ABSTRACT

Title of Document: THE EFFECT OF A SAFETY CONTROLLER ON USER PERFORMANCE THROUGH A PROSTHETIC INTERFACE

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The objective of this thesis was to examine the interaction between user safety and cognitive-motor performance during reaching movements executed with a robotic arm through a human body machine interface (HBMI). Specifically, the effects of a safety controller on user cognitive workload and kinematics were assessed during learning the control of a simulated prosthetic arm through limited head movements. The results revealed that, compared to the group performing without the safety controller, the users assisted with the safety controller exhibited: i) a lower rate of information transfer, ii) a higher cognitive workload and iii) a reduced number of times the user brought the robotic arm close to the workspace boundaries when performing the adaptive reaching task. These results suggest that the autonomous safety controller increased user cognitive workload and reduced information transfer but provided a safer environment. This work contributes to the development of assistive technology such as HBMI and neuroprosthetics.

THE EFFECT OF A SAFETY CONTROLLER ON USER PERFORMANCE THROUGH A PROSTHETIC INTERFACE

By

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Thesis submitted to the Faculty of the Graduate School of the
University of Maryland, College Park, in partial fulfillment
of the requirements for the degree of
Master of Science
2014

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Dedication

This work is dedicated to my family who has supported me throughout my graduate studies.

Acknowledgements

I would like to thank both of my advisors, Dr. Jeffrey W. Herrmann and Dr. Rodolphe J. Gentili for all of their help through the completion of this work. Additionally, I would like to thank Dr. Monifa Vaughn-Cooke for taking time to be a member of my thesis committee.

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Chapter 1: Introduction

General Overview

At the most general level human-machine interface refers to the interaction between a human and machine where specific body parts or body-related signals can be used to control the machine or the interface. Such a general concept of human-machine interface can be applied in motor rehabilitation where the basic general principle is to connect the human body (or part of the body) with a machine in order to restore motor functions. One possible way to divide motor rehabilitation technologies is to consider replacement (e.g. loss of a limb or a high level spinal cord injury) and recovery (e.g. a stroke or less severe spinal cord injury) technologies. Replacement technologies, which will be the overall focus of this thesis, aim to replace the motor functions that were lost (e.g. loss of a limb or a high level spinal cord injury) through an artificial system. This is generally based on the severity of the injury, which depends on the extent of the remaining motor functions. For example, a below-elbow amputee still has some remaining motor function available which can be used to control an electromyography (EMG) driven neuroprosthetic. However, high level spinal cord injuries, which leave an individual with minimal motor functions would most likely require a human body machine interface (HBMI) to be used with the limited remaining signals to control an external device.

The underlying principle of an HBMI is that such a system can decode the remaining available biological signals from the human body and convert them into an action that the user intends to perform [1]. Although various sensors and control approaches can be considered (e.g., switch-based control sensors, proportional sensors), an HBMI can be controlled by employing various types of biosignals such as EMG, electroencephalography (EEG) as well as eye or head movements [1].

As such, an HBMI requires some type of input signal from the user, whether it is a body movement or an electrical biosignal recorded from the muscles or the brain. In this latter case the system is generally called a brain computer interface (BCI) and sometimes neuroprosthetics. Regardless of the input signal and sensor combination, the unusual mapping between the remaining biosignals used as control signals and the movements of the external devices needs to be learned by the user [4]. Therefore, such an unusual mapping can result in an error during learning and more generally when performing a task while controlling a device. However, in order to safely learn and perform with an external device such as a robotic arm, a safety controller is needed since any motor errors during the motor learning process and/or performance could injure the user. Although there are many available options to implement a safety controller to ensure the safety of the user; an important question is how a safety controller may impact the user's cognitive-motor performance.

Therefore, this thesis will focus on how a safety controller can affect human adaptive cognitive-motor performance (e.g., kinematics and cognitive workload) through a HBMI. As a first step and in order to explore such an interaction, a HBMI controlling a simulated prosthetic arm was employed to examine how an autonomous safety control system would affect the user's cognitive-motor performance.

Human Body Machine Interfaces and Neuroprosthetics

The basic principles behind HBMI and neuroprosthetics are similar in terms of users safely learning to control devices. The fields of HBMI and neuroprosthetics (EMG or cortically driven) are interdisciplinary, integrating the fields of engineering and neuroscience. When designing such devices there are many mechanical components as well as choices of materials which require knowledge of engineering. An understanding of neuroscience is crucial since many times the device is being controlled by employing a biological signal. Furthermore, several features must be considered before implementation of a HBMI or a neuroprosthetic device. Signal detection through brain tissue or muscles to control prosthetic devices, necessary gripping force, cognitive impacts of learning to use different devices and user preferences are just a few areas of research.

Many advancements were made in both fields of HBMI and neuroprosthetics; however, there are still many aspects that need to be further examined. For instance, although there has been some work in the area of user performance in HBMI and BCI, there is still a need to further understand the cognitive-motor performance with HBMI. In particular to address the user needs and required safety constraints when a safety controller is engaged.

Consideration of the User

Besides the technical aspect it is also important to take into account the user's needs and performance. The preferences of the users need to be considered when developing any type of medical device intended to improve their quality of life. Anderson focuses on the need for more studies targeted at empirically collecting data and understanding the needs of those who use neuroprosthetic devices, specifically patients with spinal cord injuries [2]. The idea of reaching out to potential users of any type of assistive technological devices is a necessary part of development.

Additionally, as pointed out by Schultz and Kuiken [3], prosthetic devices are still far from feeling like a natural arm, and controlling such devices implies a high cognitive demand. This problem of cognitive work load may be even more important in severe amputee populations. As previously mentioned, the mapping between the control biosignals and the output of the external device is unnatural. This "reorganization process" of body parts performing functions previously taken care of by other body parts, requires the user to learn the mapping during motor performance [4]. Therefore, it is important to understand the cognitive processes such as mental workload and motor processes of the human user while performing tasks with external devices in order to better fit these systems to their users. While it is important for the users to have a device that has optimum performance it is also crucial to consider the safety of the user. Hence, the objective of the control system is to offer users the capability of safe control with minimum cognitive burden [4].

Safety

FDA Regulation

All medical devices must be approved by the Food and Drug Administration before being marketed in the U.S. Medical devices are first classified into one of three classes; Class I and II devices may potentially have some exemptions while Class III devices are generally considered high risk [5]. When a Class I or II device receives an exemption it means that the device does not need to pass the 510K requirements;

however, these devices still need to meet basic standards such as quality assurance and proper packaging [6]. Additionally, there are sixteen different medical specialty panels which could conduct a review of the device [5]. The FDA's website offers detailed instructions on how to determine the class of a medical device, which will then determine whether a Premarket Approval (PMA), 510K or de novo application is required [5].

All Class III devices must go through the PMA process [7]. If a device does not fall under PMA, then a 510K application must be completed [8]. Generally, if a device goes through the 510K process then similar devices have been previously approved. The FDA's website provides lists of when a 510K is required and when it is not [8]. The de novo application is used for "novel low to moderate risk devices" which gives manufacturers a third option for the overall application process [9]. There are two different routes to be taken within the de novo application; both allow devices approved through the de novo process to be points of reference for future 510K submissions [9].

In May 2014, the FDA released a news report about "marketing of first prosthetic arm that translates signals from person's muscles to perform complex tasks" [10]. The news release describes the DEKA arm as well as a brief summary of the review process. This medical device went through the de novo classification review process since it was considered to be a new "low- to moderate- risk" device [10].

While it is evident that the FDA has extensive regulatory policies in place to determine the safety of medical devices, the continuous creation of new devices makes it necessary to develop a standard set of guidelines to be followed by manufacturers. If there were such a set of guidelines, it could also provide direction for researchers attempting to develop new medical devices.

Case Study: The DEKA Arm

The DEKA arm is one of the greatest recent advancements in neuroprosthetics. Resnik, et al. [11] summarized the perspective of users and clinicians. Different generation prototypes of the DEKA arm were examined, including all three available configurations: radial, humeral and shoulder. One of the eleven feedback categories was End-Point Control; criticism in this area varied between the second and third generations of the arm for the shoulder configuration. For example, one of the users of the second-generation arm unintentionally hit himself in the head with the arm, while other users made note of the arm becoming immovable at the end of the shoulder's range of motion. Generation 3 users liked the end-point control; however, they still noted that special effort needed to be made when the arm came close to their bodies.

These evaluations provided by users highlight the need for an examination of the interaction between a safety mechanism and the performance of the user. Hence, through the simulation of a prosthetic arm, the research described in this thesis sought to determine whether or not a safety controller will have any kind of impact when users perform a reaching task.

Overview of Thesis and Organization

As previously mentioned this thesis addresses the topic of safety and user cognitive-motor performance relationships when developing assistive technology, specifically HBMI and neuroprosthetic devices. Usability as well as the safety of users must be taken into account when designing HBMI and neuroprosthetics for daily use by patients. The following research question was addressed here: to what extent does a safety controller affect the cognitive-motor performance of the user during a reaching task executed with a simulated robotic arm through a human-user prosthesic interface? It must be noted that although the proposed work was conducted specifically with a HBMI platform, to some extent this work could be informative for similar performance-safety interactions for traditional neuroprostheses such as EMG driven prosthetics.

