ABSTRACT

Investigations on Prosthetics / Orthotics elements developed from polymers and its composites

Key words:

Advanced Manufacturing; Anthropometric Measurements; Assistive device; CAD; Cerebral Palsy; Customized Design; Gait; Health Care; Material Optimization; Patient's Survey; Pediatric Walker; Prosthetic and Orthotic; Simulation.

Background

Due to the growing demand from consumers and industries for high-performance products, composite materials have recently gained prominence due to their better particular mechanical qualities. Researchers have concentrated on creating ecologically acceptable bio-based products from renewable resources as a result of the depletion of non-renewable resources and rising environmental degradation. Such types of biodegradable materials are very useful for medical equipment.

Rehabilitation procedures enable individuals to function more effectively following an injury or illness. Due to an increase in fatalities and man-made accidents, limb amputations to preserve human life are becoming more common. Following limb amputation, patients become reliant on the Prosthetic and Orthotics (P&O) element.

Healthcare plays a crucial role in markets and is evolving at an accelerated rate; it possesses characteristics that differentiate it from more traditional sectors and presents challenges in both the utilization of current technology and the development of new technologies. Medical researchers are exploring novel approaches to enhance healthcare items, including artificial limbs, prosthetics, implants, personalized orthotic elements, customized insoles, and surgical-planning models of internal body components, aiming for advancements that are faster and more precise.

The present research strategy is to perform an exhaustive search on numerous health concerns and healthcare items to discover a viable product for investigation. The purpose of this research is to discover and investigate the problems that humans confront throughout their lives.

Objectives

P & O facilities are accessible globally, but services often frequently fall short of expectations, both numerically and qualitatively. The majority of low-income nations have insufficient P&O facilities, are overly centralized, and produce insufficiently to fulfill demand. According to the World Health Organization, only approximately 5% of individuals who require assistive elements can effectively access them. P & O practices are not always adequate, equipment quality is frequently poor, and the quantity and qualifications of workers are insufficient to satisfy the demands. The foremost motive of this study is to categorize the latest knowledge for researchers and highlight the challenges and future directions of research in recent advancements in polymer processing for biomedical applications.

Keeping the above demands in view, research studies have been conducted on developing optimized P&O elements. The use of Advanced Manufacturing in medical element manufacturing has risen in prominence over the last several decades as the prospects for this technology have expanded significantly. This thesis work goes over the complete approach for designing, analyzing, developing, and testing innovative prosthetics and orthotics based on the needs of the patient. It is our responsibility to assist humanity by providing high-quality P&O elements at a reasonable price.

Method

The human body undergoes changes over time due to fluctuations in weight and growth, making it imperative to frequently replace and modify Prosthetic and Orthotic (P&O) elements. Consequently, these elements may not remain functional for an extended period. The necessity for continual alteration or adaptation becomes pronounced, especially when expensive materials are employed. However, only a limited number of research studies have concentrated on optimizing biomimetic structure design. There is still a discrepancy between how process parameters are influenced by material performance and design specifications. According to complicated load combinations and structural design standards, several sophisticated manufacturing and analysis procedures must also be taken into account for the maximum factor of safety.

Traditionally, individual P&O elements 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. Additive manufacturing is an advanced layer-based manufacturing process that fabricates customized prosthetics and orthotics to patient requirements directly from computer-aided design data without using part-dependant tools. In the rehabilitation field, the utilization of additive manufacturing processes has demonstrated the ability to expedite, streamline, and enhance the quality of personalized products.

The works proposed have extensively used finite element techniques for the simulation and optimization of various design concepts proposed for P&O elements. The optimized design is manufactured & realized and may undergo successful tests & evaluation proposed for novel prosthetic foot models for lower limb amputation level patients. A systematic physical examination of the lower limbs is done throughout the session to determine anthropometry, and passive range of motion, and clinical films are recorded.

The established kinematic analysis is placed via gait analysis with varied inputs to generate variable outputs, taking into account the prosthetic's typical usage circumstances. To obtain the technology for complex and low-cost artificial limbs, the links between gait analysis and prosthetic biomechanics must be strengthened. The study provided here exhibits an understanding of gait analysis for application in prosthetic creation and assessment of performance. The result of simulation and testing is reported and found to be close conformance.

