

UNIVERSIDADE ESTADUAL DE CAMPINAS Faculdade de Engenharia Elétrica e de Computação

Antonio Ribas Neto

Development of a hybrid wearable robotic orthosis prototype associated with functional electrical stimulation to assist and improve performance in hand motor function: a pilot study

Desenvolvimento de um protótipo de órtese robótica calçável (vestível) híbrida associado a estimulação elétrica funcional para assistência e melhora de desempenho na função motora da mão: estudo piloto

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"There and Back Again."

Resumo

Pessoas com deficiências nas mãos causadas pelas doenças musculoesqueléticas neurológicas e degenerativas mais comuns enfrentam problemas para realizar suas tarefas diárias. Com o objetivo de tentar ajudar essas pessoas, neste trabalho, desenvolvemos o protótipo de uma órtese do tipo luva para membros superiores que utiliza um sistema de cabos para abrir e fechar a mão, juntamente com um sistema de estimulação elétrica funcional (FES). O objetivo do protótipo é juntar as vantagens de duas tecnologias para que o dispositivo possa ser um dispositivo assistivo e reabilitativo. Diferentemente de um sistema que utiliza somente FES, nosso projeto utiliza uma estrutura mecânica para evitar o uso contínuo de FES, visando reduzir a fadiga muscular. Para tal, uma estratégia de controle híbrida foi desenvolvida, com o objetivo de aplicar FES e atuação mecânica durante o fechamento e abertura da mão, mas utilizar somente a atuação mecânica para fornecer força de preensão ao objeto. Para evitar problemas com interferência magnética em medições da atividade muscular quando é aplicada a FES, utilizamos um sensor de fibra óptica de miografia no projeto do protótipo. O protótipo foi desenvolvido e avaliado seu desempenho durante a realização de tarefas que envolvem agarrar alguns objetos com formas comumente encontradas no dia-a-dia, apresentando no final um desempenho satisfatório.

Palavras-chaves: órtese robótica; estimulação elétrica funcional; miografia da força; sensor de miografia de força; estratégia de controle híbrida; sensor de miografia de força de fibra óptica.

Abstract

People who have hand impairments caused by the most common neurological and degenerative musculoskeletal diseases face trouble to achieve their everyday tasks. With the objective of trying to help these people, in this work, we developed a prototype of a glove-type orthosis for upper limbs that uses a cable system to open and close the hand, together with a functional electrical stimulation (FES) system. The purpose of the prototype is to combine the advantages of two technologies so that the device can be an assistive and rehabilitative device. Unlike a system that uses only FES, our project makes use of a mechanical structure to avoid the continuous use of FES, aiming to reduce muscle fatigue. To this end, a hybrid control strategy was developed, with the objective of applying FES and mechanical actuation during closing and opening of the hand, but using only mechanical actuation to provide gripping force to the object. To avoid problems with magnetic interference in muscle activity measurements when FES is applied, we used a fiber optic myography sensor in the prototype design. The prototype was developed and its performance evaluated during tasks which involve grasping some objects with shapes commonly found in everyday life, presenting a satisfactory performance in the end.

Keywords: robotic orthosis; functional electrical stimulation; force myography; hybrid control strategy; optical fiber force myography.

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List of abbreviations and acronyms

- ABS Acrylonitrile Butadiene Styrene
- ADLs Activities of Daily Living
- ADC Analog-to-digital Converter
- BCI Brain-computer Interface
- BMI Brain–machine Interface
- CADEX Cable Actuated Dexterous
- CCFES Contralaterally Controlled Functional Electrical Stimulation
- COVID-19 Coronavirus Disease 2019 (a disease caused by a virus named SARS-CoV-2)
- CPM Continuous Passive Motion
- CVA Cerebrovascular Accident
- DIP Distal Interphalangeal
- DOF Degrees of Freedom
- DSP Digital Signal Processing
- EDC Extensor Digitorum Comunis
- EEG Electroencephalography
- EMG Electromyography
- EMS Electrical Muscle Stimulation
- ET Extensor Threshold
- FDS Flexor Digitorum Superficialis
- FES Functional Electrical Stimulation
- FMG Force Myography
- FSR Force Sensitive Resistor
- FT Flexor Threshold

- IBGE Brazilian Institute of Geography and Statistics
- IMU Inertial Measurement Unit
- LED Light Emitting Diode
- LVDT Linear Variable Displacement Transducer
- MEMS Micro Electro Mechanical Systems
- MUAP Motor Unit Action Potential
- NMES Neuromuscular Electrical Stimulation
- NP Neuroprosthesis
- NPs Neuroprostheses
- MCU Microcontroller Unit
- MUAP Motor Unit Action Potential
- PC Personal Computer
- RMS Root Mean Square
- RTOS Real-time Operating Systems
- sEMG Surface Electromyography
- SCI Spinal Cord Injury
- SDK Software Development Kit
- SNU Seoul National University
- TENS Transcutaneous Electrical Nerve Stimulation
- USB Universal Serial Bus
- WHO World Health Organization

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1 INTRODUCTION

The World Health Organization (WHO) estimates that more than 1 billion people in the world live with some form of disability (WHO, 2011). In Brazil, according to the Brazilian Institute of Geography and Statistics (IBGE), in 2010 there were more than 45 million with some form of disability (BRASIL, 2012). To make matters worse, people with some kind of disability also have the worst health prospects, lower levels of education, lower economic participation, and higher poverty rates compared to people without disabilities, partly due to fact that they have difficulties in having access to basic services such as health, education, employment, transport, and information, which is further exacerbated in poorer communities (WHO, 2011).

There are several causes for disabilities resulting in different types of impairments. Amongst the causes of disability, stroke (or in its medical term, cerebrovascular accident (CVA)), and spinal cord injury (SCI) can be pointed out as the leading causes of disability (WHO, c2020c; LANGHORNE; BERNHARDT; KWAKKEL, 2011). Most victims who suffer a stroke, or a SCI, and who survive, are temporarily or permanently debilitated. For the most victims suffering from stroke, one of the sequels is the lack, or weakening, of limb movements, and when this deficiency affects the upper limbs, such as hand movements, patients have to adjust themselves to a new style of life, rely upon other people to get their activities of daily living (ADL) done, which ends up affecting their quality of life. The same occurs with people who have suffered a SCI. Depending on the severity of the spinal injury, some are totally dependent on other people, others partially lose the movement of all limbs.

In the midst of all means to address these problems, rehabilitation physiotherapy (occupational therapy, motor training, training of specific tasks, among others) is still one of the resources that has given the majority of results, being employed in order to try to lead these people again to a satisfactory and productive life, avoiding or mitigating the appearance of other complications. Such methods have presented positive results for inpatients and outpatients, both for cases involving stroke (FERRARELLO *et al.*, 2011; HOWLETT *et al.*, 2015; CHI *et al.*, 2019), or SCI (RAGNARSSON, 2008; MARTIN *et al.*, 2012; HARVEY, 2016; LUO; XU; ALL, 2020).

Alongside traditional methods of therapy, the technological advancements have progressively enabled the use of various others resources (CHO; NATER, 2013; DOBKIN; DORSCH, 2013; HARVEY; GLINSKY; BOWDEN, 2016; CLAFLIN; KRISHNAN; KHOT, 2015; HATEM *et al.*, 2016; MUSSELMAN; SHAH; ZARIFFA, 2018; SHAH *et al.*, 2020), which are used for the purpose of boosting therapy, making it more motivating, or even as an appealing resource, in an attempt to seek greater and more results in a shorter period of time.

Among all these types of approaches involving treatments and available technologies, the use of functional electrical stimulation (FES) for rehabilitation has been widely used in parallel with conventional therapy (MARTIN *et al.*, 2012; HO *et al.*, 2014; IEVINS; MORITZ, 2017; HOWLETT *et al.*, 2015; HARA, 2013; ERAIFEJ *et al.*, 2017; YANG *et al.*, 2019). FES is a technique that injects small levels of electrical current applied through electrodes to activate specific muscles and nerves, being used to restore the function of the hands, legs and organs. Its application can be performed in clinics or even at home, with its purposes ranging from strengthening the hands to combating spasticity. One of the limitations of the use of FES is related to muscle fatigue, since the order of recruitment of motor units occurs in the opposite order to that of natural recruitment, that is, first the largest motor units are recruited, which are more quickly fatigued, and then smaller motor units (MARTIN *et al.*, 2012; DOUCET; LAMB; GRIFFIN, 2012; QUANDT; HUMMEL, 2014). In addition, some patients also find the use of FES painful.

Another technology that is gaining prominence is wearable robotics, and soft robotics. These types of technologies have been spreading through the use of wearable robotic orthoses, and exoskeletons (MACIEJASZ *et al.*, 2014; CHU; PATTERSON, 2018; SHAHID *et al.*, 2018). In these devices, the necessary assistance/resistance force provided to the user comes from an actuator, an electric motor, for example. In this sense, these devices can be seen as assistive technologies. These devices can also be considered rehabilitative devices if they are employed for the purpose of physical rehabilitation. However, it is known that the motor recovery (rehabilitation) of patients is associated with neural plasticity (ONIFER; SMITH; FOUAD, 2011; TAKEUCHI; IZUMI, 2013). Therefore, rehabilitation research indicates that to improve motor recovery and to induce neuroplasticity after brain injury, rehabilitation programs must include training with intensive repetitive movements and specific tasks (SUNDERLAND; TUKE, 2005; HUBBARD *et al.*, 2009), that is, an activity-based therapy, which is not always taken into account when devising orthosis and exoskeletons designs. If used for these purposes, such devices can also be used for assessment and rehabilitation at different points during the patient's rehabilitation journey.

The combination of using FES with a wearable robotic orthosis (which is a type of exoskeleton), results in a hybrid orthosis (JAILANI; TOKHI; GHAROONI, 2010; STEWART *et al.*, 2017), in which part of the forces to support or perform tasks are provided by the actuator and another part is obtained via the use of FES – if the user has any remaining strength, this also adds up to the forces previously mentioned. In the combination of the FES with the exoskeletal orthosis, the FES can be turned on or off arbitrarily as needed, and the orthosis (exoskeleton) can provide the required rigidity to support the hand position when performing tasks whilst the FES is turned off. In this

way, it is not necessary the same intensity of FES to produce the same movement, and consequently, muscle fatigue can be delayed, which in turn reduces the amount of pain in the places where the electrodes are located. However, research and development on hybrid wearable robotic orthoses (and exoskeletons) for assistive and rehabilitation purposes for these types of diseases is scarce in Brazil and worldwide, which makes it an open research topic for new contributions.

1.1 Motivation

In view of the above, this project was developed to contribute to this area, providing a hybrid orthosis (exoskeleton) that can be used as an assist-as-need exoskeleton for upper limbs of individuals with a weak grip. In other words, this project involves merging the use of FES with an exoskeleton — the glove-like orthosis — in order to obtain in only one device the advantages that the two technologies present separately, rehabilitation and assistance.

1.2 Main challenges

In addition to the use of FES associated with physical exercises, different technologies have been used as assistive and/or rehabilitation technologies for therapy, such as wearable and soft robotics. Advances in design of new components and systems (polymers, fabrics, etc.) have allowed the manufacturing of devices (such as exoskeletons, gloves, etc.) to be used in this modern branch of robotics. Nonetheless, much has to be done to bring these technologies to work together.

Despite of all these enhancements, to make things worse, most victims of stroke or SCI are residents of low- and middle-income countries, who cannot afford health care. For this reason, it is necessary to cheapen and increase the number of rehabilitative devices in order that such devices can be affordable for all. Bearing this in mind and as an attempt to contribute with research in this area, the purpose of this work is stated below.

1.3 Main goals

The main objective of this work is the creation of a low-cost hybrid wearable glove-like orthosis that can be worn on the hand, to assist and help to recover hand movements in patients who have suffered a stroke or spinal cord injury, or from degenerative diseases. It is known that FES is an efficient rehabilitative technology, however it cannot be used for extended periods of time because of muscle fatigue. On the other hand, glove-like orthosis using tendon system are devices that can be used with no restriction of time. Notwithstanding, they are assistive devices. Thus, the idea is to merge together FES and a glove-like orthosis with a tendon drive mechanism in only one device in order to have both advantages. It is hoped that these two technologies working together may be a choice of recurrence and aid in the assistance and recovery of those patients who suffer from this type of disability.

To achieve the objectives of the thesis, the study was developed with the following structure:

- Literature review: search for publications related to the state-of-the-art in this theme;
- Devised a method of a hybrid control strategy to be implemented on an orthosis;
- Selection of components and a structure to the orthosis and its design;
- Selection and development of the components to be used in the orthosis project;
- Preparation and programming of instructions in microcontrollers to implement the hybrid control strategy;
- Implementation of the prototype for experimental evaluation of results obtained.

1.4 Contributions and results

In the context of this PhD project, we succeeded in devising a new hybrid control strategy merging FES and a glove-like orthosis, in our case, to be implemented on a wearable tendon-driven glove-like orthosis.

Besides the hybrid control strategy, based on the state of the art in orthoses, a robotic hand orthosis prototype was developed that together with the hybrid strategy can help people with severe hand impairments, such as weak grip, to perform daily living task with their affected hand.

Our usable and accessible prototype orthosis was developed to be an opensource orthosis prototype that can be improved and reproduced, even with components found in Brazil.

In addition, we contributed to the research developed in Brazil on hybrid orthosis, and also to the worldwide state-of-the-art in orthoses by presenting our work at 3 conferences (1 of them abroad) and publishing 2 abstracts and 4 full paper plus 1 submission to a journal.

1.5 Thesis presentation

This thesis is organized in six chapters (including this introduction), containing background information, our contributions and the achieved results that were submitted and published to area-related conferences and journals.

The second chapter consists of a literature review on relevant terms employed in this work, including selected topics in orthoses, FES, and hybrid orthoses.

The third chapter contains information about the hybrid control strategy conception, the orthosis design and introduces other components related to the project.

The fourth chapter contains the experimental results involving the overall project, the implementation of control logic and the system architectures used for the project.

The fifth chapter deals with the discussion and final considerations about the prototype developed.

The last chapter presents the conclusions about the developed orthosis prototype employing the hybrid control strategy, exposes the difficulties faced to developed the prototype, and gives suggestions on improvements that may be performed in the whole design in future works.

1.6 Publications

During the Ph.D period, the following publications on the topic were published, chronologically organized:

- RIBAS NETO, Antonio; ROHMER, E.. Development of a hybrid wearable glovelike orthosis for the forearm using tendon-driven system and functional electrical stimulation (FES), to help people with difficulty to move their hands - partial results. In: 6th Brazilian Institute of Neuroscience and Neurotechnology (BRAINN) Congress, 2019, Campinas. Journal of Epilepsy and Clinical Neurophysiology (JECN). São Paulo: Atha Comunicação e Editora, 2019. v. 25. p. 37–38. ISSN 1676-2649.
- RIBAS NETO, Antonio; FAJARDO, J.; FUJIWARA, E.; ROHMER, E.: A hybrid control strategy using tendon-driven system and functional electrical stimulation for actuation of a wearable glove-like orthosis for the forearm. In: 6th Brazilian Institute of Neuroscience and Neurotechnology (BRAINN) Congress, 2019, Campinas. *Journal of Epilepsy and Clinical Neurophysiology (JECN)*. São Paulo: Atha Comunicação e Editora, 2019. v. 25. p. 41–42. ISSN 1676-2649.

- RIBAS NETO, Antonio; DEL PORTO, M.; FAJARDO, J.; FERMAN, V.; ROHMER, E.. A wearable underactuated robotic glove driven by myoelectric control input. In: XIV SIMPÓSIO BRASILEIRO DE AUTOMAÇÃO INTELIGENTE (SBAI), 2019, Ouro Preto, MG. Anais eletrônicos [...]. Campinas: Galoá, 2019. v. 1. p. 1–6. doi: 10.17648/sbai-2019-111433.
- RIBAS NETO, ANTONIO; FAJARDO, J.; FERMAN, V.; FUJIWARA, E.; ROHMER, E.. A hybrid control strategy for tendon-actuated robotic glove and functional electrical stimulation - A preliminary study. In: 2019 IEEE INTERNATIONAL CONFERENCE ON ADVANCED ROBOTIC AND MECHATRONICS (ICARM), 4th., 2019, Toyonaka, Japan. 2019. *Proceedings* [...]. [S.l.]: Institute of Electrical and Electronics Engineers (IEEE), 2019. p. 244–249. doi: 10.1109/ICARM.2019.8834141.
- FAJARDO, J.; RIBAS NETO, Antonio; SILVA, W.; GOMES, M.; FUJIWARA, E.; ROHMER, E.: A wearable robotic glove based on optical FMG driven controller. In: 2019 IEEE INTERNATIONAL CONFERENCE ON ADVANCED ROBOTIC AND MECHATRONICS (ICARM), 4th., 2019, Toyonaka, Japan. 2019. *Proceedings* [...]. [S.l.]: Institute of Electrical and Electronics Engineers (IEEE), 2019. p. 81–86. doi: 10.1109/ICARM.2019.8834067.
- RIBAS NETO, Antonio.; DEL PORTO, M.; FAJARDO, J.; FERMAN, V.; ROHMER, E.. An underactuated wearable robotic glove driven by myoelectric control input. *Brazilian Applied Science Review*, v. 4, p. 1492-1507, 2020. doi: 10.34115/basrv4n3-060.
- RIBAS NETO, A.; FAJARDO, J.; DA SILVA, W.H.A.; GOMES, M.K.; DE CASTRO, M.C.F.; FUJIWARA, E.; ROHMER, E. Design of tendon-actuated robotic glove integrated with optical fiber force myography sensor. *Automation*, v. 2. n. 3. p. 187-201, 2021. doi: 10.3390/automation2030012.

1.6.1 Publications in collaboration

- ANDRADE, D. T. G. et al. Human prosthetic interaction: integration of several techniques. In: XIII Simpósio Brasileiro de Automação Inteligente (SBAI), 2017, Porto Alegre (RS). p. 1209–1215. ISSN 2175 8905.
- FUJIWARA, E. et al. Optical fiber force myography sensor for applications in prosthetic hand control. In: 2018 IEEE INTERNATIONAL WORSHOP ON ADVANCED MOTION CONTROL (AMC), 15th., 2018, Tokyo, Japan. 2018. *Proceedings* [...].
 [S.l.]: Institute of Electrical and Electronics Engineers (IEEE), 2018. p. 342–347. doi: 10.1109/AMC.2019.8371115.

- FAJARDO, J. et al. User-prosthesis interface for upper limb prosthesis based on object classification. In: 2018 Latin American Robotic Symposium, 2018 Brazilian Symposium on Robotics (SBR) and 2018 Workshop on Robotics in Education (WRE), 2018, João Pessoa, Brazil. 2018. *Proceedings* [...]. [S.l.]: Institute of Electrical and Electronics Engineers (IEEE), 2018. doi: 10.1109/LARS/SBR/WRE.2018.00076.
- FUJIWARA, E. et al. Design and application of optical fiber sensors for force myography. In: 2018 SBFoton International Optics and Photonics Conference (SBFoton IOPC), Campinas, Brazil. 2018. Proceedings [...]. [S.l.]: Institute of Electrical and Electronics Engineers (IEEE), 2018. doi: 10.1109/SBFoton-IOPC.2018.8610923.
- FERMAN, V et al.. Development of a novel smart crutches based exoskeleton. In: 6th Brazilian Institute of Neuroscience and Neurotechnology (BRAINN) Congress, 2019, Campinas. Journal of Epilepsy and Clinical Neurophysiology (JECN). São Paulo: Atha Comunicação e Editora, 2019. v. 25. p. 41. ISSN 1676-2649.
- FAJARDO, J. et al. A robust H_∞ full-state observer for under-tendon-driven prosthetic hands. In: IEEE/ASME International Conference on Advanced Intelligent Mechatronics (AIM), Boston, MA, USA. 2020. Proceedings [...]. [S.l.]: Institute of Electrical and Electronics Engineers (IEEE), 2020. doi: 10.1109/AIM43001.2020.9158841. (Virtual Conference).
- FAJARDO, J. et al. LMI methods for extended H_∞ filters for landmark-based mobile robot localization. In: IEEE/ASME International Conference on Advanced Intelligent Mechatronics (AIM), Delft, Netherlands. 2021. Proceedings [...]. [S.l.]: Institute of Electrical and Electronics Engineers (IEEE), 2021. doi: 10.1109/AIM46487.2021.9517617.
- GOMES, Matheus K. et al. Detection of hand poses with a single-channel optical fiber force myography sensor: a proof-of-concept study. *Automation*, v. 3. n. 3. p. 622-632, 2022. doi: 10.3390/automation3040031.

2 LITERATURE REVIEW

This chapter conducts the essential literature review to obtain a brief acquaintance with frequently employed terms in this area and others that will be employed in this work, as orthoses, exoskeletons, and functional electrical stimulation. In addition, a background on selected subjects and studies according to the interest of this work will be provided, involving wearable orthoses, neuroprostheses, hybrid orthoses and hybrid exoskeletons developed for assistance or rehabilitation, or both of them, for upper limbs.

2.1 Common terms used in this work

Before starting our discussion, it is essential to define some terms that will be used in this chapter and throughout the work. Over the years, with recent advances in robotic technology, the authors have coined and applied different terms to refer to the emerging technologies aimed at helping people with disabilities, in some of them the main difference lies only in particular details and their interpretation.