Although competitive hypotheses can be considered here, the hypothesis was that if the safety controller used here has an effect (positive or negative) on user performance, then the kinematics and/or cognitive workload should be different when compared to the situation where no safety controller is engaged. Conversely, if both the kinematics and cognitive workload remain unchanged when the safety system is engaged, then the safety controller employed here would not affect the cognitive-motor performance of the user.

The reminder of this work is organized into four chapters. Chapter 2 presents a literature review including human factors issues. Chapter 3 includes the details of the experimental set-up and Chapter 4 presents the findings of this study. Lastly, Chapter 5 is a discussion of the results and possibilities for future studies.

Chapter 2: Literature Review

Overview

The following is a brief literature review encompassing safety and performance. A broad summary is given of assistive technologies and HBMI. An in-depth review is presented of user performance, human factors and safety controllers. These last three sections highlight a few of the major ideas used throughout this thesis. User performance is considered for neuroprosthetic devices. Human factors are discussed in terms of the development of medical devices for many types of users. Lastly, the interaction of various controllers and safety is presented.

Assistive Technologies

There are numerous types of assistive technologies available to people with motor disabilities, ranging from powered wheelchairs, with various control mechanisms to robot-assisted training for rehabilitation [4, 12]. According to Burton et al. [12] that the use of robotic devices in rehabilitation has not become common because conventional therapies are still thought to be better. However, soft robotics has been integrated with neuroprosthetics to create a field called “soft” neurorobotics [12]. This field creates a much more personalized rehabilitation experience for users because the interfaces are more natural as well as safer [12]. While this is not directly related to the development of neuroprostheic limbs, the idea of creating devices which feel natural to users is crucial. As previously stated, there is a “reorganization process” that occurs when body parts are used for functions that were originally done by other body parts [4]. Once this reorganization process takes place then the device practically becomes part of the person's body [4].

Human-Machine Body Interfaces

A HBMI can be generally divided into 4 steps: i) the acquisition of body signals (here these were limited head movements), ii) Decoding these body signals into control signals (here a basic non-adaptive system to decode the four directions was used), iii) control (here a joystick control type was used as described in [27]) and iv) sensory feedback (here visual feedback provided to the user included the simulated robotic arm displacement and velocity) [4]. Typically, a HBMI requires the user to learn a mapping with different degrees of complexity between the movements of the external device and the user's commands. Hence, advancements in this area include interfaces where both the machine and human adapt simultaneously to enhance the user's performance [4]. Most HBMI use a cursor since it is generally considered that once controlling a cursor on a computer screen is learned, then the same skills can be applied to controlling a different device [4].

For example, Javanovic and MacKenzie [13] conducted an experiment with two different control methods, where participants controlled a mouse cursor with head movements. Their movements were tracked with a web cam and a marker on the participant's forehead. Similarly, Evans et al. [27] developed a robust head controlled device working as a joystick for which the patients could perform reaching movements through head motion. Most of the work in this particular research area has focused on machine learning and to a lesser extent on human cognitive-motor states; after an extensive search none of this work seems to have focused on the relationship between the user's cognitive-motor performance and embedded safety systems. Therefore, by building upon this previous work, a HBMI is proposed where the users have to control a two degree of freedom arm with limited head motion in order to study the impact of a safety controller on human cognitive-motor performance.

User Performance

Various studies have been completed to examine user performance of prosthetic devices. Many of these studies have been done with the DEKA arm [11, 14, 15]. Resnik et al. [11] completed a comprehensive study acquiring feedback from users and clinicians about the use of the DEKA arm. While this particular study did not specifically examine user performance, it did show the capabilities of the DEKA arm. Allowing users to test the arm and provide feedback on various aspects of the usability is an idea that directly impacts their performance. Other studies examined rehabilitation with upper limb prosthetics [14], and the use of a virtual reality environment when training users [15].

Resnik et al. [14] stated that the rejection rate of upper limb prosthesis may be lowered with proper training. When clinicians are training patients they need to be aware of the cognitive load patients may feel when learning to use such a complex device [14]. Additionally, it was noted that using the DEKA arm was considered a "cognitive challenge" and some users expressed "mental fatigue" [14]. The mental demand of using new devices whether simple or complex may vary among users, hence each user's performance will vary. While many studies make generalized conclusions it is important to keep in mind the individual needs of patients. Resnik et al. [14] mentioned the creation of training sessions that are personally meaningful to every patient. Moreover, an emphasis was placed on endpoint control as well as foot controls when training users due to safety concerns [14]. If there were a safety mechanism in place this may make the training easier for users and therefore less mentally demanding.

The study completed using a virtual reality environment concluded that using this type of program could be extremely helpful for upper-limb amputees due to the numerous controls they must learn [15]. Resnik et al. [15] used a virtual environment to improve visual feedback since it can be challenging for users to learn without any type of proprioceptive feedback from the arm. A similar idea was applied for the experiment presented in this study; users were given visual feedback of how the arm was moving relative to their movements through a computer screen interface. This HBMI provides a safe environment for users to learn how to use the simulated prosthetic arm and to determine the impact of the safety controller on the user's performance.

Human Factors

Consideration of the user's needs and requirements must be incorporated into the design of all medical devices, especially when users must learn to use the device. Hence, human factors engineering is a crucial part of developing HBMI and neuroprosthetics. As highlighted in the textbook, "Introduction to Human Factors and Ergonomics for Engineers" how users process information is an important part of human factors engineering [16]. Figure 2.1 is a simplified diagram adapted from Lehto and Landry's text [16] about human processing, applied to this experiment.

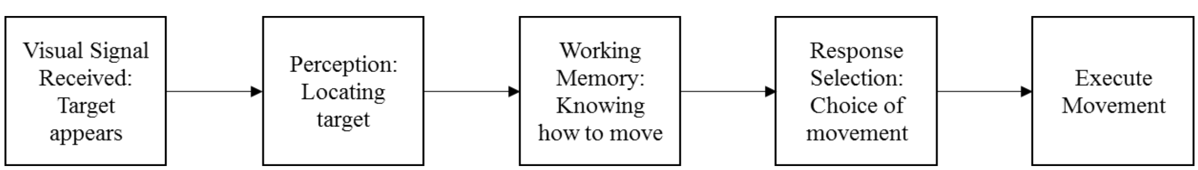

Figure 2.1: Human Processing Overview

When applied to this study, even with a simple reaching task users need to process where the next target is located in the workspace, then plan their movement in order to reach the desired target and lastly make the necessary head movements.

Another important aspect of human factors is understanding the user's information processing capabilities. Thus, although the concept of cognitive workload is relatively composite it generally refers to the allocation of working memory resources to deal with the task complexity, instruction delivery and acquisition of knowledge [28]. Such cognitive capacity of the user must be taken into account before introducing a new medical device, which could be very mentally demanding to operate successfully.

Furthermore, when designing a task for an experiment the difficulty of the task should be assessed in an objective manner. One possibility is to use Fitts' law, which is represented by an equation used to calculate an index to measure the difficulty of a task by taking into account the movement time, the distance between targets and their size [16]. His first experiment was based on people moving a pointer between two targets [16]. The index of difficulty is presented below.

$$I_d = \log_2\left[\frac{2D}{W}\right]$$

In Fitts' index of difficulty, D is the distance to the target and W is the width of the target [16]. From this the throughput can be defined providing thus an estimate of the transfer rate of information. This metric was employed in the reaching task used in this experiment.

Finally, when considering human factors, learning is an equally important component. Letho and Landry define learning as "a phenomenon where performance improves with experience" [16]. They also mention that not all changes in performance are necessarily related to learning. However, since the performance being measured in this experiment occurred in a controlled environment it is assumed that improvement in performance is based on learning.

Controllers and Safety

An extensive number of controllers have been developed for various types of robots ranging from industrial to medical. Within the design of these controllers fall issues such as performance and safety, as shown Figure 2.2 [17].

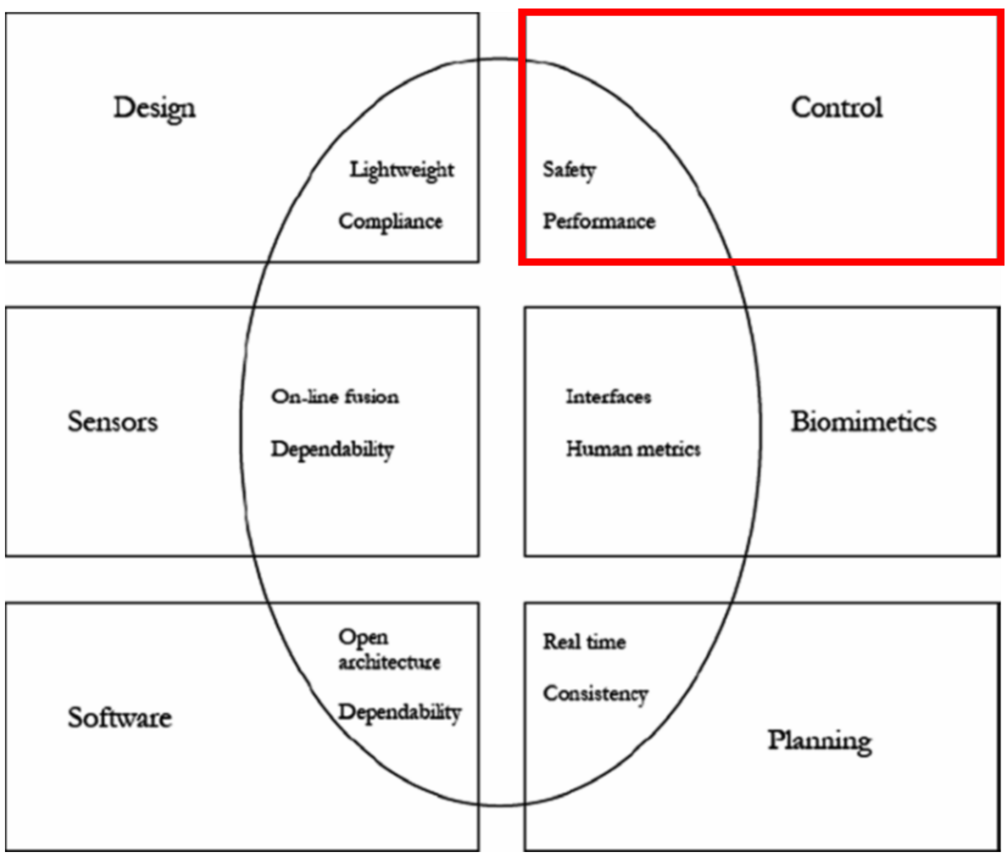

Figure 2.2: Key considerations for the design of anthropomorphic robots for human interaction [17]

