CHAPTER 1

INTRODUCTION

The use of mechanical engineering principles and biological understanding to better recognize how these areas intersect and how they might be utilized together to potentially improve people's quality of life is known as biomechanical engineering.

1.1 PROSTHETICS AND ORTHOTICS (P&O)

The prosthetics field is a discipline of medicine or surgery that deals with the creation and application of artificial body parts. A prosthesis is an artificial device that substitutes a missing body part that may have been lost due to an accident, sickness, or a congenital ailment. (Behrend, Reizner, Marchessault, & Hammert, 2011)

The orthotics field (Lusardi, Jorge, & Nielsen, 2013) is a branch of healthcare technology concerned with the design, production, and use of orthopaedic equipment. The term “orthosis” refers to an exterior gadget used to alter the functional and anatomic characteristics of the muscular and skeletal systems.

A prosthesis or orthosis (Shurr, Michael, & Cook, 2002) enables a person with a handicap or functional impairment to stay active, productive, and independent, participate in society, and live a healthy and dignified life. When suited to the individual and their surroundings, a top-quality prosthetic or orthotic has a considerable influence on the person's degree of independence and minimizes the need for professional support services.

1.1.1 Prosthetics

The utilization of prosthetics to improve people’s functioning and livelihood who have lost a limb is referred to as prosthetics. Prosthetics are used to replace lost body parts and restore normal functionality. Prosthetic components that are commonly used include artificial limbs, hearing aids, arm slings, bone plates, dental implants, and so on. Amputation (Kirkup, 2007) is the surgical removal of all or part of a limb, organ, or other body component or process. Amputation (Michael & Bowker, 2004) may be essential for several reasons, the most common of which include vascular disease, cancer, infection, trauma, and congenital abnormalities.

Amputation (LeMoyne, Amputations and Prostheses, a Topic of Global Concern, 2016) rehabilitation varies depending on the cause of the amputation as mentioned below;

(a) Traumatic amputation

Traumatic amputations can be caused by war - that is, by landmines, explosions, or firearms - or by traffic, work, or domestic accidents.

(b) Diabetic amputation

One of the most serious possible complications of diabetes is its association with neurological and vascular disease, which in its most severe form can lead to amputation. Diabetes is one of the leading causes of lower limb amputations worldwide.

(c) Congenital amputation and deformities

Congenital amputation is a condition in which there are no fetal organs at birth. Congenital amputation can result from constriction of the fibrous bands in the membrane's interaction with compounds known for causing birth abnormalities, and hereditary factors. The design of the prosthetic is selected depending on the deformity. However, there is no kind of standard, the biomechanical principles for alignment and the basic principles related to the fit remain the same.

Artificial limbs are classified into four categories. Transtibial, transfemoral, transradial, and transhumeral prosthetics are examples of these. (Almohammadi, Alnashri, Harun, Alsamiri, & Alkhatieb, 2022) (Keagy, Schwartz, Kotb, Burnham, & Johnson Jr, 1986) Figure 1.1 and Figure 1.3 depicts the various levels of upper extremity and lower extremity amputation level respectively. A trans-radial prosthetic is a prosthetic limb that replaces a lost arm below the elbow (Figure 1.2. a). A transhumeral prosthetic is an artificial limb that replaces an arm that has been amputated above the elbow (Figure 1.2. d). A transtibial prosthetic is a prosthetic limb that replaces a lost leg below the knee (Figure 1.4. b) (Culham, Peat, & Newell, 1986). A transfemoral prosthetic is a prosthetic limb that replaces a lost leg above the knee (Figure 1.4. a). Table 1.1 and Table 1.2 shows the nomenclature of the prosthetic device upper and lower extremity respectively.

Table 1.1: Prosthetic device upper extremity

Device Type		**Amputation Level**	**Nomenclature**
Prosthetic	**Upper extremity**	Shoulder Disarticulation	SD
		Wrist Disarticulation	WD
		Trans-radial (Below Elbow)	TR
		Trans-humeral (Above Elbow)	TH
		Elbow Disarticulation	ED

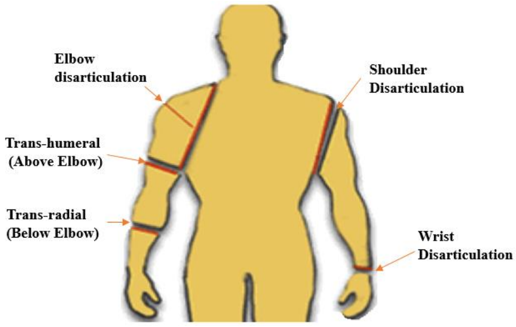


Figure1.1: Upper extremity amputation level (O&P Virtual library)



(a) Shoulder Disarticulation (b) Wrist Disarticulation (c) Trans-radial(Below Elbow)


(d) Trans-humeral (Above Elbow) (e) Elbow Disarticulation

Figure1.2: Prosthetic device upper extremity (O&P Virtual library)

Table1.2: Prosthetic device lower extremity

Device Type		***Amputation Level***	***Nomenclature***
Prosthetic	***Lower extremity***	Trans-femoral (Above Knee)	TF
		Trans-tibial (Below Knee)	TT
		Ankle Disarticulation	AD
		Knee Disarticulation	KD
		Hip Disarticulation	HD

