Division of Biomedical Engineering
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Design and Development of an Open-Source ADL-Compliant Prosthetic Arm for Transradial Amputees

MINOR DISSERTATION

In partial fulfilment of the requirements for the degree:
MSc (Med) in Biomedical Engineering by Coursework and Dissertation

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Declaration

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Abstract

Transradial amputation is traumatic – leading to the amputee having a limited ability to perform activities of daily living (ADLs). Below-elbow prostheses are prescribed. The high cost associated with prostheses results in many amputees in low-to-middle-income countries relying on government subsidised devices, which are cosmetic rather than functional, or none at all. Open-source prostheses have the potential to increase the accessibility of functional prosthetic arms, but at present are not optimised to assist the dominant hand in performing bimanual ADLs. The aim of this study is thus to design and experimentally validate an open-source prosthetic arm that is functionally optimised for the performance of ADLs in the unilateral transradial amputee population.

The ADL arm is functional open-source below-elbow prosthesis. This device is body-powered; featuring a hand terminal device with thumb abduction and adduction, and wrist pronation and supination functionality. Elbow flexion of the residual limb is used to actuate the terminal device. The prosthesis requires no existing prosthetic hardware; and the majority of parts can be 3D printed. The ADL arm is designed to reliably perform the grasps required by the non-dominant hand in two-handed ADL activities. Device validation includes functional and simulated-use components. The functional assessment uses the Anthropomorphic Hand Assessment Protocol (AHAP); while the simulated-use assessment involves a practical ADL verification, and a usability assessment using healthy volunteer participants.

The AHAP gives as result a grasping ability score (GAS) and partial GAS for ten grasp types associated with ADLs. The GAS represents the percentage of healthy limb function achievable by the prosthesis. The overall GAS of the ADL arm is found to be 68 %. The ADL arm achieved a partial GAS of greater than 75 % for four of five bimanual ADL grasps. A major design flaw resulted in a partial GAS of 33.3 % for the lateral pinch grasp type. The performance in this grasp, as well as others, would be greatly improved by the inclusion of a mechanism to lock the distal joint of the digits in extension during grasp. In this way, the hand would be better able to apply force to an object with the pads of the digits. Simulated-use validation of the ADL arm is performed on healthy participants using the designed bypass socket. The ADL assessment involves the completion of 86 ADL and instrumental ADL tasks; scored using the designed self-report questionnaire. The participant could perform all but seven tasks independently, and the perceived difficulty for tasks requiring the prosthesis was low overall. Seven healthy volunteers are used to assess the system usability. Participants performed a number of tasks and then completed the system usability scale (SUS). The perceived usability of the device is found to increase with increased device familiarity, yielding an overall score of 84.29. This result indicates that participants found the experience with the device to be 'good' overall.

In conclusion, the ADL arm is functionally competent and has proven its ability to assist in the performance of ADLs in a simulated-use environment; using healthy participants. A number of design modifications are recommended to overcome the limitations of the current design, which should be tested in the transradial amputee population to corroborate the results obtained in this study.

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I am thankful to the following people:

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List of Acronyms

3D Three-Dimemsional

ABS Acrylonitrile Butadiene Styren

ADLs Activities of Daily Living

AHAP Anthropomorphic Hand Assessment Protocol

AS Actuation Subsystem

BBT Box and Block Test

BOM Bill of Materials

CAD Computer-Aided Design

CC Creative Commons

DALY Disability Adjusted Life Year

DASH Disabilities of the Arm, Shoulder and Hand

DIP Distal Interphalangeal

DOH Department of Health

FDA Food and Drug Administration

FDM Fused Deposition Modelling

FIM Functional Independence Measure

FMEA Failure Modes and Effects Analysis

GAS Grasping Ability Score

GT Grasp Type

HS Hand Subsystem

IADLs Instrumental Activities of Daily Living

ID Inner Diameter

IP Intellectual Property

LMICs Low-to-Middle-Income Countries

MCP Metacarpophalangeal

MMDT Minnesota Manual Dexterity Test

MSc Master of Sciences

OARS Older Americans Resources and Services

OD Outer Diameter

OPUS-UEFS Orthotics and Prosthetics User Survey - Upper Extremity Functional Status

OSHW Open Source Hardware

OT Occupational Therapist

PIP Proximal Interphalangeal

PLA Polylactic Acid

PSMS Physical Self-Maintenance Scale

PVC Polyvinyl Chloride

ROM Range of Motion

SA South Africa

SAHPRA South African Health Products Regulatory Authority

SHAP Southampton Hand Assessment Procedure

SS Suspension Subsystem

STL Standard Triangle Language

SUS System Usability Scale

TAPR Tucson Amateur Packet Radio Corporation

TD Terminal Device

UCT University of Cape Town

USA United States of America

VC Voluntary Closing

VO Voluntary Opening

WHO World Health Organisation

YBC Yale-CMU-Berkeley

Chapter 1

Introduction

This chapter details an introduction to the research. This includes: a background of the project, a description of the problem being solved, the hypothesis, aims and objectives of the research, the significance of the problem, and the scope and limitations of the study.

1.1 Project Background

Human hands, part of the upper limbs, are complex and sophisticated structures that play invaluable roles in people's everyday lives. The upper limb's sophistication is clearly demonstrated by the sizeable portion of the motor and sensory areas of the brain dedicated to motor control and sensation management of hands and fingers (Flaubert et al., 2017). Primary functions of the upper extremities are sophisticated as well. These structures are responsible for fine and gross motor activities, and include more complex combinations of activities associated with self-expression, interaction with the environment, and self-care (Flaubert et al., 2017). Fundamentally, hands enable people to perform tasks required to lead independent lives.

Amputation at any level of the upper extremity significantly impacts all aspects of life. As the primary means of interaction with the environment, hands play an integral role in basic, social, occupational, and recreational activities (Saradjian et al., 2008). Transradial (below-elbow) amputation refers to the partial removal of the upper limb between the elbow and wrist joints. Such amputations are performed for various reasons, including irreparable physical trauma, certain diseases, and birth-defects (Ovadia & Askari, 2015; Flaubert et al., 2017). The incidence of upper-limb amputations in South Africa (SA) is not well documented. As of 2020, there are approximately 11 000 major upper extremity amputees living in SA, where major amputations exclude amputations more distal than wrist level (Ziegler-Graham et al., 2008).

Loss of a hand and portion of the forearm is traumatic. It significantly reduces functional ability, results in loss of sensation and cosmesis, and often has a strong negative psychological impact on the amputee (Kejlaa & Gejlaa, 1992; Raichle et al., 2008). In most scenarios, prosthetic intervention forms part of the post-surgical rehabilitative pathway for below-elbow amputees (Saradjian et al., 2008). Prosthetic

interventions are either cosmetic or functional. Cosmetic prostheses act as a visual substitution for the missing limb, while functional prostheses aim to restore some functionality lost by amputation. Prosthetic arms have proven successful in improving amputees' functional abilities (Flaubert et al., 2017). In most cases, this also leads to improved psychological outcomes in patients (Raichle et al., 2008).

The primary aim of prosthetic intervention is to aid an amputee in performing basic daily activities such as eating, dressing, and toileting (Østlie et al., 2012). Secondary goals are to provide assistance with leisure activities, work, trunk balance, and to improve body image (Østlie et al., 2012; Flaubert et al., 2017). These goals are best achieved with functional prosthetic devices. Functional prostheses are, however, expensive. Many amputees living in Low-to-Middle-Income Countries (LMICs), like SA, cannot afford cosmetic or functional prosthetic arms. These individuals must rely on public healthcare systems or private insurance to subsidise the costs associated with such interventions.

The concept of open-source medical devices is to improve device accessibility, reduce device costs, and encourage collaborative design and a sustainable value chain (Niezen et al., 2016). Open-source prostheses are made possible by the internet, which facilitates file sharing; Three-Dimemsional (3D) printing, which facilitates distributed manufacturing; and open-source hardware platforms like Arduino (Niezen et al., 2016). Numerous open-source prosthetic arm designs already exist. Designers make 3D models available on open-source platforms under the Creative Commons (CC) license bracket. These licenses protect designers' intellectual property through copyright, with various copying and distribution limitations placed on the work (Creative Commons, 2019). In the prosthetics space, designs can often be downloaded, modified, and distributed with little restriction. Open-source prosthetic arms that are currently available have two main goals: to be an inexpensive solution for child amputees who outgrow prostheses very quickly, or to replicate electric arm prostheses in an inexpensive and accessible manner (Enabling The Future, 2016b; Niezen et al., 2016). At present, a body-powered prosthetic arm intended to assist the dominant hand of a unilateral amputee in performing Activities of Daily Living (ADLs) does not exist. By increasing personal autonomy, such a device would greatly benefit adult amputees in LMICs who do not have access to functional prostheses.

1.2 Problem Description

A patient's ability to independently perform ADLs is a primary clinical indicator of personal autonomy (Ferreira et al., 2012). ADLs include eating, dressing, toileting, grooming, and ambulation. Transradial amputees are known to experience significant

difficulty in performing many of these tasks (Miguelez et al., 2009). Difficulty is most often experienced when preparing food, eating, and during personal hygiene and grooming activities (Ritchie et al., 2011; Cordella et al., 2016). This often leads to an amputee requiring assistance from a partner, family member, or carer. In addition to loss of functional ability, increased reliance on others – reduced independence – and the trauma associated with the loss of a limb can lead to a worsened psychological state in many cases (Desteli et al., 2014). To best improve the functional and psychological outcomes of a transradial amputee, a functional below-elbow prosthesis is recommended.

All citizens visiting public healthcare facilities in SA are entitled to certain subsidies provided by the Department of Health (DOH). Exclusively cosmetic, not functional, arms are subsidised by the government (Awood, 2019, Personal Interview). Cosmetic prostheses, unlike functional prostheses, cannot actively grasp or release objects (Flaubert et al., 2017). However, cosmetic prostheses can be useful for supporting or stabilising objects during bimanual (two-handed) tasks (Flaubert et al., 2017). Cosmetic prostheses are, in most cases, unable to effectively assist amputees in performing ADLs (Zenie, 2013). Functional prostheses, as the name suggests, have been shown to improve the functional ability, and in turn autonomy, of users (Flaubert et al., 2017). Due to the significant costs associated with functional prosthetic arms, many amputees in SA do not have the financial means to access such devices. Amputees must, therefore, utilise cosmetic prostheses, or none at all.

1.3 Hypothesis

Many prosthetic arm solutions exist in the open-source space. The majority of these devices, however, focus on achieving improved dexterity rather than specific grasping and release motions associated with bimanual activities. The nature of the open-source prosthesis space offers a unique opportunity to address this discrepancy. Individual features of existing designs can be replicated and combined to achieve product goals other than those intended by the original designers. By focusing on the needs of unilateral transradial amputees, a tailored solution can be achieved by proving the validity of the following hypothesis:

It is hypothesised that by leveraging existing open-source prosthetic arm designs and designing novel components, a functional prosthetic arm can be designed to facilitate the performance of daily living activities in unilateral transradial amputees.

1.4 Aim and Objectives

The aim of the proposed research is to design and experimentally validate an open-source prosthetic arm that is functionally optimised for the performance of activities of daily living in unilateral transradial amputees.

The research objectives can be broadly classified into three categories: feature selection and combination; design and integration; and validation. The primary and secondary objectives are listed below:

1. Select and combine open-source hand and arm design features for achieving ADL grasps.
    - Identify the unique components of available open-source designs that make that specific component favourable for performing ADL grasps.
    - Analyse and replicate these individual components.
    - Combine the favourable components and design elements into an ideal open-source below-elbow prosthesis.
2. Design novel features and integrate each element with the combined open-source prosthesis output from Objective 1.
    - Design a rotating wrist mechanism.
    - Design an underactuation mechanism for adaptive grasp.
    - Design a cable-lock mechanism.
3. Validate the performance of the prosthetic arm.
    - Bench test the prosthetic arm in a laboratory setting.
    - Perform a functional assessment of the device using the Anthropomorphic Hand Assessment Protocol (AHAP).
    - Assess the device's ability to perform ADLs using the designed ADL assessment protocol.
    - Assess the device usability using the System Usability Scale (SUS).

1.5 Problem Significance

The high costs associated with purchasing upper-limb prostheses means that amputees in LMICs must rely solely on public healthcare subsidies for provisions of prostheses, or manage without prosthetic intervention. In SA, government-subsidised prosthetic arms are merely cosmetic, not functional. Without active grasping capabilities, cosmetic prostheses are unable to assist amputees in performing basic daily tasks required for

personal autonomy. A functional prosthetic arm, optimised to aid in the performance of bimanual ADLs, would considerably improve the lives of transradial amputees living in SA and other countries alike.

The nature of open-source prosthetics provides a unique opportunity: existing designs can be combined to achieve goals beyond those originally intended (Niezen et al., 2016). By publishing the developed research findings in an open-source platform, there is potential for the prosthesis to reach beyond South African borders. The primary outcome of this research is an ADL-compliant prosthetic arm that aids in restoring the functional independence of below-elbow amputees. The research has long-term potential to lessen the burden of disability faced by below-elbow amputees in LMICs. It also creates a platform to increase awareness of the positive impact that open-source medical devices can have in these communities.

1.6 Research Contributions

This research involves the design, development and validation of a functional prosthetic arm. The primary aim of this research is to combine existing open-source designs in such a way that the resulting prosthesis is functionally optimised for the performance of bimanual ADLs. The secondary aim is to make the design of this device available in the open-source space for further input from other makers towards the full realisation of the designed prosthesis. The contributions of this research are thus:

- The second prototype of a below-elbow prosthesis optimised for performing activities of daily living (ADL arm V2).
- Novel design elements for a below-elbow prosthesis: wrist mechanism, underactuation mechanism, cable-lock mechanism.
- A basic protocol for assessing the ability of a prosthesis to perform activities of daily living.
- An open-source prosthesis design, that consists of:
  - The original design files, which document the device in its entirety.
  - An itemised parts list for the device.
  - A detailed cost analysis for the manufacture a single device.
  - A failure modes and effects analysis of the device in its current state.
  - Functional and usability test results for the device in its current state.
  - A plan for the open-source publication of the designed prosthesis.
- A prosthesis design upon which others can build and improve, such that the final ADL arm can contribute towards alleviating the burden of below-elbow amputation in a global context.

1.7 Publications

At present there are no publications on this work. Further testing – on a larger number of participants and on the affected population (amputees) – and a more in-depth analysis of the result – in the form of a statistical analysis, error and performance evaluation – will allow publication of papers on this research.

1.8 Study Scope and Limitations

The study focuses on the development of a below-elbow prosthetic arm that is optimised to assist in the performance of bimanual ADLs. The study aims to validate the functionality and efficacy of the ADL arm by conducting functional and simulated-use testing. The developed device is a proof of concept, validated by healthy participants. This research is completed in fulfilment of the minor dissertation portion of the MSc degree (90 credits).

The study is limited by a number of factors, in particular concerning the validation of the device. Due to the restrictions imposed by COVID-19 related lockdown regulations, the prosthesis is tested on only healthy participants. The small number of participants involved in the validation is also very limiting; with only seven participants validating the usability of the device and only one participant performing functional validation. Regarding the functional results, only the intrasubject variability is evaluated.

Chapter 2

Literature Review

This chapter presents a review of the relevant literature. The topics which are explored include upper-extremity amputation, activities of daily living, upper limb prostheses, and prostheses in the open-source space.

2.1 Amputation of the Upper Extremity

Amputation of an arm at any level can have significant impacts on all aspects of daily life. The upper limb serves as an individual's primary physical means of interaction with the environment. Hands enable human autonomy and play a fundamental role in the social, occupational, and recreational aspects of life. Compared to amputation of the lower limb, the consequences of upper-limb amputation are considered more significant (Kannenberg, 2017). This is attributed to the hand and arm being a high degree of freedom structure capable of performing a range of fine and gross motor movements in an unpredictable manner (Flaubert et al., 2017; Kannenberg, 2017). The complexity of this system is further demonstrated by the large portion of sensory and motor portions of the brain dedicated to the control of the upper limb (Flaubert et al., 2017; Kannenberg, 2017).

There are differences between the incidence and etiology of amputations in developed versus developing countries. The lack of published data regarding amputation in developing countries gives rise to difficulties in estimating the number of cases and case causes. Ziegler-Graham et al. (2008) performed a study featuring 1.6 million amputees in the United States of America (USA). The study determined that 35 % of amputations involved the upper extremity (Ziegler-Graham et al., 2008). Of this number, only 8 % were major amputations – amputations at wrist level or higher (Ziegler-Graham et al., 2008). Similarly, significantly more amputations of the lower limb occur than the upper limb in LMICs (Chalya et al., 2012; Essoh et al., 2009). In the USA, the majority of major upper-limb amputations occurred due to trauma (83 %), followed by dysvascular disease (12 %), and lastly, cancer (5 %) (Flaubert et al., 2017; Ziegler-Graham et al., 2008). The reason for amputation in LMICs is, in most cases, trauma, with motor vehicle accidents, industrial accidents, gunshot injuries, and war-related trauma being common among upper-limb amputees (Hughes & Ebadat, 2017). Another common cause for upper-limb amputations is malignancies (Chalya et

al., 2012). The incidence of disease leading to upper-limb amputation is less common (Hughes & Ebadat, 2017).

The World Health Organisation (WHO) estimates that, of the 40 million amputees living in developing countries, only 5 % have access to the prosthetic care needed (WHO, 2004). Additionally, due to the proportionately large incidence of lower-limb amputations worldwide, prosthetic intervention for upper-limb amputees is at times considered low priority, as the goal is often to benefit a large patient population (Hughes & Ebadat, 2017). In SA, it is estimated that only 25 % of upper-limb amputees are fitted with a prosthetic device, and of these, only 30 % are functional devices, with the balance being cosmetic (Kannenberg, 2017). The estimated number of amputees fitted with a functional prosthesis in the remainder of sub-Saharan Africa is only 2 %, while most are not fitted with prostheses at all (Kannenberg, 2017).

Raichle et al. (2008) conducted a study on upper-limb prosthesis use in Washington, USA. Results revealed that participants with more proximal amputations – elbow disarticulation and higher – spent more hours per day wearing prostheses (Raichle et al., 2008). Participants with more distal amputations – transradial and below – were shown to wear prostheses for a larger number of days per month (Raichle et al., 2008). This outcome may indicate that individuals with more proximal amputations have greater difficulty performing basic tasks without a prosthesis, and as such, require the device for larger portions of the day. Conversely, the latter finding may indicate that there are more significant functional limitations associated with prostheses designed to serve more proximal amputations (Raichle et al., 2008). For this reason, those with more distal amputations use their prostheses on a more regular basis, but for shorter periods of time. This notion is in agreement with a discussion that the author had with a consulting Occupational Therapist in Cape Town, SA, Michael Awood. Mr Awood communicated that there is significant need for a functional below-elbow prosthesis in SA's public healthcare sector (Awood, 2019, Personal Interview). The motivation given was that transradial amputations or higher result in a more significant functional loss when compared to minor amputations. Given the elbow joint's composition, designing a prosthetic for the elbow disarticulation level or higher is more complex than the transradial level. Hence, it would be more beneficial to design a prosthetic for the transradial level, providing an amputee with higher functional gain without significant system complexity.

Transradial amputation describes the partial removal of the arm through the long bones of the forearm – radius and ulna. Figure 2.1, (Ottobock US, 2017b)(left); (Rossouw, 2018)(right), shows transradial amputation of the arm. Loss of the hand and a portion

of the forearm significantly reduces a person's functional ability (Raichle et al., 2008). It is essential to understand the anatomy and functionality of the intact hand and forearm to fully comprehend the significance of this loss.

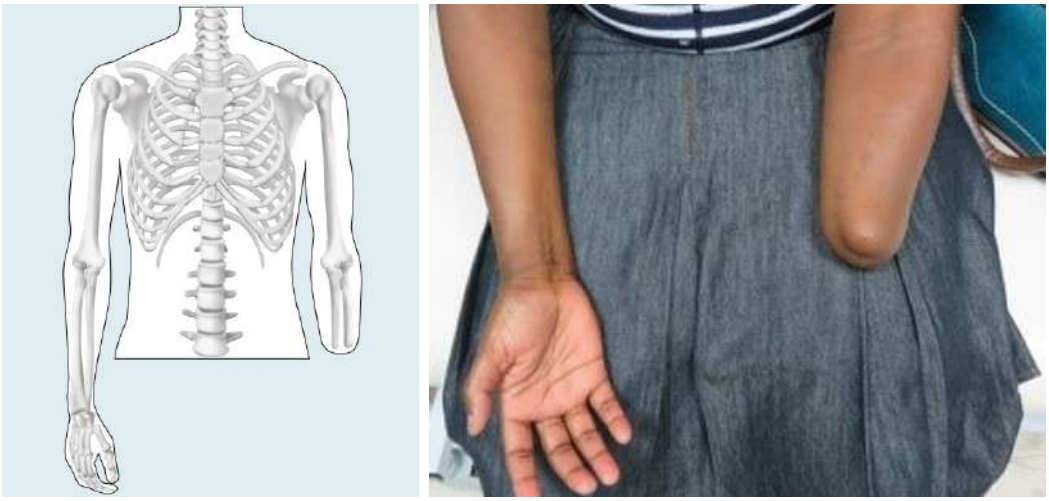


Figure 2.1: Transradial amputation of the arm.

2.1.1 Anatomy of the Upper Limb

Four distinct segments make up the upper limb. These are the shoulder girdle, arm, forearm, and the hand (Moore et al., 2014). Transradial amputation keeps the full Range of Motion (ROM) of the shoulder and elbow joints intact. The shoulder joint facilitates the ROM of the arm. These movements are abduction, adduction, flexion, extension, lateral and medial rotations, and circumduction (Moore et al., 2014). The elbow joint facilitates the ROM of the forearm. These movements are flexion and extension of the forearm (Moore et al., 2014). The movements which can be achieved by transradial amputees are shown in Figures 2.2 (BEST Performance Group, 2015) and 2.3 (Moore et al., 2014)., respectively.

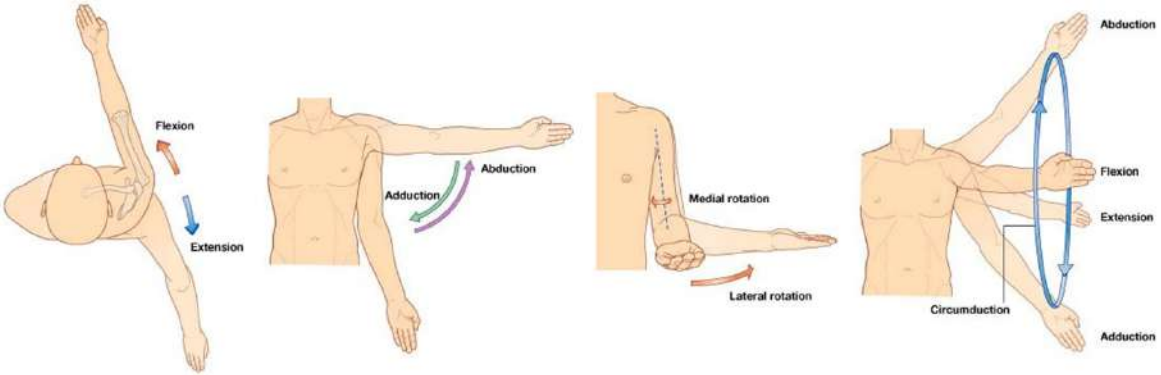


Figure 2.2: Typical movements of the shoulder joint.

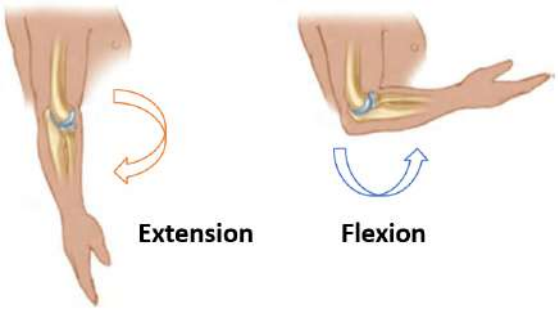


Figure 2.3: Typical movements of the elbow joint.

The forearm consists of two muscular compartments: anterior and posterior (Moore et al., 2014). Muscles of the anterior compartment pronate and flex the forearm, while muscles of the posterior compartment facilitate forearm supination and extension (Moore et al., 2014). Transradial amputees maintain a limited ability to flex, extend, pronate, and supinate the forearm. The potential for torque generation at the elbow and the extent of achievable pronation and supination depend on the amount of residual limb length preserved during amputation (Taylor, 1955).

2.1.2 Human Grasps

The complex arrangement of structures in the arm, forearm, and hand enables humans' considerable hand dexterity. Feix et al. (2016, p. 67) define a grasp as "every static hand posture with which an object can be held securely with one hand, irrespective of the hand orientation." The GRASP Taxonomy (Feix et al., 2016) is a combination of human grasp taxonomies found in literature. It is used as a grasp reference henceforth. The GRASP taxonomy is shown in Figure 2.4 (Feix et al., 2016).

Within the GRASP taxonomy, grasps are organised according to four metrics: the amount of required precision, the type of opposition, the number of virtual fingers, and the position of the thumb (Feix et al., 2016). According to the first metric, a grasp can be a power, intermediate, or precision grasp (Feix et al., 2016). Power grasps involve clamping an object between the palmar sides of the fingers and the palm, while applying pressure with the thumb (Napier, 1956). Precision grasps involve pinching an object between the pads of the fingers and the opposing thumb (Napier, 1956). Intermediate grasps combine power and precision qualities in equal proportions (Napier, 1956).

	Power						Intermediate			Precision				
Opp:	Palm		Pad				Side			Pad				Side
VF:	3-5	2-5	2	2-3	2-4	2-5	2	3	3-4	2	2-3	2-4	2-5	3
Thumb Abducted		1: Large Diameter 2: Small Diameter 3: Medium Wrap 10: Power Disk 11: Power Sphere	31: Ring	28: Sphere 3 Finger	18: Extension Type 26: Sphere 4-Finger	19: Distal	23: Adduction Grip		21: Tripod Variation	9: Palmar Pinch 24: Tip Pinch 33: Inferior Pincer	8: Prismatic 2 Finger 14: Tripod	7: Prismatic 3 Finger 27: Quadpod	6: Prismatic 4 Finger 12: Precision Disk 13: Precision Sphere	20: Writing Tripod
Thumb Adducted	17: Index Finger Extension	4: Adducted Thumb 5: Light Tool 15: Fixed Hook 30: Palmar					16: Lateral 29: Stick 32: Ventral	25: Lateral Tripod					22: Parallel Extension	

Figure 2.4: Illustration of the GRASP taxonomy.

The hand can achieve three types of opposition: pad opposition, palm opposition, and side opposition. The type of opposition is defined by the direction of the force applied to the object, relative to the plane of the palm (Feix et al., 2016). In pad, palm, and side opposition, the direction of the applied force is parallel, perpendicular, and transverse to the palmar plane, respectively (Feix et al., 2016). When several fingers apply force in a similar direction, working together as a functional unit, the fingers are classified as a single virtual finger (Feix et al., 2016). The concept of a virtual finger and the types of opposition are demonstrated in Figure 2.5 (MacKenzie & Iberall, 1994). Lastly, within the GRASP taxonomy, the thumb is either adducted or abducted (Feix et al., 2016).

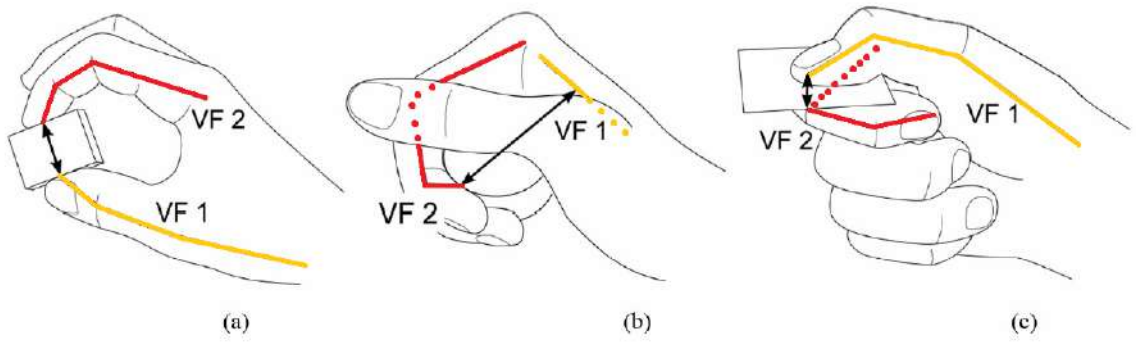


Figure 2.5: Types of opposition found in the GRASP taxonomy: a) pad b) palm c) side. The red and yellow lines represent the concept of virtual fingers.

2.1.3 Transradial Amputation

Amputation of the upper limb is defined by the level at which the limb is divided. Transradial amputation describes the division and removal of the upper limb between the elbow and wrist joints through, the long bones of the forearm – the radius and ulna. Transradial amputation is shown in Figure 2.6 (Cleveland, 2016).

It is critical to retain as much residual limb length as possible for all levels of upper-limb amputation. Doing this preserves functionality of the limb, as more healthy musculature can remain intact (Taylor, 1955). Preserving the length of the forearm during transradial amputations conserves its ROM and facilitates torque generation (Chung & Yoneda, 2018).

A large portion of forearm movement can remain intact if the proximal two-thirds of the limb can be retained. In the case of more proximal amputations, the biceps tendon can be reattached to the ulna to maintain the amputees ability to flex the elbow (Chung & Yoneda, 2018). Figure 2.7 (adapted from Taylor (1955)) shows the potential for arm

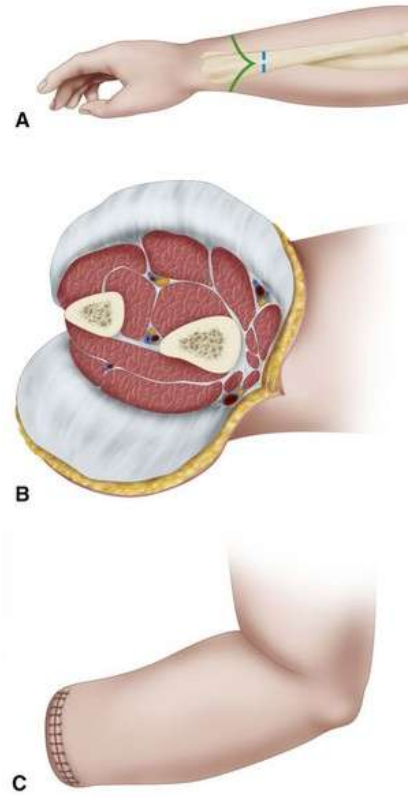


Figure 2.6: Transradial amputation – upper-limb amputation between the elbow and wrist joints.

pronation and supination for amputations at varying lengths from the elbow. This potential is predominantly determined by the residual length of the pronator teres muscle.

