CHAPTER 8

RESULT AND DISCUSSION

This chapter presents a comprehensive description of the study's findings to provide a clear picture of what was observed after data processing.

Identification and application of innovative manufacturing techniques in healthcare engineering were explored throughout this research. An attempt has been made through this research to study global and Indian health issues and identify some basic elements required in the field of prosthetics and orthotics. Customized P&O elements are the main requirements because the human body varies over time owing to changes in development and weight, the prosthetic must be replaced and adjusted regularly. This means that the P&O elements may not be used for long periods.

The methodology was developed through this research for the development of customized P&O elements using advanced manufacturing techniques.

8.1 RESULT AND DISCUSSION FOR PROSTHETICS ELEMENTS

The current creation combines the benefits of a multiaxial dynamic foot's stability with the energy storage capabilities of a high-profile dynamic foot. Another advantage of having an adjustable prosthetic foot is that it allows the manufacturer or user to choose the range of medial-lateral rotation that is most suited to the wearer's demands. An amputee can accommodate the foot on uneven terrain and can easily ascend/ descend on ramps. Even an amputee can walk/ambulate without a foot shell and participate in aquatic activities like beach /swimming by pasting the sole treaded on the bottom side of the prosthetic foot (Figure 8.1).

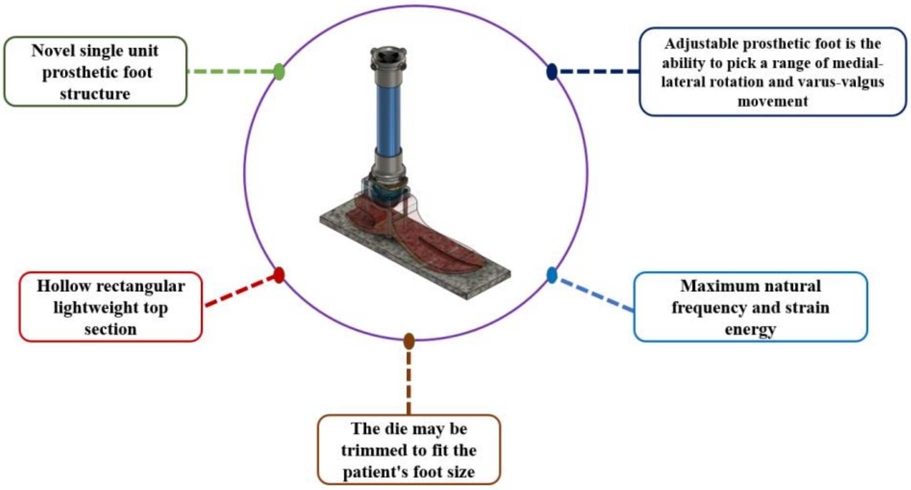

Figure 8.1: Multiaxial dynamic foot's device features

The current novelty is about a prosthetic foot comprising a hollow rectangular lightweight top section that is an integral part of the novel single-unit prosthetic foot structure. Another advantage of having an adjustable prosthetic foot is the ability to pick a range of medial-lateral rotation and varus-valgus movement, similar to the natural subtalar joint, to adapt to uneven terrain. Even as per the foot size of the patient the die can be trimmed to a smaller foot size. Attempts will be made in the die for the higher thickness of shaft, and blade for ultra-heavy amputee patients-where countries like the US have heavy patients weighing 400 to 500 lbs (same will be used with filler for routine amputee patients with a weight limit up to 120kg).

The present design approach is related to a novel single-unit prosthetic foot structure where the static structural simulation results show that considering carbon fiber composite material for a prosthetic foot structure has the lowest deformation value and highest natural frequency. The current innovation combines the benefits of a multiaxial dynamic foot's stability with the energy storage capabilities of a high-profile dynamic foot. There is a further advantage to having a prosthetic foot of different materials like carbon fiber composite suitable for heavy load situations and other polymer materials like UHMW-PE/ nylon /delrin which has a low production cost and is lightweight. Various parameters analysis is conducted on the foot structure models (Figure 8.2 to Figure 8.7) for material optimization data as described in detail in Chapter 5 (Section 5.5 Simulation data summary for various prosthetic foot models).

