Towards Modernising Trans-radial Prosthetic Socket Creation With Digital Methods

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Abstract

Current upper-limb prosthetics do not fulfil the needs and expectations of their users. As a result, device rejection and abandonment rates have remained consistently high for more than six decades, predominantly due to a lack of functionality. Many individuals with upper limb differences feel more functional without their devices. This is despite significant advances in the sophistication of available bionic hands. It is believed that this is due to a lack of advancement in upper-limb *sockets*, the component that connects the device to the user's body and enables device control. This topic has received relatively little study to date. The socket designs used in clinics today predate the invention of the majority of advanced bionics currently in use. Therefore, they are not designed to satisfy contemporary requirements. The main aims of this PhD thesis are to 1) identify the issues currently hindering progress in upper-limb prosthetics, 2) investigate novel manufacturing methods, for the benefits they could have, and 3) assess novel socket designs, to see if they could have any positive effect on the functionality and level of control that can be achieved with upper-limb prosthetic devices.

Chapter 1 covers the motives and goals of this PhD thesis, as well as an outline of the subsequent chapters.

Chapter 2, the literature review, includes a variety of fundamental subjects necessary for understanding the issues in the succeeding Chapters. An overview of relevant human anatomy, prevalent prosthetic limb styles, and the field's present challenges is provided.

Chapter 3 discusses the present state of prosthetic socket research. The Chapter is presented as a consensus of various specialists in the field, having experiences and viewpoints from both engineering research and clinical medicine. Current barriers and critical enablers of advancement within the field of prosthetic sockets are identified.

Chapter 4 presents an overview of the general methods used throughout

the PhD Thesis.

Chapter 5 evaluates the feasibility of switching to contemporary socket manufacturing techniques that are typically believed to be capable of replicating the current clinical standard. Through a practical experiment, *digitally* made sockets were trialled with individuals with trans-radial limb difference, and feedback was obtained. A key finding of this study is that clinical expertise must be incorporated into the socket manufacturing process, regardless of the method employed, in order to achieve consistently satisfactory results.

Using a mixed digital-clinical approach, **Chapter 6** builds on the findings of **Chapter 5** to create clinical standard upper-limb prosthetic socket simulators. The simulators were successfully built and enabled the recording of satisfactory EMG signals using a combination of digital scanning and traditional socket fabrication processes.

Chapter 7 looks at how longitudinal compression affects EMG control and localised muscle fatigue. The results of this Chapter show that longitudinal compression has no effect on limb fatigue, but it may prevent loss of contact between the limb and the socket wall during contractions.

Chapter 8 is the culmination of all knowledge acquired from the previous Chapters and presents a novel manufacturing method and design for a prosthetic socket simulator. The results show that combining mechanical perturbation of the limb with digital scanning can produce a reliable and useful outcome. The forearm cuffs created from these scans indicate that high pressure, longitudinal compression socket styles may reduce electrode disturbances, but increase the risk of accidental co-contractions.

Chapter 9 assesses the feasibility of implementing the methods and socket designs discussed in this thesis in clinics and makes recommendations on how this could be achieved. An outlook on the future of upper-limb prosthetic sockets is provided, as well as recommendations on when and how modern methods and designs can be realistically implemented.

Dedication

To Mam and Dad - thanks for everything :)

Declaration

This thesis is submitted to Newcastle University for the degree of Doctor of Philosophy. The research outlined within this thesis was performed between the years 2019-2023. Dr Matthew Dyson, Dr Alix Chadwell, Professor Kianoush Nazarpour, Dr Sigrid Dupan and Mrs Sarah Day supervised the doctoral research. I declare that none of the material detailed in this thesis has previously been submitted by myself for a doctoral degree or any other qualification at Newcastle, or any other university.

Acknowledgements

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Chapter 1

Introduction

1.1 Overview

There are approximately 11.54 million individuals worldwide who have had an upper-limb amputation as a result of trauma [44, 45]. Traumatic amputations account for approximately 75% of the entire upper-limb different population, with cancer, infections and congenital limb-differences being less common causes [45]. The loss of an upper-limb can have severe consequences on both the physical and mental well-being of the patient [46]. Limb-loss can lead to wounds, infections, pain, mental distress, and muscular imbalances [46–48], especially when inadequate rehabilitation and healthcare is provided [48].

The provision of a prosthetic limb is generally the standard method of rehabilitating an individual with limb-loss or limb difference [49]. For upper-limb prosthetics, this usually comprises a grasping device, such as a hand or hook, and an attachment method, generally a prosthetic *socket*. Electrically powered prosthetics, generally referred to as *bionic arms* in media reports, emerged approximately 60 years ago. Since then, extensive efforts have been invested into advancing modern prosthetic hands. Unfortunately, the same advancements have not materialised within upper-limb prosthetic sockets. In general, upper-limb sockets have been regarded as an afterthought - merely something to house electronics and attach the terminal device to. This provides a poor foundation to build upon; no amount of advanced electronics can compensate for a socket that does not create a functional connection between the residual limb and the prosthesis. Subsequently, their design and

the way they are manufactured has remained largely unchanged for decades.

This is reflected in the low satisfaction rates among upper-limb prosthesis users [50–53]. In a survey of 242 individuals with upper-limb difference, 98% of the respondents agreed that they felt *'just as or more functional'* without a prostheses [51]. Additionally, rejection rates for upper-limb prostheses have remained consistently high for several decades, at approximately 35-44%, despite recent advancements in the dexterity and technicality of bionic hands [50, 53]. State funding is limited for advanced bionic limbs in the UK and in many countries worldwide [54, 55], and self-funding is not possible for many individuals due to the high costs associated with bionic prostheses. At a minimum, an entire prosthetic limb system, inclusive of the socket and medical fees, costs £9,499 in the UK [56]. However, costs can be much higher from other private providers, with hands costing between £6,300-79,000 [57] before the cost of obtaining a prosthetic socket and medical assessments are factored in. The aforementioned high rejection rates and financial barriers to obtaining advanced prosthetics indicate the available standard of care to upper-limb amputees is falling short of their needs. This PhD thesis studies the use of digital methods to redesign upper-limb sockets to meet user demands. By putting socket design and construction methods at the centre of prosthesis manufacturing, it is hoped both the wearer experience and ease of clinical manufacturing will be improved.

1.2 Goals

The overarching goal of this doctoral research was to investigate how to improve upper-limb prosthetic sockets through novel manufacturing methods and optimise their design for comfort and control. To achieve this goal, several key aims were devised.

- Firstly, to identify the current barriers to improvement of prosthetic sockets, and discuss how these can be overcome.
- Secondly, to identify which parts of prosthesis manufacturing may benefit from digital tools, and how these can be realistically integrated into clinical practice.
- Building upon this, the practical aims of this research are to devise a novel method of manufacturing prosthetic sockets using digital tools,

then use the method to create and test an improved design of trans-radial prosthetic socket.

These aims were achieved by investigating the viability, benefits, and shortcomings of modern technology for upper-limb prosthetic socket creation, and subsequently using these findings to prototype a manufacturing method and design of upper-limb prosthetic cuff, optimised for prosthesis control.

1.3 Thesis Outline

This thesis is divided into three main parts, intended to take the reader through the end-to-end process of upper-limb socket creation.

1.3.1 Part 1: Understanding Trans-Radial Prosthetic Sockets

Firstly, **Part I: *Understanding Trans-Radial Prosthetic Sockets*** comprises Chapter 2, a literature review of the previous research regarding upper-limb prostheses, and Chapter 3, a consensus of expert opinion to fill the gap between what is common knowledge within the field and the documented evidence base.

Chapter 2, the ***Literature Review***, covers core knowledge required to understand the issues covered in this PhD thesis and presents an overview of key information about upper-limb sockets. A key finding of this Chapter is that current upper-limb prosthetic sockets are retrofitted with advanced, heavy electronics rather than being designed specifically for modern prosthesis control. As a result, many issues regarding prosthetic function and comfort stem from the prosthetic socket. However, the evidence base for upper-limb prosthetic sockets was small prior to this PhD programme. Hence, it was necessary to validate and document key information regarding prosthetic sockets.

Subsequently, Chapter 3, ***The Current State of Prosthetic Socket Research***, is a discussion of many issues that impact modern upper-limb prosthetic sockets negatively, presented in the form of a consensus of experts in the field. The aim of this was to document and publish many topics which are accepted as 'common knowledge' but are rarely discussed in the literature. The implications and roadblocks to adopting modern socket manufacturing

methods, as well as the difficulty of defining what constitutes a 'good' socket, are discussed. This Chapter identifies a lack of unanimity on how to compare sockets, which prevents innovation within the upper-limb prosthetics field.

Based on the findings of **Part I**, it was decided that the following Chapters would focus on improving: prosthesis function, mainly within the electromyography (EMG) domain, comfort, and user satisfaction. Furthermore, realistic ways to integrate modern tools such as 3D printing and digital scanning into socket manufacturing are investigated.

1.3.2 Part 2: Manufacturing Trans-Radial Prosthetic Sockets

Part II: Manufacturing Trans-Radial Prosthetic Sockets comprises Chapter 4, 5 and 6. Chapter 4 outlines the general methods and practical procedures used throughout this PhD thesis and provides details of the ethics approvals obtained for each subsequent chapter. Chapters 5 and 6 are both practical experiments investigating how 3D printing and digital scanning can be realistically and reliably integrated into clinical practice.

Chapter 5, ***Optical Scanning for 3D Printed Sockets*** shows that newer limb capture techniques still lag behind traditional hands-on methods in terms of effectiveness. The key finding of this Chapter is that digital imaging does not account for tissue compliance, and therefore post-scan computer-based contouring is effectively done blindly. This Chapter concludes that in order for digital scanning to progress as a useful tool for prosthetics manufacturing, a hybrid method, combining digital scanning and tactile processes is required.

Hence, Chapter 6, ***Remote Creation of Trans-radial Bypass Sockets*** presents a combined approach, using remote digital scanning and 3D printing in conjunction with traditional methods and clinic-based socket manufacturing. This Chapter highlights the importance of using digital manufacturing to enhance, not replace, the *artisan* skills prosthetists bring to socket manufacturing.

Additionally, the knowledge base established from Chapter 5 and Chapter 6 validated 3D printing and digital scanning as a viable method for producing prosthetic sockets, especially when prototyping. This provided the foundation required to develop novel methods for producing and designing the prototypes detailed in the final two experiments of this PhD thesis.

1.3.3 Part 3: Designing Trans-Radial Prosthetic Sockets

The last part of this thesis, **Part III: Designing Trans-Radial Prosthetic Sockets** comprises Chapter 7, a preliminary investigation into the effects of longitudinal compression on EMG control, Chapter 8, which details the design, production and testing of a novel adjustable prosthetic socket simulator featuring areas of localised compression, and its effect on EMG control, and Chapter 9, a forecast of the future of upper-limb prosthetic sockets.

In Chapter 7, ***Compression for Trans-radial Prostheses Control***, a custom rig was designed to allow single-channel EMG control trials. The results of the study indicated localised compression may support pressure maintenance within a prosthetic socket during muscle contractions by partially immobilising the soft tissues.

In Chapter 8, ***Compression-Optimised Trans-radial Prosthetic Cuff Design***, the knowledge gained from all previous Chapters was amalgamated to produce an optimised manufacturing method and design for an upper-limb prosthetic socket simulator in the form of a cuff. Both the cuff itself and the method used to produce it were evaluated and discussed.

Finally, in Chapter 9, ***Future Outlook***, a proposed method for producing upper-limb prosthetic sockets based upon the methods detailed in Chapter 8 is outlined. An outlook to the future of upper-limb prosthetic sockets is provided, with suggestions on how proposed future-work stemming from the findings of this PhD thesis can be achieved.

Part I

Understanding Trans-Radial Prosthetic Sockets

Chapter 2

Literature Review

A prosthetic limb replaces the structure, and sometimes function, of an absent limb. Prosthetic limbs fall into two main categories: upper-limb and lower-limb, with further sub-categories for different levels and severity of amputations. In order to understand the terminology used in this thesis, a brief overview of upper-limb anatomy, prosthetic device designs and current challenges is provided below.

2.1 General Terminology

When describing limb-difference, amputations and prosthetic limbs, many terms are used interchangeably. However, this is not always correct. This Section covers how to correctly describe limb-difference and relevant upper-limb anatomy.

Limb *difference, absence and deficiency* are overarching terms that describe any type of deviation from standard human limb anatomy, which includes both missing and malformed limbs. There are many terms which can be used to describe these limbs - amputation stump, residuum or residual limb are all commonly accepted terms [58–60].

Limb *amputations* fit within this category and refer specifically to instances where a previously healthy or present limb has been totally, or partially, surgically removed due to trauma, disease or another medical reason. This is sometimes referred to as *acquired* amputation [60].

Congenital limb differences also fit within the wider category of limb difference. They encompass all missing or partially missing limbs evident

at birth. For congenital limb abnormalities, it is important to differentiate between limb *deficiency* and *difference* as the latter could include individuals with supernumerary (extra) digits, who therefore would not generally require a prosthesis, whereas the term *deficiency* refers specifically to underdeveloped, absent, or partially absent limbs [61]. Anecdotally, the term limb *difference* is generally preferred. Throughout this thesis, both terms are used to refer to individuals with missing, not underdeveloped or malformed, anatomy.

For individuals with acquired limb amputation, the underlying anatomy of their residuum is generally the same as that of a healthy limb, ending at the amputation site. However, for individuals with congenital limb difference, the underlying anatomy can vary significantly [62]. Congenital limb deficiencies can be differentiated into two sub-categories. A *transverse* deficiency is where the residuum has developed regularly to a certain point, beyond which no further bones exist, hence resembling an amputation stump [58]. For example, the forearm may develop regularly to the radius and ulna, but no further bones would be present. A *longitudinal* deficiency covers all other limb deficiencies, where individual bones may be missing or partially formed [58]. For example, the radius, ulna, carpal (wrist) and hand bones may all be present, but only partially formed. Additionally, the terms *hypoplasia* or *hypoplastic* refers to bones which are present and approximately the correct shape, but much smaller than a fully developed specimen [61]. Although widely varied, there are internationally recognised standards to identify, name and describe both acquired and congenital limb difference [58, 59, 61, 63].

2.1.1 Limb Loss Prevalence

Accurately estimating the total number of individuals living with limb difference globally is not possible, due to some countries lacking national reporting of amputations and congenital limb differences. Reporting systems and academic studies vary in methods and inclusion criteria, hence are only applicable to the country, region or institute where the data was collected [64–67]. Additionally, regional estimations cannot be extrapolated to predict global levels as the leading cause of amputation differs between countries [64, 68]. Regional access to healthcare, conflict, disease prevalence and the frequency of natural disasters will all influence the demographics of the local population of individuals with limb amputation.

Despite regional differences, there are some amputation trends which ap-

pear to be consistent around the world. Men are more likely to have amputations (both upper and lower) [64, 66, 68–73] and upper-limb amputation is less common than lower-limb amputation [66, 68–72, 74, 75]. Trauma, followed by cancerous tumors, are the leading causes of upper-limb amputations overall [64, 66, 68–70, 73]. Upper-limb congenital differences are more common than lower-limb, with the combined rate of upper and lower limb differences estimated to be 2-7 per 10,000 live births globally [76]. Congenital abnormalities are the leading cause of limb difference in children, with the percentage of acquired amputations rising each year as the children get older [77–79]. In adulthood, acquired amputation accounts for the majority of limb difference [80].

Although no known conclusive global studies have been conducted, US data would suggest that the number of acquired upper-limb amputations heavily outweighs the number of children born with congenital upper-limb difference of 5.4 to 1, and out of those born with congenital limb difference, transverse deficiencies are the most common [66].

For the purpose of this thesis, the term *upper limb difference* will be used as an umbrella term to refer to the limbs of both individuals with acquired limb amputation and individuals with congenital limb difference unless otherwise stated.

2.1.2 Levels of Limb Difference

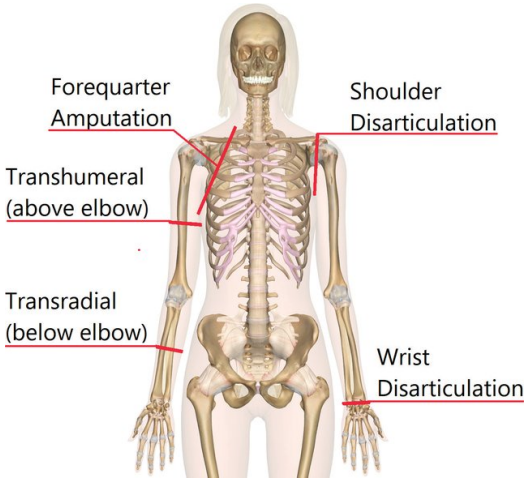


Figure 2.1: Levels of upper-limb amputation [1].

There are several different levels of upper-limb difference, as demonstrated in Figure 2.1. This doctoral research focuses on prosthetic sockets for trans-radial limb difference, hence this area of anatomy will be discussed in the most detail, however other levels will be covered briefly where relevant.

In short, a trans-radial amputation, often referred to as a *below elbow* amputation [59], is where the residual limb (*residuum*) ends between the elbow and the wrist [1]. A *wrist-disarticulation*, also shown in Figure 2.1, is visually similar, as the amputation site is below the elbow and the hand is entirely absent. However, wrist-disarticulations are different to trans-radial amputations as the entirety of the forearm is preserved, and the amputation involves the removal of all carpal bones and structures distal to that point [63, 81]. Due to their longer length, wrist-disarticulation sockets often do not feature an encapsulated elbow and instead end mid-way along the residuum [82, 83]. Additionally, short and mid-length trans-radial residuums allow more room for electronic components to be fitted within the empty space of the prosthetic socket, as shown in Figure 2.2. Due to these distinctions, prosthetic socket design and device suitability is different for those with trans-radial and wrist-disarticulation amputation.

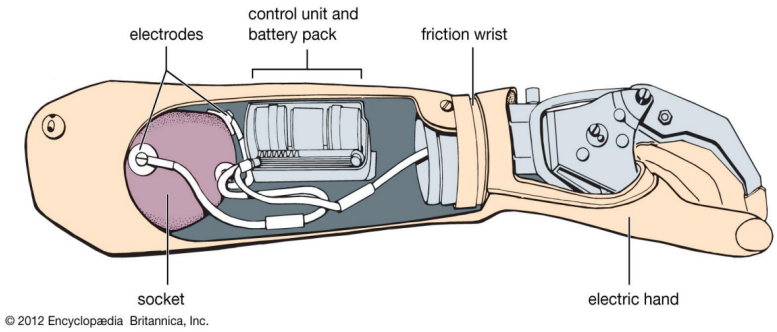


Figure 2.2: A diagram showing the location of components in a common trans-radial myoelectric prosthesis design [2]

2.1.3 Relevant Trans-radial Anatomy

Many functional outcomes of providing a prosthesis depend on the anatomy of a residuum, such as the suitability for certain socket designs, level of suspension, control, range of motion and residual space inside the prosthesis.

Hence, this Section will cover the specific elements of skeletal and muscular anatomy necessary to understand the succeeding Chapters.

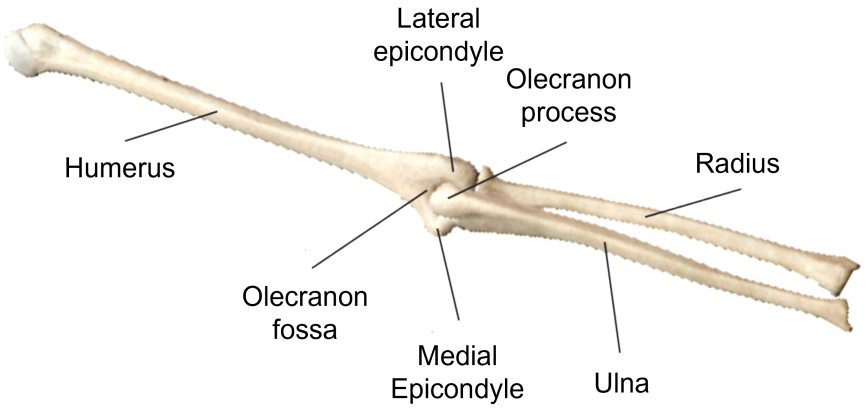


Figure 2.3: A diagram displaying key upper-limb anatomy. Image modified from [3].

2.1.3.1 Relevant Skeletal Anatomy

When assessing a trans-radial residuum, there are four key areas of skeletal anatomy to consider: the radius and ulna, the two bones running the length of the forearm, and the epicondyles and olecranon, the bony prominences of the elbow. Figure 2.3 displays their location within the forearm.

Forearm rotation is possible as the radius can rotate around the ulna [84]. This motion allows wrist pronation, where the forearm rotates inwards to allow the palm to face downwards, and supination, the opposite of pronation, where the forearm rotates outwards from the body and the palm faces up [85], as shown in Figure 2.4. For individuals with trans-radial amputation, the degree of forearm pronation and supination possible depends on the length of the residuum [86]. The longer the residuum, the more radio-ulnar rotation possible [86].

2.1.4 Relevant Muscular Anatomy

For electrically *powered* prostheses, also called *bionic* or *myoelectric* prostheses, the most common biosignals used to control the terminal device are EMG

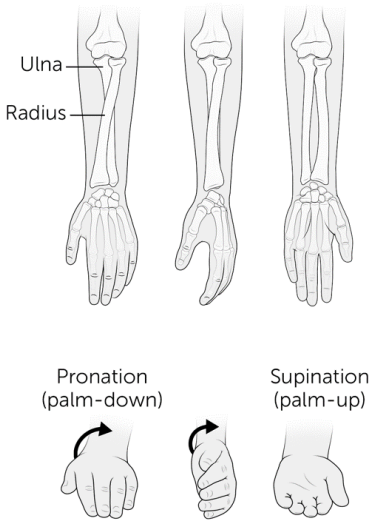
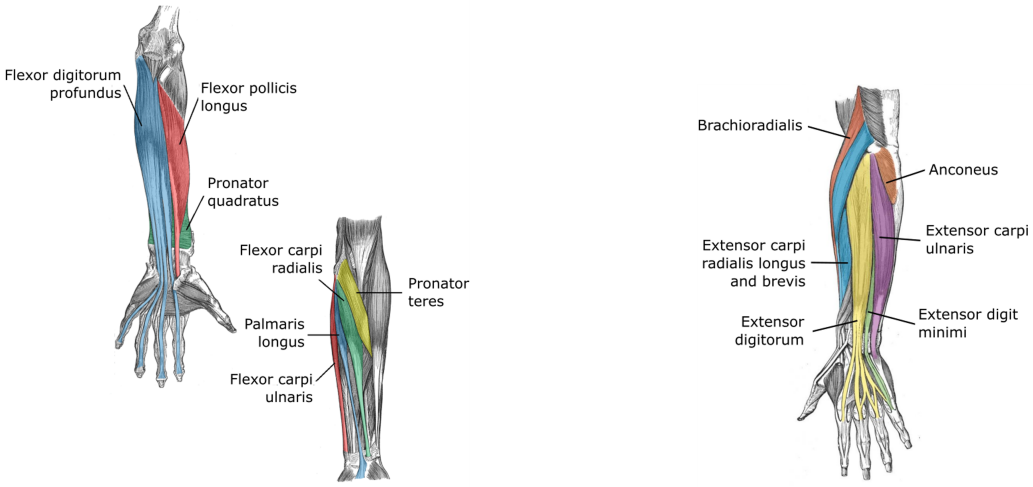


Figure 2.4: A diagram showing pronation and supination of the forearm. Image modified from [4].

(electromyography) signals. To control these prostheses, the aim is to identify muscle sites where clear EMG signals can be detected; most commonly two sites which can be activated independently from each other. Where two naturally occurring muscle groups perform opposing functions they are called *antagonistic*. There are many small, individual muscles within the forearm, as shown in Figure 2.5. The muscles are sub-divided into two groups: the wrist extensors and wrist flexors. Because of their antagonistic functions, wrist extensors and flexors are commonly used as the preferred EMG sites for trans-radial prostheses control [87]. Given that these muscles naturally perform opposing functions, teaching a wearer to voluntarily establish independent control of them is relatively simple. Combining muscle contractions from these two sites, and varying contraction lengths, allows for a simple open/close mechanism, or more complex non-intuitive commands with sufficient training [87, 88].

Magnetic resonance imaging (MRI) shows that individuals with congenital limb difference often have under-developed muscles covered with surplus 'electrically inactive' soft tissue in their deficient limb [89]. Hence, some individuals with congenital limb difference present reduced capability to generate myoelectric control signals [90]. Similarly, individuals with very short trans-radial amputation stumps may not have enough residual musculature



(a) (b)

Figure 2.5: (a) The anterior muscles of the left forearm, responsible for wrist and finger flexion and (b), the posterior muscles of the left forearm, responsible for wrist and finger extension. Images modified from [5, 6]

to provide sufficient control sites. For these individuals, techniques such as *Targeted Muscle Re-innervation* (TMR) is an option - surgically re-directing nerves from other areas of the arm into muscles which can be used for prostheses control [91]. However, this technique sometimes requires further surgery if not performed during the original amputation [81]. Additionally, maintaining healthy musculature within an amputation stump is vital for the overall well-being of individuals with amputations - maintaining the correct body posture, the limb's range of motion and reducing swelling within the limb can be achieved through appropriate muscle exercise and physiotherapy [92].

2.2 Trans-radial Device Categories and Control Mechanisms

Prosthetic limbs are modular, comprising both an attachment method such as a socket, which will be covered in detail in Chapter 2, Section 2.3.1, and commercially available parts. Whether an individual wears a socket, cuff or has an osseo-integrated bone anchor, they have a wide variety of *terminal*

devices available to choose from. Terminal device is the name for any attachment which fastens to the end of a socket, cuff or osseo-integrated bone anchor. Some terminal devices are purely optimised for function, others exist only for cosmetic reasons, and some offer a combination of the two. Similarly, some are designed to look anthropomorphic, whereas others are intentionally 'high-tech' in appearance. Ultimately, a person's choice of prosthetic terminal device is influenced by a combination of financial constraints, the type of limb difference they have, and their motivation for wearing one. Some individuals are motivated by aesthetics to wear a prosthesis [93–97], whereas others may prioritise functionality or comfort [64, 94, 97].

Given the variety of combinations of components possible, there are many different types of upper-limb prostheses available for individuals who choose to wear them. These devices fall into three main categories, based upon how they function: *passive*, *body-powered* and *powered* prostheses. There are subcategories of each type of device, divided by how the device is controlled and the functionality it allows, as shown in Figure 2.6. This Section will cover these three main categories, why the devices are categorised this way, their varying components, and when they would be appropriate to prescribe.

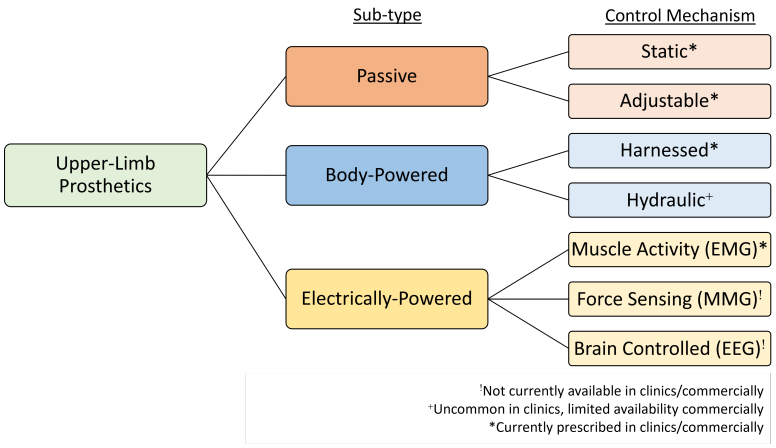


Figure 2.6: A diagram showing the different categories of upper-limb prostheses.

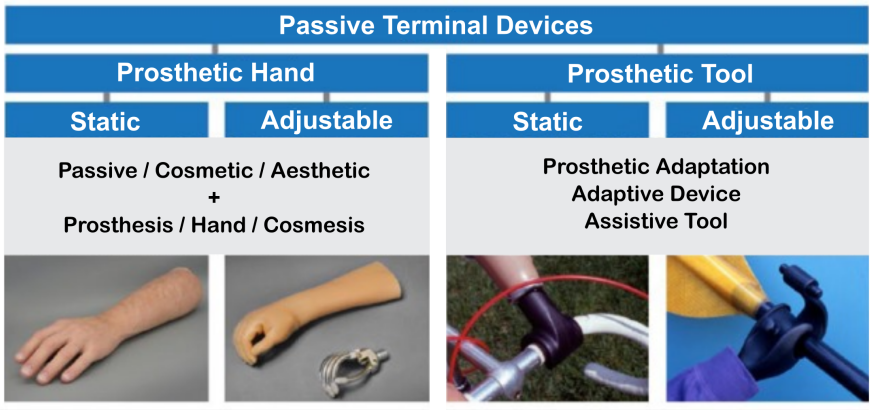


Figure 2.7: A diagram showing the different categories of passive prosthetic terminal devices. Image modified from [7].

2.2.1 Passive Devices

Passive devices are the most simplistic form of upper-limb prostheses. They are different from other types of prostheses as, in order to grasp or change their pose, an external force must be applied, usually by the wearer's other intact limb (if present) [7]. Approximately one third of individuals choosing to wear an upper-limb prosthesis choose a passive device [7]. Despite their name, passive devices can serve a variety of functions and be adjustable to grasp objects, or may purely be worn for aesthetic reasons [7]. A diagram showing the sub-categories of passive upper-limb devices can be seen in Figure 2.7.

For individuals where aesthetics are a key motivating factor to wear the device, cosmetic prostheses are a popular choice. Cosmetic hands can be highly realistic 'mirror image' silicone replicas of the intact limb [98], which the wearer may choose for psychological or aesthetic reasons [99]. *Static* cosmetic hands cannot grasp objects and are purely for aesthetics, however passive *adjustable* prostheses can be manually maneuvered into different shapes [7]. Similarly, prosthetic tools also fall under the umbrella of passive prostheses. They are either static, or must be attached manually to whatever item they are designed to grasp [7]. Prosthetic tool attachments may be required for writing, cooking or sports, with notable examples including custom training devices for elite para-athletes [100]. Figure 2.8 shows a variety of highly specialised prosthetic tools for recreational use. These devices are modified

Figure 2.8: Specialised prosthetic tools for: A) Drumming. B) A multi-purpose tool. C) Playing pool or snooker. D) Holding a skipping rope. E) Playing guitar. F) Playing hockey. Images from [8, 9].

or designed specifically to be attached to a prosthetic device and assist the wearer whilst doing a specific task, but would be classified as passive as they cannot be controlled by the wearer to perform a motion.

Passive adjustable prostheses may also feature passive wrists that allow the terminal device to be rotated. Many people who wear this type of prosthesis learn to push the terminal device against another body part, e.g. their thigh, to rotate the device as needed without the use of their other arm. In recent times, digital scanners and colour-matching technology has been used to create a variety of custom prostheses matching the participant's own dimensions [101] and skin tone [102]. This has traditionally been done manually via an artisan process involving casting and shade-matching, still used today in many clinics [98].

2.2.2 Body-Powered Devices

The concept of functional, user-controlled prostheses dates back to the early 1800's, however many early designs were impractical or prohibitively expensive [10]. In 1948, the Bowden cable was patented; this revolutionised body-powered prostheses as it allowed a simple, reliable method of operating

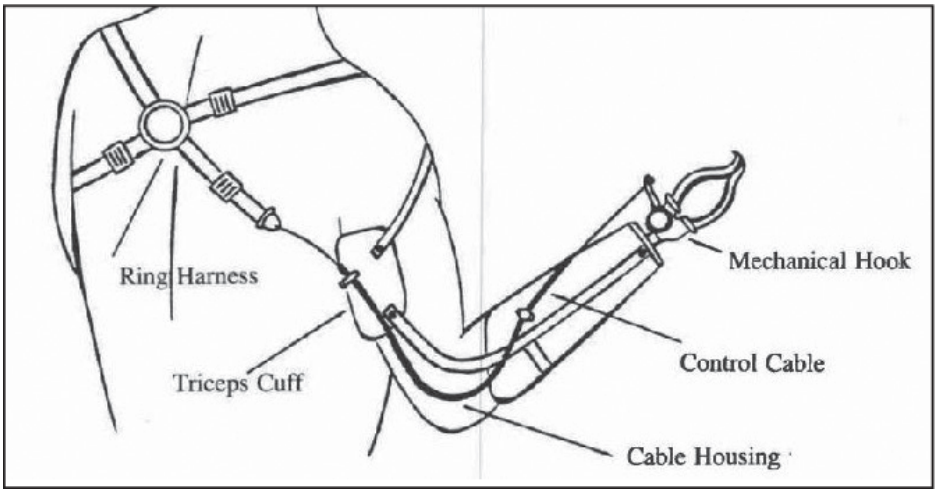


Figure 2.9: A diagram showing a basic Bowden cable system attached to a body-powered prosthesis. Image modified from [10]

a functional prosthetic device. A Bowden cable, as shown in Figure 2.9, is a strong, streamlined cord attached to a harness fitted over one or both of the wearer's shoulders [103]. There are many different harness designs which can be prescribed dependent on the needs of the wearer and residual limb length [103]. The wearer can then learn to use their own shoulder and elbow motions to vary the tension and position of the cable, hence opening and closing their prosthesis [10, 104]. Although basic, almost all body-powered prostheses prescribed and manufactured today are just variants of this design [10], which has not changed significantly since the 1950's [105].

Body-powered prostheses cost less than more advanced externally-powered prostheses [12, 106]. Furthermore, because they are mechanically operated by the wearer, body-powered prostheses naturally provide a limited amount of sensory feedback in terms of grip strength [107–109]. Most commercially available EMG prostheses lack sensory feedback in terms of grip strength [109]. Subsequently, body-powered devices are an attractive option for many individuals with upper-limb difference. However, harnessed prostheses require the Bowden cable to be in tension, and therefore cannot be operated in body positions where the cable is loose, hence the range of operation is limited [54].

The most common body-powered prosthesis is a split-hook [12], shown in Figure 2.10(a). Body-powered 'hands' are also available, which are generally

(a) (b)

Figure 2.10: (a) A typical split-hook. Image from [11]. (b) A body-powered 'hand' prosthesis with and without the cosmetic glove. Image modified from [12]

metal grippers covered by a cosmetic anthropomorphic glove, as shown in Figure 2.10(b). There are two types of body-powered device - 'voluntary opening' and 'voluntary closing' [13]. As the names would suggest, voluntary-opening devices are closed 'at rest' and the wearer must apply tension to the Bowden cable in order to open them, with voluntary-closing devices being open 'at rest' and requiring tension to clamp shut [13]. This is demonstrated in Figure 2.11. As with passive devices, manually adjustable wrist units can be added to allow the body-powered terminal device to be rotated.

In addition to harnessed prostheses, there are also hydraulic prostheses which can be operated through depressing a fluid bladder [110]. However, they are uncommon and therefore not generally prescribed or created in clinics.

2.2.3 Powered Devices

Prostheses that rely on batteries to perform gestures such as open and close are called *powered* prostheses. Arguably the most technologically advanced option commercially available, powered upper-limb prostheses were proposed as early as 1948, however they were not a realistic healthcare option until the

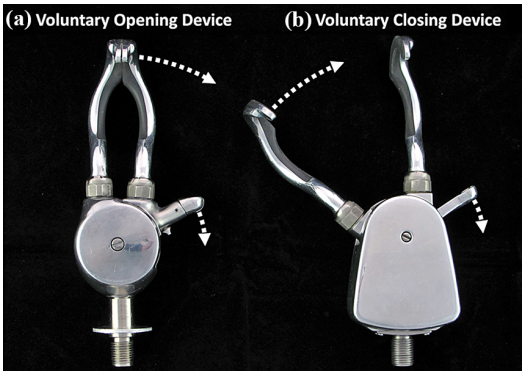


Figure 2.11: A diagram showing how voluntary opening and voluntary closing devices operate. Image from [13].

1960's [10]. This was due to modern electronics reducing bulk in the devices [10], and the rise of self-suspending sockets.

The majority of powered prostheses are *myoelectric*. In brief, myoelectric prostheses rely on muscle activity from the wearer for control. The muscle activity is detected by EMG electrodes. *Signal processing* is then used to turn the raw EMG recordings into command signals, which in turn are used to operate the terminal device. There are several types of electrodes, myoelectric terminal devices, and methods of EMG signal processing. Hence, there are a diverse variety of myoelectric prostheses available.

2.2.3.1 Terminal Devices

Powered prostheses can come with terminal devices in the form of hooks, grippers or hands, all shown in Figure 2.12. Unlike body-powered or passive prostheses, powered prostheses also offer the option of a powered wrist, actuated using EMG signals in the same manner as the terminal device.

The most simplistic option for a powered prosthesis would be a split-hook. The only difference between a body-powered and powered split-hook such as Fillauer's *Electric Terminal Device* Hook [111] is the actuation method, and therefore absence of a harness. Similar to split-hooks, myoelectric grippers are a functional, hard-wearing option, with the Griefer gripper being a common example. Both devices can only open and close, and therefore have no need for a mode-switching mechanism. Due to this, split hooks and grippers are often referred to as a one-degree of freedom (one-DOF) prostheses [112].

Figure 2.12: a) A myoelectric hook prosthesis. Image from [14]. b) A Griefer gripper. Image from [14]. c) A myoelectric 'hand' without a cosmetic glove. Image from [14]. d) A diagram of a myoelectric hand shown inside of a cosmetic glove. Image from [15]. e) A multi-articulated prosthetic hand. Image from [14].

Many bionic 'hands' are actually myoelectric grippers, as shown in Figure 2.12(c) and (d), housed within a cosmetic glove. Due to this, they cannot articulate the fingers individually.

In more recent years, multi-articulated hands have emerged that allow each or all of the fingers and thumb to move independently of each other in a series of pre-programmed grips. These hands are the most expensive option for upper-limb prostheses, powered or otherwise. For reference, a multi-articulated hand will cost in excess of £6,300 for even the cheapest options [57], whereas a standard body-powered split-hook costs around £360-510 [113, 114]. Multi-articulating prostheses which can perform anthropomorphic grips and hand gestures are called multiple DOF prostheses [115].

2.2.3.2 Signal Detection

EMG electrodes can either be *non-invasive* or *invasive* [116]. Non-invasive electrodes, generally known as 'surface electrodes' sit on the surface of the skin [117]; either affixed with an adhesive film for short-term clinical or research use, shown in Figure 2.13(a), or housed in a plastic casing featuring rod-like rubber projections which allow them to slot into and easily be removed from cut-outs in the wall of a prosthetic socket [118, 119], as shown in

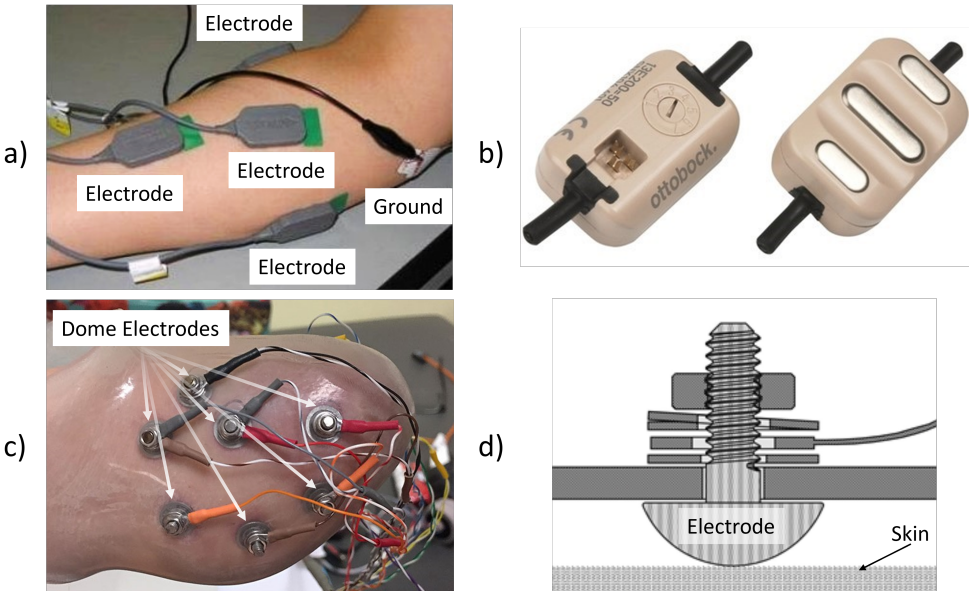


Figure 2.13: (a) Research electrodes affixed to a forearm with adhesive film. Image modified from [16]. (b) An example of a clinical standard myoelectrode, Ottobock's '13E200 MyoBock'. Image from [17]. (c) and (d) Dome electrodes featured in a Coapt pattern recognition myoelectric system. Images modified from [18].

Figure 2.13(b) [118, 120]. This style of electrode is the most common form for prosthesis control as it is the clinical standard, however some clinically available systems use 'stud' electrodes, which resemble small metal domes, shown in Figure 2.13(c) and (d). Surface electrodes are convenient as they provide a method of recording and utilising the wearer's residual musculature without requiring surgery or causing discomfort [16]. Unfortunately, this convenience comes at a cost as there are many reliability issues associated with the use of surface electrodes for EMG-controlled prostheses [38, 117, 121]. There are several sources of *noise* that can affect EMG signal quality [117, 121]. Some may originate from inside the wearer's own body, e.g. excess sweat, volume fluctuations, fatty, non-conductive tissue in the limb, and cross-talk from other muscles [117, 121]. Additional sources can come from power-lines, nearby electronics, and the way the electrode is housed within the prosthesis [117]. In general, 'predictable' sources of noise can be filtered or accounted for sufficiently, however 'unpredictable' sources such as the limb's movement

within the socket are harder to pre-empt and account for [122]. Hence, socket fit, and therefore design, can significantly affect EMG signal quality. This largely unexplored and under-researched issue will be covered in detail in Chapter 2, Section 2.4.3.

Invasive, sometimes called *intramuscular*, electrodes for prosthesis control are less common as they are still in an experimental phase of development. They are implanted into the wearer's residual limb sub-dermally which requires a surgical procedure [123]. Given the additional surgical procedure required, they pose an infection risk and may inflict further harm to the wearer. However, invasive electrodes have shown to be less susceptible to many forms of signal interference [123], and therefore may be a viable option in future decades.

Far less common would be force sensing, called mechanomyography (MMG), and brain control, called encephalography (EEG). Both are in their infancy in terms of practical usage and commercial development, however offer exciting avenues for the future which may circumvent some of the issues surrounding EMG control.

2.2.3.3 Command Systems

There are currently two realistic options for turning EMG signals into recognisable commands to control a myoelectric prosthesis: simple control systems like *proportional* and *direct* control using one or two clinical standard electrodes, or complex systems which use machine learning and *pattern recognition* [124].

Almost all clinically and commercially available myoelectric prostheses utilise direct or proportional control [124]. Using proportional control, the amplitude of the muscle contraction from the wearer is directly proportional to the magnitude of response from the prosthesis. For direct control, the wearer must contract their muscles to reach a threshold value, which activates the gesture associated with that electrode. This style of control is also sometimes called 'bang-bang' control [125]. For simplicity, proportional control works similarly to a volume or dimmer switch, whereas direct control acts like an on-off switch.

Generally, two antagonistic muscle sites are used for direct and proportional control [124], such as the forearm flexors and extensors, one to open the device and one to close it, as shown in Figure 2.14. Hence, when used in their simplest form with two sensors, they are often referred to as *dual-site*

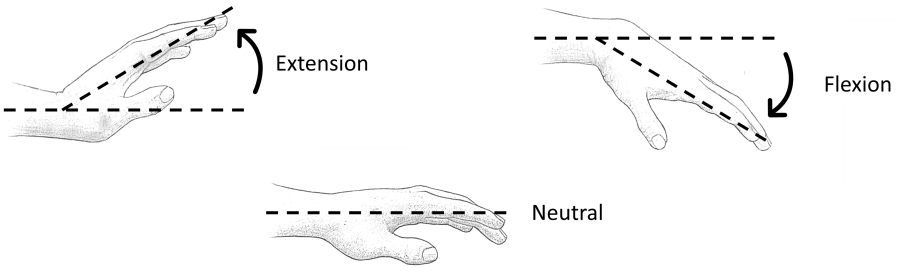


Figure 2.14: A diagram showing flexion and extension of the wrist. Image modified from [19].

control [126]. Due to the simplicity of dual-site control, it is generally used for prostheses that only perform open and close motions, such as prosthetic hooks and one-DOF 'hands' [127]. Despite the increased complexity, it is still possible to operate multiple DOF prosthesis using dual-site control with the addition of a mode-switching mechanism [45, 49, 128]. Mode-switching mechanisms allow the function of a multiple-DOF prosthesis to be changed whilst the wearer is using it. They can be mechanical, app-based, radio-controlled or utilise myoelectric signals from the body [45, 49, 127, 129]. Figure 2.15 demonstrates briefly how dual-site control can be used with a mode-switching mechanism to allow multiple grips.

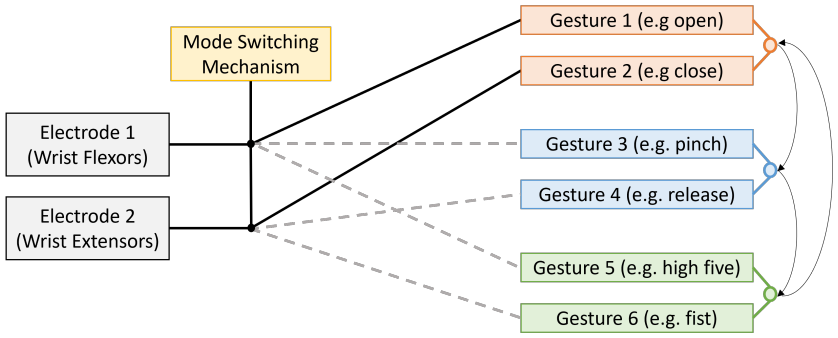


Figure 2.15: A diagram showing how two channels of EMG signals can be used to produce several sets of outcomes from the device, which the user can cycle between by activating the mode switching mechanism. Image from adapted from [20].

Physical buttons fitted to the device are an example of a mechanical mode-switching mechanism. They are a common option for multi-articulating prostheses as they are generally easy for the wearer to operate. In order to operate this kind of mode-switching mechanism, the wearer would generally need to use their intact limb to press the mode-switch button on their prostheses. Alternatively, some wearers learn to strike the button against their body to keep their intact limb free. This is also useful for individuals with bi-lateral limb difference who do not have the use of an intact upper limb. Additionally, foot-switches providing the same function have been trialled, which reduce the burden on the intact limb [130]. When the wearer must repeatedly activate the mode-switching mechanism to cycle between the available gestures it is called *sequential switching*.

Digital mode-switching mechanisms are also commercially available, such as app-based control or radio-frequency identification (RFID) tags [127, 128]. The Touchbionics app, released in 2013, was the first of its kind and allowed users to cycle between grips using their smartphone [128]. However, this form of mode-switching requires extensive use of the intact-limb, and hence is not generally suitable for individuals with bi-lateral upper-limb difference. Additionally, delaying mode-switching by necessitating the use of an app can discourage some users due to the additional time and effort required.

More commonly, gesture based control is used to diversify the functionality of direct control myoelectric prostheses. With sufficient training, wearers can learn to perform patterns of specific muscle activations which expand the functionality of their device [21, 45, 49]. As an example, the wearer may contract both muscles simultaneously, called a *co-contraction*, in order to swap the grip or gesture the hand performs. Figure 2.16 demonstrates this principle. Using this method, it is also possible to use direct control with a single EMG site by varying the level and duration of contraction to alter the outcome of the prosthesis's response instead of using co-contractions [131].

However, gesture based control can be cumbersome for the wearer, as using sequential switching with this method takes significant time and may be impractical for devices with a large number of grips. Most modern multi-articulating prosthetic hands can perform 4-6 pre-programmed grips. Hence, performing repeated contractions to cycle between modes would be impractical.

Despite offering more hand gestures, mode-switching can introduce extra delays between the user wanting to operate their prosthesis and the resultant action from the device. This is due to the repetitive muscle contractions

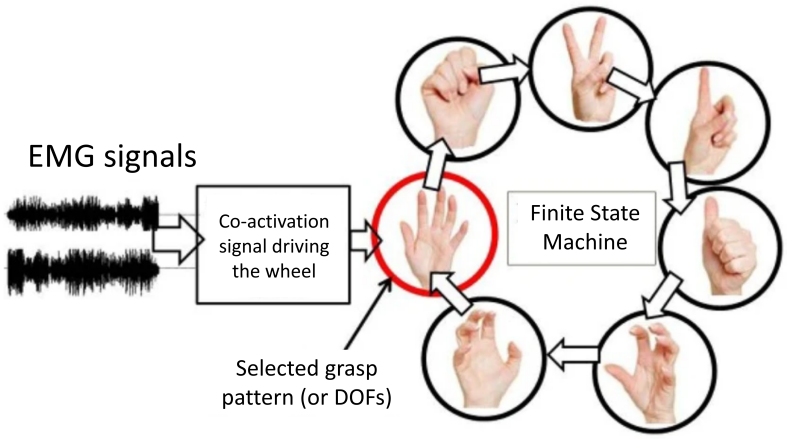


Figure 2.16: A diagram demonstrating the principle of sequential switching to swap between grip modes of a prosthetic hand using two-channel EMG control. Image from [21].

required, which can be especially impractical for devices with a high number of grasps. As an alternative, many research groups have investigated the use of *pattern recognition* instead. Pattern recognition detects patterns of muscle activation during different grasping motions (for example, making a fist requires a different pattern of muscle activation to performing a pinching motion) [132]. Machine learning can be utilised to recognise the 'signature' of each pattern, allowing multiple grips without a manual switching method [121, 132]. There are currently only three commercial providers of pattern recognition systems for prostheses control [132, 133], the CoApt 'Gen2' system, Ottobocks' 'Myoplus' and Infinite Biomedical Technologies' 'Sense'. Despite offering a greater variety of motions and restoration of function, this method is more expensive, and currently is not as reliable as the more simplistic option of direct control. Moreover, pattern recognition requires collecting a 'calibration' data set for each individual user to calibrate the system [134]. This data set may need to be repeated frequently to ensure the control system can correctly identify the muscle activity from the wearer [135–137], which can be burdensome. Pattern recognition requires more EMG sites than direct control, with all commercial systems typically using eight channel EMG [18, 138, 139]. This requires more hardware to be fitted into the prosthetic socket. Subsequently, each time the prosthe-

sis is donned or doffed the electrodes may sit in a slightly different position relative to the limb [140]. This shift in electrode position changes the skin impedance, which affects the signal being acquired, hence day-to-day usage is limited [141].

In recent years, systems based upon 'learning' have emerged as a third, promising option for myoelectric control. In academia, this is often known as 'abstract decoding', because simple movements from the wearer can be mapped to produce non-intuitive responses from the prosthesis [22]. Using direct control, contracting and relaxing the wrist flexors produces a simple response from the prosthesis - i.e. one muscle opens the terminal device and the other closes it. As this system closely mimics the actual function of the wrist flexors and extensors, it requires very little learning from the wearer. However, due to its simplicity it still relies on the aforementioned mode-switching mechanisms to change gestures. In contrast, using abstract decoding allows the same contractions to be mapped to entirely different responses and produce a wider range of gestures with no additional hardware [22]. In brief, between the two maximum independent muscle contractions possible using dual-site control, combinations of the two are mapped in a 2D space, for which different segments correspond to a different response from the prosthesis [22]. Wearers learn to operate a prosthesis using abstract decoding via 'centre-out' tasks - where no contraction corresponds to the 'rested state', denoted as the centre of a 2D map [22]. The various possible combinations of contractions are divided into discrete segments on the 2D map, which correspond to different gestures available from the prosthesis [22]. This principle is demonstrated in Figure 2.17.

Abstract decoding allows a wide variety of responses to be produced from the prosthesis without requiring additional sensors or hardware and eliminates the need for burdensome mode switching mechanisms. However, this principle only works when the wearer is prepared to learn and retain the skills required to operate a prosthesis in this manner [137]. The wearer's motor system must learn to map specific actions to arbitrary outcomes from the prosthesis [22, 137]. A benefit of abstract decoding is that the motions required to control the prosthesis can be learned ahead of time without wearing a prosthesis, known as *transfer* [137]. Home-based training systems using only simple electrode systems are being trialled [137], with gamified systems being suggested to improve the user experience and likelihood of persevering with training [142]. Although research into abstract decoding is still in its early stages, promising results from take-home trials have been reported

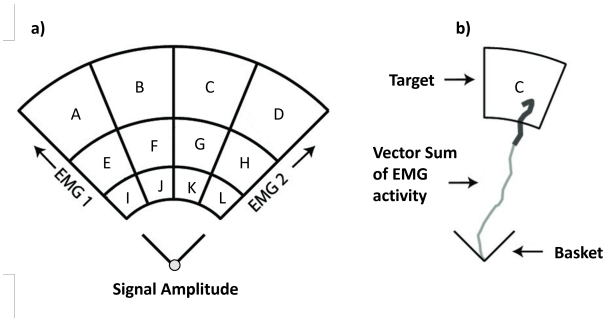


Figure 2.17: A diagram demonstrating the principle of abstract decoding. a) A 2D map, divided into 12 sections. Each section A-L corresponds to a potential different response from a prosthetic device. (b) Combining the amplitude of two EMG channels to create a vector, a cursor can be guided to a specific section. Image adapted from [22].

[137, 143]. Given their potential to provide more advanced and intuitive prosthesis control [144], significant research effort has been invested into both machine learning and software development for EMG pattern recognition and abstract decoding.

2.3 Human-Prosthesis Interfaces

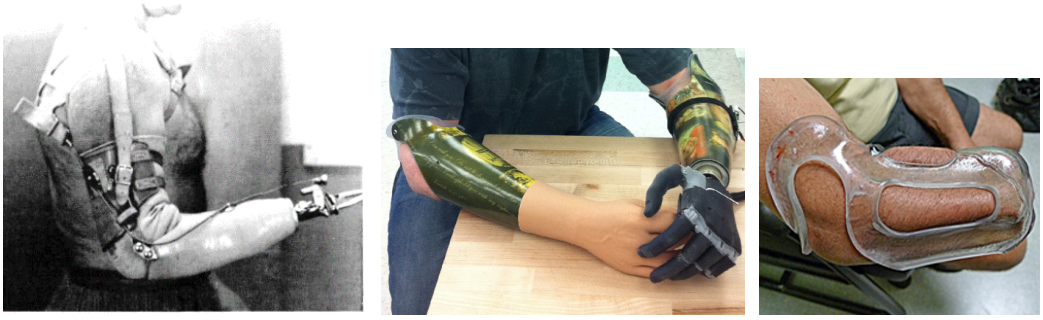
In order for an individual to wear a prosthetic limb, it must somehow attach to their body. The most common method of attaching a prosthetic device to a residual limb is via a prosthetic *socket* [86], however other options do exist. To begin, this Section discusses prosthetic sockets and the various styles available for people with trans-radial limb difference. As custom-made medical devices that must be prescribed and created by trained professionals, the subsequent Section discusses common manufacturing methods. Finally, an overview of alternative options for connecting a wearer's residual limb to their prosthesis is presented. This is to give the reader an understanding of the various prosthetic arms available, in addition to why sockets are typically the default option.

2.3.1 Trans-radial Prosthetic Sockets

Conventionally, prosthetic sockets are rigid, cup-like structures custom-made by a prosthetist to fit the anatomy of each individual residuum [145]. They are generally made from rigid thermoplastics or sturdy composites comprising resin, and soft fibres such as nylon, cotton and carbon fibre [145, 146]. The aim of a socket is to *suspend* the prosthetic limb upon the wearer's residual limb. Socket *suspension* is achieved through a combination of suction, sculpted contours around the underlying bones, socket tightness and traction against the limb [99, 146–148], and one of the main objectives when creating a prosthetic socket is to stabilise the tissue to reduce bone movement within the socket [99]. The level and shape of the contouring is determined by the prosthetist creating the socket, based on which socket style they are creating and how much contouring the patient can tolerate - largely determined by how fleshy or bony the person's limb is and whether they experience pain in their residuum [99]. Socket tightness is also determined by the prosthetist but is affected over time by volume fluctuations in the residuum, for example due to muscle gain or loss [38, 121]. Traction between the limb and the prosthesis is affected by a number of factors, such as perspiration and hairiness [149]. The relationship is complex, as there can be multiple or no layers between the socket wall and the skin, for example liners may or may not be worn in conjunction with the prosthesis, or multiple fabric limb socks. Silicone liners are a popular choice as they have a high coefficient of friction, the ratio of frictional forces opposing the motion between two surfaces [99]. Socket liners are covered in more detail in Section 2.3.1.1.

Many different types of trans-radial socket exist [99, 150]. The prosthetist assessing the residual limb will decide which style is the most appropriate based on what activities the wearer intends to undertake, and also the the shape and length of the residual limb [99, 150]. A key stage in conventional socket provision is limb casting, which allows the geometry of the limb to be captured and converted to a plaster model. A detailed overview of this procedure is covered in Chapter 5, Section 5.1.1.

Prior to the 1960's, trans-radial prostheses did not generally feature contouring around the elbow [38]. Instead, a cup-shaped socket shorter than the residual forearm length was suspended by an above-elbow cuff and harness, as shown in Figure 2.18(a). Although functional, many wearers find harnessed sockets uncomfortable and aesthetically unsatisfactory [151]. In the 1960's, battery powered prostheses became increasingly common [152],



(a) (b) (c)

Figure 2.18: (a) A trans-radial socket and suspension system without supra-condylar contouring. Image modified from [23] (b) A person with bi-lateral trans-radial limb difference wearing self-suspending trans-radial sockets. Image modified from [24]. (c) A compression-release diagnostic socket. Image modified from [25].

which removed the need for a control cable. Hence, for people choosing battery powered devices, the entire harness was now unnecessary for control [153], and the *self-suspending* socket rose to prominence. Instead of harnessing, these new designs relied on supra-condylar (above elbow) contouring for suspension [103]. There are many different variants of the self-suspending socket, with many sockets being hybrid or modified designs to suit the individual [99, 153]. However, there are several 'well known' and recognisable styles. Generally, residuum length is a key deciding factor when prescribing a socket style [150], but the patient's activity levels and personal requirements are always of paramount importance for finding them a suitable prosthesis [99].

