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Gordon Institute of Business Science
University of Pretoria

An exploratory study of the effects of Additive Manufacturing as a disruptive innovation in the medical prosthetic industry

A research report submitted by
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A research project submitted to the Gordon Institute of Business Science, University of Pretoria, in partial fulfilment of the requirements for the degree of Master of Business Administration.

13 January 2016

ABSTRACT

The introduction of a new technology or innovation can have a profound effect on any industry; sometimes it can even be a disruptive one. This disruption can affect an industry at a number of levels, including the key drivers of an industry. Additive Manufacturing (AM) is one such technology. The technology does and has shown a propensity to disrupt and subvert various industries. The medical prosthetic industry is potentially one such industry. AM has the potential to disrupt the key drivers of the industry: economics, management, manufacturing, marketing, business models, strategy and regulations. By understanding the areas that AM is most likely to affect in the industry of medical prosthetics, and how it will do so, executives can understand, plan and execute their business strategies more effectively and efficiently.

The research in this report examined the effects AM has, or would have, on the key drivers of the industry, as well as from a high-level, industry-wide perspective. A model (Table 6.9) was generated from the industry drivers that were established in Chapter 1. The model was supported by the concepts that emerged from the literature review, which also assisted in the formulation of the research schedule for the in-depth interviews. The model was effectively a guide or scorecard for assessing and grading the effects of AM on the key drivers of the industry and illuminating the key reasons and intensity for the score. Interviews were conducted with 14 interviewees who represented all areas of the industry, from academia to manufacturing. The outcomes of the interviews were processed through the model and presented both an overview of the technology's impact on the industry, as well as a more in-depth per-driver perspective.

The interviewees provided their expert opinions on the effects the technology has, or is likely to have, on the industry, if any. The final model (Table 6.9) was produced based on their responses. The results demonstrated that the majority of interviewees believed the technology would be disruptive from an industry-wide, high-level perspective. The overall score of the model reinforced this. However the majority of the interviewees' responses showed that the disruption would not be as apparent in the economics, management, manufacturing or marketing drivers of the industry, but rather in the business models, strategy and regulations. The outcomes of this research contribute to the understanding of AM and the medical prosthetic industry, and provide valuable insight to executives on how and in what driver AM technology is going to disrupt.

KEYWORDS

Additive Manufacturing. Medical Prosthetics. Disruptive Innovation.

DECLARATION

I declare that this research project is my own work. It is submitted in partial fulfilment of the requirements for the degree of Master of Business Administration at the Gordon Institute of Business Science, University of Pretoria. It has not been submitted before for any degree or examination in any other University. I further declare that I have obtained the necessary authorisation and consent to carry out this research.

David Anthony Schilperoort

13 January 2016

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1. CHAPTER ONE: INTRODUCTION TO THE RESEARCH PROBLEM

1.1. Research Title

An exploratory study of the effects of Additive Manufacturing as a disruptive innovation in the medical prosthetic industry.

1.2. Background to Research Problem

1.2.1. Medical Prosthetics

Medical prosthetics have been evolving since they were first reportedly used 3500 years ago (Norton, 2007; Finch, 2011). Wood and iron have been replaced by the much stronger and lighter carbon fibre and other synthetic composites (Norton, 2007; Finch, 2011). Advancements have also spurred on more ergonomic and dynamic designs allowing greater functionality (Norton, 2007; Finch, 2011). The technology incorporated into the prosthetics has also evolved. Myoelectric technology, for example, harnesses the user's own electric pulses to control some functions of a prosthetic (Ottobock, 2015). However, walking into a prosthetist's offices one can quickly see the craftsmanship and expertise that goes into each patient's individual prosthetic. Traditional techniques such as sanding, carving, and polishing are all still used by prosthetists to ensure their patient's prosthetic fits just right (Norton, 2007; Finch, 2011). In many respects, the creation of a medical prosthetic is as much art as it is science. The introduction of Additive Manufacturing (AM) technology may just change all that - not only how the prosthetic is manufactured, but potentially all the key drivers of the industry itself.

1.2.2. Additive Manufacturing

The term Additive Manufacturing (AM) refers to a host of techniques and technologies that use processes of joining materials by building-up objects in two-dimensional layers from 3D model data or designs known as computer aided designs (CAD) (Gu, Meiners, Wissenbach, & Poprawe, 2012). Researchers Zuniga, Katsavelis, Peck, Stollberg, Petrykowski, Carson & Fernandez (2015) claim that AM technology allows for a much cheaper, faster and more efficient prosthetic to be manufactured. Bikas, Stavropoulos, & Chryssolouris (2015) support this position stating that AM can deliver objects of very intricate and complex geometries with a minimum need for post-processing, built from tailored materials with near-zero material waste, while being applicable to a variety of materials, including plastics and metals (p.1). It is a technology that is ideally suited to fulfil the manufacturing needs of the medical prosthetic industry (Bikas, Stavropoulos & Chryssolouris, 2015). The technology has the potential to be hugely disruptive, not only because of the factors mentioned above, but also because it is portable (Project Daniel, 2013; RoboBeast, 2015; Kirkpatrick, 2015).

1.2.3. Disruptive Innovation

The book "*The Innovator's Dilemma*" by Harvard Business School Professor Clayton Christensen helped bring the concept of disruptive innovations (DI) to prominence (2000). The ideas in the book posit that entrant companies with products and technologies of seemingly inferior performance could displace or disrupt established companies. Christensen goes on to proclaim that these DIs tend to be smaller, simpler, cheaper, more reliable and convenient than established or preceding products, even though they are still based on existing technologies (2000). AM is indeed a form of DI (Weller, Kleer & Piller, 2015). This research seeks to establish whether these disruptive properties extend to the prosthetic industry, with specific focus on the industry's key drivers or market needs.

1.2.4. Medical Prosthetic Industry Drivers & Additive Manufacturing

The medical prosthetic industry in South Africa is highly dependent on imports (Business Monitor International, 2015). As it stands, virtually all the market is served by imports sourced mainly from the United States of America (USA) and Switzerland, which had import shares of 40.8% and 21.1% in 2014 respectively (Business Monitor International, 2015). This dependence on imported prosthetics has left the industry increasingly exposed to currency fluctuation, which has been predicted to be negative over the coming years - a factor that is not helped by the stagnant growth rate of South Africa (Business Monitor International, 2015). Economics are a key driver of the industry, especially given the industry's exposure to imports. AM technology has the potential to shift the control over costs back to South Africa.

In South Africa, the Health Professionals Council of South Africa (HPCSA) is the statutory body that regulates all healthcare practitioners in South Africa, including prosthetists (HPCSA, 2007). The South African Orthotic and Prosthetic Association (SAOPA) is a voluntary membership association for orthotists and prosthetists and assists members with various membership benefits, such as a discounted blanket professional indemnity and medical malpractice insurance scheme (Slabbert, 2014). Both organisations have regulatory sets of ethics and codes of conduct, which include guidelines about elements such as the scope of practice, manufacturing of prosthetics, compensation and fees, and marketing (HPCSA, 2014; SAOPA, 2003). HPCSA and SAOPA are key drivers of the industry in South Africa, creating a regulatory and legislative framework and infrastructure around which the industry can be and has been built.

AM has the potential to disrupt and undermine these frameworks because easy access to affordable and easy-to-use AM technology has the potential to undermine the authority of these two organisations (Weller, Kleer & Piller, 2015). This is a fact that has not gone unnoticed by SAOPA. In a recent document published by the association, it revealed its position on the issue of non-qualified individuals manufacturing prosthetics. It stated: "SAOPA notes with concern that other registered/non-registered persons do supply and/or fit orthoses and prostheses and this infringes on the rights of our members who have spent four years studying to qualify as a registered orthotists and prosthetists" (Slabbert, 2014, p. 6).

The set of rules and regulations laid out to all health professionals by the HPCSA, and specifically to prosthetists by SAOPA (HPCSA, 2014; SAOPA, 2003) are fairly stringent and limiting regarding what is acceptable (HPCSA, 2014; SAOPA, 2003). These types of guidelines have led to a very reserved and conservative approach to marketing for prosthetics industry in South Africa (HPCSA, 2014; SAOPA, 2003). As a result much of the marketing in the industry has been done through word-of-mouth, via testimonials and patient and doctor referrals (Slabbert, 2014). However with the advent of the Internet and the subsequent use of digital marketing channels including online social media, prosthetists have been able to open up new avenues to showcase their services, new products and testimonials to prospective clients.

AM has grown in prominence since 2012, and has been heralded by some as the proponent of the next industrial revolution (Berman, 2012). The medical sector has also recently been awash with headlines and seminars about the extraordinary benefits of 3D printing, encompassing everything from printed kidneys (Atala, 2011) to medical prosthetic limbs that cost a fraction of the conventional price (Eng, 2014). This media hype and attention has not been limited to the medical field, with much of the public's attention being placed on the technology. The stringent regulations placed on health professionals, including prosthetists, do not necessarily affect those manufacturing prosthetics outside the scope of the regulatory bodies. This has the potential to cause disruption.

The business models, practices and strategies of the prosthetic industry are also largely governed by the guidelines put forward the HPCSA (2014) and SAOPA (2003). These stipulations lack clarity and leave room for interpretation. Thus the manner in which prosthetists are compensated, and the method in which they manage key partnerships between supplier, patients and other notable persons are key drivers of this industry. This is especially true when looking at the variation in prosthetic prices. The price of a prosthetic varies greatly due to a number of factors including the functionality, material and technology used in the prosthetic, as well as the fee the prosthetist incorporates into the cost. A typical upper limb, below the elbow or hand prosthetic can range anywhere from R30 000 to R300 000 (Eng, 2014). Relatively high prices for prosthetics have the ability to draw individuals into the profession, however it is also a factor that can force people to forgo a prosthetic all together. Thus these areas are central market drivers.

By contrast, AM manufactured prostheses are a fraction of the price, take far less time to produce and, potentially, allow prosthetists the ability to work on far more patients, which seriously disrupts the established industry business models (Zuniga, et al., 2015). This may also make prosthetics accessible to the many individuals who have historically been unable to afford them.

As has been shown above, there are several market drivers or needs within the prosthetic industry. These include manufacturing practices, management, the economic standpoint of the country, legislative and regulatory bodies, marketing, business models and business strategies. The objective of this research report, therefore, is to explore the potential impact Additive Manufacturing will have on these key drivers of the medical prosthetic industry.

1.3. Research Motivation

Recent research has shown AM to be hugely disruptive (Thiesse, Wirth, Kemper, Moisa, Morar, Lasi & Minshall, 2015). It is also apparent from the research evidence already mentioned that AM is disrupting the medical prosthetic sector. AM enables small quantities of customised goods to be produced at relatively low costs (Berman, 2012). In its current form, AM disrupts the traditional manufacturing processes inherent in medical prosthetics, as well as management, marketing and finance, business models, policies and strategy (Weller, et al., 2015). However neither the extent of the disruption nor what effect it will have has yet been established.

AM is also a very interesting topic as many designs, including those for prosthetics, are freely available online. Many are offered via online open-source platforms, however there are also a growing number of pirated designs that are being hosted on torrent sites such as the Swedish file-sharing site The Pirate Bay (Appleyard, 2015). As this is still a growing industry, the full impacts of such practices are not yet known, although it is something that will definitely affect the industry in one way or another as it moves forward, particularly around intellectual property (IP) legislation, business models, policies and strategy. A look at the entertainment industry and how it has attempted to handle the issue is advisable given its extensive history in combating the same matter (Kurfess & Cass, 2014).

1.4. Academic Motivation

This research dissertation will focus on qualitatively exploring the degree to which the innovation of AM technology has and will disrupt the medical prosthetic industry. The findings of this research, like the technology, may have far-reaching consequences on the South African medical prosthetic market and particularly from an industrial, policy and development perspective.

From a business perspective, this study would assist those attempting to understand the impact of AM technology, specifically on the South African medical prosthetic industry. More specifically, the impact that this disruptive technology has on the medical prosthetic industry and how the theory of DI is able to explain and bring greater clarity to the impact AM technology will have at every level of the value chain.

1.5. Research Scope

The research will focus on the potentially disruptive effect of AM technology potentially on the medical prosthetic environment. Key areas of attention will be AM's impact on management, production, marketing, business models, strategy and intellectual property. The study will be limited to individuals working within the medical prosthetics industry as well as additive manufacturers within South Africa.

Based on current findings, it would appear necessary and useful to conduct further research into the motivational drivers of prosthetists and additive manufacturers to determine why they undertook these professions and how their values may be linked to one another. Further study into the impact the Heath Professionals Council of South Africa has on health professionals, and how it affects the introduction of new technologies is also an area of value. A final area of interest for further research is the lack of credible data surrounding the patients in need of prosthetics in South Africa and Africa as a whole. Currently there is little, if any, data on these individuals. Adding to this may be a study on the financial and socio-economic implications of not receiving a prosthetic from a South African perspective. And finally, an exploration of whether having a prosthetic should be considered a human right in South Africa should be considered.

1.6. Conclusion To Chapter One

AM is likely to have an impact along nearly every aspect of a company's value chain (Weller, et al., 2015). This means that the introduction of the technology is likely to have consequences, both intended and unintended, across a number of areas of an industry. This research will explore the impact of AM technology on the medical prosthetic industry to see what effects the technology will have on medical prosthetic businesses and whether the new technology is likely to be disruptive.

Chapter One has established the context and provided a case for examination and inspection of the impact of the disruptive innovation of Additive Manufacturing in the medical prosthetic industry.

Chapter Two lays out a thorough and critical review of the literature on this topic, including key discussions about the current literature surrounding AM and DI.

Chapter Three presents the research questions that have been formulated as a result of the gaps left by the existing research, and/or compelling sector drivers and business propositions arising from AM.

Chapter Four illustrates the research methodology that was followed during this research project.

Chapter Five shows the results of the interviews, including relevant quotes and frequency tables, as well as the limitations experienced during the research and a brief profile of each of the interviewees.

Chapter Six offers a discussion of the results in relation to the rest of this research project.

Chapter Seven proposes conclusions and recommendations, and offers suggestions for further areas for research.

2. CHAPTER TWO: LITERATURE REVIEW

2.1. Introduction

The previous chapter introduced the theme of Additive Manufacturing (AM) as a disruptive force within the medical prosthetic industry. It outlined the relevance of this subject for business in South Africa and beyond, as well as the academic motivation for this study. This chapter will review the theory base and literature regarding Additive Manufacturing and disruptive innovation theory, as summarised in Table 2.1 below, allowing for the formulation of more detailed research questions about how potentially disruptive Additive Manufacturing will be on the medical prosthetic industry.

Table 2.1: List of Constructs with Literature References

CONSTRUCT / THEMES	LITERATURE REVIEW
2.2 Definition of Additive Manufacturing	
Defining Additive Manufacturing	Gu, Meiners, Wissenbach & Poprawe (2012); Wong & Hernandez (2012); Newman, Zhu, Dhokia & Shokrani (2015); Bikas, Stavropoulos & Chryssolouris (2015).
Additive Manufacturing Processes	Wong & Hernandez (2012); Guo & Leu (2013); Rengier, Mehndiratta, Tengg-Kobligk, Zechmann, Unterhinninghofen, Kauczor & Giesel (2010); Petrovic, Gonzalez, Ferrando, Gordillo, Puchades & Griñan (2011); Syam, Mannana & Al-Ahmari (2011); Goiato, Santos, Pesqueira, Moreno, dos Santos & Haddad (2011).
Additive Manufacturing Materials	Wong & Hernandez (2012); Noorani (2006); Venekamp & Le Fever (2015); Bikas, Stavropoulos & Chryssolouris (2015); Huang & Leu (2014).
Additive Manufacturing Applications	Huang & Leu (2014); Wohlers & Caffrey (2011); Bikas, Stavropoulos & Chryssolouris (2015); Jin, Plott, Chen, Wensman & Shih (2015); Guo & Leu (2013); Giannatsis & Dedoussis (2009); Sauramo (2014); Weller,

	Kleer & Piller (2015); Wong & Hernandez (2012); Rengier et al. (2010); Negi, Dhiman & Sharma (2014).
Additive Manufacturing Benefits	Anderson (2012); Wong & Hernandez (2012); Negi, Dhiman & Sharma (2014); Petrovic et al. (2011); Cozmei & Caloian (2012).
Additive Manufacturing Disadvantages	Negi, Dhiman & Sharma (2014); Campbell, Bourell & Gibson (2012); Wong & Hernandez (2012); Mahamood, Akinlabi, Shukla & Pityana (2014); Hahn, Jensen & Tanev (2014); Royal Academy of Engineering (2013).
The Future of Additive Manufacturing	Campbell, Bourell & Gibson (2012); Ventola (2014).
Additive Manufacturing & the Medical Industry	Weller, Kleer & Piller (2015); Berman (2012); Atala, (2011); Eng (2014); Khan (2014); Wong & Hernandez (2012); Negi, Dhiman & Sharma (2014); Murphy & Atla (2014); Venekamp & Le Fever (2015); Melchels, Domingos, Klein, Malda, Bartolo & Hutmacher (2012).
Additive Manufacturing & the Medical Prosthetic Industry	Zuniga, Katsavelis, Peck, Stollberg, Petrykowski, Carson & Fernandez (2015); Ventola (2014); Wong & Hernandez (2012); Negi, Dhiman & Sharma (2014); Jin, Plott, Chen, Wensman & Shih (2015).
2.3 Disruptive Innovation Theory	
Features of Disruptive Innovation	Christensen (2014); Schiavone (2011); Yu & Hang (2010); Christensen & Raynor (2003).
Disruptive Innovation Categories	Christensen (2014); Yu & Hang (2010); Christensen & Raynor (2003).
Flaws of Disruptive Innovation	Yu & Hang (2010).
Additive Manufacturing as a Disruptive Innovation	Mohr & Khan (2015); Campbell, Williams, Ivanova, & Garrett (2011); Reeves (2009);

	Wigan (2014); Garrett (2014); Gao, Zhang, Ramanujan, Ramani, Chen, Williams, Wang, Shin, Zhang & Zavattieri (2015); Manners-Bell & Lyon (2012); Nyman & Sarlin (2014); Berman (2012); Lee (2013); General Electric, (2015); Dante (2014); Schildhorn (2014).
2.4 Additive Manufacturing & Economics	
Additive Manufacturing & Economics	Thiesse, Wirth, Kemper, Moisa, Morar, Lasi & Minshall (2015); Wohlers & Caffrey, (2011); Huang, Liu, Mokasdar & Hou (2012); Atzeni & Salmi, (2012); Campbell et al. (2011); Business Monitor International (2015); Venekamp & Le Fever (2015).
2.5 Additive Manufacturing & Management	
Additive Manufacturing & Management	Thiesse et al. (2015); Mellor, Hao & Zhang, (2014); Piazza & Alexander (2015).
2.6 Additive Manufacturing & Production	
Additive Manufacturing & Production	Thiesse et al. (2015); Mahamood et al. (2014); Guo & Leu (2013); Huang et al. (2012); Wong & Hernandez (2012); Conner, Manogharan, Martof, Rodomsky, Rodomsky, Jordan & Limperos (2014); Syam, Mannana & Al-Ahmari (2011).
2.7 Additive Manufacturing & Marketing	
Additive Manufacturing & Marketing	Clark, Callı & Callı, (2014); Kietzmann, Pitt & Berthon (2015); Conner et al. (2014).
2.8 Additive Manufacturing, Business Models & Policies	
Additive Manufacturing, Business Models & Policies	Piller, Weller & Kleer, (2015); Thiesse et al. (2015); Beyer (2014); D'Aveni (2013); Petrick & Simpson (2014); Lindemann, Jahnke, Moi & Koch (2012).
2.9 Additive Manufacturing & Business Strategies	
Additive Manufacturing & Business Strategies	Clark, Callı & Callı, (2014); Beyer (2014); Mohr & Kahn (2015).
2.10 Additive Manufacturing, Regulations & Intellectual Property	
Additive Manufacturing, Regulations &	Cozmei & Caloian (2012); Koptyug, Rännar,

Intellectual Property	Bäckström, Franzén & Dérand (2013); Kurfess & Cass (2014); Wilbanks (2013); Berman (2012); Thiesse et al. (2015); Piazza & Alexander (2015).

2.2. Definition of Additive Manufacturing

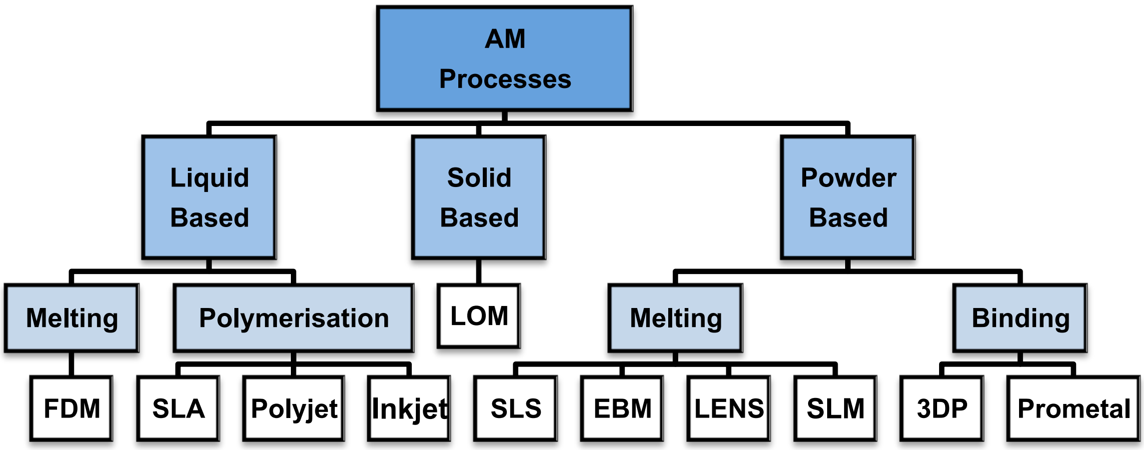
2.2.1. Defining Additive Manufacturing

According to Gu, Meiners, Wissenbach & Poprawe (2012) the term Additive Manufacturing (AM) refers to a collection of techniques and technologies that use processes of joining materials by building-up objects in two-dimensional layers from 3-Dimensional (3D) model data, otherwise known as Computer-Aided Designs (CAD). In this process, the design made in the CAD software is approximated by triangles and slices containing the information of each layer that is going to be printed (Wong & Hernandez, 2012, p.1). This is in contrast to conventional subtractive manufacturing methodologies, such as traditional machining or milling which uses a solid block of material and removes unnecessary excess until only the desired shape or design remains (Newman, Zhu, Dhokia & Shokrani, 2015). Bikas, Stavropoulos & Chryssolouris (2015) state that AM can deliver objects of very intricate and complex geometries with a minimum need for post-processing, built from tailored materials with near-zero material waste, while being applicable to a variety of materials, including plastics and metals (p.1).

2.2.2. Additive Manufacturing Processes

An overview of the different Additive Manufacturing processes can be seen in Figure 2.1. The figure details the distinctions between the processes via several different criteria, the first of which are whether they are liquid based, solid based, or powder based. According to Wong & Hernandez (2012) these processes are considered the most relevant in the past, and promising for the future of the industry.

Figure 2.1: Additive Manufacturing Processes (Wong & Hernandez, 2012, p. 3)



Key and short descriptors of each of the AM processes:

- **Fused Deposition Modelling (FDM)** where plastic filament is heated and then extruded through a nozzle.
- **Stereo Lithography (SLA)** where liquid resin is hardened by an ultraviolet laser beam.
- **Polyjet** is a process that uses inkjet technologies to deposit a photopolymer material that is cured by ultraviolet lamps.
- **Laminated Object Manufacturing (LOM)** is a process that combines additive and subtractive techniques. The layers are bonded together using pressure, heat and a thermal adhesive coating. A carbon dioxide laser cuts the material to shape.
- **Selective Laser Sintering (SLS)** is where powder is sintered by a laser.
- **Electron Beam Melting (EBM)** is similar to SLS, and is a process where powder is melted by an electron laser beam.
- **Laminated Engineered Net Shaping (LENS)** is a process where metal powder is melted by a laser beam and then injected into a specific location. It becomes molten with the use of a high-powered laser beam.
- **3D Printing (3DP)** is a MIT-licensed process in which water-based liquid binder is supplied in a jet onto a starch-based powder.
- **Prometal** is a powder-based process that prints using a liquid binder that is spurt out in jets to steel powder.
- **Inkjet Printing Techniques** are based on different kinds of fine powders such as plaster or starch.

- **Selective Laser Melting (SLM)** is a fine metal powder-based technique that uses a high-powered laser beam to create three-dimensional parts.

According to Guo & Leu (2013), recent advances in technology have extended the use of AM technology in the medical field to areas such as tissue scaffolds, artificial organs, medical devices, micro-vasculature networks, biologic chips (produced by printing/patterning cells and proteins), and most importantly for this study, prosthetics. A variety of different AM processes are utilised in these different areas (Guo & Leu, 2013). When constructing tissue scaffolding, a process that requires versatility in the use of biomaterials and complexity in the geometries and internal architectures, medical scientist rely on SLA, 3DP, FDM or SLS (Guo & Leu, 2013). The below table briefly illustrates the predominant AM technologies used in the medical sector, and their various characteristics (Rengier, Mehndiratta, Tengg-Kobligk, Zechmann, Unterhinninghofen, Kauczor & Giesel, 2010).

Table 2.2: Overview of established AM technologies used in the medical sector (Rengier et al., 2010)

AM Technology	Accuracy	Cost	Advantages	Disadvantages
Stereolithography (SLA)	+++	$$	Large part size	Moderate strength
Selective Laser Sintering (SLS)	++	$$$	Large part size, variety of materials, good strength	High cost, powdery surface
Fused Deposition Modelling (FDM)	++	$	Low cost, good strength	Low speed
Laminated Object Manufacturing (LOM)	+	$	Low cost, large part size	Limited materials
Inkjet printing techniques	+	$	Low cost, high speed, multi-material capability	Moderate strength

*The characteristics can vary depending on the specific printing system used

Medical prosthetics have used a variety of different AM processes too, including SLA (Petrovic, Gonzalez, Ferrando, Gordillo, Puchades & Griñan, 2011) SLS, SLM and FDM (Syam, Mannana & Al-Ahmari, 2011). These have been used for a number of different prosthetic applications including surgical guides for titanium implants, auricular prostheses (SLS), customised prosthetic sockets (SLS & FDM), maxillofacial prostheses, oral and maxillofacial surgeries, orthopaedic applications and forensic thanatology (various technologies), surgical guides, (SLS) guides for implants (SLS), facial prostheses (SLS), mandibular reconstruction (SLS), reconstruction of ocular orbit (SLS) (Goiato, Santos, Pesqueira, Moreno, dos Santos & Haddad, 2011).

2.2.3. Additive Manufacturing Materials

According to Wong & Hernandez (2012) the range of materials that AM is able to utilise is still limited. As it stands, it is possible for AM to print in materials such as metals and ceramics, however AM falls short when it comes to other commonly used manufacturing materials. In a process like stereo lithography (SLA) it is possible to produce a single piece using several different materials in a process known as multiple material stereo lithography (Wong & Hernandez, 2012). This process, however, is far more costly in time and effort. SLS allows one of the greatest varieties of materials that could be used, including plastics, metals, combination of metals, combinations of metals and polymers, and combinations of metals and ceramics (Wong & Hernandez, 2012). The two go on to identify that FDM is even able to print in PC-ISO, which is a medical grade polycarbonate (PC) (Wong & Hernandez, 2012). The major benefits of this is that no chemical post-processing is required, in other words there are no resins to cure and this results in a more cost effective process as well as a product that is able to be utilised in medical procedures (Wong & Hernandez, 2012; Noorani, 2006). Wong & Hernandez (2012) even posit that in a process like prometal, rocket nozzle manufacturers were able to produce parts using metals that had better properties than Computer Numerical Control (CNC) machined parts of the same material.

In more recent times Venekamp & Le Fever (2015) have shown that AM technologies have been utilised in the production of cell containing constructs. While the technology does not, as of yet, print in the cells, it instead assists in the process by preparing complex scaffolds. These scaffolds, with precise geometries that enable the creation of anatomically shaped implants, are used for tissue engineering in a computer-controlled fashion (Venekamp & Le Fever, 2015). Furthermore, the AM has also demonstrated the ability to print in a variety of more delicate and complex substances, which would have been difficult to produce had traditional approaches been adopted. These substances include food substances, chemicals for oral drugs, micro components for micro machining (functional structures that could be 5mm or less with dimension resolutions below 50μm), as well as many more (Venekamp & Le Fever, 2015).

A succinct demonstration of processes and materials used by a variety of the AM processes was given by Bikas, Stavropoulos & Chryssolouris (2015). In the table below, the researchers have neatly summarised some of the most predominant AM processes and the materials they use.

