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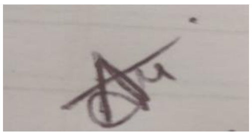


CANDIDATE DECLARATION

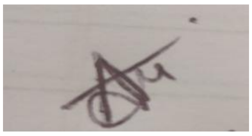
Candidate Name: **Ankushkumar Kailashbhai Patel**

I hereby affirm that the dissertation entitled:

"Examining the Role of 3D Printing in Improving Custom Prosthetic Device Manufacturing in the Indian Pharmaceutical and Medical Device Sector"

Submitted in partial fulfilment of the requirements for the degree of **Master's of Medical Devices Technology & Business at Griffith College Dublin,** represents the outcome of my own independent research and original academic effort.

This work has not been submitted, either in whole or in part, for any other degree or academic qualification at this or any other institution. All ideas, data, and references drawn from other sources have been clearly acknowledged and cited in accordance with academic conventions.



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LIST OF ABBREVIATIONS

Abbreviation	Full Form
3DP	3D Printing
AM	Additive Manufacturing
ANOVA	Analysis of Variance
AT	Assistive Technology
CAD	Computer-Aided Design
CAM	Computer-Aided Manufacturing
CDSCO	Central Drugs Standard Control Organisation
CRR	Central Rehabilitation Register
CT	Computed Tomography
EU MDR	European Union Medical Device Regulation
FDI	Foreign Direct Investment
FDM	Fused Deposition Modelling
GDPR	General Data Protection Regulation
IMDR	Indian Medical Device Rules
ICF	Informed Consent Form
ISO	International Organization for Standardization
MRI	Magnetic Resonance Imaging
NGO	Non-Governmental Organisation
P&O	Prosthetist & Orthotist
PLI	Production-Linked Incentive
PIL	Participant Information Leaflet
PPP	Public-Private Partnership
R&D	Research and Development
RCI	Rehabilitation Council of India
RiHN	Redistributed Manufacturing in Healthcare Network
SLA	Stereolithography
SLS	Selective Laser Sintering
SME	Small and Medium-sized Enterprise
SPSS	Statistical Package for the Social Sciences
TPU	Thermoplastic Polyurethane
VAT	Vat Photopolymerisation
WHO	World Health Organisation
ISPO	International Society for Prosthetics and Orthotics

ABSTRACT

This dissertation explored the role of 3D printing in the enhancement of the manufacturing of custom prosthetic devices in the Indian pharmaceutical and medical device sector. Conventional manufacturing of prosthetics in India is much centralised, labour-intensive, and expensive, and does not cater to the needs of patients, especially in the low-income areas and the rural population. It is on this backdrop that the concept of 3D printing or additive manufacturing is emerging as a disruptive technology with the potential to provide decentralised, patient-specific, and efficient solutions. This study was aimed at exploring the level of adoption, perceived benefits, challenges and enablers of 3D printing in the Indian prosthetic industry.

The study used a survey-based and quantitative research design, which included professionals in pharmaceutical/medical device organisations. Analysis was carried out with a descriptive and inferential approach, like ANOVA, one-way ANOVA, correlation, regression, etc. and focused on the adoption trends, benefits perceived, such as accuracy and faster turnaround and barriers, such as regulatory ambiguity, the control of the supply chain and high capital costs. The results indicated that the level of awareness of 3D printing is high, yet at the organisational level, full-scale adoption is low, with the majority of organisations experimenting or partially adopting the technology. Respondents stated that the main advantages were decentralised delivery and speedier production, although they were less sure about cost-effectiveness and scalability. Key barriers were regulatory uncertainty and insufficient supply of materials that are validated and biocompatible, and the key enablers were viewed to be cooperation between industry and universities and training of the workforce and regulatory transparency.

The present dissertation can be of help to the current body of literature as it puts the global trends of 3D printing in perspective to the environment in India, which depends upon the local challenges that are not reflected in the developed economies. The work presents policy recommendations to policymakers and the industry, such as enhancing regulatory structures and conducting supply chain resilience investments and developing workforce potential. Finally, the study shows that 3D printing has the potential to be transformational, but implementation in India is possible only with the coordinated effort of policies, organisational strategy, and technological preparedness.

Keywords: 3D printing, prosthetics, additive manufacturing, medical devices, India

CHAPTER 1: INTRODUCTION

The Unprecedented growth of the Indian pharmaceutical and medical device industry has reached its peak, but the manufacturing of custom-designed prosthetic parts continues to be laborious, costly, and not patient-friendly, using outdated technology. Although Borthakur (2025) stated that breakthroughs in the field of manufacturing prosthetics have been recognised on a global scale, the Indian prosthetics field has yet to leverage the use of 3D printing fully. This process is more time-efficient, cost-effective, and provides more individualised solutions. The accompanying bottlenecks are high costs of capital investment, regulatory instability, and insufficient supply of skilled manpower (Jayakrishna et al., 2023; Kumar Banga et al., 2021). This study will examine the role of 3D printing in enhancing the operational efficiencies and clinical efficacy of prosthesis production in the Indian pharmaceutical and medical device sector. The guiding research question aims to assess the extent to which 3D printing can enhance custom prosthetics manufacturing in the Indian pharmaceutical and medical devices industries. Thus, the study seeks to provide both small and medium-sized enterprises (SMEs) and policymakers with empirical data that supports decentralised, patient-centred innovation, thereby promoting the establishment of accessible and affordable healthcare in India.

1.1 Research Background and Context

The Indian pharmaceutical and medical device industries have experienced significant enhancements over the last decade, driven by increasing indigenous healthcare needs, government initiatives such as Make in India, and the rising disease burden of non-communicable diseases and traumatic injuries (KPMG, 2023). As per Borthakur et al. (2025), this vast expansion, prosthetic devices that fit patients in low-income or rural areas remains insufficiently accessible. The traditional Indian systems of prosthetic manufacturing are generally centralised, labour-intensive, and rely on ageing technologies that are ill-prepared to meet the diverse anatomical features and user preferences. This scarcity has compelled most people to do without vital equipment or settle on poorly fitted products that do not enhance mobility, comfort or dignity. Thus, this situation highlights the urgent requirements for innovative alternatives.

One major innovation addressing these gaps is 3D printing. As per Onu et al. (2025), promptly in response to these constraints, 3D printing, often referred to as additive manufacturing, has emerged as a disruptive innovation with the ability to transform biomedical practice. In prosthetic research and development, the technology enables the quick production of highly customised devices cost-effectively, perfectly fitting the patient's anatomy. Conversely, Pavan

Kalyan and Kumar (2022) state that 3D printing allows the construction of complex anatomical shapes using digital imaging technology, including MRI and CT scans, thereby improving the accuracy and precision of prosthetic limb, orthotic, and implant designs and providing the benefit of decentralised production. Such a decentralised framework is beneficial to India, where the healthcare infrastructure also differs significantly across regions, and flexibility and localisation of solutions are urgently needed. Thus, 3D printing provides a potential pathway to inclusive healthcare delivery.

However, the adoption of 3D printing in India remains limited. As in India, the penetration of 3D printing is low, even though medical and prosthetic cases demonstrate its widespread global adoption. Infrastructural deficits, regulatory ambiguity, intense entry penalties, and limited technical competencies among small and medium enterprises (SMEs) are significant barriers (Ernst, 2014). However, the potential of this technology to transform the Indian medical device industry is powerful. Pathak (2023) notes that 3D printing allows for the creation on a layer-by-layer basis and uses biocompatible materials to limit waste and enable anatomical customisation, which decreases production costs and reduces lead time because the process does not require synthesis. These potentialities are imperative in combating the limitations associated with conventional, centralised production. Moreover, the use of 3D printing in plastic and reconstructive surgery has proven to be of demonstrated effectiveness in terms of generating anatomically correct models, surgical guides, and patient-specific implants. Thus, despite clear advantages, systemic challenges continue to slow widespread adoption in India.

Moreover, clinical applications further validate its potential. As Zahid et al. (2024) confirm the topicality of 3D printing in the clinical setting by referring to its implementation in plastic and reconstructive surgery, which demonstrates that 3D-printed models and other surgical tools contribute to better preoperative planning, increased design accuracy, and ultimately save surgery time. The same procedural efficiencies can be directly applied to the field of prosthetics, where patient design and fit become key to long-term satisfaction and functionality. The ability to create anatomically accurate, cost-effective prosthetics based on patient imaging data facilitates scalability and an improvement in the quality of care, most notably in remote or underserved centres in India. This helps to suggest that lessons from surgery can inform progress in prosthetic development.

Based on these findings, new conceptual frameworks are emerging. Cornejo et al. (2022) propose the concept of anatomical engineering, a hybrid of biomedical engineering and 3D printing, which enables the reconstruction of complex biological structures. Their study demonstrates that this symbiosis between precision engineering and medical knowledge yields more viable and biocompatible prosthetics, reduces post-surgical complications, and enhances patient satisfaction. Between them, the articles highlight the usefulness of 3D printing in addressing both local, clinical, and systemic gaps in prosthetic fabrication in India. Such frameworks demonstrate the growing academic and clinical recognition of 3D printing's transformative potential.

In conclusion, the rationale for this study is clear. The technology promises decentralised manufacturing, shortened transportation routes as well as delivery, high levels of anatomical accuracy, and lower prices, which are characteristics of high relevance to the Indian scenario. Moreover, it aligns with international trends in personalised medicine and local manufacturing, which have a scalable base for inclusive healthcare. It was thus essential to demand a critical examination of the role of 3D printing in enhancing bespoke prosthetic device construction in India, particularly regarding the feasibility of operations, health effectiveness within the institute, and policy considerations. It seeks not only to define the potential but also to identify the realistic constraints facing manufacturers and healthcare providers. Thus, findings may inform and empower SMEs, policymakers, and support scalable, patient-centred solutions that they gathered information about India as part of its emerging pharmaceutical and medical device modernisation.

1.2 Research Problem

In India, the production of prosthetics remains a traditional, centralised, labour-intensive process, which is time-consuming and expensive, thus leaving major sections of the population, especially in rural and low-income areas, behind. The manual form of fabrication is not precise enough to achieve an individually tailored fit to the maximum level, resulting in reduced comfort and functionality. In the meantime, 3D printing has become a global phenomenon, offering an appealing alternative to conventional methods. It allows for the production of anatomically correct prosthetics quickly and at a low cost. However, the level of adoption of this technology in the Indian pharmaceutical and medical device industry is low. As evidenced by Borthakur et al. (2025), the Indian healthcare system has not been able to cover all the grounds on the additive manufacturing front by utilising the production of custom biomedical solutions due to a lack of regulatory, infrastructural and training-related capabilities. On the same note, Shahrubudin et al. (2022) indicate that, despite 3D printing offering the potential for enhanced material utilisation, integration of CAD software, and flexibility in multi-material design, it is not widely adopted in resource-constrained healthcare facilities. The main question, therefore, is how 3D printing can be incorporated systematically to fill the gaps in accessibility, affordability, and personalisation of prosthetic treatment available to date. The current study thus examines the feasibility of operations, stakeholder preparedness, and the policy-level drivers for the scalable integration of 3D printing in India. Therefore, this study positions itself to critically analyse the feasibility, challenges, and opportunities of integrating 3D printing in India's prosthetic sector, thereby contributing to both academic knowledge and practical healthcare improvement.

1.3 Research Aim

The research aims to examine the role of 3D printing in improving custom prosthetic device manufacturing in the Indian Pharmaceutical and Medical Device Sector.

1.4 Research Objectives

- To examine how Indian pharmaceutical and medical device companies are adopting 3D printing technologies to manufacture custom prosthetic devices.
- To recognise key operational, technical, and supply chain challenges faced by Indian manufacturers in employing 3D printing for prosthetics.
- To evaluate industry professionals' perspectives on the benefits, limitations, and scalability of 3D-printed custom prosthetics in the Indian healthcare context.
- To assess how material validation, cost efficiency, and production readiness affect adoption in Indian firms without concentrating on international regulatory constraints.
- To provide strategic recommendations for Indian medical device companies to optimise the integration of 3D printing for patient-specific prosthetic solutions.

1.5 Research Question

- How are Indian pharmaceutical and medical device companies utilising 3D printing technologies for the manufacture of custom prosthetics?
- What are the key operational, technical, and supply chain challenges faced by Indian manufacturers in implementing 3D printing for prosthetic production?
- How do industry professionals perceive the benefits, limitations, and scalability of 3D-printed prosthetics within the Indian healthcare landscape?
- How do factors such as material validation, cost efficiency, and production readiness influence the decision to adopt 3D printing technologies in custom prosthetics?

1.6 Research Significance

In this study, innovation and operational efficiency hold specific significance in the pharmaceutical and medical equipment industry in India. The fact that there has been a rising need for less expensive, individualised prosthetic appliances, particularly in the population segment of trauma patients and diabetics, is an indicator of the fact that the traditional processes of production are inappropriate due to a high cost, location requirements and insufficient customisation. In analysing the abilities of 3D printing to counter these limitations, the research delves into a technological issue that has required critical attention, particularly in terms of enhancing speed, accuracy and reducing costs in the production of prosthetics. The study is relevant to both scholarship and industrial practice, contributing to both simultaneously and sheds light on operational issues, views, and adoption impediments in the Indian context. Furthermore, it offers practical advice to small and medium-sized enterprises (SMEs) that face resource limitations, regulatory confusion, and a skills shortage among their workers. Finally, the results suggest the development of strategic directions for choice and innovation policies to embed the use of 3D printing more comprehensively, thereby encouraging improvements in patient outcomes and a distributed model of healthcare delivery.

1.7 Scope and Limitation of Research

This research will concentrate on the possibility of 3D printing in increasing the manufacturing of a prosthetic device in the Indian pharmaceutical and medical device industry. It is restricted in terms of analysing the operational feasibility, stakeholders' preparedness and policy-level drivers, with a focus on the SMEs and healthcare providers in India. The study has some weaknesses, though. The results are limited to a demographically small sample and are premised on the use of quantitative methodologies, and provide a limited summary of the patient opinions. Besides, both regulatory and infrastructural studies require second-hand data, whereas 3D printing has fast development, which can limit the generalisability.

1.8 Research Synopsis

The current study investigates the effectiveness of 3D printing technology in streamlining both the operation and clinical performance of manufacturing custom-made prosthetic devices in the Indian pharmaceutical and medical device industries. The research, divided into six chapters, begins with an introduction that outlines the background, categorises the research problem, describes the aims and objectives, and defines the scope of the research, thereby establishing the rationale and importance of the study. In Chapter 2, a critical review of the literature is conducted by evaluating available academic and industrial work on 3D printing related to healthcare, as well as the gaps, particularly in the Indian context of applications. Chapter 3 provides a description of the mixed-methods research design, outlines the data collection tools, defines the sampling strategy, and addresses ethical considerations. In Chapter 4, the results of the analysed data are introduced through thematic and statistical approaches, and their connection to the current literature and research purpose is explored. Chapter 5 is the Discussion, which highlights the key understanding, operational issues, and stakeholder views that emerged from the data. Lastly, Chapter 6 concludes the research study, summarising the findings, suggesting strategic implications, and recommending future research.

CHAPTER 2: LITERATURE REVIEW

2.1 Overview of the chapter

This chapter critically analyses the available literature to put the role of 3D printing in custom device manufacturing of prosthetic devices, more specifically in the Indian pharmaceutical and medical devices industries, into perspective. It starts with a description of the current situation in the sector and the drawbacks of the traditional approach to producing prosthetics. The review next discusses the international transformation of 3D printing in healthcare, considering its technological, clinical, and economic potential. The chapter then examines the level of adoption in India and identifies some operational, technical, and policy-related issues specific to the local environment. The systematic review provides a basis for answering the research questions and offers concise guidelines on how to improve access, customisation, and efficiency in the manufacture of prosthetics using 3D printing.

2.2 Overview of the Indian Pharmaceutical and Medical Device Sector

The health sector in India has seen a significant rise, driven by the effects of demographic change, urbanisation, and the escalating demands of the people in India. Situated at the intersection of business and healthcare, the Indian healthcare market is currently worth $ 128 billion USD, but it is expected to become twice as large (approximately $ 280 billion USD) by 2025 and is projected to rise in value by 12% annually (Manu and Anand, 2022). According to Manu and Anand (2022), part of the growth, however, that is considered critical is the medical devices industry, which is among the 20 largest global markets and is estimated to multiply 10-fold by 2025, reaching $5.2 billion and $50 billion in the coming years. This growth is supported by government-funded programs, including the Atmanirbhar Bharat Production-Linked Incentive (PLI) scheme, aimed at increasing domestic production and minimising reliance on imports (Sarwal et al., 2021). Nevertheless, on the one hand, as a result of these improvements, India imports a substantial number of medical devices, accounting for nearly 70 per cent of the total, including high-precision prosthetics. This means that there is a significant disparity between the amount of money allocated and the demand and the available production capacity in the country. To address these issues, India introduced the Indian Medical Device Rules (IMDR) in 2017 and revised them in 2020, which are designed to simplify the regulatory processes based on international standards, such as the EU MDR and FDA regulatory systems (Manu and Anand, 2022). Under this sector, it is essential to have prosthetics as a means of restorative healthcare, especially for individuals who are living with amputation.

Nevertheless, high-quality prosthetic aids are not well accessible among rural and underserved people in India. Moreover, it has observed varying trends in Foreign Direct Investment (FDI) in the medical device sector in India, as shown in Figure 1, between 2014 and 2023. The most significant inflow was during 201617, amounting to USD 3.9 million and the drastic fall to USD 0.7 million in 201718. Nevertheless, the following year shows a substantial recovery of 2022 23 (April to December) of USD 3.4 million, being condensed to three quarters only. Such recovery is an indication of the newfound investor confidence, which can be attributed to policy changes, the PLI scheme, and increasing domestic market demand for medtech solutions. This shows that India is strategically positioned as one of the global hubs in the manufacture of medical devices (KPMG, 2023).

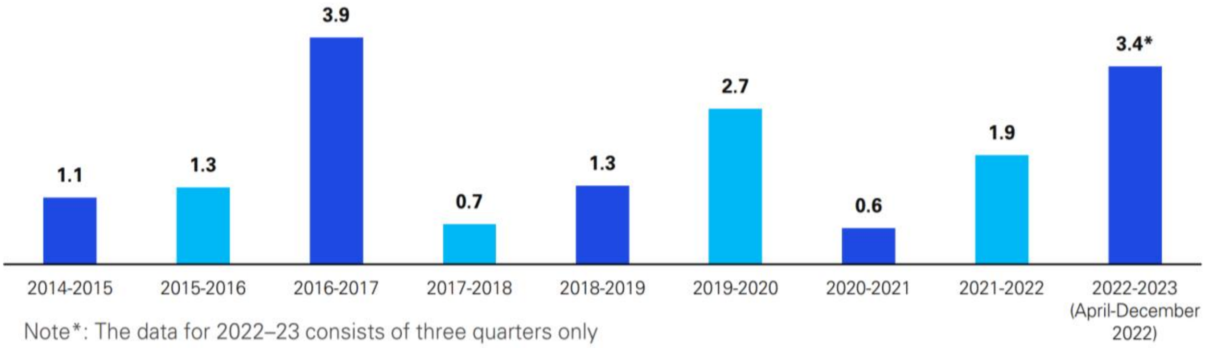

Figure 1: FDI inflow in the medical device industry in India (USD million)

(Source: KPMG India, 2023)

As reported by the Clinton Health Access Initiative (2020), only between 5% and 15% of people in low- and middle-income countries, including India, who need prosthetic devices, receive them. The failure has been attributed to the absence of decentralised models of production, a shortage of trained professionals, and inadequate end-user financing facilities. The existing system of prosthetic provision in India is immature and significantly relies on the NGO sector and foreign assistance, and moreover, may run parallel to the official systems in the country. New technologies, such as the utilisation of digital socket manufacture and 3D printing, have not been integrated to a great extent, and their use is important in saving time during the manufacturing process and maximising anatomical fit. Additionally, logistical issues and the lack of an integrated supply chain result in most prosthetic services being limited to urban centres, with rural residents having limited to no access to assistive technologies (Clinton

Health Access Initiative, 2020). Social determinants significantly contribute to inequities in access to healthcare. Out-of-pocket spending is among the highest worldwide, and infrastructural gaps between urban and rural settings hinder the uniformity of specialised medical care provision. Moreover, the COVID-19 pandemic highlighted these gaps and increased the urgency of decentralised care options, including telemedicine and home diagnostics.

2.3 Evolution of Prosthetic Manufacturing: From Conventional to Additive Technologies

Similar to the production of prosthetics, the development of the industry exhibits an increasing reliance on technological output and data-driven design. In the past, prosthetics were made by handcraft, and such production required an extensive use of plaster casting and a customisation process. These traditional techniques were non-standardised to a large extent and ultimately caused numerous problems, including a lengthy fabrication process, quality inconsistencies, and a poor anatomical fit (Barrios-Muriel et al., 2020). More so, these conventional procedures were associated with making most patients uncomfortable, developing pressure wounds, and user dissatisfaction, which eventually heightened the chances of device rejection (Raschke, 2022). Among the key drawbacks of traditional prosthetics is the inability of proper personalisation. Subtle variations in anatomy cannot always be accommodated by strain gauge production, resulting in both misalignment and inefficient motion. The fact that prosthetic vision is not designed according to both personal requirements and physiology promotes the need for a specifically tailored and anatomically correct design. As Banga et al. (2021) remark, the patient-specific design is the key to restoring biomechanical balance, functionality, and psychological well-being. Prostheses are required not only to replace a deficient limb but also to fit the user and integrate with their lifestyle.

Prosthetic production has been leveraging the additive manufacturing (AM) or 3D printing method to meet the demand for improved fit, performance, and reduced costs. In this paper, additive manufacturing (AM) and 3D printing are often used interchangeably and denote the process of creating physical objects layer by layer based on digital designs. Custom prosthetic devices refer to individual assistive devices to accommodate patient-specific anatomical and functional needs. AM enables the fabrication of a layer-by-layer development of the prosthetic component using digital models, which leads to great customisation and accuracy. Fused deposition modelling (FDM), selective laser sintering (SLS), or stereolithography are technologies that enable the fabrication of complex geometries with high repeatability and material efficiency, as designed by the user (Barrios-Muriel et al., 2020; Hesse and Ozbcan, 2021). Such a shift from traditional manufacturing to digital design will be one of the key aspects of the overall Industry 4.0 revolution. Moreover, additive technologies are making prosthetics more democratic since they democratise the production process. Low-cost 3D printers, combined with open-source CAD files, have enabled clinics and Non-Governmental Organisations (NGOs) in low-resource areas to manufacture prosthetic feet locally using these printers. Borthakur (2025) stresses that 3D scanning and digital modelling help in designing an anatomically perfect prosthesis with significantly reduced turnaround and cost. Such a decentralised model lessens the level of logistical reliance and puts quality prosthetics within reach of underserved populations. The other imperative development that AM has enhanced is material innovation. Current prosthetics can now be made from biocompatible thermoplastics, metals, and composite materials, which guarantee both strength and flexibility. Hesse and Özcan (2021) have tested the additive technique because it yields better surface roughness and bonding, which enables prosthetic components to last longer and be seamlessly integrated in uterine as well as limb bioplastication.

Moreover, the concept of Industry 4.0, which includes artificial intelligence and machine learning, has already been introduced into the design process. As stated by Raschke (2022), one can employ data analytics to predict the outcome of patient mobility, allowing for the selection of prosthetic elements based on evidence. Patients are also having a greater direct input into engineers and developers through digital channels, and the collaborative creation of designs, as well as periodic updates, through direct feedback in real-time. Personalisation is no longer a luxury, but a necessity. AM can create functional, lightweight, and attractive prosthetics, designing them specifically for use by children, athletes, and the older generation. This is especially applicable to pediatric cases, which require replacement more frequently due to growth (Barrios-Muriel et al., 2020). In addition, customisation will minimise instances of prosthetic abdication, which have historically been high, as poorly fitting and uncomfortable prosthetic devices cannot be used (Banga et al., 2021). In summary, replacing traditional past forms of prosthetic manufacturing methods with additive technologies represents a significant step forward in the direction of rehabilitation engineering.

2.4 Introduction to 3D Printing Technology in Healthcare

Additive manufacturing (AM) or 3D printing transformed the world of healthcare, especially in the fields of prosthetics, implants, and surgical instruments. In essence, AM is a process of adding layers to construct physical structures using digital 3D models. The method enables the design of intricate, bespoke, and cost-effective designs tailored to the specific requirements of a patient. According to Salmi (2021), AM applications like powder bed fusion, material extrusion, and VAT photopolymerisation are already used in all areas of medicine due to a high level of precision and the ability to manufacture individual (especially implants and surgical equipment) solutions. The use of 3D printing in the medical field has increased tremendously globally. Kim et al. (2022) developed a systematic review that highlights the fact that 3D-printed transtibial prosthetic sockets have achieved structural integrity comparable to that of established traditional laminated composite sockets. The addition of carbon fibre and distal reinforcement greatly enhances the advantages of durability, making these devices an alternative to conventional prosthetics, especially in places with limited accessibility. In the meantime, Wendo et al. (2022) speculate on the social potential of open-source 3D-printed upper-limb prostheses in low-income or conflict-torn regions, as they can offer affordable and robust alternatives to commercially high-priced variants in such locales. Community- or NGO-developed contraceptives, which allow the freedom of choice against anatomical and economic limitations of the marginalised community, are an area that these devices focus on. In the field of dentistry, Rezaie et al. (2023) highlight that the use of 3D printing has been quite active in displacing traditional dental workflow processes due to the rapid 3D printing of crowns, bridges, and implants. The evolution of dental prosthetics, utilising thermoplastics, ceramics, and biocompatible metals, has enabled greater precision in the piece, a shorter cycle time, and a more accurate fit with the patient's anatomy.

Several 3D printing technologies are applied to medical instruments, each with its own strengths. Powder bed fusion is the best method for creating metallic implants, as it offers strength and precision (Salmi, 2021). In contrast, material extrusion is usually more expensive and less accessible than implants, so it is widely used in part of the prostheses. High-resolution applications of VAT are also in dental models and surgical guides. Binder jetting and material jetting are under research and not yet common in high-stress life implants due to material limitations. The shift towards centralisation and decentralisation of healthcare delivery, as well as the need to develop more tailored solutions, is one of the factors that have contributed to the spread of 3D printing. Design-to-product time, delivery and supply chain dependencies can be reduced by the digital nature of AM, through remote design and local production in situ. It is especially powerful in poorly served areas, where it is typically infeasible to supply centralised manufacture and distribution. Murr (2020) also confirms this by discussing the use of AM in developing patient-specific orthopaedic and craniomaxillary implants, noting an increasing tendency to use titanium and other biocompatible alloys to achieve long-term integration and safety.

Additionally, 3D printing can significantly enhance the efficiency and efficacy of surgery. Using AM, pre-surgical model planning becomes easier, as well as the use of patient-specific instruments, allowing surgeons to practice and schedule the procedure using exact replicas of the anatomy. According to Tayebi et al. (2023), the combination of computer-aided design (CAD) and 3D printing has significantly reduced dental and maxillofacial treatment schedules and enhanced the precision of these processes. To sum up, additive manufacturing in healthcare represents a convergence of technological creativity and a patient-oriented approach. This will change the global face of medical products and prosthetics through unmatched customisation, lower manufacturing costs, and decentralised production methods. The convergence of high-end materials, advanced print techniques, and digital workflow systems means that 3D printing will further push the limits on how healthcare is delivered, notably in prosthetic design and patient-specific planning.