According to the survey, another design and simulation technique was used for the orthotics aspects to take into account the basic needs of the patients. A minor attempt is made to develop and analyze the Ankle Foot Orthotic (AFO) element and the Cerebral Palsy (CP) walker. This thesis work goes into the depth of these challenges and envisages the development of lightweight, compact, and very low development cycle time from concept to realization for the Orthotics elements.

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 were conducted to collect data necessary for the study. The design criteria parameters for a pediatric walker are based on device function, materials, patients, aesthetics, ease of use, and safety.

The walker described is analyzed considering the sitting and standing position of patients in the ANSYS workbench for the total deformation and stress equivalent of the different materials. Based on the findings of the research, the design and material are further improved by combining materials and dimensions to fulfill both mechanical requirements in terms of strength and ergonomics for the CP walker.

As a result, the design framework's adaptability would make it simple for a product designer to arrive at a customized design approach with specified performance characteristics efficiently and cost-effectively.

Results and Discussion

This thesis work discusses the detailed procedure for the design, analysis, development, and testing of various K-level human foot models. Various parameters are analyzed using the foot structure model for material optimization data. An object's natural frequencies are only related to properties such as material and mass properties. Through modal analysis, the result shows that the natural frequency (1363 Hz) of the Model 2 is the maximum for UHMW-PE material. So for the preparation of the foot structure, this material may be selected for the best performance of the prosthetic foot model.

3D printing technology is used for the development of the prototype model based on the optimal design data obtained. Finally, the manufacturing process for the prosthetic foot structure is completed in approximately 11 hours by using a 3-axis Vertical Milling Center machine. A graphical representation of various measured parameter values for ankle, knee, and hip angles from the gait analysis shows that the data are within the allowable range of the standard reference data for the patient's lateral view position when wearing the novel prosthetic foot model. So, for the preparation of the foot structure, this material can be selected for the best performance of the prosthetic foot model.

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. The current novelty lies in the 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.

The AFO and flex foot prosthetic parts are printed using PLA material on FDM machines. The entire process takes 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. In other words, using 3D printing to create a P&O element for a patient is significantly less time-consuming than traditional methods takes approximately 3-6 weeks on the basis of design complexity, and takes an average of 3 or 4 visits. In the future, it is intended to compare altered effects obtained by using various types of materials for the improvement of the P&O elements 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 described walker is analyzed through a static structural simulation process and from the obtained results, it is concluded that for the aluminum walker by considering the adult weight of 100 kg the maximum stress induced in the walker is 27.562 MPa in sitting and 11.781 MPa in standing position, as well as total deformation values, are 0.36145 mm and 0.50414 mm respectively that is the lowest value compared to other materials. The results of this case study are very promising, testing this element with more patients and collecting data to create future effective pediatric standard walkers.

The following are the key research contributions to knowledge as a result of this research for Prosthetics and Orthotics elements:

1. According to the findings of the review, the final focus was on the design and development of human prosthetic foot structures for below-knee amputee patients, as well as a minor attempt to be made for Orthotics element preparation employing advanced manufacturing techniques.

2. Conducted a patient survey to acquire background information on the use of Prosthetics & Orthotics elements (Jaipur foot camp of bhagwan mahaveer vikalang sahayata samiti at shree party plot, Valsad, Gujarat; Asian Physiotherapy & Research Institute, Surat, Gujarat).
3. Developed P&O model using various modeling tools (Autodesk Fusion 360, Autodesk Meshmixer).
4. Outlined a logical process for choosing the optimized parameter to create the personalized various prosthetic foot, orthotics foot shell, wrist brace, ankle foot orthotic, and CP walker.
5. Analyzed P&O elements utilizing a variety of Analysis software tools (ANSYS, Ultimaker Cura, Kinovea).
6. Emphasized polymers/composite as a material for various P&O elements.
7. Developed simplified lightweight structural components using an advanced manufacturing process (The mass of the SACH Foot Structure is discovered to be 309 grams and the mass of the Novel Foot Structure after optimization is found to be 190 grams. The development efforts by considering design optimization in Novel prosthetic foot structure show that there is a weight reduction of approximately 61.5 % in comparison with the SACH Foot Structure).
8. Utilized an appropriate advanced production technology for the development of customized P&O elements (Fused Deposition Modeling (3D Printer); 3 Axis CNC Vertical Machining Center).
9. Performed patient testing to evaluate the performance of the Novel Prosthetic foot model for lower limb amputation level patients (Evolution Healthcare Pvt. Ltd, Surat, Gujarat).