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openBrace

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Abstract

In the human body, the radial nerve runs along the underside of the arm and is responsible for the control and movement of the triceps, and extension of the wrist and fingers. The radial nerve is the most commonly injured nerve in the upper extremity following humeral fractures. Injury to the radial nerve often leads to radial neuropathy, also known as radial nerve palsy, with the loss of the ability to extend the wrist, fingers, and thumb. Orthotics exist as viable treatment options for patients with radial nerve palsy, and aim to restore functionality of the wrist and hand.

Pro-ability design, multidisciplinarity and digital fabrication are nowadays the essential ingredients to effectively improve the lives of many people and meet the demand for medical devices, objects and prostheses that fit specific problems, without resorting to mass production.

The purpose of this thesis is to design, prototype and validate a brace that helps recover wrist and finger extension for people with permanent radial nerve palsy. Thanks to the availability of a super-user (a designer with a disability) and a physical therapist, it will be possible to define precise requirements and functionalities of the brace, and then validate the prototype and implement its features.

The thesis will require probing the actual implications of open-access design and new manufacturing (3D printing and other rapid manufacturing technologies) in the field of braces, prosthetics, and medical devices. Exploration of case studies will allow for the derivation of an overview of the opportunities that design technologies and skills can offer today to restore abilities to specific users.

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Introduction

Loss of radial nerve function is clinically referred to as radial nerve dysfunction or radial nerve palsy (RNP). Radial nerve palsy is a problem associated with the radial nerve due to injury consisting of acute trauma to the radial nerve. This type of injury has both sensory and motor consequences: it interferes with nerve function of the posterior forearm, lateral three digits, and dorsal surface of the lateral side of the palm. It's motor consequences consist of nerve interruption of the muscles responsible for extension at the elbow, wrist and fingers, as well as supination of the forearm. One out of ten patients suffering from radial nerve dysfunction is due to fracture of the humerus. These injuries can be divided into high, complete radial nerve injuries or low, posterior radial nerve injury. Injury is usually identified through physical examination, but also electrodiagnostic and radiological methods can be used to determine exact location and severity. The method and level of treatment will differ from case to case, but most are usually non-operative and recover fully. Radial nerve injuries can vary in their severity, from minor contusions of the nerve that result in temporary paralysis, to the severing of the nerve itself, sometimes leading to permanent paralysis.

Causes

Injuries to the radial nerve can occur anywhere along its anatomical route, but due to its proximity to the humeral shaft and its long and tortuous course, the radial nerve is the most frequently injured nerve in the upper limb (F. 1). It is particularly vulnerable to fractures of the humeral shaft and around the elbow. Damage can be caused by pressure, stretching, or cutting of the nerve fibers. These tissues can prevent action potentials from continuing up or down axons within the nerve, interrupting signals going to and from the brain. Due to this interrupted signal, the patient can experience loss of feeling and/or motor control. Through research and examination of patient case studies, it is observed that the etiology of radial nerve palsy can be quite varied and unexpecting.

1. Humeral Fractures

The radial nerve is most commonly injured when associated with humeral fractures. The injury can be caused by the fracture itself, when the displaced humeral bone comes in contact with the nerve itself, from the manipulation of bone fragments during recovery/surgery, or through entrapment from the callus healing process.

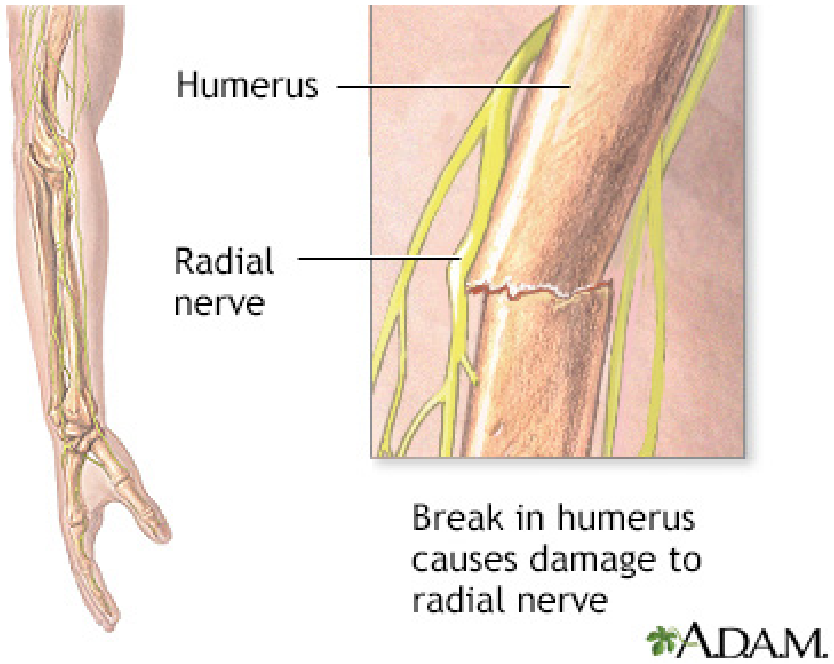


Figure 1 - Diagram of injury to radial nerve from humeral fracture..

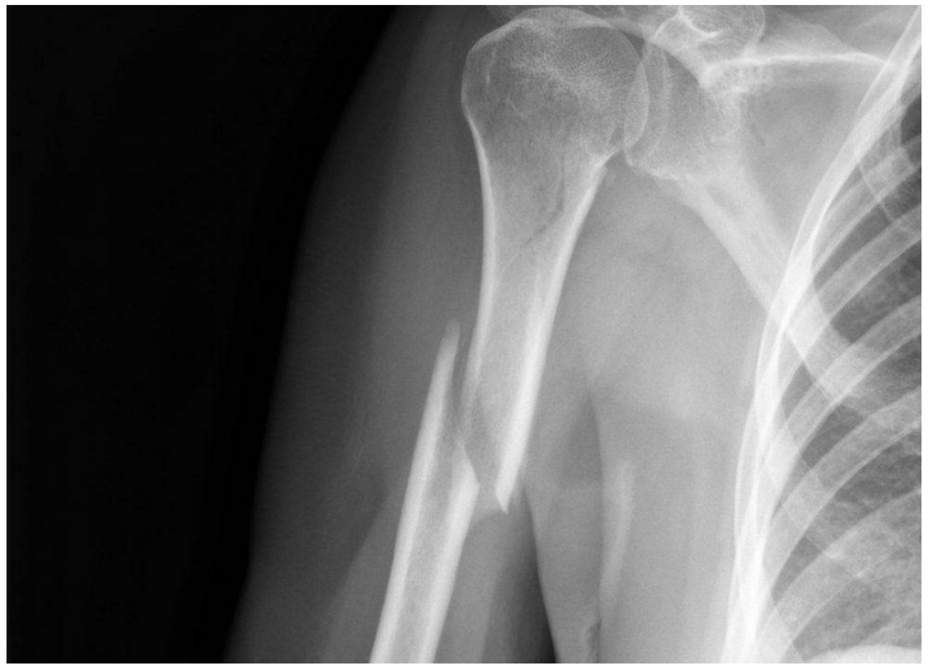


Figure 2 - X-ray of humeral fracture..

2. Gunshot
Gunshot injuries of either low or high velocity can lead to significant radial nerve damage. This type of injury is not uncommon, and is dependent on whether the projectile directly transects the nerve, or is damaged by the shock-wave effect from the projectile.

3. Sharp Objects
Sharp objects like knives or glass can be especially risky to the radial nerve. They can directly transect the nerve by means of cutting or puncture which can lead to disability. However, it is the superficial branches of the radial nerve which are most at risk to this type of trauma, and usually results in no permanent significant damage.

4. Surgical Injury
Radial nerve injuries can be an unintentional but common complication from upper limb surgery. Any part of the radial nerve and its branches can be affected by this process. The nerve can be damaged from a variety of surgical tools and movements including surgical blades, wires, during fracture manipulation, plates, screws, or even improper positioning on the surgical table.

5. Compression Injury
The most well known compression injury to the radial nerve is known as "Saturday Night Palsy" when compression of the radial nerve at the spiral groove occurs after prolonged pressure (Figure 3). The namesake comes from when an individual falls asleep with their arm in an awkward position that puts pressure directly on the nerve (Figure 4). Another common cause is from using crutches improperly for an extended period of time.

The extent and severity of the outcome from any of the listed etiologies can vary on a case by case basis. The mildest level of injury can take the form of a neuropraxia. This occurs as a compression or contusion to the radial nerve leading to temporary interruption of the electrical signals that pass through the radial nerve. In this case the radial nerve remains intact and full recovery is highly expected. A more severe form of nerve injury is known as axonotmesis, with damage to the nerve fibers themselves. This inhibits their ability to send and receive signals from the nervous system. The most severe form of damage to the radial nerve is a neurotmesis, where there is complete anatomical disruption to nerve continuity (severed). In such cases there is no possibility of spontaneous nerve recovery, and surgery is always necessary. Nerve recovery is dependent on a variety of factors including age, sex, time of repair, materials used, and the size of the defect and duration of follow-up.

Figure 3 - Nurse showing how an object such as a chair can create pressure on the radial nerve.

Figure 4 - "Saturday Night Palsy" earned it's name from patients falling asleep on their arm, usually after consuming alcohol.

1. RESEARCH

1.1 Radial Nerve Palsy

Symptoms

Radial nerve palsy has multiple sensory and motor function deficits, and can have a drastic negative effect on the patient's day-to-day life. Patients with radial nerve palsy will notice these symptoms where the radial nerve is responsible for. This includes numbness from the triceps down to the fingers, difficulty or complete inability to straighten the wrist and fingers, difficulty pinching or grasping and weakness and inability to control muscles from the triceps down to the fingers. Injuries to the radial nerve at this level typically do not affect triceps function or elbow extension, but do include the loss of wrist extension, thumb extension and abduction, and finger metacarpophalangeal joint extension. Wrist extension is considered necessary for proper flexor tendon tensioning, and as a result grasp is greatly reduced and represents a significant functional deficit after high radial nerve paralysis. The paralysis of wrist and finger extensors prevents the patient from being able to straighten the wrist and hand. This is called the 'wrist drop deformity' due to the physical appearance of the wrist falling limp.

Treatment

1. Surgical

Treatment for radial nerve palsy can be operative, non-operative or a combination of both. Radial nerve palsy related to humeral fractures occurs between 2% and 17% of patients. In cases where it is a closed fracture, treatment is usually non-operative and up to 95% of patients fully recover within 3 to 68 months. However when there is a high energy open fracture, and damage to the soft tissue and nerve is apparent, then early operative treatment is highly recommended. Surgical treatment is also explored after there is no noticeable improvement after a period of conservative treatment. Possible surgical treatments include nerve suturing and grafting, tendon transfers, and even nerve and muscle transfers.

2. Non-Operative

Non-surgical treatment can play a major role in the recovery of patients with radial palsy, especially those with a permanent diagnosis. Compression injuries can be initially treated with rest, activity modification, anti-inflammatory drugs, vitamin therapy and a period of immobilization in a functional splint. One of the most important aspects of treatment is to maintain a full passive range of motion of the affected joints by way of physical therapy exercise programs and dynamic splinting.

Figure 5 - Wrist drop as a result of damage to radial nerve.

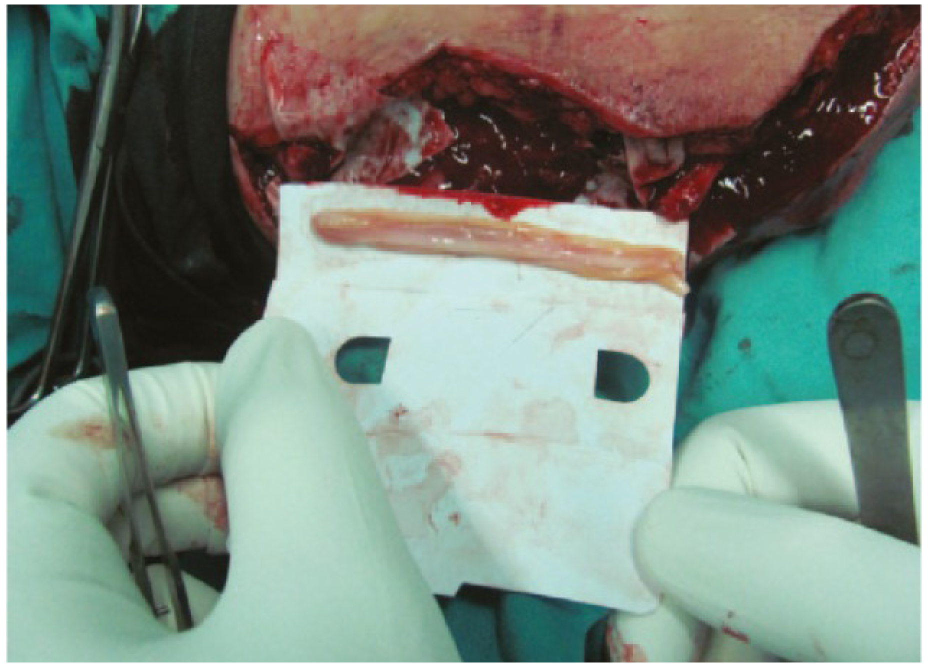


Figure 6 - Process of nerve grafting to repair radial nerve.

Figure 7 - Physical therapy of hand affected by radial nerve palsy.

Introduction
The radial nerve is the largest nerve in the upper limb of the body, and the largest terminal branch of the brachial plexus. It's course runs along the back of the arm all the way from the armpit to the hand. The radial nerve is part of the peripheral nervous system, which is responsible for sending signals from the brain to the arms and fingers, lower limbs, skin and internal organs. Subsequently it is responsible for the motor and sensory function of the upper and lower arm, forearm, wrist, and fingers. Because of its size and proximity to the humerus, the radial nerve can be particularly vulnerable to injury and compression, which can disrupt it's motor and sensory functions to the upper limb.

Function
The motor function of the radial nerve is the innervation of the medial and lateral heads of the triceps muscles, all 12 muscles in the posterior forearm, and the extensor muscles found in the wrist and fingers. Essentially the radial nerve stimulates muscles so that one can straighten and raise their elbows, wrists, hands and fingers. Sensory function provides skin innervation to different parts of the arm, forearm, and fingers. The radial nerve allows us to perceive touch, pain and temperature sensations to the back of the upper arm, forearm, and back of the hand and fingers. Disruption of the radial nerve can have motor consequences such as an inability to extend the arm, wrist, and fingers and lead to abnormal sensations throughout its sensory distribution.

Below is a list of all specific motor and sensory functions that the radial nerve is responsible for:

1. Motor

Radial
Triceps (all 3 heads)
Anconeus
Brachialis (lateral third)
Extensor carpi radialis longus

Deep Branch
Supinator
Extensor carpi radialis brevis
Extensor digitorum
Extensor carpi ulnaris
Extensor pollicis longus
Extensor pollicis brevis
Extensor indicis
Abductor pollicis longus

2. Sensory

Posterior Cutaneous Nerve
Posterior surface of the proximal third of the arm

Lower Lateral Cutaneous Nerve
Lower lateral part of the arm
Small area of skin on the forearm

Superficial Branch
Dorsum of the wrist
Lateral dorsal surface of the hand
Dorsum of the thumb
Dorsum of the index and middle fingers
Dorsum of the lateral aspect of ring finger

As we can see, the radial nerve is responsible for a vast majority of movement and sensitivity in the upper limb, especially with the hand and wrist. The radial nerve is essential for our dexterity in a variety of everyday actions and activities, and the absence of such ability would be greatly disabling.

Structure
The radial nerve is the largest of the terminal nerve branches that make up the brachial plexus. The brachial plexus is a complex bundle of nerves that control movements and sensations in one's shoulders, arms, hands and fingers. This group of nerves originates from the lower cervical area in the neck and upper chest (thoracic) portion of the spine and travels underneath the collarbone (clavicle), and then through the armpit (axilla).

The radial nerve itself starts at the lower armpit. It's origins trace back to several nerve routes (where the nerve connects to the central nervous system) that come from the C5 to C8 cervical vertebrae (the lowest spinal bones in the neck) and the T1 thoracic vertebra (the uppermost back/chest spinal bone). From these vertebrae, the radial nerve wraps along the long upper arm bone from shoulder to elbow called the humerus. From there it passes through what is called the radial tunnel, a narrow opening between the bone and muscle at the elbow. From here it branches into smaller nerves that travel down the outside of the forearm to the wrist, hand and fingers.

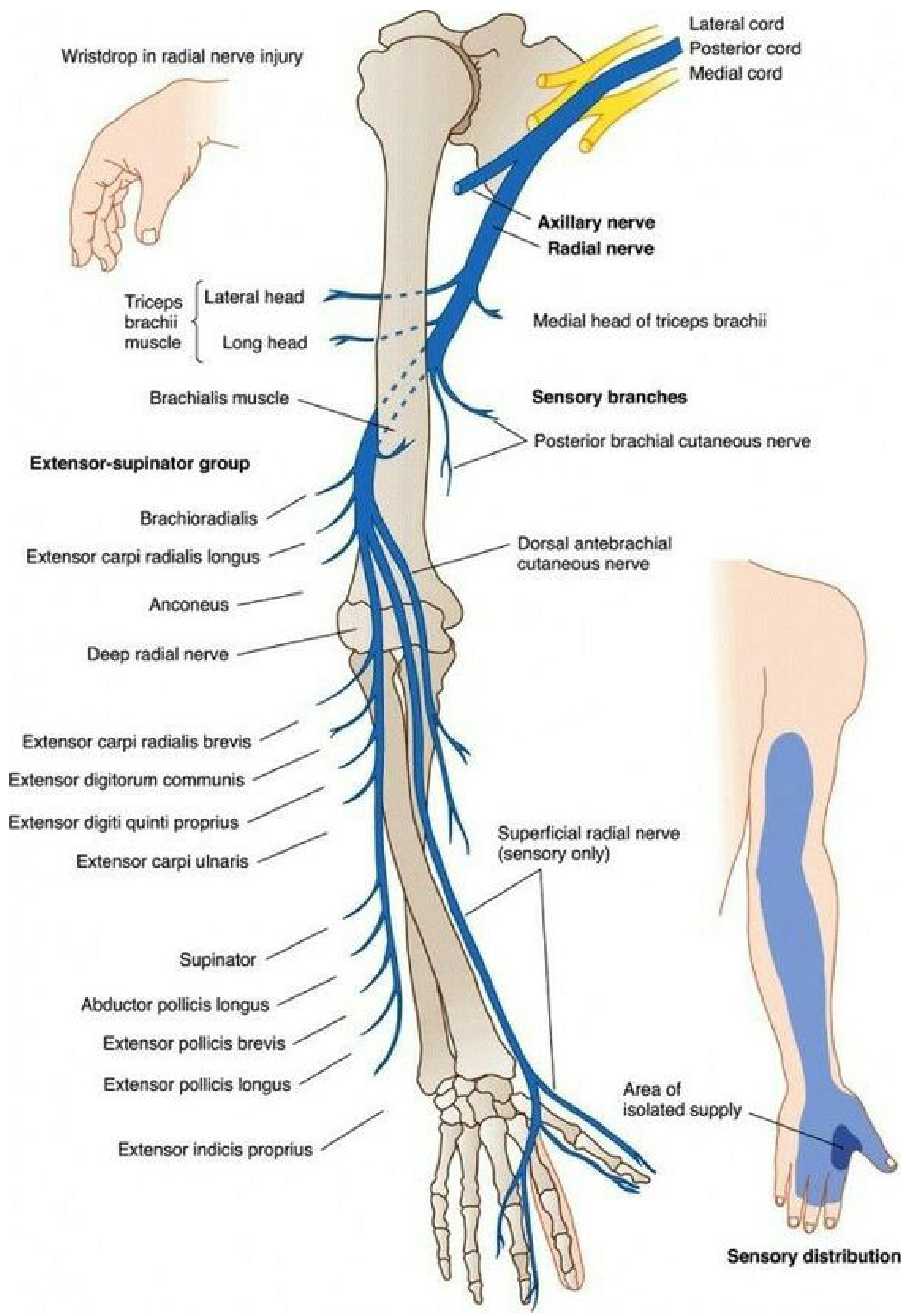


Figure 8 - Illustration showing the anatomical route of the radial nerve and its various branches.

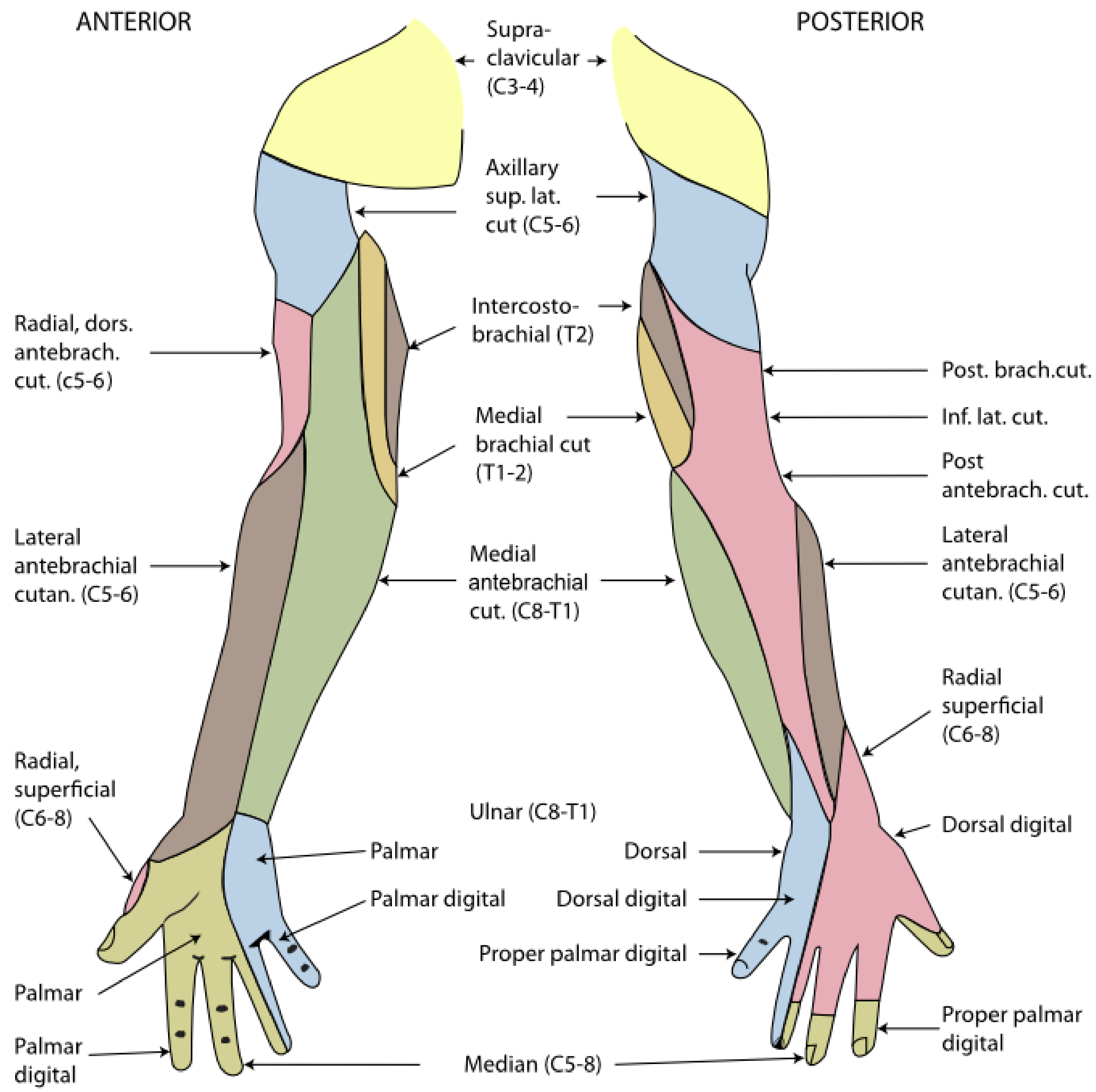


Figure 9 - Illustration showing the areas of the upper extremity that are affected by the 3 main nerve groups.

The radial nerve consists of 2 different branches along its anatomical route. The first branch called the superficial branch, provides sensory information and travels from just below the elbow to the wrist and into the hand and fingers. In the forearm it also runs along the radial artery which supplies blood to the same appendages. The other branch is called the deep branch, which provides functionality to the forearm, wrist, hand and fingers (Fig. 11). This nerve branch terminates at the wrist.

Injury

The radial nerve is the most commonly injured nerve of the arm. Injuries can occur anywhere along its anatomical route, and is especially vulnerable and most frequently injured due to humeral fractures. This is due to its closeness to the humeral shaft, where the nerve runs through a groove in the humerus (Fig. 10). However injuries can also occur from compression or sustained pressure to the nerve along its route. Other causes of injury can include a dislocated shoulder, infections, overuse, complications from surgeries, trauma, tumors or cysts. Injury of the radial nerve can lead to several different conditions with varying levels of severity. These conditions include:

1. Radial Tunnel Syndrome: Due to its natural route through the radial tunnel or groove, the muscles and ligaments surrounding the nerve can exert pressure on it over time. Also known as radial nerve entrapment.

2. Radial Nerve Palsy: Palsy is weakness or paralysis of several forearm muscles that are responsible for wrist, hand and finger extension.

3. Wartenberg Syndrome: A type of mononeuropathy that affects the radial nerve. It occurs when muscles trap or compress the nerve's superficial sensory branch in the wrist.

Some of the telltale signs of a radial nerve problem include:

- Hand or arm numbness, weakness, paralysis or pain.
- Difficulty straightening the elbows, wrists, hands or fingers
- Problems grasping, pinching or picking up objects
- Wrist drop (limp wrist that is unable to lift)

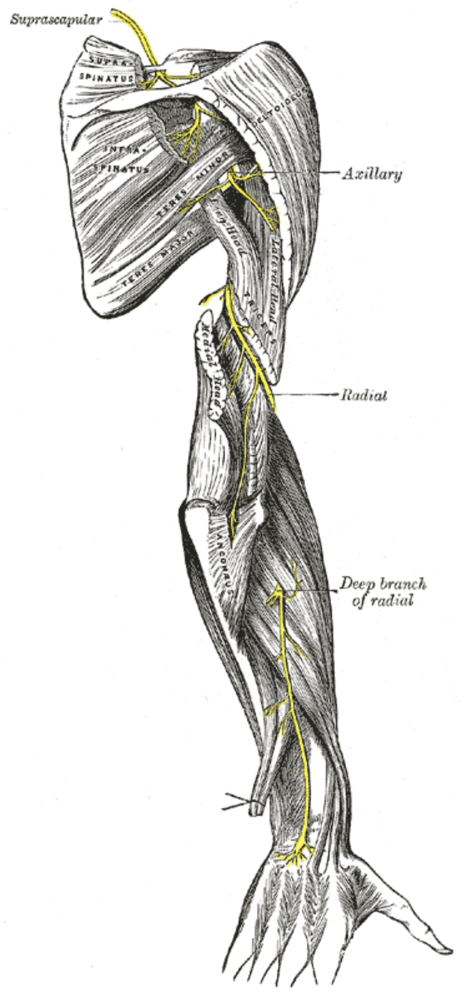


Figure 10 - Illustration showing the radial nerve transversing along the upper extremity and through the radial groove of the humerus.