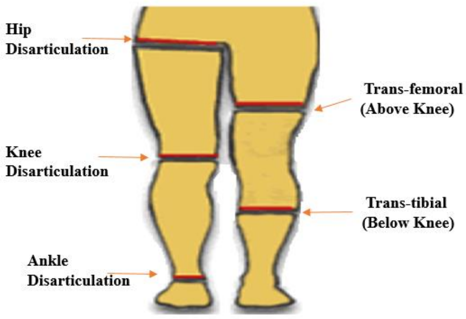
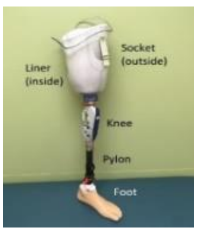
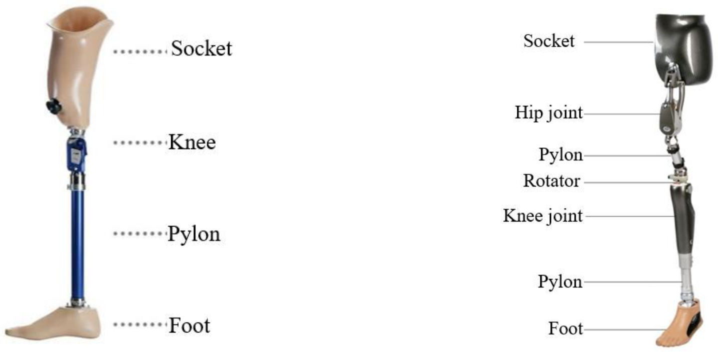


Figure1.3: Lower extremity amputation level (O&P Virtual library)



(a)Trans-femoral(Above Knee) (b) Trans-tibial(Below Knee) (c) Ankle Disarticulation



(d) Knee Disarticulation (e) Hip Disarticulation

Figure1.4: Prosthetic device lower extremity (O&P Virtual library)

In terms of function, prosthetic feet can be categorized into the following groups;

- Single-Axis Foot and Multi-Axis Foot (Perry, Boyd, Rao, & Mulroy, 1997)
- Solid Ankle Cushioned Heel (SACH) (Doane & Holt, 1983)
- Dynamic-Response Foot (Lehmann, Price, Boswell-Bessette, Dralle, & Questad, 1993)
- Elastic (flexible) Keel Foot (Torburn, Perry, Ayyappa, & Shanfield, 1990)
- Microprocessor Foot (Franks, Betts, & Duckworth, 1983)

To suit the functional demands of the person, the prosthetic must be a one-of-a-kind combination. These requirements are complicated and vary across the upper and lower limbs. Upper limb prosthetics (Cordella, et al., 2016) can help access and capture specific work tasks such as striking, drawing, lifting heavy objects, and daily tasks. Lower limb prosthetics (Laferrier & Gailey, 2010) can aid with standing, walking stability, and other sports activities. The essential components of the modular transfemoral prosthetic are shown in Figure 1.5.

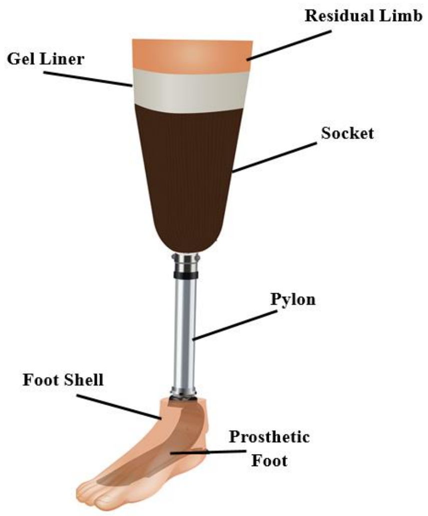


Figure 1.5: Arrangement of main elements of prosthetic (Stuart Mason Dambrot, May 2016)

The primary function of employing the main key elements of prosthetic devices is discussed shortly below.

Liner
-The liner is a flexible, cushioning material that serves as a protective cover. It decreases mobility and friction between the skin and the socket when worn over your residual limb.

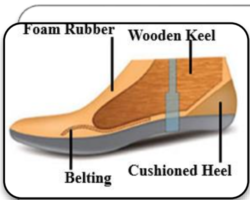
Socket
- The socket's aim is to offer structural stability to the prosthesis where it meets the residual limb. It may also have suspension features to keep the prosthesis in place.

Pylon
- To complement the residual capacity of lower limb amputees, prosthetic makers have created shock-absorbing pylons to reduce the transient stresses of foot-ground contact.

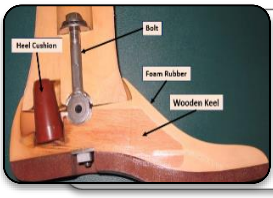
Prosthetic Foot
- Prosthetic foot with two or three axes of movement enable more ankle mobility, which helps balance the user when travelling on uneven ground.

Foot Shell
- A purely aesthetic covering for a prosthetic foot that allows for easy walking on uneven terrain.

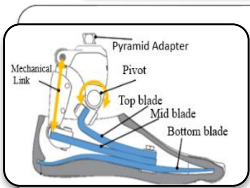
There are now several prosthetic foot components on the market for patients to utilize. The list below includes the most typical prosthetic feet worn by patients.



Non articulated foot
- The most basic type of non-articulated foot is the single axis foot. The name refers to a soft rubber heel wedge that simulates ankle motion by compressing under load during the early stages of walking's stance phase. The keel is hard, therefore there is no lateral movement but there is midstance stability. The SACH foot comes in a variety of heel heights.



Articulated foot
- They can have a restricted range of movement in either the sagittal or frontal planes to represent plantar and dorsiflexion actions as well as inversion and eversion. There are feet with varying degrees of movement amortisation.



Dynamic response foot
- Dynamic-response feet are a type of energy-storing prosthetic foot designed for active and moderately active prosthetic users who want to live a normal life. These shoes are made of innovative composite materials such as carbon graphite to give more dynamic movement and function.

❖ **Functional Level Assessment:**

K-level (Meier & Melton, 2014) (Figure 1.6 & Figure 1.7) is a scoring system used by medicare to indicate a person's potential for recovery. The system gives it a score from 0 to 4 and it indicates a person's potential for prosthetic use if they have a device that works well for them and they have completed rehabilitation to use the device properly.

