Towards a functional assistance in transfer and posture of paraplegics using FES: From simulations to experiments

Jovana Jovic

ACADÉMIE DE MONTPELLIER

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Jovana JOVIĆ

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JURY :

M. Dejan Popović	Professeur, ETF Belgrade	Rapporteur
Mme. Agnès Roby-Brami	Directrice de recherche, ISIR Paris	Rapporteur
M. Philippe Souères	Directeur de recherche, CNRS, LAAS	Examinateur
M. Philippe Fraisse	Professeur, LIRMM, UM2	Directeur de thèse
Mme. Christine Azevedo-Coste	Chargée de recherche, INRIA	Co-directrice de thèse
M. Charles Fattal	Médecin, CMN PROPARA	Co-directeur de thèse

TOWARDS A FUNCTIONAL ASSISTANCE IN TRANSFER AND POSTURE OF PARAPLEGICS USING FES : FROM SIMULATIONS TO EXPERIMENTS

JOVANA JOVIĆ

LIRMM

Laboratoire d'Informatique, de Robotique et de Microélectronique de Montpellier

INRIA

Institut national de recherche en informatique et en automatique

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ABSTRACT

Today there are around 90 million people suffering from Spinal Cord Injury (SCI) worldwide. Thanks to the progresses in emergency medical care, problems faced by SCI individuals after an accident are no longer life threatening. This has generated a shift of the priorities in medical research and practice towards improvements in their quality of life. The use of Functional Electrical Stimulation (FES) for motion restoration in paralyzed limbs proved to have a potential to provide both functional and therapeutic benefits. The aim of this thesis is to investigate solutions which would improve quality of life of paraplegics by restoring the sit-to-stand, transfer from one surface to another and standing tasks. We aim at finding a good trade-off between achievable functionality of the FES system and its simplicity in terms of number of required sensors and computational cost and, accordingly, its applicability in clinical practice and daily life of paraplegic individuals.

RÉSUMÉ

Aujourd'hui, 90 millions de personnes dans le monde souffrent de lésions de la moelle épinière. Grâce aux progrès de la prise en charge des patients, leur espérance de vie est comparable à celle du reste de la population et la priorité de la recherche médicale est désormais consacrée à l'amélioration de leur qualité de vie. La stimulation électrique fonctionnelle (SEF) permet de restaurer les mouvements des membres paralysés et a des bénéfices thérapeutiques et fonctionnels. L'objectif de cette thèse est de proposer des solutions pour l'assistance au lever de chaise, au transfert d'une surface à une autre et à la station debout. Nous souhaitons trouver un compromis entre fonctionnalité et simplicité d'utilisation en termes de nombres de capteurs requis et de complexité calculatoire et donc favoriser l'application en environnement clinique et privé.

PUBLICATIONS

International Journals

1. **J. Jovic**, C. Azevedo Coste, P. Fraisse, C. Fattal

   Upper and lower body coordination in FES-assisted sit-to-stand transfers in paraplegic subjects - A case study.

   Paladyn, Journal of Behavioral Robotics 2(4): 211-217, 2011.

2. **J. Jovic**, S. Langagne, P. Fraisse, C. Azevedo Coste

   Impact of Functional Electrical Stimulation of knee joints during Sitting Pivot Transfer motion for paraplegic people.

   International Journal of Advanced Robotic Systems, N/A, 2012.

Reviewed Conference proceedings

1. **J. Jovic**, V. Bonnet, C. Azevedo Coste, P. Fraisse *A Paradigm for the Control of Upright Standing in Paraplegic Patients.*

   EMBC'2012 : 34th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, USA (2012).

2. S. Lengagne, **J. Jovic**, C. Pierella, P. Fraisse, C. Azevedo Coste *Generation of Multi-Contact Motions with Passive Joints: Improvement of Sitting Pivot Transfer Strategy for Paraplegics.*

   BioRob'2012 : IEEE International Conference on Biomedical Robotics and Biomechatronics, Italy (2012).

3. **J. Jovic**, C. Azevedo Coste, P. Fraisse, V. Bonnet, C. Fattal *Optimization of FES-assisted rising motion in individuals with paraplegia.*

   Skills Conference 2011, France (2011).

4. **J. Jovic**, C. Azevedo Coste, P. Fraisse, C. Fattal *Decreasing the arm participation in complete paraplegic FES-assisted sit to stand.*

   IFESS'2011 : 16th Annual International FES Society Conference, Brazil (2011).

5. **J. Jovic**, V. Bonnet, P. Fraisse, C. Fattal, C. Azevedo Coste *Improving Valid and Deficient Body Segment Coordination to Improve FES-Assisted Sit-To-Stand in Paraplegic Subjects.*

   ICORR'2011 : 12th International Conference on Rehabilitation Robotics, Switzerland (2011).

Conference abstract

1. **J. Jovic**, C. Azevedo Coste,M. Benoussaad, P. Fraisse, C. Fattal *Optimizing FES-assisted sit to stand transfer initiation in paraplegic individuals using trunk movement information.*

   ISEK'2010: International Society of Electrophysiology and Kinesiology, Aablorg, Danemark (2010).

INTRODUCTION

Today, approximately 90 million people worldwide live with Spinal Cord Injury (SCI). The type of paralysis- tetraplegia (quadriplegia) or paraplegia- depends on the lesion level. In tetraplegia, the person has sustained a loss of feeling and/or movement in both upper and lower limbs. Paraplegia is the general term for the loss of feeling and/or movement in the lower part of the body. This thesis focuses on individuals who are complete paraplegic, i.e., with the loss of sensory and motor functions in their lower extremities. Thanks to improved emergency medical care, many of the problems faced by individuals with paraplegia following an accident are no longer life threatening, and their life expectancy is now comparable to that of able-bodied individuals. This has generated a shift in the priorities of medical research and practice away from survival and toward improvements in the quality of life for those living in a wheelchair. Independence is a major goal in rehabilitation. The ability to move and transfer is central to autonomous living, and therefore the manual wheelchair has become an important assistive device. However, wheelchair users are subjected to intense loads on the upper trunk and Upper Limb (U/L) muscles and joints during wheelchair propulsion, and almost every other daily activity such as transfer, driving and household activities. Consequently, musculoskeletal pain is a common complication. While the primary injury itself greatly limits personal independence, any further functional limitation due to secondary complications, could cause a decrease or even a total loss in the remaining functional independence. Due to limited mobility, the paraplegic population also faces many other medical problems related to bone loading, cardio-circulatory stimulation, and metabolic changes which increase the risk of diabetes, joint extension, pressure sores, and muscle spasticity.

Functional Electrical Stimulation (FES) to restore motion in paralyzed limbs has shown the potential to provide both functional and therapeutic benefits. The advantages of FES over conventional rehabilitation treatments are numerous. Movement restoration by FES in patients with SCI has been a subject of research for many years. Nevertheless, muscle fatique occurs rapidly in the context of FES induced muscle contractions and thus the duration of functional movements is quite limited. Consequently, the number of effective FES systems is still limited.

In light of these observations, this work aimed to develop solutions to improve the quality of life of people with SCI by restoring the movements of sit-to-stand, transfer from one surface to another and standing that are lost due to SCI. We aimed to find a good trade-off between the achievable functionality of the FES system and its simplicity in terms of the number of required sensors and the computational cost and, accordingly, applicability in clinical practice and the daily lives of paraplegic individuals. The structure of the thesis is as follows.

Chapter 1 gives a brief description of the natural control of movement in physically intact individuals and introduces SCI pathology. A short review of some of the solutions proposed to restore movement in paraplegic patients is presented, and the principles of FES are described.

Chapter 2 deals with FES-assisted sit-to-stand movement in the paraplegic population. Ways to move that minimize arm efforts and reduce the muscle fatigue induced by FES have been investigated. The chapter also validates a new closed-loop system for sit-to-stand transfer to meet the needs of paraplegic individuals through experiments with six paraplegic patients. The criterion for patient selection, the experimental setup and the protocols are explained.

In Chapter 3 the benefits of FES during sitting-pivot-transfer motion in paraplegic patients are investigated using an optimization process and biomechanical modeling of the human body. The simulation results are presented.

Chapter 4 proposes a new solution for 3D control of standing posture in SCI patients by means of FES. The proposed controller should enable prolonged standing and should be able to cope with the patient's voluntary movements. The simulation results are presented.

Chapter 5 summarizes the results and conclusions of this thesis and proposes perspectives for future investigations.

Additional aspects related to this work are described in the Appendix. This include the statement of the local ethics committee's approval of the protocol for performing experiments with paraplegic patients, additional results from Chapter 2 and descriptions of the software developed for the movement analysis presented in Chapter 2, and a description of the marker placements in the experiments described in Chapter 3.

CONTENTS

ACRONYMS

SCI Spinal Cord Injury

U/L Upper Limb

FES Functional Electrical Stimulation

CNS Central Nervous System

PNS Peripheral Nervous System

ASIA American Spinal Injury Association

MRC Medical Research Council

AFO Ankle Foot Orthosis

KAFO Knee Ankle Foot Orthosis

HKAFO Hip Knee Ankle Foot Orthosis

STS Sit-To-Stand

PID Proportional Integral Derivative

GA Genetic Algorithm

DoF Degree of Freedom

HAT Head-Arm-Trunk

VSF Vertical Shoulder Force

HSF Horizontal Shoulder Force

BW Body Weight

WL Window Length

WE Window End

Imax Maximum stimulation amplitude

Tramp Duration of the ramp

M Mean value

Max Maximal value

I	Initial value
DE	Detection Error
SPT	Sitting Pivot Transfer
Sc	Scenarios
CoM	Center of Mass
RMS	Root Mean Square error
CoM	Center of Mass
AP	Anterior-Posterior
ML	Medio-Lateral
CoP	Center of Pressure
EMG	Electromyography
LQG	Linear Quadratic Gaussian
PD	Proportional Derivative
PI	Proportional Integral
SESC	Statically Equivalent Serial Chain

1

NATURAL AND ARTIFICIAL CONTROL OF MOVEMENT

The main goal of this thesis is to propose solutions for posture and transfer movement restoration by means of FES for persons with paraplegia due to SCI. In order to design the artificial controller, it was necessary to understand the natural control of movements, and the complexity of the organs involved. This chapter therefore describes the basics of the physiological control of human movement, with a short description of the human neural and musculoskeletal system at the the beginning of the chapter[1] . Special attention is given to the anatomy of the lower limbs[1] . Next, we explore the reasons for SCI occurrence, the problems that the SCI population must cope with and the proposed systems for the restoration of functional movements of paralyzed limbs[2] . The chapter ends with the description of FES principles[2] .

1.1 NATURAL CONTROL OF MOVEMENT

1.1.1 *Nervous system*

Any human activity, from a slight gesture to physical exercise requires muscle contractions to achieve the desired movement, or to maintain a desired posture. These muscle contractions are the final result of a complex series of tasks: motion planning, generation of muscle control signals and monitoring of sensory information to allow appropriate corrections of the original plan. These tasks are performed by the nervous system which is unique in the vast complexity of thought processes and control actions it can perform. Every minute, it receives millions of bits of information from the sensory nerves and organs and then integrates all of it to determine the responses to be made by the body. The nervous system is made up of two types of cells, the neurons, the main functional units, and glial cells, which are non-neuronal and primarily support and protect the neurons.

NEURON: THE BASIC FUNCTIONAL UNIT The nervous system contains more than 100 billion neurons. Neurons are specialized in receiving, conducting and transmitting electrochemical impulses, known as action potentials. Figure 1 shows a typical neuron of a type found in the brain motor cortex. A typical neuron possesses a cell body (often called the soma), dendrites, and an axon. Incoming signals enter this neuron through synapses, which are specialized connections with other cells, located mostly on the neuronal dendrites, but also on the cell body. Depending on the type of neuron, there may

1 The content of this section is mainly based on the following references [34], [45] and [55].
2 The content of this section is mainly based on the following reference [115].

be only a few hundred or as many as 200,000 such synaptic connections from input fibers. The output signal from the neuron travels by way of a single axon leaving the neuron. This axon has many separate branches to other parts of the nervous system or peripheral body. A special feature of most synapses is that the signal normally passes only in the forward direction (from the axon of a preceding neuron to dendrites on cell membranes of subsequent neurons). This forces the signal to travel in the directions required to perform specific nervous functions.

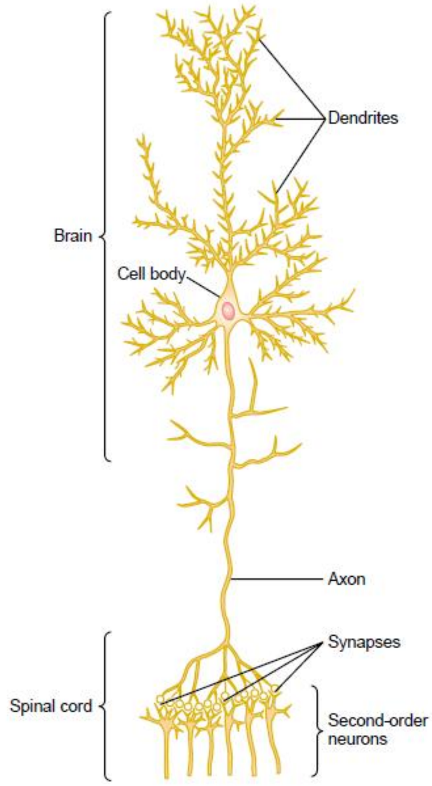


Figure 1: Structure of a large neuron in the brain, showing its important functional parts. Adapted from [55].

SENSORY PART OF THE NERVOUS SYSTEM Most activities of the nervous system are initiated by sensory experience that excite sensory receptors, such as visual receptors in the eyes, auditory receptors in the ears, tactile receptors on the body surface, and other types of receptors. This sensory experience can either cause an immediate reaction from the brain, or a memory of the experience can be stored in the brain for minutes, weeks, or even years to determine bodily reactions at some future date.

MOTOR PART OF THE NERVOUS SYSTEM The most important role of the nervous system is to control the various bodily activities. This is achieved by controlling (1) contraction of appropriate skeletal muscles throughout the body, (2) contraction of smooth muscle in the internal organs, and (3) secretion of active chemical substances by both exocrine and endocrine glands in many parts of the body. These activities are collectively called the motor functions of the nervous system, and the muscles and glands are called effectors because they are the actual anatomical structures that perform the functions dictated by the nerve signals. Figure 2 shows the motor nerve axis of the nervous system for controlling skeletal muscle contraction. Note in Figure 2 that the skeletal muscles can be controlled from many levels of the central nervous system, including the spinal cord or different parts of the brain. Each of these areas plays its own specific role, the lower regions concerned primarily with automatic, instantaneous muscle responses to sensory stimuli, and the higher regions with deliberate complex muscle movements controlled by the thought processes of the brain.

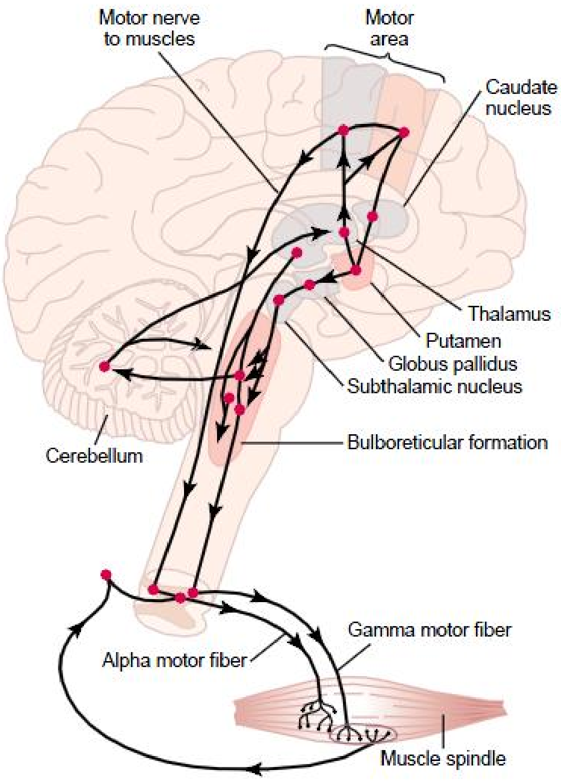


Figure 2: Skeletal motor nerve axis of the nervous system. Adapted from [55].

Anatomically, the nervous system consists of the Central Nervous System (CNS) (systema nervosum centrale), the processing area and the Peripheral Nervous System (PNS) (systema nervosum periphericum) which connects the CNS with various receptors and effectors (Figure 3).

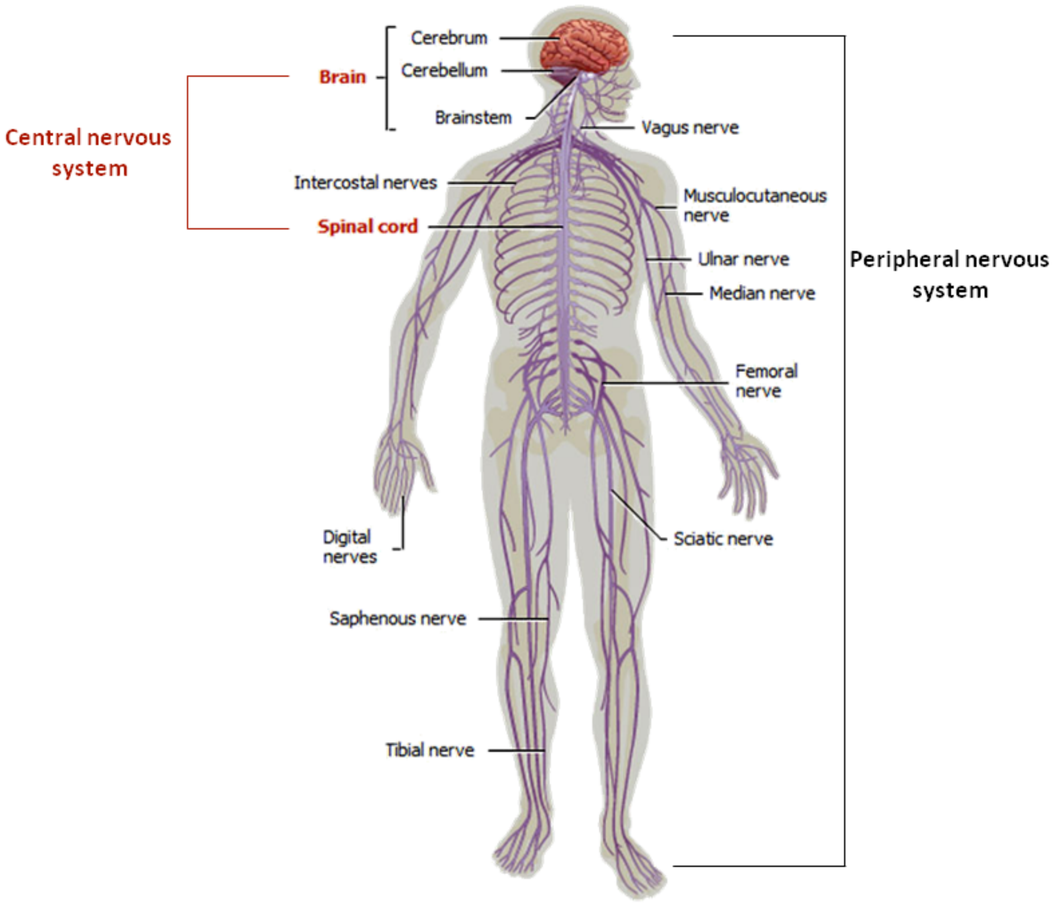


Figure 3: Nervous system of a human. Adapted from [55].

1.1.1.1 *Central nervous system*

The human nervous system has inherited special functional capabilities from each stage of human evolutionary development. From this heritage, three major levels of the central nervous system have specific functional characteristics: (1) the lower brain or subcortex, (2) the higher brain or cortex, and (3) the spinal cord.

LOWER BRAIN OR SUBCORTEX Many, if not most, of what we call the subconscious activities of the body are controlled in the lower areas of the brain: in the medulla, pons, mesencephalon, hypothalamus, thalamus, cerebellum, and basal ganglia. For instance, subconscious control of arterial pressure and respiration is achieved mainly in the medulla and pons. Control of equilibrium is a combined function of cerebellum, medulla, pons, and mesencephalon. And many emotional patterns, such as anger, excitement, sexual response, reaction to pain, and reaction to pleasure, can still occur after destruction of much of the cerebral cortex.

HIGHER BRAIN OR CORTEX The cerebral cortex is essential for most of our thought processes, and it is also an extremely large memory storehouse. One of the most important functions of the cortical level is to process incoming information in such a way that appropriate mental and motor responses will occur. The cortex never functions alone but always in association with lower centers of the nervous system. Without the cerebral cortex, the functions of the lower brain centers are often imprecise. The cerebral cortex usually converts these functions to determinative and precise operations.

SPINAL CORD The spinal cord is the main pathway for information connecting the brain and the peripheral nervous system. However, the spinal cord is not only a conduit for signals from the periphery of the body to the brain, or in the opposite direction from the brain back to the body. Even after the spinal cord has been cut in the high neck region, many highly organized spinal cord functions still occur. For instance, neuronal circuits in the cord can cause walking movements, reflexes that withdraw parts of the body from painful objects, reflexes that stiffen the legs to support the body against gravity, and reflexes that control local blood vessels, gastrointestinal movements, or urinary excretion. In fact, the upper levels of the nervous system often operate not by sending signals directly to the periphery of the body but by sending signals to the control centers of the cord, simply "commanding" the cord centers to perform their functions.

The terms used to describe spinal cord functions are the following:

1. *Spinal nerve*. The term spinal nerve generally refers to a mixed spinal nerve, which carries motor, sensory, and autonomic signals between the spinal cord and the body. Humans have 31 left-right pairs of spinal nerves, each roughly corresponding to a segment of the vertebral column: eight cervical spinal nerve pairs (C1-C8), 12 thoracic pairs (T1-T12), five lumbar pairs (L1-L5), five sacral pairs (S1-S5), and one coccygeal pair. Each spinal nerve is formed by the combination of nerve fibers from the dorsal and ventral roots of the spinal cord. The dorsal roots carry sensory axons, while the ventral roots carry motor axons. The spinal nerve emerges from the spinal column through an opening (intervertebral foramen) between adjacent vertebrae. Outside the vertebral column, the nerve divides into branches. Figure 4 shows the scheme of a spinal nerve on the right, and the body functions which spinal nerves located on different levels of the spinal cord control control, on the left.

2. *Dermatome*. A dermatome is defined as the cutaneous area whose sensory innervation is derived from a single spinal nerve (i.e., dorsal root) (see Figure 5). There are eight cervical nerves, 12 thoracic nerves, five lumbar nerves and five sacral nerves. Each of these nerves relays sensation from a particular region of skin to the brain. For example, the T1 dermatome comes to the mid-line of the forearm, the T4 dermatome is at the level of the nipples, the T10 dermatome includes the navel, the L1 dermatome is in the groin, and the S1 dermatome is at the outer edge of the foot and heel. The division of the skin into dermatomes reflects the segmental organization of the spinal cord and its associated nerves.

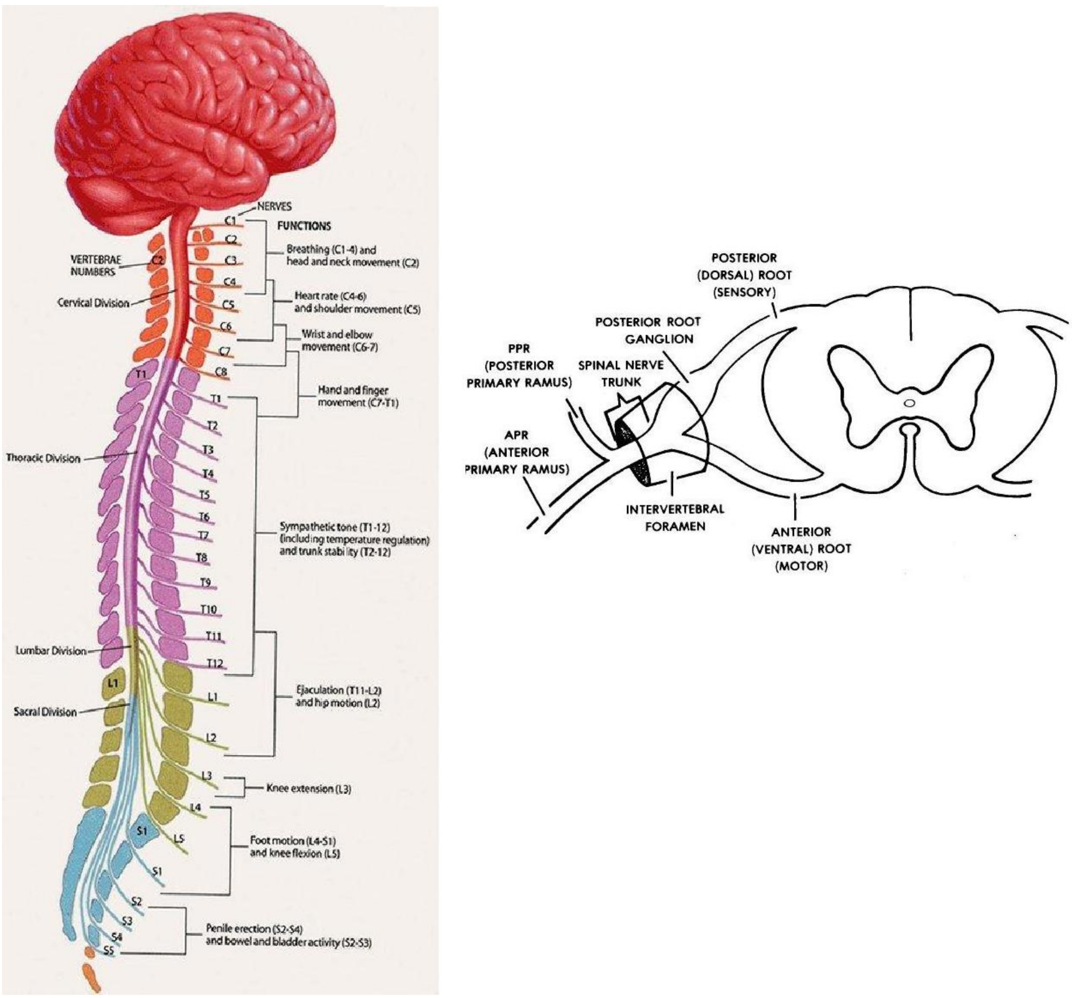


Figure 4: Spinal nerve: scheme and functions. Adapted from [8]

3. *Myotome*. A myotome is defined as the muscular distribution of a single spinal nerve (i.e., ventral root), and is thus the muscular analogue of a cutaneous dermatome. Each muscle in the body is supplied by a particular level or segment of the spinal cord and by its corresponding spinal nerve. Knowledge of the myotomes of each spinal nerve enables the clinical localization of lesions causing motor dysfunction (see Figure 5). Examples of myotome distributions in the upper and lower extremities are as follows: C1/C2-neck flexion/extension, C3-neck lateral flexion, C4-shoulder elevation, C5-shoulder abduction, C6-elbow flexion/wrist extension, C7-elbow extension/wrist flexion, C8-thumb extension, T1-finger abduction, L2-hip flexion, L3-knee extension, L4-ankle dorsi-flexion, L5-great toe extension, S1-ankle plantar-flexion, S2-knee flexion.

1.1.1.2 *Peripheral nervous system*

The peripheral nervous system consists of the nerves and ganglia outside of the brain and spinal cord. The main function of the PNS is to connect the central nervous system to the limbs and organs.

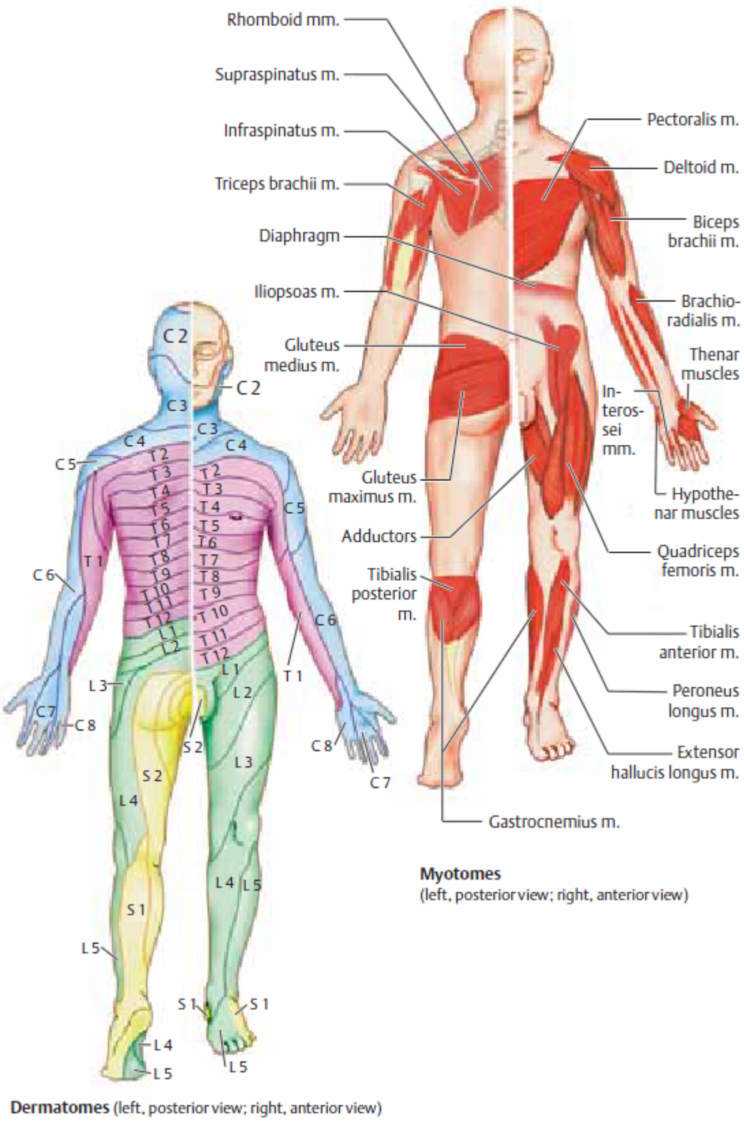


Figure 5: Dermatomes and myotomes. Adapted from [55].

Functionally, the PNS can be divided into the somatic nervous system and the autonomic nervous system. The somatic nervous system (or voluntary nervous system) is associated with the voluntary control of body movements via skeletal muscles. The somatic nervous system consists of the nerves responsible for stimulating muscle contraction, including all the non sensory neurons connected to skeletal muscles and skin. The autonomic nervous system (or visceral nervous system or involuntary nervous system) acts as a control system functioning mostly below the level of consciousness, and controlling visceral functions. It affects heart rate, digestion, respiratory rate, salivation, perspiration, pupillary dilation, urination, and sexual arousal.

1.1.2 *Skeletal muscles*

About 40 per cent of the body is skeletal muscle, and perhaps another ten per cent is smooth and cardiac muscle. In this chapter, we will focus mainly on the function of skeletal muscles because they are responsible for voluntary motions of body segments.

PHYSIOLOGICAL ANATOMY OF SKELETAL MUSCLE Each skeletal muscle is composed of several muscle fibers (Figure 6). The cell membrane of the muscle fiber is called the sarcolemma. The sarcolemma consists of the plasma membrane, and an outer coat made up of a thin layer of polysaccharide material that contains numerous thin collagen fibrils. At each end of the muscle fiber, this surface layer of the sarcolemma fuses with a tendon fiber, and the tendon fibers in turn collect into bundles to form the muscle tendons that then insert into the bones.

Each muscle fiber contains several hundred to several thousand myofibrils, which are represented by the many small open dots in the cross-sectional view of Figure 6, part C. Each myofibril (Figure 6, parts D and E) is composed of about 1500 adjacent myosin filaments and 3000 actin filaments, which are large polymerized protein molecules that cause the actual muscle contraction. These are represented diagrammatically in Figure 6, parts E through L. The thick filaments in the diagrams are myosin, and the thin filaments are actin. Note in Figure 6, part E that the myosin and actin filaments partially interdigitate and thus cause the myofibrils to have alternate light and dark bands, as illustrated in Figure 6. The light bands contain only actin filaments and are called I bands because they are isotropic to polarized light. The dark bands contain myosin filaments, as well as the ends of the actin filaments where they overlap the myosin, and are called A bands because they are anisotropic to polarized light. Note also the small projections from the sides of the myosin filaments in Figure 6, parts E and L. These are cross-bridges. The interactions between these cross-bridges and the actin filaments cause contractions. Figure 6, part E also shows that the ends of the actin filaments are attached to a so-called Z disc. From this disc, these filaments extend in both directions to interdigitate with the myosin filaments. The Z disc, which itself is composed of filamentous proteins different from the actin and myosin filaments, passes crosswise across the myofibril and also crosswise from myofibril to myofibril, attaching the myofibrils to one another all the way across the muscle fiber. Therefore, the entire muscle fiber has light and dark bands, as do the individual myofibrils. These bands give skeletal and cardiac muscle their striated appearance. The part of the myofibril (or of the whole muscle fiber) that lies between two successive Z discs is called a sarcomere. When the muscle fiber is contracted the length of the sarcomere is about 2 micrometers. At this length, the actin filaments completely overlap the myosin filaments, and the tips of the actin filaments are just beginning to overlap one another. This is the length at which the muscle is capable of generating its greatest force of contraction.

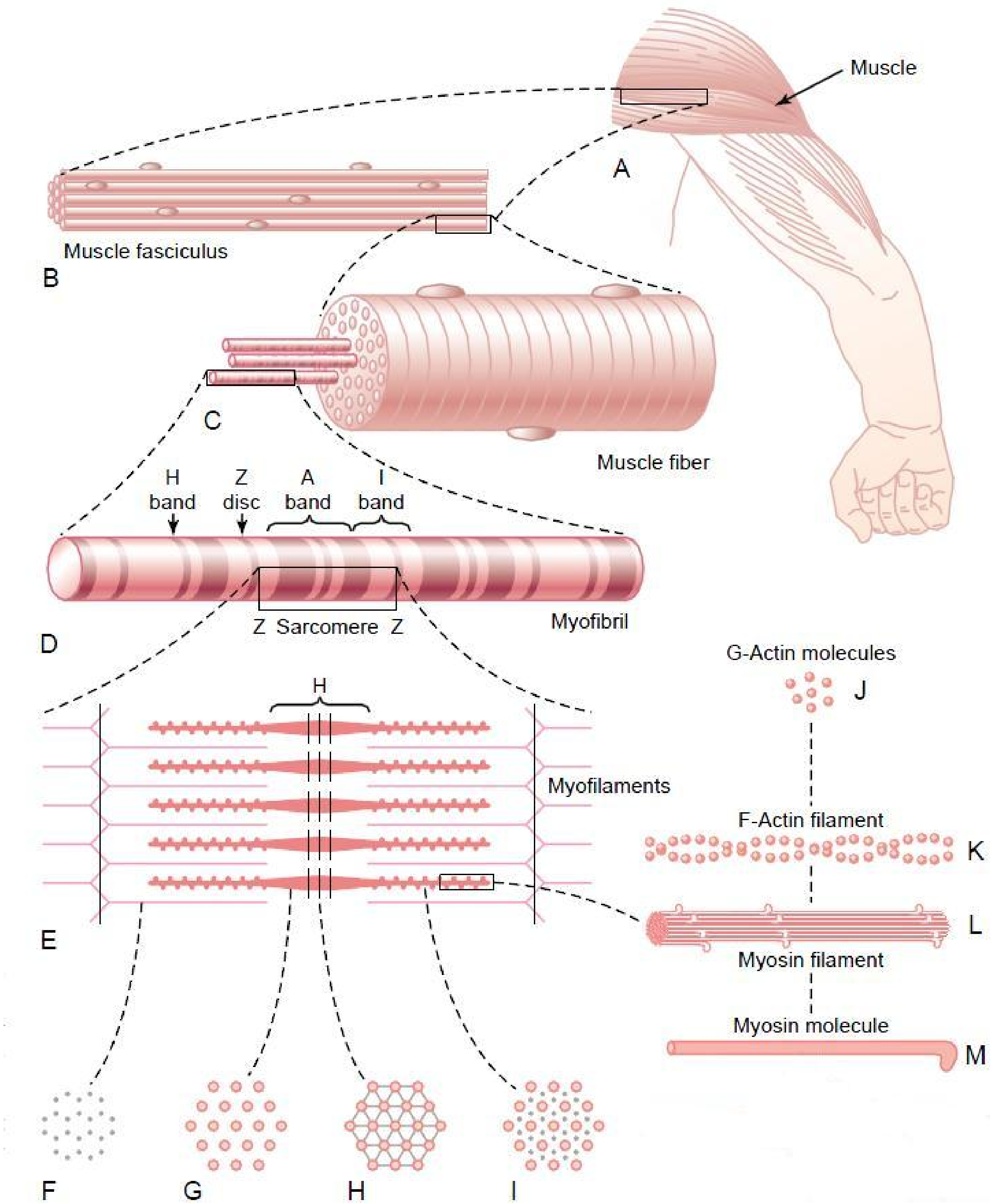


Figure 6: Organization of skeletal muscle, from the gross to the molecular level. F, G, H, and I are cross-sections at the levels indicated. Adapted from [55].

Based on observations of their contractile properties (muscle strength, contraction velocity and fatigability), muscle fibers can be divided into three types. Type I fibers, oxidative fibers, contract slowly and have high fatigue resistance. The force produced by Type I fibers rises and falls slowly, but can be kept consistent for long periods. They are mainly used for maintaining posture and sports like long-distance running. Type IIb fibers, contrary to Type I, are glycolytic fibers and respond to the action potential quite fast. They can produce high force, but they tend to fatigue easily and need a long time to recover. This type of muscle fiber is needed to generate instantaneous or vigorous motion, such as jumping or sprinting. Type IIa fibers use both oxidative and glycolytic processes for metabolism. Compared with the other two fiber types, Type IIa fibers are intermediate in terms of contraction speed, force productivity and fatigability. Single muscles may be composed of the three fiber types in different proportions, which results in compound muscle contractile properties in the different muscles [148].

GENERAL MECHANISM OF MUSCLE CONTRACTION Whatever the muscle fiber type, each muscle fiber is exclusively innervated by a single motor neuron; in contrast, a motor neuron can activate a number of muscle fibers with the same muscle fiber type [148]. The group composed of a motor neuron and all the muscle fibers it innervates is known as a motor unit, as shown in Figure 7.

The initiation and execution of muscle contraction occur in the following sequential steps:

1. Once the decision to move a body segment is made the brain will generate an electrical signal and transmit it to the spinal nerve. Further, an action potential travels along a spinal nerve to its endings on muscle fibers.

2. At each ending, the nerve secretes a small amount of the neurotransmitter substance acetylcholine.

3. The acetylcholine acts on a local area of the muscle fiber membrane to open multiple "acetylcholinegated" channels through protein molecules floating in the membrane.

4. Opening of the acetylcholine-gated channels allows large quantities of sodium ions to diffuse to the interior of the muscle fiber membrane. This initiates an action potential at the membrane.

5. The action potential travels along the muscle fiber membrane in the same way that action potentials travel along nerve fiber membranes.

6. The action potential depolarizes the muscle membrane, and much of the action potential electricity flows through the center of the muscle fiber. Here it causes the sarcoplasmic reticulum to release large quantities of calcium ions (Ca++) that have been stored within this reticulum.

7. The calcium ions initiate attractive forces between the actin and myosin filaments, causing them to slide alongside each other, which is the contractile process.

8. After a fraction of a second, the calcium ions are pumped back into the sarcoplasmic reticulum by a Ca++ membrane pump, and they remain stored in the reticulum

until a new muscle action potential comes along; this removal of calcium ions from the myofibrils causes the muscle contraction to cease.

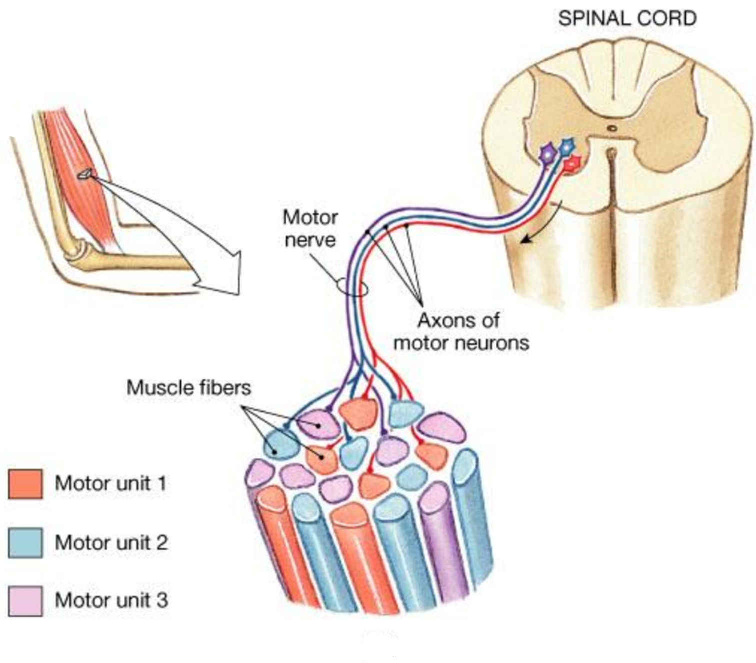


Figure 7: A motor unit composed by a motor neuron and the muscle fiber it innervates. Adapted from [6].

1.2 ANATOMY OF LOWER LIMBS

The human leg is the entire lower limb of the human body and the main parts are: the foot, the shank, and the thigh. These three segments are connected at the ankle joint, the knee joint and the hip joint.

SKELETON As shown on Figure 8, the upper part of the lower limb, or the thigh, has a single bone called the femur. This is the largest and longest bone in the human body. It has a rounded head which articulates with the acetabulum pelvis, forming the hip joint. At the knee, the femur is enlarged and it articulates with the tibia, forming the knee joint. The human lower limb also has a sesamoid-type bone that protects the front of the knee, called the patella. This kneecap is actually formed inside the tendon that connects the tibia and femur. The lower part of the lower limb has two bones, the tibia and fibula. These bones are joined by an interosseous membrane and they are relatively fixed and do not rotate around each other. The tibia has a large flat area at the knee called the tibial plateau, where it articulates with the femur. At its end, the tibia articulates with the talus of the foot and forms the ankle joint.

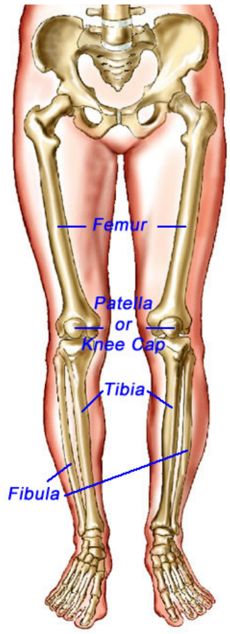


Figure 8: Bones of human lower limb. Adapted from [5].

HIP MUSCLES Movements of the hip joint include flexion and extension, abduction and adduction, and rotation. Flexion of the hip occurs when the angle between the torso and thigh is decreased. Conversely, extension occurs when this angle is increased. Abduction is the term representing the motion of bringing away mid-line of body, adduction is the movement towards mid-line. Hip abduction occurs when the femur moves outward to the side, and hip adduction occurs when the femur moves back to the mid-line. Hip rotation occurs when the femur moves along its longitudinal axis. Lateral hip rotation is when the anterior surface of the femur turns outward. The movement of the anterior surface of the femur inward is medial hip rotation.

There are several muscles [1] that contribute to the movement of the hip joint (Figure 9 and Figure 10). These muscles can be clustered in the following groups:

1. Hip flexion: iliopsoas, **sartorius**, tensor of fascia lata, **rectus femoris**, pectineus, adductor longus, adductor brevis, and gracilis (when the knee is extended).

2. Hip extension: **hamstrings [semitendinosus, semimembranosus, and biceps femoris (the long head)]**, adductor magnus (hamstring part), and gluteus maximus.

3. Hip adduction: adductor longus, adductor brevis, adductor magnus, gracilis, and pectineus.

1 The muscles that can be activated by surface functional electrical stimulation are shown in bold.

4. Hip abduction: **gluteus medius**, gluteus minimus, tensor of fascia lata, **sartorius**, piriformis (when the hip is flexed), obturator internus (when the hip is flexed), and gemelli (when the hip is flexed).

5. Hip medial rotation: **gluteus medius**, gluteus minimus, tensor of fascia lata, pectineus, **semimembranosus**, and **semitendinosus**.

6. Hip lateral rotation: obturator externus, obturator internus, gemelli, piriformis, quadratus femoris, **gluteus maximus**, **sartorius**, and **biceps femoris**.

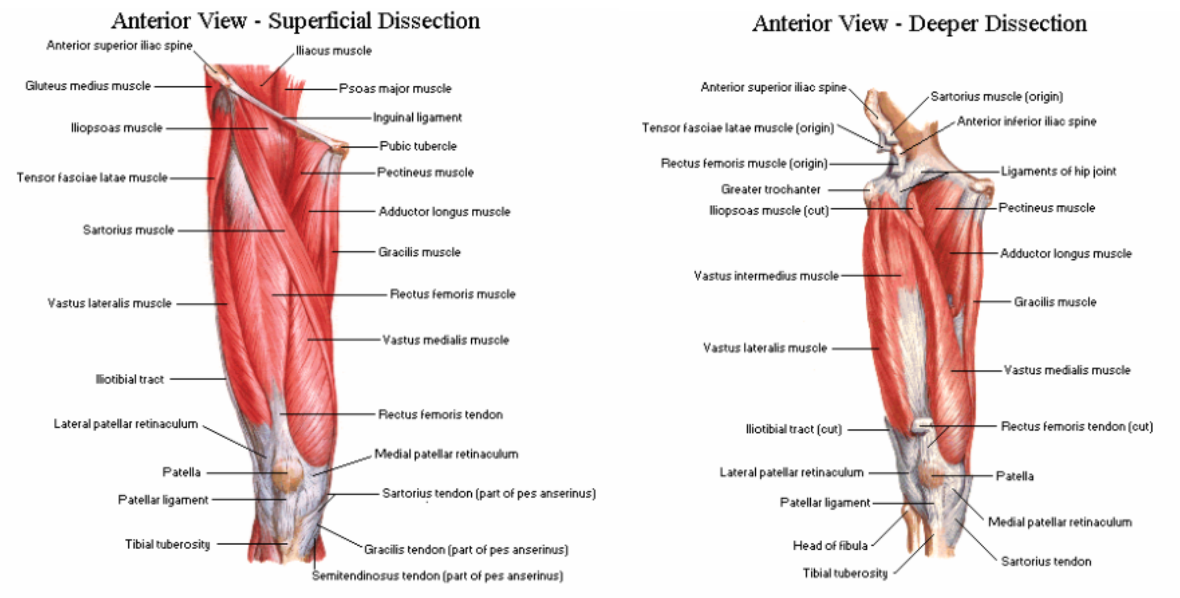


Figure 9: Anterior view of the hip and knee muscles. Adapted from [34]

KNEE MUSCLES The knee permits flexion and extension around a virtual transverse axis, as well as a slight medial and lateral rotation around the axis of the lower part of the lower limb in the flexed position. The muscles[1] responsible for:

1. Knee flexion are: **hamstrings (biceps femoris, semitendinosus, and semimembranosus)**, **sartorius**, gracilis, **gastrocnemius**, and popliteus.

2. Knee extension are: **quadriceps (rectus femoris, vastus lateralis, vastus medialis, and vastus intermedius)**.

3. Knee medial rotation are: **semitendinosus**, **semimembranosus**, and gracilis.

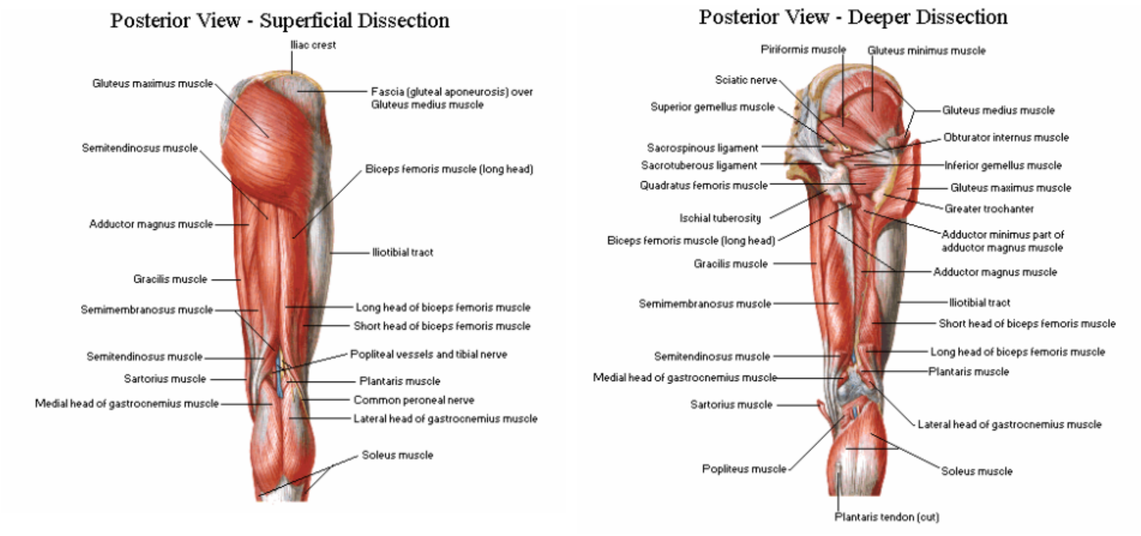


Figure 10: Posterior view of the hip and knee muscles. Adapted from [34]

4. Knee lateral rotation are: **biceps femoris** and popliteus (unlocks extended knee).

See Figure 9 and Figure 10.

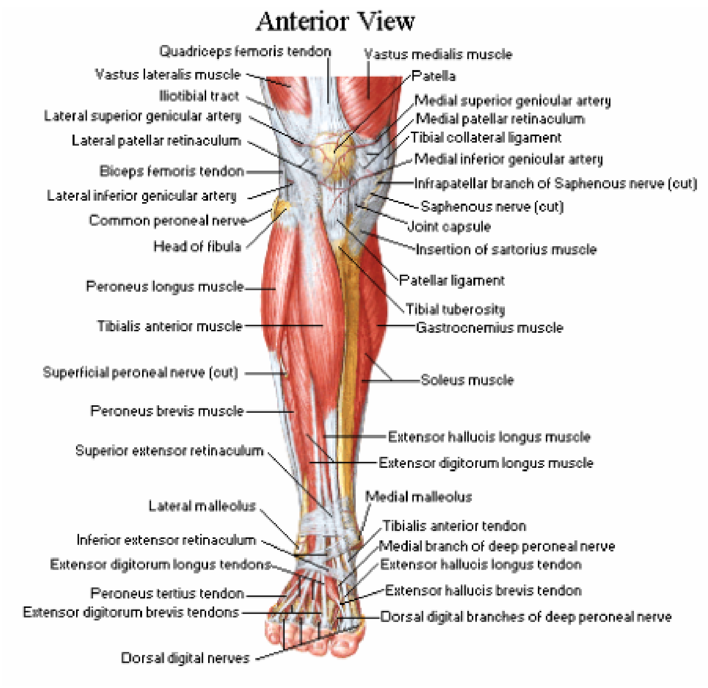


Figure 11: Anterior view of ankle muscles. Adapted from [34]

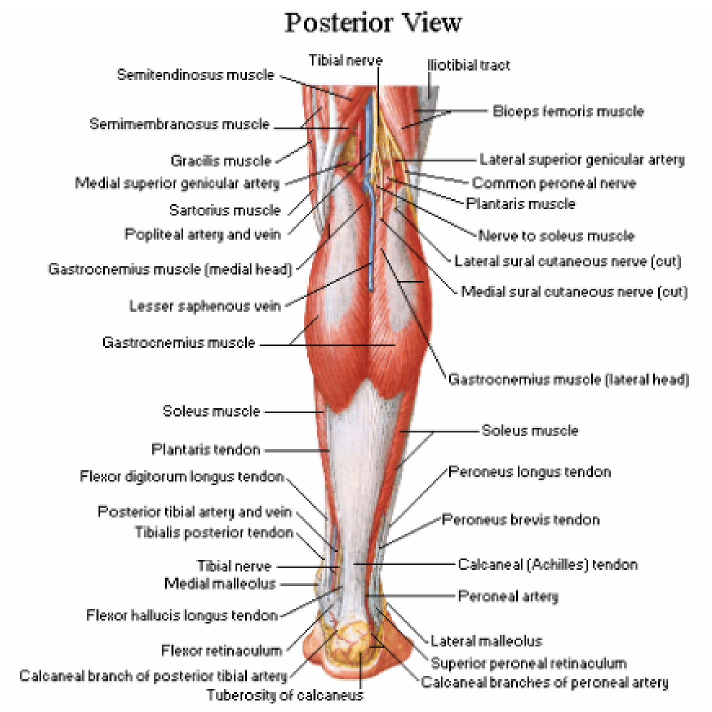


Figure 12: Posterior view of ankle muscles. Adapted from [34]

ANKLE MUSCLES Movements of the ankle joint include dorsiflexion/plantarflexion, adbuction/adduction, and inversion/eversion. Dorsiflexion is the movement that decreases the angle between the foot and the shank. Contrarily, the movement that increases the angle between the foot and the shank is called plantarflexion. Inversion is a movement in which the inner border of the foot is raised so that the plantar surface faces towards the body mid-line, and eversion is a movement where the outer border of the foot is raised so that the plantar surface feces away from the mid-line.

