
DG	51	67.0	163	Right	3	24.84	44	39	62	43
GS	75	75.0	172	Right	3	25.64	46	41	65	4

Table 9.3 – Demographic data of the sample enrolled.

Subject	Structure	Suspension system	Knee	Foot
AI	Tube-shaped, light alloy	Passive vacuum	Rheo knee	Ceterus
CS	Tube-shaped, light alloy	Passive vacuum	Rheo knee	Variflex EVO
DG	Tube-shaped, light alloy	Passive vacuum	EBS 3860	1C40
GS	Tube-shaped, light alloy	Passive vacuum	Rheo knee	Variflex EVO

Table 9.4 – Prosthetic components.

Means and standard deviations of all the investigated parameters during the three evaluation sessions are shown in Table 9.5, where * indicates significat difference between the CAT CAM and MAS conditions. The clearest results are the maximum peak value on the prosthetic side in P1 and P2 compared to P0, and a slight but not significant reduction on the sound limb.

Parameter	P0	P1	P2	F(2,6)
Sound limb peak (N)	751.23 ± 92.78	765.54 ± 148.63	723.10 ± 89.06	1.506
Prosthetic limb peak (N)	1.02 ± 0.07	1.03 ± 0.07	0.98 ± 0.04	1.653
Normalized prosthetic limb peak (N)	0.19 ± 0.06	0.26 ± 0.03	0.32 ±0.05*	6.875^
Duration (s)	3.91 ± 0.42	3.54 ± 0.41*	3.30 ± 0.29*	12.388^
Areas ratio	0.26 ± 0.09	0.29 ± 0.04	0.33 ± 0.06	1.191

Table 9.5 - Means and standard deviations of the STS test trials. Symbol * for each parameter indicates significant difference between P0 (CAT CAM) - P1 (MAS, 30 days), and P0 (CAT CAM) - P2 (MAS, 60 days), $p < 0.05$. Symbol ^ indicates significant difference for each measured variable at P0-P1-P2 with ANOVA repeated measures.

It can be also observed: the duration and areas under the force curves on both limbs with a ratio reduction in P1 and P2 with respect to that in P0, represents a clear sign of an improved symmetry of the loads on platforms. Fig. 9.11 shows the vertical force curves of the single amputee limb during the STS gesture, performed in P0 and in P2. As it can be seen, the solid line after the counter tract shows more marked peak values reaching around 300 N compared to the dotted line in which the vertical force values (Fv) are around 200 N.
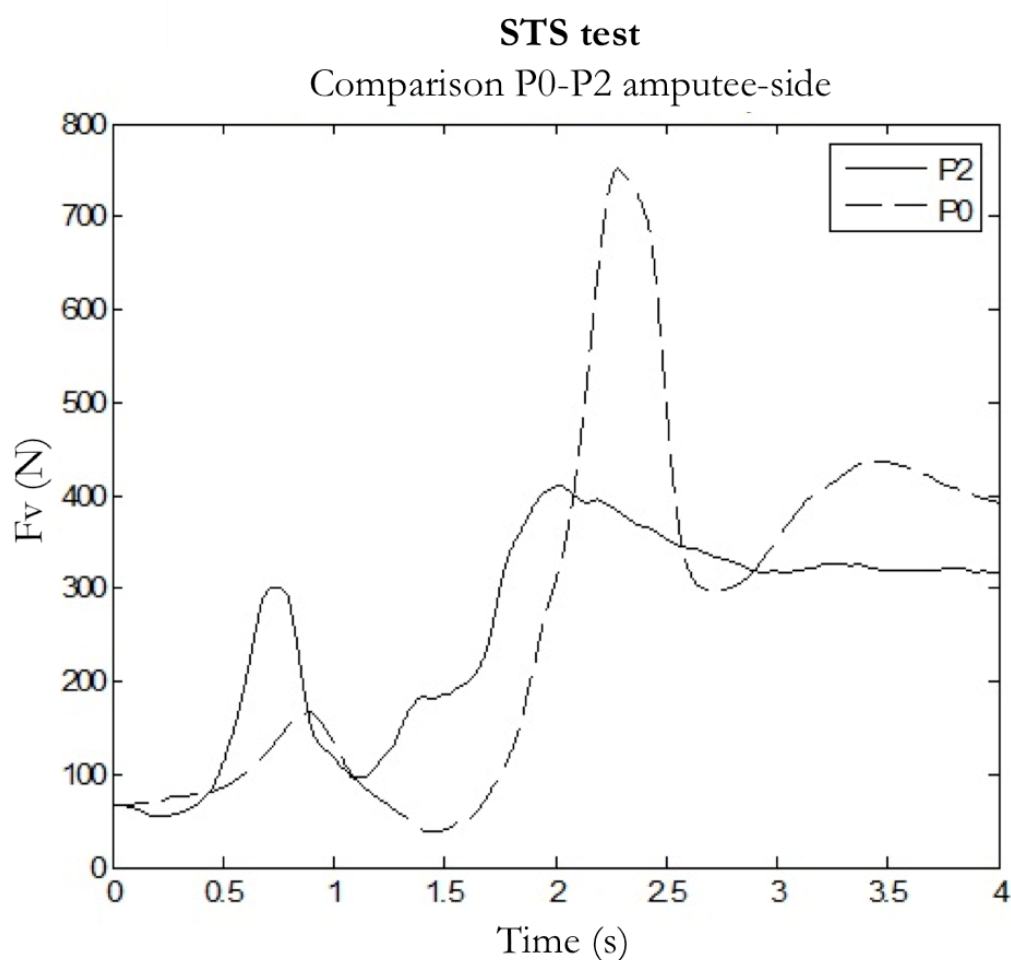

