EMERGING TRENDS IN TECHNOLOGY AND INNOVATIONS IN LOWER LIMB PROSTHETIC DEVICES

by

Nixon Oduor Opondo

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THE PURDUE UNIVERSITY GRADUATE SCHOOL
STATEMENT OF COMMITTEE APPROVAL

Dr. Linda L. Naimi, Chair
Department of Technology Leadership and Innovation

Dr. Rajeswan Sundararajan
Department of Electrical Engineering

Dr. Paul A. Asunda
Department of Technology Leadership and Innovation

Dr. Jon R. Padfield
Department of Technology Leadership and Innovation

Approved by:
Dr. Kathryne Newton

To My late father Robert Oduol Opondo and late mother Dorcas Atieno. To my wonderful wife Dorothy and my children (John, Calvin, Conrad, Dorcas, and Sylvia) and all family members for their love and support.

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“*The development of scientific principles to guide designs and evaluations is probably one of our field's greatest needs. We need to develop a healthy balance between theoretical and the more empirical approaches that have previously characterized most of the activity. Engineers need to develop the necessary knowledge to evaluate prostheses and all assistive devices”* Dudley S. Childress, PhD

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ABSTRACT

This study explored the history, present status, and future trends in assistive technologies and innovations in lower limb prostheses. The number of individuals with lower limb disability continues to rise at an alarming rate, but their mobility needs have fallen short of being fully addressed or resolved with the current level of advancement in technology despite new products being introduced into the market. One of the goals of the World Health Organization's 2030 Agenda for Sustainable Development is that people everywhere will be able to access affordable, quality health services and obtain assistive devices and products to improve their quality of life. This qualitative study used an historical approach to understand the evolution of assistive technologies and ascertain the current status of prostheses. Applying a qualitative trend analysis, I set out to examine research and development and technology innovations that may usher in a new era of assistive technologies and prostheses.

This study explored how emerging trends in assistive technologies might address future needs associated with innovations in lower limb assistive products. This study also analyzed trends in patent filing and engaged various peer reviewed journals and articles to determine if there were any new trends in technology in lower limb prosthesis. The finding of the study revealed that most capabilities and improvements in lower limb prosthesis resulted from increased integration across various technology enablers such as bionic, myoelectric sensors, Artificial Intelligence (AI), data analytic tools, IoT and 4th industrial revolution tools.

The study concluded that advancement in lower limb prosthesis would depend broadly on key technology development in advanced manufacturing (3D/4D printing), advanced materials, and advancement in robotics. Three main overarching challenges in lower limb prosthesis advancement include scarcity and high shortage of trained and qualified technicians capable of repairing advanced prosthetic devices, high product cost, and service accessibility. This study concluded that individuals with lower limb loss or impairment should be put at the center of technology and innovation to account for and fully address their physiological and psychological needs before products are released into the market.

Key words: Assistive technology, older adults, amputees, lower limb, healthcare, robotics, technology, 3D printing, 4D printing, advance materials, prosthesis devices, medical, rehabilitation, quality of life, overall satisfaction level, disability, design engineering, manufacturing, cost, regulations, FDA, quality.

CHAPTER 1. INTRODUCTION

1.1 Introduction

One of the most significant discussions in legal and moral philosophy has revolved around diversity and inclusion of persons with disability and how to help them become more independent in performing day to day tasks. According to 29 U.S. Code Chapter 31 § 3001, which is referred to as the Assistive Technology for Individuals with Disabilities Act, technology has become an increasingly important part of American life, influencing how we learn, how we conduct business, how we communicate, and even how we find fun and pursue entertainment. The Assistive Technology Act for Individuals with Disabilities (see https://www.uscode.house.gov; *29 U.S. Code Chapter 13 § 3001*) has encouraged new research and development into assistive technologies and prostheses. And this has enabled adults and children with disabilities and impairments to enjoy a better quality of life than was previously possible (https://www.parentcenterhub.org/ata/). The need for assistive technology devices (AT Devices) varies from one person to another, requiring customization of prostheses to meet their individual needs. Assistive prosthetic devices are needed when there is a change in someone's ability to stand or walk or to conduct daily life activities. Such individuals usually require physical therapy or occupational therapy to teach them how to perform daily tasks with the aid of assistive technologies and prostheses (Samuelsson & Wressle, 2009). We need to be mindful of the many challenges that continue to confront disabled people (Salazar, 2020).

Although we understand that impairment can significantly limit the functionality of individuals with lower limb disability and limb loss, it also interferes with the simplest daily activities. It takes more time, more strength, more concentration, and certainly more effort for an individual who has lost a limb to do what others who are not impaired can do in a fraction of the time. As a result, there is a continuing need to address issues that affect the quality of life for those who are disabled and certainly, those who have suffered limb loss. To work toward these goals will require technology advances and medical innovations, policy changes, industry level intervention, and collaboration among advocacy groups etc. According to the Amputee Coalition of America, nearly 185,000 US citizens undergo leg or foot amputations each year. Records suggest that more than two million Americans are amputees. (Ziegler-Graham et al., 2008, 89 (3): p. 422; Owings & Kozak, 1996). These numbers are alarmingly high, as a result, the industry may need to develop or revise existing standards and take a more holistic approach in the design and manufacturing of assistive technologies to cope with the demand.

As concluded by a recent study, people who have undergone lower limb amputations are dissatisfied with assistive devices with which they have been fitted. Many of their complaints are due to inadequate rehabilitation services, inability to afford prosthetic devices that would grant them greater mobility, and lack of access to prosthetic devices, such as those designed for athletes and others in sports) that would provide greater ease of movement (Poonsiri et al, 2020). For example, a below-knee amputation costs Medicare an average of $81,051 per person (Limb Loss Task Force/Amputee Coalition of America, 2019). Unfortunately, the number of amputations will more than double in the next thirty years. (Ziegler-Graham et al., 2008). In thirty years, the costs of professional nursing care at home for an individual who is missing a limb will be around $100,000 per year (Limb Loss Task Force/Amputee Coalition of America, 2019), which far exceeds the average income for someone on disability pay. Cost and affordability can therefore become a major factor or hinderance to accessing specialized assistive technology devices.

In response to these challenges and identified needs, this study sought to explore the path that assistive technologies have taken over the years to envision technology-enhanced prosthetics on the horizon. This research explored how robotics, material science including advanced manufacturing practices such as 3D and 4D printing can play a role in the advancement of prosthetic devices to benefit individuals with limb impairment. The first sections of the study introduced three main items which determined the scope and focus of the research study. The items included a narrative of what assistive technology devices are, whom they are made for (lower limb impairment) and the technologies involved in the production of prosthetic devices. In this case, the initial approach focused on 3D/4D printing, advanced materials, and robotics.

Personalization of assistive technology devices can be critical for individuals with lower limb loss or impairment due to varying needs of individuals impacted. As a result, design requirements should be put into consideration when customizing assistive technology devices to meet specific needs of amputees. In the past, designing and fabricating prosthetic devices used to be a daunting and challenging task due to limitations of using two-dimension (2D) manufacturing processes. However, the evolution of new technologies, such as additive manufacturing and 3D/4D printing has made it possible to manufacture complex parts quickly and efficiently (Nycz et al., 2019). 3D printing refers to certain machines that can create 3D parts or prototypes from a digital file by layering very thin 2D materials one upon another (https://www.research.va.gov/). The resulting image can then be manufactured to produce a highly customized prosthetic (Gross, 2019).

Despite many benefits of 3D printing, there are certain drawbacks and limitations. For example, additive manufactured parts not stiff and inflexible, with very little movement. In some instances, designers and manufacturers of assistive technologies have been able to install hinges for a little more freedom of movement. These hinges are often called living hinges. Where greater movement is required, ball and socket intervertebral prostheses (integrated artificial discs for joint repair), and encapsulated bearings have been incorporated (Pei, 2014). These limitations have birthed the evolution of 4D printing and advanced materials which is addressed in this study.

The emergence of new technologies especially those associated with the 4th industrial revolution has dramatically changed how we live, work, study, and communicate. Sometimes referred to as the Bionic Age or Digital Age, the 4th industrial revolution, has introduced new methods and applications of smart manufacturing, aligned with advances in technology and medical research, to create assistive devices to replace damaged or missing parts of the human anatomy (The World Economic Forum, 2022. https://intelligence.weforum.org/topics/a1Gb0000001RIhBEAW). Smart manufacturing includes 3D and 4D printing and the incorporation of new digital technologies. The main difference between 3D and 4D printing is that 3D printing produces parts that are stiff and inflexible, while 4D printing produces parts that have more flexibility and movement to them and can be produced with greater precision, thus conforming to a person's body in order to create a better fit. The World Economic Forum, 2022. https://intelligence.weforum.org/topics/a1Gb0000001RIhBEAW). Both 3D and 4D printing can be used for manufacturing prosthetic devices for lower limb amputees producing significantly superior prosthetics for those who can access or apply these technologies.

In summary, 4D printing appears to offer more options for designing, shaping, and customizing prostheses and assistive technologies for the user than 3D printing can do (Deshmukh in Sadaisivuni et al., 2020). For example, 4D printing can use shape-memory polymers to produce products with higher performance capabilities (Pei, 2014). In addition to 3D and 4D printing, advanced materials, robotics, and smart manufacturing, this study also examined digital tools as one of the emerging technologies in developing and enhancing the capabilities of prosthetics devices for individuals with limb impairment. This study explored how technologies are being integrated to impact future production of prosthetic devices. Notably, the application of digital tools in 3D and 4D printing will enhance the design and manufacturing processes and lead to the production of higher quality, more versatile assistive technologies in the future. Some of the 4th industrial revolutionary digital tools reviewed in this research included artificial intelligence, robotics, virtual reality, the internet of things, augmented reality, and data analytic tools (https://www.linknovate.com). Digital tools tend to intervene and influence several processes such as the design process, manufacturing, testing, and the final product to individuals with lower limb impairment.

Let's look at one example to amplify the relationship of digital technology and the design requirement process. The United States Department of Veteran Affairs recently invented a socket-fit-sensor to identify pressure points in lower limb prostheses. The device was capable of recording pressure data that made it possible to capture information concerning the type of movement of the patient (sitting, standing, swaying, and the like) while also allowing for extrapolation of usage information and gait information (*Prosthetic Socket Sensor Assesses Fit for Increased Com*, 2019). Here, the extrapolation of digital signals/data was seen to influence the design requirements of assistive devices such as prosthetic feet applicable to individuals with lower limb impairment. Most importantly for this study, the combination of advanced manufacturing printing process with digital threads are a part of the new emerging technological thread which ultimately is assumed to be significant in influencing how assistive technology devices are produced and manufactured for individuals with lower limb loss and impairment.

The ability to harness new and emerging technologies and manufacturing breakthroughs will enable us to produce prostheses and assistive technologies that will dramatically improve the mobility and quality of life of individuals with life-altering disabilities. As a case in point, the number of robotic prosthetic devices we currently produce will be inadequate to meet the projected 1.5 billion assistive technologies and prosthetic devices needed by the year 2050 (https://www.linknovate.com).

1.2 Statement of the Problem

Many disabled individuals, especially those who have suffered limb loss, look to assistive technologies and prostheses to help them get back some control over their lives, even doing simple things such as reaching for a plate, climbing stairs, or walking from one room to another. Many become frustrated in being unable to do the things they used to do. A sense of hopelessness or abandonment can overwhelm them. Some become frustrated due to limited access to or inability to pay for the kinds of assistive technologies or prostheses they most need. Limited use of prescribed assistive devices can be costly, physiologically, and psychologically tormenting leading to other secondary issues and to some degree hopelessness or limited access. As a result, there is a critical need to assess trends in technology and innovation of assistive prosthetics devices to address unmet needs of individuals with lower limb impairment.

Predominantly, assistive technologies for individuals with lower limb loss or impairment are developed in isolation and with varying standards impacting the rate of satisfaction of assistive devices in certain cases. Whereas meeting the needs of individuals with lower limb loss or impairment is often complex and challenging, the advancements in technology, especially 3D, 4D printing, and advanced material production, could help meet the growing need for assistive technologies and prostheses (Thatte et al., 2019).

1.3 Significance of the Problem

According to the Center for Disease Control, nearly one in every two thousand children born in the USA will be born with a limb defect (CDC, 2019b). The instances of heart disease, stroke, diabetes, cancer, etc. is nearly three times higher for individuals with disabilities than for the average person without a disability (CDC Vital Signs, May 2014). Currently there is no comprehensive industry-wide approach to manufacturing new assistive technology devices that will address existing gaps and the build-up process of certain devices which are notably tedious and done in an iterative process (Gross, 2019).

This brief background discussion indicates existing gaps in the quality, access, and affordability of prosthetic devices, which impacts millions of people around the world, suggested that just under five million people in the US alone have experienced lower limb loss and another one and a half million Americans may experience lower limb loss or amputations in the next twenty or thirty years (NSF Award#1526519, 2015-2017; https://www.nsf.gov/awardsearch/showAward?AWD_ID=1526519).

This study examined the need for changes in policies and manufacturing practices which have largely set aside development and advances in lower limb prosthetics to pursue more lucrative avenues of innovation. Studies by (Balk et al., 2018) identified that abandonment of lower limb prosthetic assistive devices has been due to equipment limitations and pain induced from device variations. Additionally, materials that are developed for healing wounds have certain limitations and do not correct the underlying issues when treating amputees; rather they only aim to treat secondary problems such as heat, sweat, pitoning, and potential of microbial growth (https://www.nsf.gov/awardsearch/showAward? AWD_ID=1838509). This emphasizes the need for more studies on material science in this field besides those already identified.

1.4 Statement of the Purpose

The purpose of this research was to comprehensively explore the history, status, and any foreseeable emerging trends and technology innovations pertaining to lower limb prosthetic devices. According to (Balk et al., 2018), we need more research in this area to meet the rising need for prosthetic devices and to ensure the best matching of protheses to patient needs that is possible.

Advances in technology and medical innovations are one of the critical areas for new research and development. It will take several years before we have a better understanding of how we can best utilize this new-found knowledge and capabilities.
(Sadaisivuni et al., 2020). Therefore, this study explored past, present and future technological advancements pertaining to assistive technology devices. Broadly, this study set forth to contribute the body of existing knowledge by looking at the interplay of various technological trends especially those of 3D and 4D printing, smart manufacturing, and robotics assistive technologies for individuals with lower limb loss or impairment.

1.5 Research Questions

This research sought to better understand the interplay of technology and innovation as they applied to assistive technologies and prosthetic devices. The questions guiding this research were:

RQ1: What are the major concerns and issues with lower limb prosthetic devices?

RQ2. What are the new and emerging trends in technology and innovation of lower limb prosthetic devices?

RQ3: To what extent will the new advances in prosthetic technology address the growing issues and needs associated with lower limb prosthetic devices?

1.6 Definitions

Advanced Prosthesis Devices (APD)- A term I coined to reference assistive technology devices engineered from 3D/4D printing methods or robotics.

Assistive technology device – "any item, piece of equipment, or product system, whether acquired commercially, modified, or customized, that is used to increase, maintain, or improve functional capabilities of individuals with disabilities" (https://www.uscode.house.gov)

Assistive technology service – "any service that directly assists an individual with a disability in the selection, acquisition, or use of an assistive technology device" (https://www.uscode.house.gov)

Disability – a person "who (1) has a physical or mental impairment that substantially limits one or more of life's major activities, (2) has a record of such an impairment, or (3) is regarded as having such an impairment." (https://webapps.dol.gov/dolfaq/go-dol-faq.asp?faqid=67)

Internet of Things (IoT) - Any "device connected to the Internet, such as a smartphone or sensor and can be combined with automated systems to scale up capability" (https://www.wipo.it)

Myoelectric control – "Advanced sensors that detect bioelectric signals from skeletal muscles or the skin surface and relate the intended movement to the artificial limb capability" (https://www.wipo.it)

Robotics – "Multifunctional Modular Integration of sensing/actuation, mechanism, and control" (https://www.robotics.usc.edu)

Smart materials – "Stimulus-responsive materials that change their shape or functional properties under certain stimuli such as temperature, solvent, pH, electricity, light, etc." (https://www.ncbi.nlm.nih.gov)

3D Printing – Also known as additive manufacturing; "a class of machines that use a digital file to create parts by stacking thin 2D layers of material to make 3D parts" (https://www.research.va.gov)

4D printing – "A fourth dimension to 3D printing that permits preprogramming of objects with respect to their response against various stimuli" (https://www.dokumen.pub)

1.7 Assumptions

The first assumption of this study is that there were limited studies on the trends of technology and innovation in lower limb prosthetic assistive prosthetic devices. The second assumption posited that individuals with lower limb loss or impairment were unsure of what products they needed to address their needs and relied fully on expert opinions. The third assumption was that most individuals with limb impairment did not have a choice or option and would accept any assistive prosthetic device if it would address some of their unmet needs. The fourth assumption was based on the growing population and scarcity of assistive technology devices. It was assumed that technology and service accessibility could not cope up with the growing demands needed to address the needs of individuals with lower limb impairment.

It was also assumed that the development of assistive technology devices had not matured to unlock the full manufacturing capability of new or advanced lower limb prosthetic devices. Finally, it was assumed that emerging technologies especially those associated with IoT, or digital capability would increase complexity in the prosthetic device therefore impacting the user long-term ability to enjoy using the product and may finally end up abandoning the equipment.

1.8 Delimitations

The initial scope and boundaries of the study was limited to 3D, 4D printing and robotics prosthetic assistive technology devices for individuals with lower limb loss or impairment but later expanded to broadly explore on other technological trends that play a role in prosthetic devices. Those included discussion on digital enabling technologies and how they would impact technology trends and innovations of prosthetic devices. As a result, the scope was expanded to include robotics into the study.

1.9 Limitations

This exploratory study was impacted by the Covid-19 pandemic making it challenging to engage in a mixed-methods research study as originally intended. At the onset of the study, I intended to interview individuals with lower limb impairment and health care professionals to determine the issues that were most important to them and their experiences with assistive technologies. But due to the pandemic, access to these vulnerable populations was denied, necessitating a change in focus and procedure. As a result, I opted to conduct a comprehensive examination of past, current, and emerging assistive technologies, this research into emerging trends in technology and innovation for lower limb prostheses will add to the cumulative body of knowledge regarding assistive technologies, technology-enhanced prostheses, and the unmet needs of disabled individuals who have experienced limb loss or impairment.

1.10 Researchers Interest and Connection with the Study

I was intrigued in conducting this study because individuals with limb disabilities impacted my life at a very early age. I was barely 13 years old when my mother passed away which resulted in my father taking me to a boarding school in rural setting. The school was located adjacent to rehabilitation center that was catering for individuals with limb impairment. For a period of 8 years, I had first-hand experience working closely with individuals with various limb disabilities. One obvious challenge that most of them faced was access to technology and assistive products including items such as a walking stick. I concluded at an early age that technology was a major factor hindering most of these people to perform some basic daily functions or activities.

Upon completion of high school and having enlisted in the military; I trained in combat engineering and specialized in mines demolitions before becoming an aircraft engineer. Both training helped to shape my overall perspective and views in humanity. From time in memorial, thousands of innocent civilians including children have lost their lives due to war including in land mines and several amputated, to date, conflict is still confirmed to being the main driver of humanitarian needs (Buitrago & Moreno-Serra, 2021). As a result, I planned to engage in this study by drawing from both my lived experience and education in engineering and technology to impact the future needs of humanity as they relate to mobility assistive technology devices. Ultimately, my aspiration is to become a consultant with a focus on bridging technology and regulatory gaps between developing countries (third world countries) and advanced countries.

1.11 Summary

Chapter 1 introduced emerging trends in technology and mainly focused on 3D/4D printing and robotics. The overall objective of this chapter was establishing the importance of exploring on the current and future state of assistive technology devices and technological impact on individuals with limb impairment who depend on prosthetic devices for mobility and in performing daily activities.

Even though most studies have overwhelming consensus on the need to innovate products for individuals with limb disabilities, technological advancement and services offered are still disjointed and lack an integrated approach in the production of lower limb prosthetic devices. These industry wide challenges are prone to impact the subject population who may suffer from high-cost implications of assistive technology products. As a result, more research is required to understand how trends in technology will impact or address gaps on unmet needs of individuals with lower limb impairments. The research questions that guided this study were intended to assist the researcher in exploring, in a thorough and comprehensive manner, the potential impact and implication of current technology trends and future innovations on prosthetic devices. Chapter 1identified needs of individuals with lower limb loss or impairment and how technology and innovation requirement impact assistive technology devices. The chapter broadly alluded to how engineering designs, product development, manufacturing, regulations, safety, and quality control play a role in technology advancement.

Chapter two was built based on problems and questions identified in chapter one. An extensive literature review was conducted to develop a broader understanding of what is entailed in lower limb prosthesis studies. This was achieved by elaborating on theoretical framework and philosophical basis focused on disability, assistive technologies, and innovations in additive manufacturing, robotics and in digital threads. Chapter two further explored on the development of historical content and context for the study of assistive technology. The chapter navigated and highlighted technological trends and identified some of the existing gaps and challenges to benefit future studies on trends in technology and innovation.

Additional work involved in chapter two included, research work on the regulatory landscape pertaining to medical devices, review of the cost implications of medical devices and impact to assistive technology. The chapter further explored both the physiological and psychological challenges faced by individuals with disability, engaged in post market surveillance analysis of medical devices, design development and manufacturing requirements including life expectancy of 3D printed prosthetic devices. These formed the basis from which I established the framework needed to explore deeper into the trends of technology involved in lower limb prosthetic devices. Without these profound studies and understanding, it is my belief that addressing the complex needs of individuals with limb impairment can be complex and challenging.

CHAPTER 2. REVIEW OF THE LITERATURE

2.1 Overview

This chapter detailed Notes used for literature searches and presented relevant themes of related topics in technology. The chapter discussed some innovations in the 4th industrial revolution such 3D/4D printing and robotics and how they have impacted technological trends of prosthetic devices. The chapter further synthesized and summarized literatures and themes developed for the study.

The first section of the literature review examined trends of advanced manufacturing technology followed by the history of Assistive Technology. Having established the foundation for the study and the challenges faced by individuals with lower limb impairment, the study looked at the regulatory landscape of medical devices followed by market surveillance and quality controls pertaining to design features of lower limb prosthesis devices, 3D/4D manufacturing practice and the integration of robotics into the discipline. Finally, the study looked at the cost of medical devices and innovation trends in technology.

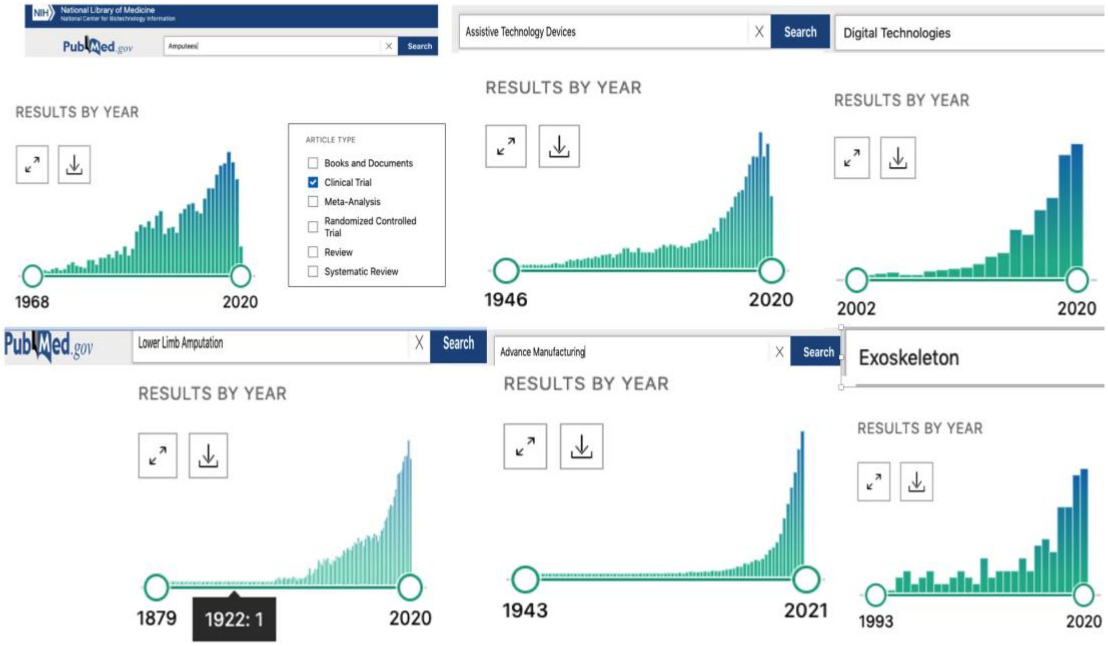
2.2 Methodology of Review

I conducted an extensive literature review from secondary Notes. Information was acquired from different databases for business, science, technology, and engineering. Review of journals was done from academic Notes, government Notes, industry white papers, conference materials, patents, and grants in assistive technology devices and from research institutions including Center of Disease Control (CDC) and the National Library of Medicine, Ovid MEDLINE, Embase, CINAHL, Cochrane Database, Google Scholar, Google patent, PubMed, Scopus, and IEEE Xplore.

The following search terms were applied to get relevant information from the database: amputation, amputees, amputees, prosthesis fitting, prosthetic device, prosthesis trend, knee prosthesis leg, joint prosthesis, lower extremity, lower limb, foot, knee, leg, thigh, ankle, joint, stump, knee replacement, knee impairment, socket, transfemoral, transtibial, unilateral or artificial limb.

Noting that clinical trials for amputees had risen significantly over the past twenty years, I decided to apply specified restriction terms to generate and study the trends for this study. Initial search was done from the National Library of Medicine database.

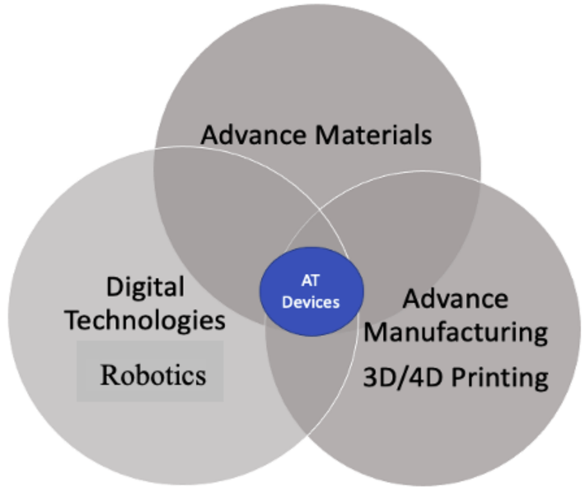
First, I had to determine the trend of clinical trials for protheses. The result revealed an uptick in 1968 which has grown exponentially over time. Similar searches were done for digital and assistive technology devices, lower limb amputation, advanced manufacturing, and exoskeleton. Results showed exponential growth as well. Figure 1 shows how I began the literature review.



Note: Compiled by the researcher.

Figure 1. *Trends in Assistive Technology in Lower Limp Prosthesis*

To shed light to notable key areas of interest for this research project and to identify the main topic of this study, a Venn diagram was constructed showing intersectionality across technology interest areas of focus areas as shown in Figure 2.



Note: Compiled by researcher

Figure 2. *Venn Diagram showing Intersectionality of Research Focus Areas*

Following an extensive literature review, the appropriate themes were identification and further classification was done. Table 1 and Table 2 are themes identified in the literature such as robotics, Advances Materials, Advanced Manufacturing such as 3D/4D and 4D printing, cost, and conventional manufacturing methods.

Table 1

Themes in Design

Theme	Topic Area	Description	Source
Design Practice	Design	Quality by design	(Patil & Pethe, 2013) , (Martinez-Marquez et al., 2018)
	Design and standards	lack of design tools	(National Academies of Sciences, 2017
	Design Challenges	Isolated design efforts	(About the Open-Source Bionic Leg Project – Open-Source Leg, n.d.)
	Design control	Regulations	(Design Control Guidance For Medical Device Manufacturers, n.d.)
	Design Control and manufacturing	Design and manifesting control	(Design Control Guidance For Medical Device Manufacturers, n.d.)
	Design and quality	Quality errors	(Balk et al., 2018)
	Design nd product development	life cycle and product development	(3D Printing's Impact on the Value Chain | White Paper | Stratasys Direct, n.d.)., (Evaluation of New Technology in Health Care — KNAW, n.d.).

Note: Compiled by researcher

Table 2

Literature Search Categories and Classification of Main Themes

Theme	Topic Area	Description	Source
Robotics	Powered exoskeleton	Powered exoskeleton	(WHO | Global Atlas of Medical Devices, n.d.).
	Robotics , Exoskeleton and rehabilitation	Exoskeleton and rehabilitation	(Magnusson & Ahlstrom, 2017).
	Robotics and Electronics	Challenges of robotics and integrated control	(Azocar et al., 2020)
	Robotics research study	justification for using soft robotics and additive manufacturing for customized prosthetic hands	(Stephens-Fripp et al., 2020)
	Robotics research study	Application of robotics in prosthesis	Price et al., (2019) , (New Algorithms Improve Prosthetics for Upper Limb Amputees, n.d.).

Theme	Topic Area	Description	Source
Advance Materialss, 3D/4D and Conventional Printing	3D Future	There is limited knowledge on the use of 3 D-printed transitional prostheses,	(Zuniga et al., 2019)
	3D future	3D future	(Ploeher & Panesar, 2020).
	3D Future research	Paucity of research on the feasibility of using this technology to fabricate prostheses.	(Ribeiro et al., 2021)
	3D market outlook	global view of 3D printing	(3D Printing Market - Global Outlook and Forecast 2020-2025, n.d.)
	3D Pringing Standards	Lack of 3D printing standards	(Zuniga et al., 2016), Wang & Yang, 2021), (Martinez-Marquez et al., 2018)
	3D prining and 3D Scanning	Benefits of 3D printing and 3D scanning technologies	(Benabid et al., 2019) , (Cruz et al., 2020). (Vickers (2019),
	3D priniting defintiton and names	What are some names for 3D printing	(Jin et al., 2017) , (Cruz et al., 2020).
	3D printers market and challenges	The efficient use of materials, along with minimized human errors, product customization, and reduced production time and cost, is the main driving factor	(3D Printing Market - Global Outlook and Forecast 2020-2025, n.d.)
	3D Printing and Material Testing	Sufficient testing of 3D designed and printed product is required for products	(Nickel et al., 2020)
	3D printing and Utilization	Limited use of prosthetic devices	(Carlson, 2005)
	3D printing challenges	Materials challenges	Wang & Yang, 2021);(Chen et al., 2017).
	3D printing challenges	3D printing limitation	(*4D Printing - Revolution or Fad?* , n.d.)., (Fallat, Sterley, Alsuhibani, and Bell, 2017),
	3D printing customization and trend	Growth trend of 3d Printing	(Chen et al., 2017). Jin et al.(2017
	3D scanning	Precision	(Benabid et al., 2019)
	3D study Future	3D-printed devices enable improvement based on the demands of prostheses users.	(Kate et al., 2017)
	3D printing report conflict	Conflicting report	(Orthopedic Prosthetics Global Market Report 2021: COVID 19 Impact and Recovery to 2030, n.d.)
	4D printing	Understanding the difference with 3D printing	("Tech Insights: 3D Printing," 2016), (4D Printing, n.d.)., (Momeni et al., 2017).
	Conventional manufacturing process and 3D	Conventional manufacturing process and 3D complements	(3D Printing's Impact on the Value Chain | White Paper | Stratasys Direct, n.d.).
	Conventional Printing	Limitations of conventional printing methods	(Nycz et al., 2019). (Momeni et al., 2017), (Deshmukh et al., 2020)..
Cost	Cost	3D Printing cost implications	(Zuniga et al., 2016)
	Cost and Compensation	Standardization of Process	(Poonsiri et al., 2020)
	Cost and insurance coverage	Cost	(Limb Prosthetics Services and Devices, n.d.).
	Cost global approach	Cost WHO	(WHO, 2017).
	Cost market and clinical trials	Cost	(Evaluation of New Technology in Health Care — KNAW, n.d.).
	Cost of prosthetic devices and production model	Cost of device is high	(*Limb Prosthetics Services and Devices* , n.d.)
	Cost of prosthetic determinants	Cost variance determination	Blough et al.(2010)
	Funding	Funding Issues	(Wendt et al., 2011)
	Funding		(*Aopa100.Org/History* , n.d.)
	Funding and Clinical studies	Costly pre-clinical and clinical studies for safety assessment before clinical approval.	(Martinez-Marquez et al., 2018)

2.3 Theoretical Framework for Disability and Assistive Technology

There are different views and theoretical arguments related to how we think about and attempt to address concerns related to disability. Researchers such (Barnes, 2016) philosophically argued that disability is socially constructed and that we should care given that people have used the discourse of disability in their civil rights and struggles. According to (Saxton, 2018), Critical Disability Theory (CDT) provides a better analysis of traditional stereotyped conceptualizations of disabled people.

It is however important to note that disability is a topic that is widely discussed across various disciplines including ethics and in gauging how the society lives. In essence, the study of disability challenges the norms in the society and social constructs on how we view and think about disability. CDT can be used to explore complexities and interchange between various social power dynamics and constructs of inclusion/exclusion, class difference, privileges, identities, normalcy, and mobility (Titchkosky, 2011).

Other scholars such as (Jefferies et al., 2018) argue that most researchers still tend to speak of the benefits and challenges of using prostheses, but very few attempt to account for and provide explanations for the differing experiences of prosthetic device users to develop a full understanding of the experience of the said users. Taking on this challenge to offer a grounded theoretical investigation as a means of establishing the impact of known or emerging concepts and technologies in the development and use of prosthesis, this study attempts to account for the breadth and depth of understanding differences in experiences and outcomes of users to provide a means to integrate extant knowledge on disability into that of trends in assistive technologies.

In establishing the context of disability studies Saxton (2018), argued that remarkable evolution that have occurred over the past 30 years that resulted in the emergence of other disciplines engaged in addressing complex issues and social factors that exist within the marginalized populations. These include cultural idealism of 'bodily beauty' which in most cases tend to negatively impact on individuals with disabilities. Even though Eugenics ideology and practice place more emphasis the "able body" as part of the beauty portraying traits of the 'human goodness', acceptability and worthiness.

It should be noted that in 1890s, these movements were meant to control the human breeding with the intent of eliminating those who were unfit. In this context, individuals with disability were considered to unfit in the society. And anyone who was not dominantly white, non-disabled, middle- and part of the upper-class was considered as unfit and different from the former. Individuals with disabilities, immigrants, people of color, and other 'undesirables' person in the society were victims of institutionalization and systematic sterilization that affected more than 70,000 people in the US (Myers, 2018).

One of the most concerning issues today involve the persistence of Eugenic thinking and philosophy on disability in the society. Even though the society has evolved over time due to technology, individuals with disabilities such as lower limb impairment have partly benefited from improved assistive technology products, but they have also been affected by how the society views them as disabled bodies and not abled bodies. The effects of eugenic thinking have been prevalent in public settings, institutions, offices, in policies and society at large. Because of Eugenic thinking, the society has continued to be divide. Those who are not disabled have been classified as abled bodies while those who are disable have been degraded and classified as disabled bodies. These notions have impacted the way the society thinks and acts. The social and biological context of able human bodies drew more interest in understanding the intersectionality on people targeted with social exclusion. This new thinking was significant in enabling the society to not only address problems associated with racial and national exclusions and limits to access related to class, but also to effectively relate these to the discourses, technologies, policies, and practices that frame our responses to disability in general and, limb difference.

