CHAPTER 7

DESIGN AND SIMULATION APPROACH OF ORTHOTICS ELEMENTS

Additive manufacturing is a sophisticated layer-based manufacturing technology that fabricates customized orthotics directly from computer-aided design data without the use of part-depending equipment. The elements, materials, and methodology of orthotic elements are covered in this chapter. Nowadays, the use of additive manufacturing technologies in the rehabilitation sector has been proven to speed, facilitate, and improve the quality of personalized products. This chapter explores the design and modeling of AFO, human wrist, and CP walker elements using advanced manufacturing technologies.

7.1 HUMAN WRIST AND FOOT BRACE

Orthotic devices allow people with disabilities or activity impairment to lead a healthier, active lifestyle while engaging in social and everyday activities. (Shurr, Michael, & Cook, 2002)

AFO is a type of external medical device (Gallogly, 2021) used to improve people's walking abilities because of the following purposes;

- To help persons with spinal cord injuries, strokes, neurodegenerative disorders, down's syndrome, and other conditions.
- To support ankles and feet.
- To stop the development of an abnormal gait throughout the duration.

AFO materials (Shahar, et al., 2019) have steadily evolved through time from various materials as shown in Figure 7.1.

Figure 7.1: The evolution of AFO materials (Patel & Gohil, 2022)

An AFO is a sort of orthotic that improves the mobility and stability of the user's gait as well as how their ankle and foot are supported or protected. The optimal criteria for an AFO are as follows (Takhakh, Jweeg, & Abbas, 2017):

- Stability and comfort when walking
- Lightweight to save energy when walking
- Strong enough to give support
- Breathability to lessen or prevent excessive perspiration
- Easy to shape personalized braces

Physical properties of the orthotic materials (Brodsky, Pollo, Cheleuitte, & Baum, 2007) include their strength, response to temperature, density, elasticity, hardness, flexibility, compressibility, durability, and resilience. Keep in mind that not all physical properties can be used as a single element when assessing the material of an orthotic device. The inaccurate appearance of hard materials and designs can result in uncomfortable devices and biomechanically harmful equipment. The main materials utilized in the production of orthotic devices include thermoplastics, composites, and foams. (Dubey & Gangwar, 2021)

All materials used in the additive manufacture of AFOs (Chen, et al., 2014) are listed in Table 7.1.

Table 7.1**:** Materials for Additive Manufacturing

Materials	**Ultimate Strength (MPa)**	**Coefficient of Thermal Expansion (µm/m°C)**	**Density (g/cm^3)**	**Max service Temperature (°C)**	**Extruder Temperature (°C)**	**Bed Temperature (°C)**	**Others Material Properties**
ABS	40	90	1.04	98	220-250	95-110	Impact resistance; heat resistance
PLA	65	68	1.24	52	190-220	45-60	A heated bed is not required
HIPS	32	80	1.04	100	230-245	100-115	Impact resistance; heat resistance; dissolvable
PETG	53	60	1.23	73	230-250	75-90	Wear resistance; chemical resistance; fatigue resistance
UHMW-PE	39	234	0.95	110 - 130	155-200	112-150	Extreme toughness and durability, strong chemical resistance, scratch and impact resistance, ease of fabrication, and a very low coefficient of friction are all advantages.
NYLON	40-85	95	1.06 - 1.14	80-95	220-270	70-90	Flexible; impact resistance; heat resistance; fatigue resistance
Carbon fiber filled	45-48	57.5	1.3	52	200-230	45-60	Heated bed not required; composite
ASA	55	98	1.07	95	235-255	90-110	Impact resistance; heat resistance; UV resistance
Polycarbonate	72	69	1.2	121	260-310	80-120	Impact resistance; heat resistance; Fatigue resistance
Polypropylene	32	150	0.9	100	220-250	85-100	Flexible; soft; wear resistance; heat resistance; fatigue resistance
Metal filled	20-30	33.75	02 - 04	52	190-220	45-60	Heated bed not required; composite
Wood filled	46	30.5	1.15 - 1.25	52	190-220	45-60	Heated bed not required; composite
PVA	78	85	1.23	75	185-200	45-60	Flexible; soft; dissolvable; fatigue resistance

7.2 ORTHOTIC MANUFACTURING TECHNIQUES

The design and development of orthotic devices utilizing the conventional lamination molding method are briefly described in this section.

7.2.1 Conventional techniques for making of orthotic

Custom orthotics are often made using a labor and time-intensive manufacturing process. Once referred by the physician, the patient will go to the clinic, where an orthotist will measure the relevant anthropometry and put the patient in a plaster cast (Roberts, et al., 2016) by wrapping the affected leg in a plaster wrap. To generate a positive cast of the leg, the cast is then poured into the negative cast. The brace is then created by heating and vacuuming (Wilson, 1974) thermoplastic sheets over a plaster mold, which is allowed to cool and then cut to the exact shape of the mold. The phases in the casting process for a fractured leg and arm are shown in Figure 7.2 and Figure 7.3 respectively.

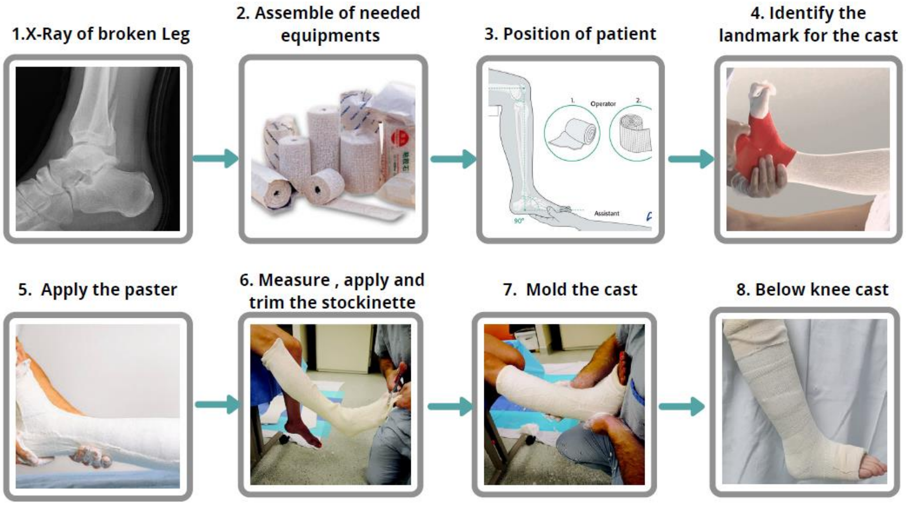


Figure 7.2: Casting process for a broken leg

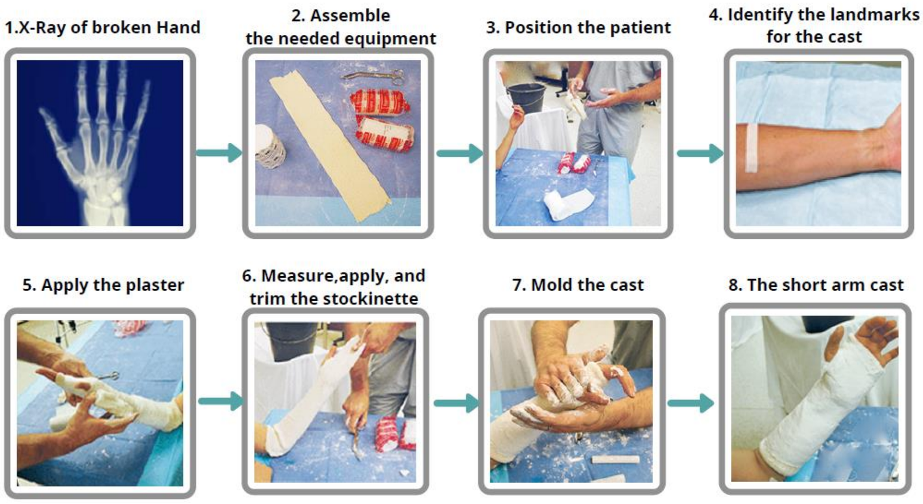


Figure 7.3: Casting process for a broken arm

Traditional foot and ankle morphometric approaches can be quite a resource and expensive, especially for AFO production, which necessitates specialized infrastructure such as a foundry room, molding furniture, plaster sinks, and non-slip floors.

Orthopaedic surgeons' knowledge is required for the manual, conventional production of P&O devices to generate high-quality goods. The patient, however, often feels uncomfortable as a result of these production techniques. Because plaster is required to obtain an object's form, getting its shape is not a simple task. The finished product can also take on its form in static conditions and lead to skin blistering on the victim.

