An Investigation into composite additive manufacturing of dynamic response paediatric prosthetic ankle-foot devices.

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ABSTRACT

This PhD research explores the potential of FFF composite additive manufacturing for producing dynamic response paediatric ankle-foot prosthetics. It addresses challenges faced by children with lower-limb absence, particularly in accessing prosthetics that support active lifestyles and sports participation. A systematic literature review identified major barriers, including the high cost and limited availability of advanced prosthetic devices. Technological limitations were also highlighted, with many existing prosthetics lacking sufficient energy return and durability for high-impact activities, leading to discomfort and reduced performance.

To evaluate the feasibility of composite additive manufacturing in this context, the research investigated the tensile strength, repeatability, and precision of additive manufacturing carbon fibre materials. A parametric study examined how different fabrication parameters, such as fibre layers, layer distribution, wall layers, and fill patterns, affect mechanical performance. Results showed that increasing fibre reinforcement significantly improved stiffness and energy return, key characteristics for dynamic response prosthetics. Logarithmic equations were developed to predict these mechanical properties, providing a tool for optimising prosthetic designs based on specific user needs.

In the final phase, an Ossur Vari-Flex Junior prosthetic foot was used as a benchmark to produce and test an additively manufactured equivalent. The additively manufactured prosthetic was assessed against American Orthotic Prosthetic Association (AOPA) classification standards for efficiency and displacement. Findings confirmed that composite additive manufacturing can produce paediatric prosthetic feet that meet dynamic response criteria, demonstrating its potential as a viable alternative to traditional manufacturing.

This PhD makes an original contribution to knowledge by advancing the understanding and application of composite additive manufacturing for paediatric prosthetic design and manufacture. It establishes a validated predictive modelling framework that enables precise control over mechanical properties, stiffness and energy efficiency, based on key fabrication parameters. The research demonstrates that additive manufacturing can produce dynamic response prosthetic feet, meeting established classification thresholds. This work paves the way for cost-effective, repeatable, and customisable prosthetic solutions, significantly enhancing accessibility for children with lower-limb absence.

GLOSSARY

ABS - Acrylonitrile Butadiene Styrene

AOPA - American Orthotic Prosthetic Association

AM - Additive Manufacturing

BS – British Standard

CAD – Computer Aided Design

CFRAM - Continuous Fibre-Reinforced Additive Manufacturing

CMM - Coordinate Measuring Machine

ESAR - Energy Storing and Returning

DIC - Digital Image Correlation

FFF – Fused Filament Fabrication

GRP – Glass Reinforced Plastic

ISO - International Organization for Standardization

MAPE - Mean Absolute Percentage Error

PA - Polyamide

PPE – Personal Protective Equipment

UTS – Ultimate Tensile Strength

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AUTHOR'S DECLARATION

The author declares that the work presented herein is entirely original. Where figures or quotes are used that are the property of a third party, they are referenced within the body of the work.

Peer-reviewed published journal papers

Various aspects of the research presented in this thesis have been published in internationally recognised journals. This approach has provided a method of peer review during the progression of the research project. These papers can be found below:

- Batley, A., Sewell, P. and Dyer, B., 2023. Facilitators and barriers for participation in sports and physical activity for children with lower-limb absence: A systematic review. Prosthetics and orthotics international, 47 (4), 368-378.

- Batley, A., Glithro, R., Dyer, B. and Sewell, P., 2023. Evaluation of Tensile Strength and Repeatability of 3D Printed Carbon Fiber Materials and Processes. 3D Printing and Additive Manufacturing, 11(5), pp.1691-1702.

- Batley, A., Glithro, R., Montalvao, D., Dyer, B. and Sewell, P., 2024. Parametric Analysis of 3D Printing Parameters on Stiffness and Hysteresis Characteristics of Paediatric Prosthetic Foot Coupon Samples. Prosthetics and Orthotics International, pp.10-1097.

- Batley, A., Dyer, B. and Sewell, P., 2024. Effect of Humidity on the Stiffness and Hysteresis of Composite 3D-Printed Paediatric Prosthetic Foot Coupon Samples. 3D Printing and Additive Manufacturing.

CHAPTER 1: INTRODUCTION & LITERATURE REVIEW

1.1 Introduction

Participation in sports and physical activity for amputees has been shown to improve their physical health, social inclusion, and overall well-being (Bragaru et al. 2012; Deans et al. 2012). Specifically, in children with disabilities, sports and recreational activities offer physical and psychological benefits such as, promoting inclusion, optimising physical functioning, and improving self-esteem and quality of life (Wind et al. 2004; Murphy and Carbone 2008; Sayed Ahmed et al. 2018). Interest in recreational activity amongst amputees has increased significantly since the 1980s (Dyer 2016), as have the development of many sport organisations for the disabled (Deans et al. 2012).

For individuals with amputations, prostheses are an integral part of their life (Grobler and Derman 2018), however due to the rapid growth of children who use prostheses, numerous appointments with specialists are required, resulting in frequently obtaining new prostheses (Sayed Ahmed et al. 2018). The high cost of a secondary dynamic response sport-specific prosthesis for children, which they could potentially outgrow within six months, has been identified as a barrier to sports participation (Sayed Ahmed et al. 2018). As the number of young traumatic amputees in the coming years is expected to rise, it is presumed that the request for specialised sport prostheses will also increase in coming years (Bragaru et al. 2012).

Prosthetics are extremely important for children with limb absence as children will suffer more damaging effects in the long term than seniors if they are deprived of appropriate prostheses (Otto 2016). However, there has been very little research and development work in paediatric-specific prosthetic products, with medical devices that are designed specifically for children lagging five to ten years behind new technology available for adults (Otto 2016). This indicates there is a strong need for development in paediatric specific lower limb prostheses (Kerfeld et al. 2018).

Children with limb absence are very active, walking on average five times more than comparable adults every day (Vannah et al. 1999). Children need prosthetic functionality more than adults as it’s vital for their development that they can reach certain milestones at an early age. If not, problems can arise that can affect them for the rest of their lives (Otto 2016). For example, fundamental movement skills such as locomotor (running and hopping), manipulative or object control (catching and throwing), and stability (balancing and twisting) are developed in childhood and are subsequently refined into context and sport specific skills (Kerfeld et al. 2018).

Producing prostheses can involve manufacturing of lot of custom and individual components, which require several, labour intensive steps (Klasson 1995; Bader 2002; Hussain and Takhakh 2017; Savsani et al. 2023). This process produces high cost per prosthetic due to the high investment costs for equipment such as an autoclave and a computer controlled cutting system, and the labour of a highly skilled professional (Klasson 1995; Bader 2002; Savsani et al. 2023), therefore making it a barrier for a lot of amputees.

Current research conducted into additive manufacturing (AM) of carbon fibre reinforced prosthetic feet has concluded that composite filament fabrication AM has the potential to serve as a fabrication method to produce energy returning prosthetic feet (Warder et al. 2018; Martulli et al. 2023), whilst also decreasing materials wastage (Savsani et al. 2023). By utilising advances in AM technologies and materials, and 3D scanning, the time scale of designing and producing sports prosthetics can be dramatically reduced (Dyer et al. 2022). However, further research is needed to test the longevity of such components and testing of energy return variability using alternative fibre reinforcement materials and locations (Warder et al. 2018).

Energy storing and returning (ESAR) prosthetic feet (Figure 1.1) play a pivotal role in enhancing mobility and physical performance for individuals with lower limb loss. These devices are specifically designed to mimic the natural movement of a human foot by absorbing and storing energy during the stance phase of walking and running, and then returning that energy during the push-off phase. This mechanism allows for a smoother and more efficient gait by reducing the amount of energy the user must use with each step (Zelik and Honert 2018). ESAR feet are particularly beneficial in sports and high-activity settings, where quick movements, agility, and sustained endurance are essential.

Figure 1.1. ESAR Foot example (Ossur Vari-Flex) (https://www.ossur.com/en-gb/prosthetics/feet/vari-flex)

For children with limb differences, ESAR feet are crucial. Since children are highly active and in critical stages of physical and motor development, they require prosthetics that can not only support but enhance their ability to run, jump, and play. A dynamic, energy-returning prosthesis enables them to participate more fully in physical activities, improving their overall development and quality of life. ESAR feet also allow children to build fundamental movement skills, such as running and hopping, which are key to their physical, psychological, and social development (Kerfeld et al. 2018). Children with lower limb absence have different gait patterns, higher energy expenditure, and face more frequent prosthetic replacements due to growth compared to adults. Thus, the ability of an ESAR foot to reduce energy consumption during movement makes it an essential tool for maintaining their activity levels and reducing fatigue. It is especially important in promoting not only inclusion in daily activities, but also in empowering them to engage competitively in sports alongside their peers.

The need for functional, durable, and cost-effective paediatric prosthetic devices remains an underexplored area in prosthetic research. Despite advancements in adult prosthetic technology, children with lower limb absence continue to face significant challenges in acquiring prostheses that meet their unique needs. The high cost of dynamic response prosthetic feet, coupled with the frequency of replacements due to children’s rapid growth, creates significant barriers to access. This research addresses these gaps by investigating the potential of composite AM to develop dynamic response paediatric prosthetic ankle-foot devices.

This research is grounded in the potential benefits of utilising AM technology and composite materials to produce dynamic response prosthetic feet tailored for paediatric use. By applying continuous carbon fibre materials and exploring a variety of AM parameters, this research seeks to improve the durability, functionality, and cost-effectiveness of dynamic response prostheses.

This research will contribute to the development of ESAR prosthetic feet that are specifically designed for children, enabling them to fully engage in physical activities, sports, and daily life with less discomfort and greater efficiency. The aim is to reduce the physical and financial burden on children and their families, while improving the long-term health and well-being of young amputees by facilitating their active participation in sports and recreation.

1.2 Literature Review

The information presented in this is derived from the published systematic literature review paper: Batley, A., Sewell, P., and Dyer, B. (2023). Facilitators and barriers for participation in sports and physical activity for children with lower-limb absence: A systematic review. Prosthetics and Orthotics International, 47(4), 368-378.

This provides a comprehensive review of the existing literature relevant to the development and use of prosthetic devices for children with limb absence, with a particular focus on sports participation. Sports and physical activity play a vital role in children’s physical, social, and psychological development, yet many prosthetic devices are not optimised for high-impact activities, limiting participation. The review addresses the key facilitators and barriers that influence children’s ability to engage in physical activity and sports, specifically highlighting the challenges and opportunities for children with limb absence. It then explores the unique requirements for paediatric-specific prostheses, emphasising the functional differences between devices for children and adults.

The literature also explores the classification and function of ESAR feet prostheses, particularly those designed for sport-specific purposes, and examines their role in enabling amputees to participate in dynamic physical activities, finally, exploring how advancements in AM technologies may overcome current limitations in the production of dynamic paediatric prostheses.

This review lays the foundation for understanding the gaps in current research and the rationale for investigating new approaches to designing and manufacturing paediatric dynamic response prosthetic feet.

1.2.1 Facilitators and barriers in sport participation for children with limb absence

A systematic literature review was conducted following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) (Page et al. 2021) (Figure 1.2) framework to identify and synthesise existing research on the facilitators and barriers to sports and physical activity participation for children with lower-limb absence. This structured approach ensured a comprehensive and reproducible analysis of the available literature.

A comprehensive search strategy was executed across five major academic databases; Medline, Scopus, Cochrane, SPORTDiscus, and CINAHL. Google Scholar was also used as a secondary source to identify additional studies. The PICO model (Population, Intervention, Comparison, Outcome) was applied to structure the search terms effectively, with Boolean operators used to refine and maximise search coverage (Table 1.1).

The search retrieved 2,786 articles, which were imported into EndNote for duplicate removal, leaving 2,751 unique articles. A title and abstract screening was conducted based on predefined inclusion criteria, followed by a full-text review to determine eligibility. Articles that met the criteria were included in the final analysis, and reference lists were manually checked for any additional relevant studies.

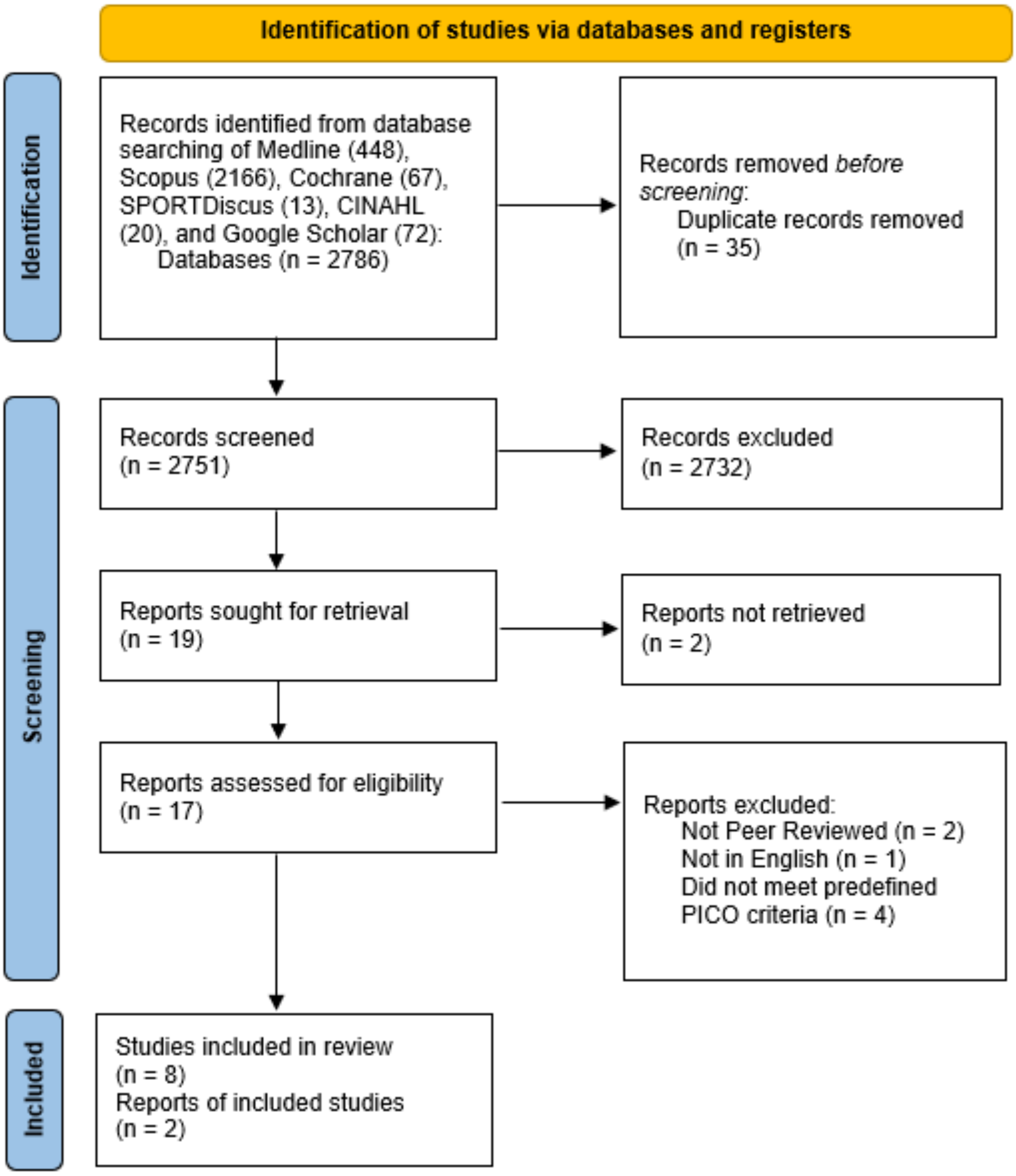

Figure 1.2. Preferred Reporting Item for Systematic Reviews and Meta-Analysis flow diagram. (https://www.eshackathon.org/software/PRISMA2020.html)

P (Population/Problem) **Children with limb absence**	**I (Intervention)** **Facilitators/Barriers**	**C (Comparison)** **N/A**	**O (Outcome)** **Participation or non-participation in sports and physical activity**
Adolescent	Facilitators		Sports
Child*	Enablers		Physical Activit*
Young Adult	Organisers		Leisure
Young Person			Exercise
Young People	Barriers		Physical Education
P#ediatric	Obstacles		
	Difficulties		
Limb Absence	Obstructions		
Disab*	Limitations		
Prosthe*			
Amput*			
Limb Defici*			

Table 1.1. PICO Search Strategy

The methodological quality of the included studies was assessed using the Mixed Methods Appraisal Tool (MMAT) (Hong et al. 2018), applied to qualitative, quantitative, and mixed-methods studies, with only studies scoring ≥60% included, and the Critical Appraisal Skills Programme (CASP) (CriticalAppraisalSkillsProgramme 2018), used to assess systematic reviews. This ensured that only studies of sufficient methodological quality were considered, strengthening the validity of the review.

A structured data extraction process was conducted, capturing key information such as study characteristics, methodology, and identified facilitators and barriers to sports participation. A thematic analysis was performed, where data were coded, categorised into hierarchical structures, and synthesised into overarching analytical themes.

The systematic review identified six key themes influencing sports participation for children with lower-limb absence. Table 1.2 provides a summary of these themes, their associated subthemes, and the specific facilitators and barriers identified.

Themes	Sub-themes	Examples (Facilitators and/or Barriers)
Prostheses	Cost Function/Technology Comfort Appearance Weight	Advances in prosthetic technology and design have laid the foundation for the growth and development of recreational and sports activities for persons with limb deficiency.
	Materials Temporary limb loss Rehabilitation Usage	Most common reasons for loss of limb use were pain and prosthesis failure. Feet, knees and cosmetic foam covers were the components most frequently failing.
Physiology	Pain Sweat Growth	Individuals with lower limb absence have altered structure and physiology of their limbs which impairs their balance, mobility, physical functioning and participation in physical activities.
	Movement Physical health Rehabilitation	Pain was most frequently reported during strenuous activities or walking on uneven ground and less frequent during quiet activities.
Enjoyment of Sport	Organised sports Paralympics Professional Athletes	The opportunity to participate in organised sports programmes locally and globally, such as the Paralympics was also a contributor to their love and passion for sports, along with having pro-league aspirations and looking up to professional athletes.
Environmental Impact	Sports facilities Opportunities School/Physical Education	Opportunities for persons with limb deficiency to participate in sports and recreational activities have increased dramatically over the past 20 years.
	Prior planning Experienced coaches	Most children expressed that their coaches understanding of their abilities shaped their experience with sport participation.
Societal Impact	Stigma Psychological health Participation	Many children reported that encouragement from parents, coaches, and friends was a motivator for sport participation as it made them feel like they were capable.
	Quality of life Social Environment Family/Peer encouragement	Children noted teasing and bullying during sport activities by their peers. Negative comments from peers or members of the public limited sport participation for some children.
Research	Lack of investment	Manufacturers consider investment in paediatric components as disproportionate for a limited return.
	Lack of literature Lack of clinical research	It is widely recognised but poorly documented that children with lower limb deficiencies have distinctly different clinical outcomes with respect to surgical and prosthetic management than adults with comparable limb differences.

Table 1.2. Overview of Literature Themes

Theme 1: Prostheses

Nearly all children with lower limb deficiencies are fitted with prostheses to improve their ability to perform daily activities (Boonstra et al. 2000; Michielsen et al. 2010). Thanks to advancements in prosthetic technology and design, opportunities are continually expanding for children and adolescents with lower limb deficiencies who wish to engage in sports and physical activities (Webster et al. 2001; Michielsen et al. 2010). However, whether prostheses act as facilitators or barriers to sports participation in children with limb absence remains a subject of debate (Sayed Ahmed et al. 2018). Prostheses can facilitate activities by enhancing functional capacity and mobility, including improving posture, strength, stability, balance, and weight distribution (Eshraghi et al. 2018; Kerfeld et al. 2018; Sayed Ahmed et al. 2018). On the other hand, issues such as prosthetic failure, poor fit, frequent growth adjustments, component size and weight, cost, comfort, and mobility limitations are significant barriers that can hinder sports participation (Vannah et al. 1999; Boonstra et al. 2000; Webster et al. 2001; Eshraghi et al. 2018; Kerfeld et al. 2018; Sayed Ahmed et al. 2018; Chhina et al. 2021).

Functionality was identified as the top priority for most children using prostheses, with their primary concerns being walking, playing sports, and attending school (Vannah et al. 1999). The weight of the prosthesis is also crucial, but with materials such as carbon fibre, titanium, and graphite, strength and energy return capabilities are now achievable without adding excessive weight (Webster et al. 2001). The functionality of children with lower limb absence is significantly influenced by their prosthetic components (Eshraghi et al. 2018), which is why many paediatric patients begin with energy-storing prosthetic feet due to their common use, affordability, durability, and general acceptance (McMulkin et al. 2004). As children improve their mobility and engage more in recreational activities, they often require prostheses that offer greater dynamic capabilities, such as a multiaxial dynamic foot for activities such as running and jumping (McMulkin et al. 2004). While some children report that their prostheses facilitate sports participation, others find them a hindrance to engaging in physical activity (Sayed Ahmed et al. 2018). Benefits such as improved posture, strength, and balance are noted, as well as the prevention of overuse of the sound limb, but drawbacks include restricted motion, discomfort, poor fit, and prosthetic weight (Sayed Ahmed et al. 2018; Chhina et al. 2021). These functional limitations not only restrict physical activities but also impact social interactions with friends and family (Chhina et al. 2021). A common reason for temporary loss of prosthesis use is device failure, particularly in components such as feet, knees, and cosmetic foams (Vannah et al. 1999). Some children also use specialised prostheses or attachments for sports

(Sayed Ahmed et al. 2018). When considering prosthetics for sports, key factors include whether the prosthesis will be used for both daily activities and sports or solely for a specific sport, as well as the physical demands and environment of the chosen activity (Webster et al. 2001). Extensive education on maintenance, care and adjustments is often required for children using prostheses in sports, as they need to recognise and address signs of impending component failure (Webster et al. 2001).

Comfort is another significant concern, with 28% of children identifying it as their top priority (Vannah et al. 1999). Over 88% of children use their prostheses for more than nine hours a day (Vannah et al. 1999; Boonstra et al. 2000). Fitting lower limb prostheses for children is generally successful and results in high levels of rehabilitation (Vannah et al. 1999), but maintaining a proper fit is essential due to the frequent growth changes in children (Webster et al. 2001). For example, a child with congenital limb deficiencies typically receives their first prosthesis around 18 months old (Boonstra et al. 2000), and due to growth, adjustments or replacements, may be necessary every 12 to 18 months (Vannah et al. 1999). Since children quickly outgrow their prostheses, parents must anticipate these changes and schedule regular appointments with prosthetists (Sayed Ahmed et al. 2018). Poorly fitting prostheses are a common barrier to sports participation (Boonstra et al. 2000; Kerfeld et al. 2018; Sayed Ahmed et al. 2018; Chhina et al. 2021), with reports from parents noting instances where their child's prosthesis would fall off during activities such as running or kicking a ball (Kerfeld et al. 2018).

Cosmesis, or the appearance of the prosthesis, was a priority for only 8% of children, with 43% being very happy and 31% somewhat happy with the look of their prosthesis (Vannah et al. 1999). When it comes to devices used for sports, appearance tends to be less important than function (Webster et al. 2001). However, recent studies (Chhina et al. 2021) suggest that appearance has become a more significant concern for children, with differences in the look of their limbs acting as a barrier to participating in social, recreational and leisure activities.

The development of prosthetic design, components, and manufacturing processes has led to more opportunities for individuals with limb loss to engage in sports and physical activities (Webster et al. 2001). Much of this progress has been driven by users who demand prosthetics that enable their full their athletic abilities rather than limit them (Webster et al. 2001). While these advances have made prosthetic failures less common, they have primarily targeted the adult market, leaving fewer options for paediatric patients.

Lastly, the high cost of secondary, sport-specific prostheses is often cited as a significant barrier to sports participation for children with lower limb absence (Sayed Ahmed et al. 2018).

Theme 2: Physiology

Children and adolescents with congenital limb deficiencies face limitations in their ability to engage in various activities due to the altered structure and physiology of their limbs. This can affect their balance, mobility, physical functioning, and participation in physical activities (Michielsen et al. 2010; Feick et al. 2016). For children with limb deficiencies, participation in sports and recreational activities plays a crucial role in helping them develop motor coordination skills and adapt to their physical limitations (Webster et al. 2001). Fundamental movement skills, such as locomotor (running and hopping), manipulative or object control (catching and throwing), and stability (balancing and twisting), are typically developed in childhood and later refined into sport-specific skills (Kerfeld et al. 2018). Children who encounter barriers to physical activity often fall behind in acquiring these essential movement skills, which increases the risk of developing secondary health and behavioural issues. The physiological barriers that children with limb deficiencies face when trying to participate in sports include mobility and functional limitations, pain, excessive perspiration and skin breakdown (Vannah et al. 1999; Boonstra et al. 2000; Webster et al. 2001; Feick et al. 2016; Eshraghi et al. 2018; Kerfeld et al. 2018; Sayed Ahmed et al. 2018; Chhina et al. 2021).

Theme 3: Enjoyment of Sport

Children's enjoyment of sports serves as a significant facilitator for their participation. Many children expressed feelings of pride, happiness, accomplishment, confidence, and fulfilment when engaging in sports (Sayed Ahmed et al. 2018). They described sports as enjoyable, entertaining, fun, energising and a chance to learn new skills (Sayed Ahmed et al. 2018). Some children highlighted the physical benefits they appreciated, such as staying healthy and fit, while others emphasised the social advantages such as meeting new people, socialising, staying connected, and being part of a team, as reasons for their love of sports (Sayed Ahmed et al. 2018). The opportunity to take part in organised sports programmes, both locally and globally, including events such as the Paralympics, along with having professional athletes as role models, further fuelled their passion for sports (Sayed Ahmed et al. 2018).

Boonstra et al. (2000) reported that over 74% of children aged five years and above participate in sporting activities, with swimming being the most common. Most children also enjoyed activities involving playgrounds, outdoor adventures, and nature-based activities in parks. However, fewer children reported enjoying activities such as dancing, team sports, martial arts and gymnastics (Kerfeld et al. 2018). Other sports in which children participated included running, cycling, basketball, hockey, football, table tennis, figure skating, baseball, skiing, curling, karate, golf and snowboarding (Vannah et al. 1999; Sayed Ahmed et al. 2018).

Theme 4: Environmental Impact

The environments in which children with lower limb amputations seek to participate in sports and physical activities can either facilitate or hinder their involvement. Over the past two decades, the availability of organised sports programs for children with limb deficiencies has grown significantly, partly due to the development of sports organisations for individuals with disabilities, which provide essential information, resources and support (Webster et al. 2001). Many children expressed that having a coach who understood their abilities positively influenced their sports experience, and encouragement from coaches served as a motivator, making them feel capable and confident in their abilities (Sayed Ahmed et al. 2018).

However, parents noted that the high costs of organised sports programmes and facilities, along with the need to drive long distances, posed challenges and acted as barriers to their children's participation in these activities (Sayed Ahmed et al. 2018). Additionally, children with lower limb absence often faced limited participation in school settings, particularly in academic, sports, and recreational activities (Chhina et al. 2021). School-based environmental barriers, feelings of isolation, as well as emotional and instrumental support from friends and teachers, were common experiences among these children (Chhina et al. 2021). Despite this, 90% of children aged four years and above attended regular primary or secondary schools, with 93% of them able to take part in physical education, although 47% experienced some level of difficulty (Boonstra et al. 2000). Some children found alternative, less physically demanding activities at school to accommodate their needs (Chhina et al. 2021).

Theme 5: Societal Impact

The social need for leisure is recognised as a key element of quality of life, particularly for individuals whose societal involvement is restricted by physical impairments

(Webster et al. 2001). Several studies emphasise that participation in sports and recreation is a significant concern for individuals with limb deficiencies, as these activities are crucial for their reintegration into the community (Sayed Ahmed et al. 2018). Children with lower limb deficiencies face a higher risk of reduced participation in social and leisure activities, which can negatively impact their quality of life (Michielsen et al. 2010). Although the full connection between participation and quality of life is not yet completely understood, both are seen as primary objectives in paediatric rehabilitation (Michielsen et al. 2010). Societal factors that facilitate participation in sports and physical activities include psychological benefits, social interaction, and encouragement from family and peers (Webster et al. 2001; Michielsen et al. 2010; Kerfeld et al. 2018; Sayed Ahmed et al. 2018). Conversely, barriers such as stigma and bullying still exist (Sayed Ahmed et al. 2018; Chhina et al. 2021).

Engaging in sports and recreational activities offers numerous psychological and emotional advantages for individuals with limb deficiencies, making these activities essential for leisure and community integration (Webster et al. 2001). The psychological benefits for children with limb absence participating in physical activities include improved self-efficacy, self-confidence, self-esteem, peer interaction, and social skills (Kerfeld et al. 2018; Sayed Ahmed et al. 2018). Children also expressed that the social aspects of sports, such as meeting new people, socialising, staying connected, and being part of a team, were major motivators for their participation (Sayed Ahmed et al. 2018). Family encouragement, in particular, was identified as one of the most significant factors influencing their involvement in sports (Michielsen et al. 2010).

However, some children reported experiencing teasing and bullying from their peers during sports activities, leading to feelings of isolation and exclusion (Sayed Ahmed et al. 2018; Chhina et al. 2021). These negative social experiences, whether from peers or the general public, served as a deterrent to participation in sports for certain children (Sayed Ahmed et al. 2018).

Theme 6: Research and Development

Reviews (Michielsen et al. 2010; Eshraghi et al. 2018; Kerfeld et al. 2018; Chhina et al. 2021) emphasise the need for more research on children with limb loss, particularly as advancements in prosthetic technology may enhance functional outcomes for children and adolescents (Eshraghi et al. 2018). Currently, the lack of clinical research, limited literature, and insufficient investment all act as barriers to sport and physical activity participation for children with lower limb absence.

It is well-known, though poorly documented, that children with lower limb deficiencies have notably different clinical outcomes in terms of surgical and prosthetic management compared to adults (Vannah et al. 1999). However, the functional abilities of children with limb deficiencies remain understudied (Boonstra et al. 2000). While there are parallels between adult and child populations in areas such as prosthesis use, social factors, and participation in sports, information from adult populations does not necessarily translate to younger individuals (Sayed Ahmed et al. 2018).

The selection of paediatric prosthetic components is much more limited than for adults, and the lack of evidence regarding the effectiveness of different paediatric components hinders clinical decision-making. As a result, clinicians often rely on personal experience and intuition rather than sound evidence (Eshraghi et al. 2018). While manufacturers focus on producing advanced, high-performance prosthetics for adults, it is children, who are often more active, that could benefit the most from these technologies (Eshraghi et al. 2018). Efforts to design and test paediatric-specific systems have been slow due to the small population size, leaving room for further development in this area (Eshraghi et al. 2018).

Although it has been suggested that understanding factors influencing participation could reduce barriers and promote physical activity in children with lower limb absence (Sayed Ahmed et al. 2018), there is limited data available, as no studies have specifically focused on this issue (Michielsen et al. 2010; Kerfeld et al. 2018; Sayed Ahmed et al. 2018). While barriers and facilitators affecting sport participation are well-documented for adults, little is known about these factors in children with limb deficiencies (Sayed Ahmed et al. 2018). This gap in knowledge highlights the need for further research on how children engage in sports and how they can be encouraged to participate in recreational activities (Michielsen et al. 2010).

1.2.2 Function/Classification of energy storing and returning feet prosthetics

ESAR prosthetic feet have revolutionised the way amputees participate in physical activities, particularly in dynamic and high-impact sports. These prosthetic devices are engineered to mimic the natural function of the human foot by storing mechanical energy during the stance phase of walking or running and releasing it during push-off. This energy return mechanism not only aids in propulsion but also enhances overall gait efficiency, allowing amputees to engage in more dynamic movements with reduced fatigue (McGowan et al. 2012).

The primary function of ESAR prosthetic feet is to replicate the biomechanical properties of the natural foot during activities such as walking, running, and jumping. When the foot strikes the ground, energy is absorbed by the prosthetic's elastic components, typically carbon fibre or other lightweight, high-resilience materials. This stored energy is then released to provide propulsion as the foot leaves the ground. In non-ESAR prostheses, energy is largely dissipated as heat, leading to less efficient gait patterns (Bowen 2014). In contrast, the energy return capability of ESAR feet provides increased propulsion and allows for a more natural gait cycle, which is critical for amputees seeking to participate in dynamic physical activities. The ability to store and return energy is particularly beneficial for amputees who engage in sports or activities requiring rapid acceleration, directional changes, or endurance. ESAR feet have been shown to reduce metabolic energy costs during ambulation, enabling amputees to perform at higher levels of physical exertion without tiring as quickly as they would with conventional prosthetic feet (Hafner et al. 2002a). This is especially important in sports, where peak performance requires high levels of energy efficiency and endurance.

ESAR prosthetic feet can be classified into various categories based on their intended use, such as walking, running, or sport-specific applications. For everyday activities, general-purpose ESAR feet like the Ossur *Vari-Flex* (Figure 1.1) provide a balance of energy return, comfort, and stability (Hafner et al. 2002a). These devices are designed to optimise function during activities of daily living, but they are often insufficient for the demands of high-performance sports.

For sport-specific purposes, specialised ESAR prosthetic feet such as *Össur's Flex-Run* (Figure 1.3) are designed to provide enhanced propulsion and shock absorption, crucial for activities such as sprinting, long-distance running and jumping. These devices are typically constructed with advanced carbon fibre composites, which maximise energy storage and minimise weight (Brüggemann 2009). Such feet also tend to have longer blade-like designs that allow for a greater range of motion, particularly during running, enabling the user to achieve higher speeds with less exertion (Beck et al. 2018).

Figure 1.3. Ossur Flex-Run (https://www.ossur.com/en-gb/prosthetics/feet/flex-run)

ESAR prosthetic feet play a crucial role in enabling amputees to participate in dynamic physical activities by providing the mechanical advantages necessary for performance in sports. The energy return properties of these prostheses allow athletes to generate greater force during push-off. Athletes using ESAR feet can achieve performance levels approaching those of non-amputees, as demonstrated by elite Paralympic sprinters who use high-performance carbon fibre running blades (Beck et al. 2018). However, despite the clear advantages of ESAR feet in sports, their functionality is often limited to specific movement patterns. For example, while running blades offer excellent energy return in straight-line sprinting, they may not perform as well in activities that require agility or lateral movements, such as basketball or soccer (Brüggemann 2009). Recent advancements in the design of ESAR prosthetic feet continue to address these limitations, focusing on improving the adaptability and versatility of the devices across a range of dynamic sports. These developments highlight the growing potential of ESAR technology to enhance amputees' participation in a wide array of physical activities, contributing to improved quality of life and social reintegration through sport.

ESAR prosthetic feet have become an essential tool in facilitating dynamic physical activity for amputees. Their ability to store and return mechanical energy enhances the efficiency and performance of amputees in both daily activities and competitive sports. As prosthetic technology continues to evolve, ESAR prosthetic feet are likely to become even more specialised, offering amputees greater opportunities to engage in diverse physical activities with increased performance and reduced physical strain.

1.2.3 Paediatric specific Prosthetics

Prosthetics play a crucial role in the lives of children with limb absence, as the long-term consequences of lacking appropriate prostheses are more severe for children than for older individuals (Otto 2016). Children generally adapt to prostheses much more effectively than adults, leading to higher rates of full prosthetic use and increased physical activity levels (Smith and Campbell 2009). On average, children with limb absence are significantly more active than adults with similar conditions, walking five times more each day (Vannah et al. 1999). Prosthetic functionality is particularly vital for children's development, as delays in reaching developmental milestones can lead to lifelong issues (Otto 2016). For instance, fundamental movement skills such as running, hopping, throwing, and balancing, which are essential for sports and other activities, are typically developed in childhood and refined into more specific skills (Kerfeld et al. 2018). Barriers to physical activity during this period can hinder skill development, leading to negative experiences and increasing the risk of secondary health and behavioural issues such as anxiety, depression, and social isolation (Kerfeld et al. 2018). Adults who use prostheses often report that overcoming barriers to physical activity in childhood was one of their earliest challenges (Kerfeld et al. 2018), and children with lower limb absence continue to report difficulties with active play and mobility (Verheul et al. 2020).