The muscles[1] contributing to the movement of the ankle joint are following (Figure 11 and Figure 12):

1. Ankle dorsiflexion: **tibialis anterior**, extensor digitorum longus, extensor hallucis longus, and fibularis (peroneus) tertius.

2. Ankle plantarflexion: **gastrocnemius**, **soleus**, plantaris, flexor hallucis longus, flexor digitorum longus, tibialis posterior, fibularis (peroneus) longus, and fibularis (peroneus) brevis.

3. Ankle inversion: **tibialis anterior**, and tibialis posterior.

4. Ankle eversion: fibularis (peroneus) longus, fibularis (peroneus) brevis, and fibularis (peroneus) tertius.

1.3 SPINAL CORD INJURY

Spinal cord injuries or diseases are frequent cause of disability and may result in the total or partial obstruction in the flow of both sensory and motor information [115]. Spinal cord injuries are most often caused by trauma, especially following motor vehicle or sports accidents [115]. The extent of the loss depends on the site of the lesion, since functions associated with spinal roots below the lesion level will lose their connection with the higher cerebral structures. This means that the brain will not receive sensory feedback from the areas of the body innervated from these roots, nor will it be able to control muscles in these areas, although the reflex responses will remain intact.

The strength of the paralyzed muscle contractions is usually graded on a Medical Research Council (MRC) scale of 0-5:

1. grade 5: muscle contracts normally against full resistance,
2. grade 4: muscle strength is reduced but muscle contraction can still move the joint against resistance,
3. grade 3: muscle strength is further reduced such that the joint can be moved only against gravity with the examiner's resistance completely removed,
4. grade 2: muscle can move only if the resistance against gravity is removed,
5. grade 1: only a trace or flicker of movement is seen or felt in the muscle or fasciculations are observed in the muscle,
6. grade 0: no movement is observed.

The most widely accepted grading system to express the consequences of spinal cord injury is the classification developed with the American Spinal Injury Association (ASIA) scale. Traumatic spinal cord injury is classified into five categories on the ASIA impairment scale [1]:

1. A indicates a "complete" spinal cord injury where no motor or sensory function is preserved.
2. B indicates an "incomplete" spinal cord injury where sensory but not motor function is preserved below the neurological level.
3. C indicates an "incomplete" spinal cord injury where motor function is preserved below the neurological level and more than half of the key muscles below the neurological level have a muscle grade of less than 3 on the MRC scale, which indicates active movement with a full range of motion against gravity.
4. D indicates an "incomplete" spinal cord injury where motor function is preserved below the neurological level and at least half of the key muscles below the neurological level have a muscle grade of 3 on the MRC scale or more.

5. E indicates spinal cord injury where motor and sensory scores are normal.

Two main classes of the SCI exist, depending on the level of the spinal cord injury. (Figure 13):

1. Tetraplegia (or quadriplegia), an injury to the spinal cord in the cervical region, with the loss of motor and/or sensory functions of head, neck, shoulder, arms, chest, stomach, hips, lower limbs, and feet.

2. Paraplegia, an injury to the spinal cord in the thoracic, lumbar, or sacral segments, with the loss of sensory and motor functions involving only the lower limbs. The body parts that may be affected are the chest, stomach, hips, lower limbs, and feet.

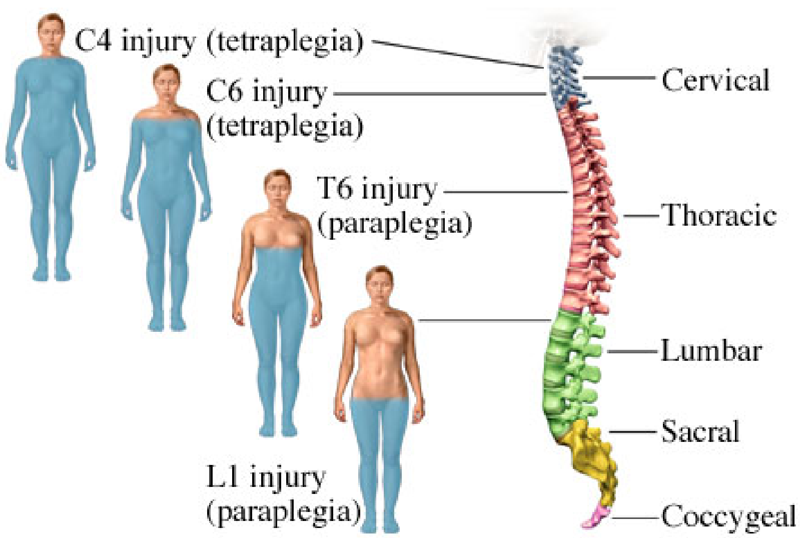


Figure 13: Levels of spinal cord injury. Adapted from [3].

As mentioned, in this thesis we will focus only on complete SCI individuals unable to voluntarily control their lower extremities. The problems faced by individuals with paraplegia are no longer related to survival after the accident, as was the case in the past. Thanks to improvements in emergency medical care, their life expectancy is now comparable to that of the able-bodied population. However, many medical problems arise from living a longer life in a wheelchair, especially in relation to the decrease in muscle mass and bone density in the lower limbs (with consequent predisposition to osteoporosis) and heart and circulatory diseases. An SCI can also result in metabolic changes, increasing the risk of diabetes. During daily activities, such as wheelchair propulsion or transfer from one surface to another, paraplegic patients put an intense load upon the muscles and joints of the upper extremities and, consequently, often experience shoulder complications. In addition to these long-term issues, paraplegic individuals experience other practical problems with a more direct effect on everyday life. These include poor (or absent) bladder control, impaired trunk balance capabilities, increased risk of pressure sores, and muscle spasticity [138].

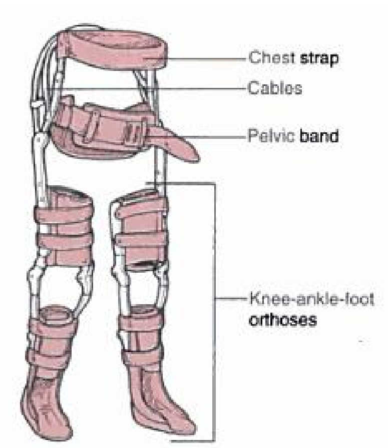
1.4 ORTHOSES

In order to restore standing and walking motion passive mechanical orthoses have been proposed. The common ones are the Ankle Foot Orthosis (AFO), Knee Ankle Foot Orthosis (KAFO), Hip Knee Ankle Foot Orthosis (HKAFO), Reciprocal Gait orthosis, and the powered orthosis.

AFO stabilizes of the ankle joints. One special designs of AFO used for standing and walking in paraplegics is the Vannini-Rizzoli stabilizing orthosis.

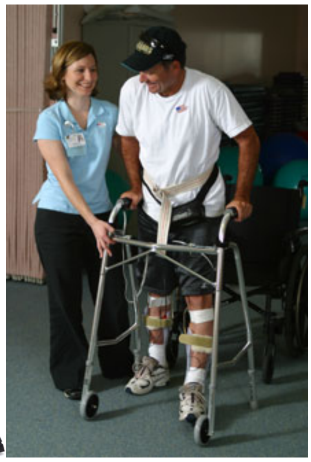
An example of KAFO is shown in Figure 14a. A typical KAFO has a fixed ankle joint. The knee joint is capable of flexion, but during standing and walking it is locked in a position of extension. Paraplegic subjects are taught to stand with hips in full extension [85].

(a) Example of KAFO orthosis.



(b) Reciprocal Gain orthosis.

(c) Ekso Bionics exoskeleton.



(d) Parastep system.

Figure 14: Orthoses for standing and walking after SCI. Adapted from [4], [7], and [127].

Another type of orthosis is HKAFO. Compared with KAFO, in HKAFO the knee joints are also locked with parallel pads. A special type of HKAFO is the Hip Guidance orthosis designed to reduce the energy expenditure of walking.

The Reciprocal Gait orthosis (Figure 14b) provides support for the trunk, pelvis and lower extremities, while allowing ambulation with the use of assistive devices such as a walker, canes or crutches. The cable system enables a coupling mechanism of the hips. While one leg is in stance, the cable provides stability of that hip through the tension created by the opposite advancing leg. As the advancing leg begins stance, the tension created at the opposite limb assists in overweighting, and a forward movement occurs [127].

An example of powered orthosis is the Ekso Bionics exoskeleton, developed in 2012 (Figure 14c). The Ekso Bionics exoskeleton supports its own 20-kilogram weight via skeletal legs and footrests and takes care of the calculations needed for each step. Patients need to balance their upper body, shifting their weight as they plant a walking stick on the right; a physical therapist then uses a remote control device to signal the left leg to step forward. In a future model, the walking sticks will have motion sensors that communicate with the legs, allowing the user to take complete control [4].

Another approach for movement restoration in the paraplegic population is functional electrical stimulation. The advantage of the FES approach over mechanical orthosis can be listed:

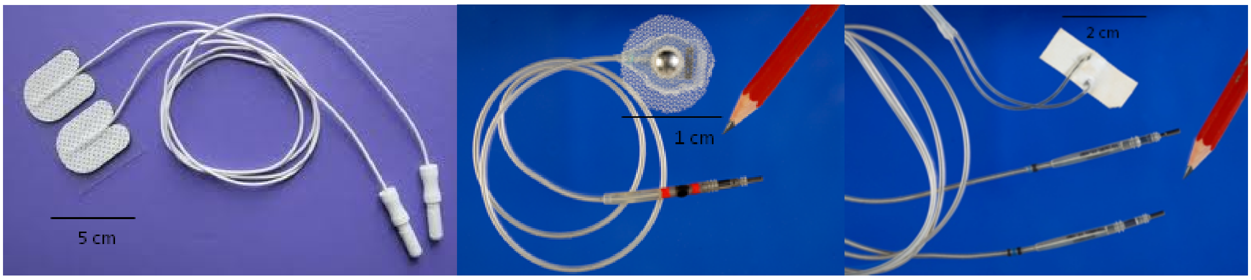
1. The patient's own muscles are used;
2. FES-provoked movements use the patient's own metabolic energy;
3. Preserved neuromuscular reflex can be functionally used;
4. FES can prevents muscle atrophy;
5. FES can reduce muscle spasms;
6. FES may improve muscle and skin blood flow and prevent bone demineralization;
7. FES orthosis has a favorable appearance, has no attachments to cause pressure spots, and does not depend on extremity size for fit, thereby eliminating problems due to a change in girth [85].

The principles of FES are described in the following section. A mechanical orthosis can be used in combination with FES, and is then called a hybrid orthosis.

The only commercial product based on FES for standing and walking after SCI is Parastep-1R (Sigmedics, Chicago, IL), which was approved for home usage in 1994 by the Food and Drugs Administration (Figure 14d).

1.5 FUNCTIONAL ELECTRICAL STIMULATION

Functional electrical stimulation can be defined as the use of an electrical stimulus to achieve muscle contraction. FES delivers trains of the electrical charge pulses, mimicking to an extent the natural flow of excitation signals generated by the CNS in non-impaired structures [115]. The muscle contraction is achieved via the depolarization of the neuron and the provoking of an action potential, determined by an electrical field generated between two electrodes [138]. Further the mechanism of muscle contraction is similar to that described in Section 1.1.2. The strength of the artificial contraction of a paralyzed muscle can be modulated by varying one of three stimulation parameters: pulse width, pulse amplitude, and pulse frequency. The muscle strength also depends on the position of the electrodes, the muscle condition at the time of stimulation (length of the muscle fibers and contraction speed) and the type of stimulated muscle. A typical FES system consists of a stimulator, electrodes and a control unit. The control unit determines the pattern of electrical stimulus for the desired movement. The stimulator generates and delivers the stimulus to the muscle of interest through the electrodes.



(a) Transcutaneous electrode. (b) Epimysial electrode. (c) Circumneural electrode.

Figure 15: Examples of the electrodes used for motor functions restoration. Electrodes (b) and (c) were developed by SUAW project.

The electrodes used to restore motor function after an injury to CNS can be transcutaneous (placed on the skin surface, shown in Figure 15a), subcutaneous (placed within a muscle), epimysial (placed on the surface of the muscle, shown in Figure 15b), intramuscular (placed inside the muscle), epineural (placed on the surface of the nerve), circumneural (wrapped around the nerve that innervates the muscle of interest, shown in Figure 15c), or intraneural (placed inside the nerve of interest). Therefore, based on the position of the electrodes, FES systems can be on the surface or implantable. The advantages of implanted vs. surface FES systems are better selectivity, repeatable excitation, and permanent positioning of the electrodes. The electrodes in implanted FES systems are placed away from pain receptors; therefore, the sensation to the user with a preserved sensory system is more pleasant. However, the disadvantage of implanted FES systems is the risk of damage due to the improper design and implantation of the system. Another major issue is the complicated surgical procedure to position the electrodes [19]. Figure 16 characterizes electrode types according to their invasiveness and selectivity.

FES stimulators can be divided into current-regulated and voltage-regulated. The electrical charge delivered to the stimulated muscle depends on the amplitude and duration of the stimulation pulses, the output impedance of the stimulator, and the impedance of the electrode-skin contact. Given that the electrode-skin contact has electro-capacitive properties, the use of voltage-regulated stimulators may result in uncontrolled electrical

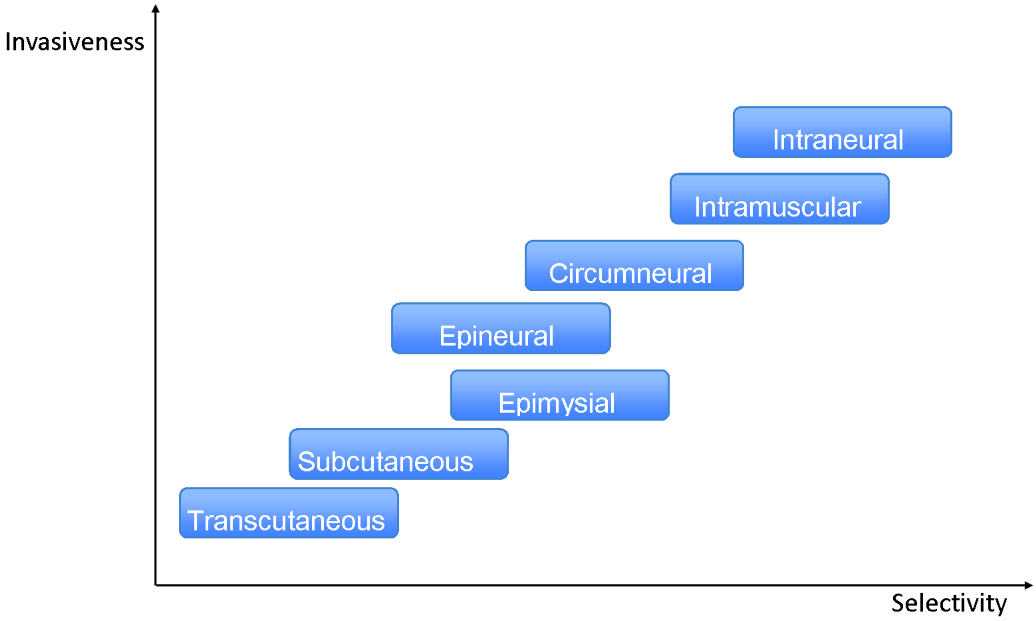


Figure 16: Characterization of the types of FES electrodes according to invasiveness and selectivity. Adapted from [62].

charges delivered to the stimulated muscles, causing pain or weak muscle contraction. Conversely, current-regulated stimulators precisely control the charge delivered to the system, but they may cause tissue damage if the surface of the used electrode is too small.

The stimulation waveform can be monophasic or biphasic. The biphasic shape is generally used for the following reasons: surface stimulation is more comfortable with biphasic stimulation pulses and, for implanted electrodes the risk of tissue damage is less with biphasic stimulation.

One of the biggest limitations of FES systems for restoring functional movements in the SCI population is the rapid onset of the muscle fatigue after FES-induced muscle contractions compared with natural muscle contractions. In a muscle contraction controlled by the CNS, the recruitment order is described by Henneman's Size Principle [60], with small slow fatigue-resistant motor units activated before the large, fast fatigable units. In FES-controlled muscle contractions, the larger muscle fibers are easily excited compared with small fibers. The frequency of natural motor neuron activation needed to achieve continuous contraction is 8-10 Hz [95]. If we take an example of the quadriceps muscle group in surface FES-controlled muscle contraction (Figure 17), the continuous contraction occurs at around 20 Hz, and in order to achieve higher muscle forces, higher frequencies are usually needed (35-50 Hz) [95]. Also, in FES-induced muscle contraction, all muscle fibers between the electrodes are activated at the same time, which is different from the asynchronous activation during natural contraction. All these factors result in a much higher rate of muscle fatigue during FES-induced muscle contraction than that seen during natural contractions.

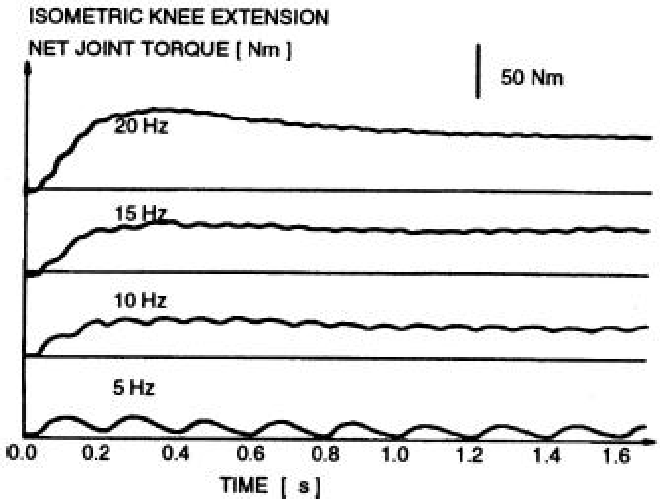


Figure 17: Knee joint torque obtained stimulating the quadriceps with surface electrodes at different frequencies. Adapted from [115].

The history of successful applications of electrical stimulation started with the artificial pacemaker, which was clinically implanted for the first time in 1958. Other applications are cochlear implants, bladder management, deep brain stimulation, drop-foot correctors for hemiplegic patients, tremor compensation and other applications for rehabilitation and therapy [19].

FES-ASSISTED MOVEMENT RESTORATION IN PARAPLEGICS As mentioned, the prolonged immobilization after SCI causes many physiological problems. FES-assisted standing can ameliorate many of them. During prolonged bed rest immobilization bone loss occurs very quickly. Disuse of large masses of bone and muscle produces losses in bone calcium, reduces bone density, and induces hypercalciuria. Passive standing therapy (around three hours per day) proved to be sufficient to induce a slow decline in the elevated calcium excretion. Urinary tract infection occurs in more than half people with SCI. Bladder pressure is about three times greater in the standing posture compared with supine posture. Urine is drained more completely during micturition in the standing position, thereby reducing the risk of bladder infections. Passive standing has been shown to produce decreased muscle tone in patients with spasticity. Due to the loss of sympathetic vascular tone and the skeletal muscle pump, patients with SCI have problems maintaining blood pressure. Prolonged standing can lead to the cardiovascular system adaptation producing functional circulation. Pressure sores are also an important medical complications after SCI. Regular standing allows sustained periods of relief to the sacral and ischial high-pressure areas of the buttocks [16]. Severe muscle atrophy occurs rapidly following traumatic SCI, and FES therapy proved to be able to prevent this atrophy [17]. In addition to the therapeutic benefits, prolonged standing has a great potential to provide functional benefits to SCI patients. It would allow paraplegics to reach further than when sitting in a wheelchair and to communicate with other people on an equal level. Also, it is a prerequisite for walking. In complete paraplegic patients, the functional benefits of standing may be greater than those of gait, since, in the foreseeable future, traveling over more than a short distance will still be easier in a wheelchair [16].

FES has proved to have great potential in functional movement restoration in the paraplegic population. The first functional electrical stimulation was applied to paraplegic patient by Kantrowitz in 1963. The quadriceps and glutei muscles of a T3 paraplegic subject were stimulated using surface electrodes. In the seventies, eighties and nineties of last century, FES as a technique for movement restoration in SCI received considerable scientific attention. A detailed biography review of the proposed systems and methods for FES-assisted standing up and standing are given in Chapter 2 and Chapter 4, respectively. However, FES-assisted applications require that the stimulation provide strong, consistent muscle force. Yet, as already mentioned muscle fatigues far more rapidly when artificially stimulated than when excited by the central nervous system. As a result, the successful implementation of FES paradigms for movement restoration has been greatly limited by premature fatigue. Consequently, the number of effective systems used in clinical and every day practice is still limited.

1.6 CONCLUSION

In this chapter, the nature of human motion and, the functioning of the neural and musculoskeletal systems are presented. However, the mechanisms of physiological muscle contractions, described in this chapter, do not apply to people with SCI. Moreover, after SCI at thoracic or lumbar spinal cord level, lower extremity functions are limited. Therefore, additional knowledge about lower limb muscle functions is presented. The list of medical complications in people with SCI is long, and solutions to make their lives easier are greatly needed. In the literature mechanical orthoses and FES have been proposed for motion restoration in paraplegic people. This chapter thus contains a brief description of the most often used orthoses. However, the solutions for the artificial control of functional motions proposed in this work are based on the use of FES. Hence, the principles of FES are presented at the end of the chapter.

2 FES-ASSISTED SIT-TO-STAND MOTION

2.1 SIT-TO-STAND MOVEMENT IN ABLE-BODIED INDIVIDUALS

Standing up is a common daily activity and a prerequisite to standing or walking. This frequently executed task is one of the most biomechanically demanding activities [119].

There is no unic definition of Sit-To-Stand (STS) motion. The manner in which the STS movement is defined in the literature depends on the aim of the study. For example, Roebroeck et al. defined the STS motion as moving the body's center of mass upward from a sitting to a standing position without losing balance [120]. Vander Linden et al. defined STS movement as a translational movement to the upright posture requiring movement of the center of mass from a stable position to a less stable position over extended lower extremities [137]. The STS movement was also described using kinematic or kinetic variables, defining different phases and events during this postural task [84], [88], [125]. Frequently used definition in the literature, provided by Schenkman et al., comprises four phases (see Figure 18). Phase I (flexion-momentum) starts with initiation of the movement and ends just before the buttocks are lifted from the seat of the chair. Phase II (momentum-transfer) begins as the buttocks are lifted and ends when maximal ankle dorsiflexion is achieved. Phase III (extension) is initiated just after maximum ankle dorsiflexion and ends when the hips first cease to extend; including legs and trunk extension. Phase IV (stabilization) begins after extension of the hips is reached and ends when all motion associated with stabilization is completed [125].

The STS movement in able-bodied subjects has been studied with the standardized clinical tests that are used in epidemiological studies and clinical testing [52], [114], [121]. Measurements of the kinetic and kinematic variables of the STS movement have been obtained using different instruments, such as force plates [88], optoelectronic systems [63], [112], [126], goniometry [66], [107], and accelerometry [49]. Numerous studies investigated the factors that influences the rising motion. These factors can be divided into few categories, chair related (e.g., chair height, arm-free vs. armrest-use condition), subject related (per example, age or muscle strength) and strategy related (per example, lower limbs and trunk position before the STS task, speed of task performance, light conditions) [70]. The analysis of these factors has suggested the following general conclusions.

A higher chair seat results in lower torque values at hip and knee joints. However, comparing the study results is difficult because study designs differ, and the chair seat height is not always based on lower-extremity length [20], [106], [107], [119], [126], [133]. Using armrests will lower the joint torques needed at the knee, probably without in-

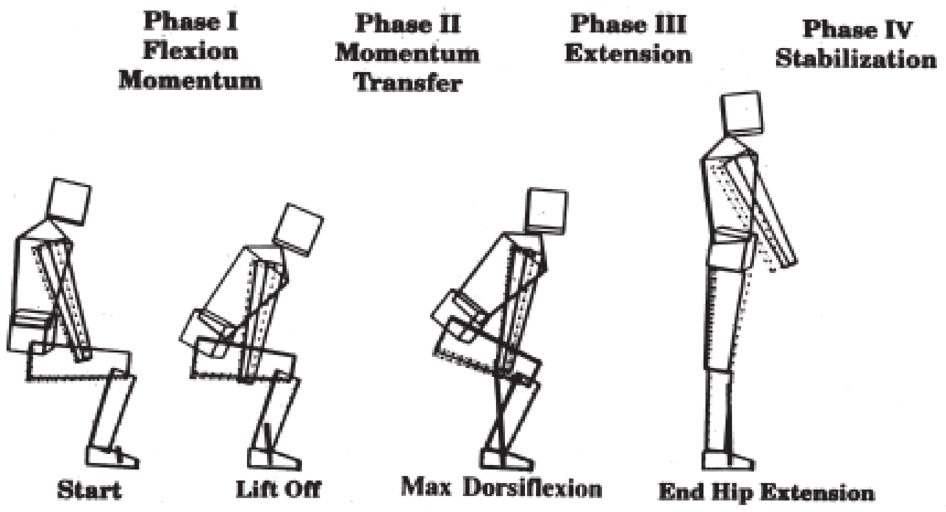


Figure 18: Four phases of sit-to-stand motion marked by four key events. Adapted from [125]

fluencing the range of joint motion [9], [10]. But to our knowledge, there have been no reports on the interaction between the height of the armrests, chair seat height, hand positioning, or their cumulative effect on STS movement performance.

The influence of trunk position has also been documented. According to Shepherd and Gentile, changing the initial trunk position to have more flexion did not change the peak of a summation of hip, knee and ankle joint torques. The duration of the extension phase was longer and a high value of a summation of hip, knee and ankle joint torques was sustained for a longer proportion of the phase, indicating that more muscle force was required [129]. Schenkman et al., described a "momentum transfer strategy" in which the momentum generated by the upper-body is used during the extension phase. In fact, healthy adults perform the STS-movement by a small flexion of the trunk, subsequently they start rising from the chair. The movement ends in an erect standing position and the achievement of stability (Figure 18) [125]. In contrast, in people with muscle weakness rising from a chair is characterized by increased flexion of the trunk prior to rising from the seat [53], [61], [146]. This strategy has been referred to as the "stabilization-strategy".

Effect of knees and feet (posterior, preferred, and anterior positions) positioning prior to the start of the STS movement appears to influence the movement strategy. A shorter movement time has been shown when the feet are placed posterior with the respect to the chair [128]. Positioning the feet more posteriorly enables lower maximum extension joint torque at the hip during STS movement, as well as lower hip flexion speed [76]. No differences were found in electromyographic activity with respect to the different feet positioning [107]. Positioning the knee more extended than preferred prior to the STS movement appeared to lead to an increase of the hip joint angular displacement, with an increase of hip extension joint torque [39]. It was also reporter that the preferred lower-extremity position gives less head movement and lower ground reaction forces [132].

Yoshioka et al. showed the influence of the speed of STS performance on the sum of the peak hip and knee joint torque values, i.e. as the STS movement time increase, the joint torque decreases [147].

No effect on movement time was found when visual control was varied [102], [103].

2.2 SIT-TO-STAND MOVEMENT IN PARAPLEGIC INDIVIDUALS

In spite of the fact that STS plays an important role in everyday life, the biomechanics of this postural task in paraplegic population have not been well documented. To the best of our knowledge, only few studies have been performed involving only couple of paraplegic subjects each.

Bahrami et al. showed that paraplegic patients standing up, with and without assistance of FES of quadriceps muscles and using arm support, perform this task in a different way than an able-bodied person, i.e. they do not use the "momentum transfer strategy". These observations suggest that the able-bodied used the constant information from the actual state of the entire body to control the whole body movement. For the paraplegic patients only a part of this information is available and thus, some significant differences are observed between the maneuver they use and the strategy used by able-bodied subjects [15].

Similar, Kamnik et al. also showed three different ways of performing this motion in paraplegic population. The first group comprised paraplegic patients whose electrically stimulated knee extensor muscles could not provide enough knee joint torque; therefore, they stood up primarily with the help of arm support. The second group was composed of regularly FES-trained patients who made better use of lower-limb support and unloaded the upper extremities. The third group was composed of paraplegic patients who simulated the behavior of the able-bodied, i.e. they pushed and pulled their bodies forward prior to standing up in order to gain some linear momentum, which is helpful in the initial standing up phase (Figure 18) [75].

Azevedo-Coste et al. compared the sit-to-stand trajectories of lower-limb joint angles and showed that the main difference between able-bodied and paraplegic subjects is the onset of leg movement with regard to trunk bending; this author hypothesized that in order to be efficient, bending the trunk forward should start before and last through knee and ankle movement [14].

2.3 FES CONTROL STRATEGIES: STATE OF THE ART

The ability to rise from a sitting to a standing position is very important for individuals with paraplegia in order to achieve minimal mobility. This movement also has functional and therapeutic benefits related to bone loading, joint extension, cardio-circulatory stimulation, and pressure sore prevention [116]. Persons with spinal cord injuries can recover the capability of standing up by using implanted or surface FES systems [50], [85], [115]. The principles of FES and its advantages over conventional rehabilitation treatment are given in Chapter 1.

The FES-assisted sit-to-stand method, which is used in clinical practice, involves open-loop stimulation of knee extensors activated by hand switches, as proposed by Kralj and Bajd. [85] and Guiraud et al. [50]. This technique works adequately in many cases [26]; however, when this strategy is applied, stimulation starts without reference to upper-body movement. Hence, the whole-body motion is not optimal and requires high joint velocity and hight upper-limb forces during the rising motion [74], which, if often repeated, may cause both damage to joint tissues and shoulder complications. Also, open-loop FES systems often use higher than needed stimulation parameters, hence the muscle contractions induced by FES tend to result in rapid muscle fatigue, which limits the following activities [14].

A number of closed-loop strategies have been proposed to solve some of these problems. Ewins et al. proposed a Proportional Integral Derivative (PID) closed-loop controller of knee joints [37]. The system was designed to move the knee angles to a hyper extended position by modifying the stimulation amplitude of the electrically stimulated knee extensors. Servo potentiometers, attached to the thighs and calves of the patient, were used to monitor the knee angles. The results showed smoother trajectories, but neither reduced upper-limb efforts nor lower terminal velocities in the knees were reported. Because of the nonlinear dynamics of muscles and the sit-to-stand motion, a PID controller does not work well for control of the STS task [93].

Other strategies, such as closed-loop ON/OFF [104] controllers have been successful in reducing terminal knee velocity during sit-to-stand maneuvers, which would preserve knee joints. The closed-loop ON/OFF control had a switching function, based on a predefined phase-plane switching curve of the desired knee angle versus knee velocity, which divided the state space of a system into regions of on and off FES commands. Greater arm force was required compared with open-loop stimulation.

Dolan et al. proposed a switching curve controller for FES-assisted sit-to-stand motion. The controller simulated the behavior of an able-bodied person by observing a phase plane defined by the knee angle-knee angular velocity relationship (Figure 19). The main goal of this controller was to control the end of both sit-to-stand and stand-to-sit motion. The controller was tested in a pilot study on a female paraplegic subject. The controller successfully decreased terminal knee velocities, but greater arm forces during the motion were reported [31]. The reported arm forces could be explained by the observation that the subject had no experience in using the system and therefore might have been applying more arm support than needed.

Davoodi and Andrews developed and compared gain scheduling PID and fuzzy logic controllers [25]. These authors used a Genetic Algorithm (GA) as an optimization approach for tuning the controllers' parameters. Both controllers, when compared with a PID or ON/OFF controller, resulted in smoother rising maneuvers and the average elec-

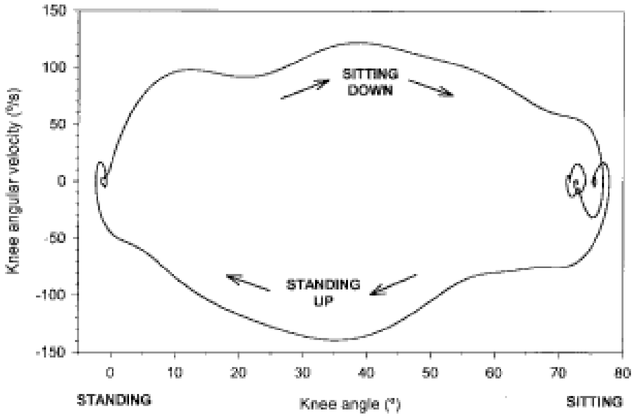


Figure 19: Typical graph of knee angular velocity in relation to angle trajectory for able-bodied individuals during standing up and sitting down. Adapted from [31]

trical stimulation required for successful motion was reduced. They were also able to reduce the arm forces but the level of the required arm support was still greater than the forces needed in the open-loop FES method. Further, the high number of GA trials required during calibration makes it inconvenient for practical use. The same group of authors proposed a fuzzy logic controller based on reinforcement machine learning for controlling FES of the lower limbs during rising maneuvers [26]. Three simulation scenarios were successfully tested: learning to compensate for weak arm forces, learning to minimize arm forces, and learning to minimize the terminal velocity of the knee and arm forces. Although this method appears to be promising, only its theoretical feasibility has been tested.

Mahboodi and Towhidkhah [93] investigated FES-assisted standing up using the nonlinear model predictive control approach. This theoretical study showed good tracking behavior for lower-limb joint angles, but it has not been experimentally tested. The arm efforts during the motion have not been analyzed.

Contrary to these "control-driven" methods, other "patient-driven" approaches based on an inverse dynamic model have been proposed [32], [33] [117], [118]. Here the action of the FES controller was adjusted to the voluntary contribution of the patient, i.e., to the hand forces or body posture. Feedback to the system consisted of joint positions or hand reaction forces, which were fed into the inverse dynamic model in order to predict the stimulation pulse duration needed for the movement. Paraplegic patients were able to control the standing up movement by their voluntary upper-body efforts. The upper-body efforts were lower, compared with sit-to-stand motion performed without FES support. However, these strategies require very accurate and realistic models (Figure 20) that are often difficult to obtain [116] and their practical real-time application remains limited [115].

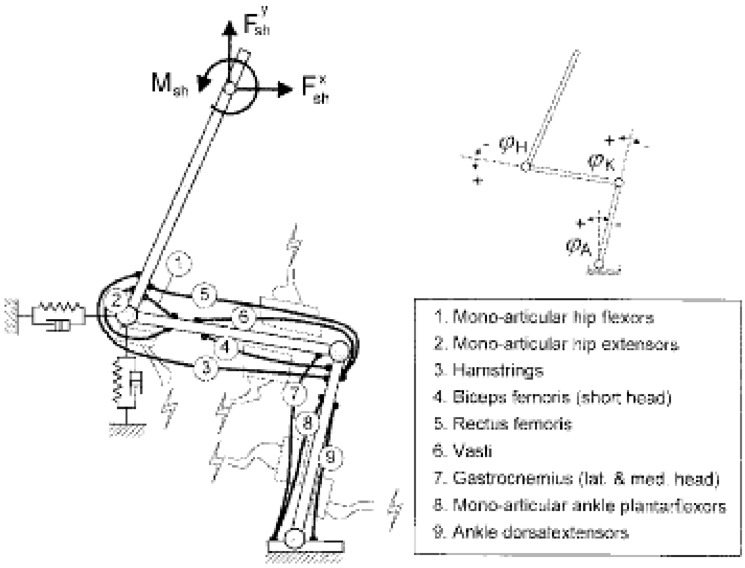


Figure 20:
Three degrees of freedom model with nine muscle groups. The forces and torque values at the shoulder represent the upper-body activities. Adapted from [117].

2.4 MOTIVATION AND GOAL OF THE CHAPTER

A high prevalence of shoulder pain has been reported in the spinal cord-injured population [124]. The impact of pain is sometimes described as worse than the loss of function itself, for example, on working ability [122]. In this chapter, we therefore report on our attempt to optimize sit-to-stand transfer by minimizing U/L participation during the motion. First, we chose a dynamic optimization method in order to find the STS pattern during the rising motion of a paraplegic subject that would minimize the U/L participation and the lower-limb torque applied during the motion (Section 2.5). In Section 2.6 we describe our experimental validation of a closed-loop system for sit-to-stand transfer for the needs of paraplegic individuals. This system should optimize rising motion by coordinating the action of the upper part of the body under voluntary control and the action of the lower limbs, which is under FES control, with the final goal of minimizing the applied hand forces during the rising motion. We experimentally tested the impact of stimulation time on applied hand forces during rising motion in six paraplegic subjects.

2.5 OPTIMIZATION OF SIT TO STAND MOVEMENT

In this section, we investigate an optimal way to perform sit-to-stand movement in terms of applied lower-limb joint torque and applied shoulder forces using dynamic motion optimization. In the motor control and biomechanics literature, a general assumption is that human beings perform a motion according to certain optimal criteria, i.e., movement control can be related to a problem of minimizing a biomechanical cost function. Therefore, optimization processes have usually been used to provide a better understanding of human postural and locomotor systems [38], [89], [92], [97], [113], [123], [135], [145]. In the field of human motion sciences, the proposed optimization algorithms generally minimize a cost function, which is the time integral of the square of a quantitative function (jerk, acceleration, torque, torque-change).

For example, Flash and Hogan suggested that the arm reaching motion minimizes the time integral of the hand position jerk [38]. Rosenbaum et al. computed optimal movement in the joint space by replacing the position jerk in the cost function [38] with the sum of joint angle jerks [123]. Uno et al. improved the optimization criterion by minimizing the torque-change, i.e., minimizing the sum of the joint torque derivatives [135].

Optimal sit-to-stand movement in able-bodied subjects was investigated by Pandy et al. [113]. Authors used a three segment 2D model that included eight muscle groups. Optimal neural excitation signals were computed by minimizing the muscle forces and their derivatives. Kuzelicki et al. studied the same task using a 3D model with 11 degrees of freedom and suggested that a combination of minimum torque, minimum torque-change and the integral of the difference between left and right ground reaction forces, in order to guarantee symmetric motion, would successfully describe rising motion in able-bodied subjects [89]. Yamasaki et al. suggested that the cost function that minimizes the sum of the ankle, knee and hip torque changes would better describe rising motion than a cost function that would minimizes the sum of the ankle, knee and hip joint jerk [145].

Due to overuse of the upper extremities, paraplegic patients often suffer from shoulder pain and rotator cuff lesions. Also, as explained in Section 1.5, muscle fatigues far more rapidly when artificially stimulated by FES than when excited by the CNS. As a result, the role of FES in applications such as standing and walking is limited. Hence, the objective in the present study was to optimize sit-to-stand motion by defining a strategy for trunk movement that can be voluntarily controlled by a paraplegic person in order to minimize U/L participation and applied lower-limb joint torques during the motion. The last was motivated by assumption that minimization of the needed joint torques decreases the muscle activation during the motion and in that way reduces muscle fatigue. Therefore, in this study we dealt with a dynamic optimization algorithm in order to find the theoretically optimal manner for performing sit-to-stand movements in paraplegic subjects. To do so, a stereophotogrammetric system and force sensors were used to acquire human data during the FES-assisted rising motion of a paraplegic subject. Based on a three-segment 2D dynamic model and the optimization algorithm, we calculated optimal hip trajectories during rising motion in terms of minimized knee and ankle joint torques for various conditions of force applied to handles. The motion computed using the optimization process was compared with the one recorded during the experiment.

2.5.1 *Human data collection*

Experimental data were collected from a paraplegic patient with no experience in FES usage. Patient information is given in Table 1. The local ethics committee approved those tests. Experiments were carried at the PROPARA rehabilitation center, Montpellier, France. Kinematic variables were measured using the stereophotogrammetric system (9 Mx cameras, VICON) at a 100 Hz sampling rate. In order to accurately estimate small postural modifications, 16 reflective markers were located on both legs at the hip, knee and ankle joints and on the top of the feet; on both arms on the shoulder, elbow and wrist joints; on the head symmetrically over the left and right temples; and on both lateral sides of the trunk approximately at vertebral level T11. ATI Industrial Automation's six degrees of freedom force sensors were mounted to handles fixed on parallel bars to record the arm efforts. Sampling frequency was 100 Hz. The experimental setup is presented in Figure 21.

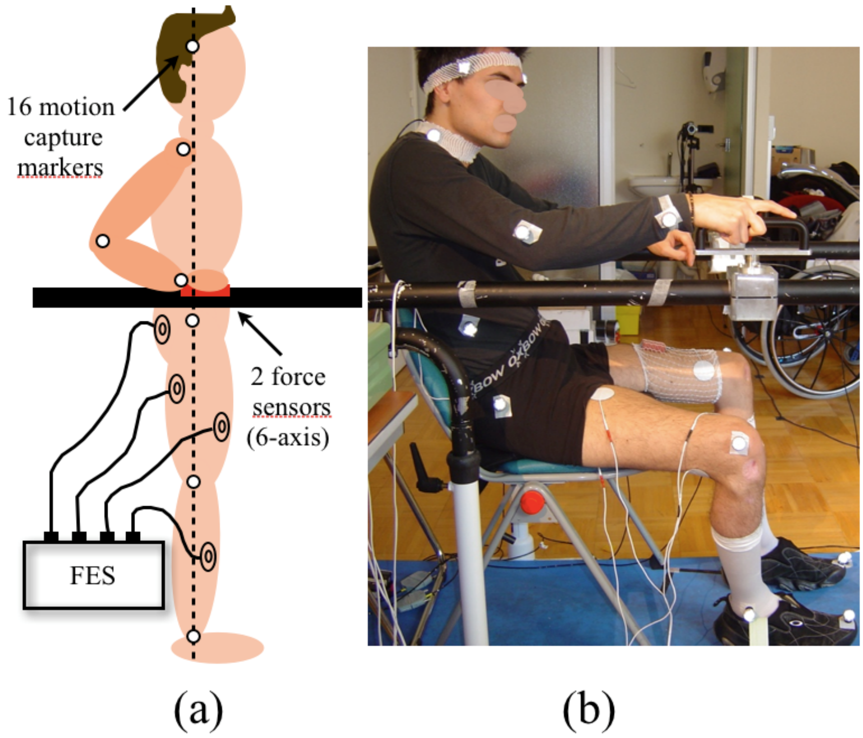


Figure 21: a) Protocol description, b) Paraplegic patient during the experiment.

To begin, the subject was asked to sit on a chair with arms on the handles and to keep his trunk straight. The position of the handles was adjusted to the patient's preference. The PROSTIM stimulator was used. PROSTIM is a programmable stimulator manufactured by MXM, France. The device provides eight bipolar channels delivering current controlled biphasic stimulation pulses, with a capacitive secondary pulse. The stimulator

Age [years]	18
Heigh [m]	1.92
Weigh [kg]	65
Gender	male
Level of the lesion	T6/T7
Post injury period [years]	7

Table 1: Subject's caracteristics

is CE marked. The experimenter manually triggered the stimulator, and the stimulation frequency and pulse width were respectively 40 Hz and 300 μs. The stimulation current amplitude was adapted to ensure joint locking. Rectangular, self-adhesive, multi-use surface electrodes (50x90 mm) were positioned over the muscles. The stimulated muscles were the quadriceps, vastus medialis, hamstring biceps femoris, gluteus maximus, and tibialis anterior. The subject was instructed to perform a sit-to-stand maneuver in his selected way. Each measurement lasted until the patient was able to the maintain standing posture. In this study, the first 6s of data acquired during one sit-to-stand trial were analyzed.

2.5.2 *Biomechanical model*

The movement was assumed to be symmetrical [15]. The head and neck were assumed to remain along the trunk. Thus, the biomechanical model used to represent the human postural system in 2D was composed of three rigid segments (shank, thigh, Head-Arm-Trunk (HAT)). The ankle, knee and hip were modeled as one Degree of Freedom (DoF) rotational joints in the sagittal plane (Figure 22). The connection between foot and support was fixed, i.e. there was no motion between them. Winter tables [143] were used to estimate segment lengths and inertial parameters of the model segments as a function of the height and body mass of the model. Inverse dynamics and estimated ground reaction forces were computed using recursive Newton-Euler equations. Integration of the dynamic model was performed using commercial modeling software LifeMOD.

LifeMOD is a registered trademark library of ADAMS specialized in modeling the human body. ADAMS software is a kinematic and kinetic simulation tool commercialized by the MCS Software. Numerous and various libraries, representing the state of the art, for modeling the interactions between two objects, are available in ADAMS software. LifeMOD can be used to create a complete musculoskeletal model, starting from the specific stature and weight of a subject, and using an anthropometric table [143]. Once this model is set, LifeMOD /ADAMS permits the calculation of the direct and inverse kinematic and dynamic models. More information about LifeMOD software can be found in [2]

To take into account the interaction between the human body and the chair and to detect the seat-off instant, we used an impact force algorithm provided by LifeMOD software and adapted to the patient's characteristics [2].

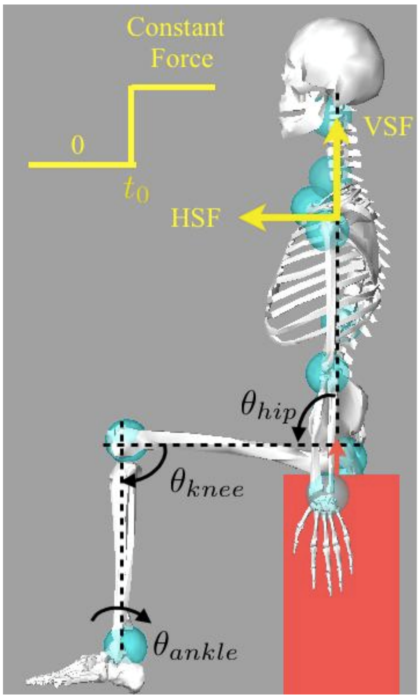


Figure 22: Used biomechanical model designed using LifeMOD software. VSF and HSF are vertical and horizontal components of the shoulder force, respectively, *to* is the seat-off moment when constant force is applied on the shoulder. θ_{ankle}, θ_{knee}, and θ_{hip} are the ankle, knee angle and, hip angles, respectively. The initial position of the ankle, knee and hip joints were $0°$, $90°$, $-80°$, respectively.

In order to simulate the function of the arms during standing up activity, Vertical Shoulder Force (VSF) and Horizontal Shoulder Force (HSF) were applied as a step function (Figure 22). At the seat-off instant, the forces on the shoulders were set to numerical value different from zero.

2.5.3 *Optimization process*

Mathematical optimization refers to the selection of the best element from some set of available alternatives. In the simplest case, an optimization problem consists of maximizing or minimizing a real function by systematically choosing input values within an allowed set of input values and computing the value of the function. More generally, optimization includes finding the "best available" values of some objective function given a defined domain, including a variety of different types of objective functions and different types of domains [47]. Choosing a cost function for modeling a human motion task is not easy, because the performance is determined by the physiological and environmental constraints imposed on the task. To generate the movement in the joint space it is necessary to find joint trajectories $q(t)$ in the motion time interval $[0, T_f]$ that minimize a cost function C and at the same time ensure a set of continuous and discrete constraints:

$$
\begin{array}{cc}
\underset{q(t)}{\operatorname{argmin}} & C(q(t)) \\
\forall i, \forall t \in [0, T_f] & g_i(q(t)) \leqslant 0 \\
\forall j, \forall t \in [0, T_f] & h_j(q(t)) = 0 \\
\forall t_k \in \{t_1, t_2, ..., t_n\} & z_k(q(t_k)) \leqslant 0
\end{array}
\tag{1}
$$

where:

- $g_i(q(t))$ represents continuous inequality constraint;
- $h_j(q(t))$ represents continuous equality constraint;
- $z_k(q(t_k))$ represents discrete inequality constraint.

The problem (1) is called an infinite programming problem because the space where $q(t)$ is defined is infinite. Usually to compute the trajectories a set of parameters X is used and the problem is turned into a semi-infinite programming problem, described by:

$$
\begin{array}{cc}
\underset{X}{\operatorname{argmin}} & C(X) \\
\forall i, \forall t \in [0, T_f] & g_i(X, t) \leqslant 0 \\
\forall j, \forall t \in [0, T_f] & h_j(X, t) = 0 \\
\forall k & z_k(X, t_k) \leqslant 0
\end{array}
\tag{2}
$$

where:

- X is the set of parameters,
- $g_i(X, t)$ is continuous inequality constraint,
- $h_j(X, t)$ is continuous equality constraint,
- $z_k(X, t_k)$ is discrete inequality constraint.

In this study, the joint trajectories are represented using the B-spline basis functions [28] with the following formulation:

$$
q_j(t) = \sum_{i=1}^{m} b_i^K(t) p_{j,i} \tag{3}
$$

where:

- $b_i(t)$ is the basis B-spline
- $p_{j,i}$ are the control points

The set of parameters $X \in R^n$ and $X = \{p_{1,1}, \cdots, p_{1,m}, p_{2,1}, \cdots, \beta, T_f\}$ where:

- $p_{j,i}$ is the i^{th} control point of joint j,
- β is a set of parameters
- T_f is the motion duration.

Now the dimension of the space, where $q(t)$ is defined, is R^n, a finite one, and $q(t)$ is described using a linear function.

The objective of our optimization process was to define one of the optimal strategies for voluntary trunk movement, while knee and ankle joint trajectories were constrained by electrical stimulation. Therefore, the optimization algorithm was expected to compute trajectories of the hip joint with respect to the trajectories of the knee and ankle measured during the experiment. Various levels of forces acting on the shoulders were tested in order to evaluate different scenarios. As mentioned before, the trajectories obtained from the optimization process were described through a cubic B-spline with five control points. The initial and final control point values corresponded to sitting and standing positions, respectively. These constraints force the model to perform the rising motion. The optimization process calculated the values of three intermediate control points, dividing the trajectory into four equal parts. In order to minimize lower limb efforts during the STS transition, the chosen cost function was the sum of the squared joint torques at ankle, knee and hip joints:

$$C = \sum_{to}^{tf} \left(\tau_a^2 + \tau_k^2 + \tau_h^2\right) \cdot T_e \tag{4}$$

In Equation 4 τ_a , τ_k, and τ_h refer to ankle, knee and hip torques respectively, *to* is the seat-off moment, *tf* is the final time and *Te* represents the sample time. Note that C was calculated after seat-off moment till the end of the motion. Solution of the optimization respected constraints:

$$\theta_{min} \leqslant \theta\,(t) \leqslant \theta_{max} \tag{5}$$

$$\theta_{min} = -100^\circ, \theta_{max} = 10^\circ \tag{6}$$

where $\theta(t)$ is the trunk angle. Specific values of the forces acting on the shoulders were chosen to simulate three different sit-to-stand conditions. In the first optimization process, the force acting on the shoulder was set to be equal to the one obtained from the experimental data. In the second optimization, the chosen force value was the half of the measured one. In the last optimization, VSF and HSF were chosen to be null, i.e., no use of arm support during STS motion.