Theoretically, this research project aligns with CDT and the intersectional approach to disability and uses them to investigate the impact of 3D/4D technologies on the development of prosthetic devices for individuals with lower limb impairment. Disability can be considered as a barrier to achieving certain functions or success due to various limitation it imposes on individuals with impairment. In the social context, to be disabled is to be disadvantaged when compared to those people who are able bodied.

The phenomenon of disability have resulted in internalized oppression on individuals with disability according to (Myers, 2018). As a result, more research is required to identify innovative solutions that increase inclusion of individuals with disability in the society granting them more opportunities to be successful, competitive and welcomed in everyday living. This research study engaged various trends in technology needed to provide insight on innovations in lower limb prosthesis needed to increase activities of individuals with limb impairment in the future. Advances in lower limb technology devices therefore address mobility challenges and increase the level of engagement of individuals with impairment in the society. Some of societal engagement that have gained traction in the recent past include the Paralympics. Despite its advances and popularity amongst individuals with limb impairment, the society has not transformed it thinking and how it views individuals with disability. Today, there is still "persistent exclusion of disabled youth and adults in community sport and recreation programs around the world" (Saxton, 2018, p,23). Notably, paralympic sport is purposefully scheduled to takes place after the main Olympic spots have ended which invertedly can be viewed as classifying individuals with limb impairment a being second to those of abled bodies in the society. As a result, there is a need for a paradigm shift in the society to shape perception and increase the level of acceptance of people disability in the community.

2.4 History of Assistive Technology for Lower Limb Prosthetic Legs

The history of artificial limb can be traced back through many years and centuries. In the past, lower limbs assistive devices were made from sticks and other wooden products available to mankind. The overall objective of lower limb assistive technology overtime has been to aid the person with limb impairment restore some of the function of their limbs and to increase their level independence, mobility and activities in the society. Artificial limbs such as a forked stick, staff, or cane were very helpful hundreds of years ago. According to Bennett Wilson (1964), the earliest recorded use of a limb prosthesis was around 484 B.C. A Persian soldier named Hegesistratus who was captured and imprisoned. He was shackled to the wall, but somehow, he managed to endure the pain and cut off one of his feet and slip his wounded leg out of the shackles (Wilson, 1964). He fashioned a crude wooden foot to help him walk upright and limped his way to freedom. Artificial limbs can be made of various products from wood to metal and plastic. The oldest known limb was found in Italy in 1858 and believed have been made around 300 B.C. (Wilson, 1964).

Many discoveries have been made around the world in pursuit of technologies used by early mankind. One that stands out amongst many was that discovered in Egypt which could be traced back more than 3500 years through their civilization (https://www.bbc.com/news/world-europe-50821392). The prosthetic feet are one of the most outstanding examples in limb technology because it signifies the importance of design and engineering efforts over time or through the ages. The ancient Egyptian designers knew about the benefits of aesthetics, weight reduction and improvements needed to increase the functionality of prosthetic devices and making them more useful to individuals with limb impairment as shown in Figure 3 below.

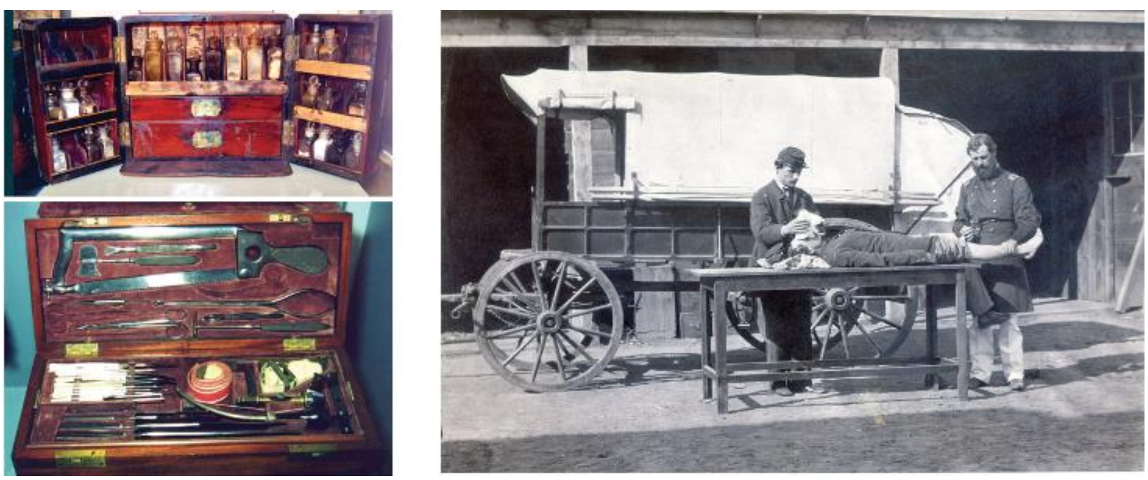
Credit: Finch, 2011.

Figure 3. *Egyptian toe (An Early Prosthetic)*

Designing of objects tend to take the centerstage in many prosthetic limb devices followed by the type of materials that they are made of. The designs of prosthetic devices must incorporate the form, fitness, and functionality of the final product. In designing of the big toe for instance, it must be strong enough to support the functionality of the remain limb and strong enough to carry the body weight. According to various studies, the big toe is believed to be responsible for supporting roughly 40% of the bodyweight (BBC News, December 17, 2019). Besides that, the primary function of a big toe is to propel the person forward as they walk. The ancient prosthetic toe was successfully utilized but due to advances in technology, modern prosthetic toes are designed and made after intensive study of an individual’s gait using cameras and other monitoring equipment (Finch, 2011.). As such, there is a need to further advance and improve design practices of lower limb prosthesis. Leverage emerging technologies such as the

3D/4D printing process will be beneficial to these advances. To effectively do this, we need to understand some of the design practices and some of the prevalent gaps that exist.

War is one of the leading causes of amputation and many service member, soldiers as well as civilians have experienced limb loss due to gun wounds, irreparable fractured bones and other calamities resulting from land mines, bombs etc. Looking at the number of causalities experienced by the US during the civil was that lasted from 1861 through 1864, there were more than 12% major amputations conducted across battlefield casualties with 33% overall mortality for lower limb amputation (Battlefield Injuries ,2013). Amputation was the most common surgical procedure for gunshot wounds, and most were done around the injury level which was important in order to preserve limb length as shown in Figure 4.



Note: Images courtesy of the National Museum of Civil War Medicine (Battlefield Injuries, 2013).

Figure 4. *A Civil War Surgeon's Portable Apothecary and Amputation Kit*

The Civil War resulted in more than 60,000 amputation surgeries which was remarkably higher than expected. The high number of casualties and loss experienced by the United States from the tragic war spurred interest in the expansion of orthotic and prosthetic (O&P) industry. The American Orthotic and Prosthetic Association (AOPA) emerged in 1917 which coincided with the time when the United States entered World War I. Generally, wars tend to impact human life and there is no war that has been fought that resulted in no deaths or amputation. World War I resulted in 2,300 American soldiers experiencing amputation and having to leave with missing limb. Following the bombing of Pearl Harbor which occurred December 7, 1941, at time when the United States had just entered World War II. By the time the war was ending, there were 18,000 amputees reported. The support of ALMA was critical at this time and their largest role was in supporting the requirements that would ensure prosthetic professionals were ready and well prepared to engage in meeting the needs of amputee and patients who would have experienced any form of limb impairment (https://www.aopanet.org).

Technology can transform how patients are treated as well as how professional engage and impact change in their fields of expertise. During the World War II era, one of the greatest successes in treating soldiers who had experienced limb amputation was brought about by the discovery and emergence of antibiotics. The primary benefit of antibiotics was that it permitted physicians provide better treatment for wounded soldiers though the control of infections and in performing internal fixations that were required on amputees.

The benefit of antibiotics transcended through the Vietnam War which was quite long lasting from 1964-1973. The Vietnam War was one of the most vicious wars experienced in the history of mankind and claimed more 58,000 lived of American service members. The dramatic was resulted in excessive number in the range of 150,000 wounded casualties. This was by far the longest war in American history but was recently overtaken by the Afghanistan war. (Ciampaglia, 2017). To date, amputation has been used in various circumstances on injured soldiers and civilians to grant them the opportunity to gain independence. The provision of lower limb prosthetic devices has helped to improved quality of life of some individuals with limb impairment (Battlefield Injuries, 2013).

2.5 Empowerment Period of Assistive Technology

The development and maturation of any technology requires the investment of capital, time and patience. The evolution of Assistive Technology can be pre-dated to the time when mankind first experienced a need for alternative tool increase their capabilities in performing or engaging in various activities. Most notably, the historical perspective of Assistive Technology according to Wendt et al (2011), occurred over three major periods namely: First was the foundation Period which covered those events that occurred prior to the year 1900. This was followed by the establishment period that that lasted from 1900 to 1972. Lastly, the empowerment period that started in the year 1973 and to the present time today.

The term assistive technology was first recognized and published in 1988 with the intent of meeting the needs of individuals with disability requiring the use of assistive technology devices. This resulted in the establishment of the Tech Act which was later repealed and replaced in 1998 with the Assistive Technology Act also known as the (AT Act whose major application areas included Augmentative and Alternative Communication (AAC) covering a wide range of areas including computer access, assisted listening, … mobility, and powered mobility as well as prosthetics (Wendt et al., 2011).

Several major developments in technology have occurred during the empowerment period that started in 1973 to date. This included the introduction of new microprocessor-controlled prosthesis systems and technologies. Both the Endolite’s swing knee and the Ottobock’s C-leg were introduced in the 1990s and benefited from technology advancement in microprocessors. The overarching benefit that these technologies included the transformation on how individuals with limb impairment could have increased ability to walk and perform a wide range of activities. (https://www.aopanet.org). With new development and benefits being on the horizon because of technology advances, there is other underlying needs that should be addressed including cost, training, service and accessibility provision needed to meet the needs of individuals with lower limb impairment. As such, there is a need to conduct more studies on trends in technology to find ways of addressing future needs and addressing future issues (Wendt et al., 2011).

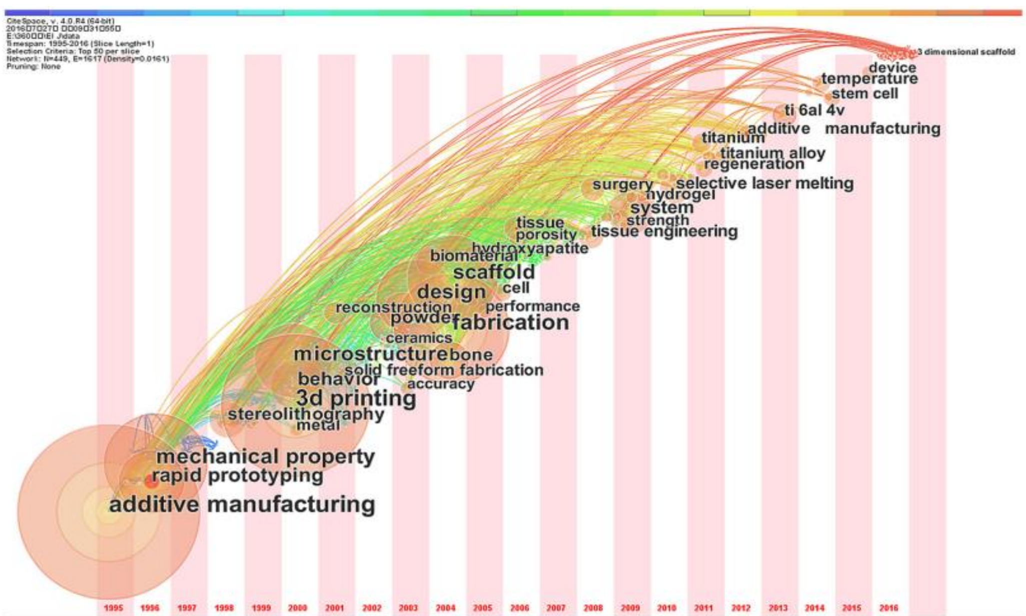
2.6 Trend Analysis of Advanced Manufacturing (3D/4D Printing)

I utilized 3D/4D printing as a baseline for engaging this study. Notably, there has been an increased industrial scale use of new materials as new devices appear and new products emerge in the market. This has led to new standards developed as old ones are constantly being updated. Given that Additive Manufacturing (AM) technology is part of Advanced Material sciences, they will need to be customized for different manufacturing capabilities to meet the diverse needs of society (Chen et al., 2017).

According to Jin et al. (2017), additive manufacturing continues to evolve through different time frames and the development trend can be observed in four main hotspots. The first is where the fundamental concepts are taken into consideration. In this inception stage, the predominant activities involved include those dealing with rapid prototyping and additive manufacturing, The second stage is where applications approach is taken into consideration which goes beyond prototyping. Examples of activities in the second stage include stereolithography and selective laser melting amongst others. The third stage involve a specific application that include fabrication, scaffold, and design etc. Finally, the fourth stage looks at trends and emerging activities that are taking place in advance materials such as stem cell, device, temperature, etc.

Based on these stages, there is a need to continue advancing the progression 3D and Advanced materials through extensive research work to benefit future advances in technology.

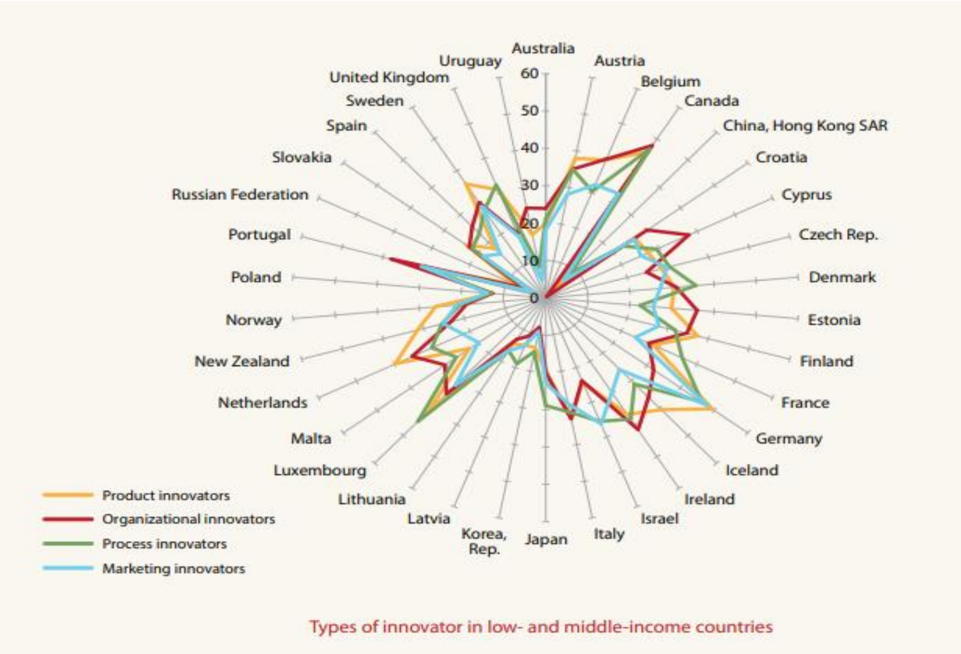
Discovering new materials will unlock many capabilities and opportunities for the future. The key to this advancement is therefore in material science. Example, the development of biomaterials with acceptable mechanical properties and compatibility will impact the future trend of additive manufacturing and materials in the medical field Wang & Yang, 2021), (Jin et al., 2017). Below is a graph depicting trends in additive manufacturing and other materials. The trend is depicted in the Figure 5 below.



Note : Jin et al., 2017 ; IMS.28(1), p26.

Figure 5. *Hotspots and Emerging Trends in Additive Manufacturing*

Globally, technological trends around the world continue to rise with increased innovation of products, process, marketing, and organization. In 2019, the Global Prosthetic financial valuation reached USD 1281.39 million with North America leading the regional market share which was expected to grow from $1.75 (Orthopedic Prosthetics Global Market Report, 2021). The increased number of trends in new technology continue to strike new interest in the industry. For this study, it is important to understand various trends in technology given that most technologies in lower limb prosthetic devices tend to intersect. Notably, looking at each country's technological growth and trend will help with identifying promising emerging technologies according to UNESCO Science Report, 2015) as shown in Figure 6.

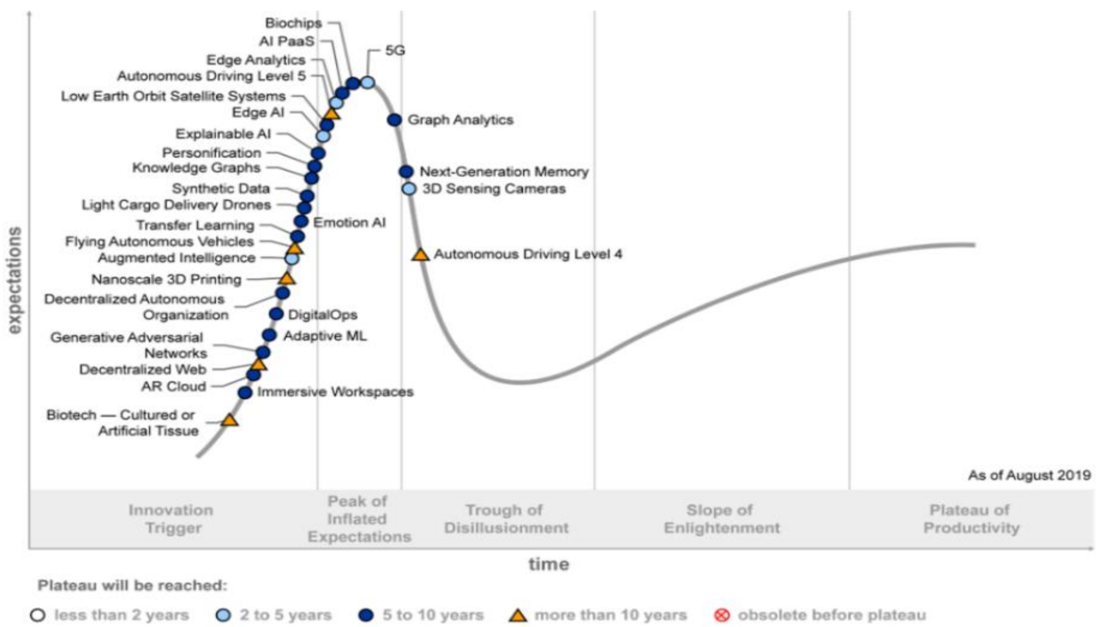


Note : UNESCO Science Report, 2015 p, 61.

Figure 6. *Types of Innovation in Low-and-Middle Income Countries*

The manufacturing industry is rapidly evolving, and more people are adapting and using new technologies such as information technology and digital tools resulting in more operationalized industry. Operational technology has experienced increased convergence with information technology which is a positive transformation into the future (UNESCO Science Report, (2015). In giving a brief synopsis on future technology landscape, UNESCO identified manufacturing as a valuable area of growth. This includes 3D printing, digital manufacturing, and lightweight manufacturing. On the digital platform, key areas of interest include those dealing with semiconductors, flexible hybrid electronics and integrated photonics.

To drive future innovation efforts, clean energy, fibers and smart textiles will be needed as well as increased among industry, academia and government stakeholders. This effort will make it possible to tap into new talent pool in the pipeline therefore benefiting future needs in research (UNESCO Science Report, 2015.). Looking at the technologies that are still emerging, it is evident that advanced manufacturing practice 3D printing along with other technologies such as augmented intelligence are amongst those identified in Gartner 2020 hype cycle for emerging technologies in Figure 7.



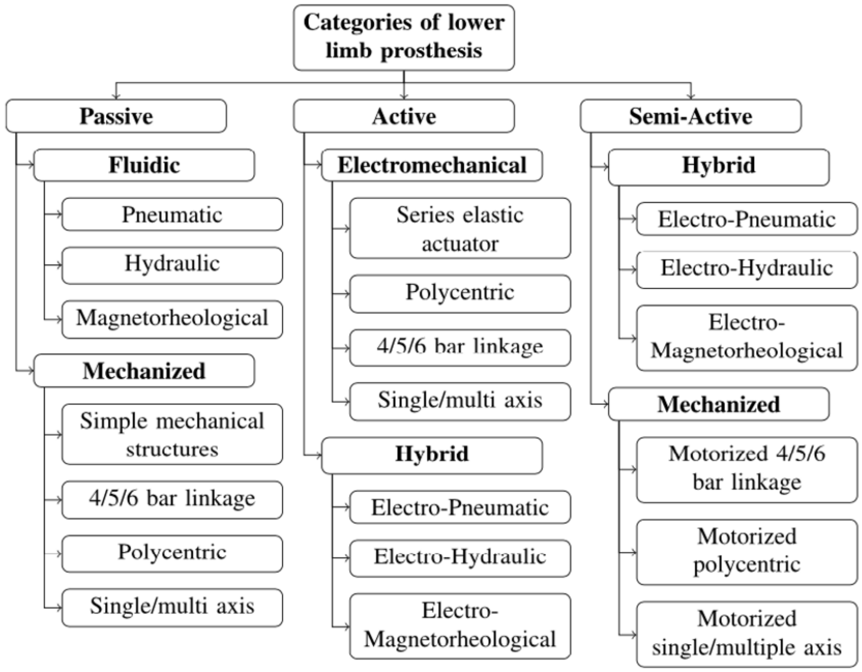
Note: Gartner Group, Roadmap, 2020.

Figure 7. *Hype Cycle for Emerging Technologies*

2.7 Lower Limb Assistive Technology Prosthetic Device

To develop effective policies and have a good sense of the area of assistive technology, it is important that one has an overarching vision while outlining resourcing priorities, state of the art, and end user experience of the devices (MacLachlan et al., 2018). According to Congressional findings that led to the passage of 29 U.S. Code § 3001, there is a need to provide additional information on assistive technology devices to people needing them to increase accessibility and independence. A major problem according to the “Triple A Study Act,” is that only one-third of people who have had or experienced amputation will receive a device and currently there are limited studies explaining how decisions are made on accessibility of equipment and how service is offered to individuals with limb impairment. To address this knowledge gap, this study attempts to explore how emerging trends in technology will address future challenges faced by individuals with limb impairment.

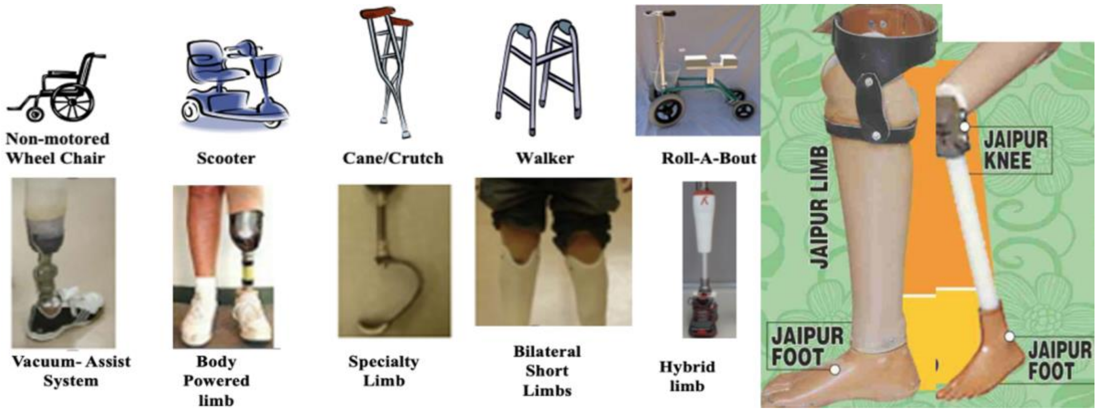
To begin with, it is important to offer some definitions and provide visualizations of the technologies that this study is concerned with to fully understand how the emerging technologies impact on assistive technology devices. Prosthetic devices come in various forms and their fabrication will depend on what part of the body they are fitted in or what functions they are indented to achieve. Prosthetic devices can be manually controlled, and some are powered and electronically controlled. Therefore, an artificial limb is a type of prosthesis that replaces a missing extremity, such as arms or legs (Limb Prosthetics Services and Devices, 2017). Individuals with limb impairment require assistive mobility devices to make it possible for them to attain some level of mobility (Carlson, 2005). US code of federal regulation in Title 21 provide some guidelines and on lower limb prosthesis and provides description of the devices and their intent. Lower limb prosthesis devices are meant to support medical needs and usually would be preassembled to fit lower limb extremities. Such devices can support the thigh or the ankle, knee, or the foot assembly (CFR - Code of Federal Regulations Title 21, 2022). Lower limb prosthetic devices that area commercially available today have been classified as passive, active, and semi-active as shown in Figure 8.



Note : Asif et al., 2021

Figure 8. *Classification of Lower Limb Prosthesis*

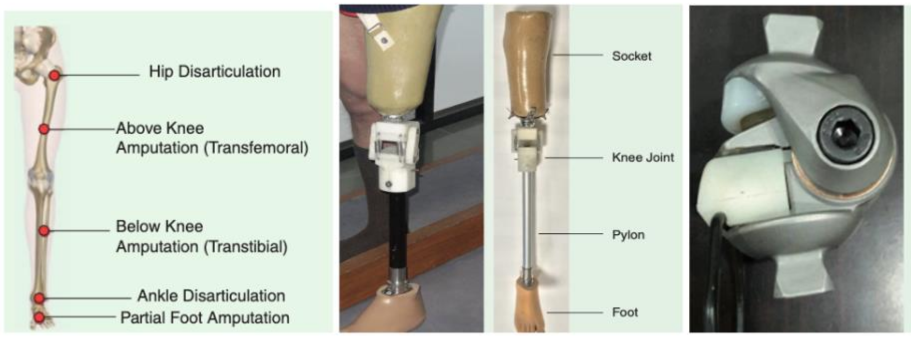
Some examples of Assistive Devices (used with prosthesis) include Non-motorized Wheelchair, scooter, walking cane or crutches, walker to assist with walking, or the roll-a-bout which is a walker with one leg support and with knee rest on platform, electric wheelchairs, electric scooters (rascal), car modifications, cane with fold-out seat etc. (Blakemore, 2018.; McFarland, 2010). Types of prosthetic lower limb prosthetics include, Mechanical (Bilateral short limbs with or without feet. these can be body-powered and do not need to be recharged), Hybrid (have a mix of electronic and body-powered parts), Specialty are those that can be used for recreational purposed including athletics and for the most part they have the ability to take on the extra shock absorption in the foot, Waterproof (e.g., shower leg, swimming leg), Cosmetic (non-functional limb), Vacuum-assisted system which has a pump or suction device embedded into it) (McFarland, 2010). Lower limb prosthetic devices can come in many forms and shapes such as those of Jaipur foot, Jaipur knee etc. To effectively engage in this study, it is important to identify various prosthetic assistive technologies as depicted in Figure 9.



Note: McFarland, 2010; Jaipur Foot, 2020

Figure 9. *Examples of Assistive Prosthetic Devices and Lower Limb Prostheses*

In addition, various parts of the lower limb prosthesis, parts of the lower limb and the prosthetic knee are presented in Figure 10.



Note : (Padi et al., 2017)

Figure 10. *Limb Amputation, Lower Limb Prosthesis and a Prosthetic Knee*

Discussions around various sections of the body sections or parts pertain to the lower limb can be challenging to understand explain without providing visual depiction of what those body parts or sections are. The lower limb comprises two sections namely above the knee, also known as transfemoral, and below the knee, referred to as transtibial. The Medicare Functional Classification Levels (K-Levels) are shown in Table 3.

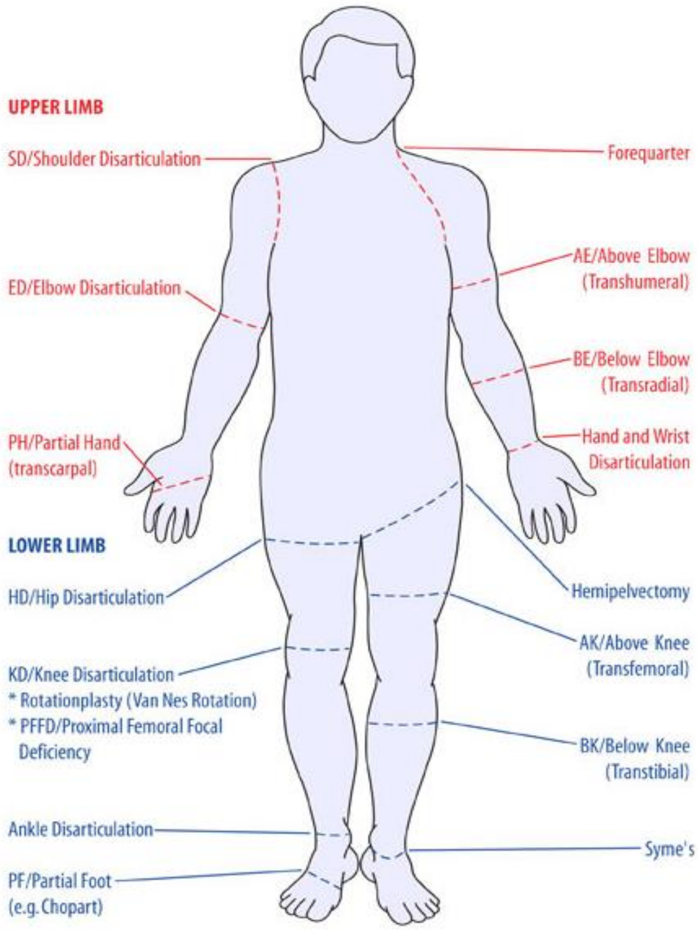
Table 3

Medicare Functional Classification Levels (K-Levels)

Lower limb extremity prosthesis Medicare Functional Classification Levels (K levels).	
Level 0:	Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility
Level 1:	Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
Level 2:	Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.
Level 3:	Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
Level 4:	Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

Note : (Balk et al., 2018)

The levels of amputation associated with lower limb prosthesis include hip disarticulation, the knee, the ankle, partial foot, below the knee, above the knee and the Syme. These levels of amputation are illustrated in the rehabilitation chart shown in Figure 11.



Note : Mosby, 2020; *Amputations*, 2022

Figure 11. *Levels of Amputation and Rehabilitation Chart*

2.8 Challenges in Lower Limbs Loss and Research Gaps

Central to this study is the recognition and conviction that people who have disabilities should be granted the rights to having their own personal mobility equipment as a Note of empowering them. The devices that they have rights should be made accessible to them and affordable without increasing of unnecessary strain. Having affordable assistive technology is paramount to the freedom of individuals with lower limb impairment. This is in accordance with the Convention of Rights of Persons with Disabilities (Magnusson & Ahlstrom, 2017).

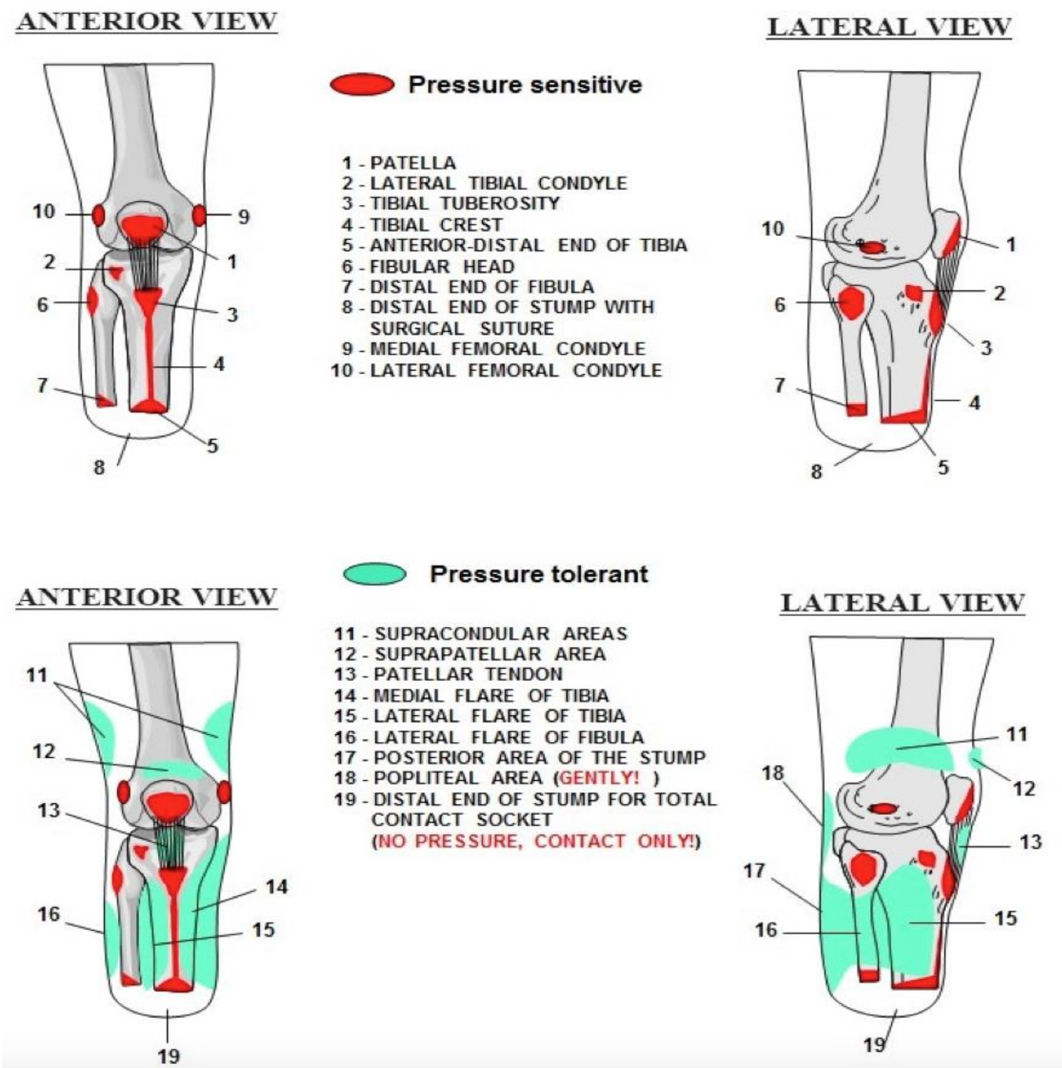
However, mobility is sometimes hampered not only by the lack of prosthetic devices but also by the quality of the fit of the device itself. It is worth noting that the quality of any prosthetic device is of great importance however if the device is not functional or useable, then the quality does not have any value. It is important that the device will fit the person needing it and perform the intended function. From existing studies with people who have had amputation or lost lower limb, it is well-known that they often suffer from different types of pain that include. Some of pains that have been documented experienced by individuals with limb impairment include those associated with ankle arthritis, other pains can come from the knee arthritis or from the hip. In some cases, the individuals with limb impairment may have stiff ankles or experience stiffness in the knee area or around their hip which causes a lot of pain (McFarland, 2010).

One specific pain that is challenging to treat is the phantom limb pain which results from lost arm or leg and is caused by lack of proper rewiring of the spinal cord and brain signals due to the lost limb. A detailed explanation of the pain includes feelings such as burning sessions, shooting pain or pains that resemble pins and needles or twisting and crushing, feeling of electric shock, temperature changes, pressure, and vibration. Despite advancement in medicine, to date, there are no drugs that can specifically treat phantom limb pain. As a result, people experiencing such symptoms end up receiving medicines for other conditions such as depression pills for epilepsy to get some relief. Even though phantom pain may take a while before going away for some people, it is not uncommon for the pain to last longer than expected or not even go away for others (Phantom Limb Pain, 2018).