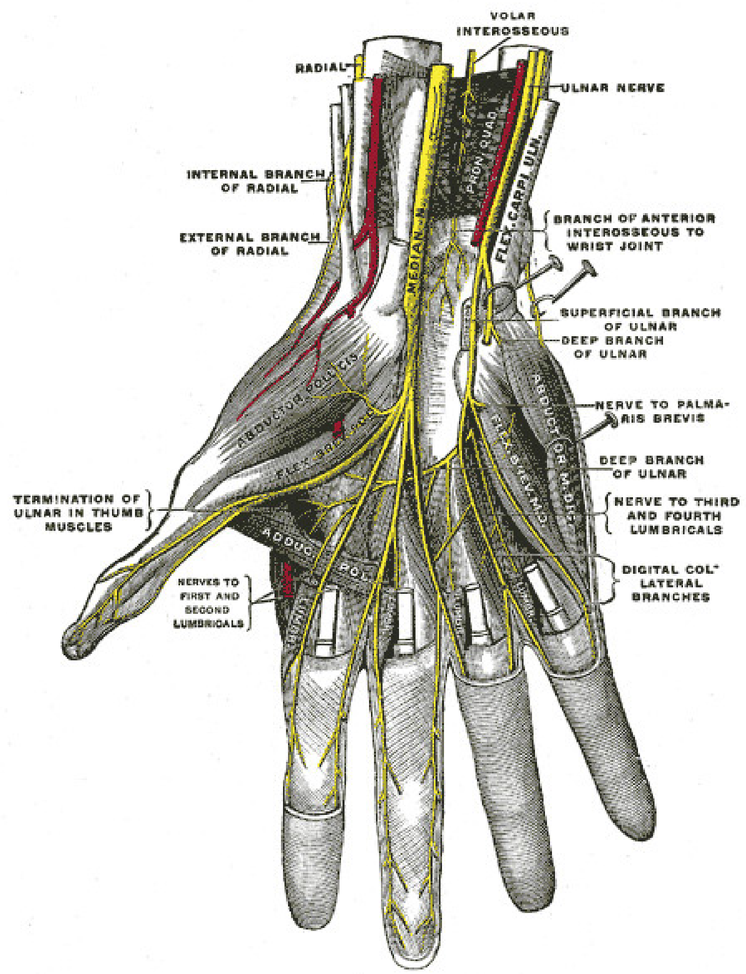


Figure 11 - Illustration showing the deep branch of the radial nerve which terminates at the wrist, as well as the nerve structure in the hand.

Introduction

The human hand is one of the most complex mechanisms in the human body, and is used to perform many functional capabilities. Its integrity and potential is essential for many daily functions. The hand is located at the end of the upper limb, composed of a combination of complex joints which enables the ability to grip, manipulate and grasp, all made possible by the usage of an opposable thumb. Multiple groups of bones, muscles, tendons, and nerves work together to perform different movements and articulations. Some biologists even believe that the presence of a hand indirectly led to the development of a larger brain of the human species. Understanding how the hand works requires an in depth look at its sensory and mechanical features.

Bony Anatomy

The hand and wrist are made up of 27 individual bones that roll, spin and slide; allowing the hand to explore and control the environment and objects. The hand is divided into 3 major groups: the carpus, metacarpus, and phalanges (Fig. 12).

The carpus controls length-tension relationships in the hand muscles that allow for fine adjustment of grip. The close proximity and number of carpal bones form a variety of different joints. The arrangement of the bones and ligaments allow for very little movement, but the joints do slide, contributing to the finer movements of the wrist. The carpal tunnel is formed in this region, where the long flexor tendons of the digits and thumb and the median nerve travel through.

The metacarpus or palm of the hand is made up of 5 different bones called the metacarpals. These bones are numbered 1-5 starting from the thumb. Each bone is formed of a quadrilateral base, shaft and rounded head. The bases of the metacarpals interact with the distal row of carpals to form joints, while the smooth round heads known as knuckles form joints with the phalanges.

The phalanges, known as fingers, consist of 14 long bones. Apart from the thumb, each finger has 3 bones while the thumb only has 2. Just like the metacarpals the phalanges are numbered 1-5 starting at the thumb. The base of each finger is curved and concave, which interacts and joints with the metacarpals, while the head is round and convex and joints with the next segment of the finger.

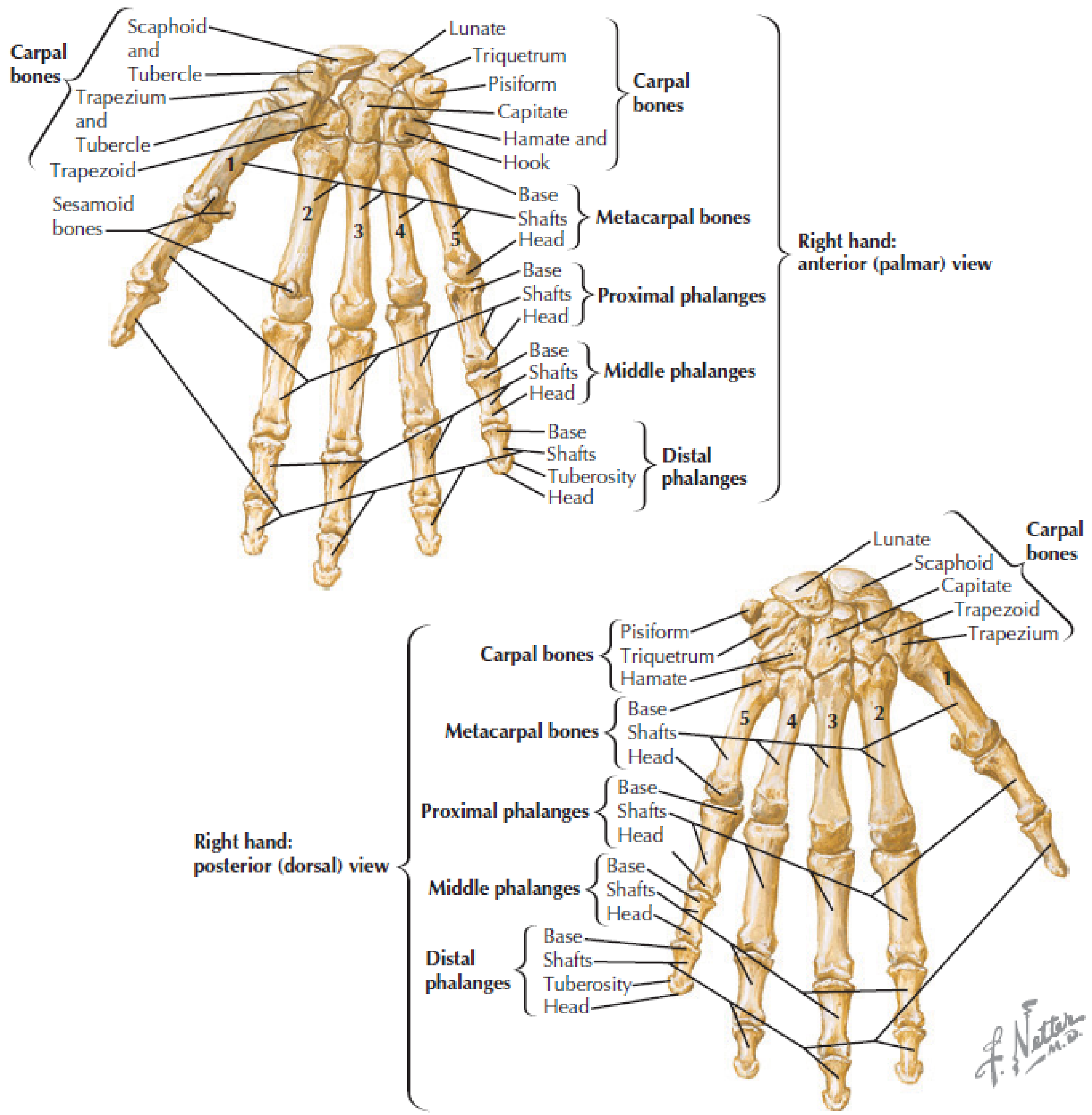


Figure 12 - Illustration showing the main bone groups of the hand, as well as the 27 individual bones that they are comprised of.

Joints of the Wrist and Hand

The wrist has 2 true degrees of freedom, with a 3rd being shared with the radioulnar joint in the forearm. Some include the radioulnar joint with the wrist because it gives it more freedom of movement. The radiocarpal and midcarpal joints allow for flexion-extension and abduction-adduction of the wrist. In the fingers there are joints between the carpals and the phalanges. The carpometacarpal joint of thumb allows for flexion-extension, abduction-adduction, circumduction, and opposition. The carpometacarpal joints of the fingers only provide flexion-extension. The metacarpophalangeal joints provide flexion, extension, abduction, adduction and circumduction to the fingers, while the interphalangeal joints at the distal (furthest) end of the fingers provide lots of flexion but minimal amounts of extension.

Ligaments of the Hand

A ligament is a fibrous tissue which connects bone to bone, holding the structures together and keeping them stable. The most important ligaments of the hand are listed below with their respective functions:

- Collateral ligaments – strong ligaments on either side of the finger and thumb joints, which prevent sideways movement of the joint.
- Volar plate – a ligament that connects the proximal phalanx to the middle phalanx on the palm side of the joint. As the joint in the finger is straightened, this ligament tightens to keep the PIP joint from bending backward.
- Radial and ulnar collateral ligaments – a pair of ligaments which bind the bones of the wrist and provide stability.
- Volar radiocarpal ligaments – a complex web of ligaments that support the palm side of the wrist.
- Dorsal radiocarpal ligaments – ligaments that support the back of the wrist
- Ulnocarpal and radioulnar ligaments – two sets of ligaments that provide the main support for the wrist.

Individual ligaments with their respective location and function are listed below:

- Posterior radiocarpal ligament – runs diagonally across the posterior aspect of the wrist and limits flexion of the wrist.
- Anterior radiocarpal ligament – runs from the anterior aspect of the distal end of the radius to the scaphoid, lunate and capitate bones of the wrist and limits extension of the wrist.
- Radial collateral ligament – runs from the styloid process of radius

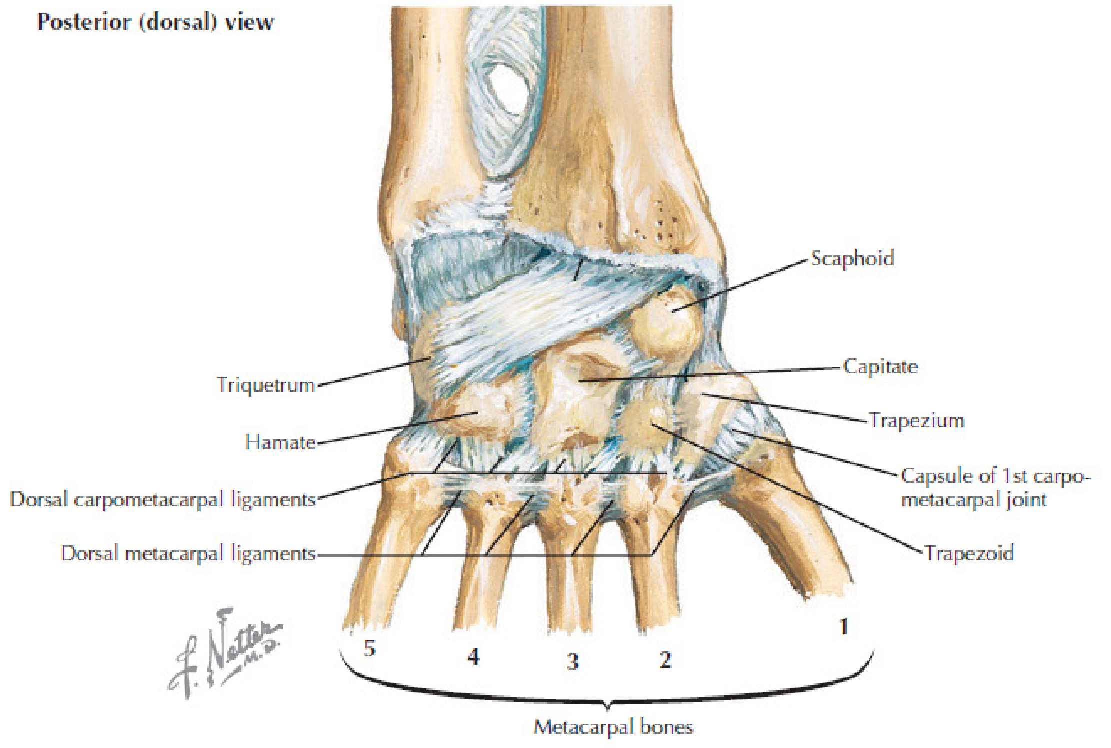


Figure 13 - Illustration showing the ligaments in grey which attach the bones of the wrist together to create joints.

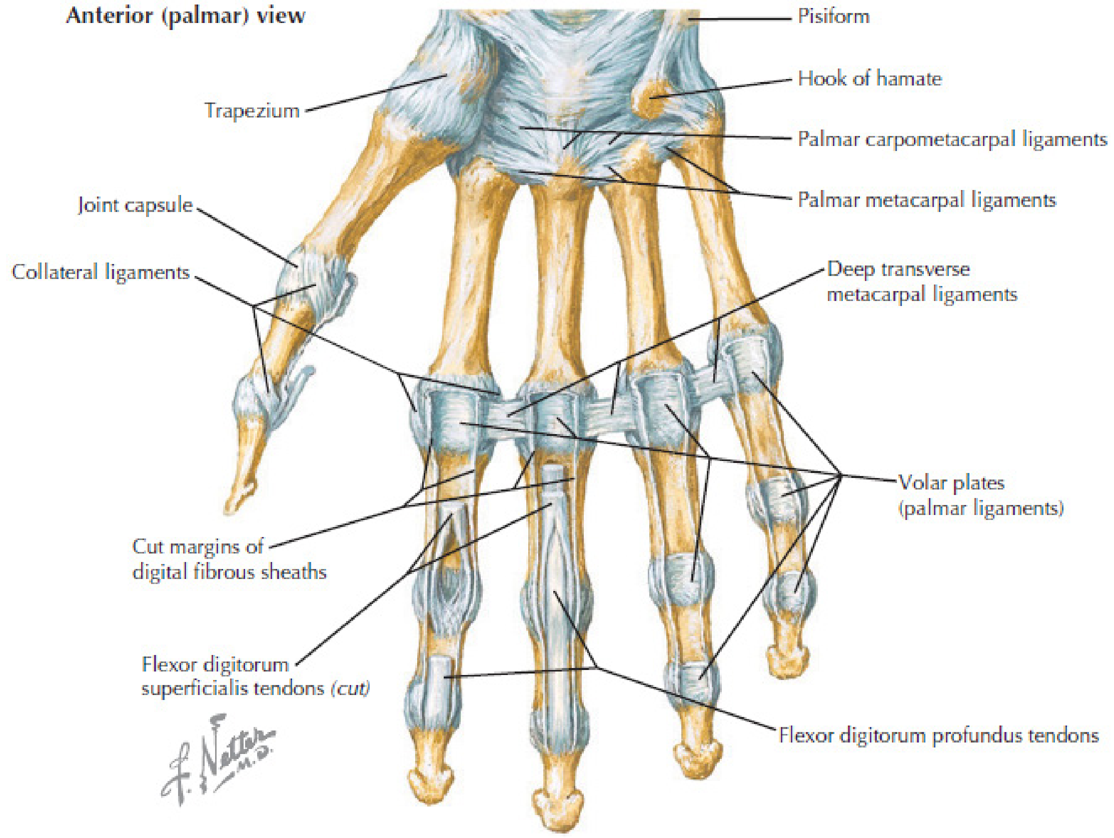


Figure 14 - Illustration showing the ligaments in grey which attach the bones of the fingers and thumb to create joints.

to the scaphoid bone and limits adduction of wrist (frontal plane).

- Ulnar collateral ligament – runs from the styloid process of the ulna to the triquetral and limits abduction (front plane).
- Anterior, posterior and interosseous carpal ligaments – runs between the carpal bones and holds carpal bones together; reinforced by the shape and interlocking structure of the bones.
- Transverse carpal ligament – located at the flexor retinaculum, it serves as the roof of the carpal tunnel which the median nerve and flexor tendons pass through.

Muscle Structure

A total of 34 muscles act upon the wrist and hand that work together in a complex way, allowing us to grasp and move objects (Fig. 15). Movements of the hand mostly originate from the muscles in the forearm and are known as extrinsic muscles which are used primarily for strength. Only the thin tendons of these muscles are located in the hand: the extensor tendons which stretch the hand run through the back of the hand to the fingertips, and the flexor tendons used for bending run through the palm to the fingers. These intrinsic muscles of the hand provide fine motor movements. Two other groups of more powerful muscles are called the thenar eminence and hypothenar eminence. These groups of muscles allow for the thumb and fingers to pull together and touch each other. A separate muscle called the adductor pollicis is used to pull the thumb towards the palm.

All of these muscles are connected to the bones of the hand with connective tissue called tendons (Fig. 16). The tendons are covered by a protective layer of tissue called a tendon sheath. The tendons travel within these tendon sheaths through a fluid that provides lubrication and protection. The muscle tendons, nerves and blood vessels running down the forearm to the hand pass through a tunnel-like passageway on the palm side of the wrist known as the carpal tunnel.

Nerves and Sense of Touch

The muscles in the hand and wrist are innervated by 3 main nerves (Fig. 17):

1. The Radial Nerve - activates the finger extensors and muscles in the wrist which are responsible for extending the hand. It also carries sensory information from the skin on the back of the hand and thumb to the brain.

2. The Median Nerve - responsible for movement of the thenar eminence muscles a portion of the lumbricals. It is also responsible

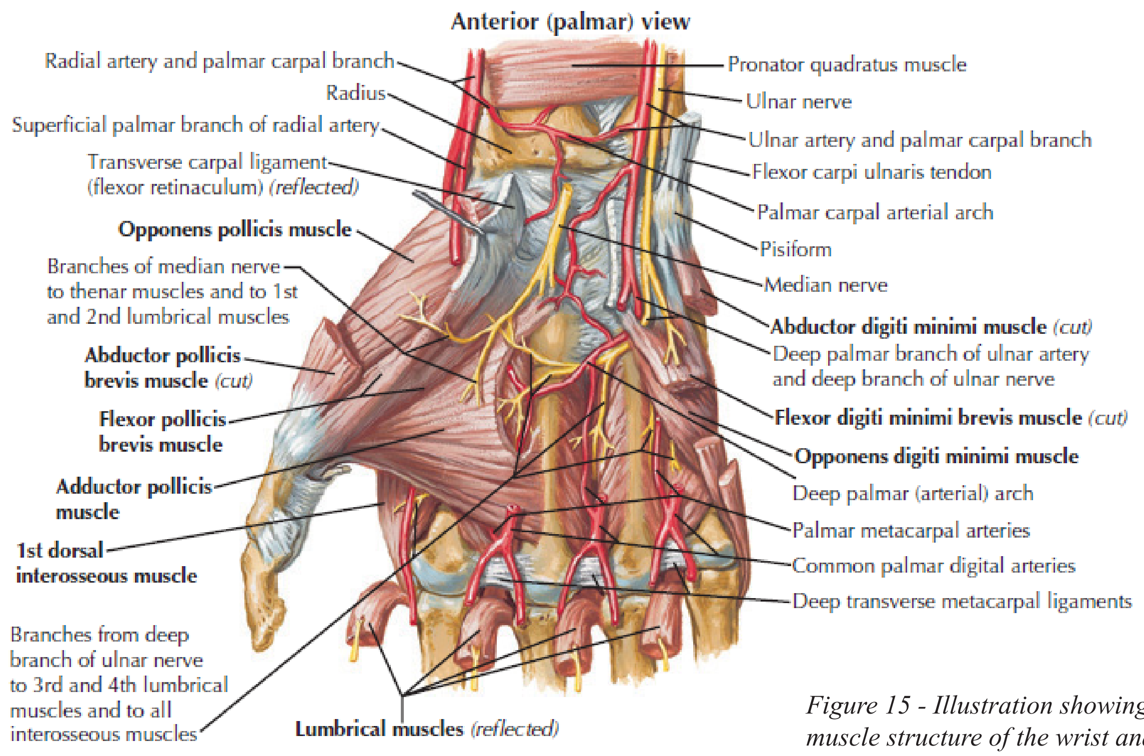


Figure 15 - Illustration showing the muscle structure of the wrist and palm.

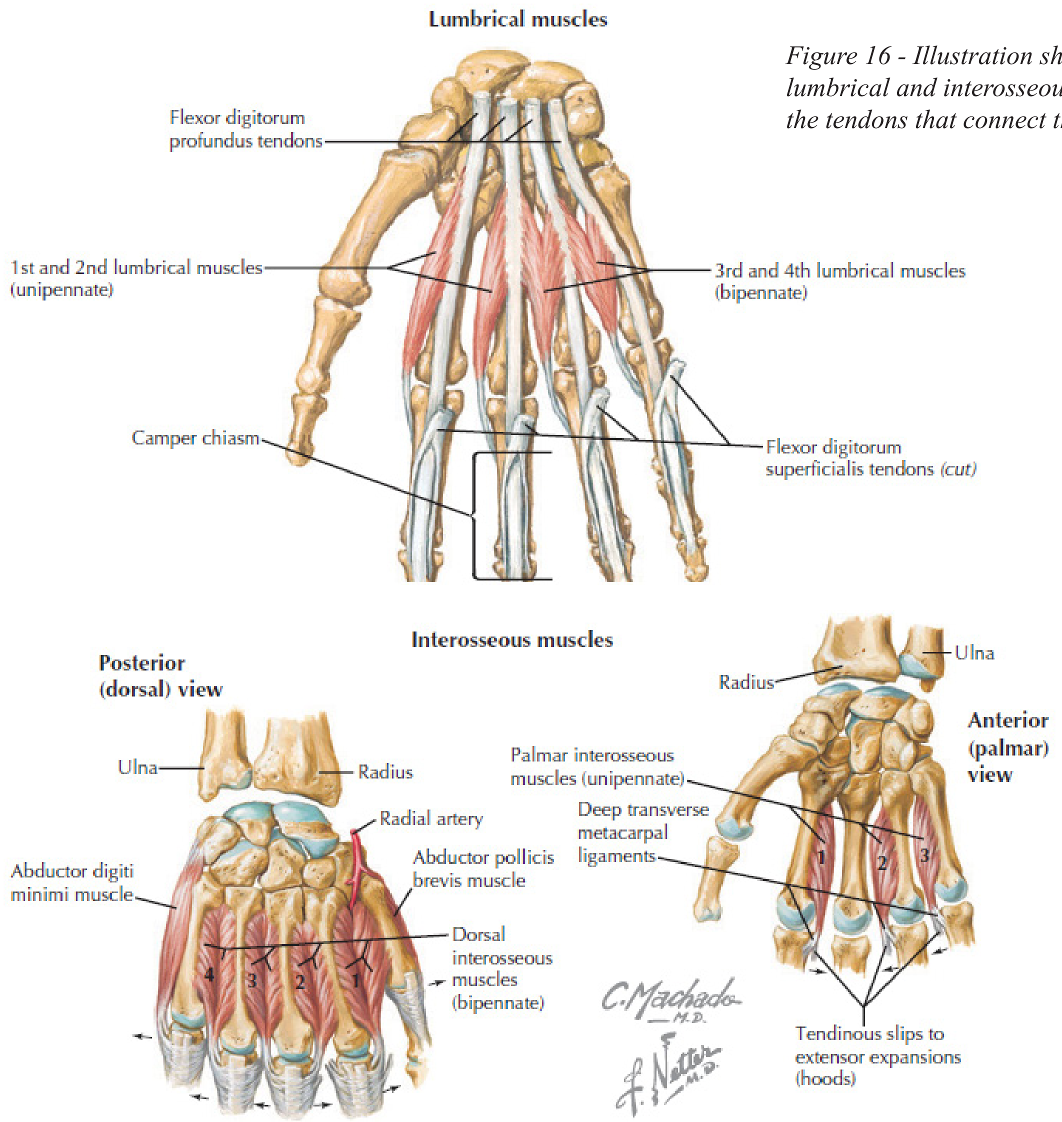


Figure 16 - Illustration showing the lumbrical and interosseous muscles and the tendons that connect them.

for the skin sensations located on the palm, thumb, index finger, and middle finger, as well as on the side of the ring finger closest to the middle finger.

3. The Ulnar Nerve - innervates the muscles of the hypothenar eminence, the muscles between the bones of the metacarpus, the muscle responsible for pulling the thumb toward the palm, and a portion of the lumbrical muscles between fingers. This nerve picks up the sensations below the little finger and the side of the ring finger that is closest to it.

These nerves are what send signals from your brain to the muscles which innervate them, causing them to move, as well as pick up signals from the environment and send them back to the brain. The fingers and the hand are stretched almost 25 million times over the course of a lifetime. There are a total of 17,000 touch receptors and nerve endings in the palm itself, which pick up sensations of pressure, movement and vibration.

Movements of the Wrist and Hand

The seamless interaction and cooperation of the bony structure, joints, ligaments and muscle structure allow the hand and wrist to perform an incredible amount of movements, gestures and grips (Fig. 18).

The wrist is capable of 3 distinct sets of movements:

1. Flexion and Extension
- Flexion is the movement of the palm bending down towards the wrist with a range of motion from 0-75 degrees.
- Extension is the movement of raising the back of the hand up and toward the forearm, with a range of motion from 0-75 degrees.

2. Supination and Pronation
- Supination is the movement of rotating the forearm into a palm up position.
- Pronation is the movement of rotating the forearm into a palm down position.

3. Ulnar Deviation (ulnar flexion) and Radial Deviation (radial flexion)
- Ulnar Deviation also known as ulnar flexion is the movement of bending the wrist toward the side of the little finger or ulnar bone. This has a range of motion of 30 degrees.
- Radial Deviation also known as radial flexion is the movement of bending the wrist inward toward the thumb or radial bone. This has a range of motion of 20 degrees.

