The 3D-Sanhand

The design of a fully 3D printed, easy-to-assemble and highly functional hand prosthesis for low resource

Sanne Tromp
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The design of a fully 3D printed easy-to-assemble and highly functional body-powered hand prosthesis for low-resource countries.

by

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Abstract

Background The majority of the amputated population is living in low-resource countries, but only a small minority has access to rehabilitating services. The accessibility of upper limb prostheses in these countries is poor due to limited technical and medical resources. 3D printing is regarded as a promising manufacturing alternative in contrast to the expensive and labour-intense conventional processes. However, the majority of the developed 3D-printed prostheses show weak functionality characteristics and do not meet basic user requirements. The goal of this research is, therefore, to design and evaluate a new body-powered prosthetic device which is fabricated with a 3D printer and easy to assemble, capable of performing high force-transmissions with an appropriate pinch force output, and meets the basic user demands.

Methods An analysis of the widely used conventional prostheses and available 3D printed prostheses has been performed, and as a result, design requirements have been set up. Based on these requirements a prototype has been designed using SOLIDWORKS, and is printed with a FDM printer. Mechanical characteristics have been measured using a test bench, and the functional performance has been evaluated by ten able-bodied subjects using the SHAP and the BBT. These results were finally compared to results of conventional prostheses, as found in the literature.

Results The final prototype of the 3D-Sanhand is presented; the 3D printed Simple to Assemble Natural-looking hand prosthesis. This prosthetic device has a one-degree-of-freedom rotating thumb and is, except for a pressure spring and an elastic rubber band, completely printed with a FDM 3D printer. The device is capable of performing a 15 N pinch with an actuation force of 24 N, which is lower than the required actuation for conventional prostheses and within the boundaries of fatigue-free use. It has a low mass of 142 gram which is a reduction of over 50% in comparison to the commercially available designs. The opening width of 75 mm is in line with conventional prostheses. The sliding mechanism in the rotation point enables the users to change the initial position of the thumb and to reduce the opening width, to allow all users to pick up objects from different sizes. User tests showed that the prosthesis was capable of picking up a variety of different object shapes and did not encounter difficulties with heavy weights. The main problems were subjected to the smoothness of the finger tips and the impossibility to pick up thin objects from the surface.

Conclusion This thesis describes the design of the first 3D printed hand that can be assembled without any technical and medical knowledge or complex tools and machinery. The hand performs a pinch force high enough to perform activities of daily living under comfortable operational forces, and that is comparable to conventional prostheses on the market. Future research should further investigate what the wear effects of 3D printed materials are on the long-term use, and should propose directions to increase the durability and efficiency of the design.

Preface

Already as a kid I was intrigued by acquiring new knowledge and skills, solving puzzles, being challenged on a technical level, and watching surgery documentaries. My broad interest in society and human made me choose to start my journey in Delft with a bachelor at the faculty of Technology, Policy & Management. As an inquisitive 18-year-old, I devoted myself to my student life in Delft, both inside and outside the university. Missing the medical aspects and technological depth, I decided to follow my path further in Mechanical Engineering to be able to start my master in Biomedical Engineering. Now I can say that this was one of the best decisions I made. During my time as a master student, I got especially interested in prostheses and am glad that I got the chance to dive into this subject for my master thesis. My internship in India was one of the best experiences so far, and was my biggest drive and motivation for the set up of my thesis. I have always wanted to do something valuable and work for a better world. I experienced my graduation time as a period in which I have learned so much, from designing and SOLIDWORKS skills, to cultural understanding and practical knowledge from the Indian soil, to individually setting up and completing a full research project.

A lot of people where part of my graduation period or have been important during my study time here in Delft. First, I would like to thank Gerwin Smit. For more than a year you have been my daily supervisor and gave me the opportunities to grow. You were there with critical feedback, but always full of enthusiasm and passion. You made me feel like you trusted me in the decisions I made, even far away in India. Thank you for the support and pleasant meetings and conversations. Furthermore, I would like to thank Jan van Frankenhuyzen who has thought me much more than I can put down on paper. You never judged me on the fact that I had no practical technical experiences and patiently explained me names and function of the tools and all other machines that I had never used before. Besides that you were always there for a great talk related to prostheses or anything else. Your motto: 'Zolang je het maar wilt leren', is one that I will take with me. I would also like to thank Dick Plettenburg and Aimée Sakes for taking place in my graduation committee.

A special thank you goes to my family and friends. My parents who gave me the opportunity to study and supported and trusted me endlessly. My sister and brothers for their support, humour and the great evenings together. My roommates who danced on the table with me and prepared the best food, but who were also always interested in my experiences and followed my path so closely. You have made me feel so at home in Delft. My study friends for all the coffee and lunch breaks, and the input in- and feedback on my project. Without your help and guidance my research would not have been as good, and the time working on it definitely not as pleasant. And everyone else who was part of my TU Delft journey in the past few years.

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Introduction

1.1. Upper extremity deficiency

Upper limb deficiency is a condition in which a part of, or the entire upper limb is missing. This often results in physical and psychological consequences for the patient. The absence of the upper limb may be caused by a congenital reduction deficiency or a traumatic amputation. The prevalence of upper limb deficiency is low. Estimated numbers indicate a prevalence of 0.8 per 10.000 inhabitants in the Netherlands and 1.4 per 10.000 in the US [1, 2]. Though, the majority of the patients is living in low-resource countries [3, 4].

In a congenital upper extremity deficiency, the deficient limb has not fully developed during pregnancy. This incidence is rare and has been estimated to be between 15 and 60 per 100.000 life births [5]. Congenital limb deficiency may be caused by genetic variation, from exposure to an environmental teratogen, or because of a gene-environment interaction [6]. Individuals with congenital amputations have never known the advantage of having two normally developed arms and hands. Traumatic amputees have lost their limb during their lives and therefore have to adapt to live with an impairment. There are geographical variations in the factors that cause traumatic amputation. In Western Europe the two most common causes are work accidents and road traffic accidents [7], in the USA and Israel is violence, including gunshot injuries, the main causative factor [8], and in Finland frostbite accounts for a striking 17% of upper limb amputation [9]. In low-resource countries, the numbers of amputation as a result of traffic accidents or infections and diseases are much higher than in western countries [10].

1.2. Upper limb prostheses

1.2.1. Prosthesis types

A prosthesis is an artificial device aiming to replace a missing body part [11]. A prosthesis can function to enhance the appearance of the missing limb and to regain function and support the amputee in activities of daily life (ADL's). A wide range of prostheses is available on the market nowadays, provided in several literature overviews [12, 13]. The main components of an upper limb prosthesis are the terminal device, the socket, and the shaft. The terminal device replaces the missing hand and provides the user functionality, including grasping, pinching or supporting objects. The socket is the interface between the prosthesis and the residual limb (stump) and is required to be created customised to enhance comfort to the patient. The shaft is the connection between the socket and the terminal device and replaces the missing part of the arm of the amputee [1].

A distinction can be drawn between active and passive prostheses. In active prostheses, the force to control the grasping mechanism derives from an internal mechanism inside the device. This working principle is in contrast to passive prostheses that function through an externally applied force to the mechanism [14].

1.2.2. Passive prostheses

Passive prostheses require external control and activation of the mechanism, for example, by the sound hand or by pushing the device against the environment [16]. In this way, the prosthesis can perform,

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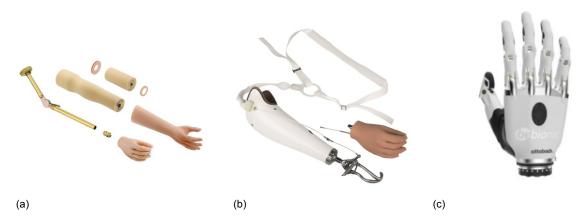


Figure 1.1: a) Ottobock passive natural-looking arm prostheses, b) Ottobock body-powered prosthetic solution, c) Ottobock bebionic hand, externally (myoelectric) powered [15].

among others, holding or supporting tasks. Some passive prostheses do not have any function at all and are also known as cosmetic or aesthetic prostheses. This type of prostheses only has the function to mask the amputation of the patient and make them feel and look 'normal'. This can be very valuable to the patient because amputees often tend to feel less confident or incomplete as a result of their impairment. In a lot of low-income countries, amputations are not socially accepted. In India, for example, an amputation is regarded as a punishment of God. Many patients, therefore, feel ashamed or judged by their environment. As a result, cosmetic prostheses are the most common type of prosthesis to find in low-resource countries [17]. Not only because most patients desire cosmetic hands over high functional hooks or grippers due to the pleasing appearance, but also because cosmetic prostheses are usually a cheaper option.

1.2.3. Active prostheses

Active prostheses can be body-powered or externally (myoelectric) powered.

Body-powered (BP) prostheses use a mechanical cable-operated system, driven by body movements of the amputee to generate forces and control the terminal device. BP prostheses are commonly controlled by a Bowden cable anchored to a shoulder harness attached to the opposite shoulder of the affected arm/hand. Cable displacement and forces provide proprioceptive feedback to the user about the opening width and applied grip forces [18]. Body-powered devices can either be voluntary closing (VC) or voluntary opening (VO). Advantages and disadvantages exist for both types of devices. In a VC mechanism, the user applies force to control the cable in order to close the prehensor to maintain a grip. A spring then re-opens the prehensor when the cable tension is released. A VO mechanism has an opposite working principle compared to the VC device. Here, the closed state is commonly maintained by a spring, and the user needs to apply enough force to overcome the spring constant in order to open the mechanism. The main advantage of VO devices is that once the object is grasped, the user does not need to exert force to maintain the grasp because the spring will ensure to hold the object. This allows the user to relax the muscles. The main limitation of this type of terminal device is that the user does not have control over the grip force since this force is equal and maximal to the spring tension [19]. Users of a VO device must maintain the required pinch or grip force throughout the entire task, which can cause fatigue. A benefit, however, is that the user can apply an appropriate force for varying tasks, and only needs to expend the energy required for that specific task.

Myoelectric-powered prostheses commonly use surface electromyography (EMG) to control the terminal device. This type of prosthesis provides visual feedback and incidental feedback but lacks proprioceptive feedback [20]. Advantages of myoelectric prostheses over body-powered include that they do not require straps or harnesses since they use electronic motors to function, more natural-looking movements as well as a higher force output and greater dexterity. The primary disadvantage of this type of prosthesis is the excessive weight, the lack of feedback, the extensive training period and high level of concentration that is needed to learn to control the device and the high costs.

1.2.4. Challenges in low-resource countries

The World Health Organization estimates that over 40 million amputees live in low-resource countries. This accounts for about 80% of the total number of affected population [3]. It is expected that this number of patients will double by 2050 as a result of the increased quality of life in these countries. The reason that the majority of the amputees is living in low-resource countries is among others, the result of less advanced technology and medical knowledge. In most western countries, amputation is rarely performed due to the high level of medical and technical experts. Moreover, diseases, civil conflicts and traumatic accidents are more common in countries without a sophisticated medical infrastructure and with limited resources. Only 1-2 % of the disabled population has access to rehabilitative services [21] and estimated is that only about a quarter of the amputated patients worldwide receive appropriate care [22]. Moreover, patients with upper-limb deficiencies are much more likely to be left untreated without any prosthetic inventions than patients with lower-limb deficiencies [23]. This can be explained by the great ability of patients to adapt to function with one hand or arm, limited acceptance of upper-limb prostheses and the low functionality of available hand prostheses. Furthermore, about 80% of the patients is not able to cover the necessary expenses to obtain a prosthetic device [23].

The lack of trained personnel in low-resource countries is a major problem in providing prosthetic limbs to needed patients [17]. Proper construction, fitment, alignment, and adjustment of prosthetic limbs is needed to construct a comfortable product, which requires a high-level skilled specialist. However, current appropriate training programs are insufficient to meet the high demand for expertise and the number of needed personnel. The World Health Organization (WHO) indicated a current shortage of approximately 40.000 trained specialists and estimated that it would take about 50 years to educate another 18.000 extra skilled professionals [22]. An elaborate description of the situation in low resource countries is provided in Appendix A.

Therefore, in order to make prostheses better accessible for the entire world population, there is an increasing demand for less complex and better affordable designs with high functionality. New designs should respond to the lack of rehabilitation physicians and specialists worldwide [24].

1.3. Technological developments



Figure 1.2: Different examples of hand prostheses created with AM technology: a) Gosselin's hand; a body powered under-actuated prosthetic hand [25], b) Cyborg Beast; a body powered prosthetic hand prosthesis for children [26], c) Handiii CYOTE; an externally (myoelectric) powered forearm prosthesis [27]

Different technological innovations attempt to create new opportunities facilitating affordable access to prosthetic care. The development of 3-dimensional (3D) printing or additive manufacturing (AM) as a method for product prototyping or fabrication of customised products has gained significant attention in the past few years. The number of upper-limb prostheses created by 3D printers increased rapidly in the past few years. Devices have been created individually and by large research communities, and several scientific papers have been published regarding research in the field of 3D printed upper limb prostheses [28]. The interest started driven by a search for affordable alternatives [29], regarding the costs of commercial available body-powered hand prostheses ranging from \$4000 to \$10.000 and externally powered hands ranging from \$25.000 to \$75.000 [30, 31]. Besides economic profits, 3D printing for production comprises more advantages and opportunities compared to other manufacturing techniques for prostheses [32, 33]:

· 3D printing allows for a high level of customisation. Devices can be personalised without adding

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extra costs or requiring different machine settings, meeting different size and shape requirements.

- · Products can be made out of one part, and therefore no further assembly is required.
- Parts can be produced cheaply and quickly from idea to product. Designing is possible at a
 distance, while the machine is portable and can easily be used in different environments and
 locations in the world.
- · Complex shapes and geometries can be created, providing high design freedom.
- · Parts can be printed against low costs.
- Parts can be made very lightweight, which is beneficial for the comfort of the user.

Drawbacks of- and problems occurring in the development of prosthetic devices while using 3D printing include [34–36]:

- The accuracy of the printed parts is highly affected by the properties of the printer. Different
 machines can result in varying properties, and the strength within one part is not likely to be
 uniform.
- Mechanical properties are often unknown and hard to predict. The strength of parts differs in direction and location.
- Current 3D printed prostheses show weak transmission ratios and a grip force that is too low to perform ADL's [37, 38].

1.4. Problem statement

People with upper limb deficiency in low resource countries have a strong demand for affordable prostheses which provide sufficient functions for daily life activities. The amount of medical specialists and technicians in these countries is inefficient to meet the amount of the patients, and especially in rural areas, patients do not have access to necessary services. 3D-Printed body-powered (BP) prostheses provide great potential to these patients, as this technique allows for a high level of customisation and complexity, and fabrication against low costs.

A recent developed prosthetic hand at our university was completely created with 3D-printing techniques and required minimal manual assembly intervention. Its non-assembly mechanism is promising, regarding the demand for easy and low-cost products. However, the current force characteristics seem not to meet functional user requirements. The required input force for operation of this terminal device is too high for comfortable use, and the resulting pinch force output is too low to perform daily activities. Thereby, the majority of the 3D printed prostheses has a robot-like or toy-like appearance, which is in contrast to the user wish of natural-looking devices. The problem statement is therefore formulated as:

The accessibility of upper limb prostheses in low-resource countries is poor due to minimal technical and medical resources. 3D printing is regarded as a promising alternative to the expensive and labour-intense manufacturing process, but available designs show low force-transmission ratios and weak functional outcomes. The majority of the 3D printed prostheses does not meet the basic user requirements and is therefore not yet regarded an equivalent alternative to commercially, highly functional available designs.

1.5. Research goal

The goal of this thesis study is to design and evaluate a new body-powered prosthetic hand which is better accessible for low-resource countries. It should be an affordable alternative that is easy-to-assemble and should be capable of performing a high force-transmission ratio with an appropriate pinch force output for good functionality, and meet basic user requirements.

The new hand device should entirely be manufactured with a 3D printer and require a low level of manual intervention or assembly. The fabrication of the final design should hence not require technical or medical skills or knowledge, or high-cost machinery. Functionally the focus should be on the force transmission. An appropriate transmission ratio should allow users to accomplish a grip force that is

sufficient to perform activities of daily living (ADLs) while requiring low actuation forces to ensure comfortable use of the device. The hand should be evaluated by quantifying its performance by mechanical and functional user tests to accurately assess whether these goals are achievable with an AM process. The results will furthermore be compared to the commercially available prosthesis to evaluate whether AM is a promising alternative to the costly and labour intensive production of hand prostheses.

1.6. Research approach

In Chapter 2, the analysis of the user requirements for hand prostheses is performed and a view on the state of the art is provided. Furthermore, the characteristics of AM are described, including design opportunities and considerations. In Chapter 3, design requirements are set up, and a conceptual design is proposed. In Chapter 4, the final design of the 3D-Sanhand is presented and described. The final design is evaluated in Chapter 5, and the obtained results are then discussed in Chapter 6. The conclusion follows in Chapter 7.

\sum

Analysis

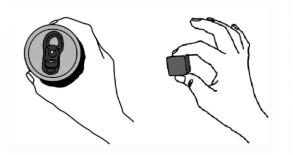
2.1. Approach

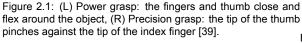
The objective of the analysis phase is to gain insight in available BP prostheses in order to obtain a clear encompassing view on the state of the art. Collecting relevant information about prosthetic characteristics, challenges and user desires will be essential to set up design requirements for the design phase. Widely used commercially available prosthetic hands and hooks will be reviewed, and information about developed 3D printed designs and their characteristics will be presented. To further understand what designing for AM means, different AM techniques will be reviewed. Opportunities and considerations will be presented, and starting points for the conceptual designs will be introduced. The focus will be subjected to the design of a terminal device, so no further elaboration of other components of complete upper-limb prostheses will be processed.

2.2. Function

2.2.1. Gripping

Humans are capable of performing fine manipulation of objects with well-coordinated digit force, through a thumb-finger opposition. The human thumb is much longer, mobile and fully opposable in comparison to the ape thumb. This enables the human to delicate motor skills and perform different grip types [41]. Different types of manual tasks, such as lifting or grasping, influence the direction of force vectors [42, 43]. Adjustments of force vector directions are being made by mechanical properties, such as object shape, surface friction or mass [42]. Napier [44] identified two main grip patterns; a precision and power grip. In a power grip the object is grasped between fingers and the palm, whereas the object is held between the tips of the fingers in a precision grip. These basic grasps can be further subdivided into six types of prehension, as shown in Figure 2.2. The mechanics of gripping distinguishes a dynamic and static part. The dynamics of gripping produces a particular grip, and the static concept indicates





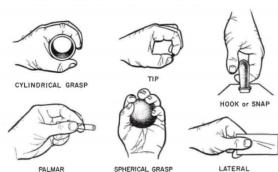


Figure 2.2: Six basic types of prehension [40].

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the final state of gripping [45].

Power grip

A power grip is performed to hold and lift objects firmly. The main function of the hand in power grip is to provide resistance to any external force that may be applied to the object within this grasp. Forming this grip, all phalanges are (partly) enclosing the object to hold it steadily. The metacarpals (the palm) are usually also in contact with the object. The dynamic phase of the power grip consists of the opening/closing of the fingers and thumb into a suitable grasping position. The actual grip is the transition to the static phase in which the object is held firmly. In a power grip, the thumb is adducted at both the MCP joint and the CMC joint. A crucial role of the thumb in a power grip has its means in the value of controlling precision. When there is a high demand for precision in a power grip, the thumb becomes adducted so that it can control the direction of the applied force in case of small adjustments of posture. When there is little de-

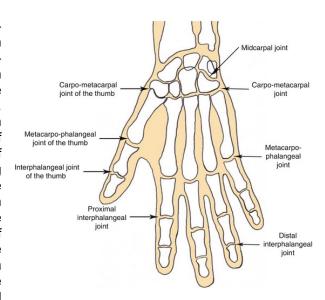


Figure 2.3: Joints in a human (right) hand, palmar side [46].

mand for precision, the thumb is wrapped over the dorsum where it acts as a reinforcing mechanism [45]. The fingers are slightly flexed during a power grip, dependent on the dimensions of the held object [44].

Pinch grip

In a pinch grip the object is pinched between the tips of the fingers and the opposing thumb. The fingers on one side and the thumb on the other side both form a jaw of a clamp. Only (some of) the distal phalanges of the hand are in touch with the object, and the metacarpals are not in direct contact with the object. In a precision grip, the MCP joint and CMC joint of the thumb are both abducted. In this grip, the thumb is also medially rotated at the CMC joint and is thus in opposing position to the phalanges of the finger [44]. The fingers are flexed and abducted at the MCP joint. This posture ensures that the sensory surface of the fingers is used to the fullest advantage, providing the most favourable opportunities for delicate adjustments of posture. A pinch grip of 10 N is sufficient for the performance of most ADLs for children [47]. It is, therefore estimated that the required pinch force for adults would be higher. Conventional VC prosthetic hands (Hosmer APRL hand 52541, Hosmer soft hand 61794, and Otto Bock 8K24 hand) show to be capable of pinching in the range of 5-41 N for a cable force of 100 N. Prosthetic hooks are generally able to perform higher pinch forces. Commercially available designs (Hosmer APRL hook 52601 and TRS hook Grip 2S) show pinch forces in the range of 30-58 N for a cable force of 100 N [48].

The opening span of a prosthesis is the maximum opening diameter of a prehensor. The object size that a prosthesis can grasp is dependent on the opening span, and so it is essential to make this span meet the ADL's. Five commercially available VC prostheses that are widely being used (Hosmer APRL VC hand, Hosmer APRL VC hook, Hosmer soft VC male hand, Ottobock 8K24 and TRS Grip 2SS) have been compared on their opening span, excluding their optional inner- or cosmetic gloves [48]. An average of 72 mm has been found.

2.2.2. Body-powered considerations

Body-powered devices are actuated by muscle strength, by means of flexion of the shoulder or elbow joint. These are delicate, small and not very powerful movements, needed to develop the output force. BP prostheses, therefore, deal with a small actuation force and require a high force transmission ratio to develop high grip force outputs. The force transmission ratio gives the ratio between the input force, the force created by the intact shoulder or elbow joint, and the output force, the force that the fingers of the prosthesis project onto the object.

2.3. Control 9

Force transmission ratio =
$$\frac{\text{Pinch force}}{\text{Actuation force}}$$
 (2.1)

The amount of dissipated energy, indicated by hysteresis, provides a quantitative measure for the efficiency of the device. In the case of a closing and opening cycle of a prosthesis, this can be indicated by the difference between the needed work to close the device and the work returned by the mechanism while releasing the cable to go back to the resting position [48]. The formula is indicated in Equation 2.2. It is advantageous to have an efficient mechanism and thus, a low hysteresis.

$$Hysteresis = W_{closing} - W_{opening}$$
 (2.2)

In which Hysteresis in [Nm], W_{closing} = Work for closing the prosthesis [Nm], W_{opening} = Work to re-open the prosthesis [Nm].

2.3. Control

Although myo-electrical prostheses are currently increasing, the use of BP devices is still large. The control of the terminal device is easy and fast and offers intuitive and straightforward control. The benefit of making use of proprioceptive feedback, the lower demand for maintenance, and the relatively low costs in comparison to electronically driven mechanisms make BP control very appropriate and easy to implement in low-resource countries. Furthermore, BP prostheses do not require batteries or motors, making it better resistance to different climate and hygienic conditions and have lower demand for maintenance. A voluntary closing design is preferred over a voluntary opening mechanism so that the user has more intuitive perception over the conducted force and thus can better control the pinch force onto the object [49, 50].

BP prostheses require the use of a shoulder harness for the actuation of the prosthetic fingers. The cable excursion is dependent and restricted to the maximum body movement. Taylor measured a maximum cable excursion of 53 ±10 mm [18], so within this range users should be capable of closing the device and performing a grip.

2.4. Cosmetics

The appearance of a prosthesis makes a significant difference in the way that users experience their device [51]. Pure functional prostheses, like BP hooks, deliver great functionality but do not look like real hands at all. Especially in countries where disabilities are not socially accepted, and where patients face social stigmas due to their condition, the desire for devices with a natural-looking appearance is strong. As a result, the appearance of the prosthesis can be a significant reason for the rejection of public usage of the prosthetic device.

It is essential to resemble a normal human hand when designing for low-resource countries. This means that the device should contain five fingers with distinguishable phalanges corresponding to human hands, constructed in skin colour. The size of the hand should meet the average size of an adult human hand, and details like nails and knuckles should be recognisable. In order to provide a natural and pleasing appearance, upper-limb prostheses are often covered with a cosmetic glove. Gloves furthermore protect the mechanism against exposure to the external world, such as dirt and moisture, and can be made of a material with a high friction coefficient to preserve a stable grip. On the other hand, multiple studies show that the durability of the gloves remains a major area of concern [52, 53]. Gloves are often expensive, require much maintenance, hinder proper functionality, and add weight to the device. The patients in low-resource settings have, in general, more practical jobs and activities during the day in less hygiene settings, so higher wear outcomes are expected in comparison to Western countries. Hooks and several 3D printed devices have shown to be functional without a cosmetic glove but did not manage to provide an appearance close to a natural look.

