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Abstract

Currently, trans-radial amputees can perform few movements with prosthetic hands. This is mainly due to low control capabilities and to the long training time that is required to learn controlling them with surface electromyography (sEMG). This is in contrast with recent advances in mechatronics, thanks to which mechanical hands have nowadays multiple degrees of freedom and, in some cases, force control. To improve the situation, we are building a large database of sEMG and hand posture data that will help the community to test and improve sEMG-based control schema for prosthetic hands. In this paper we present the stages of the database creation, namely (a) a review of sEMG-controlled prostheses, robotic hands and control methods, (b) the description of the initial setup and acquisition protocol, and (c) a preliminary data acquisition from a pool of 28 subjects. This phase helps us assessing the protocol, identifying pitfalls and correcting them.
This work is performed within the NINAPRO (Non-Invasive Adaptive Prosthetics) project with the final goal to develop a community-wide accepted database of sEMG data coming from both healthy subjects and amputees, and to assess the best way of realizing natural control of a large number of (up to 50) hand postures.

Keywords: electro myography, EMG, hand prosthetics.

Contents:

1 Introduction

Daily life of hand amputees can be difficult compared to the situation before the amputation. The state of the art in hand prosthetics usually does not offer more than a maximum of 2-3 degrees of freedom and a very coarse control of the force, due to the absence of haptic feedback. Patients most often interface with the prosthesis via surface electromyography (sEMG).

Learning how to control the device through an sEMG channel is a long and difficult process for most patients. Usually, open/close is the only movement possible. This is in contrast with recent advances in mechatronics, thanks to which mechanical hands with many degrees of freedom and fine-grained force control are being built. This fact is also in contrast with the recent advances in sEMG control, that enhance the capability of dexterous hand control from amputees [7].

Moreover, there is currently no large, public sEMG database on hand prosthetics available, nor a widely accepted recording protocol to acquire sEMG data (neither for healthy subjects nor for amputees). Therefore, there is a need for a large database suitable for the complex analysis required to control a dexterous prosthesis with several degrees of freedom and to test and evaluate new machine learning algorithms that are being creaBodyted by various research groups.

The NinaPro (Non-Invasive Adaptive Hand Prosthetics) project started in January 2011 with the aim to help fulfilling the two mentioned needs. The main goal of this project is to develop a family of algorithms able to significantly augment the dexterity control of EMG prostheses and to reduce the needed training time. NinaPro will last for three years and is subdivided into three main phases: data acquisition and analysis; augmented dexterity via posture classification or natural control; and adaptive learning. The first phase of the project consists of the implementation of a standardized acquisition protocol and of the acquisition of a large collection of data from healthy and hand-amputated persons. The successive phases are based on the analysis and classification of the acquired data. Testing the findings on the large amount of data that is planned to be collected can pave the way for a new generation of prosthetic hands.

The sEMG database will be made available to the scientific community. A challenge workshop is planned to compare the machine learning results of several research groups.

In this paper we describe the first three steps of the NinaPro project. The first is the review of the state of the art in sEMG controlled robotic hands and prostheses. The second is the implementation of the acquisition protocol that has been used for the acquisition of the initial data set. The third is the acquisition of the initial database, that consists of 28 subjects and that makes the identification of pitfalls in the acquisition protocol possible and allows correcting them.

2 sEMG Robotic Hands Control Review

2.1 Electrode Types and Placing

Surface EMG is traditionally gathered using Ag/AgCl (silver-silver chloride) surface electrodes. The most common procedure requires that the subject's forearm, or stump, be shaved first, cleaned with biocompatible alcohol and then prepared with conductive gel over the spots where the electrodes are to be placed. According to their characteristics, sEMG electrodes can be classified as:

- Single- or double–differential: single–differential electrodes gather one potential difference V = V1 − V0, where V0 is the ground reference; double-differentials gather two potentials, V1 and V2, in two spots slightly apart from each other. Then, they return V = (V1 − V0) − (V0 − V2), resulting in a signal less influenced by cross-talkBody.
- Passive or active: rather than behaving like passive voltage-sensitive devices, of which output must be amplified, rectified and filtered by an external device, active electrodes perform these operations on board, thereby greatly reducing the inter-electrode interference and the radio-frequency influence induced by the cables, which transport the signals from the electrode to the amplifier/digital converter.

In standard clinical practice, first a trained specialist searches for the remnants of high-activity muscles. Subsequently, a socket is built with holes corresponding to the maximum-activity spots found before. Once the socket and prosthesis are in place, the patient is trained to associate muscle patterns to prosthesis movements (usually open/close) or proportional use of grip force.

In research, numerous attempts at finding the right forearm muscles on healthy subjects exist (see, e.g., [1,2,3]), based upon anatomic guidelines and basic considerations on the structure of a muscle and the electric field it produces when moved voluntarily. Unfortunately, these attempts have little or no meaning when dealing with amputees since each and every amputation is unique. In [4], placements of up to 32 electrodes are described (and used) based on the severity of the amputation.

Early research on pattern matching for sEMG [5,6], recently confirmed in [4,7], prove that precise placement of electrodes is not required as pattern recognition techniques can compensate for suboptimal placement.

2.2 Dexterous Control

The word dexterity is hereby used in its commonsense meaning, applied to hand prostheses. A hand prosthesis is deemed to be dexterous if it is capable of assuming many different positions and exerting an arbitrary force. At the time of writing, such examples are scarce, both in the commercial field of application, e.g., Otto Bock's SensorHand Speed[1], Touch Bionics's i-LIMB[2], as well as in robotics laboratories. Nevertheless, as more and more dexterous hands appear, the problem of control by the patient becomes increasingly important.

Surface electromyography has been in use since the 1960s to control self-powered prostheses [8,9,10]. In this pioneering work one or two electrodes were used to control one or two degrees of freedom. Recently the use of more electrodes and more sophisticated feed-forward control schema, mainly employing machine learning methods, has led to the possibility of recognizing about 10 hand postures, and the required force to a high degree of precision (see, e.g., [11,12,13]). This is accomplished using a classifier detecting the required posture among a finite

[1] http://www.ottobockus.com

[2] http://www.touchbionics.com

set, and a regressor detecting the required force, independently of the posture.