The United Nations Convention on the Rights of the Child (www.unicef.org.uk/what-we-do/un-convention-child-rights/) recognises play as a human right, affirming that every child has the right to rest, leisure and recreational activities appropriate for their age (Kerfeld et al. 2018). Boonstra et al. (2000) found that 93% of children with lower limb absence were able to participate in physical education (PE) at school, though 47% reported frequent difficulties. Kerfeld et al. (2018) reported that 58% of parents stated their child participated in playground games with peers, but 57% also noted that their child struggled to keep up. Sport is essential for the healthy development of children, especially those with limb absence, and prosthetic rehabilitation should enable them to reintegrate fully into activities such as schooling, cycling, and sports such as football (O'Keeffe and Rout 2019).

Children have unique prosthetic and rehabilitation needs, distinct from adults (O'Keeffe and Rout 2019). It is acknowledged, though not well-documented, that children with limb absence have different clinical outcomes with prosthetic management compared to adults (Vannah et al. 1999). Gerald Stark Jr., a senior upper limb clinical specialist at Ottobock, highlights the importance of optimising prosthetic designs specifically for children (Otto 2016). Young children grow rapidly, frequently outgrowing their prostheses, necessitating more frequent replacements than older children or adults (Boonstra et al. 2000; Smith and Campbell 2009). The physical demands placed on prostheses are also greater in children due to their high levels of activity, making it unsuitable to merely downsize adult prosthetic designs (Krajbich 1998; Otto 2016). Downsizing adult components leads to loss of strength and durability, which poses a challenge in meeting the needs of paediatric users (Otto 2016).

Orthotic and prosthetic training programs do not typically specialise in paediatric care, which contributes to the limited research on the functional abilities of children with limb deficiencies (Boonstra et al. 2000) and the scarcity of literature on their participation in sports and physical activities (Kerfeld et al. 2018). While prosthetic engineering offers hope for enhancing functionality and participation in sports, the small paediatric market presents significant challenges for the development and production of prostheses tailored to children (Kerfeld et al. 2018). Only 3.4% to 5.1% of prostheses are produced for children aged one to ten years old, resulting in a lack of investment and commercial viability (Otto 2016). Manufacturers face lengthy break-even points for paediatric prosthetics, making the development of such devices less attractive despite the potential benefits (Otto 2016). However, Otto (2016) suggests that demonstrating the long-term advantages of paediatric prostheses could lead to future reimbursement and encourage investment in this area. While some prosthetic companies now offer limited paediatric product lines, much more innovation is needed (Otto 2016).

Developing prosthetics for children presents unique challenges, including packing advanced functionality into smaller devices, accommodating children's rapid growth, and balancing the expectations of both parents and children (Otto 2016). Paediatric prosthetic components are approximately 70% the size of adult components, yet they must endure more intense physical activity (Otto 2016). Experts agree that paediatric prostheses need to be innovative, durable, lightweight, and appropriately sized to meet the high activity demands of children (Otto 2016). Children's limbs continue to grow until skeletal maturity, which means they outgrow prosthetic devices quickly, often within six months (Krajbich 1998; Otto 2016). Each new prosthetic requires an adjustment period, and children may struggle to adapt if they are continually receiving new devices (Smith and Campbell 2009). Therefore, prostheses must allow for some form of growth adjustment to ensure that children can benefit from them without frequent replacements (Smith and Campbell 2009; O'Keeffe and Rout 2019).

Children, parents, and healthcare teams often have different perspectives on prosthetic needs. While children typically prioritise function and the ability to play sports and attend school, parents may focus on cosmetic appearance and durability (Vannah et al. 1999; Smith and Campbell 2009). These differences can influence how prosthetists approach fittings, as family expectations play a significant role (Otto 2016). For instance, a dynamic carbon-fibre running blade may be ideal for a child, but parents may prefer a cosmetic foot that resembles a natural limb (Otto 2016).

Running blades, though excellent for straight-line running, are not suitable for walking, playing sports, or engaging in a wide range of activities. Children require prosthetic devices that support more than just sprinting (Otto 2016). Movement skills such as walking, running, hopping, and skipping are often rated as difficult by children with lower limb absence (Kerfeld et al. 2018), and walking speed, distance, and functional balance are significantly reduced in these children (Feick et al. 2016). Parents frequently express concern about their child's running speed when using a prosthesis compared to peers (Kerfeld et al. 2018).

Prosthetic failure, including catastrophic failures, is common in children with lower limb deficiencies, with feet, knees, and cosmetic foam being the most frequently broken parts (Vannah et al. 1999). When a child's prosthesis breaks, it can significantly impact the family's daily life. Ensuring that prostheses are durable and can be quickly repaired or replaced is critical to maintaining a positive experience for the child and their family (Otto 2016). Fast access to replacement devices and services is essential for these children throughout their lives (Otto 2016).

Recent trends show that children are more open about their limb differences, and manufacturers are responding by offering prostheses that can be personalised with colours and decals, allowing children to express their individuality (Otto 2016).

1.2.4 Additively Manufactured Prosthetics

AM has previously been used to produce components such as lower limb prosthetic fairings, lower limb sockets, and upper limb prostheses (Warder et al. 2018; Bhatt et al. 2023; Savsani et al. 2023). Some notable examples of AM sports prosthetics include a cycling prosthesis for Denise Schindler, which she used to compete in the 2016 Rio Paralympic Games (Dyer et al. 2022), and an upper limb prosthetic for fencing, created for academic research purposes (Jones 2019).

Denise Schindler collaborated with Autodesk to develop the first AM prosthetic leg used in Paralympic competition (Dyer et al. 2022). The leg was made from polycarbonate, and the digital production process offered significant advantages (Dyer et al. 2022). It was much quicker to produce compared to traditional methods, where an orthopaedic technician creates a plaster cast of the residual limb and hand-produces the prosthetic, an expensive and time-consuming process, particularly for athletes whose bodies undergo frequent changes (Dyer et al. 2022). While current AM prosthetics have primarily used materials such as polycarbonate and polylactic acid, which are low-cost but lack desirable engineering properties (Jones 2019; Dyer et al. 2022), the availability of new AM materials presents opportunities for improving the strength and functionality of prosthetic devices (Jones 2019; Savsani et al. 2023).

Most sports prosthetics are highly specialised, custom-made devices produced in clinic workshops, which is a lengthy process due to the unique needs of each user and the specific functionality required (Jones 2019; Dyer et al. 2022). This bespoke nature has resulted in a limited range of commercially available sports prosthetics, with the few options on the market, such as those for cycling and swimming, being prohibitively expensive (Jones 2019).

Digitising the process of creating sports prosthetics has the potential to revolutionise the field for athletes (Dyer et al. 2022; Savsani et al. 2023). The digital workflow allows for greater collaboration between the user and designer, enabling a more interactive and personalised approach (Jones 2019). Traditional methods such as plaster casting can be replaced with 3D scanning, socket design can be done through digital sculpting, and carbon fibre hand lay-up moulding can be substituted by composite AM (Dyer et al. 2022). Additionally, the digital process allows for better visualisation of changes and significantly reduces the time required to produce a new prosthetic (Dyer et al. 2022; Savsani et al. 2023).

Research into AM carbon fibre-reinforced prosthetic feet has shown that composite filament fabrication can potentially serve as a method for producing energy-returning prosthetic feet (Warder et al. 2018; Martulli et al. 2023). However, the stiffness profiles of these prosthetic feet vary depending on the geometry and the placement of the carbon fibre reinforcement (Warder et al. 2018; Martulli et al. 2023). Further research is necessary to evaluate the durability of these components under long-term cyclic loading and to explore the impact of different fibre reinforcement materials and configurations on energy return (Warder et al. 2018). With continued iteration and testing of both designs and AM fabrication methods, it is possible that prosthetic feet produced using this approach could consistently achieve a dynamic classification comparable to industry-standard carbon fibre feet (Chen et al. 2016; Warder et al. 2018; Martulli et al. 2023).

1.3 Literature Conclusions

The results demonstrate that while there are facilitators for sports participation among children with limb absence, such as advancements in prosthetic design, increased opportunities, and the physical and social benefits associated with sports, significant barriers remain. These barriers include prosthetic failure, social stigma, and prohibitive costs, which continue to hinder many children from engaging in sports and physical activities as fully as they desire.

One of the most pressing concerns is the lack of research and investment in prosthetic technology specifically tailored for children. This gap in the literature represents a significant barrier, as children with limb absence are not receiving the latest technologies, designs, or insights that could improve their sports participation and overall quality of life. A consistent finding across the literature is the need for high-functioning, bespoke paediatric sports prosthetics that are affordable and accessible (Bader 2002; Louer Jr et al. 2021; Savsani et al. 2023).

Given the current limitations of traditional prosthetic manufacturing, which is labour-intensive, expensive, and time-consuming, AM presents a promising alternative. As previously discussed in the classification and function of ESAR prosthetic feet, advances in material science and manufacturing techniques offer the potential to create highly specialised prosthetics (Chen et al. 2016; Savsani et al. 2023). Composite AM, in particular, has been highlighted as a technology with the potential to revolutionise the field of prosthetics (Blok et al. 2018; Warder et al. 2018; McAlpine 2019; Martulli et al. 2023). By leveraging these materials, prostheses can be tailored to the unique needs of paediatric users, and AM can reduce production times and costs while improving accessibility. However, there remains a significant gap in the research regarding AM for sport-specific prosthetics.

To address these gaps, the technical work required includes focusing on optimising composite AM processes specifically for paediatric prosthetic applications. This includes evaluating both the material properties and key performance indicators, stiffness and energy efficiency, of carbon fibre-reinforced parts, and identifying the key fabrication parameters, such as reinforcement layers, wall thickness, and fibre distribution, that influence stiffness and energy return.

In conclusion, while advancements in prosthetic technology, such as ESAR feet and AM, hold great promise for improving sports participation for children with limb absence, a number of persistent barriers must be addressed. The future of prosthetics lies in the continued development of customised devices that are affordable, accessible, and able to meet the diverse needs of children.

CHAPTER 2: RESEARCH PLAN

The literature review systematically revealed the primary facilitators and barriers to sports participation in children with lower-limb absence, with the clear limitation of current prosthetic solutions being demonstrated. A key finding was the lack of available and affordable, high-performance prosthetic devices with the dynamic response needed for active children. In addition, problems with the adaptability, durability, and environmental factors of prosthetics were indicated. These results informed the research strategy regarding material choice, AM process, and mechanical testing of AM paediatric prosthetic feet. The review also confirmed the necessity for repeatability, precision, and parameter optimisation, impacting the experimental strategy employed in determining the feasibility of composite AM for dynamic response prosthetics.

2.1 Research Questions

Two comprehensive literature reviews have been undertaken as part of this research. These reviews focused on:

- The facilitators and barriers faced by children with lower limb absence when participating in physical activities;
- The current state of paediatric prosthetics designed for sport, and the use of AM across the prosthetics industry

The findings identified gaps in existing research and highlighted opportunities for innovation in materials and prosthetic design, forming the basis for this research. A significant gap exists in the development of prosthetic technology specifically tailored for paediatric users, particularly in the context of sports participation. Accessibility challenges were also identified with high costs and labour-intensive manufacturing processes limiting availability. The literature also highlights the lack of research on the application of AM for the production of sports prosthetics, despite its potential to reduce costs, improve accessibility, and enable customisation. Given the critical role of prostheses in enabling sports participation and the physiological, social, and emotional benefits associated with physical activity, further investigation into AM as a viable production method for dynamic response paediatric prosthetic feet is essential.

Based on these insights, a primary research question, supplemented by a secondary question designed to advance understanding in both AM and prosthetic technology were developed. The primary and secondary research questions driving this thesis are:

Primary Research Question:
"Is composite additive manufacturing capable of producing a dynamic response paediatric prosthetic ankle-foot device?"

Secondary Research Question:
"Can the use of composite additive manufacturing provide repeatable, and reliable dimensional accuracy and mechanical properties for this purpose?"

Further details of specific research objectives to ensure the research questions are addressed effectively are explored in subsequent sections, aiming to build upon identified knowledge gaps and contribute to the development of available and affordable, dynamic response paediatric prosthetic feet.

2.1.1 Sub-question 1: What are the specific material properties, accuracy, and repeatability metrics for various composite additive manufacturing processes and materials?

By identifying and comparing different materials and processes, this objective aims to determine which combinations are most suitable for creating reliable and repeatable prosthetic components. These insights will guide material selection and process optimisation, directly impacting the feasibility of AM for paediatric prosthetics.

2.1.2 Sub-question 2: What are the existing control mechanisms within composite additive manufacturing, and how do they influence the part strength, quality, and accuracy of produced components?

Investigating control mechanisms, such as layer height and part orientation, is essential to ensure that composite AM can consistently deliver high-quality, reliable components. Understanding the effect of these controls on mechanical properties such as strength and durability will establish foundational knowledge for producing prosthetics that can withstand the physical demands of paediatric use.

2.1.3 Sub-question 3: What are the optimal AM parameters for manufacturing a paediatric prosthetic ankle-foot unit that meets dynamic response requirements?

Determining optimal fabrication parameters is crucial for the AM process to achieve the desired mechanical performance. Parameters such as layer height, part orientation, and reinforcement patterns will influence stiffness and hysteresis. Optimising these settings will contribute to developing a prosthetic foot capable of dynamic classification.

2.2 Scope

This research is intended to evaluate composite AM as a viable production method for dynamic response paediatric prosthetic feet. The focus is strictly on the technical feasibility of using AM composite materials in creating an ankle-foot device that meets the dynamic classification limits specified by the American Orthotic Prosthetic Association (AOPA) and International Organization for Standardization (ISO) 10328 standards. The research explores material properties, process reproducibility, accuracy, and the optimisation of parameters to achieve the desired stiffness and energy return for dynamic prosthetic function. A predictive model has been developed to guide manufacturing decisions, such that specific mechanical properties can be achieved through parameter selection.

However, the research does not extend to measuring user experience, clinical trials, or long-term wear studies of the prosthetic foot in real-world settings. Nor does it consider the integration of the foot into a complete prosthetic limb system, only focusing on the ankle-foot component and not the entire prosthetic assembly, such as sockets or suspension systems. The findings of this research provide a technical foundation for AM in this use, but further studies will be required to translate these results from benchtop to bedside and ascertain practical application in actual clinical environments for paediatric prosthetic users.

2.3 Methodological Approach

The methodology chapter of this research outlines the quantitative approaches adopted to systematically assess the mechanical properties and performance characteristics of

AM prosthetic components. These tests aimed to measure material properties such as stiffness and hysteresis and were integral to a parametric study investigating how variations in AM parameters affect overall prosthetic performance. Following this experimental approach, an equation was developed to predict prosthetic performance, facilitating a more precise and controlled design process in prosthetic AM.

In line with epistemological perspectives in the prosthetics field, this research's quantitative approach aligns with the need for objective measurement and validation, building knowledge through empirical data on material behaviours and performance dynamics in prosthetics (Hawkins 2015), therefore offering precision and replicability. This research utilised a controlled laboratory setting and equipment to maintain high levels of rigour and control over the testing variables, providing reliable data. Previous studies in prosthetic development, such as those by Hawkins (2015) and Martulli (2023), have similarly relied on controlled mechanical testing to assess energy return and stiffness characteristics in prosthetic feet, demonstrating the necessity of standardised laboratory conditions to ensure repeatability and comparability of results. Other studies (Gerschutz et al. 2012; Owen and DesJardins 2020) highlight the importance of using validated testing methods, such as ISO 10328 (Standardization 2016), to evaluate structural integrity and dynamic response in lower-limb prosthetics. This research utilised a controlled laboratory setting and equipment to maintain high levels of rigour and control over the testing variables, providing reliable data.

The research design integrated data collection, processing, instrument development, and validation. This methodology relies on a deductive, hypothesis-testing approach, allowing specific variables to be systematically manipulated and measured to determine their impact on the prosthetic performance. As outlined by Babbie (Babbie 2020) and supported by Harland's (Harland 2019) research, experimental research seeks to establish the correlation between independent and dependent variables in a controlled environment. The AM parameters served as independent variables, while material properties, stiffness and hysteresis, represented the dependent variables. By comparing baseline samples with those subject to parameter modifications, the research aimed to clarify how these adjustments affect material performance metrics. By developing a rigorous methodology for material testing, based around ISO (International Organization for Standardization) 10328 (Standardization 2016) and AOPA (American Orthotic and Prosthetic Association) standards (AOPA 2010), this research contributes to the understanding of how specific material properties can impact paediatric prosthetic performance.

This methodology chapter details a quantitative experimental design aimed at understanding the role composite AM can have on the production of dynamic response paediatric feet. This approach reflects the need in the prosthetics field for validated, empirically driven insights into material selection, manufacturing optimisation, and performance prediction, ultimately contributing to enhanced prosthetic solutions via AM. Research ethics and risk assessments were obtained and reviewed throughout the duration of the research, using Bournemouth University's Research Ethics Checklist to ensure compliance with institutional ethical standards and safe research practice (Appendix 1).

2.4 Thesis Overview

This thesis is organised into ten chapters, and this section provides a summary of each chapter's content. Each chapter addresses a distinct aspect of the research, with specific objectives and conclusions that build upon the previous sections, creating a cohesive flow. The chapters are structured in a logical and mostly chronological sequence (Figure 2.1), allowing the progression from the initial research questions (section 2.3) to the final conclusions, discussions, and recommendations for future work (Chapter 10).

2.5 Chapter Summary

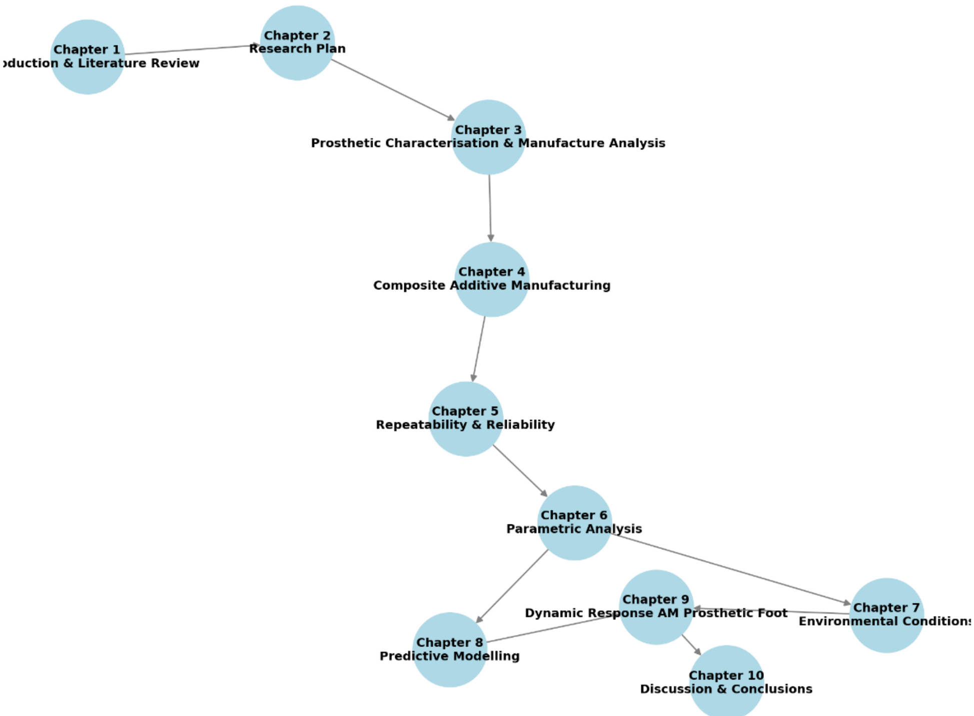

Figure 2.1. Thesis Flow Diagram

2.5.1 Chapter 3 - Prosthetic Characterisation and Manufacture Analysis

This chapter explores existing methods of prosthetic characterisation and manufacturing, focusing on how various characteristics impact prosthetic performance and functionality. By examining current manufacturing processes and their limitations, the chapter provides a foundation for understanding the specific requirements that paediatric prosthetics must meet. This analysis is critical for identifying gaps in traditional prosthetic design that composite AM might address, particularly in achieving dynamic responses devices.

2.5.2 Chapter 4 – Composite Additive Manufacturing

In this chapter, composite AM techniques and materials are reviewed to understand their applicability to prosthetic production. The chapter evaluates the mechanical properties, cost-efficiency, and design flexibility of composite materials used in AM. Insights from this chapter help determine the feasibility of implementing composite materials in paediatric prosthetic development.

2.5.3 Chapter 5 – Repeatability and Accuracy

This chapter defines the repeatability and accuracy composite AM components can achieve. The objective is to determine if AM prostheses manufactured are able to consistently meet mechanical specifications, and dimensional accuracy.

2.5.4 Chapter 6 – Parametric Analysis

The goal of this chapter is to perform a comprehensive parametric analysis to identify the most impactful AM parameters, such as layer height, part orientation, and reinforcement pattern on the prosthetic's mechanical performance. This chapter defines optimal fabrication settings that enhance the stiffness and energy return of the prosthetic foot. Findings from this chapter guide the precise adjustment of manufacturing variables for consistent, high-performance outputs in AM prosthetics.

2.5.5 Chapter 7 – Environmental Conditions

Chapter 7 defines the impact of environmental conditions, specifically humidity, on the performance of AM prosthetics. By analysing factors such as stiffness and energy efficiency differences related to exposure to the environment, this chapter establishes a basis for testing AM prosthetic accuracy in diverse settings. These considerations are crucial for paediatric prosthetics, which must withstand variable environments encountered during physical activities, ensuring both safety and functional resilience.

2.5.6 Chapter 8 – Predictive Modelling

This chapter aims to develop a predictive model that accurately estimates the stiffness and efficiency of AM composite prosthetic feet. By defining the mathematical relationships between parameters, mechanical properties, and prosthetic performance, this chapter enables the prediction of key functional outcomes. This modelling tool will provide a reliable basis for designing future prosthetic components, obtaining bespoke mechanical properties, and minimising trial-and-error iterations in the manufacturing process.

2.5.7 Chapter 9 – Dynamic Response Additively Manufactured Prosthetic Foot

The objective of this chapter is to design, produce, and evaluate a fully AM prosthetic foot that meets the dynamic response criteria required for paediatric physical activity. It defines the performance thresholds based on AOPA’s Prosthetic foot project (AOPA 2010) standards to classify the foot as a dynamic response prosthesis. The chapter assesses whether composite AM can achieve the desired functionality, representing a significant step toward making composite AM prosthetics viable for children’s sports and daily activities.

CHAPTER 3: PROSTHETIC CHARACTERISATION AND MANUFACTURE ANALYSIS

This chapter explores the mechanical properties, classification, and manufacturing procedures of paediatric prosthetic ankle-foot devices. Key mechanical properties such as stiffness, hysteresis, spring rate, and dynamic elastic response are presented because they directly affect the foot's capability to mimic natural movement and provide energy-efficient performance. The chapter also covers the overview of the classification of prosthetic feet, namely the AOPA dynamic response criteria (AOPA 2010). This chapter also compares the conventional prosthetic manufacturing techniques such as prepreg carbon fibre layup and autoclave curing with composite AM.

To ensure AM prosthetic feet meet industry standards, this study complies with BS ISO 10328 (Standardization 2016) and AOPA test requirements (AOPA 2010), testing for structural strength, energy return and displacement. By analysing these standards, this chapter provides a foundation for identifying whether composite AM can meet the thresholds to be classified as dynamic response.

3.1 Mechanical Characteristics

The mechanical performance of a prosthetic foot is influenced by several key properties, which dictate how the foot interacts with the ground and manages forces during various physical activities (Haberman and Bryant 2008). Understanding these properties is essential for optimising the function and comfort of prosthetic feet, especially for high-performance applications like running or jumping. The primary characteristics include stiffness, ESAR (hysteresis), spring rate, and dynamic elastic response (Haberman and Bryant 2008). Each of these properties plays a critical role in how effectively a prosthetic foot can mimic the natural biomechanics of the human foot.

3.1.1 Stiffness

Stiffness (K) (eq 3.1) refers to a material's resistance to deformation under an applied force. In the context of prosthetic feet, stiffness is crucial for determining how the foot responds to external forces during walking or running. Stiffness is calculated using the slope of the stress-strain curve, which represents the relationship between applied stress (force per unit area) and the resulting strain (deformation). The stiffness of the prosthetic strongly influences the function of the prosthesis, as it affects deflection during loading (Haberman and Bryant 2008).

$$K = \frac{F}{\delta} \qquad \text{(eq 3.1)}$$

Where F represents the applied force and δ is displacement.

The stiffness of a prosthetic foot also influences its ability to resist deformation under quasi-static loads, such as those experienced during standing, walking, or slow movements.. A well-engineered, stiff prosthetic foot can resist excessive deformation, thereby minimising the load on the residual limb and reducing the risk of injury or discomfort. However, an overly stiff foot may be difficult to control, affecting the user's balance and stability (Hansen and Childress 2010). It is therefore essential to achieve an optimal balance in stiffness to ensure both energy efficiency and user comfort, depending on the intended activity.

3.1.2 Energy Storage and Return (Hysteresis)

ESAR in prosthetic feet are measured through hysteresis, which describes the difference between the energy absorbed by the foot when compressed and the energy released when it returns to its original shape. The efficiency of energy return is crucial for high-performance prosthetics, particularly for activities like running or jumping (Bragaru et al. 2012). A low hysteresis value indicates minimal energy loss and a highly efficient energy transfer from the prosthetic foot to the ground.

When a prosthetic foot is loaded, energy is stored as elastic potential energy within the material. Upon unloading, the stored energy is released, contributing to forward propulsion (Hafner et al. 2002b). Measuring hysteresis involves conducting cyclic compression tests to produce force-displacement curves, from which energy loss and return efficiency can be calculated. Prosthetic feet designed for dynamic usage often use advanced carbon fibre composites to minimise energy loss, providing a spring-like effect that mimics the natural function of the human foot (Sahoo et al. 2024).

3.1.3 Dynamic Elastic Response

Dynamic elastic response refers to how a prosthetic foot behaves under dynamic loading and deformation, particularly during high-impact activities such as running or jumping. This property is closely tied to the foot's stiffness and damping characteristics. A prosthetic foot with a high dynamic elastic response can store and release substantial amounts of energy during each gait cycle, leading to a more efficient transfer of energy from the user to the ground. The dynamic elastic response is heavily influenced by the materials and design of the prosthetic foot. For instance, high-modulus carbon fibre materials are often used to achieve a more responsive and elastic behaviour (Tanaka et al. 2024). Advanced modelling and simulation techniques are frequently used during the design phase to optimise this property, predicting how the foot will perform under various loads and ensuring that it meets the needs of the user. The dynamic elastic response of a prosthetic foot determines how effectively it can mimic the natural rebound and push-off phases of human gait, which are critical for maintaining efficiency and reducing fatigue (Sahoo et al. 2024). High-performance prosthetic feet are engineered to have an ideal balance of stiffness, damping, and elasticity to provide users with a seamless and powerful movement experience (Sahoo et al. 2024).

3.2 Characterisation of Existing Prosthetic Feet

There is a vast array of different prosthetic feet developed to meet the needs of a variety of different amputees based on their mobility level, activity and lifestyle. This section focuses on the commonly used categories of prosthetic feet: Solid Ankle Cushion Heel (SACH) feet and Energy Storage and Return (ESAR) feet. Each of these types has unique characteristics that affect their performance and suitability for different user profiles. This section then also focuses on the classification of dynamic response that is being used within this research.

3.2.1 SACH

The SACH foot is a non-articulated prosthetic foot characterised by a solid internal structure with a cushioned heel. It has no moving joints or hinges, and the core is typically made from a rigid material such as wood or plastic, which is encased in a soft foam-like material that provides cushioning (Noori 2024). The heel portion compresses slightly during heel strike, absorbing some of the shock from impact, and then gradually returns to its original shape (Noori 2024). SACH feet are defined by their simplicity and limited range of motion. The rigidity of the foot structure provides stability, while the cushioned heel allows for limited shock absorption. The design mimics a basic, passive foot, providing foundational support and some level of comfort without the energy return capability found in more advanced prosthetic feet (Noori 2024). The rigid design restricts the natural movement of the ankle and foot, which can lead to a less efficient and less comfortable gait. Users may experience a "stiff" or "flat" feeling when walking (Noori 2024). An example of a SACH foot can be seen in Figure 3.1.

Figure 3.1. SACH Foot example (Ossur Balance Foot S) (https://www.ossur.com/en-gb/prosthetics/feet/balance-foot-s)

3.2.2 ESAR

ESAR feet are advanced prosthetic feet designed to store energy during the stance phase of walking and release it during the push-off phase. They are typically constructed from lightweight, high-strength composite materials such as carbon fibre, which allows the foot to flex and return to its original shape, providing a dynamic response. ESAR feet mimic the natural movement of the human foot and are often categorised as "dynamic response" prostheses (Hafner et al. 2002a; Grimmer and Seyfarth 2014; Sahoo et al. 2024). ESAR feet are defined by their ability to store mechanical energy when loaded (e.g., during heel strike and mid-stance) and then release this energy to propel the user forward during toe-off. This characteristic is crucial for replicating a natural and efficient gait. The performance of ESAR feet is often quantified by metrics such as stiffness, energy return, and spring rate, which are critical for optimising the foot's responsiveness and overall efficiency (Nolan 2008; Sahoo et al. 2024). ESAR feet are significantly more expensive than SACH feet due to their advanced materials and complex design. This can make them inaccessible for some users, particularly in low-resource settings (Sahoo et al. 2024). An example of an ESAR foot can be seen in Figure 3.2.

Figure 3.2. ESAR Foot example (Ossur Vari-Flex) (https://www.ossur.com/en-gb/prosthetics/feet/vari-flex)

3.2.3 Dynamic Response

In the context of this research, the term 'dynamic response' specifically refers to the definition provided by the AOPA (AOPA 2010). AOPA outlines dynamic response as the elastic property of a prosthetic component that is designed to deflect under load, with the ability to store and subsequently return a significant amount of energy. This ability to manage energy efficiently is crucial for prosthetic feet, especially for users who engage in dynamic and physically demanding activities, as it directly influences gait efficiency, energy expenditure and overall mobility. AOPA has established specific test thresholds in efficiency and displacement, based off the BS ISO 10328 (Standardization 2016) testing procedure, to determine whether a prosthetic foot falls into one of three categories: dynamic, rigid, or flexible. These classifications are based on the foot's ability to manage and release energy efficiently. The categorisation is crucial for matching prosthetic feet to the needs of different users, as each category serves a unique purpose and level of activity.

Understanding and quantifying the dynamic response of prosthetic feet is a critical aspect of this research. By evaluating whether the composite AM prosthetic ankle-foot device meets the AOPA test thresholds for dynamic response, this research aims to establish whether composite AM devices are suitable for enabling children with lower limb absence to engage in physical activities effectively. The goal is to determine if these prosthetic feet can provide sufficient energy return. Throughout this research, the term 'dynamic response' will consistently refer to this precise AOPA definition, with a focus on evaluating whether AM composite prosthetics can achieve or surpass the energy return capabilities required for a foot to be classified as dynamic. The emphasis on meeting or exceeding AOPA standards ensures that the findings and recommendations from this research are grounded in established and clinically relevant performance criteria.

3.3 Current Manufacturing Techniques

The manufacturing of prosthetic feet typically uses a process centred around prepreg carbon fibre and autoclave curing, a method known for producing components with superior mechanical properties (Bader 2002). Prepreg and autoclave manufacturing is very effective, but is resource intensive and involves multiple intricate steps, requiring highly skilled labour and specialised equipment.

The manufacturing process for composite prosthetic feet involves several key steps (Bader 2002). Pre-cut sheets of prepreg carbon fibre are laminated onto a mould, with each layer compacted to remove air bubbles and ensure structural integrity. The assembly is then vacuum sealed with release films, bleeder, and breather materials to regulate resin flow and eliminate air pockets before curing.

Next, the autoclave curing process applies controlled temperature and pressure to fully bond the resin matrix, producing a high-strength composite. After curing, the prosthetic component is de-moulded, precision-cut, and shaped using milling machines to meet exact specifications.

3.3.1 Limitations of Conventional Methods

While prepreg and autoclave manufacturing yield high-quality, high-performance prosthetic components, this technique comes with several significant limitations. There is a high upfront cost for essential equipment, such as autoclaves and computer-controlled cutting systems (Klasson 1995; Bader 2002). This financial barrier makes it difficult for smaller manufacturers or low-budget facilities to adopt this method. The autoclave process is also very energy intensive, adding to ongoing operational costs. For limited production runs, simple single sided moulds, often made from composite materials such as glass-reinforced plastic (GRP), are used. However, when scaling up to higher production volumes, more robust and long lasting metal tooling becomes necessary, significantly increasing the cost of production (Bader 2002). The investment in high-quality metal moulds can be prohibitive for smaller-scale manufacturers or custom prosthetic workshops. The production rate using prepreg and autoclave methods is relatively low. For a single set of tooling, it is typically not feasible to produce more than one component per working day (Bader 2002). Complex prosthetic designs, such as running blades, may take days or even weeks to complete, leading to long lead times and limiting the scalability of this manufacturing method. The process is highly labour intensive, requiring skilled technicians for tasks such as manual lay-up and quality control (Bader 2002). The need for experienced labour not only raises production costs but also introduces variability in quality based on the skill and expertise of the technician. Mistakes in the lay-up process, such as trapped air or misaligned fibres, can compromise the structural performance of the final product. The use of carbon fibre introduces several health and safety challenges (Klasson 1995). The fibres can cause skin irritation, necessitating the use of proper personal protective equipment (PPE). Incomplete resin curing poses a risk of skin exposure to harmful chemicals, and carbon fibre dust, which can become airborne during machining or sanding, presents respiratory hazards if inhaled.

The combination of high costs, labour demands, and health risks makes conventional manufacturing techniques a significant barrier to widespread access to high performance prosthetic feet. For many amputees, especially in geographical regions with limited healthcare funding, the expense associated with custom carbon fibre prosthetics can be prohibitive (Sayed Ahmed et al. 2018). This highlights the critical need for alternative manufacturing approaches that can deliver high performance while reducing costs and improving accessibility.

3.4 BS ISO 10328 & AOPA Standards

The testing procedures used in this research were designed to align closely with British Standard ISO 10328 (Standardization 2016) and the AOPA standards (AOPA 2010). ISO 10328 provides comprehensive guidelines for the structural testing of lower-limb prostheses, specifying test conditions that simulate the mechanical loads experienced during a prosthetic device's lifecycle. AOPA standards further define descriptors such as "dynamic response," categorising prosthetic components based on their energy storage and return properties. By following these well-established standards, the research ensures that the methodology adheres to rigorous, globally recognised benchmarks, thereby enhancing the reliability and reproducibility of the results.

The research adapted the ISO 10328 procedures to reflect the requirements of paediatric prosthetics. For example, the maximum force applied during testing was adjusted to simulate a user weight of 24 kg, aligning with the specifications for the Vari-Flex Junior Size 19, Category 1 prosthetic. Such adaptations ensure that the testing remains relevant to the paediatric demographic while maintaining the robustness of standardised procedures.

By adhering to ISO 10328 and AOPA standards, this research not only validates the mechanical performance of the AM paediatric prosthetic samples but also ensures that the results are grounded in proven methodologies. This alignment strengthens the reliability of the findings and supports their potential application in clinical and commercial settings.