Table 2.3: AM Processes & their Materials (Bikas, Stavropoulos & Chryssolouris, 2015)

Process	**Laser Based AM Processes**			**Extrusion Thermal**	**Material Jetting**	**Material Adhesion**	**Electron Beam**
	Laser Melting		***Laser Polymerisation***				
Name / **Material**	SLS	DMD	SLA	FDM	3DP	LOM	EBM
	SLM	LENS	SGC	Robo-casting	UP	SFP	
	DMLS	SLC	LTP		MUM		
		LPD	BIS		BPM		
			HIS		Thermo-jet		

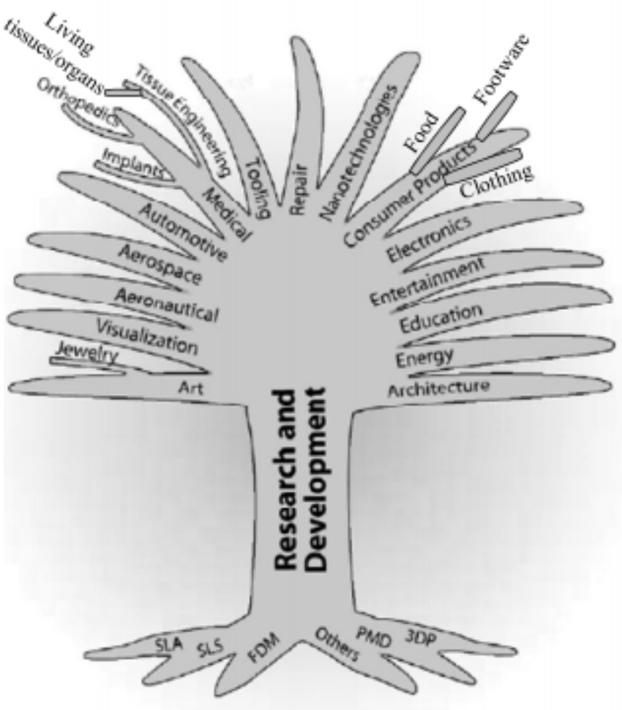
Bulk Material Type	Powder	Liquid	Solid

Thus it is fair to conclude that AM technology is able to utilise a substantially large variety of materials, from plastics and metals to more fragile and complex elements like food substances and chemicals. Huang & Leu (2014) however have proposed that more intensive materials research and development is needed. Such research, they believe, will widen the selection of acceptable materials, establish a database of the mechanical properties of parts fabricated by AM, and calculate the interaction between materials and process parameters.

2.2.4. Additive Manufacturing Applications

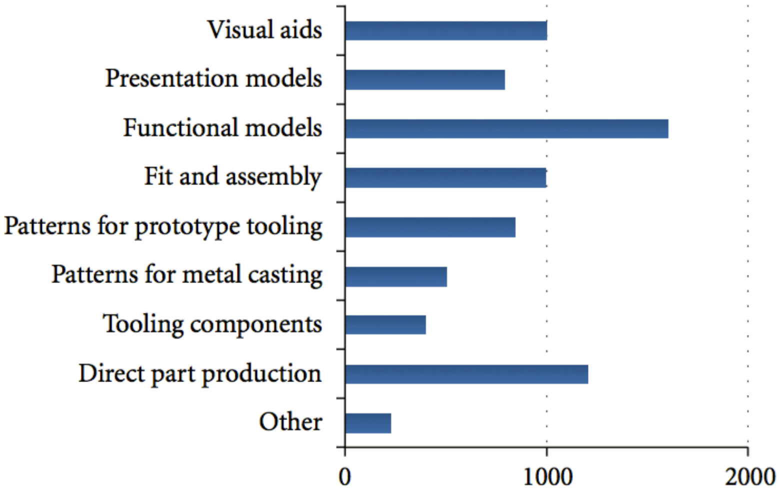
According to Huang & Leu (2014), AM is a technology that has been used in a variety of different areas of the economy, including automotive, aerospace, biomedical, energy, consumer goods, and many others. They created a tree model, seen in Figure 2.3, to demonstrate the areas that would benefit from the research and development of AM technologies. The base of the tree comprises of the many AM processes. The trunk signifies the research and development attempts that develop from these processes. The branches are the results and advantages of these attempts. New applications and benefits are expected to grow in time, and other applications will branch into significant subcategories (Huang & Leu, 2014).

Figure 2.2: Schematic Visualisation of AM Field & Research Opportunities & Efforts (Huang & Leu, 2014)



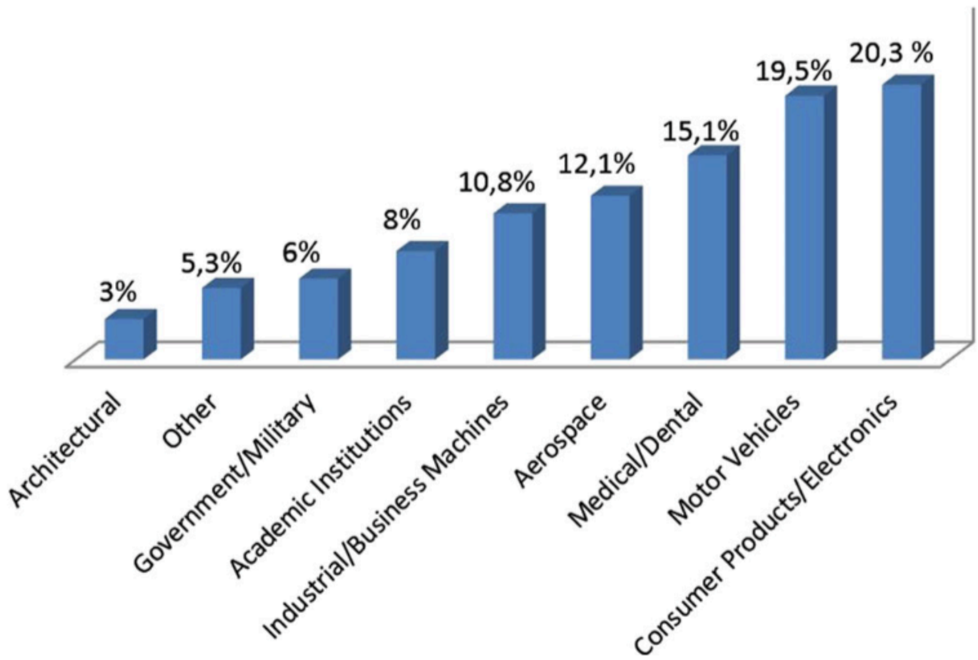
AM technologies were first created to produce models, but they have expanded since then. In a study made by Wohlers & Caffrey (2011), 24 manufacturers and 65 services of 5000+ users and costumers were surveyed. The results of this study are shown in Figure 2.3. It shows that by far the biggest use for the technology is functional models, with direct part production coming in second (Wohlers & Caffrey, 2011).

Figure 2.3: Different Uses for AM Processes (Wohlers & Caffrey, 2011)



More recently Bikas, Stavropoulos & Chryssolouris (2015) gave a graph showing the breakdown of the percentage of the industrial sectors using AM. It demonstrated that Consumer Products/Electronics held the top spot at just over a fifth of the usage (Bikas, Stavropoulos & Chryssolouris, 2015). However, most intriguing for this study, the graph also proposed that the Medical/Dental sector was the third largest user of the technology - a very promising sign for the growth of the technology in this area (Bikas, Stavropoulos & Chryssolouris, 2015), and potentially demonstrating a willingness and appetite in this sector to adopt the technology.

Figure 2.4: Industrial Sectors using AM (Bikas, Stavropoulos & Chryssolouris, 2015)



Many researchers have identified the varied nature in which AM technologies have been utilised (Jin, Plott, Chena, Wensmanc & Shih, 2015; Guo & Leu, 2013; Giannatsis & Dedoussis, 2009). They have all demonstrated two main categories that the technologies fall into: direct or indirect methods. The direct method refers to a process where the use of AM technologies is employed to create the end product itself. Indirect method refers to a process where the use of AM technologies is employed to create the tool that would be used for the production of the actual end product (Jin et al., 2015; Guo & Leu, 2013; Giannatsis & Dedoussis, 2009). According to Jin et al. (2015), medical prosthetics utilise both methods when employing AM technologies.

According to Sauramo (2014), AM technology has given people the ability to produce a wide range of items varying from titanium jawbones and Rolls-Royce jet engine parts to designer chocolates and even working guns. It has been shown to affect not only management, marketing, finance and production, but also business models, policies and strategy (Weller, et al., 2015). As a result of the rapid development in AM technologies and its applications in recent years, the economic implications of research and development activities in this area have the potential to be even more significant than AM itself.

Wong & Hernandez (2012) support the versatile nature of AM technology. In their review of the technology they demonstrate that AM can be, and has been, used for everything from manufacturing lightweight automotive and aerospace parts to creating unique chocolate masterpieces. More pertinent to this study, researchers Rengier et al. (2010) agree with this versatile characteristic of AM, and introduce the many applications that the technology is being used for in the medical field. The technology has been used to scan a patient and build a physical model to help doctors gain a better idea of what to expect and plan better procedures (Rengier et al., 2010). This, Rengier et al. (2010) believe, will save costs and time and help achieve a better result. Procedure specific tool creation through SLS is another area where AM is being utilised (Giannatsis & Dedoussis, 2009), as is SLA and FDM in the creation of prosthetic sockets (Jin et al, 2015). Not only this, but scaffolding for the engineering of bone and tissue have also been produced, allowing doctors the possibility of printing complex geometries, customised products and providing high accuracy features (Negi, Dhiman & Sharma, 2014). This, Jin et al. (2015) propose, will help patients who have lost tissue in accidents or from other reasons to recover faster and with far better results.

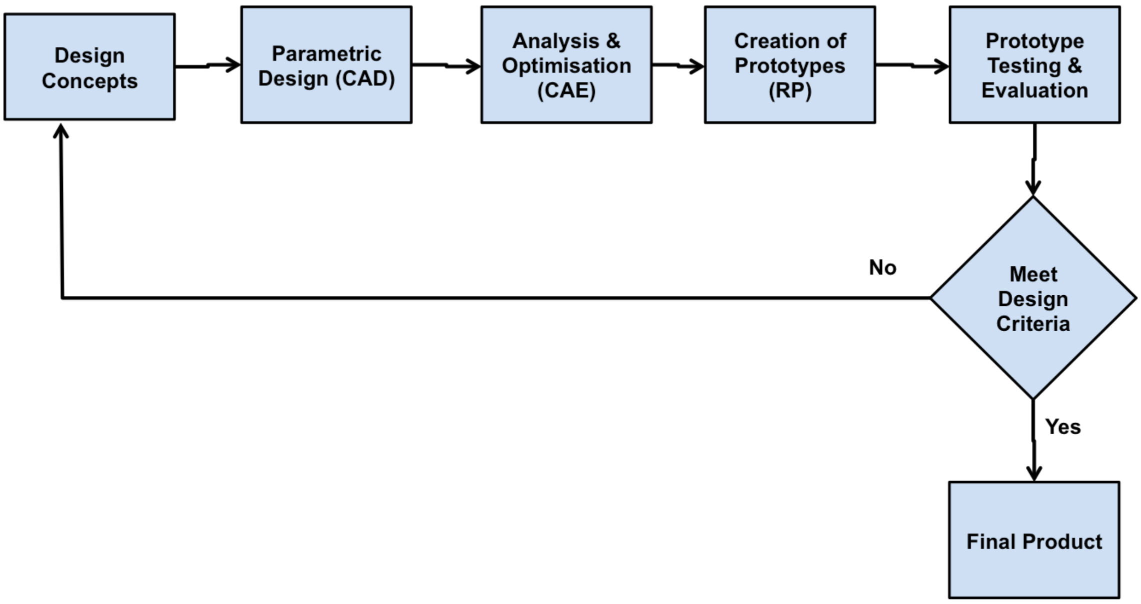
2.2.5. Additive Manufacturing Benefits

According to Anderson (2012) the most recent and noteworthy development in AM has been the arrival of extremely low-priced personal 3D printers. As a result of a string of open-source projects, which first began with the RepRap printer and then the popular Makerbot, the price of a 3D printer has fallen below $1000 and printers are found in a number of common places including schools, homes, and countless makerspaces (Anderson, 2012).

Wong & Hernandez (2012) support this benefit of AM technology, stating on numerous occasions, throughout their study, the cost effective benefit of many of the processes utilised by AM. They even go so far as to say outright that using AM technology ensures that the form of an AM printed prosthetic socket adapts better to the patient while being more cost-effective than hand or machined methods (Wong & Hernandez, 2012).

According to Negi, Dhiman & Sharma (2014) the steps involved in product development using AM, as shown in Figure 2.4, are much faster. They go on to postulate that creating models faster serves as a benefit as it saves time and there is the possibility of testing more models (Negi, Dhiman & Sharma, 2014).

Figure 2.5: Additive Manufacturing Product Development Cycle (Negi, Dhiman & Sharma, 2014)



According to Petrovic, Gonzalez, Fernando Gordillo, Puchades & Grinan (2011) some of the most important advantages of AM include:

- **Reduced lead time, material wastage and costs**, including typical savings of 80% in both cost and time over the traditional methods. Raw material wastage was also reduced by up to 40% in contrast to subtractive manufacturing processes.

- **Improved prototyping quality.** AM produces parts that satisfy the quality needs for prototype testing.

- **Complex geometry fabrication**. AM allows the fabrication of complex shaped parts of almost any geometry. The ability to create unique custom parts is another benefit.

- **No tools, moulds or punches are needed** because AM directly produces parts from the CAD data - thus none of the traditional methods such as tooling and human intervention are typically required.

Cozmei & Caloian (2012) add to this and have summarised the benefits of AM technologies by pointing out that they are particularly relevant where:

- The **volume** of fabrication is small, in other words small batch production.

- There is **complexity** in the geometries of the parts and their assembly.

- There is a need for design **complexity** and capability.

- **Shorter lead times** are a factor.

- **Customisation** and **personalisation** of the products are a necessity, and there is an opportunity to differentiate by offering unique personalised products.

- The customer base is **not centrally located**.

- Target market or suppliers have **ethical or environmental concerns**.

- The **materials** that are utilised are not **costly** and **problematic** to process by traditional methods.

2.2.6. Additive Manufacturing Disadvantages

Negi, Dhiman & Sharma (2014) believe that AM technology faces a number of concerns. These issues have inhibited the use of the technology within certain sectors. According to the researchers the predominant pitfalls of AM are: accuracy, part orientation, material properties, surface finish, pre-processing, post-processing, build speed and system cost (Negi, Dhiman & Sharma, 2014).

Campbell, Bourell & Gibson (2012) and other researchers have also identified some additional issues (Negi, Dhiman & Sharma, 2014; Wong & Hernandez, 2012):

- **Misperceptions as a result of its original name "rapid prototyping".** Currently, AM technologies are not used exclusively for prototyping. The technologies have also been used effectively in the fabrication of finished products. However many still incorrectly think of the technology as a technology made only for prototype production.

- **Strength issues.** The strength of an AM fabricated part differs depending on which axis it is tested. Typically, parts are found to be stronger when pressure is applied along the direction of the layer compared to the build-up direction. This is in contrast to conventionally manufactured items.

- **Layer thickness selection.** Similar to the way a larger amount of smaller pixels in a television gives the viewer greater resolution, the smaller the layer of thickness, the greater accuracy of the final part in AM. However these small layers have a drawback in that production using thinner layers can result in longer data processing time, larger data files and especially a longer build time.

- **Support structures cannot be reused.** The support structure material used cannot be recycled.

- **Fabrication of metal items directly.** This is a major issue currently affecting AM. Fabricating metal parts directly with AM technology is still rare in contrast to indirect methods of AM technology. Currently adequate strength and accuracy is lacking.

- **New material development.** At present AM processes commonly use materials that are polymer, paper and ceramic based. Nevertheless, researchers believe that there are numerous other exciting materials that should be concentrated on. These include materials such as magnesium, copper and biodegradable polymers.

- **Expensive AM systems.** At the moment AM systems are very costly. This is a result of high manufacturing cost and a low number of available users. According to the researchers, this type of circumstance generally happens at the initial stage of any new high-end technology. Costs eventually reduce as fabrication cost lower or the pool of viable users becomes bigger.

Mahamood, Akinlabi, Shukla & Pityana (2014) agree with this assessment of AM, stating that dimensional accuracy and poor surface finish are a major drawback of the technology. They identify the effect of stair stepping as a cause of the below-average accuracy and surface finish.

Hahn, Jensen and Tanev (2014) have also identified several technological issues associated with AM printing technologies. These involve an absence of a supportive framework, widespread underfunding, and the lack of proper industry standards. The Royal Academy of Engineering (2013) elaborated on this further, pointing out several key problems:

- **Materials**: More and better materials are needed. Recyclability of materials is also an issue.

- **Software**: Existing computer-aided design (CAD) systems are not at all suited for exploiting and investigating the design freedom of AM processes. More complex shapes are not easily designed. More user-friendly operation systems are also required.

- **Data Management**: The substantial memory storage capacity requirements are an issue.

- **Sustainability**: The democratisation of AM technology may introduce uncontrollable sustainability issues, specifically around home-users' disregard for elements such as wasted materials and energy.

- **Affordability**: As it stands, materials for AM are considerably more costly than traditional materials, such as those used in injection moulding.

- **Production Speed**: While using AM technologies for small batch production is quicker compared to traditional fabrication, higher-volume manufacturing is significantly slower.

- **Reproducibility and Reliability**: Current AM technology cannot achieve the same, relatively low – just a few parts per million – rate of rejection that conventional fabricating methods aim for.

- **Intellectual Property Rights**: The digital nature of the designs in AM allow there to be a much greater potential for users to infringe copyrights, especially in combination with 3D scanning technology.

- **Industry Standards**: There is a lack of the necessary formal commitments to businesses and fabricators that AM processes, materials, and technologies are safe and dependable.

- **Funding**: There is a need for government incentives and drivers to encourage organisations to enter the sector, as well as university research focusing on driving the awareness of potential advantages and business opportunities associated with the adoption of AM.

2.2.7. The Future of Additive Manufacturing

Campbell et al., (2012) have proposed a couple of possible predictions for the future of AM:

- **Costs to fall.** In the following ten years, low or medium cost AM systems will be accessible. This is because primary patents are going to expire, and these AM systems will be readily accessible to the public. This will increase the number of potential users, which will drive up demand and see the entry of major suppliers into the market that will bring new or improved materials, technologies and processes.

- **Improved speed.** A dominant concern to be dealt with is speed. In the future, manufacturing speed will be significantly improved with the progress of materials and design process.

- **New locations.** AM systems are expected to be in malls and other locations where customers will be able to place an order and get their product over the counter in a short timeframe.

- **Reduced variety.** Forthcoming AM machines, in association with other technology, are unlikely going to be as multipurpose as the existing AM. This is because these future systems will be exclusively created for a specific product type.

- **Simultaneous multiple materials.** In the future AM systems will have the ability to fabricate in a multitude of different materials at the same time.

- **A healthier medical world.** AM has shown great promise in the medical sector, however tissue engineering is a sector that will be heavily focused on in the future. This includes collaboration between AM and new biochemical approaches that can fabricate implants with unusual geometrical properties.

Researcher Ventola (2014) adds to this list of predictions and states that:

- **Medicine gets personal:** AM is anticipated to play a significant part in the trend toward personalised medicine, through its use in customised nutritional products, organs, and drugs.

- **Pharmaceutical impact:** AM fabrication is expected to be common in pharmacy settings. The production and circulation of drugs by pharmaceutical companies could be substituted by emailing databases of medication formulations to pharmacies, on a basis of on-demand drug printing.

- **Bioprinting of complex tissue and organs**: This is one of the most advanced AM printing applications predicted. Ventola (2014) predicted that in less than 20 years, AM will be able to fabricate a fully functioning heart. Printing out a patient's tissue as a strip may also be possible. This can be utilised to determine what medication will be most effective. It has also even been predicted that it may be possible to take stem cells from a child's baby teeth for use as a tool kit for growing and developing replacement tissues and organs.

- ***In Situ* Printing:** *In situ* printing refers to the fabrication of implants or living organs that are printed directly in or on the human body during operations. *In situ* bioprinting for repairing external organs, such as skin, has already taken place.

- **Robotics:** The improvements in the field of robotics, specifically areas like bio-printers and robot-assisted surgery, may also be pivotal to the development of this technology.

2.2.8. Additive Manufacturing & the Medical Industry

AM has been shown to affect various industries, each in a different way (Weller, et al., 2015). Consequently, a more detailed understanding of the particular impact of AM has to be taken on a per industry basis. This is done to ensure that there is a better comprehension of the impact it will have. The healthcare sector is one such industry that researchers Weller, Kleer & Piller (2015) have identified as the next logical step to research.

AM has grown in prominence and has been heralded by some researchers as the proponent of the next industrial revolution (Berman, 2012). The medical sector has also recently been awash with news headlines and TED Talks about the extraordinary benefits of 3D printing, encompassing everything from printed kidneys (Atala, 2011) to medical prosthetic limbs that cost a fraction of the conventional price (Eng, 2014). Thus, this research is topical and relevant. The effects of AM are far-reaching and it is only a matter of time before AM technology is part of everyday healthcare around the world (Khan, 2014). A more robust and comprehensive understanding of its impact on the healthcare sector is essential to capturing the value inherent in AM technology.

"Additive Manufacturing is transforming the practice of medicine," wrote Wong & Hernandez (2012, p. 1). Negi, Dhiman & Sharma (2014) agree with this characterisation of the technology and state that it has vast applications in the medical world. Some of the most notable applications identified by Negi, Dhiman & Sharma (2014) are listed below:

- **Medical models:** AM, along with other technologies, has the capability of producing intricate anatomical replica parts directly from scanned data. These AM built models offer an improved image of a specific anatomical part, contribute to detailed pre-surgical planning, assist the surgeons and medical students to practice various surgical procedures realistically, and also operate as a demonstration and communication tool between surgeons and patients.

- **SLA:** SLA is being used in biomedical applications to produce anatomical implants, customised biomedical devices and has proven to enable and hasten the rigorous preparation involved in surgical procedures.

- **SLS**: SLS technology has been used in the fabrication of dental implants, bone scaffolds and medical devices.

- **FDM:** The FDM technique provides the opportunity for production of bone models, intricate shaped parts, and guides and templates for surgery.

- **3DP:** 3DP technology has been used in the manufacturing of exact mandibular reconstruction utilising bone plates and bone grafts.

- **Not just yet:** AM technology cannot be used on a day-to-day basis due to concerns such as cost, time and availability suitable material. Regarding biomedical applications, additional study is necessary to lessen the overall cost, as well as the improvement of appropriate biomaterials.

Organ transplants will no longer be about waiting on a list for an organ to become available, but rather waiting a few days while a new organ is printed (Murphy & Atla, 2014). Venekamp & Le Fever (2015) have also reported the benefits of adopting this technology in comparison to traditional production, specifically in the production of medical stents. They identified that using AM technology afforded them the benefit customisation, a faster response time and relatively low costs.

Melchels, Domingos, Klein, Malda, Bartolo & Hutmacher (2012) concur with the findings of Wong & Hernandez (2012) and state that AM techniques will enable the production of constructs that contain cells in a manner controlled by computers. This helps bypass costly and poorly controlled manual cell seeding processes.

The researchers also focus on the importance of pursuing the development and commercialisation of the technology in a way that is acceptable to regulatory agencies (Melchels et al., 2012), stating that it is only through the collaboration of a number of different fields, such as polymer chemistry, mechatronics, computer engineering, information technology, biology and medicine that AM can efficiently and effectively translate research outcomes into real world benefits.

2.2.9. Additive Manufacturing & the Medical Prosthetic Industry

Zuniga, Katsavelis, Peck, Stollberg, Petrykowski, Carson & Fernandez (2015) have identified some of the key impacts AM technology has and will have within the medical prosthetic industry. They have reported that an AM printed prosthetic is significantly more comfortable than a traditional medical prosthetic. They have also suggested that, financially, AM prostheses are a fraction of the price, which seriously undermines the established market (Zuniga, et al., 2015). This may also open up the market to the many individuals who have historically been unable to afford the prosthetics.

Ventola (2014) concurs with this view of AM in the medical prosthetic realm. They state that prosthetics can now be made in nearly any imaginable geometry through the use of medical imaging devices such as x-ray, MRI, or CT scans. In this way, AM has been utilised effectively in the medical industry to make both typical and intricate customised prosthetic limbs and surgical implants. These can be completed sometimes within 24 hours. The capability to rapidly generate tailor-made prosthetics answers a consistent drawback of orthopaedics, where general prosthetics are frequently not enough for some patients, particularly in intricate and complex cases (Ventola, 2014).

Wong & Hernandez (2012) claim that by using AM technology manufacturers are able to ensure a better and more cost-effective prosthetic than the conventional hand-made or machined methods. Negi, Dhiman & Sharma (2014) concur with this assessment and state that in the prosthetic fabrication process, the patient's precise alignment properties are built-in to the model, permitting the construction of a biomechanically correct geometry that improves the fit, comfort and stability. The researchers go on to propose that there are always patients outside the standard range, because of factors such as size or other distinct requirements as a result of disease or genetics. AM allows medical professionals to produce a customised prosthetic that accurately fits a patient at a practical expense (Negi, Dhiman & Sharma, 2014),

Jin, Plott, Chen, Wensman & Shih (2015) conducted a study on the production of custom foot orthoses (FO), ankle-foot orthoses (AFO) and prosthetic sockets through AM means, and found that AM technology had demonstrated to be capable of fabricating custom orthotics and prosthetics with good fit and adequate strength. However, they also went on to state that some of their data demonstrated that there are clinical, technological (on both design and manufacturing) and financial barriers to overcome before the AM technology can be adopted for full-scale implementation in a service system for custom orthotics and prosthetics. The researchers also allude to the fact that there is a lack of data in this area, stating candidly that their conclusions have been made with "limited clinical evaluations" (Jin et al., 2015, p. 204).

2.3. Disruptive Innovation Theory

2.3.1. Features of Disruptive Innovation

The Theory of Disruptive Innovations (DI), also known as disruptive technology, builds fairly substantively on the work of Christensen, who brought the theory to notoriety with his first book on the topic, "The Innovator's Dilemma" (2000). The book brought to light the basics surrounding the theory of disruptive technology in a thorough and comprehensive manner (Yu & Hang, 2010). Later on, Christensen and researcher Raynor enhanced the theory by co-authoring the books "The Innovator's Solution" (2003) and "Seeing What's Next" (2004), along with many journal articles.

Christensen's theory recognises the prospect that technologies that have inferior performance still have to ability to displace and disrupt established or incumbent organisations. The theory has had a significant impact on the way individuals address matters of technology competition (Schiavone, 2011). The theory has also generated a profound effect on management practices and motivated comprehensive discussion within the world of academia sand elsewhere (Yu & Hang, 2010).

The theory describes a process where entrant companies are able to unseat established companies with products that are, initially, of inferior quality and performance, though significantly cheaper (Christensen, 2014). These inferior products would cater to the lowest end of a market, where margins are typically lowest and thus would not pose a threat to the high margin customers at the top of the market (Yu & Hang, 2010). The established companies would cede their lower-end customers to the entrant company and focus on catering, and typically over-catering, to their higher margin customers.

Eventually the entrant company would improve its product and gain higher and higher margin customers, which in many cases Christensen found that this ultimately lead to the entrant company pushing the established company from the market entirely (Christensen, 2014). In later additions to the theory, Christensen and his co-author Raynor widened the application of the theory to include services and business model innovations (Yu & Hang, 2010; Christensen & Raynor, 2003).

2.3.2. Disruptive Innovation Categories

Initially Christensen divided innovations into two categories: sustaining innovations and disrupting innovations (Christensen, 2014). Sustaining innovations were those innovations that helped maintain existing markets and values through continuous improvement and evolution. A disruptive innovation, on the other hand, was something that created an entirely new market by applying a different set of values. As a result these types on innovation eventually overtake an established market (Yu & Hang, 2010).

Christensen went on to further sub-categorise both sustaining innovations and disruptive innovations (Christensen, 2014). He divided sustaining innovations into evolutionary and revolutionary. A sustaining evolutionary innovation was one that saw an expected improvement in a product within an existing market (Christensen, 2014). A sustaining revolutionary innovation causes an unexpected improvement in a product within an existing market. It is important to note that neither of these innovations affects that market in which they exist substantially. Instead, they can be thought of as affecting the product, service or technology within a particular market (Yu & Hang, 2010).

Disruptive innovations are different. They cause changes within markets. Christensen & Raynor (2003) have separated these into low-end and new-market disruptions (Yu & Hang, 2010). Low-end disruption refers to those innovations that target the lowest margin users who are being over-serviced by the established company (Yu & Hang, 2010; Christensen). In other words the users of a high-end product who do not need all the value-adds that accompany the primary function of a product. New-market disruptions refer to innovations that allows people who previously could not access or afford a product, the ability to purchase and utilise it (Yu & Hang, 2010; Christensen & Raynor, 2003).

2.3.3. Flaws of Disruptive Innovation

The theory of DI has been very popular; however there has been a view that it is too definitive and broad in its explanations. According to Markides, different kinds of innovations have different competitive effects and produce different kinds of markets (Yu & Hang, 2010). Markides proposes that the issue with DI is that it attempts to explain all disruptive innovations, whether it is business model innovation or radical product innovation, as the same (Yu & Hang, 2010). Markides believes that each innovation should be treated as distinct phenomena (Yu & Hang, 2010). The different markets, management problems and circumstance that a particular disruptive innovation creates must be treated on a per-innovation-basis if a solid and robust understanding is to be achieved.

2.3.4. Additive Manufacturing as a Disruptive Innovation

According to Mohr & Khan (2015) AM technology has emerged as one of the most disruptive innovations to impact, among other things, the global supply chain and logistics industry. They have stated that the technology is impacting not only individuals' personal lives, but their professional lives too. They propose that this claim of disruption lies in the technology's potential to revolutionise and replace existing manufacturing technologies. This viewpoint is contrasted by others who posit that the technology merely enhances some aspects of the production process, in other words that it is evolutionary.

Mohr & Khan (2015) have, through a synthesis of the relevant literature, identified seven key areas that they feel are likely to be disrupted by AM technology:

- **Mass Customisation**: AM has the ability to tailor individualised offers to each customer. AM also allows the involvement of clients in design and production process. According to Mohr & Khan (2015), this holds potential for a shift in priorities of cost and profit management. This in turn can make a supply chain more agile and flexible, allowing a company the ability to more rapidly to react to changes in the marketplace.