2.1.4 Clinical Presentation and Outcomes

The outcomes of upper-limb amputation are twofold: functional and psychological. Losing a hand or arm can be devastating as it impacts the individual's autonomy: reducing their ability to socialise, work and participate in recreational activities (Flaubert et al., 2017; Østlie et al., 2012). These factors are often considered functional outcomes. The psychological consequences of limb amputation are equally significant (Raichle et al., 2008). Limb loss directly affects an individual's mental state and physical appearance. Upper-limb amputees often experience depression, increased anxiety, reduced body image and increased social discomfort (Desteli et al., 2014).

There is currently no standardised way to measure the functional capacity and quality of life of an amputee. Literature does, however, often use the amputee's return to work and use or abandonment of prostheses to indicate their functional outcomes. Prosthesis

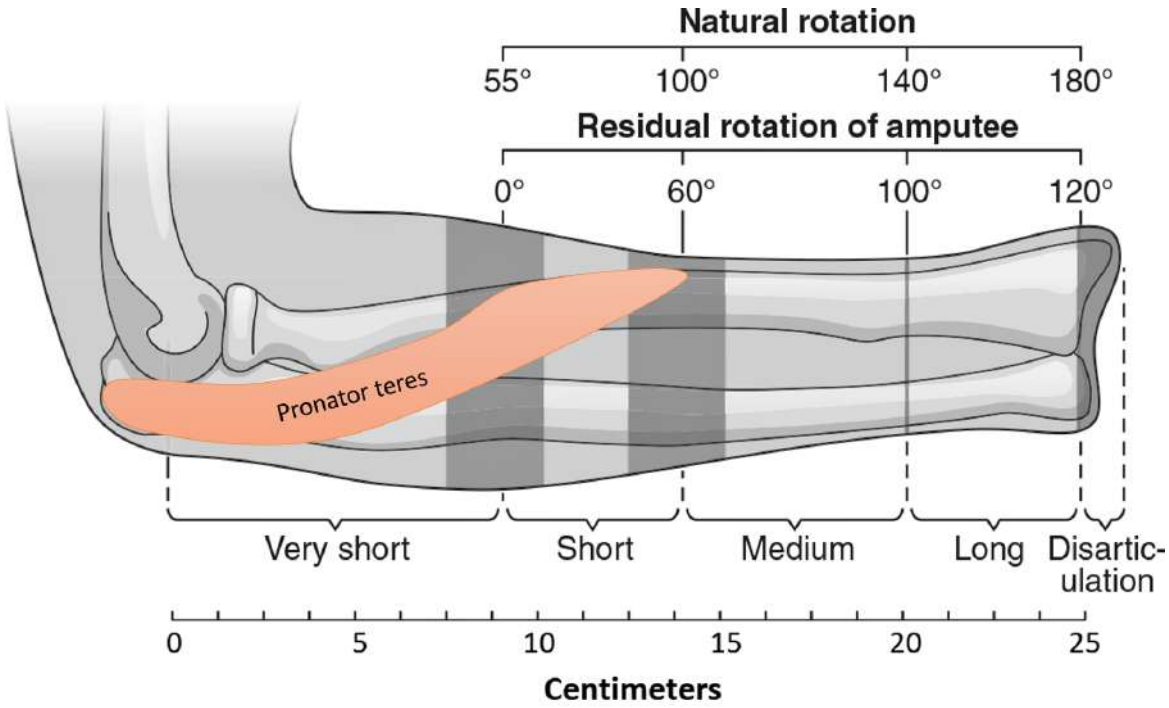


Figure 2.7: Pronation and supination potential following transradial amputation at different forearm lengths.

abandonment often results from physical discomfort or lack of sufficient functional gain (Chung & Yoneda, 2018). Biddiss and Chau (2007) reviewed over 200 articles spanning 25 years and found that the average rate of rejection for electric and body-powered prostheses were 23 % and 26 %, respectively.

The Disability-Adjusted Life Year (DALY) is a metric used by the WHO to measure the burden of a particular disease (WHO, 2014). One DALY is equivalent to one year of a healthy life lost due to mortality and morbidity (WHO, 2014). Regarding upper-limb amputations, the years lost to mortality are considered zero, as it is assumed that no premature deaths occur due to upper-limb amputation. Ro et al. (2019) conducted a study that assessed the trends in the burden of work-related upper-limb amputation in South Korea from 2004 to 2013 using the DALY metric. The study determined that, on average, between 14 and 20 years were lost per million individuals as a result of upper-limb amputation following workplace injuries during this period (Ro et al., 2019). This demonstrates the significant impact that upper-limb amputation can have on a person's life.

The psychological outcomes of upper-limb amputation depend on the individual. Psychological impacts may improve by regularly interacting with therapists, support of family, and the use of prosthetics well suited to the individual's daily needs (Saradjian et al., 2008). Individuals less satisfied with their prostheses were found to have higher

levels of body image anxiety (Murray & Fox, 2002). Prosthetic dissatisfaction often results from the device's appearance (Cordella et al., 2016). An amputee may, however, find higher value in a device with increased functionality, consequently decreasing the associated anxiety (Cordella et al., 2016). Several studies have found that early post-operative evaluation, prosthetic fitting, and prosthetic training is likely to result in positive rehabilitation outcomes (Zenie, 2013). An anthropomorphic prosthetic arm that allows the amputee sufficient functionality has the potential to improve both the functional and psychological outcomes of upper-limb amputees.

Although there is no standardised way to measure the clinical outcomes following amputation of the upper limb, an amputee's ability to perform ADLs is a metric that can be used to measure their autonomy (Wiener et al., 1990). This is a clinical measure of a person's functional independence and is often a strong indicator of basic functional ability and quality of life (Wiener et al., 1990).

2.1.5 Needs of Upper Limb Prosthesis Users

Cordella et al. (2016) carried out a literature review that assessed seven studies from 2007 to 2012 to characterise the needs of upper-limb prosthesis users. The review focused on the experiences of amputees with myoelectric, body-powered, and passive upper-limb prostheses (Cordella et al., 2016). The review determined that, in general, the most notable differences regarding user needs occurred between unilateral and bilateral amputees (Cordella et al., 2016). These differences exist because unilateral amputees most often use their prostheses to aid the intact limb, while bilateral amputees use their prostheses to interact directly with the environment (Cordella et al., 2016).

Biddiss et al. (2007) is one of the studies reviewed by Cordella et al. (2016). This study reviewed and compared the design priorities of 242 users of passive, body-powered and electric prostheses, for a range of amputation levels. The results, in no particular order, are presented in Table 2.1 (Biddiss et al., 2007).

A comprehensive list of user requirements for upper-limb prostheses is compiled. These devices must (Cordella et al., 2016):

- Perform ADLs (mainly relating to eating and dressing).
- Provide sensory feedback to the user.
- Perform actions with reasonable grip strength.
- Perform actions in a coordinated manner to attract less visual attention.

Table 2.1: Design priorities of upper-limb prosthesis users.

Passive	**Body-powered**	**Electric**
Weight	Weight	Weight
Cost	Cost	Cost
Heat dissipation	Heat dissipation	Heat dissipation
Fit	Harness comfort	Fit
Appearance	Donning/doffing	Appearance
Colour	Grip strength	Fine motor skills/dexterity
Control of opening/closing	Reliability	Reliability
Glove durability	Manoeuvrable in awkward positions	Glove durability
Appearance under clothing	Physical effort required for use	Independently moving fingers
	Wrist movement/control	Wrist movement/control
	Sensory feedback	Sensory feedback

- Have a high level of anthropomorphism.
- Perform stable grasps to prevent slippage.
- Have a functional prosthetic wrist with at least one degree of freedom.
- Have improved heat dissipation.
- Have a variety of available gloves.
- Have an open hand configuration that approximates the natural hand position.

In addition to these requirements, other factors that limit the functionality of existing arm prostheses include a lack of proprioceptive feedback and impaired visual field (Zenie, 2013).

2.2 Activities of Daily Living

Activities of daily living (ADLs) comprise a set of tasks individuals carry out on a day-to-day basis. Performance of ADLs is necessary to live independently and for personal self-care (Wiener et al., 1990). The ability to conduct such tasks is a primary measure of human autonomy (Mlinac & Feng, 2016). While ADLs are basic self-care tasks necessary for functional living, instrumental ADLs (IADLS) measure an individual's ability to live independently in a community (Mlinac & Feng, 2016). Table 2.2 presents the categories of activities associated with ADLS and IADLS.

The goals and requirements of a prosthesis optimised for ADL performance must be determined to achieve a successful design. This is done by identifying which human grasps the non-dominant hand of a unilateral amputee requires to perform ADLs.

Table 2.2: Categories of activities involved in ADLs and IADLs.

ADLs	IADLs
Bathing	Food preparation
Transferring	Household maintenance
Dressing	Transport
Eating	Finance management
Toileting	Telephone use
	Shopping
	Medication management

2.2.1 Grasps Specific to Activities of Daily Living

Many studies have investigated which grasps are used by healthy individuals to perform ADLs. Gracia-Ibáñez et al. (2018) assessed 32 healthy, right-handed people to investigate their grasp requirements. The study differentiates between the grasps required for one-handed (unimanual) and two-handed (bimanual) activities (Gracia-Ibáñez et al., 2018). The results compare the relevance of grasps for the dominant versus non-dominant hand for performing both unimanual and bimanual activities (Gracia-Ibáñez et al., 2018). The top six grasps required by the non-dominant hand in one- and two-handed tasks are presented in Table 2.3 (Gracia-Ibáñez et al., 2018), in order of relevance. Also included are the GRASP taxonomy equivalent grasps. Assuming that dominance retraining has occurred prior to prosthesis intervention, the presented grasps are those that a unilateral amputee requires from their prosthesis to successfully perform ADLs.

Table 2.3: Grasps required by the non-dominant hand for performing autonomous ADLs.

Non-dominant hand (unimanual)	**Percentage use**	**GRASP taxonomy**
Pad-to-pad pinch	46.7	Palmar pinch (9)
Non-prehensile grasp	16.2	N/A
Lumbrical grasp	15.7	Parallel extension (22)
Special pinch	9.3	Tripod (14)
Oblique grasp	4.2	Adducted thumb (4)
Cylindrical grasp	3.8	Medium wrap (3)
Non-dominant hand (bimanual)	**Percentage use**	**GRASP taxonomy**
Pad-to-pad pinch	26.0	Palmar pinch (9)
Non-prehensile grasp	23.9	N/A
Lumbrical grasp	20.8	Parallel extension (22)
Special pinch	10.4	Tripod (14)
Cylindrical grasp	8.7	Medium wrap (3)
Intermediate power-precision grasp	4.0	Index finger extension (17)

Grasps that the study found necessary were assessed by a consulting occupational therapist, Michael Awood. Although Mr Awood was mostly in agreement with the results, he suggested several additional grasps that he considered were important for the prosthetic hand to achieve (Awood, 2019, Personal Interview). The finalised list of ADL grasps required by the prosthesis, in order of importance, are:

- Medium wrap
- Adducted thumb
- Lateral grasp
- Non-prehensile
- Index finger extension

Figure 2.8 presents these ADL grasps.

Figure 2.8: Grasps required by the ADL compliant prosthetic arm.

2.3 Upper Limb Prostheses

Available upper-limb prostheses can be classified as either passive or active (Cordella et al., 2016). Passive (or cosmetic) prostheses function as a visual substitute for the missing limb (Miguelez et al., 2009). Active (or functional) prostheses are either body-powered or externally-powered (Flaubert et al., 2017). Many body-powered prostheses are driven by a cable system using the wearer's body movements (Miguelez et al., 2009). Externally-powered devices use an external source of power to provide torque for limb movement (Miguelez et al., 2009). Figure 2.9 (Medical Care Alliance, 2016; Ottobock US, 2017a, 2019, (a), (b) and (c) respectively) provides examples of cosmetic, body-powered, and externally-powered prostheses.

Cosmetic prostheses are advantageous as they are the least expensive prosthetic intervention. However, such devices offer minimal functional advantages over the residual limb beyond cosmesis (Cordella et al., 2016). As such, cosmetic prostheses cannot offer the level of functioning required for ADLs. Electric prostheses have the

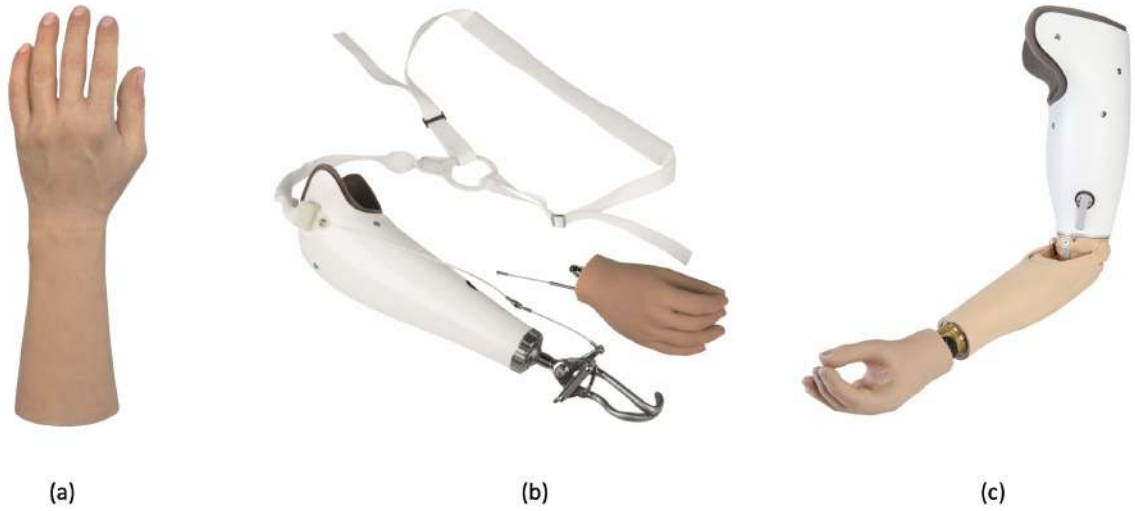


Figure 2.9: Examples of (a) cosmetic, (b) body-powered, and (c) externally-powered prostheses.

potential to offer a more advanced range of functionality than cosmetic or body-powered prostheses. This is because individual digits are often controlled by independent actuators (Flaubert et al., 2017). Electric prostheses are, however, expensive to purchase and maintain (Miguelez et al., 2009). Typically, electric prostheses are inappropriate for rural settings as they easily get damaged by water, dust, and vibrations (Miguelez et al., 2009). For these reasons, the research focuses on a body-powered prosthetic arm – cosmetic and electric solutions are not discussed further.

Many amputees are not financially able to access functional prostheses and must therefore rely on cosmetic devices or forgo prostheses altogether (Kannenberg, 2017). Patients visiting South African public healthcare facilities will be provisioned with a cosmetic prosthetic arm (Awood, 2019; Department of Health, 2018). Patients are categorised based on annual income. While some are fully-subsidised, those who pay in full can be charged up to R 10 000 for a cosmetic below-elbow prosthesis (Department of Health, 2018).

Other countries around the world have similar, or worse, public healthcare systems. Geographical separation of patients from these facilities and a lack of trained prosthetics and orthotics personnel are other well-known barriers to the provision of prosthetic interventions in these places (WHO, 2004). Some amputees may be fortunate enough to receive donated prostheses but do not have the necessary equipment or skills to fit or maintain the device, rendering it useless (Niezen et al., 2016). There is a need for prosthetic devices that focus on improved accessibility and a sustainable and cost-effective value chain.

2.3.1 Body-Powered Prostheses

The gross motor movements of an amputee are used to power body-powered prostheses (Flaubert et al., 2017). Sufficient force, dependent on the level of amputation, must be generated to control the terminal device and pre-position the forearm in space (Zenie, 2013). In most cases, movement of the upper arm, shoulder, or chest is translated to the terminal device – hook or hand – via a cabled harness system (Flaubert et al., 2017). Regarding transradial or more distal amputations, an elbow actuation system can be used to generate additional power (Miguelez et al., 2009).

Users of body-powered prostheses are challenged by the restricted physical area in which they can effectively control the terminal device (Flaubert et al., 2017; Zenie, 2013). This area is known as the functional work envelope (Flaubert et al., 2017). For the majority of existing upper-limb prostheses, the functional work envelope is limited to the region above the waist, below the shoulders, and slightly more lateral than the width of the shoulders (Vacek, 2017; Zenie, 2013). This limitation is primarily due to the restricting harness, where glenohumeral flexion generates the majority of torque (Vacek, 2017; Zenie, 2013). Figure 2.10 (Vacek, 2017) demonstrates the functional work envelope. Wearers of body-powered prostheses often find it difficult to perform grasp-and-release tasks outside of the functional work envelope, specifically near the feet or above the head (Zenie, 2013). Performance of tasks behind the back is in most cases not possible (Zenie, 2013).

Figure 2.10: The functional work envelope of a typical body-powered prosthesis.

2.3.2 Terminal Devices and Connections

Terminal devices (TDs) have two categories: hook and hand. Hook TDs provide users with a finer level of prehension and often more grip strength than hands (Zenie, 2013). As a result, hook TDs may allow the user to perform more rugged tasks (Miguelez et al., 2009). Grasping objects with a hand TD is often more intuitive and offers the user greater levels of anthropomorphism (Zenie, 2013).

Body-powered TDs are either voluntary opening (VO) or voluntary closing (VC) devices. An elastic element is responsible for returning a VO TD to the closed position, and the force produced by that elastic element limits the VO device's grasping force (Miguelez et al., 2009). VO device users rely exclusively on visual feedback when using the device for grasping and manipulating objects (Miguelez et al., 2009). With VC devices, the grasping force is proportional to the force generated by the wearer. VC devices are advantageous as the wearer is provided with force feedback. This allows users of VC devices to: feel how much force is applied to the object, gauge the size of the object being grasped, and to control the TDs grip strength incrementally (Miguelez et al., 2009). A disadvantage of VC devices is the user must maintain effort to keep the TD closed, unless a cable lock is employed (Flaubert et al., 2017). Using VC devices with an amputation more proximal than the transradial level can be difficult as large amounts of force must be generated to operate both the prosthetic elbow and the TD (Miguelez et al., 2009). The grip force required by a prosthetic device for performing ADLs is in the range of 45 – 68 N (Weir et al., 2009; Vinet et al., 1995).

A prosthetic wrist connects the TD to the arm of the prosthesis. Specialised wrist units facilitate one, or more, of four main features: TD flexion and extension, TD ulnar and radial deviation, TD pronation and supination, and quick interchange of TDs (Miguelez et al., 2009). For body-powered prostheses, using any of these functions often requires one to use the contralateral limb or an external aid (Miguelez et al., 2009). As such, wrist units on body-powered prostheses are arguably better suited to unilateral amputees. In many passive wrist unit designs, flexion/extension and pronation/supination are controlled by friction joints or optional locking positions (Miguelez et al., 2009). Flexion or rotation the wrist may give wearers the advantage of an improved visual field, resulting in superior grasp capabilities for hand TDs (Zenie, 2013).

2.4 Open-Source Prostheses

Open source is a term used to describe a creator's intellectual property (IP) that is freely available for use, modification and redistribution (RedHat, 2019). The IP can take on

a range of forms, from source code to music to medical devices, and more (Creative Commons, 2019). There are a large range of open-source licenses available to protect one's IP. Creative Commons (CC) is a non-profit organisation that has developed a free and standardised way to grant copyright permissions for a creator's IP by providing CC licences (Creative Commons, 2019). The purpose of these open-source licenses is to ensure proper attribution; and allow people to copy, distribute, adapt, and use works created by others (Creative Commons, 2019).

Beyond CC licenses there exist a number of Open Source Hardware (OSHW) licenses that are arguably better suited to medical devices than CC. OSHW describes physical artefacts whose designs are made freely available such that anyone can make, modify, sell, distribute and use this hardware (Open Source Hardware Association, 2014). Two widely used open hardware licenses include the Tucson Amateur Packet Radio Corporation (TAPR) Open Hardware License (TAPR, 2007) and the CERN open hardware license (Open Hardware Repository, 2021). In general, OSHW licenses must comply with a number of criteria, defined by the Open Source Hardware Association (Open Source Hardware Association, 2014):

1. **Documentation:** Hardware must be released with documentation including design files, and must allow modification and distribution of these design files. Design files should be in a preferred format for making changes. An open hardware license may additionally require that design files are provided in a fully documented, open format.

2. **Scope:** The portion of the design being released under the license, if not the full design, must be clearly specified.

3. **Necessary software:** If the device relies upon software to function, either the software must be obviously re-creatable from the documentation allowing the device to function as intended, or made available under an appropriate open-source license.

4. **Derived works:** The license shall allow derived works and modifications, and shall allow them to be distributed under the same license as the original work. The licence shall allow products created from the design files, the design files themselves, and derivatives thereof to be manufactured, sold, distributed and used without restriction.

5. **Free redistribution:** The license shall not restrict anyone from selling or giving away the project documentation. The license shall not require a royalty or other fee for such sale. The license shall not require a royalty or other fee related to the sale of derived works.

6. **Attribution:** The license may require derived works and documentation to provide attribution to the licensors when distributing design files, manufactured products or derivatives thereof. The license may require that the attribution is made available to the end-user when using the device normally, but will not specify a format for its display. The license may require that the derived work carry a different name or version number from the original work.

7. **No discrimination against persons or groups:** The licence may not discriminate against any person or group of persons.

8. **No discrimination against fields of endeavour:** The license may not restrict anyone from making use of the work in any specific field of endeavour.

9. **Distribution of license:** The rights granted by the license shall apply to all to whom the work is redistributed, without requiring additional license execution by these parties.

10. **License must not be specific to a product:** The rights granted to the design must not depend on the design being part of a particular larger product. If the design is extracted from the larger product and used or distributed within the terms of the hardware license, all parties to whom the hardware is redistributed should have the same rights as those granted to the original larger product.

11. **License must not restrict other hardware or software:** The license must not place restrictions on other hardware or software that may be distributed or used with the licensed hardware.

12. **License must be technology-neutral:** No provision of the license may be depend on any individual technology, specific part or component, material, style of interface or use thereof.

These criteria, which form the basis for open hardware licenses, are derived from Free and Open Source Software (FOSS) definitions and criteria which came before them (Muriillo et al., 2019). Key differences between OSHW and FOSS were introduced to account for differences between hardware and software. The differences are summarised in Table 2.4 (Muriillo et al., 2019) below.

Table 2.4: Comparison between the Open Source Definition (V1.9) and the Open Source Hardware Definition (V1.0)

Open Source Definition (V1.9)	**Open Source Hardware Definition (V1.0)**
Source code	Documentation
	Scope
	Necessary software
Derived works	Derived works
Free distribution	Free distribution
Integrity of the authors source code	Attribution
No discrimination between persons or groups	No discrimination between persons or groups
No discrimination between fields of endeavour	No discrimination between fields of endeavour
Distribution of license	Distribution of license
License must not be specific to a product	License must not be specific to a product
License must not restrict other software	License must not restrict other hardware or software
License must be technology-neutral	License must be technology-neutral

Within the OSHW definition, 'source code' is replaced with 'documentation', 'scope' and 'necessary software', as these three components are required to recreate the physical artefact in its working form (Muriillo et al., 2019). Additional changes are made regarding 'attribution', which ensures that distributed hardware is properly attributed and this attribution is made visible to the end-user (Muriillo et al., 2019). Finally, OSHW licenses must not restrict other ''hardware or software', accounting for the hardware element of these designs. Both the CC and OSHW licenses provide unique opportunities for sharing and distributing physical artefacts with little restriction. This is particularly exciting in the medical devices space.

2.4.1 Open-Source Medical Devices

The traditional medical device development pathway follows a research route, where designers carry out extensive studies to arrive at generic solutions that are widely applicable (Gibson & Srinath, 2015). Following this design process is costly and time-consuming, but ensures the safety and stability of the final product (Gibson & Srinath, 2015). Some challenges of this approach are that it is costly to device manufacturers and consumers, and that there is low customisation and often long waiting times experienced by end users (Gibson & Srinath, 2015).

Open-source medical devices are devices whose designs are freely available so that any person can study, modify, distribute, make, and even sell the designs (Niezen et al., 2016). Limitations placed on the device are determined by the chosen open-source licence. A summary of the available CC licences is presented in Figure 2.11 (Creative Commons, 2019). It is noted that not all varieties of the CC licenses are considered truly open source. Restrictions on derivatives and commercialisation are in direct contrast with the primary criteria of open source as described above. This must be taken into consideration when choosing an appropriate open-xsource license for the designed device.

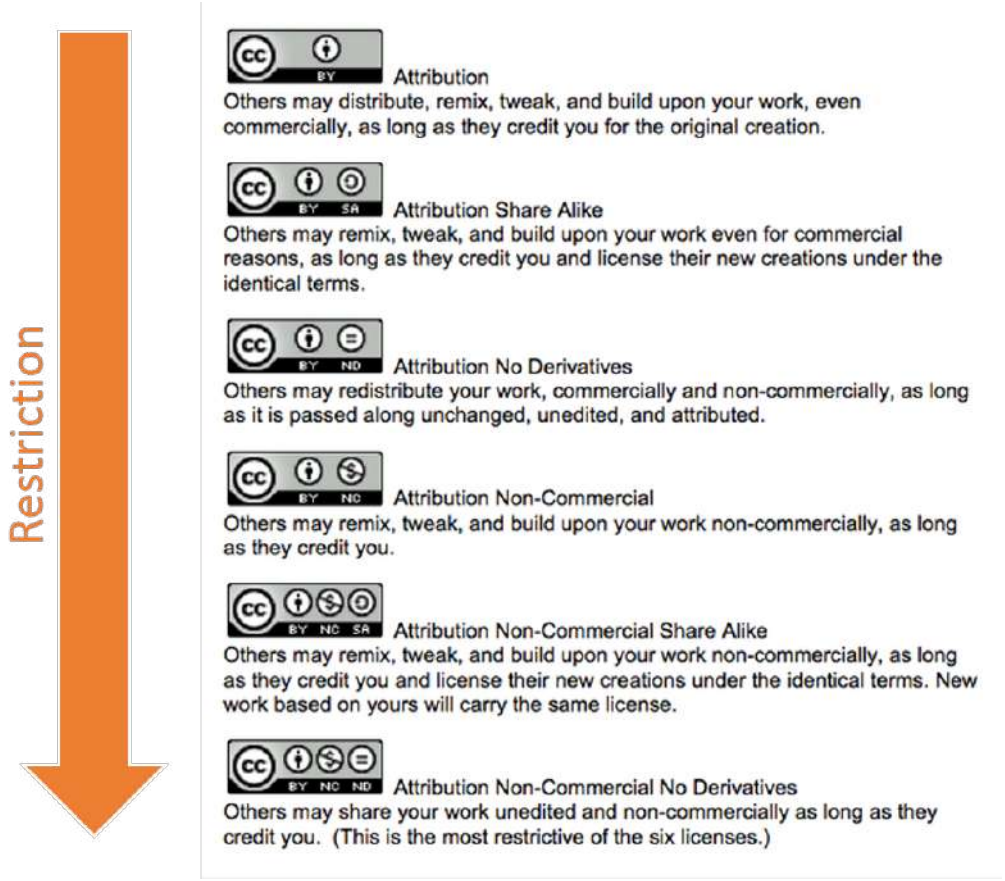


Figure 2.11: Creative Commons licences.

Open-source medical devices are advantageous as the designs are far more accessible, customisable, have a rapid turnaround time, and are less costly than devices that follow the traditional design pathway (Gibson & Srinath, 2015; Niezen et al., 2016). Disadvantages of the open source approach are that the designs are seldom regulated and can result in safety concerns associated with use (Gibson & Srinath, 2015). The safety aspects of the designed device should be considered and determined prior to publishing the design in the open-source space.

2.4.2 Additive Manufacturing

Additive manufacturing describes a fabrication process whereby solid objects are created by sequentially adding thin layers of material on top of one another (Gibson & Srinath, 2015). 3D printing is an additive manufacturing technique that utilises slicing software to convert a 3D computer-based model to a set of instructions that a 3D printer can use to create a solid model, as described above (Ten Kate, Smit, & Breedveld, 2017). The most widely available 3D printing technology is fused deposition modeling (FDM), where a plastic material is heated and extruded to create an object in a sequence of cross-sectional layers. This technology has become widely accessible since its conception, with many design software packages being open-source and 3D printer hardware being affordable enough to be purchased for personal use (Gibson & Srinath, 2015). Inexpensive desktop 3D printers are available in developing countries, making open-source 3D printed prosthetics an accessible solution in these contexts (Niezen et al., 2016; Zuniga et al., 2015).

2.4.3 3D Printed Prostheses

There are numerous advantages and disadvantages of 3D printing as a manufacturing technique for upper-limb prosthetic devices. Several are summarised in Table 2.5 (Ten Kate et al., 2017).

Table 2.5: Summary of the primary advantages and disadvantages of 3D printing for the manufacture of upper-limb prostheses.

Advantages
Can design highly complex geometries.
Objects can be made from a single part – less assembly is required.
Simple design customisation and personalisation.
Rapid pathway from design to end-product.
Inexpensive when compared to traditional approaches.
Localised manufacture.
Design modularity – devices can be inexpensively maintained and repaired.
Disadvantages
Parts have unpredictable mechanical properties.
Part size is limited to the print bed size.
Limited manufacturing materials.
No standardisation of printed part quality.

The most prominent advantage of 3D printing in the field of prosthetics is the customisability of designs (Niezen et al., 2016). This allows user-specific prostheses that

will improve individual fit, comfort, and level of anthropomorphism (Gibson & Srinath, 2015). Compared to cosmetic prostheses subsidised by the DOH, open-source 3D printed prostheses would provide amputees in SA with a functional hand at lower prices with a more rapid turnaround time (Gibson & Srinath, 2015; Awood, 2019). Prostheses are classified by regulatory bodies such as the Food and Drug Administration (FDA) and South African Health Products Regulatory Authority (SAHPRA) (FDA, 2018; Saidi & Douglas, 2018). Hence, the disadvantage of poor regulation of prostheses does not pose a significant risk to the end user. The design and print orientation of 3D printed parts must be given special attention to ensure that each part has the mechanical strength required in the direction that force is applied (Gibson & Srinath, 2015). To ensure the success of such a device in LMICs, prostheses must be fabricated from parts and using machinery that is accessible and inexpensive.

The goal of this research is to develop a prosthetic arm and hand device that can provide below-elbow amputees with the functionality needed to improve the performance of ADLs.

2.4.4 The ADL Arm

The research conducted is based on the modification of the ADL arm – existing work carried out by the authors. The ADL arm, shown in Figure 2.12, is a body-powered prosthetic arm designed to assist transradial amputees in the performance of ADLs. The device developed and depicted in Figure 2.12 is the first functional working prototype, leading to this research. The ADL arm design was completed by the primary author during the coursework component of the Master of Science (MSc) degree.