Although hard to detect visually, small changes to the way a socket is contoured can have a big impact on how the socket fits and functions. A key element of a socket is it's *trimline*, the open end of the socket which, for self suspending sockets, usually rises above the epicondyles. The *anterior* trimline is located in front of the elbow crease (cubital fold), and the *posterior* trimline is located behind the elbow, and is usually contoured and flared outwards for comfort and suspension. A diagram showing key socket terminology can be seen in Figure 2.19.

For short residual limbs, Münster or Brim sockets are generally appropriate [38, 99, 150, 153]. The Münster (sometimes spelled Muenster) socket is

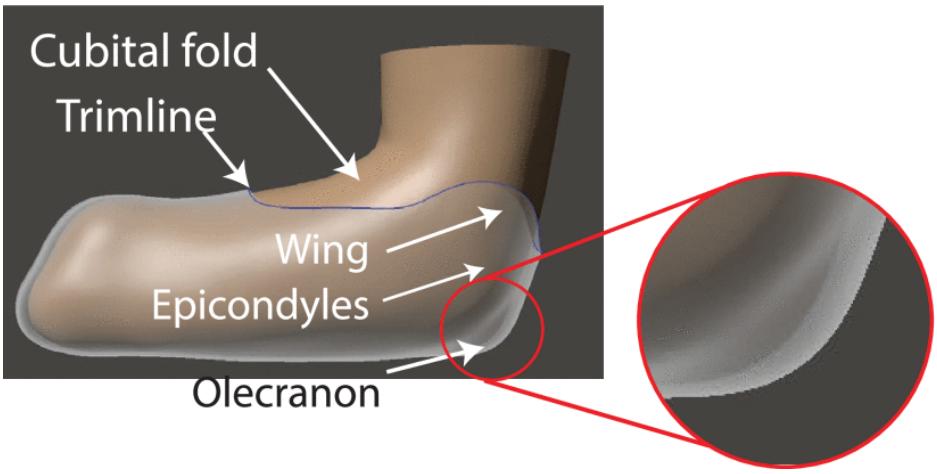
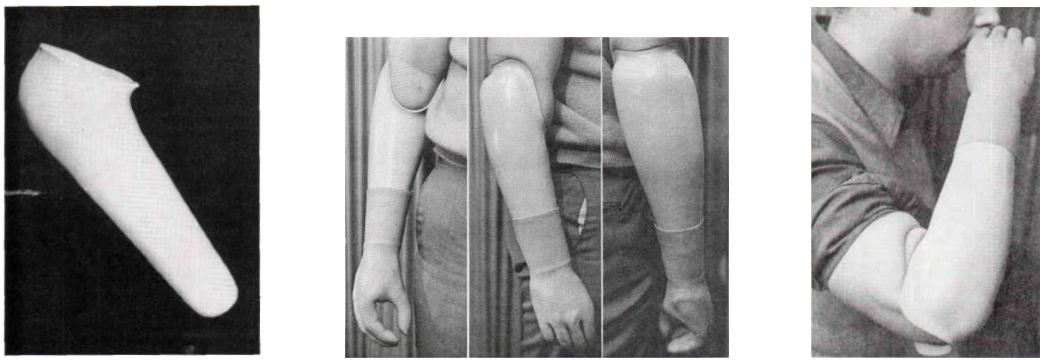


Figure 2.19: A diagram showing the key areas of a trans-radial self-suspending socket. Image from [26]

the first known self-suspending socket, described in 1959 by Hepp and Kuhn [38, 154], as shown in Figure 2.20(a). It relies on a high trimline and contours applying force to the bicep and tricep tendons for suspension [99, 154], and is cast at 90 degrees elbow flexion [155]. Although visually similar, a Brim socket is very different as it does not have the contouring present in a Münster socket, and instead relies on socket tightness and traction against the limb for suspension [99], and is cast at 60 degrees elbow flexion. Both sockets restrict the range of motion (ROM) of the limb, which is a consequence of designing a self-suspending socket that will not fall off such short residual limbs [38, 99].

For mid-length and long residual limbs, the reliance on traction against the limb to suspend the socket is reduced, as more of the limb remains to anchor the prosthesis to. The most well-known mid-length trans-radial socket design is John Billock's *Northwestern* design, and it is arguably the most recognisable trans-radial socket overall [99, 153], shown in Figure 2.20(b). The Northwestern style was first presented in 1972, and although it was designed to accommodate all lengths of residual limb [28], it is frequently used for mid-length residual limbs [99, 150], with the Münster socket and its variants generally being preferred over the Northwestern for short residual limbs. Northwestern sockets are cast at 90 degrees elbow flexion and feature a low anterior trimline [28], allowing a wider range of elbow flexion whilst wearing



(a) (b) (c)

Figure 2.20: (a) An early example of a mid-length Münster Socket. Image from [27]. (b) An early example of a mid-length Northwestern Socket. (c) The range-of-motion allowed by a well-fitted Northwestern socket, due to low anterior trimline allowing relief around the cubital fold. Images from [28]

the socket [38], as shown in Figure 2.20(c). Additionally, it features tight compression over the medial and lateral humeral epicondyles for suspension [28], however this comes at the detriment of comfort and sometimes requires wearers to build up their tolerance to wearing the socket [99]. The Northwestern style socket is still prescribed today, and many mid-length designs that have emerged since are based on its design [99]. A notable variant of the Northwestern socket is the *Strathclyde Supra Olecranon Socket* (SSOS) developed by Bill Dykes, around a decade after the introduction of the Northwestern style [99]. This was developed to improve the level of flexion possible and also to provide relief over the epicondyles, removing the need to build tolerance to the socket [99]. Several other prosthetists created their own modifications of the Northwestern socket to remedy the same issue, generally by reducing the casting angle to 70 degrees and compensating for this by raising the trimline to maintain sufficient suspension whilst improving ROM [38].

Other notable conventional trans-radial socket designs include the *three-quarter* socket developed by William Sauter in 1986 [153]. Both the Northwestern and Münster sockets are intimate fitting, which cause issues with overheating, poor ventilation and skin damage for some wearers [153]. Sauter devised that if a typical self-suspending socket was divided into quadrants, the quarter covering the olecranon provides little or no suspension benefits

and can be removed [153]. Sauter advised casting at the usual angle for the original socket designs. The only major change was liberating the olecranon through removing the lower posterior section of the socket [153]. This alleviated some of the issues associated with fully enclosed socket designs [153]. For many individuals who wear trans-radial sockets, incorporating a cut-out to leave the olecranon free does not introduce suspension issues [99], hence it is a good method for alleviating some ROM issues and ventilation. Leaving the olecranon exposed also allows some tactile feedback for the wearer.

Although varying in shape and function, for suspension, most conventional trans-radial prosthetic sockets rely on a mix of tightness, traction against the limb, or sculpting in the supra-condylar or supra-olecranon region [99]. However, some more recent socket designs rely on entirely different mechanisms for suspension - notably the *WILMER* socket, and *'Compression-Release'* sockets [25, 38, 39, 43, 99, 156, 157]. Both socket styles feature a 'windowed' design, exposing areas of tissue whilst supporting others [25].

Although not exclusively used for children, the WILMER socket focuses more on paediatrics as its design allows the socket to expand to 'grow' with the child [43]. It features steel tubes covered in soft material, which in turn leaves 75% of the residual limb exposed [156]. This design improves ventilation and allows enhanced tactile feedback [99, 156]. Due to it's non-total contact design, the soft tissues of the residual limb are not fully stabilised, hence the limb may experience higher contact pressures. This occurs as there is less area of the limb in contact with the socket to distribute forces being transmitted through it, hence higher interface pressures are applied to the soft tissues [99]. This type of socket is therefore better suited to relatively lightweight prostheses [25], for example tools, activity-specific attachments and lightweight hooks.

In contrast, the focus of compression-release sockets (CRS) is to stabilise the underlying tissues of the limb more than a regular socket [25]. Randall Alley and John Miguelez pioneered high-compression sockets with their *Anatomically Contoured and Controlled* (ACC) and *Trans-radial Anatomically Contoured Interface* (TRAC) sockets in the 1990's early 2000's. Both sockets featured aggressive contouring, simultaneously in the 'conventional' areas around the epicondyles and cubital fold, but also along the length of the residuum, paired with areas of lower compression for relief [25, 39, 157]. In 2011, Alley et al. published a paper and patent documenting a successor to both designs, the *Compression-Release* socket (now branded as HiFi or High Fidelity socket) [25]. Similar in design to previous iterations, the

new design also featured cut out 'release' areas to allow displaced tissue to relocate into [25]. The authors report improved bone stabilisation and reduced *lost motion* - where force is not directly transmitted through the limb due to the bone moving within the soft tissue, hence a delay in force transmission from the socket wall to the limb and vice versa [25]. Although promising, the levels of compression featured in the sockets are not currently published, which is concerning from a safety perspective. According to the 2011 publication, patients' limbs fitted with CRS sockets adapt to the high compression and, as a result, have increased blood flow to their limb [25]. However, the authors also note that high compression may cause ischemia if used incorrectly [25]. Even for typical upper-limb socket designs, the interface pressures between the socket wall and the soft tissues have not been investigated [99]. In general, it is recommended devices do not apply more than 2-2.7kPa (15-20mmHg) when used for extended wear [99]. However, from other medical device and lower-limb studies, it is known that pressures regularly exceed this. [99]. For example, one lower-limb study found peak pressures in excess of 100kPa (750mmHg) between the limb and socket wall during a typical gait cycle [158]. The risk of tissue damage is minimised by reducing wear-time and cyclic unloading, such as when a lower-limb socket is unloaded whilst not in contact with the ground during walking. [99, 158]. There is no cyclic unloading for upper-limb prostheses and the pattern of loading is different, therefore lower-limb data cannot be extrapolated for use with upper-limb devices.

2.3.1.1 Socket Liners and Socks

In addition to a socket, a prosthesis wearer may choose to also wear a sock or liner [159, 160]. Prosthetic socks are made from yarns of various materials such as wool, cotton and polyester [159]. They are generally knitted in a seamless design and are 'ready to wear' (i.e. non-custom). Prosthetic liners are more structured, made from either silicone or elastomeric 'gel' [99]. They can either be generic or custom-made. Both socks and liners can be used to adjust the fit of a socket, improve suspension or protect the limb from the prosthesis [25, 160, 161]. Socks tend to help absorb perspiration [161], whereas liners generally make perspiration worse [38, 162]. They can be worn in combination, with the sock worn over the liner being standard procedure [159], however they are both accompaniments to a socket and would not be worn alone to suspend a prosthesis.

Introducing a barrier such as a sock or liner between the skin and the prosthesis can have a variety of positive effects, however it does pose the issue of transmitting electrical signals from the electrodes if a myoelectric prosthesis is being worn. Previous attempts to remedy this have included cutting holes in the sock or liner, which had limited success and often damages the liner [160, 162], or creating sensorised liners [160]. So far, creating sensorised liners has been the most promising attempt [18, 160, 163]. However, they are yet to be made widely available in clinics, which is likely due to the extra time, craftsmanship, and cost associated with doing so.

2.3.2 How Prosthetic Sockets Are Made

In most developed nations, prosthetists must be certified by a national governing body in order to produce sockets [164]. Despite the contouring and shape variations between designs, the *conventional* procedure to create an upper-limb prosthetic socket is largely the same across most clinics. First, the prosthetist will record measurements from the limb and learn the patient's medical history - e.g. how their limb difference occurred and whether they experience any pain [26, 99]. Next, a *cast sock*, a thin seamless nylon sock, is placed over the limb [26, 38]. The prosthetist then marks areas of interest, such as bony prominences and electrode sites, on the limb using indelible marker [26]. A Plaster of Paris (POP) cast will then be taken of the marked limb, usually using elastic POP bandages, transferring the markings in the process [26, 32, 38]. The prosthetist will also use their hands to contour the socket whilst it is drying, to provide the required suspension [26, 32, 38]. This is referred to as the 'moulding grip', and the resulting POP bandage cast is called the *negative cast* [38]. After removal from the patient's limb, the negative cast is then filled with a POP mix to create a *positive mould*, also featuring the transferred markings [26, 32, 38, 99]. To release the positive mould, the POP bandage cast is cut away, which destroys it [26, 32]. After the positive mould has cured, it is smoothed and *rectified* by the prosthetist [26, 32, 99]. Rectification is where the positive mould is sculpted based upon the markings made earlier in the process. The prosthetist will add and remove material to areas for additional suspension and comfort [26], and flatten the areas where electrodes will be added. This process, although necessary for comfort and suspension, also destroys the original positive mould [26, 32].

At this stage, either the final socket or a *diagnostic* socket can be created

[26]. Diagnostic sockets allow prosthetists to diagnose any fit issues before the final socket is made. They are generally made using a method called *draping*. A draped, also called *thermoformed*, socket is created by heating up a sheet of thermoplastic until it is malleable and manipulating it to fit flush against a plaster model of a limb [37]. A thermoplastic is defined as a polymer that can be heated up and re-moulded repeatedly [165]. For diagnostic sockets, the socket is usually thermoformed from a clear acrylic plastic [26] to allow easy troubleshooting. However, for final sockets, other materials in different colours can be used. Because of the nature of this process, draped sockets can be easily adjusted with a heat gun [26]. This allows changes to the shape of the socket to be made and tested immediately in clinic.

When producing final sockets for patients, it is more common for a process called *lamination* to be used. In order to make a socket using lamination, layers of textiles such as cotton, carbon fibre and nylon are set with resin to produce a strong, composite material [38, 99, 166, 167]. Resin-based laminate sockets are *thermoset*, which means that their shape cannot be altered using heat once they have been produced. If electrodes are required, 'dummy' electrodes are positioned atop the positive mould before the socket is draped or laminated [38]. Although variations occur between clinics in terms of the materials and specific procedures used, the general procedure is standard [26]. In research, some novel approaches have been trialled, such as using plant-based fibres to replace the nylon-stockinette during the lamination process [145], or using thermoforming materials which can be shaped directly onto lower-limb residuums, eliminating the need for a cast [168]. However, both are in their infancy in terms of development and adoption in clinics.

Socket creation requires a highly artisan skillset [32, 164, 169]. Although guidelines exist for how to correctly create the socket in terms of materials and processing, marking and palpating the limb is very much *tacit* knowledge and relies heavily on practice, experience and skill [32, 38, 164], hence documenting this step is incredibly difficult and often does not feature in academic literature [164]. The techniques used in clinics today have not changed significantly from those described in the 1960's [155], with the only real significant change being the introduction of novel thermoplastics [166]. Other *traditional* methods of socket creation exist, such as leather working and steel forming. However, they are no longer common methods in most developed countries, and their usage is being phased out in favour of composite materials. This is likely due to a declining population of prosthetists with the skills required to produce leather and steel sockets and the additional

labour costs associated with using them.

Given the shift towards more automation and technology within most areas of healthcare, the use of newer digital methods to produce prosthetics sockets is frequently suggested [26]. Digital scanning appears to offer a convenient alternative to plaster casting [170], and 3D printing is often suggested as a relatively 'hands-off' approach to socket creation to replace draping or thermoforming [26, 164]. Some prosthetics companies, such as Openbionics, use scanning regularly as part of their workflow [171], however there is no data available to analyse how successful this is in terms of patient satisfaction. Similarly, 3D printing is often touted in the media as a faster, more high-tech, autonomous alternative to conventional sockets [26, 172]. However, few clinics have actually adopted 3D printing for producing sockets. Alongside most custom prosthetic and orthotic devices, sockets are large, and must be structurally sound. When 3D printing, the print settings (called 'slicing') greatly affect the properties of the finished print, such as the roughness, durability and strength. Even materials which are regularly used in traditional socket manufacturing and are generally regarded as 'strong', e.g. nylon, can be printed with settings that would result in brittle and unsafe prints. Additionally, in comparison to traditional methods such as draping, 3D printers may be relatively slow. Because it would be in contact with the wearer's skin, 3D printing a socket would necessitate a high quality finish, which would require more time to print. Consequently, using most methods of 3D printing, manufacturing times could easily exceed 24 hours.

2.3.3 Other Attachment Methods

Although sockets provide a non-invasive method of attaching most prostheses, for some applications they are not ideal. Sockets can introduce issues with ROM, skin breakdown and perspiration [86, 153]. In most cases, wearers who find these issues intolerable would generally abandon wearing prostheses altogether and adapt to utilising their bare residuum as much as possible. However, a small subset of wearers who find prosthetic sockets intolerable and are also determined to wear a prosthesis, may choose to anchor their prostheses using an alternative method. For some wearers, opting for prostheses mounted on 'soft' cuffs may be an option, but they generally do not offer the same functionality as a regular socket-mounted prosthesis. For those seeking functionality and load-bearing, osseointegration would be the main alternative. Unfortunately, this method comes with several drawbacks that

would generally be deemed even less favourable or cumbersome than enduring a prosthetic socket. Both alternatives will be covered in detail in the Sections below.

2.3.3.1 Osseointegration

Osseointegration, where an anchor is inserted directly into the bone in order to allow the attachment of a prosthetic limb, was developed in Sweden in the 1990's [173]. The majority of osseointegrated prostheses are trans-humeral or lower-limb. Trans-radial amputations are different as preserving radio-ulnar rotation introduces added complexity [86]. Osseointegration removes the constraints of the socket from the limb, however introduces many unique issues [86]. For example, osseointegration requires surgery which adds to the risk of infection, with some wearers finding trans-radial osseointegration uncomfortable [86, 166]. This kind of invasive procedure is unsuitable for many patients due to co-morbidities or general ill health. Hence, for individuals with trans-radial amputation, it is a relatively rare choice in comparison to a self-suspending socket, the most common method of anchoring trans-radial prostheses [86].

2.3.3.2 Soft Prostheses and Cuffs

Some individuals prefer to wear *soft* prostheses such as fabric cuffs and sleeves for attaching tools or lightweight terminal devices. Commercially available options include the Steeper cuff and Koalaa sleeve, shown in Figure 2.21 (a) and (b) respectively. As the devices are soft, force transmission is much lower than using a socket due to lacking the bone stabilisation and suspension provided by a rigid socket. Subsequently, they are limited in function and relatively uncommon and often marketed more towards the paediatric market.

2.4 Current Challenges

Given the differing priorities within the population of upper-limb prosthesis wearers, there is no definitive method of measuring the 'success' of a prosthetic arm. One wearer may be satisfied with a purely aesthetic device, whereas another may want the most technologically advanced design possible

(a) (b)

Figure 2.21: (a) Trans-radial prosthetic cuffs manufactured by Steeper. Image from [29]. (b) A below-elbow prosthetic sleeve manufactured by Koalaa. Image from [30]

[52, 53]. Accordingly, the only real metric of 'success' would be user acceptance [52, 53]. Advanced upper-limb bionic devices generally cost tens of thousands of pounds for the wrist and terminal device alone, without added medical or socket fees [57]. Despite this, the satisfaction rates for even the most advanced myoelectric systems are low, which is reflected in the high rejection rate for upper-limb prostheses of approximately 44% [53].

Two of the leading causes of myoelectric prosthesis abandonment are poor function and comfort issues [50–53, 118, 174]. Undeniably, the majority, if not all, of the comfort of a prosthesis relies on the prosthetic socket given that it is the only part in contact with the wearer's residual limb. The root cause of functionality and reliability issues associated with EMG controlled prostheses can come from a variety of origins, including the hardware, the user's ability and physiology, and several environmental factors [144, 175, 176].

There has been a significant commercial and research effort invested in developing immensely complex and technically advanced prosthetic hands [38]. These devices work and function incredibly well when connected to a computer, performing pre-programmed gestures. The issues with function and reliability arise when connected to the wearer, relying on command signals from the muscles. There has been significant research conducted into eliminating many of the 'predictable' sources of EMG disturbances and artefacts [122]. However, the study of disturbances originating from mechanical sources, i.e. the coupling between the socket, which houses the electrodes, and the skin, has received little attention [122]. The current issues affecting

EMG prosthesis control are covered in detail in Chapter 7, Section 7.1.

2.4.1 Knowledge Gap and Clinical Reporting

Within the field of upper-limb prosthetics, research into machine learning and pattern recognition for EMG control is more prominent in the literature than investigations into the socket itself. This is likely to be occurring as sockets, and other custom elements of a prosthesis, are produced on a case-by-case basis by clinicians or clinical researchers whose priority is patient satisfaction, not research output. In order to fill the knowledge gap and improve collaborations between clinics, academia and industry, the following issues must be addressed:

1. How do we document clinical knowledge which is so often under-represented in the literature?
2. How do we bridge the gap between the wealth of knowledge in clinics and industry and the research coming from engineering groups?

Chapter 3 answers these questions via a consensus of expert opinions from within the field of prosthetics provision.

2.4.2 Modernising Socket Manufacturing

For decades, the use of technology such as 3D printing and digital scanning has been promised as a solution to revolutionise prosthesis manufacturing [26]. However, this has failed to materialise, and bar the introduction of thermoplastics, trans-radial socket design has not changed significantly since the 1960's [166]. In order to see progress in this area, the following questions must be answered:

1. Should digital methods such as 3D printing and digital scanning be employed routinely in prosthetic socket manufacture?
2. If so, what are the obstacles preventing this?

Chapters 5 and 6 address these questions through practical experiments.

2.4.3 Trans-radial Socket Design for EMG Control

The extensive work of Head in 2014 [38], identified that many self-suspending upper-limb socket designs pre-date the introduction of today's high-tech prosthetic hands. Subsequently, this retrofitting has resulted in sockets which are not designed for, nor capable of, facilitating adequate myoelectric control for advanced prostheses [38]. Complex myoelectric devices rely on a secure connection between the electrode muscle sites and the sensors, however most prosthetic sockets prescribed and created in clinics today are just variants of sockets used for passive or body-powered prostheses [38]. Additionally, device weights have increased, from typical split-hooks weighing between 56-209g [177], to modern bionic hands, which vary considerably in weight and size, but common examples weigh between 350-692g [178, 179]. The additional weight of these devices increases the distal loading on an upper-limb prosthetic socket, which was not factored in to original self-suspending socket designs.

In theory, a socket which provides a tight fit around the EMG sites and restricts motion between the sensors and the limb would be ideal [38]. However, this may be at odds with patient comfort, which is a key factor for user acceptance [51]. Hence, there are several key elements of upper-limb socket design which require exploration:

1. How can the connection between device and wearer, and therefore the EMG signal transmission, be made more stable?
2. How do we optimise socket design so that it benefits both comfort and functionality?
3. How can sockets be made more comfortable, considering the additional weight of today's terminal devices?

Chapters 7, 8 and 9 address these questions by investigating and discussing how socket design can be updated to meet the needs of modern day terminal devices.

Chapter 3

The Current State of Prosthetic Socket Research

As identified in **Chapter 2**, upper-limb sockets have not adapted sufficiently over the last 60 years to facilitate reliable use of modern electronic prosthetic hands. Before trying to remedy this, it was important to revisit the literature around sockets to identify a root cause. However, documentation and methods for quantifying prosthetic socket performance are limited, especially in the upper-limb sector. In the following Chapter, the current state of prosthetic socket research is outlined. The impact it is having on progress within the field is discussed, and key enablers to assist future research are identified. This information is presented as a consensus of several experts within the field, from both research and clinical backgrounds and perspectives.

> *The Impact of Limited Prosthetic Socket Documentation: A Researcher Perspective* (J. Olsen, S. Turner, A. Chadwell, A. Dickinson, C. Ostler, L. Armitage, A.H. McGregor, S. Dupan, S. Day, 2022) is published in *Frontiers in Rehabilitation Sciences*.

3.1 Introduction

To recap from Chapter 2, at a minimum, a prosthetic arm consists of a socket and a terminal device, with optional components including wrists, electronics, batteries and aesthetic covers. Some terminal devices, such as life-like silicone prosthetic hands, are crafted by prosthetists, but the majority of the limb comprises generic, 'off-the-shelf' components. Currently, the socket is the only part of a prosthetic limb which cannot be mass-produced using any method. Furthermore, a prosthetic socket manufactured and prescribed today is unlikely to differ considerably from one manufactured in the 1960s [38]. The unchanged socket design would not be a concern if patient satisfaction rates were adequate. However, even with recent developments in bionic hand technology, abandonment rates are approximately 44%, with discomfort and myoelectric unpredictability listed as primary causes [51, 53]. Furthermore, as more advanced terminal devices have been introduced, their weight has almost tripled, from approximately 200g for a large split-hook, to over 600g for many modern bionic hands [177–179]. However, no significant changes have been observed in general trans-radial socket designs to account for this increase. Because the socket is the only component directly in contact with the wearer's limb, almost all discomfort caused by the prosthesis can be attributed to it. This could either be directly, due to it's design, or indirectly, due to inappropriate load bearing because of increasing prosthesis weight. Additionally, retrofitting newer myoelectric components into older upper-limb socket designs has caused issues with skin-electrode interfacing and reliability [38]. Hence, there is a necessity to improve upper-limb sockets to provide sufficient patient care.

Whilst conducting the literature review for this thesis, it became evident that many aspects of socket production were not documented in academic literature, especially information relating to upper-limb sockets. This lack of documentation coincides with the majority of academic and industrial research focusing on furthering technical advancements in bionic hands and myoelectric control systems. Figure 3.1 provides a visualisation for the lack of available academic literature detailing upper limb sockets (n=93), showing papers from all-time with relevant search terms in their title or abstract. In contrast to sockets, prosthetic hands (n=4,045) and myoelectric control for limb prostheses (n=13,590) have received much more research attention, resulting in more academic literature.

Hence, in order to uncover and document information required to com-

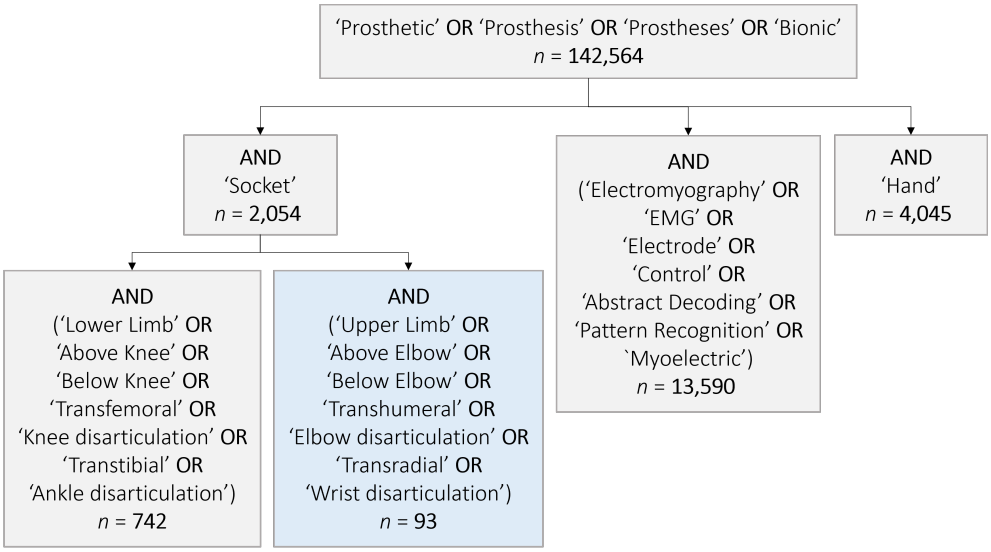


Figure 3.1: A flowchart of Pubmed search results. n = number of papers. Filtered to terms present in the title or abstract. Accessed 03/05/2023.

plete this thesis, an investigation was conducted in the form of an expert consensus. The aim of the work was to document many of the 'unwritten' rules of socket manufacturing and to investigate why this lack of evidence base has occurred. By documenting this information, it is hoped to promote awareness of these issues, hence bridging the knowledge gap between clinical socket manufacture and non-clinical research, which may be operating without the supervision or guidance of a clinician.

3.2 Methods

For the original publication of this document, the work was co-authored by Olsen (upper-limb issues) and Turner (lower-limb focus). The text below has been written solely for the purpose of this thesis and omits the lower-limb content. Hence, the published document was co-authored, but the text below is the author's own work.

3.2.1 Consensus Roles and Structure

In addition to the lead authors and in order to present a balanced and in-

formed commentary, five other biomedical engineering researchers with experience in either upper or lower limb socket research were also onboarded. Bridging the knowledge gap between 'ideal' experiments in academic research and 'real life' socket prescribing in clinics was a key focus of this investigation. Accordingly, two clinical researchers, a physiotherapist and a prosthetist, were recruited, to provide expert commentary and insight into what occurs in modern prosthetics clinics. All authors collectively reviewed, revised and agreed upon the content of the document to form a consensus.

3.2.2 Focus Areas

The 'life-cycle' of a prosthetic socket was separated into stages, beginning with the initial design phase and ending with user feedback. These steps were used to identify major unaddressed concerns and establish focus areas, defined as follows:

Design and Manufacturing:

- Before a socket is made, what documents are available about socket design?
- Why has progress in socket manufacturing stalled?
- Why are specific materials chosen, as opposed to other older materials?

Outcome measurement:

- What makes a successful socket?
- How do we document the success of a socket?
- How are socket *comfort* and *fit* defined and evaluated?

Outcome dissemination:

- How do we collate the outcomes of prosthetic socket provision to create a useful data set to inform future prosthetics research?

3.3 Design and Manufacturing

Within the field of lower-limb sockets, research has been carried out to better understand the biomechanics of loading between the residual limb and the socket. In turn, the range and complexity of suspension systems available has improved and diversified [180–185]. In contrast, except for the materials used and experimental designs which are not available in general practice, documented upper-limb socket designs and production methods have not evolved significantly for several decades [166]. The reasons for this are explored below.

3.3.1 Socket Design and Safety

Globally, there are several ways in which medical devices are classified [186]. Within the UK, the Medicines & Healthcare products Regulatory Agency (MHRA) divide medical devices into classes, with class I being the least regulated, and class III being the most tightly regulated [187]. Almost all components of a prosthetic limb fall within the class I category and must pass safety tests to obtain UK Conformity Assessed (UKCA) or equivalent certification [188]. To obtain this certification, the device would need to pass standardised safety tests, usually undertaken by a third-party with specialist equipment and training. However, unlike other 'off-the-shelf' medical devices, i.e. myoelectric hands or wrist units, all prosthetic sockets are classed 'custom-made' medical devices and are therefore exempt from UKCA and equivalent safety certification [189]. For clarity, this definition can include both standalone sockets with an attachment site suitable for a variety of terminal devices, or sockets with one irremovable tool affixed at the distal end (i.e. a specialised sports socket with a custom terminal device). Instead, the manufacturer must ensure custom-made medical devices do not cause the wearer any harm by considering factors such as biocompatibility and strength [189]. For prosthetic sockets, the prosthetist or technician who creates the socket is the sole 'manufacturer'.

There are no set guidelines as to how a prosthetist should ensure their creations are safe. Within the UK, the current relevant legislation regarding the safety of custom medical devices is Part II of the UK MDR 2002 (as modified by Part II of Schedule 2A) [189]. Given the broad variety of custom-made medical devices, these guidelines do not detail specific tests regarding how to ensure this safety. Instead, the manufacturer generally relies on using "tried-

and-tested" methods and materials to ensure patient safety. However, the International Organisation for Standardisation (ISO) have a dedicated standard for testing lower-limb prostheses (ISO 10328:2016) [190]. Although not centred around the socket component, this standard has been used in several research studies to provide a quantifiable acceptable level of strength required from a lower-limb socket [191–197]. Due to it's existence, quantifiable metrics can be used to prove novel lower-limb prosthetic socket designs and materials are of an equivalent or better safety standard. Subsequently, significant improvements in the suspension mechanisms available for lower-limb amputees have been developed over the last few decades, both in research prototypes and clinically available devices [183–185, 185]. In contrast, upper-limb devices are not mentioned in any ISO standards for prosthetics safety testing. It would be unsafe to use ISO 10328:2016 for upper-limb sockets without first validating whether the same tests and required loads are appropriate. Additionally, it would likely lead to extreme over-engineering, creating heavy sockets which would decrease patient satisfaction and comfort. Upper-limb sockets serve a different function to lower-limb sockets and therefore have a different set of design requirements. Lower-limb sockets must withstand walking and running and therefore are loaded heavily for the majority of use. In contrast, upper-limb sockets need to withstand point-loads (i.e. carrying a heavy bag), facilitate dextrous activities, and have weakened areas such as the cut-out sections for electrodes. Additionally, upper-limb sockets cannot be as bulky as lower-limb sockets due to their proximity to the torso, and to a lesser extent for aesthetic reasons. Therefore, even when research indicates a potential benefit from novel manufacturing methods or materials for upper-limb prosthetic sockets, it is difficult to prove they are safe to prescribe. This creates a bottleneck preventing innovations migrating into clinical practice.

Prosthetists utilise factors such as a person's residual limb anatomy, daily living needs, and overall health, to determine which style of prosthetic socket is best for them. There are several documented styles of trans-radial prosthetic socket [28, 43, 99, 155]. Precise data for which styles of sockets are prescribed in clinics today is not available. Currently, the most widely prescribed type of trans-radial prosthetic socket is believed to be a 'brim type hybrid,' or variations of this design, which first appeared in the 1960s [38]. The published documentation for each socket style specifies which limb lengths the design is suitable for, how and where to apply sculpting and relief areas, and how the trimlines should be fashioned. In reality, clinicians will create hybrids and modifications of designs as they see fit to benefit the patient.

These changes are not documented in literature, but are common knowledge within the field. However, as the changes made to each individual socket geometry are unique to the wearer, there is no formal record of what alterations are made. As a result, researchers can only compare their work to the original documentation for well-known socket styles when developing novel socket designs.

3.3.2 Materials

For more than a century, the materials used to make sockets have been documented; originally made from wood and metal, clinicians creating sockets transitioned to using leather, and more recently textile-resin composites and modern thermoplastics [147, 166, 198]. The general materials and procedures for creating a modern upper-limb prosthetic socket are covered in Chapter 2, Section 2.3.2. This information is well-known within the field, and detailed instructions exist in order to guide new prosthetists and technicians to manufacture sockets. However, neither national or international regulations exist for many specifics of socket creation.

In modern prosthetics clinics, *lamination* is a common method used to produce both upper and lower-limb sockets. The process involves draping layers of textile over a rectified, positive Plaster of Paris mould of the limb, and thermo-setting them with resin to create a composite socket. There are no rules as to how many layers of textile, or even which type of textile or resin, should be used to create sockets. Within a particular clinic, a local norm may be established for how many layers and which materials to use, but this information would not be publicised or widely shared. Internally, this allows the clinic to produce a repeatable standard for their sockets. Although untested, the prosthetists will know from experience that their method of manufacturing produces a socket which is strong, safe for patients to wear, and is unlikely to break. However, between clinics, the process will vary depending on which suppliers provide the materials, which materials are available, and what that particular clinic has decided is their standard process in terms of layers and thickness. The material properties of the socket depend entirely on these factors, and different resins perform inconsistently when paired with different materials [199]. This means the same patient may receive significantly different sockets provided by two clinics working independently of each other, creating geographical variations in standards of care.

In lower-limb sockets, the required strength of a socket can be reverse engineered using ISO 10328:2016, used for testing lower-limb prosthesis components [190, 194, 200]. Using ISO 10328:2016, the strength, i.e. the socket's ability to bear load, can be tested in many ways, including compressive, cyclically loaded and torsional tests [190]. For lower-limb sockets, the required strength from the socket for each test is determined by the weight of the intended wearer [200]. The strength ranges for lower-limb sockets cannot be extrapolated to upper-limb sockets, as the loading pattern is different. Lower-limb sockets are primarily designed to bear the compressive force of the user's weight whilst walking. This differs from upper-limb sockets, which support a point-load at the distal end of the socket, and aim to distribute it across the length of the residual forearm, irrespective of the user's weight. The maximum loading of modern prosthetic hands vary, with the maximum weight the hand can grasp ranging from 13kg-32kg for common commercially available models [178, 201]. Hence, it is assumed an upper-limb prosthetic socket would need to exceed this as a minimum, however it would also be important to factor in resistance to impact forces, such as a wearer tripping and falling on their prostheses, which would be weight-determined. Due to these factors, upper-limb socket manufacturing guidelines do not yet specify rated loads for upper-limb devices, nor are these values known. Similarly, less safety-critical factors are also unknown, such as the acceptable roughness of a socket interior, or the ideal weight, largely due to the vast variety of acceptable material combinations and manufacturing methods used to produce sockets.

Subsequently, the strength and material properties required from an upper-limb socket cannot be reverse engineered in a straightforward manner as it will vary with each individual's prosthesis. This limits the use of new technology in clinics, despite promising results from academia. It would neither be safe nor responsible for a prosthetist to prescribe a new material or manufacturing method without knowing how strong it actually needs to be. Conversely, research into newer materials and upper-limb socket designs have no clear-cut benchmark to exceed in terms of strength, surface finish, and weight, hence any comparisons to conventional socket manufacturing techniques and materials are highly subjective.

Although not regularly taught in modern undergraduate prosthetics and orthotics studies, some highly skilled prosthetists will still provide leather and steel sockets when requested by a patient. However, this is very rare, particularly in the UK. The reasons for widespread abandonment of older

materials such as leather are not documented. It is likely that a lack of individuals with the artisan skills necessary to make sockets from 'old' materials is the reason for their decrease in prevalence. Equally, the cost of providing devices which require above-standard levels of manual labour is prohibitive for many healthcare services, especially when composites and thermoplastics are relatively straightforward to use and inexpensive. However, without information as to why certain materials were abandoned, researchers may 're-invent the wheel' when trialling novel socket designs instead of building upon the knowledge of why some materials are no longer suitable.

3.3.3 Workflow Omission in Published Literature

Given that the majority of research studies are conducted by non-clinical researchers, a trained prosthetist or technician is generally onboarded or commissioned to provide sockets required for experiments. In some cases, the socket manufacturer may not be involved as a researcher and have no knowledge of the aims of the research study. Due to this, their techniques are rarely documented in the resulting publications. To a non-clinical researcher wishing to conduct experiments in the field of prosthetic limbs, this gives the illusion the socket does not have a large impact on the overall function of the device.

Similarly, when a participant in a research study provides their own socket, generally no details are provided in the subsequent literature regarding how it was made, what material it consists of, or how it fits. It is then not possible to gauge whether the socket has impacted the results of that study [118]. Not only does this limit the validity of many research studies, it also results in severely limited published information regarding prosthetic sockets.

In several developed countries, the occupation of 'Prosthetist and Orthotist', sometimes known as 'Orthopaedic Technician', is protected by law [202]. This means only individuals who have passed a national standard of training can enter into clinical practice using this professional title. For countries currently without this protection, the creation of regulatory bodies and the requirement of a formal, standardised qualification to work as a prosthetist is crucial [203]. Information about socket creation and fitting must not be shared irresponsibly, so as to prevent untrained individuals attempting to create prosthetic sockets for themselves or others. This work may be well-intentioned, such as in the case of individuals producing devices for charity,

but could cause further harm to the wearer if the device shatters or splinters whilst in use. Consequently, although necessary for patient safety, the legal protection around medical device provision is one of the factors which has led to a scarcity of published information for researchers to draw from.

The abilities necessary to make a socket fit correctly go far beyond what guidelines or instructions can teach. Prosthetists use their own practical experiences to assist them when producing sockets [204, 205], for example sculpting a drying plaster cast of a patient's limb using their hands, relying on the *feel* of the limb and the underlying skeletal structures as a guide. Much of this knowledge is tacit, something the prosthetist understands and utilises methodically, but may not be able to write down or verbalise to guide another prosthetist to do the same. Due to this, documenting how to actually make a socket comfortable and fit well is incredibly difficult. Without satisfaction with the socket comfort and fit, it is unlikely the wearer will continue to wear their prosthesis. Hence, despite arguably being the least technologically advanced component within an upper-limb prostheses, it is the most vital for user-acceptance and preventing abandonment.

In general, practicing clinicians are patient-facing, prescribing and producing sockets using industry-standard methods, whereas researchers, from industry, academia and some clinics are more focused on trialling and developing new prosthesis technology. This creates a cascading issue for documentation surrounding prosthetic sockets. Firstly, information directly from practicing prosthetists is rarely documented in academic literature unless they are also researchers themselves. Therefore, non-clinical researchers using information available to them to develop new sockets are unaware of issues regarding proper socket fitting. Due to this, many research studies overlook the importance of proper fitting in their methodology. This can also give rise to the incorrect notion the that one manufacturing method can easily be swapped out for another [26]. This is evident in the large interest in swapping from 'traditional' methods such as plaster casting and manual sculpting to 3D printing, digital scanning and Computer Aided Design (CAD), without thought as to how to include the prosthetist's tacit knowledge. Often, reduced manual labour or the opportunity to standardise the quality of care is cited as the reason for swapping to these methods [26]. In theory, converting plaster casting to scanning would remove the 'artisan' element of limb-shape capture, hence the process would no longer be dependent on a prosthetist's individual skill. Similarly, 3D printing as a manufacturing method is generally marketed as 'hands-free', which alludes that it does not

require technician time, unlike draping and thermoforming. In reality, converting skilled manual labour to a standardised digital process is much more complex than many researchers assume. However, without the complexities and nuance of socket fit being documented in literature, the majority of engineering-focused researchers who do not have clinical expertise will be naive to these issues, even if they are familiar with the field.

3.4 Socket Fit and Comfort

To determine whether a prosthetic limb fitting has been successful, as well as where adjustments are needed, the socket fit must be evaluated with the patient. A prosthetist will typically perform this in clinic with each individual, checking the fit of the socket and determining if the patient finds it comfortable. Socket fit and comfort are currently evaluated using basic scales, but there is no universally approved measurement scale for physicians to utilise or for users to provide feedback.

3.4.1 Definitions of Socket Fit and Comfort

Neither socket *fit* or *comfort* have a universally recognised definition and are frequently used interchangeably. It is generally agreed that socket *fit* refers to various metrics evaluated by a prosthetist relating to suspension, safety and the socket's volume capacity in comparison to the limb. In contrast, socket *comfort* is generally regarded as a subjective measure reported by the wearer relating to their perception of pain or pressure caused by the prosthesis.

If a prosthesis wearer's device is not comfortable or does not fit correctly, they are likely to reject the whole prosthesis [51, 206]. Hence, defining socket comfort and fit is important to assist the interpretation of patient's experiences. As covered in detail by Bourke, the words chosen by different individuals to convey the same experience of pain or discomfort can vary significantly depending on their culture, their ability to verbalise what they are feeling, and words that exist within their language [207]. A given degree of pressure, for example, may be uncomfortable to one individual but painful to another [207]. Additionally, the process of one person interpreting the information given by someone else is also subjective. For prosthetic socket provision, this would be the stage where a clinician processes verbal or written information from a patient at a socket review session.

Because there are no clear guidelines for what defines a good socket fit, there is sparse literature on how to determine whether a socket is well-fitting. Significant factors correlating with socket fit are interface stresses and the pressure and shear forces between the socket and residual limb [205, 208, 209]. While little is known about what constitutes good fit, a poorly fitting socket is much easier to define. This is because the majority of research discusses the medical repercussions of ill-fitting sockets or insufficient load distribution, such as skin disintegration and deep tissue damage [210–213]. Little is known regarding the day-to-day impact of inadequate socket fit on quality of life [208, 214].

3.4.2 Assessing Socket Fit and Comfort

Given the ambiguity of socket fit and comfort, it is unsurprising that there is also no definitive method of gauging either of these metrics quantitatively or qualitatively. However, although the two terms differ, there is a correlation between user-reported socket comfort and prosthetist evaluation of socket fit [215]. Anecdotally, first-hand experience of working with individuals who wear socket-mounted prosthetic limbs suggests this is not always the case, with some reporting high levels of comfort and satisfaction despite an ill-fitting socket. The 'Socket Comfort Score' (SCS) and 'Comprehensive Lower-Limb Amputee Socket Survey' (CLASS) are the most prominent scales available for assessing socket comfort [215, 216]. Neither of these scales delve into the cause of the discomfort, only the existence and extent of it. Additionally, neither are validated for upper-limb use, despite the SCS being used by NHS England for both upper and lower sockets [217]. Alternatively, the 'Trinity Amputation and Prosthetics Experience Scales' (TAPES) [218] and 'Prosthesis Evaluation Questionnaire' (PEQ) [219] query specific elements of socket fit and demonstrate high validity, however do not provide an assessment of socket comfort. As evident from the differing priorities of the various scales, there is not a consensus on which elements should be analysed, nor a clear method on how to do so [220].

So far, there has been no wide-spread analysis of which scale is best, hence it is unclear which scale should be adopted as the international *default* metric, and drawing comparisons between sockets gauged with different scales is not conclusive. Patients with reduced sensation in their limb, which is common for amputees, are not factored into many of the scales assessing socket comfort. Additionally, there are no existing scales which permit qual-

itative data to be factored into the analysis, e.g. user testimonies or clinical notes. Subsequently, some researchers develop their own bespoke, but unvalidated, surveys and scales to gain an in-depth analysis for experiments [26, 208]. Several publications suggest the need for improved quantifiable socket satisfaction metrics [221, 222], however they are yet to materialise.

Socket comfort is generally assessed using qualitative methods, such as surveys, scales and interviews [164], whereas socket 'fit' is generally gauged using physical metrics. However, there is a disparity between clinics and research groups as to the methods used to assess these metrics. For example, within research, socket fit is generally assessed using quantitative metrics, such as measuring and correcting interface pressures using experimental or specialist equipment [223–225]. In contrast, clinicians generally operate without specialised equipment when assessing socket fit [25], relying on their own expertise and observational methods such as 'postischaemic hyperemia', redness of the skin when the socket is removed [25]. Some clinics choose to use one or more of the aforementioned simple scales. However, the resultant scores might be deceptive due to differing personal experiences with pain [207], as well as individuals who have limited feeling in their residual limb [226]. As a result, changes in scores are sometimes seen as more important to evaluate than absolute scores presented.

3.5 Outcome Dissemination

The richest source of data regarding socket fitting resides within clinics. As mentioned in Chapter 3, Section 3.3.3, most clinicians do not generally focus on reporting information about socket provision to the wider community. This is because their job is to work with and provide devices for patients, hence they often do not have the time or funds to disseminate their processes through publishing. Furthermore, many prosthetists are concerned about the safety of disseminating information about creating and fitting sockets to non-clinical audiences. However, sharing certain, less critical aspects of the socket provision process could be extremely beneficial for researchers, which could be achieved without compromising patient safety. In order to assess a novel socket design, it is generally necessary to compare it to an older, equivalent design. Current comparisons using the aforementioned scales and surveys available only take into account how the wearer is feeling at the time, but do not provide an in-depth picture of the person's views about their prosthesis

during daily activities. A wealth of knowledge is lost without data on day-to-day fluctuations in prosthesis satisfaction. Additionally, in-clinic prosthesis adjustments are not generally shared as case studies. Without this, valuable information regarding why sockets were revised is lost, e.g. mechanical failure, discomfort and volume fluctuation. Even when case studies are shared in academic literature, they do not represent the wider patient demographic, and an opportunity to gather information regarding the performance of different socket styles and prosthetic interventions is missed.

Upper-limb socket fittings are significantly less frequent than lower-limb [99], and atypical cases are frequent due to the wide variety of upper-limb amputation levels possible and congenital limb differences. Due to this, there are fewer clinicians with an in-depth knowledge of upper-limb prosthesis provision [38], despite the task of restoring upper-limb function arguably being more complex than lower-limb.

3.6 Proposed Recommendations

Having a shared, global data pool between clinics and researchers would be highly beneficial to learn from, and would increase the availability of information about upper-limb socket fitting. In order for this to be possible, a standard reporting procedure would be required. This would require clinicians to document and share anonymised information regarding their patients' limb health, shape, cause and level of limb difference, alongside the socket styles and materials used to achieve a satisfactory prosthesis for that individual. This information could then be accessed by other clinicians and researchers attempting to provide or create a prosthesis for another individual. By creating a shared pool of data regarding which sockets work best, or did not work, for different limb types, it is hoped a therapeutic and satisfactory solution could be reached for individuals with limb difference more efficiently, making 'rare' upper-limb cases less challenging for clinics who do not often see individuals with upper-limb difference.

Additionally, more clarity concerning what is regarded as socket fit, and how this differs from socket comfort is required. A universal definition would enable a standardised clinical assessment tool which could be used by clinicians and researchers alike to evaluate sockets being prescribed to patients, and sockets trialled in research.

To preserve safety and allow faster adoption of modern materials, inter-

national testing standards inclusive of upper-limb prostheses are required. Standardised reporting and testing of prosthetic sockets would strengthen evidence emerging from research investigating novel designs of prosthetic sockets. The tests should include how strong a socket needs to be, in terms of impact and also general load bearing. The standard should also include recommendations for weight and surface finish, to allow sockets produced using new materials to be compared on a like-for-like basis to their predecessors. Although important, this work would require significant investment of time and funds due to the destructive testing required.

3.7 Chapter Summary

- More published information is required regarding socket creation, fitting and assessment.
- The terms socket 'fit' and 'comfort' need clear, universal definitions.
- Without enhanced data sharing between clinics and researchers, socket research is unlikely to progress.

Part II

Manufacturing Trans-Radial Prosthetic Sockets

Chapter 4

General Methods

In this Chapter, a general overview of the methods which are used repeatedly in the subsequent chapters of this PhD programme are outlined.

4.1 Introduction

This Chapter provides a broad overview of the techniques that are utilised regularly throughout the following Chapters of this PhD degree. Methods with particular parameters that change in various experiments will be specifically indicated in the relevant Chapter and Section.

4.2 Ethics

For all studies involving participants, ethical approval was obtained using the Newcastle University internal ethical approval procedure. All ethical approvals can be found in Appendix A. An ethical approval for the entire PhD thesis was obtained at the beginning of the project, attached as Appendix A.1. The relevant ethical approval(s) will be referenced locally in each chapter.

4.3 Optical Scanning

There are many types of scanner which can be used to capture the surface of objects, usually relying on the triangulation of visible or infrared light. *Optical* scanning is used as an umbrella term to include all scanning methods which capture what can be seen by the naked eye, i.e. an object's surface, rather than its properties or internal structure. In this PhD programme, digital scanning is repeatedly used as an inexpensive option for capturing limb geometry that can be executed outside of a limb clinic and without supervision from a prosthetist. This is due to the fact it is non-contact and therefore poses no risk of harming a participant if performed incorrectly.

4.3.1 Obtaining a Limb Scan

Many experiments in this PhD thesis required the scanning of participant's upper limbs. In all experiments, participants were shown how to hold their limb (the 'scanning position') and told to maintain this for the duration of the scan. To assume the scanning position, the researcher performing the scan demonstrated the position to the participant, with their palm facing inwards, holding the regular casting angle relevant for the socket style in that particular study, with their radius stacked directly above their ulna. For

each individual experiment, the angle of elbow flexion held during the scanning position will be stated in the relevant Section. The participants were then asked to replicate this position and, with consent, had their arm manually adjusted into position by the researcher if necessary. In general, skin pigmentation, tattoos and scar tissue provide adequate reference points for digital scanning, however reflective markers can be helpful for limbs that do not have distinguishable texture or characteristics. Subsequently, reflective scanning markers (10mm diameter) were adhered to certain limbs to assist position tracking during the scanning procedure if necessary. The markers do not affect the geometry of the scan significantly, but make the scanning procedure much more reliable by helping the scanner track it's position in 3D space. During the scan, the participant held their limb still whilst the scanner operator rotated the scanner around the limb radially. The operator moved the scanner around, whilst visually inspecting the resulting scan on a laptop screen, to confirm all areas of the limb had been captured, and repeating the rotations of the scanner as necessary to capture the entire limb. The scanning area was kept free from debris and objects in the near vicinity were cleared away, so that only the participant, seated if necessary, and the scanner operator holding the scanner were present. Where possible, a room with bright, natural light coming from multiple directions was chosen to reduce shadows. Additionally, where possible, plain, matte flooring was preferred, ideally in a colour contrasting to the participant's skin such as grey or blue.

There were two scanners used in the subsequent experimental chapters of this thesis: the Creaform 'GoScan!50' (resolution 0.5mm) [227], and the 3DSystems 'Sense v1' scanner (resolution 1mm) [228]. For each experiment, the specific scanner used will be noted in the relevant methods section.

4.3.2 Scan Evaluation

A major defect in a scan could consist of a significant missing section which could not be restored retrospectively in CAD without compromising limb capture accuracy. Figure 4.1 shows example scans obtained from a participant. Figure 4.1(a) shows a scan with a major defect for which it was necessary to retry, whereas Figure 4.1(b) shows an acceptable scan.

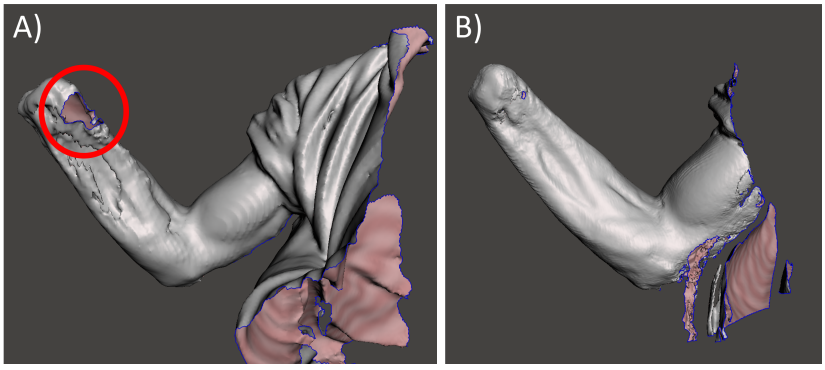


Figure 4.1: Two limb scans taken from the same participant. (a) Shows a scan which was deemed unacceptable because of the large missing section at the distal end of the limb, as highlighted by the red circle. (b) Shows an acceptable scan, free from large missing sections or artefacts, with only minor defects and small missing areas present on the surface of the scan.

4.4 General CAD Procedures

Autodesk Meshmixer, a free program, was used to process the scans in order to eliminate artefacts, fill in holes, and conduct smoothing. Autodesk Meshmixer features an auto-fix feature where defects such as holes are identified by the software and can be individually patched to form one complete mesh. Each defect was auto-fixed separately and visually inspected to ensure that the repair was satisfactory. When auto-fix was not available or adequate, the researcher corrected the defect manually. This procedure entailed manually selecting the defect's edges and applying patches until it was fixed.

4.5 3D Printing

The term 3D printing describes a form of additive manufacturing. Although many different types of 3D printing exist, the term is usually used to describe methods which involve heated and extruded polymers deposited layer-by-layer through a moving nozzle. This type of 3D printing is the most commonly recognised and used method of 3D printing and is generally called 'Fused Filament Fabrication' (FFF). Numerous experiments in this PhD thesis required FFF printing of custom components. This was accomplished with FFF printers ranging from approximately £1500 to £5000 per printer. In the

respective Chapters, printer specifications for each experiment will be stated.

4.5.1 3D Slicing

Before a model can be 3D printed, it is necessary for the print to be 'sliced'. In general, FFF prints are not solid material, but instead feature grid or honeycomb-like structures, called 'infill', inside a solid shell of material. This allows the strength of the print to be preserved whilst also making it light. This is one of the main benefits of 3D printing over many conventional manufacturing methods. The outer shell thickness and the density of the infill are determined when the print is sliced. This converts CAD models into a set of commands and coordinates that the 3D printer can interpret, called 'gcode'. The slicer settings and software used will be noted in the relevant Chapters.

4.6 EMG experiments

Many of the experiments detailed in this PhD thesis involve EMG recording. In the following sections, details of common procedures and the equipment used are outlined. In all EMG tasks, participants were allowed one practice block (one full set of trials) to familiarise themselves with the procedure, but were not required to complete the block once they were competent.

4.6.1 EMG Site Location

There are various approaches to locating suitable EMG sites on the forearm for myoelectric control, with clinics typically taking a different approach to researchers. In general, clinicians will use a specialised device, such as an Ottobock Myoboy [38, 118], to help locate adequate electrode sites. Typically, researchers will use whatever electrodes are available in their lab in conjunction with specially written software to provide a real-time visualisation of the EMG activity. The end result is the same, but it does not necessitate the use of specialised clinical equipment such as a Myoboy. Furthermore, it is preferred by researchers because the quantitative output can be recorded, viewed, and analysed at a later time.

For all experiments in this PhD programme, the researcher palpated the limb while the participant flexed and contracted their wrist flexor or extensor

muscle groups independently, as is customary during a clinical assessment. SENIAM standards were followed in order to locate the optimal EMG sensor location along the forearm muscles once located by palpation [229], and DELSYS best practice guidelines were followed when using DELSYS electrodes [230]. After the approximate EMG sites had been located, DELSYS™ EMG sensors were affixed to the limb with DELSYS™ adhesive film. When a single channel recording was required, a DELSYS™ *Trigno* or *Mini* EMG sensor was used. When two-channel recording was required, either two Trigno or Mini EMG sensors were used, or a DELSYS™ Quattro sensor. The Quattro features four EMG heads, however only two were ever necessary. When using a Quattro, the two spare EMG heads were positioned as appropriate around the limb in support locations and in these cases data from the additional EMG heads was not recorded. Locations are detailed in the relevant subsequent Chapters. The sensor placements were confirmed as satisfactory by examining raw EMG traces in real-time on a screen. Participants were asked to perform brief bursts of wrist flexion and extension so that a sufficient signal-to-noise ratio could be visually confirmed. The procedure was repeated as required, and the electrodes relocated as necessary until two satisfactory antagonistic muscle sites were found for each participant. After determining the final electrode positions, an outline was drawn around the sites with a marker pen.

4.6.2 EMG Calibration

The general EMG calibration procedure used for all experiments in this PhD thesis is based upon the methods used by Dupan et. al [231]. Two EMG states were recorded at each EMG site: 1) data representative of baseline EMG activity, y_{min}, and 2) data representative of a typical muscle contraction, y_{max}. The value of y_{max} could either be recorded at the participant's maximum *comfortable* contraction (MCC), or the participant's maximum *voluntary* contraction (MVC). When using MCC, participants were informed prior to calibration that they would need to repeat the contraction many times throughout the experiment, hence they should aim for a comfortable, repeatable level of contraction to prevent discomfort during the trials. When using MVC, participants were asked to perform a maximum exertion contraction. The Mean Absolute Value (MAV) of the EMG recordings taken directly from the electrodes is denoted as y. The EMG data was recorded using an update rate of 10 ms and then smoothed using a 750 ms window.