Prior to express the difference between *rehabilitation* (or *rehabilitative*) *technologies* and *assistive technologies* to promote upper limb recovery or assistance, let us consider the terms orthosis, exoskeleton, and prosthesis. A suitable definition for orthosis and exoskeleton was written by Hugh Herr as "in general, the term 'exoskeleton' is used to describe a device that augments the performance of an able-bodied wearer, whereas the term 'orthosis' is typically used to describe a device that is used to assist a person with a limb pathology" (HERR, 2009). Tucker and colleagues define *prosthesis* as "a device which supplants a missing limb," and they add that although there are exceptions, orthoses and exoskeletons typically act in parallel with the limb, while prostheses act in series with the residual limb (TUCKER et al., 2015). Slightly more elaborate definitions for orthosis and exoskeleton can be found in Schnieders and Stone (2017). Despite the fact that the definitions for *orthosis* and *exoskeleton* are apparently simple, the distinction is not all that easy in practice. Such misunderstanding arises because both of them can be devised to be assistive orthotic systems for supporting, moving or improving the functioning of disabled members due to disease or injury. In this case, the wearable structures called exoskeletons are not conceived to be used only for able-bodied wearers, but also for disabled persons. In the same way, when an orthosis is employed to support and enhance movements of impaired limbs, it is playing the role of an exoskeleton. Therefore, the terms are often used interchangeably by all authors of research on this area.

Concerning the term *rehabilitation* (or *rehabilitative*) *technology* that laypersons mistake for *assistive technology*, let us make clear some concepts regarding these technologies, which terms have stemmed from rehabilitation and assistive. According to WHO (c2020b), rehabilitation "is a set of interventions needed when a person is experiencing or is likely to experience limitations in everyday functioning due to ageing or a health condition, including chronic diseases or disorders, injuries or traumas." The aim of rehabilitation is enabling individuals to do their daily life activities; its success depends on many variables as the nature and severity of the disease (disorder, or injury), the accessibility of health and rehabilitation services, the financial conditions (poverty) of the people with disability, family support, among other things. Exercises by therapeutic means to improve the condition of physical functions, the use of electrical stimulation to activate and retrain weakened or paretic muscles of upper-limb affected by a stroke with purpose to regain coordination and dexterity are some examples of rehabilitation. Notwithstanding, sometimes, rehabilitation does not reverse or undo the damage caused by disease or trauma, but rather helps to maintain or return the individual to optimal health within the limitations imposed by the disease/injury, functioning, and well-being. Thus, in this context, rehabilitation (or rehabilitative) technology is the use of technology to help people with disabilities *restore* or *improve* a function which has been affected by a disability due to illness, injury or aging, to its former capacity or state.

On the other hand, the term *assistive* can be defined as "providing aid or assistance; *specifically*: designed or intended to assist a disabled person in performing an activity, task, or function especially in an independent manner" (MERRIAM-WEBSTER, 2020). As such, the terms *assistive device*, or *assistive technology*, may refer to any item, service, tool, piece of equipment, whether it is acquired commercially, modified, or customized, that is used to *help*, *increase*, *maintain*, or *improve* the functional capabilities of individuals with disabilities to perform activities that might otherwise be difficult or impossible (WHO, 2011). Crutches, orthoses, wheelchairs, and tricycles for people with mobility impairments, or white canes, magnifiers and talking books for people with visual impairments are some examples of assistive devices. Their availability and acquisition depend on several environmental and personal barriers, such as proximity to centers that offer these products and technology, personal income, motivation, and self-esteem. As can be seen, both rehabilitative and assistive technology are technologies which aim at helping persons with disabilities to successfully complete activities at school, home, work, and in the community.

2.2 Brief Fundamentals on Functional Electrical Stimulation (FES) for rehabilitation

As established previously, when the disability is associated with physical disabilities, rehabilitation seeks to develop compensatory strategies as well as to induce

neural plasticity and recovery. People who have had their nervous system damaged by neurological disorders as stroke or SCI, have disrupted communications between the brain and body. Such damages produce a rapid denervation of muscle resulting in weakness or paralysis, which in turn affects the movement and the ability to perform activities of daily living (ADLs). Trying to find a way to rehabilitate these individuals, investigators have tried to modify neuromuscular activity via electrical stimulation and thus to restore such functions (DOUCET; LAMB; GRIFFIN, 2012).

A wide variability of articles can be found in literature, regarding the several different methods, or modalities, of applying electrical current to modify neuromuscular activity, with purposes ranging from decreasing pain and inflammation to improving function and strength. In this work, we are interested in the aspects of electrical stimulation aimed at rehabilitation and functional purposes. For this reason, henceforth only FES will be considered, but a rough outline concerning the main types and their leading purposes is given below:

- Neuromuscular electrical stimulation (NMES): this is an ample and generic term, which authors employ to refer to repeated application of current to elicit repetitive contraction of innervated muscle by depolarizing local motor nerves; used in activation of skeletal muscle for strengthening, and for functional purposes;
- Transcutaneous electrical nerve stimulation (TENS): application of current using surface electrodes to activate peripheral nerves; typically used for the purpose of modulating pain (for pain relief);
- Electrical Muscle Stimulation (EMS): application of current using surface electrodes positioned on the skin in direct proximity to the muscles to be stimulated to generate a muscle contraction: intended for strengthening muscles;
- Functional electrical stimulation (FES): application of electrical current to directly enable a functional movement.

Extending the concept of FES to make it clearer, FES is the application of electrical current to the skin, on the nerve or over the belly's muscle of neurologically impaired individuals, to induce a muscle contraction and thereby causing movement in the muscles which are paralyzed, or partially paralyzed, in order to restore motor function. The motivation for using FES systems is to work around the injured central circuitry caused by lesion and to activate neural tissue, contracting muscles to provide function to what is otherwise a nonfunctioning limb or structure (CHAE; SHEFFLER; KNUTSON, 2008). As we will see later, the most widely use of FES in upper limbs is to perform grasp and release movements, with FES delivered by device stimulators that can be referred to as grasp-release stimulators.

The use of FES in therapy has a considerable history, and its use for stimulation traces back to 1790, when Luigi Galvani connected wires to a frog's legs and observed that the legs twitched when given a shock from the output of an electrostatic machine (CAMBRIDGE, 1977). Later, in one of the earliest clinical experiments conducted by Moe and Post in 1962 (MOE; POST, 1962), the term FES was coined to refer to the use of electrical stimulation to produce functionally useful contraction to accomplish functional tasks such as standing, ambulation, or ADL. Shortly before 1962, FES had already been used with this purpose by Liberson and colleagues in 1961 (LIBERSON et al., 1961). It was the first time FES was used for stroke rehabilitation, with the idea of lifting the drop-foot of a hemiplegic patient with a portable electronic stimulator. Since then, several studies have shown that FES, associated to the training of functional tasks, is an effective treatment in the reestablishment of motor function in upper and lower limbs of physically debilitated patients. Nowadays, thanks to advances in electronics and electrode design, FES can be administered both in clinics, by means of rehabilitation programs, and by self-treatment at home using portable stimulators, or other devices as a *neuroprosthesis* (which will be addressed below). One can say that the main goal of FES in stroke and SCI patients' upper limbs is to help recover lost hand functions, in particular the ability to reach, grasp, hold and release objects, and tremor management; in lower limbs FES meets the needs of several purposes as preventing muscle atrophy, improving the gait performance, reducing muscle spasticity, increasing muscle strength, for standing and walking, and others (BALDI et al., 1998; MANGOLD et al., 2005; RAGNARSSON, 2008; KOBETIC et al., 2009; RUPP et al., 2012; HO et al., 2014; MARQUEZ-CHIN; POPOVIC, 2020; KAPADIA; MOINEAU; POPOVIC, 2020; ALON; LEVITT; MCCARTHY, 2007; CHAE; SHEFFLER; KNUTSON, 2008; HARA et al., 2008; YOU; LIANG; YAN, 2005; GALLEGO et al., 2013a; LEE, 2020; KAPADIA; MOINEAU; POPOVIC, 2020; MARQUEZ-CHIN; POPOVIC, 2020).

As seen above, FES has several modalities which can be applied through different forms (for more details, see Chae, Sheffler and Knutson (2008) and Knutson *et al.* (2015)), although all delivering devices consist of electrodes that are connected to a stimulator, and a controller. Describing all its characteristics is outside the scope of this work, but since stimulation electrodes play an important role in interfacing the tissue with the stimulation unit, it is important to comment some aspects concerning two types of electrodes, namely transcutaneous (surface electrodes), and subcutaneous (such as implanted electrodes and (nerve) cuff electrodes). Subcutaneous electrodes use an invasive way to access the muscles for current injection; electrodes implantation needs a surgical intervention, and there exists a possibility of infection following the process, although such approach provides high stimulation specificity (MICERA *et al.*, 2010; KNUTSON *et al.*, 2015). Differently, surface electrodes (or transcutaneous electrodes) do not require surgery, and for this reason they are the least invasive; they are also the most conventional types as well, employed regularly in most studies involving FES application. Nevertheless,

due to this type of electrode being placed over skin (on the muscle surfaces), it presents the least muscle selectivity, providing selective activation only for muscles close to the surface (QUANDT; HUMMEL, 2014; HO *et al.*, 2014). Therefore, stimulation of deep muscles often requires higher stimulation current, which in turn generates discomfort, since skin receptors are also activated, and may result in simultaneous contraction of undesired muscles.

Furthermore, besides skin irritation and pain, FES systems have a chief limitation as a reaction to muscle stimulation, which is muscle fatigue (MICERA *et al.*, 2010; KNUTSON *et al.*, 2015; KOUTSOU *et al.*, 2016). Muscular fatigue arises because the recruitment order of muscle fibers by FES application is not fiber selective, occurring in opposite order rather than the natural one. Indeed, in the volitional movement, the motor units asynchronously activate the muscle fibers; first large superficial fatigable motor units are recruited, then smaller motor units, allowing a fine control of contraction from low to tetanic level. On the other hand, the electrical field created by FES technologies first activates, in a synchronous way, the same set of large muscle fibers under a stable surface electrode (and smaller fibers close to the electrode).

To deal with these two major drawbacks, there are some strategies suggested in the literature. As for the selective problem, a solution is to increase the selectivity of the surface electrodes by using electrode arrays, which can use several electrical contacts to increase selectivity (MICERA *et al.*, 2010; KOUTSOU *et al.*, 2016). Concerning muscle fatigue, several investigators have evaluated techniques to mitigate its effects. Buckmire and colleagues support the idea that muscle fatigue can be mitigated using multiple electrodes or nerve-based electrodes (BUCKMIRE *et al.*, 2018). In a broader way, Koutsou and colleagues separate the methods of precluding muscle fatigue into two approaches, (i) closed-loop control strategies to control electrical stimulator parameters, and thus modulating muscle fiber temporal recruitment, and (ii) advances in surface FES electrodes technology, as the resorting to surface arrays electrodes and cuff electrodes (nerve-based electrodes) (KOUTSOU *et al.*, 2016). In fact, regardless of the method to be used, as most FES applications do not make use of multiple electrodes or nerve-based electrodes nor the FES delivering devices employ elaborated control strategies, such troubles persist.

In view of the shortcomings mentioned above, when delivering electrical stimulation for FES, in order to reduce fatigue and discomfort, and optimize force and results, a series of parameters must be customized: frequency, pulse width/duration, duty cycle, intensity/amplitude, ramp time, pulse pattern, program duration, program frequency; and muscle group activated should be taken into account. Typically, for upper limb muscle stimulation, the stimulation frequency is in the range of 12–50 Hz, and the strength of the muscle contraction is modulated by changing either the pulse amplitude (typically 0-40 mA) or pulse width (typically $30-500 \ \mu$ s) (CHAE; SHEFFLER; KNUTSON, 2008;

DOUCET; LAMB; GRIFFIN, 2012).

Finally, in recent years investigators have been focused on a promising development that involves a hybrid combination of surface FES with an orthosis or an exoskeletal bracing. For example, for upper limbs, when reducing the amount of stimulation and it alone is insufficient to produce a specific movement, an orthosis may be used to support and facilitate hand function. In the case of lower limbs, while using electrical stimulation to facilitate standing and walking, an exoskeleton can provide stability locking, unlocking or coupling the joints as necessary to delay fatigue, or it can inject small amounts of assistive power when the stimulated responses are too weak or fatigued to complete a movement (DOLLAR; HERR, 2008; HO *et al.*, 2014). The solutions involving hybrid approaches between FES and orthosis, FES and exoskeleton, or FES and robot, for FES-induced muscle fatigue reduction are the called *hybrid orthoses*, *hybrid exoskeletons*, and *hybrid robot devices*, respectively. Both hybrid orthosis and hybrid exoskeletons utilize FES-based approaches, i.e. they are activated by FES, but usually, the substantial difference between them lies in that hybrid exoskeletons are generally designed for patients with spinal cord injuries, and hybrid orthoses are for the rest of the cases, although that is not a rule.

Regardless all efforts made until here, it seems that there is still so much to be done, and research on such approaches still is in its infancy. As a result, discovering an effective solution for the muscle fatigue problem remains an open field of investigation in which few studies are being carried out, and that is why this work is being conducted to contribute with the state of the art on hybrid orthoses.

2.3 Overview on Wearable Robotics Devices Features for Hand Assistance and Rehabilitation

In this section, we will provide a general overview on wearable robotics for hand assistance and rehabilitation, focusing our attention on orthoses. At this time, no specific project will be addressed, only the common characteristics will be pointed out, leaving that part to Section 2.4.2.

Over the last years, robots have ceased to be useful only in industrial environments and have extended to other segments. Research into new components has enabled robotics to migrate from a bulky and rigid structure to a practical, useful and flexible structure, making way for the called *wearable robotics*. Wearable robotics are advanced robotic systems characterized by appropriate shape, kinematic, and weight factors to be worn on the human body with the function of either assisting and augmenting or restoring human limb function (PONS; CERES; CALDERÓN, 2008).

Another innovation brought by these studies are the named *soft robotics*. There

are a couple of definitions for soft robotics in literature, but in general lines, soft robotics are biologically inspired systems/machines, capable of autonomous behavior, that are primarily composed of materials with compliance similar to biological materials (MAJIDI, 2013; RUS; TOLLEY, 2015). This novelty also helped to bridge the gap between machines and people, allowing robotics to be worn by humans. Despite the terms having a reasonably difference in concepts, most authors make use of them without distinction; it is very common to find expressions such as *soft wearable glove*, *soft exoskeleton*, *soft robotic hand exoskeletons*, and *wearable soft-robotic glove*, to name but a few.

Currently, projects combining wearable robotics, soft actuators and flexible textile materials are used to develop wearable and soft robotic devices. When regarding robotic devices for assistance and/or hand rehabilitation, as can be seen in Maciejasz *et al.* (2014), Chu and Patterson (2018) and Shahid *et al.* (2018), wearable robotics and soft robotics are being applied in many studies and hold promise as a solution to be used by patients suffering from devastating motor deficits caused by brain injury and neurological diseases. These up-to-date robotic inventions operate alongside human limbs and are present in exoskeletons, exosuits and in wearable robotics orthoses, both of them being the interfaces for human–robot interaction, playing an important role in the development of rehabilitative and assistive robotic devices.

There are a considerable number of characteristics related to wearable robotics orthoses, and organize all that information in an intelligible way is not an easy task. For the purpose of use in this work, Fig. 2.1 has a big picture of the main characteristics involving wearable robotics systems for hand assistance and rehabilitation — for the sake of simplicity not all features were pointed out.



Figure 2.1 – General picture of wearable robotics for hand assistance and rehabilitation.

Source: Elaborated by the author, 2020.

As seen in Fig. 2.1, we can separate wearable robotic orthoses into two cate-

gories, conventional orthoses and hybrid orthoses. Leaving aside those traditional, static, rigid splints to restrict motion, conventional orthoses here refer to dynamic cutting-edge mechatronic devices, composed of a powered structure whose purpose is to assist task accomplishment, and help to restore lost or weak functions, generally following a disease or a neurological condition. Hybrid orthoses are a kind of orthosis encompassing all the conventional orthoses' characteristics, but besides the powered structure, they are increased of a FES module for helping to perform the tasks that conventional orthoses are developed for. Both conventional orthoses and hybrid orthoses can be employed to assist and rehabilitate upper or lower limbs. As for the FES method delivered in hybrid orthoses, it can be fixed, when it is simply turned on or off for a given amount of FES, or proportional to muscle activity. For example, surface electrodes can pick up the electromyography (EMG) signal from muscle and stimulate the target muscle in proportion to an integrated signal, and then the orthosis induces greater muscle contraction because electrical stimulation is proportional to the EMG signal.

Concerning the type of assistance that an orthosis provides when performing a task or in a rehabilitation program, two sorts of orthoses stand out, active orthoses and passive orthoses. An active orthosis is a device that provides some sort of active motion assistance to assist limbs movement via at least one actuator, for example reaching and grasp in the case of upper limbs. In contrast, *passive orthoses* are devices that do not move the limbs, but may resist the movement when exerted in a not defined path, or in a wrong direction, through the use of parts as springs or brakes. The main difference between them is that active orthoses may be used by subjects completely unable to move their limbs, whereas in the case of passive orthoses the subjects must be able to move their limbs to a certain extent. It is worth mentioning that movements in which subjects do not perform any effort result in no functional improvements. Another comment is that in the case of hybrid orthoses using FES, a combination of active-passive (or semi-active) assistance can be reached, in which a structure comprised of rigid components or a brake can support movement and hold the limb in the position once the target position is achieved with FES, and thus enabling the muscles to relax and preventing fatigue. In these hybrid systems, an assisted-as-needed control strategy, or a shared control methodology must be implemented for managing such assistance. Additional information upon other types of assistance and modes can be found in Maciejasz et al. (2014), Resquín et al. (2016), Chu and Patterson (2018), Zhang et al. (2018), and Dunkelberger, Schearer and O'Malley (2020).

Prostheses, exoskeletons or orthoses need a means by which their behavior can be controlled accordingly with human's goals and intents. The way for controlling such devices is through detecting the user intent. There are several ways to detect the user's intention, the main ones are pointed out in Figure 2.1. Limiting our scope to upper limb orthoses, the main control inputs may vary from simple and cheap to complex and expensive. Currently available technologies include key/button press mechanisms, bending/flex sensors (for wrist flexion detection, for example), surface electromyography (sEMG), optical fiber, electroencephalography (EEG), and many others, as force myography (FMG), eye tracking system, brain-computer interface (BCI) or brain-machine interface (BMI), and voice commands. Key/button and bending/flex sensors are the simplest and cheapest methods, by contrast EEG systems are one of the most complex and expensive ones. One can say that the way employed for detection generally depends on the residual capabilities of the user, but this is not a rule to be followed in all cases. For instance, in cases of SCI, if the user has some volitional control of their arm muscles, sEMG signal from volitionally-controlled muscle(s) can trigger an orthosis; with respect to individuals with complete muscle function loss, brain-computer interfaces have also been explored to allow users to control arm movements by observing electrical activity in the brain (DUNKELBERGER; SCHEARER; O'MALLEY, 2020). According to Chu and Patterson (2018), the most common control input is sEMG due to its trade-off between reliable signal acquisition and ease of implementation. Optical fibers also are an auspicious method to be employed for user intent detections; and few works have been drawing on such technique. Alternatively, more than one way can be combined in the same project, producing a multi-modal approach (FOUGNER et al., 2012). For example, flex sensors and pressure sensors can be used along with sEMG to control an orthosis, or sEMG combined with voice recognition. For a broader overview comprising other user intent detection methods, we suggest the reader to see Maciejasz et al. (2014), Chu and Patterson (2018), Gull, Bai and Bak (2020) and Rzyman *et al.* (2020).

Both conventional and hybrid active devices considered until now are chiefly actuated by a type of power source belonging to one of the three categories, electrical, hydraulic or pneumatic actuators. Electrical actuators are most common because of their ease to provide and store electrical energy as well as their relatively higher power (MACIEJASZ *et al.*, 2014), followed by pneumatic actuators, which have been gaining prominence with the spreading use of the soft robotics technology. Each one of them has its advantages and disadvantages, and for a more detailed analysis over actuators, the reader is referred to Maciejasz *et al.* (2014), Gopura *et al.* (2016), Shahid *et al.* (2018) and Dávila-Vilchis *et al.* (2020). In the case of pneumatic or hydraulic actuators, in most situations, they can be attached directly to the limb that is desired to be actuated. On the other hand, in projects involving electrical actuators, a power transmission method may be needed, for example tendon/cables systems, linear actuators, and others. A great variety of exo-gloves and exoskeletons utilize linear actuators or Bowden cable systems for supplying assistance for executing ADLs to theirs users.

As pointed out before, here, once again the concepts involving the wearable structures – active (or powered) orthoses and exoskeletons – overlap. The active orthoses conceived to be assistive devices for helping people with disabilities match with exoskeleton developed to assist people with the same condition. Thus, although the features above are related to wearable orthoses, exoskeletons also share most of them (for more information on exoskeletons see Heo *et al.* (2012), Gopura *et al.* (2016) and Gull, Bai and Bak (2020)).

Finished here our overview on the main features of wearable robotics devices for upper limbs, in what follows, selected projects previously linked with this research proposal and their basements will be selected.

2.4 Related Work

From now on, we will be concerned with studies dealing with soft wearable robots for upper limbs, whose projects are intended to assist in performing ADLs and also for rehabilitation of hand movements. Henceforth, attention will be given to some relevant approaches related to this research proposal, chosen arbitrarily. These approaches will include devices, underactuated or not, which make use specifically of tendon-driven systems as power transmission method, but other selected works which do not make use of those systems are also considered, whenever necessary.

This section is separated into three subsections, the first comprising devices purely using FES for assisting ADLs and rehabilitation of upper limbs, the second discusses selected wearable tendon-driven orthoses with features resembling those in this work, and the third considers hybrid orthoses and hybrid exoskeletons for hands.

2.4.1 Neuroprostheses (NPs) for assisting ADLs and rehabilitation of upper limbs

As seen in section 2.2, there are several distinct modalities for applying electrical current in restorative therapy, though all of them use a device responsible for furnishing the conditioned signal of electrical current, which can be provided from a versatile bench, a portable stimulator, or any other devices. Due to being marketed devices, versatile benches and portable stimulators are the most known, and are more commonly found in clinics and rehabilitation centers, for general purposes. Other devices that delivery FES for facilitating a specific movement, as grasp and release motions, are referred to as *neuroprostheses* (NPs) (POPOVIC; TOMOVIC; SCHWIRTLICH, 1989).