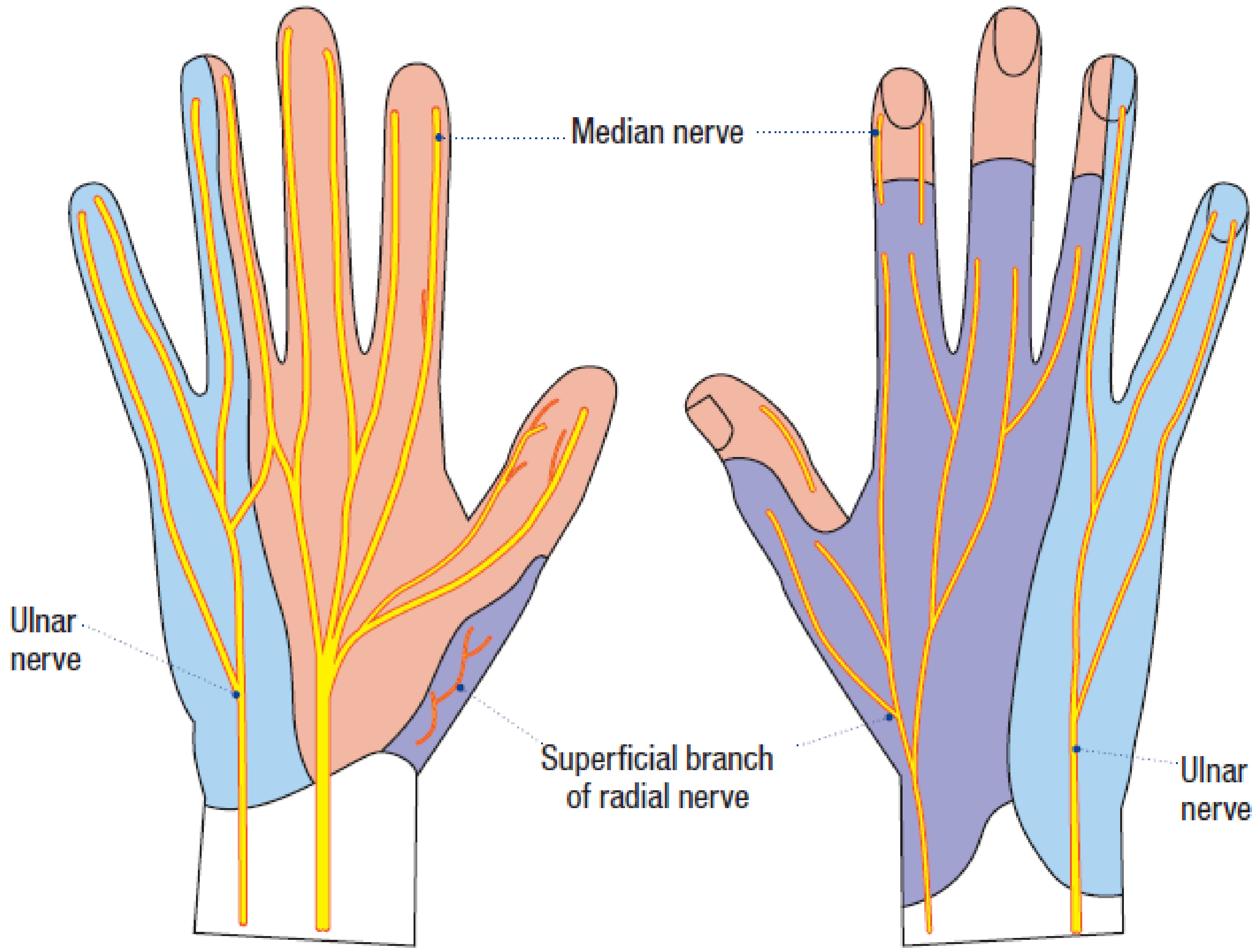


Figure 17 - Illustration showing the sensory areas of the hand which are affected by each nerve. .

The fingers of the hand are capable of 2 distinct sets of movements:

1. Flexion and Extension

- Flexion of the fingers involves bending at the metacarpophalangeal and interphalangeal joints toward the palm, making a closed fist. For the thumb, the flexion brings the thumb back against the index finger or the palm of the hand.
- Extension of the fingers involves straightening at the metacarpophalangeal and interphalangeal joints away from the palm, straightening the fingers in line with the wrist and hand. For the thumb, the extension moves the thumb away from the palm of the hand.

2. Abduction and Adduction

- Abduction in the fingers involves spreading the fingers apart, creating a star shape. For the thumb, abduction moves the thumb away from the palm at a 90 degree angle, forming a ‘thumbs-up’.
- Adduction in the fingers involves drawing the fingers together so that they are touching, with the thumb returning to its anatomical position next to the index finger.

Grip

All of these different sets of movements of the wrist and fingers work together to accomplish different types of grips. The dexterity of the hand is heavily reliant on the two types of distinct grips; Power and Precision grips. An object’s size, shape, weight and ease of handling can help determine which type of grip is best suited for the task or situation. A power grip is better suited for large, heavy objects, while a precision grip is better suited for smaller, more delicate objects.

1. Power Grip

- Used to accomplish things like carrying heavy objects or holding onto a handle (Fig. 19). With a power grip, the object is held in the palm of the hand, and the flexor tendons pull the fingers and thumb tight so they can grasp the object. The power grip is made possible by the ability of the fingers to be flexed (bent) with the thumb to be positioned opposite of the fingers. The heavier the object and smoother the surface is, the more strength is needed to maintain grip. A more powerful grip is possible when the wrist is held in some degree of extension, which is innervated by the radial nerve.

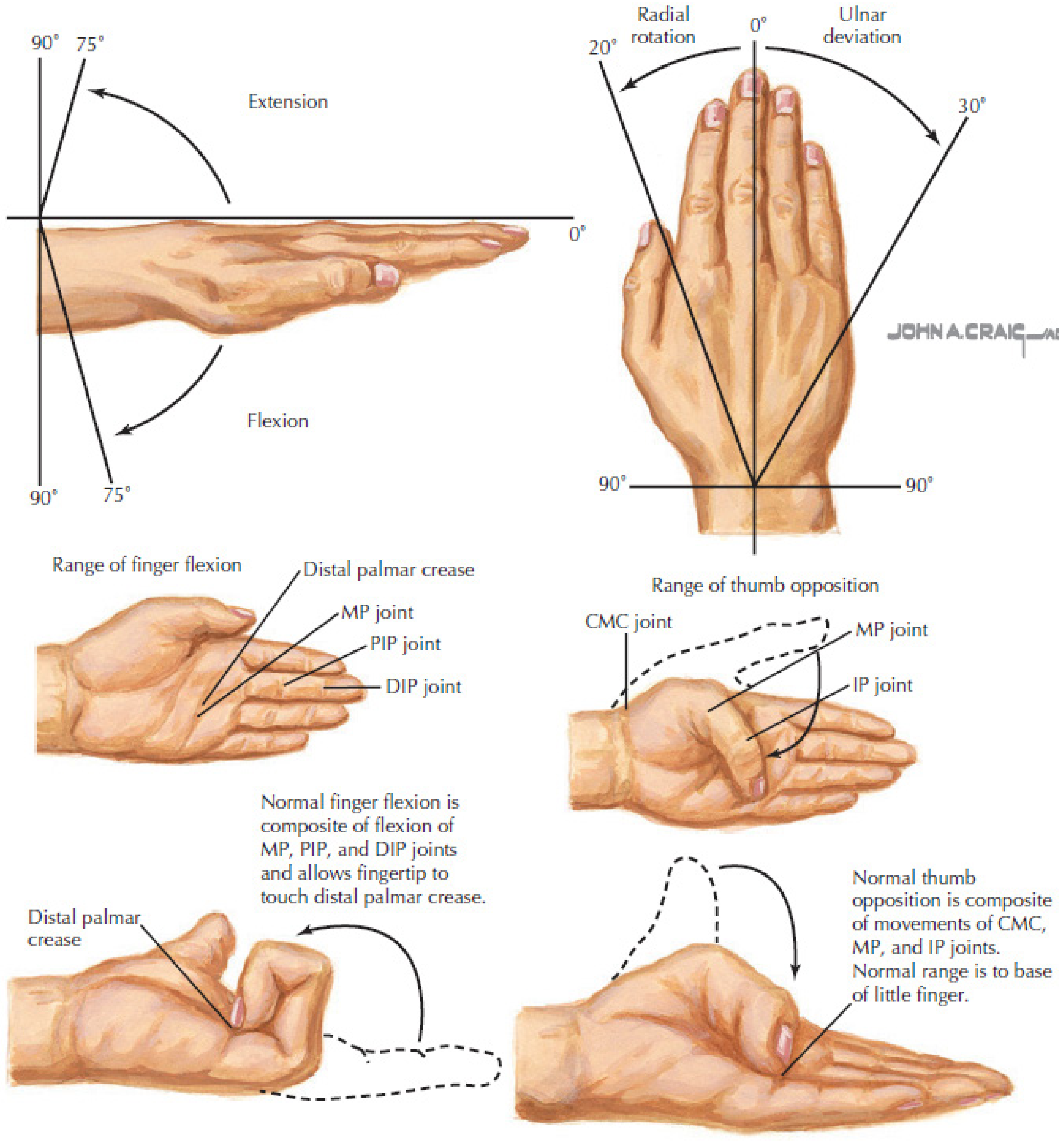


Figure 18 - Illustration showing the different movements of the hand and range of motion of the wrist and fingers.

2. Precision Grip

- Used to move small and delicate objects, for example writing, sewing or drawing. With a precision grip the thumb and index finger work together like a pair of tweezers (Fig. 20). Since the thumb is positioned opposite of one or more fingertips, it allows the hand to grip even very small objects like pencils or delicate instruments in a very controlled way.

Grip strength and function is almost entirely dependent on the flexor muscles of the hand. These muscles are mainly innervated by the median nerve. Radial nerve palsy affects the radial nerve which is responsible for innervating the extensor muscles of the hand. These muscles do not directly contribute to grip movements, but are necessary for returning the hand back to a relaxed position and releasing grip. In turn loss of extension on the hand can severely impact a person's ability to switch and release a grip, leading to extreme difficulty with daily tasks and loss of dexterity.

Figure 19 - An example of a power grip; a high strength grip using the palm, thumb, and fingers to grasp an object.

Figure 20 - An example of a precision grip; fine motor movements usually using the thumb and index finger to carry out precise and delicate tasks.

Introduction

One of the most popular and widespread non-operative treatments for radial nerve palsy and many other conditions is the use of an orthotic device. Simply put, orthotic devices are "mechanisms used in the field of orthotics, a branch of medical knowledge and treatment related to the straightening or correcting of problems in a human's muscles or skeletal system." Many conditions that affect how a person walks, stands, positions their spine, or otherwise naturally moves can be aided by an orthotic device. Bracing and splinting can be used to maintain fracture and joint alignment during the healing process and to unload weight-bearing forces. They can either be applied immediately at the time of injury or used as part of a progressive treatment course after conventional casting or traction. These devices can either be prefabricated or custom made depending on the patient's case.

History

The modern idea of a splint as we now know it has actually been in use for hundreds of years (Fig. 21). For centuries doctors, physicians and medicinemen alike used bandages and homemade devices to immobilize and support injured limbs. Before the modern health specialization of orthopedics, the physician or surgeon built the devices themselves or enlisted the help of local craftsmen. Only in recent years has hand splinting become part of a trained and specific discipline. The numerous injuries resulting from the First and Second World Wars and a large number of polio patients stimulated the development of orthotics and prosthetics in the early 20th century (Fig. 22). The famous hand surgeon Bunnell once said "Splints should be standardized as much as possible to facilitate the large volume of work done by many people." The outbreak of Polio was one of the biggest catalysts for developing standard orthotic designs.

Principles and Goals

According to noted authors in the field of orthoses, the clinical reasons for splinting encompasses a large scope. Splints immobilize, mobilize, restrict motion, or transmit torque. Analysis of an even larger pool of cited purposes a total of 6 remain constant over a time period of more than 50 years:

1. Increase function
2. Prevent deformity
3. Correct deformity
4. Protect healing structures
5. Restrict motion

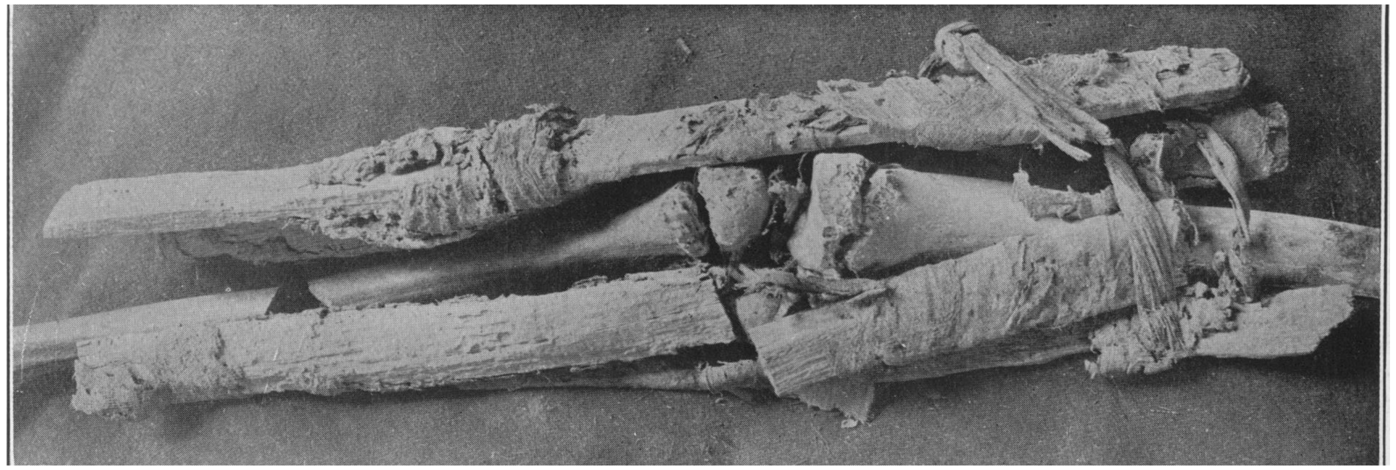


Figure 21 - Photo of one of the oldest known splints, dating back to ancient Egypt.

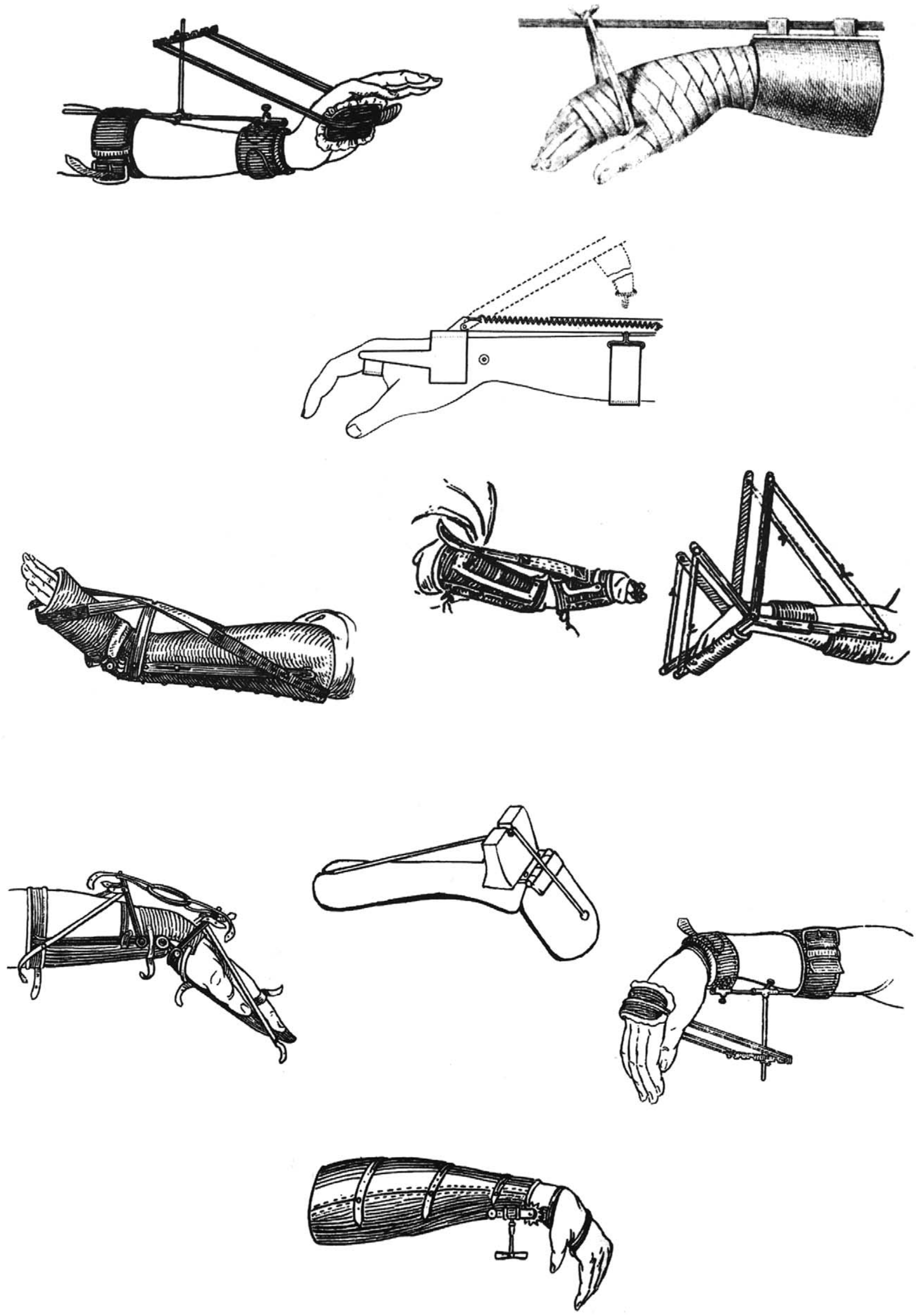


Figure 22 - Illustration showing a collection of splint designs from the 18th-20th centuries.

6. Allow tissue growth/remodeling

The level of importance of these goals of the orthotic device relate directly to the diagnosis of the patient and their level of recovery. At the same time there are a number of principles or guidelines which apply to all manners of orthotic intervention, regardless of diagnosis:

1. Promote User-Centeredness

In a User-Centered treatment process there is a symbiotic relationship between physio-therapist and user. The therapist provides knowledge of pathology, healing, biomechanical and orthotic principles, and technical knowledge of various materials and fabrication. The user contributes their personal knowledge of their own situation and how it affects their occupational performance. This process seeks to identify and address the user's individually unique needs and concerns to develop and orthotic treatment that best fits their lifestyle.

2. Optimize Usability

Usability refers to the effectiveness, efficiency, and satisfaction with which users can engage in various activities throughout different environments while wearing their orthosis. Client stories have illustrated that in order to optimize usability, an orthosis must be comfortable, convenient, effective, and have minimal hindrance on their occupation. In a study conducted by Wielandt et al, 3 main factors were identified which affected the usability of a given design:

- The user's perception of its durability, dependability, and appearance; awkwardness of use; level of fatigue during use; and level of embarrassment and pain.
- The presence or absence of the user's anxiety about their condition.
- The user's ability to recall their training and exercises.

The durability of an orthotic is responsible for its long term usability, and relies on correct material selection, construction and robust construction with firmly attached components such as outriggers.

3. Optimize Comfort

Discomfort adversely affects how long and regularly a user will wear an orthotic device. For this reason it is vitally important that an orthosis should cause no pain to the user. Pain can arise from pressure points or unwanted stress to the tissues which is an indication that the device is causing some degree of harm to the body. Additionally, when a part of the body is immobilized which interferes with natural patterns of movement, the user will compensate with other motions, leading to muscle fatigue and joint pain.

4. Optimize Convenience

User input is important to ensure the device suits their lifestyle, especially for long-term use. The user must be able to easily and intuitively remove and equip the device whenever they need to. It is important to seek the most convenient option for the user that will enable them to maintain occupational performance while also meeting biological goals. In order for this to happen there needs to be a clear understanding of the user's roles and the environments they function in.

5. Optimize Cosmesis

The appearance and aesthetics of the orthosis should be considered important to the user and deserves careful consideration. Since the user will be wearing the device so often, it becomes a part of their natural environment and their daily outfit. Many users (but not all) prefer their orthosis to be inconspicuous and draw as little attention as possible. Some exceptions may include younger users, athletes, or those who may find inherent value in the orthosis and celebrate its presence. Cosmetic defects such as marks, rough edges, impressions from hands, and soiling can detract from the appearance of the orthosis. Light-colored thermoplastics and fabric in particular can quickly become soiled and look unattractive and dirty.

6. Less is More

Many of the guidelines listed here can be accomplished using a minimalist design approach. A minimalist approach with regards to size, weight, and rigidity; visibility; amount of skin covered; number of restricted joints; material thickness; complexity; and ease of maintenance. Creating an orthosis that is as light as possible while providing adequate support can be particularly important to children and users with muscle weakness.

7. Identify and Address Biological Goals

Biological goals are those that address maintaining or restoring optimal health, integrity, stability, mobility, and function of biological tissues within the neurovascular and musculoskeletal systems. This is generally the responsibility of the hand therapist who is equipped with knowledge of anatomy and the user's diagnosis. It is important to identify what is responsible for the limited mobility, and design an orthotic that targets them.

8. Minimize Harm
The orthotic device should ultimately add benefit to the user's life, not create a hindrance. At the very least it needs to minimize any kind of biological harm. This can include pressure points; burns from molding thermoplastic, undue stress to tendons or joints, adverse effects of immobilization such as atrophy; muscle fatigue; skin maceration and reactions; edema; and sleep disturbance.

9. Incorporate Sound Fabrication Principles
Planning a well thought design and fabrication strategy is essential to ensuring the orthotic is safe, effective, usable, comfortable, and durable. Some sound design principles include increasing surface area, conforming the orthosis to the contours of the body, increasing rigidity using contours, padding bony areas, rounding corners and many more that will be explained in detail.

10. User Understanding
The user must clearly understand the rationale of the orthotic, when to wear it, how to put it on and make adjustments, and how to care for it and maintain it. A helpful tool can be distributing written and verbal instructions, as well as guidelines for care and cleaning, how and when to remove the device, and how to recognize signs of poor fit and how to make adjustments.

11. Monitor and Modify
Monitoring is the evaluation and collaboration with the user to determine whether or not the orthotic treatment is meeting its goals identified by the user and therapist. Modifications to the orthosis can occur when the monitoring process identifies problems with the device itself or the way the user interacts with it; such as pressure points or restriction of motion. Modifications may also be required when personal, occupational, or environmental situations change, or when response to the intervention does not meet expectations.

12. Evaluation
Ultimately evaluation of the orthosis and treatment program can identify the extent to which biological and occupational goals have been met or not. Continued collaboration between the user and therapist can lead to revisions to the device and treatment plan, increasing the quality of care and effectiveness of the orthosis. This continuous improvement benefits not only the individual user but also for other future users.

Splint Types
The different types of splints in use can be described under 4 main classifications: static, dynamic, serial static, and static progressive. The main purposes of these splints can be further classified by their intention to mobilize or immobilize the targeted joint.

1. Static Splint
   A static splint is one which is molded or applied directly to the hand that maintains the hand or joints in a single fixed position (Fig. 23). It can be worn continuously for a period of time to promote healing, or removed periodically for exercise. Static splints are used mainly to rest tissues, provide external support, or intermittently gain or maintain motion that has little resistance.

2. Dynamic Splint
   A dynamic splint provides constant force to the targeted joint/s. Typical construction consists of a molded plastic base secured directly to the hand or forearm. Force is generated by either a stretched rubber band or sprung wire via an outrigger that is attached to the base (Fig. 24). The outrigger ensures the force is directed at or close to a 90 degree angle to the long axis of the bone. While the splint is worn there is constant force applied, even as movement improves over time. Dynamic splints are removable, and as a result the force is intermittent.

3. Serial Static Splint
   Static splints are molded in a stationary position with the targeted tissues at maximum length (Fig. 25). They are changed frequently to account for the decreased resistance in the tissues over time. This splint is worn for long periods of time in order to adapt the tissue to a new position. Ideally this splint is changed every other day or twice a week. For patients living far from their care provider, the logistics of frequent visits can be quite difficult.

4. Static Progressive Splint
   Static progressive splints can be identical to dynamic splints in terms of construction and use of an outrigger, but the force applied is not dynamic. Instead of a rubber band or spring, tension is maintai ned once fitted, usually by means of Velcro or other components which can be adjusted in small increments (Fig. 26). Static progressive splinting concentrates the force through the surface area of the splint part applying the pressure, and allows the user to make adjustments.

Figure 23 - A thermoformed plastic static splint that holds the affected body part in a fixed position.

Figure 24 - A dynamic splint constructed of thermoformed plastic and an elastic outrigger system which allows movement of the fingers.

Figure 25 - A serial static splint of thermoformed platic which holds the tissues of the arm at maximum length.

Figure 26 - A static progressive splint made of thermoformed plastic and an outrigger which applies constant pressure that can be adjusted incrementally.

Splinting for Nerve Injuries

While splints for tight joints apply force, those used for hand affected nerve injuries constrain motion to create a reproduction of normal hand muscle balance and function. The famous hand surgeon and pioneer in hand splinting Dr. Bunnell stated that "to substitute for the lost motion with just enough force so that when the opposing normal muscles are relaxed, the parts fall into the corrected position, and yet allow the normal muscles, when activated, to carry out the full range of motion." Essentially splints for nerve injuries to the hand, seek to create an artificial tendon system which replaces the loss of function in the hand due to the inability to innervate certain muscles.

A hand that has been affected by radial nerve palsy has the potential for normal function because sensitivity in the palm remains intact, as well as extrinsic flexors and intrinsic muscles. According to experts and journals in the field, a splint for radial nerve palsy should "support the wrist and establish normal tenodesis (Fig. 27)." Furthermore many authors recommend using a dynamic splint or static splint to stimulate a more normal tenodesis. Using a splint with a static line that allows full finger flexion and functional wrist extension in order to restore the most range of motion to the hand and obtain the highest amount of grip strength.

The most important objective in splinting a high radial nerve injury is to support the wrist in extension, enhancing hand function and preventing overstretching of the extensor muscle groups. For most patients the use of a wrist extension splint is sufficient to allow satisfactory hand use. Extension outrigger atachments are sometimes considered excessive and should be uused in situations in which full digital extension is required for successfull accomplishment of given tasks (Fig. 28). Since these are substitution splints, and are worn almost always, low-profile outrigger configurations are preferable (Fig. 29).

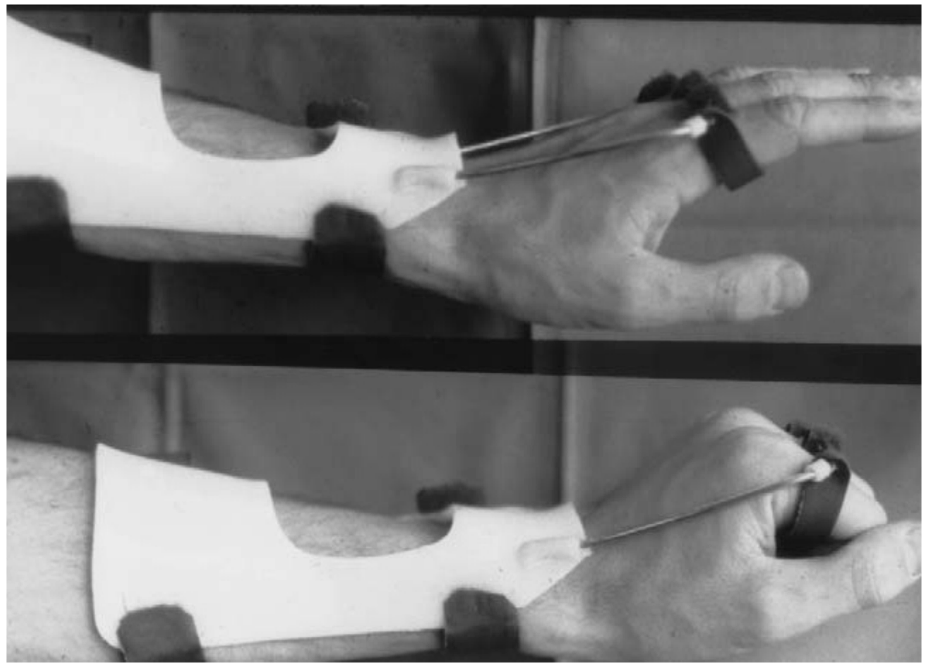


Figure 27 - An example of a hybrid static/dynamic splint that supports the wrist and enables normal tenodesis.

Figure 28 - An example of how dynamic outriggers enable full digital movement.