In all of the subsequent trials, the EMG was normalised using constants derived from the MAV recordings. Normalised muscle activity, y_{norm}, was calculated as:

$$y_{\text{norm}} = (y - y_{\text{min}})/(y_{\text{max}} - y_{\text{min}}). \tag{4.1}$$

4.6.3 EMG Tracking Task

In an EMG tracking task, the EMG signal amplitude from a muscle contraction can be mapped to an arbitrary output, such as the movement of a cursor on a screen. Tracking tasks are used to evaluate a participant's ability to perform EMG control under a given set of circumstances, for example, trying a novel prosthetic socket style. During the EMG tracking tasks in this PhD programme, participants were shown how to track a 1-dimensional moving target with a digital cursor on a screen using their muscle activity. The height of the cursor was controlled by the amplitude of muscle activity. The cursor and target were shown to participants on a large television screen (55" diagonal screen size). During a typical trial a target would be presented and rise to a pre-determined height, which could be described as percentage of y_{norm}.

4.7 Pressure

Several of the later experiments in this PhD programme involved the application of pressure to the forearms of participants. There was no specific pre-existing literature to guide the level of compression applied to participants' forearms. In the subsequent Sections, the estimation used to determine safe pressure levels is described, followed by the method that enabled pressure monitoring during the relevant experiments. Although not an International Standard (SI) unit, therapeutic compression garments are almost always graded in mmHg. Hence, this is the unit that many clinicians would recognise and use for compression devices instead of kPa. Accordingly, all pressure measurements will be given in both kPa, the SI unit, followed by the corresponding mmHg measurement. For reference:

$$1kPa \;=\; 7.501\ mmHg$$

4.7.1 Pressure Management

Chang et al. established a parabolic relationship between the magnitude of compression applied to the human body, time and safety, valid between 2 and 7 hours of wear-time [232]. Assuming no shear forces, where P = pressure applied normal to the skin in kPa and t = time in hours [232]:

$$Pt \ = \ 32kPa.h$$

Subsequently, for all experiments in this PhD thesis, the maximum allowable pressure was calculated using Chang's measure [232]. None of the experiments were expected to exceed a total of two hours, which would result in a maximum allowable pressure of 16kPa (120mmHg). However, two hours is not a realistic wear-time for a prosthetic arm, hence the range of allowable pressure was lowered to half this value 8kPa (60mmHg), giving a theoretical maximum wear time of 4 hours. Achieving exactly 8kPa per bar would be extremely difficult due to structural differences between individual participant's arms and also the different structures within the arm. For example, on the underside of the forearm, there is less soft tissue to cushion the bone structure, so pressure will rise faster, whereas cushioned areas will be more pressure tolerant. A target range of 6.7-9.3kPa (50-70mmHg) was established, with a tolerance range of 5.3-10.7kPa (40-80mmHg).

4.7.2 Pressure Measurement

Ohmite FSR07Ce Force-Sensing Resistors (FSR's, Ohmite, USA) were used to monitor the pressure applied to participant's forearms. Pressure data was sampled at 1000Hz, via Firmata firmware on a Teensy™ 4.0 board. In both experiments, they were mounted inside custom-made depressor bars which were part of the bespoke apparatus detailed in each relevant Chapter. The depressor bars were designed specifically to house the FSRs's in a way that would facilitate reliable and repeatable measurements. As per the manufacturer's recommendations, it was necessary to have a flat surface area which would depress the FSR without covering the entire sensor, to allow air to escape [233]. Additionally, as the recordings were to be compared against each other, it was necessary to keep the depressor area consistent across trials. A two-part bar design was devised, where the upper-part of the bar featured a recess for the FSR to be affixed to, and the lower-part of the bar featured protruding cylindrical depressors, shown in Figure 4.2(a). The two halves of

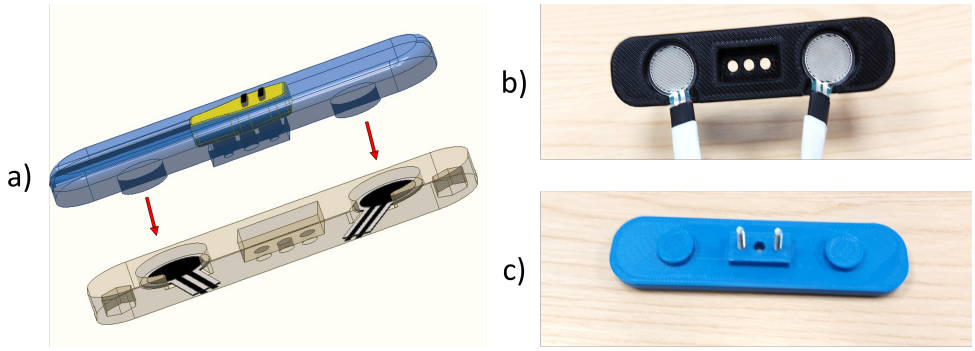


Figure 4.2: (a) A CAD rendering of both halves of a compression bar. The FSRs, shown in black, and the electrode, shown in yellow, fit within the bar. (b) The upper half of the bar, 3D printed in black PLA with two Ohmite FSR's recessed into it. (c) The lower half of the bar, printed in blue PLActive material, showing the protruding screws which allow it to be affixed to the upper half of the bar. The recess for the electrode covers the screws, hence they are not uncomfortable for the wearer as the skin is protected by the electrode.

the bar can be seen independently in Figure 4.2(b) and 4.2(c). Two screws, loosely secured with hex nuts, were recessed into the EMG sensor cavity of the bar for stability and to keep the two halves together.

A calibration procedure was performed to convert the FSR output to Pressure (mmHg). This was achieved by placing known calibration weights atop the bars with the sensors inside in increasing increments (0.1-5kg) to establish a relationship between force and displayed FSR output. Whilst the recordings were taken, the bars were placed on a flat, stable surface. A mean of five FSR output recordings was taken for each weight, repeated with three randomly chosen FSR07CE sensors. An exponential curve was fitted to the resulting dataset, giving FSR output vs weight (kg). This was converted to pressure using applied force (weight $\times$ gravity) divided by the approximate area of the bar (0.0024mm^2). The resulting conversion was then used to allow real-time visualisation of the pressure applied by each depressor bar, based on the FSR output from the sensors inside it. All equations used and the calibration curves are attached in Appendix B.1.

4.7.3 Pressure Application

Whilst applying pressure to the forearm during experiments, a real-time colour-coded visualisation was displayed on a laptop screen to the researcher. Green indicated that the FSR was registering a pressure of 50-70mmHg, the ideal range, yellow indicated 40-50mmHg or 70-80mmHg, the outer ranges of the acceptable levels, and red indicated less than 40mmHg or more than 80mmHg, which was either too low or too high respectively. Throughout all experiments, four depressor bars were used at a time, and each depressor bar had two FSRs embedded within it. With one FSR situated proximal and one distal along the forearm, it was possible to view both the individual pressure readings or the average per bar. Hence, for the visualisation of pressures available to the researcher, one window displayed the recordings from each individual bar (8-channel) and one window displayed the average pressure per bar (4-channel). The 8-channel visualisation was used to fine-tune each bar so that the pressure was around the same level at both the proximal and distal end, however for gauging whether the bar was in the acceptable range, the average pressure per bar from the 4-channel visualisation was used. Throughout any stages that involved pressure application, participants were encouraged to vocalise any issues or discomfort they were experiencing. If necessary, the pressure was reduced in specifically uncomfortable areas to the lower bounds of the acceptable pressure range.

4.7.4 Simultaneous EMG and Pressure Data Processing

When required, EMG and FSR data was synchronised and processed via the Axopy experimental library to provide a real-time visualisation of both signals [234].

4.8 Neutral Limb Position

In multiple experiments, participants were asked to position their dominant arm into a 90 degree elbow flexion pose with their wrist in an upright position, as shown in Figure 4.3 - henceforth referred to as the *neutral position*. This position was demonstrated by the researcher whilst wearing the compression rig for clarity.

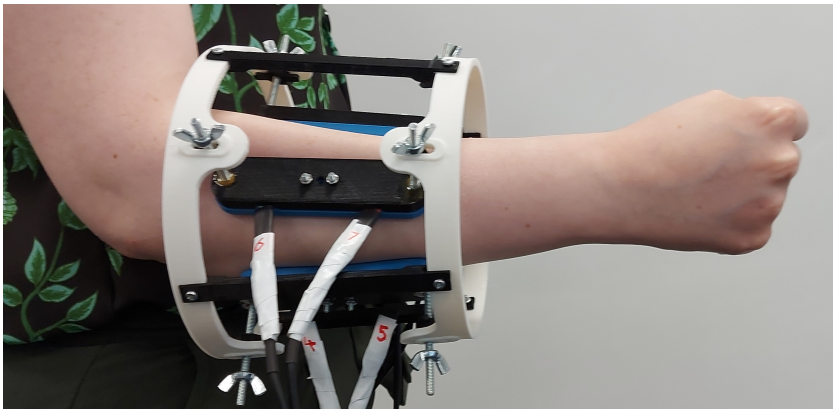


Figure 4.3: The *neutral* position, demonstrated whilst wearing the compression rig.

Chapter 5

Optical Scanning for 3D Printed Sockets

As established in Chapter 2, prosthetic sockets must be updated to facilitate the use of new, high-tech terminal devices. Making sockets using digital technology could potentially be part of the solution to achieving this. Despite being frequently suggested as an alternative to traditional procedures, a common, clinically-accepted method for doing so has yet to be found. As discussed in Chapter 3, it is likely that progress has been hindered by a lack of research and insufficient documentation. Through a practical experiment trialling digitally manufactured sockets with amputees, this Chapter evaluates the feasibility of switching directly to modern manufacturing processes using techniques that are commonly assumed to be able to replicate the current clinical standard. Their potential benefits and drawbacks are discussed alongside clinical commentary.

> *3D-Printing and Upper-Limb Prosthetic Sockets: Promises and Pitfalls* (J. Olsen, S. Day, S. Dupan, K. Nazarpour, M. Dyson, 2021) is published in IEEE Transactions on Neural Systems and Rehabilitation Engineering *(TNSRE)*.

5.1 Introduction

In this Chapter, the aims of the practical experiment were to determine:

1. Whether purely digital manufacturing could be used to create reliably satisfactory trans-radial diagnostic sockets in terms of comfort and fit as perceived by the wearer, accompanied by clinical commentary from a supervising clinically trained expert.
2. Which procedures of 'conventional' socket manufacturing are difficult to replicate
3. Which elements of digital manufacturing would actually be beneficial to incorporate in standard practice

The procedure was devised to use inexpensive digital scanning and 3D printers, as are used in many engineering and technology focused research labs. The objectives were to acquire participant feedback on the digitally created sockets to explore their views, alongside expert prosthetist commentary and supervision.

5.1.1 Conventional Processes

Using conventional methods, manufacturing a prosthetic socket requires several different steps, many of which require skilled manual labour from a prosthetist or technician. These methods can typically result in a comfortable socket produced within a reasonable amount of time [32]. However, despite being widely used, current socket manufacturing methods have many drawbacks, and several research studies have shown a need to optimize current trans-radial sockets in terms of comfort, aesthetics, and other factors [38, 50, 174].

5.1.1.1 Patient Evaluation

Usually, the initial step to obtaining a custom-made prosthetic socket is for the patient to attend a limb-clinic or hospital to be assessed and cast by a prosthetist. Some of these stages could be completed via a virtual appointment, such as inspecting the limb and gauging the patient's overall health. However, although possible, home-casting would be impractical due

to the mess and range of materials required. Hence, home-casting is very rare. Following the initial appointment to be cast, a number of in-person follow-up clinic visits are generally required to dispense and test the socket, and possibly to try an intermediate diagnostic socket [32, 235, 236]. These visits are performed to ensure the prosthesis is meeting the patient's needs and is not causing pain or damage to their residuum. According to a study which assessed 935 individuals with major upper and lower limb amputations based in the United States, nine clinic visits per year are typical for amputees [237]. However, this will vary significantly based upon the level of healthcare that is accessible to each individual. Additionally, patients can expect to wait approximately two to five weeks between their first fitting appointment and their second visit to trial the socket [238–241]. The actual process of manufacturing a socket is relatively fast and can be performed in a matter of days. However, due to the artisan, manual nature of socket making, the turnaround time entirely depends on the workload and other commitments of the prosthetist at the time.

5.1.1.2 Plaster Casting and Positive Model Creation

In conventional socket making, the plaster of Paris (POP) wrap, which is used to capture the residual limb geometry, is also used as a mould for a 'plaster pour'. This process yields a 'positive' model, which is simply a POP replica of the residual limb. The model incorporates any markings made on the limb by the prosthetist, as well as any hand-sculpting that occurred as the original plaster wrap hardened. The markings are required so that the prosthetist can *rectify* the positive model. Rectification is an industry-wide term used in the UK for the manual adjustments a prosthetist makes to the plaster positive, although it has other names in different countries. The prosthetist will add material to the plaster positive where appropriate. For example, material may be added to create a low-pressure 'relief' area in the final socket. Similarly, material can be removed where tightness is required, e.g. sanding down the area where an electrode is to be placed to create a flat surface with an intimate fit to the skin. The positive model is also smoothed all-over to create a good surface to drape or laminate the final socket upon. Although this is a convenient method of transforming the negative plaster wrap into a positive plaster model, it is also an irreversible and destructive process. Once the plaster wrap has been used as a mould, it has to be cut away from the plaster positive, destroying it in the process.

Hence, the negative cannot be saved for creating another socket or for future reference. Additionally, if a mistake is made, there is no way to solve this once the wrap has been destroyed [32], and another visit to clinic for the patient to be cast again would be required [32, 235].

It is almost guaranteed that as the cast's geometry is replicated through the various stages that some degree of accuracy is lost. Moreover, in clinics where transparent, draped *diagnostic* sockets are used, the entire process described earlier is repeated twice. The first plaster positive is used to create a diagnostic socket, which is then used as a mould to create a second plaster positive, requiring the destruction of the diagnostic socket in the process. Hence, at each stage, details captured in the previous plaster cast may be lost, and there are opportunities for irreversible errors to occur, requiring the entire procedure to be repeated. Subsequently, from a clinical standpoint, re-making an unsatisfactory socket requires significant effort, is time-consuming [236, 242] and can be an expensive process. Additionally, it is not known whether volumetric and geometric errors resulting from the multi-stage casting process affect the final fit of a 'traditionally' produced socket and the level of inaccuracy introduced at each casting stage has not been studied.

5.1.1.3 Monitoring Limb Health

It is important to monitor the health of a residual limb over time to check for deterioration in the health of the limb, especially in the case of acquired amputation [243]. The volume and composition of a limb can indicate many consequential conditions that may occur post-amputation. Volume changes in the limb could indicate cause for concern - i.e. loss of muscle volume can leave the limb unsupported and lead to conditions such as oedema [212]. The destructive nature of conventional plaster casting means that there is neither a physical or digital record of the limb available to refer to at a later stage [32, 244].

5.1.1.4 Socket Creation

Due to the artisan nature of socket creation covered in Chapter 3, there can be significant inconsistencies in how sockets are produced between clinics. Many materials are required to manufacture laminated composite sockets - the type of resin, the textiles used to provide structure to the socket, and the

quantity of layers can all vary. Because there are so many different acceptable variations of materials which can be combined to produce a laminated socket, it is hard to standardise across the field. Therefore, the quality, strength and finish of sockets can vary significantly [199], even if the general procedure is the same globally.

5.1.2 Digital Processes

Over the last decade, there has been a surge in interest in digital manufacturing technologies [245, 246]. Digital scanning and 3D printing have been proposed as potentially transformative technology in the field of prosthetic limbs [31, 245–248], due to the potential benefits they offer.

5.1.2.1 Digital Scanning

Digital scanning is often suggested as an alternative to plaster casting as it is non-contact and mess free [249], is non-destructive and can be performed anywhere with low-cost technology. It also offers the option of a potentially waste-free socket production method when combined with an additive manufacturing method, eliminating the need for mould disposal [249].

Arguably, the most important improvement scanning offers is the ability to create a permanent digital record of the limb over time [32, 244]. This allows the prosthetist or technician processing the scans to refer back to them at any stage, either in the case of mistakes in socket provision or to monitor the health of the limb. Additionally, low-cost digital 3D scanners, such as app-based smartphone scanning and photogrammetry, can accurately record the volume and shape of residual limbs and existing sockets [33, 34]. This makes digital scanning an attractive option financially. Positive results such as these, which purely emphasise the *accuracy* of digital scanners, are partly why digital scanning is now perceived as the sensible route forward for limb-shape capture.

However, in general, little attention is paid as to how the scans should actually be processed once they are with the prosthetist. In a normal casting, the prosthetist can use the *feel* of the limb to guide the sculpting of the plaster cast. With a digital scan, the prosthetist does not have this tactile information to rely on, and is effectively working 'blind' whilst performing rectifications and cannot ask the patient in real-time whether something causes discomfort or hurts. This may result in the rectification being per-

formed in the wrong areas or to the wrong degree of severity. Currently, this could only be remedied by the prosthetist taking detailed notes about the limb, which is limited in accuracy, or by adding another scanning step such as magnetic resonance imaging (MRI) or computed tomography (CT) scanning. Both of these options are prohibitively expensive and would take significantly longer than creating a plaster cast. Using a casting sock when scanning can compress the tissues lightly, which is advantageous to the fit, however this still does not give the prosthetist any tactile information to use when they are creating the socket.

5.1.2.2 Computer Aided Design and 3D Printing

A combination of CAD software and 3D printing is often suggested as a modern alternative to plaster pours, manual rectification and thermoforming or laminating a socket. Lower limb 3D printed sockets have seen some early successes in terms of increased comfort and decreased contact pressure [31], however similar results are yet to be documented for upper-limb sockets. Despite this, 3D printing opens up many opportunities to use new materials for socket creation which may provide benefits to the wearer.

Upper-limb prosthetic sockets are currently made of thermoformed polymers such as polypropylene or resin-based composites [37]. Because neither of these materials are breathable, the limb may get excessively sweaty and warm during extended periods of wear [250]. Excessive perspiration inside the socket can be a contributing factor to amputation-related skin infections [250]. To counteract this, some amputees use limb socks to assist in absorbing moisture, but this method is incompatible with EMG controlled prostheses as direct skin contact is necessary, which the limb sock would prevent. As a result, this is solely an option for harnessed upper-limb prostheses, whereas myoelectric prosthesis users must use the bare socket or use a makeshift solution such as cutting holes in fabric liners. The severity of this problem is compounded by the fact that excessive perspiration can impair the quality of myoelectric signals. Hence, the ability to use new, breathable materials may help minimise limb overheating, skin infections and improve myoelectric signal transmission.

Using 3D printing allows a wider range of materials and designs than when using conventional methods. For example, specialist antibacterial skin-safe filaments have recently been developed [251], and breathable lattice designs can easily be created in CAD software. ‘Smart’ materials and design such

as these are generally not feasible using traditional methods. Hence, in theory, there are countless benefits to utilising 3D printing in socket provision. However, many reports suggesting its usage for prosthetics applications focus on it being 'faster', 'cheaper', or 'better' [192, 252, 253]. These benefits are yet to be proved for socket manufacturing, as 3D printing has not been adopted widely in prosthetics clinics. In contrast, 3D printing is a common option for creating grasping devices [246, 254]. Subsequently, some experts have stated that 3D printing is unlikely to have a substantial impact on the manufacturing processes of upper-limb sockets, given that current techniques are generally satisfactory [245]. So far, an entirely digital workflow which can produce reliable results is yet to be found for upper-limb socket manufacturing, hence the clinical relevance of this study.

5.2 Methodology

In this study, multiple sets of 3D printed diagnostic sockets were created for upper-limb different participants. Each participant received two sockets, created from the same base file in CAD. One socket was 'rectified' digitally to have contours in the supracondylar and supraolecranon region, whilst the other was not rectified and featured no contouring. A survey featuring likert scales and open ended discussion questions was developed and implemented to acquire verbal feedback from the participants, which was then converted into categorised responses. Throughout the study, clinical advice, supervision and commentary was sought, in order to reduce the risk of harm to participants and to provide insight into how the method compares to traditional manufacture.

5.2.1 Ethics

This study (Ref: #16602/2018), Appendix A.2, was given approval by Newcastle University's internal ethics committee.

5.2.2 Participants

Six individuals with trans-radial limb deficiency were recruited to take part in the study via the National Centre for Prosthetics and Orthotics (NCPO, Strathclyde, UK). Of the participants, one presented with congenital limb

deficit and the rest were acquired amputees. Only one bi-lateral trans-radial amputee took part and the rest had unilateral limb difference. In this case, the participant was treated as a unilateral amputee, with only the participant's dominant limb being scanned for the study. Three of the six volunteers experienced varied degrees of pain and phantom limb experiences. Participant details are shown in Table 5.1.

5.2.3 Conventional Processes

Institutions can electively apply for accreditation from the International Society for Prosthetics and Orthotics (ISPO), who provide guidance on education standards for prosthetics and orthotics training courses [255]. The accreditation is optional in many countries, and ISPO do not specify exact manufacturing methods or materials for producing sockets. Given the variations in methods and materials used in prosthetic socket manufacturing around the world, the first aim of this experiment was to capture a realistic example of how upper-limb sockets are conventionally produced in a modern clinic. To do this, the trans-radial socket production technique taught at the Strathclyde NCPO, an ISPO accredited institution, was observed. This was undertaken to enable replicating the 'standard' method using digital tools. Despite the specifics of procedures varying between different clinics and countries, the general steps are outlined below.

5.2.3.1 Patient History

Each individual patient requiring a prosthesis will present with different day-to-day requirements from their device [99]. Before beginning to create a prosthetic limb, the prosthetist will generally assess the patient in person to locate any painful areas of the limb (i.e. where neuromas or scar tissue may be present). This is achieved by visually inspecting the limb and palpating it where necessary. The prosthetist will also use this appointment to learn about how the patient acquired their limb difference. Additionally, the prosthetist will gather information about their medical history, including any co-morbidities, and the patient's expectations for their prosthetic device in order to custom-make the most suitable prosthesis for them. Detailed measurements of the participant's residual limb are taken, including measurements of their intact forearm and hand (if present) so that the patient's prosthesis can be matched to this and geometrical symmetry can be achieved.

Table 5.1: A table summarising the participant's gender (M = Male, F = Female), the age category they were part of at the time of the study, and details about their limb difference and prosthesis use.

Participant	Age Bracket	Gender	Amputation	Prosthesis Use	Notes
1	50-60	M	Acquired – trans-radial	Uses several sockets for different applications with static (passive adjustable) attachments - i.e. sports, driving. Doesn't usually wear a prosthesis for leaving the house. Previous experience using a myoelectric device.	Phantom sensations at distal amputation site and minimal pain. Pain is worse in the cold.
2	40-50	F	Acquired - trans-radial	Uses several sockets for different applications with static and body powered attachments - i.e. cooking, driving. Doesn't usually wear a prosthesis for leaving the house. Previous experience using a myoelectric device.	Occasional phantom sensations and pain at distal amputation site.
3	30-40	M	Acquired – trans-radial	Myoelectric prosthesis used daily for their job.	No pain or sensations reported.
4	20-30	M	Congenital – trans-radial	Various sockets (body powered attachments) for specific tasks such as going to the gym, driving. Doesn't usually wear a prosthesis for leaving the house.	N/A as congenital.
5	60+	M	Acquired – trans-radial	Various sockets (body powered/static attachments) used for specific tasks.	No pain or sensations reported.
6	60+	M	Acquired – trans-radial	Various sockets with body powered and static (passive adjustable) attachments for specific tasks such as craft activities. Usually wears a passive anthropomorphic prostheses when leaving home. Previous experience using a myoelectric device	Severe nerve damage at distal end of limb. Constant pain and phantom sensations.

5.2.3.2 Limb Preparation

Before plaster casting can commence, it is first necessary to prepare the limb. The electrode positions are found using a device such as an Ottobock Myoboy [118], which allows the prosthetist to easily measure the quality of EMG signal coming from a particular site, signalled either by the Myoboy emitting an audio signal or LED light, for which the intensity varies depending on the quality of signal achieved. Within signal processing, the term 'gain' refers to any procedure that increases the amplitude of a signal by a given factor. It is possible to adjust the 'gain' on most clinical standard electrodes. When using an Ottobock Myoboy, the gain on each electrode is adjusted to a 'medium' level, which corresponds to an arbitrary value of 3 or 4 on the electrode's gain adjustment dial [118].

5.2.3.3 Plaster Casting

To find a central location above the patient's most prominent wrist flexor and wrist extensor muscles, the clinician will typically palpate the patient's limb. These areas work well as electrode sites for EMG control because exercising independent, voluntary control over them is generally not difficult due the the underlying muscles providing an antagonistic function. The patients are then instructed to continually relax and contract each muscle one at a time, until a comfortable level of contraction is reached. The aim is for the patient to be able to activate both muscles independently without activating the antagonistic muscle at the same time. Upon initially placing the electrodes on the limb, the signal level is recorded [118]. To refine the positioning of the electrodes, the sensor is moved half its width in each direction along the skin, and the amplitude of the signal is recorded with each change in position. If a signal with a larger amplitude is found, the process is repeated until the optimised electrode location is found [118]. The prosthetist will then mark this area with indelible pencil on the limb.

The prosthetist will then also mark other important areas of the limb with an indelible pencil, such as the olecranon, epicondyles, and any sensitive or painful regions. All markings except those for the electrode sites are generally made on top of a *limb sock*. The limb sock helps transfer the markings to the cast, but also protects the limb whist plaster casting. For the electrode sites, the areas are generally marked directly onto the limb and transferred to the limb-sock (if being used). If additional protection is required, the

limb can be wrapped in a thin plastic film (e.g. cling film) after making the markings on the limb/sock, but before plaster casting commences. Next, the prosthetist will wrap the residuum in bandages pre-soaked with POP. Whilst the bandages are curing, the prosthetist uses their fingers to form the 'moulding grip' around the cast. This technique involves applying pressure above the epicondyles and sometimes above the olecranon to help sculpt the cast as it dries. This sculpting assists the suspension of the socket when it is manufactured. The depth of indentation the prosthetist makes is not a pre-determined value, and instead based upon the prosthetist's experience and their knowledge of the patient's limb. For someone with a fleshy, muscular residuum, the depth and pressure applied would be much higher than for someone with a slender, more bony residuum. Experienced prosthetists can vary the pressure they are applying intuitively to account for this. Once the plaster cast has cured fully, it is carefully cut away from the patient using specialist shears using a singular incision. Generally, this incision runs the length of the cast, parallel to the bones on the underside of the cast.

5.2.3.4 Positive Model Creation

A 'positive' model of the limb is required to manufacture the socket upon. To create this, the cut made along the plaster cast is repaired to form a custom mould. The mould is filled with POP and allowed to cure. During this process, the indelible pencil markings from the limb sock transfer to the plaster model. After curing, the original plaster cast is cut away from the plaster positive. This process destroys the plaster cast beyond repair, and it is then discarded. Rectification, as described in Chapter 5, Section 5.1.1.2, is then performed on the plaster model to produce a smooth model. It is important to note that at this stage, the model will not accurately represent the geometry of the limb. Instead it has been optimised by the prosthetist to produce the correct shape socket. Additionally, it is assumed some volumetric and geometric accuracy is lost during the plaster pour and smoothing processes, however this has not yet been studied.

5.2.3.5 Socket Creation

At this stage, either the final socket, or an intermediary 'diagnostic' socket can be produced. If being used, a diagnostic socket allows the prosthetist to create a 'trial' version of the final socket using a fast procedure such as ther-

moforming. This involves vacuum-shrinking or draping a transparent sheet of plastic over the plaster model. Thermoformed material is advantageous for diagnostic sockets, as it means it can be re-worked slightly after the diagnostic socket has been produced using only heat. During a prosthetist's assessment of a diagnostic socket, they can therefore alter the socket 'on the go' using only a heat-gun to perfect the fit. This then creates an 'ideal' mould to create another plaster positive (via another plaster pour) to create the final socket with. During this procedure, the thermoformed diagnostic socket is sawn away from the plaster positive, which destroys the socket in the process.

Many clinics do not create a diagnostic socket due to the additional manual labour it requires. Instead, these steps can be skipped and the prosthetist can create the final socket using the first plaster positive. However, the 'final' socket cannot generally be altered significantly once created. This is because the most common method for creating a final socket is to create a composite based material which uses thermoset resins. Thermoset materials cannot be re-moulded using heat in the way that thermoformed materials can due to differences in the molecular structure of the two types of materials [256]. Thermoset 'laminated' sockets are created using layers of textile, such as nyglass bandages [145]. The textile is applied in layers upon the plaster positive and then set using resin which creates a strong, durable, skin-safe material. This reaction is exothermic and generates some heat whilst curing occurs. A second layer of lamination is then applied atop the first, to form the outer layer of the prosthesis. Areas that allow other components to attach to the socket are added, i.e. attachment sites for a wrist or harnesses (if required). Once the socket has been produced, the prosthetist or technician will affix 'off-the-shelf' additions such as electrodes, wiring, wrist-units and terminal device attachment sites. This creates a medical device which contains both custom-made and generic CE marked components.

5.2.4 Digital Replication

To establish a comparable procedure, all stages of the conventional method were to be digitally recreated, up to the creation and testing of a diagnostic socket. The second fitting of a 'final' socket was omitted, as the steps required to do this are effectively a repeat of previous steps.

5.2.5 Clinical Involvement

In order to remove the element of prosthestist skill level affecting the socket manufacturing procedure, all experimental procedures were carried out by the author, a non-clinical researcher. As a safety precaution a professional prosthetist was consulted for advice on optimal practices for creating trans-radial sockets before commencing the experiment with the participants. This approach was adopted to reduce the possibility of causing pain or injuries to the participants. Following this, the author conducted all digital scanning, socket construction, testing and data collection with participants without clinical intervention. However, any sessions which required direct participant contact were observed by the professional prosthetist as a secondary safety procedure. The prosthetist also provided commentary as to how the method deviated from traditional manufacturing, and which elements could lead to potential drawbacks from a clinical perspective.

5.2.6 Equipment

To record the shape of the residual limbs, a low-cost optical scanner was used (Sense v1, 3DSystems, USA) [228]. Although now discontinued, the scanner cost approximately £300 at the time of purchase. Technical details of the scanner and scanning procedure can be found in Section 4.3.1.

5.2.7 Socket Style

A socket based upon the principles of the *Strathclyde Supra-Olecranon Socket* (SSOS) was created for all participants. This socket style was chosen as the SSOS can accommodate a vast array of trans-radial amputees. For this design, the prosthetist usually applies a moulding grip above the olecranon during plaster casting to ensure adequate suspension is achieved in the resulting socket. The primary function of the wings around the epicondyles is to provide rotational stability and to a lesser degree, further suspension. Casting angle is important for a SSOS socket, with 90 degrees elbow flexion being the ideal angle to create suspension over the olecranon.

5.2.8 Limb Capture Procedure

As optical scanning is a non-contact process, it was not necessary to protect the limb from chemicals or plaster. Hence, there was no need to utilise casting socks and these were omitted for the scanning process. Limb markings were not conducted for two key reasons. Firstly, the scanner did not support the capture of texture (colours). Due to this, geometry-only scans were obtained and the markings would not have been accessible to view at a later date. Secondly, marking the limb is a skilled task usually conducted by the prosthetist. This method was devised to be as repeatable and low-skill as possible to reduce variations which could occur whilst performing it. The scanning procedure is outlined in Chapter 4, Section 4.3. 90 degrees elbow flexion was used for the scanning position to match the casting angle of a regular SSOS casting. Multiple scans for each participant were conducted until a scan which appeared to be free from major defects, as defined in Chapter 4, Section4.3.2, was achieved, with a maximum of four attempts per participant. Figure 5.1(a) shows a participant having their limb scanned.

5.2.8.1 CAD Process

Firstly, the scans were processed as detailed in Chapter 4, Section 4.4. A visualisation of this can be seen in Figure 5.1(b) To determine the approximate location of reference points like the epicondyles, cubital fold, and olecranon, the scans were visually reviewed. These regions served as guides for the trimlines, which were drawn above the reference points.

Firstly, an 'unmodified' socket was created directly from the scan without being contoured or significantly modified in CAD software. To achieve this, any minor holes in the scan were patched, light smoothing was applied to the whole scan and trimlines were drawn and digitally 'cut'. This scan was saved as a base file. The second socket was 'modified' with contouring designed specifically to mimic the application of the moulding grip and the post-casting shaping that a prosthetist would undertake. Using the base file, an indentation was created above the olecranon and epicondyles in the CAD software. The depth of the indentations varied between 1-3mm, depending on how well cushioned or bony the participant's limb was. Limbs with more cushioning, soft tissue present can tolerate higher levels of contouring, hence had deeper indentations. The indentations were then smoothed so that they blended with the rest of the socket, and then the scan was saved as the 'mod-

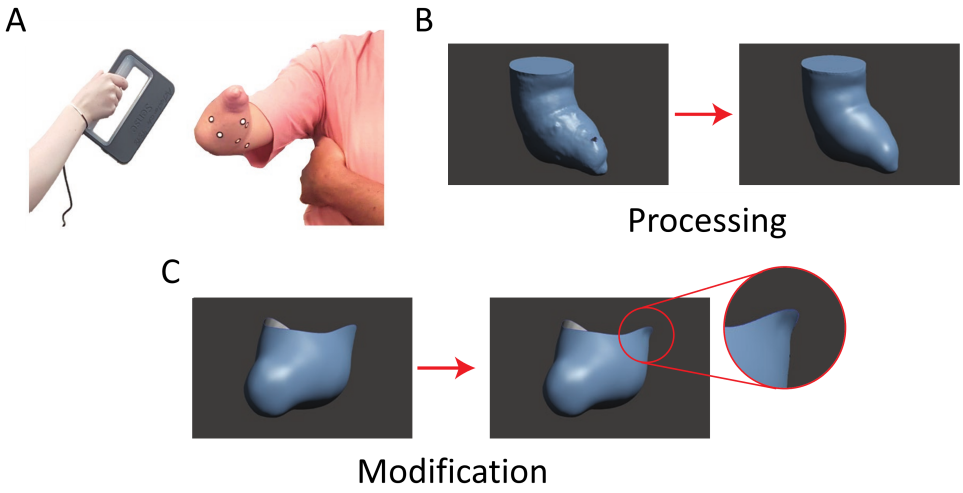


Figure 5.1: (a) A participant being scanned with the Sense Scanner. Their limb is covered in reflective scanning markers to assist the scanner's tracking. (b) A scan of the participant's limb, shown before and after initial processing. Minor holes have been patched and gentle smoothing applied to the whole scan. (c) The difference between a pair of 'unmodified' and 'modified' sockets, with the contouring above the epicondyles for the modified socket highlighted in the red circle.

ified' socket. Using these methods, the overall geometry and trimlines were kept the same for both sockets, with only the contouring (or lack of) being noticeably different.

For some participants with complex needs such as neuropathic pain and sensitive areas of their limb, several pairs of modified/unmodified sockets were produced. Where this was required, different trimlines were drawn and saved as distinct base files. This was to ensure each participant would be able to try at least one pair of sockets on the testing day without being restricted by pain or tight trimlines. The only difference between each participant's pairs of sockets were the trimline and wing height, and the only difference within each pair was whether or not it was modified or unmodified with contouring. An illustration of the distinction between the two sockets can be seen in Figure 5.1(c). The contouring applied within Autodesk Meshmixer to assist suspension can be seen highlighted in red in Figure 5.1(c).

Autodesk Recap was used to convert the triangular meshes from Autodesk

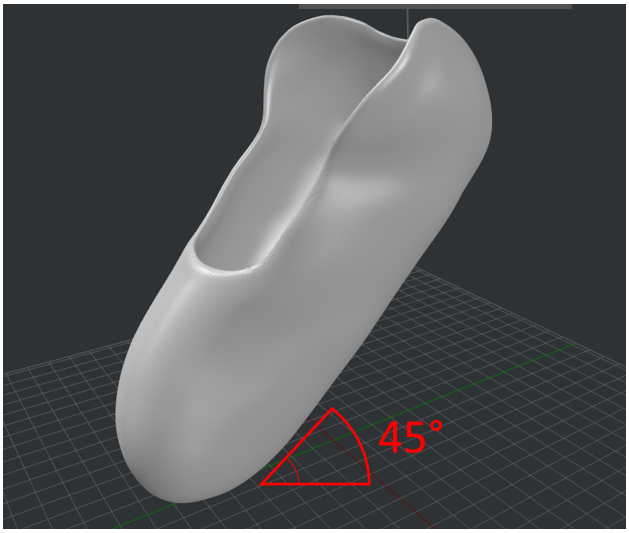


Figure 5.2: A CAD model of a prosthetic socket ready to be 3D printed, oriented 45 degrees relative to the print bed.

Meshmixer into quad meshes. This was necessary as the next program used to create the sockets, Autodesk Fusion, is only compatible with quad meshes. Using Autodesk Fusion, all of the socket files were extruded outwards by 4mm using the extrude function. Autodesk Fusion allows 'soft' edges to be created using this function, which ensured the trimlines would not be sharp against the patient's skin. The models were then exported as .stl (standard triangle language) files which are compatible with 3D printer software. Prior to printing, the models were 'sliced' using Ultimaker Cura and Ideamaker, as detailed in Chapter 4, Section 4.5.1.

5.2.9 Socket Manufacturing

The general procedures used for 3D printing the sockets are outlined in Chapter 4, Section 4.5. Three different types of FFF printers were used to create the sockets: an Ultimaker 2+, an Ultimaker 3 (Ultimaker, Netherlands), and a Raise3D Pro (Raise3D, China). Generic PLA (Polylactic Acid), PLActive, an antibacterial PLA/Copper Nanocomposite (Copper3D, Chile/USA), and 'Guidel!ne™' (Taulman, Georgia, USA) medical grade PET-G (Glycol Modified Polyethylene Terephthalate) were utilised as filaments for printing the sockets. The properties of the three materials used are summarised in Ap-

pendix C.1. As a compromise between strength and speed, the sockets were printed with a 0.4mm nozzle, 0.18mm layer height, 15% infill, and a 45 degree rotation relative to the print bed, as shown in Figure 5.2. Numerous studies have shown that the orientation of layers within a 3D printed specimen can affect it's strength [257–260]. The weakest part of a 3D print under a tensile force is perpendicular to the layers [260], whereas the opposite is true for compressive forces [259]. Consequently, creating layers where the forces are applied at a tangent to the socket instead of directly between the layers is advisable. Hence, for the sockets it was sensible to print at 45 degrees, with the layers running diagonally to the radius and ulna, to give strength in multiple directions and also to minimise the support material required. The speed at which the print was extruded and the nozzle temperature varied depending on the combination of printer and material used, so for each filament, the manufacturer's recommended settings were applied in the corresponding slicing software. To enable for a fair comparison, the printer model, material utilised, slicing software, and printer parameters were kept the same between each pair of modified/unmodified sockets. After printing, some of the pairs of sockets required light manual sanding. This was due to a process called 'stringing', where the extruded material exiting the nozzle of a FFF printer is stretched across a hollow section of a print creating small 'strings' of unwanted material.

5.2.10 Survey Preparation

In order to obtain feedback from the participants regarding the 3D printed sockets, several standardised interview questions were prepared. The aim was to keep the discussion semi-structured, so that the participant's responses could easily be collated, whilst still leaving scope for discussion with the participants. It was necessary to devise custom interview questions for this study as currently, no scales evaluating socket fit and comfort are validated for upper-limb amputees. The survey consisted of multiple choice questions, denoted 'MC', and open ended discussion-based questions, denoted 'D'. Where likert scale answer options were provided, detailed descriptions of each 'level' 1-5 were provided to assist the participant in choosing an answer. All questions and potential multiple choice answers can be found in Appendix C.2. The survey comprised the following Sections:

5.2.10.1 Survey Part 1: Socket Comfort

Section 1 of the survey was designed to investigate how the participants felt solely about the comfort of the socket. The questions, and the reasons they were asked, were as follows:

(a) What are your initial thoughts wearing the socket – is there anything you notice that is particularly comfortable or uncomfortable? **(D)**

(b) On a scale of 1 – 5 where 5 is the most comfortable and 1 is the least comfortable – what would you rate this socket? **(MC)**

(c) Which area(s) do you find to be the least comfortable about the socket? **(MC)**

(d) Which area(s) do you find to be the most comfortable about the socket? **(MC)**

(e) Are there any specific areas of the socket that you think need modification? If so, where and how? **(D)**

Question 1(a), was proposed as an open discussion. The participants were encouraged to share their initial thoughts and their responses were transcribed. Question 1(b) was proposed as a 1-5 likert scale, where 5 was the most comfortable, and 1 was the least comfortable, with detailed descriptions of each level. The descriptions of each level can be found in Appendix C.2.

To obtain a more detailed picture of the specific issues (if any) the patients had with the sockets, three further follow up questions were asked. Question 1(c) and 1(d) explored which areas of the sockets the participant's found to be the most and least comfortable, with the choice of: trimlines, 'elbow grip' (a simplified term for the supracondylar suspension provided by the wings), the amputation site/distal end of the socket, or 'other'. Participants were encouraged to select all that applied. Question 1(e) was proposed as another discussion question, to ensure any issues that were not covered previously regarding socket comfort were raised.

5.2.10.2 Survey Part 2: Socket Suspension

Section 2 of the survey was designed to explore how secure the participants felt wearing their diagnostic sockets. The questions comprised:

(a) On a scale of 1 – 5 where 5 is the most secure and 1 is the least secure – what would you rate this socket? **(MC)**

(b) On a scale of 1 – 5 where 1 is too tight and 5 is too loose – what would you rate this socket **(MC)**

(c) Do you have any comments you would like to add about the security or tightness of the socket? **(D)**

Socket comfort and socket suspension can often be antagonistic to each other. A looser, more comfortable socket may not provide sufficient suspension, and vice versa. Due to this, questions 2(a) and 2(b) were included to determine whether the socket was sufficiently affixed to the limb and uncover any concerns that participants had about the socket slipping off. As in Chapter 5, Section 5.2.10.1, question 2(c) concluded the Section with an open-ended discussion to ensure the participants could share all of their concerns without restriction.

5.2.10.3 Survey Part 3: Wear Duration

As comfort and socket 'fit' can be very subjective, Section 3 of the survey was added to give a quantifiable measure regarding how long the participants believed they could tolerate the sockets.

(a) On a scale of 1 – 5 where 5 is the longest duration and 1 is the shortest duration – how long do you estimate you could use this socket without experiencing pain or discomfort? **(MC)**

(b) Do you have any comments you would like to add about how long you estimate you could wear this socket without experiencing pain/discomfort?

For question 3(a), a likert scale of defined durations was used to gauge the participant's views on this question. The options ranged from being able to wear the sockets all day without pain or discomfort (option 5) to not being able to wear the socket at all for any length of time due to discomfort (option 1), as detailed in Appendix C.2. As above, this Section of the survey concluded with an open ended discussion question, 3(b) to capture any of the participants further views.

5.2.10.4 Survey Part 4: Comparison to Own Socket

As in Chapter 5, Section 5.2.10.3, this Section was added to provide another method of gauging the success of the 3D printed sockets.

> (a) If you use a rigid socket regularly (i.e. without a gel liner): on a scale of 1 – 5, where 5 is much more comfortable and 1 is much less comfortable – what would you rate this socket compared to the socket you use regularly? **(MC)**

As before, a likert scale of options was provided to the partipants to assist in answering the question.

5.2.11 Testing Protocol

The participants were provided with the modified (labelled socket 'A') and the unmodified socket (labelled socket 'B'). Participants had no indication as to which socket was which. The sequence in which the sockets were tested was balanced so that half tried the unmodified first and half tried the modified socket first. In the case where a participant had several pairs of sockets produced for them, they were asked to try all 'A' or all 'B' sockets (depending on their testing sequence), choose which trimline was the most appropriate for them and all other pairs were discarded. Each participant only provided feedback for one modified/unmodified set of sockets. All participants completed the survey in the presence of the interviewer and the supervising prosthetist. Any responses from the participants which were outside the scope of the likert scale answers provided, or involved verbal comments, were noted by the interviewer.

Figure 5.3(a) depicts an example of a pair of sockets, and Figure 5.3(b) shows a participant trying their unmodified socket. During testing, no terminal device or load was connected to the socket. To assess the suspension of the sockets, the participants were asked to assume the scanning position whilst wearing their sockets, as defined in Chapter 5, Section 5.2.8. Once in position, a slight, brief, downward force was applied manually to the distal end of the socket. After the survey, participants were notified as to which sockets had been modified and which had not. After that, participants were encouraged to try on the sockets again and provide any further comments if they wished to do so. Several participants elected to try their own sockets

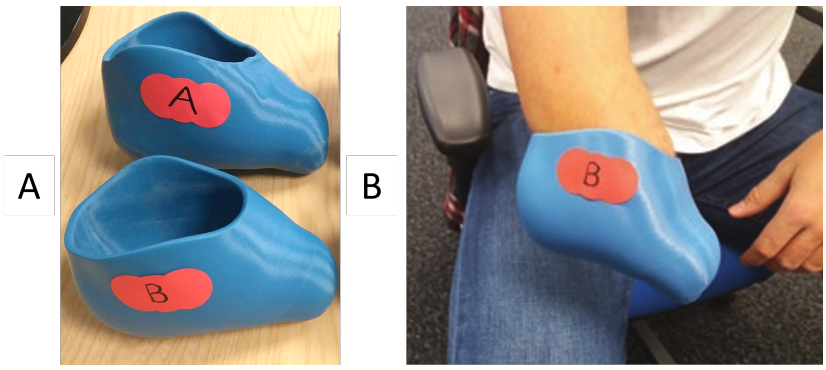


Figure 5.3: (a) A pair of modified and unmodified sockets. (b) A participant testing their 'unmodified' socket, marked as socket 'B' to preserve the ambiguity of testing order during the feedback session

alongside the 3D printed ones for comparative purposes. Participants who usually used limb socks were allowed to to try the 3D printed sockets on with limb socks if they wished, to allow a closer comparison to what they were accustomed to.

5.3 Results

The results of this study are divided into two main Sections. Firstly, the practical and financial differences of both digital and conventional socket creation are compared quantitatively. Secondly, the feedback from the participants is presented, with key quotes included.

5.3.1 Quantitative Analysis

Depending on factors such as lighting, marker adhesion and the texture of the participant's limb, scanning required approximately 2-15 minutes per residuum. Completing the rectification process in the aforementioned Autodesk CAD suites required approximately 30 minutes to process the raw scan into a final set of modified/unmodified sockets. It was possible to create sets of sockets for all of the participants. The time taken to print the sockets ranged from 12 hours for the fastest print to 17 hours for the longest print, with an average of 15 hours for the participant pool. The removal of support material and hand sanding after the sockets were printed required

around 5 minutes per individual socket. The weight of the sockets averaged at 93.6g using the slicer-calculated value (inclusive of the support material which was later removed). Each socket cost ≈£3 when using PLA filament, ≈£9 for PLActive, and ≈£10 for Taulman's Guidel!ne™, calculated using the slicer-provided filament useage per print. The specific print times and filament weights calculated for each participants's sockets can be found in Appendix C.4. The software used to process the scans were all free for academic use. For a regular license, Autodesk Recap costs £390 annually and Autodesk Fusion costs approximately £420 annually. Autodesk Meshmixer, Ultimaker Cura and Raise3D's Ideamaker are all free to use.

5.3.2 Survey Results

Four of the six participants (P1-4) were able to take part in the feedback session. One participant's (P5) sockets were too loose for them to provide conclusive feedback, thus they were unable to complete the survey. Additionally, the feedback session with another participant (P6) was terminated prematurely to prevent patient harm. A particularly sensitive area of the patient's limb was not disclosed or discussed during the initial medical history interview with the participant prior to scanning their limb. Consequently, trialling the 3D printed sockets may have caused them discomfort. The responses from the four participants who did complete the survey are summarised below. In all Sections, the italicised texts are verbatim quotes from the participants. Interview transcripts in their raw form can be found within Appendix C.3. During the interview, the participants were asked to clarify any answers they gave that were inconclusive. The notes in Appendix C.3 do not include any discussion that was unrelated to the study, i.e. general conversation with the participant. The comments provided by participants were utilised to generate categorical data, which comprised responses such as 'satisfied', 'adjustment required', and 'dissatisfied'. It is challenging to gauge how satisfied an individual is with their socket because assessing socket comfort and fit is largely subjective, even in clinics. Positive feedback with no complaints was categorised as 'satisfied', positive feedback with minor concerns was categorised as 'modification required', and significant issues or mostly negative feedback was categorised as 'dissatisfied'. A summarised view of the results regarding comfort and suspension can be seen in Figure 5.4.

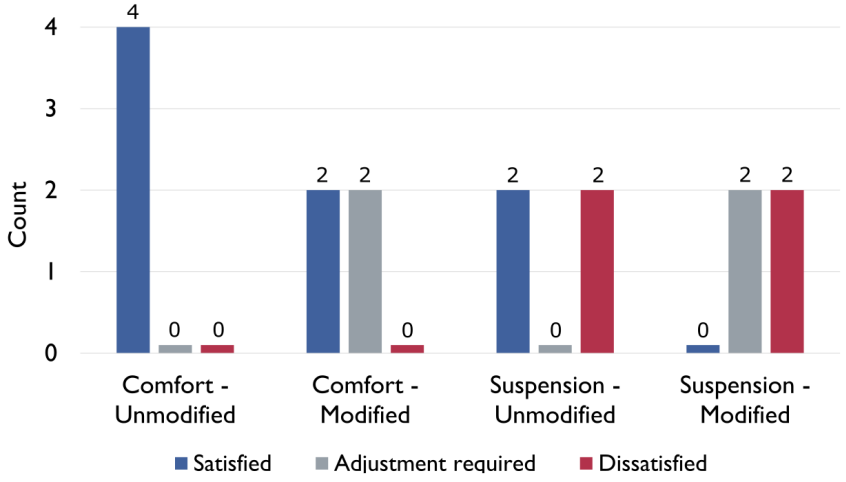


Figure 5.4: A summarised overview of the participants' experience with the two main components that determine socket fit: comfort and suspension, corresponding to part 1 and part 2 of the survey results.

5.3.2.1 Survey Results Part 1: Socket Comfort

During testing, all four participants reported that their unmodified socket was *very comfortable*. The opinion from the modified sockets was divided: two participants reported their modified socket was *very comfortable*, whilst the other two participants raised minor issues with the modified sockets that needed to be improved. One participant (P1) quoted, regarding their unmodifed socket:

> *... the most comfortable socket I've ever tried.*

Overall, comfort was scored exceptionally favourably in the responses, with only minor issues raised by the participants. In terms of specific issues raised, two participants (P3 and P4) stated that they would prefer if the trimline, specifically in the area above the olecranon, was lower in both their unmodified and modified sockets. One participant (P4) stated:

> *... it's not uncomfortable, just different to what I usually use.*

Similarly, two participants (P1 and P2) reported tightness around the inner wing of their modified sockets. One participant (P2) said:

... the inside wing causes a bit of friction, which if I wore it for a long time might get sore.

Overall, the localised issues that were raised by the participants were all quite minor and concerned the socket trimlines, the wings and proximal contouring applied in the CAD modification stage.

5.3.2.2 Survey Results Part 2: Socket Fit

Two participants found their unmodified socket to be secure when a physical force was applied to check the suspension. The other two participants found their unmodified suspension to be entirely inadequate. The results for the modifed socket were even less favourable, with two participants requiring improvements to suspension, and two finding the suspension entirely dissatisfactory. For one participant (P1) who was satisfied with the suspension of their unmodified socket, remarked that they believed they could:

... suspend my entire bodyweight with this (socket).

In contrast, one particpant (P3) who was dissatisfied with the suspension that was accomplished stated about both their modified and unmodified sockets that:

It's not secure. I can take it off easily.

In general, the suspension of the sockets was inadequate. Despite this, the majority of participants felt more secure in their unmodified socket than the modified variant.

5.3.2.3 Survey Results Part 3: Wear Duration

For both their unmodified and modified sockets, one participant (P3) believed they could wear their socket 'all day' when asked how long they thought they could tolerate their sockets without experiencing pain. Two participants (P1 and P4) were apprehensive about their modified socket but believed they could wear their unmodified socket all day. Due to issues with the inner wing, one participant (P2) was uncertain they would be able to tolerate either of their sockets for an extended duration of time.

5.3.2.4 Survey Results Part 4: Comparison to Own Socket

Two participants (P2 and P3) stated that they preferred their regular socket above both of their 3D printed sockets when asked to compare the two. One participant (P4) was uncertain of how to compare the sockets because they were so different from what they were familiar with. One participant (P1) liked their unmodified 3D printed socket more than any they had ever been given from professional limb clinics.

5.3.2.5 Survey Results: Additional Comments

Following the conclusion of the structured interview, several participants opted to provide further comments. Participant P1 remarked:

> *... I prefer this (method)... some of my sockets have required so many refitting sessions and visits to the clinic... it took so much time... you have demonstrated that you can create a socket that fits perfect and has all the requirements including load bearing and has very little or no pressure points.*

When their scans were displayed on a screen, multiple participants stated that they were impressed by the degree of detail produced by the inexpensive digital scanner.

5.3.2.6 Results Summary

Overall, success rates for achieving a socket which the participant found to be comfortable and secure was low. Complete socket satisfaction was only achieved with two participants (P1 and P4) with the unmodified socket variant. Socket suspension was a significant issue, affecting at least one variant of each participant's sockets. The stages at which the digital manufacturing method 'failed' each participant is shown in Figure 5.5.

5.4 Discussion

In this study, the aims were to assess whether trans-radial diagnostic sockets could be reliably produced using 3D printing and digital scanning by a novice operator. Success was gauged via feedback from participants, using a custom questionnaire, and through clinical observation and commentary.

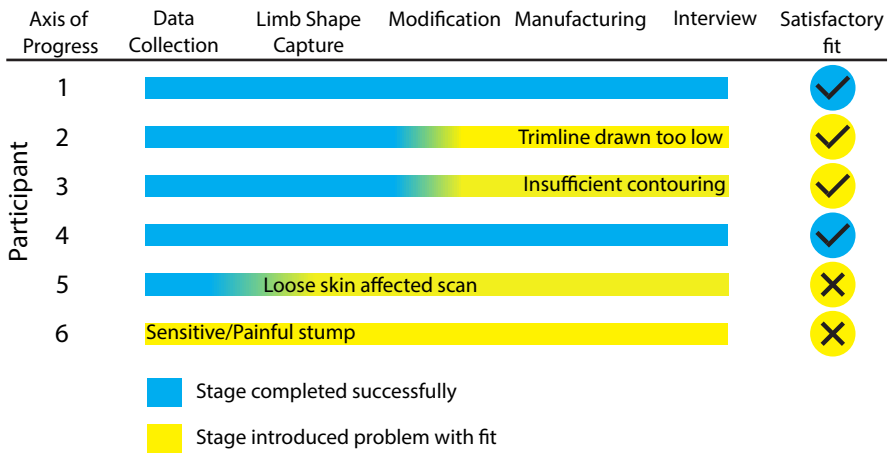


Figure 5.5: A chart outlining the several production steps that influenced the way the sockets fit. The chart indicates how satisfied each participants was overall, and if applicable, at which stage of manufacturing the digital method 'failed'.

It was found that digital methods can be used to successfully create comfortable and well-fitting upper-limb diagnostic sockets, however not reliably. The method was vulnerable to many of the same issues faced by prosthetists using traditional methods, e.g. the skill of the operator. The study provided many learning opportunities regarding modern socket production techniques. In the following discussion section, an expert clinician's commentary is provided, covering why it was likely certain sockets succeeded where others failed. Secondly, the results of the study are reviewed and the limits of the study and potential future research directions are discussed. In the final Sections, the safety and legality of 3D printing, as well as any potential future advantages are discussed alongside the contrasting priorities and opinions of the scientific and clinical stakeholders in socket manufacturing.

5.4.1 Clinical Commentary

It appears the technical team's lack of clinical experience played a significant role in the occasions where participants were dissatisfied with their sockets. The biggest issue, according to participants P2 and P3, was the fit of the wings, trimlines, and proximal contouring. Similar to the conventional socket making workflow, even relatively minor adjustments to the digital

CAD rectification process may have resulted in noticeably different comfort and security levels. When deciding how to adjust the socket, modifications are typically based on experience, and frequently the *feel* of the limb is a crucial consideration. These approaches are extremely challenging to adapt into a digital process, especially for inexperienced operators. The sockets provided to participant P5 were too loose, likely due to loose skin on the remaining limb. This was likely to have been avoidable with the use of a limb sock, as it would have compressed and smoothed the tissues during the scan, as the socket would once donned. Hence, optical scanning alone can be prone to failure when it comes to collecting complex physical traits required for optimal fit. A particularly sensitive region around the epicondyles of participant P6 was not noted during the interview and therefore was not taken into consideration during the diagnostic socket modification. Irrespective of the method used to manufacture participant P6's sockets, this issue would mean they would need to be altered or re-made from scratch.

Prosthetists see significantly more patients with lower-limb difference than upper-limb, and out of the upper-limb population, many have relatively unique amputations and daily-living needs from their prosthesis [99, 261, 262]. Consequently, it is to be expected that the existing ISPO standards do not specify one singular technique or material in order to manufacture upper-limb sockets. It is challenging to capture and recreate conventional processes in a digital workflow. The two alternatives available to clinicians who want to include digital approaches into their practices are to create their own workflow or invest in a pre-made prosthetics and orthotics software package. Traditional CAD software packages are incredibly adaptable but also involve a difficult transition period, because they were not created expressly to produce prostheses and therefore have a high skills barrier to entry. As an alternative, specialised prosthetics and orthotics CAD software is available, for example the CanFit™ system developed by Vorum [36], or WillowWood's OMEGA™ system, both comprising proprietary scanners and complementary software [263]. However, these systems are generally expensive, both in terms of initial outlay and cost per socket. Additionally, there is little published research examining the potential benefits and limitations when they are used for upper-limb populations.