Given that there is no medical solution to these types of pain, developing comfortable prosthetic medical devices for individuals with lower limb loss can provide some level of comfort that improves their quality of life (QoL). When looking at the development of medical devices specifically lower prosthetic limbs, there have been improvements over the years, but technology has not fully matured despite advances in 3D printing or newer manufacturing practices combined with other Internet of Things (IOT) interphases (Wendt et al., 2011, Nickel et al., 2020, Zuniga et al., 2016).

Even though most people are still fitted with a prosthesis (artificial leg) to make them able to walk again, there are many challenges that still need to be overcome including healing which can take incredible effect on the quality of life for amputees and their families (Ontario Health Technology Assessment, 2019a; Gupta et al., 2018).

Pain can be caused to individuals with lower limb impairment from various sources including those caused by interface from the device or sometime from contact between the residual limb area and the device itself. There are many pressure-sensitive pain points that designers must pay attention to when making devices fitted in the residual limb in order to provide additional comfort and avoid inducing unnecessary pain to the user. Figure 12 illustrates the various pressure points that people who have experienced lower limb amputation may experience. Understanding the significance of each pain point is critical during product design and development.



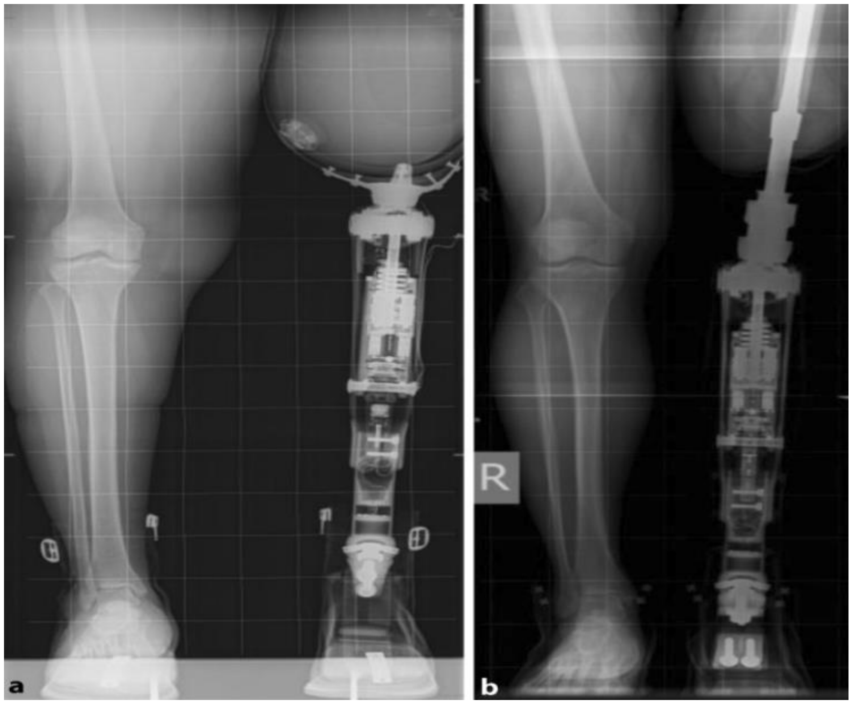
Note: Lower Limb Prosthetic Sockets and Suspension Systems, 2020.

Figure 12. *Pressure Tolerant and Pressure-Sensitive Areas of the Stump*

In preparation for the field studies, I carried out a considerable review of literature that illustrated other challenges associated with lower limb amputation most notable being the healing process. This can be slow and to some degree very painful. Studies by (Montgomery et al., 2009) identified that there is a lot of variances around the volume of the residual limb. In some cases, and, depending on the types of activities taking place within a day in relation to the weight of the amputee, the volume of the residual limb can vary from −11% to 7% which can have a significant impact on the user quality of life such as experiencing pain and difficulty when attempting to wear prosthetic socket. Individuals with limb impairment and especially transfemoral amputees tend to have extreme difficulty trying to regain normal movement.

One of the biggest challenges faced by this class of amputees has been on the level of energy that they need to utilize when trying to walk. A person with two limbs can walk in most cases without experiencing pain and may have the right level of energy and balance. This assumption may not be applicable to those people who have experienced transfemoral amputation because they must use approximately 80% additional energy to walk which can be very exhaustive. (Limb Prosthetics Services and Devices, 2017). This gap has not been fully addressed even with powered prosthetic devices or with designing and manufacturing of lightweight prosthetic devices (Lipschutz, 2017; Price et al., 2019; Stephens-Fripp et al., 2020).

Other studies conducted on assistive technologies concluded that there are ongoing technological limitations and challenges including the need to develop new materials with capability of reducing skin morbidity in amputee (https://www.nsf.gov/awardsearch/showAward? AWD_ID=1838509). To solve challenges of conventional artificial prosthetics, surgeons have been able to insert metal rods that are implanted in the lower limb making it possible to screw in the artificial leg thereafter. This process is called osseointegrated prosthetic implantation (OIP) which is formed in the bone making it possible to connect the artificial leg. According to Gupta et al. (2018) OIP offer unrestricted ranges of motion, improved sensory feedback, and better sitting comfort with reduced soft-tissue problems this technology is not yet widely available, and is also very expensive costing up to $100,000 per procedure. Other research studies have found that OIP may have certain disadvantages such as potential bone infection or fracture that may occur due to activities and aging that may lead to more complication over time (Hochgeschurz et al., 2021). See Figure 13.



Note: Upright position with socket prosthesis (view a) with osseointegration prosthesis (view b) (Frölke et al., 2017)

Figure 13. Upright Position with Socket Prosthesis

In line with the future medical and industrial needs, more studies are required that will help to overcome clinical challenges and to provide an accurate and timely diagnosis of implant such as OIP that could loosen over time or lead to unexpected infections (Ehrensberger et al., 2019). In reference to this research study on emerging trends in technology on lower limb prosthesis, it is timely to note that there are safety concerns applicable to 3D printable implantable metallic materials. Some of the concerns relate to material porosity that could lead to potential infections in the future when dealing with implantable limb prosthesis and more research is still needed in this area (Ni et al., 2019; Frölke et al., 2017).

2.9 Regulatory Landscape of Medical Devices

Regulations play several important roles such as establishing oversight and monitoring of medical devices before and after they are introduced into the market. This helps to improve safety of products utilized by millions of individuals with disabilities around the world. Over the past decade, waiting time guarantees were a common policy tool in several countries such as Finland (Health at a Glance 2015). From a research standpoint, it can be presumed that most amputees will need prosthetic limbs or other limb assistive medical devices. This is becoming more common due to increasing incidences of conditions leading to limb loss.

In the US for example, the population of the African Americans (AA) is lower than that of the while American however when it comes to the level of amputation, the population of AA are likely to experience four-time more amputation compared to the while peers. On the other hand, the 55% of persons with diabetes who may have experienced or had a lower extremity amputation are still likely to have the second leg amputated within 2-3 years which would be such a short time to experience dual amputation in anyone's lifetime ("Limb Loss Statistics," n.d.). Therefore, the increasing demand placed on lower limb prosthesis requires medical device manufacturers, medical facilities and professionals all ensure that the right devised is delivered to the patient on time.

These medical devices also need to be tracked for quality and safety improvements, warranty, profit, and cost control reasons. Overall, developing good controls including policies and regulations that cover a wider spectrum of medical device requirements seeks to ensure that medical devices are safe. However, manufactures, medical professionals, and even individuals with disabilities face several challenges as they recommend, wait, produce, or deliver service associated with assistive technologies such as prosthetic feet and knee replacement devices.

Several clinical studies have been conducted on pharmaceutical devices and products to establish their benefits prior commercialization.

Looking at lower limb prosthetic devices, it is critical for regulator to ensure that all safety issues are addressed in the study despite the high demand of prosthetic devices. When evidence-based research studies on product performance are conducted, guidelines should be provided to ensure that both the pros and cons of different research approaches involved in the study are shared (KNAW, 2014). Looking at the medical device requirements in the US, the Medical Device Amendments Act of 1976 was created to increase the level of safety on medical devices by requiring that the devices being produced are registered before taking them to the market (University of Cape Town, 2019). Other countries around the world have regulations on medical device. For example, in European Union, the Medical Device Regulation Act of 2017 was set to achieve similar purpose on safety, registration and tracking. Looking at developing countries such as in Africa. The African Medicines Regulatory Harmonization (AMRH) initiative was established to enhance safe and quality of essential medicines for priority and neglected diseases (African Medicines Regulatory Harmonisation, 2019). There has been increased regulation in Africa and the need to drive regulatory harmonization in the region. To increase effective approach in regulation landscape, 11 Regional Centres of Regulatory Excellence (RCOREs) was launched in 2014 (Ndomondo-Sigonda et al., 2017). Other regulatory key players include NEPAD agency working through the AMRH program to manage capacity and strengthen the regulation in the whole of African and are part of RCOREs as shown in Figure 14.

Note: *RCOREs | AUDA-NEPAD*, 2019.

Figure 14. *Regional Centers of Regulatory Excellence*

The African Vaccine Regulatory Forum (AVAREF) consisting of 55 African countries was created by the WHO in 2006. The intent of AVAREF was to formalize capacity building and establish a platform that would seek to drive and increase regulatory oversight on clinical trials in Africa. In 2016, a revised version of the governance structure was adopted which expanded the scope and included medical products as part of the new operating model (AVAREF, 2017). Their overall objective was to ensure close alignment with AMRH requirements for a more comprehensive framework and higher ethical standards (Ndomondo-Sigonda et al., 2017).

In the United States of America (USA), medical device regulation involves medical device reports (MDRs) system that captures and provide reports needed to assist with tracking of medical devices that have resulted in deaths, serious injuries, and malfunctions. The MDR are helpful in addressing devise safety issues and device performance as well as risk issues. An example of how MDR reports for years 2016 to 2021 of suspected device that were associated with deaths of users or resulted in serious injuries or equipment malfunctions have continued to drop as shown in Table 4.

Table 4

Medical Device Reports (MDRs: 2016 to 2021

New Search | show TPLC since 2021 | Back to Search Results

Device	Assembly, Knee/Shank/Ankle/Foot, External
Regulation Description	External assembled lower limb prosthesis.
Product Code	ISW
Regulation Number	890.3500
Device Class	2

MDR Year	MDR Reports	MDR Events
2016	10	10
2017	4	4
2018	3	3
2019	6	6
2021	1	1

Device Problems	MDRs with this Device Problem	Events in those MDRs
Adverse Event Without Identified Device or Use Problem	7	7
Device Operates Differently Than Expected	7	7
Loose or Intermittent Connection	3	3
Improper or Incorrect Procedure or Method	1	1
Physical Resistance/Sticking	1	1
Electrical /Electronic Property Problem	1	1

Note: *MAUDE - Manufacturer and User Facility 54 Device Experience*, 2022

As depicted in Table 4, the year 2016 only had a total of 10 incidents reported and remarkably, nothing was reported in the year 2020. This is one of the challenges faced with self-reporting systems that heavily rely on the device manufacturers. Today, North America is still considered a market leader in prosthesis devices manufactured (Orthopedic Prosthetics Global Market Report, 2021).

It is worth noting that there are still many opportunities and challenges that need to be addressed for effective standardization and harmonization of regulation of prosthetic medical devices given that some countries are dependent on donor support or lack the skill set to fully implement the regulatory efforts or oversight required on medical device prosthetic limbs.

A study by Ndomondo-Sigonda et al. (2017) that included East African Community (EAC) established that developing countries highly depended in government for funding and relied heavily on donor support on medical devices. Given that there is insufficient funding and various gaps in regulations across developing countries and in the regions of Africa, it could be beneficial that future studies investigate innovative ways to increase medical equipment accessibility in developing countries to meet the growing needs of individuals with limb impairment in the region.

2.10 Post Market Surveillance

Most developed countries such as the US and EU require Post market surveillance (PMS) on medical devices and good datasets that can be used to managing the records of various Manufacturers responsible for PMS as part of quality management system (IMDRF, 2020). When conducting PMS, there should be clear guidelines followed that ensure that the product under review is an authorized product and can be auditable and reported. Monitoring of products during PMS ensure that variations in standards can be addressed, tested. The overall framework of PMS includes product monitoring for good manufacturing practice, monitoring of advertising and promotion activities needed to establish product safety controls (Ndomondo-Sigonda et al., 2017). Finding a strategic balance of key priorities and having a good repository registry is important for tracking post market incident. The main purpose of the International Medical Device Regulators Forum (IMDRF) has therefore been to assist with establishing essential methods of ensuring that devices and outcome registries have identifiers that can allow tracking and secondly, it ensure that there is essential principle for managing data Note for medical devices as related to safety, performance, and reliability (Patient Registry, 2015).

Despite historical and notable structural challenges in Africa, there has been some remarkable improvements in regulations including in the quality control and in PMS oversight (Ndomondo-Sigonda et al., 2017). In the US, medical device reports (MDRs) continue to provide information pertaining to the tracking of medical devices however it is also considered as a passive surveillance system due to its limitations such as incomplete submissions of reports by manufacturers. This is because the MDR is based on trust of self-reporting by device manufactures. Notable challenges in MDR include inaccurate, untimely, unverified, or biased data (MAUDE, 2022).

In conclusion, there is a need to have reliable registries and regulations in place to support pre and post market surveillance activities of medical devices. Currently, there are different models of registries available such as those owned (1) by the government (2) professional societies or (3) independent entities. Regardless of the model, there is a need to have clear requirements that will support and increase collaborations taking place between regulators and healthcare professionals as well as manufacturers. The key focus of such requirements is around the optimization of patient safety based on new medical technology becomes available readily available in the market today. There are more than 500,000 types of medical devices in circulation (KNAW, 2014). Amongst those devices in the market are those that impact the lives of individuals with lower limb impairment that this study is focused on. Understanding of the trends in technology and howe medical devices are regulated and controlled provides additional insight to this study. To gain an inadept understanding of how lower limb prostheses devices are introduced into the market based on various trends, I found it essential to review the technology readiness scale applicable to assistive technology as a methodology for assessing product readiness to the market as shown in Figure 15.

Note: WIPO (2021)

Figure 15. *NASA Technology Readiness Scale (TRL) Adapted for Assistive Technology*

2.11 Tracking medical devices throughout product service life cycle

According to Articles 4 and 26 of the Geneva Convention, government is held responsible for ensuring that appropriate assistive technology devices are made available to individuals with disability and the devices should be affordable. Additionally, the people who are being provided with assistive devices should be well trained to ensure that they are safe when using assistive products (MacLachlan et al., 2018). Tracking of medical devices in developing countries is more difficult compared to those of developed countries.

In developing countries, medical devices are not affordable and are mainly made available through donations and charity. Upon acquiring of these devices, most user are still not able to cope up with the mechanisms for repairing or maintaining the devices (Global Atlas of Medical Devices, 2020). Tracking of medical devices poses a major challenge in developing countries whose registry systems have not matured.

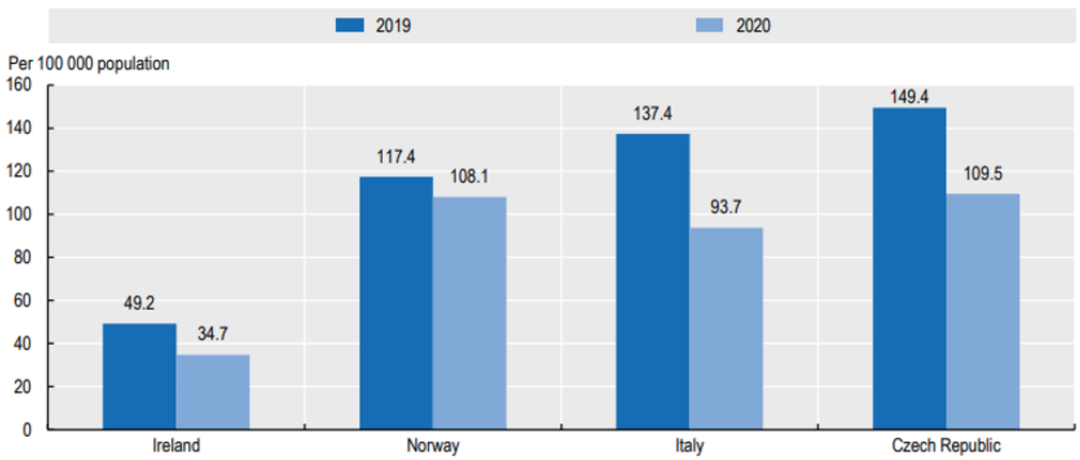
A cross national survey study by (Magnusson & Ahlstrom, 2017) in two low-income countries were done and comprised of 222 patients in Sierra Leone and Malawi to gauge the level of assistive technology use. The study found that assistive devise usage was at 86% but that more 50% of the devices needed repair. The study concluded that access to repairs and servicing were of great importance in developing countries. Tracking of medical devices can therefore vary from region to region, available services, regulations, governance, donor support, county, or private entity engagement and even more so, the involvement of manufacturers or developers of medical devices.

A National Institutes of Health study by Carlson (2005) was conducted and it documented the rates of prosthesis. The result revealed that prosthetic use based on upper limb amputation varied from 27 to 56 percent compared to 49 and 95 percent for lower-limb amputation (LLA). According to CDC report, data that detail the usage rates various types of prostheses and assistive devices have been harder to find compared to those that provide track surgical procedures and admission on lower extremity amputation (Extrapolations: CDC, 2015). Figure16 depict report tracking of major lower extremity amputation for adults with diabetes.

Note: OECD, 2015)

Figure 16. *Major Lower Extremity Amputation in Adults with Diabetes*

Advances in medical technology have been beneficial in terms of introducing less invasive surgical procedure when performing knee surgeries and other limb amputations. The introduction of better medicine and anesthesia have increased patient safety and health outcomes. According to OECD (2021), OECD countries experienced sharp declines in the number of surgeries related on hip and knee during the COVID-19 surge. The knee replacements in the year 2020 declined by 30% across Italy, the Czech Republic and Ireland and by 8% in Norway in 2019 as shown in Appendix B and in Figure 17.

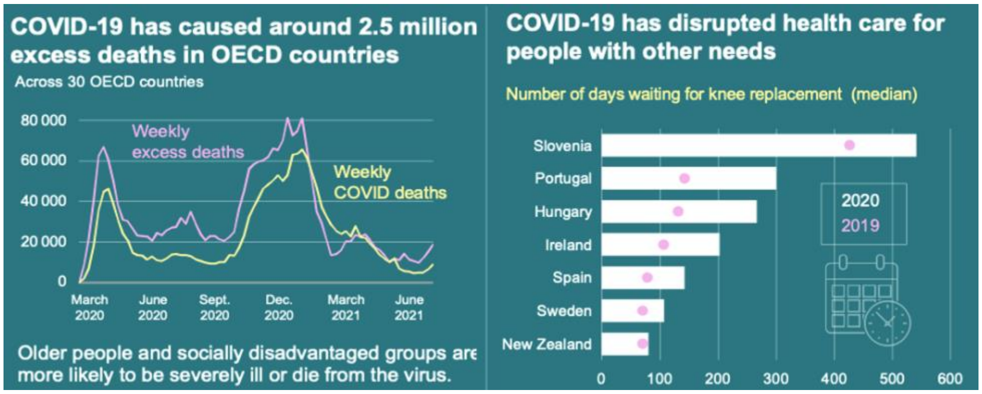


Source: OECD (2021[30]), "OECD Health Statistics", *https://doi.org/10.1787/health-data-en.*

Note. OECD, 2021

Figure 17. *Knee Replacement Surgery in Selected OECD Countries, 2019-2020*

In 2021 during the Covid-19 pandemic, OECD countries experienced around 2.5 million excess deaths with more than 90% recorded and the waiting time for knee replacement lasted more than 400 days in countries such as Slovenia. See Figure 18.



Note. (OECD, 2021)

Figure 18. *Covid-19 Death toll and Disruption in Health care.*

2.12 Design and Production of Medical Devices

Medical devices have a relatively short development phase which are often impacted by the high level of controls imposed on clinical studies that to some extent may not adequately reflect or represent the accurate safety and effectiveness of their conditions in the real-world (IMDRF, 2020). The short development phase all starts with the conceptual idea, designs development, test trials, and production of the final product. On an average, most medical devices have a short product life cycle ranging of 2.5 years depending on the type of medical device however other devices such as those associated with imaging have an average of on 6 or 7 years that may be required between various incremental modifications time periods (KNAW, 2014). The price of medical devices dictates the level of maintenance cost that the devices will require over time. Low-cost devices may warrant disposition after a short period of time compared to those that cost more.

The price of medical devices (MD) can be quite elastic depending on the market demand. For example, if the manufacture opts to control the supply chain by influencing the market segment by introducing low-cost new products devices to become more competitive and to get the biggest share in the marketplace given that the orthotics and prosthetics (O&P) market is valued at roughly $ 4.4 billion, with $ 1.7 billion in lower-limb prosthetics. (Cutti et al., 2019). This market dynamic can have a detrimental effect on the design and production of lower limb prosthetic devices and on those who depend on them for daily life activities. It is therefore important that researchers take into consideration how all these aspects can impact or influence the emerging trends in technology in lower limb prosthetic devices.

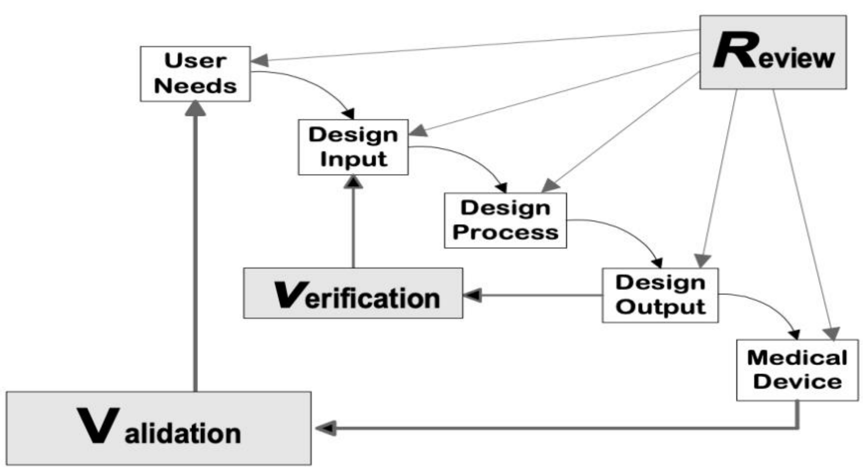
The design guidance for medical devices including manufacturing processes, modifications or improvements of existing device designs can be cross-referenced using available quality systems standards and national regulations guidelines. Regulatory guidelines requiring compliance when engaged in the design and development of lower limb prosthetic devices have been established by the ISO (International Standards Organization), FDA (Food and Drug Administration), WHO (World Health Organization), among others. For example:

1. **ISO 9001:1994** – Quality Systems: Model for Quality Assurance in Design, Development, Production, Installation, and Servicing (https://www.iso.org/standard/16534.html)
2. **ISO 9999:2016** – Assistive Products for persons with Disability – Classification and Terminology (https://www.iso.org/standard/60547.html)
3. **ISO 13485:1996** – Quality Systems Medical Devices Particular Requirements for the Application of ISO 9001 (https://www.iso.org/standard/22098.html). Note: compliance with the ISO 13485 quality management system, which prioritizes risk reduction and safety, is a requirement for producing medical devices with a risk classification above Class I
4. **FDA 21 CFR § 820** – Medical Devices: Quality Systems Regulation (https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820?toc=1)

5. **FDA 21 CFR § 820.30** – Design Controls (https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820/subpart-C/section-820.30)

In addition, many countries have established internal regulatory guidelines as well, such as the Quality Systems Regulations monitored by the Japanese Ministry of Health and Welfare (Design Control Guidance For Medical Device Manufacturers, 1997) and the Food and Drug Administration regulations of the United States. Donors and purchasing organizations, such as United Nations, World Health Organization, and the Global Fund, who provide medical devices and medical services to developing countries such as those in Africa, require these countries to comply with regulatory guidelines ensuring that medical devices manufactured at a site are compliant with ISO 13485 or ISO 9001 (WHO, 2017).

During the design phase, the development of basic requirements using a logical sequence is beneficial to the production of the development of a lower limb prosthetic device. First, it is important to capture the needs of user. This is followed by a review of the design input, design process, design outputs and a medical review of the product before release as depicted in Figure 19 (Design Control Guidance For Medical Device Manufacturers, 1997).



Note: *Design Control Guidance for Medical Device Manufacturers*, 1997.

Figure 19. *Design Controls Process*

Looking at the development phase of biomechanical product made using 3D models, it can be noted that product optimization is possible, and it can be done in the early phase of the build process. This is important because 3D printing provides the capability to build and optimize the final product at the same time according to Benabid et al., (2019). The customization of lower limb prosthesis depicts how product build and optimization can be achieved as illustrated in Figure 20.

Note: Design of a custom prosthetic implant (Benabid et al., 2019).

Figure 20. *Reconstruction of Amputated Lower Limb*

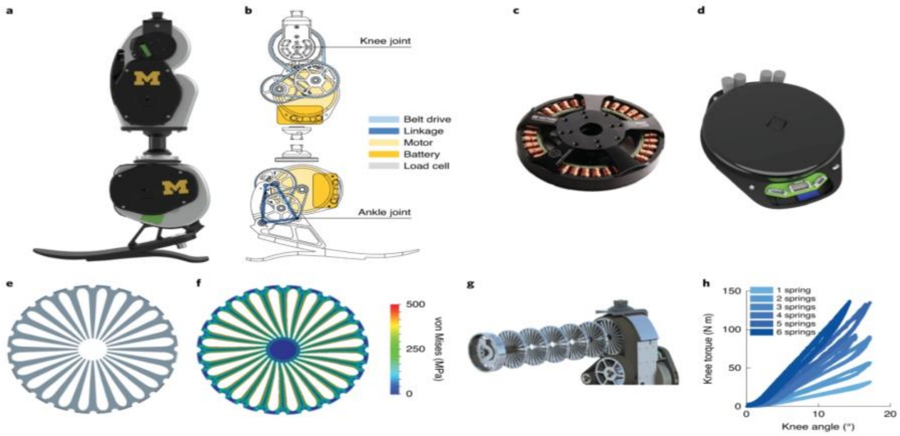
Following a design and prescribed printing process can be beneficial however the emergence of new printing techniques and materials are continually emerging challenging the current practice, standards, and regulations. 3D printing has indeed opened a plethora of opportunities needed to drive innovation and advanced manufacturing practice beyond where it is now. Today, 3D is still considered to be in its infancy and poses more opportunity for growth (3D Printing Market, 2020).

In many parts of the world, people are continuing to be more innovative due to increasing access to new technologies such as 3D printing which is one of the key areas in the Advanced Materials (Jin et al., 2017; Cruz et al., 2020a) for unlocking unmatched creativity and providing empowerment through problem solving such as the creation of prosthesis devices for individuals with lower limb amputation. In certain cases, people who have suffered from limp loss have taken matters in their own hands and developed homemade prosthetic devices for their own use. Example Following the loss of a finger in a woodshop in May 2011, Richard Van a carpenter from South Africa was able to design and develop his own prosthetic device based which provided a breakthrough permitting him to re-engage in normal activities upon being released from the hospital (Knochel, 2016).

Compared to conventional manufacturing techniques such which involved chipping or taking off some of the unwanted parts from a material either by drilling or milling and turning; 3D printing or Additive Manufacturing (AM) provides more freedom for the innovative design, culture, and creativity of customized or personalized products (Chen et al., 2017). These capabilities have resulted in the creation of open-Note platforms including many innovation hubs allowing users to create 3D models and Do It Yourself (DIY) projects in creating their own prosthetic devices from societies such as the Robohand project with collection of 3-D models and instructions for developing new iterations of prosthetics devices.

In Africa, the AfriLabs is one of the innovation centers across 49 African countries constituting of a growing network of more than 268 organizations (https://afrilabs.com/). AfriLabs has continued to empower entrepreneurs, technologists, and inventors by providing a collaborative platform bridging the gap across various disciplines. Currently, AfriLabs is considered as one of the open space pillars of innovation and represents one of the largest technology hubs in Africa (https://www.afrilabs.com). As such, AfriLabs is a key building block for the next generation of thinkers.

Open Note helps to drive innovation and unlock creativity. One key challenge in the development of lower limb prostheses that are safe, reliable, and responsive to real-world settings has been due to lack of standardization. Even today, many innovators are still using different robotic hardware and materials which constrains a unified approach to robotic prosthetic product development. As a result, Michigan University developed an Open-Note Leg (OSL) providing users with a lower entry barrier in conducting research needed to drive standardization improvements in the development of robotic knee prosthetic devices due to mixed standard and variance in design approach that exist in the industry (Azocar et al., 2020).



Note: Azocar et al., 2020

Figure 21. *The OSL and its Design Counterparts*

In the US, legislation cases of breakthrough medical device innovations are stricter than in the European Union (EU) countries drawing industry to choose Europe for new devices innovation for faster entry into the market. US in some cases apply the more flexible 510(k) procedure to replace PMA (Design Control Guidance For Medical Device Manufacturers, 1997). In comparison to developing countries, the availability of various types of assistive technology devices are largely determined by available notes and donations. The biggest hinderance to assistive technology devices in developing countries is largely due to culture, affordability, limited funds and job scarcity. As a result, there is a need to investigate whether there is an efficient distribution system exist for individuals with limb impairment who are not able to access nor afford assistive technology devices (Toolkit on Disability for Africa, 2016.).

The continued presence of world best in class companies in prosthetic devices such as Jaipur foot (https://wwwjaipurfoot.org) and Ottobock (https://www.ottobock.com/en-us/homepage), who are largely commercial, will continue to influence regulatory standards in developing countries (Ottobock, 2021). The emergence of donor organizations such as Jaipur foot which is largely focused in providing free assistive technology devices including lower limb prosthesis is significant improving the lives of individuals with limb impairment in developing countries. This is because by far, Jaipur foot have been able to distribute over 1.9 million prosthetic devices around the world at no cost to the user.

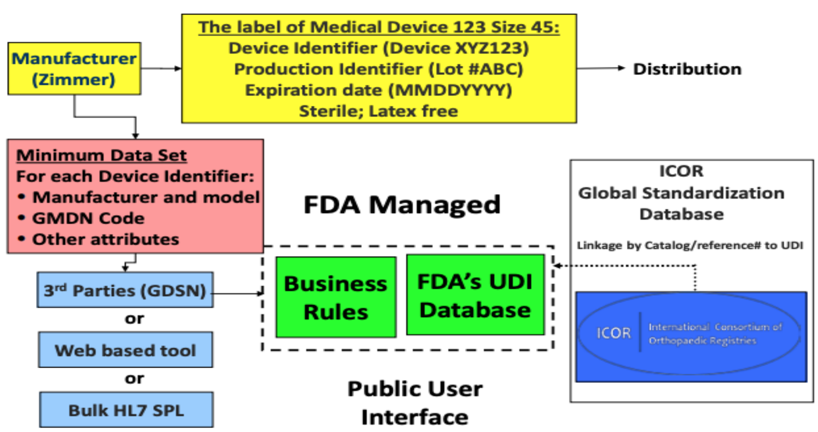
The Jaipur below-knee prosthesis shanks are fabricated from durable polyethylene pipes and the socket are vacuum-formed with polypropylene sheet. The total contact of the socket and the devices provides better sensory feedback to the wearer and have been beneficial in reducing edema (Jaipurfoot, 2020). Ottobock provides modern devices and support to individuals with limb challenges around the world. Essentially, the purpose and mission of these large organization are closely similar in terms of trying to provide services and prosthetic devices to individuals with limb impairment and to help them regain some of their independence. See Figure 22.

Note: Ottobock Africa, 2021; Jaipur Foot, 2020.

Figure 22. *Ottobock in Africa (Top); Jaipur Foot in India (Bottom)*

There are several key benefits that have resulted from using Jaipur foot. Most notably, the Jaipur foot have been reported to have a short fitting cycle time making it possible to rapidly fit a prosthetic user with a functional device in the same day or the next day depending on the level of complications. In looking at the quality of Jaipur leg, they are known to be bio-mechanically fabricated and well-aligned with the standard global practices. Additionally, Jaipur foot look like the natural human limb and provide a wide range of use by the amputee. They can be used for walking on uneven terrains, squatting, sitting cross-legged, running, climbing a mountain or a tree, riding a bicycle or driving a car minimal maintenance. They also benefit the user who may want to walk in or swim in water given that they are waterproof and permit amputees walk barefoot or with shoes on (Jaipur Foot, 2020).

Finally, once a device has been produced and is ready for the market, the medical device must be labelled for identification. Labeling of medical devices is required and is applicable to all countries. However, the U.S. FDA mandated a Unique Device Identifier (UDI) rule which requires manufacturers to apply UDI code identifying model and production characteristics of medical devices which are then populated in the Global Unique Device Identification Database (Patient Registry, 2015) as shown in Figure 23.

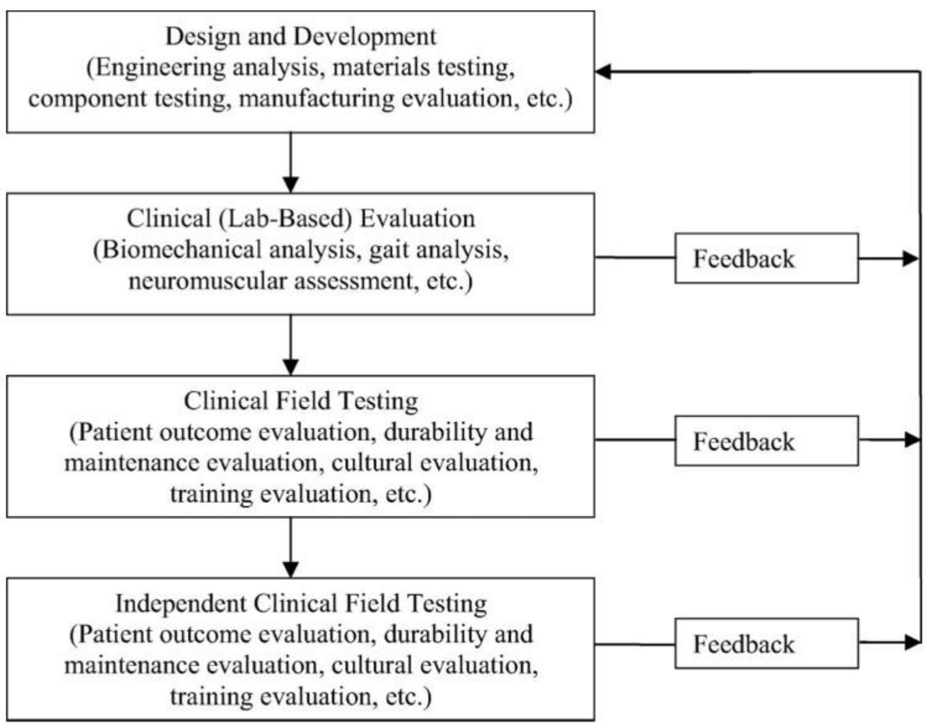


Note: Patient Registry, 2015

Figure 23. *Unique Device Identifier (UDI) Process*

2.13 Design Practice and Gaps

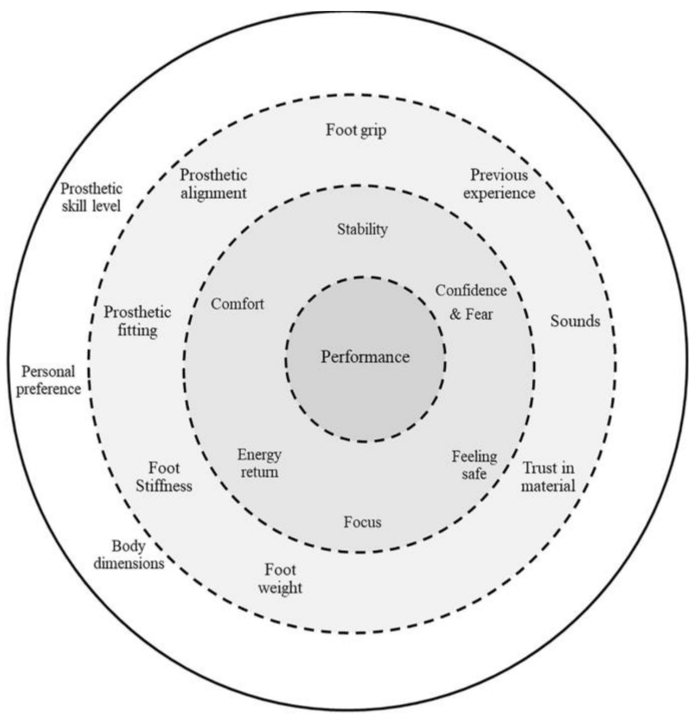
Design practices are intended to capture engineering requirements involved in the design process therefore ensuring that the process in captured, is repeatable and can be replicated across engineering discipline. Design practice provides a good frame of reference for engineers and support best practices and engineering knowledge transfer. Studies have shown that despite advances experienced in lower limb prosthetic design, the increasing needs and desires of several prosthetic device users have not been fully met with current products in the market (Stephens-Fripp et al., 2020). This gap needs to be address through design practices to define the needs of the customer or prosthetic device user. The development strategy for a prosthetic device is shown in Figure 24.