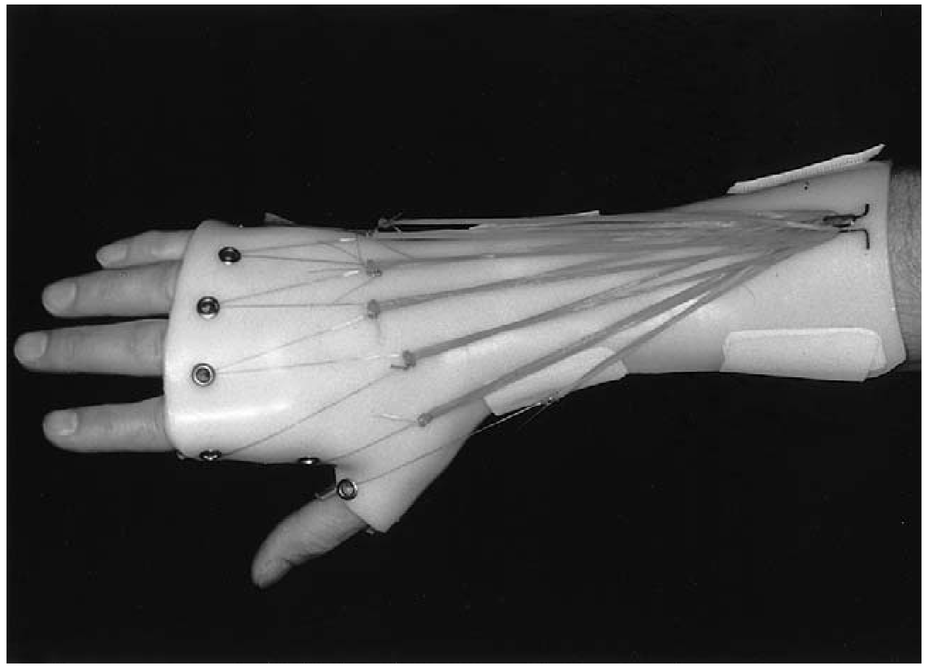


Figure 29 - An example of a low-profile outrigger splint, which is significantly streamlined compared to traditional outriggers.

Summary

The process of providing an orthosis to a user and implementing it into their daily life is not an easy task and should not be taken lightly. Orthoses can have an incredible impact on the quality of one's occupational performance from both their positive and negative effects on biological structures. The benefits of an orthosis can only be realized if they are actually worn by the user. It takes a unique blend of creativity, expert knowledge, and problem-solving skills to meet the unique requirements of each user and their diagnosis. Constant collaboration, monitoring and modification processes, and a holistic user-centered approach are necessary to optimize outcomes. This involves considering the complete user picture by identifying biological issues and occupational barriers.

The principles listed in this user-centered approach are aimed at developing an orthosis that enables current and future occupational performance while minimizing the hindrance and harm to the body. An ideal orthosis is comfortable, lightweight, aesthetically pleasing, and above all convenient to use. These traits are enhanced by taking a less-is-more approach to design.

The general principles of design provide a basic framework on which the design and fabrication of any upper extremity splint must be based. At the same time specific principles may be altered by individual patient cariables and fuunction requirements, and as such will influence the final configuration of the splint. Experienced professionals in the clinical field of orthotics does not necessarily employ these principles one by one like a checklist, but rather simultaneously, adding, eliminationg, and supplementing them with innovation and creativity. The challenge is to create a splint that not only meets the functional objectives bt also is acceptable and well tolerated by the patient.

Introduction

The term 'Open Source' is one which many may have heard of, but are still unfamiliar with what it really means. There are many definitions that describe Open Source, but the general idea is very simple: Allow the source code for a piece of software available to all, so that anyone may modify it to better suit their needs and redistribute the improved version to others. With this mantra, it's possible to create a community of both users and developers/producers to improve the quality and functionality of the software or product. In short, Open Source requires that anyone can obtain and modify the source code and then freely redistribute any derived works they create from it. The term Open Source originally and still mainly applies to digital artifacts and software. However as the movement has evolved, it's expanded into many different sectors and industries, all the while maintaining the same basic principles that it started from.

Origins

The origins and history of Open Source can be traced back to the beginning of software development itself. Open Source is not a new idea, with its roots starting in the early 1980's, but it has been steadily gaining popularity in the design, information technology, and business industries. In 1984 a man named Richard Stallman created the Free Software Foundation and the GNU project. He did this as a result of the collapse of the software-sharing community at the MIT AI Lab. Many of his colleagues had left to join companies making proprietary software. He coined the term free software to demonstrate his philosophy that programmers should have access to the source code of a software so that they could modify it to suit their needs. Stallman also developed what is called the GNU General Public License (GPL) which enabled and protected him to see and modify the source code for any software that he wrote, as well as any modifications that anyone else made to it. The original and long standing goal of Stallman through his GNU project, was to make it so that no one would ever have to pay for software again. The actual term Open Source was not coined until more than a decade later, when a group of leaders in the free software community came together in 1997. The group's main concern was to find a way to promote the ideas of free software to people who had originally shunned the concept. At the time, the Free Software Foundation was pushing an anti-business message, thus keeping the world from really appreciating the power of free software. From these discussions a new term was born to describe their movement: Open Source.

The Open Source Definition

The meaning of Open Source goes much further beyond just providing access to source code. In order to better encapsulate the meaning and identity of what is or isn't Open Source, a set of guidelines were created from the Debian Free Software Guidelines. The distribution terms of open-source software must comply with the following criteria:

1. Free Redistribution
   The license shall not restrict any party from selling or giving away the software as a component of an aggregate software distribution containing programs from several different sources. The license shall not require a royalty or other fee for such sale.

2. Source Code
   The program must include source code, and must allow distribution in source code as well as compiled form.

3. Derived Works
   The license must allow modifications and derived works, and must allow them to be distributed under the same terms as the license of the original software.

4. Integrity of The Author's Source Code
   The license may restrict source-code from being distributed in modified form only if the license allows the distribution of "patch files" with the source code for the purpose of modifying the program at build time. The license must explicitly permit distribution of software built from modified source code. The license may require derived works to carry a different name or version number from the original software.

5. No Discrimination Against Persons or Groups
   The license must not discriminate against any person or group of persons.

6. No Discrimination Against Fields of Endeavor
   The license must not restrict anyone from making use of the program in a specific field of endeavor. For example, it may not restrict the program from being used in a business, or from being used for genetic research.

7. Distribution of License
   The rights attached to the program must apply to all to whom

the program is redistributed without the need for execution of an additional license by those parties.

8. License Must Not Be Specific to a Product
   The rights attached to the program must not depend on the program's being part of a particular software distribution. If the program is extracted from that distribution and used or distributed within the terms of the program's license, all parties to whom the program is redistributed should have the same rights as those that are granted in conjunction with the original software distribution.

9. License Must Not Restrict Other Software
   The license must not place restrictions on other software that is distributed along with the licensed software. For example, the license must not insist that all other programs distributed on the same medium must be open-source software.

10. License Must Be Technology-Neutral
   No provision of the license may be predicated on any individual technology or style of interface.

Adhering to these guidelines ensures that each Open Source project being developed is done to the same standards as the rest. These standards help protect the integrity of the project and license(s), provides greater clarity to the Open Source movement in general, and ensures interoperability for any potential contributors.

Gratis vs. Libre

The English language does a poor job of distinguishing the true meaning of free when applied to the context of Open Source software. The adjective free is most commonly used with 2 different meanings:

1. Gratis - Means "free" in the sense that something is being supplied or provided without the need for payment or compensation, regardless of its value.

2. Libre - Means "the state of being free, liberty, or having freedom".

Many who are unfamiliar with the Open Source movement, or Free Software Movement, can find this ambiguity confusing and can lead to false expectations. In simple terms, a good or service - software in this context - can either be gratis i.e costing $0, or libre, where the user on consumer can use the software in any way they want. Even more confusion can arise when it is realized that these two types of "free" software are not necessarily contemporaneous. The Free Software Foundation explains this distinction particularly well:

"Free software" means software that respects users' freedom and community. Roughly, it means that the users have the freedom to run, copy, distribute, study, change and improve the software. Thus, "free software" is a matter of liberty, not price. To understand the concept, you should think of "free" as in "free speech," not as in "free beer". We sometimes call it "libre software," borrowing the French or Spanish word for "free" as in freedom, to show we do not mean the software is gratis.

Gratis usually refers to access without a price barrier, while *libre* refers to the allowance to modify and re-use without a permission barrier. Both forms of free software have their place within the Open Source movement, and it is usually up to the author to determine how "free" their software is.

A Culture of Community

Open access and collaboration are two of the largest pillars of the open source movement. The open source community is what is at the heart of the movement. The community is responsible for the brainstorming, development, maintenance, and enhancement of its projects. The outcomes are often then reused to create even more innovative projects. The guiding force in the open source movement revolves around participation and the desire to develop innovative projects for others to use, not profits. Even despite the presence of a strong proprietary software industry, practices in the software development world have always been rooted in community and sharing. The Internet itself was an open, collaborative effort, and was the precursor to the modern open source movement as we know it. Amy Jo Kim,, author of Community Building on the Web, defines a community as: "...a group of people with a shared interest, purpose, or goal, who get to know each other better over time." (p.29). Perhaps one of the most famous community driven projects that was fueled by a common shared interest and purpose, was the Linux operating system headed by Linus Torvalds. As a student in 1991 he posted his intentions of creating a free operating system to a USENET mailing list. What happened next was one of the most widely collaborative projects in the history of the world, and 22 years later, Linux powers 95% of the top 500 most powerful supercomputers in the world. Within the last 2 decades, the Open Source community has been growing at an extremely high rate, evidence of its general success and acceptance. Between the years 2000-2005, the Open Source community website SourceForge documented an increase of projects from 1,362 to 82,719, and registered users from 7,908 to 864,996. The Open Source community is alive and well, and growing larger every day.

A Platform for Innovation

The open source community serves as a giant ecosystem of innovators who are sharing information instead of competing with one another. The inclusive and collaborative nature of the Open Source movement is both the origin and ongoing stimulation of its creative productivity. In the Open Source ecosystem, a single actor or group can start with an idea, socialize it, and engage with an audience to develop it into a solution that addresses a particular question or challenge. All of this can be done without having to adhere to corporate budgets, angel investors, and without the permission of anyone. The freedom to create and release is in the hands of the community. At the same time this entire process is occurring in the commons, where anyone can freely observe, access, and modify what they want. This allows the project to achieve a great deal of exposure, attracting talent and collaborators who can help to add value and improve the project. The community are also the ones responsible for testing a product. In the context of open source software, the community often assumes the role of the debugging team. With so many users testing and verifying the code, they simultaneously identify bugs and fix them as the software is being developed. As an individual, having access to an immense pool of innovative ideas and collaborators can be extremely beneficial. For instance, a lot of the work may already be done and documented for a given project or idea, which can drastically reduce the design timeline and time to market. Projects which build upon preexisting innovations, spun-off, and re released add additional layers of new and innovative ideas, ready for the next person to use. Producing work in a highly visible and accessible environment can create a safe place for people to experiment, further improving the likeliness of innovation.

The Internet: Enabling Innovation

The Internet is well regarded as the key enabler propelling the Open Source movement and the free flow of ideas in the 21st century. It helps people all over the world connect with each other and find common interests. Through social media, forums, depositories and other websites, people can easily communicate, share information, and conduct activities together. Running an Open Source project could be considered nearly impossible without the power of the Internet. An Open Source project, most of all, requires people. Many projects start with an individual or small group of people that have a software or product that they feel others would find useful. The project can be advertised through a variety of channels and online groups. Through the power of the search engine, someone anywhere in the world can locate a project and try it out. They can express their interest in the project and tell others about it, and give feedback directly to the creators or original authors on how to improve it. Today we have many sophisticated online collaboration and communication tools that make it even easier to run a project virtually. Video conferencing software like Zoom or Teams allows multiple people to communicate directly and exchange information. Collaboration tools like Miro offer a platform for people to remotely collaborate and work hands on with a project. Websites like Github, Grabcad, and Thingiverse just to name a few, offer a depository where anyone can upload and download source code or other files pertaining to the Open Source project. The Internet is perhaps more beneficial to Open Source projects than working in person, because the connected and distributed nature of the project benefits from being accessible by anyone, anywhere, at any time.

Benefits of going Open Source

The draw to going Open Source for a given project or service will vary on a case by case basis depending on many factors. In general however, the following reasons can apply to many who are considering going the Open Source route.

1. Visibility and Ubiquity
   When a project is run Open Source, it's existence and nature are visible to everyone, both outside and inside the sphere of the project. This visibility facilitates the presentation of plans, goals, features, and statements of progress. It also opens up additional communication channels, such as direct dialogue between developers, users, and companies. This open nature of sharing promotes the spread of information to a larger audience. When more people know about a project, more people can get involved, and more people can benefit from it.

2. Training and Education
   The best way of learning design and new skills is by reading and studying what others have done before. This ties closely in with Visibility because anyone who is interested can openly access and use the source code and design documents, and have more direct communication with the authors of the project.

3. Design Discipline
   Open Source development requires making almost all design decisions open to the public. Design and implementation proposals are made in writing, and resulting decisions are documented. All of this material is archived and available to everyone. This process of documentation creates a need to

express issues in a clear and succinct way, which leads to better understanding of the material. This level of discipline improves the quality of the design process.

4. Creating Dialogue
   Open Source is a great way to engage with a broad group of people. Being able to communicate directly with users or customers can lead to invaluable insight that would rarely be accessible otherwise. It is relatively rare for an outsider to be interested in helping a company with its proprietary products, and frequently outsiders are not in a position to know enough about a company's strategy/business/products to offer advice. In an Open Source environment, outsiders and insiders interact in an open forum, where knowledge is shared and accessed freely.

5. Design Help
   Opening up the design process to the community allows for the free flow of advice for design and implementation. In many cases users also play the role of a designer by providing good direction, feedback, and in some cases pure design contributions. User feedback, coupled with the practice of incremental development and frequent updates, helps keep a project relevant and focused on what is important.

6. Limited Resources
   Many groups who create Open Source projects do so because they do not have the resources of a larger company who makes proprietary products. The Open Source movement is based on a gift economy and collaboration. Most often the work done in Open Source projects are volunteer and without the motivation of money involved. Most Open Source projects are also accessible completely free, benefiting the end user who may be pursuing Open Source products because there is little to no cost in doing so.

7. Improved Quality
   When releases are made to the community early in the development process and in further incremental stages, bugs and issues are more likely to be caught and resolved. When the source code of software is made available to outside developers/users, bugs can be located and fixed. Outsiders can also add in useful features that weren't originally conceived by the core team due to time constraints - adding value and usability to the project.

Introduction

Open Source Hardware (OSHW) is an emerging phenomenon of physical products being developed under the open source principles originally defined by the Open Source Initiative in 2007. When the Open Source movement was born, the primary interest and application was that of developing Open Source Software for public use. The exponential spread and development of digital fabrication tools, and more importantly affordable accessibility of said tools, has spurred the so-called "Maker-Movement", aimed at disrupting traditional means of industrial production. In this context of emerging distributed manufacturing, the users, whether scientists, professionals, or simply consumers, fabricate products themselves from digital plans that are openly shared. By providing the bill of materials, schematics, assembly instructions, and general procedures needed to fabricate the product, the OSHW movement has been benefiting from mass-scale peer review and collaboration that has already been so beneficial in developing free and open source software. The OSHW movement has a huge potential to be a driving force of change in social, economic, and environmental contexts, but has yet to be fully realized.

Defining Open Source Hardware (OSHW)

In order for there to be clarity, continuity, and standardization across time and space, there is a need for a common, shared and accepted definition of what constitutes as OSH. This definition is provided by the Open Source Hardware Association (OSHWA), the largest recognized governing body regarding OSHW. According to OSHWA:

"Open Source Hardware (OSHW) is a term for tangible artifacts — machines, devices, or other physical things — whose design has been released to the public in such a way that anyone can make, modify, distribute, and use those things."

On the discrepancy between hardware and software:

"Hardware is different from software in that physical resources must always be committed for the creation of physical goods. Accordingly, persons or companies producing items ("products") under an OSHW license have an obligation to make it clear that such products are not manufactured, sold, warrantied, or otherwise sanctioned by the original designer and also not to make use of any trademarks owned by the original designer."

This definition is intended to help provide guidelines for the development and evaluation of licenses for OSHW.

Principles of OSHW

The OSHWA has additionally provided a set of guiding principles to assist with the development and evaluation of licenses for OSHW. The distribution terms of Open Source Hardware must comply with the following criteria:

1. Documentation
   The hardware must be released with documentation including design files, and must allow modification and distribution of the design files. Where documentation is not furnished with the physical product, there must be a well-publicized means of obtaining this documentation for no more than a reasonable reproduction cost, preferably downloading via the Internet without charge. The documentation must include design files in the preferred format for making changes, for example the native file format of a CAD program. Deliberately obfuscated design files are not allowed. Intermediate forms analogous to compiled computer code — such as printer-ready copper artwork from a CAD program — are not allowed as substitutes. The license may require that the design files are provided in fully-documented, open format(s).

2. Scope
   The documentation for the hardware must clearly specify what portion of the design, if not all, is being released under the license.

3. Necessary Software
   If the licensed design requires software, embedded or otherwise, to operate properly and fulfill its essential functions, then the license may require that one of the following conditions are met:
   a) The interfaces are sufficiently documented such that it could reasonably be considered straightforward to write open source software that allows the device to operate properly and fulfill its essential functions. For example, this may include the use of detailed signal timing diagrams or pseudocode to clearly illustrate the interface in operation.
   b) The necessary software is released under an OSI-approved open source license.

4. Derived Works
   The license shall allow modifications and derived works, and shall allow them to be distributed under the same terms as the license of the original work. The license shall allow for the manufacture, sale, distribution, and use of products created from the design files, the design files themselves, and derivatives thereof.

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

6. Attribution
   The license may require derived documents, and copyright notices associated with devices, to provide attribution to the licensors when distributing design files, manufactured products, and/or derivatives thereof. The license may require that this information be accessible to the end-user using the device normally, but shall not specify a specific format of display. The license may require derived works to carry a different name or version number from the original design.

7. No Discrimination Against Persons or Groups
   The license must not discriminate against any person or group of persons.

8. No Discrimination Against Fields of Endeavor
   The license must not restrict anyone from making use of the work (including manufactured hardware) in a specific field of endeavor. For example, it must not restrict the hardware from being used in a business, or from being used in nuclear research.

9. Distribution of License
   The rights granted by the license must apply to all to whom the work is redistributed without the need for execution of an additional license by those parties.

10. License Must Not Be Specific to a Product
    The rights granted by the license must not depend on the licensed work being part of a particular product. If a portion is extracted from a work and used or distributed within the terms of the license, all parties to whom that work is redistributed should have the same rights as those that are granted for the original work.

11. License Must Not Restrict Other Hardware or Software
    The license must not place restrictions on other items that are aggregated with the licensed work but not derivative of it. For example, the license must not insist that all other hardware sold with the licensed item be open source, nor that only open source software be used external to the device.

12. License Must Be Technology-Neutral
    No provision of the license may be predicated on any individual technology, specific part or component, material, or style of interface or use thereof.

Open Source Hardware in the Healthcare Industry

Innovations in the medical field have been responsible for improving quality of life and public health. Medical devices can help with preventing diseases, diagnose, treat, and cure patients with a variety of health disorders. However advancements in the medical technology field are not always available and accessible to everyone. This is especially true with middle-low income communities. The primary barriers hindering product adoption are fragmented regulation, high prices, and inadequate solutions for local markets (Carpentier, 2021). To exemplify this, the World Health Organization reports that in the field of cardiac disease alone, more than 2 million patients die each year due to inadequate access to an appropriate heart implant (Ochasi & Clark, 2015).

Two main pillars of the open source movement - access and distribution - are why open source hardware development is so appealing to the medical technology industry. Making a hardware design available under an open-source license allows anyone to be able to improve and contribute to the design, allowing for very rapid and inexpensive innovation. Designs can also be modified for specific use cases, allowing for quicker turnaround. Additionally many open-source products are designed to be repaired, lengthening the product life cycle and potentially reducing negative environmental impact.

In just the past 2 years, we have been able to observe how open source hardware development can have a beneficial impact on health related crises. Amidst the ongoing Covid-19 pandemic and related supply chain disruptions, the OSHW movement spurred the decentralized production of various Personal Protective Equipments. The ability for a product to be designed, and then openly and freely shared to others in different parts of the world led to the rapid response of production and peer-reviewed improvements. Another example of how the described attributes of OSHW can overcome barriers to healthcare equipment is shown perfectly by the Glia Foundation's 3D printed stethoscope. The stethoscope is regarded as one of the most standard and ubiquitous pieces of equipment to doctors worldwide. In spite of this high necessity, a reliable stethoscope costs anywhere from $90-$200 USD, and can be very difficult to obtain in low resource communities. While working in Gaza, Dr. Tarek Loubani created an open-source design for a stethoscope that costs just $3 USD to print.

Introduction

Digital technology is enabling new alternatives to industrial, large scale production. Computer-aided design (CAD) tools encode objects as information, allowing designs to be freely and easily shared online - one of the defining principles of the open source movement. Digital fabrication machines transform this information in cyberspace into tangible 3D objects, allowing for precise, one-off production of physical goods. A variety of sophisticated off-the-shelf electronic components enable complex devices from digital designs, a process we can think of as personal manufacturing.

Since open source hardware involves treating physical objects as digital information, it suggests that we may be able to apply principles and practices from other kinds of online collaboration to the design of hardware. Tried and true examples such as Open Source Software, Wikipedia and Github incorporate the creativity of many individuals working freely from the direction and constraints of an overarching market or company, in a process known as peer production. This method of peer production works so well because the production of digital goods like computers and software are widely distributed, the Internet and tools like Webex or Zoom make communication easy and efficient, and the work is divided into pieces that individuals can work on based on their interests, needs, and abilities. This same peer production model can be applied to the development of open source hardware to create a viable alternative to mass production for many types of goods and technologies.

This type of process yields results that are very distinguishable from those that are industrially produced. Such products are optimized for translation from digital design to physical objects. They make use of a variety of manufacturing processes, from the now ubiquitous and ultra accessible 3d printing to laser cutting, laser scanning, CNC machining, and circuit board fabrication. The process allows usage of a variety of materials and unique aesthetics. The designs can be adapted by individuals for their own needs and interests, and allows for different business models, in which objects can be made on demand or in small quantities to serve specific markets or particular individuals.

3D Printing

Open source hardware products and projects are particularly appealing and beneficial to produce through digital manufacturing technologies such as 3D printing. Digital manufacturing production methods have created a new paradigm of production called distributed manufacturing where users, either experts or simple consumers, fabricate products themselves from digital plans. When the first Open Source 3D printer RepRap was created, it cost roughly $2000 to build. In the year 2022, a basic FDM 3D printer can be purchased for as little as $100-$200. Now anyone in the world can easily purchase and set up a desktop 3D printer, and begin manufacturing in their bedroom. The low cost and ubiquity of desktop 3D printers have allowed the average person to be able to prototype and fabricate sophisticated products that were previously only possible by means of expensive tooling and production methods. However that is not to say that 3D printers are a cheap and low fidelity method of production. Even the less expensive units can produce accurate and detailed results with the right tuning and skill. There still exist industrial level 3D printers that cost thousands of dollars that are being used by large companies like General Electric and Hewlett Packard. In recent years there has been an exponential rise in designs for hardware released under open-source, creative commons licenses, or placed in the public domain. From this new paradigm of production, open-hardware has been benefiting from this mass-scale method of peer review and collaboration, and has shown to be a widely successful method of developing OSS and OSHW. Simultaneously, the availability and accessibility of these digital designs has driven an explosive growth in 3D printing and development. For many like scientists, researchers, or medical professionals, the need to access highly-customized low-volume products, this method of manufacturing can have extremely high value. For many average consumers, the availability of 3D printing capabilities in certain environments can be incredibly empowering and give access to low cost production of goods.

CNC Milling and Cutting

3D printing is considered an additive manufacturing process because material is added to create the final product. There are other subtractive manufacturing processes that remove material from a larger piece of stock to create the final product. Laser cutters cut 2D shapes out of plywood, cardboard, acrylic, metal, fabric, and other flat materials. Vinyl cutters do the same but with a knife that cuts through thin materials like paper and vinyl. Water-jet cutters can handle stronger and thicker material like wood, metal, and glass, by using a stream of highly pressurized water with some type of aggregate suspended in it. Other machines like mills and routers work in three or more dimensions and remove material from solid stock by use of a rotating cutting bit. Compared to 3D printers, these cutting and milling tools have the advantage of being able to work with a larger variety of materials that are impossible or expensive to use with 3D printers. On the other hand they are more limited in the geometries they can produce and require more steps in fabricating or assembling the parts.

Access to Fabrication Tools
Access to digital fabrication processes and tools can be achieved in a variety of ways. Some machines, especially 3D printers and vinyl cutters, are targeted to individuals via low-cost and easy to use models. Local workshops, Maker Spaces, or FabLabs provide access to larger, messier, and more expensive machines. They also offer access to knowledge, providing opportunities for people to learn how to use the machines from a community of like-minded individuals. Online services like shapeways.com or similar, offer an alternative for those without local, hands on access. These services can provide a larger variety of processes and materials than those found in a local workshop, and don't require the need to learn how to use the machine directly. On the downside, these services operate essentially as a centralized means of production, and are subject to using standard supply chain methods. As a result there is greater time required to produce and transport the products, as well as lack of direct control over the process can make it difficult to iterate and refine designs. Additionally, online services generally have higher per-part prices than direct machine access because the need to cover the cost of the machines, labor, and infrastructure.

Design Principles for Digital Manufacturing

1. Use standard parts and materials
   This allows others to make use of an open source design better because the parts/materials that it relies on are widely available. This may require foregoing components or materials that are convenient to you if they're not available to others.

2. Understand and design for the fabrication process used
   Different fabrication processes are good for different things, and come with their own set of constraints. By designing for a specific process, you can take advantage of its strengths, avoid its weaknesses, and ultimately make it easier for someone to produce and replicate on their own. Not everyone will have the same access to specific machines, so avoid designing using obscure or unique processes.

3. Pursue unique meanings, functions, and aesthetics
   The power and efficiency of mass production make it hard to compete with it on its own terms. Try to avoid designing products in a way that makes more sense to use mass production methods. Take advantage of the benefits of personal fabrication which allows us to make products in small quantities and to find audiences that aren't well served by existing commercial products.
4. Iterate faster, cheaper, and easier
   A key benefit of digital fabrication is that every part it produces can be different. Use this to rapidly iterate a design. Having direct access to a machine can yield multiple different iterations in an afternoon as opposed to a week or a month.

5. Document and provide source files
   Someone who wants to produce or modify your design will need more than just the CAD file. Include parts list, bill of materials, assembly instructions, user documentations or anything else that would be of use. This helps not just with the production process, but allows the design to be changed, improved, and shared with others.

Summary
Digital manufacturing offers a viable alternative to centralized mass production for the creation of a variety of products. A successful design needs to be designed with the intent of this method of personal production, taking careful consideration with the selection of the manufacturing process, materials used, the geometry of the design itself, and its level of accessibility and feasibility. Providing documentation is extremely important to the success of a design's replicability and potential to grow and develop as an open source project. While personal production will certainly not replace mass production on a grand scale, in certain situations like low scale production for underserved audiences, it can be a more viable alternative.