2.5.4 *Data processing*

The trajectories of the reflective markers, recorded during the experiment, were corrected by a low-pass filter (Butterworth, fourth order, cut-off frequency of 5 Hz). The data acquired using the stereophotogrammetric system and the force sensors mounted on the handles were used to get the trajectories of ankle, knee and hip joints and the forces acting on the shoulders. For each joint, the dynamic torques were computed based on the inverse dynamic method, i.e. using the Newton-Euler equations. The sum of the absolute joint torques after the seat-off instant until the end of the motion was calculated.

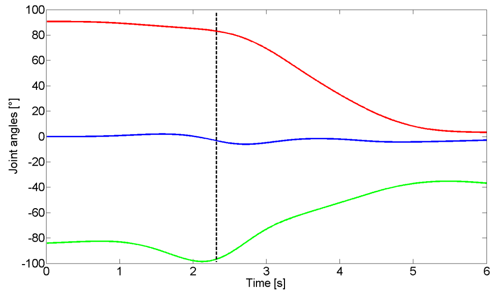
For all optimization processes, we calculated the sum of the absolute joint torques after the seat-off moment until the end of the motion and compared them with the sum of the absolute joint torques calculated from experimental data in order to validate our method. All computations were performed using MATLAB[1] software.

2.5.5 *Results*

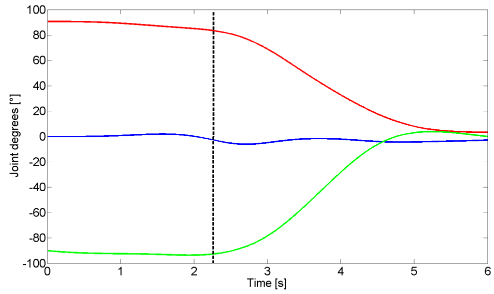
In Figure 23a trajectories for ankle, knee and hip measured during the experiment are presented. The patient was instructed to bend his trunk forward before the stimulator was triggered. The measured amplitude of the reaction forces acting on the left shoulder was 22% and 3,5% of the patient's Body Weight (BW) for the vertical and horizontal components, respectively. The sum of the absolute values of the ankle, knee and hip torques during rising motion was $1.8762 \cdot 10^5$ Nm.

The results of the optimization algorithm are presented in Figure 23b, Figure 23c and Figure 23d. In Figure 23b the amplitudes of the applied vertical and horizontal shoulder forces were 22% and 3,5% of the patient's BW respectively, i.e., it had the same numerical values as the measured shoulder force. The results of the optimization process suggested that in this case the forces provided by the upper extremities and stimulated lower limbs were enough to lift the body upward and that the inertia of the trunk was neither necessary nor optimal in terms of joint torques. The sum of the absolute joint torques in this case was $7.7112 \cdot 10^4$ Nm which was less that the sum of the joint torques calculated from the experimental data. In Figure 23c the optimization results are presented for vertical and horizontal shoulder forces of 22% and 1.75% of the patient's BW. In Figure 23d optimization results with 0 BW, i.e., without arm support, are presented. In this case, the results suggested that the patient should use a strategy similar to that of an able-bodied person: prior to standing up, he should bend his body

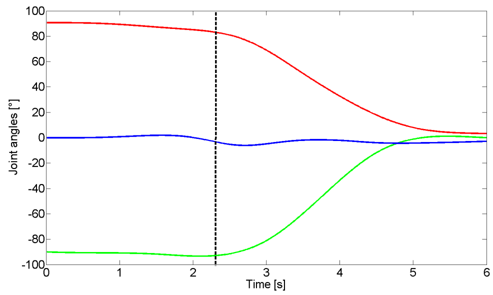
1 MATLAB is a registered trademark of The MathWorks, Inc.



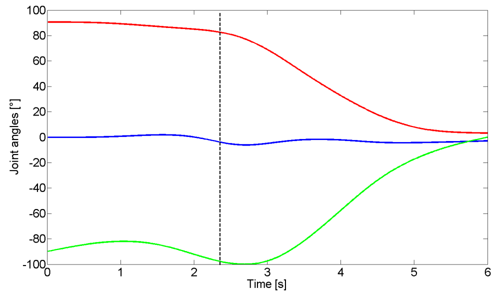
(a) Lower limb trajectories measured during the experiment.



(b) Optimization result with vertical shoulder force of 22%BW and horizontal shoulder force of 3, 5%BW.



(c) Optimization result with vertical shoulder force of 11% BW and horizontal shoulder force of 1.75%BW.



(d) Optimization result without applied shoulder force.

Figure 23: Lower limb trajectories for ankle, knee and hip are presented. The blue line is the ankle angle, the red line is the knee angle and the green line is the hip angle. The dashed bar marks the beginning of the seat-off phase.

forward in order to use the linear momentum of the trunk, which is helpful during the lift phase of the rising motion (phase II described in [126]). Knee extension should start about 500 ms before the maximum trunk angle, and finish at approximately the same time as the trunk motion. The sum of the absolute joint torques for these cases were, respectively, $8.6642 \cdot 10^4$ Nm and $1.0705 \cdot 10^5$ Nm.

For easier comparison, the sum of the absolute joint torques calculated from the experimental data and the three optimization processes are depicted in Figure 24. The first case corresponds to the torque calculated using the experimental data. Cases 2, 3 and 4 show the results of optimization processes with VSH=22%BW and HSF=3.5% BW, VSH=11%BW and HSF=1.75% BW, and VSF=0% and HSF=0% of BW, respectively.

2.5.6 *Conclusion*

The results of the present study show that, within the frame of the optimization, it is possible to find the theoretically optimal hip trajectory to minimize the sum of the ankle, knee, and hip torques during sit-to-stand motion. Different levels of applied U/L

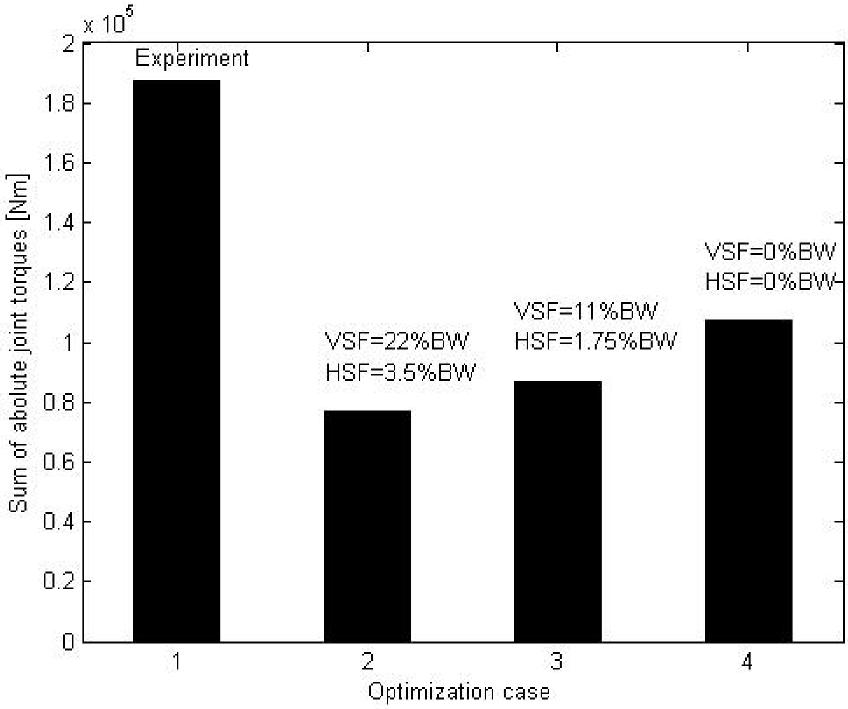


Figure 24: Sum of the absolute value of ankle, knee, and hip torques during standing up motion.

efforts lead to different strategies in terms of trunk trajectory. Among the strategies that paraplegic patients employ to stand-up [75], one of the most optimal is similar to that used by able-bodied people. In other words, for the initial position of the patient in our experiment and for reduced lifting forces provided by the upper extremities, the patient should bend his body forward and stimulation should be triggered about 500ms before the maximum trunk angle in order to use the linear momentum of the trunk in the seat-off phase.

We believe that this information could be used to teach paraplegic subjects how to perform the motion and trigger a closed-loop sit-to-stand FES system from trunk motion information. Using this approach, we would optimize FES-assisted sit-to-stand motion and give the patient an active role in controlling his motion and posture.

2.6 Coordination of lower and upper parts of the body during STS movement

It has been shown that trunk orientation and acceleration in able-bodied individuals present low inter and intra-variability and therefore may be good characteristic signatures of the sit-to-stand task [12]. To be efficient, bending the trunk forward should precede leg movement and last throughout knee extension [12], [72], [73]. Therefore, Héliot developed a system that uses trunk acceleration information to coordinate the motion of the trunk, which is under the patient's voluntary control, and the motion of the lower limbs, which are under FES control. The proposed approach, unlike other

Figure 25: Wireless system used in this study.

"patient-driven" approaches described in Section 2.3, does not require a complex model of paraplegic standing up and is based on the observation of trunk movement during rising motion and a detection algorithm, which triggers a pre-programmed stimulation pattern [59], [58]. A detailed description of the system is given below.

In Section 2.5, we showed that trunk motion plays an important role in performing the STS task. In order to perform sit-to-stand motion with minimal participation of hand forces and minimal torque, paraplegic subjects should bend their trunk forward before the seat-off moment. We showed that leg motion should start an about the maximal point of trunk bending. The goal of this study was to teach paraplegic patients to perform this trunk motion and to artificially start the leg motion by using the system developed by Héliot. Here, we aim at find the optimal moment for starting a pre-programmed stimulation pattern with respect to the trunk motion in order to decrease arm participations during the movement. Also, the goals of this study are to experimentally validate the FES closed-loop system for sit-to-stand transfer in paraplegic subjects and to test whether this system is able to recognize STS movement and automatically trigger leg stimulation at the optimal moment with respect to trunk motion, in order to decrease arm participation during this motion.

2.6.1 *Method*

2.6.1.1 *Approach*

The system developed by Héliot was used in this study. It is based on a wireless system to acquire trunk acceleration in the sagittal plane during rising motion, with a stimula-

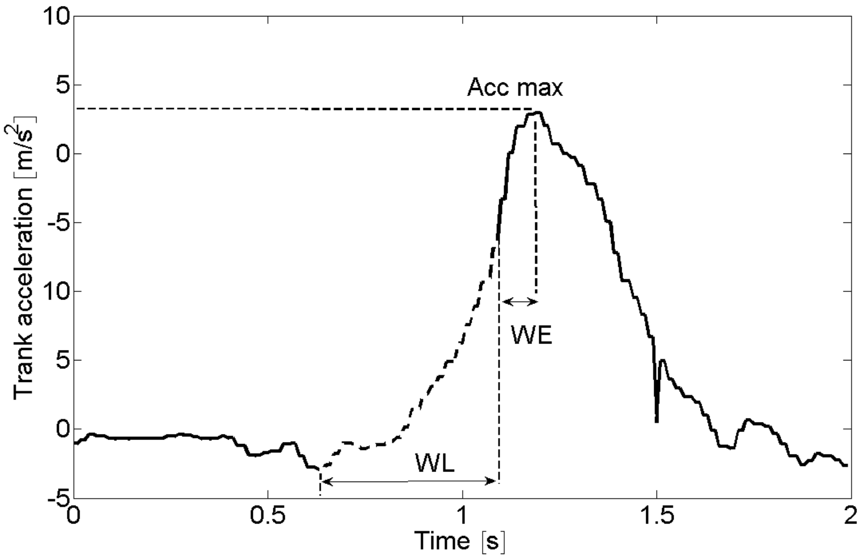


Figure 26: The trunk acceleration signal in the sagittal plane. Accmax represents the maximum of trunk acceleration in the sagittal plane, WE and WL are window end and window length, respectively. The dotted line represents an example of a reference signal built from this acceleration signal.

tor and a detection algorithm that triggers a pre-programmed stimulation pattern. The architecture of the wireless system is based on two kinds of nodes:

1. a motion sensing node including a one-axis accelerometer;
2. a master node responsible for operating the network and monitoring the measurements.

Both types of nodes are prototypes developed by INRIA, France. They are based on the same core technology. The core is composed of a 16-bit microcontroller (TI MSP430) and a 2.4 radio transceiver (TI CC2500). It is capable of acquiring data from the accelerometer sensor using standard communication buses and interfaces (SPI, I2C, ADC, etc.) and synchronizing with the master node. The acquired data are written on a laptop computer. Since this system is designed to be used in the everyday life of a paraplegic person, the low weight and the small size of the board should are important. The board dimensions are 3.5 cm x 1.5 cm and it weights 6 g without the battery. We used a battery with a capacity of 1.2 Ah. The wireless system is shown in Figure 25, and more information about it is given in [13],[21]. The accelerometer measures the acceleration of movement in the horizontal plane with a sampling frequency of 100 Hz. The technical characteristics of the accelerometer are the following: nonlinearity ±2% of full scale; 0 g offset accuracy ±0.04 g; maximal value of 0 g offset long term accuracy ±1%. An example of a trunk acceleration signal is shown in Figure 26. The detection algorithm consisted of an online comparison of the acceleration of the ongoing motion with the reference pattern (a typical pattern characterizing the sit-to-stand transfer for each subject) using Pearson's

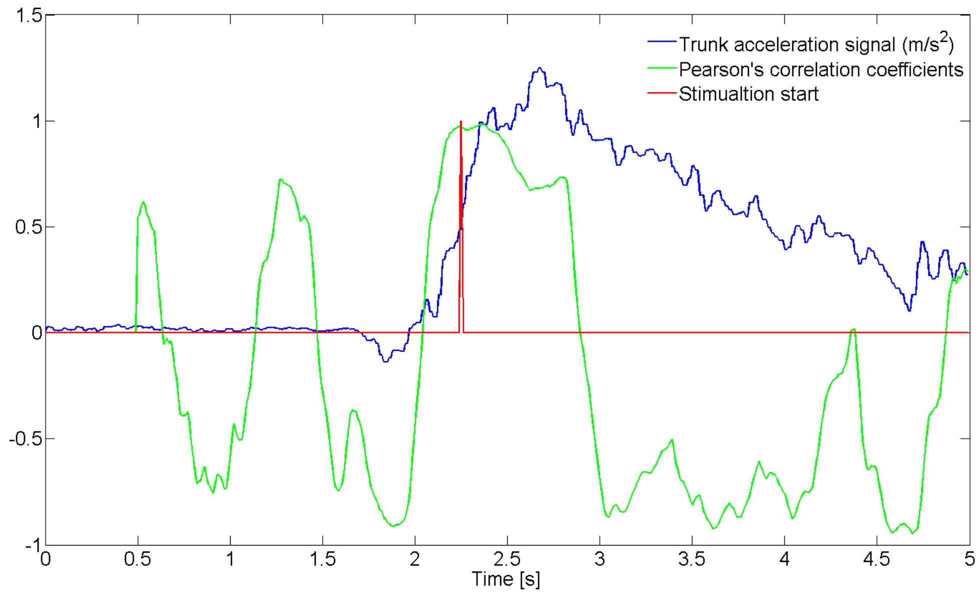


Figure 27: Pearson's correlation coefficient (green line) between the reference signal and trunk acceleration signal (blue line). When the trunk acceleration signal shows the pattern corresponding to the reference signal, the correlation coefficient increases and becomes close to 1. The red line marks the beginning of stimulation.

correlation coefficients. The reference pattern was built from one or more recorded accelerometer signals in the sagittal plane from the same subject. The signal was truncated by defining a time window of the desired length, Window Length (WL), terminating at the instant when the stimulator should be triggered, Window End (WE). The length of the window was set to 300 ms. An example of a reference pattern is shown in Figure 26.

The main goals of this study were to validate the ability of the system to automatically trigger the stimulator and to experimentally estimate the impact of the value of WE, i.e., the instant when the stimulator is triggered, on arm participation during the sit-to-stand motion of a paraplegic subject. Provided that the reference pattern contained N samples, the correlation between the last N samples of the ongoing signal and the N reference samples was computed using the following equation:

$$C(k) = \frac{1}{N} \sum_{n=1}^{N} \frac{(x(k-N+n)-\bar{x})(y(n)-\bar{y})}{\sqrt{\sigma(x)^2 \sigma(y)^2}} \tag{7}$$

for $k \geqslant N$, where x is the measured signal and y the reference pattern, $\sigma(x)$ and, $\sigma(y)$ are standard deviations of the x and y signal, and $\bar{x}$ and, $\bar{y}$ are mean values of the x and y signal, respectively. N is the number of samples of a reference pattern; in this study N was set to 30 (0.3 x 100).

When the movement begins, the correlation coefficient starts to change. As the measured signal approaches the point from which the reference is defined, the correlation coefficient increases. Its maximum value should be close to 1 if the ongoing acceleration signal matches the reference pattern. When the coefficient reaches the threshold, the motion is recognized as the sit-to-stand pattern and a command signal for beginning the stimulation is sent to the pre-programmed stimulator (see Figure 27). The threshold value of the correlation coefficient for this study was set between 0.8 and 0.95, depending on the subject. As part of this strategy, the subject was instructed to project his trunk forward before seat-off began in order to use trunk inertia during the motion.

To summarize, once the trunk acceleration signal in the sagittal plane was recorded using manual triggering and the reference pattern was computed, the protocol for the algorithm was described below as follows:

1. Acquire a trunk acceleration signal in the sagittal plane.
2. Compute the correlation coefficient, C, for the given reference pattern, for last N samplings of a measured signal.
3. Compare C with the threshold value.
4. If C is lower than the threshold value, go back to 1. If C is bigger than the threshold value, go to 5.
5. Send the command signal to the stimulator.

The computations were performed in Python programming language. The graphical interface of the software is shown on Figure 28.

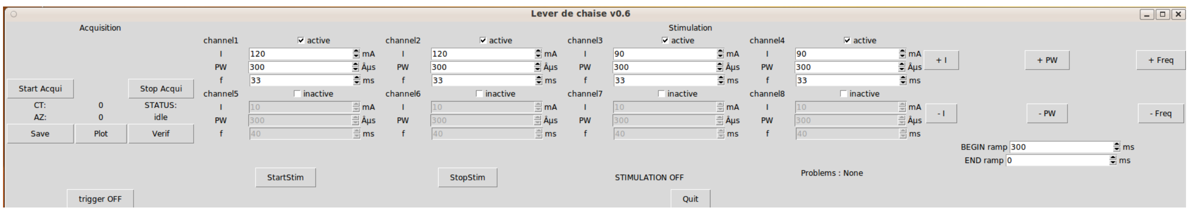


Figure 28: Graphical software interface.

The ability of the algorithm to detect sit-to-stand motion and trigger a stimulator, as well as to differentiate between similar motions, such as grasping, was successfully tested in able-bodied subjects [59], [71]. Here, we present a study involving six complete paraplegic subjects in order to evaluate the feasibility of a new approach to FES assisted sit-to-stand. Three questions were addressed:

1. Are paraplegic patients able to control their trunk motion sufficiently to perform reproducible trunk motion?
2. Does the timing of leg stimulation have an impact on upper-limb effort?
3. Is the proposed closed-loop system able to automatically trigger leg stimulation?

Subject	1	2	3	4	5	6
Age [years]	41	42	45	25	29	49
Height [m]	1.71	1.81	1.71	1.92	1.83	1.76
Weight [kg]	70	72	73	65	67	95
Gender	male	male	male	male	male	male
Level of the lesion	T6	T6/T7	T4	T6/T7	T4	T6/T5
Post injury period [years]	25	16	4	7	7	18
MRC[1] Quadriceps right	3	4	3	4	3	3
MRC[1] Quadriceps left	3	4	3	4	3	3
MRC[1] Biceps femoris right	3	3	3	3	2	2
MRC[1] Biceps femoris left	3	3	3	3	2	2
Imax Quadriceps right [mA]	120	120	120	120	120	120
Imax Quadriceps left [mA]	130	120	120	120	120	120
Imax Biceps femoris right [mA]	120	100	90	100	80	70
Imax Biceps femoris left [mA]	120	100	90	100	80	70

Table 2: Subjects' and stimulation characteristics

Day 1 Mapping session	Day 2 Training session	Day 3 Training session	Day 4 Measurement session	Day 5 Measurement session

Table 3: Schematic representation of experimental protocol

2.6.1.2 *Protocol*

Experimental data were collected from six complete complete paraplegic subjects. Approval to perform these tests was obtained from the local ethics committee. A detailed description of the ethics agreement is given in Appendix A (in French). All subjects had experience in FES usage. The subjects' characteristics are presented in Table 2. All subjects undertook one muscle mapping session, two muscle training sessions and two measurement sessions (Table 3). The experiments were conducted at the PROPARA rehabilitation center, Montpellier, France.

MAPPING SESSION Using FES, we tested the condition of the following muscles of the subjects: quadriceps (vastus medialis and vastus lateralis) and biceps femoris. The subjects' muscle strength under the influence of FES was assessed with the MRC scale of 0-5. Electrodes were positioned on the skin over the motor point of the muscles to

1 Under FES.

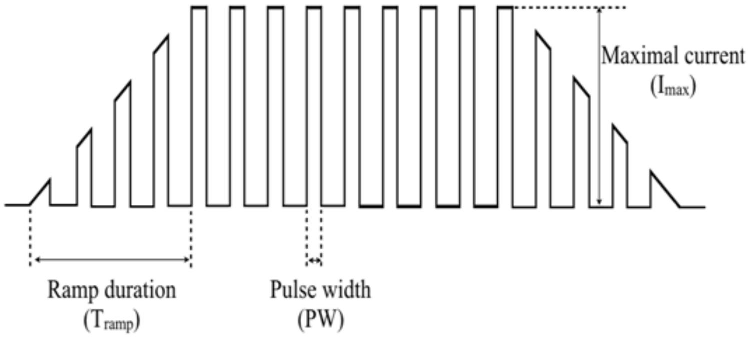


Figure 29: Shape of a stimulation train.

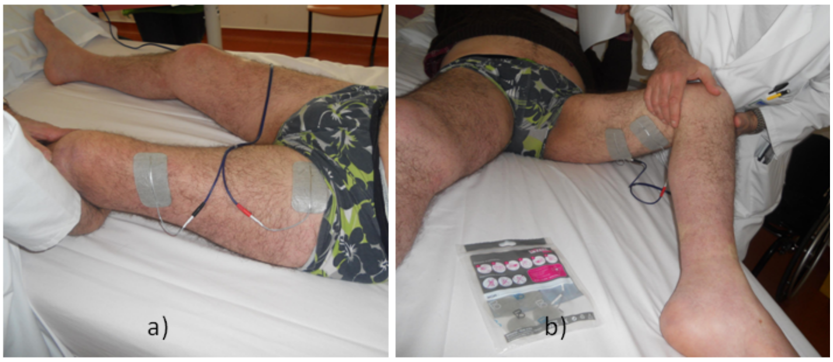


Figure 30: Electrode positioning over the quadriceps (a) and biceps femoris (b) muscles during the mapping session.

be contracted. During the mapping session, we defined the Maximum stimulation amplitude (Imax) that would be capable of inducing muscle contraction and ensuring joint locking (Table 2). The stimulation parameters were a pulse width of 300 µs and a frequency of 30 Hz. These parameters remained approximately the same throughout the study. A CEFAR® stimulator was used. Rectangular, self-adhesive, multi-use surface electrodes (50x90mm) were positioned over the muscles. An example of electrode positioning during the mapping session is shown in Figure 30.

TRAINING SESSION Each subject undertook two training sessions. During these sessions they became familiarized with the experimental setup. At the beginning of each session, the subject was sitting on a chair. The quadriceps muscle group and biceps femoris were stimulated, starting with a stimulation amplitude of 30 mA and increasing until Imax was reached. This was repeated until the subject was able to perform sit-to-stand motion and maintain standing posture for a couple of seconds. To ensure smoother muscle contraction, the stimulation train was ramped. The Duration of the ramp (Tramp) was set to 300 ms (see Figure 29). The experimental setup, the initial and final positions of the subjects, and one paraplegic subject during the experiment are depicted in Figure 31.

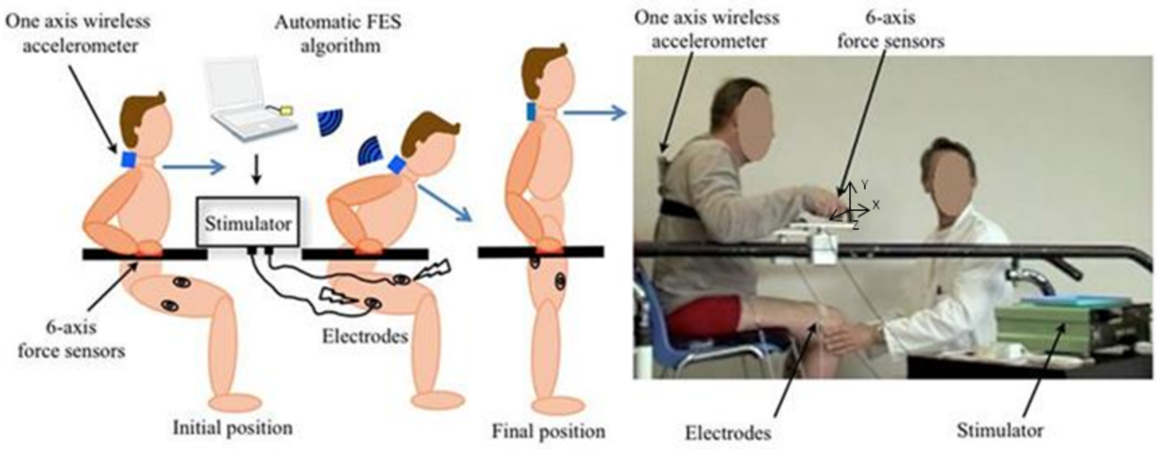


Figure 31: Initial and final positions of the patient and protocol description.

MEASUREMENT SESSION Each subject undertook two measurement sessions within one week. The kinematic data were acquired by the described wireless system. The accelerometer was mounted on a harness that was positioned between the subject's shoulder blades and fixed in the same position for all the experimental sessions. ATI Industrial Automation's force sensors with six degrees of freedom were mounted on handles on a set of parallel bars in order to record arm efforts. The sampling frequency of the force sensors was 100 Hz. A video camera recorded each subject's profile during each measurement session. A video projector was connected to the camera and positioned in front of the subject, who could therefore see his profile. The stimulation current amplitude was set to Imax. For the same reason as in the training session, the stimulation train was ramped with a ramp time of 300 ms (Figure 29). The same muscles were stimulated as in the training session. To begin, the subject was sitting on the chair with arms resting on the handles (Figure 31). The positions of the handles were adjusted according to the subject's height and preference. All subjects were instructed to keep the trunk straight and vertical if possible, and to perform the rising motion, following the experimenter's signal, by propelling the trunk forward before the seat-off phase commenced. At the beginning of each measurement session, they performed a sit-to-stand motion using only their arm support. This was so that the hand forces recorded during these trials could be compared with those recorded during FES-assisted motions. For the second rising motion, stimulation was triggered manually by the experimenter. The trunk acceleration measured in this trial was used to build the reference signal. Subsequent trials were performed using our detection algorithm. The number of trials depended on the subjects's ability (fatigue and muscle response to FES) to repeat the sit-to-stand motion. As discussed above, the goals of this study were to experimentally validate a closed-loop system and to analyze the influence of WE on hand forces during the motion. Taking into account the results shown in Section 2.5 and the time delay between sending the command signal to the stimulator and muscle contraction, the motion most similar to that of able-bodied subjects should be one in which stimulation starts around maximum acceleration of the trunk. Reduced hand forces were expected at these values. In order to find the optimal timing for the start of the stimulation, we tested our algorithm for different values of WE: 400 ms, 300 ms, 200 ms and 0 ms, (i.e. the delay before trunk acceleration reaches its maximum value). Each measurement continued for a few seconds after standing posture was reached.

2.6.2 *Subject selection*

The most important criteria for inclusion in this study were the following:

1. Age between 18 and 65 years;
2. Level of the lesion at or below T4;
3. A on the ASIA scale: "complete" spinal cord injury with no motor or sensory function preserved;
4. Neurological stability for more than 6 months;
5. Ability to sit for at least 2 hours in a wheelchair;
6. Full muscle contraction achieved for a stimulation amplitude less than 150mA;
7. Full range of motion in hip, knee and ankle joints.

The most important criteria for subject exclusion from this study were the following:

1. Spasticity in the lower limbs causing balance problems;
2. Body weight more than 100kg;
3. Limited joint motion at the hip, knee and ankle joints;
4. Patient's refusal to give written consent.

More details are given in Appendix A.

2.6.3 *Data processing*

FORCE SENSOR DATA PROCESSING Using the forces recorded under the patients' hands, the sum of the left hand resultant force and right hand resultant force were calculated using the following equation:

$$F = F_{left} + F_{right} = \sqrt{Fx_{left}^2 + Fy_{left}^2 + Fz_{left}^2} + \sqrt{Fx_{right}^2 + Fy_{right}^2 + Fz_{right}^2} \tag{8}$$

The Mean value (M) and Maximal value (Max) of F were calculated for each rising phase of each sit-to-stand trial. For each sit-to-stand trial the Initial value (I) of the hand forces was calculated, using Equation 8, as the mean value of F for 500 ms before beginning the STS motion. Computations were done using MATLAB software.

DETECTION OF SIT-TO-STAND MOTION In order to represent the ability of a paraplegic subject to produce repeatable trunk motion over trials the following mathematical operations were conducted. We analyzed the trunk acceleration signal before Accmax (Figure 26). First, each trunk acceleration signal was time-normalized to 100 samples. Then, Pearson's correlation coefficients, were calculated between the acceleration signals from the second (manually triggered) and subsequent FES-assisted sit-to-stand trials for each subject using the following equation:

$$\mathrm{CorrCoeff}(i) = \sum_{n=1}^{100} \frac{(x(n) - \bar{x})(y(n) - \bar{y})}{\sqrt{\sigma(x)^2 \sigma(y)^2}} \tag{9}$$

where x is the acceleration signal from the second (manually triggered) trial and y is the acceleration signal from the following trials, $\sigma(x)$ and, $\sigma(y)$ are standard deviations of the x and y signal, and $\bar{x}$ and, $\bar{y}$ are mean values of the x and y signal, respectively. For each subject, the mean value of Pearson's correlation coefficients over all the FES-assisted trials was calculated as follows:

$$\bar{CC} = \frac{1}{n} \sum_{i=1}^{n} \mathrm{CorrCoeff}(i) \tag{10}$$

where $\bar{CC}$ is the mean value of CorrCoeff, and n is the number of FES-assisted trials for one subject. The results are presented in Table 4.

The effectiveness of our algorithm was calculated as the number of trials that the algorithm was able to detect as sit-to-stand trials and trigger the FES system over all the trials performed using our detection algorithm (see Table 4).

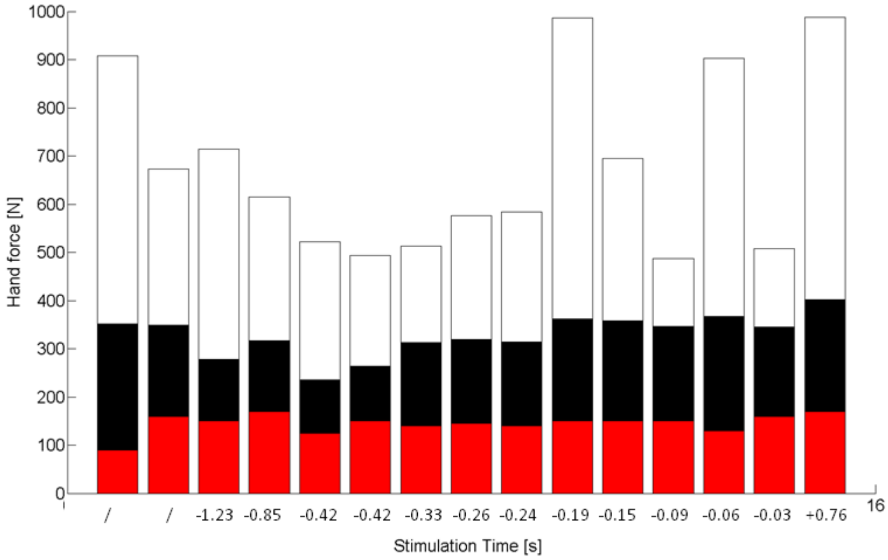
The accuracy in detecting the sit-stand motion of the detection algorithm was assessed by calculating the so-called Detection Error (DE) (see Table 4) as the following:

$$DE = |WE"real" - WE\_desired| \tag{11}$$

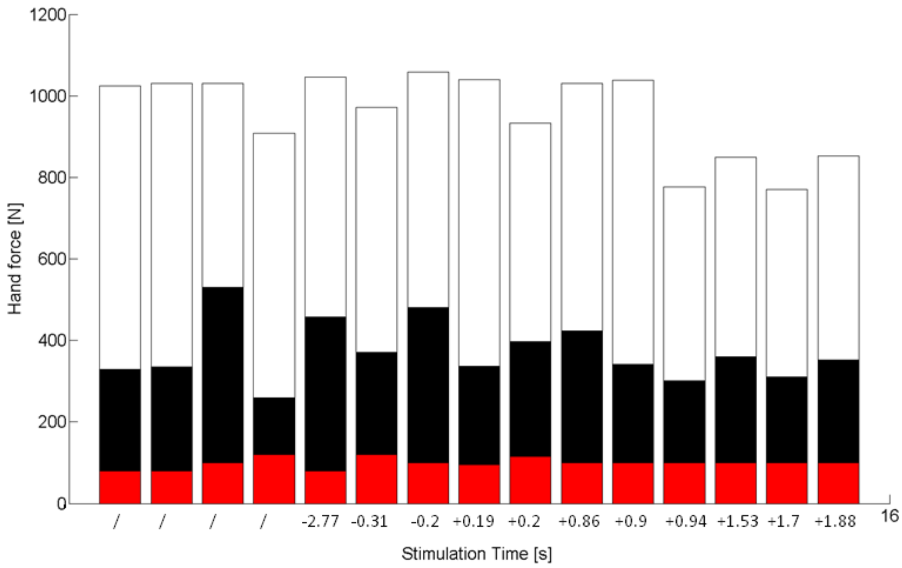
In Equation 11 WE_desired represents the desired stimulation time and WE "real" is the stimulation time actually achieved. All the computations were done using MATLAB software.

2.6.4 *Results*

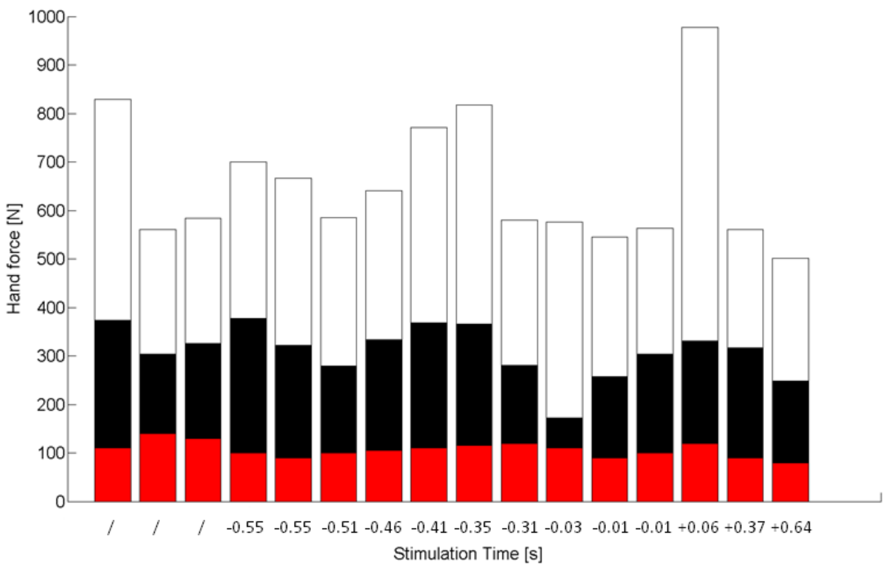
As stated above, the goal of this study was to answer the following questions:



(a) Subject 1.

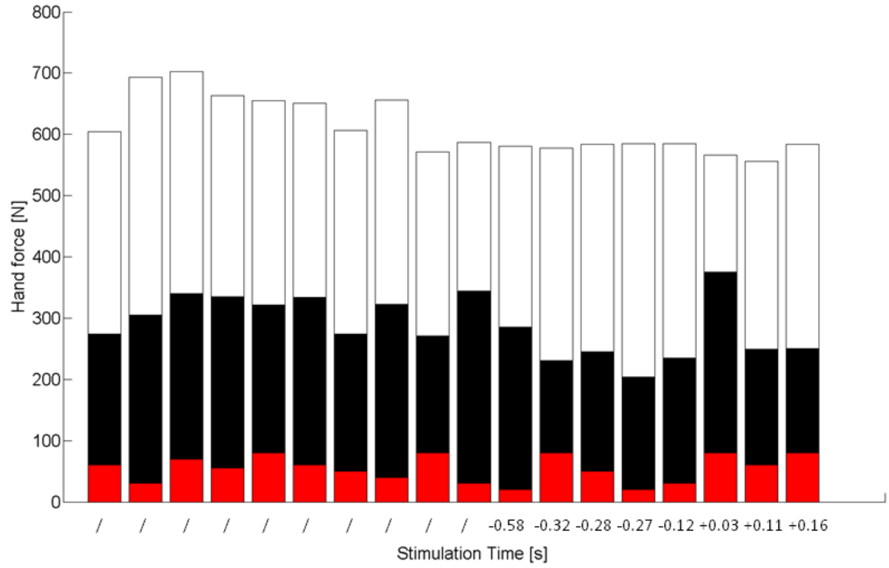


(b) Subject 2.

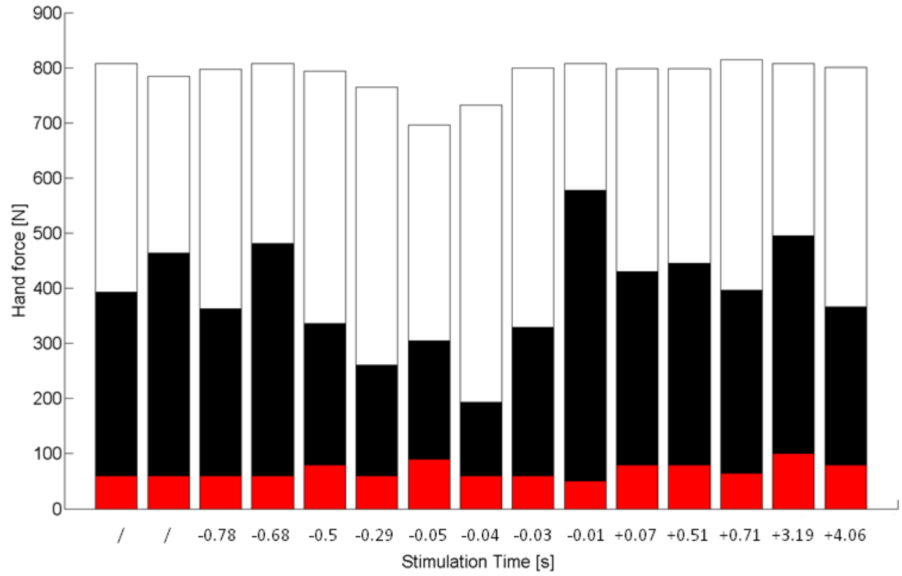


(c) Subject 3.

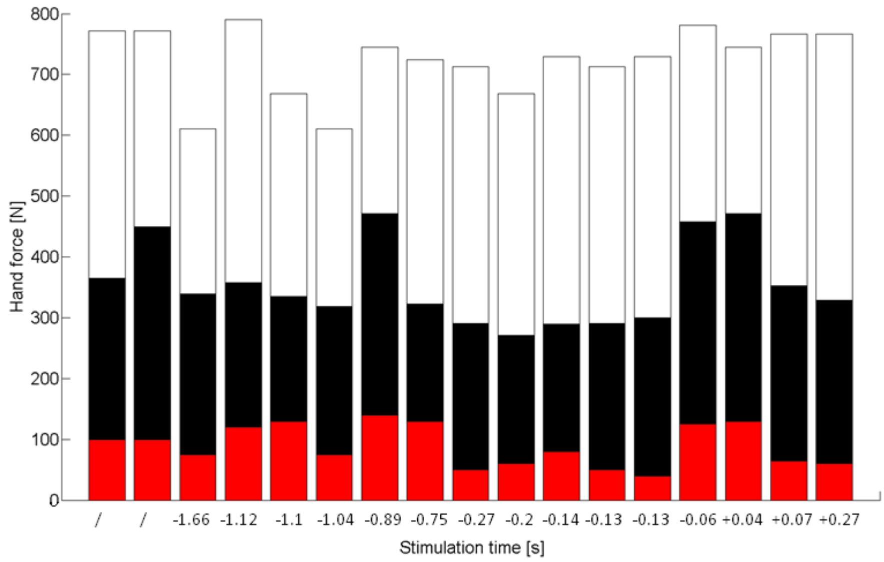
Figure 32: M (black), Max (white) and I (red) values calculated over each STS trial for each subject.



(d) Subject 4.



(e) Subject 5.



(f) Subject 6.

Figure 32: M (black), Max (white) and I (red) values calculated over each STS trial for each subject.

1. Are paraplegic subjects able to produce repeatable trunk motion?
2. Is the proposed closed-loop system able to detect sit-to-stand motion and automatically trigger leg stimulation?
3. Is there an influence of the timing of leg stimulation relative to trunk acceleration on upper-limb efforts?

2.6.4.1 *Trunk motion reproduction and detection of sit-to-stand motion*

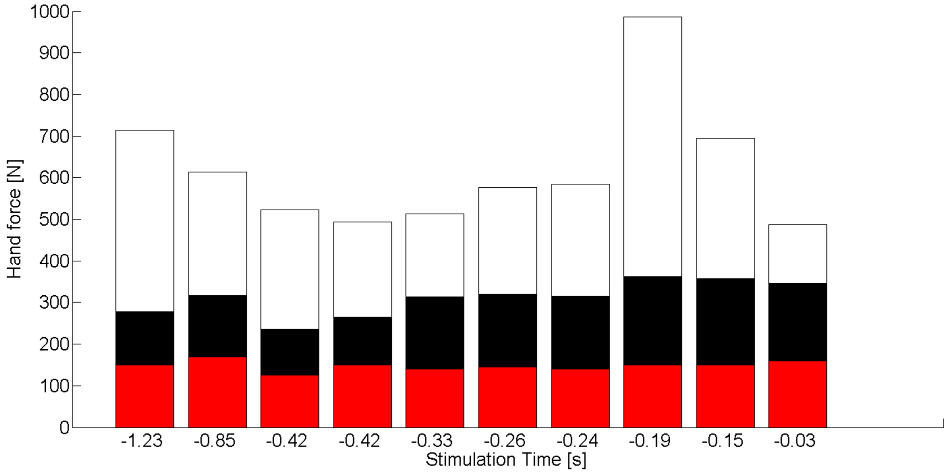
The mean value of Pearson's correlation coefficients between the acceleration signals from the manually triggered and subsequent FES-assisted sit-to-stand trials for each subject is given in Table 4. It also shows the mean, maximal and minimal values of DE for all sit-to-stand trials performed using the detection algorithm during the two measurement sessions for each subject, the effectiveness of our algorithm, and the number of STS trials performed with the detection algorithm for each subject.

Here some differences between the subjects should be mentioned. Subject 3 and subject 5 had a higher level of lesion (T4) than the other subjects and the results for these two subjects were similar in terms of $\bar{CC}$ values, effectiveness and values of DE. The same conclusion applied to subjects 1, 4 and 6 with a T6 lesion level. Subject 4 evinced muscle weakness in one quadriceps muscle and hip flexion problems, which might have affected the results of this study. Subject 2 was not motivated to participate in the study and expressed difficulties in following the instructions during the experiments. Therefore, trunk motion repeatability was lower compared with the repeatability of other subjects. The success of our method was based on the ability of the subject to reproduce a reference pattern, hence in the case of subject 2 the effectiveness of our algorithm was low (2 out of 11 trials successfully detected as STS motion). Consequently, this subject probably should not be taken into consideration. It seems that the subject's condition (lesion level, muscle spasticity) and motivation to follow the instructions is crucial for the ability of our system to recognize STS motion and automatically trigger electrical stimulation.

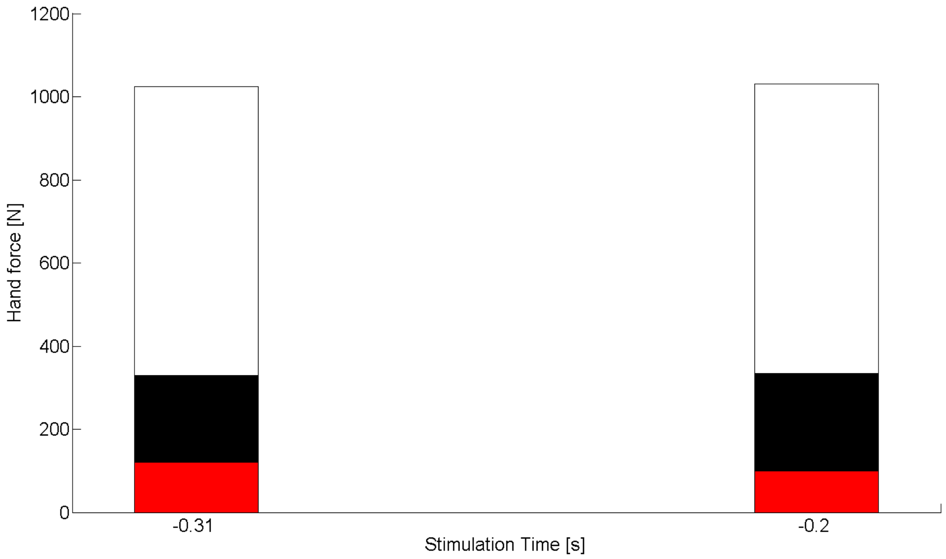
From Table 4, it can be seen that in the cases of subjects 1, 3, 5, and 6, who were able to produce repeatable trunk motion, the effectiveness of our system was satisfactory. Also, one of the reasons for failure to detect of STS motion could be wireless communication problems with the acceleration sensor. A new generation of acceleration sensors developed by INRIA, France should overcome this problem.

For all subjects, the mean DE had acceptable value. In the case of subjects 1 and 6, the mean value of DE was high compared with that of the other subjects, probably due to the high value of maximal DE in one of the trials.

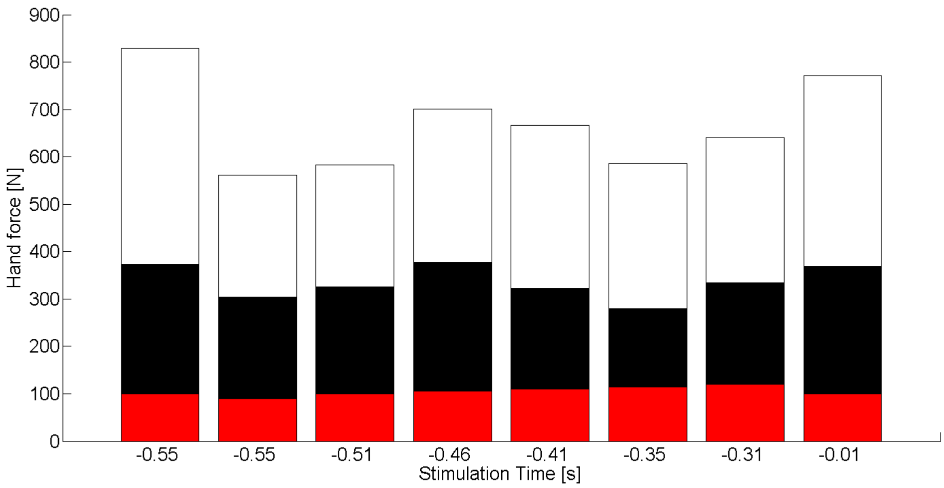
It is very important to mention that all subjects used the system for two sessions only. We believe that with suitable training the subjects would improve their trunk motion per-



(a) Subject 1.

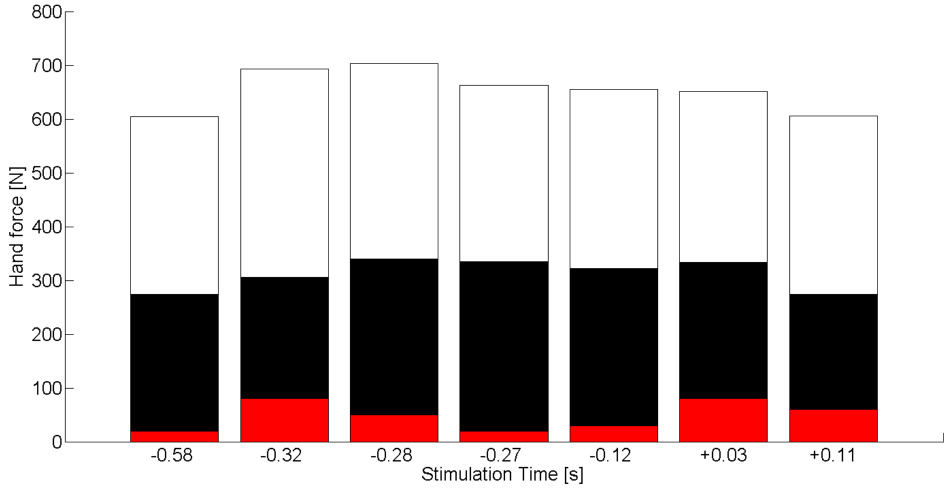


(b) Subject 2.

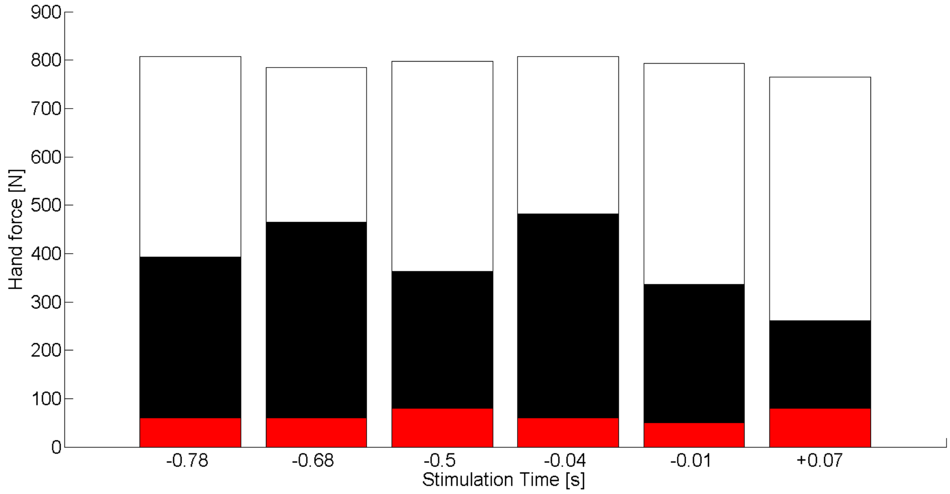


(c) Subject 3.

