Table of Contents

List of tables

List of figures

1. Task Clarification

The problem statement mentioned above does set a certain ground rule to design the patient-specific hand orthosis. According to the problem statement a patient-specific hand orthosis must be developed for a certain hand injury which can be manufactured without a conventional plaster cast. The above said hand orthosis can be integrated with hi-tech functions which give an added value to both the patients and therapists in treating the hand injury. However, a discussion was carried out prior to the start of the project to clear out all possible areas of confusion to proceed in the right direction. Some of the concerns which arose and were verified with the professor in charge are as shown below:

- Material of the product: According to the Problem statement, the required specification is that the hand orthosis is to be manufactured without a conventional plaster cast. So, any material can be used such as alloys of metals, composites etc.
- Weight of the product: The weight of the product was not specified. There was no hinderance during the development of the product but according to ergonomics, maintenance, materials, and manufacturing process the product should be light weight which could be easily handled by the patients and the therapists for treating and fitting the orthoses.
- Cost of the product: There is no budget restrictions as this is just a concept model, but the economic expenses should be as low as possible if the model is produced/manufactured.

2. Literature Review

Several research papers and journal articles have been deeply studied throughout the course of this project development. Sections have been distributed where findings of the research paper are presented systematically. The primary findings of the literature review are presented below:

2.1 Concept of Orthosis

Orthotics is a medical speciality that focuses on the design and application of orthoses, or braces. An *orthosis* is a brace, splint, or other artificial external device serving to support the limbs or spine or to prevent or assist relative movement. The proper word for an externally applied device that is created and fitted to the body to accomplish one or more of the following objectives is an orthosis such as (i) Controlling biomechanical alignment (ii) To correct or accommodate deformity (iii)To protect and support and injury (iv) to assist rehabilitation (v) To reduce pain (vi) To increase mobility (vii)To increase Independence

Different types of Orthosis:-

- Cervical Orthosis
- Cervical Thoracic Orthosis
- Spine Orthosis
- Arm
- Wrist/Hand orthosis
- Hips
- Knee Orthosis (KO)Brace
- Ankle Foot Orthoses

2.2 Different types of Hand Orthosis

As mentioned there are various types of Orthosis which can be fitted into an individual. Each individual orthosis has a specific purpose. Hand Orthosis is a device that is attached to the hand, wrist and fingers in order to stabilise the joint or immobilise fingers, hand or wrist. In orthotics, fitting orthoses to the patient is essential for rapid treatment process. Every orthosis made by an orthopedic surgeon is patient-specific. A functional orthosis device seeks to improve the ability to complete tasks in everyday life. There are multiple hand orthoses available in today's world that are fitted to the patient's hand to achieve different functions based on the problems associated.

A. Static Orthosis

Stabilization, support, and protection are the three main goals of a static orthosis. To immobilize or limit motion at a joint, a static orthosis is employed. It maintains a certain body part in a secure position and is rigid. This kind of orthosis does not put undue strain or pressure on the body part(s) it covers. The primary objective of static orthosis is to assist in remodeling the interior tissues that are now causing you issues. Movement can be painful when these tissues around your joints are tight, whether this is the result of an underlying problem or after surgery.

Figure 1. Static Orthosis

[Source: https://www.assh.org/handcare/blog/advice-from-a-certified-hand-therapist-types-of-custom-orthoses]

B. Static Progressive

A static progressive orthosis is designed to enhance motion gradually. This kind of orthosis applies steady pressure or stretch to the joint's maximum range of motion. Modifications are made to the orthosis to increase the position and stretch once the tissues (joint, muscles, tendons, and ligaments) have adapted to the position and a stretch is no longer felt. This happens as many times as necessary to reach the range of motion objectives. Therapists utilize static progressive orthoses, a kind of mobilization orthosis, to assist their patients in regaining passive motion in rigid joints and tissues.In order to promote passive motion, this type of orthosis adds non-elastic components to provide force to the stiff joint or tissue and maintain it in the end-range position. The client is told to exert more force while the joint or tissue gradually adapts to a new end-range position. Static progressive orthoses allow for gradual changes in tissue location in this way.

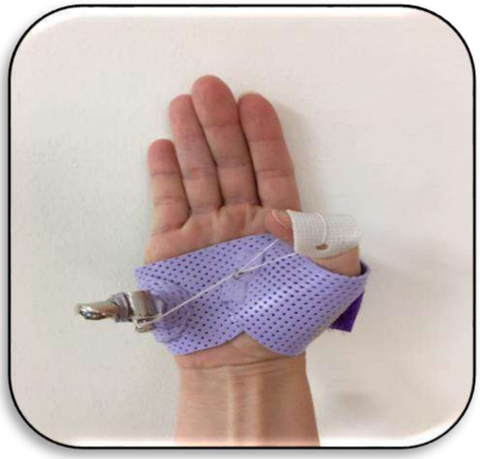

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Figure 2. Static Progressive Orthosis

[Source: *https://www.assh.org/handcare/blog/advice-from-a-certified-hand-therapist-types-of-custom-orthoses*]

C. Dynamic Orthosis(for increasing motion)

Stretch is what a dynamic orthosis is there for when it comes to increased motion. A dynamic orthosis allows a stiff body component to move in the opposite direction while continuously stretching it in the other way. Rubber bands are frequently utilized to provide the stretch.

Figure 3. Dynamic Orthosis(for movement)

[Source: *https://www.assh.org/handcare/blog/advice-from-a-certified-hand-therapist-types-of-custom-orthoses*]

D. Dynamic Orthosis(for function)

A dynamic orthosis for function is designed to support body components during motions that might be lost as a result of an injury, surgery, or other diseases.

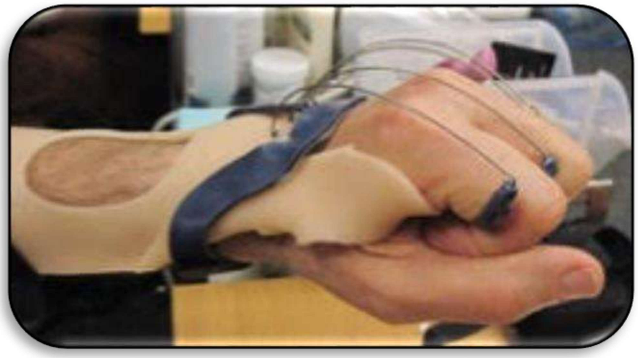

Figure 4. Dynamic Orthosis(for function)

[Source: https://www.assh.org/handcare/blog/advice-from-a-certified-hand-therapist-types-of-custom-orthoses]

The creation of static, dynamic, and static progressive custom orthoses requires specialized training for hand therapists. He or she will take great care to ensure a proper fit and will stretch as necessary. The hand therapist must pay close attention to angles and pull directions when making different types of orthoses using wires, rubber bands, Velcro, and other materials. Throughout the treatment, the orthosis and progress will be carefully watched.

3. MARKET RESEARCH

Market research on hand orthoses would involve collecting information on the demand for such devices, including factors such as the prevalence of hand and wrist conditions, demographics of the affected population, and trends in healthcare usage and treatment preferences. The research would also explore the competitive landscape, analyzing the various manufacturers and their products, pricing strategies, distribution channels and marketing approaches. In addition, market research on hand orthoses would also seek to understand the needs and preferences of patients, doctors, and other stakeholders in the healthcare industry, in order to identify opportunities for improving product design, marketing, and distribution. Overall, the goal of market research on hand orthoses would be to provide insights that can be used to develop effective marketing strategies, optimize product design, and improve patient outcomes, while also identifying new opportunities for growth and innovation in this important area of healthcare.

3.1 Who Uses Hand Orthosis?

People generally affected with the following disorders; injuries use customized hand orthosis:

- Stroke
- Arthritis
- Tendon injuries
- Broken bones
- Pain
- Burns
- Nerve Injuries

- Stiffness
- Weakness

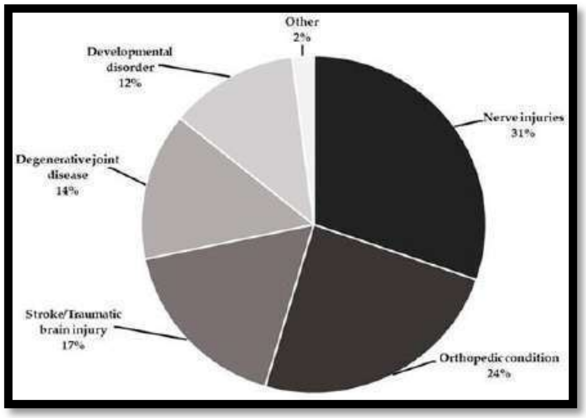

Figure 5. Pie Chart depicting percentage of individuals with various hand injuries
[Source: https://www.mdpi.com/1660-4601/19/15/8995]

In this project we are mainly focused on creating Hi-tech Dynamic orthoses by integrating various possible functions that have added value for patients and therapists. Dynamic Orthoses are frequently used by people who have suffered from strokes, paralysis or spinal cord injuries. The lower and upper motor functions of the hemiparetic limbs are typically affected by stroke. Specific muscle weakness, inappropriate muscle tone, improper postural adjustments, lack of mobility, incorrect timing of pattern components, abnormal movement synergies, loss of interjoint coordination, and loss of feeling are the key characteristics seen in hemiparetic patients. These disabilities are frequently connected. Due to the difficulty of the hand's muscles and joints to regulate, the hand is likely to be compromised and affected by the aforementioned symptoms following a stroke. Thus, it restricts the patient's autonomy in daily living (ADL) and may cause long-term disability.

3.2 Major medical providers in the industry

The most popular medical manufacturers in orthosis are listed below. This includes both static and dynamical hand orthotics providers.

1. Becker Orthopedic UK Ltd
2. Joint Active Systems Inc. (JAS)
3. MyOmo Inc.
4. Neu Medical Co Ltd.
5. Saebo Inc.
6. Essex Orthopedics Inc.
7. Thuasne
8. Juzo
9. Allard USA Inc

10. DJO LLC.

A. BECKER ORTHOPEDIC UK LTD - UM-3.3LL

It was created by Becker Orthopedic in 2018 and is often only used in the UK and Middle East. The wrist, DIP, and PIP joints II–V receive dynamic extension force from this splint. Fixation of MCP joints II–V is provided via the detachable MCP extension block. This orthosis is used to treat wrist and metacarpal orthoses brought on by De Quervain syndrome, wrist tendonitis, and Carpal Tunnel Syndrome. With this specific model, the patient is able to extend their fingers, bend their wrists, and extend their fingers.Some of the disadvantages of this dev)ice are(i) Long term wear discomfort (ii)Requirement of additional help of wearing the device (iii) Lack of maneuverability with individual finger flexions.

Figure 6. Becker Orthopedic UK Ltd- UM-3.3LL

[Source: https://www.beckerorthopedic.com/Product/PrefabricatedOrthoses/UpperLimb/UM-3.3]

B. MYOMO-MYOPRO ORTHOSIS

An adaptable orthosis called the MyoPro may be able to restore function to hands and arms that have been paralyzed due to a stroke, brachial plexus injury (BPI), cerebral palsy, or another neuromuscular disorder or injury. It operates entirely non-invasively, without the need of implants, by sensing the weak nerve signals (myoelectric signals) from the skin's surface and then turning on small motors to move the limb in the desired direction without the use of electrical stimulation. After wearing the gadget, the patient can immediately resume normal movements, providing a short yet effective fix.

Figure 7. MYOMO-MYOPRO ORTHOSIS

[Source: https://exoskeletonreport.com/product/myopro/]

Some of the issues in the above orthotic device are (i) Excessive pain in shoulder, arm or hand during facilitated range of motion (ii) It’s appearance has customers hesitant to perform outdoor functions which include shopping and other common activities (iii) The device is a permanent fixture to the condition and is not designed to heal the patients over time unlike other similar products.

C. NEU MEDICAL - STAT-A-DYNE™ WHFO

It is used to treat joint stiffness in the wrist and hand after an injury when there are deficiencies in range of motion (ROM). These include Wrist Tendonitis and Arthritis. Patients with distal radius fractures, crush injuries, MP and IP stiffness, long extrinsic flexor and extensor tightness, tight wrist and finger capsules, lacerations, and avulsion injuries are prescribed this. The wrist, finger, and long extrinsic stretch of the extensors are all dynamically extended by this splint. Common issues that patients that have used and are using this particular model includes(i) Tendency for the finger grips to slip and be removed partially from the hand during certain strenuous grip exercises (ii) Its jutting out cables hook onto things in the surroundings making it difficult for the patient to freely engage in daily activities with their surroundings.

Figure 8. NEU MEDICAL -STAT-A-DYNE™ WHFO
[Source: https://neumedicaldme.com/statadyne-whfo]

D. SAEBO – SAEBO FLEX
It is a dynamic Wrist Hand Finger Orthosis (WHFO) that is made to order and is cable- and finger-driven in extension. The orthosis has two functions: it supports the hand in a functional position and permits the user to use their hand for functional movements such wrist flexion, lengthy extrinsic extensor stretches, and digit flexion. It is made to support the wrist of a person who has neurological impairment, lengthy extrinsic flexor and extensor tightness, wrist and digit capsular tightness, arthritis, and severe grip spasticity. Common issues that patients that have used and are using this particular model includes (i) Tendency for the fingers to slip out of the digits during use(ii) The need for additional supervision to adjust the tightness(iii) Exposed wires and spring allow for dirt buildup reducing ease of use if not maintained carefully.

Figure 9. SAEBO-SAEBO FLEX
[Source: https://www.saebo.com/shop/saeboflex/]

4. Product Design and Development

The process of product design and its development must come through several processes in sequence followed by a number of iterations that repeat back and forth between these steps. The designing procedure encloses several subtopics like task identification, target setting, analysis, structuring, project management, modelling and standardization. Several guidelines are prevalent that guide a product development team through these sequential steps to ease the overall process of product design and development. This project uses the VDI 2221 methodology and its different phases for its completion.

VDI Standard 2221

This standard is mainly focused in describing the methodology for developing and designing the technical systems as well as products. It covers the general principles of methodical development and design for any industry. The primary focus of this methodology lies under the methodology development from the designer's perspective and considering the influences of several collateral disciplines. The whole designing process can be divided into two essential elements:

Problem Solving Micro Cycle

This micro cycle helps in taking the selection decisions based on evaluation of alternatives. The cyclic execution leads towards the improvement of problem solutions. The different phases in this micro cycle with their brief explanation has been presented below:

i) Problem Analysis: Collecting all the required starting and other information related to problem at hand

ii) Problem formulation: Clear and precise formulation of problem based on the analysed information

iii) System synthesis: Searching for principal solution ideas and their possible combinations

iv) System analysis: Analysis of the solution concept concerning defined criteria

v) Evaluation: Evaluation of the developed solution concept regarding predefined criteria

vi) Decision: Decision about implementation, modification, or rejection of the concept

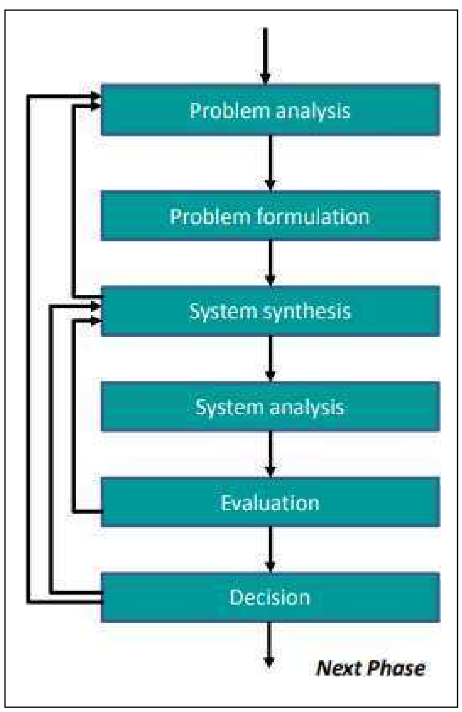

Figure 10. VDI 2221- Micro Cycle

General Designing Methodology - Macro Cycle

This design model is divided into seven working steps:

i) Task Analysis

This is the initial phase of the macro cycle which includes tasks like gathering all the required starting information and determination of work tasks for each member of the team. The outcome of this step is the Requirement List of the project/ product.

ii) Functional determination

This task is carried out after the requirement list has been created after the task analysis. This step includes the listing of system and product information and structuring them into partial functions that need to be accomplished by the system. The output of this step is “Functional Structure”

iii) Search for solution structures

This task includes the major tasks like searching for solution principles that could carry out the desired functions. Solutions could be able to fulfil the partial functions which can be then linked to accomplish the whole functional structure generated earlier. The outcome of this stage is “Work Structure” or the “Solution Structure ".

iv) Outline in realisable module

In this stage the major task of segmenting the principal solutions is carried out. Formulation of subsystems and elements of subsystems that are the requirement for implementation of the solution and determined. A “Modular Structure” is then generated as an output of this stage.

v) Preliminary design

With the help of modular structure, a rough design of the essential modules is generated. These might include Circuit diagrams, rough sketches etc.

vi) Detailed Design

This stage includes the concretizing and refining the preliminary design. Other tasks include designing the groups and auxiliary components of the project. Outcome of this stage are scaled drawings, parts list, blueprints etc.

vii) Product Documentation

This is the final stage in VDI 2201 Macro cycle which includes transforming the artefacts generated in the design to become practical specification, further this step also involves determining the manufacturing feasibility of the designed product. The outcome of this step are all the generated artefact of the complete process and the manuals for the product designed.