7.2.2 The orthotic Additive Manufacturing technique

Because of the capacity to create complicated items with great accuracy in a short amount of time, fused disposition modeling has freed the minds of professionals from many disciplines. The creation of novel materials and supporting technology like as 3D scanners (Farhan, Wang, Bray, Burns, & Cheng, 2021) has expanded the range of 3D printer uses. The advent of rapid prototyping, in particular, is generating a transformation in rehabilitative technology by allowing for the creation of one of a kind prosthetics, tissues, implantation, and other products.

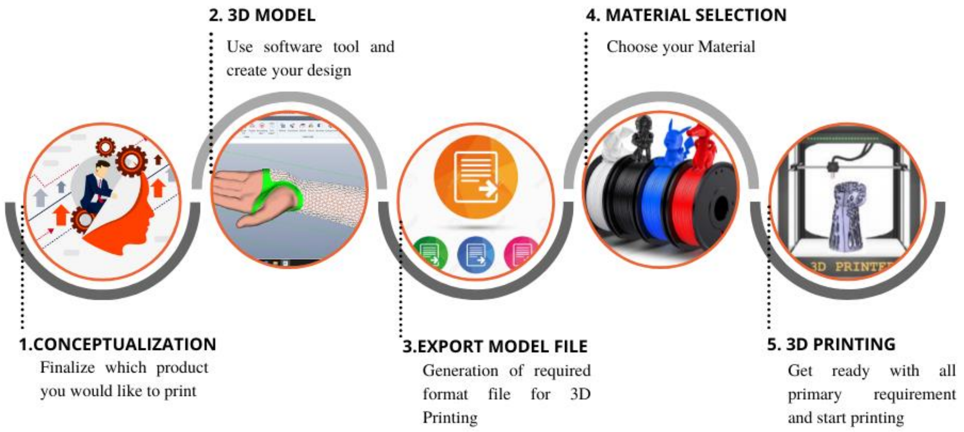


Figure 7.4: 3D printing process flow

Table 7.2 compares conventional and AM techniques, taking into consideration factors.

Table 7.2: Assessment between traditional and AM processes (Patel & Gohil, 2022)

Parameters	Conventional Approach	AM
Producing period	Four weeks	One-Two days
Rate of production	Costly	Economical
Necessary labor skills	• Detail-oriented • Physical skill • Physical endurance • Problem-solving abilities	• Operating and creating skills for 3D software

Steps in manufacturing	• Cast creation using landmark identification • Cast correction • Molding technique • Trimming and cutting of edges	• 3D imaging • Modeling • 3D printing tool for slicing • 3D Printing

The creation and manufacturing process consists of four parts (Figure 7.4). The initial component of a 3D object of a person’s arm and ankle braces was scanned using a 3D scanner (Lochner, Huissoon, & Bedi, 2012). The second section covers modeling using the 3D program “Autodesk Meshmixer”. The third section discusses configuring the slicing program with all the necessary settings, and the last section discusses utilizing AM to create personalized wrist and leg brace as shown in Figure 7.5 & Figure 7.6 respectively.

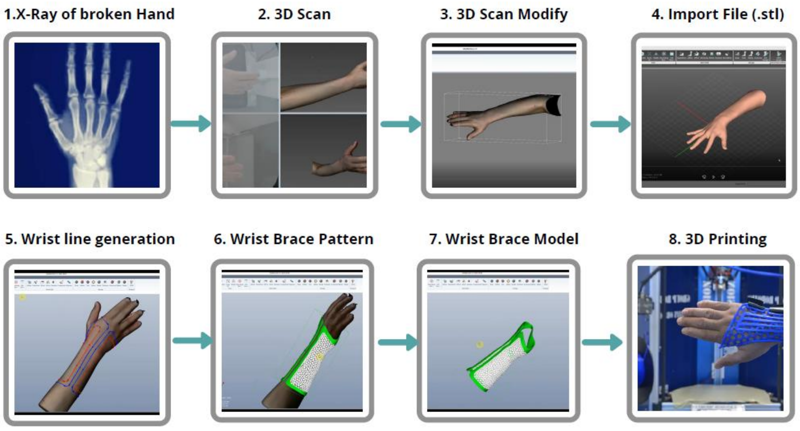


Figure 7.5: 3D printed hand/wrist brace

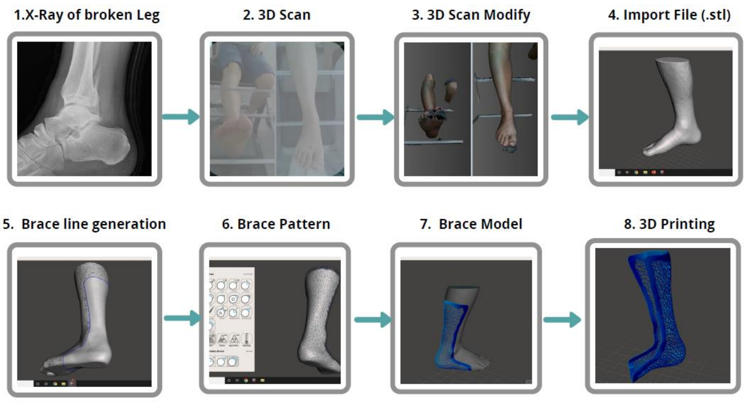


Figure 7.6: 3D printed leg brace

a) Phase 1 (Data acquisition and 3D scan)

The medical professional is always on the lookout for new cutting-edge technology to help enhance regular operations. Portable 3D scanners (Rosicky, Grygar, Chapcak, Bouma, & Rosicky, 2016) are frequently used in the industry for this purpose, bringing up new possibilities for the creation of individual P&O equipment. The technique of creating and measuring point cloud coordinates of an object's surface in 3D space is known as "3D Surface Imaging" (x, y, z). The terms "3D surface imaging" and "3D imaging" should be clearly distinguished. Key benefits of integrating 3D scanning with 3D printing include;

- Create the perfect fit
- Portability
- Create low-cost prosthetics
- Edit for "orphan" conditions.

All six hand positions were evaluated for scan comfort, quality, and scan time, as shown in Figure 7.7 below.

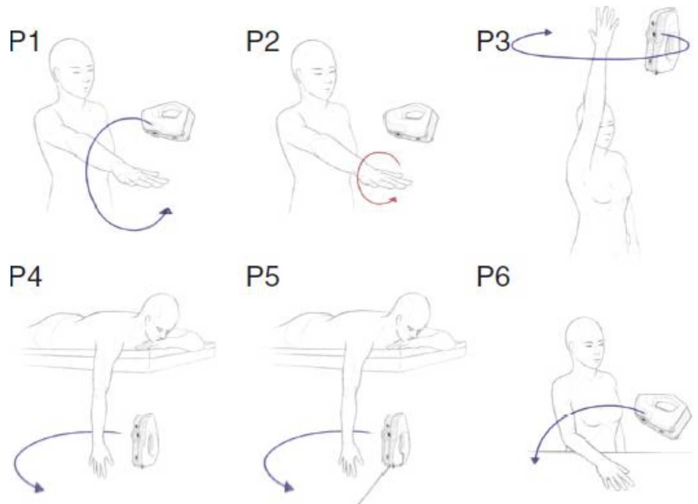


Figure 7.7: A graphical depiction of hand-scanning places

b) Phase 2 (Modeling)

❖ *Design and development of human wrist brace*

The second part involves modeling with the 3D "Autodesk Meshmixer" software after completing the 3D scanning of the human wrist brace, as shown in Figure 7.8. Change can be created and edited using this free modeling software for 3D objects. (de Souza, Schmitz, Pinhel, Setti, & Nohama, 2017)

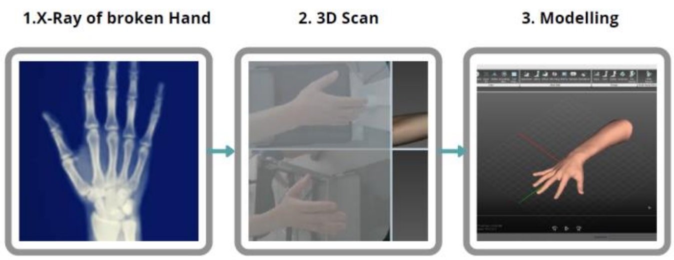


Figure 7.8: 3D model of the wrist brace

The amount of thickness of the substance was estimated after making a replica of the orthopedics' surface and applying offsets. When making the brace, a thickness of 2 mm was used. Selection of materials and thickness were essential for endurance and mobility to reduce the damage throughout repetitive use and installation for specific components. Figure 7.9 depicts the full modeling procedure of the human wrist brace.