Note : Quinlan et al., 2020

Figure 24. *Product development strategy for prosthetic technologies.*

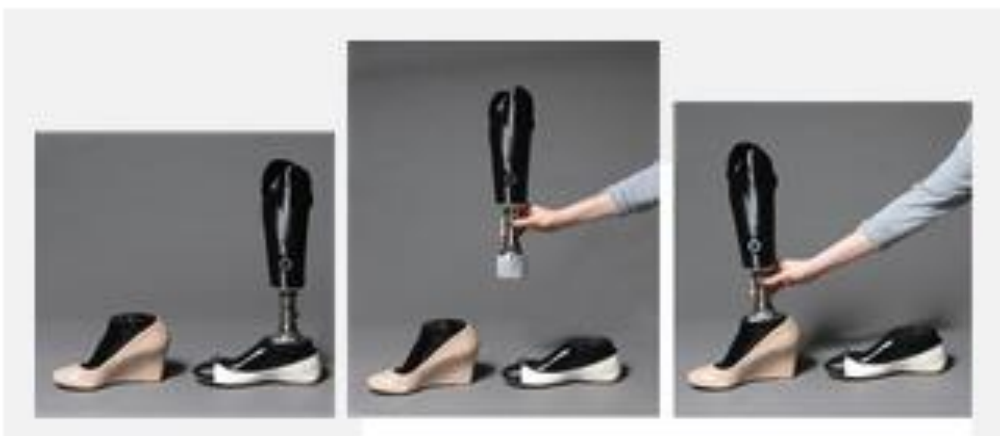
At each of the stages of prosthetic development shown above, there is a feedback process which should continually drive improvement throughout development, production, and adaptation of the prosthetic technology. When designing any outfit for amputees such as prosthetic sport feet, detailed planning and analysis of several requirements must be accounted for. According to (Poonsiri et al., 2020), there are several factors that influence the satisfaction of what amputee's wear. When designing a prosthetic sports foot, the performance must be given the highest consideration because it influences the level of satisfaction. Looking at the factors influencing prosthetic sports feet, it can be deduced that prosthetic users have a higher preference to devices that provide best performance compared to those that do not, as shown in Figure 25.



Note: Poonsiri et al., 2020.

Figure 25. *Factors Influencing Satisfaction with Prosthetic Sports Feet*

Today, most commercially available prosthetic feet can only be used with shoes of single heel height therefore limiting the number of heel-height adjustable prosthetic feet. These limitations pose a wide range of disadvantages including that they can only be used within a narrow range of heights (0 – 2 inches) and require manual alignment changes by the user. Despite these limitations in this area, researchers at the U.S. Department of Veterans Affairs recently developed a prosthetic ankle-feet system configured for use with various shoes having a wide range of heel heights making it possible to accommodate a much broader range of heel heights (up to 4 inches) without instability or unsightly mismatch between the plantar surface of the foot and the interior of the shoe however more research and work in still required. 3D printed prototypes of prosthetic devices provide the needed advantage for test products during such studies (TechLink, 2019) as shown in Figure 26.



Note: Prosthetic ankle-feet system configured for use with various shoes having a wide range of heel heights (TechLink, 2019).

Figure 26. *Prosthetic Ankle-Feet System Configured for Use with Various Shoes*

Strength testing is an integral part of any design feature. Correctly designed engineered parts should be to withstand certain strength tolerance such as torsion and tensile strength amongst other loadings. Studies by (Nickel et al., 2020) found that modern socket designs have been able to withstand a higher load test of ISO 10328 compared to those they previously tested on elevated load. In essence, they determined the load testing and strength can be improved over time using various conditions and parameter. In their case, they conducted twenty-four 3D-printed transtibial prosthetic sockets load testing using ISO 10328 and discovered that successive design improvements resulted in increased strength and variation of the final design therefore demonstrating consistent performance improving through various test iterations. This proves that good design practice can yield great results on the material strength.

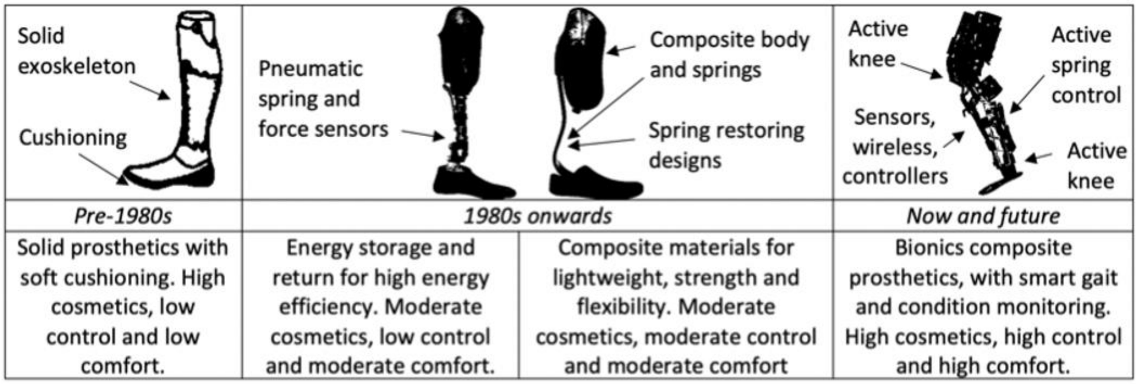
Designing safety into the product is important and should be a top requirement for any medical device (Cutti et al., 2019). Given that 3D printing is becoming so prevalent, it is easy to design and build custom-made prosthetic outfits from home. Safety can be easily compromised without knowledge of quality and safety standards stipulated by the International Organization for Standards (ISO). For example, quality systems standards ISO 9001 and 1994 provide guidance for quality assurance in design, development, production, Installation, and servicing. This is not any different from standards set to guide FDA process prescribed in Quality Systems Regulation, 21 CFR Part 820, Subpart C which provides the guidance needed to support the Design Controls of medical devices (*Design Control Guidance For Medical Device Manufacturers*, 1997). It is important for this study to look at how regulations impact the trends in technology associated with lower limb prosthetic devices because the medical database maintained by FDA can also be a Note for identifying technologies that have been recently registered by various device manufacturers.

In summary, when designing or making prosthetic device, the final product should have a natural feel so that the user is comfortable therefore finding convenient of its use. A prosthetic device should also be light in weight so as not to exhaust the user. The flexibility and ease of duplicating or replicating prosthetic devices will is integral for innovation and rapid prototype capabilities offered as a result. Currently the design and build of prosthetic devices is lacking standardization due to high variance in material difference and hardware (Azocar et al., 2020). This understanding benefits this research study by shading light into some of the trends and technology areas that can be investigated in the future to drive better standardization of lower limb prosthetic devices.

2.14 Robotics and Lower Limb Prosthetic Devices

Central to this study is looking at how emerging technologies and their applications in the field of assistive technologies are unlocking unmatched capabilities of how we design, manufacture, and utilize prosthetic devices for lower limb impairments. Comparing below-the-knee prosthetic devices currently in the market to those used several decades ago, it is noticeable that the basic principles have not changed and both devices aimed at assisting the user regain a portion of their independence. Looking at robotics and its implication on lower limb prosthetic devices, it can be deduced that assistive technology has been beneficial in the improvement of mobility.

According to a report by (Bionic Prosthetic Legs, 2019), the first bionic module of a knee joint was developed by a German prosthetics company named Ottobock in 1997. Today the company have integrated electronic knee modules and electronic ankles in the Symbionic Leg. Water-proof bionic knees that have been developed today make it possible for user to engage in all other kinds of water activities. According to (Jia et al., 2019), power provision in prosthetic devices include innovation in energy harvesting rechargeable on-board battery system that have been incorporated with smart devices, sensors, power actuators and materials that make enable gait and condition monitoring in bionics prosthetic legs as shown in Figure 27 below.



Note. (Jia et al., 2019)

Figure 27. *The Evolution of Lower Limb Prosthetics*

According to the World Intellectual Property Organization, n.d.), there are more inventions and innovations that are taking place and more patent activities have been filed on emerging assistive technology with more than 117,209 just on conventional technology. As such, it is important for inventors to protect what they have created or provide intellectual property protection through patent filing as shown below.

Note. (Asif et al., 2021) and USPTO *(patent document US10624766B2)*

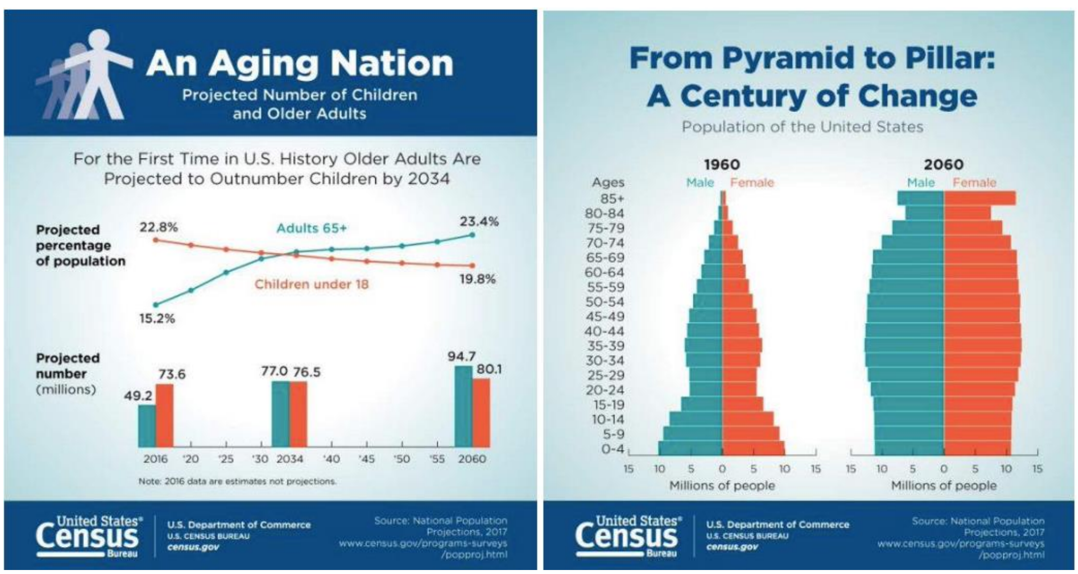
Figure 28. *Prostheses Patents: Passive, Active, Semi-Active, and Smart.*

Robotics plays a critical role in prosthetics even though it is complex compared to conventional prosthetic assistive devices. Within the robotic system, there are several other technologies that are integrated into the control systems making the robot complete. Lower limb robotic systems have a combination of different electronics, signal processors, modules, actuators, and other mechanical devices needed to improve mobility of the end user. Sophisticated computer models of the human body have been designed as the next generation that will determine the effectiveness of future robotic prosthetic devices. Advanced robotic prosthetic devices will likely impact how human interact computerized lower limb devices. It is possible that this may also impact the mental demand placed on prosthetic users however, acceptance of new technology is increasing becoming necessary and may not be an issue in the future.

Machine learning and modeling of various algorithms will continue to shape how we interact and interface with prosthetic devices in the future (Stephens-Fripp et al., 2020; Lipschutz, 2017; Price et al., 2019). 3D printed components make up some of the fabricated parts consumed in assembling robotic limbs due to light weight, prototyping, quick turnaround time and customization of the prosthetic product (Stephens-Fripp et al., 2020) ;(Azocar et al., 2020). This research study therefore posits that the 3D printing process and advanced materials play an integral part in the design and manufacturing of lower limb prosthetic devices.

Challenges experienced by individuals with limb impairment related using robotic devices include suffering from extreme discomfort resulting from device use. Example, robotic ankles are intended to improve mobility of amputees, but they can also be a Note of discomfort due to high internal socket pressures resulting in limited prosthesis use (Kennedy LaPrè et al., 2016). In some cases, robotic assistive devices can be cumbersome to use and can be frustrating to the user. Some of the annoyance that may be experienced from using robotic prosthetic devices can be due to their bulky size that can make them heavier and unbearable to use. In some cases, these devices can be noisy due to the motors that are built inside them, or they can also run out of energy when the battery is drained off.

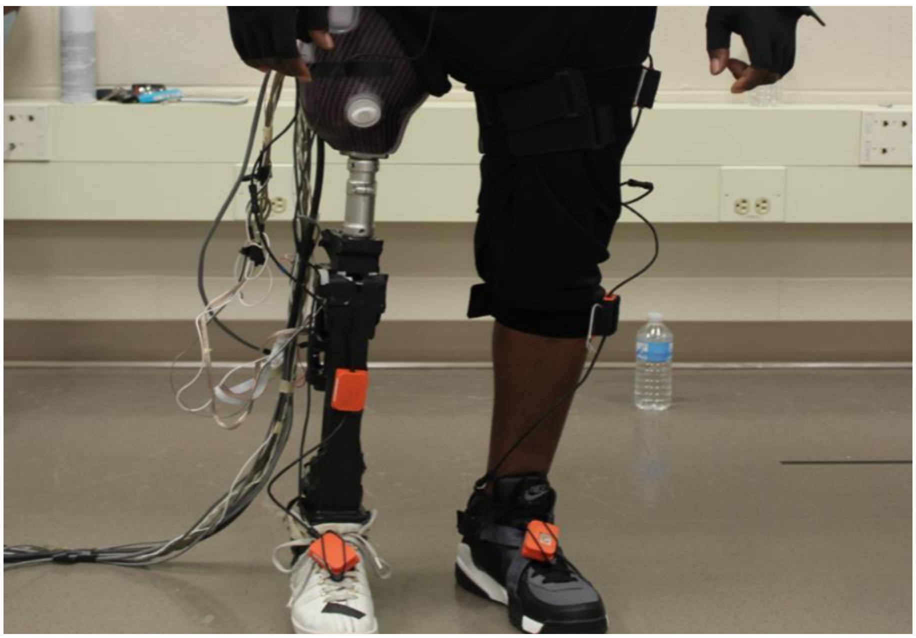
Future research must explore how to implement better hierarchical control of algorithms (https://www.nsf.gov/awardsearch/showAward?AWD_ID=1526519*)*. Even though lower-limb prostheses that provide power are currently being developed for younger users, they tend to be risky for older people due to their weight even though older people may still benefit from powered legs to help them get out of a chair if they are light enough to use while walking without affecting balance (Global Atlas of Medical Devices, 2020). Given that older adult tends to be more at risk, the design and manufacturing of lower limb prosthetics should be more inclusive to account for the projected older adults who are expected to outnumber their children by the year 2034 according to US Census report for 2018 shown in Figure 29.



Note. (US Census 2018)

Figure 29. *The Age Pyramid for the United States*

The market on Advanced powered prosthetic knee (APK) and those pertaining to ankle joints are increased due to the rising demand of exoskeletons. These medical technologies have been significantly assisted with the restoration of essential body functions that would otherwise render some individuals with limb impairment immobile and incapable of engaging in daily activities (Wendt et al., 2011). The design and development of exoskeletons is a complex process requiring repackaging of different electronics and control systems aimed at supporting motion around the hip and the knees. Exoskeletons are one of the most advanced robotics systems in the market and could benefit future development and studies in prothesis that this research aim at addressing. APK testing is depicted in Figure 30.



Note: Shipman & University, 2020.

Figure 30. *Advanced Exoskeletons Technology*

Even though powered lower limb prosthetics have been very beneficial in supporting mobility of amputees, they have also been known to cause accidents due to unexpected errors in the technology which may result to injury of the user including falling, stabling and may even lead to death in some cases. As a result, more research is still needed that examines exactly what happens when these technologies fail in order to identify gaps for developing a new generation of more robust powered prostheses (Shipman & University, n.d.). Contrary to this, there is a need to look at the benefit of alternative robotic systems such as those made from advanced materials and referred to as soft robotics. Shifting of the human mindset toward thinking about the capabilities that can be provided by soft robotics will benefit how we look at cost and weight as well as new ways devices can function while improving the quality of life of those individuals with limb impairment (Stephens-Fripp et al., 2020). Even though soft materials like polymers even though are in their early stage of use, they can be more beneficial to gripping, manipulation, traction, and many physical interaction tasks. Studies by Price et al., (2019) determined that sophisticated computer models of the human body have been designed are being designed as the next generation of robotics that will have an impact of prosthetic devices.

There is ongoing research and development of real time control of a powered prosthetic leg using implanted Electromyography (EMG) Signals with sensory feedback following a leg amputation because walking with a prosthetic limb is especially difficult. As such, robotic prostheses that provide power are being developed and may help people walk with less effort because, the onboard mechanical sensors will provide information to tell the prosthesis what to do at each stage of walking however, the user cannot easily tell the prosthesis what they want it to do (Real Time Control of a Powered Prosthetic Leg Using Implanted EMG Signals with Sensory Feedback, n.d.) Another new paradigm is being unlocked by neuro implantable prosthesis (also called neural prosthetics) that will focus on the development and interaction of artificial prosthetic devices with the nervous system to restore motion and mobility. Combining leg muscle EMG signals with mechanical sensor information makes the control system work better and feel more natural. This can be done by implanting special sensors (MyoNodes) into leg muscles to transmit EMG information wirelessly to a base station on the prosthesis (Burt, 2020; Limb Prosthetics Services and Devices, 2017).

The development of robotic powered prostheses with several built-in mechanical sensors have increased. More capabilities continue to be realized due to information and data gathered and analyzed using computer algorithm (Advanced Control Systems for Powered Prosthetic Legs, 2016) to recognize various patterns of sensor generated during gait to accurately control powered devices as shown in Figure 31.

Note: Robotic powered prosthetic leg using electromyographic (EMG) signals. (Advanced Control Systems for Powered Prosthetic Legs, 2016)

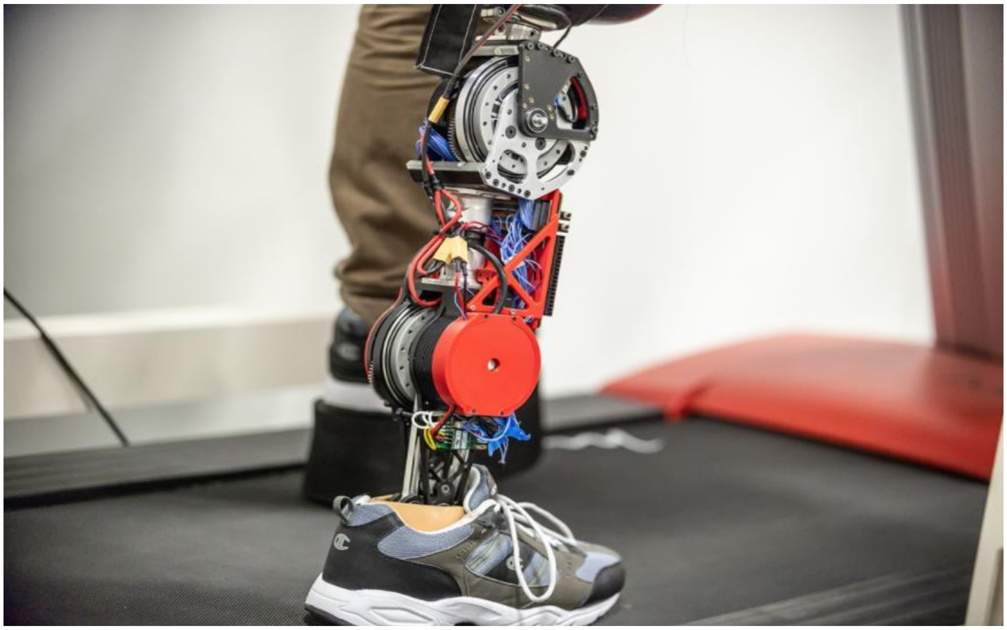
Figure 31. *Robotic powered prosthetic leg using electromyographic*

Lower-limb prostheses that provide power are currently being developed for younger users and tend to be riskier for older people due to their weight; however, older people may still benefit from powered legs to help them get out of a chair (WHO | Global Atlas of Medical Devices, 2020). Newly developed innovative powered hybrid Leg are known to be of lightweight and allows the device to change state from active power to passive power if battery is depleted. In the case that the actuators are damaged, additional safety radiancy will be provided by making the device passive. In the passive state, the device can still be used safely by the user from one location to the next. The advantage of hybrid leg is mainly provided by the light weight and the power option capability that is built inside it as shown in Figure 32 below (Intuitive Control of a Hybrid Prosthetic Leg During Ambulation, 2019).

Note: Intuitive Control of a Hybrid Prosthetic Leg During Ambulation, 2019.

Figure 32. *Hybrid Leg*

Other advances in lower limb prosthetic devices have been on development on the materials used for building lightweight low maintenance devices. Examples include those prosthetic limbs that have been designed and made with materials from the International Space Station. The design aspect of any prosthetic device can vary. Some prosthetic devices can be made to have motors built inside them while others may not require complex gadgets. Ultimately, it all depends on the intent of the device being improvised. Example of complex designs include the free-swinging knee with regenerative braking features with capability of being controlled a typical prosthetic; this limb has additional capability such as being able to recapture and regenerate its own energy with features allowing to store energy with tractions of the foot on the ground as shown in Figure 33 below.



Note: Moore, 2020.

Figure 33. *Prosthetic Leg Using Small Motors Courtesy of the International Space Station* (ISS)

There has been an increasing interest in the development lower limp prosthetic in pursuit of determine the most suitable materials. The overall objective is to find materials that are durable, lightweight and those that will provide the most comfort to the user. These efforts have resulted in testing and trying out a wide spectrum of novel ideas including using various materials from the space station as shown in Figure 34.

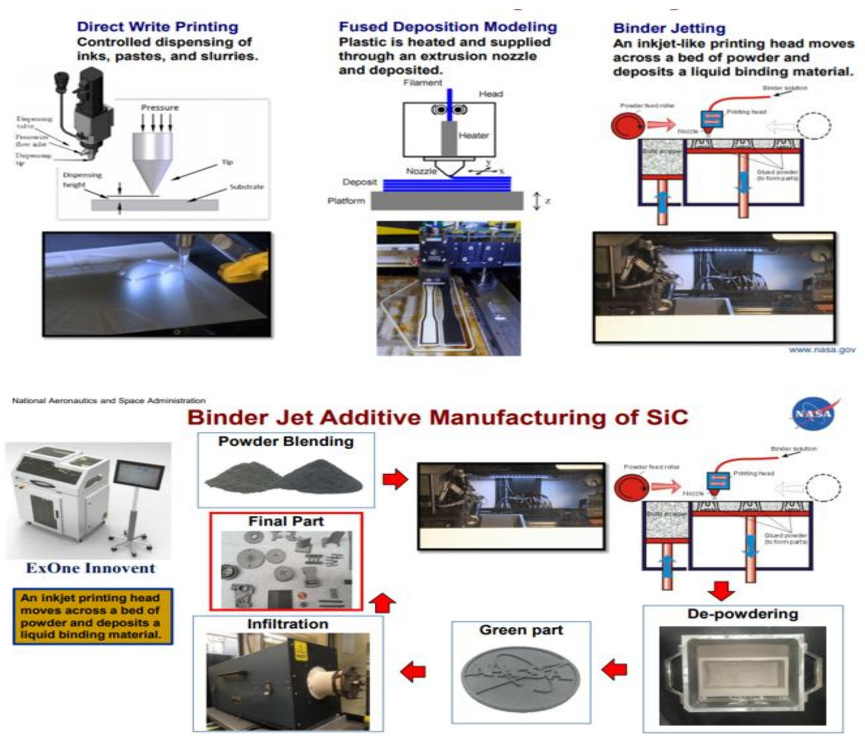
Note: Moore, 2020. World Economic Forum.

Figure 34. *Parts from the International Space Station*

The advances in prosthesis devices can also be largely attributed to the presence of myoelectric which provide the Note of control signals. The first of these signals were first time by Battye et al. in 1955 however the application and use of these pulse for electric stimulation and to test the feedback signal in 1970 (Kato, 1978). Today most amputees dream of being able to control their limbs the way that others do, without even really thinking about it which has been made possible through myoelectric control systems according to Overman (2017). There are several ongoing research in neuroscience where scientists trying to improve how brain signals travel down the nerves and control limb movement to optimize bionic prosthetic limbs (Overman, 2017; Rapp et al., 2019).

2.15 Additive Manufacturing (AM) 3D Printing

3D printing resulted from 2D printing. Whereas 2 D printing subtracts materials from the object, the 3D printing is achieved by adding layer of materials to an object and is easier to customize when fabricating assistive technology products (Wendt et al., 2011; Researchers Explore 3D Printing to Help Vets with Disabilities, 2016). 3D printing or additive manufactured parts generally tend to be static and inanimate except for but they can also be tricky to work around with especially when creating functional parts such as the joints or hinges and event be ball socket in a lower limb prosthetic device that require encapsulated bearings (Pie, 2014; Bell et al.,2017). Today, there are different ways of performing 3D printing which have been brough about by increased technology and innovation as shown in Figure 35.



Note: NASA | Halbig, 2019.

Figure 35. *Different Ways that AM Technologies are Applied in Manufacturing Products*

In the past, designing and fabricating prosthetic devices used to be daunting and challenging task due to limitations of using two-dimension (2D) manufacturing process, however, the evolution 3D printing methods have added more capabilities in the industry making it possible to innovate and create novel items that were in the past imaginable to the mind. The increased possibilities provided by 3D printing has made it possible to manufacture complex parts (Nycz et al., 2019)

The American Society for Testing Materials (ASTM) International Committee defines 3D printing as "the process of joining materials to make objects from three-dimensional model data, usually layer upon layer, as opposed to subtractive manufacturing methodologies, such as traditional machining" (2017).

Several researchers support that additive manufacturing is one of the newest technologies in the medical market (Martinez-Marquez et al., 2018; Bell et al., 2017). It should be noted that the concept of 3D printing was largely driven by the advancement of three key areas: software, equipment, and people (*3D Printing's Impact on the Value Chain | White Paper | Stratasys Direct*, n.d.). Understanding the impact of new manufacturing practices such as 3D printing is therefore of significance even in the field of prosthetic limbs and will benefit individuals with limb impairment given that various products will result from this novel technology.

Additive Manufacturing (AM) uses terms such as "Rapid Prototyping," "Solid Free-form Fabrication," and "Three-Dimensional Printing." AM Technology is one of the key areas in the Advanced Materials (Jin et al., 2017). This being the case, AM fits well in the definition of Megatrends technologies which are referred to by OECD and those technologies have an impact on a large-scale (OECD, 2016). According to recent studies (Bell et al., 2017), however, most 3D printing is still relatively a new technology that threatens to turn manufacturing on its head. As a result, there is a need to not only address complex problems associated with the end user experience but also to change policies to influence an industry wide standardized approach when designing, manufacturing, and releasing of prosthetic assistive technology devices for use by individuals with limb loss and limb difference. 3D printing can be achieved in various forms. I was able to summarize and compile various forms of 3D printing by showcasing the advantages and limitations as shown in Table 5.

Table 5

Types of 3D Printing, Advantages, and Limitations

Summary of 3D Printing Methods		
Printing Technique	**Summary of Advantages**	**Limitations**
Selective laser sintering (SLS)	Can be highly utilized with wide range of printable materials. Is powder based which can be re-used. Provides clean finished structure	The internal structure is porous with rough surface finish requiring post printing process to be accomplished.
Selective laser melting (SLM)	Can adjust properties while printing. The cost is low, easy to assemble and utilize with good mechanical properties.	It is expensive and relatively slow.
Laser direct metal deposition (LDMD)	localization of heat making it possible to print metals with high melting point. Provide good fabrication for gradient materials and shaped parts	Has poor surface roughness with low dimensional accuracy
Selective electron beam melting (SEBM)	Provides high density for printed parts and higher strength. Can be used for brittle materials and had the ability to produce multiple parts simultaneously.	Requires vacuum environment and had poor surface finish which requires post printing process. It is also expensive with low dimension accuracy of the part.
Laser-induced forward transfer (LIFT)	Easy to operate and does not require vacuum or clean room environment. Can produce very small-scale part processing and allows for a wide range of printed materials	Limited to small batch production and small size parts with thin layer resulting in weak structural support.
Atomic diffusion additive manufacturing (ADAM)	Provides high quality with excellent surface at low cost. Capable or precise printing on of complex structures. Great performance and permits batch production.	Require long lead time to produce parts.
Nanoparticle jetting (NPJ)	Provides high speed at a low printing cost. It is simple, safe to operate with resultant of a high-resolution product and good surface finish.	Product temperature tolerance is lower
Inkjet 3D printing (3DP)/binder jetting	Safe to operate and provide low cost and safe printing capabilities.	Has poor surface quality with low precision.

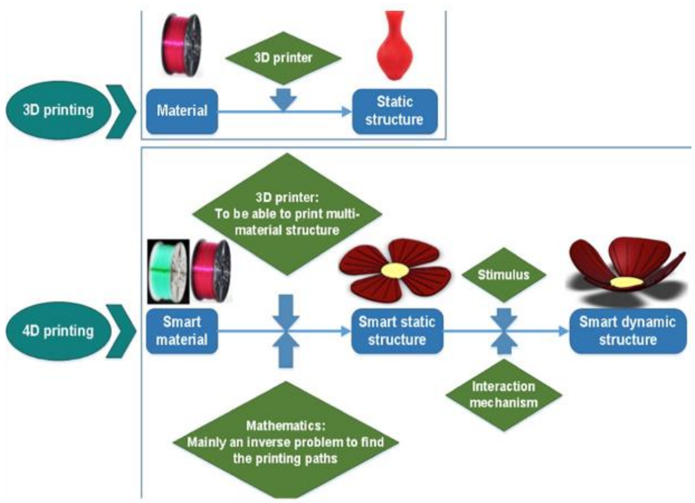
Note. Compiled by this researcher with credit to Wang & Yang, (2021)

2.15 Advance Materials 4D Printing

4D printing are revolutionary technology analogous to 3D by adding a fourth dimension that permits preprogramming of objects with respect to their response to various stimuli such as light, temperature, and so on (Deshmukh et al., 2020). The combined technologies will continue to unlock novel and innovative opportunities in the manufacturing process of lower limb prosthetic devices for individuals with limb impairments. Both 3D and 4D printing can be used for manufacturing prosthetic devices for lower limb amputees. The emergence of new technologies, especially those associated with the 4th industrial revolution (digital tools) play a significant intervening role that influences the modernization of the manufacturing process.

The concept of 4D printing came about because of Skylar Tibbits, a research scientist at MIT university who was challenged to find out if it was possible to make an object without relying on sensors or chips or how fluid could make something without wires or motors (Rieland, 2018). This resulted in the creation of the MIT Self Assembly Lab. According to MIT research scientist Tibbits, 4D printing allows the user to create objects that could change their shape (Tech Insights, 2016).

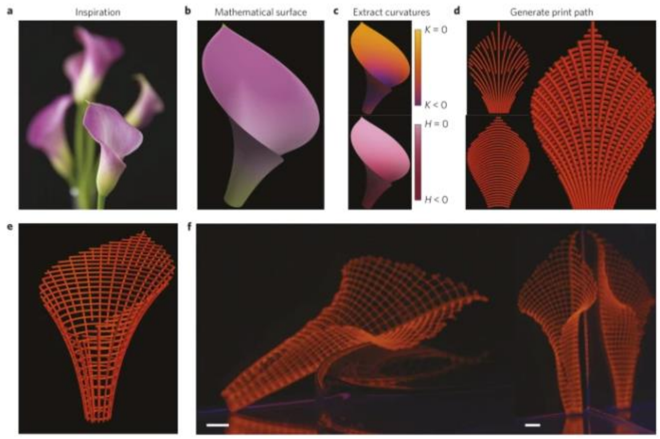
The 4D printed parts will advance medical industry and provide additional technological making it possible to treat various body deformities such as those associated spinal injuries, fracture fixation, joint, knee replacement and other related orthopedics applications (Javaid & Haleem, 2020). Figure 36 illustrates the difference between 3D and 4D printing.



Note: Deshmukh et al., 2020.

Figure 36. *A Review of 4D Printing in Comparison with 3D Printing*

The 4D printing process involve harnessing of continuous and a very detailed control that takes place over the print path that are predicted by models making it possible to mimic complex curvature while forming different shapes (Gladman et al., 2016) such as those shown of the native calla lily flowers in Figure 37.



Note: Sydney Gladman et al., 2016

Figure 37. *Predictive 4D Printing of Biomimetic Architectures.*

In summary, both 3D and 4D printing can be used for manufacturing prosthetic devices for lower limb amputees. The emergence of new technologies, especially those associated with the 4th industrial revolution (digital tools) play a significant intervening role that influences the modernization of the manufacturing process (Tech Insights, 2016; Pie, 2014; Momeni et al., 2017). Advances in material science will continue to shape the future of lower limb prosthesis devices. This is important in this research study because watching the trends of material advances will help to define how future lower limb prosthetic devices are made. Material science will also define the quality of life experienced those who depend on limb prothesis devices to conduct daily activities.

2.16 Quality Control, standardization, and Regulations

Quality control and standardization are integral when dealing with lower limb devices because they directly relate to safety issues that could impact individuals with limb impairment. There are various challenges that have been noted relating to standardization. Most notably, the current standardization methods that are continually applied to traditional manufacturing process are not all suitable or fully compatible when dealing with new advance technology such as the 3D printing. The main reasons include the various ways that each method achieve or produce the final product. In the case of 3D printing which adds layer of material to an object may require different approach than the 2D printing that subtract layer of materials to obtain a final product. According to (Martinez-Marquez et al., 2018), it lacks standardization and requires better quality control processes.

The other noticeable difference between 2D and 3D printing process is 3D require more customization making it challenging to do a mass production of various products such as those pertaining to lower limb prosthetic devices that tend to experience high variance across the demographic needs of individuals with limb impairments. Given that advances on technology have been moving at an accelerated pace, it has been equally challenging for regulations to cope up with new changes. Some of the notable challenge faced by regulatory bodies include those related to new product safety assurance and quality control (Bell et al., 2017) ;(Martinez-Marquez et al., 2018).

Another area of challenge involves the lack of design tools, qualification and certification control requirements. This is because of the increase level in process variability and continued lack of stable industry standards (National Academies of Sciences, 2017). According to the Department of Robotics, Michigan State University, studies in amputation are fragmented with retarded progress compared to other technological and innovative ventures (Open-Note leg, 2019).