Introduction

Thorough material analysis and ultimately selection, is crucial to the success of a functional physical product. There are a variety of determining factors which can influence the decision making process including functional requirements, material properties, the environment, manufacturing process, and human centered attributes. In the scope of this project it will be important to analyze and identify potential materials that are compatible with digital manufacturing methods. Additionally considerations must be made regarding the functional performance of the brace and recognizing which materials can withstand the forces being applied to it. Finally the needs of the end user must be taken into account when selecting materials for a product. In this case needs such as comfort, light weight, durability and aesthetic appeal will all have an influence on which materials are used for the final product. Examining materials that are traditionally used in the fabrication of orthotics can serve as a good starting point for analyzing tried and true materials, while also exploring ways of incorporating new and innovative ones.

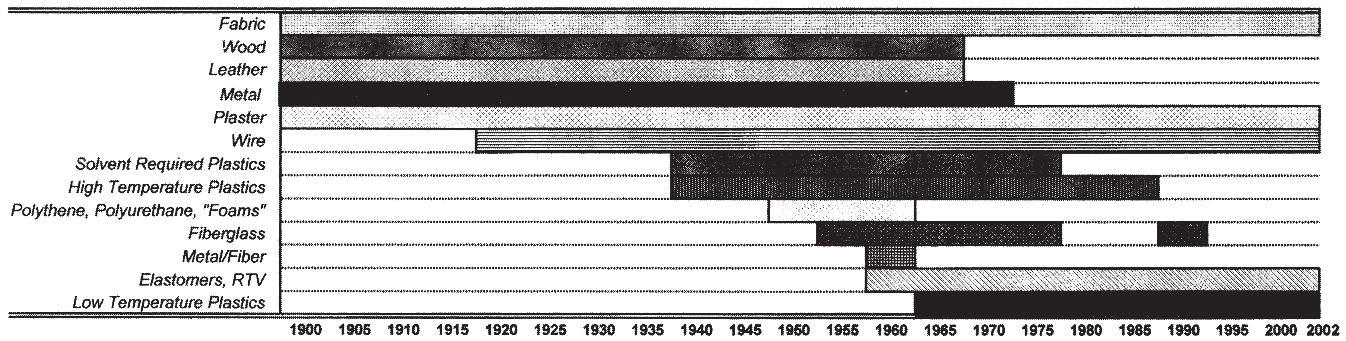
Materials Used in Upper Limb Orthoses

Ever since their first uses in ancient history, orthoses have been constantly evolving in design and material usage. The first splints were constructed of mostly organic materials, consisting of plant fibers, branches, fabric, leather, and natural adhesives. The usage of different materials often overlapped in time that of others, and from the 1900s onwards, there was no time frame during which only one material was available for splinting purposes. Many advances in materials used to fabricate splints were driven by material innovation during wars. During World War I, Plaster of Paris and aluminum were used to create a majority of splints for upper limb rehabilitation. After World War II, aluminum alloys were the materials of choice until the 1960's, playing a major role in the treatment of polio patients. At the same time a plastics revolution was well underway, and many new polymers were being developed like urethanes, silicones, and thermoplastics. These materials were revolutionary because the polymers were lightweight, strong, and offered greater flexibility for working them.

Today, many orthoses utilize a thermoformable plastic as the main splint material because it is very easy to create a custom fit orthosis with it. The plastic simply needs to be heated to a specified temperature, and in its glass-like state, can be bent and shaped over the desired body part, and as it cools it hardens again. Other materials frequently seen in modern orthoses include different kinds of elastomers like rubber bands for tension systems, fabrics and foams and other textiles for cushioning and strapping, and even spring steel or other small metal components for moving parts and fastening.

During the 20th century, major advancements were made in splinting material technology. The rapid transition of materials - from natural fiber based like wood and fabric, to metal and plaster, and eventually sophisticated plastics - was unprecedented. The advancements and adoption of new materials was largely credited to rapid development in combat and aerospace technology throughout numerous wars. Today splints are more effective than ever because of these material innovations.

Figure 30 - A graph showing the usage of different materials in splint applpications of time.



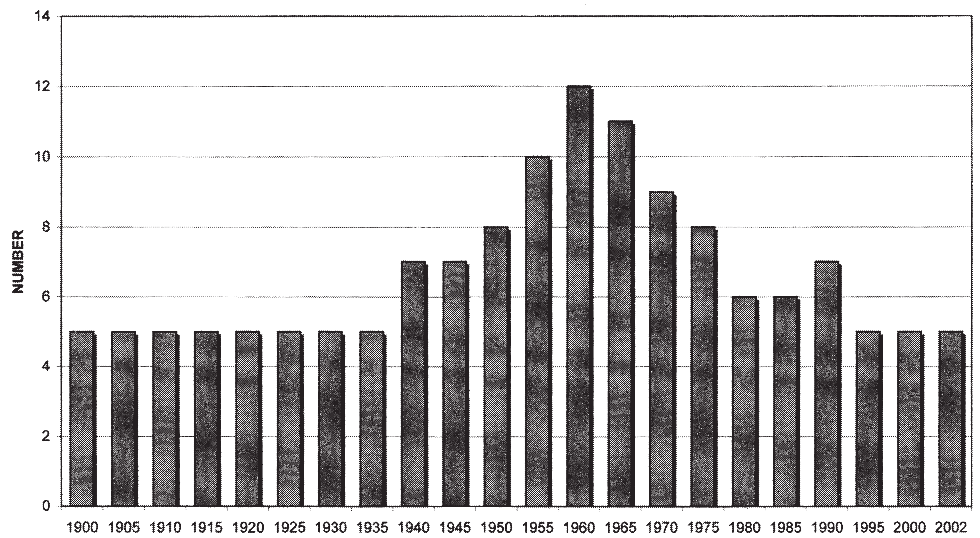


Figure 31 - A graph showing the number of materials simultaneously being used in splint applications over time.

3D Printed Thermoplastics

Many types of thermoplastic materials are used in the process of Fused Deposition Modeling (FDM) 3D printing. In this application the thermoplastic is fed into the 3D printer as a spool of filament. As it enters the printer's extruder, it is heated up to melting temperature, extruded out of the nozzle, and cools on the bed to form the part. There are many different thermoplastics available for use, but they vary greatly in their material properties, ease of use, and cost. I will examine a handful of the most common 3D printable thermoplastics that are available.

1. Polylactic Acid (PLA)
   PLA is by far the most popular 3D printed thermoplastic for multiple reasons. It is incredibly easy to work with, cheap, and is fairly stiff allowing it to be used for a wide variety of applications. It is also one the more environmentally friendly filaments because it is created from renewable resources in the form of crops such as corn or sugarcane, and as a result is biodegradable as well.

   Pros:
   a. Low cost
   b. Good stiffness and strength
   c. Good dimensional accuracy
   d. Very easy to print

   Cons:
   a. Low heat resistance
   b. Low chemical and UV resistance
   c. Brittle

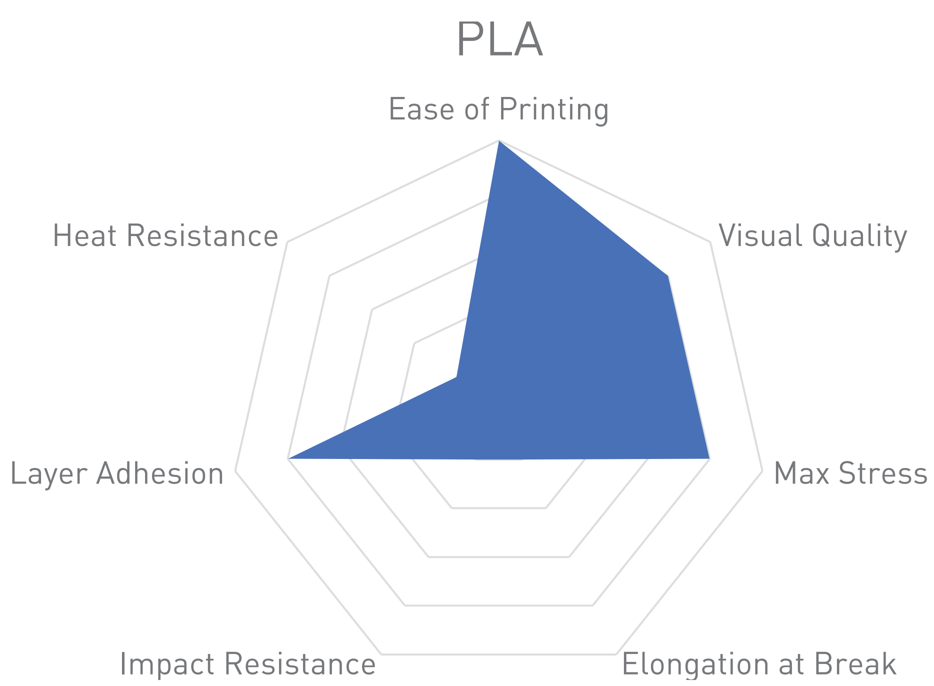


Figure 32 - Radial graph depicting material properties of PLA.

2. Polyethylene Terephthalate Glycol (PETG)
   PETG is a modified version of the plastic commonly used to manufacture water bottles. It is a semi-rigid material with good impact resistance, but a slightly softer surface. Benefits from great thermal characteristics. PETG is a good choice of filament for applications that require strength and good chemical/water resistance. PETG is regarded as an easy to print filament, and doesn't give off toxic fumes.

   Pros:
   a. Glossy and smooth surface finish
   b. Easy to print
   c. No harmful fumes
   d. Good chemical and UV resistance

   Cons:
   a. Poor bridging and stringing characteristics while printing
   b. Slightly more expensive than PLA

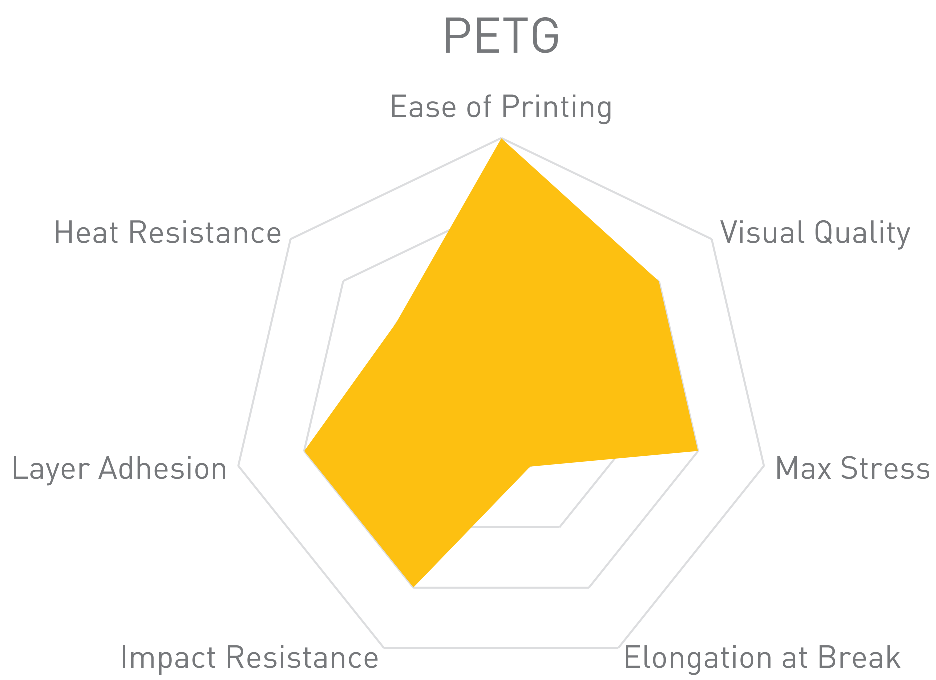


Figure 33 - Radial graph depicting material properties of PETG.

3. Acrylonitrile Butadiene Styrene (ABS)

ABS is a well known polymer in the product design industry. It is frequently used in injection molding and 3D printing. ABS is very popular due to its low cost and good mechanical properties such as its toughness and impact resistance. ABS also has a higher glass transition temperature so it is more suitable for higher temperature or outdoor applications. However when printing ABS requires significantly higher temperatures, gives off harmful fumes, and is prone to warping. It is generally accepted that ABS is a more difficult material to work with because of this.

Pros:

a. Low cost
b. Good impact and wear resistance
c. Good print quality and surface finish
4. Excellent heat resistance

Cons:

a. Very prone to warping while printing
b. Requires heated bed and printing enclosure
c. Produces toxic fumes while printing
d. Parts tend to shrink leading to poor dimensional accuracy

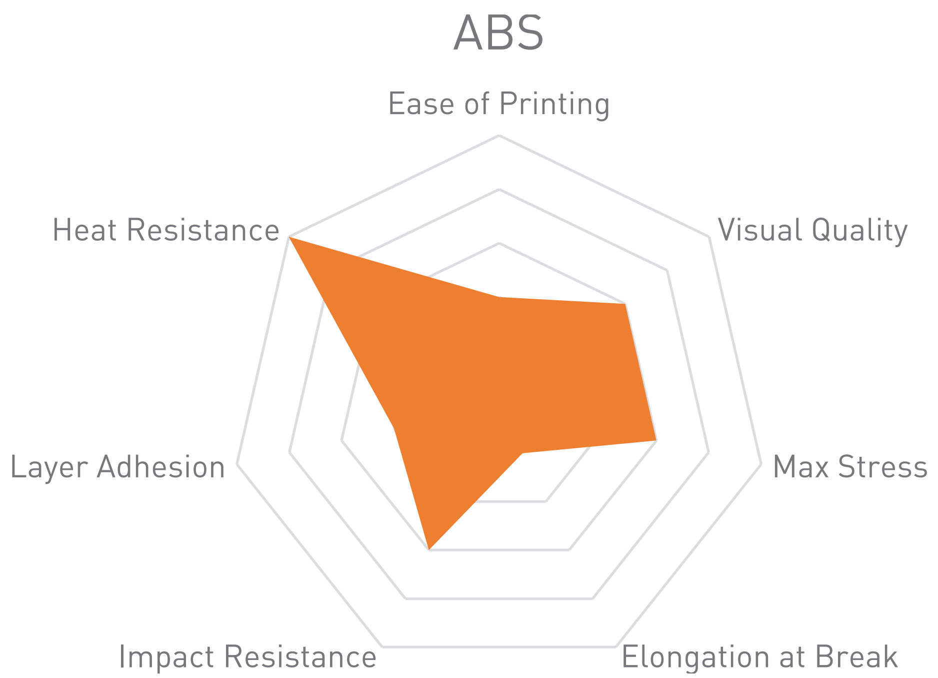


Figure 34 - Radial graph depicting material properties of ABS.

4. Thermoplastic Polyurethane (TPU)

TPU is a unique material because it is an elastomer composed of hard plastic and rubber, allowing the material to stretch and flex. TPU is the most common elastomer to be used with 3D printers. Different brands of filament will have a varying level of elasticity and stiffness depending on the durometer of the material. One caveat is that in order to print this filament successfully, the printer must be equipped with a direct drive system, which may incur slightly higher costs of the machine.

Pros:

a. Flexible and soft material
b. Excellent vibration dampening
c. Long shelf life
d. Good impact resistance

Cons:

a. Higher difficulty to print
b. Requires direct-drive extruder
c. Higher cost of filament
d. Much slower printing speed

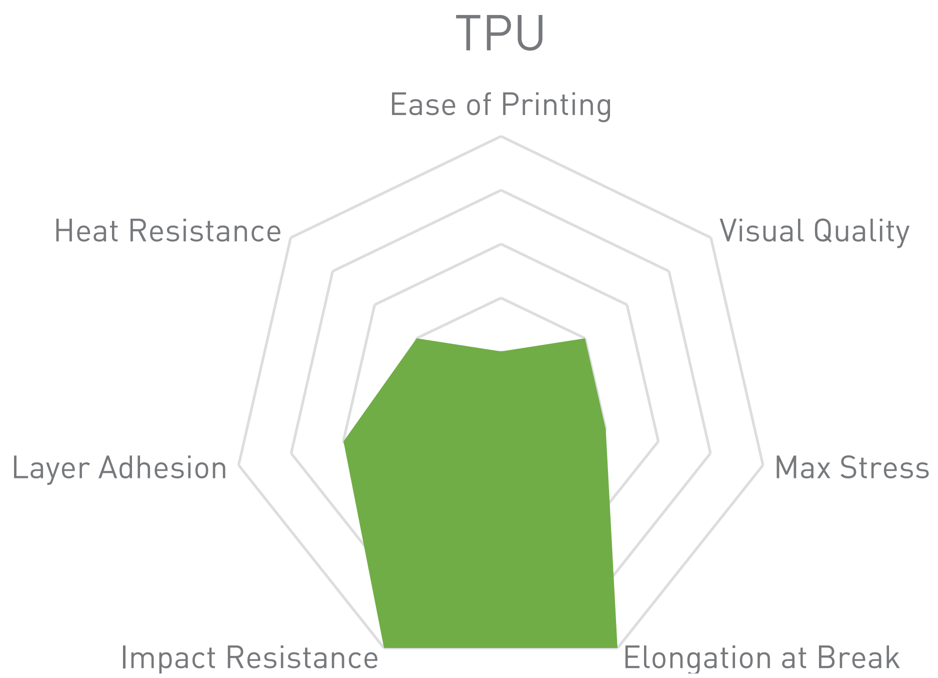


Figure 35 - Radial graph depicting material properties of TPU.

Fabrics, Foams and Textiles

Fabric, foam , and textile materials offer numerous advantages in orthosis design and fabrication. The main draw to using these materials is their flexibility, warmth, and comfort that they provide. Traditionally fabrics and textiles were the main composition of orthoses because of their flexibility, ubiquity, and ease of manipulation. While today's orthoses have shifted more to the use of plastics for the main splinting material, we still see the use of fabrics, foams, and textiles for two main applications: strapping and padding.

1. Polyurethane Foam
   Polyurethane foams are used in varying densities as padding material underneath the thermoplastic body or shell of the orthosis. They are manufactured in a variety of thicknesses and sizes, as well as with adhesive backing for easily applying to the splint. These foams are offered under a variety of different brand names, with manufacturers combining different additives for changing the foam's viscosity and density. A notable variety is known as memory foam.

2. Woven Cotton (Moleskin)
   A heavy cotton fabric noted for its softness and durability. Commonly known as Moleskin, it is a soft, dense, and thick cotton cloth that protects exposed skin against painful blisters, calluses, and hot spots caused by repeated movement or friction. This product is also available with an adhesive backing for easy application to the skin or other surface.

3. Fleece and Felt
   A more common material that is still used in the construction of splints are fleece and felt textiles. These are warmer and softer materials that provide cushioning, padding, and next-to-skin comfort. Felt can be made of natural wool fibers, rayon, or a blend of the two. Artificial fleece is commonly made of polyester.

4. Hook-and-loop Strapping
   More commonly known under the name Velcro, hook-and-loop strapping is an incredibly versatile and widely used material. These strap systems are generally composed of two components: two fabric strips which are attached to the opposing surfaces to be fastened. The first component features tiny hooks, while the other has loops. When pressed together the hooks catch on the loops and the two pieces are fastened temporarily.

Metals, Elastics, and Wires

These materials comprise smaller miscellaneous components of dynamic splints. This includes the tension systems, various screws, crimps and other fasteners, and other small moving parts.

1. Spring Steel
   As the name implies this is a type of steel that has a very high yield strength, enabling it to return to its original shape despite significant deflection or twisting. Spring steel is commonly used in dynamic orthoses for tension systems that return the fingers or joints to their resting position. These may come in the form of traditional coiled springs, or less commonly flat springs.

2. Elastic Bands
   These are no different than common office supply rubber bands. They are available in a variety of durometers that affect their elasticity, making them stronger or weaker. In most orthoses they attach to the outrigger system to provide tension to the fingers or joints, and bring them back to resting position.

3. Wires
   There are 2 main types of wires used in orthotic devices. The first is made from steel produced in a variety of diameters. Steel is known for its strength and durability, but at the same time adds weight and is prone to corrosion. Steel also will wear faster against other softer materials. The other type of wire used is a nylon based wire that is similar to fishing line. Nylon wire is extremely strong, durable, light weight, and can be manufactured in a variety of colors and transparencies.

Introduction
The analysis of a user profile is typically conducted during the design phase of a project, usually with strong implications which influence the decision making process. In the context of this project however this examination is just as important during early explorations of research in order to better understand the user's condition and occupational situation. This project offers a unique opportunity of working with a "super-user", where the end user is also a designer, and as a result heavily invested in the project outcome. Furthermore the nature of the condition constitutes the need to have a very close relationship between designer, user, and physical therapist in order to properly design a solution which meets the biological and occupational needs of the user, and is validated by a medical professional.

The User
Name: Fabio Di Liberto
Age and Gender: Middle-Aged Male
Occupation: Brand Innovation Consultant and Professor of Design
Family: Married, father of three children and a dog
Personality: Very extroverted and personable individual. Does well in social situations and is empathetic.
Lifestyle: Fabio leads a dynamic, busy lifestyle; he enjoys exercising and working with his hands
Activities: Cooking, sewing, DIY, plant care, walking the dog, running during lunch, doing pilates

Diagnosis
Fabio was involved in a motorcycle accident 8 years ago and sustained severe injuries. He was affected by a fractured humerus, which severed his radial nerve. He underwent multiple surgeries including a nerve/tissue transplant at an attempt to regain function and innervation of his left arm.

Fabio's diagnosis can be considered unique because he suffers from a permanent condition of radial nerve palsy. Most patients that suffer from radial nerve palsy recover from non-operative treatment, or they respond positively to surgery. Rarely does this condition lead to a permanent paralysis of the muscles innervated by the radial nerve.

While Fabio's condition mainly affects his upper appendage, the impact of the paralysis has begun to affect his overall body posture, including recurring epicondylitis (inflammation of the tendons surrounding the elbow) of the right arm due to overloading and overcompensating.

Radial Palsy has negatively affected the user in everything from minor to major day-to-day activities. This includes but is not limited to:

- Getting dressed (zippers and buttons, tying shoes)
- Cooking (using utensils, draining pasta, slicing/buttering bread)
- Hygiene (wash face/hands, shave, bathe)
- Exercising (yoga, riding a bike, stretching)
- Travel/Commuting (holding onto metro/tram railing, driving, carrying bags)
- Intimacy (picking up daughter, holding/dancing with wife, hugging, massage, etc.)
- Hobbies (playing cards, sewing, reading, using a camera, DIY, making art, playing piano)

The human hand plays such a vital and distinct role in our daily lives, and the loss or partial loss of functionality can be realized very apparently. Over the years Fabio reports that he has been able to cope and treat his condition through therapy and assistive devices. According to him, the biggest challenge about living with Radial Nerve Palsy is *"Retraining your brain on certain things you would naturally do but can't do anymore. It's the small things."*

Treatment
The loss of dexterity and movement of his left hand has affected nearly every aspect of Fabio's life. In order to recover the lost extension in his forearm, wrist, and fingers, Fabio has undergone numerous surgeries and physical treatments. This includes exercises with a professional physiotherapist, and the use of different orthotics to restore mobility.

Immediately after sustaining injuries from his accident, Fabio underwent major surgery to reset his fractured humerous, and also attempt to repair his damaged radial nerve. While most patients experience a recovery after surgery, Fabio never regained functionality of his radial nerve.

Fabio maintains a steady exercise and therapy regimen under direction from his physical therapist that has extensive working knowledge of his condition. This includes going to see the therapist in person, in order to monitor his progress and recieve feedback, as well as completing exercises on his own that his therapist has instructed him to do. Continual exercise of the appendage ensures it does not atrophy, and helps to buuild strength and maintain full motion of the joints.

Perhaps the most important and frequently used method of treatment is the utilization of an assistive arm brace. These orthoses are designed specifically for nerve injuries where there is a loss of muscle function in the upper apendage. These devices help to stabilize the wrist and hand but also help restore extensor functionality.

Fabio has used primarily 3 different orthotic braces/splints over the years:

1. Ro+Ten Brace: This is Fabio's preffered brace because it is the most functional and restores the most movement of the wrist and individual fingers seperately. However it is cuumbersome, high profile, and looks medieval. Wearing this brace can also be a safety concern because the user frequently gets caught/stuck on things due to its protruding outrigger structure that can also bump into people or objects.

2. Benik Brace: This is the most comfortable brace because of its neoprene material. It is also convenient because it is low-profile and doesn't require the user to remove it before/after taking off a jacket. It also dries fast so its good for activities like exercising or swimming. On the other hand, it lacks some functionality due to the wrist being completly fixed, and the thumb is quite handicapped as well.

3. Saebo Glove: This brace can be considered the most innovative or high-tech of the three. It looks cool, and the individual O-rings which control tension of each joint work quite well. It enables articulation of each joint, and the tension is also adjustable depending on the user's needs. However the glove covers the fingers and most of the palm, leading to loss of sensitivity and tactile feedback. Additionally, it is complicated and time consuming to put on, the O-rings constantly fall off, and leads to fatigue after 1 or 2 hours of use.

Other products/tools that Fabio has used or tried including simple wrist braces, wrist bands, modified gloves, elastic bands/materials, single finger splints, and even kinesio tape.

Overall, the user is dissatisfied with the treatment options offered worldwide and is actively searching for an alternative solution. A more in-depth product analysis will be conducted to better understand the strengths and shortcomings of the above mentioned braces.

Social Stigma

Generally, there is a stigma associated with physical disabilities, and can be a difficult thing for patients/users to deal with especially in social situations. Fabio doesn't seem to be affected by this due to his extroverted and confident personality, but it is something he notices and is aware of. In fact, he thinks it is an interesting concept to wear the brace as a "piece of jewelry". He has had many encounters with other people that started because they noticed his arm brace. He also notes that his children can sometimes experience secondhand discomfort because of this. While this may not be a big issue for Fabio, the physical appearance and aesthetic of the orthotic should be a design consideration for a more universal design, and to enable others who are not so socially comfortable.

Prognosis and Outlook

As stated earlier, Fabio is still searching for a more adequate orthotic device that will mesh more easily with his lifestyle. According to him, there is an utmost importance on the functionality of the brace, with the strong desire to have it integrate more seamlessly with his body and be more "low-profile".

Working with Fabio provides a unique experience to work with a "super-user" (a designer with said disability) towards an end product that suits his biological and occupational needs, while also gaining invaluable feedback and insight due to his design sensibility. Fabio describes this duality of being both a designer and end user as having created "an obsession" to find the perfect solution to his needs. It will be important to work closely with the user and their physical therapist closely in order to continually develop, modify, and validate a successful solution.

This project hopes to address all of Fabio's needs while developing a new and innovative orthotic solution that can be replicated and accessed by anyone living with a similar condition.

Introduction

This section aims too take an in-depth look at the three different arm braces that the user has experience interacting with. From both user feedback and design observations, the goal is to identify which aspects of these products work well and conversly which aspects are a hinderance.

Arm Braces

1. "Ro+Ten" Outrigger Brace (Bunnell-Oppenheimer Type)

   This style of brace/splint is one of the oldest and classic used splints for radial palsy or users with loss of hand/wrist movement. This is the user's most preferred wrist brace to use, accounting for roughly 60% of his usage. What the user likes most about this brace is it's high level of functionality above all else. According to the user this brace gives him the most restored functionality of his fingers and wrist. On the other hand the level of comfort and physical size can be limiting in certain situations and over long periods of wearing it.

   One of the biggest gripes the user has about this brace is that it is a "high-profile" brace, meaning it's physical size and awkwardness prevent the user from doing certain things like putting on/taking off a jacket. While this may seem like a trivial issue, it is of great importance to the user because of the time and inconvenience it takes to remove and equip the brace every time.