Figure 9.11 - Peaks of vertical force (Fv) in P0 (dotted line) and P2 (solid line) of the same participant (AI).

The same trend is found in Figure 9.12, where the total contribution of the both limbs during the STS task is shown. It can be noticed the red area reduction in P2 (compared to the same in P0) and the increasing of the orange area.
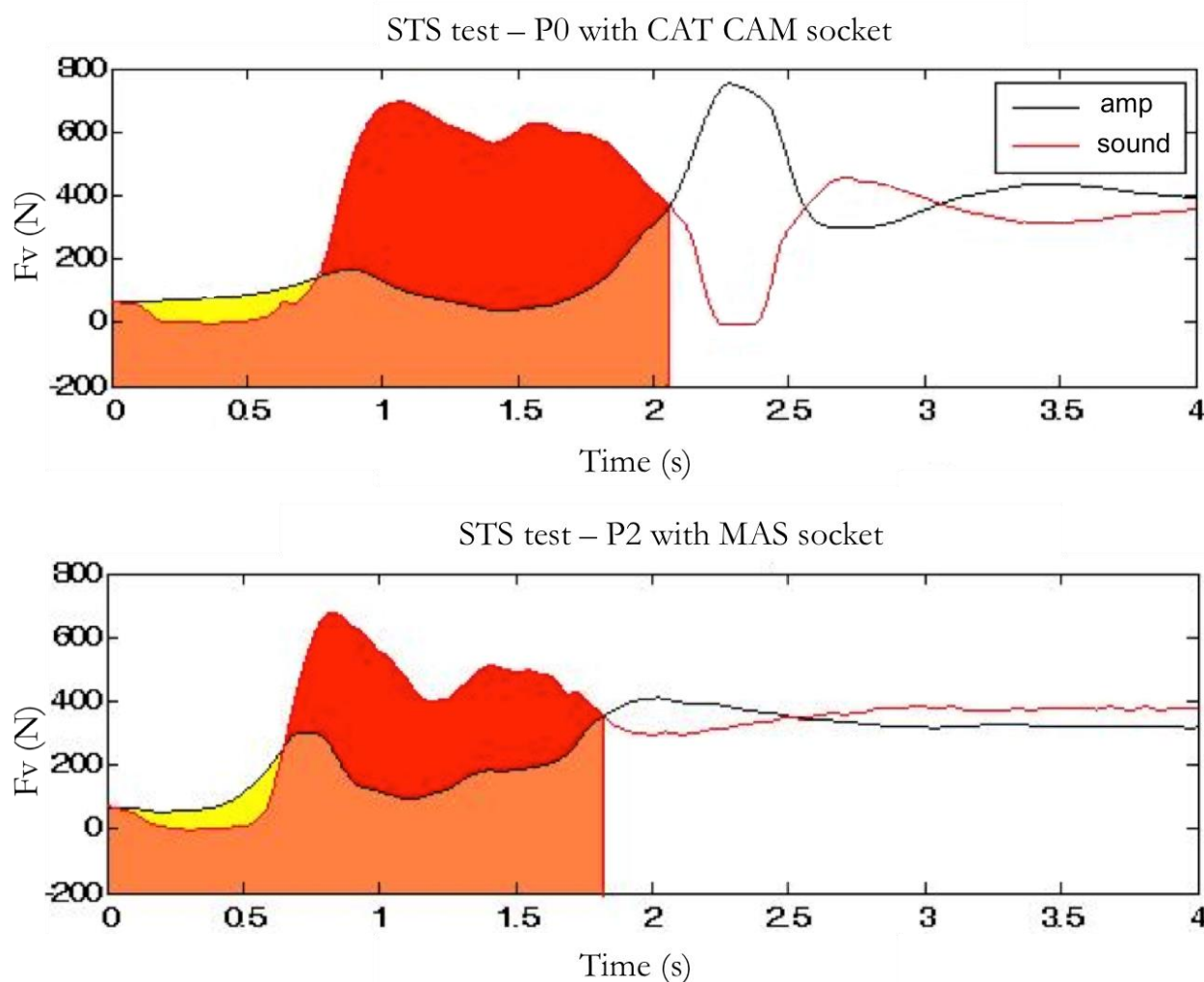
Figure 9.12 – Areas under the curves of the vertical force (Fv) of both sides (amputee and sound limbs) in P0 and P2