3.4.1 ISO 10328 Static Proof Test

The ISO 10328 static proof test is designed to evaluate the structural integrity under static loads of the prosthetic foot. The test simulates the maximum loads that a prosthetic component might experience during normal use. The procedure involves applying a controlled static load at a specific rate until the specified force is reached. A pre-load of 50N is first applied to ensure proper seating and alignment of the test specimen. Once the pre-load has been achieved, the test progresses with a loading rate of 200 N/s. The load is held at this level for 30 seconds, to assess the component's ability to withstand the maximum load without permanent deformation, cracking, or failure. The controlled loading rate and hold time allow for accurate and reproducible assessment of the prosthetic's structural performance. By adhering to these parameters, the static proof test ensures that the prosthetic meets safety and performance standards, protecting users from potential failures during use.

The keel and heel components of the prosthetic foot are tested on surfaces set at +20° and -15° respectively (Figure 3.3). These angles replicate the forces experienced during key phases of the gait cycle. The +20° surface simulates dorsiflexion, representing the loading conditions when the user applies force to the forefoot during toe-off. The -15° surface simulates plantarflexion, replicating the initial loading experienced during heel strike. Testing the prosthetic components at these angles is crucial, as these positions represent the extremes of load bearing and energy transfer during walking and running.

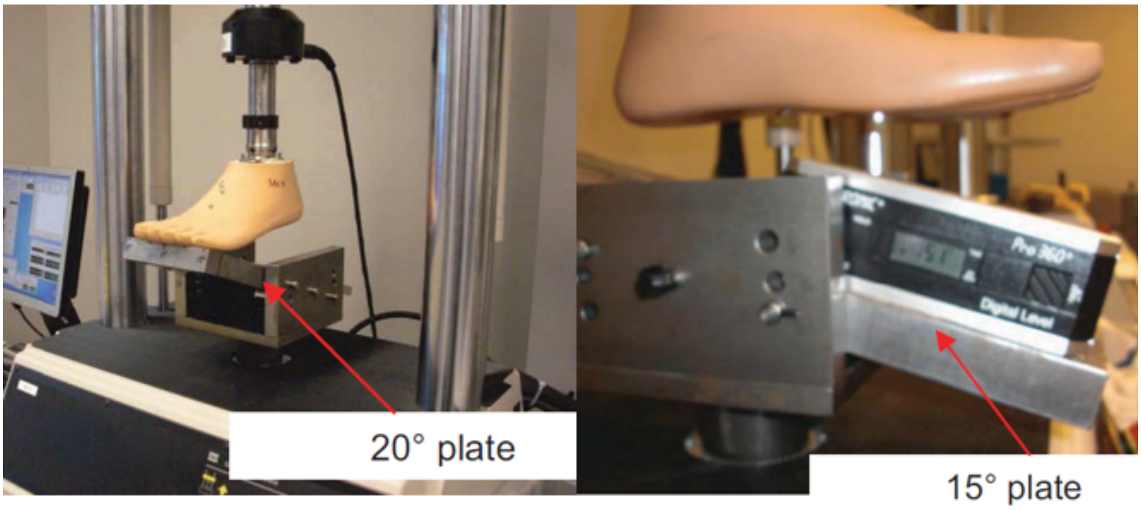

Figure 3.3. AOPA Test Set Up (AOPA 2010)

3.4.2 AOPA Testing and Classification Thresholds

The AOPA testing procedure (Appendix 2) closely mirrors the ISO 10328 static proof test in evaluating the mechanical performance of prosthetic components, with one key difference. The AOPA procedure does not include a holding period at maximum load. It focuses on the loading and unloading curves to assess energy return and displacement. This method evaluates the mechanical properties of the keel and heel by determining their displacement under load and the percentage of energy returned during unloading.

Data collected during testing is analysed using the trapezoidal rule to calculate the area under the force-displacement curves for both the loading and unloading curves (Yeh 2002).

Prosthetic keels are categorised into either the rigid, flexible, or dynamic classification (AOPA 2010) criteria, based on the following displacement and energy return under loading:

- Rigid Keel: Displays less than 25 mm of displacement under the specified load. Energy return is not applicable as these keels are designed for stiffness and stability rather than energy efficiency.
- Flexible Keel: Exhibits a displacement of 25 mm or greater but returns less than 75% of energy during unloading, indicating reduced efficiency in energy storage and return.
- Dynamic Keel: Achieves a displacement of 25 mm or greater and returns 75% or more of energy, reflecting high energy efficiency and responsiveness suitable for dynamic activities.

Prosthetic heels are categorised into either dynamic or cushioned (AOPA 2010) also based on their displacement and energy return characteristics, using the following thresholds:

- Dynamic Heel: Demonstrates a displacement of 13 mm or greater or achieves an energy return of 82% or more. Meeting either the displacement or energy return criterion qualifies the heel as dynamic, ensuring energy-efficient performance during heel strike and transition phases.
- Cushioned Heel: Fails to meet the 13 mm displacement and/or 82% energy return threshold, indicating reduced energy efficiency. These heels are typically designed for comfort and shock absorption rather than dynamic energy return.

The AOPA testing procedure provides a standardised framework for evaluating the performance and classification of prosthetic components. This enables the consistent classification and identification of prosthetics to meet the functional and energy efficiency requirements necessary for various user needs and activity levels.

3.5 Chapter Conclusions

This chapter has provided an overview of the prominent factors influencing the design, performance, manufacturing, testing, and classification of prosthetic feet, with a focus on paediatric applications. By analysing mechanical properties, existing prosthetic foot types, manufacturing techniques, and standardised testing procedures, the research establishes a solid foundation for evaluating the suitability of AM prosthetic components in terms of function, performance, durability, and manufacture.

The mechanical characteristics of stiffness, ESAR (hysteresis), spring rate, and dynamic elastic response are paramount in designing prosthetic feet that can effectively mimic natural biomechanics. The classification of prosthetic feet into SACH and ESAR categories, as well as the integration of AOPA's ‘dynamic response’ criteria, highlights the extensive range of available options and the importance of tailoring and understanding prosthetics to meet specific user needs. The research shows how advanced materials such as carbon fibre composites in ESAR feet can provide superior energy return and dynamic performance compared to simpler designs such as SACH feet, which prioritise stability and shock absorption.

The detailed evaluation of conventional manufacturing techniques, such as prepreg and autoclave curing, reveals their ability to produce high performance components while also highlighting significant limitations, including high costs, energy intensive processes, and low production scalability. These barriers emphasise the need for AM methods, such as additive manufacturing, to enable access to advanced prosthetics and address issues of affordability and efficiency. These barriers are heightened for paediatric users due to their rapid growth and need of frequent replacement prosthetics when growing.

The use of established testing standards, including BS ISO 10328 and AOPA classification thresholds, ensures that the research remains grounded in proven methodologies. The integration of these standards allows for robust evaluation of prosthetic components, particularly in assessing energy return, displacement, and structural integrity under simulated real-world conditions. The use of +20° and -15° surface angles during testing further replicates critical phases of the gait cycle, ensuring that prosthetic feet are evaluated under realistic loading scenarios.

This chapter demonstrates that while traditional manufacturing and testing methods provide valuable benchmarks for evaluating prosthetic feet, there is significant potential for innovation through the adoption of AM and composite materials. By aligning the research with established standards and exploring new manufacturing avenues, this work aims to contribute to the development of prosthetic feet that offer enhanced performance, durability, and accessibility, ultimately improving the quality of life for paediatric users.

CHAPTER 4: COMPOSITE ADDITIVE MANUFACTURING

Chapter 3 highlighted the role of stiffness, hysteresis, spring rate, and dynamic elastic response in determining the function and performance of prosthetic feet. It also presented some of the primary limitations of traditional carbon fibre prepreg and autoclave curing, including high cost, labour intensiveness, and long production time, which limit accessibility and scalability, particularly for paediatric users who require frequent prosthetic replacement due to growth. With these limitations in mind, composite AM has the potential to revolutionise prosthetic foot production with a cheaper, more flexible, and scalable production alternative. This chapter explores the variety of composite additive AM and techniques that currently exist to establish their suitability to meet the performance criteria defined in Chapter 3.

4.1 Overview

This chapter explores composite AM, focusing on Fused Filament Fabrication (FFF) technology, which remains the most widely used technique in the AM industry due to its versatile applications, diverse material compatibility, and straightforward fabrication processes and controls (McAlpine 2019; Russo et al. 2019). In composite AM, two main FFF-based approaches are commonly used: fabrication with short reinforcement fibres mixed in a thermoplastic matrix, and continuous fibre reinforcement. These FFF composite methods allow for precise fibre placement and layer-by-layer structural optimisation, thereby enhancing both design flexibility and mechanical performance (Blok et al. 2018).

Markforged offer composite fabrication with carbon fibre, kevlar and fibreglass reinforcements (Figure 4.1), In continuous fibre reinforcement, strands of composite materials are embedded within the thermoplastic matrix (Figure 4.1), distributing loads effectively across the entire length of the fibre, which in turn enables the material to withstand higher forces and impacts in targeted orientations (Markforged 2023). On the other hand, short carbon fibre composites use small, randomly oriented fibres integrated within the matrix. Though lacking the directional load distribution capabilities of continuous fibres, chopped fibres provide enhancements in overall strength, stiffness, and dimensional stability across all part orientations (Markforged 2023).

Figure 4.1. Suite of Continuous Fibre reinforcement (Markforged)

The base thermoplastics used in FFF composite fabrication often exhibit lower mechanical properties compared to traditional engineering materials such as aluminium or steel (Blok et al. 2018). Adding reinforcements, however, broadens their applicability by improving strength and stiffness; for instance, incorporating short carbon fibres (~0.1 mm) can increase these properties by up to 65%. However, the FFF technique may limit the full potential of short fibre reinforcements due to issues such as fibre pullout before fibre breakage, which affects strength performance (Blok et al. 2018).

Continuous fibre fabrication extrudes entire strands of reinforcement materials such as carbon fibre, offering considerably greater performance benefits compared to unreinforced thermoplastics (Blok et al. 2018). This technology has expanded possibilities in lightweight, high-strength applications across various industries. Continuous carbon fibre parts can reach strengths 8 times that of Acrylonitrile Butadiene Styrene (ABS) and even surpass aluminium's yield strength by approximately 20%, achieving material properties of up to 700 MPa and stiffness of 50 GPa (Blok et al. 2018). Limitations include, only getting reinforcement perpendicular to the build direction and having the restricted ability to place fibres along sharp angles and small radii, making certain geometries impractical for continuous composite fabrication (Blok et al. 2018).

In addition to material choice, machine parameters significantly affect the mechanical performance of FFF fabricated components. Variables such as layer height, wall thickness, part orientation, temperature, infill density, and infill pattern each play a role (Hodzic and Pandzic 2019). For composite fabrication, infill pattern is especially crucial; research demonstrated that tensile strength improved with triangular over rectangular infill in composite parts (Naranjo-Lozada et al. 2019), illustrating how subtle adjustments can impact material behaviour under load.

4.1.1 Material Extrusion Process

The material extrusion process within FFF involves a thermoplastic filament being heated, extruded through a nozzle, and deposited layer-by-layer on a build platform to form a three-dimensional object (Figure 4.2). This process allows a range of materials to be extruded, making it suitable for applications that demand specific mechanical properties or structural qualities. The flexibility of FFF lies in its accessibility, material versatility, and potential for property control through process parameters (Krishnanand and Taufik 2021).

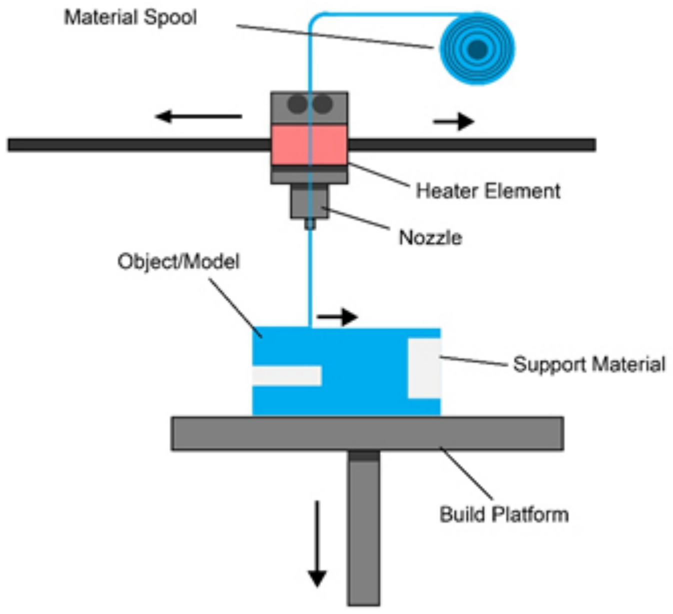

Figure 4.2. FFF Process (Loughborough University Additive Manufacturing Research Group)

In FFF, material is thermally bonded within and between layers as it cools, resulting in an anisotropic structure. This anisotropy means that mechanical properties vary significantly across different directions, with strength and stiffness often greatest along the axis of printed tracks (Chen et al. 2022). Research highlights that the layers tend to have superior mechanical properties in the primary (1-axis) direction, while secondary (2-axis) and tertiary (3-axis) directions exhibit reduced tensile strength and stiffness, similar to orthotropic behaviour in fibre composites (Ahn et al. 2002). Therefore, controlling FFF parameters is crucial for producing structurally sound components, especially in applications requiring predictable performance.

At the mesoscale, features such as contact area between adjacent tracks and void content within the part play essential roles in determining structural integrity and overall mechanical strength (Zhang et al. 2025). Fabricated parts inevitably contain voids or gaps between tracks, contributing to void density, which can negatively impact tensile strength and dimensional stability (Batley et al. 2023).

4.1.2 Composite Material Extrusion

The process of composite material extrusion in AM introduces unique design capabilities and complexities by incorporating fibre reinforcements directly into the extruded material. With the use of reinforcement fibres such as carbon, composite FFF offers significantly improved mechanical properties compared to standard polymer-only fabrication. As outlined by the ISO/ASTM52900-15 standard (Standardization 2021), composite extrusion can involve either short fibre or continuous fibre reinforcement (Figure 4.3), each with distinct influences on part strength, flexibility, and potential applications. Optimising lay-up orientation in composite fabrication allows for tailored mechanical properties across layers, enabling highly specific load distribution and mechanical performance.

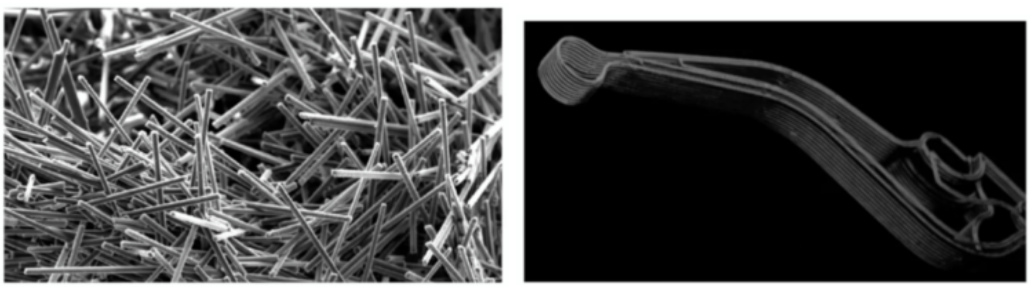

Figure 4.3. Short and Continuous Fibre reinforcement (Markforged)

In both continuous and short fibre reinforced composites, the lay-up orientation of fibres is a critical factor that allows for the customisation of a part's properties. Adjusting lay-up can enable parts to bear higher loads in specific directions, achieving strength and stiffness where it is needed most (Blok et al. 2018). By leveraging composite AM’s ability to accurately place reinforcements, manufacturers can achieve design freedom similar to traditional laminated composite manufacturing but with a lower cost and greater automation potential (Markforged 2023). As fibres are laid layer-by-layer, the structure can be optimised at each level, ensuring enhanced strength, stiffness, and even resistance to fatigue in certain directions, opening new applications where precise load bearing and weight-saving are required (Markforged 2023).

Markforged's development of machines capable of extruding continuous fibre composites, such as the Mark One and Mark Two (Figure 4.4), marked a significant milestone in accessible composite AM. These machines can process continuous carbon fibre reinforced with PA (polyamide), achieving mechanical properties that surpass typical polymer AM machines (Blok et al. 2018). This increased strength and stiffness have enabled new use cases in industries requiring lightweight, high-strength components, such as aerospace and automotive manufacturing. With ongoing development, the accessibility and range of applications for these machines are expected to expand further.

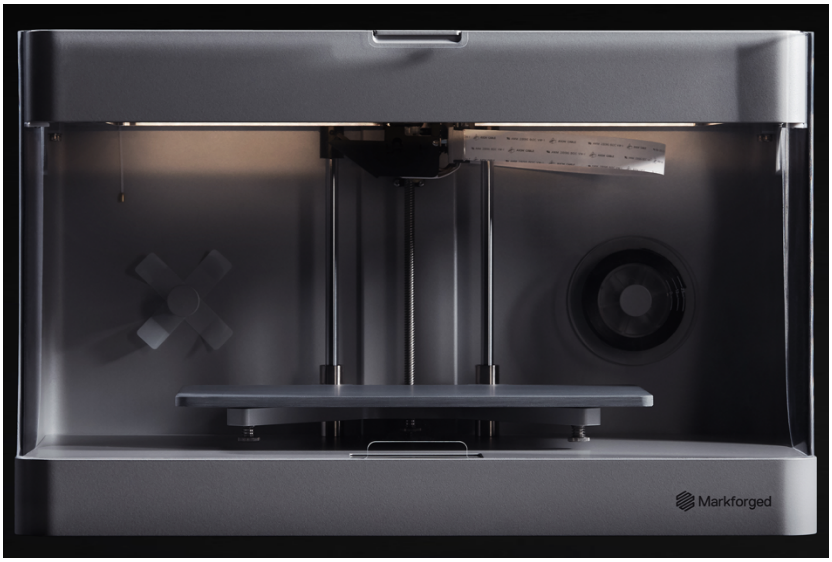

Figure 4.4. Markforged Mark Two Machine (Markforged)

Despite the advancements, limitations do exist, particularly with void formation and fibre pull-out during fabrication. In short-fibre-reinforced parts fibres can pull out from the matrix rather than breaking, limiting the achievable strength improvements and diminishing the potential for consistent, high-strength output (Ferreira et al. 2019; Fu et al. 2019). The extrusion process often results in voids within the material, which can compromise the structural integrity of the component. These voids are especially problematic in applications demanding reliable load-bearing performance, as they reduce the bonding area and introduce points of potential failure within the material.

4.2 Matrix Materials

In composite AM, matrix materials are essential for binding and supporting reinforcement fibres, distributing applied loads, and contributing to the part's mechanical properties (Rajak et al. 2019; Van de Werken et al. 2020). The choice of matrix material directly impacts performance, strength, and versatility, affecting factors such as interlayer bonding and durability in the final composite structure. Thermoplastics are the most commonly used matrix materials in composite AM, and their compatibility with fibre reinforcements ensures that parts have tailored mechanical properties.

Thermoplastics such as ABS, PA (or Nylon) and PLA, are the most widely used matrix materials in composite AM (Ngo et al. 2018; Van de Werken et al. 2020). They offer a range of mechanical properties, from high-impact resistance to lightweight durability. Thermoplastics serve as the foundation of the matrix phase, embedding fibres to achieve optimal load distribution, dimensional stability, and improved performance. The specific application and performance goals determine the matrix material choice, as it must bond effectively with the fibre reinforcement to ensure strong interlayer adhesion and mechanical durability (Rajak et al. 2019).

ABS (Acrylonitrile Butadiene Styrene):

ABS is one of the most widely used thermoplastics in composite AM due to its impact resistance, ease of processing, and affordability (Ngo et al. 2018). ABS is a tough, engineering-grade thermoplastic known for its balance of strength, flexibility, and resistance to various environmental factors. ABS is frequently used for automotive parts, consumer electronics and various functional prototypes, particularly where cost efficiency and robustness are essential (Ngo et al. 2018).

Polyamide (PA, Nylon):

Nylon-based matrix materials are popular due to their flexibility, durability and good adhesion with reinforcement fibres (Ngo et al. 2018). Nylon is a strong, flexible, and wear-resistant thermoplastic, often used in industrial-grade composite fabrication. Markforged's Onyx material is a leading composite matrix in the industry, known for its strength, stiffness, and excellent surface finish due to its carbon micro-fibre infused PA matrix (Markforged 2023). Onyx is a PA based material combined with micro-carbon fibres, giving it increased strength and rigidity compared to unfilled polymers. It has a unique matte finish that enhances both aesthetic appeal and surface durability. Onyx provides a high strength-to-weight ratio, improved thermal stability, and stiffness. It also offers enhanced dimensional stability, making it ideal for functional parts subjected to repeated stress or temperature variations (Blok et al. 2018). Onyx is widely used in industrial applications, including aerospace and automotive industries, for functional parts requiring durability and lightweight characteristics, such as jigs, fixtures, and custom tools (Markforged 2023).

Polylactic Acid (PLA):

PLA is a biodegradable thermoplastic popular for prototyping and low-load applications, with good printability and a lower environmental impact (Ngo et al. 2018). PLA is an affordable, easy-to-print thermoplastic with a relatively low melting point, commonly used in educational and prototyping environments (Ngo et al. 2018). PLA-based composites offer moderate strength and stiffness but are limited in flexibility and thermal resistance (Ngo et al. 2018). PLA is primarily used in prototyping, visual models, and non-load-bearing applications.

Matrix materials define many of the mechanical properties achievable in composite AM, affecting the quality of reinforcement distribution, interlayer adhesion, and final part performance (Ngo et al. 2018). ABS and Onyx, for example, each offer unique benefits: ABS excels in affordability and toughness, while Onyx provides high stiffness and excellent surface quality for functional parts. Each matrix material, when combined with appropriate reinforcement, enhances the design freedom of composite AM, expanding possibilities for both custom and mass-produced parts. Selecting the optimal matrix material is fundamental to maximising the mechanical properties of the composite and ensuring that the part meets the required specifications for its intended use (Blok et al. 2018).

4.3 Fibre Reinforcements

The most common composite materials used in AM are carbon fibre, Kevlar, and fibreglass (Ferreira et al. 2019). Each material has distinct mechanical properties and applications, as well as advantages and limitations that influence their use.

Carbon Fibre:

Carbon fibre is used in composite AM due to its high strength-to-weight ratio, stiffness, and thermal stability. Its strength and low density make it particularly suitable for structural and load-bearing applications in aerospace, automotive, and sports equipment (Zhang et al. 2024). However, carbon fibre has limitations, such as high cost and brittleness, which can lead to fracture under certain types of impact or stress (Zhang et al. 2024).

Kevlar

Kevlar, known for its high impact resistance and flexibility, provides a balance of durability and strength in AM applications. Its shock-absorbing characteristics make it suitable for protective equipment and parts that experience significant vibration or impact, such as in military and aerospace industries (Markforged 2023). However, Kevlar's relatively low stiffness compared to carbon fibre can limit its use in applications where high rigidity is required, though its resistance to abrasion and fatigue adds value in certain applications (Blok et al. 2018).

Fibreglass

Fibreglass is a more affordable alternative that offers moderate strength and stiffness. It is corrosion-resistant and electrically insulating, making it suitable for marine and electrical applications. Despite its lower performance compared to carbon fibre and Kevlar, fibreglass remains valuable for less demanding applications, providing sufficient mechanical properties at a reduced cost (Rajak et al. 2021). However, fibreglass parts are heavier than carbon fibre alternatives, which limits their use in weight-sensitive applications.

4.4 Fibre – Matrix Coupling

The interaction between fibres and the matrix material plays a fundamental role in determining the mechanical performance of the resultant material. Ensuring that fibres are fully wetted and impregnated by the matrix material is essential, as the quality of the fibre-matrix interface directly impacts the strength, stiffness, and durability of the fabricated component. Voids around fibres indicate incomplete wetting, and the number of these voids has been found to increase with higher fibre contents which can lead to a weak fibre-matrix interface (Blok et al. 2018). Any inconsistencies, such as defects or voids, can introduce weak points in the structure, compromising load transfer and reducing overall mechanical properties (Blok et al. 2018).

Microscopy analysis of components fabricated in Onyx reveal a high-quality fibre-matrix interface, with effective layer adhesion and compaction, contributing to an even surface finish (Batley et al. 2023). Uniform distribution and compact layering indicate good fibre impregnation, minimising the risk of structural flaws (Batley et al. 2023). Optimising fibre-matrix coupling is essential in composite AM to achieve high-strength, reliable parts.

4.5 Chapter Conclusions

This chapter has explored the complexities and potential of FFF composite AM, and the impact of both short and continuous fibre reinforcement techniques. The use of reinforcement fibres has transformed thermoplastic-based FFF into a process capable of producing high-strength, lightweight components suitable for a range of applications. Short fibre composites offer cost-effective, isotropic reinforcement, although limited by their lower directional strength, whilst continuous fibre fabrication processes offer improvements in mechanical properties, enabling the production of AM components that rival the strength of metals such as aluminium (Table 4.1). The matrix materials used, including ABS, Nylon, and PLA, each play an essential role in determining final part properties by affecting fibre bonding, structural cohesion, and compatibility, although fibre-matrix coupling continues to present challenges due to potential voids and fibre pull-out issues.

Material	**Tensile Strength**	**Tensile Modulus**
Aluminium	186-510 Mpa	69-75GPa
CRFP (Epoxy Matrix)	550-10.5e3 Mpa	69-150 Gpa
ABS-CF10	37.7 MPa	3.34 GPa
Onyx	40 MPa	2.4 GPa
Onyx + Carbon Fibre	800 MPa (Carbon Fibre)	60 GPa (Carbon Fibre)

Table 4.1. Mechanical Properties Comparison

CHAPTER 5: REPEATABILITY AND ACCURACY OF ADDITIVE MANUFACTURING MATERIALS AND PROCESSES

The information presented in the following chapter is derived from the original published research paper: Batley, A., Glithro, R., Dyer, B. and Sewell, P., 2023. Evaluation of Tensile Strength and Repeatability of 3D Printed Carbon Fiber Materials and Processes. 3D Printing and Additive Manufacturing.

5.1 Overview

As the adoption of AM with composite materials increases across industries such as aerospace, automotive, and medical applications due to its ability to create structurally efficient and customised parts that are high-strength, and lightweight, it’s important to understand and quantify the material properties that designers and engineers rely on to make informed material choices. This chapter explores the repeatability and accuracy of AM material and processes claimed by manufacturers, providing a foundation for establishing if the mechanical properties of AM materials and components meet the specifications stated in manufacturer data sheets.

The chapter details a study designed to replicate the manufacturing and testing processes used by AM material manufacturers, specifically focusing on tensile strength testing. By replicating the manufactures build parameters and processes, and testing procedures, this study allows for a direct comparison between the tensile properties obtained in a real world setting and those published by manufacturers. These comparisons are essential for determining the accuracyof manufacturer-provided data and for understanding how consistently these properties can be achieved in practice.

This chapter addresses the research questions by assessing if composite AM materials are capable of delivering the consistency and accuracyneeded for prosthetic applications. It checks the repeatability and precision of mechanical properties in multiple parts to see if composite AM can create parts with predictable and reproducible attributes. Through the examination of critical parameters such as tensile strength, stiffness, and strain at break, this research supplies critical data to inform Sub-question 1 regarding material properties and reproducibility of composite AM. The chapter also examines how closely manufacturer-provided material properties reflect actual performance, adding to Sub-question 2 by evaluating whether existing control mechanisms in AM processes are adequate to produce high-quality, dependable outputs. They will also guide subsequent discussion of optimum process parameters (Sub-question 3), leading to optimisation of AM settings to deliver paediatric prosthetic ankle-foot devices required stiffness, energy return, and dynamic response. By establishing the consistency and accuracyof composite AM, this chapter plays a fundamental role in determining whether AM can serve as a viable alternative to traditional prosthetic manufacturing methods.

5.2 Methodology

This research methodology is designed to replicate the processes and parameters used by manufacturers when establishing material property data. By replicating the manufacturers' methods and process settings, the study aims to statistically assess the repeatability and accuracy of the resulting data when compared to published values. This replication is essential for valid comparisons, as even slight differences in parameters can significantly alter a material's properties. For example, changes in specimen orientation impact mechanical characteristics such as anisotropy, while variations in layer and fibre orientation directly influence strength, stiffness, and ductility (Melenka et al. 2016; Hu et al. 2022). Fibre orientation has a notable effect on strength, especially relative to loading direction (Melenka et al. 2016; González-Estrada et al. 2018; Sanei and Popescu 2020).

A comprehensive review of scientific literature, combined with an analysis of the manufacturers' processes, was conducted to identify and align all relevant process parameters that could affect test outcomes. As a result, key factors were identified as fill density, layer and fibre orientation, slicing software, layer height, wall and roof/floor layers, total layers, build orientation and fabrication temperature (Van Der Klift et al. 2015; Torrado and Roberson 2016; Hodzic and Pandzic 2019; Todoroki et al. 2020; Hoshikawa et al. 2021; Yavas et al. 2021). These parameters were then carefully matched to the manufacturers' standards.

5.2.1 Materials and AM Machines

Two different AM machines and three materials were utilised in this research. The Stratasys F170 (Stratasys Inc., Israel) was used to produce specimens in ABS-CF10, while the Markforged Mark Two (Markforged Inc., Massachusetts) was used to fabricate specimens in Onyx and in Onyx with continuous carbon fibre reinforcement. These machines and materials were chosen through a combination of convenience sampling and their standing within the AM industry. Both machines and materials are industry leading within composite AM.

The manufacturers have provided the following brief descriptions of their materials:

- ABS-CF10: 'Stratasys ABS-CF10 combines standard ABS material with 10% chopped carbon fibre by weight. The result is a low moisture-sensitive FDM® thermoplastic 50% stiffer and 15% stronger than standard ABS 3D printing material.' (Stratasys 2021)
- Onyx: 'Onyx is a micro carbon fibre filled nylon. It's 1.4 times stronger and stiffer than ABS and can be reinforced with any continuous fibre.' (Markforged 2021)
- Carbon Fibre continuous fibre reinforcement: 'Carbon fibre has the highest strength-to-weight ratio of our reinforcing fibres. Six times stronger and eighteen times stiffer than Onyx.' (Markforged 2021)

Material properties provided by the manufacturers (Markforged 2021; Stratasys 2021) are shown in Table 5.1.

Material Properties			
Machines	**Material**	**Tensile Strength**	**Tensile Modulus**
Stratasys F170	ABS-CF10	37.7 MPa	3.34 GPa
Markforged Mark Two	Onyx	40 MPa	2.4 GPa
Markforged Mark Two	Onyx + Carbon Fibre	800 MPa (Carbon Fibre)	60 GPa (Carbon Fibre)

Table 5.1. Manufacturer provided material properties

5.2.2 CAD and Fabrication Process

For each material, 3D CAD models of dog bone tensile test specimens were modelled in SolidWorks (Dassault Systèmes, Massachusetts). The specimen dimensions were obtained from the standards used in the manufacturers' original testing to maintain geometric consistency. ABS-CF10 specimens fabricated on the Stratasys F170 followed the ASTM D638 (Type I) (Figure 5.1) standard (Standardization 2014), while the Onyx and Onyx with continuous carbon fibre reinforcement specimens adhered to the ASTM D638 (Type IV) (Figure 5.2) standard (Standardization 2014).

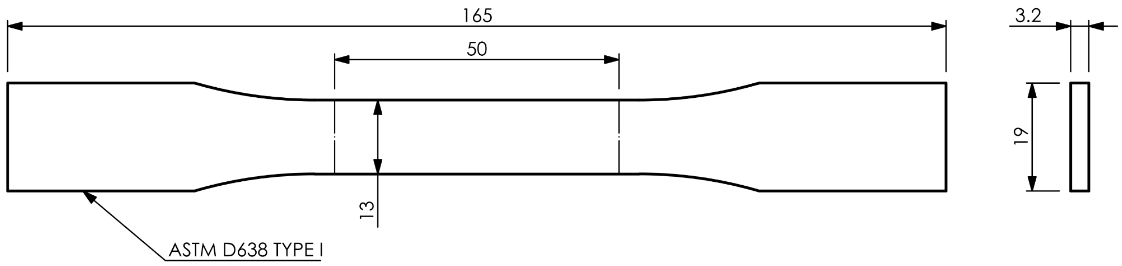

Figure 5.1. ASTM D638 (Type I) Specimen

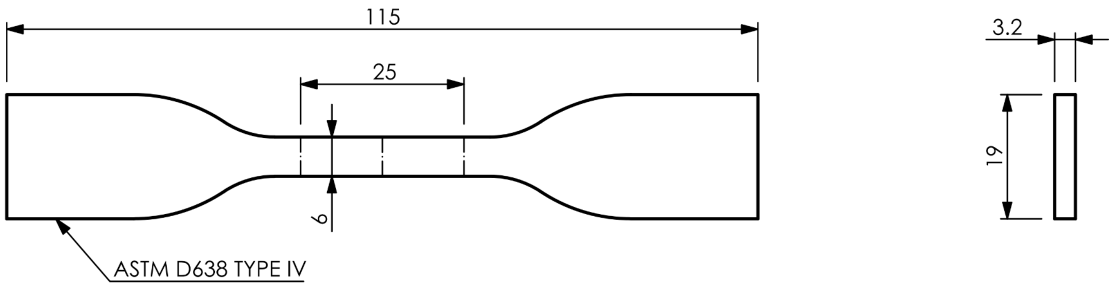

Figure 5.2. ASTM D638 (Type IV) Specimen

The CAD models were then transferred to the manufacturers' slicing software, where the chosen parameters were applied, as detailed in Table 5.2.

Table 5.2. Specimen Fabrication Parameters

Parameters										
Machine + Material	**Fill Density**	**Fill Pattern**	**Layer/Fibre Orientation**	**Software**	**Layer Height**	**Wall Layers**	**Roof/ Floor Layers**	**Total Fibre layers**	**Total Layers**	**Build Orientation**
Stratasys F170 - ABS-CF10	100%	Solid	± 45	Grab CAD	0.254mm	1	1/1	N/A	75	XZ
Markforged Mark Two - Onyx	100%	Solid	± 45	Eiger	0.125mm	2	4/4	N/A	26	XY
Markforged Mark Two - Onyx + CF	100%	Solid + Isotropic reinforcement	Onyx: ± 45 CF: 0	Eiger	0.125mm	2	4/4	8	26	XY

Five specimens were fabricated per material, meeting the ISO 527-1 testing standard requirement (Institution 2019). Each specimen's width and depth were measured using an Axiom too CMM (Aberlink Ltd., Gloucestershire, UK), last calibrated in January 2023, with measurement accuracy up to 2.4 micrometres to verify cross-sectional area and dimensional precision.

5.2.3 Mechanical Testing and Digital Image Correlation

Mechanical tensile tests were carried out using a ZwickRoell Z030 (ZwickRoell Ltd., Worcestershire, UK) testing machine with a 10kN load cell, last calibrated in June 2022. Testing speeds were matched to the conditions outlined in the manufacturers' testing procedures: 2 mm/min for ABS-CF10 and 2.54 mm/min for Onyx and Onyx with carbon fibre reinforcement. The resulting test data was recorded, and the plots were created using Microsoft Excel (Microsoft, Washington).

To measure strain distribution across the sample surfaces during testing, a Dantec Dynamic digital image correlation (DIC) system (Dantec Dynamics, Denmark) was employed. DIC, an optical strain measurement technique, tracks deformation by analysing speckle patterns on the material's surface, providing a full-field measurement of longitudinal strain. This approach, combined with tensile testing, yields detailed insights into the specimen's mechanical behaviour. The system was configured with two cameras mounted on a tripod at a fixed distance from the test specimen. The use of a stereo camera setup, although the specimen geometry was relatively flat, was selected to ensure accurate three-dimensional displacement tracking and out-of-plane movement detection, which enhances measurement fidelity and mitigates potential misalignment or setup variation.