K Level Descriptors;

Level 0

No portability at all. This patient was unable to move to another position, with or without assistance, despite the addition of a prosthetic. This category is also used as the base level for all other level comparisons.

Level 1

Very little mobility. This type of patient can move on their own with the help of a prosthetic leg. There should be a flat, straight path at a steady walking pace.

Level 2

Reduced mobility. This patient can move to another position with the assistance of a prosthetic, as well as adapt to small changes in the walking surface. Small changes in walking speed can also be done at this level.

Figure 1.6: K1 and K2 mobility level (Sions, et al., 2018)

Level 3

Moderate/normal mobility. At this level, the patient can move to other positions while adjusting to most variations of the walking surface while varying their walking speed.

Level 4

Great mobility. These patients are capable of performing all of the tasks previously mentioned in addition to the ability to apply pressure, high impact, and stress on the prosthetic.

Figure 1.7: K3 and K4 mobility level (Sions, et al., 2018)

The general consideration for all of them is that it helps improve a person's quality of life and increases their independence. Limb replacement prosthetics help people increase their movement and mobility. They may help someone walk or go for a nice run.

1.1.2 Orthotics

The creation and manufacturing of external orthotics as a measure of a patient's therapy requires accuracy and ingenuity. Common orthotic interventions include spinal jackets, neck, footwear, insoles, braces, splints, calipers, etc. (Patel & Gohil, 2022)

Orthotic is a man-made device meant to fulfil a patient's biomechanical (Hamill & Knutzen, 2006) demands the following fundamental reasons:

- Avoiding inefficient patient movement
- Aiding in injury healing and enabling regular movement and activity
- Reducing load force
- Assisting with reintegration

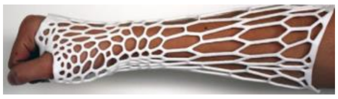
These devices (Table 1.3) are typically prescribed for brief periods or to treat minor clinical complaints. There are a variety of ready-to-use & tailor-made orthotic devices used for many musculoskeletal disorders (Buckle, 2005) as shown in Figure 1.8 & Figure 1.9. These are specialized equipment, and only a certified Prosthetist or Orthotist should be able to fix them.

Table 1.3: Upper and lower extremity orthotic

Device Type	Amputation Level		Nomenclature	Uses
Orthotic	***Upper extremity***	(a) Finger Orthotic	FO	To avoid losing range of motion
		(b) Hand Orthotic	HO	Correction of orthopaedic maladjustments using both mobile and immobile functionality
		(c) Wrist Hand Orthotic	WHO	To support weak muscles and/or immobilise or inhibit wrist motion
		(d)Elbow Orthotic	EO	Allowing movement within a safe range of motion
		(e) Elbow Wrist Hand Orthotic	EWHO	As a foundation for outrigger attachments to fabricate mobilisation orthotics that give a controlled stretch toward improved elbow extension or flexion.
		(f)Shoulder Orthotic	SO	Preventing or alleviating glenohumeral subluxation and hemiplegic shoulder pain
	Lower Extremity	(g) Foot Orthotic	FO	To provide foot support and enhance foot posture
		(h) Knee Orthotic	KO	To avoid knee flexion or extension instability
		(i) Ankle Foot Orthotic	AFO	Supporting weak limbs or repositioning a limb with tight muscles in a more natural posture

	(j) Knee Ankle Foot Orthotic	KAFO	To help the leg muscles and support the joints
	(k) Hip Knee Ankle Foot Orthotic	HKAFO	To enable hip and pelvic stability while standing and walking with assistive aids
Spinal	(l) Cervical Thoracic Lumbar Sacral Orthotic	CTLSO	To enhance healing and relieve the discomfort by stabilizing the head and neck as well as the spine following surgery or in the case of a spinal fracture.
	(m) Cervical Orthotic	CO	Resting and supporting the neck, allowing muscles to relax and any irritation to dissipate
	(n) Thoracic Lumbosacral Orthotic	TLSO	To slow the growth of scoliosis-related spine curves.
	(o)Lumbosacral Orthotic	LSO	To offer lumbar spine support


(a) Finger orthotic


(b) Hand Orthotic


(c) Wrist Hand Orthotic


(d) Elbow Orthotic


(e) Elbow Wrist Hand Orthotic


(f) Shoulder Orthotic


(g) Foot orthotic


(h) Knee Orthotic


(i) Ankle Foot Orthotic


(j) Knee Ankle Foot Orthotic


(k) Hip Knee Ankle Foot Orthotic

Figure 1.8: Orthotic device upper and lower extremity


(l) Cervical-thoracic-lumbosacral orthotic


(m) Cervical orthotic

(n) Thoracic lumbosacral orthotic

(o) Lumbosacral orthotic

Figure 1.9: Orthotic device -spinal

1.1.3 Materials used for P&O devices

Depending on the specific patient's demands and the type of device they receive, common materials such as thermoplastics, carbon fiber, and other 3D printed materials are utilized in prosthetics and orthotics. (Vanaei, Parizi, Salemizadehparizi, & Vanaei, 2021) (White, Weber, & White, 1972) (Lipskin, 1971)

The body consists of intimate parts that, if lost, cannot fully be replaced. Fortunately, researchers all across the universe are attempting to replace each component of the body to transform all of us becoming cyborgs. Figure 1.10 depicts some of the technologies that aid in the P&O of the human body. (Shahar, et al., 2019)