All results uniformly indicate that the patient's intention can be detected from the signal obtained from a few commercial electrodes. In some recent cases this has already been demonstrated on amputees [7].
To the best of our knowledge, currently there is no established method/protocol that a patient or healthy subject should follow to train a dexterous prosthesis. Examples appear in [11,14,12] for different numbers of classes (hand postures) to be recognized and/or forces. In nearly all cases, a pattern recognition schema is applied to a chunk of sEMG signals gathered over a specific time-window. The subjects are asked to voluntarily assume a posture for a determined time, during which the ground truth is ascertained. Only in [7,15] a somehow deeper investigation in the matter is carried out; in the latter particularly, three training strategies are tried (imitating a healthy teacher, bilaterally moving in the same way, and looking at a mirror device).
In the field of prosthetics, a codification of 33 hand grasps is described in [16]. Several codifications of hand grasps and postures have been realized in the field of hand taxonomy to describe the intrinsic hierarchical structure of hand postures [17,18,19]. Further classifications have been made by clinicians to evaluate the functionality of hands [20].

2.3 Medical and sEMG Databases

The creation of publicly available databases is an instrument that in the last decade has largely promoted and supported research in various areas of artificial intelligence, including medical imaging. The impact of such databases can be considerably enhanced when they are coupled with challenge evaluations, targeting every year different aspects of the research problem. Benchmarks such as ImageCLEF [21,22] for medical image retrieval or BioCreative [23] for biomedical text analysis have shown how much impact standard data sets can have in terms of comparing techniques and lowering the entry burden for research groups not directly involved in the medical field. Reference data sets [24] and evaluation methodologies can help to compare techniques and really advance fields [25]. In many countries and particularly in the USA, NIH (National Institutes of Health) and NCI (National Cancer Institutes) funded projects consistently aim at making all created data sets available, in order for the entire research community to profit from them.
One of the most successful examples of this strategy is the Cross Language Evaluation Forum (CLEF)[3]. This event promotes research and development in multi-lingual information access by developing an infrastructure for the testing, tuning and evaluation of information retrieval systems operating on European languages. By creating test suites of reusable data researchers can always compare their tools to the state of the art and data are only created once. The first evaluation campaign of this series was organized in 2000, and it has been running every year since. The number of tasks proposed grew from four in 2000 to seventeen, grouped under eight main themes, in 2009. In 2004, a medical image retrieval task was first proposed that has been running since has attracted a growing number of participants. In 2009 and 2010 ImageCLEF also hosted a robot vision task.
Another success story is the PASCAL Visual Object Class challenge (PASCAL VOC)[4]. Proposed since 2005 under the umbrella of the network of excellence PASCAL[5], it has been running since with an important impact on the computer vision community. The main goal of the challenge is to recognize objects from a number of visual object classes in realistic scenes. The

[3] http://www.clef-campaign.org
[4] http://pascallin.ecs.soton.ac.uk/challenges/VOC
[5] http://www.pascal-network.org

databases proposed, the experimental settings and evaluation procedures have become a very influential tool in the targeted community.
As of today, research on prosthetic hands does not have any similar instrument. Each group acquires the data to its own research independently, and it does not make it publicly available. Examples of data sets collected to the aim of analyzing sEMG data for hand prosthetics are reported [3,4,5,6,7,12,13,14,15,26,27], but none of these data sets have been officially published, nor do they respect a strict acquisition/storage protocol. The situation stays the same with other examples of sEMG signals collected for slightly different tasks such as, e.g., the analysis of phantom-limb pain or the level of after-amputation cortical reorganization [28,29]. This makes the evaluation of systems for prosthetics extremely hard; we believe that the release of the NinaPro database can have a profound impact on the research community.

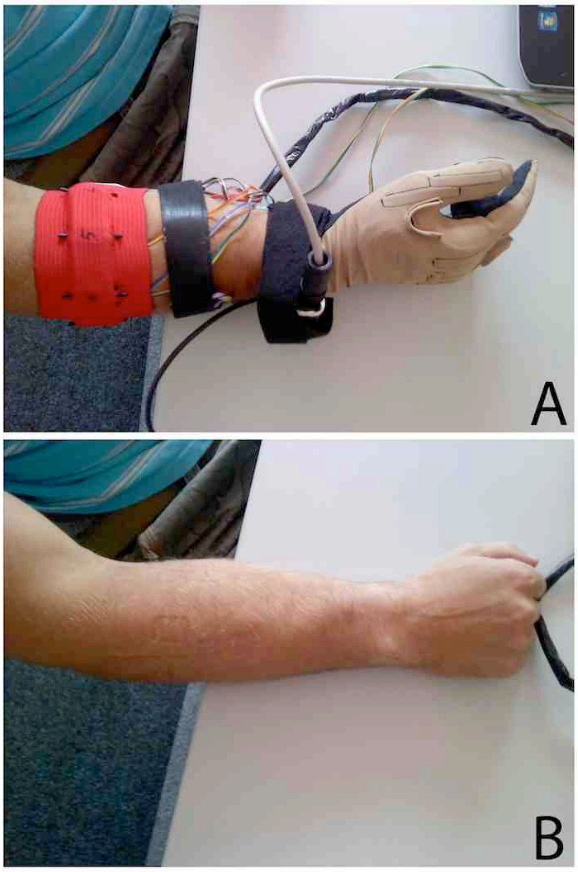

Figure 1: A. Forearm and hand of a non-amputated subject with the acquisition setup on. B. Forearm and hand of the same subject

3 Acquisition Protocol

The experimental acquisitions are performed on healthy controls and on amputated patients with the supervision of trained persons.
The acquisition setup consists of:

- One laptop with a PCMCIA Slot (DELL Latitude E5520).
- One Digital Acquisition Card (National Instruments DAQCard-6024E for PCMCIA).
- Ten sEMG electrodes (Otto Bock 13E200=50). The electrodes are connected to a printed circuit board with a 68-pin female connector.
- One National Instruments SHC68-68M-EPM cable. The cable connects the printed circuit board to the PCMCIA digital acquisition card.
- One Cyberglove II (CyberGlove Systems LLC) with 22 sensors (three flexion sensors per finger, four abduction sensors, a palm-arch sensor, and sensors to measure wrist flexion and abduction). The data-glove is connected to the laptop via Bluetooth.
- One 2-axes inclinometer (Kübler 8.IS40.23411). Like the sEMG electrodes, the inclinometer is connected via the printed circuit board and the National Instruments SHC68-68M-EPM to the PCMCIA digital acquisition card into the laptop.
- A custom acquisition software was specifically implemented to acquire the data from all of the peripherals in synchronyzation.