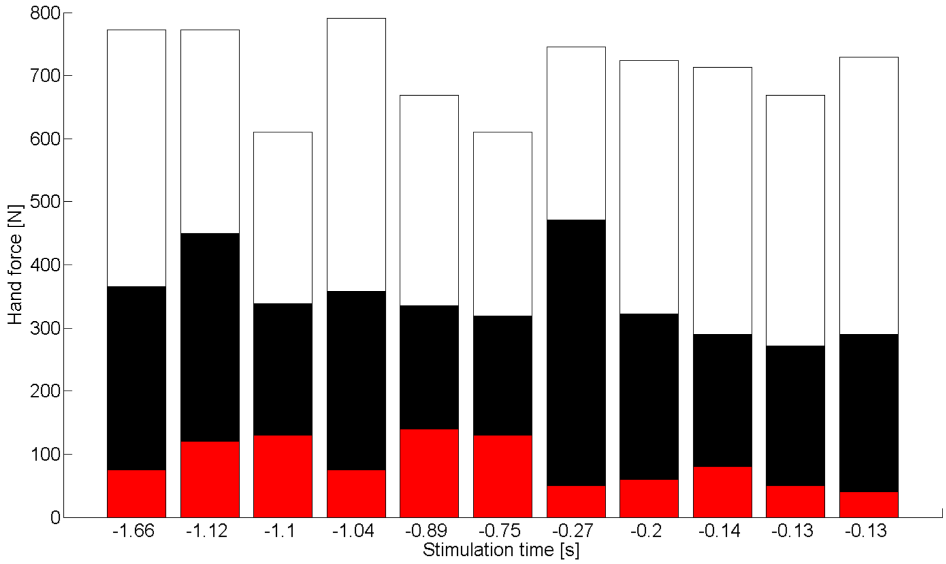
Figure 33: M (black), Max (white) and I (red) values calculated over each STS trial performed using the detection algorithm for each subject.



(d) Subject 4.



(e) Subject 5.



(f) Subject 6.

Figure 33: M (black), Max (white) and I (red) values calculated over each STS trial performed using the detection algorithm for each subject.

Subject	1	2	3	4	5	6
$\bar{CC}$	0.753	0.513	0.692	0.726	0.679	0.713
Mean value of DE [s]	0.352	0.055	0.1	0.21	0.246	0.561
Maximal value of DE [s]	1.23	0.1	0.46	0.58	0.68	1.59
Minimal value of DE [s]	0.04	0.01	0	0.03	0.01	0.06
Number of performed STS trials	11	11	12	14	8	12
Effectiveness of the system	10/11	2/11	8/12	7/14	6/8	11/12

Table 4: Detection algorithm performance and trunk motion reproduction. See Section 2.6.3.

formance, so that acceleration signals would be more repeatable and the overall ability of the system to trigger the stimulator at the desired instant would increase.

2.6.4.2 *Impact of stimulation time on upper-limb effort*

Figure 32 shows the M, Max and I values for each rising phase of each sit-to-stand trial. The symbol "/" on the x axis represents the trials during which the subjects stood up using only the arm support. The other bars represent sit-to-stand trials performed using the FES system. The numbers on the x axis represent the stimulation time in seconds with respect to the maximum trunk acceleration. Negative values indicate that the stimulator was triggered before Accmax. Similarly, positive values mean that stimulation started after Accmax, i.e. after seat-off. Graphs showing the M and Max values of the hand forces for all subjects with the respective time scales are given in Appendix B. Observing these figures, it seems that, in the cases of subjects 1, 3, 4, 5 and 6, the timing of stimulation application (WE) had an influence on the measured U/L support forces. The best compromise between the lowest mean and maximum value of the hand forces seems to have been achieved for:

1. the trials where the command signal was sent to the stimulator at 0.42 s, 0.33 s, 0.26 s, and 0.24 s before maximum trunk acceleration, in case of the subject 1;
2. the trials where the command signal was sent to the stimulator at 0.31 s, 0.03 s, and 0.01s before maximum trunk acceleration, in case of the subject 3;
3. the trials where the command signal was sent to the stimulator at 0.32 s, 0.28 s, 0.27 s, and 0.12 s before maximum trunk acceleration, in case of the subject 4;
4. the trials where the command signal was sent to the stimulator at 0.29 s, 0.04 s, and 0.03 s before maximum trunk acceleration, in case of the subject 5;
5. the trials where the command signal was sent to the stimulator at 0.27 s, 0.2 s, 0.14 s, and 0.13 s before maximum trunk acceleration, in case of the subject 6.

The best results for these paraplegic subjects were achieved for trials in which electrical stimulation was triggered between 0.4 s and 0s before the maximum of the trunk acceleration. In other words, the lowest hand forces were recorded for the motion that was similar to that of able-bodied subjects in terms of trunk motion and the beginning of leg motion with respect to the trunk acceleration signal. As depicted in Figure 32, it seems that if the stimulation trigger appears after the maximum value of trunk acceleration, i.e. after the seat-off phase, the stimulation can be seen as an external perturbation creating additional hand forces.

Here, it should also be mentioned that in the following cases:

1. when stimulation started 0.19 s before Accmax, in the case of subject 1, and
2. when stimulation started 0.01 s before Accmax, in the case of subject 5,

the mean and maximal hand forces had higher values than expected, which probably could be explained by strong spastic contractions of the leg muscles.

In the case of subject 2, there appeared to be no connection between the hand forces and the moment of stimulation, probably due to the fact that the difference between the timing of stimulation application among trials was great. As we suggested in Section 2.6.4.1, this subject should not be taken into account.

It seems that there was no connection between the initial value of the hand forces before the sit-to-stand motion and the ones recorded during the motion.

The M, Max and I values of the applied hand forces for the trials successfully detected as STS motion are shown in Figure 33. These trials had the desired trunk motion, i.e. the subjects bent their trunks forward before the seat-off moment, and, as expected, for almost all they had the lowest values of applied hand forces during the motion.

2.6.5 *Discussion and conclusion*

The objective of this study was to experimentally validate the approach developed by Héliot relating to functional rehabilitation techniques for the lower extremities. Unlike the "control-driven" approaches, described in Section 2.3 this system takes into account the contribution of trunk inertia to sit-to-stand motion and does not require a predefined reference input for lower-limb trajectories, which would need to be adjusted to each subject. In addition, due to the task dynamics and the nonlinearities of the postural system, the development of a closed-loop control law remains challenging. In this approach, generation of motion in paralyzed limbs is driven by the patient's voluntary trunk motion. Compared with other "patient-driven" approaches, this system does not require complex modeling. Finally, only one accelerometer, which is easy to use in clinical applications, is required.

The difficulties in conducting this study were numerous. It took six months to obtain ethics committee approval to perform the experiments with paraplegic subjects. The complete text of the ethics agreement is presented in Appendix A. The study was time consuming. We remind the reader that each patient undertook one mapping session, two training sessions and two measurement sessions on five different days. Consequently, there were not many complete paraplegic patients willing to participate. The subjects were all different in terms of muscle capacity, muscle spasm, and lesion level, and each experimental session therefore needed to be adapted to the subject's needs. Last, the experiments had to be adapted to the patients' abilities and thus, they lasted more than a year (starting on January 7, 2011, and ending on February 2, 2012).

From the results we present here, we can conclude that the paraplegic subjects, except subject 2, were able to produce repeatable trunk motion and that, in the cases where the acceleration and reference signal were similar, our algorithm was able to recognize sit-to-stand motion and properly trigger leg stimulation at the desired instant. Also, the stimulation timing seemed to influence the applied hand forces during the motion, and the best results were achieved for trials in which motion was similar to that of able-bodied subjects in terms of trunk motion and the beginning of the leg motion with respect to the trunk acceleration signal. In contrast, in the case where simulation was triggered after the seat-off phase, the recorded arm efforts were higher and, in that case, stimulation could be seen as an external perturbation for the paraplegic subjects. It appears that the subject's medical condition and motivation have an influence on the performances of the proposed system, and thus on the results. For example, applied hand forces could increase when the subject feels unsecured or uncomfortable with the system. However, these conclusions should not be generalized due to the low number of trials per subject.

In the future, the robustness of the system should be improved by improving the sensor and its positioning. The same approach could also be used on similar motions, such as transfers from wheel-chairs to car seats or beds, by both complete and incomplete paraplegic subjects. The final validation of our system will need to be performed with one or more paraplegic patients in their daily environment during a prolonged period of time in order to investigate subject adaptation to the system. We believe that with extra training, it should be possible to improve the performances of the paraplegic subjects and, at the same time, to improve system performance with respect to the stimulation trigger instant.

2.7 CONCLUSION

In this chapter, the following contributions to the problem of FES-assisted sit-to-stand motion were proposed.

First, we computed one of the optimal strategies for performing the rising motion in a paraplegic person. We showed in computer simulations that, in order to obtain a motion that minimizes arm participation and the torque applied to the lower-limb joints, paraplegic patients should perform a rising motion similar to that of able-bodied subjects, i.e., they should bend their trunk forward before the seat-off moment. Also, the coordination between hip motion and the electrically stimulated lower limbs plays an important role, and leg motion should start at a point around maximum of trunk bending.

Second, we experimentally validated a new "patient-driven" system for controlling rising motion in SCI patients in six paraplegic subjects. The proposed system automatically triggers leg stimulation at the optimal moment with respect to trunk motion with the goal of decreasing arm participation during this motion. We showed experimentally that the moment of triggering the FES system, i.e. the moment of beginning of the leg motion with respect to the trunk movement, indeed seemed to have an influence on the hand forces applied during the STS movement, which is in accordance with the results obtained in computer simulations. Also, we showed that the new control strategy was able to recognize sit-to-stand motion and trigger leg stimulation at the desired instant, and therefore it could be used in clinical practice and the everyday lives of paraplegic patients.

Video analysis software was developed to study the joint coordination during STS movement. The software is computationally efficient and easy to implement in clinical settings. The software was not presented in this chapter, because its use does not give any additional information related to the questions addressed here. It has, however, been successfully tested in a clinical environment. More details are given in Appendix C.

Using the approach described in this chapter we were able to give paraplegic patients an active role in controlling their rising motion. The ability to achieve STS transfer with minimal participation of the upper-limbs would greatly improve daily life for paraplegic individuals and help to preserve long-term shoulder integrity.

Some ideas and figures from this chapter have appeared in the following publications:

1. **J. Jovic**, C. Azevedo Coste, P. Fraisse, and C. Fattal. *Upper and lower body coordination in fes-assisted sit-to-stand transfers in paraplegic subjects - a case study.* Paladyn. Journal of Behavioral Robotics, 2(4): 211-217, 2011.

2. **J. Jovic**, V. Bonnet, P. Fraisse, C. Fattal, and C. Azevedo Coste. *Improving valid and deficient body segment coordination to improve fes assisted sit to stand in paraplegic subjects.* ICORR'2011 : 12th International Conference on Rehabilitation Robotics, Switzerland (2011).

3. **J. Jovic**, C. Azevedo Coste, P. Fraisse, V. Bonnet, and C. Fattal. *Optimization of FES assisted rising motion in individuals with paraplegia.* Skills Conference 2011, France (2011).

4. **J. Jovic**, C. Azevedo Coste, P. Fraisse, and C. Fattal. *Decreasing the arm participation in complete paraplegic FES-assisted sit to stand.* IFESS'2011 : 16th Annual International FES Society Conference, Brazil (2011).

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3 FES-ASSISTED SITTING-PIVOT-TRANSFER MOTION

3.1 SITTING PIVOT TRANSFER MOVEMENT IN PARAPLEGIC INDIVIDUALS

Based on the observations and results we presented in the previous chapter on FES-assisted sit-to-stand transfer in complete paraplegic patients, we believe that our approach might find an application in FES-assisted sitting pivot transfer motion. In this case incomplete spinal cord-injured patients may benefit, as well as complete paraplegic patients.

Transferring from a wheelchair to a treatment table, bed, tub/shower bench, toilet seat or car seat, and vice versa, are all examples of typical Sitting Pivot Transfer (SPT) performed by individuals with SCI. When initiating SPT, paraplegic individuals move their wheelchairs as close as possible to the target seat. They move the buttocks forward, close to the front edge of the seat of the wheelchair and, with the help of their arms, firmly place their feet on the floor. Then they place one hand, called the trailing hand, in a stable position on the wheelchair and the other hand, known as the leading hand, on the target surface far enough to leave sufficient space for the buttocks. From this starting position they bend their trunk forward and sideways, while lifting up their bodies and sustaining their weight with the arms. After that, with a very rapid twisting motion they place the buttocks on the target seat. The transfer is concluded when they again reach a seated postural stability. Performance of SPT varies from individual to individual depending on the subject's characteristics, like lower-limb spasticity, and environmental factors, like wheelchair design [43], [82]. The performance of SPT may rank among the most demanding functional mobility activities for the U/Ls [40]. On average, a spinal cord-injured person with a lesion level at the thoracic or lumbar spinal cord segment performs 14-18 SPTs per day [41], [43]. Usually, SPT is divided into three distinct phases (Figure 34):

- Pre-lift is the preparatory phase that ends when the buttocks are raised from initial seat (seat-off);
- Lift when most of the body weight is supported by the upper extremities;
- Post-lift is the re-balancing phase, when the subject is seated on the new seat.

The lift phase lasts for 40% of the entire duration of the transfer and this duration is not influenced by the differences that the subject may encounter between the starting seat and the target one [43].

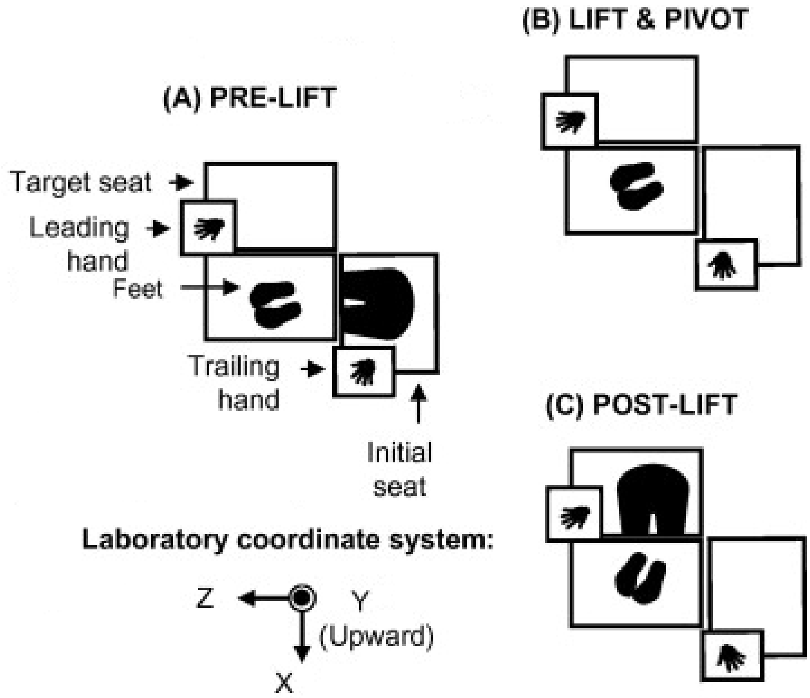


Figure 34: Three distinct phases of SPT. Adapted from [43]

In order to investigate the characteristics of the SPT technique, an experimental setup is usually composed of force sensors to allow the recording of reaction forces and the center of pressure under the trailing hand, leading hand, buttocks and feet; EMG sensors to investigate the activation patterns of the U/L muscles; and optoelectronic and stereophotommetric systems to investigate the movement from a kinematic point of view [30], [40], [41], [81], [82], [83], [134], [136].

Gagnon et al. studied and described the kinematics of SPT by varying the seat heights for individuals with SCI (Figure 35) [40]. At the beginning of the movement, it was possible to see the abduction and flexion of the leading shoulder with a slightly flexed elbow of this arm, while the trailing shoulder was adducted and extended and the trailing elbow was flexed. After this starting position, the subject rapidly bent his trunk forward around the seat-off, followed by the leading shoulder extension, while the leading elbow started flexion. The trailing shoulder was in neutral position (no change in flexion/extension angle) while the trailing elbow started the flexion. In the second part of SPT, the lift phase, trunk flexion continued, with the leading shoulder moving into flexion and adduction, while the trailing shoulder flexed and abducted until the end of lift phase. The leading elbow continued to progress into flexion, while the trailing elbow moved into extension. At the end of the transfer, the leading shoulder reached a near-neutral position, whereas the shoulder of the trailing arm was flexed and the elbow extended.

Many studies have analyzed forces and torques acting on the upper limbs, buttocks and feet [40], [41], [44], [81], [82], [83].

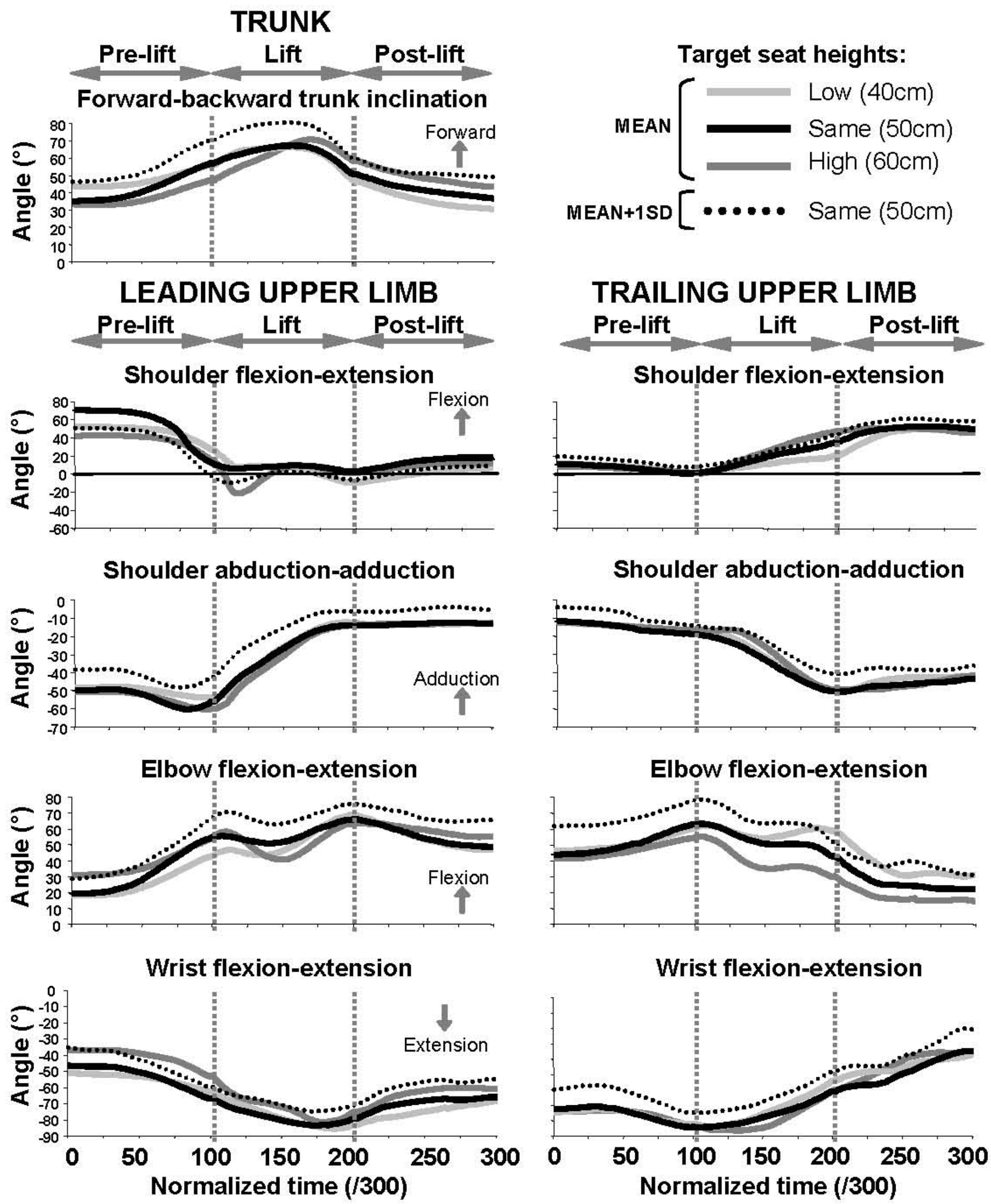


Figure 35: Angular displacement of trunk, shoulders, elbows and wrists during SPT between surfaces of different heights. Adapted from [44].

Gagnon et al. studied [40] and quantified [41] the horizontal and vertical reaction forces under the trailing and leading hands during SPT between same and different (target surface higher or lower than the initial surface) height surfaces in individuals with SCI (Figure 36). They found a significant difference between the trailing and leading hands concerning values of the U/L forces during the lift phase, i.e. a higher force value was measured underneath the trailing hand compared with the leading hand. Figure 36 shows the difference between the trailing and the leading hand concerning vertical forces. At the beginning of the transfer, most of the body weight is loaded on the trailing hand, and then there is a shift. During the lift phase, the vertical force on the leading hand increases while the one on the trailing decreases and in the last part of the lifting phase of the transfer the situation is the opposite of the initial one, i.e., the leading hand is the one subjected to a greater load.

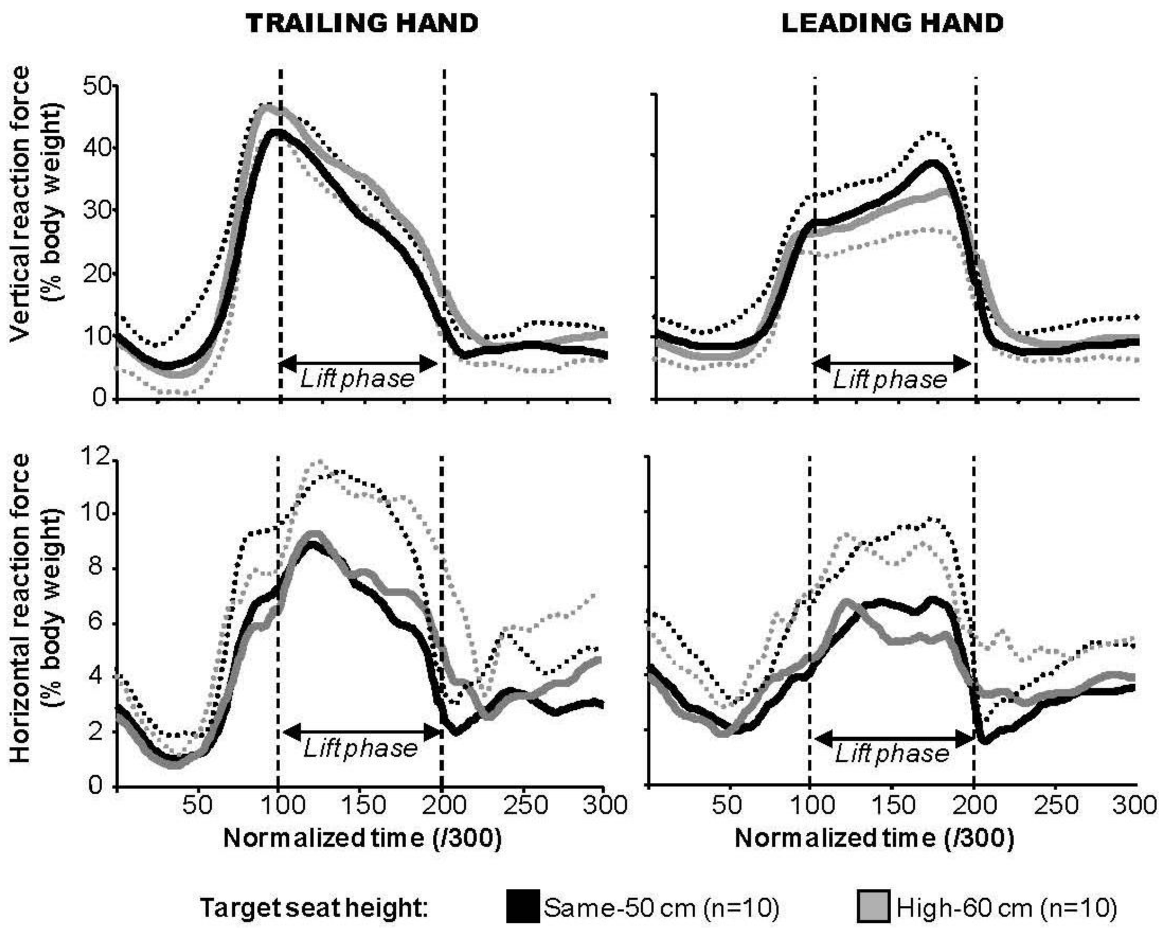


Figure 36: Time course of mean vertical and horizontal reaction forces during SPT between surfaces of different heights. Start and end of pre-lift, lift, and post-lift phases are indicated with vertical dashed lines. Solid lines correspond to mean values, and dotted lines represent standard deviations. Adapted from [44]

Analyzes of the SPT between two surfaces of different heights (Figure 35 and Figure 36), have demonstrated that the transfer is not very different from a kinematic point of view from the transfer between surfaces with the same height, on the contrary, there are significant changes in the kinetic variables. Raising the height of the target seat with respect the initial one produces higher vertical reaction force values for the trailing hand, concerning both mean and peak values [41]. This observation was supported by Gagnon et al. (Figure 37). In Figure 37, the paraplegic subject appears to shift a considerable amount of weight to his U/L around seat-off, with more weight being initially supported by the trailing U/L. The trailing U/L is then progressively unloaded while

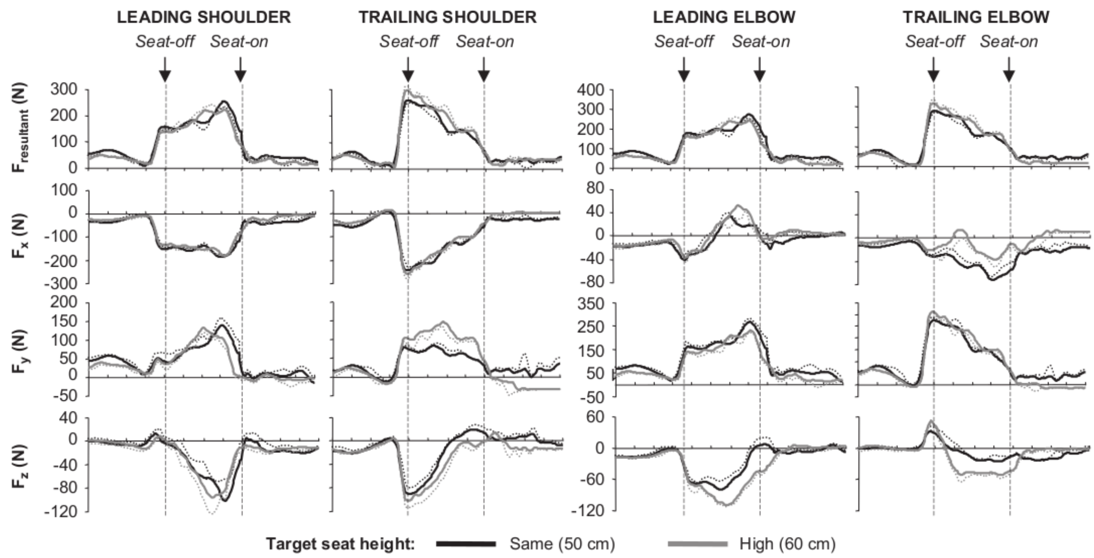


Figure 37: Forces at the leading and trailing shoulders and elbows. Solid lines correspond to mean values and dotted lines are ± standard deviation. The vertical dashed lines represent the beginning and the end of the lifting phase. Adapted from [40]

the resultant force continues to increase at the leading elbow and shoulder when the buttocks move toward the target seat. Both shoulder joints are continuously exposed to greater posterior shearing forces (Fx) than vertical forces (Fy), while elbow joints are predominantly exposed to vertical forces (Fy) [40].

Gagnon et al. studied the vertical and horizontal forces at the shoulder and elbow (Figure 38) and concluded that the posterior component of force was higher at the trailing shoulder than that at the leading shoulder, while there was no significant difference between the shoulders with regard to the vertical component of the force. At both the leading and trailing elbow joints, similar force values were observed. Concerning the torque values, no relevant differences were noted between the leading and trailing shoulders. The flexion and extension torque values at the elbow joints had smaller amplitudes compared with the torque values at the shoulder joints. The highest value of the net elbow flexion torque was reached at the leading joint, while no differences were noted between extensor torque values at the leading and trailing elbows [42].

Considerable scientific effort has been focused on experimental studies to analyze the kinetics and kinematics of SPT movement. To the best of our knowledge, the scientists have focused their attention only on the performance of SPT, the influence of functional electrical stimulation on the SPT maneuver has not been investigated thus far.

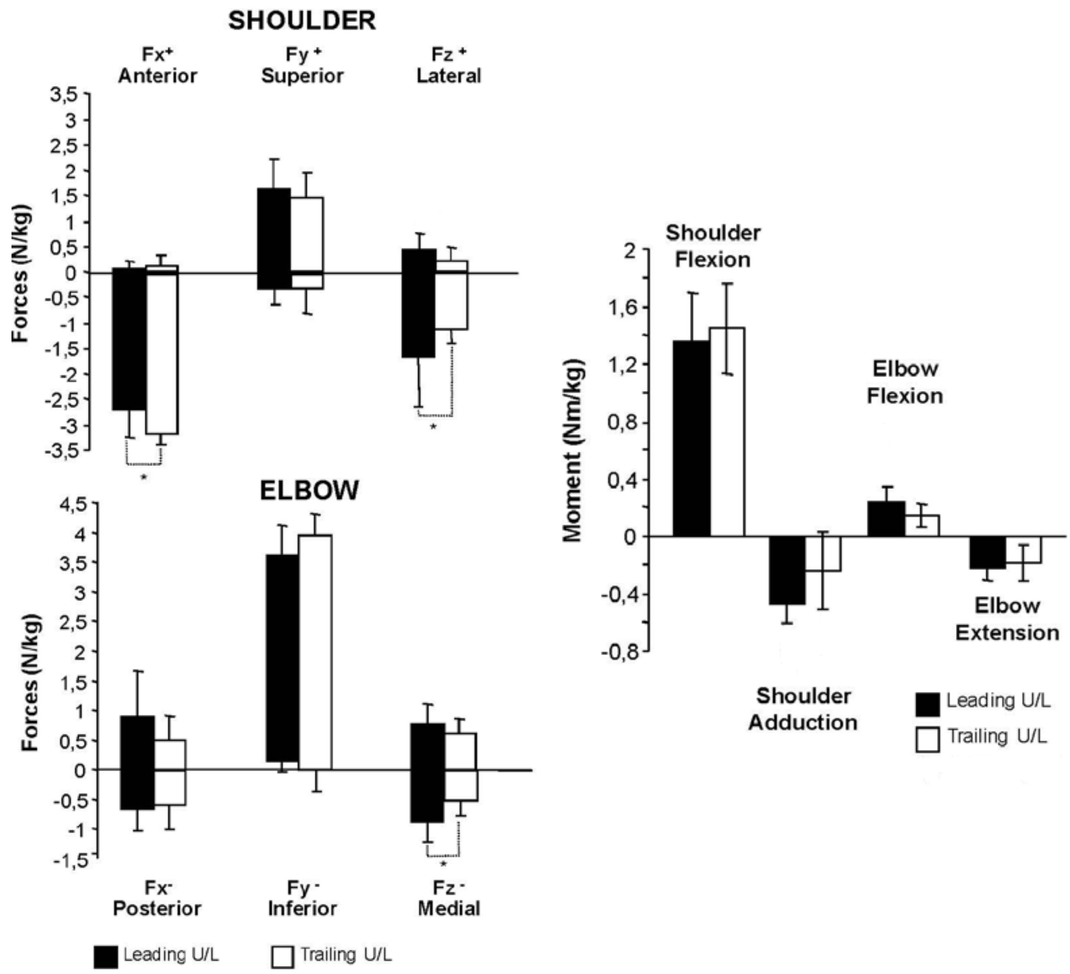


Figure 38: Bar graphs showing the mean ± standard deviation of the peak net forces (right) and peak net torque values (left) at shoulder and elbow during SPT. Adapted from from [44]

3.2 MOTIVATION AND GOAL OF THE CHAPTER

We remind the reader that paraplegic individuals must rely on their upper extremities for stability and mobility. In the chronic stage after SCI, soft tissue structures are exposed to overuse in the activities of daily living, like, transfer tasks in which the shoulder becomes a weight-bearing joint. Hence, the risk of shoulder pain and musculoskeletal disorders is higher in persons with paraplegia compared with the able-bodied population. The aim of this work was therefore to enhance the scientific research concerning paraplegic SPT by investigating first, the ability of an optimization process to predict SPT trajectories in able-bodied subjects and, second, the influence of FES on hand forces applied during the movement [1]. In this chapter, we present the biomechanical model and

1 This work was performed in collaboration with Sebastien Lengagne, Karlsruhe Institute of Technology, Germany, who provided modeling and optimization software and in the context of the supervision of Camilla Pierella, Master thesis (ERASMUS Master program).

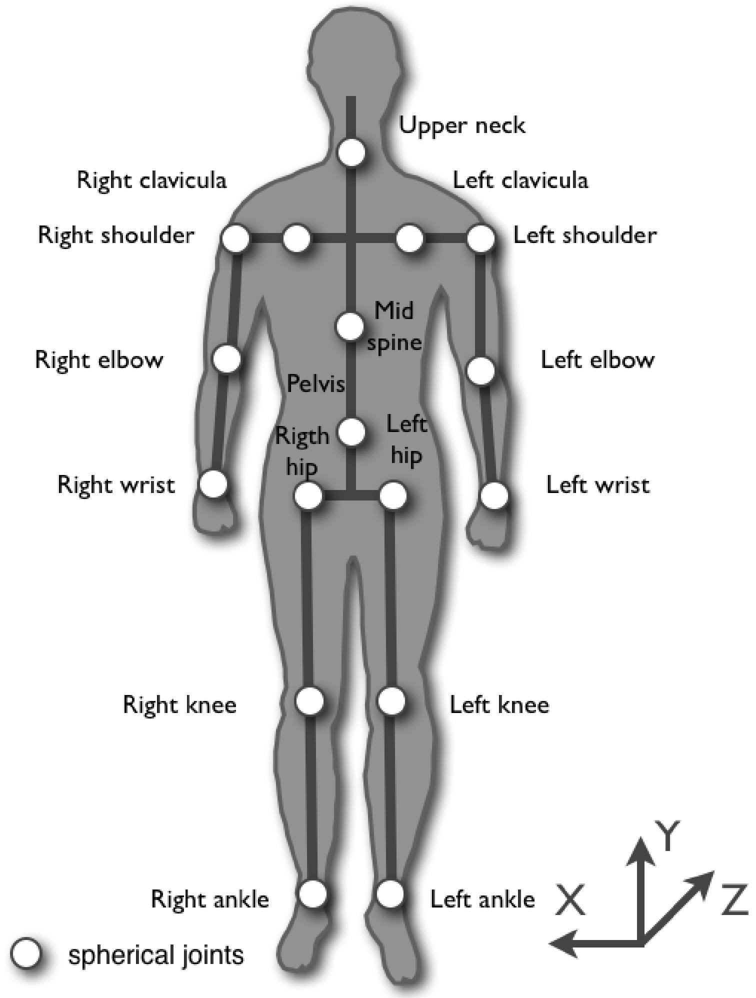


Figure 39: Biomechanical model used in the study.The origins of all joint frames are at the centers of joints. The origin of the global reference frame is 7 cm below center of rotation of right ankle joint.

a cost function. Then, the details about the experiments performed with an able-bodied subject are given. The results and conclusion close this chapter.

3.3 KINEMATIC MODEL

The biomechanical model of a human body, which is shown in Figure 39, was used in this study. The model consists of 19 segments and 18 spherical joints, i.e. 54 degrees of freedom. Note that six DoF of the neck had a constant value of 0° during the entire simulation. Despite the existence of more realistic models for the knee and shoulder joints [46], [108], we assumed that spherical joints could describe the behavior of whole body motion quite well. The joint limits are presented in Table 5. The segmental and inertial parameters of the model are computed using the anthropomorphic Winter tables [143]

Table 5: Joints limits for the biomechanical model (in radians).

Joint	θ_x	θ_y	θ_z
Pelvis	$-0.87 : 0.61$	$-0.70 : 0.70$	$-0.09 : 0.09$
Mid-spine	$-0.61 : 0.47$	$-0.34 : 0.34$	$-0.63 : 0.63$
Lower neck	$-1.13 : 0.70$	$-0.61 : 0.61$	$-0.61 : 0.61$
Upper neck	$-1.13 : 0.70$	$-0.61 : 0.61$	$-0.61 : 0.61$
Left clavicula[1]	$-0.01 : 0.01$	$-0.15 : 0.15$	$-0.15 : 0.15$
Left shoulder[1]	$-2.26 : 3.14$	$-2.26 : 0.00$	$-1.04 : 0.52$
Left elbow[1]	$-0.001 : 2.79$	$-1.57 : 1.57$	$-0.01 : 0.01$
Left wrist[1]	$-1.22 : 0.87$	$-0.01 : 0.01$	$-0.52 : 0.35$
Left hip[1]	$-0.87 : 1.65$	$-0.35 : 1.13$	$-0.61 : 0.61$
Left knee[1]	$-2.26 : 0.001$	$-0.01 : 0.01$	$-0.01 : 0.01$
Left ankle[1]	$-0.69 : 0.52$	$-0.34 : 0.34$	$-0.34 : 0.34$

3.3.1 *Dynamic modeling and balance*

To study the contact forces of the hands, we start from the dynamic model as presented:

$$\begin{bmatrix} \Gamma \\ 0 \end{bmatrix} = \begin{bmatrix} D_1(q,\dot{q},\ddot{q}) \\ D_2(q,\dot{q},\ddot{q}) \end{bmatrix} + \begin{bmatrix} J_1^T(q) \\ J_2^T(q) \end{bmatrix} F \tag{12}$$

where $q \in R^n$ is a vector containing the joint positions, $\Gamma \in R^n$ the vector of the joint torques, $D_1 \in R^n$ and $D_2 \in R^6$ the dynamic effects (sum of inertia, Coriolis, centrifugal and gravity) due to the joint trajectories, $J_1 \in R^{n \times 3N_f}$ and $J_2 \in R^{6 \times 3N_f}$ the components of the Jacobian matrix and $F = \{F_1, F_2, \ldots\}$ the vector of the contact forces. The generalized formulation of the inverse dynamic model is computed using the position and orientation of the waist as a global reference frame. The position and orientation of the waist are computed starting from the position and orientation of the right foot which is assumed to be constant.

3.3.2 *Computation of the contact forces*

Equation 12 emphasizes the link between the joint trajectories $q(t)$, the contact forces $F(t)$ and the joint torques $\Gamma(t)$. For the given joint trajectories, there is an infinity of solutions for forces-torque couples. Here, we present how to find a set of contact forces that compensates the dynamic effects, ensures the desired torques, and encourages balance as much as possible.

1 For the right part of the model the values of θ_y joint limits are the opposite.

Due to the non-planar contact points, we could not use a classical method like the zero moment point [140] to characterize balance. In order to ensure balance and respect the torque boundaries, the contact forces must counter the dynamic effects and take into account the friction in order to avoid undesired sliding.

$$D_2 + J_2^T F = 0 \tag{13}$$

$$\forall e \;\; [\Gamma_e] = D_{1,e} + J_{1,e}^T F \tag{14}$$

$$\forall i \in \{1, \dots, N_f\} \;\; \begin{cases} F_i^n > 0 \\ {F_i^t}^2 \leqslant \mu_i^2 {F_i^n}^2 \end{cases} \tag{15}$$

where F_i^n and F_i^t are the normal and tangential components of the contact forces F_i, μ_i is the friction coefficient and $D_{1,e}$ and $J_{1,e}^T$ are the e^{th} line of D_1 and J_1^T. Equation 13 and Equation 15 refer to the balance criteria presented in [57] which states that the contact wrench sum must remain in the contact wrench cone to ensure balance.

To solve Equation 13 and Equation 14, the Moore-Penrose pseudo-inverse matrix of the Jacobian matrix can be used. However, the pseudo-inverse matrix minimizes the instantaneous norm of the contact forces, without any effect on the friction or sliding constraints. We consider the contact forces that are as close as possible to the normal direction to the contact surface, i.e. that are the solutions to the following problem:

$$\begin{gathered} \min \tfrac{1}{2} \textstyle\sum_i \beta_i (\alpha_i \|F_i^t\|^2 + {F_i^n}^2) \\ \sum_i \left(\begin{bmatrix} \hat{P}_i A_i \\ A_i \end{bmatrix} [F_i] \right) + [D_2] = 0 \\ \textstyle\sum_i (\eta_{e,i} [F_i]) + D_{1,e} - [\Gamma_e] = 0 \end{gathered} \tag{16}$$

where $\hat{P}_i \in R^{3\times3}$, $A_i \in R^{3\times3}$ and $\eta_{e,i} \in R^3$ appear in the decomposition of the Jacobian matrix J_2^T and J_1^T. β_i is a weight value to modify the repartition of the different contact forces and α_i is a coefficient that gives more importance to the tangential components with regard to the normal one for each contact force. The balance is monitored by the global optimization process. The solution to the problem expressed in Equation 16 is:

$$F_i = W_i^{-1} \begin{bmatrix} \hat{P}_i A_i & A_i & \eta_{e,i} \end{bmatrix} \Omega^{-1} \begin{bmatrix} D_2 \\ D_{1,e} - [\Gamma_e] \end{bmatrix} \tag{17}$$

with:

$$\Omega = \sum_i \left(\begin{bmatrix} \hat{P}_i A_i \\ A_i \\ \eta_{e,i} \end{bmatrix} W_i^{-1} \begin{bmatrix} \hat{P}_i A_i & A_i & \eta_{e,i} \end{bmatrix} \right) \tag{18}$$

with $W_i = \text{diag}(\beta_i \alpha_i, \beta_i \alpha_i, \beta_i)$ (we assume that the z-axis is the normal direction of the contact forces) and $\Omega \in R^{(6+N_e)\times(6+N_e)}$ is a square matrix that can easily be inverted by using, for instance, the Gauss-Jordan algorithm. After computing the contact forces, the joint torques can be computed using Equation 12.

3.4 OPTIMIZATION PROCESS

The aim of the work here was to investigate if dynamic optimization can be a suitable method for studying the sitting pivot transfer. More information about optimization process and its application in biomechanics and robotics field is given in Section 2.5.

Due to low inter-intra subject reliability in performing the transfer, the high redundancy of the system (human body) that executes the task, and the changes in the environmental constraints, like the type of wheelchair or the difference in height between the starting and target surfaces, the definition of a cost function is a challenging task. We considered the cost function C to be the weighted sum of joint torques and joint jerks, as presented:

$$C(q) = a \int_0^T \sum_i \Gamma_i^2 dt + b \int_0^T \sum_i \dddot{q}_i{}^2 dt \tag{19}$$

where:

- $\dddot{q}_i$ is the joint jerk,
- Γ_i is the joint torque.

The numerical values of the coefficients $a = 1e-2$ and $b = 1e-5$ were set heuristically to have human like motions with the HRP-2 robot in [90]. The open source software package IPOPT [141] was used.

3.5 THE SCENARIOS ANALYZED IN THE STUDY

The optimal STP trajectories were calculated for nine Scenarios (Sc). The first scenario, Sc 1, represented the behavior of an able-bodied subject, allowing for variations in the knee joint torque values. In the other scenarios the torque values of the knee joints were constant during the motion. In the second scenario, Sc 2, the knees torque values were set to 0 Nm and this represented the behavior of a paraplegic subject performing the motion without FES assistance. Other scenarios, from the third (Sc 3) to the ninth (Sc 9), represented a paraplegic subject with a lesion level at lumbar part of spinal cord (subject is able to control flexion/extension of the hips voluntarily) performing an FES-assisted SPT task, and the torque values of the knee joints were the following: Sc 3: 5 Nm, Sc 4: 10 Nm, Sc 5: 15 Nm, Sc 6: 20 Nm, Sc 7: 30 Nm, Sc 8: 40 Nm, and Sc 9: 50 Nm. The virtually stimulated muscles were the quadriceps and biceps femoris.

The following simplifications were made:

- for Sc 2 -Sc 9, voluntary control of the knee joints is not possible,
- the virtually stimulated bi-articular muscles produce torque control only at the knee joints,
- stimulation parameters do not change during the transfer and no stimulation leads to a null knee joint torque.

3.6 EXPERIMENTAL VALIDATION

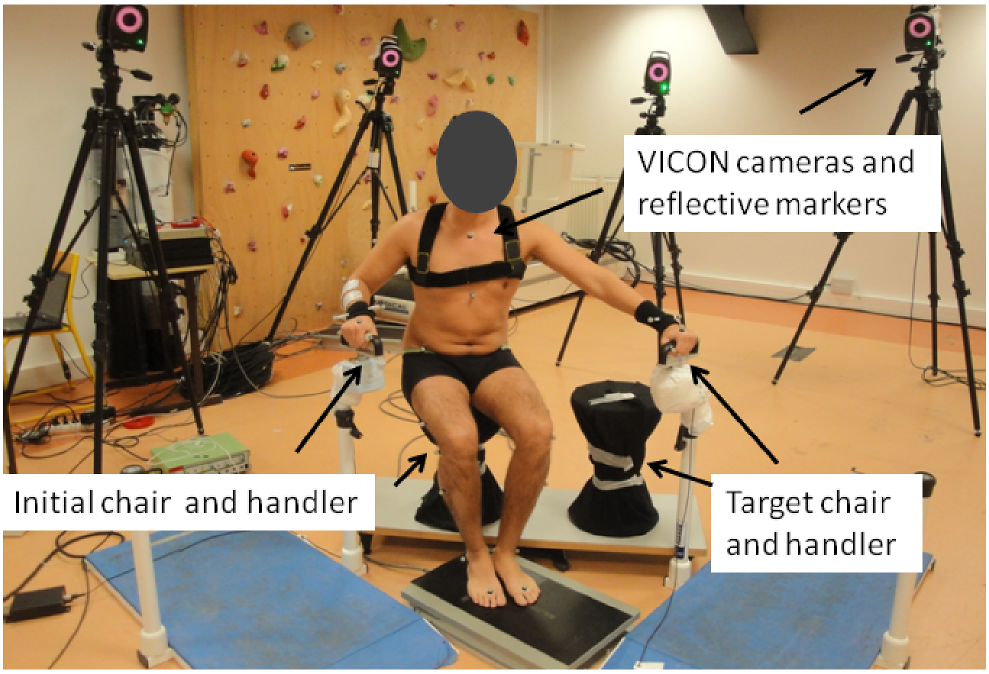


Figure 40: Experimental setup.

One able-bodied subject (male, age: 29 years, height: 1.75 m, weight: 72 kg) participated in this study. The angle between the initial and target chair was about 20°. Two handles, one on the right side of the initial chair and the other on the left side of the target chair, were installed. The height of the handles was adjusted to the height of the

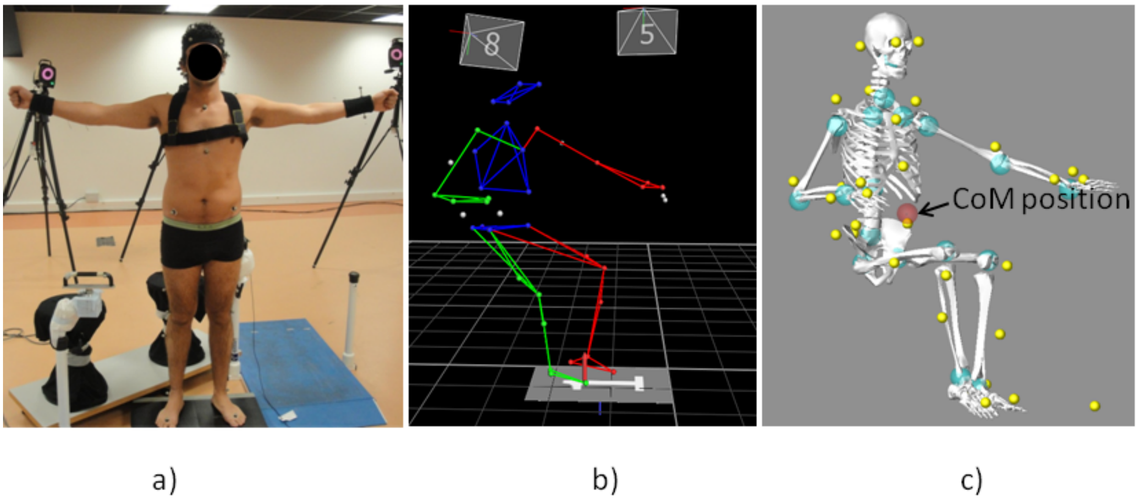


Figure 41: Principle of the acquisition of human kinematic data. A whole-body template of 35 reflective markers (a) was used to track the motion of each limb (b). The corresponding markers were used to lead a specified kinematic model (c) allowing the estimation of center of mass trajectories.

chair and the subject's preferences. The experimental set-up is presented in Figure 40. An eight-camera system (MX, VICON) was used to record the 3D trajectories of 35 reflective markers located on anatomical landmarks specified in a commonly-used whole-body template model, VICON Plug-In-Gait (see Appendix D), as shown in Figure 41. The subject was instructed to assume comfortable foot placement, place both hands on the handles, and keep the back straight and the same position of the feet and hands during the experiment. The initial position of the subject is shown in Figure 40. On a signal from the experimenter, the subject performed the sitting pivot transfer five times at his selected speed and his preferred way.

3.7 DATA PROCESSING

The kinematic model, which consisted of 19 segments and 18 spherical joints, was created using the LifeMOD commercial biomechanical software [2]. The model had the same properties as the one described in Section 3.3. The origin of the global reference frame was 7 cm below the center of rotation of the right ankle joint. The subject's body length was measured and applied to the human model. The mass, center of masses and inertia of body segments were computed using the anthropomorphic Winter table [144]. The recorded reflective markers were used to guide the kinematic model in order to estimate the joint kinematics. Starting from these joint trajectories the Center of Mass (CoM) location was estimated in the global reference frame (Figure 41). The joint kinematic estimation was performed using LifeMOD software. The reliability and accuracy of the Plug-In-Gait template for the CoM estimation has been demonstrated in human movement research for a walking task [54]. Each trial was time-normalized to 100 samples.

Figure 42: Illustration of computed SPT motion of an able-bodied subject.

The mean and the standard deviation of the CoM trajectories between the five trials were computed. In order to compare the optimization data and the experimental data, Root Mean Square error (RMS) and Pearson's correlation coefficients were computed between CoM positions estimated from the experimental data and the ones computed using our optimization process. Computations were performed using MATLAB software.

3.8 RESULTS AND DISCUSSION

As mentioned in Section 3.2, the goals of this work were to:

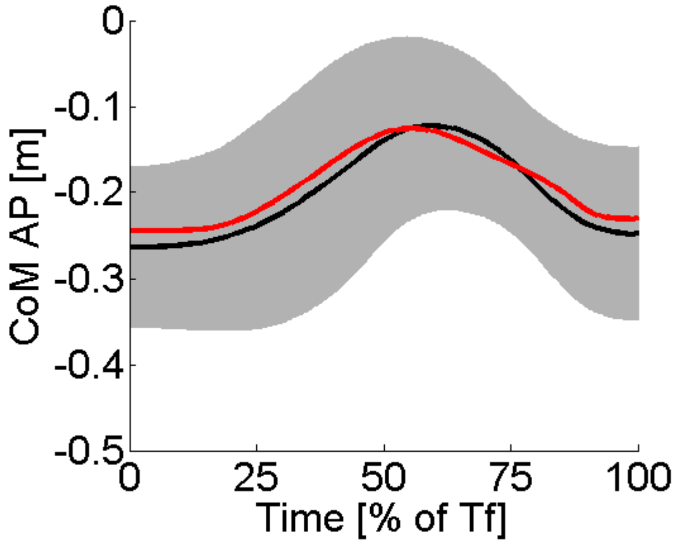
- investigate the ability of the optimization process to predict the SPT trajectories in an able-bodied subject and validate the cost function;
- simulate and investigate the influence of FES on arm effort during the SPT motion of a paraplegic person.

