CHAPTER 3

RESEARCH STATEMENT AND OBJECTIVES

3.1 RESEARCH MOTIVATION

Due to population growth, poverty, illness, and violent conflict, the number of people in need of rehabilitation services is increasing every year (Figure 3.1). Existing rehabilitation services are far from meeting this growing need. In low-income countries, the need for P & O elements is growing significantly. Although it is difficult to obtain numbers on the exact need for prosthetics and orthotics in low-income countries, it is estimated that 24 million people (0.5% of the total population) may need them. Due to illness, accidents, natural disasters, ongoing conflicts, and their aftermath, demand is constantly increasing, outpacing the expansion of P & O services in most countries.

P & O facilities are available in all countries, but services often do not meet the needs, both quantitatively and qualitatively. The majority of low-income countries have insufficient P&O infrastructure, are overly centralized, and produce insufficiently to fulfill the demand. According to the World Health Organization, perhaps only 5% of people who require assistive devices can access and utilize them. The P & O techniques used are not always appropriate, the quality of the equipment is often poor, and the number and qualifications of staff are not sufficient to meet the needs.

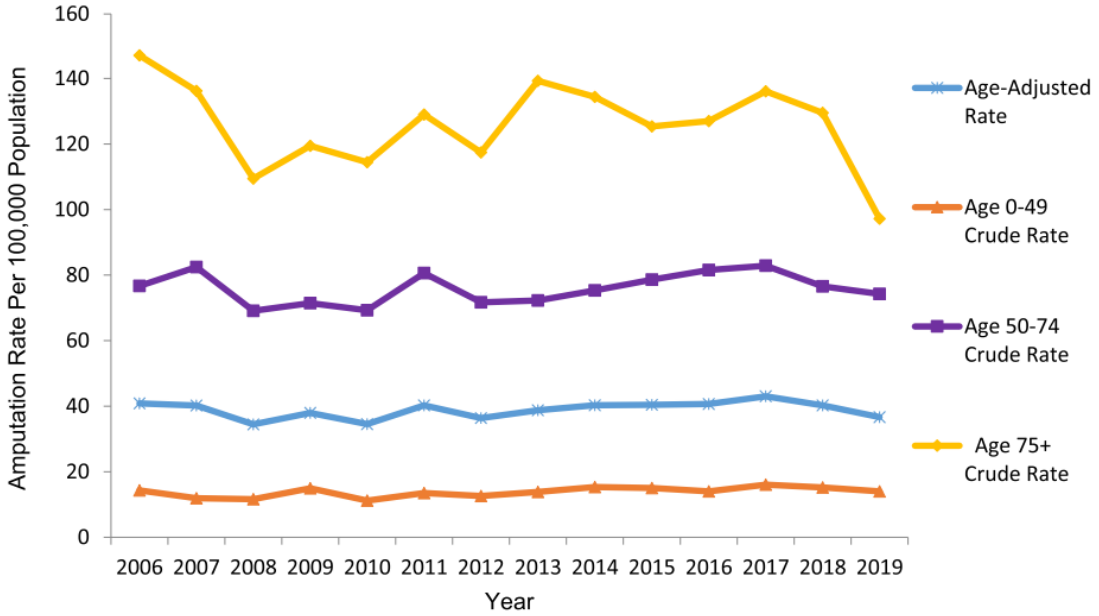

Figure 3.1: Crude amputation rates by year, adjusted for age and stratified by age (Essien, Kopriva, Linassi, & Zucker-Levin, 2022)

Because the human body varies over time owing to changes in development and weight, the prosthetic must be replaced and adjusted regularly (Figure 3.2). This means that the prosthetic may not be used for long periods. If the materials used are expensive, the need for this constant change or adjustment can be high. For overcoming poor functionality and controllability of previous prosthetic devices, the biomimetic approach has appeared as suitable for considering novel forms and functions closer to biological models.

Ongoing research in the field of bioengineering has improved a model of a prosthetic that closely reproduces the functioning of a real biological modal by improving the safety and accessibility of prosthetic limb manufacturing. The study's findings are based on the compatibility of current and projected material characteristics, helping to provide more cost-effective and environmentally friendly alternatives while maintaining the properties required for prosthetic devices. This outcome is likely to assist patients and carriers who lack this important skill to live independently at a young age.

A developing country like India alone reports more than 0.5 million amputees and a figure as large as 2350 is added about every year. According to the World Health Organization, India has the greatest number of road accidents in the world.