Figure 2.2 [17] represents the issues that need to be considered when developing anthropomorphic robots for human-interaction. The focus of this thesis is represented in the highlighted block of control, encompassing safety and performance in Figure 2.2.

Although De Santis et al. [17] focused on human-robot interaction, some of the same ideas apply to the development of safe HBMI and neuroprosthetic devices. Additionally, De Santis et al [17] highlighted that the movements of the robot should be similar to that of human movements when completing the same task, since the user most likely has a "mental model" of how the robot should behave. The same is true for the development of HBMI and neuroprosthetic devices; the device should look and move in a manner that resembles the user's mental expectations. These ideas must be considered when developing a safety controller.

One type of controller proposed for movement control involves PID controllers and neural networks. For example, Cong and Liang [18] developed a "PID-like neural network controller" with three nodes in the hidden layer; an integral, a proportional and a derivative node. This controller could be used for single-input/multi-output systems. They also developed a set of rules to update the weights online using the resilient back-propagation algorithm with sign values instead of gradient decent values [18]. This approach involved machine learning and was beyond the scope of the question addressed in this thesis.

Potential fields are another type of controller used with robot movement. The underlying concept behind potential fields is that obstacles exert repulsive forces and targets exert attractive forces onto the robot [19]. Then the summation of forces determines the direction of movement and velocity of the robot [19]. This is an approach which has been applied in various methods. For instance, Kulic and Croft [20] presented an approach in which they developed a danger index and then used "the gradient of the danger index as the potential field." During the planning stage there was a tradeoff between safety and distance. This threshold could be adjusted depending on the emphasis placed on safety. These authors also presented another approach, which expanded on their previous work where they presented “goal seeking and obstacle avoidance functions” based on potential field functions [21]. The obstacle avoidance function partially inspired the safety controller used in this thesis and will be expanded upon later. Additionally, Ikuta et al. [22] developed a “safety evaluation method,” which could be applied to human-care robots. While this is not directly related to medical devices, one issue this study discussed was ensuring an appropriate distance was kept between the robot and human when the robot braked to reduce force [22]. This idea was also taken into consideration when developing the safety controller applied in this experiment.

With the aforementioned ideas in mind, as a first step, penalty functions were considered to be an appropriate type of safety controller that allowed manipulation of the interactions between the safety controller and the user’s cognitive-motor performance in this study. There are many different methods to implement a penalty function [23, 24, 25]. For example previous studies defined the “safety margin” by the “region in which the penalty function is nonzero” [23]. In this study the penalty function was used to adjust the robot’s path and define a “safe” distance through which the robot can move around the obstacle [23]. Additionally, they discussed the form of the penalty function and suggested that the simplest form is a piecewise linear function [23].

Galicki incorporated a penalty function into the control algorithm to avoid any collisions [24]. Inequality constraints based on Euclidean distances between the end-effector and obstacles were used. The penalty function had positive values in obstacle neighborhoods and was equal to zero outside of these neighborhoods [24]. This study suggested that an advantage of using exterior penalty functions is that only active collision avoidance constraints by trajectory generation are considered, limiting the computational load [24]. This study incorporated the gradient of the penalty function into the control law [24].

Another possible approach is minimizing the penalty function when a collision is detected [25]. Inequalities and thresholds were incorporated into the penalty function as well as joint constraints [25]. As shown here there are various approaches to develop and incorporate penalty functions into a control scheme. The section, Proposed Safety System Design will provide a detailed explanation of the penalty function used for the study presented in this thesis.

Chapter 3: Experimental Design

Goal of the Study

The goal of this study was to determine whether a safety controller would affect the performance of the user during a reaching task through a human-user prosthetic interface. This thesis sought to determine if there would be a trade-off between a safer device and better performance. Furthermore, an objective of this thesis was to attract attention to the need for the development of safety regulations for this new field of medical devices.

How the System Works

To simulate the use of a prosthetic arm, an algorithm was developed to show a two degree of freedom arm moving within a defined workspace. The arm can only move in the following directions: up, down, left and right (no diagonal motion). A lower boundary was defined in order to limit the arm from reaching areas of the workspace that were beyond the user's vision field. The outer boundary represents potential obstacles or other individuals located in the environment, while the inner boundary is meant to represent the actual user. If the user comes into contact with either of the boundaries, then he/she has to move away from the boundary to continue moving the arm. Figure 3.1 shows what a user sees when using the simulated prosthetic arm.

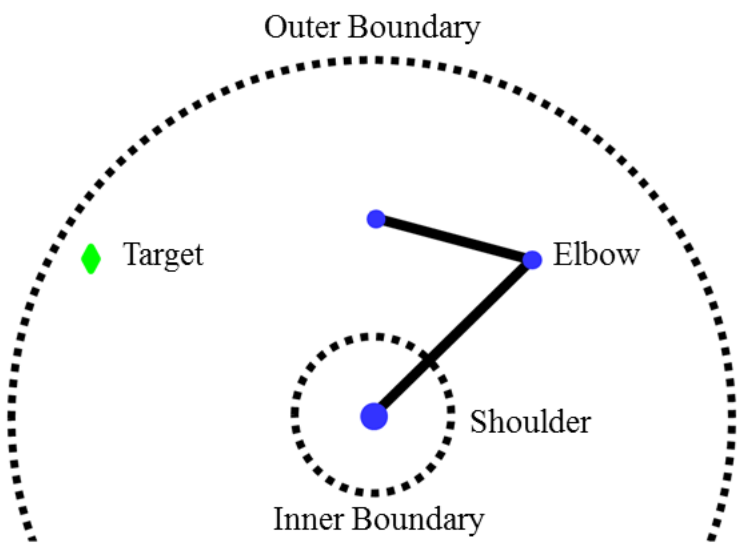

Figure 3.1: Diagram detailing visual interface

Users can control the simulated arm by moving their heads in the desired direction of movement. Sensors are placed on the user's forehead and chin as shown by Figure 3.2 (adapted from Gentili et al. [26]).

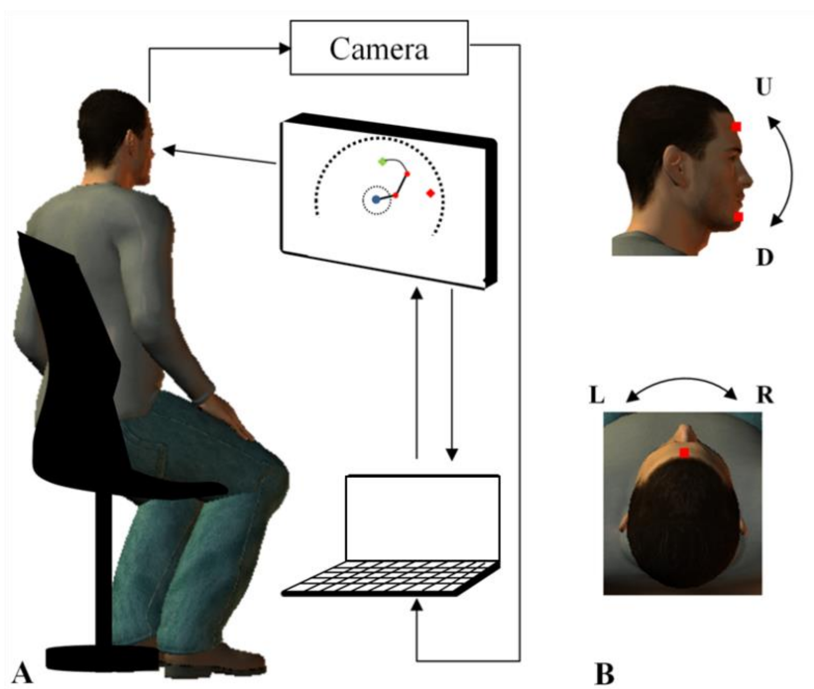

Figure 3.2: Experimental Set-Up

The X, Y coordinates of the sensors are recorded by the Optotrack™ system and then sent into a separate algorithm to calculate the inverse kinematics of the arm, which is then used to move the simulated arm within the defined workspace. The inverse kinematic equations that are used to calculate the position of the end of the simulated arm are based on the angles of the shoulder and elbow, which are denoted by θ_1 and θ_2 respectively. These equations are based on Denavit-Hartenberg parameters and the reference frame being placed at the base of the shoulder.

$$X = L_1 \cos\theta_1 + L_2 \cos(\theta_1 + \theta_2)$$

$$Y = L_1 \sin\theta_1 + L_2 \sin(\theta_1 + \theta_2)$$

In the experiment conducted here, the reaching task was further restricted by a safety controller. The velocity of the arm was kept constant except when the safety controller was engaged. The algorithm for the safety controller is based on a braking system, which slows down the simulated arm's velocity when the end of the arm moves too close to a certain distance of the inner or outer boundary. Figure 3.3 shows how the braking system fits into the current system design.