The computed SPT motion is illustrated in Figure 42.

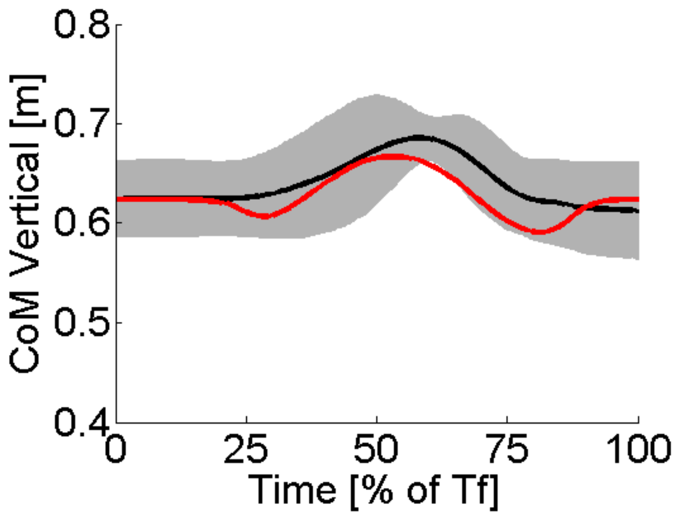
3.8.1 *The ability of the optimization process to predict SPT trajectories*

Optimal SPT trajectories were calculated using the cost function described in Section 3.4. In Figure 43 the trajectories of CoM position in Anterior-Posterior (AP), vertical, and Medio-Lateral (ML) directions are presented. It can be observed that the differences between the computed CoM positions and those calculated from the measured data in the anterior-posterior and vertical directions were not greater than the variability among the different trials for the same subject. The difference between the calculated CoM position in the ML direction and the corresponding one estimated from the experimental data was slightly greater than in the other two directions.

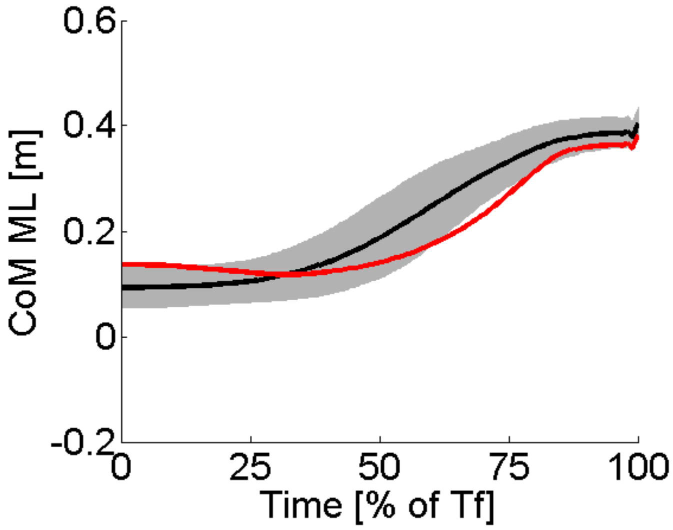
Table 6 presents the RMS error and Pearson's correlation coefficients calculated between the CoM position computed using our optimization process and the CoM position calculated using the experimental data for all five trials. It can be observed that the RMS error was less than 10 cm in the AP direction (Trial 5) and the ML direction (Trial 1). Pearson's correlation coefficients indicate that the optimization process was able to predict



(a)

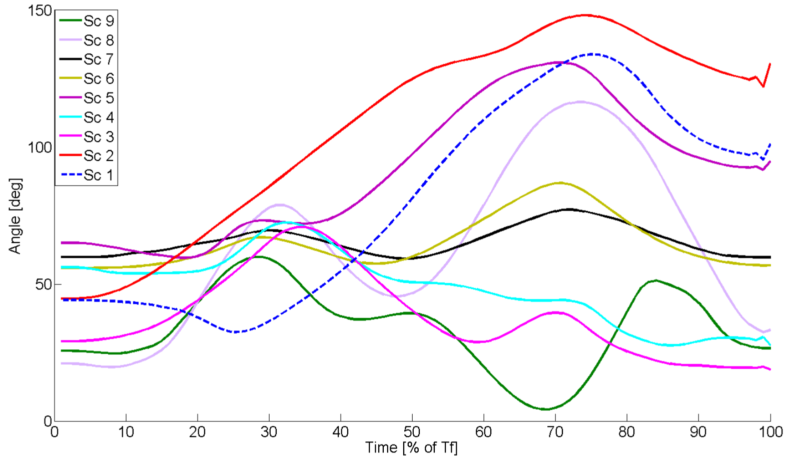


(b)

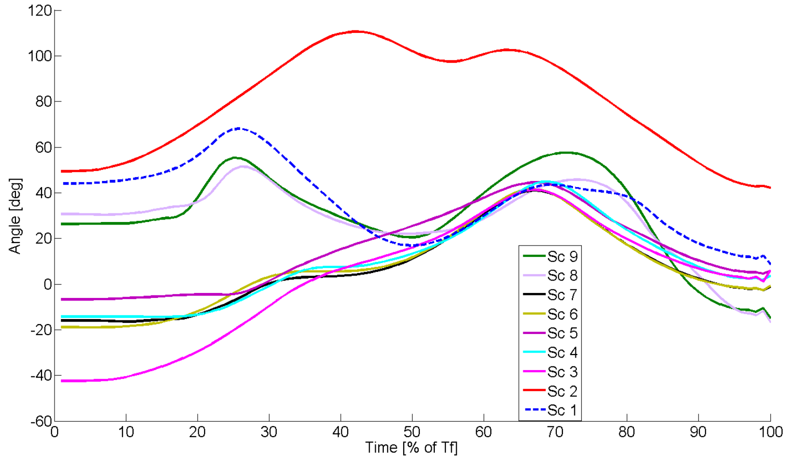


(c)

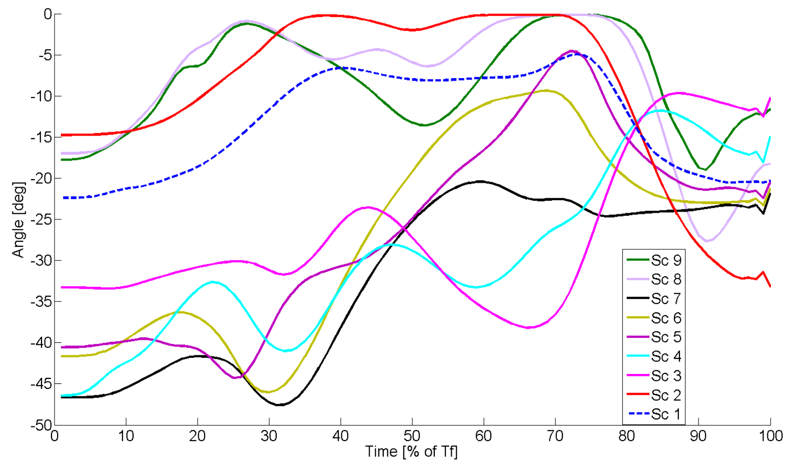
Figure 43: Computed CoM position (red line) , mean value of CoM positions estimated from the experimental data (black line) and its plus/minus standard deviation (gray line) in AP (a), vertical (b), and ML (c) directions in an able-bodied subject.



(a) Leading elbow flexion/extension

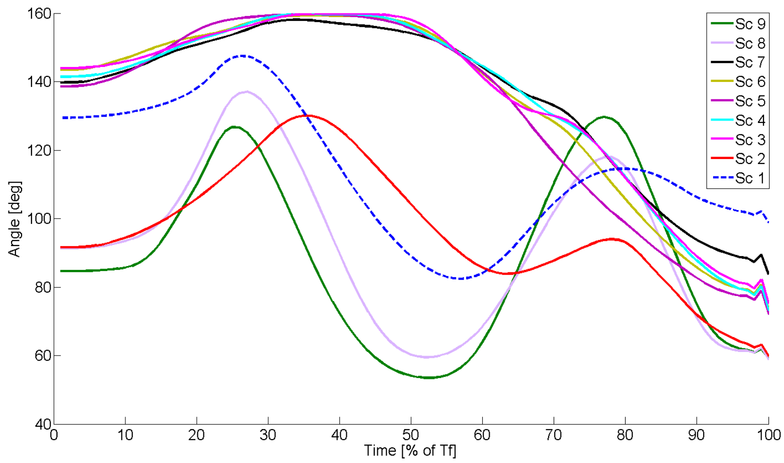


(b) Leading shoulder flexion/extension

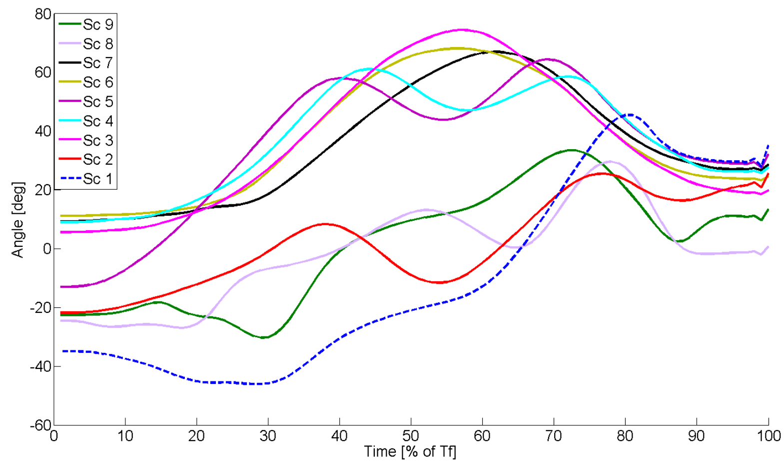


(c) Leading shoulder abduction/adduction

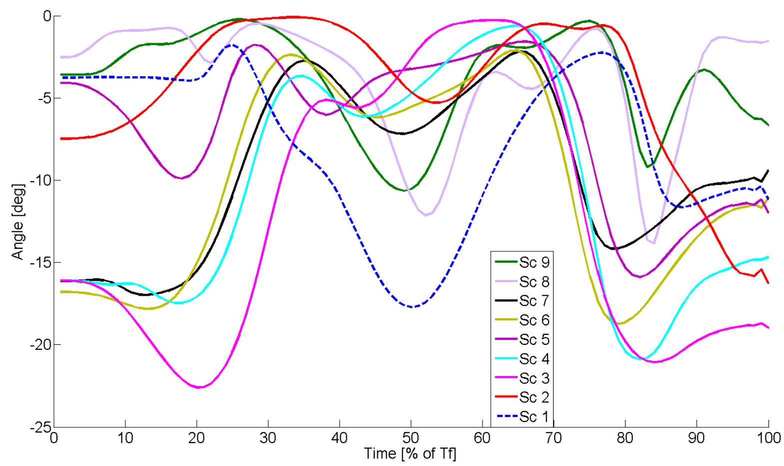
Figure 44: Time history of the U/L joints for all optimization scenarios. In (a), (b), (c) and (d) positive values correspond to flexion and negative values correspond to extension. In (e) and (f) positive values correspond to adduction and negative values correspond to abduction.



(d) Trailing elbow flexion/fxtension

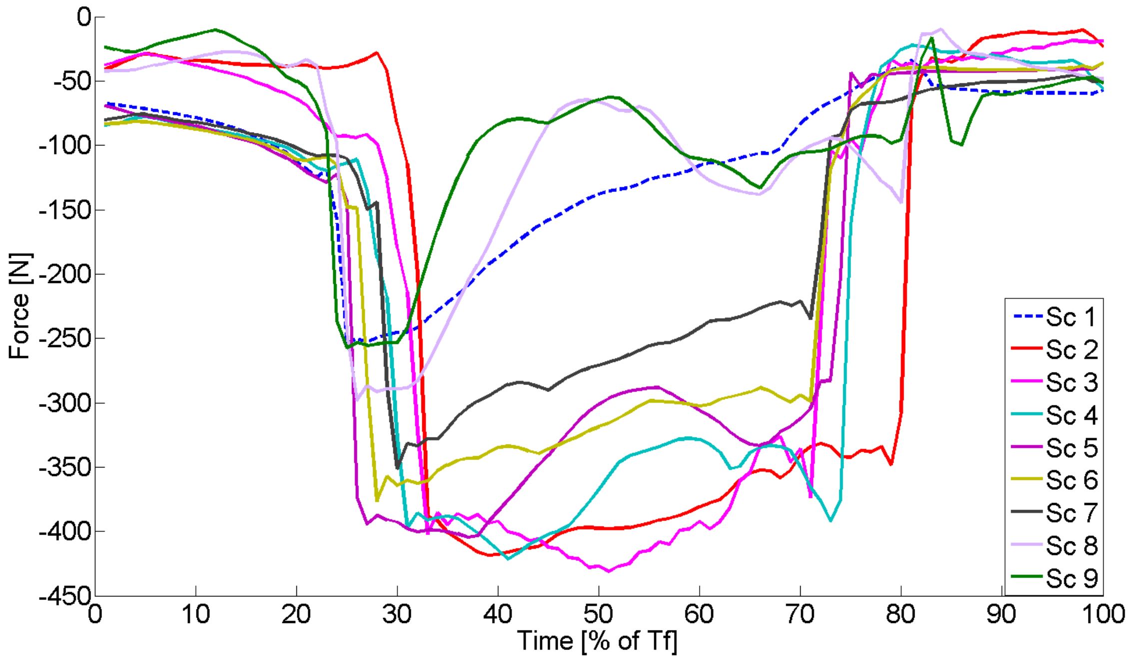


(e) Trailing shoulder flexion/extension

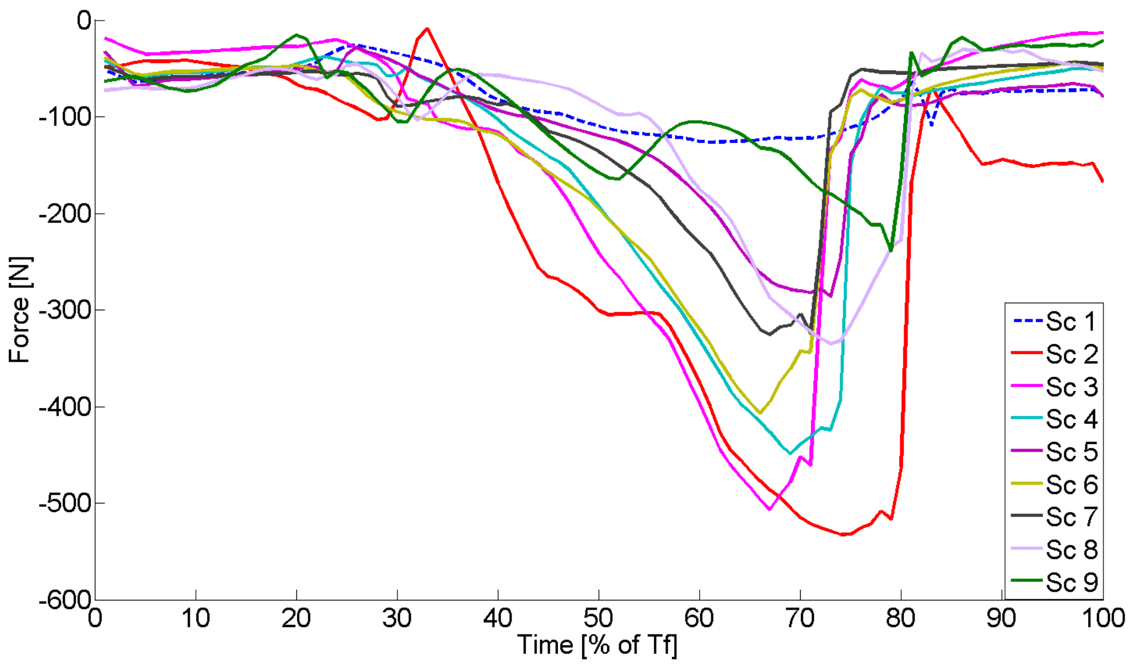


(f) Trailing shoulder abduction/adduction

Figure 44: Time history of the U/L joints for all optimization scenarios. In (a), (b), (c) and (d) positive values correspond to flexion and negative values correspond to extension. In (e) and (f) positive values correspond to adduction and negative values correspond to abduction.

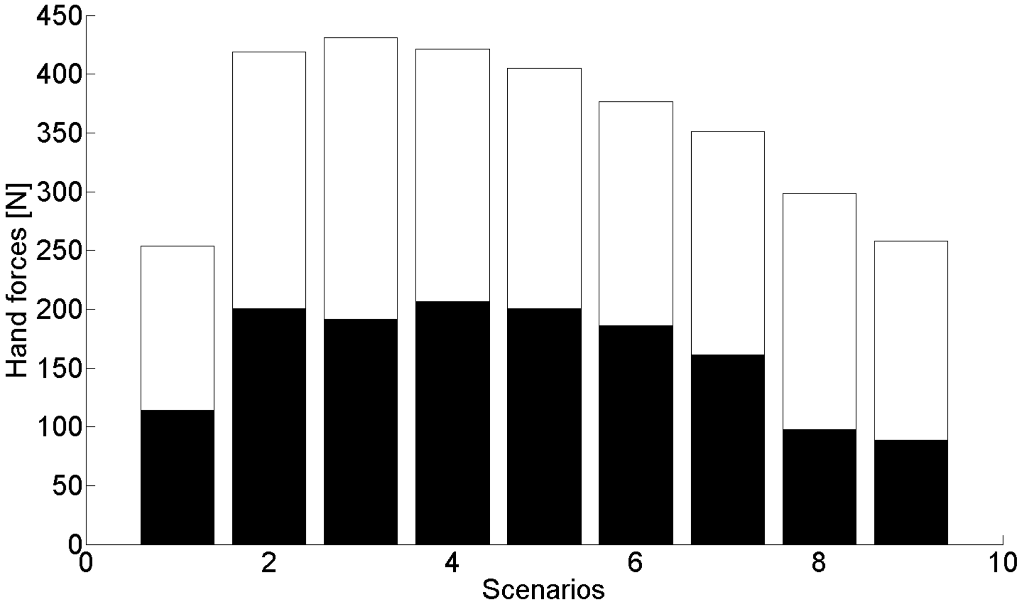


(a) Calculated hand forces for all optimization scenarios under the trailing hand.

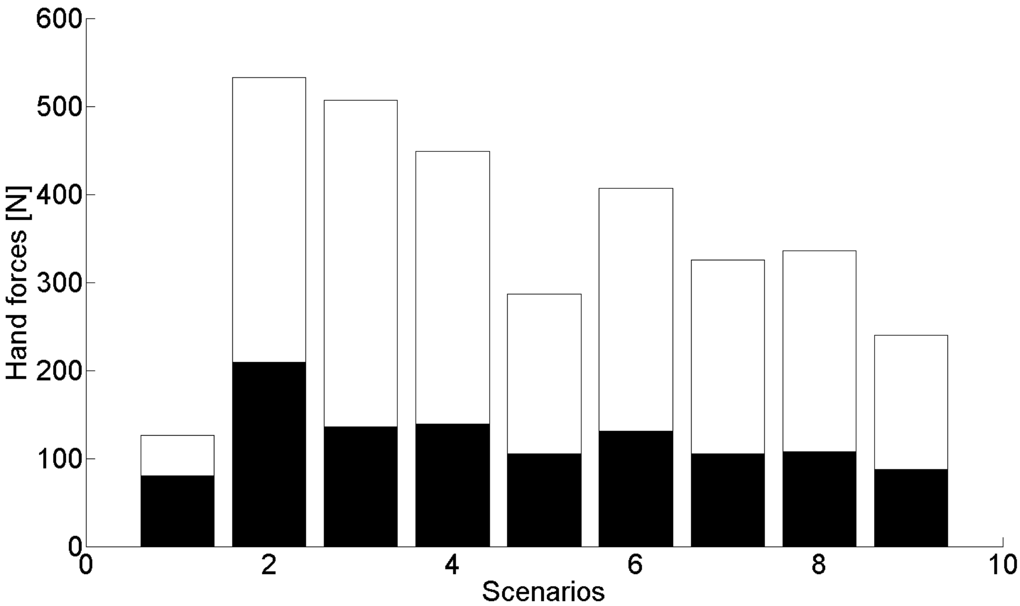


(b) Calculated hand forces for all optimization scenarios under the leading hand.

Figure 45: Calculated hand forces for all optimization scenarios.



(a) Mean (black) and maximal (white) values of trailing hand forces for all optimization scenarios.



(b) Mean (black) and maximal (white) values of leading hand forces for all optimization scenarios.

Figure 46: Mean (black) and maximal (white) values of hand forces for all optimization scenarios. Sc 1, represents the behavior of an able-bodied subject. Other scenarios represent a paraplegic subject with constant torque values of the knee joints: Sc 2: 0 Nm, Sc 3: 5 Nm, Sc 4: 10 Nm, Sc 5: 15 Nm, Sc 6: 20 Nm, Sc 7: 30 Nm, Sc 8: 40 Nm, and Sc 9: 50 Nm.

Table 6: RMS error and Pearson's correlation coefficients calculated between the CoM positions computed using the optimization process and the CoM positions calculated using the experimental data.

	Number of Trial	1	2	3	4	5
CoM AP	RMS	0.1	0.0873	0.0741	0.0507	0.081
	Correlation Coefficient	0.6732	0.2951	0.1069	0.7178	0.6402
CoM Vertical	RMS	0.0581	0.0511	0.0409	0.056	0.0452
	Correlation Coefficient	0.6552	0.6732	0.6706	0.7395	0.6908
CoM ML	RMS	0.0863	0.0716	0.0481	0.0687	0.1078
	Correlation Coefficient	0.9017	0.9722	0.9939	0.9191	0.8643

quite well the behavior of our subject in the ML and vertical direction. The prediction of CoM positions in the AP direction for Trials 2 and 3 was less successful. It should be noted that the calculation of the CoM positions using the experimental data introduced certain errors and that the biomechanical models we used had an approximate nature .

The shoulder and elbow joint trajectories during SPT motion, expressed as the percentage of motion duration, are shown in Figure 44. The joint patterns reveal that, for almost all optimization scenarios, the subject relied on bilateral shoulder adduction. At the beginning of the motion, a trailing shoulder extension was required for scenarios Sc 1-2, Sc 5, and Sc 8-9, at the end of the motion this switched to shoulder flexion for all scenarios. The leading shoulder showed flexion during the transfer, except for Sc 3-7 where shoulder extension was needed at the beginning of the motion and switched to flexion before seat-on moment. An elbow flexion was required during the motion at the both, the leading U/Ls and trailing U/Ls. This kind of behavior has been reported in the literature (Figure 35). The difference could be explained by differences in arm positioning on the leading and trailing surfaces.

3.8.2 *Influence of FES assistance on hand forces during SPT motion*

After validating our approach, we calculated the contact forces on the hands using the biomechanical model presented in Section 3.3. As described in Section 3.5, we analyzed nine different scenarios. The values of the vertical hand forces calculated during our scenarios are presented in Figure 45. The mean and maximal values of the vertical hand forces are given in Figure 46. As expected, the contact forces under the hands were lower in the case of an able-bodied person (Sc1) compared with a paraplegic person performing the motion without FES assistance (Sc 2). In addition, the analyses of the hand forces calculated during the other scenarios (Figure 45 and Figure 46) indicate that the functional electrical stimulation of the knee extensors impacted the performance of SPT motion. It can be noted that the contact forces of the hands decreased when the equivalent knee joints torques produced by the electrical stimulation increased. Also, the motion of the able-bodied subject, represented by the first bar, produced mean hand force relatively similar to that of the eight scenarios. It seems that Sc 8 may be a good trade-off (for this specific subject) between the minimization of the hand forces and the stimulation amplitude.

3.9 CONCLUSION

In this chapter we explored two problems concerning paraplegics' SPT motion through computer simulations:

- the ability of an optimization process to predict SPT trajectories in able-bodied subjects;
- the influence of FES on hand forces applied during the SPT movement.

First, we proposed a dynamic optimization method in order to predict the SPT motion of an able-bodied subject. The cost function was the sum of the lower-limb joint torques and joint jerks. Next, using the VICON system, we recorded the 3D trajectories of 35 reflective markers located on the body of the able-bodied subject during SPT motion. The joint kinematics were estimated using LifeMOD commercial biomechanical software. We validated our optimization approach by comparing the computed SPT trajectories with the ones estimated from the data recorded during the experiment. Last, we used the optimization tool to analyze the influence of FES on the SPT maneuver in paraplegic persons.

The results of this study indicate that it is possible to describe the sitting pivot transfer of an able-bodied subject within the frame of optimization theory. Taking into account the body dynamics and kinematics, the proposed method was able to reproduce motion with the CoM trajectories that was quite close to the one estimated from the data acquired during the experiments. We showed that FES applied on paralyzed lower limbs has an impact on arm efforts during SPT motion. From the results presented in this study, there thus seems to be a good trade-off between the stimulation parameters and therefore induced muscle fatigue, and minimized hand forces. Also, by not using high stimulation amplitude, incomplete paraplegic patients, some of whom have sensory functions preserved below the lesion level, could benefit from FES.

In addition to modeling of dynamics and kinematics of human body, future studies could model muscle behavior and determine the optimal FES pattern needed to minimize the muscle fatigue of stimulated lower-limb muscles during SPT motion. One perspective would be to use the algorithm designed for FES-assisted sit-to-stand motion to facilitate sitting pivot transfer motion in paraplegic patients. The algorithm, presented in Section 2.6, was tested for SPT motion in five able-bodied subjects and proved to be able to recognize SPT transfer motion. It is now ready to be tested in a clinical environment. In the future, we plan to test the algorithm in experiments with complete and incomplete paraplegic patients.

This chapter proposes some contributions to resolving the problem of paraplegics' SPT motion.

First, to our knowledge, the optimization process as a tool to study SPT has been investigated here for the first time. The results of this study could be helpful in referring various rehabilitation therapies. It is easier and faster to generate human-like motion than to measure this motions on human subjects. This requires the definition of a suitable cost function. The approach introduced here addressed the issue by finding and verifying a cost function. In addition to rehabilitation purposes, other applications involving human motion, such as computer graphics or humanoid robotics, might benefit from this efficient computation of movement trajectories.

Second, the literature concerning FES-assisted SPT in paraplegic patients is limited. To our knowledge, no study has yet investigated the influence of FES on the hand forces applied during SPT motion in these patients. Here, we have showed that FES might be useful in decreasing arm participation during the transfer motion. Transferring from one surface to another with minimal participation of the upper limbs could help to prevent shoulder complications in the population with SCI.

The author of this thesis contributed to this study by closing the loop between robotics tools such as optimization and the field of human motion science. The author designed and performed the experiments with an able-bodied subject, estimated the CoM trajectories from the experimental data, validated the method by comparing the computed and estimated CoM positions, participated in finding a suitable cost function, and interpreted the results of this study.

Some ideas and figures from this chapter have appeared in the following publications:

1. **J. Jovic**, S. Lengagne, P. Fraisse, and C. Azevedo Coste. *Impact of Functional Electrical Stimulation of Knee Joints during Sitting Pivot Transfer Motion for Paraplegic People.* International Journal of Advanced Robotic Systems, N/A, 2012.

2. S. Lengagne, **J. Jovic**, C. Pierella, P. Fraisse, and C. Azevedo Coste. *Generation of Multi-Contact Motions with Passive Joints: Improvement of Sitting Pivot Transfer Strategy for Paraplegics.* BioRob'2012 : IEEE International Conference on Biomedical Robotics and Biomechatronics, Italy, 2012.

4 FES-ASSISTED UNSUPPORTED STANDING

4.1 PROLONGED STANDING IN ABLE-BODIED INDIVIDUALS

Human postural system has been studied since XIX century and, consequently, the literature dealing with it the is well documented. The term human postural system in the literature refers to a multi-joint system regulated by the CNS in order to perform a desired task while the balance is maintained [109]. One movement, even the simplest, implies the coordination of numerous DoF and muscles and can be consider as a perturbation from an equilibrium point of view. The researchers in human movement science are studying the mechanisms that allow human beings to regulate its posture, while managing redundancies. In order to study the mechanisms of standing in humans many experimental paradigms have been proposed. These experimentations consist essentially in studying the response of the postural system to an external perturbation.

The most important work in the field is probably that of Nashner and McCollum [109]. In this study, the authors have shown that, depending of the magnitude of the perturbation, the postural system will recover balance in the sagittal plane using mainly the ankle joints if the perturbations are small and using mainly the hip joints in the case of higher perturbation amplitudes. Later, researchers showed that not only the amplitude of the joints are important, but also their coordination [18].

Using recent engineering tools, a very large number of postural models have been developed to understand and reproduce these observations [142]. It appears that pendulum systems with one or two DoF are able to describe the dynamics of the postural system in the sagittal plane and that the main control variable used by the CNS is the CoM [101]. Nevertheless, these models and the associated experimental paradigms have dealt with very specific and constrained tasks.

It has been demonstrated that the control of the CoM in the ML plane is primarily due to activation of the hip abductor and adductor muscle groups through a load-unload mechanism. This has been found to be independent from the ankle muscle activation that controls the CoM positions in the AP direction [94].

The literature is nevertheless unclear and the studies much less numerous with regard to the case of 3D unconstrained prolonged standing (more than 10 minutes) for healthy subjects, which is close to our objective of finding an optimal strategy for prolonged standing to meet the needs of paraplegic subjects. This is probably due to the observation that, in this case, the patterns observed at the joint levels are more complex and subject dependent. The most widely studied variables for prolonged standing are the Center of Pressure (CoP) and Electromyography (EMG) signals of lower limbs and lower back muscles [36], [56].

The work of Duarte and Sternad, using CoP trajectories and/or CoP velocity, showed three main strategies in able-bodied subjects [35] (see Figure 47):

1. Shifting: a fast displacement of the average position of the CoP from one region to another;

2. Fidgeting: a fast and large displacement followed by a return of the CoP to approximately the same position;

3. Drifting: a slow continuous (ramp-like) displacement of the average position of the CoP.

Two CoP patterns per minute were observed in average [36]. Different interpretations of the existence of these strategies were provided, such as the minimization of muscle fatigue or the reduction of discomfort [56]. However to our knowledge, no study has yet been conducted to determine the relationships between these strategies and the joint coordination or EMG signals during prolonged standing.

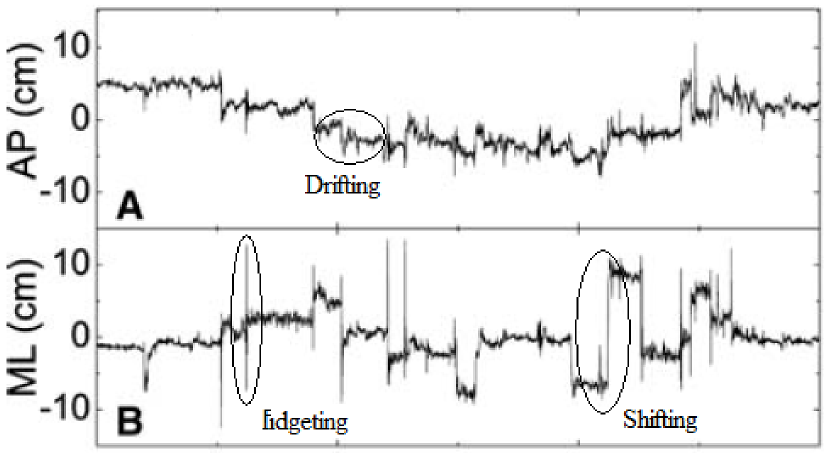


Figure 47: Typical CoP displacement during prolonged standing in the AP and ML planes showing the three different CoP strategies. Adapted from [35]

To our knowledge, the biomechanics of prolonged standing have not been studied in the case of paraplegic subjects. In contrast, the effects of prolonged standing exercises, as a method to improve health conditions in the paraplegic population have been reported. For more information see Section 1.5.

4.2 FES CONTROL STRATEGIES: STATE OF THE ART

The first application of functional electrical stimulation to paraplegic patient was preformed by Kantrowitz in 1963. The quadriceps and glutei muscles of a T3 paraplegic subject were stimulated using surface electrodes. The patient achieved standing posture and maintained it for couple of minutes. The next similar trial was performed using an implanted FES system at Rancho Los Amigos Hospital in California in 1970. This team implanted stimulators to both femoral and gluteal nerves to obtain the contraction of knee and hip extensors. A T5 paraplegic subject was able to stand with the help of an FES system, crutches and ankle braces [16]. The first continuous FES-supported standing program was conducted by Kralj et al. in 1979. The early approach used open-loop stimulation of the knee extensors. The hips were hyper-extended and the subjects used their arms to maintain balance. Due to fatigue, the subjects were able to stand for only a couple of minutes [86]. This method was improved by proposing posture switching in order to allow the muscles to relax. The patient could manually change the stimulated muscle groups depending on the standing posture [87]. In the year 2000, Guiraud et al. used an implanted FES system with 16 channels to stimulate both epimysial (12 channels) and nerve (4 channels) electrodes for standing and walking. Two patients participated in their study. The system was controlled by the patients using push buttons. The control parameter could be selected from two options: stimulation current intensity or pulse width. The patients were able to control the stimulation level. One patient achieved stable standing for up to 15 minutes but could not perform another task while standing because he needed to use his hands to stabilize his posture [51].

Majority of the FES-assisted systems provide open-loop stimulation of the knee extensors [85]. Even though this type of stimulation is commonly used in clinical practice, there are several limitations. This include muscle fatigue and need for the patients to keep the arms engaged in maintaining the standing posture, which makes standing non-functional. Open-loop control cannot compensate for external disturbances or changes in internal parameters, such as a loss of muscle force caused by fatigue. In contrast, closed-loop control exhibits good disturbance rejection properties and would enable paraplegic patients to maintain standing posture despite disturbances. Therefore, many research groups have worked on restoring "arm-free" standing by means of closed-loop FES-assisted systems.

Jaeger showed theoretically that it might be possible to restore quiet standing using a closed-loop FES system. The author interpreted the human body as a single-link inverted pendulum, assuming that the knee and hip joints are locked. The author used a classical PID controller to investigate arm-free FES-assisted standing and to control the position of the ankle joints by applying needed torque values [67].

Marsolais et al. used electrodes implanted bilaterally in the quadriceps, hamstring, tensor, sartorius, gracilis, gluteus maximus, foot dorsiflexor and soleus muscles in three paraplegic patients (with lesion level at T 8/9, T11, and T4). A set of four PID controllers were used in parallel to control the position of each knee and ankle joint. The stimulator provided stimulation to the ankle plantar flexors only when the knee flexion error was less than five degrees and stimulation to both ankle plantar flexors and quadriceps when the knee flexion error exceeded five degrees [96].

Davis et al. implemented a closed-loop FES system and performed experiments with a T10 paraplegic patient. The patient had an implanted Nucleus FES-22 stimulator to control knee flexion/extension, and the knee angles were monitored by goniometers. The knee goniometers were sensed for a ten-degree buckle, and the stimulator corrected the buckle, which occurred between 3% and 8% of the standing time. Stability was achieved with the Andrews ankle-foot orthosis. The use of accelerometers for trunk inclination and vertical acceleration provided additional information for controlling sit-to-stand and sitting motions. The patient was able to achieve standing for one hour and perform a one-handed task with an object of 2.2 kg. The same principle was used in another T10 patient using surface stimulation over both femoral nerves. The patient achieved uninterrupted standing typically for 30 minutes, with maximal duration up to 70 minutes [24].

A more complicated model was proposed by Khang and Zajac. The authors used a planar three DoF model which included nonlinear muscular-tendon properties. Arm movement was modeled as external disturbances. The model included 13 muscles in the lower limbs. The algorithm they developed calculated the optimal muscle activation that would enable standing posture and minimize energy expenditure. This study was motivated by the assumption that minimizing muscle activation would reduce muscle fatigue. This approach was not experimentally tested with human subjects [78], [79].

The first experimental attempt to apply FES closed-loop control for prolonged standing in paraplegic subjects was performed by Hunt et al. in 1997. They proposed a single inverted pendulum model, with all the joints above the ankle braced. Plantarflexor muscles were stimulated. The proposed controller was a two-level tree-nested Linear Quadratic Gaussian (LQG) controller, which controlled the position of the ankle joints. The controller had ankle moment feedback (inner loop) and inverted pendulum ankle angle feedback (outer loop). The inner loop regulated the ankle moment by applying a stimulation pulse width, while the outer loop stabilized the body regulating the inclination angle by providing the desired reference moment for the inner loop. The total moment requested by the outer loop was distributed equally as a reference moment to separate the inner loop controllers for the left and right muscles. Thus, if only one side become fatigued, the stimulation parameters to this side would increase, though not necessarily with an increase in moment as the stimulation saturated. However, the non fatigued side might still have the ability to generate additional moment. The control scheme is given in Figure 48. Standing in the paraplegic subject was limited to 30-40 s due to muscle fatigue and spasticity [64], [105].

The approach was improved by Gollee et al. in 2004. The inner loop was considered as a single input-single output system that regulated the total ankle moment. The same

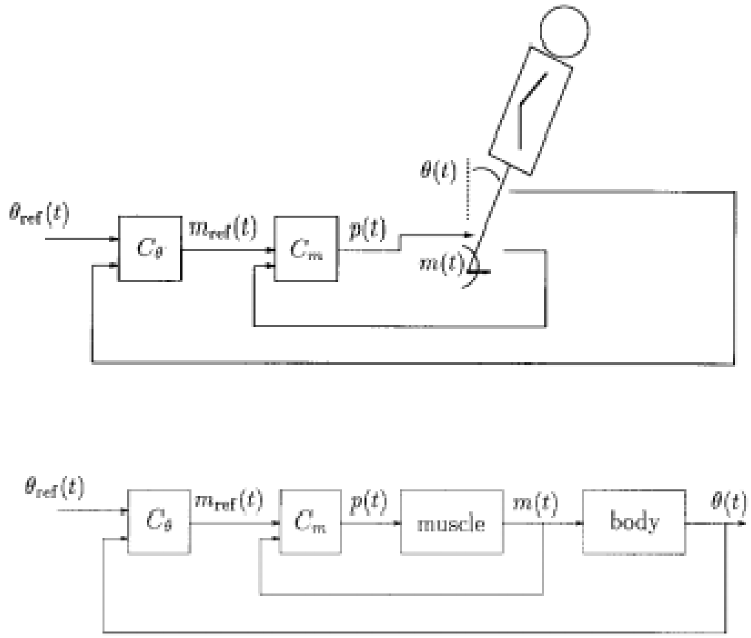


Figure 48: Feedback control of unsupported standing: θ(t): measured ankle angle, m(t): measured ankle moment, p(t): muscle stimulation (constant amplitude and frequency, variable width pulses), θref(t): angle set-point, mref(t): moment set-point, Cθ: angle controller, and Cm: moment controller. Adapted from [64].

stimulation was applied to both muscles in such a way that the total moment generated by both sides followed the moment requested from the outer loop. The structure of the inner loop was simplified since only a single controller was requested. The differences in the strength of the muscles were compensated for. The second improvement addressed the method of controller design. Instead of using an LQG controller, the authors used a pole-placement method for both the inner and outer control loops. The authors reported experiments with standing up to several minutes [48].

In 1998, Matjacic and Bajd used a double inverted pendulum model, and the knee joints were maintained in an extended position. The authors developed a closed-loop double inverted pendulum model including neural system delay, trunk muscle dynamics, body segmental dynamics, and a linear quadratic regulator optimal controller. The analysis of the double inverted pendulum model revealed that as long as the ankle stiffness was appropriate, the model could be stabilized by controlling only the lumbosacral joint, which some paraplegic patients can control voluntarily [98], [99].

Mihelj and Munih also combined the FES control of an ankle joint with voluntary upper-body activities and showed that by applying optimal control theory the ankle torque could be minimized [100].

Hunt et al. experimentally investigated the control of paraplegic ankle joint stiffness using FES while standing. One able-bodied and one paraplegic person participated in the study. The authors showed that desired ankle stiffness control can be achieved using FES but that it is limited by the strength of the muscles [65] .

Jaime et al. combined the work of Hunt et al. and Matjacic and Bajd and experimentally proved that a subject had no difficulties in maintaining balance during standing while being supported by closed-loop controlled ankle stiffness using FES [69].

Soetanto et al. used a Proportional Derivative (PD) controller to stabilize the position of the joints of a triple inverted pendulum model in the sagittal plane including complex musculotendon properties during quiet standing (Figure 49 and Figure 50). In this computer simulation study, the authors showed that the controller could stabilize paraplegic standing posture for a couple of seconds [131].

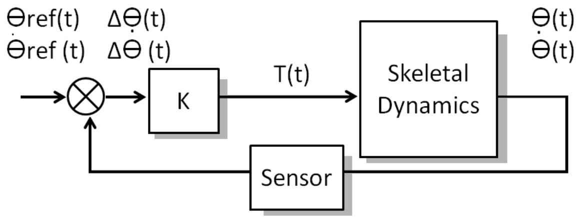


Figure 49: A block diagram of a PD controller for the skeletal dynamics. K is the controller gain. θref(t) are the reference positions for the body links. Adapted from [131].

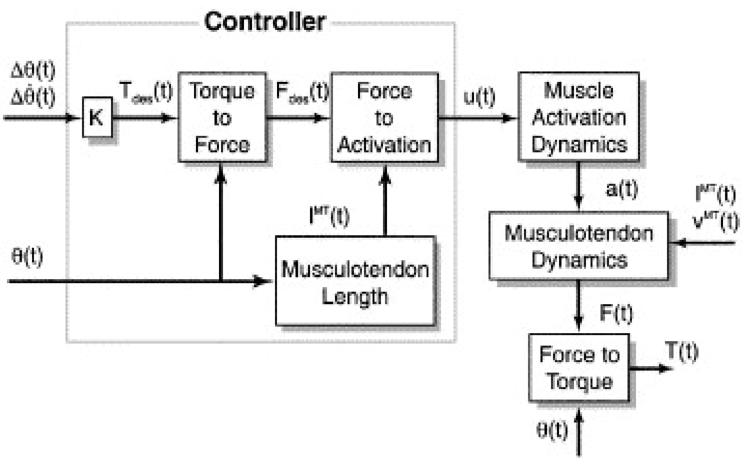


Figure 50: The control action u(t) produced by the FES controller is computed from the desired joint torque Tdes(t) (or the desired musculotendon force Fdes(t)), produced by the PD controller of Figure 49. Adapted from [131].

Before a practical system for paraplegic standing can be developed, some limitations in the above-mentioned models need to be addressed. These models assume that the motions of the legs are identical and that there is no motion in the frontal plane. However, these assumptions are incorrect [80]. Therefore, Kim et al. proposed a 3D model with 12 DoF. This 3D model has been used to show that FES-assisted arm-free standing is possible using a PD controller in the joint space. The authors found that controlling six out of 12 DoF of the lower legs enables the determination of the unique torque input that leads to stable standing for a couple of seconds [80].

Nataraj et al. used PD feedback of the desired lower-limb joint positions to drive a neural network trained to produce a muscle activation pattern. The PD gains were optimized to minimize the U/L effort required to stabilize the human body against disturbances [110], [111].

Audu et al. published a study in 2011 reporting an investigation of the ability of a SCI person to affect changes in standing posture with FES assistance. To do so, the authors developed a 3D musculoskeletal model composed of 21 bone segments connected through 21 joints. This model was actuated by 32 Hill-type muscle elements. The muscle activations required to execute shifting maneuvers with upper-limb forces less than 10% of body weight were determined via a dynamic optimization process. The study demonstrated that it is possible to identify and activate an optimal set of paralyzed lower-extremity and trunk muscles to manage posture switching during a standing task with minimal upper-extremity effort [11].

4.3 MOTIVATION AND GOAL OF THE CHAPTER

The above-described approaches focused on the control of each individual joint, i.e., joint space control. In these cases, the balance of the postural system was not directly controlled. This could be problematic, especially when only the lower limbs are controlled. Our application deals with slow dynamic motion for which safety is a primary concern and thus for which the projection of the CoM must be contained in the base of support. During paraplegic quiet standing, two concurrent controllers act in parallel, with the physiological system under CNS control, and an artificial FES system. The upper part of the paraplegic's body is under voluntary control, therefore artificial controllers should be designed to take into account the actions of the intact part of the body and to assist users in their task.

For humans the CoM provides an indicator of stability and is thus an essential parameter in postural stability [22]. By controlling the CoM position in the paraplegic person, the voluntary motions under CNS control are taken into account. Therefore, in this chapter we propose a whole-body controller based on control of the CoM position. The goal was to develop a simple balance controller which would enable quiet standing in individuals with SCI by means of FES, while taking into account the voluntary motion of the upper limbs. The controller should enable prolonged standing by simulating the behavior of an able-bodied subject during the standing task, i.e., by imposing posture switching and thus allowing the stimulated muscles to relax. The proposed approach is based on the ten DoF biomechanical model explained in Section 4.4. Section 4.5 describes a statically equivalent serial chain method, used to express the CoM position of the human model. The validity of our approach was tested using real human CoM trajectories and by applying perturbations in simulation during quiet standing. The Proportional Integral (PI) controller used in this study is described in Section 4.6. Experiments on two able-bodies subjects and experimental data processing are described in Section 4.7 and Section 4.8, respectively. The results and conclusions are given at the end of the chapter.

4.4 BIOMECHANICAL MODEL

The biomechanical model to represent the human postural system in 3D was composed of five rigid segments (shanks, thighs, HAT) connected by ten cylindrical hinge joints (Figure 51). Winter tables [143] were used to estimate the segment lengths and inertial parameters of the model segments as a function of the height and body mass. Inverse dynamics and estimated ground reaction forces were computed using recursive Newton-Euler equations. Integration of the dynamical model was performed using LifeMOD commercial modeling software.

Several techniques have been developed for CoM estimation in humans. The most widely used ones are based on anthropometric data [29], [143]. Using those methods, large estimation errors can be made, mostly due to a mismatch between the subject and the data that are used. When a subject-specific estimation of body parameters is needed, medical images such as magnetic resonance imaging or computer tomography are usually analyzed [68]. Segment properties can also be estimated by using ground reaction forces and video motion capture data and solving the inverse dynamic equation [139]. In 2009, Cotton et al. developed a new subject-specific representation of the CoM and proposed to describe the CoM location as a Statically Equivalent Serial Chain (SESC). The main advantage of the subject-specific SESC method, compared with previously described methods, is the simple and accurate identification of the parameters involved in computing the CoM position. Therefore, the SESC modeling process was used in this study to obtain a serial-chain-like model (Figure 51) to determine the CoM positions of the human model. This process describes the equations of CoM location by merging segmental parameters and thus is very efficient in terms of computational cost. More details about the method is given in Section 4.5.

4.5 COM MODELING

It is possible to locate the center of mass of any linkage by means of a serial chain. In this chain, each link is represented by a set of constants determined from the geometric

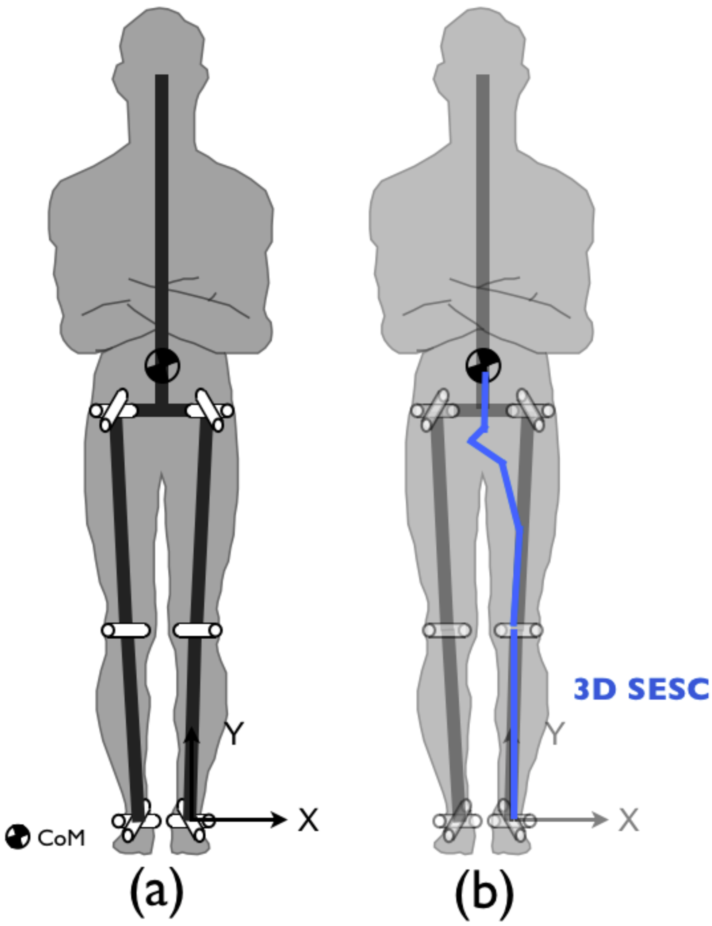


Figure 51: Biomechanical model of the postural system (a). Representation (blue line) of the 3D statically equivalent serial chain used to estimate the CoM location (b).

configuration and mass distribution of the original link [27]. Cotton et al. indicated that the orientation of these virtual links is identical to the orientation of the corresponding links in the original chain [22], [23].

For example, take the chain with an n number links as presented in Figure 52. Each link has a mass attached to it, represented by $m_i \dots m_n$, at a position c_i on the link's frame. The total mass is given by $\Sigma m_i = M$. The homogeneous transformation between links is given by:

$$T_i = \begin{bmatrix} A_i & d_i \\ 0 & 1 \end{bmatrix} \tag{20}$$

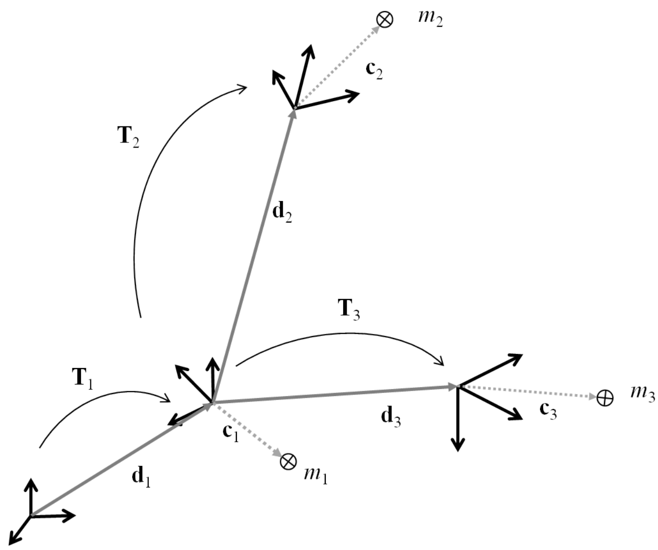


Figure 52: Tree structured chain showing the position of each link's mass. Adapted from [22].

where A_i is a 3-by-3 matrix containing the relative orientation and vector d_i determines the position of the frame's origin measured from the origin of link $i-1$. The chain's CoM (CoM) can be determined as follows:

$$\begin{aligned}\begin{Bmatrix} \mathrm{CoM} \\ 1 \end{Bmatrix} &= \frac{m_1}{M} T_1 \begin{Bmatrix} c_1 \\ 1 \end{Bmatrix} + \frac{m_2}{M} T_1 T_2 \begin{Bmatrix} c_2 \\ 1 \end{Bmatrix} \\ &+ \frac{m_3}{M} T_1 T_3 \begin{Bmatrix} c_3 \\ 1 \end{Bmatrix}\end{aligned} \tag{21}$$

After performing the necessary operations, Equation 21 can be rewritten as:

$$\mathrm{CoM} = d_1 + A_1 r_1 + A_1 A_2 r_2 + A_1 A_3 r_3 \tag{22}$$

with

$$\begin{aligned} r_1 &= \frac{1}{M}(m_1 c_1 + m_2 d_2 + m_3 d_3) \\ r_2 &= \frac{1}{M}(m_2 c_2), r_3 = \frac{1}{M}(m_3 c_3) \end{aligned} \tag{23}$$

When dealing with revolute and spherical joints r_i is a constant vector that describes the static properties of the SESC. Equation 22 may also be written as the matrix multiplication:

$$CoM = \begin{bmatrix} I & A_1^* & \dots & A_n^* \end{bmatrix} \begin{Bmatrix} d_1 \\ r_1 \\ \vdots \\ r_n \end{Bmatrix} = BR \tag{24}$$

where A_i^* represents the absolute orientation of link i. In our example $A_1^* = A_1$, $A_2^* = A_1 A_2$ and $A_3^* = A_1 A_3$. Matrix B is then of size 3-by-3(n+1) and is composed of the individual rotation matrices. Vector R contains the segment properties of the SESC chain. It was observed in [22], that Equation 24 is akin to the direct geometric model of a serial chain with links described by r_i. From Equation 24 the following equation can be written:

$$R = B^+ CoM \tag{25}$$

Now, measuring different CoM positions subject-specific parameters R could be identified.