The data acquisition of each subject lasts for about two hours, including placing and removal of the electrodes and an explication of the actions.
First the subject is asked to answer some general and clinical questions. The collected data include age, gender, weight, height, laterality, work, hobbies related to the use of hands and current self reported health status. If the subject is amputee, he is asked also to give some clinical data regarding the amputation. The data include the date of the amputation, the type of accident that caused it, any clinical note, if he was ever subject to an sEMG prosthesis and, in this case, for how long.
Subsequently, the electrodes are placed on the right forearm according to the indications described in paragraph II.A. The subject is asked to wear the CyberGlove on the right hand, and the inclinometer is fixed with Velcro straps on the top of the glove to detect hand rotations.
Then, a movie that describes how the experiment has to be performed is shown to the subject.
Amputated subjects are asked to think to repeat what is shown on the screen with both hands. In the meanwhile, they are doing the same movement with the healthy hand. The other subjects are asked to repeat what is shown on the screen with the right hand.
Finally, the subject is asked to do first a training sequence (that lasts for about 15 minutes) and then three exercises (that last together for about 1 hour and 20 minutes). The movements that are performed in the training sequence and the exercises are described thoroughly in paragraph II.B.

3.1 Electrode Types and Placing

The choice of the electrode type is particularly important to realize a database useful both for the scientific community and for further industrial applications. As described in paragraph II.A, we could choose between several kinds of electrodes (active or passive, single or double differential). We chose active double-differential electrodes (Otto Bock 13E200=50), because they are described as the best choice for hand prosthetics control in the literature [2] and because they are widely used both in scientific research and in industrial applications.

Active double–differential electrodes do not require cleaning/shaving, a fact that makes the acquisition process easier. Moreover, the signal of the electrodes can be input directly to an entry-level digital acquisition card and, since after rectification and filtering the bandwidth of the signal lies below 25Hz, no high-speed computing is required. To make the acquisition portable, we completed the acquisition setup with a National Instruments 6024E PCMCIA Digital Acquisition Card and a Dell Latitude laptop.
The signal obtained by the Otto Bock 13E200=50 electrodes consists of a rectified signal, indicating the summed average activity of the underlying motor units. This rather smooth signal, which has a lag of about 200ms, gives a good indication of the number of underlying motor units and their average firing frequency and thus a measure for the amount of force that the measured muscle exerts. A further decision of particular importance for the acquisition protocol is the place of the electrodes on the arm for healthy and amputated subjects. As described in paragraph II.A, there are three main trends regarding this problem: first, to place the electrodes on the maximum activity spots of the muscles; second, to place the electrodes on anatomically correct positions; third, to place the electrodes in equally spaced positions. We decided to use the second and the third method in order to realize a database useful for comparing both approaches. Therefore, we placed 8 electrodes at equal distances just beneath the elbow, while 2 electrodes are placed in spare positions. In order to maintain the place of the electrodes approximately constant in every subject, the 8 equally spaced electrodes are fixed on an elastic armband that is placed on the forearm in a constant position with respect to the radio-humeral joint (Figure 1A). The two spare electrodes are placed on each subject respectively on the flexors of the finger muscles and on the extensors of the finger muscles (Figure 1A).

3.2 Dexterous Control

The objective of this part of the acquisition protocol is to push the current state of the art in prosthetic hand posture classification from handling a maximum of 12 postures towards up to 40-50 postures through the application of machine learning techniques on a consistent database. In the literature there is currently no established method/protocol that an amputee or healthy subject has to follow to train a robotic hand. In the NinaPro acquisition protocol we selected 52 movements from the robotics and the taxonomy literature and from the DASH (Disabilities of the Arm, Shoulder and Hand) protocol for functional movements [21].
These postures are subdivided into four main classes:

- Finger basic movements (Figure 2);
- Hand static postures (Figure 3);
- Wrist basic movements (Figure 4);
- Hand grasps and functional movements (20 gestures from [16] and 3 functional movements, Figure 5).

The subject is asked to do first a training sequence and then the three exercises. The training sequence lasts for about 15 minutes, and consists of three repetitions of all the movements of the first three classes and of three movements of the fourth class.
In the exercises for the recording each movement is repeated 10 times. The first exercise lasts for 15 minutes, and includes 12 basic finger movements. The second exercise lasts for 25 minutes, and includes the 17 movements included in the static hand posture and basic wrist movement groups. Finally, the third exercise lasts for 30 minutes, and includes 20 hand grasps and 3 functional movements with several objects (Figure 5). In order to avoid errors related to fatigue and its influence on the sEMG signal, the subject is asked to rest for 5 minutes between the training sequence and the first exercise, and then between each exercise.

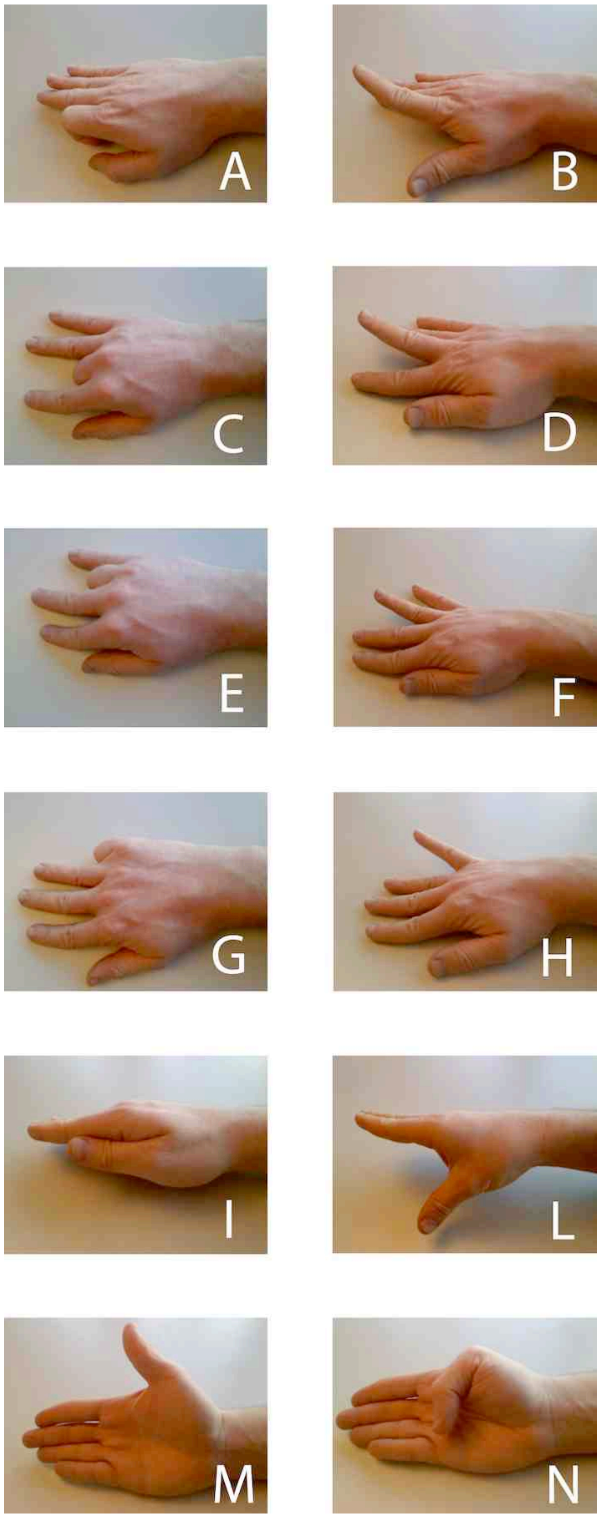

Figure 2: Fingers basic movements. A. Index flexion, B. Index extension, C. Middle flexion, D. Middle extension, E. Ring flexion, F. Ring extension, G. Pinkie flexion, H. Pinkie extension,