Additional research is required to determine the failure modes of 3D printed sockets. In terms of rigidity and other qualities, conventional textile-resin composite sockets are dependable and generally behave predictably, even if their strengths and properties can vary. To guarantee that pros-

thetists can employ digital techniques with confidence, clinically validated mechanical testing of a range of materials and designs when applied specifically to socket making is necessary.

5.4.2 Study findings

This study trialled a realistic digital adaption of the conventional approach for manufacturing sockets for the upper limb. Due to this, low-cost technology with a low skills barrier to entry was utilised. Individuals with transradial upper-limb difference evaluated the sockets and provided feedback regarding comfort and suspension. Expert clinical opinion and supervision was solicited to analyse the feedback from participants first-hand, and explain why particular complications arose. The findings of the study indicate that modern technology is susceptible to the same issues as conventional socket manufacture when not operated by an expert. Therefore, swapping to a technology-based method is unlikely to standardise the levels of care a patient receives, and instead still relies heavily on the skill of the prosthetist. This corroborates anecdotal evidence that using an uninformed plug-and-play strategy for creating prostheses using optical scanning and 3D printing is improbable to yield adequate results [264].

Frequently, the primary justification for using 3D printing and digital scanning in prosthetics is that they are quicker, less expensive, and more effective than conventional techniques [31, 265]. Quantifying any time or money savings made possible by modern digital workflows is challenging due to the scarcity of documents pertaining to the procedures in conventional prosthetics and orthotics clinics. In Figure 5.6, the estimated timeframe of the digital socket manufacturing approach from this study is displayed in comparison to conventional methods. As shown in Table 5.2, the digital manufacturing saves time compared to common traditional manufacturing pathways, assuming no mistakes are made. However, as shown in Figure 5.6 the key benefits are not necessarily just time savings, but instead a decreased need for human labour in the event of a mistake, i.e. eliminating the need for a second plaster casting. However, given the rate at which the 3D printing sector is growing, it is fair to expect 3D print speeds will rapidly increase. If this occurs, digital workflows may soon be able to offer same-day prostheses with minimal manual labour, when operated by a clinical expert.

In clinics, the prosthetist can try the cast on the limb prior to the plaster pour and rectification stages. This means that generally, the prosthetist

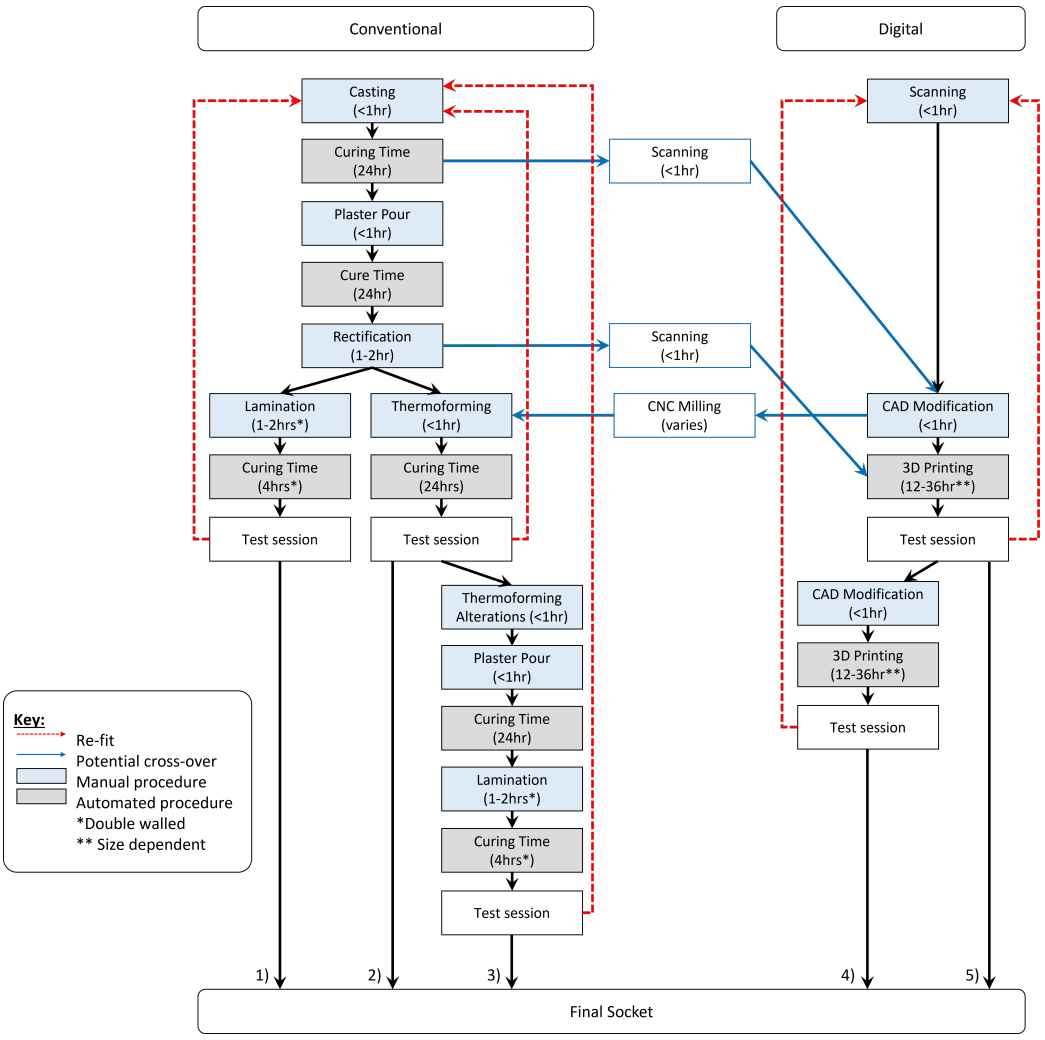


Figure 5.6: A flow diagram showing estimated socket manufacturing times using conventional and digital methods. Timings approximated using [31–37] and both the University of Salford and University of Strathclyde socket manufacturing guidelines for: 1) Lamination only. 2) Thermoforming only. 3) Lamination with a thermoformed diagnostic socket. 4) 3D Printing with a diagnostic socket. 5) 3D Printing only.

will already know what post-casting rectification and sculpting needs to be undertaken to ensure adequate suspension and comfort. When using a completely hands-free scanning method, that opportunity is lost. Additionally,

Table 5.2: A table of the manufacturing times associated with each method, and the time added per re-fit if that method was used. DS = Diagnostic Socket, D = Draped.

Method	Manufacturing Pathway	Minimum Time (hours)	Maximum Time (hours)	Time Per Refit (hours)
Conventional	Lamination (without DS)	56	58	+ 56-58
	Lamination (with D-DS)	107	109	+107-109
	Draping (without DS)	76	77	+76-77
Digital	Without DS	14	38	+14-38
	With DS	27	75	

if digitising the process reduced the amount of contact-time prosthetists had with patients, it would remove some of the opportunities for patients to share their concerns with their clinician. However, there are potential benefits to using digital methods in the manufacturing stages of socket creation. Typically, any comfort or suspension issues are addressed in clinic during the initial fitting appointment with the patient, either with the final socket or an intermediate diagnostic socket. Using digital tools, there are several methods by which this rectification could be made possible. Due to the extruded nature of FFF printing, many 3D printer filaments can be thermoformed indefinitely. Hence, a 3D printed socket could be heated and reshaped in the same manner as a diagnostic or thermoformed socket, and therefore could also serve as the final socket. This would eliminate the need for a second plaster pour, whilst also allowing a wide variety of materials and socket shapes to be created. Alternatively, if a 3D printed socket was not desired, the adjustments required to make the socket fit better could be approximated on the CAD model, or the inside of the re-worked PLA diagnostic socket could be scanned and digitised, as seen in Figure 5.6. Although promising, it is evident from Figure 5.6 that in certain circumstances, the conventional method may be more efficient. Crucially, regardless of the tools or methods used, the element of prosthetist skill cannot yet be separated from socket fitting when the capabilities and limitations of modern technology are observed.

5.4.3 Study Limitations

A consequence of using a low-cost scanner was that the limb scans could not be viewed in colour. Subsequently, it was very challenging to create the trimlines and mould the shape of the wings in CAD. In order to draw the trimline cut, it is crucial to mark the appropriate parts of the limb as preparation. If a scanner with more functionality had been used, limb markings would have been utilised. The existing clinical standard method of making sockets might be more closely compared in a future research study by using a scanner and software combination that captures colour. However, scanners with such capabilities would require a higher cost outlay, which was not the aim of this study.

The questionnaire used to obtain feedback from the participants was bespoke for this study, and therefore not validated. This was necessary, as a suitable upper-limb survey does not exist. A valid upper-limb socket assessment survey would have been preferable if available, and should be developed to facilitate studies such as described in this chapter. Additionally, the sample size was relatively small (n=6). This is typical for preliminary upper-limb studies, due to limited numbers of upper-limb different individuals available and willing to participate in research within a given region. Future work into this area should use a wider population size, and ideally include paediatric volunteers. It was not possible to account for participant's familiarity with their own sockets resulting in potential negative feedback towards the 'new' sockets. This issue could affect both conventional manufacturing methods or novel ones such as the method presented in this study. Asking for wearer feedback on prosthetic sockets is highly subjective, as covered in Chapter 3, hence this was an unavoidable limitation of the study.

Out of the six participants, only two individuals found either of their sockets to be secure, despite the fact that the majority of participants found their sockets to be quite comfortable. However, attaining socket comfort without socket suspension is virtually pointless, and vice versa. Future studies should look at how digital techniques might be used to provide better socket suspension for upper-limb patients.

The diagnostic sockets were only worn by the participants for a brief period of time, up to approximately 20 minutes, and with no terminal device connected. Only a brief, manual, downwards force was applied by the supervising prosthetist to assist with gauging the suspension. As a result, the security and comfort while supporting weight were not evaluated thoroughly.

In a future study, it would be insightful to evaluate the socket whilst a permanent load or terminal device was attached, and whilst the participant used the device in various angles and positions. Furthermore, if loading is introduced, the safety of the sockets under load would also need to be considered. This could be achieved by either conducting mechanical testing or stress modelling as a precaution. In this investigation, only the SSOS style socket was created due the the length of the residual limbs present in the participant pool. Future research should include individuals with different lengths and shapes of trans-radial residuums and take into account additional socket styles that could be more effectively adapted to a digital workflow, i.e. those that require less contouring. The success of the socket as a whole depends on correctly choosing a socket design that is appropriate for the length of the residual limb.

5.4.4 Safety and Legality of 'Modern' Socket Manufacturing Techniques

The durability of upper-limb prosthetic sockets is poorly documented [266], as a variety of variables influence the mechanical characteristics of the finished product [266–268]. It has been shown that lower-limb sockets made via 3D printing can unexpectedly fail entirely [269]. However, due to the existence of the international standard for safety and durability testing of lower-limb prosthetic devices (ISO 10328/2016), 3D printed trans-tibial sockets have shown encouraging results [194, 266]. As there is no upper-limb equivalent standard, comparing the safety of novel methods is difficult - especially in the case of 3D printing, as the choice of raw materials and slicing options are essentially endless. Some studies have questioned whether digital scanning is as effective as conventional limb-shape capture techniques [270]. As with 3D printing, the equipment and conditions in which the scan is taken can affect the end result dramatically. Additionally, it is difficult to translate research into clinical practice since prosthetics and orthotics learning centres are not required by ISPO guidelines to teach students about digital approaches. Given that the aim of this study was to test the benefits and vulnerabilities of the method used, not to produce final, usable sockets, the final strength and material properties of the sockets was not taken into consideration for this study. Future studies investigating 3D printing as a method for producing final sockets should take this into consideration.

5.4.5 Media Representation

Whether the user wants their limb to look natural and anthropomorphic, or intentionally 'stand-out' with a futuristic design, the aesthetics of prosthetic limbs are undeniably important [50]. This sets prosthetic limbs apart from many other medical devices, which rarely cross-over into the territory of being considered fashionable or a device for self-expression. Hence, prosthetic limbs feature frequently in media coverage, for example, Openbionics obtained brand endorsements from Disney, Marvel and several high-profile celebrities to promote 3D printed prostheses.

Unfortunately, misconceptions concerning the use of digital technology, such as 3D printing, in the creation of upper-limb prosthetics has been exacerbated by media accounts [264], possibly due to the general audience they are targeted towards. Consequently, the ethos that modern technology is a ready-made solution and a necessary replacement for 'old' conventional methods of socket creation has proliferated. The clinical community is aware that this is far from the current reality. In practice, clinics first introduced some elements of digital manufacturing methods around 30 years ago [271], but they have yet to be incorporated in widespread standard practice. For example, digital scanning is sometimes adopted into NHS socket making [239], albeit for lower-limb sockets, and it is quite uncommon.

5.4.6 Researcher's Commentary

As discussed in Chapter 3, the complex and delicate manual manufacturing procedures performed in prosthetics clinics are not well documented, and the way in which different clinicians create sockets is rarely investigated [272]. There are widespread discrepancies in different clinician's approaches to socket manufacturing, since procedures are largely based upon their own experiences, opinions and implicit knowledge [32, 204, 205, 255, 273]. The term 'prosthetist and orthotist' is named as a 'protected profession' in many European countries, and most developed nations employ a similar regulatory system [274–276]. This protection means that only qualified individuals are allowed to design, prescribe and administer prosthetic devices in the areas in which the regulations apply [274–277]. Although well-intentioned, the availability of instructions and cheap materials to construct DIY prostheses either for personal use or donation to limb-charities is concerning from a safety perspective [278]. This is because they have the potential to cause harm if

manufactured incorrectly [278]. This issue emphasises the need for discretion when sharing information about clinical socket manufacturing in accessible and public formats [164]. Consequently, it is difficult for researchers working within prosthetics, but outside of the clinical field, to comprehend and appreciate the highly skilled techniques required to make a socket fit successfully.

5.4.7 Potential Benefits

Outside of the actual socket creation process, digitisation presents a wide range of possible benefits. In contrast to conventional approaches, digital scans and designs can be quickly saved and disseminated via the internet in real-time. These advantages would enable a more consistent quality of treatment regardless of location by allowing clinicians and consumers to consult with peers and experts in the field. Shared digital data may be of great use when supplemented by clinical notes outlining the results of specific prosthetic procedures. Such information would make it possible for prosthetists working on uncommon or difficult cases to look for related instances and contact colleagues with relevant experience, which in turn would speed up the process of producing a successful socket. Prosthetics treatments captured digitally throughout time would yield measurable data that may one day be used to train computational techniques. For example, enhanced data sharing would allow trends to be observed as to which limb shapes and socket styles are better suited to digital manufacturing. The use of computational methods like finite element analysis, which has been suggested to enhance the loading conditions inside sockets, is also made possible by digitisation [169]. Additionally, common 3D printer filaments such as PLA, which is recyclable back into filament form, have the potential to reduce the amount of discarded sockets going to landfill, which is not currently possible with thermoset resin-textile composite sockets.

Additionally, .. requires the disposal of the plaster moulds. Similarly, lamination produces thermoset devices, which cannot be repurposed or remoulded. It is worth mentioning drape forming can be used to make final sockets, and although rare for UL final sockets, it can be remoulded. However, PLA, a common 3D printer filament is both thermoforming and has the potential to be recycled and turned back into a useable filament.

5.5 Conclusions

A completely digitised, affordable approach to creating trans-radial diagnostic sockets was devised and investigated in this research study. Participants' opinions were sought in the form of an interview and survey, supervised and informed by clinical expertise. Safety issues and the possible advantages of using computerised technologies for socket generation were reviewed along with the divergent viewpoints of the scientific and clinical sectors. Regardless of the techniques utilised, the study's findings showed that clinical competence is essential for producing prosthetic sockets that fit well. To enable clinicians to make educated choices about whether and how to use digital manufacturing in their clinics, the discussion emphasised the necessity for regulated and enhanced safety testing of 3D printed prostheses. For the development of digital solutions that benefit patients and clinicians, more cooperation between the clinical and research communities is necessary.

5.6 Chapter Summary

- A workflow comprising a combination of 3D printing, CAD software and digital scanning can be used to create prosthetic sockets, but their success heavily depends on the clinical experience of the operator, as with traditional methods.
- There are many potential benefits of digital manufacturing methods. However, there are practical hurdles to overcome before they can be considered a viable option in clinics, such as the ability to document tactile information about the limb when using non-contact limb capture methods like digital scanning.
- Regulated and enhanced safety testing is required to assess the safety of 3D printed prosthetic sockets.
- This work was conducted to counter glamourised media reports which have led to the public belief that current upper-limb prosthetics are more capable and reliable than they are.

Chapter 6

Remote Creation of Trans-radial Bypass Sockets

As emphasised in Chapter 5, regardless of the tools used to create the socket, the input of an experienced clinician is critical to the socket manufacturing process. In this Chapter, a hybrid approach is used: non-clinical researchers perform the initial stages of manufacturing a clinical-standard bypass socket, while a clinical team performs the final stages remotely. This study had two primary goals. First and foremost, the study was designed to enable socket-based research that would have been impossible to complete without access to custom-made bypass sockets during the COVID-19 lockdown. However, the primary goal of this study was to investigate whether this method could be applied to regular socket fittings with some modifications and thus provide home-based care to individuals in need of a new prosthetic socket.

> *Remote Creation of Clinical-Standard Myoelectric Trans-radial Bypass Sockets During COVID-19* (J. Olsen, J. Head, L. Willan, S. Dupan, M. Dyson, 2021) is published in 43rd Annual International Conference of the IEEE Engineering in Medicine & Biology Society *(EMBC)*.

6.1 Introduction

As discussed in Chapter 5, in-person clinic visits are almost always required for patients seeking a new prosthetic socket, and the expertise of a prosthetist is critical to the socket's outcome. However, there are numerous reasons why visiting a clinic may be impractical. Due to mobility issues, living a long distance away from their limb clinic, or leading a busy lifestyle, amputees may find frequent visits to their prosthetist inconvenient. However, amputees are not the only group affected by this problem. There is currently no standardised or convenient method for researchers to obtain clinical standard devices for experiments.

Upper-limb patients are a relatively small sub-set of the amputee population [279]. In order to operate a myoelectric prosthesis, training and occupational therapy is of paramount importance [279]. However, when recruiting for prosthetics studies, people who have never used a prosthesis before, referred to as 'naive' or 'novice' participants, are frequently required [279]. Consequently, limb-intact volunteers are frequently recruited for research studies, especially for piloting and early-stage research, as there are more people in this category who are reliably available. This way, limb-different volunteers are not 'wasted' on pilot studies which may not work. Subsequently, using a 'bypass socket' with limb-intact individuals is one common method used to investigate prosthesis control. [42]. Bypass sockets are intended to allow people who have intact limbs to wear and operate a terminal device, such as a prosthetic hand, in a way that mimics wearing a prosthesis [42]. There are several designs of trans-radial bypass sockets available, [42], some of which can be used with many different limb sizes, [107, 118, 280–285], while others are custom-made for each individual wearer [286, 287]. Custom fitting bypass sockets are generally form-fitting devices manufactured to a clinical standard in a procedure very similar to that of a standard socket. As a result, visiting a prosthetist in a limb-centre is usually required in order to obtain this type of bypass socket. Obtaining clinical-standard devices is especially difficult for research labs without a nearby limb-centre or partner hospital.

Consequently, developing a remote-fitting method that allows the prosthetist to handcraft the socket in clinic could benefit both patients and researchers. For patients, the option for remote fitting could save them time and reduce disruptions to their lives. This would be consistent with the UK National Health Service's (NHS) long-term plans. Chapter 4 of the 'NHS Long Term Plan' to be implemented between 2020 and 2025, outlines plans

to make care more accessible by enabling the widespread use of digital tools across the NHS, such as allowing outpatient appointments to be made virtually [288]. Meanwhile for researchers, a remote socket creation method could allow research to continue when travel is not possible or practical. For example, when travel restrictions were imposed during the COVID-19 pandemic, the relevance of a clinically validated remote-fitting technique became evident.

Due to social distancing guidelines and travel restrictions, visiting clinics became impossible throughout the COVID-19 lockdown. The majority of experimental protocols could be modified to comply with the regulations and guidelines in effect at the time in order for ongoing prostheses control studies to continue. Many of the studies, however, were entirely dependent on the availability of custom-made bypass sockets. There were no guidelines in the literature at the time on how to remotely fit trans-radial sockets or bypass sockets [289]. As a result, in order to facilitate the progression of several time-critical research studies, it was necessary to develop a novel method for creating bypass sockets remotely while still utilising a prosthetist's expertise and artisan skills.

The aim of this research was to see if digital techniques like 3D printing, CAD software, and digital scanning could be combined with traditional processes like plaster casting, hand sculpting, and lamination to create successful, clinical-standard trans-radial bypass sockets. The objectives of this study were to develop a novel manufacturing procedure, produce several sockets remotely, and evaluate them with volunteers for comfort and myoelectric control ability. It was hoped that by validating this method for creating bypass sockets as a proof of concept, a clear method for creating actual prosthetic sockets for limb-different individuals could be proposed. The work was a collaboration between a technical team at Newcastle University (UK) and a clinically trained team at the University of Salford (UK).

6.2 Methodology

Two limb-intact participants were recruited for the study. Ethical approval was obtained (Ref: 20-DYS-050), attached in Appendix A.3, and all relevant COVID-19 guidance was followed. Both participants were myoelectric-control researchers in need of a custom-made trans-radial bypass socket. To be clear, the term 'technical team' refers to the Newcastle University re-

searchers that performed the optical scanning, 3D printing, and digital aspects of the following socket fitting procedure. Similarly, the term 'clinical team' refers to the clinically trained researchers and technicians at the University of Salford who remotely carried out the 'conventional' steps of the socket manufacturing process. To facilitate this, a novel workflow was developed, and the process followed is outlined below. The sockets were then tested by the technical team in Newcastle with the participants. The bypass socket's ability to facilitate myoelectric control and the overall comfort of the sockets were used as metrics for success.

6.2.1 Technical Steps Workflow

A physical model of the limb had to be present with the clinical team at the time of socket creation in order to incorporate the prosthetist's tactile skills into the final socket. Plaster casting in person, however, was not possible due to travel restrictions imposed during the COVID-19 pandemic. As a result, optical scanning was chosen as an alternative method for capturing each limb's geometry. In summary, 3D printed 1:1 scale replica models of the limbs were produced. The models featured tactile markings to allow the clinical team to find key areas of the limb, such as the EMG sites. To achieve this, scanning, CAD modifications and 3D printing were undertaken. The models were then sanitised and posted to the Salford clinical team. The steps of these procedures are outlined in detail below.

6.2.1.1 Pre-scan Preparation

Prior to the technical team commencing scanning, the clinical team was consulted to document what they would normally do during a regular socket casting. The goal was to use digital tools to replicate this procedure as closely as possible. The clinical team advised that during a casting, patients would be told to make a fist with their palm facing inwards, while holding their forearm at 70 degrees elbow flexion, with the radius stacked directly above the ulna. A prosthetist would usually check the angle during the plaster cast, and patients would be required to hold this position until the cast dried. To replicate this, the same positioning was used whilst the participants maintained the scanning position. A 70 degree cardboard protractor was printed so that the angle of the participants' arms could be easily checked before and during the digital scans. Additionally, as is customary for most

socket-fitting methods, measurements of key areas of the limbs were taken. The measurements taken were the length of the limb, from the olecranon process to the wrist joint, and the total width at the epicondyles. These were taken to verify the scanner had accurately captured the limb to the correct scale and to assist the clinical team during later stages of manufacturing. Because the bypass sockets' primary function would be to facilitate myoelectric control, it was necessary to locate suitable EMG sites on each participant. The procedure to locate and mark the EMG sites for the wrist flexors and extensors is detailed in Chapter 4, Section 4.6.1. An example of the marks made prior to scanning can be seen in Figure 6.1(a). Then, to simulate how a prosthetist might fit a typical socket, the limbs of the participants were palpated around the epicondyles and olecranon to identify bony prominences [26]. These areas were also marked on the limb.

6.2.1.2 Scanning Protocol

A Creaform GOScan! 50 [227] was used to scan the limb, following the general procedure outlined in Chapter 4, Section 4.3. The scanner was selected because it enabled colour capture, making it possible to modify the scan in a CAD program whilst viewing the marks on the limb. An example scan is shown in Figure 6.1(a). Each participant underwent the whole scanning process in less than 5 minutes while adhering to COVID-19 regulations. Full details of the scanner's resolution and how the scan was performed can be found in Section 4.3.1.

6.2.1.3 CAD Workflow

Autodesk Meshmixer was used to process the scans. First, any immediately noticeable flaws were manually fixed following the procedure described in Chapter 4, Section 4.4. Such holes and defects can be seen highlighted by the red and blue pins in Figure 6.1(b). In Figure 6.1(c), a digitally corrected model is shown. Once a satisfactory scan with no holes or defects was obtained, the hand section of each limb section was smoothed to remove intricate details. This was acceptable because high accuracy around the hand was not required, and having fewer intricate details reduces the possibility of a failed 3D print.

Using conventional procedures, the markings made by the prosthetist would transfer between all stages of cast taking and plaster pouring. How-

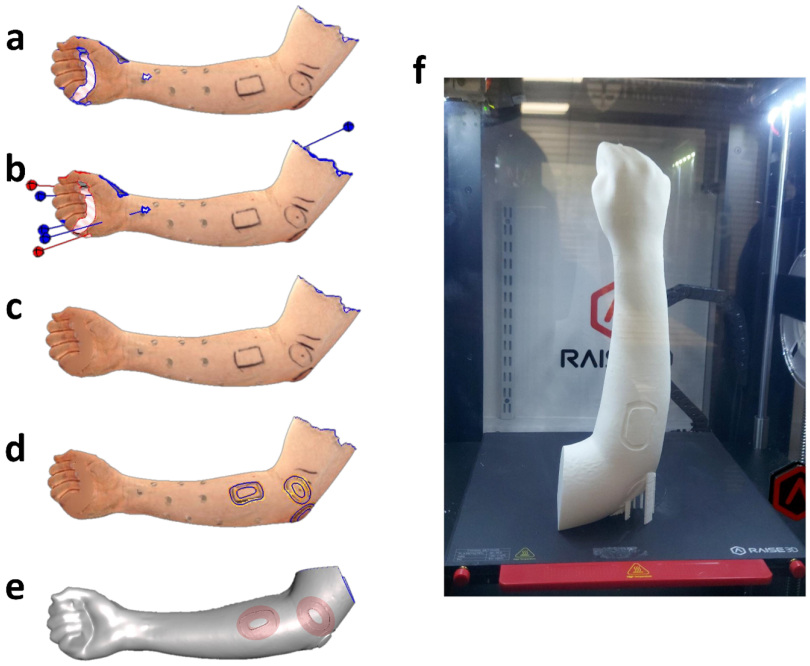


Figure 6.1: The various steps involved in digitally correcting limb scans. (a) A raw, unedited scan showing small defects such as holes and missed areas. The scanning markers and limb markings around the EMG sites and bony prominences can be seen on the limb. (b) The defects in the scan are automatically recognised in Autodesk Meshmixer and highlighted by the red and blue pins. (c) A scan which has had the defects remedied to form a complete mesh free from holes. (d) The markings indicating the positions of the electrode sites and bony prominences were traced manually in CAD. (e) The highlighted areas are recessed to produce a tactile indention on the model, as indicated in red. (f) A 3D printed limb replica featuring the tactile recessed markings to indicate the aforementioned key areas. Before sending the models to the the clinical team, the support material that is visible in the photo was manually removed.

ever, because the scans were going to be 3D printed, the marks visible to the technical team on the scans would not be visible on the final print if another step was not added to account for this. Printing with multiple filaments is possible, so the markings could have been indicated visually by creating a 3D print with two different colours. However, 3D prints with only one active

nozzle, and thus only one filament, are less likely to fail than those with two or more filaments printed concurrently, and can be produced faster and to a higher quality finish. It was decided that creating tactile markings would be more reliable than using a two-filament print. To do this, the marker drawings visible on the scan were manually retraced and recessed into the computer model by 1mm, as seen in Figure 6.1(d) and Figure 6.1(e) respectively. This allowed the clinical team to find and utilise the markings, but did not have a significant effect on the model's geometry after printing.

6.2.1.4 3D Printing Procedure

The models were printed using 1.75mm diameter Raise3D Premium PLA (poly-lactic acid) filament on Raise3D Pro2+ printers. The proprietary slicing software that accompanies Raise3D printers, ideaMaker, was used to prepare the 3D models for printing. IdeaMaker is free to download and use. A layer height of 0.2mm was used as extreme detail was not needed in the final prints. A 20% infill setting was used to strengthen the structure, as it was assumed the print would not need to withstand significant stress. These settings were chosen as a compromise between the quality of finish and speed. For overhanging structures of more than 60 degrees, auto-generated breakaway support was included. In Figure 6.1(f), a complete 3D-printed arm replica can be seen. The breakaway support material was physically removed with tweezers after printing, and the models were then sanitised before being sent to the clinical team.

6.2.2 Clinical Workflow

The second stage of creating the bypass sockets was completed remotely at the University of Salford (UK). To achieve this, the clinical team modified the typical procedure for generating a trans-radial socket via lamination to produce the bypass socket suitable for limb-intact individuals. The key stages of manufacturing are outlined below.

6.2.2.1 3D Model Preparation

Initially, creating the bypass sockets directly upon the 3D printed model was considered by the clinical team. However, due to the prints being manufactured from PLA filament, this was not possible. The 'glass transition

temperature' (Tg) of a polymer is the temperature at which it begins to transform from hard and brittle to ductile and malleable. This is due to the movement of carbon chains within the material [290]. For PLA, this transformation occurs at around 60 degrees Celsius, and ends at 155 degrees Celsius, which is when it reaches it's melting point [290–293]. Depending on the type used, the thermoforming polymer sheets used to create a draped socket are generally heated to above 100 degrees before being shaped around the plaster limb model [37, 294]. Similarly, acrylic resins, such as those used to create laminated sockets, undergo an exothermic reaction as they cure [295]. Depending on the specific brand of resin used, this reaction often exceeds 60 degrees [295]. Hence, both procedures would deform a PLA limb model. Consequently, it was decided the PLA models would be converted into a plaster model. Wraparound POP casts of the 3D printed limbs were manufactured in order to create a negative mould. The outer layer was carefully removed when it had cured, filled with POP mixture, and allowed to set for 15-25 minutes. The positive plaster model, a precise replica of the 3D printed model created from plaster, was revealed after the outer wrap cast was removed. The recessed regions indicating the positions of bony prominences and EMG sensor sites were traced with indelible pencil prior to any plaster wrapping, and this was used to transfer markings between the various stages of casting.

6.2.2.2 Rectification

As per the clinical standard, the rectification procedure was directed by the marked regions. The prosthetist performing the rectification manually sculpted the positive mould to be more comfortable around the bony prominences by adding material. To allow the electrodes to sit closer to the skin in the finished socket, the marked areas denoting the EMG locations were flattened by light sanding. After being lightly smoothed all over, the cast was allowed to dry fully.

6.2.2.3 Lamination

The clinical team created double-layer bypass sockets. This design mimics a regular double-walled trans-radial socket, and therefore had many of the same attributes. The sockets featured an adjustable wraparound strap to enable easy donning and doffing, whilst also allowing a secure fit to be achieved when

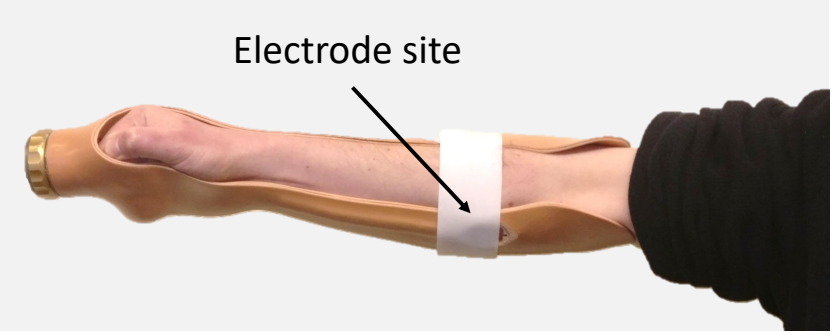


Figure 6.2: A finished bypass socket with an adjustable strap for tightening. The Figure depicts one of the EMG locations.

tightened. The clinical team's typical lamination procedure used for regular upper-limb sockets was amended to create the bypass sockets. For a regular prosthetic socket, the wings are flexible enough that the wearer can push their residuum into the socket without using excessive force, and the socket stays suspended due to a combination of suction and skin friction. Even for tight sockets, a limb sock can be used by the wearer to pull the residuum into place within the socket. However, due to the presence of the participant's hands, creating an entirely encapsulated socket was not possible. Instead, the clinical team devised a design that enclosed the whole arm and hand, but left the thumb and top of the arm visible via a channel that runs the length of the socket, as shown in Figure 6.2. The inclusion of the channel was the only major deviation from the standard lamination procedure. Although created specially to help the limb-intact participants don and doff the bypass sockets, some designs of prosthetic sockets also feature open channels to assist donning and doffing [296]. The stages involved in the lamination procedure are briefly described as follows.

Firstly, a PVA (polyvinyl acetate) bag was moistened in a damp towel for several minutes and stretched over the plaster model. PVA bags are commonly used in vacuum forming to separate the resin from the plaster model [297]. Because PVA is water soluble, moistening the bag first makes it easier to stretch over the model and conform to the irregular shape of the cast without creasing [297]. The length of time a PVA bag is left to absorb moisture can affect the final lamination, as it affects how pliable the bag becomes. A drier PVA bag is less pliable, and therefore creates more tension under vacuum, which results in a thinner, and therefore weaker, lamination

[297]. Conversely, a damper PVA bag is more flexible and constricts the resin less, creating a thicker and stronger lamination [297]. The length of time the PVA bag is left to absorb moisture is important to control both the mechanical properties and the aesthetics of the final socket. Many of the stages of lamination are conducted under vacuum. This is to help the various layers of the lamination conform to the plaster model evenly. In order to remove wrinkles from the PVA bag that could have negatively affected the inner surface of the final socket, vacuum was applied. PVA bags are translucent, hence the markings were still visible at this point in the process.

Next, dummy electrodes were adhered to the PVA bag covered plaster model atop the relevant marked locations. Dummy electrodes are single-use replicas of standard size clinical electrodes which can withstand being set within the resin under vacuum. They are destroyed when removed from the finalised socket. Regular clinical standard electrodes have semi-rigid 'rods' protruding from each side, as shown in Figure 6.3. These rods, sometimes called arms, are to allow the electrode to be suspended within the socket whilst also allowing a small degree of movement with the limb. In a single walled prosthetic socket, the recesses for the arms are within the lamination. In a double walled prosthetic socket, the recesses are generally on the inner layer and leave the recess exposed so the electrode can easily be pressed in and out, with the outer layer being used to secure the electrode in place. During the lamination procedure, felt was placed beneath the dummy electrodes. This is required for two reasons: 1) to keep the dummy electrode arms from deforming towards the model when vacuum was applied, and 2) to act as a spacer between the limb model and the electrode dummy, allowing resin to form a sufficiently thick wall for the electrode arm recess to sit within.

On top of the inner PVA bag, four layers of nyglass stockinette were applied to the plaster model of the arm. Another PVA bag was moistened and applied atop all layers, and suctioned to the limb model using the vacuum. Next, specialist laminating resin was mixed with a hardening agent and poured in between the two PVA bags, to soak through the layers of nyglass textile. The technician creating the socket then manually pushed the resin through the bag under vacuum conditions so that an even coating was achieved. The socket was left for between 1 and 2 hours to cure fully. This process created the inner layer of the bypass socket. To create the outer layer, the outer PVA bag from the first socket layer was removed, a wrist 'former' was fitted to the inner socket layer and sealed with specialist wax. Wrist formers, like the dummy electrodes, are used to create an internal void

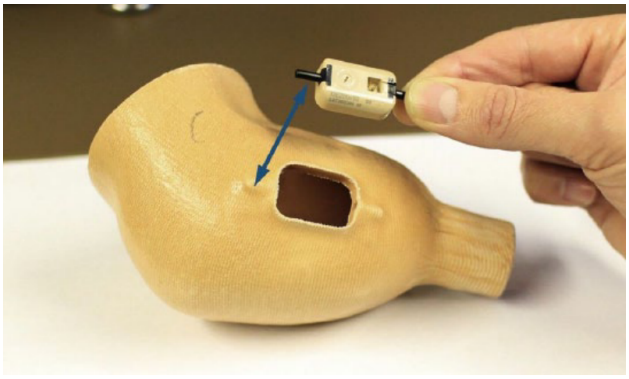


Figure 6.3: An image of a clinical standard electrode. The black, semi-rigid, plastic rods projecting from either side of the electrode and the corresponding recesses within the socket wall are highlighted with a blue arrow. Image from [38]

within the socket of the exact size required to fit a mass-manufactured component at a later stage of manufacturing. A 3-ply casting sock was then applied to the entire inner socket layer. This was to provide a spacer between the inner and outer socket layers, to allow tolerance for push-fitting and separating the two layers once both were fully cured. A moistened PVA bag was then applied over the cast sock to prevent the two layers touching and sticking together during the second curing process. Talc was applied to assist pulling the PVA bag over the cast-sock spacer. Once again, the vacuum was applied to smooth the PVA bag to the layers underneath it and prevent wrinkles in the final socket. After allowing the PVA bag to dry slightly, an EVA (ethylene-vinyl acetate) strip was affixed either side of the limb model, running the length underside of the forearm. This step is done to create a channel in the resulting outer-layer of the socket, to provide a void for electrical cabling to fit within. Following this, six layers of nyglass stockinette were applied. For the outer socket, the previous resin-curing procedure was repeated.

Once fully cured, the PVA bags were removed and the trimlines marked on the socket. The sockets were then removed from the plaster limb model and the trimlines cut with a router. A rotary polishing mop was used to smooth the sharp edges of the trimlines to prevent them hurting the wearer. After separating the inner and outer layers of the bypass socket, the wax holding the wrist former was melted using a heatgun and the wrist former

was removed. To remove the myoelectric dummy units, a router was used to grind down the inner layer of the socket until the dummies were visible. At this point, the outer layer was re-positioned around the inner layer and a hole drilled through both layers simultaneously to mark the position of the electrode sites. After separating the layers again, the outer layer was ground down around the electrode sites to allow them to be visible from the outside of the socket. The dummies were then removed from the inner layer and replaced with clinical standard electrodes. Due to the double-layer design, the electrodes are suspended by their rods on the outside of the inner layer, and held in place by the outer layer, preventing them from moving within the socket. Sealing paste was used to fit a lightweight friction wrist unit to the outer socket, and allowed to cure. Finally, the two layers of the socket were slotted together and a self-adhesive, heavy duty hook and loop strap adhered to the underside of the socket. The sockets were then sanitised and posted back to the technical team.

6.2.3 Testing

Both the comfort and myoelectric performance of the sockets were evaluated by the technical team. When participants wore the bypass socket, myoelectric capability was determined by whether or not it was possible to get effective control signals from both electrode locations.

Clinical standard surface myo-electrodes (RSL Steeper SEA200) were integrated with Axopy [234], a Python experimental library for human-computer interface studies, via an Arduino which sampled data at a frequency of 1000Hz [234]. Using the Axopy library, a straightforward, one-dimensional EMG tracking task was designed.

Before the EMG trial began, the participants were asked if the bypass socket felt comfortable and whether any areas felt loose.

6.2.3.1 EMG Calibration

With the participant holding their arm in the neutral position whilst wearing the bypass socket, the calibration procedure defined in Chapter 4, Section 4.6.2 was performed on both the extensor and flexor EMG sites. In all subsequent trials y_{norm} was utilised for EMG control. It is important to note that clinical standard electrodes provide a minimal level of signal filtering as standard, therefore the output is not 'raw' EMG.

6.2.3.2 EMG Task

The EMG task was designed to be as simple as possible, as the only aim was to verify the positions and quality of contact achieved from the EMG sensors within the bypass sockets. Further details on EMG tracking tasks can be found in 4, Section 4.6.3. A visualisation of the task shown to participants in this experiment is shown in Figure 6.4.

There were four different target bands, which were visually the same for all participants. However, the effort required to hit them was scaled based upon the normalisation constant achieved during the calibration process for each specific participant. For example, a target height of 100 was equal to a y_{norm} of 1. The target band percentages were defined as follows: 15% to 26% y_{norm} (band 1), 26% to 41% y_{norm} (band 2), 41% to 65% y_{norm} (band 3) and 65% to 100% y_{norm} (band 4). These bands were chosen as they were successfully used in multiple previous EMG experiments [231, 298]. Despite having four targets, note that the bands are not split into four even quartiles. This is to display a range of EMG skill, even with a relatively simple task. During low exertion contractions, obtaining fine motor control is easier, hence a narrower band (15% to 26% y_{norm}). In contrast, during a high exertion contraction, achieving precise control is more difficult, hence a wider acceptable range for the target band (65% to 100% y_{norm}). Cursor deviation from the target band was measured between the outer bounds of the target band and the outer circumference of the cursor. Hence, if any point of the cursor was within the target band this was classed as zero deviation.

Each block of the task consisted of 16 trials. The target orders were randomised using Python's *random* function, with each of the four target heights being presented four times within each block of 16 trials. A minimum of one block of the task was run for each EMG site to verify myoelectric control, i.e. one block to verify the flexor EMG site and once again to verify the extensor EMG site. The exact number of blocks was not specified because the goal was simply to demonstrate that the EMG sensor contact provided by the bypass sockets was adequate for effective control. Only one muscle site was tested per block. Upon removing the bypass socket after the trial, the limb was visually inspected for light indentations from the EMG electrode contact pads.

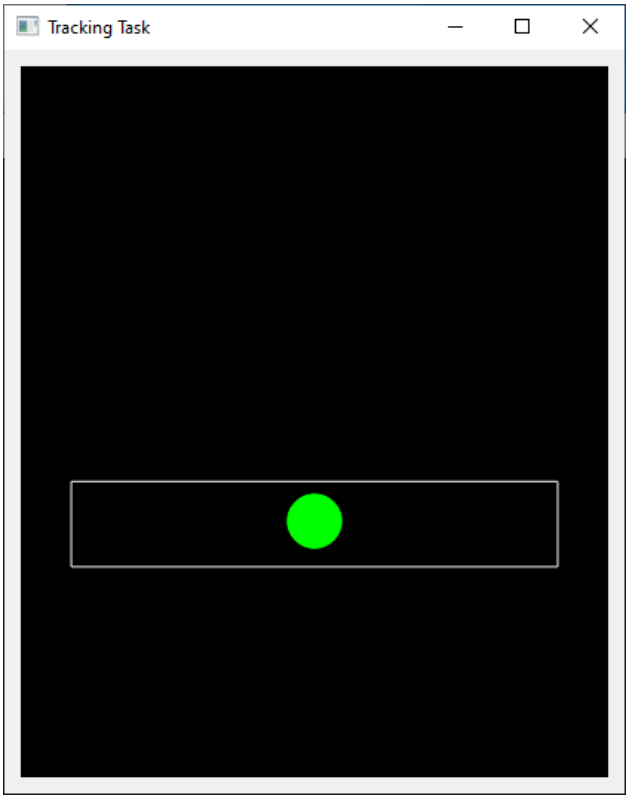


Figure 6.4: An example of a band 2 (26% to 41% y_{norm}) target, shown as it was on screen to the participants. The green cursor is inside the target band, hence the participant was managing to hold the correct level of EMG activation for this trial.

6.3 Results

Before beginning the EMG testing, the fit of the sockets was visually confirmed by the technical team. No obvious gaping or fit issues were detected. This Section reports the comfort and fit of the bypass sockets, their capacity for EMG control and the observed electrode contact. These factors were all used as metrics to gauge the success of the bypass sockets.

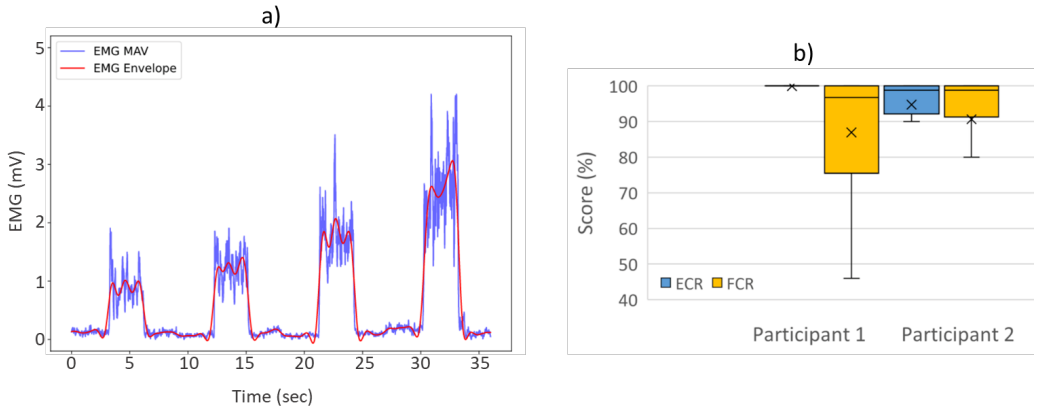


Figure 6.5: (a) At all four target heights, an EMG signal was acquired from one of the participants' wrist flexor muscle group using clinical electrodes and a bypass socket, as shown in the plot. The blue trace displays the EMG MAV data with minimal filtering applied, as output by a clinical standard electrode, and the red trace shows the EMG MAV envelope with further filtering. (b) A box plot of the participants' tracking task scores, with whiskers representing the upper and lower quartiles. ECR stands for extensor carpi radialis, while FCR stands for flexor carpi radialis.

6.3.1 Comfort

In response to being asked about the comfort of the bypass sockets, no participants reported any regions of pain, suggesting that all were a good fit. Additionally, both participants explicitly stated that they found their bypass socket comfortable.

6.3.2 EMG Performance

During the EMG tracking task, both of the participants who were examined were capable of controlling the cursor, and "clean" EMG signals were evident in the experimental data from both of the participants. Figure 6.5(a) displays some representative examples of the experimental EMG data. As can be seen in Figure 6.5(b), the mean score for targets held by the extensor group was 92.8%, while the mean score for the flexor group was 88.2%.

6.3.3 Electrode Contact

After the bypass socket was removed at the end of the trials, mild indentation on the skin from prolonged contact with the electrode pads was visible in both participants. This served as an indication that satisfactory skin-electrode contact had been obtained. Figure 6.6 is an example of an indentation that was observed after the bypass socket was removed.

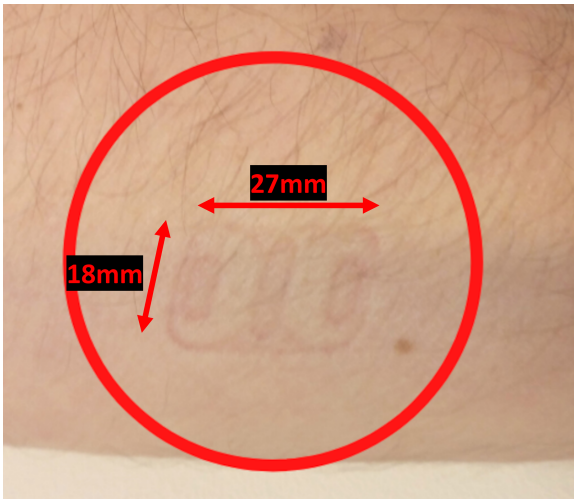


Figure 6.6: After participants removed their bypass sockets post EMG testing, light indentation from the electrodes was observed by the technical team. This indicated good skin-electrode contact had been achieved. Indentation is highlighted in red.

6.4 Discussion

Amid the COVID-19 lockdown period in the UK, a unique approach of constructing trans-radial bypass sockets was conducted as a collaboration between separate teams of technical (non-clinical) researchers at Newcastle University (UK) and clinical researchers at the University of Salford (UK). Both participants were able to successfully complete an EMG tracking task, demonstrating effective EMG control. All of the bypass sockets fit the participants comfortably and facilitated effective EMG contact. In this Section, the limitations and reflections of the study are discussed, as well as the potential opportunities that using remote socket fitting could facilitate.

6.4.1 Limitations

Due to the remote nature of the procedure, the fit of the bypass sockets could not be estimated until they were tried by participants during testing. This posed a danger of wasting clinical time and resources if an improperly fitting socket was produced which would then have had to be re-made from scratch. Other than the measurements and markings made by the technical team prior to scanning, the prosthetists and technicians were effectively working 'blind' during the lamination stages. Additionally, if used in clinical practice, remote fittings may lead to other limb-related health issues that would be detected at fitting appointments being overlooked. Additionally, when performed on limb-intact individuals, limb palpation is a simple procedure. This procedure may be more difficult for individuals with limited musculature in their residuum, and a non-clinical individual may struggle to find the EMG sites.

No quantitative measurements were employed to determine the fit of the bypass sockets. Instead, participants' verbal input and visual checks, such as noting any indentations made on the skin by the electrodes, were utilised to determine if the fit was adequate. In clinics, the fit would be checked rigorously by a trained prosthetist because load bearing and potential skin breakdown would need to be considered. However, as this study focused on bypass sockets, achieving optimal socket fit was less important and performing brief fit checks was adequate.

Furthermore, using only two participants resulted in a small set of results. However, because the main goal was to develop, pilot, and report on a viable method of remote bypass socket creation, data from a large participant pool was not required. The study's findings show that the method was feasible and that sufficient EMG contact was achieved for both participants. However, if the method were to be developed further, either for a more in-depth study or for real prosthetic sockets, a larger participant pool would be beneficial.

6.4.2 Reflections

Despite the fact that both of the sockets were successful, some of the manufacturing stages could have been executed more efficiently. For example, printing the model arms from PLA unintentionally resulted in several extra stages being added to the manufacturing workflow. Initially, the clinical team attempted to use the PLA model in the lamination procedure, as they

were unaware of the low deflection temperatures affecting PLA. Equally, the clinical team had not considered the exothermic reaction which takes place whilst the lamination resin cures, or the heat required to create a thermoformed socket. As a result, several stages, including plaster casting and a plaster pour, were added to the workflow for each bypass socket. This greatly increased the time and effort required to produce the devices. Using a different material or method to manufacture the arm models could have avoided this issue, such as using resin 3D printing or milling the arms from a heat resistant material. In retrospect, regardless of the material used, the slicer settings of 20% infill did not create prints with a sufficient strength to withstand being placed in a vacuum. If repeating the procedure again, a much higher infill should be used to improve the strength of the prints. For compressive forces, high infill percentages between 80% to 100% with 2D infill patterns such as grids and triangles have been found to produce the strongest prints [299]. In terms of material choice, the majority of FFF printer filaments would not be suitable, as many have a glass transition temperature of below 150 degrees Celsius [300]. To allow for either thermoforming or lamination, a resin print created using the selective-laser sintering (SLS) method would be more appropriate and convenient. Several commercially available SLS resins have a heat deflection temperature over 200 degrees Celsius, hence are more appropriate for the heat-based procedures conducted in clinic. Additionally, resin prints tend to have a smooth and high quality finish, making them ideal for biomedical purposes.

Unlike in the previous Chapter, this study demonstrated that it is possible to use digital methods for creating prosthetic sockets without compromising the quality of the finished device. Previously, in Chapter 5, all stages were carried out by 'novice', non-clinical researchers. This study showed that as long as the 'artisan' stages of socket manufacturing are handled by a qualified clinician, some elements of digital manufacturing can be successfully introduced.

6.4.3 Future Opportunities

Although this study solely focused on the creation of trans-radial bypass sockets for limb-intact individuals, it would be possible to refine the technique in order to enable remote fitting for limb-deficient individuals in need of a regular prosthetic socket. This could be invaluable for patients who are unable to travel to specialist hospitals, either due to ill-health, lack of time

or the desire for home-based care. Equally, the past few years have demonstrated the need for flexibility in the way we provide healthcare to patients. There is a constant demand for healthcare services, but as shown during the COVID-19 pandemic and associated local lockdowns, sometimes those services must evolve to be provided remotely, or semi-remotely. This study used a high-cost digital scanner, but several other studies have now shown similar successes in the field of prosthetics and orthotics using significantly cheaper technology [33, 301]. For example, smartphone scanning via the use of photogrammetry is becoming a more viable option for healthcare providers due to advances in the resolution of smartphone cameras. This could provide the patients themselves the means to scan and record their own limb geometry from home, whilst still facilitating a qualified prosthetist to conduct the artisan procedure of socket manufacturing in clinic. Some companies, such as Starband and Openbionics, already use smartphone scanning as an acceptable method for capturing their patient's geometry [302, 303]. Additionally, this route could open the door to providing international aid - allowing prosthetists to work from different countries and provide care in dangerous zones without needing to be physically present. Outside of patient-facing healthcare, a remote method could help facilitate future collaborations between clinical and non-clinical teams within industry and academia.

6.5 Chapter Summary

- Chapter 5 showed the unreliable results which occur when clinical expertise is omitted from socket manufacturing. Building upon that, this Chapter incorporated both modern, digital manufacturing methods and artisan clinical skills.
- The method included optical scanning, CAD, and 3D printing and conventional techniques such as plaster casting, hand sculpting, and laminating.
- Through this hybrid digital-conventional approach it was possible to create clinical standard trans-radial bypass sockets.
- It is likely a similar workflow could be used to create prosthetic sockets for patients via home-based care.

Part III

Designing Trans-Radial Prosthetic Sockets

Chapter 7

Compression for Trans-radial Prostheses Control

As covered in Chapter 2, both socket design and manufacturing methods have not changed significantly for several decades. Specifically, there are no trans-radial socket styles designed to improve myoelectric control. Instead, conventional designs are used, which fall short of facilitating the needs of advanced device users. Hence, investigating new styles of trans-radial socket for their effect on EMG control is necessary. The previous two Chapters, 5 and 6, investigated modern manufacturing methods and their potential benefits and drawbacks. This Chapter focuses on socket design, and what changes are necessary to enable better EMG control. In this two-part study, the effect of a custom-built LC simulator on EMG control and forearm fatigue was explored.

> *Does Trans-radial Longitudinal Compression Influence Myoelectric Control?* (J. Olsen, S. Day, S. Dupan, K. Nazarpour, M. Dyson, 2022) is published in the Canadian Prosthetics and Orthotics Journal *(CPOJ)*.

7.1 Introduction

As discussed in Chapter 2, regardless of the manufacturing methods used, the fundamental design of trans-radial prosthetic sockets must be updated to meet modern demands. So far, no style of trans-radial prosthetic socket has been designed prioritising reliable EMG control. Similarly, it is not known which existing styles of socket perform better when used in conjunction with EMG. Consequently, many advanced prosthetic terminal devices suffer from unreliable EMG input signals. The following Sections discuss what factors can negatively impact EMG signal acquisition and processing, and the impact poor EMG control has on wearers, clinicians and research.

7.1.1 Factors Affecting EMG Control

There are many factors which can impact the quality and reliability of myoelectric signals when using non-invasive, surface electrodes [121, 304]. These factors have the potential to cause inaccuracies when the signal is being interpreted by a command system, leading to unexpected events such as involuntary opening or closing of the terminal device [122]. There are many general sources of signal disturbances, which affect all EMG controlled devices. Although not an exhaustive list, common sources include nearby electronics causing electrical noise within the signal, 'cross-talk' - where part of the signal originates from an unintended muscle group, muscle fatigue, the conductivity of the electrode due to moisture or perspiration, and power line interference [121, 304]. Many of these sources of signal disturbance, sometimes called 'artefacts', cannot be eliminated entirely, only factored into the subsequent signal processing to either reduce or minimise their impact. Additionally, as they are relatively predictable, minimising the impact of these particular sources of artefacts for surface electrodes has been widely studied [122].

However, there are additional sources of EMG artefacts that stem directly from the prosthesis itself, notably the way the electrode interfaces with both the socket and the residual limb. The two key sources are *motion artefact* and electrode *lift-off*. As, in theory, these sources of signal disturbance can be prevented through optimised prosthesis design, they will be the focus of this investigation, and their origins discussed in detail below.

7.1.1.1 Motion Artefact

Motion artefact is a common EMG disturbance affecting myoelectric prostheses. It originates from relative motion between the target muscle group within the residual limb and the EMG sensor [304]. Motion artefact can be caused by: 1) the forearm moving quickly whilst wearing a socket-mounted prostheses with electrodes embedded within the socket wall, 2) changes to the limb volume whilst the muscles contract during motion, which in turn affects the chemical balance between the limb and the electrode, or, 3) a direct hit to the electrode or the prosthesis [304].

When the EMG sensor moves relative to it's target muscle the phenomena is sometimes called 'electrode slippage' [38]. This can cause a build up of electrical *charge* between the skin and the sensor [38]. When this charge is transferred into the electrode, a false activation of the terminal device may occur [38]. Clinical standard EMG sensors are particularly prone to this, as they are what are known as 'dry' electrodes [305].

7.1.1.2 Electrode lift-off

In extreme cases, physical disturbances to the EMG sensor can lead to total detachment from the limb, sometimes called electrode *lift* or *lift-off* [38, 122]. When total EMG sensor detachment occurs, several different disruptions to the voltage registered by the EMG sensor can occur, many of which can result in a false activation of the terminal device [38]. In general, the sensor will also then re-join the limb in an unpredictable way, causing the subsequent phenomena of sensor *touchdown*, which can also register as false EMG activity [122].

Improper socket design or fit can also cause electrode lift-off. Short term fluctuations in limb volume are generally due to fluid retention, whereas in the long term, muscular atrophy (mass loss) or hypertrophy (mass gain), can result in the limb changing shape [121]. Additionally, when the muscles shorten during contractions, they increase in girth to maintain their volume[306], which increases localised forces between the limb and the socket wall in some areas [223, 307]. One study investigating the use of custom-made indenter pads for upper-limb socket creation reported an increase of approximately 850 grams-force between the limb and the pad during a forearm muscle contraction [223]. The majority of clinical standard trans-radial prosthetic sockets are made from rigid or semi-rigid materials such as resin

composites or thermoplastics which are not flexible enough to conform to the limb dynamically [208]. Hence, if the limb is smaller than when the socket was fitted, the excess void space within the socket may lead to EMG sensor lift-off or touchdown events. In 2020, Stavdahl et al. established that electrode touch-down with the skin after partial or complete loss of contact is one of the key disturbances responsible for unreliability in myoelectric prostheses [122].