2.5. Comfort

Consumer complaints concerning comfort aspects of body-powered prostheses generally include excessive weight, harness discomfort, excessive wear temperatures, and sweating [12, 52]. Literature shows that excessive weight could be a reason for rejection of the prosthesis, or could reduce the wearing time due to comfort reasons [54]. High comfort complaints emanate from socket fitment onto

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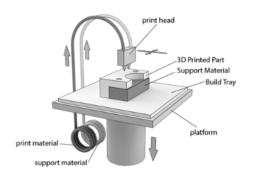
the stump and not directly connected to the skeleton. Hence the prosthesis is experienced as a large load on the stump of the patient [55]. Although a human hand has an average weight of 400 grams, distal to the wrist and excluding the forearm extrinsic muscles [56], a prosthesis with similar weights is experienced too heavy due to the lack of muscles in the device. Current commercial prostheses are available in the range of 113 - 615 grams [57], with optimal comfort experiences with a device as lightweight as possible. The BP Ottobock hand prosthesis has a frame weight of 220 gram, while including the inner glove and cosmetic glove the mass adds up to 423 gram. The TRS hook has a total weight of 318 gram and is used without gloves [58].

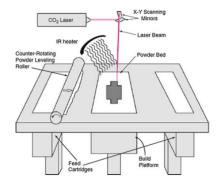
High operation forces can lead to undesirable fatigue in the muscles of the shoulder, reducing the daily wearing time of a prosthetic device. In order to reduce the input effort of the user, it is desirable to develop a device that is fully functional with low actuation forces. The study of Hichert et al. [59] showed that operation forces should be maintained at a maximum of 38 N for female users and 66 N for male users, in order to operate a prosthesis fatigue-free during a day. The BP Ottobock prosthesis without gloves (8K24, size $7\frac{3}{4}$)) requires a cable force of 78 N to pinch 15 N, which rises to 98 N after the addition of the gloves. The TRS BP hook requires 33 N for a 15 N pinch [58].

2.6. Additive Manufacturing (AM) for product construction 2.6.1. AM processes

AM refers to the technology that a model, generated using a three-dimensional (3D) Computer-Aided Design (CAD) system can be fabricated directly without product planning [60]. This technique allows for 2-dimensional (2D) layer to layer addition of material to construct a 3D product [32, 33] wherein each layer a thin cross-section of the original CAD data represents, rather than by subtracting material from a larger piece of material. Objects are created by fusing or depositing materials, such as plastics, metals and ceramics [61, 62], dependent on the used type of printing. In this way, AM significantly simplifies the process of complex object production from CAD data.

AM techniques are classified into seven different categories, according to the ASTM standards [63]. These groups are different from each other in the way that the layers are created and in the way that the layers bond to each other. An overview of the different groups is provided in Table 2.1.





(a) Fused Deposition Modeling (FDM) [64]

(b) Selective Laser Sintering (SLS) [60]

Figure 2.4: Printing techniques; a) FDM printer; Melted filament is extruded through a nozzle that moves in the x-y plane to form a solid part, b) SLS; the laser fuses the particles together and forms a solid object

Material extrusion includes a process that deposits material through a nozzle that moves in the x-y plane [65]. The filament is heated inside the liquefier, where it melts and becomes suitable for deposition. Fused Deposition Modeling (FDM) printers are the most common printers, especially for private property or small businesses, mainly because of the ease of use and the low costs in comparison with other techniques. Powder bed fusion is a process that utilises a thin layer of material that is spread over the build platform. This layer is selectively processed with an energy source, a laser or an electron beam, that fuses the specific region. A new layer of powder is subsequently spread across the previous layer using a roller and fused to the previous layer by the energy source [60]. The unfused powder remains in position and has to be removed during post-processing. Selective Laser Sintering (SLS) and Direct Metal Laser Sintering (DMLS) are two technologies that make use of a high-

Table 2.1: Classification of AM processes based on ASTM, and their basic properties [60].

Categories	Technologies	Printed 'ink'	Power source	Strengths / weaknesses
Material extrusion	FDM	Thermoplastics	Thermal energy	Low-cost extrusion machineMulti-material printingLimited part resolutionPoor surface finish
	SLS, DMLS	Poly-amides, polymer	High-powered laser beam	- High accuracy and details - Fully dense parts - High specific strength and stiffness
Powder bed fusion	SLM, EBM	Atomised metal powder, ceramic powder	Electron beam	- Powder handling and recycling - Support and anchor structure - Fully dense parts
Vat photo- polymerisation	Stereo- lithography	Photo-polymer, ceramics	Ultraviolet laser	 High building speed Good part resolution Over-curing scanned line shape High cost for supplies and materials
Material jetting	Polyjet / inkjet printer	Photo-polymer, wax	Thermal energy, photo-curing	Multi-material printingHigh surface finishLow-strength material
Binder jetting	Indirect inkjet printing	Polymer powder, ceramic powder, metal powder	Thermal energy	 Full-colour objects printing Require infiltration during post-processing Wide material selection High porosities on finished parts
Sheet lamination	LOM, UAM	Plastic film, metallic sheet, ceramic tape	Laser beam	- High surface finish -Low material machine, process cost - Decubing issues
Directed energy deposition	LENS, EBW	Molten metal powder	Laser beam	 Repair of damaged / worn parts Functionally graded material printing Requires post-processing machine

powered laser beam. In contrast, Selective Laser Melting (SLM) and Electron Beam Melting (EBM) use a power source in the form of an electron beam. *Vat photopolymerisation* processes make use of liquid photopolymers contained in a resin vat. The build platform moves downwards while the resins react to ultraviolet radiation (UV) and become solid after a chemical reaction. After completion, the vat is drained, and support has to be removed [66]. Stereo-lithography (SLA) is the technology that is used most often. *Material jetting* is a process that deposits droplets of liquid photopolymers using piezo printer heads. The liquid material solidifies by using UV radiation or thermal energy depending on the used AM technology [67, 68]. *Binder jetting* processes generally use two materials. A metal/ceramic based material and a binder material that acts as a kind of glue between the layers [69]. The binder material is usually a liquid that is deposited over the layer of solid powder material in order to form part cross-sections. The object is then formed where the powder is bound to the liquid binder. The unbound powder remains in position, and several post-processes are required after finishing printing [70]. *Sheet lamination* processes use metallic sheets that are locally being treated by an energy source, usually

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with ultrasonic waves or through a laser [71]. In this way, the required shape is cut from the layer and bonded in place. Adding layer by layer will construct the object. *Directed energy deposition* (DED) processes are typically used to repair or add material to existing parts. The technique uses an injected metal powder along with an energy source. As the material is being deposited, the heat source instantly melts the material and adds a layer of substrate in this way. This process is being repeated until all layers have solidified [60]. DED techniques can be divided into Laser Engineered Net Shaping (LENS), which uses powder flow as a feedstock, and in Electronic Beam Welding (EBW), using traditional metal wires as a feedstock [71].

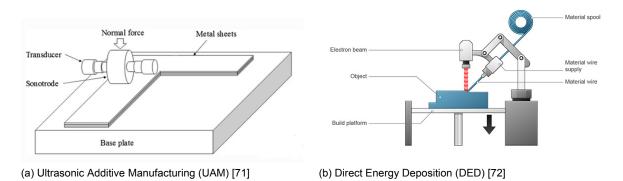


Figure 2.5: Printing techniques; a) UAM, a sonotrode moves over a laid out metal sheet to provide ultrasonic vibration and pressure to bond the sheet with the previous layer(s), b) DED, deposition of material is simultaneously melted by a heat source.

2.6.2. Design for AM: Opportunities and benefits

Designing for AM is the development of a product and optimise its characteristics by careful consideration of production system properties, design goals, and manufacturing constraints [73]. AM processes have different production times and cost drivers than traditional manufacturing techniques and hence require different approaches to quality control [74, 75].

AM technologies provide a broad range of different materials, as shown in Table 2.1. Some technologies allow for printing of dual materials, providing the use of multiple material properties within one part. Multiple processes can create products in full colour, by adding this to raw materials or by using different coloured feedstocks [79, 80]. AM furthermore provides internal geometry freedom which can be beneficial to increase functionally and improve performance. It is used to create integrated wiring conduits, recesses for combined part designs and complex internal pathways [74].

One of the major advantages of AM in comparison to conventional assembly methods is the possibility to create non-assembly mechanisms. This type of mechanism is fabricated through a process that does not involve the assembly of parts. Components in such a mechanism are integrated into the structure of an opposing part during fabrication with an AM machine [81]. This principle enables

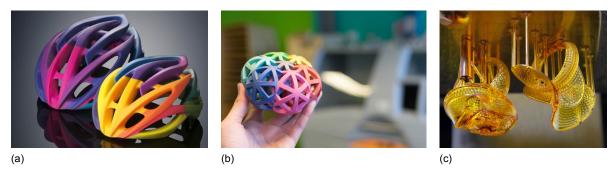


Figure 2.6: AM parts in full colour: a) helmet printed using fused deposition modelling [76], b) organic shape printed in sandstone with binder jetting [77], c) organic shape printed with support structures using vat polymerisation [78].

the construction of complex and functional mechanisms regardless of specialised manufacturing resources, making it immediately functional after construction [37]. In this way assemblies with movable parts, such as slider mechanisms, joints, hinges and gears, can directly be produced. AM, therefore, permits the construction of complex geometries and shapes in a single step, removing the need for skilled technical personnel or labour-intensive procedures [37].

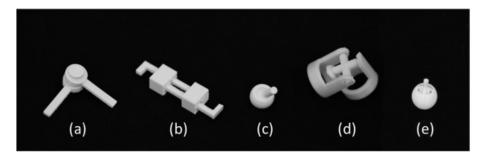


Figure 2.7: Examples of joint concepts created by non-assembly AM. a) Revolute joint, b) Prismatic joint, c) Spherical joint, d) Universal joint, e) Cage-in-socket joint. [37]

2.6.3. Design for AM: Constraints and considerations

Although AM is often recommended to have unlimited potential, there are several properties and constraints that designers need to take into account.

AM requires digital computer-aided design (CAD) models that digitally represent the developed part. There is no human intervention in the translation of these models to the physical product. Therefore it is crucial to develop a complete and high-quality design. This type of designing is in contrast to conventional manufacturing methods where humans can have more control over the development of parts during fabrication. CAD systems are furthermore not capable of generating different inner-structures, denote colour, indicate material variation within a part, specify the chosen material or indicate tolerances [74]. As a result, an interface that specifies part structures and determines the properties of the object is always needed.

The layer by layer addition of a part construction often, nearly always, result in characteristic surface roughness. The inter-space between two layers can initiate cracks and material failure. These

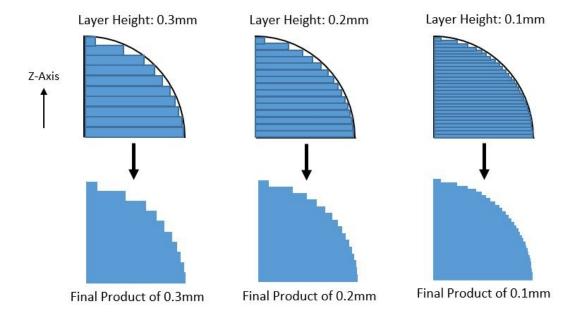


Figure 2.8: The effect of layer height on curved surfaces is significant [82].

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properties are caused by weak interlayer bonding leading to anisotropic behaviour within the object [83]. There are several ways to influence the material properties of the constructed part. An important aspect to take into account is the printing direction. Surfaces parallel or directly subjected to the building platform at a zero degree orientation, have a higher surface smoothness [84]. Furthermore, printer specifications like layer height, wall thickness and printer speed influence the accuracy of the printed part. Other options to increase surface finish include modification of the part or post-processing operations such as chemical or mechanical polishing [85].

Each state/layer must be capable of resisting forces that are applied during the addition of layers, such as gravitational loads, internal forces derived from thermal and residual stresses and external forces applied by the printer. By orienting the part to maximise its strength during the build and adding support structures, mechanical effects can be compensated, and non-supported structures can be created [74]. Optimisation of the printing orientation can contribute to reduced printing time and costs. Furthermore, it is essential during designing to consider the impact of support structures on the final part. Some supporting systems, for example, have to be broken off and can damage the resulting part or add surface irregularities [86].

2.7. Hand prostheses developed with AM

Over the past ten years, a significant development in the design of upper-limb prostheses using 3D printers for manufacturing. Ten Kate et al. [28] provided a review on 3D printed upper limb prostheses. They showed that the majority of the created hands (46/58) was made using the FDM material extrusion technique. The primary argument for choosing for this technique is the low machine costs, the simple process and the possibility to use a wide range of materials. Other chosen techniques are SLS (6/58), SLA (1/58) and polyjet printer (1/58). Advantages of these techniques are that smaller details can be printed and hence higher design freedom. The majority of the designs (45/55) used cables/cords to close the prosthesis, while the remainder used mechanical linkages. Different methods have been found to open the prosthesis, varying from cables/cords, mechanical linkages, elastic cords or bands to compliant mechanisms. Nearly all hands implemented multiple joints and DOF, although only 24 of the hands are able to perform a power and precision grip. Thereby only one hand specified the ability to provide fingertip forces and grip loads. Therefore it is uncertain how current prostheses perform. Two 3D printed prostheses have been created at the TU Delft and will be analysed below.

2.7.1. 100 Dollar Hand







Figure 2.9: 100 Dollar hand, a 3D printed mechanical prosthesis with metal linkage mechanism, attached to locally produced socket in India.

The 100 Dollar Hand is a mechanical prosthesis, designed by the Delft Institute for Prosthetics and Orthotics (DIPO). The casing is completely manufactured by an FDM printer and therefore very suitable for low-cost production. The body-powered cable actuation causes the metal laser cut cross-bar linkage mechanism to close the fingers and perform a grip. A tension spring will open the fingers to move

back to the resting, open position. This 1-Degree of Freedom (DOF) prosthesis managed to be very lightweight and resistant to different weather conditions, water and dirt. Ten patients have been fitted with this prosthesis during my time in India. The overall results were very positive, and the prosthesis has been regarded as a promising solution in the ask for high-functional low-cost prostheses. One of the biggest requests from fitted users was to develop a more natural-looking prosthesis since they did not feel comfortable with others mentioning their impairment. Furthermore, my personal biggest concern is directed to the manufacturing process of the hand. Although a large part can be processed with a 3D printer, high precision post-processing is needed to assemble the device as well as the need of a laser-cutter and a variety of different machines and tools to adjust specific screws and metal parts. Even if all these necessities are present, like in the Robotics Lab at the university, it is still a very time-consuming and labour intense job.

2.7.2. Juan's Hand



Figure 2.10: Juan's prosthetic hand, all components are printed with a dual-extruder FDM printer. Three three different materials have been used; PLA (white), TPU (blue) and nylon (black). The whippletree mechanism equally distributes the force over the fingers.

Recent research at the TU Delft focused on the same design problem as dealt with in this report. Juan S. Cuellar reacted with his design on the ask for a production process that requires less technical knowledge and time. He created a non-assembly device, in the design of a hand prosthesis that was constructed entirely with an FDM printer and hardly needed any intervention to manufacture different pieces together. His design is shown in Figure 2.10 and comprises of multiple DOF. He used a dualextruder machine for the construction and made use of three different types of materials. The used materials are PLA (white) for construction of the palm and fingers, TPU (blue) to construct tendon-like wires and fingerpads and nylon (black) to create muscle-like strings for activation of the fingers. The materials have been chosen based on their elastic properties. PLA is very stiff and is therefore used for rigid parts, while TPU has a higher ductility and has thus better abilities to deform without yielding. Nylon has elastic behaviour that can be regarded in the middle of TPU and PLU. His design showed the design capabilities of AM and the possibilities to create non-assembly devices. The functional performance, in terms of required actuation force and fingertip force output, is weak. A high actuation force is required to enclose the fingers, due to high stiffness on the joints caused by high counteracting forces of the elastic strings. Furthermore, the stiffness of the nylon actuation strings hinders the bending motion, causing a higher required actuation force. Though, this stiffness is essential to ensure the strength of the part. The tendon-like wires seem to be fragile, but no fatigue or durability tests have been performed yet.

Conceptual design

3.1. Approach

The human hand can perform such a great diversity of movements that a prosthetic device will always be a compromise of functions. In this chapter, design requirements will be set up to emphasise the important user aspects to work on. The requirements follow up on the analysis of the previous chapter and comprise of the manufacturing type, function, control, cosmetics, comfort, durability and costs. In Table 3.1 quantitative measures will be given to the minimum requirement and the wished outcome, and in the subsections 3.2.1-3.2.7 the requirements will then be explained. Based on these requirements, a conceptual design in terms of working principles, boundaries and embodiment is thereafter proposed.

3.2. Design requirements

Table 3.1: Design aspects with their requirements and wishes.

Aspect	Parameter	Requirement	Wish
	Printer type	75% parts printed with FDM	Fully printed with FDM
Manufacturing	Assembly time	≤ 10 min	≤ 5 min
	Number of parts	≤ 5	Non-assembly mechanism
2. Control	Actuation type	VC	VC
Z. Control	Cable excursion	≤ 53 mm	≤ 43 mm
	Grip type	Pinch grip	Pinch + power grip
3. Function	Opening width	≥ 70 mm	≥ 75 mm
3. Function	Pinch force	≥ 15 N	≥ 20 N
	Transmission ratio	≥ 0.4	≥ 0.5
4. Cosmetics	Shape	Human like	Human like
4. Cosmelics	Dimensions	Human like	Human like
5. Comfort	Mass	≤ 250 g	≤ 200 g
5. Comort	Operation force	≤ 38 N	≤ 38 N
6 Durability	Cycles without	≥ 300.000	> 600.000
6. Durability	intervention	≥ 300.000 	≥ 000.000
7. Costs	Material costs	≤ 50 €	≤ 30 €

3.2.1. Manufacturing type

The created design should be fully printable with an FDM printer to offer an alternative to the time consuming and demanding manufacturing process of current hand prostheses. The FDM printer is regarded the most promising due to the low machine costs, the simple process and the possibility to use different materials and colours. In this way, the device can ultimately be locally fabricated and manufactured and is portable and usable in rural areas or in medical clinics that did not have prosthetic machinery before. The FDM machine is operative with little knowledge, and the design should be

created in such a way that post-processing is minimal. The assembly of the final product should be easy, not requiring practical technical or medical knowledge, and manual labour should take a maximum of ten minutes per prosthesis. This to respond to the lack of trained personnel and the provision of jobs to the uncertificated population. In order to facilitate the assembly process, the design should take as less as possible parts, preferably it should contain a non-assembly mechanism.

3.2.2. Control

The control mechanism of the prosthesis should be BP so that the user can benefit from the proprioceptive feedback and has control over the performed force onto an object [49, 50]. The maximum cable excursion to completely close the hand should be 53 mm with a wish of 43 mm. In this way, all users are able to use the full cycle of the device and grasp a broad range of object sizes.

3.2.3. Function

The prosthesis should be designed to be able to perform at least a pinch grip. Wished is that the design is also capable of performing a power grip. It should furthermore be able to grasp a broad range of objects and should, therefore, have a minimum opening span of 70 mm, preferably larger than 75 mm. Although the hand should completely be designed with a 3D printer, it is required to have at least similar pinch forces to commercially used BP prostheses created with conventional manufacturing techniques. In order to meet all ADL's it is required that the final design should be able to pinch an object with 15 N under comfortable operation. BP prostheses have to deal with a quite small actuation force since it is derived from a small shoulder or elbow movement. In functional terms, it is therefore essential that the necessary actuation should not exceed the maximum actuation force that is experienced comfortable by users. The transmission ratio between the input force, the actuation force, and the output force, the pinch force onto the grasped object, should be optimal and minimal 0.4 as calculated below. Wished is to be able to grasp 20 N under comfortable use. The transmission ratios are then calculated, as shown below.

minimal transmission ratio =
$$\frac{\text{minimal pinch force}}{\text{maximal actuation force}} = \frac{15\text{N}}{38\text{N}} \approx 0.4$$
 wished transmission ratio = $\frac{20\text{N}}{38\text{N}} \approx 0.5$

3.2.4. Cosmetics

In low-income countries, and especially in rural areas, the acceptance of deformities is very low [87]. Patients, therefore, have a desire to mask their deficiency and have a high demand for a natural-looking product. For a better acceptance of the prosthesis, the device should resemble a human hand as close as possible. Therefore the hand prosthesis should meet the dimensions and shape of an average human hand, the texture should resemble the human skin, and the colour should be adjustable to the skin colour of the patient.

3.2.5. Comfort

Excessive weight is one of the major reasons for rejection of prostheses and thus it is required to create a lightweight design [12, 52]. The entire hand, including the mechanism, should weigh significantly less than an average human hand of 400 grams to compensate the perception of an external load onto the stump of the patient. It is therefore required that the mass is lower than 250 gram, but preferred to be less than 200 gram.

High operation forces can lead to undesirable fatigue, reducing the daily wearing time of a prosthetic device. Therefore operation forces should be maintained at a maximum of 38 N for female users and 66 N for male users, to operate the device fatigue-free during an entire day [59]. It is required that both men and women are capable of using their prosthesis without comfort problems. Therefore the required maximum operation force will be stated at 38 N. Higher forces could be accepted for non-repetitive, short term tasks. However, the basic ADL's should be able to perform with these stated actuation forces.

3.2.6. Durability

People in lower-income or less-developed countries tend to have less access to health services, and the poor have, in general, less access to health services than the rich population [88]. The geographic spread of the health centres, usually located only in the big cities, complicates the accessibility to proper care. Therefore it is essential to put high importance to the durability of the product since it is likely that patients will have difficulties to reach prosthetic centres in order to obtain repairs. A prosthesis undergoes about 1200 cycles a day, based on a wear time of about eight hours [89]. This means that the device should have to withstand 300.000 cycles without creating any deformities or losses in function, in order to support an amputee during a year without the need of maintenance. Preferably maintenance should even be needed only once in 2-3 years.

3.2.7. Costs

Studies show that the poorer the country, the larger the amount of total health expenditure out of pocket [88]. Literature furthermore estimates that about 80% of the amputees in low-resource countries is not capable of covering needed costs required for prosthetic fitment [23]. It is, therefore, essential to have significantly low material costs. The cost of the conventional ALIMCO BP prosthesis is assumed plausible to semi-expensive by local prosthetists. The total fitment of the ALIMCO hand costs about 100 euros and includes socket fabrication costs and wages of about 25 euros. This means that the estimated product cost of the terminal device is about 75 euro. In comparison, the monthly income per capita in India is estimated on 11.254 Rupees, equivalent to about 138 Euro [90]. It would be desirable to create a device that is cheaper than the current design and sums up to a maximum of half of the monthly income per capita. Therefore the total material costs of the terminal device of the prosthesis should be maximal 50 euro, and preferable lower than 30 euro.

3.3. Grasping Mechanism

3.3.1. Suitable transmission mechanisms for AM

Transmission is a term that includes all different types of mechanisms to develop the movement of forces or energy from a place where it was generated to a location where it is applied to perform work. Evidently, it is desirable to work with an efficient mechanism and thus, a high transmission ratio and low frictional losses. Within the to develop design, there are are two required mechanisms that have to be taken into account; the type of flexor and the type of extensor. The flexor will be used to close the prosthesis and enable a grip, while the extensor is used to open the prosthesis. The majority of the current VC prostheses use cables or non-elastic cords as a flexor, and thus chose to use a non-printed material [28]. The remainder uses mechanical linkages to actuate the mechanism. A large number of examples uses elasticity to extend the mechanism back to the initial open position. This can be done in the form of cords or bands, but also through elasticity in the joints by using compliant mechanisms [28]. Compliant connections are flexible mechanisms that gain their motion through elastic body deformation [91]. An alternative can be to use cables/cords or mechanical linkages.

Several prostheses that were developed with an AM process show weak force transmission ratios. This results in the requirement of high actuation forces and small pinch force outputs. The cause can be found in different aspects. First, the use of cables, mainly for flexion of the fingers, in several designs suffers from high developed friction. Non-guided wires rubbing against the part surfaces develop high friction and thus demand high actuation forces. Extra friction on the joints can furthermore evolve due to inaccuracy of the printer, that often results in rough surfaces and deteriorated smooth sliding of the cables. Compliancy of the joints furthermore often requires much force and adds hysteresis effects due to arose friction [92]. Thereby, the required energy to perform a grip, in general, is dependent on the number of used joints and thus the DoF in the design. Every extra joint will need extra force to perform a movement, and add friction to the system. A specific issue that rises while using AM is the inaccuracy of printed parts. The layer-to-layer building process can develop small gaps or unequal structures that can add friction in joints or deteriorate smooth movement of parts. These aspects can affect the rigidity of the mechanism and add hysteresis effects [93].

The five most important transmission types are mechanical transmission, hydraulic transmission, pneumatic transmission, magnetic transmission and electrical transmission. Since the focus of this design is on an affordable and simple mechanical hand prosthesis, hydraulic, pneumatic, magnetic and electrical transmission are not applicable and will be disregarded from further evaluation. Different ex-

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amples of mechanical transmission can be found. In Table 3.2 these transmission types are compared based on their functionality and suitability for application in the function of a flexor or extensor.