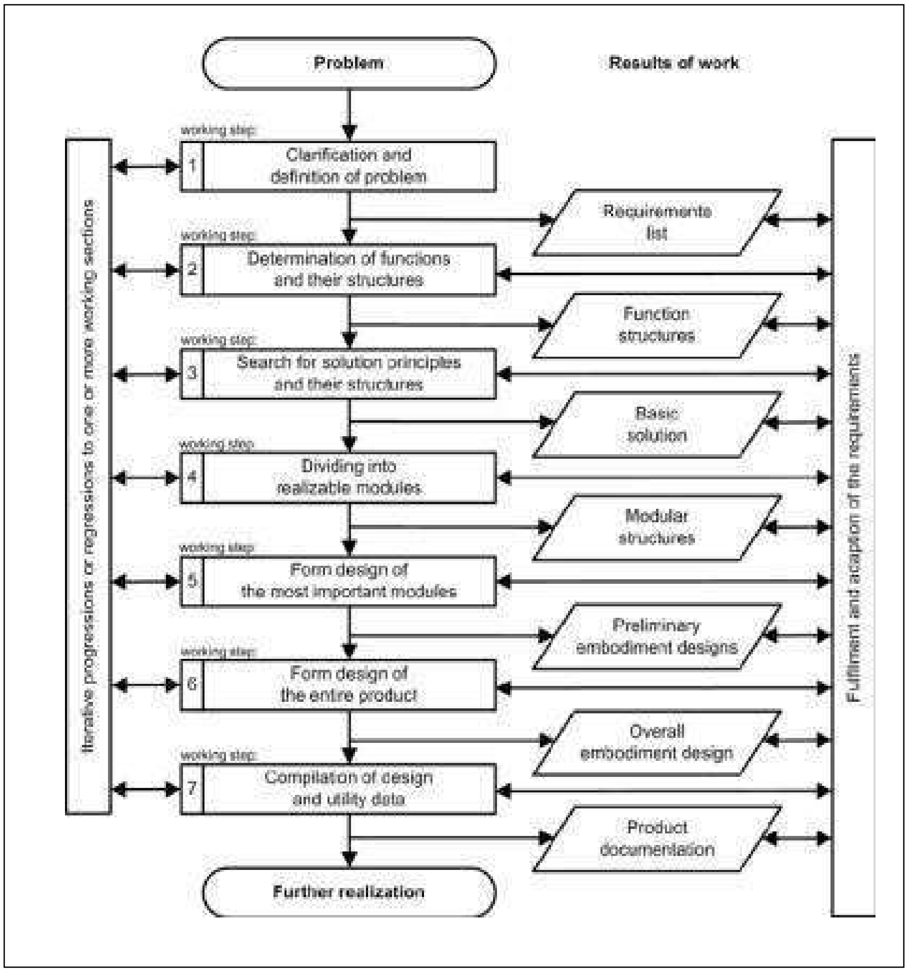

Figure 11. VDI 2201 Macro Cycle

5. 3D Designing

Three-dimensional design technology is the must-have design tool – and it's not just for the biggest aerospace and automotive manufacturers who require their suppliers to provide 3D models. Research shows 3D design and engineering is increasingly prevalent among mainstream manufacturers as well. In fact, estimates put spending at $7 billion worldwide on 2D and 3D design technology and data management solutions. There lie several benefits in generating a 3d model of a product. To mention some, enhancing the product development stages, room for error and modification, maintaining standardization throughout the project as well as in cross project tasks, better convey and storage of data etc. Several tools are available in the market that support cross platform 3D product designing. This not only reduces the cost and time but also provides excess room for creativity and efficiency.

6. Requirement List

The customer's needs and wants are all included in the requirements list in an ordered and structured manner. It informs the manufacturer or producer of the precise requirements the consumer has for a product.
When creating a comprehensive list of requirements, it is crucial to be specific about the objectives and the conditions under which they must be fulfilled. The customer's "demands" or "wishes" must be used to communicate the ensuing requirements.
Demands are obligations that must always be fulfilled. The product or solution is deemed unacceptable by the consumer if it falls short of even one of these requirements.
However, 'wishes' are demands that have to be taken into account wherever possible. It is not required to comply.

6.1 Compiling the Requirements List:

The following general method of compiling a requirements list is recommended:

- Identify the requirements

  a. Look for technical needs in the client contract or the sales documentation, then specify and record them.
  b. Determine the quantitative and qualitative data by using the items on the checklist.
  c. Create scenarios that take into account every stage of the product's life in order to extract additional needs.

- Refine by asking
- What goals must the solution meet?
- What qualities must it possess?
- What characteristics must it not possess?
- Gather additional data.
- Be specific with your requests and demands.
- If at all possible, provide a priority rating to your wishes: major, medium, or small.

- Arrange the requirements in a clear order
- Specify the main goal and the key attributes.
- Divided into distinct subsystems, functions, assemblies, etc., or in line with the primary headings of the check list.

- Enter the requirements list on standard forms and circulate it among interested departments, licensees, directors, etc.
- Examine objections and amendments and, if necessary, incorporate them into the requirements list.

  The conceptual design phase can begin after the task has been adequately explained and the relevant departments have determined that the given requirements are both technically and financially feasible.

  Once created, the requirements list is an incredibly important source of data regarding the desired or needed qualities of the product, making it tremendously helpful for future advancements, supplier negotiations, etc.

It has recently been noted that the creation of a requirements list is a very effective strategy for solution development and has been widely embraced by the industry, at least for original designs.

Table 1. Requirement List

User: O.-v.-G.-Universität Magdeburg		**Requirements list for Patient Specific Orthosis**	**Identification Classification Page**
Changes	**D/W**	**Requirements**	**Responsible**
02/12/2022	**D**	**<u>Geometry</u>**: The four components of the dynamic hand orthosis are, • Forearm base • Finger gutter • Elastic outrigger mechanism- strings, hard springs with 3D printed base and soft springs • Resistance adjustment system	Mohammed Sarfas https://link.springer.com/chapter/10.1007/978-3-319-96098-2_70
02/12/2022	**W** **D** **W**	**<u>Kinematics</u>**: • Patient should be able to grip-release a grip ring of minimum 9 kg with the hemiplegic hand. • Range of motion of MP joint increases when wearing the orthosis. • Providing stroke patients with spasticity the biomechanical advantage of allowing pulp grip and release.	Mohammed Sarfas and Siddarth R Nair https://link.springer.com/chapter/10.1007/978-3-319-96098-2_70
02/12/2022 25/03/2023	**D** **W**	**<u>Forces</u>**: • Quick and easy method to measure forces is using Haldex Gauge. • Between 100 and 250 grams of force on an individual finger. • Forces -45 degrees of flexion, power grip force of 14N-20N	Godwin Andrew https://www.orfit.com/blog/dynamic-orthoses-and-force-application/
02/12/2022 25/03/2023	**D** **W**	**<u>Energy</u>**: • Stroke patients should tolerate the orthosis for at least 6 hours daily. • Should be efficient in significantly decreasing self-reported spasticity and pain. • A 6-month period output should be reduced wrist contractures. • Energy source-12V Lithium ion Battery cell actuates electrohydraulic pump which has to generate 30N force with 41 mm stroke length (Motor torque - 5Nm)	Mohammed Sarfas and Godwin Andrew https://pubmed.ncbi.nlm.nih.gov/23949058/
02/12/2022	**D**	**<u>Material</u>**: • Combination of Metals and Composites • Good Strength and Flexibility. • Relatively good strength and	Godwin Andrew and Nithin Kanikyaswamy https://www.researchgate.net/publication/324085144_Materials_for_Exoskeletal_Orthotic_and_Prosth

25/03/2023	**W**	acceptable thermal shrinkage. • PCL-Polycaprolactone	etic_Systems
02/12/2022	**W** **D**	**<u>Signal</u>**: • Bending sensors, potentiometer, and inertial measurement unit (IMU). • User interacts with the device through its mechanism, but additional interactions can be provided through the command signal or user feedback.	Gautam Reddy Jayaprakash and Vinayak https://jneuroengrehab.biomedcentral.com/articles/10.1186/s12984-016-0168-z
02/12/2022	**W** **D** **W** **D** **D**	**<u>Safety</u>**: • Sharp edges of the devices are either sanded down or covered using protective material such as plastic shrink wrappers. • No exposed sharp edges • All electrical components (sensors and wirings) are covered using cable sleeves. • An interface must be kept over the skin to avoid friction. • Concern must be given while fastening straps. • Worn for about 6 to 8 hours daily.	Linia Thomas and Shrujan Bangalore Nagesh
02/12/2022	**D** **D** **D** **W** **W** **W**	**<u>Ergonomics</u>**: • Non-invasive • Light weight • Easy-to-use • Mechanically transparent • Cover as much natural ROM • Provide the user with additional extension forces that allow them to handle objects.	Nithin Kanikyaswamy and Siddarth R Nair https://link.springer.com/article/10.1007/s10514-016-9589-6 https://jneuroengrehab.biomedcentral.com/articles/10.1186/s12984-019-0543-7
02/12/2022	**D** **D** **D**	**<u>Quality Control</u>**: • EU MDR 2017/745 (EU Medical Devices Regulation) • ISO 13485 • ISO 15378	Ambaprasad Ganapathi Hegde https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
02/12/2022	**D** **D** **D**	**<u>Production and Assembly</u>**: • Additive manufacturing (3D Printing) • Manual Assembly • The manufactured orthoses were generally very lightweight	Linia Thomas and Ambaprasad Ganapathi Hegde https://doi.org/10.1016/j.clet.2022.100559
02/12/2022	**D** **D** **D** **D** **D** **D**	**<u>Operation</u>:** • Ability to grasp or hold the objects • Improving alignment • Optimize wrist/hand position at rest and enhance performance by controlling its range of motion. • Reducing pain • Optimizing grip strength	Shrujan Bangalore Nagesh https://web.wpi.edu/Pubs/E-project/Available/E-project-032217-152256/unrestricted/Design_of_a_Hand_Orthosis.pdf

		• Ability to resist water	
02/12/2022	**D** **D** **D** **D**	**Maintenance**: • Regular adjustments with basic hand tools • Check for Signal connections • Regular check for extended hand motion. • Routine cleansing of product with common household cleaners.	Gautam Reddy Jayaprakash https://web.wpi.edu/Pubs/E-project/Available/E-project-032217-152256/unrestricted/Design_of_a_Hand_Orthosis.pdf
02/12/2022	**D**	**Recycling**: • Recycling (Reuse, reprocessing, waste disposal, storage) • Reusing Motors, Springs and Electrical devices • Recycling Hand Frame Mount, Plastic materials • Waste Disposal	Abhinandan Shyam Sunder Shetty
02/12/2022	**W**	**Cost**: Costs (Maximum permissible manufacturing costs ,, cost of tooling , investment and depreciation) • Maximum permissible Manufacturing cost - $700 • Cost of Tooling - $ 100 • Depreciation value (for lifespan of 5 year)- $ 400 • Retail value - $2500	https://web.wpi.edu

7. Functional Structure

A function structure is created when sub functions are meaningfully and harmoniously combined into an overall function. This structure can then be changed to fulfill the overall purpose. The envisioned system is organized into phases and functions based on the requirements specified and the literature review. The inputs for the black box model are HMI, material and energy. The system is divided into four sub- functions; hand movement and grabbing the object, movement of hand with object, placing the object at desired location and safety. The safety function operates in parallel to all the other three sub functions. The outputs of the process are heat dissipated, motion, work done.

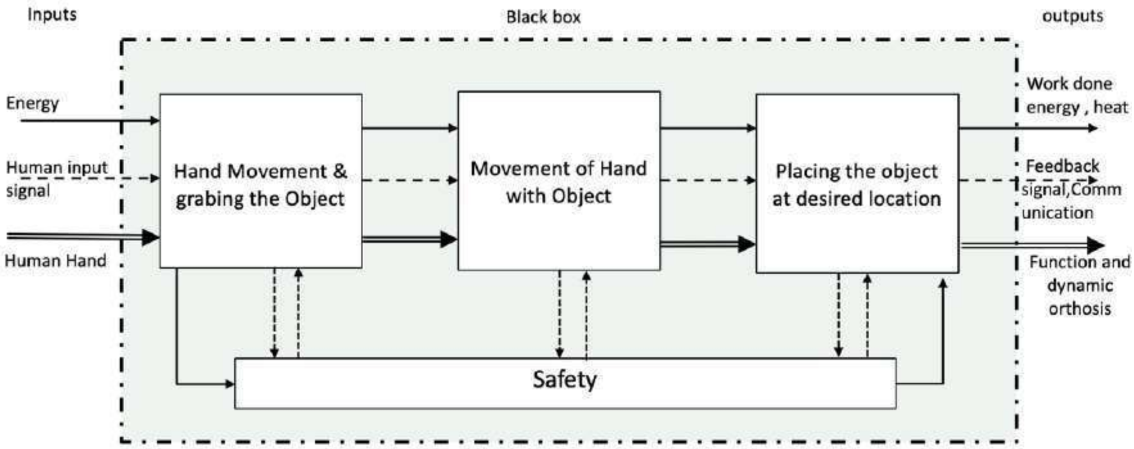

Figure 12. Surface Level Extraction

7.1 Hand Movement and grabbing the object.

In the first phase of hand orthosis, it is required to move the hand and grab the object which is placed at a specific location. The main components of the system are controller and actuator. The controller receives energy and information from human as input. This energy is converted (for example, from electrical energy to mechanical energy) for controlling and actuating the movement of the hand. The material input which is the human hand is fixed and positioned to start the movement. The input signal from human is controlled for actuation. The actuator here starts initiating the wrist and finger movement of the hand. Before the hand movement, the controller also confirms the positioning of the hand orthosis. The wrist and finger movement are initiated and the object is grabbed from the specific location. The energy outputs are motion, heat and noise from grabbing the object. The signal outputs are when the movement is completed, object is grabbed and position signal and the material output is the functioning of orthosis.

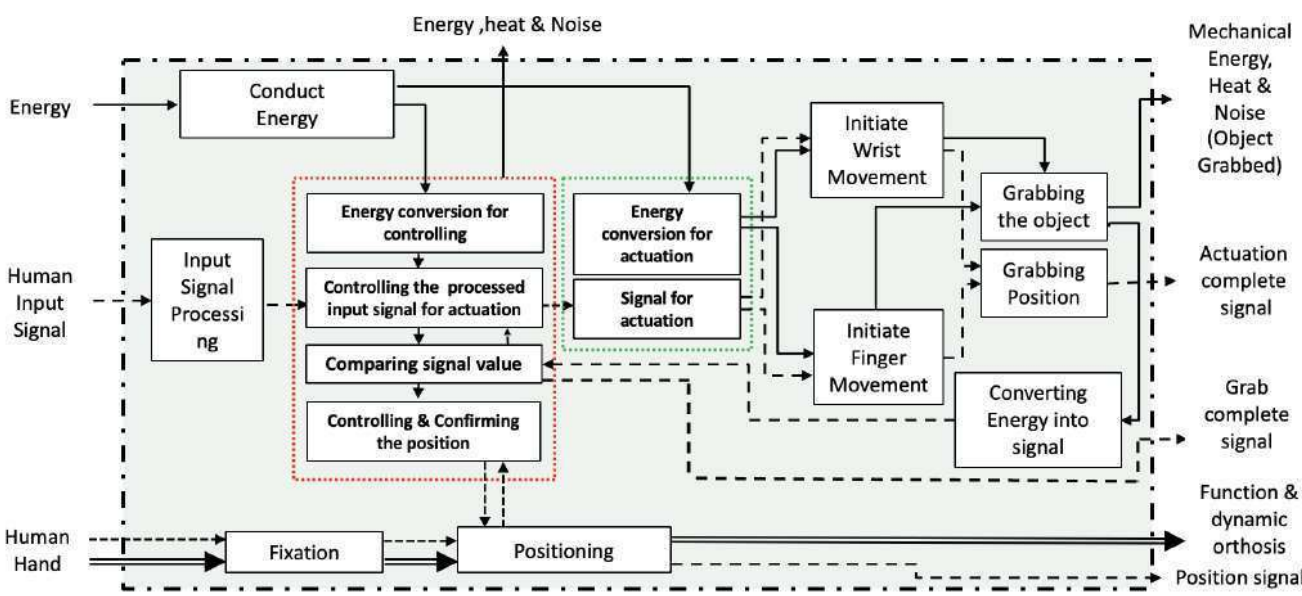

Figure 13. Sub - Function (Hand Movement and grabbing of the object)

7.2 Movement of Hand with object.

In this phase, it is required to move the hand with the grabbed object. Here the controller receives energy and information from human as input. There is an energy conversion (for example, from electrical energy to mechanical energy) for controlling and actuating the movement of the hand. The input signal from human is controlled for holding the object and moving the hand with the object. The actuator receives this signal and initiates wrist and finger movement for holding the object. The processed input signal for movement of the hand is controlled and passed to the actuator. Now the actuator starts initiating the movement of the hand with the grabbed object. The energy outputs are motion, heat and noise from holding the object. The signal outputs are when the movement with holding the object is completed and the signal to release the object.

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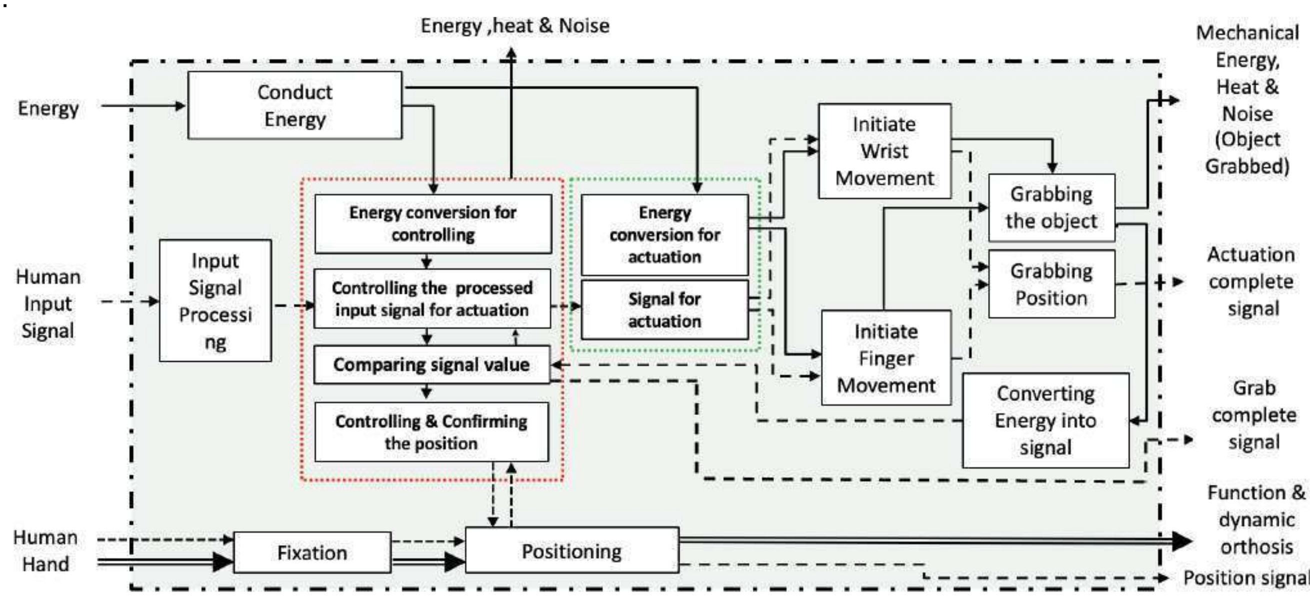


Figure 14. Sub - Function (Movement of Hand with Object)

7.3 Placing the Object at desired location.

In the last phase of hand orthosis, we aim to place the grabbed object at a desired location. The controller receives energy and information from human as input. The energy is converted (for example, from electrical energy to mechanical energy) for controlling and retracting the movement of the hand. The input signal from human is controlled and passed for retraction process. This initiate retracting the wrist and finger movement which leads to releasing the grabbed object from the hand to the particular location. Finally, the object is placed at a desired location. The energy outputs are motion, heat and noise produced while placing the object and the signal output from the completion of retraction process.