   The aesthetic appearance of the brace itself is unappealing and medieval. For the user, this is not exactly an issue because of his extroverted personality and indifference to the stigma that surrounds it. In fact the user reports forming many new relationships due to the conversations he has regarding his arm brace. However for other users the physical appearance can be quite important, and can lead to social awkwardness or embarrassment from literally wearing one's medical condition on their sleeve. There is a definite opportunity to design the brace to a more unique aesthetic and attractive aesthetic.
   The user reports semi-frequent breakage of the rubber bands that provide elasticity to the fingers, which requires him to replace them with a non original hair band. The entire brace itself requires replacing after a certain amount of time and wear, requiring the purchase of an entirely new assembly.

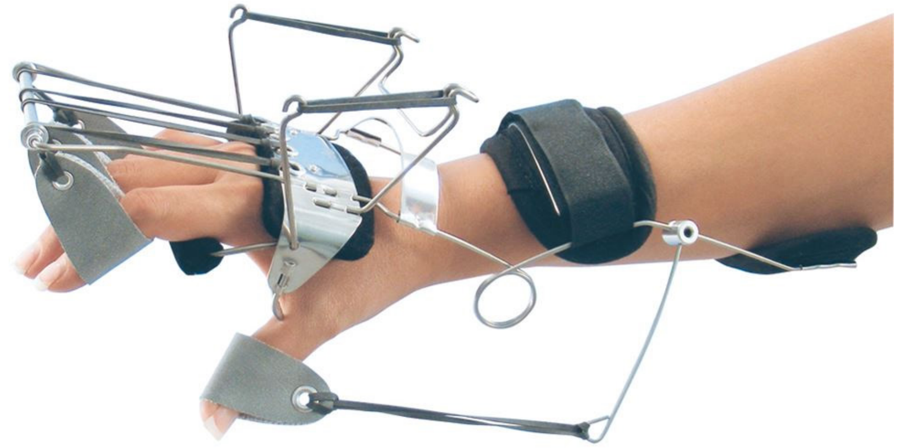


Figure 36, 37 - Photographs of common Oppenheimer outrigger type mobilization splints.

2. Benik Brace
The user reports using this splint approx. 40% of the time. This splint is reported to be the most comfortable of the 3 products. Made from a thermoplastic material and neoprene, it's able to be molded to the patient's forearm, and can be used in the water as it is quick to dry. One of the user's biggest compliment of this brace is it's low profile and slim, allowing the user to remove/equip a jacket without having to remove the brace.

On the other hand, this splint allows less flexibility, with the wrist being completely braced. This may result in a higher grip strength, at the cost of less mobility and functionality of the hand. The Benik brace restores extension of the digits but the thumb is the most penalized and suffers from less mobility. The splint also offers an arguably more aesthetically pleasing appearance because it does not utilize an outrigger mechanism. With this brace the fingertips remain exposed, allowing greater sensitivity and tactile feedback, which is noted as being very important to the user.

With this brace there is little to no long term maintenance involved, with fewer moving parts, and less likely to break over time. We can safely consider this brace to be the most durable of the three in use, resulting in lower cost overtime. Total product weight is approx. 156 grams and product cost approx. $150 USD.

Figure 38, 39 - The front and back of view of the Benik neoprene brace.

3. Saebo Glove

The Saebo Glove is a high end hand/wrist splint that restores extension to the digits. It is a lightweight and low profile design with multiple levels of adjustability that can be changed on each digit independently. The individual O-rings that provide tension and elasticity lead to a highly functional device, with full articulation of each finger joint, but does still have its drawbacks

The Saebo Glove is complex and time consuming to take on and off, and as a result does not fit well with the user's lifestyle. The user also reports that the O-rings frequently fall off, and need to be replaced with the provided ones. The splint uses a variety of materials such as cloth, plastic, and silicone. User reports a high build quality and construction.

While each finger can be extended and articulated very well, the wrist and lower forearm are splinted (fixed). Additionally while the palm is exposed, the entire fingers are covered in fabric, which is not pleasing to the user due to loss of sensitivity. The user also reports fatigue after wearing the glove for extended periods of time (2 hours or more). The user rarely, if ever uses this splint due to the reasons stated above. Cost is ~$300 USD.

Figure 40, 41 - Front and back views of the Saebo Glove.

2. BRIEF
2.1 Design Opportunity

Design Opportunity
Radial Nerve Palsy and it's associated symptom known as 'wrist drop deformity' consist of loss of wrist, hand and thumb extension. The resulting functional impairment to the hand is significant and can have a drastic disabling effect on a person's day-to-day life. Orthotic devices such as splints and braces, paired with closely monitored physical therapy can be a beneficial recovery and assistive tool. There are many orthotic devices in use to assist patients with radial nerve palsy and restore function to the wrist and hand. Some of these devices work very well functionally, but can be a hassle and burden for many aspects of daily life. Moreover these medical devices can come at a high cost to the patient, and more often than not require customization and professional fitment.

The goal of this project is to design, prototype and validate an accessible and open-source arm orthotic for a user with permanent radial nerve palsy. The orthotic should help recover wrist and finger extension, enabling the user to perform basic daily functions and live a normal lifestyle. While it is important that the brace has a high level of functionality, it also needs to assume a level of comfort and aesthetics, to seamlessly integrate with all aspects of the user's lifestyle.

The exposed implications and benefits of open access design and rapid manufacturing technology that were discovered during the research phase of this project, will be leveraged during the design phase in order to achieve a concept which not only satisfies the requirements of the design brief, but also serve as a foundation for further innovation and improvement across space and time. Furthermore, the concept that is developed will serve as an example of the opportunities that design technologies offer to restore abilties to specific users within the fields of braces, prosthetics, and medical devices in general.

Functional Design Goals
- Design an orthotic that restores extension functionality and movement of the wrist, fingers and thumb. The design should work in parallel with the natural biomechanics of the hand, wrist and forearm, and not inhibit movement in any way.

- Provide all day comfort and reduce or eliminate the amount of fatigue that the user experiences from wearing the orthotic.

Physical Design Goals
- Design a more low-profile arm brace that minimizes interference with the user and their environment. Current orthotics in use such as the Oppenheimer splint are bulky and awkward, and require the user to equip and remove them several times a day.

- A design which is robust, with fewer and easily replacable parts in order to simplify manufacturing and assembly, as well as reducing long term maintenance. This will benefit the ability of the orthotic to be manufactured anywhere in the world using commonly sourced materials and parts, as well as lowering the barrier of accessibility, by being more affordable and durable.

Accessibility Design Goals
- Design with the intent to be manufactured with primarily 3D printing or other digital/distributed manufacturing methods. This method of manufacturing will enable people to access care no matter where they are. Even people in 1st world countries can struggle to find reliable and affordable access to healthcare products and services. This issue is even worse in low income and remote communities where there is no well established supply chain or healthcare network.

- Design with the intent of releasing the project/product as open source. (Design under an open source license). Designing hardware and products under an open source license have documented benefits to innovation and cooperation. Developing this orthotic as an open source device would enable anyone to access and use it for free, but also open the door to a network collaboration and improvement over time.

Design Process
Creating a structured design process is essential to ensuring that the design opportunity is taken full advantage of and that as many design goals are met as possible. In this way the project achieves more transparency, organization, efficiency, and ultimately leads to better design results where solutions have a direct and clear connection to the problems which they aim to solve.

From the very beginning, it was clear that there was the need to harness a Human Centered Design process. The 'Human Centered Design' (HCD) process was a term and process coined and pioneered by the renown design company IDEO. Tim Brown, the executive chair of IDEO describes design thinking in general as "...a human-centered approach to innovation that draws from the designer's toolkit to integrate the needs of people, the possibilities of technology, and the requirements for business success." A HCD is a creative problem solving process that places the user at the very center of the project. Solutions generated through this process have immense possibilities of adding value to the user's life which are tailored to their needs.

The Human Centered Design process (HCD) can be broken down into 6 basic steps:

1. Observation - The first step is about learning directly from the end user by engaging in conversation, observing behavior, listening to their needs, and using empathy to place yourself in their situation.

2. Ideation - Taking the information gathered during observation and begin brainstorming on it, generating as many ideas as possible.

3. Rapid Prototyping - Creating simple and quick prototypes allows the process to spring from the ideation phase and begin exploring concepts which can be tested with the user.

4. User Feedback - This is the most critical phase of the process. Testing these rapid prototypes with the user initiates another phase of observation.

5. Iteration - This phase is all about building upon what we learned during user feedback sessions, improving the concept, and producing higher quality prototypes.

6. Implementation - After many cycles of prototyping, feedback, and iteration, a solution has the opportunity to be validated based on user feedback and design goals that have been achieved.

Identifying User Pain-Points

While this particular Oppenheimer brace has been analyzed during the research phase of the project, it was important to more specifically understand where the orthosis fails the user, and where improvements can be made. A more in depth analysis was carried out by observing the user wearing the orthosis and listening to testimonies. It is important to identify these pain points early on in the design process in order to have a greater understanding of the user-product relationship in context, and a better chance of being able to design a superior solution that fits their needs.

While the user praises this type of orthosis because of its overall good mechanical functionality, there are many shortcomings that the user experiences in daily life which deserve attention.

1. The first and most apparent is the striking physical appearance of the brace and its bulkiness. The many different outrigger attachments protrude from the brace at different angles and directions. When worn the brace is dimensioned at approx. 35x12x10cm, occupying an envelope of 4.200 cubic centimeters.

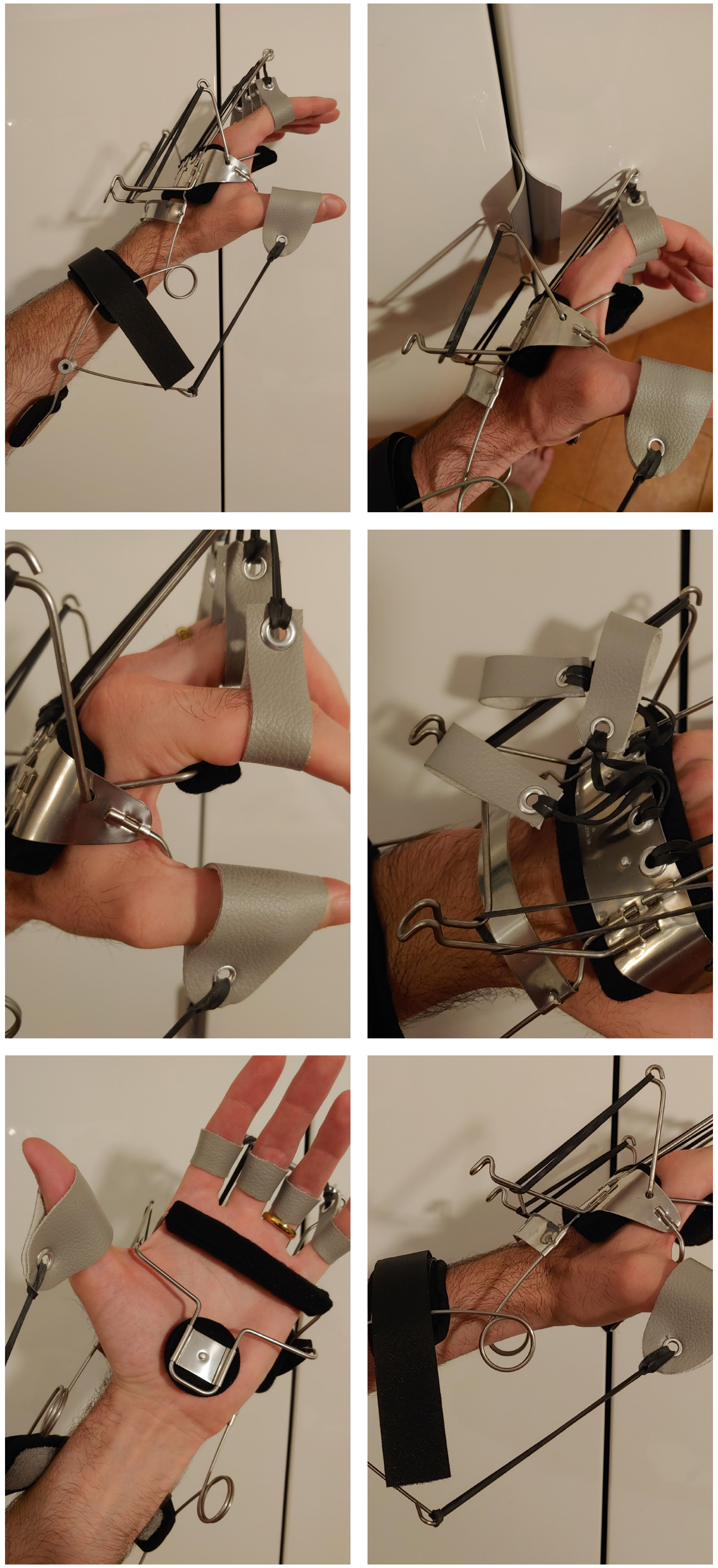
2. The general bulkiness and protruding outriggers can frequently get caught on objects in the surrounding environment, creating a hazard.

3. Rubber bands are used as elastic elements which replace the function of the extensor muscles. While this is a simple method, the rubber bands frequently go bad or break, and the user has reported substituting them with hair bands.

4. When the slings are removed from the fingers there is nothing holding them in place, and they often go flying and get tangled.

5. Due to the design of the orthosis, a large portion of the palmar surface of the hand is obstructed, causing loss of touch sensitivity, and interrupts many daily activities such as working out, sports, and even clapping.

6. The outrigger for the thumb does not rotate with the hand, and is instead fixed on the wrist portion of the brace. This exerts tension on the thumb when the wrist is being bent, and places counter tension on the wrist when in extension.



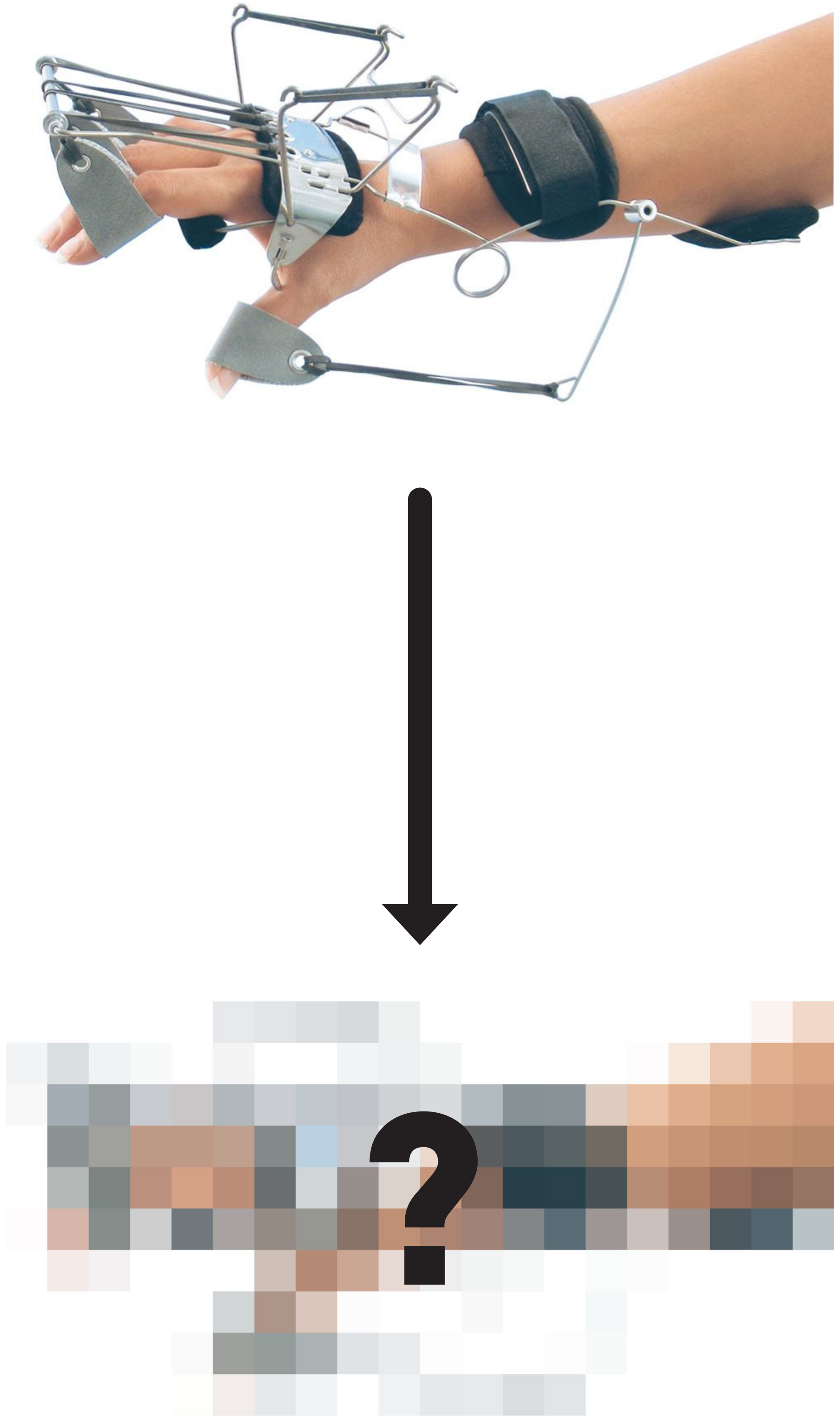
Design Rationale

Based on many in-depth interviews with the user and analyzing their needs, habits, and behaviours, the decision was made to focus on designing a new outrigger type brace based on the Oppenheimer design. This was done for a variety of reasons:

- The outrigger type brace is the most widely used brace in clinical applications because of it's effectiveness and rehabilitative ability.
- The user prefers this type of brace among the other's they have tried because it is the most comfortable, easiest to use, and is the most functional.
- This type of brace has been changed very little over time, and offers the most opportunity for creating an innovative and disruptive solution.
- The outrigger type brace is a comparatively "low-fi" solution against the other braces, and a result has great potential to be easily replicated and using simple and readily available materials.

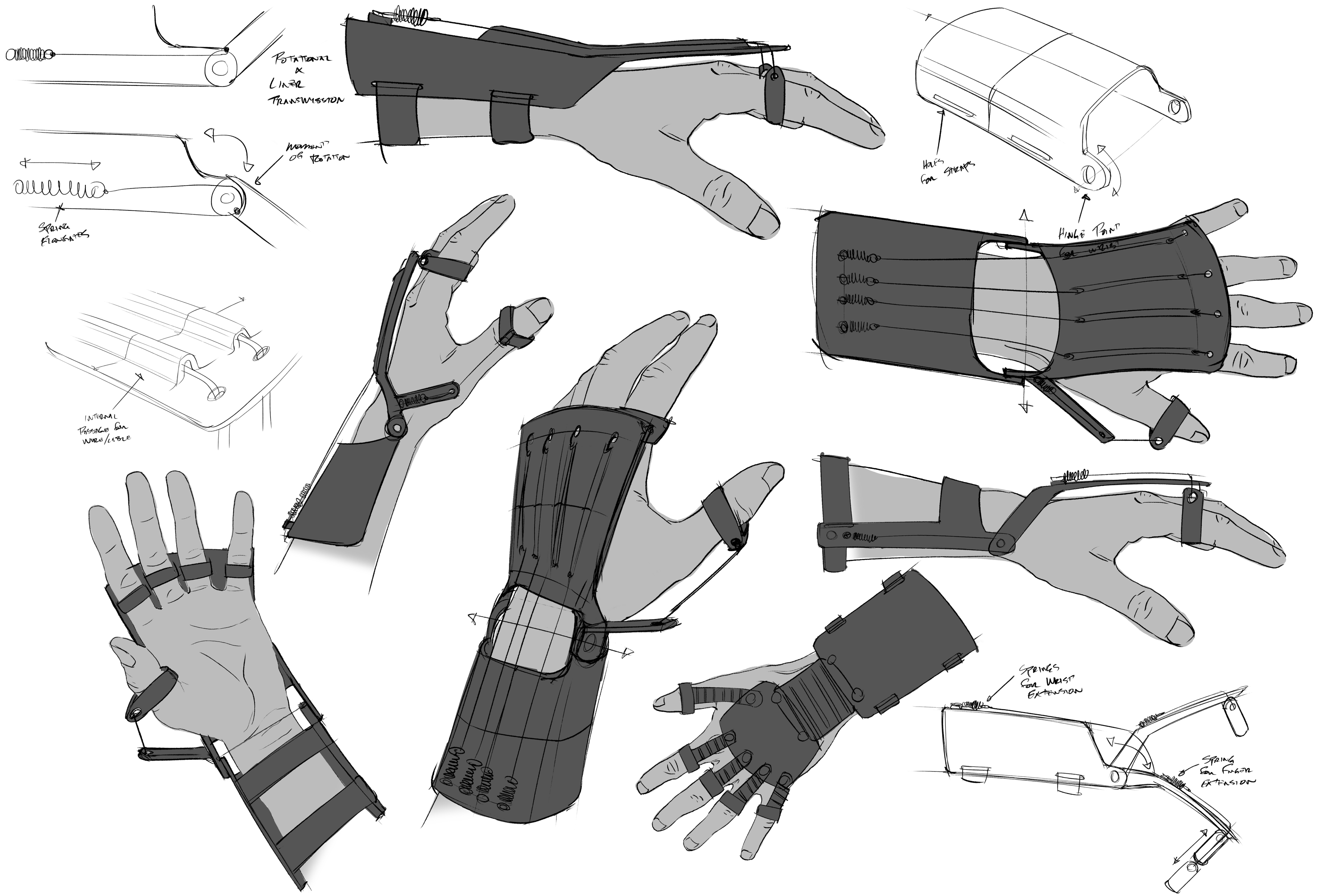
This approach was taken in order to feasibly create a satisfying solution within the time span of the thesis project (6 months). Arriving at a solution which satisfies the requirements of the original thesis brief, while at the same time creating a solution which satisfies the needs of the user, is the most important goal of this project.

A realized product which is fully functional, comfortable, easy to manufacture and replicate, economical, and most of all accessible, will be considered a successful representation and proof of the research and design conducted in this thesis project, and will serve as a stable foundation for further development and improvement.



3. CONCEPT D`ESIGN

3.1 Initial Ideation



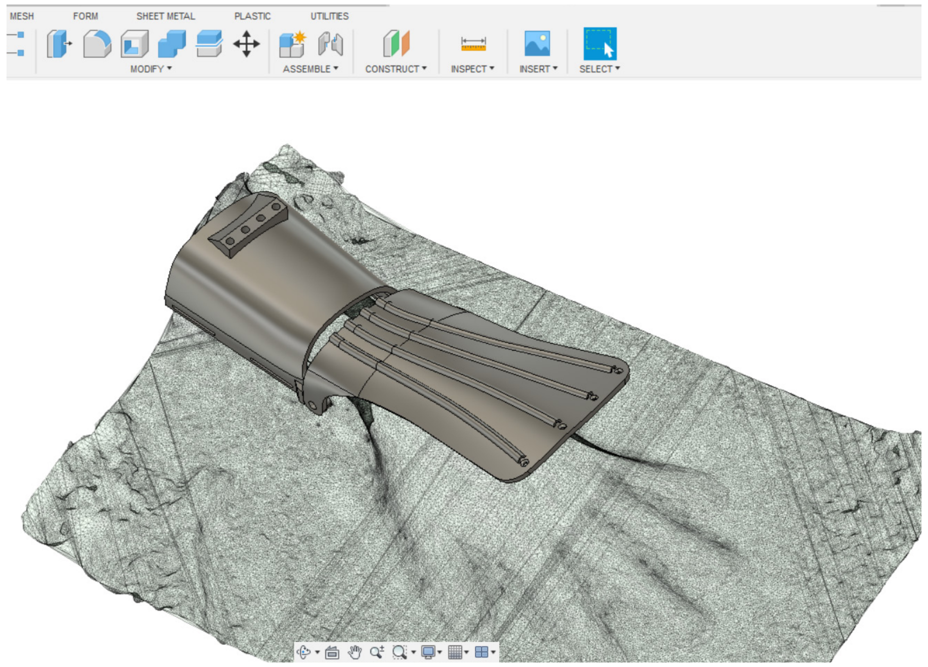
Digital Fabrication for Rapid Prototyping

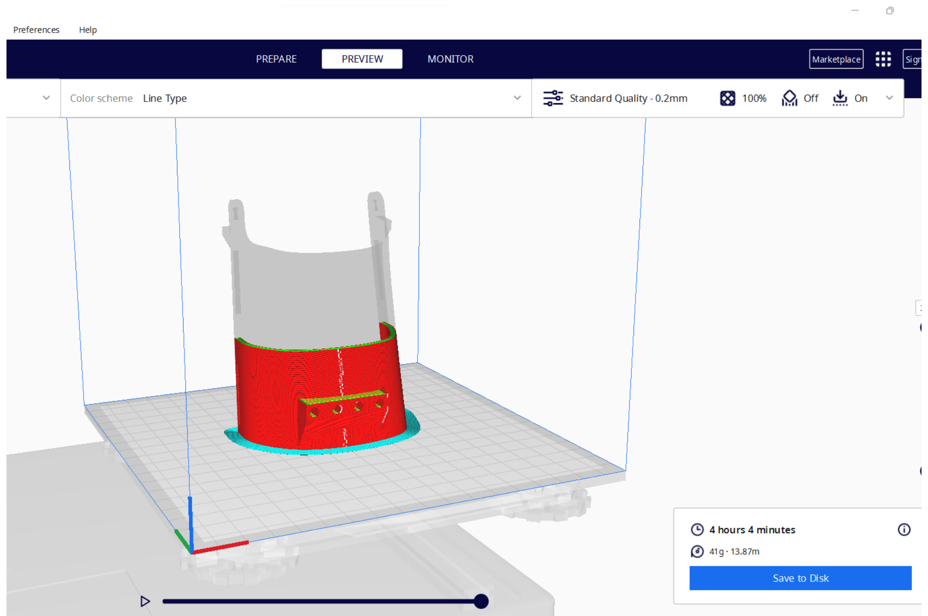
3D printers and other digital fabrication tools offer immense capabilities for creating relatively quick but more importantly accurate and high fidelity mockups. Traditional methods for creating prototypes consisted of much more labor intensive processes like cutting, carving, and sanding different materials like foam or wood, usually producing a semi-functional or completely aesthetic prototype. The mass proliferation of 3D printers in the last decade has led to the creation of a much more economical and accessible tool which is now common for individuals to own.

Using a 3D printer in the context of this project allows us to create highly customizable, accurate, and most importantly fully functional prototypes. A 3D printer also fits the ideology behind Human Centered Design extremely well, where iterations are completed often and need to be individualized.

The general process of creating a rapid prototype with 3D printing is to first create a 3D CAD model of the object to be produced. That digital model is then put into a slicer software, where parameters can be changed such as printing speed, material specifications, and much more. The slicer software then slices the model into individual lines of G-Code, which the 3D printer can read as instructions, and finally print the final model into a tangible object.

Even though 3D printing is heavily used in this project, there are still some manual processes in order to make the prototype fully functional. This includes any post processing such as trimming and removing support material, adding fasteners and assembling the prototype together with other components. In this case springs, nylon wire, screws, and finger slings are assembled together to get a working dynamic orthosis for the user to equip and test.