A mechanical linkage is an assembly of connected bodies to transmit forces or movements. The simplest linkage is a lever, a link that transmits forces around a fixed point. This transmission type is suitable for printing, has theoretically very low friction losses, and is robust and compact. The flexor will, therefore, be designed with a lever. The extensor needs some sort of elasticity and will always perform work in the opposite moving direction in order to return the hand to the resting position.

Ability to print Force transmission Robustness Compactness

Flexor

Cables
Cords/wires
Linkages
Gears

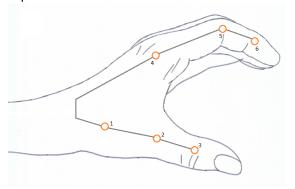
Extensor

Tension spring
Elastic band
Compliant joint

Table 3.2: Design aspects with their requirements and wishes.

3.3.2. Selection of operating joints

The prosthetic hand will only contain the required joints to perform a pinch and a power grip. The remaining joints will be static to prevent friction losses on the joints. In Figure 3.1, the schematic representation of the joints in the human thumb and fingers is illustrated. As earlier described in Chapter 2, the thumb and each finger consist of three distinguishable joints. A combination of the movements in the different joints will lead to a specific grip function. In a pinch grip the thumb is in an opposing position to the phalanges of the finger. The MCP and CMC joint of the thumb are abducted, and the IP joint is flexed, while the MCP joint of the finger is abducted and the PIP and DIP joints are slightly flexed [44, 94]. In a power grip, the CMC and CMP joint of the thumb are abducted, the IP joint is extended, and all the joints in the fingers are slightly bent towards the palm according to the object size. This is also represented in Table 3.3.



	Joint	Pinch grip	Power grip
1	CMC thumb	Abducted	Abducted
2	MCP thumb	Abducted	Abducted
3	IP thumb	Flexed	Extended
4	MCP finger	Abducted	Flexed
5	PIP finger	Flexed	Flexed
6	DIP finger	Flexed	Flexed

Figure 3.1: Schematic representation of joints in human hand.

Table 3.3: Position of joints in the human hand during pinch and power grip.

For the selected grasping functions three basic working principles can be distinguished: 1) bending of one or multiple joints in both the fingers and thumb, 2) bending of one or multiple joints in the fingers, 3) bending of one or multiple joints in only the thumb. Regarding the good functional outcomes of prosthetic hooks in comparison to hands [48, 95], there will be chosen to move only one part of the hand. This will include the fingers or the thumb, and hence the working principle of a gripper will be mimicked. The movable part will be responsible for gripping an object and pressing it securely into the static part to perform a grip. There has been chosen to develop a design with a movable thumb and static fingers in a natural slightly flexed position because of a few aspects. First, rotating a thumb will be able to perform the selected grasping types by only rotating one joint, and therefore, friction effects on joints are minimised to only one position. Second, the large cylindrical static area of the

palm and fingers can be used to firmly press the object into. This surface ensures a reference point while grasping an object. Lastly, the dorsal side of the hand is visually the most visible and therefore, the most important to look natural during a resting position. Making this part static will ensure that the fingers do not have to perform some form of hyper-extension to ensure a large opening width.

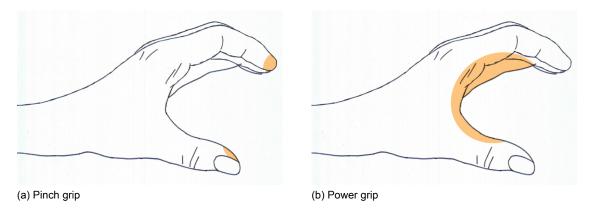


Figure 3.2: Area's of the hand in contact with an object during a a) pinch grip and b) power grip.

3.3.3. Working principle: Movable thumb

The thumb will be positioned exactly opposite to the edge between the index and middle finger. In this way the gripped contact area during a pinch grip will be larger since three fingers (tripod pinch grip) instead of two are used to perform a grip. The fingers and thumb naturally bend towards each other during a pinch grip. In order to ensure that the hand can perform a pinch grip with only a moving thumb, the thumb needs to be elongated. The rotation punt of the thumb will be located precisely between the MCP joint of the thumb and the MCP joint of the finger. The rotation point will have a significantly large area to ensure solidity. Hence, the created movement will be comparable to the combined movement of the MCP and IP joint of the thumb. The thumb will be slightly hyper-extended in the resting position to ensure a large opening width and facilitate gripping objects of different sized.

The simplest linkage mechanism is a lever, a link that transmits forces around a fixed point. The ideal lever does not dissipate or store energy, and thus, in theory, there are no friction effects in the system. These advantages, together with the possibility to print the mechanism, make a lever mechanism suitable to perform the rotating movement. The distance from the tip of the thumb, the position that is in contact with the object, to the centre of the rotation point can be regarded as one side of the lever principle. The bar is subjected to the actuation cable running to the rotation centre is considered to be the other distance (Figure 3.5a). An ideal lever is shown in Figure 3.3. The mechanical advantage of this lever can be determined by the balance of moments around the rotating point (Figure 3.3):

$$M_1 = a \cdot m_1 g, \quad M_2 = b \cdot m_2 g$$
 (3.1)

M = moment [N], m_1 , m_2 = mass [kg], g = gravitational force equivalent [m/s²], a,b = distance [m]

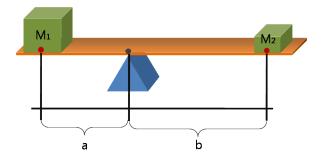


Figure 3.3: Lever principle. The lever is in balance if $m_1 \cdot a = m_2 \cdot b$. Figure from [96].

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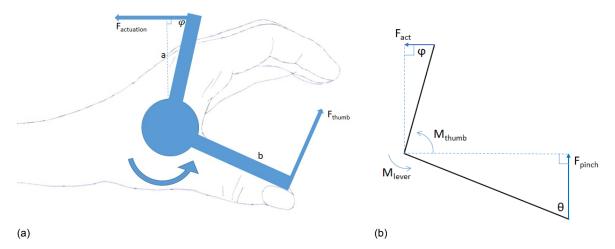


Figure 3.5: Left hand: a) Visualised working principle of the grasping mechanism, b) Free Body Diagram (FBD)

The law of the lever, assuming no losses due to friction or elasticity of the material is then a ratio of the distances from the point of application of the forces to the rotational point of the system:

$$a \cdot F_1 = b \cdot F_2 \tag{3.2}$$

In contrast to the ideal representation of the lever in Figure 3.3, the lever mechanism of the hand will not work with a single linear beam. The length and direction of the thumb are fixed according to the position of the rotation point. This length is dependent on the required length to close the fingers. The length of the lever should be significantly large to minimise the required actuation force, but small enough to optimise the appearance. Preferably the lever would fit entirely into the palm of the hand and would not be visible in the resting position. Therefore the lever will at least be smaller than the length of the thumb. The direction of the lever in resting (begin) position should be rotated in the opposite direction regarding the movement direction of the

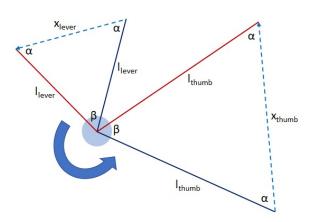


Figure 3.4: Schematic representation of the path of the lever and thumb, left hand.

imaginary extension of the thumb (see Figure 3.4). In this way, the lever is better positioned regarding the direction of the actuation force, and thus will the beam fit better in the palm of the hand.

The lever arm is measured from the axis of rotation to the point of application of the force (see Figure 3.5a). The moment that the actuation force can develop is therefore dependent on the angle between the force and the handle (Equation 3.3). The transmission of forces through a lever is optimal when the applied force is perpendicular to the lever arm and thus $sin(\varphi) \approx 1$.

$$asin(\varphi) \cdot F_{act} = bsin(\theta) \cdot F_{thumb}$$
 (3.3)

$$l_{lever}sin(\varphi) \cdot F_{act} = l_{thumb}sin(\theta) \cdot F_{thumb}$$
(3.4)

In order to determine the required length of the lever, Equation 3.4 is solved for the most unfavourable angle of φ and θ between the axis of rotation and the point of application of the force. The angle θ is dependent on the object size. The force will always be perpendicular onto the object but the angle of the thumb will vary. The minimum length of the lever has to be larger if $l_{lever} \cdot sin(\theta)$ is larger. Therefore the most unfavourable value for θ is 90 degrees, resulting in $sin(\theta) = 1$.

The most unfavourable angle for φ can be found in the outermost positions, the positions where the prosthesis is fully open or fully closed. The lever will so be designed that the perpendicular point of

activation is exactly at the point of half of the path of the lever. In this way the lever transmission is the most efficient. Therefore the angle can be derived from Figure 3.4. The known lengths of the thumb (l_{thumb}) and the opening width (x_{thumb}) are 77 mm and 75 mm respectively. The maximum actuation force under comfortable prosthesis usage is 38 N, and the minimum corresponding pinch force is 15 N, as stated in Table 3.1. The wished output pinch force is 20 N under a 38 N actuation. The calculations are shown below.

$$l_{lever} = \frac{l_{thumb} \cdot sin(\theta) \cdot F_{thumb}}{sin(\varphi) \cdot F_{act}}, \qquad \varphi = \alpha = cos^{-1} \left(\frac{\frac{1}{2}x_{thumb}}{l_{thumb}}\right) = cos^{-1} \left(\frac{\frac{1}{2} \cdot 75}{77}\right) = 60.9^{\circ}$$

$$l_{lever} = \frac{77 \cdot sin(90) \cdot 15}{sin(60.9) \cdot 38} = 35 \text{mm}, \qquad l_{lever} = \frac{77 \cdot sin(90) \cdot 20}{sin(60.9) \cdot 38} = 46 \text{mm}$$

The cable excursion is dependent on the length ratios between the lever and the thumb. The path of the thumb between the resting position and the fully open position equals the opening width. The path between the resting position and the closed position of the lever can, therefore, be calculated using the ratio between the lengths (Equation 3.5) and the length of the lever. A lever length of 46 mm still fits into the palm of the hand and seems to fulfil the cosmetic requirements. Hence, this lever length will be used to maximise the pinch force on the thumb.

$$\frac{x_{thumb}}{x_{lever}} = \frac{l_{thumb}}{l_{lever}}$$

$$x_{lever} = \frac{x_{thumb} \cdot l_{lever}}{l_{thumb}} = \frac{75 \cdot 46}{77} = 45 \text{mm}$$
(3.5)

3.3.4. Sliding mechanism of the lever and thumb

The maximum cable excursion determines whether a prosthetic user is capable of controlling the entire opening width of the device. The theoretical cable excursion can be calculated using the length of the lever and the rotational angle.

$$x_{cable} = \frac{2\pi}{360} \cdot \beta \cdot l_{lever} = 47$$
mm

The theoretical cable excursion would be, neglecting the frictional effects, within the stated requirements but would not fulfil the wished value. It is therefore assumed that not all users will be able to make use of the entire opening width. In practice, that will mean that there will be users that are not capable to fully close the hand to perform a pinch grip and thus will not be able to perform tasks that include grasping of very thin objects, like paper, a layer of clothing or coins. As a solution, a sliding mechanism that changes the position of the thumb with respect to the lever is proposed. This mechanism changes the angle between the lever and thumb and so the opening width can be decreased in case of delicate tasks. Another advantage of this mechanism is that the lever can be 'tuned' to the position of the highest force transmission (perpendicular to the actuation force) so that higher grip forces can be achieved under equal actuation forces while requiring smaller body movements. The control of the hand will, therefore, also be faster.

The sliding mechanism will be created inside the rotating thumb and will be the connection between the separate lever and thumb parts. In this way, both parts fall exactly in a circular cavity created at the place of the interdigitalis between the index finger and the thumb. Using a small pressure spring, the connecting pin can be pressed, and the thumb and lever are able to rotate separately from each other. Releasing the pin that is connected inside the thumb, will ensure that it fits into one of the holes of the lever. In this way, both parts are securely connected and will rotate simultaneously after actuating the lever. Besides mechanical advantages, this mechanism also contains cosmetic benefits. Instead of a slightly hyper-extended thumb, not corresponding to the natural resting position of the hand, the thumb can adduct towards the palm.

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3.4. Physical embodiment

The majority of the created hand prostheses have tried to visualise the human hand as natural as possible, within the functional boundaries. Most commercially available designs, like the Ottobock hand, choose to fit the mechanism into a cosmetic glove to achieve cosmetic advantages. Gloves can have a more skin-like structure and customised colour matching the skin of the user. However, glove replacement is regarded as one of the leading maintenance issues, and costs are considerably high [98, 99]. Thereby the expectation of even higher wear effects in less developed and hygienic environments than in Western countries is plausible, especially presuming that the majority of the users is involved in intense labour jobs. Gloves furthermore add weight to the device and can hinder the functionality. Therefore there is decided to exclude the use of a cosmetic glove for this design.

Although in most examples of 3D printed prostheses the shape of a hand is distinguishable, cosmetically still much is left to improve. From personal experiences in Indian clinics, I know the enormous desire of patients to look normal, and contradictory to the Western opinion they do not fancy robot-like or futuristic designs. To respond to their wish and to optimise human features



Figure 3.6: Artec Eva handheld 3D scanner [97].

within the design, I have chosen to use a 3D model of my own hand. The dimensions of my hand are close to the average hand dimensions of the North Indian population, with a hand length of 18.5 cm versus 18.27 cm for Indian men and 16.81 cm for Indian women, and a handbreadth of 8.0 cm versus 8.25 cm for Indian men and 7.41 cm for Indian women [100]. A constructed setup with two Artec Eva handheld scanners was used to obtain the model. The 3D point accuracy of this type is up to 0.1 mm and the 3D resolution up to 0.5 mm [97]. The scanners have been placed in two different positions onto a framework to achieve optimal scanning results. The frame rotates around the object (my hand) in around three seconds and captures the image. A complete 3D model of the hand and a part of the lower arm had been created by combining the results of both scanners, as shown in Figure 3.7. The model is very detailed and even includes, besides the rough characteristics of a hand, distinguishable tendons and veins. The fingers are held in a natural position, slightly flexed at the PIP and DIP joints but extended in the CMC joint to preserve maximum opening width.

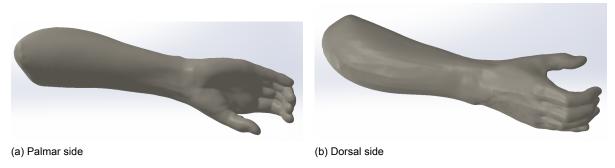


Figure 3.7: 3D model of my hand and lower arm, used as a base for the design of the prosthesis.

The lower arm up to, and including the wrist will be removed from the model since the terminal device will in practice, be connected to a customised socket. The thumb will be detached from the model and lengthened according to the opening width and a rotation cavity will be created inside the interdigitalis between the index finger and thumb. A small cover will furthermore be subjected on top of the rotation point to keep the thumb and lever parts in place.

Final Design

4.1. Approach

This chapter describes the final design and characteristics of the prototype. The design has been developed using SOLIDWORKS as well as the presented renders. The full drawings of the described parts can be found in Appendix B.

4.2. Fingers and thumb design

The fingers and palm are used from the model in original size and shape dimensions. The fingers are flexed in the PIP and DIP joints, and extended in the CMC joints. In comparison to the original hand model, the thumb is lengthened and rotated. The thumb is 18 mm longer in the final prototype than in the real hand and has a total length of 78 mm measured from the centre of the rotation point to the point of where it exerts a pinch force. The rotation of the direction of the thumb was required to ensure a tripod grip between the index finger, middle finger and thumb (see Figure 4.1). As a result, a larger contact area is created, and a more stable and firm grip can be performed onto the object. In this way, a higher grip force is developed [38, 101]. The thumb is lengthened between the MCP and IP joint to preserve a natural appearance. The thumb is able to rotate in one degree-of-freedom (DOF), comparable to the movement characteristics of a gripper.

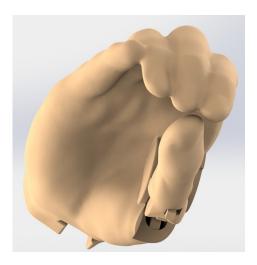
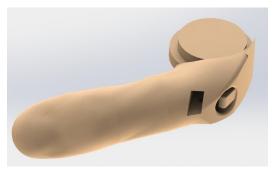
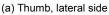
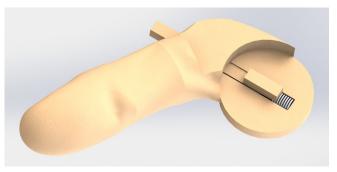


Figure 4.1: The thumb closes exactly between the index and middle finger to optimise the grip surface.







(b) Thumb, bottom

Figure 4.2: The thumb; a) Lateral, the attachment point for the elastic band is visible as well as the cavity for the pin, b) Bottom and interior, a pressure spring is placed below the extension of the pin and the pin is subjected through the width of the thumb.

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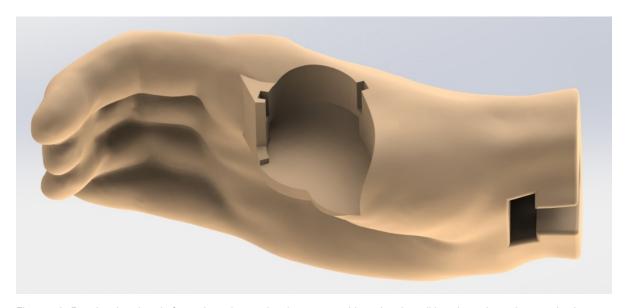


Figure 4.3: Rotational cavity; platform where the rotational parts are subjected and small housing to keep the parts in place.

4.3. Sliding mechanism inside the rotational cavity

The rotational point consists of separate parts that are placed on top of each other in the rotational cavity, and move simultaneously. The rotational cavity is positioned in the palm of the hand at the location of the interdigitalis. This the most natural position. There is no fixed connection between the parts, but they are bonded due to the shape conformity of the design. A small platform and surrounded housing have been created to secure the parts in the proper position and offer solidity to the design. The rotational cavity is extended through the inside of the finger, compassing the rotational space for the lever part. In the resting position, the lever falls entirely within the palm. The sliding mechanism fits precisely inside the cavity. The lever part is first subjected onto the platform and will provoke the rotation of the thumb after actuation. The lever and thumb are connected through a small pin. The thumb contains a small pin and pressure spring inside the design. The pressure spring forces the pin outwards the rotational centre, inside one of the holes of the lever. The top then closes the rotational cavity.

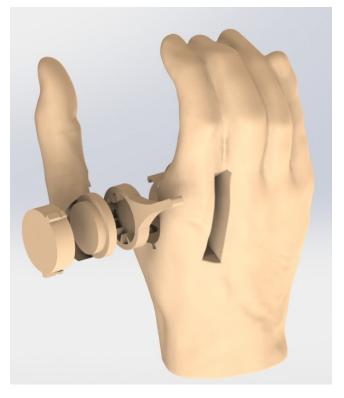


Figure 4.4: The lever, thumb and top fit subsequently inside the rotational cavity of the palm.

4.4. Lever design

The lever has an internal space with lever teeth to determine the three configurations of the thumb. The first position is the position in which the thumb is completely open and the lever completely positioned to the left. In this way the potential user can take advantage of the entire opening width and close it from the fully open position. The second position is useful for delicate movements, since it reduces the opening span. In the third position, the lever is rotated but the thumb is still in the fully open position.

4.4. Lever design 27

The possible span of the lever is small and thus this position is only useful if a user wants to grip large objects. The advantage of this position is that the angle between the lever and the actuation force is closer to the perpendicular position and thus a higher force transmission can be accomplished.

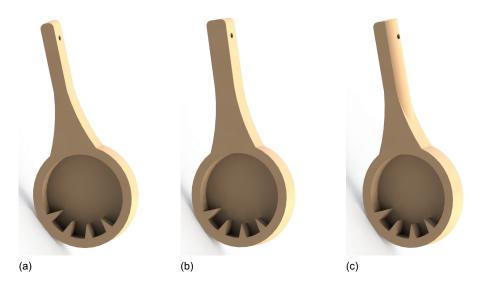


Figure 4.5: Three lever designs; a) basic design, b) thickened design, c) bulging design.

The lever is the part where the highest forces are expected since the cable is here attached. Three designs have been proposed; the 'basic design' consisting of a 4 mm width, a 'thickened design' consisting of a width of 6 mm, and a 'bulging design' with a reinforced surface (see Figure 4.5). The first design is desirable since it has a small width, and thus the cavity in the palm has to be the smallest. The second design is expected to behave similar to the first design, but able to withstand higher stresses than the first design due to higher thickness. The third design will due to its bulging shape distribute the stresses better over the surface.

The printed parts are not uniform, and the levers will not be printed completely solid (80% infill). The stresses in a certain position are dependent on the print direction and how the layers are positioned. The parts have to withstand uniaxial stresses since the actuation force is the only load on the part.

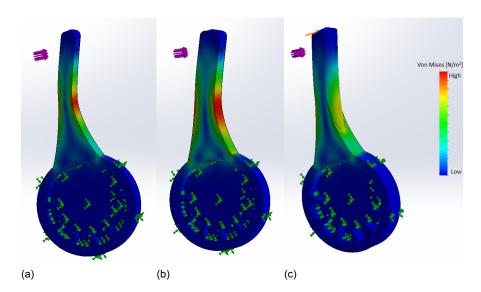


Figure 4.6: SOLIDWORKS von Mises stress analysis, application of equal force onto the three different concepts. The legend of each figure is different, a) is used as a reference, b) is a factor $\frac{1}{2}$ lower and c) is a factor $\frac{3}{4}$. The quantitative values do not provide added value due to the anisotropic characteristics of the printed parts.

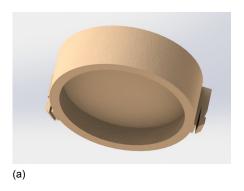
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Therefore, it is not possible to perform regular stress calculations. Hence, SOLIDWORKS simulations are used to approach the stress distribution over the parts (see Figure 4.6).

The figures do not provide quantitative values since these could not be calculated accurately. The figures show how the stresses are distributed over the parts. The applied forces onto the different concepts are equal, but the scale of the legend of the configurations is different. Using concept 1 (a) as a reference, the scale of concept 2 (b) is a factor $\frac{1}{2}$, and concept 3 (c) a factor $\frac{3}{4}$ lower. In concept 1 and 2, the stresses are concentrated onto a small rectangular surface on the inside of the curved surface. In concept 3, the stresses are distributed over a larger area and not uniformly spread onto the width of the part. In practice, this means that the highest stresses can be found at the centre line of the beam, and decreases while moving to the sides. Hence, it is expected that concept 3, even though the scale in concept 2 is lower, can withstand higher application forces without breaking than concept 2. Though, it is unclear at which application forces the lever designs will break, and thus whether an extended concept on the basic first concept is required. Therefore, the different designs will be mechanically tested and evaluated in Chapter 5 in order to choose the best concept ultimately.

4.5. Top

The top part has the function to close the rotational cavity and ensure the parts in place. The inside of the bottom of the top part is hollow. In this way the thumb fits exactly inside the top and stays in place. The top contains two pins that slide inside the palm. Through the springy character (see Figure 4.7), created in the ends of the pin, it slides easily through the cavities and fixes behind the small beam in the cavity. The working principle can be compared to the click system of backpack closing system.



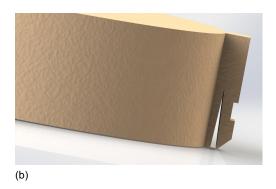


Figure 4.7: The top of the rotational cavity; created to keep the sliding mechanism in place. a) The inside is hollow to fit in the thumb, b) The lateral pins have a springy character to fix themselves behind a small beam inside the palm.

4.6. Printer specifications

The design is entirely created with FDM printers. A dual-extruder printer with soluble support has been used to reduce post-processing time and complications, and to allow for higher shape complexity. Support with PLA would, for example, not make it possible to create a hole for fixation of the elastic band. Three different types of printers have been used during the process; the Ultimaker 3, the Ultimaker S3 and the Ultimaker S5. All printers showed good performances for the large parts, although significant outcome differences have been observed. The surface of the parts printed with the Ultimaker S5 is more smooth and detailed, and the accuracy is more reliable. Critical parts, like the plugs of the top and its springy end, showed varying results on the Ultimaker 3 and 3S because the printed edges are not entirely straight and contain small bumps.

The palm and the parts have been printed separately because they have been printed with different printer specifications. The overview of specifications can be found in Table 4.1. Surfaces of parts that are directly printed onto the printer platform are more smooth than in other positions of the fabrication. In order to prevent friction losses, the rotating planes have been printed directly on the surface platform. The volume of the palm is in size the most substantial aspect of the device, and therefore it is vital to minimise the mass. Furthermore, this part does not have to withstand high forces, and hence the infill is set to only 20%. Since the lever, thumb and pin are more fragile and have to withstand higher forces,

their infill is set to 80%. During the development process, the first print of the palm showed that water had entered the inner structure through small gaps in the wall due to printer inaccuracy. To prevent further water leakage, the wall thickness had been increased to 1.2 mm, which seemed to be sufficient to overcome this problem.