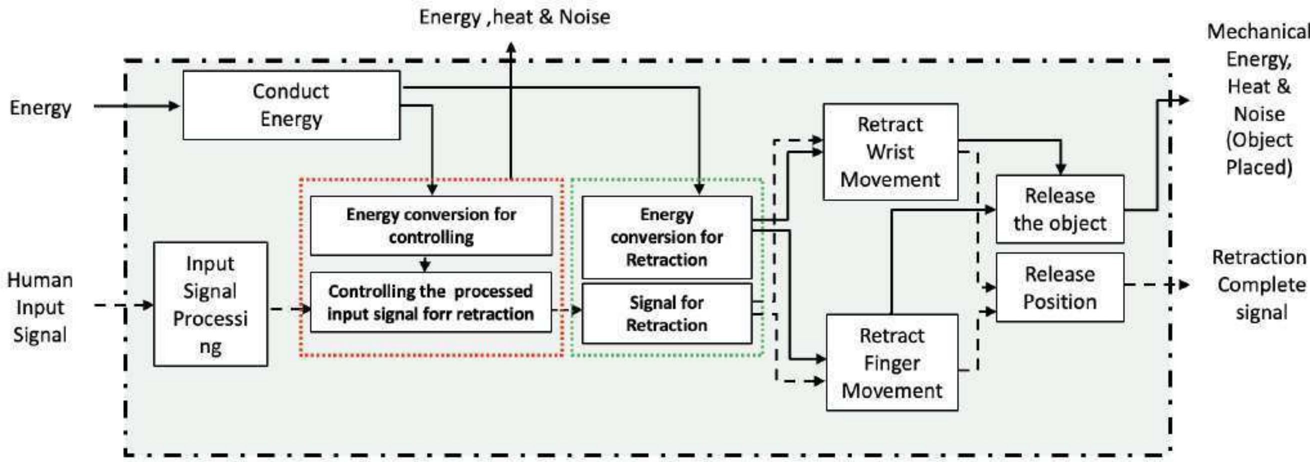


Figure 15. Sub - Function (Placing the Object at desired location)

7.4 Safety Function

The safety function acts in parallel to all the other functions in order to ensure safety across all the phases of the hand orthosis. The energy is received as input to the controller to control and run the safety protocols. There are mainly two signals: external system failure signal and internal system failure signal. The external system failure signal works when an obstacle is detected near the orthosis or when water or any other substances falls on the orthosis. The internal system failure signal ensures the functioning of all the internal components of the hand orthosis. When a failure is detected, the signal is passed to the controller and a warning is produced in the form of an alarm sound and a red light. This cut off the power supply and the system reaches the safety position. The outputs received here are the final safety state of the hand and energy dissipation from the power supply.

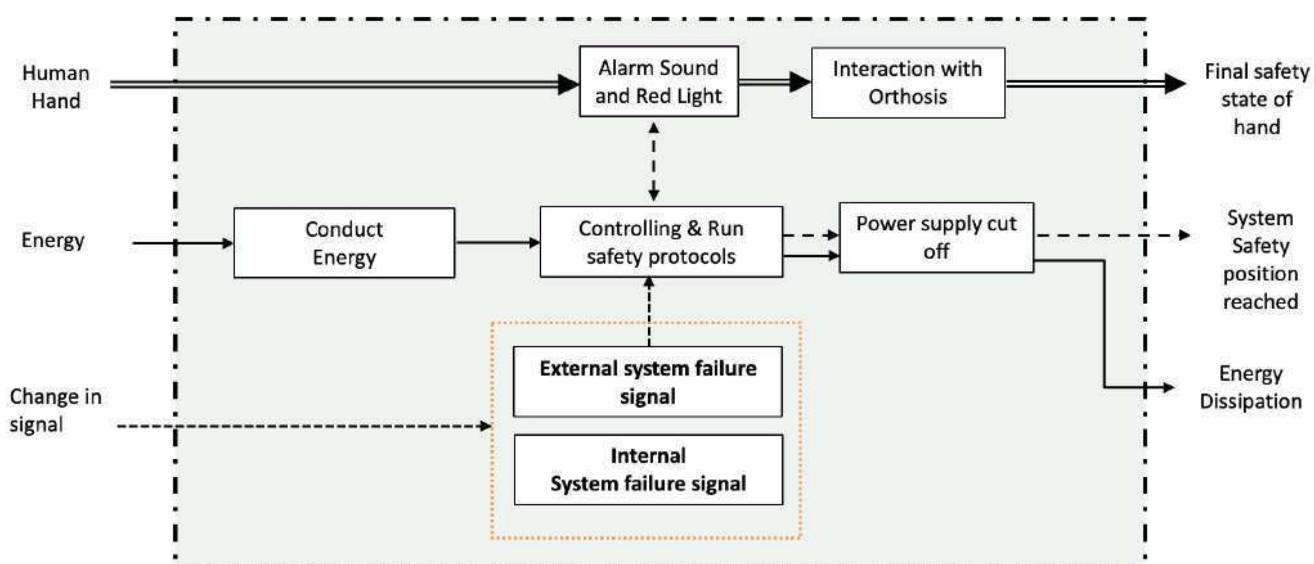


Figure 16. Sub - Function (Safety)

7.5 Overall Function

The Overall function structure combines all the sub functions (Hand Movement and grabbing the object, Movement of Hand with object, Placing the object at desired location, Safety Function) to perform the desired function of dynamic hand orthosis. All the sub functions are dependent on each other and perform in sequence with safety function running parallelly to other functions to ensure safety during the operation. The overall function structure has all the necessary components and has the right flow of inputs to achieve the desired outputs i.e. Dynamic hand orthosis, this overall Function Structure framework will help us to look into various working principles solutions which contributes to the overall product design and development of Dynamic Hand orthosis.

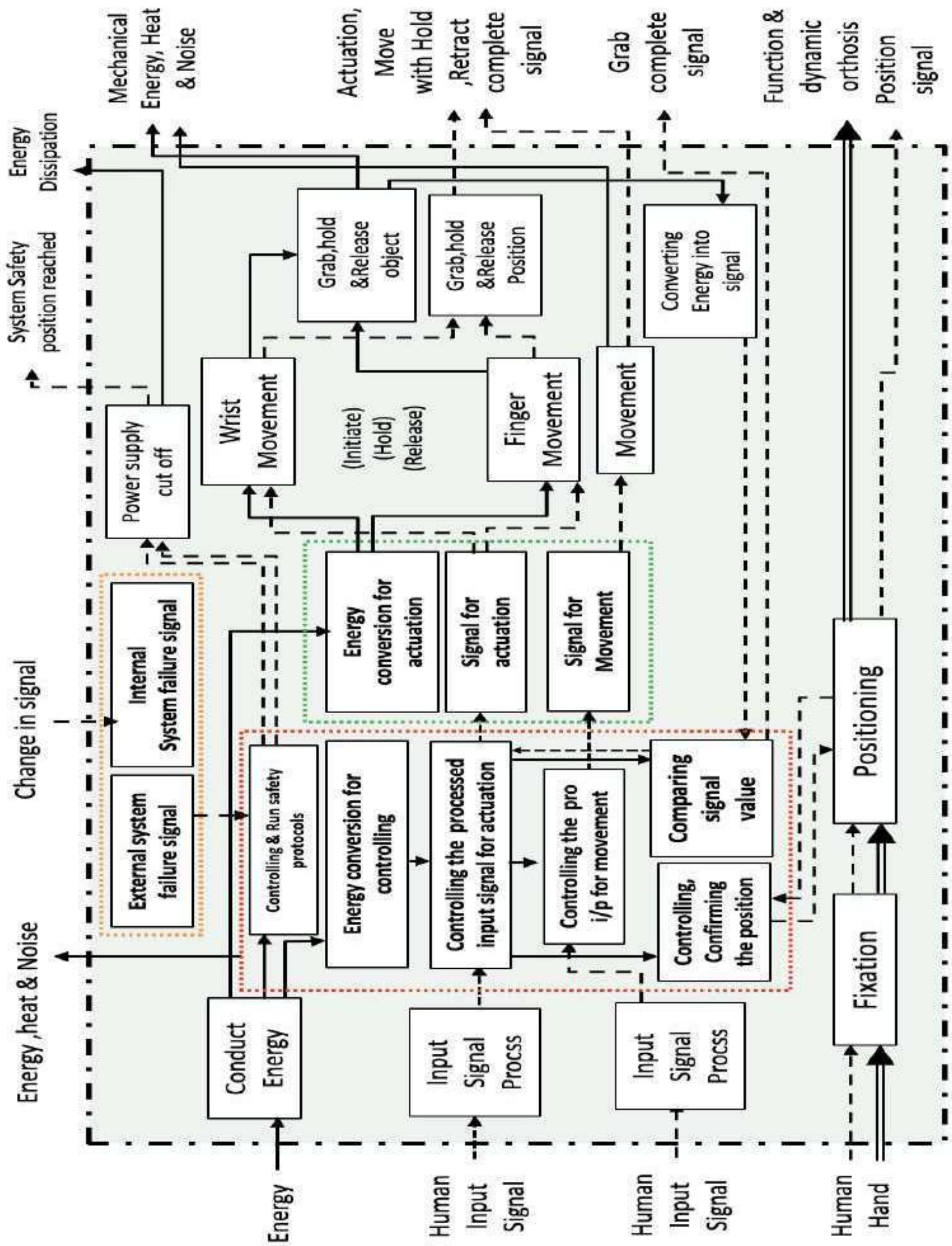


Figure 17. Overall Functional Structure

8. Finding the Working principle

The working principle can be derived from various sub-functions, which eventually combine to form the principle working structure. These principles must reflect various physical effects and characteristics in order to satisfy the given sub-function.

Besides satisfying the functional and working interrelationships, a solution must also satisfy certain generalor task-specific constraints. These can be classified under the following headings:

- Safety in the wider sense of reliability and availability
- Ergonomics: ease in human–machine interface
- Production facilities and type of production
- Quality control throughout the design and production process
- Assembly during and after the production of components
- Transport inside and outside of the factory
- Operation intended use, handling
- Maintenance upkeep, inspection and repair
- Expenditure costs and schedules
- Recycling reuse, reconstitution, disposal, final storage

In order to find and evaluate suitable solutions to satisfy each sub-function, we have followed general methods for finding and evaluating solutions

a) Product Planning
b) Solution Finding Methods
c) Evaluating solution

8.1 Product planning

There are many different methods utilized in the planning and product development process, which are categorized into general methods and problem-specific approaches. Conventional, intuitive, and discursive approaches are also included in the generic methods. The advantages of each strategy are numerous. The sort of approach to be used will be chosen based on the problem type, the information that is available, the stage of the process, and the knowledge and expertise of the designers.

8.2 Solution finding methods

Conventional
Methods Intuitive
Methods
Discursive Methods
Methods for Combining Solutions

i) Conventional Methods

Conventional Techniques
Analysis of Natural Systems
Analysis of Existing Technical Systems

Measurements and Model Tests
Conventional Techniques: This strategy uses tried-and-true techniques like literature study, association report review, trade show exhibitions, rival catalogs and presentations, patent research, etc.

Analysis of Existing Technical Systems: In this method, new or improved solution variants are generated from the existing technical systems in a step-by-step manner.

Measurements and Model Tests: The most important sources of information are measurements of existing systems, model tests which were supported by similar analysis and experimental studies.

ii) Intuitive Methods

Many engineering designers use intuition to solve complex technological issues. One of the most popular techniques for developing ideas and solutions worldwide was first developed by Osborn. It entails having a constructive, largely unstructured discussion about ideas and solutions with a group of like-minded but diverse persons in a supportive setting. It depends on each participant generating ideas and memories through conversation with group members and attempting to translate these ideas into solutions for a specific issue.
As Galtung of the International Peace Research Institute in Oslo has: “The good idea is not discovered or undiscovered; it comes, it happens”. This intuitive method is further consisting of following techniques:

Brainstorming
Synectics
Combination Method

Brainstorming: This approach entails brainstorming sessions in which numerous open-minded individuals share their ideas. The memory and thought associations are stimulated throughout these sessions. A group will typically have 5 to 15 members with leadership as needed. All thoughts will be written down, illustrated with sketches, or recorded. The developed concepts and sketches will be the subject of additional debate and evaluation.

Team Falcons conducted routine brainstorming sessions to ensure that after a thorough research that would be conducted on a period basis, the information gathered could be applied in the best possible way to develop the drone. Some of the brainstorming inputs from various members of the team are as shown below. These inputs have been provided over the course of several months and have played a part of their own during various phases of development.

Synectics: This is comparable to the brainstorming method, with the difference that the aim is to develop ideas with the help of analogies from non-technical or semi-technical fields. A group is formed with no more than 7 people with leadership. Presentation, familiarization, grasping the problem is conducted and familiar assumptions will be rejected with the help of analogies drawn from other spheres. One of the analogies is compared with the existing problem. A new idea is further developed from comparison.

Combination Method: The different methods are combined to meet particular cases. Any one of these methods taken by itself may not lead to the required goal. The brainstorming sessions end up with a dry flow of ideas, Synectic procedure is introduced to generate new ideas. A new idea or an analogy may radically change the approach and ideas of the group. A summary of what has been discussed may lead to new ideas. The explicit use of the methods of negation and reappraisal and of forward steps can enrich and extend the variety of ideas.

iii) Discursive Methods

Methods with a discursive bias provide solutions in a deliberate step-by-step approach that can be influenced and communicated. This method does not exclude intuition. Intuition can make its influence felt during individual steps and in the solution of individual problems. This method is further classified as follows:
Systematic Study of Physical Processes
Systematic Research with the Help of Classification Schemes
Use of Design Catalogues

Systematic Study of Physical Processes: Various solutions can be derived from the analysis of the relationship of the variants with solutions of known physical processes and physical variables

Systematic Research with the Help of Classification Schemes: a systematic presentation of data is always helpful with usage of morphological matrices. A step-by-step combination of various boxes of morphological charts which includes various rows and columns with solution principles are used to derive different solution principles.

Use of Design catalogue: Refer to collection of known and proven solutions to design problems. These design catalogues could be found in design handbooks, textbooks, company catalogues and primarily contain list of machine elements, standard parts, materials, bought-out components, etc. but may also contain physical effects, working principles and principal solutions for sub-functions

iv) Methods for Combining Solutions

With the help of the methods listed above we find various solutions to individual sub-functions. It is important to synthesize a compatible combination of the solution to each sub-function. This can be achieved by:

- Systematic Combination
- Combining With the Help of Mathematical Methods

8.3 Evaluating solution

Selecting Solution Variants: The use of systematic selection procedure greatly facilitates the choice of promising solutions from a number of proposals. The selection procedure involved two steps: elimination and preference by using a selection chart.

9. Morphological Box

By analyzing every potential aspect that could have an impact on the situation, the morphological box is a creative thinking tool that can be utilized to come up with answers for complex problems. The goal is to rationally break down the complex issue into smaller components and determine every potential resolution for each of these components. This approach was devised by Fritz Zwicky to simplify things. Some creative techniques, such as affinity diagramming and brainstorming, are used to create ideas for specific aspects of a difficult problem, but not for the entire issue. By breaking the problem down into manageable components, ideas or solutions can be developed, Morphological Box solves this problem. These ideas are combined to create multiple solutions.

Input Energy: The input energy for Hand orthosis can be of three types: Chemical, Electrical and Mechanical.

Chemical: The possible solutions for using chemical energy as input for hand orthosis are:

1) Liquids: Liquid-based energy conversion or energy transfer mechanisms within a hand orthosis is a possible solution, which would require a complex infrastructure, including pumps, valves, and intricate tubing systems.
2) Metabolic: Metabolic energy, derived from biochemical reactions within the human body, is predominantly utilized by the body's organs and tissues for their functioning. Harvesting metabolic energy to directly power a hand orthosis is also a possible option.

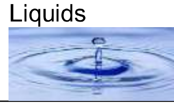
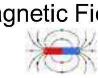
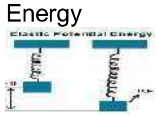
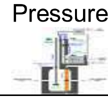
Electrical: There are several possible solutions for using electrical energy as input for a hand orthosis. Here are a few examples:

1) Battery-Powered Orthosis: One common approach is to incorporate a battery-powered system into the hand orthosis. The electrical energy from the battery can be used to drive motors or actuators that provide assistance and helps to perform specific movements.
2) Capacitor: Capacitors can store electrical energy and release it when needed. In a hand orthosis, a capacitor can be charged using an external power source or energy harvesting techniques, such as motion or vibration. Once charged, the capacitor can provide electrical energy to drive motors, actuators, or sensory systems within the orthosis.
3) Magnetic Field: Magnetic fields can be harnessed through electromagnetic induction to generate electrical energy. In a hand orthosis, this can be achieved by incorporating a coil and a magnet. When the magnet moves within the coil, it induces an electrical current in the coil. This generated electrical energy can be used to power electronic components or recharge batteries within the orthosis.
4) Solar Panels: Solar panels when integrated into a hand orthosis can capture sunlight and convert it into usable electrical power. The acquired solar energy can be stored in batteries or used directly to power sensors, motors, or control systems.