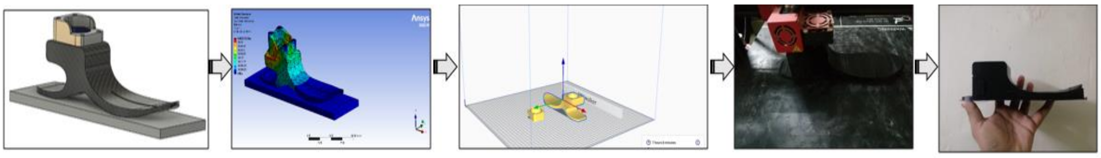

Figure 8.2: Design and development process of the prosthetic foot model 1

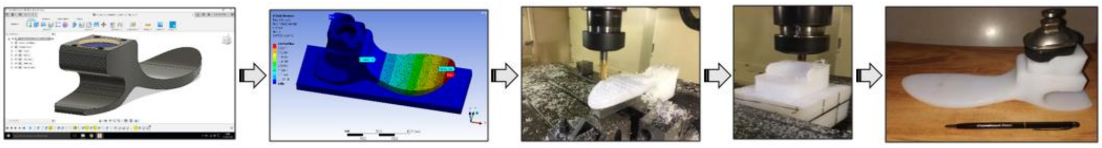

Figure 8.3: Design and development process of the prosthetic foot model 2

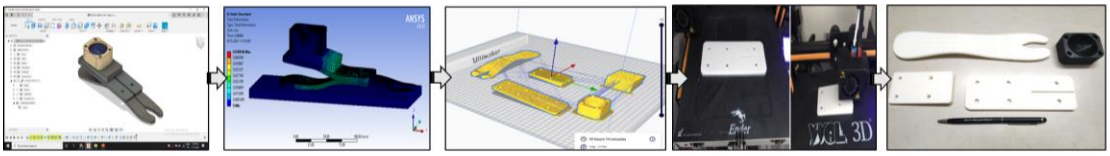

Figure 8.4: Design and development process of the prosthetic foot model 3

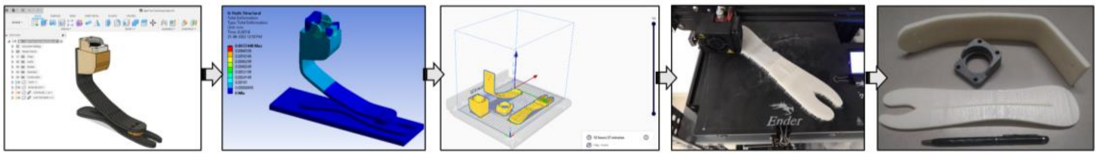

Figure 8.5: Design and development process of the prosthetic foot model 4

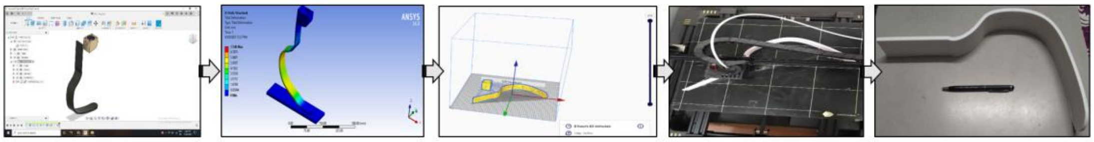

Figure 8.6: Design and development process of the prosthetic foot model 5

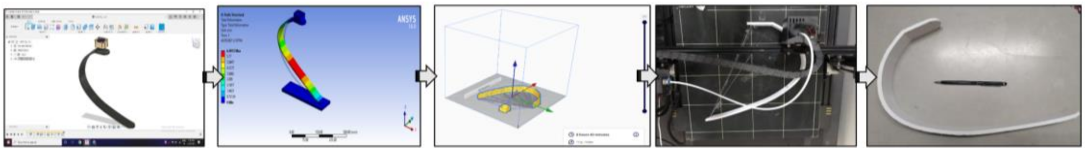

Figure 8.7: Design and development process of the prosthetic foot model 6

Many factors must be considered while building a better physical prototype for any new product, and the same is true when utilizing the prototype as a benchmark. Based on these criteria, designers may select an acceptable sort of prototype approach for their new product (Figure 8.8). Finally, the innovative multiaxial foot mechanism is created with a 3-axis Vertical Milling Center device and fitted to patients for product assessment. Throughout the gait study, a standardized physical examination of the lower limbs is performed to ascertain anthropometry and passive range of motion, and standardized clinical films are collected, as detailed in detail in Chapter 6 (Development & testing of the novel prosthetic foot).