2.5 3D Printing for Custom Prosthetics: Global Best Practices

Other developed nations, such as the US, Germany, South Korea, Vietnam, and Nepal, have shown progressive development in 3D printing for prosthetics, illustrating the benefits of localised, personalised, and cost-effective solutions. Their best practices insightfully provide possibilities for enhancing the healthcare sector through stakeholder engagement, facilitated by technological integration and its benefits to equity and innovation. The utilisation of 3D printing in the design of prosthetic sockets has also revealed outstanding advantages of the method during application in low- and middle-income countries, such as Vietnam. A case report by Phan et al. (2025) demonstrated that combining 3D scanning and fused deposition modelling (FDM) to implement a digital workflow resulted in faster fabrication of more anatomically accurate sockets at lower costs. It has enabled the delivery of this method even in remote areas, demonstrating scalability and responsiveness comparable to conventional plaster casting and manufacturing with moulds (Phan et al., 2025). Similarly, a co-creation initiative in Nepal, spearheaded by Oldfrey et al. (2023), showed how collaborating with global technical knowledge and local innovation can achieve a sustainable AT system. With 3D printing, the design of locally made prosthetic feet was customised, such as overcoming the weakness of generic imported prosthetic feet in terrains with mountains. The project enhanced patient satisfaction and functionality, developed local technicians, and decreased reliance on foreign supply chains. It strengthened the commendation of place-based designing, local participation, and policy advocacy (Oldfrey et al., 2023). In well-to-do nations like the United States, additive manufacturing has revolutionised the way prosthetics are produced. According to Bhatia and

Sharma (2014), 3D printing is no longer limited to mere prototyping. Still, it is being used in the real clinic, especially in the fabrication of upper-limb prostheses and personalised sockets. Adaptations like stereolithography (SLA), selective laser sintering (SLS), and inkjet printing have enabled tight-fitting and early prototyping with low production expenses and minimal clinical wait time. It has improved clinical performance and user satisfaction by enhancing anatomical fit, reducing weight, and incorporating cosmeticization into custom design (Bhatia and Sharma, 2014). Moreover, it is projected that the total number of 3D printing and additive manufacturing machines installed worldwide reached more than 2.2 million in 2023 (Figure 2) (Statista, 2024). This ramp showcases the evolving accessibility and mainstream adoption of 3D printing technologies, such as in the healthcare and prosthetic production industries.

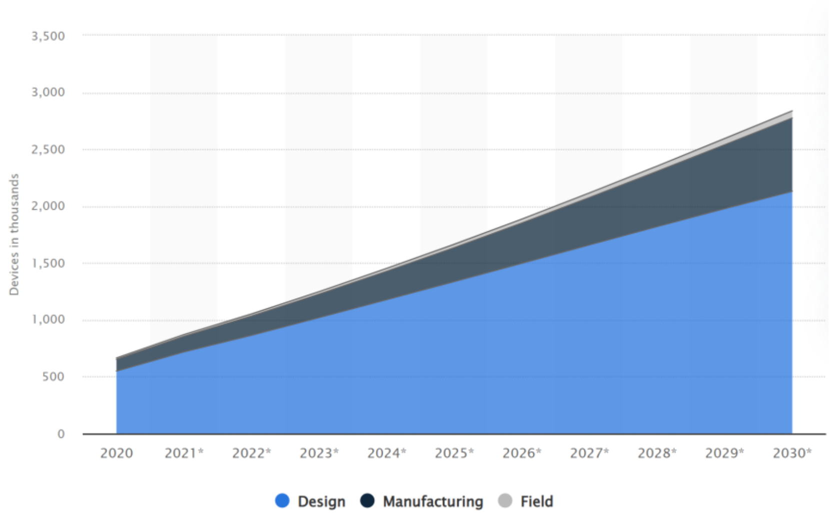

Figure 2: 3D printing & additive manufacturing devices worldwide from 2020 to 2030

(Source: Statista, 2025)

Additionally, Bolliger (2022) notes that in Germany, the simplification of CAD/CAM with additive technology has enabled the creation of prosthetic sockets with better shapes, which distribute loads more effectively and reduce discomfort. The research found that digitisation minimises human errors and increases repeatability. In clinics, patient satisfaction increased because fitting sessions were fewer, and they became more comfortable (Bolliger, 2022). A similar case has occurred in South Korea, particularly with 3D printing, in manufacturing socket prosthetic devices, such as those for upper-limb amputees. The article by Dave et al. (2024) mentions that FDM and SLA can be used to integrate a biosensor into a prosthetic device, enabling active diagnostics, healing, and performance monitoring in real-time. The combination of innovative materials and sophisticated printing converges to enhance patient experience and facilitate long-distance observation, making healthcare much more integrated (Dave et al., 2024). In all these environments, the suitability of decentralised production models cannot be overstated. Conventional centralised production has frequently been unable to address the specific needs of remote or underserved populations.

In contrast, the idea of localised, on-demand (and in-repair) digital production hubs featuring 3D printers and open-source design files enables the printers to be used. It minimises lead times, ensures rapid customisation, and reduces the need for large stocks or complex supply chain logistics (Oldfrey et al., 2023; Nguyen et al., 2025). All these global best practices support the paradigm of patient-centred care through affordable, scalable, and digitally enabled prosthetics. A mutually sustainable approach toward an inclusive innovation in healthcare would be the synergy between local execution models and global expertise in innovation.

2.6 Adoption of 3D Printing in India's Prosthetic Manufacturing

The use of 3D printing to produce prosthetics in the Indian market is slowly gaining popularity, with more people becoming aware, driven by the price factor and indigenous development. However, today, deployment remains at an early stage, and occasional, although mostly influential, applications are in medical colleges, individual practices, and tech in startups (Gomes et al., 2024). Academic institutions, such as Dibrugarh University and IIT Ropar, are making critical contributions, with academics proving that 3D printing can be used in a biocompatible manner in personalised healthcare, including prosthetic limbs, dental structures, and surgical representations (Pathak et al., 2023). To achieve the anatomical perfection associated with patient-specific prosthetics, these institutions are taking advantage of Fused Deposition Modelling (FDM) and Stereolithography (SLA) technologies, resulting in reduced fitting time and post-operative complications with the prosthetics. Another effort that helps significantly is the small and medium industries (SMEs) that offer low-cost prosthetics with the help of a 3D desktop-sized printer and printable materials that can be recycled. Grassroots innovation has also been observed in additive manufacturing, with new startups like Inali Foundation and Robo Bionics providing prosthetic limbs to people in rural areas at a significantly lower cost compared to traditional methods (Gomes et al., 2024). Besides, Jain et al. (2024) claimed that the efforts of privately owned orthopaedic clinics have introduced 3D printing and CT-scan data to produce individualised sockets and lower-limb components tailored to the person's shape. Such developments indicate that India can implement decentralised 3D printing to make prosthetics, which would have a ground-breaking impact on care delivery in underserved areas. Nevertheless, the structural and system-related constraints are present. The main obstacle is the absence of powerful infrastructural platforms; much of the countryside and secondary care facilities lack the necessary equipment, including 3D printers, software, and essential imaging systems such as MRI or CT scans (Gomes et al., 2024). There is also a lack of trained personnel who can operate CAD design, post-processing, and organ biocompatibility testing. That skills gap is a drawback to wholesome clinical implementation, as more and more engineering and healthcare students are accessing 3D technologies in the academic environment (Pathak et al., 2023).

Ambiguous regulatory issues additionally complicate the adoption environment. There is no national health policy, nor is there a policy by the Central Drugs Standard Control Organisation (CDSCO) on how to certify 3D-printed prosthetics, implants, or orthopaedic aids in India. In their absence, the clinicians and manufacturers are reluctant to increase usage as they have medico-legal concerns and fear liability. In a recent review, it was noted that despite the vast potential of additive manufacturing to democratise prosthetic access, India needs to develop combined policy support, transparent access regulation for medical devices, and inter-sectoral operations cooperation, inclusive of government, research, and industry interests (Gomes et al., 2024). Despite these shortcomings, the future looks promising. 3D printing innovation has a fertile environment in India, with the demand of the Indian market focused on cheap and customisable solutions required by the amputees, either as a result of trauma or congenital disabilities. Moreover, PPP and state subsidies (as per the Atal Innovation Mission and the Make in India campaign) might encourage the prior generation of 3D printing components and bio-safe substances on the domestic scale (Pathak et al., 2023). The overall generation of decentralised centres of expertise in medical 3D printing around the nation will be able to alleviate manufacturing issues and reduce the delayed runtimes of patients, also significantly enhancing the rehabilitation progress of prosthetics. Summarily, the 3D printing alternative in India for fabricating prosthetics is developing in capacity but has tremendous prospects along the academic, SME, and health innovator angles. The move to scaled clinical applications of isolated pilot studies will necessitate overcoming infrastructure bottlenecks, developing technical competencies, and attaining favourable regulatory measures. By coupling technology, policy, and education, India has great potential to become a world leader in decentralised low-cost prosthetic solutions.

2.7 Operational, Technical, and Supply Chain Challenges

The numerous applications of 3D printing in prosthetic production expose highly complex operational, technical, and supply chain issues that directly affect material validation, cost efficiency, regulatory compliance, and stakeholder input. One of the significant technical questions is about material validation and biocompatibility. Karabegovic and Tabakovic et al. (2025) point out that materials used in healthcare robotics and prosthetics must meet strict demands, including tensile strength, elasticity, and biocompatibility, as specified in ISO 10993. One of the main features they emphasise is that such polymers, when applied in 3D printed parts, need to be able to withstand at least 100 autoclave sterilisation runs without any structural deformation, retaining both their antimicrobial and hypoallergenic properties. These criteria are not easy to attain in low-cost, decentralised fabrication setups, with inconsistencies in materials. Additionally, the quality assurance systems for lab-to-fab translation are lacking. Luo et al. (2020) establish that medical-grade flexible materials, although advanced in academic fields, have not enabled several of their advances to be replicated in the industrial world due to the unavailability of methods that can provide common platforms to screen developments, programming platforms, and repeatable processes. The ability to scale translations of flexible electronics (such as indwelling sensors in prosthetics) to scalable products is hindered by mismatched capabilities and the lack of industrial validation systems. At the cost and production preparedness level, Parry (2023) observes that additive manufacturing enables the creation of mass customisation in terms of individual components and allows for the production of small batches on demand. Still, the cost of early investments in industrial-grade printers, including training, is significant, particularly in small healthcare units or prosthetic labs. She also points out a trade-off between the high resolution needed to achieve anatomical accuracy and the slow speed of some 3D printing technologies, such as SLA and SLS, which prohibits quick responses in situations like emergency 3D printed prosthetic fittings. Considering supply chain facilities, the Redistributed Manufacturing in Healthcare Network (RiHN) White Paper (Phillips et al., 2020) examines the disruption of centralised production of prosthetics by decentralised production alternatives based on additive manufacturing.

However, this model has several limitations, including regulatory uncertainty, skills gaps at the local unit level, and poor interoperability between different supply chain nodes. Especially raising pilot-scale, custom-fit prosthetics to a distributed service network necessitates the use of strong digital libraries to support designs, decentralised material screening, and real-time quality control in many systems today. Stakeholders' opinions also reveal initiator piles. The prosthetists' and engineers' perspective in Sweden also expressed an unwillingness to adopt 3D-printed sockets due to concerns about structural integrity, the lack of empirical patient outcome data, and the inadequacy of cross-training between prosthetists and engineers in CAD software (Hörnell and Lindahl 2024). Clinicians are alarmed by unpredictable fit problems when low-resolution scans are used or when there is a problem with printer compatibility. Regarding clinical interface, the clinicians interviewed during the review about this topic by Parry (2020) warn that one should not think that 3D printing by definition will decrease errors. They claim that inadequate post-processing, for example, edge finishing or wrong thickness of the wall, can irritate the skin or pressure sores, pain, especially in users with sensitive skin (pediatric or geriatric). The regulatory bottlenecks are also explained by Karabegović and Tabakovic et al. (2025), that the times to gain biocompatibility and functional approval are 18 months to 24 months on average. This curve does not align with the fast iteration cycle of 3D printing, where devices can be prototyped in weeks. The issue of delays in approval affects the effectiveness of using 3D-printed prosthetics in medical practice. Additionally, Parry (2023) and Phillips et al. (2020) draw similar conclusions regarding scalability, which remains limited by infrastructure. Most places do not have access to materials such as medical-grade thermoplastic polyurethane (TPU), titanium powder, or an annealing and finishing post-processing unit. Moreover, the IT infrastructure necessary to maintain accurate records of the digital design, which is crucial for achieving the reproducibility of prosthetics and meeting liability requirements, is rarely present in flexible manufacturing units. Lastly, manufacturers, though optimistic, worry about the return on investment. Luo et al. (2020) note that sectors are reluctant to take steps to switch to additive manufacturing lines and dedicate investments without reliable information on the quality of the products, the number of defects, maintenance expenses, and the costs of consumable materials, compared to traditional lines. This is evident in the interviews with stakeholders conducted by Parry, where manufacturers raise the concept of high wastage rates in the early stages of prototyping as a deterrent to business feasibility.

2.8 Strategic Opportunities and Policy Implications for 3D Printing in India

The high rate of 3D printing (3DP) advancement in India presents immense opportunities for localised, patient-centric manufacturing, particularly in the production of prosthetics. 3DP is personalised and allows point-of-care production to meet the individual anatomical and functional requirements of Indian patients. This technology has made possible the strategy of decentralised models, where rural and tier-2 city clinics have the option of in-house or partnered 3D printing, eliminating reliance on centralised suppliers and long logistical chains (Mauro et al., 2024). The policy environment that will enable this transition is changing. According to a study conducted by Venkateswaran (2015), the draft additive manufacturing policy of India discusses the promotion of indigenisation, encouraging the establishment of at least 100 new startups in this industry by 2025, with institutional support and the development of standards. These policy regimes recognise the strategic use of localisation, notably in cost-cutting and improving affordability for the economically less fortunate strata. As an illustration, point-of-care 3DP technologies can be utilised in point-of-care solutions applied in public hospitals, which would help deliver patient-specific prosthetics more efficiently, thereby spending fewer resources on the process. The SMEs and medical facilities contributing to the scaling of the ecosystem have become essential. Management expert Segers (2017) suggests that SMEs should adopt strategic alliances and open innovation models to remain competitive in the prospective high-tech sector, such as biotechnology and 3D printing. He also observes that a cluster of biotech with university R&D and entrepreneurial spin-offs has worked in Belgium and can shape the Indian approach to bio-innovation clusters, which can include the integration of 3DP into healthcare-centric clusters. In India, this indicates that SMEs, in collaboration with academic institutions, will have the opportunity to tap into government R&D incentives, prototyping laboratories, and domain expertise as they design prosthetics tailored to local demands.

As a healthcare provider, it is crucial to develop capacity through training and technical integration. According to Venkateswaran (2024), critical determinants of clinician acceptance of CAD models are the skills barrier in deciphering them or working with 3D printing (3DP) hardware. Public-private partnerships (PPPs) upskilling programmes can help make adoption at the primary and secondary care levels easier. Additionally, more open forms of innovation, such as sharing design libraries of prosthetic sockets or limb models, can accelerate development in regions with diverse patient demographics. Key to this strategy is the role of government and policy reform. The authors Venkateswaran (2024) emphasise that there should be a unified national policy facilitating 3DP by creating clarity and regulatory frameworks, financial incentives, and quality assurance mechanisms. They suggest instituting so-called innovation sandboxes where hospitals, 3DP companies, and regulators can partner to launch new solutions to prosthetic issues without the months of delay in approval. Moreover, Segers (2016) proposes the creation of regional innovation cycles that would support interactions between academia, startups, and state-owned institutions, which could be implemented in India through special bio-innovation belts. To sum up, the way forward for 3D printing potential in India entails localisation, SME and provider empowerment, and the adoption of future-oriented policies. India can develop a sustainable ecosystem of self-sustaining, scalable, and inclusive systems that provide high-quality, customised prosthetics to the diverse population of the country through regional clusters, eliminating regulatory bottlenecks, and investing in infrastructure and training.

2.9 Research gap and conceptual Diagram

Figure 3 illustrates the conceptual framework, which is a visual representation of the multidimensional factors that influence the adoption of 3D printing and custom prosthetic production by Indian companies. It addresses important issues such as acceptance, obstacles to functioning, material and cost factors, and the industry's perspective. Amidst these advances, a significant research gap remains in understanding how these factors interact specifically in the case of India, where there is ambiguity in regulation, infrastructural limitations, and low stakeholder preparedness for diffusion. The available literature does not provide in-depth information on the prospects of additive manufacturing and its integration with the prosthetic market in India, as well as the role of local SMEs, healthcare innovators, and decentralised production systems.

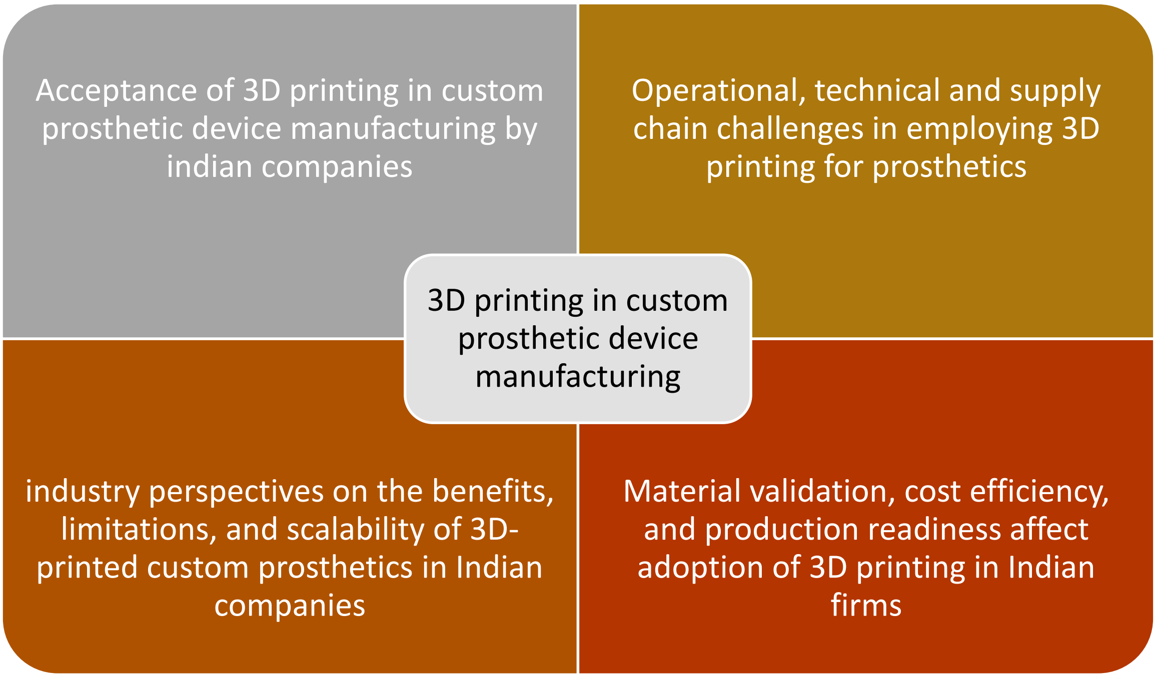

Figure 3: Conceptual framework of research

2.10 Conclusion of the chapter

This literature review indicates the disruptive nature of 3D printing as it revolutionises prosthetic fabrication in the pharmaceutical and medical devices industry of India. Although global best practices are favoured due to customisation, cost efficiency, and decentralised care, in India, adoption is in its initial stages yet exhibits a promising outlook. Additive manufacturing can bridge the gaps in the areas of accessibility, quality, and personalisation. Nevertheless, operational, regulatory, and infrastructural worries should be addressed.

Coherent policy reforms are needed to support strategic cooperation among SMEs, policymakers, and healthcare providers.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Introduction

The chapter presents the research methodology with the help of the research onion model chosen to explore the use of 3D printing to enhance the fabrication of custom prosthetics in the Indian pharmaceutical and medical device industry. It elaborates on the research philosophy, approach, design, data collection method and type of analysis done to address the objectives of the study. Considering the technology and operation intricacies associated with the topic, a positivist philosophy was chosen to guarantee objective examination, whereas an inductive strategy was adopted to permit patterns and realisations to develop within the data. This research will use a descriptive research design and collect the quantitative data via a structured and closed-ended web-based questionnaire, where the target population will be the professionals who are currently working in the area of 3D printing and prosthetic development. The sampling strategy, ethical considerations and statistical tools to be used to analyse the data are also explained in the chapter. On the whole, the methodology will result in the provision of high-quality, generalisable, and policy-relevant information that can guide strategic innovation of the healthcare manufacturing sector in India.

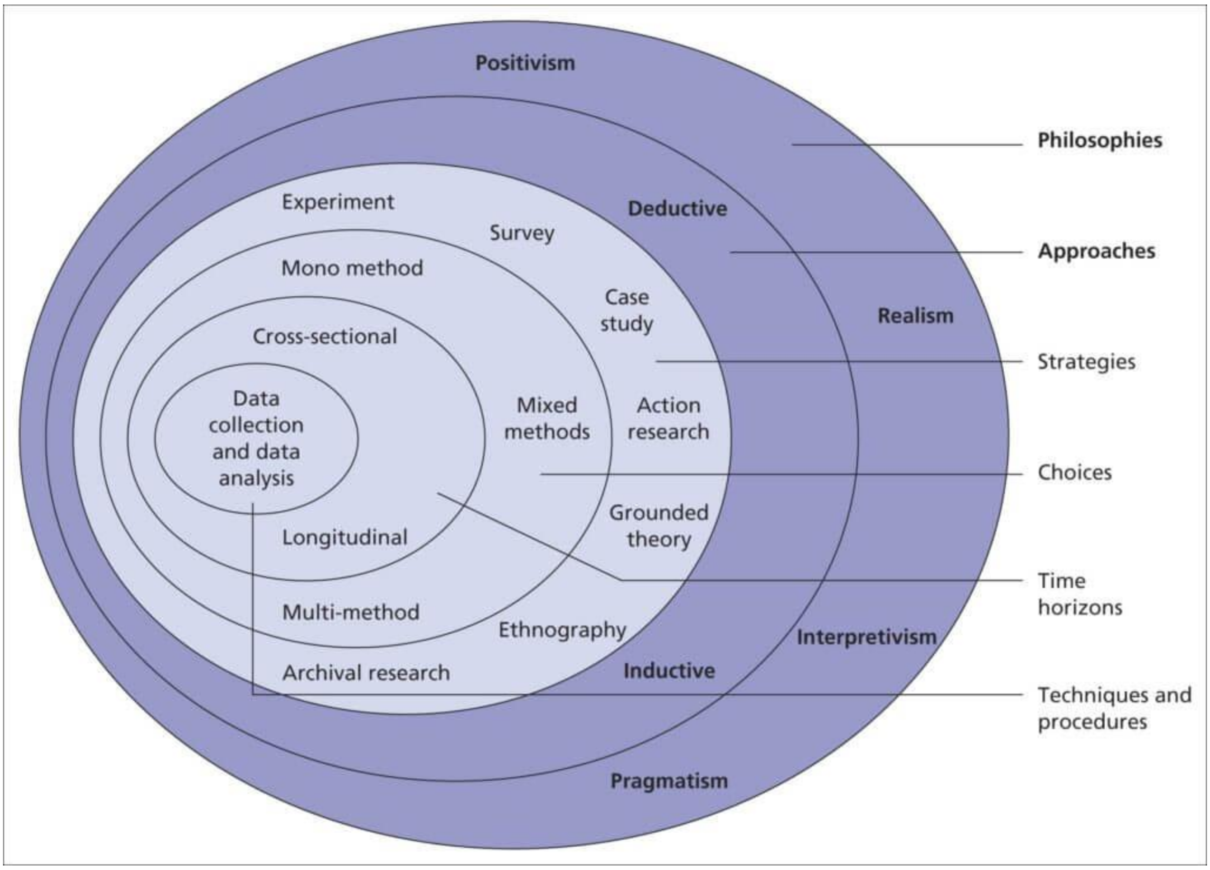

Figure 4: Research onion model

Source - (Saunders et al., 2019).

3.2 Research Philosophy

The philosophy of this study is a positivist approach because it emphasises objectivity, measurement and the identification of observable trends. Positivism suggests that reality is external and can be analysed using scientific methods and is also based on empirical evidence (Saunders et al., 2019). At the positivism probed against the quantitative aspect, this aspect seeks to evaluate the level and trend of adoption processes, the status of operation, and beliefs in the usage of 3D printing in the manufacture of prosthetics amongst the Indian pharmaceutical and medical equipment companies. Knowledge, according to this philosophy, should be based on observable data and the researcher is supposed to be neutral in that he or she is to use structured tools, in this case, it is the standardised Likert-scale survey items to acquire measurable data and this is where the researcher can use statistical analysis (Creswell & Poth, 2018). This will allow us to study the relationship between variables like perceived usefulness, production preparedness and organisational readiness to develop 3D printing technology. Descriptive and inferential statistics would go hand in hand with the positivist approach, where the essence is to test assumptions and generalise the results in a similar setting or industry.

Positivism is especially helpful in determining industry trends, testing hypotheses, and coming up with insights that can be generalised to all areas and the types of companies (Park, et. al., 2020). In this research, the structured online questionnaire provides the possibility of attitude and behaviours being objectively measured, and consistent data collection and data analysis (Bell et al., 2022). The substance of this research is the quantitative one resting on the tradition of positive research. This philosophical position proves the purpose of producing evidence-based recommendations, which can guide policy and strategy in the sector of medical devices, which is being developed in India.

3.3 Research Approach

The research of this study is inductive, indicating that its research method is based on developing a set of theories and ideas through analysing the received data, but not on testing existing ideas. Induction is especially appropriate when the objective includes describing a sophisticated and under-researched phenomenon, such as the incorporation of 3D printing in the production of prosthetic devices in India and constructing patterns or themes based on real-life experience (Saunders et al., 2019).

An inductive approach justifies the goal of the study to investigate operational, technical and strategic problems of professionals working in the industry concerned, their awareness, their perceptions and their expectations towards applying 3D printing. Inductive orientation is suitable for the study since the research aims at gaining an understanding of the actual practices and readiness, attitudes (instead of ensuring certain models) (Creswell & Poth, 2018). In this study, the survey will contain quantitative data, i.e., Likert-scale answers and multiple-choice responses. Although descriptive and correlation analysis will assist in the identification of the arising patterns, the qualitative part using the literature will be analysed thematically in finding the patterns regarding stakeholder perception, contextual deterrence and material preparedness. The findings will then be used to advise on practical and strategic guidelines for the Indian medical device industry.

Besides, this inductive method is associated with a research approach that is robust and flexible enough to deal with mixed-methods research, as insights are prompted without being informed by a binding structure of the theories (Research-Methodology, 2025). It is especially useful in exploratory research, when new learning can and should not be superimposed on a statistical base but has to be formed on it (Bell et al., 2022). Through the use of an inductive approach, the paper will provide evidence-based knowledge reflecting the realities, constraints, and innovation opportunities within the developing prosthetic production environment in India.

3.4 Research Design

This study employs a mixed-methods descriptive research design because it allows an in-depth analysis of the way in which 3D printing technologies are currently being applied in creating custom prosthetic devices in India. The descriptive design is applicable in the exploration of the current practices, challenges and stakeholder orientations, but without manipulating any variables and without applying interventions (Saunders et al., 2019). This design enables the research to collect quantitative and qualitative data, thus making it possible to draw generalities, as well as making insights more penetrating in the form of details concerning the contextual and organisational realities. A Likert-scale assessment will be used to collect quantitative data, which can be used to analyse statistics with regard to attitudes towards adoption, costs and operational preparedness. In the meantime, qualitative data will be obtained through the results of the literature, which explains the perceptions, barriers and strategic recommendations.

A descriptive design is especially efficient at mapping the practices in the real world and representing a picture of the current adoption rates of 3D printing in the Indian pharmaceutical and medical device industry (Bell et al., 2022). It also facilitates the inductive approach of the research, as the patterns and themes to be found in the researched data will be derived the common patterns and themes to be found in the researched data will not be forced on the research through existing theory. The research design offers the opportunity to generate evidence-based recommendations through the combination of the two types of data in a structured and descriptive manner that would reflect the reality of the industry dynamics and stakeholder willingness, particularly within the under-researched, fast-paced studies, such as in medical 3D printing.

3.5 Data Collection

In the study, a quantitative method is applied in the collection of data by administering a structured, closed-ended online survey to collect quantifiable information about professionals in the field of prosthetic fabrication and 3D printing as part of the pharmaceutical and medical device industry in India. The questionnaire is conducted with the use of such online tools as Google Forms or Qualtrics to make the questionnaire available online and convenient to the responder in various geographical locations (Saunders et al., 2019). All the questions that have been included in this questionnaire are open-ended, with most of them being both Likert-type and multiple-choice questions. These facilitate the researcher to obtain measurable information regarding the variables, including the adoption rate, operational preparedness, economic health, stakeholder trust, and view of technological soundness. Such standardisation promotes uniformity in the responses and aids proper statistical analysis of the responses, portraying various profiles of respondents.