In Table 9.6 are summarized all functional data as mean and standard deviation recorded with the portable gas analyzer. As reported, HR rest, SSWS, HR SS, VO_2 SS, RER, gradually improve from the first to the last evaluation phase.

Phase	HR rest (bpm)	SSWS (m/min)	HR SS (bpm)	VO_2 SS (ml/kg/min)	ECW (ml/kg/m)	RER SS

P0	83.06±18.03	57.99±10.40	137.89±17.95	19.62±3.43	0.35±0.11	0.88±0.09
P1	85.00±13.34	57.58±12.21	136.50±23.12	19.02±1.80	0.32±0.10	0.89±0.04
P2	75.74±10.04	59.60±12.12	118.78±18.05	17.18±2.62	0.30±0.08*	0.81±0.24

Table 9.6 - Functional data during walking P0: fitting an Ischial Containment Socket; P1 and P2: fitting MAS. HR: heart rate; SSWS: self-selected walking speed; VO_2: oxygen consumption; SS: steady state; ECW: energy cost of walking; RER: respiratory exchange ratio; bpm: beats per minute. Significant differences are highlighted when P1 is different from P0 and when P2 is different from P0 or from P1, $p<0.05$.

The main result of the metabolic parameters is the significant reduction of ECW in P2 with respect to P0 (when the subject wore the CAT CAM socket) or to P1 (when the subject wore the MAS but was still adapting to the new condition). In Figure 9.13 a more detailed analysis of this trend is given for each participant: ECW lowered significantly with the MAS practice; in subjects CS and DG the improvement is more marked than in the other two.
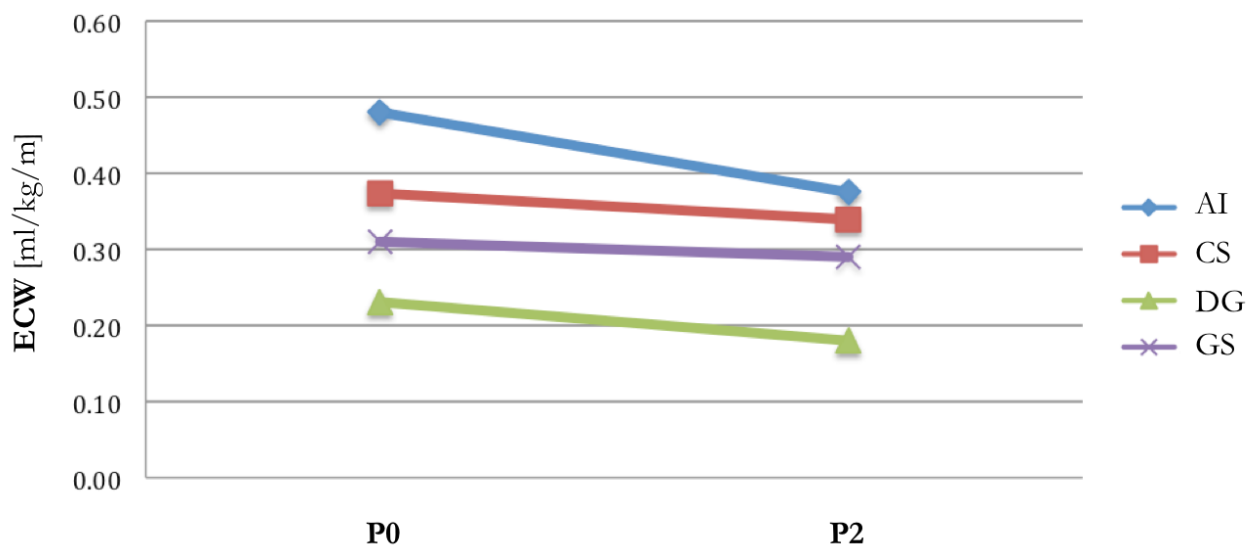
Figure 9.13 – ECW during the 6MWT: comparison between P0 (CAT CAM) and P2 (MAS 60 days).

The distance covered over six minutes (6MWD) improve significantly after the socket replacement (Fig. 9.14) Two subjects covered longer distance at P2 compared to P0.
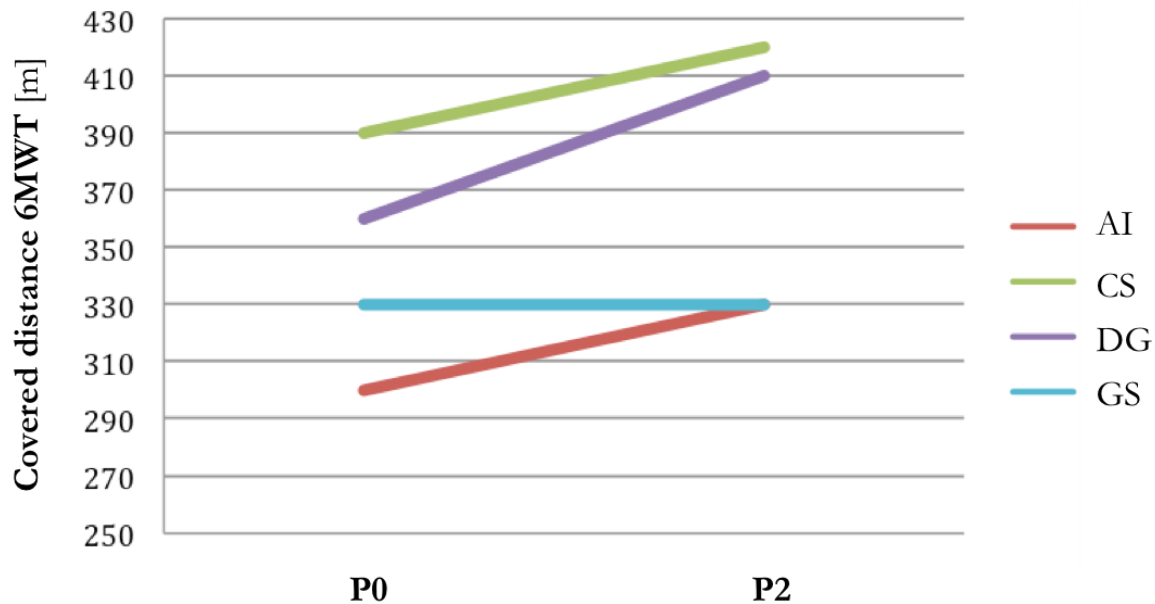

Figure 9.14 - 6MWD: Distance walked over the six minutes at P0 and P2.