Mechanical: The possible solutions for using Mechanical energy as input for a hand orthosis are:

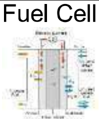
1) Elastic Energy: This can be used by incorporating elastic bands or springs into the hand orthosis design. When the user stretches or compresses these elastic components, they store potential energy. The stored energy can be released to provide assistance to facilitate hand movements.
2) Hydraulic Energy: This can be employed in hand orthoses with hydraulic systems. A hydraulic system consists of a fluid-filled network of tubes or channels and a piston-like mechanism. When the user applies force or pressure to the system, it generates hydraulic energy that can be utilized to drive actuators or provide assistance for hand movements.
3) Hand Crank: A hand crank mechanism can be integrated into a hand orthosis to convert the user's manual rotational input into mechanical energy. By turning the hand crank, the user can generate mechanical energy that can be used to power specific functions of the orthosis, such as finger extension or grasping.
4) Spring Energy: Spring energy can be employed by incorporating springs into the hand orthosis. When the user compresses or stretches the springs, they store potential energy. The energy stored in the springs can be released to assist hand movements.

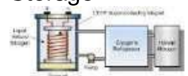
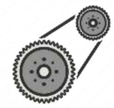
Table 2. Morphological Box – Methods Available to find solutions (Energy)

Solutions →		1	2	3	4
Subfunctions ↓					
Input Energy Type	Chemical	Liquids 	Metabolic 		
	Electrical	Battery 	Capacitor 	Magnetic Field 	Solar Panels 
	Mechanical	Elastic Energy 	Hydraulic / Pneumatic Pressure 	Hand Crank 	Spring 

Energy storage: The different energy storage methods are categorized into three: Chemical, Electrical and Mechanical.

1) Chemical: The possible chemical energy storage methods are:
Lead acid batteries which is a type of rechargeable battery commonly used for energy storage. They can be employed in hand orthosis to store electrical energy. Then, Fuel cells can also be utilized as an alternative energy storage and power generation system for hand orthosis. The other possible solution is Organic molecular storage which refers to the concept of using organic molecules as a means of storing energy. By incorporating organic molecules with energy storage capabilities into the orthosis, chemical reactions could be harnessed to store and release energy as needed.
2) Electrical: The possible electrical energy storage methods are by means of Capacitor, Battery, Super conduction and Supercapacitors. Superconducting magnetic storage involves utilizing superconducting materials to store electrical energy in the form of a magnetic field. They can be employed to store electrical energy for powering motors, actuators, or other electronic components. Then, supercapacitors can be utilized to store electrical energy and provide short bursts of power for driving motors, actuators, or electronic components.
3) Mechanical: The possible mechanical energy storage methods are Pressure tank, Spring, Flywheel and Wind-up spring. Pressure tanks can be employed in hand orthosis to store energy in the form of compressed gas or fluid. Springs are commonly used in hand orthosis to store and release mechanical energy. They can also be utilized to assist finger movements, provide resistance, or support specific hand functions. Flywheels can be integrated into hand orthosis to store rotational energy. The flywheel is spun at high speeds, storing kinetic energy in its rotational motion. Then, Wind-up springs can also be used as energy storage in hand orthosis. The user manually winds up the spring, storing potential energy. As the spring unwinds, the potential energy is released, driving the hand orthosis's movements or providing assistance to the user's hand.

Energ y Stora ge	Chemica l	Lead Acid 	Fuel Cell 	Organic Molecular Storage 	

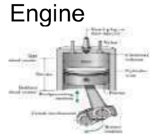
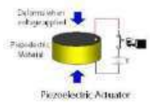
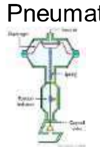
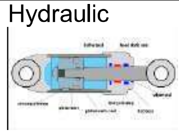
	Electrical	Capacitor 	Super Conduction Magnetic Energy Storage 	Supercapacitors 	Battery Cell 
	Mechanical	Pressure Tank 	Spring 	Flywheel 	Wind-up Spring 

Actuation: Below provided are the possible methods of actuation. They generate motion or applies force to assist or enhance hand movements.

1) Chemical: A combustion engine can be used as an actuation method in hand orthosis to generate mechanical power. The engine can be integrated into the orthosis and powered by a fuel source such as gasoline or diesel. The combustion process converts the chemical energy of the fuel into mechanical energy, which can then be harnessed to drive the hand orthosis and assist hand movements. Then, Muscle actuation is also another possible solution which involves utilizing the natural muscle contractions of the user to drive the hand orthosis. The orthosis can be designed to augment the user's muscle movements, provide additional strength, or assist with specific hand functions.

2) Electrical: The various possible actuation methods are solenoid, piezoelectric, smart fluid and Dc motor. Solenoids are electromagnetic devices that can convert electrical energy into linear motion. They can be employed in hand orthosis to generate linear movements or forces. Piezoelectric actuation is another method which can be utilized in hand orthosis to produce fine and precise movements. Smart fluid actuation is another method which can be employed in hand orthoses to provide variable resistance or damping. By controlling the applied electric or magnetic field, the fluid's viscosity can be adjusted, allowing for customized assistance during hand movements. Also, DC motors are commonly used as actuation methods in hand orthosis. They convert electrical energy into mechanical rotation. By controlling the current and voltage applied to the motor, the orthosis can generate rotational motion, which can be used to drive gears, levers, or other mechanical components.

3) Mechanical: The various possible actuation methods are Pneumatic, Hydraulic, Series elastic actuators and Electro hydraulic actuators. Pneumatic actuation involves the use of compressed air to generate motion or forces. In hand orthoses, pneumatic actuators can be utilized to provide assistance, resistance, or controlled movements. Then, Hydraulic actuation involves the use of pressurized fluids, typically oil or hydraulic fluid, to generate motion or forces. Hydraulic systems can provide precise control and high-power output in hand orthoses. The next method is by Series elastic actuators, which utilize a compliant element, such as a spring, in series with an actuator to provide force control and mechanical compliance. The compliant element acts as a buffer, absorbing and releasing energy during movements. Then, Electro-hydraulic actuators can also be used which combine hydraulic systems with electrical control. They use electrically driven pumps or valves to control the flow of hydraulic fluid, enabling precise and responsive actuation.

	Chemical	Combustion Engine 	Muscle 		
Actuation	Electric	Solenoid 	Piezoelectric 	Smart Fluid 	DC Motor 
	Mechanical	Pneumatic 	Hydraulic 	Series Elastic Actuators 	Electro-hydraulic 

The next subfunctions are the Joint articulation methods, Under actuation and number of under actuation possible in a Hand orthosis.

Joint articulation function in hand orthosis refers to how the orthosis replicates or assists the natural movement of hand joints. Different design approaches are used to achieve joint articulation, including monocentric, polycentric, and jointless systems.

1) Monocentric articulation: It involves the use of a single hinge joint to replicate the movement of a specific joint in the hand. This design approach is commonly used for simple finger orthosis.

2) Polycentric articulation: It involves the use of multiple hinge joints to replicate the movement of a joint or series of joints in the hand. This design approach allows for a more comprehensive replication of the hand's natural movements.

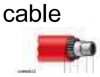
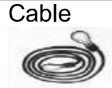
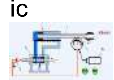
3) Jointless articulation: It involves a design approach that eliminates the use of discrete hinge joints in the orthosis. Instead, it focuses on utilizing flexible or compliant materials to mimic joint movement and provide articulation. Also, the under actuation can be around joints, finger and across the thumb.

Table 2. Morphological Box – Methods Available to find solutions (Mechanical)

Solutions → / Subfunctions ↓	1	2	3	4
Joint Articulation	Monocentric 	Polycentric 	Jointless 	
Under actuation	Across Joints	Across Fingers	Across the thumb	
Number of Under actuation	1	2	3	

Below provided are certain solutions for the subfunction Transmission. It refers to the mechanism or system used to transmit or transfer forces, motions, or control signals from the actuator or power source to the desired points of action within the orthosis. This is possible through Cable Conduits, Pulley System, Direct Linkage and Fluidic transmission.

1) Cable conduits: They are commonly used in hand orthoses to transmit forces from an actuator to specific points of action within the device. Some commonly used examples are Bowden cable, Push pull cable, Shaft and flexible shaft.
2) Pulley system: A pulley system is often employed to transmit forces and motion in hand orthosis. The system consists of one or more pulleys and a cable or cord that runs around them. The cable is connected to the actuator on one end and to the movable component on the other end. As the actuator pulls or releases the cable, the pulleys redirect the force or motion, transmitting it to the desired component or joint within the orthosis.
3) Direct linkage: It refers to the use of mechanical linkages, such as rods, gears, universal joint and levers, to transmit forces or motion in hand orthosis.
4) Fluidic transmission: It involves the use of a fluid medium, such as hydraulic or pneumatic systems, to transmit forces or motion. In hydraulic transmission, pressurized fluid is used to generate and transmit forces. Pneumatic transmission uses compressed air to achieve similar effects, with the air pressure driving the movement of the actuator and subsequently transmitting it to the orthosis.

Transmission	Cable Conduits	Bowden Cable 	Push pull cable 	Flexible Shaft 	Shaft 
	Pulley System	Cable 	Belt 	Chain 	
	Direct Linkage	Direct/bar linkage 	Gears 	Cam-followers 	Universal Joint 
	Fluidic transmission	Hydraulic 	Pneumatic 		

The positioning subfunction is vital for the overall operations of the Hand Orthosis device as it helps keep the device in a firm position. Few Solutions that can help achieve this subfunction involve

1. Velcro straps, commonly used in hand orthosis devices to secure and adjust the fit of the orthosis around the hand and wrist. The straps can be tightened or loosened to accommodate variations in hand size and swelling, can be easily fastened and unfastened, making it convenient for regular use and adjustments.
1. Silicone dots are sometimes incorporated into hand orthosis devices to enhance their functionality and improve grip. The silicone dots are strategically placed on the surface of the hand orthosis, typically on the palm or fingers. These dots create friction and improve grip, making it easier for the wearer to hold and manipulate objects. The silicone dots help stabilize the hand and provide tactile feedback, which can enhance the wearer's ability to grasp and manipulate objects with more control and precision.
2. Pull straps are commonly used in hand orthosis devices to assist with donning (putting on) and doffing

(taking off) the orthosis, as well as adjusting the fit and tension of the device. Pull straps are attached to the hand orthosis and provide a means to easily put on and remove the orthosis. By pulling on the straps, the wearer or caregiver can slide the orthosis onto the hand or remove it without excessive force or difficulty.

3. Magnetic straps are occasionally used in hand orthosis devices as an alternative fastening method. Magnetic straps utilize magnets embedded within the orthosis material to secure the device around the hand and wrist. The magnets create a secure connection when brought close together, allowing for easy fastening and removal.
4. Belts are occasionally used in hand orthosis devices to provide additional support and stabilization. Belts in hand orthosis are typically used to enhance stability and immobilize the hand and wrist. They can help restrict movement and prevent unwanted flexion, extension, or rotation of the affected hand or wrist.

Furthermore, additional subfunction is added that represents the combination of one of these above-mentioned solutions.

Table 2. Morphological Box – Methods Available to find solutions (Signal)

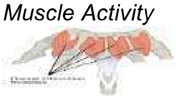
Solution / *Subfunction*	*1*	*2*	*3*	*4*	*5*
Positioning	*Velcro straps* 	*Silicon Dots* 	*Pull straps* 	*Magnetic Straps* 	*Belts* 
Number of positioning	*1*	*2*	*3*	*4*	

Further, we are looking for solutions that can monitor an activity for command signals. Certain suitable solutions were found for this purpose.

1) Monitoring nerve activity in a hand orthosis device involves the use of specialized sensors or electrodes to measure and analyse the electrical signals generated by the nerves in the hand and forearm. It's important to note that monitoring nerve activity in a hand orthosis device requires specialized equipment and expertise. The specific techniques and sensors used may vary depending on the purpose and goals of the monitoring, as well as the clinical setting in which the device is being utilized. Functional Electrical Stimulation (FES) is a technique used in hand orthosis devices to stimulate nerves in the hand and forearm using electrical currents. FES can be integrated into hand orthosis devices, where electrodes are strategically placed on the skin to deliver electrical stimulation to the targeted muscles or nerves. The orthosis holds the electrodes in place and ensures proper alignment and contact with the muscles or nerves.
2) Monitoring muscle activity in a hand orthosis device involves the use of sensors or electrodes to detect and measure the electrical signals produced by the muscles in the hand and forearm. It's important to note that monitoring muscle activity in a hand orthosis device requires specialized equipment and expertise. The specific techniques, sensors, and electrode placements used may vary depending on the goals and requirements of the monitoring, as well as the specific clinical or functional needs of the wearer. Electromyography (EMG) is a commonly used technique in hand orthosis devices to monitor and assess muscle activity in the hand and forearm. Myoelectric signals are commonly used in hand orthosis devices to control and operate the device based on the electrical activity of the muscles in the forearm. Myoelectric signals are generated by the contraction and relaxation of muscles. In hand orthosis devices, surface electrodes or sensors are placed on the skin over specific muscles in the forearm to detect these

signals. The myoelectric signals are then processed and used to control the movements of the hand orthosis. The success and usability of the system may vary depending on factors such as the user's residual muscle activity, electrode placement, signal quality, and the complexity of the desired hand movements.

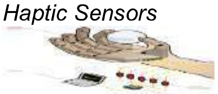
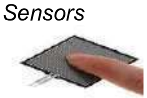
3) Monitoring brain activity for a hand orthosis typically involves the use of electroencephalography (EEG) techniques to detect and analyse the electrical signals produced by the brain It's important to note that monitoring brain activity for hand orthosis control is an active area of research and development. While there have been advancements in brain-computer interface technology, the practical implementation of brain-controlled hand orthoses is still in the experimental stage and not yet widely available for clinical use.

Monitored Activity	*Nerve Activity* 	*Muscle Activity* 	*Brain Activity* 		
Command Signal Interpreting Type	*Single*	*Series*	*Parallel*		
Command Signal	*Electroencephalography (EEG)* 	*Electromyography (EMG)* 	*Functional Electrical Stimulation* 	*Myoelectric Signals* 	

We need Microcontrollers that will be the control system for our Hand orthosis. 2 possible solutions were found to be viable.

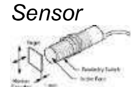
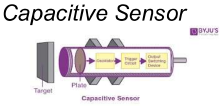
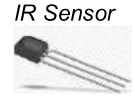
1) Microcontrollers will act as the control hub that enables precise and coordinated movements. This compact electronic component process input signals from sensors, such as myoelectric sensors or switches, and translate them into commands for actuating the orthosis. With their signal processing capabilities, microcontrollers convert analog signals into digital data, facilitating real-time feedback and monitoring of hand orthosis functions. Their programmability allows for customization, ensuring the device can be tailored to meet the specific needs and preferences of individual users. Additionally, microcontrollers efficiently manage power consumption, optimizing the overall performance and longevity of the hand orthosis device.

2) PLC, or Programmable Logic Controller, is not commonly used in hand orthosis devices. PLCs are industrial control systems typically employed in manufacturing and automation processes to monitor and control machinery or equipment. However, in the context of hand orthosis, which focuses on assisting individuals with hand impairments, the PLC can technically be utilised for higher data processing activities.

Control System	*Microcontroller* 	*PLC* 			
Feedback Signal	*Haptic Sensors* 	*Force/Pressure Sensors* 	*Auditory* 	*Visual* 	

Below provided are certain solutions for the subfunction for position signal. They will enable the control through microcontrollers.

1) Limit Switch: A limit switch is a mechanical device used to detect the presence or absence of an object or to indicate the position of a moving part. In a hand orthosis device, limit switches can be used to sense the limits of movement or specific positions, providing feedback signals to the control system.
2) Image Sensor: An image sensor is a device that captures images or video by converting optical images into electronic signals. In the context of a hand orthosis device, an image sensor can be used to detect objects in front of the hand, thus generating a feedback signal allowing the device to respond accordingly.
3) Proximity Sensor: A proximity sensor detects the presence or absence of an object within a specified range without any physical contact. In a hand orthosis device, a proximity sensor can be used to detect the proximity of objects or the position of the hand, enabling the device to adjust its behaviour based on the detected distance.
4) Capacitive Sensor: A capacitive sensor measures changes in capacitance to detect the presence or proximity of objects. In a hand orthosis device, a capacitive sensor can be utilized to detect the position or touch of the hand, providing position signals to control the device's movements or functions.
5) IR Sensor: An IR (Infrared) sensor detects infrared radiation emitted or reflected by objects. In a hand orthosis device, an IR sensor can be used to detect objects that the human is trying to interact with. This information can be used to send position signals and control the orthosis device accordingly.

Position Signal	*Limit Switch* 	*Image Sensor* 	*Proximity Sensor* 	*Capacitive Sensor* 	*IR Sensor* 

Below provided are certain solutions for the subfunction for position signal. They will enable the control through microcontrollers.

1) Laptop: A laptop is a portable computer device that typically features a larger screen and keyboard. It can be used for data visualization in hand orthosis devices by displaying graphical user interfaces, real-time feedback, or monitoring data. Laptops provide a larger screen size and more computing power for complex visualizations and data analysis.
2) Smartwatch: A smartwatch is a wearable device that is worn on the wrist and offers various functionalities beyond timekeeping. Smartwatches can display simple visualizations such as notifications, alerts, or basic data representations. In a hand orthosis device, a smartwatch can be used to provide real-time feedback, control settings, or display simple visual cues related to the orthosis's operation.
3) Mobile: A mobile device, such as a smartphone or tablet, is a portable computing device with a touchscreen interface. Mobile devices are widely used for data visualization in hand orthosis devices due to their compact size and versatility. They can display interactive graphical user interfaces, charts, graphs, or even augmented reality overlays to provide feedback, instructions, or control options.
4) AR Headset: An AR (Augmented Reality) headset is a wearable device that overlays digital information or virtual objects onto the real-world environment. AR headsets can provide immersive data visualization in hand orthosis devices by overlaying visual cues, instructions, or virtual representations of the hand's movements or position. They offer a hands-free experience and enable users to interact with the visualized data or virtual elements directly.

These data visualization devices can be used in hand orthosis devices to present real-time feedback, control options, or visual cues to users. The choice of device depends on factors such as the complexity of the visualizations, user preferences, and the level of immersion required in the hand orthosis application.