Figure 2.12: The ADL arm V1.

The ADL arm was developed by selecting and combining favourable components of existing open-source designs available in the CC space and designing novel components to achieve a solution functionally optimised for the performance of bimanual ADLs.

The ADL arm uses torque generated by flexion of the elbow joint to actuate the hand TD. The prosthesis is suspended using Velcro straps that secure the device to the biceps and forearm of the amputee. The hand TD is voluntary closing. Each digit is restored to its resting position by an elastic element. Notable features of the design are the underactuation mechanism, which facilitates adaptive grasp; the rotating thumb mechanism, which allows adduction and abduction of the thumb; and the rotating wrist mechanism, which allows pronation and supination of the TD.

Testing of the ADL arm yielded the following results that are relevant to this study:

- The hand TD weighs 127 g.
- The hand has a grasp diameter of 105 mm.
- The tension developed in the actuation cord from the elbow mechanism is 34.15 N.

This research seeks to further develop the ADL arm into a parametric prosthetic arm design that is more suitable for modification and fabrication with limited resources. The new design will boast additional functionality to the first prototype and will aim to overcome the limitations of the first iteration, discussed in Section 3.

Chapter 3

Design Methodology

This chapter outlines the methodology followed when designing the ADL Arm V2. The design process began with a consideration of the parameters which affect the overall device efficacy. The initial system parameters were identified by reviewing the available literature, through discussion with consulting OT, Michael Awood, and through the testing of the first prototype. The defined system parameters are:

- The hand's ability to perform the grasps required for bimanual ADLs.
- The stability of the grip in these configurations.
- The stability of the attachment of the prosthesis to the residual limb.
- The physical effort required to use the device.
- The overall mass of the device.
- The system does not require existing prosthetic hardware to function.

Design of the prosthesis proceeded with the design and integration of three subsystems: Hand Subsystem (HS), Actuation Subsystem (AS), and Suspension Subsystem (SS). Figure 3.1 presents considerations for the design of each subsystem.

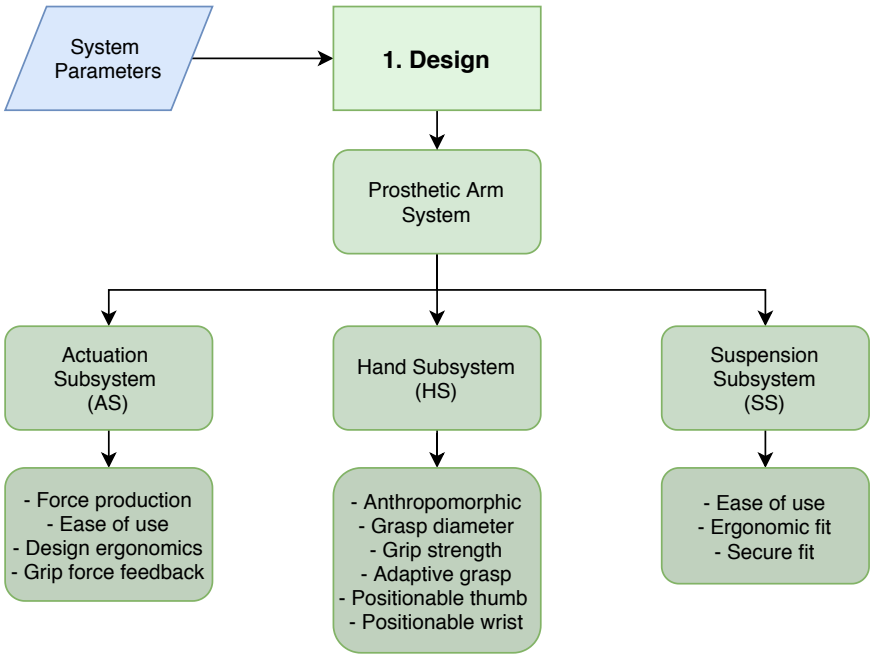


Figure 3.1: Prosthetic arm subsystems and essential considerations.

3.1 Hand Subsystem Design

The hand subsystem (HS) functions as the interface between the prosthesis and the physical environment. Its role is to translate the force generated by the AS to the TD such that the TD can grasp objects. Considerations for the HS based on the defined system parameters include:

- Dimensions and proportions – The hand should be sized and proportioned such that it has a level of anthropomorphism relative to the amputee's residual healthy limb. This will allow the user to perform movements in a more coordinated and intuitive manner, and gives the device a degree of cosmesis.
- Digit configuration – Digits should be arranged such that the hand can grasp objects of various shapes and sizes. The thumb must be able to achieve adduction and abduction.
- Material surface quality – The chosen material's surface quality must provide sufficient grip to achieve a stable grasp on objects with varying surface qualities.
- Material weight – The chosen material should be lightweight to ensure the prosthetic hand does not exceed a maximum mass of 364 g (one standard deviation less than the average hand mass) (Cuellar et al., 2018; Kay & Rakic, 1972).

- Material availability – The chosen material should be readily available and inexpensive to source. Fabrication of the hand should be possible using FDM 3D printing technology, and all additional components should be easy to source in LMICs.
- Connection to actuation subsystem – The prosthetic wrist should act as a secure connection between the hand and forearm of the prosthesis. The wrist must support the mass of the hand as well as the grasped object. The wrist must facilitate TD pronation and supination.
- Restorative component – This must be in place to restore the digit's positions to the natural hand position following actuation. The component should provide minimal resistance to TD actuation. It must not undergo plastic deformation over time.
- Digit kinematics – The way the digits move is critical to the success and stability of the achieved grasp. Relative movements within each digit must be considered. For a successful grasp, each digit should flex first at the proximal joint and then at the distal joint. This mimics the natural kinematics of a healthy hand and ensures the objects are not pushed out of the grasp.

3.2 Actuation Subsystem Design

The actuation subsystem (AS) functions to generate the force required to actuate the TD. Force is generated using the wearer's body movement and is transmitted to the HS by a cable system. Considerations for the AS based on the defined system parameters include:

- Material properties
  - Cable: The chosen material should experience minimal elastic or plastic deformation under tension.
  - Cable track: The chosen material should allow the cable to move through it with minimal friction.
- Tension adjustment – The tension of the actuation cables must be adjustable.
- Force generation – The AS must produce sufficient force for the hand TD to grasp a range of objects securely.
- Mechanical advantage – The system should utilise mechanical advantage to minimise the effort required by the user while maximising the generated force.

- Digit actuation mechanism – The hand must contain a differential motion mechanism to distribute the force generated by the AS between the digits.
- Material availability – The chosen materials should be readily available and inexpensive to source. Fabrication of the AS should be possible using FDM 3D printing technology and all additional components should be easy to source in LMICs.
- Grip maintenance – As the prosthesis is voluntary closing, a cable-lock mechanism should form part of the AS to ensure that a stable grip can be maintained on the object without the user having to sustain this effort. The cable-lock system must be reliable and intuitive to use.
- Additional hardware – The AS should be standalone, requiring no existing prosthetic hardware to function.

3.2.1 Body Movement for Torque Generation

Typically, a harness and cable system is used by transradial amputees to produce torque for TD actuation (Flaubert et al., 2017). Using the contralateral shoulder to produce this force is preferred as the amputee does not need to alter the movement pattern of the residual limb to use achieve grasp (Flaubert et al., 2017). A novel way to produce the required torque, which does not require existing cable and harness hardware, would be advantageous (Awood, 2019, Personal Interview). To meet these goals, movement of the amputated limb, rather than the intact limb, would need to produce this force. The ROM of the shoulder and elbow are guaranteed movement patterns achievable by transradial amputees. The amount of pronation and supination that the residual limb can achieve depends on the length of the forearm that is retained – associated with the attachment of the pronator teres muscle (Taylor, 1955). Figure 2.7 in Section 2.1.3 is a visual representation of this concept.

Using forearm rotation to generate torque would be beneficial; it would be the most elegant way to produce force without disrupting normal body movement patterns. However, given that the amount of rotation depends on the length of an amputee's residual limb, a solution using forearm rotation would not be suitable for all transradial amputees. It is therefore not explored further.

Normal ROM of the elbow joint is 60 ° flexion and 90 ° extension (Soucie et al., 2011). The useful range of shoulder adduction (elbow flexed and hand positioned in front of the body) is approximately 90 ° (Soucie et al., 2011). Figure 3.2 (Ding et al., 2018)

demonstrates these movements. The shoulder and elbow ROM provides a large area for force generation. Using the residual motion of the amputated limb would require a mechanism that translates motion into torque.

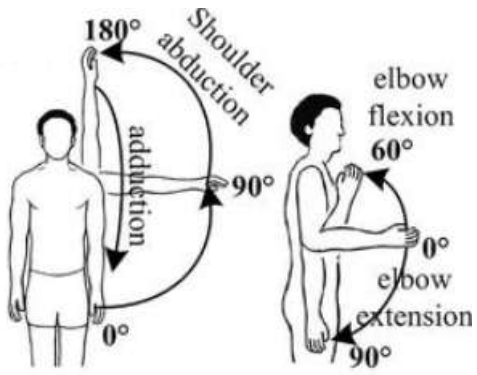


Figure 3.2: Shoulder and elbow ROM that can be used to produce torque.

The selected method of torque generation uses a hinge joint that sits laterally and medially of the natural elbow joint. When the elbow is flexed, a cable running posteriorly on the hinge is pulled taught. The effective cable length is reduced as a result of the increased angle of wrap of the cable. This cable tension is used to actuate the hand TD. Additional leverage is achieved by modifying the cable's interface with the hinge; creating a bowstring effect in the cable. This modification further reduces the effective cable length and increases the force produced. This concept is demonstrated in Figure 3.3; where the effective cable shortening due to the elbow modification is shown in red.

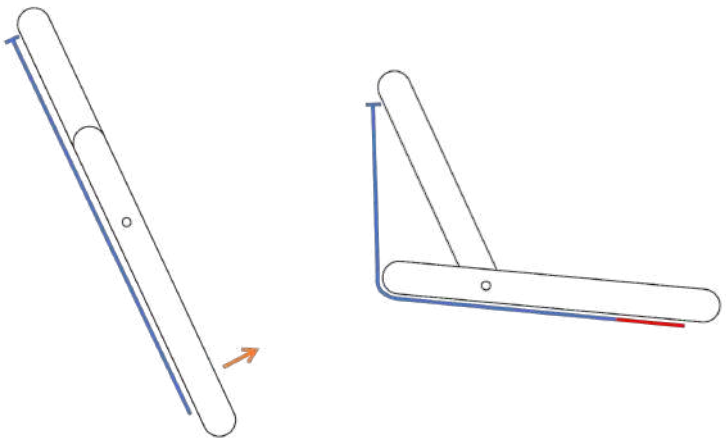


Figure 3.3: Demonstration of the effect that altering the shape of the cable's interface with the hinge has on the effective cable length during elbow flexion.

3.2.2 Motion Differential Mechanism for Adaptive Grasp

Hand prostheses powered by body movements offer simple and intuitive control. Voluntary closing control is preferred because it provides the wearer with proprioceptive force feedback during prosthesis use (Cuellar et al., 2018). Body-powered prosthetic hands are often underactuated. This implies that all digits are controlled by a single cable transmitting force from the AS to the hand (Flaubert et al., 2017). The usability of a prosthetic hand improves significantly with the implementation of adaptive grasp (Cuellar et al., 2018). Adaptive grasp is advantageous as it allows the digits to adapt to the shape of an object, improving grip (Ten Kate et al., 2017). Adaptive grasp is likely so successful as it approximates a 'synergies' concept of the hand. Hand synergies is a concept borrowed from neurosciences, where the brain uses the hand as an organised ensemble rather than as a number of individual parts (Piazza et al., 2019). In this way, underactuated prosthetic hands may better approximate natural hand motion than fully actuated ones.

To achieve adaptive grasp in a body-powered prosthesis, a motion differential mechanism must be implemented (Cuellar et al., 2018). A whippletree is an example of such a mechanism. In this mechanism, all of the digits are actuated by a single driving force that is transmitted through the whippletree mechanism via links to each digit (Cuellar et al., 2018). A restorative spring mechanism in each digit returns the hand to the natural position following each grasp. Figure 3.4 (Cuellar et al., 2018) is a schematic of a whippletree mechanism that facilitates adaptive grasp.

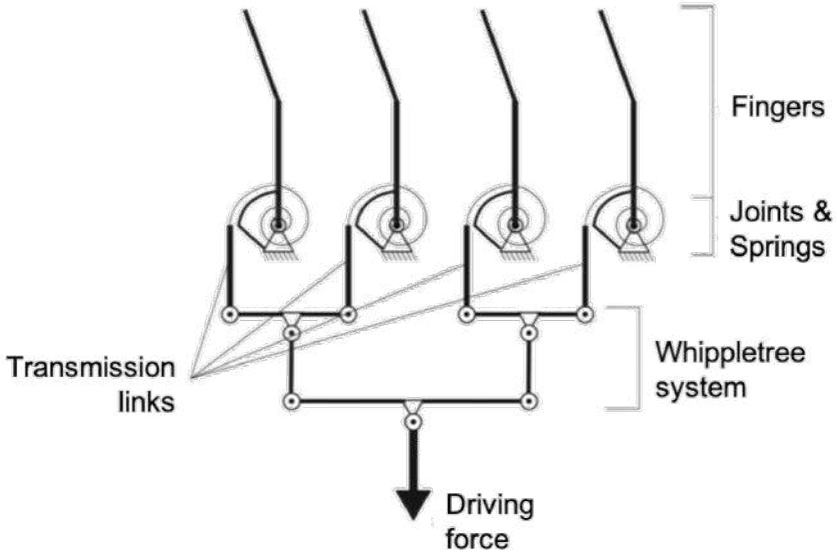


Figure 3.4: Whippletree mechanism for achieving adaptive grasp in a hand prosthesis.

3.3 Suspension Subsystem Design

The purpose of the suspension subsystem (SS) is to attach the prosthesis to the residual limb of the amputee. Considerations for the SS based on the defined system parameters include:

- Ease of use – The SS should facilitate simple donning and doffing of the prosthesis.
- Comfort – The SS should ensure that the prosthesis is comfortable to wear for extended periods. The device should not cause pain, discomfort, or skin irritation. Consideration should be made for heat dissipation to reduce sweating.
- Attachment stability – The SS should ensure that the device is securely attached to the residual limb. The device should not slip down or rotate during use.

Chapter 4

Design Outcomes

This chapter discusses the implementation of the design considerations outlined in Chapter 3. Progression from the initial prototype (ADL arm V1) to the final working proof of concept (ADL arm V2) is detailed.

4.1 Hand Subsystem

The hand subsystem (HS) design comprises four working parts: digits, thumb mechanism, wrist mechanism, and underactuation mechanism. All parts were designed in SolidWorks computer-aided design (CAD) software. The HS design follows.

4.1.1 Digits

The hand is composed of five digits: four fingers and a thumb. The basic structure of a digit is shown in Figure 4.1. Each digit consists of a proximal and distal segment. All four fingers have identical distal segments, while the index and middle fingers have longer proximal segments than the ring and pinky fingers. Segments are hinged together and to the body of the palm at the distal and proximal joints, respectively. The thumb has a rotating segment that forms part of the palm. It also has a proximal and distal segment connected by a hinge joint. A length of 3D printing filament is used as a hinge pin at each joint. 3D printing filament has a consistent diameter. It is strong and ductile enough for this purpose. The pin is secured by a friction fit, but it can also be heated and remoulded at the ends to secure its position in the hinge. The pinhole diameter is parametrised in the 3D model to account for possible variations in filament diameter.

Each digit features a channel that extends the length of its palmar side to house the actuation cord for that digit. The cord is fixed at the fingertip. Applying tension to the cord flexes the digit; releasing cord tension extends the digit. The digit is extended by the restorative spring elements. The actuation cord and its fixation point are illustrated in Figure 4.1.

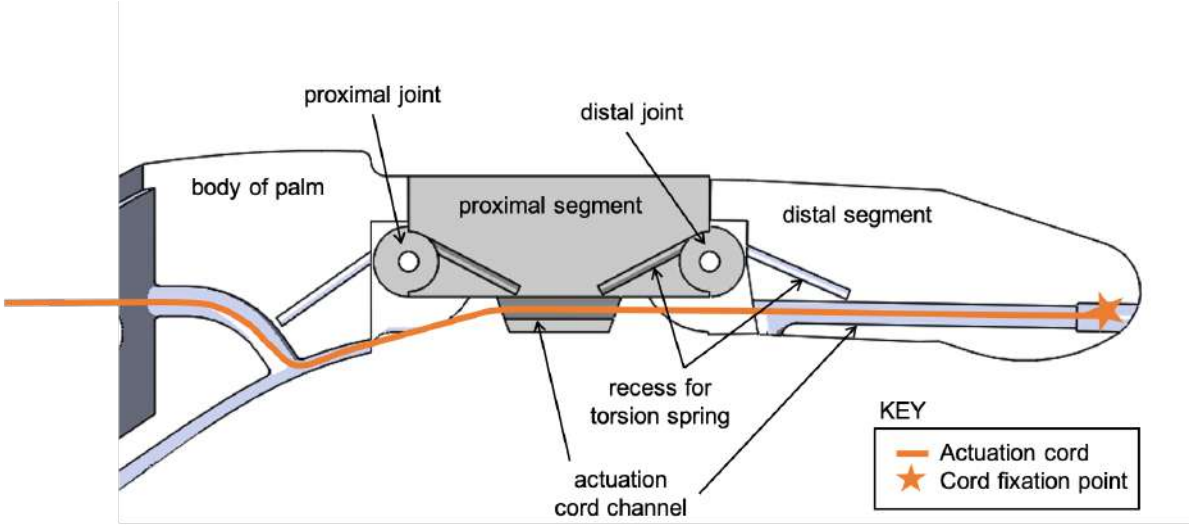


Figure 4.1: Cross section of a typical digit.

Unlike in V1, the ADL arm V2 uses torsion springs as the restorative element at each joint. Torsion springs have an advantage over elastic cords: the springs are less likely to undergo plastic deformation over time as a result of material degradation. Using springs also allows the restorative torque to differ between the proximal and distal joints, facilitating the appropriate digit kinematics for a secure grasp. A disadvantage of using torsion springs is that the springs are more difficult to procure than elastic cords.

The decision to exclude distal interphalangeal (DIP) joints – as are found in the anatomical hand – was made to decrease the TD's complexity and to reduce the total number of parts. A study conducted by Ten Kate et al. (2017) found that of a total of 56 reviewed 3D printed upper-limb prostheses, DIP joints were absent in approximately 45 %. During testing of the first prototype, the two-segment configuration did not demonstrate any notable disadvantage to hand functionality. The configuration was thus unchanged in this final version.

4.1.2 Thumb Mechanism

The thumb is designed based on the Galileo Hand V2.0, an open-source mechanical prosthesis (Turing Laboratory, 2014). Frontal and transverse sections of the implemented swivel thumb mechanism are shown in Figures 4.2 and 4.3, respectively. The proximal segment of the thumb rotates around a central pin, threaded into the palm. The thumb's rotational position is locked when a rivet is threaded through one of the positional locking holes in the palm. The red dashed line in Figure 4.2 (a) shows the restriction by the rivet. Rotation is unlocked when the rivet is lifted out of the holes by the spring-loaded button, as visualised in Figure 4.2 (b). There are four locking positions in the ROM of the thumb.

These allow the thumb to rotate approximately 90 °, in 30 ° increments. The ROM is limited by the physical boundary created by the solid body of the palm. The red dashed line in Figure 4.3 illustrates this restriction of movement.

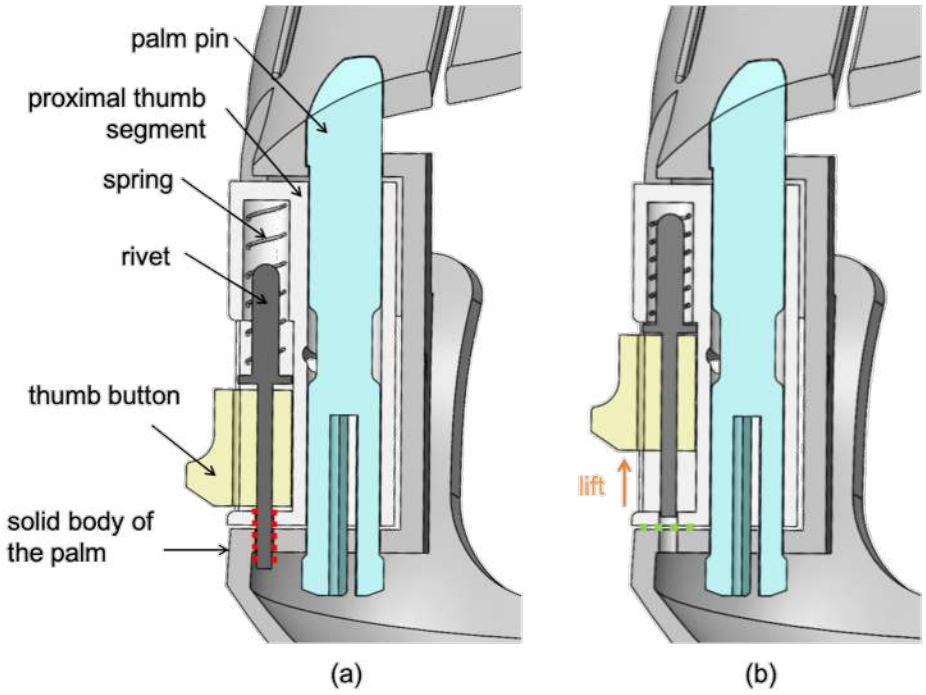


Figure 4.2: Frontal section through the swivel thumb showing the central pin (axis of rotation) as the attachment mechanism to the solid body of the palm.

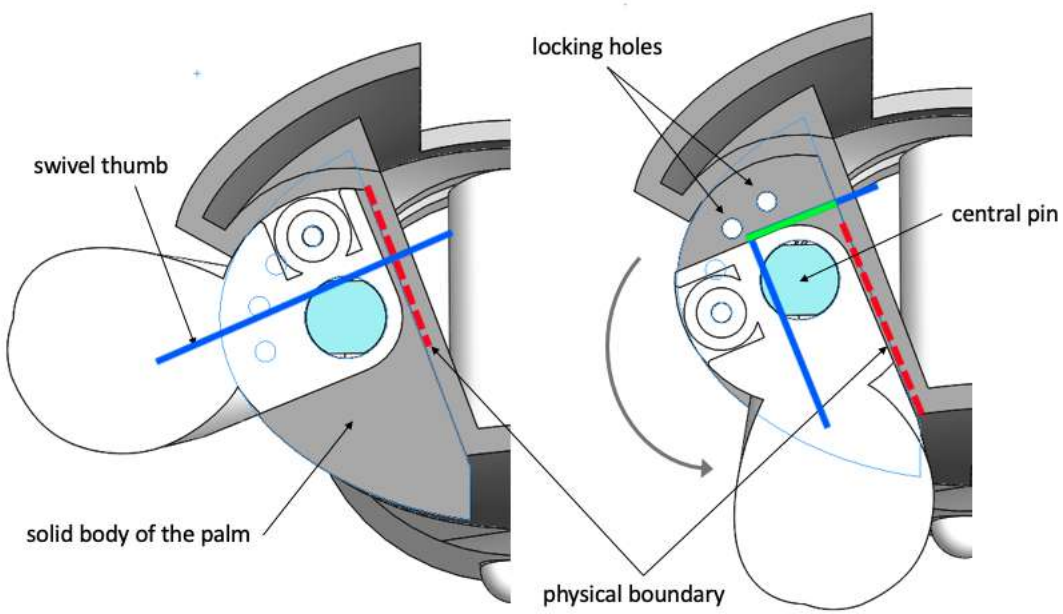


Figure 4.3: Transverse section through the swivel thumb, viewed from above, showing the thumb in the fully adducted (left) and abducted (right) positions.

Lateral grasp is a grasp shape where an object is gripped between the pad of the thumb and the radial side of the index finger (Feix et al., 2016). In a lateral grasp, the thumb is adducted. To achieve this motion in an underactuated prosthetic hand, the thumb must be activated at a delayed start time as compared to the fingers. In a medium wrap grasp, an object is held against the palm by the fingers and thumb (Feix et al., 2016). The thumb is abducted in this grasp. Successfully performing this grasp requires the thumb to be activated with only a small delay with respect to the fingers.

Achieving the described grasp kinematics in a mechanical prosthesis requires slack in the thumb actuation cable to be altered between the adducted and abducted thumb positions. The cable's trajectory through the proximal thumb segment is modified in the final design to make this possible. There is more slack in the cable when the thumb is adducted. This means that for the same applied cable tension, tension at the cable's fixed position in the thumb is developed later than if the cable was less slack. This concept is demonstrated in Figure 4.3 – the green portion of the line represents the effective cable shortening between the adducted (left) and abducted (right) thumb positions. The successful performance of lateral and medium wrap grasps, as a result of this modification, are demonstrated in Figures 4.4 and 4.5, respectively.

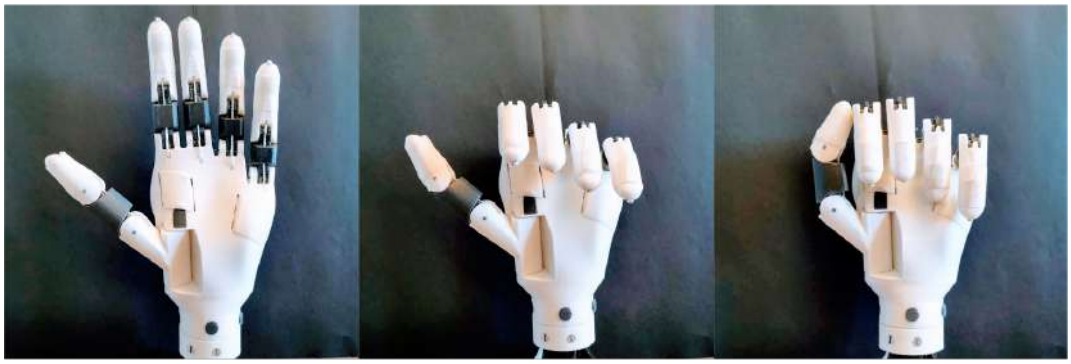


Figure 4.4: Lateral grasp (thumb adducted), performed by the ADL arm.

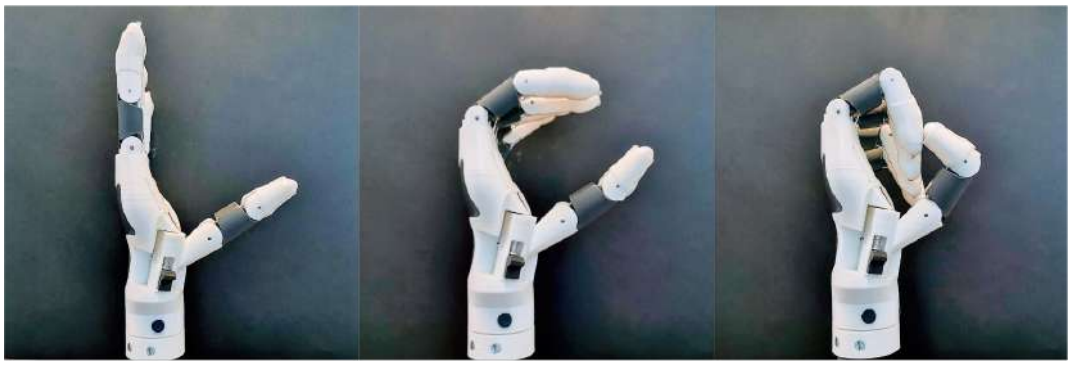


Figure 4.5: Medium wrap grasp (thumb abducted), performed by the ADL arm.

4.1.3 Wrist Mechanism

The wrist mechanism functions to attach the hand TD to the prosthesis and enables TD pronation and supination. The mechanism's proximal cuff is fixed to the forearm part of the suspension mechanism, while the distal cuff (fused with the hand TD) is allowed to rotate around it. A spring-loaded button mechanism is used to lock the hand in one of three positions: 0 °, 85 ° pronation, and 76 ° supination. Figure 4.6 demonstrates the implemented rotating wrist mechanism.

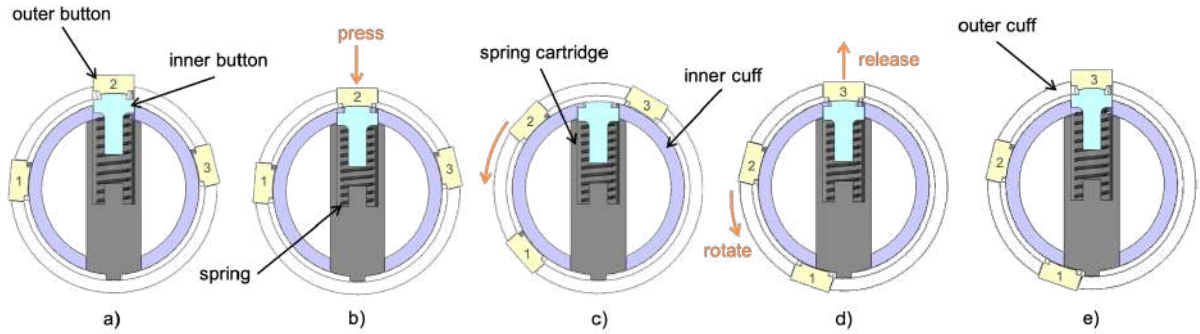


Figure 4.6: Transverse section through the wrist demonstrating the rotating wrist mechanism. Subfigures show: (a) 0 ° locking position, (b) button press, (c) outer cuff rotation, (d) button release, and (e) 85 ° locking position.

The wrist design was identified as a weakness of the ADL arm V1. The wrist was not sufficiently stable to grasp heavy objects. The implemented button mechanism required the thickness of the cuffs to be low, resulting in part weakness. The ADL arm V2 sees a redesign of the wrist. An inner and outer button are used to allow for an increase in proximal and distal cuff thickness. The result is a more secure attachment. Figure 4.7 shows the differences between the first and final wrist designs.

The first prototype, Figure 4.7 (a), uses a single button that must be compressed such that its outward-facing surface aligns with the distal cuff's inner circumference. The button overlap (indicated in red) is reduced to zero, and the distal cuff can rotate with respect to the fixed proximal cuff. The edge where the cuffs rotate with respect to one another is indicated in green. The distal cuff's thickness had to be less than 2 mm, or the button was difficult to press and the mechanism became cumbersome to use.

The new design, Figure 4.7 (b), uses two buttons. When the outer button is compressed, the inner button aligns with the proximal cuff's outer circumference, and the outer button aligns with the distal cuff's inner circumference. This allows the distal cuff to rotate with respect to the proximal cuff. The edge where the cuffs slide past one another is, again, indicated in green. In the new design, each cuff has a thickness of 4 mm. This considerably

improves the stability of TD attachment. The button is also far easier to press than the first prototype.