7.1.1.3 Prosthesis Weight

Even within a tight-fitting socket with adequate skin contact, the underlying musculature will move relative to the sensors during contractions and arm motion. This phenomena is exacerbated by heavy terminal devices, which create a point load at the distal end of the prostheses. Many modern bionic hands surpass 600g in weight, which is almost three times that of a standard split-hook [308, 309], the devices for which many current trans-radial socket designs were originally made for. This problem is less severe when using a myoelectric gripper or split-hook since the device itself is light, hence this was not as much of an issue when myoelectric devices first became popular in the 1960s and 1970s. However, many modern bionic hands, even those which can be used with simple dual-site control, exceed the original design parameters of most self-suspending trans-radial prosthetic sockets. This is an example of how terminal device technology has advanced beyond the current capabilities of modern socket technology for upper-limb prosthetics, which has remained largely stagnant for several decades.

7.1.1.4 Dry vs. Wet Electrodes

Dry electrodes do not feature a stabilising electrolytic layer of gel in between the electrode and the residual limb the way 'wet' electrodes [305], such as those used for echocardiograms (ECG's) do. They are convenient, as they do not require an adhesive layer to function, but unfortunately have several drawbacks to their usage. Firstly, the impedance of the electrode is innately larger [305]. Additionally, as the sensor merely rests upon the surface of the skin and is not adhered to it, the connection has less stability than a wet electrode [305]. By design, this makes dry electrodes more sensitive to motion artefact, electrode slippage and signal noise [305]. Skin impedance varies with the moisture and oil present on the skin, hence slipping from one

area to another can affect the baseline EMG signal. Current trans-radial prosthetic socket designs require users to don their device by pushing their residual limb into the socket. Hence, using wet electrodes for a prosthesis which is worn daily would not be possible.

7.1.2 The Impact of Current Socket Design on Myoelectric Control

Variation in the external forces applied to a prosthetic limb will always result in some relative displacement between the EMG sensors and the limb due to the compliance of the soft tissues [122]. If a person wearing a myoelectric prostheses is performing rapid movements, such as during exercise, differentiating signal artefacts from useful and intentional muscle activity can be especially difficult [304].

7.1.2.1 Research Impact

Many of these issues do not appear as frequently in research studies because sockets are not always used when assessing novel EMG processing systems or prototyping prostheses designs. Able-bodied volunteers are frequently recruited for EMG studies, which is reasonable given that their anatomy is similar to that of acquired amputees. Additionally, there is a wider pool of available participants, allowing for larger studies with sufficient statistical power. However, because they are limb-intact, either a bypass socket must be used, which limits the study's validity because the mechanical coupling and load bearing is not the same as a regular socket, or the sensors are simply affixed using adhesive film. The latter is commonly used in EMG research because it provides a reliable and repeatable method of isolating the effect of the specific EMG processing system under investigation. However, because socket-specific causes of EMG disturbance are not induced, the findings' applicability to real-world applications is limited. Additionally, this can lead to the severity of socket-related EMG issues being overlooked as a research problem.

7.1.2.2 Clinical Impact

The impact of relative motion between the muscles and the socket cannot be accurately assessed in clinics until the wearer is able to use a functional

version of their myoelectric prostheses. This is because, when prosthetists identify suitable EMG muscle sites in clinic, the limb is in a static resting position, e.g. flexed at 90 degrees or hanging by the side of the wearer's torso. Using current clinical tools, it is not practical to confirm the muscle sites would still be valid in a wide range of positions. If the unreliability of the EMG signals results in intolerable levels of wearer dissatisfaction with their device, generally a different form of prostheses (i.e. body powered or static) will be offered, creating extra work for clinics and resulting in abandoned devices.

7.1.2.3 Impact on Wearers

Out of the possible false activations, *involuntary opening* of the prosthesis is arguably the most dangerous potential outcome [122]. This is because the wearer may drop a hazardous item (i.e. a hot drink, something that could shatter) or the wearer may be using their prosthetic limb for bodily support (i.e. holding on to a grab rail). Besides being a safety concern, unpredictable responses and reliability issues are commonly stated by amputees as a reason for non-wear or dissatisfaction with their myoelectric prostheses [51, 310]. Hence, preventing motion artefact is of paramount importance, even for simple EMG controlled prostheses.

One of the main proposed benefits of using a myoelectric prosthesis over a body-powered alternative is that it has a wider *workspace* in which it can be used. For clarity, the workspace is defined as the area in which a prosthesis wearer can both reach and successfully operate their device. Body powered prostheses generally require a harness and can only be used in a limited workspace where the user can maintain tension on the Bowden cable, thus allowing them to open and close their prosthesis [311]. In theory, myoelectric prostheses do not have this limitation and can be used in a wider workspace, such as in situations where the Bowden cable would lose tension, i.e. above the user's head. However, current trans-radial prosthetic sockets do not restrict the motion of the underlying muscles relative to the skin due to their cup-like rigid design. Hence, even if the socket is relatively tight fitting and has enough skin friction to prevent the limb from moving within the socket, there is no mechanism to prevent the muscles from moving beneath the skin. When the underlying muscular structures move relative to the skin and electrode, the risk of cross-talk EMG activity being detected increases. As muscle cross-talk can lead to false activations of myoelectric

prostheses, this issue can both endanger and frustrate wearers, and potentially reduce their trust in their device. As a consequence, the reality of myoelectric upper-limb prostheses is that they are afflicted by similar operational workspace issues to harnessed prostheses. However, instead of the physical limitations imposed by a body powered prostheses, the limitations of myoelectric prostheses are caused by limb-position related EMG signal artefacts and classification errors instead [312–314]. This negates one of the main benefits of using a myoelectric prostheses over of a body-powered one.

As established by Head in 2014 [38], current designs of upper-limb prosthetic socket result in a trade-off between comfort and control. A tighter fitting socket can offer more stability and security [315]. Unfortunately, tighter sockets result in higher interface pressures [315], which can cause the wearer discomfort, excess perspiration, and risk reducing the blood flow to the limb, and eventually tissue breakdown [25, 250, 315, 316]. The levels of pressure applied by tight-fitting upper-limb sockets is thus far unknown and is a relatively understudied area [99], as covered in Section 2.3.1. However, 6.9-12.5kPa (51.8-93.8mmHg) have been recorded as well-tolerated pressures inside conventional upper-limb sockets [223]. It is assumed 'high-compression' styles such as longitudinal compression sockets exceed these values due to their additional compressive contours.

In contrast, a looser socket will generally be more comfortable for the wearer and allow a wider range of motion and more limb rotation within the socket. The downside of this is that the security of the connection between the EMG sensor and the limb is likely to be compromised, increasing the risk of electrode lift-off and providing less stabilisation to the underlying tissues.

It is hypothesised that reducing relative motion and mechanical disturbances between the electrodes and their target muscle sites will improve the quality and reliability of myoelectric control. Even if options such as implanted EMG sensors become more accessible and reliable in the future, there will always be patients who are ineligible for this option or prefer non-invasive solutions. Therefore, there is both an immediate and long-term need for a non-invasive, dependable socket design suitable for amputees to suspend and control their prostheses. To address this issue, several attempts have been made to improve myoelectric control in trans-radial sockets, described below.

7.1.3 Existing Measures

As covered in Chapter 2, Section 2.4.3, today's modern terminal devices and the electronics required to control them are retrofitted into trans-radial prosthetic socket designs which pre-date their existence [38]. Furthermore, as discussed in Chapter 2, Section 2.2.3.3, the majority of upper-limb prosthetics research is centred on the development of novel terminal devices and EMG signal processing systems. However, because of the persistently low satisfaction rates with myoelectric upper-limb prostheses over the last 60 years, it has only recently been acknowledged that this approach is not producing the desired advancement in standards of care. Consequently, it is now becoming clear that the mechanical coupling between the socket, electrode, and residual limb is a key limiting factor in trans-radial prostheses development.

Attempts to address motion artefact and electrode lift off have so far relied only on retrofitting new devices or making adjustments to current EMG processing systems. Head et al. tested adjustable electrode housings in 2016, with promising results [119]. The researchers created an electrode housing that enables an expert prosthetist to change the electrode's alignment in respect to the limb to assist in properly aligning its angle [119]. The Southampton Hand Assessment Procedure (SHAP) - a reliable and tested industry standard technique for measuring a prosthesis wearer's abilities while using their device - was used to assess amputees in this study [119]. When using the customised electrode housing instead of the standard electrode housing, participants displayed significantly higher levels of myoelectric control competence [119]. These findings add to the growing body of data that mechanical linkage of existing electrodes and the limb, rather than progressively advanced technology, can lead to major gains in myoelectric control. However, the electrode housing described in this study would most likely require regular maintenance or adjustment as the limb volume changed over time, and it would not counteract a significant change in limb geometry. Additionally, adjustable electrode housings are yet to be made available commercially, hence widespread adoption is not yet possible.

In terms of pressure maintenance, it appears that allowing some sort of adjustability to a socket's volume to counterbalance daily volume changes in the residual limb is the logical solution. No data is available for the amount of volume fluctuations that upper-limb amputees encounter in their residuum. Daily volume fluctuations in lower-limb residuums whilst wearing a prosthetic socket have been reported between -3.5% to +10.9% [317]. However, as this

topic has not been investigated, it is unknown whether lower-limb data can be extrapolated for upper-limb use. It is presumed that upper-limb fluctuations would be different to lower-limb due to the different loading conditions and difference in limb size. Despite the levels of volume fluctuations being so far un-quantified, several researchers have tested adjustable upper-limb prosthetic sockets with the aim of improving a variety of different factors, such as biomechanical stability and comfort [146, 318, 319]. Both overly tight and too loose sockets may pose problems for the wearer, leading them to abandon their prostheses completely. Hence, this problem extends beyond myoelectric control since maintaining proper socket fit is also vital for comfort.

Many commercially available adjustable prosthetic socket options, such as the Ottobock Revofit2, which uses the 'Boa' system, allows the outer shell of a prosthetic socket to be constricted or loosened to fine-tune the socket's fit [320]. However, this technology is not automatic and must be modified manually by the wearer. This forces the user to actively maintain their own socket fit, which can be cumbersome. Active pressure management socket systems exist, but they are currently limited to the lower limb. This is because sockets featuring actively managed pressure systems are generally much larger and heavier. Upper-limb prosthetic designs must be inconspicuous, lightweight, and be able to sit close to the torso. This is necessary for the wearer's comfort and because a bulky socket would be impractical.

Despite some promising improvements to existing prosthetic systems, no trans-radial prosthetic socket design has been developed specifically to improve EMG control. In recent years, other novel trans-radial prosthetic socket designs have emerged, but they were developed with other key objectives in mind, namely biomechanical stability. The Section that follows discusses their untapped potential for improving myoelectric control.

7.1.4 Potential Routes to Improvement

In order to remedy issues surrounding the mechanical coupling of the EMG sensors to the limb, it was hypothesised that partially immobilising the soft tissues would result in enhanced EMG control capabilities. Various prosthetic socket designs have arisen with the objective of enhancing biomechanical stability, most notably those employing longitudinal compression (LC) [25, 39, 157, 319].

LC sockets were developed to help immobilise underlying bone structures, hence providing better biomechanical stabilisation. Arguably the most

prominent example of LC sockets are Alley et al.'s 2011 'compression-release' sockets (CRS) [25], sometimes referred to as *HiFi* or *High Fidelity*. They feature contoured socket walls to provide areas of high compression running parallel to the radius and ulna and cut out regions where the displaced tissue can move into, hence the term compression-*release* [25]. Predecessors to the compression-release system include the *Anatomically Contoured and Controlled Interface* (ACCI), also developed by Alley et al. in 2002, and the *Trans-radial Anatomically Contoured* socket by Miguelez et al. in 2003. However, these designs did not feature cut-out release areas to accommodate tissue displacement from the compression. The release areas are critical to LC working effectively [25], hence the CRS design of socket will be referred to as the 'standard' form of LC socket throughout this Chapter. However, for clarity, LC is a design feature which could be applied into many designs of prosthetic sockets and is not limited to one specific socket design. Features such as the presence, style and severity of contouring around the olecranon, epicondyles, cubital fold and the distal end of the residual limb are used to differentiate the socket designs [25, 39, 157].

Longitudinal compression sockets are mainly marketed for comfort and gait purposes. Many of the manufacturer's purported benefits relate more to lower-limb prostheses and load-bearing [25]. In theory, the compression bars running parallel to the residual limb act in a stabilising manner to prevent the underlying soft tissues moving in relation to the remaining skeletal structure, a phenomenon named 'lost-motion' [25]. Lost motion is defined as the relative motion between the residual bones and the soft tissues of the limb during loading and movement [25]. Figure 7.1 shows how the residual radius and ulna move inside a trans-radial residuum when the socket is loaded distally. At the distal end of the socket the bone structures have moved to push against the top of the prosthetic socket wall in order to counteract the downwards force being applied from the distal load. It is this kind of relative displacement of the soft tissues relative to the socket that can cause some forms of motion artefact.

According to the principle of LC sockets, the compressed regions stabilise the underlying components and decrease lost motion, therefore enhancing biomechanical stability [25]. Conventional CRS sockets are fitted using a protected procedure which only trained professionals can perform [25]. The procedure used to create CRS sockets is patented by the manufacturer, Biodesigns, and only clinical professionals who have completed a specialist training course and acquired a license from the manufacturer may perform it. It is

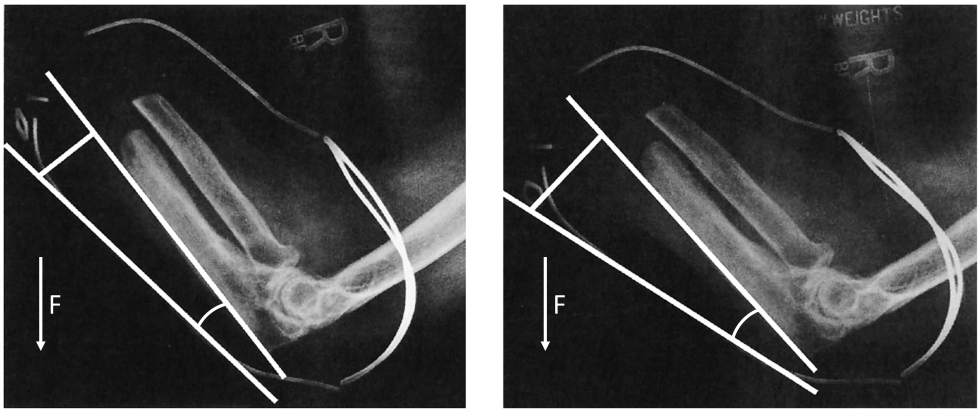


Figure 7.1: An X-ray of a trans-radial residuum inside of a Münster socket, one of the first self-suspending trans-radial prosthetic socket designs. The letter 'F' represents the direction of loading. (a) Shows the limb without distal loading. (b) Shows the limb with distal loading. Note how the angle between the socket wall and the residual radius and ulna has increased at the distal end. Image modified from [39].

also stated in the corresponding 2011 publication that this restriction is put in place to safeguard wearers, as the level of compression applied could be harmful if applied wrongly [25]. The procedure is similar to that described in Chapter 2, Section 2.3.2. However, during the casting step, the prosthetist applies 2-4 bar-shaped depressors and applies pressure on top of them. This is done in order to indent the cast around the residuum to produce regions of deliberate localised compression [25]. The prosthetist performing the CRS cast determines the position of the bars based on underlying tissue shape and avoiding main blood vessels [25].

Despite the fact that LC socket design is centred on biomechanics, there is a possibility that they may benefit myoelectric control by reducing the risk of electrode slippage and lift-off due to the tissue stabilising design. It is unclear whether the manufacturer investigated whether mounting the electrodes for myoelectric CRS sockets on compression struts or a membrane covering the relief area is more effective. The text from the 2011 publication indicates that they should be mounted on a membrane within the release areas, with no mention of mounting them on the compression struts [25]. The images in the publication, on the other hand, show the electrodes mounted on the compression struts [25], as shown in Figure 7.2. According to anecdotal

Figure 7.2: The inside of a compression-release socket featuring EMG sensors, highlighted in blue circles, mounted within the compression struts. Image from [25].

evidence, the electrodes are typically located on the compression bars of upper-limb LC sockets. It is unclear whether this is the most effective method for myoelectric control, but mounting upon the compression bars does have the advantage of not requiring an additional membrane.

Additional benefits of LC sockets on residuum physiology have not yet been described. Since LC sockets give areas of both high and low pressure, their mechanism of action is expected to be comparable to that of 'directional compression' garments, which provide specific zones of variable compression [321]. While directional compression garments have been proven to decrease physiological reactions that would cause muscle fatigue during activities such as sports and exercise [322, 323], LC sockets have not been studied to see whether they have the same advantage. Moreover, high pressure should be used with care since severe localised compression may cause tissue ischemia and skin disintegration [324, 325].

7.1.4.1 Safety

When external pressure is applied to the soft tissues of the human body, it can be both medically therapeutic and dangerous, depending on the location and

magnitude. Medically, compression garments can be used to boost circulation and prevent life-threatening conditions such as deep-vein thrombosis [326]. Athletes may wear compressive clothing to enhance sporting performance or assist recovery, with several studies finding compression garments can reduce both physical processes leading to muscle fatigue and the wearer's perception of fatigue [321–324, 327–331].

The LC sockets currently available in prosthetics provide a different kind of compression to a sleeve or garment. Garments provide a 'hoop' of even compression around a limb, with no relief areas. In contrast, longitudinal-compression sockets have areas of high compression and 'relief' areas of low or no compression. Due to this, safety data from compression garments cannot be extrapolated for use with LC sockets. Instead, the closest existing data sets relate to other prolonged point-loads caused by medical devices, such as wheel-chairs and other orthotics. In general, this kind of pressure is unwanted and the focus is to remove or reduce it, hence these data sets are limited in their translation to therapeutic point-loads. However, these data sets do show that safe and tolerable levels of pressure vary significantly for different areas of the body [232, 324–326, 332, 333]. Hence, estimating safe levels of localised compression for residual upper-limbs is a complex issue.

Alley et al. reported observing increased blood flow to residual limbs whilst wearing a compression-release socket [25], but did not publish quantitative figures to support this claim. However, this would align with similar research into compression garments which result in increased blood-flow to their respective target areas [327]. In addition to quantitative measurement, there are also visual indicators to help gauge whether compression is at a tolerable level, for example observing 'postischaemic hyperemia' [25]. This method involved observing the duration of time necessary for red indentations left by the compression device to fade. Additionally, it is important to take the wearer's general health into account - frail skin, blood-pressure regulation issues and certain co-morbidities are contraindications for high-pressure devices.

Currently, in the absence of other guidance, estimates like Chang et. al's [232], as discussed in Chapter 4, Section 4.7, are the closest we can get to knowing the actual safe pressure levels that can be applied in LC sockets.

7.1.5 Clinical Relevance and Study Aims

To date, the potential for enhancing upper-limb myoelectric prosthesis control using LC sockets has not been studied. The aim of this study was to investigate the potential impact of LC on three essential elements critical to the use of myoelectric prostheses:

- EMG control, via a target-tracking task.
- Electrode-skin contact, via pressure measurements.
- Muscle fatigue, via an isometric contraction of the forearm muscles whilst in an either compressed or uncompressed state.

The objectives of this study were to:

- Develop a bespoke rig capable of compressing the forearm at a specific pressure range while simultaneously recording EMG data from the underlying muscles.
- Monitor the pressure the rig applied to the forearm during trials using off-the-shelf force sensing resistors (FSRs), by integrating them into the design of the rig to allow real-time, closed-loop monitoring.
- Perform EMG analysis on the recordings of the isometric contractions to detect potential differences in muscle fatigue experienced by compressed and uncompressed forearm muscles.

We hypothesised that since the target muscles were immobilised, LC would give improved myoelectric control.

7.2 Methodology

This study was approved by the Newcastle University local ethics committee (Ref: 20-DYS-050 and 11532/2020), attached in Appendices A.3 and A.4. The participant pool for this study consisted of twelve right-hand dominant volunteers, aged 20-40 years old. All participants were able-bodied (sex: 7 male, 5 female).

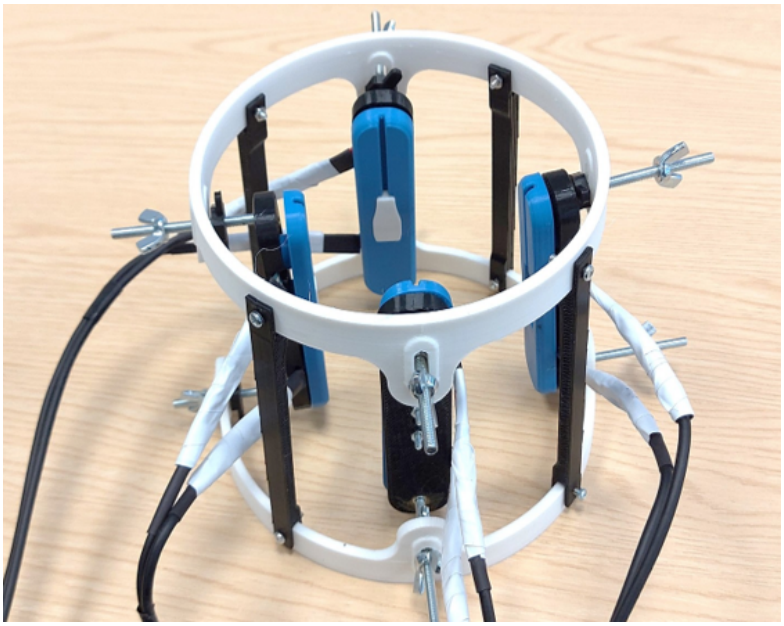


Figure 7.3: The 3D printed compression rig. The white outer rings featured slots to allow some adjustment of the position of the bars in terms of distance along the radius/ulna and also to allow the bars to conform to the taper of the forearm.

7.2.1 Equipment

EMG recordings were obtained using single-channel DELSYS™ Mini EMG sensors (DELSYS, USA) at 2000Hz. Pressure recordings were acquired using the equipment and methods detailed in Chapter 4, Section 4.7. Additionally two digital dynamometers (CAMRY, USA) were used for the second phase of the experiment in order to induce forearm fatigue.

To apply compression during the experiment, a custom prosthesis simulator was designed, shown in Figure 7.3. All engineering drawings for the custom made components can be found in Appendix D.2. The simulator featured adjustable height depressor bars, to imitate the struts featured in a regular LC socket. It is reported that four depression bars provides the greatest stability for LC of the forearm [25], hence the simulator also featured four bars. The simulator was designed to work on either able-bodied or limb-different individuals, with each bar being evenly spaced around the rig. The depth of the bars were adjustable to allow the simulator to be

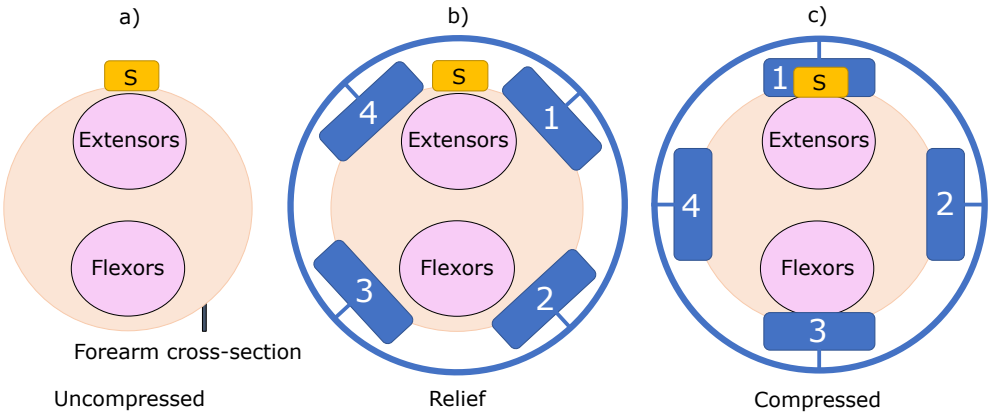


Figure 7.4: The three different configurations tested during this experiment. The approximate location of bars 1, 2, 3 and 4 and the test rig can be seen relative to the wrist extensor and flexor muscle groups. The letter 'S' denotes the position of the DELSYS™ mini electrode, which is the same positioning for all three configurations. (a) The 'Uncompressed' configuration. The electrode is adhered with a self-adhesive film and no rig is present. (b) The 'Relief' configuration, where the bars compress either side of the target muscle and the sensor is affixed with self-adhesive film. (c) The 'Compressed' configuration, where the compression is applied directly above the target muscle.

tightened and loosened to varying levels of compression on participants of different diameter forearms.

7.2.2 Pressure Application

There is no known literature which would suggest in which position to apply localised compression relating to EMG control. Existing literature generally only covers bone stabilisation. Hence, for this experiment, three configurations were examined. The three compression configurations were as described below:

Uncompressed - The EMG sensor was adhered to the skin in the identified EMG site atop the extensors using adhesive film, but no external compression was applied, as shown in Figure 7.4(a).

Relief - As before, the EMG sensor was adhered to the skin using adhe-

sive film, but external compression was applied to the forearm using the simulator. The simulator was rotated so that the compression bars were placed equidistantly either side of the EMG sensor, as shown in Figure 7.4(b). The sensor was placed in the uncompressed 'relief' area.

Compressed - In this configuration, the compression bar was located directly above the EMG sensor, with the recess in the bar encapsulating the sensor to ensure a firm connection with the limb, as shown in Figure 7.4(c). Pressure held the sensor in position and no adhesive film was necessary.

The extensor EMG site was located using the procedure detailed in Chapter 4, Section 4.6.1. However, instead of using adhesive film to secure the EMG sensor, the socket simulator and EMG sensor were then positioned onto the arm in the 'compressed' position, as described above, with bar 1 securing the extensor electrode. Throughout all configurations, the EMG sensor was located in this area, irrespective of the location of the compression bars. In the *uncompressed* and *relief* configurations, a 3D printed electrode dummy was used to plug the recess in the depressor bar where the EMG sensor would sit in the *compressed* configuration.

The aim was to get all bars within the ideal pressure range, as defined in Chapter 4, Section 4.7. However, this was not always possible. In general the pressure applied by bar 1, as seen in Figure 7.4, was approximately 2kPa (15mmHg) higher than the pressure applied by bar 3, regardless of the amount of fine-tuning by the researcher. This is because in both the *relief* and *compressed* conditions, bar 1 was either atop or next to the extensor muscle group. The extensors are collectively a smaller group of muscles than the flexors, hence they provide less cushioning for the bar. A cross-sectional view of the forearm can be seen in Figure 7.5, with the wrist flexors highlighted in green, and wrist extensors highlighted in blue. Hence, as the rig was tightened and the bars began to apply pressure to the limb, bar 1 compressed the tissue to the bone quicker than bar 3. This anatomical difference resulted in the higher pressure readings for bar 1. However, for all recorded tasks, the researcher ensured all bars were still within the allowable range of pressure, despite regional differences around the limb.

7.2.3 Experimental Protocol

The experiment was split into two phases. In the first phase, participants completed a simple EMG control task using their dominant arm, in which

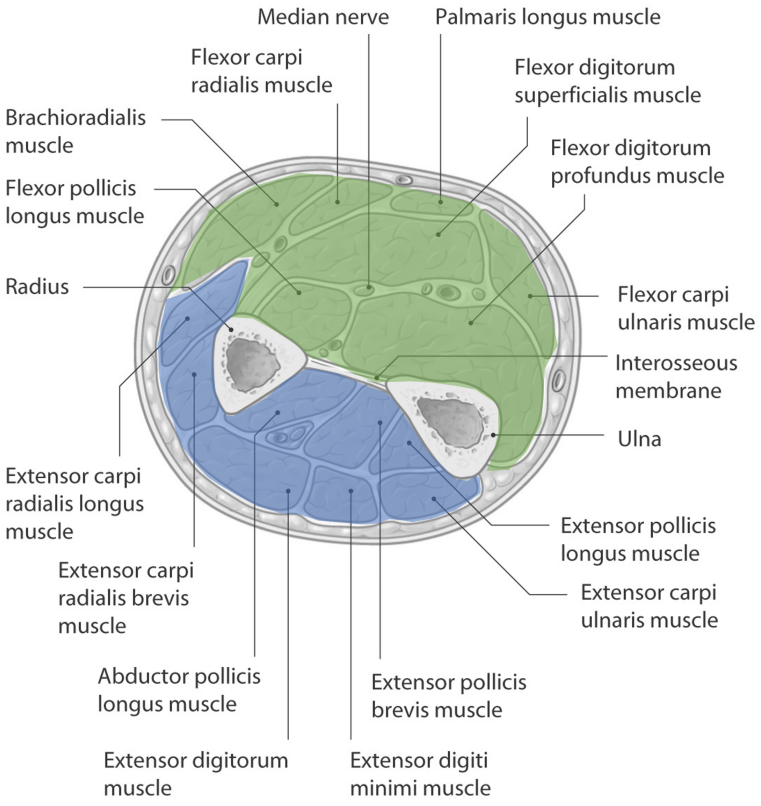


Figure 7.5: A cross-sectional view of the muscles present in the anterior forearm. The wrist extensor group are highlighted in blue, and the wrist flexor group are highlighted in green. Image modified from [40].

single-channel EMG was recorded simultaneously with 4-channel pressure readings. In the second phase, forearm fatigue was measured during a bi-manual, isometric contraction, which was recorded with single-channel EMG sensors on both arms.

7.2.3.1 EMG calibration

The EMG calibration procedure described in Chapter 4, Section 4.6.2 was used to obtain the participants' wrist extensor MVC. In all subsequent trials y_{norm} of the MVC was utilised for EMG control.

As there are three simulator configurations, as described in Chapter 7,

Section 7.2.2, the EMG calibration was performed in whichever configuration was necessary for each participant's first block of EMG trials. The testing order for the configurations was counterbalanced evenly between participants, i.e. the conditions were tested on the participants first, second and third an equal number of times across the participant pool in order to minimise the influence this had on the results.

7.2.3.2 EMG control task

To test the effect of the different pressure configurations on EMG control, a simple 1-dimensional myoelectric target tracking task was devised. The data processing and visual elements of the task were written using the Python programming language, using the AxoPy library [234]. General details regarding the EMG target tracking task can be found in Chapter 4, Section 4.6.3.

Only the extensors were used for control in this task. The moving target was represented by the white line, and the cursor was represented by a green ball, as shown in Figure 7.6(a). The target height corresponded to either 25% or 100% of y_{norm}. The target would rise gradually to the maximum target height, hold at this height for 0.5 seconds, and then descend back to the starting position. A visualisation of the target path and a sample EMG trace is shown in Figure 7.6(b). Participants were instructed to hold their arm in the *neutral* position for each block of trials, but could relax between blocks to prevent forearm fatigue or discomfort. Each block of trials featured 10 'low' (25% y_{norm}) and 10 'high' (100% y_{norm}) trials (total 20 per block). The low and high targets were displayed in a random order. The duration of both 'high' and 'low' trials was the same, hence the target moved faster during the 'high' trials as it had further to rise and fall within the same time window.

Participants were allowed one practice block of 20 trials to familiarise themselves with the task. They were not required to finish the block if they did not want to, once the researcher was satisfied they had shown competency with the task. This block of recordings was not included in the subsequent data analysis. In total, four blocks of 20 trials were performed in each pressure configuration, resulting in a total of 240 trials per participant.

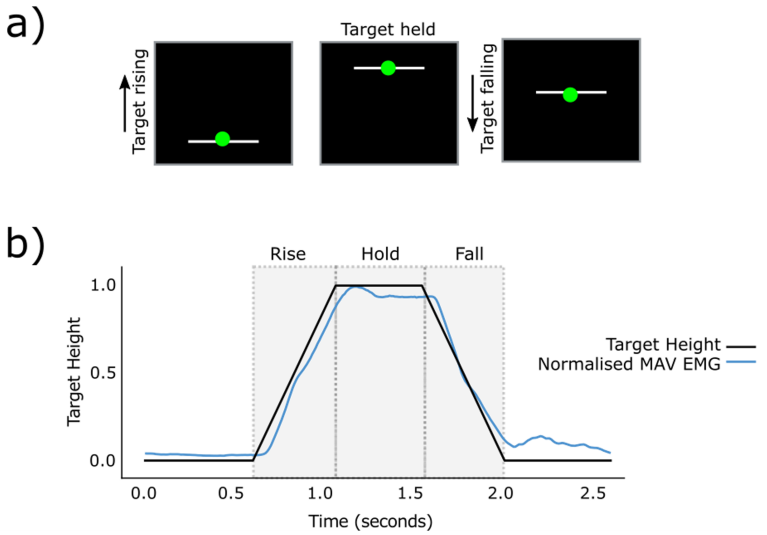


Figure 7.6: (a) An example of how the task appeared on screen as it was given to the participants. (b) A high-target task sample plot and accompanying EMG activity illustrate how the participant tracked the height of the target. The grey section emphasised in the graph split into three, correlating to the rise, hold time, and fall of the on-screen target was utilised to determine participant scores.

7.2.3.3 EMG analysis

The absolute value of the difference between the participant's normalised MAV and the target was calculated for each data point in the recording, measured from the centre of the target to the centre of the cursor. This data was split into three sections: rise, hold, and fall. The data points for each participant's absolute deviation per section were averaged for all of their trials in each configuration to produce scores. This produced 12 average scores, one per participant, for each control section and pressure configuration. To check whether the score distributions were normally distributed, a Shapiro-Wilks test ($p<0.05$) was used. The majority of the score sets were found to be non-normally distributed. To assess whether the score sets were statistically significant between the three pressure configurations, Friedman tests ($p<0.05$) were performed with the data split into 1) rise, hold and fall sections of the trials, and 2) low and high targets.

7.2.3.4 Pressure data collection

Whilst the participants were completing the EMG control task in the *compressed* configuration, the pressure readings registered from all bars was simultaneously recorded for offline analysis. The aim of this investigation was to see if the compression rig could keep pressure on opposing sides during contractions, potentially preventing electrode lift-off. Consequently, the relief and uncompressed conditions were bypassed for this part of the study, as neither applied force directly above the electrode. Additionally, only pressure data from bars 1 and 3 was utilised. Bar 1 provided data for the pressure directly above the electrode, atop the wrist extensors, and bar 3 provided data as to what was occurring at the opposing side of the compression rig, atop the approximate area of the wrist flexors.

7.2.3.5 Pressure data analysis

The pressure data recorded during the compressed configuration was split into low target trials and high target trials. The grouped data was then averaged for both target heights to obtain a mean pressure fluctuation over the whole trial period.

7.2.3.6 Forearm fatigue task

The physiological consequences of fatigue on muscles differ based on the severity and duration of the task, the individual completing the task, and the muscle being studied [328, 334]. As existing research into localised forearm fatigue is limited, it was unclear how long this recovery period would be before the muscles returned to their regular, unfatigued state.

A pilot test was used to assist in the design of the experimental protocol. After completing a single maximal isometric contraction, the volunteers who took part in the pilot reported that they thought their forearms were still fatigued several hours after the trial ended. Extending the experiment into a multi-day study would have introduced more variables, because muscle fatigue can be influenced by a number of physiological factors. These include the concentrations of various ions and neurotransmitters in the bloodstream, the food and supplements the person has consumed recently, and dehydration [335, 336].

Consequently, the experiment was designed to include one, bi-manual fatigue task per participant. This was done to reduce complexity, minimise

physiological fluctuations that could affect the results, and keep the experiment to a single day. Due to this, only two configurations could be tested. During the task, participants wore an EMG sensor on both forearms, as described for the *compressed* and *uncompressed* configurations, and the *relief* condition was not used.

During the fatigue task, participants were instructed to perform a continuous isometric contraction using their maximal strength whilst holding a dynamometer in each hand, i.e. grip the dynamometer as hard as they could for as long as they could, and then release them both simultaneously. This procedure was a variation of previous fatigue experiments such as those described by Klass et al. and Gilliani et al. [337, 338]. For this experiment, handheld dynamometers were used to avoid the need for specialised equipment. To lessen the impact of structural differences in the musculature between the two forearms [339–342], the testing order was balanced over participants so that compression was applied to the dominant arm and non-dominant arm an equal number of times.

7.2.3.7 Forearm fatigue analysis

The length of participant recordings was variable based on how long they contracted their muscles for during the fatigue task. The EMG data acquired was trimmed to only include the time where the participant was actively contracting. This was achieved by manually checking each data set and removing the data where the muscles were inactive before and after the isometric contraction. The time frame where the participant was contracting was called the 'active data'. As each participant started and ended both of their forearm contractions simultaneously, the data for both the compressed and uncompressed arm was trimmed using the same time parameters. Following this, a median frequency analysis was performed using 1 second intervals for every active data file. Changes in the median frequency of an EMG recording are a well-established means of determining muscle fatigue [343]. The difference between the first and last data points of the median frequency analysis were used to calculate a percentage difference for each participant's data set. Shapiro-Wilks tests were used to check whether the percentage decrease data sets were normally distributed. Wilcoxon's rank analysis ($p < 0.05$) was used to assess whether the fatigue data sets were statistically significant between the compressed and uncompressed configuration. To see if limb dominance affects fatigue, the Shapiro-Wilks and Wilcoxon rank analyses were repeated

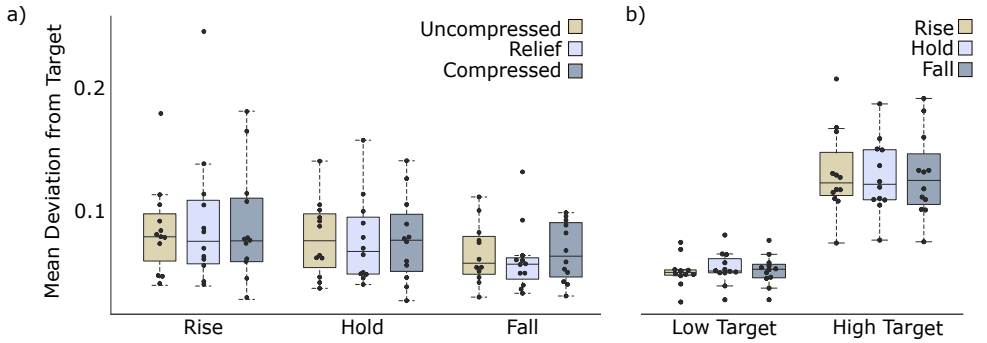


Figure 7.7: Outcomes of myoelectric target tracking control exercises. Mean absolute deviation from the target for (a) all trials' rise, hold, and fall periods, and (b) low and high targets. The upper and lower box bounds indicate the upper and lower quartiles, and the centre line represents the median in all box plots. The whiskers of the plots represent the maximum and minimum excluding outliers.

with data split into dominant and non-dominant arm recordings, instead of compressed and uncompressed. Due to significant noise in two participants' fatigue EMG traces, they were omitted from the study.

7.3 Results

The next Sections discuss the results from the control task, pressure analysis, and fatigue task.

7.3.1 Control results

Figure 7.7(a) displays the mean scores that participant's achieved during the rise, hold and fall periods of the tracking task, split into the three rig configurations trialled for this part of the investigation. Figure 7.7(b) shows the mean scores during the same task periods split into low target height trials and high target height trials. Between all three pressure configurations, no significant difference was observed in the rise ($p = 0.717$), hold ($p = 0.920$) or fall ($p = 0.717$) time periods. Although unrelated to the rig configuration, there was a small non-significant reduction in mean deviation from the target in the fall section of the task compared to the rise and hold sections.

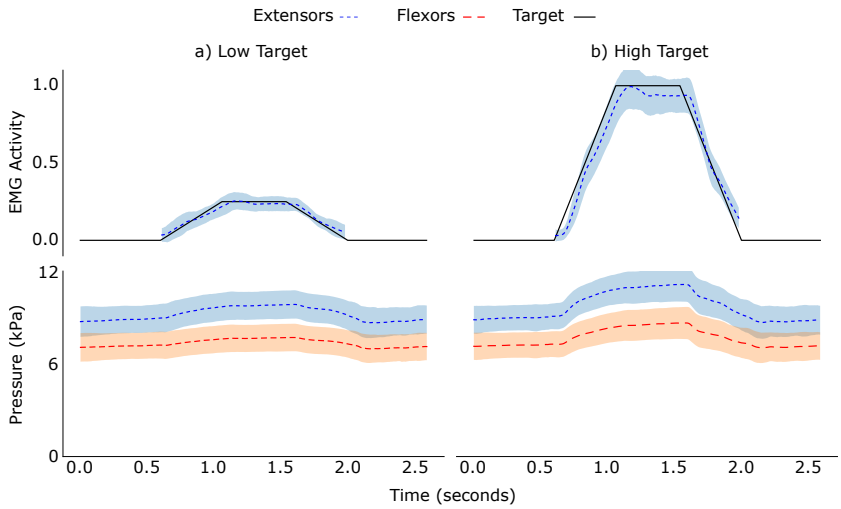


Figure 7.8: The mean EMG recording and accompanying mean pressure recordings taken from bar 1 (the extensors, shown in blue) and bar 3 (flexors, shown in red) across all compressed configuration trials, from all subjects in a) the low target trials and b) the high target trials. The target height at any given moment in time is depicted by the black line, while the coloured bands depict the standard deviation of the averaged data sets. For the EMG recordings, only the rise, hold and fall period are shown, as only these time periods were assessed. Because of anatomical differences mentioned in detail in Chapter 7, Section 7.2.2, the pressure recorded above the extensors was consistently roughly 2kPa (15 mmHg) greater than the pressure recorded above the flexors.

Unsurprisingly, a significantly higher error was observed for the high target trials, due to the distance covered by the target being larger within the time-frame, i.e. a faster moving target. However, even when split down into the three pressure configurations, there was still no significant difference in mean deviation from the target for high ($p = 0.77$) or low ($p = 0.368$) target trials. The average score attained by the individuals as the trial progressed was plotted over time, and a weak trend ($R^2 = 0.349$) towards error reduction was noted as participants completed more trials. Appendix D.1 displays this trend.

7.3.2 Pressure results

The mean changes in the pressure recorded across all participant's compressed configuration trials with corresponding mean EMG activity are shown in Figure 7.8. The data is split into low target trials, shown in Figure 7.8(a), and high target trials, shown in Figure 7.8(b). In this figure, the pressure recorded from bar 1, above the extensors is seen to be consistently 2kPa (15 mmHg) greater than the pressure recorded from bar 3, above the flexors, due to the anatomical differences explained in Chapter 7, Section 7.2.2. This difference was exacerbated during contractions performed in high-target trials, as displayed in the figure. Regardless, the pressure variations for both bars across the high and low target groups exhibited a comparable trend. Both the extensor and flexor pressure plots demonstrate an increase in pressure during contractions (the rise, hold and fall period) for both high and low target trials. Hence, this test demonstrated that whilst wearing the compression rig, pressure increased at opposite sides of the rig simultaneously during contractions.

7.3.3 Fatigue results

The rates of fatigue for the compressed versus uncompressed arm and the dominant versus non-dominant arm are contrasted in Figure 7.9. In both the compressed and uncompressed configurations, there was no significantly different change in the participant's arms' mean rate of fatigue ($p = 0.182$), however the compressed configuration did display a slightly smaller mean reduction in median frequency. For this specific test, the results do not show the same fatigue-decreasing impact as observed in preceding studies using compression clothing [323]. The rates of fatigue in the dominant and nondominant arms did not differ significantly ($p = 1$) from one another.

7.4 Discussion

The objective of this study was to evaluate and quantify the impact of LC on key wearability-related aspects for EMG prostheses, including control, maintaining electrode-to-skin contact, and muscular fatigue. According to the findings of this study, the participant's closed-loop control skills in our myoelectric target tracking task were not significantly impacted by mild LC of their forearm. As the control task progressed, the participant's average

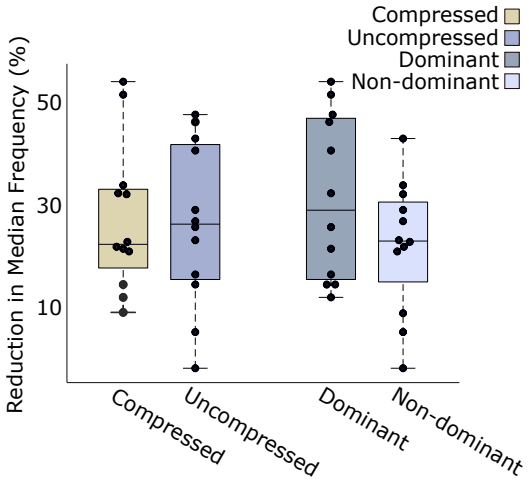


Figure 7.9: Rates of fatigue for the compressed and uncompressed arms, as well as the dominant and non-dominant arms. For the median frequency analysis of the EMG recordings from each arm, the rate of fatigue is calculated as the scalar of the trendline. The whiskers indicate the maximum and minimum, omitting outliers, while the centre line represents the median. The top and lower box bounds correspond to the respective upper and lower quartiles.

mean deviation from the target decreased, hence improving their accuracy over time, as shown in Appendix D.1. This trend, which likely is accountable for some of the variability in the results, is suggestive of participant learning as they repetitively performed the task. However, given the simplicity and duration of the task, it is improbable that this trend influenced the results significantly.

Given that the control task results showed that LC had no effect on myoelectric control within this study, these findings suggest that traditional socket designs would be just as effective for single-channel myoelectric control. Conventional designs come with the added benefit of being tried and tested for socket safety, as well as generally achieving acceptable levels of socket fit and comfort for the wearer. However, most standard clinical transradial sockets have a relatively inflexible, hard design with EMG sensors recessed within the socket wall. As discussed in Chapter 2, Section 2.2.3.3, dual-channel EMG control is usually achieved using the wrist flexors and extensors, which are almost equidistant radially around the forearm. Con-

ventional socket designs paired with this EMG set-up are vulnerable to 'electrode lift-off,' which occurs when the residual limb pushes against one side of the socket during movements, contractions, or load-bearing [38, 119]. This can cause the opposite side of the limb to disengage from the socket wall and the electrode embedded within it, resulting in a loss of contact between the electrode and the skin [38, 119]. As illustrated in Figure 7.8, the pressure data recorded during compressed configuration trials suggests that incorporating electrodes into LC bars can be employed to sustain pressure at the socket-skin interface during muscle contractions. There are several avenues to further this research. Ideally, an investigation with amputee or limb-different individuals who regularly operate myoelectric prostheses would be performed on a long-term basis. As an initial step, it would be helpful to know whether the maintenance of pressure observed in this study impacts two-channel control, which is more commonly used in clinics. To do this, a prosthetic socket or prostheses simulator which allows the bars to be adjusted radially around the forearm would be necessary to facilitate accurate positioning above or around key muscle groups for a wide range of individuals.

Forearm fatigue rates did not change significantly between the compressed and uncompressed configurations. However, the drop in median frequency was marginally reduced for the compressed configuration. This indicates that the limbs fatigued slightly less than in the uncompressed configuration, as was expected. There was no significant difference in fatigue rates between the dominant and non-dominant limbs, hence supporting the idea that although balancing the testing order between the participant's dominant and non-dominant limb was performed, it was not necessary and did not impact the results.

To summarise, both the myoelectric control and fatigue task data showed that the LC socket simulator had little influence on factors relevant to single-channel EMG control of an upper-limb prosthesis. However, the pressure task data suggests that LC bars could be used to maintain electrode contact during prosthesis use. This may also be useful for decreasing well-known but poorly understood phenomena such as the 'limb position effect', where attempting to operate a myoelectric prostheses out of a given workspace decreases the reliability of the outcome [307]. The purpose of the struts in LC sockets is to displace tissue and decrease 'lost motion' [25], hence it is reasonable to assume they would be beneficial to remedying this particular issue. Further work will be required to gauge to what extent the maintenance of pressure observed in this study would benefit multi-channel EMG control.

7.4.1 Pressure and Safety

Although no precedent exists in published literature, it is expected that even the highest pressure value in this study's tolerance range is much lower than the pressures applied by most LC sockets. The 2011 publication by Alley et al. instructs the clinician to 'compress the tissue against the long bone [...] until it no longer yields' [25]. Based on pilot analyses it was evident that even at well over 16kPa (120mmHg) there was still ample scope to further compress the tissue, suggesting pressures used in clinical practice today may be extremely high.

7.4.2 Study Limitations

As the existing literature on this area of socket design is particularly sparse, many of the protocols for this experiment were chosen due to the author's experience. There were several limitations which serve as opportunities to improve future research for their similarity to real life prosthesis control. Due to a lack of specialised equipment, this study used regular handheld dynamometers and assessed hand-grip strength rather than isolating and fatiguing only the wrist extensors. Typically, studies examining compression for sports applications are undertaken across numerous, longer recording sessions [321, 322, 328, 344, 345], as they have a much wider and larger target demographic. However, this study only looked at single recordings of the participant's maximal isometric muscular forearm contraction. Hence, a more detailed investigation in the future would be useful to confirm any correlation between LC sockets and limb fatigue.

Additionally, the socket simulator used in this study did not support distal loading to emulate using a terminal device. Several of the parameters examined in this study would have been affected by loading. Due to this, future studies should account for this or consider a compression rig which allows distal loading or the attachment of a terminal device. Moreover, the control task and pressure data were only collected at 90 degrees elbow flexion. It is known that limb-position can significantly affect a user's ability to operate their prostheses [307]. In essence, the 'limb-position effect' is where a user is trained to use their myoelectric prostheses in a fixed arm position, but then uses their prosthesis in different positions during daily use, which results in a degradation of performance from the device [346]. To further investigate the impact of LC on myoelectric control, future tests should record

a range of arm postures. The socket simulator featured compression bars in a uniform arrangement around the limb. This approach allowed us to examine if localised, LC impacted EMG characteristics for single channel control. However, adjustable compression bar placements would be required to see whether the findings transfer to multi-channel EMG and pressure-maintenance over several sensor sites.

7.4.2.1 Participants

To reduce the influence of limb length and structural variability, only able-bodied subjects were selected for this study. This enabled a fair comparison of various compression options. As a result, a simulator was created to allow able-bodied individuals to participate. The literature relating compression simulators to actual LC sockets is limited, with Sang et al. presenting the only known earlier example. In general, individuals with acquired limb differences have musculature that is similar to that of an able-bodied person, albeit shorter or partially removed. This is particularly true when the amputation was elective as, in general, more of the musculature can be saved. Hence it is likely that the compression rig would have worked in a similar fashion for acquired amputees as it did for the able-bodied volunteers. However, they may require shorter or narrower compression bars to accommodate the length and form of their residuum. Contrary to this, in individuals with congenital limb difference, irregular muscle structures and hypoplasia are more common. For these individuals, a design such as the one featured in this experiment, with the bars fixed at 90 degree spacing relative to each other, may not be suitable. For this study, the positioning of bars 2-4 was not critical, as only the extensor muscle site underneath or next to bar 1 was assessed. Hence, for future studies, it should be possible to rotate the bars around the forearm to allow them to be positioned closer or further apart, as necessary to suit each individual. This would also be useful to allow the bars to be placed directly above both the extensor and flexor groups at the same time, as they are generally not precisely positioned at 180 degrees from one another. Ideally, these studies would be conducted with amputees who routinely use a myoelectric device.

7.5 Chapter Summary

- Longitudinal compression in an evenly distributed 4-bar socket simulator does not impair single-channel EMG control nor does it decrease fatigue behaviour of the wrist-extensor muscles during a high-intensity isometric contraction.
- Pressure data presented in this study reveals that LC, when applied tangentially to the target muscle, aids the maintenance of contact between the limb and the socket at both the target muscle site and the opposing side of the socket.
- Consequently, LC sockets may assist multi-channel myoelectric control systems when the sensors are embedded into the compression struts and positioned directly above the target muscle.

Chapter 8

Compression-Optimised Trans-radial Prosthetic Cuff Design

The key aims of this PhD research were to:

1. Investigate the viability, benefits and shortcomings of modern technology for upper-limb prosthetic socket creation.
2. Use these findings to prototype a manufacturing method and design of upper-limb prosthetic device, optimised for prosthesis control.

Chapters 2-7 fulfilled the first aim. In the final Chapter of this PhD thesis, the original aims of the PhD are revisited and the preceding work is summarised. Building upon the findings of the previous Chapters, a novel socket manufacturing method and cuff design were devised. The manufacturing method, featuring a hybrid digital-tactile approach, was trialled and evaluated. Following this, an in-depth investigation into the prosthetic cuff's impact on EMG control was conducted.

8.1 Introduction

As demonstrated in Chapters 5 and 6, a limb's characteristics and underlying structures need to be accounted for when digital scanning. Chapter 6 outlined one method for this, with the addition of clinical notes and tactile markings. As an alternative, it is thought that using compression to sculpt the limb tissue whilst it is scanned could provide another method to hand-sculpting a cast [347]. Using longitudinal compression (LC) depressor bars may enable this. However, the impact of LC sockets on dual-channel EMG control, the system most commonly used in clinics, is yet to be researched. Subsequently, research was necessary to explore whether LC could be a viable option for both enhancing EMG control and providing a modernised limb-capture method.

8.1.1 Study Aims and Objectives

Based upon the findings of the previous Chapters, two key aims for the final investigation of this PhD thesis were devised. The first aim was to determine whether a novel method of manufacturing prosthetic sockets could be devised using LC bars. The second aim was to design an optimised trans-radial prosthetic socket prototype, featuring LC, and test it for it's effect on forearm myoelectric control.

The primary focus of the two goals is different. The first aim focuses on whether the way trans-radial prosthetic sockets are manufactured can be improved through the findings of this PhD thesis. The second aim focuses on improving the current design of trans-radial prosthetic sockets. This will be achieved by evaluating and quantifying the benefits, if any, of LC on dual-channel EMG control. Similarly, within both aims there are several key sub-aims and metrics which can be used to assess their outcome. Below, the purpose of each aim and the specific objectives that will be used to achieve them are discussed in detail.

8.1.1.1 Digital Scanning and Longitudinal Forearm Compression

As discussed in Chapters 5 and 6, most current methods of digitally scanning residual limbs to capture their geometry do not feature tactile steps. The limb is scanned 'blind' and information about the soft tissue compliance is lost. Ideally, it would be possible for a prosthetist to be able to apply the 'moulding

grip' whilst a digital scan was taken. This would bring a tactile element to the digital scan that would account for the tissue compliance, and so that the *rectification* process would be guided by the indentations in the scan. However, this would not be possible as subtracting the prosthetist's hand from the scan would be too complex to perform reliably in CAD, because the hand is not a uniform known shape. Additionally, it is unlikely that the hand would remain sufficiently still for the scan to be accurate.

It is conceivable that applying some form of grip or clamp to the limb whilst scanning would be a more suitable option to bring a tactile element to digital scanning. The rig would need to be a known shape, so that the CAD model of it could be aligned and deducted from the scan accurately. Compression bars redistribute the soft tissues of a residual limb in a way that is biomechanically advantageous for load distribution when applied correctly [25]. Hence, they provide a novel opportunity to compress a residual limb whilst leaving the majority of it's geometry on display. It is hypothesised that if a scan was to be performed whilst compression bars were affixed to the limb, a scan which takes into account tissue compliance could be produced, thus making a digital process tactile. As the bars would be of a known size and shape, they could easily be aligned with the scanned bars and turned into a prosthetic socket design, thereby eliminating the need for most post-scanning rectification and contouring.

Previous research in this PhD thesis has shown that the most significant barrier to adopting digital tools as viable alternatives for socket manufacturing is a lack of tactile input during the early stages of production. As a result, this method has the potential to make a significant clinical difference. This Chapter will investigate whether using a combination of digital scanning and LC can be used to create a prototype socket design, in the form of a cuff, suitable for able-bodied participants.

8.1.1.2 Longitudinal Forearm Compression and EMG Control

Chapter 7 demonstrated that LC helps maintain contact between the limb and the socket at opposing sides during contractions. However, no benefit to single-channel EMG control or limb-fatigue was observed during a simple target-tracking task. It is hypothesised that a noticeable improvement would be seen when using dual-channel control, as this would require a secure connection between the limb and the electrodes at more than one area inside the socket. To investigate this, a prosthetic socket prototype featuring LC was

assessed for it's impact on dual-channel myoelectric control. The prototype was created using the aforementioned digital scans described in Chapter 8, Section 8.1.1.1.

8.1.1.3 Objectives

There were four key objectives in the final Chapter of this PhD research:

- Firstly, to create a fully adjustable compression rig that allows accurate compression bar positioning for dual-site EMG control.
- Secondly, to scan participants' limbs whist wearing the compression rig to obtain a digital scan that takes into account the wearer's soft tissue compliance.
- Next, to create 3D printed LC cuffs from the scans as a form of prototype trans-radial prosthetic socket simulator (suitable for the able-bodied participants).
- Finally, to test the 3D printed cuffs for their effect on EMG control and limb stabilisation.

8.2 Methods

To correspond to the four key objectives outlined above in Section 8.1.1.3, the methods used in this investigation are split into four corresponding Sections.

8.2.1 Ethics

This study was approved by the Newcastle University local ethics committee (Ref: 20-DYS-050 and 23877/2022), attached in Appendices A.3 and A.5.

8.2.2 Participants

Five able-bodied participants were recruited to take part in this study (4 male, 1 female). All participants were gauged to be healthy individuals by the researcher at the time of the study.

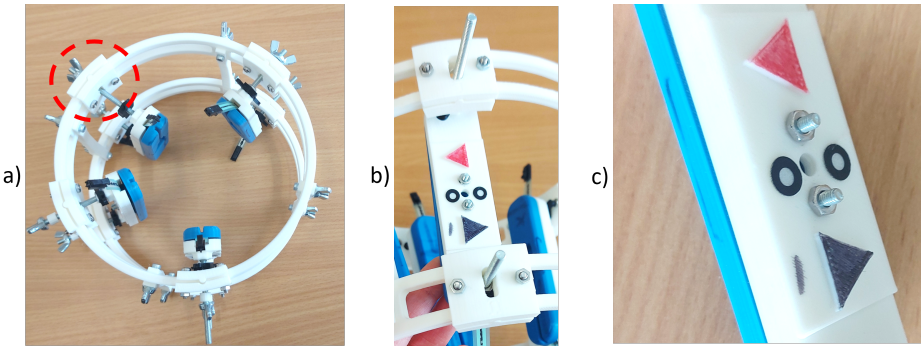


Figure 8.1: The compression rig, comprising several custom-made 3D printed components. (a) The slider mechanism which allowed the bars to be rotated around the arm. One of the eight sliders (two per bar) is highlighted by a red circle. (b) The locus-shaped slots within the sliders which allowed a small amount of axial and angular adjustment of the bars (c) The two triangular tactile markers added to each bar to assist the scanning and alignment process. Also visible are two reflective scanning markers added to each bar.