Prior to testing, specimens were spray-painted matte white and then lightly speckled with black paint to create a high-contrast random speckle pattern. This pattern was essential for accurate correlation and tracking of surface deformation throughout the loading cycle. Camera calibration was performed using a standard 9x9 dot calibration grid, and calibration residuals were kept below 0.02 pixels to ensure high measurement accuracy.

The DIC data was processed using Dantec's Istra 4D software, with subset size and step size set to 25 pixels and 5 pixels respectively, optimised through preliminary sensitivity analysis to balance resolution and computational efficiency. A noise floor study was conducted by capturing a series of static images over a 60-second period with no applied load. This confirmed that the system's displacement noise was significantly lower than the observed mechanical variation between samples. As a result, confidence can be placed in the strain measurements and the subsequent derivation of elastic modulus values.

The elastic modulus was determined from the initial linear segment of the stress-strain curve using force data from the ZwickRoell Z030 and strain data obtained through DIC. Figure 5.3 shows the testing set up, including the mounted DIC cameras and lighting arrangement.

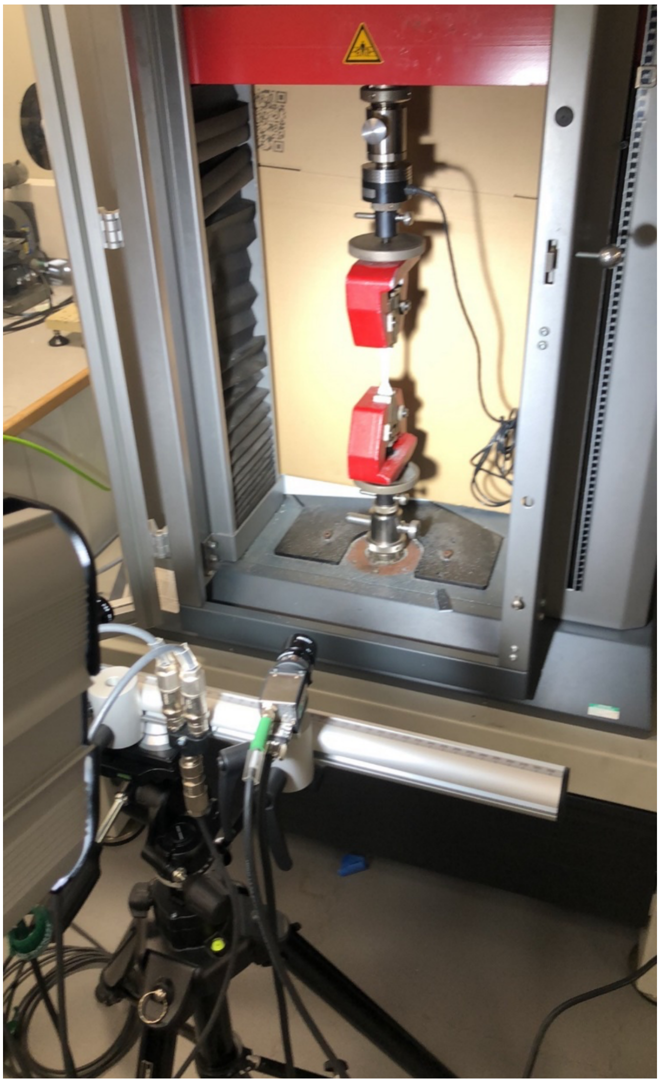

Figure 5.3. Mechanical Test Set Up

5.2.4 Microscopy

After mechanical testing, the specimens underwent visual inspection utilising a Keyence VHX-5000 digital microscope (Keyence Ltd., Milton Keynes, UK). This advanced microscopy technique enabled a high-resolution examination of the material's microstructure and part quality. This provides critical insights into the fibre-matrix interface, including the distribution, size, and orientation of the fibres, as well as the identification of any defects present in the fabricated specimens. Microscopic analysis is particularly crucial in this context, as it allows an understanding of how these microstructural features influence the mechanical properties of AM materials to be developed.

5.3 Dimensional Accuracy

Dimensional accuracy in AM is essential for ensuring that the final component is manufactured closely to its original CAD model, maintaining the intended geometry and fit for its application. This section investigates the dimensional accuracy of the specimens.

5.3.1 Repeatability

In this context, repeatability refers to the extent to which each specimens' dimensions were comparable to each other, indicating the AM machines ability to produce repeatedly dimensionally identical components. Mean and standard deviation values were calculated for each specimen's width and depth measurements. Dimensional repeatability is an important factor with any manufacturing technique as it ensures that each component maintains consistent dimensions. This consistency is particularly relevant for applications where accuracyin geometry is critical. The samples exhibited generally consistent results with small standard deviations, suggesting good repeatability across multiple parts. As seen in Tables 5.3 and 5.4, the standard deviations remained low across different materials and machines, indicating that each machine could produce components with a high degree of dimensional stability across repeated builds.

Sample Width Measurement (mm)				
Material Sample	**Nominal**	**Measured Avg.**	**S. D.**	**p-value**

Stratasys F170 - CF10	13.00	13.06	0.04	<0.001
Markforged Mark II - ONYX	6	6.03	0.03	<0.003
Markforged Mark II - ONYX + 8 Layers CF @ 0°	6	6.03	0.02	<0.001

Table 5.3. Sample Width Measurement

Sample Depth Measurement (mm)				
Material Sample	**Nominal**	**Measured Avg.**	**S. D.**	**p-value**
Stratasys F170 - CF10	3.2	3.21	0.02	<0.162
Markforged Mark II - ONYX	3.2	3.30	0.03	<0.001
Markforged Mark II - ONYX + 8 Layers CF @ 0°	3.2	3.36	0.03	<0.001

Table 5.4. Sample Depth Measurement

5.3.2 Accuracy

Accuracy, in this context, refers to the extent to which the measured dimensions of the samples match the intended CAD dimensions, indicating the AM machines capacity to reliably achieve the desired geometry. An unpaired student's t-test was conducted for each material and AM method to compare the measured dimensions against the nominal values (Mishra et al. 2019). Each t-test was conducted using all five samples for each parameter being analysed. A p-value of <0.05 indicated a statistically significant difference, demonstrating that the differences between nominal and measured values were unlikely to be due to chance.

As indicated by the p-values in Tables 5.3 and 5.4, the measured dimensions deviated significantly from the nominal dimensions for most samples, aligning with findings from previous studies on the dimensional accuracy of AM tensile test specimens (González-Estrada et al. 2018; Pyl et al. 2018). However, minor deviations from the nominal CAD dimensions were observed across some measurements, particularly for samples fabricated using ABS-CF10, where the deviations were within an acceptable range. This deviation can be critical for designers, as understanding the discrepancy allows them to make necessary adjustments in the design phase to account for minor dimensional inaccuracies in fabricated components.

5.3.3 Analysis

Both the Stratasys F170 and Markforged Mark Two machines consistently maintained repeatable dimensional accuracy, however, there were notable differences in their ability to reliably achieve the exact nominal dimensions specified in the CAD models. Certain dimensions across multiple samples from each machine deviated significantly from the nominal values, as evidenced by p-values <0.05 in both width and depth measurements for several materials.

The Stratasys F170 showed a higher consistency in dimensional accuracy for ABS-CF10 specimens compared to the Markforged machine, particularly in width measurements. However, slight deviations were still present, suggesting that while the F170 machine is capable of achieving close to nominal dimensions, it cannot always perfectly replicate the intended CAD dimensions. These deviations could be impactful depending on the application's tolerance requirements. For critical applications, such as in mechanical or structural components where precise fit and alignment are essential, even small dimensional deviations could compromise performance or lead to component misalignment.

The Markforged Mark Two had a higher dimensional deviation with Onyx and Onyx with continuous carbon fibre. This outcome may reflect differences in material properties between ABS-CF10 and Onyx, as well as variations in machine design, layer deposition methods and composite fibre integration. Continuous carbon fibre reinforcement introduces complexities due to fibre alignment challenges, which can affect layer bonding and overall dimensional stability. For applications requiring high strength and stiffness in composites, the Mark Two provides benefits in material performance but may require design compensations to accommodate these dimensional inconsistencies.

This analysis highlights that when using AM with composite materials, designers and engineers must consider potential limitations in dimensional accuracy when using these materials. For applications that demand exact dimensional conformity, additional post-processing such as CNC milling, or iterative adjustments may be necessary to achieve the desired fit. This insight underscores the importance of a detailed understanding of the interaction between specific materials, process capabilities, and parameter settings in AM to meet certain dimensional requirements.

5.4 Mechanical Properties

The mechanical properties studied of the AM composite materials were ultimate tensile strength (UTS), strain at break, and Elastic modulus. The UTS test was conducted to determine the maximum load that the material would withstand before failure to facilitate material consistency among multiple parts. This was necessary to verify the repeatability of the AM process and to confirm that all samples possessed the required strength levels. The break strain was measured to determine how repeatably the material could be strained before failure, to determine whether the fabrication process was introducing any variability that would affect the ductility and overall reliability of the material. Elastic modulus was experimented on to quantify the stiffness of the material and ensure that all components had equal mechanical properties. By comparing a number of samples' modulus values, the study was able to ascertain whether there were differences in the structural soundness of the material, reaffirming the strength of the AM process. These tests were chosen specifically to quantify how reproducible and consistent the mechanical properties of the AM composite materials were so that prosthetic devices could be manufactured with predictable and consistent performance.

The testing was supplemented by DIC. DIC was instrumental in accurately measuring strain across the entire specimen surface, offering a full-field analysis of deformation patterns under tensile load (Figures 5.4 and 5.5). This approach allowed for an in-depth understanding of the mechanical properties of the AM samples, helping to determine the repeatability and reliability of AM composite materials against the mechanical properties stated by the manufacturers. Each material’s performance was evaluated to understand the extent to which samples met or deviated from the manufacturer specifications and to assess whether these materials can deliver consistent results across multiple samples.

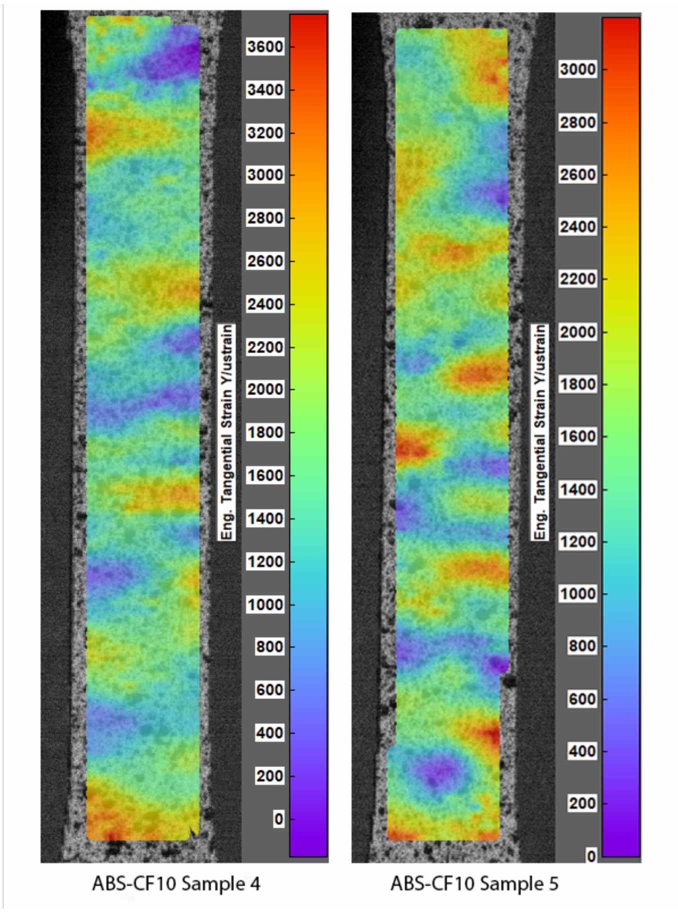

Figure 5.4. ABS-CF10 DIC Data

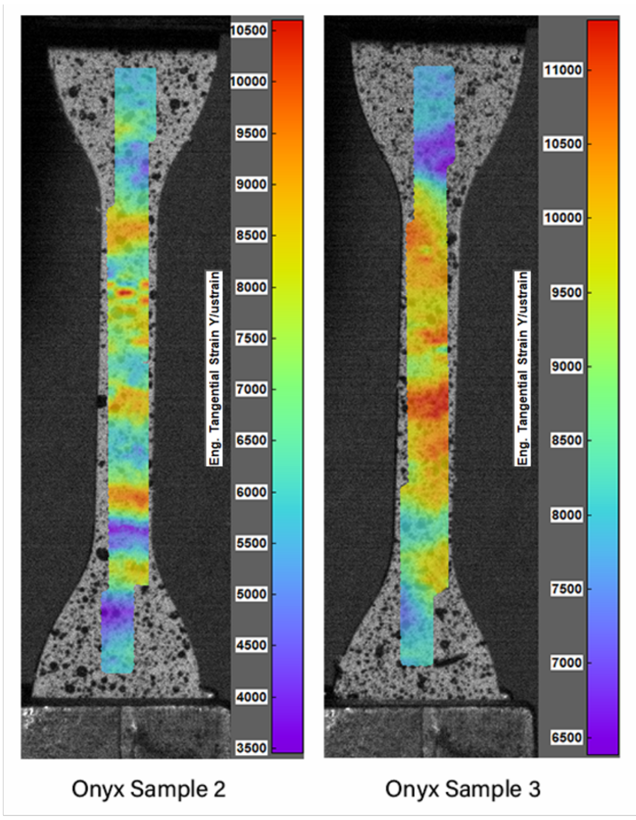

Figure 5.5. Onyx DIC Data

5.4.1 Repeatability

Repeatability in this mechanical testing refers to the ability to achieve consistent results across multiple tests conducted on samples produced under identical conditions. This consistency is particularly crucial in AM, where variations in process parameters can lead to discrepancies in the mechanical properties of fabricated parts.

For ABS-CF10 fabricated on the Stratasys F170, tensile strength was measured across five samples. These tests revealed a high degree of repeatability (Figure 5.6), evidenced by a standard deviation of 0.34 MPa, indicating minor variation between specimens. However, the average tensile strength observed utilising true stress was 33.04 MPa, approximately 12.36% below the manufacturer's stated value of 37.7 MPa. Despite being consistent within the samples tested, the underperformance in tensile strength highlights a potential gap between the manufacturer's expected results and the actual strength achievable in a real-world setting. These findings are in line with those found by Gonzalez-Estrada (2018).

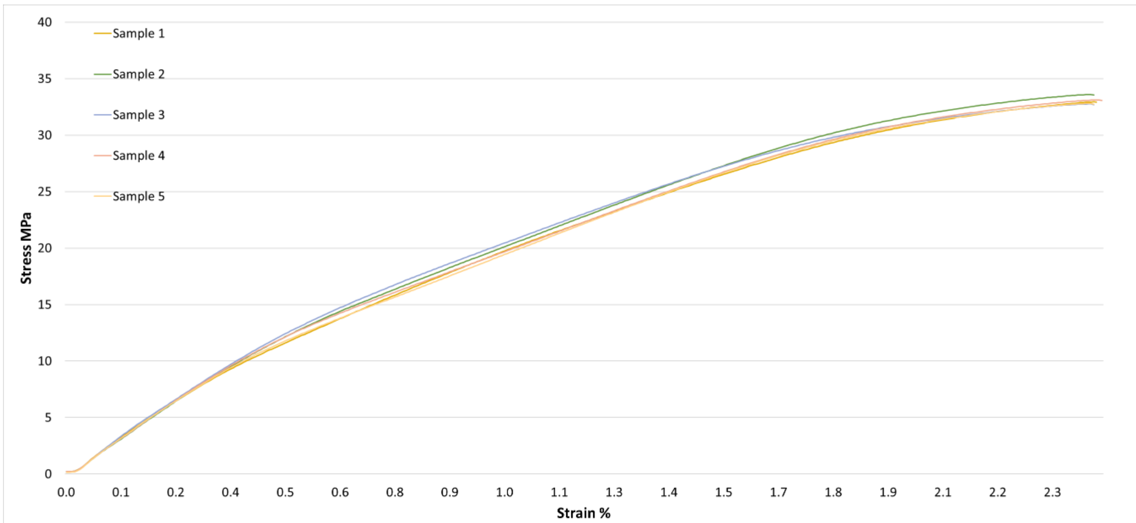

Figure 5.6. ABS-CF10 Tensile Test Results

The Onyx material fabricated on the Markforged Mark Two exhibited strong repeatability in tensile strength results, with a low standard deviation of 0.7 MPa across samples. On average, the tensile strength was measured at 44.17 MPa, exceeding the manufacturer's value of 40.64 MPa by 8.66% (Figure 5.7). The consistency within the samples can be attributed to the uniform distribution of fibres within the nylon matrix and excellent layer adhesion, which was further supported by microscopy analysis showing minimal voids and well-bonded layers (Figure 5.8). These findings indicate that Onyx consistently delivers predictable mechanical performance under controlled conditions, making it a reliable choice for applications requiring a balance between strength and weight.

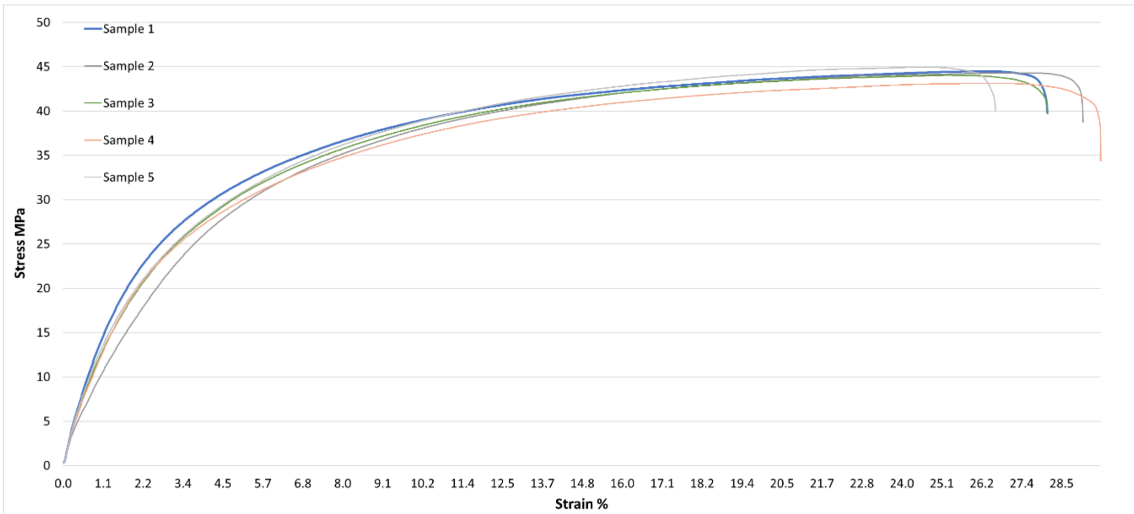

Figure 5.7. Onyx Tensile Test Results

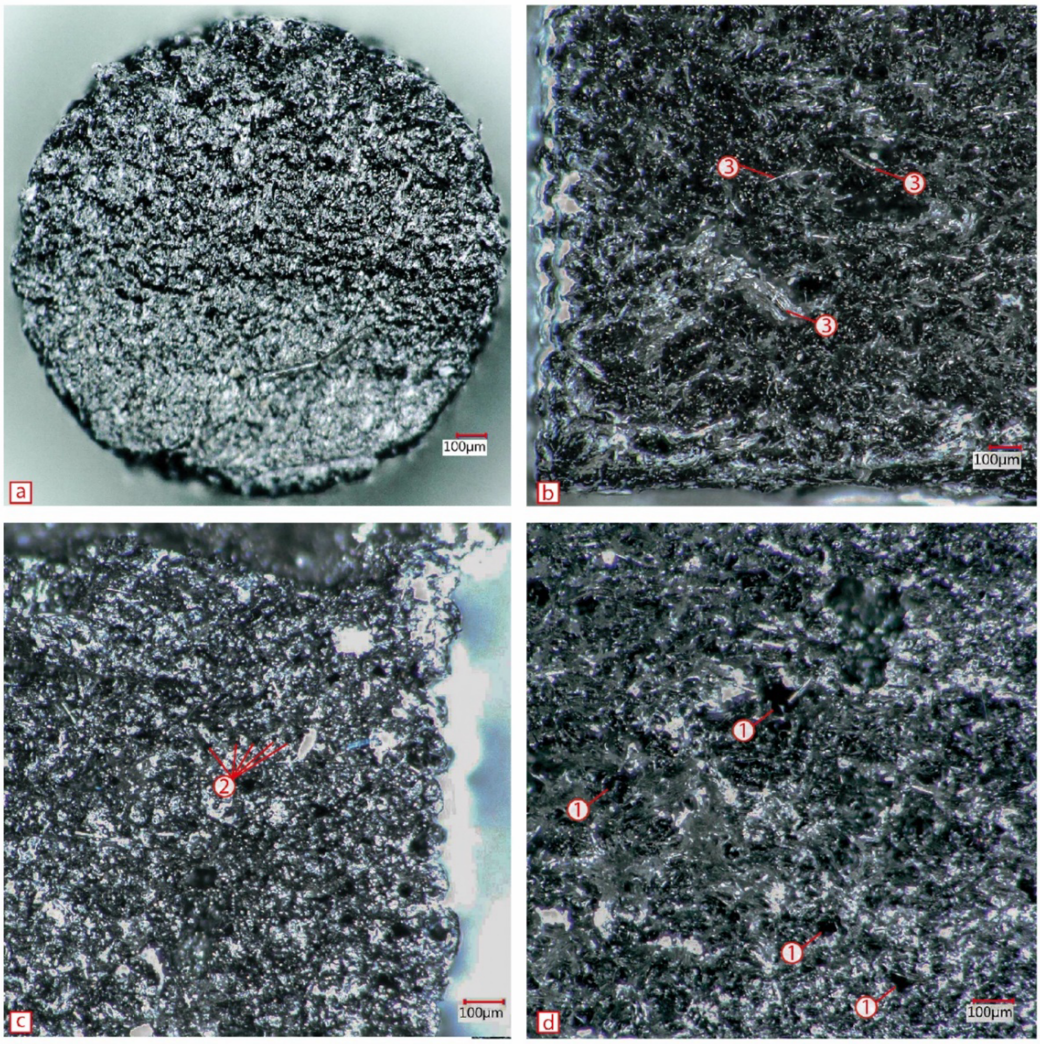

Figure 5.8. Onyx Microscopy. (a) Cross section of Onyx filament x150 magnification. (b) Onyx specimen cross section x150 magnification. (c) Onyx specimen cross section x200 magnification. (d) Onyx specimen cross section x200 magnification.

(1) Significant voids, (2) Uniform interbead voids between layers, (3) Fibre pullout.

Onyx with continuous carbon fibre reinforcement displayed greater variability, with a standard deviation of 8.71 MPa in tensile strength across samples (Figure 5.9). Although the average tensile strength exceeded the manufacturer’s reported value, the higher standard deviation suggests that the incorporation of continuous carbon fibres may introduce inconsistencies, potentially due to challenges in achieving uniform fibre placement and adhesion within the matrix. Continuous fibres are more challenging to integrate evenly, especially around complex geometries, as they require precise alignment to maximise load-bearing potential. These findings suggest that while continuous carbon fibre reinforcement can significantly enhance strength, it may be less repeatable than chopped fibre reinforcements, especially for parts with complex shapes or sharp contours.

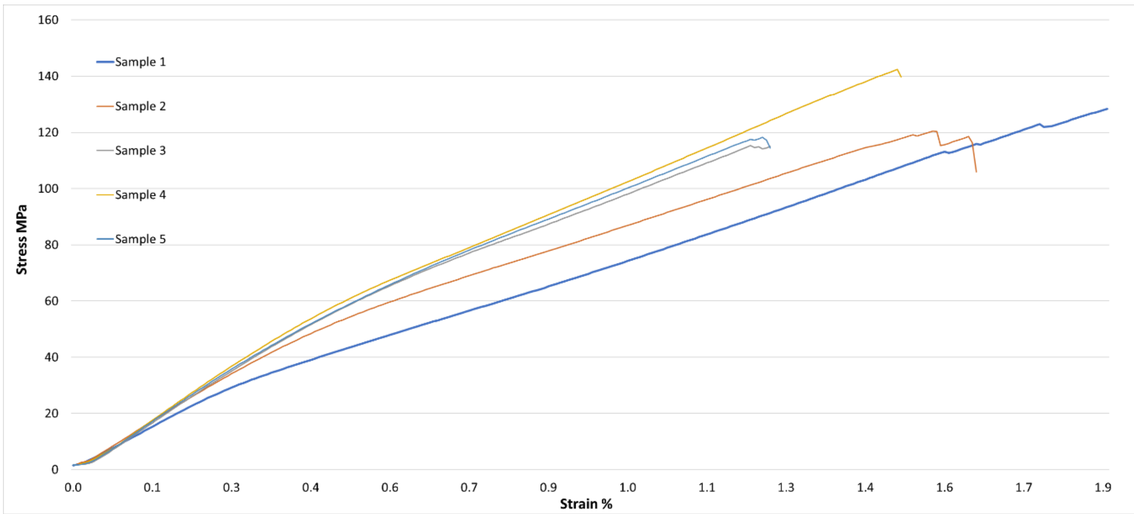

Figure 5.9. Onyx + Carbon Fibre Tensile Test Results

5.4.2 Accuracy

Accuracy in these mechanical properties is defined by how closely the observed results align with the manufacturer-provided specifications, providing an indicator of whether a material can meet performance expectations under different manufacturing or testing conditions. Assessing accuracy helps to determine if the material properties are genuinely reflective of what can be expected in practical applications, or if they only apply under ideal conditions.

For ABS-CF10, while the tensile strength results were consistent, they did not reach the manufacturer’s specified values. Microscopy on broken specimens and density analyses (Figure 5.10) revealed potential causes for this discrepancy, including poor layer adhesion (1), leading to voids in the internal structure of the sample; interbead voids seen between layers (2); along with fibre pullout at the fracture surface and associated cavities (3). These voids are likely formed due to suboptimal fibre-matrix integration, resulting in reduced load transfer between the carbon fibres and the ABS matrix. This weak fibre-matrix interface may lead to fibre pullout during tensile loading, rather than fibre breakage, therefore limiting the material’s ability to achieve maximum tensile strength. The density of the ABS-CF10 samples was approximately 95% of the material’s stated density, indicating a 4.67% void content. This void content, combined with weak fibre-matrix coupling, accounts for the reduced mechanical performance relative to the manufacturer's values. For designers and engineers, this indicates that ABS-CF10 may not always meet performance benchmarks without careful control of the manufacturing environment and process parameters.

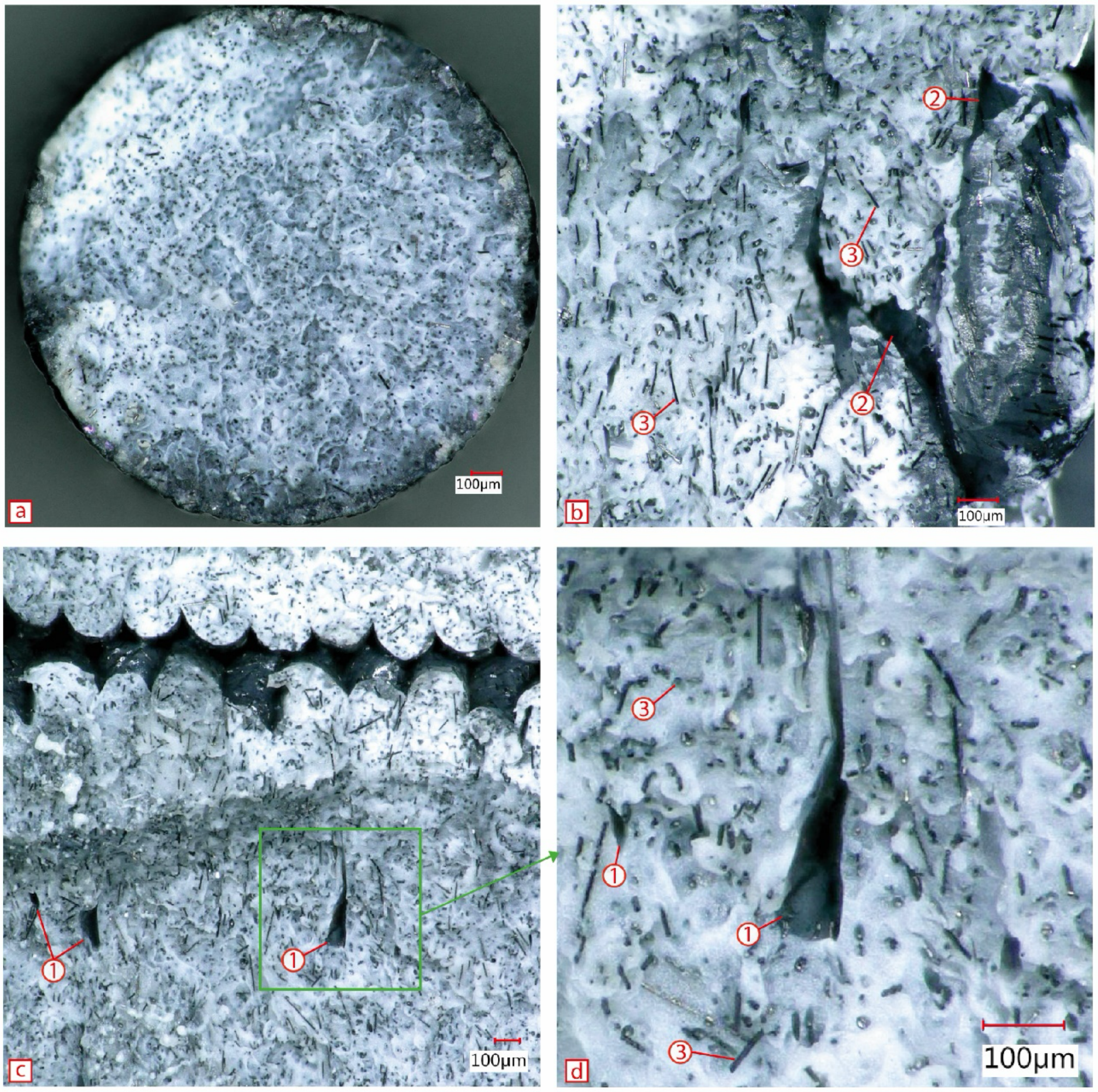

Figure 5.10. ABS-CF10 Microscopy. (a) Cross section of ABS-CF10 filament x150 magnification. (b) ABS-CF10 specimen cross section x150 magnification. (c) ABS-CF10 specimen cross section x100 magnification. (d) ABS-CF10 specimen cross section x200 magnification.

(1) Internal voids, (2) Uniform interbead voids between layers, (3) Fibre pullout.

Onyx demonstrated a high level of accuracy, with tensile strength results exceeding manufacturer expectations by 8.66%. Microscopy analysis indicated minimal inter-layer voids, well-distributed fibres, and robust fibre-matrix adhesion. The density analysis revealed that the samples were 89.47% of the theoretical density of the Onyx material, consistent with reported values in literature and confirming a void content range typical for Onyx. The reliable performance of Onyx can be attributed to consistent manufacturing quality, effective bonding, and fibre-matrix coupling that facilitates efficient load transfer. These findings validate the accuracyof Onyx in applications requiring dependable strength, if process settings are meticulously controlled.

For Onyx with continuous carbon fibre reinforcement, the tensile strength values achieved were higher than those reported by the manufacturer, averaging 15% higher than the expected tensile strength. Despite achieving higher-than-expected strength, variability between samples suggests that continuous fibre reinforcement may introduce challenges in achieving uniform material properties. This variability was observed in the stress-strain curves (Figure 5.9), where intermittent drops in stress indicate fibre breakage events before the final fracture, a characteristic of continuous fibre composites that have two distinct stiffness phases. This phase difference creates a stress transfer bottleneck when fibres fail locally, further explaining the variability. Microscopy analysis (Figure 5.11) revealed significant fibre pullout (3), larger voids around fibre layers (2), and a layered structure that caused some interfacial defects (1). This suggests that, while reliable for high-strength applications, Onyx with continuous carbon fibre reinforcement may require specific design considerations and quality controls to ensure consistent performance across multiple parts.

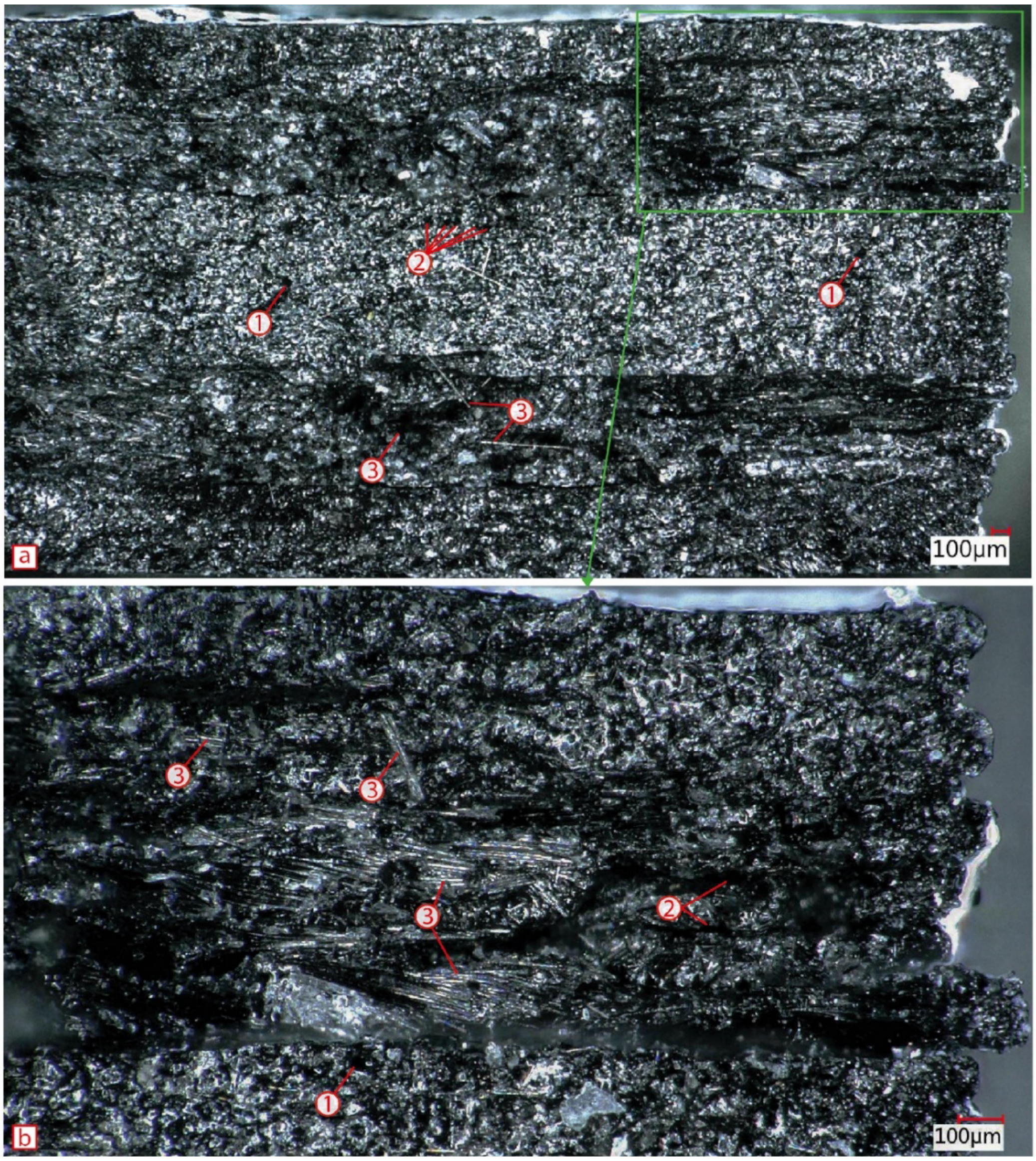

Figure 5.11. Onyx + Carbon Fibre Microscopy. (a) Onyx+CF specimen cross section x50 magnification. (b) Onyx+CF specimen cross section x200 magnification.