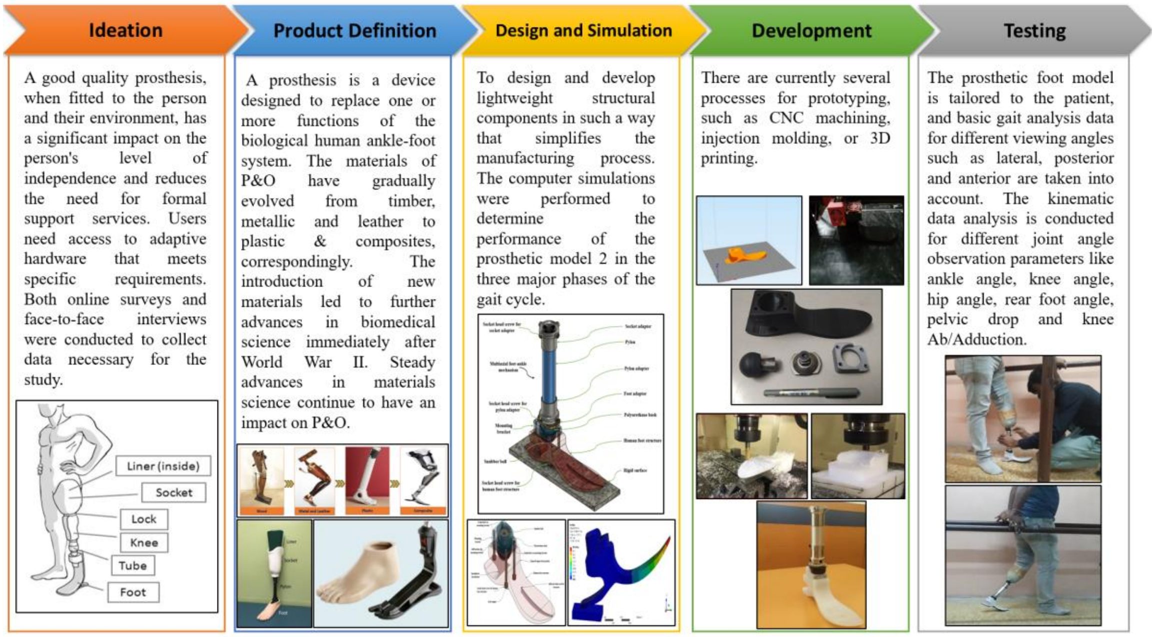

Figure 8.8: Development and testing process for a novel prosthetic foot

The special feature of this foot is that it allows testing of ankle stiffness over a wide range of motion, similar to physiological ankle stiffness and range of motion. The novel foot design shows a reduction in weight compared to previous prototypes, maintaining structural integrity, and allowing proper operation according to the patient's requirements.

The current development pertains to a revolutionary single-unit prosthetic foot that may absorb shocks during ambulation while also transferring energy efficiently between heel strike and toe-off and improving stability.

8.2 RESULT AND DISCUSSION FOR ORTHOTICS ELEMENTS

Individual orthotics devices are traditionally created using plaster molds, which necessitate many patient visits and demand a significant amount of labor and time to construct. As a result, our primary focus is on the process of rapidly designing and constructing lightweight structural components while simplifying the production process. The creation of a methodology for the construction of tailored human orthotics foot shell, wrist brace, ankle foot orthotic, and CP walker utilizing an advanced manufacturing approach is studied in this part.

Rehabilitation techniques help people function better after injury or illness. The use of Advanced Manufacturing in medical device manufacturing has grown in popularity over the past decades as the opportunities for this technology rapidly expand. Traditionally, individual P&O devices are manufactured using plaster molds, which require multiple patient visits, and take a lot of effort and time to produce. Therefore, our main attention is the process of designing and developing lightweight structural components quickly with a simplification of the manufacturing process.

The AFO and flex foot prosthetic parts were printed using PLA material on FDM machines (Figure 8.9 & Figure 8.10). The entire process took less than 7 hours, with an average hands-on time of only 10-15 minutes for AFO parts and about 10 hours for flex-foot prosthetics.

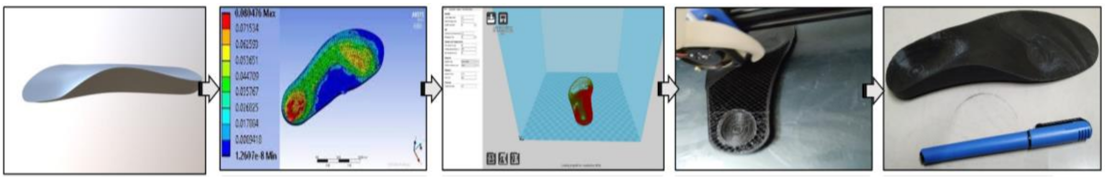

Figure 8.9: Design and development process of the orthotics foot shell model

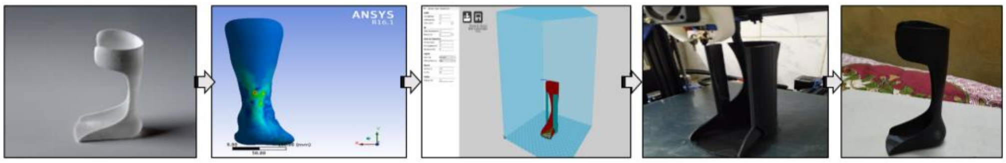

Figure 8.10: Design and development process of the Ankle Foot Orthotic model

In other words, using 3D printing to create a P&O device for a patient is significantly less time-consuming than traditional methods. In the future, it is intended to compare altered effects obtained by using various types of materials for the improvement of the P&O devices by the AM method.