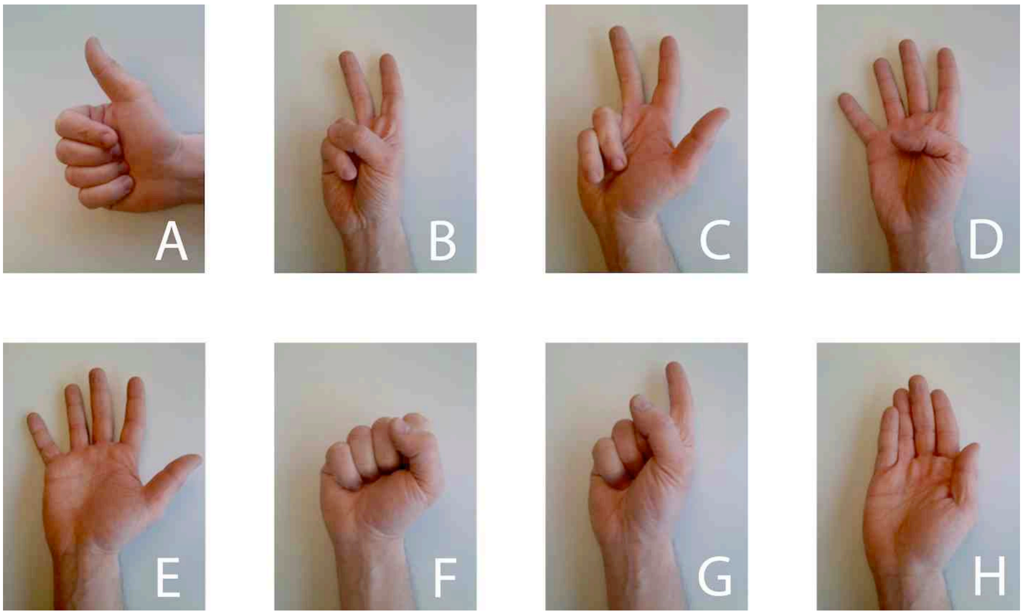

Figure 3: Hand static postures. A. Thumb up, B. Flexion of ring and little finger; thumb flexed over middle and little, C. Flexion of ring and little, D. Thumb in opposition towards the base of the little finger, E. Abduction of the fingers, F. All fingers flexed together, G. Point, H. Fingers closed together.

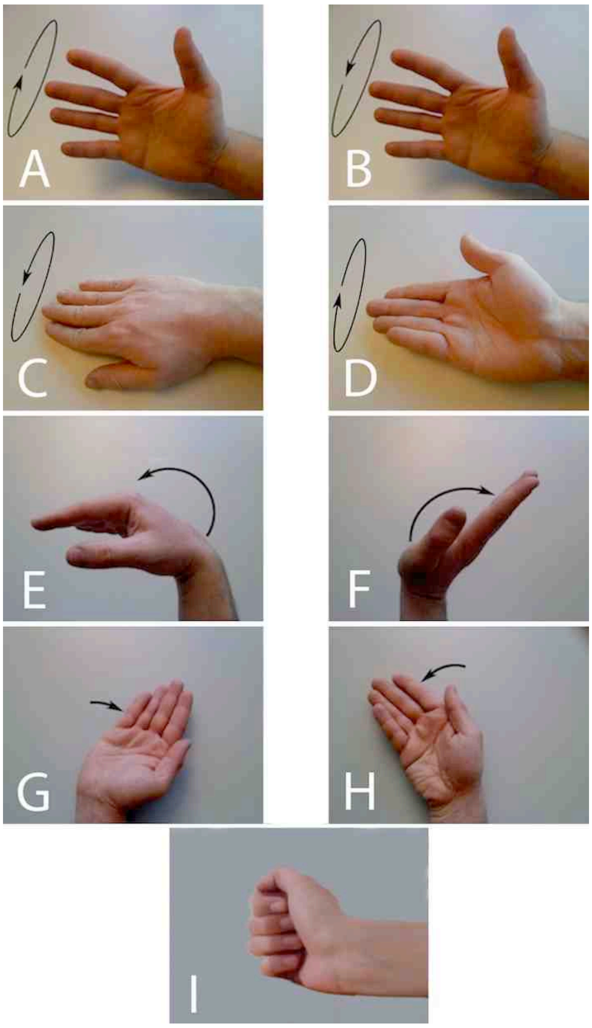

Figure 4: Wrist basic movements. A. Wrist clockwise roll, B. Wrist anticlockwise roll, C. Wrist pronation, D. Wrist supination, E. Wrist flexion, F. Wrist extension, G. Wrist abduction,