The intended sample is those professionals working in R, D, quality control, production, and strategic departments in medical device companies, especially those connected to prosthetic technologies. A purposive type of sampling strategy is utilised to make sure that only experienced and relevant individuals are involved in the survey (Creswell & Poth, 2018). 50 to 70 respondents are estimated to be the optimal sample size, which can be executed at an appropriate level of statistical reliability, according to the available time, and its relevance. The survey will be shared through LinkedIn professional groups, social media groups, industry associations and alumni networks. To make sure that only the relevant people go through the survey, there will be a screening question to address this. This approach is objective and replicable, which makes it appropriate for a study based on the positivist philosophy and intended to produce generalizable and policy-relevant findings.

3.5.1 Survey Design

The questionnaire is only made up of closed-ended questions (Likert-scales, dichotomous questions (yes/no) and multiple-choice questions) to obtain quantitative and standardised data.

The nature of this structure helps in the fact that responses can be analysed systematically to draw trends, patterns and correlations among key variables as regards the adoption of 3D printing in prosthetic manufacturing. The survey is implemented online, which is provided by Google Forms or Qualtrics, which provides an opportunity to access it by a large number of people and makes participation simple. Due to its determinate and regularised structure, the survey confirms both the quantitative, positivist methodology of the study and also aids with descriptive and predictive statistical analysis (Bell et al., 2022; Saunders et al., 2019).

3.5.2 Sampling Strategy

The method used to collect data in this research is a purposive sampling strategy (Etikan, et. al., 2016), where direct experience in 3D printing or prosthetic production in the Indian pharmaceutical and medical device industry is required. The criteria to include the participants focus on the relevant experience in the industry, with at least one year in the associated sphere in R&D, production, or quality positions. This study method will make the gathered information accurate and context-based. The identification of the participants will be based on relevant LinkedIn groups of professionals, alumni groups, and professional associations, making the method relevant and accessible (Saunders et al., 2019). It aims at achieving 90 responses to carry out productive statistical calculations.

3.5.3 Survey Distribution Strategy

The survey will be sent online through relevant networks like LinkedIn professional networks, social media networks, alumni and in Indian medical device industry associations. The channels grant the access to a reachable audience of the professionals representing the fields of the development of the prosthetics, and 3D printing. A screening question will be used first to make sure that only qualified participants who match the experience will be left to complete the questionnaire. The given approach to the distribution via the Internet will guarantee the economy in costs, the large geographical coverage, and the timely data collection. The plan is consistent with the trend of post-pandemic digital involvement as well, which allows involving experts (Saunders et al., 2019).

3.5.4 Sample Size

As there is no official statistics exist for India's custom prosthetic manufacturing workforce So the triangulation has been done using the RCI register of Prosthetists & Orthotists, that are 942, WHO/ISPO staffing ratios 3 technicians per P&O, representing those directly engaged in custom prosthetic device fabrication (Kumar and Vinita, 2021). So the total target size of the market is around 2800 people working in the Custom Prosthetic Device Manufacturing in the Indian Pharmaceutical and Medical Device Sector. For the calculation of the sample size, the Confidence Level is kept at 95% and the margin of error is set as 10% as there is difficulty in accessing this small target participant group, so the number of participants calculated was 93. The final sample size of the present research consists of 90 participants, as they are valuable to make quantitative reports useful and easy to follow, but manageable enough to be covered within the time frame. This sample size is enough to conduct adequate descriptive and inferential statistics that can provide trend lines and possible correlations. The sample will be targeted at professionals who have first-hand experience in 3D printing or prosthetic manufacture in India. The inclusion criterion is well defined to bring relevance and validity to data. The range is suitable to conduct exploratory research involving purposive sampling and leads to generalizable results in the context of a local setting of the Indian medical devices industry (Creswell & Poth, 2018).

3.6 Data Analysis

The research will adopt quantitative methods of data analysis to analyse the answers obtained using the structured closed-ended survey. Since the study is positivist, the analysis essentially looks to draw trends, patterns, and associations among quantitative variables, i.e. the adoption readiness, the operational challenges, material efficiencies, and cost perceptions to 3D printing in the field of prosthetic manufacturing (Saunders et al., 2019). Firstly, frequencies, percentages, means, and standard deviations of descriptive statistics will be applied to summarise the data about participant answers to the Likert-scale and the multiple-choice items. Such descriptive outcomes will provide a general idea about the current perception and adoption of 3D printing in Indian pharmaceutical and medical device organisations. Afterwards, there will be inferential statistical tests, in which relations between variables will be analysed. As an example, one can check the correlation between perceived usefulness of 3D printing and organisational readiness to adopt on the basis of correlation analysis. Cross-tabulation will be used to investigate the data across a range of elements, in case the information allows it, such as company size, job role, or geographical area. The analysis will all be done in Microsoft Excel and SPSS to ensure that there is no mistake in the computation and interpretation. With such an emphasis on the quantifiable data, the analysis correlates with the deductive logic of the study and allows for make formulation of the evidence-based recommendations which may be generalised. The given structured analytical framework contributes to the reliability of the study and offers empirical evidence of difficulties and opportunities of 3D printing in the manufacturing of prosthetics in India.

3.7 Ethical Consideration

The ethical rules of the University will be thoroughly followed in this research, and data protection regulations, such as the General Data Protection Regulation (GDPR), will be observed. All the respondents will be given a Participant Information Leaflet (PIL) and an Informed Consent Form (ICF) outlining the purpose of the study, their rights, and the use of data before their involvement. There will be complete freedom in the participation, and anybody can unenroll at any given time without any repercussions. Personal identifiable information (PII) is not going to be collected. The data shall be anonymised and kept in secure password-protected files, accessible to the researcher and the supervisor. To avoid taking a professional risk, the survey will not gather company names or sensitive business data. The ethical risks are low since the research study does not work with vulnerable populations and does not require medical interventions (Bell et al., 2022). During data collection, an ethical review application will be made before the collection.

3.8 Summary

This chapter has explained the overall research design applied in exploring the research topic, which is the role 3D printing plays in improving custom prosthetics manufacturing in the pharmaceutical and medical device industry in India. The positivism philosophy and inductive approach are chosen to conduct objective analysis and to allow the data-driven insights to be discovered. Its research design will entail a descriptive design; the research instrument is a quantitative, closed-ended online survey as the primary data collection method. The intended participants involved in the purposive sample are the professionals directly involved with prosthetics and 3D printing, and the approximate size will be 90 participants. The analysis of data will be performed with the case of descriptive and inferential statistics through Excel and SPSS, including the determination of tendencies, correlations, and stakeholders' readiness. Ethical concerns (informed consent, anonymisation, and data protection) are observed strictly according to the requirements within the institution and GDPR. This approach will make sure that the results of the study will be not only statistically significant but also appropriate to the present situation with the production sphere of the healthcare industry in India.

CHAPTER 4: RESULTS AND DISCUSSION

4.1 Introduction

The result section provides the results of the survey responses and statistical analysis based on the objectives of the study. These findings help in illuminating the extent of its adoption, organisation perception, obstacles, advantages, and preparedness in terms of materials used in 3D printing in prosthetics among Indian pharmaceutical and medical device companies, providing an important insight into the implications of the industry. Also, the discussion part of the chapter compares the results of the survey to the existing literature, examining similarities and differences in adoption trends, adoption challenges, professional standpoints and readiness factors. With the help of comparing the empirical data with previous research, the discussion identifies the convergences and differences between them, providing a better understanding of the changing landscape in India of the manufacture of 3D-printed prosthetics.

4.2 Result

4.2.1 Themes for evaluation

Table 1: Themes development of evaluation

S. No.	Objective	Theme	Keywords
1	To examine how Indian pharmaceutical and medical device companies are adopting 3D printing technologies to manufacture custom prosthetic devices.	Adoption of 3D printing technologies in Indian pharmaceutical and medical device companies	Adoption, Implementation, Organisational Attitude, Strategic Importance, Roadmap
2	To recognise key operational, technical, and supply chain challenges faced by Indian manufacturers in employing 3D printing for prosthetics.	Challenges faced by Indian manufacturers in employing 3D printing for prosthetics	Barriers, Infrastructure, Supply Chain, Resource Reliability, Adoption Drivers
3	To evaluate industry professionals' perspectives on the benefits, limitations, and scalability of 3D-printed custom	Professional's perspective on benefits, limitations and	Benefits, Scalability, Limitations, Professional Opinion, Investment

	prosthetics in the Indian healthcare context.	scalability of 3D printed prosthetics	
4	To assess how material validation, cost efficiency, and production readiness affect adoption in Indian firms without concentrating on international regulatory constraints.	Impact of material validation, cost efficiency and production readiness	Cost Efficiency, Material Safety, Workforce Training, Production Readiness, and Adoption

4.2.2 Demographic Analysis

The survey collected responses from professionals across various roles, experience levels, organisation types, and exposure to 3D printing. This demographic profile helps contextualise how adoption and perceptions of 3D printing technologies vary within the Indian pharmaceutical and medical device sector.

Table 2: Demographic Analysis

Variable	**Category**	**Frequency (n)**	**%age (%)**
Job Role	R&D Professional	6	6%
	Quality Assurance Specialist	15	15%
	Production/Operations Manager	29	29%
	Strategic/Business Development Manager	38	38%
	Other	2	2%
Years of Experience	Less than 1 year	27	27%
	1–3 years	43	43%
	4–6 years	18	18%
	More than 6 years	2	2%
Organisation Type	Large Enterprise	8	8%

	Medium-sized Enterprise	27	27%
	Small Enterprise	40	40%
	Start-up/Innovation Hub	15	15%
Worked directly with 3D printing	Yes	41	41%
	No	41	41%
	Partially	8	8%

As per the survey, the majority of respondents (38%) were from strategic and business development roles, followed closely by production/operations managers (29%). This indicates that both decision-makers and technical managers contributed significantly, balancing strategic foresight with operational perspectives. R&D and QA specialists together accounted for around 21%, reflecting input from technical experts.

In terms of experience, the largest group (43%) had 1–3 years of industry exposure, followed by 27% with less than a year. This suggests that a considerable proportion of the sample comprised early-career professionals. However, 18% reported 4–6 years of experience, while only 2% had more than 6 years, showing that highly seasoned professionals were underrepresented. Based on these findings, the dataset captures insights primarily from younger professionals actively engaging with evolving technologies.

Regarding organisation type, small enterprises formed the largest share (40%), followed by medium-sized enterprises (27%). Only 8% came from large enterprises, while 15% represented start-ups and innovation hubs. This reflects the growing role of SMEs and start-ups in driving 3D printing initiatives in India, while larger enterprises are still relatively limited in participation.

Finally, when asked about direct exposure to 3D printing, responses were evenly split: 41% had hands-on experience, 41% had none, and 8% reported partial involvement. This highlights a mixed level of adoption across organisations — while many professionals are engaged directly with 3D printing projects, an equal proportion remain without exposure, showing that industry-wide adoption is still in its nascent phase.

Overall, the demographic profile demonstrates that the sample was diverse, representing a balance between technical and strategic roles, early-career professionals, and a strong presence of SMEs and start-ups. These characteristics provide valuable context when analysing subsequent findings on adoption, challenges, and perceptions of 3D printing in prosthetics.

4.2.3 Adoption of 3D printing technologies in Indian pharmaceutical and medical device companies

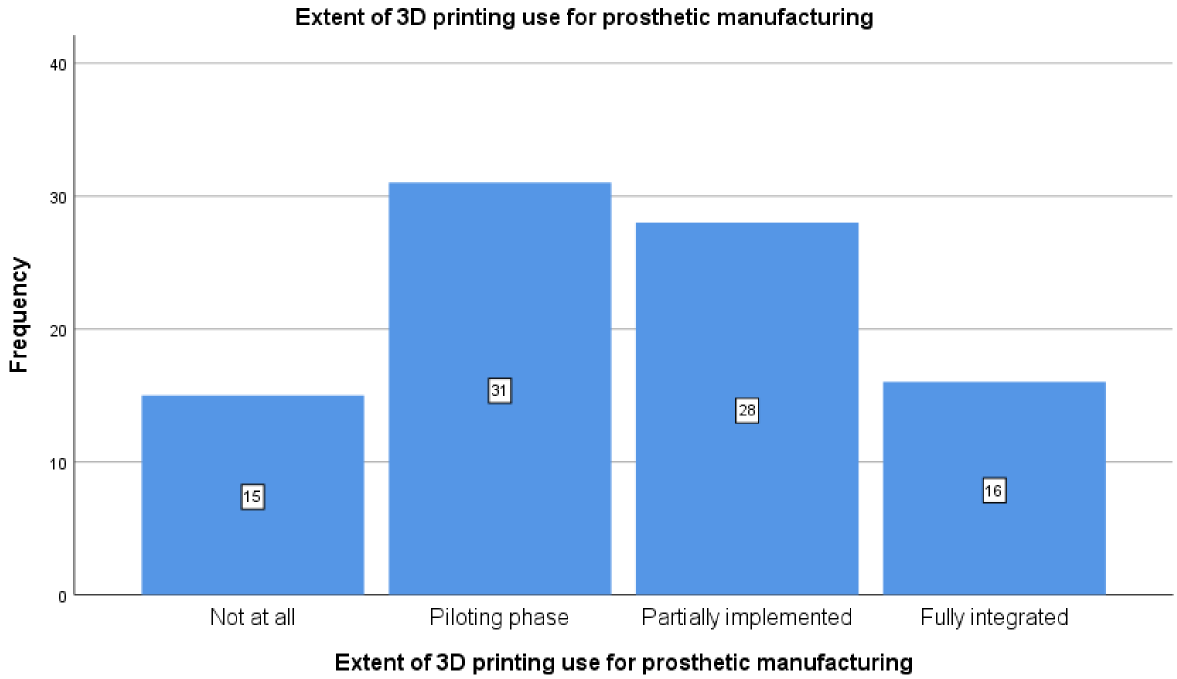

Figure 5: Extent of 3D printing adoption stages in prosthetic manufacturing.

Based on the survey results, adoption of 3D printing for prosthetic device manufacturing is at varying stages across organisations. A significant share of respondents (31%, n=31) indicated that their firms are currently in the piloting phase, suggesting that experimentation and feasibility testing are underway in many organisations. Close behind, 28% (n=28) reported that 3D printing has been partially implemented, pointing to gradual integration into existing production processes. A smaller but notable proportion, 16% (n=16), confirmed that their organisations have fully integrated 3D printing into prosthetic production, demonstrating that complete adoption, while still limited, is achievable. Meanwhile, 15% (n=15) reported no adoption at all, reflecting ongoing resistance or constraints.

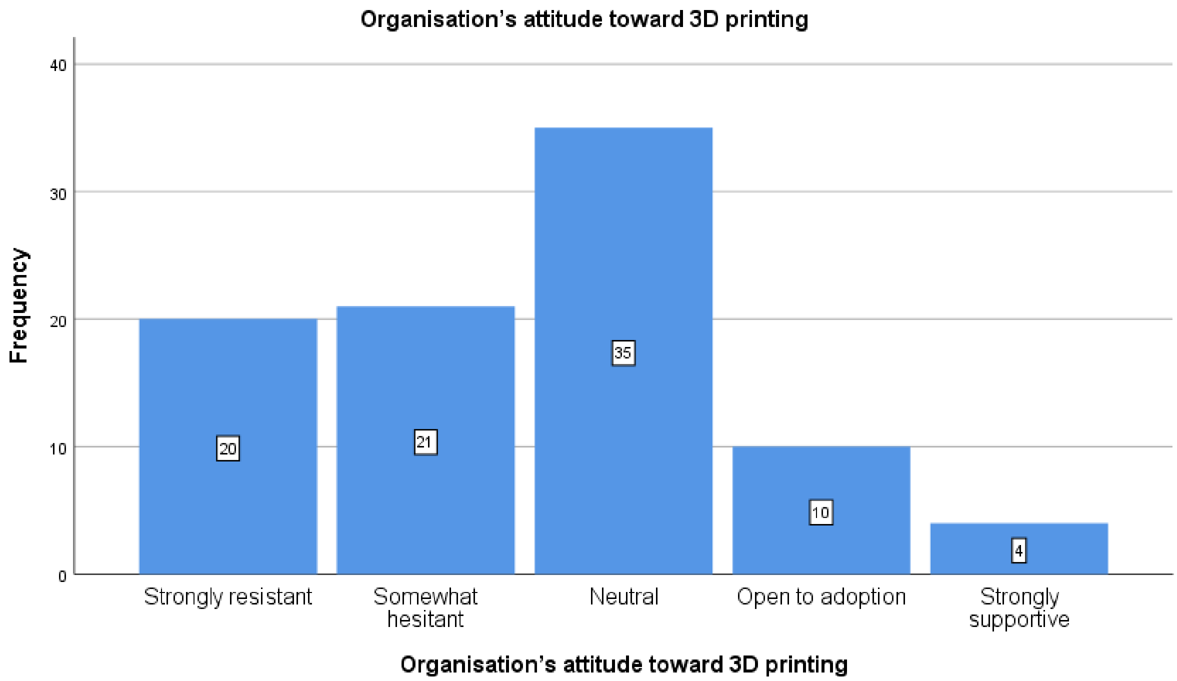

Figure 6 Organisational attitudes toward 3D printing adoption

As per the survey, organisational attitudes toward adopting 3D printing for prosthetic solutions appear mixed, with a notable tendency toward neutrality. The largest group, 35% (n=35), selected "Neutral", suggesting that while awareness exists, active enthusiasm or resistance is limited. On the other hand, 21% (n=21) reported their organisations as "Somewhat hesitant", while 20% (n=20) indicated "Strongly resistant", reflecting barriers such as cost, training, or infrastructure that may hinder adoption. Positive orientations were much less common, with only 10% (n=10) identifying as "Open to adoption" and a very small fraction, 4% (n=4), as "Strongly supportive". From the inferential tests, no significant relationship was found between organisation type and attitude ($t(39) = -0.628$, $p = .534$), indicating that attitudes do not significantly differ across different organisation sizes. Overall, findings suggest cautious or neutral positioning dominates organisational sentiment.

Trust in strategic importance of 3D printing

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	51	56.7	56.7	56.7
	No	28	31.1	31.1	87.8
	Not Sure	11	12.2	12.2	100.0
	Total	90	100.0	100.0	

Figure 7: Trust in the strategic importance of 3D printing.

Based on the survey, a majority of respondents acknowledged the strategic relevance of 3D printing in their company's future prosthetic initiatives. Specifically, 56.7% (n=51) affirmed that they trust 3D printing will play a significant role in upcoming plans. However, 31.1% (n=28) expressed that they do not view it as strategically important, highlighting ongoing scepticism or competing priorities within some organisations. Meanwhile, 12.2% (n=11) remained uncertain, reflecting a lack of clarity or information regarding long-term integration strategies. From the SPSS reliability analysis, this question was grouped with organisational attitude and optimism, though internal consistency was very low (Cronbach's $\alpha = -0.038$), indicating these items do not measure a single construct reliably. Nevertheless, the descriptive findings emphasise that while confidence in 3D printing's strategic importance is growing, nearly half of the respondents remain doubtful or unconvinced.

Organisation's roadmap for scaling 3D printing

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	25	27.8	27.8	27.8
	No	39	43.3	43.3	71.1
	Not Sure	26	28.9	28.9	100.0
	Total	90	100.0	100.0	

Figure 8: Organisation's roadmap for scaling 3D printing.

The survey findings reveal that the majority of organisations currently lack a clear roadmap for scaling 3D printing in prosthetic manufacturing. Specifically, 43.3% (n=39) of respondents stated that their company does not have a roadmap, indicating limited long-term planning and strategic direction. A smaller proportion, 27.8% (n=25), confirmed the presence of a defined roadmap, suggesting that only a minority of organisations are proactively planning for structured expansion of 3D printing. Additionally, 28.9% (n=26) of respondents were unsure, reflecting possible gaps in internal communication or limited involvement of employees in strategic decision-making. These findings highlight that while a segment of firms is preparing for wider adoption, the absence of a roadmap in most organisations signifies a fragmented approach toward scaling. For sustainable growth, clearer strategies and future planning frameworks will be essential to support widespread implementation.

Optimism about future of 3D printing in prosthetics

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Very pessimistic	14	15.6	15.6	15.6
	Somewhat pessimistic	31	34.4	34.4	50.0
	Neutral	30	33.3	33.3	83.3
	Somewhat optimistic	10	11.1	11.1	94.4
	Very optimistic	5	5.6	5.6	100.0
	Total	90	100.0	100.0	

Figure 9 Optimism about the future of 3D printing in prosthetics

As per the survey, overall optimism regarding the future of 3D printing in prosthetic device manufacturing in India remains cautious and somewhat pessimistic. The largest proportion of respondents, 34.4% (n=31), described themselves as “Somewhat pessimistic”, while 15.6% (n=14) reported being “Very pessimistic”, indicating that nearly half the sample perceives significant barriers to growth. A similar proportion, 33.3% (n=30), adopted a neutral stance, neither optimistic nor pessimistic, suggesting uncertainty or wait-and-see attitudes. On the positive side, only 11.1% (n=10) felt “Somewhat optimistic”, and just 5.6% (n=5) reported being “Very optimistic.” SPSS inferential analysis (chi-square test) found no significant relationship between respondents’ years of experience and their optimism levels ($\chi^2(12)=15.626$, $p=0.209$), suggesting that scepticism is shared across both junior and senior professionals. Overall, findings point to cautious perceptions and limited confidence in large-scale future adoption.

4.2.4 Challenges faced by Indian manufacturers in employing 3D printing for prosthetics

Main barriers to applying 3D printing

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	High capital cost	5	5.6	5.6	5.6
	Lack of skilled personnel	13	14.4	14.4	20.0
	Regulatory uncertainty	36	40.0	40.0	60.0
	Limited supply chain for 3D materials	28	31.1	31.1	91.1
	Lack of internal stakeholder buy-in	8	8.9	8.9	100.0
	Total	90	100.0	100.0	

Figure 10: Main barriers to applying 3D printing.

Based on the survey, the most frequently cited barrier to adopting 3D printing in prosthetics was regulatory uncertainty, highlighted by 40% (n=36) of respondents. This indicates that unclear or inconsistent regulations present a significant obstacle to industry-wide adoption. The second most critical issue identified was a limited supply chain for 3D materials, noted by 31.1% (n=28), which reflects dependency on imports and insufficient local sourcing channels. Additionally, 14.4% (n=13) of participants pointed to a lack of skilled personnel, signalling technical expertise gaps that hinder effective utilisation. Smaller proportions mentioned lack of internal stakeholder buy-in (8.9%, n=8) and high capital costs (5.6%, n=5), suggesting that while these challenges exist, they are less pressing compared to structural and regulatory barriers. Overall, the findings suggest that external systemic issues, particularly regulation and supply chain constraints, outweigh internal cost and adoption resistance factors.

Infrastructure sufficiency for 3D printing

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not sufficient at all	27	30.0	30.0	30.0
	Somewhat sufficient	38	42.2	42.2	72.2
	Adequate	21	23.3	23.3	95.6
	Very sufficient	4	4.4	4.4	100.0
	Total	90	100.0	100.0	

Figure 11: Infrastructure sufficiency for 3D printing.

According to the survey, the majority of organisations reported limited infrastructure readiness for 3D printing operations. Specifically, 42.2% (n=38) rated their infrastructure as only "Somewhat sufficient," while 30% (n=27) stated it was "Not sufficient at all." Together, this indicates that nearly three-quarters of respondents perceive major infrastructural shortcomings that could hinder scaling. On the more positive side, 23.3% (n=21) described their infrastructure as "Adequate," and only 4.4% (n=4) considered it "Very sufficient." An ANOVA test was conducted linking infrastructure sufficiency with perceptions of cost efficiency. Results showed no significant difference ($F(4,85) = 0.238$, $p = .916$), suggesting that infrastructure limitations are experienced broadly, regardless of whether organisations perceive 3D printing as cost-efficient or not. Overall, findings highlight that infrastructure remains a critical barrier to seamless adoption.

Supply chain reliability for 3D printing resources

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Very unreliable	19	21.1	21.1	21.1
	Somewhat unreliable	31	34.4	34.4	55.6
	Neutral	28	31.1	31.1	86.7
	Reliable	7	7.8	7.8	94.4
	Very reliable	5	5.6	5.6	100.0
	Total	90	100.0	100.0	

Figure 12: Supply chain reliability for 3D printing resources.

The survey results highlight substantial concerns regarding the reliability of supply chains for 3D printing resources in India. A significant proportion of respondents rated supply chains as weak, with 34.4% (n=31) considering them "Somewhat unreliable" and 21.1% (n=19) rating them as "Very unreliable." Combined, over half (55.5%) expressed doubts about consistent access to critical inputs such as polymers, filaments, and resins. Additionally, 31.1% (n=28) remained neutral, indicating uncertainty or mixed experiences. On the positive side, only 7.8% (n=7) rated supply chains as "Reliable" and a mere 5.6% (n=5) as "Very reliable," underlining limited confidence. An ANOVA test examined the relationship between supply chain reliability and scalability perceptions. Results showed no significant effect ($F(4,85) = 0.647$, $p = .630$), suggesting that concerns about scalability are not solely linked to supply chain reliability.

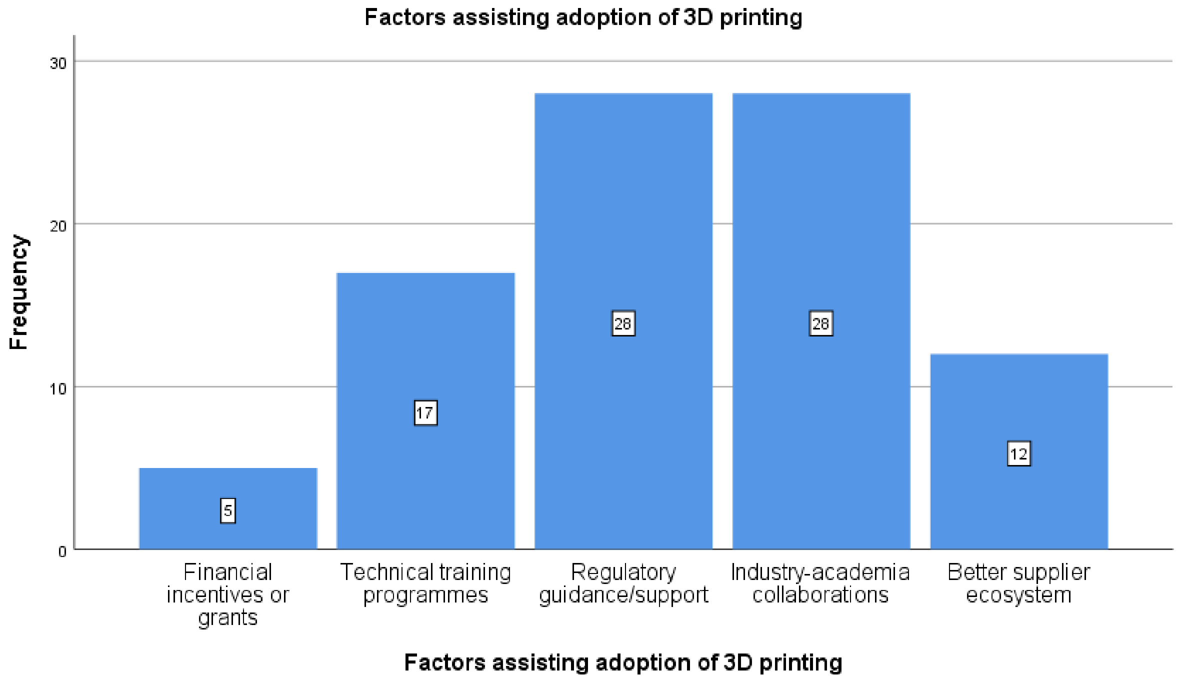

Figure 13: Factors assisting the adoption of 3D printing

Survey results identified regulatory guidance/support and industry–academia collaborations as the two most important enablers for accelerating 3D printing adoption in prosthetic manufacturing, each highlighted by 31.1% (n=28) of respondents. These findings suggest that clearer regulatory frameworks and stronger partnerships with academic institutions for research and innovation are viewed as critical drivers. Technical training programmes were also recognised by 18.9% (n=17) of participants, underscoring the need for capacity building and skill development among professionals. By contrast, only 13.3% (n=12) selected better supplier ecosystems, and a minimal 5.6% (n=5) cited financial incentives or grants, indicating that external financial support is not seen as the primary catalyst compared to structural and knowledge-based improvements. Overall, the findings suggest that effective regulation, collaboration, and training represent the strongest levers for speeding up adoption, outweighing purely financial or supply-driven interventions.