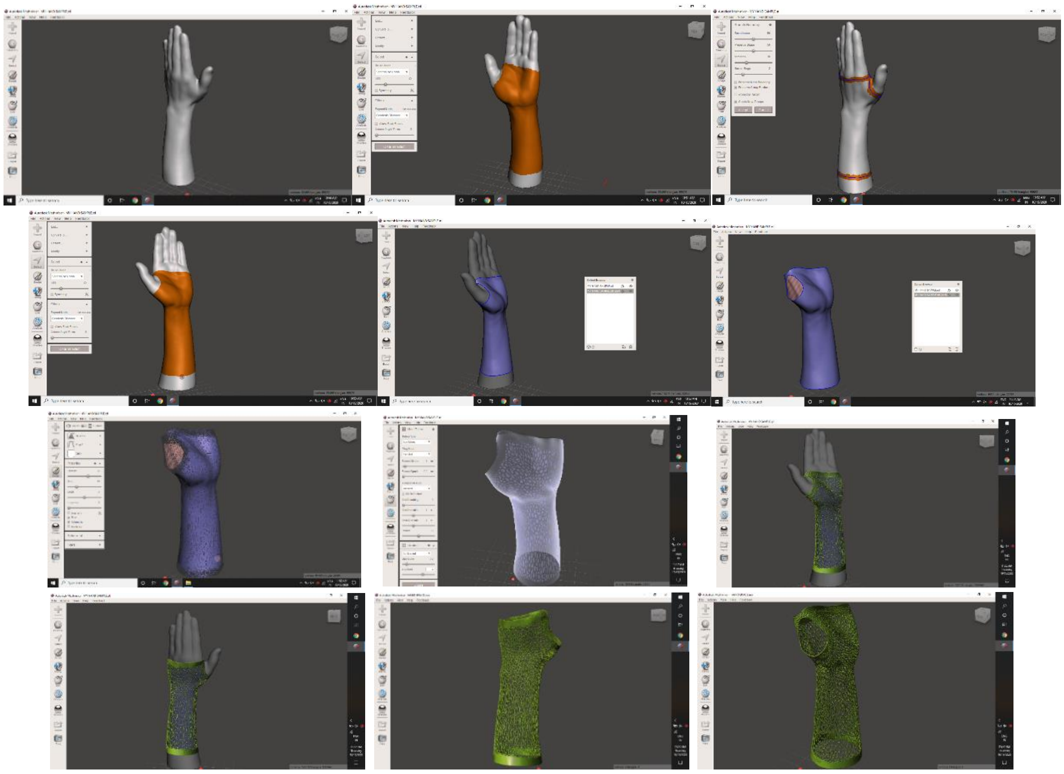


Figure 7.9: Modeling of hand/wrist brace

❖ *Design and development of foot brace*

Ankle orthotics are devices designed to control and support ankle movement in the event of foot drop problems. Walking problems depend on several factors, including diseases of the spinal cord, brain, nerves, or muscles. 3D scanning of the human leg (Figure 7.10) and CAD models of AFO (Dal Maso & Cosmi, 2019) were designed in "Autodesk Meshmixer" software as shown in Figure 7.11. With 3D printing, personalized devices for people with disabilities can be expected to be given at a low cost. (Surmen & Arslan, 2021)

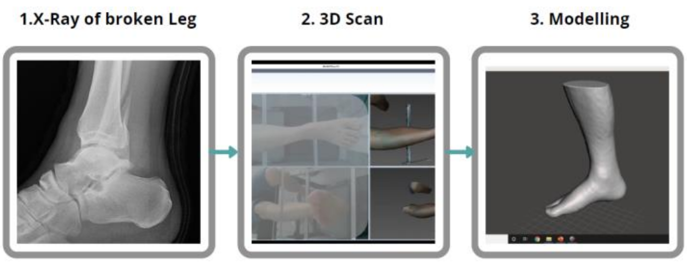


Figure 7.10: 3D model of the leg

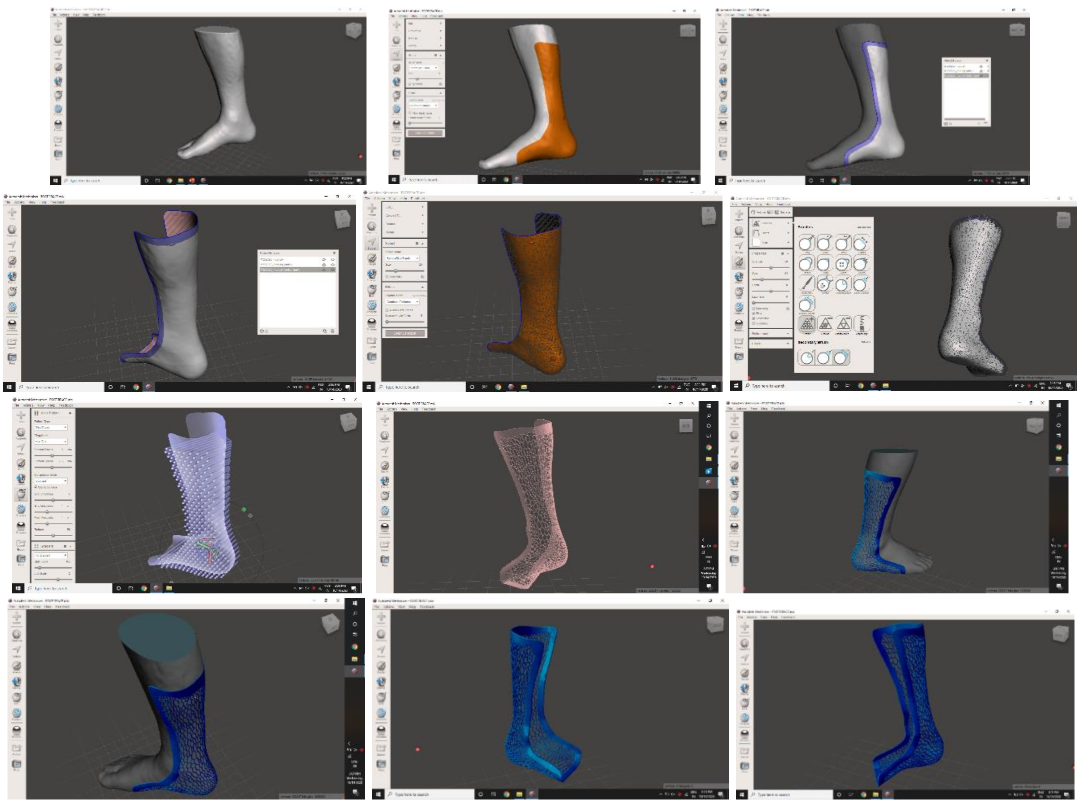


Figure 7.11: Modeling of foot brace

c) Phase 3 (3D Printing slicing tool)

Slicing is the technique of determining printer tool routes based on a three-dimensional model file. This is done with different tools known as slicing tools (Šljivic, Pavlovic, Kraišnik, & Ilić, 2019). Slicing is a critical step in 3D printing that involves using software to turn an item model into 3D printer instructions. Essentially, the program separates the object model into layers. Then, for each of these levels, a value is assigned that indicates how to construct it. Slicing your 3D model entails separating your design into distinct layers. The program then creates the tool path that will be used by the printer to print. Figure 7.12 depicts the software route from the input STL file to the output G-code file.

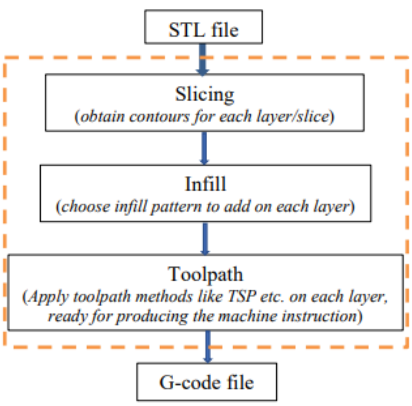


Figure 7.12: Software flow from STL input to G-code output

There are several slicing instruments, each having advantages and disadvantages. Print outcomes can be significantly impacted by the quality of the slices. A decent slicing tool calculates the top and lower layers in addition to each layer separately. Slicing tools (Baumann, Bugdayci, Grunert, Keller, & Roller, 2016) may significantly enhance print outcomes when working with intricate shapes and structures. The quantity of results returned by a classifier is correlated with popularity in well-known search engines. Each software is made for different user skill levels, including beginners, enthusiasts, expert users, and professionals. To prevent typos, the majority of slicing applications provide a preview option. A robust open-source slicing engine developed over years by internal experts and user input is at the core of Ultimaker Cura.