Emphasis on quality controls in the development of quality and safety standards for future development of reliable prosthetic devices is important. The application of a Quality by

Design (QbD) approach can help to ensure that products are designed and manufactured correctly from the beginning without errors variations (Balk et al., 2018). The concept of QbD was first created by Dr. Joseph Juran to increase the level of quality during the design and build process of a product and service delivery has been widely used in the industry. The success of QbD resulted in it being adopted the US Food and Drug Administration (FDA) and the primer for their quality process.

Quality control requires consistent standards to match or exceed perceived quality expectations. The build design requirements are therefore expected to be within allowable tolerance and specification to meet defined quality standards. 3D printing is however faced with many challenges. Amongst those challenges that may impact standards and quality include the product durability as a result of environment, variance in material and due to limitations imposed by printing standards (Zuniga et al., 2016) ;(Wang & Yang, 2021) ;(Martinez-Marquez et al., 2018).

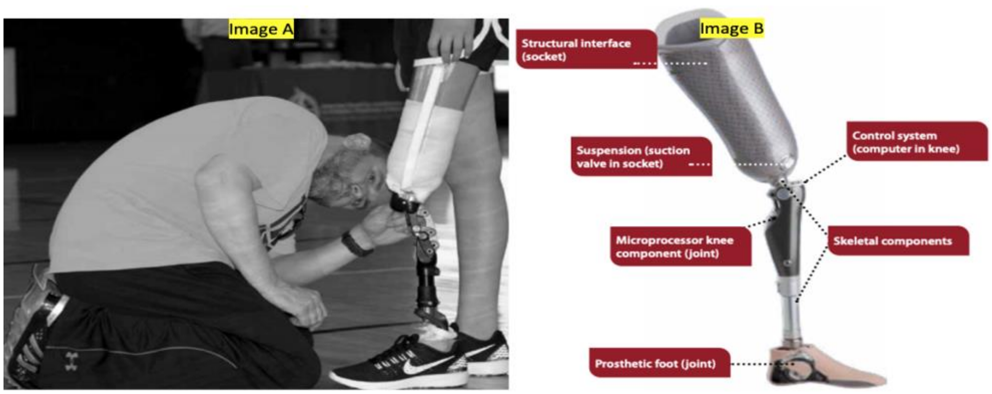
2.17 Rehabilitation and Support

Losing part of the normal body function can derail various normal activities impacting even basic duties and these extraneous circumstances can lead to paralysis and is some cases the patient may not only experience weakness in their muscles but also loose the required coordination to be able to walk again. There are various injuries that can occur to central nervous or musculoskeletal systems of the body that can render one to be disabled and even be bedridden resulting in high reliance on others for support. Having the ability to receive rehabilitation care can be of great benefit to those people who have been fitted with lower limb prosthetic devices or have been amputated.

To receive rehabilitation care means that one can be fitted with prostheses, and various adjustment of devices may be required. Recent research indicates that quality of life may be the same in individuals with partial foot and below-knee amputation requiring more research to drive confidence in the advising people facing difficulty with decisions about lower limb amputation (Studies Seeking Limb Loss Participants, Amputee Coalition, n.d.).

According to (Cutti et al., 2019) prosthetic rehabilitation treatments are expected to double by 2050 and the number of limb loss is expected double by the year 2050 to 3.6 million (Extrapolations: CDC, 2015). This information is important in the studying of trend in technology associated with lower limb prosthetic devices. The projections provided are leading indicators that the demand for lower limb prosthetic devices will continue to go up in the future and researchers need to find innovative ways to address the needs of individuals with new technologies that are on the horizon. Additionally, future utilization of new technologies such as virtual reality will complement prosthesis training by improving the functionality of the missing body part (Phelan et al., 2021).

Individuals with lower limb impairment can benefit from rehabilitation services after being fitted with mobility devices because they face different challenges such as having a device that is too heavy, uncomfortable, takes too long to put on and take off. Lower limb prosthesis can cause too much fuss resulting in unbearable pain to the user that is why it is very important that lower limb devices are to provide high level of comfort while still being reliable so that the user does not have to change or go through various devices in during the day. Even though individuals with lower limb impairment may outgrow their devices due weight or age requiring them to be re-fitted, it is important to understand these series of iterations between care, rehabilitation and equipment fitting can take a remarkable toll on the person experiencing disability resulting in high level of frustration and difficulty coping or adapting or even being grumpy and noisy depending on the situation or circumstances (McFarland, 2010). Figure 38 below shows a patient being fitted with a lower limb prosthetic device.



Note: Rehabilitation for Improving Patient-Centered Outcome (Image A) and Composition of a Prosthesis (Image B) (Limb Loss Task Force White Paper, 2019).

Figure 38. *Rehabilitation for Improving Patient-Centered Outcome*

2.18 Cost of Prosthetic Devices and Device Accessibility

Traditional fabricated or conventional manufacturing process tend to be slow and costly. The end-product may also be uncomfortable to the end user compared to those that have been made using advanced methods such as 3D printing made from 3D scanned images. The modern method of designing and fabricating lower limb prosthetic devices is less costly and easy to adjust to precision. 3D printing capability make is possible to for the application of reverse engineering techniques such as 3D scanning followed by rapid proto typing. These capabilities make it possible to capture stump’s size and shape and have a digital 3D model for manufacturing prosthetics sockets and other parts within a short period of time therefore saving time, cost and labor while still being able to provide better contact between prosthetics and the patients lower limb (Benabid et al., 2019; Cruz et al., 2020; Ribeiro et al., 2021; Vickers, 2019)

Even though 3D printing provide a lot of insight into various capabilities of the technology, not all researchers agree that it is cost effective not nor that the materials are superior compared to those fabricated through conventional methods. A study by (Kate et al., 2017) comparing 58 devices specifications and kinematic based on 3D printing methods determined that some user acceptance, functionality and durability of the 3D-printed prosthetic devices was lacking. As a result, more research and work are still needed in this area. Despite technological advances in 3D printed prosthesis, improvements in the functionality of these devices are lacking and needed (Schwartz et al., 2020; Zuniga et al., 2019).

The price point of prosthesis has continued to remain high despite new advances. This is partly because of high customization and very low mass production of lower prosthetic devices. A study by (Blough et al., 2010) found that cost depends on three main characteristics namely, the type of prosthetic device, level of limb loss, and the functional capability of the device. On an average, below-knee amputation costs Medicare $81,051 per person less the cost of caring for professional nursing at home estimated to be $100,000 per year. Basic artificial limbs may have insurance cap restrictions as low as $2,500 or less a year while the cost for limb prosthetic devices allowing patients to stand and walk on level ground vary from $5,000 to $7,000. On an average, lower limb prosthetic devices range between $5,000 and $15,000 (Limb Prosthetics Services and Devices, 2017).

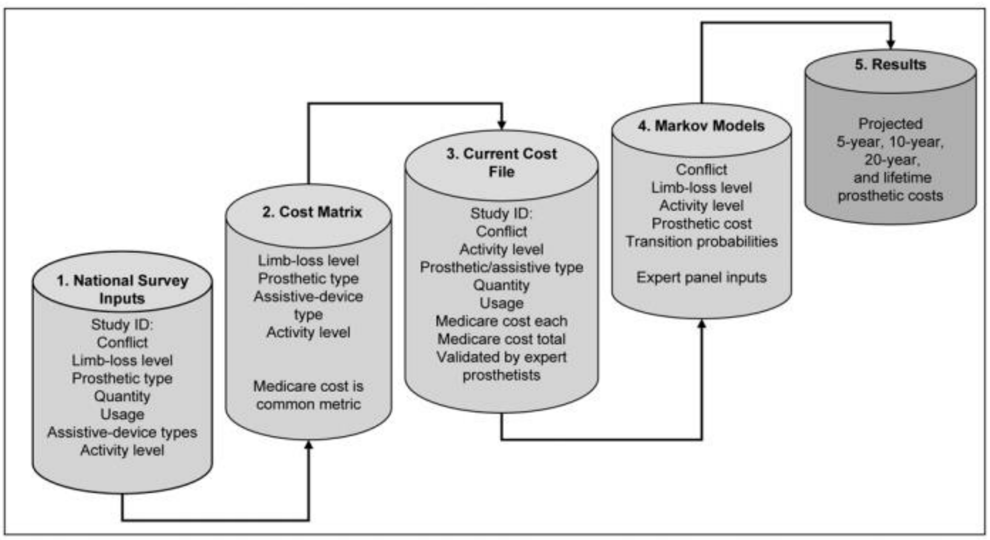
Given that the average number of people who go through amputation in the United States is about 185,000 annually (Limb Prosthetics Services and Devices, 2017) There are opportunities to leverage on 3D printing technologies to improve prosthesis devices, reduce cost, make it affordable to users to change devices more frequently without incurring or worrying about affordability while going through pain and suffering with low quality of life due to amputation limb difference. This is unlike in developing countries where the availability of assistive technology largely depends on people having the funds; otherwise, they must rely on government assistance or receive donations from donors (Toolkit on Disability for Africa | DISD, 2016).

Regardless of location, individuals with lower limb impairment should benefit from 3D printing capabilities such as those exemplified by Agile Orthopedics in Colorado whose model is based on Uber framework focused on bringing/taking convenience to those in need. Their mobile clinic is fitted with 3D scanners, making it possible to perform complete evaluation of the patient to provide them with 3D printed prosthetic device with close collaboration with physical therapist to ensure the prosthetic fits the patient's daily needs (Greenhalgh, 2019). Such a model would not be possible with conventional fabrication processes. A Statewide or national scale adoption of this model would be ideal but challenging.

The level of satisfaction with the provision process of assistive devices has been low due to poor or low in many parts of the work including in advanced countries. Poor services also include those associated with rehabilitation, poor process of purchase, and poor accessibility of prosthetic devices (Poonsiri et al., 2020). The impact of poor service provision has resulted in only one third of those who have had limb prosthesis receiving prosthetic device. This number is remarkably low compared to the demand and needs that many individuals with lower limb impairment have.

According to a whitepaper compiled by the limb loss task force, differences in technologies and payer perception have a major impact on the overall cost of prosthesis devices and the quality of life of users. For example, the cost of hydraulic and microprocessor knees and feet can drive up a two- or three-fold increase in cost which payers are not willing to meet due to the perception that patients with limited mobility also have a shorter life expectancy, so, a higher investment for a shorter amount of time may not be worth it. The task force proposed that there is a need to investigate less expensive technologies that are smart technologies developed for this type of population as a priority (Limb Loss Task Force, 2019).

3D printing innovation integrated with other IoT may play a greater role as a result but, to some degree, it is quite difficult to evaluate whether a new medical device offers any advantages, and what those advantages are (Martinez-Marquez et al., 2018) given that technologies have not fully matured, and some have not completed their full lifecycle. As a result, it is still beneficial to capitalize on existing knowledge and continue innovating while advancing 3D printing capabilities in support of lower limb prosthetic devices in the future. A depiction of costs for prosthetic and assistive devices is shown in Figure 39.



Note : (Blough et al., 2010).

Figure 39. *Steps for Projecting Costs for Prosthetics and Assistive Devices after War*

The continued integration in the application of emerging technologies has led more interest in neuro-prosthetic limbs which can cost nearly $100,000 per limb (Limb Prosthetics Services and Devices, 2017). The nature of war continues to change due to new technology trends and innovations including in the making of future soldiers. Technology has continued to unlock several capabilities including the advances in the development of human augmented technologies which has been largely based on a wide range of human domains such as those that pertain to physiological as well as those that are focused on the cognitive and social aspect of the human needed to increase interaction with robotic exoskeletons, smart textiles, drugs, and seamless man-machine interfaces (NATO Science & Technology Organization. (2020) as shown in Figure 40.

Note. NATO Science & Technology Organization, 2020; credit: US ARMY/DARPA

Figure 40. *The Future Soldier*

Looking at Central African Republic (CAR), the country relies heavily on international donation or external donors such as the International Committee of the Red Cross (ICRC). The donation comes in different forms but are also needed for funding for materials, training, and salaries. Having local the presence of local prosthetics workshop such as the one in central Bangui tin helpful for repair, fabrication and provision of prosthetic devices as shown in Figure 41.

Note: (Bangui, 2019).

Figure 41. *A Central African Republic Clinic Making Artificial Limbs*

2.21 R&D in Advanced Manufacturing and Materials

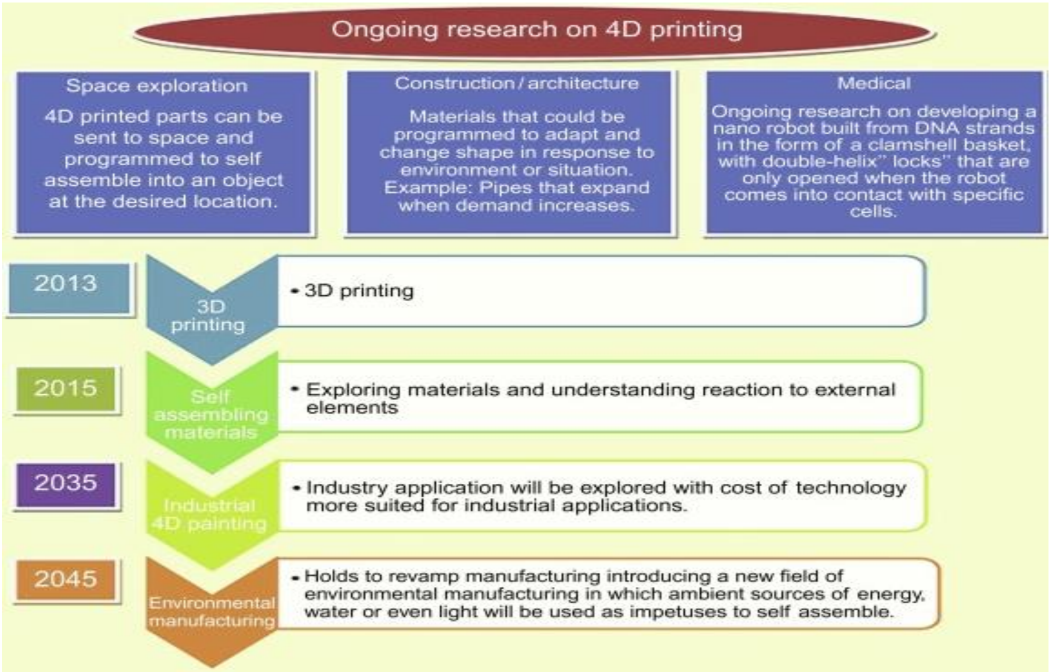
The convergence of technologies is enabling industries to do things that were considered uneconomical or even impossible a few years ago (5 Hot Trends to Watch at the Additive Manufacturing Users Group Conference - ABI/INFORM Trade & Industry - ProQuest, 2016). Application of AM is widespread in the aerospace field, medical field, building industries and so on. Collaboration between industries and research institutes is key for the advancements of AM. Leading research centers such as NASA need to increase their knowledge and understanding of the materials, processes, analysis, inspection and validation methods for AM parts, standardization development of qualification and certification methodologies including property validation, computational materials, and Process monitoring Vickers (2019). To-date, UNESCO is concerned about limited innovation hubs for emerging technologies (UNESCO Science Report, 2015).

A look at the American Society for Testing Materials (ASTM), I was able to determine that ASTM in continuing to establish standards in AM to ensure that this emerging technology remains safe. On the other hand, the NIST lab continued to maintain their focus on measurement of additive manufacturing and on the performance of robotic technologies applicable to advanced manufacturing (National Academies of Sciences, 2017a; Jin et al., 2017). It is with recognition that the growing need for lower limb prosthesis and the ongoing work that the health communities, manufacturing institutes, and research centers are on the increase and the breadth of knowledge around AM will continue to grow as it continues to define the state of the art and future of AM technologies (Vickers, 2019) as shown in Figure 42.

Note: Vickers, 2019.

Figure 42. *Manufacturing Institutes Involved in AM Technologies*

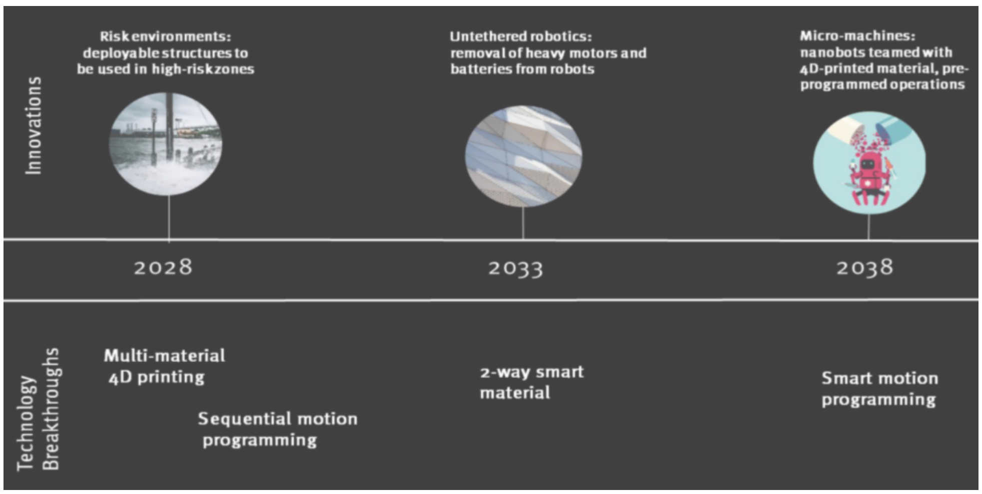
The application of 4th Industrial Revolutionary tools such as 3-D printing, 4D printing, self-assembly materials including bioprinting, artificial intelligence will continue to define the future of lower limb prosthetic devices as shown in Figure 43.



Note: Deshmukh et al., 2020.

Figure 43. *Continuing Research: 3D and 4D Printing*

Looking into the future, studies have projected that by 2028 4D printing could be used to produce deployable structures. Additional projects stipulate that, by 2033, two-way smart materials could be created and ultimately the creation of nanobots by the year 2038, as shown in the Figure 44 below (The 4D Printing Revolution Is Upon Us, 2017). Figure 44 presents a glimpse of future directions for 4D printing.



Note: *The 4D Printing Revolution Is upon Us*, 2017

Figure 44. *The Future of 4D Printing*

CHAPTER 3. METHODOLOGY

3.1 Overview

This chapter presents a discussion of the research methods and the procedures by which the study was undertaken. This chapter discusses research design, how the data were collected and analyzed, and ends with a chapter summary.

3.2 Ethical Considerations

Precautionary measures will be undertaken to protect the integrity of this research study. I sought approval from Purdue University department of leadership innovation and technology to conduct this qualitative trend analysis. Ethical research means there was no attempt to distort or misrepresent the data or findings and everything was recorded and reported as truthfully as possible (Sekaran et. al., 2016). In preparation for this study, I completed training offered by the CITI program on responsible conduct of research (RCR) and human subject research administered through Purdue university.

I followed strict protocol and adhered to the academic guideline and requirements throughout the study. Given that most data collected for this study were generated from online databases and other electronic data Notes, I followed APA formatting guidelines and cited all notes that were used in the study. I respected the rights of authors and paid appropriate attributions to them. Permissions were sought for certain contents for the study that needed to be downloaded for analysis. Credits for content were awarded throughout this study for articles and journals used.

3.3 Rationale

Current estimates are that nearly two million adults and children in the United States were either born with limb defects or underwent amputations later in life (https://www.amputee-coalition.org). According to a recent report from the Amputee Coalition in concert with the CDC (Centers for Disease Control), perhaps as many as 28 million adults and children in the United States may need to undergo amputations of arms or legs in the next thirty years. It is estimated that more than ninety percent of these will be elderly citizens (Limb Loss Task Force/Amputee-Coalition.org, 2019). The CDC reported that for every 1900 children born in the U.S., one or more will have a noticeable limb defect in the arms or legs or in some cases, both extremities (CDC, 2019).

In a recent federally funded study, researchers concluded that approximately 4.7 million adults and children who have stroke, and multiple sclerosis, would greatly benefit from the uses of active lower-limb exoskeleton prostheses. (https://www.nsf.gov/awardsearch/showAward?AWD_ID=1526519). The same study predicted that by 2050, less than thirty years from today, more than 1.5 million adults and children in the U.S. will undergo lower limb amputations (https://www.nsf.gov/awardsearch/ showAward?AWD_ID=1526519).

In examining the high cost of prosthetic devices today, Cutti, Lettieri, and Verni, (2019) predicted the gap would widen and deepen between what was possible and what was sustainable. There is a growing need to investigate the impact of the emerging technologies such as 3D printing, 4D printing, advanced manufacturing practice, and robotics on design and manufacturing practice of prosthetic devices fitted for individuals living with lower limb loss or impairment. 3D printing was found to be widely used in nearly all lower limb prosthesis devices due to its capability for creating affordable and usable prostheses (Wendt et al., 2011, Nickel, Barrons, Owen, Hand, Hanson, 2020, Zuniga et al., 2016). This study investigated emerging trends in technology, specifically robotics and 3D/4D printing of prosthetic devices which have had a great impact on individuals with limb impairment or limb loss.

3.4 Research Design

This was a qualitative study using an historical approach and a modified qualitative trend analysis to examine past, present, and future trends in technology-enhanced prosthetics. The research design enabled me to capture data from various secondary Notes and systematically analyze each item for its relevance to this study. According to Sekaran & Bougie (2016), research design serves as a roadmap or purposeful plan of action for collecting and analyzing data that will enable the researcher to answer research questions. It is “a logical plan for getting from here to there, where here may be designed as the initial set of questions to be answered and there is some set of conclusions (answers) about these questions" (Yin, 2009, p. 20).

Developing an appropriate research design was an important of this study because if provides guidance of the process to be followed in collecting the desired data and how that data should be analyzed. The “general principle is that the research strategy or the methods or techniques employed must be appropriate for the questions you want to answer” (Muehlenfeld & Roberts, 2019, p. 13). Qualitative research is exploratory.

I reviewed hundreds of journal article, websites, research studies, patents, and book chapters focusing on lower limb assistive technology manufacturing and healthcare practices were reviewed which formed a significant part of the qualitative element of this study. The literature review provided the much-needed background for the analysis of the state of the art of technology trends, gap design practice and policy, as well as the evolution of prosthetic devices.

I used a constructive research approach for the elements of this study that involved engineering and manufacturing practices involved in lower limb prosthetic development. Constructive research methods provided a systematic approach to conducting the research (McGregor, 2018). I followed a six-step phased approach in conducting this study, following a table developed by McGregor (2018, p.11).

Phase One: Finding relevant practical problems with strong research potential (McGregor, 2018, p. 11)

I conducted an extensive literature review that comprised several hundred articles, research studies, websites, and patents on 3D/4D printing, lower limb prosthesis devices, emerging technologies that intersect with advanced manufacturing practice such as 3D scanning, robotics etc. to determine existing gaps and research opportunities before moving into the second phase to explore the trends of technology and innovations needed to address the unmet needs of individuals with lower limb impairment.

Phase Two: Obtain a general and comprehensive understanding of the topic (McGregor, 2018, p. 11)

This required disciplined understanding of current status and analysis of existing research work and industry practice on prosthesis, lower limb loss, 3D printing and advanced manufacturing practice, policies and regulations governing the holistic body of knowledge in medical device industry. I conducted a comprehensive literature review of past, present, and future advances in assistive technologies and in particular, lower limb prosthetic devices.

Researchers, such as Azocar et al., (2020), have posited that the design and building of prosthetic devices is not standardized requiring more work in the to address the prevalent gap.

Phase Three: Innovate (i.e., construct a solution idea) (McGregor, 2018, p. 11)

I explored technological trends in lower limb prosthetic devices to uncover possible solutions and innovations to address the unmet needs of individuals with lower limb loss or impairment. The innovative solutions proposed for this study was based on fore-sighting future technologies prosthetics given that few studies have fully engaged the novelty of 4D printing of prosthetic devices despite the perceived benefits that it would provide even though several researchers attest that this novel technology has not yet matured (Wang & Yang, 2021; Ratto et al., 2021).

Phase Four: Demonstrate that the solution works (McGregor, 2018, p. 11)

I explored how the application of foresight tools could be applied to predict future trends in prosthetics assistive technologies and lower limb prosthetic devices.

Phase Five: Show theoretical connections and the research contribution of the solution concept (McGregor, 2018, p. 11)

I proposed possible solutions and directions for future research that would enhance knowledge in academia, industry, and organizations interested in innovations in assistive technologies and especially lower limb prosthetics.

Phase Six: Examine the scope of applicability of the solution (McGregor, 2018, p. 11)

This exploratory study examined past developments in assistive technologies, current use of prosthetic devices, and future trends and advancements in technology-enhanced prosthetic devices, particularly focusing on lower limb prosthetic devices. The findings in this study may have industry-wide applications and may lead to more sustainable solutions in the future for the research and development of assistive technologies and greater global access to technology-enhanced prosthetic devices in the future.

3.5 Qualitative Methodology

This research study combined an historical research design with qualitative trend analysis to examine, past, current, and future trends in assistive technology innovation. I began with in-depth analysis of literatures peer review literatures and patent filing analysis to gain insight into the trend of emerging technology associated with lower limb prosthetic devices. I used secondary Notes coming from academia, business and industry, science, health care, technology and engineering, law, and government agencies and organizations. I reviewed hundreds of articles, journals, government reports, white papers, conference materials, and patents. I also reviewed nearly one hundred authoritative websites, such as the National Library of Medicine, Center for Disease Control and Prevention, the National Science Foundation database, PubMed, Web of Science, Scopus, JSTOR, Amputee Coalition, CINAHL EMBASE, U.S. Department of Education, U.S. Department of Labor, Congressional laws and statutes, U.S. Patent and Trade Organization, and more.

The internet and the use of search engines made it possible to have access to unlimited articles and publications that enriched this study. Some of the terms used included 3D printing, additive manufacturing, prosthesis, amputation, amputees, lower limb differential, bionic, orthotics, artificial legs, limb implant, leg disability etc. Textual documents reviewed included journals, peer reviewed articles, research studies, theses, conference proceedings, unpublished manuscripts, reports, newspapers, google scholar peer reviewed documents, and various databases. I also watched YouTube videos to gain insight to the study problems and to the research questions posed.

Key benefits of qualitative data include access to unlimited Notes of information which is also a great tool for textual information gathering. Other advantages of qualitative methods include the ease of creating content or generating new contents. These content ideas can be turned into data to create value for the study. The flexibility of qualitative methods makes it easy to follow-up on any missing information, therefore increasing accuracy in data collection. In this context, I relied mainly on internet Note and was able to retrieve sufficient data for the study while also reading through various reviews.

The disadvantage of the qualitative method is due to the burden of analyzing data from various Notes (Sekaran, 2003). In some cases where face to face meeting is required but not practical in cases of Covid-19 pandemic due to safety measures. Another challenge of this qualitative method involves research interpretation which can be affected by research bias and subjective interpretations of findings. However, my experience in this research area is equally important. As an engineer, I was able to rely on some of my expertise in engineering and manufacturing in evaluating emerging trends in technology and innovation of prosthetic devices.

Another disadvantage of qualitative methods is that there is a potential data loss which can impact the accuracy of the results. In my case, most data were downloaded into my computer and backed up in the college server. The challenge of losing data was therefore mitigated. I was able to extract the required data for study and analysis throughout the phase of this research. The other downside of this type of method is that bias can be introduced in the study or influenced by the researcher themselves either consciously or unconsciously. Finally, the results and conclusion may not be readily accepted due to lacking statistical and supportive data from the study even though the effort for the research itself was laborious and time consuming.

3.6 Qualitative Data Analysis

Qualitative data analysis is an "inductive and systematic process of coding, organizing the data into categories, and identifying patterns (i.e., relationships) among the categories" (McMillan & Schumacher, 2006, p. 364, cited in Opondo, 2016).

Data were downloaded into a Microsoft Excel spreadsheet. I then categorized the data and establish key filters in the data field columns. Patent data was derived from searches of patents on the United States Patent Office (USPTO) website (https://www.uspto.gov). Patent analysis for this research was critical in identifying some of the emerging trends in technology associated with lower limb prosthetic devices. Date ranges were set, and data were categorized into various technology types and limb sections. The lower limb is comprised of various sections such as the thigh, knee, foot, ankle, and so on. The types of patents were further classified as active prosthetic, semi-active or passive for a more detailed analysis. The analysis included filtering through to identify which institutions were most interested in patent filing and filtering down to the individual patents that were filed to really establish the basis for specific elements driving new trends in technology. A similar analysis of patent filing trend was completed from the Google patent database.

The third data analysis was done on literatures identified for this study. Data was downloaded from the main Notes and main themes established. I established admission criteria for articles and journals that would be admitted into to study. Duplicate data were deleted and those articles journals that did not meet the established criteria were also dropped. Classification of data was completed with main themes established for each in support of the study. Upon completion of analysis, graphs and charts were used for presentation of the data results presented from the data in a readable and understandable form (Creswell, 2007).

The last part of the study involved using a modified qualitative trend analysis which resembles a comprehensive SWOT analysis technique. SWOT stands for strength, weaknesses, opportunities and threats (SWOT). This was achieved by looking into Social, Technological, Economic, Ecological and Political (STEEP) factors pertaining to emerging trends in technology associated with lower limb prosthesis.

3.7 Reliability and Validity

For this study, content validity was measured based on the impact an article had on the industry and level of accepted reviews or citations. This ensured that the articles admitted for the study had adequate representation and were a representative set of various views of researchers on specific topic area or concept. Some examples of content used in this study included reports from various consortiums including those from NASA and World International Patent Office whose reports have been utilized for policy change. Content that involved patents used in this study were considered reliable because filed patents come from a verifiable and reliable Note. Another example of Industry reports utilized in this study included those from NASA Technology Readiness Level (TRL) assessment which has been used as an industrywide primer as a reliable approach for technology readiness. I applied various measurement techniques such as reviewing levels of citation made on peer reviewed content to qualify and induct them into this qualitative study.

3.8 Summary

In this chapter, I discussed my research design, Notes for data collection, procedures for collecting the data, and how I proposed to analyze the data. Chapter 4 presents an analysis of the data. Chapter 5 discusses the conclusions and major findings of this research and presents recommendations.

CHAPTER 4. PRESENTATION AND ANALYSIS OF DATA

Chapter 4 will discuss findings of the study, detail existing gaps, analyze available qualitative data, provide findings and results therefore contributing to the existing body of knowledge. This chapter comprises of three main sections. The first section is focused on data collection process, description of the data, categorization of the data, analysis of data and presentation of the data. The second section categorize the main chapters of the study by identify relevant studies and providing a summary of each study and analysis of trends. The final section provides a summary of content covered in chapter four.

4.1 Discussion of data collection process

Systematic literature search was conducted using various secondary data Note for qualitative data collection. The main data Notes I used were chosen based on their ability to provide larger number of search results, the intuitiveness of the database, ability to show reviews, range of useable filters such as the classification of data Note (journals, dissertations, conference papers etc.), ability to export data for analysis and presentation. The data Notes chosen were, PubMed, Scopus, Cochrane Database, EMBASE, Google Scholar, Google patent, USPTO Database Web of Science, Ovid MEDLINE, and IEEE Xplore. Other databases Notes such as FASEB and Web of Science.

The following keywords were identified to be the main domain names used in the search field; amputee, amputation, bilateral, unilateral, lower limb, transfemoral, stump, transtibial and limb impairment. Four levels of search strategies were applied to ensure that enough bandwidth of data was captured across several the databases.

The texts used for the search included:

1. Amputation, amputee, amputees
2. Prosthesis fitting or prosthetic device or prosthetic knee or knee prosthesis leg or joint prosthesis or Prosthetic ankle
3. Lower extremity or Lower limb or foot or knee or leg or thigh or ankle joint or stump, or knee replacement or knee impairment or foot or feet or hip or leg or thigh or stump or socket
4. Lower limb loss, lower limb impairment
5. Transfemoral and/or transtibial or unilateral or artificial limb or disarticulation

Several tactics and restrictions were applied during the search. The first search was unrestricted, and the result was too broad for the study. To narrow down the search, I added layers of data restriction to only capture peer reviewed articles within a specified timeframe. Other incremental restrictions were then applied to guide the rest of the screening effort for the study. Those restriction included the following:

(i). Article must focus on lower limb impairment, limb amputation or limb loss and

(ii). Article should address technology area dealing with lower limb.

(iii). The article must be written by a group of authors to eliminate bias

(iv). The article for review admission must be within 5 years since publication

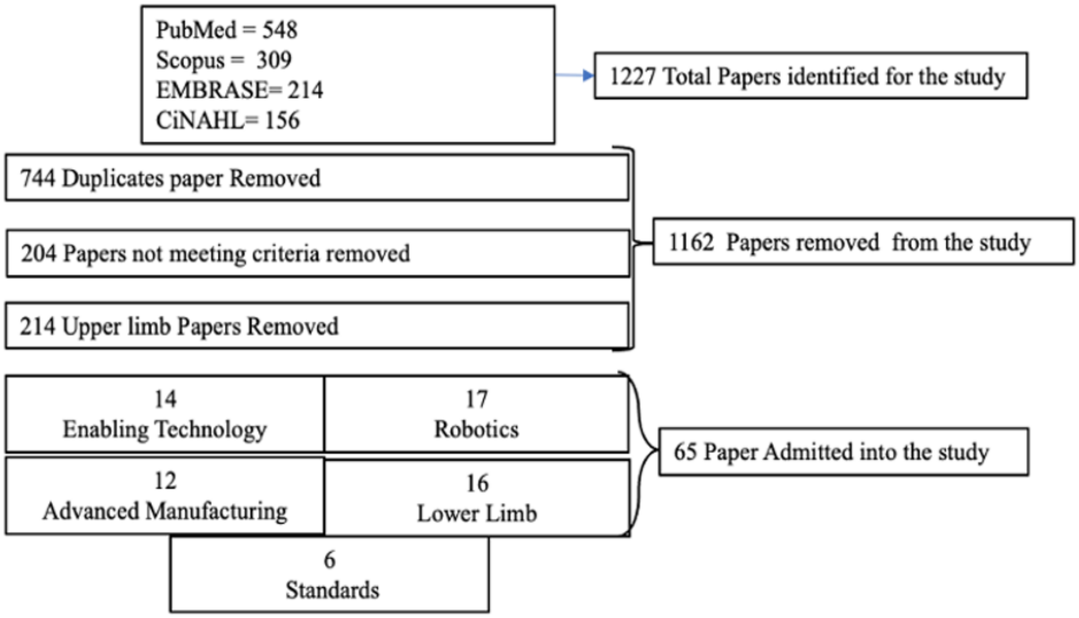
(v). Articles with patterns in patents in lower limb prosthesis would be prioritized

I also found it necessary to admit papers that focused on enabling technologies beyond those dealing with just the lower limb prosthesis. This was necessary because of new trends and capabilities in prosthesis have resulted from IoT, AI, Sensors, imaging technologies amongst other digital tools. These digital tools are key drivers in terms of unlocking innovations and capabilities of prosthetic devices therefore improving the quality of life across people with limb impairment.

4.2 Description of Data Conditioning and Analyses

Upon data admission, further synthesis was done starting with a complete review of abstract and a list of developed in an excel spreadsheet to identify which articles would be needed for the study. A dull text of publications was then selected and categorized for the study and were based on technology type or the design intent. Specific technology types were further categorized based on intent. Example, lower limb prosthesis devices included those that pertain to all parts of the lower limb regardless of feet, ankles, knees, sockets, or suspension. Those were categorized separately from documents that discussed focused on advanced manufacturing such as 3D or 4D printing. Those were categorized together advanced materials. Robotics were categorized with exoskeletons and lastly, enabling technologies included sensors and other digital elements improving the capabilities of the prosthetic device.