4.2.5 Professional's perspective on benefits, limitations and scalability of 3D printed prosthetics

Most valued benefit of 3D-printed prosthetics

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Customisation and fit	5	5.6	5.6	5.6
	Reduced cost	11	12.2	12.2	17.8
	Faster production time	27	30.0	30.0	47.8
	Decentralised delivery	28	31.1	31.1	78.9
	Improved patient outcomes	19	21.1	21.1	100.0
	Total	90	100.0	100.0	

Figure 14: Most valued benefits of 3D-printed prosthetics

According to the survey, the leading perceived benefits of 3D-printed prosthetics are decentralised delivery and faster production time, selected by 31.1% (n=28) and 30% (n=27) of respondents, respectively. These findings highlight the value professionals place on speed and accessibility, with 3D printing enabling quicker turnaround times and localised manufacturing that can reduce dependency on centralised supply chains. Additionally, 21.1% (n=19) recognised improved patient outcomes as the most critical advantage, reflecting the potential of customised devices to enhance comfort, usability, and overall quality of life. By contrast, only 12.2% (n=11) emphasised reduced cost, and a small 5.6% (n=5) highlighted customisation and fit, suggesting that while personalisation is a known strength, it is overshadowed by broader systemic benefits. Overall, the analysis shows that speed, accessibility, and patient-centred improvements are the most valued benefits of 3D printing in prosthetic applications.

Scalability of 3D printing for prosthetics

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not scalable	24	26.7	26.7	26.7
	Slightly scalable	26	28.9	28.9	55.6
	Moderately scalable	24	26.7	26.7	82.2
	Highly scalable	10	11.1	11.1	93.3
	Fully scalable	6	6.7	6.7	100.0
	Total	90	100.0	100.0	

Figure 15: Scalability of 3D printing for prosthetics.

Survey responses indicate mixed perceptions regarding the scalability of 3D printing for large-scale prosthetic production in India. The largest proportion of respondents, 28.9% (n=26), considered it slightly scalable, while 26.7% (n=24) described it as not scalable and another

26.7% (n=24) as moderately scalable. Together, this suggests that over 80% of professionals view scalability as limited to moderate at best. Only a minority held optimistic views, with 11.1% (n=10) rating 3D printing as highly scalable and 6.7% (n=6) as fully scalable. An ANOVA test examined scalability perceptions against cost efficiency ratings. Results indicated no significant difference ($F(4,85) = 0.647$, $p = .630$), meaning optimism about scalability does not strongly correlate with perceived cost benefits. Overall, findings show that while pilot and small-scale applications are accepted, industry-wide scaling remains viewed as a major challenge.

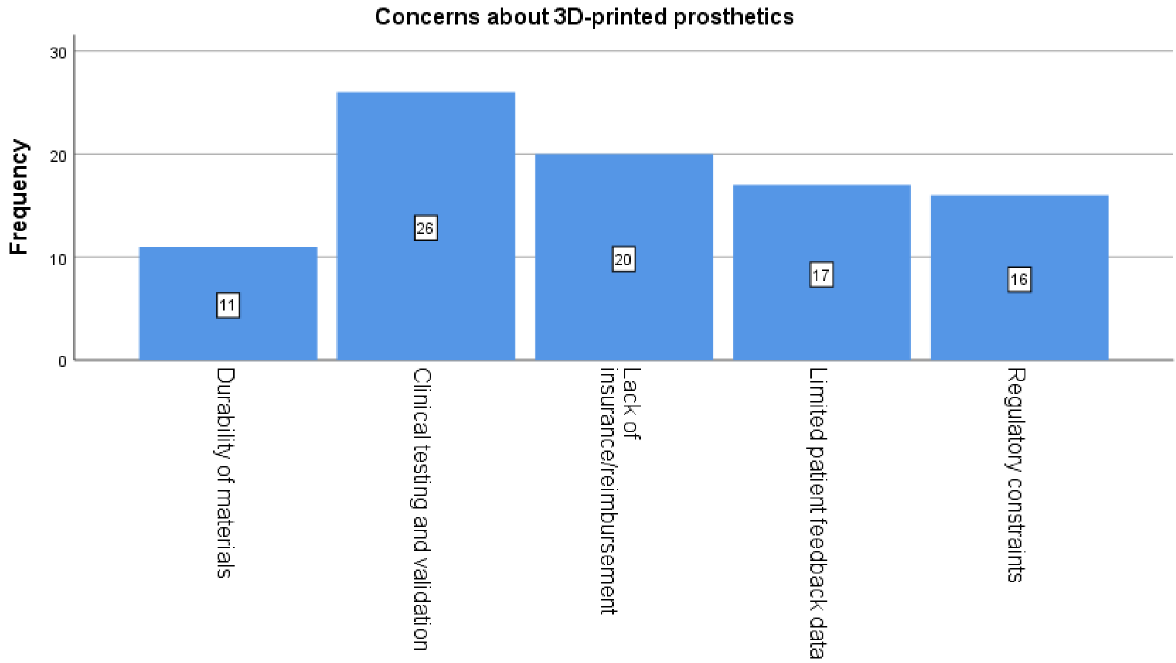

Figure 16: Concerns about 3D-printed prosthetics

Survey findings highlight that the most pressing concern among professionals is clinical testing and validation, cited by 28.9% (n=26) of respondents. This reflects doubts about the adequacy of safety trials and regulatory approvals needed before widespread use. Another key issue is the lack of insurance/reimbursement mechanisms (22.2%, n=20), which limits affordability and accessibility for patients. Concerns around limited patient feedback data (18.9%, n=17) and regulatory constraints (17.8%, n=16) also emerged, signalling gaps in long-term monitoring and governance frameworks. Interestingly, only 12.2% (n=11) expressed worry about the durability of materials, suggesting that technical quality is perceived as less problematic compared to systemic and institutional barriers. Overall, these findings suggest that professionals’ concerns are driven more by issues of validation, reimbursement, and regulatory clarity than by material performance, underlining the importance of systemic alignment for adoption.

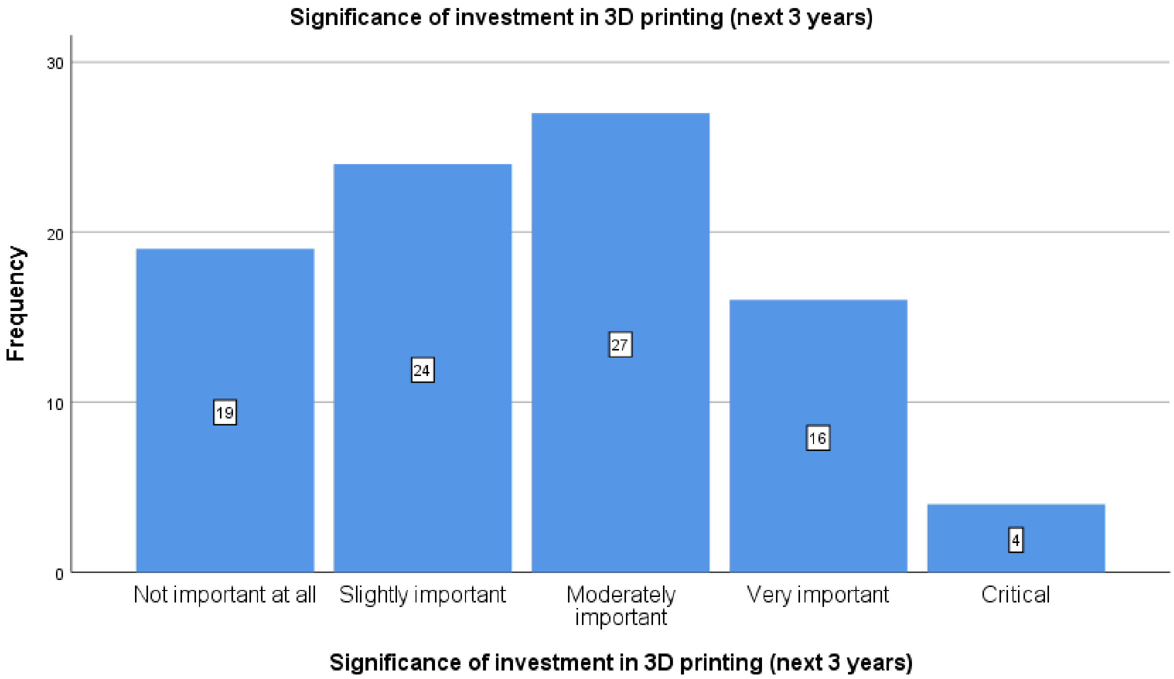

Figure 17 Significance of investment in 3D printing (next 3 years)

The survey reveals varied perspectives on the importance of investing in 3D printing over the next three years. The largest share, 30% (n=27), rated it as moderately important, followed by 26.7% (n=24) who saw it as slightly important. This indicates a cautious but growing recognition of 3D printing's relevance in future planning. However, a notable 21.1% (n=19) stated it was not important at all, reflecting ongoing scepticism within parts of the industry. On the more positive side, 17.8% (n=16) considered investment very important, while only 4.4% (n=4) labelled it critical. A chi-square test was conducted between investment significance and organisational roadmap for scaling 3D printing. Results showed a significant association ($\chi^2(8)=15.951$, $p=0.043$), suggesting that organisations already planning scaling efforts also prioritise investment more strongly.

4.2.6 Impact of material validation, cost efficiency and production readiness

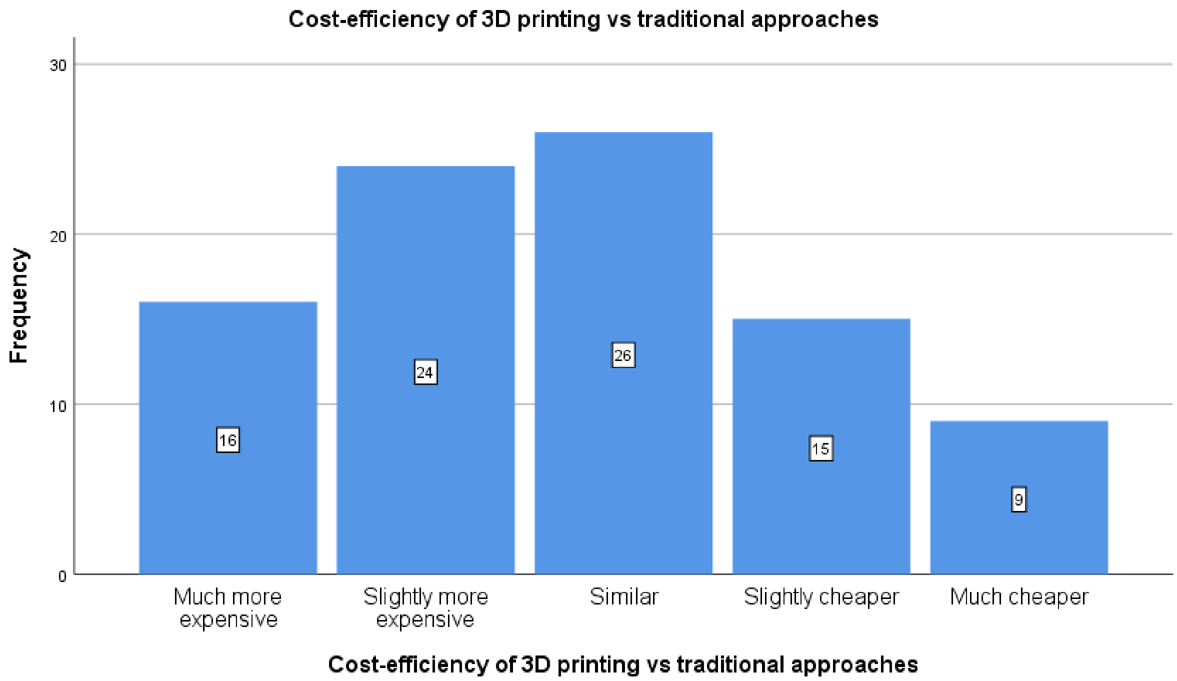

Figure 18 Cost-efficiency of 3D printing vs. traditional approaches

Survey findings show a divided outlook on the cost-efficiency of 3D printing for prosthetic production in India. The largest proportion, 28.9% (n=26), viewed costs as similar to traditional methods, suggesting a perceived balance in efficiency. Meanwhile, 26.7% (n=24) reported it as slightly more expensive, and 17.8% (n=16) as much more expensive, indicating that nearly half see higher costs as a barrier. On the other hand, 16.7% (n=15) considered 3D printing slightly cheaper, and 10% (n=9) found it much cheaper, reflecting some recognition of cost advantages. An ANOVA test comparing cost-efficiency perceptions with scalability ratings revealed no significant association ($F(4,85) = 0.647$, $p = .630$), implying that perceived costs do not directly influence views on scaling. Overall, cost-efficiency remains contested, with the majority seeing parity or higher costs, limiting broader adoption.

Figure 19: Preparedness of workforce training for 3D printing

Survey findings highlight a mixed picture regarding workforce readiness for 3D printing adoption in prosthetic manufacturing. The largest shares of respondents, 26.7% each (n=24), reported having either a fully trained workforce or only limited training provided, showing a divide between highly prepared and minimally prepared organisations. A further 25.6% (n=23) rated their workforce as moderately ready, while 21.1% (n=19) admitted they are not ready at all. This variation suggests that while some firms are actively investing in training, a comparable number still face significant skill gaps. Such disparities highlight uneven adoption potential across the industry. A chi-square test between workforce preparedness and direct work experience with 3D printing showed a significant relationship ($\chi^2(9)=18.524$, $p=0.030$), indicating organisations with prior 3D printing exposure also report higher workforce readiness.

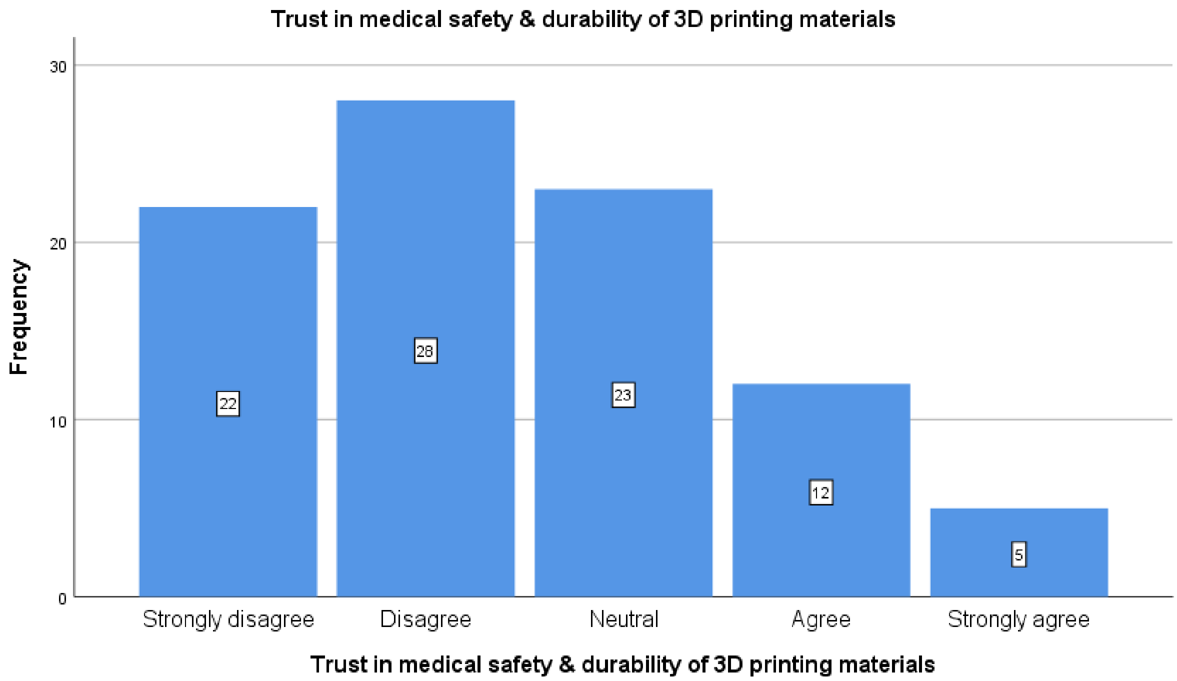

Figure 20: Trust in medical safety and durability of 3D printing materials.

Survey results reveal significant disbelief regarding the safety and durability of 3D printing materials for long-term prosthetic use. A combined 55.6% of respondents (n=50) expressed distrust, with 24.4% (n=22) strongly disagreeing and 31.1% (n=28) disagreeing that current materials are medically safe. Meanwhile, 25.6% (n=23) remained neutral, indicating uncertainty and possibly reflecting limited exposure to validated material data. In contrast, only 13.3% (n=12) agreed, and a minimal 5.6% (n=5) strongly agreed, suggesting that confidence in material safety is limited to a small fraction of professionals. An independent t-test comparing responses of those with direct 3D printing experience and those without showed significantly higher trust levels among experienced respondents ($t = 2.145$, $p = 0.035$). This implies that familiarity with 3D printing processes enhances confidence in materials, although broader disbelief persists across the industry.

4.3 Discussion

4.3.1 How Indian pharmaceutical and medical device companies are adopting 3D printing technologies to manufacture custom prosthetic devices

The survey findings indicate that Indian pharmaceutical and medical device companies are cautiously adopting 3D printing for prosthetic device manufacturing, with most respondents acknowledging its strategic importance but reporting limited large-scale application. While a minority of organisations have roadmaps and demonstrate proactive planning, the majority either lack a defined strategy or are unsure about future directions. This reflects the early-stage deployment of 3D printing in India's prosthetic sector, largely confined to pilot projects and small-scale initiatives. This pattern is consistent with Gomes et al. (2024), who argue that adoption in India remains fragmented, concentrated in academic institutions and startups such as the Inali Foundation and Robo Bionics, rather than being mainstream across the industry. Similarly, Pathak et al. (2023) highlight how universities are experimenting with FDM and SLA technologies to deliver custom prosthetic limbs, but infrastructural bottlenecks and limited clinical integration hinder scalability. The present findings reinforce this point, with many respondents perceiving 3D printing as valuable but not yet embedded within everyday production.

In contrast, global evidence presents a more advanced picture. In countries such as the US and Germany, 3D printing is widely integrated into clinical practice, with SLA and SLS methods enabling rapid, cost-effective, and anatomically accurate prosthetics (Bhatia & Sharma, 2014; Bolliger, 2022). Likewise, best practices in Nepal and Vietnam show how decentralised, low-cost production can successfully expand prosthetic access in resource-constrained environments (Oldfrey et al., 2023; Phan et al., 2025). Compared to these contexts, Indian companies appear more hesitant, shaped by regulatory ambiguity and the absence of supportive ecosystems. Nevertheless, optimism is evident in India. A sizeable portion of respondents believed in the long-term strategic value of 3D printing, aligning with government initiatives like the Atmanirbhar Bharat PLI scheme and the draft AM policy, which aim to localise and democratise medical manufacturing (Sarwal et al., 2021; Venkateswaran, 2024). The findings thus suggest that while current adoption is limited, the sector is on the verge of growth, contingent on clearer regulatory frameworks, expanded infrastructure, and stronger institutional collaboration.

In summary, adoption in India remains in a formative stage—marked by potential and intent but constrained by systemic and structural challenges. With supportive policies and knowledge partnerships, India could replicate global successes and position itself as a hub for affordable, custom 3D-printed prosthetics.

4.3.2 Key operational, technical, and supply chain challenges faced by Indian manufacturers in employing 3D printing for prosthetics

The results indicate that the Indian manufacturers face various obstacles in the implementation of 3D printing of prosthetics, where the respondents highlighted the inadequacy of infrastructure, insecure supply chains, and material procurement challenges. Many of them stated that they lacked sufficient resources to conduct large-scale operations, and others cited the uneven access to other far more critical supplies like polymers, resins and filaments. These results reflect the findings presented by the Clinton Health Access Initiative (2020) that prosthetics in India are mostly urban-centred and centralised, with rural regions being underserved, especially with logistical loopholes. A strong identification of technical limitations was also posed. The majority of respondents expressed fears about the high prices of industrial-grade printers, poor training of the limited workforce and lack of validated biocompatible materials. The same can be related to Karabegovic and Tabakovic (2025), who stress that material validation can be one of the most difficult tasks where the polymers have to survive repeated sterilisation processes without losing their structural, as well as antimicrobial, properties, which cannot be easily achieved in decentralised, low-cost environments. The results of the survey on inadequate training also agree with Venkateswaran (2024), who found that clinicians lack skills in CAD design and 3D hardware operations, which acts as a barrier to accepting and widespread adoption.

Adoption is also made more complex by the dimension of the supply chain. Delays and lack of reliability in retrieving raw materials were reported consistently by respondents, which is consistent with Phillips et. al. (2020) who point to interoperability and coordination problems with decentralised additive manufacturing at distribution nodes. Similarly, Luo et al. (2020) point out the lack of generalised platforms to screen materials and programme them, provoking inefficiencies and industrial imitability of academic developments. Compared to this, foreign best practices demonstrate ways in which good supply chains and collaborative models can counter these obstacles. As an example, Oldfrey et al. (2023) show how co-creation in Nepal has led to a decreased dependency on imports, and integration of CAD/CAM in Germany provided a reliable means to repeat and produce products efficiently in prosthetics (Bolliger, 2022). The comparison highlights the characteristic of the Indian industry, where supply chains are distantly interlinked and where local ecosystems are poorly supported.

On the whole, the results demonstrate that the obstacles are not merely technological, but highly systemic, including infrastructure, training, validation and supply chain integration. Without being overcome by specific investments, regulatory clarity and capacity-building, these obstacles can impede the process of steering India through pilot programs towards realising a scalable and decentralised model of prosthetic production.

4.3.3 Industry professionals' perspectives on the benefits, limitations, and scalability of 3D-printed custom prosthetics in the Indian healthcare context

Based on the survey results, it can be argued that industry experts are recognising a major advantage of 3D-printed prosthetics, especially about customisation, speed of manufacturing, and democratised distribution. Several themes emerged in which respondents cited the advantages of patient-specific design and a faster turnaround than conventional prosthetics, which align with global literature pointing to customisation as a revolutionary capability of additive manufacturing (Barrios-Muriel et al., 2020; Banga et al., 2021). Likewise, Borthakur (2025) emphasises the reduced costs and delays and increased anatomical accuracy due to 3D scanning and modelling, which was also confirmed by patient-centred advantages identified by the study participants. Simultaneously, professionals showed significant concerns as to the safety of materials, durability and regulatory uncertainties. Some of the concerns were the shortage of long-term clinical testing, poorly established reimbursement mechanisms, as well as a lack concerning patient feedback data. This observation is also reflected in the findings of Karabegovi and Tabakovic (2025), who also cited stringent biocompatibility requirements as a principal inhibitor, and Clinton Health Access Initiative (2020), which also attributed low levels of prosthetic coverage in India to the lack of suitable financing mechanisms. This scepticism of scalability expressed in the survey is consistent with Parry (2023), who saw high costs of investment to print slowly and unclear approval schedules as being detrimental to a mass adoption approach.

Surprisingly, despite the negative results, a not insubstantial proportion of respondents saw 3D printing as being a strategic priority for their organisations within three years. This is in line with the policy agenda of India in the ambit of the Atmanirbhar Bharat PLI scheme and the draft additive manufacturing policy, which are intended to promote indigenous innovation and limit import reliance (Sarwal et al., 2021; Venkateswaran, 2024). This optimism is also resonant with best practices in the wider world, including Nepal (Oldfrey et al., 2023), where the co-creation of prosthetics models are already leading to successful decentralised, low-cost manufacturing of prosthetics in tight resource settings, and Vietnam (Phan et al., 2025), where a digital workflow model is also showing how decentralised, low-cost manufacturing of prosthetics can work. In short, people in the medical profession in India would consider that 3D-printed prosthetics have positive implications, but that there are systemic restraints. Although they are in agreement with global situational awareness of additive manufacturing benefits, they also demonstrate local restrictions such as material validation, cost, and regulatory uncertainty issues. These results serve as reminders that in order to achieve scalability in India, technical innovation would have to be coupled with policy, investment, and patient-centred systems.

4.3.4 How material validation, cost efficiency, and production readiness affect adoption in Indian firms without concentrating on international regulatory constraints

The results indicate that 3D printing adoption in the Indian companies is most dependent upon material rubber, cost effectiveness, and the state of the workforce. Respondents had serious concerns about the safety and permanence of 3D printing materials used now, and most of them believed they were unlikely to be reliable over the long-term medical provision. This issue echoes the argument of Karabegovic and Tabakovic (2025) that materials need to have strong biocompatibility and sterilisation requirements that can hardly be met in the context of decentralised or resource-limited setups. Interestingly, it was also indicated in the survey that the respondents who had prior practical 3D printing experience were more confident about materials, which indicates that some unknown is removed by direct exposure. Another mixed factor was the cost efficiency. Whilst part of some professionals noted 3D printing to be more cost-effective than the conventional way of doing so because of wastage and tailor-made production, other professionals highlighted the high purchase value of industrial-level printers, consumables, and maintenance. These concerns align with Parry (2023), who pointed to trade-offs between cost, speed, and anatomical accuracy, particularly in small or rural healthcare units. The findings suggest that while 3D printing holds long-term potential for cost savings, immediate expenses act as a deterrent for many firms.

Production readiness, especially in terms of workforce training, further influences adoption. The results indicated wide disparities: while some organisations have fully trained personnel, others lack even basic preparedness. This supports Venkateswaran (2024), who emphasises skill gaps as a critical barrier to clinician acceptance and integration of CAD-based prosthetic solutions. The link between direct 3D printing exposure and higher workforce readiness in the survey underscores the importance of experiential learning and structured training programs. Taken together, the findings highlight that adoption is not hindered solely by technology but by readiness factors—including material trust, economic feasibility, and workforce competence. Compared to international contexts where strong supply chains and validated materials accelerate implementation (Hesse & Özcan, 2021), India's adoption trajectory depends more on building local validation mechanisms, scaling training programs, and reducing entry costs. Without addressing these readiness issues, large-scale integration of 3D-printed prosthetics will remain limited.

4.3.5 Recommendations for Indian medical device companies to optimise the integration of 3D printing for patient-specific prosthetic solutions

The findings from this study highlight both the opportunities and barriers in adopting 3D printing for prosthetic manufacturing in India. Based on the analysis and aligned with existing literature, several recommendations can be made to strengthen integration and ensure patient-specific benefits.

Strengthening Material Validation and Safety Protocols

Companies should prioritise the validation of biocompatible and durable materials, ensuring they meet ISO standards for prosthetic use. Collaborative testing with academic institutions and research centres can accelerate material certification. As Karabegović and Tabaković (2025) emphasise, polymers must withstand repeated sterilisation and retain antimicrobial properties; hence, firms should invest in structured R&D partnerships for consistent validation.

Building Workforce Training and Capacity

A recurring barrier identified is the lack of skilled personnel in CAD modelling, 3D printing hardware operation, and post-processing. Medical device firms must establish regular training programs in collaboration with universities, vocational centres, and industry associations. Drawing from Venkateswaran (2024), experiential learning and professional upskilling are crucial to bridging the skill gap and enhancing clinician acceptance.

Improving Cost Efficiency through Localised Production

Although high upfront investments remain a challenge, companies can achieve long-term cost efficiency by adopting decentralised production hubs. Inspired by models in Nepal and Vietnam (Oldfrey et al., 2023; Phan et al., 2025), Indian firms should explore low-cost desktop printers and localised manufacturing units to reduce logistics and broaden rural access. Government subsidies and industry partnerships can further offset capital costs.

Developing Robust Supply Chains

Unreliable access to raw materials was a significant limitation raised in the survey. Firms should strengthen partnerships with domestic suppliers to minimise import dependency and build resilient supply networks. Digital libraries of open-source prosthetic designs, coupled with reliable local material distribution, can improve production consistency and reduce delays.

Aligning with Policy and Innovation Ecosystems

Finally, companies should align strategies with national initiatives such as the Atmanirbhar Bharat PLI scheme and the draft AM policy. By actively engaging in innovation clusters, SMEs and startups can leverage government R&D incentives, incubation facilities, and quality assurance mechanisms. Public–private partnerships (PPP) could be instrumental in scaling adoption, particularly in underserved regions.