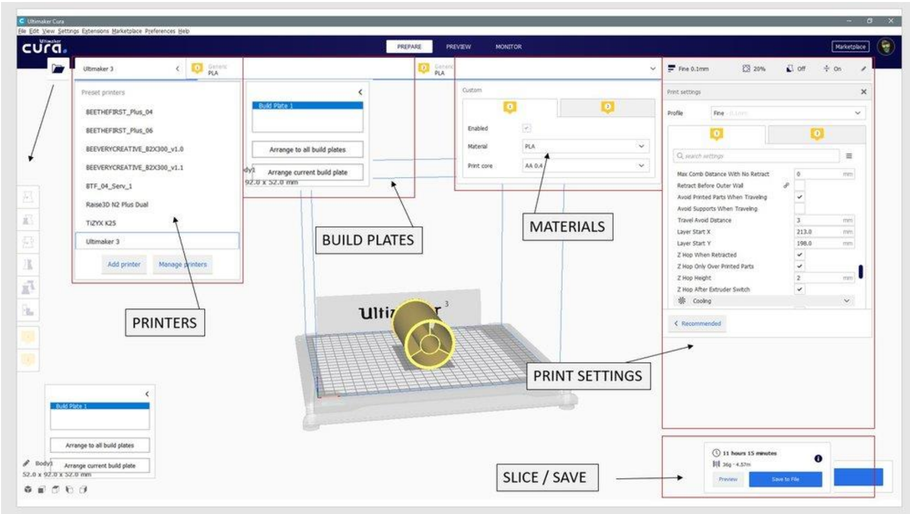


Figure 7.13: Ultimaker Cura user interface

The print settings page of the Ultimaker Cura offers two modes: suggested mode and custom mode. While the custom option provides additional settings for seasoned users, the suggested mode is ideal for novices. A variety of user interface components in custom mode may be utilized to change the print configuration. The appearance and operation of these user interface elements are demonstrated in Figure 7.13 to Figure 7.15.

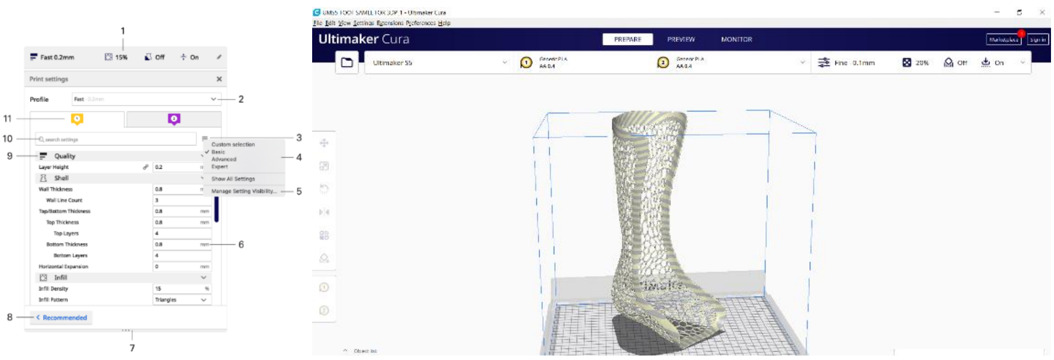


Figure 7.14: Part uploaded in Ultimaker Cura

Human footrest models are used in case studies based on readily available material (PLA) and specially designed 3D printers. The parameters (Beattie, et al., 2021) (Fernandez-Vicente, Calle, Ferrandiz, & Conejero, 2016) for the production line are shown in Table 7.3.

Table 7.3: The printing processes assessed parameters (Ramesh, Rajeshkumar, & Balaji, 2021)

Sr. No.	*Parameter*	*Value / Data*
1	Height of the layer	0.2 mm
2	Filament diameter	1.75 mm
3	Filament flow	100 %
4	Nozzle size	0.4 mm
5	Print speed	50 mm/s
6	Enable retraction	Yes
7	The thickness of the shell	1.2 mm
8	Bottom/Top thickness	1.2 mm
9	Fill density	80 %
10	Printing temperature	195 ℃
11	Bed temperature	60 ℃
12	Support type	Everywhere as per requirements

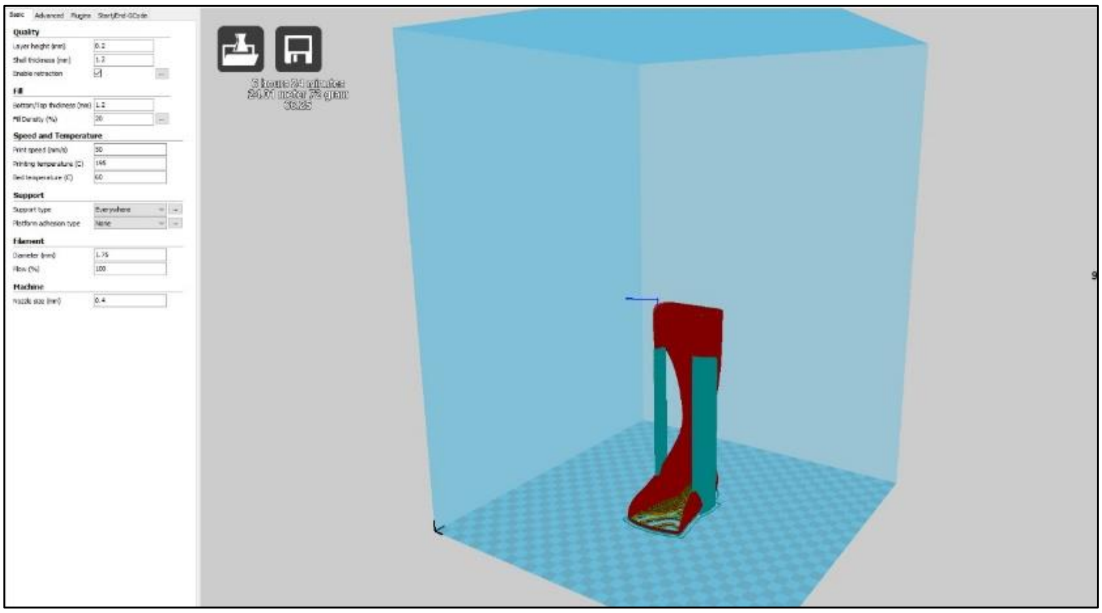


Figure 7.15: Setting 3D printing parameters in slicing software

d) Phase 4 (AM process)

FDM technique has broadened the range of engineers in different disciplines since complex items may be built rapidly and with great precision.

Rapid prototyping offers the following clear benefits to engineers, design and development teams;

- Ability to explore and implement concepts faster.
- Apply iterative design and incorporate changes that allow product evaluation and testing.
- Be able to convey the concept concisely and effectively.
- Ability to thoroughly test and improve concepts.
- Save time and money without the need for setup or tools.

Figure 7.16: 3D printed AFO part

On FDM machines, AFO pieces (Sarma, et al., 2020) were printed with PLA material (Figure 7.16). A single 3D-printed personal gadget may be created in less than 6.5 hours. The entire procedure was completed in less than 7 hours. This amounts to only 10-15 minutes of real work time. When compared to previous methods, this was an estimate and it takes significantly less time to produce a single patient brace utilizing 3D printing.

7.3 RESULT AND DISCUSSION FOR ORTHOTIC DEVICES

Rehabilitation procedures enable people to perform more effectively following an injury or sickness. The use of 3D printing in the manufacturing of medical devices has risen in prominence over the last several decades as the prospects for this technology have expanded significantly.

Individual orthotic devices are traditionally created using plaster molds, which necessitate many patient visits and demand a significant amount of labor and time to construct. When constructing an individual orthopedic surgery utilizing current technology, the measures indicated in this report should be taken. The portable imaging system is easy to use and requires only one person and computational systems. Because of the scanner's portability, working is possible anywhere. When the person is immobilized or unable to move, this is a significant improvement over the traditional plaster technique.

When developing an orthotic device, it is necessary to collect the segments in the correct format. If the scanned model has faults, it cannot be utilized as a positive. Because the original model must be clean and exact, no machining is necessary. When a 3D scan model is edited, it may cause a mismatch between the device's surface and the body's surface, resulting in erroneous device design. As a result, our primary focus is on the process of rapidly designing and constructing lightweight structural components while simplifying the production process for considering the above critical process data collection by proper practice to eliminate errors.

7.4 CEREBRAL PALSY (CP) WALKER

Cerebral Palsy is a condition that impairs mobility and posture. Because of muscle weakness, lack of coordination between muscle groups, hunched posture, poor balance, and changes in muscle tone, children with CP walk more strenuously than healthy subjects.

The Gross Motor Function Classification System (Figure 7.17) (Palisano, et al., 1997) cerebral palsy is largely focused on voluntary movement, with a focus on sitting and mobility. A major criterion in defining the five-level classification system is that the differences in levels should be meaningful in everyday life. Determine the level that best reflects your current capabilities and limitations. (McCormick, et al., 2016)

- *Level I (Walks without limitations)*

Children use all of their athletic talents, including running and leaping, but they lose speed, balance, and coordination.

- *Level II (Walks with restrictions)*

In most environments, children walk or climb stairs with railings. Rough terrain, slopes, crowded areas, or confined spaces can make it difficult to walk or balance long distances. Children can walk long distances with the help of physical assistance, portable mobile devices, or bicycles. Children have little capacity to accomplish basic motor skills like running and leaping.