Usually, the use of FES as a neuroprosthesis (NP) consists of self-treatment at home by means of a neuroprosthetic neuromuscular stimulation system, and for this reason, the primary intent of an NP is to enable patients to execute functional tasks with the affected upper limb while using the device as part of routine daily living (KNUTSON *et al.*, 2015; CUESTA-GÓMEZ *et al.*, 2017). For such applications, these devices must generate at least two grasp patterns, namely the lateral grasp also called key grip or pinch
grasp, and the palmar grasp called cylinder grip or power grasp (RUPP *et al.*, 2015). In the same neuroprosthetic device, a robotic orthosis for example, multiple technologies can be integrated to enable the mobility of hands, as brain–computer interface (BCI) for decoding the type of movement/grasping (input), FES to activate the hand muscles (output), and a control algorithm (e.g. artificial intelligence) to manage and combine all command input or input information and achieve shared control of the arm's movement (KILGORE, 2016; BITBRAIN, c2018).

Some of the first NPs using FES for grasp-release function were developed in the 1990s, to be used for people with hand disabilities (IJZERMAN *et al.*, 1996; PROCHAZKA *et al.*, 1997), followed by other projects employing electrical stimulators to produce the same movements (THORSEN; SPADONE; FERRARIN, 2001; POPOVIC; POPOVIC; KELLER, 2002; MANGOLD *et al.*, 2005). NPs for upper limbs can be separated essentially into two types, those that employ implanted electrodes (percutaneous stimulation), and those that make use of surface electrodes (transcutaneous stimulation). In what follows, we will discuss some selected types of NPs, starting with three well-known NPs, the FreeHand[®] system, the Bionic Glove, and the Handmaster system. Afterwards, at the end of this section, we will provide a list of selected references comprising additional information about these and other NPs.

FreeHand[®] system is the most known NP for grasping with implanted electrodes (PECKHAM *et al.*, 2001). Designed to be used by people with quadriplegia as a result of a spinal cord injury (at the C5 and/or C6 level), a first generation of this device consisted of stimulators implanted in the user's chest, and the electrodes were positioned on the motor points of the arm and hand muscles (see Fig. 2.2a). The system provided two types of grasp patterns: lateral pinch, in which the thumb closes against the side of the index finger, as when holding a key; and palmar grasp, in which the index and long fingers close against the thumb, as when holding a glass. It provided unilateral hand grasp by using contralateral shoulder movements to generate control signals. One disadvantage of this system was that users had to have some use of an upper arm or shoulder. A second-generation of the Freehand[®] system was also developed (see Fig. 2.2b), eliminating the need for the external shoulder position sensor (KILGORE *et al.*, 2005). Despite the good results with patients, the system was discontinued due to the high costs of implanting (and repairing) multiple electrodes, cables and stimulator systems (LAWRENCE, 2009; HO *et al.*, 2014).

The Bionic Glove, one of the first NPs employing surface electrodes, was a grasp-release FES device developed by Prochazka and colleagues in the University of Alberta in the 1990s (PROCHAZKA *et al.*, 1997). The fingerless glove was designed to operate as a tenodesis grasp enhancer, improving the function of the paralyzed hand after SCI, and later modified for people with stroke (see Fig. 2.3a); it could be used only by patients with sufficient wrist control. When the glove was donned, noninvasive FES sensors

Figure 2.2 – The implantable NP FreeHand[®] system.

(a) FreeHand system with motion sensor in contralateral shoulder.



Source: Adapted from Peckham et al. (2001).

(b) FreeHand system without shoulder sensor.



Source: Adapted from Peckham and Knutson (2005).

came into contact with the skin, and the signals coming from the glove detecting voluntary wrist movement were used to control FES of muscles either to produce hand-grasp or to open the hand. In this project, three channels of electrical stimulation to stimulate finger flexors, extensors, and thumb flexors were used. The stimulation was triggered via push-buttons on the controller (a control box), and the control signal came from a wrist-position sensor (an inductive linear variable displacement transducer (LVDT)) mounted in the garment (see Fig. 2.3b). One major advantage of the system was the easy donning and doffing of the glove, although as disadvantage, its use was limited to wearers with active extension of the wrist, because the stimulation was controlled by means of an integrated wrist position sensor. Despite these clinical success, the device was subsequently discontinued, and superseded by an evolved device called the Rehabtronics wireless triggered hand stimulator, as shown in Fig. 2.3c) (PROCHAZKA, 2018).

The Handmaster NP (see Fig. 2.4a) is other project involving surface electrodes for FES. Created by NESS Ltd., Ra'anana, Israel (IJZERMAN *et al.*, 1996), this device combined a wrist-hand orthosis to provide stabilization with muscle activation of the paralyzed forearm and hand via integrated surface electrodes (SNOEK, 2005). The Handmaster device was a safe non-invasive hybrid NP which had been developed for therapy and restoration of hand function to the paralyzed upper limb in selected subjects with C5 or C6 SCI (tetraplegia), stroke, and brain injuries (ALON; MCBRIDE, 2003). The control unit allowed the user to select from among 2 exercise modes (which provided repetitive stimulation to the targeted finger and thumb extensor and flexor muscles, in order to improve strength and muscle condition) and 3 functional modes (grasp, key-grip and hand open). This NP was controlled with a push button that triggered the hand opening and closing function. Currently, the system underwent a slighty update, including a version with wireless configuration (see Fig. 2.4b), and it can be found by Figure 2.3 – The NP Bionic Glove; in (b) the illustration indicates the position of electrodes, sensor and controller in different perspectives, and further to the right, details of voluntary wrist flexion and extension for gripping and releasing a cylindrical object, respectively (tenodesis grasp and release, from up to down).



the name NESS H200, available in the United States through BioNESS Inc., Valencia (CA), <<u>https://www.bioness.com/NewsMedia/Media_Gallery/H200.php</u>>. One of the advantages of the Handmaster is that it is very easy to put on (donning) and to take of (doffing).

After these works, other grasping NPs utilizing traditional transcutaneous electrodes emerged. These grasp-release stimulators employed different man-machine interfaces by which the users could control the FES device. One of them, the ETHZ-ParaCare NP was designed to improve grasping and walking functions in SCI and stroke patients (POPOVIĆ *et al.*, 2001). It was one of the first portable and programmable surface stimulators, projected to satisfy the requirements for EMG controlled NPs (see Fig. 2.5a). Originally designed for C5 complete SCI subjects, it could also be used by subjects with lower level lesions, such as C6 and C7 complete SCI subjects; or C5 and lower lesion incomplete SCI subjects. When used in upper limbs it could generate either a palmar or a lateral grasp, but not both. The system could be controlled with proportional EMG, discrete EMG, push button, and sliding resistor control strategies. One of the main disadvantages of this system was that it required between 7 min and 10 min to don and doff it (POPOVIC; POPOVIC; KELLER, 2002). This problem was addressed with the development of a glove that housed the stimulation electrodes and the command sensors (see Fig. 2.5c). The software of ETHZ ParaCare and the hardware platform available with

Figure 2.4 – The Handmaster NP and its evolution.

(a) The Handmaster system consists of a spiral wristextension splint housing the electrode array which was connected to the control unit by a thin flexible cable.



Source: Snoek (2005).

(b) The H200[®] wireless system: (1) lightweight orthosis, (2) wireless handheld control unit.



Source: Bioness Inc. (2012).

Compex SA, Switzerland, resulted in a commercially available device called the Compex Motion (see Fig. 2.5b) (KELLER *et al.*, 2002).

In 2007, Knutson and colleagues (KNUTSON *et al.*, 2007) devised a system to conduct experiments concerning contralaterally controlled functional electrical stimulation (CCFES). The CCFES is a treatment aimed at improving recovery of volitional hand function in patients with hemiplegic stroke. With an instrumented glove (the command glove) worn on the strong hand (the non-paretic hand), the patient controls the intensity of electrical stimulation to the paretic hand via volitional opening of the non-paretic hand. The stimulator delivers up to 3 independent monopolar channels of biphasic current, each channel providing proportional intensity of stimulation in response to an analog input

- Figure 2.5 The portable FES systems for grasping: ETHZ-ParaCare stimulator and the Compex Motion stimulator.
 - (a) The portable FES system ETHZ-ParaCare.



Source: Popović et al. (2001).

(b) The Compex Motion stimulator with the EMG electrodes, the data cards and the stimulation electrodes.



Source: Popovic, Popovic and Keller (2002).

(c) Patient with the neuroprosthesis for grasping: palmar grasp (left) and lateral grasp (right).



Source: Popovic and Keller (2004).

from three bend sensors attached on the dorsal side of the index, middle, and ring fingers of the non-paretic hand. For additional information regarding CCFES, we suggest Knutson *et al.* (2012).

More recent, other sophisticated prototypes of NPs with enhanced capabilities for implementation of control algorithms and for interfacing sensors were also developed for research purposes. Gallego and colleagues developed a NP for tremor management through the control of muscle co-contraction (GALLEGO *et al.*, 2013a; GALLEGO *et al.*, 2013b). The NP applies forces to the tremulous limb through transcutaneous neurostimulation with the purpose of co-contracting the affected muscles and then altering the inherent low pass filter properties of human muscles, attenuating the tremor, without affecting the concomitant voluntary movement. Fig. 2.7 has an image of the NP prototype and a plot with the representation of the tremor attenuation when the NP is switched on. The NP has a multimodal interface comprising EEG, sEMG, and MEMS (Micro Electro Mechanical Systems) inertial sensors (solid state gyroscopes), that manages when FES is triggered. Figure 2.6 – (a) The CCFES consists of a stimulator, a command glove, and surface electrodes. The command glove is a bike or batting glove with the three bend sensors attached to the glove with Velcro straps. (b) Volitional opening of the non-paretic hand produces a proportional intensity of stimulation to the paretic hand extensors with an intensity that is proportional to the degree of opening of the glove. The system enables patients with hemiplegia to practice tasks.





Source: (a) Knutson *et al.* (2015); (b) Knutson *et al.* (2007).

For further information concerning these and other types of neuroprostheses, in addition to the references already cited, the reader is referred to Thorsen, Spadone and Ferrarin (2001), Peckham *et al.* (2001), Popović *et al.* (2001), Popovic, Popovic and Keller (2002), Alon and McBride (2003), Peckham and Knutson (2005), Mangold *et al.* (2005), Kilgore *et al.* (2005), Ragnarsson (2008), Micera *et al.* (2010), Ho *et al.* (2014), Venugopalan *et al.* (2015), and Ajiboye *et al.* (2017).

In spite of the fact that the use of these neuroprostheses appears to have a positive impact on subjects' lives when applying to perform ADLs functions, such technology has several drawbacks. As previously commented, because most them are purely FES-based devices, to a given degree all these systems share the same problems: somewhat limited muscle selectivity, increased rate of muscle fatigue, and complexity in application due to the problems with positioning of the electrodes (mainly at a very early stage of primary rehabilitation) (MICERA *et al.*, 2010). In the most critical case, the implanted electrodes, the system provides more selectivity than the stimulation with the surface electrodes, however in case of a system failure, the subject with the system would require a major surgery in order to restore the system's function (POPOVIC *et al.*, 1998). Furthermore, to make things worse, the access to the devices are limited because mostly they are not commercially available, and many devices are only available in clinical trials Figure 2.7 – NP for tremor management. (a) The concept design envisioned the NP as a textile substrate that integrated the neurostimulation electrodes, the gyroscopes and the control electronics, (b) the final prototype, and (c) example of the controller of the NP actuating on tremor: solid line is the estimation of tremor, dashed line and dotted line are the amplitude of the current applied at the extensors and flexors, respectively. The instant at which the NP was triggered is signaled with an arrow.



Source: Adapted from Gallego et al. (2013b).

in specialized rehabilitation centres. Besides, the overall cost of commercially available devices continues to be expensive (CONNOLLY *et al.*, 2014). For example, the NESS H200[®] (formerly Handmaster) is the only commercially available upper limb device using surface FES, and its price is close to the thousands of dollars, which presents a barrier to its widespread use.

In addition, in cases of subjects that have weak residual muscle activity, a device providing only FES may not be enough to generate forces and movement to perform ADLs as eating or grooming. For example, for many people with SCI, FES alone is not sufficient to restore reaching and grasping movements. Moreover, individuals with weak shoulder function cannot support their own arm weight. In cases such as these, a mechanical system can be developed to provide some support, an orthosis, an exoskeleton, or an anti-gravity support mounted on the wheelchair, for instance, which combined with electrical stimulation can produce sufficient force to effectively contribute to the achievement of ADLs.

For the reasons aforementioned, the demand for devices more affordable is high, which leverages investigators to seek for devices that may fill these shortages. Thanks to the advances in robotics, several devices for assistance and rehabilitation are under development to try to overcome these limitations. Projects combining soft/wearable actuators and flexible textile materials are being used to develop soft/wearable robotic devices comprising wearable robotics gloves, exoskeletons, and also hybrid assistive systems, called *hybrid neuroprostheses*. The hybrid neuroprostheses consist of a combination of FES and an orthosis (as a glove-like garment) with actively driven structures (RUPP *et al.*, 2015). These hybrid assistive systems merging FES and externally powered and controlled brace are more commonly referred to as *hybrid orthoses*, or *hybrid exoskeletons*. Some selected

works involving wearable robotics gloves are considered in the next section, and hybrid orthoses (or some hybrid exoskeletons) will be covered in Section 2.5.

2.4.2 Wearable robotics orthoses projects for hand assistance and rehabilitation using tendon-driven systems

To help to alleviate the burden of recovery and rehabilitation from physiotherapists, over the past 20 years several investigators have developed a broad range of wearable robotics orthosis and exoskeletons for upper limbs for providing assistance to perform ADLs and by some way to promote rehabilitation. Boosted by advances on robotics, electronics and new components, research on wearable robotics devices for assistance and rehabilitation for hand boomed, opening up a whole gamut of new opportunities for designing such devices aimed to help disabled people. If you google terms such as "wearable robots", "exoskeletons for hand", or "soft robotics glove", a huge amount of files such as papers and figures will pop up on the screen. As commented in section 2.3, due to this massive quantity of information and different approaches, separate and classify the projects involving wearable robotics orthoses for hand assistance and rehabilitation would be a mammoth task. However, an overview comprising the main features of these devices was illustrated in Fig. 2.1.

We can affirm that current devices available for hand rehabilitation are composed of either glove-like orthoses or hand exoskeleton systems. When compared to hand exoskeleton systems, wearable robotics gloves can be made lighter and more compact, in a way that they can be worn and used comfortably. Moreover, when it comes to exoskeletons having rigid mechanical links, this leads to an undesirable result because they need to be well aligned with human joints, what in turn often leads onto a bulky structure.

Based on the mechanical design and the type of actuation of a robotic glove, in what follows, we will focus our attention to wearable robotics designs that make use of tendon-driven systems as a power transmission method to execute flexion and extension movement of hand's fingers. Nevertheless, in this category there are many devices. Therefore, we will consider some examples of devices, arbitrarily selected based on two criteria: (1) devices whose actuators are located on the hand, or near it, as on the forearm, and (2) devices with actuators remotely placed, such as attached to the waist, into a backpack, or fixed in a structure, like a bench or a wheelchair. It is worth commenting that when using tendon-driven systems it is possible to locate actuators remotely, what diminishes the weight of these wearable devices. Another comment is that we will not coin or use any new terms other than the same terms and names that authors employed in their works. We will close this subsection with two examples in which authors improved the devices' projects.

In 2013, Delph II et al. (2013) created a soft robotic glove intended for stroke rehabilitation, with integrated sEMG sensing to aid in the movement and coordination of gripping exercises (see Fig. 2.8 (a)). This glove utilized a Bowden cable system to open and close a patient's hand, actuating independently all five fingers using position or force control (regulated through motor current). The hand movement could be controlled in terms of three different control modes: switch interface, programmed finger position, or using sEMG, this latter having the ability to provide active resistance or assistance, that is, it makes the glove provide a resistive force opposing the opening or closing of the hand against the users intended movement. Kevlar[®] cables were used as tendons, actuated by servomotors (one for each finger), mounted in a backpack including battery power sources. The Kevlar[®] cables were fed through polyethylene tubing and the system is capable of generating a maximum 15 N grip force. As for safety issues, a pin was implemented that can be pulled in case of a sudden need, breaking the connection between the cables coming off the hand and the cables that are being actuated from the servos, preventing in this way finger hyperextension and hyperflexion; each spool is also limited by the rotation and the servo was designed to operate within these parameters.

Figure 2.8 – (a) Soft robotic glove with integrated sEMG sensing created by Delph II et al. (2013); (b) empowered wearable soft glove by Xiloyannis et al. (2016); (c) CADEX glove from Kim and Park (2018); and (d) wearable assistive soft hand exoskeleton developed by Bützer et al. (2020).



In 2016 Xiloyannis and colleagues presented the design and modelling of a tendon-driving unit for empowering a wearable soft glove (see Fig. 2.8 (b)) (XILOYANNIS

et al., 2016). Exploiting the concept of hand postural synergies, the authors employed only one motor to move 8 degrees of freedom of the hand (flexion/extension of the thumb, index and middle fingers). A Bowden cable transmission, with Teflon-coated steel cables (Sava Industries, \emptyset 0.686 mm) and Teflon-lined sheaths, was used to locate the motor on a belt or in a backpack. To wind and unwind the cable, a feeder mechanism comprised of an array of three pairs of spools was developed to actuate the fingers in a way that the retraction of the agonist causes release of the antagonist. Such device avoids the slacking of the cable, prevents derailing of the tendons, and eliminates the need of pre-tensioning them. In addition an electromechanical clutch was used to lock the system and unload the motor, for power saving during static posture. No information about weight, the method used for user intent detection or safety issues was provided.

In 2018, Kim and Park devised a cable actuated dexterous (CADEX) glove for rehabilitation of the hand for patients with neurological diseases (see Fig. 2.8 (c)) (KIM; PARK, 2018). The CADEX glove consists of a soft silicon-fabricated exotendon glove, tendon sheath (Teflon tubes), and actuating module. Although the CADEX glove assists only the movements of two fingers (the index and middle fingers actuated together) and the thumb (actuated separately), it has 7 exotendons (Dyneema wires with a line thickness of 0.19 mm) actuated by 7 servomotors. The exotendons are carefully affixed to the glove's structure to provide dexterity, especially dexterous motion for the thumb. CADEX glove also has stretchable parts in order to accommodate various hand sizes, and plastic beads connected to the end of the exotendons and cables for limitating the stroke of the exotendon actuation. The weight of the soft exotendon glove is 120 g and the exotendon force can reach up to 12 N. No information about the method used for user intent detection was informed, but authors expressed interest in including a way that could use bio-signals, such as EMG, for this purpose, in future works.

In a recent publication, a research team of ETH Zürich and Kyushu University, presented the design of RELab tenoexo, a fully wearable assistive soft hand exoskeleton for daily activities (BÜTZER *et al.*, 2020). Authors adapted a previous developed three layered sliding spring blade mechanism (ARATA *et al.*, 2013) to be worn as an exoskeleton on the dorsal side of the fingers whose final displacement results in the motion that mimics flexion/extension of a human finger. RELab tenoexo consists of a hand module with two actuated degrees of freedom and passive thumb opposition (see Fig. 2.8 (d)), and a backpack (for storing motors, electronics, and battery). The backpack is connected to the hand module through a modified Bowden-cable-based force transmission system which makes use of steel wires (tendons) as ropes (HOFMANN *et al.*, 2018). The design combines features of rigid link structures and soft mechanisms for actuating all five fingers: index, middle, ring and little fingers are connected mechanically and they are actuated together for generating flexion/extension movements; the thumb is actuated to produce flexion/extension motions, but it is also endowed with a manual rack and pinion mechanism

that allows abduction/adduction position, and this way to allow the four most frequently used grasp types (palmar pinch, medium wrap, parallel extension, and lateral pinch). The hand exoskeleton is controlled using a control board with several status LEDs for feedback, two push buttons for user intention detection (to trigger the opening and closing of the hand exoskeleton), a sliding potentiometer to manually adjust and control the desired force levels for flexing and extending, and a slide switch to select different actions depending on the control mode (three of them), for example between the "full hand grasp" condition, that allows all the five digits flex and extend simultaneously for opening and closing the hand, and "thumb only grasp" condition, which provides lateral grasps, being by default all the fingers flexed and only the thumb flexes and extends upon the command from the trigger. To control the hand exoskeleton, measurements of the overall bending angle of the Bowden cables obtained from a third cable (a sensing wire), a dynamic feed-forward-friction compensation model, and the desired force set from the control board are took into consideration, and henceforth to calculate the required motor torque to permit RELab tenoexo grasp adaptation to the object to be grasped. RELab tenoexo can be also controlled with the Myo armband (RYSER et al., 2017). Moreover, the modular device RELab tenoexo offers three different types of fixations to the hand and fingers that can be chosen according to the user's preference. The hand module weights 148 g and the backpack 730 g.

Other projects concern wearable robotics orthoses with cable systems located in the hand or forearm. In 2014, Lee, Landers and Park (2014) developed a biomimetic device (see Fig. 2.9 (a)), the Biomimetic Hand Exoskeleton Device (BiomHED), to assist patients in producing complex hand movements with a limited number of actuators. BiomHED is a controlled cable-driven exoskeleton-type device that is worn as a glove, and actuated by exotendons that mimic the geometry of the major tendons of the hand, expected to enable effective "task-oriented" training of the hand post-stroke. To transmit tension to the exotendons, seven light-weight brushed dc motors with gearheads were placed on a forearm brace designed to be worn by subjects. For each finger (index, middle, ring and little), four cables (SAVA1024, Sava Industries Inc., Riverdale, NJ, USA) were routed through custom thermoplastic guides (thickness 4 mm) attached to the dorsal and palmar aspects of the glove (see Fig 2.9 (a)) such that tension applied to each of these cables produced coordinated finger movements. The thumb is controlled by four cables that replicate the anatomical structure of the four thumb muscle-tendon units. There is no information on which motor drives each finger. Since the authors were concerned about evaluating system performance whether it was capable of reproducing the distinct joint coordination patterns of human muscle-tendon units or not, no volitional control of the device was taken into consideration. No additional information regarding safety was provided in the work, other than that in Lee, Landers and Park (2013), which mentioned that the motors' torques are monitored and the system will turn off if excessive joint torque is detected or

an emergency switch is pressed. The entire forearm apparatus including motors and the brace weighs less than 1 kg. In a later work, the design of a feedback control system for controlling posture of the finger is under research (KIM; LEE; PARK, 2014).