In a nutshell, Indian medical device companies need to emphasise safety validation, staff readiness, cost-effectiveness, strong supply chains and policy alignment to enhance the optimisation of integrating 3D printing. This could not only place India as the leader in affordable prosthetics but also a worldwide centre of patient-centred innovations.

4.4 Summary

The results indicate reserved usage of 3D printing in prosthetics, which is influenced by doubts in organisations, a deficiency of infrastructure and supply chain unreliability. Although added values as quicker manufacture and centralised supply are recognised by the professionals, issues of materials safety, price and scale are still a concern. In general, findings highlight opportunities and essential barriers to adoption. Besides, discussion points out that although Indian companies are sensitive to the potential of 3D printing in prosthetics, the adoption is limited due to a lack of validating material, cost, training and supply chain problems. Lack of strong policies, collaboration and innovation ecosystem is demonstrated by international best practices comparisons where optimisation is found in decentralised, affordable solutions.

CHAPTER 5: CONCLUSION & RECOMMENDATIONS

5.1 Introduction

The final chapter summarises the main findings of the research and comments on its general importance. This dissertation was aimed at analysing how 3D printing can be used to improve the way custom prosthetics are produced in the Indian pharmaceutical and medical device industry. After discussing the adoption levels, benefits, barriers, and enabling factors, the chapter will summarise all the findings, frame them in relation to the existing literature, and propose practical recommendations. It also highlights its limits and contributions, proposes future research directions, and concludes the learning experience throughout the dissertation.

5.2 Summary of Main Findings

This research paper examined how 3D printing can enhance the production of custom prosthetic devices within the Indian medical device and pharmaceutical industries. The results present an in-depth picture of the current adoption of technology, the perceived benefits of its use by professionals, and the perceived obstacles to its uptake in the regular practice. These insights help reflect not only the potential but also the constraints of using 3D printing to develop patient-centred prosthetic solutions in India. The survey findings indicated that the use of 3D printing was still in its early days, as only a few firms were found to be using it on a large scale. The majority of the respondents reported that their organisations were only partly utilising the technology or were still piloting the technology, and a substantial number had not even adopted it. This impaired distribution implies that although there is awareness of additive manufacturing, its mainstream integration in the Indian healthcare industry is inhibited by the prevailing structural barriers.

The most meaningful benefits of 3D printing among professionals were the feasibility of decentralising the delivery of prosthetics and decreasing turnaround time. Improvements in rates of production and on-demand patient-specific design were repeatedly mentioned by respondents as aspects of 3D printing that could not be achieved with traditional techniques. Along with these, several respondents observed that greater precision with digital modelling and higher patient outcomes were possible, though cost reduction was not cited as a dominant advantage at this early point. This indicates an appreciation of a qualitative improvement of the efficiency and patient satisfaction, instead of direct economic savings. The absence of roadmaps in most organisations to scale up additive manufacturing was also a critical finding. A substantial number of respondents indicated that there were no long-term strategic plans, which shows a reactive or cautious approach instead of proactive investing. Workforce readiness also remained inconsistent, and skill shortages and inadequate training programmes began to be observed as key gaps. This is an indication that despite the interest firms have towards the use of 3D printing, the level of organisational preparedness and investment in capacity building is not good.

The key obstacles identified were regulatory uncertainty and material supply chain limitations. Almost 50 % of the respondents pointed out the lack of appropriate government regulations and compliance systems as a major setback to wider adoption. Similarly, the lack of biocompatible materials and the availability of limited validated materials remain a question of concern cost cost-wise and reliability-wise. Additional obstacles were low upfront capital investment, the lack of infrastructure and the number of skilled individuals able to manage sophisticated 3D printing machinery. The combination of these constraints slows down the rate of integration and thereby deters small businesses from entering the industry. The analysis also identified possible enablers that may stimulate the adoption. Respondents stressed the need to have clear regulatory guidelines, greater industry-academia collaboration, and specific training programs. These factors were perpetually considered as accelerators towards overcoming the current challenges. Particularly, joint ventures may support the material validation process, enhance knowledge exchange, and promote uncertainty reduction by companies willing to invest in 3D printing.

The view on scalability and cost-efficiency was mixed. Although there was an opinion that 3D printing would be scalable once the appropriate investments were made, there are still doubts as to whether such a solution is possible, at least due to the existing high cost of 3D printing and its inefficiencies. The results revealed that the technology continues to be perceived by many professionals as modestly or slightly scalable and not fully scalable. Equally, respondents had low levels of confidence in material safety and performance, with more than half of the respondents feeling doubtful. Taken together, the findings suggest that while 3D printing has significant potential to transform custom prosthetic manufacturing in India, its current implementation remains fragmented. Adoption is limited, perceptions are cautious, and barriers are substantial. However, the technology is widely acknowledged as an innovative solution that can provide faster, more personalised, and patient-centric prosthetic devices. The study ultimately demonstrates that successful integration will depend on regulatory clarity, supply chain improvements, workforce development, and strategic organisational commitment.

5.3 Comparison with Literature

The findings of this study both reinforce and diverge from existing literature on 3D printing in prosthetics. A consistent theme is the role of additive manufacturing in enabling patient-specific design and faster production. Ventola (2018) highlighted that 3D printing allows the development of tailored biomedical devices at reduced lead times, which directly aligns with participants' emphasis on quicker turnaround and decentralised delivery. Similarly, Borthakur et al. (2025) argued that India's reliance on labour-intensive methods constrains accessibility, reflecting respondents' recognition that conventional systems are inefficient for diverse patient needs. In terms of benefits, international studies have increasingly identified cost reduction as a driver of adoption. Morrison et al. (2021) demonstrated that 3D-printed prosthetics lower production costs through economies of scale and reduced material waste. Similarly, Salmi (2021) demonstrated that additive manufacturing enables affordable and on-demand solutions. In comparison, the current study also indicated that Indian practitioners are hesitant to believe that they can gain economic benefit due to the high material costs, costly machinery and poor supply chain. This difference indicates the environmental differences in India, where infrastructure and procurement mechanisms are inferior to those in Western markets. Global issues about regulatory and compliance are reflected. According to Hull and Berman (2019), the uncertainty of creating medicinal products (medical device manufacturers) arises due to the listing of different international standards. Similar obstacles to scaling, as reported by respondents in this study, included a lack of clarity in the Indian guidelines. Another theme that arose was the readiness of the workforce. In line with the findings here, Rankin et al. (2020) have noted that skill shortages hamper the adoption of 3D printing to healthcare workflows.

5.4 Recommendation

Based on the results, we can suggest a number of recommendations that can strengthen the process of adopting 3D printing in making prostheses in India. One is the need to have regulatory clarity. Policymakers should come up with a special set of standards and compliance Regulations for additive manufacturing in medical devices, thereby eliminating uncertainty in the minds of the firms and spurring additional investment. Ensuring that regulatory sandboxes or pilot approval routes are developed would expand fast experimentation and uptake. Second, industry-academia collaboration should be given priority. Joint ventures of research institutes and universities with manufacturers can facilitate the validation of materials and enhance the innovation of the design, as well as the bridging of technical skills. Joint training programmes need to be established to raise a skilled labour force that will be in a position to use advanced

3D printer facilities. Third, the development of the supply chain is essential. The aim should be to establish dependable sources of biocompatible materials in India instead of relying on expensive imports, and maintain quality. Centralised networks of suppliers will support the involvement of SME in the industry.

Lastly, there must be strategic organisational planning. Organisations are expected to develop adoption roadmaps that will include pilot projects before they upgrade to large-scale operations. Investment in in-depth cost-benefit analysis and evidence-based business cases would aid in the demonstration of long-term economic viability. Collectively, these can go a long way in establishing 3D printing as a revolutionary solution to affordable and accessible prosthetic care in India. On the whole, this study reinforces global literature concerning gains of accuracy, personalisation, and innovation, but broadens the discussion to the Indian context by rationalising issues unique to India. In comparison to the Western adoption experiences that are focused on cost-effectiveness, the Indian adoption is influenced by the elements of regulatory ambiguity, material validation, as well as the limitations of the workforce, which highlights that alternative problem-solving necessitates a localised approach.

5.5 Limitations and Contributions

Although the current study will be a great contribution to the body of knowledge on the adoption of 3D printing in the manufacturing of prosthetics in India, the study has its own limitations. First, the sample was not that large and represented primarily the professionals of the pharmaceutical and medical device industry. This reduces the extent to which findings can be generalised, given that the voice of policymakers, patients, and suppliers was not included directly. Second, the study had a cross-sectional research design capturing the perception at one time only; hence, the study is limited in its ability to explain the emerging trends as the technology and its regulatory environment evolve. Third, the use of self-reported survey data might have created sources of bias in terms of organisational readiness and cost-effectiveness perceptions. Lastly, the lack of clinical outcomes is limited by not being able to assess long-term patient outcomes of 3D printed prosthetics.

With these limitations, the study still has a number of significant contributions. It contributes to the small number of studies available on 3D printing in the Indian prosthetics industry by providing context-specific evidence on the proportion of adopters, perceived strengths and weaknesses and roadblocks. The results offer tangible suggestions to regulators, firms, and educators that the lack of regulatory clarity, training, and supply chain development is urgent. In academic terms, the study will add value as it will contextualise experiences in India in the context of global concerns and highlight certain universal challenges as well as local limitations.

5.6 Future Research

Future research should expand the scope of inquiry to include multiple stakeholder perspectives, such as patients, healthcare providers, policymakers, and suppliers, to capture a holistic view of 3D printing adoption in prosthetics. Longitudinal studies would be valuable in tracking changes in perceptions, adoption levels, and cost-effectiveness over time, providing stronger evidence for policy and investment decisions. Additionally, clinical outcome studies are needed to evaluate how 3D-printed prosthetics impact patient mobility, comfort, and quality of life compared to conventional devices. Comparative research between India and other developing economies could also highlight similarities and differences in adoption trajectories, offering lessons for scaling. Finally, future studies should integrate economic modelling to assess long-term cost–benefit outcomes, while also investigating sustainable supply chain solutions for biocompatible materials. Such research will not only deepen academic understanding but also guide industry and government in building a more resilient and accessible prosthetic ecosystem.

5.7 Final Reflection

Completing this dissertation has been both a challenging and rewarding experience. The process of exploring 3D printing in prosthetic manufacturing enhanced research, analytical, and critical thinking skills while deepening understanding of how technological innovation interacts with regulatory, economic, and social realities. One of the most significant learning points was recognising the gap between global narratives of additive manufacturing and the practical constraints within India. Engaging with literature, designing the methodology, and analysing data strengthened the ability to connect theory with practice and to evaluate complex issues systematically. The experience also improved time management, academic writing, and problem-solving abilities, as it required balancing multiple tasks and adapting to unexpected limitations, such as data constraints. Overall, the dissertation journey fostered greater confidence as a researcher, providing valuable insights that will contribute to future academic, professional, and personal development while highlighting the importance of resilience and adaptability in scholarly work.

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APPENDICES

Appendix 1: Ethics Application & Declaration Form

Innopharma education

GRIFFITH COLLEGE

Ethics Application & Declaration Form

DISSERTATION TITLE: “Examining the Role of 3D Printing in Improving Custom Prosthetic Device Manufacturing in the Indian Pharmaceutical and Medical Device Sector”

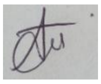
RESEARCHER’S NAME: Ankushkumar Patel

PROGRAMME OF STUDY: Medical devices technology & Business

SUPERVISOR'S NAME: Dr. Favour Okosun

DECLARATION:
The information in this application form is accurate to the best of my knowledge. I undertake to abide by the principles outlined by Innopharma/Griffith College ethics policy in my research dissertation. I confirm that I have completed a full ethics assessment for my research dissertation as per the college guidelines. I will not begin my primary research until such approval from my supervisor and/or ethics Committee has been obtained.
I pledge to carry out my research according to the Innopharma/Griffith College academic integrity standards. Any results presented in my dissertation will be from my own, original research, I will reference and/or acknowledge any material or sources used in its preparation and I will not plagiarise the work of anyone else.

For Student:

STUDENT SIGNATURE: 

DATE: 07-07-2025

The research contained within this *Favour Okosun* research dissertation proposal has been approved.

For Supervisor:

Ethics Committee Approval Required: Yes ☐ No ☐

SUPERVISOR SIGNATURE:

DATE: 07/07/2025

For Ethics Committee (if required):

Ethics Committee Approval Given: Yes ☐ No ☐

ETHICS COMMITTEE MEMBER SIGNATURE:

DATE:

NOTE: Supervisors are responsible for ensuring their students fill in this form correctly and that all ethical areas have been considered.

SECTION 1: DESCRIPTION OF RESEARCH STUDY

1.1 Purpose and objectives of research *[300 words maximum/ use literature review findings to guide]*

This research will aim to examine the potential and possible application of 3D printing technology in the Indian pharmaceutical and medical equipment industry to enhance the fabrication of tailor-made prosthetics. India has a large population that experiences high rates of limb loss through accidents, diabetes and congenital cases, which necessitates the need to provide the population with affordable patient-specific prosthetics. Conventional prosthetic production is tedious, centre-based, and expensive, thereby restricting availability, particularly in resource-limited environments. The research acknowledges that 3D printing is a type of additive manufacturing that, using digital processes, has the potential to deliver personalised, affordable, and scalable solutions because of efficiency when using materials and fast prototyping.

The mainstream implementation of 3D printing in the Indian medical device industry is still lacking, even though it has global potential. There are obstacles such as the high costs of capital, the shortage of qualified staff, unstable regulatory environments, and disjointed supply chains. The scope of these challenges is especially noticeable in small and medium-sized enterprises (SMEs) that are a significant part of the Indian medtech ecosystem. Thus, the study examines the preparation, attitudes, and capability of industry experts engaged in prosthetic manufacturing.

Proposed Research Objectives

- To examine how 3D printing technologies are being accepted by Indian pharmaceutical and medical device companies to manufacture custom prosthetic devices.
- To recognise key operational, technical, and supply chain challenges faced by Indian manufacturers in employing 3D printing for prosthetics.
- To evaluate industry professionals' perspectives on the benefits, limitations, and scalability of 3D-printed custom prosthetics in the Indian healthcare context.
- To assess how material validation, cost efficiency, and production readiness affect adoption in Indian firms without concentrating on international regulatory constraints.
- To provide strategic recommendations for Indian medical device companies to optimise the integration of 3D printing for patient-specific prosthetic solutions.

1.2 Research methodology:

The study will use a mixed-methods research design, which will be informed by a pragmatic philosophical approach to not only interview participants and obtain quantitative data, but also to conduct a qualitative analysis of the introduction of 3D printing in India, as it relates to the production of prosthetics.

The online survey will be conducted by using a structured questionnaire, using Google Forms as the mode of primary data collection. The questionnaire will contain both Likert-scale and open-ended questions to measure the perceptions of usefulness, cost-efficiency, technical readiness and adoption trends and get qualitative answers on implementation challenges, regulatory issues and organisational preparedness. This combination of two forms will provide the gathering of both measurable patterns and context-based experiences.

The target population is people who are professionals in the field of pharmaceutical and medical devices firms in India, and specifically those who are directly connected to the R&D, quality assurance, production and operations in the field of prosthesis or 3D printing. It will use a purposive method of sampling where at least one year of experience in the industry will be required to induce the respondent.

The survey will be circulated through the professional networks of the LinkedIn industry groups, medical device forums, and alumni associations to distribute the survey among respondents working in different cities and industry clusters in India. A screening question will be added so that the participants can answer on the inclusion criteria.

A moderate amount of 90 participants constitutes the target factor that seeks depth and generalizability. The quantitative data will be analysed through descriptive statistics and correlation test by using Excel or SPSS program, whereas the qualitative response will be analysed through thematic analysis, where the key themes will be extracted to the Technology Acceptance Model (TAM).

The ethical procedures, including informed consent, anonymity, and adequacy of data storage, will be adhered to, and only aggregate or anonymised data will be provided.

The given approach provides a strong, multi-faceted picture of how 3D printing is and can be used in the Indian prosthetic manufacturing industry.

SECTION 2: POSSIBLE ETHICAL ISSUES

Answer 'yes' or 'no' to the following questions.

SUBJECT MATTER

Does the research proposal involve:

Research into specific company activities that would be deemed sensitive or confidential	No
Research into politically and/or racially/ethnically and/or commercially sensitive areas	No
Sensitive, personal, professional or corporate issues	No

RESEARCH PROCEDURES

Does the research proposal involve:

Research that might damage the reputation of companies or participants	No
Research that may negatively affect the reputation of Griffith College/Innopharma	No
Use of personal records without consent	No
Use of company data without consent	No

The offer of any inducements to participate	No
Audio or visual recording without consent	No
Using a language other than English	No

PARTICIPANTS

Does the research proposal involve:

People who are not competent and/or fluent in English	No
Does your research group include any of the following vulnerable groups	No

(Adults with psychological impairments; Adults with learning difficulties; Adults under the protection/control /influence of others (e.g. in care/prison); Relatives of ill people (e.g. parents of sick children); Hospital or GP participants recruited in a medical facility; persons under the age of 18)

If you have answered NO to ALL questions, please go straight to Section 4.

If you have answered YES to ANY question in SECTION 2, you must fill in SECTION 3.

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

[Only fill in this section if you answered YES to ANY of the questions in Section 3. For example, if you answered yes to including participants who are not fluent in English, you might put forward a plan that offers your survey in two languages to take this into account. Another example could be a study where the researcher wants to include information about the care received by children with a long-term condition but it would not be ethical to approach the children directly but it might be acceptable to instead ask parents questions about their child's care. If these plans are acceptable to your supervisor, you may not need to apply for ethical approval from the Ethics Committee].

3.1. If your ethics relates to ***Subject Matter***, outline your action plan to work around any sensitive issues.
3.2. If your ethics relates to ***Research Procedures***, outline your action plan to deal with possible ethical issues in your research procedures.
3.3. If your ethics relates to ***Participants***, outline how you will protect vulnerable persons or those that do not have English as their first language.

SECTION 4: ABOUT YOUR PARTICIPANTS

4.1. Outline your participant profile and why you have chosen them for this study

The respondents used in the study will include industry stakeholders and practitioners who will be serving in the Indian pharmaceutical and medical device industry, specifically regarding prosthetic device design, manufacturing, quality control, research and development (R&D), operations, as well as strategic management. These persons are those who either have experience or are aware of the use and adoption of 3D printing technology in manufacturing prosthetics.

The participants of this group have been chosen because they will be most capable of offering real, experience-driven information about the latest possibilities and challenges related to 3D printing in custom prosthetics. They are essential to the knowledge of technical, operational and organisational adoption factors. The methodology all participants be recruited to ensure that their answers are informed and relevant to this research will require at least one year of work experience in the medical device and pharmaceutical manufacturing industry in India.

The research does not involve vulnerable subjects or patients, or minors and does not address sensitive health data.

4.2 How do you plan to gain access to/contact/approach your participant(s).

The participants will be contacted via online job sites, LinkedIn, where the link to the survey will be posted in the relevant groups related to the medical equipment and 3D printing industry. Through pharmaceutical and medtech alumni networks and relations in India, the invitation will be shared as well. In this digital method, searching will be fast and efficient, and it will still uphold ethical standards, such as voluntary participation, eligibility screening, and informed consent materials.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

5.1 **Participant Information Letter (PIL) for participants**

[You must submit an information letter for participants with this application, as part of your appendices document. For online surveys, it is sufficient to include a paragraph summarising and explaining the purpose of the research at the beginning of the survey. In all other research e.g. interviews, phonecalls, a PIL should be provided to each participant before they are asked for their consent to take part. A template PIL is available in Moodle].

Please confirm below that your information letter covers:

Description of the research topic and method	Yes
Details of what participation will involve	Yes
Rights to anonymity	Yes
Confidentiality	Yes
Rights to withdraw from the research	Yes
The contact details of the researcher and supervisor (if necessary)	Yes

5.2 **Informed Consent Form (ICF) for participants**

This study uses an online survey, and informed consent will be attained through a mandatory consent section at the start of the survey. Respondents must check two boxes indicating:
(1) They understand the purpose and voluntary nature of the study
(2) They agree to participate.

Please indicate below if your research requires a signed consent form by selecting the relevant option only:

.
No: my research study involves an online survey only and/or does not require signed consent

SECTION 6: STORAGE OF DATA

[Please ensure that you are abiding by GDPR and the national Data protection laws https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/).

*The student is responsible for storage of data and this will be handed over to the college in an electronic format as part of the thesis submission i.e. primary data and completed ICFs where applicable will be added to the primary data folder on moodle. The rationale is to keep data **as long as it is still useful** and there is an intention to use it further **for research** so if this is not the case then this can be stipulated here and a shorter retention period given.]*

6.1. How will you store the research data, and for how long? How will you manage data protection issues?

All research data will be stored safely using password-protected digital folders in a personal computer, with the researcher being the only person with access to the computer. An encrypted external drive will also hold a backup copy of the same to keep the data secure, so that its integrity and recovery are possible. To ensure additional compliance, raw data will be anonymised and consent confirmations will be uploaded to the lead data folder in Moodle, as it is required by Griffith College.

None of the personally identifiable information (PII) will be gathered except for verifying the professional background of the participant. All survey responses will be anonymised at the point of collection. The use of data will only be for academic research purposes and reported in aggregate to preserve details of confidentiality.

All the data will be stored for up to two years after confirmation of the final exam board, according to the recommendations of Griffith College. Subsequently, any data will be irretrievably eliminated according to data protection best practices and GDPR.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

7.1 **Non-Disclosure Agreement (NDA)**

Will the final dissertation contain any information pertaining to any source what would warrant the use of a Non-Disclosure Agreement (NDA) e.g. industry-based research?

No

7.2 **Student consent**

If a Non-Disclosure Agreement (NDA) is not required, does the Student consent to allow their completed dissertation to be held/published by Innopharma/Griffith College?

Yes

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

8.1 **Viva Recording**

The Dissertation viva will be recorded. This recording may be used to facilitate assessment by Innopharma staff, a third reader if necessary and/or if requested by the external examiner for the Programme. The recording will be held in line with current GDPR guidelines and will not be made publicly available.

SECTION 9: DOCUMENT CHECKLIST

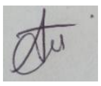
NOTE: Applicants must attach the following documents in electronic format to the appendix.

Which documents are added to the appendix? Please tick N/A if not applicable:

9.1 Participant Information Letter (PIL) for participant	Yes
9.2 Informed Consent Form (ICF) for participant	N/A
9.3 Questions/survey for interviewees/focus groups etc *(can be in draft form)*	Yes
9.4 Any other documents e.g. Non-Disclosure Agreement	N/A

I confirm that this application is complete and all required documents are included in the appendix.

For Student:

STUDENT SIGNATURE: 

Appendix 2: Participant Information Letter

Examining the Role of 3D Printing in Improving Custom Prosthetic Device Manufacturing in the Indian Pharmaceutical and Medical Device Sector

I would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

WHO I AM AND WHAT THIS STUDY IS ABOUT

My name is Ankushkumar Patel, and I am currently completing my MSc dissertation at Griffith College. This study is part of my academic requirement for the MSc in Medical devices technology & business.

The study focuses on understanding the extent of adoption of the 3D printing technology as a manufacturing technology in the production of custom prosthetic devices in the pharmaceutical and medical devices industry of India. It will concentrate on the opinions of professionals such as yourselves who have direct information in this developing field.

WHAT WOULD TAKING PART INVOLVE?

In case you agree to participate, an online survey will be requested of you. This will involve multiple-choice questions and open-ended questions concerning your experience, insights, and perceptions when it comes to using 3D printing in prosthetics. It will require some 10-15 minutes. The activity will be fully online, and there are no interviews or audio/video recordings.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

You will be invited based on your background in the Indian medical device or pharmaceutical industry, specifically in areas linked to prosthetics, manufacturing, research and development or even operations. Your opinion can be useful in learning about the application and perception of 3D printing in the industry.

DO YOU HAVE TO TAKE PART?

This is a voluntary study. You can refuse to answer any question, and give notice to withdraw at any time without suffering any disadvantages. Should you want to quit once you have initiated the survey, there is a way to do that, and it is by closing the browser window.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

No direct personal risks or advantages of participation are related. Your responses will be reflected in scholarly studies about technology adoption within India and could help in future innovation policy. Your answers are anonymous and will not request any company-specific or confidential information.

WILL TAKING PART BE CONFIDENTIAL?

Yes. All answers will be anonymous, and not a single personal detail will be gathered. The survey will not require your name, company name or contacts. Data will be kept under a password and will only be accessed by the researcher and the academic supervisor. Confidentiality can only be violated in case of a severe threat to safety or potentially unlawful conduct that needs to be disclosed.