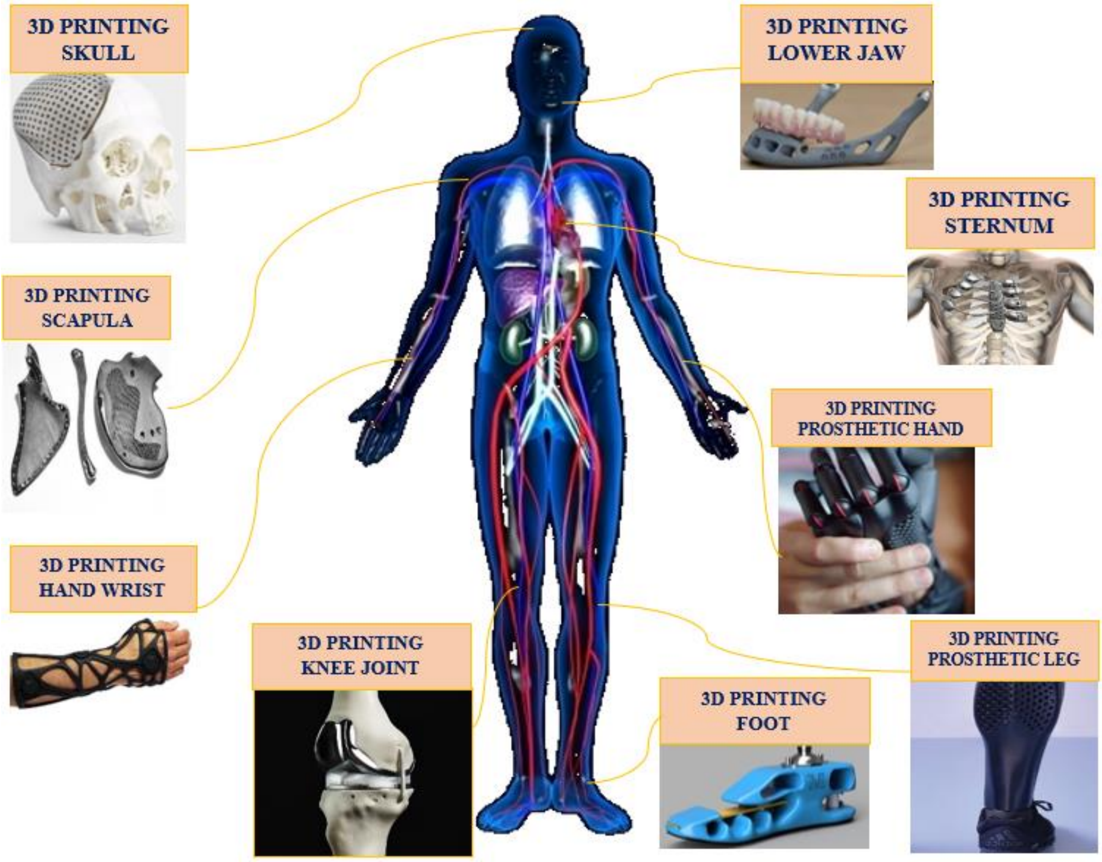


Figure 1.10: P&O assistive devices in the human body (Patel & Gohil, 2022)

As technology advances, equipment that replaces organs, prosthetic organs, and limbs are increasingly being used, allowing patients to live a more normal life. As shown in

Figure 1.11, biomaterial developments have enabled doctors and researchers to replace harmful body components with organic or synthetic materials such as metals, ceramics, and polymers. (Niinomi, 2002)

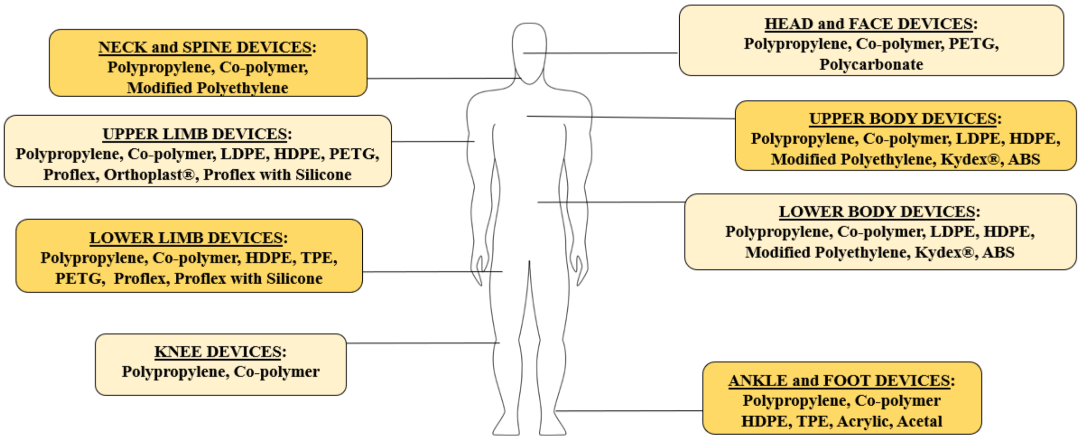


Figure 1.11: Body parts replacement materials (Song, et al., 2018)

These materials (Table 1.4) may be used to make the optimum device for the patients, with varied resistances, stiffness, and masses that are as close to the patient's level of exercise and the unit use as feasible. It provides you with several alternatives for creating a new device. (Hukins, Leahy, & Mathias, 1999)

Table 1.4: Biomedical application materials (Hench & Polak, 2002)