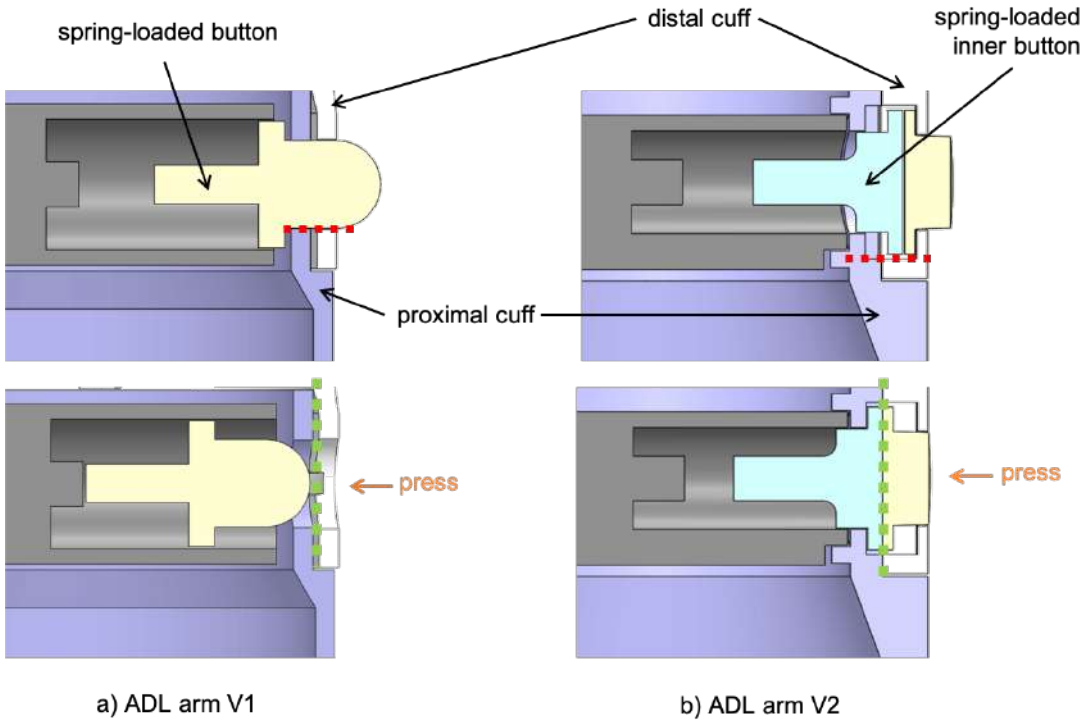


Figure 4.7: Comparison between the wrist mechanisms for the first and final prototypes. Button overlap (red) prevents the distal cuff from rotating with respect to the proximal cuff. Pressing the button allows the distal cuff to rotate, as the parts can slide past one another (green).

The first prototype of the ADL arm only had one wrist button. The new design necessitates three outer buttons – one in each locking position. With three outer buttons rather than one, the position of the button which is engaged (the release button) is less obvious than in the initial design. The spring cartridge, however, forms part of the proximal, fixed portion of the wrist. As such, the position of the release button is independent of the rotational position of the TD. This concept is demonstrated in Figure 4.8. Locating the release button becomes more intuitive as familiarity with the device increases.

The distal cuff features a circumferential slot to prevent unintentional detachment of the TD while the release button is depressed. A pin on the reverse side of the spring cartridge is bound by the slot during use, keeping the TD securely attached. The pin and release slot must be aligned to remove the TD. To correctly position these elements, align the arrows on the exterior of the wrist. The lock and release positions of the wrist cuffs are shown in Figure 4.9. This TD release mechanism facilitates disassembly for TD exchange and maintenance.

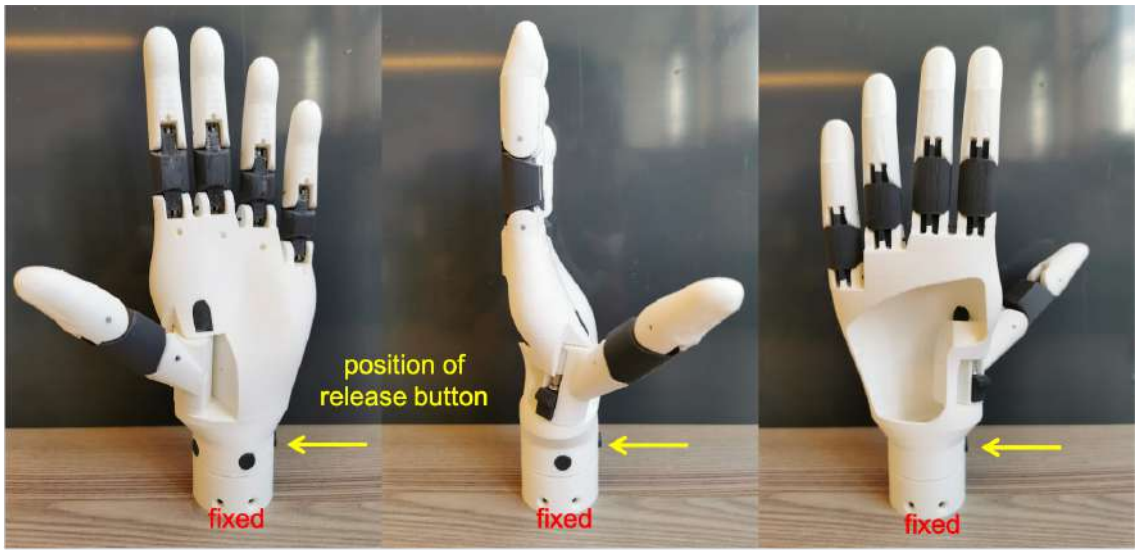


Figure 4.8: Demonstration of the fixed position of the button required to release the locking position of the wrist, with varying rotational positions of the TD.

Figure 4.9: Alignment of the arrows on the wrist segments, resulting in detachment of the hand TD. Orange arrows indicate the direction of movement.

4.1.4 Underactuation Mechanism

The hand TD is underactuated – it has a lower number of actuators than degrees of freedom. A whippletree mechanism is employed to distribute the force across the digits. Force is distributed between the fingers when the digits come into contact with an object, allowing the fingers to conform to the object's shape. Without this mechanism, all fingers would come to a halt when a single digit encountered an obstruction. The hand's ability to conform to an object is known as adaptive grasp. Adaptive grasp allows the hand to grip irregularly shaped objects with more stability, as all fingers can be in contact with the object's surface. This allows a larger frictional force between the hand and the object, assisting in slippage prevention. The functional principle surrounding the whippletree is demonstrated in Figure 4.10.

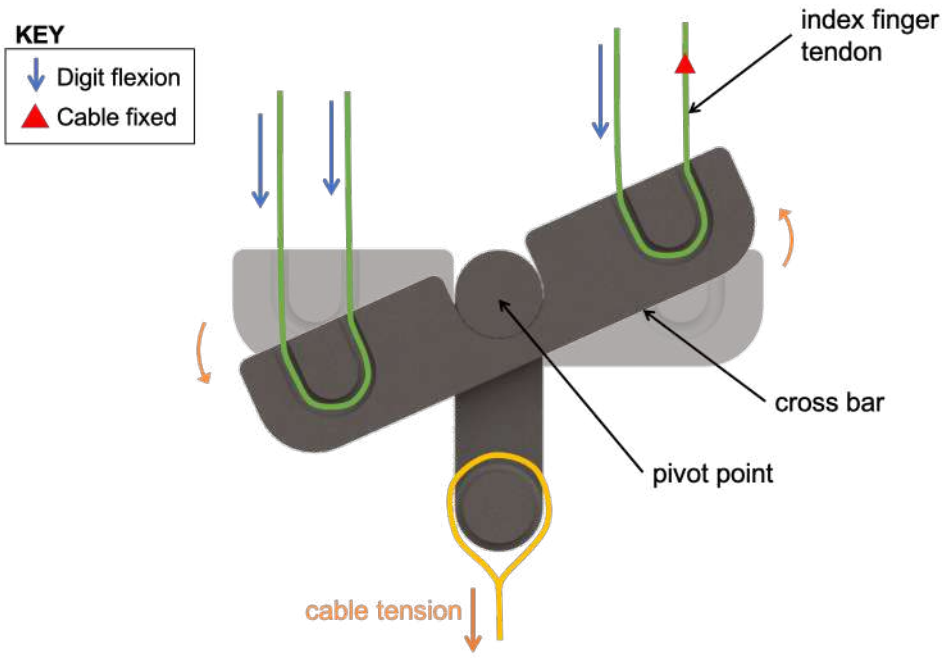


Figure 4.10: Demonstration of the differential motion resultant in the whippletree when only the index finger comes into contact with an object.

Space constraints within the palmar space necessitated a miniaturised whippletree. A cross section and photograph of the implemented underactuation mechanism are shown in Figures 4.11 (a) and (b), respectively.

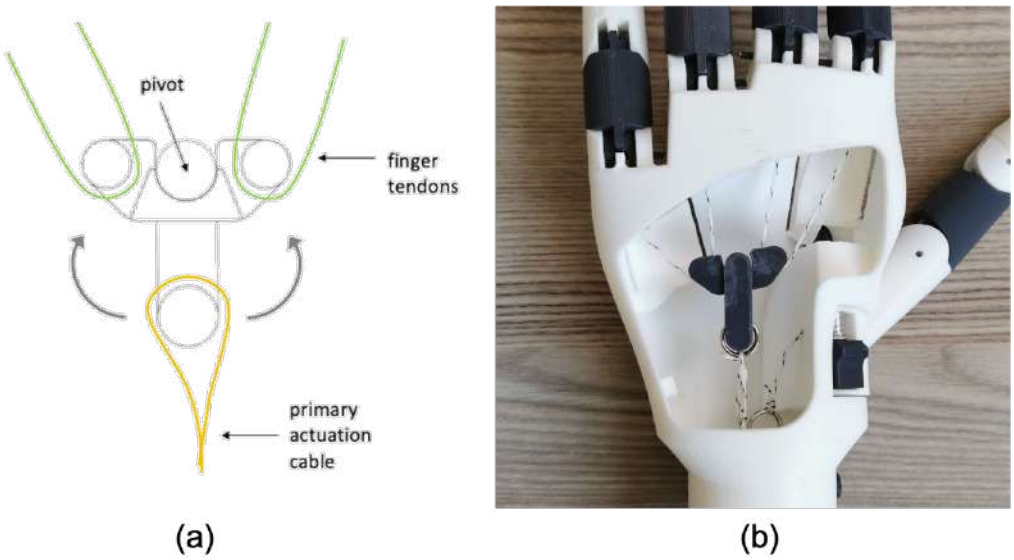


Figure 4.11: Implemented miniaturised whippletree mechanism; (a) cross section and (b) photograph.

The thumb is not coupled with the remainder of the digits in the underactuation mechanism. The thumb tendon runs alongside the primary actuation cable in the

forearm and is independently fixed to the humeral cuff. This is to ensure that activation of the thumb suffers a small delay, facilitating in performance of grasps where the thumb acts as a stabiliser, namely lateral grasp. This also allows the thumb to be tensioned independently of the fingers, making the grasp customisable to the type of objects being grasped for certain activities.

4.2 Actuation Subsystem

The actuation subsystem (AS) is responsible for translating elbow flexion into cable tension to actuate the hand TD. To achieve this, the AS comprises an elbow mechanism and a cable-lock mechanism. The working principles of these mechanisms are presented in Sections 4.2.1 and 4.2.2, respectively.

4.2.1 Elbow Actuation Mechanism

A hinged elbow joint allows relative motion between the humeral and forearm cuffs of the prosthesis. The motion at this joint is responsible for the actuation of the TD. To achieve this, a bowstring effect is created in a cable fixed to the humeral cuff at one end and the whippletree in the palmar space at the other. The bowstring effect increases the angle of wrap of the cable when the elbow is flexed, reducing the effective length of the cable and, in turn, producing tension in the actuation cable. An additional cable is associated with the thumb. Elbow flexion has an identical effect on this cable but is activated at a greater flexion angle. Figure 4.12 demonstrates the shortening effect produced by elbow flexion at the elbow joint.

The shape of the cable's interface with the hinge is modified to reduce the actuation cable's effective length. Testing of the first prototype found that tension development in the cables was insufficient for the hand to grasp heavy or slippery objects. The shape of the elbow joint was therefore modified in the final prototype of the ADL arm to combat this insufficiency. The differences are shown in Figure 4.13.

The actuation cables attach to the tensioning mechanism on the humeral cuff. This mechanism involves a tensioner box bolted to the humeral cuff, and two sliding tensioner pins. The tension of the actuation cords is set by tightening or loosening the hex bolts that thread into the tensioner pins. The tensioner box and pins are printed in white filament. Figure 4.13 (a) displays these components most clearly.

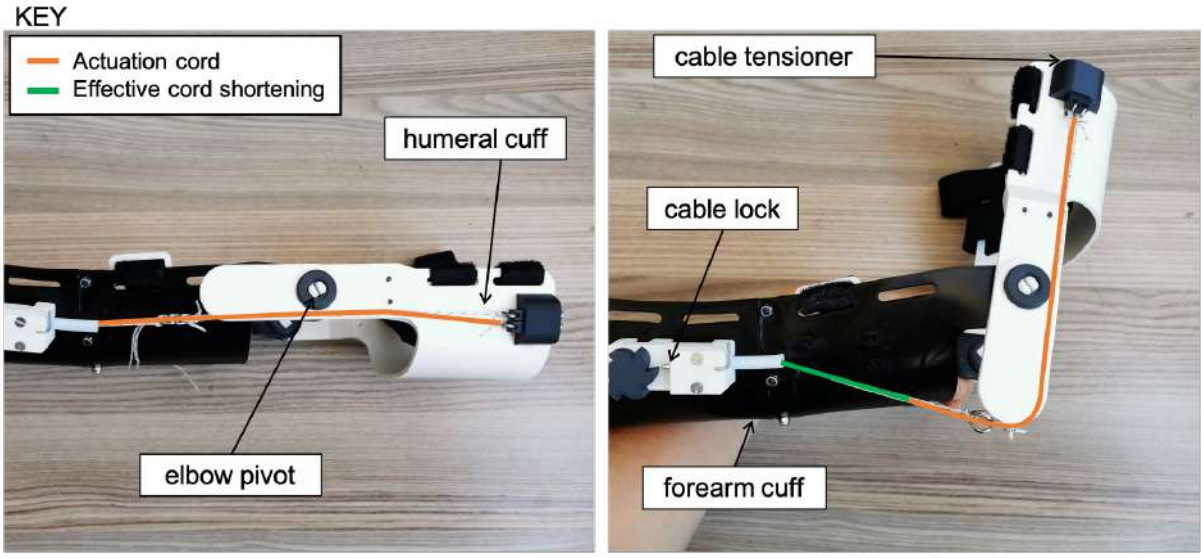


Figure 4.12: Demonstration of the effect of elbow flexion on the actuation cables.

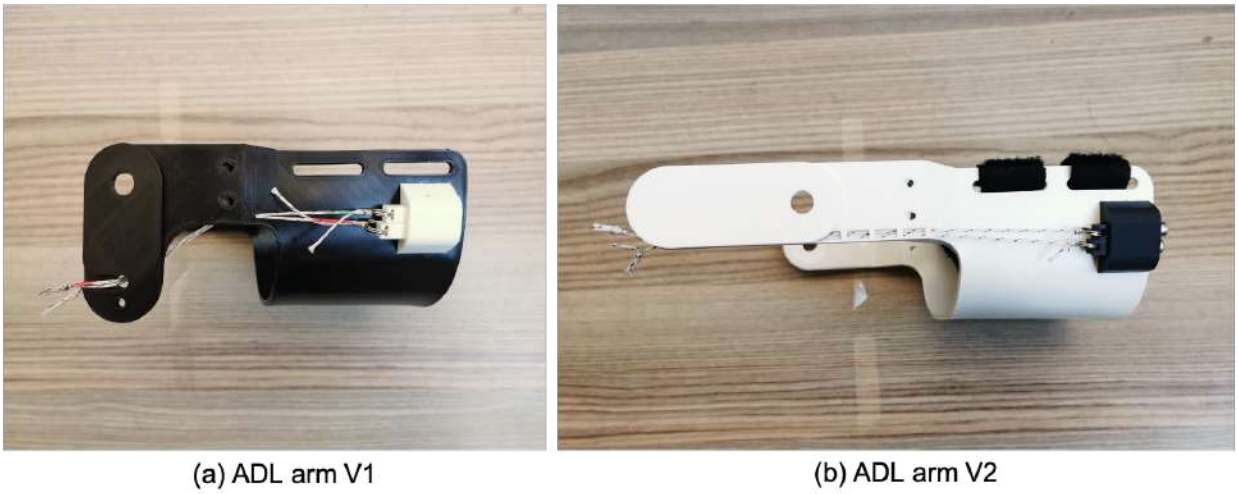


Figure 4.13: Comparison between the elbow modifications in (a) the first prototype and (b) the final design.

4.2.2 Cable Lock Mechanism

Unlike prototype one, the final prototype implements a cable-lock mechanism. This is advantageous as the device is voluntary closing, implying that elbow flexion must be maintained to keep a grip on the object. A cable lock maintains the grip on an object without requiring sustained physical effort from the user. With a cable lock, objects can be grasped away from the body, increasing an amputee's functional work envelope when wearing the device.

The designed cable-lock mechanism uses friction to fix the cable and maintain tension in the digits of the hand. The functional principle of the cable-lock mechanism is shown in Figure 4.14. Friction is created between a bolt and a rubber washer within the cable lock housing. The bolt is threaded onto a fixed nut within the cable lock housing. Turning the bolt clockwise increases friction between the bolt and rubber washer, locking the cable in place. Once the cable lock is engaged, a user can extend the arm without losing grip on the object. Turning the bolt anti-clockwise decreases friction, releasing the cable.

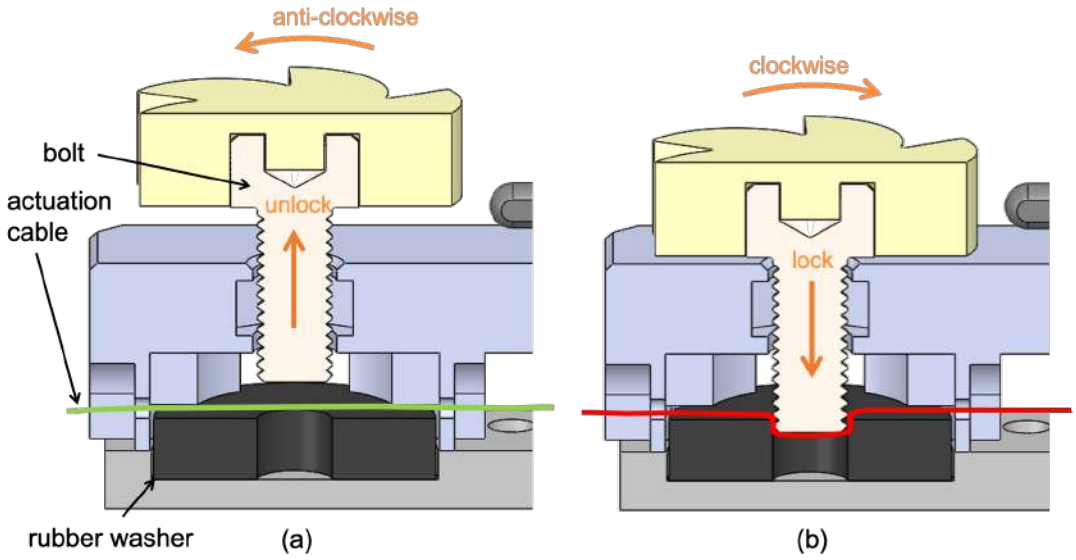


Figure 4.14: Functional principle of the cable-lock mechanism.

A spring-loaded button locks the rotational position of the bolt when the cable lock is engaged. The button – a modified rivet – interfaces with a 3D printed cap for the bolt to prevent the bolt from loosening itself. The rivet is pulled back to release the cable lock, and the bolt's cap can then rotate freely again. The spring-loaded bolt-locking mechanism is demonstrated in Figure 4.15.

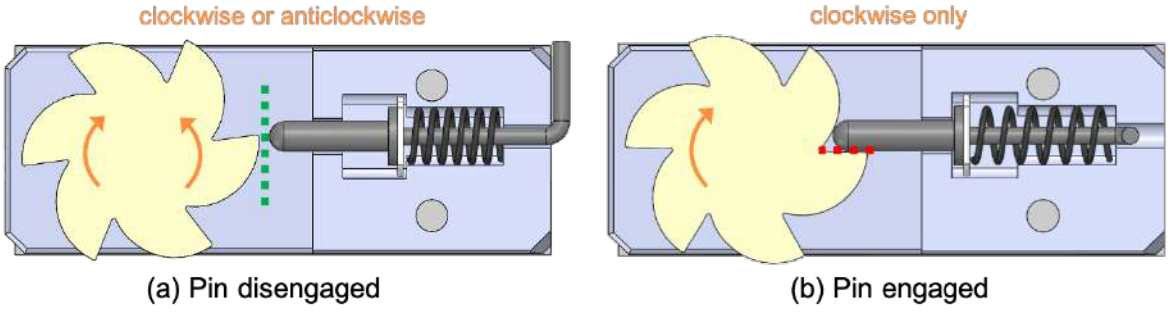


Figure 4.15: Functional principle of the spring-loaded bolt-locking mechanism.

4.3 Suspension Subsystem

The suspension subsystem (SS) includes a forearm and humeral cuff that articulate at a hinge joint at the elbow. This subsystem has a range of functions: to attach the prosthesis to the amputee, to act as a fixation point for the AS, and to support and provide attachment for the HS. The interface between the forearm and humeral cuffs – the elbow joint – allows tension development in the cable system. It is responsible for the actuation of the TD.

To meet the design requirements, the SS must be sturdy, must fit the residuum comfortably and securely, and must be easy to don and doff. A strong and user-customisable solution suits these needs. The forearm and humeral cuffs of the ADL arm V1 were moulded from 3 mm thick Polyvinyl Chloride (PVC) sheeting. The insufficient bed size of an average FDM 3D printer (220×220 mm) – too small to print the full length of a forearm cuff – prompted this decision. 3D printed attachment struts were secured to the moulded sheeting with nuts and bolts. Although a reasonable solution, the need to purchase plastic sheeting, mould this plastic at high heats, and affix additional 3D printed components made this solution undesirable.

The final design features an entirely 3D printable SS. The forearm cuff is printed in two pieces. These are connected via a modified bolt-through bridle joint before moulding occurs. The result is a lightweight, strong, and comfortable forearm cuff. The forearm and humeral components are printed as flat sheets and moulded to the shape of the amputee's residual limb. This method is advantageous because minimal 3D printing material is used as support material, and parts can be remoulded as the form factor of the residual limb changes over time. The 3D printed cuffs are secured to the arm by a series of Velcro straps. This attachment method is inexpensive, comfortable, and adjustable. Securing the prosthesis with Velcro also facilitates easy, one-handed donning and doffing of the prosthesis. This is necessary to meet the design requirements. The printed and assembled SS is shown in Figures 4.16 (forearm cuff) and 4.17 (humeral cuff).

4.3.1 Bypass Socket

A bypass socket is designed to enable healthy participant testing of the ADL arm. The bypass socket functions to extend the HS beyond the length of the healthy hand while still allowing the wearer to actuate the TD using elbow flexion. The bypass socket has a forearm cuff made from three, rather than two, pieces. The bypass socket's forearm cuff maintains all prosthesis functionality but facilitates device validation without requiring amputee participation. Figure 4.18 shows the designed bypass socket.

Figure 4.16: 3D printed, assembled, and moulded forearm cuff; featuring AS cable-lock mechanism.

Figure 4.17: 3D printed and moulded humeral cuff; featuring AS tensioning mechanism.

Figure 4.18: Designed bypass socket that enables non-amputee participants to use the ADL arm.

4.4 Physical Manifestation

The physical prototype of the ADL arm is an assembly of 3D printed parts and accessible hardware components. An itemized list of all components of the ADL arm V2 is given in Appendix A. All 3D printed parts were fabricated using a *Creality Ender 3* FDM printer. FDM printed parts suffer an inherent weakness in planes parallel to the print bed, between layers. Some parts, such as the proximal wrist, were designed as an assembly of smaller components. This is to ensure adequate strength of each part in the appropriate direction, and to minimise the amount of required support material during printing.

4.4.1 Sizing

The physical prototype of the ADL arm is designed to fit an average-sized adult female. The CAD model of the prosthesis is, however, based on several variable parameters. Model parameters can therefore be altered to match the unique dimensions of an amputee's residual limb.

Design customisability is advantageous in the open-source space. CC-licensed designs are typically published as Standard Triangle Language (STL) files. These are 3D representations of objects that use a series of triangles to represent the object's surfaces. In contrast, CAD model files (such as SolidWorks part files) represent objects as a series of 3D features. Modifying STL files is often limited to scaling and slicing in one or more of the coordinate planes. Scaling a standardised part to match the dimensions of the user in this way is only appropriate if all parts of the design are 3D printed. In a design that utilises standardised hardware, simple scaling is not feasible.

4.4.2 Material Selection

Choosing materials for fabrication of the ADL arm prioritises suitability to the application, accessibility, and cost. Material selection can be divided into three categories: 3D printed parts, surface materials, and additional hardware components.

3D Printed Parts

The two most common 3D printing materials are Acrylonitrile Butadiene Styrene (ABS) and Polylactic Acid (PLA). ABS is favoured for its low cost and tough and durable parts that can withstand high temperatures. PLA is favoured for its ease of use, dimensionally accurate parts, and low cost. The lower temperature nature of PLA makes it favourable as parts can be thermoformed post-printing.

The forearm and humeral cuffs, which make up the suspension mechanism, are printed from PLA filament. The resulting parts can be thermoformed by being placed in hot water or applying direct dry heat using a hair dryer or heat gun at a low temperature. The inherent weakness between layers in the humeral cuff is overcome by reinforcing the elbow struts with bolts. This reinforcement is shown in Figure 4.19. All other parts are printed from an ABS-derived filament – FormFutura TitanX. The resulting parts are tough and durable.

Figure 4.19: Reinforcement of the elbow struts to overcome the inherent weakness of 3D printed parts between layers.

Surface Materials

Choosing the material that interfaces with the object being grasped is integral to ensuring a secure grasp. Most suitable for this application would be a material with a large coefficient of friction that can conform and adhere to the 3D printed parts. The chosen surface material is self-amalgamating silicone tape, specifically Alcolin Silicone Tape (Figure 4.20). Given that this product is not an adhesive, there will not be any residue left on the parts if the tape needs to be removed and replaced. The tape sticks only to itself. Slots must therefore be made in the palm, through which the tape can be thread and fold back on itself. The tape also wraps around the tips of the digits, ensuring a secure grasp on almost any object. Figure 4.20 shows the silicone tape, attached to the HS of the ADL arm V2. Silicone tape can be purchased at most hardware stores, making this an accessible solution.

Additional Hardware

The various subsystems use additional hardware components which are not 3D printed. Each digit joint (10 in total) within the HS uses a $4 - turn,\ 0.4\ mm,\ 5\ mm\ OD$ torsion spring as the restorative element and a length of 3D printing filament as the hinge pin.

Figure 4.20: Silicone tape (outlined in red) used on the fingertips and palm to increase friction with the object being grasped, resulting in a more secure grip.

The wrist and thumb mechanisms each use a standard pen spring (approximately $25 \times 5 \times 0.5$ mm in size) to spring-load the buttons. The thumb mechanism uses a standard 3.2×10 mm blind rivet to fix its rotational position. The HS is fixed to the forearm cuff by four $M3 \times 8$ mm countersunk bolts fastened into four $M3$ locknuts.

Within the AS, the tensioner box is fixed to the humeral cuff with two countersunk self-tapping screws. The two tensioner pins are each tensioned with $M3 \times 15$ mm bolts. The cable lock uses a single $M5 \times 12$ mm hex-head bolt and nut combination. The $M5$ bolt interfaces with a rubber washer ($OD - 18.4$ mm and $ID - 4.2$ mm) to create the friction lock on the cable. The bolt-locking mechanism of the cable lock uses a 3.2×10 mm blind rivet and standard pen spring. Two $M3 \times 13$ mm bolts secure the cap on the bolt-locking mechanism. The cable lock itself is affixed to the forearm cuff using six $M3 \times 13$ mm countersunk bolts and $M3$ nuts embedded within the cable lock housing.

The actuation cords travel the length of the forearm cuff within an $OD - 6$ mm, $ID - 4$ mm Teflon tube. This choice is made to minimise friction between the elbow joint and the HS. The actuation cord itself is an 80 lb braided fishing line chosen for its resistance to stretch. The two-part forearm cuff's bolt-through bridle joint makes use of five $M3 \times 5$ mm countersunk bolts and locknuts.

With the exception of the torsion springs – custom-manufactured by Gellini Spring Manufacturers in Cape Town, SA – all components can be purchased at either a hardware store, fishing supplies store, or fasteners retail store.

4.5 The ADL arm V2

The ADL arm V2 – the final design or the ADL arm – is a functional below-elbow prosthesis designed for ADL performance in unilateral transradial amputees. Figures 4.21 to 4.24 are photographs of the prosthesis.

Figure 4.21: Top view of the ADL arm V2, showing the wrist in the supinated position, the thumb in full adduction, and the Velcro straps of the suspension mechanism.

Figure 4.22: Side view of the ADL arm V2, showing the tensioning mechanism on the humeral cuff, the elbow actuation mechanism, the cable-lock mechanism on the forearm cuff, the wrist in the neutral position, and the thumb fully adducted.

Figure 4.23: Close up of the ADL arm V2, viewed proximally, showing the palmar side (left) and the dorsal side (right) of the hand TD.

Figure 4.24: Hand TD of the ADL arm V2, showing the swivel thumb, rotating wrist, digits with actuation cords, and white silicon grip elements on the digits and palm.

4.6 Failure Modes and Effects Analysis

Failure Modes and Effects Analysis (FMEA) is a tool used to proactively identify ways in which a new process or device may fail, to assess the potential impacts of those failures, and explore possible ways to mitigate identified failures. This type of analysis helps avoid adverse effects before occurrence rather than reacting and accounting for impacts post-occurrence. Emphasising failure prevention rather than reaction improves safety in the use of the new device or process. Three metrics are used to numerically assess each failure mode: severity of impact, probability of the failure occurring, and probability of detection. Each metric is given a score out of ten. The rating scale for each is presented in Table 4.1. The final score for the failure mode is a result out of 1000, determined by multiplying the scores for each metric together. This result is used to prioritise design changes to implement in the next iteration of the device.