8.2.3 Compression Rig Creation

A rig to allow the compression bars to be moved around the limb radially and apply pressure was developed. All engineering drawings for the custom made components can be found in Appendix D.2. The design builds upon the test rig used in Chapter 7. As such, pressure recordings were also acquired using the equipment and methods detailed in Chapter 4, Section 4.7. In the last design, the angular position of the bars around the forearm was fixed to 90 degrees between each bar. This did not allow for the bars to be accurately positioned atop both the wrist flexor muscle group and the extensor muscle group simultaneously. To allow radial rotation of the bars relative to the forearm, a slider mechanism was added, as shown in Figure 8.1(a). The sliders could be loosened with a screwdriver to allow movement of the bars. Once the approximate positions of the flexors and extensors were found, the sliders were adjusted to corresponding positions and tightened to prevent radial rotation of the bars whilst the compression rig was in use. The sliders also featured locus shaped slots to allow a minimal amount of axial and angular adjustment to the bar's positioning along the arm, as shown in Figure 8.1(b).

As in the previous design, the bars and circular collars that house the

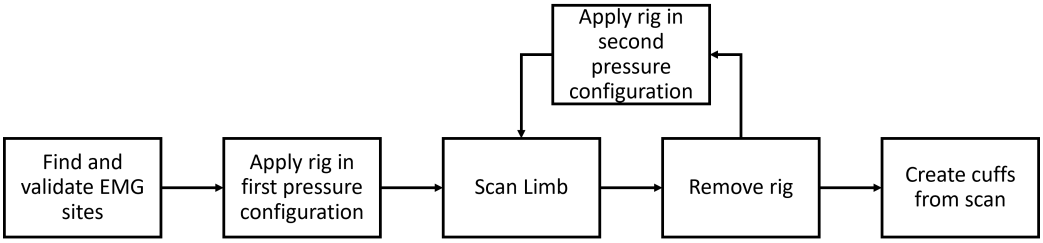


Figure 8.2: A summary of the steps undertaken to obtain limb scans using the hybrid digital-tactile approach described in this Chapter.

bars were both 3D printed using PLA for all parts not in contact with the skin, and PLActive for the parts interfacing with the skin. Metal hardware such as bolts, screws and wing nuts were used to construct the pressure-adjustable mechanism of the rig. Additionally, tactile markers were added to the outer section of the compression bars, as shown in Figure 8.1(c). The markers consisted of two triangles, one black and one red, extruded by 1mm. The markers were added so that the CAD models of the bars could easily be aligned with the digital scans of the limb and rig by aligning the vertices of the triangles present on the bars.

8.2.4 Pre-compressed Limb Scanning

As discussed in Chapter 3, there are no universally accepted metrics for gauging the outcome of prosthetic sockets, and none which are validated for prototyping novel socket designs. Consequently, to provide a comparable reference for the high-pressure cuff to a clinical standard socket, for each participant, a low pressure cuff was also produced. The general design of the cuffs was kept the same to minimise the differences in geometry between the two designs, and both cuffs featured four struts running parallel to the radius and ulna. The full procedure for creating the cuffs is described below. A summarised flow chart of steps is shown in Figure 8.2.

8.2.4.1 EMG positioning

A DELSYS™ Quattro sensor was used. The EMG positions were located and marked using the method described in Chapter 4, Section 4.6.1. Care was taken to avoid placing the 'support' sensor heads atop any sensitive areas that

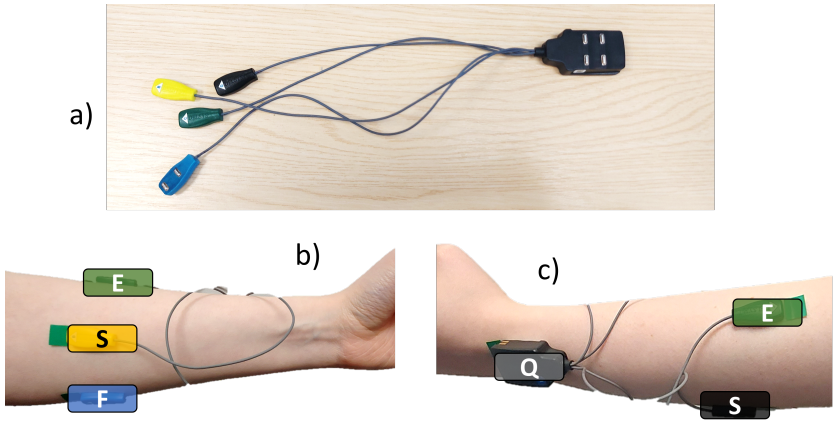


Figure 8.3: (a) A DELSYS™ Quattro sensor with four EMG heads. (b-c) The electrode arrangement affixed to the forearm with DELSYS™ adhesive film. 'E' indicates the extensor electrode, 'F' the flexor electrode, 'S' indicates support bar electrodes (not analysed in this study) and 'Q' indicates the main unit of the Quattro.

may cause discomfort once pressure was applied. The sensor arrangement is shown in Figure 8.3.

8.2.4.2 Pressure Application

Firstly, the compression rig was loosened fully, using the wing nuts shown in Figure 8.4. Two wing nuts were threaded onto the bolts protruding from the compression bars, one below the slider to adjust the pressure of the rig, and one above the slider for stability. The bars were rotated along the rig's slider mechanism so that one bar was aligned with the extensor EMG site, and one aligned with the flexor EMG site. The support bars were placed approximately half-way between the flexor and extensor bars on either side of the limb. This was done to provide mechanical stability in the design of the brace. Effort was made to avoid any major blood vessels or uncomfortable areas by palpating the limb first to find appropriate areas. Next, the compression rig was applied and tightened so that all bars fit within the acceptable compression range described in Chapter 4, Section 4.7. Henceforth, this configuration is referred to as the *high compression* cuff.

Once the rig was positioned correctly and tightened, the quality of the

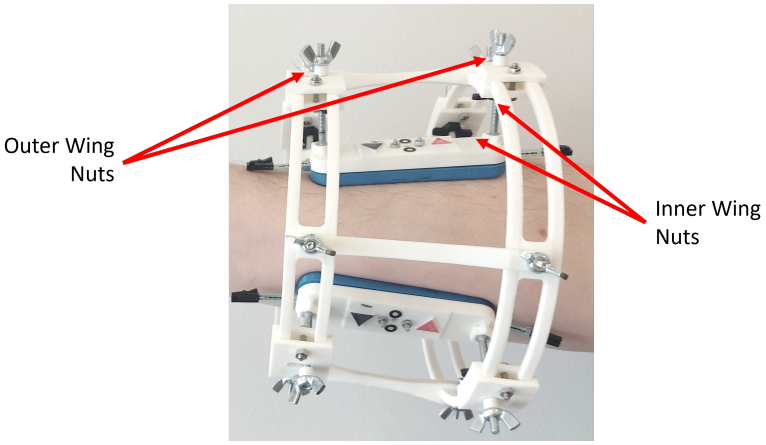


Figure 8.4: The wing nuts used to tighten and loosen the compression cuff. The inner wing nuts comprised a standard hex nut adhered inside a flat 3D printed casing to convert it into a custom wing nut that took up a minimal amount of space. The outer wing nuts were standard metal components.

EMG signals were verified, and the limb was scanned using a 3DSystems Sense v1 digital scanner [228]. Both procedures are detailed in Chapter 4, Sections 4.7 and 4.3 respectively. Effort was made to ensure the final scan had captured the eight triangular markers from the four compression bars clearly. The rig was then loosened so that the bars were still in contact with the skin, but as little pressure as possible was being applied to the limb. This configuration will be called the *low compression* cuff going forwards. No set quantitative bounds were defined for achieving the loose compression configuration, to accommodate the different anatomy and prevalence of soft tissue present on different participant's limbs. Instead, it was decided the bars would be loosened until the skin friction between the bars and limb was just enough to prevent the rig from slipping down the participant's arm when gently shaken. This was to simulate what is believed to be similar to the skin contact many standard fit prosthetic sockets have, where there is enough skin friction between the socket and limb to suspend the device, but not enough to prevent major mechanical disturbances. To recap, the majority of a regular trans-radial socket's suspension comes from the supracondylar contouring, not skin friction, hence even a well-suspended socket may be relatively non-compressive. The scanning and EMG validation procedure were repeated for the low-pressure condition. The entire procedure resulted in two scans of the

limb, one featuring the rig applied in the high compression configuration and one in the low compression configuration.

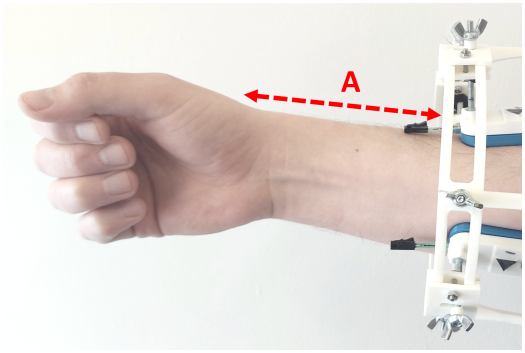


Figure 8.5: Measuring the distance between the wrist (radial styloid process) and the compression bars. Measurement was taken in the area labelled A.

The distance from the participant's wrist (radial styloid process) to the distal tip of the compression bars was measured in both pressure configurations, as shown in Figure 8.5. The measurements from both pressure configurations were almost equal, but were averaged nonetheless. This was to allow accurate positioning of the cuff created at a later date. It was important to note this, because the pressure would be different due to the limb physiology if the cuff created from the scans was positioned lower or higher along the limb. This issue would not affect amputees as their sockets are designed to encapsulate the entire residual limb.

8.2.5 Cuff Creation

In this study, only the position of the compression bars relative to each other was important for the CAD procedure. Furthermore, only the position of the triangular markers on the upper-side of the compression bars were necessary to reconstruct the bars and their position in the digital domain. Accordingly, the scans were trimmed to remove any hand or elbow areas captured by the scanner. This reduced visual noise and made the scans easier to process, reducing the overall processing time. The scans were minimally processed, as described in Chapter 4, Section 4.4. Artefacts within the scan were only removed if they obstructed view of the markers.

The processed scans were imported to *CloudCompare*, an open-source 3D point cloud processing software. CloudCompare allows multiple CAD

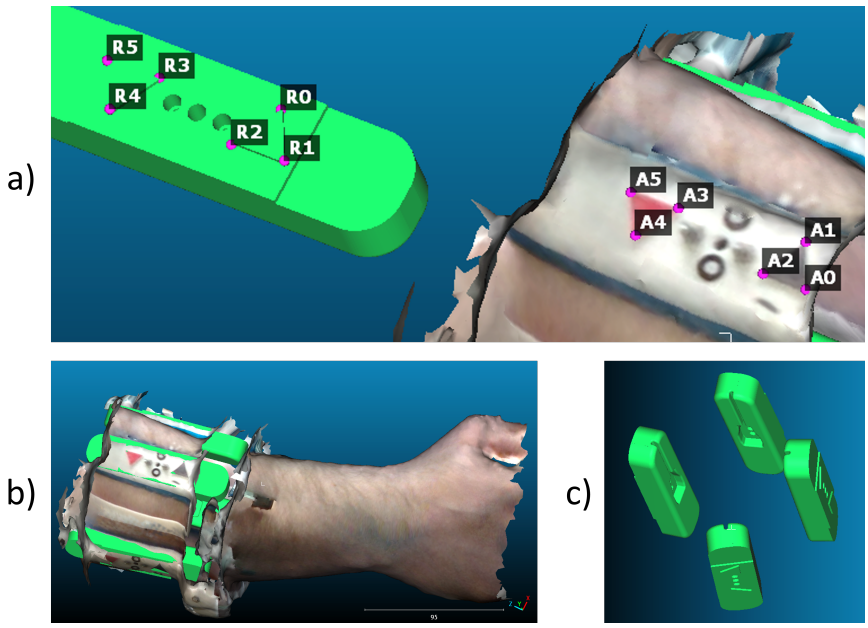


Figure 8.6: A summary of the alignment procedure undertaken in Cloudcompare. (a) Matching reference points were manually selected on both the CAD model and the scan of the bars. (b) A snapshot of all four bars aligned with a scan. (c) Once the limb scan is hidden, the CAD models of the four bars remain correctly positioned relative to each other in 3D space.

models to be aligned in 3D space using matching reference points between the models. Four compression bar CAD models were also imported into each scan, and aligned using the triangular markers. This was achieved by selecting all three vertices of both triangles of each bar, to make six reference points, and then using CloudCompare to fit the CAD model of the bar to the scanned version. Manual adjustment was performed when auto-alignment did not achieve a match which aligned well with the scanned image. Once all bars were aligned, the original scan was removed leaving the four bars, as summarised in Figure 8.6.

The model containing the four bars was then exported as a mesh from CloudCompare and into Autodesk Fusion. Within Autodesk Fusion, the mesh representations of the bars were replaced with identical Autodesk Fusion CAD models. This step was necessary as it is not possible to build directly upon mesh files within Fusion, and file type conversion degrades the

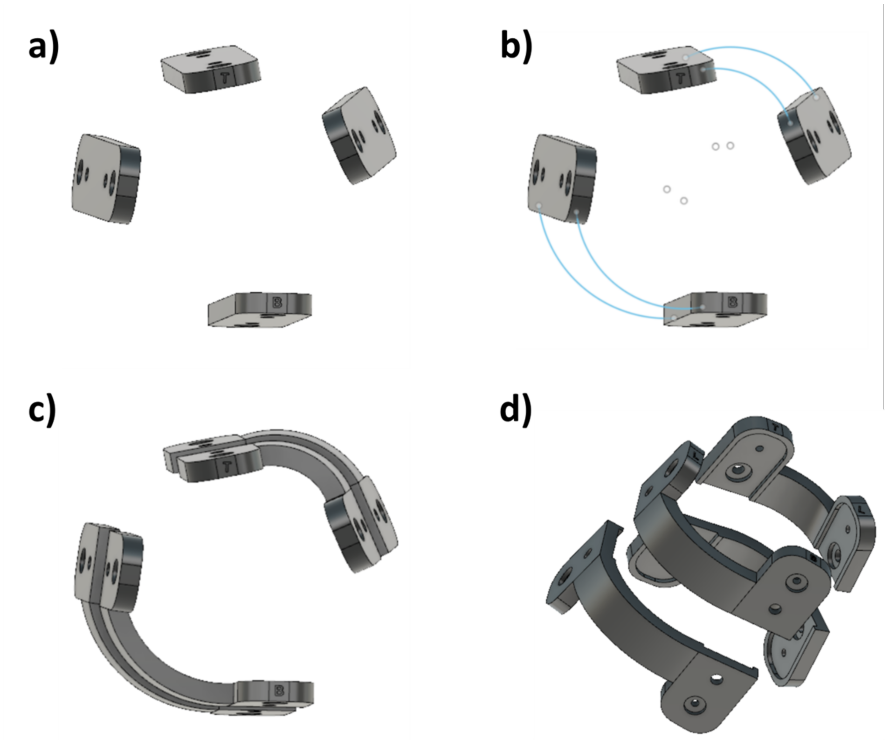


Figure 8.7: A summary of the steps necessary to create the cuffs in Autodesk Fusion (a) The CAD models of the bars are imported, pre-aligned relative to one another in 3D space from Cloud-compare. (b) Arcs are drawn between the flat faces of the bars. (c) Using the arcs as guide rails, the flat faces of the bars are 'lofted' between each other. (d) A side view of the finished cuff pieces.

accuracy of the model. Hence, the meshes were replaced so that the models could be altered and built upon in Autodesk Fusion. Arcs were drawn between the bars 1 and 2, and 3 and 4, as shown in Figure 8.7. Using these arcs, support structures were built between the bars. This created the foundations for each compression cuff. The CAD process was repeated for both the high compression and low compression scans for each participant.

The compression cuff was designed so that the compression bars were screw-in, and could be re-used, reducing the total 3D print time for the study. Additional holes were created to screw on a tightening mechanism at a later stage. The modular design allowed the rigs to be 3D printed in con-

venient, smaller pieces. Ratchet straps were used as a tightening mechanism. Originally intended for sports purposes, the ratchet mechanism allowed easy tightening and loosening of the compression cuff and provided a quick-release mechanism, as shown in Figure 8.8.

(a) (b)

Figure 8.8: An example of a finished cuff worn by a participant viewed from the (a) dorsal (exterior) and (b) ventral (interior) side of the forearm.

8.2.6 Cuff Testing

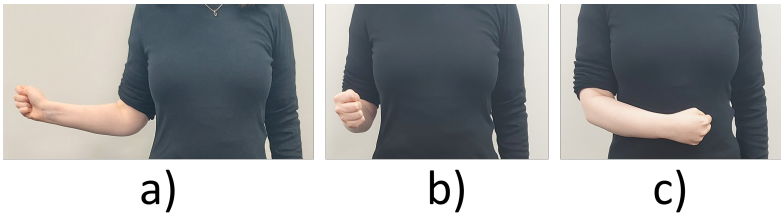


Figure 8.9: (a) External shoulder rotation (b) The neutral position (c) Internal shoulder rotation.

A simple EMG task was devised in order to assess the participant's ability to meet a predetermined threshold for both their extensor and wrist flexor groups in different limb positions. As all participants were right-handed, the right arm was used for all EMG tasks. The calibration procedure to establish the participant's maximal comfortable contraction (MCC) and baseline EMG activity was performed as described in Chapter 4, Section 4.6.2. The target threshold, $y_{norm} = 1$, was set to the MCC. The task used five different limb

positions. With the forearm flexed to 90 degrees, participants were shown how to maintain this position whilst rotating their shoulder to -85 (position 0), -45 (position 1), 0 (position 2), 45 (position 3), and 85 (position 4) degrees. Shoulder rotation can be performed internally and externally whilst maintaining the same angle of flexion at the elbow. Shoulder rotation with a flexed forearm is shown in Figure 8.9.

The participants stood at a set distance from a table during the task. The table was labelled with five markers, as outlined in Figure 8.10. A large TV screen was positioned behind the table. The on-screen display showed five targets, corresponding to the physical markers on a table. During the task, a randomly selected target was displayed on the screen and the participant was required to move their arm to the corresponding position indicated by the marker on the table. Once their limb position was verified visually by the researcher, a second visual cue, an arrow, was displayed to the participant. A left facing arrow signified that the participant should contract their flexors, and a right facing arrow indicated they should contract their extensors. The protocol for the EMG task is summarised in Figure 8.10. Each participant performed three blocks of 50 trials for each brace condition, totalling 300 trials. Within each block of 50 trials, each target was shown 10 times, and out of those 10, 5 were flexor trials and 5 were extensor trials. Rest breaks of up to ten minutes were provided between blocks of trials. The participant was required to wear the test rig continuously for all three blocks for each brace condition to eliminate the need to reposition the sensors. Full details of the task can be found in Appendix E.1.

Assessing a user's proficiency, ability and reliability when using dual-channel EMG control is not straightforward. The task must be simple, or the effect of *learning* may bias the results. The improvement of participant EMG skills in complex or long-duration EMG tasks has been observed in previous myoelectric control investigations [137, 298]. Conversely, lengthy, repetitive EMG training procedures may result in poor engagement from the participant, as observed with actual prosthesis users [348]. Therefore, a simple task was preferred for this investigation. However, with a simple EMG control task, it is likely that wearers will achieve good accuracy, regardless of detrimental or beneficial adjustments made to their EMG recording system, i.e. a poor socket or a well fitting socket. Accordingly, multiple metrics were observed to gauge the impact of changes to the way electrodes were interfaced with the limb: target accuracy, EMG anomalies and unwanted muscle activations, EMG amplitude, and forearm range of motion.

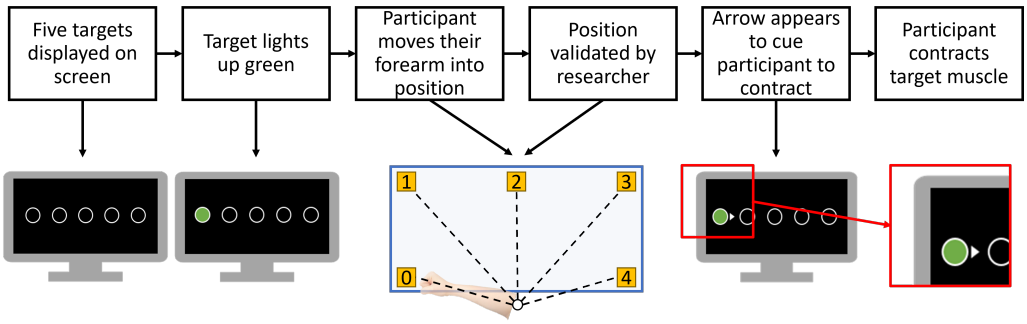


Figure 8.10: A diagram summarising the key stages of the EMG task. Firstly, the five targets as displayed at the start of each trial. A target was randomly selected and lit up green, this cued the participant to rotate their shoulder to align with the corresponding physical target on the table in front of them. After their limb position was visually verified, the randomly selected cue to either flex (a left arrow) or extend (a right arrow) was displayed. The arrow is highlighted in a red box for clarity.

8.2.6.1 Target Accuracy

Target accuracy was measured in the form of pass/fail percentages. A pass was defined as when the target muscle signal met or exceeded the target threshold of $y_{norm} = 1$ within the assessed part of each EMG trial. When the target muscle signal did not meet or exceed $y_{norm} = 1$ within the assessed time period, the trial was classed as a fail. For both the high and low pressure brace trials, it was possible to quantify how many failures occurred.

8.2.6.2 Anomalies and Unwanted Muscle Activity

Trials were categorised into 'passes', with and without co-contraction, and 'fails', where either only the antagonist muscle, or neither muscle hit the threshold, $y_{norm} = 1$, as shown in Figure 8.11. Full details can be found in Appendix E.2. In addition, EMG activity prior to the participants commencing the trial was recorded and analysed. This was because, assuming participants are following the protocol, any unprompted EMG activity detected during this period was artefactual. Because signals could indicate EMG sensor detachment, disturbance or motion artefact, the results were categorised to gauge how many trials featured pre-trial disturbances. The rates of occurrence for each type of EMG disturbance were analysed and

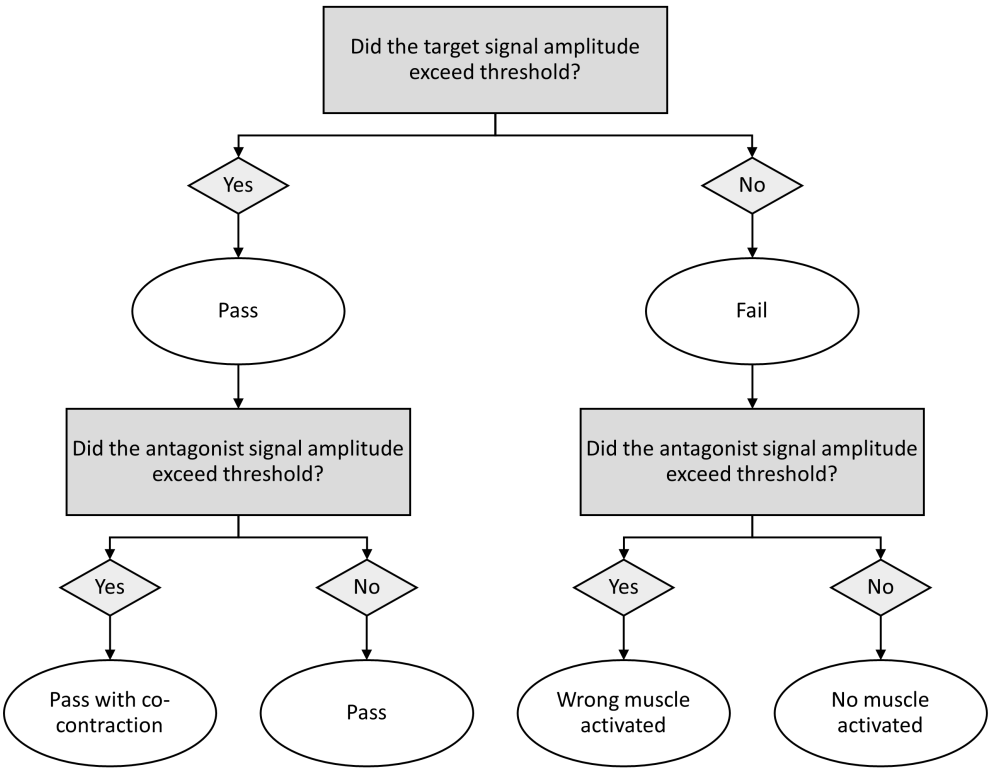


Figure 8.11: A flow diagram outlining how the trial results were categorised.

compared between the high and low pressure brace conditions.

8.2.6.3 Target and Antagonist EMG Activity Amplitude

The maximum amplitude of the EMG MAV detected during the assessed time-period of each trial was analysed for the target and the antagonist muscles. This was done to gauge and compare the overall amplitude of contractions performed by the wearer during both the high pressure and low pressure brace trials. Similarly, the difference between the maximum EMG amplitude of the target and antagonist muscle recordings were assessed to determine whether the cuff pressure configuration impacted EMG signal to noise ratio.

8.2.6.4 Forearm Range of Motion

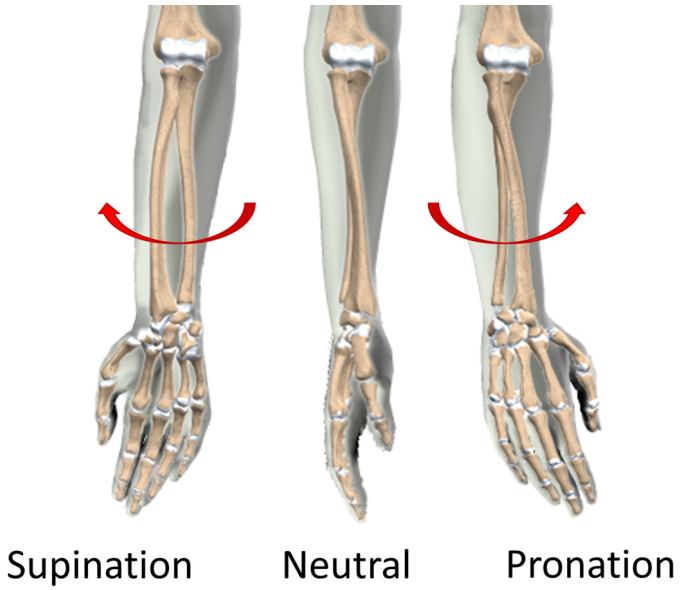


Figure 8.12: A diagram showing rotation of the radius and ulna bones during forearm pronation and supination. Image modified from [41].

Forearm rotation (wrist pronation/supination) occurs by the radius and ulna twisting around each other, as shown in Figure 8.12. This motion requires movement of the underlying bone structures. It was hypothesised that the high pressure cuff would inhibit some of this motion, supporting the theory that LC sockets can reduce *lost motion* between the skeleton and the soft tissues. Before donning either of their cuffs, the wrist pronation and supination range of motion (ROM) was assessed for each participant. Each participant sat with their humeral bone parallel to their torso with their forearm flexed at 90 degrees with their hand making a fist. With the researcher lightly supporting their olecranon, participants were asked to rotate their forearm inwards (pronate) and outwards (supinate) as far as they could comfortably without inducing pain. Participants were asked to hold a pencil in their fist whilst performing these actions to assist measuring their ROM. A manual goniometer was used for measurements, and readings were taken three times and an average value was attained. A variation of the procedure which does not require the participant to hold an object whist rotating their

forearm is pictured in Figure 8.13. The procedure is a standard ROM measurement method and is described in [349]. The same ROM measurement process was repeated for each cuff condition.

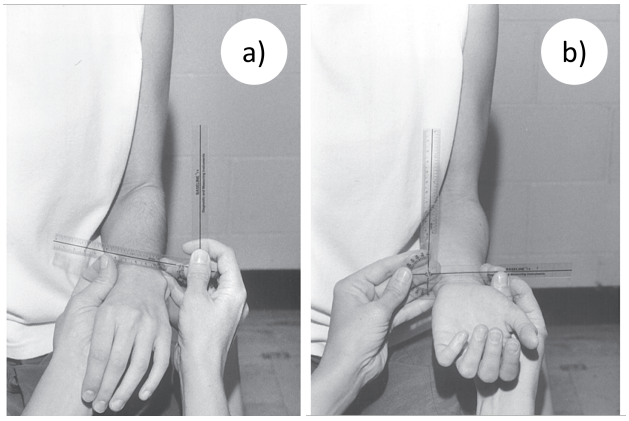


Figure 8.13: To evaluate the forearm's range of motion, goniometry is being used. (a) Shows forearm pronation. (b) Shows forearm supination.

8.3 Results

The results of this study compare the participant's performance in the EMG trial and their forearm ROM whilst wearing the high pressure and low pressure cuffs. In the first Section, a visual outline exemplar result types is provided. Next, participant accuracy in the EMG task and a breakdown of performance is presented. Subsequently, the prevalence of EMG artefacts per target area is analysed, followed by a comparison of EMG amplitudes recorded in both pressure conditions. The final Section of results compares uncompressed ROM with the participant's ROM whilst wearing their cuffs.

8.3.1 Sample Results

Figure 8.14 displays four sample EMG trace plots from the experiment. The target muscle, the muscle being observed for that particular trial, is shown in red and the corresponding antagonist activity is shown in black. The vertical dotted lines represent the recorded trial period where the directional target (the command to flex or extend their forearm) was displayed on screen. The

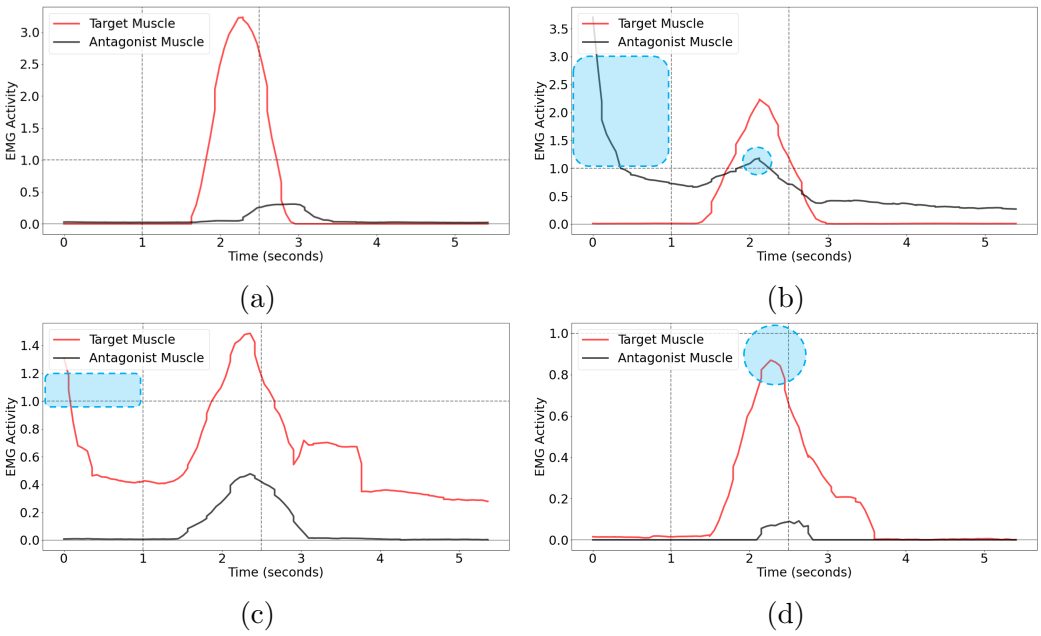


Figure 8.14: Four sample plots showing the different kinds of EMG activity observed during the EMG control task. (a) A *regular* 'pass' trial. (b) An example of antagonist signal disturbance in the pre-examined period and also a subsequent, unrelated co-contraction, where both the target muscle and the antagonist muscle hit the target threshold. (c) An example of target muscle signal disturbance in the pre-examined period. (d) A 'failed' trial due to insufficient amplitude in the muscle contraction.

horizontal line with a value of one represents the activation threshold, $y_{norm} = 1$, based on each individual participant's calibration data, as detailed in Chapter 4, Section 4.6.2. Subplot 8.14(a) displays a *regular* plot - where the participant passed the trial with no EMG anomalies. The target muscle contraction amplitude surpasses the threshold, but the antagonist remains sub-threshold, and no EMG disturbances can be observed. Subplot 8.14(b) is an example of EMG signal disturbance on the antagonist channel prior to the examined period of the trial whilst the limb was stationary and in the correct position for the trial. This could be due to mechanical disturbance of the sensor or total sensor detachment. Subplot 8.14(b) also displays an example of a pass with co-contraction, both the target and antagonist muscle signals surpassed the EMG threshold within the examined period of the

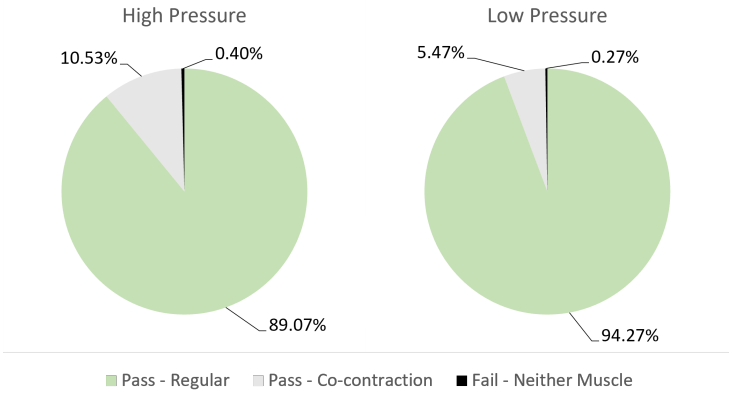


Figure 8.15: The average percentage between participants of types of passes and fails for the high pressure and low pressure cuff trials.

trial. Subplot 8.14(c) shows an example of EMG signal disturbance in the pre-examined period on the target muscle channel. Finally, Subplot 8.14(d) shows an example of a failed trial. In this instance, the correct muscle was contracted, but there was insufficient activity to surpass the threshold.

8.3.2 Passes and Fails

Figure 8.15 displays the mean passes and fails for the EMG control task for both the high pressure and low pressure cuff trials. The amount of overall passes was not notably different, with the high pressure average pass rate being 99.6% and the low pressure average pass rate being 99.73%. Within the 'pass' trials, the co-contraction rate with the high pressure cuff was almost double (10.53%) the rate of the low pressure cuff (5.47%). All recorded failures were due to the participant not reaching the EMG threshold with either muscle.

8.3.3 Signal Disturbances

Figure 8.16 shows the amount of EMG signal disturbances, where either muscle surpassed the activation threshold in the pre-trial period, for both the high pressure and low pressure cuffs. The disturbances are split between targets 0-4. As expected, more disturbances occurred at the outermost targets (targets 0 and 4) and the least where the limb was in a central position (target

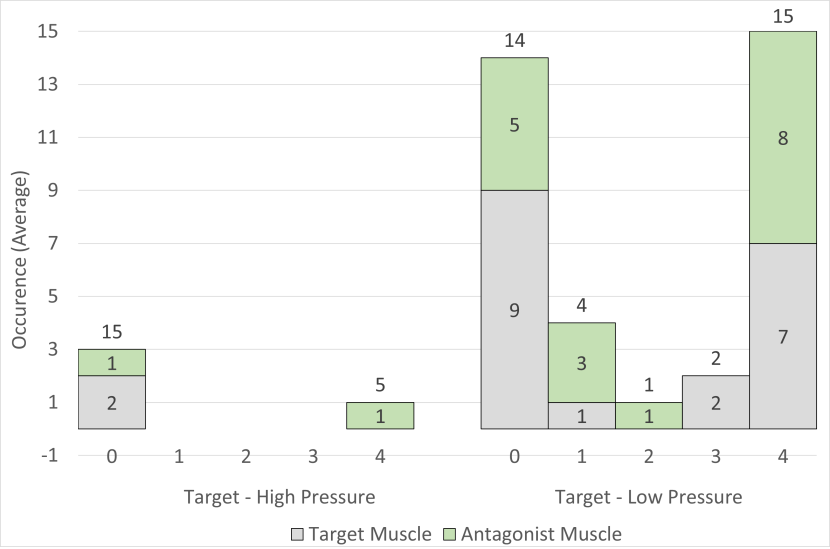


Figure 8.16: Average number of artefacts detected in the pre-trial period using the high and low pressure cuffs. Target muscle channel disturbances are shown in grey, and antagonist channel disturbances shown in green.

2). There were 4 total EMG disturbances recorded for the high pressure cuff, 2 for the target muscle and 2 for the antagonist muscle, averaging at 0.8 per participant. In comparison, there were 36 total EMG disturbances recorded for the low pressure cuff, 19 for the target muscle and 17 for the antagonist muscle, averaging at 7.2 per participant. Hence, there were considerably more EMG disturbances recorded with the low pressure cuff.

8.3.4 Antagonist Activity

Figure 8.17 shows the maximum amplitude recorded within the examined trial period for both the target and antagonist muscle, averaged across all trials for both the high pressure and low pressure cuff. On average, the antagonist maximum amplitude was marginally larger for the antagonist in the high pressure cuff (0.434), versus the low pressure cuff (0.386). In comparison, the maximum amplitude was considerably lower for the target muscle in the high pressure cuff (2.801), versus the low pressure cuff (3.306).

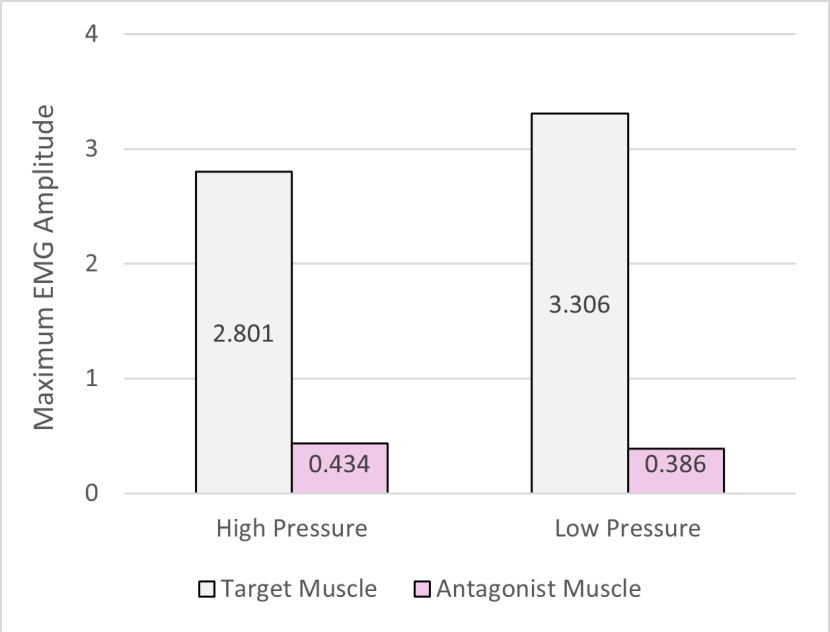


Figure 8.17: A bar graph showing the maximum amplitude of the target muscle averaged across all trials compared to the antagonist muscle, for both high pressure and low pressure cuffs.

8.3.5 Range of Motion

Figure 8.18 shows the variation of allowable forearm pronation and supination ROM between the participants when wearing no cuff, the low pressure cuff and the high pressure cuff respectively. There is no notable difference between the uncompressed and low pressure cuff conditions, however the allowable ROM is considerably lower when wearing the high pressure cuff.

8.4 Discussion

A custom, adjustable, forearm compression rig was created to facilitate dual-site EMG control and real-time pressure monitoring. Whilst wearing the rig, participants had their limb scanned, which was used to create two 3D printed longitudinal compression cuffs per participant: one *high pressure* and one *low pressure*. It was possible to complete the scanning procedure using the aforementioned hardware for all participants. In total, ten scans were

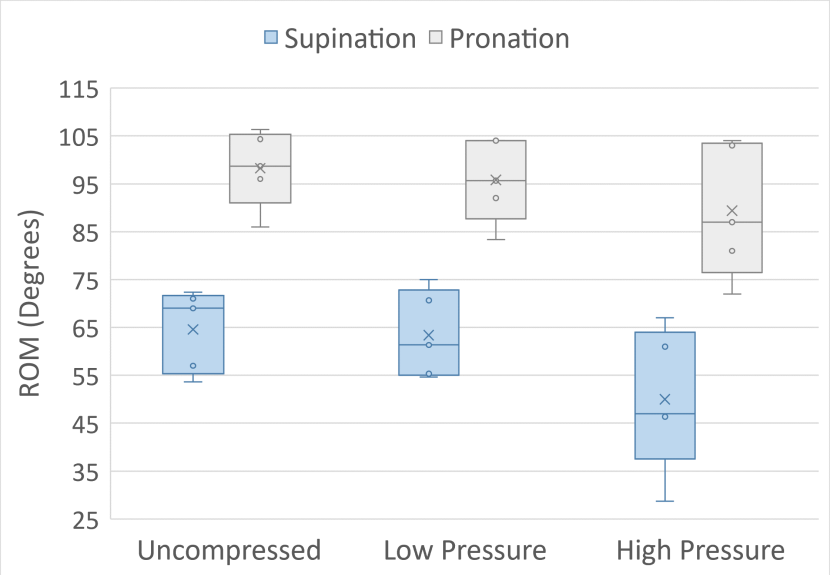


Figure 8.18: A box and whisker plot showing the ROM available whilst the participant's limb was uncompressed and whilst they were wearing the low pressure and high pressure cuffs. Forearm supination is highlighted in blue and forearm pronation in grey. The whiskers represent the upper and lower bounds, with the box representing the upper and lower quartiles. The 'X' marker represents the mean, and the median line is shown inside each box.

obtained using this method resulting in five pairs of cuffs. The cuffs were tested for their effect on EMG control, EMG anomalies and forearm range of motion. All participants carried out the EMG tasks and ROM testing successfully. It was found that unwanted EMG anomalies occurred much less frequently whilst wearing the higher pressure cuff. However, the risk of accidental co-contractions was increased with the high pressure cuff due to the reduction of difference in amplitude between the commanding muscle and its antagonist. In the below Sections, the results of the study, it's clinical relevance and limitations are discussed.

8.4.1 Analysis of Results

There was a negligible difference in control results, as measured by pass / fail rates, between the high and lower pressure conditions. This was probable, given the simplicity of the task, however was still important to confirm. The

other metrics revealed more about the actual effect of compression on EMG control. The EMG disturbance data reveals a distinct trend. Disturbances occur most frequently when the limb is operated at the extremities of the workspace, i.e. targets 0 and 4, and much more frequently when a low pressure cuff is used. In contrast, there were very few motion EMG disturbances detected in the high pressure cuff condition. Therefore, high pressure LC has the potential to prevent motion artefacts, and potentially other factors contributing to the *limb position effect*, when a prosthesis is used outside of the normal operating workspace. It is unclear whether this is due to restricted tissue movement within the cuff, but the ROM data from this study suggests that the high pressure cuff restricts forearm rotation within it.

However, the EMG data showed a reduction in the target muscle amplitude in the high compression cuff, and a small increase in the antagonist muscle amplitude. Hence, there may be a less clear distinction between the two EMG channels. Although the difference in amplitude between the target and the antagonist was still considerable in both cuffs, more accidental co-contractions were recorded in the high pressure cuff. This suggests that at higher pressures, antagonist muscle activity is either higher, or detected more strongly due to the maintenance of pressure within the cuff. This has the potential to impair EMG control. As a result, LC for EMG control has both advantages and disadvantages that should be investigated further. Prosthesis users can usually be trained to reduce accidental co-contraction of muscles, whereas mechanical disturbances are unpredictable and have proven difficult to prevent in other trans-radial socket designs. As a result, there is genuine potential for LC to improve EMG control reliability, particularly when using the limb outside of the usual workspace.

8.4.2 Clinical Relevance

Despite numerous claims that modern technology can improve prosthetics for users, digital manufacturing of sockets has not gained widespread popularity in clinics. Although promising, several practical reasons, such as the difficult task of attempting to turn a tactile procedure into a non-contact digital scanning procedure, make adoption of digital methods more difficult than often assumed. A hybrid digital-tactile method of limb shape capture is presented in this study, with promising results. Subsequently, actual prosthetic sockets could be manufactured in this manner. Even without the use of LC, a vice that simulates the moulding grip to produce supracondylar suspension could

be designed to aid digital scanning, allowing contouring to be applied while eliminating the need for physical plaster casts.

In theory, a combination of the prosthetist's artisan skills and the benefits of digital manufacturing could provide an improved patient experience in terms of both actual socket design and overall healthcare experience. Digital manufacturing allows for a broader range of socket designs, home-based care, and permanent limb records for long-term monitoring. However, future research should prioritise the retention of skilled labour provided by prosthesists and the use of technology to facilitate this rather than replace it.

8.4.3 Study Limitations

As a preliminary investigation into the fundamental effects of LC on both socket manufacturing and EMG control, there were many limitations to what could feasibly be studied. The key limitations of the study are discussed in the following Sections, as well as the future work needed to clarify any outstanding questions about LC.

8.4.3.1 Participant Pool

The participant pool for this study was relatively small, with only five participants. Additionally, out of those five, all were able-bodied. It was necessary to use able-bodied participants for this study as applying significant compression to the forearm in the form of a socket or cuff is still a relatively under-researched area, hence the safety of this procedure can only be estimated and is not currently known for sure. Accordingly, recruiting participants with limb difference would be inadvisable. Many individuals with limb loss have some degree of nerve damage, loss of sensation in their limb, or phantom limb pain. Light touching of the residual limb can trigger phantom limb pain [350], and pressure must be applied carefully to amputees who experience this issue. Similarly, as some amputees lack sensation in their residual limb, they may not immediately be aware if a device was causing pain. Although using able-bodied participants limits the applicability of the study for prosthesis design, it was an appropriate approach given the early stage of the research.

8.4.3.2 Cuff Comparison to a Real Socket

As all participants were able-bodied, it was necessary to create a prosthetic socket simulator cuff instead of actual prosthetic sockets. The main limitation of this is that loading could not be applied in a manner which is realistic for a point-load suspended on the end of a trans-radial prosthetic device. Many prosthetic bypass socket designs exist, which offer the same functionality as a prosthetic cuff, however they generally do not entirely encapsulate the limb. Of the many distinct positions to attach a terminal device, none of them accurately represent the way a prosthetic limb suspends a terminal device at the distal end, because the limb-intact wearer's hand must be taken into account. This usually results in the hand being suspended above, below or to the side of the wearer's actual hand [42, 279], which increases the moment on the device and makes user perception of the terminal device more cumbersome and heavy than if it was situated on the end of a regular prosthetic socket. The various configurations for bypass sockets/cuffs can be seen in Figure 8.19. To avoid complications trying to assess the effect of compression on the actual EMG control, the cuff was not loaded with a distal weight, as doing so would not have resulted in a realistic comparison.

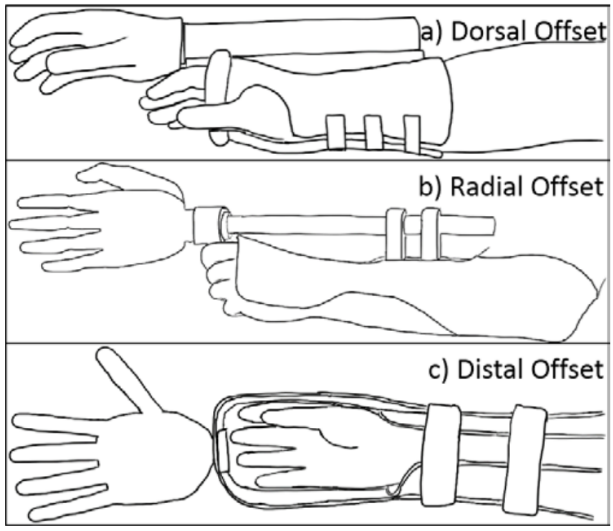


Figure 8.19: The various styles of bypass socket with the terminal device load offset in different areas. (a) A dorsal offset. (b) A radial offset. (c) A distal offset. Image taken from [42].

8.4.3.3 Sensor Accuracy

Force sensitive resistors were used to gauge the pressure applied by the initial adjustable compression rig used during the scanning procedure. Force sensitive resistors are convenient as they are thin, lightweight and are simple to use. However, they are generally not used for precision force sensing as they are prone to several errors, such as *hysteresis*, which can result in lag, drift errors and non-linearity [351, 352]. Despite this, their purpose in this study was primarily to provide an approximation of pressure, hence their use was acceptable. In future iterations, load cells could be used to provide greater accuracy [353]. This would increase the cost outlay as load cells are generally much more expensive than FSR's.

8.5 Chapter Summary

- Longitudinal compression can be applied prior to digital scanning to capture tissue compliance. Custom-made devices can be produced using these scans, using LC hardware as reference points to align pre-made components to in a CAD software.
- In this preliminary study, a high-pressure LC cuff outperformed a low-pressure equivalent for minimising EMG disturbances that create false activations of a prosthetic device. This effect was particularly prominent when the device was used at the extremities of the arm's range of motion, suggesting this style of socket may prevent or minimise the *limb position effect*.
- Whilst wearing the high pressure cuff, the maximum recorded amplitude of the muscle the wearer intended to contract decreased, whilst the amplitude of activity of the antagonist increased marginally. This indicates that LC style devices may have an impact on the effort expended by a wearer in order to perform contractions, but also have the potential to inadvertently increase the risk of co-contractions.

Chapter 9

Future Outlook

This Chapter outlines potential future work that could stem from this PhD thesis. First, an overview is provided of how the method and design discussed in Chapter 8 could be applied to upper-limb sockets. Following that, specific goals for progress in the field of upper-limb prosthetics are outlined.

9.1 Introduction

Firstly, a method for manufacturing trans-radial prosthetic sockets using pre-compressed limb scanning is outlined. Secondly, an outlook for the future of upper-limb prosthetics is provided, with key recommendations as to how progress within the sector can realistically be achieved.

9.2 Compression Optimised Trans-radial Prosthetic Socket Design

In Chapter 8, a novel method for creating prosthetic cuffs with longitudinal compression was described and evaluated. Based on preliminary results, this cuff style appears to maintain pressure on opposing sides of the device during muscle contractions and reduce mechanical disturbances to the electrodes. This approach has the potential to facilitate a more stable coupling between the residual limb and the EMG sensors used to control a prosthesis, despite an increased risk of accidental co-contractions.

Firstly, additional research should be conducted to determine whether the compression levels described in this study represent the safe upper limits when applied to amputees in otherwise good health. Given that amputees are more likely to have nerve damage and possibly diminished sensation in their residual limbs, this must be taken into account. Secondly, a wider scope of research should be conducted with a larger population of volunteers, including those with upper-limb deficits, to see if the results observed in this thesis can be replicated. Furthermore, additional research is required to determine how best to stabilise tissues when attempting to improve EMG control, rather than simply the biomechanical locking of underlying bone structures. If the results of additional research show positive effects on EMG control, an adapted version of the methods and cuff design described in Chapter 8 would be required to produce sockets.

A prosthetic socket based on the cuff from Chapter 8 would look very similar in terms of design. The four bars and pressure adjusting straps would remain as a feature of the socket. The only significant difference would be the addition of an above-elbow support piece, similar to the WILMER socket design, as shown in Figure 9.1. An above-elbow support would improve load bearing over a cuff alone. At this stage, the 'socket' could still be trialled by able-bodied participants, because it would remain open at the

distal end. For use with amputees and individuals with trans-radial limb deficit, a detachable distal forearm or wrist section could mount onto the distal end of the compression bars. The distal section would house electronics, a battery, and allow for the attachment of a terminal device.

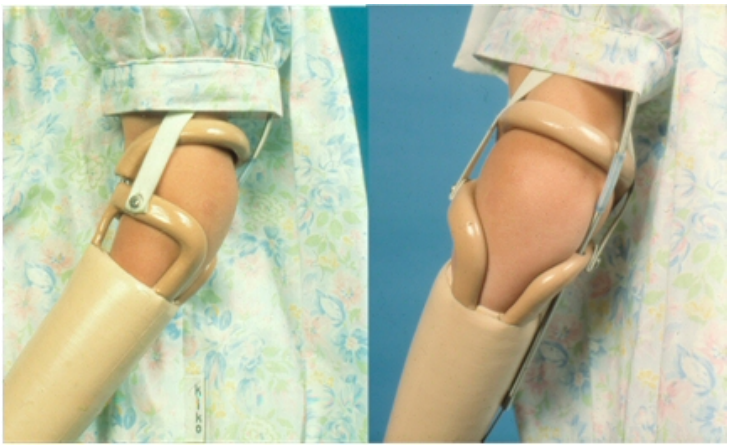


Figure 9.1: The WILMER socket, featuring above-elbow support. Image from [43].

The scanning procedure would largely be the same. The exception would be the addition of above-elbow contouring. To accomplish this using the methods described in Chapter 8, it may be necessary to use a specially shaped depressor to contour around the epicondyles and olecranon while scanning. Different length depressor bars would be required for different patients, however these could easily be pre-printed for efficiency. The process to correct the limb scan would be identical, with the depressors' known shapes subtracted to leave a pre-compressed limb scan. If the CAD model was CNC milled into a positive model, the socket could also be manufactured using traditional methods. High-density polyurethane foam for CNC milling is inexpensive, costing approximately £30-50 per block from one NHS supplier [354]. The cost of milling would depend on whether the procedure was done within the clinic or outsourced, for which the fees would vary by provider and size of the limb model being milled. Additionally, if outsourced, CNC milling potentially induce delays to socket production due to transport time, moving the model between facilities. Alternatively, the socket could be produced using 3D printing or other forms of additive manufacturing.

The depressor bars, above-elbow support, and forearm/wrist unit would

all be modular and replaceable in the socket design. This modular design would not only facilitate adjustability and personalisation, allowing the socket to be adapted to the wearer's limb over time, it would also allow for easy replacement of various components. The design of both the cuffs in Chapter 8 and the proposed socket in this Chapter feature an open frame with exposed skin in the uncompressed areas. It is hoped this would help with ventilation and limb-cooling, and it is expected excess sweating would be reduced. This may also have a positive effect on the quality of attainable EMG signals, which should also be investigated in future work.

9.3 Future Outlook

It is hoped that by furthering some of the findings of this PhD thesis with future research, the quality of care available to upper-limb different patients can be significantly improved. The key goals would be to:

1. Give patients greater control over their care by providing options for remote or fewer visits without compromising on the safety or quality of their prostheses. Patients could opt to continue using current procedures, but they would also have the option to use a remote system if it better suited their care needs or lifestyle.

2. Patients would have better-functioning devices, and it would be simpler to diagnose socket issues. Digital tools, when used correctly, could reduce some of the variations in quality of care that depend on the clinician's individual skills and experience, without removing clinical skills from the procedure altogether. Properly designed sockets would eliminate the issue with electrode-limb interfacing, leaving only standard device failure, which cannot be avoided, and wearer training, for which there is a vested interest in, and ongoing research to improve.

3. As sufficient evidence of their safety and efficacy would be available, clinicians would have the confidence to use novel materials and manufacturing techniques. Standardised training for clinicians would be made available and incorporated into ISPO education guidelines. Utilising a shared network of previous sockets and interventions, it would be faster to discover effective solutions for rare cases.

Objectives enabling these goals to be achieved are detailed below, separated by the three primary divisions of this PhD programme: 1) understanding, 2) manufacturing, and 3) designing sockets for upper-limb prostheses.

9.3.1 Understanding Trans-Radial Prosthetic Sockets

As concluded in Chapter 3, measuring upper-limb socket comfort and satisfaction is complex and current methods do not work well. A specialised, validated, upper-limb socket assessment scale would foster innovation in the field and allow for a standardised comparison between novel socket designs and older, existing sockets. The scale would need to validate control, functionality, and user satisfaction in addition to socket comfort and suspension. This makes data collection and analysis more complicated, which is why many lower-limb scales cannot be used. This scale could be developed in a similar manner to the existing 'Prosthetic Socket Comfort Score' [215], but with additional factors taken into account. Additionally, a standardised outcome reporting network would aid in the development of novel socket designs. This could be achieved via a secure, online platform only accessible to practitioners and researchers. Given the small population of upper-limb amputees, data sharing for particularly unique cases would be beneficial.

It is evident from Chapters 3 and 5 that 3D-printed sockets for upper limb prosthetics require more stringent safety guidelines. A better understanding of how to use modern manufacturing techniques safely would be a good place to start. These investigations should describe how the mechanical properties of a socket can be affected by different materials and print settings. Ideally, this would evolve into a specialised ISO standard, which would also facilitate innovation in the field.

9.3.2 Manufacturing Trans-Radial Prosthetic Sockets

Many of the media-reported advantages of 3D printing for prosthetic sockets are oversimplified, exaggerated, and at times simply false. Nevertheless, as discussed in Chapters 5 and 6, there are a number of potential advantages to adopting digital processes in prosthetics clinics.

It seems that a tactile approach to digital scanning is required when scanning body parts, particularly the upper limbs. Potential avenues include a technique similar to the one described in Chapter 8 of this thesis, which involves mechanical perturbations of the limb using objects of a known shape

that can be easily removed from scans, to account for tissue compliance. Potentially, objects that depress the limb around the epicondyles and olecranon could be developed, along with a specialised prosthetics and orthotics CAD programme that subtracts these objects automatically from scans. This would enable prosthetists to apply their moulding grip without holding the patient's limb, simultaneously digitising the limb's geometry and eliminating the variation in tactile skills that can affect the fit of the final socket. Alternatively, using detailed markings of the limb and taking notes, as described in Chapter 6, may provide an alternative solution. This method offers the greatest potential for home-based, remote, or low-resource care, as a bystander with minimal training could perform the scans while a clinician produces the actual sockets. In future research, these methods should be clinically validated on patients requiring upper-limb sockets and a standard procedure should be established.