This research project involved 1227 papers that were initially identified for the study, restrictions and filters were applied and duplicates of 744 papers removed. 204 papers did not meet the gated admission process and were therefore not included. Some of the studies that were excluded were focused on comparing clinical studies or were dealing with other implant products. A total of 214 papers were removed because they were associated with upper limb and not lower limb prosthesis that this study is focused on. A total of 65 papers were admitted into to support this study because they met the inclusion criteria. The papers admitted in the study were further categorized and classified to meet the intended focus area technologies involved. These were broken down into the following categories namely, lower limb prosthesis (16 papers), robotics (17 papers), enabling technologies (14 papers), advanced materials and advanced manufacturing (12 paper) and standards (12 papers). A study from multiple papers would control bias. Figure 45 below details the data collection study plan.

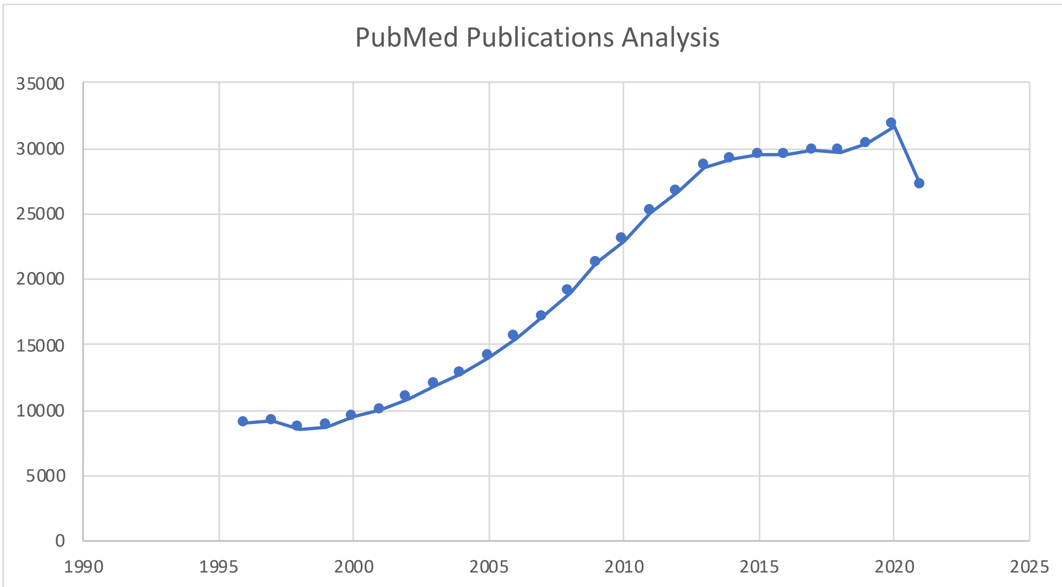


Note: Compiled by this researcher

Figure 45. *Breakdown and classification of articles and citations admitted into the study*

4.3 Presentation of the data

The next section demonstrates how documentations from two secondary data Notes PubMed and Scopus were analyzed to identify trends in publications related to lower limb amputation. This tremendous effort of narrowing down to the preferred articles applicable for review in support of this research. Understanding the trends in specific subject area across several publication could reveal several things such as, growing, or declining interest in the subject or societal needs or behavior over a period that may need to be addressed etc. These trends could also be influenced the changing landscape in the society such as changed in technology, politics, environmental or economic factors. In this case, both PubMed and Scopus data Notes revealed that a steady increase in publications in subject areas around lower limb impairment or lower limb prosthesis from the year 1997 though the year 2022 as shown in Figure 46 below.

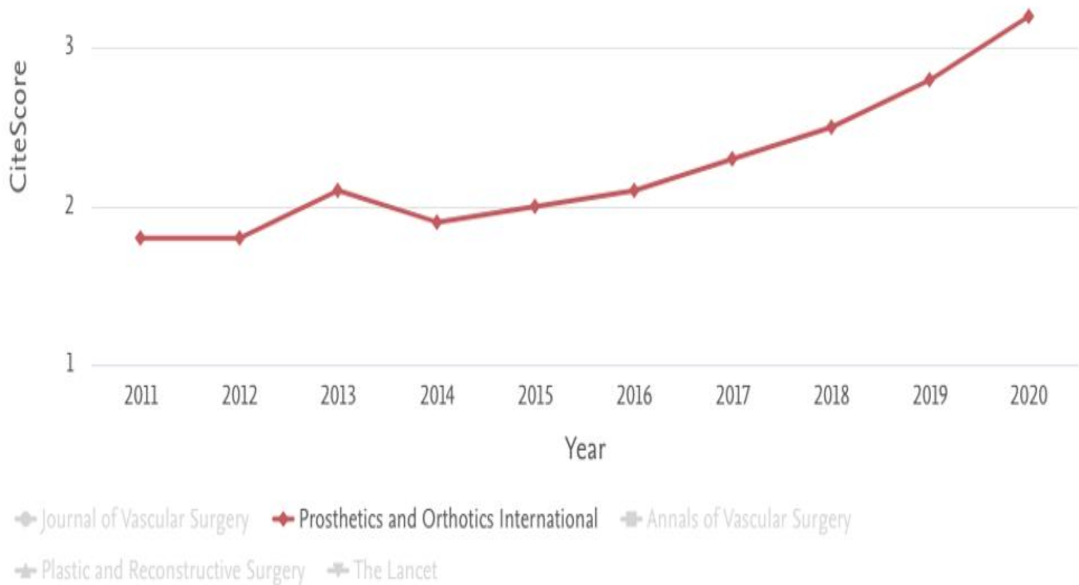


Note: PubMed Database, n.d.

Figure 46. *PubMed Publicatios- Amputation Trend from 1997 to 2022*

Looking through the PubMed database this reseacher found that there were no trends prior to 1914 which could probably be attributed to world War I. Trends in the database started 1945 which could then be attributed to injuries from world war II and no major trends in publications until in the 2000s. To date, over 30,000 publications have been captured in the last decade showing interest in this area of study.

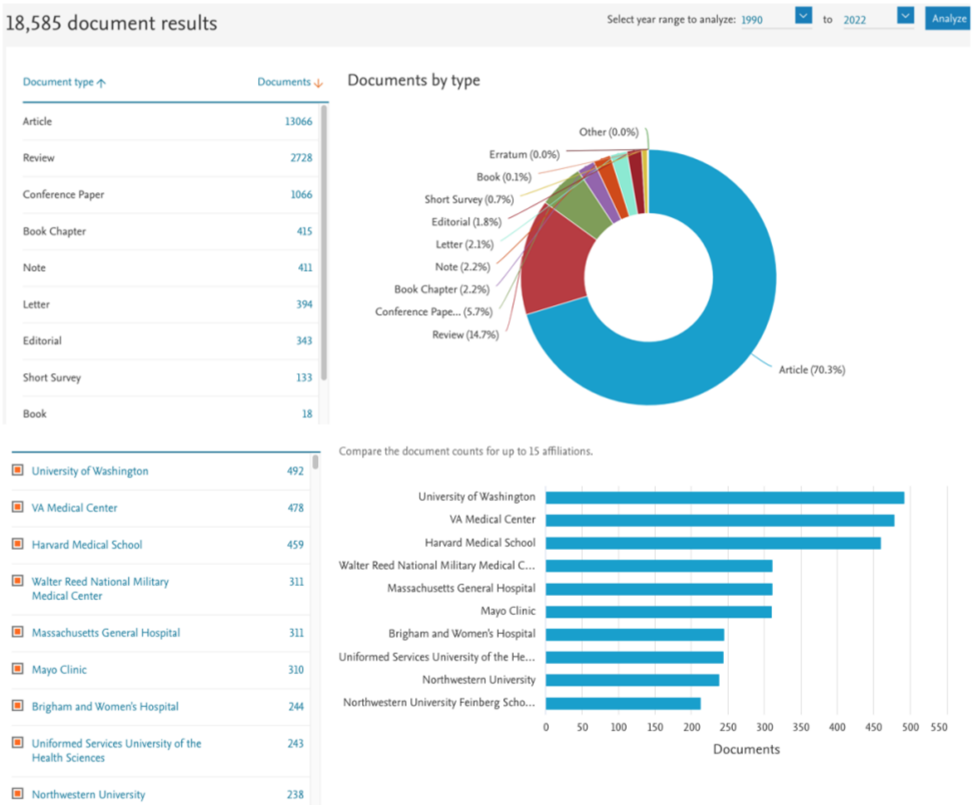
Looking at the Scopus database between 2011 to 2020, the total number of publications related to amputation was below two thousand in 2011 and has steadily gone up over the years. This trend is also a good indicator of interest in this area of focus as shown in Figure 47 below.



Note: Scopus Database

Figure 47. *Number of Scopus Publication on Amputation Trend from 2011 to 2022*

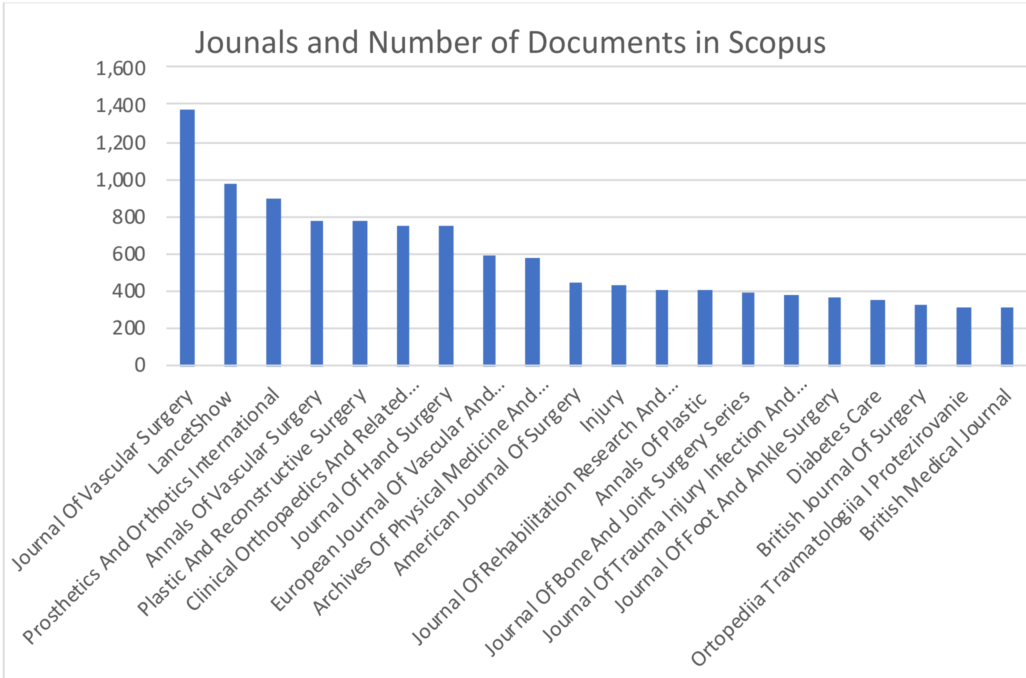
Further breakdown of data analysis was conducted on amputation and prosthetist to guide this research on specific articles and institutions of interest suitable for benchmark studies in support of this research. University of Washington, VA medical Center, Harvard Medical School, Walter Reed Medical Center, and MIT were leading institution with most publications. These key findings shade light and guided me to other secondary information Notes. In this case, I utilized the USPTO patent office to search for lower limb prosthetics patents (Appendix C and D) filed by various academic institutions and corporations. This effort shaded light and provided rich data needed for understanding and analyzing technology trends associated with lower limb prosthetic devices. A breakdown of document types and the institutions actively involved in submitting articles dealing with lower limb prosthesis. See Figure 48.



Note: Compiled by researcher from Scopus database

Figure 48. *Breakdown of Scopus Document Type on Lower Limb Amputations*

In addition to understanding the instututions involved in prosthetic devices, I found the following publicaion Note useful for this study: Prosthetics and Orthotics International was one of the Notes. The second helpgul Note useful Note in order was the Archives Of Physical Medicine And Rehabilitation, Journal Of Rehabilitation Research, IEEE Transactions On Neural Systems And Rehabilitation Engineering and Proceedings Of The Annual International Conference Of The IEEE , Engineering In Medicine And Biology Society EMBS, Gait And Posture, Plos One, Clinical Biomechanics, Journal Of Biomechanics and Ortopediia Travmatologiia I Protezirovanie. Figure 49 below shows some of the leading publications within the subject area of lower limb prosthesis.



Note. Developed by this researcher with data from Scopus

Figure 49. *Journals and Documents Published on Lower Limbs: 1990-2022*

A broad range of articles associated with lower limb prosthetic devices were reviewed. It was challenging to come up with complete information from one single database Note despite millions of medical related articles being readily available in several database. The most tasking effort was in data disseminate and coming up with relevant documents for this study. This challenge was attributed to the fact that most authors or article only addressed methods and provided specific improvements recommendations limited to a particular segment of the lower limb such as the ankle or the foot with most falling short of addressing the whole system such as the entire lower limb as a system. As a result, I was compelled to find additional key information supportive to this study from industry Notes including looking for white papers on technology trends, studying trends in patent from United States Patent and Trade Office (USPTO) and from World Intellectual Property Office (WIPO). This was by far the most effective way finding key information for this study.

In summary, I engaged in the review of more than peer reviewed 65 journal articles, read through 150 abstracts, and scanned through more than 60,000 patents, reviewed 8 conference papers, browsed searched through various prosthetic associations, organizations, and industry consortiums and proceedings from the International Society for Prosthetics and Orthotics World Congress.

4.4 Categorize Information in Chapters

Final papers selected for review were those written by a group of authors on a specific subject area in technology. Comparison was done with other papers that have been written on the same subject and various views were captured to mitigate risk associated with induction of bias. The next section will focus on the review of each selected chapter of the study namely, lower limb prosthetic devices, advanced manufacturing, advanced materials, robotics, enabling technologies and studies of technology trend based on patent analysis shown in Table 6.

Table 6.

Table Chapters Admitted into the Study for Review

Chapters Admitted in the Study	Purpose of the chapter in the study
Lower Limb Prosthetic Devices	To identify various forms of lower limb prosthesis in the market and future trend
3D and 4D printing	To demonstrate capabilities so manufacturing process in prosthesis
Robotics	To establish the framework for integrating future technologies and applications
Enabling Technologies	To unlock and accelerate innovation capabilities through integration
Advanced Materials	To define future prosthetic devices and innovation
Patents and innovation	To identify technology trends using patent analysis
Standards	To address industry challenge in standards due to speed of innovation

Note: Compiled by researcher

4.5 Technology Trend Review Through Patent Filing Analysis

Extensive patent analysis was done by this research taking on a quad-view approach. First, a review the works of (Asif et al., 2021) whose focus was on the advancement of lower limb prosthesis. The second approach was a review of industry report compiled the World Intellectual Property Organization (WIPO) on patents related to assistive technology, the third approach involved a search for filed patents from USPTO and finally the fourth approach was to look through the Google patent database to complete to extract and download patents for further analysis. This was very important because trends in technology can be studied by looking at the trend of patent filing. Patents are also known to be evidence-based tools that have been used several times and proven to provide valuable information to inform decision-making and policy formulation

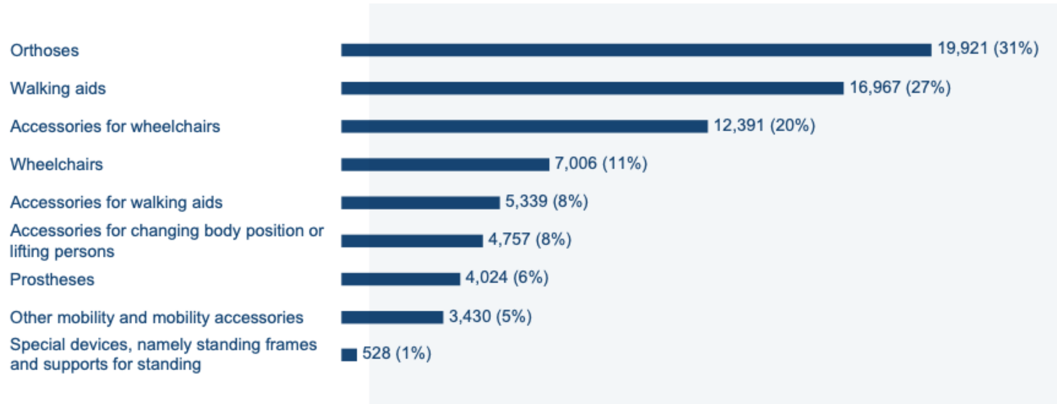
In summary, I engaged the works of Asif et al. (2021), USPTO and WIPO to complete a personal analysis of patent filing to articulate the trend in lower limb prosthetic device technology therefore contributing to the existing body of knowledge.

The review of research work done by (Asif et al., 2021) was important to this research study because it shade light in areas that this study has focused on related to trends in lower limb prosthetic devices. Their research work looked at sixty studies that engaged various aspects of lower limb amputation. More specifically, they looked at various advances of designs and development on lower limb prosthetic devices including the functionality and the control systems.

Their research findings revealed that patent trend analysis was based on different parts of lower limb prosthesis. First, they determined that patent filing and trends on knee prosthesis was higher and consisted of a total of 228 patents (48%), while those related to the ankle ranked second in filing with about 131 patents (28%) on their sample size (Asif et al., 2021). The patents that were filed for foot were ranked third with 105 patents (22%) filed. The lowest number of patents filed were those associated with the hip design with only 11 patents (2%) in the database. They highlighted various challenges and domains used in the patent search (Asif et al., 2021). Their study proposed that future designs of prosthetic devices should have some component that are bio-compatible, lightweight, and easy to use by normal human gait therefore eliminating or reducing phantom limb pain.

Another study that was very important in advancing my research on trends in technology on lower limb prosthetic device was that reported by the World Intellectual Property Organization (WIPO). Their report which comprised of expert opinion informed my research on how to use patent analysis to identify trends in technology. The WIPO report published in the year 2020 focused on those patents that had been filed on most assistive technology trends from the year 1998 to 2019. The results revealed that activities on conventional technology had gone up eight times which was a good indicator emergence of new technologies. The number of patent filings in this domain had risen from 15,592 to 117,209 patents (WIPO, 2020) which was quite remarkable and very helpful to my research.

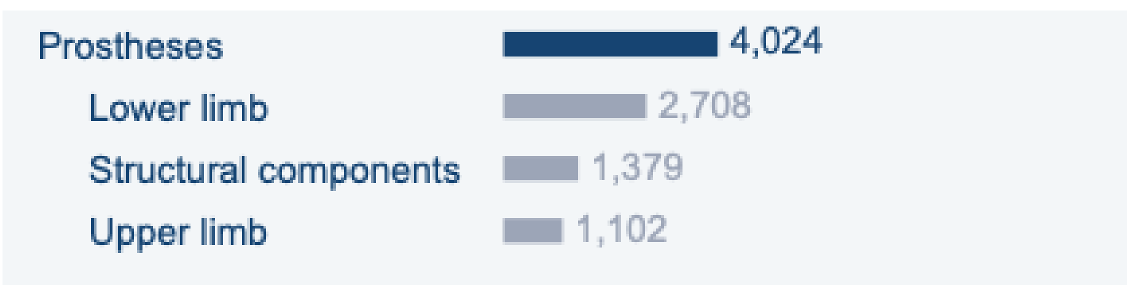
Given that this was WIPO’s first report, they provided insightful tip so how to conduct a patent search and to use classification for various patent families to overcome challenges with patent search results which I experienced prior to this study. According to (WIPO, 2020), patent documents are usually classified into multiple categories followed by sub-categories which can sometime be very broad making it challenging to analyze given that there are more than 63,245 conventional assistive technology related patent families that can be identified and grouped under nine main categories adding to the wide spectrum of complexity in during the analysis phase. The Prosthesis related patents in WIPO's report comprised 6% of the dataset. See Figure 50.



Note. (WIPO, 2020).

Figure 50. *Patent Families Filed on Conventional Mobility Assistive Technology 1998-2019*

After I understood how to go about reviewing various patent families, I decided to focus on the main section of the report dealing with lower limb prothesis. It revealed that there were a total 2,708 patents filed for lower limb as shown in Figure 51.



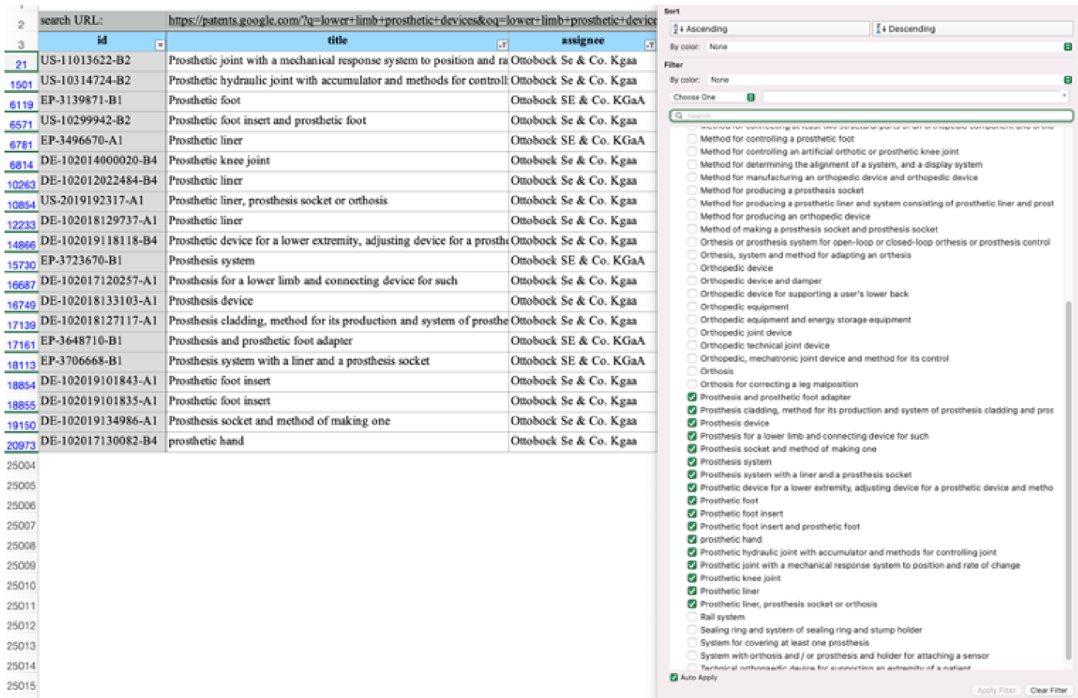
Note. (WIPO, 2020).

Figure 51. *Detailed breakdown of patents related to lower limp prostheses*

My next effort was to review and analyze patents using the Google patents database. Using the Google patent search, I applied the search terms applicable to lower limb prosthetic, and a total of 20,973 hits came up of search results within the year 2016 to through 2022. The results were downloaded in an excel file format. See Table 7.

Table 7.

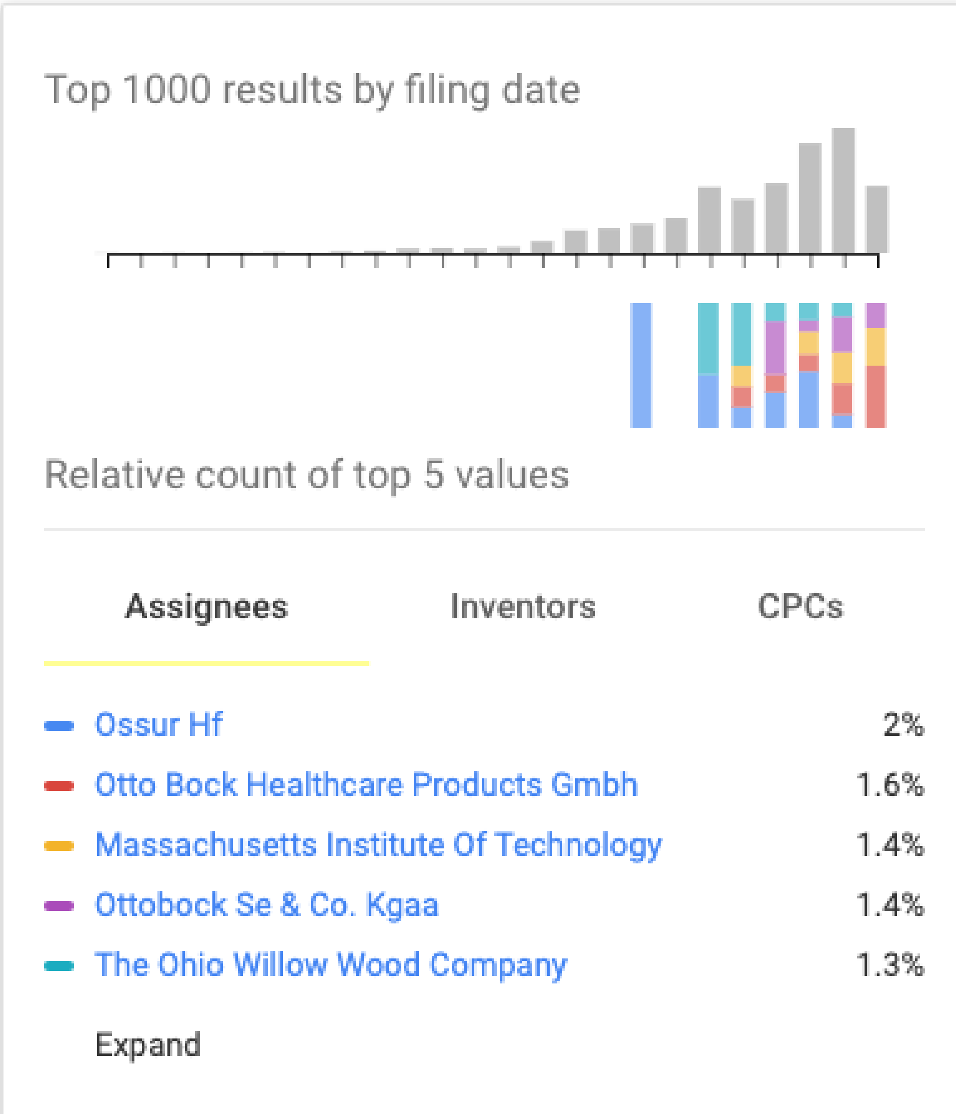
Patent Filing Search to Identify Trends in Lower Limb Prosthetic Devices



id	title	assignee	publication dat	grant date
US-11013622-B2	Prosthetic joint with a mechanical response system to position and rate	Ottobock Se & Co. Kgaa	2021-05-25	2021-05-25
US-10314724-B2	Prosthetic hydraulic joint with accumulator and methods for controlling	Ottobock Se & Co. Kgaa	2019-06-11	2019-06-11
EP-3139871-B1	Prosthetic foot	Ottobock SE & Co. KGaA	2019-07-17	2019-07-17
US-10299942-B2	Prosthetic foot insert and prosthetic foot	Ottobock Se & Co. Kgaa	2019-05-28	2019-05-28
EP-3496670-A1	Prosthetic liner	Ottobock SE & Co. KGaA	2019-06-19	
DE-102014000020-B4	Prosthetic knee joint	Ottobock Se & Co. Kgaa	2021-03-11	2021-03-11
DE-102012022484-B4	Prosthetic liner	Ottobock Se & Co. Kgaa	2020-06-04	2020-06-04
US-2019192317-A1	Prosthetic liner, prosthesis socket or orthosis	Ottobock Se & Co. Kgaa	2019-06-27	
DE-102018129737-A1	Prosthetic liner	Ottobock Se & Co. Kgaa	2020-05-28	
DE-102019118118-B4	Prosthetic device for a lower extremity, adjusting device for a prostheti	Ottobock Se & Co. Kgaa	2021-02-18	2021-02-18
EP-3723670-B1	Prosthesis system	Ottobock SE & Co. KGaA	2021-06-16	2021-06-16
DE-102017120257-A1	Prosthesis for a lower limb and connecting device for such	Ottobock Se & Co. Kgaa	2019-03-07	
DE-102018133103-A1	Prosthesis device	Ottobock Se & Co. Kgaa	2020-06-25	
DE-102018127117-A1	Prosthesis cladding, method for its production and system of prosthesi	Ottobock Se & Co. Kgaa	2020-04-30	
EP-3648710-B1	Prosthesis and prosthetic foot adapter	Ottobock SE & Co. KGaA	2021-09-15	2021-09-15
EP-3706668-B1	Prosthesis system with a liner and a prosthesis socket	Ottobock SE & Co. KGaA	2021-05-05	2021-05-05
DE-102019101843-A1	Prosthetic foot insert	Ottobock Se & Co. Kgaa	2020-07-30	
DE-102019101835-A1	Prosthetic foot insert	Ottobock Se & Co. Kgaa	2020-07-30	
DE-102019134986-A1	Prosthesis socket and method of making one	Ottobock Se & Co. Kgaa	2021-06-24	
DE-102017130082-B4	prosthetic hand	Ottobock Se & Co. Kgaa	2019-07-04	2019-07-04

Note. Lower Limb Prosthetic Devices - Google Patents, n.d.

An overview was done on leading manufacturer in lower limb prosthesis devices and further analysis done to determine technology trend based on patent filing. The top 5 manufactures who filed patents on lower limb prostheses are shown in Figure 52.



Note. Lower Limb Prosthetic Devices - Google Patents, n.d.

Figure 52. *Top 5 manufactures who filed patents on lower limb prosthetic devices*

According to the World Intellectual Property Organization (2021), the patent protection on assistive technology predominantly exist in the following five key markets segments namely China, U.S.A, Europe, Japan and the Republic of Korea. In trying to determine who are the key players in the manufacturing of prosthetic devices, I found that the German company Ottobock and Ossur were market leaders. Some the most advanced lower limb prosthetic devices commercially available in the market today have been compiled and shown in Table 8.

Table 8.

Advanced Lower Limb Prosthetic Devices and Associated Manufacturers

Advanced Lower Limb Prosthetic Devices	**Manufacturer**	**Description**
C-Leg:	German company Ottobock	4th generation, the most common bionic module and used by millions of people worldwide, Used in sport and rehabilitation
Rheo Knee XC	Ossur company	Is the most advanced microprocessor-controlled prosthetic knee capable of monitoring the user activities (It is predictive)
Proprio Foot	Ossur company	World's first AI controlled ankle-foot prostheses. The module can independently perform automatic ankle flexion and extension movements when walking up and down stairs, and functions nearly as a healthy human limb.
The Genium prosthetic knee	Ottobock	Fully waterproof and can recreates a natural physiological gait pattern. The module utilizes a rare function for walk-to-run function allows for various walking pattern
Symbionic Leg	Ossur	Fully bionic and allows most complex patients with short above-knee stumps and bilateral amputations to socialize and return to active lifestyle. Recreates a physiological gait pattern and allows for walking up and down stairs and engaging in sports activities.

Note. Compiled by this researcher with credits to WIPO and Asif et al., (2021).

In summary it seems that trends in lower limp prosthetic are focused on the following: advanced prosthetics, myoelectric controls, 3D printed prosthetics, neuro-prosthetics and in exoskeletons. According to WIPO analysis there are noticeable new trends in technology related to advanced prosthetics and exoskeletons. The WIPO report identified that the rate of patent filing in 3D printed prosthetics and orthotics had gone up to 89% between 2013 and 2017. The main patent categories and leading applicants are shown in Table 9.

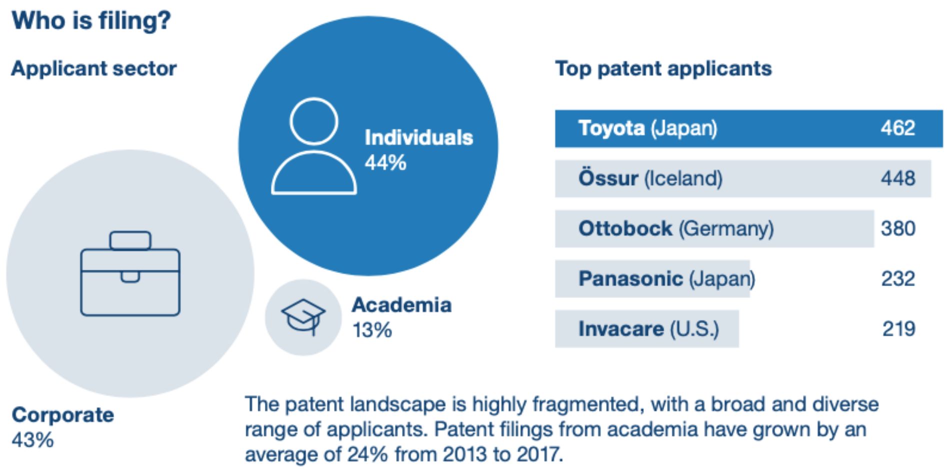
Table 9.

Leading Patent Applicants by Category of Emerging Mobility Technology

Main category	Leading applicants
Advanced prosthetics – smart prosthetics	Ottobock, Germany MIT, U.S. Össur, Iceland
Advanced prosthetics – myoelectric control	Ottobock, Germany Harbin Institute of Technology, China Össur, Iceland
Advanced prosthetics – 3D-printed prostheses/orthoses	Mainly Chinese universities, including Shanghai Jiao Tong University and Xian Jiaotong University
Advanced prosthetics – neuroprosthetics	NDI Medical, Germany Ottobock, Germany
Advanced walking aids – balancing aids	Toyota, Japan Equos Research, Japan Honda, Japan Samsung, Republic of Korea
Advanced wheelchairs	Sichuan Golden Ridge Intelligence Science and Technology, China Tianjin Shuangyuan Electric Power Equipment, China Shenzhen Glory-Medical Engineering, China
Exoskeletons	Honda, Japan Ekso Bionics, U.S. National Rehabilitation Center, Republic of Korea University of California, U.S. Robert Bosch, Germany University of Tsukuba, Japan

Note. World Intellectual Property Organization, 2021

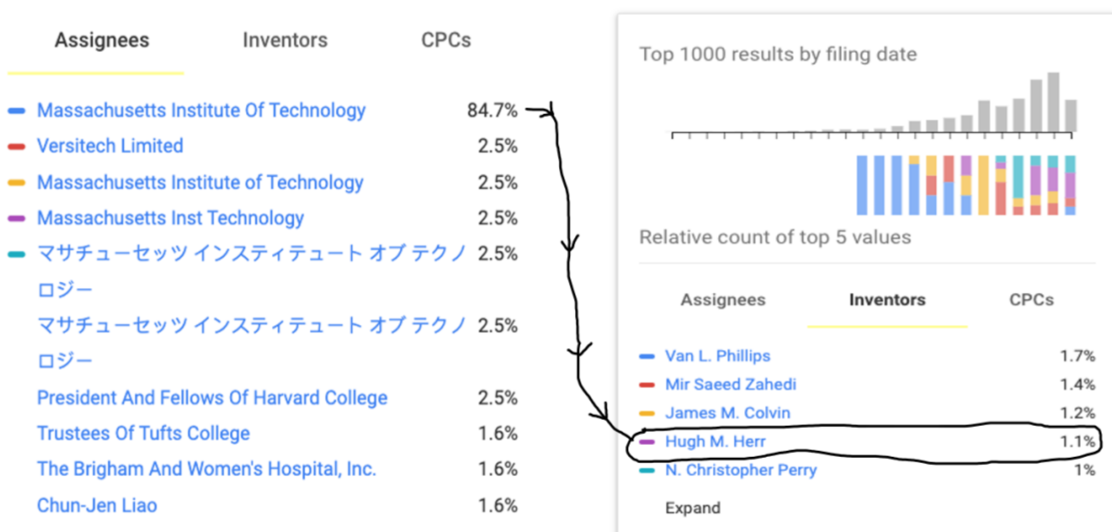
Given that the patent landscape is broadly dispersed across various categories of assistive technology devices, the number of patent filings related to lower limb prosthesis in academia had grown significantly and averaged 24% from 2013 to 2017 according to WIPO (2020) report while filing by corporates filed at 43%. In a nutshell, patents that were filed individuals ranked the highest at 44% which could be an indicator of various activities taking place in various innovation hubs. A summary of depicting which sectors ae active in patent filing are shown in Figure 53.