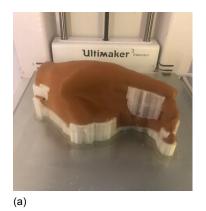
Table 4.1: Printer specifications for final design.

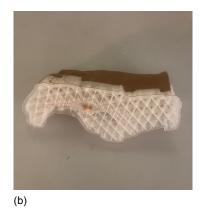
	Hand palm	Hand parts
Layer height	0.1 mm	0.1 mm
Wall thickness	1.2 mm	1.0 mm
Infill	20 %	80 %
Print speed	70 mm/s	70 mm/s
Used material	PLA: 118 g	PLA: 24 g
Used support	PVA: 43 g	PVA: 11 g
Printing time	1d, 7h, 30 min	8h, 30 min

During the first print, it was observed that there are small dimensional deviations between the SOLIDWORKS drawings and printed parts. This prevented the parts from fitting exactly into each other. A margin of 0.2 mm per connected side (so $2 \cdot 0.2$ in case of a circle) seemed sufficient to overcome this problem. Therefore 0.2 mm has been used as a safety margin to ensure that the parts fit into each other without exerting high frictional forces during a rotational movement.

4.7. Final design assembly

The assembly of the final design contains a few steps. The different steps are explained below, starting at the moment that the FDM print is finished, up until the complete prototype.





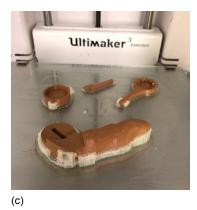


Figure 4.8: The parts of the prototype after printing. Soluble support (white in the pictures) has been used and the palm and parts have been printed separately. a) shows the palm after printing, b) the support structure of the palm and, c) the printed thumb, lever, top and pin.

- 1. Remove the parts from the build plate of the printer and put them in the water for about a day.
- Slide the pin into the thumb and put the pressure spring in the cavity of the thumb, below the extended rod of the pin. Press the pin inwards and put the thumb and the lever onto each other. Connect the two parts by releasing the pin, which then falls into one of the holes inside the lever.
- 3. Lay the connected parts into the rotational cavity of the palm and suppress the lever through the cavity. Connect the combined thumb and lever to the palm by stretching an elastic band between the two parts. Click the top part into the thumb cavity to close the rotational mechanism.
- 4. Lastly, a M12 bolt can be placed inside the wrist, and a standard prosthesis socket connector can be attached.

After the assembly of all parts, the final prototype is constructed. In Figure 4.9 the final visualisation of the 3D-Sanhand is presented; the 3D printed Simple to Assemble Natural-looking hand prosthesis.

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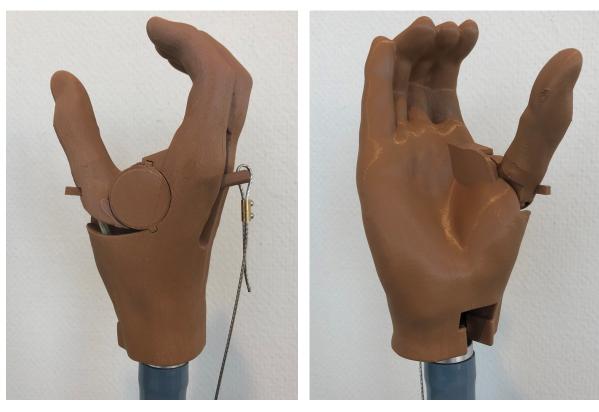




Figure 4.9: The final design of the 3D-Sanhand: the 3D printed Simple to Assemble Natural-looking hand prosthesis.

Evaluation and Results

5.1. Approach

The goal of the evaluation is to quantify and objectively obtain mechanical and user information about the working characteristics of the final design. The evaluation will be subdivided into mechanical and functional aspects and a user functionality part. First, the prototype will be tested mechanically to obtain quantitative data about the functional performance and assess the force characteristics within the working principle. Then the prosthesis will be tested by ten able-bodied subjects using the Southampton Hand Assessment Procedure (SHAP) and the Box and Block Test (BBT) to clinically validate the effectiveness of the prototype. The obtained results will be useful to compare the performance to commercially available prostheses.

5.2. Mechanical and functional evaluation and results

5.2.1. Experimental setup

Multiple parameters will be tested in this study to quantify the mechanical performance of the created prosthesis. Three parameters could be obtained directly from the test setup; the cable actuation force, the pinch force between the fingers and the displacement of the activation cable of the prosthesis. These values are obtained by manually operating the test bench through the actuator spindle. The cable displacement causes an actuation force which results in a pinch grip. Pictures of the test setup are presented in Figure 5.1. The schematic overview of the setup is represented in Figure 5.2 and the specifications of the used components are described in Table 5.1.

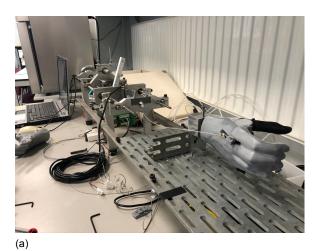




Figure 5.1: Setup of the used test bench: a) Setup test bench, b) Prosthesis performing a pinch grip with a pinch force sensor between the fingers.

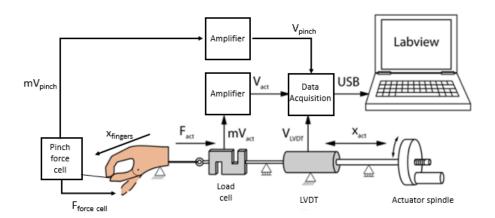


Figure 5.2: Schematic overview of the test setup. The displacement, actuation force and pinch force are measured. LVDT = linear variable differential transformer, F_{act} = force activation cable (pull force), mV_{act} = voltage pull force sensor (unamplified), mV_{pinch} = voltage pinch force sensor (unamplified), mV_{pinch} = voltage pinch force sensor (amplified), USB = universal serial bus. Adapted figure from [58].

Table 5.1: Specifications of the components used for the test bench setup.

Component	Specification
Force sensor	Zemic: FLB3G-C3-50kg-6B
Pinch force sensor	Double leave spring with strain gauges
Linear displacement sensor (LVDT)	Schaevitz: LCIT 2000
Amplifier	Scaime: CPJ
Power supply	EA: EA-PS 3065-05 B
Computer interface	National Instruments: NI USB-6008

Four different tests will be executed:

- Lever test: The three different lever concepts (see Section 4.4) will be assembled in the palm and the actuation force will be increased up to 200 N to examine the maximum stress that the lever can withstand without breaking.
- 2. Opening and closing test: The prosthesis is actuated carefully from a fully open position until the device is completely closed (without exerting pinch forces). The cable will then be released until the device is fully open again. During this test the displacement and the actuation force are measured.
- 3. 15 N Pinch force test: From a fully open position the prosthesis will be actuated. A pinch force sensor will be placed between the fingertips of the device and the parameters will be measured until a pinch force of 15 N is reached. The displacement, the actuation and the pinch force are measured.
- 4. 100 N Actuation test: From a full open position the actuation force will be increased until an actuation force of 100 N is reached. A pinch force sensor will be placed between the fingers, the generated pinch and actuation force are then measured.

With the obtained data from the above tests, the excursion range of the activation cable is determined. Furthermore, the work for opening and closing the device is calculated by integrating the required activation force over the displacement of the cable (path length) over which the force is acting (Equation 5.1).

$$W = \int_0^l F_{act}(x) \cdot dx \tag{5.1}$$

In which W = Work [Nm], l = cable excursion [m] at closed position, $F_{act}(x) = \text{actuation force as function}$ of the cable excursion, x = cable excursion.

The needed work is calculated for closing and re-opening the device and for closing and pinching 15 N. The hysteresis follows from the previous calculation and provides a quantitative measure for the efficiency of the device. The hysteresis is the effect that the state of the system is dependent on history, as indicated in Equation 2.2.

In order to minimise frictional effects, the rotating parts have been treated with plastislip. All the tests used two elastic bands as an extensor and were repeated three times to obtain an average value. The resulted data was then processed using MATLAB, and several plots were created to visualise the performance. The function smooth has been used to optimise the visualisation. The complete MATLAB script that was created to calculate quantitative values and visualise the performance can be found in Appendix C. The results of the tests are shown in Section 5.2.3 to 5.2.5. Quantitative data is provided in Section 5.2.6.

5.2.2. Lever tests and evaluation

The performance of the three lever designs is shown in Figure 5.3. The subjected parts are intended to withstand actuation forces increased up to 200 N. Two elastic bands have been used as an extensor for this test. The corresponding values are presented in Table 5.2.

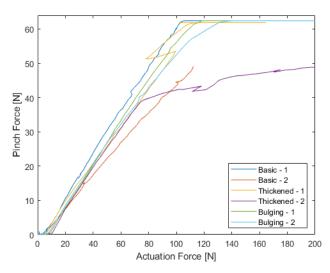


Figure 5.3: The lever tests: The actuation force is increased up to 200 N and the corresponding pinch force is presented.

Table 5.2: Actuation tests of three different lever designs as described in Section 4.4. The forces are increased up until 200 N or the breaking point.

		Concept	t 1:	Concept 2	:	Concept 3:		
		basic de	esign	thickened	design	bulging design		
ĺ		Max. Fact [N]	F_{pinch} [N]	Max. F_{act} [N]	F_{pinch} [N]	Max. Fact [N]	F _{pinch} [N]	
Ì	Trial 1	131.8	62.4	164.5	61.9	200.0	62.4	
	Trial 2	112.3	49.1	200.0	48.8	200.0	62.4	

The first concept, the basic design with a width of 44 mm, was not able to withstand an actuation of 200 N. The breaking point was at the expected location and the other parts inside the hand did not show any deformities. The thickened design broke at the expected place during the first trial and was able to withstand 200 N during the second trial. During the second trial the gear tooth, inside the lever, broke while trying to keep the pin in place. Concept 3, the bulging design, did withstand the stress inside the lever but showed a small breakage of the gear tooth and the pin bent (see Figures 5.4 and 5.5). The parts seem to withstand actuation forces up to about 160 N before deformations were visible. The pinch force increased until a maximum has been reached.





Figure 5.4: Break point in concept 1 (left) and concept 2 (right). Figure 5.5: Deformation of the pin and broken lever teeth.

5.2.3. Closing and opening test

The measured activation force in the cable and cable displacement during the opening and closing test are plotted in Figure 5.6a. The hysteresis is the difference between the required work to close the prosthesis and the work that is returned by the system. The area below a force-displacement curve represents the performed work. Hence, the hysteresis can be visualised as the difference between the work for opening and closing the prosthesis, as shown in Figure 5.6b-d.

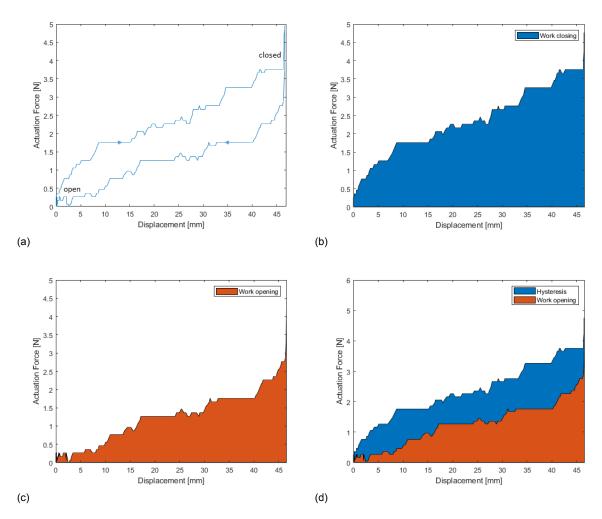


Figure 5.6: a) Hysteresis cycle, the measured actuation force as a function of the cable displacement during one closing / opening cycle. The test started at a fully open position with an actuation force and displacement of 0 N and 0 mm respectively. At the maximum achieved force and displacement, the device is closed. b) The performed work during one closing & c) opening cycle can be represented by the area below the activation force - cable displacement curve. d) The difference between the work done during closing and opening is the hysteresis.

5.2.4. 15 N Pinch force test

The required work for closing the prosthetic hand and pinching 15 N is shown in Figure 5.7a. The thickness of the pinch sensor and its casing is 10 mm, and so the given values are associated with an opening width of 10 mm. In Figure 5.7b, the required actuation force is plotted against the pinch force.

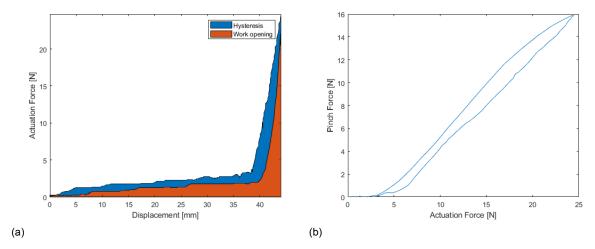


Figure 5.7: Result 15 N pinch force test: a) Work required to close the device and pinch 15 N, b) Required actuation force to pinch 15 N.

5.2.5. 100 N Actuation test

The performance of the pinch force while increasing the actuation force up to 100 N is shown in Figure 5.8. It was already observed during the execution of the tests that the results were diverse, and so there has been chosen to repeat the test five times instead of three. All different trials have been plotted. The literature stated that an amputee could use a BP prosthesis fatigue-free during a full day with an actuation force of maximum 38 N. Therefore, also the pinch force at an actuation force of 38 N is assessed from these tests. The result is shown in Table 5.3.

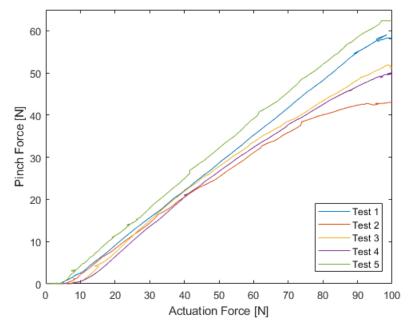


Figure 5.8: Measured pinch force output with a cable actuation force up to 100 N, five trials are performed.

36 5. Evaluation and Results

5.2.6. Mechanical Results

The quantitative results of the previously described experiments are shown in Table 5.3.

Table 5.3: Quantitative result of mechanical tests. The mean is provided with its standard deviation.

Max. cable	Work	Hysteresis	Work closing	Hysteresis	Actuation	Pinch force at	Pinch force at
excursion	closing	cycle	+ pinch 15 N	closing + pinch	at 15 N	38 N actuation	100 N actuation
(mm)	(Nmm)	(Nmm)	(Nmm)	15 N (Nmm)	pinch (N)	force (N)	force (N)
46.6 ±0.09	109.6 ±4.3	52.3 ±5.1	153.6 ±7.8	66.9 ±3.7	24.4 ±1.5	21 ±1.6	53 ±7.6

5.3. User evaluation

5.3.1. Experimental setup

A total of ten subjects, six men and four women, participated in the tests. All participants are able-bodied subjects in the age of 19-26 and did not have any previous experience in controlling BP prostheses. Nine participants are right-handed, and one participant is left-handed. There has been chosen to use able-bodied subjects due to time limitations. The TRS Prosthetic simulator (SIMR) was attached to the right lower arm of the subjects to locate the prosthetic device as an extension of their normal hand. A figure-nine shoulder harness and a Bowden cable enabled the subject to control the terminal device. Two elastic bands have been used in the mechanism to ensure proper re-opening of the hand. Two user tests have been performed; the Southampton Hand Assessment Procedure (SHAP) and the Box and Block Test (BBT). All participants were able to practise a few minutes before they started the SHAP. After completion of the SHAP, the BBT has been performed twice.

The SHAP is a clinically validated hand function test that is applied to assess musculoskeletal and neurological conditions but was originally developed to evaluate the effectiveness of upper-limb prosthesis [102]. Participants use a form-board while executing self-timed tasks. Twenty different tasks are selected, as shown in Table 5.4. The tasks are divided into abstract object tasks using two different weights, matching the six different prehensile patterns, and simulated activities of daily living (ADLs). All tasks need to be performed within the maximum time of 100 seconds. If the subject is not able to perform the task, it will be noted as a score of 100 seconds and regarded a failure. The complete SHAP assessor's protocol can be found in Appendix E.

Table 5.4: The task included in the SHAP. Each task is timed by the participant and recorded on an assessment sheet by the assessor [102].

Abstract Object Tasks	Activities of Daily Living (ADLs)
1. Spherical (light / heavy)	7. Pick up coins
2. Tripod (light / heavy)	8. Button board
3. Power (light / heavy)	Simulated food cutting
4. Lateral (light / heavy)	10. Page turning
5. Tip (light / heavy)	11. Jar lid
6. Extension (light / heavy)	12. Glass jug pouring
	13. Carton pouring
	14. Lifting a heavy object
	15. Lifting a light object
	16. Lifting a tray
	17. Rotate key
	18. Open/close zip
	19. Rotate a screw
	20. Door handle

The BBT measures unilateral gross manual dexterity and is used for patients with a wide range of neurological diagnoses. The BBT includes a wooden box that is divided into two compartments. Participants are asked to move, one by one, a maximum amount of blocks from one compartment to the other within 60 seconds. The number of blocks is registered. The BBT method of use as prescribed by Methiowetz et al. [103] can be found in Appendix G.

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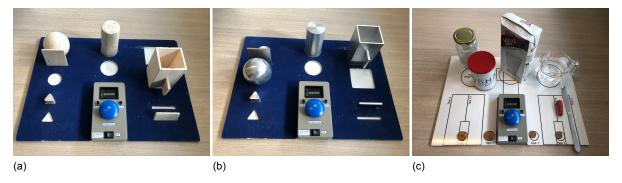


Figure 5.9: Setup of the SHAP: a) Light weighted and b) heavy abstract objects that need to be picked up by the subject and moved to the front slot. c) A selection of the objects used for the ADL tasks.



Figure 5.10: Setup of the Box and Block Test. Participants have to move as many blocks as possible from one department to the other within 60 seconds.

5.3.2. SHAP results

The complete score forms of the user tests can be found in Appendix F. The averaged results of the first part of the SHAP, the abstract object task, is shown in Table 5.5. All participants were able to perform the light- and heavy weighted tasks without problems except for the spherical (ball) object. The diameter of the ball was too large to fit into the hand, making it impossible to grasp or lift the ball.

Table 5.5: SHAP result of manipulating light and heavy weight abstract object tasks, mean and standard deviation are presented.

	Light objects		Heavy objects	
Task	Percent Yes [%]	Time [sec]	Percent Yes [%]	Time [sec]
Spherical	10	90.36 ±30.47	0	100.00 ± 0.00
Tripod	100	10.47 ± 9.03	100	7.66 ± 5.10
Power	100	7.03 ± 3.12	100	14.03 ±23.50
Lateral	100	7.05 ± 1.84	100	10.81 ± 6.97
Tip	100	6.89 ± 2.23	100	8.67 ± 5.25
Extension	100	6.02 ± 2.03	100	7.27 ± 3.16

The results of the ADL tasks are shown in Table 5.6. Some of the activities have failed for all participants. Picking up smooth objects that were positioned flat on the surface seemed to be unachievable. This resulted in failed performance for the tasks 'picking up coins' and 'simulated food cutting'. Holding the objects (coins and knife) from a lifted position is possible but not fulfilling the task. Lifting a heavy (jar filled with water) and a light object (empty tin can) was not possible due to the large diameter of the

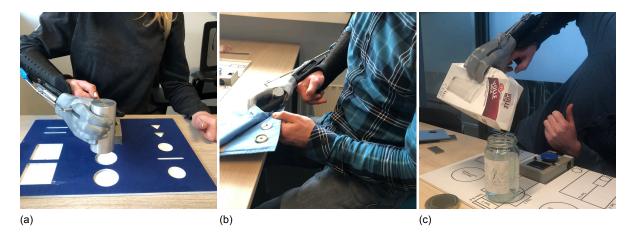


Figure 5.11: Subjects performing tasks of the SHAP, a) Heavy weight power task, b) Button board, c) Carton water pouring.

objects, which was unable to fit into the hand. Other causes of task failure were mainly subjected to the smooth surface of the objects and to the movement limitations caused by the prosthesis simulator. As a result, the participants had difficulties in performing a secure grip or had to move their lower arm in unnatural angles/positions to be able to grasp the object. The subjects did not seem to encounter problems with the weight of the objects. Several subjects indicated that adjustment of the sliding lever mechanism facilitated the task, especially regarding delicate precision tasks.

Table 5.6: SHAP result of activities of daily live tasks. Percentage that was able to perform the task within 100 seconds, and the average time and standard deviation has been presented.

ADL task	Percent yes [%]	Average time [s]
Pick up coins	0	100.00 ± 0.00
Button Board	100	42.16 ±17.71
Simulated food cutting	0	100.00 ± 0.00
Page Turning	90	31.38 ±34.97
Jar Lid	70	47.27 ±40.94
Glass jug pouring	90	33.64 ±26.00
Carton Pour	100	26.00 ±11.60
Lifting a heavy object	10	94.99 ±15.86
Lifting a light object	0	100.00 ± 0.00
Lifting a tray	100	4.63 ± 2.14
Rotate a key	80	41.54 ±39.69
Open/close zip	20	87.11 ±29.17
Rotate a screw	10	91.91 ±25.58
Door Handle	100	4.06 ± 1.50

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5.3.3. BBT results

The performance of ten subjects on the BBT over the two different trials is shown in Table 5.7 and Figure 5.12. The participants did not show to have difficulties with picking up blocks, in terms of a secure grip performance or weight. The blocks that were placed exactly adjacent without space between them were hard to pick up. However, all participants seem to be possible to create some interspace by shaking the fingers in the box. The number of blocks that the participants were able to move within one minute increased in the second trial in comparison to the first trial, in the case of nine out of ten subjects. That means that the subjects on average got faster and more skilful due to learning effects. Several participants noted at the end of the user trials that the body-powered actuation felt more and more natural.

Table 5.7: Result BBT; Two trials; the amount of blocks that the subject was able to move from one department to the other within 60 seconds. Mean is provided with its standard deviation (SD), the median and the interquartile range (IQR).

		Participant (number of blocks)												
	1	2	3	4	5	6	7	8	9	10	Mean	SD	Median	IQR
Trial 1	21	18	19	18	16	17	21	15	18	21	18.4	2.2	18	4.3
Trial 2	26	19	21	21	21	19	19	22	20	22	21.1	2.2	21	3.0

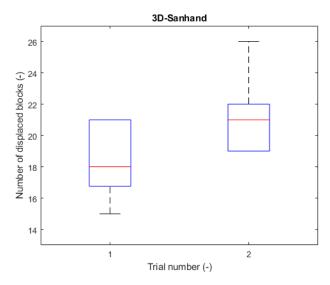


Figure 5.12: Boxplot, presenting the scores of the 3D-Sanhand on the BBT during two trials.



Discussion

6.1. Approach

This chapter will review and compare the results of the mechanical tests and the user tests, comprising of the SHAP and BBT, of Chapter 5 to conventional prostheses. The design characteristics of the final prototype will then be compared to the previously stated requirements as set in Table 3.1, to assess whether these requirements have been fulfilled. Finally, future research directions will be proposed.

6.2. Mechanical performance

In order to quantitatively assess the mechanical performance of the developed design, it will be compared to different existing BP devices on the market. There has been chosen to take up the '100 Dollar Hand' and Juan's Hand since these devices are created with similar objectives and manufacturing procedures. Furthermore, two commercially available devices have been taken up in the comparison, the TRS BP hook and the Ottobock 8K24 size $7\frac{3}{4}$ without gloves and including an inner and cosmetic glove, since these prostheses are widely used. The data for the Ottobock hands and the TRS hook has been obtained through the research by Smit et al. [48]. The data for the 100 Dollar Hand and Juan's Hand have been obtained through executed measurements, see Appendix D. Table 6.1 presents the characteristics of the six prosthetic devices.

Table 6.1: Overview of mechanical and geometrical properties of the tested and commercially available prostheses.

	Mass (g)	Opening width (mm)	Maximum cable excursion (mm)	Work closing (Nmm)	Hysteresis cycle (Nmm)	Work closing + pinch 15 N (Nmm)	Actuation force at 15 N pinch (N)	Pinch force at 100 N actuation (N)
100 Dollar Hand	250	60	58 ±1.4	277 ± 5	124 ± 5	288 ± 6	43 ±1.0	37
Juan's Hand	95	130	23 ±0.5	335 ±28	263 ±27	995 ±27	115 ±4.7	13
Ottobock frame	220	100	60 ±0.5	1624 ± 8	389 ±19	1545 ± 1	78 ±0.3	28
Ottobock with gloves	423	57	38 ±0.3	1710 ±20	681 ±23	1636 ±29	98 ±0.5	14
3D-Sanhand	142	75	47 ±0.1	110 ± 4	52 ± 5	154 ± 8	24 ±1.5	53
TRS hook	318	72	49 ±0.1	284 ± 3	52 ± 1	243 ± 3	33 ±0.2	58

6.2.1. Maximum cable excursion

For body-powered activation of the terminal device, a shoulder harness is required. A high maximum cable excursion demands a larger body movement in order to fulfil the trajectory. Taylor measured a maximum cable excursion of 53 ±10 mm [18]. The developed design is not within the range minus one

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standard deviation, implying that not all users can fully close the device from the completely open position. Only the Ottobock mechanism without gloves fulfils this range, although the Ottobock prosthesis is rarely used without gloves. Therefore the developed design can at least be considered comparable to existing designs. In contrast to the other devices, the sliding mechanism of the 3D-Sanhand enables the user to change the initial position of the thumb and to reduce the opening width in case of delicate movements. In this way, the maximum required cable excursion for a specific task can be adjusted and hence users will be able to pick up objects from different sizes.