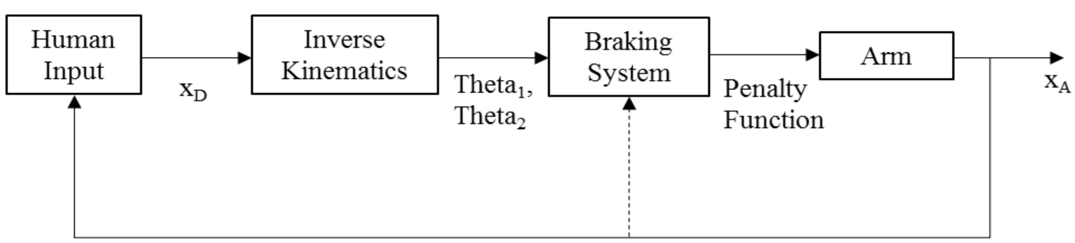

Figure 3.3: Overall System Design with Braking System

Proposed Safety System Design

System Development: PID and Potential Fields

Several systems were considered during the development of the safety system for this experiment. Initially a PID controller was considered since it is a common type of controller and easily programmable. A simulated PID controller was attempted with the obstacle avoidance function presented in Kulic and Croft [21]. However, due to the structure of the prosthetic interface a PID controller was not a good fit with the existing system.

As previously mentioned, a second option which was considered was potential fields. Kulic and Croft [21], highlighted approaches to safety studied by other researchers such as slowing down or stopping a system, moving away from an obstacle and minimizing force if a there is a collision. Additionally, Kulic and Croft [21] stated that a problem with these approaches is determining when the safety measures need to become active. They developed a safe path planning algorithm by constructing a cost function, which incorporated a goal seeking function, an obstacle avoidance function, and a danger criterion [21]. Their obstacle avoidance function was based on distance, which partially inspired the penalty function used in this thesis.

Penalty Functions

The third option was a penalty function, which was used for the braking system in this thesis. As noted by Galicki [24] the computational efficiency of a penalty function was one benefit of using it within this study. Additionally, as shown by the literature review, penalty functions are applicable in various situations and versatile in implementation. For example, Willms and Simon [23], defined “safety” as when the penalty function is a nonzero number; however, Galicki [24] defined closeness to the obstacle with positive nonzero numbers. Hence, definitions and restrictions are flexible.

Two types of penalty functions were considered; sigmoid and proportional; however, a proportional penalty function was used for testing. The proportional penalty function created a more gradual stop in this particular system. The penalty function used in this study was based on the distance between the end-effector of the simulated arm and the inner/outer boundaries. For each boundary there was a specified threshold; once either threshold was crossed then the velocity of the arm slowed down until reaching zero at the boundary. The closer the end-effector came to a boundary the more it was forced to slow down. Figure 3.4 shows the locations of the inner and outer thresholds relative to the boundaries, as well as the targets within the 2D workspace. The inner boundary is at a distance of ten units from the center, while the outer is at a distance of eighty units. The inner threshold is at a distance of twenty-five units from the center and the outer threshold is at a distance of sixty-five units.

It is important to note that in this particular system the term “velocity” was used to mean the perceived speed of the arm to the user. The “velocity” perceived by the user is dependent on the response time of the system to the user’s inputs. Hence, to make the arm appear like it was slowing down there must be an increase in the response time of the system.

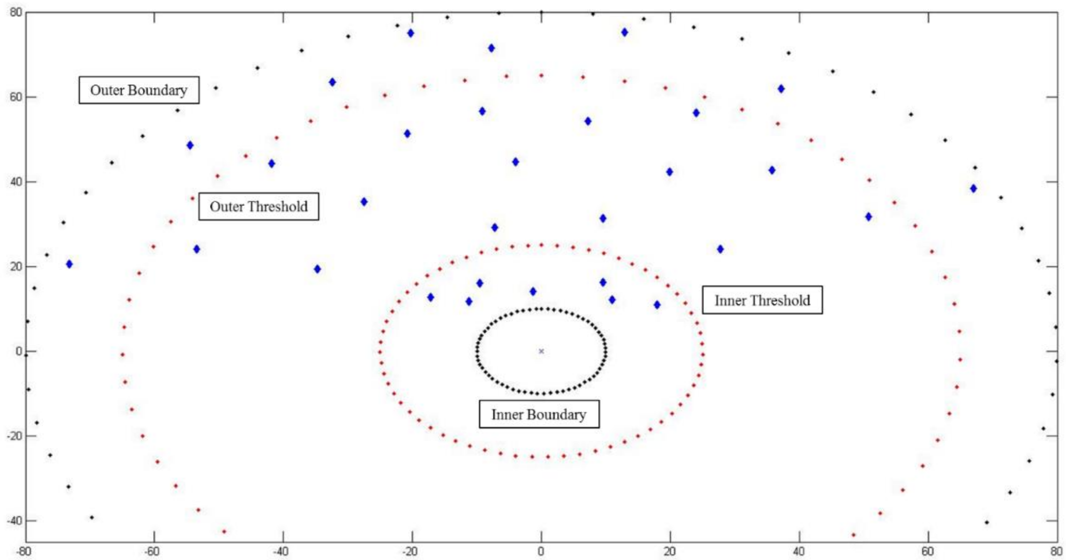

Figure 3.4: Graphical Representation of Workspace

Let T_{out}, X, B_{out}, and K_{out} represent the outer boundary threshold, the location of the end-effector, the outer boundary and the outer gain, respectively. Then, the proportional penalty function *PF(X)* for the outer boundary can be expressed as follows:

$$PF(X) = \begin{cases} \left[1 - \left|\dfrac{T_{out} - X}{B_{out} - T_{out}}\right|\right] x\ K_{out}, & X \geq T_{out} \\ 1, & X < T_{out} \end{cases}$$

The location of the end-effector was calculated based on the Euclidean distance of the end-effector from the center. The next equation is the same, except that the inequalities have been adjusted to account for the distance of the inner boundary. This adjustment must be made since the distance of each boundary and each boundary threshold is located at a different point in the workspace, relative to the center. In this equation, let T_{in}, X, B_{in}, and K_{in} represent the inner boundary threshold, the location of the end-effector, the inner boundary and the inner gain. Then, the proportional penalty function *PF(X)* for the inner boundary can be expressed as follows:

$$PF(X) = \begin{cases} \left[1 - \left|\frac{T_{in} - X}{B_{in} - T_{in}}\right|\right] x\, K_{in}, & X \leq T_{in} \\ 1, & X > T_{in} \end{cases}$$

The following equation is representative of the general format used to calculate the deceleration of the end-effector.

$$System\ Response\ Time = \ Initial\ System\ Response\ Time\ x\ [2 - PF(X)]$$

The system response time must be multiplied by $[2 - PF(X)]$ because when the arm was in the "neutral" zone then $PF(X) = 1$, hence the initial system response would then be multiplied by one and be maintained. When either boundary was approached the penalty function would approach zero and hence the system response time could be multiplied by a maximum of two. Therefore, when the arm approached the inner or outer boundary the response time of the system increased and the perceived "velocity" by the user decreased.

Figure 3.5 shows the changes in "velocity" as the arm moves closer to either boundary as well as in the "neutral zone." The horizontal axis shows the distance from the center point (0, 0). It must be noted that, as a very first step, although it was initially planned to consider symmetric constraints (i.e., the same velocity reduction) for both the inner and outer boundaries, some parameters of the safety system were not updated as planned and thus lead to a parameterization that generated asymmetric constraints. The only difference is that in this latter case, the safety controller reduced the arm velocity to a slower velocity for the inner compared to the outer boundary providing thus a more conservative safety controller when the robotic arm is located at a closer range from the user (see Figure 3.5).