In addition, future research on limb scanning could investigate the feasibility of automated scanning and specialised jigs for pre-compressing the limb. Similar inventions include MIT's 'fitsocket' - a specialised rig featuring automated depressors that simultaneously capture the tissue compliance and geometry of a residuum [355], developed for the lower-limb population. However, creating or buying specialist clinical equipment involves financial investment and requires workshop space and staff training. If the equipment enabled the fitting of sockets that facilitated more reliable prosthesis control, and subsequently reduced the current 44% rejection rates [53] it's cost and the space it occupied may be justifiable. However, in general it is hard for clinics to financially justify special equipment for a relatively small-subset of the amputee population. Consequently, the device would likely need to serve multiple purposes, such as aiding in the fitting of upper-limb orthotics (i.e. wrist braces).

9.3.3 Designing Trans-Radial Prosthetic Sockets

Despite increased interest in invasive, implantable electrodes, surface-electrode controlled prostheses will remain a popular choice for the foreseeable future, as many patients are medically ineligible or simply prefer non-invasive methods. It is inevitable that as prostheses become more advanced, more electrodes will be installed within upper-limb sockets to facilitate incoming pattern recognition and abstract decoding-based systems. Consequently, current problems with mechanical instability and poor interfacing between the

limb and the sensor sites will be exacerbated.

As discussed in Chapters 7 and 8, it appears that sockets with longitudinal compression affect the interface between the EMG electrodes and the limb differently than conventional socket shapes. The preliminary findings of this thesis suggest that mechanical disturbances of the electrodes are reduced, but the difference in EMG amplitude between the target muscle and its antagonist decreases, thereby increasing the risk of accidental co-contraction. Further investigation is required to validate and explore these findings in individuals with upper-limb difference. Additionally, further research is needed into the safety of this particular design, to determine the long-term effects of applying high compression to trans-radial residuums, particularly in cases where the patient has existing nerve damage. As covered in Chapter 5, comfort without suspension is effectively useless for prosthetic sockets, and vice versa. The same holds true for ensuring consistent EMG control; therefore, any disadvantages to comfort must be weighed against the potential advantages of EMG control.

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Appendix A

A.1 Ethical Approval 1

Jenny Olsen (PGR)

From: Policy & Information Team, Newcastle University <noreply@limesurvey.org>
Sent: 19 April 2021 13:10
To: Jenny Olsen (PGR)
Subject: Ethics Form Completed for Project: The effect of localised compression on electromyographic signals from the forearm Jennifer Olsen

Ref: 11532/2020

Thank you for submitting the ethical approval form for the project 'The effect of localised compression on electromyographic signals from the forearm' (Lead Investigator: Jennifer Olsen). Expected to run from 20/04/2021 to 30/09/2021.

Based on your answers, the University Ethics Committee grants its approval for you to start working on your project. Please be aware that if you make any significant changes to your proposal then you should complete this form again, as further review may be required. This confirmation may be used within a research portfolio as evidence of ethical approval. Please note: this confirmation will be the only correspondence you should expect to receive as evidence of ethical approval. There will be no other confirmation provided. You may now proceed with research. If you have any queries, please review the internal and external ethics FAQ pages before contacting res.policy@ncl.ac.uk.

The UK government has placed strict restrictions on direct social contact in order to limit the spread of the COVID-19 coronavirus. Researchers must not begin - or continue to conduct - any project involving direct contact with human participants until the current restrictions are lifted. Any ethics approvals for such projects received automatically during this period will not be valid.

Best wishes

Research, Policy, Intelligence and Ethics Team,

Newcastle University Research Office

University Ethics Form Version 3

Applicant Details (922)

Is this approval for a: (11240)

Type: (!/list-dropdown)

A2 - Student Project

What type of degree programme is being studied? (11319)

Type: (!/list-dropdown)

A3 - Postgraduate Research (e.g. PhD)

Name of Principal Researcher (11241)

Type: (S/text-short)

Jennifer Olsen

Please enter your email address (11258)

Type: (S/text-short)

j.olsen@ncl.ac.uk

Please select your school/academic unit (11242)

Type: (!/list-dropdown)

A3 - School of Engineering

Please enter the module code (11243)

Type: (S/text-short)

Please enter your supervisor's email (11259)

Type: (S/text-short)

matthew.dyson@ncl.ac.uk

Please select your supervisor's school/unit: (11244)

Type: (!/list-dropdown)

A3 - School of Engineering

Project Details (923)

Project Title (11245)

Type: (S/text-short)

The effect of localised compression on electromyographic signals from the forearm

Project Synopsis (11257)

Type: (T/text-long)

Mild localised compression will be applied to the forearm of participants via a 3D printed rig, whilst they perform a simple EMG (electromyography) control task and a simple fatigue task. The control task involves controlling a cursor on a screen with the forearm muscles and the fatigue task involves gripping a dynamometer for around 10-20 seconds. Surface EMG recordings are taken from the participant's limb throughout the tests. The procedure is non-invasive and the levels of compression are deemed safe due to previous research indicating so. The aim of the study is to see whether safe levels of compression impact EMG control and fatigue.

Project start date (11260)

Type: (D/date)

20/04/2021

Project end date (11261)

Type: (D/date)

30/09/2021

Is the project externally funded? (11262)

Type: (!/list-dropdown)

A3 - No

Does your project involve collaborators outside of the University? (11265)

Type: (Y/yes-no)

No [X]

Existing Ethics, Sponsorship & Responsibility (930)

Has ethical approval to cover this proposal already been obtained? (11267)

Type: (Y/yes-no)

No [X]

Will anyone be acting as sponsor under the NHS Research Governance Framework for Health and Social Care? (11270)

Type: (Y/yes-no)

No [X]

Do you have a Newcastle upon Tyne Hospitals (NUTH) reference? (11272)

Type: (Y/yes-no)

No [X]

Will someone other than you (the principal investigator) or your supervisor (for student projects) be responsible for the conduct, management and design of the research? (11274)

Type: (Y/yes-no)

No [X]

Animals (I) (924)

The Animals (Scientific Procedures) Act **defines protected animals as: 'any living vertebrate other than man...in its foetal, larval or embryonic form.....from the stage of its development when:**

(a) in the case of a mammal, bird or reptile, half the gestation or incubation period for the relevant species has elapsed; and

(b) in any other case, it becomes capable of independent feeding'.

In practice 'Protected' animals are all living vertebrates (other than man), including some immature forms, and cephalopods (e.g. octopus, squid, cuttlefish).

Using this definition, does your research involve the observation, capture or manipulation of animals or their tissues?

(11246)

Type: (Y/yes-no)

No [X]

NHS, Health & Social Care: Facilities, Staff & Patients (I) (925)

Will the study involve participants recruited by virtue of being NHS patients or service users, their dependents, their carers or human tissues or the use of NHS & Health/Social Care Facilities or otherwise require REC approval? (11247)

Type: (Y/yes-no)

No [X]

Human Participants in a Non-Clinical Setting (I) (926)

Does the research involve human participants e.g. use of questionnaires, focus groups, observation, surveys or lab-based studies involving human participants? (11249)

Type: (Y/yes-no)

Yes

Does the study involve any of the following? (11250)

Type: (M/multiple-opt)

a. The study involves children or other vulnerable groups; including those who are relatively or absolutely incapable of protecting their own interests, or those in unequal relationships e.g. participants who are subordinate to the researcher(s) in a context outside the research? (11356)

b. The study requires the co-operation of a gatekeeper **defined as someone who can exert undue influence) for initial access to the groups or individuals to be recruited e.g. students at school, members of a self-help group, or residents of a nursing home?** NB. The IoN & School of Psychology volunteer pools are not considered gatekeepers

c. It is necessary for participants to take part in the study without their knowledge and consent e.g. covert observation of people in non-public places?. (11358)

d. Deliberately misleading participants in any way? (11359)

e. Discussion of sensitive topics e.g. sexual activity or drug use?* (11360)

f. The administration of drugs, placebos or other substances (e.g. food substances, vitamins) to the study participants. (11361)

g. Invasive, intrusive or potentially harmful procedures of any kind?* (11362)

h. Obtaining blood or tissue samples?* (11363)

i. Pain or more than mild discomfort? (11364)

j. Psychological stress, anxiety, harm or negative consequences beyond that encountered in normal life? (11365)

k. Prolonged or repetitive testing i.e. more than 4 hours commitment or attendance on more than two occasions? (11366)

l. Financial inducements (other than reasonable expenses and compensation for time)? (11379)

Data (I) (927)

Does the research involve the viewing, usage or transfer of sensitive data or personal data as defined by the General Data Protection Regulation (GDPR) **or data governed by statute such as the** Official Secrets Act 1989 / Terrorism Act 2006 **, commercial contract or by convention e.g. client confidentiality? (If you are unsure please tick YES and complete the sub-questions). (11251)**

Type: (Y/yes-no)

No [X]

Environment (I) (928)

Will the study cause direct or indirect damage to the environment or emissions outside permissible levels or be conducted in an Area of Special Scientific Interest or which is of cultural significance? (11253)

Type: (Y/yes-no)

No [X]

International Projects (I) (929)

Will the research be conducted outside of the UK or European Economic Area (EEA) , or will it involve international collaborators outside the EEA? (11255)

Type: (Y/yes-no)

No [X]

Next Steps (931)

Based on your responses your project has been categorised as (ethically) low risk and no further review is required before you start work. You will receive a formal approval email on submission of this form. Should your project change you may need to apply for new ethical approval. (11282)

Type: (X/boilerplate)

Supporting Documentation (940)

Please upload any documents (not uploaded elsewhere in the application) which you think are relevant to the consideration of your application. (11308)

Type: (|/upload-files)

Summary and Submission (941)

Thank you for completing the University's Ethical Review Form. Based on your answers the University is satisfied that your project has met its ethical expectations and grants its ethical approval.

Please be aware that if you make any significant changes to your project then you should complete this form again as further review may be required. Confirmation of this decision will be emailed to you.

Please complete the declaration to submit your application.

Declaration

I certify that:

(11314)

Type: (M/multiple-opt)

[X]

the information contained within this application is accurate. (11441)

[X]

the research will be undertaken in line with all appropriate, University, legal and local standards and regulations. (11442)

[X]

I have attempted to identify the risks that may arise in conducting this research and acknowledge my obligation to (and rights of) any participants. (11443)

[X]

no work will begin until all appropriate permissions are in place. (11444)

A.2 Ethical Approval 2

Ethics Form Completed for Project: Creating upper-limb prosthetics sockets using 3D scanning and printing

Policy & Information Team, Newcastle University <noreply@limesurvey.org>

Fri 01/11/2019 10:50

To: Jenny Olsen (PGR) <J.Olsen@newcastle.ac.uk>

Ref: 16602/2018

Thank you for submitting the ethical approval form for the project 'Creating upper-limb prosthetics sockets using 3D scanning and printing' (Lead Investigator:Jennifer Olsen). Expected to run from 04/11/2019 to 31/12/2023.

Based on your answers the University Ethics Committee grants its approval for your project to progress. Please be aware that if you make any significant changes to your project then you should complete this form again as further review may be required. If you have any queries please contact res.policy@ncl.ac.uk

Best wishes

Policy & Information Team, Newcastle University Research Office

res.policy@ncl.ac.uk

University Ethics Form Version 2.1.1

Date submitted
01/11/2019 11:50:03

Applicant Details

Is this approval for a:
Student Project [A2]

What type of degree programme is being studied?
Postgraduate Research (e.g. PhD) [A3]

Name of Principal Researcher:
Jennifer Olsen

Please enter your email address
j.olsen@newcastle.ac.uk

Please select your school / academic unit
School of Engineering [A3]

Please enter the module code

Please enter your supervisors email:
matthew.dyson@newcastle.ac.uk

Please select your supervisor's school/unit:
School of Engineering [A3]

Project Details

Project Title
Creating upper-limb prosthetics sockets using 3D scanning and printing

Project Synopsis
The project involves participants making two visits to participate in the study. The first visit will involve a scan will be taken of the participant's limb using a hand-held 3D scanner. The participant will be asked to hold their limb in a fixed position while data is acquired. Skin-safe markers may be attached to the limb to help with the scanning process. On their second visit, the participant will be asked to try on 3D printed sockets that were created from the scan of their limb (whilst wearing a sock liner if the participant prefers to do so) and asked for feedback about the fit, comfort and security of the sockets.

Project start date
04/11/2019

Project end date
31/12/2023

Is the project externally funded?
No [A3]

Does your project involve collaborators outside of the University?
Yes [Y]

Please provide a list of the collaborating organisations?
Strathclyde University

Existing Ethics, Sponsorship & Responsibility

Has ethical approval to cover this proposal already been obtained?
No [N]

Will anyone be acting as sponsor under the NHS Research Governance Framework for Health and Social Care?
No [N]

Do you have a Newcastle upon Tyne Hospitals (NUTH) reference?
No [N]

Will someone other than you (the principal investigator) or your supervisor (for student projects) be responsible for the conduct, management and design of the research?
No [N]

The Animals (Scientific Procedures) Act defines protected animals as: 'any living vertebrate other than man…in its foetal, larval or embryonic form……from the stage of its development when— (a)in the case of a mammal, bird or reptile, half the gestation or incubation period for the relevant species has elapsed; and (b)in any other case, it becomes capable of independent feeding'. In practice 'Protected' animals are all living vertebrates (other than man), including some immature forms, and cephalopods (e.g. octopus, squid, cuttlefish). Using this definition, does your research involve the observation, capture or manipulation of animals or their tissues?
No [N]

Will the study involve participants recruited by virtue of being NHS patients or service users, their dependents, their carers or human tissues or the use of NHS & Health/Social Care Facilities or otherwise require REC approval?
No [N]

Does the research involve human participants e.g. use of questionnaires, focus groups, observation, surveys or lab-based studies involving human participants?
Yes [Y]

Does the study involve any of the following? [a. The study involves children or other vulnerable groups; including those who are relatively or absolutely incapable of protecting their own interests, or those in unequal relationships e.g. participants who are subordinate to the researcher(s) in a context outside the research?]

Does the study involve any of the following? [b. The study requires the co-operation of a gatekeeper (defined as someone who can exert undue influence) for initial access to the groups or individuals to be recruited e.g. students at school, members of a self-help group, or residents of a nursing home? NB. The IoN & School of Psychology volunteer pools are not considered gatekeepers in this case.]

Does the study involve any of the following? [c. It is necessary for participants to take part in the study without their knowledge and consent e.g. covert observation of people in non-public places?.]

Does the study involve any of the following? [d. Deliberately misleading participants in any way?]

Does the study involve any of the following? [e. Discussion of sensitive topics e.g. sexual activity or drug use?]

Does the study involve any of the following? [f. The administration of drugs, placebos or other substances (e.g. food substances, vitamins) to the study participants.]

Does the study involve any of the following? [g. Invasive, intrusive or potentially harmful procedures of any kind?*]

Does the study involve any of the following? [h. Obtaining blood or tissue samples?*]

Does the study involve any of the following? [i. Pain or more than mild discomfort?]

Does the study involve any of the following? [j. Psychological stress, anxiety, harm or negative consequences beyond that encountered in normal life?]

Does the study involve any of the following? [k. Prolonged or repetitive testing i.e. more than 4 hours commitment or attendance on more than two occasions?]

Does the study involve any of the following? [i. Financial inducements (other than reasonable expenses and compensation for time)?]

Does the research involve the viewing, usage or transfer of sensitive data or personal data as defined by the General Data Protection Regulation (GDPR) or data governed by statute such as the Official Secrets Act 1989 / Terrorism Act 2006, commercial contract or by convention e.g. client confidentiality? (If you are unsure please tick YES and complete the sub-questions).
Yes [Y]

Will the study involve any of the following? [a. The study involves sharing of sensitive or personal data outside the European Economic Area.]

Will the study involve any of the following? [b. The study involves collection or analysis of sensitive data which will be identifiable within the project outputs and could potentially cause harm.]

Will the study involve any of the following? [c. The study involves collection or analysis of personal data without explicit consent.]

Will the study involve any of the following? [d. The study involves collection or analysis of information covered by the Official Secrets Act 1989, Terrorism Act 2006, commercial contract or licence?]

Will the study involve any of the following? [e. The study involves the collection, viewing or dissemination of materials which could be considered; extremist, sensitive, or terrorism related?]

Will the study cause direct or indirect damage to the environment or emissions outside permissible levels or be conducted in an Area of Special Scientific Interest or which is of cultural significance?
No [N]

Will the research be conducted outside of the European Economic Area (EEA) or will it involve international collaborators outside the EEA?
No [N]

Next Steps

Based on your responses your project has been categorised as (ethically) low risk and no further review is required before you start work. You will receive a formal approval email on submission of this form. Should your project change you may need to apply for new ethical approval.

Supporting Documentation

Please upload any documents (not uploaded elsewhere in the application) which you think are relevant to the consideration of your application.

filecount - Please upload any documents (not uploaded elsewhere in the application) which you think are relevant to the consideration of your application.
0

Thank you for completing the University's Ethical Review Form. Based on your answers the University is satisfied that your project has met its ethical expectations and grants its ethical approval. Please be aware that if you make any significant changes to your project then you should complete this form again as further review may be required. Confirmation of this decision will be emailed to you. Please complete the declaration to submit your application. Declaration I certify that: [the information contained within this application is accurate.]
Yes [Y]

Thank you for completing the University's Ethical Review Form. Based on your answers the University is satisfied that your project has met its ethical expectations and grants its ethical approval. Please be aware that if you make any significant changes to your project then you should complete this form again as further review may be required. Confirmation of this decision will be emailed to you. Please complete the declaration to submit your application.

Declaration

I certify that:

[the research will be undertaken in line with all appropriate, University, legal and local standards and regulations.]

Yes [Y]

Thank you for completing the University's Ethical Review Form. Based on your answers the University is satisfied that your project has met its ethical expectations and grants its ethical approval. Please be aware that if you make any significant changes to your project then you should complete this form again as further review may be required. Confirmation of this decision will be emailed to you. Please complete the declaration to submit your application.

Declaration

I certify that:

[I have attempted to identify the risks that may arise in conducting this research and acknowledge my obligation to (and rights of) any participants.]

Yes [Y]

Thank you for completing the University's Ethical Review Form. Based on your answers the University is satisfied that your project has met its ethical expectations and grants its ethical approval. Please be aware that if you make any significant changes to your project then you should complete this form again as further review may be required. Confirmation of this decision will be emailed to you. Please complete the declaration to submit your application.

Declaration

I certify that:

[no work will begin until all appropriate permissions are in place.]

Yes [Y]

A.3 Ethical Approval 3

CERTIFICATE OF ETHICAL APPROVAL

Project #: 20-DYS-050

Project Title: Simultaneous Control of Multiple Degrees of Freedom in Myoelectric Hand Prostheses (SimCon)

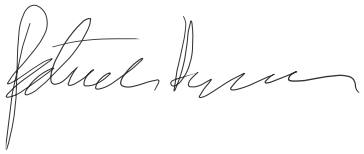
This certificate confirms that the application made by **Matthew Dyson and Kianoush Nazarpour (Staff in Engineering)** was **APPROVED SUBJECT TO CONDITIONS** on 06/07/2020

Conditions of approval (If applicable):

i. You must issue and follow a clear protocol regarding CV19 hygiene and liability
ii. Participants should be aware that their address data is being held. You must destroy this as soon as the couriering is complete.
iii. You must **not** recruit participants through any routes affiliated to the NHS. This includes using data from previous NHS studies.

*It is the responsibility of the applicant to ensure that any conditions of approval are fully met before proceeding with the research. Applicants are also required to notify the Faculty Ethics Committee (sage.ethics@ncl.ac.uk) if they wish to make any changes to the design/methods/participants of the study **before** commencing with any changes.*

*If you receive any complaints or encounter any issues during the implementation of your research study, please contact the Ethics Committee via SAGE.Ethics@newcastle.ac.uk. Please **do not** respond directly to the complaint.*

Signed: 

Date**: 6/7/2020**

A.4 Ethical Approval 4

Jenny Olsen (PGR)

From: Policy & Information Team, Newcastle University <noreply@limesurvey.org>
Sent: 19 April 2021 13:10
To: Jenny Olsen (PGR)
Subject: Ethics Form Completed for Project: The effect of localised compression on electromyographic signals from the forearm Jennifer Olsen

Ref: 11532/2020

Thank you for submitting the ethical approval form for the project 'The effect of localised compression on electromyographic signals from the forearm' (Lead Investigator: Jennifer Olsen). Expected to run from 20/04/2021 to 30/09/2021.

Based on your answers, the University Ethics Committee grants its approval for you to start working on your project. Please be aware that if you make any significant changes to your proposal then you should complete this form again, as further review may be required. This confirmation may be used within a research portfolio as evidence of ethical approval. Please note: this confirmation will be the only correspondence you should expect to receive as evidence of ethical approval. There will be no other confirmation provided. You may now proceed with research. If you have any queries, please review the internal and external ethics FAQ pages before contacting res.policy@ncl.ac.uk.

The UK government has placed strict restrictions on direct social contact in order to limit the spread of the COVID-19 coronavirus. Researchers must not begin - or continue to conduct - any project involving direct contact with human participants until the current restrictions are lifted. Any ethics approvals for such projects received automatically during this period will not be valid.

Best wishes

Research, Policy, Intelligence and Ethics Team,

Newcastle University Research Office

University Ethics Form Version 3

Applicant Details (922)

Is this approval for a: (11240)

Type: (!/list-dropdown)

A2 - Student Project

What type of degree programme is being studied? (11319)

Type: (!/list-dropdown)

A3 - Postgraduate Research (e.g. PhD)

Name of Principal Researcher (11241)

Type: (S/text-short)

Jennifer Olsen

Please enter your email address (11258)

Type: (S/text-short)

j.olsen@ncl.ac.uk

Please select your school/academic unit (11242)

Type: (!/list-dropdown)

A3 - School of Engineering

Please enter the module code (11243)

Type: (S/text-short)

Please enter your supervisor's email (11259)

Type: (S/text-short)

matthew.dyson@ncl.ac.uk

Please select your supervisor's school/unit: (11244)

Type: (!/list-dropdown)

A3 - School of Engineering

Project Details (923)

Project Title (11245)

Type: (S/text-short)

The effect of localised compression on electromyographic signals from the forearm

Project Synopsis (11257)

Type: (T/text-long)

Mild localised compression will be applied to the forearm of participants via a 3D printed rig, whilst they perform a simple EMG (electromyography) control task and a simple fatigue task. The control task involves controlling a cursor on a screen with the forearm muscles and the fatigue task involves gripping a dynamometer for around 10-20 seconds. Surface EMG recordings are taken from the participant's limb throughout the tests. The procedure is non-invasive and the levels of compression are deemed safe due to previous research indicating so. The aim of the study is to see whether safe levels of compression impact EMG control and fatigue.

Project start date (11260)

Type: (D/date)

20/04/2021

Project end date (11261)

Type: (D/date)

30/09/2021

Is the project externally funded? (11262)

Type: (!/list-dropdown)

A3 - No

Does your project involve collaborators outside of the University? (11265)

Type: (Y/yes-no)

No [X]

Existing Ethics, Sponsorship & Responsibility (930)

Has ethical approval to cover this proposal already been obtained? (11267)

Type: (Y/yes-no)

No [X]

Will anyone be acting as sponsor under the NHS Research Governance Framework for Health and Social Care? (11270)

Type: (Y/yes-no)

No [X]

Do you have a Newcastle upon Tyne Hospitals (NUTH) reference? (11272)

Type: (Y/yes-no)

No [X]

Will someone other than you (the principal investigator) or your supervisor (for student projects) be responsible for the conduct, management and design of the research? (11274)

Type: (Y/yes-no)

No [X]

Animals (I) (924)

The Animals (Scientific Procedures) Act **defines protected animals as: 'any living vertebrate other than man...in its foetal, larval or embryonic form.....from the stage of its development when:**

(a) in the case of a mammal, bird or reptile, half the gestation or incubation period for the relevant species has elapsed; and

(b) in any other case, it becomes capable of independent feeding'.

In practice 'Protected' animals are all living vertebrates (other than man), including some immature forms, and cephalopods (e.g. octopus, squid, cuttlefish).

Using this definition, does your research involve the observation, capture or manipulation of animals or their tissues?

(11246)

Type: (Y/yes-no)

No [X]

NHS, Health & Social Care: Facilities, Staff & Patients (I) (925)

Will the study involve participants recruited by virtue of being NHS patients or service users, their dependents, their carers or human tissues or the use of NHS & Health/Social Care Facilities or otherwise require REC approval? (11247)

Type: (Y/yes-no)

No [X]

Human Participants in a Non-Clinical Setting (I) (926)

Does the research involve human participants e.g. use of questionnaires, focus groups, observation, surveys or lab-based studies involving human participants? (11249)

Type: (Y/yes-no)

Yes

Does the study involve any of the following? (11250)

Type: (M/multiple-opt)

a. The study involves children or other vulnerable groups; including those who are relatively or absolutely incapable of protecting their own interests, or those in unequal relationships e.g. participants who are subordinate to the researcher(s) in a context outside the research? (11356)

b. The study requires the co-operation of a gatekeeper **defined as someone who can exert undue influence) for initial access to the groups or individuals to be recruited e.g. students at school, members of a self-help group, or residents of a nursing home?** NB. The IoN & School of Psychology volunteer pools are not considered gatekeepers

c. It is necessary for participants to take part in the study without their knowledge and consent e.g. covert observation of people in non-public places?. (11358)

d. Deliberately misleading participants in any way? (11359)

e. Discussion of sensitive topics e.g. sexual activity or drug use?* (11360)

f. The administration of drugs, placebos or other substances (e.g. food substances, vitamins) to the study participants. (11361)

g. Invasive, intrusive or potentially harmful procedures of any kind?* (11362)

h. Obtaining blood or tissue samples?* (11363)

i. Pain or more than mild discomfort? (11364)

j. Psychological stress, anxiety, harm or negative consequences beyond that encountered in normal life? (11365)

k. Prolonged or repetitive testing i.e. more than 4 hours commitment or attendance on more than two occasions? (11366)

l. Financial inducements (other than reasonable expenses and compensation for time)? (11379)

Data (I) (927)

Does the research involve the viewing, usage or transfer of sensitive data or personal data as defined by the General Data Protection Regulation (GDPR) **or data governed by statute such as the** Official Secrets Act 1989 / Terrorism Act 2006 **, commercial contract or by convention e.g. client confidentiality? (If you are unsure please tick YES and complete the sub-questions). (11251)**

Type: (Y/yes-no)

No [X]

Environment (I) (928)

Will the study cause direct or indirect damage to the environment or emissions outside permissible levels or be conducted in an Area of Special Scientific Interest or which is of cultural significance? (11253)

Type: (Y/yes-no)

No [X]

International Projects (I) (929)

Will the research be conducted outside of the UK or European Economic Area (EEA) , or will it involve international collaborators outside the EEA? (11255)

Type: (Y/yes-no)

No [X]

Next Steps (931)

Based on your responses your project has been categorised as (ethically) low risk and no further review is required before you start work. You will receive a formal approval email on submission of this form. Should your project change you may need to apply for new ethical approval. (11282)

Type: (X/boilerplate)

Supporting Documentation (940)

Please upload any documents (not uploaded elsewhere in the application) which you think are relevant to the consideration of your application. (11308)

Type: (|/upload-files)

Summary and Submission (941)

Thank you for completing the University's Ethical Review Form. Based on your answers the University is satisfied that your project has met its ethical expectations and grants its ethical approval.

Please be aware that if you make any significant changes to your project then you should complete this form again as further review may be required. Confirmation of this decision will be emailed to you.

Please complete the declaration to submit your application.

Declaration

I certify that:

(11314)

Type: (M/multiple-opt)

[X]

the information contained within this application is accurate. (11441)

[X]

the research will be undertaken in line with all appropriate, University, legal and local standards and regulations. (11442)

[X]

I have attempted to identify the risks that may arise in conducting this research and acknowledge my obligation to (and rights of) any participants. (11443)

[X]

no work will begin until all appropriate permissions are in place. (11444)

A.5 Ethical Approval 5

Ethics Form Completed for Project: The effect of localised compression on electromyographic signals from the forearm Jennifer Olsen
Policy & Information Team, Newcastle University <noreply@limesurvey.org>
Fri 24/06/2022 16:14
To:

- Jenny Olsen (PGR) <J.Olsen@newcastle.ac.uk>

Ref: 23877/2022

Thank you for submitting the ethical approval form for the project 'The effect of localised compression on electromyographic signals from the forearm ' (Lead Investigator: Jennifer Olsen). Expected to run from 27/06/2022 to 31/01/2023.

Based on your answers, the University Ethics Committee grants its approval for you to start working on your project. Please be aware that if you make any significant changes to your proposal then you should complete this form again, as further review may be required. This confirmation may be used within a research portfolio as evidence of ethical approval. Please note: this confirmation will be the only correspondence you should expect to receive as evidence of ethical approval. There will be no other confirmation provided. You may now proceed with research. If you have any queries, please review the internal and external ethics FAQ pages before contacting res.policy@ncl.ac.uk.

In order to limit the spread of COVID-19, any research projects which include direct contact with human participants must adhere to local physical distancing guidelines and the restrictions imposed by the government of the country in which the research is being undertaken.

Best wishes

Research Policy Intelligence and Ethics Team,

Research Strategy & Development
res.policy@ncl.ac.uk

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Best wishes

Research Policy Intelligence and Ethics Team,

Research Strategy & Development
res.policy@ncl.ac.uk

Appendix B

B.1 FSR Calibration

Figure A: Calibration curve for the FSR07CE sensor

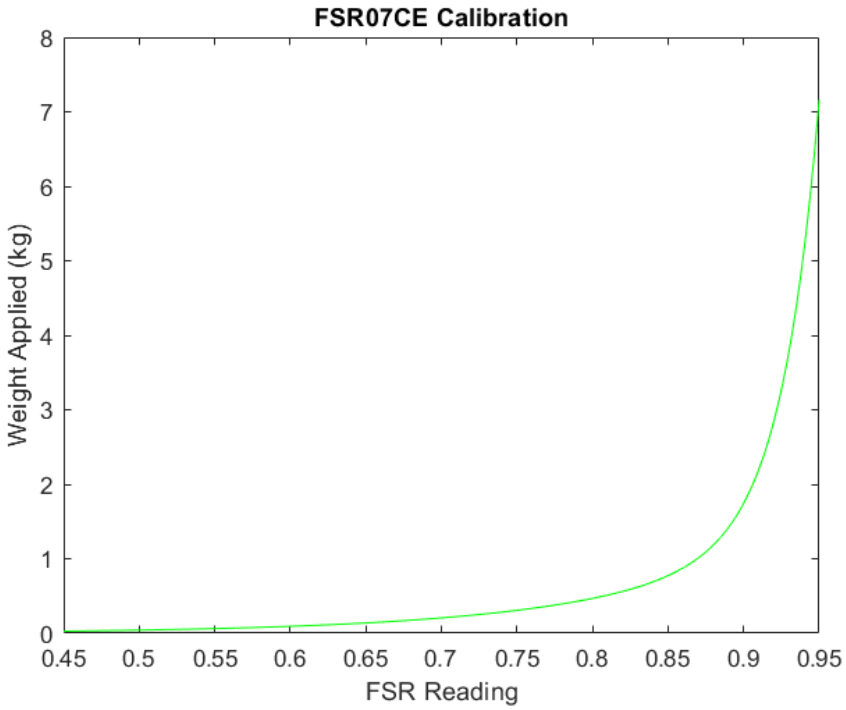


Figure B: FSR output vs. Pressure applied by each bar (mmHg). Green signifies the ideal pressure range (50-70mmHg), yellow signifies the acceptable pressure range (40-80mmHg) and red signifies the unacceptable pressure ranges (<40mmHg or >80mmHg).

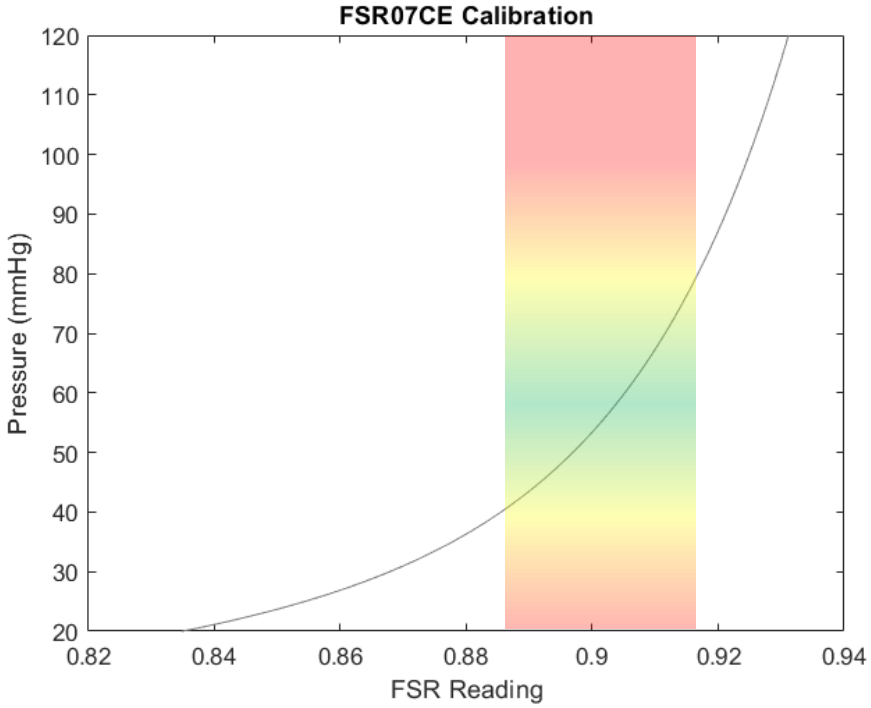


Table A: The values used to calculate approx. mmHg.

Approx. area of bar (m^2)	0.0024
Gravity (m/s^2)	9.81
Calibration Mass(es) (kg)	0.1 - 5
Force (N)	Mass (kg) * Gravity (m/s^2)
Pressure (Pa)	Force (N) / Area (m^2)
Pressure (kPa)	Pa / 1000
Pressure (mmHg)	kPa * 7.50062

Appendix C

C.1 Material Properties

Material		PLA	PLActive	Guidel!ne
Generic Name		Poly Lactic Acid	Poly Lactic Acid with copper nanoparticles	Polyethylene Terephthalate Glycol
Brand		Generic	Copper 3D	Taulman
Printing Temperature		180-210	190-210	242-252
Melting Temperature		210 +/- 10		220
Melting Point		145-160	145-160	
Tensile strength (MPa)	ISO 527	49.5 (yield)/ 45.6(break)		
	ASIM D882		60 (yield)/ 53(break)	
	ASTM D412-15a			47.2(break)
Tensile Elongation (%)	ISO 527	5.2		
	ASIM D882		6	
	ASTM D412-15a			5.9
Tensile Modulus (MPa)	ISO 527	2346.5		
	ASIM D882		3600	
	ASTM D412-15a			1941
Notched Izod Impact (J/m)	ISO 180	5.1		
	ASIM D256		16	
Specific gravity g/cc	ASTM D1505	1.24		
	D792		1.24	

C.2 Interview Questions

Patient Reference Number: Date:

Socket Satisfaction Rating: About Participant

From birth (congenital) / Acquired (amputation)?

Does the patient have a socket? Y / N

If so, does the patient use their socket regularly? Y / N

If yes, does the patient use a terminal device with their socket? Y / N

If yes, what kind of device(s)? Circle all that apply:

A prosthesis Utensil Tool Hook Other (describe)……

If yes, how is the device(s) powered? Circle all that apply:

Passive static Passive adjustable Body Powered Myoelectric

Does the patient currently experience any pain/phantom sensations in their limb? Y / N

If so, describe the sensations and where they occur:

……

……

Socket Satisfaction Rating: About the Socket being assessed

Description of limb (level & side): (e.g. trans-radial, right arm)

Type of socket being assessed: (e.g. Brim, SSOC)

Assessment with / without terminal device? If yes, describe: (e.g. i-limb hand, approx. weight)

Manufacturing method: (e.g. traditional cast, digital scan and 3D print, etc.)

1: COMFORT

1A: What are your initial thoughts wearing the socket – is there anything you notice that is particularly comfortable or uncomfortable?
.....
.....

1B: On a scale of 1 – 5 where 5 is the most comfortable and 1 is the least comfortable (see descriptions of each level) – what would you rate this socket?				
5	4	3	2	1
Very Good	Good	Okay	Bad	Very Bad
Very comfortable, no area(s) of pain or discomfort at all	Overall comfortable, no major area(s) of pain or discomfort	Bearable comfort, some area(s) that could be improved	Uncomfortable, area(s) of mild-moderate discomfort or pain	Severely uncomfortable, major areas of discomfort or pain

1C: Which area(s) do you find to be the <u>least</u> comfortable about the socket? Tick all that apply			
Trimline	Elbow grip	Amputation site/distal end of socket	Other (describe) ……

1D: Which area(s) do you find to be the <u>most</u> comfortable about the socket? Tick all that apply			
Trimline	Elbow grip	Amputation site/distal end of socket	Other (describe) ……

1E: Are there any specific areas of the socket that you think needs modification? If so, where and how?
.....
.....

2: SECURITY & FIT

2A: On a scale of 1 – 5 where 5 is the most secure and 1 is the least secure (see descriptions of each level) – what would you rate this socket?				
5	4	3	2	1
Very Good	Good	Okay	Bad	Very Bad
Very secure, no concerns at all of socket coming off	Quite secure, no major concerns of socket coming off	Somewhat secure, some concerns of socket coming off	Not secure, quite concerned about socket coming off	Severely secure, certain socket will come off

2B: On a scale of 1 – 5 where 1 is too tight and 5 is too loose (see descriptions of each level) – what would you rate this socket?				
1	2	3	4	5
Much too tight	Slightly tight	Ideal fit	Slightly loose	Much too loose

2C: Do you have any comments you would like to add about the security or tightness of the socket?
.....
.....

3: LONG-TERM USE

3A: On a scale of 1 – 5 where 5 is the longest duration and 1 is the shortest duration (see descriptions of each level) – how long do you estimate you could use this socket without experiencing pain or discomfort?				
5	4	3	2	1
Could wear for an entire day without pain or discomfort	Could wear for a few hours without pain or discomfort	Could wear without pain or discomfort, but only for a few minutes	Could wear for a few minutes but causes discomfort	Could not wear for any length of time, causes pain/discomfort

3B: Do you have any comments you would like to add about how long you estimate you could wear this socket without experiencing pain/discomfort?
.....
.....

4: COMPARISON TO OWN SOCKET

4A: If you use a rigid socket regularly (i.e. without a gel liner): on a scale of 1 – 5, where 5 is much more comfortable and 1 is much less comfortable (see descriptions of each level) – what would you rate this socket compared to the socket you use regularly?				
5	4	3	2	1
Much more comfortable than own socket	Slightly more comfortable than own socket	Same as own socket	Slightly less comfortable than own socket	Much less comfortable than own socket

C.3 Interview Transcripts

Below are the raw interview notes taken during the feedback session. Notes were taken by co-author Olsen. The quotes are direct from the participants. Only quotes relevant to the study were captured. Conversation irrelevant to the study and identifying details were omitted.

M = Modified, UM = Unmodified

Participant 1 (Unmodified socket tried first)

	Unmodified	Modified
Q1	Very comfortable, easy to don. I think it's actually the most comfortable socket I've ever tried.	Comfortable but slightly harder to don than UM due to inner wing.
Q2	This feels very secure, I could suspend my entire bodyweight with this (referring to the socket)	This one doesn't feel as secure as the first* (*first = UM)
Q3	None.	The inner wing causes some pressure so I'd probably change that.
Q4	All day, it's very comfortable.	I'm unsure because of that inner wing.
Q5	It's extremely comfortable and I'm really happy with fit. It's the best socket fit I've ever tried on.	This one is not as good as the first because of the wing.
Additional	Personally, I prefer this (referring to the method) for getting a socket. Some of my sockets have taken so many refitting sessions and visits to the clinic, when you add it up it took so much time. I am totally amazed with the results of these sockets. As I showed you the prosthetic I have for weight lifting prosthetic and is not ideal and that was after 3 visits with time and cost and I think what you have demonstrated is that you can create a socket that fits perfect and has all the requirements including load bearing and has very little or no pressure points. (Participant also stated they were impressed with the quality of the scan when shown their scan on screen)	

Participant 2 (Unmodified socket tried first)

	Unmodified	Modified
Q1	Very comfortable, the extension range is good, the length is good. It's a bit snug at the end* so pressure might be a problem long term but it feels comfortable. (*end = distal amputation site)	This feels the same as the first one* except it feels looser. (*first = UM)
Q2	It's not secure, I can remove it quite easily (referring to the socket), it's a bit loose around the elbow because the trimlines are low, they need to be	This one is looser than the first, it actually feels lower too.

	about 1cm higher, it's not far off though, maybe not even 1cm.	
Q3	As I said, the trimline could be higher but it's not far off, 1cm or less higher on the wings would be ideal.	With this one, the inside wing causes a bit of friction, which if I wore it for a long time might get sore.
Q4	I'm not sure.	It's the same as the first socket, the wing might cause problems if I wore it for a long period of time.
Q5	I prefer my usual socket as I can rotate in it really well, I use it for driving so I find that useful. I'd usually wear socks under my socket too.	Same as the first, except this one is looser so the first socket was better out of the two.
Additional	Both the sockets were better with a sock, except then they felt a bit snug. Overall they really weren't far off being a good fit, I think with small changes the fit would be quite good. (Participant also stated they were impressed with the quality of the scan when shown their scan on screen and also commented on how many detailed the sockets were in comparison to others they had received.)	

Participant 3 (Modified socket tried first)

	Unmodified	Modified
Q1	Same as the first*, feels very comfortable, no issues. (*first = M)	It feels very comfortable, no issues with it.
Q2	This isn't secure either, but the first was less secure. This one is a bit better in terms of grip. I can still take it off quite easily though.	It's not secure, I can take it off easily.
Q3	Same as the first really.	The left wing needs a bit of modification and the back is higher than my usual (socket) but not bad. I do like the socket and I find it extremely comfortable but I'd be worried about the security, I think it's because of the low trimline.
Q4	All day.	All day.
Q5	Same as the first.	I'd say it's similar to my own socket but slightly less preferable due to security issues.
Additional	(Participant stated they were impressed with the quality of the scan when shown their scan on screen, particularly the details that could be captured.)	

Participant 4 (Modified socket tried first)

	Unmodified	Modified
Q1	Same, very comfortable.	. Very comfortable

Q2	This one feels secure.	It doesn't feel completely secure.
Q3	Same (as the first*). (*first = M)	Not really, the trimline at back could be lowered but it's not uncomfortable, just different to what I usually use.
Q4	All day.	I'm not sure.
Q5	Same as the first.	Not sure because it's different to my usual, not bad, just different, so it's hard to compare.
Additional	None	

Participant 5

Sockets were much too loose to gauge comfort or security (i.e. not in full contact with the limb) so the feedback session was terminated.

Participant 6

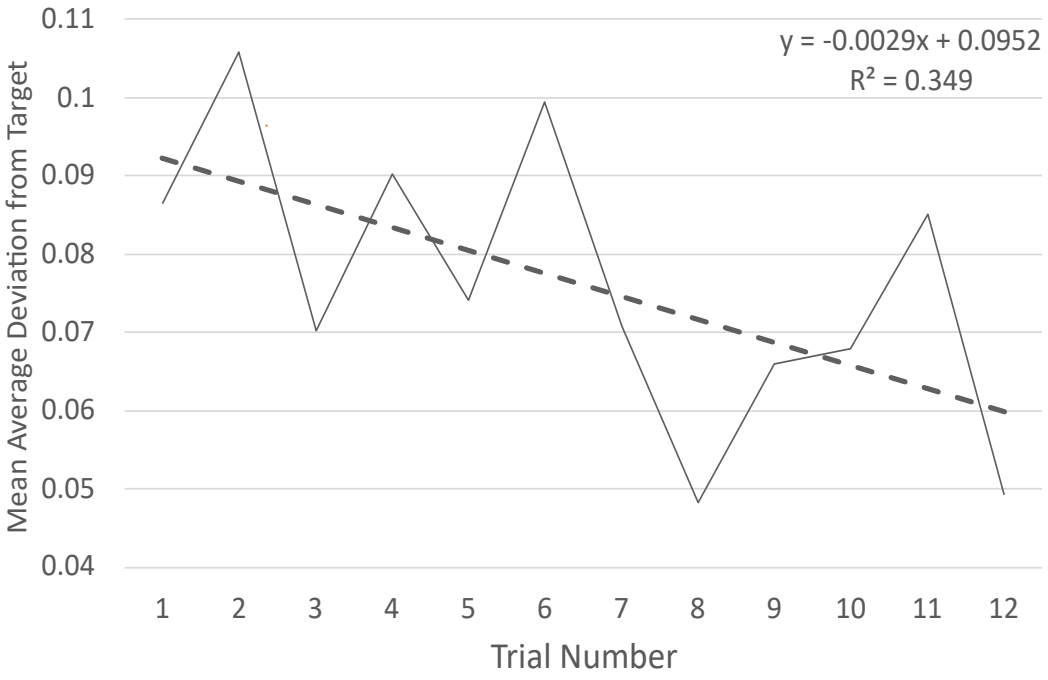
Feedback session terminated as participant divulged that a channel is usually created to relieve pressure over their inner epicondlye (due to nerve damage) after the sockets were manufactured.

C.4 3D Printing Costs and Timings

Participant	Print time (PLA Settings)	Socket weight incl. support material (grams)	Cost (£) - PLA	Cost (£) - PLActive	Cost (£) - Guidel!ne
P1	16:18:00	103.30	3.35	10.25	10.93
P2	14:27:00	87.70	2.84	8.70	9.28
P3	14:16:00	92.00	2.98	9.13	9.74
P4	12:01:00	78.00	2.53	7.74	8.25
P5	17:36:00	107.40	3.48	10.65	11.37
P6	14:59:00	93.10	3.02	9.24	9.85
Mean	14:56:10	93.58	3.03	9.28	9.90

Appendix D

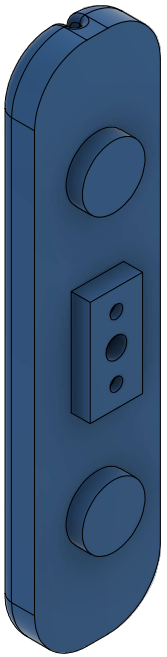
D.1 Participant EMG Deviation Over Time


y = -0.0029x + 0.0952
R² = 0.349
Mean Average Deviation from Target
0.11
0.1
0.09
0.08
0.07
0.06
0.05
0.04
1
2
3
4
5
6
7
8
9
10
11
12
Trial Number

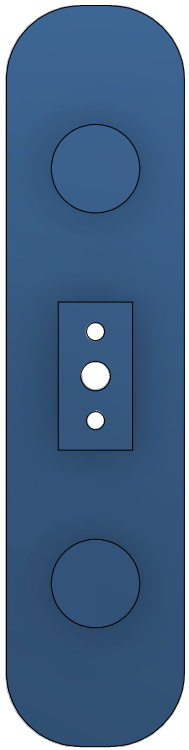
D.2 Engineering Drawings

Notes:

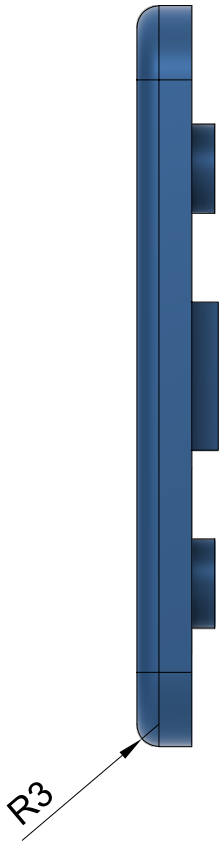
1) All edges on the outer surfaces visible in front view chamfered as dimensioned in the drawings to prevent injury to the wearer's skin. R1 for around electrode and R3 for outside of bar.



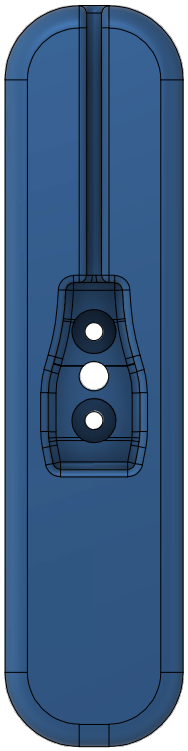
Rear View

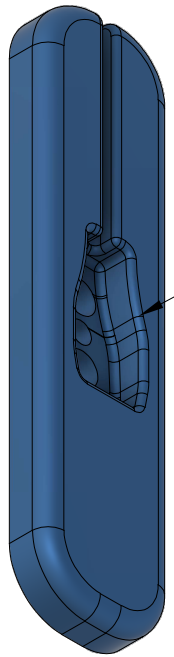


Side View



Front View

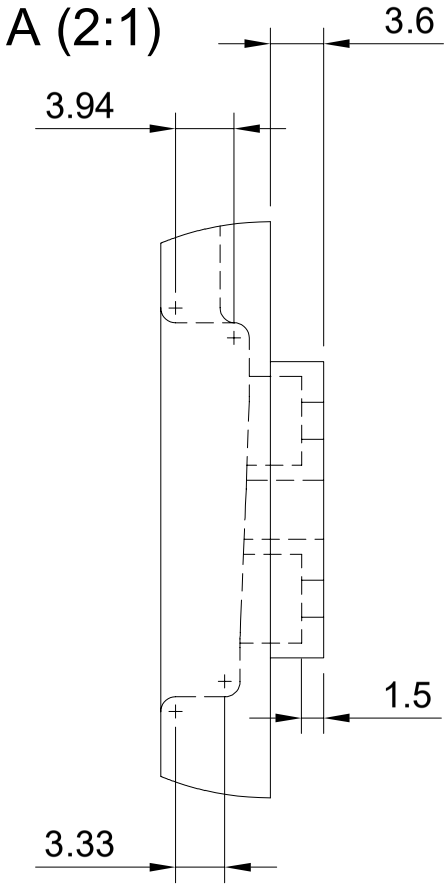


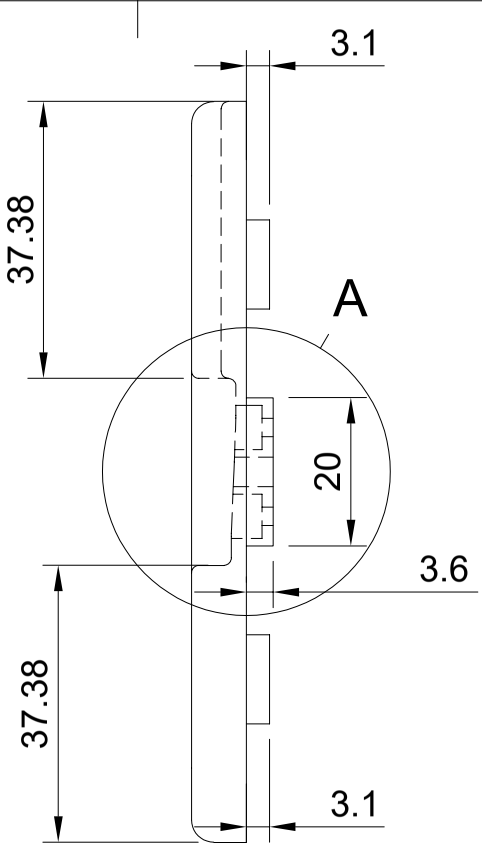


Tolerance 0.1mm unless otherwise stated.

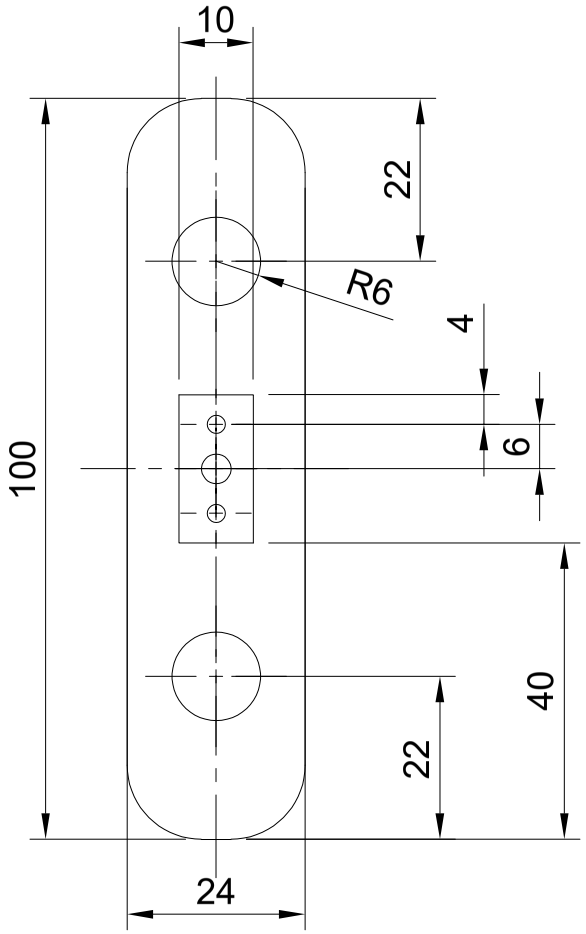
Created by: Jennifer Olsen		Material: PLActive 1.75mm filament
Created date: 24/08/2023	Units: mm	Manufacturing Method: SLS Printed
Title: Lower Bar		Manufacturing Notes: 0.2mm layer height, 35% infill
School: Newcastle University	Scale: 1:1 unless otherwise stated	Sheet: 1/3

Note: Tolerance 0.1mm unless otherwise stated.





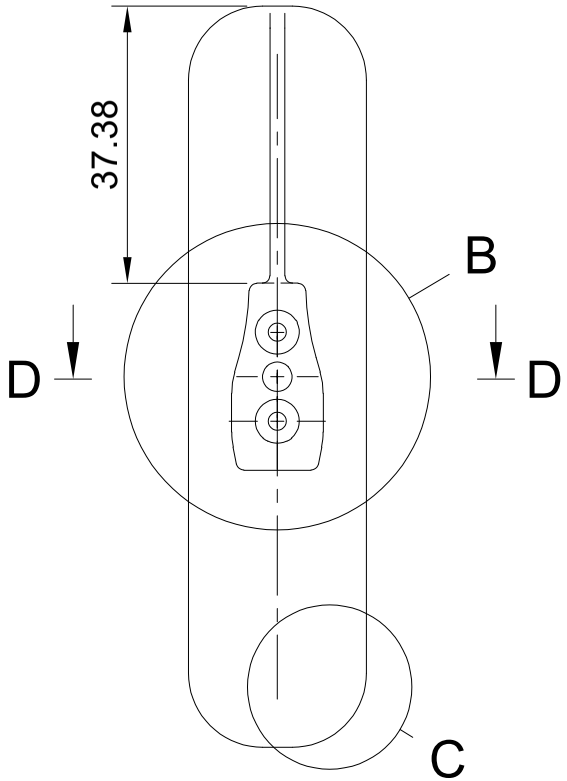
Side View

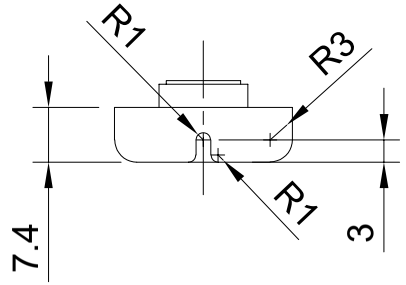


Rear View

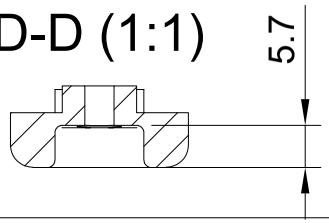
Created by Jennifer Olsen		Material PLActive 1.75mm filament
Created date 24/08/2023	Units mm	Manufacturing Method SLS Printed
Title Lower Bar		Manufacturing Notes 0.2mm layer height, 35% infill
School Newcastle University	Scale 1:1 unless otherwise stated	Sheet 2/3

Front View



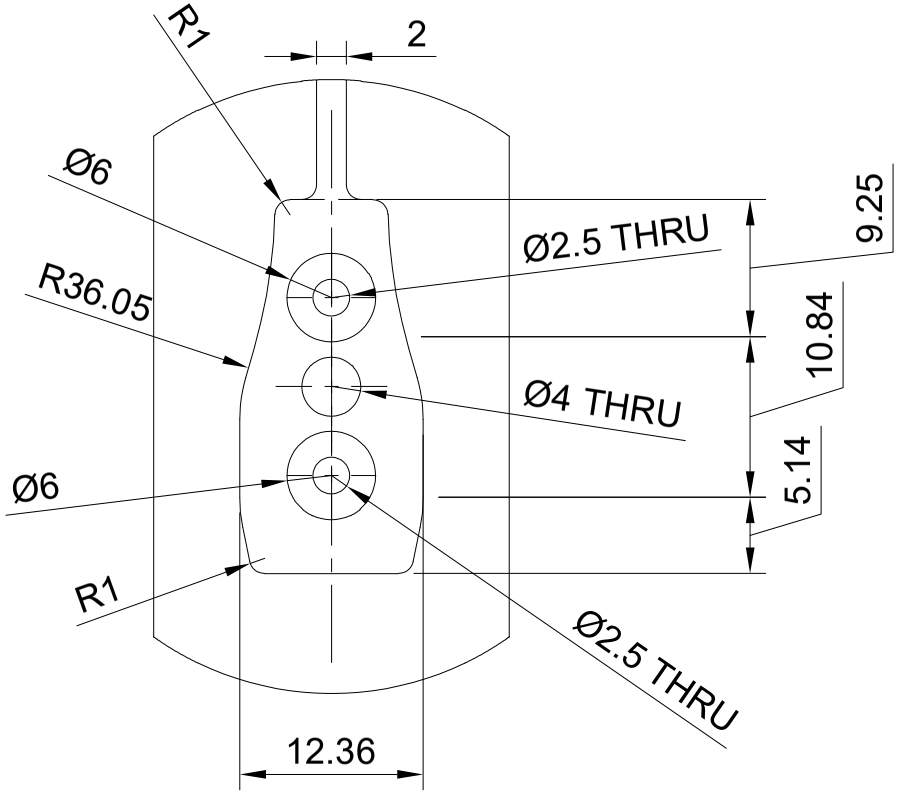


D-D (1:1)

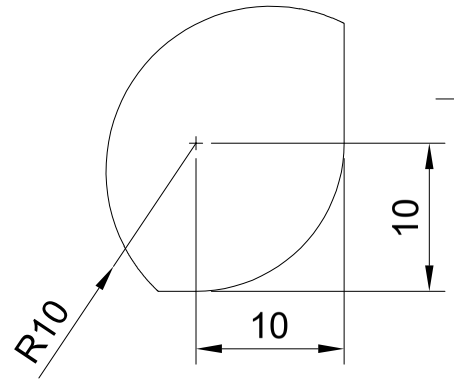


Note: Tolerance 0.1mm unless otherwise stated.