6.2.2. Work and hysteresis

In comparison to the other prostheses, the 3D-Sanhand requires a small work to close the prosthesis entirely. This could be explained by the simple mechanism that hardly encounters frictional losses and contains a significantly low opposing extensor force in comparison to other designs. The used elastic bands have a low spring constant, and therefore a low actuation force is sufficient to close the hand. The use of plastislip between the rotating plastic parts significantly decreased the frictional effects and therefore contributed to a better efficient system. The needed work to close the device and develop a 15 N pinch is higher than to close the device. This is in contrast to the performance of the Ottobock hand and the TRS hook, that show lower developed work for a 15 N pinch due to the smaller opening width and thus lower loading effects of the spring.

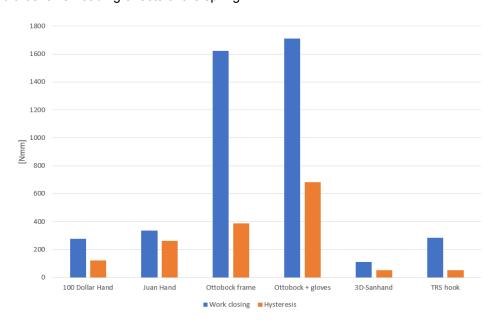


Figure 6.1: Required work to fully close the prosthesis and the dissipated energy during the closing / opening cycle.

The hysteresis is low in comparison to other devices, as a direct result of the low required work to close the device. This is also illustrated in Figure 6.1. However, the dissipated energy as a percentage of the total work is considerably high. The dissipated energy of the 3D-Sanhand due to material internal friction is 48% of the total work to perform a cycle, in contrast to 18%-45% in other designs. Only the Juan Hand showed a lower systems efficiency with a loss of 79%. The percentage of dissipated energy is not directly a reason of concern, since in practise only the amount of energy that users need to perform is of importance since users will not be able to differentiate the amount of friction. However, the use of elastic bands explain the hysteresis effect, because of the bad efficiency of rubber bands. This is caused by the changing length of the rubber band between the loaded and unloaded phase. More energy was required when loading the system than was returned to the system in the unloaded phase. In the loaded phase of the prosthetic device, the actuation force rotates the thumb and makes the band stretch out. In the unloaded position the band contracts and moves the thumb back to the open position. The elastic force from the bands is considerably low and does not correspond perfectly to Hooke's law. After multiple repetitions, the length of the rubber bands will become longer in unloaded position and thus develop even higher hysteresis effects. In practice, this will cause functionality problems because the hand will not always open properly to the resting position. Thereby, in a patient-setting, a Bowdencable will be used, and thus extra frictional forces are expected. It is questionable whether the elastic bands can deliver a sufficient force to ensure proper functionality. In the long term, it is therefore expected that rubber bands are not the best solution in terms of efficiency and durability.





Figure 6.2: Two configurations of the palm with different type of extensors, a) Double elastic rubber band, b) Tension spring.

In order to evaluate the possible effectiveness of the elastic bands, a comparative test has been set up. A closing-opening cycle has been performed as well as a 15 N pinch force test to assess the behaviour under load. The mechanical properties have been analysed while varying the amount (1-3) of used elastic bands in the design. The elastic bands have been replaced after one full test, to minimise wear effects on the results. Furthermore, the design has been adapted to install a tension spring inside the palm. In this way, the behaviour of the elastic bands could be compared to a tension spring. The results of this test are displayed in Table 6.2. The hysteresis cycles during the tests are plotted in Figure 6.3.

Table 6.2: Mechanical properties of the prototype with the use of varying types of extensors; one, two or three elastic bands or the application of a tension spring.

	Work closing	Hysteresis	Work closing +	Hysteresis	Actuation force
	[Nmm]	cyle [Nmm]	pinch 15 N [Nmm]	15 N pinch [Nmm]	at 15 N pinch [N]
1 elastic band	62.7 ± 1.8	31.9 ± 1.5	105.6 ± 8.2	52.7 ± 4.0	23.7
2 elastic bands	109.6 ± 4.3	52.3 ± 5.1	153.6 ± 7.8	66.9 ± 3.7	24.4
3 elastic bands	199.1 ±17.8	137.2 ±17.4	274.5 ±26.7	174.1 ±22.7	27.2
Spring	164.9 ± 4.9	61.4 ± 2.8	159.7 ± 4.9	65.2 ± 2.5	26.9

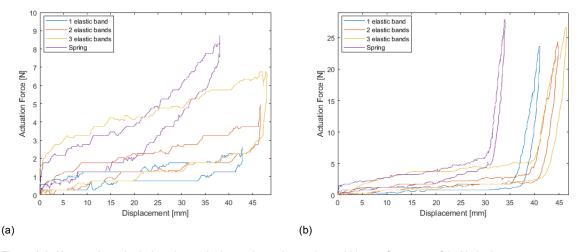


Figure 6.3: Hysteresis cycle during a) one closing and opening cycle, and b) a performance of 15 N pinch.

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The results include the hysteresis for one closing and opening cycle and the hysteresis for a 15 N pinch. During the user tests, it was already observed that the application of one elastic band in the mechanism was not sufficient to ensure proper re-opening of the thumb. Therefore, this configuration cannot be assumed to be a good alternative. The required work for the configuration with two elastic bands is lower than for the spring configuration, while three elastic bands require more work than the spring. The amount of friction in the closing and opening cycle is considerably high, which can be explained since only low forces are included in the mechanism. The hysteresis under load, in the case of a 15 N pinch cycle, has similar results for two elastic bands and spring and worse results for the use of three elastic springs.

From the tests, it is not possible to conclude that the use of extra elastic bands will improve the efficiency of the system. Furthermore, it was shown that the use of a spring requires a larger work to perform a closing and opening cycle than the configuration with two elastic bands (which is assumed sufficient for patient use), but similar results under load. The hysteresis effects are better with a spring. Required actuation forces for a pinch of 15 N are not significantly different between the four different tests and therefore not a reason to renounce one of the alternatives. Furthermore, it is essential to take into account that during these tests, the elastic bands have only been used for a minimal amount of time. It is expected that the wear down is fast, deteriorating the performance of the bands and developing even higher hysteresis effects.

6.2.3. Actuation force and pinch force

The required actuation force to close the device and to perform a pinch force of 15 N is well within the range of fatigue-free long-duration operation, as described by Hichert at all [59]. They stated that females could operate a BP prostheses fatigue-free up to 38 ± 17 N. In contrast, males can handle forces up to 66 ± 23 N. The design furthermore shows promising results in comparison to other devices, needing much lower actuation forces to provide a 15 N pinch. At an actuation force of 100 N only the TRS hook can perform a higher pinch force output than the 3D-Sanhand.

In the lever tests from Section 5.2.2 the actuation force was increased up to 200 N. It was observed that the pinch force rises under an increased actuation force, up to a maximum of about 63 N. The design seems not to be able to perform higher pinch forces without the deformation or breakage of internal parts. Therefore it is recommended to limit the actuation force to a maximum of 150 N.

6.3. User functionality test

6.3.1. SHAP

The SHAP test was performed by ten subjects to assess the functional performance of the 3D-Sanhand. Several other hand prostheses have performed the SHAP test before; the i-LIMB hand and the DMC plus hand (both with gloves) have been tested by a 45-year-old man with a wrist disarticulation and their functionality profiles have been published [104]. The SHAP test was furthermore completed by 40 able-bodied subjects using the Raptor Reloaded hand. The results of 14 ADLs have been published and have been taken up for comparison [105].

Table 6.3: Comparison of the SHAP functionality profiles of the i-Limb, DMC plus hand and the 3D-Sanhand. The average is provided and for the 3D Sanhand also the standard deviation. The values for the i-Limb and DMC plus hand are adopted from van der Niet et al. [104].

Functionality profile	i-LIMB hand	DMC plus hand	3D-Sanhand
Spherical	90	90	19 ±12.0
Tripod	32	76	24 ± 6.9
Power	51	75	16 ± 5.5
Lateral	23	69	34 ±16.5
Tip	42	39	17 ± 7.8
Extension	55	81	49 ±14.6
Index of functionality	52	74	33 ± 8.3

The 3D-Sanhand scored considerably lower than the i-LIMB and DMC plus hand. The limitations of the design of the 3D-Sanhand can first explain this result. Some cylindrical objects are too large to fit within the opening of the hand, users struggle to pick up smooth objects due to the slipperiness of

the finger pads, and it turned out to be very tough to pick up thin objects from the surface. Besides these limitations, the big difference can be explained by the lack of experience of the able-bodied subjects in comparison to the skilled subject that tested the i-LIMB and DMC plus hand. The able-bodied subjects had only practised the control of the hand a few minutes, and hence it is assumed that their performance would improve with more practice. Furthermore, the relatively large standard deviations for the functionality profiles indicate substantial performance differences between the subjects. The relatively small sample size could be the cause of this outcome, but it also suggests that there is room for improvement of the scores. Lastly, it would be better to compare the design to hand prosthesis with identical control systems. The i-LIMB and DMC plus hand are both myoelectrical prostheses, able to perform higher forces that are not dependent on the bodies movement. Unfortunately, no data on the SHAP performance of BP designs are available.

Table 6.4: SHAP outcomes of tasks associated with activities of daily living. The results of the Raptor Reloaded are obtained from Dally et al. [105] and are compared to the 3D-Sanhand.

	Raptor Reloaded	3D-Sanhand		
ADL task	Percent yes in	Percent yes in	Percent yes in	
ADL IASK	30 seconds [%]	30 seconds [%]	100 seconds [%]	
Pick up coins	30	0	0	
Button Board	100	20	100	
Simulated food cutting	25	0	0	
Page Turning	100	60	90	
Jar Lid	80	50	70	
Glass jug pouring	45	60	90	
Carton Pour	40	70	100	
Lifting a heavy object	100	0	10	
Lifting a light object	100	0	0	
Lifting a tray	35	100	100	
Rotate a key	0	60	80	
Open/close zip	10	10	20	
Rotate a screw	0	10	10	
Door Handle	70	100	100	

The design and purpose of the Raptor Reloaded is much closer to the 3D-Sanhand. It is a 3D-printed hand prosthesis for children and adults in low-resource countries and works through elbow or wrist actuation. The study of Dally et al. The design and purpose of the Raptor Reloaded is much closer to the 3D-Sanhand. It is a 3D-printed hand prosthesis for children and adults in low-resource countries and works through elbow or wrist actuation. The study of Dally et al. [105] published only the success percentage for the Raptor Reloaded in the first 30 seconds. From the comparison, two main aspects are remarkable. The Raptor Reloaded has better performance in picking up a broader range of object sizes and enabling a stable grip onto smooth objects. The 3D-Sanhand, however, shows better grip forces characteristics. Not a single subject was able to rotate a key with the Raptor Reloaded because the required grip force was higher than the hand could perform. This cause was also applicable for the weaker results on the door handle, the glass jug pouring, the carton pour and the lifting of a tray. The 3D-Sanhand did not fail due to force limitations but to difficulties to perform a firm and secure grip. It would be beneficial to improve the grip performance by adding high frictional (anti-slip) material onto the finger tips. Investigation of different fingertip shapes could improve the ability to lift object from the flat surface.

6.3.2. Box & Block Test

The study, published by Haverkate et al. [106], assessed three commonly used BP prostheses on their functional performance using the BBT. A total of 21 able-bodied subjects performed the tests with a prosthetic simulator. In their setup, the test was repeated nine times per device, three times on three different days. Only the quantitative data of the ninth (last) trial has been published and taken up for comparison in Table 6.5. Ten subjects performed the BBT with the 3D-Sanhand in only two trials, due to limited time.

The subjects that have performed user tests with the 3D-Sanhand have all completed the SHAP and

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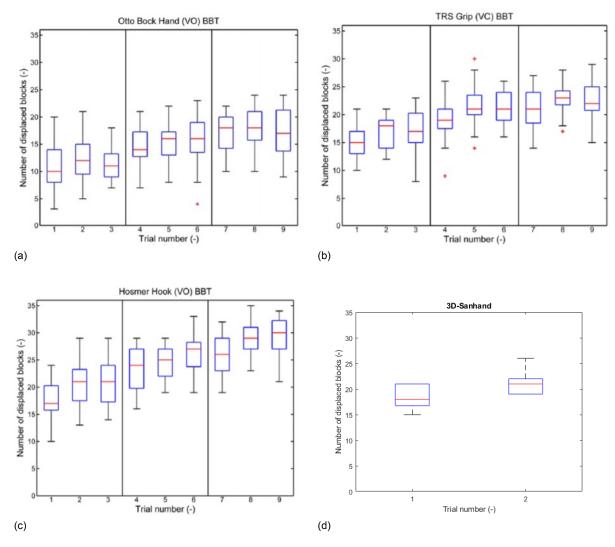


Figure 6.4: a-c): Scores of the Ottobock hand, the TRS grip and Hosmer Hook respectively on the BBT (n=21) during nine trials at three different days [106], and d) Scores of the 3D-Sanhand (n=9) during two trials on the same day.

the BBT. Therefore, the order in which the tests are performed could influence the outcomes of the tests due to obtained learning effects. Since only the scores of the conventional prostheses on the BBT in the ninth trial were published, there has been chosen to let all subjects complete the SHAP first. In this way, they had some user experiences before starting the BBT, and hence the second trial of the BBT with the 3D-Sanhand is compared to the ninth trial with the conventional prostheses. The performance of the 3D-Sanhand is significantly better than obtained with the Ottobock hand, but both the TRS Grip and the Hosmer Hook show better performance than the 3D-Sanhand. The study of Haverkate et al. showed a decreased variance in subsequent trials and improved scores as a result of improved control skills in subsequent trials. This is also visible in the two trials with the 3D-Sanhand, obtaining significantly better results in the second trial. Therefore it is expected that an increase in trials with the 3D-Sanhand will further improve the performance. Visually comparing the first two trials to the first two trials of the commercial prostheses (Figure 6.4), similar results can be observed. However, it is unclear what the learning effect of the execution of the SHAP, prior to the BBT, has been on the performance on the BBT. Finally, it is plausible to conclude that the performance on the BBT is comparable to conventional prostheses and the functional outcome promising.

Table 6.5: BBT result, compared to the results of the Ottobock Hand, the TRS Grip and the Hosmer Hook. VO = voluntary opening, VC = voluntary closing [106].

	Number of blocks				
	3D-Sanhand (VC)	Ottobock Hand (VO)	TRS Grip (VC)	Homer Hook (VO)	
Mean	21.1	17.4	29.4	29.4	
SD	2.2	4.3	3.7	3.7	
Median	21.0	17.0	22.0	30.0	
IQR	3.0	7.5	4.3	5.3	

6.3.3. Recommendations user tests

In general, there can be concluded that the executed user tests show that the 3D-Sanhand is capable of accomplishing different grip patterns and performing different activities. For some tasks comparable results to conventional prosthesis have been found, for other tasks, weaker performances have been obtained. These findings have resulted in design suggestions, as proposed in the previous sections. It would be valuable further to investigate user functionality with potential end-users in daily situations. This because the current tests have been performed in a controlled environment by able-bodied subjects that are not experienced with hand prostheses, which is different from the real situation.

6.4. Assessment design requirements

In this section, the setup requirements of Chapter 3 will be compared with the final design aspects and characteristics will be explained. An overview of the results can be found in Table 6.6.

Table 6.6: Fulfilment of stated requirements. The column 'Realisation' provides the characteristics of the final design, in the subsequent columns is presented whether this meets the previously stated requirement and wish.

Aspect	Parameter	Realisation	Requirement		Wish	
	Printer type	Full FDM printed	75% parts printed with FDM	~	Full FDM printed	*
1. Manufacturing	Assembly time	<2 min	<10 min	V	≤ 5 min	/
_	Number of parts	7	≤ 5	×	Non-assembly	*
2 Control	Actuation type	VC	VC	~	VC	V
2. Control	Cable excursion	49 mm	≤ 53 mm	V	≤ 43 mm	*
	Grip type	Pinch + Power grip	Pinch grip	~	Pinch + power grip	V
0	Opening width	75 mm	≥ 70 mm	V	≥ 75 mm	/
3. Function	Pinch force	21 N for F_{act} = 38 N	\geq 15 N for F_{act} =38 N	V	\geq 20 N for F_{act} =38 N	/
	Transmission ratio	0.54	≥ 0.4	V	≥ 0.5	/
4. Cosmetics	Shape	Human like	Human like	~	Human like	V
4. Cosmetics	Dimensions	Deviating thumb	Human like	×	Human like	×
E Comfort	Mass	142 g	<250 g	~	<200 g	V
5. Comfort	Operation force	24 N	≤ 38 N	V	≤ 38 N	/
6. Durability	Cycles without intervention	Replaceable parts	>300.000	×	>600.000	×
7. Costs	Material costs	€12,41	<€50,00	V	<€30,00	V

6.4.1. Manufacturing

The created prosthetic hand consists of five rigid FDM printed parts. The parts have been printed with a dual-extruder printer using soluble support. In this way, no manual post-processing is required. The wish to create a non-assembly has been renounced because of strength and friction considerations. A small compression spring and an elastic band have furthermore been used and thus the requirement to fully print the prosthesis has not been fulfilled, and the total amount of parts exceeds the requirement. The prosthesis is easy to assemble and does not require any technical skills or knowledge. Dependent on the experience of the assembler, it is possible to put the components together less than two minutes. Therefore the wish to design a device that is easy to assemble with minimal manual intervention has been achieved. The assembly time and the required level of skill to manufacture the prosthesis is as-

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sumed more critical than the number of parts. Therefore there can be concluded that the design meets the goal to create an alternative to the highly complicated and time-consuming production process of prosthetic devices.

6.4.2. Control

The design contains a VC control system and is compatible with standard sockets and wrist units. It has a maximum cable excursion of 49 mm and therefore meets the requirement to develop a design that needs less than 53 mm for a full cycle. The wish of 43 mm is not reached, but the developed sliding mechanism inside the rotation point will enable all users to grasp any object that fits into the hand. If a patient would want to grasp small or thin objects, the angle between the lever and thumb could be reduced. Hence all users will be capable of closing the hand to perform a grip. The wished value has thus not been achieved, but the functional demand to enable every person to make use of the full opening width has been realised.

6.4.3. Function

The 3D-Sanhand is capable of performing a pinch grip. The phalanges of the fingers and thumb are rigid since the design uses only one rotational joint. Therefore, it is not possible to perform an adaptive grip, and thus the phalanges are not capable to entirely enclose different object types. The joints in the fingers, however, are fixed in a slightly flexed position that is comparable to a power grip posture, and the gripping performance is similar to a power grip. The maximum opening width of the prototype is 75 mm and hence meets the wished value. However, during the SHAP, it was observed that the opening width was not sufficient to perform all ADL tasks. Therefore, it is recommended to enlarge the opening span in the future development of the hand.

The prosthesis was capable of performing a 15 N pinch grip using an actuation force of 28 \pm 1.5 N. Therefore the transmission ratio results in: $\frac{15}{28} = 0.54$. These values are well within the functional requirements and are similar or better than conventional prostheses. The performance of the elastic bands is regarded weak. Not only because they need to be replaced often, but also because they seem to be too weak to provide sufficient opening functionality. Due to extra friction on the Bowden cable, there was observed that the hand did not always return appropriately to the full opening position. This hindered the subject from using the device adequately. The weak performance of the elastic bands is also visible in the mechanical tests showing poor hysteresis effects. The spring force in the elastic bands is close to the frictional forces within the mechanism, resulting in reduced efficiency.

6.4.4. Cosmetics

The shape of the hand is conforming the shape of the human hand. A 3D model of my own hand has been used and contributed to a much more detailed representation than could have been created with manual SOLIDWORKS design. The resting position of the fingers is natural, slightly flexed. In order to maximise the natural appearance and not lose the width of the opening span, the thumb had to be elongated in comparison to the original length. Therefore the dimensions of the thumb deviate from the true size, although this was not detected by uninformed observers. The layer-by-layer addition of material during the print has contributed to a more natural surface. Although it is solid plastic, the surface is similar to fingerprints and human skin structures. Materials that are used for gloves feel more natural and are closer to human-like hands, but the exclusion of bulging and tears makes this fabrication technique a considerable alternative.

The cavity on the dorsal side of the palm for the lever is aesthetically not pleasing. In the resting position, the protruding lever falls within the palm, but especially during actuation, it becomes clearly visible. It in the future, it would be desirable to fit the lever mechanism completely in the palm. The top of the rotational cavity on the palmar side, is also aesthetically not pleasing and is especially striking due to the diverge printing structure.

6.4.5. Comfort

The prosthesis is very lightweight with a total mass of 142 g. This is well below the wished mass of 200 grams and also in perspective to conventional prosthesis a very appealing alternative. A total fitment will also include a socket, and wrist unit to secure the terminal device onto the body of the patient. Future research should focus also to develop these parts with a low mass to preserve the obtained

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weight benefits.

The gripping design requires an actuation force of 28 N to perform a 15 N pinch grip, which is assumed appropriate to perform most activities of daily living fatigue-free. A pinch force of 21 N was obtained with an actuation force of 38 N, which was used as a boundary for comfortable use of the device for female users [59]. Males are assumed to be able to handle forces up to 66 N fatigue-free, and will therefore be able to exert even higher pinch forces without exhaustion of the muscles.

6.4.6. Durability

No fatigue tests have been performed with the final design, so exact data on these aspects is not available. The device has been designed in such a way that parts can easily be replaced. The mechanism is so simple that users can demount en re-assemble the device by themselves. In this way, it was intended that amputees would be provided with some additional parts and a bunch of replaceable elastic bands during their fitment. In this way, the failed parts could be replaced without a visit to a prosthetics clinic.

During the mechanical and user tests different aspects regarding the durability of the design were already visible after short-time testing. The lever tests showed that the lever was able to withstand an actuation of 200 N without breaking or deformation, but internal parts in the mechanism were affected. It is estimated that the parts, the pin, the gear teeth and the thin wall around the rotational cavity, are reliable up until a cable actuation of 150 N. Higher actuation forces will develop stresses causing the parts to break or deform, hence losing proper functionality. Another problem occurred during the user tests when subjects performed power forces onto an object. The top of the rotational cavity could get loose as a result of repeated opening/closing executions. The sliding mechanism then loses its connection, and as a result, the device became uncontrollable. During these incidents, which were on the scale of one out of three subjects, the springy ends of the top could be affected and break off.

In order to prevent these failures and to create a more durable and reliable device, it is recommended to investigate different materials and consider the use of metal or steel alternatives. It is assumed that small 3D printed parts, created with PLA using a FDM printer, have limited performance. Literature showed that maximum cable operational forces that subjects can perform are an average of 257 N [59]. The 3D-Sanhand is not capable of withstanding this peak force, and therefore reinforcement of parts is essential before amputees should use the device.

6.4.7. Costs

The total costs for the fitment of an upper-limb prosthesis are divided into the production costs for the socket and terminal device and the required manual labour. The production costs for the terminal device comprise of the depreciation costs for the printer and the material costs for each individual product. The prototypes have been developed with a dual-extruder Ultimaker printer, which is more expensive and complex than a single extruder printer, to enable the use of PVA as support material. The material costs comprise of the costs for the use of PLA and PVA, which are €33,00 per 750 g and €39,95 per 350 g respectively [107]. There has been chosen to use Ultimaker materials for reliable print results, although there are cheaper filaments available on the market. The total material costs will be: $T = \frac{142}{750} \cdot €33,00 + \frac{54}{350} \cdot €39,95 = €12,41$. This is excluding the elastic band and pressure spring. The material costs are within the predefined requirements.

For future expansion, it would be valuable to investigate print outcomes with FDM printers from different brands, since Ultimakers are among the most expensive printers on the market. Thereby, repairs of Ultimaker parts are more complex, harder to acquire at some places in the world, and more expensive than for instance parts from a Prusa 3D printer. Furthermore, it is outstanding that the support material costs are such a considerable amount (about half) of the total material costs. These costs could be decreased by about one-third if PLA would have been used instead of PLA.

6.5. Future directions

Future application of this project has its main strength in the simplicity of the concept. All required parts can be fabricated with a 3D-printer and assembled without any technical or medical knowledge. As described in previous sections, it is recommended to develop the proposed prototype further to improve grasping characteristics, the strength of the mechanism and hence the durability. Then, the project could be taken up to the next level.

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The design and idea are very suitable for customisation, adjusted to each individual patient. Implementation can be imagined as a mobile prosthetic clinic. In this way, patients living in rural areas, or in countries without sophisticated clinics can be treated. Here, patients can get their, if still present, unattached hand scanned. This scan will be used to mirror the image and create a model of their amputated hand that is exactly equal to their opposed hand. By application of the mechanism in the palm, a customised product can be created.