- *Level III (Walks with the assistance of a handheld mobility gadget)*

Children walk with portable mobile devices in most indoor spaces. With the help of assistance, children can climb the stairs and grab the railing. Children can use wheeled mobility over long distances and drive themselves over short distances.

- *Level IV (Self-mobility with constraints; powered mobility may be used)*

Most children employ exercise techniques that need physical help or activity. With physical support, you can walk short distances at home. Alternatively, if deployed, children can use electric mobility or a body support scooter.

- *Level V (Pushed in a manual wheelchair)*

In all contexts, children are conveyed in a manual wheelchair. Children have a limited capacity to regulate leg and arm motions and maintain head and torso positions against gravity.

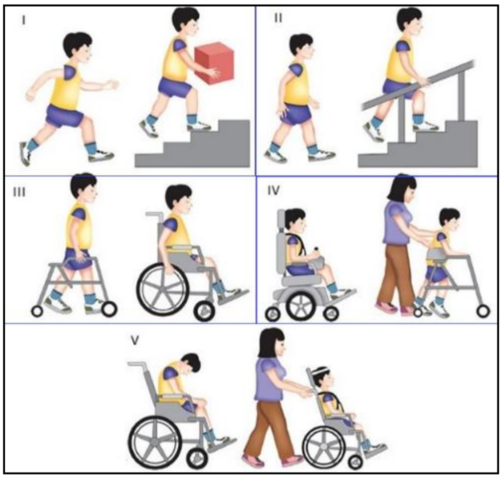


Figure 7.17: Levels of the GMFCS classification scheme (Palisano, et al., 1997)

There are two main assistive walking devices namely anterior and posterior (Figure 7.18). Walking devices are divided into two categories: pediatric walkers and gait trainer walkers. Posterior or reverse walkers are placed behind the user and in the anterior walker user is standing in front of the walker frame.

Figure 7.18: Anterior (left) and posterior (right) standard walkers (Poole, Simkiss, Rose, & Li, 2018)

The pediatric walker is designed for children who might be capable of their weight assisting them to construct power and increase the right posture. A pediatric walker is used while a toddler is already capable of enduring weight and taking steps and essentially makes use of the walker for stability help.

On the other hand, pediatric gait trainers (Figure 7.19) are mainly used in therapeutic and clinical settings and have many adjustable features. These features are designed for different levels of mobility for users with disabilities. This makes the device a larger, heavier, more technical, and more expensive piece of equipment than is commonly considered a walker.

Figure 7.19: Gait trainer walker (Agrawal, et al., 2013)

A gait trainer walker device is designed to adequately stabilize, support, and assist persons with disabilities by providing weightless support and postural alignment to ensure safe walking practice. Composed of a front unit, a rear unit, or both, crutches act as auxiliary crutches and support more weight and balance than regular crutches. (Dobson, Morris, Baker, & Graham, 2007)

Walking aids are available in a variety of sizes and configuration models on the market; still, the selection of these devices creates issues that should be based on a person's physical abilities, requirements, capacity, financial issues, availability, convenience, approachable, and so on.

Some of the walking devices on the market are difficult to use, have poor balance and directional control, inconvenient for carers, exaggerate handicaps, socially unpleasant, have a single function, and appear painful.

However, this issue may be recognized by beginning with the need and solving it using a participation-based strategy. A systematic design method for an assistance walker is developed based on a review process that includes internal characteristics such as age, body weight, height, gender, walking skills, and self-confidence, as well as exterior ones such as environmental circumstances, social life, and so on.

Prediction through simulation is a replacement for testing and intervention on the actual system. It is used when conventional experimentation is too risky, expensive, time-consuming, or inconvenient. Material optimization data for the various load situations on the walker is analyzed in our simulation technique to get the best optimal design condition.

7.5 PARTICIPATORY APPROACH AND IDENTIFY DESIGN REQUIREMENTS FOR CP WALKER

There are currently several versions of pediatric walkers on the market for front and rear. According to the literature, the use of a posterior walker can improve speed, stability, and trolley flexion/pelvic tilt, and most walker users and their parents prefer a posterior walker. By using a pediatric posterior walker, children affected by cerebral palsy may improve their posture and walking ability. (Sharma & Bajracharya, 2021) (Alazem, et al., 2019)

- *Participatory approach*

Users need access to adaptive hardware that meets specific requirements. All children are made up differently and have cerebral palsy in different parts of their bodies. Therefore, there is a need for a posterior pediatric walker that can adapt to the various needs of users. Both online surveys and face-to-face interviews (Figure 7.20) were conducted to collect data necessary for the study. (Susmartini, Herdiman, & Priadythama, 2021) (Sarker, Karim, Ahamed, Sultana, & Islam, 2020)

Figure 7.20: Patients using commercial walkers

User identification design requirements are met using questionnaires. Criteria used as input for conceptual design are mentioned in below Table 7.4.

The purpose of this study is to collect information on current pediatric walking aids used by children with CP, or recommended by pediatric therapists, to provide future pediatric walkers for infants with cerebral palsy. (Rodríguez-Costa, et al., 2021) (George, Levin, & Ryan, 2020)

Table 7.4: Pediatric walkers surveyed in this study

Device name	Key feature	Product image
Kid walk gait trainer	• Positioning options rotate away for easy user placement and positioning • Seats and support system move as per the patient's movement • Allows your body to move naturally while reducing weight and fatigue • Wheel configuration and small turning radius	Posterior walkers 
Lite gait walkable	• A manually adjustable yoke provides a comfortable fit • The best component for different user needs • Promotes balance, adjustment, strength and endurance	Posterior walkers 
Rifton pacer gait trainer	• Easily attach prompts and support • Improve your child's stability and confidence	Anterior and posterior 

R82 Crocodile	• A backstop prevents the device from rolling backward • Width and height adjustable twist grip with handle • Orientation lock to keep the crocodile aligned	Anterior walkers 
EasyStand Zing pediatric MPS multi-positioning stander	• Add a positioning component • Broaden your horizons of learning and involvement • Helps improve and maintain range of motion • Easy to adjust to prone, supine, and vertical positions	Posterior walkers 
Kaye 4-wheel walker	• Available in 6 sizes from toddler to adult • All models fold for easy storage and transport • Enable users to participate in more social activities in more diverse environments	Posterior walkers 
Leapfrog assistive walker	• An automatic and intuitive gas spring conversion system is built into this device • Children can walk, stand, and sit with this device • As the child gains strength, the strength gradually diminishes	Anterior walkers 
Aspire vogue carbon fiber walker	• Super lightweight carbon fiber frame • Detachable front carry bag • Easy lockable clip when folded • Height adjustable	Anterior walkers 

There are several things to consider for new product development as mentioned below for a specific application. By evaluating the work presented in this article, one can infer that a walker is most beneficial for recovery and support. But in some areas, this traditional walker can be improved to get satisfaction from the patients by considering the following points;

- Modular design that is easy to use and puts less strain on the arm which reduces walking effort.
- The stability of the walker is of great concern as the rollover is a major factor for existing traditional walkers.
- All models of walkers are mainly used for the elderly but not for patients with memory impairment. There, technology can make a big shift in these people’s beliefs.
- Most available walkers work for one purpose only, i.e. walking only, but not systems for sitting during prolonged walking or standing.

- *Identify design requirements*

The human factor plays a large role in developing devices suitable for use by children. Human design focuses on creating designs that meet users’ capabilities, constraints, and requirements. For example, environmental factors and ergonomics have a huge influence on the design of human elements. This type of design is especially important for walkers to ensure that the child can use the device.

The design criteria parameters for a pediatric walker are based on device function, materials, patients, aesthetics, ease of use, and safety as shown in below Figure 7.21.

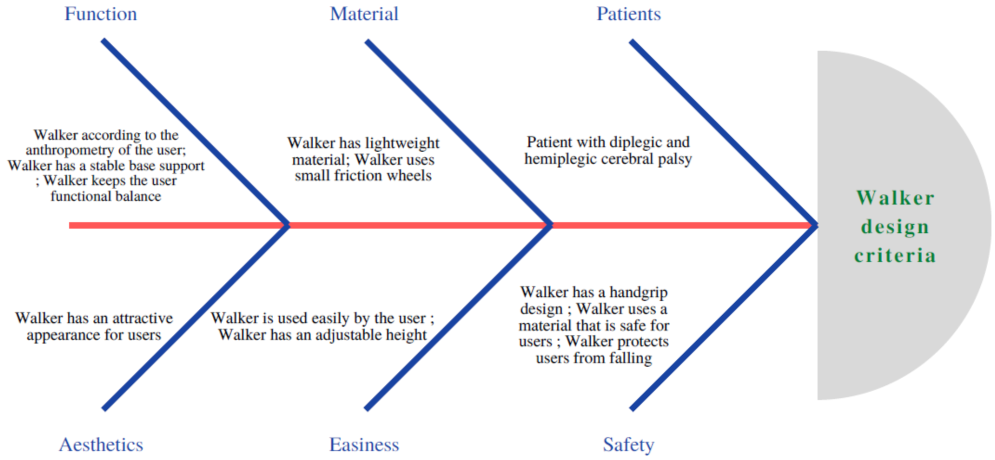


Figure 7.21: Walker design criteria (Lestari, Susmartini, & Herdiman, 2020)

During this step of data collection from participants, the researchers presented the goal of the study on the basis of the survey and the patient's requirements. Participants who live or work with children with CP and use a walking device were questioned about the practice's advantages. When no new idea was given and there was a recurrence of thoughts among the individuals, data saturation occurred and finally based on the feedback of the participant's need metrics data was prepared as mentioned in below Table 7.5.