HOW WILL THE INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

The responses to the surveys will be saved in an encrypted digital folder. The researcher and supervisor will be the only ones with access. The data will be stored securely until certification of my MSc degree. Data in anonymised form will be stored within two years after the approval of the final results by the examination board. You also have the right to obtain the information you have sent to the organisation at any other time throughout this term under the Freedom of Information legislation.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

My MSc dissertation at Griffith College will contain the results of this study. The dissertation can be deposited in the college library, and it may be made available online. All of the data will be published without disclosing your identity or organisation.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

Name: Ankushkumar Patel
Affiliation: Medical devices technology & business, Griffith College Dublin
Email: ankushkumarkailashbhai.patel@student.griffith.ie

Name: Dr. Favour Okosun
Email: **favour.okosun@griffith.ie**

Appendix 3: survey questions

1. What is your current job role?

- R&D Professional
- Quality Assurance Specialist
- Production/Operations Manager
- Strategic/Business Development Manager
- Other (please specify)

2. How many years of experience do you have in the medical device or pharmaceutical industry?

- Less than 1 year
- 1–3 years
- 4–6 years
- More than 6 years

3. What kind of organisation do you work in?

- Large Enterprise
- Medium-sized Enterprise
- Small Enterprise
- Start-up/Innovation Hub

4. Have you worked directly with 3D printing in any project or department?

- Yes
- No
- Partially

5. To what extent is 3D printing presently used in your organisation for prosthetic device manufacturing?

- Not at all
- Piloting phase
- Partially implemented
- Fully integrated

6. How would you rate the complete attitude in your organisation toward applying 3D printing for prosthetic solutions?

- Strongly resistant
- Somewhat hesitant
- Neutral
- Open to adoption
- Strongly supportive

7. Do you trust that 3D printing has strategic importance in your company's upcoming prosthetic plans?

- Yes
- No
- Not sure

8. What are the main barriers to applying 3D printing in prosthetics, in your opinion?

- High capital cost
- Lack of skilled personnel
- Regulatory uncertainty
- Limited supply chain for 3D materials
- Lack of internal stakeholder buy-in

9. How sufficient is your current infrastructure to support 3D printing operations?

- Not sufficient at all
- Somewhat sufficient
- Adequate
- Very sufficient

10. How reliable is the supply chain for obtaining 3D printing resources (polymers, filaments, resins) in India?

- Very unreliable
- Somewhat unreliable
- Neutral
- Reliable
- Very reliable

11. In your view, what is the most valued benefit of 3D-printed prosthetics?

- Customisation and fit
- Reduced cost
- Faster production time
- Decentralised delivery
- Improved patient outcomes

12. How scalable do you trust 3D printing to be for the large-scale production of prosthetics in India?

- Not scalable
- Slightly scalable
- Moderately scalable
- Highly scalable
- Fully scalable

13. What worries do you have about 3D-printed prosthetic devices?

- Durability of materials

- Clinical testing and validation
- Lack of insurance/reimbursement
- Limited patient feedback data
- Regulatory constraints

14. How would you rate the cost-efficiency of 3D printing for prosthetic production compared to traditional approaches?

- Much more expensive
- Slightly more expensive
- Similar
- Slightly cheaper
- Much cheaper

15. How prepared is your organisation in terms of workforce training for accepting 3D printing?

- Not ready
- Limited training provided
- Moderately ready
- Fully trained workforce

16. Do you trust current materials used in 3D printing are medically safe and durable for long-term prosthetic use?

- Strongly disagree
- Disagree
- Neutral
- Agree
- Strongly agree

17. Which of the following would most assist in quickening 3D printing adoption in your organisation?

- Financial incentives or grants
- Technical training programmes
- Regulatory guidance/support
- Industry-academia collaborations
- Better supplier ecosystem

18. How significant is it for your company to invest in 3D printing over the succeeding 3 years?

- Not important at all
- Slightly important

- Moderately important
- Very important
- Critical

19. Does your organisation have a roadmap for scaling 3D printing for prosthetics?

- Yes
- No
- Not sure

20. Overall, how optimistic are you about the future of 3D printing in prosthetic device manufacturing in India?

- Very pessimistic
- Somewhat pessimistic
- Neutral
- Somewhat optimistic
- Very optimistic

Appendix 4: SPSS output

Descriptive Statistics

Frequencies

Statistics

		Current job role	Years of experience in medical device/pharma industry
N	Valid	90	90
	Missing	0	0
Mean		3.17	1.94
Std. Error of Mean		.101	.081
Median		3.00	2.00
Mode		4	2
Std. Deviation		.963	.770
Variance		.927	.592
Skewness		-.652	.398
Std. Error of Skewness		.254	.254
Kurtosis		-.293	-.380
Std. Error of Kurtosis		.503	.503
Range		4	3
Minimum		1	1
Maximum		5	4
Sum		285	175
Percentiles	10	2.00	1.00
	20	2.00	1.00
	25	3.00	1.00
	30	3.00	1.30
	40	3.00	2.00
	50	3.00	2.00
	60	4.00	2.00
	70	4.00	2.00
	75	4.00	2.00
	80	4.00	3.00
	90	4.00	3.00

Frequency Table

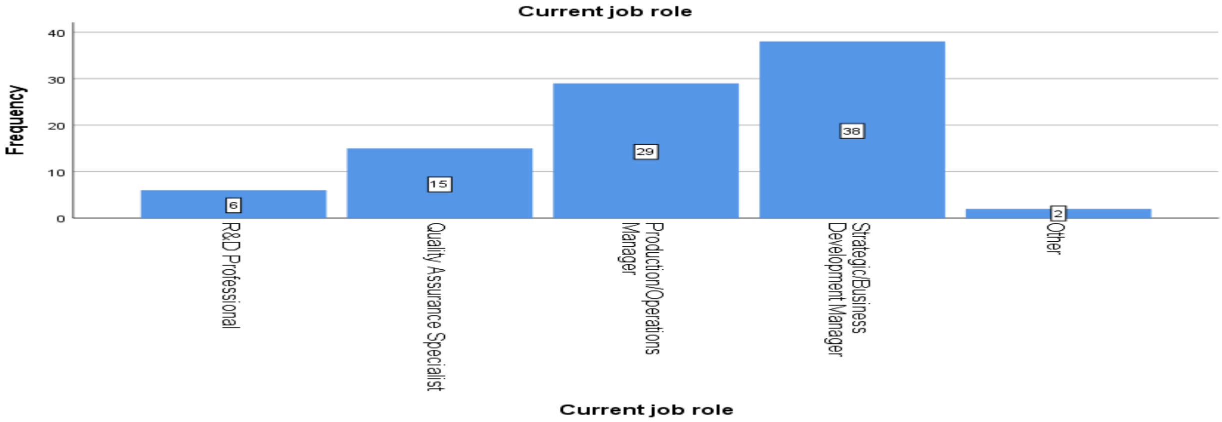
Current job role

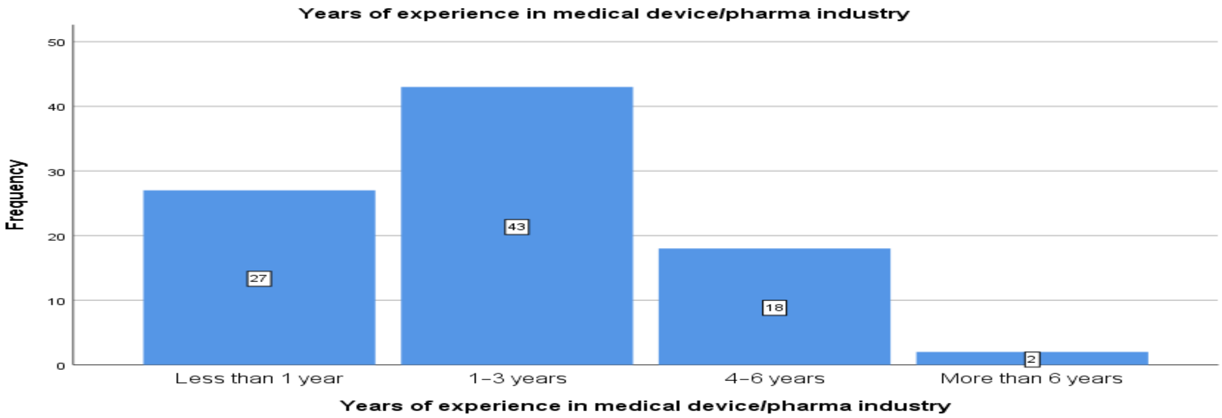
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	R&D Professional	6	6.7	6.7	6.7
	Quality Assurance Specialist	15	16.7	16.7	23.3
	Production/Operations Manager	29	32.2	32.2	55.6
	Strategic/Business Development Manager	38	42.2	42.2	97.8
	Other	2	2.2	2.2	100.0
	Total	90	100.0	100.0	

Years of experience in medical device/pharma industry

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Less than 1 year	27	30.0	30.0	30.0
	1–3 years	43	47.8	47.8	77.8
	4–6 years	18	20.0	20.0	97.8
	More than 6 years	2	2.2	2.2	100.0
	Total	90	100.0	100.0	

Bar Chart





Frequencies

Statistics

		Type of organisation	Worked directly with 3D printing
N	Valid	90	90
	Missing	0	0
Mean		2.69	1.63
Std. Error of Mean		.090	.068
Median		3.00	2.00
Mode		3	1[a]
Std. Deviation		.856	.644
Variance		.734	.415
Skewness		-.226	.518
Std. Error of Skewness		.254	.254
Kurtosis		-.516	-.639
Std. Error of Kurtosis		.503	.503
Range		3	2
Minimum		1	1
Maximum		4	3
Sum		242	147
Percentiles	10	2.00	1.00
	20	2.00	1.00
	25	2.00	1.00
	30	2.00	1.00
	40	3.00	1.00
	50	3.00	2.00
	60	3.00	2.00
	70	3.00	2.00
	75	3.00	2.00
	80	3.00	2.00
	90	4.00	2.00

a. Multiple modes exist. The smallest value is shown

Frequency Table

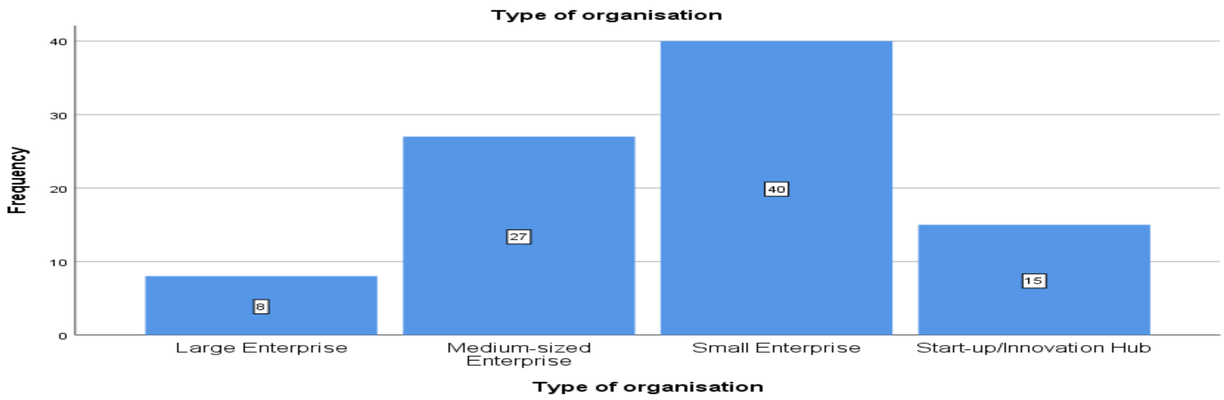
Type of organisation

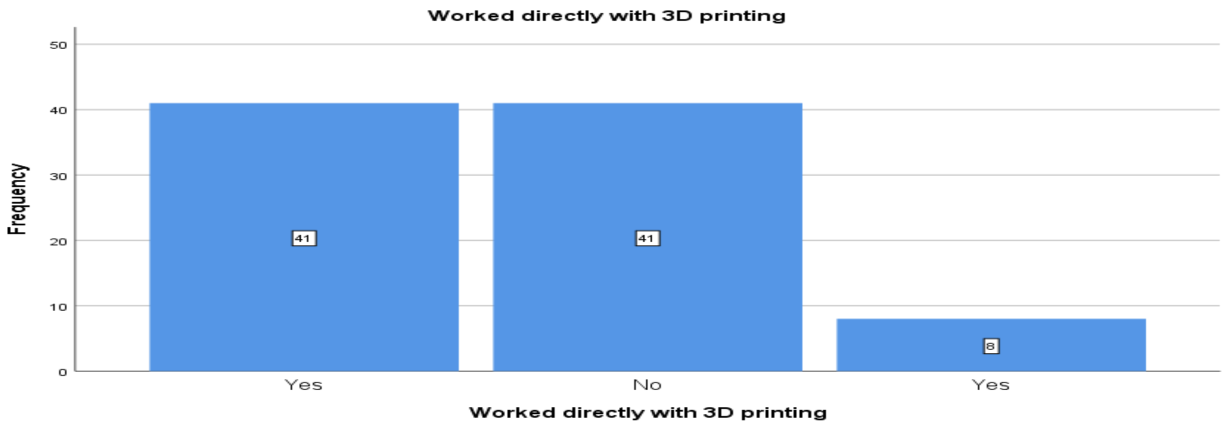
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Large Enterprise	8	8.9	8.9	8.9
	Medium-sized Enterprise	27	30.0	30.0	38.9
	Small Enterprise	40	44.4	44.4	83.3
	Start-up/Innovation Hub	15	16.7	16.7	100.0
	Total	90	100.0	100.0	

Worked directly with 3D printing

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	41	45.6	45.6	45.6
	No	41	45.6	45.6	91.1
	Yes	8	8.9	8.9	100.0
	Total	90	100.0	100.0	

Bar





Frequencies

Statistics

		Extent of 3D printing use for prosthetic manufacturing	Organisation's attitude toward 3D printing
N	Valid	90	90
	Missing	0	0
Mean		2.50	2.52
Std. Error of Mean		.103	.115
Median		2.00	3.00
Mode		2	3
Std. Deviation		.974	1.094
Variance		.949	1.196
Skewness		.037	.206
Std. Error of Skewness		.254	.254
Kurtosis		-.962	-.506
Std. Error of Kurtosis		.503	.503
Range		3	4
Minimum		1	1
Maximum		4	5
Sum		225	227
Percentiles	10	1.00	1.00
	20	2.00	1.00
	25	2.00	2.00
	30	2.00	2.00
	40	2.00	2.00
	50	2.00	3.00
	60	3.00	3.00
	70	3.00	3.00
	75	3.00	3.00
	80	3.00	3.00
	90	4.00	4.00

Frequency Table

Extent of 3D printing use for prosthetic manufacturing

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not at all	15	16.7	16.7	16.7
	Piloting phase	31	34.4	34.4	51.1
	Partially implemented	28	31.1	31.1	82.2
	Fully integrated	16	17.8	17.8	100.0
	Total	90	100.0	100.0	

Organisation's attitude toward 3D printing

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Strongly resistant	20	22.2	22.2	22.2
	Somewhat hesitant	21	23.3	23.3	45.6
	Neutral	35	38.9	38.9	84.4
	Open to adoption	10	11.1	11.1	95.6
	Strongly supportive	4	4.4	4.4	100.0
	Total	90	100.0	100.0	

Frequencies

Statistics

		Trust in strategic importance of 3D printing	Main barriers to applying 3D printing
N	Valid	90	90
	Missing	0	0

Mean		1.56	3.23
Std. Error of Mean		.074	.105
Median		1.00	3.00
Mode		1	3
Std. Deviation		.705	.995
Variance		.497	.990
Skewness		.881	-.278
Std. Error of Skewness		.254	.254
Kurtosis		-.483	-.133
Std. Error of Kurtosis		.503	.503
Range		2	4
Minimum		1	1
Maximum		3	5
Sum		140	291
Percentiles	10	1.00	2.00
	20	1.00	2.20
	25	1.00	3.00
	30	1.00	3.00
	40	1.00	3.00
	50	1.00	3.00
	60	2.00	3.60
	70	2.00	4.00
	75	2.00	4.00
	80	2.00	4.00
	90	3.00	4.00

Frequency Table

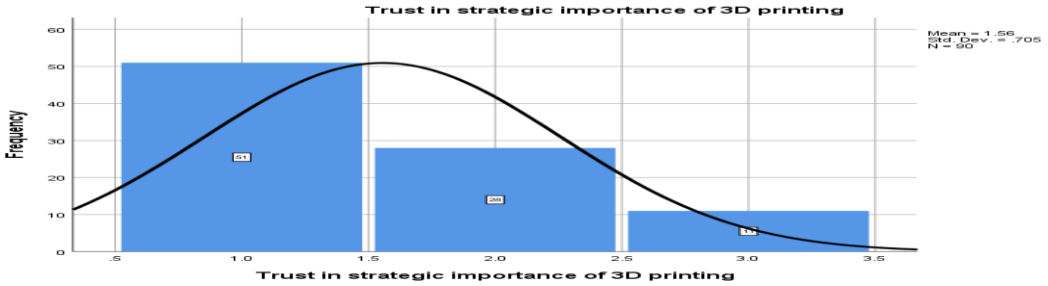
Trust in strategic importance of 3D printing

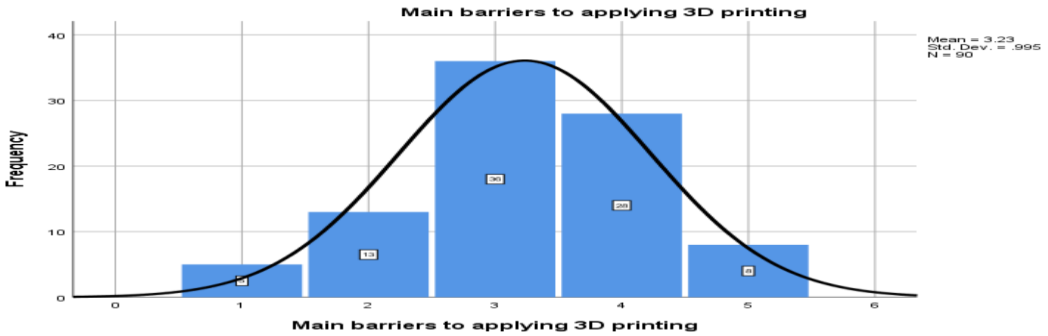
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	51	56.7	56.7	56.7
	No	28	31.1	31.1	87.8
	Not Sure	11	12.2	12.2	100.0
	Total	90	100.0	100.0	

Main barriers to applying 3D printing

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	High capital cost	5	5.6	5.6	5.6
	Lack of skilled personnel	13	14.4	14.4	20.0
	Regulatory uncertainty	36	40.0	40.0	60.0
	Limited supply chain for 3D materials	28	31.1	31.1	91.1
	Lack of internal stakeholder buy-in	8	8.9	8.9	100.0
	Total	90	100.0	100.0	

Histogram





Frequencies

Statistics

		Infrastructure sufficiency for 3D printing	Supply chain reliability for 3D printing resources
N	Valid	90	90
	Missing	0	0
Mean		2.02	2.42
Std. Error of Mean		.089	.114
Median		2.00	2.00
Mode		2	2
Std. Deviation		.848	1.081
Variance		.719	1.168
Skewness		.410	.560
Std. Error of Skewness		.254	.254
Kurtosis		-.546	-.056
Std. Error of Kurtosis		.503	.503
Range		3	4
Minimum		1	1
Maximum		4	5
Sum		182	218
Percentiles	10	1.00	1.00
	20	1.00	1.00
	25	1.00	2.00
	30	1.30	2.00
	40	2.00	2.00

	50	2.00	2.00
	60	2.00	3.00
	70	2.00	3.00
	75	3.00	3.00
	80	3.00	3.00
	90	3.00	4.00

Frequency Table

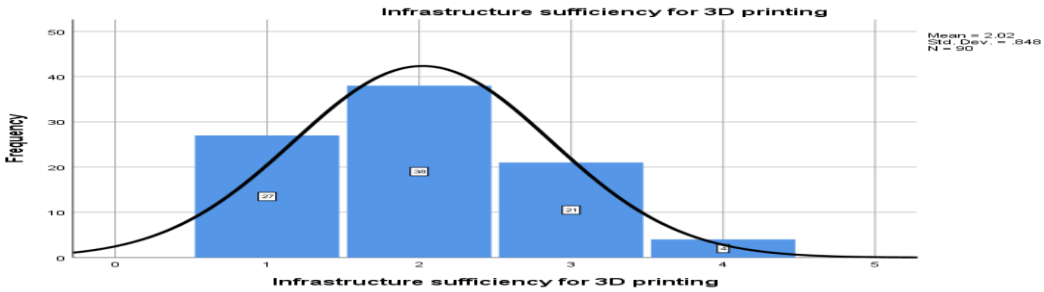
Infrastructure sufficiency for 3D printing

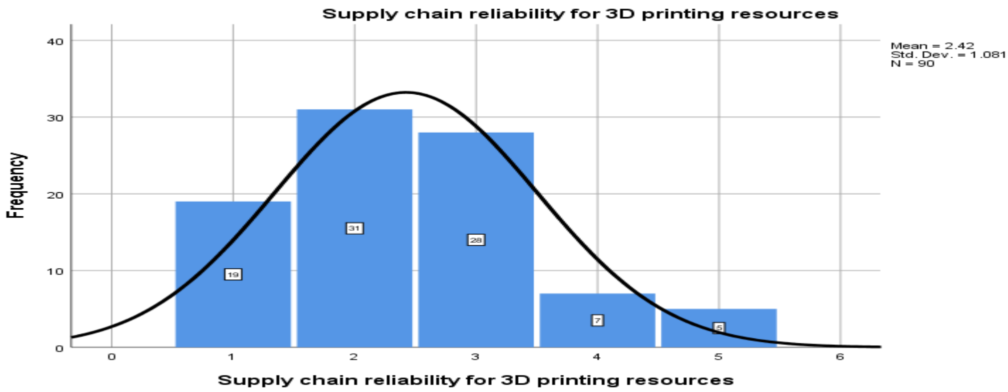
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not sufficient at all	27	30.0	30.0	30.0
	Somewhat sufficient	38	42.2	42.2	72.2
	Adequate	21	23.3	23.3	95.6
	Very sufficient	4	4.4	4.4	100.0
	Total	90	100.0	100.0	

Supply chain reliability for 3D printing resources

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Very unreliable	19	21.1	21.1	21.1
	Somewhat unreliable	31	34.4	34.4	55.6
	Neutral	28	31.1	31.1	86.7
	Reliable	7	7.8	7.8	94.4
	Very reliable	5	5.6	5.6	100.0
	Total	90	100.0	100.0	

Histogram





Frequencies

Statistics

		Most valued benefit of 3D-printed prosthetics	Scalability of 3D printing for prosthetics
N	Valid	90	90
	Missing	0	0
Mean		3.50	2.42
Std. Error of Mean		.119	.125
Median		4.00	2.00
Mode		4	2
Std. Deviation		1.124	1.190
Variance		1.264	1.415
Skewness		-.412	.517
Std. Error of Skewness		.254	.254
Kurtosis		-.466	-.532
Std. Error of Kurtosis		.503	.503
Range		4	4
Minimum		1	1
Maximum		5	5
Sum		315	218
Percentiles	10	2.00	1.00
	20	3.00	1.00
	25	3.00	1.00
	30	3.00	2.00
	40	3.00	2.00
	50	4.00	2.00
	60	4.00	3.00
	70	4.00	3.00
	75	4.00	3.00
	80	5.00	3.00
	90	5.00	4.00

Frequency Table

Most valued benefit of 3D-printed prosthetics

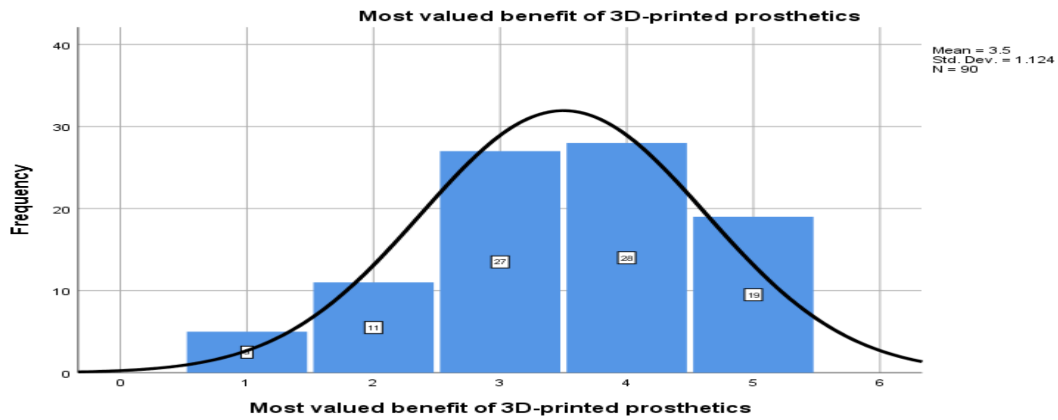
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Customisation and fit	5	5.6	5.6	5.6
	Reduced cost	11	12.2	12.2	17.8

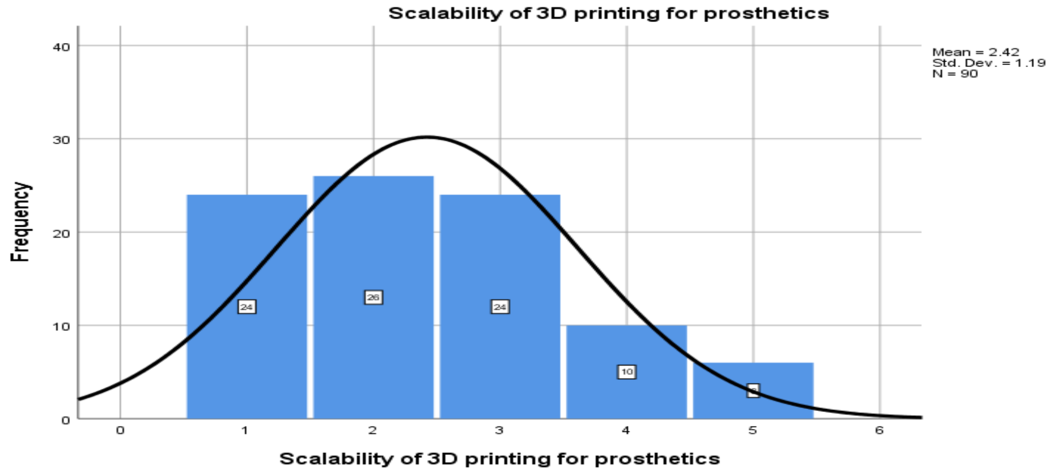
		Frequency	Percent	Valid Percent	Cumulative Percent
	Faster production time	27	30.0	30.0	47.8
	Decentralised delivery	28	31.1	31.1	78.9
	Improved patient outcomes	19	21.1	21.1	100.0
	Total	90	100.0	100.0	

Scalability of 3D printing for prosthetics

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not scalable	24	26.7	26.7	26.7
	Slightly scalable	26	28.9	28.9	55.6
	Moderately scalable	24	26.7	26.7	82.2
	Highly scalable	10	11.1	11.1	93.3
	Fully scalable	6	6.7	6.7	100.0
	Total	90	100.0	100.0	

Histogram





Frequencies

Statistics

		Concerns about 3D-printed prosthetics	Cost-efficiency of 3D printing vs traditional approaches
N	Valid	90	90
	Missing	0	0
Mean		3.01	2.74
Std. Error of Mean		.137	.129
Median		3.00	3.00
Mode		2	3
Std. Deviation		1.302	1.223
Variance		1.697	1.496
Skewness		.135	.242
Std. Error of Skewness		.254	.254
Kurtosis		-1.125	-.816
Std. Error of Kurtosis		.503	.503
Range		4	4
Minimum		1	1
Maximum		5	5
Sum		271	247
Percentiles	10	1.00	1.00
	20	2.00	2.00
	25	2.00	2.00
	30	2.00	2.00
	40	2.00	2.00
	50	3.00	3.00
	60	3.00	3.00
	70	4.00	3.00
	75	4.00	4.00
	80	4.00	4.00
	90	5.00	4.90

Frequency Table

Concerns about 3D-printed prosthetics

		Frequency	Percent	Valid Percent	Cumulative Percent

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Durability of materials	11	12.2	12.2	12.2
	Clinical testing and validation	26	28.9	28.9	41.1
	Lack of insurance/reimbursement	20	22.2	22.2	63.3
	Limited patient feedback data	17	18.9	18.9	82.2
	Regulatory constraints	16	17.8	17.8	100.0
	Total	90	100.0	100.0	

Cost-efficiency of 3D printing vs traditional approaches

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Much more expensive	16	17.8	17.8	17.8
	Slightly more expensive	24	26.7	26.7	44.4
	Similar	26	28.9	28.9	73.3
	Slightly cheaper	15	16.7	16.7	90.0
	Much cheaper	9	10.0	10.0	100.0
	Total	90	100.0	100.0	

Frequencies

Statistics

		Preparedness of workforce training	Trust in medical safety & durability of 3D printing materials
N	Valid	90	90
	Missing	0	0
Mean		2.58	2.44
Std. Error of Mean		.116	.123
Median		3.00	2.00
Mode		2[a]	2
Std. Deviation		1.101	1.162
Variance		1.213	1.351
Skewness		-.073	.467
Std. Error of Skewness		.254	.254
Kurtosis		-1.312	-.584
Std. Error of Kurtosis		.503	.503
Range		3	4
Minimum		1	1
Maximum		4	5
Sum		232	220
Percentiles	10	1.00	1.00
	20	1.00	1.00
	25	2.00	1.75
	30	2.00	2.00
	40	2.00	2.00
	50	3.00	2.00
	60	3.00	3.00
	70	3.00	3.00
	75	4.00	3.00
	80	4.00	3.00
	90	4.00	4.00

a. Multiple modes exist. The smallest value is shown

Frequency Table

Preparedness of workforce training

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not ready	19	21.1	21.1	21.1
	Limited training provided	24	26.7	26.7	47.8
	Moderately ready	23	25.6	25.6	73.3
	Fully trained workforce	24	26.7	26.7	100.0
	Total	90	100.0	100.0	

Trust in medical safety & durability of 3D printing materials

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Strongly disagree	22	24.4	24.4	24.4
	Disagree	28	31.1	31.1	55.6
	Neutral	23	25.6	25.6	81.1
	Agree	12	13.3	13.3	94.4
	Strongly agree	5	5.6	5.6	100.0
	Total	90	100.0	100.0	

Frequencies

Statistics

		Factors assisting adoption of 3D printing	Significance of investment in 3D printing (next 3 years)
N	Valid	90	90
	Missing	0	0
Mean		3.28	2.58
Std. Error of Mean		.115	.120
Median		3.00	3.00
Mode		3[a]	3
Std. Deviation		1.092	1.141
Variance		1.192	1.303
Skewness		-.206	.198
Std. Error of Skewness		.254	.254
Kurtosis		-.621	-.807
Std. Error of Kurtosis		.503	.503
Range		4	4
Minimum		1	1
Maximum		5	5
Sum		295	232
Percentiles	10	2.00	1.00
	20	2.00	1.00
	25	2.75	2.00
	30	3.00	2.00
	40	3.00	2.00
	50	3.00	3.00
	60	4.00	3.00
	70	4.00	3.00
	75	4.00	3.00
	80	4.00	4.00
	90	5.00	4.00

a. Multiple modes exist. The smallest value is shown

Frequency Table

Factors assisting adoption of 3D printing

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Financial incentives or grants	5	5.6	5.6	5.6
	Technical training programmes	17	18.9	18.9	24.4

		Frequency	Percent	Valid Percent	Cumulative Percent
	Regulatory guidance/support	28	31.1	31.1	55.6
	Industry-academia collaborations	28	31.1	31.1	86.7
	Better supplier ecosystem	12	13.3	13.3	100.0
	Total	90	100.0	100.0	