(1) Significant defect, (2) Large voids around fibre layers, (3) Fibre pullout.

5.5 Chapter Conclusions

This chapter has investigated the repeatability and accuracy of composite AM materials, focusing on both dimensional accuracy and mechanical properties. The findings have highlighted a significant issue in AM: inconsistencies between manufacturer-stated material properties and the values achieved in experimental testing. The results demonstrated that Stratasys's ABS-CF10 did not achieve its expected tensile strength, achieving a value 12.36% lower than quoted by the manufacturer. This deficit was attributed to factors such as poor fibre-matrix wetting, significant void content, and weak interfacial bonding, all of which were confirmed through microscopy and density analysis. The presence of large voids and insufficient bonding limited the load transfer between the carbon fibres and ABS matrix, reducing the composite's overall strength.

However, both Markforged materials, Onyx and Onyx with continuous carbon fibre, exceeded the manufacturers stated tensile strength values by 8.66% and 15.31%, respectively. This overperformance can be attributed to high-quality process parameters, effective fibre-matrix wetting, minimal void content, and rigorous quality control measures. The microscopy analysis showed good layer adhesion, evenly distributed fibres, and proper bonding, all contributing to the superior mechanical properties observed. However, despite the high tensile strength, Onyx with continuous carbon fibre reinforcement exhibited greater variability in results, indicating that while continuous fibres can significantly boost strength, they also introduce challenges in achieving consistent results.

The discrepancy between the two systems highlights the influence of machine architecture and processing control on the final material properties. The Stratasys Fortus system, while robust, is less specialised for composite fabrication, and its broader material compatibility may limit optimisation for fibre–matrix interactions. However, Markforged machines are purpose-built for composite AM, offering optimised head designs, deposition paths, and thermal conditions tailored for fibre-reinforced materials. These distinctions in machine design and process control likely contribute to the differing outcomes, underscoring that not all AM platforms can be expected to perform equally, especially for high-performance composite applications.

Dimensional accuracy was another aspect evaluated in this chapter. The measurements taken using an Axiom too CMM revealed that while both machines delivered repeatable results, their accuracy in meeting nominal dimensions varied. The Onyx material showed better dimensional stability compared to ABS-CF10 and Onyx with continuous carbon fibre, which exhibited the largest deviations. Statistical analysis, including mean values, standard deviations, and p-values, further supported these findings, emphasising that deviations from nominal dimensions can impact the predictability and performance of fabricated components in practical applications.

The final conclusion of this study is that designers and engineers cannot rely solely on manufacturer data sheets when selecting materials for critical applications. Validation testing is essential to ensure that AM fabricated components meet the necessary performance and dimensional standards. The discrepancies between manufacturer claims and actual performance underscore the importance of understanding the limitations of AM processes, including potential variations in fibre-matrix interaction, void formation, and the influence of process parameters.

In summary, while composite AM shows great promise for producing high-strength, lightweight components, this chapter has illustrated that achieving reliable and repeatable results requires careful consideration of quality, material properties, and machine-specific variables.

One limitation of this study is the absence of reproducibility testing across different machines or production batches. While repeatability was assessed by testing multiple samples produced under consistent conditions on a single machine, reproducibility defined as the ability to achieve consistent results across different machines, was not investigated. This limits the generalisability of the findings, as the observed material behaviours may vary on other machines or in different environments. Additionally, only five samples were fabricated and tested for each material. Although this sample size was sufficient to identify general trends in mechanical behaviour and dimensional accuracy, it restricts the statistical power of the analysis and may not fully capture the variability inherent in composite AM. Future work should explore inter-machine reproducibility and include a larger sample size to more robustly evaluate the accuracy, repeatability, and scalability of composite AM processes for critical prosthetic applications.

5.6 Contribution to Research Questions

This chapter contributes directly to the core research questions of this thesis by assessing the repeatability and accuracy of composite AM materials. The findings provide essential validation of the feasibility of AM for prosthetic foot production, particularly in ensuring consistent mechanical properties and dimensional accuracy which are key factors for producing reliable and high-performing dynamic response prosthetics. These results provide confidence that composite AM can produce repeatable and reliable mechanical properties, supporting its potential as a viable method for dynamic response paediatric prosthetic foot production. However, they also highlight critical considerations moving forward, such as the need for strict quality control, process validation, and design adjustments to account for dimensional inaccuracies. This chapter reinforces the potential of AM for prosthetic applications while identifying key challenges that must be addressed to ensure repeatable and reliable production of high-performance, dynamically responsive prosthetic feet.

CHAPTER 6: PARAMETRIC ANALYSIS OF ADDITIVE MANUFACTURING PARAMETERS

The information presented in the following chapter is derived from the original published research paper: Batley, A., Glithro, R., Montalvao, D., Dyer, B. and Sewell, P., 2024. Parametric Analysis of 3D Printing Parameters on Stiffness and Hysteresis Characteristics of Paediatric Prosthetic Foot Coupon Samples. Prosthetics and Orthotics International.

6.1 Overview

The mechanical performance of composite AM prosthetic components is influenced by internal parameters such as layer height, part orientation, reinforcement distribution, and fibre placement. These factors directly impact key mechanical properties of the device such as stiffness, hysteresis, and energy return, which are essential for ensuring dynamic response in prosthetic feet. Previous chapters established the feasibility (Chapter 4) and repeatability (Chapter 5) of composite AM. This chapter builds on these findings by systematically analysing how specific parameters affect structural and mechanical performance. Understanding these relationships is crucial for refining the manufacturing process and ensuring the prosthetic feet meet the necessary AOPA dynamic response classification thresholds.

This parametric analysis directly addresses the primary research question: “Is composite additive manufacturing capable of producing a dynamic response paediatric prosthetic ankle-foot device?” By optimising process parameters, this study aims to determine whether AM can consistently produce prosthetic feet that achieve the required stiffness and energy return for dynamic function. Without careful parameter optimisation, even high-quality composite materials may not meet these functional demands. This chapter also contributes to Sub-question 3: “What are the optimal AM parameters for manufacturing a paediatric prosthetic ankle-foot unit that meets dynamic response requirements?” By systematically evaluating the effects of machine settings on mechanical properties, this research identifies the most influential parameters for enhancing stiffness and energy efficiency, in AM prosthetic ankle-foot devices.

This chapter bridges the gap between material feasibility (Chapter 4) and full-scale prosthetic production (Chapter 9). By defining optimal AM parameters, it ensures that the final prosthetic designs meet the necessary mechanical standards while remaining cost-effective, functional, and accessible. The data gathered will directly inform the final prosthetic ankle-foot design, ensuring that AM technology can be successfully utilised to produce dynamic response paediatric ankle-foot devices.

6.2 Methodology

The methodological approach undertaken in this study was designed to systematically understand the effect of AM parameters on stiffness and hysteresis properties in specifically designed coupon samples. This approach involves CAD modelling, fabrication, mechanical testing, DIC, and microscopy to assess each parameter's contribution to the mechanical performance of paediatric prosthetic components.

6.2.1 Parameter Selection and Definition

An extensive review of literature on paediatric prosthetic devices, AM techniques, and mechanical testing methodologies identified specific parameters that can influence the mechanical properties (Hodzic and Pandzic 2019; Naranjo-Lozada et al. 2019; Batley et al. 2022b; Batley et al. 2023), namely stiffness and hysteresis, of AM prosthetic feet. The key parameters identified include:

- Force Applied: Varying force impacts the mechanical response and resilience of the prosthetic material. The applied force directly correlates with the material's deformation and energy dissipation characteristics, offering insights into the load-bearing capabilities and durability of the prosthetic foot.

- Number of Fibre Layers: Fibre layers significantly influence structural integrity and energy return in composite AM fabricated prosthetics. Increasing fibre layers can enhance both stiffness and load-bearing capacity, essential for ensuring stability and functionality in dynamic environments. The study systematically examines fibre layer numbers to find optimal configurations for paediatric use.

- Fibre Distribution Pattern: The distribution of fibres affects the mechanical reinforcement throughout the structure, impacting stiffness and hysteresis.

Investigating patterns such as uniform and grouped distributions enables a deeper understanding of efficiency in energy storage and load management.

- Fibre Fill Orientation: The orientation of fibre layers can influence how the fibres contribute to overall stiffness and flexibility. Orientations at angles such as 0° and 45° are compared to evaluate their effectiveness in achieving the desired mechanical characteristics.

- Matrix Fill Pattern: The fill pattern of the matrix material, for example solid and hexagonal, play a critical role in load distribution and energy efficiency. The study assesses how matrix fill patterns affect the prosthetic's structural integrity and durability under various load conditions.

- Number of Walls: The number of wall layers can impact strength, and energy return characteristics of the prosthetic foot. Optimising number of walls can potentially enhance both stiffness and energy efficiency, providing an essential balance between material usage and structural integrity.

Table 6.1 outlines the parameters used for the control sample. For each parameter under investigation, only that specific parameter was varied, while all other parameters were kept identical to those of the control sample (as detailed in Table 6.2).These parameters were selected based on previous research, which has demonstrated their influence on the final mechanical properties of AM components, and that could be directly controlled within the slicing software.

The range for each of the parameters was selected based on both the constraints of the slicing software, and the need to achieve a broad enough range to observe and quantify its effect on mechanical performance. Where there were constraints imposed by the slicing software, the range was established to enable realistic use in the AM process. For the other parameters, a wider range was chosen to fully investigate their effect on the mechanical properties. This approach ensures the research records meaningful differences in performance, giving valuable information for the optimisation of the AM process.

The applied forces align with the ISO 10328 testing procedure (Standardization 2016) for safety, adapted from adult standards, ensuring that the results are both relevant and comparable to established prosthetic testing methodologies.

Force Applied (N)	**Number of Fibre Layers**	**Fibre Distribution Pattern**	**Fibre Fill Orientation**	**Matrix Fill Pattern**	**Number of Walls**
557	40	x10 Even Spaced	Isotropic 0,45	Solid	2

Table 6.1. Control Sample Parameters

Specimen	Force Applied (N)	Number of Fibre Layers	Fibre Distribution Pattern	Fibre Fill Orientation	Matrix Fill Pattern	Number of Walls
1.1	480	40	x10 Even Spaced	Isotropic 0,45	Solid	2
1.2	557	40	x10 Even Spaced	Isotropic 0,45	Solid	2
1.3	619	40	x10 Even Spaced	Isotropic 0,45	Solid	2
1.4	644	40	x10 Even Spaced	Isotropic 0,45	Solid	2
2.1	557	0	x10 Even Spaced	Isotropic 0,45	Solid	2
2.2	557	40	x10 Even Spaced	Isotropic 0,45	Solid	2
2.3	557	80	x10 Even Spaced	Isotropic 0,45	Solid	2
2.4	557	120	x10 Even Spaced	Isotropic 0,45	Solid	2
3.1	557	40	X5 Even Spaced	Isotropic 0,45	Solid	2
3.2	557	40	X10 Even Spaced	Isotropic 0,45	Solid	2
3.3	557	40	x20 Even Spaced	Isotropic 0,45	Solid	2
3.4	557	40	x40 Even Spaced	Isotropic 0,45	Solid	2
4.1	557	40	x10 Even Spaced	Isotropic 0,45	Solid	2
4.2	557	40	x10 Even Spaced	Isotropic 0	Solid	2
4.3	557	40	x10 Even Spaced	Isotropic 45	Solid	2
4.4	557	40	x10 Even Spaced	Concentric	Solid	2
5.1	557	40	x10 Even Spaced	Isotropic 0,45	Solid	2
5.2	557	40	x10 Even Spaced	Isotropic 0,45	Triangular	2
5.3	557	40	x10 Even Spaced	Isotropic 0,45	Hexagonal	2
5.4	557	40	x10 Even Spaced	Isotropic 0,45	Rectangular	2
5.5	557	40	x10 Even Spaced	Isotropic 0,45	Gyroid	2
6.1	557	40	x10 Even Spaced	Isotropic 0,45	Solid	1
6.2	557	40	x10 Even Spaced	Isotropic 0,45	Solid	2
6.3	557	40	x10 Even Spaced	Isotropic 0,45	Solid	3
6.4	557	40	x10 Even Spaced	Isotropic 0,45	Solid	4

Table 6.2. Parametric Fabrication Parameters

6.2.2 Data Acquisition and CAD Modelling

An Össur Vari-Flex Junior (Össur, Reykjavík, Iceland), size 19, was measured using an Axiom too (Aberlink Ltd., Gloucestershire, UK) Coordinate Measuring Machine (CMM). This foot model was selected for the research due to its comfort, dynamic performance, and strong energy return characteristics that align with the goals of this research, which aims to achieve similar outcomes through AM as the manufacturing process. Precise measurements of the foot's dimensions, contours, and structural elements were captured and imported into SolidWorks (Dassault Systèmes, Massachusetts) CAD software. A comprehensive CAD model was created, maintaining the foot's geometry and structural properties.

A specific portion of the CAD model, representing key components such as the arc profile and toe height, were selected for generating foot-representative coupon samples (Figure 6.1). This isolated section served as the foundation for creating the coupons, enabling a cost-effective, time-efficient, and controlled approach to analyse specific material properties and structural attributes. This method reduces the complexity and resources required compared to replicating the entire prosthetic keel. The coupon geometry and test setup are shown in Figure 6.2.

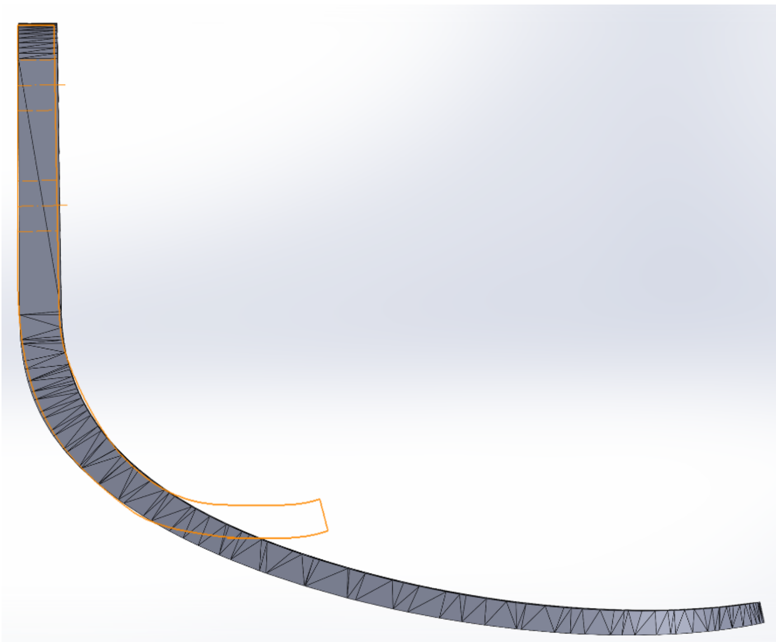

Figure 6.1. Coupon Geometry Portion Design

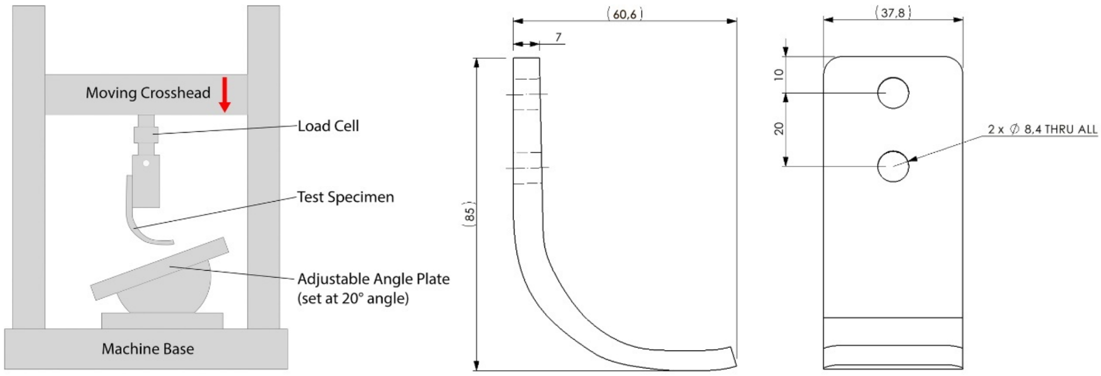

Figure 6.2. Coupon Geometry and Test Setup

6.2.3 Slicing and Fabrication

The file geometries for AM fabrication were prepared using Eiger software (Markforged Inc., Massachusetts), which utilises advanced slicing algorithms to transform 3D CAD models into sequential 2D layers (toolpaths) that guide the AM machine. This software enabled precise slicing of the coupons, allowing fine control over parameters that impact the final mechanical properties of the samples. The coupon samples were produced on a Markforged Mark Two machine (Markforged Inc., Massachusetts) using Onyx material and continuous strand carbon fibre reinforcements. Markforged's Onyx material consists of a nylon base filled with micro carbon fibres for enhanced strength and durability (Markforged 2021). The samples were fabricated on their side, producing a build height 37.8mm.

6.2.4 Mechanical Testing

Compression testing was conducted using a Zwick Roell Z030 testing machine (ZwickRoell Ltd, Worcestershire, UK), last calibrated in June 2022. The procedure was based on the ISO 10328 standard (Standardization 2016), adapted specifically for a paediatric user with a maximum weight of 24 kg, which aligns with the maximum weight capacity specified for the Vari-Flex Junior Size 19, category 1. Displacement and deformation during the compression tests were measured using a Dantec Dynamic DIC system (Dantec Dynamics, Denmark). The DIC system consisted of two synchronised high-resolution cameras arranged in a stereo configuration, positioned to view the entire surface of the prosthetic foot during loading. All samples were fabricated on their side edge, with the layers fabricated perpendicular to the loading direction to replicate typical prosthetic use.

The use of DIC was necessary due to potential compliance in the test machine system, which may introduce discrepancies between actual specimen deformation and the machine's crosshead displacement readings. DIC allows for full-field surface tracking using a speckle pattern applied to the sample prior to testing. The software tracked displacement vectors over time and extracted local strain fields. For this study, axial displacement in the load direction was isolated from the DIC data to calculate stiffness, with displacements extracted from two consistent reference points located on the anterior and posterior edges of the prosthetic component.

While DIC offers enhanced accuracy over machine crosshead data, some limitations were acknowledged, including sensitivity to lighting conditions, potential errors in repeatable selection of reference points, and minor noise fluctuations in low-deformation regions. However, efforts were made to maintain consistent speckle contrast, camera calibration, and lens alignment across all tests to ensure measurement reliability.

Force-displacement data gathered from the tests, along with DIC measurements, were used to calculate the stiffness (according to Hooke's law) (eq. 6.1) and efficiency (based on hysteresis) (eq. 6.2) of each sample. Stiffness (k) and efficiency (e) were defined as follows:

$$k = \frac{F}{x} \qquad \text{(eq. 6.1)}$$

$$e = \frac{U_{unloading}}{U_{loading}} \times 100\% \qquad \text{(eq. 6.2)}$$

Where F represents the compressive force measured by the load cell, x is the displacement, and $U_{loading}$ and $U_{unloading}$ are the work done during the loading (compressive) and unloading (rebound) cycles, respectively. More generally, the work U (eq. 6.3) between two points 1 and 2 can be calculated as:

$$U = \int_1^2 F dx \qquad \text{(eq. 6.3)}$$

The Values of $U_{loading}$ and $U_{unloading}$ are determined by calculating the area under the force-displacement curve for both the loading and unloading cycles, which is achieved through numerical methods such as the trapezoidal rule. This combined use of compression testing and DIC provided a detailed understanding of the samples' stiffness and energy efficiency characteristics.

6.2.5 Microscopy

Microscopy analysis was conducted using a Keyence VHX-5000 digital microscope (Keyence Ltd., Milton Keynes, UK) to examine the internal structure of the samples. This analysis focused on identifying voids, fibre-matrix interface quality, delamination, and any internal defects introduced during the fabrication process that might affect the mechanical performance of the coupons. To ensure precision in sectioning, all samples were consistently sliced through the curve of the coupon using a surface table, jig, and height gauge, maintaining a precise and uniform slice location across samples.

6.3 Results of Parameter Variation

6.3.1 Overview

The analysis of parameter variations highlights the relationship between AM process settings and the mechanical performance, relating to stiffness and energy efficiency, in AM prosthetic components. These results were calculated within a 0.5 to 2 mm displacement range. This displacement range was chosen to ensure consistency, remove potential errors from slippage, and keep the measurements within the material's linear response phase.

Force/Displacement Curves

Figure 6.3 illustrates the force-displacement curves obtained for each variation in the six parameters outlined in Table 6.2. These curves reveal the deformation characteristics of each sample under applied load, providing a visual representation of how each parameter adjustment affects the load-bearing properties of the material. Key insights into the load distribution and response under stress are gathered from these curves, which form the foundation for calculating stiffness and energy efficiency.

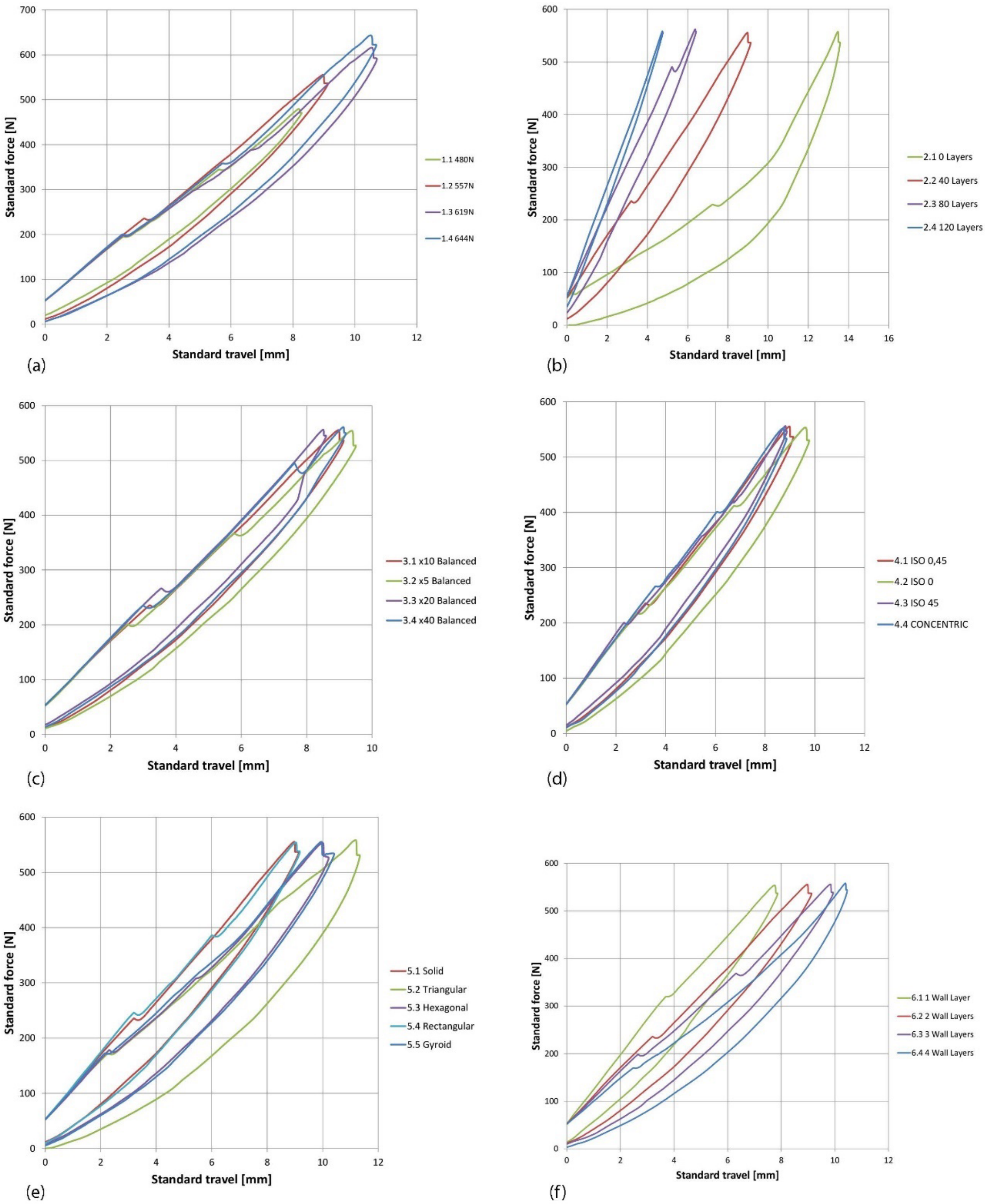

Figure 6.3. Parametric Force/Displacement Results. (a) Force. (b) Number of Fibre Layers. (c) Fibre Distribution Pattern. (d) Fibre Fill Orientation. (e) Matrix Fill Pattern. (f) number of Walls.

Table 6.3 presents the calculated stiffness values and efficiency percentages based on hysteresis for each parameter variation tested. These results reflect the impact of specific parameters on the performance of the material in terms of energy retention and release.

These results indicate that each parameter contributes to the mechanical performance of the prosthetic component, with particular parameters yielding more prominent effects on stiffness and energy efficiency. Different fibre layer quantities affect stiffness and hysteresis, guiding fibre reinforcement optimisation. Various fibre fill orientations impact stiffness and hysteresis, informing optimal reinforcement configurations. Examination of matrix fill patterns show their contribution to stiffness and hysteresis, aiding material selection and component design. Varying walls influence stiffness and hysteresis, guiding build parameter optimisation.

Specimen	Stiffness (N/mm)	Efficiency (%)
1.1	57.35	78
1.2	59.99	72
1.3	58.27	60
1.4	60.33	67
2.1	24.13	58
2.2	59.99	72
2.3	85.05	82
2.4	106.13	91
3.1	61.27	67
3.2	59.99	72
3.3	61.13	72
3.4	62.59	74
4.1	59.99	72
4.2	59.89	67
4.3	64.47	73
4.4	60.21	69
5.1	59.99	72
5.2	53.98	58
5.3	55.57	69
5.4	61.31	69
5.5	56.45	64
6.1	72.19	73
6.2	59.99	72
6.3	56.62	68
6.4	48.76	59

Table 6.3. Parametric Stiffness and Efficiency Results

The variations studied here offer valuable insights for selecting optimal AM machine parameters tailored to meet the functional demands of paediatric prosthetic feet, ensuring that they provide the necessary support, flexibility, and energy return for dynamic activities.

6.3.2 Discussion

6.3.2.1 Force Applied

The observed decrease in efficiency with increasing applied force during compression testing aligns with expectations. Despite variations in force levels, the stiffness values among the tested coupons remained consistent, with differences of less than 5% across samples. This suggests that higher forces result in more pronounced deformation, altering the internal structure and subsequently reducing energy storage properties within the material.

Microscopy analysis (Figure 6.4) confirms the notable deformation in samples subjected to elevated forces, revealing features such as increased carbon fibre pull-out (1), tearing within the internal structure (2), and larger voids (3). These characteristics indicate the material's limitations in maintaining structural integrity under high loads, highlighting the critical need for design and material optimisation to enhance mechanical resilience and reduce deformation under stress. Additionally, this evidence emphasises the importance of setting appropriate user weight categories to ensure safe and efficient performance in practical applications.

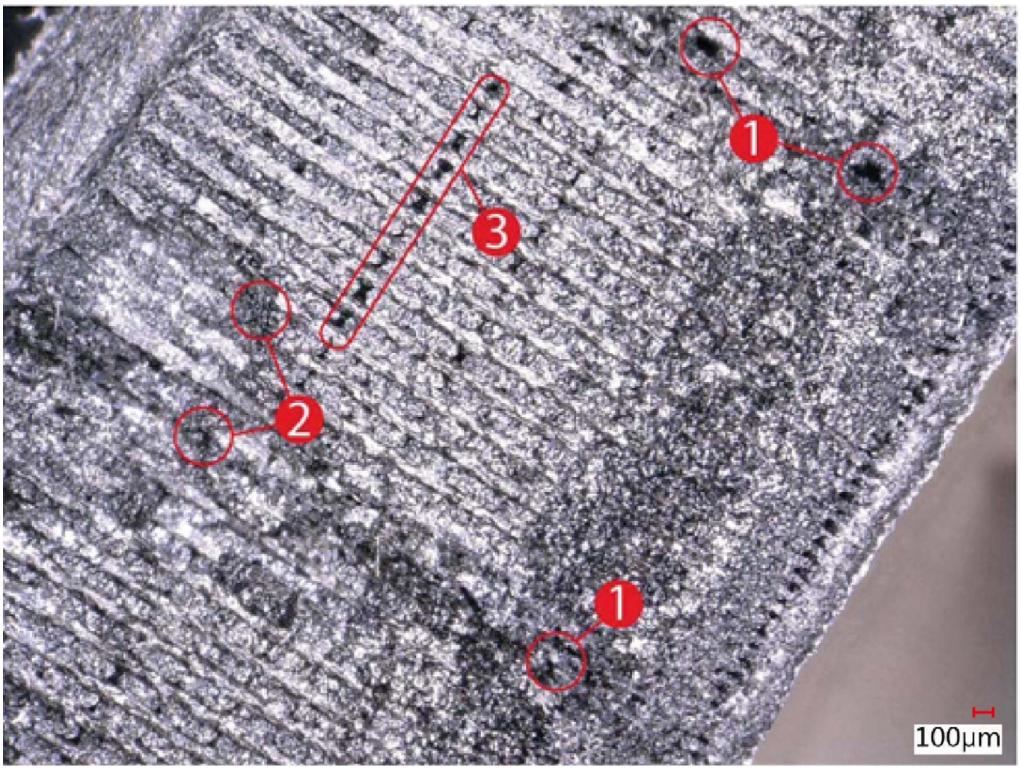

Figure 6.4. Parametric Microscopy analysis

6.3.2.2 Number of Fibre Layers

The number of fibre layers within the coupon proves to be the parameter with the most pronounced effect on both efficiency and stiffness. Results show an efficiency range from 58% for the coupon without continuous fibre layers to 91% efficiency with 120 continuous fibre layers. This notable increase highlights the critical role that fibre layers play in enhancing ESAR capabilities.

The impact of fibre layers on stiffness is also substantial. The coupon with 40 fibre layers displayed a stiffness of 59.99 N/mm, whereas the coupon with 120 layers showed a significantly higher stiffness of 106.13 N/mm. This increase in stiffness aligns directly with the number of fibre layers, confirming that fibre quantity is a key determinant of the mechanical properties of the coupon. These findings align with prior studies examining the influence of fibre volume fraction on stiffness and energy return largely attributable to the reinforcing nature of continuous carbon fibres (Chacón et al. 2019; Sanei and Popescu 2020). As the number of fibre layers increases, so does the structural integrity of the material, leading to greater stiffness and a more efficient energy storage and release mechanism. This improvement is tied to the mechanical attributes of both the fibre and matrix materials. Carbon fibres, noted for their low hysteresis due to non-viscoelastic properties, contribute to minimal energy loss, as reflected in these findings. As fibre content rises, increasing the fractional volume of fibres while reducing that of the matrix, hysteresis is reduced further.

By carefully adjusting the number of fibre layers in the keel's design, it is possible to tailor the mechanical characteristics of prosthetics to better suit the specific needs of paediatric users. This targeted optimisation may lead to AM prosthetic keels with enhanced energy return efficiency, benefiting dynamic performance and user experience.

6.3.2.3 Fibre Distribution Pattern

The arrangement of carbon fibre layers, particularly the choice between uniform spacing (placing one fibre layer at a time sandwiched between matrix material) and grouped placement (stacking multiple fibre layers together within matrix material), revealed notable differences in the efficiency and stiffness of the coupons. Specimens with uniformly spaced fibre layers demonstrated superior efficiency and higher stiffness compared to those with grouped layers.

This outcome can be attributed to the bonding quality within the composite. The uniform spacing arrangement promotes an even distribution of individual fibre layers throughout the specimen, with each fibre layer encapsulated on both sides by the matrix material. This configuration strengthens the interlayer bonding between carbon fibres and the surrounding matrix, thereby enhancing load transfer, efficiency, and energy storage. In contrast, the grouped fibre placement leads to weaker bonding between adjacent carbon fibre layers, resulting in less effective energy transfer and reduced structural integrity. Microscopy results support these observations (Figure 6.5); the interfaces between individual carbon fibre layers and the matrix material in uniformly spaced specimens display minimal voids, fractures, or signs of delamination, indicative of strong adhesion (Figure 6.5 - a), whereas, interfaces between adjacent carbon fibre layers in grouped arrangements often show micro-cracks and separations, highlighting weaker interlayer bonds (Figure 6.5 - b).

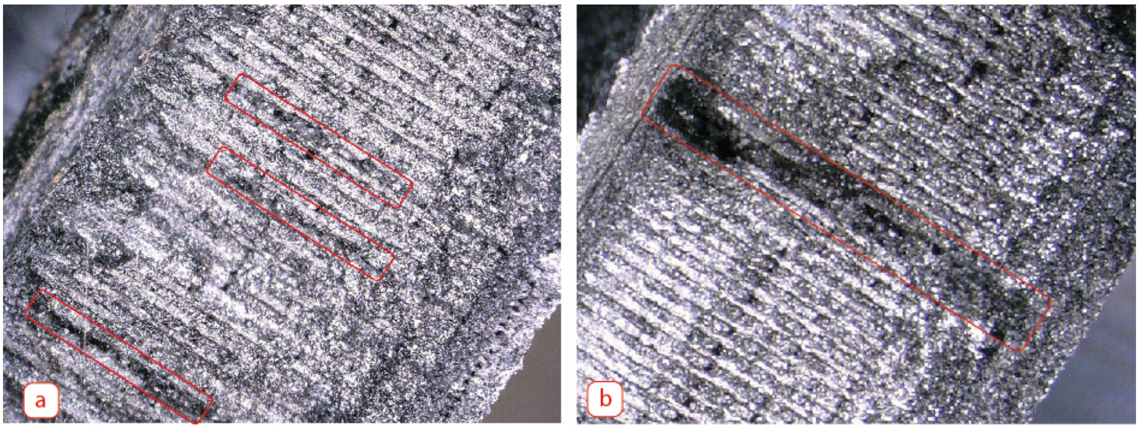

Figure 6.5. Spacing of Reinforcement Fibres. (a) Specimen 3.4 x50 magnification. (b) Specimen 3.2 x20 magnification.

These findings underscore the importance of a design approach that prioritises uniform spacing of individual carbon fibre layers within the matrix, as it can improve the efficiency and overall performance of the prosthetic component.

6.3.2.4 Fibre Fill Orientation

The orientation of fibre material within the samples, as illustrated in Figure 6.6, plays a crucial role in influencing both efficiency and stiffness. The isotropic fill setting from Markforged arranges fibres in a zig-zag pattern, simulating individual unidirectional layers typical of a laminated composite. Each isotropic fibre layer alternates in orientation to achieve unidirectional strength within a group of fibres (Markforged 2023). The findings revealed distinct patterns in efficiency across orientations, with the 45° isotropic fill showing the highest efficiency at 73%, attributed to the continuous distribution of carbon fibre layers along the sample's curve. In contrast, isotropic fill at 0° showed the lowest efficiency at 67%, primarily due to its vertical fibre arrangement, which terminated early due to spatial limitations.