Figure 2.9 – (a) The BiomHED device (LEE; LANDERS; PARK, 2013); (b) the soft robotic glove of Biggar and Yao (2016); (c) the GRASPY glove (POPOV; GAPONOV; RYU, 2017).



Afterwards, considering a principle of suction-based gripping inspired by how an octopus is capable of wrapping around objects, Biggar and Yao (2016), used two-layered rubber gloves to developed a cable-driven soft and wearable robotic glove as shown in Fig. 2.9 (b). Suction cups (a silicone-rubber compound) were passed through cuts into the inner rubber glove, on the palmar side (phalanges of the fingers) to hold the glove to the user's hand during action while a vacuum between this inner and the outer rubber glove ensures tight fit of the glove by extracting air between the layers and the skin. The suction cups also serve as anchor points and guides for the cables which are threaded through them inside a series of segments of plastic tubing. Plastic caps were fixed at the fingertips to anchor the end of the cables. Three fingers (thumb, index and middle) were chosen to be actuated by three micro motors with pulley, with one for each finger, wind and unwind the cables responsible for closing the hand. Finger extension is powered by an elastic band that is stitched onto the back of the hand, enabling the fingers to quickly extend back to their initial position as soon as motor's reverse setting is selected to slacken the cable. The motors are placed on an arm plate (shin guard) that can wrap around the wearer's forearm, and also have the control on-off-on switches attached to it. The small air pump is connected to the glove by rubber tubing, and its end is glued by rubber cement into a position between the inner and outer gloves; the vacuum pump is away separated from the rest of the glove to reduce the total worn weight of the wearer's arm. Finally, there is

neither information about the generated force by the glove nor about the type of cable used in the project.

The GraspyGlove (see Fig. 2.9 (c)) is an underactuated cable-driven glove-type exoskeleton, conceived by Popov, Gaponov and Ryu (2017) to satisfy the requirements of portability and high power-to-weight ratio simultaneously, having one of the highest power-to-weight ratio amongst the existing portable systems for hand assistance. The glove is capable of performing both a precision grip and a power grip, and it does not impose any constraints on the mobility of other joints of the arm, as the wrist. Such performance was reached allocating the motors directly on a light rigid plate on the dorsal side of the hand, what makes it direct motor placement and improves transmission efficiency. For this reason, motors transfer the force by low-friction cables (Dyneema, low-friction lines \varnothing 0.6 mm) without the use of any intermediary mechanisms to route the tendons, such as Bowden cables. This arrangement preserves full mobility of the wrist, does not require any type of mechanism to transfer the motor energy to the fingers which in turn decreases the power losses in transmission and allows smaller, less powerful motors, but on the other hand the main drawback is that the motors increase the weight of the overall wearable device. Due to the motor being placed on the dorsal side of the hand, the cables need to be routed from the actuators travelling to the palmar side around both sides of the hand, via sheaths. Excluding the little finger, all the other fingers are supported in flexion and extension motions by respective bidirectional actuators, that is, each single motor (a total of 4 motors) supports both flexion and extension per finger, and when a motor starts to rotate, one tendon wraps around a capstan while the other one unwinds from it, which results in the flexion or extension of the finger. The capstans were used in the motor to prevent slack in the cables, consisting of two interconnected cylinders designed accordingly with finger kinematics through a customization process, resulting in capstans with different diameters for each cable. For user intent detection, Graspy Glove has installed an infrared distance sensor at the palmar side of the wrist, and an additional flex sensor was attached at the little finger inside the glove, this later used for stopping, opening and closing the hand at any time by flexing or extending wearer's little finger. Graspy Glove also has push buttons installed at the tip of every finger and the thumb for stopping grasping motion when the grasped object exerts enough force to press it. Further, the angles between the phalanges are measured by using resistive flex sensors. The maximum pinch force provided by the device was experimentally measured to be 16 N, and the weights of the wearable part and the whole system are 250 and 340 g, respectively.

In 2018 Park *et al.* (2018) presented a multimodal underactuated wearable exotendon hand orthosis to be worn for patients whose input control signals may be inherently abnormal signals, as those present in stroke patients (see Fig. 2.10 (a)). In the previous work (PARK *et al.*, 2016), authors investigated the capability of a single-actuator device mounted on a forearm splint to assist whole-hand movement patterns through a

network of exotendons (tendons routed on the surface of the hand) driven by linear electric actuators, causing flexion and extension movements to the digits, except for the thumb. No information on user intent detection was provided. In a second version, Meeker *et al.* (2017) implemented a single sensing modality using an EMG sensor (Myo Armband) placed on the forearm to predict the user's intended hand state, and a push button was considered for directly controlling the wearable orthosis in some experiments. In this second version only finger extension movements are supported by the orthosis. In the last version (2018), the multimodal approach comprises the following sensors: the EMG sensor (Myo Armband); a encoder for motor position measurements so as to provide information about combined finger movements; a pressure sensor (force sensitive resistor (FSR)) was installed at the thumb's fingertip to detect interactions between the subject and any grasped objects; and bend-sensitive resistors attached to the dorsal side of each finger (index, middle, ring and little fingers) to measure joint flexion and acquire information about user intent. Still making use of one actuator to move all the fingers, index, middle, ring and little fingers are actuated using one exotendon for each finger, generating fingers extension movement, whilst thumb has two exotendons for adjusting the thumb's abduction and extension movements. Here again, only fingers' extension is provided by the orthosis. As for the device's weight and safety issues, in the 2016's version, authors employed a mechanical coupling including permanent magnets for connecting the motor and exotendons, which disengages when tendon forces exceeded the maximum load supported by the magnets, and the device's weight was not informed; in the 2017's version the tendons on each finger were attached to a cloth ring on the middle phalanges rather than on the fingertips to avoid finger hyperextension, and the device weighs 135 grams; finally in the 2018's orthosis, the components that serve as an anchoring point for the tendons prevent hyperextension of the distal interphalangeal (DIP) joints, and no information about weight was provided. In both designs, authors were concerned with evaluating features related to design feasibility of a wearable orthosis for finger extension movements for stroke patients with a single actuator. Therefore, there is neither information about the generated force for grasp by the gloves other than that limited by the orthoses' components, nor about the type of cable used in the projects.

Envisioning a device that could both assist in completing ADLs and support recovery of motor coordination for SCI population, Rose and O'Malley presented in 2018 an underactuated hybrid hand exoskeleton, the SeptaPose Assistive and Rehabilitative (SPAR) Glove (ROSE; O'MALLEY, 2019). To overcome design limitations of fully rigid or fully soft devices, the project leverages rigid and soft elements to serve as an assistive device to return the ability to perform ADL, see Fig. 2.10 (b). As the name suggests, this underactuated, tendon-driven glove-like exoskeleton enables seven hand poses which support most ADLs, focusing special attention to lateral pinch grasps. Both fingers are actuated by a flexible Bowden cable transmission system with Kevlar[®] tendons (Spear-It,

Figure 2.10 – (a) Multimodal wearable exotendon hand orthosis by Park *et al.* (2018); (b) the SPAR Glove (ROSE; O'MALLEY, 2019).



braided cable \emptyset 1 mm), utilizing seven brushless DC motors (three for thumb, two for index finger, and the last two for the other fingers – all of the fingers have separate flexion and extension actuation), placed on the forearm. Small and ring fingers are coupled in softgoods, and they are passively coupled to the middle finger, sharing the same motors; the index finger and thumb are actuated individually. Differently from other projects employing spool, in SPAR Glove motors coupled with screw drives with planetary gearheads for linear motion of the tendons are applied and thus, the system does not present cable derailment. A detail concerning the sheaths is that instead of using the traditional coiled steel housing, SPAR Glove uses segmented bicycle conduits (aluminum link housing from Jagwire). For sensing and recording grasp pose, in addition to motors' encoders, sensors at fingers tip were used (low-profile buttons – LilyPad button board, Sparkfun), as well as linear position transducers; this is one of the few gloves employing such range of instruments for these purposes. The intent detection system of the SPAR Glove comprises flexible resistors (bend sensors) located at the wrist for measuring the tenodesis grasp, and the Myo armband for EMG detection. Finally, for safety, finger hyperextension is prevented by means of small segmented links denominated hyperextension vertebrae, and these also serve as the termination point for the Bowden cable transmission. SPAR Glove's grasp force is estimated at 40 N, and its weight is 0.220 kg.

In 2015, studies conducted by SNU Biorobotics Laboratory into soft wearable robotics for people with disability, resulting in the construction of a soft wearable hand robot called the Exo-Glove (see Fig. 2.11 (a)) (IN *et al.*, 2015). This is a custom-made glove that transmits forces through a Bowden cable system to induce flexion and extension of the fingers (thumb, index and middle finger) by a bioinspired soft tendon routing system. As

the glove is made with stretchable fabrics, thimble-like straps were stitched at the fingers' tips to anchor and reroute the tendons inside Teflon tubes and pulleys were attached to the dorsal side and on the left and right sides of the phalanges, also with Teflon tubes, as shown in Fig. 2.11 (b). In an end of the cable systems's sheaths there is a rigid brace customized to the shape of the hand to anchor the sheaths (see Fig. 2.11 (b)), and in the other extremity the sheaths are fixed to a slack prevention mechanism with a passive braking mechanism (see Fig. 2.11 (c)), which is coupled to the actuators. The glove also employs a differential mechanism that allows adaptive grasping to achieve stable grasping (see Fig. 2.11 (d) and ((e)). The authors used a simple bend sensor as the control input, detecting wrist motion for triggering the motors and thus, controlling the exoglove. The glove part of the system weighs 194 g, it is able to provide a pinch force of 20 N, and a wrap grasp force of 40 N. Later the research team developed a newer version, the Exo-Glove Poly (see Fig. 2.11 (f)), a waterproof exo-glove composed of silicone wich also enables three fingers (KANG et al., 2016). The other main differences from the previous Exo-Glove is that Exo-Glove Poly was developed to permit adjustment to different hand sizes, to protect users from injury and enable ventilation, besides the control input has changed, the bending sensor using the tenodesis effect was substituted for a simple button. In 2017, to increase the change to practical use of the Exo-Glove Poly, magnets were embedded into the wearable part of Exo-Glove Poly for easy donning and doffing (see Fig. 2.11 (g)), and a tendon length adjustment mechanism was designed to adapt to different hand sizes by changing length of the tendons (LEE et al., 2017). In a forth improvement, Kang and colleagues presented the Exo-Glove Poly II (see Fig. 2.11 (g)), in which no rigid materials were used Kang *et al.* (2019a). Moreover, the number of actuators was reduced from 2 to 1; the customized brace was substituted for a soft tendon anchoring support able to adapt to different hand sizes, and a passive thumb structure was integrated to fit all thumb sizes and for opposing the thumb to create favorable grasping. Both the versions used the Bowden cable system along with an under-actuated tendon-driven mechanism proposed in Jeong et al. (2015), which worked properly due to a passive braking mechanism, avoiding slackness and derailment of tendon, common problems in systems with this type of drive. Thanks to this well-clever designed mechanism for winding and unwinding the cables, the previous projects employed only 2 motors to actuate the three fingers. Finally, in the lastest version (KANG et al., 2019b), researchers at the Seoul National University (SNU) and KAIST presented the project developing a method based on a machine learning algorithm that predicts user intentions for wearable hand robots by utilizing a first-person-view camera.

And in a most recent publication, Gerez, Chen and Liarokapis (2019) and colleagues proposed two compact, wearable, and lightweight assistive exo-gloves for grasping capabilities enhancement (Fig. 2.12 (c)). One of the devices uses a body-powered mechanism (Fig. 2.12 (a)) whereas the other device is an underactuated, motorized solution (Fig. 2.12 (b)). The tendons moving the fingers are made out of a low friction braided fiber

Figure 2.11 – (a) Exo-Glove; (b) Details of the manufactured exoglove; (c) actuation system with built-in slack prevention mechanism; (d) index and middle moving identically in the Exo-Glove adaptive mechanism and in (e) the middle finger is fixed while the index finger moves; (f) Polymer-based tendondriven wearable robotic hand – the Exo-Glove Poly; (g) the Exo-Glove Poly II.



Source: (a), (c), (d) and (e) Adapted from In *et al.* (2015); (b) Adapted from Jeong *et al.* (2015); (f) Kang *et al.* (2016); (g) Kang *et al.* (2019a).

of high-performance UHMWPE (Ultra-High Molecular Weight Polyethylene), which are routed inside Polyurethane tubes. Three 3 mm polyurethane tubes for tendon routing are used. Moreover, in the motorized prototype, the authors used an EMG sensor (MyoWare muscle sensor), attached to the forearm skin, to detect the muscle activities and trigger the mechanism (via simple thresholding of EMG signals) for grasping motion. The prototype of the body-powered mechanism costs USD 92 to be produced, and weighs 335 g, whereas the motorized prototype weighs 562 g and costs USD 349. There is no information concerning possible derailment of the cables, although in both approaches the project allows the fingers to adapt to the surface of objects; in the body-powered mechanism by means of a spring loaded differential mechanism, and in the motorized prototype, via a differential mechanism with two pulleys (Fig. 2.12 (f)). In the same year, Dwivedi and colleagues slightly altered the robotic exoglove's project, making the glove to be able to actuate four digits (index, middle, ring, and thumb) (see Fig. 2.12 (e)), and implemented a muscle-machine interface, which combines EMG and FSR sensors ((Fig. 2.12 (e))) to decode the user's intentions and discriminate between different grasp types (DWIVEDI et al., 2019). The final prototype had an increasing in weight and cost, 1150 g for the full device and ~ 1000 USD to be manufactured in parts.

Besides these projects, there are other devices working in a similar way, as in Cao and Zhang (2016), reducing the number of motors and using the sEMG signal recorded

Figure 2.12 – Side view of the proposed assistive devices (exo-gloves): (a) body-powered exo-glove transmits the forces of the upper body to the human fingers;
(b) motorized exo-glove uses a single smart motor for actuation purposes;
(c) view of the soft exo-glove designed for both devices (both of them are tendon-driven); (d) the muscle-machine interface with EMG and FSR sensors; (e) new glove's design with the wearable sleeve, and (f) the four-output differential mechanism.



Source: (a), (b) and (c) Gerez, Chen and Liarokapis (2019); (d) and (e) Dwivedi *et al.* (2019); (f) Gerez and Liarokapis (2019).

from surface electrodes to control the motors, employing a proportional control method. Vargas and colleagues (VARGAS *et al.*, 2017), combined soft robotics and brain-computer interface for stroke rehabilitation. Meeker and colleagues (MEEKER *et al.*, 2017) explored the feasibility of using EMG signals recorded in the forearm by an EMG armband with 8 sensors (the Myo armband) to control a hand orthosis for functional assistance in pick and place tasks, amongst others.

Based in the literature review, it appears that over the years, interest in soft wearable technologies such as robotic exo-gloves and exoskeletons for assistive and rehabilitation purposes has increased. There is a tendency to use the Bowden cable system in wearable soft robotics glove associated with underactuated systems. The reason behind this seems obvious: using Bowden cables systems it is possible to locate the actuation system off the hand and therefore to reduce the weight of the devices on the user's hand.

Although people with hand disabilities may benefit from the use of the aforementioned devices, receiving active support for achieving several tasks in everyday life, or for retraining hand functions, such devices are not a cure-all for hand recovery. In fact, hand rehabilitation demands a great number of movements per session along with hours of practice with intensive repetitive movements and specific tasks (SUNDERLAND; TUKE, 2005; HUBBARD *et al.*, 2009; YOZBATIRAN; FRANCISCO, 2019), in which active participation from patients is fundamental. If the assistive device provides a continuous passive motion (CPM) in which it moves the hand's articulation passively (without a patient's active action) that will result in poor or no functional improvements. For those with some residual muscle capability, studies suggest that when voluntary efforts from the patient are involved greater neuroplastic changes are reached (LOTZE *et al.*, 2003; VOLPE *et al.*, 2004; PEREZ *et al.*, 2004; BARSI *et al.*, 2008; REINKENSMEYER *et al.*, 2013; McGIE *et al.*, 2014; WANG *et al.*, 2017).

On the other hand, for those with no or very weak residual motor capability, or for those whom rehabilitation interventions have not been able to restore functional movement, assistive technologies may represent a viable solution for replacing lost function (DUNKELBERGER; SCHEARER; O'MALLEY, 2020). Therefore, to enhance plasticity of the central nervous system, and so to further improve the therapeutic effects of assistive devices, a number of hybrid systems involving wearable robotics devices - hybrid orthoses and hybrid exoskeletons - and functional electrical stimulation have been developed to restore functions. Such hybrid devices, referred to also as hybrid neuroprostheses, employ FES to control the paralyzed muscles, aiming at improving or restoring muscle function, and thus promoting neuroplastic changes in motor circuits. Some of such devices are considered in the next section.

2.5 Some hybrid robotics systems for upper limbs

As mentioned in the previous sections, NMES applied as FES modality potentially can restore sensory-motor functions of upper limbs. However, orthoses or exoskeletons operating exclusively by FES systems are fated to present some limitations on functioning. Besides the fatigue elicited by the repeated muscle stimulation, such approach sometimes lacks of accuracy and repeatability necessary to position the limb for functional tasks, as a consequence of the high complexity, electro-mechanical delays in muscle actuation, and non-linearity of the musculoskeletal system that preclude the accurate and reliable control of movements (RESQUÍN *et al.*, 2016; DUNKELBERGER; SCHEARER; O'MALLEY, 2020). Moreover, because the treatments with FES need to precisely activate each target muscle, this leads to a great number of FES electrodes to stimulate muscles. Another disadvantage is that most FES devices lack mechanical supports for the limbs which are weak as a result of not being used due to the disability.

Robotics devices on the other hand, when used as assistive devices, have the potential to restore function, providing repetitive and precise assistance or resistance to a user, as well as they can be very suitable for patients with motor disorders caused by stroke or spinal cord disease because high-dosage and high-intensity training can be delivered, increasing the exposure of the patient to the treatment. Nevertheless, most robotic solutions are bulky, what limits portability and restricts its use to rehabilitation centers, or have high power requirements to operate, limiting their applicability to restore functional independence in a home environment (STEWART *et al.*, 2017). Additionally, in robot-assisted therapies patients may adopt a passive attitude and let the robot drive the movements without performing any effort, resulting in muscle atrophy and no functional improvements (RESQUÍN *et al.*, 2016).

The combined use of FES and robotic technology has been proposed as a solution to overcome the individual limitations of these systems operating separately while preserving their advantages. These hybrid robotic rehabilitation systems try to balance power contribution between robotics devices, namely orthoses and exoskeletons, and muscle stimulation and also focus in a way to increase portability. In addition, if patients have some residual muscle capability, as in the case of stroke patients, an assistas-need control strategy can be implemented in such devices, thus the robotic device provides assistance only when the user is not able to execute the movements by their own capabilities (RESQUÍN *et al.*, 2016; STEWART *et al.*, 2017).

For these reasons, some investigators started to develop some hybrid orthoses and hybrid exoskeletons, for upper limbs making use of FES. Unfortunately, despite the fact that such systems seem to be a promising intervention to restore arm and hand functions, studies on this field are sparse and outcomes are still in the early stages, with most of the applications performed by robots. Furthermore, an obstacle to be dealt with is the use of residual muscle electromyographic signal, when this exists, to control the devices and dose the intensity of FES at the same time. Having that said, in what follows, we selected some examples of hybrid orthoses, or hybrid exoskeletons; the features of some of them will be highlighted.

A great part of hybrid approaches employing FES focus on structures comprised of robots or exoskeletons aiming at sensory-motor function improvement of upper extremity, as in the shoulder, elbow, arm, or wrist, and not specifically at hand recovery. For example, Freeman *et al.* (2009) developed a robotic workstation for use by stroke patients to increase sensory-motor control of their impaired upper limb (see Fig. 2.13 (a)). A research group at Arizona State University developed and introduced for the first time in 2005 a wearable robotic exoskeleton system for stroke rehabilitation, the Robotic Upper Extremity Repetitive Therapy (RUPERT) (HE *et al.*, 2005; SUGAR *et al.*, 2007). Afterwards, some of the same team of coworkers have conducted other studies and approaches, investigating the use of FES for wrist training (ZHANG *et al.*, 2011), and reaching and grasping training (HUANG; TU; HE, 2016; TU *et al.*, 2017b; TU *et al.*, 2017a), resulting in the system shown in Fig. 2.13 (b).

Rong and coworkers designed in 2017 a multi-joint robot and NMES hybrid system for the coordinated upper limb physical training at the elbow, wrist and fingers Figure 2.13 – Hybrid robotics devices for rehabilitation: (a) robotic workstation for the upper extremity rehabilitation using FES; (b) the Robotic Upper Extremity Repetitive Therapy (RUPERT); (c) NMES and robot hybrid system for upper limb rehabilitation; (d) assist-as-need upper-extremity hybrid exoskeleton for reduction of FES-induced muscle fatigue in rehabilitation.



Source: (a) Freeman *et al.* (2009); (b) Tu *et al.* (2017a); (c) Rong *et al.* (2017); (d) Stewart, Pretty and Chen (2019).