Figure 3.2: Human prosthetic and orthotic elements

3.2 PROBLEM DEFINITION

India has the largest young traumatic amputee population in the world. As India is a developing country, the highest number of prosthetic/ Aids & appliance fittings are done free of cost through various schemes of the Government of India like ADIP/ Sarwa Sikha Abhiyaan/ Assistive schemes/CSR. National Institutes/ State Government Centers/DDRC/ Charitable Institutions/ NGOs play also a major role. Additionally, private clinics and multinational companies are operating in the country; however, only a limited portion of the population can afford and access their services.

Because of variations in growth and weight, the human body changes with time, so it is necessary to **replace and adjust** the P&O regularly. This means that the P&O elements may not be used for long periods. If the materials used are **expensive,** the need for this constant change or adaptation can be high.

However, very few studies are dedicated to investigating the optimization of biomimetic structural design. Still, there is a gap in the dependencies of process parameters on **design requirements** and **material performance**. Some **complex manufacturing** and **analysis processes** also need to be considered for the maximum factor of safety according to complex load combinations and structural design criteria.

Table 3.1: Applicability of manufacturing process for various engineering materials (Singh, I.,2017)

Basic Category of Materials	Primary forming processes (Additive)		Deforming processes (Formative)		Material Removal Processes(Subtractive)		Joining Process (Consolidation)		Property changing processes
	Traditional	Advanced	Traditional	Advanced	Traditional	Advanced	Traditional	Advanced	Traditional
Metals	A	B*	A	A	A	A	A	A	A
Alloys	A	B*	A	A	A	A	A	A	A
Polymers	A	A	B	B	B	A	B	B	C
Ceramics	A	C	C	C	B	A	B	C	C
Composites	A	C	C	C	B	A	B	B	C

Table 3.1 above describes the suitability of various manufacturing procedures for various types of engineering materials. “A” denotes widely used, “B” indicates not frequently used, “C” indicates not used, and “*” denotes that further research is being done. Now regarding polymer-only **property changing processes, heat treatment process** is not very common for polymers. Rest all A & B. So, this table summarizes the process of processing polymers. Now for Composite no of ‘c’ are there. Only two processes are widely used for Composite. Rest is not frequently used or under the

research stage. Therefore, the topic becomes even more important as an engineer that basic understanding is required of the various processes utilized for polymer-based composite.

Therefore, cost-efficient prosthetic parts that are created using **economical technology** are significantly needed. Hopefully, this study proposes to investigate Prosthetics and Orthotics elements by considering different material behavior, design/parameter consideration, customized design, and advanced manufacturing using polymer/composite.

So to overcome such problems and limitations, the research area will be covered on the topic entitled *"Investigations on Prosthetics / Orthotics elements developed from polymers and its composites".*

3.3 NEED FOR STUDY

The highest amputee population is of lower limbs where transtibial /below the knee are more in numbers. Most amputees in India are K3-level ambulators with prosthetics, where they constantly walk on uneven terrain. Here is the need for a low-cost multi-axial prosthetic foot to negotiate farmland/staircases/ ramps/ uneven road surfaces.

Based on the field survey, India does not have any K3 and K4 level foot manufacturing units widely. (India has only K1 and K2 level foot manufacturing units). The cost of K3 and K4 level foot devices which are available in other countries are approximately 1, 50,000 ₹ and 2, 50,000 ₹ respectively.

The multiaxial foot-ankle mechanism is designed in such a way that it will be fitted on a lower limb prosthetic endoskeleton system with a 30 mm tube pylon and adapter worldwide.

There is a scope for the development of Prosthetics / Orthotics elements through the latest advanced manufacturing techniques e.g. Additive manufacturing, CNC Machines, etc.

Optimization and parametric study in terms of the dimensional of Prosthetics / Orthotics elements with a combination of various materials is not found adequately in the literature. For prosthetic foot design, the device needs to be lightweight to facilitate mimicking the maximum range of motions of the anatomical foot.

3.4 RESEARCH OBJECTIVES

Various methods have been proposed to overcome the difficulties faced by early researchers and introduce new types of techniques. Therefore, this research proposes new and cost-effective materials that retain the properties required in the medical field. The objectives of the present research are:

- To investigate patients' specific needs for prosthetics and orthotics elements as per requirements.
- To carry out a patient survey to obtain basic information regarding the use of P&O elements.
- To create a P&O model using various modeling tools.
- To adopt suitable parameters for the development of P&O elements for analysis purposes.
- To evaluate P&O elements utilizing a variety of computational software tools.
- To highlight and project polymers/composite as a material for the development of various P&O elements.
- To develop simplified lightweight P&O elements.
- To adopt suitable advanced manufacturing techniques for the development of tailor-made P&O elements.
- To conduct patient testing for the evaluation of the performance of the novel prosthetic foot.