Data Visualization	*Laptop/Monitor* 	*Smartwatch* 	*Mobile* 	*AR Headset* 	

10. Variant selection

Using the solutions of the morphological box, several orthosis variants can be designed. However, the team has brainstormed and displayed 3 variants below which could be the best suited to our requirements. Variant 1 was the final chosen variant after all considerations.

Variant 1

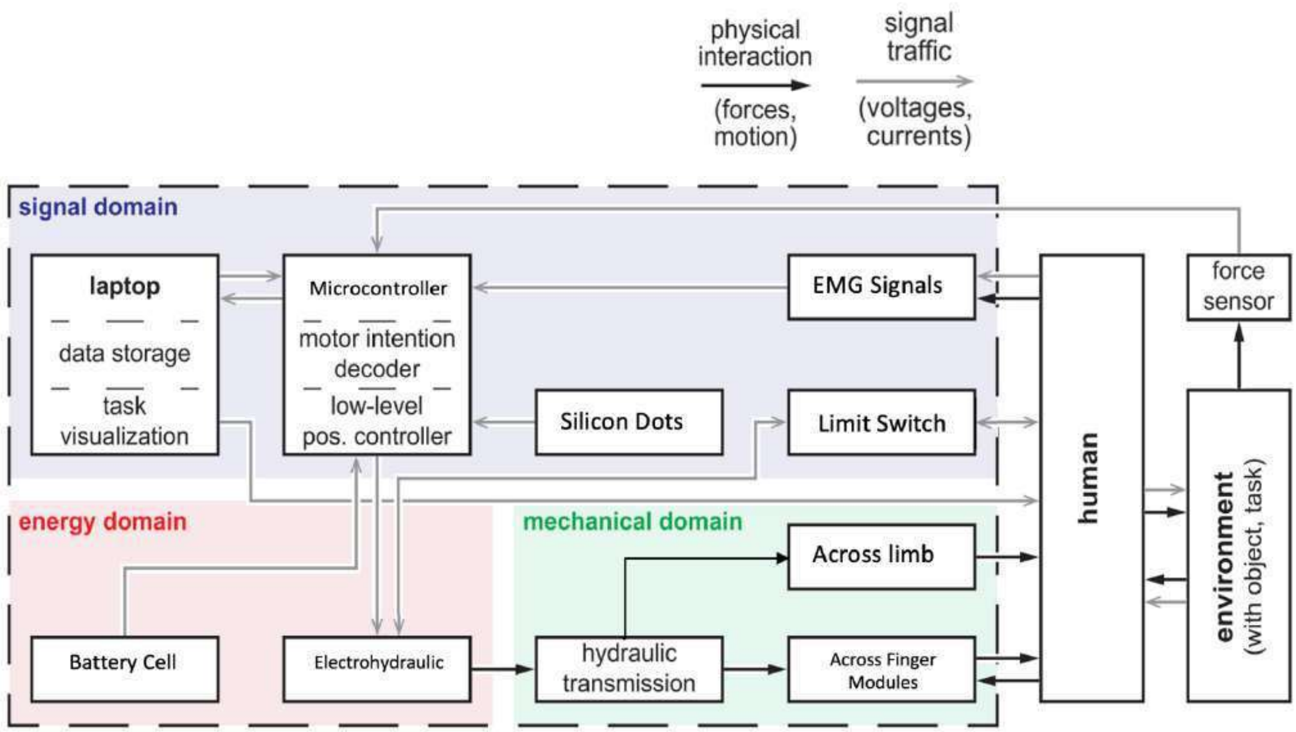


Figure18. Electrohydraulic powered, EMG and limit switch signaled Hand orthosis Function structure

Solutions → / Subfunctions ↓	1	2	3	4
Input Energy Type Electric	Battery	Capacitor	Magnetic Field	Solar Panels
Energy Storage	Capacitor	SCMEC	Supercapacitors	Battery Cell
Actuation	Pneumatic	Hydraulic	Series Elastic Actuators	Electrohydraulic
Joint Articulation	Monocentric	Polycentric	Jointless	
Underactuation	Across Joints	Across Fingers	Across the limb	
Number of under Actuation	1	2	3	
Transmission	Hydraulic	Pneumatic		
Positioning	Velcro Straps.	Silicon Dots	Pull straps	Magnetic Straps
Monitored Activity	Nerve Activity	Muscle Activity	Brain Activity	
Command Signal Interpreting Type	Single	Series	Parallel	
Command Signal	Electroencephalography (EEG)	Electromyography (EMG)	Functional Electrical Stimulation	Myoelectric Signals
Control System	Microcontroller	PLC		
Feedback Signal	Haptic Sensors	Force/Pressure Sensors	Auditory	Visual
Position Signal	Limit Switch	Image Sensor	Proximity Sensor	Capacitive Sensor
Data Visualization	Laptop/Monitor	Smartwatch	Mobile	AR Headset

Table 3. Morphological Box

In the above **variant 1** batteries are incorporated to the hand orthosis device to provide the input energy. The electrical energy from the battery can be used to drive motors or actuators that provide assistance and helps to perform specific movements. Superconducting magnetic storage are utilized involves utilizing superconducting materials to store electrical energy in the form of a magnetic field. They can be employed to store electrical energy for powering motors, actuators, or other electronic components. Electro-hydraulic actuators are used which combine hydraulic systems with electrical control. They use electrically driven pumps or valves to control the flow of hydraulic fluid, enabling precise and responsive actuation. Joint articulation function in hand orthosis refers to how the orthosis replicates or assists the natural movement of hand joints. Polycentric articulation involves the use of multiple hinge joints to replicate the movement of a joint or series of joints in the hand. This design approach allows for a more comprehensive replication of the hand's natural movements where under actuation is done across limbs and fingers and the under actuation 2 refers to moderate limitation of hand movement or muscle function. The transmission mechanism is used to transmit or transfer forces, motions, or control signals from the actuator or power source to the desired points of action within the orthosis. In this variant transmission is done by pressurized fluid which is used to generate and transmit forces. The positioning subfunction is vital for the overall operations of the Hand Orthosis device as it helps keep the device in a firm position. Velcro straps, are used in hand orthosis devices to secure and adjust the fit of the orthosis around the hand and wrist. The straps can be tightened or loosened to accommodate variations in hand size and swelling, can be easily fastened and unfastened, making it convenient for regular use and adjustments which is further depicted in the 3D Cad Model. Monitoring muscle activity in a hand orthosis device involves the use of sensors or electrodes to detect and measure the electrical signals produced by the muscles in the hand and forearm. It's important to note that monitoring muscle activity in a hand orthosis device requires specialized equipment and expertise. Electromyography (EMG) is a commonly used technique in hand orthosis devices to monitor and assess muscle activity in the hand and forearm. Myoelectric signals are commonly used in hand orthosis devices to control and operate the device based on the electrical activity of the muscles in the forearm. Myoelectric signals are generated by the contraction and relaxation of muscles. In hand orthosis devices, surface electrodes or sensors are placed on the skin over specific muscles in the forearm to detect these signals. The myoelectric signals are then processed and used to control the movements of the hand orthosis where the command signal interpreting type is single. Microcontrollers will act as the control hub that enables precise and coordinated movements. This compact electronic component process input signals from sensors, such as myoelectric sensors or switches, and translate them into commands for actuating the orthosis. With their signal processing capabilities, microcontrollers convert analog signals into digital data, facilitating real-time feedback and monitoring of hand orthosis functions. Force/Pressure sensors are incorporated that can measure forces exerted by the user on the interface to provide the feedback signal. A limit switch is a mechanical device used to detect the presence or absence of an object or to indicate the position of a moving part. In this variant limit switches are used to sense the limits of movement or specific positions, providing feedback signals to the control system. A laptop is a portable computer device that typically features a larger screen and keyboard. It can be used for data visualization in hand orthosis devices by displaying graphical user interfaces, real-time feedback, or monitoring data. Laptops provide a larger screen size and more computing power for complex visualizations and data analysis.

Variant 2

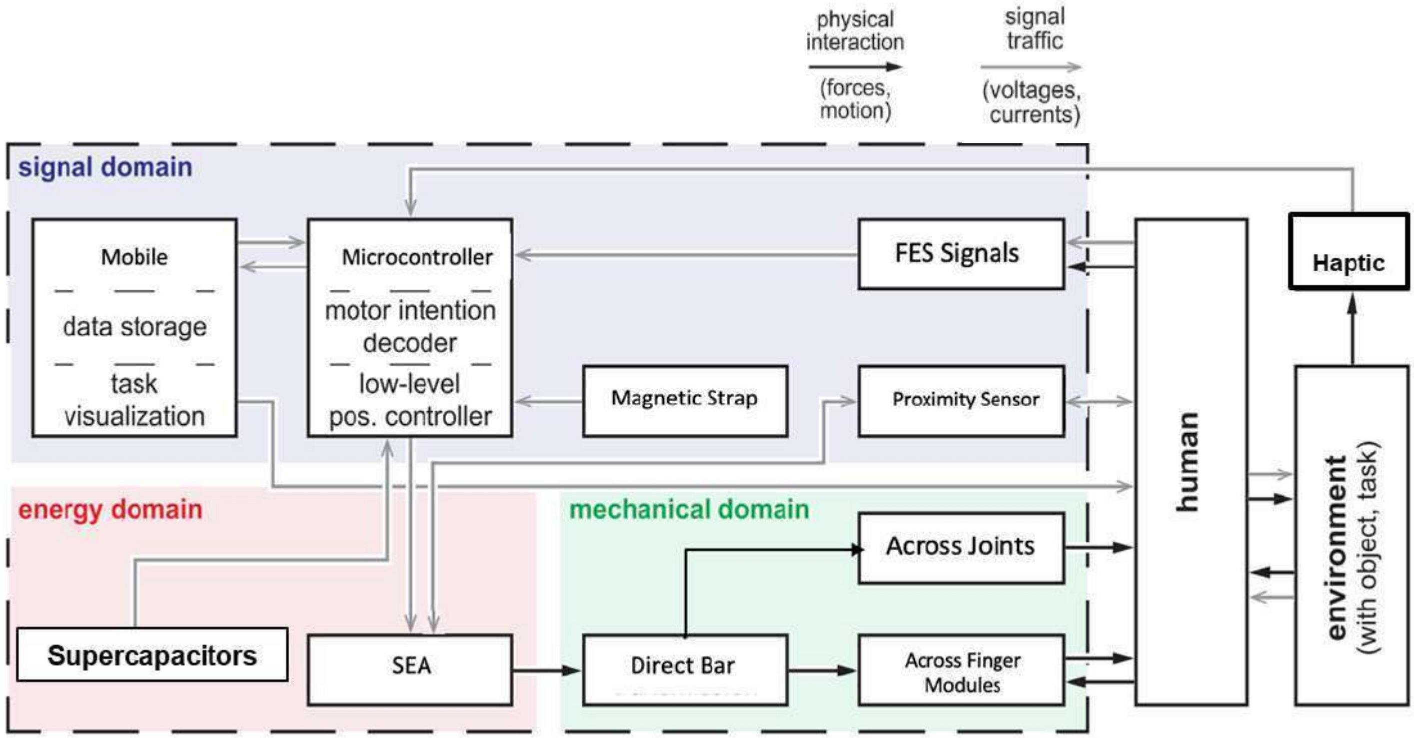


Figure19. SEA powered, FES and proximity sensor signaled hand orthosis function Structure

Solutions → / Subfunctions ↓	1	2	3	4
Input Energy Type Electric	Battery	Capacitor	Magnetic Field	Solar Panels
Energy Storage	Capacitor	SCMEC	Supercapacitors	Battery Cell
Actuation	Pneumatic	Hydraulic	Series Elastic Actuators	Electrohydraulic
Joint Articulation	Monocentric	Polycentric	Jointless	
Underactuation	Across Joints	Across Fingers	Across the limb	
Number of under Actuation	1	2	3	
Transmission	Hydraulic	Pneumatic	Direct/bar linkage	

Positioning	Velcro Straps.	Silicon Dots	Pull straps	Magnetic Straps
Monitored Activity	Nerve Activity	Muscle Activity	Brain Activity	
Command Signal Interpreting Type	Single	Series	Parallel	
Command Signal	Electroencephalography (EEG)	Electromyography (EMG)	Functional Electrical Stimulation	Myoelectric Signals
Control System	Microcontroller	PLC		
Feedback Signal	Haptic Sensors	Force/Pressure Sensors	Auditory	Visual
Position Signal	Limit Switch	Image Sensor	Proximity Sensor	Capacitive Sensor
Data Visualization	Laptop/Monitor	Smartwatch	Mobile	AR Headset

Table 4. Morphological Box

In the above **variant 2** the solar panels are used for input energy which when integrated into hand orthosis can capture solar energy and convert it into usable electric power. Then, supercapacitors can be utilized to store electrical energy and provide short bursts of power for driving motors, actuators, or electronic components. The next actuation method is by Series elastic actuators, which utilize a compliant element, such as a spring, in series with an actuator to provide force control and mechanical compliance. The compliant element acts as a buffer, absorbing and releasing energy during movements. Joint articulation function in hand orthosis refers to how the orthosis replicates or assists the natural movement of hand joints which in this case is done by polycentric articulation which involves the use of multiple hinge joints to replicate the movement of a joint or series of joints in the hand. This design approach allows for a more comprehensive replication of the hand's natural movements where under actuation is done across joints and fingers and the under actuation 1 refers to mild limitation of hand movement or muscle function. The transmission mechanism is used to transmit or transfer forces, motions, or control signals from the actuator or power source to the desired points of action within the orthosis. In this variant transmission is done using compressed air to achieve similar effects, with the air pressure driving the movement of the actuator and subsequently transmitting it to the orthosis. Magnetic straps are used in this variant as an alternative fastening method. Magnetic straps utilize magnets embedded within the orthosis material to secure the device around the hand and wrist. Monitoring nerve activity in a hand orthosis device involves the use of specialized sensors or electrodes to measure and analyse the electrical signals generated by the nerves in the hand and forearm. Functional Electrical Stimulation (FES) is a technique used in hand orthosis devices to stimulate nerves in the hand and forearm using electrical currents. FES can be integrated into hand orthosis devices, where electrodes are strategically placed on the skin to deliver electrical stimulation to the targeted muscles or nerves where the command signal interpreting type is single. Microcontrollers will act as the control hub that enables precise and coordinated movements.

This compact electronic component process input signals from sensors, such as myoelectric sensors or switches, and translate them into commands for actuating the orthosis. With their signal processing capabilities, microcontrollers convert analog signals into digital data, facilitating real-time feedback and monitoring of hand orthosis functions. Haptic sensors are incorporated as tactile sensors that can measure forces exerted by the user on the interface to provide the feedback signal. A proximity sensor detects the presence or absence of an object within a specified range without any physical contact. In a hand orthosis device, a proximity sensor can be used to detect the proximity of objects or the position of the hand, enabling the device to adjust its behaviour based on the detected distance. A mobile device, such as a smartphone or tablet, is a portable computing device with a touchscreen interface. Mobile devices are widely used for data visualization in hand orthosis devices due to their compact size and versatility. They can display interactive graphical user interfaces, charts, graphs, or even augmented reality overlays to provide feedback, instructions, or control options.

Variant 3

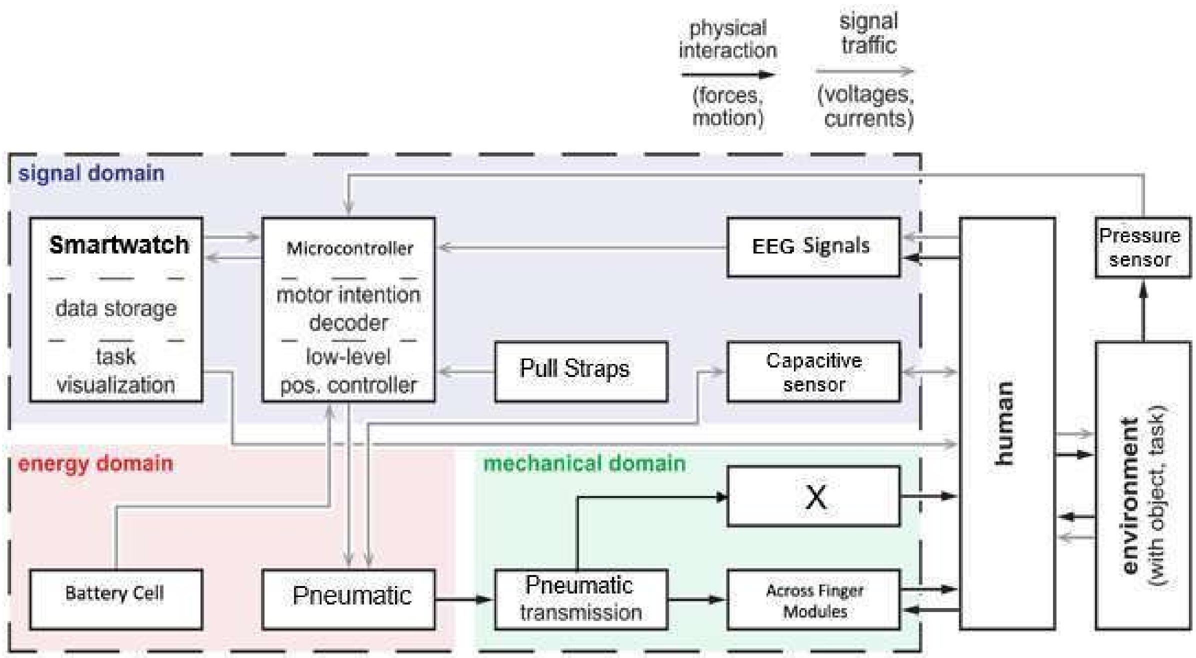


Figure 20. Pneumatic powered, EEG and capacitive sensor signalled hand orthosis

Solutions → / Subfunctions ↓	1	2	3	4
Input Energy Type Electric	Battery	Capacitor	Magnetic Field	Solar Panels
Energy Storage	Capacitor	SCMEC	Supercapacitors	Battery Cell
Actuation	Pneumatic	Hydraulic	Series Elastic Actuators	Electrohydraulic
Joint Articulation	Monocentric	Polycentric	Jointless	
Underactuation	Across Joints	Across Fingers	Across the limb	
Number of under Actuation	1	2	3	
Transmission	Hydraulic	Pneumatic		
Positioning	Velcro Straps.	Silicon Dots	Pull straps	Magnetic Straps
Monitored Activity	Nerve Activity	Muscle Activity	Brain Activity	
Command Signal Interpreting Type	Single	Series	Parallel	
Command Signal	Electroencephalography (EEG)	Electromyography (EMG)	Functional Electrical Stimulation	Myoelectric Signals
Control System	Microcontroller	PLC		
Feedback Signal	Haptic Sensors	Force/Pressure Sensors	Auditory	Visual
Position Signal	Limit Switch	Image Sensor	Proximity Sensor	Capacitive Sensor
Data Visualization	Laptop/Monitor	Smartwatch	Mobile	AR Headset