The position of CoM is a function of the joint angle position, q:

$$CoM = f(q) = \begin{bmatrix} I & A_1^* & \dots & A_n^* \end{bmatrix} \begin{Bmatrix} d_1 \\ r_1 \\ \vdots \\ r_n \end{Bmatrix} = BR \tag{26}$$

From Equation 26, following equation can be written:

$$C\dot{o}M = J_{CoM} \dot{q} \tag{27}$$

where $C\dot{o}M$, J_{CoM}, and $\dot{q}$ are CoM velocity, the Jacobian matrix, and joint velocity, respectively. Equation 27 can be used to control CoM position and, therefore, the following equation can be obtained:

$$\varepsilon_{CoM} = J_{CoM} \varepsilon_q \tag{28}$$

The simple solution of the problem can be expressed as:

$$\varepsilon_q = J^+ \varepsilon_{CoM} \tag{29}$$

The general solution of the problem can be expressed using the following equation:

$$\varepsilon_q = J^+_{CoM}\varepsilon_{CoM} + (I - J^+_{CoM}J_{CoM})Z \tag{30}$$

where I, J_{CoM} and J^+_{CoM} are the identity matrix, the Jacobian matrix, and its pseudo-inverse matrix, respectively. Z represents any function.

4.6 POSTURAL CONTROLLER

The problem consists in finding the values of the lower-limb joint torques, T, that would minimize the tracking error, ΔCoM, of the CoM estimated from the experimental data. Here, only the CoM 3D positions are set, making the system relatively redundant to the task. The robotics literature provides a number of solutions for the inverse kinematic problem [77], [130] in the presence of redundancies. One of the most popular is the so-called gradient projection method [91]. This method use a suitable scalar objective function to reduce the number of possible kinematic solutions while reliable Cartesian quantities are tracked. As mentioned before, the general solution of the inverse kinematic problem can be written as [130]:

$$\varepsilon_q = J^+_{CoM}\varepsilon_{CoM} + (I - J^+_{CoM}J_{CoM})Z \tag{31}$$

where I, J_{CoM} and J^+_{CoM} are the identity matrix, the Jacobian matrix and its pseudo-inverse matrix, respectively. The Jacobian expresses the relationship between the velocity of the CoM in the global reference frame and the joint velocities. Z is the so-called null space vector that minimize a scalar function representing the task constraints. This is obtained because the term (I-J^+J) projects Z onto the null space of the Jacobian matrix. In this work the Z function keeps the lower-limb joint angles away from their physiological limits, q_{max} and q_{min}, and has the following form:

$$q_{mean} = \frac{1}{2}(q_{max} + q_{min}) \tag{32}$$

$$Z(q) = -2(q - q_{mean})e^{(q - q_{mean})^2} \tag{33}$$

where q_{mean} is a vector that contains the mean values of the joint positions. In order to track of the CoM in the Cartesian space, a proportional-integral controller was designed:

$$\varepsilon_{CoM} = K_P\Delta CoM + K_I\Delta CoM \tag{34}$$

where K_P and K_I are the proportional and integral corrective gains, respectively. The controller scheme is shown in Figure 53. Here, FKM is the forward kinematics model, PI is the proportional and integral controller in the Cartesian space, and Z is the null space vector. The values of the gains were empirically determined to be stable through all simulations: K_P: 350, K_I: 250. The numerical value of gain K is 1 Ns.

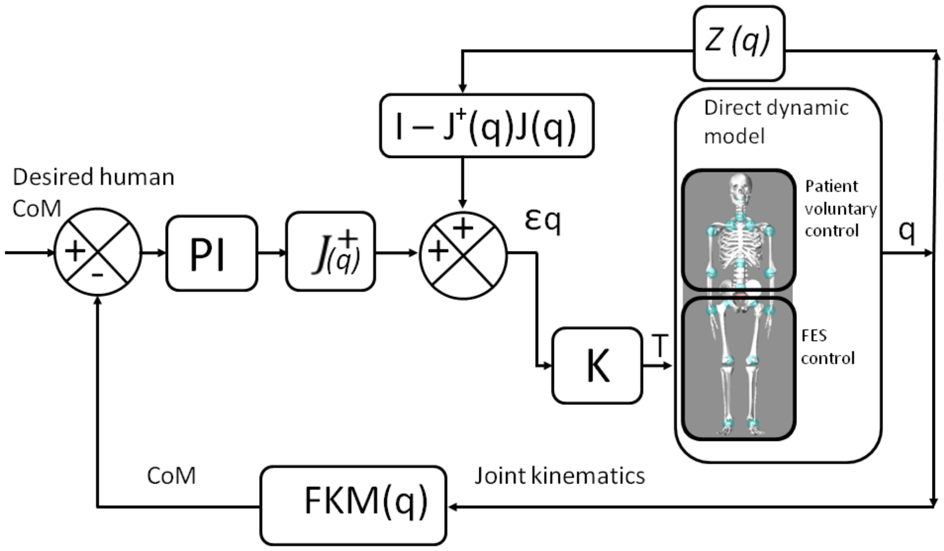
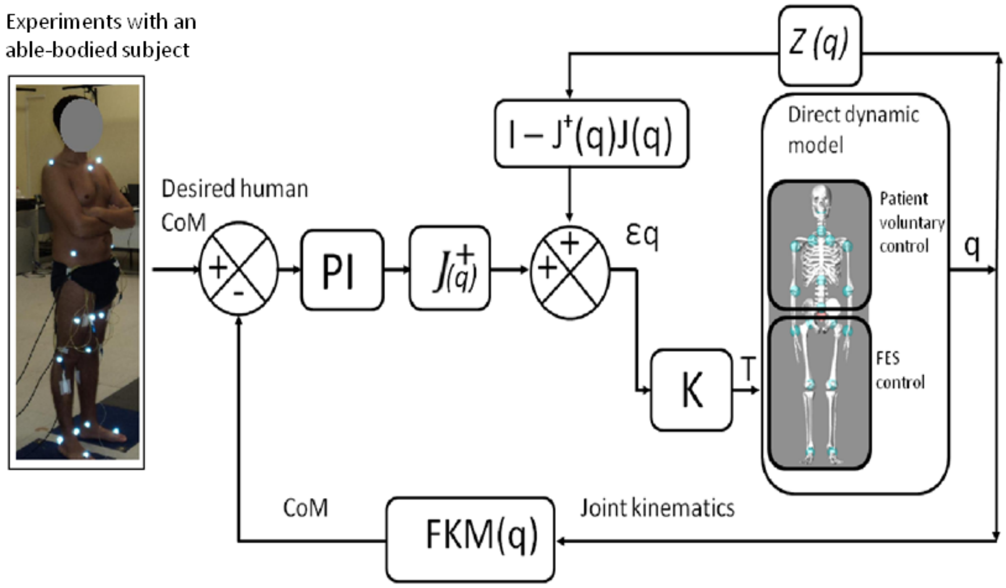
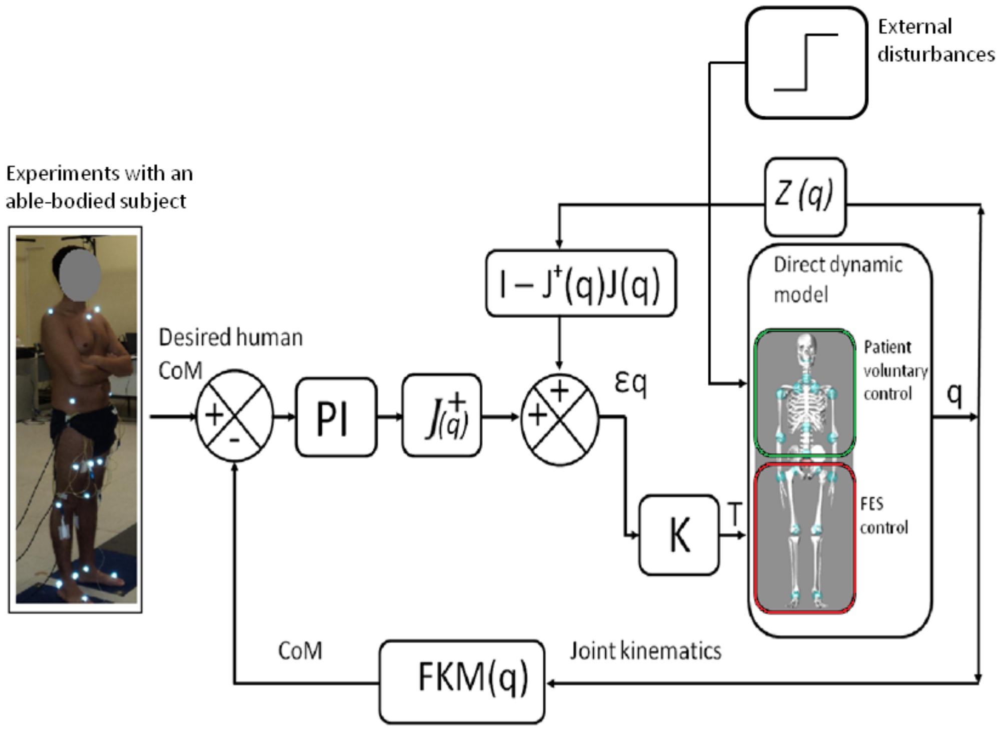


Figure 53: Block diagram of the proposed postural controller. The controller follows the desired 3D CoM positions and controls the lower limbs by applying torque at ankle, knee and hip joints (10 DoF).

In order to validate our approach and test the robustness of our controller, two scenarios were evaluated. In the first case, the controller tracked the human CoM estimated from the experimental data collected from two able-bodied subjects, and the joint patterns produced by our closed-loop controller and the ones obtained during the above-described experiment were compared (see Figure 54a). Second, while tracking the human CoM, external disturbances were applied on the upper part of the body to simulate subject's voluntary motion while our controller was controlling the lower limbs (see Figure 54b). To do so, step functions were applied on the joints at the T level of the spinal cord to create a disturbance similar to bending first in the antero-posterior and then in the medio-lateral axis. Also, in order to simulate a grasping like motion, a step function was applied on the right shoulder joint in the AP direction (see Figure 55). The amplitude of the step applied on the thoracic joint in the AP direction was Astep=40° during Tstep=5 s and appeared at 100 s of the simulation while the amplitude of the step on the joint in the ML direction was Astep=10° during Tstep=10 s and appeared at 200 s of the simulation. Concerning the motion applied on the shoulder, the value in the AP direction changed at 400 s with Astep=90° during Tstep= 60 s. The initial values of all joints were 0°. A summary of the applied disturbances is given in Table 7. Note that



(a) Scenario 1.



(b) Scenario 2.

Figure 54: Block diagram of the two scenarios used to test the robustness of the proposed postural controller.

the shoulder and thoracic joints were used only in the computation of the total CoM location and were not directly controlled.

Anatomical Location	Joint at thoracal level	Joint at thoracal level	Right shoulder
Direction	AP	ML	AP
Initial joint value [°]	0	0	0
Amplitude [°]	40	10	90
Time occurrence [s]	100	200	400
Duration [s]	5	10	60

Table 7: Applied disturbances

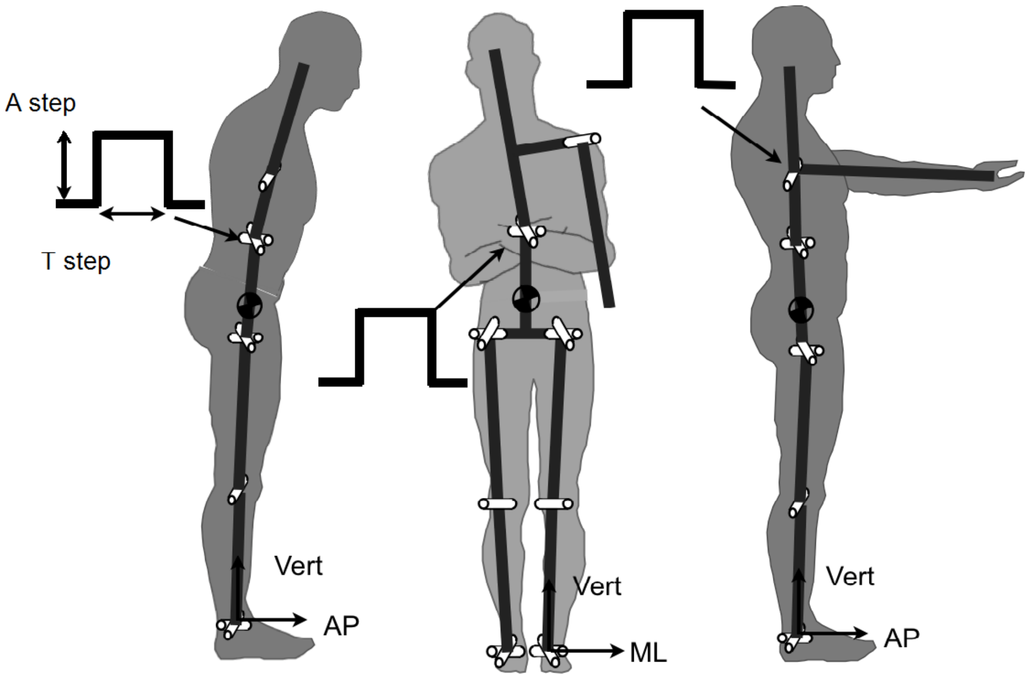


Figure 55: Applied disturbances used to simulate voluntary upper body motions.

4.7 HUMAN DATA COLLECTION

The aim of the experiment[1] was to provide a database of human CoM trajectories and joint coordinations that can be used to evaluate our approach. Two healthy young volunteers were included in the study. Their characteristics are given in Table 8. These participants were asked to keep their arms crossed on the chest, the trunk straight and the soles flat on the ground during the entire test. Starting from this position, they were then asked to stand as comfortably as possible while watching a documentary during ten minutes. No other constraints were specified to the participants in order to let

1 Acknowledgment to LABLAB, Department of Human Movement and Sports Sciences, University of Rome "Foro Italico", Italy. This work was in part supported by a French-Italian collaboration program PHC GALILEE 2011-2012 (number: 26078TE).

Subject	Age [years]	Height [m]	Weight [kg]	Gender
1	29	1.75	72	male
2	24	1.63	50	female

Table 8: Subjects' characteristics

them freely choice in their postural strategy. Kinematic variables were measured using a stereophotogrammetric system (9 Mx cameras, VICON). In order to accurately estimate small postural modifications, 20 reflective markers were located on both legs on the heels, the second metatarsal heads, the lateral and medial malleolus and epicondyles, the anterior and posterior superior iliac spines, and both acromia. The experimental setup and one subject during the experiment are presented in Figure 56.

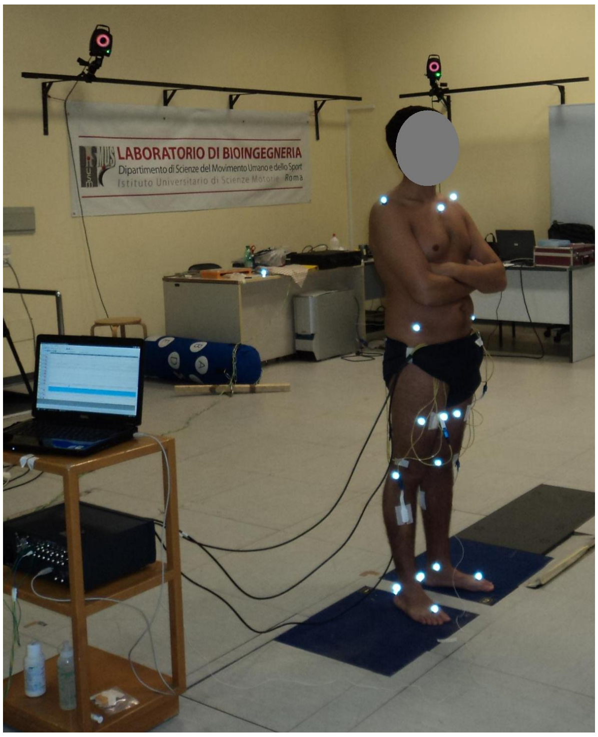


Figure 56: Able-bodied subject during the experiment.

4.8 DATA PROCESSING

The recorded reflective marker trajectories were used to estimate the position of the center of rotation of each joint and to drive the motion of the mechanical model shown in Figure 51. The joint kinematic estimation was performed using LifeMOD software.

The lengths of the body segments were measured on the subject and applied to the human model. The masses, center of masses and inertia of the bodies were computed using the anthropomorphic Winter table [143]. LifeMOD software was used to estimate the total 3D CoM trajectories corresponding to the above-described mechanical model. CoM trajectories were expressed in the global reference frame located at the center of rotation of the left ankle through rigid transformations using the SESC method. The RMS error between the CoM position estimated from the experimental data and its tracking by our closed-loop controller was calculated.

4.9 RESULTS AND DISCUSSION

A graphical illustration of the results is given in Figure 57. The results (Figure 58) show the good tracking of CoM obtained from the stereophotogrammetric system with the proposed closed-loop approach. One can see that, despite the large and abrupt motions of the CoM when the subjects were changing the support leg, the proposed postural controller was able to follow the 3D CoM trajectories.

Figure 59 illustrates the ability of our closed-loop controller to maintain balance and follow the desired CoM position even when external disturbances were applied, as described in Section 4.6. It can be seen that, after a short transitory phase (around 10 s), the controller was able to continue CoM tracking.

A set of joint patterns obtained during the control simulations was compared with the ones estimated from the experimental data for both subjects for the right leg in Figure 60 and for the left leg in Figure 61. One can see that similar general patterns are reproduced by our approach. However, differences concerning the amplitudes can be observed. These discrepancies may have been induced by the approximate nature of the model and especially by its rigid structure. Also, the natural standing and rest positions in human do not correspond to zero angles, as they do in the model due to LifeMOD software limitations. This would explain the offset difference observed on some joint angles. In the model used in this study, the upper part with respect to the lower part of the body did not move during the simulation, which was not the case during the experiments with human subjects. Also, using a pseudo-inverse Jacobian matrix system is redundant therefore, having different initial conditions would result in having different sets of possible solutions.

The RMS error between the CoM position estimated from the experimental data and its tracking by our closed-loop controller for both subjects are presented in Table 9.

RMS [m]		CoM AP	CoM Vertical	CoM ML
No disturbances	Subject 1	0.0071	0.0027	0.0037
No disturbances	Subject 2	0.003	0.0009	0.003
With disturbances	Subject 1	0.0293	0.0115	0.0162
With disturbances	Subject 2	0.0066	0.0064	0.0353

Table 9: RMS error between the desired CoM positions and the ones obtained with the proposed closed-loop controller.

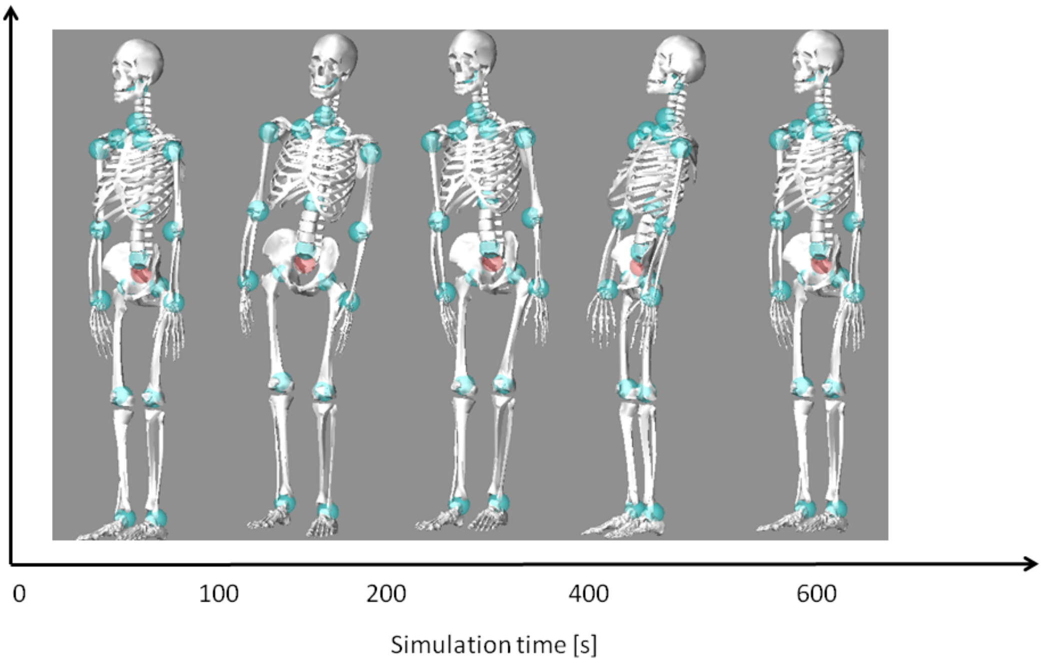
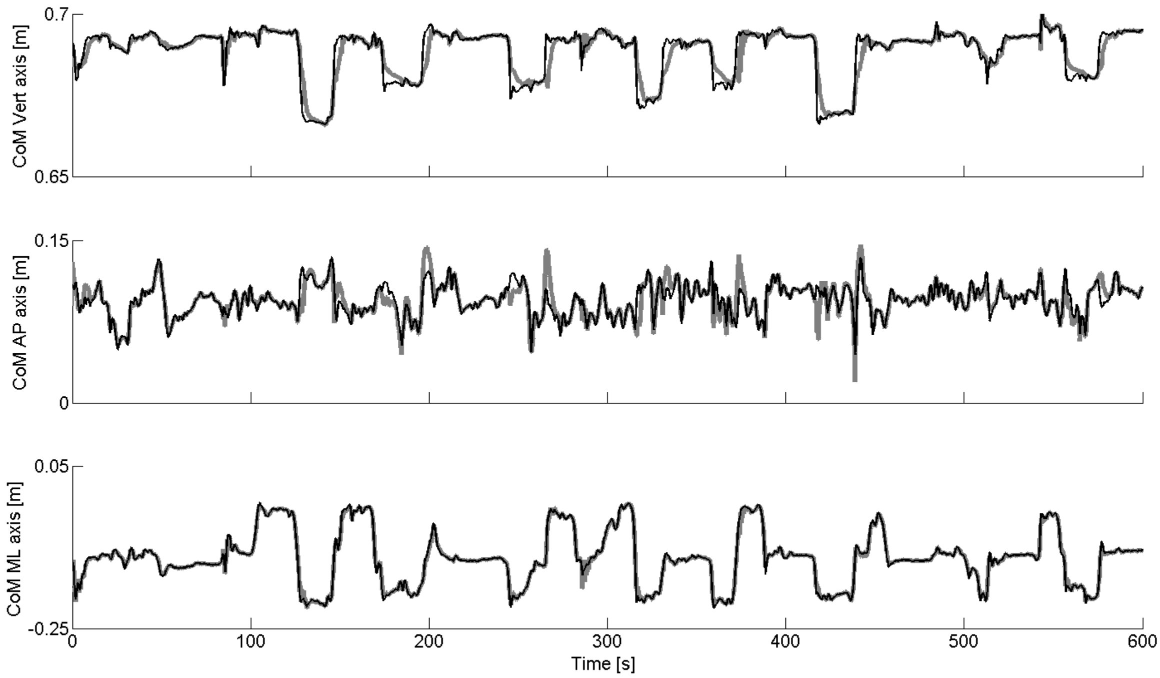


Figure 57: Graphical illustration of the results.

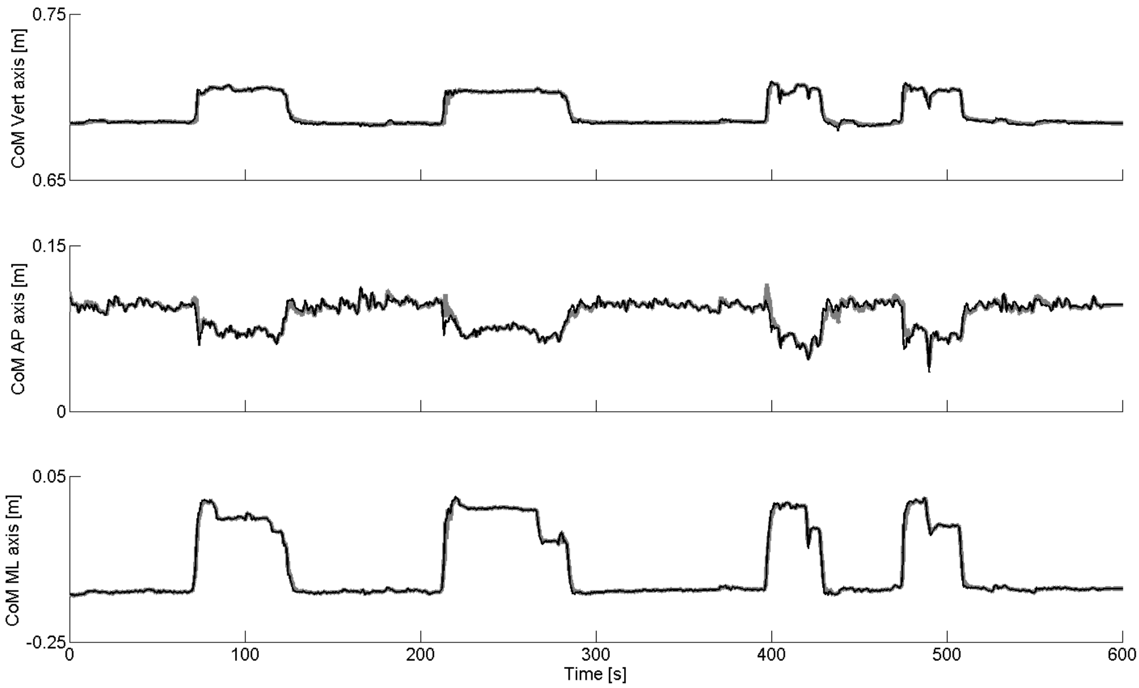
4.10 CONCLUSION

The primary contributions of this work are the following.

In this chapter we propose a new paradigm for controlling prolonged standing in paraplegic subjects, which was inspired by humanoid robot control. In order to maintain balance in an arm-free standing system, the voluntary control of the upper part of the body needs to be integrated with artificial control of the lower limbs. Therefore, contrary to the work presented in the literature, we propose an approach that directly controls the balance of the postural system and takes the voluntary motions of a subject into account by controlling CoM positions during the task. The controller should be able to keep the projection of the CoM in the base of support even during the patient's voluntary movements, which could result in arm-free standing. Its performances was evaluated using a computer model that simulates the skeletal dynamics of a human

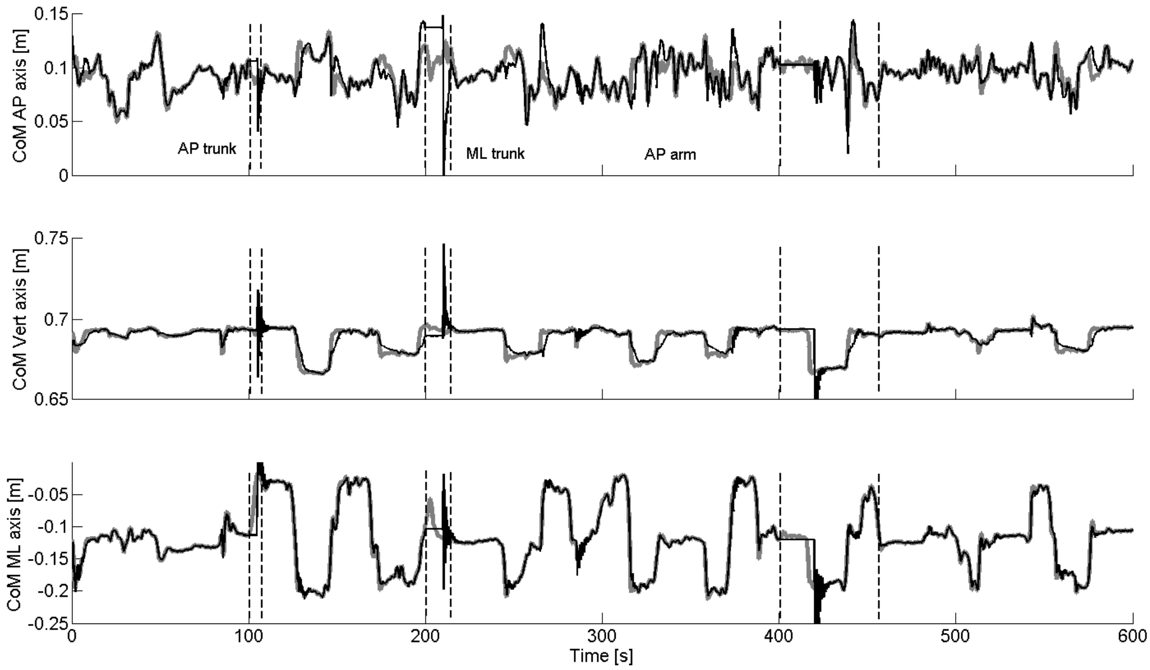


(a) Subject 1.

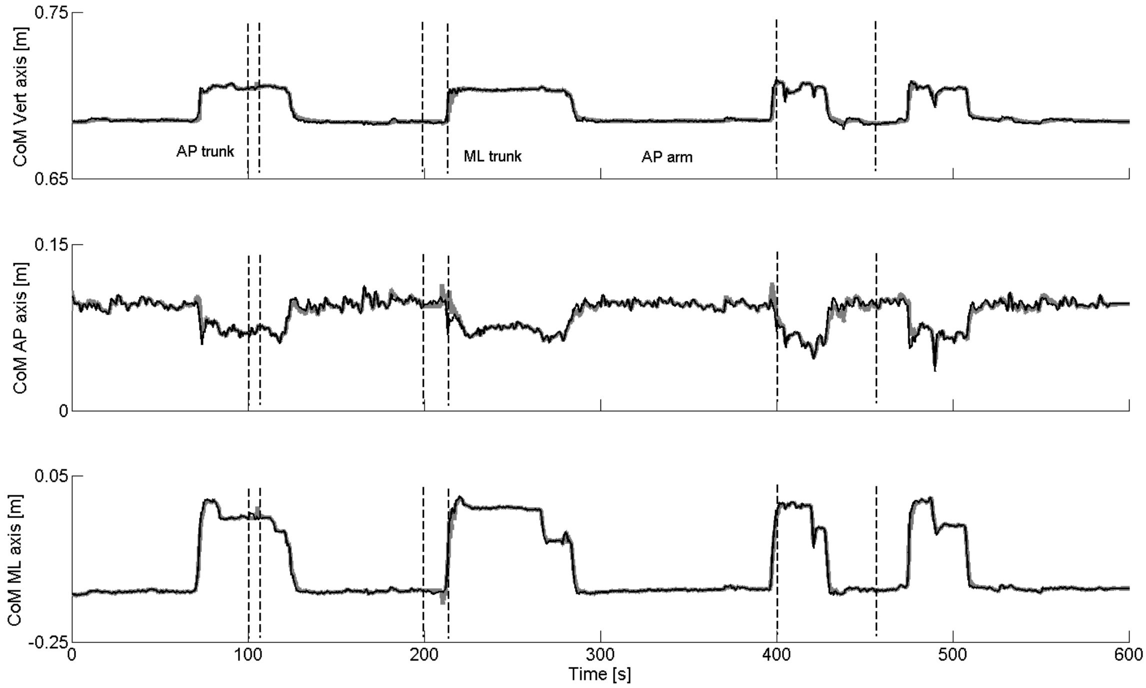


(b) Subject 2.

Figure 58: Tracking of human CoM by the proposed closed-loop controller for both subjects. The CoM trajectories obtained from the stereophotogrammetric system are indicated by gray lines and model output is indicated by black lines.

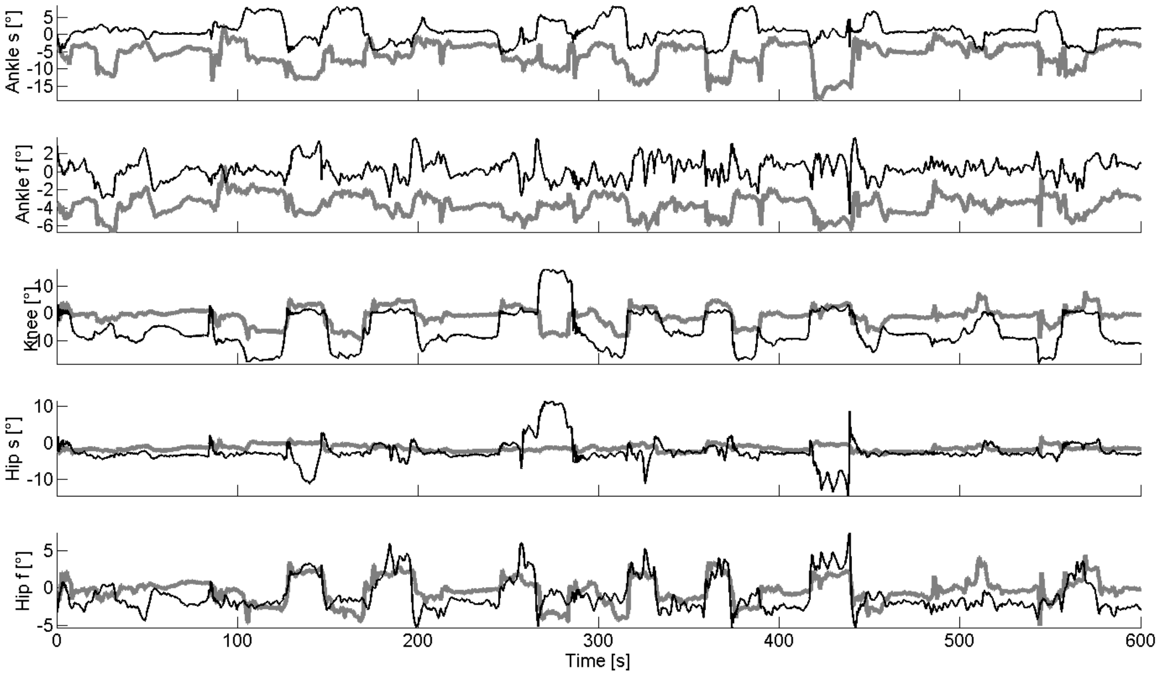


(a) Subject 1.

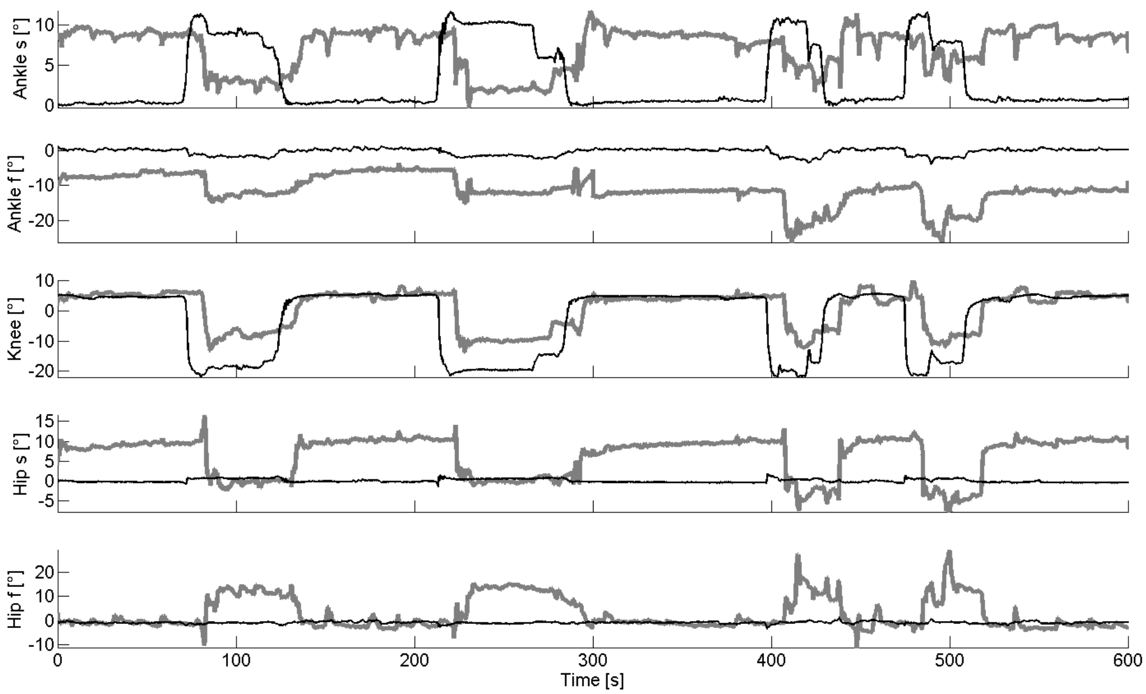


(b) Subject 2.

Figure 59: Tracking of human CoM by the proposed closed-loop controller under perturbations indicated by dashed lines for both subjects. The CoM trajectories obtained from the stereophotogrammetric system are indicated by gray lines and model output is indicated by black lines.

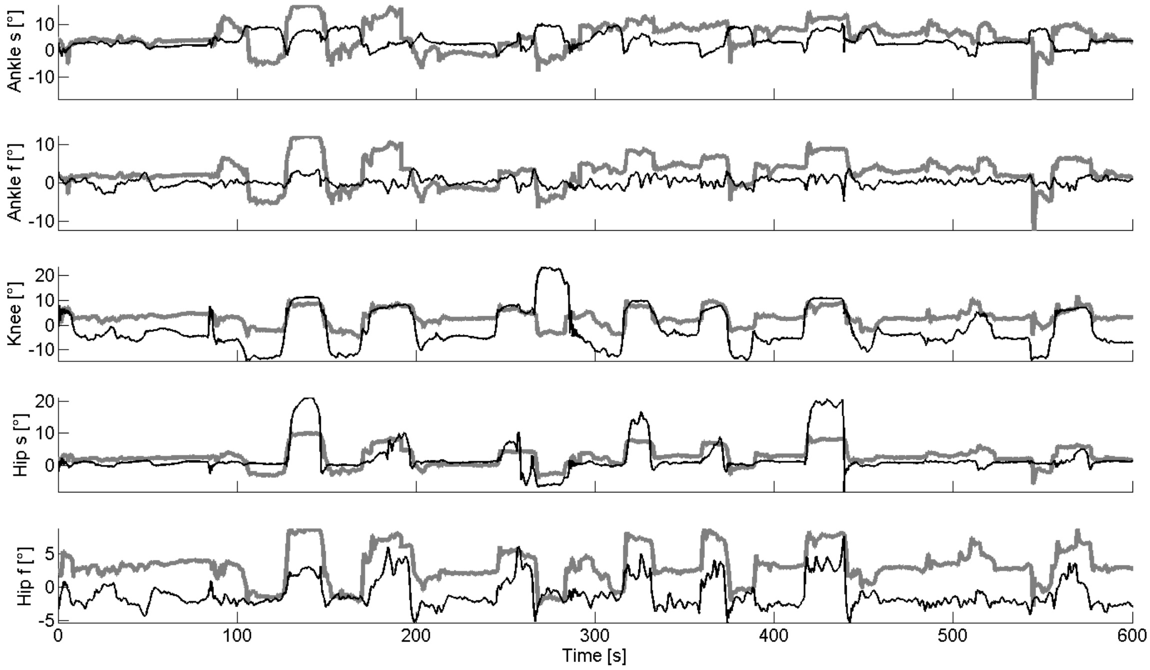


(a) Subject 1.

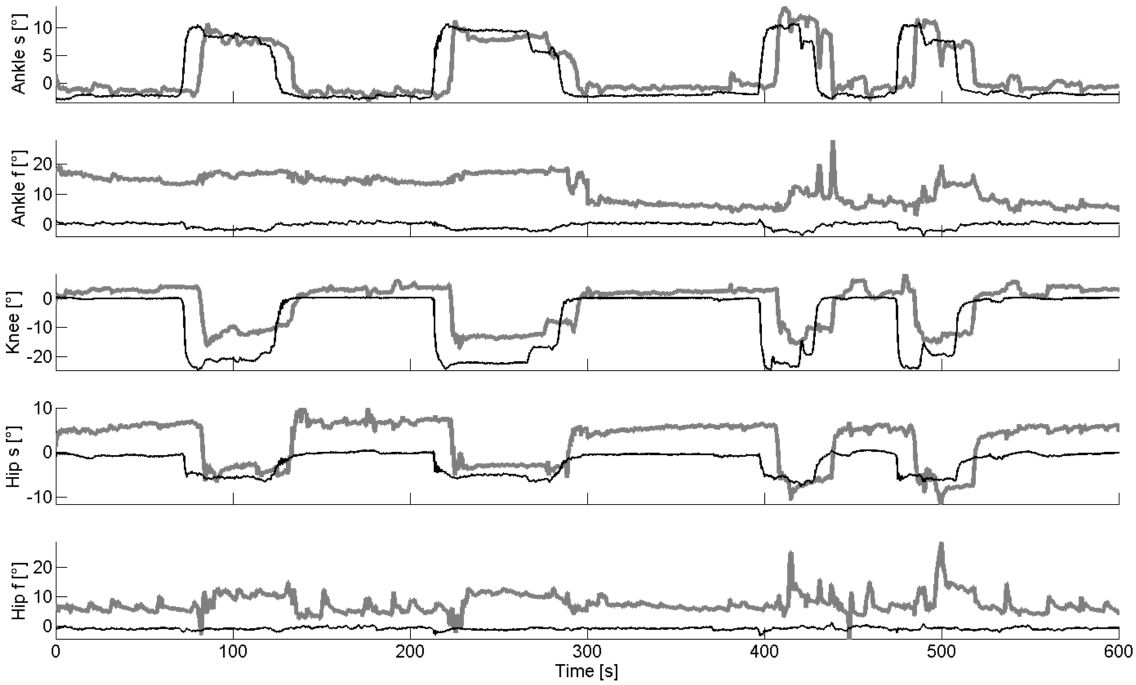


(b) Subject 2.

Figure 60: Joint patterns produced by our closed-loop approach (black lines) and the ones measured in right human leg (gray lines) for both subjects. The joint trajectories measured using stereophotogrammetric system are indicated by gray lines and model output is indicated by black lines.



(a) Subject 1.



(b) Subject 2.

Figure 61: Joint patterns produced by our closed-loop approach (black lines) and the ones measured in left human leg (gray lines) for both subjects. The joint trajectories measured using stereophotogrammetric system are indicated by gray lines and model output is indicated by black lines.

body. The controller appeared to be able to track human CoM recorded during ten minutes of quiet standing with good precision. The robustness of our controller was tested by applying external disturbances on the upper part of the body, simulating patient voluntary movements, while the controller was controlling the lower limbs. The controller proved able to recover from the disturbances and continue the CoM tracking after a short transitory period. The set of joint patterns obtained during the control simulations was compared with the ones estimated from the experimental data.

The novelty in the research on CoM control and estimation leads us to believe that recent inexpensive tools such as Kinect cameras could be successfully used to track CoM in real time and provide input of our algorithm. The Kinect system is portable and easy to transport and, accordingly, has a many advantages for rehabilitation purposes [27]. In addition to Kinect, other motion capture sensors, such as inertial measurement units or goniometers, could be used to measure joint angles and provide input to the algorithm. This remains an open question and an objective.

The final goal of this study is to control standing posture in paraplegic subjects by means of FES. Therefore, in order to calculate the needed FES parameters, our model should be extended by adding muscle properties and controlling muscle activation instead of joint torques.

Some ideas and figures from this chapter have appeared in the following publication:

J. Jovic, V. Bonnet, C. Azevedo Coste and P. Fraisse. *A Paradigm for the Control of Upright Standing in Paraplegic Patients.* EMBC'2012 : 34th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, USA, 2012.

5 DISCUSSION AND CONCLUSION

In recent decades, a considerable amount of research has been focused on the field of rehabilitation engineering for people with SCI. Several control strategies to regain functional standing and facilitate transfer movements have been proposed for people confined to wheelchairs. However, the developments to date remain inapplicable in the daily lives of paraplegic individuals outside the hospital.

The main goal of this thesis was to investigate FES-based methods for restoring posture and transfer movement in SCI persons. We aimed at proposing a solution which would represent a good trade-off between the functionality of these methods and the simplicity of the equipment and algorithms, in the hope that a simple and easy to wear and take off design would meet with better acceptance from users. The research was guided by three main questions:

- What would be the best way to perform FES-assisted STS movement in SCI patients that would minimize upper-limb effort and muscle fatigue? And once the answer was found, another question arose: would it be possible to design a practical system that would encourage this type of movement in paraplegic patients?
- Would FES of the knee extensors reduce arm efforts during the sitting pivot transfer motion from one surface to another in the SCI population?
- And finally, would it be possible to develop an FES controller that would enable prolonged standing in individuals with SCI while taking into account the voluntary motions of the intact parts of the body?

This chapter provides the summarized answers to these questions, which are also the main contributions of this thesis, and perspectives for future investigations.

FES-ASSISTED SIT-TO-STAND MOTION Standing up is a common daily activity and a prerequisite to standing or walking. By optimizing STS movement in the SCI population, artificial control of the subsequent motions can be improved. In the chapter titled "FES-assisted sit-to-stand motion" we present a dynamic optimization process and show that one of the optimal ways for the paraplegic population to perform the rising motion is similar to that of able-bodied people, i.e., prior to standing up, the patients should push and pull their trunks forward. The calculated motion should reduce upper-limb participation and lower-limb joint torques.

In the same chapter, we experimentally validate a new FES approach for controlling rising motion in SCI patients by performing an experiment with six paraplegic subjects.

As part of the strategy of the system, the patients were instructed to perform a rising motion in a manner previously calculated as optimal. The sensor used in the system was a single accelerometer, which makes the system practical for everyday use. We experimentally show that the system is able to recognize STS motion and automatically trigger the electrical stimulator at the desired time instant, which influences the applied hand forces during the STS movement.

We believe that the proposed FES system has a potential for clinical and everyday use in the lives of SCI people. However, some technical improvements are called for, including more robust sensor positioning and improvements related to overcoming certain issues with wireless sensor communication. As the final validation of the system, we propose a study with one or more paraplegic patients for a prolonged period of time in order to investigate patient adaptation to the system and to obtain user feedback, which we believe should be the principal measure of system quality.

FES-ASSISTED SITTING PIVOT TRANSFER MOTION In the chapter titled "FES-assisted sitting pivot transfer motion" we investigate the use of FES during SPT motion in paraplegic patients. The biomechanics of SPT motion are well documented; however, the use of FES has not been investigated thus far. Experiments with patients are time-consuming and rather complicated; hence, we propose an optimization process together with a biomechanical model of the human body to study the influence of FES on SPT performances. After validating our method by performing experiments with an able-bodied subject, the influence of FES of the knee extensors on upper-limb effort is studied. Through computer simulations, we show not only that FES can decrease arm participation during the motion, but also that there is a good compromise between the applied stimulation amplitude and the consequently induced muscular fatigue and minimized arm efforts.

The biomechanical model nevertheless does not include muscle properties. Therefore, the model should include muscle modeling in order to find an optimal FES pattern to produce the desired SPT movement. We believe that the algorithm developed for FES triggering in STS motion, which was presented in Chapter 2, would facilitate SPT movement. By using the results of this study to reduce the FES amplitude value, incomplete paraplegic patients could also potentially use this system. Further experiments with SCI persons should be performed in order to validate this hypothesis.

FES-ASSISTED UNSUPPORTED PROLONGED STANDING Finally, in the chapter titled "FES-assisted unsupported standing" we propose a new paradigm for controlling prolonged standing in paraplegic subjects. Even though there are many control systems proposed in the literature, the ones used in clinical practice are simple and mainly based on open-loop systems that do not take into account the voluntary motions of the patients.

We believe that the integration of artificial control systems and natural ones under control of the CNS would be an effective solution. Hence, we propose an approach that takes the voluntary movements of the patient into account and controls balance during a standing task by controlling CoM positions. Patients should thus be able to perform daily activities using the intact upper part of the body while standing. The controller proved to be able to track for ten minutes the CoM recorded during the experiments with able-bodied subjects. By tracking the CoM of an able-bodied person, the controller could mimic the human CNS control system, which alternately activates different muscle groups of the lower limbs during this postural task. By using this strategy, the muscle fatigue induced by FES would be reduced and prolonged standing in people with SCI could be enabled.

The model should be improved by including muscle properties and calculating the FES parameters needed to produce the desired movements. Finally, experiments with paraplegic patients should be performed in order to validate this approach. Kinect cameras could be used to track the CoM in real time and provide input about our algorithm.

In this thesis, we have touched on the complexity of finding effective assistive devices for transfer and standing for people who have lost the ability to perform these tasks voluntarily. The biomechanics of human motion are quite complex and the outcome of the pathology we are dealing with is severe. Furthermore, the paraplegic population is quite diverse concerning the lesion level and the muscle conditions, and assistive devices should be adapted to each patient individually. All of the aforementioned factors make this type of study very challenging. In this thesis, some of the aspects of the problem related to motion restoration have been investigated. The authors find that the results reported in this thesis are promising and believe that scientific research should proceed in this direction. We also hope to continue the collaboration with medical staff, as we strongly believe that effective solutions will be found through the collaborative work of engineers, clinicians and patients.

Part I

APPENDIX

A

APPENDIX A

Ethical agreement

Titre du projet

Optimisation du transfert assis-debout sous électromyostimulation fonctionnelle du patient paraplégique : Etude préliminaire

N°ID RCB:

Promoteur

Centre Mutualiste Neurologique Propara, Montpellier 34090

Directeur

Mr. Jérôme Combescure

Investigateur Coordinateur

Dr. Fattal Charles

Adressez toute correspondance à :

Charles Fattal, Médecin chef, Centre Mutualiste Neurologique Propara, 263, rue du Caducée - Parc Euromédecine - 34195 Montpellier Cedex 5

TABLE DES MATIERES

Titre du protocole :

Optimisation du transfert assis-debout sous électromyostimulation fonctionnelle du patient paraplégique : Etude préliminaire .

A- IDENTITE DU PROMOTEUR

Centre Mutualiste Neurologique Propara, Directeur Mr. Jérôme Combescure

B-EQUIPE COORDONNATRICE

Nom du Responsable et investigateur coordinateur: Dr. Charles Fattal (Médecin Chef d'établissement)

Nom du Chef de Service: Dr. Charles Fattal

Personnes associées : Mr Patrick Benoit, Kinésithérapeute,
Mr Farid Khial, Attaché de Recherche Clinique

Etablissement : Centre Mutualiste Neurologique Propara

C-EQUIPES COLLABORATRICES

EQUIPE COLLABORATRICE

Nom du Responsable de l'équipe : Mr. David Guiraud, Chargé de recherche INRIA

Personnes associées : Philippe Fraisse, Professeur d'Université,
Christine Azevedo, Chargée de recherche INRIA,
Jovana Jovic, étudiante en thèse

Equipe : DEMAR (DEambulation et Mouvement ARtificiel)

Etablissement : LIRMM / INRIA 161 Rue Ada, 34392 Montpellier Cedex 5

E-LIEUX DE RECHERCHE

L'étude sera réalisée au Centre Mutualiste Neurologique Propara (34090 Montpellier).