- **Resource Efficiency**: AM has greater resource efficiency in comparison to most conventional, subtractive production methods (Campbell, Williams, Ivanova, & Garrett, 2011). This has led some authors to propose that the rapid success of AM will initiate a change of view on material savings during production, smart redesign of components, and the ability to utilise recycled materials in the printing process (Reeves, 2009; Wigan, 2014).

- **Decentralisation of Manufacturing**: The relocation of manufacturing through AM can bring considerable benefits in the form of on-location production and consumption as well as quicker responses to changes in demand. Relocating manufacturing with AM can improve time-to-market, responsiveness, and the degree of agility in the supply chain for small volumes of products, particularly those that require high technological specifications (Garrett, 2014).

- **Complexity Reduction**: AM is a powerful tool to reduce complexity, specifically in the supply chain, whether it's the consolidation of components into a single product or the manufacturing process that can be simplified significantly (Gao, Zhang, Ramanujan, Ramani, Chen, Williams, Wang, Shin, Zhang & Zavattieri, 2015). Consequently, there is great potential for savings on internal cost and time through reduced supply chain complexity.

- **Rationalisation of Inventory and Logistics**: AM allows for production to happen on demand as well as at the point of consumption. As a result the need for the transportation of physical goods is removed, as are warehousing and logistics (Manners-Bell & Lyon, 2012). Furthermore, the movement of physical goods across the globe is no longer necessary and can be substituted by sending electronic files for the printers (Nyman & Sarlin, 2014). Warehouses can be replaced with digital inventory in the form of CAD files for the entire product portfolio which this further reduces the number of SKUs and the total number of stored parts.

- **Product Design and Prototyping**: AM technology is so versatile it can produce a number of fundamentally different outputs cheaply, easily, and quickly (Mohr & Khan, 2015). Therefore, AM can play a key role in creating innovative processes for manufacturing and testing prototypes as well as new or up-dated product designs (Berman, 2012; Lee, 2013). AM can also be used in the direct manufacturing of products or product components (General Electric, 2015).

- **Legal and Security Concerns**: Legal concerns have been and will continue to be an important topic of discussion in relation to AM (Dante, 2014; Schildhorn, 2014). Some researchers argue that anything that can happen will happen, including the printing of harmful objects such as guns or the bypassing of legal checks built into a traditional supply chain (Schildhorn, 2014). Furthermore, due to the fact that the current underlying legal framework does not consider the copying of physical objects, it is ill equipped to define clear rules for the use of 3D printers. Thus, there is great uncertainty regarding the future impacts in areas such as personal injury, intellectual property theft, and product liability.

In conclusion, Mohr & Khan (2015) expressed that, “the impact of AM has enormous potential to disrupt the status quo. This disruptive innovation threatens not only the established paradigms in the manufacturing industry, but also applies to legal and security concerns” (p. 23). These key areas are a central focus in this study, as are the key drivers of the medical prosthetic industry, as shown in the Chapter 1, many of which overlap.

2.4. Additive Manufacturing & Economics

Additive Manufacturing (AM) denotes a family of manufacturing techniques that allow for the production of physical objects layer by layer from digital 3D blueprints (Thiesse, et al., 2015). As of 2013, the global market for AM, including all products and services, grew to $3.07 billion with a compound annual growth rate (CAGR) of 34,9%. Experts estimate the size of the AM market in six years' time to be around $10,8 billion (Wohlers & Caffrey, 2011).

According to Huang, Liu, Mokasdar & Hou (2012) as the standing of AM grows in the global economy, so does its impact on the world. The introduction of AM technology into an economy has a knock-on effect that impacts more than just the manufacturing sector. For example, in the global healthcare sector there has always been a strong need for high-quality and economically efficient healthcare (Huang, Liu, Mokasdar & Hou, 2012). For such care to be successful it also needs to be personalised, tailored to the specific characteristics and needs of each patient (Huang, et al., 2012). In this respect, AM technology is perfectly suited to provide such standards, and has been already. AM technology has been utilised to produce customised surgical implants and assistive devices (Huang, et al., 2012). This allows medical practitioners to perform their duties with customised, high-quality implements no matter whether they are in a developing or developed country. This in turn improves the general healthcare of a country and affords the population of a country the ability to function at a much higher level of productivity.

In a study that compared two different technologies of part fabrication, the traditional high-pressure die-casting and the direct metal laser sintering additive technique (SLS), researchers Atzeni & Salmi (2012) found that AM was far superior to the traditional process of fabrication. They concluded that AM reduced time and costs from the design phase to manufacturing (Atzeni & Salmi, 2012). They also demonstrated that AM provided financial gains, efficiency growths and process improvements in design, analysis, testing and manufacturing (Atzeni & Salmi, 2012). With regards to time, they identified a further AM advantage was that once the part design is released; production begins immediately (Atzeni & Salmi, 2012). Delays due to tooling or traditional fabrication that normally take several weeks of work are avoided. Delays are costly (Atzeni & Salmi, 2012). Eliminating those delays leads to a considerable financial benefit. These types of benefits have a significant impact on a country's economics.

However, Atzeni & Salmi (2012) also cautioned that there is still a high cost associated with materials and AM machines, at an industrial scale. They go on to claim though, that as soon as AM technologies are able to integrate into common production processes, it is rational to expect a reduction in the cost of AM systems and subsequently in the near future, the point at which break even is met is expected to herald in a move towards production volumes on a much larger scale (Atzeni & Salmi, 2012).

"The impact of the so-called Digital Fabrication on economies, social life, entrepreneurship, and innovation is without any doubt fundamental," (p. 144) wrote Thiesse, et al. (2015) in their assessment of the economic impact of AM. They go on to claim that AM empowers those innovative individuals and enterprises that want to take their ideas from a digital design into a physical object (Thiesse, et al., 2015). The researchers also allude to the digital nature of AM technologies, and how particular platforms like Thingiverse allow individuals to share ideas with other individuals around the world with minimal effort (Thiesse, et al., 2015). Campbell, Williams, Ivanova & Garrett (2011) go on to forecast that AM technology would usher in a time where designs, instead of products, would be the elements that are shipped around the world. These designs would be in the form of digital files that can be printed anywhere by any printer that can meet the design parameters. The Internet was the technology that first eradicated the barrier of distance as a factor in moving information. Now AM removes it for the world of material. Similar to the way a written document can be emailed as a PDF and printed in a 2D format, an "STL" design file – the file format used predominantly in AM – can be sent instantaneously to the other side of the world through the Internet and printed in a three dimensional format (Campbell, Williams, Ivanova & Garrett, 2011).

Moreover, Thiesse, et al. (2015) propose that a "tool-free" or AM manufacturing approach enables the production of individual parts and small batches without any set-up time affecting the resources. This ensures an elimination of temporal and monetary input in the construction and production of tools. Furthermore, capital-intensive provision of specific production facilities and production specialists is reduced to a minimum. Thus, conventional manufacturing know-how loses a majority of its significance. As a consequence, manufacturing becomes independent of location, time and know-how. Instead of capital- and machine-intensive production locations, AM enables a service-oriented ''Print on Demand'' infrastructure. This results in the possibility of separating product development and production, leading to new business models that focus either on services within product development or on offering manufacturing resources" (p. 142). This idea that AM allows manufacturing to become independent of location, time and know-how, has huge disruptive consequences for the medical prosthetic industry in South Africa. The industry, as already mentioned, is heavily dominated by imports (Business Monitor International, 2015). If what Thiesse, et al. (2015) posit holds true, AM has the potential to completely subvert that economic statistic of the industry.

Campbell, Williams, Ivanova & Garrett (2011) agree with these potential effects of AM technology. They state that a given fabrication facility would have the ability to print a wide variety of products without retooling as AM also allows each print to be customised without additional cost being incurred (Campbell et al., 2011). Very relevant to the possible impact on the South African prosthetic industry, given our vast reliance on imports, the researchers propose that production and distribution of material products could begin to be de-globalised as production is brought closer to the consumer (Campbell et al., 2011). Campbell et al. (2011) go on to suggest that this diversion away from what has become “traditional fabrication platforms” such as China, back to the countries where the products are consumed, diminishes global economic imbalances as export countries’ surpluses are brought down and importing countries’ dependence on imports lessen.

Venekamp & Le Fever (2015) have stated quite plainly the need for research into the impact AM will have on an economy. In their research they identified that there has been much conjecture about how AM will affect elements such as supply and demand, and more generally the overall economic impact the technology will have upon society (Venekamp & Le Fever, 2015). They go on to explain that these types of socio-technical issues are vitally important and that they have, for the most part, been ignored in the literature at the moment (Venekamp & Le Fever, 2015). One possible socio-economic and political impact is established by Campbell et al. (2011) is that AM could possibly result in a decreased need for labour in manufacturing, which could in turn be politically destabilising in some economies while in others, especially aging societies, it might be beneficial, allowing them the capacity to produce more goods with fewer people while lessening dependence on imports.

2.5. Additive Manufacturing & Management

According to Thiesse, et al. (2015) AM is seen in many organisations, by staff and management alike, as a tool limited to production. Thus, they conclude, management can fall into the trap of neglecting the benefits and effects it may have else where in an organisation. Some researchers have proposed a more holistic consideration when it comes to the value creation based on the specific business strategy that is necessary in order to exploit the full benefits of AM (Thiesse, et al., 2015). A more present consideration for managers, raised by researchers Mellor, Hao & Zhang (2014), is the need for an implementation framework to ensure a smooth and unproblematic adoption of the technology.

Piazza & Alexander (2015), researchers who compiled a summary of the literature of AM, assert that the best way to achieve the growth in advanced manufacturing, like Additive Manufacturing, is through innovation, entrepreneurship, and investment. They wrote this from a municipal and provincial perspective, however these properties can be transferred to a more organisational point of view (Piazza & Alexander, 2015). Piazza & Alexander (2015) go on to propose that some of the most successful ways of fostering these elements are to:

- **Nurture the Right Environment**: Focus on creating an environment amenable for the development of technologies, such as Additive Manufacturing, that drastically improve production processes or that is transformable into innovative new products.

- **Focus on the Benefits**: Realise the opportunity that AM poses to start-ups and small and medium-sized manufactures.

- **Find and Fix the Gaps**: Identify and close the gaps in the services, and supporting infrastructure and manufacturers' needs. Create supporting infrastructure that is equipped with the necessary services or supporting mechanisms. Ensure there is no mismatch between the scale and/or quality of the supporting infrastructure and needs of AM system.

- **Get a Go-To Person**: Designate an intermediary, valued by all relevant stakeholders (particularly industry). This is essential not only for the design of an effective policy framework but also for ensuring lasting support for Additive Manufacturing as a high priority.

- **Take Action**: Assemble immediate investments and mobilise support for the future.

- **Demonstrate the Benefit of Taking The First Step**: Recognise the first-mover advantage in securing some early achievements and building momentum.

- **Change the Way you Perceive**: Realise that traditional metrics should be updated for advanced manufacturing. More specifically, managers need to develop new metrics to capture manufacturing as a driver of innovation, productivity, and competitiveness.

Furthermore, Piazza & Alexander (2015) have also identified several challenges or barriers to widespread adoption of AM. A factor that may inhibit a manager's ability to adopt the technology into his or her own organisation (Piazza & Alexander, 2015):

1. **Bias Toward Conventional Manufacturing:**
   a. AM has long been used for prototyping, but the technology is now being used to directly manufacture products in small batches. As a result most manufacturers see AM as a tool for prototyping and small batch manufacturing, but not for large production runs.

2. **Economic/Cost Difficulties:**
   a. High capital and material costs
   b. Most parts are optimized for conventional manufacturing
   c. How cost savings can be actualized through materials and assembly
   d. Necessary improvements in AM product performance
   e. Supply chain geared toward traditional manufacturing

3. **Intellectual Property (IP):**
   a. IP protection is important to recuperate investments made in the development of AM technologies
   b. Estimates indicate that IP losses due to 3D printing will reach $100 billion by 2018.
   c. IP is considered a major issue since the marginal cost of 3D printing is significant.

4. **Educational Challenges:**
   a. AM is a multidisciplinary area, therefore it is difficult to train the workforce because technologies involve a variety of disciplines (modelling, physics, metallurgy, and statistics).

b. Difficult for one person to have adequate expertise in all areas to understand technology development

5. **Materials Capacity:**
   a. One of the biggest challenges to widespread adoption of AM is the small amount of materials (for example polymers, metals, and ceramics) that can be used to fabricate items.

2.6. Additive Manufacturing & Manufacturing

According to Thiesse, et al. (2015) AM has two distinct differences when compared to traditional goods production. These two variances regard flexibility and efficiency. Flexibility relates to an organisation's capability to either react quickly to demand changes or offer a wide range of product variations. Efficiency speaks to performance and management of indicators such as variable cost and lead-time (Thiesse, et al., 2015). It is posited that these two features of production are traditionally diametric, in the sense that it is not possible to achieve maximum flexibility and maximum efficiency at the same time (Thiesse, et al., 2015). Technology is what has traditionally limited the simultaneous improvement of both these features. However, AM technology extends the arm of both flexibility and efficiency, and allows for a number of advancements that were not possible in traditional manufacturing (Thiesse, et al., 2015). AM production allows for the creation of objects that were impossible before, and is able to be automated (Thiesse, et al., 2015). As a result it removes the need for human labour and consequently improves efficiency. Finally, AM allows companies to cost-efficiently switch from traditional mass production to new areas of mass customisation (Thiesse, et al., 2015). Here, companies use AM for the purpose of offering their customers a broader product range, individualised products, or shorter product life cycles over time (Thiesse, et al., 2015).

Table 2.4: Contrast Between Traditional Machining & Different AM Processes (Huang et al., 2012)

Technique	Acronym	Raw Material	Energy Consumed	Fixture & Tooling	Laser Used	Solid Residues	Liquid Residues	Aerosol Residues
Machining		Steel, aluminium, alloy	Mechanical energy	Yes	No	Tool scrap, chips	Fluid mix (cutting, cooling)	Tool particulate, fluid vapour
Stereo Lithography	SLA	Liquid photo-polymer	UV laser beam	No	Yes	Small amount of resin, removed supports	No	No
Selective Laser Sintering	SLS	Nylon, metal, ceramic, paraffin wax	High power laser beam	No	Yes	Material chips	No	No
Fused Deposition Modelling	FDM	Nylon, ABS, ceramic, investment casting wax, alloy	Heat	No	No	Material chips, removed supports	No	No
Laser Engineered Net Shape	LENS	Metal, binder	High power laser beam	No	Yes	Material chips	No	No
Laminated Object Manufacturing	LOM	Paper, polymer, metal, ceramic	High power laser beam, heat	No	Yes	Material chips	No	No
Three-Dimension Printing	3DP	Metal, ceramic, binder	Piezoelectric nozzle, heat	No	No	Material chips, removed supports	No	No

Accuracy

Mahamood, Akinlabi, Shukla & Pityana (2014) state that dimensional accuracy is an issue with AM technology. It is an issue that needs to be addressed, according to them, before the technology can be widely accepted. Layer height control is one way in which AM is trying to compensate for this lack of accuracy, however little else has been achieved in this area. Stair stepping is a cause of the below-average accuracy and surface finish. Guo & Leu (2013) support Mahamood et al. (2014) assertions saying, “Although AM techniques have progressed greatly, many challenges remain to be addressed. These challenges include the limited materials that can be used in AM processes, relatively poor part accuracy caused by the “stair-stepping” effect” (p. 216).

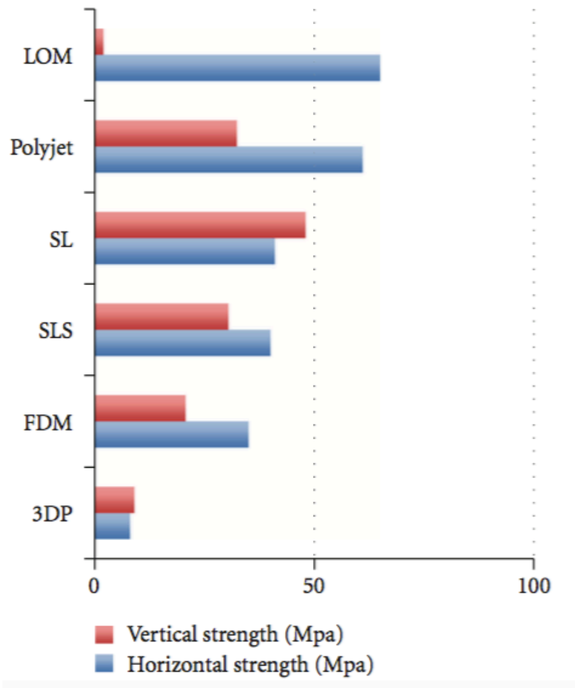
Strength

Huang et al. (2012) demonstrated that strength is a key factor, and in many ways an issue, of AM production. They stated that with suitable control of production considerations, desired geometric properties such as accuracy and surface finish, and material properties such as strength and ductility of a part can be achieved (Huang et al., 2012)

Huang et al. (2012) also identified that size affected the strength of AM produced objects, and that this was a limitation of the technology. They proposed that AM processes frequently utilise materials such as liquid polymers, or a powder comprised of resin or plaster, to build object layers. These materials leave AM incapable to produce bigger items as a result of the deficiencies in material strength. Bigger items also generally are unrealistic because the increased amount of time needed to finish the build process (Huang et al., 2012).

In an empirically conducted strength comparison test the properties of non-metal Additive Manufacturing processes were compared (Wong & Hernandez, 2012). Researchers specifically tested how AM produced objects fared when created in the building direction (vertically) and perpendicular to the building direction (horizontally). They found very little influence in the building direction in 3DP but an enormous influence in LOM. Figure 2.5 is an illustration of this comparison of the strength between LOM, Polyjet, SL, SLS, FDM, and 3DP processes (Wong & Hernandez, 2012).

Figure 2.6: Tensile Strength of Various AM Processes (Wong & Hernandez, 2012)

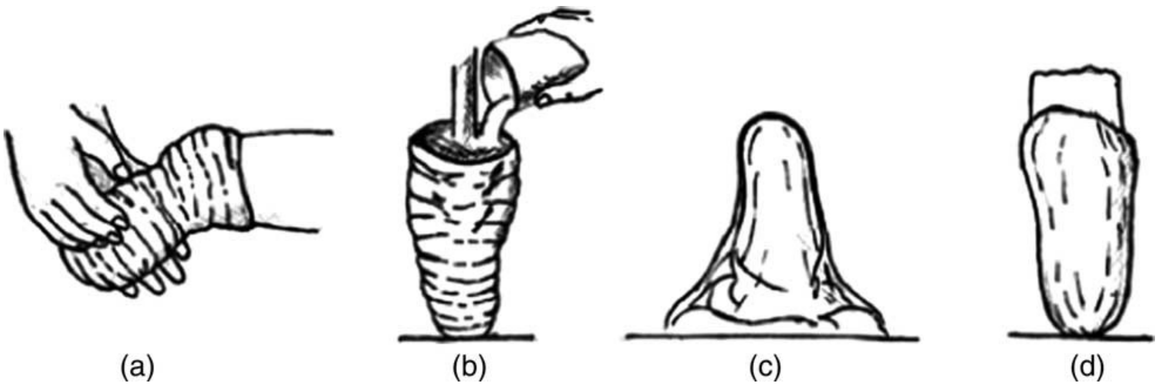


Speed

Conner, Manogharan, Martof, Rodomsky, Rodomsky, Jordan & Limperos (2014) identified the speed of production as a benefit of AM technologies. The researchers state that, "companies need to be agile, seek out and quickly exploit opportunities, while scanning for the next competitive advantage then pivoting to it. The process of reconfiguring assets and organisations to pivot is expensive and lengthy for companies that have conventional manufacturing assets. Additive Manufacturing enables agility. Unlike conventional manufacturing, there is no need to retool for each product design. If there is a need to increase production-build volume, companies can purchase additional 3D printers or they can seek out service providers, participate in regional shared printer consortiums, or (for small items) even order from networks of distributed private printers" (Conner et al., 2014, p. 74).

Syam et al. (2011) points out the benefits of AM technologies when it comes to prosthetic socket fabrication. They determine that the conventional methods of socket prosthetic fabrication were time consuming and labour intensive. They broke the fabrication process into three distinct segments: measurement, rectification and fabrication. First the physical measurements of an amputee were noted. Then a plaster wrap cast was taken, and a positive mould of the amputee's stump was then created by filling the wrap with plaster of Paris. The rectified shape of the positive mould was compared with previously taken shape data on the amputee's stump. The refinement process was carried out until a comfortable shape was achieved. This conventional process is shown below (Syam et al., 2011).

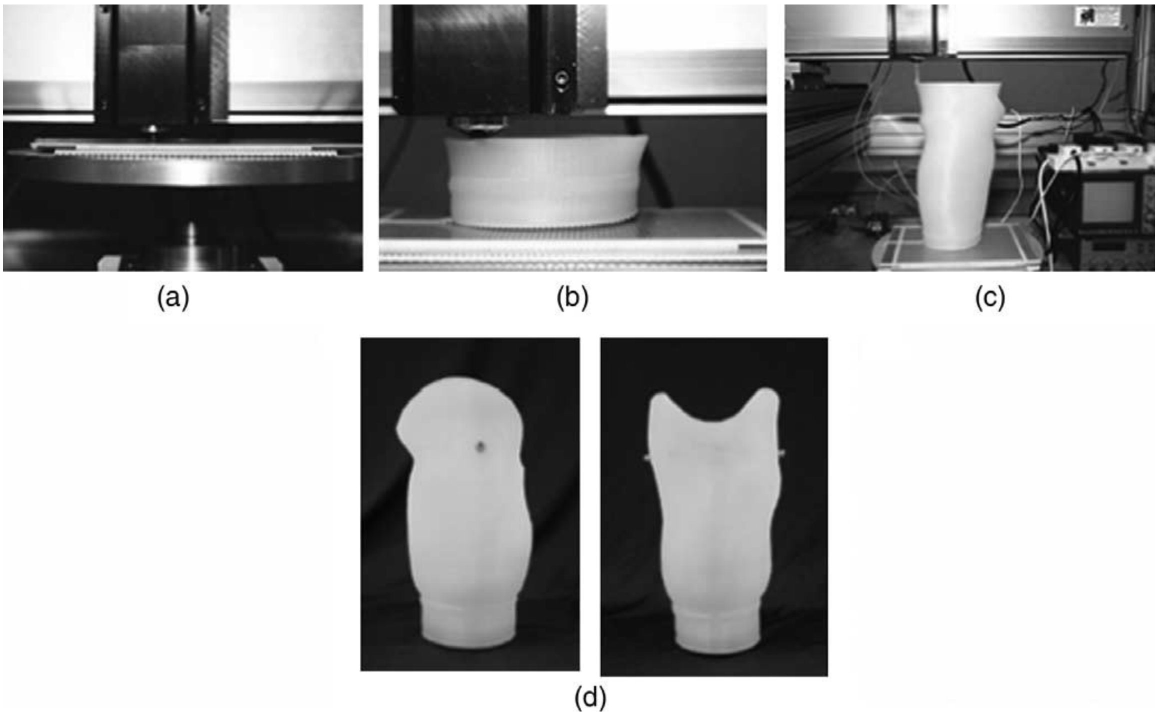
Figure 2.7: Conventional prosthetic socket fabrication process (Syam et al., 2011)



(a) Physical measurement, (b) Positive mould, (c) Rectification from positive mould, (d) Final refinement model

This is in contrast to the FDM process of creating the same socket. In this process faster and less labour intensive process 3D data images of the positive mould were scanned. The data was processed in a CAD system to obtain a 3D CAD model. A STL file was generated from the CAD model. For the fabrication process a FDM machine is employed (Syam et al., 2011).

Figure 2.8: FDM prosthetic socket fabrication process (Syam et al., 2011)



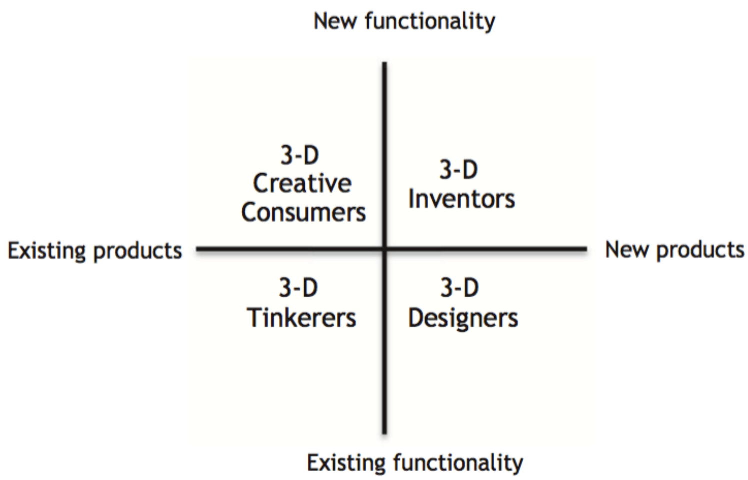
*(a) Start process, (b) In process, (c) After process, (d) Final physical model

2.7. Additive Manufacturing & Marketing

According to Clark, Callı & Callı (2014) AM has consequences beyond manufacturing. AM affords consumers the same opportunities given to retailers. Both are now able to design and produce new products. They are both capable of selecting materials, colours and so forth. AM technology also allows consumers the opportunity to produce quality, custom-made products from home. This has significant implications because individuals will be both the producers and consumers (Clark, Callı & Callı. 2014). Marketers see this as both a challenge and opportunity. Co-creation is a word that is used to explain the way in which marketers propose to address this issue. By creating and designing products with their consumers, marketers believe they will be able to maintain a relationship with customers. Additional experiences and services is what have been suggested (Clark, Callı & Callı. 2014). However the simplicity and ease-of-use may not be as straightforward as speculated. This may benefit marketers and allow them to fill the needs gap.

Kietzmann, Pitt & Berthon (2015) have identified four different types of consumers the will be active through AM. These individuals can be divided into two dimensions: those working on existing or new products, and those whose printed objects improve or sustain the functionality of the original product experience. These dimensions are displayed in Figure 2.9.

Figure 2.9: AM Customer Profiles (Kietzmann, Pitt & Berthon, 2015)



Conner, Manogharan, Martof, Rodomsky, Rodomsky, Jordan & Limperos (2014) concur with the co-creation elements brought up by Clark, Callı & Callı (2014). They show that the mobile phone divisions of organisations like Google and Motorola have teamed with 3DSystems to develop a continuous AM process for their smartphones. Their approach involves a modular, plug-and-play printed smartphone structure enabling users to add or remove functionality during the life of the phone. Motorola has already invested in the web-based infrastructure for customisation with its Moto Maker website and marketing campaign (Kietzmann, Pitt & Berthon, 2015). Such actions illustrate the digital direction that marketing may head down, all of which may have huge implication for prosthetists in the future. If scanning technology is able to adequately examine a person's body and supply them with a variety of different designs and solutions for their prosthetic, then prosthetists may find themselves' wanting.

2.8. Additive Manufacturing & Business Models

AM will force the creation of new value chains and business models (Piller, Weller & Kleer. 2015). Due to the need to exploit economies of scale, traditional production of goods has typically been located far from the end-user. This has resulted in a number of additional costs being added to a product, as well as time lost in the process (Piller, Weller & Kleer. 2015). AM technology allows for the generation of products to happen significantly closer to the user, in some cases in the home of the consumer. However, speculation on this matter has been shown to be particularly murky, with many suggesting possible obstacles for the technology. Some have conjectured that, as a result of AM, existing manufacturers may reduce prices significantly and make their offerings far more appealing and competitive. Entrenched centralised conventional manufacturing systems may also be far harder to disrupt than has been forecast, and the threshold of adoption by consumers may not be as low as previously understood (Piller, Weller & Kleer, 2015). Thus creation of new value chains and business models should be done on a per-company basis and should be updated and revised often in these early stages (Thiesse, et al., 2015).

Beyer (2014) agrees with these statements, saying that AM is a transformative technology. AM is a technology that has consequences for all areas of an organisation's value chain, from suppliers, manufacturing to logistics, wholesalers, and retailers. All organisations need to review the way they do business. Beyer (2014) further purports that by thinking strategically and creatively with AM in mind, organisations are able to completely reimagine whole processes of business at remarkable savings, and to essentially transform business models in a way similar to what the Internet had done.

According to D'Aveni (2013), "businesses all along the supply, manufacturing, and retailing chains will need to rethink their strategies and operations" (p. 34). Petrick & Simpson (2014) agree with this statement and propose that for some industries and products, the rise of AM will replace the competitive dynamics of traditional economies-of-scale production with an economies-of-one production model enabled by AM. In other words, the future of manufacturing will be governed by two principles: economies-of-scale for exchangeable parts fabricated in large volumes, and economies-of-one for highly customisable items that can be built layer by layer. Each model brings its own sources of competitive advantage and economic factors. These distinctions are displayed in Table 2.3.