9.4 Discussion and further studies

This study is intended to design a new instrumental protocol for the comparison between two different prosthetic sockets in TF subjects. Several measurements were made, investigating different aspects and parameters of the TF motor ability. So far, preliminary results of the instrumented STS test and 6MWT are reported.

STS motor task (often used during activities of daily living) is one of the most studied in the clinical and rehabilitative field, given its simplicity and short duration in the execution. However, it requires great physical effort as a good intersegmental coordination and a substantial contribution by the extensor musculature of the lower-limbs and the spine, in order to generate forces and moments suitable to carry out the entire articular range for the rising from the chair. Among the four investigated parameters of STS, especially two were the most significant (data also supported by statistical analysis): the execution duration and the force peak generated by the prosthetic limb. Indeed, in literature very high rising times indicate a negative performance factor, as well as low ground reaction forces or not equal between the two lower-limbs indicate load compensation on other anatomical structures. It can be noted (Figure 9.11) that during the first instants of the motor task, the prosthetic limb curve increases, because the MAS socket keep the gluteal and ischial region free to move.

The new MAS wings shape, as well as the rear less marked cutting line of the socket, allow to keep gluteus maximus muscle more activated, a greater freedom of movement and an adducer femoral line especially in the preliminary phase, at the time of the buttock detachment from the chair. It is conceivable that the different acclimation time to the new socket and the low sample size of subjects enrolled did not allow finding a statistical significante for this parameter.

New MAS socket design is replacing previous sockets but there are few available data in the literature, which assess functional exercise capacity improvement after socket replacement. The research paper of Traballesi et al. (2011) showed a significant improvement in the metabolic cost of walking after the implementation of the MAS design compared to the CAT CAM socket. This was a good starting point to evaluate

the beneficial effects of the new socket. However, the execution of the gait test with a portable gas analyzer is often not well tolerated among trans-femoral patients. In addition, the deep biomechanical mechanisms that may contribute to the reduction of the aerobic load could not be explained only by a clinical assessment. Thus, gait analysis is a valid tool to collect biomechanical data but expensive, time and high technical skills requiring.

In agreement with Traballesi et al. (2011), the ECW was significantly lower after the socket replacement, whereas HR SS, VO$_2$ SS and SSWS did not show a significant trend from the first to the last evaluation maybe because the participants were not sedentary before socket substitution and their rest capacity were already good at P0 (Table 9.6). However, socket change positively affects HR SS, VO$_2$ and SSWS because they show an improvement trend. It is not easy to compare data obtained from the current literature, because the etiology of the amputation and demographical data are partially responsible for the lifestyle adopted the subjects involved. In addition, prosthesis users in this study were all long-term users, but they have different age, amputation etiology and prosthetic components (Table 9.3; Table 9.4). Despite of this high inter subject variability, reduced ECW was observed in all subjects after 60 days of continous use of MAS. It is conceivable that the socket change may be considered as the factor that mainly influenced the ECW during the 6MWT. This interpretation is supported by Traballesi and Orendurff results (Traballesi et al., 2011; Orendurff et al., 2006). The positive adaptation at the new socket design was also confirmed by the significant improvement of the 6MWD.

This study analyses a small sample of four trans-femoral subjects. It should be noted that recruiting subjects that accept a socket change is not an easy task, having to face with a long term intervention. Even if the sample was extremely small, significant improvement in socket change from the conventional CAT CAM to the MAS socket were found in STS motor task and ECW. The walking speed slight increased with MAS design maybe because subjects perceived their walking as more safe; faster gait means more aerobic and mechanical load and probably relates to better walking economy. Indeed, amputees frequently adopt a walking speed that is even lower than the most efficient gait.