Sr No.	Materials	Applications
1	**Polyethylene (PE, UHMWPE)**	Prosthetic joints, acetabular liners, and knee inserts made of ceramic hard tissue composites, orthopaedic and dentistry bone cement, drain, and catheter tubing.
2	**Polylactide (PLA)**	Meniscus reconstruction; crack treatment; interfering screw; suture clamps.
3	**Acrylonitrile Butadiene Styrene (ABS)**	Wrist hand orthotics, AFO, and other custom orthotic devices.
4	**Polycaprolactone (PCL)**	Surgery; bone reconstruction; dentistry orthopedic implant.
5	**Polyether Ether Ketone (PEEK)**	Spinal surgery, screws, joint replacement, osteosynthesis plates and intramedullary nails.
6	**Polypropylene (PP)**	Hernia repair using non-biodegradable sutures.
7	**Poly Lactic-co-Glycolic Acid (PLGA)**	Connective tissue, interfering fasteners, bones and tissue replacement, artificial skin, and wound healing are all options.
8	**Polyurethanes (PU)**	Artificial heart bladders, bone tissue, control valves, vascular grafts.
9	**Poly Methyl Meth Acrylate (PMMA)**	Adhesive resin cement is used in tooth restoration, while bone adhesive is utilized in bone replacement.
10	**Polyethylene Terephthalate (PET)**	Non-biodegradable sutures, vascular grafts, implant fixation, hernia repair, and ligament reconstruction.

1.2 COMPOSITE MATERIALS

The composite material is described as a combination of two immiscible components with different structures (Figure 1.12), which can meet the diverse design and requirements with weight savings as compared to conventional materials. (Tsai & Hahn, 2018)

Composites are used to manufacture thousands of products that fall into three extensive groups: purchaser, industrialized, and innovative. Composites are considered a revolutionary underway in aerospace, automobile, medical, nuclear industries, sports, electronic, marine, military type recreational fields, etc. (Clyne & Hull, 2019)

Composite is one of the important materials in this era and it has been used for a long time. The significant demands made on engineers to improve performance and reliability at a reduced cost require the ability to understand the mechanical behaviour of the material and components under service conditions. (John, Dean, & Karyn, 1986)

As a result, composites are the outcome of attempts to address the need for high-performance engineering materials. The combination of different parts in a unique structure has made it possible to obtain new materials with better properties than individual parts. (Lubin, 2013)

"A composite material is a substance system made up of a mixture or combination of two or more macro components that differ in structure and chemical composition and are insoluble in each other." (Jones, 2018)

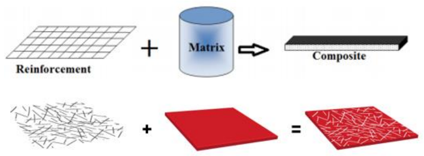


Figure 1.12: Constituents of composite material

1.2.1 *Classification of composite material*

The microstructure of the component provides a convenient basis for classifying them for purpose of the study, processing, and analysis. There are two basic methods to combine these materials. (i) By inserting one material into the other (ii) By bonding them layer by layer. The phase composition is generally at the macroscopic level and the layered composition is at the macroscopic level. (Altenbach, Altenbach, & Kissing, 2004)

Depending upon the purpose for which the insert is added, the composites made by phase composition can be divided into the following types;

- Filled composites: If the insert is added primarily to reduce the cost or to alter a physical property other than the mechanical properties, it is called a filled composite. The insert, in this case, is called a filler.
- Reinforced Composites: If the insert is added primarily to improve the mechanical properties, it is called reinforcement and the composites are called reinforced composites.

The matrix phase of the composites serves the following purposes;

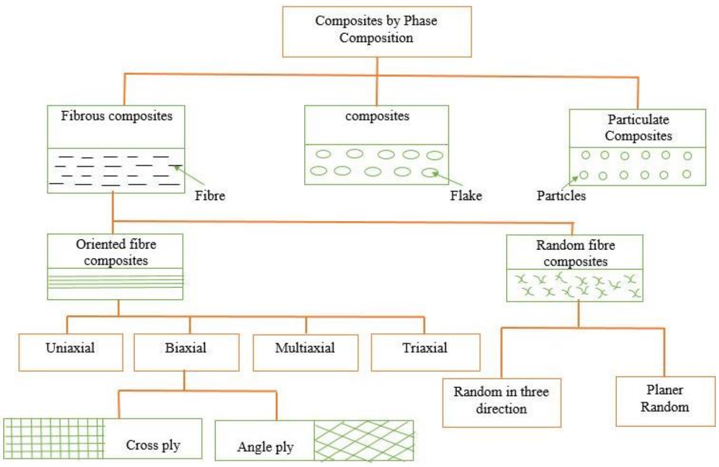
- The matrix phase provides a medium for binding reinforcements and holding them in solid form.
- Protects reinforcements from environmental degradation.
- This helps transfer loads from one insert (fiber, flake, or particle) to another nearby insert.
- It provides the texture, color, durability, finish, and other functional characteristics required for the final product.

The material of engineering can be broadly classified into three families namely: polymers, metals, and ceramics. It is possible to insert the second phase into these three families of materials and make composites.

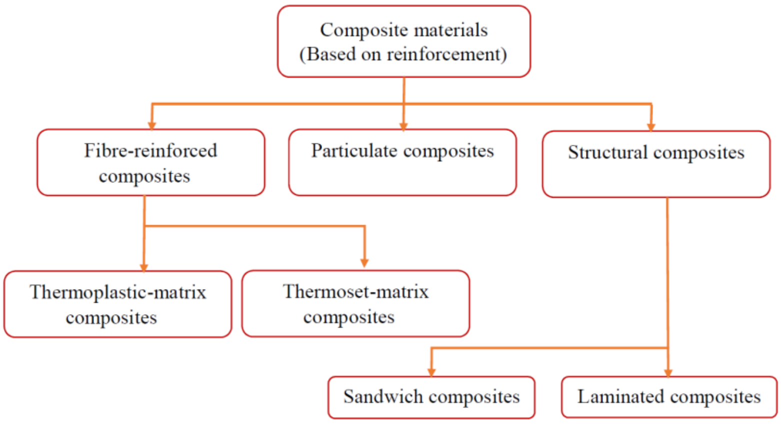
Depending upon the family of material used, the matrix system composites are classified into;

a) Polymer Matrix Composites (P.M.C)
b) Metal Matrix Composites (M.M.C)
c) Ceramic Matrix Composites (C.M.C)

A schematic representation of the classification of composites based on phase composition, reinforcement, and matrix is shown in Figure 1.13.