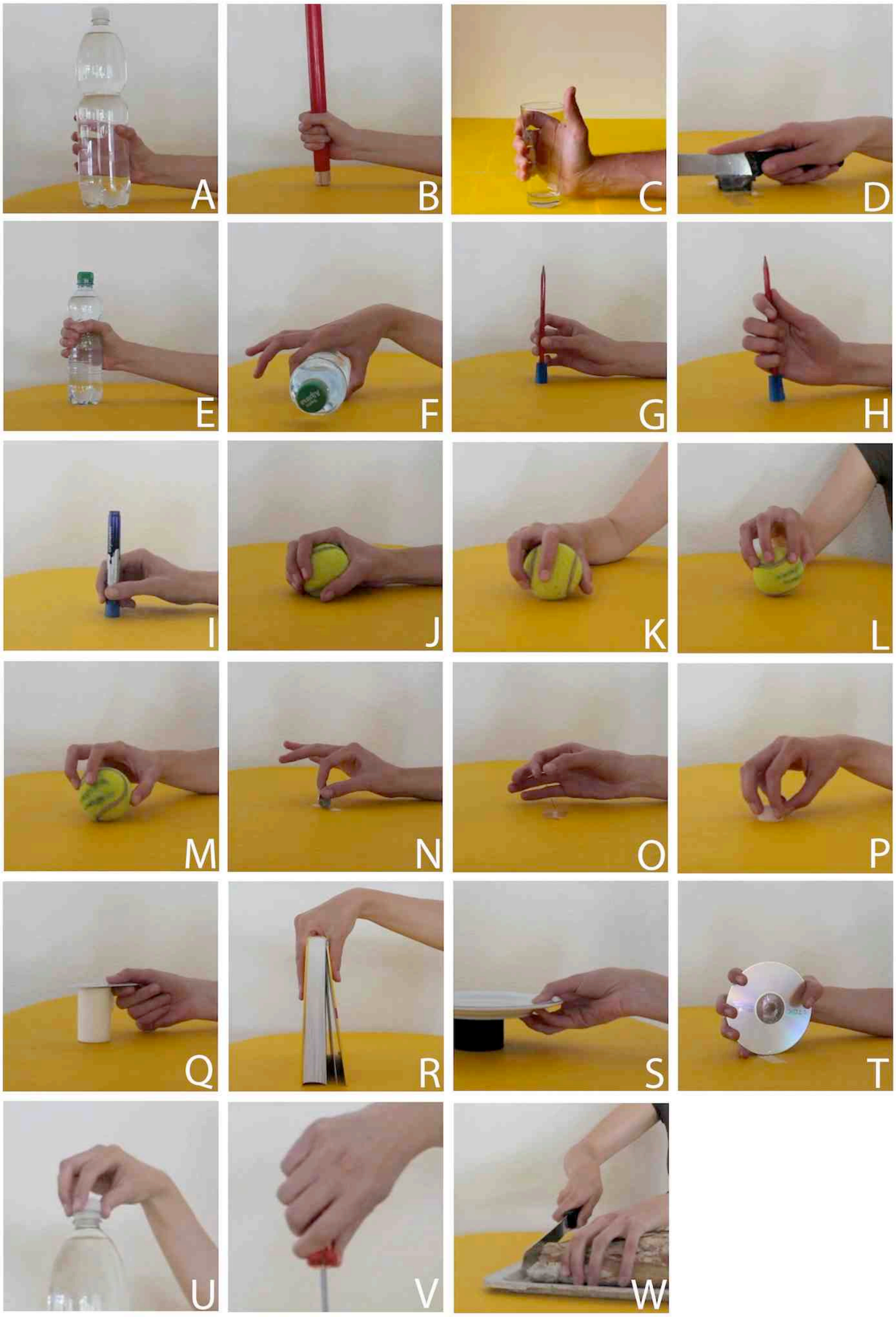

Figure 5: Grasps. A. Large diameter, B. Small diameter , C. Fixed hook, D. Index finger extension, E. Medium wrap, F. Ring, G. Prismatic 4 fingers, H. Stick, I. Writing tripod, J. Power sphere, K. Sphere 3 fingers, L. Precision sphere, M. Tripod, N. Prismatic pinch, O. Tip pinch, P. Quadpod, Q. Lateral, R. Parallel extension, S. Parallel flexion, T. Power disk, U. Open a bottle with a tripod grasp, V. Turn a screw keeping a screwdriver with a stick grasp, W. Imitate to cut something with an index finger extension grasp

4 Database

The experimental acquisitions were performed on healthy controls and on amputated people by trained persons.
For each subject were acquired the following clinical and experimental data:

- name
- surname
- acquisition date and time of the day
- acquisition Location
- age
- gender
- height
- weight
- laterality
- job
- hobbies
- self reported health status at the moment of the acquisition

For amputated patients, were acquired also the following data:

- exact place of the amputation
- type of accident or reason for the amputation
- information about the time and the reasons of the amputation)
- previous use of sEMG prostheses
- in case of previous use of an sEMG prosthesis, how long the subject have been using it.

The clinical and experimental data were stored in the database together with sEMG data, the data from the Cyberglove and the data from the inclinometer.
All data are stored on a web-based database to facilitate sharing them within the scientific community. Three text files are stored for each of the three exercises. The three files include one file with the data from the 10 sEMG electrodes and from the inclinometer, one file with the data from the 22 sensors Cyberglove and one file with the data regarding the movie timing. Five pictures are also stored with the data. Three of them consist of a preview of the data of each exercise (Figure 6), while the remaining two pictures are photographs of the forearm and of the hand with and without the acquisition setup (Figure 1).
Internally, we keep a record of the identity of all the subjects. However, the data are depersonalized when exported for sharing and for analyses, therefore no re–identification of persons will be possible by external groups through the entire duration of the project. This approach will make sure that personal data will be acquired and treated according to ethical aspects at all times in order to ensure privacy.
The initial NinaPro database is currently stored in the web based database (Figure 7): it consists of 30 acquisitions of 28 subjects. Two of the 30 acquisitions are repetitions of a single exercise for subjects that had been already acquired, and were performed due to problems in the previous data sets. The subjects can be grouped in 27 healthy controls and 1 amputee, 21 males and 7 females, 26 right handed and 2 left handed. The average age is 28.1 years with standard deviation 3.4 years. The initial NinaPro database is currently under analysis and evaluation, in order to assess the protocol, identify pitfalls and correct them, and can be downloaded from the NinaPro web based database[6].