According to the literature, the implementation of a suitable prosthetic component as the MAS should reduce the stride-to-stride fluctuations thanks to a better cooperation between the stump and the socket during walking. Practically, comparing gait variability changes after a socket replacement is difficult because the amputee's gait is characterized by numerous compensation strategies at different level that can be considered as confounding factors. Furthermore, the acclimation period chosen to re-test participants may be not so long to allow the achievement of less variable walking pattern.

The sample extension and the data analysis of all investigated parameters in this study might become the object of future studies. In particular, it could be interesting to correlate the ECW data with those of MIMU during the 6MWT, in order to investigate if the accelerometric parameters can be sensitive to the highlighted changes. Moreover, it could be of particular interest regarding the stereophotogrammetric analysis the study of hip kinematics with both sockets, for quantifying the different articular excursion and the correlation with the energy cost results obtained.

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Chapter 10
GENERAL CONCLUSIONS

The general purpose of this thesis was to provide fact-finding and operational tools in order to identify an accurate and reliable methodology for the motor ability assessment of prosthetized lower-limb amputees, both during gait and stereotypic motor tasks. This methodology is intended to constitute a valid and conventionally recognized reference for the amputee rehabilitation team, both for the functional assessment of the patient and for the technical-clinical evaluation of the prosthetic modules used. The perspective purpose is to verify the feasibility to identify a set of parameters particularly sensitive to the variability of clinical aspects related to the lower-limb amputee motor ability that can, therefore, be measured by a simple, low cost, wearable instrumentation, making them intelligible and useful to the clinical team and exportable in a remote supervision context.

A deep literature review about the state of art on the motor ability assessment in lower limb amputees revealed the clinical and biomechanical parameters mainly investigated, underlining a clear lack of consensus within the scientific community (Chapter 2).

Indeed, the main issues related to the amputee rehabilitation may macroscopically be attributable to the post-surgical effects, to the changes in residual limb volume (the first cause of the pistoning effect) and the lack of guidelines both the patient's functional evaluation, and the most suitable choice of prosthetic components to be used.

The proper choice is often derived from the particular clinical experience of the prosthetist and the rehabilitation team and should take into account the patient's MFCL functional mobility level (K_i, i=1,..,4).

The diversity of the selected results, methods and tools used to describe the motor ability of the lower-limb amputees can be only explained by the different research aims considered in the reviewed literature. This picture of diversity reveals a lack of consensus among researchers on the important aspects of motor ability in lower-limb amputees.

According to the latest guidelines promoted by he World Health Organization (WHO), the formulation of a prognostic judgment, the appropriateness of a clinical care pathway or the outcome measures of a therapy, are based on the observation of the functional limitation both at the level of the whole person (disability or skill lacking) and at the level of the single organ or apparatus (damage). In the specific case of the lower-limb amputee patient, the evaluation can be articulated on two different levels: a first general, concerning the motor ability and quality of life as a function of that (level of independence), and a second local one, concerning the specificity of each single prosthetic module which composes the entire prosthetic chain in the relationship with the motor function of the person concerned.

The research activity of the present thesis was oriented on different works, characterized according to the two levels of investigation (general and local) suggested by WHO.

Chapters 4 and 5 are concerned to a general assessment, on the upper body accelerations in lower-limb amputees through the use of inertial measurement units, following respectively mono- and multi-sensory approach, highlighting different characteristics of the general motor ability.

With respect to previous studies investigating upper-body stability during gait in younger and long-time prosthesis users, lower stability, harmony, and symmetry in a sample of subjects with amputation upon dismissal from rehabilitation hospital were found (Chapter 4). A clear trend depending on level of amputation and type of prosthesis for the stability, harmony, and symmetry evaluated on the sagittal plane was also identified. Accelerations in the medio-lateral direction seemed more related to motor control than biomechanical issues. The use of a single triaxial accelerometer (i.e., a low-cost, wearable, and easy-to-use device) can provide useful quantitative and objective information about important gait features. The common walking tests performed in clinics on subjects with amputation, such as the 10 m walking test or the 6 min walking test just measure speed of walking without providing information about the optimization of other important aspects of gait. The study also showed that fast speed may not be a safe choice, because it may lead to less symmetric gait, exposing subjects to a higher risk of falling. In training people with amputation to use prostheses, researchers should focus interventions on the