Conclusion

This thesis describes the design and evaluation of the 3D-Sanhand. This 3D-printed BP hand prosthesis is the first terminal device that can be produced and assembled without technical and medical knowledge, or complex tools and machinery, and has a high force transmission. It is therefore a unique solution for application in low-resource countries dealing with a shortage in medical and/or technical specialists. The product fabrication does not require manual post-processing and the final product can be assembled in less than two minutes. The prosthetic hand performs a pinch force high enough to perform activities of daily living under comfortable operational forces, and that is comparable to conventional prostheses on the market. The prosthetic hand is comfortable to wear because it is operational fatigue-free, and has a low mass of 142 gram. It has an attractive appearance, being based a model of a real human hand, and the total material costs of rounded 12 euro offer a promising alternative to the expensive devices on the market. Future research should further investigate what the wear effects of 3D printed materials are on the long-term use, and should propose directions to increase the durability and efficiency of the design.



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Appendices



Situation sketch

In the period from half of February - half of May 2019 I have been in India to investigate the possibilities of development, improvement and implementation of the 100 Dollar Hand in local clinics in India. During this time I have visited and worked with twelve different clinics, rehabilitation centres and hospitals. My experiences and obtained knowledge during this period have been the motivation and drive for the completion of this thesis project. The insight and practical understanding of the situation there was my guidance and basis for the way I set up this design project.

Therefore, this chapter comprises of a short description of the situation in local clinics in India, the affected patients and their wishes and needs, and how these aspects have lead to my understanding of the necessities that are required to develop a successful product.

Background

India is a country with a very low health performance [108]. The main cause can be found in the inadequate set up of their system [109]. The available healthcare resources are too low to serve the gigantic population and the distribution over the country is unequal. The majority of the medical specialists is involved in the private health sector [110], although only a small minority of the population is financially capable to make use of these services. Therefore the majority of the inhabitants is dependent on the public sector, which provides services free of cost. Public hospitals can only be found in the big cities and waiting lists can take up to a year due to shortage in specialists and resources. Based on the statistics of the Ministry of Statistics and Programme implementation, 2.21% of the Indian population is disabled. The majority of these patients is living in rural areas, and the number of affected people is still increasing [111]. This results in nearly 100 million physically disabled people [112].

The only low-cost upper-limb prosthesis that is available on the Indian market is the ALIMCO hand. This voluntary opening design is provided by the Indian government, but the available quantity does not meet the gigantic demand of the disabled population. The performance, in terms of weight, ease of operation and grip force, is weak in comparison to commercially available devices in Western countries.



Figure A.1: Below-elbow upper limb prosthesis with ALIMCO terminal device. Socket is produced in a local clinic.

Clinics and workshops

India only contains ninety public hospitals with dedicated prosthetic or orthotic departments. All economical less privileged patients were dependent on these hospitals that are usually far away from their home place. As a response, a handful of non-profit organisations, funded by charity, interplay in this

64 A. Situation sketch

field with the aim of providing free devices to the needy population. These centres are usually run by one professional prosthetist&orthotist (P&O) and a few internally trained technicians. These technicians usually did not have any education and learned the work on the job. Several Indian clinics serve patients in neighbouring countries, like Pakistan, Vietnam, Laos and Cambodia, because the situation there is even worse. These countries have a lower educated population and less developed transport and social system.

The fitment of an upper-limb prosthesis consists of a few steps; measurements of the limb and stump of the patient, fabrication of the negative and positive mould using Plaster of Paris (POP), fabrication of socket using a high density polyethylene pipe, attachment of the wrist unit and terminal device. The terminal device is directly operational, so no adjustments have to be done on the mechanics.

The available tools and machinery in the clinics is minimal and usually obtained through charity gifts. The clinics that I visited had, for example, just one screwdriver and one hammer. This often resulted in inappropriate usage of tools and weak product fabrication in terms of precision and care.

Patients

Machine accidents, electrical burns and traffic accidents are the major causes for amputations. The number of patients in India is not only much higher because of the lack in safety protocols and extreme traffic situations, but also because health provision and accessibility is worse and patients are not treated in time after their accidents. Patients often have to travel a long distance in order to reach hospitals or health centres. Remote places are difficult to reach and public transport is slow. Thereby the distances are large and a large majority of the population does not have the financial capacities to pay for the journey. Therefore, the effort to travel to prosthetic centres is large. People have to spend a lot of time and money, and are not able to come for regular follow-up sessions or repairs.

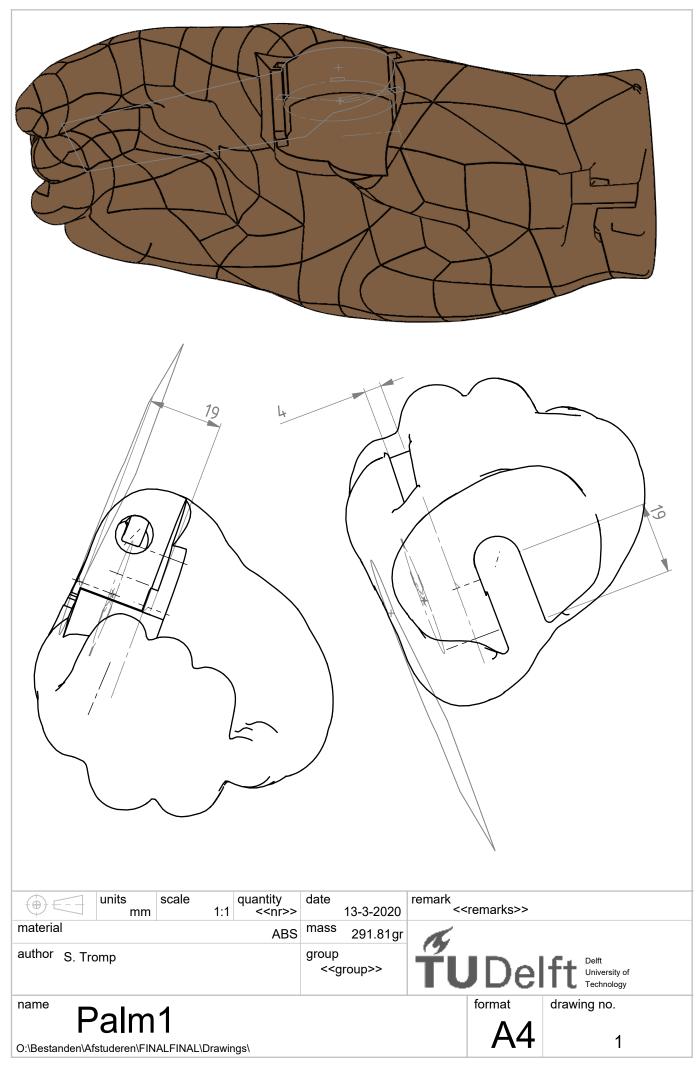
Patients in India feel ashamed of their impairment and try to hide it in public. Therefore the cosmetic aspect of a prosthesis is at least as important as the functional aspect. It is assumed that the majority of the patients will not wear the device is it does not meet a natural appearance.

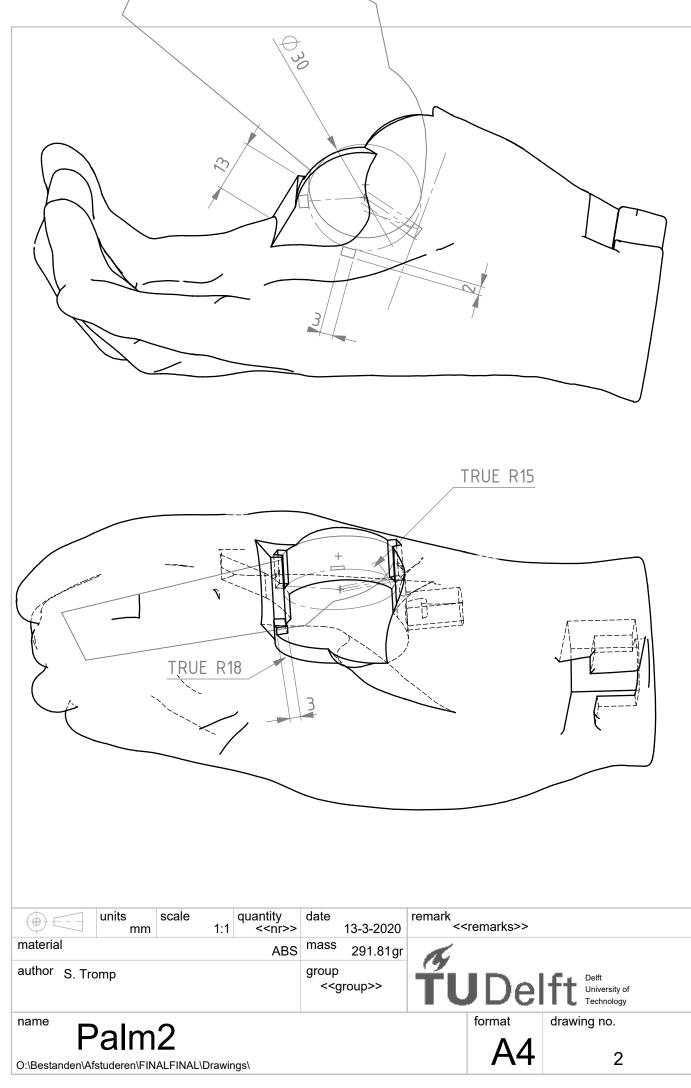
Summary

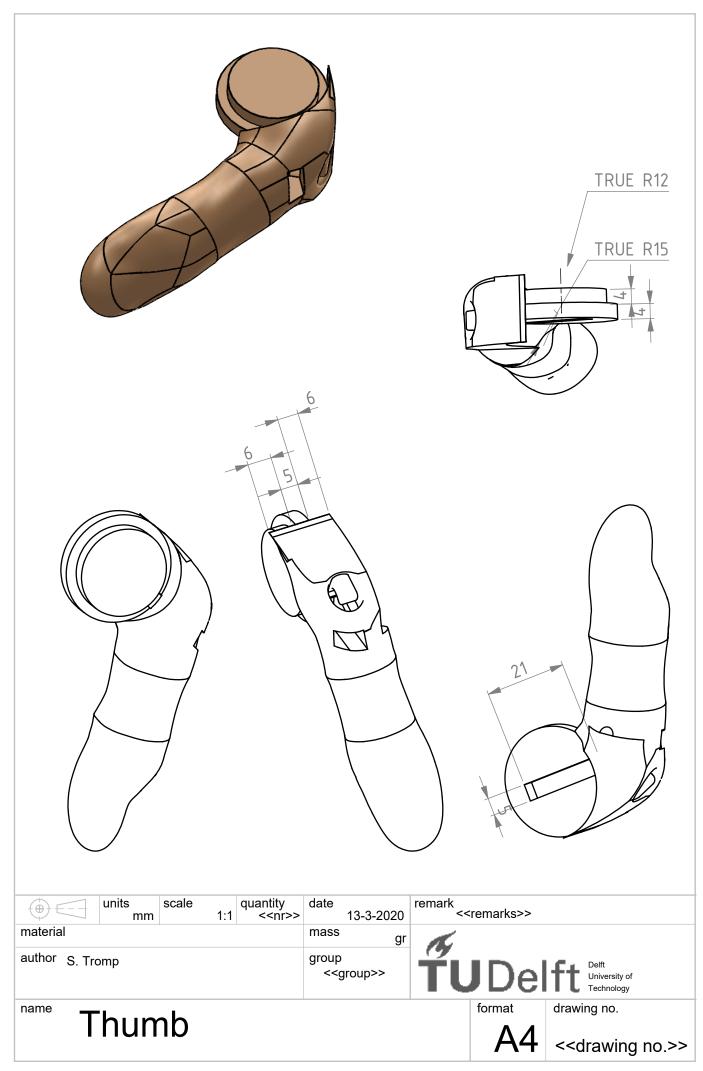
This situation sketch already points out some important aspects that should be taken into account. In summary this comprises of:

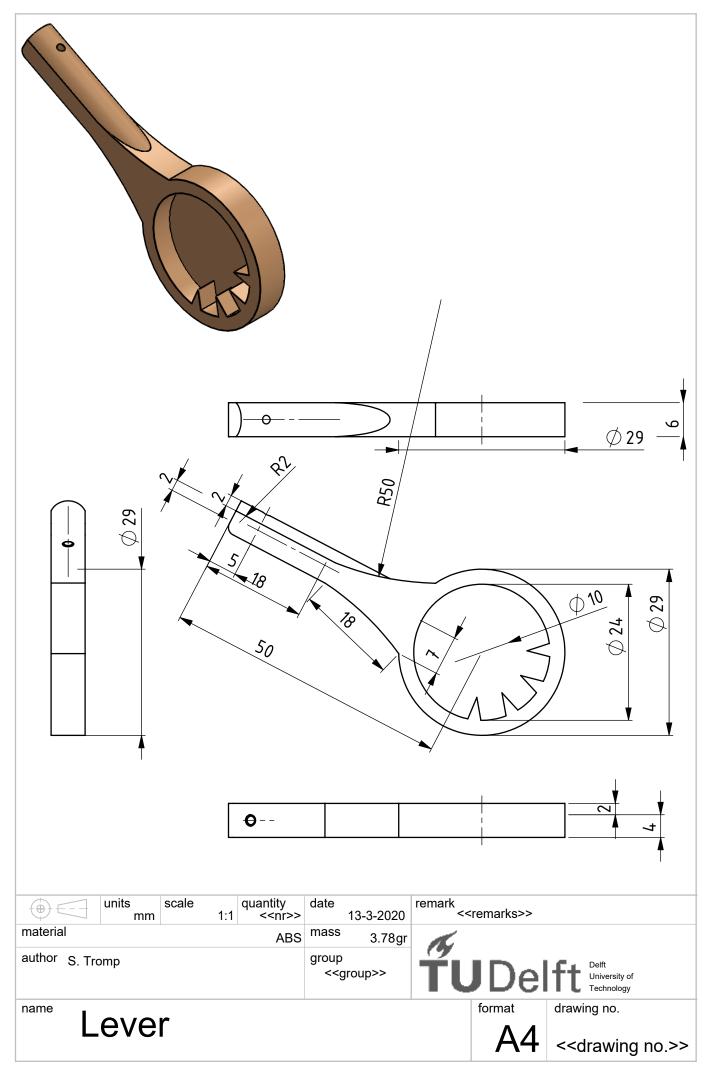
- The accessibility to health centres is bad, and it is a large effort in terms of time and money to reach prosthetic clinics.
- There is a shortage in low-cost upper-limb prostheses and the only available design has a weak functional performance.
- The resources in prosthetic hospitals or clinics are limited.
- The amount of patients is large, and majority of the patients has low financial possibilities.
- The cosmetic aspects of a prosthesis is as important as the functional aspect.

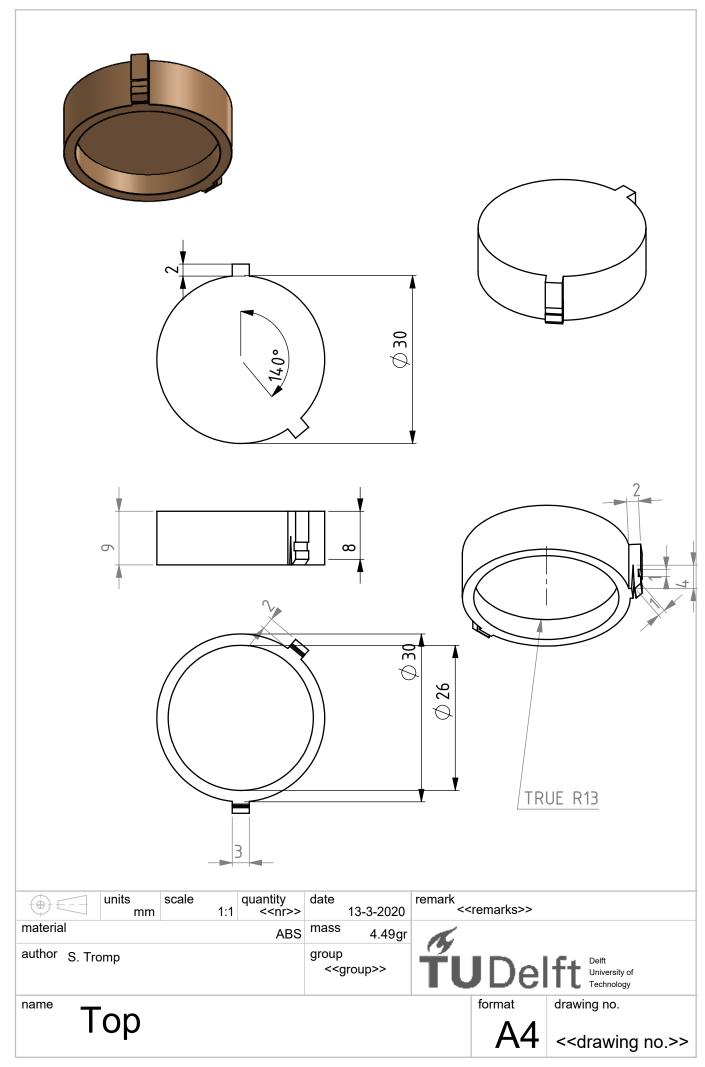
SOLIDWORKS Drawings

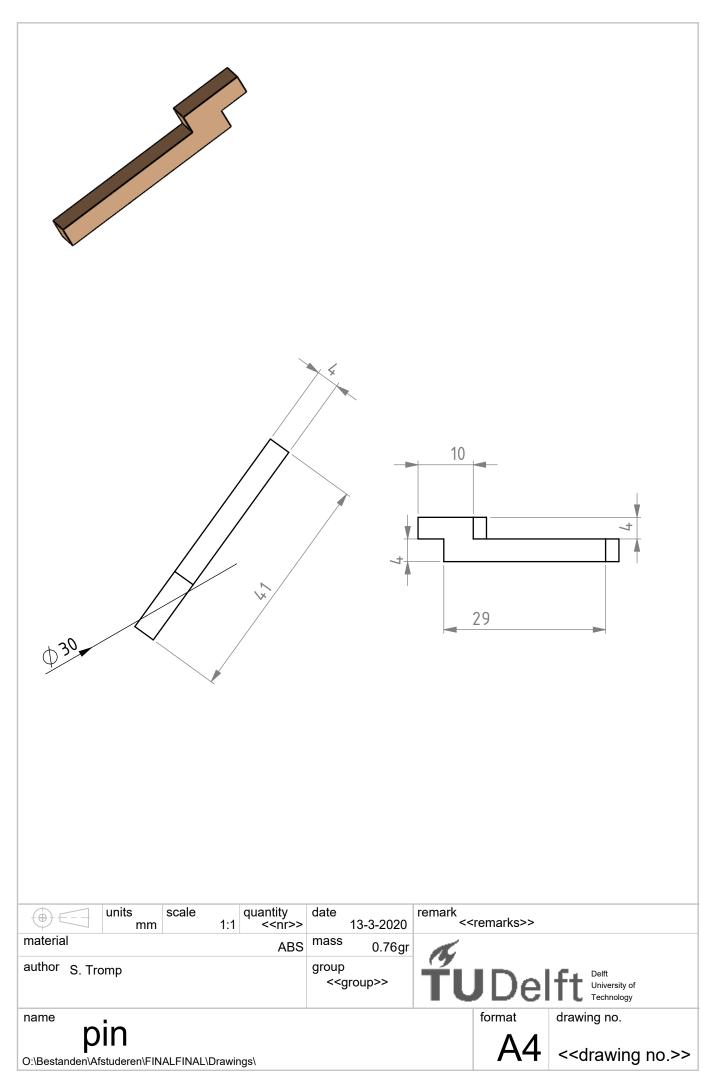














MATLAB code: Mechanical Tests

Lever test

```
clc
 clear all
 close all
concept1_1 = readtable('leverconcept1_1');
  concept1_2 = readtable('leverconcept1 2');
  concept2 1 = readtable('leverconcept2 1');
  concept2_2 = readtable('leverconcept2_2');
  concept3_1 = readtable('leverconcept3_1');
  concept3_2 = readtable('leverconcept3_2');
 %% Specification Values
 Fact_1_1 = -table2array(concept1_1(:,8));
                                              % [N]
  Fact_1_2 = -table2array(concept1_2(:,8));
                                              % [N]
  Fact_2_1 = -table2array(concept2_1(:,8));
                                              % [N]
  Fact_2_2 = -table2array(concept_2_2(:,8));
                                              % [N]
  Fact_3_1 = -table2array(concept3_1(:,8));
                                              % [N]
                                              % [N]
  Fact_3_2 = -table2array(concept3_2(:,8));
                                                % [N]
  Fpinch_1_1 = table2array(concept1_1(:,11));
  Fpinch_1_2 = table2array(concept1_2(:,11));
                                                % [N]
  Fpinch_2_1 = table2array(concept2_1(:,11));
                                                % [N]
  Fpinch_2_2 = table2array(concept2_2(:,11));
                                                % [N]
  Fpinch_3_1 = table2array(concept3_1(:,11));
                                                % [N]
                                                % [N]
  Fpinch_3_2 = table2array(concept3_2(:,11));
                                          % [mm]
 d_1_1 = table2array(concept1_1(:,9));
 d_1_2 = table2array(concept1_2(:,9));
                                          % [mm]
                                          % [mm]
 d 2 1 = table2array(concept2 1(:,9));
 d 2 2 = table2array(concept2 2(:,9));
                                          % [mm]
 d_3_1 = table2array(concept3_1(:,9));
                                          % [mm]
  d_3_2 = table2array(concept3_2(:,9));
                                          % [mm]
 %% Maximum actuation force
 % Concept 1
  [maxvalue, Index_1_1] = max(Fact_1_1);
                                          % Find max actuation force and
     index number
```

```
% Max actuation force that the lever
  maxFact_1_1 = maxvalue;
      could withstand
  maxPinch 1 1 = Fpinch 1 1(Index 1 1); % Corresponding pinch force
39
  [maxvalue, Index_1_2] = max(Fact_1_2); % Find max actuation force and
      index number
  maxFact_1_2 = maxvalue;
                                      % Max actuation force that the lever
      could withstand
  maxPinch_1_2 = Fpinch_1_2(Index_1_2); % Corresponding pinch force
  % Concept 2
45
  [maxvalue, Index_2_1] = max(Fact_2_1); % Find max actuation force and
      index number
  maxFact_2_1 = maxvalue;
                                      % Max actuation force that the lever
      could withstand
  maxPinch_2_1 = Fpinch_2_1(Index_2_1); % Corresponding pinch force
48
  [maxvalue, Index_2_2] = max(Fact_2_2); % Find max actuation force and
      index number
                                      % Max actuation force that the lever
  maxFact_2_2 = maxvalue;
      could withstand
  maxPinch 2 2 = Fpinch 2 2(Index 2 2); % Corresponding pinch force
52
53
  % Concept 3
  [maxvalue, Index_3_1] = max(Fact_3_1); % Find max actuation force and
      index number
                                      % Max actuation force that the lever
  maxFact_3_1 = maxvalue;
      could withstand
  maxPinch_3_1 = Fpinch_3_1(Index_3_1); % Corresponding pinch force
57
58
  [maxvalue, Index_3_2] = max(Fact_3_2); % Find max actuation force and
      index number
                               % Max actuation force that the lever
  maxFact 3 2 = maxvalue;
      could withstand
  maxPinch_3_2 = Fpinch_3_2(Index_3_2); % Corresponding pinch force
61
  %% Plots
63
64 figure (1)
65 plot(smooth(Fact_1_1(1:Index_1_1)),smooth(Fpinch_1_1(1:Index_1_1)))
67 plot (smooth (Fact_1_2(1:Index_1_2)), smooth (Fpinch_1_2(1:Index_1_2)))
68 hold on
plot(smooth(Fact_2_1(1:Index_2_1)), smooth(Fpinch_2_1(1:Index_2_1)))
70 hold on
plot(smooth(Fact_2_2(1:Index_2_2)),smooth(Fpinch_2_2(1:Index_2_2)))
72 hold on
73 plot (smooth (Fact_3_1(1:Index_3_1)), smooth (Fpinch_3_1(1:Index_3_1)))
74 hold on
75 plot(smooth(Fact_3_2(1:Index_3_2)),smooth(Fpinch_3_2(1:Index_3_2)))
76 xlabel('Actuation Force [N]')
77 ylabel('Pinch Force [N]')
18 legend ('Basic - 1', 'Basic - 2', 'Thickened - 1', 'Thickened - 2', '
      Bulging - 1', 'Bulging - 2')
79 xlim([0 200])
<sub>80</sub> ylim([0 64])
```