Table 4.1: FMEA rating scale.

Metric	Minimum Score (1)	Maximum Score (10)
Severity Impact	Inconsequential	Device Unusable / Injury
Occurrence Probability	Highly Improbable	Inevitable
Detection Probability	Immediately Detectable	Imperceptible

FMEA of the ADL arm is conducted on the subsystems of the device. Failure modes are scored based on the defined rating scale, yielding a relative risk for each failure mode of the device. The results are presented in Table 4.2. Following device scoring, possible failure modes, potential effects of failure, possible causes of failure, and the current controls in place to avoid failure are investigated. These are presented in Table 4.3.

The highest score for a particular failure mode is 140 – the device cannot grasp heavy objects. This mode of failure is inherent to the nature of 3D printed prosthetic devices as the strength of FDM printing materials is not high when compared to more traditional fabrication materials, and the mechanical properties of 3D printed parts rely heavily on the settings utilised by the individual printing the parts. These parts are prone to breaking when exposed to significant loads. Another reason for this failure may be a design flaw, where the elbow actuation mechanism cannot achieve sufficient grasp force in the TD to grip heavy objects. Although this failure mode poses a significant potential risk, the severity of its impact is not high. The majority of everyday tasks for which the prosthesis is designed should not harm the device.

Table 4.2: FMEA of the ADL arm – risk analysis scores in terms of severity impact, occurrence probability, and detection probability.

Subsystem	**Possible Failure**	**Severity Impact Score**	**Occurrence Probability Score**	**Detection Probability Score**	***Total Failure Risk Score***
Hand	3D printed digits break	7	2	2	*28*
	Cord fixation failure	8	2	3	*48*
	Hinge pin failure	8	7	2	*112*
	3D printed proximal wrist cuff breaks	10	2	3	*60*
	Object slips from hand	7	2	2	*28*
	3D printed whippletree breaks	10	3	3	*90*
	Large object cannot be grasped	4	5	1	*20*
	Heavy object cannot be grasped	5	7	2	*70*
Actuation	Actuation cord failure	10	2	4	*80*
	Heavy object cannot be grasped	5	7	4	*140*
	Light object cannot be grasped	9	2	4	*72*
	Tensioner box failure	10	3	2	*60*
	Tensioner pin failure	10	3	3	*90*
	Cable lock cannot maintain cable tension	4	5	4	*80*
	3D printed elbow pins break	10	3	1	*30*
	3D printed humeral cuff breaks	10	2	1	*20*
Suspension	Prosthesis slips/rotates on residual limb	7	5	2	*70*
	Inability to accommodate biceps/forearm diameter	9	2	2	*36*
	Forearm or humeral cuff breaks	10	3	1	*30*

Other notable points of failure for the device include hinge pin failure, failure of the 3D printed whippletree and tensioner pins, insecure attachment of the prosthesis, and failure of the actuation cord. Given the modularity of a 3D printed prosthesis, each component identified as a weakness can be kept accessible as spare. If a component fails, it can be removed and replaced relatively easily. These include additional 3D printed parts, Velcro straps, and a braided actuation cord. A large majority of the failure modes – especially those involving failure of 3D printed parts – occur as a result of fabrication or assembly error. It is advised that manufacturers of the open-source ADL arm prosthesis become familiar with the fabrication and assembly guide before printing the device. This will likely result in a more positive and durable output device, with greater longevity and less user frustration in the long term.

Table 4.3: FMEA of the ADL arm – possible failure modes, potential effects, possible causes, and current controls.

Subsystem	Possible Failure	Potential Effect(s)	Possible Cause(s)	Current Controls
Hand	3D printed digits break	One or more digits become detached Secure grasp cannot be achieved	Material failure Fabrication error	Parts printed from ABS Recommended fabrication settings included
	Cord fixation failure	One or more digits are not actuated Secure grasp cannot be achieved	Material failure Assembly error	Parts printed from ABS Heavy duty actuation cord used Nots secured with super glue
	Hinge pin failure	One or more digits become detached Secure grasp cannot be achieved	Material failure Design flaw	Pin material is ABS Design is user-customisable
	3D printed proximal wrist cuff breaks	Hand detaches - device unusable	Material failure Fabrication error Physical trauma to device	Parts printed from ABS Recommended fabrication settings included Device confirmed to withstand normal daily use
	Object slips from hand	Secure grasp cannot be achieved	Silicone tape damaged Design flaw	Silicone tape is inexpensive and easy to replace Device confirmed to perform well in expected use scenarios
	3D printed whippletree breaks	Digits cannot be actuated - device unusable	Material failure Fabrication error	Parts printed from ABS Recommended fabrication settings included
	Large object cannot be grasped	User frustration	Design flaw	Device confirmed to perform well in expected use scenarios
	Heavy object cannot be grasped	User frustration Potential user harm	Material failure Design flaw	Silicone tape has a large coefficient of friction Device confirmed to perform well in expected use scenarios
Actuation	Actuation cord failure	Hand cannot be actuated - device unusable	Material failure Fabrication error	Parts printed from ABS Recommended fabrication settings included
	Heavy object cannot be grasped	User frustration Potential user harm	Design flaw	Device confirmed to perform well in expected use scenarios
	Light object cannot be grasped	User frustration	Design flaw	Device confirmed to perform well in expected use scenarios
	Tensioner box failure	Hand cannot be actuated - device unusable	Material failure	Parts printed from ABS
	Tensioner pin failure	Hand cannot be actuated - device unusable	Material failure	Parts printed from ABS
	Cable lock cannot maintain cable tension	Physical effort must be maintained to maintain grasp	Material failure Design flaw	Rubber washers are inexpensive and easy to replace Device confirmed to perform well in expected use scenarios
	3D printed elbow pins break	No actuation - device unusable	Material failure Fabrication error	Parts printed from ABS Recommended fabrication settings included
	3D printed humeral cuff breaks	No actuation - device unusable	Material failure	Parts reinforced with steel bolts
Suspension	Prosthesis slips/rotates on residual limb	User experiences difficulty using the device User discomfort User emotional distress	Velcro strap failure Velcro strap too loose Inappropriate sizing	Velcro is inexpensive and easy to replace Adjustable length straps Design is user-customisable
	Inability to accommodate biceps/forearm diameter	User cannot fit - device unusable User discomfort	Design flaw	Design is user-customisable
	Forearm or humeral cuff breaks	Cannot attach to residuum - device unusable	Material failure Fabrication error	Recommended fabrication settings included Parts reinforced with steel bolts

4.7 Open Source Plan

The plan for the open-source aspects of the device is detailed in this Section. This plan should address all aspects of the device that correspond to the criteria for OSHW in Section 2.4. The plan is laid out in five categories, where the required documentation, chosen license, plan for file sharing, considerations for safety and guide for further contribution are explored in detail.

4.7.1 Documents

To satisfy the criteria for OSHW, all documents required to understand, make, modify, distribute and use the design should be included with the design files themselves – which should in the preferred format for making modifications (Open Source Hardware Association, 2014). Listed below is the suggested documentation for the ADL arm when publishing to the public domain.

1. **Project overview:** Including an introduction and background, the problem description, the aims and objectives of the project, the chosen license, the scope of this license, a list of included documents, a list of included design files and a list of required software.
2. **Design files:** All original SolidWorks design files in their fully modifiable format.
3. **License:** A plaintext or PDF copy of the chosen license.
4. **Photographs:** Photographs or renders of the assembled device.
5. **Instruction documents:** A number of documents to guide users in the manufacture and use of the device.
    - **3D printing and fabrication guide:**
      This document should at least include the:
        - Recommended 3D printing materials and print parameters.
        - Recommended print orientations for the 3D printed parts.
    - **Assembly guide:** Detailing how to assemble the device from the 3D printed parts and other materials.
    - **User manual:** Detailing how to use the fully assembled prosthesis.
6. **Completion status:** Describing the maturity level of the project and the tasks completed to date on the device.

7. **Design predecessors:** A document listing and attributing the open-source designs from which the borrowed components of the ADL arm V2 were taken. Including the licensing requirements placed on ADL arm by those components.

8. **Bill of materials**: A comprehensive list of materials and tools required to manufacture the device.

9. **Safety information:** Including a device risk analysis, a statement that the design is still a work in progress, and a disclaimer absolving the designer of accountability for the potential risks of the device.

10. **Contribution guide:** A description of how individuals can contribute to the project, including the specific tasks to be completed to improve the completion status of the prosthesis.

4.7.2 License

Although an open-hardware license (such as CERN-OH or TAPR) is preferred for medical devices, the original license of the borrowed design components must be considered and upheld in the derived device. A summary of the borrowed design components and their respective licenses is presented in Table 4.4 (Turing Laboratory, 2014; Enabling The Future, 2016a).

Table 4.4: Summary of the original licenses of the borrowed design components featured in the ADL arm V2.

Mechanism	Derived from	Original license
Rotating thumb	Galileo Hand V2.0	CC-BY-NC
Hinged Elbow	UnLimbited Arm V2.1	CC-BY-NC-SA

Both the Galileo Hand and the UnLimbited Arm are licensed under Creative Commons licenses, where the attribution (BY) and non-commercial (NC) clauses are common to both designs. These elements dictate that to use of each of these designs, the original designer must be given appropriate credit, and the manufactured product may not be used for commercial purposes (Creative Commons, 2013). Furthermore, the share-alike (SA) attribute of the UnLimbited Arm dictates that derived designs should be shared under the same license as the original (Creative Commons, 2013). This implies that derivatives of the UnLimbited Arm may also not be used for commercial purposes. In the case of the ADL arm V2, the chosen license is dictated by the restrictions set in place by

using design elements from the UnLimbited Arm. The ADL arm must be licensed under CC-BY-NC-SA.

The non-commercial clause of this CC license renders it to be not a true open source device – it does not comply with the criteria in the definition of OSHW (presented in Section 2.4). To enable the ADL arm to fully comply with the OSHW, and hence allow it to be licensed with an open hardware license, the dependency on the UnLimbited Arm should be removed by redesigning the elbow mechanism in a future iteration.

4.7.3 Sharing

At its current stage of development, the ADL arm is not yet ready to be released in the public domain. Further design modification and validation steps are required prior to the design's release. Additionally, prior to publication, a successful application must be made to NIPMO (National Intellectual Property Management Office) to have the IP released. This application process has already been started by UCT's Research Contracts and Innovation department (see Appendix B). A preliminary suggestion for where and how the device should be shared is detailed below.

The ADL arm should be shared with the appropriate documentation as suggested in Section 4.7.1 above. The device should be shared under the CC-BY-NC-SA license, unless the dependency upon the UnLimbited Arm is removed. The design files and associated documentation should be shared on a platform which targets the open sharing of open-source healthcare solutions. Examples of such platforms include: UBORA (UBORA, 2018), Open Source Medical Supplies (OSMS, 2020) and Carables (Carables, 2020).

Of these platforms, the UBORA e-infrastructure should be preferred. This platform has been designed as a framework for open-source medical devices which encourages compliance with medical device standards such as *Regulation (EU) 2017/745 – Medical Device Regulation* and *ISO 13485 – Medical Device Standard* (De Maria et al., 2020). Designers wishing to publish their devices on this platform are required to engage fully with all aspects of the design process. Requirements include a needs identification, risk level and standards identification, a consideration of the project management aspects, and full documentation in the form of a pre-production design dossier (De Maria et al., 2020). Expert mentors are available on the platform to vet devices, give advice, and ensure adherence with the strict safety regulations for medical devices (De Maria et al., 2020).

4.7.4 Safety considerations

To ensure the safety and efficacy of open-source medical devices, designers should use the currently accepted medical device standards and regulations as a guide in their design processes (De Maria et al., 2020). An important aspect of safety is identifying the risk associated with the device. In the Section prior, an FMEA is performed. The FMEA proactively identifies ways in which the device can fail, assesses the level of potential harm and explores ways to prevent these failures. With further iterations of the ADL arm, the associated device risk should be reassessed. Additionally, to more strictly adhere to current medical device standards, the FMEA risk analysis should be used as a starting point for a comprehensive risk management assessment in accordance with *ISO 14971 - Risk Management for Medical Devices* (referred to as RM henceforth).

Key differences exist between these approaches to the risk associated with a device. Where an FMEA assesses possible failures in a design, RM is based on identifying *hazards* (potential sources of harm) and how they lead to *hazardous situations* (circumstances in which people, property, or the environment are exposed to hazards) (Speer, 2016). The focus on all possible hazardous situations, with or without the presence of failure, distinguishes RM from a FMEA (Speer, 2016). The RM process is used to: identify hazardous situations, estimate and evaluate risks, and develop, implements and monitor the effectiveness of risk control measures (International Organization for Standardization, 2019; Speer, 2021). The development of a RM process is recommended by UBORA for all of its medical device submissions (UBORA, 2018).

Applying ISO 14971 for Risk Management

To demonstrate the value of this approach to risk management, two significant failure modes from the FMEA are explored using the ISO 14971 RM framework. Two significant failure modes – *Heavy object cannot be grasped* and *Tensioner pin breaks* – are chosen for this demonstration. The risk assessment starts with identifying hazards associated with use and misuse of the product. From these, the foreseeable sequences of events leading to hazardous situations must be identified. The resulting *harms* (injury or damage to people, property or the environment) must also be explored. This assessment is demonstrated using the chosen failure modes in Table 4.5.

The level of risk is estimated for each of the harms according to their estimated *severity* (a measure of the possible consequences of a hazard) and *likelihood of occurrence*. It should be noted that there is no medical device industry standard for estimating risk (severity and likelihood) and one should use objective evidence (such as similar

Table 4.5: Risk analysis of the two chosen failure modes using the RM approach.

Hazard	**Foreseeable sequence of events**	**Hazardous situation**	**Harm**
Falling object	- User grasps object heavier than specified maximum	Heavy object slips from grasp	- User injury - Object damaged - Environment damaged
Functionality (inability to grasp)	- Tensioner pin printed in incorrect orientation - Prosthesis used normally - Tensioner pin breaks - Prosthesis cannot grasp	Object slips from grasp	- User injury - Object damaged - Environment damaged

products, regulatory data, white papers etc.) to support these estimates (Speer, 2021). The resulting level of risk is deemed either acceptable, or unacceptable; where an unacceptable amount of risk should be addressed by risk control measures. A risk estimation for the chosen failure modes is shown in Table 4.6.

Table 4.6: Risk estimation and evaluation of the two chosen failure modes using the RM approach.

Hazardous situation	**Severity**	**Likelihood**	**Risk evaluation**	**Acceptability**
Heavy object slips from grasp	Serious	Occasional	Medium	Unacceptable
Object slips from grasp	Minor	Probable	Medium	Unacceptable

Often, a matrix similar to the one shown in Figure 4.25 (Speer, 2021) is defined to evaluate the level of risk associated with each hazardous situation. Based on this example table, the risk associated with both failure modes is estimated as 'medium'. This level of risk is deemed unacceptable, according to the Risk Management Procedure in the Risk Management Plan (defined in the early stages of RM). As such, risk control measures should be devised and implemented to decrease the risk associated with the hazardous situations.

Figure 4.25: Example risk acceptability matrix for evaluating the risk of hazardous situations as part of the RM procedure.

In many cases it may seem simplest to implement risk control measures that reduce risk through providing additional information to a label or instruction manual. Risk control

measures, however, should be prioritised as follows (Speer, 2021):

1. Inherent safety by design.
2. Protective measures in the actual medical device and/or manufacturing process.
3. Information for safety, such as labelling and instructions for use.

Most often, implementing control measures will result in a reduced likelihood of harm, while the severity of harm remains unchanged. Possible risk control measures for the first failure mode are:

- Increase the grip strength of the prosthesis as to decrease the probability of heavy objects being dropped.
- More clearly label the device with its weight limit. Emphasise this in the use guide. Include additional warnings on all documentation.

Possible risk control measures for the second failure mode are:

- Specify the print orientations of the parts for the manufacturing process, such that the 3D printed parts demonstrate the appropriate mechanical properties for normal use.

Once implemented, the risk posed by the hazardous situations can be re-estimated. In both cases, after implementing the specified risk control measures, the likelihood of occurrence of harm decreased. The re-evaluation of risk is shown in Table 4.7.

Table 4.7: Risk re-estimation and re-evaluation of the two chosen failure modes following the implementation of the risk control measures.

Hazardous situation	**Severity**	**Likelihood**	**Risk evaluation**	**Acceptability**
Heavy object slips from grasp	Serious	Remote	Low	Acceptable
Object slips from grasp	Minor	Occasional	Low	Acceptable

For both failure modes, the remaining risk is evaluated as ‘low’. It was decided early in the RM process that this level of risk is considered acceptable, and as such this decision is documented in the RM file.

It can be seen from this brief exploration into ISO 14971 RM that this procedure is a valuable way to iteratively reduce the risk associated with a medical device. Performing RM can significantly decrease device risks, especially if implemented early on in the design process.

The importance of the document '3D printing and fabrication guide' (recommended by this open source plan) is further demonstrated by this example. Failure of the 3D printed parts is identified as a significant failure mode of the prosthesis by the FMEA. The best way to decrease the probability of occurrence of this hazardous situation is to implement and follow a guideline for printing these parts. This guideline is essential for the safety and efficacy of the final prosthesis.

4.7.5 Contribution guide

The purpose of a contribution guide is to document the ways in which individuals can contribute to the project to improve the readiness level of the design. The recommended technical improvements for the ADL arm are discussed in detail in the 'Design Validation' and 'Results and Discussion' Sections that follow. It is expected that improvements that have yet to be made by the time that the device is deemed ready to enter the public domain should be included in this document.

Beyond technical improvements, it is suggested that changes are made to improve the 'open-ness' of the design. Examples of such changes include:

- Recreate the CAD files in open-source CAD software such as FreeCAD, OpenSCAD or Onshape.
- Redesign the elbow mechanism such that the ADL arm is no longer considered to be devived from the UnLimbited Arm.
- License the ADL arm under an appropriate OSHW licence.

Chapter 5

Design Validation

This chapter details the validation of the developed prosthesis. The ADL arm is validated using two procedure types: a functional assessment and a simulated-use assessment.

5.1 Functional Assessment

The functional capabilities of a prosthetic device can be tested in several ways. Commonly used protocols include the Southampton Hand Assessment Procedure (SHAP), Box and Block Test (BBT), and the Minnesota Manual Dexterity Test (MMDT). These tests primarily measure the manual dexterity of the prosthetic hand and, as such, its ability to perform precise movements (Makofske, 2011). The Anthropomorphic Hand Assessment Protocol (AHAP) assesses the functionality and level of anthropomorphism of a prosthesis (Llop-Harillo et al., 2019). This assessment is advantageous as the functional and cosmetic qualities of a prosthesis are well known to contribute towards a more positive psychological state of an amputee. The AHAP also uses an object set that is simple and inexpensive to replicate. The AHAP is thus used to functionally validate the ADL arm.

5.1.1 Anthropomorphic Hand Assessment Protocol

AHAP aims to reliably measure the grasping ability of anthropomorphic hands. In this case, grasping ability is defined as the hand's ability to effectively grasp and maintain a stable grip on an object while the arm moves around (Llop-Harillo et al., 2019). AHAP is a valuable tool for prosthesis validation because it uses a standardised object set, evaluates both functionality and human-likeness of grasp execution, and can be used to evaluate a range of hand prostheses with differing actuation and control mechanisms (Llop-Harillo et al., 2019). The objects used in the protocol form part of the Yale-CMU-Berkeley (YCB) standardised object set, ensuring the protocol's repeatability.

As results, the testing protocol gives:

1. A total Grasping Ability Score (GAS): which quantifies the hand's ability to perform the full set of grasps.

2. A partial GAS: which quantifies the hand's ability to perform each specific grasping task.
3. A qualitative indication of the advantages and disadvantages of the hand, its control mechanism, and its actuation mechanism.
4. A starting point to identify the reasons for failed tasks/grasps. The protocol is designed to identify difficulties experienced with grasping and a classification thereof.

The protocol consists of 26 tasks and uses ten grasp types associated with performing ADLs (Vergara et al., 2014). Eight of the ten grasps have three variations in object size, weight, and surface properties. Table 5.1 (Feix et al., 2016; Llop-Harillo et al., 2019) presents the AHAP grasps and GRASP taxonomy equivalents. A visual representation of the 26 AHAP tasks can be found in Appendix C.

Table 5.1: AHAP tested ADL grasp shapes and GRASP taxonomy equivalents.

AHAP Grasp Shape	**GRASP Taxonomy Equivalent**
Hook	Medium Wrap/Fixed Hook
Spherical Grip	Sphere 4-finger
Tripod Pinch	Tripod
Extension Grip	Parallel Extension
Cylindrical Grip	Medium Wrap/Large Diameter
Diagonal Volar Grip	Adducted Thumb
Lateral Pinch	Lateral Grasp
Pulp Pinch	Prismatic 3-finger
Index Pointing/Pressing	Index Finger Extension
Platform	Non-prehensile

The grasp shapes tested in the protocol represent those required for one-handed (unimanual) and two-handed (bimanual) ADL activities. AHAP is thus more extensive than required by this research. The full protocol is, however, used to assess the ADL arm as insights regarding improvements for future device iterations will be gained. Such insights will come from the fourth type of result, previously listed, given by the testing protocol.

For each of the 26 objects in the set, a number of steps are performed as part of the procedure. A trained operator (the author) instructs the participant to carry out each step. A summary of these are:

1. The operator shows the participant the object and the correct posture to grasp the object.

2. The participant practises the task/grasp for one minute.
3. The operator passes the participant the object.
4. The participant uses the prosthetic hand to grasp the object with the palm facing upwards. The operator releases the object immediately once it has been grasped. The participant maintains the grasp for three seconds.
5. The participant slowly rotates the hand while maintaining the grip of the object, until the palm faces downwards (180 ° rotation). The participant maintains the grasp for three seconds.
6. The participant releases the object.

Each grasping task consists of two parts: grasp (step four) and maintain (step five). For the grasp portion, a score of 1 is given for a successful grasp of the correct grasp type, 0.5 if the grasping posture differs from the specification, and 0 if the prosthesis cannot grasp the object. For the maintain portion, a score of 1 is awarded if there is no observable object movement during hand rotation, 0.5 indicates visible object movement but it is not dropped, and 0 if the object is dropped during motion. The definition of grasp success differs per grasp type. Appendix D presents descriptions of each grasp's conditions for success. Partial (per grasp type) and total GAS are obtained by normalising with respect to the total possible number of points. A score of 100 % is the best-case scenario and corresponds to functionality and anthropomorphism similar to that of a healthy human hand.

Not all AHAP tasks are representative of those used in bimanual ADLs. A subset of the required tasks using grasps identified in Section 2.2.1 – medium wrap, adducted thumb, lateral grasp, index finger extension, and non-prehensile – are used as a measure for device success. Of the 11 tasks using these grasps, a score of at least 1 must be achieved for each of the five grasp types specified. That is to say that at least one object per grasp type, and not necessarily all object variations, must be grasped successfully. Additionally, the grasp must be maintained on at least one object during the movement part of testing. If the results meet these criterion, the device will be considered a success at this stage. Once the device's grasping ability has been verified, it will be assessed for its ability to assist in bimanual ADLs.

5.2 Simulated Use Assessment

Simulated use testing of the ADL arm is performed in two stages. In the first stage, the device is tested for its ability to assist in ADLs. In the second stage, the overall device usability is assessed.

5.2.1 ADL Assessment

A number of protocols are used to assess a patient's ability to perform ADLs. Typically these are used to gauge how much assistance a patient requires and what the most appropriate living arrangement for the patient will be. Mlinac and Feng (2016) suggest that the six most common assessment tools for measuring ADL performance are: the Katz Index, the PSMS (Physical Self-Maintenance Scale), Lawton and Braby IADL scale, the Barthel Index, the OARS (Older Americans Resources and Services) questionnaire and the FIM (Functional Independence Measure). In addition to these, the DASH (Disabilities of the Arm, Shoulder and Hand) and OPUS-UEFS (Orthotics and Prosthetics User Survey - Upper Extremity Functional Status) measures provide indications of upper limb physical function in performing ADLs (Luchetti et al., 2015). By analysing and consolidating these various scales and assessment tools, an ADL/IADL task list is developed.

The consolidated task list is a self-report questionnaire which allows the user of the prosthesis to quantify the usefulness of the prosthetic device for performing a range of ADL and IADL tasks from each category. The questionnaire is designed to measure:

- If the task can be performed without assistance.
- If the prosthesis was used in performing the task.
- The grasping role (direct/indirect/passive) of the prosthesis.
- The perceived difficulty experienced when performing the task.

In a direct grasp, the object is grasped directly by the prosthesis; in an indirect grasp, the object is placed into the prosthesis' grasp by the healthy hand; and in a passive grasp, the prosthesis is used to carry, support or push/shove during the task (Van Lunteren et al., 1983). The ADL assessment self-report questionnaire can be found in Appendix E.

One healthy participant, the author, will conduct the ADL assessment of the ADL arm. The author is the individual who is most familiar with the device and as such is the user who will be the best estimate of someone who is trained to use the ADL arm.

The testing procedure is as follows:

1. Prepare.
    - The participant spends two minutes familiarising themself with the questionnaire.
    - The participant ensures all required objects are available/easily accessible.

- The participant ensures that a proxy is available to assist with a task if need be.

2. The participant dons the ADL arm.
3. The participant performs a task from the list.
    - The participant asks for assistance if needed.
4. The participant completes the questionnaire for the current task.
5. Repeat steps 3 and 4 until no tasks remain.
6. The participant doffs the ADL arm.

Once the ADL testing of the device is complete, the device must be tested for its usability.

5.2.2 Usability Assessment

System usability is assessed using six healthy participants in the laboratory setting. The usability assessment is performed by three categories of participant: those with no familiarity with the device; those with theoretical experience with the device; and those who were involved in the testing of prototype one. It is important to measure the usability of the device to validate the quality of the user experience when using the prosthesis. This is done to ensure all measures can be taken to effectively and efficiently satisfy the end user.

The procedure followed by each participant is as follows:

1. The operator explains the testing procedure.
2. The operator demonstrates the tasks to be completed by the participant.
3. The operator wraps the participant's left hand to simulate the experience of having an amputation.
4. The participant performs the specified activities with their dominant hand and 'stump'.
5. The participant unwraps their left hand.
6. The participant dons the ADL arm.
7. The participant is allowed two minutes to familiarise themselves with the device and practise grasping objects.
8. The participant uses the ADL arm to perform the specified activities. These include:
    (a) Pick up the chips can, engage the cable lock and simulate eating.
    (b) Pick up the water bottle, open the lid and simulate drinking.

   (c) Pick up the apple, rotate the wrist and simulate peeling/cutting.
   (d) Hold the newspaper and simulate reading.
   (e) Fold the towel.
   (f) Pick up the 5 l bottle with two hands.
   (g) Grasp the toothbrush and apply toothpaste.

9. The participant doffs the ADL arm.
10. The participant completes the System Usability Questionnaire.

The chosen set of activities require each participant to use the full range of functionality of the ADL arm. Utilised functionality includes:

- Wrist rotation.
- Thumb rotation.
- Engage and disengage the cable-lock mechanism.
- Grasp object directly, indirectly and passively.
- Grasp objects with differing shapes/sizes/surface qualities.
- Don and doff the prosthesis.

Using the full range of functionality of the device allows a fair assessment of the device's usability. System usability is scored according to the System Usability Scale (SUS) (Brooke, 1996). The SUS questionnaire, which provides a quantitative measurement of device usability and user experience, can be found in Appendix F. Scoring of the SUS is as follows (Brooke, 1996):

- For odd numbered questions, subtract 1 from the user given score (1-5) – giving a score of $0 - 4$.
- For even number questions, subtract the user given score (1-5) from the number 5 – giving a score of $0 - 4$.
- Sum the responses and multiply the result by 2.5 to obtain a score out of 100.

It should be noted that the resulting number is not a percentage. A study by Bangor et al. (2008) found that the average SUS score is 68, while anything above 68 is considered above average. A 'good' score is one larger than 72.75, an 'excellent' score is larger than 85.58 and the 'best imaginable' score is 100. The obtained SUS will be evaluated against this scale.

Chapter 6

Results and Discussion

To validate the developed below-elbow prosthesis, the physical properties of the device, and its ability to function for its intended use, must be assessed. Prior to collecting any user data, ethics approval was granted by the UCT Human Research and Ethics Committee. The ethics approval letter can be found in Appendix G.

6.1 Physical and Mechanical Properties

The physical and mechanical properties of the ADL arm are evaluated on a subsystem basis. Following this, the manufacturability of the device is investigated.

6.1.1 Hand Subsystem

A number of metrics are used to evaluate the HS. These are: the mass of the TD, the ROM of the digits, wrist and thumb, the achievable grasp diameter and the grip force producible in the hand. According to literature, the mass of the terminal device must not exceed 364 g (Cuellar et al., 2018; Kay & Rakic, 1972). This corresponds to one standard deviation less than the average hand mass. The hand TD of the ADL arm is measured to weigh 104 g.

The ROM of the digits and thumb determine the size and shape of object that can be grasped by the ADL arm. The ROM of the rotating thumb informers what grasp shapes can be achieved. The ROM of the wrist facilitates favourable positioning to grasp objects and the manipulation of objects that are within the hand's grasp. The ROM of a digit is analysed at both the proximal and the distal joints. These correspond to the metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joints in the natural hand. The measured ROM of the components of the HS are presented in Table 6.1 below. The ROM of the digits informs the achievable grasp diameter. The measured grasp diameter of the designed hand is 114 mm.

The combination of appropriate digit kinematics, a reasonable grip force, and a high friction grip surface enable a hand TD to securely grasp a range of objects. The grip force of the TD is measured using a hand grip dynamometer. The shape of the dynamometer

Table 6.1: ROM results for the HS compared to the ROM of the healthy hand (Hume, Gellman, Mckellop, & Brumfield, 1990).

Component	Description	Device ROM (°)	Healthy ROM (°)
Digit	PIP	0-112	0-120
	MCP	0-90	0-90
Thumb	PIP	0-80	0-90
	MCP	0-95	0-70
Swivel thumb	Adduction	30-0	40-0
	Abduction	0-60	0-50
Wrist	Pronation	0-85	0-90
	Supination	0-76	0-90

necessitates this reading to be taken in the medium wrap grasp shape. The setup for this measurement is shown in Figure 6.1. The HS's maximum achievable grasp force is 36.3 N.

Figure 6.1: Experimental setup for measuring the grip force of the TD using a hand grip dynamometer.

Discussion

The ROM of the designed TD is comparable to the healthy hand. The achievable ROM allows the hand to mimic the kinematics of the healthy hand, allowing it to securely grasp objects of a range of sizes, weights and surface qualities. The swivel thumb can achieve the full range of adduction and abduction of the healthy hand. This allows the hand to perform grasps such as lateral pinch and medium wrap, which require the thumb to be in

the adducted and abducted positions, respectively. The achievable wrist pronation allows the hand to be rotated such that directly grasping objects on a surface is possible. Once a secure grasp has been achieved, the wrist can be rotated to the supinated position for the user to have better visualisation of and access to the object.