most impaired aspect of walking, i.e., symmetry, a feature recently shown to be crucial for optimizing physiological gait. In the study reported in Chapter 5 was used a multi-sensory approach, focusing on the quantitative assessment of upper body accelerations during gait and of their attenuation from the pelvis to the head, in transtibial amputees using three wearable magneto-inertial sensors. The availability and accessibility of the inertial measurement equipment, in fact, does not limit its everyday use by clinicians. Moreover, characterizing how head stabilization is managed during gait in lower limb amputees can be potentially useful to study gait patterns, including compensatory ones. In this respect, the potential role of trunk movements for compensating asymmetries in lower limb patterns was highlighted, specifically involving decreasing/increasing accelerations at the different body levels. The adopted biomechanical parameters were fruitful in highlighting gait differences between amputee and able-bodied subjects and can be used to support therapists and physicians either to drive the design of innovative intervention protocols or to prescribe prosthetic devices, and to monitor their efficacy in terms of gait stability. Indeed, the evaluation of upper body accelerations can be related not only to the monitoring and assessment of the amputees rehabilitation training, but also to the assessment and the design of prosthetic components. In the first case this approach might rappresent an analysis tool for stability in order to quantify compensation movements during walking. In fact, lower limb amputees present gait deviations and postural asymmetries as trunk forward inclination (due to i.e. weakness of hip extensors). Angles values provide the magnitude of compensation movements but not the dynamics with which these occur. Regarding the second field of application, the knowledge of the upper body accelerations distribution can be a useful tool for verifying the goodness of prosthesis design characteristics. Indeed, all the prosthetic elements that act as "shock absorbers" (i.e. carbon fiber feet, type of suspension system, etc.) directly affect the accelerations at the pelvis and trunk level. For instance, the damping time of the oscillations could be a parameter discriminating the goodness of the prosthetic components used.

In this context, the attenuation coefficients C_{ij} may represent a useful synthetic index for the objective assessment of the mobility of the amputee person associated with the

traditional clinical approach. Further studies may test the ability of these indices to assess and monitor the outcomes of different therapeutic interventions.

Switching over to a local level of investigation, Chapters 6 and 7 report two studies on the comparison between different prosthetic feet, depending on the mobility level of the amputee subjects provided by MCFL scale (K1-K2: Chapter 6; K3-K4 Chapter 7).

For instance, in case of low level of mobility (as elderly people) it is preferred to renounce to the dynamic foot features possibly causing an excessive forward propulsion and put safety and self-confidence aspects as stability as first target, also in relation to falls prevention.

To identify the most appropriate prosthesis and improve user efficiency and safety, it is also important to study the effect of different feet on a specific category of amputees.

After the replacement of the SACH with a multi-axial foot, the hypomobile subjects enrolled in Chapter 6 maintained the same level of stability and perceived safety, while presenting a significant albeit slight improvement in some important clinical aspects of lower limb amputee's daily living, as overall mobility, balance, general comfort and the perceived satisfaction with their own prosthesis. The findings presented in Chapter 6 demonstrate that a multi-axial foot represents an alternative solution with respect to the conventional SACH in the prescription of prosthetic feet for hypomobile transtibial amputees. Thus, the range of prosthetic devices available to practitioners involved in amputee rehabilitation is increased, therefore allowing them to select the most appropriate solution for each specific subject based on their clinical experience. In Chapter 7, a microprocessor-controlled adaptive prosthetic ankle, that automatically adjusts dorsiflexion during the swing phase of gait, was compared with a conventional carbon fiber energy storing prosthetic foot. The results of this study indicate that the microprocessor-based device is capable of reducing energy cost of walking in all the studied conditions, level walking and treadmill at different slopes, and with statistical significance on floor, despite its extra weight. Moreover, the acclimation time for the new generation device was also identified in 90 days.