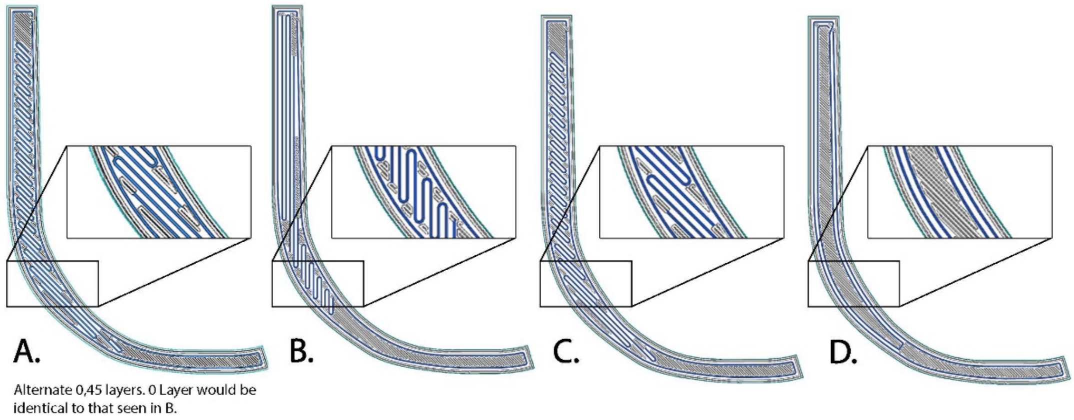

Figure 6.6. Fibre Reinforcement Orientations. (a) Isotropic 0,45. (b) Isotropic 0. (c) Isotropic 45. (d) Concentric.

The concentric fill pattern, characterised by an outer loop running the entire part length and an inner loop terminating near the curve's midpoint, exhibited an efficiency of 69%. Interestingly, an alternating isotropic fill at 0° and 45° showed an efficiency of 72%, even with layers oriented at 0°, which typically yield lower stiffness.

These efficiency variations can be explained by how the fibre orientation affects load distribution and energy storage. The continuous fibre layout at 45° optimises fibre engagement across the sample, while the 0° vertical alignment results in less efficient energy transfer due to interrupted fibre continuity. Stiffness variations among samples were minimal, but the lower stiffness noted in the 0° isotropic fill correlated with reduced efficiency, indicating compromised load-bearing capability.

These findings underscore the importance of optimising carbon fibre orientation to enhance energy storage and transfer. The superior efficiency observed in the 45° isotropic fill highlights its potential for keel designs, where effective load distribution is essential.

6.3.2.5 Matrix Fill Pattern

The matrix fill pattern, shown in Figure 6.7, demonstrated notable effects on both efficiency and stiffness. The solid fill pattern delivered the highest efficiency at 72% and a stiffness of 59.99 N/mm. The rectangular fill closely followed, achieving 69%

efficiency and a slightly higher stiffness of 61.31 N/mm, despite its infill density being 92% compared to the solid fill. This suggests that while solid fill offers optimal load transfer and energy transmission, rectangular fill may provide comparable performance benefits while conserving material, cost, and reducing manufacturing time. The solid infill pattern's uninterrupted structure enables more effective load transfer, enhancing load-bearing capacity and energy transmission for superior efficiency. In contrast, rectangular fill, although denser than some other patterns, includes gaps that slightly reduce load transfer efficiency.

The triangular infill pattern, which showed early signs of failure at 8.5 mm of travel, recorded the lowest efficiency at 58% and a stiffness of 53.98 N/mm with an infill density of 55%. This pattern's relatively low stiffness and reduced infill percentage present challenges in maintaining structural integrity. On the other hand, hexagonal infill demonstrated 69% efficiency and a stiffness of 55.57 N/mm with a 62% infill, making it a viable option for balancing material usage and mechanical performance. Similarly, the gyroid pattern achieved moderate efficiency at 64% and a stiffness of 56.45 N/mm, with an infill density of 52%, though it required a longer fabrication time.

The ability to reach high efficiency and stiffness with patterns like solid and rectangular fills while conserving material resources underscores the potential for more sustainable, cost-effective designs. Strategic choices among fill patterns can help balance efficiency, stiffness, and manufacturing time depending on the specific application requirements.

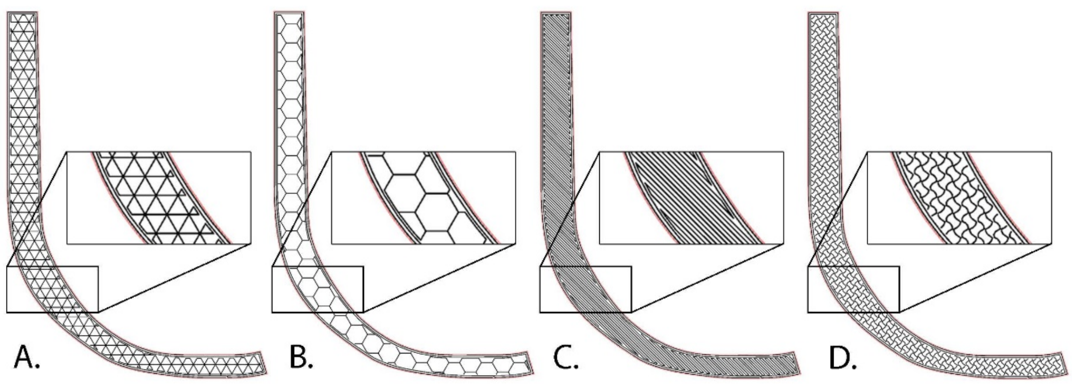

Figure 6.7. Matrix Fill Patterns. (a) Triangular. (b) Hexagonal. (c) Rectangular. (d) Gyroid.

6.3.2.6 Number of Walls

The variation in the number of walls within the samples reveals a distinct trend, where fewer walls result in improved efficiency and increased stiffness. This outcome appears linked to a redistribution of material and load-bearing structures, allowing samples with fewer walls to accommodate a larger infill area at the core of the coupon. This expanded infill region promotes a more effective distribution of reinforcing fibres, enhancing the sample's mechanical properties.

For example, as can be seen in Figure 6.8, the single-wall sample (a), with its single wall layer, supports a single loop of fibre reinforcement combined with concentric and 45° infill patterns that extend through two-thirds of the curve. This configuration yields an efficiency of 73% and a stiffness of 72.19 N/mm. In contrast, the four-wall sample (d) shows reduced efficiency at 59% and a lower stiffness of 48.76 N/mm, as the multiple wall layers constrain the infill space, thereby limiting fibre reinforcement opportunities.

Reducing the number of walls, while ensuring the necessary structural integrity, can optimise efficiency and stiffness in prosthetic components. This approach offers potential advantages for paediatric prosthetic keels, enhancing energy return and mechanical performance for young users. Overall, these findings highlight the importance of thoughtful material distribution and infill design in shaping the mechanical properties of paediatric prosthetic components.

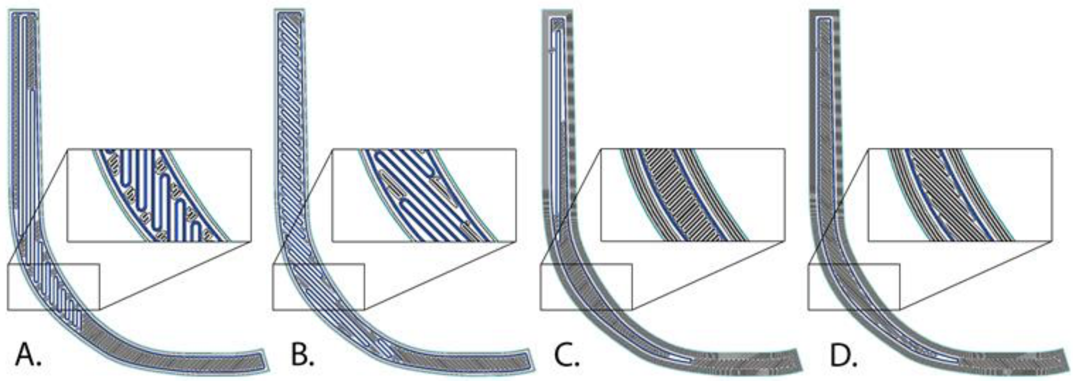

Figure 6.8. Wall Layers. (a) 1 Wall layer, Reinforcement 0º. (b) 1 Wall layer, reinforcement 45º. (c) 4 Wall layers, Reinforcement 0º. (d) 4 Wall layers, Reinforcement 45 º.

6.4 Chapter Conclusions

The findings from this research emphasise the effect of specific AM parameters on the mechanical characteristics and functional performance of paediatric prosthetic components, in terms of stiffness, and efficiency. This systematic analysis provides a detailed understanding of how parameter selection, including applied force, fibre layer configuration, matrix fill pattern, and wall layers, directly impacts the overall energy return and structural integrity of the components.

A key takeaway is the importance of parameter optimisation in tailoring the mechanical properties of paediatric prosthetic keels to meet specific needs. For example, the applied force during testing directly influenced load-bearing capacity and energy dissipation, demonstrating the potential for precise customisation. Among the parameters studied, the number and distribution of fibre layers were especially influential, with uniform spacing yielding marked improvements in both efficiency and stiffness. The matrix fill pattern emerged as a critical factor, with solid fill achieving the highest efficiency and stiffness, indicating its potential for optimising energy return in prosthetic applications. These findings underscore the capability of composite AM to support customisation in paediatric prosthetic design, enabling the production of keels that meet both the performance and comfort needs of young users.

CHAPTER 7: ENVIROMENTAL CONDITIONS

The information presented in the following chapter is derived from the original published research paper: Batley, A., Dyer, B. and Sewell, P., 2024. Effect of Humidity on the Stiffness and Hysteresis of Composite 3D-Printed Paediatric Prosthetic Foot Coupon Samples. 3D Printing and Additive Manufacturing.

7.1 Overview

This chapter examines how environmental conditions, particularly humidity, affect the mechanical properties of AM paediatric prosthetic components. Understanding the impact of environmental exposure is essential for ensuring that prosthetic devices maintain their structural integrity and functional performance throughout their lifespan. The durability and performance of AM prosthetic components can be compromised by environmental factors (Ma et al. 2021; Nikiema et al. 2023; Távara et al. 2023), with humidity being a critical concern due to its significant impact on materials such as Onyx, a nylon-based polymer reinforced with carbon fibre (Markforged 2021).

This chapter investigates the effects of humidity on stiffness and hysteresis, in composite AM prosthetic coupon samples. Both these properties play a crucial role in determining the ability of a prosthetic foot to mimic natural movement and provide dynamic response functionality, as outlined in Chapter 3: Prosthetic Characterisation and Manufacture Analysis. Changes in these properties due to humidity exposure could compromise the prosthetic's ability to meet the AOPA dynamic response classification criteria, which was a key focus in Chapter 3 and Chapter 9. To assess these effects, this chapter presents the results of a 90-day examination of humidity exposed samples, analysing mechanical degradation trends over time to establish how environmental exposure may influence long-term prosthetic performance.

The findings from this study contribute to the thesis research questions by addressing the secondary research question, which seeks to determine whether composite AM can provide repeatable and reliable dimensional accuracy and mechanical properties for paediatric prosthetic production. By quantifying how environmental factors affect mechanical reliability, this chapter provides critical insights into whether composite AM is a viable alternative to traditional manufacturing techniques for paediatric prosthetics.

This chapter highlights the importance of environmental understanding in the development of AM paediatric prosthetics, ensuring that they remain durable, and reliable in real-world conditions. By identifying how humidity affects performance, this research helps inform future strategies to mitigate these effects, therefore contributing to the creation of prosthetic devices that offer greater longevity, and consistent mechanical properties.

7.2 Methodology

This study design evaluates the effects of ageing and humidity on the mechanical properties of coupon samples, which replicate a segment of the Össur Vari-Flex Junior prosthetic foot (Össur., Reykjavík). These are the same geometry as the coupons used in the parametric study (Chapter 6) and can be seen in Figure 6.1. A total of 28 samples were fabricated using a Markforged Mark 2 3D machine (Markforged Inc., Massachusetts) with Onyx. 25 samples were exposed to a controlled environment at an average 34.9% relative humidity and room temperature for up to 90 days. Daily humidity levels are detailed in Table 7.1. The duration of the study was guided by the data, with testing continuing until mechanical properties stabilised.

Days Exposure	Relative Humidity Level
0	33%
2	33%
4	33%
6	34%
8	34%
10	33%
12	32%
14	33%
16	33%
18	35%
20	34%
25	35%
30	35%
35	34%
40	33%
45	33%
50	34%
55	34%
60	34%
65	32%
70	33%
75	34%
80	33%
85	34%
90	33%

Table 7.1. Daily Humidity Levels

To understand the effects of humidity exclusion, three additional samples were stored in a locked dry box with desiccant for 60 days. Mechanical testing was conducted using a Zwick Roell testing machine (ZwickRoell Ltd, Worcestershire, UK), following a modified ISO10328 (Standardization 2016) procedure, with forces adapted to replicate use by paediatric users. This testing tracked changes in stiffness and hysteresis, with measurements initially taken every two days, then extending to every five days as the study progressed.

Following mechanical testing, microscopy was used to visually examine any structural changes attributed to humidity exposure. Data was systematically recorded and analysed in Microsoft Excel (Microsoft., Washington), and plotted to identify trends and quantify shifts in mechanical properties over time.

7.2.1 Computer Aided Design (CAD)

Data acquisition and CAD modelling of the coupon samples utilised the same approach as the previously detailed parametric analysis study detailed in Chapter 6.

7.2.2 Materials and Fabrication

The materials selected for this study were Onyx, and continuous carbon fibre reinforcement, both supplied by Markforged (Markforged Inc., Massachusetts). The chosen process parameters align with those used in previous parametric analysis testing. Each sample was fabricated with 40 fibre layers. The fibre orientation followed a 0/45° layout with a single concentric fibre ring to improve overall strength and stiffness. A solid fill pattern was applied to achieve maximum density and structural integrity. These settings were selected to harness the strength and stiffness enhancements provided by the combination of Onyx and continuous carbon fibre reinforcement. Figure 7.1 shows the structure and slicing from the software.

The 40-layer fibre configuration in a 0/45° orientation with a concentric ring was chosen to maximise multidirectional reinforcement, essential for the varied forces that a prosthetic foot endures. A paediatric prosthetic foot must withstand constant cyclic loads from activities such as walking and running, impacts from jumping or sudden movements, and exposure to environmental factors such as humidity and temperature changes. The 0/45° fibre orientation provides essential multidirectional reinforcement, allowing the foot to absorb and adapt to these forces. Additionally, the concentric fibre ring further reinforces structural integrity, enabling the prosthetic foot to support the dynamic activities of an active child.

Eiger software (Markforged Inc., Massachusetts) was utilised to prepare the samples for fabrication. Eiger’s advanced slicing algorithms convert 3D CAD models into precise 2D layers (toolpaths), guiding the AM machines process and ensuring accuracy (Batley et al. 2022a).

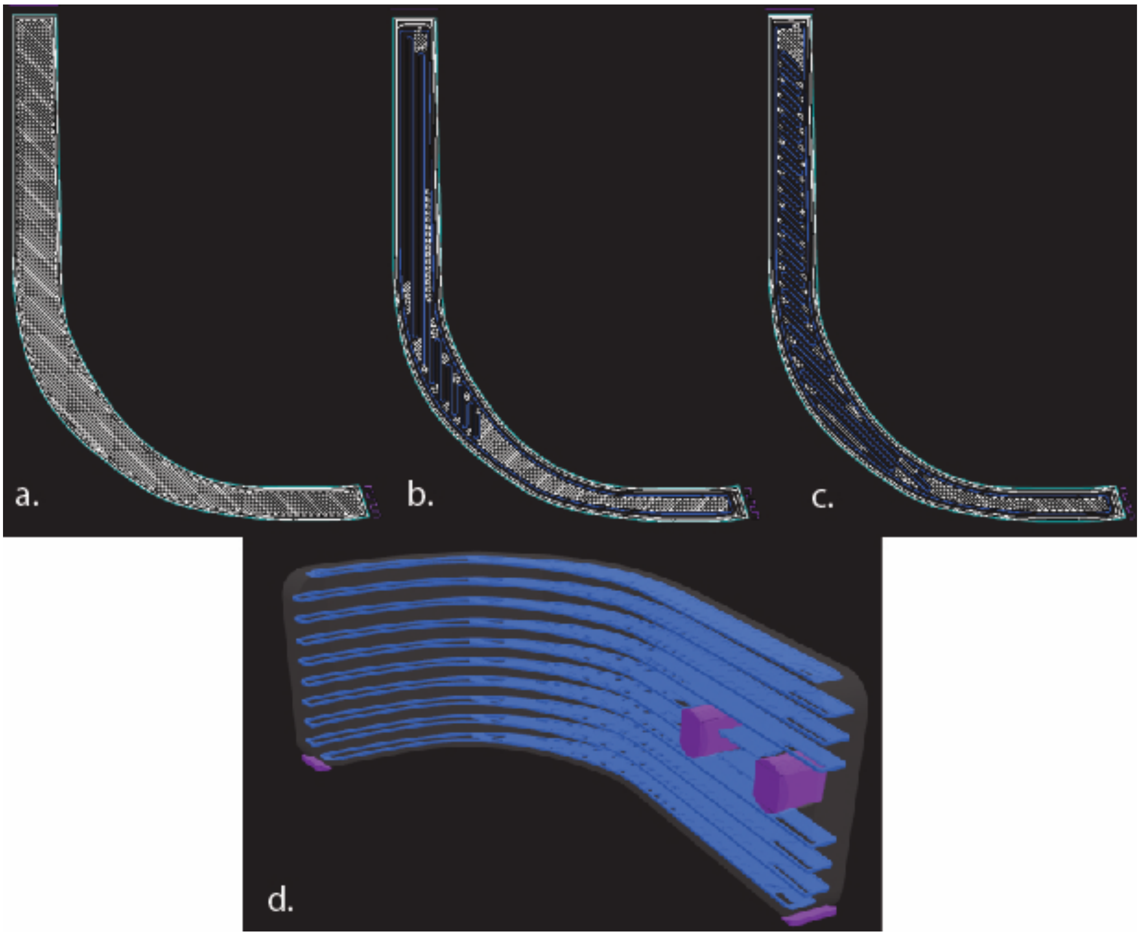

Figure 7.1. Coupon Structure and Slicing

7.2.3 Mechanical Testing

The mechanical testing methodology utilised the same approach as the previously detailed parametric analysis study detailed in Chapter 6.

7.2.4 Microscopy

One day after each sample's compression test, a visual inspection was conducted using a Keyence VHX-5000 digital microscope (Keyence Ltd., Milton Keynes, UK), enabling high-resolution analysis of the samples' microstructure. This detailed examination provided insights into the degree of structural degradation, presence of micro-cracks, and alterations at the fibre-matrix interface. The microscopy analysis identified signs of moisture absorption, including swelling, where the material expands as it absorbs water, and delamination, where layers within the composite separate. Such morphological changes, linked to extended exposure to high humidity, could significantly affect the mechanical properties of the samples.

7.3 Results

7.3.1 Stiffness

The impact of ageing and humidity exposure on the stiffness of composite AM paediatric prosthetic foot samples was methodically examined over a 90-day period. Data collected at intervals revealed a notable trend of decreasing stiffness correlating with increased humidity exposure (Figure 7.2). To ensure consistency and reliability, stiffness values were calculated within a displacement range of 0.5 to 2 mm, aligning with the material's linear response. Detailed stiffness values across all samples are presented in Table 7.2.

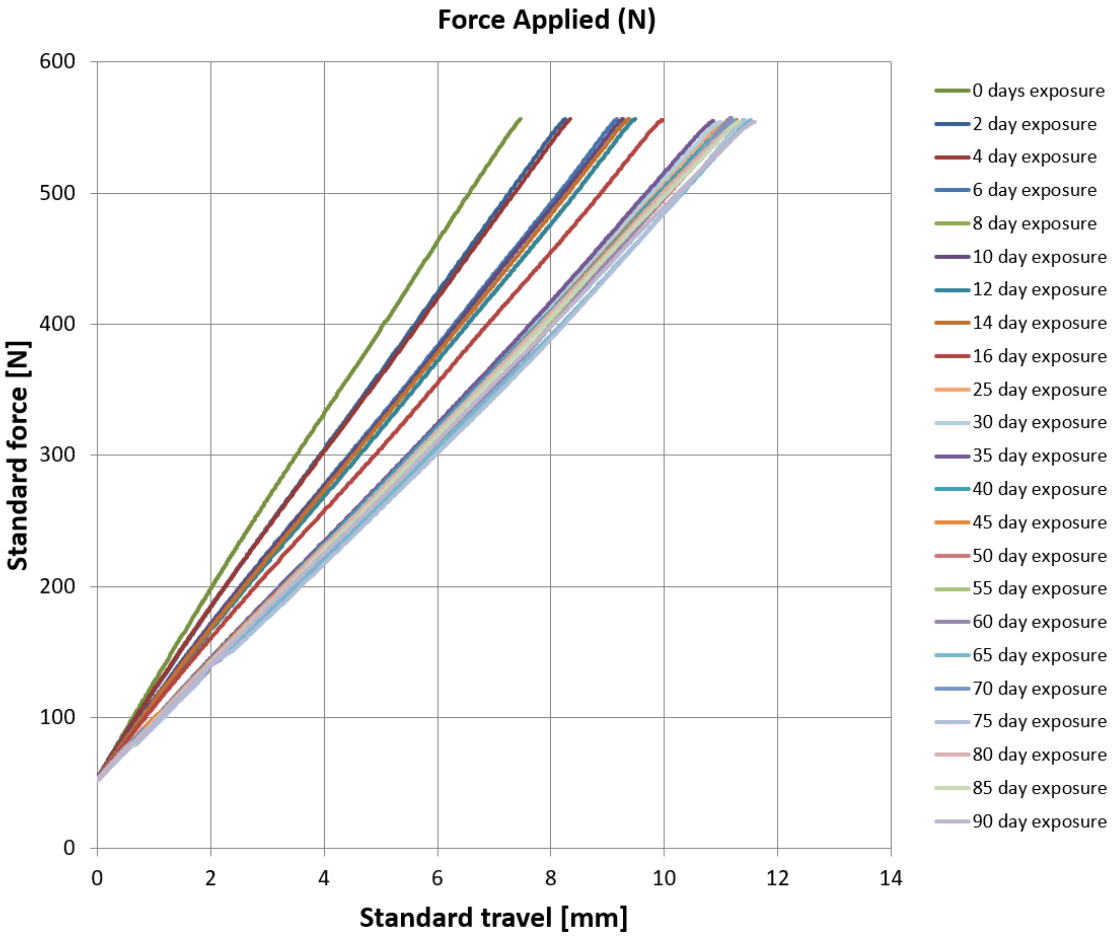

Figure 7.2. Stiffness vs. Days of Exposure Test Results

Days Exposure	Stiffness (N/mm)
0	71.93
2	64.05
4	64.35
6	58.09
8	56.94
10	57.76
12	56.34
14	56.70
16	53.00
18	51.87
20	48.32
25	46.38
30	45.59
35	45.91
40	44.78
45	44.84
50	43.85
55	43.22
60	43.66
65	44.67
70	44.26
75	43.93
80	44.52
85	43.50
90	43.33

Table 7.2. Stiffness vs. Days of Exposure Test Results

The baseline measurement, taken immediately after fabrication on day 0, recorded the initial stiffness at 71.93 N/mm. Yet, within just two days, the stiffness value of the coupon dropped to 64.05 N/mm, indicating an early sensitivity of the material to moisture absorption. This decreasing trend continued over the initial two weeks, reaching 56.7 N/mm by day 14. The most substantial decline in stiffness occurred within the first 20 days, with values decreasing to 48.32 N/mm. This rapid initial drop suggests that the material quickly absorbs moisture from the surrounding environment, which accelerates the reduction in mechanical properties early in the exposure period.

Between days 25 and 60, the stiffness values showed a more gradual decline, measured at 46.38 N/mm on day 25, 45.59 N/mm on day 30, and stabilising near 43.66 N/mm by day 60. This gradual plateau, as depicted in Figure 7.3, suggests a reduction in moisture uptake or perhaps a saturation point in the material's structure, where moisture-related degradation slows down.

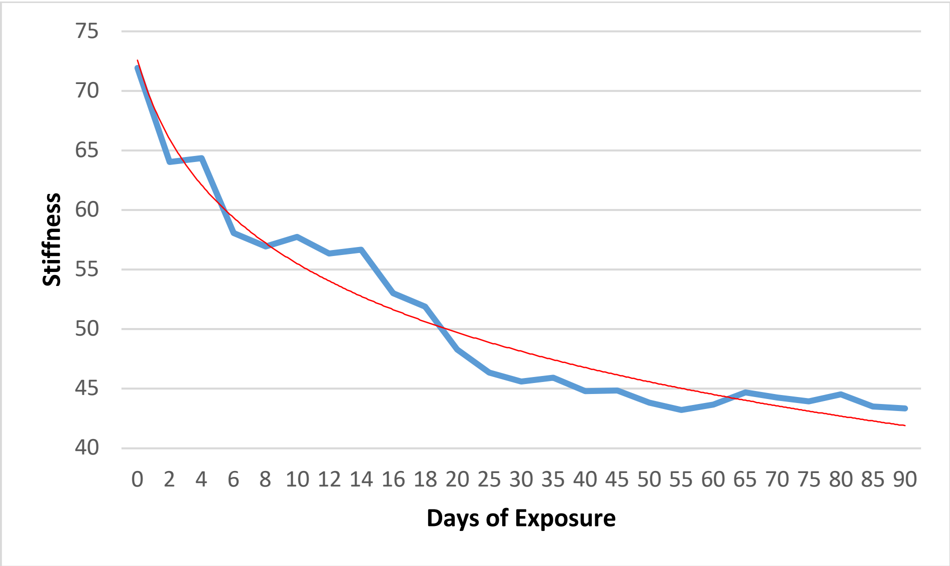

Figure 7.3. Stiffness Results Showing Exponential Decay Trend (Blue) and Exponential Relationship (Red)

By day 90, the cumulative exposure resulted in a nearly 30% decrease in stiffness, dropping from the initial 71.93 N/mm to 43.33 N/mm. This considerable reduction underscores the pronounced effect that prolonged humidity exposure has on the structural integrity and stiffness of the prosthetic material.

The control samples, stored in a dry box with desiccant for 90 days, demonstrated markedly higher stiffness retention, with minimal degradation over the test period (Figure 7.4). The stiffness values for these control samples are listed in Table 7.3 and highlight the preservation benefits of a dry storage environment. However, even these samples showed a slight reduction from the original stiffness measurement of 71.93 N/mm recorded on day 0, likely attributable to natural material ageing. The gradual decline in the control samples indicates that, while a desiccant environment effectively limits moisture-related degradation, it cannot fully prevent inherent changes in the material over time, such as internal stress relaxation and microstructural adjustments. These findings reinforce that dry storage conditions significantly aid in preserving stiffness, although they do not eliminate all ageing effects.

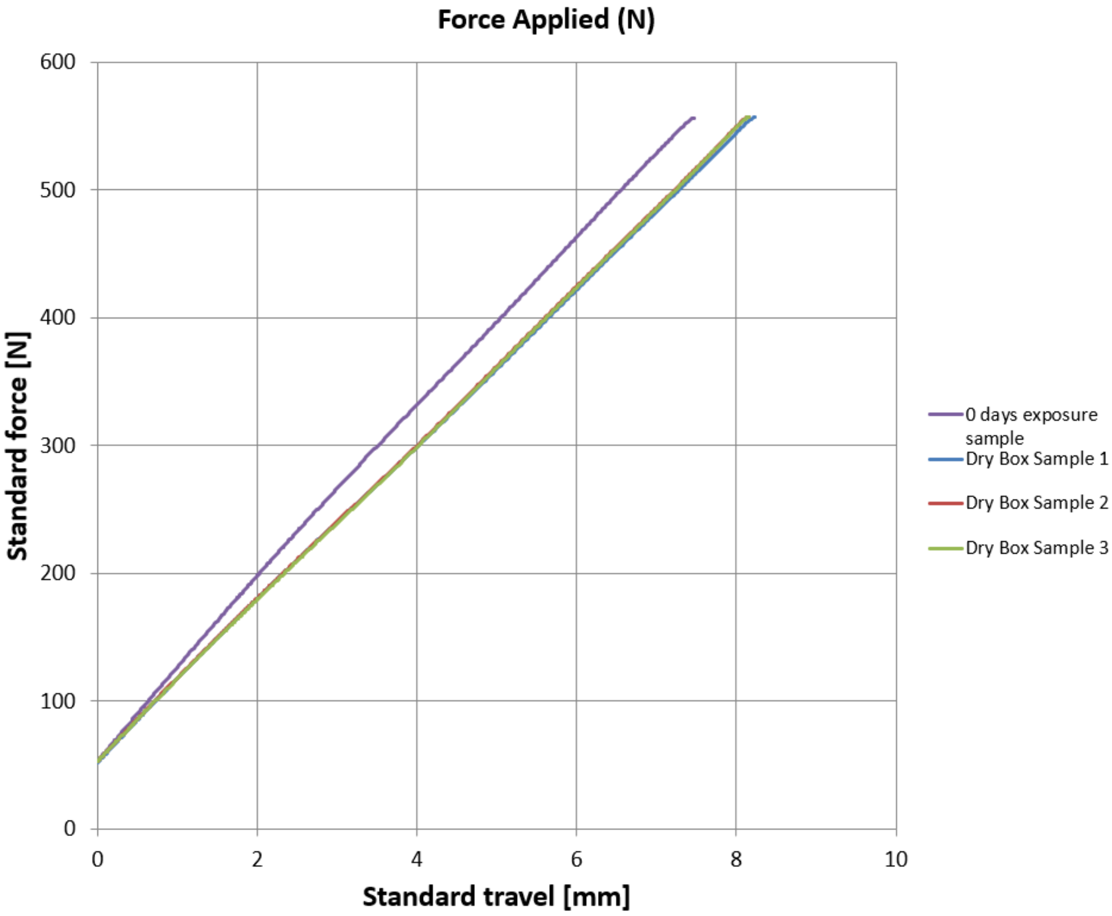

Figure 7.4. Stiffness Test Results for Dry Box Samples

0 Day Exposure	71.93N/mm
Control 1	63.37N/mm
Control 2	62.94N/mm
Control 3	62.52N/mm

Table 7.3. Stiffness Results for Control Samples Stored in Dry Conditions

The reduction in stiffness observed in the samples can largely be attributed to the hygroscopic characteristics of the nylon matrix within the Onyx material (Ma et al.

2021). As moisture permeates the material, it causes plasticisation, which diminishes the rigidity and load-bearing capacity of the structure (Eftekhari and Fatemi 2016). Absorbed water molecules may interact with the micro carbon fibres, potentially weakening the fibre-matrix interface, further contributing to the overall stiffness loss (Eftekhari and Fatemi 2016). These insights highlight the crucial role of environmental considerations, particularly humidity, in the design and material selection for paediatric prosthetic components manufactured via AM.

7.3.2 Hysteresis

Hysteresis efficiency plays a fundamental role in the functionality of paediatric prosthetics, as minimal hysteresis is essential for supporting energy-efficient movement in young users. The effects of ageing and humidity on hysteresis efficiency were examined over the same 90-day period as stiffness (Figure 7.5). Detailed hysteresis values for each sample are presented in Table 7.4.

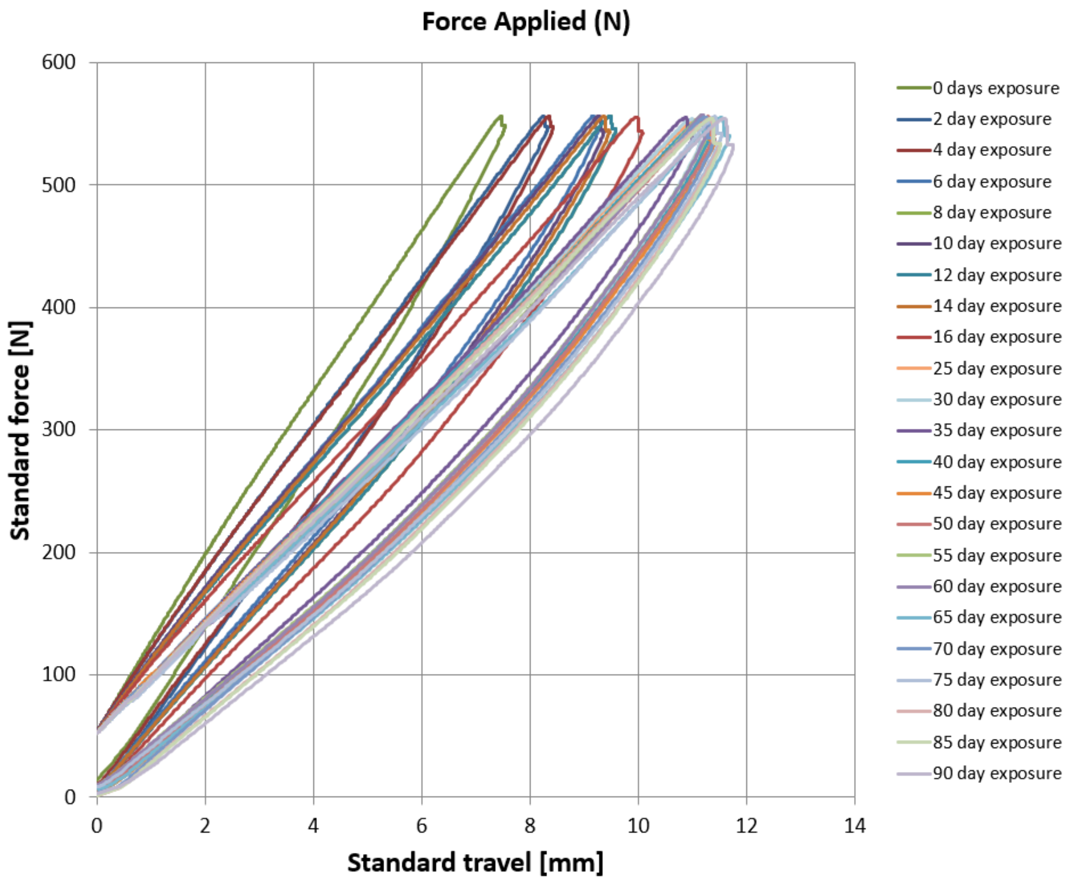

Figure 7.5. Hysteresis vs. Days of Exposure Test Results

Days Exposure	Efficiency %
0	83
2	82
4	82
6	81
8	81
10	80
12	81
14	81
16	79
18	79
20	78
25	76
30	77
35	79
40	77
45	76
50	79
55	79
60	79
65	78
70	76
75	77
80	74
85	74
90	73

Table 7.4. Hysteresis vs. Days of Exposure Test Results

The initial hysteresis efficiency of the samples was recorded at 83.00%. Over time, efficiency displayed a gradual decline, with stable values observed during the first two weeks, reaching 81% by day 14. By day 90, efficiency had decreased further to 73%. This decline was not linear (Figure 7.6); intermittent fluctuations were observed, which may result from the complex interplay between absorbed moisture and the composite material. As moisture penetrates the structure, it interacts with internal components, leading to periodic stress adjustments and structural changes, which can cause transient increases or decreases in hysteresis efficiency.