D-CARACTERISTIQUE DE L'ETUDE

Durée de l'étude : 18 mois

Nombre de sujets prévus : 10

Type d'étude : Etude prospective dite de faisabilité

1. PROTOCOLE

Résumé

Justification : La stimulation électrique fonctionnelle (SEF) a montré sa capacité à activer les muscles des membres paralysés, chez les blessés médullaires, pour assurer un transfert assis-debout puis une station debout. Néanmoins, ces mouvements restent coûteux d'un point de vue énergétique et de faible portée fonctionnelle. Particulièrement, la phase de transfert demande une participation très importante des membres supérieurs, notamment des épaules et délétère à long terme. De plus, la phase de transfert met en jeu des niveaux de stimulation électrique importants qui fatiguent prématurément les muscles. La survenue d'une fatigue musculaire précoce limite le maintien de la posture érigée.

Objectif : une meilleure coordination du déclenchement de la stimulation électrique des membres inférieurs avec un mouvement du haut du corps devrait permettre d'optimiser la phase de transfert et de diminuer les efforts au niveau des membres supérieurs et de réduire l'intensité des stimulations électriques musculaires appliquées. Nous souhaitons ici explorer la possibilité de déclencher la stimulation électrique des membres inférieurs à partir de l'observation de l'accélération du haut du corps. Nous étudierons également l'impact d'une meilleure coordination sur les efforts mis en jeu au niveau des membres supérieurs.

Sujets et méthodes : les sujets sont des blessés médullaires complets sensitifs et moteurs (ASIA A) dont les muscles sous lésionnels restent stimulables. Le protocole expérimental consiste dans un premier temps à évaluer la capacité des muscles devant être stimulés à fournir des niveaux de contraction suffisants pour une verticalisation. Dans un deuxième temps le protocole prévoit plusieurs séances d'entraînement au transfert d'une position assise à une position debout de façon à préparer les sujets à se lever sous stimulation électrique et à utiliser le haut de leur corps. Enfin deux séances permettront de réaliser les essais relatifs au déclenchement de la stimulation à partir de l'observation des mouvements du tronc. Quelques essais préliminaires permettront de construire un patron d'accélération de référence du tronc.

Le **critère de jugement principal** est l'écart entre l'instant de déclenchement effectif (TES) de la stimulation électrique relativement à la courbe d'accélération réelle du tronc et l'instant de déclenchement de stimulation défini (TDS) sur la courbe d'accélération de référence du tronc.

Le **critère de jugement secondaire** est la différence entre les forces de réaction au niveau des mains en appui sur des barres pendant la phase de lever mesurées à différents instants

de déclenchement de la stimulation (valeurs moyennes, valeurs maximales, RMS).

Résultats attendus: les enjeux clinique et scientifique sont importants puisque les résultats attendus de l'étude sont : 1) la mise en place d'un système de déclenchement de la stimulation électrique pour le transfert d'une position assise à une position debout de façon précise et répétable mettant en œuvre une coordination du haut et du bas du corps, 2) la possibilité de réduire la fatigue liée au transfert et permettre à terme de prolonger la durée de la station debout, 3) la préservation des épaules pendant le transfert.

1.2 Objectifs de l'étude

1.2.1 Objectif principal :

L'objectif principal est le déclenchement automatique de la stimulation électrique de membres inférieurs d'un sujet paraplégique à partir de l'observation des mouvements volontaires du haut du corps pour un transfert de la position assise à la position debout.

1.2.2 Objectifs secondaires :

Les objectifs secondaires sont :

- de réduire l'appui des membres supérieurs sur les barres parallèles pendant le transfert
- de diminuer les niveaux de stimulation électrique nécessaires pour réaliser le lever
- de prolonger la durée de la station debout après réalisation du transfert

1.3 Etat actuel des connaissances

Les bénéfices d'une verticalisation chez le sujet lésé médullaire sont à la fois psychologiques et physiologiques. La décharge des points d'appuis permet de réduire les risques d'escarres, la station debout semble diminuer les troubles du tonus musculaire et a un impact parfois positif sur le plan cardiovasculaire (Figoni, 1984). En réalité, les effets positifs s'expriment surtout au travers de bénéfices ressentis (Eng *et al.*, 2001), les patients rapportent entre autres une réduction du nombre d'infections urinaires, un meilleur transit intestinal, une amélioration de la spasticité. Ce sont surtout des paraplégiques qui l'expriment dans une étude portant sur l’utilisation de fauteuils verticalisateurs (Dunn *et al.*, 1998). Il y a aussi une demande forte de verticalisation pour des raisons fonctionnelles émanant de patients désireux d’être à hauteur d’autres personnes et/ou d’atteindre des objets situés en hauteur. Les fauteuils verticalisateurs utilisés de nos jours peuvent difficilement être embarqués dans une voiture et sont rarement utilisés en dehors de leur domicile par les patients. La stimulation électrique fonctionnelle (SEF) consiste à appliquer un courant électrique au niveau des muscles afin de provoquer leur contraction. La SEF permet ainsi de verticaliser un sujet paraplégique par lésion médullaire complète (Kralj *et al.*, 1983; Cybulski *et al.*, 1984). Dans sa version implantée la SEF est une solution censée apporter flexibilité et simplicité d’utilisation aux patients. Néanmoins, pour des raisons diverses, elle ne permet pas aujourd’hui d’assurer un aplomb 1) fiable et sécurisé, 2) prolongé et 3) fonctionnel avec possibilité de libérer une main. En effet, les contractions musculaires provoquées par stimulation électrique sont rapidement soumises à une fatigue qui limite fortement la durée de la station debout. Pour supporter le poids du corps, les niveaux d’intensité de stimulation et de contractions musculaires sont très élevés, donc contraignants au niveau énergétique. Par ailleurs, la stimulation électrique active prioritairement les fibres musculaires les plus fatigables. À défaut de proposer une solution pour limiter la survenue de la fatigue certains auteurs proposent de la détecter et d’observer son évolution. Les efforts de support des membres supérieurs sont ainsi souvent utilisés pour évaluer la performance de la stimulation (Bajd *et al.*, 1984; Kamnik *et al.*, 1999; Bajd *et al.*, 1999). Le transfert assis-debout ("Sit to Stand", STS en anglais) est un pré requis à la station debout qui sollicite énormément les performances physiques (Kerr *et al.*, 1997). Dans le contexte de la SEF, la stimulation maximale des extenseurs de genoux généralement mise en oeuvre durant le processus de lever est très contraignante. Par ailleurs, les efforts mis en jeu au niveau des membres supérieurs sont trop importants chez des individus déjà "fragilisés" au niveau des épaules (pathologies de coiffe des rotateurs) du fait des efforts de propulsion et des transferts fauteuil. L’efficacité du STS chez les sujets valides repose sur deux stratégies : 1) la stratégie du transfert du moment qui consiste à utiliser le haut du corps pour générer un moment alors que le corps est toujours en support sur le siège et le sol et 2) la stratégie dite de stabilisation lorsque la force musculaire est limitée qui consiste à positionner le centre de masse dans une position favorable c’est à dire dans la base de support créée par les pieds juste avant le décollement de la chaise (Riley *et al.*, 1991; Lindemann *et al.*, 2003). Chez les sujets valides, le mouvement du tronc précède l'action des jambes : le lever est impossible sans l'utilisation des bras si l'inertie du tronc n'est pas exploitée et associée à une préparation posturale et une action adaptées au niveau des jambes (Héliot *et al.*, 2005; Ramdani *et al.*, 2007). Chez le sujet paraplégique sous stimulation électrique la coordination du tronc et des jambes n'existe plus (Roebroek *et al.*, 1994). Plusieurs études se sont intéressées au problème du contrôle de la coordination du tronc et des jambes pour réduire les efforts des membres supérieurs et améliorer l'équilibre (Donaldson *et al.*, 1996; Riener *et al.*, 2000; Riener *et al.*, 1998; Jaime *et al.*, 1996).Dans la plupart des cas, l'équipementmis en oeuvre dans un contexte de recherche ne peut pas être envisagé pour une utilisation quotidienne de la SEF. L'utilisation de capteurs embarqués sur le sujet permet d'avoir accès à des informations précises (Williamson *et al.*, 2000). Les efforts de support (Kamnik *et al.*, 2005) ont déjà montré leur pertinence dans un schéma de commande de la stimulation en boucle fermée. Nous proposons ici d'utiliser ce type de mesures (Azevedo *et al.*, 2007) pour coordonner le haut et le bas du corps et pour estimer l'évolution de la fatigue. L'objectif est que l'utilisateur puisse en quelque sorte téléopérer la stimulation de ses jambes en utilisant son tronc comme un "joystick" et puisse être informé pour modifier sa posture, voire s'asseoir, lorsque la fatigue intervient (Azevedo-Coste *et al.*, 2005; Azevedo *et al.*, 2005).

1.4 Résultats acquis sur le sujet

Dans un travail théorique et expérimental préalable, nous avons établi un modèle informatique de muscle strié squelettique capable de simuler son fonctionnement. Pour cela on doit estimer ou mesurer pour chaque muscle et chaque patient, des valeurs de constantes (paramètres du modèle) qui conditionnent la réponse du modèle. Ces constantes numériques sont : masse musculaire, viscosité, raideur, longueur de l'élément contractile et des tendons, et temps de réponse. Nous avons effectué des validations sur animal où nous avons montré que le modèle était capable de prédire précisément la réponse mécanique du muscle. Les mesures expérimentales, et les simulations numériques ont ainsi donné les mêmes résultats. Le modèle est, par ailleurs, capable de rendre compte des propriétés contractiles connues du muscle (relations force-longueur et force-vitesse de Hill notamment) (Makssoud H *et al*. 2004)**.** Ce modèle sera utilisé dans le cadre de l'étude pour répondre aux objectifs principal et secondaires.

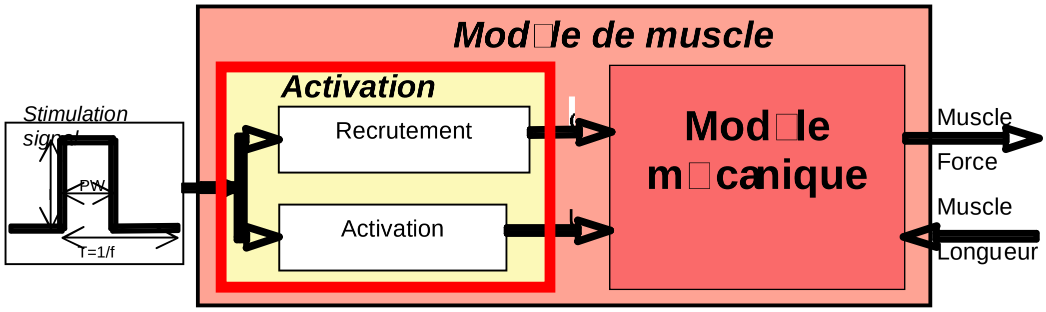


Figure 1 : structure du modèle. L'entrée est constituée des paramètres de la stimulation (intensité largeur d'impulsion et fréquence), le modèle calcule en sortie la force générée au cours du temps.

Nous avons par ailleurs une longue expérience de l'utilisation de la SEF. Ainsi, plusieurs études expérimentales utilisant soit la SEF externe ou la SEF implantée ont été menées chez l'homme (Guiraud D *et al* 2006) lors d'un autre protocole sur l'unique patient implanté en Europe. Le stimulateur externe Prostim que nous utilisons couramment a été conçu par notre laboratoire et industrialisé à travers un transfert technologique (Guiraud D *et al* 2000). Il est marqué CE et répond aux normes européennes médicales en vigueur.

1.5 Caractéristiques de la recherche

Il s'agit d'une étude prospective de type préliminaire.

1.6 Population

1.6.1 Faisabilité

Le Centre Neurologique Mutualiste Propara est spécialisé dans la prise en charge de lésions médullaires aiguës et chroniques.

1.6.2 Modalités d’inclusion

Les patients blessés médullaires seront recrutés au sein du Centre Neurologique Mutualiste Propara (Montpellier) par le médecin investigateur.

1.6.3 Critères d’inclusion

Chaque patient devra obligatoirement répondre à tous les critères suivants :

*Critères d'inclusion non spécifiques à l'étude :

❶recueil du consentement écrit éclairé signé.

❷sujet bénéficiant d’un système de sécurité sociale ou équivalent.

❸sujet n'étant pas en période d'exclusion par rapport à un autre protocole

*Critères d'inclusion spécifiques à l'étude:

❶18 ans ≤ âge ≤ 65 ans,

❷lésion traumatique complète : définie par un score A à l’aide de l’échelle AIS (Frankel modifié) ASIA A : déficit moteur et sensitif complet sous lésionnel

Il s’agit d’un standard de description de la lésion médullaire ayant l’objet d’un consensus international.

❸stabilité neurologique (absence de modification du testing musculaire) > 6 mois,

❹capacité à rester assis au minimum 2 heures en fauteuil roulant

❺liberté articulaire complète des hanches et des genoux

❻cartographie (mapping) électrique positif des muscles avec une cotation minimum de 4/5 MRC pour le quadriceps, les ischio-jambiers et les jambiers antérieurs (tibialis anterior)

❼seuil de stimulation et de diffusion des muscles étudiés inférieur à 150 mA d’intensité.

❽patient déjà verticalisé

1.6.4 Critères de non-inclusion

*Critères de non inclusion non spécifiques à l'étude:

❶participation à une étude thérapeutique dans le mois précédent l'inclusion

❷non affilié à un régime de sécurité social, ou non bénéficiaire d'un tel régime

❸refus de participer à l'étude

❹inaptitude à donner un consentement

*Critères de non-inclusion spécifiques à l'étude:

❶spasticité et contractures en flexion ou extension des membres inférieurs à caractère déstabilisant

❷limitations des mobilités articulaires passives des membres inférieurs douloureuses ou non (flexum de hanche, flexum de genou, équin des chevilles…)

❸pathologie cardio-vasculaire instable (coronaropathies, HTA majeure, insuffisance cardiaque etc.)

❹port d'un stimulateur cardiaque

❺escarre ou cicatrice d'escarre pelvien ou au niveau des membres inférieurs.

❻problèmes dermatologiques contre-indiquant l'application d'électrodes de surface

❼poids corporel >100kg

❽refus du patient de donner leur consentement écrit.

❾grossesse

❿pathologie orthopédique des hanches et genoux

❶❶ Epilepsie instable

1.6.5 Critères de sortie d'étude

❶patient perdu de vue

❷patient décédé

❸retrait du consentement éclairé et refus d'utilisation des données

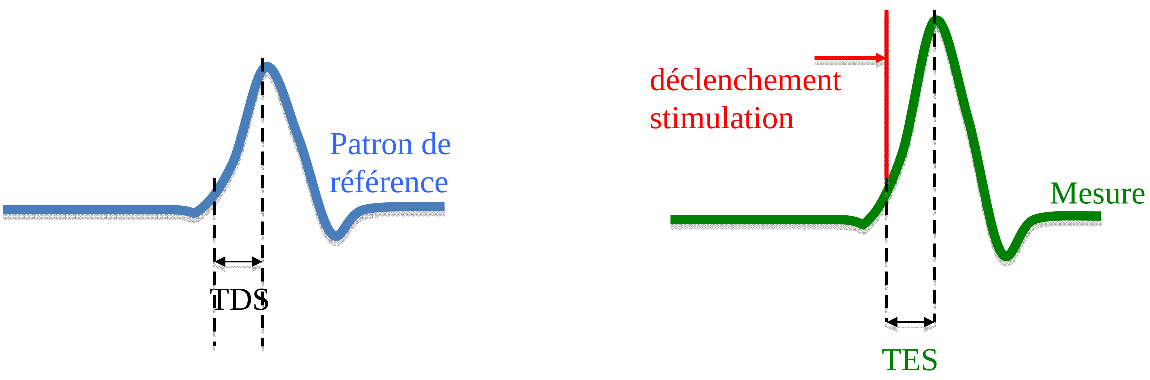
❹diagnostic en cours d'étude, d'un problème cutané ou infectieux

1.7 Méthodologie

1.7.1 Critères d'évaluation

- Critère de jugement principal

Il s'agit de l'écart (msec) entre l'instant de déclenchement effectif (TES) de la stimulation électrique relativement à la courbe d'accélération réelle du tronc et l'instant de déclenchement de stimulation défini (TDS) sur la courbe d'accélération de référence du tronc.



- Critères de jugement secondaires

- Mesure de forces de réaction issus des efforts d'appui des mains sur les barres mesurés pendant la phase de lever pour différents instants de déclenchement de la stimulation
- Mesure de forces de réaction issus des efforts d'appui des mains sur les barres pendant la station debout en fonction des instants de déclenchement de la stimulation
- Mesure de la durée de maintien de la station debout en fonction des instants de déclenchement de la stimulation

1.7.2 Facteurs de confusion potentiels

Variables définissant les facteurs de confusion

Les facteurs de confusion ont essentiellement deux origines :

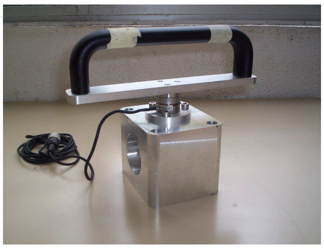
1. Une activité réflexe importante (spasticité et spasmes) perturbant le mouvement.
2. Une fatigue musculaire importante.

Afin de réduire l'impact de ces facteurs, les périodes d'expérimentation choisies seront la fin de matinée pour éviter la recrudescence matinale au réveil de la spasticité et la fatigue de fin de journée.

1.8 Outils utilisés

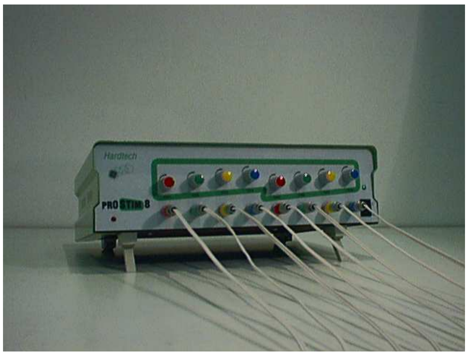
L'ensemble du matériel est couramment utilisé en milieu clinique et dans les centres de rééducation pour patients para et tétraplégiques. Il est non invasif. L'ensemble des matériels en contact électrique direct avec le patient est conforme aux normes médicales en vigueur.

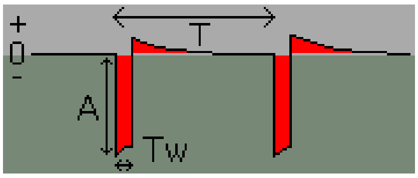
1.8.1 Barres parallèles et poignées de mesures en effort



Les barres parallèles sont couramment utilisées dans les centres de rééducation. Elles sont équipées de poignées fixes permettant la mesure des efforts exercés par le patient au niveau de ses mains. L'illustration montre le système avec les deux poignées et une personne valide simulant la posture.

1.8.2 Stimulateur électrique externe PROSTIM





Ce stimulateur est marqué CE et répond aux normes médicales (EN46000) en vigueur sur la sécurité d'utilisation. Il est relié au secteur au travers d'une alimentation intégrée aux normes médicales. Il est relié à un ordinateur non connecté au secteur au travers d'une liaison isolée optiquement. Les sorties de stimulation sont isolées au travers d'un transformateur d'impulsion. Il comporte 8 canaux contrôlés en fréquence (1/T), courant (A) et largeur d'impulsion (Tw). Les électrodes seront placées de telle sorte que 8 muscles (coté droit et gauche) parmi les suivants soient stimulés :

- Quadriceps Vaste externe
- Quadriceps Vaste interne
- Tibialis Anterior
- Biceps femoris

1.8.4 Mesures des données d'accélérométries

Cette mesure se fera à l'aide de capteurs magnéto accélérométriques pour la mesure de l'inclinaison du tronc (un seul capteur placé sur le tronc).

Nous utiliserons des modules de mesure génériques (ou nœuds capteurs) WSN430 (http://worldsens.citi.insa-lyon.fr/). Un module est intégré dans un boitier en plastique. Il ne représente aucun danger car il n'impose qu'une très faible contrainte mécanique (90 g soit moins de 1% du poids du membre inférieur) et aucun contact électrique. Un module est par ailleurs alimenté en basse tension (3,7 volts).

Un module est constitué de 2 cartes électroniques développées à l'INRIA assemblant plusieurs composants électroniques standards utilisés dans des dispositifs grand public ou médical :

- le micro-contrôleur de TI MSP430
- le composant radio TI Chipcon CC1100 qui émet sur la bande de fréquence 868 Mhz avec une portée de quelques mètres
- le capteur d'accélération 3 axes LIS3LV02DQ de ST Microelectronics
- le gyromètre 1 axe LY530AL de ST Microelectronics
- le gyromètre 2 axes IDG5000 d'Invense
- le magnètomètre 3 axes HMC5843 d'Honeywell

L'alimentation électrique est assurée par une pile commerciale 5 volts rechargeable. Il n'y aucun élément d'alimentation électrique qui tombe sous la directive Basse Tension 2006/95/CE.

Tout les détails de fabrication du noeud capteur sont ouverts (licence creative commons) et disponibles sur le site web : http://senstools.inria.fr

Le modules de mesure «accélérométrique» utilise les données d’un des accéléromètres uniquement et permet de mesurer l’accélération du tronc sur lequel il est placé. Les données sont envoyées en continu via une liaison radio à un ordinateur portable pour y être stockées et traitées en continu pour permettre de déclencher le stimulateur.

L’algorithme de détection est basé sur une analyse de corrélation entre 1) un patron accélérométrique de référence construit à partir de données recueillies lors de levers déclenchés par l’expérimentateur et 2) les données recueillies en temps réel. Lorsque le coefficient de corrélation dépasse le seuil fixé par l’expérimentateur, le stimulateur est déclenché automatiquement.

1.9 Analyse statistique

L’objectif principal de l’étude est de suggérer la pertinence d’un asservissement du déclenchement de la stimulation électrique des muscles sous-lésionnels du paraplégique aux données d’accélérométrie du tronc.

Dans le cadre d’une étude de faisabilité, aucun traitement statistique n’est prévu sur les données des 10 patients inclus.

1.10 Déroulement de l'étude

1.10.1 Lieu de réalisation de l’étude

Les patients blessés médullaires seront inclus au sein du Centre Mutualiste Neurologique Propara. L’ensemble des expérimentations se fera pour chaque centre dans une salle d’exploration dédiée à la recherche sous la responsabilité du médecin investigateur.

1.10.2 Modalités de recueil du consentement

Les patients seront informés des objectifs ainsi que des risques et des bénéfices liés à l’étude par le Dr C. Fattal. Une notice d’information reprenant les grands axes de l'étude (objectifs, personnes responsables, examens pratiqués, évènements indésirables, bénéfices attendus, …) sera également présentée. Une fois que les médecins auront répondu aux différentes questions, et qu'ils se seront assurés de la bonne compréhension de l'étude par le patient, un formulaire de consentement éclairé lui sera remis. Le patient aura la possibilité de le signer immédiatement ou de se réserver un délai de réflexion.

1.10.3 Contenu des visites "patient"

V0: Visite d'inclusion

Après recueil du consentement, un examen clinique sera pratiqué dans les deux centres par le Dr C. Fattal visant à évaluer des facteurs d’inclusion et d’exclusion. Il comprend

1. un examen clinique
2. un recueil des pathologies liées à la lésion neurologique.
3. Cartographie musculaire par SEF de surface :

Si le patient répond aux critères d’inclusion et ne présente pas de critères de non-inclusion, il bénéficiera d’une cartographie musculaire par SEF de surface. Cette technique consiste à déterminer les points moteurs et d’ajuster les niveaux de stimulation. Elle permet de déterminer les seuils de stimulation, les seuils de diffusion musculaire et la cotation musculaire maximale des muscles sélectionnés pour l'étude.

Cet examen sera réalisé par un kinésithérapeute ou une personne formée spécifiquement à cette technique. La durée estimée est de 1 heure.

Les muscles en question :

*** Quadriceps**

- vaste externe
- vaste interne

*** Ischio-jambiers :** - biceps femoris

*** Jambier antérieur** (tibialis anterior)

V1(V0+1J) ;V2(V0+2J);V3(V0+3J),V4(V0+4J),V5(V0+5J):Séances d'électrostimulation à visée d'entraînement musculaire en conditions fonctionnelles

En station assise entre les barres parallèles équipées de capteurs d'effort, les 8 muscles seront stimulés (PROSTIM) simultanément, à intensité de courant croissante jusqu'au seuil de diffusion aux muscles adjacents.

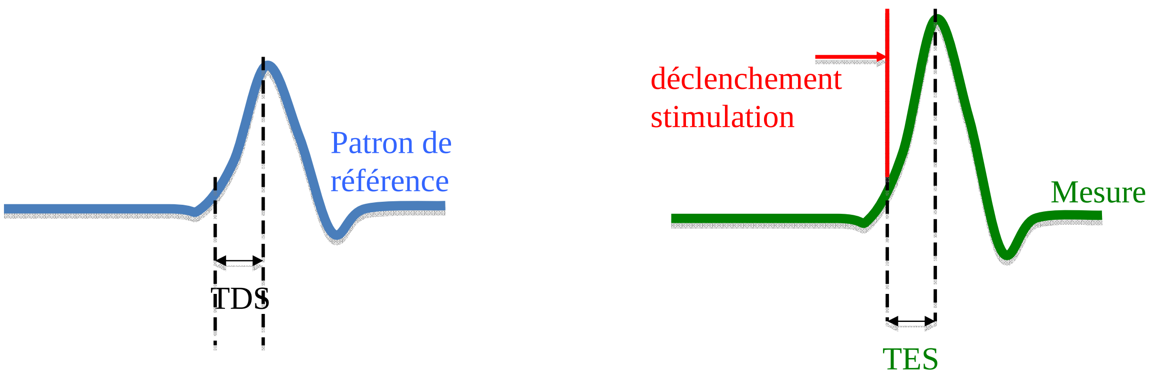
L'entraînement sera terminé (sans aller au delà de 5 sessions) lorsque le patient sera capable de réaliser un transfert assis-debout et maintenir la station debout 15 sec.

Les accélérations du tronc et les efforts d'appui sur les barres parallèles seront enregistrés.

Des vidéos montrant le mouvement du tronc adéquat seront projetées pour renvoyer au patient l'image de sa verticalisation.

V6 (V0+6J): Lever de chaise déclenché sur un mode manuel puis sur un mode automatique

La première étape consistera à enregistrer l'accélération du tronc lors d'un transfert déclenché manuellement. Cette courbe nous servira de patron de référence (cf ci dessous) .



On enchaînera plusieurs cycles de stimulation jusqu'à ce que la fatigue ne permette plus de réaliser des levers corrects :

<u>1er cycle</u>

Lever de chaise déclenché à TDS (temps défini de stimulation)= t0ms

Repos

Lever de chaise déclenché à TDS = t1ms

Repos

Lever de chaise déclenché à TDS = t2ms

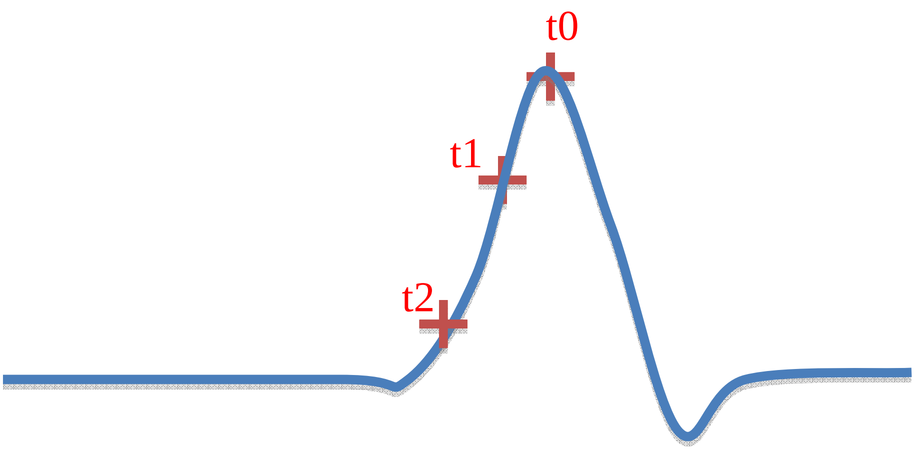
Repos

<u>2ème cycle</u>

Lever de chaise déclenché à TDS = t0ms

Repos

Etc..



t0 = t0 ms avant le pic d'accélération du tronc

t1 = t1 ms avant le pic d'accélération du tronc

t2 = t2 ms avant le pic d'accélération du tronc

les valeurs exactes seront ajustées aux patrons de références individuels.

On sauvegardera les données d'accélérométrie et les enregistrements des capteurs d'effort.
Un écran sera placé devant le patient de façon à ce qu'il voit son profil en station debout.

Le patient n'est pas informé du type de déclenchement (passage du mode manuel en mode automatique) afin de maintenir l'effort spontané dans le transfert assis-debout.

V7 (V0+7J): Lever de chaise déclenché sur un mode manuel puis sur un mode automatique

Idem V6.

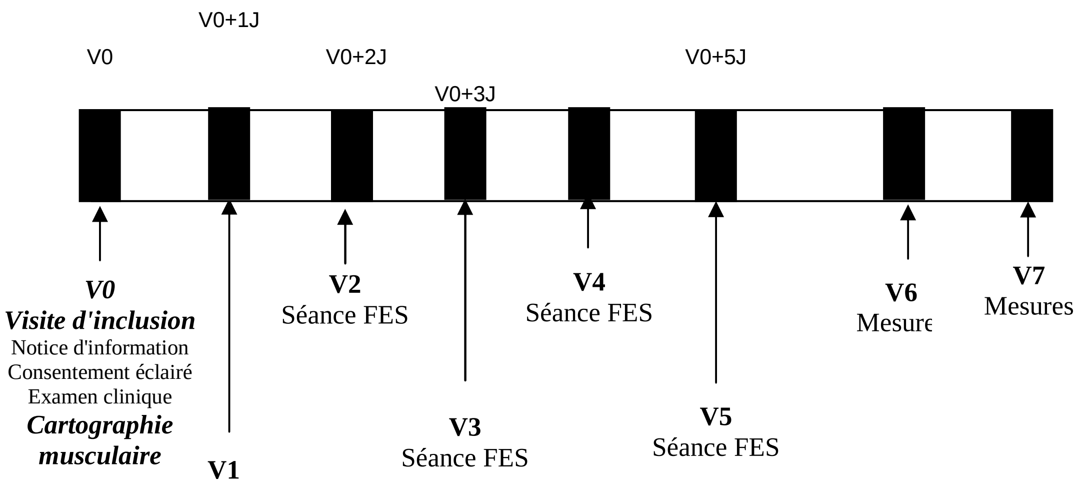
Tableau 1. Récapitulatif de l'expérimentation

	Visite d'inclusion (V0)	V1 à V5	V6	V7
Examen médical préalable	X			
Information	X			
Consentement	X			
Cartographie musculaire par SEF de surface	X			
Séances d'électrostimulation pour l'entraînement		X		
Mesures			X	X
CI/CE		x	x	x

1.11 Le calendrier de l’étude

La période d’inclusion débutera dès l’autorisation de début d’étude octroyé par la CNIL. En effet, un certain nombre de patients ont dors et déjà donnés leur accord de principe pour participer à cette recherche. La durée de l’étude (recrutement+expérimentation+traitement des données) est prévue sur 18 mois.

Schéma récapitulatif du protocole expérimental



2. EVENEMENT INDESIRABLE

2.1 Définition

L'article L 1123-8 du Code de la Santé Publique définit un événement indésirable grave comme tout événement qui :

a entraîné la mort,

a mis en jeu le pronostic vital, c'est à dire que le patient présente un risque de décès imminent lié à la survenue de l'événement. Cette définition n'inclut pas un événement qui, s'il était survenu dans une forme plus sévère, aurait alors entraîné le décès du patient.

a entraîné une hospitalisation ou une prolongation d'hospitalisation,

a causé l'apparition d'une invalidité ou d'une incapacité significative temporaire ou permanente

* Evènement indésirable (EI) lié à l'étude**:**

L'apparition d'un érythème sous les électrodes de surface sera contrôlée après chaque séance et aucune stimulation ne sera renouvelée en absence de disparition complète de la rougeur.

Le risque de fracture reste exceptionnel eu égard à l'absence de mise en contrainte des os de la cuisse et de la jambe mais doit être mentionné.

Le risque de chute est contrôlé par la présence de 3 personnes autour du patient (face au patient et sur les côtés) et par le maintien en place du fauteuil roulant à l'arrière.

2.2 Recueil des EI/EIG

Recueil des EI /des EIG**:**

Ces EI et EIG seront enregistrés dans le cahier d'observation prévu à cet effet et les EIG rapportés dans sans délais au promoteur de l'étude, à l'aide d'un formulaire prévu à cet effet. Le promoteur de l'étude se chargera de transmettre les informations au CPP.

3. CONSIDERATIONS ETHIQUES

-Les personnes recrutées pour cette étude ne pourront être incluses dans un autre protocole durant toute la durée de ce dernier.

-Aucune indemnisation ne sera versée aux participants qui se prêtent à cette recherche.

-Avant toute inclusion nous nous assurerons de l'absence de période d'exclusion pour un autre protocole, puis procèderons à l'inscription sur le fichier national des personnes qui se prêtent à des recherches biomédicales.

Cette étude sera réalisée dans le cadre de la loi Huriet du 20 décembre 1988 modifiée par la loi du 9 Août 2004. Elle ne pourra démarrer qu'après accord de la CNIL.

Le consentement signé des sujets sera recueilli après qu'ils aient été clairement informés de l'objectif et de l'intérêt potentiel de l'étude, de ses modalités et des risques prévisibles liés à cette recherche.
Les formulaires de consentement signés seront conservés par le promoteur et par chaque centre pendant 30 ans.
Les données individuelles seront strictement confidentielles. Elles ne pourront être consultées que par des personnes collaborant à cette recherche et soumises au Secret Professionnel. Ces données seront informatisées dans un fichier présentant des garanties de protection prévues par la loi et les sujets pourront accéder à tout moment aux données les concernant par l'intermédiaire du médecin responsable de l'étude. Une déclaration de la recherche sera effectuée auprès de la Commission Nationale Informatique et Libertés.
Enfin, les règles de Bonnes Pratiques Cliniques, telles que décrites dans la recommandation européenne « Good Clinical Practice, CPMP/ICH/135/95 » seront appliquées à cet essai.

Le promoteur a contracté une police d'assurance en responsabilité civile auprès de la Société Hospitalière d'assurances Mutuelles sous le n°106188 (en annexe).

4. RESULTATS ATTENDUS ET PERSPECTIVES

les enjeux clinique et scientifique sont importants puisque les résultats attendus de l'étude sont : i) la mise en place d'un système de déclenchement de la stimulation électrique pour le transfert d'une position assise à une position debout de façon précise et répétable mettant en œuvre une coordination du haut et du bas du corps, ii) la possibilité de réduire la fatigue liée au transfert et permettre à terme de prolonger la durée de la station debout, 3) la préservation des épaules pendant le transfert.

5. EVALUATION DE LA BALANCE BENEFICE/RISQUE

Le bénéfice escompté pour les personnes participant à cette recherche porte essentiellement sur la possibilité de réaliser un transfert assis-debout dans les meilleures conditions de maîtrise du coût énergétique et de protection des membres supérieurs.

L'idée sous-jacente à ce protocole est de faciliter la mobilité au fauteuil, de permettre des transferts en pivots après réalisation du transfert assis-debout et de participer ainsi à améliorer la qualité de vie de ces patients.

A l'opposé les risques liés à cette étude sont très limités et reposent uniquement sur la SEF. Dans les conditions d'utilisation recommandée, seules des rougeurs au niveau des électrodes, sans conséquence pour le patient peuvent être constatées.

6. REFERENCES BIBLIOGRAPHIQUES

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ANNEXES

ANNEXE I

Curriculums des investigateurs

NOM : Fattal

PRENOM : Charles

DATE DE NAISSANCE : 30 juillet 1963

FONCTIONS : Médecin Chef d'établissement

TITRES : Docteur en médecine et Docteur en Sciences

DATE D'OBTENTION DU DIPLOME : 1982

N° D'INSCRIPTION AU CNO : 34/11561

SPECIALITES ET QUALIFICATIONS :
Médecine Physique et Réadaptation

NOM DE L'ORGANISME :Centre Mutualiste Neurologique Propara

ADRESSE : Parc Euromédecine, 263 rue du Caducée, 34090 Montpellier

Téléphone : 04 67 04 67 04 Télécopie : 04 67 04 68 76

E-Mail : c.fattal@propara.languedoc-mutualite.fr

PRINCIPALES PUBLICATIONS :

1. Bone loss in spinal cord-injured patients: from physiopathology to therapy. Maïmoun L, **Fattal C**, Micallef J-P, Peruchon E, Rabischong P. Spinal Cord. 2005; 13:
2. Motor capacities of upper limbs in tetraplegics: A new scale for the assessment of the results of functional surgery on upper limbs. **Fattal C**. Spinal Cord, 2004 ; 42: 80 – 90
3. Assessment of the abilities of the tetraplegics after functional surgery of the upper limbs: Concepts, Methodology and Preliminary results. **Fattal C**, Micallef J-P, Chavet P, Enjalbert M. Archives of Physiology and Biochemistry. Volume 110 September 2002, supplement 1-132, 114.
4. Isolated musculo-cutaneous nerve palsy in a spinal cord injury: Case report. **Fattal C**, Weber J, Beuret-Blanquart F. Spinal Cord. 1998; 36: 591-592
5. Validation d'une grille de capacités motrices du tétraplégique opéré du ou des membres supérieurs. **Fattal C**, Thery JM, Micallef JP. Annales de Médecine Physique et de Réadaptation, 2004 ; 47 : 537-545

Date:
25/3/2008

Signature:

ANNEXE II

Renseignements attestant que les garanties prévues pour les personnes qui se prêtent à la recherche sont respectées

A- Personne responsable de l'étude et investigateurs

Notre équipe a une grande expérience dans les domaines de la rééducation fonctionnelle ainsi que dans l'utilisation de la SEF chez les patients blessés. Cette expérience a été rapporté dans de nombreuses publications [21-25,27].

B-Homologation des appareils

L'ensemble du matériel est couramment utilisé en milieu clinique et dans les centres de rééducation pour patients blessés médullaires. Le personnel qui l'utilise a été formé à son usage.

C-Informations transmises aux personnes qui se prêtent à cette étude.

Les sujets sollicités pour participer à l'étude seront informés par un entretien préalable avec l'investigateur-coordonnateur. Une note d'information jointe au formulaire de consentement leur sera remise.

D-Modalités de recueil du consentement

Après avoir été informé de l'étude et avoir lu la note d'information, les patients devront parapher chaque page du document d'information et signer le formulaire de consentement. Un délai de réflexion de 1heure sera laissé.

E- Attestation d'assurance

Un exemplaire du protocole a été adressé au cabinet d'assurance Société Hospitalière d'assurances Mutuelles sous le n° po ur confirmer que ce programme entre dans les clauses du contrat que le Centre Mutualiste Neurologique Propara a contracté par son intermédiaire et qu'il faut engager la procédure d'assurance de ce protocole selon les termes de la loi de Santé Publique. Une attestation de présomption d'assurance est jointe.

ANNEXE III

Demande d'autorisation CNIL

PROTOCOLE ENTRANT DANS LE CADRE DE LA CNIL

Oui ☒ **Non ☐**

1) Si vous avez coché la case Oui, préciser SI :

Des données collectées dans le cadre de votre étude, seront transmises ou reçues par l'Investigateur coordonnateur ?

Oui ☒ **Non ☐**

Si oui, avant de déclarer le protocole auprès de la CNIL, l'accord du Comité Consultatif sur le Traitement de l'Information en matière de Recherche dans le domaine de la Santé (CCTIRS) devra être obtenu.

2) Si vous avez coché la case Non, cela signifie que :

Votre projet de recherche ne comporte aucun traitement de données à caractère personnel de façon directe ou indirecte.

Définitions :

- **Données à caractère personnel :** toute information relative à une personne physique identifiée ou qui peut être identifiée, directement ou indirectement,

- **De façon directe :** Fichier nominatif,

- **De façon indirecte :** existence d'informations susceptibles de permettre l'identification des personnes physiques, soit par référence à d'autres fichiers ou listes nominatives (Ex: Numéro de sécurité sociale ou numéro d'ordre renvoyant à une liste nominative de référence même établie sur support papier), soit encore par recoupement d'informations surtout si l'échantillon de la population concernée est restreint (Ex : Date de naissance, commune de résidence, pathologie rare....).

ANNEXE IV

Note d’information & consentement

Note d'information

Madame, Monsieur,

Nous vous proposons de participer à une étude de recherche biomédicale intitulée «Optimisation du transfert assis-debout sous électromyostimulation fonctionnelle du patient paraplégique : Etude préliminaire» dont le Centre Mutualiste Neurologique Propara est le promoteur, et le Dr. Charles Fattal est l'investigateur coordinateur. Ce document a pour but de vous informer sur cette étude. Lisez-le attentivement et n'hésitez pas à demander tout renseignement complémentaire.

Pourquoi faire cette recherche ?

La stimulation électrique fonctionnelle (SEF) a montré sa capacité à activer les muscles des membres paralysés, chez les blessés médullaires, pour assurer un transfert assis-debout puis une station debout. Néanmoins, ces mouvements restent coûteux d'un point de vue énergétique et de faible portée fonctionnelle. Particulièrement, la phase de transfert demande une participation très importante des membres supérieurs, notamment des épaules et délétère à long terme. La phase de transfert met en jeu des niveaux de stimulation électrique importants qui fatiguent prématurément les muscles. La survenue d'une fatigue musculaire précoce limite le maintien de la posture érigée.

Objectif de l'étude

Une meilleure coordination du déclenchement de la stimulation électrique des membres inférieurs avec un mouvement du haut du corps devrait permettre de faciliter la phase de transfert, de diminuer les efforts au niveau des membres supérieurs et de réduire l'intensité des stimulations électriques musculaires appliquées. Nous souhaitons ici explorer la possibilité de déclencher la stimulation électrique des membres inférieurs à partir de l'observation de l'accélération du haut du corps. Nous étudierons également l'impact d'une meilleure coordination sur les efforts mis en jeu au niveau des membres supérieurs.

Déroulement de l'étude

Une visite d'inclusion, une séance de repérage musculaire (cartographie) suivies de 5 séances d'électrostimulation sont prévues. Les mesures ne seront effectuées que lors des dernières séances V6 et V7.

	Visite d'inclusion (V0)	V1 à V5	V6	V7
Examen médical préalable	X			
Information orale et écrite	X			
Signature du Consentement	X			
Cartographie musculaire par SEF de surface	X			
Séance d'électrostimulation pour l'entraînement		X		
Mesures			X	X
CI/CE		X	X	X

Le protocole se déroule sur le site du Centre Mutualiste Neurologique Propara

Risques liés à l'étude

Les examens pratiqués dans cette étude sont sans risque pour vous.

-Pour l'électrostimulation, aucun risque n'a pu être démontré chez les patients dans une utilisation normale. Seules des rougeurs au niveau des électrodes peuvent être observées

-Pour la verticalisation vous serez assistés par 3 personnes pour votre sécurité afin d'éviter la moindre chute.

Bénéfices attendus

Les bénéfices attendus de l'étude pour les personnes participant à cette recherche portent essentiellement sur la possibilité de réaliser un transfert assis-debout dans les meilleures conditions de maîtrise du coût énergétique et de protection des membres supérieurs. Cela signifie la possibilité de réduire la fatigue liée au transfert, de permettre à terme de prolonger la durée de la station debout et la préservation des épaules pendant le transfert.

L'idée sous-jacente à ce protocole est de faciliter la mobilité au fauteuil, de permettre des transferts en pivots après réalisation du transfert assis-debout et de participer ainsi à améliorer la qualité de vie de ces patients.

Si vous avez la moindre question concernant cette recherche, n'hésitez pas à la poser à votre médecin au cours ou à l'issue de l'étude. Il se fera un devoir d'y répondre clairement.

Cette étude est réalisée dans le cadre de la Loi Huriet du 20 décembre 1988 modifiée par la Loi du 9 août 2004. Elle a reçu l'avis favorable du Comité de Protection des Personnes (CPP) de Nîmes, le ***JJ/MM/AA*** .

Le promoteur a souscrit une assurance garantissant, pour cette recherche, sa Responsabilité Civile auprès de la Société Hospitalière d'assurances Mutuelles sous le n°106188. Les frais occasionnés par l'étude sont à la charge du promoteur.

Les données de santé à caractère personnel, recueillies dans le cadre de ce projet de recherche, sont strictement confidentielles : elles ne pourront être consultées que par des personnes collaborant à ce projet de recherche et soumises au Secret Professionnel. Conformément à la législation en vigueur, le traitement de ces données a fait l'objet d'une demande de déclaration auprès de la Commission Nationale de l'Informatique et des Libertés (CNIL), article 40-1 et suivants de la Loi « Informatiques et Liberté » du 6 janvier 1978, modifiée par les lois n°94-548 du 1er juillet 1994, n°2002-303 du 4 mars 2002 et 2004-801 du 06 août 2004). Ces données seront informatisées dans un fichier présentant les garanties de protection prévues par la Loi et vous pourrez exercer vos droits d'opposition (article 40.4), d'accès (article 39) et de rectification (articles 40) à tout moment par l'intermédiaire du médecin responsable de l'étude le Docteur Charles Fattal, ou d'un médecin de votre choix, dans un délai de huit jours.

Vous êtes bien entendu libre de refuser de participer à cette recherche ou, si vous acceptez, de retirer votre consentement à tout moment sans avoir à vous justifier et sans que cela n'affecte les soins qui pourront être donnés.

Vous n'entrerez dans cette étude qu'après signature de votre consentement et son inscription au Fichier National des Personnes qui se Prêtent à des Recherches Biomédicales, selon les procédures réglementaires. Vous avez la possibilité de vérifier l'exactitude des données le concernant et vous pourrez demander leur destruction ultérieure.

Pour tout problème ou question concernant cette étude, que ce soit au sujet de vos droits en tant que participant à une étude clinique ou tout dommage lié à l'étude, vous pouvez contacter le Dr. Charles Fattal (Centre Mutualiste Neurologique Propara; tel: 04 67 04 67 04).

CONSENTEMENT ECLAIRE

Je soussigné (e) :

Prénoms et Nom :………………………………….

Adresse :

....…………………………………….

Accepte par la présente de participer en toute connaissance de cause à la recherche biomédicale intitulée : Optimisation du transfert assis-debout sous électrostimulation fonctionnelle du patient paraplégique : **Etude préliminaire**, dont le promoteur est le Centre Mutualiste Neurologique Propara et conduite par le Dr Charles Fattal.

Je connais la possibilité qui m'est réservée de participer à cette étude ou de retirer mon consentement à tout moment quelle qu'en soit la raison et sans avoir à la justifier et sans aucune conséquence sur les soins et les traitements qui me seront donnés ultérieurement.

Je certifie sur l'honneur que je bénéficie d'un régime de sécurité sociale.

Les données de cette étude resteront strictement confidentielles. Nous n'autorisons leur consultation que par les personnes qui collaborent à la recherche, désignées par l'investigateur. En application de la loi "Informatique et Liberté" du 6 Janvier 1978, modifiée par les lois n° 94-548 du 1er Juillet 1994, n°2002- 303 du 4 mars 2002 et n°2004-801 du 6 août 2004. Nous acceptons que les données enregistrées à l'occasion de cette étude puissent faire l'objet d'un traitement informatisé par le promoteur ou pour son compte. Nous avons bien noté que les droits d'accès (article 39) et de rectification (article 40), que nous ouvrent les textes susvisés, pourront s'exercer à tout moment auprès du Dr. Charles Fattal, et que les données nous concernant pourront nous être communiquées directement ou par l'intermédiaire d'un médecin de notre choix.

Je précise que l'objectif de l'étude, les conditions et la durée de sa réalisation m'ont été clairement indiquées par le médecin dont le nom figure ci-dessus ainsi que les avantages, les contraintes et les risques prévisibles y compris en cas d'arrêt de l'étude avant son terme. J'ai bien noté que j'ai le droit d'être informé des résultats globaux de cette recherche selon les modalités qui m'ont été précisées dans la note d'information

Je m'engage à ne participer à aucun autre protocole pendant le mois qui suit l'inclusion dans la présente étude.

J'ai été informé(e) de mon inscription sur le Fichier National des Personnes qui se prêtent à des recherches Biomédicales et j'ai la possibilité de vérifier l'exactitude des données me concernant contenues dans ce fichier et leur destruction ultérieure.

J'ai reçu les résultats de l'examen médical préalable qui m'ont été communiqués par l'intermédiaire du médecin de mon choix.

Il m'a été remis une notice d'information et j'ai toutes les informations nécessaires à la prise de ma décision.

J'ai lu et reçu un exemplaire de ce formulaire de consentement et j'accepte de participer au présent protocole.

En retour de ma participation, j'ai été avisé que je ne recevrais aucune indemnité.

Fait à ...., le.........................

Signature du Patient.

Signature du médecin-investigateur:

Un exemplaire à remettre au patient.

ANNEXE V

Attestation d'assurance

ANNEXE VI

Attestation AFSSAPS

ANNEXE VII

Attestation de conformité des appareils

C.P.M. ISTITUTO RICERCHE PROVE ANALISI S.r.l.
Via Artigiani, 63 - 25040 BIENNO (BS) - Tel. 0364/300342-300509 - Fax 300354

GRUPPO

En exécution de l'article 11 de la directive 93/42/CEE concernant le rapprochement des législations des états membres relatives aux dispositifs médicaux

CPM Istituto Ricerche Prove Analisi Srl
Via Artigiani, 63
25040 BIENNO (BS)

accrédité par décret du Ministère de la Santé, Institut Supérieur de la Santé, et nommé auprès de la Commission Européenne Direction Générale III – Industrie sous le numéro 0398

ATTRIBUE LE

CERTIFICAT DE D'APPROBATION DU SYSTEME D'ASSURANCE DE LA QUALITE DE LA PRODUCTION
(Annexe V de la directive 93/42/CEE)

n° 99-7005.C.V.M/01

- Identification du dispositif médical : Appareil d'électrostimulation musculaire non invasif
- Dénomination commerciale Type : Stimulateur PROSTIM
- Fabricant : HARDTECH
  Z.I. chemin de Farjou
  34270 CLARET (France)
- Responsable UE : HARDTECH
  Z.I. chemin de Farjou
  34270 CLARET (France)
- Champ : site de CLARET

Nous déclarons qu'une évaluation a été menée selon les exigences de la transposition en droit italien de l'annexe V de la directive 93/42/CEE. Nous certifions que le système d'assurance de la qualité de la production est conforme aux exigences de la directive susmentionné. Les résultats de l'évaluation figurent dans le rapport n°99.7005.R.V.M/01.

Cette attestation est valable pour une période de trois ans à compter de la date d'émission.

Bienno, 30 mars 1999

P.I Urbano Strada
Responsabile U.T.S.P dispositivi medici

Ing. Bartolomeo Piccardo
Procuratore

Document authentifié par tampon sec

Cette attestation comporte une page et un annexe. L'attestation originale est rédigée en deux exemplaires en langue italienne transmis au demandeur. Cette traduction doit être accompagnée de l'attestation originale qui seule fait foi. Aucun duplicata ne sera délivré.
Tout projet d'adaptation importante du système de qualité doit être communiqué à l'organisme notifié qui en a décidé l'approbation.