Table 5. Morphological Box

In the above **variant 3** batteries are incorporated to the hand orthosis device to provide the input energy. The electrical energy from the battery can be used to drive motors or actuators that provide assistance and helps to perform specific movements. Capacitors store electrical energy and release it when needed. In tgis hand orthosis, a capacitor can be charged using an external power source or energy harvesting techniques, such as motion or vibration. Once charged, the capacitor can provide electrical energy to drive motors, actuators, or sensory systems within the orthosis. In this variant of hand orthosis, pneumatic actuators are utilized to provide assistance, resistance, or controlled movements. Joint articulation function in hand orthosis refers to how the orthosis replicates or assists the natural movement of hand joints which in this case is done by Jointless articulation which involves a design approach that eliminates the use of discrete hinge joints in the orthosis. Instead, it focuses on utilizing flexible or compliant materials to mimic joint movement and provide articulation where where under actuation is done across fingers and the under actuation 1 refers to mild limitation of hand movement or muscle function. The transmission mechanism is used to transmit or transfer forces, motions, or control signals from the actuator or power source to the desired points of action within the orthosis. In this variant transmission is done using compressed air to achieve similar effects, with the air pressure driving the movement of the actuator and subsequently transmitting it to the orthosis. Pull straps are used in hand orthosis devices to assist with donning (putting on) and doffing (taking off) the orthosis, as well as adjusting the fit and tension of the device. Pull straps are attached to the hand orthosis and provide a means to easily put on and remove the orthosis. By pulling on the straps, the wearer or caregiver can slide the orthosis onto the hand or remove it without excessive force or difficulty. Monitoring brain activity for a hand orthosis typically involves the use of electroencephalography (EEG) techniques to detect and analyze the electrical signals produced by the brain It's important to note that monitoring brain activity for hand orthosis control is an active area of research and development where the command signal interpreting type is single. Microcontrollers will act as the control hub that enables precise and coordinated movements. This compact electronic component process input signals from sensors, such as myoelectric sensors or switches, and translate them into commands for actuating the orthosis. With their signal processing capabilities, microcontrollers convert analog signals into digital data, facilitating real-time feedback and monitoring of hand orthosis functions. Force/Pressure sensors are incorporated that can measure forces exerted by the user on the interface to provide the feedback signal. A capacitive sensor measures changes in capacitance to detect the presence or proximity of objects. In a hand orthosis device, a capacitive sensor can be utilized to detect the position or touch of the hand, providing position signals to control the device's movements or functions. A smartwatch is a wearable device that is worn on the wrist and offers various functionalities beyond timekeeping. Smartwatches can display simple visualizations such as notifications, alerts, or basic data representations. In a hand orthosis device, a smartwatch can be used to provide real-time feedback, control settings, or display simple visual cues related to the orthosis's operation.

11. Identifying Evaluation Criteria

Variant Analysis for each Functional Structure was carried out. Initially, different variants of solution for each of the functional structures were selected from the morphological box. Then, different evaluation criteria were adopted to choose the best suited variant for each of the functional structures.

Initially, Preliminary Argument Balance was applied using which advantages and disadvantages of individual variants were listed down in the table. Those variants which were unable to meet the requirement of project were eliminated directly from this evaluation criteria. Once the list of possible variants was minimized, the property variables were defined for the assessment of these selected variants. The property variables were provided with weightage using the Ranking Matrix. The Ranking Table was formed where these variables were entered in descending order as per their weightage.
Finally, Utility Value Analysis was performed on each of the variants. The score from 0 to 10 was provided for each of the variants for each of the property variables. The score was then multiplied with the weightage for each of the property variables to obtain the weighted value. At the end the weighted value was added

and the variant that had more value was selected for the design.

11.1 Variant Analysis
Evaluation Methodology:

These are the few evaluation methodologies that we can use to evaluate the variants. Few methods require tools which are costly and may require a lot of time, considering all the parameters, we choose four methodologies, which are Argument balance, Ranking and Preference matrix, Selection List, and Utility Value Analysis.

11.2 Argument balance

Variants	Advantages	Disadvantages
Electrohydraulic powered, EMG and limit switch signaled Hand orthosis	• EMG method is non-invasive in nature. • Silicon dots provide high accuracy in terms of positioning and Velcro straps in terms of fit. • Better grip accuracy due to connections only across fingers and joints. • Light weight and compact • Greater data visualization and fast processing (laptop)	• Less portable because of laptop device. • Use of mechanical components like limit switch for feedback signal.
SEA powered FES and proximity sensor signaled hand orthosis	• Better grip due to connections across joints. • Mobile device is used for data visualization, more portable. • Series elastic actuator provides high degree of position accuracy.	• FES are more intrusive, which carries risks like infection or tissue damages. • Bulky model due to direct bar linkages. • Multiple positioning mechanisms improve wearability but hinder ease of fit, magnetic strap-ons may be challenging.
Pneumatic powered EEG and capacitive sensor signaled hand orthosis	• Jointless articulation results in a glove like support to the hand orthosis. • Capacitive sensors can detect changes in the capacitance of materials in response to pressure or movement.	• Due to air compressibility, pneumatic actuators may backlash. Significant motion is lost, which causes latency. • Electroencephalography will need another decoder device which reduces device portability.

Table 6. Argument Balance

The outcome of the argument balance is analyzed and the findings show that the SEA powered, FES and proximity sensor signaled hand orthosis variant is more intrusive in nature and it can damage the tissues leading muscle fatigue. For the Pneumatic powered EEG and capacitive sensor signaled hand orthosis variant, the main disadvantages are the backlash of the pneumatic actuators, by which significant motion is lost which causes latency. Also, EEG requires additional decoder device which reduces device portability. Therefore, these two variants have more disadvantages when compared to Electrohydraulic powered, EMG and limit switch signaled Hand orthosis.

11.3 Property variables

The further evaluation of the variants was carried out by using the following property variables:

1. Signals
2. Functions
3. Safety
4. Ergonomics
5. Cost
6. Simple Assembly
7. Ease of Maintenance

11.4 Ranking Matrix

According to R. Wenzel, J, Muller and R. Gutush: The Ranking Matrix procedure is the “Determination of the value of the evaluation criteria based on general judgments.”

11.5 Construction of the matrix:

It Involves a matrix where the rows represent the criteria being evaluated and the columns represent the criteria being used to evaluate them. The cells are then filled with score to which each options satisfies the criteria.

Criteria that are to be evaluated are noted down along the first row and first column. We have chosen criteria to evaluate. Each criterion was evaluated and ranked in comparison with the remaining 6 parameters. The criterion with the highest number was ranked first and the one with the least number was ranked last.

Assigning the Ranks: The ranking is given in descending order. The row with the highest number is ranked 1. Subsequently, rank 2 is awarded for the next highest number. Similarly, rank 3 and rank four. Since some of the rows share the same number, they’ll possess the same ranking as their corresponding row.

Property Variables	Simple Assembly	Ease of Maintenance	Safety	Ergonomics	Signals	Function	Cost	Sum (+)
Simple Assembly		-	-	+	-	-	-	1
Ease of maintenance	+		-	-	-	-	-	1
Safety	+	+		+	+	-	+	5
Ergonomics	-	+	-		-	-	-	1
Signals	+	+	-	+		-	-	3
Function	+	+	+	+	+		+	6
Cost	+	+	-	+	+	-		4
Sum (-)	1	1	5	1	3	6	4	21

Table 7. Ranking Matrix for Property Variables

Based on the outcome from the ranking matrix, following Rank Table was generated:

Rank	Property Variable	Weightage
1	Function	0.28
2	Safety	0.23
3	Cost	0.20
4	Signals	0.14
5	Simple Assembly	0.05
6	Ease of Maintenance	0.05
7	Ergonomics	0.05

Table 8. Rank Table for property Variable

11.6 Utility Value Analysis:

Utility Value Analysis is a Weighted comparison of degrees of target fulfilment, says C. Zangemeister. his approach makes weighted comparisons easier to apply, giving the ability to prioritize the evaluation criteria. It is a technique that may be used to solve any problem and calls for modest to medium expenditure. Using a function known as the objectives tree, the assessment criteria are derived from the objectives. In order to assure simple evaluation, this makes it easier to divide primary objectives into one or more layers of sub-objectives. The evaluation criteria are formed by the lowest level sub-objectives. Weightages are assigned after the evaluation criteria are derived, either on a scale of 0 to 1 or from 0-100. The utility-value points (table.3) are then assigned using only integer values in the range of 0 to 10.

Construction of Matrix:

The evaluation criteria are imported from the Ranking Matrix. The weightage percentage of each criterion is calculated, with the aid of Ranking Matrix, such that the sum of all the weightage is equal to 1. Using the Value scale for Utility Value Analysis, the score each variant has achieved (unweighted sub-values), in relation to each criterion, is set up.

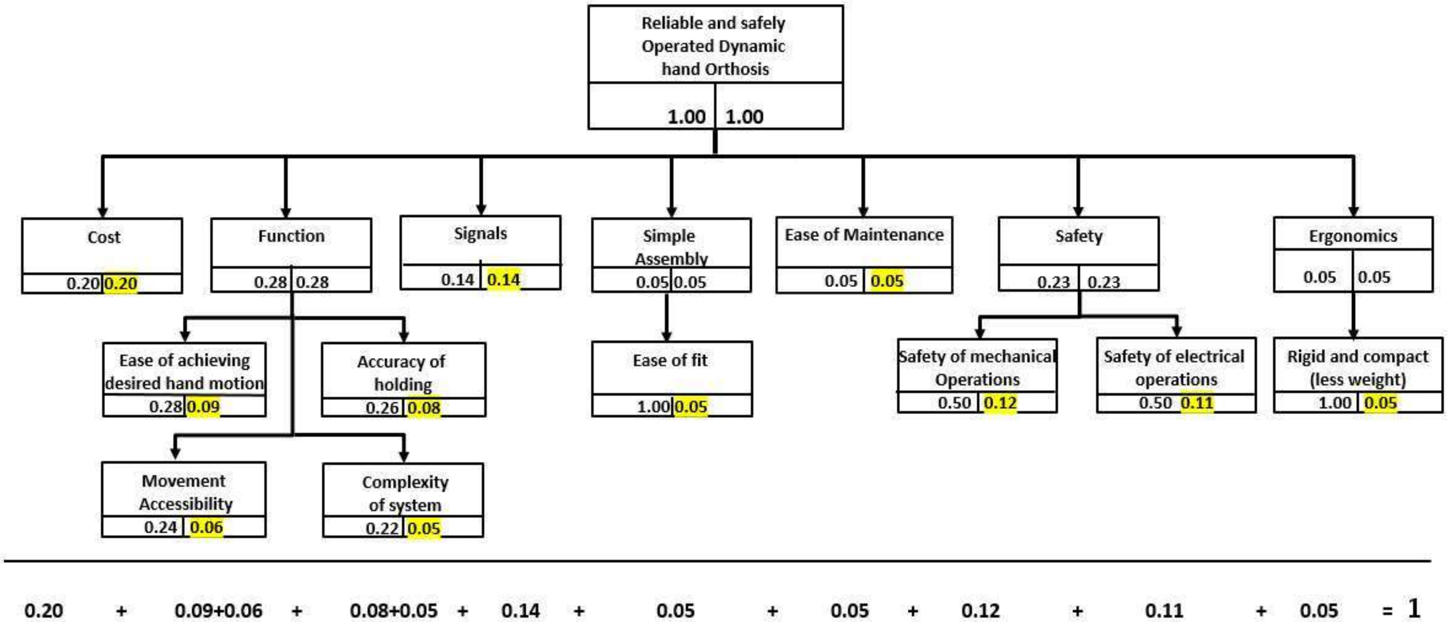


Figure 21. Objective Tree

Stepwise determination of the weighting factors of objectives of a target system

Value	Meaning	Magnitude
0	Absolutely useless solution	Very low
1	Very flawed solution	
2	Weak solution	Low
3	Viable solution	
4	Adequate solution	Moderate
5	Satisfactory solution	
6	Good solution with minor deficiencies	High
7	Good solution	
8	Very good solution	Very High
9	Solution exceeding the target	
10	Ideal solution	Ideal

Table 9. Value scale for utility-value analysis

Sl. No.	Property Variables	Parameters	Weight	Solution Variants								
				Variant 1			Variant 2			Variant 3		
				Magnitude	Value	Weighted value	Magnitude	Value	Weighted value	Magnitude	Value	Weighted value
1	Ergonomics	Weight	0.05	Less	7	0.35	Less	7	0.35	Less	5	0.25
2	Safety of electrical operations	Stability	0.11	High	8	0.88	Moderate	6	0.66	Moderate	5	0.55
3	Accuracy of holding	Accuracy	0.08	High	7	0.56	Moderate	5	0.40	Moderate	5	0.32
4	Ease of achieving desired hand motion	Velocity/displacement	0.09	High	8	0.72	High	7	0.63	Low	4	0.45
5	Ease of fit	Simplicity of assembly	0.05	Moderate	6	0.30	Moderate	5	0.25	Low	4	0.20
6	Movement Accessibility	Distance	0.06	High	7	0.42	High	7	0.42	High	6	0.36
7	Safety of mechanical operations	Stability	0.12	High	8	0.96	Moderate	6	0.72	Low	4	0.48
8	Ease of Maintenance	Price/Time	0.05	Moderate	6	0.30	Low	4	0.20	Low	4	0.30
9	Signals	Response	0.14	High	5	0.70	Moderate	4	0.56	Low	4	0.70
10	Cost	Price	0.20	Moderate	4	0.8	Adequate	5	1	High	6	0.80
11	Complexity of system	No. of moving parts	0.05	Adequate	4	0.20	Adequate	4	0.20	Adequate	6	0.30
	Overall Score		**1**			**6.19**			**5.39**		**4.71**	**X**

Table 10. Evaluation between variants using Utility value analysis

The 3 variants were evaluated with different parameters and property variables and the weighted values were provided according to it. As per the above Utility value analysis, the overall score of variant 1 is greater than variant 2 and variant 3. Therefore, variant 1 is the prominent winner and it is the best suited option. Due to less overall score, variant 3 was eliminated from the further evaluation.

11.7 Weighted Value Profile Comparison

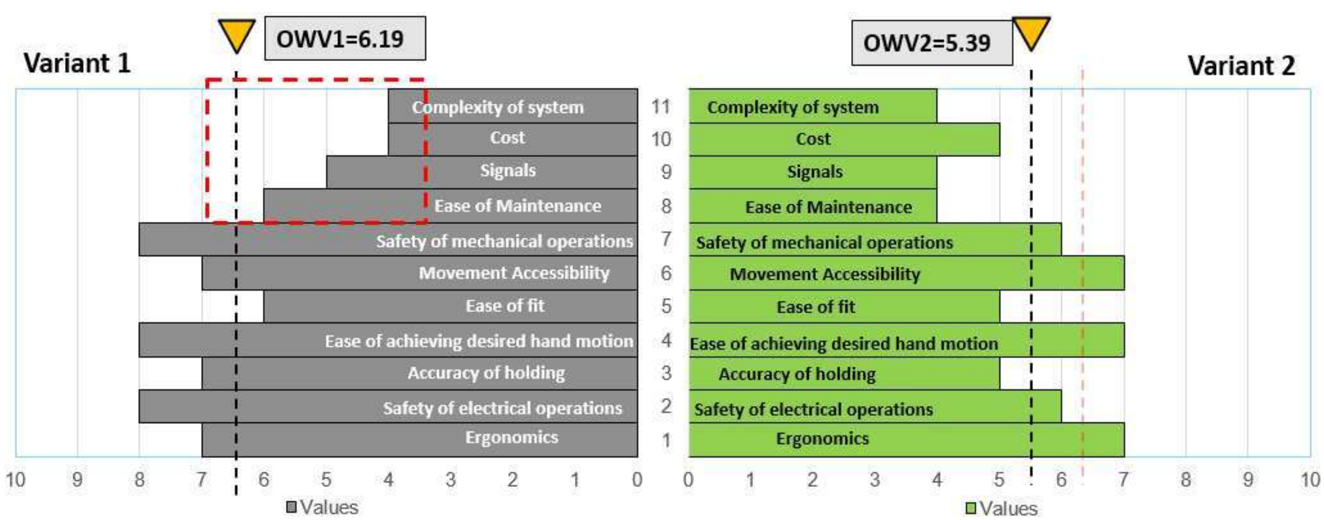


Figure 22. Weighted Value profile Comparison

To understand the above analysis better, a weighted value profile comparison between variant 1 and variant 2 was carried out. On the X-axis, unweighted sub values are plotted and weighted sub-values in the Y-axis. Variant 1 has less cost and higher signal response compared to variant 2. Also, variant 1 and variant 2 has same complexity of system. Furthermore, Variant 1 has higher safety of operations and ease of achieving desired hand motion when compared to variant 2. Hence, variant 1 was selected as the optimal solution.

11.8 Other Possible Variants :

Other variants	Advantages	Dis-advantages
Electrohydraulic powered, capacitive sensor signalled hand orthosis	• Capacitive sensor allows the orthosis to detect and respond to a variety of hand movements and positions and real-time feedback.	• 2 different circuits to control • Capacitive sensor needs to be calibrated • Hence, makes it a bulky model
Pneumatic powered, proximity sensor signalled hand orthosis	• Light weight and compact • Adjustable and precise control • Quiet Operation	• Due to the backlash, the hand movement maybe delayed which leads to false readings of sensor. • Also, Pneumatic powered, we need to provide filtered air which is of higher maintenance
SEA powered, limit switch signalled hand orthosis	• Precise control and force sensing • Intuitive limit switch signalling	• Adding limit switch sensors to SEAs can increase their complexity and cost, which may be a disadvantage in some applications. • Limit switch sensors can increase the time it takes for an SEA to move to a new position because the sensors must be activated before the motor can start moving the load.