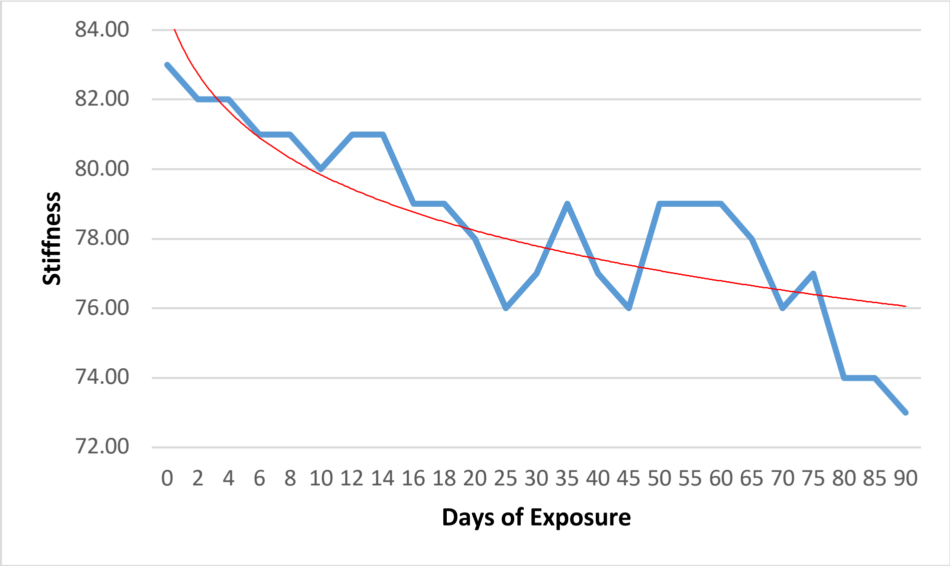

Figure 7.6. Hysteresis Results Showing Exponential Decay Trend (Blue) and Exponential Relationship (Red)

The progressive decline in hysteresis efficiency holds significant implications for the performance and durability of paediatric prosthetics. As the material absorbs moisture, it increases in elasticity, resulting in increased deformation and energy dissipation during movement (Ma et al. 2021). This loss of energy with each step translates to higher energy expenditure for the young user, potentially leading to quicker fatigue and reduced engagement in physical activities. These findings suggest that prolonged humidity exposure accelerates material degradation, which could decrease the functional lifespan of the prosthetic. Because of this, understanding and mitigating humidity's impact on hysteresis efficiency is essential for enhancing prosthetic durability and user comfort.

It is also important to consider that the polymeric matrix used in these composite prosthetics exhibits viscoelastic behaviour. This means that some of the reduction in hysteresis efficiency over time could be partially influenced by time-dependent, reversible mechanical responses rather than permanent structural damage. However, no visual signs of delamination or cracking were identified, further supporting the conclusion that environmental factors are primarily responsible for the changes observed. Nonetheless, the potential interaction between viscoelastic effects and humidity absorption should be explored further to fully isolate and quantify their individual contributions.

The control samples stored in a dry box with desiccant material over a 60-day period retained their original hysteresis efficiency values, with two samples maintaining the initial 83% efficiency and the third sample showing only a slight decrease to 82%. This stability, as shown in Figure 7.7, highlights the significant role of a dry storage environment in preserving hysteresis properties and underscores the role humidity plays in mechanical degradation.

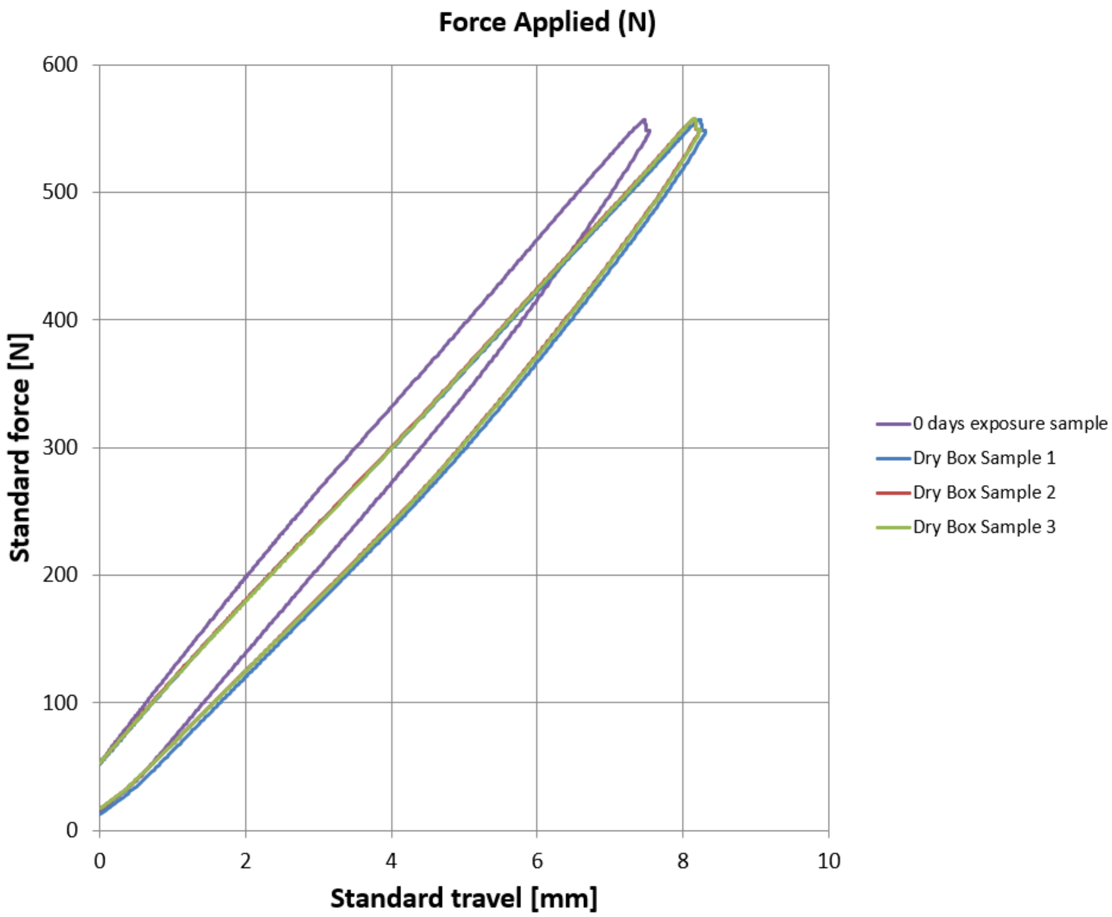

Figure 7.7. Hysteresis Efficiency Results for Dry Box Samples

The observed reduction in hysteresis efficiency among humidity exposed samples is largely attributed to the nylon matrix’s hygroscopic nature within the Onyx material. Moisture absorption increases the material’s elasticity, causing greater deformation under cyclic loading and leading to higher energy loss. Absorbed moisture can weaken the fibre-matrix interface between the carbon fibre and nylon, thereby reducing load transfer efficiency and diminishing hysteresis efficiency (Távara et al. 2023). This demonstrates the importance of incorporating moisture-resistant strategies, such as protective coatings or controlled storage environments, to prolong the lifespan and performance reliability of paediatric prosthetics manufactured with Onyx.

7.3.3 Microscopic Structural Analysis

Microscopic examination of the test samples (Figure 7.8) conducted with a Keyence VHX-5000 digital microscope provided clear insights into the structural changes that occurred with increased humidity exposure. Initial analysis at 0 days exposure displayed a uniform, compact microstructure with minimal voids and strong layer adhesion. As exposure time progressed, distinct signs of structural degradation became increasingly apparent.

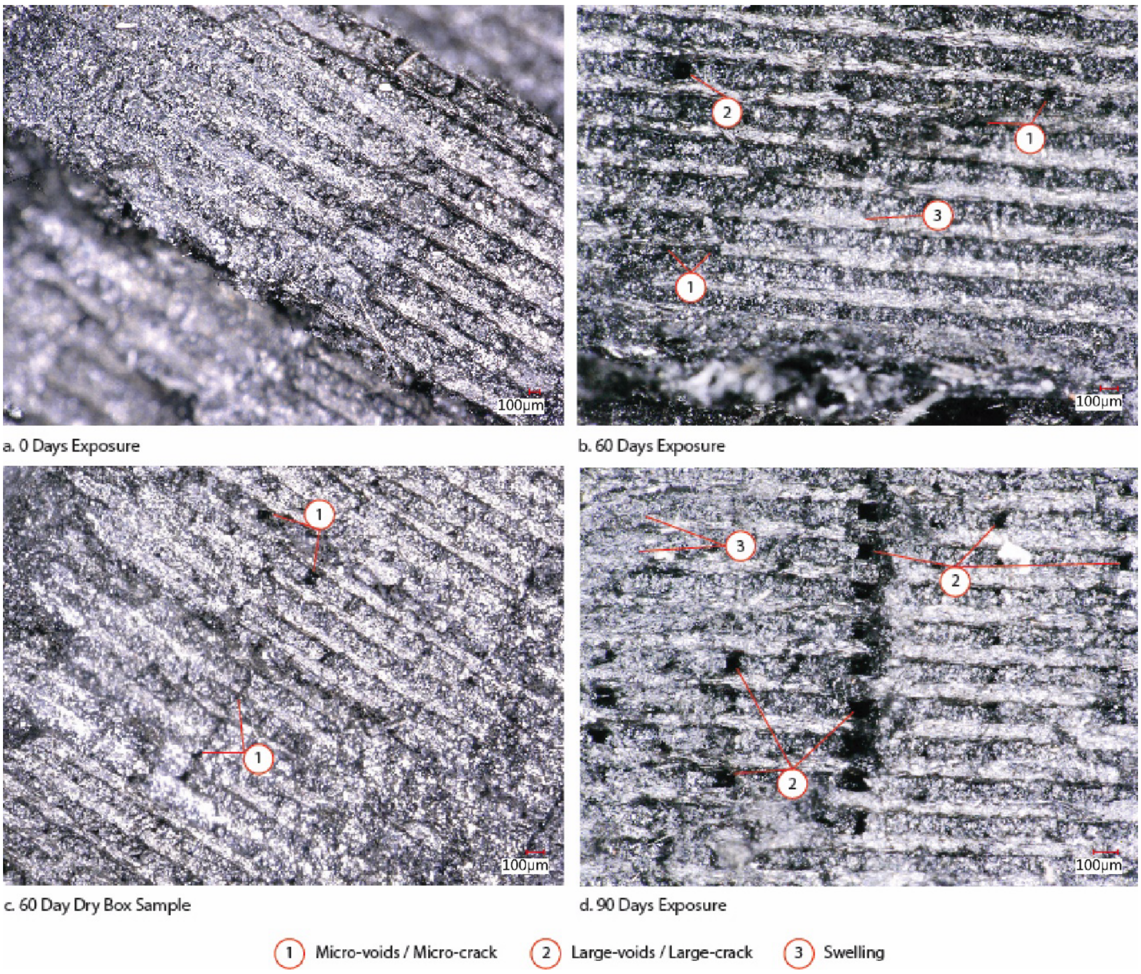

Figure 7.8. Humidity Microscopy Analysis

Microscopic analysis revealed evidence of water absorption, which manifested as micro-voids and microcracks within the samples. During the early stages of exposure (10 and 20 days), small voids appeared sporadically and progressively intensified. By 60 to 90 days, these voids had expanded significantly, especially in the Onyx matrix, due to swelling. This process weakened the material's structural integrity, ultimately reducing its stiffness and load-bearing capability.

Humidity exposure impacted layer adhesion and compaction. The layers initially demonstrated strong bonding and compactness, but as moisture was absorbed, interfacial bonding weakened, leading to delamination and increased spacing between layers. This reduction in layer adhesion compromised the material's ability to evenly distribute loads, contributing to the decrease in both stiffness and mechanical performance over time.

These microscopic observations correlated well with the mechanical testing results. The initial uniform microstructure at 0 days supported the highest measured stiffness (71.93 N/mm) and hysteresis efficiency (83%). As structural integrity was compromised by micro-voids and cracks, stiffness dropped to 43.33 N/mm by 90 days, and hysteresis efficiency fell to 73%. The rapid initial decline in stiffness aligned with early void and crack formation, while the plateau in new void formation after 60 days corresponded to a slower degradation rate, reflected in the stabilisation of stiffness values.

Samples stored in a controlled dry environment for 90 days displayed some degradation but were substantially less affected than those exposed to high humidity. The dry box samples exhibited only minor void formation and a few microcracks, indicating that while the dry environment did not completely prevent degradation, it did reduce structural damage. The matrix material in the dry box samples showed minimal swelling, maintaining a more compact structure, better preserved layer adhesion, and a generally stable microstructure compared to samples exposed to moisture.

7.4 Impact and Implications

7.4.1 Environmental Impact on Material Performance

The environmental impact on the mechanical performance of the AM paediatric prosthetic foot coupon samples was clear, particularly in the reduction of both stiffness and hysteresis efficiency over a 90-day humidity exposure period. The material demonstrated clear signs of degradation after being exposed to the environment for a number of days, and this analysis can be broken into four primary themes; the overall reduction in stiffness, the rapid initial stiffness decline, the subsequent exponential decay trend of mechanical properties, and the benefits of a controlled, dry environment.

A consistent finding across published studies is the overall reduction in stiffness due to humidity exposure. In this study, stiffness decreased from 71.93 N/mm to 43.33 N/mm over the 90-day period (Table 7.2), a reduction of approximately 40%. This is in line with findings by Nikiema et al. (2023), who observed up to a 66% reduction in stiffness in Onyx samples after 165 days in 50% relative humidity conditions, and Tavara et al. (2023), who noted a 57% reduction over a 60-day period. The slightly faster exponential decay trend observed in this study may be attributed to the carbon fibre reinforcement within the samples, providing additional structural integrity and resistance to moisture-induced degradation compared to samples made solely of Onyx (Ghabezi et al. 2025). This highlights how material composition, especially the inclusion of carbon fibre, plays a significant role in the durability and mechanical performance of composites under environmental conditions.

Another important observation is the rapid decline in stiffness within the first day of humidity exposure, supported by similar findings in existing literature. This study showed an initial sharp decrease from 71.93 N/mm to 64.05 N/mm within the first two days. Such an immediate response to humidity was also observed by Ma et al. (2021), who found the most significant changes in mechanical properties within the first day of exposure. This early stage of degradation highlights the need for quick protective measures to mitigate the effects of environmental humidity on prosthetic materials.

Following this initial decline, the mechanical properties began to stabilise, with stiffness reduction exponential decay trend around the 60-day mark. This trend aligns with results from Nikiema et al. (2023), who reported that their specimens began to stabilise around 82 days of exposure. This pattern suggests that while early exposure to humidity can result in significant degradation, the rate of decline slows over time, reaching a point of relative stability in mechanical properties.

The samples stored in a dry box with desiccant material showed a much smaller reduction in stiffness compared to those exposed to humidity. Over a 60-day period, stiffness for these samples decreased by an average of just 13.5%. This aligns with Tavara et al. (2023), who noted only a 14% reduction in stiffness over the same period for samples stored in a desiccator. These results underscore the stabilising impact of a controlled, dry environment, which plays a critical role in preserving the mechanical integrity of the material by reducing moisture absorption and associated structural degradation.

7.4.2 Implications for Additively Manufactured Paediatric Prosthetics

The findings from this study underscore critical considerations for designing and manufacturing paediatric prosthetic devices via AM. The effect of humidity on the mechanical properties of the composite materials used in this study emphasises the importance of accounting for environmental factors when designing and manufacturing these prosthetics. Results indicate that the materials tested are susceptible to mechanical degradation under humid conditions, which can significantly compromise the functionality and reliability of the prosthetic devices. Such degradation may lead to a reduction in stiffness and energy return, potentially impacting the prosthetic's support and efficiency for young users.

One of the most prominent observations is the rapid initial decline in mechanical properties within the first few days of exposure, highlighting a phase where newly manufactured prosthetic devices are particularly sensitive to environmental conditions. This early stage of degradation is crucial, as it can sharply reduce performance shortly after the device is manufactured. This period of increased susceptibility suggests that interventions such as protective coatings or environmental controls, are essential to ensure the long-term durability, effectiveness, and safety of AM paediatric prosthetics in varied settings. Addressing this initial sensitivity to humidity can have the ability to significantly extend the lifespan and performance consistency of these devices.

7.5 Chapter Conclusions

This chapter has examined the effects of ageing and humidity on the mechanical properties, stiffness and hysteresis, of composite AM paediatric prosthetic foot coupon samples. The findings show a deterioration in these properties over time, highlighting the importance of considering environmental factors in the design and manufacture of AM paediatric prosthetics. Key outcomes include a 30% reduction in stiffness and a drop in hysteresis efficiency from 83% to 72% over a 90-day humidity exposure period, showing the critical impact of prolonged humidity on their mechanical performance.

Mechanical testing showed a rapid initial decline in stiffness within the first few days of humidity exposure, followed by a gradual stabilisation around day 60. This early-stage degradation is primarily due to the hygroscopic nature of the Onyx nylon matrix, which absorbs moisture and undergoes plasticisation, weakening the material's structural integrity. Hysteresis efficiency exhibited a consistent decrease, indicating reduced energy return and higher energy loss. Such degradation may negatively impact the mobility and endurance of paediatric users, as the prosthetic device loses its ability to efficiently support dynamic movements.

Microscopic analysis supported these findings, showing that humidity exposure led to structural changes within the composite material. Voids and microcracks began forming early in the exposure period and grew increasingly pronounced over time. These defects act as stress concentrators, significantly reducing the material's stiffness and overall strength. Prolonged humidity exposure also weakened interlayer adhesion and compaction, causing delamination and widening interlayer spacing, which further undermines the device's mechanical resilience.

The implications of this study are critical to addressing the primary and secondary research questions regarding the feasibility of composite AM for paediatric prosthetic ankle-foot devices. The considerable impact of humidity on mechanical properties highlights the need for strategies that enhance material resilience, ensuring repeatable and reliable mechanical properties over time. The findings suggest that the application of protective coatings, such as epoxy, or environmentally controlled storage could mitigate performance degradation, allowing AM prosthetics to maintain their stiffness and energy return capabilities in real-world conditions. This study also reinforces the importance of Sub-question 2, which examines existing control mechanisms within composite AM. The results demonstrate that environmental exposure must be factored into AM quality control measures, particularly for prosthetic components that require high-performance consistency. Without addressing humidity-induced degradation, AM prosthetics may fail to meet the necessary AOPA dynamic response classification criteria, affecting their long-term viability for paediatric users engaging in sports and physical activities.

This chapter shows the importance of developing comprehensive design and manufacturing strategies that account for humidity-related degradation. These challenges must be overcome to ensure that composite AM prosthetic feet remain viable, high-performing, and accessible solutions for paediatric users.

CHAPTER 8: PREDICTIVE MODELLING OF MECHANICAL PROPERTIES

8.1 Overview

The ability to accurately predict the mechanical properties of composite AM paediatric prosthetic ankle-foot devices is essential for ensuring consistent performance, repeatability, and reliability. This chapter outlines the development and application of a mathematical framework that enables the prediction of stiffness and energy efficiency of AM prosthetic ankle-foot devices. This predictive model is based on data gathered from the parametric studies in Chapter 6 which provided insights into how AM process parameters impact mechanical behaviour. By integrating these findings into a predictive framework, this chapter aims to provide a systematic approach for producing desired mechanical performance.

The primary research question of this thesis requires the ability to precisely control and replicate mechanical properties to meet performance classifications. Predictive modelling directly contributes to this by offering a method to pre-determine mechanical properties before manufacturing, ensuring that fabricated prosthetic feet achieve the necessary stiffness and energy return for dynamic response classification. This chapter also addresses the secondary research question, which investigates whether composite AM can provide repeatable and reliable mechanical properties. By creating a predictive model, variability in mechanical outcomes due to fabrication inconsistencies can be mitigated, improving repeatability and reliability in the production process. This aligns with Sub-question 1, which explores how specific material properties and manufacturing processes impact mechanical consistency. If the model can accurately predict stiffness and energy return based on AM processes, consistent performance across multiple prosthetic feet without relying solely on iterative physical testing can be achieved.

This chapter combines experimental data and practical application, surpassing trial-and-error manufacturing towards a data-driven approach for optimising composite AM prosthetic ankle-foot devices. By ensuring that manufacturing decisions are based on predictive accuracy, this research advances the feasibility of composite AM as a viable, repeatable, and cost-effective method for paediatric prosthetic production.

8.2 Log-log Relationships

Log-log relationships are a powerful analytical method used to linearise exponential, non-linear data, enabling more straightforward interpretation and analysis (Wester 2019). In this research, a log-log relationship was used to investigate the dependency between process parameters and the mechanical properties of AM paediatric prosthetic feet. The log-log transformation (eq. 8.1) simplifies exponential relationships into linear forms, expressed as:

$$\log Y = m \times \log(x) + \log(c) \quad \text{(eq.8.1)}$$

Where Y represents the mechanical property of interest (e.g., stiffness or energy efficiency), x represents the parameter under investigation (e.g., fibre layers, infill density), m is the slope of the line representing the sensitivity of Y to changes in x, and $\log(c)$ is the intercept that accounts for the baseline or intrinsic value of Y. In this study, the log-log relationship turned complex data into a straight-line format, allowing the analysis of how specific parameters influenced mechanical properties. By plotting $\log Y$ against $\log(x)$, the slope (m) and intercept ($\log(c)$) were calculated through regression analysis, providing insight into each parameter's effect.

8.3 Parameter Significance

Determining parameter significance was crucial for refining the predictive model to ensure it accurately reflected meaningful relationships between variables. The R^2 value, or coefficient of determination, was used to assess the fit of the log-log regression for each parameter. The R^2 value measures the proportion of variance in the dependent variable (Y) that is predictable from the independent variable (x), with values closer to 1 indicating a stronger relationship (Nakagawa and Schielzeth 2013).

In this study, only parameters with R^2 values above 0.9 were retained for further modelling. This threshold ensured that the parameters included in the final model had a statistically significant impact on stiffness or energy efficiency. Parameters with R^2 values below 0.9 were excluded to prevent introducing false correlations into the model. This filtering process refined the dataset, highlighting the key processing parameters that meaningfully influenced the mechanical properties of the prosthetic samples. This statistical evaluation provided confidence in the relationships identified and validated the robustness of the model. By focusing only on significant parameters, the predictive model was designed to provide highly accurate forecasting (Moreno et al. 2013).

8.4 Predictive Modelling Equations

The predictive modelling equation was constructed based on the log-log relationships and statistical evaluation of parameter significance. After identifying the parameters with R^2 values above 0.9, the exponential form of the log-log relationship (eq. 8.2) was applied:

$$Y = x^{a} \times 10^{c} \qquad \text{(eq. 8.2)}$$

Where *a* is the slope derived from the log-log regression, 10^c is the baseline constant, and x represents the significant parameter values.

To create a comprehensive predictive equation incorporating all significant parameters, the model was expanded into:

$$Y = K \times (x^{a}\, Values\ of\ significant\ parameters) \qquad \text{(eq.8.3)}$$

Where K is a proportionality constant determined experimentally. Each x^a term represents a parameter's contribution, raised to its respective power (a), derived from the regression analysis. This formulation allows the combined effects of multiple parameters to be integrated into a single predictive framework.

The predictive equation serves two primary purposes:

- Predicting Outcomes: Given specific parameter values, the equation can estimate the resulting stiffness or energy efficiency of the prosthetic foot.
- Parameter Optimisation: By inverting the equation, it is possible to determine the parameter settings required to achieve a target mechanical property, enabling performance-driven design.

8.4.1 Stiffness Predictive Equation

The predictive modelling for stiffness was developed by focusing on the parameters identified as statistically significant through the parametric analysis. Figure 8.1 graphically represents the R^2 values for these parameters. The following parameters demonstrated R^2 values above the 0.9 threshold, indicating a strong correlation with the mechanical property of stiffness:

Force: $R^2 = 0.9787$, indicating a strong correlation with stiffness.

Number of Fibre Layers: $R^2 = 0.9612$, reflecting a very strong correlation.

Number of Wall Layers: $R^2 = 0.9776$, showing a strong correlation among the parameters.

The fibre distribution parameter, which had an R^2 value of 0.5701, was excluded due to its weak correlation, ensuring the predictive equation focused only on meaningful relationships.

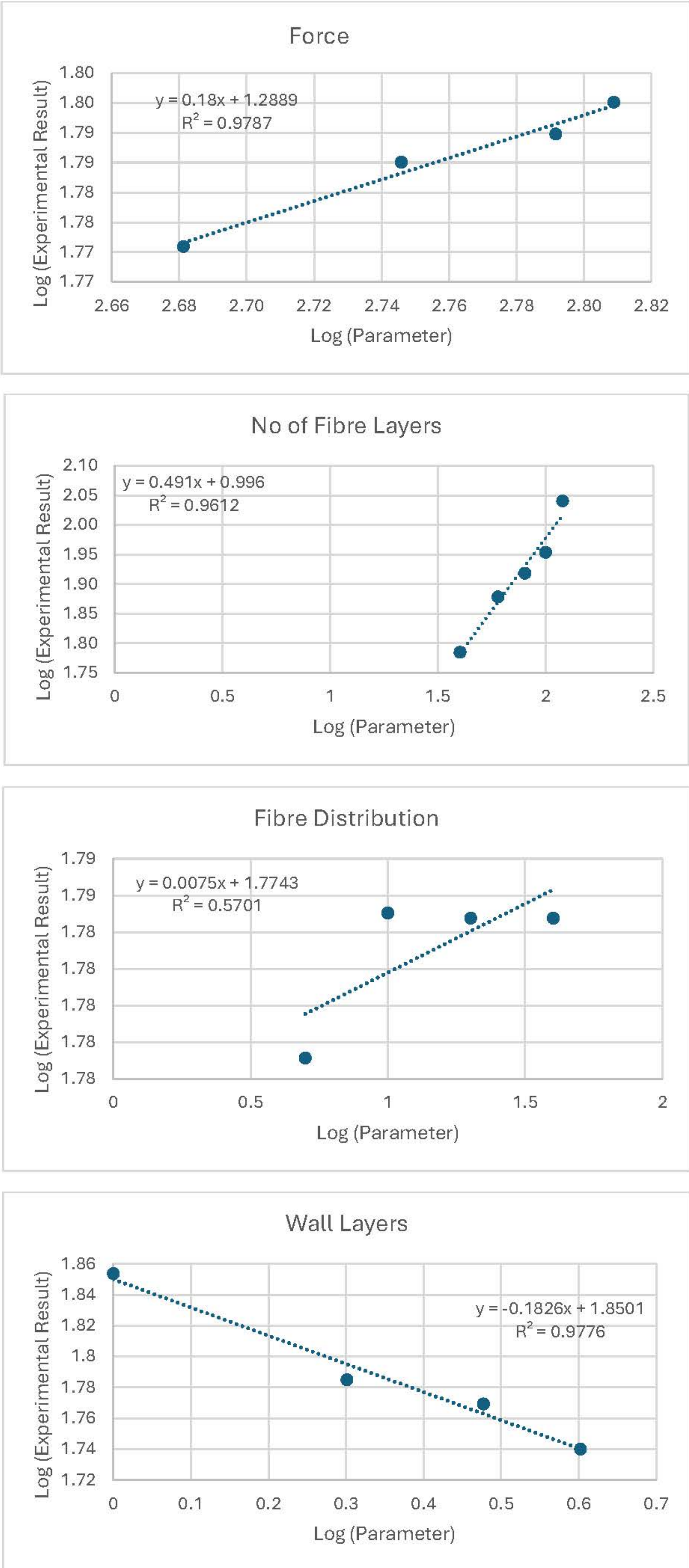

Figure 8.1. Stiffness Parameters R^2 values

Using the results of the log-log regression, the following exponents (Xa) were determined for the included parameters:

Force: Xa =0.18

Number of Fibre Layers: Xa = 0.49

Number of Wall Layers: Xa = −0.18

These exponents quantify the sensitivity of stiffness to each parameter. The stiffness predictive equation was derived as:

Y = K × (Force 0.18 × Fibre Layers 0.49 × Wall Layers −0.18) (eq. 8.4)

Y represents stiffness, K is a proportionality constant derived from experimental data. To calculate K, the predictive equation was rearranged, and experimental data for Y (stiffness) and parameter values were substituted (eq. 8.5). Using the outcomes from the parametric testing, the constant K was determined to be 3.63 (Appendix 3). This value standardises the equation and accounts for intrinsic material and process factors.

$$K = \frac{\mathrm{Y}}{(\mathrm{Force}\ 0.18 \times \mathrm{Fibre\ Layers}\ 0.49 \times \mathrm{Wall\ Layers}\ -0.18)} \qquad \text{(eq. 8.5)}$$

The predictive equation was validated by comparing the predicted stiffness values to the experimental results from the parametric study (Appendix 4). The high level of agreement between the predicted and actual values confirmed the accuracy of the model, demonstrating its ability to produce highly accurate forecasting (Table 8.1, Figure 8.2).

Sample Number	Experimental Values	Predictive Model Values
1.1	59.01	59.29
1.2 (Control)	60.96	60.96
1.3	61.63	62.06
1.4	62.39	62.51
2.2	75.59	74.31
2.3	82.95	85.58
2.4	89.95	95.49
2.5	109.87	104.44
6.1	71.42	69.12
6.3	58.8	56.55
6.4	54.97	53.66

Table 8.1 – Stiffness Predictive v Experimental Results

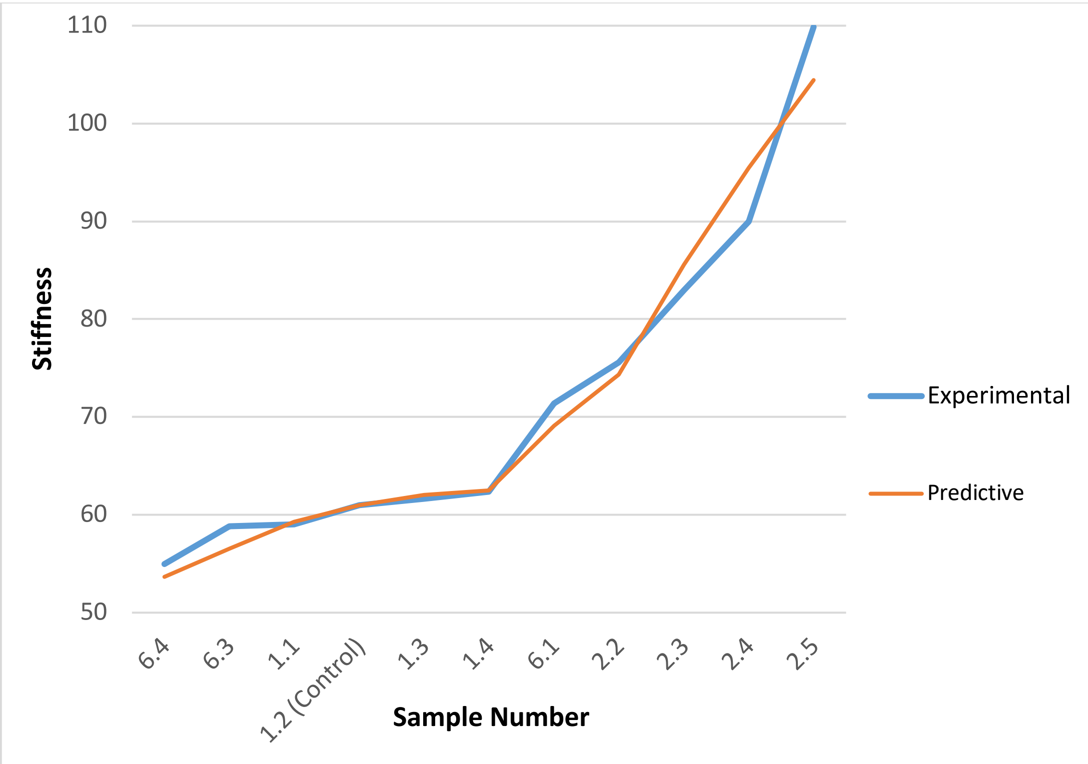

Figure 8.2. Stiffness Predictive v Experimental Results

To assess the accuracy of the predictive model, a coefficient of determination (R^2) was calculated, yielding a value of 0.971. This high R^2 value indicates a strong correlation between the predicted and experimental stiffness values, confirming the model's reliability for forecasting mechanical performance.

This predictive model has practical applications in both design and manufacturing. It gives the ability to predict stiffness of a paediatric prosthetic foot based on specific values for force, number of fibre layers and number of wall layers. Also, by inverting the equation, manufacturers can determine the optimal settings for these parameters to achieve a desired stiffness value. This allows for precision-driven design tailored to user requirements.

The stiffness predictive equation represents a significant advancement in the design of AM paediatric prosthetics, offering a reliable tool for predicting and optimising mechanical performance. By focusing on parameters with strong statistical significance, the model ensures both accuracy and practicality, paving the way for customisable and efficient prosthetic solutions. However, a limitation of this model is the relatively small sample size used in its development, which may affect the generalisability of the findings. Future research with a larger dataset would help to further validate and refine the predictive capabilities of the model.

8.4.2 Efficiency Predictive Equation

The predictive modelling for efficiency was constructed by focusing on the parameters identified as statistically significant from the parametric analysis. Figure 8.2 graphically represents the R^2 values for these parameters. Parameters with R^2 values above 0.9 were included in the model, demonstrating their strong correlation with efficiency. The selected parameters were:

Force: $R^2 = 0.9964$, indicating a strong correlation with efficiency.

Number of Fibre Layers: $R^2 = 0.9894$, reflecting a very strong correlation.

Fibre Distribution: $R^2 = 0.9423$, demonstrating a strong correlation and inclusion in the equation.

Number of Wall Layers: $R^2 = 0.9697$, showing an exceptionally strong correlation.

The high R^2 values for these parameters validate their statistical significance and their direct influence on efficiency, ensuring a robust and accurate predictive model.

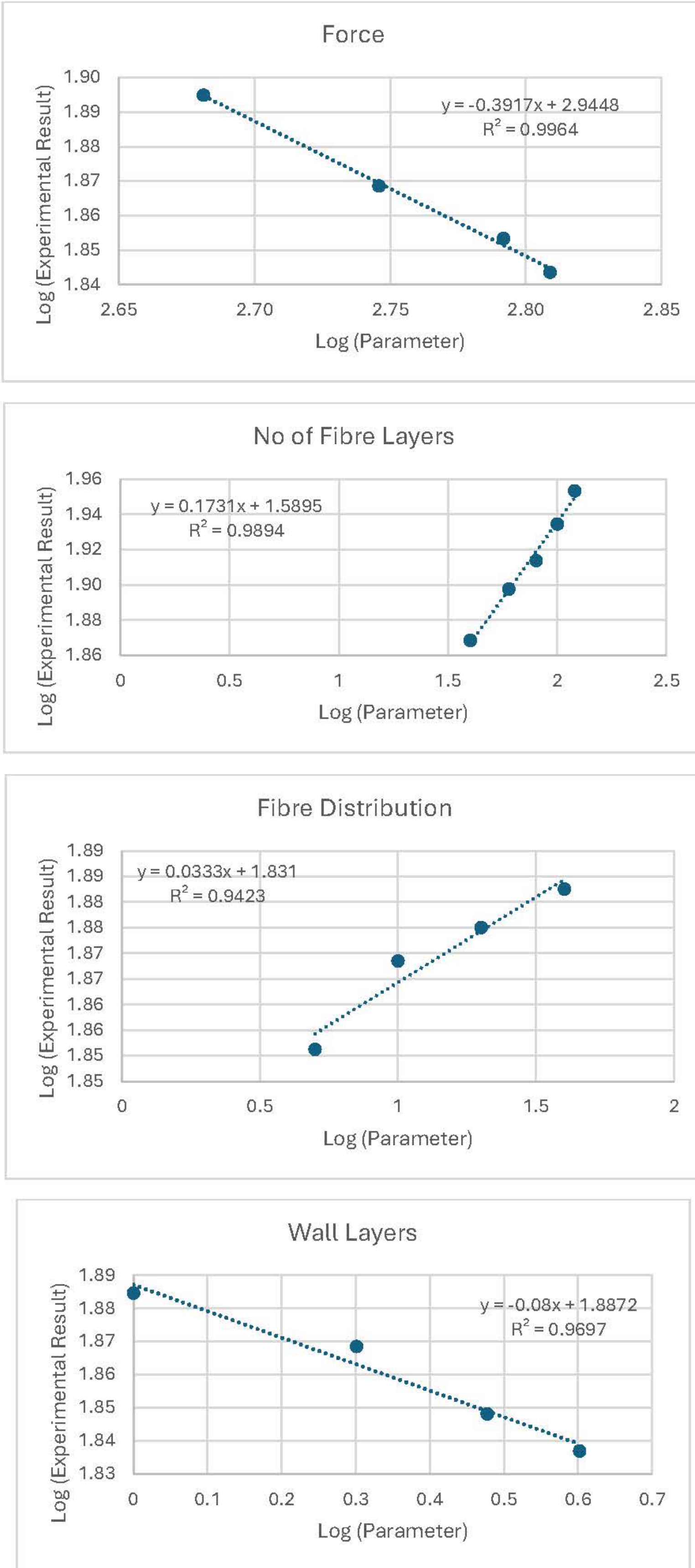

Figure 8.3. Efficiency Parameters R^2 values

Using the results from the log-log regression (Christensen 2006), the following exponents (Xa) were determined for each included parameter:

Force: Xa = −0.39

Number of Fibre Layers: Xa = 0.17

Fibre Distribution: Xa = 0.03

Number of Wall Layers: Xa = −0.08

These values quantify the sensitivity of efficiency to changes in each parameter. The predictive equation for efficiency was developed as:

$$Y = K \times (\text{Force}{-0.39} \times \text{Fibre Layers}0.17 \times \text{Fibre Distribution}0.03 \text{ x Wall Layers}{-0.08}) \quad \text{(eq.8.6)}$$

Y represents efficiency, K is a proportionality constant derived from experimental data. To calculate K, the equation was rearranged, and experimental data for Y (efficiency) and the parameter values were substituted. Using the results from the parametric study, K was determined to be 459.04 (Appendix 3). This constant accounts for the intrinsic material properties and manufacturing conditions that are not explicitly represented by the individual parameters.

$$K = \frac{\text{Y}}{(\text{Force}{-0.39} \times \text{Fibre Layers}0.17 \times \text{Wall Layers}{-0.08} \times \text{Fibre Distribution}0.03)} \quad \text{(eq. 8.7)}$$

The predictive model was validated by comparing its outputs to the experimental efficiency values obtained from the parametric study (Appendix 4). The close alignment between predicted and observed values confirmed the model's reliability for predicting efficiency (Table 8.2).