Based on the design criteria 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 second design was an iteration of the first design with four legs type frame structure and four swivel wheels. 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 (Figure 8.11). As a child develops, the walker's folding seat and frame construction may be modified to accommodate various height positions.

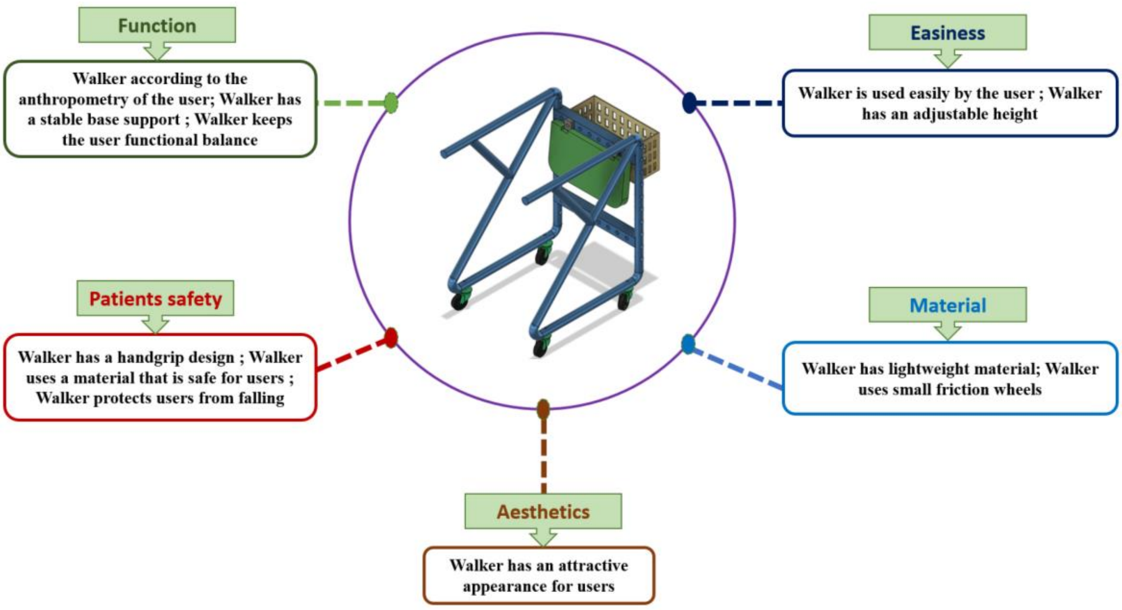

Figure 8.11: Walker device features

The novel concept of the CP walker is designed as a multipurpose device, it can be reconfigured with four main functions: standing and walking mode, standing and sitting mode, floor sitting mode, and wheelchair mode. The floor-sitting mode can be accessed by mounting the seat with a collar on the bottom-most position.

The device has a wide range of features, including a variety of removable accessories such as a light frame structure with various adjustable and customizable components for height adjustment, and a storage box for personal items, including independently adjustable handles and/or ergonomic grips.

Finite element modeling was used to develop a walker design and investigate its stability. The walker's stress and total strain analysis were examined using ANSYS, and the findings are shown in the table. According to the results, the Eq. stresses induced for the child configuration model were 5.51 MPa & 11.02 MPa in the sitting position and 2.35 MPa & 4.71 MPa in the standing position for person weight 20 kg & 40 kg respectively, Aluminum was the suitable material based on material properties compared to the other materials.

The Eq. stresses induced for the Adult configuration model were 13.78 MPa & 27.56 MPa in the sitting position and 5.89 MPa & 11.78 MPa in the standing position for a person weight 50 kg & 100 kg respectively, Aluminum was the suitable material based on material properties compared to the other materials.

According to the results, the total deformation induced for the child configuration model is 0.07 mm & 0.14 mm in the sitting position and 0.10 mm & 0.20 mm in the standing position for a person weight 20 kg & 40 kg respectively, Aluminum was a suitable material based on material properties compared to the other materials. The total deformation induced for the adult configuration model was 0.18 mm & 0.36 mm in the sitting position and 0.25 mm & 0.50 mm in the standing position for a person weight 50 kg & 100 kg respectively, Aluminum was the suitable material based on material properties compared to the other materials.

Chapter 7 (Design and simulation approach of orthotics elements) describes the static structural simulation study for total deformation and equivalent von-mises stress for various materials of the frame and collar components.