Product Testing Session

As stated earlier, the most important phase of the Human Centered Design process is engaging with the user, and getting hands on feedback about the prototype in use. This can involve direct questioning, receiving user testimonials, or simply observing the user perform activities and their behavior. During the first user testing session, there was expected to be a large amount of feedback due to the level of development of the initial prototypes, and this was the first time observing the user in person.

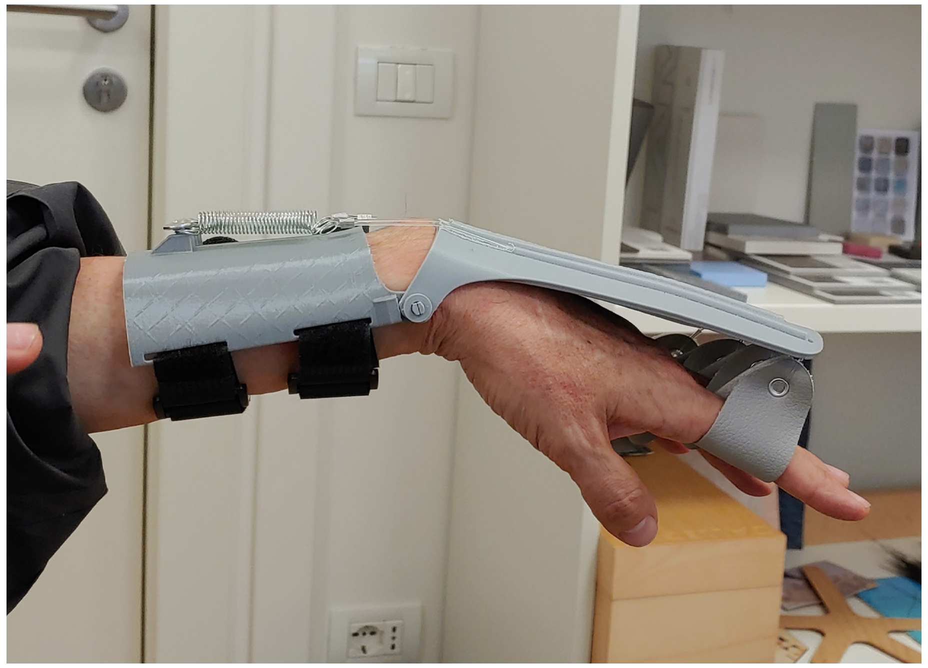
The first round of testing was successful in many ways because it reinforced certain design decisions and revealed many shortcomings early on in the design process. Initial physical fitment was close, which was an indicator that bodily measurements were taken and used correctly. As far as the functional assessment, many issues were pointed out indicating the need to make changes to the design. These included:

1. The user absolutely preferred and needed the brace to provide movement about the axis of the wrist. One of the concepts that was tested was a one-piece design which kept the wrist fixed. The user ultimately preferred the concept that had wrist functionality.

2. Springs fixed toward the end of the wrist portion of the brace, further up the forearm, were connected to finger slings via nylon filament. While this consolidated the springs out of the way and away from the hand, the routing of the filament interfered with wrist extension.

3. There was not enough spring tension in order to keep the wrist bent in extension in a normal resting position. Spring tension/ method of force would need to be revised in further iterations.

4. This design concept proposed a "low profile outrigger design" which substantially reduced the bulk of the orthosis, and deleted many protruding wires and outriggers seen in the Oppenheimer orthosis. This was positively received by the user, however the outrigger height would need to be increased in order to keep the phalanges at a proper angle in extension during a natural resting position.



Design Revisions

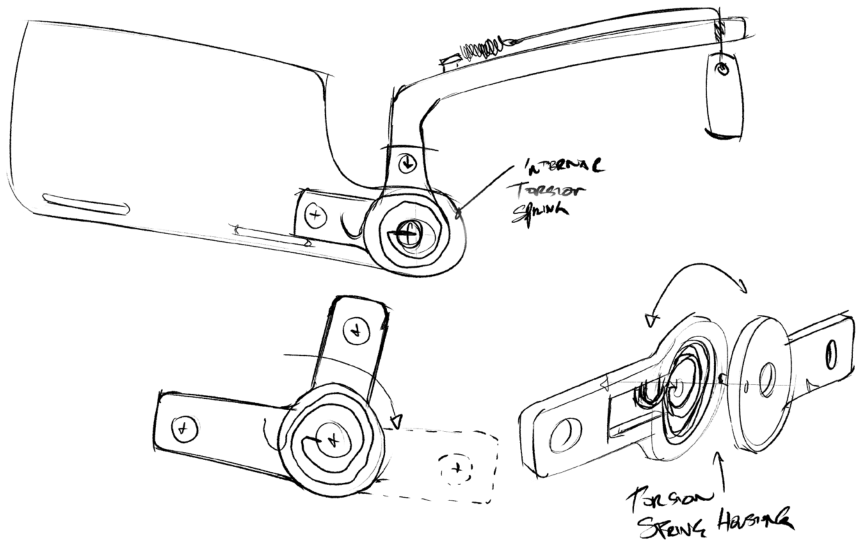
After the first round of user testing, and obtaining key takeaways, new directions could be explored and built upon to create the next round of design iterations. Again due to the nature of 3D printing, miniscule or drastic changes could be made to a design and then prototyped in a matter of minutes or hours. An added benefit of 3D printing is that it is a relatively passive activity; the printer can be producing the next prototype, and meanwhile the designer is able to work at the same time on other tasks.

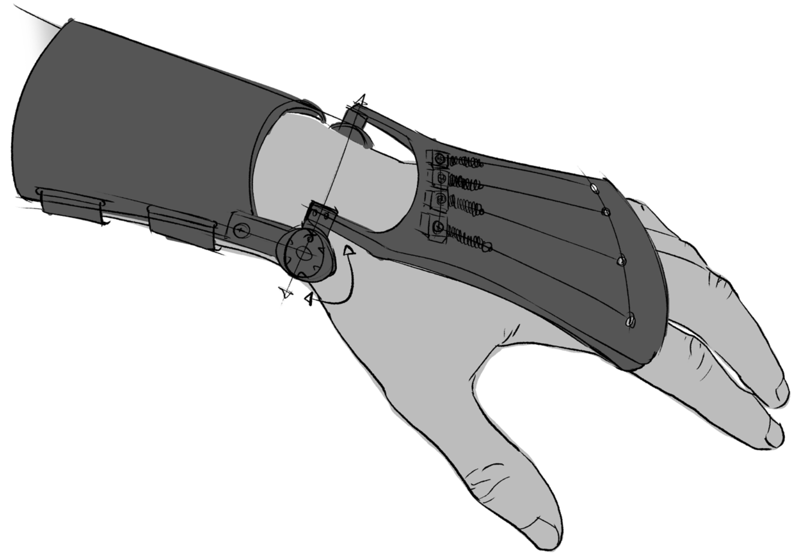
During this design stage, the mechanism for creating spring tension necessary for holding the wrist up was thoroughly thought out. One method that was explored was applying a linear spring to a rotational movement by way of an idler pulley. This would relocate two springs to the side of the wrist gauntlet, and would attach to the pulley with the same nylon filament. However during prototyping sessions, the mechanism was placing too much stress on the crimps for the filament and slippage would often occur. This also required a higher load spring, which put more stress on the gauntlet itself, and stored an immense amount of energy, which could be a hazard if anything broke and the spring went flying; which it did multiple times during testing.

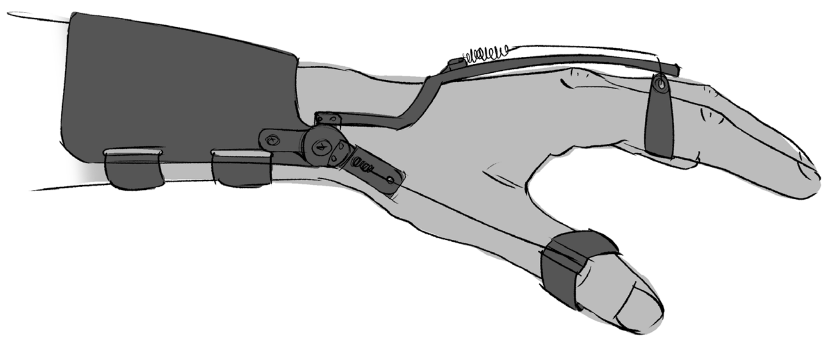
Another direction was to integrate a torsion spring directly into the wrist joint of the orthosis. This would be a similar mechanism to the Oppenheimer brace which has been proven effective, but would result in cleaner packaging because the wrist would be fully contained within a plastic housing. The spring used is a commonly found door handle spring of 2.5mm in thickness. This spring is able to provide adequate force when properly pretensioned, is a standardized part that is easy to find, and is relatively low profile.

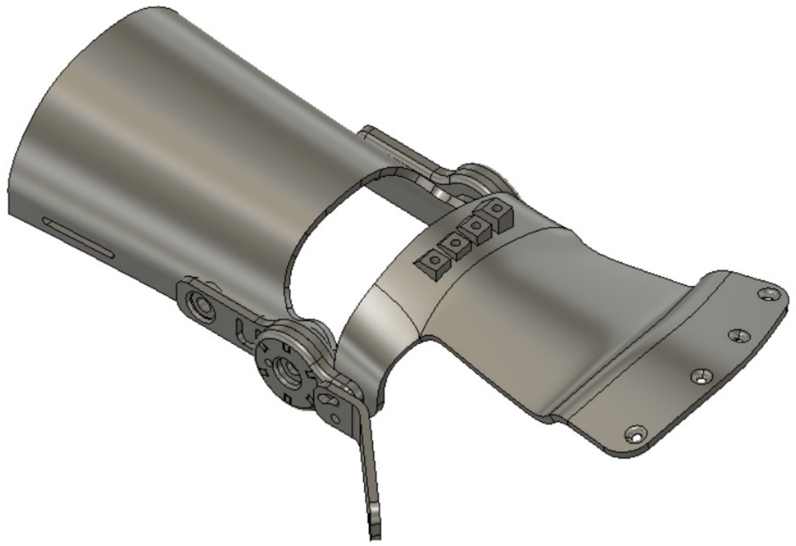
The springs responsible for finger extension were relocated to the dorsal (back) side of the hand. This dramatically shortens the length that the spring and filament need to travel across the brace, and removes any interference with the wrist during flexion and extension. Additionally, the height in which the outrigger surface was offset outward in order to raise the fingers higher when they are extended. This allows for a more natural resting position of the hand and generates more smooth and efficient force on the fingers.

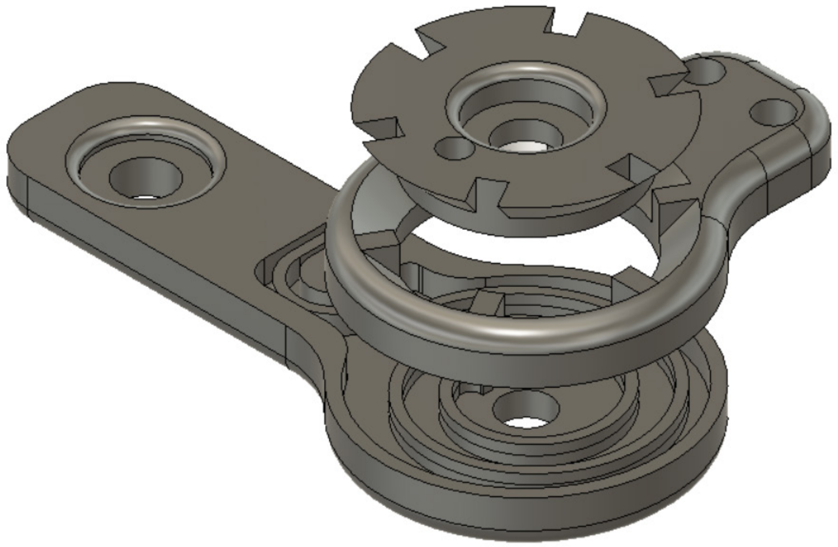
During this iteration, padding was also introduced to the brace, to reduce the amount of skin to plastic contact, and reduce any discomfort or pain on pressure points. 5mm foam from a yoga mat was used because it is cheap, easy to find, and proves to be effective.

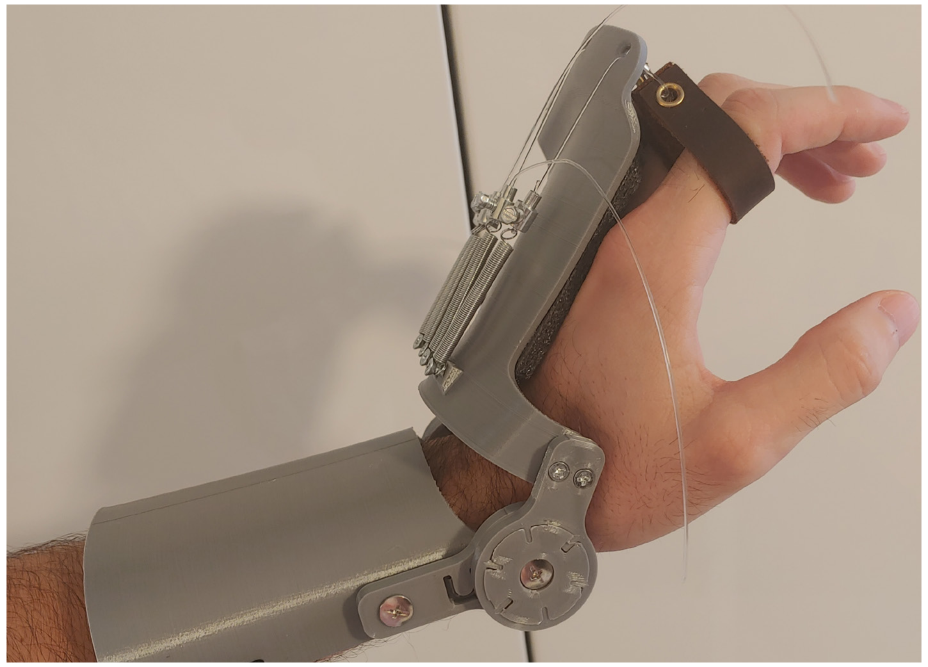


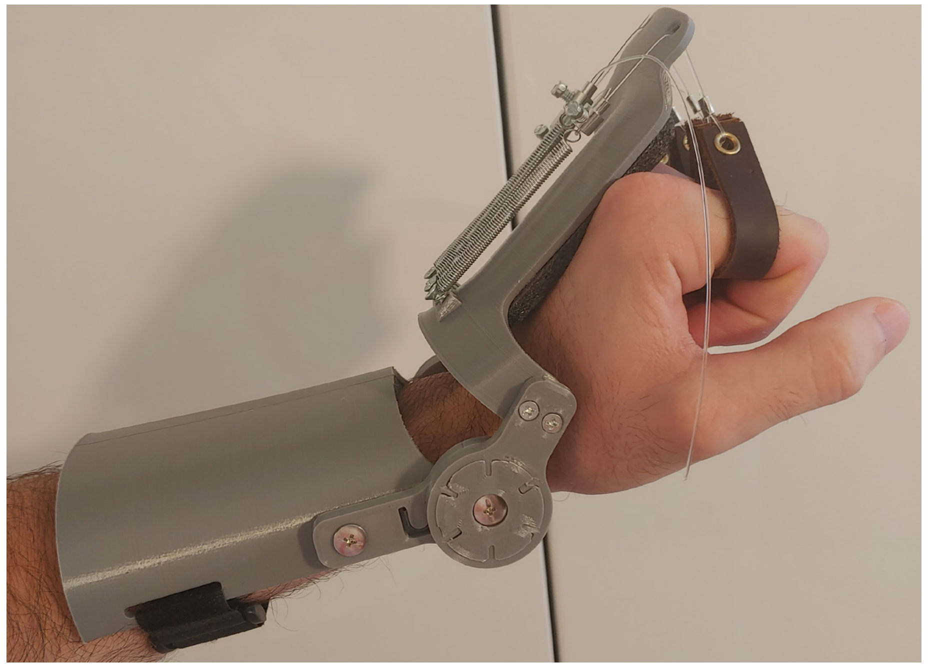


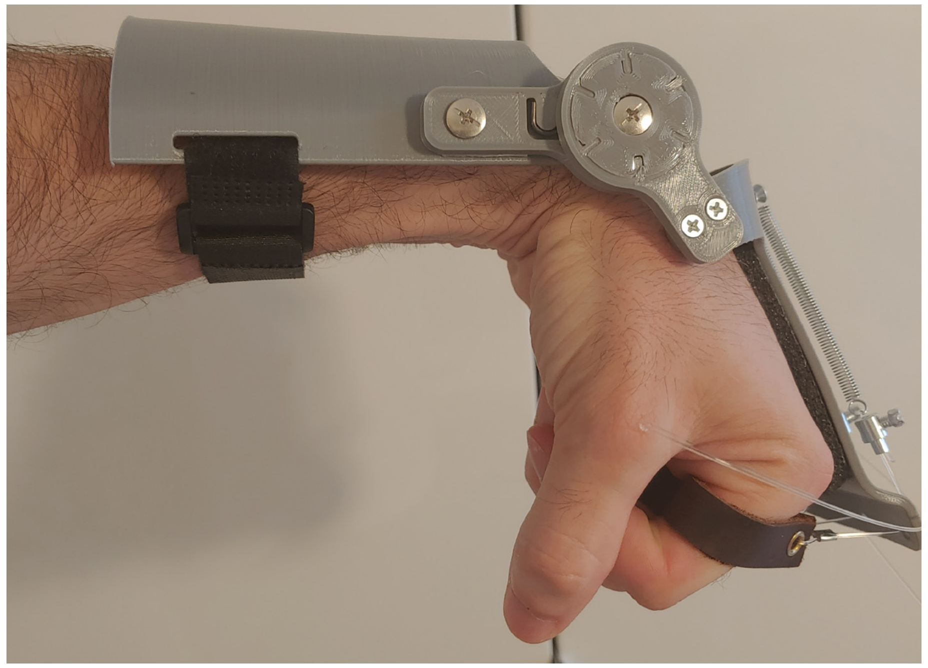


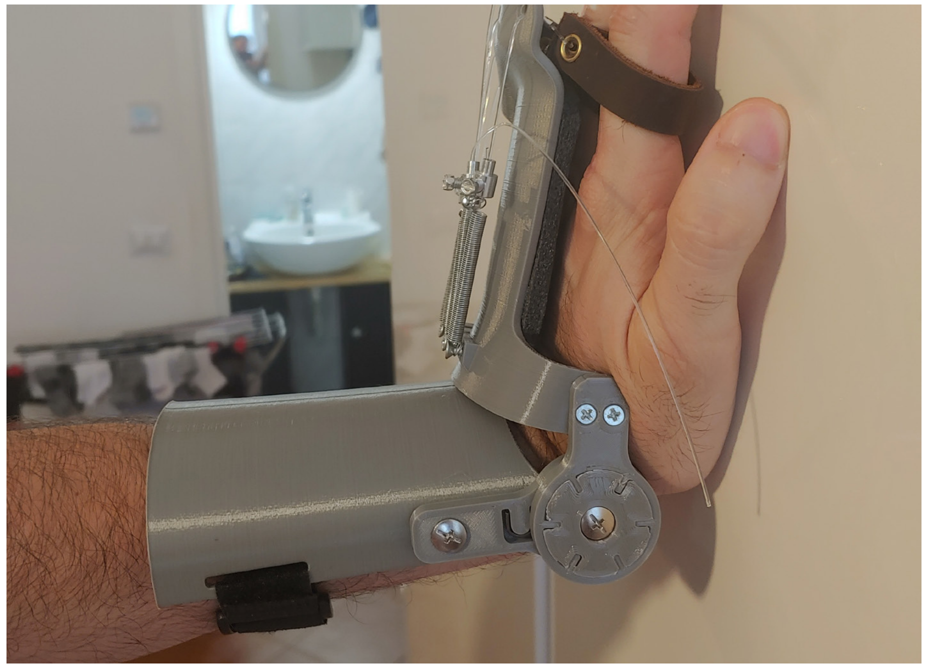












Product Testing Session

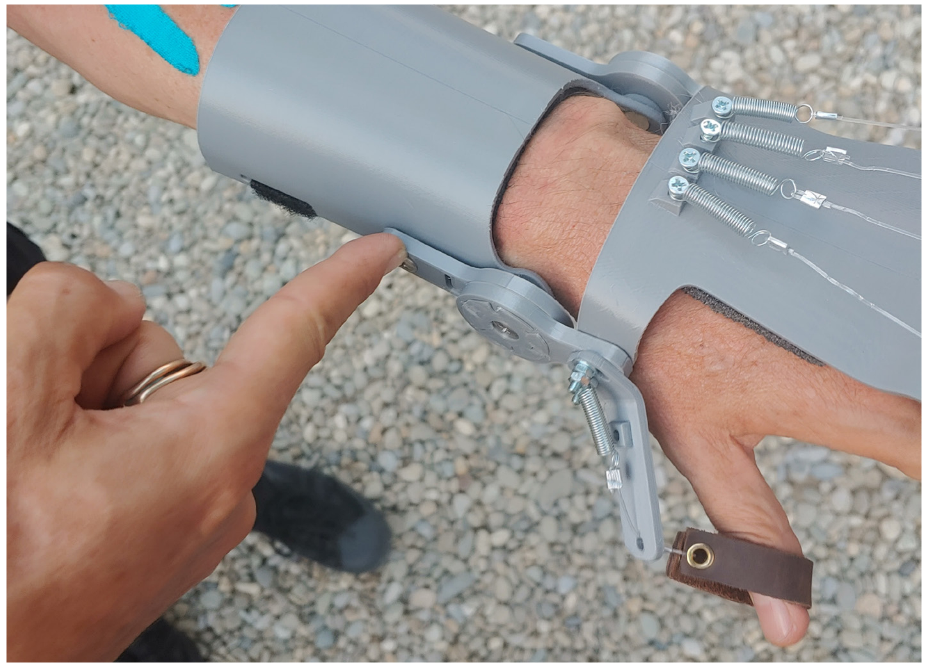
The second round of testing sought to observe the intended benefits and improvements of the new design iterations. There was an immediate and noticeable increase in overall comfort and performance of the brace. The adjustments made to the height of the low-profile outriggers made a positive difference in the resting position of the hand, and the torsion springs proved to be superior compared to the use of linear springs for wrist extension.

One of the biggest and most notable benefits of this design, is the fact that the entire palmar surface of the hand is unobstructed. This gives the user the most amount of tactile feedback and sensitivity that they have experienced in years.

The redesigned wrist joint of the brace also enables the wrist to be bent to nearly 90 degrees in extension, allowing for more comfortable exercise and sport activities such as doing pilates and even riding a bike. However during testing a weakness in the design was revealed, and it was discovered that the plastic piece that interfaces with the torsion spring is not strong enough to withstand such strong force concentrated on such a small area.

The overall fitment and dimensions of the brace are satisfactory to the user, and the foam cushioning is comfortable, but more exploration can be done in terms of material usage.

Some issues of note with this concept were the postioning and angle of the thumb outrigger, and the possibility of integrating the wrist hinge housing pieces into the brace itself in order to reduce part count and bulkiness.

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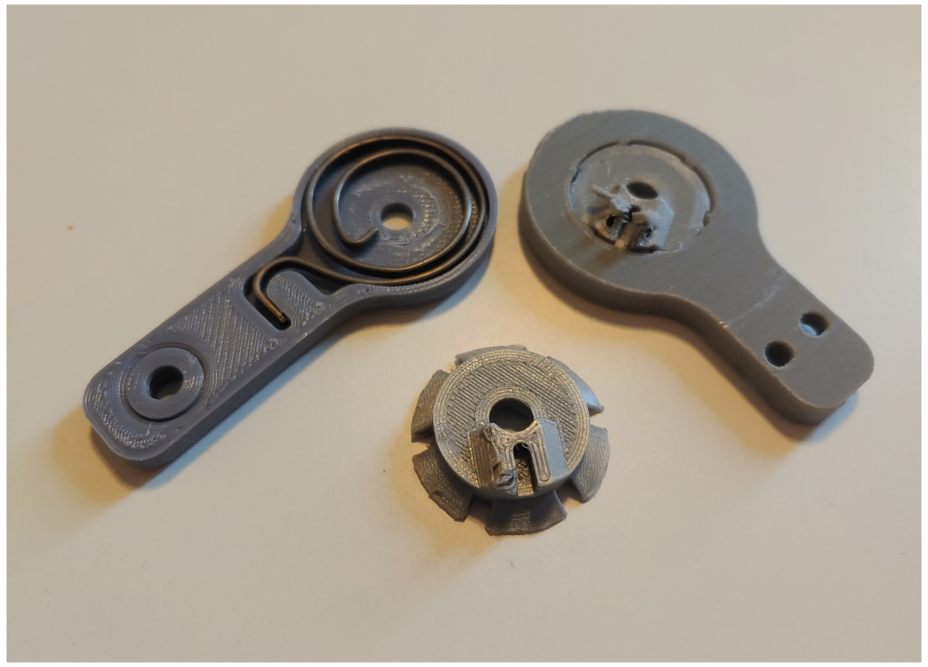
Concept Refinement

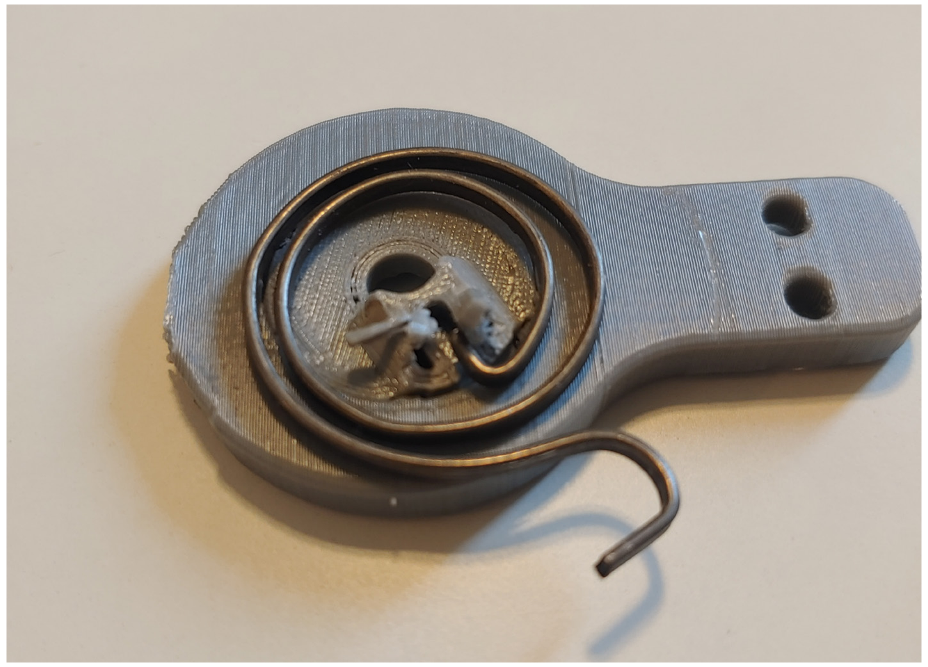
The user feedback gained from the second testing session saw validation of positive design changes that were made during the iterative process, and as expected revealed more opportunities for improvement. However in general it can be considered that the concept is beginning to converge and getting closer to achieving a functional product that the user can implement for an extended period of time.