According to Weir et al. (2009), most ADLs require a prehensile forces in the range of $0 - 67\ N$. This value depends on the coefficient of friction between the object at the gripping surface of the hand (Weir et al., 2009). No distinction is made between unimanual and bimanual activities. The ADL arm's achievable grip force of 36.3 N falls in the middle of this range. Further practical testing must be done to establish if the designed grip force and gripping surface are suitable for performing bimanual ADLs.

6.1.2 Actuation Subsystem

The AS is evaluated by measuring the force that can be produced by the elbow mechanism and the effectiveness of the cable lock in preventing slip of the actuation cord. To measure these two metrics, the prosthesis is disassembled and set up in the testing configuration as shown in Figure 6.2. The force is measured using a hanging fish scale with a 5 g resolution.

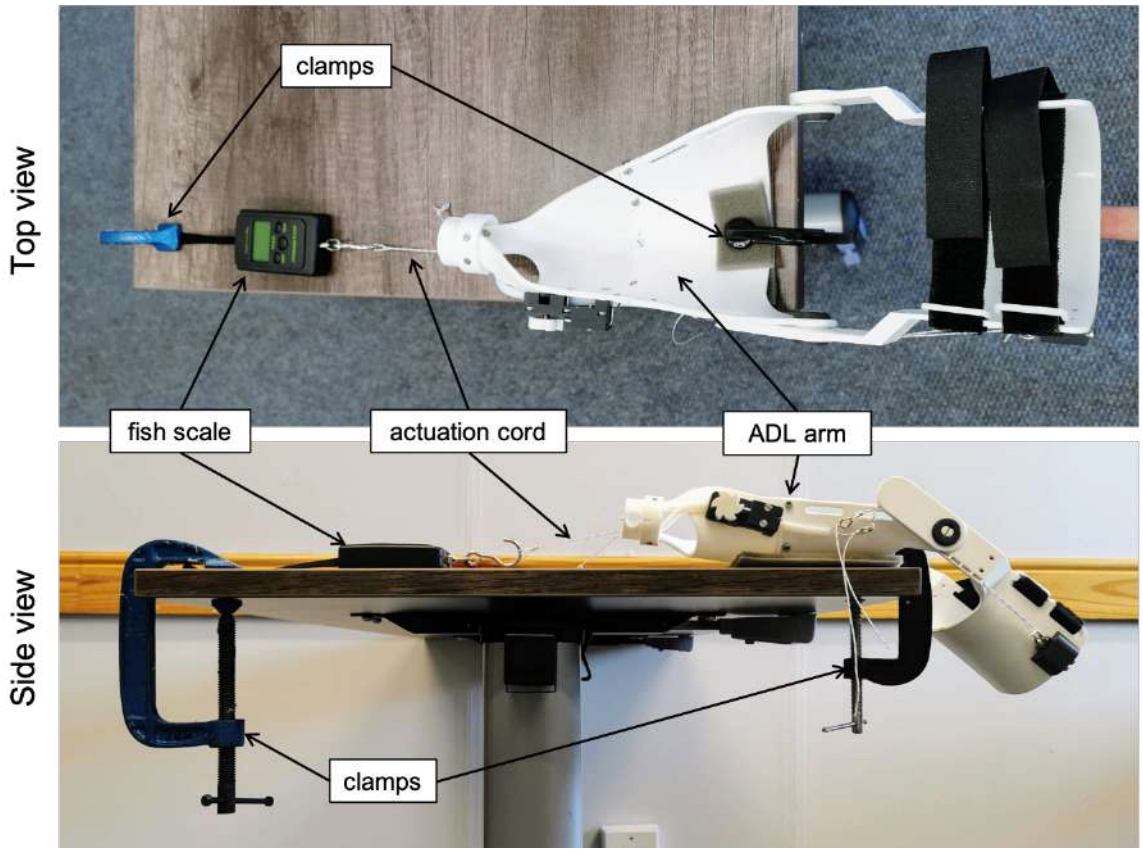


Figure 6.2: Experimental setup for measuring the force producible by the AS and the maintaining force of the cable lock.

To measure the achievable tensile force, the elbow mechanism is flexed from the fully extended position to the angle of maximum flexion. This angle is determined by the tensioning of the primary actuation cord, where the maximum achievable angle corresponds to a point where the elbow mechanism remains intact but shows signs of stress. This condition is shown in Figure 6.3. The force measurement is taken five times and averaged. The elbow mechanism is found to produce 42.63 N of tensile force in the actuation cables.

Figure 6.3: The stopping condition is where the elbow mechanism (viewed here from above) shows signs of stress but remains intact.

The effectiveness of the cable lock is measured by applying tension to the actuation cables when the cable lock is engaged. The maximum force that the system can withstand without the cable slipping is considered the upper threshold that the cable lock can maintain. The average maintenance force of the cable lock system is 58.42 N.

Discussion

The elbow mechanism is able to produce approximately 43 N of tensile force to transmit to the hand. The producible tensile force and the grip force measured in the hand are not the same. This may be due to the shape of the hand TD and the hand grip dynamometer not being suitable for accurate measurement. Another reason for the discrepancy may be loss of energy because of friction within the digits, or simply that the transmission of cable tension to grip force is not a 1:1 ratio. The force ratio between the AS and HS is roughly 7:6.

It became apparent during testing that the design of the elbow hinge was a limiting factor

to how much force the elbow mechanism could produce. If more force was applied than the stopping condition in Figure 6.3, the outer stopper would fall off and the humeral cuff may detach from the forearm cuff. Modifications should be made in the design of the elbow hinge and the cable alignment to remedy this problem in future iterations.

The cable lock maintenance force is sufficient for this design as it exceeds the maximum producible tensile force in the actuation cables. During AS testing, one of the tensioner pins broke. This is noted to be a flaw in the fabrication of this element and could be remedied by changing the print orientation of the tensioner pin parts.

6.1.3 Suspension Subsystem

Assessing the effectiveness of the SS is challenging as this is a subjective matter. The comfort and stability of the SS are directly dependent on the device sizing and the post print thermoforming process. One metric that can be measured is the average time taken to don and doff the prosthesis. This is measured during the usability assessment of the device detailed in Section 6.3.2. In this testing procedure, seven participants donned, tested and doffed the prosthesis. The average times taken to don and doff the prosthesis are 13.3 and 6.73 seconds, respectively.

Discussion

It was noted during testing that the time taken to don the prosthesis was highly dependent on the clothing item worn by the test subject. Participants who were wearing long sleeved clothing items took notably longer to don the prosthesis than those who were not. This is, however, an inconsequential amount of time, considering that the prosthesis may be worm for several minutes or hours at a time.

6.1.4 Manufacturability

The manufacture of the ADL arm requires: the purchase of materials, the fabrication of 3D printed parts and the assembly of the prosthesis. The bill of materials (BOM) for the ADL arm can be found in Appendix H, Table H.1. Once the materials have been purchased the parts must be 3D printed.

3D Printed Part Fabrication

The ADL arm was fabricated using a *Creality Ender 3 Pro* FDM 3D printer, and two variations of *FormFutura* 1.75 *mm* filament – *Easyfil PLA* and *TitanX*. A summary of the

time and costs associated with fabricating the 3D printed parts is presented in Table 6.2. A more detailed version can be found in Table H.2 of the Appendix. All print-time and filament-usage values are estimates found by importing the STL files into *PrusaSlicer* slicing software, and preparing the print.

Table 6.2: Summary of the time and costs associated with the fabrication of the 3D printed parts.

Subsystem	**Number of parts**	**Estimated print time (hours)**	**Used filament (g)**	**Estimated filament cost (R)**	**Estimated electricity cost (R)**	**Estimated operation costs (R)**	**Total cost (R)**
Hand	23	27.02	154.94	92.96	13.51	31.34	137.81
Actuation	12	3.28	18.08	10.85	1.64	3.81	16.30
Suspension	13	16.40	172.38	119.88	8.20	19.02	147.10
Totals		46.7	345.4				**301.21**

Between the subsystems, a total of 48 parts must be printed. The total print time, excluding the time taken to heat up the print bed and nozzle, and to cool the bed to remove the print, is 46 h 42 m. The total amount of filament required is 345 g, of which approximately 164 g is PLA, and 181 g is ABS. Estimating the associated fabrication costs involves summing the material, electricity and operation costs. The material costs are calculated using the current price (March 2021) of *FormFutura* filament on BuildVolume3D's website (BuildVolume, 2021b).

The electricity costs are estimated based on the unit price per kilowatt hour (kWh) charged by the City of Cape Town, and the average measured power consumption of the *Ender 3* while printing TitanX (high temperature) filament. The power consumption is measured using a *Sonoff Pow R2* Energy monitoring WiFi switch (pictured in Figure 6.4 (Sonoff, 2020)). The average electricity cost is found to be R 0.5/h. To calculate the estimated operation costs, a fixed cost is added per hour of printing. This amount is equal to the cost of the 3D printer, if it were to be completely paid off in six months. The total cost of the 3D printer, R 5 099, is divided by the number of hours in 6 months, 4392, to yield an operation cost of R 1.16/h (BuildVolume, 2021a).

Device assembly

Assembly of the ADL arm requires an able-bodied individual with a small number of basic tools. These include: a pair of side cutters, a screwdriver, a pair of pliers, a small file, a box cutting or craft knife, and a tube of superglue. Before assembly can take place, the 3D printed support material must be removed. Any rough edges should be trimmed or sanded so that the parts articulate smoothly with respect to one another.

Figure 6.4: The Sonoff Pow R2 energy monitoring WiFi switch.

The two forearm cuff halves should be attached together, and the cable lock housing base should be attached, prior to moulding the forearm and humeral cuffs. Once the parts are moulded, all parts can be assembled with the appropriate hardware listed in the BOM. Once the device has been assembled, the actuation cords should be tensioned to meet the requirements of the user.

The total price of additional hardware used to assemble the ADL arm is R 329. This results in the total price of manufacture of the ADL arm, without labour, being R 630. Even without the inclusion of labour, this price is significantly less than a subsidised cosmetic below-elbow prosthesis which costs in the range of R 10 000.

6.2 Functional Testing

Functional testing of the ADL arm is done using the AHAP protocol described in Section 5.1. For each grasp type, three iterations of the grasp and maintain procedures were performed. The full set of results obtained during testing are presented in Appendix I. In accordance with AHAP, the GAS is an indicator of the proficiency of the hand to perform the full set of grasping tasks. The GAS of the ADL arm is found to be 68 %. The device scored 67.3 % and 68.7 % in the grasp and maintain categories respectively. The normalised partial GASs for the ADL arm are shown in the chart in Figure 6.5 below. Grasps identified as bimanual ADL grasps are shown in green, while the remainder of grasps are shown in orange. The results are explored with respect to each GT in the sections that follow.

6.2.1 Hook

The hook grasp – a variation of medium wrap – is essential for performing bimanual ADLs. The hook grasp is correct if contact is made between the object and the palmar

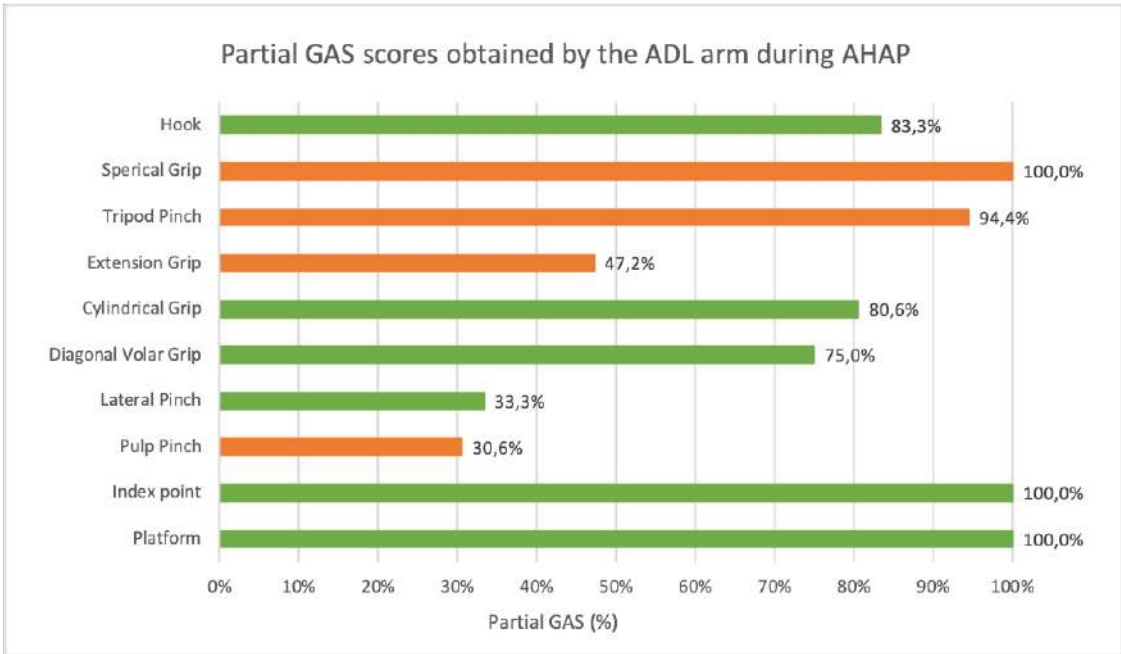
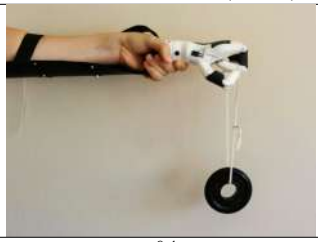


Figure 6.5: Partial GAS scores obtained by the ADL arm during functional testing using the AHAP.

side of at least three fingers. The results obtained for the hook GT are show in Table 6.3.

Table 6.3: Results obtained by the ADL arm for the hook GT of the AHAP.

Object	**Skillet lid (T1)**	**Pitcher base (T10)**	**Weight & rope (T19)**
Task			
Grasp	100 %	100 %	50 %
Maintain	66.7 %	100 %	83.3 %
Partial GAS		83.3 %	

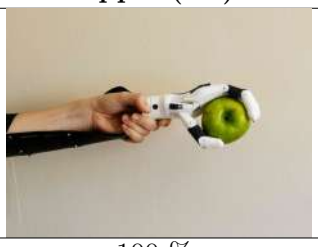
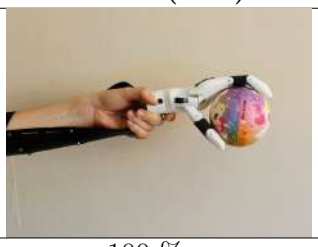
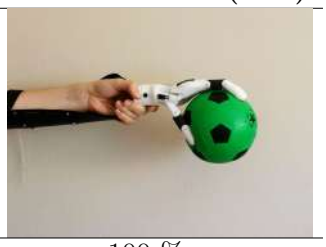
The ADL arm achieved an average score of 83.3 % in both grasping and maintaining for the hook grasp tasks. The hand successfully grasped the skillet lid and pitcher base in all three trials, while in all three rope and weight trials, the grasp was not considered a success as the rope wrapped around the palm rather than against the palmar side of the fingers. In two of three maintain tasks involving the skillet lid, the object moved during hand rotation, but was not dropped. This may be as a result of uneven weight distribution of the object, insufficient grasp force of the TD or insufficient friction between the hand and the object.

To improve the stability of grasp, the grip force can be increased by adjusting the tension pins in the tensioner box or changing the surface material in contact with the object – the grip element. A grip element with a larger coefficient of friction or that is more compressible will increase the surface area in contact with the object, improving the grasp.

6.2.2 Spherical Grip

Spherical grasp is considered correct if the object is in contact with the palmar side of the thumb, at least three fingers and the palm. Table 6.4 shows the results obtained for the spherical grip GT.

Table 6.4: Results obtained by the ADL arm for the spherical grip GT of the AHAP.

Object	**Apple (T2)**	**Softball (T11)**	**Mini soccer ball (T20)**
Task			
Grasp	100 %	100 %	100 %
Maintain	100 %	100 %	100 %
Partial GAS		100 %	

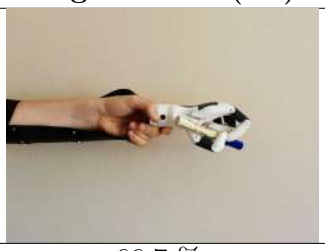
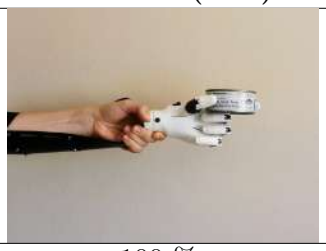
The ADL arm scored particularly well in both the grasp and maintain portions of the spherical grip tasks. The objects had surface textures with low and high friction coefficients, ranged in size from small to fairly large and had a range of weights. The grasp diameter and grip characteristics of the hand were sufficient to grasp and maintain these objects correctly in all trials. The partial GAS for the spherical grip GT was 100 %. In this test, the object diameter and mass were inversely proportional. In future testing, it may be valuable to test this GT with a large diameter object with a larger mass than the mini soccer ball.

6.2.3 Tripod Pinch

The tripod pinch GT is considered successful if the object is in contact with the radial side of the middle finger, and the palmar sides of the distal segments of both the thumb and index fingers. The results of the tripod pinch GT are presented in Table 6.5.

The ADL arm experienced difficulty grasping the large marker correctly – in two of three trials. The kinematics of the index finger and thumb, and the fact that the thumb is not

Table 6.5: Results obtained by the ADL arm for the tripod pinch GT of the AHAP.

Object	**Large marker (T3)**	**Tuna can (T12)**	**Golf ball (T21)**
Task			
Grasp	66.7 %	100 %	100 %
Maintain	100 %	100 %	100 %
Partial GAS		94.4 %	

coupled with the fingers in the underactuation mechanism, is assumed to be the reason for this failure. During grasp, the distal segment of the thumb would continue to flex at the distal joint when it came in contact with the marker (rather than applying force to the marker with its palmar side). With the tip of the thumb in contact with the marker, the grasp was considered incorrect. Once the marker was grasped, however, the grasp could be maintained, yielding a score of 100 % for the maintain trials of this task.

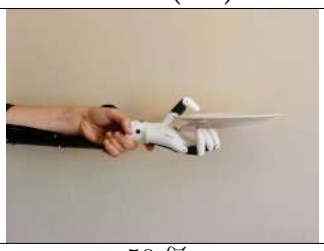
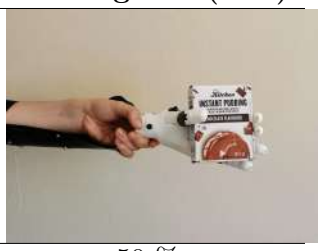
The ADL arm did not have difficulty grasping the tuna can or the golf ball correctly, nor did it have difficulty maintaining these grasps. The overall GAS for the tripod pinch GT was 94.4 %.

6.2.4 Extension Grip

A correct extension grip posture involves contact between the object, and the palmer side of the thumb and distal segments of at least three fingers. In this grasp it is important that the angle between the object's primary axis and the plane of the distal finger segments is less than 30 °. For box-shaped objects, the palmar side of the thumb and fingers must be opposite one another, and must be in contact with the side of the box with the largest area. The results obtained by the ADL arm for this GT are shown in Table 6.6.

The ADL arm is unable to perform the extension grip correctly. This is a flaw of the design, where the grasp kinematics do not allow much, if any, grip force to be generated while the digits's distal joints are in extension. In both the plate and cracker box tasks, the object could be gripped but the angle between the plane of the distal finger segments was greater than 30 °in all trials. In the pudding box trial, the grasp could only be achieved with the digits in contact with the side of the box with a smaller area. The overall grasp score for extension grip was thus 50 %.

Table 6.6: Results obtained by the ADL arm for the extension grip GT of the AHAP.

Object	**Plate (T4)**	**Crackers box (T13)**	**Pudding box (T22)**
Task			
Grasp	50 %	50 %	50 %
Maintain	0 %	33.3 %	100 %
Partial GAS		47.2 %	

The lack of secure grasp resulted in the objects being dropped in all three maintain trials of the plate, and two of three maintain trials of the cracker box tasks. The grasp could be maintained on the pudding box in all cases due to the lightweight nature and small size of the object. The difficulty in performing the extension grip GT is evinced by its low partial GAS of only 47.2 %.

6.2.5 Cylindrical Grip

The cylindrical grip is another GT that is important in performing bimanual ADLs. The GRASP taxonomy equivalents of this GT are medium wrap and large diameter grasp. This grip is considered mostly equivalent to the hook grip, differing in that the wrist is in the neutral, rather than pronated, position; changing the direction of the gravitational force vector on the object.

A successful cylindrical grasp involves contact between the object and the palmer sides of the thumb, at least three fingers and the palm. Additionally, the the angle between the main axis of the thumb and the and the main axis of the object's grip surface must be more than 60 °. Table 6.7 shows the ADL arm's results for this GT.

Much like with the hook grip, the ALD arm performed well in the cylindrical grip tasks scoring a partial GAS of 80.6 % overall for the GT, and 100 % and 61.1 % in the grasp and maintain trials, respectively. The main reason for the hand's poor performance in the maintain portion was the task involving the electric drill. The drill available for testing with was significantly heavier than the object specification in the YCB object set. The drill is measured to weigh 1323 g, rather than the specified 895 g.

The nature of the 3D printed parts is weakness when it comes to grasping heavy objects. To improve the stability of the grasp on the object the prosthetic wrist would need

Table 6.7: Results obtained by the ADL arm for the cylindrical grip GT of the AHAP.

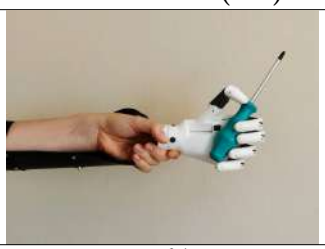
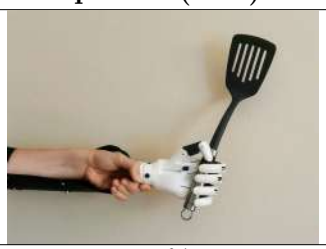
Object	**Chips can (T5)**	**Coffee can (T14)**	**Power drill (23)**
Task			
Grasp	100 %	100 %	100 %
Maintain	100 %	66.7 %	16.6 %
Partial GAS		80.6 %	

to be further reinforced to support the shear force experienced. In addition to this, an improvement in the hand's grip strength would improve the stability of grasp – the object would be less likely to move during hand movement. The mass of the coffee can as well as its smooth surface texture is assumed to be the reason that it was dropped during one of three maintain trials. Cleaning the silicone tape between the first and second trials showed a marked improvement in the hand's ability to maintain grasp on this object.

6.2.6 Diagonal Volar Grip

The GRASP taxonomy equivalent of the diagonal volar grip is adducted thumb. Adducted thumb grasp is identified as essential for performing bimanual ADLs. To perform a successful diagonal volar grip the object must be in contact with the palmar side of the thumb, at least three fingers and the palm. The angle between the the axis of the thumb segments and the symmetry plane of the object must be less than 30 °. The results for the diagonal volar grip GT are presented in Figure 6.8.

Table 6.8: Results obtained by the ADL arm for the diagonal volar grip GT of the AHAP.

Object	**Screwdriver (T6)**	**Spatula (T15)**	**Skillet (T24)**
Task			
Grasp	50 %	50 %	50 %
Maintain	100 %	100 %	100 %
Partial GAS		75 %	

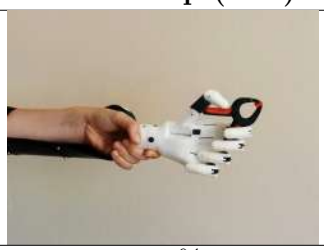
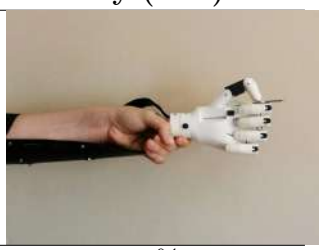
Much like extension grip, the ADL arm was unable to correctly form the diagonal volar

grip GT. In both cases, the reason for this failure is the kinematics of the digits. Increasing tension in the actuation cord caused the thumb to flex at the distal joint rather than causing the palmar side of the the distal segment of the thumb to apply pressure on the object. Unlike with extension grip, this did not prevent the hand from grasping each object securely. This is evinced by the resulting score of 100 % for the maintain trials on average. The hand could grasp the objects, as well as maintain grip on them, indicating that the partial GAS of 75 % for this GT is more of an indicator of lacking anthropomorphism in this GT rather than functional performance.

6.2.7 Lateral Pinch

The lateral pinch, or lateral grasp, GT is another of the five grasps required for successful performance of bimanual ADLs. In the correct lateral pinch posture, the object is in contact with the palmar side of the distal segment of the thumb and the radial side of the index finger. Table 6.9 shows the AHAP results for the lateral pinch GT.

Table 6.9: Results obtained by the ADL arm for the lateral pinch GT of the AHAP.

Object	**Bowl (T7)**	**Small clamp (T16)**	**Key (T25)**
Task			
Grasp	33.3 %	33.3 %	50 %
Maintain	0 %	66.7 %	16.7 %
Partial GAS		33.3 %	

Of the bimanual ADL grasps, the device performed worst in this GT. In only the key task was the ADL arm able to grasp the object in all three grasp trials. For the bowl and clamp tasks, the object was dropped during the grasp part in one of three trials. The device was best at maintaining grasp on the clamp, with the object not being dropped once it was grasped in both cases. The performance was, however, poor overall. The ADL arm achieved a grasp score of 38.9 % and a maintain score of 27.8 %. The partial GAS for the lateral pinch GT was 33.3 %.

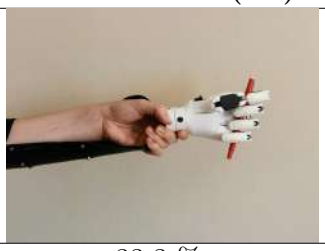
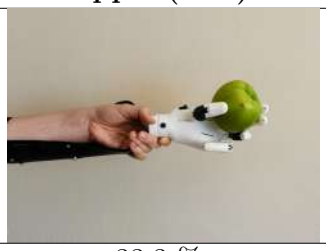
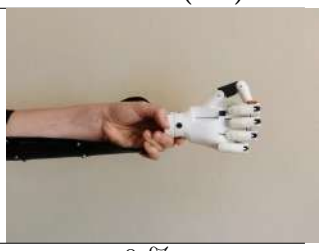
The poor performance in this GT shows a major flaw in the design of the thumb. As with diagonal volar grip and extension grip; flexion of the thumb at the distal joint plays a role in preventing the thumb from applying sufficient force to the object to perform a secure grasp. To remedy this problem it may be necessary to change the position of the

cord fixation point in the distal thumb segment, to include a mechanism to lock the distal segment for certain grasps, or to remove the distal joint all together – having rather only a single thumb segment.

6.2.8 Pulp Pinch

For the pulp pinch GT to be considered correct, the object must be in contact with the palmar side of the distal segments of the thumb and index finger, without any contact with the palm. The results obtained for the pulp pinch GT are presented in Table 6.10.

Table 6.10: Results obtained by the ADL arm for the pulp pinch GT of the AHAP.

Object	**Small marker (T8)**	**Apple (T17)**	**10c coin (T2)**
Task			
Grasp	33.3 %	33.3 %	0 %
Maintain	66.7 %	50 %	0 %
Partial GAS		30.6 %	

The ADL arm cannot successfully perform the pulp pinch GT. Much like with the other GTs that yielded unsatisfactory results, the kinematics of the digits are at fault. A pinching action requires the digit to flex at the proximal joint while the distal joint remains in extension. This type of movement is necessary for opposing forces to be produced between the palmar sides of the thumb and index fingers – pad opposition (see Figure 2.5). There is no mechanism in place to achieve this type of movement in the ADL arm. The average grasp and maintain scores for the pulp pinch GT were 22.2 % and 38.9 %, respectively. The pulp pinch partial GAS was 30.6 %.

6.2.9 Index Point / Platform

Both index point and platform are grasps identified as necessary for bimanual ADLs. Their GRASP taxonomy equivalents are index finger extension and non-prehensile grasp, respectively. A successful index point involves contact between the object and the palmar side of the distal segment of the index finger; and results in the starting of the timer. In a correct platform grasp, the object is in contact with the palm, and the angle between and fingers and the palm is less than 30 °. The results obtained by the ADL arm for these non-prehensile grasps are shown in Table 6.11.

Table 6.11: Results obtained by the ADL arm for the index point and platform GTs of the AHAP.

Object	**Timer (T26)**	**Plate (T18)**
Task		
Grasp	100 %	100 %
Maintain	100 %	-
Partial GAS	100 %	

The ADL arm was able to correctly start and stop the timer using the index point GT, as well as perform a correct platform GT to hold the plate. The device scored 100 % in the grasp, maintain parts resulting in a partial GAS of 100 %.

6.2.10 Summary

The results obtained for the functional testing of the ADL arm were mixed. The obtained results are summarised in Table 6.12. Grasps involving cylindrical objects of a range of diameters, weights and surface materials were mostly successful. The kinematics of the digits ensured that these objects could be grasped correctly and securely. This is evinced by their high grasp and maintain scores. In some GT's, such as diagonal volar grip, the digit kinematics prevented the hand from being able to perform a correctly shaped grasp, but did not prevent a secure grasp from being performed.

In most cases, the inability of the thumb to apply force with the palmar side of its distal segment resulted in poor grasp and maintain scores. A means to allow the thumb to perform pad opposition would greatly improve the hand's ability to perform lateral grip and diagonal volar grip. This would in turn improve the ADL arm's bimaual ADL grasp performing ability. A means to allow the remainder of the digits to apply force to objects with the pad of the distal segment would improve the hand's performance in the extension grip, tripod pinch and pulp pinch.

Table 6.12: Visual representation of the ADL arm V2's ability to perform the grasps in the AHAP protocol.