Table 2.5: Economies-of-Scale versus Economies-of-One (Petrick & Simpson, 2014)

	Economies-of-Scale	Economies-of- One
Source of competitive advantage	Low cost, high volume, high variety	End-user customisation
Supply chain	Sequential linear handoffs between distributed manufacturers with well-defined roles and responsibilities	Non-linear, localised collaboration with ill-defined roles and responsibilities
Distribution	High volume covers transportation costs	Direct interaction between local consumer/ client and producer
Economic model	Fixed costs + variable costs	Nearly all costs become variable
Design	Simplified designs dictated by manufacturing constraints	Complex and unique designs afford customisation
Competition	Well-defined set of competitors	Continuously changing set of competitors

Petrick & Simpson (2014) add to the understanding of the emerging dynamics of economies of one by suggesting that there are five likely outcomes:

1. There will be scarce well-defined parameters in the design-build-deliver paradigm.

2. Design and fabrication will be closely linked via experimentation.

3. Competitive advantage will exist through designs that are simple to fabricate and assemble, as well as through designs that are highly customised and complex. The real challenge will arise when manufacturers are looking for simple designs, and customers are seeking customised, complex products.

4. The closeness between supplier, manufacturer, and customer will become a factor. Localised production will be more feasible as well as more desirable.

5. Planning will be shortened considerably from long term to real time.

Focusing on the issue of costs, Lindemann, Jahnke, Moi & Koch (2012) have suggested that the rating of the cost drivers that they studied showed that there is a significant cost reduction potential associated with AM. However, they also demonstrated that labour costs still make a significant part on pre and post processing of a build. They further propose that the costs and benefits of AM are strongly dependent on the industry that it is being utilised in. Quality assurance costs also have to be taken into account. They noted that these assurance costs are significantly higher in the aerospace or medical industry compared to other industries. That highlights the need of an industry-specific investigation of AM-costs over the whole lifecycle.

2.9. Additive Manufacturing & Strategy

According to Clark, Callı & Callı (2014) AM will have a marked impact on business strategies, introducing new intermediaries to support consumers, reducing the power of suppliers if not replacing them altogether, and requiring a redefinition of the product design to product delivery value chain. A shift in focus onto the valuable aspects of the value chain will follow (Clark, Callı & Callı, 2014). Those with the ability to influence customers will, as before, be the ones with the most influence in the boardroom. The value perceived by customers is bound to alter as a result of AM, as consumers are able to produce their own goods. Thus the shift in business strategy will be towards service and co-creation (Clark, Callı & Callı, 2014).

In a research piece put forward by Beyer (2014) the researcher makes reference to a McKinsey Institute study. The study identifies five disruptions that are being or will be caused by AM, which senior executives must prepare for. The five disruptions are:

1. **Accelerated product development cycles**. A significant reduction in the time allocated to product development was an important advantage of the first AM systems.

2. **New manufacturing strategies and footprints**. As expenses fall and the capabilities of AM systems grow, the range of parts that can be economically manufactured using additive technologies will increase significantly. Thus many

industries are poised to utilise AM as a means to directly fabricate end products.

3. **Shifting sources of profit**: AM technologies have the ability to disrupt the way companies add value to their products and services. Mass customisation and new design possibilities are two characteristics of the technology that are most relevant to achieving such a disruption.

4. **New capabilities**: Beyer (2014) identifies the lack of available knowledge on design for AM. He also demonstrated that many manufacturing company executives are aware of this shortcoming and feverishly trying to collate their design intellect.

5. **Disruptive competitors**: The speed and efficiencies of the technology allows new businesses to easily and effortlessly come to realisation. These new businesses leverage off the highly customisable or collaborative design characteristics of the technology. These businesses are able gain insights from consumer tastes and build relationships that incumbent organisations typically struggle to match. Over time, these new businesses could disrupt entire industries, moving the source of competitive advantage away from the typical ability to fabricate high volumes at low cost.

Beyer (2014) goes on to propose that, “Every company, every industry, and every government should think strategically and globally about what this technology will mean. Progressive companies are looking past the prototyping stereotypes and developing manufacturing strategies utilising AM equipment, processes, and materials for high volume production. Thinking strategically allows these companies to imagine AM’s potential to reinvent entire business processes at tremendous savings, and to essentially transform business models in a manner similar to what has been brought about by the Internet. That is not to minimise the tactical benefits. Clearly there are tremendous costs, time, and competitive benefits to being able to design and additive manufacture a part in two weeks versus the 90 days that might be required by traditional manufacturing methods. But business owners and executives also need to understand the strategic shifts that will follow in the wake of the tactical benefits” (p. 064701-6).

This statement by Beyer (2014) links very succinctly to the work of Mohr and Kahn (2015) described on page 29. They discussed the likely areas that AM will disrupt. They illuminate the resource efficiencies of the technology, and thus the savings associated with the technology. They elaborate on the transformation of the business models and the decentralisation of elements like manufacturing. They also allude to the costs, time, and competitive benefits inherent in the product and design and prototyping stage. However, unlike Mohr & Kahn (2015), Beyer (2014) only refers to the Internet as something that has followed a similar trajectory as AM, and does not discuss the potential pitfalls of the two technologies.

2.10. Additive Manufacturing, Regulations & Intellectual Property

According to Cozmei & Caloian (2012), "Additive Manufacturing technology converts the way how product is purchased, produced and delivered and will lead to a manufacturing renaissance in high-wage economies but also will respond to the attributes of flexibility, re-configurability and sustainability which could uphold the myriad primary production demands of the future society" (p. 462). Cozmei & Caloian (2012) go on to state that for financial reasons, at this time, the adoption of such a technology would include only advantages. Research and development activities are being stimulated, the profit invested in the acquisition of Additive Manufacturing technological equipment could be exempt from taxation, among other things. But the virtual content has enjoyed less tax certainty. Countries will have to consider and debate this challenge and focus on elements such as guidelines for tax so as to offer greater clarity and understanding of tax in the area of the virtual business. New business models brought about through AM do not fit into conventional paradigms of taxation. Merely, the uncertainty that has become the norm will continue to endure until the law catches up with the virtual world (Cozmei & Caloian, 2012). Tax is just one of the many areas surrounding current regulations where AM poses a considerable disruptive threat to the status quo.

Notably, from the perspective of this study, Koptyug, Rännar, Bäckström, Franzén & Dérand (2013) proposed existing regulations that in many ways are aiming for standardisation. This, they concluded, is not surprising as these regulations were put together before it was possible to manufacturer objects the way AM can. As a result, they state, certain efforts should be made by those working in the medical and technological field to help regulatory bodies in modifying out-dated regulations to allow for the opportunities provided by the AM technologies (Koptyug et al., 2013).

As AM grows to become more readily available around the world, it starts to face the matter of intellectual property (IP) infringement. However many feel that AM itself will be a force to be reckoned with when it comes to IP (Kurfess & Cass, 2014). Given that IP legislation varies from country to country, the issue of IP infringement is extremely complicated. The idea of co-creation also raises new questions around ownership. However looking to other industries such as entertainment may assist in the development of a robust and dynamic answer to the question of IP (Wilbanks, 2013). Some researchers have proposed the need for governments to tighten existing intellectual property regulations due to the ease of copying and distributing the designs used in AM through online portals and other mediums (Berman, 2012).

According to Thiesse, et al. (2015) Thingiverse is a website where individuals can share 3D models or CAD files. Since these models are available under Creative Commons licenses, they can be downloaded, adopted, and printed. Currently the site holds about 100,000 3D models. This has already led to a total of approximately 17,000,000 downloads from the platform. All in all, about 50,000 active users belong to the community. These users have already written about 100,000 comments and have created about 50,000 collections. The community is still growing (Thiesse, et al., 2015). Cozmei & Caloian (2012) believe that this type of platform may lead to design file piracy. This, they state, will emerge as a new form of fraud related to intellectual property rights, because everything in the virtual world is intellectual property.

Piazza & Alexander (2015) have suggested that there is a sizeable need for regulation of AM. As it stands, individual industries are regulating AM within the construct of the organisation's mandate. For instance, in the USA this would be the FDA for medical devices, or the HPCSA and SAOPA in South Africa. However there are no overarching standards for AM (Piazza & Alexander, 2015). Piazza & Alexander (2015) concluded that standards should be established. Metrics (measurement methods and performance metrics) and process (standards on how to construct a product and ways to facilitate repeatability) are the two areas they proposed as a starting point for this. They also demonstrated the need for organisation and coordination between industries utilising AM technology. They believed that industry collaboration could only come about through the engagement of all stakeholders (government, academia, and industry) (Piazza & Alexander, 2015).

2.11. Conclusion to Chapter Two

Based on the review of the literature in this Chapter Two above, gaps have been identified in the literature on the potential effects of the disruptive innovation of AM technology on the medical prosthetic industry, and specifically the effects the technology may have on key drivers of the industry, economics, management, manufacturing, marketing, business models and policies, business strategies, and the legalisation and regulations.

In this chapter, AM technology was unpacked in detail, demonstrating the wide variety of processes, materials and applications that make up the technology. The literature surrounding the benefits and disadvantages of the technology were also illustrated, as were its effects so far on the medical industry. Literature revealed the vast number of applications that AM had been used for in the field, including implants, cell culturing and, most pertinent to this study, prosthetics. This chapter presented a number of observations that had been made with relation to AM and medical prosthetic industry. It demonstrated that, “the future holds great promise for AM as a technology and for end users as a result” (Berman, 2014, p. 162). However it also showcased the lack of in-depth literature around the effects of the technology on the industry.

In this chapter the Theory of Disruptive Innovation was also discussed. The literature around the theory is substantial and areas such as its features, categories and flaws were introduced. The concept of AM as a disruptive innovation was also made apparent. It is definitely an innovation that rates highly on the disruption scale. As Mohr & Khan (2015) say, “AM has enormous potential to disrupt the status quo. This disruptive innovation threatens not only the established paradigms in the manufacturing industry, but also applies to legal and security concerns” (p. 23). However, this chapter also showed that the label of AM as a disruptive innovation is not yet fully established when it comes to the medical prosthetic industry. As some have argued in this chapter, AM may simply be an evolutionary step, rather than a revolutionary one.

AM technologies’ effects on key drivers of the prosthetic industry were also discussed in this chapter. These included literature and discussions on the technologies’ effects so far and potential future impact on elements such as economics, management and managers’ ability to effectively adopt the technology (Piazza & Alexander, 2015). The effects the technology has on production, marketing and business models and strategies were also examined. Finally, the effects the technology is having and will have on legalisation, regulation and intellectual property were also reviewed. This area in particular displayed the gaps in our understanding, and the need to attempt to understand the effects in order to better handle any negative effects that may result from the technology. As was mentioned in the chapter, efforts should be made by those working in the medical and technological field to help regulatory bodies in modifying out-dated regulations to allow for the opportunities provided by the AM technologies Koptyug et al. (2013).

Given the importance of assessing the impact of the technology from an industry specific perspective, further research into this area is warranted in this research project Accordingly, this research project will answer the research questions detailed in Chapter Three below.

3. CHAPTER THREE: RESEARCH QUESTIONS

3.1. Introduction

The purpose of this chapter is to define the precise purpose of this research project. As demonstrated in Chapter Two above, this topic is new, under-researched and should be studied on a industry-by-industry basis (Weller, et al., 2015). As such, the existing literature on Additive Manufacturing and the medical prosthetic industry does not provide sufficient solutions to the research objectives, and this research project will use research questions and unstructured in-depth interviews in accordance with the exploratory research methodology detailed in below (Malhotra, 2010).

Based on this the following research questions are posed:

3.2. Research Questions

3.2.1. Research Question One

What is the impact of the disruptive innovation of Additive Manufacturing technology on the medical prosthetic industry?

3.2.2. Research Question Two

What impact does Additive Manufacturing have on the economics of the medical prosthetic industry?

3.2.3. Research Question Three

What impact does Additive Manufacturing have on the management of the medical prosthetic industry?

3.2.4. Research Question Four

What impact does Additive Manufacturing have on the production of the medical prosthetic industry?

3.2.5. Research Question Five

What impact does Additive Manufacturing have on the marketing of the medical prosthetic industry?

3.2.6. Research Question Six

What impact does Additive Manufacturing have on the business models and policies of the medical prosthetic industry?

3.2.7. Research Question Seven

What impact does Additive Manufacturing have on the business strategies of the medical prosthetic industry?

3.2.8. Research Question Eight

What impact does Additive Manufacturing have on the regulations of the medical prosthetic industry?

3.3. Conclusion to Chapter Three

These are the eight research questions that this study sought to answer. Chapter Four will discuss the method that was adopted to answer these questions.

4. CHAPTER FOUR: RESEARCH METHODOLOGY

4.1. Introduction

The design of this research was determined by the underlying purpose of the study (Saunders, Lewis & Thornhill, 2012). The purpose of this study was to establish what the present and future impact of AM technology would be on the medical prosthetic industry. As has been demonstrated earlier in this proposal and in the extensive research that has been done on the matter, the implications of AM technology can be extensive. However it has also been substantiated that the influence of AM technology must be assessed on a per industry basis (Weller, Kleer & Piller, 2015). Researchers must not fall into the pitfall of applying a broad umbrella perspective of the effects of AM technology, similarly to what Markides (2006) alludes to in his research on disruptive innovation. The digital age has also ushered in the era of the sharing economy, crowd funding and co-creation (Wilbanks, 2013). The free and open exchange of ideas and knowledge has extended into property. This has driven some industries, most notably the entertainment industry, to rethink the way that they do business. Luckily, for most, the piracy of products has been largely limited to products that could be transferred digitally. However the advent of AM technology has and will change that (Thiesse, et al., 2015). Through researching the disruptive innovation of AM technology and the impact it has on an industry, a greater understanding and appreciation for the technology has been gained. This allows for a much more effective and efficient utilisation and adoption of the technology, in spite of the potential pitfalls posed by the technology. This research has attempted to answer the questions raised by AM technology, and assess the effects it will have on the medical prosthetic industry.

4.2. Research Design

Research methodology experts such as Tharenou, Donohue & Cooper (2007), Saunders Lewis & Thornhill (2012) and Malhotra (2010), are in agreement that the research design to be used must be determined by the underlying purpose of the study. In the case of this study this was to understand the present and future effects that Additive Manufacturing technologies will have on the medical prosthetic industry. The research method that was followed was a direct approach, completed through exploratory research, having obtained primary data through qualitative research, specifically by way of in-depth interviews.

This research followed an exploratory qualitative design with in-depth interviews. Saunders, Lewis & Thornhill (2012) explain that a qualitative design studies the stakeholders' meanings and the relationships between them. Thus this approach was ideal in drawing out the effect on the disruptive innovation of Additive Manufacturing on the medical prosthetic industry. It also assisted in shedding light on the various aspects of the medical prosthetic industry that may be affected and their relationships between one another. This method was also chosen because of the small samples that were used, and according to Malhotra (2010), when small samples are used and when the aim of the study is to gain specific insights or to better understand the subject that is posed in the research questions, a qualitative research method should be employed.

4.2.1. Rationale for Research Method: Exploratory Research

Saunders, Lewis & Thornhill (2012) go on to explain that exploratory research design seeks to explore general information concerning a topic not particularly well understood by the researcher. This type of study can also provide insights and greater illumination on issues or situations (Saunders, Lewis & Thornhill, 2012). Given the diverse nature of the research required for this study of AM technology in the context of the medical prosthetic market, this particular type of approach was ideal. The researcher of this study was aware that they were trying to explore a topic that was not particularly well understood by the researcher. Given also the novelty of Additive Manufacturing in the medical arena and the limited amount of credible research literature done on it in general and specifically in South Africa, this approach was ideally suited for this study.

4.2.2. Research Process: Direct Approach

This study also utilised a direct approach. A direct approach refers to when the purpose or goal of the study is explained to the participant of the research, or if the purpose of the research is obvious to the participant (Malhotra, 2010). Given the novelty of the technology in the medical prosthetic industry, the researcher anticipated a slight lack of understanding of the implications of the technology. Thus through the use of a direct approach, with open questions posed, this direct approach was extremely beneficial to give some context of this study to the participants, and as a result allowed them to provide the best contributions they could.

This research also utilised primary data. This is when researchers do direct research in an attempt to answer the specific research problems (Malhotra, 2010). In other words the researcher of this study collected data specifically for the research project that was undertaken (Saunders, Lewis & Thornhill, 2012). This was the appropriate tack for this research because, as aforementioned, there was a lack of critical and peer reviewed data surrounding the disruptive effects of Additive Manufacturing on the medical prosthetics industry. The use of data collected from credible participants, who have a wealth of knowledge in their respective areas to contribute, was invaluable to this study given the diversity of research questions posed.

4.2.3. Primary Data & In-Depth Interviews

This primary data was collected via in-depth interviews with participants or stakeholders. In-depth interviews, also known as unstructured interviews, are a form of direct, personal interview during which loosely structured questions are posed to the interviewees in order to probe their underlying attitudes, beliefs, motivations and feelings on the research topic (Malhotra, 2010). The interviews were more around the exploration of particular themes or areas of research than a set list of questions. This approach supported the specific varied areas of the research questions, as it allowed the interviewer the ability to gain the most insight possible from each of the interview candidates. In some cases participants were unable to provide accurate answers to the questions posed by the researcher. This was likely due to underlying reasons that were not immediately apparent to the participants themselves. The values, emotional drivers and motivations are items that are often deeply embedded in the subconscious of the participant, and often disguised from the outside world through rationalisation and other ego defences. This is particularly relevant for the prosthetists and AM manufacturers, who were clearly threatened by one another with SAOPA having begun legal and regulatory action against some of the AM manufacturers who had produced prosthetics (Slabbert, 2011). According to Malhotra (2010), in such case the most appropriate means of extracting that information is through qualitative research. Due to the unsettling and threatening nature of a disruptive innovation such as Additive Manufacturing in the medical prosthetic industry, these ego defences were likely to arise in participants, and thus an in-depth interview procedure was aptly suited to best tackle these issues.

4.2.4. Secondary Data

Secondary data sources, including company websites and brochures, were also utilised to add depth to the interviews (Kirkwood & Walton, 2010) and helped develop a more robust and well-rounded understanding of the context of each. Use of secondary data assisted the triangulation process and improved the credibility of the data gathered in the interviews.

4.3. Population

The population of this research was limited to any stakeholder that is or was directly affected by medical prosthetics created through the means of Additive Manufacturing. This includes prosthetists, technicians, prosthetic retailers and prosthetic manufacturers. In selecting stakeholders it was important to screen them objectively to ensure that they were appropriate to the study. When identifying potential interviewees, personal networks were made use of, as were websites like www.saopa.co.za, www.hpcsa.co.za, www.samedicalspecialists.co.za and www.tut.ac.za. However, access and availability was the final deciding factor.

4.4. Unit Of Analysis

A unit of analysis is an element for analysis, including individuals, pairs groups, companies and industries (Saunders, Lewis & Thornhill, 2012). For this study the unit of analysis was each of the stakeholders and their opinions.

4.5. Sampling Method & Size

Typically, sampling in qualitative research is done for relevance and not representation. Given that there was no available sampling frame – a list of all the members of the population being studied –, none was utilised (Saunders, Lewis & Thornhill, 2012), so non-probability sampling techniques were used. These techniques are ideally suited when the total population number may not be known and when resources are limited (Cooper & Schindler, 2014). A purposive sampling technique was also employed. Purposive sampling is utilised to purposefully select a small sample group when data collecting on qualitative research. Purposive sampling relies on the judgement of the researcher to select interviewees who would best answer the questions and objectives posed by the research (Saunders, Lewis & Thornhill, 2012). This idea links very nicely with the initial comment that sampling in qualitative research is about relevance and not representation.

The judgement that did contribute to the sample selection was due to the researcher's ability to connect with credible and senior individuals who operate in the various segments of the medical prosthetic and Additive Manufacturing industry. In other studies following a similar methodology and philosophy, a pattern emerged that demonstrated that 10 to 15 participants was the appropriate number to gather enough data to draw a useful conclusion (Kirkwood & Walton, 2010). Therefore this study targeted 14 interviewees in order to gain sufficient data on the effects of the disruptive innovation of Additive Manufacturing on the medical prosthetic industry. This study targeted on average two to three participants from each of the different segments within the medical prosthetic industry in order to gain a greater perspective on effects on the industry as a whole.

4.6. Measurement Instruments

Unstructured in-depth interviews were used in this research study, utilising open-ended questions in order to gain the greatest insight and understanding around the themes brought up in the research questions.

Below find a rough outline of the questions that were posed:

1. What industry do you operate in?

2. What has been your experience of Additive Manufacturing (AM) in the medical prosthetic industry?

3. How has Additive Manufacturing affected the way you approach management?

4. How has Additive Manufacturing changed the way medical prosthetics are manufactured?

5. What impact has Additive Manufacturing had on the marketing of the medical prosthetic industry?

6. How has Additive Manufacturing changed on your business models and policies?

7. What impact does Additive Manufacturing have on your business strategies?

8. What impact does Additive Manufacturing have on the intellectual property legalisation and regulations of the medical prosthetic industry?

9. How disruptive do you think Additive Manufacturing has been and will be on the medical prosthetic industry?

10. Are there any other comments or areas of discussion that we have not gone over and that you wish to discuss?

4.7. Data Gathering Process

In-depth interviews are unstructured and so the use of open-ended questions is employed to ensure the researcher is able to effectively explore the participants' underlying thoughts and feelings with regards to each of the research questions (Saunders, Lewis & Thornhill, 2012). With this in mind, the rough outline questions were used in a general manner to initiate areas of focus, and then from that, more probing questions will be employed to gain deeper explanations. These probes included complex probes, reflective probes and crosschecks, story telling and verbal cues, though these depended on the interviewer's responses during the interview and the appropriateness of the situation (Saunders, Lewis & Thornhill, 2012). Other techniques such as laddering, hidden issue questioning and symbolic analysis were also made use of during the in-depth interviews (Malhotra, 2010).

As already mentioned above (in section 4.2.4.) secondary data sources, including company websites and brochures, were utilised to add in-depth understanding to the interviews (Kirkwood & Walton, 2010) and to develop a more robust and well-rounded understanding of the context of each. The use of secondary data also assisted in the triangulation process and improved the data credibility gathered in the interviews. Only data available in the public domain, like websites and brochures, were used.

Given the healthcare nature of this study it was critical that the utmost was done to ensure the ethical and appropriate collection of data was conducted at all times. Thus discretion always fell on the side of the individuals involved and privacy was always assured if requested. Appropriate allocation of codes and withholding descriptors are techniques of achieving these goals (Crowe, Cresswell, Robertson, Huby, Avery & Sheikh, 2011). All healthcare and academic ethical clearance documentation can be found in the appendix of this study.

4.8. Analysis Approach

Analysis began with the transcription of the interviews. These transcriptions were analysed using the content and frequency analysis technique and subsequently organised around themes that arose in the interviews. From there an indexing system was established and codes and labels were incorporated into each of the paragraphs and sentences in accordance with the aforementioned themes. This process, as well as the data itself, was continuously refined and reviewed. The use of Altals.ti 7 Qualitative Data Analysis Software was employed to conduct the analysis. Altals.ti is qualitative data software that is available to researchers at the Gordon Institute of Business Science. A systematic data reduction was followed. This was done to streamline the data by organising it into themes and clusters in order to combine, relate and diverge the concepts that emerge from the themes (Silverman, 2011).

4.9. Data Reliability & Validity

4.9.1. Reliability

According to the researchers Tharenou, Donohue & Cooper (2007) reliability is about ensuring a researcher’s ability to duplicate the data collected if the same methodology was followed by someone else. Triangulation was used to achieve reliability in this study. This was achieved, for instance, by also having applied secondary data sources and verification to data analyses.

4.9.2. Internal Validity

Validity is comprised of two segments. These are external and internal. The first of these segments, internal validity, was achieved in this study by attributing the correct cause and effect, therefore interpreting the results of the study correctly, without bias (Saunders, Lewis & Thornhill, 2012). This could also have been achieved by way of triangulation, by using multiple sources of data (Saunders, Lewis & Thornhill, 2012).

4.9.3. External Validity

External validity speaks to the extent to which findings from one group may be generalised to other groups (Saunders, Lewis & Thornhill, 2012). This study sought to mitigate the issue of external validity by undertaking multiple interviews with multiple experts.

4.10. Confidentiality & Anonymity

This study has been through and been approved by two rigorous ethical board committees, the Ethical Committee of the Gordon Institute of Business Science (GIBS) and the Health Ethical Committee of the University of Pretoria.

The approval of this research required the permission of department and organisational heads prior the ethical approval. This came in the form of a signed permission letter (Exhibit 5 in Appendix). Informed consent letters in the form of PICD2 forms (Exhibit 7 in Appendix) were also signed by each of the interviewees, prior to any interviews being conducted. The names of interviewees have also been withheld in the quotes to ensure their anonymity. All healthcare and academic ethical clearance documentation can be found in the appendix of this study, including the PICD2 and permission letter, as well as a copy of the letter of confirmation of healthcare ethical clearance from the University of Pretoria.

So as to preserve a state of anonymity of the interviewees all through the study, the publication of this dissertation and any additional material that may follow afterwards, no names or identifiers of interviewees were recorded in the digital audio recordings of such interviews or in the transcriptions thereof.

Additionally, the transcriptions resulting from the digital audio recordings of the interviews are kept confidential, and are held securely by the Data Storage Facility at GIBS (Exhibit 4 in Appendix).

4.11. Limitations

Reliability is a potential limitation of this research. Reliability refers to the ability of another researcher to conduct the same study, using the same methodology and producing the same results (Saunders, Lewis & Thornhill, 2012). It relates to the consistency of the findings that emerge from the raw data. As already mentioned, this research aimed to make use of triangulation that assisted in corroborating or refuting the data collected. This helped mitigate the potential limitation of reliability (Saunders, Lewis & Thornhill, 2012).

The validity of the study was also at risk, internally and externally. Internal validity refers to the extent to which findings can be attributed to interventions rather than any flaws in a researcher's research design (Saunders, Lewis & Thornhill, 2012). While external validity relates to the extent to which findings from a particular study are generalised to all relevant contexts (Saunders, Lewis & Thornhill, 2012). These two limitations were mitigated in this study through triangulation, using multiple sources of data and multiple interview candidates.

Another limitation of this study lies with the research. During in-depth interviews the role of the interviewer is pivotal to the interview process, and in the collection, analysis and interpretation of that data. Thus the outcome of the research is substantially dependant on the ability and experience of the researcher (Saunders, Lewis & Thornhill, 2012). As a means of mitigating this risk, a qualified, independent, external individual was used in the transcription process. The researcher endeavoured to be substantially versed in the various literatures of in-depth interviews prior to the commencement of the interview process.

4.12. Conclusion to Chapter Four

In this chapter the research methodology that was followed for this research report was explored. It demonstrated that this research methodology utilised a direct approach, having done exploratory research, having obtained primary data through qualitative research, specifically by way of in-depth interviews of 14 candidates working within the Additive Manufacturing and medical prosthetic industry.

The next chapter will present some of the data gathered during these in-depth interviews, specifically framed in the context of the research questions outlined in Chapter Three.

5. CHAPTER FIVE: RESULTS

5.1. Introduction

In this chapter the results of the study are presented, and these correspond with the research questions stipulated in Chapter Three. The research sample consisted of 14 credible and senior candidates who operate in the various segments of the medical prosthetic and Additive Manufacturing industry. In the medical prosthetic sample group, orthotists, hospital executives, international and local prosthetic manufacturing executives, a researcher, tertiary level academic coordinators and a maxillofacial prosthetist were selected to gain a variety of insights into their rich knowledge and vast experiences in the field. In the Additive Manufacturing sample group, two Chief Executive Officers (CEO) and founders of Additive Manufacturing were selected, both with a number of years' experience in the industry, and in manufacturing medical prosthetics utilising AM technology.

The list below provides some information about the interviewees including their codes, their position and the type of organisation.

Table 5.1: Interviewee List

#	Interviewee Code	Position	Company	Group	Interview Length
1	The Researcher	Prosthetist, Orthotist & Researcher	Medical Orthotics & Prosthetics Practice	Medical Prosthetic	51:41
2	The Administrator	Managing Director (MD)	Medical Orthotics & Prosthetics Practice	Medical Prosthetic	43:14
3	The Non-Profit MD	Managing Director (MD)	Non-Profit Organisation	Medical Prosthetic	64:20
4	The International Manufacturer	Managing Director (MD)	International Orthotics & Prosthetics Manufacturer	Medical Prosthetic	21:14
5	Prosthetist & Orthotist #1	Prosthetist & Orthotist	Medical Orthotics & Prosthetics Practice	Medical Prosthetic	30:07
6	The Academic Coordinator #1	Academic Coordinator of Prosthetics & Orthotics	Local Tertiary Education Institution	Medical Prosthetic	16:03
7	The Holding Company Director	Marketing & Business	Medical Holding	Medical Prosthetic	56:05

		Development Director	Company		
8	The Holding Company GM	General Manager (GM)	Medical Holding Company	Medical Prosthetic	56:05
9	Prosthetist & Orthotist #2	Prosthetist & Orthotist	Medical Orthotics & Prosthetics Practice	Medical Prosthetic	55:10
10	The 3D Printer #1	CEO & Founder	AM Printers	Additive Manufacturers	30:00
11	The 3D Printer #2	CEO & Founder	AM Printers	Additive Manufacturers	55:30
12	The Anaplastologist	Anaplastologist	Medical Anaplastologist Practice	Medical Prosthetic	25:51
13	The Local Manufacturer	General Manager (GM)	Local Orthotics & Prosthetics Manufacturer	Medical Prosthetic	25:46
14	The Academic Coordinator #2	Academic Coordinator of Prosthetics & Orthotics	Local Tertiary Education Institution	Medical Prosthetic	54:44

5.2. The Interviews

Interviews were conducted with 14 senior candidates of the medical prosthetic and Additive Manufacturing sector, spanning a range of areas from different parts of South Africa. The results of the interviews will be presented below, in terms of the abovementioned categories. Additionally, information was gathered from brochures provided by the interviewees themselves and from their websites, where applicable.