Significance of investment in 3D printing (next 3 years)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Not important at all	19	21.1	21.1	21.1
	Slightly important	24	26.7	26.7	47.8
	Moderately important	27	30.0	30.0	77.8
	Very important	16	17.8	17.8	95.6
	Critical	4	4.4	4.4	100.0
	Total	90	100.0	100.0	

Frequencies

Statistics

		Organisation's roadmap for scaling 3D printing	Optimism about future of 3D printing in prosthetics
N	Valid	90	90
	Missing	0	0
Mean		2.01	2.57
Std. Error of Mean		.080	.112
Median		2.00	2.50
Mode		2	2
Std. Deviation		.757	1.061
Variance		.573	1.125
Skewness		-.019	.428
Std. Error of Skewness		.254	.254
Kurtosis		-1.236	-.195
Std. Error of Kurtosis		.503	.503
Range		2	4
Minimum		1	1
Maximum		3	5
Sum		181	231
Percentiles	10	1.00	1.00
	20	1.00	2.00
	25	1.00	2.00
	30	2.00	2.00
	40	2.00	2.00
	50	2.00	2.50
	60	2.00	3.00
	70	2.00	3.00
	75	3.00	3.00
	80	3.00	3.00
	90	3.00	4.00

Frequency Table

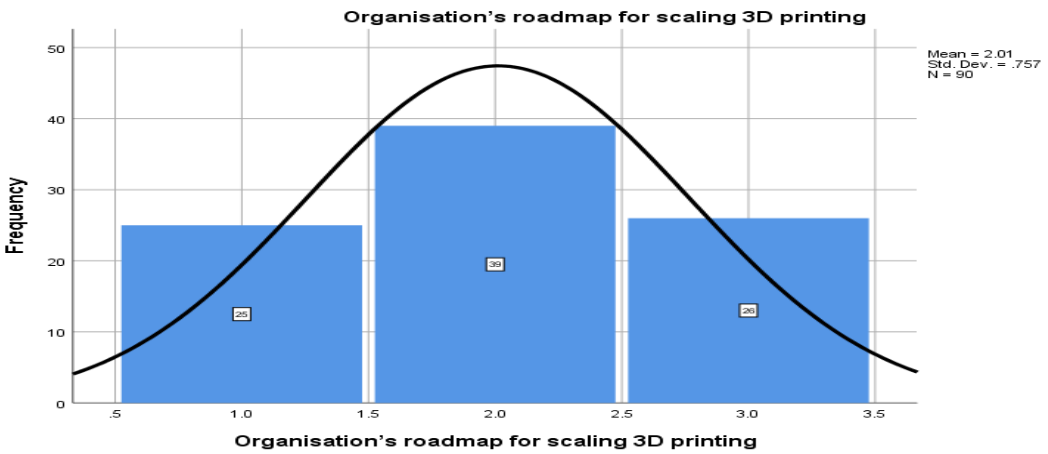
Organisation's roadmap for scaling 3D printing

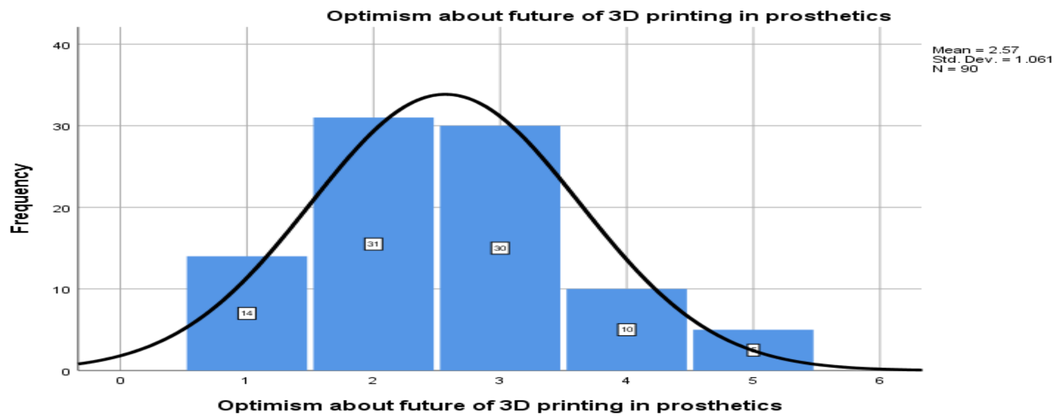
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	25	27.8	27.8	27.8
	No	39	43.3	43.3	71.1
	Not Sure	26	28.9	28.9	100.0
	Total	90	100.0	100.0	

Optimism about future of 3D printing in prosthetics

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Very pessimistic	14	15.6	15.6	15.6
	Somewhat pessimistic	31	34.4	34.4	50.0
	Neutral	30	33.3	33.3	83.3
	Somewhat optimistic	10	11.1	11.1	94.4
	Very optimistic	5	5.6	5.6	100.0
	Total	90	100.0	100.0	

Histogram





Frequencies

Statistics

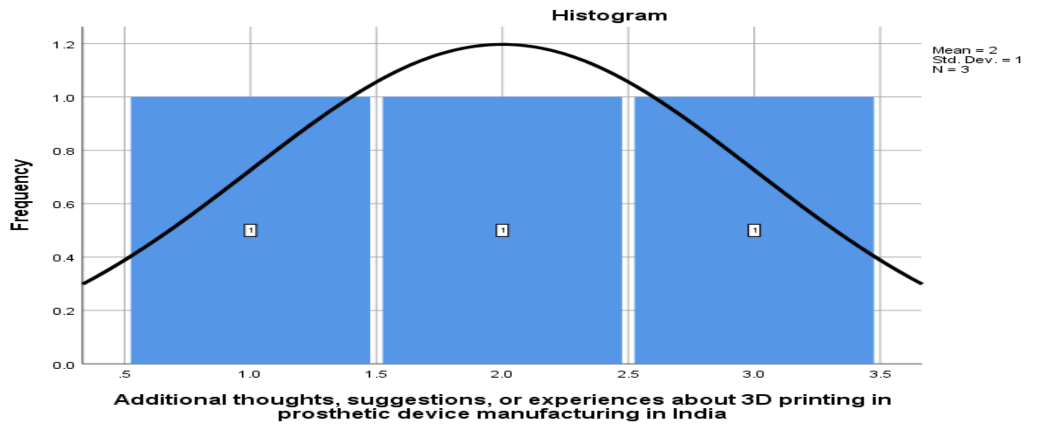
Additional thoughts, suggestions, or experiences about 3D printing in prosthetic device manufacturing in India

N	Valid	3
	Missing	87
Mean		2.00
Std. Error of Mean		.577
Median		2.00
Mode		1[a]
Std. Deviation		1.000
Variance		1.000
Skewness		.000
Std. Error of Skewness		1.225
Range		2
Minimum		1
Maximum		3
Sum		6
Percentiles	10	1.00
	20	1.00
	25	1.00
	30	1.20
	40	1.60
	50	2.00
	60	2.40
	70	2.80
	75	.
	80	.
	90	.

a. Multiple modes exist. The smallest value is shown

Additional thoughts, suggestions, or experiences about 3D printing in prosthetic device manufacturing in India

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	1	1.1	33.3	33.3
	Might have clear vision on upcoming 3D products	1	1.1	33.3	66.7
	Na	1	1.1	33.3	100.0
	Total	3	3.3	100.0	
Missing	System	87	96.7		
Total		90	100.0		



Descriptive

Descriptive Statistics

	N	Range	Minimum	Maximum	Sum	Mean		Std. Deviation	Variance	Skewness		Kurtosis	
	Statistic	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic	Statistic	Std. Error	Statistic	Std. Error
Years of experience in medical device/pharma industry	90	3	1	4	175	1.94	.081	.770	.592	.398	.254	-.380	.503
Current job role	90	4	1	5	285	3.17	.101	.963	.927	-.652	.254	-.293	.503
Main barriers to applying 3D printing	90	4	1	5	291	3.23	.105	.995	.990	-.278	.254	-.133	.503
Most valued benefit of 3D-printed prosthetics	90	4	1	5	315	3.50	.119	1.124	1.264	-.412	.254	-.466	.503
Concerns about 3D-printed prosthetics	90	4	1	5	271	3.01	.137	1.302	1.697	.135	.254	-1.125	.503
Valid N (listwise)	90												

Reliability Analysis (Cronbach's Alpha)

Reliability

Scale: Barriers_Scale

Case Processing Summary

		N	%
Cases	Valid	90	100.0
	Excluded[a]	0	.0
	Total	90	100.0

a. Listwise deletion based on all variables in the procedure.

Reliability Statistics

Cronbach's Alpha[a]	Cronbach's Alpha Based on Standardized Items[a]	N of Items
-.038	-.052	3

a. The value is negative due to a negative average covariance among items. This violates reliability model assumptions. You may want to check item codings.

Item Statistics

	Mean	Std. Deviation	N
Organisation's attitude toward 3D printing	2.52	1.094	90
Trust in strategic importance of 3D printing	1.56	.705	90
Optimism about future of 3D printing in prosthetics	2.57	1.061	90

Inter-Item Correlation Matrix

	Organisation's attitude toward 3D printing	Trust in strategic importance of 3D printing	Optimism about future of 3D printing in prosthetics
Organisation's attitude toward 3D printing	1.000	-.104	.013
Trust in strategic importance of 3D printing	-.104	1.000	.040
Optimism about future of 3D printing in prosthetics	.013	.040	1.000

Inter-Item Covariance Matrix

	Organisation's attitude toward 3D printing	Trust in strategic importance of 3D printing	Optimism about future of 3D printing in prosthetics
Organisation's attitude toward 3D printing	1.196	-.080	.015
Trust in strategic importance of 3D printing	-.080	.497	.030
Optimism about future of 3D printing in prosthetics	.015	.030	1.125

Summary Item Statistics

	Mean	Minimum	Maximum	Range	Maximum / Minimum	Variance	N of Items
Item Means	2.215	1.556	2.567	1.011	1.650	.326	3
Item Variances	.939	.497	1.196	.699	2.407	.148	3
Inter-Item Covariances	-.012	-.080	.030	.110	-.375	.003	3
Inter-Item Correlations	-.017	-.104	.040	.144	-.387	.005	3

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Organisation's attitude toward 3D printing	4.12	1.682	-.046	.011	.071
Trust in strategic importance of 3D printing	5.09	2.352	-.046	.012	.026
Optimism about future of 3D printing in prosthetics	4.08	1.533	.035	.002	-.208[a]

a. The value is negative due to a negative average covariance among items. This violates reliability model assumptions. You may want to check item codings.

Scale Statistics

Mean	Variance	Std. Deviation	N of Items
6.64	2.749	1.658	3

ANOVA with Tukey's Test for Nonadditivity

			Sum of Squares	df	Mean Square	F	Sig
Between People			81.541	89	.916		
Within People	Between Items		58.763	2	29.381	30.903	.000
	Residual	Nonadditivity	10.718[a]	1	10.718	11.968	.001
		Balance	158.519	177	.896		
		Total	169.237	178	.951		
	Total		228.000	180	1.267		
Total			309.541	269	1.151		

Grand Mean = 2.21

a. Tukey's estimate of power to which observations must be raised to achieve additivity = -.721.

Hotelling's T-Squared Test

Hotelling's T-Squared	F	df1	df2	Sig
78.726	38.921	2	88	.000

Intraclass Correlation Coefficient

	Intraclass Correlation[b]	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound	F Test with True Value 0 Value	df1	df2	Sig
Single Measures	-.012[a]	-.120	.117	.964	89	178	.572
Average Measures	-.038[c]	-.474	.285	.964	89	178	.572

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.

b. Type C intraclass correlation coefficients using a consistency definition. The between-measure variance is excluded from the denominator variance.

c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

Chi-Square Test of Independence along with Cramer's

Crosstabs

Case Processing Summary

	Cases Valid N	Valid Percent	Missing N	Missing Percent	Total N	Total Percent
Worked directly with 3D printing * Type of organisation	90	100.0%	0	0.0%	90	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	9.718[a]	6	.137
Likelihood Ratio	11.142	6	.084
Linear-by-Linear Association	.003	1	.959
McNemar-Bowker Test	.	.	.[b]
N of Valid Cases	90		

a. 6 cells (50.0%) have expected count less than 5. The minimum expected count is .71.

b. Computed only for a PxP table, where P must be greater than 1.

Directional Measures

			Value	Asymptotic Standard Error[a]	Approximate T[b]	Approximate Significance
Nominal by Nominal	Lambda	Symmetric	.172	.092	1.774	.076
		Worked directly with 3D printing Dependent	.245	.115	1.888	.059
		Type of organisation Dependent	.100	.102	.933	.351
	Goodman and Kruskal tau	Worked directly with 3D printing Dependent	.070	.045		.051[c]
		Type of organisation Dependent	.052	.032		.032[c]

	Uncertainty Coefficient	Symmetric	.057	.029	1.975	.084[d]
		Worked directly with 3D printing Dependent	.066	.033	1.975	.084[d]
		Type of organisation Dependent	.050	.025	1.975	.084[d]
Ordinal by Ordinal	Somers' d	Symmetric	.029	.096	.302	.763
		Worked directly with 3D printing Dependent	.027	.089	.302	.763
		Type of organisation Dependent	.031	.104	.302	.763
Nominal by Interval	Eta	Worked directly with 3D printing Dependent	.302			
		Type of organisation Dependent	.088			

a. Not assuming the null hypothesis.
b. Using the asymptotic standard error assuming the null hypothesis.
c. Based on chi-square approximation
d. Likelihood ratio chi-square probability.

Symmetric Measures

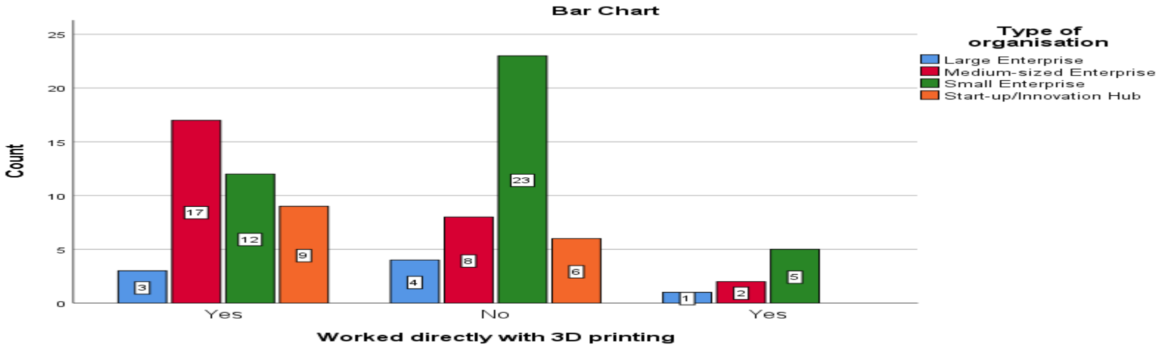
		Value	Asymptotic Standard Error[a]	Approximate T[b]	Approximate Significance
Nominal by Nominal	Phi	.329			.137
	Cramer's V	.232			.137
	Contingency Coefficient	.312			.137
Ordinal by Ordinal	Kendall's tau-b	.029	.096	.302	.763
	Kendall's tau-c	.027	.090	.302	.763
	Gamma	.045	.149	.302	.763
	Spearman Correlation	.034	.107	.317	.752[c]
Interval by Interval	Pearson's R	-.005	.102	-.051	.959[c]
Measure of Agreement	Kappa	-.050	.046	-1.078	.281
N of Valid Cases		90			

a. Not assuming the null hypothesis.
b. Using the asymptotic standard error assuming the null hypothesis.
c. Based on normal approximation.

Risk Estimate

	Value
Odds Ratio for Worked directly with 3D printing (Yes / No)	[a]

a. Risk Estimate statistics cannot be computed. They are only computed for a 2*2 table without empty cells.



Crosstabs

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Years of experience in medical device/pharma industry * Optimism about future of 3D printing in prosthetics	90	100.0%	0	0.0%	90	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	15.626[a]	12	.209
Likelihood Ratio	16.871	12	.155
Linear-by-Linear Association	.866	1	.352
McNemar-Bowker Test	.	.	.[b]
N of Valid Cases	90		

a. 13 cells (65.0%) have expected count less than 5. The minimum expected count is .11.
b. Computed only for a PxP table, where P must be greater than 1.

Directional Measures

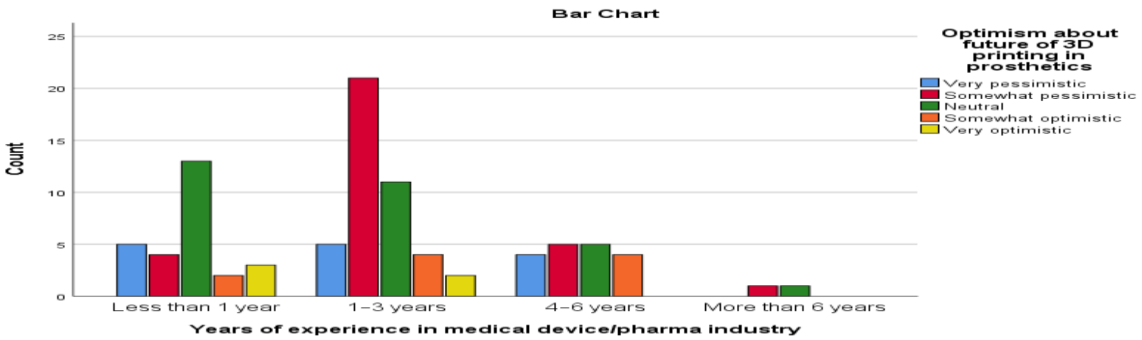
			Value	Asymptotic Standard Error[a]	Approximate T[b]	Approximate Significance
Nominal by Nominal	Lambda	Symmetric	.113	.081	1.338	.181
		Years of experience in medical device/pharma industry Dependent	.064	.129	.481	.631
		Optimism about future of 3D printing in prosthetics Dependent	.153	.064	2.243	.025
	Goodman and Kruskal tau	Years of experience in medical device/pharma industry Dependent	.082	.042		.038[c]
		Optimism about future of 3D printing in prosthetics Dependent	.056	.029		.068[c]
	Uncertainty Coefficient	Symmetric	.074	.031	2.357	.155[d]
		Years of experience in medical device/pharma industry Dependent	.084	.035	2.357	.155[d]
		Optimism about future of 3D printing in prosthetics Dependent	.066	.028	2.357	.155[d]
Ordinal by Ordinal	Somers' d	Symmetric	-.088	.096	-.918	.359
		Years of experience in medical device/pharma industry Dependent	-.083	.090	-.918	.359
		Optimism about future of 3D printing in prosthetics Dependent	-.094	.103	-.918	.359
Nominal by Interval	Eta	Years of experience in medical device/pharma industry Dependent	.257			
		Optimism about future of 3D printing in prosthetics Dependent	.132			

a. Not assuming the null hypothesis.
b. Using the asymptotic standard error assuming the null hypothesis.
c. Based on chi-square approximation
d. Likelihood ratio chi-square probability.

Symmetric Measures

		Value	Asymptotic Standard Error[a]	Approximate T[b]	Approximate Significance
Nominal by Nominal	Phi	.417			.209
	Cramer's V	.241			.209
	Contingency Coefficient	.385			.209
Ordinal by Ordinal	Kendall's tau-b	-.088	.096	-.918	.359
	Kendall's tau-c	-.081	.088	-.918	.359
	Gamma	-.125	.136	-.918	.359
	Spearman Correlation	-.100	.110	-.943	.348[c]
Interval by Interval	Pearson's R	-.099	.104	-.930	.355[c]
Measure of Agreement	Kappa	.089	.059	1.490	.136
N of Valid Cases		90			

a. Not assuming the null hypothesis.
b. Using the asymptotic standard error assuming the null hypothesis.
c. Based on normal approximation.



Independent Samples t-Tests

T-Test

Group Statistics

	Worked directly with 3D printing	N	Mean	Std. Deviation	Std. Error Mean
Optimism about future of 3D printing in prosthetics	Yes	41	2.61	1.159	.181
	No	41	2.61	.972	.152

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Optimism about future of 3D printing in prosthetics	Equal variances assumed	.925	.339	.000	80	1.000	.000	.236	-.470	.470
	Equal variances not assumed			.000	77.627	1.000	.000	.236	-.470	.470

T-Test

Group Statistics

	Organisation's attitude toward 3D printing	N	Mean	Std. Deviation	Std. Error Mean
Type of organisation	Strongly resistant	20	2.65	.671	.150
	Somewhat hesitant	21	2.81	.928	.203

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Type of organisation	Equal variances assumed	1.087	.304	-.628	39	.534	-.160	.254	-.673	.354
	Equal variances not assumed			-.633	36.418	.531	-.160	.252	-.671	.352

One-Way ANOVA

Oneway

Descriptives

Scalability of 3D printing for prosthetics

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum	Between-Component Variance
						Lower Bound	Upper Bound			
Very unreliable		19	2.26	1.098	.252	1.73	2.79	1	5	
Somewhat unreliable		31	2.39	1.430	.257	1.86	2.91	1	5	
Neutral		28	2.39	.994	.188	2.01	2.78	1	4	
Reliable		7	2.57	.976	.369	1.67	3.47	1	4	
Very reliable		5	3.20	1.304	.583	1.58	4.82	2	5	
Total		90	2.42	1.190	.125	2.17	2.67	1	5	
Model	Fixed Effects			1.199	.126	2.17	2.67			
	Random Effects				.126[a]	2.07[a]	2.77[a]			-.031

a. Warning: Between-component variance is negative. It was replaced by 0.0 in computing this random effects measure.

Test of Homogeneity of Variances

		Levene Statistic	df1	df2	Sig.
Scalability of 3D printing for prosthetics	Based on Mean	1.931	4	85	.113
	Based on Median	1.090	4	85	.367
	Based on Median and with adjusted df	1.090	4	80.339	.367
	Based on trimmed mean	1.792	4	85	.138

ANOVA

Scalability of 3D printing for prosthetics

			Sum of Squares	df	Mean Square	F	Sig.
Between Groups	(Combined)		3.724	4	.931	.647	.630
	Linear Term	Unweighted	3.572	1	3.572	2.484	.119
		Weighted	2.449	1	2.449	1.703	.195
		Deviation	1.275	3	.425	.295	.829
Within Groups			122.232	85	1.438		
Total			125.956	89			

Robust Tests of Equality of Means

Scalability of 3D printing for prosthetics

	Statistic[a]	df1	df2	Sig.
Welch	.538	4	18.638	.710
Brown-Forsythe	.683	4	33.061	.609

a. Asymptotically F distributed.

Post Hoc Tests

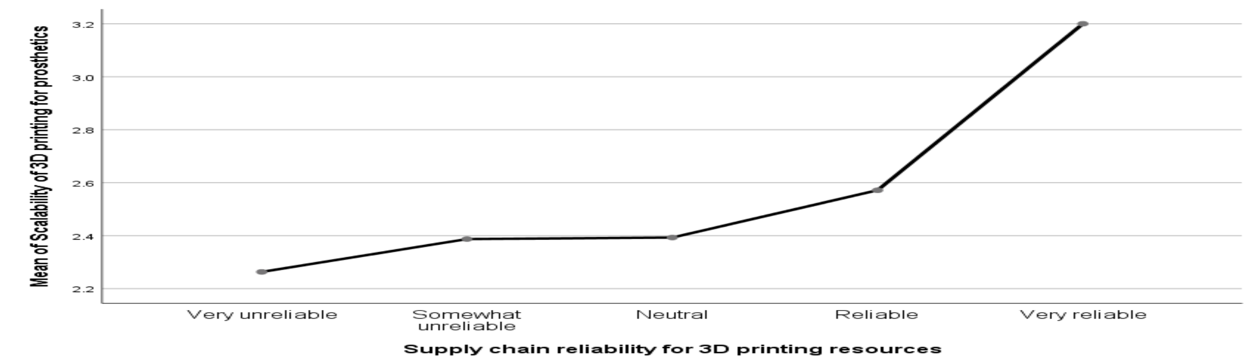
Homogeneous Subsets

Scalability of 3D printing for prosthetics

	Supply chain reliability for 3D printing resources	N	Subset for alpha = 0.05 1
Student-Newman-Keuls[a,b]	Very unreliable	19	2.26
	Somewhat unreliable	31	2.39
	Neutral	28	2.39
	Reliable	7	2.57
	Very reliable	5	3.20
	Sig.		.372
Tukey HSD[a,b]	Very unreliable	19	2.26
	Somewhat unreliable	31	2.39
	Neutral	28	2.39
	Reliable	7	2.57
	Very reliable	5	3.20
	Sig.		.372
Tukey B[a,b]	Very unreliable	19	2.26
	Somewhat unreliable	31	2.39
	Neutral	28	2.39
	Reliable	7	2.57
	Very reliable	5	3.20
Duncan[a,b]	Very unreliable	19	2.26
	Somewhat unreliable	31	2.39
	Neutral	28	2.39
	Reliable	7	2.57
	Very reliable	5	3.20
	Sig.		.110
Scheffe[a,b]	Very unreliable	19	2.26
	Somewhat unreliable	31	2.39
	Neutral	28	2.39
	Reliable	7	2.57
	Very reliable	5	3.20
	Sig.		.514
Gabriel[a,b]	Very unreliable	19	2.26
	Somewhat unreliable	31	2.39
	Neutral	28	2.39
	Reliable	7	2.57
	Very reliable	5	3.20
	Sig.		.520
Ryan-Einot-Gabriel-Welsch F	Very unreliable	19	2.26
	Somewhat unreliable	31	2.39
	Neutral	28	2.39
	Reliable	7	2.57
	Very reliable	5	3.20
	Sig.		.630
Ryan-Einot-Gabriel-Welsch Range	Very unreliable	19	2.26
	Somewhat unreliable	31	2.39
	Neutral	28	2.39
	Reliable	7	2.57
	Very reliable	5	3.20
	Sig.		.731
Hochberg[a,b]	Very unreliable	19	2.26
	Somewhat unreliable	31	2.39
	Neutral	28	2.39
	Reliable	7	2.57
	Very reliable	5	3.20
	Sig.		.520
Waller-Duncan[a,b,c,d]	Very unreliable	19	
	Somewhat unreliable	31	
	Neutral	28	
	Reliable	7	
	Very reliable	5	

Means for groups in homogeneous subsets are displayed.
a. Uses Harmonic Mean Sample Size = 10.788.
b. The group sizes are unequal. The harmonic mean of the group sizes is used. Type I error levels are not guaranteed.
c. Type 1/Type 2 Error Seriousness Ratio = 100.
d. There are no homogeneous subsets for alpha = 0.05.

Means Plots



Descriptives

Infrastructure sufficiency for 3D printing

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean Lower Bound	95% Confidence Interval for Mean Upper Bound	Minimum	Maximum	Between-Component Variance
Much more expensive	16	2.19	1.047	.262	1.63	2.75	1	4	
Slightly more expensive	24	1.96	.751	.153	1.64	2.28	1	4	

Similar		26	1.96	.824	.162	1.63	2.29	1	3	
Slightly cheaper		15	2.00	.756	.195	1.58	2.42	1	3	
Much cheaper		9	2.11	1.054	.351	1.30	2.92	1	4	
Total		90	2.02	.848	.089	1.84	2.20	1	4	
Model	Fixed Effects			.863	.091	1.84	2.20			
	Random Effects				.091[a]	1.77[a]	2.27[a]			-.032

a. Warning: Between-component variance is negative. It was replaced by 0.0 in computing this random effects measure.