(see Fig. 2.13 (c)) (RONG *et al.*, 2017). In previous studies, the researcher team designed a series of voluntary intention-driven rehabilitation robotics for physical training at the elbow, the wrist and fingers (HU *et al.*, 2007; SONG *et al.*, 2008; HU *et al.*, 2009; HU *et al.*, 2013) employing the residual EMG signal from the paretic muscles to control the robots to provide assistive torques to the limb for desired motions. In order to improve the muscle coordination during robot assisted training, the investigators team integrated NMES into the EMG-driven robot as an intact system for wrist rehabilitation (HU *et al.*, 2012; HU *et al.*, 2015). In 2019, Stewart and colleagues developed an innovative portable assist-as-need hybrid exoskeleton for reduction of FES-induced muscle fatigue for upper extremity (see Fig. 2.13 (d)) (STEWART; PRETTY; CHEN, 2019). This is one of the only devices inside this category whose control strategy takes into consideration the FES-induced muscle fatigue.

Other three examples of hybrid robotic devices are the works of Schill *et al.* (2011), Pedrocchi *et al.* (2013), and Rupp *et al.* (2015). Schill and colleagues developed the OrthoJacked in 2011 (SCHILL *et al.*, 2011). OrthoJacked is a modular, hybrid neuro-

orthosis aimed at both functional restoration and training of the restricted or completely lost hand and arm functions in high tetraplegic SCI individuals. The system combines the advantage of orthotics in mechanically stabilising joints together with the possibilities of FES for activation of paralysed muscles, for providing shoulder and elbow with enough functional capacity to place the hand voluntarily in space. The system is comprised of three types of actuators, FES application to achieve basic grasping patterns and hand functions, flexible fluidic actuators for elbow flexion/extension movements, and mechanical actuators for the shoulder joint (see Fig. 2.14 (a)), the later mounted at the wheelchair so that the user does not have to carry any additional weight. Other components for the systems, such as the energy supply and the pump for the fluidic actuators, can also be integrated into a wheelchair. A set of surface electrodes (four pairs) for stimulation are arbitrarily placed on the forearm muscles to generated the necessary patterns for grasping objects (see Fig. 2.14 (b)). For user intent detection, at least three pairs of EMG sensors were employed to control the hybrid orthosis, two of them placed on the forearm to control grasping and the wrist movement, and another pair was fixed to the upper arm to control the elbow joint. To detect the grasping movement, measure the wrist angle, and determine angular position of the elbow, optical fibre sensors, bending sensors, and a Hall sensor were utilized, respectively. Besides the problem involving EMG crosstalk amongst neighbouring muscles, the authors had to deal with the problem that arises when using EMG and FES at the same time. FES application adversely affects or even damages the functioning of conventional EMG sensors, and for this reason a special analogue filter circuit was used for suppression of the FES artefacts in the recorded EMG signal consisting of the so-called M-waves (M-waves represent the level of muscle excitation caused by FES, they contain information on muscle contractions elicited and the parcel of FES pulses merged). Authors also employed an automated procedure for optimal positioning of the EMG sensors, and for adaptation of FES electrodes position. As for safety issues, the OrthoJacket safety is ensured by inherent compliance of the actuators, by mechanical stops and by limited moments that can be applied to the upper limb. Fig 2.14 (c) has an image of the prototype developed for elbow training.

Figure 2.14 – (a) OrthoJacket with its relevant components; (b) electrode positions for generation of a lateral grasp, and (c) components of a hydraulically driven elbow training system prototype.



Source: (a) and (b) Schill *et al.* (2011); (c) Schulz *et al.* (2009).

Rupp and colleagues devised a noninvasive hybrid BCI-controlled upper extremity NP to individuals with high SCI (tetraplegic subjects) (RUPP et al., 2015). First, the authors developed the NP as an electrode sleeve to the forearm (RUPP et al., 2012). The NP uses an 8-channel surface stimulator that provides FES to perform functional tasks. Afterwards, to define the appropriate electrode positions, a self-adhesive Velcro strip is stuck on the top of the electrodes and the complete forearm is then covered by a Neopren sleeve, manufactured according to the individual anatomy (see Fig. 2.15a). In a second stage, the authors introduced an input modality of a hybrid BCI for managing the combination of FES and an orthosis, and thus creating a hybrid neuroprosthesis (see Fig. 2.15b). For both cases, based on the multifunctionality of the Freehand system, the NP uses the same interface of recording the user's shoulder movements for generation of two grasp patterns: elevation of the left shoulder induces closing of the hand for achieving lateral pinch and then grasping small items, and depression of the shoulder, leading to hand opening, causing a palmar grasp for manipulating larger objects.

Figure 2.15 – Noninvasive hybrid neuroprostheses.

(a) Electrode positions (a), electrodes fixed with Velcro strips in the Neopren sleeve,

and the mounted forearm sleeve (c). (b) (b) The hybrid NP systems.



Source: Adapted from Rupp et al. (2015).

The investigators Pedrocchi and colleagues developed a prototype of a multi-



modal NP for daily upper limb support denominated MUNDUS, and coupled the NP to a wheelchair (PEDROCCHI *et al.*, 2013; FERRANTE *et al.*, 2014). The MUNDUS platform was created aiming people at a middle stage of disability, for cases when the individuals have to make a great effort to restore the reduced or missed motor functions. Therefore, the system combines an antigravity lightweight and non-cumbersome exoskeleton, closed-loop controlled neuromuscular electrical stimulation for arm and hand motion, and potentially a motorized hand orthosis, for grasping interactive objects (see Fig. 2.16). The MUNDUS NP embraces three interfaces for controlling the NP: an EMG amplifier and/or a USB-button for individuals which present residual functional control of the arm and/or hand muscles; an eye tracking system for users who do not have residual functional voluntary activation of arm and hand muscles, but they can still control the head and gaze fixation; and a BCI interface for users lacking the ability to move their eyes and thus, are not able to fix different locations on the screen of the eye tracking system. One limitation of MUNDUS is related to its application to people with amyotrophic lateral sclerosis, due to the lack of responsiveness to electrical stimulation.

Figure 2.16 – The MUNDUS neuroprosthesis.

(a) The hand module with the stimulation arrays embedded in the garment (a) and the robotic hand orthosis (b).



(b) The NP systems worn by a test participant in a wheelchair.



Source: Adapted from Pedrocchi et al. (2013).

Finally, we would like to mention the work of Brazilian authors Varoto, Barbarini and Cliquet Jr (2008). As far as we are concerned, this is the only Brazilian work published on hybrid systems, and one of the earliest developments (likely the first) of a hybrid upper limb exoskeleton. In 2008, the authors developed a prototype of a hybrid system aimed at partial upper limb sensory-motor restoration for quadriplegics that present voluntary movements of the shoulder and scapula (see Fig. 2.17). The device was composed of an elbow dynamic orthosis that provided elbow flexion/extension with forearm support, a wrist static orthosis and neuromuscular electrical stimulation for grasping generation, and a glove with force sensors that allowed grasping force feedback. The hybrid systems was triggered by the patient's voice command, which was coupled to a conventional two-channel electrical stimulator to perform grasp. The movements provided by the hybrid system, combined with the scapular and shoulder movements performed by the patient, aided quadriplegic individuals in tasks that involve reach and grasp movements. In addition, for the sensory feedback during palmar or lateral grasp, the glove had two user interface modes, (i) a visual mode, which indicated the intensity of the force applied by the fingers through 10 LEDs – the larger the force, the more LEDs were lit, and (ii) an audio mode – the larger the force, the higher the audio frequency emitted by a buzzer; the modes might be selected by a switch. No explicit information was given on how the user could control the elbow flexion/extension movement.

Figure 2.17 – (a) Patient with elbow dynamic orthosis, (b) glove with force sensors and (c) design and components of the elbow dynamic orthosis.



Source: Adapted from Varoto, Barbarini and Cliquet Jr (2008).

In addition to these devices mentioned here, a wider literature review embracing other proposed devices as well as hybrid robotic systems for upper limb rehabilitation can be found in Maciejasz *et al.* (2014), Gopura *et al.* (2016), Resquín *et al.* (2016), Stewart *et al.* (2017), Yue, Zhang and Wang (2017), Chu and Patterson (2018), Zhang *et al.* (2018) and Dunkelberger, Schearer and O'Malley (2020).

2.5.1 Sensor for user intent detection and for the glove control

As seen in section 2.3, there are several ways to detect user intention for controlling orthoses. In orthoses projects, it is very common to find the control strategy based on sEMG detection for the applications of neuroprosthetic devices control due to the compromise between reliable signal acquisition and ease of implementation. In a conventional orthosis, the sEMG signals are employed to control the orthosis, triggering the actuators for opening and closing the orthosis. In hybrid orthoses, the sEMG signal may play other roles; generally it is considered as an FES feedback signal, which indicates the state of the stimulated musculoskeletal system (DURFEE; DENNERLEIN, 1989; ZHANG *et al.*, 2011; HAYASHIBE, 2016; KAHL; HOFMANN, 2016), or as an input signal for FES application control, dosing FES for instance (LI; HU; TONG, 2008; HU *et al.*, 2009; SCHILL *et al.*, 2011; KLAUER; IRMER; SCHAUER, 2015; ZHOU *et al.*, 2018b; ZHOU *et al.*, 2018a; SA-E; FREEMAN; YANG, 2018).

With regard to muscle signal detection and recording, there are some procedures and setups to be followed. The selection of the electrode type to be used depends on the methodology employed and on which is the object of interest. Though sEMG signals are subject to drawbacks such as maintaining robust electrode contact with the skin, and the recording of other nearby muscles (EMG crosstalk), sEMG is preferred because it is more convenient to use and it employs a non-invasive method. Two well-explained insights concerning sEMG can be found in De Luca (2002) and Garcia and Vieira (2011). According to De Luca (2002), the electrodes must be placed on the bellies of the muscles, where the target muscle fiber density is the highest. However, in the case of the orthoses for hand rehabilitation, if the interest is to carry out the measurement to distinguish the movements of the five digits (perhaps not the case of this project), the measurements need to be taken at several points of the subject's forearm and therefore, several electrodes are necessary. In the case of the forearm, given that is it necessary to respect a recommended distance between the electrodes from 1 to 2 cm, the tendency is to use small electrodes. Moreover, larger electrodes are more likely to produce the EMG crosstalk.

An other important issue that must be taken into consideration in the case when it is dealt with FES application is that the sEMG signal is strongly affected by FES due to the fact that the motor unit action potential (MUAP) is evoked and synchronized by the external stimuli, generating the called M-waves (MERLETTI; KNAFLITZ; DE LUCA, 1992). Thus, the recorded sEMG is then the summation of synchronous action potentials associated with each high current stimulation pulse from FES, which have much higher magnitude as compared to the EMG signal generated by the muscle signals (see Fig. 2.18 (a)). Therefore, the artifacts from the stimulation presented in the sEMG signal must be eliminated or reduced as much as possible in order to obtain only the muscle signal, as represented in Fig. 2.18 (b). M-waves may also be monitored and have been used as a means for detection, monitoring and controlling muscle fatigue (LIBERSON, 1994; CHESLER; DURFEE, 1997; TEPAVAC; SCHWIRTLICHE, 1997; HEASMAN *et al.*, 2000; WINSLOW; JACOBS; TEPAVAC, 2003; MULLA; SEPULVEDA; COLLEY, 2011). In addition to the drawback imposed by the signal cross-talking between adjacent muscles, sEMG sensors are prone to signal inconsistency due to interference from ambient noise, such as transmission from fluorescent lighting and televisions, changes in electrochemical signals due to sweat or humidity, and electrode shifts as a result of limb movement (CHO *et al.*, 2016). Due to the complexity of recording and processing sEMG regarding muscle fatigue or for controlling FES application, deal with the sEMG signals still remains challenging, requiring specific and custom-made equipment for rejecting artifacts from the stimulation (YOCHUM *et al.*, 2010; YOCHUM *et al.*, 2012; LI *et al.*, 2016).

Figure 2.18 – Example of artifact removal: (a) sEMG signal from EMG board; (b) sEMG without artifacts.



In recent years, a different technique called force myography (FMG), involving sensors for monitoring physical activities or for human-machine-interface applications has gained prominence (XIAO; MENON, 2019). FMG is the mechanical counterpart of the sEMG, in which the hand movements and intentions emerge from the radial pressures exerted by the forearm muscles (FUJIWARA; SUZUKI, 2018). Due to the technique being noninvasive, it can be considered an appealing alternative to the traditional sEMG in biomedical applications, mainly due to its simpler signal pattern, immunity to electrical interference and robustness to sweating (WU *et al.*, 2020). One of the well-know approaches of FMG involves the use of force sensitive resistors (FSRs) on the surface of the limb to detect the volumetric changes in the underlying musculotendinous complex, and in this way to register the variation of muscle stiffness patterns around a limb, the forearm for example, during different movements (CHO *et al.*, 2016; ANVARIPOUR; SAIF, 2018; GODIYAL *et al.*, 2019; XIAO; MENON, 2019). A common configuration is an FSR strap prototype, as that shown in Fig. 2.19 (left), but other arrangements may be made, as the one shown in Fig. 2.19 (right).

Figure 2.19 – FSR strap prototype developed at MENRVA Research Group (left), and socket with FSR bands to be donned on the forearm stump by people with transradial amputation (right).



Source: Left Cho et al. (2016), and right Ferigo et al. (2017).

Additionally to FSRs, other types of force sensors are employed in FMG (ZHENG *et al.*, 2022; WANG *et al.*, 2022), including an emerging pressure measurement sensor mainly composed of multimode optical fiber. As a means to circumvent the complexity of using sEMG with FES, this work applied optical fiber sensors to measure FMG signals due to their lightweight, high sensitivity, and immunity to electromagnetic noise (FUJIWARA *et al.*, 2017; FUJIWARA; SUZUKI, 2018). A brief explanation about the FMG-based optical fiber sensor employed in this project is given in section 3.3.2.

Despite all efforts made by the investigators in conducting research on such devices, commercial devices are scarce, and this shortage compels more and more investigation. There is an extensive need for affordable, practical, and multidimensional devices to assist the therapist in upper extremity rehabilitation. In 2018, the WHO estimated that only 1 in 10 people worldwide in need had access to assistive technology due to high costs and a lack of awareness, availability, trained personnel, policy, and financing (WHO, c2020a).

In addition, there is a lack of devices that can operate as assist-as-need tools, i.e. most of the wearable robotic glove-like orthoses are assistive technologies, and therefore they lack rehabilitation potential. On the other hand, FES systems are rehabilitative technologies, however the extensively use of such resource causes muscle fatigue, which limits its application for long periods of time. Seeking to overcome the limitations that these technologies have when employed alone and extend their advantages, the goal of this project is to develop a prototype of a wearable hybrid orthosis, employing a tendon-driven system as power transmission and use electrical stimulation such as FES. Figs. 2.20 and 2.21 have the illustrations with the conception of the project, and the main design features of the orthotic glove design, respectively, whose details will be covered in the next chapters. To the best of our knowledge, this is the first work involving a wearable hybrid robotics

tendon-driven orthosis and FES for upper limbs.

Figure 2.20 – Hybrid wearable robotic glove-like orthosis idea for grasping.



Figure 2.21 – Main characteristics of the wearable robotics glove for hand assistance and rehabilitation - the check markers represent the characteristics of the glove developed in this work.



Source: Elaborated by the author, 2020.

3 HYBRID CONTROL STRATEGY CON-CEPTION AND WEARABLE ROBOTIC ORTHOSIS DEVELOPMENT

As the title implies, this chapter describes the concepts involving the hybrid control strategy conception and the orthosis development to underpin the idea behind the hybrid control strategy merging FES and the tendon-driven orthosis. In addition, glove manufacturing will be covered, regarding the wearable robotic glove design and fabrication, and its appended components will be introduced as well.

3.1 Hybrid Control Strategy Conception and Proposal of the Hybrid Control Strategy

It is known that the extended use of FES has limitations due to muscle fatigue. This muscle fatigue occurs because FES induces an unnatural motor unit recruitment order (DOUCET; LAMB; GRIFFIN, 2012). The main idea backing up the hybrid control strategy is to try to get around this hindrance and widen the using time of FES without muscle fatigue. The hybrid control strategy was conceived to be used together with the wearable robotic tendon-driven orthosis due to its peculiarities, as will be commented below.

To understand the methodology, let us first consider a grasping movement obtained by means of using only FES. A generic waveform of FES is represented in Fig. 3.1 (a), with ramp up and ramp down time, and a period of time window, between t_1 and t_2 , during which the stimulation with FES is kept constant. The ramp up time is a transient phase used to progressively excite the muscle, that is, changing the rate at which the current achieves the maximal amplitude, imitating how muscles are normally recruited for function. In addition, using the ramp up will make the procedure more comfortable for the user. The ramp down period is also a transient phase in which occurs the gradual fall of stimulation intensity, mimicking relaxation of voluntary contraction. The plane current waveform between the time span t_1 and t_2 is the extended period of stimulation which is mainly responsible for the muscle fatigue. Since muscle fatigue is related to the stimulation time, by reducing stimulation time the muscle fatigue may be reduced. To make the explanation even clearer, imagine a user suffering from hand disability, unable to close their hand. The user uses only FES for closing a hand, and keeps objects grasped between the time span t_1 and t_2 . During this time interval, the hand is purely sustained closed by stimulation of the muscles responsible for closing the hand. The longer the time window between t_1 and t_2 , the sooner the muscles of the user's hand will become fatigued.



Figure 3.1 – (a) Generic waveform of FES. (b) Waveform for FES + Orthosis.

Source: Elaborated by the author, 2020.

Now, let us consider Fig. 3.1 (b). The FES waveform represented in Fig. 3.1 (b) has also ramp up and ramp down time, but it has a plane waveform different from Fig. 3.1 (a). In the time window between t_1 and t_2 , it is possible to have a period of time sustained by the orthosis' tendon-driven system + FES. Consider the same user from the previous example, maintaining the same object grasped only with FES. If FES is turned off, it is probable that such object will fall. However, if the user is wearing an orthosis with tendon-driven actuator for example, in this time window, the orthosis can provide the necessary force to maintain the hand closed even without FES. That is the concept of the hybrid control strategy.

The rationale for using this procedure for the stimulation of the hand muscles is to try to minimize the time the muscles remain under stimulation, and consequently reduce muscle fatigue. A similar strategy is employed in lower limbs exoskeletons/orthosis, where by switching off the FES and activating the brakes to stiffen the orthosis during standing, the device only requires the patient's muscles to be used during motion, and consequently this enables the FES to be used much more frequently (with shorter duty cycle), reducing muscle fatigue.

Making use of the hybrid control strategy just presented, to keep the object grasped, the orthosis must have a means to provide the necessary force for that to happen, in this case a nonbackdrivable mechanism for tendon actuation, and if possible, preferably with a passive energy saving mechanism. The force (torque) provided by the hybrid control strategy from the FES and orthosis parts to the assistive (and rehabilitative) device could be described by an equation as in Eq. (3.1):

$$Assistance_{orthosis+FES} = Assistance_{orthosis} + Assistance_{FES}$$
(3.1)

where, $Assistance_{orthosis+FES}$ represents the resultant support from the orthosis-FES device, $Assistance_{orthosis}$ is the supportive force(torque) provided by the orthosis part

applied to a manipulated object, and $Assistance_{FES}$ is the electrical stimulation parcel from the FES part applied to the FES electrodes on target muscles, i.e. flexor digitorum superficialis (FDS) and the extensor digitorum comunis (EDC) muscles in this study (see Fig. 3.2). In such a way, it is possible to make an analogy between the area under the FES curve and muscle fatigue: the longer the FES is applied, the faster the muscle fatigues.

Figure 3.2 – Target muscles for fixing FES electrodes: flexor digitorum superficialis (FDS) is a flexor muscle located in the anterior compartment of the forearm, whose function is to flex (bend) the fingers, and extensor digitorum communis (EDC) is a muscle of the posterior forearm, sometimes referred to as extensor digitorum communis, whose function is to extend the fingers.



Source: Adapted from Rehab My Patient (2020a) and Rehab My Patient (2020b).

To date, to the best of our knowledge, the current state-of-the art in this field is not showing anything similar to this hybrid FES/tendon approach. Moreover, it is worth commenting here that this approach allows to add FES between t_1 and t_2 , if wanted, and at the same time, other wave forms may be employed, as represented in Fig. 3.3 (a) and (b). Another interesting comment is that, if a strategy for detecting muscle fatigue is developed, the FES system can be turned off and the orthosis can operate only as an assistive device.

Finally, to close this section, Fig. 3.4 contains a representation with the time instants that will be employed in the hybrid control strategy in this work, which will be involved in the control logic whenever motors are activated to open or close the hand with the orthosis.

3.2 Glove Design

As introduced in the previous section, when the FES is switched off, it is necessary to establish a means that can provide some rigid support for grasping and Figure 3.3 – Other suggested waveforms for the hybrid strategy using FES and the tendondriven orthosis: (a) ramp down period occurs only when there is an intention of opening the hand, or releasing an object grasped, for example; (b) the waveform can be adjusted to have a ramp up and ramp down period between the time window t_1 and t_2 .



Source: Elaborated by the author, 2020.

Figure 3.4 – Points of interest of the hybrid control strategy associated with t_0 and t_2 , when the FES is switched in ramp up and ramp down mode, respectively.



Source: Elaborated by the author, 2020.

holding objects. Amongst the various wearable hand devices, or hand exoskeletons, a wearable glove-like orthosis can meet this requirement.

Since we are dealing with the human hand with several degrees of freedom (DOF), a suitable choice for the structure is one whose material is pliable instead of a rigid one. Therefore, to develop the glove-like orthosis, it was considered important to select a glove that provided comfort, lightweight, softness, cheapness, but with fabric strong enough to withstand the tensile forces generated by the tendons employed to actuate the fingers. Note that incidentally, unlike the rigid structure of conventional robots, these flexible wearable robots can be easily deformed when forces are exerted on them, which is a disadvantage under certain circumstances.