Note: World Intellectual Property Organization, 2021

Figure 53. *Synopsis of Who is Filing Patents on Lower Limb Protheses*

I conducted an extensive search and analysis specifically on patent trends in academia with focus on MIT listed as one of the top inventors in prosthesis. A follow-on deeper search and analysis was done to identify what focus areas of invention the institution was interested and who were the top invention submitter on lower limb prosthetic. In this case it was Hugh Herr as shown in Figure 54.



Note. Compiled by this researcher.

Figure 54. *The Top 5 Academic Institutions and Their Respective Inventors*

The works of Hugh Herr were further analyzed for trend to see if a connection could be made with trends from other studies. The findings were quite consistent with technology trends, leaning towards systems improvement of controls and actuation, robotics, neuromechanical systems and sensors as compiled by this researcher and the works of Herr summarized in Table 10.

Table 10.

Patents Filed by Hugh Herr from MIT Reviewed for Trend Analysis

1. Active ankle foot orthosis (H. Herr, 2014)
2. Artificial human limbs and joints employing actuators, springs, and variables (H. M. Herr, 2020)
3. Model-based neuromechanical controller for a robotic leg (H. M. Herr, 2014a)
4. Artificial ankle-foot system with spring, variable-damping, and series-elastic (H. M. Herr, 2016b)
5. Artificial joints using agonist-antagonist actuators (H. M. Herr, 2020)
6. Peripheral neural interface via nerve regeneration to distal tissues (H. M. Herr, 2016a)
7. Passive artificial knee (Arelekatti, 2019)
8. Artificial joints using agonist-antagonist actuators (H. M. Herr, 2014b)
9. Model-based neuromechanical controller for a robotic leg (H. M. Herr, 2014a)

Note. Compiled by this researcher.

Analysis was done to further explore what type of patents were filled by Massachusetts Institute of Technology as shown in Table 11.

Table 11.

Prosthetic Device Trend Analysis Based on Patent Review from MIT

1	search URL:	https://patents.google.com/?q=lower+limb+prosthetic&assignee=Massachusetts+Institute+Of+Technology&oq=lower+limb+prosthetic+		
2	Patent id	Title	Assignee	Publication
3	WO-2021257640-A1	Soft neuroprosthetic limb with simultaneous myoelectric control and tactile feedback	Massachusetts Institute Of Technology, SI	12/23/21
7	WO-2020247052-A1	Shape optimization for prosthetic feet	Massachusetts Institute Of Technology	12/10/20
9	EP-3914758-A1	Additively manufactured mesh materials, wearable and implantable devices, and systems and methods for manufacturing the same	Massachusetts Institute of Technology	12/1/21
10	WO-2020086721-A2	Neural efferent and afferent control of spring equilibrium, damping, and power in backdrivable and non-backdrivable series-elastic actuators comprising variable series stiffness mechanisms	Massachusetts Institute Of Technology	4/30/20
13	US-2020022823-A1	Artificial joints using agonist-antagonist actuators	Massachusetts Institute Of Technology	1/23/20
14	US-10962707-B2	Method for forming thermal-responsive fibers	Massachusetts Institute Of Technology	3/30/21
17	WO-2019074950-A1	Method for neuromechanical and neuroelectromagnetic mitigation of limb pathology	Massachusetts Institute Of Technology	4/18/19
18	WO-2019028388-A1	Passive and slope adaptable prosthetic foot ankle	Massachusetts Institute Of Technology	2/7/19
20	US-2020188138-A1	Locking and Damping Mechanism for a Prosthetic Knee Joint	Massachusetts Institute Of Technology	6/18/20
21	US-2020085595-A1	Method For Design And Manufacture of Compliant Prosthetic Foot	Massachusetts Institute Of Technology	3/19/20
22	WO-2018208714-A1	Spring design for prosthetic applications	Massachusetts Institute Of Technology	11/15/18
23	US-2018141274-A1	Multimaterial 3D-Printing With Functional FIber	Massachusetts Institute Of Technology	5/24/18
29	US-2017246492-A1	Elastic Element Exoskeleton and Method of Using Same	Massachusetts Institute Of Technology	8/31/17
33	WO-2017120484-A1	Method and system for providing proprioceptive feedback and functionality mitigating limb pathology	Massachusetts Institute Of Technology	7/13/17
34	US-10639171-B2	Transfemoral rotator using push button spring clips	Massachusetts Institute Of Technology	5/5/20
35	US-10405997-B2	Passive artificial knee	Massachusetts Institute Of Technology	9/10/19
36	US-10588759-B2	Artificial human limbs and joints employing actuators, springs and variable-damper elements	Massachusetts Institute Of Technology	3/17/20
37	US-2016338857-A1	Artificial ankle-foot system with spring, variable-damping, and series-elastic actuator components	Massachusetts Institute Of Technology	11/24/16
40	US-9975249-B2	Neuromuscular model-based sensing and control paradigm for a robotic leg	Massachusetts Institute Of Technology	5/22/18
45	US-10993639-B2	Feedback method and wearable device to monitor and modulate knee adduction moment	Massachusetts Institute Of Technology	5/4/21
49	US-9381642-B2	Wearable robot assisting manual tasks	Massachusetts Institute Of Technology	7/5/16
50	US-10561563-B2	Optimal design of a lower limb exoskeleton or orthosis	Massachusetts Institute Of Technology	2/18/20
58	US-9369005-B2	Energy extraction	Massachusetts Eye & Ear Infirmary, Mass	6/14/16
59	US-10179195-B2	Method comprising contacting tissue with a cross-linkable polyester prepolymer	Massachusetts Institue Of Technology	1/15/19
60	CN-105209900-A	Sensor, method for forming the same, and method of controlling the same	ÂçóÊ¥ãÁêÜÂ∑•Â§ßÂ≠¶, Ë∫ªÁúÅÁêÜÂ∑•Â	12/30/15
61	US-10137011-B2	Powered ankle-foot prosthesis	Massachusetts Institute Of Technology	11/27/18
62	US-9149370-B2	Powered artificial knee with agonist-antagonist actuation	Massachusetts Institute Of Technology	10/6/15
68	US-9498401-B2	Robotic system for simulating a wearable device and method of use	Massachusetts Institute Of Technology	11/22/16

gp-search-20220308-200123

Ready 44 of 118 records found

Note: Compiled by this researcher

So far, technology trend in lower prosthetic devices seems to be consistent and moving towards automation. Further research finding revealed that there is more interest towards capability improvements of sensing devices and actuation control systems. Filtering and looking through exhaustive list of patents, it was evident that innovations trend is capitalizing on enabling technologies for motion and control systems with integration of sensors as shown below.

1. Sensing system and method for motion-controlled foot unit (Jónsson, 2016)

2. Actuator assembly for prosthetic or orthotic joint (Martin, 2014)

3. System and method for determining terrain transitions

4. System and method for motion-controlled foot unit

5. Systems and methods for actuating a prosthetic ankle

6. System and method for motion-controlled foot unit

Below is an extract of control strategies on lower limb prosthetic devices that were researched by Asif et al. (2021) as shown in Table 12.

Table 12.

Control Strategies for Lower Limb Prosthesis

Control strategies for lower limb prosthesis.

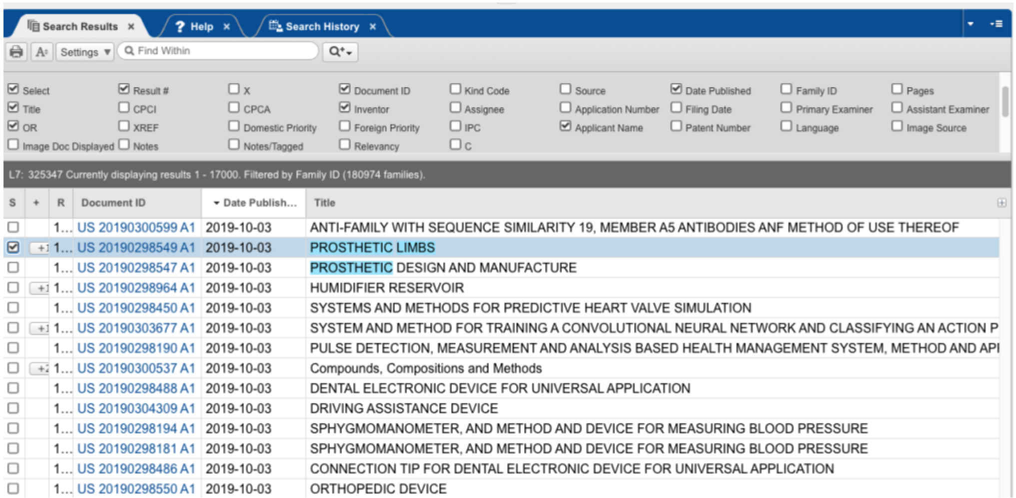
Nature of work	Controlling strategy	Outcomes
Powered below-Knee prosthesis	Finite-state control	Natural movement and adaptable
Powered ankle-foot prosthesis	Finite state controllers	High mechanical power and torque
Powered prosthetic intervention	Finite-state impedance control	Enhanced awareness, stability, & power
Knee and ankle control	Impedance control	Reduced clinical challenges
Virtual prosthetic leg	Feedback linearization	Biomimetic and robust
Transfemoral prosthesis	Least square approach	Estimation of knee impedance
Transitions b/w ground and ramps	Fuzzy logic control	Effective control scheme
Mechanical knee	Predictive control	Better approximation of human gait
Dynamic swing phase model	Langrange dynamic analysis	Input compensation for better accuracy
Powered lower limb prosthesis	Adaptive dynamic programming	Testing of 300 gait cycles

Note: Asif et al., 2021

I conducted a final search and analysis with data extracted from the United States Patent Office (UPTO) data base. I accessed the database using the patent public search feature. Searching for prosthetic patents was quite exhaustive and challenging. To narrow down to specific patents associated with lower limb prosthetic devices the following key search terms were uses: prosthesis, lower limb, prosthetic devices etc. and there were 325,347 related patents. After filtering through 17.000 patent and selecting those that were applicable for this study. Table 13 illustrates a patent trend search using the USPTO online database.

Table 13.

Illustration of a Patent Search of USPTO database



S	+	R	Document ID	Date Publish...	Title
☐		1...	US 20190300599 A1	2019-10-03	ANTI-FAMILY WITH SEQUENCE SIMILARITY 19, MEMBER A5 ANTIBODIES ANF METHOD OF USE THEREOF
☑	+	1...	US 20190298549 A1	2019-10-03	PROSTHETIC LIMBS
☐		1...	US 20190298547 A1	2019-10-03	PROSTHETIC DESIGN AND MANUFACTURE
☐	+	1...	US 20190298964 A1	2019-10-03	HUMIDIFIER RESERVOIR
☐		1...	US 20190298450 A1	2019-10-03	SYSTEMS AND METHODS FOR PREDICTIVE HEART VALVE SIMULATION
☐	+	1...	US 20190303677 A1	2019-10-03	SYSTEM AND METHOD FOR TRAINING A CONVOLUTIONAL NEURAL NETWORK AND CLASSIFYING AN ACTION P
☐		1...	US 20190298190 A1	2019-10-03	PULSE DETECTION, MEASUREMENT AND ANALYSIS BASED HEALTH MANAGEMENT SYSTEM, METHOD AND API
☐	+	1...	US 20190300537 A1	2019-10-03	Compounds, Compositions and Methods
☐		1...	US 20190298488 A1	2019-10-03	DENTAL ELECTRONIC DEVICE FOR UNIVERSAL APPLICATION
☐		1...	US 20190304309 A1	2019-10-03	DRIVING ASSISTANCE DEVICE
☐		1...	US 20190298194 A1	2019-10-03	SPHYGMOMANOMETER, AND METHOD AND DEVICE FOR MEASURING BLOOD PRESSURE
☐		1...	US 20190298181 A1	2019-10-03	SPHYGMOMANOMETER, AND METHOD AND DEVICE FOR MEASURING BLOOD PRESSURE
☐		1...	US 20190298486 A1	2019-10-03	CONNECTION TIP FOR DENTAL ELECTRONIC DEVICE FOR UNIVERSAL APPLICATION
☐		1...	US 20190298550 A1	2019-10-03	ORTHOPEDIC DEVICE

Note. USPTO, 2019

A download of the selected on lower limb prosthetic ranging from 2016 through 2022 was done in a pdf format and then extrapolated into an excel spreadsheet for further breakdown and analysis. In comparison with Google patent database, I found that USPTO database to be quite complex even though with rich features and information. A closer look at the most recent patents submitted, it was also evident that there is a growing interest in exoskeleton, robotics, virtual reality for rehabilitation and control systems shown in the Table 14.

Table 14.

Results of a USPTO Patent Search for Lower Limb Prosthetic Devices

22	US-20200038279-A1	2020-02-06	EXOSKELETON FOR LOWER-LIMBS	10
23	US-20200038745-A1	2020-02-06	GEAR (GAME ENHANCING AUGMENTED REALITY): A LOWER LIMB ALTERNATIVE CONTROL INTERFACE FOR COMPUTERS	21
24	US-D899608-S	2020-10-20	Amputated limb cover	5
25	US-20200353308-A1	2020-11-12	UPPER AND LOWER LIMB WALKING REHABILITATION DEVICE	12
26	US-10004613-B1	2018-06-26	Limb socket liner sealing system	16
27	US-20180168813-A1	2018-06-21	PROSTHETIC DEVICE WITH ANTIBIOTICS	12
28	US-20180301057-A1	2018-10-18	Prosthetic Virtual Reality Training Interface and Related Methods	22
29	US-20190001493-A1	2019-01-03	MULTI-BAR LINKAGE, LOWER-LIMB EXOSKELETON ROBOT USING THE SAME, AND METHOD OF CONTROLLING THE SAME	17

Note. USPTO, 2021

4.6 Lower Limb Prosthetic Design

Design consideration of a prosthetic device is critical because of resultant implication on the end user. Having studied more that 1000 patents from the United State Patent Office (USPTO), Google patents, and WIPO. I was able to confirm that the design of prosthetic devices needs to be simple yet detailed enough and easy to understand the functional elements that will make it achieve the intended use. In looking at the work of (Lara-Barrios et al., 2018) whose study focused on design improvements in the gait system. They found that it was important to improve stability and control system of the gait movement. To achieve this, they collected experimental data for analysis and included those collected during various activities such as on level ground, slope, stairs, running, jumping, cycling, etc. This was followed by a review of the structural design and biomechanical compliance and finally on the control system which focused on actuation technology, their study investigated electro-mechanical, hydraulics, pneumatics, magneto/electro rheology controls. In summary, the design and build up process of a lower limb prosthetic devices can be complex and but rewarding if the intended objective is achieved.

According to Sensinger et al.(2010), design optimization of lower limb prosthetic devices will depend on factors such as bio-compatibility, cosmic, lightweight, and on the feedback of patients who already used a similar design. That said, the range of design factors can vary depending on the needs of the user, the material to be used in the design, technologies that will be integrated in the design etc. The range is quite broad. Conclusively, I believe future designs should be novel and consider the abilities offered by various innovation hubs and open innovations.

4.7 Enabling Technologies

Analysis of studies associated with enabling technologies by the World Intellectual Property Organization (2021) identified that emerging assistive products may any one or a combination of several enabling technologies. These enabling technologies can be in anyone or more of the following, artificial intelligence (AI) or it can be related to the Internet of Things (IoT) or associated with brain computer or those of machine interface and advanced sensors. What was interesting in this research discovery is that the primary intersectionality of disciplines in emerging assistive technologies was the involvement of information technology (IT). This can take various forms including application of data science, which is focused on data analytics, the integration of materials science and finally the introduction of neuroscience in future technology. These enabling technologies will continue to boosts the pace of innovation in the near foreseeable future noting that technology and communications being at the forefront of digital transformation due to automation, robotics, the Internet of Things (IoT) or artificial intelligence (AI) (Towards 2050, 2018). All these combined indicate that the future emerging technology trend of will include furtherance of IoT which has been promising and is expected to have a high economic impact estimated between USD 2.7 trillion and USD 6.2 trillion annually by 2025 (OECD, 2016). It is estimated that there will be an estimate of 500 billion interconnected items by 2030 (NAT) Science & Technology Organization, 2020).

A survey conducted with senior executives across thirteen industries in ten countries revealed that more than 80% of the 250 executive agreed that IoT and smart devices will have the highest disruptive impact within five-year and 30-year timeframe and that the use of sensors and other devices will be key in improving efficiency (Towards 2050, 2018). Advances in myoelectric sensor system (IMES) will provide solutions for collecting various signals from the amputee's muscles and translating them into prosthetic movements (*Research and Development. Ossur.Com*, n.d.). As technologies evolve medical devices continue to be linked making them smarter due to big data optimization. Notably, one of the top five tech trends driving medical devices forward is big data (Rotter, 2015).

4.8 Robotics in Prosthetic Devices

A review of robotic roadmap conference paper initiated by Robotics Science and Systems (RSS) conference and developed by the Computing Community Consortium (CCC) comprising of experts involved in the industry and academia was done. The conference paper revealed that significant progress had been made in robotics over the years due to advancement in information technology (IT) and access to inexpensive computing hardware, sensors, and improved user interfaces. Several key challenges were identified for future research that include the need to identify how to overcome major adoption limitation of robot manipulation systems, new materials, integrated sensors, and planning control methods. Most importantly a new approach of the control system is required driving researcher to be engaged in studies of realities and dynamic system such as machine learning approaches and ultra-fast simulation tools needed for new optimization approaches.

The document summarized the overall societal benefits and opportunities on how robotics will continue to unlock human imagination making it possible to innovate and create models not attainable in the past. This includes state-of-the-art lower-limb prostheses with powered knees and ankles, and control software that effectively coordinate motion and include lower-limb exoskeletons for gait training and rehabilitation purposes. With these new technological trends, individuals with disability can improve their quality of life and regain some level of independence including the ability to have privacy, access to education and employment. The white paper concluded that more innovation research are needed, and appropriate policy frameworks to ensure responsible adoption and utilization of latest technology (*A Roadmap for US Robotics, 2020*). Example new technologies include powered prostheses equipped with localized wireless connectivity augmented to Internet connectivity through a smartphone or portable media device (LeMoyne, 2016).

One study that was interesting during this exploratory research addressed the gaps of children and prosthetic robotic devices. A study by (Stewart-Height et al., 2021) investigated the control and design that would involve the selection of robotic walkers. Objectively, they wanted to find out how to effectively address gaps in robotic assistive technology devices. Additionally, their study took keen interest in children with impairment and looked at their mobility needs to determine ways to effectively get them to engage in outdoor activities. They concluded that children with lower limb disabilities could benefit from robotic assistive technology if these devices were designed to function more effectively in irregular surfaces. Future studies should therefore explore how to advance capability of lower limb prosthetic devices in various terrains. This finding was significant because it points to some of the unmet needs in children that could potentially be addressed by advances in technology in the future.

The last study that was also important to inform my research was focused on bionics and robotics. Studies by (Jia et al., 2019) revealed that advances in lower limb prosthetics was moving towards bionics which include those of active ankle and knees. Another area of interest has been in the development of smart prosthetics which have mainly focused on gait and condition monitoring. The increased level of sensor integration including micro-electromechanical system (MEMS) accelerometers, could benefit the advances that are need in the development of microcontrollers which will enhance communication controls and better actuations that will eventually increase device functionality.

With all these new developments, future studies must take into consideration how to improve electrical power given that most of the element identified will need some power Note to be more effective across the board. According to (Jia et al., 2019), future power Note will need to be derived from kinetic energy harvesting to recharge small on-board battery which are integral in sustainment of active systems especially if they are deemed to have minimal impact on weight or size of the device. The benefit of such systems besides the ability of having recoverable power levels include improved functionality and support of other system that depend on energy Note to function. Having a system with long battery life are therefore a very important aspect of development needed in lower limb prosthetic devices to benefit future needs. As such, future research work and studies will be required to improve the stability of power or energy

Note and to ensure longevity of use to benefit people with limb impairment relying on advanced prosthetic devices.

4.9 Bionic Legs Prosthetic Devices

Extensive review was done on the works of (Rapp et al., 2019) on current trend on prosthetic product development with focus on bionic limbs. The use and application of bionic prosthetic limbs have been predominately to increase and enhance the function and lifestyle of the persons who have lost part of their body or experienced amputation. By looking at four segmentations appliable to bionic limbs their study found that bionic prosthetic limbs were rapidly advancing with the ability of artificial limbs and that there were more activities and advanced in the control system including those related to computer and the brain including sensation technology to improve signal communication.

These researcher (Rapp et al., 2019) concluded that despite increased level in advances in technology was still abandonment of devices due to deficient functionality of the equipment, compatibility with the subject, fragile design, and complex control methods. The finding of their research also found that an in-depth knowledge of this field was lacking, and more extensive understanding are necessary in the future. In studying and looking at lower limb prosthetic devices, I found it vital to look broadly into the life of a person with lower limb impairment and the challenges that they may face in terms of treatment, rehabilitation, services, and reception to equipment. Based on these remarks, (Rapp et al., 2019) point out that people with limb impairment face various challenges that ultimately lead to equipment abandonment.

4.10 Bionic Robotics and Exoskeleton

Comprehensive research and analysis report was done based on North Atlantic Treaty Organization (NATO) Science & Technology Organization (S&TO) that focused on reviewing technology trends from 2020 through 2040. The key areas that struck the interest of this researched in the NATO report included those studies that focused on advances and technological convergence in material, information and human sciences and the development of biosensors. These developments were important in this research because they focused on what was on the horizon in terms of building new human augmented technologies that will potentially change capabilities of the future soldier.

These capabilities will mainly be found in the design advancement and development future exoskeletons. According to NATO report, is predicted that by 2025 the exoskeleton market will be 1.8 billion USD which is up from 68 million USD in 2014 (NATO Science & Technology Organization, 2020). Notable research in this areas of interest will include the ability for the brain signals to be sent directly to the prosthetic to control up to 26 joints in the future (Padi et al., 2017) or application of algorithm and data analytics to capture and analyze users intentions that can be used for developing agile gyroscopic knees that flex and extend, allowing users to climb stairs and ride a bike is very promising to the future. These were not possible in the past due to weight, materials and design features (Sensinger et al., 2010). Experts say that 50 percent of the human body is currently replaceable with artificial implants and advanced prosthetics (*The Future of Artificial Limbs*, 2018). These synergies combined with the Internet of Things (IoT) will shape the future lower limb prosthetic devices.

4.11 Myoelectric Sensors

Various studies revealed that advances in neuroscience and microelectronics are bringing the visions of science fiction closer to reality every year and the trends is expected to continue in the future. Studies by (Campbell et al., 2020) revealed that myoelectric control are playing a key role in the development of different human-computer interfaces including those related to lower limb prosthesis control systems and device design. The shortcoming and challenges identified in myoelectric control is the lack of reliability in practical conditions and difficulty for some user to control. As such, I propose that advancement of myoelectric controls will impact how prosthetic devices are designed for people who have suffered from lower limb impairment and who may benefit from advancement in neuro-prosthetics. According to Hong et al. (2018), major emphasis is needed in identify techniques for connecting the human nervous system with a robotic prosthesis to provide a more intuitive response in how humans interact with prosthetic devices. Future studies and trends will therefore focus on the advancement of neurotechnology and artificial intelligence (OECD, 2016) including robotic prosthetic devices fitted for people with limb impairment. Future advances should take into consideration development of better microchip making it possible to control prostheses via smartphone and microprocessor-controlled knee joints with Bluetooth interfaces continue to be produced today despite global shortage (Microprocessor-Controlled Knee Joints with Bluetooth Interfaces Continue to Be Produced despite Global Shortage, 2021). Additional studies and research are needed to compel how the brain control the prosthetic as if it is a real limb which will be an important step in helping amputees prove their own quality of life (Chadwell et al., 2020);(Sensinger et al., 2010).

Looking at case studies and specifically the works of (Cooke et al., 2016) to demonstrate the importance of technology integration as a potential solution to improving the quality of life of people with quadrupled limb amputation. (Cooke et al., 2016) looked at 5527 cases of lower limb amputation that occurred in Japan from (1968–1997) on quadruple amputation. The key learning point in their study was in showcasing how various integrations of technology can impact and benefit amputees therefore making them productive member of the family or society. In context with this study, I would like to highlight that in certain cases, not all limbs with impairment are considered candidates for prosthetic devices but most will certainly qualify for some sort of assistive technology devices. As a result, rare cases such as those involving quadrupled amputation could be further reviewed as technology advances in the future. In this case, (Cooke et al., 2016) showcased a study conducted in 2012 on a quadrupled amputee known as CX with bilateral trans humeral with unusual challenge having all residual limbs being very short.

The CX case study reflected on current needs and future needs of methods and technologies that would enhance function and life satisfaction for people with limb impairment. Their study concluded that without technology, candidates like would not attain the desired independence, mobility and quality of life and 'would most likely spend his days watching television and being cared for by others' according to (Cooke et al., 2016). Real-life experience such as those of CX continue to inspire scholars to research deeper into emerging technology trends for innovative solutions aimed at impacting the quality of life of people experiencing complex and rare situations such as having quadrupled amputation. Holistically, we need to look into the future to determine how to advance the development of prosthetic devices to meet complex need.

4.12 Advanced Materials, 3D/4D Printing, and Imaging

Studies by (Kumar et al., 2017) on biomaterials and tissues engineering determined that lower-limb prosthetic device are sophisticated and that they needed to be made simple and elegant. Their study found that extensive research on implantable stumps was underway and could eradicate the need for a socket. Similar studies by (Padi et al., 2017) study related to advance material and knee joint, they point out that found that knee joints of polymer construction were light in weight and are easy to use and maintain. This suggests that developing lightweight materials would benefit the level of amputee's comfort, and suspension therefore resolving challenges around the socket due to better material technology. (Kumar et al., 2017) noted in their study that parallel developments in bioprinting, prosthetics, and robotics, super-human-like body parts will no longer be just a fantasy but a reality in the future which goes beyond science fictions that often presents scenarios of an exceptionally evolved and highly technological mankind (Lara-Barrios et al., 2018). Researchers are developing new prosthetic skins and limbs that restore not just movement but touch as well as demonstrated in 2018 by researchers at Johns Hopkins University who created an electronic skin to help restore a sense of touch to amputees (*FTI_2021_Tech_Trends_Volume_All.Pdf*, 2020). In future, 3D printing is expected to be the mainstream manufacturing technique by 2050 due to increasing number of applications and leading medical device companies continue to invest in the technology (Towards 2050, 2018).

A review of the science and technology trend report presented by NATO for the year 2020 to 2040 identified that at the cutting edge of research will be in the development and exploitation of new materials. The new materials discussed in the report was referred to as Novel Materials and Manufacturing (NMM) which are artificial materials with unique and novel properties. I believe that discoveries of new material will impact how prosthetics are designed and manufactured to benefit people with lower limb impairment (Padi et al., 2017).

4.13 3D printable materials selection using different parameters

To identify which materials are suitable for 3D printing, I conducted used a computer software called material wizard to what materials would be suitable for 3D printing based on various parameters such as heat deflection, tensile strength etc. First, the researcher selected the 3 fabrication methods that the tool offered. Those included additive 3D printing, CNC machining and Urethane Casting. Selecting all three methods revealed 92 materials that were found inside the tool that could be tested for various properties as shown in Table 15.

Table 15.

Material Selection Wizard for 3D Printing

Technology

Additive (3D Printing) | CNC Machining | Urethane Casting

Key Characterisics — Choose all that apply. Note some combinations

Rigid | Flexible
Low Friction | Heat Resistant
Bio-compatible | Clear/Translucent

Material Properties — Click on a Material name for more information.

Heat Deflection (°F)
Tensile Strength (psi)
Tensile Modulus (psi)
Flexural Strength (psi)
Flexural Modulus (psi)
Elongation @ Break (%)
IZOD Impact (ft.-lb./in.)
Hardness Shore A
Hardness Shore D

92 materials found.

RESET FILTERS

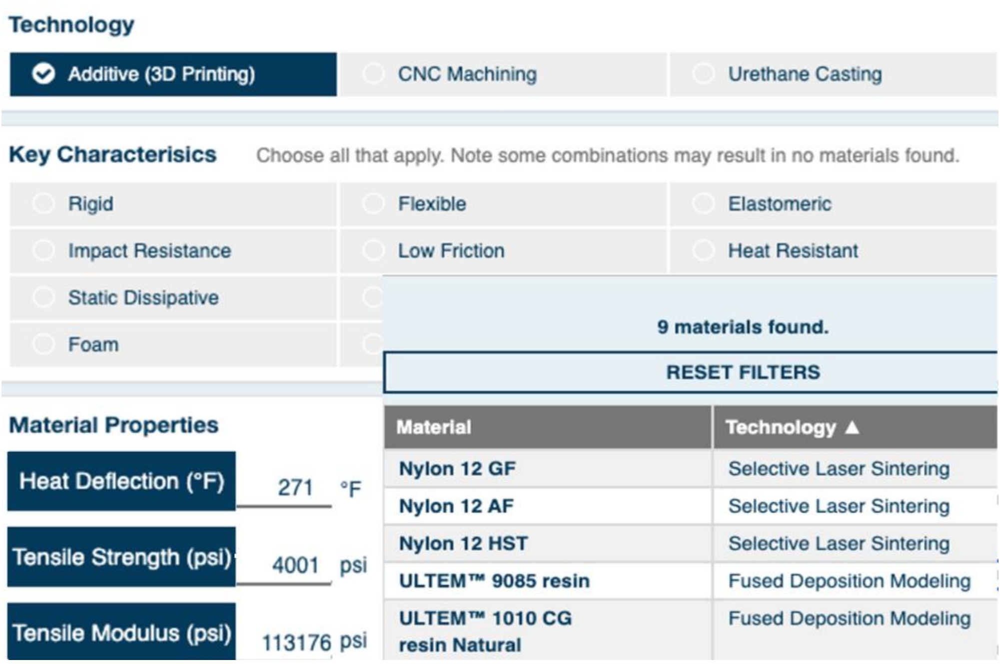
Nylon 12 PA	Selective Laser Sintering
Nylon 12 GF	Selective Laser Sintering
Nylon 12 AF	Selective Laser Sintering
Nylon 12 HST	Selective Laser Sintering
Flex TPE	Selective Laser Sintering
Nylon 11 EX	Selective Laser Sintering
Rigur	PolyJet
ABS CNC	CNC Machining
40lb. Modeling Board	CNC Machining
Acrylic	CNC Machining
G10 Fiberglass	CNC Machining
Nylon 6/6	CNC Machining
Nylon GF 30%	CNC Machining
Polycarbonate	CNC Machining
Polyethylene	CNC Machining
Polypropylene	CNC Machining
PEEK	CNC Machining
PVC	CNC Machining
PEEK 30% GF	CNC Machining
G10 FR Fiberglass	CNC Machining
AFP3100	Urethane Casting

Note: Material Selection Wizard Tool for 3D printing, CNC machining and urethane casting using Material Wizard Simulation (*Material Wizard | 3D Printing Materials | Stratasys Direct Manufacturing*, 2019)

The next step was focused on identifying which materials would be ideal for 3D printing based on different parameters within the characteristics of heat deflection, tensile strength, and tensile modulus. The set parameters levels selected for the test were as follow; heat deflection (271°F), tensile strength (4001 psi) and tensile modulus (113176 psi). The result associated with these parameters revealed that there were 9 materials that could be used for additive manufacturing (3D printing). This virtual testing revealed that the capabilities offered by 3D printing are enormous and that designing, and fabrication of 3D printed lower limb prosthetic devices can be customized to include various material characteristics as depicted in Table 16.

Table 16.

Review of 3D Material Selection Using Various Parameters



Note: 3D material selection matrix with parameters for heat deflection, tensile strength, and tensile modulus (Material Wizard | 3D Printing Materials, 2019)

I deduced out of this exercise that most materials regardless of the manufacturing process selected can be tested for various characteristics such as rigidity, impact resistance, static dissipate, foam, flexibility, low friction, chemical resistance, multi-color, elastomeric, heat resistance, biocompatibility, over-mold, toughness, flame retardant, clear/translucent, high strength, ultra-violet stability and high resolution or high detail. It can therefore be concluded that the life expectancy of 3D printed prosthetic devices for lower limbs in relation to traditional production processes such as CNC machining varies depending on the material selections used, complexity of the design and how the device eventually be utilized.

4.14 Cost

A thorough review was done on the cost of lower limb prosthetic devices looking through various literatures including white paper reports compiled by the Bioengineering Institute Center for Neuroprosthetic (*Limb Prosthetics Services and Devices*, 2017). The white paper was comprehensive, revealing that the cost of lower prosthetic devices varies depending on what they are made of the functional capabilities they provide, and level of complexity as shown in Table 17.

Table 17.

Cost Assessment of Lower Limb Prosthesis

COST ASSESMENT OF LOWER LIMB PROSTHESIS

Prosthesis Description	Cost
Basic artificial limbs insurance cap restrictions range from $2500	$2,500
Cost for limb prosthetic devices allowing patients to stand and walk on level ground	$5,000 to $7,000.
Allow the person to become a "community walker," able to go up and down stairs and to traverse uneven terrain	$10,000
Facilitate running and functioning at a level nearly indistinguishable from someone with two legs.	$12,000 to $15,000
Contain polycentric mechanical knees, swing phase control, stance control and other advanced mechanical or hydraulic systems	$15,000 or more
Exoskeletons in commercial sectors is quite limited due to their high cost	$25,000 per suit or more
Below-knee traditional prosthetic cost of roughly (Reidel, 2017).	$1,500 to $8,000

Note. Compiled by researcher.

According to (Rapp et al., 2019), future development of prostheses will depend greatly on demand and may vary from county to county or regions. For example, for developing countries, the market for low-cost limited function prosthetic leg devices will continue to expand to meet the needs while considering of funding restrictions common in all third world economies. For more advanced countries like US and Europe, the cost of advance prosthetic devices will continue to rise with demand and increased awareness of new advanced prosthetic devices such as bionic prosthetic devices. Notably, Rapp et al. (2019) pointed out that cost was far hindering market growth. Cost is therefore a major challenge that should be considered when designing and manufacturing prosthetic devices and hopefully, the emergence of new technologies will play a role in reducing the cost associated with acquiring or maintain a prosthetic device which is essential for people with limb impairment.

Looking across OECD countries, cost challenges seem to be prevalent regardless of what county, region or continent one is from because. For example, in OECD countries, only one-fifth of all spending on health care comes directly from patients through out-of-pocket (OOP) payments (OECD, 2021). This amount is quite high given not all OECD countries are wealthy. I believe that policy change on cost of lower limb prosthetic devices will benefit people with limb impairment in the future and that technology will continue to play a key role as quoted by Roy Amara, past president of The Institute for the Future "We tend to overestimate the effect of a technology in the short run and underestimate the effect in the long run." (Myers, 2018, p.994).