Test of Homogeneity of Variances

		Levene Statistic	df1	df2	Sig.
Infrastructure sufficiency for 3D printing	Based on Mean	1.630	4	85	.174
	Based on Median	1.223	4	85	.307
	Based on Median and with adjusted df	1.223	4	80.198	.308
	Based on trimmed mean	1.384	4	85	.246

ANOVA

Infrastructure sufficiency for 3D printing

			Sum of Squares	df	Mean Square	F	Sig.
Between Groups	(Combined)		.709	4	.177	.238	.916
	Linear Term	Unweighted	.015	1	.015	.021	.886
		Weighted	.047	1	.047	.063	.803
		Deviation	.663	3	.221	.297	.828
Within Groups			63.246	85	.744		
Total			63.956	89			

Robust Tests of Equality of Means

Infrastructure sufficiency for 3D printing

	Statistic[a]	df1	df2	Sig.
Welch	.175	4	32.337	.950
Brown-Forsythe	.217	4	50.513	.928

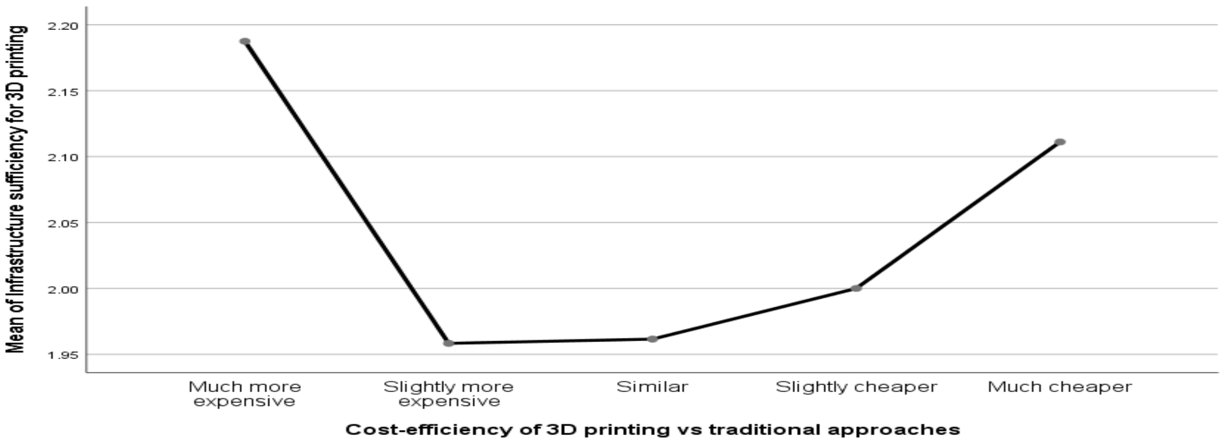
a. Asymptotically F distributed.

Infrastructure sufficiency for 3D printing

	Cost-efficiency of 3D printing vs traditional approaches	N	Subset for alpha = 0.05 1
Student-Newman-Keuls[a,b]	Slightly more expensive	24	1.96
	Similar	26	1.96
	Slightly cheaper	15	2.00
	Much cheaper	9	2.11
	Much more expensive	16	2.19
	Sig.		.946
Tukey HSD[a,b]	Slightly more expensive	24	1.96
	Similar	26	1.96
	Slightly cheaper	15	2.00
	Much cheaper	9	2.11
	Much more expensive	16	2.19
	Sig.		.946
Tukey B[a,b]	Slightly more expensive	24	1.96
	Similar	26	1.96
	Slightly cheaper	15	2.00
	Much cheaper	9	2.11
	Much more expensive	16	2.19
Duncan[a,b]	Slightly more expensive	24	1.96
	Similar	26	1.96
	Slightly cheaper	15	2.00
	Much cheaper	9	2.11
	Much more expensive	16	2.19
	Sig.		.518
Scheffe[a,b]	Slightly more expensive	24	1.96
	Similar	26	1.96
	Slightly cheaper	15	2.00
	Much cheaper	9	2.11
	Much more expensive	16	2.19
	Sig.		.968
Gabriel[a,b]	Slightly more expensive	24	1.96
	Similar	26	1.96
	Slightly cheaper	15	2.00
	Much cheaper	9	2.11
	Much more expensive	16	2.19
	Sig.		.997
Ryan-Einot-Gabriel-Welsch F	Slightly more expensive	24	1.96
	Similar	26	1.96
	Slightly cheaper	15	2.00
	Much cheaper	9	2.11
	Much more expensive	16	2.19
	Sig.		.916
Ryan-Einot-Gabriel-Welsch Range	Slightly more expensive	24	1.96
	Similar	26	1.96
	Slightly cheaper	15	2.00
	Much cheaper	9	2.11
	Much more expensive	16	2.19
	Sig.		.944
Hochberg[a,b]	Slightly more expensive	24	1.96
	Similar	26	1.96
	Slightly cheaper	15	2.00
	Much cheaper	9	2.11
	Much more expensive	16	2.19
	Sig.		.997
Waller-Duncan[a,b,c,d]	Slightly more expensive	24	
	Similar	26	
	Slightly cheaper	15	
	Much cheaper	9	
	Much more expensive	16	

Means for groups in homogeneous subsets are displayed.
a. Uses Harmonic Mean Sample Size = 15.605.
b. The group sizes are unequal. The harmonic mean of the group sizes is used. Type I error levels are not guaranteed.
c. Type 1/Type 2 Error Seriousness Ratio = 100.
d. There are no homogeneous subsets for alpha = 0.05.

Means Plots



Correlation Analysis (Pearson / Spearman

Correlations

Descriptive Statistics

	Mean	Std. Deviation	N
Years of experience in medical device/pharma industry	1.94	.770	90
Optimism about future of 3D printing in prosthetics	2.57	1.061	90

Correlations

		Years of experience in medical device/pharma industry	Optimism about future of 3D printing in prosthetics
Years of experience in medical device/pharma industry	Pearson Correlation	1	-.099
	Sig. (2-tailed)		.355
	Sum of Squares and Cross-products	52.722	-7.167
	Covariance	.592	-.081
	N	90	90
Optimism about future of 3D printing in prosthetics	Pearson Correlation	-.099	1
	Sig. (2-tailed)	.355	
	Sum of Squares and Cross-products	-7.167	100.100
	Covariance	-.081	1.125
	N	90	90

Nonparametric Correlations

Correlations

			Years of experience in medical device/pharma industry	Optimism about future of 3D printing in prosthetics
Kendall's tau_b	Years of experience in medical device/pharma industry	Correlation Coefficient	1.000	-.088
		Sig. (2-tailed)	.	.334
		N	90	90
	Optimism about future of 3D printing in prosthetics	Correlation Coefficient	-.088	1.000
		Sig. (2-tailed)	.334	.
		N	90	90
Spearman's rho	Years of experience in medical device/pharma industry	Correlation Coefficient	1.000	-.100
		Sig. (2-tailed)	.	.348
		N	90	90
	Optimism about future of 3D printing in prosthetics	Correlation Coefficient	-.100	1.000
		Sig. (2-tailed)	.348	.
		N	90	90

Correlations

Descriptive Statistics

	Mean	Std. Deviation	N
Supply chain reliability for 3D printing resources	2.42	1.081	90
Scalability of 3D printing for prosthetics	2.42	1.190	90

Correlations

		Supply chain reliability for 3D printing resources	Scalability of 3D printing for prosthetics
Supply chain reliability for 3D printing resources	Pearson Correlation	1	.139
	Sig. (2-tailed)		.190
	Sum of Squares and Cross-products	103.956	15.956
	Covariance	1.168	.179
	N	90	90
Scalability of 3D printing for prosthetics	Pearson Correlation	.139	1
	Sig. (2-tailed)	.190	
	Sum of Squares and Cross-products	15.956	125.956
	Covariance	.179	1.415
	N	90	90

Nonparametric Correlations

Correlations

			Supply chain reliability for 3D printing resources	Scalability of 3D printing for prosthetics
Kendall's tau_b	Supply chain reliability for 3D printing resources	Correlation Coefficient	1.000	.114
		Sig. (2-tailed)	.	.197
		N	90	90
	Scalability of 3D printing for prosthetics	Correlation Coefficient	.114	1.000
		Sig. (2-tailed)	.197	.
		N	90	90
Spearman's rho	Supply chain reliability for 3D printing resources	Correlation Coefficient	1.000	.139
		Sig. (2-tailed)	.	.191
		N	90	90
	Scalability of 3D printing for prosthetics	Correlation Coefficient	.139	1.000
		Sig. (2-tailed)	.191	.
		N	90	90

Multiple Linear Regression

Regression

Descriptive Statistics

	Mean	Std. Deviation	N
Optimism about future of 3D printing in prosthetics	2.57	1.061	90
Organisation's attitude toward 3D printing	2.52	1.094	90
Infrastructure sufficiency for 3D printing	2.02	.848	90
Supply chain reliability for 3D printing resources	2.42	1.081	90
Trust in strategic importance of 3D printing	1.56	.705	90

Correlations

		Optimism about future of 3D printing in prosthetics	Organisation's attitude toward 3D printing	Infrastructure sufficiency for 3D printing	Supply chain reliability for 3D printing resources	Trust in strategic importance of 3D printing
Pearson Correlation	Optimism about future of 3D printing in prosthetics	1.000	.013	.248	.093	.040
	Organisation's attitude toward 3D printing	.013	1.000	.181	.040	-.104
	Infrastructure sufficiency for 3D printing	.248	.181	1.000	.137	.017
	Supply chain reliability for 3D printing resources	.093	.040	.137	1.000	-.090
	Trust in strategic importance of 3D printing	.040	-.104	.017	-.090	1.000
Sig. (1-tailed)	Optimism about future of 3D printing in prosthetics	.	.451	.009	.192	.354
	Organisation's attitude toward 3D printing	.451	.	.044	.356	.165
	Infrastructure sufficiency for 3D printing	.009	.044	.	.099	.438
	Supply chain reliability for 3D printing resources	.192	.356	.099	.	.199
	Trust in strategic importance of 3D printing	.354	.165	.438	.199	.
N	Optimism about future of 3D printing in prosthetics	90	90	90	90	90
	Organisation's attitude toward 3D printing	90	90	90	90	90
	Infrastructure sufficiency for 3D printing	90	90	90	90	90
	Supply chain reliability for 3D printing resources	90	90	90	90	90
	Trust in strategic importance of 3D printing	90	90	90	90	90

Variables Entered/Removed[a]

Model	Variables Entered	Variables Removed	Method
1	Trust in strategic importance of 3D printing, Infrastructure sufficiency for 3D printing, Supply chain reliability for 3D printing resources, Organisation's attitude toward 3D printing[b]	.	Enter

a. Dependent Variable: Optimism about future of 3D printing in prosthetics
b. All requested variables entered.

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics: R Square Change	F Change	df1	df2	Sig. F Change	Durbin-Watson
1	.260[a]	.068	.024	1.048	.068	1.544	4	85	.197	2.066

a. Predictors: (Constant), Trust in strategic importance of 3D printing, Infrastructure sufficiency for 3D printing, Supply chain reliability for 3D printing resources, Organisation's attitude toward 3D printing
b. Dependent Variable: Optimism about future of 3D printing in prosthetics

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	6.782	4	1.695	1.544	.197[b]
	Residual	93.318	85	1.098		
	Total	100.100	89			

a. Dependent Variable: Optimism about future of 3D printing in prosthetics
b. Predictors: (Constant), Trust in strategic importance of 3D printing, Infrastructure sufficiency for 3D printing, Supply chain reliability for 3D printing resources, Organisation's attitude toward 3D printing

Coefficients[a]

		Unstandardized Coefficients		Standardized Coefficients			95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
Model		B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	1.778	.504		3.530	.001	.777	2.780					
	Organisation's attitude toward 3D printing	-.029	.104	-.030	-.276	.783	-.235	.178	.013	-.030	-.029	.956	1.046
	Infrastructure sufficiency for 3D printing	.306	.135	.244	2.271	.026	.038	.573	.248	.239	.238	.948	1.055
	Supply chain reliability for 3D printing resources	.063	.104	.064	.603	.548	-.144	.270	.093	.065	.063	.973	1.028
	Trust in strategic importance of 3D printing	.058	.159	.039	.366	.715	-.258	.375	.040	.040	.038	.980	1.021

a. Dependent Variable: Optimism about future of 3D printing in prosthetics

Coefficient Correlations[a]

Model			Trust in strategic importance of 3D printing	Infrastructure sufficiency for 3D printing	Supply chain reliability for 3D printing resources	Organisation's attitude toward 3D printing
1	Correlations	Trust in strategic importance of 3D printing	1.000	-.048	.092	.108
		Infrastructure sufficiency for 3D printing	-.048	1.000	-.136	-.182
		Supply chain reliability for 3D printing resources	.092	-.136	1.000	-.005
		Organisation's attitude toward 3D printing	.108	-.182	-.005	1.000
	Covariances	Trust in strategic importance of 3D printing	.025	-.001	.002	.002
		Infrastructure sufficiency for 3D printing	-.001	.018	-.002	-.003
		Supply chain reliability for 3D printing resources	.002	-.002	.011	-5.437E-5
		Organisation's attitude toward 3D printing	.002	-.003	-5.437E-5	.011

a. Dependent Variable: Optimism about future of 3D printing in prosthetics

Collinearity Diagnostics[a]

				Variance Proportion			
Model	Dimension	Eigenvalue	Condition Index	(Constant)	Organisation's attitude toward 3D printing	Infrastructure sufficiency for 3 printing	Sup
1	1	4.496	1.000	.00	.01		1
	2	.192	4.842	.00	.10		2
	3	.155	5.381	.00	.40		2
	4	.119	6.146	.00	.26		6
	5	.038	10.940	1.00	.24		0

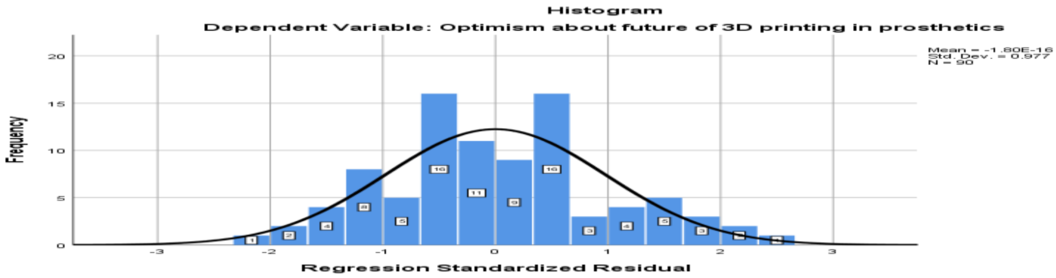
a. Dependent Variable: Optimism about future of 3D printing in prosthetics

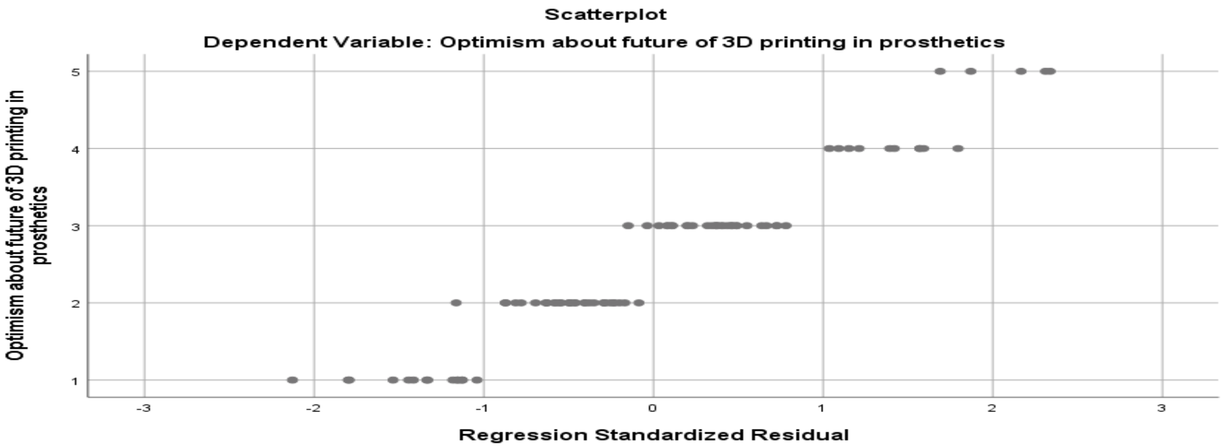
Residuals Statistics[a]

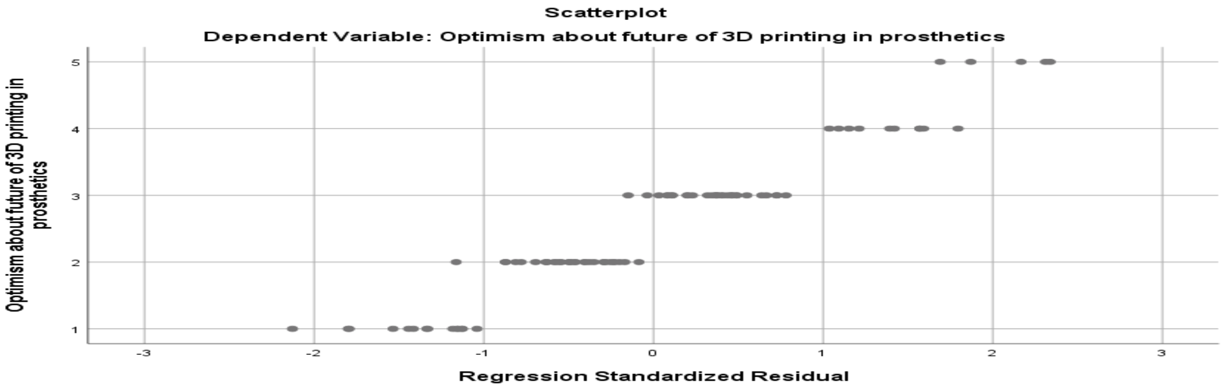
	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	2.09	3.23	2.57	.276	90
Residual	-2.230	2.450	.000	1.024	90

Std. Predicted Value	-1.726	2.402	.000	1.000	90
Std. Residual	-2.128	2.338	.000	.977	90

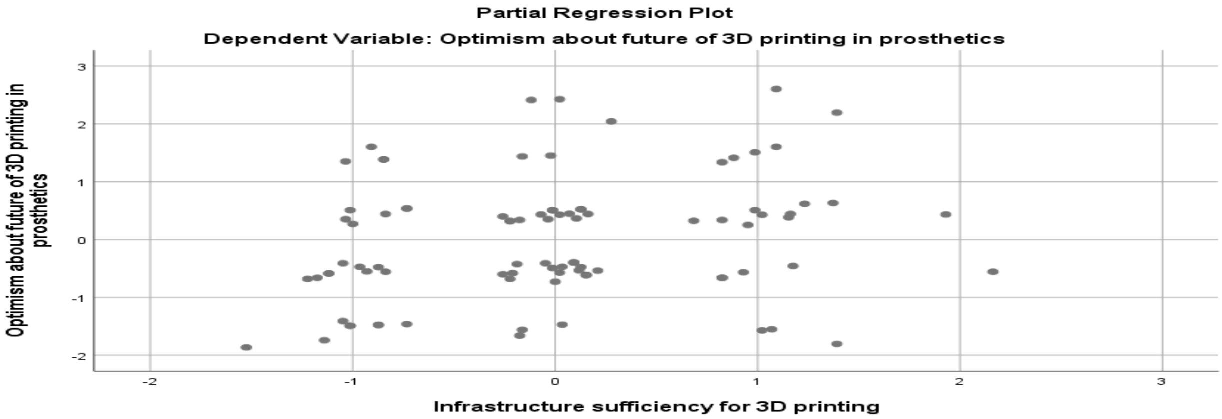
a. Dependent Variable: Optimism about future of 3D printing in prosthetics

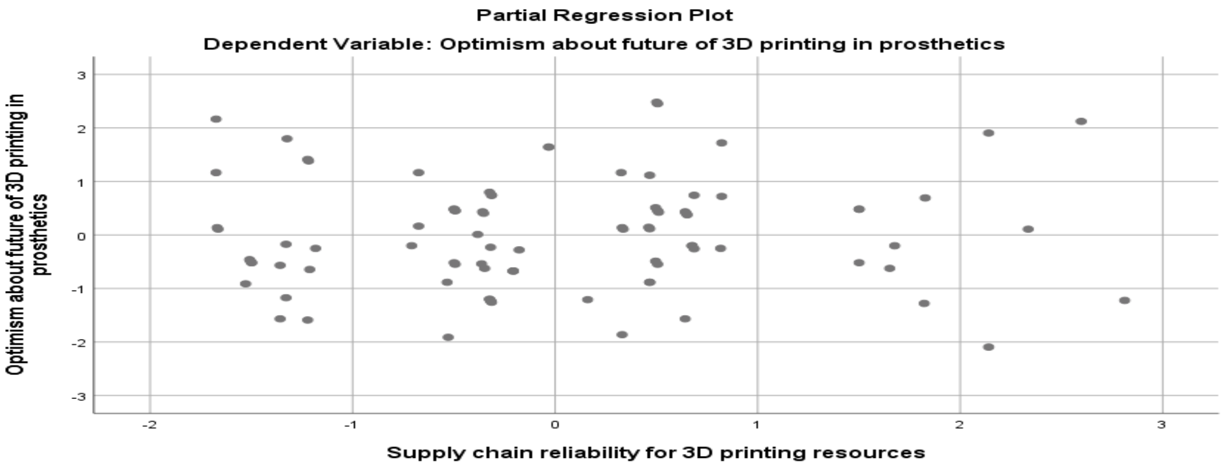


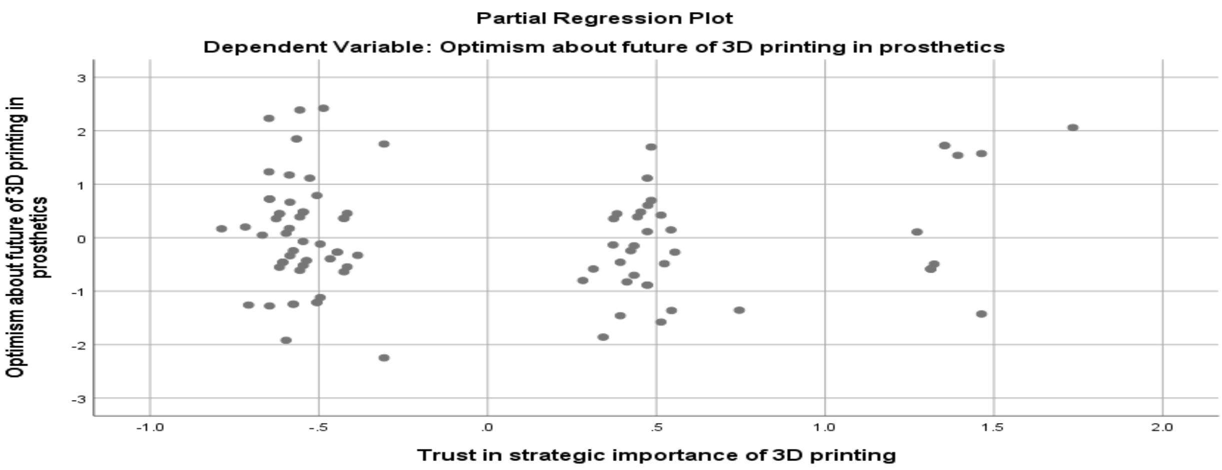





Partial Regression Plot
Dependent Variable: Optimism about future of 3D printing in prosthetics
Optimism about future of 3D printing in prosthetics
Organisation's attitude toward 3D printing


Partial Regression Plot
Dependent Variable: Optimism about future of 3D printing in prosthetics
Optimism about future of 3D printing in prosthetics
Infrastructure sufficiency for 3D printing


Partial Regression Plot
Dependent Variable: Optimism about future of 3D printing in prosthetics
Optimism about future of 3D printing in prosthetics
Supply chain reliability for 3D printing resources



Factor Analysis (Optional)

Factor Analysis

Descriptive Statistics[a]

	Mean	Std. Deviation	Analysis N
Infrastructure sufficiency for 3D printing	2.19	1.047	16
Supply chain reliability for 3D printing resources	1.94	.998	16
Preparedness of workforce training	2.44	1.315	16

a. Only cases for which Cost-efficiency of 3D printing vs traditional approaches = Much more expensive are used in the analysis phase.

Correlation Matrix[a,b]

		Infrastructure sufficiency for 3D printing	Supply chain reliability for 3D printing resources	Preparedness of workforce training
Correlation	Infrastructure sufficiency for 3D printing	1.000	.267	.179
	Supply chain reliability for 3D printing resources	.267	1.000	.429
	Preparedness of workforce training	.179	.429	1.000
Sig. (1-tailed)	Infrastructure sufficiency for 3D printing		.159	.254
	Supply chain reliability for 3D printing resources	.159		.049
	Preparedness of workforce training	.254	.049	

a. Only cases for which Cost-efficiency of 3D printing vs traditional approaches = Much more expensive are used in the analysis phase.
b. Determinant = .754

Inverse of Correlation Matrix[a]

	Infrastructure sufficiency for 3D printing	Supply chain reliability for 3D printing resources	Preparedness of workforce training
Infrastructure sufficiency for 3D printing	1.083	-.253	-.085
Supply chain reliability for 3D printing resources	-.253	1.284	-.505
Preparedness of workforce training	-.085	-.505	1.232

a. Only cases for which Cost-efficiency of 3D printing vs traditional approaches = Much more expensive are used in the analysis phase.

KMO and Bartlett's Test[a]

Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.574
Bartlett's Test of Sphericity	Approx. Chi-Square	3.720
	df	3
	Sig.	.293

a. Only cases for which Cost-efficiency of 3D printing vs traditional approaches = Much more expensive are used in the analysis phase.

Anti-image Matrices[a]

		Infrastructure sufficiency for 3D printing	Supply chain reliability for 3D printing resources	Preparedness of workf e training
Anti-image Covariance	Infrastructure sufficiency for 3D printing	.924	-.182	-.064
	Supply chain reliability for 3D printing resources	-.182	.779	-.319
	Preparedness of workforce training	-.064	-.319	.812
Anti-image Correlation	Infrastructure sufficiency for 3D printing	.668[b]	-.215	-.074
	Supply chain reliability for 3D printing resources	-.215	.552[b]	-.402
	Preparedness of workforce training	-.074	-.402	.564[b]

a. Only cases for which Cost-efficiency of 3D printing vs traditional approaches = Much more expensive are used in the analysis phase.
b. Measures of Sampling Adequacy(MSA)

Communalities[a]

	Initial	Extraction
Infrastructure sufficiency for 3D printing	1.000	.352
Supply chain reliability for 3D printing resources	1.000	.663
Preparedness of workforce training	1.000	.582

Extraction Method: Principal Component Analysis.
a. Only cases for which Cost-efficiency of 3D printing vs traditional approaches = Much more expensive are used in the analysis phase.

Total Variance Explained[a]

	Initial Eigenvalues			Extraction Sums of Squared Loadings		
Component	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	1.596	53.213	53.213	1.596	53.213	53.213
2	.844	28.144	81.357			
3	.559	18.643	100.000			

Extraction Method: Principal Component Analysis.
a. Only cases for which Cost-efficiency of 3D printing vs traditional approaches = Much more expensive are used in the analysis phase.

Component Matrix[a,b]

	Component
	1
Supply chain reliability for 3D printing resources	.814
Preparedness of workforce training	.763
Infrastructure sufficiency for 3D printing	.593

Extraction Method: Principal Component Analysis.
a. 1 components extracted.
b. Only cases for which Cost-efficiency of 3D printing vs traditional approaches = Much more expensive are used in the analysis phase.

Reproduced Correlations[a]

		Infrastructure sufficiency for 3D printing	Supply chain reliability for 3D printing resources	Preparedness of workforce training
Reproduced Correlation	Infrastructure sufficiency for 3D printing	.352[b]	.483	.452
	Supply chain reliability for 3D printing resources	.483	.663[b]	.621
	Preparedness of workforce training	.452	.621	.582[b]

Residual[c]	Infrastructure sufficiency for 3D printing		-.216	-.274
	Supply chain reliability for 3D printing resources	-.216		-.192
	Preparedness of workforce training	-.274	-.192	

Extraction Method: Principal Component Analysis.
a. Only cases for which Cost-efficiency of 3D printing vs traditional approaches = Much more expensive are used in the analysis phase.
b. Reproduced communalities
c. Residuals are computed between observed and reproduced correlations. There are 3 (100.0%) nonredundant residuals with absolute values greater than 0.05.

Component Score Coefficient Matrix[a]

	Component
	1
Infrastructure sufficiency for 3D printing	.372
Supply chain reliability for 3D printing resources	.510
Preparedness of workforce training	.478

Extraction Method: Principal Component Analysis.
Component Scores.
a. Only cases for which Cost-efficiency of 3D printing vs traditional approaches = Much more expensive are used in the analysis phase.

Component Score Covariance Matrix[a]

Component	1
1	1.000

Extraction Method: Principal Component Analysis.
Component Scores.
a. Only cases for which Cost-efficiency of 3D printing vs traditional approaches = Much more expensive are used in the analysis phase.