Closing and opening test

```
clc
  clear all
  close all
  % SH - Inport data
  SH_work_1 = readtable('SH_work1.txt');
  SH_work_2 = readtable('SH_work2.txt');
  SH_work_3 = readtable('SH_work3.txt');
  % SH - Specification Work closing / opening
10
  F_pull_1 = table2array(SH_work_1(:,8));
                                               % [N]
11
  F_pull_2 = table2array(SH_work_2(:,8));
                                                % [N]
12
  F_pull_3 = table2array(SH_work_3(:,8));
                                               % [N]
                                             % [mm]
  d 1 = table2array(SH work 1(:,9));
15
  d 2 = table2array(SH work 2(:,9));
                                             % [mm]
16
  d_3 = table2array(SH_work_3(:,9));
                                             % [mm]
17
  % Calculation Work & hysteresis
19
  % Calculation maximum cable excursion
  x_{cable_1} = max(d_1) - min(d_1);
  x_{cable_2} = max(d_2) - min(d_2);
  x cable 3 = \max(d 3) - \min(d 3);
  x_cable = mean([x_cable_1 x_cable_2 x_cable_3]);
  std_x_cable = std([x_cable_1 x_cable_2 x_cable_3]);
  %Measurement 1
27
  [maxvalue, Index] = max(d 1); % Find point of closed position
28
  pos_d1 = Index;
  d1\_close = d\_1(1:pos\_d1);
31
  F1\_close = F\_pull\_1(1:pos\_d1);
  d1_{open} = d_1(pos_d1+1:length(d_1));
  F1_{open} = F_{pull_1(pos_d1+1:length(F_pull_1));}
  work_close_1 = trapz(d1_close,-F1_close);
36
  work_open_1 = trapz(d1_open, F1_open);
  Hysteresis_1 = work_close_1-work_open_1;
39
  %Measurement 2
40
  [maxvalue, Index] = max(d_2); % Find point of closed position
  pos_d2 = Index;
42
43
  d2\_close = d_2(1:pos_d2);
  F2\_close = F\_pull_2(1:pos\_d2);
  d2 \text{ open} = d 2(pos d2+1:length(d 2));
  F2\_open = F\_pull\_2(pos\_d2+1:length(F\_pull\_2));
47
  work_close_2 = trapz(d2_close,-F2_close);
  work open 2 = trapz(d2 \text{ open}, F2 \text{ open});
50
  Hysteresis_2 = work_close_2-work_open_2;
51
  %Measurement 3
  [maxvalue, Index] = max(d_3); % Find point of closed position
```

```
pos_d3 = Index;
  d3 close = d 3(1:pos d3);
57
  F3\_close = F\_pull\_3(1:pos\_d3);
  d3_{open} = d_3(pos_d3+1:length(d_3));
  F3_{open} = F_{pull_3}(pos_d3+1:length(F_pull_3));
60
61
  work_close_3 = trapz(d3_close,-F3_close);
  work_open_3 = trapz(d3_open,F3_open);
  Hysteresis 3 = work close 3-work open 3;
  % Averaged values
  Work_close = mean([work_close_1 work_close_2 work_close_3]);
  std_close = std([work_close_1 work_close_2 work_close_3]);
  Work_open = mean([work_open_1 work_open_2 work_open_3]);
  std_open = std ([work_open_1 work_open_2 work_open_3]);
  Hysteresis = mean([Hysteresis_1 Hysteresis_2 Hysteresis_3]);
  std_Hysteresis = std ([Hysteresis_1 Hysteresis_2 Hysteresis_3]);
73
  %% Plots
74
  figure (1)
  plot ((d_2), smooth(-F_pull_2))
  xlabel('Displacement [mm]')
  ylabel('Actuation Force [N]')
  xlim([0 53])
  ylim([0 16])
80
  figure (2)
  area(d2_close, smooth(-F2_close))
  xlabel('Displacement [mm]')
  ylabel('Actuation Force [N]')
  xlim([0 53])
  ylim ([0 16])
  legend('Work closing')
  %[0.85 0.33 0.10]
91
  figure (3)
a=area(d2\_open,smooth(-F2\_open))
 xlabel('Displacement [mm]')
 ylabel('Actuation Force [N]')
 legend('Work opening')
  xlim([0 53])
  ylim([0 16])
97
  figure (4)
  area(d2 close, smooth(-F2 close))
  hold on
  area(d2_open, smooth(-F2_open))
  xlabel('Displacement [mm]')
  ylabel('Actuation Force [N]')
  xlim([0 53])
  ylim([0 16])
  legend('Hysteresis', 'Work opening')
```

15N Pinch force test

1 ClC

```
clear all
  close all
  % SH - Inport data
  SH_Pinch_1 = readtable('SH_pinch1.txt');
  SH_Pinch_2 = readtable('SH_pinch2.txt'
  SH_Pinch_3 = readtable('SH_pinch3.txt'
  %% Specification 15 N pinch
  F_pull_1 = table2array(SH_Pinch_1(:,8));
                                                % [N]
                                                % [N]
  F pull 2 = table2array(SH Pinch 2(:,8));
  F pull 3 = table2array(SH Pinch 3(:,8));
                                                % [N]
                                                   % [N]
  F_{pinch_1} = table2array(SH_{pinch_1}(:,11));
  F_pinch_2 = table2array(SH_Pinch_2(:,11));
                                                   % [N]
15
  F_{pinch_3} = table2array(SH_{pinch_3}(:,11));
                                                   % [N]
  d_1 = table2array(SH_Pinch_1(:,9));
                                              % [mm]
  d_2 = table2array(SH_Pinch_2(:,9));
                                              % [mm]
  d_3 = table2array(SH_Pinch_3(:,9));
                                              % [mm]
20
  %% Calculation Work & hysteresis for pinching 15 N
23
  %Measurement 1
  [maxvalue, Index] = max(F_pinch_1);
                                           % Find point of closed position
  pos_d1 = Index;
27
  d1\_close = d\_1(1:pos\_d1);
  F1\_close = F\_pull\_1(1:pos\_d1);
  d1_{open} = d_1(pos_d1+1:length(d_1));
  F1_{open} = F_{pull_1(pos_d1+1:length(F_pull_1));}
31
32
  work close 1 = trapz(d1 close, -F1 close);
  work open 1 = trapz(d1 \text{ open}, F1 \text{ open});
  Hysteresis_1 = work_close_1-work_open_1;
35
  %Measurement 2
  [maxvalue, Index] = max(F_pinch_2);
                                           % Find point of closed position
38
  pos_d2 = Index;
39
  d2\_close = d_2(1:pos_d2);
  F2\_close = F\_pull\_2(1:pos\_d2);
42
  d2_{open} = d_2(pos_d2+1:length(d_2));
  F2\_open = F\_pull\_2(pos\_d2+1:length(F\_pull\_2));
  work_close_2 = trapz(d2_close,-F2_close);
46
  work_open_2 = trapz(d2_open, F2_open);
47
  Hysteresis_2 = work_close_2-work_open_2;
  %Measurement 3
  [maxvalue, Index] = max(F_pinch_3);
                                           % Find point of closed position
  pos_d3 = Index;
  d3\_close = d_3(1:pos_d3);
  F3\_close = F\_pull\_3(1:pos\_d3);
  d3_{open} = d_3(pos_d3+1:length(d_3));
  F3_{open} = F_{pull_3(pos_d3+1:length(F_pull_3))};
```

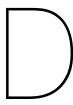
```
work close 3 = trapz(d3 close, -F3 close);
   work open 3 = trapz(d3 \text{ open}, F3 \text{ open});
   Hysteresis_3 = work_close_3-work_open_3;
  % Averaged values
   Work_close = mean([work_close_1 work_close_2 work_close_3]);
   std_close = std([work_close_1 work_close_2 work_close_3]);
  Work_open = mean([work_open_1 work_open_2 work_open_3]);
   std open = std ([work open 1 work open 2 work open 3]);
   Hysteresis = mean([Hysteresis 1 Hysteresis 2 Hysteresis 3]);
   std Hysteresis = std ([Hysteresis 1 Hysteresis 2 Hysteresis 3]);
  %% Calculcation cable force for 15 N pinch
71
  % Test 1
  Index = find(F_pinch_1>15);
                                   % Find where Actuation exceeds 100 N
  Fact_1 = -F_pull_1(Index(1:1)) \% [N]
  % Test 2
  Index = find(F pinch 2>15);
                                   % Find where Actuation exceeds 100 N
   Fact_2 = -F_pull_2(Index(1:1)) \% [N]
  % Test 3
   Index = find(F pinch 3>15);
                                  % Find where Actuation exceeds 100 N
   Fact_3 = -F_pull_3(Index(1:1)) \% [N]
   F_act = mean([Fact_1 Fact_2 Fact_3])
   std_F_act = std ([Fact_1 Fact_2 Fact_3])
83
  %% Plots
   figure (1)
   area(d1 close, smooth(-F1 close))
87
   hold on
   area(d2 open, smooth(-F2 open))
  xlabel('Displacement [mm]')
   vlabel('Actuation Force [N]')
   xlim([0 inf])
   ylim([0 inf])
   legend('Hysteresis','Work opening')
   figure (3)
  plot(d_1, smooth(F_pinch_1))
  hold on
  plot(d 2,smooth(F pinch 2))
   hold on
   plot(d_3, smooth(F_pinch_3))
   xlabel('displacement [mm]'
ylabel('Pinch Force [N]')
102
   xlim([35 inf])
   ylim([0 inf])
   legend('1','2','3')
   title ('Displacement vs Pinch Force')
107
   figure (2)
109
   plot (smooth(-F_pull_1), smooth(F_pinch_1))
   xlabel('Actuation Force [N]')
   ylabel('Pinch Force [N]')
113 xlim([0 inf])
```

```
14 ylim([0 inf])
```

100 N Actuation test

```
clc
  clear all
  close all
  % SH - Inport data
  SH_Pull_1 = readtable('SH_pull1.txt');
  SH_Pull_2 = readtable('SH_pull2.txt');
  SH Pull 3 = readtable('SH pull3.txt');
  SH_Pull_4 = readtable('SH_pull4.txt');
  SH_Pull_5 = readtable('SH_pull5.txt');
  % SH - Specification 100 N actuation
11
  F_pull_1 = table2array(SH_pull_1(:,8));
                                               % [N]
  F_pull_2 = table2array(SH_pull_2(:,8));
                                               % [N]
                                               % [N]
  F pull 3 = table2array(SH Pull 3(:,8));
  F_pull_4 = table2array(SH_pull_4(:,8));
                                               % [N]
  F_pull_5 = table2array(SH_Pull_5(:,8));
                                               % [N]
  F_{pinch_1} = table2array(SH_{pull_1(:,11))};
                                                 % [N]
                                                 % [N]
  F_{pinch_2} = table2array(SH_{pull_2(:,11))};
19
  F_{pinch_3} = table2array(SH_{pull_3(:,11))};
                                                 % [N]
  F_{pinch_4} = table2array(SH_{pull_4(:,11))};
                                                 % [N]
  F_{pinch_5} = table2array(SH_{pull_5(:,11))};
                                                 % [N]
  d_1 = table2array(SH_Pull_1(:,9));
                                             % [mm]
  d_2 = table2array(SH_Pull_2(:,9));
                                             % [mm]
                                             % [mm]
  d_3 = table2array(SH_Pull_3(:,9));
26
  d_4 = table2array(SH_Pull_4(:,9));
                                             % [mm]
27
  d_5 = table2array(SH_Pull_5(:,9));
                                             % [mm]
  % Calculate pinch force for 100 N actuation
30
  % Test 1
31
  Index = find(-F_pull_1 > 100);
                                    % Find where Actuation exceeds 100 N
  x1 100N = Index(1:1);
  Pinch_{100N_{1}} = F_{pinch_{1}}(Index(1:1)); % [N]
  % Test 2
  Index = find(-F_pull_2 > 100);
                                    % Find where Actuation exceeds 100 N
  x2\ 100N = Index(1:1);
  Pinch_{100N_{2}} = F_{pinch_{2}}(Index(1:1)); % [N]
38
  % Test 3
  Index = find(-F_pull_3 > 100);
                                    % Find where Actuation exceeds 100 N
  x3_{100N} = Index(1:1);
  Pinch_{100N_{3}} = F_{pinch_{3}(Index(1:1))}; % [N]
  % Test 4
  Index = find(-F pull 4 > 100);
                                    % Find where Actuation exceeds 100 N
  x4\ 100N = Index(1:1);
  Pinch 100N 4 = F pinch 4(Index(1:1)); % [N]
  % Test 5
  Index = find(-F_pull_5 > 100);
                                    % Find where Actuation exceeds 100 N
  x5 100N = Index(1:1);
49
  Pinch_{100N_{5}} = F_{pinch_{5}}(Index(1:1)); % [N]
  % Averaged values
  Pinch_100N = mean([Pinch_100N_1 Pinch_100N_2 Pinch_100N_3 Pinch_100N_4
```

```
Pinch_100N_5]);
  std_pinch = std([Pinch_100N_1 Pinch_100N_2 Pinch_100N_3 Pinch_100N_4
      Pinch_100N_5]);
55
  %% Plots
  figure (1)
57
  plot(-F_pull_1, F_pinch_1)
  hold on
plot(-F_pull_2, F_pinch_2)
61 hold on
plot(-F_pull_3, F_pinch_3)
  hold on
  plot(-F_pull_5, F_pinch_5)
xlabel('Activation Force [N]')
  ylabel('Pinch Force [N]')
  xlim([0 inf])
  ylim([0 65])
  legend('1','2','3','5')
  title ('Activation vs Pinch')
71
72 figure (2)
  plot (smooth(-F_pull_1 (1:x1_100N)), smooth(F_pinch_1 (1:x1_100N)))
73
  hold on
<sup>75</sup> plot (smooth(-F_pull_2(1:x2_100N)), smooth(F_pinch_2(1:x2_100N)))
76 hold on
77 plot (smooth(-F_pull_3(1:x3_100N)), smooth(F_pinch_3(1:x3_100N)))
  hold on
  plot (smooth(-F_pull_4 (1:x4_100N)), smooth(F_pinch_4 (1:x4_100N)))
  hold on
  plot (smooth(-F_pull_5 (1:x5_100N)), smooth(F_pinch_5 (1:x5_100N)))
  xlabel('Actuation Force [N]')
83 ylabel('Pinch Force [N]')
 xlim([0 100])
85 ylim([0 65])
86 legend('Test 1', 'Test 2', 'Test 3', 'Test 4', 'Test 5')
```



45

Mechanical tests 100 Dollar Hand & Juan Hand

The mechanical tests for the 100 Dollar Hand and Juans Hand are equally performed as described in Section 5.2.3-5.2.5. The visual and quantitative results are shown in this Appendix.

100 Dollar Hand

Table D.1: Quantitative results of mechanical testing. The mean is provided with its standard deviation.

Max. cable excursion (mm)	Work closing (Nmm)	Hysteresis cycle (Nmm)	Work closing + pinch 15 N (Nmm)	Actuation force at 15 N pinch (N)	Pinch force at 38 N actuation force (N)	Pinch force at 100 N actuation force (N)
58 ±1.4	277 ±5	124 ±5	288 ±6	43 ±1.0	11.7 ±0.9	37 ±0.6

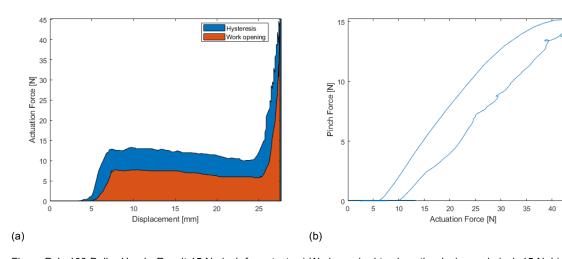


Figure D.1: 100 Dollar Hand - Result 15 N pinch force test: a) Work required to close the device and pinch 15 N, b) Required actuation force to pinch 15 N.

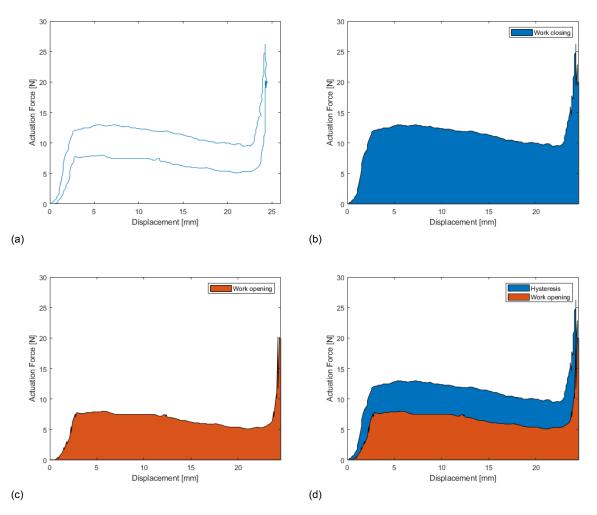


Figure D.2: 100 Dollar Hand - Closing and opening test: a) Hysteresis cycle, the measured actuation force as a function of the cable displacement during one closing / opening cycle. The test started at a fully open position with an actuation force and displacement of 0 N and 0 mm respectively. At the maximum achieved force and displacement the device is closed. b) The performed work during one closing & c) opening cycle can be represented by the area below the activation force - cable displacement curve. d) The differences between the work done during closing and opening is the hysteresis.

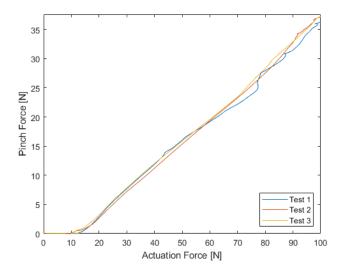


Figure D.3: 100 Dollar Hand - Measured pinch force output with a cable actuation force up to 100 N, three trials are performed.

Juan Hand

Table D.2: Quantitative results of mechanical testing. The mean is provided with its standard deviation.

Max. cable excursion (mm)	Work closing (Nmm)	Hysteresis cycle (Nmm)	Work closing + pinch 15 N (Nmm)	Actuation force at 15 N pinch (N)	Pinch force at 38 N actuation force (N)	Pinch force at 100 N actuation force (N)
23 ±0.5	335 ±28	263 ±27	995 ±27	115 ±4.7	1.4 ±0.5	13 ±1.6

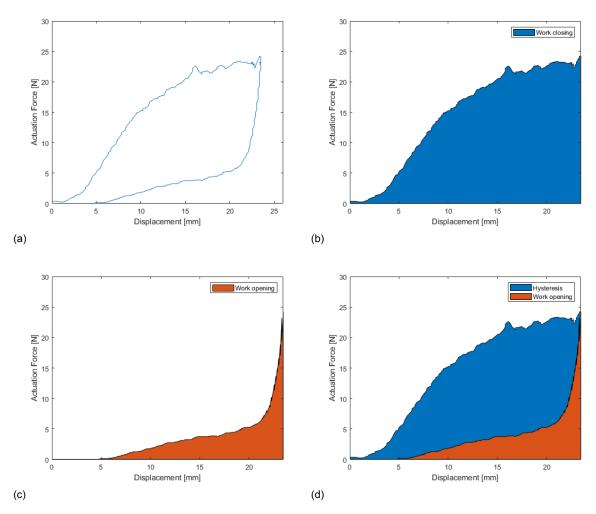


Figure D.4: Juan Hand - Closing and opening test: a) Hysteresis cycle, the measured actuation force as a function of the cable displacement during one closing / opening cycle. The test started at a fully open position with an actuation force and displacement of 0 N and 0 mm respectively. At the maximum achieved force and displacement the device is closed. b) The performed work during one closing & c) opening cycle can be represented by the area below the activation force - cable displacement curve. d) The differences between the work done during closing and opening is the hysteresis.

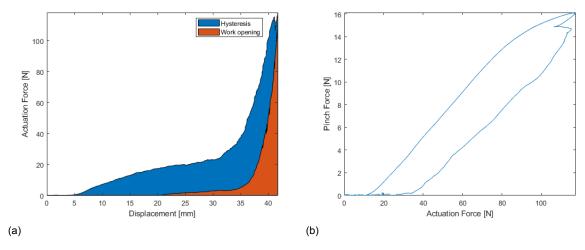


Figure D.5: Juan Hand - Result 15 N pinch force test: a) Work required to close the device and pinch 15 N, b) Required actuation force to pinch 15 N.

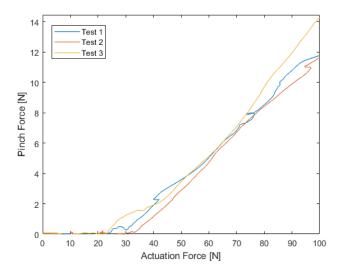


Figure D.6: Juan Hand - Measured pinch force output with a cable actuation force up to 100 N, three trials are performed.

SHAP Protocol



Assessor's

SHAP

Protocol



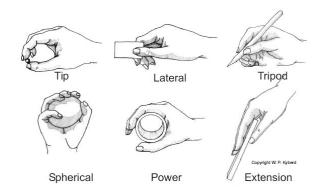
General Information

The Southampton Hand Assessment Procedure (SHAP) has been formed based on the analysis of grip patterns, and their frequency of use in Activities of Daily Living (ADL) tasks. Therefore it is considered to cover the wide range of prehensile tasks the hand usually undertakes (with the omission of specific occupational or recreational requirements).

The test consists of the manipulation of a series of both lightweight and heavyweight abstract objects. These are intended to directly reflect specific grip patterns, whilst also assessing the strength and compliance of the grip. This is followed by 14 ADL tasks. To ensure standardisation, the assessor's test procedure must be followed, whilst objectivity is maintained by participant self-timing. A complete assessment is expected to take around 20 minutes to complete (including all of the relevant explanations to the subject).

The procedure is designed to provide a score of functionality, which can be equated with a percentage; hence on completion of the test a score of optimum hand function is obtained. This score provides a tangible result describing the level of hand impairment, e.g. the participant has 75% of optimum hand function. As the procedure has been designed to be standardised and objective, this score cannot only be used for comparative assessments of a participant's performance throughout a course of treatment, but also provides information on their level of function (this is with respect to the benchmark of an unimpaired participant).

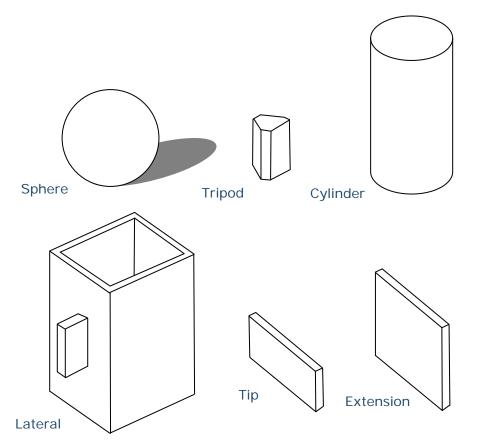
The protocol outlined in the following pages provides details for the assessor concerning the setup and execution of the test. The assessor is required to demonstrate each task to the descriptions given. The following diagram may help identify the appropriate grip patterns.





Contents of SHAP Test

Quantity	Item
1	Test case containing all SHAP equipment
1	Backboard mounted in case with lock & key, door hand and zip
1	SHAP form-board
1	Foam insert containing all objects
1	Timer unit
6	Lightweight abstract objects (see figure below)
6	Heavyweight abstract objects (see figure below)
1	Lock and key mounted on backboard
1	Zip mounted on backboard
4	Coins (2 x 1p and 2 x 2p)
1	Button board with 4 buttons attached
1	Plasticine block
1	Knife
1	Note card
1	Glass jar with lid
1	Glass jug
1	Cardboard juice carton
1	Empty tin with plastic lid
1	Door handle mounted on backboard
1	Metal arrow unit
1	Screwdriver



SHAP Abstract Object Tasks



Assessor's SHAP Protocol

Setting up the SHAP

The participant should be seated at a table with arms resting on the table. The participant's elbows should be at a 90° angle.

Place the SHAP form-board in front of the participant blue side facing upward, approximately 8cm from the front edge of the table. Fit the timer unit into the space provided in the front of the board. For each of the SHAP abstract object tasks, the board should be moved from left to right so that each task is directly in front of the participant, thereby ensuring no bias toward either hand dominance. The SHAP case and all ADL objects can be removed from the table during this first phase of the assessment.

Procedural Notes

Each task should be demonstrated to the participant using slow, clear movements, ensuring that the participant is aware of the appropriate grip for completion of the abstract object tasks.

It is important to note that the demonstration should be carried out using the corresponding hand under assessment, to avoid any confusion for the participant.

Prosthesis users should be encouraged to practice each task, prior to timing it, in order to determine the most appropriate technique as many users usually carry out tasks with the natural hand alone. Due to the difficulties associated with myoelectric prostheses, if it is apparent that the device has failed to respond to user demand, then a note should be made, and a retest allowed. If the device is similarly unresponsive during the second task, a note should be made of the difficulties encountered.

In other circumstances, the participant should be given only one chance to carry out the timed task. The time taken to complete each task, the appropriate grip pattern if identifiable should be recorded, as well as any relevant notes.

When establishing any form of normative data, it is imperative that the task is carried out fully. Due to the need to complete a task in the minimum amount of time there is often a temptation to 'rush' the task without actually fulfilling the exact requirements. Under these circumstances the task should be repeated.



Completing the SHAP Test

In the forthcoming document, normal text denotes instructions for assessors. *Text in italic text denotes instructions to be read to participants.* The SHAP website contains video demonstrations to help with accurate placement of the ADL tasks on the form board (please refer to http://www.shap.ecs.soton.ac.uk/about-usage.php for further guidance on completing the SHAP tasks).

SHAP Abstract Object Tasks

The 6 lightweight objects are to be completed first. If a participant cannot complete a task, this could be recorded as C/C (Cannot Complete) on the supplied SHAP test data sheet. All lightweight abstract objects are completed, followed by all heavyweight abstract objects.