4.15 Standards

Studies by (Haji Ghassemi et al., 2019) identified that robot standards and sensing technology based on current ethical frameworks required periodic review given that there are moral and ethical concerns which need to be taken into consideration every time a robotic equipment or device is granted to users. In this case, advanced lower limb prosthetic devices that are robotic in nature and must some extend can be programed using a computer.

Looking at material standards, (Andrysek, 2010) identified that ISO standards for mechanically testing such as those focused on structural integrity of prosthetic components should be evaluated for fitness of use, functionality, and durability of components in the field. This will ensure that manufacturing is producing products that meet safety standards based on advanced manufacturing methods. The overarching concern has been a lack of standards in some areas that 3D printing is involved in.

According to (Spaulding et al., 2020), standardization lack in biosafety of 3D printed metallic medical devices which may impact biocompatibility, degradation performance, and biological activity of the materials. These types of concerns have direct implication on lower limb medical prosthetic devices such as those that are implantable on socket stumps found within the lower limb prosthesis (Asif et al., 2021)

4.16 Education and Training

Education and training could be the key to help scholars unlock and re-imagine the significance that technology and innovation will play in the future. To understand the full breath of prosthetic device development, I looked into the works of (Spaulding et al., 2020) whose study focuses on education standards in prosthetic and orthotic curriculum. In their research, they investigated the current state of prosthetic and orthotic education which comprised of approximately 140 clinicians in prosthetist and orthotist (P&O) programs and 17 P&O technician pro-grams that currently exist worldwide.

On the curriculum and education framework, their study investigated prosthetic and orthotic (P&O) education standards, the 2018 ISPO (International Society of Prosthetic and

Orthotic) Education Standards and WHO Standards. The result revealed that there was a significant shift moving from a structure and content-based focus curriculum to a process and outcomes competency-based outcome. (Spaulding et al., 2020) also pointed out that for the prosthetist, it was no longer sufficient just to know the trade but to be able to integrate and collaborate with other medical experts such as doctors, therapist as well as engineers and manufactures to meet the needs of the patient. This includes professional competencies that align with societal health goals, including equity, quality, and efficiency.

Based on these findings, I believe the future development of lower limb prosthetic devices should apply system engineering concept in capturing system requirements starting from the end user and looking through to the component level of the prosthetic device and delivery to meet the needs of people with limb impairment. Which aligns with modern vision of ISPO of having "world where all people have equal opportunity for full participation in society." (Anderson et al., 2020, p. 366). Ultimately, there is a need to increase collaboration across industry, government, academic institutions and professions in various fields and industries.

4.17 Summary

A total of 1227 papers were identified in the study. 744 papers removed since they were duplicates, 204 papers did not meet the inclusion criteria and 65 paper were admitted for review and categorized for focus on lower limb prosthesis (16 papers), robotics (17 papers), enabling technologies (14 papers), advanced materials and advanced manufacturing (12 paper) and standards (12 papers).

Analysis for patent filing trend was completed to identify new trends in technology. I investigated more than 6,000 patents and identified key players in prothesis patent filing. This included various manufactures, academic institutions, and individual contributors. Key data points that supported this section of the study could be attributed to WIPO, USPTO and Google patent database.

Looking back at all the studies, I was able to identify the needs in addressing unmet challenges faced by people dealing with lower limb impairment. Currently the demand for prosthetic devices is higher than the supply of products in the market. Affordability and cost are a major factor and most advanced prosthetic devices are quite expensive. Looking into advancement in manufacturing process, 3D and 4D printing are still in their infancy stage and have not fully mature. The technological trend in lower limb prosthetic devices is showing exponential growth in recent years and there is more innovation taking place based on various studies and patent filing analysis that this study was engaged in.

As a result, there is a need to conduct more research and development (R&D) especially in advanced materials to unlock more innovation and to help expand on new manufacturing methods and capabilities. Secondly, there is a need to advance enabling technologies such as micro-chips and sensors which are in high demand and are needed to advance and improve capabilities of lower limb prosthetic devices and equipment's therefore impacting the life of people with limb impairment. Most importantly, cost, affordability, and accessibility of assistive technology devices will still need to be addressed as the trends in technology landscape continue to change. Chapter 5 presents the major findings of this research.

CHAPTER 5. CONCLUSION, DISCUSSION, AND RECOMMENDATIONS

5.1 Conclusion

In this section, I discuss my findings for the research questions that guided this study. The guiding questions were:

RQ1: What are the major concerns and issues with lower limb prosthetic devices?

RQ2. What are the new and emerging trends in technology and innovation of lower limb prosthetic devices?

RQ3: To what extent will the new advances in prosthetic technology address the growing issues and needs associated with lower limb prosthetic devices?

This study has investigated assistive technologies issues and potentials and explored emerging trends in technology innovation that promise to change assistive technologies, and in particular, lower limb prostheses, in revolutionary new ways.

Previous research on lower limb prosthesis devices identified numerous benefits and identified various shortcoming associated with lower limb prosthetic devices. One overarching benefit is that these devices can help to improving the quality of life of individuals with limb impairment. On the other hand, short coming includes bad experiences by the end user such having increased pain induced because of using a prosthetic device.

Central to this research study was the identification of new trends in technology associated with lower limb prosthetic devices. I investigated hundreds of peer reviewed articles, studies, industry journals and white papers. I conducted a technology focused trends analysis based on patent filing to deduce the following major findings.

I found there is a remarkable growth and interest in the industry with increased trends in technology in prosthetic devices. Some of the areas that showed increasing interest involve the following: bionic, robotics, exoskeleton, neurotechnology, myoelectric sensors, advanced materials, imaging technology such as scanning, 3D printing and 4D printing, Artificial Intelligence (AI) and data analytics. The span of these enabling technologies to have unlocked previously unmet needs and capabilities therefore increasing the spectrum of the end user experience with various prosthetic devices.

Looking into regulations, safety and quality, this study found that there is variance in standards on how prosthetic devices are manufactured or fabricated requiring further intervention. On safety, there are concerns that new technologies are being introduced into the market too fast and that safety was lagging and was more reactionary after the fact instead of being put first above everything else. Regarding quality, the study found that some of the newer technologies such as 3D/4D printing had not fully matured and that their full potential and quality will be realized in the future. These findings suggest that in general, there is a need for more R&D work that needs to be done in this area.

Another major finding in this study is that more focused research work is needed on areas dealing with enabling technologies which are also presumed to be the key technology drivers unlocking innovation capabilities in lower limb prosthesis development. These enablers include bionic, myoelectric sensors, Artificial Intelligence (AI) and data analytics. The range of enabling technologies to have increased over the years and have impacted how prosthesis devices are made. This trend is expected to continue and will help to define what is on the horizon for individuals with lower limb impairment.

The final finding from this study pertain to shortage of trained and qualified professions in the industry who are needed to support with the maintenance and fitting of prosthetic equipment. Given that there is tremendous technology advancement in prosthesis involving both electronic and mechanical systems, the competency gap of technical persons will continue to grow which is a major risk that needs to be taken into consideration. According to (Spaulding et al., 2020) maintaining a technical edge in technology is a function of the society and require investment in maintaining that edge. As a result, I believe that there is a need to have more collaboration across government, industry, and academic institution. More funding and increased invest in R&D and policy changes would potentially bridge the existing knowledge gaps.

From this study, the following conclusions can be drawn; first, the relevance of new trends in emerging technology is imperative to the future advancement of lower limb prosthetic devices and to the quality of life of people who depend on them. Secondly, there is a need to policy intervention given that cost, affordability, and accessibility is still a major factor hindering certain class of people from drawing the full benefit of prosthetic devices especially those that offer autonomous features and provide additional comfort to the user. Currently, cost continues to be a major factor and a below-knee amputation costs and on average, a traditional prosthetic cost of roughly $1,500 to $8,000 and may only have a lifespan of no more than 4–5 years (Reidel, 2017).

Lastly, this study found that the future of robotics, advanced manufacturing (3D printing), advanced imaging technologies (3D scanning) and advanced materials are integral in establishing the basic framework for prosthetic devices. The ability to conduct a rapid proto typing with 3D printing capabilities has played a major role in meeting emergent needs of those with lower limb impairment. The wait time has been reduced and customization of products have been easy to achieve. The key challenge has been around mass production of prosthetic devices. Overall, this study found that trends in technology around lower limb prosthesis is very promising and will play a major and impactful role in the industry.

5.2 Discussion

RQ1: What are the major concerns and issues with current lower limb prosthetic devices?

In response to question number one #1, I found that even though there are many patents that have been filed showing remarkable growth in innovations and technology with various improvements from component level to the actual prosthetic device, there are still challenges that need to be addressed. More holistically, some of the challenges need to be addressed at the industry wide level with new policies put in place to re-enforce on existing standards, safety, and regulations on prosthetic products.

Another concern I noted was the lack of industrywide standards to regulate how prosthetic devices should be made. There are however various standards that address material requirement and quality.

One overarching challenge is that most lower limb prosthetic devices are development isolation therefore lacking an industry wide approach. This has been however attributed to high variance in the customization needs to ensure the device fits the intended user. According to Balk et al. (2018), gaps in the design and manufacturing of prosthetic devices are due to difference in standards, materials, and customizations.

Additionally, safety standards pertaining to advanced manufacturing methods have been addressed by (Spaulding et al., 2020), who expressed concern regarding lack of standardization of 3D printed metallic medical devices citing urgent safety issue because there is no international standard evaluation system that has been established to address this concern. Looking at standard associated with robotic prosthetic products, there have been ethical issues associated with breech of data privacy given that some smart prosthetic devices can capture personal information beyond what the user can control. As a result, (Haji Ghassemi et al., 2019) pointed out that the Institute of Electrical and Electronics Engineers IEEE decided to set forth an ambitious program on standards under the banner of the IEEE P7000 series which includes standards on Data Privacy Processes (P7002).

The other concerns involved cost, affordability, and access to equipment. This study found that a large majority of individuals with lower limb loss or impairment are not able to afford assistive prosthetic devices on their own without additional help and support. According to (Limb Lost Task Force, 2019), a below-knee amputation costs Medicare an average of $81,051 per person which may not be sufficient to cover all the needs. A serviceable below-the-knee prosthesis that allows the user to stand and walk on level ground range from $5,000 to $7,000 while a prosthetic leg also referred to as "community walker," which allow user to be able to go up and down stairs and to traverse uneven terrain will range from $10,000 and a prosthetic leg with computer-assisted devices start in the $20,000 to $30,000 price range which is a major issue. On the other hand, the full demand is prosthetic devices is so high with the Global Prosthetic Market currently valued at USD 1281.39 million (Orthopedic Prosthetics Global Market Report, 2021).

RQ2. What new and emerging advances in lower limb prosthetic technology are on the horizon?

In response to question number two #2, I found promising developments in lower limb prosthetic technology over the next 30 years. By scouting through various data Notes including industry foresight studies, what's on the horizon for lower limb prosthetic technology include major integration of various technologies specifically in material science, 4D printing, IoT, nano-scale manipulation of materials, mixed materials printing, use of AI and other digital enabling technologies. My personal articulation on what is on the horizon included unmatched level of human intelligent systems with increased autonomy.

Experts say that 50 percent of the human body is currently replaceable with artificial implants and advanced prosthetics (Future of Artificial Limbs, 2018) therefore, future lower limb prosthetic devices will not only be comfortable to wear but will have unmatched capabilities and sensing systems. I foresee a future filled with smart systems that are ubiquitous with centralized sensor and control systems.

Given that the trend of technology is headed towards bio-technology engineering and neuro-technology, the ability of quantum computing systems may be used in creating future humans. These future humans will have more human–robotic interfaces, bionic body parts supported by increased cutting-edge medicine that will make it possible to recover from very severe injuries quickly and easily (Bos et al., 2016). I concluded that what's on the horizon for lower limb prosthesis technology will therefore depend on heavy integration of human intelligent systems highly interconnected and distributed to seamlessly unlock the full potential of technology and humans.

According to (OECD, 2016), the ten emerging technologies identified in the report included Internet of Things; big data analytics; artificial intelligence; neurotechnology; nano/ microsatellites; nanomaterials; additive manufacturing; advanced energy storage technologies; synthetic biology; and blockchain (2016). Other scholars agree that future developments in bioprinting, prosthetics, and robotics including making of a super-human-like body parts (Padi et al., 2017).

RQ3: To what extent will the new advances in prosthetic technology address the ongoing concerns and issues with lower limb devices?

In response to question number two #3, I found that advancement in lower limb prosthetic technology alone is not sufficient for addressing all the ongoing concerns and issues associated with lower limb devices. Several studies agree that living with limb loss or disability can have both a physiological and psychological impact on the individual and to some extent lead to hopelessness. As a result, when addressing issues related to disability from a design and manufacturing standpoint, the needs of the end user should be taken into consideration to reduce other challenges such as equipment abandonment. Designing good products that are comfortable, meets the intended function and easy to use will address some of the basic needs of individuals with lower limb impairment.

On the other hand, advanced smart prosthetic devices may partly resolve some of the concerns and issues that are not able to be resolved by conventional lower limb devices that may have certain limitations. More end user capabilities have been realized from advanced prosthetic devices because of innovation and increased human creativity. This has led to the realization of devices being used in various activities such as in underwater, mountain climbing, ice skating, skiing, and various other Paralympic competitive activities etc. In addition to this, users have been able to attain certain levels of independence therefore improving their quality of life. It can therefore be concluded that new advances in prosthetic devices may partially resolve some of the concerns and issues with lower limb devices.

Looking into cost, affordability, and service provision as an issue; reduction in cost and affordability of the lower limb prosthetic device will be more appealing to most users who are not able to afford certain devices compared to those who can. Improved service provision will make it possible to easily access to counseling, equipment exchange, repair services and training on various aspects of prosthesis therefore meeting some of the needs of people suffering from lower limb impairment.

Looking into advanced materials and advanced manufacturing practice; the ability to produce custom made products quickly making them accessible and affordable is of importance. However, there is limitation when it comes to mass production of lower limb impairment because most of these devices have require to be customized. Technology can therefore address some of the concerns if better materials and agile production system can increase the level of production needed to match or exceed the current shortage and demand of lower limb prosthetic devices.

5.3 Recommendations

I recommend that the technology framework on lower limb prosthesis should be re-enforced ensuring that people come first at the center of all innovations. To do this more effectively, improvements on regulations pertaining to quality and safety of products is required to ensure full protection of individuals with lower limb impairment. A second layer of regulatory requirement with focus on inventors in the open space innovation hubs should be developed to ensure that basic training on both the psychological/physiological are provided and recognition certificates awarded to those inventions that are centered on both aspects requirements to bridge the existing gap between open space innovation.

The second recommendation I would make involves developing a system framework supportive of the Technology Readiness Level (TRL) assessment of lower limb prosthetic devices to ensure that requirement of minimal viable product list is sufficient to meet the needs of the design intent and that of the user. This approach will ensure that key critical elements associated with enabling technologies are captured and safely integrated in the concept and design phase during the build process of lower limb prosthetic device. Ultimately, this framework will act as baseline for asynchronous integration of digital tools into the prosthetic device. According to (World Intellectual Property Organization, 2020), on an average, experts' assessment of TRL on emerging technologies to be somewhere between proof-of-concept and minimum viable product stage. This means that there is still more work that needs to be done to ensure that there is increased end-user acceptance of new products being introduced in the market

This research study recommends that more R&D should be done advanced materials and develop even better ways of integrating them into current and future advanced manufacturing platforms such as in 3D/4D printing. More research is still needed in understanding the durability and strength of advanced materials. Therefore, finding right material alloy including polymers and soft materials will benefit future technologies.

On the digital front, I recommend increasing support for the research and development of enabling technologies for lower limb prosthetic devices such as IoT, sensors, chips, myoelectric, chips, nontechnology etc. will unlock future capabilities of lower limb prosthesis devices. More emphasis should study the whole prothesis system to attain the correct level of controls on the prosthetic device and mitigating any risk or injuries to the user.

One overarching challenge that needs to be addressed is on training and education. Currently there is a high shortage of qualified technical personnel cable of servicing advanced prosthetic devices which may have a major implication on the development of advanced prosthetic devices. This concern needs to be addressed early to avoid future impacts. According (Padi et al., 2017), it will take approximately 50 years to train 18,000 more skilled professionals given that the current shortfall is in the range of 40,000 technicians.

Policy changes and interdisciplinary collaboration: Given that the demand of lower limb prosthetic device is higher that the available equipment in the market, there is an urgent need for policy change to address issues associated with cost, funding, training, service provision and research barriers. Increased interdisciplinary research is required across industry, government, and academia to drive more innovation and to overcome funding constrains. Increasing these capabilities and opportunities will accelerate innovation therefore benefiting furtherance of advancement of lower limb prosthesis.

5.4 Implications for future research

Many studies have been conducted on lower limb prosthesis devices, but most have not engaged on what's on the horizon studies focusing on emerging trends in technology on lower limb prosthesis. This study is one of few that have taken a holistic approach providing context that addressed some of the challenges and needs individuals with limb impairment while also engaging on technological needs with focus on what is on the horizon for lower limb prosthesis devices. As such, future research work should build upon this work and further evaluate new trends in technology innovations as they apply to lower limb prosthesis.

Drawing from previous research work on unmet needs of individuals with limb impairment, future studies should address both the psychological and physiological needs of individuals with disabilities, especially those with lower limb loss and impairment, to ensure that the lower limb prosthesis devices are investigated as a whole system with the end user at the center of all design.

5.5 Conclusive Remarks

To this end, this research study has provided insight into some of the challenges faced by individuals with lower limb loss or impairment and how new trends in technology could impact them. This author has therefore proposed that a framework that posit that the prosthesis device end user should be put at the center of all design requirements ensuring that most of their needs are captured upfront. To do this more effectively, I have proposed the establishment of a minimal viable list to be created to define the required baseline of all future lower limb prothesis designs and production given that the number of open space innovation have increased remarkably and therefore the associated risk to the end user.

More studies and research work should be done on advance materials and advanced manufacturing practice to increase the level or agility and readiness of future manufacturing process. The integration of 4th industrial revolutionary tools will continue act as an enabler unlocking more capabilities of lower limb prosthesis devices (see Appendix E).

More work is still required in establishing full and better control of smart and advanced prosthetic devices that have various elements of a robot. Better control functions and sensors will ultimately increase safety of the end user. Lastly, technology advancement has unlocked unmatched capabilities of lower limb prosthesis devices and improved the quality of life of individuals with limb impairment. There are more than 40 new technologies in the horizon (See Appendix H and Appendix I) that could potentially impact how future prosthetic devices are made. Relentless effort is therefore required in policy change in terms on regulating safety standards and increasing monitoring efforts to ensure the highest level of safety in technologies that are introduced to the market. This includes power nodes and energy transmitting devices which can cause electrical shock or burns to the user.

Ethical concerns are another area of interest especially in terms of protecting the end-user data that have been collected to support automation efforts with smart advanced prosthesis devices with computer chips. The increase in humanistic intelligent systems, machine learning (ML) including data analytics, advanced algorithms and mathematical models will play a key role helping with future decision capabilities across the peripheries and spectrum on the new trends in technology are on the horizon that will support the World Health Organization’s 2030 agenda for Sustainable Development. They express the need for every person, in every location around the world, to have access to affordable health care services, and they hope that persons with disabilities will have access to customized and affordable assistive technologies and prostheses to permit them to enjoy a higher quality of life at home, in school, in the workplace, and in society.

5.7 Summary

Chapter 5 addressed the three central research questions that this study aimed at answering and provided recommendations therefore contributing the existing body of knowledge. This study found that the demand for lower limb prosthetic devices is higher than the current supply. Some of the key emerging technologies that this study believes will be impactful to the horizon of prosthetic limb devices in the next 30 years included bionic, robotics, exoskeleton, neurotechnology, myoelectric sensors, advanced materials, imaging technology such as scanning, 3D printing and 4D printing, Artificial Intelligence (AI), and data analysis.

Therefore, the integration of 4th industrial revolutionary tool will continue defining the future of lower limb prosthesis devices.

This chapter also identified that regulations, safety, quality, and industry stands were critical and should be considered in every aspect of the design and development of prosthesis device. Additionally, this chapter discussed about increasing R&D collaboration across industry partners, government, and academic institution.

This study suggested that their individuals with lower limb challenges should be put at the center of every innovation and development pertaining to prosthetic devices. In this context, the study proposed that a framework should be establishments as baseline of capturing minimal viable design requirements needed to meet the needs of the end users.

In terms of cost, affordability, and service provision, one of the findings of this study was that a policy change would provide the most ideal approach for overcoming various financial and service provision constraints given that the overall population of those in need is higher that the available equipment in the market while cost is still a major factor.

This study also found that advanced materials and advanced manufacturing practice coupled with enabling technologies would unlock innovation therefore addressing some of the future needs in the industry. This study addressed overarching concerns related to scarcity and shortage of qualified technicians who would service advanced prosthetic devices to meet future needs. I remain hopeful that the future will present new opportunities for the less able in society to become productive, active, and respected members, wherever they may live.

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APPENDIX A. HUMAN RESEARCH CERTIFICATE OF COMPLETION

CITI PROGRAM

Completion Date 11-Dec-2020
Expiration Date 10-Dec-2024
Record ID 39420251

This is to certify that:

NIXON OPONDO

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

Human Research
(Curriculum Group)
Group 2.Social Behavioral Research Investigators and Key Personnel
(Course Learner Group)
1 - Basic Course
(Stage)

Under requirements set by:

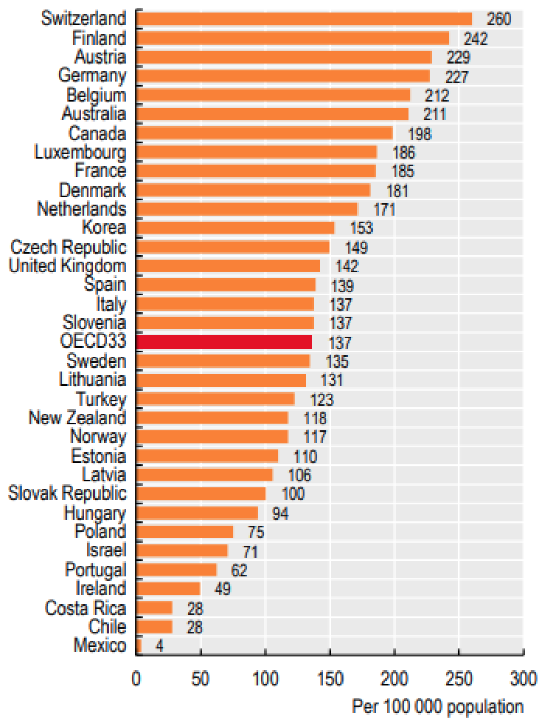
Purdue University

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w7aad6f11-7191-439f-8d77-784bfa51a45a-39420251

APPENDIX B. OECD 2019-20 DATA

Figure 5.26. **Knee replacement surgery, 2019 (or nearest year)**



Source: OECD Health Statistics 2021.

APPENDIX C. LOWER LIMB PROSTHESIS PATENTS

	PAT. NO.	Title
60	9980779	limb metrics
61	9962273	Adjustable socket system
62	9956094	Adjustable prosthetic interfaces and related systems and methods
63	9925071	Prosthetic and orthotic devices and methods and systems for controlling the same
64	9895240	Powered prosthetic hip joint
65	9877851	Adjustable seal system, seal component and method for using the same
66	9848822	Prosthesis and orthosis slip detection sensor and method of use
67	9808357	Reactive layer control system for prosthetic and orthotic devices
68	9795303	Medical hyperspectral imaging for evaluation of tissue and tumor
69	9707106	Adjustable seal system, seal component and method for using the same
70	9622884	Control systems and methods for gait devices
71	9549828	Modular prosthetic sockets and methods for making same
72	9532877	Robotic device and method of using a parallel mechanism
73	9486334	Vacuum prosthesis with force sensing member
74	9474633	Alignable coupling assembly for connecting two prosthetic limb components
75	9468543	Modular prosthetic sockets and methods for making same
76	9468542	Prosthetic socket and socket liner with moisture management capability
77	9443203	Ambulation prediction controller for lower limb assistive device
78	9387096	Feedback control systems and methods for prosthetic or orthotic devices
79	9351854	Actuator assembly for prosthetic or orthotic joint
80	9345428	Hyperspectral imaging of angiogenesis
81	9308642	Systems and methods for adding or subtracting energy to body motion
82	9295841	High-frequency electrical nerve block
83	9289316	Quasi-active prosthetic joint system
84	9278014	Method for aligning a prosthesis
85	9271851	Systems and methods for actuating a prosthetic ankle
86	9204805	Medical hyperspectral imaging for evaluation of tissue and tumor
87	9201988	Process and system for generating a specification for a customized device, and device made thereby
88	9161848	Systems and methods for prosthetic suspension system
89	9044349	Modular prosthetic sockets and methods for making same
90	9044346	Powered prosthetic hip joint
91	9017418	Control systems and methods for prosthetic or orthotic devices
92	8978224	Modular prosthetic sockets and methods for making same
93	8971984	Hyperspectral technology for assessing and treating diabetic foot and tissue disease
94	8956421	Dynamic support apparatus and system
95	8920517	Modeling and desired control of an energy-storing prosthetic knee
96	8915968	Prosthetic and orthotic devices and methods and systems for controlling the same
97	8882852	Dynamic support apparatus and system

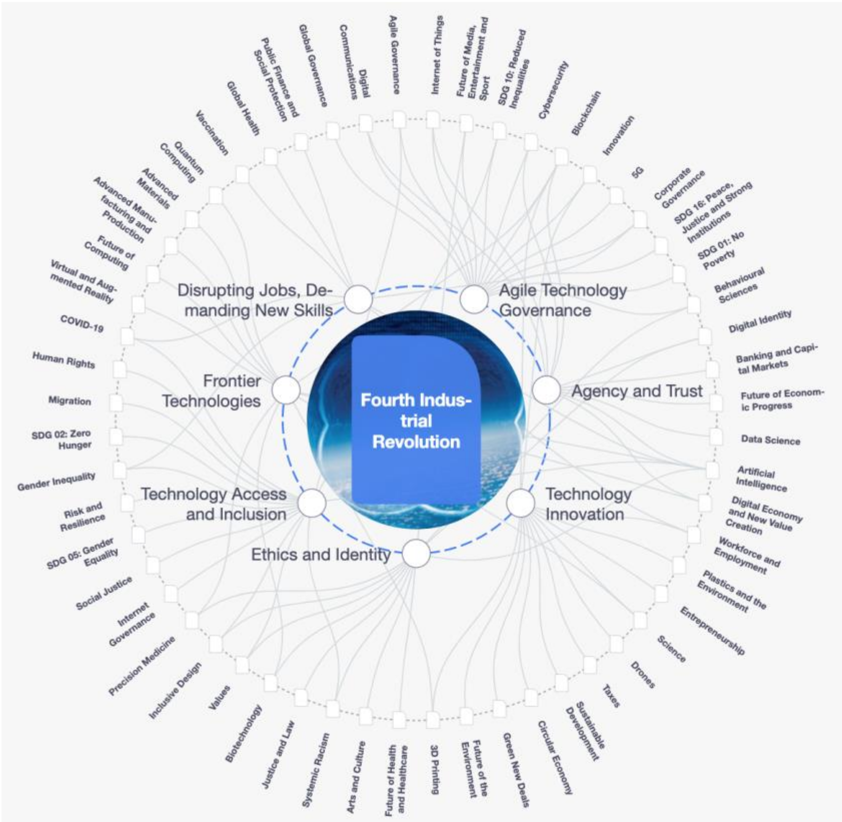
Note. (*Lower Limb Prosthetic Devices - Google Patents*, n.d.)

APPENDIX D. LOWER LIMB PROSTHESIS PATENTS

	PAT. NO.	Title
97	8882852	Dynamic support apparatus and system
98	8870970	Dynamic support apparatus
99	8852292	System and method for determining terrain transitions
100	8845754	Dynamic support apparatus and system
101	8821588	Method for anchoring prosthetic and orthotic devices
102	8801802	System and method for data communication with a mechatronic device
103	8784502	Method for aligning a prosthesis
104	8771372	Lower limb prosthetic device with a wave spring
105	8758449	Socket liner for artificial limb
106	8721737	Passive ankle prosthesis with energy return simulating that of a natural ankle
107	8709097	Actuator assembly for prosthetic or orthotic joint
108	8702811	System and method for determining terrain transitions
109	8696764	Further improvements to ankle-foot prosthesis and orthosis capable of automatic adaptation to sloped walking surfaces
110	8657886	Systems and methods for actuating a prosthetic ankle
111	8655433	Hyperspectral imaging in diabetes and peripheral vascular disease
112	8598815	Controllable transverse rotation adaptor
113	8555715	devices
114	8538570	Process and system for manufacturing a customized orthosis
115	8496715	Pneumatic connections for prosthetic socket
116	8443501	Adjustable prosthetic interfaces and related systems and methods
117	8409297	Robotic prosthesis alignment device and alignment surrogate device
118	8215186	Lower-limb prosthesis force and moment transducer
119	8074559	Dynamic support apparatus and system
120	8057550	Transfemoral prosthetic systems and methods for operating the same
121	RE42,903	Electronically controlled prosthetic knee
122	8048172	Actuator assembly for prosthetic or orthotic joint
123	7942935	Device and system for prosthetic knees and ankles
124	7922775	Pulsating pressure chamber and method for fluid management
125	7922774	Method for aligning a prosthesis
126	7896927	Systems and methods for actuating a prosthetic ankle based on a relaxed position
127	7886618	Lower-limb prosthesis force and moment transducer
128	7799091	Control system for prosthetic knee
129	7691154	Systems and methods of controlling pressure within a prosthetic knee
130	7670385	Internal socket and fitting system for a prosthesis
131	7637959	Systems and methods for adjusting the angle of a prosthetic ankle based on a measured surface angle
132	7632315	Vacuum chamber socket system
133	7531006	Sensing system and method for motion-controlled foot unit

Note. (*Lower Limb Prosthetic Devices - Google Patents*, n.d.)

APPENDIX E. FOURTH INDUSTRIAL REVOLUTION

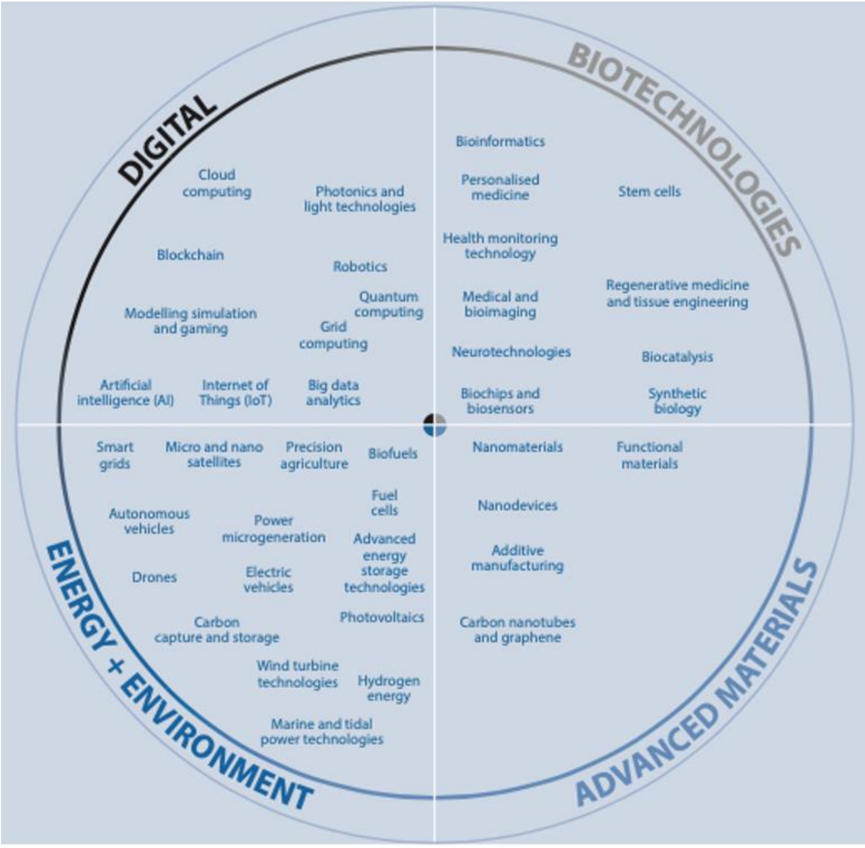


Note. (*World Economic Forum*. Strategic Intelligence n.d.)

APPENDIX F. 106 TECHNOLOGICAL TRENDS

Note. (*NTT DATA Technology Foresight 2021*, n.d.)

APPENDIX G. 40 KEY AND EMERGING TECHNOLOGIES FOR THE FUTURE



Note. OECD 2016 (FUTURE TECHNOLOGY TRENDS. OECD Science, Technology and Innovation Outlook 2016)

VITA

Dr. Nixon Oduor Opondo

EDUCATION

Doctor of Technology (DTech) 2022
Purdue University, Polytechnic Institute
Thesis: Emerging Trends in Technology and Innovations in
Lower Limb Prosthetic Devices

Doctor of Business Administration (DBA) 2014
National Graduate School of Quality Management
Concentration: Quality Systems Management, (2014).

Master Certificate in Lean Six-Sigma Blackbelt 2009
University of Notre Dame
Major: Project Management and Executive Leadership Strategies

Master's in Business Administration (MBA) 2009
American Public University System
Concentration: International Business Management

Master's of Applied Sciences (MS) 2006
University of Central Missouri
Concentration: Industrial Technology Management

Bachelor of Science (BS) 2003
University of Central Missouri
Major: Aviation Technology

CERTIFICATIONS AND LICENSES

Federal Aviation Administration (FAA) 2000
Airframe and Power Plant (A&P) License
Oklahoma Ground School

PROFESSIONAL EXPERIENCE

Quality and Process Engineer
Intellectual Property Management Specialist
Manufacturing Technology Analyst and Manufacturing Engineer
Flight Test Maintenance Technician and Inspector

Airline Flight Line Mechanic
General Aviation Aircraft Maintenance Technician

TEACHING EXPERIENCE

Adjunct Faculty, School of Science and Technology, University of Central Missouri.

- Teaching graduate and undergraduate classes in Lean Six-sigma and Industrial Technology Management

PUBLICATIONS

Opondo, N. (2016). *Effects of Applying Lean in the Office during Employees' Award Nomination Process - ProQuest*, n.d. https://www.proquest.com/docview/1846984317

BIO

Nixon Opondo is a Process and Quality Engineer with extensive experience in aircraft maintenance, manufacture engineer planning, manufacturing technology, project management and intellectual property (IP) protection. Nixon is a holder of FAA Airframes and Powerplant (A&P) License with over10 years of hands-on experience working on both military and commercial aircrafts. Nixon earned his first Doctoral degree in Quality System Management from the National Graduate School of Quality Management and is completing his second terminal degree in Technology Leadership and Innovation from Purdue University. Nixon earned his Master of Science (M/S) degree in Industrial Technology from the University of Central Missouri (UCM), and a Master of Business Administration (MBA) in International Business from American Public University (APU). He holds a Bachelor of Science (BS) degree and Associate of Science in Aviation Technology from UCM.

Nixon also works as an adjunct faculty at UCM school of Industrial Technology teaching both the graduate and undergraduate students on various subjects. Nixon is married with 3 boys and 2 girls. When not engaged with work or school, Nixon enjoy spending time mentoring youths and young adults in STEM programs or support senior citizens in the community. Nixon serves an appointed member of the Snohomish County Council on aging.