Grasp type (AHAP)	Grasp type (GRASP)	Objects and task order		
Hook	Medium wrap	✓ Skillet lid (T_{01})	✓ Pitcher base (T_{10})	✓ Wood blocks with rope (T_{19})
Spherical grip	Sphere 4-finger	✓ Plastic apple (T_{02})	✓ Softball (T_{11})	✓ Mini soccer ball (T_{20})
Tripod pinch	Tripod	✓ Large marker (T_{03})	✓ Tuna can (T_{12})	✓ Golf ball (T_{21})
Extension grip	Parallel extension	✗ Plate (T_{04})	✗ Cracker box (T_{13})	✗ Chocolate pudding box (T_{22})
Cylindrical grip	Medium wrap	✓ Chips can (T_{05})	✓ Coffee can (T_{14})	✓ Power drill (T_{23})
Diagonal volar grip	Adducted thumb	✓ Screwdriver (T_{06})	✓ Spatula (T_{15})	✓ Skillet (T_{24})
Lateral pinch	Lateral grasp	✗ Bowl (T_{07})	✗ XS clamp (T_{16})	✗ Key (T_{25})
Pulp pinch	Prismatic 3-finger	✗ Small marker (T_{08})	✗ Plastic pear (T_{17})	✗ Washer 10mm (T_{26})
Index pressing	Index finger extension	✓ Timer (T_{09})		
Platform	Non-prehensile	✓ Plate (T_{18})		

6.3 Simulated-use Testing

Simulated-use testing of the ADL arm was completed by seven healthy, right-hand dominant individuals. The designed bypass socket was used for this portion of testing. The bypass socket is pictured in Figure 4.18.

6.3.1 ADL Assessment

The ADL testing protocol, as described in Section 5.2.1, requires the author to don the prosthesis and perform a number of ADL and IADL tasks. The full set of captured results for this testing procedure can be found in Appendix J. The results obtained and a discussion thereof follows.

ADL Results and Discussion

Of the 49 ADL tasks in the questionnaire, only four task required assistance from the proxy. These were: open a tight jar (11), open and pour from a 2 l bottle (19), tie shoelaces (26) and groom nails (34). Difficulty was experienced in both opening tasks

due to insufficient grip force of the hand on the object. Both the jar and the bottle would rotate within the hand's grasp and the task could not be completed. This could be remedied by increasing the grip force of the hand, replacing the grip element with a material of a higher coefficient of friction or by using an assistive device for this purpose. With or without the prosthesis, tieing the shoelaces is a task that requires a high level of prehension in both hands. Purchasing shoes without shoe laces would be a suitable solution to this problem. Grooming the nails on the healthy hand would require assistance from either another person or a device specialised for this purpose.

Of the remaining ADL tasks, the highest perceived difficulty was associated with tasks in the feeding and dressing categories – this is in agreement with the literature (Ritchie et al., 2011; Cordella et al., 2016). Regarding feeding, using a knife and fork to cut food (8) was rated a 4, the highest difficulty prior to being unable to perform the task. The reason that this task was difficult was due to the narrow, flat handle of the fork. The fork was grasped indirectly and used to pierce and hold food while the dominant, knife-holding, hand was used to cut. Performing the task was frustrating as the grasp on the fork was not secure. It is recommended that specialised cutlery or devices designed to increase the diameter of the handle of the fork be purchased for use by amputees. Feeding tasks involving opening bottles and jars with tight lids were difficult. Improving the grip force of the TD will reduce the perceived difficult experienced in these tasks.

In the dressing category, most difficulty was experienced with buttoning a shirt with front buttons (28) and zipping a jacket (29). Both of these tasks are bimanual tasks that require a moderate level of prehension from both the dominant and non-dominant hands. Performing these tasks was possible, but frustrating. In the jacket zipping task, it is recommended that one side of the jacket must be grasped indirectly, the cable-lock must be engaged, and then the zip must be connected and zipped up. For the button-up shirt, it is recommended that the shirt is held in place by the prosthesis while the dominant hand locates and threads the buttons.

It is noted that for the majority of ADL tasks (approximately 66 %) the prosthesis was not used. This was either because the described task could be performed with one hand (26 %), it was more intuitive to use the dominant hand and residuum to perform the activity (26 %), or that the use of the hands was not required for performing the task (14 %). This is not to say that the ADL arm could not have been used for many of these tasks, had the need arisen. It simply implies that for many of the specified ADLs, it felt easier to not use the device.

IADL Results and Discussion

The ADL arm performed similarly well in the IADL tasks, with only three tasks requiring assistance from the available proxy. These tasks were: perform heavy housework (10), do garden work (28) and use a hammer and nail (36). Although the inability to perform these tasks unassisted could be inconvenient, they are not essential for personal autonomy.

Of the remaining IADL tasks, shopping independently for all purchases (13) and stirring in a bowl (15) were rated to have a perceived difficulty of 4. It is assumed that shopping independently implies that the user leaves their home, travels to the shops and purchases items. If the user were to do their shopping online, the perceived difficulty would be rated at a level 2. Stirring in a bowl is difficult because the digits of the ADL arm are in flexion when the device is close to the body at the average counter height. If a cable exclusion mechanism were to be implemented, this task would be less difficult. The bowl could be held against the body with the hand TD in the non-prehensile position, while the dominant hand could be used to stir.

The prosthesis was not used in approximately 43 % of the IADL tasks. Approximately 38 % of tasks required only one hand, while 5 % of tasks were easier to perform with the residual limb and dominant hand. Overall the ADL arm proved valuable in the performance of the ADL and IADL tasks. This implies that this device could be an asset to unilateral transradial amputees. Validating this result in amputee participants is required to confirm this result.

6.3.2 Usability Assessment

Usability testing took place over two days in the Anatomy Building at UCT Health Sciences Campus. Each of the seven healthy participants spent approximately $15 - 20$ minutes completing the testing protocol described in Section 5.2.2. Following testing, each participant was asked to complete a SUS to rate the usability of the system. The SUS questionnaire template can be seen in Table F.1 of the Appendix. The results of the usability assessment are presented in Table 6.13.

Table 6.13: SUS results obtained by seven participants using the ADL arm.

Level of experience	**Prior use**			**Prior theoretical**				**None**			**Overall SUS score**
Question	**1**	**2**	**Mean**	**3**	**4**	**5**	**Mean**	**6**	**7**	**Mean**	
1	4	4		4	4	5		3	4		
2	1	1		2	1	1		2	2		
3	5	5		4	4	4		4	4		
4	3	1		1	1	1		1	1		
5	5	5		5	5	5		4	4		
6	1	1		1	1	1		1	2		
7	4	5		4	5	5		5	5		
8	2	3		3	2	1		3	1		
9	4	4		2	4	4		2	3		
10	1	1		2	1	1		1	2		
Total score	85	90	**87.50**	75	90	95	**86.67**	75	80	**77.50**	**84.29**

The total scores for each participant were calculated as described in Section 5.2.2. With the SUS, a score of 68 is considered average, while a score greater than 72.75 is 'good' and a score greater than 85.58 is 'excellent' (Bangor et al., 2008). A visual representation of the scoring system is shown in Figure 6.6 (Smyk, 2020).

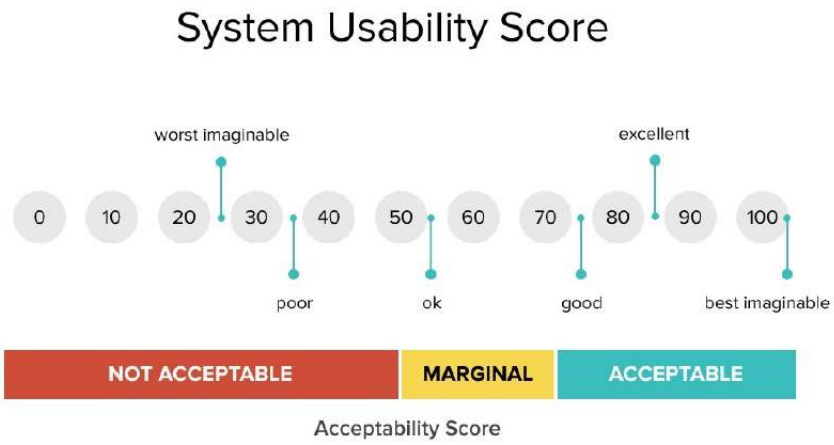


Figure 6.6: A visual representation of the scoring outcome of the SUS.

Three categories of participant, each with differing levels of familiarity with the ADL arm, performed the usability testing protocol. These were: prior use experience (participants were involved in the testing of V1); theoretical experience (participants knew of the device but have never used it); and no experience. Participants with prior use experience rated the device 87.5, prior theoretical experience rated the device 86.67, and no prior experience rated the device 77.5. These results imply that greater familiarity with the device leads to improved perceived usability. This finding could indicate that prosthetic

training may lead to lower prosthesis abandonment rates among amputees. The ADL arm achieved a mean usability score of 84.29, making it in the upper range of the 'good' category.

The obtained mean scores may not accurately represent the usability of the ADL arm. In situations where results data is not normally distributed, such as is the case for a usability assessment, a non-parametric analysis is preferred. Were there to be a larger number of participants, presenting the median and interquartile range would more accurately represent the obtained results. In this case, due to the small number of participants, the mean arguably presents a more easily understood and interpreted result. Additionally, a true SUS score would require the usability assessment protocol to be performed by transradial amputees. It is recommended that future iterations of the device be tested in the target population on a larger group of participants.

Chapter 7

Conclusions and Recommendations

The aim of this research was to design and experimentally validate an open-source prosthetic arm that is functionally optimised for the performance of activities of daily living in unilateral transradial amputees. To achieve this research aim, a number of objectives, as set out at the onset of the research, needed to be met. The primary objectives were:

1. Select and combine open-source hand and arm design features for achieving ADL grasps.
2. Design novel features and integrate each element with the combined open-source prosthesis output from Objective 1.
3. Validate the performance of the prosthetic arm.

In designing and validating the ADL arm V2 in accordance with the objectives, the research aim is met. This chapter details the conclusions resulting from the design and validation processes as described in the chapters prior. Based on these outcomes, a number of recommendations for future work are presented.

7.1 Conclusions

The conclusions of this research are grouped into three sub-categories. These relate to the design of the prosthesis, its validation, and the overall outcomes of the research.

7.1.1 Prosthesis Design

By identifying the grasps required for bimanual ADLs, and investigating the current upper-limb prosthesis landscape in LMICs, a design specification for an open-source ADL-compliant prosthesis is generated. This device should: be able to reliably perform the five identified grasps; attach securely and comfortably to the amputee; and not require existing prosthetic hardware to function. The design of an open-source prosthesis allows favourable design features to be borrowed from existing open-source designs. Novel features are designed to compliment this result and to meet the design specification.

The ADL arm V1 – previous work completed by the authors – is a stand-alone body-powered prosthetic arm used as a basis for this research. The design outcome of this research, the ADL arm V2, is a parametrised version of the ADL arm V1 that aims to overcome the shortcomings of the first prototype, and better meet the needs of users in LMICs.

The ADL arm V2 features a much improved hand subsystem. All digits are parametrised, with the thumb having a modified cable trajectory to better achieve the desired ADL grasp kinematics. The hand subsystem features a reinforced and modified wrist mechanism. The wrist facilitates hand pronation and supination, and can support heavier objects than the ADL arm V1. A redesign of the digits results in a grasp diameter that is improved from 105 mm in V1 to 114 mm in V2.

The actuation subsystem of the ADL arm V2 features a modified elbow actuation mechanism. This modification enables the elbow mechanism to generate 42.63 N; a significant improvement over the 34.15 N of V1. The modified elbow actuation mechanism and hand design produce a grip force of 36.3 N in the hand terminal device. The cable-lock mechanism is a new addition to V2. The implemented cable lock can maintain a cable tension of up to 58.42 N without slip, allowing the wearer to maintain grasp on objects without continuous effort.

Unlike in prototype one, the suspension subsystem is completely 3D printed. The forearm cuff is printed in two pieces and joined with a modified bolt-through bridle joint. Printing the suspension subsystem parts from PLA filament allows the parts to be thermoformed; creating a user-specific fit. The average times taken by seven users to don and doff the prosthesis are 13.3 and 6.73 seconds, respectively.

The manufacture and assembly of the ADL arm requires an able-bodied individual with access to a 3D printer, some additional hardware and materials, and basic tools. The fabrication of the 3D printed parts is estimated to take a duration of 46 h 42 m, and to cost R 301.21. The estimated total cost of manufacturing a single ADL arm is R 630.20.

7.1.2 Prosthesis Validation

Experimental validation of the ADL arm V2 is completed through functional and simulated-use testing. Functional validation involves the completion of the AHAP, while simulated-use testing involves a ADL assessment followed by usability testing of the device.

AHAP assessment of the ADL arm V2 yielded a GAS of 68 %. Of the bimanual ADL grasps, the device performed best in the non-prehensile (index point and platform), hook and cylindrical grip GTs; which achieved partial GAS scores of 100 %, 83.3 % and 80.6 %, respectively. The ADL GT resulting in the worst performance, lateral grip, scored a partial GAS of 33.3 %. The reason for the poor performance was the inability of the thumb to apply force while the distal joint was in extension. This was also the reason for the partial GAS of 75 % for the diagonal volar grip GT. In this GT the ADL arm obtained a perfect maintain score, but the grasp score was only 50 %, as the correct shape could not be achieved. Performance in the remainder of GTs ranged from good to poor, where power grasps (like spherical grip) achieved good scores and precision grasps (like pulp pinch) scored poorly. Overall AHAP performance could be significantly improved by the inclusion of a mechanism to lock the distal joint's of each digit in extension during grasp. A more reliable representation of the device's functional ability will be obtained if the device is tested on a larger number of participants.

Simulated use testing of the ADL arm V2 is considered successful. Of the combined total of 86 ADL and IADL tasks in the ADL assessment, the user required assistance from the proxy with only seven tasks. Specific difficulty was experienced with tasks requiring high grip strength where an object grasped by the hand had to resist rotational motion. Difficulty was also experienced during tasks where a moderate level of prehension was required by both hands; such as during closing buttons and doing zippers. Heavy labour tasks such as housework, gardening and doing all shopping independently were perceived as difficult. Much of the difficulty experienced during the ADL assessment protocol could be alleviated by using assistive devices designed for these purposes.

The usability of the ADL arm V2 was judged by seven healthy participants with differing levels of prior experience with the device. The usability scores increased with greater device familiarity; with individuals who had prior use experience rating the device to have a usability of 87.5 – an 'excellent' score. The mean device usability for all participants was 84.29, indicating that overall participants found their experience with the device to be 'good'.

7.1.3 Overall Outcomes

The ADL arm V2 is proven to be functionally competent in both a theoretical and a simulated-used environment. The hand could perform four of five ADL grasps effectively, but the inability of the device to adequately perform lateral grasp is a concern and should be addressed urgently in the next iteration of the design. During simulated-use, the device proved able to assist in an array of bimanual activities, where the perceived

difficulty when using the ADL arm prosthesis was rated low overall. The device is rated 'good' from a usability standpoint.

7.2 Future Recommendations

The ADL arm V2 could be considered a success, as it was theoretically able to meat the research aim. There is, however, room for improvement in both the design of the prosthesis and further device validation.

7.2.1 Prosthesis Design

A number of modifications could be made to the design of the ADL arm to improve its functional performance, as well as its ability to assist in bimanual ADLs. The future design recommendations, in order of importance are:

- Include a mechanism to lock digits at the distal joint, such that grasps involving an extended distal segment (pinch grasps) can be achieved. This will potentially improve the TDs ability to perform the following AHAP GTs: lateral pinch, extension grip, pulp pinch and diagonal volar grip.
- Modify the elbow hinge such that it can withstand more force production. This could involve: changing the shape of the hinge pins; changing the cable trajectory on the forearm cuff (so that force is applied to the lateral hinge of the bicep cuff at an angle that does not encourage hinge separation); and/or having a moulding template for the hinge portions of the forearm and bicep cuff that aligns these parts to achieve relative motion in the same plane during device use. These modifications will result in a larger producible grip force and a device which feels more secure to operate.
- Alter the print orientation of the tensioner pins for improved part strength.
- Improve the grip element such that a high coefficient of friction can be maintained for prolonged periods without requiring cleaning.The silicon tape tends to attract particulate matter, resulting in a lower coefficient of friction if it is not cleaned regularly. Replacing this element with a grip element that is more compressible and less prone to attract dirt will improve the surface area in contact with the object improving the grip of the TD.
- Improve the cable-lock mechanism. A less cumbersome cable lock will improve the user's experience with the device. Ways to do this could be to have a cable lock that works using a cam mechanism. A cable lock which is easier to engage and

release will make it more likely that objects can be voluntarily released after being held at a distance from the body. This could improve the functional work envelope of the wearer of this device.

- Include a cable exclusion mechanism, such that non-prehensile grasps can be performed while the elbow is in flexion and the hand is close to the body.
- Further reinforce the wrist so that heavier objects can be grasped. This will allow the TD to have a greater resistance to shear force. This can potentially be achieved by increasing the overlap between the inner and outer cuffs of the rotating wrist; by reducing the clearance between the cuffs; or possibly by further thickening the parts.
- Replace the existing tensioning mechanism with one featuring longer tensioner pins and bolts. This will ensure that there is more capacity for cable tensioning.
- Include removable padding inside the forearm and bicep cuff to improve comfort and breathability. This will improve the user's experience of the design. Having the skin in direct contact with the plastic can become uncomfortable after longer periods of wear.

7.2.2 Prosthesis Validation

To improve the validity of the obtained results, the following recommendations should be implemented with regards to the experimental testing procedure:

- Validate the use-performance of the ADL arm (ADL and usability assessment) in the transradial amputee population. Compare the experience of amputees using the ADL arm to their existing prosthetic hardware or to their experience performing ADLs without a prosthesis.
- Validate both the functionality and usability of the device with a larger number of participants. This will greatly improve the statistical significance of the obtained results, and allow intersubject variability to evaluated in the functional testing results.
- Include an evaluation of the AHAP performance of other existing open-source body-powered prostheses. Compare the results to those obtained by the ADL arm and postulate reasons for the differences in performance between them.
- Include the cost of labour into the cost analysis of the ADL arm, so that a more accurate representation of the expected cost per device can be established.

- Develop a Risk Management Plan in accordance with *ISO 14971 – Risk Management for Medical Devices*. This aligns with best practises for open-source medical devices to ensure the safety and efficacy of the device.

7.3 Final Remarks

The ADL arm, a functional-below elbow prosthetic arm, has been designed and validated. The device is an improved and parametrised version of the ADL arm V1 – prior work by the author. The ADL arm has been proven to be functionally competent; through both a functional and simulated-use assessment. The results obtained using healthy-participant validation show promise that the ADL arm could be an asset to unilateral transradial amputees in LMICs. A number of recommendations for future work have been presented. Most notably, the device's performance in the lateral grasp GT must be improved, and the device should be tested in the target population to gain a true representation of the performance of the ADL arm.

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A Itemized list of all parts of the ADL arm V2

The physical manifestation of the ADL arm V2 comprises of a number of 3D printed parts and easy-to-source hardware components. Table A.1 is an itemised list of all components in the system. The labelled ADL arm V2 is shown in the series of Figures that follow. Figure A.1 is the key used henceforth in this Section.

Table A.1: Itemised list of all the components of the ADL arm system.

#	Component	#	Component
1	Finger distal	24	Countersunk bolt M3
2	Finger proximal short	25	Locknut M3
3	Finger proximal long	26	Nut M3
4	Thumb distal	27	Socket head cap screw M5
5	Thumb proximal	28	Rubber washer
6	Thumb palm	29	Rivet bent
7	Palm pin	30	Teflon tube
8	Palm	31	Velcro
9	Wrist proximal	32	Whippletree cross bar
10	Wrist outer button	33	Whippletree pivot
11	Forearm cuff distal	34	Thumb button
12	Forearm cuff proximal	35	Pen spring
13	Cable-lock housing bottom	36	Rivet straight
14	Cable-lock bolt head cap	37	Primary actuation cable
15	Cable-lock housing top	38	Thumb actuation cable
16	Humeral cuff	39	Wrist spring cartridge
17	Elbow outer stop	40	Wrist outer button
18	Elbow pin	41	Tensioner box
19	Elbow inner stop	42	Tensioner pins
20	Velcro buckle	43	Tensioning bolts
21	Finger tendon cord	44	Cable lock washer
22	Silicone grip tape	45	Torsion spring
23	Digit hinge pin		

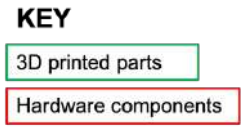

Figure A.1: Key used in the labelled views of the ADL arm.

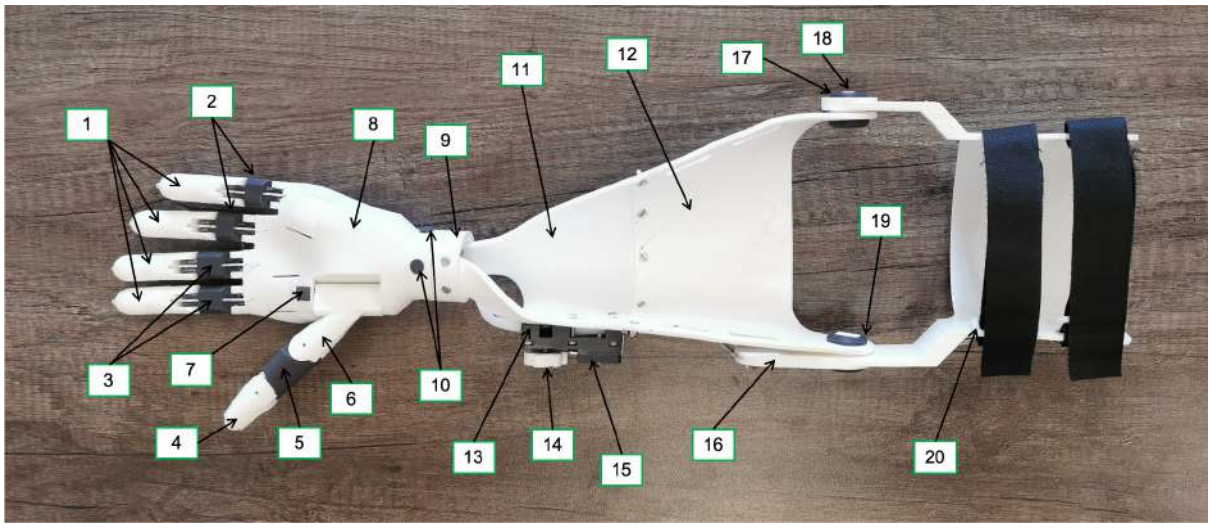

Figure A.2: Labelled top view of the 3D printed parts of the ADL arm V2.

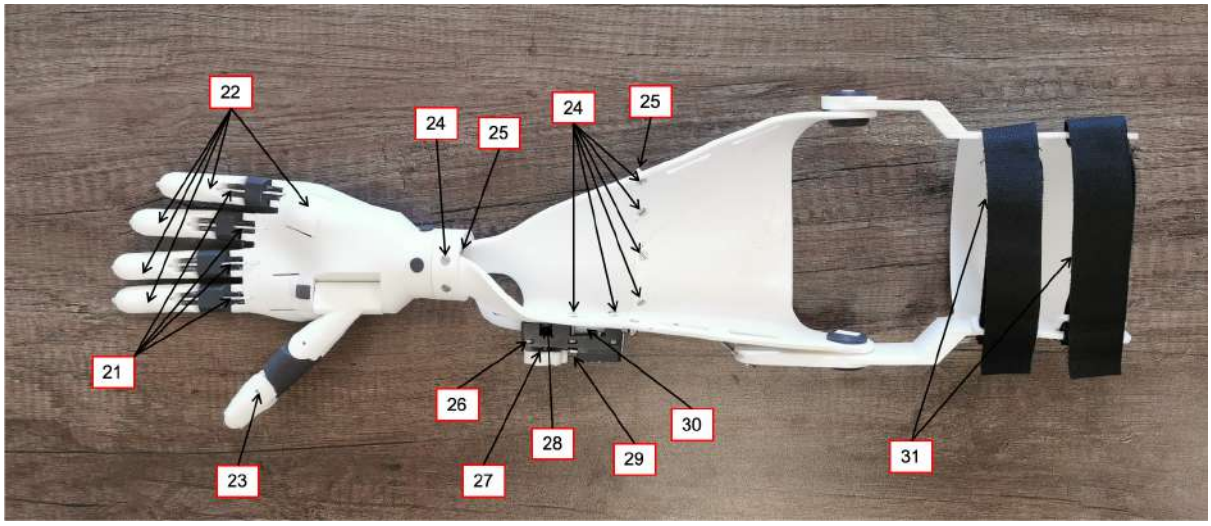

Figure A.3: Labelled top view of the hardware components of the ADL arm V2.

Figure A.4: Labelled close-up view of the torsion springs used in the hand TD.

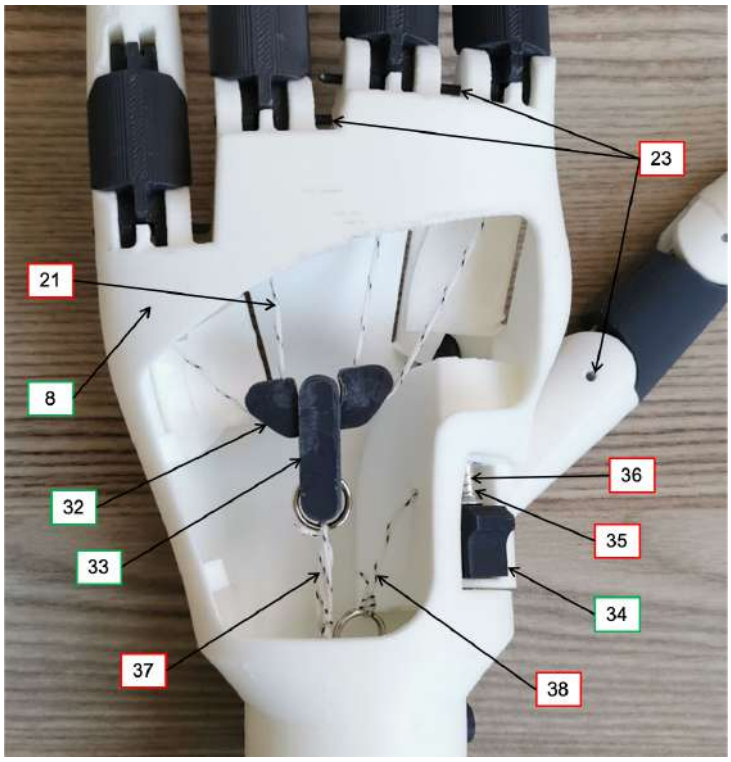

Figure A.5: Labelled top view of the components housed inside the palmar space of the ADL arm V2.

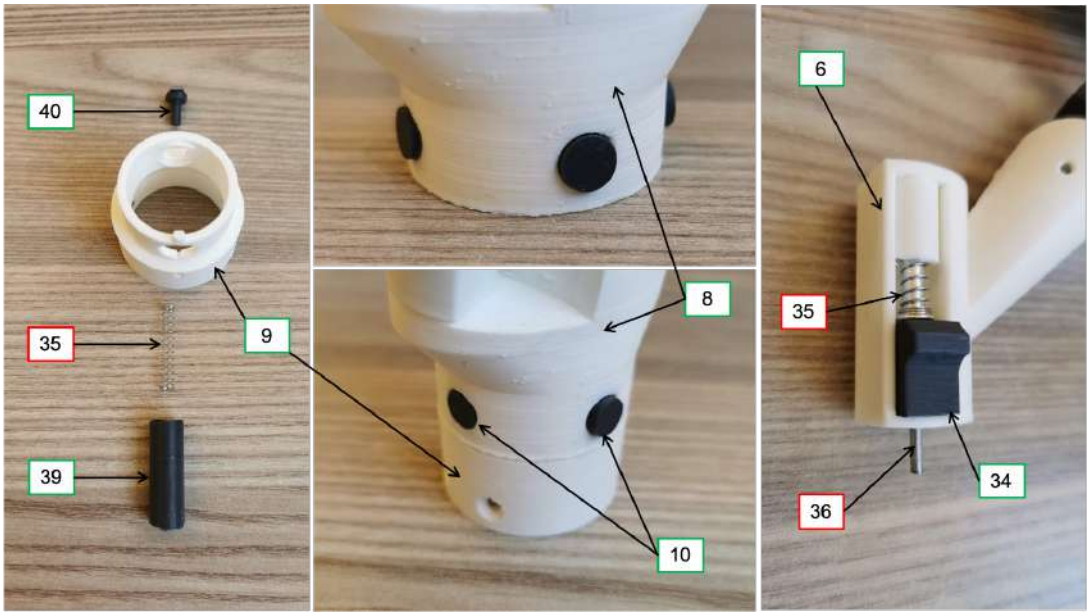

Figure A.6: Labelled views of the wrist and thumb mechanism components.

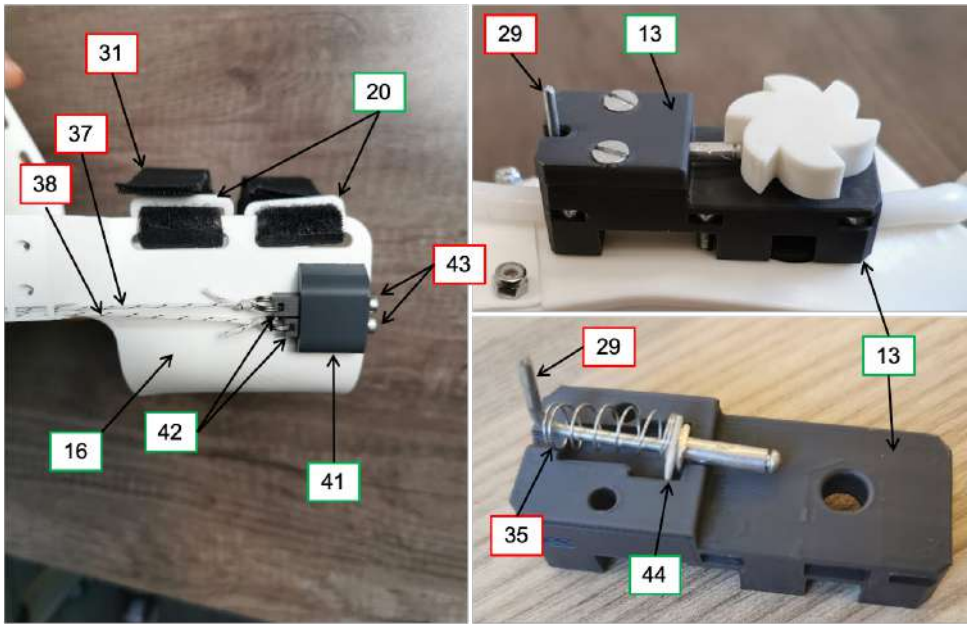

Figure A.7: Labelled views of the components of the tensioning and cable-lock mechanisms of the ADL arm V2.

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23 September 2021

Ms Naomi Ngoasheng
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By Email: (naomi.ngoasheng@nipmo.org.za)

NIPMO Reference Number: UCT-2020-341

Dear Naomi

IP1 Referral: Open source ADL compliant prosthetic arm with novel wrist (UCT ref.: Timm Prosthesis Open Source)

We refer to the above non-actionable disclosure submitted to NIPMO during the April 2020 IP7 reporting period. This invention arose as part of a Master's in Biomedical Engineering project, the goal of which was to create an **open-source**, **mechanical** prosthetic arm.