Table 11. Advantages and Disadvantages of Other Variants Combinations

By taking into account the previously mentioned variations and switching the actuators with the sensors and other sub-functions. Three further variants were investigated to see what combinations of hand orthosis would be possible. Later, a argument balance was carried out, and resulted in many disadvantages and turned out that these variations are not appropriate for the objective of our project.

11.9 Optimal solution

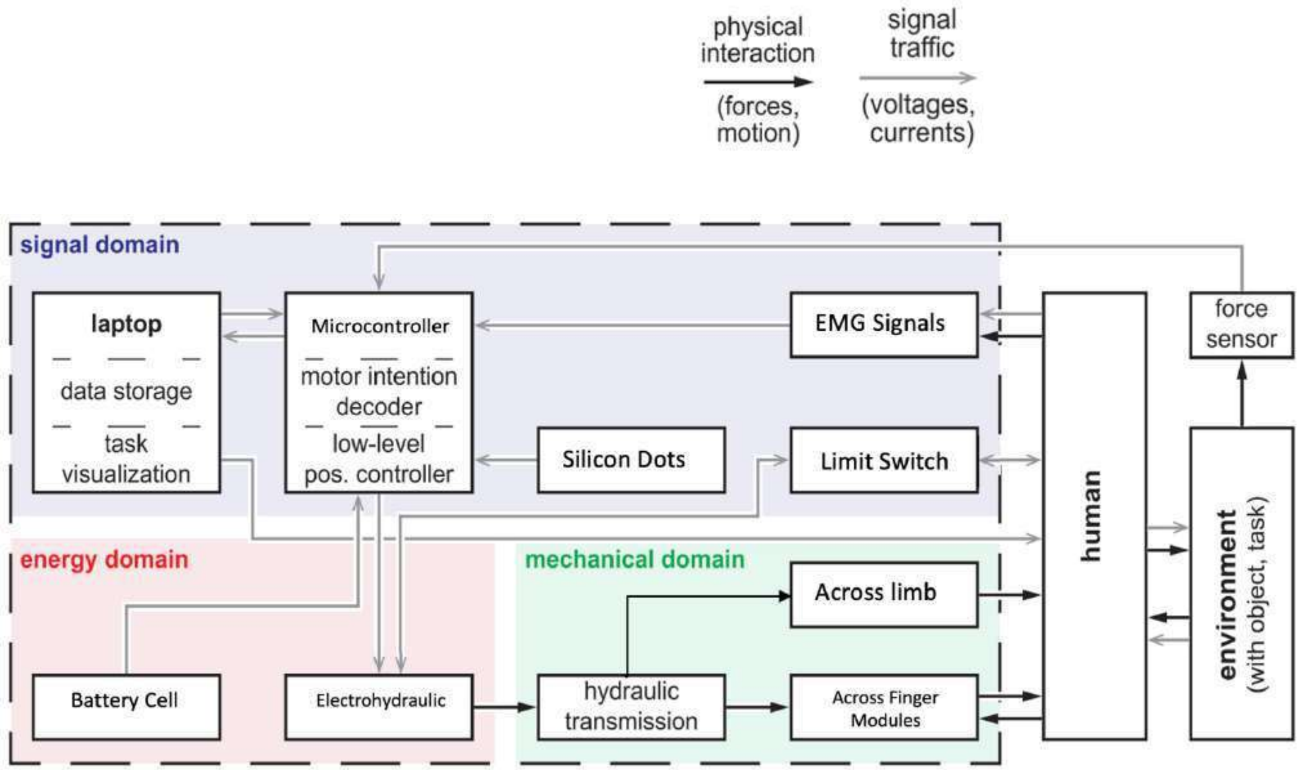


Figure 23. *Electrohydraulic powered, EMG and limit switch signaled Hand orthosis Function Structure*

Electrohydraulic system utilizes hydraulic power to control the mechanical components. The electric motor actuates the hydraulic pump, which generate mechanical force and motion. sEMG or Surface electromyography is used to measure the muscle activity. By integrating sEMG sensors into an electrohydraulic system, it can detect the muscle activity associated with the specific motion, and that signal can be used to activate the electrohydraulic system to control accordingly. In the electrohydraulic system, limit switches can be used to monitor the position of mechanical components, sending a signal to the system controller to stop the system or trigger a specific action. Silicon dots enhances overall grip strength and the raised dots prevent slippage or shifting of the orthosis, allowing the user to hold objects more securely with less effort.

Overall, SEMG sensors detect the patient's muscle activity, which is then translated into commands for the electrohydraulic system. The pressure sensors detect the force applied by the patient's hand, enabling the orthosis to adjust the grip strength accordingly. The limit switch provides safety mechanisms, ensuring the orthosis operates within safe and predefined ranges.

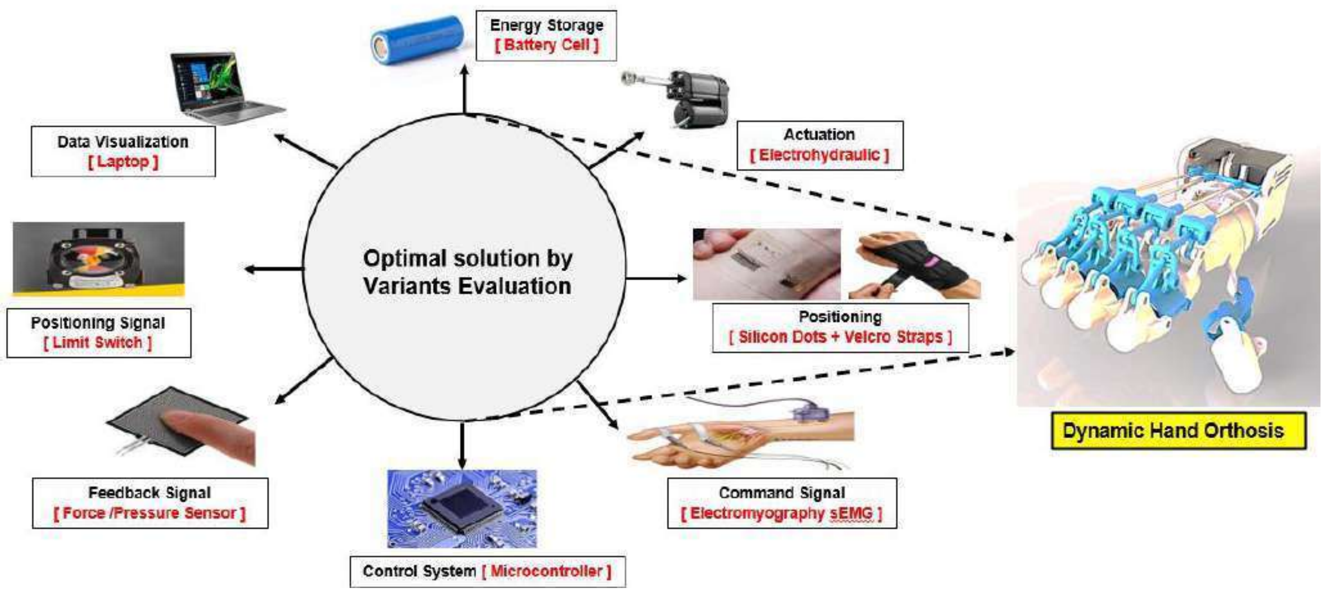


Figure 24. Optimal Solution by Variants Evaluation

12. EMBODIMENT DESIGN

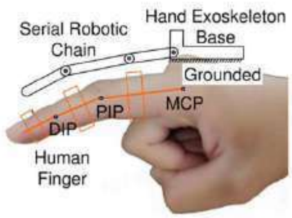
As the design process is an iterative process, different components of the hand orthosis device were evaluated at different times. A hybrid finger design was then created by combining the best components of the finger designs. Next, thumb designs were created and rated with the hybrid finger design. Finally, mechanical advantage design concepts were created and rated to establish a final design made up of the best finger, thumb, and mechanical advantage components. It was determined that the finger motion was the primary focus of the design since it was both more complex and more important which is why the finger designs was initially designed. The final design is a combination of the selected concepts from the thumb, finger and mechanical advantage comparisons**.** This final design combines the hybrid finger design, the thumb distal phalanx incremental motion design which is shown in the below figures.

CAD DESIGN

12.1 FINGER EXOSKELETON

Finger exoskeleton CAD Modelling involves using computer-aided design (CAD) software to create a digital representation n of a finger exoskeleton. In this case the Solid works was used to design the finger exoskeleton. The goal in designing the finger exoskeleton mechanism was to have low reaction forces at the finger joints, while achieving maximum range of motion at the finger joints. According to certain studies on the arm, anatomical breakdown (the motion of various joints independently of one another) is preferable to complex arm movements for rehabilitation (. Instead of the neurological effort required, the complexity of the activity is determined by the number of anatomical joints engaged in accomplishing the action.
Motor learning is improved by segmenting simultaneous shoulder abduction-adduction, flexion-extension, internal-external rotation, and elbow flexion-extension along sinusoidal paths. The metacarpophalangeal (MCP), proximal interphalangeal (PIP), and distal interphalangeal (DIP) joints make up the Index finger (Figure 2(a)). The MCP joint has two degrees of freedom (DOFs), which are abduction-adduction and flexion-extension (up-down and side-to-side motion). The PIP and DIP joints can only move in flexion and extension. Proximal, middle, and distal phalanges are the names of the three finger phalanges, respectively which is

represented in the below figure.



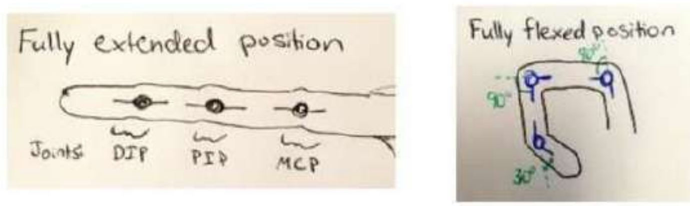
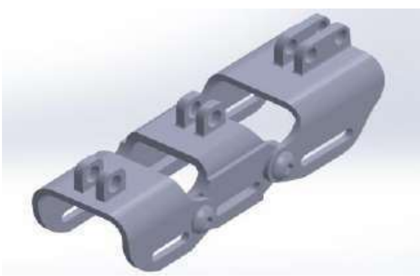


Figure 25. Kinematics of Finger Exoskeleton *Figure26. Finger Exoskeleton*

According to the above kinematic chains in the system and the degree of freedom analysis, the blow CAD design was modelled.



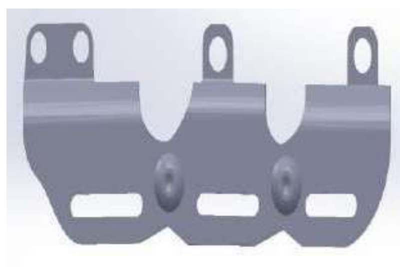


Figure 27. Isometric view of finger exoskeleton *Figure 28. Side view* *Figure 29. Top View*

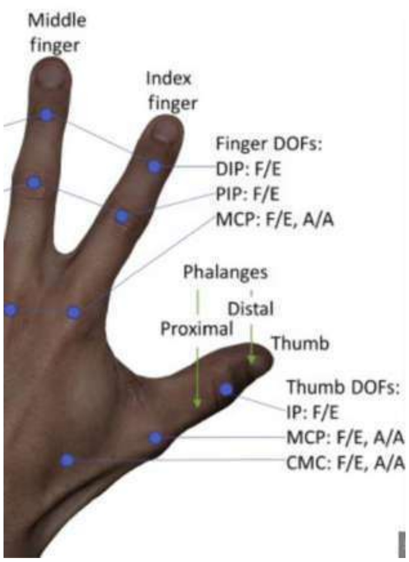
The above finger exoskeleton consists of individual segments which are modelled for each phalange of the finger. For each phalange 1 slot has been provided for better fit and positioning. Polycentric joints are used to connect each of the parts. Button head socket head screws are used in the joints. The geometric design considerations are given below in the table.

Phalange	Proximal (Knuckle)	Medial (Middle)	Distal (Nail End)
Length(mm)	23	14	17
Thickness(mm)	1.5	1.5	1.5
Inner Width(mm)	19	16	19
Model Parts			

Table 12. Geometrical dimensions of Finger Exoskeleton

12.2 THUMB EXOSKELETON

A crucial evolutionary trait of humans is the motion of the thumb and the capacity for thumb-finger opposition, which makes it feasible to grab and manipulate items, especially little ones, with one hand. The thumb is made up of three joints: the carpometacarpal joint (CMC), which is at the base of the palm and is primarily in charge of opposing motion in the thumb; the metacarpophalangeal joint (MCP); and the interphalangeal joint (IP), which is primarily in charge of flexion and extension in the thumb. Carpometacarpal flexion-extension (CMC FE), carpometacarpal abduction-adduction (CMC AA), metacarpophalangeal flexion-extension (MCP FE), and interphalangeal flexion-extension (IP FE) are the four main DOFs that make up the human thumb. To activate these four DOFs and prevent the exoskeleton-human joint axis misalignment issue, the thumb exoskeleton's mechanism uses three closed-loop chains. The thumb carpometacarpal bone forms a closed-loop chain with the CMC chain, which has two DOFs and is made up of four revolute joints and one prismatic joint. The exoskeleton and thumb interact via a sliding joint, which guarantees that only natural pressures are exerted on the phalanx. Thumb abduction and adduction action is made possible by one of the revolute joints. The MCP and IP chains both have four revolute joints, which provide each chain one DOF as depicted in the below figure.



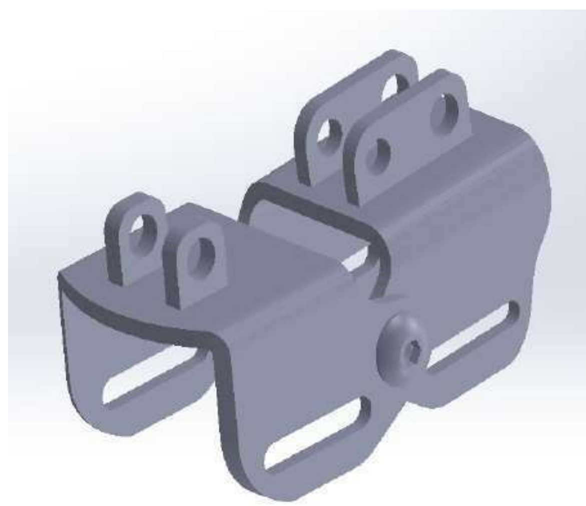


Figure 30. Kinematics of Thumb Exoskeleton *Figure 31.* Isometric view of Thumb's Exoskeleton

According to the above kinematic considerations, the thumb exoskeleton design was generated.

Isometric view of Thumb's Exoskeleton

The above thumb exoskeleton consists of only 2 independent phalanges. Individual segments are modelled for each phalange of the finger. There has been 1 slot provided to each phalange part for better fit and positioning. Button head socket head screws are used to connect the 2 parts.

Linkages, screws and nuts are provided above the fingers as shown in the below CAD Model.

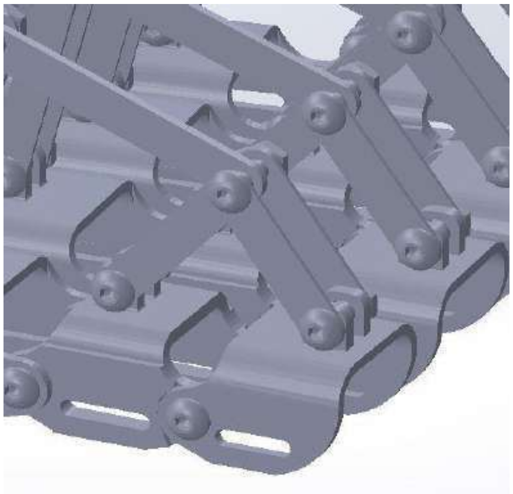


Figure 32.Linkages above the fingers

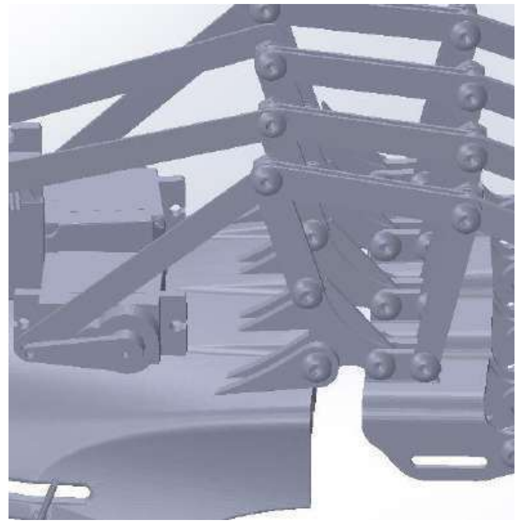


Figure 33. Linkages connecting palm with fingers

Part	Description	Dimensions
Linkage type 1	Positioned above fingers	Length- 30 mm Thickness- 1.5 mm
Linkage type 2	Connecting palm to fingers	Length- 89 mm Thickness- 1.5 mm
Screws and nuts	Button head hex screw and hex nut	M3 bolts with 10 mm length

Table 13. Geometrical dimensions of Various Linkages

12.3 PALM SUPPORT PANEL

A palm support panel in a hand orthosis is a component designed to provide stability and support to the palm and wrist area. The palm support panel is typically a rigid or semi-rigid insert that is positioned on the palmar side (palm side) of the orthosis. It extends from the wrist area to the base of the fingers, covering the palm and providing a supportive surface. The panel is usually made from materials such as thermoplastic, metal or carbon fiber. The primary purpose of the palm support panel is to provide stability and maintain proper alignment of the hand and wrist. It helps to immobilize the wrist joint and prevent excessive movement, which can be beneficial in cases of wrist pains, fractures or other injuries that require immobilization. The panel also helps to distribute pressure more evenly across the palm, reducing the risk of localized discomfort or pressure sores. Additionally, the palm support panels can assist in positioning the hand and fingers in functional or therapeutic alignment. It can be contoured to promote a more neutral position, reducing abnormal muscle tone or contractures that may occur due to certain conditions like stroke or neurological disorders like in our case of study.