The 14 individuals interviewed came from a variety of ethnic, linguistic and experiential backgrounds. All of them were South African, 10 were male and four were female. The interviewees ranged in age from their early thirties to mid-sixties, with an average age of around the mid forties. One of the individuals was even a double amputee themself, which added an additional perspective to the study. It was fortunate to have had such a diversity of individuals in this sample in terms of age, race and experience, given that these were the interviewees that were available and willing to be a part of the in-depth interviews. The slight bias in male interviewees has been noted, and is simply a result of availability.

5.3. The Sample

As spoken about in Chapter Four, both GIBS and Health Board ethical approval was attained for this study on the understanding that identifiers would not be kept or offered in this study. Therefore the candidates interviewed have been presented in the order the order that they were interviewed and a brief descriptor of them and their organisations has been offered below:

5.3.1. The Researcher

This interviewee is a fully qualified and practising medical orthotist and prosthetist who has a passion for research and new technologies. He has been practising in KwaZulu-Natal for 18 years. He has a practice in two places, both of which are private practices, however he has done work for public facilities from time to time. His passion lies in finding out what new technology is out there and, through research, how to utilise that technology in the manufacturing of his orthotics and prosthetics. His research has currently led him to investigate the opportunities and benefits posed by AM technology, specifically in the production of prosthetic sockets. His research typically produces a lot of designs, including small inventions that better the profession and the services it offers by creating better devices. He himself is not only focused on manufacturing custom-made devices, like prosthetics, but also the manufacturing of off-the-shelf mass production devices, thus his expertise in both the realm of prosthetics and AM technology is significant. His research is published on his website for anyone to read through and examine. This interview was conducted telephonically, due to distance and time constraints.

5.3.2. The Administrator

This interviewee is the manager of a two-person medical orthotics and prosthetics practice in Gauteng. The practice sells and manufactures orthotics and prosthetics on site. His wife is the medical orthotist/prosthetist and he manages all the other elements of the practice, which includes everything from procurement to sales and marketing. The practice is just off a main road, located in a small shopping centre. The practice includes a reception where all off-the-shelf products are on display, such as inner soles, bracing, compression stockings for varicose veins and shoes for diabetics. The practice's workshop where the prosthetics and orthotics are produced is at the same location. The practice features posters of many international orthotic and prosthetic manufacturers, including the likes of international brands like the Icelandic Össur or the German Ottobock. This interviewee had had little contact with AM technology, however he had a firm grasp of the technology through his own research and interest in the area. As an administrator of a medical prosthetic practice, he also had substantial knowledge about the business operations of the industry, from supply chain management to marketing operations.

5.3.3. The Non-Profit MD

This interviewee is the manager of the non-profit leg of a medical orthotics and prosthetics practice in Gauteng. This interviewee is a double lower limb amputee himself, the result of a tragic accident when he was a young boy. In his mid-thirties now, the interviewee has experienced much of what the South African prosthetic industry has to offer. He has experienced issues around cost and technical expertise, so much so that he used to travel to Europe to the manufacturers to acquire his prosthetics because the costs were so similar. An avid sportsman, he was unfortunate to miss out on a Paralympics debut in London as a result of an unfortunate injury that his rowing partner picked up days before the event. The non-profit, started in 2009, is the result of a prosthetist who came back to South Africa after working overseas at Össur Global. Össur had developed a new socket manufacturing technology, which was much faster than previous methods. This prosthetist believed this new technology could dramatically help South Africans; specifically children who he often felt were neglected when it came to the prosthetics in South Africa, particularly because of the high costs associated with prosthetics. This neglect, he believed, could lead to children not attending school, which meant they did not have any chance of a life going forward. This interviewee has a firm grasp of AM technology through his own research, and because that the non-profit had utilised the technology and experimented with it.

5.3.4. The International Manufacturer

This interview candidate is the managing director of large international manufacturer responsible for most of the Southern African Development Community (SADC) region, with responsibilities that include marketing and sales. Manufacturing is done exclusively overseas. The organisation has been in South Africa for almost five years and his role is to drive the manufacturer's presence in Africa. He is based in Gauteng, and the office displays wheelchairs and a variety of different prosthetic limbs, predominantly legs on display. This interviewee has had experience with AM technology, through the many conferences and showcases he is exposed to locally and abroad.

5.3.5. The Prosthetist & Orthotist #1

This interviewee is a fully qualified and practising medical orthotist and prosthetist, operating in Northern Gauteng. Having qualified from the local university of technology, he now operates on the second floor of a shopping complex. The practice is comprised of himself and an administrative assistant. The majority of the prosthetics are manufactured at the practice. Typically, a Plaster of Paris technique is utilised where a mould of a patient's residual limb is taken, then the mould is filled with Plaster of Paris, and that replica is used to create the prosthetic. Components such as the knee and ankle components are sourced from Europe; while newly popular AM printed prosthetic covers are sourced from Canada. This interviewee has an understanding of AM from his own research of the technology.

5.3.6. The Academic Coordinator #1

This individual is the Head Of Department (HOD) of a South African university of technology. He is also known as the Academic Coordinator of the Medical Orthotics and Prosthetics department of the university. His responsibilities include the admission of and registration of students, as well as the marketing and advertising of the university and, specifically, the Medical Orthotics and Prosthetics department. A qualified medical orthotist and prosthetist himself, this interviewee has great knowledge of the inner workings of the prosthetics industry, dealing regularly with bodies like SAOPA and the HPCSA. This interviewee had extensive knowledge of AM technology, having worked with new technologies and researchers on a daily basis. This interview was conducted telephonically, due to distance and time constraints.

5.3.7. The Holding Company Director

This interviewee is the marketing and business development director of a medical holding company operating out of Northern Gauteng. Having started off in advertising, she now heads up all the marketing of the group. The company was founded in 1989, and its brochure states that the organisation has established itself as one of the leading Black investment companies currently steering the health care industry in Africa. One of the stated characteristics of the holding group is its ability to consistently remain abreast of competition by using the latest technology and proven business models. The company operates in several African countries, and holds a number of different medical subsidiaries including hospital services, an orthotics manufacturer and a prosthetics manufacturer. This interview included the marketing director and the general manager in the same interview, as they felt that this would add more value. This interviewee had an understanding of the technology, however her expertise lay in the high level operations of the organisation, which would be invaluable when assessing the impact AM technology would have on the business models and strategies of the industry.

5.3.8. The Holding Company GM

This interview candidate is the General Manager (GM) of a medical holding company, founded in 1989, operating out of Northern Gauteng. The company brochure states that the organisation has established itself as one of the leading Black Investment companies currently steering the health care industry in Africa. One of the stated characteristics of the holding group is its ability to consistently remain abreast of competition by using the latest technology and proven business models. The company operates in several African countries, and holds a number of different medical subsidiaries including hospital services, an orthotics manufacturer and a prosthetics manufacturer. This interview consisted of the marketing director and the general manager in the same interview, as they felt that this would add more value to the interview. This interviewee had a good grasp of the technology. Her real expertise, however resided in the more upper level operations of the organisation, which would be invaluable when assessing the impact AM technology would have on the business models and strategies of the industry.

5.3.9. The Prosthetist & Orthotist #2

This individual is a fully qualified and practising medical orthotist and prosthetist, operating in the Western Cape. The interviewee has been practising for a number of years, and manufacturers his prosthetics at the practice, while sourcing the foot and knee components, as well as microprocessors from elsewhere. One of the only myoelectric prosthetic specialists in South Africa, this interviewee has a vast knowledge of the more advanced technologies utilised in prosthetics today. This interviewee had extensive knowledge of AM technology through his own experiences and research on the technology. This interview was conducted telephonically, due to distance and time constraints.

5.3.10. The 3D Printer #1

This interviewee is arguably one of, if not the, most prominent and sometimes controversial names in the South African AM world. This interviewee's interest in AM technology began after an unfortunate accident in which he lost several fingers. Searching for a solution, he decided to investigate AM technology, and in the process founded two organisations. One is a 3D printer manufacturing company, and the other is a non-profit organisation that has developed an AM prosthetic hand open source CAD file that is free to source online and print. Initially printing and distributing the prosthetic hand himself, he has since pulled back from producing the hand and lets others print it themselves, as a result of a number of cease-and-desist letters he received from the HPCSA. Both organisations operate out of Gauteng. The AM prosthetic hand design has, according to this interviewee's brochure and website, helped hundreds of amputees around the world, specifically in areas where there are many amputations as a result of war, or where medical facilities are scarce, like Syria. Historically focused on an AM printed prosthetic hand, the interviewee has now developed an AM printed prosthetic leg. The printers he manufactures are designed to be robust and uncompromising, with optional extras such as a solar panel and 20-hour battery.

5.3.11. The 3D Printer #2

This interviewee is an industrial designer by trade and operates out of Gauteng. He does end-to-end industrial design, which means he will take someone's idea, sketch or brief from infancy all the way through to producing the product, either doing the work himself or completing it through a range of suppliers. He has been operating in the space for around 15 years, and along the way he picked up AM printing as a tool. He was one of the first people to utilise AM technology in South Africa. Initially, he used to send designs to the CSIR to get them printed via Stereo Lithography (SLA). This interviewee had a deep and intricate knowledge of production and had a large, industrial scale milling and FDM machine on site. His expertise in printing for medical purposes was also significant, having printed various pre-surgical models, jaw implants and, most importantly, prosthetic products before.

5.3.12. The Anaplastologist

This interviewee is the only registered anaplastologist in South Africa, with her profession using prosthetics to restore body image. This encompasses everything that is aesthetic, including the fingers, toes, noses, ears and breasts. Operating out of a private hospital in Gauteng although she has her own workshop elsewhere, the interviewee currently uses very traditional methods to make her prosthetics. This includes techniques like carving them by hand. She does claim that she is starting to try and move more into 3D printing, because carving can take a week of labour whereas 3D printing takes her about half a day.

5.3.13. The Local Manufacturer

This interviewee is the general manager of a local orthotic and prosthetic manufacturer situated in a factory on the outskirts of Northern Gauteng. This interviewee is a fully qualified medical orthotist and prosthetist. The organisation is one of the few local prosthetic manufacturers, and consists currently of about 40 onsite workers. Production consists of very basic prosthetic and orthotic elements, and utilises unskilled labour. Materials such as steel are sourced locally, while plastics are produced through injection moulding onsite. The vast majority of production, storage and logistics happen onsite, while an additional admin team sits elsewhere in the province. However, new management has advised that all elements will soon be at a single location, the factory. Her expertise in the area of AM technology was substantial, as she had been experimenting and researching the technology in collaboration with local additive manufacturers for some time.

5.3.14. The Academic Coordinator #2

This interviewee is the Head Of Department (HOD) of a South African university of technology. She is also known as the Academic Coordinator of the Medical Orthotics and Prosthetics department of the university. She is also a lecturer and a fully qualified medical orthotist and prosthetist. Her rooms are full of hi-tech equipment and materials including the some of the latest prosthetic components from Össur and Ottobock, as well as a 4D printer, which is similar to a CNC milling machine. It is currently used to cut model limbs and body parts out of solid blocks of material. This interviewee, much like the other academic coordinator, has great understanding of the inner workings of the prosthetics industry, dealing regularly with bodies like SAOPA and the HPCSA, as well as being at the forefront of the techniques and technologies that the next group of young prosthetists will have going out into the world. This interviewee's knowledge and experience of AM technology was good. She had been researching the technology and been exposed to it on a number of occasions, for example students submitting research reports on the effectiveness of the technology.

5.4. Analysis of In-Depth Interview Data

As mentioned in Chapter 4, analysis began with a process of transcribing the recorded interviews. These transcriptions were analysed using the content and frequency analysis technique, after which they were organised around themes that arose in the interviews. From there, an indexing system was established and codes and labels were incorporated into each of the paragraphs and sentences in accordance with the aforementioned themes. This process, as well as the data itself, was continuously refined and reviewed. The use of Altals.ti 7 Qualitative Data Analysis Software was employed to conduct the analysis. Altals.ti is qualitative data software that is available to researchers at the Gordon Institute of Business Science. A systematic data reduction was followed. This was done to streamline the data by organising it into themes and clusters in order to combine, relate and diverge the concepts that emerge from the themes (Silvermen, 2011).

5.5. Research Question One

What is the impact of the disruptive innovation of Additive Manufacturing technology on the medical prosthetic industry?

5.5.1. Introduction

This question attempted to identify the current and future impact that Additive Manufacturing technology may have on the medical prosthetic industry. The aim of this research question was to gain an understanding, from the interviewees, of how disruptive they believed Additive Manufacturing technology would be, and in what areas that would most likely be. The question also attempted to assess whether the interviewees felt the industry and themselves felt threatened by the technology, and whether they believed the technology was a hindrance or help. Table 5.2 below illustrates the responses by the interviewees.

Table 5.2: Impact of AM on the medical prosthetic industry

#	Interviewees:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Total
	Disruptive	✖	✖	✖		✖		✖	✖		✖	✖		✖	✖	10
	Not disruptive				✖		✖			✖			✖			4
1	Cheaper		✖	✖	✖	✖	✖			✖					✖	7
1	Aesthetics		✖		✖	✖					✖	✖	✖	✖		7
3	Threat				✖	✖	✖								✖	4
3	Just another Tool			✖	✖					✖			✖			4
5	Limited			✖	✖								✖			3
5	Still in its infancy					✖							✖		✖	3
5	Faster							✖	✖				✖			3
8	More functional		✖	✖												2
8	More productive				✖	✖										2
10	Greater customisation				✖											1

5.5.2. Disruptive

Ten out of the 14 candidates interviewed mentioned that they believed AM technology to be disruptive. Below are some of the quotes relating to these answers.

The Prosthetist & Orthotist #1 (5): “I think it is going to be very disruptive”.

The Holding Company Director (7): “So in that sense it is very disruptive and that is why we are careful in terms of how quickly you implement and how quickly you phase in new technology”.

The Academic Coordinator #2 (14): “It is definitely going to disrupt”.

The Anaplastologist (12): “3D printing is going to take everything over. It is going to be fantastic”.

The 3D Printer #1 (10): “AM is very disruptive. It damages the industry, but they had their chance”.

5.5.3. Cheaper

Seven out of the 14 interviewees mentioned that they believed AM technology would be disruptive as a result of its ability to radically reduce cost. Below are some of the quotes relating to these answers.

The Administrator (2): "So as long as the patient is also made aware that this is a 3D printed thing, it is not a certified thing, yes your main… What is the word? The biggest plus on getting them is obviously it is cheaper as well, and it is functional to a degree".

The Non-Profit MD (3): "What RoboHand did was it brought forward a new thinking, or type of thinking, to the market and made it very cost effective".

The Non-Profit MD (3): "So it is becoming a lot more effective because of the way technology has moved in the last five to 10 years, it is becoming affordable, where you could probably get a micro-processor 3D printed hand for two or three thousand dollars, which is cheap compared to what has been happening before".

The Prosthetist & Orthotist #1 (5): "The guys can do the socket for much cheaper and so forth".

The Academic Coordinator #1 (6): "You know so 3D printing is not going to revolutionise speed or anything, it is just going to make it a lot more easy to duplicate a type of prosthesis with adjustability if you want it quite quickly. And possibly the cost will come down because you are using less materials".

The Academic Coordinator #2 (14): "So 3D printing is not going to make the process faster. What it is going to do is it is going to cost less and it is going to… that is actually all".

5.5.4. Aesthetics

Seven out of the 14 interviewees mentioned that they believed AM technology would be particularly disruptive to the aesthetics of prosthetics. Below are the quotes relating to some of these answers.

The Administrator (2): "I think the 3D printing might add to the industry because you can make it look a lot nicer".

The International Manufacturer (4): "Globally we have a few contracts with 3D manufacturers, specifically on the cosmetic side of things, non-weight bearing, so we have some really nice cosmetic covers that people can have 3D printed, and that is happening".

The International Manufacturer (4): "So we see 3D printing at this stage more in having an impact on the cosmetics – that is where we see it at the moment".

The Prosthetist & Orthotist #1 (5): "In SA I must tell you 90% of the guys walking in here want a cosmetic fun cover, or something cover".

The 3D Printer #2 (10): "That is what they want, they want Robocop legs. They don't want a leg that looks like a leg anymore".

The Academic Coordinator #2 (14): "And it is also a personal thing. Some don't want it to be noticed. If you do the ankle it must be exactly the same as the other ankle otherwise they are not happy so your cosmetics must be very good. Some it is their party trick. They want to use it as their party… it is their attention… it is their claim to fame".

5.5.5. Just Another Tool

Four out of the 14 interviewees mentioned that they believed AM technology to be disruptive. Nearly all the interviewees who felt that the technology was not disruptive, said that it was simply another tool which individuals like prosthetists could use. Below are some of the quotes relating to these answers.

The International Manufacturer (4): "It is just a different tool. Whether that is more expensive than current ways or more effective than current ways we don't know at this stage; we know it has taken us a long time to integrate a carver into our current business portfolio, so it is early days for printing for us, but we are in the process of understanding it and seeing what implications it will have for our business".

The Prosthetist & Orthotist #2 (9): “So I don’t see 3D printing as scanning, converting, printing the final prosthesis. I see it as a step within the process to make the process quicker”.

The Prosthetist & Orthotist #2 (9): “You see why I really see it at this stage more as a useful tool for somewhere in the process”.

*The Anaplastologist #2 (13): “*So eventually with 3D we will get to that point but then like you say you get people who print out the positives and you get people who print out the negative. So I have seen both – and they both work really well”.

5.6. Research Question Two

What impact does Additive Manufacturing have on the economics of the medical prosthetic industry?

5.6.1. Introduction

Research Question Two was posed to try and reveal the current and future impact that Additive Manufacturing technology may have on the economics of the medical prosthetic industry. The aim of this research question was to gain an understanding, from the interviewees of how disruptive they believed Additive Manufacturing technology would be on elements such as the import and export rate, and in what areas that would most likely be. Table 5.3 below, illustrates the responses by the interviewees.

Table 5.3: Impact of AM on the economics of the medical prosthetic industry

Rank	Type of Response	Frequency
1	It won't change much or anything	6
2	Lower end of the market	4
2	Big manufacturers will simply adapt	4
2	Still cheaper in China	4
5	It will take a while to have any real impact	3
5	AM will force the industry towards forward integration	3
7	Education is a bigger driver of this change than AM tech	2
8	AM in SA will bring spill over benefits	1
8	AM will affect local economics, particularly our reliance on overseas production	1

5.6.2. It Won't Change Much Or Anything

Four of the interviewees mentioned six times that they believed AM technology would not be particularly disruptive with regards to the economics of medical prosthetic industry. Below are the quotes relating to some of these answers.

The International Manufacturer (4): “It won’t. It’s that simple”.

The International Manufacturer (4): “At this stage I think we are a long way away from having 3D printing being that disruptive. Because you need a certain value; 3D printing is not quick. We can do probably ten on our carver instead of one on the 3D printing. So you have a problem of time there”.

Prosthetist & Orthotist #1 (5): “So I don’t think it is going to have such a massive impact”.

The Academic Coordinator #1 (6): “I don’t think it will be disruptive”.

The Academic Coordinator #1 (6): “No, look in terms of components it wouldn’t be worth trying to manufacture components via 3D printing, unless you could 3D print components and have them locally manufactured”.

The Academic Coordinator #2 (14): “No change. The 3D printing is not going to change that.”

5.6.3. Lower End of the Market

Four of the interviewees each mentioned that they believed AM technology would be particularly disruptive to the lower end of the market with regards to the economics of the medical prosthetic industry. Below are the quotes relating to some of these answers.

Prosthetist & Orthotist #1 (5): “Your lower end patient, patients that haven’t got a job, comes out of rural areas, that is definitely somewhere where they can incorporate this and it’s going to be of big benefit I think.”

The 3D printer #2 (11): "If your average person could lose a leg and, after they have finished being terribly depressed, can get up and go – alright, what can I do about this, they don't go to the doctor and the doctor says it is going to be about R530 000 and they go what! And then go home and cry some more.

"If you can get up and go – what colour would I like my leg in?

And go down the road or go to a friend, go and look on Thingiverse, go look on a catalogue, go and get the leg, send him your measurements and have it as easy as getting anything else".

The Local Manufacturer (13): "That patient that [RoboHand] is helping is most probably a patient that you are never going to find in the formal orthotic/prosthetic section, because it is guys who come from far rural areas, that cannot afford anything better than that. So anyway he is not going to take any business away from you, why not leave him to help the poor people?"

5.7. Research Question Three

What impact does Additive Manufacturing have on the management of the medical prosthetic industry?

5.7.1. Introduction

Research Question Three sought to identify the current and future impact that Additive Manufacturing technology may have on the management of the medical prosthetic industry. The aim of this research question was to gain an understanding, from the interviewees, of how disruptive they believed Additive Manufacturing technology would be on elements such as the adoption of technology by management, and their willingness or reluctance to integrate new technology, specifically Additive Manufacturing, into the organisation. Table 5.4 below illustrates the responses by the interviewees.

Table 5.4: Impact of AM on management of the medical prosthetic industry

Rank	Type of Response	Frequency
1	**AM technology adoption issues:**	**21**
	Adoption is scary	5
	Adoption costs	3
	Takes a long time	3
	AM is not an integrated system	2
	Prosthetists are averse to new technology	2
	Proving the tech	2
	Too complex	2
	Prosthetists don't see the benefits	1
	Societal issue	1
2	**AM technology adoption incentives**	**5**
	First mover advantage	3
	Financial benefit	1
	Easier than conventional manufacturing	1
3	**Prosthetics is a small, niche industry with low R&D**	**2**

Research Question Three demonstrated two major themes regarding the adoption of AM technology by management, and their efforts to integrate it into their organisations. These are shown above in Table 5.4.

5.7.2. AM Technology Adoption Issues

The seven interviewees mentioned 21 times that they believed AM technology would not be particularly disruptive with regards to the management of medical prosthetic industry because of certain issues, ranging from the complexity of the technology, to the cost of implementing it effectively. Below are the quotes relating to some of these answers.

The International Manufacturer (4): "A lot of our overseas managers are technical in their original training, so yes, it is not just business models that will change for them".

Prosthetist & Orthotist #1 (5): "3D printing at this stage I think is scaring some people".

3D Printer #1 (10): "Managers have a fear of persecution when adopting new technology like Additive Manufacturing".

The Holding Company GM (8): "So affordability when you have got new technology tests can be quite expensive, but the fantastic thing about new technology is you find the cost goes up. So the minute that happens then you are going to start seeing that impact and once that happens it is also important to be a forerunner and a fore player in the industry".

Prosthetist & Orthotist #2 (9): "Then you are going to make 3D specifics for the industry, make a printer that can print it in a certain medium and it will be integrated so everything works together – the scanner works with the software, the software works with the printer and you don't have to figure out. Because that is usually the challenge, the prosthetist is not trained, they are trained on a medical basis, and then if the software technology is too complicated we can't use it or it is difficult or we shy away from it".

5.7.3. AM Technology Adoption Incentives

Five respondents mentioned five times that they believed AM technology would be particularly disruptive to the management of medical prosthetic industry because of certain incentives that the technology offered, including financial, manufacturing and strategic benefits. Below are the quotes relating to some of these answers.

The International Manufacturer (4): "Look I mean I can't talk for others, but what I can say is that we all follow the money".

3D Printer #2 (11): "The reason rapid prototyping I think is really the thing right now, it's the in process, because it is reasonably easy to pick up".

The Holding Company GM (8): "So it is almost as if you are saying I anticipate disruption, but let me plan strategically so that I am not one of the ones that lag behind because it might just put you out of business".

5.8. Research Question Four

What impact does Additive Manufacturing have on the production of the medical prosthetic industry?

5.8.1. Introduction

Research Question Four attempted to identify the current and future impact that Additive Manufacturing technology may have on manufacturing in the medical prosthetic industry. The aim of this research question was to gain an understanding from the interviewees of how disruptive they believed Additive Manufacturing technology would be on elements such as the time, cost and labour involved in the prosthetic manufacturing process. Table 5.5 below, illustrates the responses by the interviewees.

Table 5.5: Impact of AM on the production of the medical prosthetic industry

Rank	Type of Response	Frequency
1	**A lack of adequate…seriously hinders the technology**	**76**
	Materials	24
	Complexity	20
	Strength	14
	Cost saving benefit	10
	Speed	3
	Quality	3
	Intuitiveness	1
	Accuracy	1
2	**Future potential**	**19**
3	**AM is ideally suited for sockets and cosmetics**	**16**
4	**AM cannot disrupt the technical understanding of prosthetists**	**15**
5	**AM is disruptive because of its…**	**15**
	Time saving benefits	4
	Customisation benefits	2
	Ability to free up prosthetists	2
	Design freedom benefits	1
	Duplication benefits	1
	Accuracy	1
	Medical grade material	1
	Cost saving benefits	1
	Efficiency benefits	1
	All-in-one solution characteristics	1
6	**AM is just another tool in the prosthetic process**	**10**

Nine of the interviewees mentioned 76 times that they believed AM technology would not be particularly disruptive to the manufacturing of medical prosthetic industry because of certain inadequacies of the technology. The most prolific of these inadequacies related to materials, complexity and strength. Many interviewees identified AM as specifically beneficial and disruptive to the production of medical prosthetics sockets and aesthetic elements such as covers and veneers. Six respondents mentioned 15 times that they believed AM technology would be particularly disruptive to manufacturing in the medical prosthetic industry because of certain benefits inherent in the technology. Five interviewees mentioned 19 times that they believed AM technology would be particularly disruptive to the future of the medical prosthetic industry. Below are the quotes relating to some of these answers.

5.8.2. A lack of adequate…seriously hinders the technology

Prosthetist & Orthotist #2 (9): “So it does have its applications in terms of say printing mechanical components, but again the material used has limitations in terms of colour, texture, and so forth. So there are a lot of limitations”.

The International Manufacturer (4): “When we look at the application of 3D printing to a lot of those components, yes you can 3D print individual components, but you would need to go into some very strong materials before you start replacing the knee joints and other elements”.

The Researcher (1): “But the stuff they are manufacturing at the moment are all toys, they are not really proper prosthetics. They are not proper active hardened things. They are all toys”.

The Administrator (2): “All of these are carbon fibre, so this is your prosthetic and it is made with carbon fibre because its strong, it bounces back and it does what it needs to do, where your 3D printer is just a plastic composite, which if you start off with it, I promise you all it is going to do is crack”!

Prosthetist & Orthotist #2 (9): “The application at this stage is very, very basic, you know if you look at those printed hands, they are really only for a very specific group of patients, in other words people who have lost only the fingers, and it is quite expensive”.

5.8.3. Future potential

The Researcher (1): “At the moment, AM technology is not printing that much prosthetically, no. But having said that, in two years’ time there is a good possibility that they will! Because I believe this manufacturing is really at the beginning of Additive Manufacturing”.

The 3D Printer #1: "The printers get cheaper, things will become more available, faster, better, more".

The Anaplastologist (12): "It is! I mean 3D printing is going to change your lives eventually".

The Anaplastologist (12): "I think we just need somebody to write us that code, that program to sort it out. And that will make prosthetics a lot cheaper, and readily more available, then we can really go up in Africa and just print legs for everybody".

The International Manufacturer (4): "So with 3D I think you are going to have a much shorter cycle and if anybody really invests in the area then maybe a five year horizon. But my challenge to you is commercial viability".

The Holding Company Director (7): "It will speed it up, it will definitely speed it up, production will happen much more quicker, we will be able to have much more output and again instead of having to do manual checks of your bill of materials it will be automatic almost. It will just make things so much easier."

5.9. Research Question Five

What impact does Additive Manufacturing have on the marketing of the medical prosthetic industry?

5.9.1. Introduction

Research Question Five was intended to ascertain the current and future impact that Additive Manufacturing technology may have on the marketing of the medical prosthetic industry. The aim of this research question was to gain an understanding, from the interviewees of how disruptive they believed Additive Manufacturing technology would be on elements such as the regulations and marketing practices and techniques involved in the prosthetic manufacturing process. Table 5.6 below illustrates the responses by the interviewees.

Table 5.6: Impact of AM on marketing of the medical prosthetic industry

Rank	Type of Response	Frequency
1	**No impact:**	**15**
	Regulatory restrictions	7
	Lack of awareness and understanding among the public	3
	Still going to be based on referrals and conferences	5
2	**Impact:**	**9**
	Internet and social media becomes more involved	5
	AM brings the big manufacturers closer to the customer	1
	AM will bypass current regulations	1
	AM makes prosthetics no longer about brand but about function and process	1
	AM is a good gimmick	1

The majority of interviewees' responses demonstrated a belief that there would be little, if any, impact on the marketing practices of the medical prosthetic industry as a result of AM technology. The top reason that they felt there would be little disruption was because of the strict statutes and rules imposed on the industry by the regulatory bodies, HPCSA and SAOPA. Below are the quotes relating to some of these answers given by the interviewees.

5.9.2. No impact

The Local Manufacturer (13): "Look there is not much marketing you can do as an orthotist/prosthetist because you are very restricted by the Health Council in advertising".

The Researcher (1): "Well it would be exactly the same, I mean the marketing wouldn't change. We wouldn't walk around advertising. Most people don't just randomly come off the street to a prosthetist. You initially have to be amputated, you initially have to go to the doctor, you would have initially got an orthotist that that doctor prefers to use, and if marketing says I can make a socket for a wider range of people, I would use that to my benefit as a doctor. I would say 'we have got this guy who is making a socket and we are doing research on it' and I would explain it to him. I would use that like a benefit".