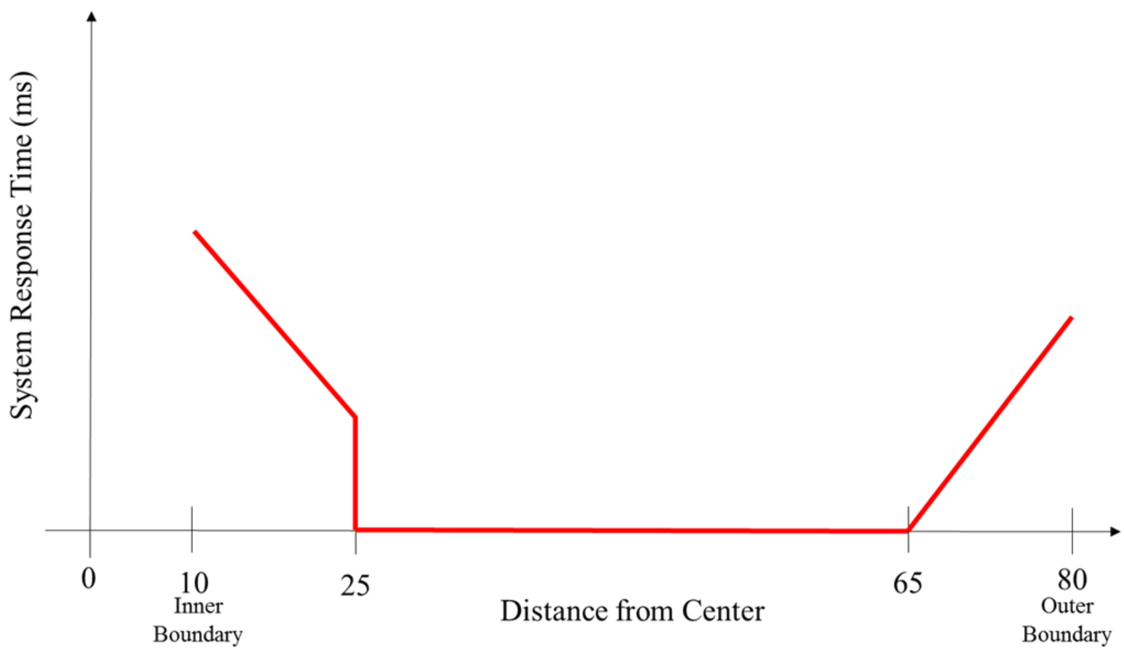

Figure 3.5: Changes in “Velocity”

Variables and Design

As previously indicated, the system being studied is a simulated prosthetic arm, which is controlled by user head movements in four directions; up, down, left and right. There were two groups; the control group performed the reaching task without the braking system and the other group performed the task with the braking system. Hence, the independent variable for this experiment was the use of the braking system.

The dependent variables can be broken into two categories: questionnaires and kinematics. The questionnaires include two Visual Analog Scales (VAS), one about the braking system and the other about the cognitive work load. A NASA Task Load Index (TLX) questionnaire was also used for assessing the cognitive work load. The kinematic variables included the number of head commands to reach a target, the movement length between targets, the time needed to reach a target, throughput (combination of speed and accuracy) [13] and the number of times the end-effector entered in the neighborhood space (1%, 2% and 5% before the boundary) of either boundary or came in contact with either boundary.

This was a between-subject design since once a participant became acquainted with the system it would be difficult to determine whether or not the braking system was affecting his or her performance. There were ten participants per group.

Methods

Twenty healthy participants without known neurological disease and normal or corrected vision were recruited from the University of Maryland for this experiment which was approved by the Institutional Review Board from the University of Maryland, College Park. Each participant was treated the same regardless of his or her designated group. The same instructions were given with the exception that participants in the braking system group were told about the braking system. Before beginning the experiment, the participants were briefly familiarized with the display and it was explained that sensors would be placed on their foreheads and chins. The process of the Optotrak™ camera taking in the position of the sensors to move the arm was briefly explained in order to emphasize the importance of the sensors. Additionally, they were told that they could move their heads in only four directions, and were told how to select the targets. Selection of the targets was based on opening and closing the mouth. It was explained that once the target changed from red to green, then they would be able to move towards the target. There was emphasis placed on the instructions to avoid either of the boundaries. Lastly, if participants were unable to move away from either boundary at any point throughout the experiment, then they were provided with further instruction on how to move. These additional directions were not thought to impact the participant's performance since i) directions were only provided as needed to allow the subject to the chance to perform the task completely and ii) the learning of this simple sensorimotor map is procedural.

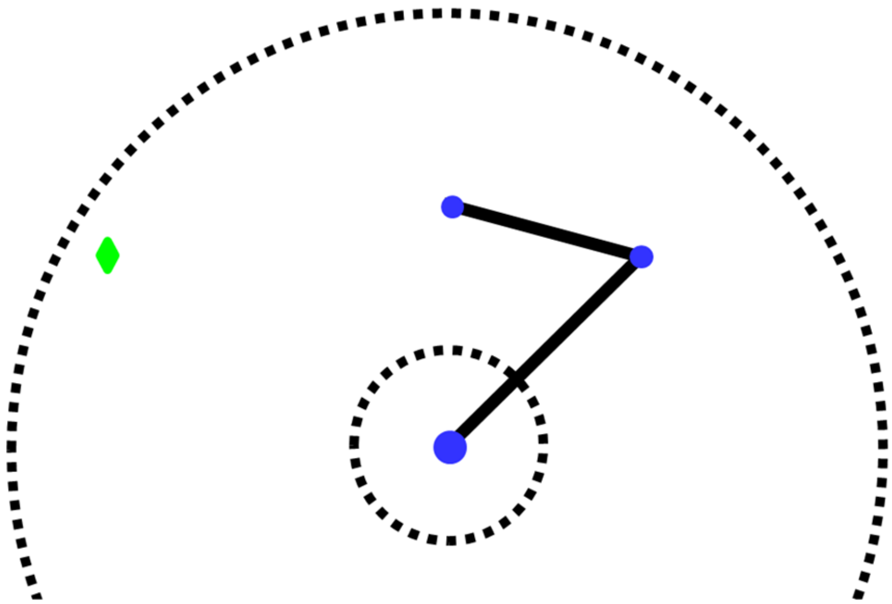

Figure 3.6: Diagram shown to participants prior to start of experiment

Both groups were told that they would be asked to reach 150 targets through the prosthetic arm interface. This number of targets was selected due to previous studies [26]. The velocity of the arm when it was not beyond the threshold of either boundary was set to a moderate velocity. The determination of this velocity was based on the preliminary results of another study, in which we found that the performance of participants at slow and fast velocities was dependent on how mentally demanding the reaching task was for them.

After completion of the reaching task, participants were asked to answer questionnaires about the cognitive work load and the braking system. These questionnaires are presented in the appendices. Two different questionnaires were used to determine if there was consistency in the participant’s responses about cognitive work load. The VAS was used in two different questionnaires due to success in using this scale for past studies.

Data Processing and Analysis

Analysis was done for each group and then compared for significance. For both VAS questionnaires and the NASA TLX scale the average, standard deviation and standard error were calculated. All questionnaires were compared using the t-test if the assumption of normality was valid and if not, then a Mann-Whitney test was used. The kinematic variables (the number of head commands to reach a target, the movement length between targets, the time needed to reach a target, throughput and the number of times the end-effector entered in the close neighborhood or touched one of the boundaries) were analyzed for each group separately and then compared for significance. After normalizing the kinematic data with respect to the Euclidian distance between successive targets, the average, standard deviation, variance and maximum were analyzed for each of these variables, prior to testing for significance.

Chapter 4: Results

Questionnaires

For all graphs presented the standard error is shown as well as whether or not the comparison was statistically significant. Table 4.1 shows the levels of significance. As shown by Figure 4.1, both the VAS and the NASA TLX questionnaires showed a significantly higher mental demand for the safety group ($t(18) = 2.75$; $p < 0.05$ and $t(18) = 2.101$; $p = 0.05$). The composite index is a percentage average of the question referencing mental demand for the VAS and the NASA TLX questionnaire. This measure also showed significance ($t(18) = 2.732$; $p < 0.05$). All other results for the questionnaires were not significantly different.

	p
*	<0.05
**	<0.01
***	<0.001
◊	<0.10 (marginal significance)