Table 7.5: CP walker patient's needs

Sr. No.	Need	Rating (out of 5)
1	Walker design according to the anthropometry of the user	3
2	Walker has a stable base support	4
3	Walker keeps the user's functional balance	4
4	Walker has lightweight material	4
5	Walker uses small friction wheels	2
6	Walker has an attractive appearance for users	2
7	Walker is used easily by the user	3
8	Walker has an adjustable height as per the patient's body	5
9	Walker has a handgrip design	4
10	Walker uses a material that is safe for users	4
11	Walker protects users from falling	4
12	Patients need less help from caregivers	4
13	Durable construction finish for long-term use	5
14	Pediatric walker come supported by wider supporting legs, adjustable knobs, and other supports for comfortable walking	3

15	Low physical effort for usage	4

The reliability and validity of the conclusions of the criteria presented in the questionnaire were checked. This was followed by an analysis and description of the design requirements for the pediatric walker.

7.6 DESIGN AND SIMULATION APPROACH FOR CP WALKER

There are different types of pediatric walkers, but most of the products on the market cannot meet all patient's needs. However, this design ignores the rapid growth and typical activities of young children. A user's posture, mobility, and sociability are essential factors in a child's development. Proper posture and mobility allow users to develop the skills necessary to walk independently of the walker. (Decker, McMahon, Foley, & Nassar, 1919)

- Design approach

Our goal is to develop an adaptable, user-friendly, and aesthetically pleasing pediatric walker for the physical and social development of children with cerebral palsy (Anuar, Selvam, & Mahamud, 2016) (Ismail, 2012). By considering the normal height of the male person (Table 7.6), other body parts dimensions were measured for the CP walker structure design as shown in Figure 7.22 & Figure 7.23 for standing and sitting positions respectively.

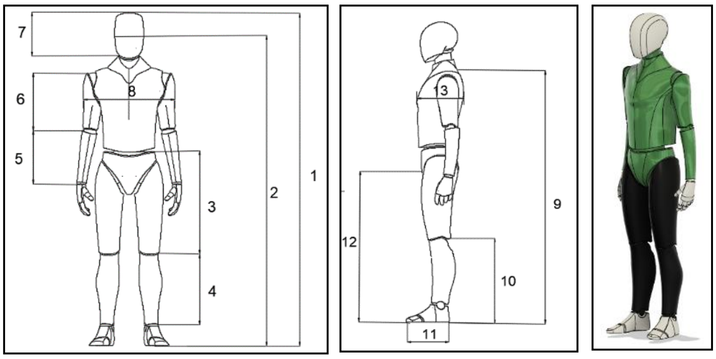


Figure A Figure B

Figure 7.22: Measurements in standing posture

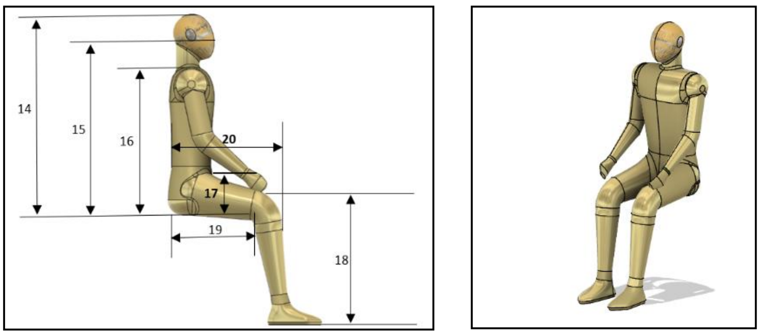


Figure C

Figure 7.23: Measurements in sitting posture

Table 7.6: Anthropometric measurements (Farooqui & Shahu, 2016)

Figure no.	Sr. no.	Measurements	Human body key sizes (mm)
		A. Measurements in standing posture	
Figure A	1	Height	1763
	2	Eye height 1	1647
	3	Thigh length	489
	4	Calf length	388
	5	Lower arm length	249
	6	Forearm length	329
	7	Head height	234
	8	Shoulder width	453
Figure B	9	Shoulder height 1	1436
	10	Tibia height	466
	11	Foot length	260
	12	Perineum height	830
	13	Chest thick	223
		B. Measurements in sitting posture	
Figure C	14	Sit height	954
	15	Eye height 2	838
	16	Shoulder height 2	628
	17	Thigh thick	137
	18	Knee height	518
	19	Sit deep	480
	20	Arm knee distance	582

Based on the design criteria (Wang, Dzul-Garcia, Bolding, & Raybon, 2019) and weaknesses of previous walker designs, a walker design that can meet the needs of the user has been created. One of the advantages of this walker design is that it keeps the user in balance and prevents the user from tipping over. The walker trainer concept design is called the application of assistive technology. (Bartlett, 2017)

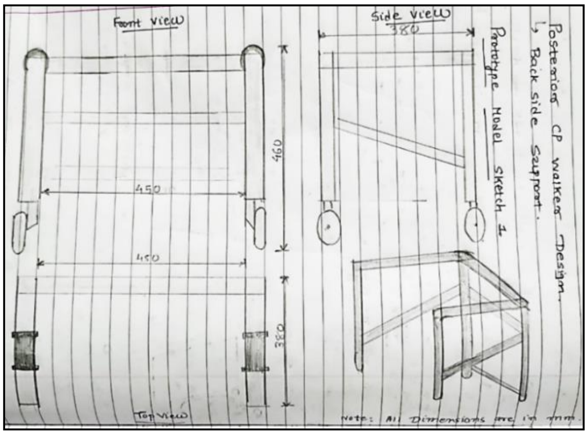


Figure 7.24: CP walker prototype sketch 1

The first design was most similar to the existing design with four legs, four wheels, and a rectangular structure surrounding the user as shown in Figure 7.24. However, we realized that this design did not solve the volume problem and could provide too much mobility, thus being less advantageous and negatively impacting the user’s posture. Conceptual designs were created, by traditional drawing, as shown in 2D and 3D images.

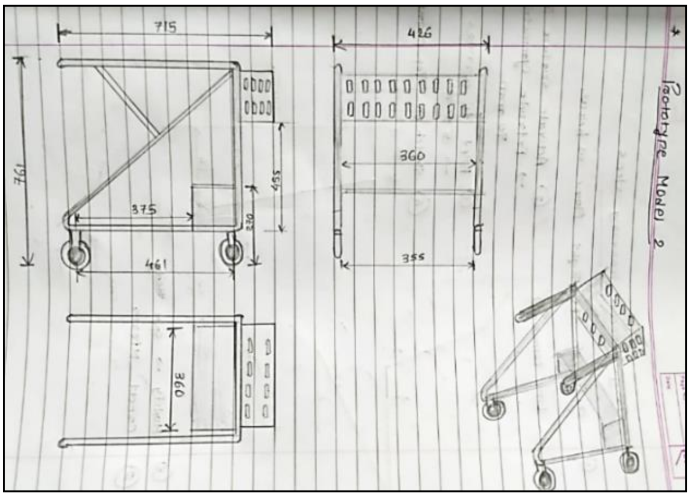
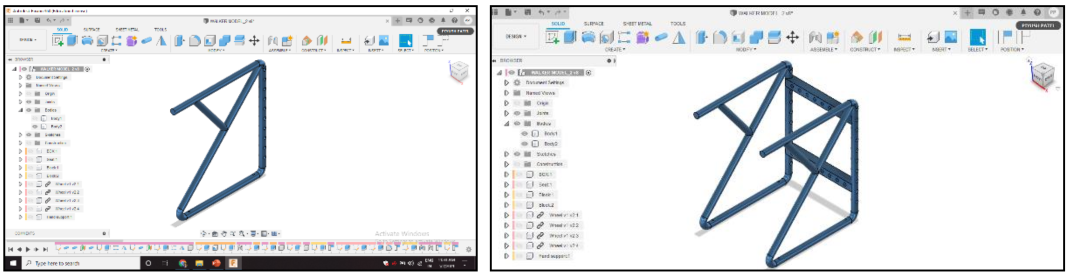


Figure 7.25: CP walker prototype sketch 2

The second design was an iteration of the first design with four legs type frame structure and four swivel wheels as shown in Figure 7.25. A front swivel wheel provides mobility for the user and a rear wheel provides stability by limiting front wheel movement. The handle with grip controls the user’s mobility provided by the rotating wheel. This design reduces the bulk of the device as it better fits the user. As the child grows, the walker’s folding seat and frame can be changed to meet different height positions.