Prosthetist & Orthotist #2 (9): "In terms of my marketing I bought a practice that was established 36 years ago, and obviously I have a network of referral people that I obviously look after, people that get injured and have accidents – those people know me and I give good service and I write reports to them and I look after the network".

5.9.3. Impact

The Anaplastologist (12): "I think it would attract more people if they know that you are using 3D printing because they love the gimmick and the change and the something new. As orthotists, prosthetists, we are not really allowed to market ourselves that much".

The International Manufacturer (4): "In our industry every technology that comes brings us closer and closer to the consumer".

The International Manufacturer (4): "So then your websites become more relevant, your social media becomes more relevant, but your actual interaction with the person becomes higher – physical interaction: people think you can do everything on the internet – you can't – even a scan needs to be a scan of a certain element, still needs to be measured properly with your hands, to be felt, to understand. So I think all of these will bring us closer to the consumer and it will flatten China".

Prosthetist & Orthotist #1 (5): "I think if any company can start doing your 3D printing for you it is going to become commercialised and they will be able to do advertising and in magazines and stuff. There are guys who already do that. But advertising and all that type of stuff".

5.10. Research Question Six

What impact does Additive Manufacturing have on the business models and policies of the medical prosthetic industry?

5.10.1. Introduction

Research Question Six focused on determining the current and future impact that Additive Manufacturing technology may have on the business models of the medical prosthetic industry. The aim of this research question was to gain an understanding from the interviewees of how disruptive they believed Additive Manufacturing technology would be on elements such as organisational structure and value creation. Table 5.7 below, illustrates the responses by the interviewees.

Table 5.7: Impact of AM on the business models of the medical prosthetic industry

Rank	Type of Response	Frequency
1	**Changes:**	**15**
	More time, productivity and efficiency	5
	Drive focus towards the lower end of the market	3
	Push large international manufacturers towards central fabrication	2
	Bigger impact on the smaller short liners	1
	Shift towards cloud based services	2
	Shift for large manufacturers as suppliers of designs	1
	Focus on updates rather than holding on to patents	1
2	**No changes:**	**4**
	No change	2
	Just another tool	1
	Unclear	1

It was clear from a large number of interviewees' responses that many of them believed that the technology would disrupt many of the traditional business models that the industry had in place. Many felt that speed, productivity and efficiencies in business models would be improved. Others had interesting ideas on what the new business models would look like, including a cloud-based model where large manufacturers would rent out CAD files to smaller firms or even individuals to utilise on their own printers. Others posited the reverse, where the large manufacturers would become central fabrication facilities where smaller firms or even individuals would send through designs to be manufactured. Below are the quotes relating to some of these answers given by the interviewees.

5.10.2. More time, productivity & efficiency

Prosthetist & Orthotist #1 (5): "I think it is going to change much – you are going to have a quicker turnaround time obviously".

The Academic Coordinator #1 (6): "In terms of 3D printing what it would do is it would speed up the process of delivery in the sense that you could scan your patient's residual limb, do your rectification, and build up on a CAD program of sorts, input it in to your 3D printer and then put out your prosthetic socket. So you are doing away with three or four steps of the process".

5.10.3. Push large international manufacturers towards central fabrication

The International Manufacturer (4): "So we haven't gone that route but these types of technology may force us down that route and into central fabrication".

5.10.4. Shift towards cloud-based services

The Researcher (1): "So what is going to happen is I think that these bigger companies kind of save their business models, save what they have got. What I think they should start thinking about is making the printable files available eventually on a cloud system that you can then… you know I was talking about this whole cloud software development thing, that they would then provide say the SPI files or an optic file for let's say a left foot okay, because they have been doing the designs for it, and then they have also done designs on knees. So you don't have to go and design a whole new knee, you have already got the designs for it".

5.10.5. Push towards forward integration

The International Manufacturer (4): "Globally the trend is for suppliers to forward integrate because it is a small market, which as it becomes more and more competitive they forward integrate, because it is the only way you can go. We have resisted the challenge in SA because it is a massive expanse and we already have an existing high level of private practitioners which covers the country".

5.11. Research Question Seven

What impact does Additive Manufacturing have on the business strategies of the medical prosthetic industry?

5.11.1. Introduction

Research Question Seven attempted to establish what the current and future impact that Additive Manufacturing technology may have on the business strategies of the medical prosthetic industry. The aim of this research question was to gain an understanding from the interviewees of how disruptive they believed Additive Manufacturing technology would be on elements such as the management of key partnerships, particularly with reference to suppliers and other business affiliates. Table 5.8 below illustrates the responses by the interviewees.

Table 5.8: Impact of AM on the business strategies of the medical prosthetic industry

Rank	Type of Response	Frequency
1	**Impact:**	**20**
	Push towards collaboration	10
	Importance of being the first-mover	3
	More and new suppliers	3
	AM comes a cost to human labour	2
	Supplier prices to increase	1
	Universities to integrate medical and engineering curriculums	1
2	**No impact:**	**3**
	No change	3

Given the interviewees' responses it was evident that a push towards collaboration was the predominant view of how AM technology would affect business strategy in the industry moving forward. There was also little thought shown towards AM not impacting the business strategies of the industry. It is interesting to note the identification, especially in South Africa as a developing country, that some of the interviewees had identified that AM is likely to lead to job losses. Below are the quotes relating to some of these answers given by the interviewees.

5.11.2. Push towards collaboration

The Researcher (1): "It is still very early days as to whether one could 3D print a socket, but once again you still need the technical expertise and the clinical expertise to design".

The International Manufacturer (4): "So we see 3D printing at this stage more in having an impact on the socket manufacturing process. That's… socket and orthotics, that areas, cosmetics – that is where we see it at the moment. But it doesn't solve a complete problem because you still need people who know what they are doing to utilise the tool".

Prosthetist & Orthotist #1 (5): "The thing is AM printers don't know how to shape a leg – I do – but they have got the expertise to do that, and I believe it's quite a course to start

3D printing and stuff, it is not just something you buy the printer and you start 3D printing".

The Anaplastologist (12): "I would love there to be more regulation, and I would love the HPCSA to be more active in this. But not in an aggressive way to say 'listen this is our situation and prosthetics isn't just a medical thing anymore'. It's not. And we need to work together, and we need to find that midway otherwise we are going to lose it all".

5.11.3. No change

The Administrator (2): "I don't think we will change to 3D printing, I don't".

The Local Manufacturer (13): "I don't think it will change. All I can see is you are going to have a bigger choice of products available. That is about the change I would see. The product range will get wider".

5.12. Research Question Eight

What impact does Additive Manufacturing have on the legalisation and regulations of the medical prosthetic industry?

5.12.1. Introduction

Research Question Eight sought to identify what the current and future effects that Additive Manufacturing technology may have on the regulatory and legislative frameworks of the medical prosthetic industry. The aim of this research question was to gain an understanding, from the interviewees, of how disruptive they believed Additive Manufacturing technology would be on elements such as the regulatory bodies like the HPCSA and SAOPA, particularly with reference to intellectual property. Table 5.9 below, illustrates the responses by the interviewees.

Table 5.9: Impact of AM on the regulations of the medical prosthetic industry

Rank	Type of Response	Frequency
1	Need for further certification and enforcement due to the rise of the unqualified creator	36
2	Need for regulations that drive collaboration	10
3	Lack of protection by the regulatory bodies	10

4	AM exacerbates the transfer of IP/designs	5
5	Free exchange of ideas	4

The responses of ten of the interviewees' illustrated the impact that they believed Additive Manufacturing technology would have on the industry. By far the most pressing issue for interviewees was the need for further certification and enforcement by the regulatory bodies. It is useful to remember that the majority of the interviewees have a vested interest in how the medical industry's regulatory bodies deal with the use of AM technology, especially when it comes to the unqualified to create prosthetics. These individuals - unqualified creators - are competition, and so it is natural for the qualified individuals to feel threatened by these newcomers. The leaning towards those operating in the traditional prosthetic industry in those interviewed in this study should also be noted when assessing table 5.9 above and the subsequent quotes below.

5.12.2. Need for further certification & enforcement due to the rise of the unqualified creator

The Administrator (2): "When it comes to be put on to the patient, whatever connection piece there is between the patient's stump and that hand, needs to be custom made. And only an orthotist or prosthetist can do that".

The International Manufacturer (4): "As soon as somebody is doing it for commercial value, and they are making claims to the product it should be regulated. We suffer from a lack of regulations for medical devices in SA".

The International Manufacturer (4): "If they are then obviously it is in contravention of the Healthcare Professionals Council and something needs to be done to either enable it or to regulate it.

Prosthetist & Orthotist #1 (5): "You do get that, people working out of the garage. So ja it is going to become a problem and it is definitely something that is going to be from the beginning they will have to make it… because all the people say it is a grey area".

The Local Manufacturer (13): "I would love there to be more regulation, and I would love the HPC to be more active in this. But not in an aggressive way to say 'listen this is our situation and prosthetics isn't just a medical thing anymore'. It's not. And we need to work together, and we need to find that midway otherwise we are going to lose it all".

5.12.3. AM exacerbates the transfer of IP/designs

The 3D Printer #2 (11): "What if everyone could do that, I just thought I would post it on…and if people look for it they can download it and find a friend who has a 3D printer".

The Anaplastologist (13): "Obviously 3D printing is going to make it easier because what stops you from scanning in this prosthetic foot and just printing it? I think copyright and intellectual property should be started managing differently, because you can't stop it – there is no way".

The Anaplastologist (13): "Everything is changing and that has to change. You can't go 'Well this is my idea'. They are going to take it anyway and you are just going to get angry and precious about your work or foot at the end of the day. So there has to be some way – either people have done the research and development and they do need money and credibility for that. So I don't know how you would do that".

5.13. Conclusion to Chapter Five

This chapter laid out the data that emerged from the in-depth interviews of 14 candidates in the medical prosthetic and Additive Manufacturing industry. The following chapter will discuss the findings in relation to previous research made apparent in Chapter Two.

6. CHAPTER SIX: DISCUSSION OF RESULTS

6.1. Introduction

In this chapter the findings of the research presented in the previous chapter are comprehensively discussed in relation to the literature that was reviewed in Chapter Two. This chapter offers insights into the findings as investigated through the in-depth interview questions utilised in this study. The data gained through the interview process answers the eight research questions, collected from the 14 interviewees from two sample groups, namely those in the medical prosthetics industry and those in the Additive Manufacturing industry. From this, the data coding and analysis allowed for the consolidation and refinement of data, producing insights into the nature of the impact of Additive Manufacturing on the medical prosthetic industry.

The research results discussed in this chapter contribute to an improved understanding of the current and future effects of the technology on the industry. The relevance of the results and the existing literature in context with this study are discussed in the next section. Parallels and differences are brought to light, as are points of interest.

6.2. Discussion of Results for Research Question One

What is the impact of the disruptive innovation of Additive Manufacturing technology on the medical prosthetic industry?

6.2.1. Introduction

This question was posed to identify the current and future impact that Additive Manufacturing technology may have on the medical prosthetic industry. The aim of this research question was to gain an understanding from the interviewees of how disruptive they believed Additive Manufacturing technology would be, and in what areas that would most likely be. The question also attempted to assess whether the interviewees felt the industry and themselves felt threatened by the technology, and whether they believed the technology was a hindrance or help. The results of the in-depth interview, data coding and analysis portions of the study illustrated the following results:

6.2.2. Discussion

The data from this particular question demonstrated whether the interviewees felt that AM technology was or would be a disruptive force in the medical prosthetic industry, and why they thought that was so. Table 5.2 displayed the responses of each of the individuals. This is really a two-part question, assessing whether interviewees felt the technology was disruptive or not, and then why they thought the technology was so. Based on the frequency and aggregated counts across the two sample groups of 14 interviewees, the top ranked response to whether the interviewees believed the technology was disruptive was "yes", with over 70% of the respondents being of this opinion. The most predominant reason for why they thought Additive Manufacturing would be disruptive was that it was cheaper, or would be cheaper, and that it had significant applications when it came to the aesthetics of prosthetics.

In the context of the existing literature these assertions support Mohr & Kahn's (2015) proposals that stated that the key areas where Additive Manufacturing technology is likely to be disruptive is in resource efficiency, complexity reduction and product design and prototyping. These are all areas where Mohr & Kahn (2015) believed savings and efficiencies could be found. It also confirms the assertions of Zuniga et al. (2015), who stated that they found Additive Manufacturing printed prosthetics to be significantly cheaper, a fraction of the cost of a conventional prosthetic. Furthermore, this links neatly to Christensen's (2014) definition of a disruptive innovation as an element that is initially inferior in quality and performance, but significantly cheaper.

Aesthetics and the ability to personalise one's prosthetic was another area where many of the interviewees believed Additive Manufacturing would be disruptive. This again supports Mohr & Kahn's (2015) predictions that an area of disruption for AM technology is in mass customisation. Additive Manufacturing technologies' ability to create tailored offerings for each individual is a disruptive force, according to Mohr & Kahn (2015) and the interviewees. This also reinforces Cozmei & Caloian's (2012) proposition that one of the beneficial characteristics of AM technology is the trend towards personalised products, and AM technologies' ability to provide unique, personalised products.

Interestingly, nearly all the interviewees who felt that AM technology was not disruptive believed that it was simply another tool. This assertion is explained by Christensen's (2014) categorisation of innovations. In this case there were the four interviewees who felt that AM was simply a sustaining innovation (Christensen, 2014), an evolution step, an expected improvement within an existing market (Christensen, 2014).

6.2.3. Conclusive findings for Research Question One

The results indicated that the vast majority of interviewees believed that Additive Manufacturing was or would be a disruptive innovation for the medical prosthetic industry. The financial benefits of the technology and its ability to create customised products on a mass scale were the two notable features that made it disruptive. The assertion by many who felt the technology was not disruptive because it was simply another tool for individuals in the industry to use is also interesting and is explained by Christensen (2014) as a sustaining innovation, rather than a disruptive innovation. Given that it was one of the introductory and very high level questions posed to the interviewees, it is important to reserve judgement on whether Additive Manufacturing technology is a disruptive force in the medical prosthetic industry. A deeper and more thorough assessment of each of the main drivers, as established in Chapter 1, must be established. These will be introduced in the following sections. Table 6.1 presents the disruptiveness of the technology, according to each section, with the most significant factors represented. The frequency and aggregation of these most dominant factors will be collated, and will ultimately result in a determination of the overall disruptiveness of the technology, as well as a disruptiveness score per driver.

Table 6.1: AM as a Disruptive Innovation – RQ1: Disruptive

Industry Drivers	Disruptive	Economy	Management	Production	Marketing	Business Models	Business Strategy	Regulations	Overall Disruptiveness
Dominant Factors	“Cheaper” 7								
	“Aesthetics” 7								
	“Just another Tool” 4								

Disruptive	14								14
Not Disruptive	4								4

6.3. Discussion of Results for Research Question Two

What impact does Additive Manufacturing have on the economics of the medical prosthetic industry?

6.3.1. Introduction

Research Question Two set out to identify the current and future impact that additive manufacturing technology may have on the economics of the medical prosthetic industry. The aim of this research question was to gain an understanding from the interviewees of how disruptive they believed Additive Manufacturing technology would be on elements such as the import and export rate, and in what areas that would most likely be. The results of the in-depth interview, data coding and analysis portions of the study illustrated the following results.

6.3.2. Discussion

The data from this particular question demonstrated whether the interviewees felt that Additive Manufacturing technology was or would be a disruptive force in the medical prosthetic industry, and why they thought that was so. Table 5.3 in the previous chapter displayed the responses of each of the individuals. The dominant response from interviews was that “It won't change much, or anything”. However this was not a very dominant response with only six mentions of this view. These conjectures about how little, if any, impact Additive Manufacturing will have economically are in contrast to the literature examined. Atzeni & Salmi (2012) for instance indicated that they found Additive Manufacturing, specifically SLS, to be superior to traditional fabrication, particularly from a financial, design and production perspective. *The International*

Manufacturer, by contrast, claimed that, “At this stage I think we are a long way away from having 3D printing being that disruptive, because you need a certain value. 3D printing is not quick. We can do probably ten on our carver instead of one on the 3D printing. So you have a problem of time there”. This type of statement, referring to the superiority of the carver – a traditional subtractive manufacturing device for the production of medical prosthetics – contradicts the assertions of Atzeni and Salmi (2012).

An interesting new aspect, not brought up in the literature at all, is the second ranked factor: “Lower end of the market”. This particular area was raised by both sample groups, including those closest to the issue such as the Local Manufacturer and the Prosthetist & Orthotist #1. This lack of insight into the economic impact of AM technology links to the recent study conducted by Venekamp & Le Fever (2015). The two researchers concluded that there has been a serious lack of research done on the economics of the technology, particularly around its socio-technical and economic implications. The findings of this research, and the lack of readily available and obvious data to support or refute its findings, are evidence of this.

Another dominant aspect that came up in the interviews was that Additive Manufacturing would not have a huge impact on the economics of the industry, particularly because “big manufacturers would simply adapt”. Many interviewees believed that, once Additive Manufacturing technology was sufficiently ubiquitous enough and started to exert pressure on global manufacturers, that they would simply move their manufacturing operations to South Africa. This is in agreement, in some ways, to what the literature says, particularly what the researchers Campbell, Williams, Ivanova & Garrett (2011) said. They said that Additive Manufacturing technology allows for the production and distribution of material products to begin to become more localised as production is brought closer to the consumer. This statement is in agreement with what some of the interviewees proposed, that the manufacturing would indeed be brought closer to the consumer, but what Campbell, Williams, Ivanova & Garrett (2011) did not specifically identify was the ability of large manufacturers to adapt and follow this trend. So while interviewees agree that manufacturing would be pulled away from “manufacturing platforms” like China, or in this case predominantly Germany and Iceland, back to the countries where the products are consumed, and that it may reduce global economic imbalances as export countries’ surpluses are reduced and importing countries’ reliance on imports shrink (Campbell, Williams, Ivanova & Garrett, 2011), they did not agree that this will necessarily have a large impact on the economics of the industry as there was still the possibility that prices for the products may still stay the same as they were internationally, and even remain in their international denomination. Thus any benefits of local production and distribution would be nullified if the threat of currency fluctuation were still a factor.

This change in operations and the seemingly open future of the technology and manufacturers, in many ways, supports the Thiesse et al. (2015) statement that Additive Manufacturing will lead to new business models where there will be a refocusing on the part of manufacturers to whether they will be providers of product development or offer manufacturing resources. However these topics are addressed in more detail in Research Question Six: Business Models.

An interesting factor to note is how some researchers (Campbell, Williams, Ivanova & Garrett, 2011) and interviewees have stated how they believe Additive Manufacturing will or will not disrupt the economics of the industry in relation to the production of medical prosthetics, particularly with reference to the idea of localisation. However some suggested that the digital nature of the technology allowed for an increasingly globalised world at the same time. Thiesse et al. (2015) and Campbell et al. (2011) spoke of online platforms such as Thingiverse and the almost instantaneous transference of digital designs and ideas that these platforms allow. This almost diametrically opposed idea of moving towards a less, and at the same time, more globalised world is supported by some of the interviewees, particularly the *3D Printer #2*, who stated that: “If you can get up and go – what colour would I like my leg in? And go down the road or go to a friend, go and look on Thingiverse, go look on a catalogue, go and get the leg, send him your measurements and have it as easy as getting anything else”. This type of statement and the supporting literature demonstrates the local and global economic characteristics of AM technology, and how AM technology has the potential to subvert and disrupt established economic principles from a macro- as well as micro-economic standpoint.

6.3.3. Conclusive findings for Research Question Two

The results of the interviews indicated that the majority of interviewees felt that AM technology would have little effect on the economics of the medical prosthetic industry. The most prevalent reason for this, given by the interviewees, was that large international manufacturers of medical prosthetics – those who have an overwhelming hold on the South African market – would adapt to the changes brought on by the technology. Interviewees believed that these large manufacturers would establish operations in the country and begin production here. This they believed was not disruptive to the economics of the industry as the financial benefits of the technology were likely to be nullified as manufacturers kept old pricing models and may still be affected by currency fluctuation.

Another area where conclusive findings were made was around the lack of literature surrounding the more social aspects of the economics of the industry, as confessed by Venekamp & Le Fever (2015). The ignorance of literature in the area was confirmed by findings in this question, particularly around the potential impact the technology held for the lower end of the market, among those individuals who are typically unable to afford the high price tag associated with prosthetics, or have to wait on long – sometimes two- to three-year long – waiting lists. The temporal and financial benefits of the technology for such individuals, especially in a developing country such as South Africa, is immense, however the lack of research into the effects leaves the comments by the interviewees of this study uncorroborated and unsupported.

The technology also allows for an almost paradoxical impact on the economics of the medical prosthetic industry, particularly regarding the economic phenomenon of globalisation. On the one hand, the technology appears to be reversing the effects of globalisation by potentially forcing large, international manufacturers to establish local operations in countries they historically exported to. While on the other hand, the digital nature of the technology seems to be proliferating the characteristics of globalisation, allowing for the almost instantaneous transmission of ideas and designs to almost anywhere across the globe.

Contrasting with Research Question One, Research Question Two showed that many of the interviewees did not feel that Additive Manufacturing would be as disruptive to the economic factors associated with the medical prosthetic industry. Table 6.2 presents an updated version of the disruptiveness of the technology, factoring in the medical prosthetic industry driver of the economy.

Table 6.2: AM as a Disruptive Innovation – RQ2: Economy

Industry Drivers	Disruptive	Economy	Management	Production	Marketing	Business Models	Business Strategy	Regulations	Overall Disruptiveness
Dominant Factors	"Cheaper" 7	"No Change" 6							
	"Aesthetics" 7	"Lower end of the market" 4							
	"Just another Tool" 4	"Big manufacturers will simply adapt" 4							
Disruptive	14	4							18
Not Disruptive	4	10							14

6.4. Discussion of Results for Research Question Three

What impact does Additive Manufacturing have on the management of the medical prosthetic industry?

6.4.1. Introduction

Research Question Three sought to identify the current and future impact that Additive Manufacturing technology may have on the management of the medical prosthetic industry. The aim of this research question was to gain an understanding, from the interviewees, of how disruptive they believed Additive Manufacturing technology would be on elements such as the adoption of technology by management, and their willingness or reluctance to integrate new technology, specifically Additive Manufacturing, into the organisation. The results of the in-depth interview, data coding and analysis portions of the study illustrated the following results.

6.4.2. Discussion

The vast majority of responses given in the interviews revealed that Additive Manufacturing technologies' ability to disrupt the management of the medical prosthetic industry was and would be severely hampered by a number of issues. The pitfalls of the adoption of the technology were mentioned 21 times, and ranged from psychological factors such as the fear of the unknown that managers felt in adopting the technology, to financial factors where managers simply believed the technology to be too costly to adopt. Many of these issues are aligned to those identified by Piazza & Alexander (2015).

Piazza & Alexander (2015) identified that cost difficulties would be a barrier to the adoption of the technology. Costs were one of the most discussed issues by the interviewees for why managers would struggle to adopt and implement the technology in their organisations. A bias towards conventional manufacturing is another barrier for the adoption of Additive Manufacturing, according to Piazza & Alexander (2015). This type of barrier can explain the most frequently discussed issue brought to light by the interviewees: "Adoption is scary". This fear is simply a symptom of managers' inability to see the organisational benefits of Additive Manufacturing technology, as well as Additive Manufacturing technology's inability to pose a clear and consistent argument for the overwhelming need for its implementation. The perspective is supported succinctly by *The International Manufacturer* when he said: "A lot of our overseas managers are technical in their original training, so yes, it is not just business models that will change for them…". What *The International Manufacturer* is saying here is that many of the international managers within the medical prosthetic industry are not managers by education, but instead are qualified prosthetists, a view that held true for the vast majority of individuals interviewed in this study. Thus a change in technology utilised by managers would mean an erosion, if not elimination, of some of their technology skills and expertise in the areas they were managing. Thus an aversion to new technology is only natural, as demonstrated by Piazza & Alexander (2015) and the interviewees, like *The International Manufacturer.*

This aversion to the technology because of a skills gap is another barrier discussed by Piazza & Alexander (2015) and the interviewees, with the former alluding to education challenges. This reluctance to adopt the technology they proposed was because of the multidisciplinary nature of the technology, as well as the difficulty for one person to gain an adequate grasp of all these areas. This aversion was discussed by a number of interviewees, particularly in their comments where they said that “Additive Manufacturing is not an integrated system” or it is “Too complex”.

The interviewees’ dominant focus on the manufacturing and production aspects of AM technology links to the Thiesse et al. (2015) statement that many managers typically fall into the trap of neglecting the benefits and effects of the technology that it may have elsewhere in an organisation. This aversion to the complexity and multifaceted nature and benefits of the technology has led many managers, including the ones interviewed in this study, to ignore the intrinsic value creation benefits inherent technology (Thiesse et al., 2015). Thus the holistic considerations of implementing the technology are largely overlooked, resulting in what Mellor, Hao & Zhang (2014) would define as a rough and problematic adoption of the technology by managers.

Some of the Additive Manufacturing technology adoption incentives discussed by the interviewees support the elements brought up by Piazza & Alexander (2015). Realising and focusing on the benefits inherent in the technology is one such benefit discussed by both Thiesse et al. (2015) and Piazza & Alexander (2015) alike. In the interviews some of the interviewees explained that they felt managers could or should not ignore the key benefits of the technology, such as first mover advantage, financial benefit, and that it is easier than conventional manufacturing. The first of these benefits – first mover advantage – was also identified by Piazza & Alexander (2015) as a key factor in the successful implementation of the technology.

Finally, another issue regarding the adoption of the technology pertinent to this study, from a South African medical prosthetic industry perspective, is the perspective by one of the interviewees that “prosthetics is a small, niche industry with low R&D”. *The Prosthetist & Orthotist #2* discussed the fact that within South Africa, the medical prosthetic industry is a very small, niche industry with low R&D. This is a result of a number of factors according to him, including the small market size and the lack of realisable customers; in other words customers who can actually and consistently pay for the prosthetics. However, it must be said that this is simply a symptom of a developed world perspective of the medical prosthetic market in a developing country such as South Africa. A recent study by Phillips, Zingalis, Ritter & Mehta (2015) proposed that of the 650 million individuals worldwide who suffer from a disability, 80% reside in resource-constrained countries such as South Africa. Thus this developed world perspective of the medical prosthetic market is not adequate. This links to the Piazza & Alexander (2015) declaration that successful Additive Manufacturing technology implementation requires managers to change the way they perceive the market, specifically, how they capture value and utilise metrics to perceive innovation, productivity and competiveness from a developing world perspective, contrasted with the traditional developed world mind-set.

6.4.3. Conclusive findings for Research Question Three

The findings from the data of this study revealed that the vast majority of responses given in the interviews revealed that Additive Manufacturing technology's ability to disrupt the management of the medical prosthetic industry was and would be severely hampered by a number of issues. These included psychological concerns such as the fear associated with implementation of the technology, as well as financial concerns, where the technology was considered simply too expensive for managers to adopt.

A lack of perspective on the holistic benefits and implications of Additive Manufacturing technology was also found, as purported by Thiesse et al. (2015) and Piazza & Alexander (2015). A myopic perspective on the technology was shown by a number of interviewees, which confirmed the assertions made in the literature.

Some interviewees mentioned the incentives of the technology discussed in the literature of Piazza & Alexander (2015). However these types of comments and responses came up very infrequently, in contrast to their reservations about the technology.

Lastly, a point of interest and observation was the seemingly inadequate perception of managers within the medical prosthetic industry to address the large and distinctive prosthetic market within developing or resource-constrained countries such as South Africa. Their historical, developed or resource-rich countries outlook on the market had lead some of the interviewees to believe that the market was a small, niche industry with low research and development. Data and statistics gathered by the researcher showed that it is in fact a much larger market, with unique and diverse characteristics; characteristics that require a change in perspective from management within the industry.

Thus it was found in this study that the management of Additive Manufacturing technology, predominantly managers' ability to adopt the technology into their organisations and thus the technologies ability to disrupt, was severely inhibited by a number of factors. Table 6.3 presents an updated version of the disruptiveness of the technology, factoring in the medical prosthetic industry driver of the economy.

Table 6.3: AM as a Disruptive Innovation – RQ3: Management

Industry Drivers	Disruptive	Economy	Management	Production	Marketing	Business Models	Business Strategy	Regulations	Overall Disruptiveness
Dominant Factors	"Cheaper" 7	"No Change" 6	"AM technology adoption issues" 21						
	"Aesthetics" 7	"Lower end of the market" 4	"AM technology adoption incentives" 5						
	"Just Another Tool" 4	"Big manufacturers will simply adapt" 4	"Prosthetics is a small, niche industry with low R&D" 2						
Disruptive	14	4	5						23
Not Disruptive	4	10	23						37

6.5. Discussion of Results for Research Question Four

What impact does Additive Manufacturing have on the production of the medical prosthetic industry?

6.5.1. Introduction

Research Question Four sought to identify the current and future impact that Additive Manufacturing technology may have on the manufacturing sector of the medical prosthetic industry. The aim of this research question was to gain an understanding from the interviewees of how disruptive they believed Additive Manufacturing technology would be when it comes to elements such as the time, cost and labour involved in the prosthetic manufacturing process. The results of the in-depth interview, data coding and analysis portions of the study illustrated the following results.

6.5.2. Discussion

Similar to the question of management above, the findings of this study discovered that a significantly large proportion of the interviewees felt that Additive Manufacturing technology had serious inadequacies when it came to posing a serious disruptive threat to the key medical prosthetic industry drivers of manufacturing.