Stump volume fluctuactions and changes, due to various reasons (i.e. environmental, humoral and psychological factors, cyclic mechanical stresses during gait, atmospheric

changes, working hours etc.), led to a redistribution of body fluids and, consequently, a redistribution of the loads acting on the stump, with the development of pressure gradients that cause pain and functional limitation. These pressure gradients can also lead to developing the pistoning effect (one of the main causes of heat, sweating, dermatological disorders as ulcers, swelling and general discomfort and pain) between the residual limb and the socket. Pistoning is therefore the vertical movement of the stump within the socket. It is minimized by an appropriate suspension system that secures the socket to the amputee's stump, guaranteeing prosthesis efficiency. When pistoning occurs, the prosthesis fit is deteriorated and, as a consequence, a reduction of amputee's mobility and autonomy occurs. Chapter 8 reported a study designed to evaluate the efficiency of suspension system passive vacuum based with 5 rings and a traditional urethane sealing suspension sleeve. The pistoning effect was measured through a new methodological protocol designed ad hoc. This methodology allows for the measurement of the relative movement between stump and socket when this latter is subjected to incremental vertical loads in a clinical context. In order to optimize the method, a system was specifically designed and developed allowing the modular distal application of loads, minimizing measurement errors due to the knee flexion. Using the hypobaric Iceross Seal-In X5 (HIS), there were fewer pistoning movements in the socket. This was associated with a statistically significant improvement in quality of life, as reported by users. Moreover, HIS use led to improvement on the Houghton scale, which indicates more intensive and safe use of the prosthesis. This study also shows that in unilateral transtibial amputees, the HIS suction system (compared with that of the suction suspension system) reduces pistoning and improves quality of life.

The analysis of local prosthetic components ends with the one that is typically less influenced by the technological innovation in prosthetics, which is the socket. Nowadays, prosthesis users still highlight that one of the most critical problems is represented by the relationship with the prosthesis at the socket interface level. Due to the advent of the innovative MAS socket, an ad-hoc experimental protocol was designed for motor ability assessment in transfemoral amputees, investigating all the biomechanical aspects of the prosthetic sockets' use (Chapter 9). Even if the recruited

sample was small, significant improvement in socket change from the conventional CAT CAM to the MAS socket were found in two motor task, typical of daily living such as Sit To Stand and Level Walking. The new MAS wings shape, as well as the rear less marked cutting line of the socket, allow to keep gluteus maximus muscle more activated, a greater freedom of movement and an adducer femoral line especially in the preliminary phase of the sit to stand, at the time of the buttock detachment from the chair. The walking speed slight increased with MAS design maybe because subjects perceived their walking as more safe; faster gait means more aerobic and mechanical load and probably relates to better walking economy. Indeed, amputees frequently adopt a walking speed that is even lower than the most efficient gait.

As an overall conclusion, the measures to be carried out and the parameters to be evaluated to support motor ability assessment in lower limb amputees depend on both the level of investigation to achieve and on the available measurement tools and human resources of the rehabilitation center. These outcome measures must be as more simple and intelligible as possible for the medical staff. The instrumental gait analysis for amputees is currently limited to a few prosthetic centers equipped with expensive laboratories. The feasibility of using magneto-inertial sensors in this context was explored, possibly overcoming these limitations, being a low-cost, small size and wearable technology. This technology can also widen the possibility to perform quantitative measurements also outside the lab, in daily life environment or where the amputee follows a rehabilitation program for restoring his/her gait function in clinical settings. The use of intuitive interfaces can definitely be of help to rehabilitation practictioners for the interpretation of the acquired data.

The investigated parameters, experimental protocols and methodologies proposed in this thesis for the assessment of motor ability in the lower limb amputee patient can represent a reference tool to guide surgical, rehabilitative and reintegrative (i.e. (adapted physical activity) decisions. It is to highlight that the lower limb amputee patient needs a multidisciplinary rehabilitation team (doctor, physical therapist, prosthetist, psychologist, etc.), able to build a custom rescue project to optimize the remaining motor abilities. The traditional clinical approach and that objective related to the mere instrumental data

represent necessary but not sufficient conditions if indipendently taken. In this context, the bioengineer can have a crucial role not only for technical activities such as the experimental set-up design, data processing, interpretation of measured parameters, etc., but above all he/she should ensure synergy between the two cited approaches through a proactive behavior and an efficient communication.

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