"A series of objects will be placed on the board. The task involves moving the object from the rear slot on the board to the front slot. Only the hand under assessment (dominant hand) should be used for any of these tasks, including the starting and stopping of the timer."

Spherical Place the 'spherical object' in the appropriate rear slot. Place the 'tip object' in the slot between the rear and front 'spherical object' slots to create a small barrier. Move the board so that these slots are directly in front of the participant whilst maintaining the approximate 8cm distance from the front of the table. Using the spherical grip move the object over the barrier and place it in the front slot.

"Start the timer, pick up and move the object as demonstrated with as few mistakes as possible, and <u>as quickly as possible</u>, to the front slot. Complete the task by depressing the blue button on the timer again."

Tripod Place the 'tripod object' in the appropriate rear slot. Using a tripod grip, move the object to the front slot.

"Start the timer, move the object as demonstrated and as quickly as possible to the front slot and then stop the timer."

Power Place the 'power object' in the appropriate rear slot. Move the board so that these slots are directly in front of the participant whilst maintaining the approximate 8cm distance of the board from the front of the table. Using the power grip, pick up the object and move it to the front slot.



"Start the timer, move the object as demonstrated and as quickly as possible to the front slot and then stop the timer."

Lateral Place the 'lateral object' in the appropriate rear slot with the handle facing toward the participant. Move the board so that these slots are directly in front of the participant whilst maintaining the approximate 8cm distance from the front of the table. Using the lateral grip, pick up the object by the handle and move it to the front slot.

"Start the timer, move the object as demonstrated and as quickly as possible to the front slot and then stop the timer."

Tip Place the 'tip object' in the appropriate rear slot. Using a tip grip, move the object to the front slot.

"Start the timer, move the object as demonstrated and as quickly as possible to the front slot and then stop the timer."

Extension Place the 'extension object' in the appropriate rear slot. Using an extension grip, move the object to the front slot.

"Start the timer, move the object as demonstrated and as quickly as possible to the front slot and then stop the timer."

The procedure above should now be repeated, in the same order using the heavyweight abstract objects.

Once completed, remove all the abstract objects from the table and turn over the form-board. Place the board directly in front of the participant for <u>all</u> ADL tasks at approximately 8cm from the front of the table.



Activities of Daily Living

As before, each task should be demonstrated to the participant using slow, clear movements, ensuring that the participant is aware of the appropriate procedure.

The 'Optional' instructions should be used when the assessor feels that the participant would be unable, is uncomfortable, or unnatural in using the demonstrated grip.

To avoid repetitive filling/emptying of objects with water for the pouring tasks (jug, carton and full jar tasks), it is advisable to fill a separate container with approximately 1 litre of water. It may also be advisable to have a towel nearby to clear any spillage.

"The second stage of this assessment consists of 14 everyday activities, which should be timed in the same manner by pressing the blue button to start and stop the timer. Again tasks should be completed as quickly as possible, with as few mistakes as possible, using only the appropriate hand unless otherwise stated."

Pick Up Coins Arrange the two 2p and two 1p coins in the designated areas on the board. Place the glass jar in the designated spot for this task with the lid removed. Pick up each coin in turn by sliding the coin to the edge of the board using a tip or tripod grip and drop each coin into the glass jar. Move from right to left. Reset the task for the participant.

"Start the timer, lift each coin in turn as quickly as possible, and drop it in the jar as demonstrated. Repeat that for all the coins and then stop the timer."

[OPTIONAL: If you feel unable to pick up the coins as demonstrated, you may use any method you wish, whilst only using one hand.]

Button Board Place the button board to the right of the timer unit if assessing the right hand, and to the left if assessing the left hand. The buttons should be farthest from the timer unit. Undo each button in turn, using only the assessed hand in a tripod grip. The other hand may be used to steady the board, but may not assist in the task. The button board should remain on the form-board at all times. Reset the task for the participant.



"Start the timer and using only the appropriate hand, undo all four buttons in any order as demonstrated and as quickly as possible. You may steady the button board with your other hand so that it remains on the form-board throughout the task. Then stop the timer using only the appropriate hand."

Simulated Food Cutting Place the knife to the side of the timer unit (right side for right-handed assessments, left side for left-handed assessments). Place the plasticine 'food item' in the designated area on the form board (mould to look like a sausage and fit approximately the area on the form board). Pick up the knife, using the other hand to steady the plasticine. Cut it clearly into two sections. Then replace the knife on the form board. Reset the task by remoulding the plasticine for the participant.

"Start the timer, use the knife provided to cut the plasticine clearly into two pieces, as demonstrated and as quickly as possible. You may use the other hand to steady the plasticine. Return the knife to its starting position on the board and the stop the timer."

Page Turning Place the piece of card in the designated area on the opposite side of the platform to the hand under assessment. Using an extension or tripod grip, pick up the card, turn it over as if turning the pages of a book and place it on the opposite side of the form board (on the side under assessment). Reset the task for the participant.

"Start the timer lift and turn over the card as if you were turning the pages of a book and place the card on the opposite side of the board as demonstrated and as quickly as possible. Then stop the timer."

Jar Lid The lid should be placed on the empty glass jar and tightened only with sufficient force as would be expected for everyday use/self storage. The jar should be placed in the designated area on the form board. Both hands should be used for this task. Pick up the jar using a power grip with the non-dominant hand, undo the lid and return both the jar and the lid to the designated areas on the platform. Reset the task for the participant.

"Start the timer, pick up the jar and undo the lid with the hand under assessment as demonstrated and as quickly as possible. Return the jar and lid to the platform as demonstrated and stop the timer."



Glass Jug Pouring Fill the glass jug with 100ml of water (100ml is marked on the jug). Place the jug in the designated area of the form board with the handle of the glass jug pointing the right for right-handed participants, and to the left for left-handed participants. Place the glass jar (without the lid) on the designated left area for right-handed participants and the right for left-handed participants. Lift the glass jug by the handle using a lateral grip and show how to pour the water into the glass jar. Reset the task for the participant.

"Start the timer and whilst ensuring as little spillage as possible, pour the water from the jug into the jar as demonstrated and as quickly as possible. Replace the jug on the board and then stop the timer."

Carton Pouring Empty the glass jar from the previous task and replace the jar in the same position on the form board. Fill the carton with 200ml of water (measured out in the glass jug). Place the carton in the designated area on the form board with the spout of the carton pointing toward to glass jar (according to the handedness defined for the previous task). Pick up the carton using a power grip and show how to pour the water into the glass jar. Reset the task for the participant.

"Start the timer and whilst ensuring as little spillage as possible, pour the water from the carton into the jar as demonstrated and as quickly as possible. Replace the carton on the board and then stop the timer."

Lifting a Heavy Object Fill the glass jar with water to the top of the label and tighten the lid. Place the jar in the designated area on the form board, on the left side of the board for right-handed participants and the right side of the board for left-handed participants. Place the empty carton lengthways along the middle of the form board (without obstructing the timer unit) to create a barrier. Lift the jar over the carton using a power grip and place on the opposite side of the form board in the designated area. Reset the task for the participant.

"Start the timer, move the jar over the carton to the other side of the board as demonstrated and as quickly as possible. Then stop the timer."

[THE WATER CAN NOW BE DISPOSED OF AND WILL FORM NO FURTHER PART IN THE ASSESSMENT.]



Lifting a Light Object Place the empty tin (with the plastic lid on) in the same position on the board as defined for the jar in the previous task and keep the carton in the same position on the form board creating a barrier. Lift the tin over the carton using the power grip and place on the opposite side of the form board in the designated area. Reset the task for the participant.

"Start the timer, move the tin over the carton to the other side of the board as demonstrated and as quickly as possible. Then stop the timer."

[PLACE THE SHAP CASE ON THE TABLE DIRECTLY INFRONT OF THE PARTICIPANT AND APPROXIMATELY 8cm FROM THE FRONT EDGE OF THE TABLE. PUT THE FOAM INSIDE THE CASE AND KEEP THE LID OF THE CASE OPEN. PLACE THE TIMER UNIT IN THE CASE ON THE FOAM INSERT IN THE APPROPRIATE POSITION. THE FINAL 5 TASKS WILL INVOLVE THE USE OF THE CASE.]

Lifting a Tray Place the form board ADL side up, on the table to the left of the case for right-handed participants and to the right for left-handed participants. Place the form board slightly overhanging the edge of the table with the long edge facing forwards. The timer unit should remain in the case. Both hands should be used to pick up the form board using a lateral or extension grip. Assuming a right-handed participant: lift the form board from the left side, over the case whilst remaining seated and place it on the table to the right side of the case. Reset the task for the participant.

"Start the timer, move the tray from the left/right to the right/left hand side of the case as demonstrated and as quickly as possible. Then stop the timer."

Rotate Key Return the form board to the case ADL side up, placing in on top of the foam insert (the timer unit should fit neatly in its original position on the board without moving it from the foam). Turn the key to the white mark using the lateral grip.

"Start the timer, rotate the key as demonstrated and as quickly as possible to the white mark and release the key (at which time the key will spring back to its start position) and then stop the timer."

Open/Close Zip Ensure the zip is closed. Open and close the zip using a lateral or tip grip.

"Start the timer, open and close the zip as demonstrated and as quickly as possible and then stop the timer."



Rotate a Screw Place the screwdriver in the designated area on the form board on the right side for right-handed participants and the left for left-handed participants. The arrow unit is mounted on a clip, which should be attached to the front of the case (again, the right side for right-handed participants and the left for left-handed participants). Use the area directly in front of the screwdriver between the lock and the handle on the case. Ensure the arrow is pointing upward. Use two hands to guide the screwdriver to the screw and rotate it 90° clockwise to the mark on the clip using one hand only. Hold the screwdriver in a power grip. You may hold the clip on the top of the case to keep it stable with your other hand. Reset the task for the participant.

"Start the timer and use the screwdriver to rotate the screw a quarter turn clockwise to, or beyond the white mark as demonstrated and as quickly as possible. Once completed, the screwdriver should be replaced on the platform and the timer stopped. Two hands may be used to guide the screwdriver to the screw, but only the appropriate hand should be used for turning the screw. Your other hand can be used to steady the top of the arrow unit."

Door Handle Rotate the door handle using a power grip until it is fully open, then release the handle.

"Start the timer, rotate the door handle until it is fully open and then release it as demonstrated and as quickly as possible. Then stop the timer."

SHAP Score Forms



Participant ID

Assessor			
Your SHAP Times Abstract Objects Light Sphere:	100.00	Heavy Sphere:	1

100.00 Light Tripod: Heavy Tripod: 4.56 3.72 Light Power: Heavy Power: 4.53 4.84 Light Lateral: Heavy Lateral: 7.13 7.35 Heavy Tip: 7.28 Light Tip: 6.63 Light Extension: 5.25 Heavy Extension: 6.63

Activities of Daily Living (ADLs)

Accidition of Dully =	·····9 (/· <i>-</i> - <i>)</i>		
Pick Up Coins:	100.00	Lifting a Heavy Object:	100.00
Button Board:	35.75	Lifting a Light Object:	100.00
Simulated Food Cutting:	100.00	Lifting a Tray:	8.09
Page Turning:	100.00	Rotate Key:	8.13
Jar Lid:	100.00	Open/Close Zip:	58.00
Glass Jug Pouring:	34.22	Rotate A Screw:	100.00
Carton Pouring:	16.51	Door Handle:	4.72

Your SHAP Scores

Functionality Profile

Spherical:	18	Tripod:	33
Power:	19	Lateral:	31
Tip:	23	Extension:	37

Index of Function Score

Index of Function: 33



Assessor	
Your SHAP Times	

Abstract Objects

Light Sphere:	100.00	Heavy Sphere:	100.00
Light Tripod:	8.72	Heavy Tripod:	9.44
Light Power:	5.15	Heavy Power:	5.03
Light Lateral:	5.38	Heavy Lateral:	5.81
Light Tip:	3.57	Heavy Tip:	2.47
Light Extension:	2.59	Heavy Extension:	3.97

Activities of Daily Living (ADLs)

iving (ADES)		
100.00	Lifting a Heavy Object:	49.85
30.38	Lifting a Light Object:	100.00
100.00	Lifting a Tray:	4.37
11.07	Rotate Key:	6.84
100.00	Open/Close Zip:	100.00
23.03	Rotate A Screw:	100.00
27.82	Door Handle:	2.93
	100.00 30.38 100.00 11.07 100.00 23.03	Lifting a Heavy Object: 30.38 Lifting a Light Object: 100.00 Lifting a Tray: 11.07 Rotate Key: 100.00 Open/Close Zip: 23.03 Rotate A Screw:

Your SHAP Scores Functionality Profile

Spherical:	13	Tripod:	22
Power:	19	Lateral:	48
Tip:	29	Extension:	57

Index of Function Score



Participant ID	
Assessor	

Abstract Objects

Light Sphere:	100.00	Heavy Sphere:	100.00
Light Tripod:	33.28	Heavy Tripod:	5.19
Light Power:	14.00	Heavy Power:	5.47
Light Lateral:	3.50	Heavy Lateral:	3.68
Light Tip:	11.63	Heavy Tip:	21.84
Light Extension:	6.31	Heavy Extension:	4.59

Activities of Daily Living (ADLs)

Activities of Bully E			
Pick Up Coins:	100.00	Lifting a Heavy Object:	100.00
Button Board:	25.75	Lifting a Light Object:	100.00
Simulated Food Cutting:	100.00	Lifting a Tray:	4.16
Page Turning:	47.20	Rotate Key:	88.43
Jar Lid:	100.00	Open/Close Zip:	100.00
Glass Jug Pouring:	21.71	Rotate A Screw:	100.00
Carton Pouring:	38.47	Door Handle:	3.03

Your SHAP Scores

Functionality Profile

Spherical:	6	Tripod:	20
Power:	11	Lateral:	42
Tip:	6	Extension:	39

Index of Function Score



Participant ID	
Assessor	

Abstract Objects

Light Sphere:	100.00	Heavy Sphere:	100.00
Light Tripod:	8.16	Heavy Tripod:	7.25
Light Power:	5.50	Heavy Power:	6.72
Light Lateral:	9.63	Heavy Lateral:	26.84
Light Tip:	9.22	Heavy Tip:	6.96
Light Extension:	7.47	Heavy Extension:	8.32

Activities of Daily Living (ADLs)

/ total training or During =			
Pick Up Coins:	100.00	Lifting a Heavy Object:	100.00
Button Board:	45.62	Lifting a Light Object:	100.00
Simulated Food Cutting:	100.00	Lifting a Tray:	2.96
Page Turning:	85.19	Rotate Key:	100.00
Jar Lid:	46.44	Open/Close Zip:	100.00
Glass Jug Pouring:	45.25	Rotate A Screw:	100.00
Carton Pouring:	47.50	Door Handle:	6.37

Your SHAP Scores

Functionality Profile

Spherical:	0	Tripod:	22
Power:	17	Lateral:	11
Tip:	12	Extension:	34

Index of Function Score



Assessor	
Your SHAP Times Abstract Objects	

Light Sphere: 100.00 Heavy Sphere: 100.00 Light Tripod: Heavy Tripod: 6.53 21.41 Light Power: Heavy Power: 7.84 80.20 Light Lateral: Heavy Lateral: 8.62 8.53 Heavy Tip: Light Tip: 5.85 6.47 Light Extension: 4.97 Heavy Extension: 11.31

Activities of Daily Living (ADLs)

rectification of party =	(/ 12 - 2 /		
Pick Up Coins:	100.00	Lifting a Heavy Object:	100.00
Button Board:	47.78	Lifting a Light Object:	100.00
Simulated Food Cutting:	100.00	Lifting a Tray:	7.22
Page Turning:	10.25	Rotate Key:	100.00
Jar Lid:	12.47	Open/Close Zip:	100.00
Glass Jug Pouring:	100.00	Rotate A Screw:	100.00
Carton Pouring:	38.59	Door Handle:	4.63

Your SHAP Scores

Functionality Profile

Spherical:	13	Tripod:	12
Power:	9	Lateral:	19
Tip:	15	Extension:	45

Index of Function Score



Participant ID	
Assessor	

Abstract Objects

Light Sphere:	100.00	Heavy Sphere:	100.00
Light Tripod:	6.13	Heavy Tripod:	5.41
Light Power:	3.96	Heavy Power:	4.75
Light Lateral:	8.31	Heavy Lateral:	13.75
Light Tip:	7.40	Heavy Tip:	5.56
Light Extension:	8.94	Heavy Extension:	6.04

Activities of Daily Living (ADLs)

rectivities of Parity =	(/ 12 - 2 /		
Pick Up Coins:	100.00	Lifting a Heavy Object:	100.00
Button Board:	88.13	Lifting a Light Object:	100.00
Simulated Food Cutting:	100.00	Lifting a Tray:	3.22
Page Turning:	5.84	Rotate Key:	15.06
Jar Lid:	9.38	Open/Close Zip:	100.00
Glass Jug Pouring:	15.00	Rotate A Screw:	100.00
Carton Pouring:	15.50	Door Handle:	2.75

Your SHAP Scores

Functionality Profile

Spherical:	29	Tripod:	23
Power:	19	Lateral:	32
Tip:	13	Extension:	62

Index of Function Score



Participant ID	
Assessor	

Abstract Objects

Light Sphere:	100.00	Heavy Sphere:	100.00
Light Tripod:	18.91	Heavy Tripod:	5.75
Light Power:	5.40	Heavy Power:	5.16
Light Lateral:	8.56	Heavy Lateral:	7.38
Light Tip:	4.90	Heavy Tip:	12.41
Light Extension:	6.10	Heavy Extension:	14.04

Activities of Daily Living (ADLs)

Activities of Bully E			
Pick Up Coins:	100.00	Lifting a Heavy Object:	100.00
Button Board:	38.19	Lifting a Light Object:	100.00
Simulated Food Cutting:	100.00	Lifting a Tray:	4.25
Page Turning:	30.22	Rotate Key:	27.88
Jar Lid:	9.03	Open/Close Zip:	100.00
Glass Jug Pouring:	21.75	Rotate A Screw:	100.00
Carton Pouring:	20.12	Door Handle:	2.65

Your SHAP Scores

Functionality Profile

Spherical:	27	Tripod:	17
Power:	18	Lateral:	36
Tip:	12	Extension:	25

Index of Function Score



Assessor	
Your SHAP Times Abstract Objects	

Light Sphere: 100.00 Heavy Sphere: 100.00 Light Tripod: Heavy Tripod: 7.22 7.34 Light Power: Heavy Power: 10.43 15.81 Light Lateral: 7.22 Heavy Lateral: 18.13 Heavy Tip: Light Tip: 6.56 7.38 Light Extension: 8.91 Heavy Extension: 6.94

Activities of Daily Living (ADLs)

/ (
Pick Up Coins:	100.00	Lifting a Heavy Object:	100.00
Button Board:	35.72	Lifting a Light Object:	100.00
Simulated Food Cutting:	100.00	Lifting a Tray:	2.38
Page Turning:	8.22	Rotate Key:	45.94
Jar Lid:	67.50	Open/Close Zip:	100.00
Glass Jug Pouring:	44.62	Rotate A Screw:	100.00
Carton Pouring:	19.81	Door Handle:	6.59

Your SHAP Scores

Functionality Profile

Spherical:	17	Tripod:	27
Power:	6	Lateral:	13
Tip:	16	Extension:	55

Index of Function Score



Assessor	•••••
Your SHAP Times Abstract Objects	

Light Sphere:	100.00	Heavy Sphere:	100.00
Light Tripod:	7.34	Heavy Tripod:	6.68
Light Power:	7.81	Heavy Power:	8.31
Light Lateral:	6.34	Heavy Lateral:	9.06
Light Tip:	6.62	Heavy Tip:	7.50
Light Extension:	5.75	Heavy Extension:	5.68

Activities of Daily Living (ADLs)

Activities of Bully E	iving (ADES)		
Pick Up Coins:	100.00	Lifting a Heavy Object:	100.00
Button Board:	44.50	Lifting a Light Object:	100.00
Simulated Food Cutting:	100.00	Lifting a Tray:	7.29
Page Turning:	8.06	Rotate Key:	19.12
Jar Lid:	14.47	Open/Close Zip:	100.00
Glass Jug Pouring:	18.03	Rotate A Screw:	100.00
Carton Pouring:	21.28	Door Handle:	4.15

Your SHAP Scores

Functionality Profile

Spherical:	21	Tripod:	24
Power:	15	Lateral:	39
Tip:	15	Extension:	63

Index of Function Score



Assessor				
Your SHAP Times Abstract Objects	<u>5</u>			
Light Sphere:	3.63	Heavy Sphere:	100.00	
Light Tripod:	4.68	Heavy Tripod:	3.59	
Light Power:	5.69	Heavy Power:	4.00	
Light Lateral:	5.78	Heavy Lateral:	7.54	
Light Tip:	6.47	Heavy Tip:	8.81	
Light Extension:	3.87	Heavy Extension:	5.21	
Activities of Daily	Living (AD	Ls)		
Pick Up Coins:	100.00	Lifting a Heavy Object:	100.00	
Button Board:	29.75	Lifting a Light Object:	100.00	

Lifting a Tray:

Open/Close Zip:

Rotate A Screw:

Door Handle:

Rotate Key:

Your SHAP Scores

Page Turning:

Glass Jug Pouring:

Carton Pouring:

Jar Lid:

Functionality Profile

Spherical:	42	Tripod:	35
Power:	24	Lateral:	65
Tip:	30	Extension:	69

7.75

13.43

12.78

14.37

Index of Function Score

Simulated Food Cutting: 100.00

Index of Function: 51

2.38

4.00

13.09

19.12

2.78



BBT Protocol

Method of Use

Equipment Required

- Stopwatch
- Wooden box dimensioned in 53.7 cm x 25.4 cm x 8.5 cm
- Partition (should be placed at the middle of the box, dividing it in two containers of 25.4 cm each)
- 150 wooden cubes (2.5 cm in size)

Set-Up

- A test box with 150 blocks and a partition in the middle is placed lengthwise along the edge of a standard-height table
- · The patient should be seated on a standard height chair facing the box
- 150 blocks should be in the compartment of the test box on the side of the patient's dominant hand
- The examiner should face the patient so she or he could view the blocks being transported

Description

The patient is allowed a 15-second trial period prior to testing

- Individuals are seated at a table, facing a rectangular box that is divided into two square compartments of equal dimension by means of a partition.
- One hundred and fifty, 2.5 cm, coloured, wooden cubes or blocks are placed in one compartment or the other.
- The individual is instructed to move as many blocks as possible, one at a time, from one compartment to the other for a period of 60 seconds.
- Standardised dimensions for the test materials and procedures for test administration and scoring have been provided by Mathiowetz et al, 1985 [103].
- To administer the test, the examiner is seated opposite the individual in order to observe test performance.
- The BBT is scored by counting the number of blocks carried over the partition from one compartment to the other during the one-minute trial period.
- Patient's hand must cross over the partition in order for a point to be given, and blocks that drop or bounce out of the second compartment onto the floor are still rewarded with a point.

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- Multiple blocks carried over at the same time count as a single point.
- · Higher scores on the test indicate better gross manual dexterity.

Scoring

Clients are scored based on the number of blocks transferred from one compartment to the other compartment in 60 seconds [103]. Score each hand separately. Higher scores are indicative of better manual dexterity. During the performance of the BBT, the evaluator should be aware of whether the client's fingertips are crossing the partition. Blocks should be counted only when this condition is respected. Furthermore, if two blocks are transferred at once, only one block will be counted. Blocks that fall outside the box, after trespassing the partition, even if they don't make it to the other compartment, should be counted.

Patient Instructions

Detailed patient instructions as outlined by Mathiowetz et al.

"I want to see how quickly you can pick up one block at a time with your right (or left) hand [point to the hand]. Carry it to the other side of the box and drop it. Make sure your fingertips cross the partition. Watch me while I show you how."

Transport three cubes over the partition in the same direction you want the patient to move them. After a demonstration say the following:

"If you pick up two blocks at a time, they will count as one. If you drop one on the floor or table after you have carried it across, it will still be counted, so do not waste time picking it up. If you toss the blocks without your fingertips crossing the partition, they will not be counted. Before you start, you will have a chance to practice for 15 seconds. Do you have any guestions?"

"Place your hands on the sides of the box. When it is time to start, I will say ready and then go."

Trial period: Start the stop watch at the word go. When 15 seconds has passed, say "stop." If mistakes are made during the practice period, correct them before the actual testing begins.

On completion of the practice period, transport the cubes to the original compartment.

Continued with the following directions:

"This will be the actual test. The instructions are the same. Work as quickly as you can. Ready." [Wait 3 seconds]

"Go."

"Stop." [After 1 minute, count the blocks and record as described above]

"Now you are to do the same thing with your left (or right) hand. First you can practice. Put your hands on the sides of the box as before. Pick up one block at a time with your hand, and drop it on the other side of the box."

"Ready." [Wait 3 seconds] "Go."

"Stop." [After 15 seconds]

Return the transported blocks to the compartment as described above.

"This will be the actual test. The instructions are the same. Work as quickly as you can."

"Ready." [Wait 3 seconds]

"Go."

"Stop." [After 1 minute, count the blocks and record as described above]