(a)



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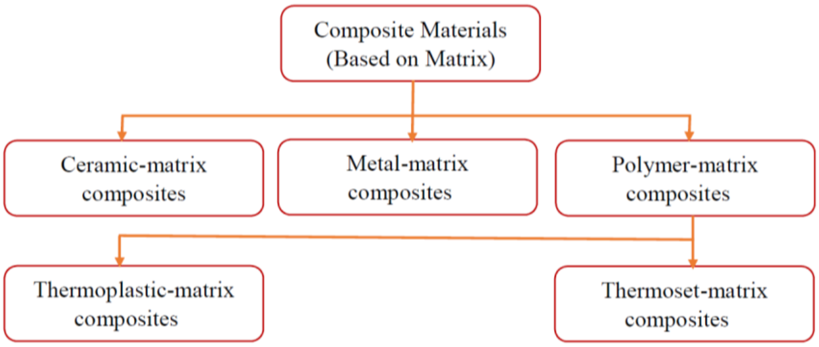


(c)

Figure 1.13: Composite classification (a) Based on phase composition
(b) Based on reinforcement (c) Based on matrix

1.2.2 Overview of advantages and limitations of composite material

❖ ***Advantages of composite material***

The following are some of the advantages of composites that are superior to those of conventional materials. (Daniel, Ishai, Daniel, & Daniel, 2006) (Kaw, 2005)

- *Light weight*

One of the primary points of interest in utilizing a composite material is weight decrease so it is utilized in the diverse structure.

- *Design flexibility*

Composites can be meant to give qualities for explicit design circumstances. Results of complex shapes can be effectively formed with no material wastage. This gives designers the ability to come up with virtually any shape or structure.

- *High strength*

High, directional quality makes structures and properties conceivable that can't be accomplished with ordinary materials. Plan of composites to be future stronger than aluminum or steel.

- *Corrosion resistance*

Composite by and large can be made erosion safe and climate-safe. Therefore, they are strong and they require less system for upkeep.

- *Dimensional stability*

When wet or dry, hot or cold, synthetic materials keep their shape and size. Directional characteristics may be obtained via real fiber bearing.

- *Low thermal conductivity*

Composites are incredible separators and they don't decidedly lead to warmth or cold in a composite.

- *Thermal expansion*

Fiber composites' increment should not be as much as metals'. Controlled extensions up to zero development permit high-exactness utilization in optical estimation, machine segments, or space industry applications.

- *Non-conductive*

Composites are not conductors of electricity due to their enormous size. This property makes them vulnerable to things like electric sinks and circuit boards in appliances. In the case of attractive conductivity, it is possible to make some composites conductive.

- *Non-magnetic*

They can be used around sophisticated electronics. Because of the beautiful lack of resistance, the large magnets used in MRI (magnetic resonance imaging) equipment work better.

- *Durable*

Composite structures have a long life, thus, they require less support. Numerous composites have been in service for a large portion of a period.

- *Radar transparent*

Straight composites are ignored by radar signals, which makes composites perfect for usage any place radar hardware runs, whether on the ground or not.

- *Part consolidation*

A single composite material part can replace a whole civilization of metal parts. Reducing the number of pieces in a machine or building saves time and avoids the need for maintenance during the equipment's life. Furthermore, the pieces may be modified, providing a great level of versatility.

- ***Disadvantages of composite material*** (Jones, 2018) (Barbero, 2010)

- *Delamination*

Composites can “split” between layers where they are more sensitive since they are frequently made up of multiple treatment layers in a covering structure.

- *High cost*

Because these are relatively new materials, they are costly.

- *Complex fabrication*

The manufacturing process is frequently time-consuming and complex, which raises the cost.

- *Damage inspection*

Delamination and fractures in composites are mostly internal, necessitating the use of complicated test equipment to detect them. Fix presents new troubles, for the accompanying causes;

- Materials require cold stockpiling ship and have restricted timeframes of realistic usability.
- Hot relieving is important for some conditions that require extraordinary gear.

- *Composite to metal joining*

Metals expand and contract more than composites owing to temperature changes. Composites are stiffer than wrought metals and subsequently are all the more effortlessly broken.

1.2.3 Current status and future prospects

The innovation of composite materials (Nicolais, Meo, & Milella, 2011) has encountered fast advancement over the most recent forty years. A portion of the hidden reasons and inspirations for this advancement are;

- Significant progress in materials science and innovation in the zone of fibers, polymers, and ceramics. (Dobrzański, 2006)
- Requirements for smart material for the future of the rehabilitation industry. (Hassani, et al., 2020)
- Development of amazing and advanced mathematical techniques for basic investigation utilizing modern computer technology.
- Characterization techniques for the damage in composite material enable researchers to devise selection criteria to select the most appropriate technique. (Ahmed, Wang, Tran, & Ismadi, 2021)

- 3-D printing composite materials for P&O elements. (Nugroho, Dong, & Pramanik, 2021)
- Additive manufacturing has enormous promise for a wider application. (Hajare & Gajbhiye, 2022)
- Polymer composite development as a relevant bio material for hard tissue purposes. (Mehta, Saini, Singh, Singh, & Buddhi, 2022)

The primary guiding principle in the development process, as articulated by the aerospace industry (Zweben, 1981), initially emphasized performance through weight reduction. Subsequently, the emphasis shifted towards cost efficiency with the integration of increasingly common materials. Despite these two imperatives, there is now a fundamental need for quality assurance, reproducibility, and consistency of control throughout the structure's lifetime.