As established in section 2.4.2, there are several different types of gloves that can be used to enable patients to perform basic hand movements, these including the use of hydraulic/pneumatic systems, soft robotics technologies (which utilizes soft elastomeric materials and a wearable glove), linear actuators, tendon-driven mechanisms, and others. The first three options have their advantages, however taking into consideration that in Brazil we lack some components for the manufacture of wearable gloves using such technologies, we opted for a tendon-driven mechanism mainly because its components can be easily purchased in the local market. Additionally, the choice for a tendon-driven glove was deliberate due to the characteristics that this type of glove can offer beyond its wearability and high power-to-weight ratio. Furthermore, its most important feature is that if employed a Bowden cable system for actuation, it allows locating the motors away from the hand, reducing the weight of the orthosis, which is very important in such projects.

3.2.1 Choice of the glove for the prototype

Some types of gloves, including Kevlar[®], polyester and leather gloves, as well as the combination of other fabrics, were analyzed. A good option would be a custom-made glove. However, such choice could increase the prototype cost and it could take more time than expected due to budget limitations and the bidding process. Hence, a viable alternative was to select a ready-made glove, in this case a pair of bicycle gloves made out of polyester and neoprene was chosen considering the characteristics aforementioned. Figure 3.5 has an image of the chosen glove including criteria as poor workmanship quality, type of fabric, and lack of enough pliability. The glove dimensions were based on the author's hand, and it was necessary to make some slight adjustments, such as to cut off the surplus fabric in fingertips and sewing it again.

Figure 3.5 – Chosen glove for the project.



Source: Elaborated by the author, 2018.

3.2.2 Glove setup for tendon-driven system

For the project of the glove utilizing tendons, there are also different configurations to attach the tendons to the glove. The starting point of analysis was based on some works as Kang *et al.* (2016), In *et al.* (2015), and Cao and Zhang (2016). After consideration, it was decided to use a tendon configuration similar to the Exo-Glove (IN *et al.*, 2015).

According to some grasp taxonomy studies (BULLOCK *et al.*, 2013; LIU *et al.*, 2016; FEIX *et al.*, 2016), thumb, index and middle fingers are the most important fingers participating in the various grasp types, whilst ring and pinky fingers appear to be secondary. Hence, thumb, index and middle fingers were chosen to be actuated by two motors, the thumb being actuated by one motor whereas index finger and middle finger share the same driving motor. As can be seen, there are fewer actuators than DOF, which characterizes an underactuated system. That said, for the glove to perform the grasps with a reduced number of motors, a differential mechanism was employed. In the case of robotic hands, a differential mechanism utilizes a type of transmission mechanism with the purpose of employing the power of one actuator to drive the open/close motion of all the fingers of a robotic hand collectively (BIRGLEN; GOSSELIN, 2006). In other words, it means that this adaptive mechanism allows the robotic glove to adjust itself (i.e. its fingers) to an irregularly shaped object without complex control strategies and sensors; and in this way producing a stable grasping¹, reducing the cost and the weight of the final device.

To provide a structure for routing the cables that mimic hand's tendon functions, pieces of straight tubes were stitched in phalanges dorsal and distal sides. In addition, to turn the inner cable around, U-shaped tubes were stitched on the fingertips of thumb, index, and middle fingers, as well as in the connection between fingers and palm, thereby producing the necessary support for the tendons. In the first and second version of the glove developed here, since there were no Teflon tubes available, a makeshift solution for testing was used. In the first version, we resorted to a copper capillary tube of domestic refrigerators, and in the second version, to small red plastic extension straws which come together lubricating spray (see Fig. 3.6). In the two first versions employing stopgap solutions, the friction between tendons and tubes was too high, making the project unfeasible. Finally, tubes made of Teflon, presenting low friction factor and resistance to abrasion, were employed.

Another detail concerns the glove's fabric. As the glove's fabric is flexible, it stretched when tendons were drawn. Thus, thimble-like caps made from inextensible fabric were stitched at the fingertips to act as anchor points for the tendons, providing a firm support for the U-shaped Teflon tubes rounding fingertips. Moreover, they allow the fingers to move in the intended direction (finger extension/flexion) when tendons force the

¹ In robotic grasping, the *stable grasping* definition is usually associated with complex mathematical analyses involving stability under disturbance input. Here, for our study, we will limit our definition to just saying that the grasping is stable if the manipulated object is firmly held by the hand and that the grasp remains stable without object slipping during the whole manipulation process.

Figure 3.6 – Evolution of the glove versions for the project with (a) copper capillary tube, (b) small red plastic extension straws, and (c) Teflon tubes.



Source: Elaborated by the author, 2018.

thimbles.

3.2.3 Sheaths and tendons for the Bowden cable system

As established before, in the orthosis design, it is important to keep heavy components, such as motors, as far away as possible from the hand and forearm, so as to avoid any unnecessary physical effort from the user. For this reason, a Bowden cable system was employed for this purpose, consisting of sheaths and cables.

This wearable robotic glove project employs a flexible tendon routing system inspired by the human musculoskeletal system. In this way, it is important to select the cable correctly, since the cable will perform the tendons functions. As for inner cable, steel or stainless steel wire can be used, and even a solid wire can be applied for short distances. For this application, Kevlar[®] cable, fishing line or another flexible cable could be selected as tendons. Kevlar[®] cables were disregarded because they could not work properly with the cable winder, generating slips and consequently slacks. At first option, a fishing line was used, a nylon coated wire from Marine Sports to act as tendons (see Fig. 3.7 (a)). It was a low-cost solution, but when the tests were conducted, it was discarded due to its high stiffness. The second cable chosen to work as tendons was the flex-rite[®] bead stringing wire (21 strand nylon-coated stainless steel micro-wire), from Bead Smith[®] (see Fig. 3.7 (b)). The conducted experiments indicated that the capacity of this cable to adjust to the spool body surface was superior when compared to that presented by the fishing line, showing no slip or slacks, but at a cost of ten times greater than the fishing line.

Regarding the sheaths, an appropriate option to be used as sheaths for routing the tendons was an off-the-shelf solution – a bicycle brake outer casing. Pneumatic tubes made out of polyurethane were also taken into consideration, but despite being cheaper, they revealed high friction when tested with the bead stringing wire. As for the two remaining sheaths seen in Fig. 3.7 (c), the braided one (upper) was very rigid and therefore difficult to bend. Therefore it was discarded and a 0.2" (5.08 mm) galvanized spiral wire sheath (lower) was selected due to its flexibility.
Figure 3.7 – (a) Fishing line used in the first approach. (b) Bead stringing wire. (c) Bicycle brake cable housing chosen to operate as sheaths.



Source: Elaborated by the author, 2018.

An important issue related to the use of a cable system in this configuration concerns the fact that when the pulling force is applied to the tendons, the Bowden cable sheaths have a tendency to go towards the fingers. To prevent this from happening, a 3D-printed bracelet is used to anchor the sheaths on the glove, as seen in Fig. 3.6. Thus, giving support to the Bowden cables, one end of the sheaths is fixed to the actuator side whereas the other is anchored to the 3D-printed armband support adapted to the shape of the hand. Finally, Velcro straps were used to firmly fasten the armband around the user's hand.

3.2.4 Tendon actuator mechanism

In tendon-driven mechanisms it is essential to keep pre-tension to tendons to avoid cable derailment. However, pre-tension can cause discomfort and injuries on fingers, and increase friction along the tendon route. Therefore, a slack prevention mechanism is necessary, capable of avoiding pre-tension to the tendons. The device used here for actuating the tendons is a clever mechanism based on In *et al.* (2016). This device is a very important component of the Bowden cable system. To sum up its main characteristics, (1) this invention can manage in a plain manner the problems of cables, derailment in similar projects involving tendon actuation; (2) making use of one-way clutches (similar to ratchet bearings), it is inherently a nonbackdrivable device, that is, it does not need energy to maintain stopped the tendons movement even when the motor responsible for turning the mechanism is shut off, what represents energy saving; (3) since it is nonbackdrivable, it applies unidirectional friction to keep the tendon strained inside of the device while enabling slack to the tendon part out of it, which is important to avoid injuries in the hands by tension; (4) furthermore, it is a mechanism which can wind flexor tendon of each finger set when rotating in one direction and, at the same time, unwind the extensor tendon, and vice versa. Figure 3.8 (a) has an exploded view drawing of the mechanism and in (b) it is shown an image of the mechanism printed using 3D printing.

In order to understand how it works, Figure 3.9 depicts a partial view of the

Figure 3.8 – (a) Exploded view of the tendon actuator mechanism. (b) Tendon actuator mechanism.



Source: Elaborated by the author, 2018.

main parts of the cable winder mechanism. When the spool (5) is rotated, it winds or releases the tendon for hand joints flexion or extension, respectively. Spool and feeder roller (2) are coupled by a pair of spur gears (4), though each feeder roller can rotate freely only in one direction due to the assembly with the one-way clutches (3) between the shaft and feeder roller. As the spool rotates, the one-way clutch blocks the feeder roller and causes it to drag the tendon out of the mechanism. The idler roller (1) can rotate freely in any direction, but it presses the tendon on the feeder roller and thus provides enough friction for pulling out the tendon. To warranty drag force when tendons are being released, the diameter of the spool and feeder roller and the transmission between them are designed to make the linear velocity on the feeder roller surface higher than the tendon unwinding speed on the spool.

Figure 3.9 – Cable winder with nonbackdrivable mechanism: (a) front view and (b) back view. Note: 1 - idler roller, 2 - spur gears, 3 - feeder roller, 4 - one-way clutch, 5 - spool.



Source: Elaborated by the author, 2019.

The tendon actuator mechanisms are driven by two Dynamixel AX-12A+ smart servos coupled to the spool shafts, and controlled by a high performance microcontroller unit (MCU) based on the ARM Cortex-M4F architecture.

As previously established, due to most activities of daily living involve the thumb, index, and middle fingers, instead of driving each digit separately, a differential

mechanism composed by a pair of servo motors (Dynamixel AX-12A+ Smart Servo) was used to provide a stable grip and optimize the required number of actuators: one motor is responsible for the thumb while the other simultaneously controls the index and finger movements.

To provide information over fingertip contact during grasping, an FSR, with a round sensing area of 0.5" (12.7 mm) in diameter was glued on the digital pulp of the index fingertip. That is a simple and reliable method to provide grip force feedback instead of assessing the motor currents through sensors or state observers. The signal coming from the FSR is mainly used to stop the glove flexion movement, and indirectly provide a signal for stopping the extension movement. Fig. 3.10 has an image of the glove ready and its main components. Other solution for generation of touch information could be to attach the FSR to the digital pulp of the thumb, or to both digits. However, the experiments conducted revealed that gluing the FSR to the index finger pulp provided enough reliability to perform the task and control the closing movement of the glove-like orthosis.

Figure 3.10 - (a) Glove-like orthosis and its components; (b) back of the glove.



Source: Elaborated by the author, 2020.

3.3 Other Components Related to the Project

3.3.1 FES Module

To conduct the experiments with FES, a shield developed to be used with Arduino[®] was applied. The proposed circuitry was built by Barelli and colleagues (BARELLI *et al.*, 2016). The shield (see Fig. 3.11) provides two constant current independent stimulation channels with the integration of up to 8 channels by cascade connection. The output signal consists of a symmetric biphasic pulses, of 300 μ s width and 20 Hz frequency.

In order to avoid fatigue and discomfort, the stimulation frequency used in the experiments will be set in the span of 20-40 Hz, closely to physiological rates of motor unit discharge. As for the ramping of stimulation frequency, for user comfort, it will be kept between 1 to 3 s; ramp up time equal to 3 s (2 second ramp up is often adequate for comfort), ramp down time equal to 5 s; intensity of current 10 to 20 mA (in people with



Figure 3.11 – Integration of shield with the Arduino[®].

Source: Barelli et al. (2016)

motor impairment, the intensities are between 20 and 40 mA). It is worth mentioning that these parameters are estimations and may be adapted according to the user's sensibility.

The FES subsystem waits for the MCU command to assist the hand in close/open movements through electrical stimulation. The microcontroller also disables this module according to the FSR input or the servo motor time-out event. The parameters of the several signals of current and frequency generated by the device may be manipulated in several waveform modulations to produce pulsed or continuous output. Then, active rectangular electrodes (Carci Trode, 3×5 cm² area) placed on the motor points of the target muscles apply the electrical stimulation to flex and extend the finger joints, respectively.

3.3.2 FMG-based optical fiber sensor for user intent detection and for the glove control

Now, let us close this chapter briefly approaching the content over the sensor for user intent detection and for the glove control.

The FMG-based optical fiber sensor used in this work is composed of subsystems, and its functioning is described as follows. The optical fiber FMG sensor subsystem detects the hand open/close intentions required to switch the state machine in the MCU and drives the robotic glove. An optoelectronic interrogator unit sends the raw FMG signals to the microcontroller. Then, the MCU proceeds with data reduction and thresholding operations. In Fig. 3.12 (a) the interrogation setup of the sensor is depicted (WU *et al.*, 2020).

In short, the functioning of the sensor is related to the level of attenuation that the light suffers when it travels from side to side across the core of the fiber. Such light attenuation varies when the fiber is subjected to mechanical perturbations or when the bending radius is changed; the more severe the mechanical perturbation or bending are, the more the light is attenuated (BERTHOLD, 1995). Therefore, the light attenuation can Figure 3.12 – Optical fiber FMG sensor: (a) interrogation system, (b) force transducer and (c) photography of the fabricated device.



Source: Ribas Neto et al. (2021)

be modulated by the magnitude of the applied forces and displacements to the fiber, what can be made by fastening the sensor to specific locations on the user forearm by means of Velcro straps in order to assess the muscular activities (FUJIWARA; SUZUKI, 2018).

In the optical fiber sensor shown in Fig. 3.12 (a), light emitted by an 820 nm LED source (HFBR-0400, Agilent Technologies) is launched into multimode silica fibers ($\sim 2 \text{ m} \log 62.5/125 \text{ core/clad}$ diameters). The optical signal is modulated by the optomechanical transducer, whereas output intensity is measured by a photodetector (HFBR-24X6, Agilent Technologies) conditioned by instrumentation amplifier and filter circuits and subsequently processed in the MCU (WU *et al.*, 2020).

The optomechanical transducer (Fig. 3.12 (b)) is comprised of a fiber microbending device with L = 60 mm length and $\Lambda = 10$ mm periodicity. As the corrugated structure mechanically deforms the waveguide, core-guided light modes are coupled to radiation modes and yield optical losses, therefore the output light intensity can be correlated to the input force or displacement (BERTHOLD, 1995). Even though the muscle response can be assessed using other types of fiber sensors, the microbending approach demands a more straightforward interrogation setup and presents improved linearity, dynamic range, and stability (FUJWARA *et al.*, 2018). The transducer was fabricated in an Ultimaker 3 Extended 3D printer using acrylonitrile butadiene styrene (ABS) filament, whereas fixation is provided by Velcro straps.

A pair of microbending transducers are used for monitoring the FDS and the EDC muscles and detecting the grasp and hand open intentions, respectively. The information obtained by FMG sensors is further applied to the robotic glove control.

3.3.3 List of Materials used in the Project

In what follows, the materials and components used in this project are listed in Table 3.1, with their respectively prices. It is worth commenting here that the Myo armband, the motors and the U2D2 converter were not bought specifically for this project, they are components reused from other projects. Furthermore, they cannot be promptly applied to a portable device.

Item	Component	Unit Price	Total $(R\$)$
1	Glove (a pair)	R\$ 47.5	47.5
2	Cables (10 m)	R 9.36	93.6
3	Sheaths (6 m)	R\$ 4.0	24.0
4	One-way clutches (2 un.)	R 14.00	28.00*
5	Bearings (8 un.)	R 15.65	125.2
6	Teflon tubes (0.25 m)	R 4.0/m	1.0^{*}
7	Motors (2 un.)	US\$ 44.9	332.26
8	Myo armband (1 un.)	US\$ 200.0	740.0
9	U2D2 (1 un.)	US\$ 49.9	184.63
10	Screws (several)	_	60.0
11	Circlips (several)	_	60.0
12	Plastic for printing (0.06 kg)	R 70.0/kg	4.2
13	Hinge (1 un.)	R 1.5	1.5
14	Velcro straps (1 m)	R 6.0	6.0
Unit cost for an orthosis			R\$ 1707.89

Table 3.1 – List of Material and Components used in the Project.

Note: The value used for current exchange rate was related to the year of 2019, when the exchange rate was US\$ 1.00 = R\$ 3.70.

* These components were donated.

The integration of the subsystems and the functioning of the overall system are described in the next chapter.

4 EXPERIMENTAL RESULTS

In this chapter we cover the experimental results, procedures and analysis involving the practical experiments carried out during the assessment of the glove. The chapter starts covering the experiments with the glove and the Myo Armband application in order to test the glove. The second group of experiments is related to the use the glove driven by the optical fiber FMG sensor input, followed by the experiments using the FMG sensor and FES.

4.1 Glove Driven by Myoelectric Control Input - The Myo Armband Application

As aforementioned, this was the simplest approach employed to test just the functioning of the glove. A healthy young adult (aged 36 years, a man) participated in the study. The subject was right handed and reported to have no known neurological, psychiatric or hand disabilities. The subject gave his written informed consent before the experiments.

In this experiment, the Myo gesture control armband (see Fig. 4.1) was used as a sensor to detect the user intention. The Myo armband is a device that works collecting muscles' activity via 8 units of stainless steel sEMG sensors, and arm position from an Inertial Measurement Unit (IMU). The Myo armband is worn on the user's forearm and can provide raw sEMG data related with the intended movement at a sample rate of 200 Hz, and IMU data at a sample rate of 50 Hz. The communication between Myo and computer is made via Bluetooth using an included USB bluetooth adapter, a dongle. The first time the user wears the armband it is necessary to conduct a brief calibration, which is made through the Myo software development kit (SDK) installed previously on the personal computer (PC) (RIBAS NETO *et al.*, 2020).

Figure 4.1 – Myo armband.



After sitting comfortably in a chair with the forearm suspended, the individual performed a sequence of grasping, holding, and releasing some objects with common form

found in ADL by triggering the robotic glove with his flexion and extension motion intents for a familiarization session with the glove.

The control strategy employed with the Myo armband was implemented to be as simple as possible. Three out of the six promptly gestures provided by Myo armband were used in the control strategy: wave in, wave out and spread fingers; as shown in Figure 4.2.

Figure 4.2 – Hand postures used in the control loop: (a) wave in, (b) wave out, and (c) spread fingers gestures.



Source: Elaborated by the author, 2019.

The use of these gestures is associated with the control strategy as follows: with the Myo armband on the forearm, the muscles' activity is continuously measured and used to close, open, or hold the glove position, considering the user's intention. The Myo armband detects the muscles' activity related to the intention of flexion or extension of the wrist, and the states are deduced from the signals acquired using a package called MyoMex¹, a package developed in MatLab code to access data from Myo (TOMASZEWSKI, 2020), which in turn, runs into MatLab. With the states extracted, the strategy of control was designed using a state machine of three states as shown in Figure 4.3. The use of the FSR sensor was discharged because the user was on charge of the control, that is, the user flexed the wrist as much as they wanted to close the glove in order to grab an object, or they extended the wrist as much as they wanted to open the glove.

The first state, "State $\neq 1$ ", is associated with the "Spread Fingers Gesture", the second and third states, "State = 2" and "State = 3", are associated with "Wave in Gesture" and "Wave out Gesture", respectively, which in turn are linked with the flexion and extension movements of the user's wrist. The algorithm takes into account the three states as follows: while the initial condition "State $\neq 1$ " is true, the algorithm allows opening or closing the hand. When the user develops a wave in gesture, that is, a wrist flexion intention, related to "State = 2", the motors responsible for closing the hand are turned on, and the wearable robotic glove starts to close. It is kept closing as long as the user sustains this intention. If the user develops a wave out gesture (wrist extension

¹ MyoMex is a package, written in a simplified m-code class, that enables to stream data from Myo at up to 50 Hz (IMU) and 200 Hz (EMG and meta data) in the MatLab environment and Simulink.

Figure 4.3 – Main thread flowchart showing the logic control of the system. Note: Wave in Gesture = Flexion Movement; Wave out Gesture = Extension Movement.



Source: Elaborated by the author, 2019.

intention), which corresponds to "State = 3", the robotic glove starts to open by changing the direction of the motors. It is kept opening whilst the user remains with this intention. Again, when the user ceases the intention, the motors are turned off and the glove holds its position. Thus, the algorithm remains in a *while loop*. The glove continues in this state until a new intention of the user for closing or opening the hand is detected by the Myo armband. When the user executes a spread fingers gesture (which changes "State $\neq 1$ " to "State = 1"), the code exits the loop and then it is necessary to reinitialize the algorithm in MatLab.

The system architecture employed to implement the control strategy is shown in Fig 4.4. The muscles activity signals provided by the Myo armband are sent to a PC through a bluetooth low-energy connection. The data are applied in a developed software routine into MatLab, using the MyoMex package. The flexion and extension movements of the glove fingers are operated by two Dynamixel AX-12A+ Smart Servos. Each motor is coupled to a tendon actuator mechanism. As motors rotate, they transmit forces to the glove's fingers making use of the Bowden cable/tendon system. Finally, the motor control signals are sent from the PC to the motors using the U2D2 device, a small size USB communication converter that enables to control and operate the motors via the PC.

To qualitatively assess the glove performance, as well as to validate the control strategy, a 37-year-old healthy male volunteer carried out some experiments. Three objects with common shapes found in everyday life were used (insulating tape, stick glue, and water bottle). The satisfactory results are shown in Figure 4.5. As can be seen, the implemented differential mechanism allows the actuated fingers to easily adapt to the objects surface, as was expected. Moreover, it is worth to mention that as a result of using the differential mechanism, it is possible to execute the pinch grasp motion.



Figure 4.4 – System architecture overview using the Myo gesture control armband sensor.

Source: Elaborated by the author, 2020.

Figure 4.5 – Objects used in the tests for hand grasping using the glove: (a) insulating tape; (b) stick glue; (c) water bottle.



Source: Elaborated by the author, 2019.