The invention is a mechanical prosthetic arm, indicated for unilateral transradial amputees. The purpose of this invention is to provide below-elbow amputees with the ability to perform Activities of Daily Living (ADLs). The prosthetic arm is intended to support the dominant hand in the performance of these activities. To do so effectively, the hand must be able to perform a subset of human grasp patterns. This is achieved in the design through the implementation of a swivel thumb locking mechanism that allows the hand terminal device to perform adduction and abduction-like movements of the thumb. Additionally, a rotational wrist locking mechanism allows the prosthesis to perform pronation and supination, further improving the functional optimisation of the prosthesis for performing ADLs.

There exists a comprehensive range of prosthetic arm designs both on the market and in the open-source space. The inventor has selected, and combined favourable components of

existing open source-prosthetic arm designs whose creative commons (CC) licence states that derivatives are allowed (see below list of open-source designs on which this innovation is based).

Design element	Source	License
Rotating thumb	https://www.instructables.com/Galileo-Hand-3D-Printed-Prosthetic-Hand/ (documentation) https://www.thingiverse.com/thing:655432 (part files)	CC-BY-NC
Hinged elbow mechanism	https://hub.e-nable.org/s/e-nable-devices/wiki/page/view?title=Unlimbited+Arm+v2.1 (documentation) https://www.thingiverse.com/thing:1672381 (part files)	CC-BY-NC-SA

In addition, a rotating wrist mechanism has been designed as a novel addition to the ADL arm. The wrist joint has the following functions:

- Form a secure connection between the forearm part and the terminal device.
- Facilitate the relative rotation between the forearm part and the terminal device.
- Prevent rotation beyond a limited range of motion.
- Lock the angle of rotation in one of three different locking positions.

The combination of a standalone elbow-powered device that facilitates adaptive grasp, has a thumb swivel mechanism and can facilitate wrist pronation and supination could be potentially inventive. This combination is unseen in the existing open-source **mechanical** technologies, although many of these features and especially their combination is typically only seen in electrically powered devices.

We assessed the novel rotating wrist and swivelling thumb features and felt that although these may be potentially patentable features (not fully tested), we did not support filing a patent application, the main reason being that the final product may not be commercialised for financial gain due to the restrictive creative commons CC-BY-**NC**-(SA) licenses associated with both the rotating thumb and the hinged elbow-mechanism. In its current state, we would not be able to recover the costs associated with filing patents. One possibility would be to

remove the dependency of the prosthesis on existing open-source components by redesign or using truly open-source components not limited to non-commercial use. This, however, will require extensive redevelopment of the prosthesis and there are currently no clear plans to do this. It may form part of a future project at the Department.

The main inventor has already accepted work in the industry and will soon complete her Master's in Biomedical Engineering. Having discussed this with the inventor and supervisor, it is still their wish to ultimately make the final design available as a truly open-source device, with all design materials being public domain and the final product being made available using an open-source hardware license such as CERN (https://ohwr.org/project/cernohl/wikis/Documents/CERN-OHL-version-2) and TAPR (https://tapr.org/the-tapr-open-hardware-license/).

Furthermore, experience at UCT has shown that it is extremely difficult and unlikely to commercialise proprietary IP in the domain of mechanical prosthetic hands or arms, since it is a very niche market and designs often need to be customised for a specific patient. The cost of regularly approvals is likely to far outweigh financial returns that can be achieved.

RC&I therefore supports the modality suggested of making the prosthesis available via an open-source license and recognises that in this way, social impact is still possible. We further attach open-source plan that was submitted as part of the Master's project, for background. This plan includes a section on how product risk will need to be dealt with if the design is to be made available open source.

We hereby request permission from NIPMO to put this innovation into public domain.

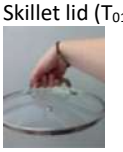
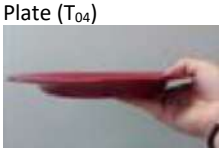
Yours sincerely

Signature Removed

PD Hoekstra
Intellectual Property Manager
Department of Research Contracts & Innovation (RC&I)
University of Cape Town

C AHAP task list

Table C.1: AHAP task list including task number and GRASP taxonomy equivalent grasp. Adapted from Llop-Harillo et al. (2019).

Grasp type (AHAP)	Grasp type (GRASP)	Objects and task order		
Hook	Medium wrap / Fixed hook	Skillet lid (T_{01}) 	Pitcher base (T_{10}) 	Wood blocks with rope (T_{19}) 
Spherical grip	Sphere 4-finger	Plastic apple (T_{02}) 	Softball (T_{11}) 	Mini soccer ball (T_{20}) 
Tripod pinch	Tripod	Large marker (T_{03}) 	Tuna can (T_{12}) 	Golf ball (T_{21}) 
Extension grip	Parallel extension	Plate (T_{04}) 	Cracker box (T_{13}) 	Chocolate pudding box (T_{22}) 
Cylindrical grip	Medium wrap / Large diameter	Chips can (T_{05}) 	Coffee can (T_{14}) 	Power drill (T_{23}) 
Diagonal volar grip	Adducted thumb	Phillips screwdriver (T_{06}) 	Spatula (T_{15}) 	Skillet (T_{24}) 
Lateral pinch	Lateral grasp	Bowl (T_{07}) 	XS clamp (T_{16}) 	Key (T_{25}) 
Pulp pinch	Prismatic 3-finger	Small marker (T_{08}) 	Plastic pear (T_{17}) 	Washer 10mm (T_{26}) 
Index pointing/ pressing	Index finger extension	Timer (T_{09}) 		
Platform	Non-prehensile	Plate (T_{18}) 		

D Conditions for grasp success in the AHAP

To evaluate each grasp type using AHAP, the correctness of the grasp must be assessed according to the conditions listed in Table D.1 (Llop-Harillo et al., 2019).

Table D.1: Conditions for a successful grasp for each of the grasp types used in the AHAP.

Grasp	**Condition for Success**
Hook	The object is in contact with the palmar side of at least three fingers.
Spherical Grip	The object is in contact with the palmar side of the thumb and at least three fingers, and the palm.
Tripod Pinch	The object is in contact with the radial side of the middle finger and the palmar side of the distal segments of the thumb and index finger.
Extension Grip	The object is in contact with the palmar side of the thumb and the palmar side of the distal segment of at least three fingers. The angle between the distal finger segments and the side of the object must be less than 30 °. For boxes, contact of the thumb and fingers must be on opposing sides of the box; the sides in question are those of the larger area.
Cylindrical Grip	The object is in contact with the palmar side of the thumb, at least three fingers, and the palm. The angle between the main axis of the thumb and the main axis of the object's grip area must be greater than 60 °.
Diagonal Volar Grip	The object is in contact with the palmar side of the thumb, at least three fingers, and the palm. The angle between the plane of the thumb segments and the symmetry plane of the object must be less than 30 °.
Lateral Pinch	The object is in contact with the palmar side of the distal segment of the thumb and the radial side of the index finger.
Pulp Pinch	The object is in contact with the palmar side of the distal segments of the thumb and index finger, without any contact with the palm.
Index Point	The object is in contact with the palmar side of the distal segment of the index finger, and the timer is started.
Platform	The object is in contact with the palm. The angle between any finger and the palm must be less than 30 °.

E ADL assessment questionnaire

Self-Report ADL Questionnaire

Healthy subject testing of a below-elbow prosthetic arm for transradial amputees

The tasks detailed below will be rated according to four metrics: if assistance is required to perform the task, the use of and role played by the prosthesis, and the perceived difficultly associated with performing the task.

Assistance required:

- Assistance required (R) – help is required to complete the task
- Assistance not required (NR) – could complete the task without help

Prosthesis used:

- Yes (Y)
- No (N)

Role of prosthesis:

- Direct (D) - object is grasped directly by the prosthesis
- Indirect (I) - object is placed into the prosthesis' grasp by the healthy hand
- Passive (P) - prosthesis was used to carry, support or push/shove

Perceived difficulty (DASH):

1. No difficulty
2. Mild difficulty
3. Moderate difficulty
4. Severe difficulty
5. Unable

Activities of Daily Living

ADLs		Assistance Required (R/NR)	Prosthesis used (Y/N)	Role of prosthesis (D/I/P)	Perceived difficulty (1-5)
#	**Bathing**				
1	Wash hair				
2	Wash body				
3	Wash hands				
4	Wash face				
5	Wash genitals				
#	**Feeding**				
6	Get food from plate into mouth				
7	Use knife to cut food				
8	Use knife and fork to cut food				
9	Spread butter				
10	Clean up after meals				
11	Open a jar (tight)				

12	Open a jar (moderate)				
13	Drink from a small cup				
14	Drink from a mug				
15	Use fork or spoon				
16	Open/pour from a 340ml can				
17	Open/pour from a 500ml bottle				
18	Open/pour from a 1l box				
19	Open/pour from a 2l bottle				
#	**Dressing**				
20	Put on and take off prosthesis				
21	Select clothes from cupboard				
22	Dress upper body				
23	Dress lower body				
24	Put on jacket / coat				
25	Button pants				
26	Tie shoelaces				
27	Put on/remove a tshirt				
28	Button shirt with front buttons				
29	Zip jacket				
30	Put on socks				
31	Put on shoes				
#	**Grooming**				
32	Brush hair				
33	Blow dry hair				
34	Groom nails				
35	Shave				
36	Brush teeth				
37	Skincare routine				
#	**Toileting**				
38	Goes to toilet				
39	Arrange clothing				
40	Clean genital area				
41	Use female hygiene products				
#	**Continence**				
42	Self-control of urination				
43	Self-control of defecation				
#	**Transferring**				
44	Move in and out of bed				
45	Move in and out of chair				
46	Get on and off the toilet				
47	Get in and out of the shower				

#	Mobility				
48	Walk				
49	Stairs				

Instrumental Activities of Daily Living

iADLs		Assistance Rating Scale (R/NR)	Prosthesis used (Y/N)	Role of prosthesis (D/I/P)	Perceived difficulty (1-5)
#	**Use phone**				
1	Use phone to dial saved numbers				
2	Use phone to dial unsaved numbers				
3	Use phone to receive calls				
4	Use phone to send text message				
#	**Do personal laundry**				
5	Carry a laundry basket				
6	Hang laundry				
7	Fold a bath towel				
8	Fold clothing items				
9	Perform light daily household tasks (dish washing, bed making, sweeping)				
10	Perform heavy household tasks (wash floors, scrub shower)				
#	**Travel/purchase**				
11	Travel independently on public transport / in own car				
12	Travel accompanied on public transport / in own car				
13	Shop independently for all purchases (groceries or clothes)				
#	**Food preparation**				
14	Plan and cook full meals				
15	Stir in a bowl				
16	Peel vegetables / fruit				
17	Open a bag of chips				
18	Use scissors				
19	Twist the lid of a small bottle				

#	**Self-management**				
20	Take medication in correct dosage at correct time				
21	Manage financial matters independently				
22	Make day-today purchases				
23	Take a bank note out of wallet				
24	Do banking (pay bills, pay rent, budget, keep track of income)				
#	**Household tasks**				
25	Turn a key				
26	Push open a heavy door				
27	Place an object on a shelf above your head				
28	Do garden work				
29	Carry a shopping bag / briefcase				
30	Carry a heavy object (over 5kg)				
31	Change a lightbulb overhead				
32	Write name legibly				
33	Open a door with a knob				
34	Open a drawer with a handle				
35	Use a key in a lock				
36	Use hammer and nail				
37	Open an envelope				

F System usability scale

The system usability scale (SUS) is scored using the template shown in Table F.1 (Brooke, 1996).

Table F.1: The System Usability Scale. Responses range from 1 (Strongly Disagree) to 5 (Strongly Agree).

Question	**Rating (1-5)**
I think that I would like to use this system frequently	
I found this system unnecessarily complex	
I thought the system was easy to use	
I think that I would need the support of a technical person to be able to use this system	
I found the various functions in this system were well integrated	
I thought there was too much inconsistency in this system	
I would imagine that most people would learn to use this system very quickly	
I found this system very cumbersome to use	
I felt very confident using the system	
I needed to learn a lot of things before I could get going with this system	

The resulting system usability score is out of a total of 100 points. The result is, however, not a percentage. A visual representation of the categories of SUS outcome are shown in Figure F.1 (Smyk, 2020).

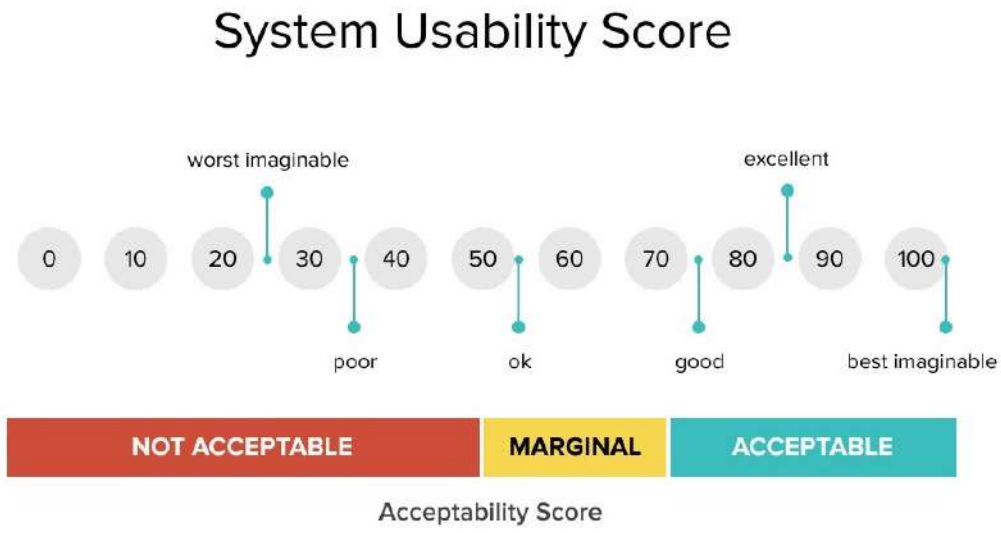


Figure F.1: A visual representation of the scoring outcome of the SUS.

G Ethics approval letter

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

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Groote Schuur Hospital
Observatory 7925
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Website: www.health.uct.ac.za/fhs/research/humanethics/forms

12 February 2021

HREC REF: 796/2020

A/Prof S Sivarasu
Division of Biomedical Engineering
Room 7.17, Anatomy Building FHS
Email: sudesh.sivarasu@uct.ac.za
Student: tmmlar001@myuct.ac.za

Dear A/Prof Sivarasu

PROJECT TITLE: THE DESIGN AND DEVELOPMENT OF AN OPEN-SOURCE ADL-COMPLIANT PROSTHETIC ARM FOR TRANSRADIAL AMPUTEES MSC CANDIDATE -MISS LARA TIMM

Thank you for your response letter, addressing the issues raised by the Faculty of Health Sciences Human Research Ethics Committee (HREC).

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020 & 06 July 2020.

Approval is granted for one year until the 28 February 2022.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that the student: Miss Lara Timm will also be involved in this study.

Please quote the HREC REF 796/2020 in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON: FACULTY OF HEALTH HUMAN RESEARCH ETHICS COMMITTEE

HREC/REF 796/2020sa

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

HREC/REF 796/2020sa

H Manufacture the ADL arm

Manufacture of the ADL arm involves the fabrication of the 3D printed parts and the purchase of a number of standard hardware components. The estimated bill of materials for the manufacture of one unit of the ADL arm, excluding labour costs, is shown in Table H.1. The detailed cost breakdown of the 3D printed part fabrication costs is shown in Table H.2 on the following page.

Table H.1: Estimated bill of materials for all components of the ADL arm prosthesis.

Item	**Unit price (R)**	**# items**	**Price (R)**
3.2x10mm blind rivet	0.42	2	0.84
Pen spring	5.00	3	15.00
⌀5mm helical torsion springs	18.00	10	180.00
Dacron fishing line 50lb	1.70	2	3.40
Silicon tape	110.00	0.3	33.00
M3 bolt steel	0.80	19	15.20
M3 nut steel	0.80	6	4.80
M3 locknut	1.15	9	10.35
M5 bolt	7.00	1	7.00
M5 nut steel	0.60	1	0.60
Superglue	36.00	1	36.00
Rubber washer	15.00	1	15.00
Teflon tube ⌀6mm	39.00	0.2	7.80
3D printed parts	-	48	301.21
			630.20

Table H.2: Detailed time and cost analysis for the fabrication of the 3D printed parts of the ADL arm.

Subsystem	Part	Quantity	Estimated print time (hour/min)	time (h)	time(min)	Used filament (g)	Filament type	Filament cost per gram (R)	Estimated filament cost (R)	Estimated electricity cost (R)	Estimated operation costs (R)	Total cost (R)
Hand	Finger distal	4	3h25m	3	25	21.58	ABS	0.6	12.95	1.71	3.96	18.62
	Finger proximal long	2	1h11m	1	11	6.94	ABS	0.6	4.16	0.59	1.37	6.13
	Finger proximal short	2	1h9m	1	9	6.52	ABS	0.6	3.91	0.58	1.33	5.82
	Thumb tip	1	51m	0	51	4.52	ABS	0.6	2.71	0.43	0.99	4.12
	Thumb middle	1	55m	0	55	5.32	ABS	0.6	3.19	0.46	1.06	4.71
	Thumb palm	1	2h	2	0	9.26	ABS	0.6	5.56	1.00	2.32	8.88
	Thumb button	1	21m	0	21	0.7	ABS	0.6	0.42	0.18	0.41	1.00
	Thumb pin	1	19m	0	19	1.75	ABS	0.6	1.05	0.16	0.37	1.58
	Palm	1	10h38m	10	38	74.86	ABS	0.6	44.92	5.32	12.33	62.57
	Palm cover	1	3h18m	3	18	11.22	ABS	0.6	6.73	1.65	3.83	12.21
	Whippletree cross bar	1	17m	0	17	0.87	ABS	0.6	0.52	0.14	0.33	0.99
	Whippletree pivot	1	13m	0	13	0.88	ABS	0.6	0.53	0.11	0.25	0.89
	Wrist proximal 6mm	1	1h16m	1	16	8.23	ABS	0.6	4.94	0.63	1.47	7.04
	Wrist spring cartridge	1	51m	0	51	1.48	ABS	0.6	0.89	0.43	0.99	2.30
	Wrist spring button	1	10m	0	10	0.28	ABS	0.6	0.17	0.08	0.19	0.44
	Wrist outer button	3	7m	0	7	0.53	ABS	0.6	0.32	0.06	0.14	0.51
Actuation	Cable lock housing bottom	1	1h25m	1	25	8	ABS	0.6	4.80	0.71	1.64	7.15
	Cable lock housing top	1	14m	0	14	1.33	ABS	0.6	0.80	0.12	0.27	1.19
	Cable lock washer	1	1m	0	1	0.05	ABS	0.6	0.03	0.01	0.02	0.06
	Bolt head cap	1	16m	0	16	1.7	ABS	0.6	1.02	0.13	0.31	1.46
	Bolt thread cap	1	4m	0	4	0.08	ABS	0.6	0.05	0.03	0.08	0.16
	6mm tube bracket	4	24m	0	24	2.27	ABS	0.6	1.36	0.20	0.46	2.03
	Tensioner box	1	38m	0	38	3.15	ABS	0.6	1.89	0.32	0.73	2.94
	Tensioner pin	2	15m	0	15	1.5	ABS	0.6	0.90	0.13	0.29	1.32
Suspension	Forearm distal	1	3h14	3	14	36.49	PLA	0.7	25.54	1.62	3.75	30.91
	Forearm proximal	1	4h33m	4	33	52.08	PLA	0.7	36.46	2.28	5.28	44.01
	Bicep cuff	1	7h24m	7	24	75.9	PLA	0.7	53.13	3.70	8.58	65.41
	Elbow joint pin	2	15m	0	15	1.42	ABS	0.6	0.85	0.13	0.29	1.27
	Elbow joint cap inner	2	19m	0	19	2.14	ABS	0.6	1.28	0.16	0.37	1.81
	Elbow joint cap outer	2	14m	0	14	1.6	ABS	0.6	0.96	0.12	0.27	1.35
	Velcro buckle	4	25m	0	25	2.75	ABS	0.6	1.65	0.21	0.48	2.34
Totals		**48**	**46h42m**	**36**	**642**	**345.4**			**222.04**	**23.35**	**54.17**	**301.21**

I AHAP scores for the ADL arm

Table I.1: ADL arm scores from the AHAP functional assessment.

Grasp Type (GT)	**Task #**	**Object**	**Grasp 1**	**Maintain 1**	**Grasp 2**	**Maintain 2**	**Grasp 3**	**Maintain 3**	**Task Total (max 153)**	**GT Total**	**GT Total Normalised**
	1	Skilled lid	1.0	0.5	1.0	1.0	1.0	0.5	5.0		
	10	Pitcher base	1.0	1.0	1.0	1.0	1.0	1.0	6.0		
Hook	19	Weight with rope	0.5	1.0	0.5	1.0	0.5	0.5	4.0	15.0	83.3
	2	Apple	1.0	1.0	1.0	1.0	1.0	1.0	6.0		
	11	Softball	1.0	1.0	1.0	1.0	1.0	1.0	6.0		
Sperical Grip	20	Mini soccer ball	1.0	1.0	1.0	1.0	1.0	1.0	6.0	18.0	100.0
	3	Large marker	0.5	1.0	0.5	1.0	1.0	1.0	5.0		
	12	Tuna can	1.0	1.0	1.0	1.0	1.0	1.0	6.0		
Tripod Pinch	21	Golf ball	1.0	1.0	1.0	1.0	1.0	1.0	6.0	17.0	94.4
	4	Plate	0.5	0.0	0.5	0.0	0.5	0.0	1.5		
	13	Cracker box	0.5	0.0	0.5	0.5	0.5	0.5	2.5		
Extension Grip	22	Instant pudding	0.5	1.0	0.5	1.0	0.5	1.0	4.5	8.5	47.2
	5	Chips can	1.0	1.0	1.0	1.0	1.0	1.0	6.0		
	14	Coffee can	1.0	0.0	1.0	1.0	1.0	1.0	5.0		
Cylindrical Grip	23	Power drill	1.0	0.0	1.0	0.5	1.0	0.0	3.5	14.5	80.6
	6	Screw driver	0.5	1.0	0.5	1.0	0.5	1.0	4.5		
	15	Spatula	0.5	1.0	0.5	1.0	0.5	1.0	4.5		
Diagonal Volar Grip	24	Skillet	0.5	1.0	0.5	1.0	0.5	1.0	4.5	13.5	75.0
	7	Bowl	0.5	0.0	0.5	0.0	0.0	0.0	1.0		
	16	Small clamp	0.0	0.0	0.5	1.0	0.5	1.0	3.0		
Lateral Pinch	25	Key	0.5	0.0	0.5	0.0	0.5	0.5	2.0	6.0	33.3
	8	Small marker	0.5	1.0	0.5	1.0	0.0	0.0	3.0		
	17	Pear	0.0	0.0	0.5	0.5	0.5	1.0	2.5		
Pulp Pinch	2	10 mm washer	0.0	0.0	0.0	0.0	0.0	0.0	0.0	5.5	30.6
Index point	26	Timer	1.0	1.0	1.0	1.0	1.0	1.0	6.0	6.0	100.0
Platform	18	Plate	1.0	-	1.0	-	1.0	-	3.0	3.0	100.0
								Total points:	104.0		
								GAS (%):	68.0		

Table I.2: ADL arm scores comparing the *grasp* and *maintain* portions of the protocol.

Grasp Type (GT)	**Task #**	**Object**	**Grasp Total (max 78)**	**Normalised grasp total**	**Maintain Total (max 75)**	**Normalised maintain total**
	1	Skilled lid	3.0		2.0	
	10	Pitcher base	3.0		3.0	
Hook	19	Weight with rope	1.5	83.3	2.5	83.3
	2	Apple	3.0		3.0	
	11	Softball	3.0		3.0	
Sperical Grip	20	Mini soccer ball	3.0	100.0	3.0	100.0
	3	Large marker	2.0		3.0	
	12	Tuna can	3.0		3.0	
Tripod Pinch	21	Golf ball	3.0	88.9	3.0	100.0
	4	Plate	1.5		0.0	
	13	Cracker box	1.5		1.0	
Extension Grip	22	Instant pudding	1.5	50.0	3.0	44.4
	5	Chips can	3.0		3.0	
	14	Coffee can	3.0		2.0	
Cylindrical Grip	23	Power drill	3.0	100.0	0.5	61.1
	6	Screw driver	1.5		3.0	
	15	Spatula	1.5		3.0	
Diagonal Volar Grip	24	Skillet	1.5	50.0	3.0	100.0
	7	Bowl	1.0		0.0	
	16	Small clamp	1.0		2.0	
Lateral Pinch	25	Key	1.5	38.9	0.5	27.8
	8	Small marker	1.0		2.0	
	17	Pear	1.0		1.5	
Pulp Pinch	2	10 mm washer	0.0	22.2	0.0	38.9
Index point	26	Timer	3.0	100.0	3.0	100.0
Platform	18	Plate	3.0	100.0	-	-
		Total points:	52.5		51.5	
		Score (%):	67.3		68.7	

J ADL testing scores for the ADL arm

Table J.1: ADL assessment results for the ADL arm.

ADLs		Assistance Required (R/NR)	Prosthesis used (Y/N)	Role of prosthesi (D/I/P)	Perceived difficulty (1-5)
#	**Bathing**				
1	Wash hair	NR	N	-	2
2	Wash body	NR	N	-	2
3	Wash hands	NR	Y	P	1
4	Wash face	NR	N	-	2
5	Wash genitals	NR	N	-	2
#	**Feeding**				
6	Get food from plate into mouth	NR	N	-	2
7	Use knife to cut food	NR	Y	D	3
8	Use knife and fork to cut food	NR	Y	I	4
9	Spread butter	NR	N	-	3
10	Clean up after meals	NR	Y	I/P	2
11	Open a jar (tight)	R	Y	D	5
12	Open a jar (moderate)	NR	Y	D	3
13	Drink from a small cup	NR	N	-	1
14	Drink from a mug	NR	N	-	1
15	Use fork or spoon	NR	N	-	1
16	Open/pour from a 340ml can	NR	Y	D	1
17	Open/pour from a 500ml bottle	NR	Y	D	2
18	Open/pour from a 1l box	NR	Y	D	3
19	Open/pour from a 2l bottle	R	Y	D	5
#	**Dressing**				
20	Put on and take off prosthesis	NR	N	-	1
21	Select clothes from cupboard	NR	N	-	1
22	Dress upper body	NR	N	-	2
23	Dress lower body	NR	N	-	3
24	Put on jacket / coat	NR	N	-	3
25	Button pants	NR	N	-	3
26	Tie shoelaces	R	-	-	5
27	Put on/remove a tshirt	NR	N	-	2
28	Button shirt with front buttons	NR	Y	I	4
29	Zip jacket	NR	Y	I	4
30	Put on socks	NR	N	-	2
31	Put on shoes	NR	N	-	2
#	**Grooming**				
32	Brush hair	NR	N	-	1
33	Blow dry hair	NR	Y	I	2

Table J.1: ADL assessment results for the ADL arm (cont.).

ADLs		Assistance Required (R/NR)	Prosthesis used (Y/N)	Role of prosthesis (D/I/P)	Perceived difficulty (1-5)
#	**Grooming**				
34	Groom nails	R	-	-	5
35	Shave	NR	N	-	2
36	Brush teeth	NR	N	-	1
37	Skincare routine	NR	N	-	1
#	**Toileting**				
38	Goes to toilet	NR	Y	P	1
39	Arrange clothing	NR	N	-	2
40	Clean genital area	NR	N	-	1
41	Use female hygiene products	NR	Y	I	2
#	**Continence**				
42	Self-control of urination	NR	N	-	1
43	Self-control of defecation	NR	N	-	1
#	**Transferring**				
44	Move in and out of bed	NR	N	-	1
45	Move in and out of chair	NR	N	-	1
46	Get on and off the toilet	NR	N	-	1
47	Get in and out of the shower	NR	N	-	1
#	**Mobility**				
48	Walk	NR	N	-	1
49	Stairs	NR	N	-	1

Table J.2: IADL assessment results for the ADL arm.

IADLs		Assistance Required (R/NR)	Prosthesis used (Y/N)	Role of prosthesis (D/I/P)	Perceived difficulty (1-5)
#	**Use phone**				
1	Use phone to dial saved numbers	NR	Y	I	1
2	Use phone to dial unsaved numbers	NR	Y	I	2
3	Use phone to receive calls	NR	N	-	1
4	Use phone to send text message	NR	Y	I	1
#	**Do personal laundry**				
5	Carry a laundry basket	NR	N	-	1
6	Hang laundry	NR	N	-	3
7	Fold a bath towel	NR	Y	I	1

Table J.2: IADL assessment results for the ADL arm (cont.).

IADLs		Assistance Required (R/NR)	Prosthesis used (Y/N)	Role of prosthesis (D/I/P)	Perceived difficulty (1-5)
#	**Do personal laundry**				
8	Fold clothing items	NR	Y	I	1
9	Perform light daily household tasks (dish washing, bed making, sweeping)	NR	Y	D/I	3
10	Perform heavy household tasks (wash floors, scrub shower)	R	N	-	3
#	**Travel/purchase**				
11	Travel independently on public transport / in own car	NR	Y	P	3
12	Travel accompanied on public transport / in own car	NR	Y	P	3
13	Shop independently for all purchases (groceries or clothes)	NR	Y	D/I/P	4
#	**Food preparation**				
14	Plan and cook full meals	NR	Y	D/I/P	3
15	Stir in a bowl	NR	Y	D	4
16	Peel vegetables / fruit	NR	Y	I	2
17	Open a bag of chips	NR	Y	I	2
18	Use scissors	NR	N	-	1
19	Twist the lid of a small bottle	NR	Y	D	2
#	**Self-management**				
20	Take medication in correct dosage at correct time	NR	Y	I	2
21	Manage financial matters independently	NR	N	-	1
22	Make day-today purchases	NR	Y	I	2
23	Take a bank note out of wallet	NR	Y	I	2
24	Do banking (pay bills, pay rent, budget, keep track of income)	NR	N	-	1
#	**Household tasks**				
25	Turn a key	NR	N	-	1
26	Push open a heavy door	NR	N	-	1
27	Place an object on a shelf above your head	NR	N	-	1
28	Do garden work	R	-	-	5
29	Carry a shopping bag / briefcase	NR	N	-	1
30	Carry a heavy object (over 5kg)	NR	N	-	1
31	Change a lightbulb overhead	NR	N	-	1
32	Write name legibly	NR	N	-	1
33	Open a door with a knob	NR	N	-	1
34	Open a drawer with a handle	NR	N	-	2
35	Use a key in a lock	NR	Y	I	3
36	Use hammer and nail	R	-	-	5
37	Open an envelope	NR	Y	I	2