Table 4.1: Levels of Significance

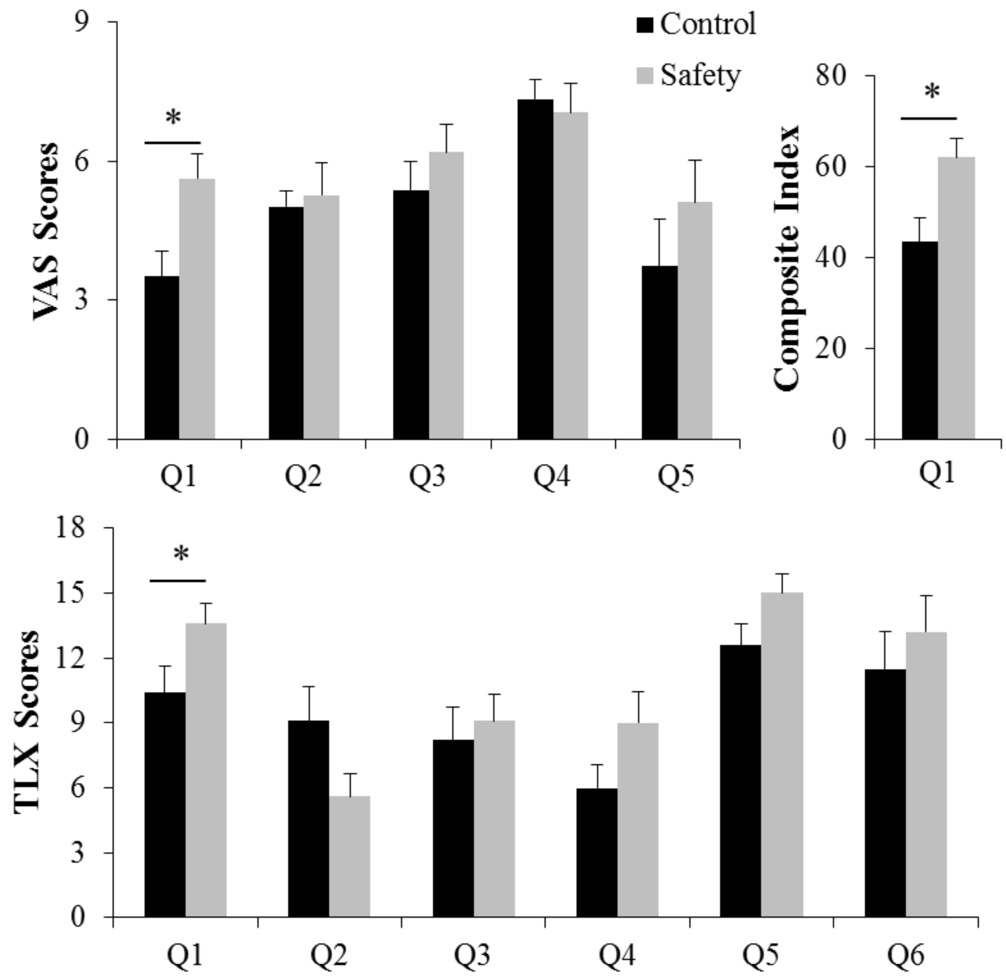

Figure 4.1: Averages of VAS and TLX scores and the Composite Index

Q1	How mentally loaded did I feel while performing the reaching task?
Q2	How hard it was to perform the reaching task?
Q3	How effortful it was to perform the reaching task?
Q4	How much did I have to concentrate to perform the reaching task?
Q5	How tired was I after the reaching task?

Table 4.2: VAS Questionnaire

Q1	How mentally demanding was this task?
Q2	How physically demanding was this task?
Q3	How hurried or rushed was the pace of the task?
Q4	How successful were you in accomplishing what you were asked to do?
Q5	How hard did you have to work to accomplish what you were asked to do?
Q6	How insecure, discouraged, irritated, stressed and annoyed were you?

Table 4.3: NASA TLX Questionnaire

Figure 4.2 shows the responses of the safety group to the braking questionnaire. It is important to note that question 4, is missing one participant's response and two other participants returned after the experiment to respond. Many participants agreed that the braking system did affect their cognitive workload and that regaining control after the braking system took over was at least somewhat difficult. When asked if they had a preference for controlling the braking system only three out of ten participants responded no. Lastly, informal discussions after the experiment revealed that some participants felt the need to "adjust" to the changes in velocity due to the braking system, which felt mentally demanding.

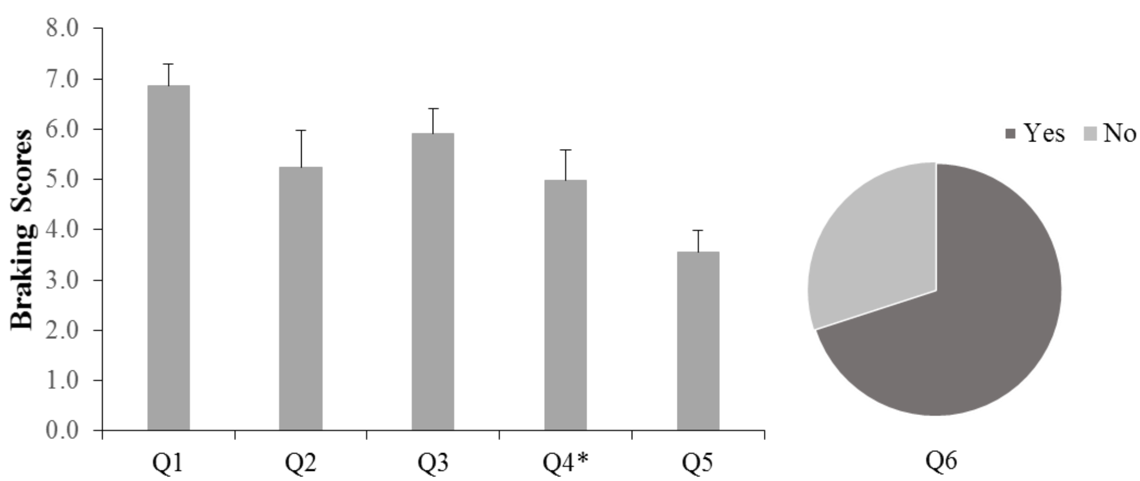

Figure 4.2: Braking System Questionnaires, *Q4 missing data and delayed collection

Q1	The braking system affected my cognitive work load [strongly agree, strongly disagree]
Q2	The braking system took over too late [strongly agree, strongly disagree]
Q3	Regaining control after the braking system took over was [easy, difficult]
Q4	To what extent did the braking system hinder your learning [not at all, severely]
Q5	The deceleration of the braking system was [too slow, too fast]
Q6	Would you prefer to have control over the braking system?

Table 4.4: Braking System Questionnaire

Kinematics

Figures 4.3 to 4.6 show comparisons of all participants regardless of group, across early and late periods of the trails. The early period is defined as the first fifty trials, while the late period is defined as the last fifty trials. Each figure shows the average of the mean, standard deviation, variance and maximum across the twenty participants. For every five trials across the fifty, the necessary statistic was calculated and then averaged for each of the periods per participant. Then this value was averaged across the twenty participants. Within each figure the variables of count, movement time, movement length, root-mean square error (RMSE) and throughput (combination of speed and accuracy) [13] are presented. The term count refers to the number of head commands to reach a target.

When comparing the mean between early and late periods in the trials, there was a significant difference for the count ($F(1,18) = 10.473$; $p < 0.01$), movement time ($F(1,18) = 10.481$; $p < 0.01$), movement length ($F(1,18) = 10.251$; $p < 0.01$) and throughput ($F(1,18) = 131.913$; $p < 0.001$). The difference in the RMSE was marginally significant ($F(1,18) = 3.294$; $p = 0.086$).

For the standard deviation there was a significant difference for the count ($F(1,18) = 5.716$; $p < 0.05$), the movement length ($F(1,18) = 5.641$; $p < 0.05$), the throughput ($F(1,18) = 98.095$; $p < 0.001$). The difference for the movement time was marginally significant ($F(1,18) = 4.023$; $p = 0.060$). Comparison of the variance between early and late periods in the trials, revealed a significant difference for the throughput ($F(1,18) = 30.973$; $p < 0.001$).

Comparison of the maximum showed a significant difference for the count ($F(1,18) = 7.152$; $p < 0.05$), the movement time ($F(1,18) = 5.442$; $p < 0.05$), the movement length ($F(1,18) = 7.125$; $p < 0.05$) and the throughput ($F(1,18) = 107.685$; $p < 0.001$).

Additionally, the throughput for each group was compared as shown by Figure 4.7. There was a significant difference between the mean throughput of the control group and the safety group ($F(1,18) = 1035.124$; $p < 0.001$). There was a marginally significant difference for the standard deviation ($F(1,18) = 3.298$; $p = 0.086$) and the maximum $F(1,18) = 4.039$; $p = 0.060$); however, there was no significant difference for the variance between the groups.