B (2:1)

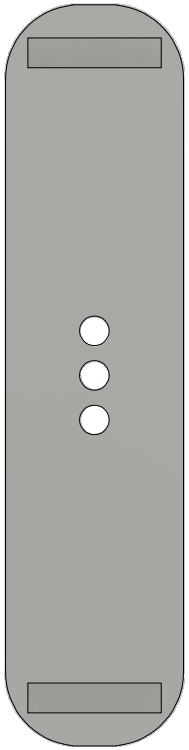


C (2:1)

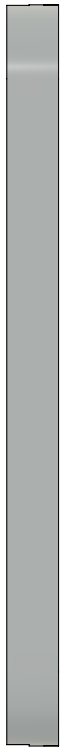


Created by Jennifer Olsen		Material PLActive 1.75mm filament
Created date 24/08/2023	Units mm	Manufacturing Method SLS Printed
Title Lower Bar		Manufacturing Notes 0.2mm layer height, 35% infill
School Newcastle University	Scale 1:1 unless otherwise stated	Sheet 3/3

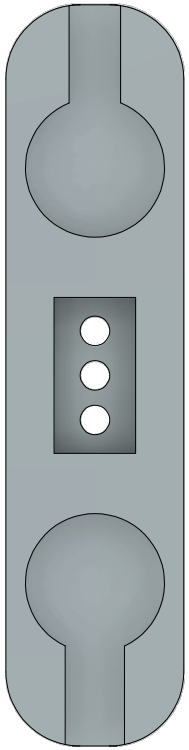
Rear View

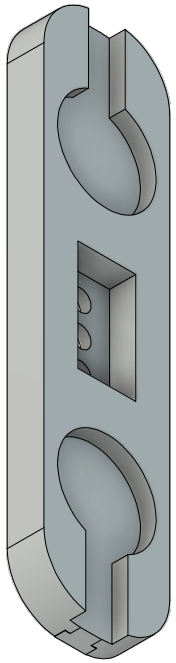


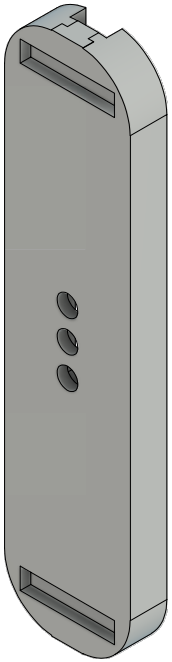
Side View



Front View

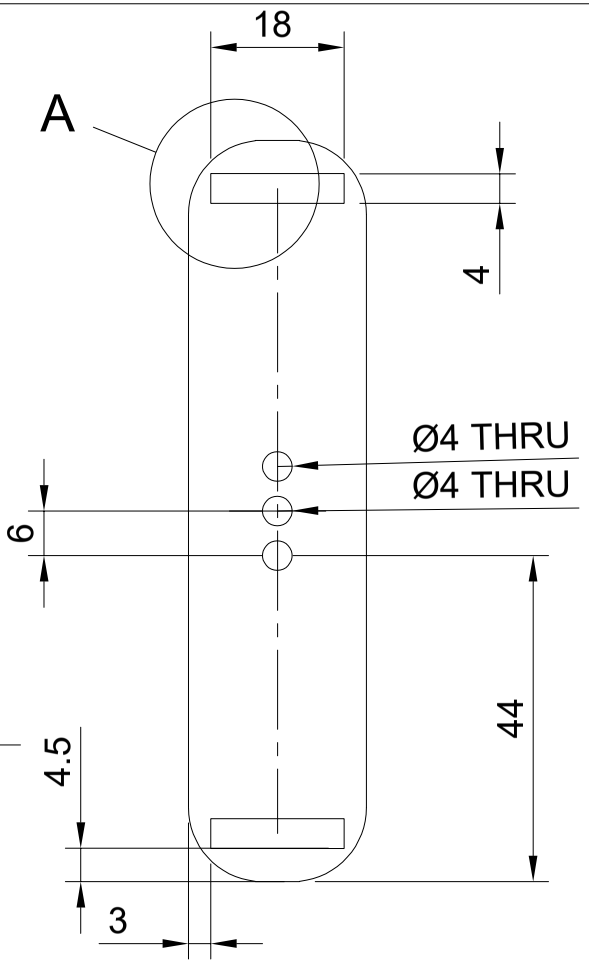




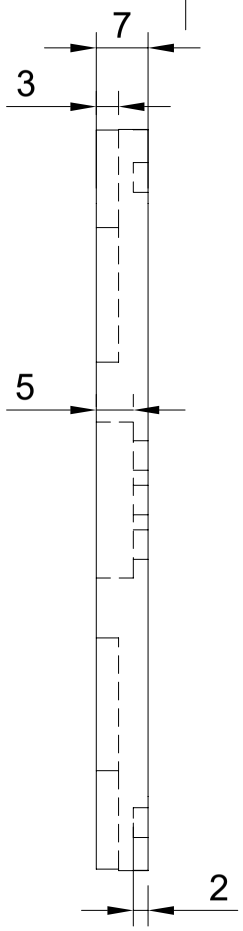


Note: Tolerance 0.1mm unless otherwise stated.

Created by Jennifer Olsen		Material PLActive 1.75mm filament
Created date 24/08/2023	Units mm	Manufacturing Method SLS Printed
Title Upper Bar Part 1/3		Manufacturing Notes 0.2mm layer height, 35% infill
School Newcastle University	Scale 1:1 unless otherwise stated	Sheet 1/2

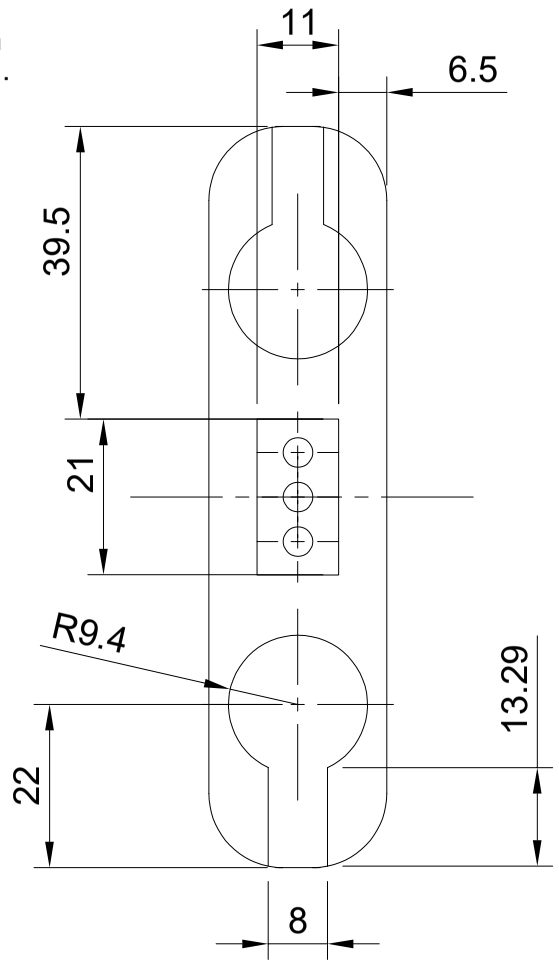


Rear View

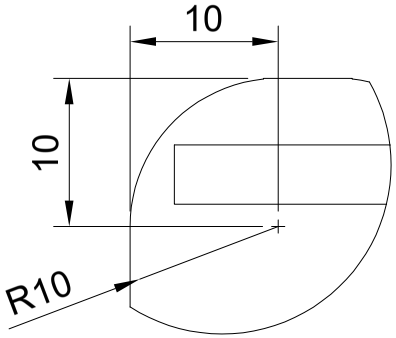


Side View

Note: Tolerance 0.1mm
unless otherwise stated.



Front View



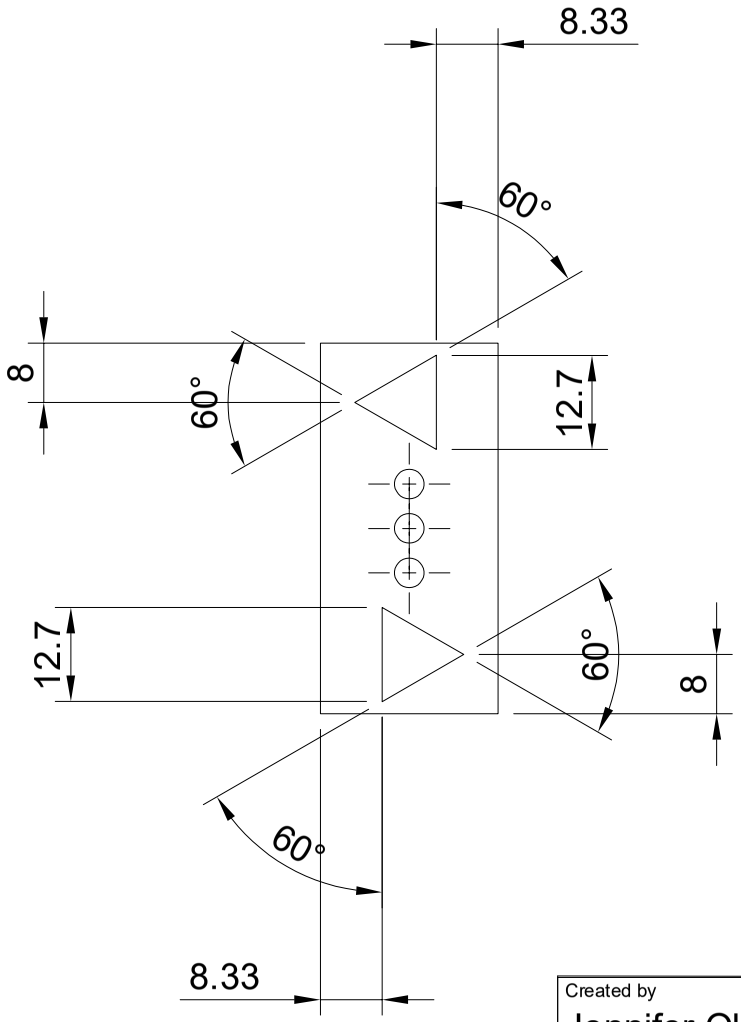
A (2:1)

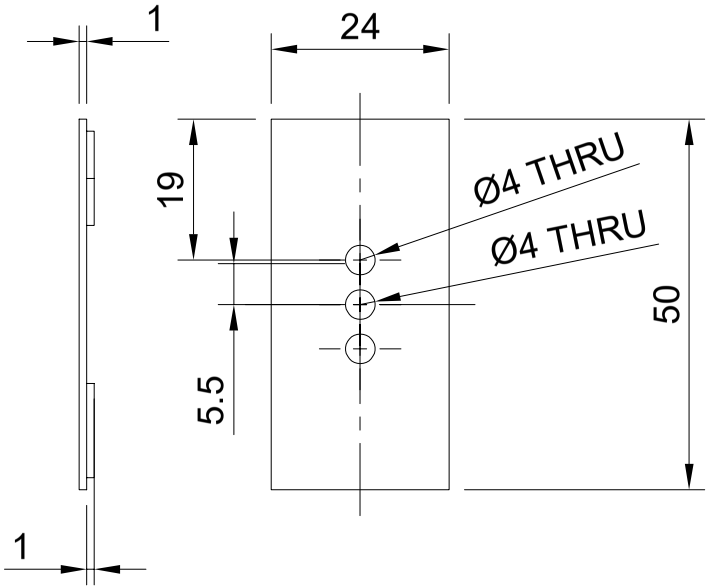
Created by Jennifer Olsen		Material White PLA 1.75mm filament
Created date 24/08/2023	Units mm	Manufacturing Method SLS Printed
Title Upper Bar Part 1/3		Manufacturing Notes 0.2mm layer height, 35% infill
School Newcastle University	Scale 1:1 unless otherwise stated	Sheet 2/2

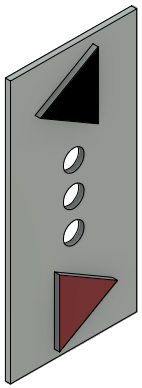
Notes:

1) SLS printed in white PLA, then black and red marker triangles coloured by hand with permanent marker.

Note: Tolerance 0.1mm unless otherwise stated.

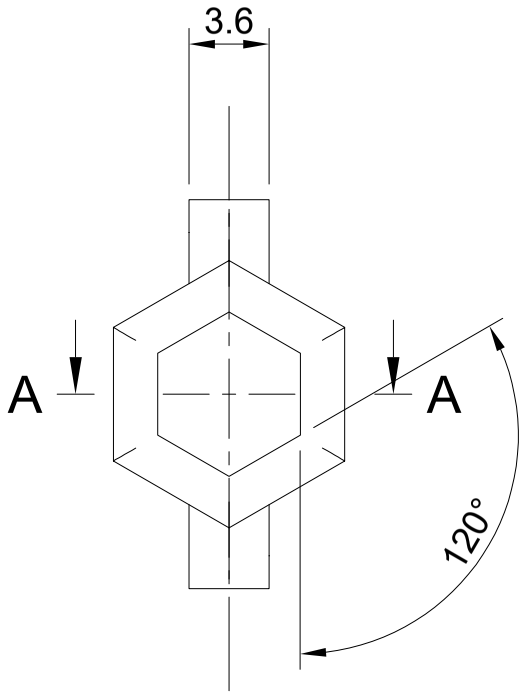


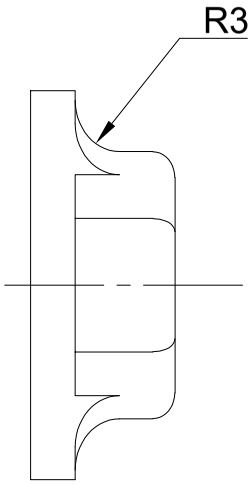


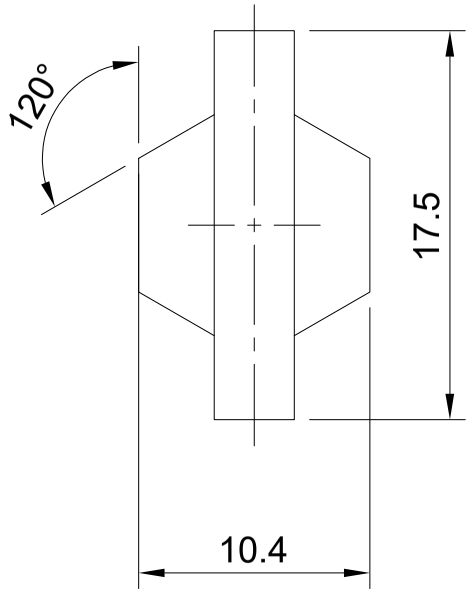


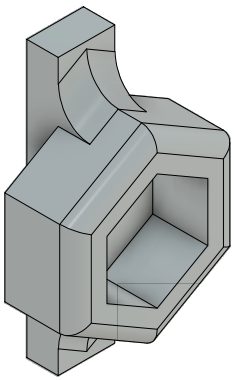
Created by: Jennifer Olsen		Material: White PLA 1.75mm filament
Created date: 24/08/2023	Units: mm	Manufacturing Method: SLS Printed
Title: Upper Bar Part 2/3		Manufacturing Notes: 0.2mm layer height, 35% infill
School: Newcastle University	Scale: 1:1 unless otherwise stated	Sheet: 1/1

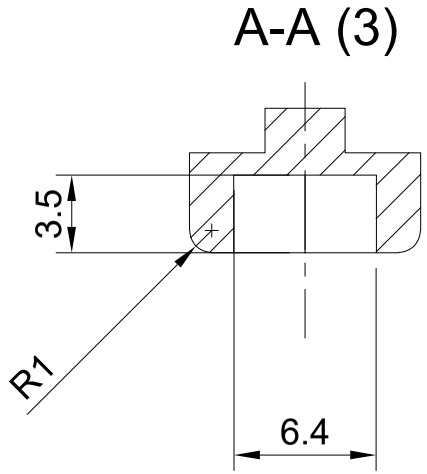
Note: Tolerance 0.1mm unless otherwise stated.





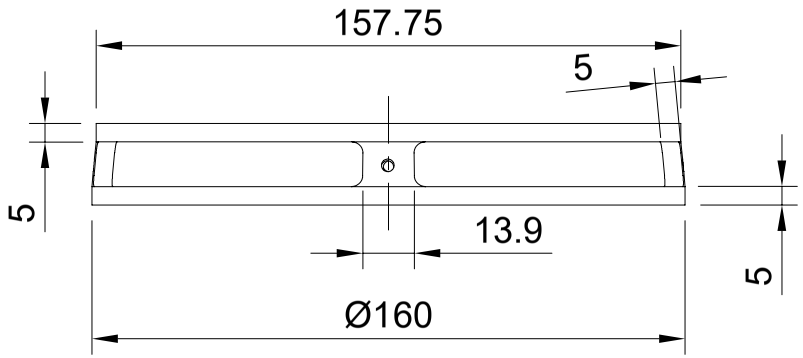


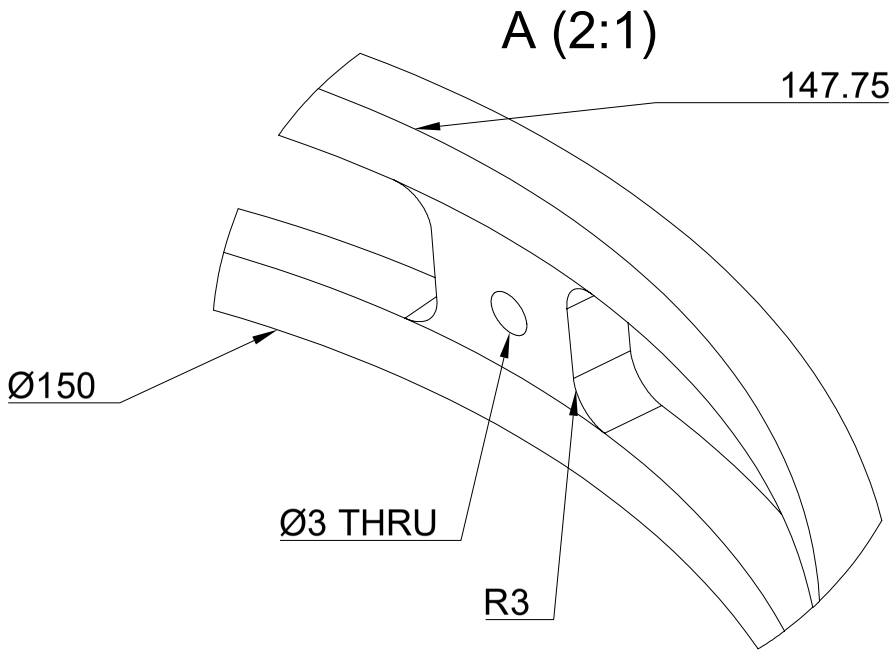


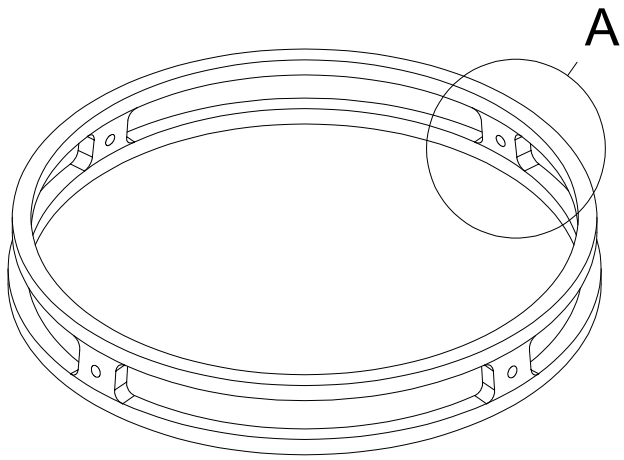


Created by Jennifer Olsen		Material White PLA 1.75mm filament	
Created date 24/08/2023	Units mm	Manufacturing Method SLS Printed	
Title Upper Bar Part 3/3		Manufacturing Notes 0.2mm layer height, 35% infill	
School Newcastle University	Scale 3:1 unless otherwise stated		Sheet 1/1

Note: Tolerance 0.1mm unless otherwise stated.

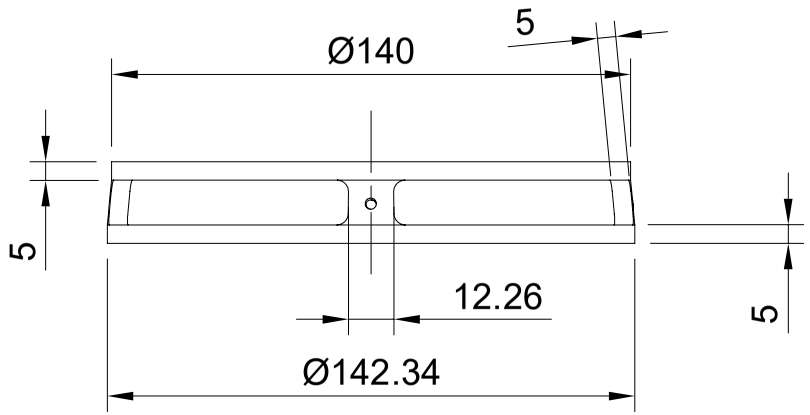


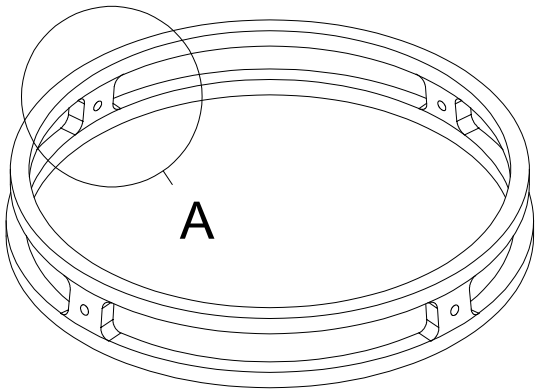




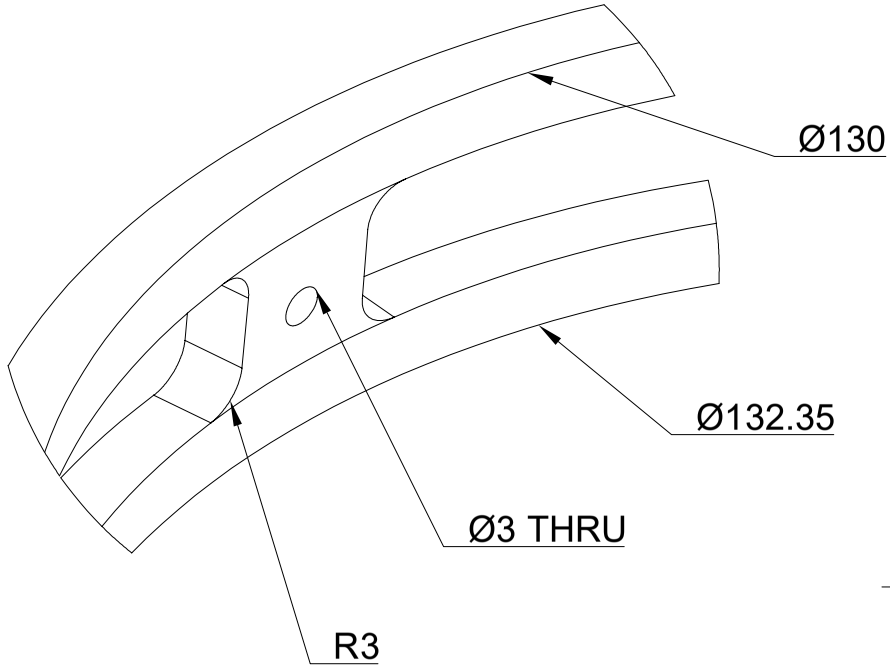
Created by Jennifer Olsen		Material White PLA 1.75mm filament
Created date 24/08/2023	Units mm	Manufacturing Method SLS Printed
Title Lower Ring		Manufacturing Notes 0.2mm layer height, 35% infill
School Newcastle University	Scale 1:2 unless otherwise stated	Sheet 1/1

Note: Tolerance 0.1mm unless otherwise stated.



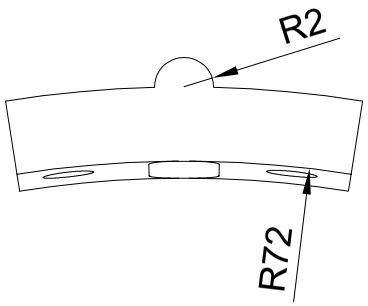


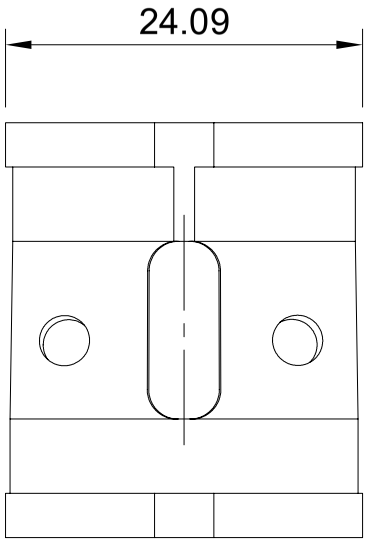
A (2:1)

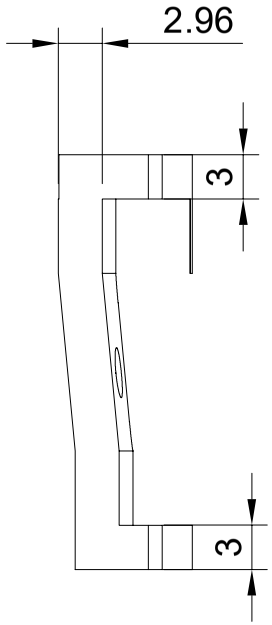


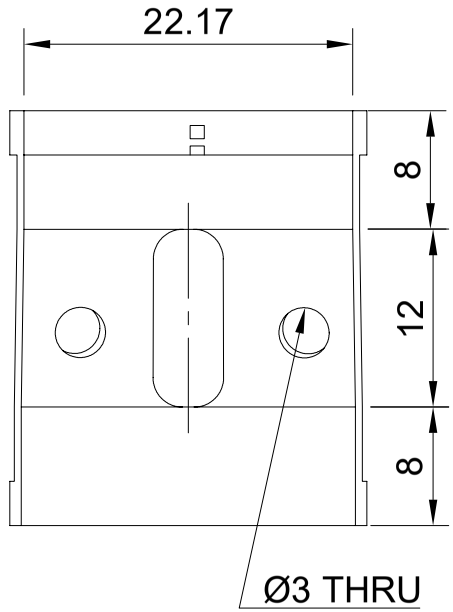
Created by Jennifer Olsen		Material White PLA 1.75mm filament
Created date 24/08/2023	Units mm	Manufacturing Method SLS Printed
Title Upper Ring		Manufacturing Notes 0.2mm layer height, 35% infill
School Newcastle University	Scale 1:2 unless otherwise stated	Sheet 1/1

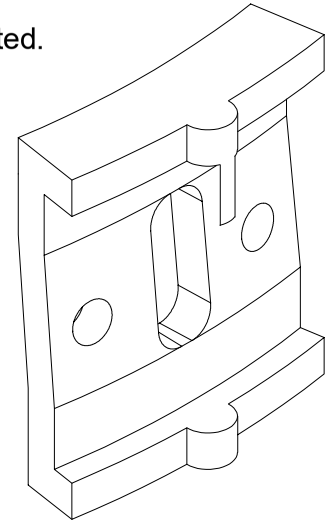
Note: Tolerance 0.1mm unless otherwise stated.

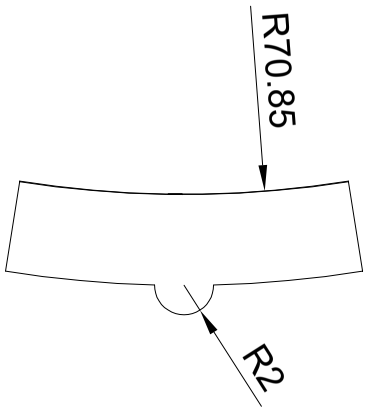




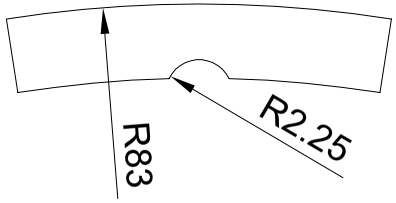


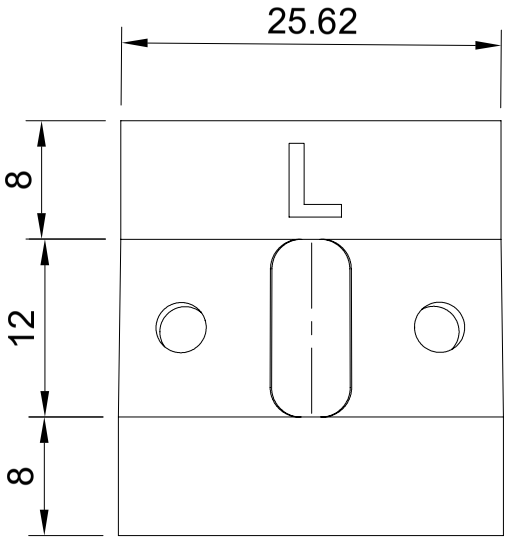


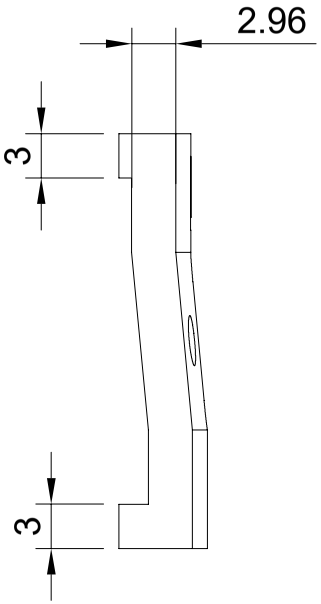


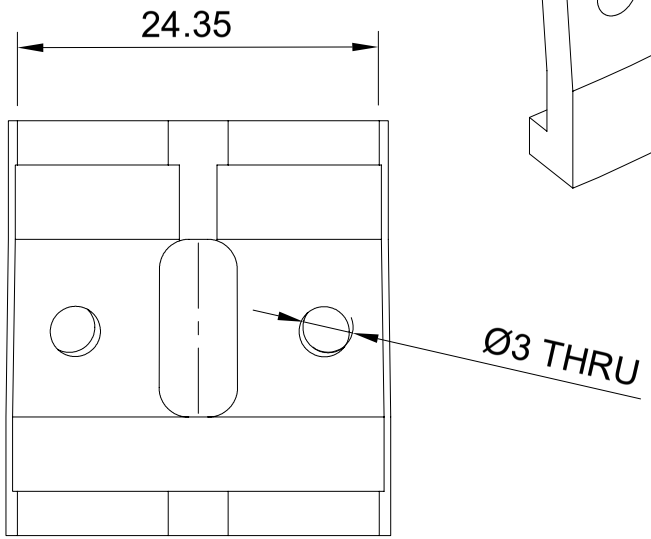


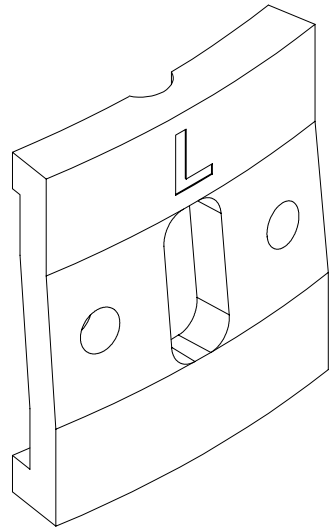
Created by: Jennifer Olsen		Material: White PLA 1.75mm filament
Created date: 24/08/2023	Units: mm	Manufacturing Method: SLS Printed
Title: Lower Clamp Inner		Manufacturing Notes: 0.2mm layer height, 35% infill
School: Newcastle University	Scale: 2:1 unless otherwise stated	Sheet: 1/1

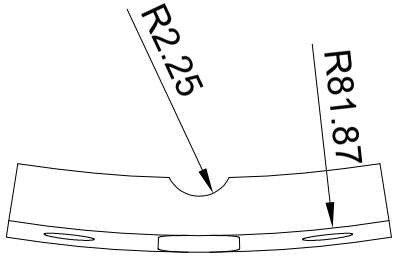








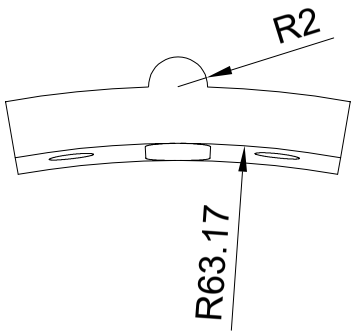


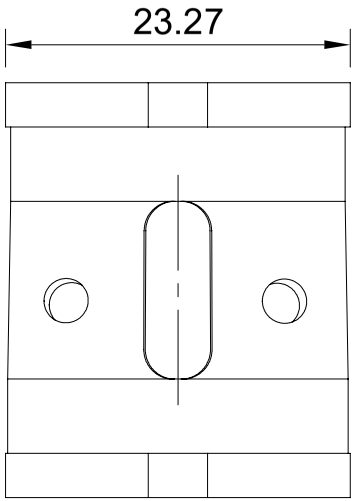


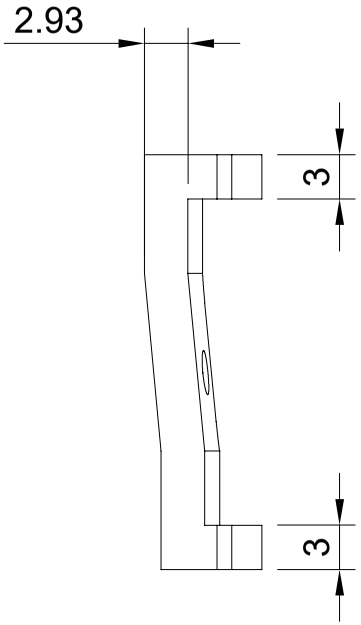
Note: Tolerance 0.1mm unless otherwise stated.

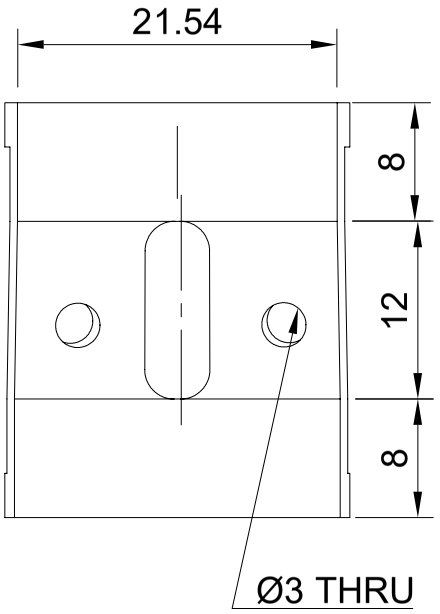
Created by Jennifer Olsen		Material White PLA 1.75mm filament	
Created date 24/08/2023	Units mm	Manufacturing Method SLS Printed	
Title Lower Clamp Outer		Manufacturing Notes 0.2mm layer height, 35% infill	
School Newcastle University	Scale 2:1 unless otherwise stated		Sheet 1/1

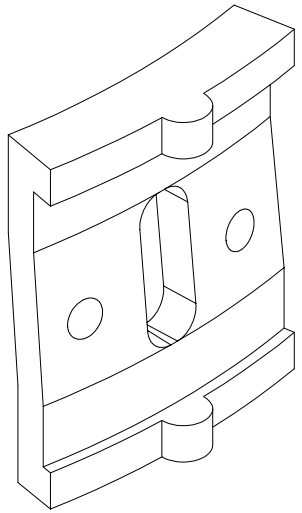
Note: Tolerance 0.1mm unless otherwise stated.

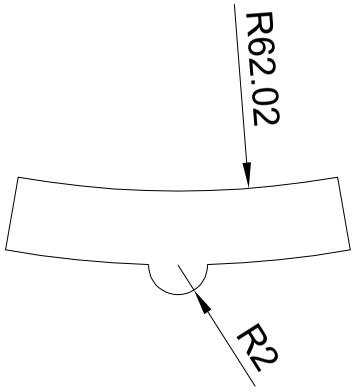






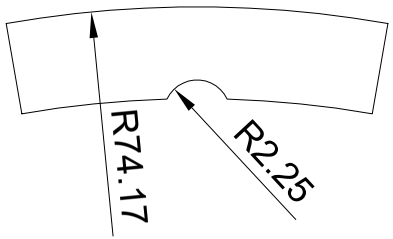


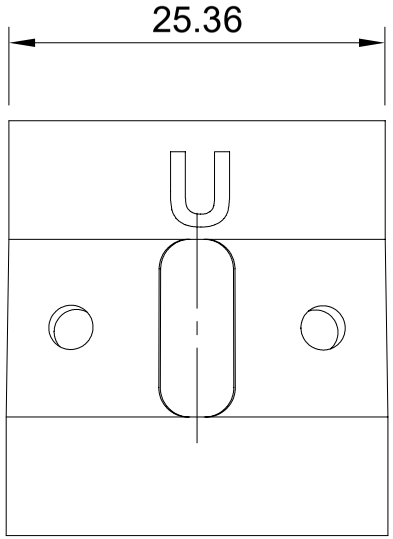


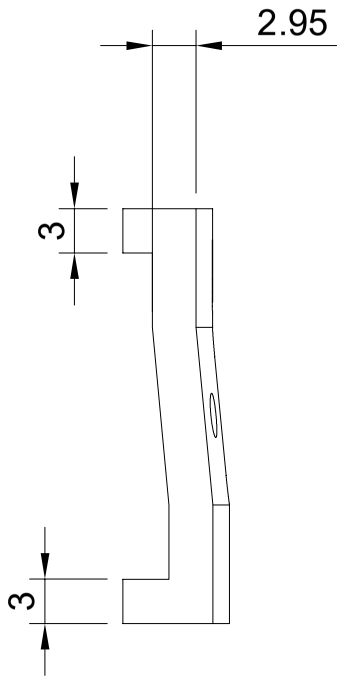


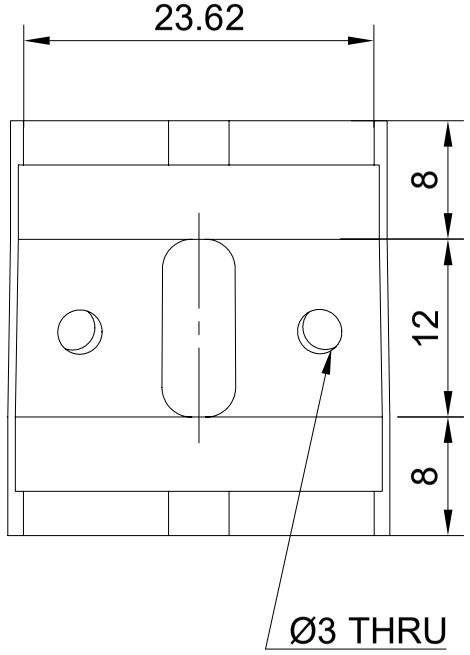
Created by: Jennifer Olsen		Material: White PLA 1.75mm filament
Created date: 24/08/2023	Units: mm	Manufacturing Method: SLS Printed
Title: Upper Clamp Inner		Manufacturing Notes: 0.2mm layer height, 35% infill
School: Newcastle University	Scale: 2:1 unless otherwise stated	Sheet: 1/1

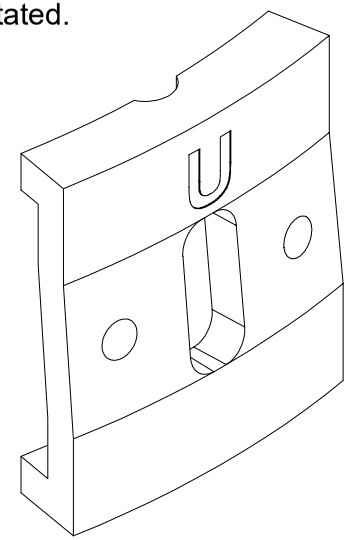
Note: Tolerance 0.1mm unless otherwise stated.

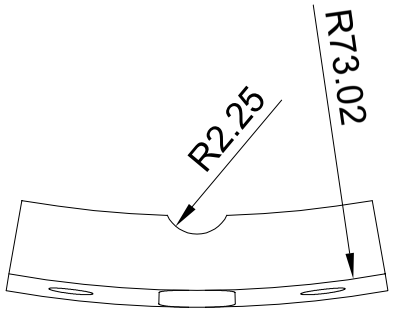






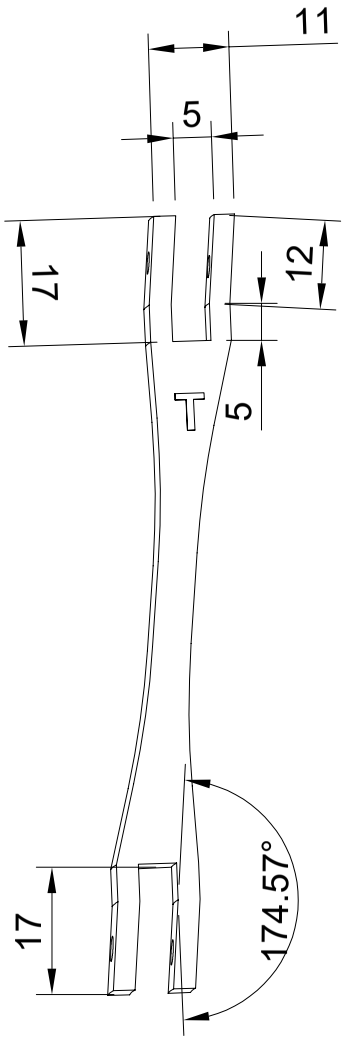


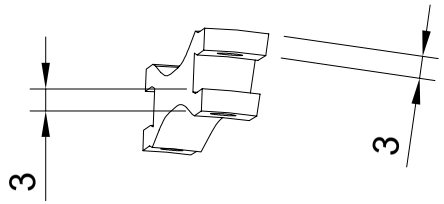


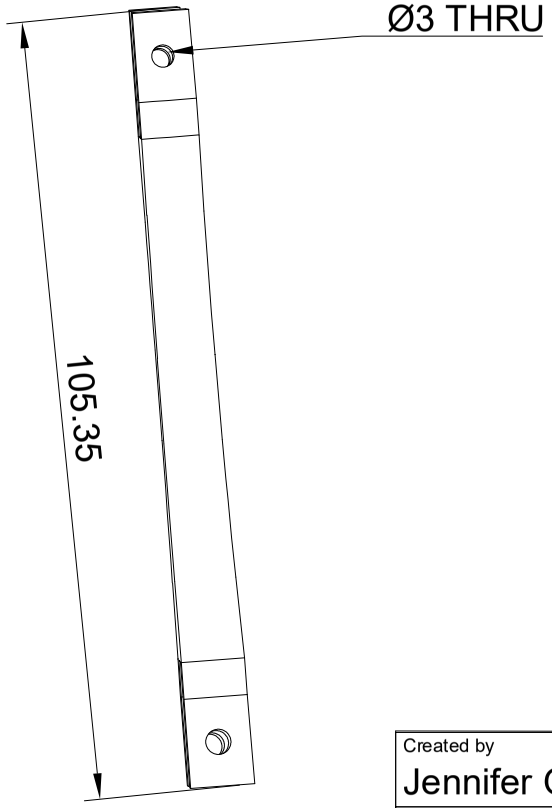


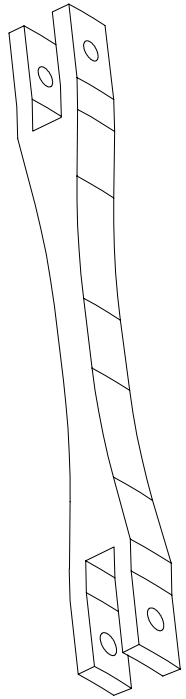
Created by: Jennifer Olsen		Material: White PLA 1.75mm filament
Created date: 24/08/2023	Units: mm	Manufacturing Method: SLS Printed
Title: Upper Clamp Outer		Manufacturing Notes: 0.2mm layer height, 35% infill
School: Newcastle University	Scale: 2:1 unless otherwise stated	Sheet: 1/1

Note: Tolerance 0.1mm unless otherwise stated.



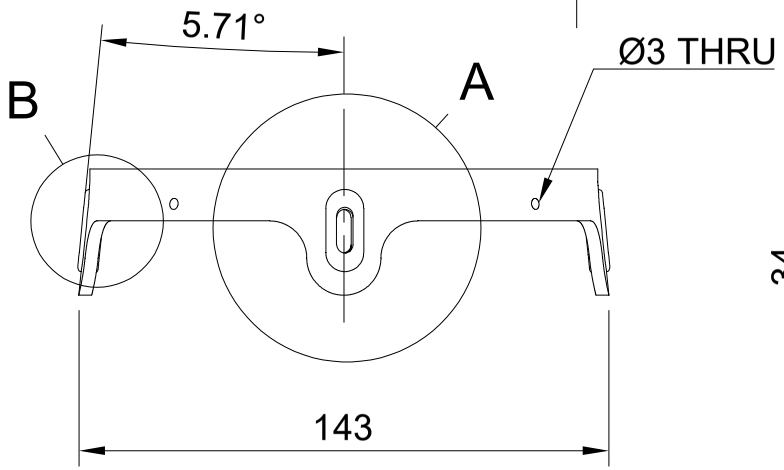






Created by Jennifer Olsen		Material White PLA 1.75mm filament
Created date 24/08/2023	Units mm	Manufacturing Method SLS Printed
Title Strut		Manufacturing Notes 0.2mm layer height, 35% infill
School Newcastle University	Scale 1:1 unless otherwise stated	Sheet 1/1

Note: Tolerance 0.1mm
unless otherwise stated.



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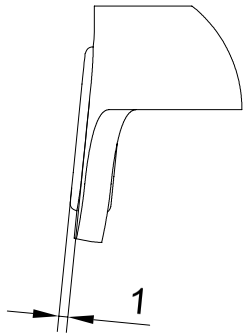

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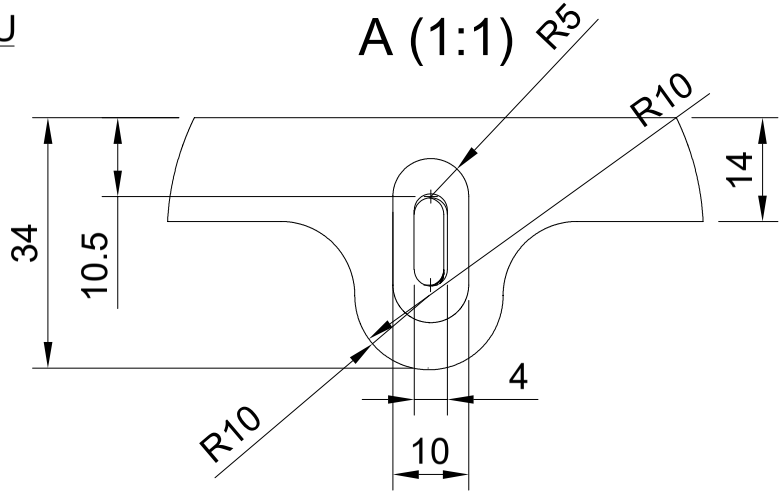
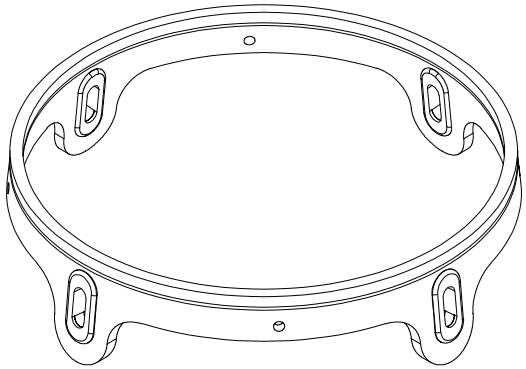
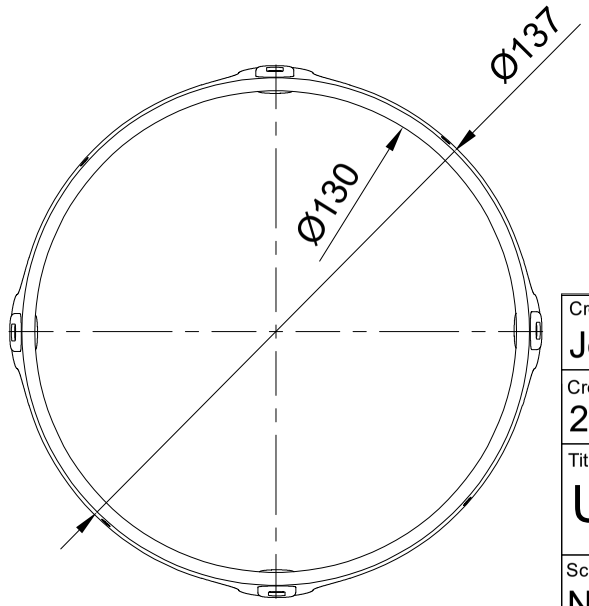
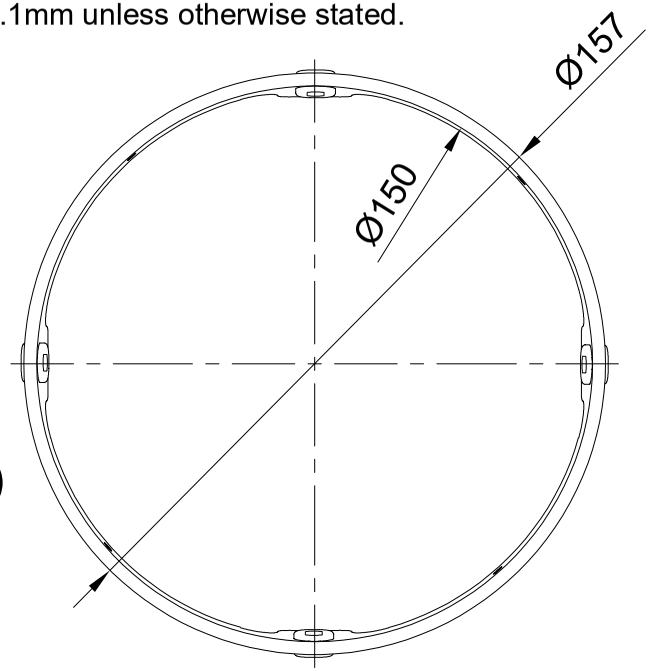




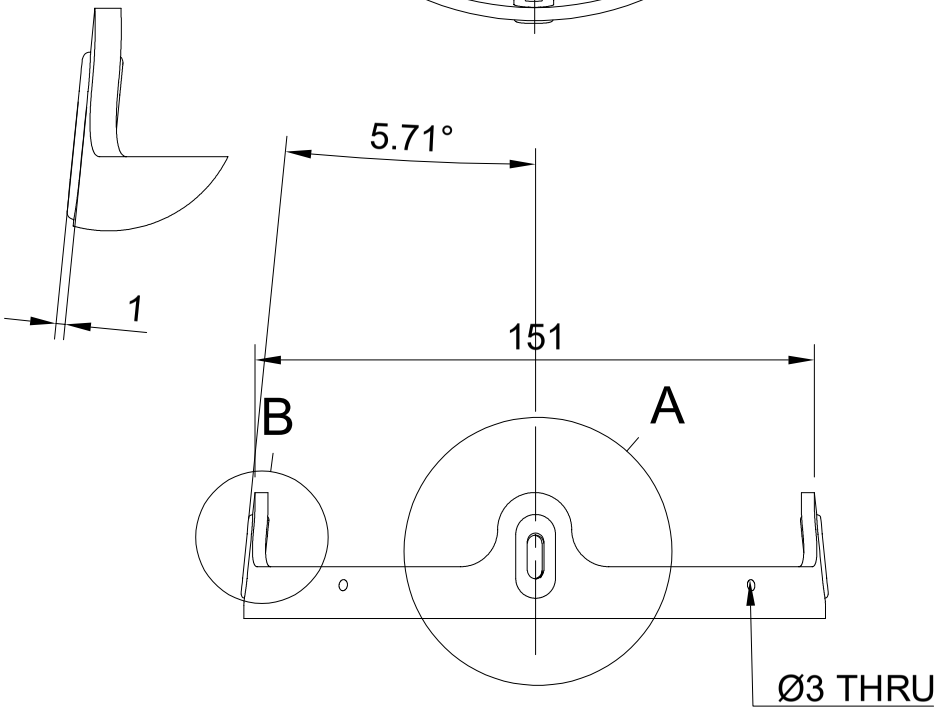


Created by: Jennifer Olsen		Material: White PLA 1.75mm filament
Created date: 24/08/2023	Units: mm	Manufacturing Method: SLS Printed
Title: Upper Locus Ring		Manufacturing Notes: 0.2mm layer height, 35% infill
School: Newcastle University	Scale: 1:2 unless otherwise stated	Sheet: 1/1

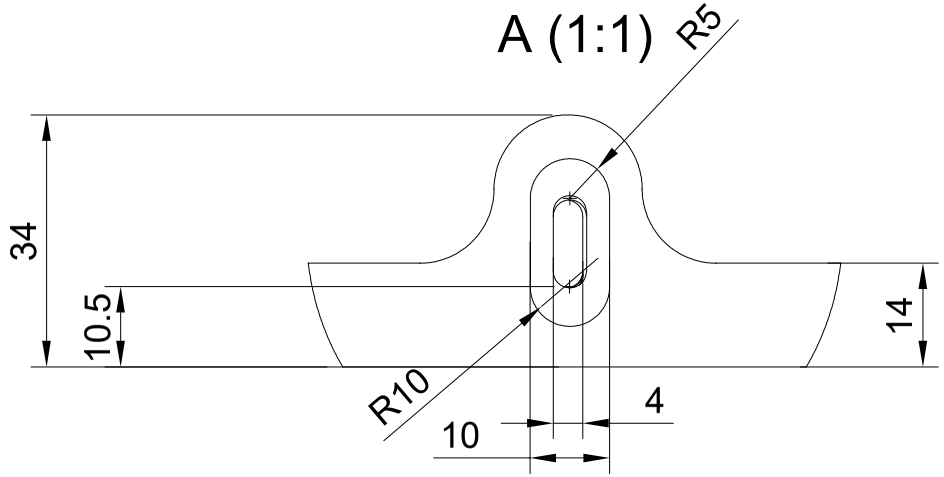
Note: Tolerance 0.1mm unless otherwise stated.

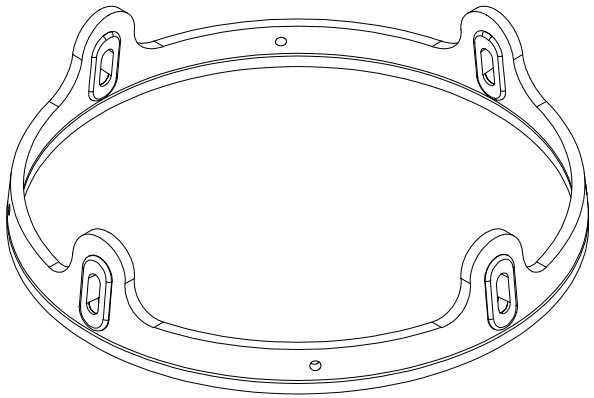


B (1:1)



A (1:1)





Created by Jennifer Olsen		Material White PLA 1.75mm filament	
Created date 24/08/2023	Units mm	Manufacturing Method SLS Printed	
Title Upper Locus Ring		Manufacturing Notes 0.2mm layer height, 35% infill	
School Newcastle University	Scale 1:2 unless otherwise stated		Sheet 1/1

Appendix E

E.1 EMG Task

The targets were displayed on a screen as a row of five black circles with a white border. Corresponding targets were marked on a table in front of the participant, so that they only needed to point their flexed forearm at the correct physical target, corresponding with the target shown on screen, in order to perform the trial. Once in the correct limb position, a further instruction was shown to the participants on screen in the form of an arrow. A left arrow corresponded to a flexor contraction and a right arrow corresponded to an extensor contraction. Each step of the trial was controlled by the examiner, who was required to press a button to move each trial to the next stage. Before the position was displayed on screen, the examiner would press a button, a beep noise was played to alert the participants to the new target on screen, and the target would be displayed in the form of a lit-up green circle. Once the examiner had visually confirmed that the participant had moved their limb into the correct position, they pressed the trigger button again, which resulted in another beep noise being played aloud, and trigger the visual cue for the type of contraction the participant should perform. To do this, an arrow was shown on screen to the participant, left facing for a flexor contraction and right facing for an extensor contraction.

E.2 Pass Fail Analysis

In order to further analyse the trial passes and fails, both the target muscle activity (the muscle being observed for the trial), and the antagonist muscle activity (the muscle which was inactive for the trial) was assessed. For trials

which were recorded as a 'pass', the results will be sub-divided into two conditions: 1) A regular 'pass', where the target muscle met the threshold but the antagonist muscle did not, or 2) a 'co-contraction', defined as where both the target muscle and the antagonist muscle hit the target threshold. This is important to observe, as in most EMG processing systems for EMG control, accidentally performing a co-contraction would lead to an unexpected response from the prostheses. Similarly, for the trials which were recorded as 'fails', the results will be subdivided into two further categories: 1) neither muscle met the threshold, i.e. the contraction was not performed to the correct amplitude or the participant did not contract at all, or 2) the wrong muscle was activated, i.e. the antagonist met the threshold but the target muscle did not. The latter condition would signal a lapse in concentration from the wearer, not an actual missed trial.