[6] http://ninapro.hevs.ch

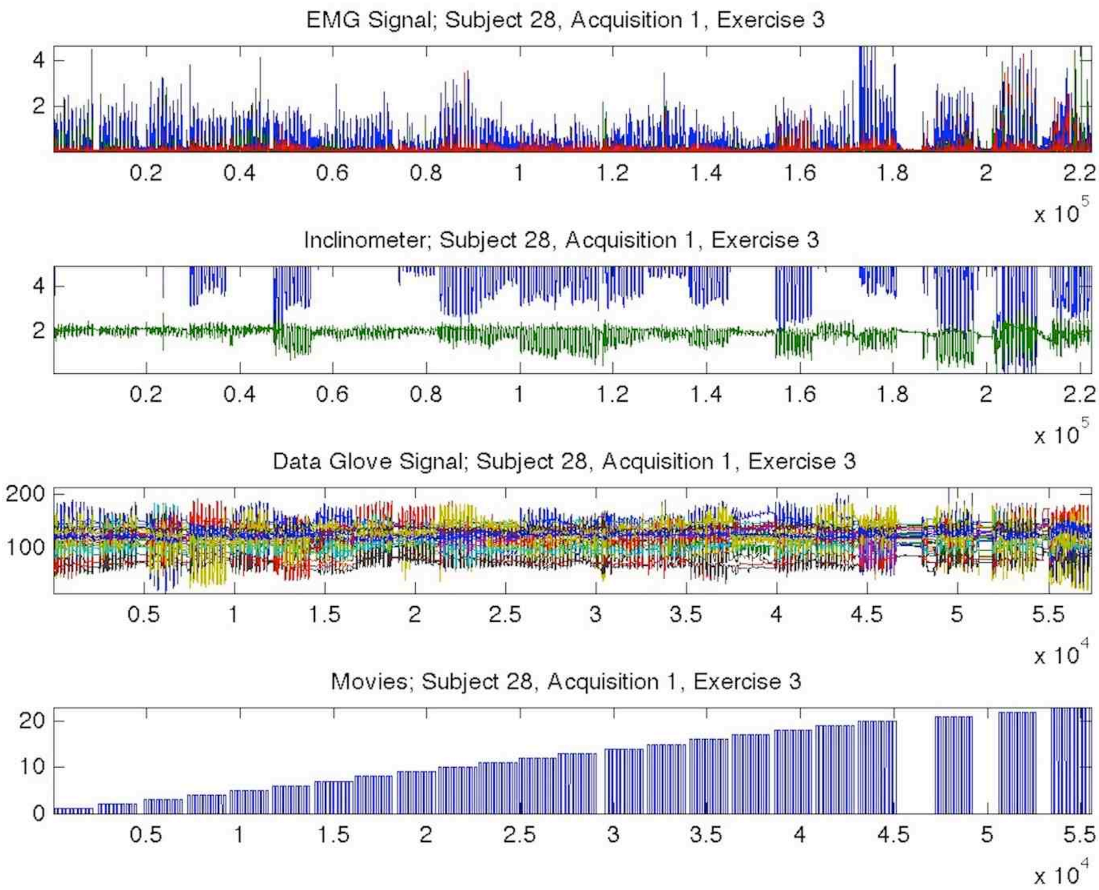

Figure 6: Example of data preview image. Subject 28, Acquisition 1, Exercise 3.

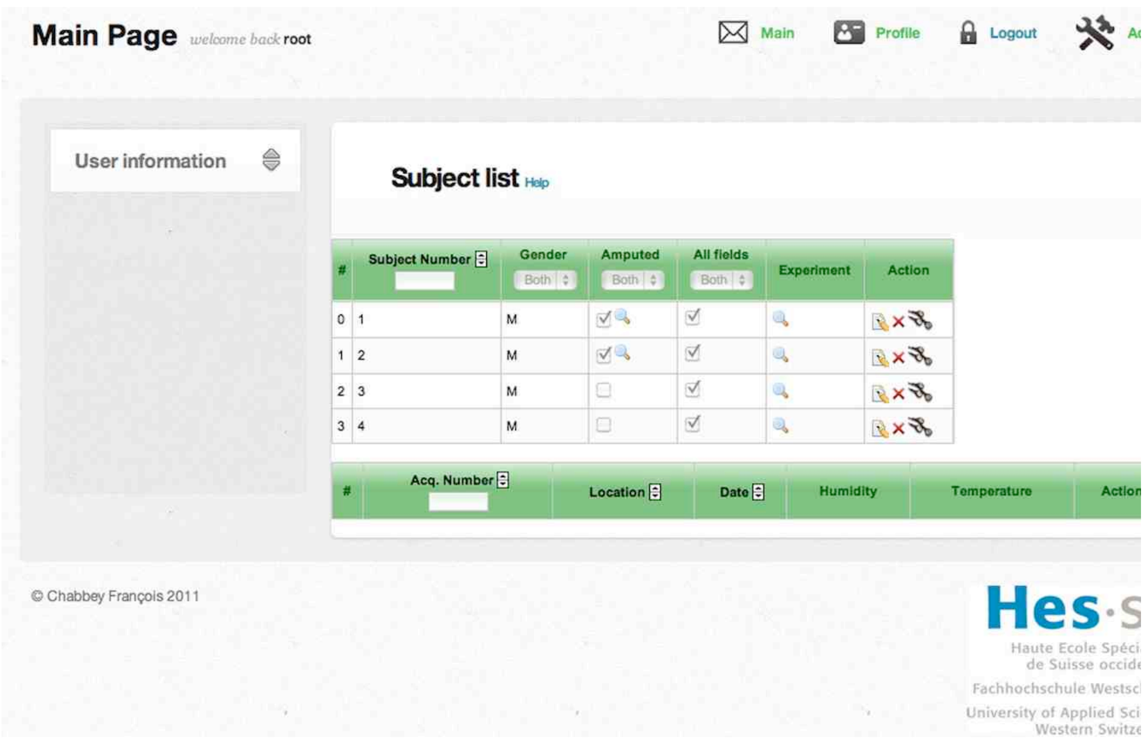

Figure 7: Graphical interface of the NinaPro web based database. Subjects list page.

5 Conclusions

The NinaPro Project aims at becoming a benchmark in the field of dexterous robotic prostheses control. Currently, amputated persons can perform only few movements with prosthetic hands. This contrasts with recent advances in mechatronics, thanks to which mechanical hands with many degrees-of-freedom and force control are being built.

In this paper we review the literature of sEMG controlled prostheses and robotic hands to create the acquisition protocol of the NinaPro project that we introduce in detailed form. We then present the initial NinaPro Database.

The scientific literature prescribes active double–differential electrodes as the best choice for hand prosthetics control. Currently, three main methods are suggested for the placement of the electrodes on the forearms of the subject (first to place the electrodes on the maximum activity spots of the muscles; second to place the electrodes on anatomically correct positions; third to place the electrodes in equally spaced positions). Regarding the hand gestures to be analyzed, many single gestures have been described both in robotics and in hand taxonomy, but there is no established method/protocol that a patient or healthy subject should follow. Finally, the absence of large sEMG databases for dexterous robotic hand control may currently be a blocking part in the field.

The acquisition protocol that we propose is based on a review of the literature of hand taxonomy and robotics. It combines the acquisition of clinical and experimental data with the acquisition of 52 different hand movements. The movements are recorded using 10 sEMG electrodes (8 placed uniformly on the forearm, 2 placed on the fingers flexor and extensor muscles), one Cyberglove with 22 sensors and one 2 axes inclinometer.

The installation of the NIDAQ-6024E PCMCIA Card was not possible with Microsoft Windows 7 and Vista, both in 64 and 32 bits versions. Trying several different configurations delayed the beginning of the acquisitions of two weeks. Finally, we succeed in installing the National Instruments acquisition card using Microsoft Windows XP 32 bits.

The initial Ninapro database consists of 30 acquisitions of 28 subjects (27 healthy controls and 1 amputee), and can be downloaded from the NinaPro web based database.