Figure 4.6 has an example of how the logic control of the system represented in Figure 4.3 works, with the EMG signals recorded associated with the wave in and wave out gestures to grip a little toy. Approximately between the time window 0 and 1.5 s (see Flexor signal in Fig. 4.6 (b) upper), the wave in gesture (wrist flexion) is performed, closing the hand. Notice that there is a slight variation in the EMG signal associated with the EMG extension movement (see Extensor signal in Fig. 4.6 (b) lower). Between 1.5 and 2.0 s, the toy is kept grasped and there is a small variation in both signals. Between the time window 2.5 and 4.0 s, the wave out gesture (wrist extension) is performed, opening the hand. The suddenly variation after the instant 4.5 s is related to the spread fingers gesture.



Figure 4.6 – (a) A little toy used for testing the pinch grasp, and (b) EMG signal recorded from Wave in and Wave out gestures.

Source: Elaborated by the author, 2019.

4.2 Glove Driven by sEMG Input with FES Application

An attempt was made to evaluate the glove system with FES and sEMG control input, and thus realize a proof of concept involving the hybrid control strategy proposed. This experiment was conducted mainly in order to compare the signal of sEMG with the signal of FMG; the sEMG signal was recorded without and with the noise generated by FES, while the FMG signals was recorded with no FES. The experiment was carried out making use of sEMG sensors and FES, with no suppression of artifacts. Fig. 4.7 shows the architecture used in the experiment for applying FES and recording the sEMG signals. The architecture for recording FMG signal is presented in the next section.

With the purpose of evaluating the influence of FES on the sEMG and to compare the sEMG signal to an FMG measurement, the experiment consisted in recording



Figure 4.7 – System architecture overview to control the glove with sEMG signals.

Source: Elaborated by the author, 2020.

the sEMG signal on the EDC muscle side when applying FES on FDS muscle side.

For the FES application, two active, rectangular self-adhering electrodes (Carci Trode, dimensions 3 x 5 cm), were placed over the motor point of the targeted muscle (on the FDS site - outside forearm). The electrode sites were cleansed with 70% isopropyl alcohol for removing skin fat, but not shaved. The sEMG signal was collected using the MyoWare muscle sensor with 3 pre-gelled disposable electrodes (Kendall, shape/size round/24 mm diameter, thickness 1 mm), the 2 target electrodes of the sensors were placed at the EDC region while the reference electrode of the MyoWare sensor was placed at the elbow portion. The sEMG signals were recorded with a sample rate of 1 kHz, and filtered using an IIR Elliptic Band-Pass filter of order 20 with a pass-band from 100 to 480 Hz and quantized for single precision. The filter was implemented using the Biquad Cascade IIR Filters Using a Direct Form II Transposed Structure from the CMSIS-DSP API for ARM Cortex-M4 microcontrollers (GOUDA, 2012). Fig. 4.8 has the representation of the signals processed.

As can be seen in Fig. 4.8, part (a) has the artifacts of an sEMG signal with no FES applied on the target muscles, part (b) has the stimulation artifacts in the sampled sEMG signals with FES, whereas (c) represents an FMG measurement recorded by the FMG sensors placed on the FDS site without FES. The sEMG signal recorded in Fig. 4.8 (b) consists of the so-called M-waves, which represent the level of muscle excitation caused by FES. It is clear from the results that the sEMG signal cannot be used for controlling the glove without an auxiliary procedure of suppression of artifacts when recording sEMG signals using FES. Note that, thanks to the sEMG signal recorded with FES containing the known characteristic frequency of FES, it is possible to filter the signal, eliminating the influence of FES. However, it is an additional procedure to be implemented. On other other hand, note that the FMG signal appears as a signal without abrupt spikes, with smooth changes, very different from the sEMG signal with no FES.

Figure 4.8 – Representation of the sEMG recorded on EDC muscle when FES is applied on FDS: (a) sEMG artifacts recorded without the influence of FES; (b) M-waves containing the influence of the FES; (c) FMG signal.



4.3 Glove Driven by Optical Fiber FMG Sensor Input

In these experiments, the FMG sensor described in subsection 2.5.1 was used. The experiments involved two healthy volunteers $(34 \pm 2 \text{ years old})$ without hand disabilities following the Ethical Committee recommendations. The experimental protocol was the same as described in the previous section, but with the exception that the FMG sensors need a fast calibration for each volunteer, as explained later, and they were firmly fixed to the target muscles set on the forearm with Velcro straps.

The system overview of the FMG-based control robotic glove can be seen in Fig. 4.9. In this setup, a pair of optical fiber sensor, i.e. a pair of microbending transducers, is placed on the FDS and the EDC muscles for monitoring and detecting the grasp and hand open intentions, respectively. The information obtained by the FMG sensors is further applied to the robotic glove control.

The system architecture block diagram to implement the control strategy for this configuration is shown in Fig. 4.10, and its description is the following: a simple controller using optical-fiber FMG was implemented with a high performance MCU based



Figure 4.9 – Overview of the FMG-based robotic glove.

Source: Elaborated by the author, 2020.

on the ARM Cortex-M4F architecture. This MCU has digital signal processing (DSP) capabilities due to its SIMD instruction set and two separate stack pointers ideal for real-time applications through the use of real-time operating systems (RTOS) (WICKERT, 2015). The system takes advantage of the CMSIS-RTOS RTX 5 which is designed for Cortex-M processor-based devices in order to implement two different threads (sampler and control threads) that run in a concurrent way (GOUDA, 2012). On the sampler thread, two channels of FMG signals are collected using the on-chip ADC with sample rate of 1 kHz, and then are processed through a single-threshold method in order to detect the On and Off timing of the muscles, by comparing the RMS value with predefined thresholds whose values depend on the desired sensibility required to detect the user intent with least possible effort (FAJARDO *et al.*, 2017). Moreover, a single channel of FSR is sampled in the same thread with the aim of controlling the pressure with which the user grabs the objects. Details about the control strategy adopted on the control thread are described below based on Fig. 4.11.

In the control strategy represented in Fig. 4.11, the state of the muscles activity is continuously measured and used to close, open, or hold the position of the glove by monitoring the signals coming from the two optical fiber FMG transducers. These devices detect the muscle activity related to the intention of closing or opening the hand, and the state of holding position is deduced from the signals acquired. After the signal conditioning stage, the voltage output spans the range of 0 to 3.3 V. The MCU processes both signals to calculate the RMS value of a 10 ms time window in order to be compared with predefined Figure 4.10 – Block diagram showing the system architecture of the optical fiber FMG driven controller and the wearable robotic glove.



Source: Elaborated by the author, 2020.

thresholds of FMG values to actuate the glove through the driving motors. The strategy of control was designed using a state machine of four states as shown in Fig. 4.11. In the initial state ("State 0"), when the hand is completely opened and the user tries to perform a grasp, the FMG transducer placed on the flexor set of muscles captures a signal that is proportional to the deformation produced by the group of muscles and that is also related to the force that they performed. If the FMG flexor RMS value (F) is greater than the predefined FMG flexor threshold (FT), the state machine switches to the "State 1" and turns on the motors responsible for closing the hand. The hand closes until the RMS value calculated from the FSR signal is greater than a threshold settled in a force set-point, leading the system to switch to the "State 2". This set-point is defined as $SP = \alpha F_{max}$, where F_{max} is the maximum value taken from a time window of 100 ms of FSR RMS values and α is a proportional gain used to calibrate the desired relationship between the force performed by the flexor group of muscles and the grip strength measured by the FSR sensor. The FSR sensor is attached to the index finger and provides signal when the finger presses the object's surface intended to be grasped. The motors remain in this state until the user performs a contraction that captures the intention of opening the hand and release the object. In this way, the FMG transducer placed on the EDC group of muscles detects a deformation in the same way as the flexors.

Hence, whether the FMG extensor RMS value (E) is greater than the FMG extensor threshold (ET), the system switches to the "State 3" and the glove starts to open by changing the motors direction. For the sake of simplicity and taking advantage of the capabilities of an RTOS, the elapsed time T (in ms) during which the glove remains closing until stopping is stored in the variable *Timer* from the transition of the "States θ to 1", and then it is used to open the glove by the same amount of time, returning the glove to the opened hand position and to the "State θ ". This procedure guarantees that the glove is kept always in the initial position, that is, in the neutral position for the wrist with the hand opened. The glove remains in this state until a new user intention for closing the hand is detected by the FMG transducer on the FDS site.



Figure 4.11 – Main thread flowchart showing the control strategy of the system.

Source: Ribas Neto et al. (2021).

Figure 4.12 – Examples of sensor waveforms for adjusting the threshold levels: (a) FMG sensor response to hand close intention; (b) FMG sensor response to hand open intention; (c) FSR response to a cylindrical grasp. The horizontal lines indicate the thresholds.



Source: Ribas Neto et al. (2021).

The FMG sensor calibration aforementioned was conducted as follows: the calibration preceded the experiments to set up the threshold levels FT and ET. With the transducers attached to the bellies of the FDS and EDC muscles' regions through Velcro straps, the individual performs hand close and open movements. Fig. 4.12 (a) and (b) show examples of FMG waveforms acquired in one calibration session. In this example, based on the average peak values, FT and ET are empirically set to 2 V to avoid misdetection due to unintentional contraction of muscles. To obtain the FSR set-point *SP*, a volunteer wearing the glove grasps and releases the a cylindrical bottle for measuring the average grip force F_{max} . As observed in Fig. 4.12 (c), the FSR output voltage related to F_{max} is 0.6 V. Choosing $\alpha = 0.9$ empirically yields a set-point that is SP = 0.54 V (remember that $SP = \alpha F_{max}$). The servo motor and FES assistances are disabled in these tests to assess the user's natural reactions. Nevertheless, one may adjust the threshold values to tailor the grasp sensitivity after relocating the glove and transducers or changing the user.

To validate the control strategy depicted in Fig 4.11, and keep evaluating the performance of the glove, all the sensor signals, FMG flexor RMS value, FMG extensor

RMS value, and FSR signal, were recorded during the manipulation of some items with forms commonly found in ADL. Here, the manipulated items include (a) a glue stick (2 cm diameter), (b) an adhesive tape roll (5 cm), (c) a bottle (8 cm) and (d) a cylindrical toy (3.5 cm), as shown in Fig. 4.13.

Figure 4.13 – Objects used in the test: (a) glue stick, (b) adhesive tape roll; (c) bottle, and (d) toy.



Source: Elaborated by the author, 2021.

Figures 4.14 (a) and (b) have signals conditioned of the manipulation of a glue stick and an adhesive tape roll. As can be noted in Fig. 4.14 (a), until approximately 2.3 s the systems is in "State 0", which indicates the motors are stopped and the hand is opened. When the flexion movement intention is detected by the FMG sensor placed on the FDS muscle site, the state changes to "State 1" and the glove starts closing. The dashed line represents the On and Off state of the motor, where 0 V represents the Offstate of the motors. The hand is kept closing until the FSR signal surpasses a threshold and then switches to "State 2". It implies the FSR touched the surface of the object, and the motors are stopped. When the extension movement intention is detected by the FMG placed on the EDC muscle, the state changes to "State 3" and the glove starts opening. Finally, "State 3" remains until the specified time is met, i. e. by the same time that "State 1" remains in high level, and thus switches again to "State 0". It means that the glove is fully opened again and the motors are stopped. The system continues in this state until a new flexion movement intention is detected, restarting the control loop. Fig 4.14 (b) shows the same signals evaluated, but related to the task of grasping an adhesive tape roll. Since the task makes use of the differential mechanism, signal shapes vary greatly.

Between period of time 4 and 6 s, the FSR signal starts increasing, because the index finger touched the object's surface. However, the glove remains closing because middle finger is bending. When the middle finger closes totally, approximately in 9 s, the Figure 4.14 – Signals from grasping (a) a stick glue and (b) an adhesive tape roll. S0: motors are stopped and robotic glove is opened. S1: robotic glove closing.
S2: grasp, motors are stopped. S3: hand opening. Note: FMG FDS = FMG flexor RMS value; FMG EDC = FMG Extensor RMS value; FSR = FSR signal.



Source: Elaborated by the author, 2020.

force is distributed between the two fingers and FSR signal starts increasing again, up to the motors stop in the "State 2". Comparing the difference between the amplitude and the shape of the signals in Figs. 4.14 (a) and (b). For each task developed, as for those represented in Fig. 4.13, we will have several different times for switching the states, but the procedures are the same. Furthermore, the noisy FMG FDS spikes appearing in Fig. 4.14 (b) are due to involuntary muscle contractions performed by the user during the test. But due to the control strategy adopted, they do not influence the drive of the motors, because the state of the motors during the first two states, depends only on the FSR and FMG EDC signals correspondingly.

The waveforms of the signals recorded from the manipulation of the bottle and a toy can be seen in Fig. 4.15 (a) and (b), respectively. Note that, the duration of states S1 and S3 depends on the size of objects. For example, the contact occurs later for the toy (3,5 cm) and earlier for the bottle (8 cm), respectively, due to the different diameters.

As can be seen, the manipulator promptly responds to the FMG commands, wherein the FDS muscle triggers the motors to assist hand closing (transition between S0 and S1), and the EDC stimulus starts opening the hand as the volunteer bends the wrist for extension (transitions between S2 and S3). Furthermore, the FSR signal halts the motion to grab the object with adequate contact force.



Figure 4.15 – Signals from grasping (a) a (b) bottle and a toy.

Source: Elaborated by the author, 2020.

Once the system operation is determined by the FSR signals to interrupt the servo motors, for safety issues, it is necessary to prevent the glove from keep closing in case of false–negative events, for example, due to the lack of contact between FSR and the object surface. Besides, the range of glove joints extension must be limited during hand opening to avoid injuries. In this sense, a software condition was implemented in which a standard time — time spent to close the hand from a neutral position (open palm) until the fingers are completely flexed (clenched fist) in a comfortable way — was recorded and used as a restriction for closing and opening the robotic glove. This also guarantees that the hand returns to its resting position because speed of the motors is constant.

4.4 Glove Driven by Optical Fiber FMG Sensor and operating with FES Application

For these experiments, the stimulation module described in subsection 3.3.1 was attached to the former system configuration in the previous section. Figure 4.16 has a representation of the system with the FES module coupled to the robotic glove system, and Fig. 4.17 has an example of the real system with the setup involving the FMG sensors and electrode arrangements on the forearm for FES application on the target muscles sets.

The experimental protocol followed for these experiments was the same of the previous section in addition to the following steps due to the FES application: for the FES



Figure 4.16 – System configuration using FES.

Source: Elaborated by the author, 2020.

application, two active, rectangular self- adhering electrodes (Carci Trode, dimensions 3 x 5 cm), were placed over the motor point of the targeted muscle (as shown in Fig. 4.19). The electrode sites were cleansed with 70% isopropyl alcohol for removing skin fat, but not shaved. Initial stimulation parameters were: symmetrical square biphasic pulses width; stimulation frequency equal to 25 Hz; ramp up and ramp down time, 2 s and 2 s, respectively; pulse width 150 μ s; sustained (maintenance pulse) depended on the experiment and on the subject sensitivity.

Figure 4.17 – FMG and electrodes arrangements on the forearm for driving the robotic glove employing FES on EDC and FDS muscles.



Source: RIBAS NETO et al. (2019).

Revisiting the main thread flowchart portrayed in Fig. 4.11, the FES and tendon-driven systems can be simultaneously enabled in states 1 and 3 or turned off in states 2 and 0 to create a hybrid control strategy (RIBAS NETO *et al.*, 2019). The new main thread flowchart for this control strategy is illustrated in Fig. 4.18.

Figure 4.18 – Main thread flowchart showing the control strategy of the system employing FES.



Source: Elaborated by the author, 2020.

To implement the control hybrid strategy, a slight change was made in the previous system architecture. The new architecture with the FES module is depicted in Fig. 4.19, in which the FES module represented by the Arduino UNO and Shield Stimulator has been added.

Figure 4.19 – Block diagram showing the system architecture of the hybrid controller and the wearable robotic glove employing FES.



Source: Elaborated by the author, 2020.

To appraise the hybrid control strategy, the same tasks were conducted using the same objects of the previous tests, the glue stick, the adhesive tape roll, the bottle, and the toy. The signals recorded from the experiments are plotted in Figs. 4.20 and 4.21, wherein V_FES is the stimulation signal; frequency and amplitude are reproduced out of scale for the sake of visualization. Upon receiving an FMG flexion intent, electrical stimulation is applied in conjunction with tendons actuation to assist the grasp with minimal muscular fatigue. FES input stops as the FSR senses the object surface, thus the

Figure 4.20 – Signals from grasping (a) a glue stick and (b) an adhesive tape roll. S0: motors are stopped and robotic glove is opened. S1: robotic glove closing and FES acting. S2: grasp, motors and FES are stopped. S3: hand opening and FES acting. Note: FMG FDS = FMG flexor RMS value; FMG EDC = FMG Extensor RMS value; FSR = FSR signal; V_FES = stimulation signal representation (frequency and amplitude out of scale).



Source: Elaborated by the author, 2020.

object is held by the tendons mechanism. Reverse stimulation occurs in response to FMG extension intent, returning the hand to the rest pose.

Fig. 4.20 is related to Fig. 4.18 as follows: when detected the user's intention to close the hand (FMG Flexor RMS value greater than a FMG Flexor Threshold collected by an optical FMG sensor placed on the FDS muscle area), the actuating system responsible for closing the hand is turned on as well as the FES system. The FES system is activated and the hand is kept closing until the signal coming from the FSR glued on the index fingertip (see Fig. 4.16) surpasses a settled force setpoint. When it happens, it means that the glove touched an object's surface, and both tendon actuating system and FES are switched off. The user's hand remains in this posture, with the object grasped, until a new intention of opening the hand is detected, which is detected by another FMG sensor placed on the EDC muscle area. In conventional orthoses using only FES, the grasp is maintained exclusively by the use of FES (see Fig. 3.1 (a) in section 3.1), the extended period of time which is responsible for provoking muscle fatigue.

When the FMG Extensor RMS value coming from the FMG placed on EDC muscle exceeds a FMG Extensor Threshold, the FES is turned on, the rotation of the motors is reversed, and the hand starts to open. To simplify the control related to the opening of the hand, the hand remains opening and FES actuating, for the same time as glove was kept closing. This procedure ensures that the hand returns to its resting

Figure 4.21 – Signals from grasping the (a) bottle and (b) the toy. S0: motors are stopped and robotic glove is opened. S1: robotic glove closing and FES acting. S2: grasp, motors and FES are stopped. S3: hand opening and FES acting. Note: FMG FDS = FMG flexor RMS value; FMG EDC = FMG Extensor RMS value; FSR = FSR signal; V_FES = stimulation signal representation (frequency and amplitude out of scale).



Source: Elaborated by the author, 2020.

position, that is, with the hand opened. The same input control is used to switch the FES off. Thus, the glove is ready to perform another movement. In this approach, for security issues, the system operation is also running under the time constraints for opening and closing the hand, as the previous experiments.

The task regarding the adhesive tape roll test has results similar to the task considering the glue stick task. As can be seen in Fig. 4.20 (b), the main difference remains on the contribution of the use of the differential mechanism, i.e. the fingers adaptation to the surface's object, which can be seen approximately in the time of 5 s. Notice that the FSR signal begins to increase when the index finger touches the object. However, after the instant 5 s it seems there is a slight slip of the sensor, resulting in a fall of signal coming from FSR. Actually, thanks to the differential mechanism, the force exerted by the tendons causes the middle finger to begin to flex, until it reaches a point where the forces are in equilibrium and the FSR restores contact with the tape until the FSR threshold is reached.

Another point worth commenting on is that during states S1 and S3 in Figs. 4.20 and 4.21, the plots do not present any, or almost none, influence from sEMG signal. That is because the threshold of the FMG detection circuit was adjusted conveniently so as not to respond to involuntary muscle stimuli, even under the use of FES.

5 DISCUSSION AND FINAL CONSIDERA-TIONS

In the present study, we aimed at the development of a low-cost hybrid wearable glove-like orthosis prototype that might be worn on the hand, to assist and recover hand movements in patients who have suffered a stroke or spinal cord injury, or suffer from degenerative diseases. As the main goal, it was met. However, some comments are necessary.

As seen at the grasp-evaluation experiments, the glove-like orthosis driven by the optical fiber FMG sensor presented reliable results for both mechanical and FESassisted actuation, allowing the manipulation of different objects. The adaptive mechanism employed allows the robotic glove to adjust the fingers to several shapes of objects, establishing appropriate physical contact without complex control strategies and sensors. If, on the one hand, the soft structure collaborates to achieve these outcomes, on the other hand, it makes it difficult to precisely control the positioning of the fingers, since soft structures do not have such rigidity to do so. Conversely, soft gloves are less bulky than rigid structures, contributing to reducing the weight of the devices, which in turn affects the user's comfort and natural movements.

Regarding the motors utilized in this project, the smart servos were chosen due to their ease of programming and connection to the cable winding mechanism, despite the fact that the facilities offered by servos were not being used. We could have chosen direct current motors, and developed a different way to control the over-closing or over-opening the hand. In our project, we created a means to provide a straightforward way to detect the contact force, triggering the state machine to sustain the pose and secure the object employing an FSR. The use of the FSR was an innovative resort to obtain a plain solution to deal with the limit matter of how much to open or close the hand. Without the FSR we would need a different control strategy for the motors, for example, the current control approach, as used in other works. In fact, most related articles in the area do not present any comment or solution to this issue.

In respect of the use of FES, it is difficult to achieve precise and repeatable movement using this technique isolated, and it may be painful for the patient. The proposed hybrid control strategy working alongside with the tendon-driven glove was conceived to handle these hindrances, providing FES assistance when wished or necessary. Furthermore, the control strategy opens the door to the unexplored assessment of fatigue, since the open-source FES device allows to establish when and how to dose FES by just setting some parameters. With reference to the system's autonomy, further tests must comprise the system connected to a battery instead of the utility power, especially regarding the impact of the FES on consumption.