Interviewees mentioned 76 times that they believed Additive Manufacturing technology would not be particularly disruptive to the manufacturing of medical prosthetic industry because of certain inadequacies of the technology. The inadequacies included things such as materials, complexity, strength, cost, speed, quality, intuitiveness and accuracy. Many of these are in alignment with the issues of the technology brought up by Negi, Dhiman & Sharm (2014). However it should be noted that many of the interviewees were referring to the current state of the technology, in relation to the medical prosthetic manifesting process when they were responding in the matter. This is significant, as will be shown later, because the future potential of the technology – according to the literature and interviewees alike – is greatly positive.

The proposition by the interviewees that there was a lack of adequate materials supports much of what was proposed in the literature. For instance, The Royal Academy of Engineers (2013) stated that the range of materials that AM is able to utilise is still limited, and that processes that are able to print in a multitude of materials almost simultaneously are few. Wong & Hernandez (2012) also go on to further solidify the “material inadequacy” comments of the interviewees by stating that even in cases where multiple material Additive Manufacturing is possible, that this process is particularly time-consuming and requires significant effort. Thus for a comprehensive process, such as prosthetic manufacturing where a number of different materials are required, in an efficient and timely manner, Additive Manufacturing is found wanting.

However, utilising Additive Manufacturing technology to manufacture a single-material aspect of medical prosthetic fabrication such as prosthetic socket can be disruptive, as confirmed by the literature (Syam et al., 2011) and the interviewees interviewed in this study. interviewees mentioned 16 times that Additive Manufacturing was ideally suited for the manufacturing of sockets and cosmetics, reinforcing the claims made by Syam et al. (2011) in their study which stated the beneficial characteristics of Additive Manufacturing technology when it came to this particular and crucial aspect of prosthetic fabrication. The researchers claimed that the Additive Manufacturing process fabricated a socket faster and with less labour; a statement that was backed up by the comments of the interviewees.

Aesthetics and cosmetics, including elements such as personalised and unique prosthetic covers and maxillofacial prosthetics, were another aspect that interviewees believed Additive Manufacturing technology was and would disrupt the industry. This linked succinctly to the claims of Cozmei & Caloian (2012) who stated that Additive Manufacturing technology would be particularly relevant where there is a need to personalise products and there is an opportunity to differentiate by offering unique personalised products. The increasing need and trend towards personalised prosthetic products was made evident throughout many of the interviews. *The Anaplastologist*, the only South African individual qualified to fabricate maxillofacial prosthetics in the country, testified to this fact, as did others including *Prosthetist & Orthotist #2* who felt the complementary scanning technology significantly assisted his productivity when creating a silicon prosthetic, such as a silicon prosthetic ear. All these elements link back to the major disruptive benefit of Additive Manufacturing technology as identified by Negi, Dhiman & Sharm (2014) in the literature.. The ability to quickly and effortlessly reiterate products afforded to developers by Additive Manufacturing technology is a hugely beneficial and disruptive characteristic of the technology, one that significantly undermines the traditional process of fabricating similar prosthetic products. This disruptive aspect of AM technology and the medical prosthetic and medical industry as a whole is reinforced by the prediction of Ventola (2014) that the industry is moving towards a far more personalised approach, and Additive Manufacturing is poised to play an important role in that.

Lastly, as mentioned earlier, while many of the interviewees believed the technology had little, if any, hope of being a disruptive force when it came to the manufacturing of medical prosthetics, many did believe that Additive Manufacturing technology had great future potential, as does the literature. Campbell et al. (2012) for example espoused improvement in costs, speed and materials – the three key areas where Additive Manufacturing was found wanting according to the literature (Negi, Dhiman & Sharm, 2014) and the interviewees. Thus while many are in agreement about the lack of disruption to the status quo that the technology is likely to cause, they are also in agreement that the future of the technology is far more likely to have a disruptive effect on the industry.

6.5.3. Conclusive findings for Research Question Four

As has been demonstrated in the discussion above and the table below, Additive Manufacturing technologies as they stand are not a very disruptive force in the medical prosthetic industry. Currently, the numerous inadequacies of the technology – as stated in the literature and confirmed by the responses of the interviewees in the in-depth interviews of this study – revealed it to be severely lacking in areas such as materials, complexity and strength. Thus presently, it is definitely not a disruptive technology for the manufacturing of the industry. However the future impact of the technology, as costs fall, speed improves and material develop, will in all likelihood mean that it will become an incredibly disruptive technology to the manufacturing of medical prosthetics. This outlook on the technology is held not only by many of the interviewees interviewed in this study, but also by the authors reviewed in the literature (Campbell et al., 2012; Ventola, 2014). Table 6.4 presents an updated version of the disruptiveness of the technology, factoring in the medical prosthetic industry drivers of manufacturing.

Table 6.4: AM as a Disruptive Innovation – RQ4: Production

Industry Drivers	Disruptive	Economy	Management	Production	Marketing	Business Models	Business Strategy	Regulations	Overall Disruptiveness
Dominant Factors	"Cheaper" 7	"No Change" 6	"AM technology adoption issues" 21	"A lack of adequate… seriously hinders the technology" 76					
	"Aesthetics" 7	"Lower end of the market" 4	"AM technology adoption incentives" 5	"Future potential" 19					
	"Just Another Tool" 4	"Big manufacturers will simply adapt" 4	"Prosthetics is a small, niche industry with low R&D" 2	"AM is ideally suited for sockets & cosmetics" 16					
Disruptive	14	4	5	35					58

Not Disruptive	**4**	**10**	**23**	**76**					**113**

6.6. Discussion of Results for Research Question Five

What impact does Additive Manufacturing have on the marketing of the medical prosthetic industry?

6.6.1. Introduction

Research Question Five was intended to ascertain the current and future impact that Additive Manufacturing technology may have on the marketing of the medical prosthetic industry. The aim of this research question was to gain an understanding, from the interviewees of how disruptive they believed Additive Manufacturing technology would be on elements such as the regulations and marketing practices and techniques involved in the prosthetic manufacturing process. The results of the in-depth interview, data coding and analysis portions of the study illustrated the following results.

6.6.2. Discussion

The findings from investigation into this particular key driver of the medical prosthetic industry exposed the feeling that the majority of the interviewees interviewed tended toward Additive Manufacturing having little, if any, impact on the marketing of the medical prosthetic industry. There were three major reasons given by respondents as to why they believed Additive Manufacturing had and would have little impact on the marketing of the industry. These reasons include regulatory restrictions, a lack of awareness and understanding among the public, and reluctance to move away from the traditional marketing approaches of referrals and conferences. These responses are not aligned to the literature. The regulatory restrictions of the industry, as discussed in Chapter 1, appear to have a far stronger and longer-lasting impact on the industry than Additive Manufacturing. These restrictions stifle the co-creation possibilities of Additive Manufacturing technology, as proposed by Conner et al. (2014) and Clark, Calli & Calli (2014). The idea of a website where individuals are able to create their own unique prosthetics from a prescribed selection of designs, similar to the Motorola Moto Maker campaign identified in the study by Kietzman, Pitt & Berthon (2015), is something many of the interviewees felt was not realistic given the restrictions placed on the industry (HPCSA, 2014; SAOPA, 2003).

However, there was also a fair amount of responses by interviewees that suggested that Additive Manufacturing would have an impact on the marketing of the industry. Many of the responses made by the interviewees supported the concepts of co-creation as espoused by Conner et al. (2014) and Clark, Calli & Calli (2014). The notion that Additive Manufacturing technology will drive a deeper need for the creation of sustainable relationships between the customer and the manufacturers is something in the literature of Clark, Calli & Calli (2014) that is reinforced by the presence of responses like that of *The International Manufacturer*: "In our industry every technology that comes brings us closer and closer to the consumer".

A point of interest is the grey area where additive manufacturers such as *AM Printer #1* and *AM Printer #2* stand. As the *Prosthetist & Orthotist #1* demonstrated: "I think if any company can start doing your 3D printing for you it is going to become commercialised and they will be able to do advertising and in magazines and stuff". This is a loophole in the regulations, and an area where AM technology may be able to severely disrupt the traditional status quo of referrals and conferences.

6.6.3. Conclusive findings for Research Question Five

The majority of the data collected in the interviews did not align with the literature. The stringent regulatory marketing restrictions placed on the industry by the HPCSA (2014) and the SAOPA (2003) has lead many of the interviewees to believe that the industry will maintain its traditional marketing practices of referrals and conferences. However, there were some that felt that disruption might occur, that the disruptive concept of co-creation (Conner et al., 2014; Clark, Calli & Calli, 2014) may become a reality. The fact that Additive Manufacturing fabricators potentially sit outside the restrictions of the HPCSA (2014) and the SAOPA (2003) may lead to some increasingly disruptive influences on the marketing of the industry. Table 6.5 presents an updated version of the disruptiveness of the technology, factoring in the medical prosthetic industry driver of marketing.

Table 6.5: AM as a Disruptive Innovation – RQ5: Marketing

Industry Drivers	Disruptive	Economy	Management	Production	Marketing	Business Models	Business Strategy	Regulations	Overall Disruptiveness
Dominant Factors	"Cheaper" 7	"No change" 6	"AM technology adoption issues" 21	"A lack of adequate… seriously hinders the technology" 76	"No Impact" 15				
	"Aesthetics" 7	"Lower end of the market" 4	"AM technology adoption incentives" 5	"Future potential" 19	"Impact" 9				
	"Just another tool" 4	"Big manufacturers will simply adapt" 4	"Prosthetics is a small, niche industry with low R&D" 2	"AM is ideally suited for sockets & cosmetics" 16	-				
Disruptive	14	4	5	35	9				67
Not Disruptive	4	10	23	76	15				128

6.7. Discussion of Results for Research Question Six

What impact does Additive Manufacturing have on the business models of the medical prosthetic industry?

6.7.1. Introduction

Research Question Six focused on determining the current and future impact that Additive Manufacturing technology may have on the business models of the medical prosthetic industry. The aim of this research question was to gain an understanding from the interviewees of how disruptive they believed Additive Manufacturing technology would be on elements such as the organisational structure and value creation. The results of the in-depth interview, data coding and analysis portions of the study illustrated the following results.

6.7.2. Discussion

The findings of the study revealed that almost 80% of responses indicated that Additive Manufacturing was already or would cause disruptive change to the current business models of the medical prosthetic industry. This supports the claims of Piller, Weller & Kleers' (2015), D'Aveni (2013) and Beyer (2014) that the proliferation of Additive Manufacturing will see the creation of new value chains and business models. The most dominant reason that arose in the data for this was that Additive Manufacturing would allow those in the industry to become more productive and efficient, as well as have more time. This also links to the assertions made by Piller, Weller & Kleer (2015) that Additive Manufacturing technology leads to the fabrication of products significantly closer to the user. This statement is almost verbatim to what one of the interviewees responded - *The International Manufacturer*: "In our industry every technology that comes brings us closer and closer to the consumer".

Piller, Weller & Kleer (2015) also asserted that entrenched centralised conventional manufacturing may be a far harder aspect of the business model to disrupt than predicted. This is again true for the data collected in this study, with some interviewees proclaiming that Additive Manufacturing would push large international manufacturers towards central fabrication.

The concept of Economies-of-One purported by Petrick & Simpson (2014) has also found support in the data collected in this study. The characteristics of Economies-of-One as described by Petrick & Simpson (2014) link closely to the remarks made by some of the interviewees. The source of competitive edge coming through end-user customisation is something that is very apparent in this technology according to the candidates interviewed, as discussed in the previous section on marketing and co-creation (Conner et al., 2014; Clark, Calli & Calli, 2014). The move from a distribution layout that focused on high volume output to cover transportation cost, to more direct interactions between local consumers and producers is an assertion made by Petrick & Simpson (2014) that is supported by the findings in this data, specifically in the theme of "Push large international manufacturers towards central fabrication ".

The other characteristics of Economics-of-One (Petrick & Simpson, 2014) also show significant commonality to the responses given by the interviewees. This is particularly relevant when looking at the types of business models that interviewees felt would emerge as a result of Additive Manufacturing technology. One response was that AM technology would see a "shift towards cloud based services". Another stated that there would be "a shift for large manufacturers as suppliers of designs", and finally another proclaimed that "Additive Manufacturing would push medical prosthetic organisations to focus on updates rather than holding on to patents". These types of new business models are characterised by Petrick & Simpson (2014) in their explanation in the literature about the concept of the Economics-of-One. A design system that focuses on creating complex, unique and customised designs is something that is inherent in all of these new business models stated above. The move towards an economic model where nearly all costs become variable as a result of Additive Manufacturing technology, is another area common to all these new business models discussed by the candidates interviewed. In accordance with the statements made by Lindemann et al. (2012), the impact of Additive Manufacturing technology must be investigated on an industry-specific basis, and this has certainly been apparent in the proposed business models.

Less than a quarter of the responses given in the in-depth interviews demonstrated the interviewees' feelings that Additive Manufacturing technology would have little or no effect on the business models of the industry. This in contrast to much of what was discussed in the literature. Some responses indicated a feeling that Additive Manufacturing technology was simply "just another tool" for individuals to use in the industry, a sustaining innovation rather than a disruptive one (Christensen, 2014).

6.7.3. Conclusive findings for Research Question Six

The data in this study surrounding the industry driver of business models, demonstrated a high level of the existence of complementary data and literature. A large proportion of interviewees' responses showed an inclination towards the likelihood of Additive Manufacturing technology having a disruptive impact on the existing business models of the industry. In some cases the shift was for large manufacturers to become central fabrication facilities where designs could be printed, other interviewees espoused the opposite view: large manufacturers become the distributor of designs to be printed by consumers/clients. Another advocated that Additive Manufacturing would push medical prosthetic organisations to focus on updates rather than holding on to patents; a precursor to the issue of intellectual property rights and how best to approach this will be discussed in a following section. These all demonstrated very similar characteristics to what Petrick & Simpson (2014) term Economics-of-One. All these elements, in spite of the limited few that say that technology will have no effect, demonstrate a significant feeling by the interviewees interviewed, and supported by the literature, that Additive Manufacturing technology is and will be a disruptive force in the business models of the medical prosthetic industry. Table 6.6 presents an updated version of the disruptiveness of the technology, factoring in the medical prosthetic industry driver of business models.

Table 6.6: AM as a Disruptive Innovation – RQ6: Business Models

Industry Drivers	Disruptive	Economy	Management	Production	Marketing	Business Models	Business Strategy	Regulations	Overall Disruptiveness
Dominant Factors	"Cheaper" 7	"No Change" 6	"AM technology adoption issues" 21	"A lack of adequate… seriously hinders the technology" 76	"No Impact" 15	"Changes" 15			
	"Aesthetics" 7	"Lower end of the market" 4	"AM technology adoption incentives" 5	"Future potential" 19	"Impact" 9	"No changes" 4			
	"Just Another Tool" 4	"Big manufacturers will simply adapt" 4	"Prosthetics is a small, niche industry with low R&D" 2	"AM is ideally suited for sockets & cosmetics" 16	-	-			
Disruptive	**14**	**4**	**5**	**35**	**9**	**15**			**82**
Not Disruptive	**4**	**10**	**23**	**76**	**15**	**4**			**132**

6.8. Discussion of Results for Research Question Seven

What impact does Additive Manufacturing have on the business strategies of the medical prosthetic industry?

6.8.1. Introduction

Research Question Seven attempted to establish what is the current and future impact that Additive Manufacturing technology may have on the business strategies of the medical prosthetic industry. The aim of this research question was to gain an understanding from the interviewees of how disruptive they believed Additive Manufacturing technology would be on elements such as the management of key partnerships, particularly with reference to suppliers and other business affiliates. The results of the in-depth interview, data coding and analysis portions of the study illustrated the following results.

6.8.2. Discussion

The data collected and analysed in this study showed that over 85% of the interviewees believed Additive Manufacturing technology did and would have an effect on the business strategy of the medical prosthetic industry, while the interviewees responded only three times to say that Additive Manufacturing would have no impact. A large number of the interviewees' responses said that Additive Manufacturing technology would push those in the industry towards collaboration. What they meant by this was that they felt that the current standoff between the individuals using Additive Manufacturing and the prosthetist, as illustrated in the SAOPA document regarding the matter (Slabbert, 2014), was a strategy that was going to change. It was going to change to one of collaboration, where the skills of the prosthetist were combined with the skills of the additive manufacturer. This perspective is in alignment to the literature of Clark, Callı & Callı (2014) who proposed, like the candidates interviewed, that Additive Manufacturing will have a marked impact on the business strategy of those in the industry. It will see the introduction of new intermediaries and a reduction in power of current suppliers (Clark, Callı & Callı, 2014). This is what will result from the interviewees' push towards collaboration: a shift away from the established and traditional supplier, to having new, far more localised fabrication facilities, perhaps even a facility where co-creation is possible, as mentioned in the Marketing section above and in the literature of Clark, Callı & Callı (2014).

This concept of a removal or decentralisation of traditional manufacturers or suppliers as a result of Additive Manufacturing technology is something that is discussed in the literature of Beyer (2014) and Mohr & Kahn (2015). The candidates interviewed also support this idea. This is shown in their comments that a push towards collaboration will see the manufacturing and consumption of medical prosthetic products occurring, if not at the same location, very close to one another. In other words the interviewees felt, as did Beyer (2014) and Mohr & Kahn (2015), that Additive Manufacturing would lead to something that they termed “direct fabrication”.

An interesting point brought up by one of the respondents, namely the *Academic Coordinator #2*, and perhaps a point for further investigation due to the lack of literature on the matter, was how and whether universities were integrating medical and engineering curriculums to best equip those health professional shifting from the academic world to the real world. This blind spot in the industry is supported in the research of Beyer (2014) who stated that one of the five disruptions that would result from Additive Manufacturing technology is the introduction of new capabilities inherent in the technology. Beyer (2014) goes on to state that many executives had not yet factored in and acquired a firm grasp of these new capabilities and it was something they were scrambling to do. This lack of understanding and the clear and obvious benefits of Additive Manufacturing technology (Wong & Hernandez, 2012) is something that one interviewee very close to the matter found is likely to disrupt the academic side of the medical prosthetic industry and may see an overlapping of two faculties that have historically been quite separate in South Africa.

Lastly, some interviewees did feel that Additive Manufacturing would have little, if no effect on the medical prosthetic industry. *The Local Manufacturer* for one said that: “I don’t think it will change. All I can see is you are going to have a bigger choice of products available. That is about the change I would see. The product range will get wider”. This is quite contradictory to the literature however, as Beyer (2014) believes that this broadening of product range is one of the effects that will disrupt the industry, resulting from an evermore efficient and cost-effective Additive Manufacturing technology. Thus while interviewees such as *The Local Manufacturer* believe that Additive Manufacturing technology may not have a disruptive effect on the industry, the literature says that for the very same reason, it will.

6.8.3. Conclusive findings for Research Question Seven

The findings of this research demonstrated that both the interviewees and the literature, for the most part, believed that Additive Manufacturing technology was and would disrupt the medical prosthetic industry. This disruption would likely come in the form of collaboration between the Additive Manufacturing interviewees and the prosthetic interviewees; individuals who have recently been at odds with one another in South Africa (Slabbert, 2014). This would likely lead to the reduction of traditional suppliers and see the rise of more centralised, direct fabrication. A notable factor, not readily taken into consideration in this study or many others for that matter, is the effects that Additive Manufacturing is having on the education system, a significant and important a feature as any in the industry. This study also found that while there were those interviewees that felt that Additive Manufacturing would have no impact on the industry, their reasoning was counterintuitive when contrasted to the literature. Table 6.7 presents an updated version of the disruptiveness of the technology, factoring in the medical prosthetic industry driver of business strategies.

Table 6.7: AM as a Disruptive Innovation – RQ7: Business Strategies

Industry Drivers	Disruptive	Economy	Management	Production	Marketing	Business Models	Business Strategy	Regulations	Overall Disruptiveness
Dominant Factors	"Cheaper" 7	"No Change" 6	"AM technology adoption issues" 21	"A lack of adequate… seriously hinders the technology" 76	"No Impact" 15	"Changes" 15	"Impact" 20		
	"Aesthetics" 7	"Lower end of the market" 4	"AM technology adoption incentives" 5	"Future potential" 19	"Impact" 9	"No changes" 4	"No Impact" 3		
	"Just Another Tool" 4	"Big manufacturers will simply adapt" 4	"Prosthetics are a small, niche industry with low R&D" 2	"AM is ideally suited for sockets & cosmetics" 16	-	-	-		
Disruptive	14	4	5	35	9	15	20		102
Not Disruptive	4	10	23	76	15	4	3		135

6.9. Discussion of Results for Research Question Eight

What impact does Additive Manufacturing have on the regulations of the medical prosthetic industry?

6.9.1. Introduction

Research Question Eight sought to identify what the current and future effects that Additive Manufacturing technology may have on the regulatory and legislative frameworks of the medical prosthetic industry. The aim of this research question was to gain an understanding from the interviewees of how disruptive they believed Additive Manufacturing technology would be on elements such as the regulatory bodies like the HPCSA and SAOPA, particularly with reference to intellectual property. The results of the in-depth interviews, data coding and analysis portions of the study illustrated the following results.

6.9.2. Discussion

The overall results indicated that Additive Manufacturing would have a disruptive impact on the regulations of the medical prosthetic industry. The aggregated results for both sample groups denoted the top ranked impact on the regulations of the medical prosthetic industry was and would be the “need for further certification and enforcement due to the rise of the unqualified creator”. This type of response arose 36 times, 26 more times than any other responses from the interviewees interviewed. This supports the assertions made by Koptyug et al. (2013), who stated that certain efforts should be made by those working in the medical and technological field to help regulatory bodies in modifying out-dated regulations to allow for the opportunities provided by the Additive Manufacturing technologies. This type of statement, as well as the support it receives from the interviewees, helps support the need for collaboration, as demonstrated in the previous to sections. A factor that is further reinforced by one of the second most cited responses, that there is a “need for regulations that drive collaboration”.

Piazza & Alexander (2015) have also proposed similar actions, stating that there is a sizable need for regulations when it comes to Additive Manufacturing. This is a rather worrying aspect of Additive Manufacturing technology in the medical prosthetic industry, because of another frequent response given by the interviewees: a "lack of protection by the regulatory bodies". A lack of protection by the regulatory bodies, namely the HPCSA and the SAOPA, is an extremely worrying factor, especially given the fact that many are concerned about the issue of intellectual property (IP) when it comes to Additive Manufacturing technology, as demonstrated in the literature of Kurfess & Cass (2014), Berman (2012), Thiesse et al. (2015) and Cozmei & Caloian (2012).

IP is an area specifically discussed by the interviewees five times in the interviews. Some even cited the exact online design-sharing platform, Thingiverse, that Thiesse et al. (2015) made reference to in the literature. Similar to what Cozmei & Caloian (2012) purport, the interviewees alluded to the fact that AM technology and platforms such as Thingiverse exacerbate the transfer of IP/designs.

Lastly, if the issue of updating regulations and intellectual property rights to best address the concerns around Additive Manufacturing technology within the medical prosthetic industry it is best, as demonstrated by Piazza & Alexander (2015), that all stakeholders are involved, including government, academia and industry across both Additive Manufacturing and medical prosthetic groups.

6.9.3. Conclusive findings for Research Question Eight

The findings of this research demonstrated a high likelihood of regulations of the medical prosthetic industry being disrupted, if indeed it has not been disrupted already. A need for further certification and enforcement due to the rise of the unqualified creators is an area of great concern shown by the interviewees and is supported by the literature, while a need for inclusion, rather than exclusion, is likely to be the best method of doing this. This is however, made an even harder task if the concerns raised by the interviewees are true and that the regulatory bodies, HPCSA and SAOPA, lack the required regulatory clout. This is especially worrying if the issues around IP, as raised by both the literature and the interviewees, become a reality. The need for these concerns to be addressed is summed up in the statement by *The Anaplastologist*: "Obviously 3D printing is going to make it because what stops you from scanning in this prosthetic foot and just printing it? I think copyright and intellectual property should start to be managed differently, because you can't stop it – there is no way".

Table 6.8: AM as a Disruptive Innovation – RQ8: Regulations

Industry Drivers	Disruptive	Economy	Management	Production	Marketing	Business Models	Business Strategy	Regulations	Overall Disruptiveness
Dominant Factors	"Cheaper" 7	"No Change" 6	"AM technology adoption issues" 21	"A lack of adequate… seriously hinders the technology" 76	"No Impact" 15	"Changes" 15	"Impact" 20	"Unqualified creators" 36	
	"Aesthetics" 7	"Lower end of the market" 4	"AM technology adoption incentives" 5	"Future potential" 19	"Impact" 9	"No changes" 4	"No Impact" 3	Need for regulations that drive collaboration" 10	
	"Just Another Tool" 4	"Big manufacturers will simply adapt" 4	"Prosthetics is a small, niche industry with low R&D" 2	"AM is ideally suited for sockets & cosmetics" 16	-	-	-	"Lack of protection by the regulatory bodies" 10	
Disruptive	**14**	**4**	**5**	**35**	**9**	**15**	**20**	**56**	**158**
Not Disruptive	**4**	**10**	**23**	**76**	**15**	**4**	**3**	**-**	**135**

6.10. Conclusion to Chapter Six

6.10.1. The Model

The model, illustrated in Table 6.9, demonstrates the overall disruptiveness of the technology. It not only illustrates this but also illuminates the disruptiveness of the technology as it pertains to each of the key drivers of the medical prosthetic industry. This model also highlights the dominant factors associated with the driver and the technology and provides an aggregated frequency. In the final two rows of the model are the overall scores for each key driver, of which there were two possible categories: Disruptive and Non Disruptive. The cells with colour left in them represent the higher of the two numbers. The model also offers a ranking of each of the factors. This model is intended to be a comprehensive summary and visual guide to illustrate the disruptiveness of Additive Manufacturing in the medical prosthetic industry. Its aim is to give a succinct and high-level observation of the findings of this study. For more in-depth examination of the conclusions made in this study, readers should go to the relevant section.

6.10.2. Conclusion

As the model shows, Additive Manufacturing technology – as predicted in the initial research question – is and will be a disruptive force within the medical prosthetic industry. However that disruption is not felt in each of the key drivers, and within each driver the intensity of disruption varies. The highest of each of these have been given a coloured font to highlight to superiority. The key drivers of economy, management, manufacturing and marketing have all been found to be areas where Additive Manufacturing technology is not likely to disrupt, with manufacturing being the least likely at the moment. Business models, business strategy and regulations are areas of the industry where the technology is likely to disrupt, with regulations being the area where disruption is most likely according to the in. This has all demonstrated the fact that Additive Manufacturing technology is and is likely to be a disruptive force within the medical prosthetic industry.

The research objectives, as posed by the eight research questions in Chapter 3, have therefore been met and contribute to the current literature of disruptive innovations, Additive Manufacturing and the medical prosthetic industry.

Table 6.9: AM as a Disruptive Innovation – Overall Disruptiveness

Industry Drivers	Disruptive	Economy	Management	Production	Marketing	Business Models	Business Strategy	Regulations	Overall Disruptiveness
Dominant Factors	"Cheaper" 7	"No Change" 6	"AM technology adoption issues" 21	"A lack of adequate… seriously hinders the technology" 76	"No Impact" 15	"Changes" 15	"Impact" 20	"Unqualified creators" 36	
	"Aesthetics" 7	"Lower end of the market" 4	"AM technology adoption incentives" 5	"Future potential" 19	"Impact" 9	"No changes" 4	"No Impact" 3	Need for regulations that drive collaboration" 10	
	"Just Another Tool" 4	"Big manufacturers will simply adapt" 4	"Prosthetics is a small, niche industry with low R&D" 2	"AM is ideally suited for sockets & cosmetics" 16	-	-	-	"Lack of protection by the regulatory bodies" 10	
Disruptive	**14**	**4**	**5**	**35**	**9**	**15**	**20**	**56**	**158**
Ranking per Driver	(8)	(12)	(11)	(3)	(10)	(6)	(5)	(2)	
Not Disruptive	**4**	**10**	**23**	**76**	**15**	**4**	**3**	**-**	**135**
Ranking per Driver	(12)	(9)	(4)	(1)	(6)	(12)	(15)	(16)	

7. CHAPTER SEVEN: CONCLUSION

7.1. Introduction

In the previous chapter the research findings were discussed in the context of existing literature about Additive Manufacturing, the medical prosthetic industry and its key drivers. This chapter will briefly look at the main findings made by this study. After which some recommendations to business will be presented, consideration of the limitations of the research and the implications for future research will then be provided. Lastly, concluding remarks regarding the research report will be presented.

7.2. Findings

7.2.1. Research Question One

What is the impact of the disruptive innovation of Additive Manufacturing technology on the medical prosthetic industry?

This study, combined with the supporting literature, found that many believe that, from a complete high-level perspective, Additive Manufacturing technology will have a disruptive effect on the medical prosthetic industry. The dominant reason for this disruption is that the technology allows for the production of medical prosthetic products that are more cost-effective than existing production methods.

The findings of this study also indicated that Additive Manufacturing will have the biggest disruptive effect on the aesthetic aspects of the industry; this includes things like covers, but also the designs of prosthetics themselves. These assertions are largely supported by the literature (Mohr & Kahn, 2015; Zuniga et al., 2015; Cozmei & Caloian, 2012). However, not everyone felt that Additive Manufacturing technology would be a disruptive force within the industry. The majority of the individuals who felt this way believed that Additive Manufacturing was simply another tool to be used to improve the industry, as Christensen termed it (2014), a sustaining innovation, rather than a disruptive innovation.

7.2.2. Research Question Two

What impact does Additive Manufacturing have on the economics of the medical prosthetic industry?