The Ninapro initial database is currently under analysis and evaluation. This phase will help us assess the protocol, identify pitfalls and correct them.

The NinaPro project hopes to aid the development of a new generation of sEMG-based prosthetic control methods by giving the opportunity to the scientific community to test the research findings on a very large collection of data and by testing many optimized machine learning tools on the data.

Moreover, it will have multiple applications, as it will permit to analyze the sEMG generated by controls and amputated people. First it will make possible to analyze the differences between different kinds of amputations, second it will make evident which kind of movements amputees can still reproduce with the remnants of their muscles, and finally it will also help to develop new strategies to train amputees to learn how to use sEMG prostheses.

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Appendix A

Formulaire de base
pour la soumission d'un projet de recherche biomédical

Soumis à **la commission cantonale valaisanne d'éthique médicale** le 03.01.2011

Désignation du projet de recherche soumis (selon protocole)

NINAPRO - Non-Invasive Adaptive Hand Prosthetics

☒ Premier avis
☐ Avis ultérieur
N° de réf. CER : N° de réf. Swissmedic / OFSP :

Investigateur (responsable relevant du champ de compétence de la CER)

Nom, prénom, titre : Müller, Henning, Prof. Dr.
Fonction : Professeur
Adresse : HES-SO, TechnoArk 3, 3960 Sierre
Tél. : 027 606 9036 Fax : 027 606 9000 E-mail : henning.mueller@hevs.ch

☒ Autres collaborateurs (selon liste ci-jointe)

Investigateur principal en Suisse (en cas d'essai clinique multicentrique)

Nom, prénom, titre : Caputo, Barbara, Dr.
Fonction : Chercheur senior
Adresse : IDIAP, Centre du parc, Rue marconi 19, 1920 Martigny
Tél. : 027 721 1737 Fax : 027 721 7712 E-mail : bcaputo@idiap.ch

Promoteur

Entreprise / institution : pas d'entreprise impliqué
Personne responsable en Suisse :
Adresse :
Tél. : Fax : E-mail :

Principale source de financement (s'il ne s'agit pas de l'entreprise promotrice)

Entreprise / institution : Fonds national Suisse de la recherche Scientifique
Personne responsable en Suisse : Patricia Jungo
Adresse : Wilhainweg, Berne
Tél. : 031 308 21 41 Fax : E-mail : pjungo@snf.ch

Autres sources de financement

Entreprise / institution :
Personne responsable en Suisse :
Adresse :
Tél. : Fax : E-mail :

Entreprise / institution :
Personne responsable en Suisse :
Adresse :
Tél. : Fax : E-mail :

Entreprise / institution :
Personne responsable en Suisse :
Adresse :
Tél. : Fax : E-mail :

Organisme de recherche sous contrat (CRO)

Nom :
Adresse :
Personne de contact :
Tél. : Fax : E-mail :

Type de projet de recherche

☐	Médicaments, phase ☐ I ☐ II ☐ III ☐ IV	☐	Transplantations
☐	Dispositifs médicaux, certifiés ☐ oui ☐ non	☐	Recherche fondamentale
☐	Produits radiopharmaceutiques	☐	Epidémiologie
☐	Produits sanguins	☒	Etudes portant sur les données des patients
☐	Produits immunobiologiques	☐	Ostéopathie, physiothérapie, sciences infirmières
☐	Chirurgie		
☐	Radiothérapie	☐	Recherche sur des embryons (*in vitro*)
☐	Essais de thérapie génique	☐	Pathologie
☐	Essais génétiques	☐	Essais psychothérapeutiques
☐	Autres :		

Produit(s) testé(s)
(principe[s] actif[s] et nom[s] de marque)

aucun

Produit(s) de comparaison
(principe[s] actif[s] et nom[s] de marque)

aucun

Description en quelques mots-clés du projet de recherche

The research aims at measuring muscle signals, first of healthy persons and in year 2 also from hand-amputated patients to improve the machine learning for the use of prostheses.
The project is a collaboration between IDIAP, the German Aerospace Center (DLR) and the HES-SO Valais (physiotherapy and business informatics sections).
No products will be given to the patients nor any stimulation with electrical signals.
Informed consent will be requested from all persons and a minimal demographic data set will be acquired (age, gender, weight, height, etc.) including parameters that might have an influence on the electrical signal. None of the parameters will aloow fon n identification of the person.

Quelles sont vos considérations éthiques qui justifient l'essai en question ?

The goal of the project is the improvement of current hand prostheses that are hard for an amputated person to learn and that only allow very basic movements with usually one degree of freedom. The methods to be developed will allow for quicker and easier learning and for more complex movements.

Nombre prévu de sujets de recherche

Relevant de la compétence de la CER : around 80 En Suisse : around 80 Dans le monde : around 80

Participation de populations particulièrement vulnérables

☒	Non				
☐	Oui, soit :	☐	Sujets sains	☐	Personnes mineures
		☐	Personnes en institution	☐	Pers. incap. de discern. ou interdites
		☐	Urgences	☐	Patients en phase terminale
		☐	Autres :		

Nombre prévu de sites de recherche relevant de la compétence de la CER

☒ 1 ☐ Plusieurs (selon liste ci-jointe)

Autres cantons où le projet de recherche est mené ☐ Aucun

☐	AG	☐	AI	☐	AR	☐	BE	☐	BL	☐	BS	☐	FR
☐	GE	☐	GL	☐	GR	☐	JU	☐	LU	☐	NE	☐	NW
☐	OW	☐	SG	☐	SH	☐	SO	☐	SZ	☐	TG	☐	TI
☐	UR	☐	VD	☒	VS	☐	ZG	☐	ZH				

Autres pays où le projet de recherche est mené ☐ Aucun

☐ FL ☐ Autres, soit :

Durée du projet de recherche

Début prévu du projet de recherche (recrutement du premier sujet de recherche) : 1.5.2011
Fin prévue du projet de recherche (dernier sujet de recherche, dernière visite) : 30.6.2013

Ce projet fait-il ou a-t-il déjà fait l'objet d'une évaluation par d'autres commissions d'éthique en Suisse ?