New degrees of progress proceed in all zones. For instance, new kinds of carbon strands have been given higher gauges and absurd strain. Thermoplastic grids are utilized under express conditions since they are exceptional, have a low affectability to moisture impacts, and are significantly more feasibly satisfying to tremendous scope amassing and fixing. Woven surfaces and short-fiber fortresses related to fluid trim strategies are widely utilized. The course of action of structures and frameworks fit for working in certified conditions has pushed brought examine up in high-temperature composites, including high-temperature polymer lattice, metal-network, clay grids, and carbon/carbon composites. Another zone of intrigue is that of the suggested smart composites and structures joining dynamic and inert sensors. Another area of interest is the application of nanocomposites and multiscale cross-breed composites with multifunctional properties. (Chamis, 1984)

The utilization of customary and new composite materials is related to the improvement of assembling procedures. The collecting system is one of the hugest stages in controlling the properties and ensuring the idea of the finished thing. A ton of activity is given to the sharp arrangement of composites zeroed in on the headway of broad and financially sensible techniques for the assembling of moderate, pragmatic, and strong composites. This combines the development and application of cutting-edge equipment, programming, and electronic recognition and controls.

The advancement of composite materials, though still ongoing, has reached a period of significant advancement. Opportunities for what's to come are splendid for a variety of reasons. Firstly, the cost of key constituents is decreasing due to market advancements. Secondly, manufacturing processes are becoming more cost-effective as experience is gained, techniques are refined, and innovative methods are introduced. More cutting-edge high-volume applications, for instance, in the vehicle business and system, are developing the use of composites phenomenally. The necessity for imperativeness conservation spikes more livelihoods of lightweight materials and things. The prerequisite for multi-convenience is showing new troubles and open entryways for the headway of new material structures, for instance, nanocomposites with updated mechanical, electrical, and warm properties. The availability of various extraordinary instinctive computer programs and recreation strategies makes an auxiliary plan and examination clearer and logically reasonable for engineers. Additionally, the development is eagerly updated by a more energetic time of engineers and scientists practiced and arranged in the field of composite materials.

1.3 ADDITIVE MANUFACTURING -EVOLUTION

Apart from some initial work in the early 1990s, there hasn't been much standardization effort in Germany because Additive Manufacturing (AM) (Wong & Hernandez, 2012) is a relatively new technology. (Wohlers & Gornet, 2014) Under the direction of the German Society of Mechanical Engineers, Virtual Desktop Infrastructure (VDI), a specific recommendation on fast prototyping / VDI3404 / was issued in 2007.

In 2009, the American Society of Mechanical Engineers began building its standardization system in collaboration with the American Society for Testing and Materials. (Antoniac, 2016)

Standard terminology for Additive Manufacturing Technologies was published by the committee F42 on Additive Manufacturing in the fall of 2009. Among other definitions, the name "Additive Manufacturing" was defined by this committee. A layer-based automated manufacturing technique known as "Additive Manufacturing" (AM) uses 3D CAD data to produce scaled 3D objects without the need for part-dependent tools.

Finally, Figure 1.14 is a graphical representation of the workshop participants' vision for AM Explore. There are various AM forms on the base. The storage compartment talks about the innovative work efforts that result from these advances.

The branch is an agent test of the results and benefits of these efforts and is reflected in the research needs and initiation of this archive. It is normal for new uses and benefits to evolve over time and for different uses to diverge into notable subcategories such as the medical and artistic disciplines.

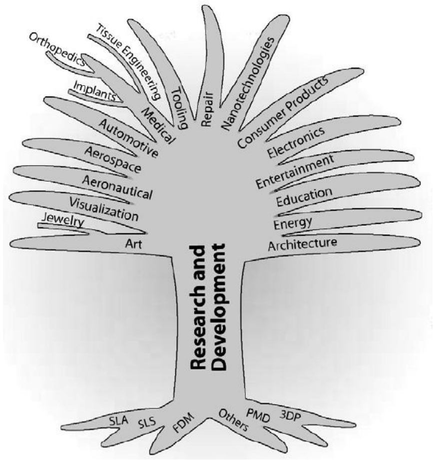


Figure 1.14: Schematic visualization of the AM domain and research efforts and opportunities (Ghomi, Khosravi, Neisiany, Singh, & Ramakrishna, 2021)

1.3.1 Additive Manufacturing process

AM's approach to craftsmanship is flexible, adaptable, distinctively adjustable, and deeply relevant to most elements of modern creation. (Prakash, Nancharaih, & Rao, 2018) AM's core focus remains on customizing low-volume, high-value items for rapid production. An automated manufacturing technique called AM uses layers to produce scaled 3D things directly from 3D CAD data without the need for tools that depend on specific parts. (Mellor, Hao, & Zhang, 2014) (Piyush Patel, Piyush Gohil, 2021)