Specific features to improve include making the wrist hinge which interacts with the torsion spring more robust. During testing, the immense force that is transferred to the center of the spring is concentrated to a very small point which interfaces with the 3D printed plastic. Testing has shown that the printed plastic is not hard enough to withstand these forces and a solution should be found which enables greater durability of the parts.

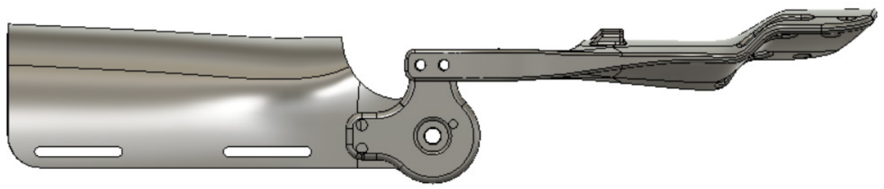
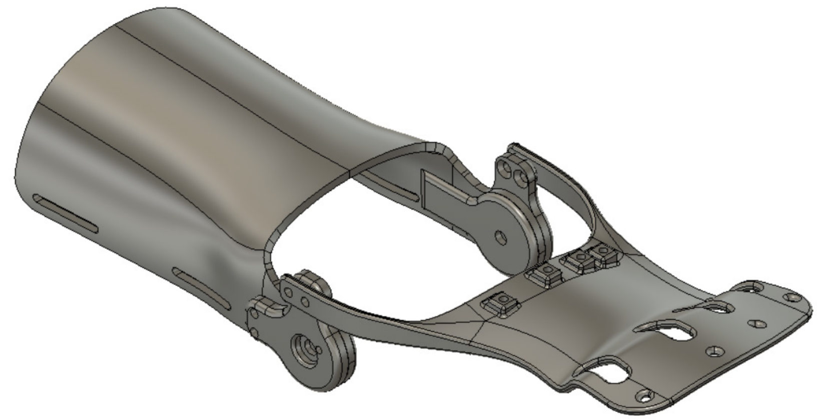
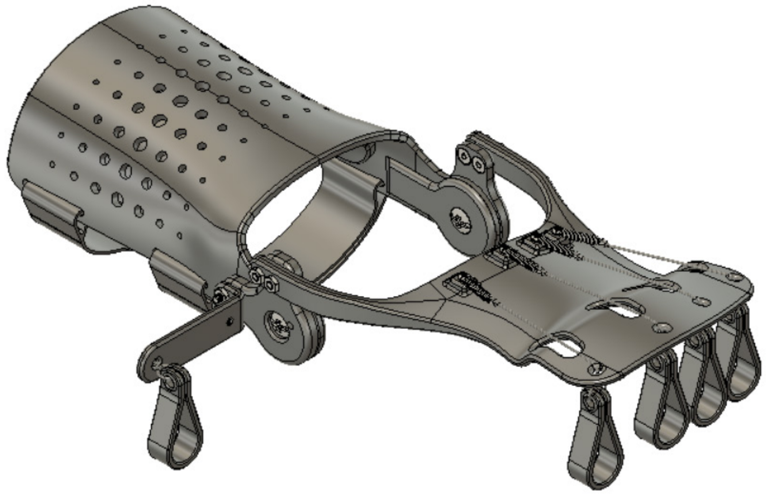
This was accomplished by designing a thru hole into the hinge in which a metal set screw will be threaded into. This set screw will be what interfaces with the spring and is expected to be much more effective and durable.

The housing which contains the torsion spring is currently constructed of 2 separate pieces which are then fastened to the main body of the brace. In order to reduce bulk and part count, the hinges should be integrated into the main body of the brace in a suitable way so that less parts are needed to be printed and assembled together. This also creates a more streamlined appearance of the brace and reduces its overall size.







Creating a business model is a strategic tool for visualizing and mapping out stakeholder interaction, where flows of information and resources occur, and helps to further shape individual aspects of the project by revealing points of interaction and implied issues with the overall strategy of providing a product or service.

Key Partners
- Open Source Contributors/Collaborators
- 3D Printing suppliers
- Physical Therapists
- End Users

Key resources acquired from partners
- User centered research
- Clinical information from physical therapists
- 3D printing supplies such as filament and replacement parts

Key Activities Performed by Partners
- Providing user centered feedback
- Providing clinical feedback
- Providing high quality materials and tech support when needed
- Providing shared knowledge and labor contributions

Key Activities
Due to the nature of digital and distributed fabrication methods that are used to produce the final product, as well as the sharing of source files, we completely circumnavigate the traditional systems of a linear based economy. There are no central means of production being used, and therefore in most cases there is no need to utilize traditional shipping/transit channels, or dealing with the associated costs and logistics.

This decentralized method of production and design, can promote a stronger bond between the designer/producer and the end user by way of faster and more direct communication, user centered design process, and interactive changes that can be made with rapid prototyping.

In regards to revenue streams, they are also positively disrupted. The end user has many choices in regards to the acquisition of the product and the method of payment. Because the design is offered as free to use, end users can freely download and produce the design without need to directly pay for the files. There are of course costs still involved with production, but they are significantly less because the end user or consumer will only be required to pay for the cost of materials they use, or for labor they hire to produce the product for them. Alternatively, the user or consumer can purchase the product directly from the producer (myself), more economically than what is available on the market due to the low cost of digital fabrication, and the philanthropic nature behind the project.

Key Resources
Physical - Raw materials for 3D printing (filament, replacement parts, tape, etc.), other materials used in construction (hardware, foam, fabric, straps, etc.), shipping materials in some cases (boxes, packaging, instructions, etc.)

Intellectual - Intellectual resources come from multiple sources in this business model, including the designers, contributors, end user, and physical therapists. Additional intellectual resources required come from the need of the appropriate open source copyright and licenses, as well as legal information that waives all legal responsibility from the producer of the designs.

Human - Human resources are always needed, even in fully automated solutions. In this case there is the need to maintain contact with end users, facilitate communication between partners and collaborators, and human resources to manufacture the product and maintain the production equipment.

Financial Resources - As stated before, the open source design files are intended for free use, but there will always be costs involved in production no matter the situation. In any case the end user is still responsible for providing financial resources to actually produce the final product. This can be paid either directly to the original designer/producer (myself), fablab/maker space, or possibly even the physical therapist or clinic.

Value Propositions
The value proposition being offered aims to provide end users with a customized and tailored dynamic orthotic device that is achieved through an interactive, user centered design process. By providing this solution to the end user, the orthotic device fulfills the need for a more accessible, economical, and higher performing product which can more easily integrate with a user's lifestyle. By offering the design as an open source, free to use product, end users overcome a comparably high barrier to access that they encounter with other orthotic products on the market. This also appeals to many who wish to modify the

design further to better fit their needs, as well as clinical physical therapists who can produce the design in house and work directly with their patients.

Cost Structure

The driving force behind this project is an economic one, and the goal is not to create a profitable business venture per say, but more or less to be able to allow anyone access to an orthotic device if they need one. That being said there are still costs involved and the end user will still be responsible for expending resources in order to obtain the physical end product.

When purchased directly from the original producer (myself), costs involved will include:

- The cost of raw materials (the amount of filament used for each print), other materials and fasteners required to build the product like springs, wires, screws, foam etc.
- The cost of energy required to print the device
- The cost of labor required to print and assemble the device
- The cost of shipping and transit fees

If the end user decides to produce the final product themselves, these costs can vary in size and shape. In this case again the user is responsible for paying:

- The raw materials to produce the product, which they may already have or will need to purchase from a source of their choosing
- The energy needed to print the product themselves

In such cases where the end user simply takes the files for production, and finds a local producer such as a fablab or makerspace, again the costs included will be similar to the ones above, but can vary depending on where they go.

This business model can be considered as a hybridization of a cost and value driven approach. On one hand the nature of decentralized production and free to use open source designs allow for low cost production. Additionally, there are no overheads, salaries, or bureaucratic decisions involved in the pricing scheme in producing the product. Finally as stated before, there are no economic or profit producing intentions behind this product. There is a conversely intrinsic mission statement to offer a high quality product that can be obtained with the least amount of money.

Revenue Streams

For many people around the world, especially those in developing countries, the cost and access to quality healthcare services can either be too expensive, non-existent, or ill equipped. It is hard to say exactly the out of pocket costs that the average user would spend on an orthotic device, because that can depend on business relationships between care providers and insurance companies. In this specific case, the user reports spending anywhere between 100-600 euros for their orthotic devices, depending on the type. For many seeking treatment the dollar amount does not matter because there is either no other option, or they desperately seek/need treatment, and the value of living a healthy life can not be labeled with a price. Again it is the mission of this project to use digital fabrication techniques with open source distribution to provide a low cost solution to anyone in need.

In this case product pricing is not affected by the scale of production, because production is not centralized and is very low scale. When offered directly from the producer (myself) there will be a fixed price based on the amount of material used, cost of materials, and labor involved. However when paying for a third party service to produce the product, costs will undoubtedly vary depending on the region and cost structure of said party.

Customer Relationships

In this context customer relationships can be synonymous with end user relationships. With this project I have established a healthy and informative relationship with the end user due to the nature of the user centered design approach, where constant and clear communication, and physical testing is required to develop the end product. This end user relationship needs to be well integrated into the business model because the quality of the relationship between designer and user directly affects the quality of the product.

Customer relationships can be foreseen to become more complex albeit still manageable when an additional partner is brought into the equation. In situations where the end user produces the product with a 3rd party such as a makerspace or fablab, there will need to be established communication channels between designer, user, and producer incase of any issues that arise.

Another context can be considered when the end user is working directly with their physical therapist or clinic to obtain the orthosis for their treatment. In this context a line of communication between designer, user, and therapist needs to be established in order to make changes with the design or aid in the assembly and use of the orthosis.

Customer Segments
Above all, the most important customer segment in this business model is the end user. The quality of care that they receive and allowing access to care will determine whether or not the product is successful. This product is being designed for an incredibly niche market. There are very few cases of radial palsy or side effects from stroke which require this device, compared to many other diseases and conditions that exist. However the nature of user centered, iterative design and small scale, decentralized production perfectly fit situations exactly like this.

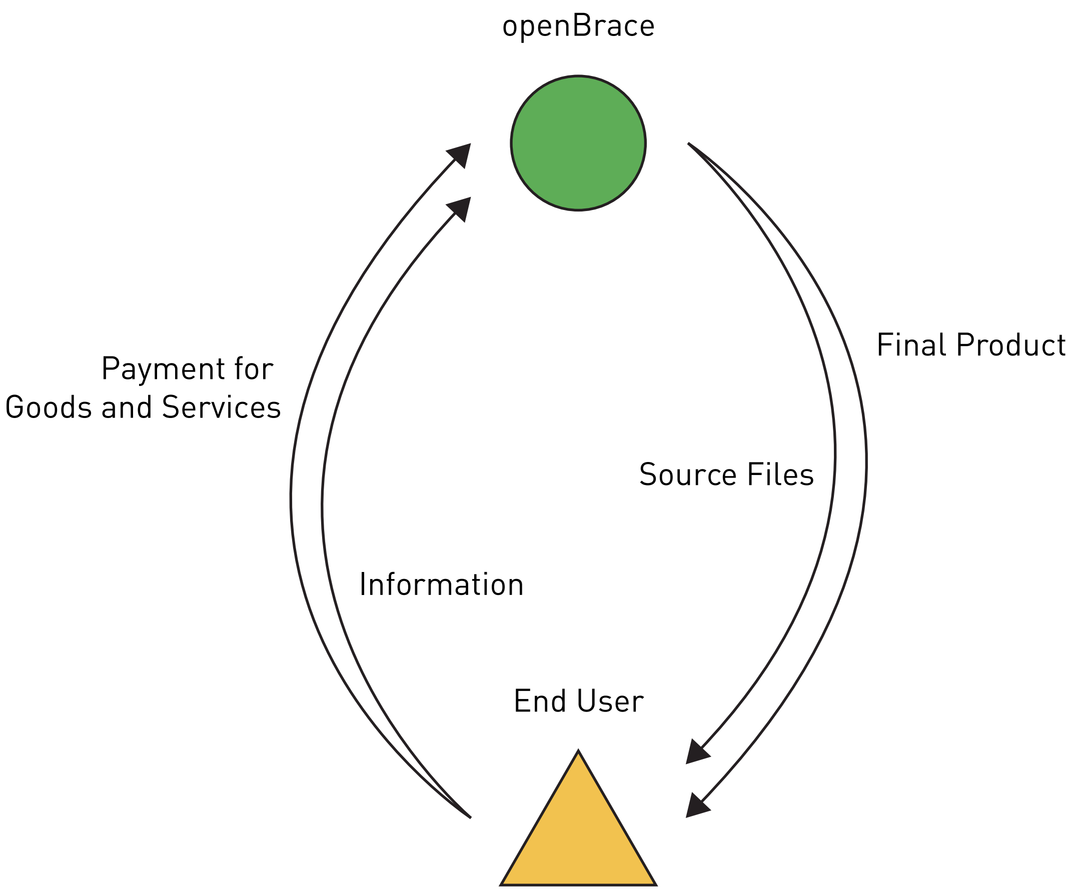
Channels
As shown through research, movements like the open source initiative, and maker movement were made entirely possible through the power of the internet. Now more than ever, people use the internet to communicate, share information, consume products and services, and even receive care. People today are more comfortable with these methods of consumption than ever before, especially post COVID-19 pandemic. Effective communication and design has been carried out using the internet as a platform for collaboration during this project. From experience with this project, in person contact has been incredibly necessary for developing the product and determining sizing and fitment. However with more work and iterations I foresee that the product can reach a stage where the need to test fit in person will no longer be required.

Awareness - Awareness can be made to this project by way of social media platforms, sharing the initiative with medical journals, websites, and clinics, and even word of mouth.

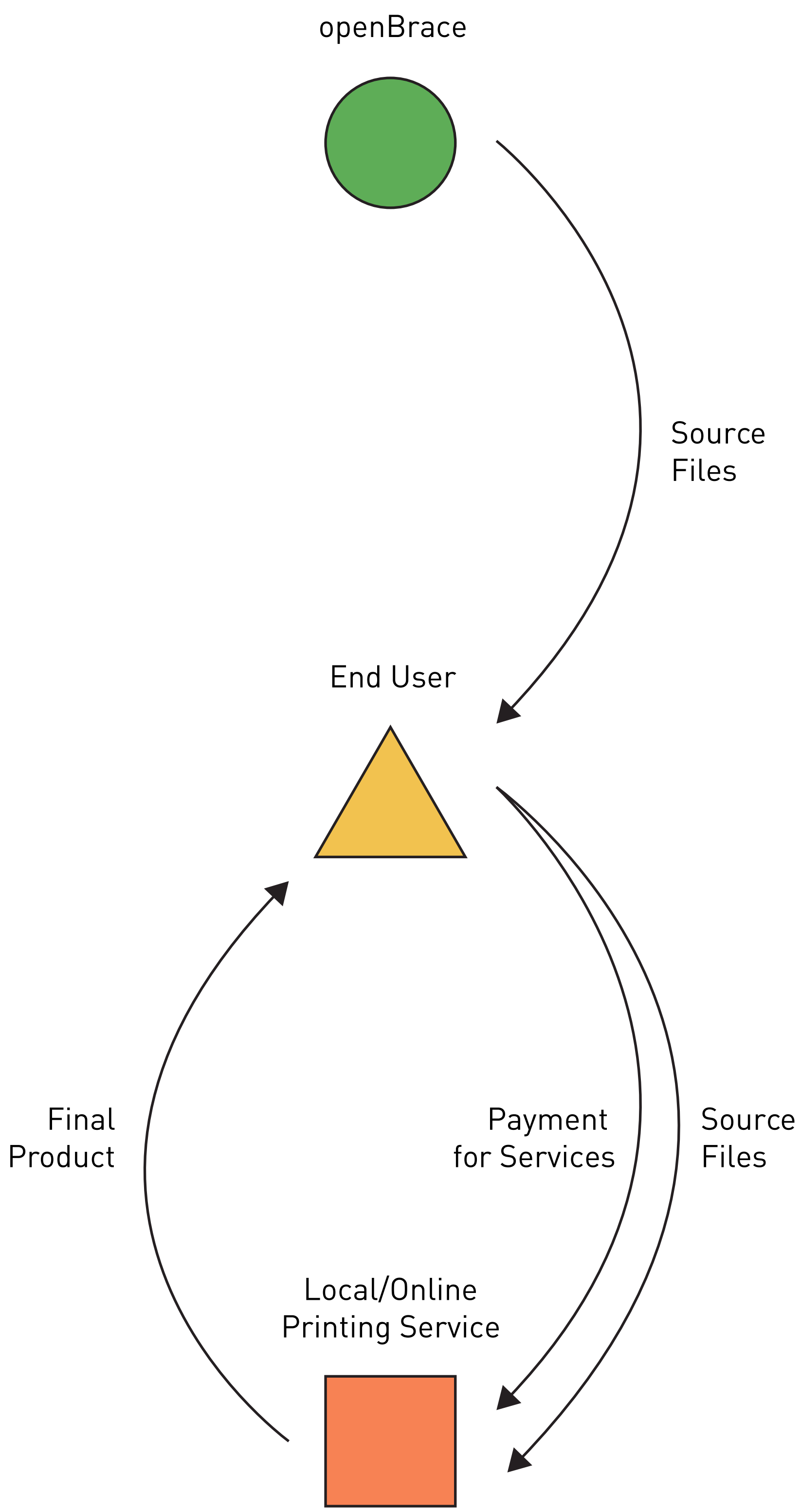
Evaluation - The project's value proposition can be seen through the research and findings in this paper, and further user testing, focus groups, and testimonials.

Purchase - If the user is purchasing directly from myself, a planned website/platform is being developed where users can view the product, download files, or request one to be made.

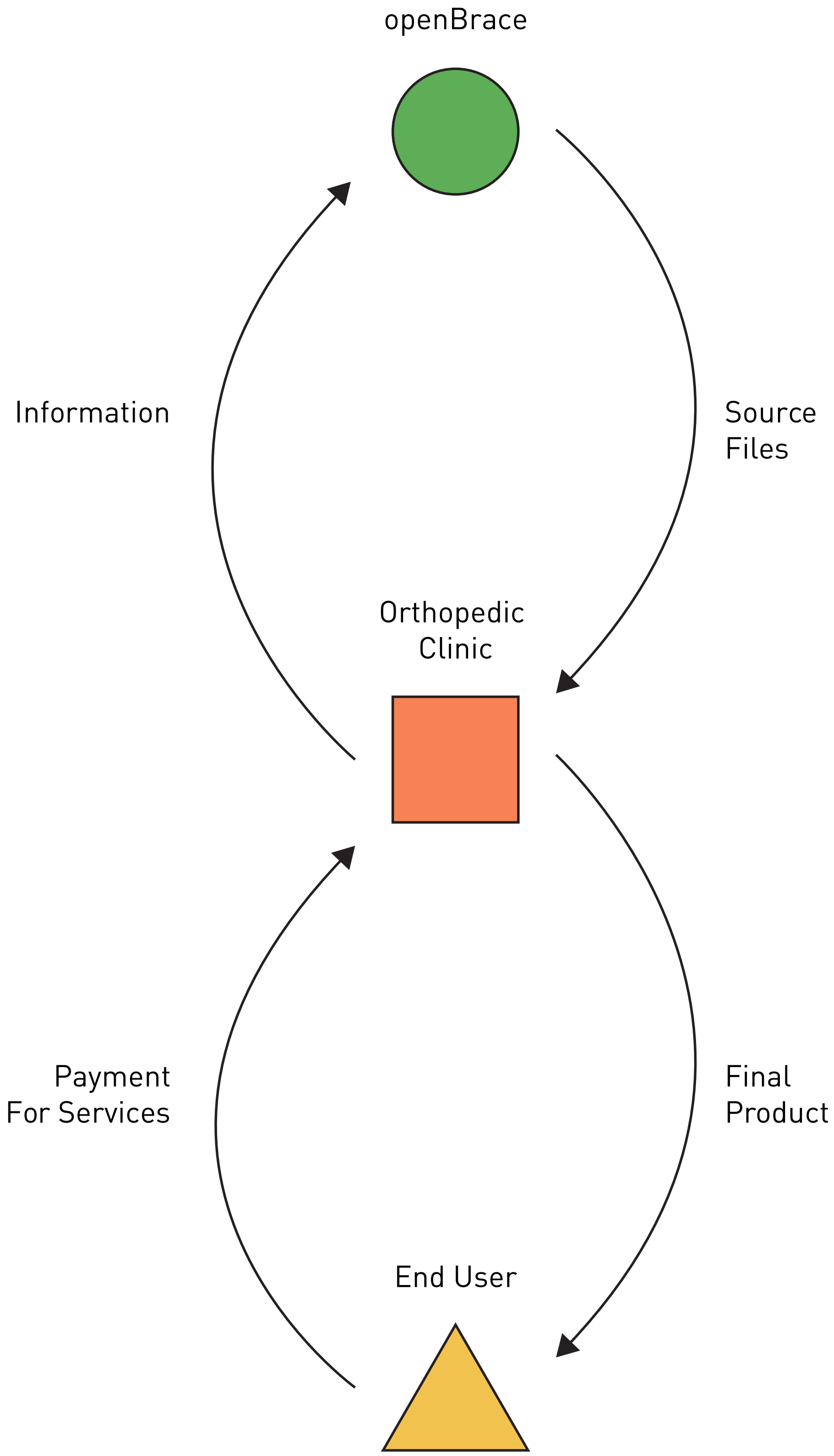
Delivery - At this point in time, delivery is foreseen to be carried out by existing transit supply chains.
After sales - Post purchase customer support can be offered through direct communication such as email or video conference.



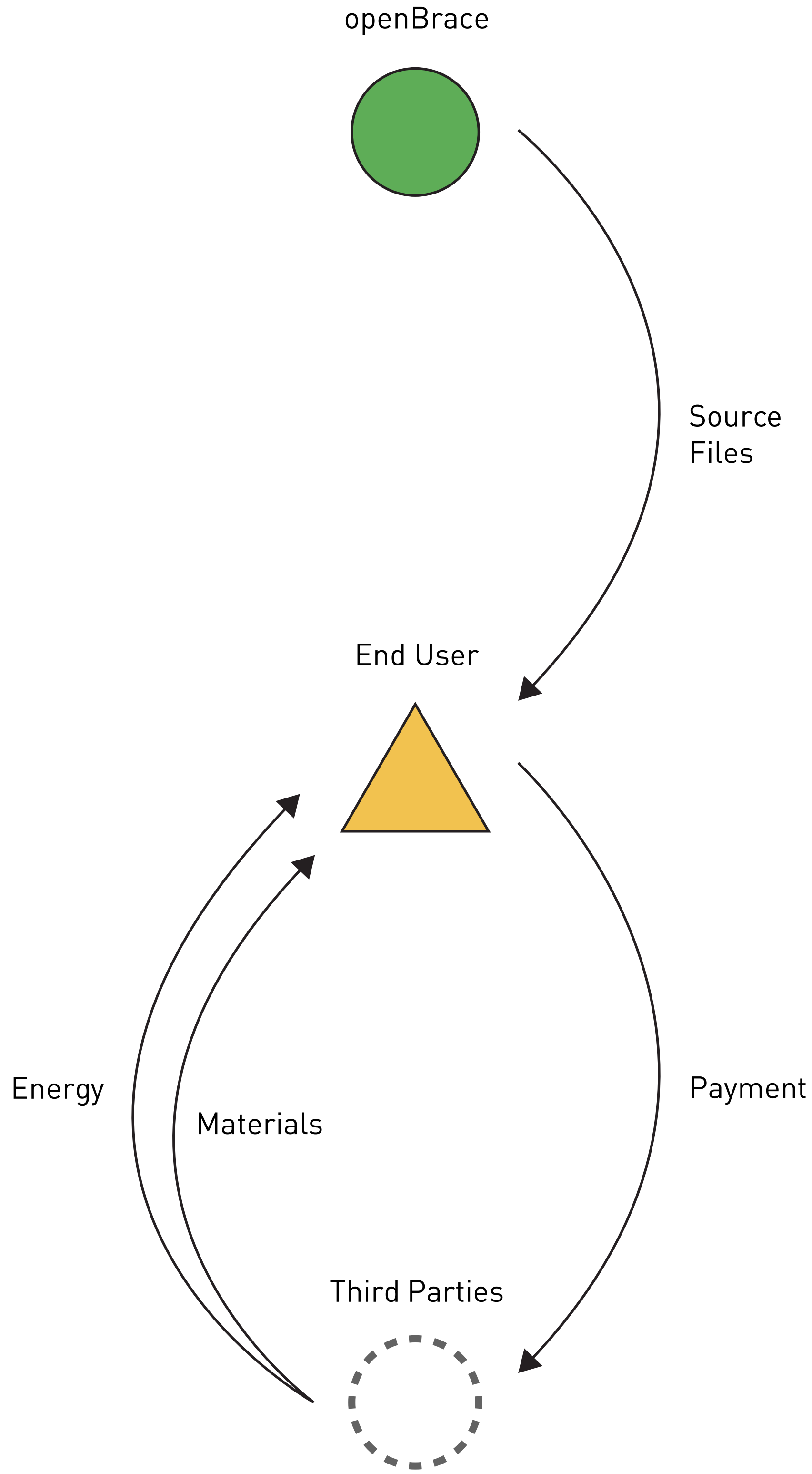
Scenario 1
Scenario 1 describes a typical B2C type of relationship where the consumer (end user) directly interacts with the business (producer/designer) in order to acquire goods and services. In this scenario payment and information is exchanged for the product(s).



Scenario 2.a
Scenario 2.a describes one of two scenarios where a secondary producer is involved that is responsible for fabricating the final product. In this scenario a local or online printing service is being used. The end user first acquires source files for free, and gives them to the printing service, along with payment, in exchange for the final product, services rendered, and other costs incurred.



Scenario 2.b
Scenario 2.b is the second possible scenario that involves interactions with a secondary producer. More and more orthopedics/prosthetics are becoming involved with 3D printing in house. In this case the end user's Orthopedic clinic or physical therapist is involved in the production of the final product.



Scenario 3
Scenario 3 is where the end user is directly responsible for the production of the final product, and all costs associated with it. This scenario may or may not involve a variety of 3rd parties such as material suppliers, or retail stores. In this case the user acquires the source files for free, and exchanges payment for the materials and energy they need to produce the final product themselves.

Closing Thoughts

Months of research, exploration, interacting with the user, and exercising the human centered design process have resulted in a functional, tangible, and replicable solution. Within the context of this thesis project, we can consider the functional goals of the project to be completed, and the user considers the current iteration of the product to be more than satisfactory. However the design potential and aspirations will drive the innovation of this concept well beyond the 6 month time frame of this thesis project. The current iteration of the orthosis will serve as an excellent basis for continued development and exploration into new and improved concepts for a wearable medical device. At this moment, this thesis project has proven that using digital fabrication, with a human centered design process, is a viable and effective way for producing a customized, low budget, and functional orthosis. However there are plans to take the project even further than the educational environment in which it was started. I hope to achieve this by:

Continuing to work with the user to develop more mature concepts
Leveraging the collective knowledge and labor of the open-source community
Building new partnerships with other users and medical professionals, and others in the industry orthotics/prosthetics community
Exploring new and improved methods of digital manufacturing, especially in 3D printing
The potential of new and ever evolving materials
Exploring applications of technology and electronics for rehabilitation devices

Overall, the project has been an immense learning experience, and a discovery of how important and powerful the design process is within the contexts of medical devices, and the impact that they can have on the end user.

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