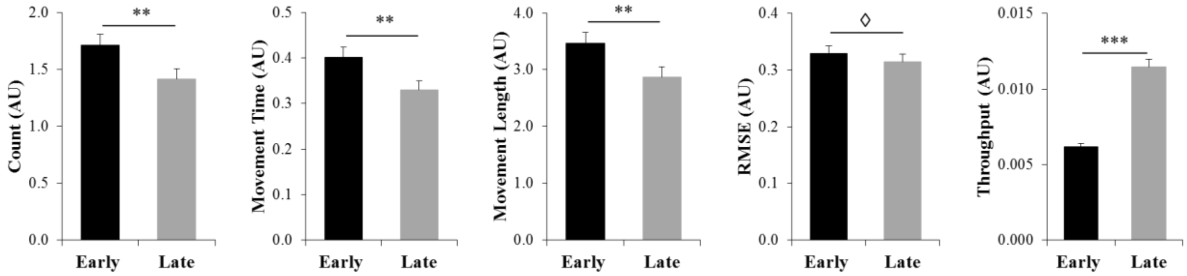

Figure 4.3: Mean for early and late periods

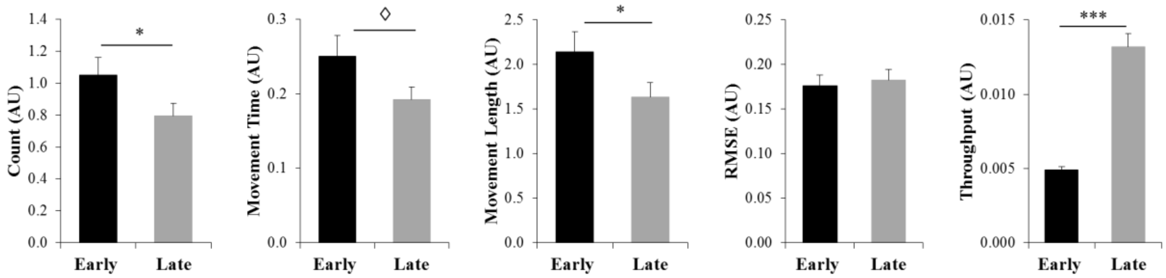

Figure 4.4: Standard Deviation for early and late periods

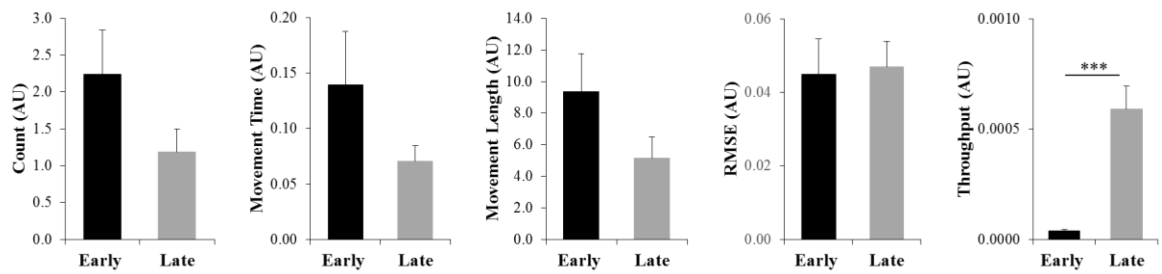

Figure 4.5: Variance for early and late periods

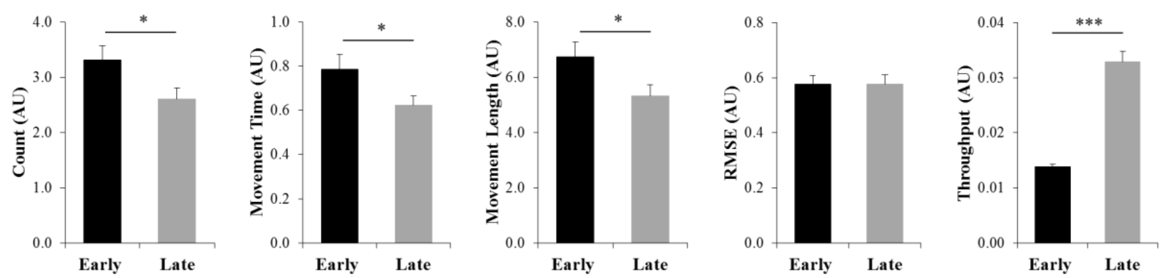

Figure 4.6: Maximum for early and late periods

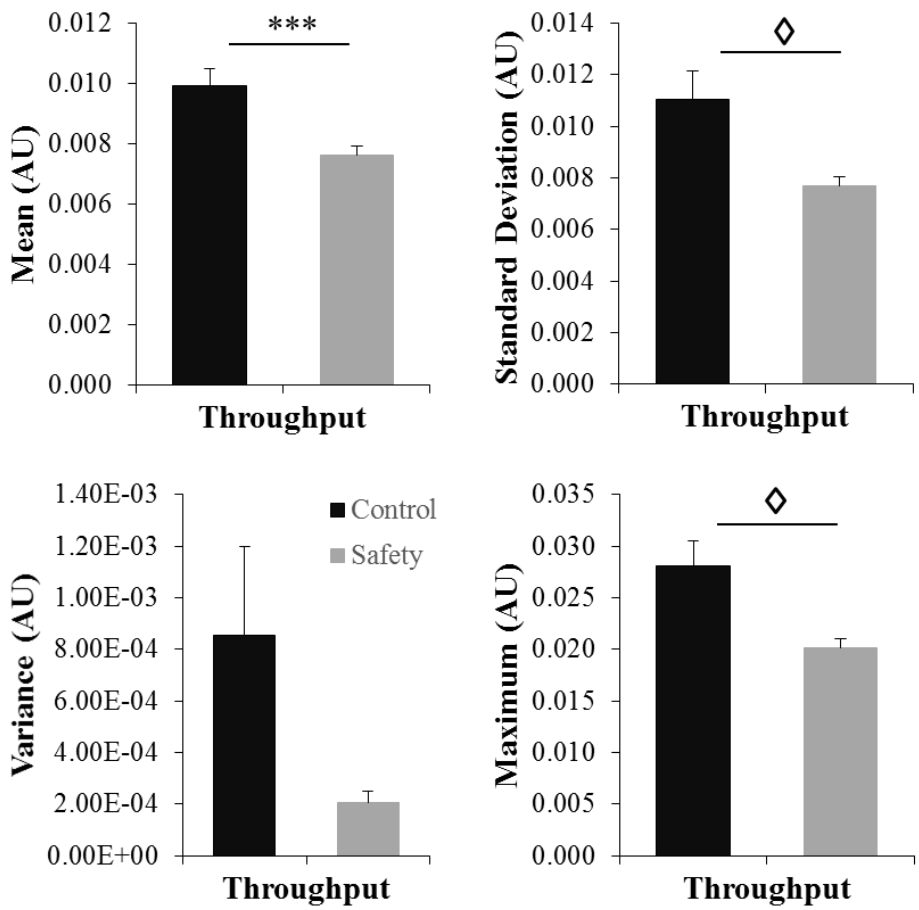

Figure 4.7: Comparison of throughput between the control and safety group

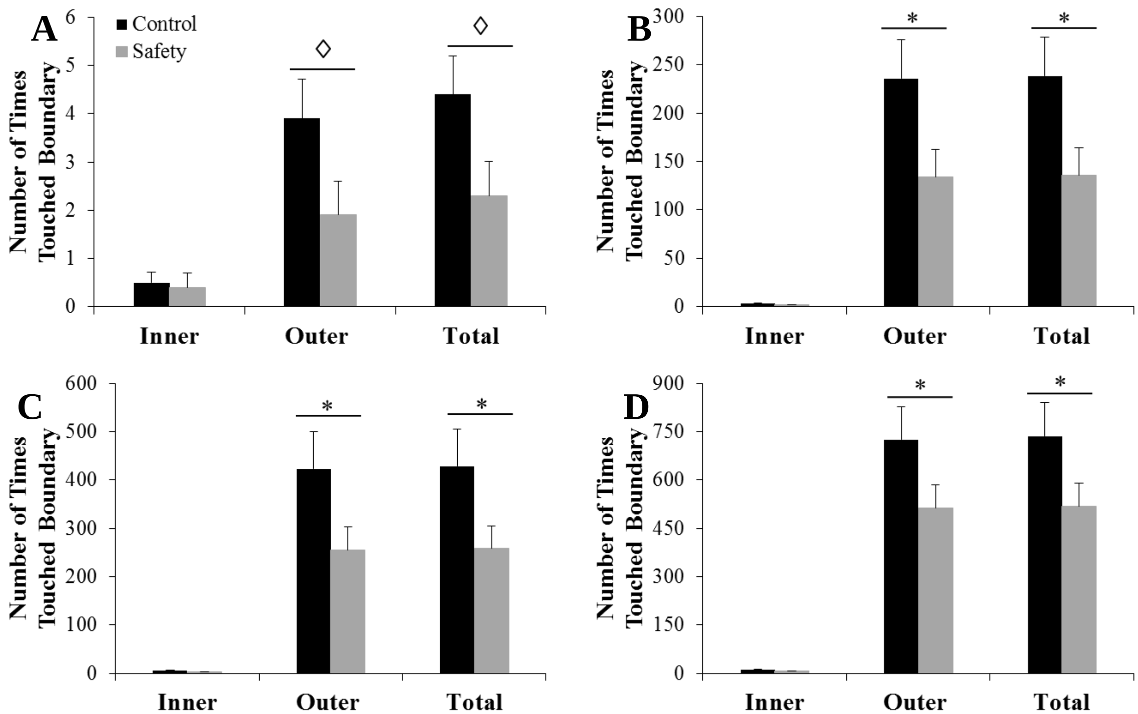

Figure 4.8: Comparison of control and safety group by number of approaches to either boundary. A: within 0% from boundary, B: within 1% from boundary, C: within 2% from boundary and D: within 5% from boundary

The final comparison considered the number of times each group touched the inner and outer boundary. On average the safety group touched both the inner and outer boundary less often than the control group did. This could be attributed to the decrease in the velocity of the arm from the braking system.

Figure 4.8 shows comparisons of the number of times each boundary was approached as well as the total number of times either boundary was touched (and within the range of the boundary). The difference was marginally significant for the total ($p = 0.065$) and a particularly strong trend at the outer boundary ($p = 0.051$), between the two groups when the number of touches were counted at exactly the boundary. Consistent with these findings, when the same analysis was done for distances at 1%, 2% and 5% from either boundary, there was a significant difference between the control and safety groups for the outer boundary as well as the total number of times either boundary was touched (all had a significance of $p < 0.05$). There was no significant difference for the inner boundary regardless of the distance from the boundary.

Chapter 5: Discussion, Conclusion and Future Work

Discussion

Overview

Overall the findings revealed that both the control and the safety group learned how to control the arm as suggested by the significant differences in kinematics between the early and late periods. In addition, while the rate of information transfer (throughput) was higher for the control group, the safety group generally did not approach too close to the boundary, which reduced the risk of collision with the simulated robotic arm. Finally, the data revealed that, when the workspace boundary was approached the decrease in the arm's velocity by the safety system forced participants to adjust to the new velocity; this increased mental demand for the safety group compared to the control group. In summary, these results revealed that while the safety controller resulted in an increase in user cognitive workload and a decrease in throughput, it also contributed to providing a safer environment and system.