☐ Oui (veuillez dans ce cas joindre le[s] préavis correspondant[s]) ☒ Non
☐ En cours auprès de :

La présente demande est accompagnée des documents suivants :

	Document	Nombre Exemplaires
☒	Formulaire de base daté et signé	12
☒	Protocole du projet de recherche daté et signé Version originale du 1.3.2011	12
☐	Protocole modification (datée et signée) n° du modification (datée et signée) n° du	
☐	Dernière version du protocole daté et signé (y compris modifications) du	
☒	Résumé du protocole en langage courant	12
☒	Information du sur le recrutement des sujets de recherche (y compris textes d'annonce et questionnaires), médias prévus (préciser)	12
☒	Information destinée aux sujets de recherche	
	☐ en allemand (du)	
	☒ en français (du)	12
	☐ en italien (du)	
	☐ en d'autres langues : (du)	
☒	Déclaration de consentement des sujets de recherche	
	☐ en allemand (du)	
	☒ en français (du)	12
	☐ en italien (du)	
	☐ en d'autres langues : (du)	
☐	Etendue et nature de l'indemnité versée aux sujets de recherche	
☐	Etendue et nature de l'indemnité versée aux investigateurs	
☐	Certificat / police d'assurance applicable(s) au site de recherche (du)	
☐	Attestation du promoteur concernant la couverture des préjudices (du)	
☐	Confirmation (du) que le responsable désigné pour la Suisse se déclare prêt à assumer ses obligations en Suisse conformément à l'art. 7, al. 3 OClin	
☐	Contrats conclus entre le promoteur et l'investigateur ou entre un organisme de recherche sous contrat (CRO, Call Center) et le promoteur ou l'investigateur	
☒	Curriculum vitae de l'investigateur daté et signé ; CV des co-investigateurs	12
☐	Liste des autres investigateurs impliqués dans les sites de recherche relevant de la compétence de la CER, état au	
☐	Liste des autres collaborateurs relevant de la compétence de la CER, état au	
☐	Littérature scientifique	
☐	« Investigator's Brochure » (du)	
☐	Préavis / décision(s) d'autres commissions d'éthique	
☐	Autres documents spécifiques selon le type d'étude (dispositifs médicaux, thérapie génique etc.) :	

Date : 03.01.2011

Signature de l'investigateur responsable : ....

A remplir par la commission d'éthique lorsque les documents ne sont pas mentionnés dans la décision de la CER :

La commission d'éthique certifie avoir reçu et examiné tous les documents mentionnés ci-dessus.
Pour la commission d'éthique :

Nom, prénom, fonction : ....

Date : ....

Signature : ....

Appendix B

Projet de recherche – analyse des signaux électromyographiques des muscles moteurs de la main en vue d'adaptation de prothèses pour les personnes amputées de la main.

1. Objectif de l'étude :

Cette étude a pour but d'analyser les différents paramètres d'activités musculaires et les aptitudes cognitives qui permettent à une personne d'utiliser ses mains pour les activités quotidiennes de la vie courante. Les résultats de cette étude permettront aux personnes amputées de la main d'apprendre à utiliser et à gérer une prothèse de main pour les mouvements fonctionnels journaliers.

2. Déroulement de l'étude :

Les séances de collection de données seront conduites par des physiothérapeutes et des chercheurs formés à cette intention. A l'aide d'électrodes fixées sur l'avant-bras par une bande de velcro© et reliées à un ordinateur, vous serez amenés à réaliser différents mouvements avec votre main. Les électrodes fixées sur votre avant-bras enverront des signaux d'activité à l'ordinateur qui les transformera en courbes en fonction de l'activité demandée. Ces courbes permettent aux chercheurs d'avoir une représentation des activités musculaires/nerveuses nécessaires à la réalisation des mouvements fonctionnels de la main. De plus, nous vous demanderons de remplir un questionnaire sur vos données personnelles.

3. Votre participation :

Afin de réaliser ces analyses, nous avons besoin de la participation de 40-100 sujets (20-40 personnes amputées de la main et 20-60 personnes sans amputation). Votre participation consiste à être présents pour ces analyses

- La durée approximative d'une session d'enregistrement y inclus le remplissage du formulaire qui devrait durer environ 60 minutes.
- Le lieu des enregistrements pourrait soit se trouver à la clinique de SUVA à Sion, soit dans les locaux de la HES-SO Valais/Wallis ou soit dans les locaux du centre de recherche IDIAP.
- On prévoit à priori une à trois séances d'enregistrement pour pourvoir analyser des influences sur les données aussi pour la même personne; avec une petite nombre de personnes plus de séances pourraient être fait en accord avec la personne.

Vous pouvez à tout instant décider d'interrompre votre participation à cette étude, sans aucun préjudice.

4. Risques et inconvénients :

Votre participation à cette étude ne comporte aucun risque. Les électrodes fixées sur votre avant-bras n'envoient aucun courant, ceci n'engendre donc aucune sensation ni aucune douleur.

5. Avantages :

Cette étude va permettre aux chercheurs d'analyser les composantes myographiques des activités fonctionnelles de la main, et de transférer ces nouvelles connaissances pour une adaptation optimale des prothèses de main chez les personnes amputées.

6. Confidentialité :

Toutes les données acquises durant ces séances seront traitées de manière confidentielle. Pour les besoins de l'étude elles pourront être transmises à des tiers seulement de manière totalement anonym. Les noms des personnes sont stockées à tout moment totalement séparé des données même.

7. Personne de contact :

Pour toute question ou demande d'information supplémentaire au sujet de cette étude, vous pouvez contacter le chef de projet de la HES-SO Valais Wallis, M. Henning Müller, par téléphone au 027 606 90 36 ou par e-mail à l'adresse suivante : henning.mueller@hevs.ch

Une assurance de RC est élaboré chez la Valoise assurance.

Projet de recherche – analyse des signaux électromyographiques des muscles moteurs de la main en vue d'adaptation de prothèses pour les personnes amputées de la main.

Le-la soussigné-e

- ✓ certifie avoir été informé sur les objectifs et le déroulement de l'étude
- ✓ affirme avoir lu attentivement et compris les informations écrites fournies en annexe, informations à propos desquelles il a pu poser toutes les questions qu'il souhaitait
- ✓ certifie avoir été informé des risques éventuels qui sont associés à cette étude
- ✓ atteste qu'un temps de réflexion suffisant lui a été accordé
- ✓ certifie avoir été informé qu'il pouvait interrompre à tout instant sa participation à cette étude sans préjudices d'aucune sorte
- ✓ a été informé que les données recueillies pendant l'étude pourront être transmises à des tiers sous couvert d'anonymat. Seuls les investigateurs directs auront connaissance de votre identité et seront tenus au secret professionnel
- ✓ s'engage à informer l'investigateur responsable de tout phénomène inattendu pouvant survenir pendant cette étude et à se conformer aux recommandations de l'investigateur responsable de l'étude
- ✓ accepte de participer à cette étude

Le-la participant-e :

Nom : ……………………………. Prénom : ……………………………..

Signature : ………………………..

L'investigateur-trice :

Nom : ……………………………. Prénom : ……………………………..

Signature : ………………………..

Lieu et date : …………………………………..….

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