Analyzing the user intention detection system, the FMG sensor presented satisfactory results, detecting in a simple way, without many adjustments, the volume variation of the FDS and EDC muscles of the users who tested the glove prototype. However, in individuals who have a high degree of motor impairment, that is, who have low muscle volume variation, intention detection is prone to have some detection failures. For example, individuals who have a low residual level of muscle activity have limited hand movement. In these cases, another control strategy may be necessary for detecting the user's intention – a solution based on wrist extension and flexion movements would be an adequate and simple way to activate the glove and the FES system, or the use of pushbuttons, as some authors resorted in the works presented in the literature review. In cases where individuals have hemiplegia, the FMG sensor can be placed in the healthy hand, or the more usual control system may be applied, the use of sEMG. Anyway, if there is no other alternative than sEMG, then it is necessary to use recorded signal processing to deal with the M-waves due to the influence of FES.

Regarding the glove's quantitative metrics, some characteristics such as weight, degrees of freedom per finger, maximum grip forces, and the range of finger joints of robotic gloves may be found in literature. Motors and the use of batteries are the main components to hinder and limit the reduction of light weight of the overall devices. In our project, the use of the Bowden cables system helps to transfer most of the weight off the hand. With the sheaths connected to the glove and the same leaning upon the scale of the balance, the glove weights 153 g. Although information about the quantitative metrics serve as a guideline for the design of robotic gloves, it is a thorny question to conduct an unbiased comparative analysis since these parameters depend on several criteria such as performed task, grasp type, and manipulated object characteristics, to name a few.

In our first version, we used a cable winder manufactured by 3D printing using acrylonitrile butadiene styrene (ABS). After the tests were done, 2 new cable winders were produced using stainless steel to substitute the 3D-printed mechanism and 2 more to expand the actuation to the rest of the fingers - Fig. 5.1 has an image with the two types of cable winders. The second version has not yet been used. Each 3D-printed mechanism weights 163 g and the stainless-steel one weights 331 g. These values are not so important because the mechanisms are far from the glove, and they can be connected to the user's waist or to a wheelchair, if applicable.

Despite the integrated nature, the proposed robotic glove has drawbacks concerning the rigid mechanical structure, demanding developments toward a portable and soft design. Regarding portability, a compact control box should accommodate the motors, microcontroller unit, and battery. The proposed system is still bulky due to several connect moduli such as servo motor, FES, optical interrogator, and the MCU, which implies that

Figure 5.1 – Cable winder manufactured by additive manufacturing (3D printing) on the left, and manufactured by subtractive manufacturing (machined) on the right.



Source: Elaborated by the author, 2020.

the procedure of donning or doffing the glove takes around 10 minutes. This aspect requires hardware miniaturization into a compact unit. Moreover, all the examples restrict the range of possible grasps, usually comprising a single-precision grip through the activation of the thumb, index, and medium fingers, making them unable a priori for multi-gesture control. Lastly, complementary studies must consider individuals with severe motion impairments, as this certainly affects the magnitude of FMG signals and require improvements to the hybrid control architecture.

Last but not less important, we would like to comment about the main difficulties faced to reach the results here shown. First, Brazil lacks of staff, suppliers to provide and deliver most pieces and equipment employed in this project. It was very difficult to buy the items used in the project, and even when they were found in Brazil, they were too expensive. Moreover, the acquisition of equipment via public bids is a cumbersome and bureaucratic process, delaying any research. The second point has to do with the difficulty of finding people to undergo experiments, even the ones who have any impairments on the hands. As a third difficulty, in our case, we might cite the COVID-19 pandemic which we experienced while chasing the final results of this work. Put aside the pandemic, it is evident how difficult i is to produce research in our country.

6 CONCLUSION

Based on the literature review, it was seen that repetitive motion exercises help to re-map the motor function in the brain in case of SCI and stroke. Additionally, the application of conventional therapy associated with FES can result in better outcomes owing to the FES proven rehabilitative capability. Moreover, it appears that soft wearable robotic orthoses for hand are a promising approach for home rehabilitation. Research in this direction has already resulted in many works presenting different types of soft wearable exo-gloves to be used as assistive technology.

Following this trend dictated by these studies, we developed and presented a glove-like orthosis prototype integrated with an optical fiber sensor. Apart from the current devices relying on underactuated mechanisms triggered with sEMG machine learning classifiers or pneumatic soft-actuators controlled by switches, the synergy between an FMG-based posture detection system and a robotic glove prototype creates an assist-as-need device for individuals with upper-limb disabilities.

Furthermore, an additional FES stimulation apparatus is available for operation through a tendon-driven system, electrical stimulation, or a fusion of both. To dose FES operating in parallel with the tendon-driven system, a hybrid control strategy was devised, which may be employed for other orthoses since they have a way to provide support for the hand when the FES is turned off. The optical fiber sensor ensures no competition with FES due to its immunity to electromagnetic interference. Furthermore, upgrading the system functionalities is feasible by connecting extra units, including sEMG and vision-based intention detection modules.

As mentioned before, based on the preliminary results, from a general point of view, the glove-like orthosis driven by optical fiber FMG sensor presented satisfactory results for both mechanical and FES-assisted actuation, allowing the manipulation of different objects.

For near and long term, some future works may be asserted. Despite the promising results, the FMG detection requires some residual level of muscle activity and may present unsatisfactory performance for individuals with severe impairments; a possible solution comprises moving the sensor to another region with greater voluntary residual control. Moreover, the instrumented glove can be slightly hard to don/doff onto the hands. Hence, future developments must focus on redesigning the glove to facilitate these tasks and change the fabric into a more hygienic material. Integration with other user interfaces such as sEMG, BCI, and computer vision is also under investigation to improve intentions assessment regardless of the user condition. In addition, improvements in software and

hardware will provide an embedded solution to ease portability and enable tests with potential users.

Another field of work to be explored is the formulation of a means of measuring the muscle fatigue and then to provide stimulation inversely proportional to the measurement of the user's muscle activity, that is, as the muscle activity goes down, FES should also be decreased. It means that if muscles are fatigued, the tendon-actuated orthoses must provide the total support for the hand to develop the ADLs, and the FES dosing must be ceased. This implies developing a shared control strategy to dose FES based on muscles fatigue. Considering control of fatigue, very few devices' designs have been developed to detect or monitor muscle fatigue. This is an open wide research field, and the few methods only focus on reduction/remedial efforts, rather than use it as an active control component.

Finally, despite all research being conducted on orthoses and hybrid orthoses aiming at assistance and restoration of functional reaching and grasping, commercially solutions in Brazil and worldwide are scarce. Besides development of hybrid orthoses/exoskeletons focusing on strategies to avoid muscle fatigue seems to be just beginning, what is an open door for research opportunities in this area. Therefore, envisioning that our work presents groundwork to be used in prototypes for hand orthoses in a near future, this work also aimed to provide its significant contribution to the use of the robotic-assisted technologies for rehabilitation of hand movements.

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ANNEX A – Free and Informed Consent Form

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Órtese robótica para abertura e fechamento da mão de pessoas com pegada fraca utilizando estratégia de controle híbrida

Pesquisadores responsáveis: Antonio Ribas Neto e Eric Rohmer Número do CAAE:

Você está sendo convidado a participar como voluntário da pesquisa "Órtese robótica para abertura e fechamento da mão de pessoas com pegada fraca utilizando estratégia de controle híbrida". Este documento, chamado Termo de Consentimento Livre e Esclarecido, visa assegurar seus direitos como participante e é elaborado em duas vias, uma que deverá ficar com você e outra com o pesquisador.

Por favor, leia com atenção e calma, aproveitando para esclarecer suas dúvidas. Se houver perguntas antes ou mesmo depois de assiná-lo, você poderá esclarecê-las com o pesquisador. Se preferir, pode levar este Termo para casa e consultar seus familiares ou outras pessoas antes de decidir participar. Não haverá nenhum tipo de penalização ou prejuízo se você não aceitar participar ou retirar sua autorização em qualquer momento.

Justificativa e objetivos:

As pessoas que sofrem com pegada fraca nas mãos causados por doenças neurológicas e musculoesquelética degenerativas comuns, como por exemplo acidente vascular cerebral (AVC) ou lesão na medula espinhal, enfrentam dificuldades para manipular objetos e realizar suas tarefas cotidianas. Além de impactar drasticamente a vidas dessas pessoas, essas enfermidades também criam impacto financeiro para o Estado, já que a maioria dos indivíduos são tratados em hospitais e centros públicos e, estes por sua vez, muitas vezes não dispõem de recursos suficientes e apropriados para o acolhimento e tratamento desses indivíduos.

Muitas vezes a pegada fraca é uma sequela proveniente desses tipos de doenças, mas que se tratadas logo de início, ela pode ser evitada, ou suas consequências amenizadas. Para ajudar essas pessoas a recuperarem novamente os movimentos das mãos e assim a sua autonomia, o uso de órteses com fins assistivos, ou de reabilitação, é de extrema importância.

Tendo isso em mente, neste trabalho é apresentado um protótipo de uma órtese robótica tipo luva para ser calçada (vestida) na mão. A órtese é uma luva robótica que utiliza um sistema de cabos (tendões) para abrir e fechar a mão, e dessa forma ela pode ser utilizada como um dispositivo assistivo, ou seja, dar assistência às pessoas para realizarem suas tarefas, como segurar um copo de água, pegar uma fruta ou outra atividade. O projeto da órtese também utiliza estimulação elétrica funcional, que é uma técnica utilizada para ajudar na reabilitação de movimentos, fortalecer músculos, entre outras aplicações, mas que quando utilizada por tempo prolongado gera fatiga muscular. O propósito do projeto dessa órtese é alcançar em um só dispositivo as vantagens que essas tecnologias têm quando são utilizadas separadamente, produzindo uma órtese que possa dar assistência e também reabilitar os movimentos das mãos. O controle da abertura e fechamento da mão utilizando o sistema de cabos e a estimulação elétrica ao mesmo tempo é feito por meio de uma estratégia de controle chamada *estratégia de controle híbrida*.

No Brasil, as pesquisas envolvendo esses tipos de órteses são escassas, e as órteses não estão disponíveis para o mercado, deixando o acesso a esse tipo de tecnologia indisponível a centenas de brasileiros. Visando reverter esse cenário, procura-se desenvolver um protótipo órtese que sirva de base para novas pesquisas e para a produção de novas órteses para fins de assistência e reabilitação.

manipular objetos com formas comuns encontradas no dia-a-dia; avaliar o funcionamento da *estratégia de controle híbrida* que controla o sistema de acionamento por tendões e a estimulação elétrica funcional e; recolher informações para melhoria do projeto da órtese no sentido de contribuir com futuras pesquisas sobre dispositivos assistivos e de reabilitação, assim como refinar as técnicas de seleções das ações, bem como a confiabilidade e conforto de uso da órtese.

Procedimentos:

Participando do estudo você está sendo convidado a utilizar a órtese robótica tipo luva para avaliar e testar o seu funcionamento e controle através da manipulação de alguns objetos com formas comuns do nosso dia-a-dia.

Durante os experimentos de avaliação, um dos pesquisadores estará sempre acompanhando o procedimento podendo, eventualmente, pará-lo, se necessário. Você poderá ser convidado mais de uma vez para realizar os testes a fim de analisarmos a evolução do projeto e uso da órtese e sua opinião sobre a usabilidade, funcionamento e controle da mesma.

O local de realização dos testes será dentro do Laboratório de Computação e Automação da Faculdade de Engenharia Elétrica e Computação da UNICAMP. O tempo total estimado para realização dos testes não deve ser superior a 2 (duas) horas.

Os procedimentos que serão realizados são descritos detalhadamente a seguir:

1. Sua chegada/explicação

Chegando ao local dos experimentos, será apresentado a você a órtese de mão, o eletroestimulador, os objetos a serem manipulados, os sensores e os eletrodos a serem utilizados. Os detalhes da órtese serão mostrados e o pesquisador responsável irá explicar como ela pode ser manipulada/operada através das demonstrações. Será explicado também como funciona o estimulador elétrico, a sensação provocada pela estimulação elétrica e a familiarização com os dispositivos. A partir disso, as tarefas começarão a ser executadas. O tempo estimado para essa etapa é de 10 a 20 minutos.

- 2. Posicionamento dos eletrodos de eletroestimulação no antebraço do usuário Nesta etapa, um dos responsáveis pela pesquisa irá solicitar que o voluntário se sente confortavelmente na cadeira e estenda um de seus braços sobre a mesa. Será solicitada permissão do usuário para a limpeza do local no antebraço utilizando álcool, onde os eletrodos de estimulação serão fixados. Logo depois de fixados os eletrodos, será perguntado se o usuário se sente confortável com os eletrodos e caso não esteja, poderá retirar a qualquer momento. Após isso será feito um teste de estimulação para o voluntário se familiarizar com a sensação de estimulação elétrica. A qualquer momento, se o usuário não se sentir confortável com o procedimento, poderá desistir sem nenhum ônus. Tempo estimado para essa etapa é de 5 a 10 minutos.
- 3. Posicionamento da órtese e sensores no usuário Nesta etapa, um dos responsáveis pela pesquisa irá pedir para você colocar a luva e serão feitos os procedimentos necessários para fixação desta na sua mão. Logo depois, no antebraço, com o auxílio de tiras de Velcro, serão fixados os sensores para controle da órtese. A posição dos sensores será determinada por palpação, e uma vez fixados serão calibrados para abertura, fechamento e demais posturas necessárias da mão para os experimentos. Será perguntado se

Rúbrica do pesquisador:______Rúbrica do participante:____

ANNEX A. FREE AND INFORMED CONSENT FORM

você se sente confortável com os componentes e luva fixados no seu antebraço, e caso não esteja, poderá retirar a qualquer momento. Tempo estimado para essa etapa é de 5 a 10 minutos.

4. Uso da órtese

A seguir você será solicitado a realização de alguns testes para a familiarização do funcionamento, operação e controle da órtese e sensores, juntamente com a estimulação elétrica, e também para a manipulação de alguns objetos. Se você se sentir confortável com a órtese e decidir continuar, será dado início aos experimentos para gravação dos dados dos sensores e possíveis filmagens da manipulação dos objetos. Tempo estimado para essa etapa é de 5 a 10 minutos.

5. Experimentos e gravação dos dados

Para avaliar a órtese e seu funcionamento, nesta etapa será solicitado a você para manipular alguns objetos com forma comuns encontradas no dia a dia, como por exemplo, uma caneca, um bastão de cola, pegar uma bola, segurar uma garrafa de água, manusear um dado, pegar uma caneta, pegar uma bola, segurar um copo com água, utilizar um borrifador de água, entre outros objetos cotidianos. Nestes procedimentos, os sinais coletados pelos sensores, e os vídeos gravados, serão armazenados. Tempo estimado para essa etapa é de 15 a 30 minutos.

6. Entrevista

Você é a parte essencial no desenvolvimento desse projeto. Dessa forma, será conduzida uma entrevista para saber a sua opinião sobre a sua experiência em utilizar a órtese de mão, com perguntas como ``como foi a sua experiência, quais suas sugestões, quais as suas sugestões, críticas e quais as suas expectativas". A entrevista será realizada durante e após o uso da órtese. Tempo estimado para essa etapa é de 5 a 10 minutos.

Geral:

Apesar de ser um método extremamente seguro, a estimulação elétrica pode causar alguma dor momentânea devido à sensibilidade e tolerância à aplicação de corrente elétrica, pode causar alguma irritabilidade ou coceira na pele devido ao aumento da irrigação sanguínea, e se aplicada de maneira errada, com eletrodos com problemas de aderência, a estimulação elétrica pode te expor a alguns tipos de riscos, como queimaduras na região dos eletrodos, rompimento de vasos sanguíneos e capilares causando hematomas, e sensações de choques mais fortes. Na presença destes sintomas o teste será interrompido. Além disso, você estará sendo observado e consultado frequentemente e, a qualquer momento, se ocorrer qualquer incômodo que seja desagradável, você deverá notificar o responsável pelos experimentos e os testes serão interrompidos imediatamente. A partir da correta execução do procedimento, os riscos são mínimos, não havendo nenhuma evidência específica de alguma consequência imediata ou tardia, embora após o tratamento, pode haver marcas rosadas na pele onde os eletrodos foram colocados, mas geralmente desaparecem em uma hora. Os riscos são maiores para pacientes que fazem o uso de próteses metálicas e marca passo, e por esse motivo estes fazem parte do grupo de exclusão.

O presente estudo oferece risco controlado à saúde, e os pesquisadores se disponibilizam a dar assistência a você por eventuais intercorrências. Caso você vier a sofrer qualquer tipo de dano Rúbrica do pesquisador:_______Rúbrica do participante:______

resultante de sua participação na pesquisa, previsto ou não neste TCLE, você tem direito à indenização, por parte do pesquisador, patrocinador e das instituições envolvidas.

À princípio, não existe nenhum benefício previsto para os participantes da pesquisa, não é obrigatória e não trará riscos previsíveis. No entanto, ao final desta pesquisa, esperamos em caso de sucesso com relação aos objetivos propostos, contribuir com o desenvolvimento de tecnologia assistiva e de reabilitação nacional, e internacional, de forma a proporcionar, em um futuro próximo a possibilidade de melhoria da qualidade de vida de alguns pacientes que possuem pegada fraca provenientes de doenças musculoesquelética ou neurodegenerativa, como acidente vascular cerebral (AVC), lesão na medula espinhal (SCI) ou traumas. O desenvolvimento de um dispositivo que possa ser utilizado no dia a dia e que contribua com assistência e ao mesmo tempo reabilitação motora da mão facilitará a execução de tarefas cotidianas e com isso irá melhorar o estado físico, mental e social desses indivíduos.

Você não receberá nenhum pagamento por sua participação nesta pesquisa, mas será garantido a você e seu acompanhante, quando for o caso, o ressarcimento de despesas decorrentes da participação no estudo, tais como transporte e alimentação nos dias em que for necessária sua presença para a coleta de dados fora ou após a sua rotina de trabalho.

Caso queira, você poderá desistir da sua participação a qualquer momento, sem que isso lhe cause nenhum prejuízo. Você será acompanhado e assistido pelo pesquisador responsável e a sua equipe durante esses procedimentos, podendo fazer perguntas sobre qualquer dúvida que apareça durante todo o estudo. Os dados coletados (fotografias e vídeos das partes de seu corpo utilizando a órtese – antebraço e mão) estarão sob o resguardo científico e o sigilo profissional, e contribuirão para o alcance dos objetivos deste trabalho e para posteriores publicações dos dados em revistas especializadas e/ou em encontros científicos e congressos, sem nunca tornar possível a sua identificação, garantindo o sigilo de sua participação.

Para o uso de sua imagem, fotografia, ou vídeos das partes envolvidas na pesquisa, será solicitado a você a assinatura do "Termo de autorização de uso de imagem, fotografia ou filme", para permitir o uso desses dados em nossas pesquisas e divulgação dela – maiores informações sobre o uso estão no termo. Esses dados coletados ficarão armazenados por tempo indeterminado, mas poderão ser apagados assim que os resultados forem publicados e/ou que a pesquisa seja concluída. Caso opte por não assinar o "Termo de autorização de uso de imagem, fotografia ou filme", as imagens, fotografias e vídeos de suas partes envolvidas na pesquisa não serão divulgados.

Para quaisquer dúvidas, você pode contatar os pesquisadores responsáveis: Dr. Eric Rohmer (tel. (19) 3521-0247, e-mail: eric@dca.fee.unicamp.br, endereço: Faculdade de Engenharia Elétrica e Computação - Av. Albert Einstein, 400, UNICAMP, CEP: 13083-859, Cidade Universitária, Campinas, SP).

Em caso de denúncias ou reclamações sobre sua participação e sobre questões éticas do estudo, você poderá entrar em contato com a secretaria do Comitê de Ética em Pesquisa (CEP) da UNICAMP das 08:30hs às 11:30hs e das 13:00hs as 17:00hs na Rua: Tessália Vieira de Camargo, 126; CEP 13083-887 Campinas – SP; telefone (19) 3521-8936 ou (19) 3521-7187; email: cep@fcm.unicamp.br.

O Comitê de Ética em Pesquisa (CEP).

Rúbrica do pesquisador:______Rúbrica do participante:____

Versão: Junho-2020

ANNEX A. FREE AND INFORMED CONSENT FORM

O papel do CEP é avaliar e acompanhar os aspectos éticos de todas as pesquisas envolvendo seres humanos. A Comissão Nacional de Ética em Pesquisa (CONEP), tem por objetivo desenvolver a regulamentação sobre proteção dos seres humanos envolvidos nas pesquisas. Desempenha um papel coordenador da rede de Comitês de Ética em Pesquisa (CEPs) das instituições, além de assumir a função de órgão consultor na área de ética em pesquisas

Consentimento livre e esclarecido:

Após ter recebido esclarecimentos sobre a natureza da pesquisa, seus objetivos, métodos, benefícios previstos, potenciais riscos e o incômodo que esta possa acarretar, aceito participar e declaro estar recebendo uma via original deste documento assinada pelo pesquisador e por mim, tendo todas as folhas por nós rubricadas:

Nome do (a) participante:	
Contato telefônico:	
e-mail (opcional):	
(Assinatura do participante ou nome e assinatura d	Data:/

Responsabilidade do Pesquisador:

Asseguro ter cumprido as exigências da resolução 466/2012 CNS/MS e complementares na elaboração do protocolo e na obtenção deste Termo de Consentimento Livre e Esclarecido. Asseguro, também, ter explicado e fornecido uma via deste documento ao participante. Informo que o estudo foi aprovado pelo CEP perante o qual o projeto foi apresentado e pela CONEP, quando pertinente. Comprometo-me a utilizar o material e os dados obtidos nesta pesquisa exclusivamente para as finalidades previstas neste documento ou conforme o consentimento dado pelo participante.

(Assinatura do pesquisador)

Rúbrica do pesquisador:______Rúbrica do participante:____

__ Data: ____/____/_____.