ANNEXE VIII

Cahier d'observation

N° centre : |__| N°patient |__|__| **Initiales du Patient : |__| |__|**

CAHIER D'OBSERVATION

TITRE DE L'ETUDE

Optimisation du transfert assis-debout sous électromyostimulation fonctionnelle du patient paraplégique : Etude préliminaire

INVESTIGATEUR COORDINATEUR: DR CHARLES FATTAL

Centre Mutualiste Neurologique Propara

ADRESSE: Centre Mutualiste Neurologique Propara, 263 rue du Caducée, Parc Euromédecine-34090 Montpellier

Tel: 04.67.04.67.04 Fax: 04 67 04 67 00 E-mail : c.fattal@propara.languedoc-mutualite.fr

PROMOTEUR : Centre Mutualiste Neurologique Propara 263 rue du Caducée, Parc Euromédecine-34090 Montpellier

PROTOCOLE : Optimisation du transfert assis-debout sous électromyostimulation fonctionnelle du patient paraplégique : Etude préliminaire

VISITE D'INCLUSION V0

Date de V0 : |__|__| |__|__| |__|__||__|__|

DEMOGRAPHIE

Année de naissance : 19|__|__| Sexe Masculin ☐ Féminin ☐

EXAMEN CLINIQUE

Poids : |__|__|__| kg Taille |__|__|__| cm Index de masse corporelle |__|__| kg/m²

Fréquence cardiaque: |__|__|__|

Pression artérielle (mmHg) Systolique |__|__|__| Diastolique |__|__|__|

CRITERES D'INCLUSION DES PATIENTS:

		OUI	NON
1	Age > 18 et < 65 ans	☐	☐
2	Lésion traumatique complète: échelle ASIA : A	☐	☐
3	Durée post-lésionnelle > 6 mois	☐	☐
4	Stabilité neurologique > 6 mois	☐	☐
5	Capacité à rester au minimum 2 heures en fauteuil roulant	☐	☐
7	liberté articulaire complète des hanches et des genoux	☐	☐
8	Cartographie (mapping) électrique positif des muscles avec une cotation minimum de 4/5 MRC pour le quadriceps et de 3/5 MRC pour les glutei maximus (grands feissiers).	☐	☐
9	seuil de stimulation et de diffusion des muscles étudiés <150mA.	☐	☐

10 Patient déjà verticalisé à raison d'au moins 1 fois par mois ☐ ☐
11 Patient ayant signé le consentement éclairé ☐ ☐

12 Sujet non privé de liberté (par décision judiciaire ou administrative) ☐ ☐

13 Sujet majeur n'étant pas protégé par la loi ☐ ☐

14 Sujet affilié à un régime de sécurité sociale ou équivalent ☐ ☐

11 Sujet n'étant pas en période d'exclusion par rapport à un autre protocole ☐ ☐

12 Sujet enregistré dans le fichier national ☐ ☐

<u>Important</u> : si une ou plusieurs réponses 'NON' sont cochées, le sujet n'est pas inclus dans l'étude

CRITERES DE NON INCLUSION DES PATIENTS	**OUI**	**NON**
1 Age <18 ans ou > 65 ans	☐	☐
2 Refus du patient de donner son consentement	☐	☐
3 Absence d'un des critères d'inclusion	☐	☐
4 Spasticité et contractures en flexion ou en extension des membres inférieurs à caractère déstabilisant	☐	☐
5 Pathologie du genou	☐	☐
6 Limitations des mobilités articulaires passives et membres inférieurs douloureuses ou non	☐	☐
7 Pathologie cardio-vasculaire instable (coronnaropathies, HTA majeure, insuffisance cardiaque, etc…)	☐	☐
8 Patient porteur d'un stimulateur cardiaque	☐	☐
9 escarre ou cicatrice d'escarre pelvien ou au niveau des membres inférieurs.	☐	☐
10 problèmes dermatologiques contre-indiquant l'application d'électrodes de surfaces	☐	☐
11 Poids corporel excessif (>100 kg)	☐	☐

12 Grossesse	☐	☐
13 Epilepsie instable	☐	☐

<u>Important</u> : si une ou plusieurs réponses 'OUI' sont cochées, le sujet n'est pas inclus dans l'étude

RENSEIGNEMENTS SUR LA LESION MEDULLAIRE (A L'INCLUSION)

Date de la lésion : |__|__| |__|__| |__|__||__|__| **Age lors de la lésion: |__|__|**

Ancienneté de la lésion : |__|__| mois ou |__|__| ans

Niveau lésionnel moteur :……..

Niveau lésionnel sensitif :……..

Score Asia moteur/100 : |__|__||__| (cf annexe)

Score Asia sensitif tact/112: |__|__||__| (cf annexe)

Score Asia sensitif piqûre/112: |__|__||__| (cf annexe)

Score d'Ashworth modifié pour la spasticité du quadriceps droit|__|

Score d'Ashworth modifié pour la spasticité du quadriceps gauche|__|

Score de Penn pour les contractures |__|

Cause de la lésion :

✓ Traumatique **OUI☐ NON☐**

❶Accident de la route **OUI☐ NON ☐** ❷Chute **OUI☐ NON ☐**

❸Accident de sport **OUI☐ NON ☐** ❹Agression **OUI☐ NON ☐**

❺Autres, **OUI☐ NON ☐**

Si oui précisez : :…………………………..

✓ Chirurgicale **OUI☐ NON ☐**

✓Autres **OUI☐ NON ☐**

Si oui précisez :………………… Si oui précisez :………………

Traitement pris au long cours

(traitement à tropisme musculaire : Baclofène, myorelaxant, …)

Traitement N°1 : posologie : date début |__|__| |__|__| |__|__||__|__|

date de fin |__|__| |__|__| |__|__||__|__|

Traitement N°2 : posologie : date début |__|__| |__|__| |__|__||__|__|

date de fin |__|__| |__|__| |__|__||__|__|

Traitement N°3 : posologie : date début |__|__| |__|__| |__|__||__|__|

date de fin |__|__| |__|__| |__|__||__|__|

Traitement N°4 : posologie : date début |__|__| |__|__| |__|__||__|__|

date de fin |__|__| |__|__| |__|__||__|__|

Traitement N°5 : posologie : date début |__|__| |__|__| |__|__||__|__|

date de fin |__|__| |__|__| |__|__||__|__|

Traitement N°6 : posologie : date début |__|__| |__|__| |__|__||__|__|

date de fin |__|__| |__|__| |__|__||__|__|

Traitement N°7 : posologie : date début |__|__| |__|__| |__|__||__|__|

date de fin |__|__| |__|__| |__|__||__|__|

Programme de rééducation en cours

Durée totale d'immobilisation au lit : |__|__| semaines

Date de première mise au fauteuil |__|__| |__|__||__|__|

Durée post-lésionnelle à la première mise au fauteuil |__|__|__| jours

Type de programme de rééducation :

-verticalisation : **OUI☐ NON ☐**

Date de première verticalisation |__|__| |__|__| |__|__|

Si oui précisez le type de programme:

………………………………………………………………………………………………
………………………………………………………………………………………………
………………………

-kinésithérapie : **OUI☐ NON ☐**

Si oui précisez le type de programme:

………………………………………………………………………………………………
………………………………………………………………………………………………
………………………

Le patient possède un stimulateur personnel : **OUI☐ NON ☐**

Marque : Modèle :

Affections secondaires liées à la lésion neurologique

Le patient a-t-il développé un ostéome ? : **OUI ☐** **NON ☐**

Date : |__|__| |__|__| |__|__||__|__|

Localisation :

Traitement :

Le patient a-t-il développé une complication de décubitus (escarre, thrombo-phlébite, etc.)? : **OUI** ☐ **NON** ☐

Date : |__|__| |__|__| |__|__||__|__|

Localisation :

Traitement :

Le patient a-t-il développé une fracture sans traumatisme important ? :

OUI ☐ **NON** ☐

Date : |__|__| |__|__| |__|__||__|__|

Localisation :

Traitement :

Le patient a-t-il développé une spasticité ou des spasmes en flexion ou extension ?

OUI ☐ **NON** ☐

Date : |__|__| |__|__| |__|__||__|__|

Localisation :

Traitement :

Cartographie musculaire

MUSCLES STIMULES	Fréquence (Hz)	Largeur d'impulsion (µs)	Seuil d'intensité de stimulation (mA)	Seuil d'intensité de diffusion (mA)	Cotation MRC	Incidents rencontrés (douleur, brûlure etc.)
Quadriceps droit (Vaste externe)						
Quadriceps droit (Vaste interne)						
Quadriceps gauche (Vaste externe)						
Quadriceps gauche (Vaste interne)						
Tibialis Anterior droit						
Tibialis Anterior gauche						
Biceps femoris droits						
Biceps femoris gauches						

EVENEMENT INDESIRABLE

Le patient a-t-il été sujet à un problème médical?

OUI ☐ NON ☐

Si OUI, veuillez remplir la **page 7** concernant les évènements indésirables

LES EVENEMENTS INDESIRABLES GRAVES DOIVENT ETRE RAPPORTES IMMEDIATEMENT AU PROMOTEUR

J'ai revu toutes les données de cette visite et je certifie que ces données sont justes et complètes

Date : |__|__| /|__|__| /20 |__|__| **Signature de l'investigateur**

PROTOCOLE : Optimisation du transfert assis-debout sous électromyostimulation fonctionnelle du patient paraplégique : Etude préliminaire

VISITE 1 : Séance d'entraînement 1

Date de V1 : |__|__| |__|__| |__|__||__|__|

MUSCLES STIMULES	intensité de stimulation (mA)	Largeur d'impulsion (µs)	Fréquence (Hz)	Temps de stimulation Total (s)	Observations
Quadriceps droit (Vaste externe)					
Quadriceps droit (Vaste interne)					
Quadriceps gauche (Vaste externe)					
Quadriceps gauche (Vaste interne)					
Tibialis Anterior droit					
Tibialis Anterior gauche					
Biceps femoris droits					
Biceps femoris gauches					

N° centre : |__| N°patient |__|__| **Initiales du Patient : |__| |__|**

EVENEMENT INDESIRABLE

Le patient a-t-il été sujet à un problème médical depuis la dernière visite?

OUI ☐ NON ☐

Si OUI, veuillez remplir la page 7 concernant les évènements indésirables

LES EVENEMENTS INDESIRABLES GRAVES DOIVENT ETRE RAPPORTES IMMEDIATEMENT AU PROMOTEUR

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Date : |__|__| /|__|__| /20 |__|__| **Signature de l'investigateur**

PROTOCOLE : Optimisation du transfert assis-debout sous électromyostimulation fonctionnelle du patient paraplégique : Etude préliminaire

VISITE 2 : Séance d'entraînement 2

Date de V2 : |__|__| |__|__| |__|__||__|__|

MUSCLES STIMULES	intensité de stimulation (mA)	Largeur d'impulsion (µs)	Fréquence (Hz)	Temps de stimulation Total (s)	Observations
Quadriceps droit (vaste externe)					
Quadriceps droit (vaste interne)					
Quadriceps gauche (vaste externe)					
Quadriceps gauche (vaste interne)					
Tibialis Anterior droit					
Tibialis Anterior gauche					
Biceps femoris droits					
Biceps femoris gauches					

EVENEMENT INDESIRABLE

Le patient a-t-il été sujet à un problème médical depuis la dernière visite?

OUI ☐ NON ☐

Si OUI, veuillez remplir la page 7 concernant les évènements indésirables

LES EVENEMENTS INDESIRABLES GRAVES DOIVENT ETRE RAPPORTES IMMEDIATEMENT AU PROMOTEUR

J'ai revu toutes les données de cette visite et je certifie que ces données sont justes et complètes

Date : |__|__| /|__|__| /20 |__|__| **Signature de l'investigateur**

PROTOCOLE : Optimisation du transfert assis-debout sous électromyostimulation fonctionnelle du patient paraplégique : Etude préliminaire

VISITE 3 : Séance d'entraînement 3

Date de V3 : |__|__| |__|__| |__|__||__|__|

MUSCLES STIMULES	intensité de stimulation (mA)	Largeur d'impulsion (µs)	Fréquence (Hz)	Temps de stimulation Total (s)	Observations
Quadriceps droit (vaste externe)					
Quadriceps droit (vaste interne)					
Quadriceps gauche (vaste externe)					
Quadriceps gauche (vaste interne					
Tibialis Anterior droit					
Tibialis Anterior gauche					
Biceps femoris droits					
Biceps femoris gauches					

N° centre : |__| N° patient |__|__| **Initiales du Patient : |__| |__|**

EVENEMENT INDESIRABLE

Le patient a-t-il été sujet à un problème médical depuis la dernière visite?

OUI ☐ NON ☐

Si OUI, veuillez remplir la page 7 concernant les évènements indésirables

LES EVENEMENTS INDESIRABLES GRAVES DOIVENT ETRE RAPPORTES IMMEDIATEMENT AU PROMOTEUR

J'ai revu toutes les données de cette visite et je certifie que ces données sont justes et complètes

Date : |__|__| /|__|__| /20 |__|__| **Signature de l'investigateur**

PROTOCOLE : Optimisation du transfert assis-debout sous électromyostimulation fonctionnelle du patient paraplégique : Etude préliminaire

VISITE 4 : Séance d'entraînement 4

Date de V4 : |__|__| |__|__| |__|__||__|__|

MUSCLES STIMULES	intensité de stimulation (mA)	Largeur d'impulsion (µs)	Fréquence (Hz)	Temps de stimulation Total (s)	Observations
Quadriceps droit (vaste externe)					
Quadriceps droit (vaste interne)					
Quadriceps gauche (vaste externe)					
Quadriceps gauche (vaste interne)					
Tibialis Anterior droit					
Tibialis Anterior gauche					
Biceps femoris droits					
Biceps femoris gauches					

EVENEMENT INDESIRABLE

Le patient a-t-il été sujet à un problème médical depuis la dernière visite?

OUI ☐ NON ☐

Si OUI, veuillez remplir la page 7 concernant les évènements indésirables

LES EVENEMENTS INDESIRABLES GRAVES DOIVENT ETRE RAPPORTES IMMEDIATEMENT AU PROMOTEUR

J'ai revu toutes les données de cette visite et je certifie que ces données sont justes et complètes

Date : |__|__| /|__|__| /20 |__|__| **Signature de l'investigateur**

PROTOCOLE : Optimisation du transfert assis-debout sous électromyostimulation fonctionnelle du patient paraplégique : Etude préliminaire

VISITE 5 : Séance d'entraînement 5

Date de V5 : |__|__| |__|__| |__|__||__|__|

MUSCLES STIMULES	intensité de stimulation (mA)	Largeur d'impulsion (µs)	Fréquence (Hz)	Temps de stimulation Total (s)	Observations
Quadriceps droit (vaste externe)					
Quadriceps droit (vaste interne)					
Quadriceps gauche (vaste externe)					
Quadriceps gauche (vaste interne)					
Tibialis Anterior droit					
Tibialis Anterior gauche					
Biceps femoris droits					
Biceps femoris gauches					

EVENEMENT INDESIRABLE

Le patient a-t-il été sujet à un problème médical depuis la dernière visite?

OUI ☐ NON ☐

Si OUI, veuillez remplir la page 7 concernant les évènements indésirables

LES EVENEMENTS INDESIRABLES GRAVES DOIVENT ETRE RAPPORTES IMMEDIATEMENT AU PROMOTEUR

J'ai revu toutes les données de cette visite et je certifie que ces données sont justes et complètes

Date : |__|__| /|__|__| /20 |__|__| **Signature de l'investigateur**

PROTOCOLE : Optimisation du transfert assis-debout sous électromyostimulation fonctionnelle du patient paraplégique : Etude préliminaire

VISITE 6: Mesures

Date de V6 : |__|__| |__|__| |__|__||__|__|

MUSCLES STIMULES	intensité de stimulation (mA)	Largeur d'impulsion (µs)	Fréquence (Hz)	Temps de stimulation Total (s)	Observations
Quadriceps droit (vaste externe)					
Quadriceps droit (vaste interne)					
Quadriceps gauche (vaste externe)					
Quadriceps gauche (vaste interne)					
Tibialis Anterior droit					
Tibialis Anterior gauche					
Biceps femoris droits					
Biceps femoris gauches					

TABLEAU

Critère de jugement principal :

Essai	TDS	TES	Remarques
t0			
t1			
t2			
t0			
t1			
t2			
t0			
t1			
t2			

Critère de jugement secondaire :

Phase de transfert assis-debout

Essai	Moyenne force résultante poignée gauche (N)	Moyenne force résultante poignée droite (N)	Maximum force résultante poignée gauche (N)	Maximum force résultante poignée droite (N)	RMS force résultante poignée gauche (N)	RMS force résultante poignée droite (N)	Durée transfert (s)
t0							
t1							
t2							
t0							
t1							
t2							
t0							
t1							
t2							

Moy-ennes	Moyenne force résultante poignée gauche (N)	Moyenne force résultante poignée droite (N)	Maximum force résultante poignée gauche (N)	Maximum force résultante poignée droite (N)	RMS force résultante poignée gauche (N)	RMS force résultante poignée droite (N)	Durée transfert (s)
t0							
t1							
t2							

Station debout

Essai	Moyenne force résultante poignée gauche (N)	Moyenne force résultante poignée droite (N)	Maximum force résultante poignée gauche (N)	Maximum force résultante poignée droite (N)	RMS force résultante poignée gauche (N)	RMS force résultante poignée droite (N)	Durée transfert (s)
t0							
t1							
t2							
t0							
t1							
t2							
t0							
t1							
t2							

Moye-nnes	Moyenne force résultante poignée gauche (N)	Moyenne force résultante poignée droite (N)	Maximum force résultante poignée gauche (N)	Maximum force résultante poignée droite (N)	RMS force résultante poignée gauche (N)	RMS force résultante poignée droite (N)	Durée transfert (s)
t0							
t1							
t2							

EVENEMENT INDESIRABLE

Le patient a-t-il été sujet à un problème médical depuis la dernière visite?

OUI ☐ NON ☐

Si OUI, veuillez remplir la page 7 concernant les évènements indésirables

LES EVENEMENTS INDESIRABLES GRAVES DOIVENT ETRE RAPPORTES IMMEDIATEMENT AU PROMOTEUR

J'ai revu toutes les données de cette visite et je certifie que ces données sont justes et complètes

Date : |__|__| /|__|__| /20 |__|__| **Signature de l'investigateur**

VISITE 7: Mesures

Date de V7 : |__|__| |__|__| |__|__||__|__|

MUSCLES STIMULES	intensité de stimulation (mA)	Largeur d'impulsion (µs)	Fréquence (Hz)	Temps de stimulation Total (s)	Observations
Quadriceps droit (vaste externe)					
Quadriceps droit (vaste interne)					
Quadriceps gauche (vaste externe)					
Quadriceps gauche (vaste interne)					
Tibialis Anterior droit					
Tibialis Anterior gauche					
Biceps femoris droits					
Biceps femoris gauches					

TABLEAU

Critère de jugement principal :

Essai	TDS	TES	Remarques
t0			
t1			
t2			
t0			
t1			
t2			
t0			
t1			
t2			

N° centre : |__| N°patient |__|__| **Initiales du Patient : |__| |__|**

Critère de jugement secondaire :

Phase de transfert assis-debout

Essai	Moyenne force résultante poignée gauche (N)	Moyenne force résultante poignée droite (N)	Maximum force résultante poignée gauche (N)	Maximum force résultante poignée droite (N)	RMS force résultante poignée gauche (N)	RMS force résultante poignée droite (N)	Durée transfert (s)
t0							
t1							
t2							
t0							
t1							
t2							
t0							
t1							
t2							

Moy-ennes	Moyenne force résultante poignée gauche (N)	Moyenne force résultante poignée droite (N)	Maximum force résultante poignée gauche (N)	Maximum force résultante poignée droite (N)	RMS force résultante poignée gauche (N)	RMS force résultante poignée droite (N)	Durée transfert (s)
t0							
t1							
t2							

N° centre : |__| N°patient |__|__| **Initiales du Patient : |__| |__|**

Station debout

Essai	Moyenne force résultante poignée gauche (N)	Moyenne force résultante poignée droite (N)	Maximum force résultante poignée gauche (N)	Maximum force résultante poignée droite (N)	RMS force résultante poignée gauche (N)	RMS force résultante poignée droite (N)	Durée transfert (s)
t0							
t1							
t2							
t0							
t1							
t2							
t0							
t1							
t2							

Moye-nnes	Moyenne force résultante poignée gauche (N)	Moyenne force résultante poignée droite (N)	Maximum force résultante poignée gauche (N)	Maximum force résultante poignée droite (N)	RMS force résultante poignée gauche (N)	RMS force résultante poignée droite (N)	Durée transfert (s)
t0							
t1							
t2							

EVENEMENT INDESIRABLE

Le patient a-t-il été sujet à un problème médical depuis la dernière visite?

OUI ☐ NON ☐

Si OUI, veuillez remplir la page 7 concernant les évènements indésirables

LES EVENEMENTS INDESIRABLES GRAVES DOIVENT ETRE RAPPORTES IMMEDIATEMENT AU PROMOTEUR

J'ai revu toutes les données de cette visite et je certifie que ces données sont justes et complètes

Date : |__|__| /|__|__| /20 |__|__| **Signature de l'investigateur**

N° centre : |__| N°patient |__|__| **Initiales du Patient : |__| |__|**

PROTOCOLE : **Optimisation du transfert assis-debout sous électromyostimulation fonctionnelle du patient paraplégique : Etude préliminaire**

Enregistrement des Effets Indésirables

Le malade a-t-il présenté des effets indésirables ? Oui ☐ Non ☐

Si Oui, les décrire ci-dessous (entourer un seul chiffre).

Effet indésirable	**Date** (J.M.A.)	**Visite**	**Intensité** 1 = Légère 2 = Modérée 3 = Sévère	**Facteurs déclenchants *** 1 = aucun 2 = la maladie actuelle 3 = une maladie intercurrente 4 = Lié à un médicament	**Actions entreprises** 1 = Aucune 2 = Surveillance accrue 3 = traitement correcteur	** L'effet indésirable est-il grave ? 1 = Non 2 = Oui	Relation avec l'étude 1=non lié 2=probable 3=possible 4=peu probable 5=non évaluable a
	Début /__/__/ /__/__/ /__/__/ Fin /__/__/ /__/__/ /__/__/		1 2 3	1 2 3 4	1 2 3	1 2	1 2 3 4.5
	Début /__/__/ /__/__/ /__/__/ Fin /__/__/ /__/__/ /__/__/		1 2 3	1 2 3 4	1 2 3	1 2	1 2 3 4.5
	Début /__/__/ /__/__/ /__/__/ Fin /__/__/ /__/__/ /__/__/		1 2 3	1 2 3 4	1 2 3	1 2	1 2 3 4.5
	Début /__/__/ /__/__/ /__/__/ Fin /__/__/ /__/__/ /__/__/		1 2 3	1 2 3 4	1 2 3	1 2	1 2 3 4.5
	Début /__/__/ /__/__/ /__/__/ Fin /__/__/ /__/__/ /__/__/		1 2 3	1 2 3 4	1 2 3	1 2	1 2 3 4.5

* Plusieurs chiffres peuvent être entourés dans cette colonne

** **Rappel de la définition d'un événement indésirable :**

Un événement indésirable grave est défini comme tout événement qui, quelle que soit la dose :

- a entraîné la mort,
- a mis en jeu le pronostic vital
- a entraîné une hospitalisation ou une prolongation d'hospitalisation,
- a causé une invalidité significative persistante ou un handicap,

- se traduit par une anomalie congénitale

Commentaire

....

....

........…………………………………………………………….

Données certifiées conformes au dossier médical Date |__|__| /|__|__| /20 |__|__|

Signature:

RAPPORT PRELIMINAIRE CONCERNANT UN EVENEMENT INDESIRABLE GRAVE (EIG)

Cette fiche doit être faxée dans les plus brefs délais, et, la page du cahier d'observations concernant les événements indésirables complétée.

Promoteur:
Centre Mutualiste Neurologique Propara
Adresse:
263 rue du Caducée- Parc Euromédecine 34195 Montpellier cedex 5

Investigateur : Dr Charles Fattal

Service :Centre Mutualiste Propara
N°tel : 04.67.04.67.04

Titre de l'étude : Modélisation de l'activité musculaire sous lésionnelle chez le blessé médullaire en vue de l'utilisation de l'électrostimulation à des fins trophiques et fonctionnelles

N° centre : |__| N°patient |__|__| Sexe M ☐ F ☐

Année de naissance : |___I I___I |_____I

Début de l'étude : **|___| |___| |_____|**

Arrêt de l'étude : Oui ☐ Non ☐ si oui quand : |_|_| |_|_| |_|_|

Date de l'E.I.G. (jour/mois/année) : **|__| |__| |____|**

Description de l'E.I.G. et mesures prises :	Nature de l'E.I.G. : ☐ Décès ☐Susceptible de mettre la vie en danger

	□ Invalidité ou incapacité □ Hospitalisation ou prolongation d'hospitalisation □ Autre, préciser
Evaluation initiale de la causalité du médicament à l'essai : (si votre étude ne concerne pas le médicament, cochez la case sans objet) Non lié □ Probable □ Non évaluable □ Sans objet □	
Lié au □ Protocole d'étude oui □ non □ □ Autre :	

Date : |__|__| /|__|__| /20 |__|__|

Signature (+ tampon du service) :

FICHE DE FIN D'ETUDE

	OUI	NON
1 Etude poursuivie à son terme?	□	□

Si NON, compléter les items suivants

2 Nombre de jours de suivi depuis inclusion dans l'étude **I__I__I __I**

	OUI	NON
3 Sortie d'étude par décision de l'investigateur	□	□
4 Sortie d'étude par décision du (de la) patiente	□	□
5 Motifs de la sortie d'étude:		
5.1 Evénement indésirable grave	□	□

□***<u>Compléter le bordereau de la déclaration d'événement indésirable</u>*** **(page..)**

	OUI	NON
5.2 Mauvaise compliance	□	□
5.3 Manque d'efficacité	□	□
5.4 Abandon	□	□
5.5 Perdu de vue	□	□

5.6 Décès □ □

5.7 Autre □ □

préciser___________________________

Données certifiées conformes au dossier médical

Date : I__I__I I__I__I I__I__I

Nom et signature de l'investigateur :

ANNEXE DU CRF: SCORE ASIA

Évaluation motrice

	D	G	
C2			
C3			
C4			
C5			Flexion du coude
C6			Extension du poignet
C7			Extension du coude
C8			Flexion du médius (P3)
T1			Abduction du 5e doigt
T2			
T3			
T4			
T5			
T6			
T7			
T8			
T9			
T10			
T11			
T12			
L1			
L2			Flexion de la hanche
L3			Extension du genou
L4			Dorsiflexion de cheville
L5			Extension du gros orteil
S1			Flexion plantaire de cheville
S2			
S3			
S4-5			

0 = paralysie totale
1 = contraction visible ou palpable
2 = mouvement actif sans pesanteur
3 = mouvement actif contre pesanteur
4 = mouvement actif contre résistance
5 = mouvement normal
NT, non testable

Score «motricité» : /100
Contraction anale : oui/non

Score ASIA

Date de l'examen
|_|_||_|_||_|_|_|_|

Identité du patient

Niveau neurologique* { Sensitif droite ☐ gauche ☐ ; Moteur droite ☐ gauche ☐

*Segment le plus caudal ayant une fonction normale

Lésion médullaire** : Complète ou Incomplète

** Caractère incomplet défini par une motricité ou une sensibilité du territoire S4-S5

Échelle d'anomalie ASIA : A B C D E

A = complète : aucune motricité ou sensibilité dans le territoire S4-S5

B = incomplète : la sensibilité mais pas la motricité est préservée au-dessous du niveau lésionnel, en particulier dans le territoire S4-S5

C = incomplète : la motricité est préservée au-dessous du niveau lésionnel et plus de la moitié des muscles testés au-dessous de ce niveau a un score < 3

D = incomplète : la motricité est préservée au-dessous du niveau lésionnel et au moins la moitié des muscles testés au-dessous du niveau a un score ≥ 3

E = normale : la sensibilité et la motricité sont normales

Préservation partielle*** { Sensitif droite ☐ gauche ☐ ; Moteur droite ☐ gauche ☐

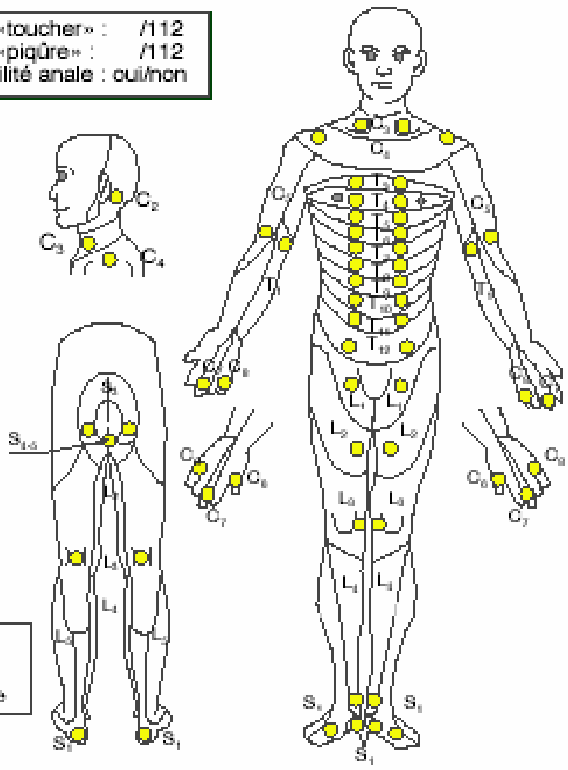
*** Extension caudale des segments partiellement innervés

Syndrome clinique :
- Centromédullaire ☐
- Brown-Sequard ☐
- Moelle antérieure ☐
- Cône terminal ☐

Évaluation sensitive

	Toucher D	Toucher G	Piqûre D	Piqûre G
C2				
C3				
C4				
C5				
C6				
C7				
C8				
T1				
T2				
T3				
T4				
T5				
T6				
T7				
T8				
T9				
T10				
T11				
T12				
L1				
L2				
L3				
L4				
L5				
S1				
S2				
S3				
S4-5				

Score «toucher» : /112
Score «piqûre» : /112
Sensibilité anale : oui/non



0 = absente
1 = diminuée
2 = normale
NT, non testable

ATTESTATION

Je soussigné, Docteur Charles Fattal , certifie que les données recueillies dans ce cahier d'observation sont réelles et exactes.

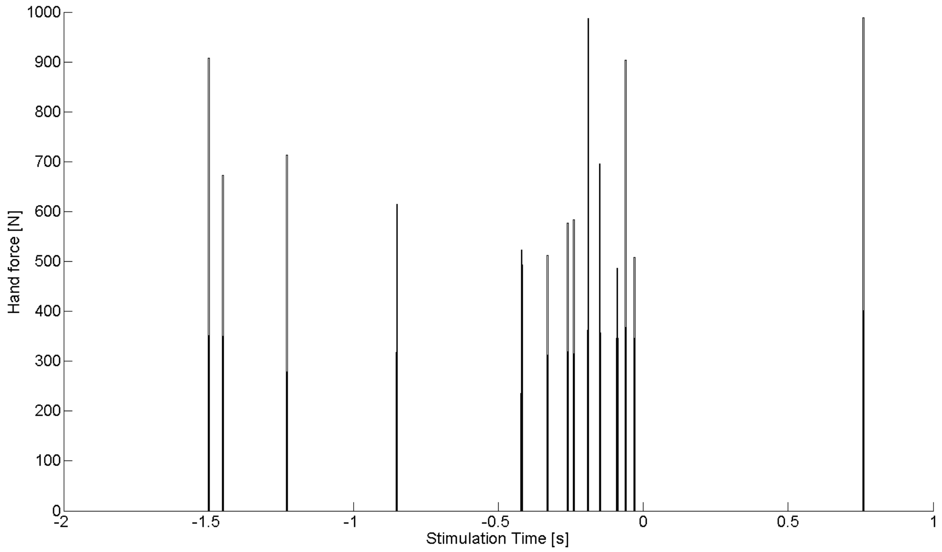
Date : |__|__| |__|__| |__|__|__|__|

Signature et cachet du service

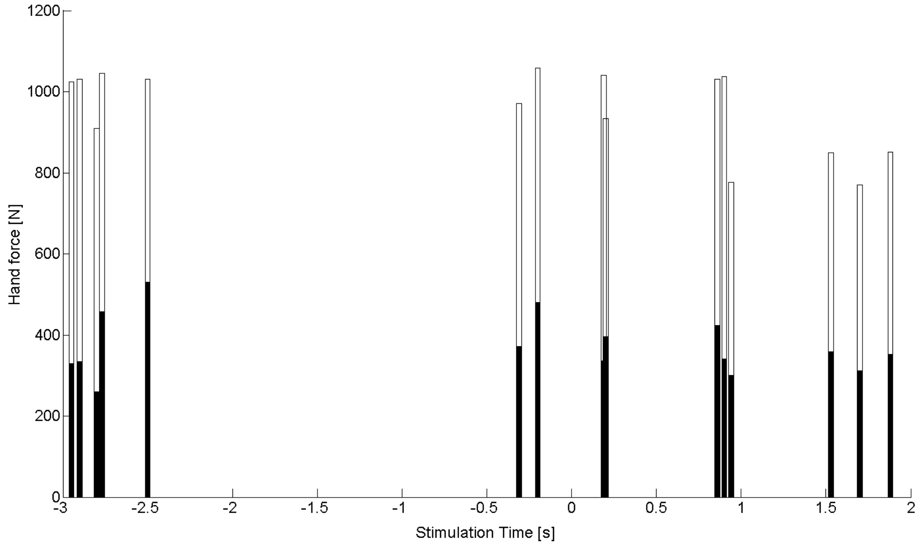
B

APPENDIX B

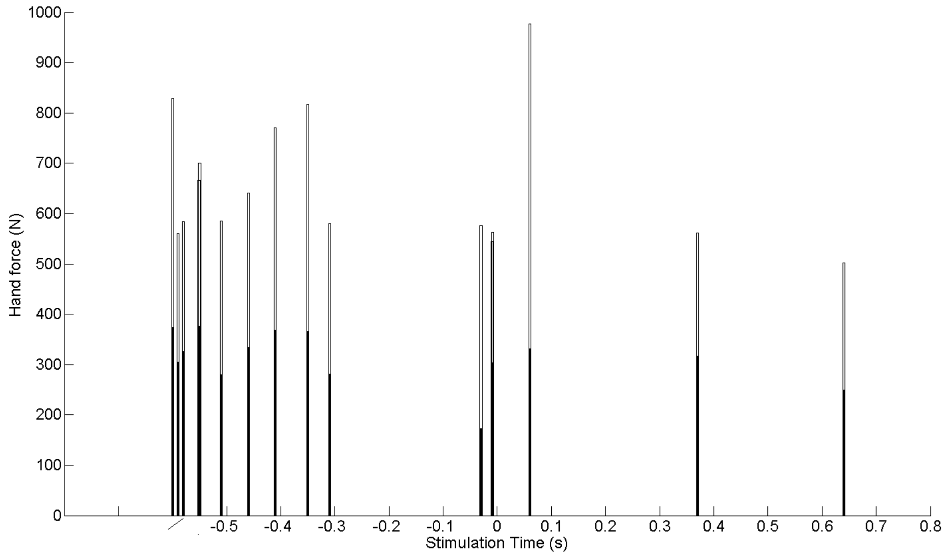
Hand forces recorded during STS experiments



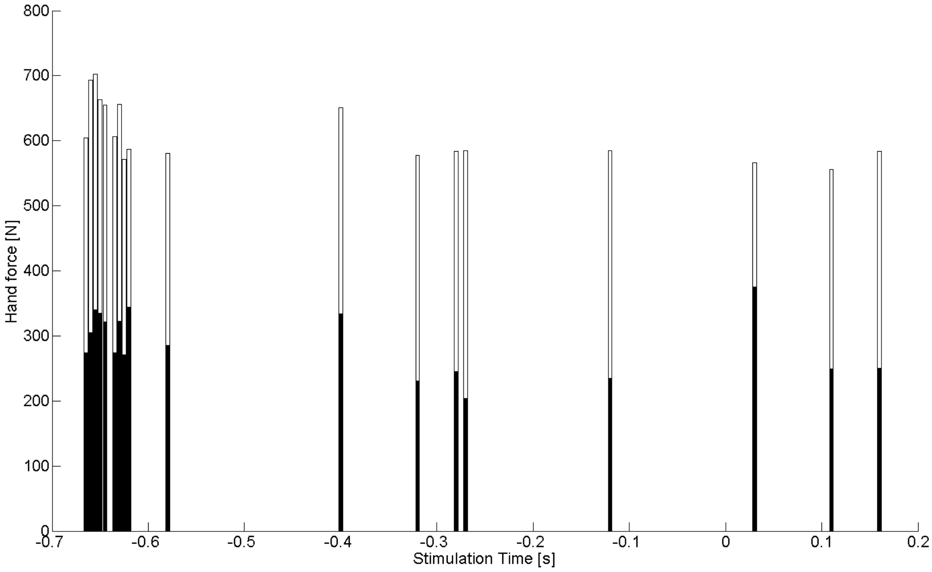
(a) Subject 1.



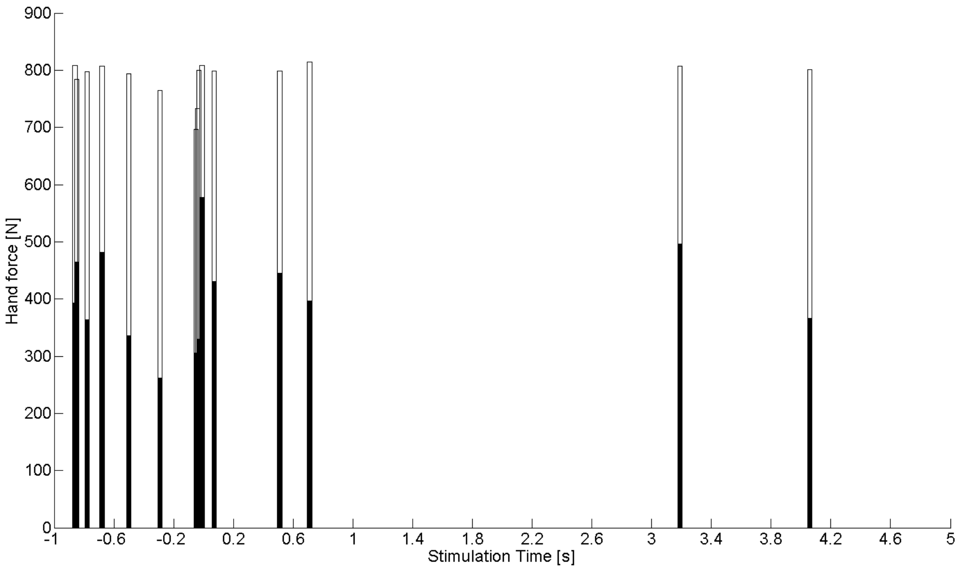
(b) Subject 2.



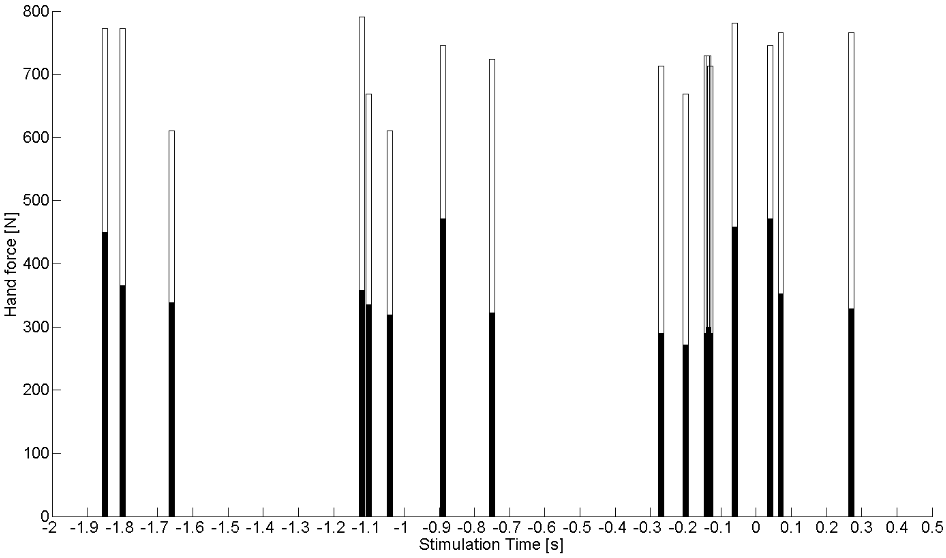
(c) Subject 3.



(d) Subject 4.



(e) Subject 5.



(f) Subject 6.

Figure 61: M (black), and Max (white) values calculated over each sit-to-stand trial for each subject.

C

APPENDIX C

Video analysis software

We have developed video analysis software for analyzing joint coordination during sit-to-stand movement, which is easy to implement in clinical settings. The software is based on the estimation of markers placed on the patient's body. A video camera records each STS trial. Four red markers should be positioned on the patients' shoulder, hip, knee and ankle (Figure 62).

Figure 62: Position of four red markers on patient's body.

The software[1] estimates the position of the four markers through the recorded trials. Knowing the X and Y coordinates of each marker, hip and knee joint angles can be estimated. For each STS trial maximum of the trunk angle, as well as the beginning of the knee angle change marking the beginning of the rising phase (phase II in [125]) of the STS motion, can be estimated.

ΔT can be computed as the time difference between the occurrence of the maximum trunk angle and the change in knee angle (see Figure 63). Negative values indicate that the maximum trunk angle occurred before the knee angle change. Similarly, positive values indicate that the maximum trunk angle occurred after the knee angle change, i.e., after seat-off. An example of data analyzed using this software is given in Figure 64. The symbol "/" on the x axis represents the trials during which the subjects stood up using only the arm support. The other bars represent sit-to-stand trials performed using the FES system. The numbers on the x axis represent the stimulation time in seconds with respect to the maximum trunk acceleration. Negative values indicate that the stimulator was triggered before Accmax. Similarly, positive values mean that the stimulation started after Accmax, i.e. after seat-off.

1 Acknowledgment: S. Duruon, IDH team, LIRMM, Montpellier, France.

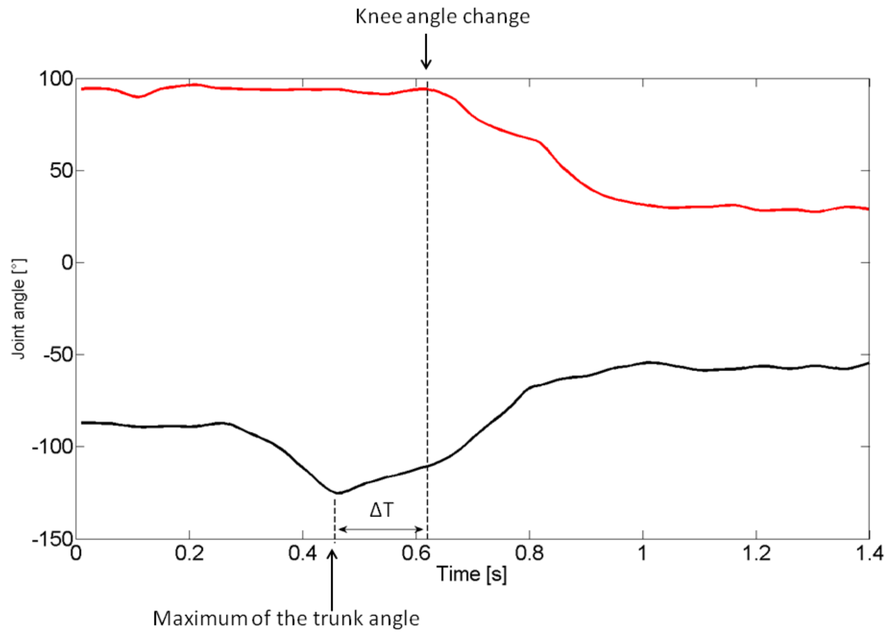


Figure 63: ΔT definition. The red line represents the knee angle, the black line represents the hip angle during the lift phase of sit-to-stand motion.

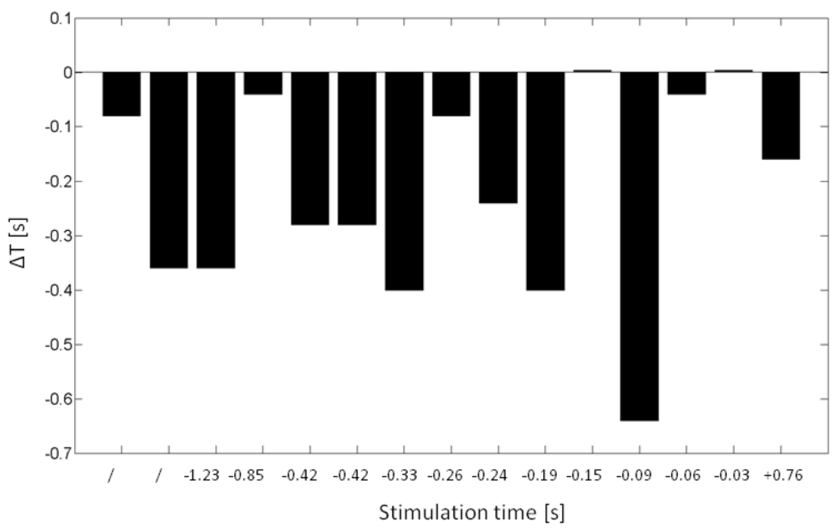


Figure 64: Δ T values calculated over each sit-to-stand trial for one subject.

D

APPENDIX D

Plug-In-Gait marker placement

Figure 65 displays where Plug-In-Gait markers should be placed on the subject. Where left side markers only are listed, the positioning is identical for the right side.

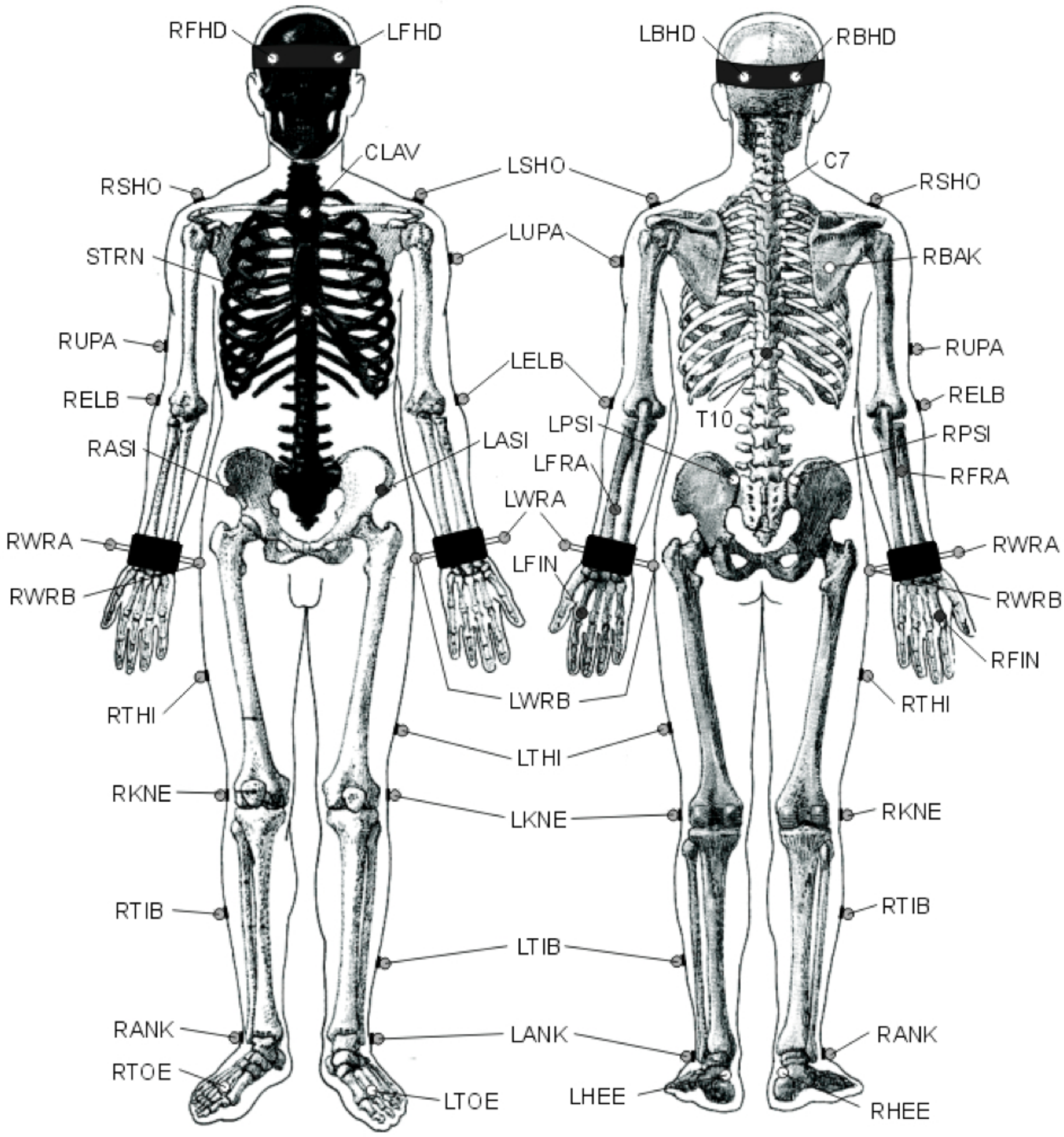


Figure 65: Plug-In-Gait marker placement

Upper body

Head Markers		
LFHD	Left front head	Located approximately over the left temple
RFHD	Right front head	Located approximately over the right temple
LBHD	Left back head	Placed on the back of the head, roughly in a horizontal plane to the front head markers
RBHD	Right back head	Placed on the back of the head, roughly in a horizontal plane to the front head markers

Torso Markers		
C7	7th cervical vertebrae	Spinous process of the 7th cervical vertebrae
T10	10th thoracic vertebrae	Spinous process of the 10th thoracic vertebrae
CLAV	Clavicle	Jugular notch where the clavicles meet the sternum
STRN	Sternum	Xiphoid process of the sternum
RBAK	Right back	Placed in the middle of the right scapula. This marker has no symmetrical marker on the left side. This asymmetry helps the auto-labeling routine determine right from left on the subject

Arm Markers		
LSHO	Left shoulder marker	Placed on the acromio-clavicular joint
LUPA	Left upper arm marker	Placed on the upper arm between the elbow and shoulder markers. Should be placed asymmetrically with RUPA
LELB	Left elbow	Placed on the lateral epicondyle approximating the elbow joint axis
LFRA	Left forearm marker	Placed on the lower arm between the wrist and elbow markers. Should be placed asymmetrically with RFRA
LWRA	Left wrist marker A	Left wrist bar thumb side
LWRB	Left wrist marker B	Left wrist bar pinkie side

Hand Markers		
LFIN	Left finger	Actually placed on the dorsum of the hand just below the head of the second metacarpal

Lower body

Pelvis		
LASI	Left ASIS	Placed directly over the left anterior superior iliac spine
RASI	Right ASIS	Placed directly over the right anterior superior iliac spine
LPSI	Left PSIS	Placed directly over the left posterior superior iliac spine
RPSI	Right PSIS	Placed directly over the right posterior superior iliac spine
SACR	Sacral wand marker	Placed on the skin mid-way between the posterior superior iliac spines (PSIS). An alternative to LPSI and RPSI

Leg Markers		
LKNE	Left knee	Placed on the lateral epicondyle of the left knee
LTHI	Left thigh	Place the marker over the lower lateral 1/3 surface of the thigh, just below the swing of the hand, although the height is not critical
LANK	Left ankle	Placed on the lateral malleolus along an imaginary line that passes through the transmalleolar axis
LTIB	Left tibial wand	Similar to the thigh markers, these are placed over the lower 1/3 of the shank to determine the alignment of the ankle flexion axis

Foot Markers		
LTOE	Left toe	Placed over the second metatarsal head, on the mid-foot side of the equinus break between fore-foot and mid-foot
LHEE	Left heel	Placed on the calcaneous at the same height above the plantar surface of the foot as the toe marker

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