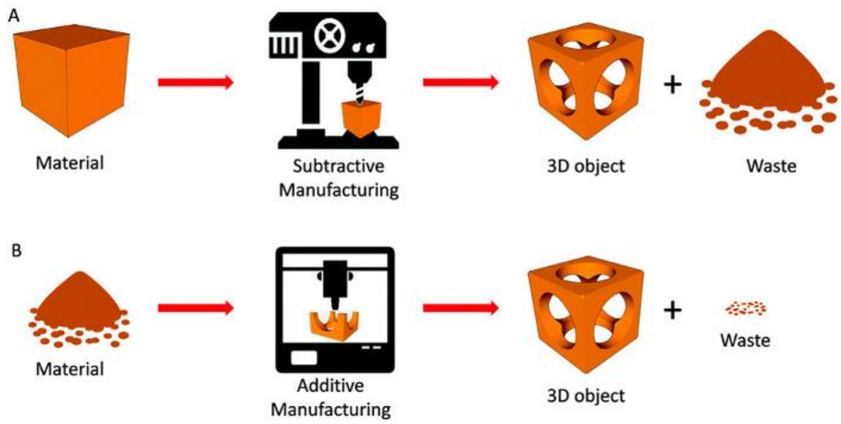
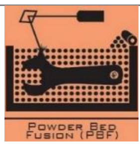
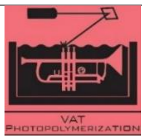
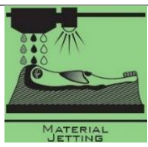
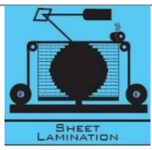


Figure 1.15: Subtractive vs Additive Manufacturing (Chen Cheng & Wang , 2020)

This suggests that CNC machining begins with a square of material (Figure 1.15) and eliminates material to create the completed product. CNC machining incorporates exceptional dimensional precision as well as a wide range of fine materials, including wood, metal, and plastic.

In any case, today added substance fabricating is the most well-known term in industry markets while 3D printing is progressively utilized in the purchaser advertise. (Srivatsan & Sudarshan, 2015) Seven groups of Additive Manufacturing as indicated by ASTM F2792 standards are recorded below in Table 1.5.

Table1.5: Various Additive Manufacturing Process (DelVecchio, 2021)

AM Process	**Schematic diagram**	**Strengths**	**Typical materials**
Powder Bed Fusion		• Significant complication; • The powder acts as a support material; • A diverse variety of materials.	Sand, plastics, metals, ceramic powders
Vat Photo polymerization		• Extreme precision and intricacy; • Smooth surface finish; • Large construction area.	Photopolymer resins with UV curability
Binder Jetting		• Full-color printing is possible; • There is high output; • A variety of materials are used.	Sand, metal, ceramic, glass, and powdered plastic
Material Jetting		• A high degree of precision; • Full-color components are possible; • Multiple materials are possible in a single part.	Wax, polymers, and photopolymers
Sheet Lamination		• Rapid volumetric growth rates; • Allows for combinations of metal foils, including embedding components; • Relatively inexpensive (non-metals).	Paper, plastic, and metallic foils and tapes
Material Extrusion		• Multiple colors are possible; • It is inexpensive and practical; • It can be used in an office context; • The parts are structurally sound.	Thermoplastic slurries, liquids, and pellets; filaments; and pellets
Directed Energy Deposition		• Highest single-point deposition rates; • No direction or axis restrictions; • Effective for repairing and adding features; • The use of numerous substances in a single component.	Metal wire and powder in conjunction with ceramics

1.3.2 Research opportunities in AM

Table 1.6 summarize the challenges and opportunities by considering the different level sector in the Additive Manufacturing domain. (Gupta, Weber, & Newsome, 2012)

Table 1.6: The challenges and research needs in Additive Manufacturing (Guo & Leu, 2013) (Seepersad, 2014)

Levels	Challenges	Research Needs
Material-level	• Variation in properties due to recycling of material • Material cross-contamination • Heterogeneity of particle sizes	• Safety guidelines for handling powders and reducing fire and inhalation dangers • Precise control over particle size, mixes, and composition
Part-level	• Optical measuring techniques create a large quantity of point cloud data; new algorithms are required to synthesize this data • Polishing and post-process machining of free-from geometries is done manually and is costly • Coordinate measuring instruments struggle to measure freeform surface geometries	• Post-process finishing to enhance the surface and geometric integrity of free-form surfaces and facilitate the removal of supports • Standardization of test processes; geometric dimensioning and tolerancing (GD&T); and metrology of AM components • Design rules and support structure optimization
Process-level	• Need to track multiple process variables • Repeatability is ensured by careful calibration of process machine components • Thermal physics is complicated, and modeling is confined to component deformation	• Adoption of best practices, such as post-process cleaning, as standards • Effective and accurate modeling and simulations to foresee future issues • In-process monitoring, sensing, and control to guarantee that components are manufactured according to specification • Process improvement to boost production volume and speed
Enterprise-level	• Several systems are linked to the cloud or OEM servers • AM suppliers, design bureaus, and facilities are dispersed throughout several areas. The types and capacities of systems differ amongst facilities • Traditional production technicians are inexperienced with powder handling	• New ways to hands-on teaching and training to teach the concepts of AM processes to the next generation of users • Logistics and supply chain implications of AM • Cyber security to guard against digital thread infiltration in AM and preservation of design intellectual property • Safety & human-factors implications of AM

The scientific and technological issues related to the development, materials, and metrology of AM products will influence market acceptance and economic opportunities. (Chen, He, Yang, Niu, & Ren, 2017)

1.4 ORGANIZATION OF THESIS

The framework for the thesis is described as follows:

- **Chapter 1** provides general information about Prosthetics and Orthotics (P&O) elements, composite material, and the Additive Manufacturing process.
- **Chapter 2** discusses the literature survey carried out for the present work with pros and cons and patents related to prosthetics and orthotics devices.
- **Chapter 3** includes research motivation, problem definition, the need for study, and research objective.
- **Chapter 4** provides general information about human body anthropometry.
- **Chapter 5** covers the design and simulation approach of prosthetic foot models of different versions.
- **Chapter 6** points out the manufacturing and testing process of the prosthetic foot.
- **Chapter 7** includes the design and simulation approach of orthotic elements.
- **Chapter 8** covers the result and discussion of prosthetic and orthotic elements.
- **Chapter 9** summarizes the conclusion drawn from current research and future scope in the P&O field.