It's important to note that the specific design and features of palm support panels may vary depending on the purpose and requirements of the hand orthosis. Hand orthoses with palm support panels are often customized to fit the individual's hand anatomy and specific needs. They can be fabricated by orthotists or occupational therapists who specialize in designing and fitting orthotic devices. Proper fitting and adjustment of the orthosis are essential to ensure optimal support and comfort. It is important to note that the forces acting on palm support panels can vary depending on the individual's specific condition, the purpose of the orthosis, and the activities they engage in. The design and material properties of the panel will influence how it distributes and resists forces.

The following CAD Model shows a palm support panel which is connected to the wrist side part by polycentric joints. It has housing for actuators and controllers which are given above the palm. Slits are designed for Velcro straps to adjust/position the panel on to the palm.

Figure 34. Isometric view of palm support

12.4 WRIST SUPPORT PANEL

A wrist support panel in a hand orthosis is a component designed to provide stability, immobilization and support to the wrist joint. It is typically located on the dorsal(back) side of the orthosis and extends from the wrist area to a certain distance along the forearm.

The wrist support panel can be made of various materials, including rigid thermoplastic, metal or carbon fiber. The choice of material depends on the level of support and immobilization required, as well as the individual’s specific needs.

The primary functions of the wrist support panel in a hand orthosis are as follows:

i. Stability and Immobilization: The panel helps to stabilize the wrist joint, limiting excessive movement and promoting proper alignment. It can be beneficial for conditions such as wrist sprains, fractures, tendonitis, or after surgical procedures that require immobilization during the healing process.
ii. Load Distribution: The wrist support panel assists in distributing forces and pressure more evenly across the wrist joint and forearm. This can help alleviate localized discomfort or pain and prevent pressure sores that may occur due to prolonged immobilization.
iii. Alignment: The panel may have specific contours or shaping to encourage a more neutral or functional alignment of the wrist. It can help counteract deformities, contractures, or abnormal muscle tone that can occur as a result of certain medical conditions or injuries.
iv. Customization: Wrist support panels can be customized to fit the individual's wrist anatomy and specific requirements. They can be fabricated by orthotists or occupational therapists who specialize in designing and fitting orthotic devices. Proper fitting and adjustment of the wrist support panel are crucial for optimal support, comfort, and effectiveness.

It’s important to note that the design and features of wrist support panels can vary depending on the type and severity of the wrist condition, as well as the individual’s functional needs. Some hand orthosis may incorporate a combined palm and wrist support panel to provide comprehensive support to both areas.

The following CAD Model shows a wrist support panel which is provided with four holes to allow for wire connection for the actuators and feedback sensor. Two slots have also been created to allow for fastening via Velcro straps.

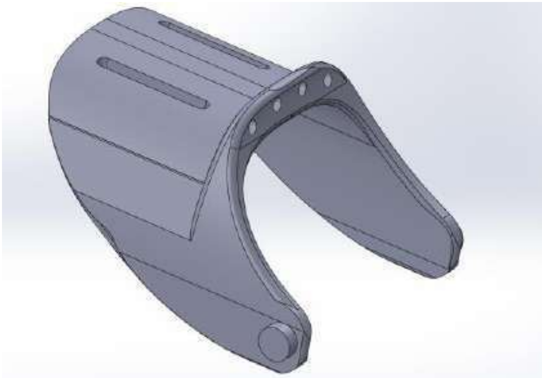


Figure 35. Isometric view of Wrist support Panel

Figure 36. Front View of Wrist Support panel

12.5 HAND ORTHOSIS MODEL

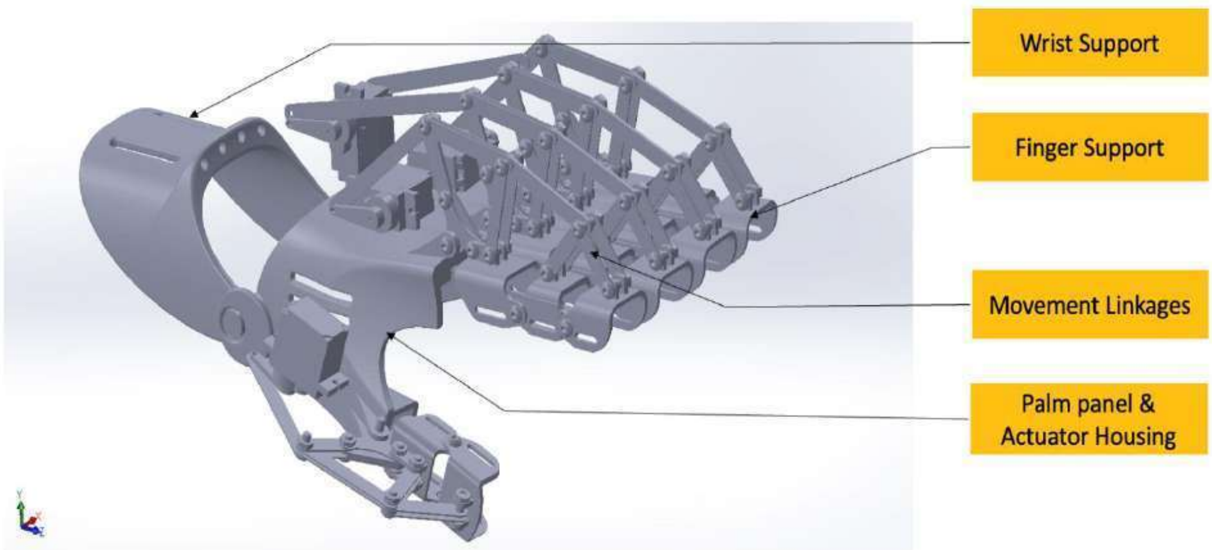


Figure 37. Isometric view of Hand Orthosis Model

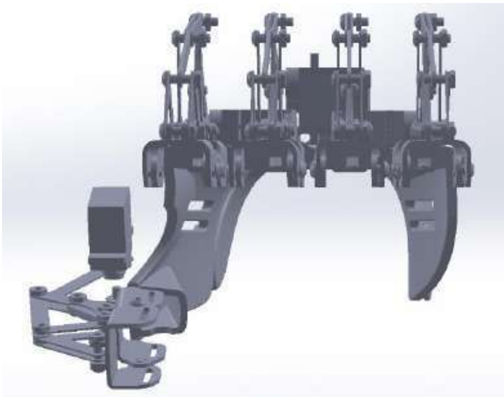


Figure 38. Front View of Hand Orthosis Model

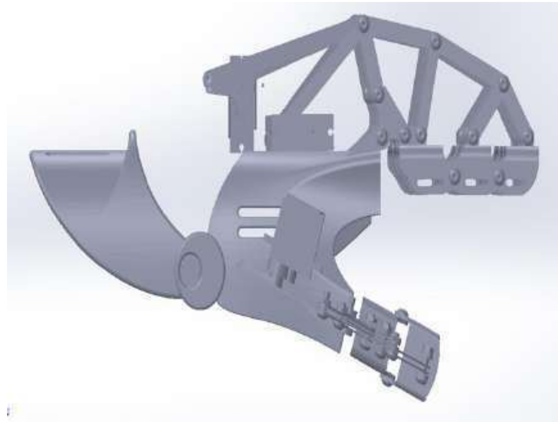


Figure 39. Side view of Hand Orthosis Model

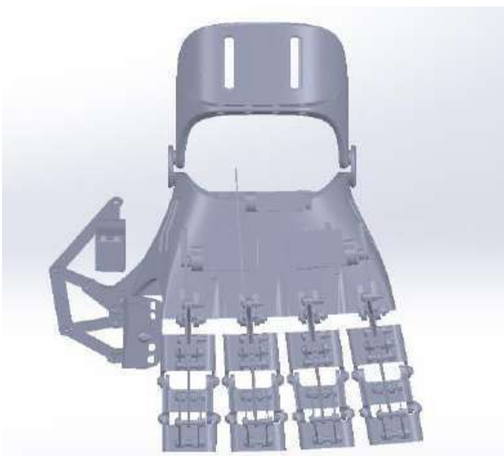


Figure 40. Top View of Hand Orthosis

Figure 41. Hyperlink of 3D CAD Model

13. POSITION ANALYSIS

The orthosis device must be capable of supporting both the power and pincer grips in order to fulfill the appropriate functional requirements. The position analysis section examines how to demonstrate compliance with these design requirements by using the kinematics of the hand and the orthosis device.

The thumb and index figure's updated 2D schematic diagram is shown in the below figure. The forward kinematic equations for the thumb can be solved using this graphic. The equations used in Figures to determine where the tip of the thumb should be in 2D space are based on the angles of the joints (1, 2) and the lengths of the fingers (l1, l2).

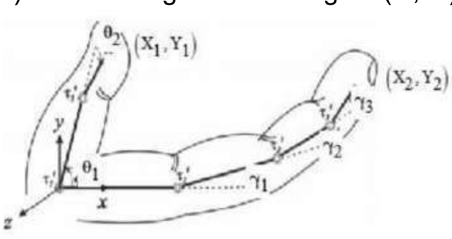


Figure 42. Hand Coordinate System

$$X_1 = l_1 \cdot \cos(\theta_1) + l_2 \cdot \cos(\theta_1 + \theta_2)$$

$$Y_1 = l_1 \cdot \sin(\theta_1) + l_2 \cdot \sin(\theta_1 + \theta_2)$$

Figure 43. Thumb Forward Kinematic Equation

The kinematics of the fingers were developed using a similar technique. Equation 8 depicts the derived kinematic equations. The length of the metacarpal joint is denoted by the symbol d in the below equation. In addition to having varied-sized hands, each individual also has greatly different joint proportions. The range of motion of each person's hand has a significant impact on the orthosis's device.

$$X(\gamma_2) := d + l_1 \cdot \cos(\gamma_1) + (l_2) \cdot \cos(\gamma_2 + \gamma_1) + (l_3) \cdot \cos(\gamma_3 + \gamma_2 + \gamma_1)$$

$$Y(\gamma_2) := l_1 \cdot \sin(\gamma_1) + (l_2) \cdot \sin(\gamma_2 + \gamma_1) + (l_3) \cdot \sin(\gamma_3 + \gamma_2 + \gamma_1)$$

Figure 44. Fingers Forward Kinematic Equation

The thumb and finger locations in the X and Y axes were plotted to confirm that it was possible to form the pincer grasp. The two distinct lines depict the fingers' paths as they are turned 90 degrees from their initial positions. The findings demonstrate that there is a configuration that can produce a pincer grasp in which the finger tips will actually touch.

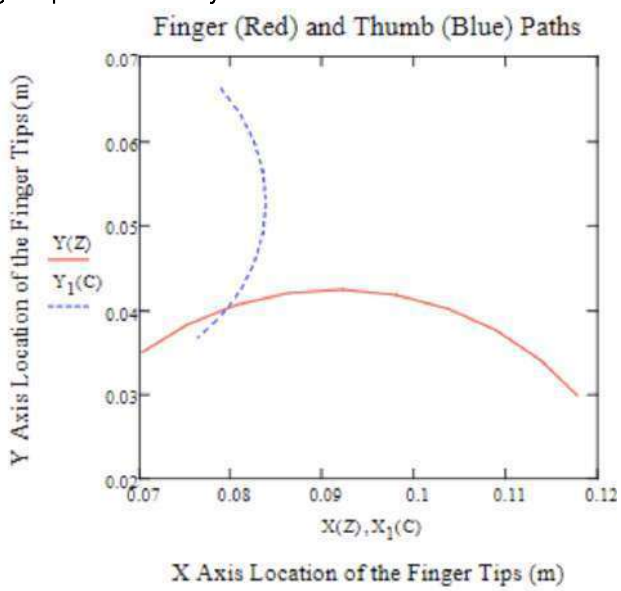


Figure 45. Finger and Thumb Location Graph

14. MANUFACTURING PROCESS

Whether a production sector is focused on mass production or the creation of specialized parts, additive manufacturing technology (AMT) is becoming increasingly popular. It offers a proportionally balanced structure with a fantastic overall sustainable performance to address a beneficiary's needs. In the past few years, AMT has been universally adopted as a sustainable and efficient platform across all manufacturing sectors. The strategic involvement of Am in the medical industry with topologically optimized products can ensure the performance substantiality over its rivals in a competitive global environment by meeting economic, environmental and aesthetic issues.

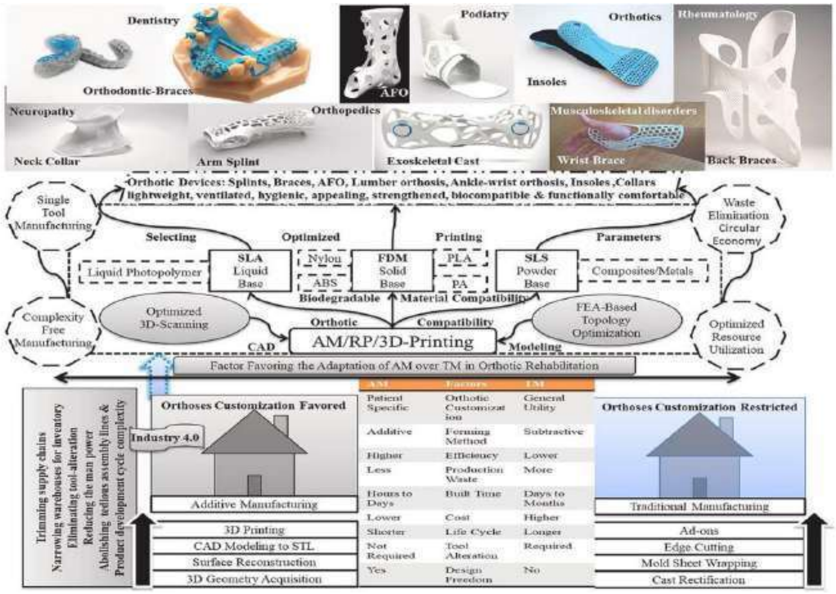


Figure 46. Rise of additive manufacturing in orthotic rehabilitation

The above picture represents about the use of additive manufacturing in the medical industry to manufacture orthotics, exoskeletal cast, wrist braces etc. In this project one the highly plausible manufacturing process in order to manufacture dynamic hand orthosis would be additive manufacturing process where the computer-aided design (CAD) software can be used to create a digital model of the orthosis based on the patient's hand measurements. The digital model is then sent to a 3D printer, which builds the orthosis layer using material like thermoplastics or elastomers. In Dynamic hand Orthosis, the individual components require adjustable components, such as springs or hinges, to provide the desired range of motion. In such cases, the manufacturing process may involve a combination of techniques mentioned such as 3D printing, Injection Molding, along with the integration of off-the-shelf or custom-made adjustable components.

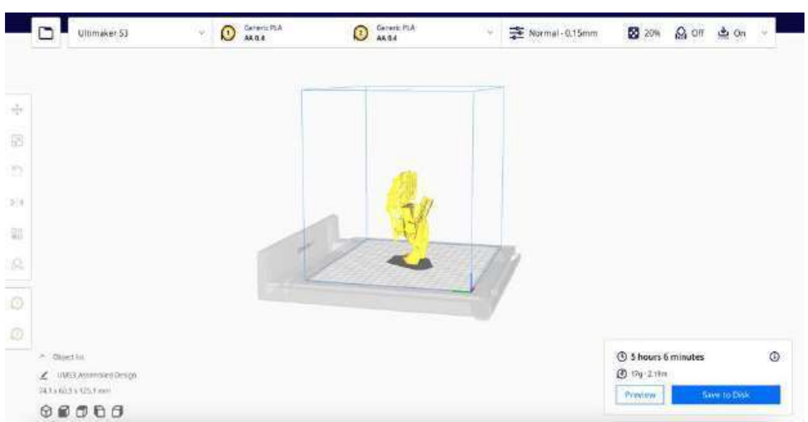


Figure 47. Ultimaker Cura

In Our Project we tried using Ultimaker Cura to produce scaled size product. Ultimaker Cura offers a user-friendly interface with a range of features to streamline the 3D printing process. It is a versatile tool that can be utilized to produce scaled-size products. The below figure shows the dynamic hand orthosis being printed in Ultimaker cura with Ultimaker S3 printer. The printer depicts that the scaled dynamic Hand orthosis with dimensions 74.1*60.0*125.1 mm can me produced in 5 hours and 6 minutes where the infill

density 20% given.
The plausible manufacturing for dynamic hand orthosis in the future world would be additive manufacturing because of time and cost efficiency, lightweight and comfortable, various material variety, Complex intricate geometries and the customization that it can provide.

15. CONCLUSION:

The dynamic hand orthosis designed for stroke patients sets a new standard in orthotics by integrating advanced functions that offer unparalleled value for both patients and therapists. With stroke-related hand impairments, it is crucial to provide patients with an orthosis that not only offers support but also promotes active rehabilitation. The patient-specific orthosis is equipped with sophisticated sensors capable of detecting hand movements, muscle activity, and force exertion. This real-time data is analyzed by intelligent algorithms embedded within the orthosis, allowing for adaptive and responsive support.

The integration of dynamic features within the orthosis provides stroke patients with personalized therapy experiences. By offering adjustable tension mechanisms, patients can gradually increase resistance, facilitating progressive strengthening exercises and promoting neuroplasticity. Additionally, the orthosis incorporates interactive interfaces and haptic feedback, engaging patients in therapeutic gaming scenarios that encourage repetitive hand movements and enhance motor skill recovery.

For therapists, the patient-specific orthosis with integrated functions represents a powerful tool for assessing progress and tailoring treatment plans. The precise data captured by the orthosis allows therapists to objectively analyze the effectiveness of rehabilitation techniques, enabling evidence-based decision-making. Furthermore, therapists can remotely monitor patients' performance and remotely adjust parameters within the orthosis, facilitating personalized therapy sessions and minimizing the need for frequent in-person visits.

In summary, the development of a patient-specific high-tech orthosis for stroke patients with integrated dynamic functions signifies a groundbreaking advancement in orthotics. By redefining the traditional plaster cast method and embracing technology-driven solutions, this project offers a paradigm shift in hand injury rehabilitation. The dynamic hand orthosis provides stroke patients with personalized support, promotes active participation in therapy, and fosters neurorecovery. Therapists benefit from advanced data analysis and remote monitoring capabilities, facilitating optimized treatment plans and personalized care. This project embodies the fusion of technology, patient-centered care, and scientific innovation, opening new horizons for rapid and effective rehabilitation for stroke patients with hand impairments.

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