Impact of the Safety System on Kinematics

When the safety system was engaged, the arm velocity was reduced when the inner and outer boundaries were approached which resulted in a significant decrease of the throughput for the safety compared to the control group. Consistently, it must be noted that although the difference was non-significant, the movement time was increased for the safety group compared to the control group. Additionally, compared to the control group, due to the presence of the safety system, the safety group had a reduced number of approaches to the neighborhood of either boundary reducing the likelihood of touching either boundary. It must be noted that the safety system here was designed to have the arm slow down as the boundary was reached compared to the control group where the arm reached the boundary at full velocity. Although the difference was non-significant, it appears that the braking system provided participants more time to regulate arm movements and therefore this group overall tended to move the simulated arm with fewer of head commands while the robotic end-effector path was shorter and straighter compared to the control group.

Therefore, overall the safety system reduced the rate of information transfer (throughput [13]) and decreased the number of contacts with either boundary while not significantly altering the other movement parameters. Hence, these suggest there is a limited trade-off between safety and performance in terms of kinematics for the specific safety system considered here. The velocity employed here was very moderate; however, operating the arm at higher velocities may cause more drastic changes in the kinematics and result in a greater trade-off between safety and performance.

Impact of the Safety System on the User’s Cognitive Workload

Although a conservative approach which used a very moderate arm velocity was employed, the safety system affected not only the kinematics, but also the cognitive workload of participants. More precisely, the engagement of the safety system resulted in an increase of the user's cognitive workload. One possible explanation could be related to the fact that a change in arm velocity would affect the mapping that the participants had to learn to control the simulated robotic arm. It was previously suggested that in order to operate a HBMI the user has to learn the mapping between the arm displacements and velocity of the controlled device (here the robotic arm) and the motor command of the user (here the head movements) [4]. Thus, although both groups had to learn this mapping, when the safety system was engaged for certain targets (50% of the total number of targets), the arm's velocity was automatically progressively decreased for the participants of the safety group. Therefore, when the simulated robotic arm was close to the boundaries, the safety system autonomously changed the arm displacements and velocity that was visually fed back to the participants forcing the user to "recalibrate" the altered sensorimotor mapping being encoded for those workspace areas. Such changes in velocity generated by the safety controler likely altered the sensorimotor mapping when the arm was close to the boundaries and thus, resulted in an increase of the cognitive workload of the participants in the safety group. However, the participants of the control group (who controlled the robotic arm without a braking system) did not have the arm changing velocity when entering in the neighborhood of the boundaries and thus had to learn a more homogenous mapping leading to a smaller workload.

Interestingly a recent cognitive workload study involving the learning of a mapping revealed that the cognitive workload was progressively reduced as the mapping was being encoded [29]. Although this study was different from the study presented here, it is consistent with the idea that learning different mappings can result in changes in cognitive workload. Such an increase in cognitive workload while employing an automatic safety system was not trivial since previous human factor studies suggested that certain levels of automation could reduce the user's cognitive workload [30]. Thus, it could have been easily predicted that the reduction in velocity would have provided users with more time to regulate their motor commands and therefore, reduce the cognitive workload compared to the control group which performed at a continuously higher velocity. Such a hypothesis may be verified if the arm were operated at higher velocity.

In fact, the present results are in accordance with the idea that automation can impact in some cases positively, but also negatively the user's cognitive-motor performance [31]. For instance, although not related to safety systems, a previous study suggested that a system could cause complacency when users assume all functions are proceeding normally, but in reality they are overlooking a system malfunction [31]. While obtained with a simple safety controller and limited task constraints, the present findings would likely change with a different safety controller design and parameters. As such, it is reasonable to consider that the same trade-off principles and methods could be somewhat applied to various safety systems in order to assess their impact on cognitive-motor performance for HBMI. Thus, this work contributes to the work which consists of designing efficient safety controllers that reach the safety criterion while assessing if such systems facilitate, keep stable or compromise the user's cognitive-motor performance.

Applications

The impact of the safety system on the mental demand of the user must be considered in the development of HBMI and neuroprosthetic devices. While the safety of users is extremely important it is also important to consider the amount of effort required to properly control a device. If users are completely consumed by the control of the external device, they would not be able to perform another task such as a social interaction or handling an unexpected event [29]. Hence, while the safety controller should prevent the external device from harming the user, the user still needs to have enough mental demand to function while controlling the device. With various safety controllers there is most likely an optimal trade-off between safety and performance.

As previously mentioned, the DEKA arm is an excellent example of advancements in the field of neuroprosthetics. However, as highlighted by Resnik et al. [11] extensive training was required from users to become skilled at controlling the arm. If a safety controller were put in place this may eliminate some of the burden placed on the user to become an expert at controlling the device in order to prevent any type of self-inflicted injury. The safety controller may remove some of the pressure placed on the user, if the user is comfortable with the safety controller and still feels in control of the device.

Through the completion of extensive studies on the interaction of safety and performance as well as removing some of the burden from the user during training, guidelines could be established for development of different types of assistive technology. Additionally, such a set of guidelines could be of assistance to the FDA when developing regulations for the rapidly growing fields of HBMI and neuroprosthetics.

Limitations and Future Work

This study which is a first step towards a more comprehensive interaction between the safety system and the user cognitive-motor performance in HBMI had several limitations. First, the present results were obtained through an extremely simple safety system and the default velocity was imposed on all participants. Second, the external device to control was a simple virtual robotic arm with two degrees of freedom guided in a 2D workspace. Third, the participants of this study were all healthy, however, it would be critical to examine patients with severe motor disabilities (e.g., spinal cord injury) since such assistive systems target such a patient population. Lastly, although participant’s comments were informally gathered after the experiment, no qualitative data analyses were conducted. This may have been more beneficial if formally connected to other data collection.

Therefore, future work will examine the difference between more complex safety controllers while taking into consideration the user’s preferred velocity prior to completion of the task. Additionally, future work needs to examine how inter-individual differences may lead to better cognitive-motor performance (most likely guided by previous experiences) while facing a given level of challenge. There is also a need for future work to consider how feedback (e.g., visual, auditory) in relation to the safety controller could impact the user’s motor performance and cognitive workload. Lastly, future studies would greatly benefit from the use of objective physiological measures of cognitive workload (e.g., EEG, [29]) as well as formal collection and analyses of subject’s feedback through interviews. In conclusion, this work contributes to the approach of designing an efficient safety system that meets safety criterion while assessing its effects on the user's cognitive-motor performance.

Appendix A: General Visual Analog Scale

Subject # ________________ Trial # _______________

Visual Analog Scale

Please put a vertical line through the rectangle at the point that best represents how you feel right now. The ends of each rectangle represent the opposite extremes of the **same** variable. Ex.

No Pain Worst Pain

How *mentally loaded* did I feel while performing the reaching task?

Not loaded Completely Loaded

How *hard* it was to perform the reaching task?

Not all Completely overwhelmed

How *effortful* it was to perform the reaching task?

Extremely easy | Not easy at all

How much did I have to *concentrate* to perform the reaching task?

A little | Concentrated a lot

How *tired* was I after the reaching task?

A little tired | Very tired

Appendix B: NASA Task Load Index

Figure 8.6

NASA Task Load Index

Hart and Staveland's NASA Task Load Index (TLX) method assesses work load on five 7-point scales. Increments of high, medium and low estimates for each point result in 21 gradations on the scales.

XXXX Research #	Task	Date

Mental Demand — How mentally demanding was the task?

Very Low — Very High

Physical Demand — How physically demanding was the task?

Very Low — Very High

Temporal Demand — How hurried or rushed was the pace of the task?

Very Low — Very High

Performance — How successful were you in accomplishing what you were asked to do?

Perfect — Failure

Effort — How hard did you have to work to accomplish your level of performance?

Very Low — Very High

Frustration — How insecure, discouraged, irritated, stressed, and annoyed wereyou?

Very Low — Very High

Appendix C: Braking System Questionnaire:

1. The braking system affected my cognitive work load.

Strongly Disagree — Strongly Agree

2. The braking system took over too late (i.e. too close to the boundary?).

Strongly Disagree — Strongly Agree

3. Regaining control after the braking system took over was

Extremely Easy — Extremely Difficult

4. To what extent did the braking system hinder your learning?

Not at All — Severely

5. The deceleration of the braking system was

Too Slow — Too Fast

6. Would you prefer to have control over the braking system instead of it being automatic?

YES NO

Appendix D: Instructions

These were the notes used when explaining the task to a participant.

1. Explain task in a general manner
    a. Reach the targets by controlling the arm through head movements, want the end of the arm to move to reach the target
    b. State that there are 150 targets
    c. Move as fast and straight as possible to the target
    d. Describe targets (show screen shot of arm)
    e. Head movements
        i. Notion of four quadrants. Can't move diagonally, must move in one of four directions
        ii. Selection – open and close mouth, must be done for each target
        iii. Explain coming back to center if having difficulty and then making next move
    f. Boundaries – better to avoid, but not an essential requirement.
    g. For Safety Group: mention that arm will slow down as the boundaries are approached
2. Describe how to move when arm gets stuck
3. Notify subject when he/she completed most of the targets and when he/she is near the end

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