The CP walker CAD model was developed with “Autodesk Fusion 360” software, and the process flow for the design of the main components is shown in the below Figure 7.26 to Figure 7.28.



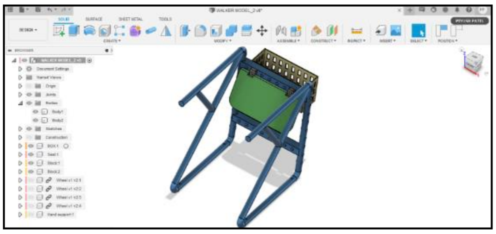


Figure 7.26: CP walker design process

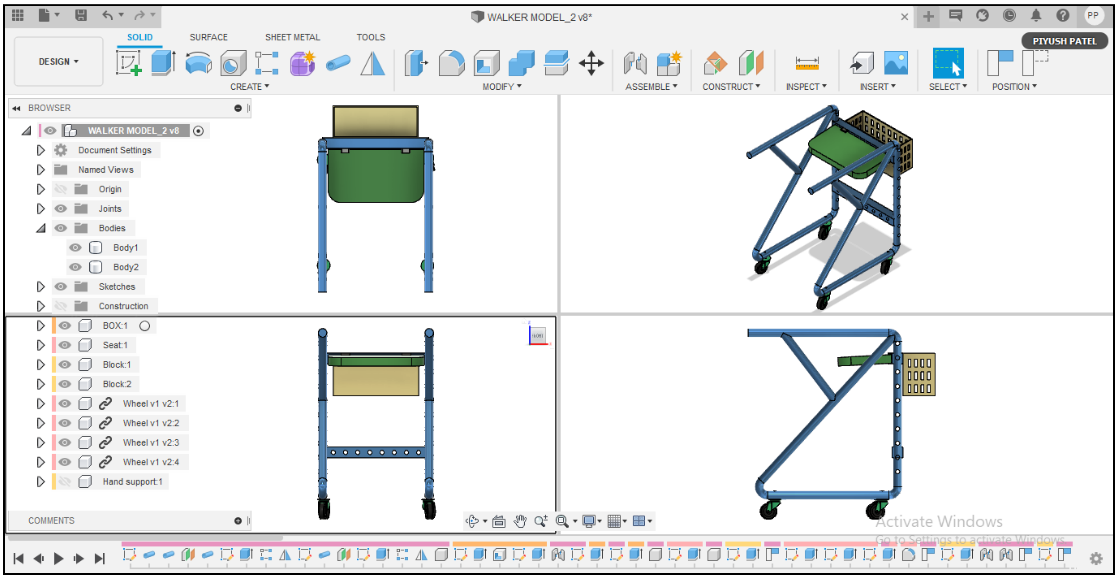
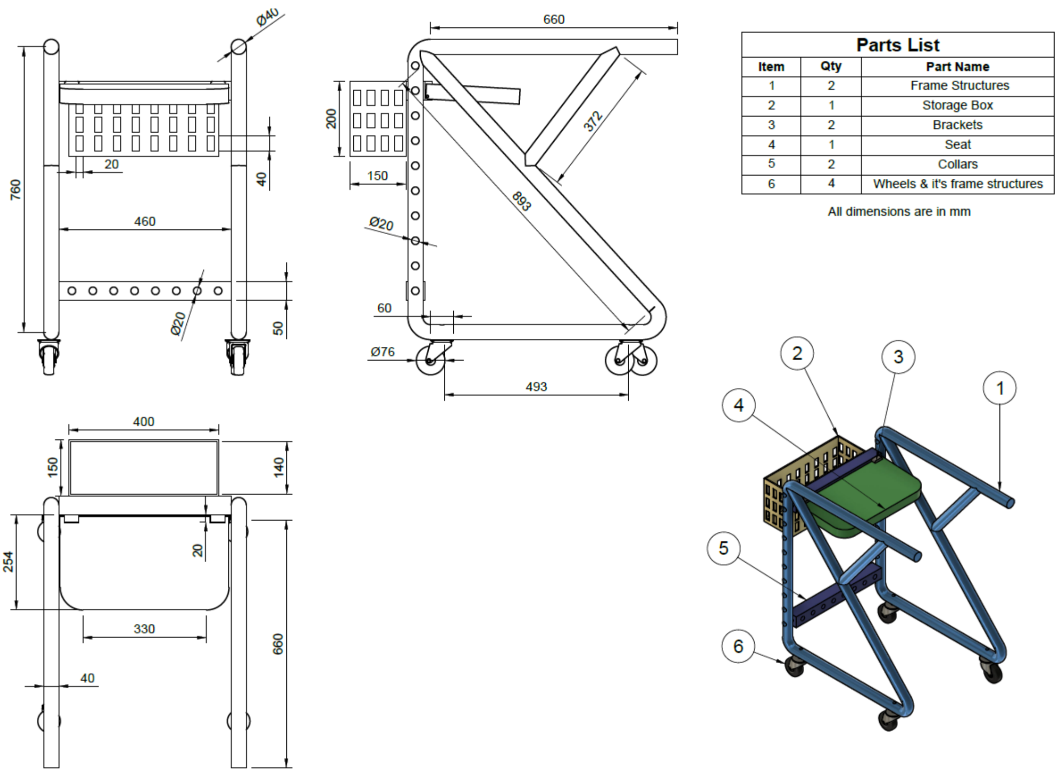


Figure 7.27: Different CAD views of CP model



Parts List		
Item	**Qty**	**Part Name**
1	2	Frame Structures
2	1	Storage Box
3	2	Brackets
4	1	Seat
5	2	Collars
6	4	Wheels & it's frame structures

All dimensions are in mm

Figure 7.28: CAD drawing of CP walker model

All components such as a folding seat and frame structure, collars, brackets, storage boxes, wheels, and its frame structure are designed and assembled in Autodesk Fusion 360 software as shown below in Figure 7.29. The primary requirements of all components used in the CP walker assembly process are described below.

- *Frame structure*

A pair of mating frames are attached to the handlebars and folding mechanism, one on each side of the user, to support the user's load. It is designed to be compactly folded to the left and right.

- *Collars*

They can slide along the vertical section of the frame structure and height adjustment is possible as per the user's requirements by just locking with the holes.

- *Seat*

The seat is used in walkers for patient comfort and safety. The seat has a folding mechanism that takes up less space. The seat has a support link that is linked to the frame with collar support on the structure to withstand the weight. The frame construction has many holes spaced a set distance apart that may be used to connect the seat position to the collar support as per the patient's requirement.

- *Brackets*

These are used to attach to the seat to get some degree of freedom with a side frame.

- *Storage boxes*

To store some patient's luggage in a box it is attached to the back side of the frame structure.

- *Wheels and their frame structure*

The rotatable front wheel provides mobility for the user and the rear wheel provides stability by limiting the movement of the front wheel. It is recommended to install the wheels under the subframe as they are spacious and can easily go over small obstacles and curbs.

The individual components are shown in below Figure 7.29. The material details of all components are mentioned in below Table 7.7.

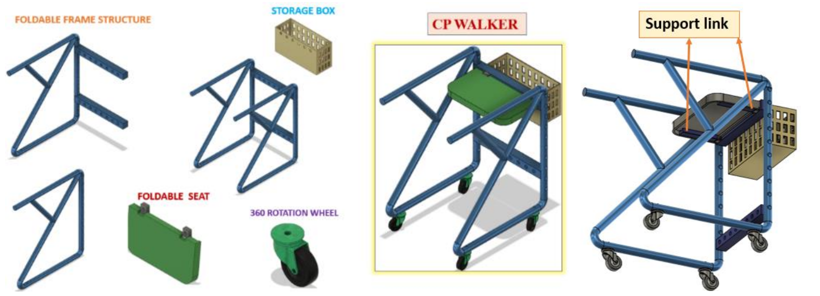


Figure 7.29: CP walker components

Table 7.7: CP walker parts material details

CP WALKER'S PARTS DETAILS	
A Group parts list and materials	**B Group parts (Variable material)**
1) Wheel: Polyethylene	1) Collar : AL/SS/C/ABS/POM/PLA/PET/PEEK/N/Ti
2) Wheel frame structure: Al	2) Seat : AL/SS/C/ABS/POM/PLA/PET/PEEK/N/Ti
3) Bracket: Al	3) Frame : AL/SS/C/ABS/POM/PLA/PET/PEEK/N/Ti
4) Storage box: PLA	

The developed walker has two configuration modes, standing mode, and walking mode, as shown in Figure 7.30 & Figure 7.31.