Through this study, along with the supporting literature, it has been established that Additive Manufacturing technology would have little effect on the economics of the medical prosthetic industry. The most prevalent reason for this given by the interviewees was that large international manufacturers of medical prosthetics – those who have an overwhelming hold on the South African market – would adapt to the changes brought on by the technology.

The findings also revealed the temporal and financial benefits of the technology for individuals, especially in a developing country such as South Africa. However, the lack of literature and research surrounding the more social aspects of the economics of the industry and the impact of Additive Manufacturing technology was another area where conclusive findings were made, as confessed by Venekamp & Le Fever (2015) and this study.

Interestingly, this study uncovered the seemingly paradoxical impact the technology has and may have on the economics of the medical prosthetic industry, particularly regarding the economic phenomenon of globalisation (Thiesse et al., 2015; Campbell et al., 2011).

7.2.3. Research Question Three

What impact does Additive Manufacturing have on the management of the medical prosthetic industry?

The findings from the data of this study revealed that Additive Manufacturing technology's ability to disrupt the management of the medical prosthetic industry was and would be severely hampered by a number of issues. These included:

- Adoption is scary
- Adoption costs
- Takes a long time

- Additive Manufacturing is not an integrated system
- Prosthetists are averse to new technology
- Proving the tech
- Too complex
- Prosthetists don't see the benefits
- Societal issues

A point of interest and observation was raised by the seemingly inadequate vision of managers within the medical prosthetic industry to address the large and distinctive prosthetic market of developing or resource-constrained countries such as South Africa (Phillips et al., 2015).

7.2.4. Research Question Four

What impact does Additive Manufacturing have on the production in the medical prosthetic industry?

Combined with the supporting literature, this study found that Additive Manufacturing technologies, as they stand, are not a very disruptive force in the manufacturing aspect of the medical prosthetic industry. This is mainly due to the numerous inadequacies of the technology listed below:

- Materials
- Complexity
- Strength
- Cost saving benefit
- Speed
- Quality
- Intuitiveness
- Accuracy

However the future impact of the technology, as costs fall, speed improves and material develop, will in all likelihood see it become an incredibly disruptive technology to the manufacturing of medical prosthetics (Campbell et al., 2012; Ventola, 2014).

7.2.5. Research Question Five

What impact does Additive Manufacturing have on the marketing of the medical prosthetic industry?

The key findings of Question Five demonstrated the misalignment of current literature and the stringent regulatory marketing restrictions placed on the industry by the HPCSA (2014) and the SAOPA (2003), with many interviewees believing that the industry will maintain its traditional marketing practices of referrals and conferences. However, there were some that felt that disruption might occur, that the disruptive concept of co-creation (Conner et al., 2014; Clark, Calli & Calli, 2014) may become a reality. The fact that Additive Manufacturing fabricators potentially sit outside the restrictions of the HPCSA (2014) and the SAOPA (2003) may lead to some increasingly disruptive influences on the marketing of the industry.

7.2.6. Research Question Six

What impact does Additive Manufacturing have on the business models and policies of the medical prosthetic industry?

The candidates interviewed displayed a high level of correlation between their statements and the literature. The vast majority of the responses demonstrated an inclination towards Additive Manufacturing technology having a disruptive impact on the existing business models of the industry. In some cases the shift was for large manufacturers to become central fabrication facilities where designs could be printed, while other interviewees espoused the opposite view that large manufacturers will become the distributor of designs to be printed by consumer/clients. Another advocated that Additive Manufacturing would push medical prosthetic organisations to focus on updates rather than holding on to patents.

These all demonstrated very similar characteristics to what Petrick & Simpson (2014) term Economics-of-One. All these elements, in spite of the limited few that say that technology will have no effect, demonstrate a significant feeling by the interviewees interviewed, and supported by the literature, that Additive Manufacturing technology is and will be a disruptive force on the business models of the medical prosthetic industry.

7.2.7. Research Question Seven

What impact does Additive Manufacturing have on the business strategies of the medical prosthetic industry?

The findings of this research demonstrated that both the interviewees and the literature, for the most part, believed that Additive Manufacturing technology was and would disrupt the medical prosthetic industry. This disruption would likely come in the form of collaboration between the Additive Manufacturing interviewees and the prosthetic interviewees; individuals who have recently been at odds with one another of late in South Africa (Slabbert, 2014). This would likely lead to the reduction of traditional suppliers and see the rise of more centralised, direct fabrication.

A notable factor, not readily taken into consideration in this study or many others for that matter, are the effects that Additive Manufacturing is having on the education system, a significant and important a feature as any in the industry. This study also found that while there were those interviewees that felt that Additive Manufacturing would have no impact on the industry, their reasoning was counterintuitive when contrasted to the literature. Figure 6.7 presents an updated version of the disruptiveness of the technology, factoring in the medical prosthetic industry driver of business strategies.

7.2.8. Research Question Eight

What impact does Additive Manufacturing have on the regulations of the medical prosthetic industry?

The findings of this research demonstrated a high likelihood of regulations of the medical prosthetic industry being disrupted, if indeed they have not been already. A need for further certification and enforcement due to the rise of the unqualified creators is an area of great concern shown by the interviewees and supported by the literature, while a need for inclusion, rather than exclusion, is likely to be the best method of doing this. This however, is made even a harder task if the concerns raised by the interviewees are true and that the regulatory bodies of HPCSA and SAOPA lack the required regulatory clout. This is especially worrying if the issues around IP, as raised by both the literature and the interviewees, are to become a reality.

7.2.9. Conclusion to Findings

Based on the aggregated findings of this study in Chapter 5 and the subsequent discussion of these findings in Chapter 6, this research can conclude that Additive Manufacturing technology – as predicted in the initial research question – is and will be a disruptive force within the medical prosthetic industry. However that disruption is not felt in each of the key drivers, and within each driver the intensity of disruption varies. The highest of each of these have been given a coloured font to highlight superiority.

The key drivers of economy, management, manufacturing and marketing have all been found to be areas where Additive Manufacturing technology is not likely to disrupt, with manufacturing being the most unlikely. Business models, business strategy and regulations are areas of the industry where the technology is likely to disrupt, with regulations being the area where disruption is most likely. This has all demonstrated the fact that Additive Manufacturing technology is already, and is likely to continue to be a disruptive force within the medical prosthetic industry.

The model, illustrated in Table 6.9, demonstrates the overall disruptiveness of the technology. It not only illustrates this but also illuminates the disruptiveness of the technology as it pertains to each of the key drivers of the medical prosthetic industry.

7.3. Recommendations for Stakeholders

The interview data and findings from Research Questions One to Eight demonstrated, subsequently the following recommendations focus on themes that arose through the research process.

Additive Manufacturing is disrupting the medical prosthetic Industry. It is thus crucial that the industry takes note of the technology, and this includes those in all aspects of the industry from academia and prosthetists to the international and local manufacturers. It is perhaps the most important time for policy makers and regulatory bodies. They need to begin significant dialogue in anticipation of these challenges to the current global economic standing.

7.3.1. Recommendations for academia

The influence which academia, namely the Tshwane University of Technology (TUT) and the Durban University of Technology (DUT), has on the impact, adoption and utilisation of a technology like Additive Manufacturing is vast. Thus the application and incorporation of the technology into the curriculum is a recommendation of this study, especially given the inevitable disruption of the industry by the technology. These technical universities should also look into the possible overlapping of the medical prosthetic and engineering curricula. This is a strategy that can assist in the cross-pollination of ideas and techniques, allowing for budding prosthetists and engineers to gain a firmer grasp of technologies like AM, and perhaps even create a new one in collaboration with the engineers.

7.3.2. Recommendations for prosthetists

Additive Manufacturing technology has already, and is expected to continue to have a disruptive impact on the industry. Prosthetists should utilise the technology however they feel most comfortable. Given the uncertain nature of the disruption of the technology in areas such as the business models, prosthetists should experiment with the technology, using it as an aid, as a tool, as a means to directly fabricate, all to try to refine and discover the areas where Additive Manufacturing is most effective. Obviously, any experimentation should not come at the expense, in any way, to the patients involved.

This study would recommend prosthetists utilise this technology to attempt to disrupt the current market focus of the industry, which, as has been shown in this study, has been historically built on a model suited to developed countries. The dynamics of a resource-constrained country such as South Africa are unique and present its own set of challenges. The materials, designs, and pricing models – to name but a few – are all things which Additive Manufacturing technology will and can help prosthetists adapt their offering to suit the needs of their patient better.

Collaboration is a final recommendation to prosthetists by this study. Collaboration between a prosthetist and an Additive Manufacturer allows a practice to gain a significant competitive edge through the technical expertise of both individuals.

7.3.3. Recommendations for manufacturers

This study has shown that the technology is not currently a disruptive force in manufacturing, however looking at the future potential and trends of the technology, it the researcher believes that it will be influential going forward.

As a result manufacturers, both local and abroad, need to uncover the best possible ways to utilise the technology in the future. This research revealed some of the new business models that may be best suited to manufacturers, from becoming the central fabrication location where individuals send their designs to be printed to manufacturers, such as Össur and Ottobock, pivoting and becoming the distributors of digital prosthetic designs.

7.3.4. Recommendations for managers

This study would advise that managers utilise the steps put forward by Piazza & Alexander (2015) to create a friendly and hospitable environment that is conducive to the adoption of the technology. Similar to the recommendations about experimentation and business models made above, managers should do the same, and assess the best way to incorporate the technology into their organisation. Not bringing such a disruptive innovation into the fold is likely to lead to dire consequence, as many others have come to find out.

7.3.5. Recommendations for marketers

While the findings of this study illustrated that Additive Manufacturing has and will have little, if any effect on the industry, the ability for others outside the direct influence of the HPCSA and SAOPA guidelines poses a potential prospect or threat for far more effective and dynamic marketing opportunities.

7.3.6. Recommendations for regulatory bodies

As stated in the introduction of this section, the need to begin significant dialogue in anticipation of the challenges posed by Additive Manufacturing to the current global and local economic standing is imperative. Thus regulatory bodies such as the HPCSA and SAOPA need to reassess their guidelines to account for this new technology. They need to drive the industry towards collaboration and not isolation. Those interviewees who have superior knowledge about the technology and its potential, need to be seen as valuable assets to the industry. Their knowledge must be utilised to create a better and more competitive industry within the country and globally.

The same regulatory body must utilise the full weight at its disposal to control and prevent the proliferation of unqualified creators. Those creating prosthetics not in collaboration with qualified medical prosthetists, pose a threat to the wellbeing of individuals who, in all likelihood, are not going to refuse help.

7.4. Limitations of The Research

Reliability was a potential limitation of this research. Reliability refers to the ability of another researcher to conduct the same study, using the same methodology and producing the same results (Saunders, Lewis & Thornhill, 2012). It relates to the consistency of the findings that emerge from the raw data. As already mentioned this research aimed to make use of triangulation that assisted in corroborating or refuting the data collected. This helped mitigate the potential limitation of reliability (Saunders, Lewis & Thornhill, 2012).

The validity of the study was also at risk, internally and externally. Internal validity refers to the extent to which findings can be attributed to interventions rather than any flaws in a researcher's research design (Saunders, Lewis & Thornhill, 2012), while external validity relates to the extent to which findings from a particular study are generalised to all relevant contexts (Saunders, Lewis & Thornhill, 2012). These two limitations were mitigated in this study through triangulation, using multiple sources of data and multiple interview candidates.

Another limitation of this study lies with the research. During in-depth interviews the role of the interviewer is pivotal to the interview process, and in the collection, analysis and interpretation of that data, and thus the outcome of the research is substantially dependant on the ability and experience of the researcher (Saunders, Lewis & Thornhill, 2012). As a means of mitigating this risk a qualified, independent, external individual was used in the transcription process. The researcher endeavoured to be substantially versed in the various literatures of in-depth interviews prior to the commencement of the interview process.

A few of the interviews were also conducted, as a result of circumstances, telephonically. Telephone interviews limited the researcher's ability to gain a visual context for the organisation in which the interviewee operated. Typically, telephone interviews were also established via a fairly bad quality line, and so on numerous occasions both the interviewee and interviewer were either disconnected or unable to communicate effectively with one another. As a result particular time and effort was given to the transcription and refinement of these interview recordings to ensure all information was correctly and succinctly transcribed.

7.5. Suggestions for Future Research

Based on current findings, it would appear necessary and useful to conduct further research into the motivational drivers of prosthetists and additive manufacturers to determine why they undertook these professions and how their values may be linked to one another.

Further study into the impact the HPCSA and SAOPA has on health professionals, and how they affect the introduction of new technologies would also be an area of value.

A final area of interest for further research is the lack of credible data surrounding the patients in need of prosthetics in South Africa and Africa as a whole. Currently there is little, if any, data on these individuals.

Adding to this may be a study on the financial, as well as socio-economic implications of not receiving a prosthetic from a South African perspective, and finally, an exploration of whether having a prosthetic should be considered a human right in South Africa, should be considered.

7.6. Conclusion

This study added depth to the idea that Additive Manufacturing is a disruptive innovation within the industry of medical prosthetics. This study added to literature through the research and provided valuable insights into the depth of current and potential disruption that would affect the industry. Furthermore, this study has contributed to the body of research relating to disruptive innovation and Additive

Manufacturing in the medical prosthetic industry by extending the existing components, constructs and illustrating the interconnectedness thereof. The research findings have contributed to providing a more detailed impression of the effects of the disruptive innovation of Additive Manufacturing on the medical prosthetic industry, with particular reference to the key drivers of the industry.

The results from this research were presented in a model that offers a conceptual framework representation of the impact of the technology across the key drivers of the industry. The research findings have contributed to providing a more detailed impression of the disruptive innovation of Additive Manufacturing on the medical prosthetic industry and provided a progressive view of the disruptive nature of the technology and its impact on the medical prosthetic industry.

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9. APPENDIX

9.1. Exhibit 1: In-Depth Interview Schedule

An exploratory study of the effects of additive manufacturing as a disruptive innovation in the medical prosthetic industry.

1. Depth Interview Questions

PREAMBLE

Hello, my name is ______________________________, and I will be discussing medical prosthetics and additive manufacturing with you.

Please note that I have offered the participant confidentiality and they have chosen to waive/accept this offer.

As part of my MBA studies at the Gordon Institute of Business Science (GIBS), I am conducting a research project aimed at understating the industry effects of additive manufacturing (AM) on the medical prosthetic industry. The research will help assess the impact AM technology will have on different elements along the medical prosthetic industry value chain.

LET THE INTERVIEWEE TELL THEIR STORY AND USE THE QUESTIONS BELOW AS PROBES/REMINDERS

Main Questions	Possible Probes	Possible Clarifying Questions
1. What is your role?	- What industry do you operate in? - What is the size of the organisation? - Is the organisation a multi national corporation (MNC)?	- Can you expand a little on this? - Can you tell me anything else? - Can you give me some examples?

2. What has been your **experience** of additive manufacturing (AM) in the medical prosthetic industry?	- Can you explain how AM technology works?	

3. How **disruptive** do you think AM has and will be on the medical prosthetic industry?	- What is your understanding of a disruptive innovation? - Do you feel threatened by this technology? - Do you think that this will be a hindrance to the medical prosthetic industry?	
4. What do you think are the **economic** implications of AM technology on the medical prosthetic industry?	- Size? - Growth? - Import/Export?	
5. Do you think AM will affect the way organisations are **managed**?	- How do you think it will affect management styles? - Do you consider the technology to be a benefit or a burden? - Have you found it difficult to get top management and other members of staff to adopt the technology? - Does the technology align with long-term visions of the organisation?	

6. How will AM technology change the way medical prosthetics are **manufactured**?	- What technique were you using before? - Do you consider this a benefit or a hindrance? - How have people adapted to AM technology? - How have you found the availability of skilled technicians able to operate the technology?	
7. How do you think AM technology will affect the **marketing** of medical prosthetics?	- How is this different from how you operated before? - Do you consider this technology an advantage or disadvantage? - In your opinion, how do you think this will change going forward?	
8. How will AM technology affect **business models and policies**?	- How has AM altered the organisational structure? - How has AM altered how you did business previously?	
9. How will AM affect	- Do clients, supplier	

business strategies?	and other business affiliates utilise the technology? - Do you see it as a competitive advantage?	
10. What impact will AM have on the **intellectual property legislation and regulations** of the medical prosthetic industry?	- Have you had problems with piracy before? - How do you commonly handle piracy issues?	
11. Are there any other comments or areas of discussion that we have not gone over and that you wish to discuss?		
Conclusion of Interview		

Thank you for taking the time to participate in this research.

9.2. Exhibit 2: Endorsement Notice #1

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.
- FWA 00002567, Approved dd 22 May 2002 and Expires 20 Oct 2016.
- IRB 0000 2235 IORG0001762 Approved dd 22/04/2014 and Expires 22/04/2017.

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UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee

29/10/2015

Endorsement Notice

Ethics Reference No.: Temp2015-02321

Title: An exploratory study of the effects of additive manufacturing as a disruptive innovation in the medical prosthetic industry

Dear David Schilperoort

The **New Application** as supported by documents specified in your cover letter for your research received on the 26/10/2015, was approved, by the Faculty of Health Sciences Research Ethics Committee on the 28/10/2015.

Please note the following about your ethics approval:
- Please remember to use your protocol number (**Temp2015-02321**) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, or monitor the conduct of your research.

Ethics approval is subject to the following:
- The ethics approval is conditional on the receipt of 6 monthly written Progress Reports, and
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

Dr R Sommers; MBChB; MMed (Int); MPharMed.
Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

☎ 012 354 1677   🖷 0866516047   deepeka.behari@up.ac.za   http://www.healthethics-up.co.za
✉ Private Bag X323, Arcadia, 0007 - 31 Bophelo Road, HW Snyman South Building, Level 2, Room 2.33, Gezina, Pretoria

9.3. Exhibit 3: Endorsement Notice #2

Gordon Institute
of Business Science
University of Pretoria

Dear David Schilperoort

Protocol Number: **Temp2015-02286**

Title: **An exploratory study of the effects of additive manufacturing as a disruptive innovation in the medical prosthetic industry**

Please be advised that your application for Ethical Clearance has been approve subject to the following conditions.

Medical ethics is required.

Once you have made this minor amendment and submitted the changes to the Research Coordinator, you will be allowed to continue collecting your data.

We wish you everything of the best for the rest of the project.

Kind Regards,

Adele Bekker

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9.4. Exhibit 4: Declaration for the Storage of Research Data

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Declaration for the storage of research data and / or documents

I, the principal researcher, David Schilperoort of the study, titled, An exploratory study of the effects of additive manufacturing as a disruptive innovation in the medical prosthetic industry will be storing all the research data and / or documents referring to the above-mentioned study in the Business Administration Department at the University of Pretoria-GIBS Library

We understand that the storage of the mentioned data and / or documents must be maintained for a minimum of 15 years from the commencement of this study.

Start date of study: 01/10/2015

Anticipated end date of study: 13/01/2016

Year until which data will be stored: 01/10/2030

Name of Principal Researcher	Signature	Date
David Schilperoort		23/09/2015

Name of Supervisor	Signature	Date
Irfaan Khota		25/09/2015

Name of Head	Signature	Date
Beulah Muller		25.09.2015

9.5. Exhibit 5: Request for Permission to Conduct Research

Gordon Institute of Business Science
University of Pretoria

REQUEST FOR PERMISSION TO CONDUCT RESEARCH

Dear Ms/Mr,

I am a full time MBA Student at the Gordon Institute of Business Science (GIBS), conducting research on the medical prosthetic industry, and am trying to find out more about the disruptive effects of additive manufacturing on the industry.

I am hereby seeking your consent to conduct qualitative interviews within your organisation.

If you have any concerns or queries, please contact my supervisor or myself. Our details are provided below.

Your permission to conduct this study will be greatly appreciated.

Researcher: David Schilperoort

Email: 15384722@mygibs.co.za

Phone: +27 83 553 6126

Supervisor: Irfaan Khota

Email: irfaan@idc.co.za

Phone: +27 11 269 3621

Signature of Approval by Acting Head: ________________________

Print Name in Full: ________________________

Date: ________________

9.6. Exhibit 6: Informed Consent Letter

Informed Consent Letter

I am a Full Time Entrepreneurship MBA Student at the Gordon Institute of Business Science (GIBS), conducting research on the medical prosthetic industry, and am trying to find out more about the disruptive effects of additive manufacturing on the industry.

Our interview is expected to last about an hour, and will help us understand how this relatively new application of this technology will change the landscape of the industry.

Your participation is voluntary and you can withdraw at any time without penalty.

I confirm that confidentiality of all the information and data collected will be maintained throughout this research and the publication of the dissertation and any articles that may follow thereafter. Data representation in all publications will also ensure anonymity and confidentiality.

I also confirm that the digital audio recording of our interview and the transcriptions thereof will also be kept confidential. During the writing of my dissertation I will ensure such confidentiality by restricting access to this data to as few people as possible and specifically only to those who are under legal obligation to keep such data confidential and by destroying the data thereafter and only keeping one copy in the GIBS archives.

If you have any concerns, please contact my supervisor or myself. Our details are provided below.

Researcher: David Schilperoort

Email: 15384722@mygibs.co.za

Phone: +27 83 553 6126

Supervisor: Irfaan Khota

Email: irfaan@idc.co.za

Phone: +27 11 269 36

Signature of Participant: ________________________ Date: ________________

Signature of Researcher: ________________________Date: ________________

2

9.7. Exhibit 7: Participant's Information & Informed Consent Document

Updated 23/09/2014

PICD 2

PARTICIPANT'S INFORMATION & INFORMED CONSENT DOCUMENT

STUDY TITLE: An exploratory study of the effects of additive manufacturing as a disruptive innovation in the medical prosthetic industry

SPONSOR: N/A

Principal Investigators: DAVID SCHILPEROORT

Institution: GORDON INSTITUTE OF BUSINESS SCIENCE

DAYTIME AND AFTER HOURS TELEPHONE NUMBER(S):

Daytime numbers: 083 553 6126

Afterhours: 083 553 6126

DATE AND TIME OF FIRST INFORMED CONSENT DISCUSSION:

				:
dd	**mmm**	**ivy**		**Time**

Dear Participant

Dear Mr. / Mrs. .... date of consent procedure ……../……..../……....

1) INTRODUCTION

Page 1 of 4

Updated 23/09/2014

You are invited to volunteer for a research study. This information leaflet is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this leaflet, do not hesitate to ask the investigator. You should not agree to take part unless you are completely happy about all the procedures involved. In the best interests of your health, it is strongly recommended that you discuss with or inform your personal doctor of your possible participation in this study, wherever possible.

2) THE NATURE AND PURPOSE OF THIS STUDY

You are invited to take part in a research study. The aim of this study is to evaluate the possible impact of additive manufacturing on the medical prosthetic industry. The healthcare sector in South Africa faces major challenges. One of the challenges is access to affordabile, quality and functional medical prosthetics. Thus efforts to simplify processes, reduce costs and improve on quality should be given importance.

3) EXPLANATION OF PROCEDURES TO BE FOLLOWED

This study involves answering some questions with regards to aspects of the medical prosthetic industry and your opinions regarding the impact of the adoption of additive manufacturing technology within the industry.

4) RISK AND DISCOMFORT INVOLVED.

There is no risk and discomfort involved. However you may have the right to defer from answering a particular question(s).

5) POSSIBLE BENEFITS OF THIS STUDY.

It will help us understand the possible impact of additive manufacturing on the medical prosthetic industry.

6) I understand that if I do not want to participate in this study, I will still receive standard treatment for my illness.

7) I may at any time withdraw from this study.

8) HAS THE STUDY RECEIVED ETHICAL APPROVAL?

This Protocol was submitted to the Faculty of Health Sciences Research Ethics Committee, University of Pretoria, telephone numbers 012 3541677 / 012 3541330 and written approval has been granted by that committee. The study has been structured in accordance with the Declaration of Helsinki (last update: October 2013), which deals with the recommendations guiding doctors in biomedical research involving human/subjects. A copy of the Declaration may be obtained from the investigator should you wish to review it.

9) INFORMATION If I have any questions concerning this study, I should contact:

Mr …David Schilperoort…………………………. tel : ……………………..or cell: ……083 553 6126…………………

10) CONFIDENTIALITY

All records obtained whilst in this study will be regarded as confidential. Results will be published or presented in such a fashion that participants remain unidentifiable.

11) CONSENT TO PARTICIPATE IN THIS STUDY.

I have read or had read to me in a language that I understand the above information before signing this consent form. The content and meaning of this information have been explained to me. I have been given opportunity to ask questions and am satisfied that they have been answered satisfactorily. I understand that if I do not participate it will not alter my management in any way. I hereby volunteer to take part in this study.

I have received a signed copy of this informed consent agreement.

....	....
Staff name	Date
....	....
Staff signature	Date
....	....
Investigator's name	Date
....	....
Investigator's signature	Date
....	....

Updated 23/09/2014

Witness name and signature Date

VERBAL PATIENT INFORMED CONSENT (applicable when patients cannot read or write)

I, the undersigned, …………………………………………...…, have read and have explained fully to the patient, named ……………….. and/or his/her relative, the patient information leaflet, which has indicated the nature and purpose of the study in which I have asked the patient to participate. The explanation I have given has mentioned both the possible risks and benefits of the study and the alternative treatments available for his/her illness. The patient indicated that he/she understands that he/she will be free to withdraw from the study at any time for any reason and without jeopardizing his/her treatment.

I hereby certify that the patient has agreed to participate in this study.

Staff Name ______________________
(Please print)

Staff Signature ______________________ Date ______________

Investigator's Name ______________________
(Please print)

Investigator's Signature ______________________ Date ____________

Witness's Name ______________ Witness's Signature __________ Date ____________
(Please print)

(Witness - sign that he/she has witnessed the process of informed consent)

9.8. Exhibit 8: Declaration of Helsinki

Declaration of Helsinki

Preamble

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

General Principles

3. The Declaration of Geneva of the WMA binds the physician with the words, “The health of my patient will be my first consideration,” and the International Code of Medical Ethics declares that, “A physician shall act in the patient's best interest when providing medical care.”

4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

5. Medical progress is based on research that ultimately must include studies involving human subjects.

6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best

proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.

10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

11. Medical research should be conducted in a manner that minimises possible harm to the environment.

12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

13. Groups that are underrepresented in medical research should be provided appropriate access to participation in research.

14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

Risks, Burdens and Benefits

16. In medical practice and in medical research, most interventions involve risks and burdens.

Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.

17. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.

Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.

18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed.

When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

Vulnerable Groups and Individuals

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

All vulnerable groups and individuals should receive specifically considered protection.

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

Scientific Requirements and Research Protocols

21. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

22. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.

The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.

In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.

Research Ethics Committees

23. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

Privacy and Confidentiality

24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

Informed Consent

25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

26. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest,

institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

All medical research subjects should be given the option of being informed about the general outcome and results of the study.

27. When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship.

28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.

29. When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about

participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative. The potential subject's dissent should be respected.

30. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician must seek informed consent from the legally authorised representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorised representative.

31. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient-physician relationship.

32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.

Use of Placebo

33. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:

Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or

Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention

and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.

Extreme care must be taken to avoid abuse of this option.

Post-Trial Provisions

34. In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

Research Registration and Publication and Dissemination of Results

35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and

conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

Unproven Interventions in Clinical Practice

37. In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.

I have read the above and accept it.

…………………………….

Signature of Principle Investigator on this Friday the 09/09/2015

9.9. Exhibit 9: Turnitin Originality Report

An exploratory study of the effects of Additive Manufacturing as a disruptive innovation in the medical prosthetic industry by David Schilperoort

From Test your originality (GIBS Information Center)

- Processed on 11-Jan-2016 17:40 SAST
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Thiesse, Frédéric, Marco Wirth, Hans-Georg Kemper, Michelle Moisa, Dominik Morar, Heiner Lasi, Frank Piller, Peter Buxmann, Letizia Mortara, Simon Ford, and Tim Minshall. "Economic Implications of Additive Manufacturing and the Contribution of MIS", Business & Information Systems Engineering, 2015.

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http://www.hindawi.com/isrn/me/2012/208760/

4
1% match (publications)

Beyer, Christiane. "Strategic Implications of Current Trends in Additive Manufacturing", Journal of Manufacturing Science and Engineering, 2014.

5
< 1% match (Internet from 30-Jun-2015)
http://timreview.ca/article/855

6
< 1% match (Internet from 19-Apr-2015)
http://repository.up.ac.za/bitstream/handle/2263/40181/Harmse_South_2013.pdf?seque

7
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Submitted to University of Technology, Sydney on 2015-08-18

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http://www.tma-sa.com/info-centre/knowledge-base/doc_download/63-the-status-of-post-commencement-finance-for-business-rescue-in-south-africa.html

9
< 1% match (publications)
Cozmei, Cătălina, and Florentin Caloian. "Additive Manufacturing Flickering at the Beginning of Existence", Procedia Economics and Finance, 2012.

10
< 1% match (Internet from 21-Jun-2014)
http://upetd.up.ac.za/thesis/available/etd-03172010-113713/unrestricted/dissertation.pdf

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13
< 1% match (publications)
Bikas, H., P. Stavropoulos, and G. Chryssolouris. "Additive manufacturing methods and modelling approaches: a critical review", The International Journal of Advanced Manufacturing Technology, 2015.

14
< 1% match (publications)
Lecture Notes in Production Engineering, 2015.

15
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http://strategic-technology-roadmapping.com/pdfs/Economies_of_One.pdf

16
< 1% match (student papers from 30-Oct-2015)
Submitted to CITY College, Affiliated Institute of the University of Sheffield on 2015-10-30

17
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Submitted to Coventry University on 2016-01-04

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