Figure 7.30: Standing position with walker

Figure 7.31: Sitting position with walker

- Simulation Approach

Finite element modeling was used to develop a walker design and investigate its stability (Figure 7.32). Static structural FEA was implemented to ensure that the walker was manufactured without any safety concerns for the user. (Hajdarević & Busuladžić, 2015)

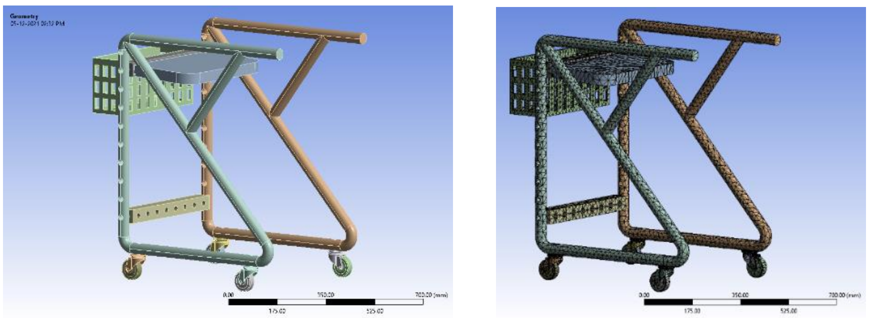
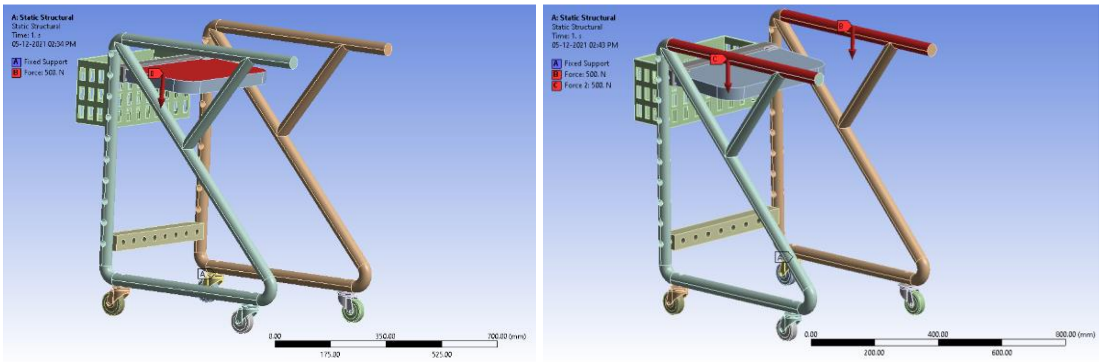


Figure 7.32: Static structural FEA model

The side frame was considered the most vulnerable because the normal force applied by the user across the seat and the normal force acting in the opposite direction to the wheel caused bending stress.

Group A components (wheel & its structure, bracket, and storage box) were prepared using common materials as shown in Table 7.7, and the evaluation of various materials for Group B components (frame, seat, collar) was analyzed through static structural modeling.

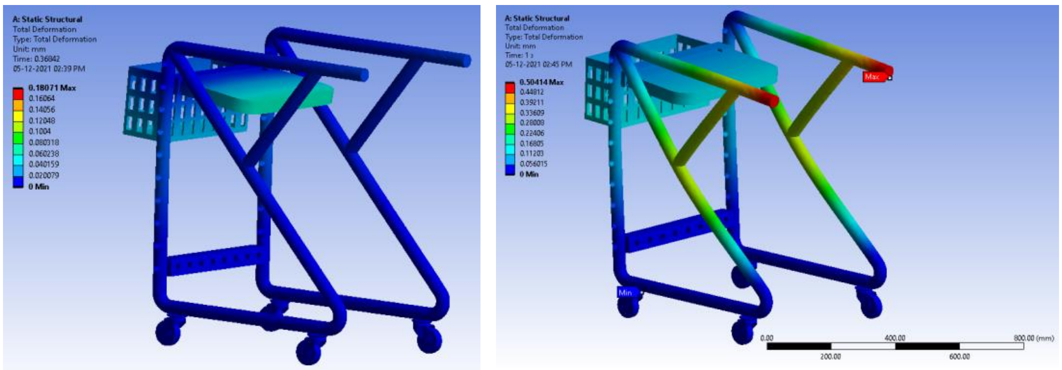
The total force applied to the seat frame was 1000 N, taking into account that the patient could weight no more than 50 kg and that the safety factor stayed at 2. The 1000 N load was distributed uniformly throughout the seat frame texturing (Figure 7.33).



(a) Sitting position (b) Standing position

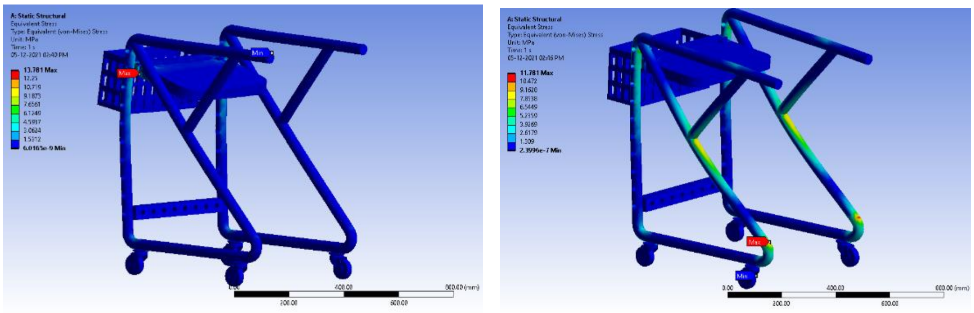
Figure 7.33: Load applied on walker during sitting and standing position

The static structural simulation analysis for total deformation and equivalent von-mises stress for the aluminum material of the frame and collar components are shown in below Figure 7.34 & Figure 7.35.



(a) Sitting position (b) Standing position

Figure 7.34: Total deformation analysis during sitting and standing position



(a) Sitting position (b) Standing position

Figure 7.35: Equivalent stress analysis during sitting and standing position

The walker described was analyzed considering sitting and standing positions in the ANSYS workbench for the total strain and stress equivalent of the different materials, as shown in Table 7.8.

Table 7.8: CP walker material analysis data

Sr no.	B Group parts (Frame, seat, collar) material list	Sitting position		Standing position	
		Total deformation (mm)	*Equivalent stress (MPa)*	*Total deformation (mm)*	*Equivalent stress (MPa)*
1	*S.S*	0.06995	15.404	0.18648	11.828
2	*Aluminum*	0.18071	13.781	0.50414	11.781
3	*Titanium*	0.1357	14.316	0.3725	11.723
4	*CFRC*	1.4583	25.005	5.5527	20.723
5	*PEEK*	3.0165	27.116	9.1893	18.402
6	*PLA*	3.3591	27.892	10.26	18.903
7	*PET*	3.9756	29.117	12.211	19.543
8	*Acetal resin (POM)*	3.9998	29.185	12.283	19.621
9	*ABS+PC Plastic*	4.5683	30.122	14.092	20.089
10	*Nylon 6/6*	7.6217	33.24	23.854	21.78

The density of stainless steel, aluminum, titanium, and carbon fiber composite is 7.5, 2.7, 4.5, and 1.6 g/cm^3 respectively. The cost of stainless steel, aluminum, titanium, and carbon fiber composite is 190, 140, 1600, and 6500 Rs/kg respectively. Therefore, the material of the frame structure was made from aluminum and the rest of the parts were made from different materials as shown in Table 7.7.

7.7 RESULT AND DISCUSSION FOR CP WALKER

A walker design that can satisfy the user's demands has been developed based on the design criteria and shortcomings of earlier walker designs. This walker's balance-preserving features stop the user from toppling over, which is one of its benefits.

There are several things to consider for new product development as mentioned above for a particular medical field. The selection of materials for the final analysis resulted from examining the first four results. Aluminum is the most popular material due to its low cost and ease of processing. Stainless steel is also preferred because it has low CTE and high hardness but has the disadvantage of being heavier.

To create a walker design and test its stability, finite element modeling was performed. ANSYS was used to investigate the walker's stress and total strain analysis, and the results are displayed in Table 7.8. According to the results, the Eq. stress induced by the aluminum walker was 13.781 MPa in the sitting position and 11.781 MPa in the standing position, aluminum was the suitable material based on material properties compared to the other materials. Therefore, from the observation data preferable material for the mainframe structure of the CP walker device is aluminum.