Sample Number	Experimental Values	Predictive Model Values
1.1	78.5	78.31
1.2 (Control)	73.88	73.88
1.3	71.33	70.88
1.4	69.75	69.79
2.2	79.00	79.25
2.3	82.00	83.29
2.4	86.00	86.57
2.5	89.80	89.35
3.2	71.00	72.19
3.3	75.00	75.60
3.4	76.30	77.37
6.1	76.67	78.09
6.3	73.88	71.52
6.4	68.70	69.89

Table 8.2 – Efficiency Predictive v Experimental Results

This equation can be used for predicting efficiency. Using specific values for force, number of fibre layers, wall layers, and fibre distribution, the model can estimate the efficiency of the prosthetic foot. It can also be utilised for parameter optimisation by rearranging the equation, to determine the specific parameter settings required to achieve a target efficiency value. This capability supports the creation of energy-efficient prosthetic designs tailored to user needs.

The efficiency predictive equation offers a powerful tool for the design and optimisation of AM paediatric prosthetics. The ability to predict and fine-tune efficiency based on key processing parameters enhances the potential for creating customised prosthetics that balance energy return, user comfort, and overall performance. Again, a limitation of this model is the relatively small sample size used in its development, which may affect the generalisability of the findings. Future research with a larger dataset would help to further validate and refine the predictive capabilities of the model.

8.4.3 Validation

The validation of the predictive model developed in this research was conducted using the Mean Absolute Percentage Error (MAPE) (De Myttenaere et al. 2016) (eq. 8.8). MAPE is a mathematically driven metric for evaluating the accuracy of predictive models, as it quantifies the average percentage error between predicted and actual values. The formula for MAPE is as follows:

$$\text{MAPE} = \frac{1}{n}\sum_{i=1}^{n}\left|\frac{At-Ft}{At}\right| \qquad \text{(eq. 8.8)}$$

At is the actual value from experimental data, Ft is the predicted value from the model, and n is the number of data points. This metric provides a percentage error, making it useful for assessing the performance of the predictive model. A lower MAPE indicates that the model is highly accurate, with minimal deviation between actual and predicted values.

For the stiffness predictive model, the calculated MAPE was 2.43%, indicating a high level of accuracy (Appendix 4). This value demonstrates that, on average, the predicted stiffness values deviated from the actual experimental results by only 2.43%. Such a small error margin indicates that the predictive model reliably estimates the stiffness of AM paediatric prosthetic feet, providing confidence in its application for design and manufacturing purposes.

The MAPE value for the efficiency predictive model was 1.05%, which is even lower than the MAPE for stiffness (Appendix 4). This exceptionally small error margin indicates that the predictive model for efficiency is even more reliable, with just over 1% deviation from actual experimental results on average. Such a low MAPE value reflects the high accuracy of the efficiency model in capturing the relationships between key parameters, force, number of fibre layers, wall layers, and fibre distribution, and the mechanical property of energy return. The efficiency model's low MAPE can be considered extremely useful, as energy return is a critical factor in the performance of prosthetic devices. Predicting this property with such precision enhances the ability to design prosthetics that optimise energy storage and return during use, which is essential for user mobility and comfort.

The MAPE values for both stiffness (2.43%) and efficiency (1.05%) signify that the predictive models are highly robust and reliable. In general, a MAPE value below 10% is considered highly accurate for most predictive modelling applications (Moreno et al.

2013), and values closer to 0% indicate near-perfect predictions (Moreno et al. 2013). These achieved MAPE values reflect the following:

- Accuracy in Predicting Stiffness and Efficiency: The low MAPE values demonstrate that the predictive models accurately capture the relationships between key parameters and the mechanical properties of stiffness and efficiency. The efficiency model's MAPE of 1% underscores its highly accurate forecasting.
- Practical Reliability: The predictive model can be trusted to make reliable predictions for both stiffness and efficiency across a range of parameter values. This level of accuracy is critical when tailoring prosthetic designs to meet specific performance requirements, such as energy return for dynamic users or stiffness for stability.
- Validation of Parameter Selection: The low error rates validate the decision to include only parameters with high statistical significance ($R^2 > 0.9$) in the predictive equations. This filtering process ensured that the models focused on the most impactful variables, avoiding noise or irrelevant factors that could compromise accuracy.

The MAPE values highlight the practicality and reliability of the predictive models in designing AM prosthetic feet with tailored mechanical properties. The low percentage errors make these models feasible for real-world applications, where the ability to predict stiffness and efficiency accurately is crucial for ensuring user comfort, performance, and safety. The validation confirms that the methodology, employing log-log relationships and regression analysis, provides a robust foundation for quantifying the impact of fabrication parameters.

For stiffness, the MAPE of 2.43% ensures that the model can reliably estimate the load-bearing capacity of a prosthetic foot. For efficiency, the MAPE of 1.05% provides an exceptionally accurate tool for optimising energy return during cyclic loading. Both models enable performance-driven design, where parameter values can be adjusted to meet specific user needs. By achieving these low MAPE values, the predictive models offer reliable tools for the prosthetic design process. These models significantly reduce the need for iterative testing and prototyping, enabling manufacturers to optimise processing parameters and material usage with confidence. This capability supports the development of AM paediatric prosthetics that combine high performance, customisation, and cost-efficiency. A key limitation however is that the models are only valid within the tested parameter range, meaning predictions outside this range may not be accurate or reliable. The models are also based on controlled experimental conditions, where the samples were tested within 2h hours of fabrication, and therefore do not take into account environmental factors, as described in Chapter 7. Future work should aim to expand the tested range and validate the models under different conditions to enhance their robustness and applicability.

8.5 Application of Predictive Modelling

This predictive modelling equation provides a tool for designing and customising AM paediatric prosthetic feet to meet specific performance requirements. Using the derived equation, designers can input desired stiffness or energy efficiency values and calculate the corresponding processing parameters necessary to achieve these outcomes. This capability significantly enhances the design process by shifting it from trial-and-error experimentation to a precise, data-driven methodology.

For example, if a paediatric prosthetic foot requires a specific stiffness to accommodate the user's weight and activity level, the predictive model can identify the optimal combination of fibre layers, infill density, and other parameters to achieve this stiffness. Similarly, for applications prioritising energy efficiency, the model can guide the selection of parameters that maximise energy return during cyclic loading.

By integrating the predictive modelling approach into the design and manufacturing workflow, prosthetic developers can:

- Improve Efficiency: Reduce the time and cost associated with iterative testing and prototyping.
- Enhance Performance: Tailor prosthetic properties to meet the unique needs of individual users, optimising comfort, mobility, and energy expenditure.
- Ensure Consistency: Standardise manufacturing processes to produce prosthetics with predictable and reliable performance characteristics.

To evaluate the robustness and generalisability of the predictive model, a validation step was carried out where five data points were randomly chosen and included from the training set. The model was then used to predict the stiffness and efficiency values for these data points. The resulting MAPE was 2.49% for stiffness and 1.11% for efficiency, only slightly higher than the original MAPE values of 2.43% and 1.05% respectively when the full dataset was used. This minimal increase in error demonstrates that the model retains strong predictive accuracy even when applied to less data points. Such performance reinforces confidence in the model's ability to reduce the need for extensive physical prototyping by accurately forecasting mechanical outcomes based on parameter inputs.

The use of predictive modelling also facilitates scalability and adaptability. As new materials and AM technologies are introduced, the modelling framework can be updated to incorporate additional parameters or refine existing relationships. This adaptability ensures that the approach remains relevant and effective in advancing the field of AM prosthetics.

8.6 Chapter Conclusions

This chapter has established a robust framework for predicting the mechanical properties of AM paediatric prosthetic feet; stiffness and energy efficiency. Through a detailed parametric study and the application of log-log relationships, the research has demonstrated the ability to systematically evaluate and quantify the influence of key parameters. By selecting statistically significant parameters ($R^2 > 0.9$) and incorporating them into predictive equations, the study has provided a reliable method for estimating mechanical outcomes and guiding design decisions.

The development of stiffness and efficiency predictive equations highlights the strength of this methodology. For stiffness, parameters such as force, number of fibre layers, and wall layers were identified as key contributors, with high R^2 values validating their inclusion. Similarly, for efficiency, an expanded set of parameters, including force, fibre layers, wall layers, and fibre distribution, demonstrated strong predictive power. The calculated constants K (3.63 for stiffness and 459.04 for efficiency) integrate the properties of the materials and processes, allowing the equations to generate accurate predictions when compared to experimental results.

The validation of these predictive models is a key component of their reliability and practical applicability. The models were assessed using the MAPE, a metric that quantifies the average deviation between predicted and experimental results. For stiffness, a MAPE value of 2.43% demonstrated the high accuracy of the predictive model, while for efficiency, the MAPE was even lower at 1.05%, reflecting exceptional reliability. These low MAPE values confirm the models' precision and reinforce their utility for predicting mechanical properties in real-world applications. The validation process also confirmed the robustness of the parameter selection, as only those with significant R^2 values were included in the equations, ensuring strong predictive relationships.

These predictive equations enable a new innovation in the design and manufacturing of AM prosthetic devices. By inputting desired mechanical properties, designers can precisely determine the processing parameters required to achieve these targets. This capability reduces reliance on iterative prototyping, optimises resource utilisation, and accelerates development time. The equations allow designers to balance stiffness, energy efficiency, and user-specific needs, creating prosthetic feet tailored to individual mobility requirements and performance goals.

The predictive model developed in this chapter directly addresses the research questions of this thesis by providing a systematic method for evaluating if composite AM can reliably produce a dynamic response paediatric prosthetic ankle-foot device. By developing mathematical models that predict key stiffness and energy efficiency based on processing parameters, this research contributes to the primary research question by determining if composite AM can achieve the necessary mechanical performance for dynamic response classification. The predictive models also address the secondary research question by assessing the repeatability and reliability of mechanical properties in AM prosthetic components. The ability to accurately predict stiffness and efficiency ensures that the manufacturing process is both controlled and optimised, reducing variability and improving consistency across multiple parts. This directly informs Sub-question 1, as it quantifies the relationship between processing parameters and mechanical outcomes, helping to define material properties and repeatability metrics for different composite AM processes.

This chapter also touches upon Sub-question 2. By integrating processing parameters into a predictive framework, the study builds an understanding of existing control mechanisms in composite AM and their impact on desired mechanical performance. Finally, this chapter directly addresses Sub-question 3 by enabling the identification of optimal AM parameters for manufacturing a paediatric prosthetic ankle-foot unit that meets dynamic response requirements. The predictive modelling framework allows for parameter adjustments to achieve specific mechanical targets, reducing the need for extensive physical prototyping and accelerating the design process.

Overall, this chapter strengthens the feasibility of composite AM for paediatric prosthetic applications by ensuring that mechanical properties can be both predicted and controlled. By linking experimental findings with predictive modelling, this research advances the development of accessible, high-performance, and cost-effective prosthetic solutions tailored to paediatric users.

CHAPTER 9: DYNAMIC RESPONSE ADDITIVELY MANUFACTURED PROSTHETIC FOOT

9.1 Overview

This chapter presents the culmination of this research, integrating findings from previous chapters to directly address the primary research question: ‘Is composite additive manufacturing capable of producing a dynamic response paediatric prosthetic ankle-foot device?’. The ability of a prosthetic foot to deliver dynamic response, as defined by the AOPA, depends on its capacity to deflect under load, store energy, and return it efficiently (AOPA 2010). This case study evaluates if composite AM prosthetic feet can meet these requirements and be classed as dynamic response and compares the performance to a traditionally made dynamic prosthetic foot.

The research conducted in earlier chapters provides the foundation for this study. Chapter 3 established the key mechanical properties that influence prosthetic performance, such as stiffness, hysteresis, and energy return, and examined the limitations of traditional manufacturing methods. This highlighted the need for alternative approaches that could enhance accessibility and performance while maintaining reliability. Chapter 4 explored composite AM techniques, detailing the material and process considerations that influence the structural behaviour of AM prosthetics. The repeatability and reliability of AM composite materials were assessed in Chapter 5, ensuring that mechanical properties remained consistent across multiple parts, which is essential in determining whether AM can produce components capable of dynamic response. Chapter 6 investigated key parameters that affect stiffness and energy return, providing insights into the optimal configurations for maximising performance. Chapter 7 examined the impact of environmental factors such as humidity on AM composite materials, ensuring that performance degradation over time was considered. Finally, Chapter 8 introduced a predictive modelling approach to optimise mechanical properties, enabling more precise control over stiffness and energy efficiency in prosthetic design.

Building upon these findings, this chapter presents a case study that implements the research into a full-scale prosthetic foot, manufactured using AM, and the connector from Aluminium. The geometry of the Össur Vari-Flex Junior prosthetic foot (size 19)

(Figure 9.1) is used as the reference design to eliminate variability caused by shape and structure, ensuring that observed performance differences result solely from the materials and manufacturing method. By systematically validating the stiffness and energy return of the AM prosthetic foot against AOPA classification thresholds, this chapter determines whether composite AM is a viable alternative to traditional manufacturing techniques. The outcome of this study will assess whether an AM approach can deliver the dynamic response necessary for paediatric users, supporting the broader research aim of developing high-performance, cost-effective prosthetic feet that enable children to engage in physical activity.

Figure 9.1. Össur Vari-Flex Junior Prosthetic Foot (https://www.ossur.com/en-gb/prosthetics/feet/vari-flex-junior)

9.2 Methodology

9.2.1 Data Acquisition and CAD

The CAD data for the keel and heel components (Figure 9.2) of the prosthetic foot were already established during previous research and detailed in earlier chapters of this thesis. This prior work provided precise geometries for these key components, ensuring that their designs were available for use in the current study. However, this research involved the additional data acquisition, CAD modelling, and manufacturing of the prosthetic foot pyramid connector (Figure 9.3). This component is critical as it serves as the interface between the assembled prosthetic foot and the prosthetic user's socket, replicating the fixing method used in the Össur Vari-Flex Junior prosthetic foot.

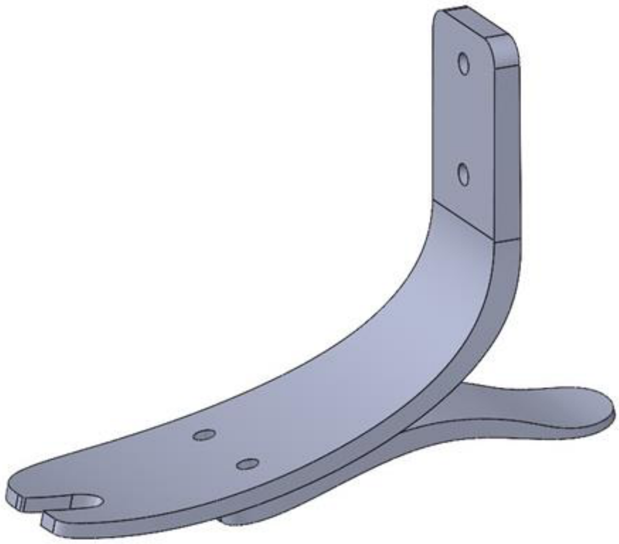

Figure 9.2. Keel and Heel CAD Data

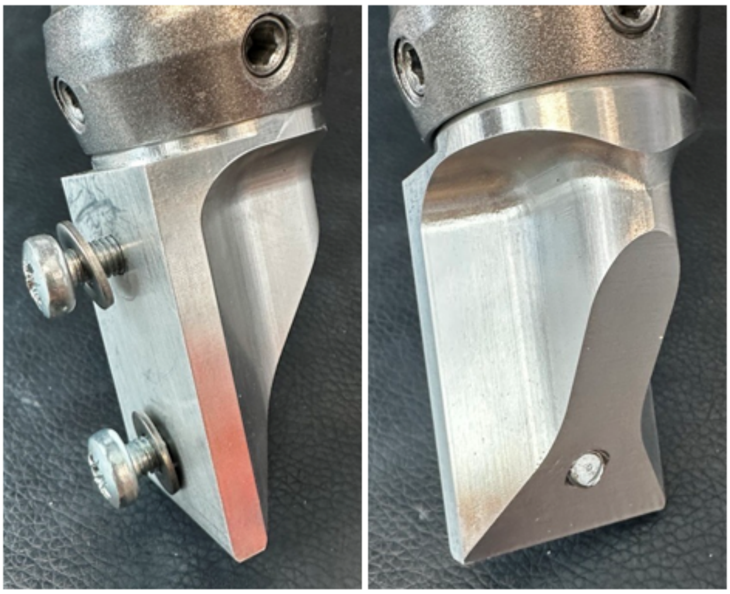

Figure 9.3. Manufactured Pyramid Connector

The pyramid connector's dimensions, contours, and structural features were measured using an Axiom too Coordinate Measuring Machine (CMM) (Aberlink Ltd., Gloucestershire, UK), calibrated in January 2023. This ensured high-accuracy data capture, mirroring the rigorous methodology employed for the keel and heel components in previous research. The precise measurements allowed for the creation of a detailed CAD model using SolidWorks (Dassault Systèmes., Massachusetts).

To maintain consistency with the Össur Vari-Flex Junior design and functionality, the pyramid connector was manufactured from aluminium 6082 using a HAAS TM-1 (Haas Automation., Norwich, UK) 5-axis CNC milling machine. This step ensured that the pyramid connector was fabricated to the same standards as the commercial prosthetic foot, maintaining consistency in the testing process and eliminating variability caused by connection methods. By replicating the Össur Vari-Flex Junior's fixing method, the research focused solely on evaluating the effects of AM and composite materials used for the keel and heel.

9.2.2 Parameter Selection

The selection of parameters for the AM prosthetic foot was informed by research conducted in earlier chapters, ensuring that the final design aligns with the aim of developing a dynamic response paediatric prosthetic ankle-foot device. The methodologies developed throughout this thesis, mainly the parametric study in Chapter 6, and predictive modelling in Chapter 8, informed the choices made in this chapter. The information gathered in those chapters provided the necessary data to optimise key parameters such as fibre reinforcement ratio, layer distribution, and wall thickness, ensuring that the final prosthetic design is able to meet the required mechanical outputs.

The parametric study showed the significant influence of parameters, such as fibre reinforcement percentage, orientation, and wall thickness, on the mechanical properties of AM components. This study demonstrated that increasing the number of continuous carbon fibre reinforcement layers resulted in higher stiffness and reduced hysteresis, while still allowing for functional deformation. These findings led to the selection of a reinforcement ratio of one-third continuous carbon fibre and two-thirds Onyx for both the keel and heel of the prosthetic foot. This balance was chosen to optimise load-bearing capacity while preserving the elasticity required for efficient energy return.

For the final designs, continuous carbon fibre was applied to every third layer, meaning approximately one out of every three layers contained reinforcement, with Onyx used as the surrounding matrix material. The reinforcement layers were evenly distributed throughout the structure to ensure consistent mechanical behaviour and minimise localised stress concentrations. Predictive modelling then further refined the selection process by enabling a quantitative evaluation of how different reinforcement distributions would impact stiffness and efficiency. The model confirmed that a layered reinforcement strategy, where carbon fibre is evenly spaced throughout the structure, maximises load distribution without introducing excessive rigidity.

Based on these findings, the keel was fabricated with 153 carbon fibre reinforcement layers and the heel with 138, ensuring a controlled and uniform stiffness profile that aligns with the required dynamic response classification criteria. A single wall layer was also incorporated to enhance the cross-sectional area of reinforcement within the prosthetic allowing for increased structural integrity and mechanical properties. Solid infill fabrication was used with a layer height of 0.125mm, and the components were fabricated on their side profile.

This final selection of fabrication parameters directly supports the primary research question by determining whether composite AM can produce a dynamic response paediatric prosthetic ankle-foot device. By directly integrating findings from parametric testing and predictive modelling, whilst also considering the findings relating to repeatability and reliability, and environmental impacts, this chapter establishes a well-validated approach to manufacturing a prosthetic foot that balances mechanical performance, material efficiency, and durability.

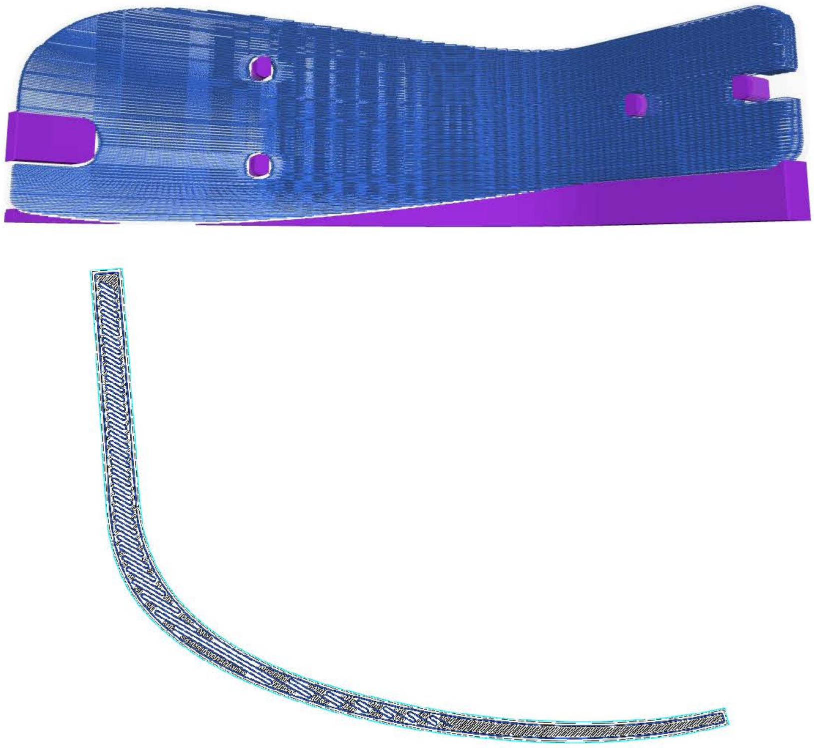

Figure 9.4. Keel Fabrication

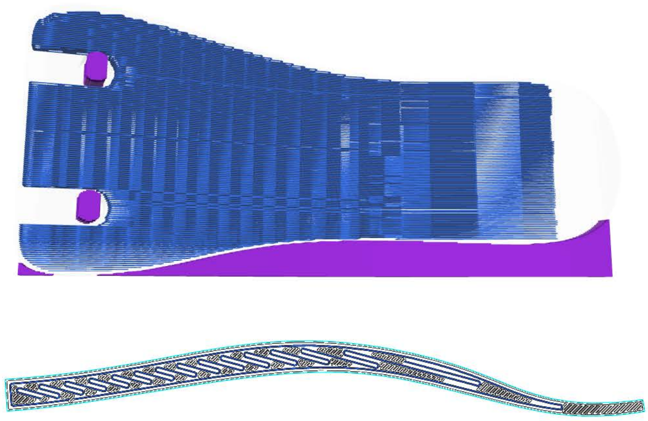

Figure 9.5. Heel Fabrication

9.2.3 Slicing and Fabrication

The geometries for fabrication were prepared using Eiger software (Markforged Inc., Massachusetts), which uses advanced slicing algorithms to convert the CAD model into sequential 2D layers (toolpaths) for the AM machine. The prosthetic feet were produced on a Markforged Mark Two using Onyx and continuous strand carbon fibre reinforcements.

Three complete prosthetic feet were fabricated to ensure comprehensive testing and account for variability in the manufacturing process. Fabricating multiple samples allowed for rigorous evaluation of mechanical properties across different specimens, ensuring the results' reliability..

9.2.4 Mechanical Testing

Compression testing was conducted to evaluate the prosthetic feet's stiffness and energy efficiency characteristics under realistic loading conditions. Compression tests were performed using a Zwick Roell Zwicki Z2.5 testing machine (ZwickRoell Ltd, Worcestershire, UK). The testing followed the ISO 10328 standard and AOPA testing procedure, adapted for a paediatric user with a maximum weight of 24 kg, aligning with the weight capacity of the Vari-Flex Junior Size 19, category. Force-displacement data were collected during compression testing, allowing the calculation of stiffness (k) and energy efficiency (e).

For the keel, an angle plate set at 20° was used (Figure 9.6), and for the heel an angle plate at -15° was used to replicate the forces experienced during the toe-off and heel-strike phases of walking. The testing procedure was as follows:

The component was loaded to 50 N to ensure proper seating of the test specimen and settle the testing machine. They were loaded to a peak force of 400 N (an adapted force for the paediatric application) and then unloaded. The loading rate was maintained at 200 N/s to ensure consistency. No holding period was applied at the peak load, following the AOPA procedure. Three prosthetic feet were manufactured, and each one of these underwent five compression tests.

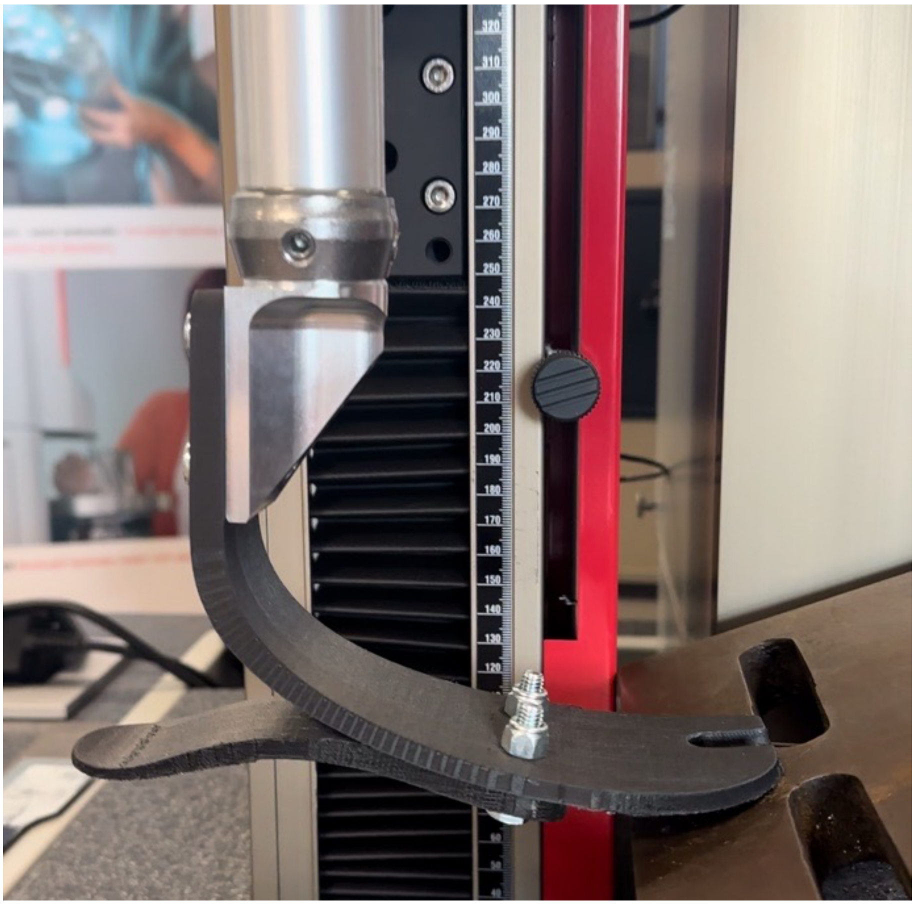

Figure 9.6. Keel Test Set Up

9.2.5 Dynamic Classification

The results from the mechanical testing were analysed against AOPA's thresholds for dynamic classification to determine whether the AM prosthetic feet could be categorised as dynamic response devices. The AOPA classification relies on displacement and energy return criteria, assessing whether the foot demonstrates sufficient deflection and energy efficiency to meet the standards for dynamic performance. This step was critical in evaluating whether composite AM could produce prosthetic feet capable of enabling paediatric users to engage in physical activities effectively.

9.3 Results

9.3.1 AOPA Testing thresholds

The AOPA testing procedure states that the keel and heel must produce the following results in order to be classified as dynamic:

- Dynamic Keel: Achieves a displacement of 25 mm or greater and returns 75% or more of energy, reflecting high energy efficiency and responsiveness suitable for dynamic activities.

- Dynamic Heel: Demonstrates a displacement of 13 mm or greater or achieves an energy return of 82% or more. Meeting either the displacement or energy return criterion qualifies the heel as dynamic, ensuring energy-efficient performance during heel strike and transition phases.

9.3.2 Additively Manufactured Keel Results

The results of the AM keel compression tests are detailed in Table 9.1 below, showcasing the energy efficiency (%) and displacement (mm) recorded for each of the three prosthetic feet over five consecutive tests. The purpose of these repeated tests was to assess the stability and consistency of the mechanical performance, particularly whether the results changed with successive loadings.

Prosthetic Keel 1		
Test No.	**Efficiency (%)**	**Displacement (mm)**
1	85%	27.73
2	85%	27.76
3	86%	27.68
4	86%	27.60
5	86%	27.63
Average	86%	27.68
S.D	0.49	0.06

Prosthetic Keel 2

Test No.	Efficiency (%)	Displacement (mm)
1	86%	27.62
2	86%	27.60
3	87%	27.60
4	87%	27.66
5	87%	27.66
Average	87%	27.63
S.D	0.49	0.03

Prosthetic Keel 3		
Test No.	**Efficiency (%)**	**Displacement (mm)**
1	84%	28.36
2	85%	28.39
3	85%	28.32
4	85%	28.29
5	86%	28.33
Average	85%	28.34
S.D	0.63	0.03

Table 9.1 - Additively Manufactured Keel Compression Test Results

The results indicate a high level of consistency in both energy efficiency and displacement across multiple tests for each prosthetic. No significant degradation in performance was observed after repeated loadings, suggesting that the AM prosthetic keels maintain their mechanical properties under cyclic loading. The overall averages of 85.73% efficiency and 27.88 mm displacement meet the criteria for dynamic classification as per AOPA standards, which require a displacement of 25 mm or greater and efficiency of 75% or higher. This demonstrates the potential of AM to produce paediatric prosthetic feet that meet dynamic response requirements. Figure 9.7 shows the AM keel in compression testing at its maximum deflection.

Figure 9.7. Keel Maximum Deflection

9.3.3 Additively Manufactured Heel Results

The results of the AM heel compression tests are detailed in Table 9.2, showcasing the energy efficiency (%) and displacement (mm) recorded for each of the three prosthetic feet over five consecutive tests.

Prosthetic Heel 1		
Test No.	Efficiency (%)	Displacement (mm)
1	89%	15.16
2	89%	15.17
3	89%	15.13
4	89%	15.14
5	89%	15.13
Average	89%	15.15

Prosthetic Heel 2		
Test No.	Efficiency (%)	Displacement (mm)
1	89%	15.14
2	89%	15.14
3	90%	15.12
4	90%	15.11
5	90%	15.11
Average	90%	15.12

Prosthetic Heel 3		
Test No.	Efficiency (%)	Displacement (mm)
1	89%	15.31
2	88%	15.3
3	89%	15.26
4	89%	15.3
5	89%	15.29
Average	89%	15.29

Table 9.2. Additively Manufactured Heel Compression Test Results

The results show excellent consistency in energy efficiency, with coefficient of variation values of 0%, 0.62%, and 0.49% respectively. The coefficient of variation values for displacement again indicate excellent consistency with values of 0.11%, 0.1%, and 0.14% respectively, across repeated tests for each prosthetic heel. No significant changes in performance were observed, indicating the robustness of the AM heels under cyclic loading conditions.

The overall averages of 89.13% efficiency and 15.19 mm displacement surpass the AOPA standards for dynamic classification, which require a displacement of at least 13 mm or an efficiency of 82% or greater (AOPA 2010). These findings confirm that the AM prosthetic heels meet the dynamic response requirements, demonstrating their suitability for paediatric prosthetic applications.

9.4 Discussion

The results from the keel and heel compression tests demonstrate that the AM prosthetic feet not only meet but consistently exceed the thresholds established by the AOPA standards for dynamic classification (AOPA 2010). This validates the capability of the materials and processes used in this research to produce prosthetic components that deliver the dynamic response required for paediatric applications.

The keels achieved an average energy efficiency of 85.67% and an average displacement of 27.77 mm. Both metrics exceed the AOPA dynamic keel classification thresholds, which require a minimum displacement of 25 mm and an energy return efficiency of 75% or greater. The consistent performance across all tests indicates that the AM process, with its optimised parameters, produces keels capable of sustaining repeated dynamic loads while maintaining high energy efficiency and appropriate flexibility. This is crucial for enabling natural and energy-efficient movement during activities like walking and running.

The heels demonstrated an average energy efficiency of 89.13% and an average displacement of 15.19 mm, surpassing the dynamic heel classification thresholds of at least 13 mm displacement or 82% energy return efficiency. These results confirm the ability of the AM heels to absorb and return energy efficiently, ensuring comfort and responsiveness during heel strike and transition phases of gait. The exceptional consistency across all tests further validates the reliability of the materials and manufacturing methods.

The consistent performance of the keels and heels in meeting dynamic classification criteria demonstrates that AM using Onyx and continuous carbon fibre reinforcement is a viable alternative to traditional manufacturing methods. This is particularly significant for paediatric prosthetics, where dynamic response is essential for supporting active lifestyles and enabling children to engage in physical activities.

9.5 Ossur Vari-Flex Junior Comparison

The performance of the AM prosthetic feet were compared to that of the Össur Vari-Flex Junior to evaluate their dynamic response capabilities. The stiffness and hysteresis efficiency values from the tests conducted on both the keels and heels reveal notable differences, providing insights into the areas requiring optimisation in the AM process. Figures 9.8 and 9.9 graphically represent the averages of the each of AM keel and heel results respectively, with the results from the Össur Vari-Flex Junior.

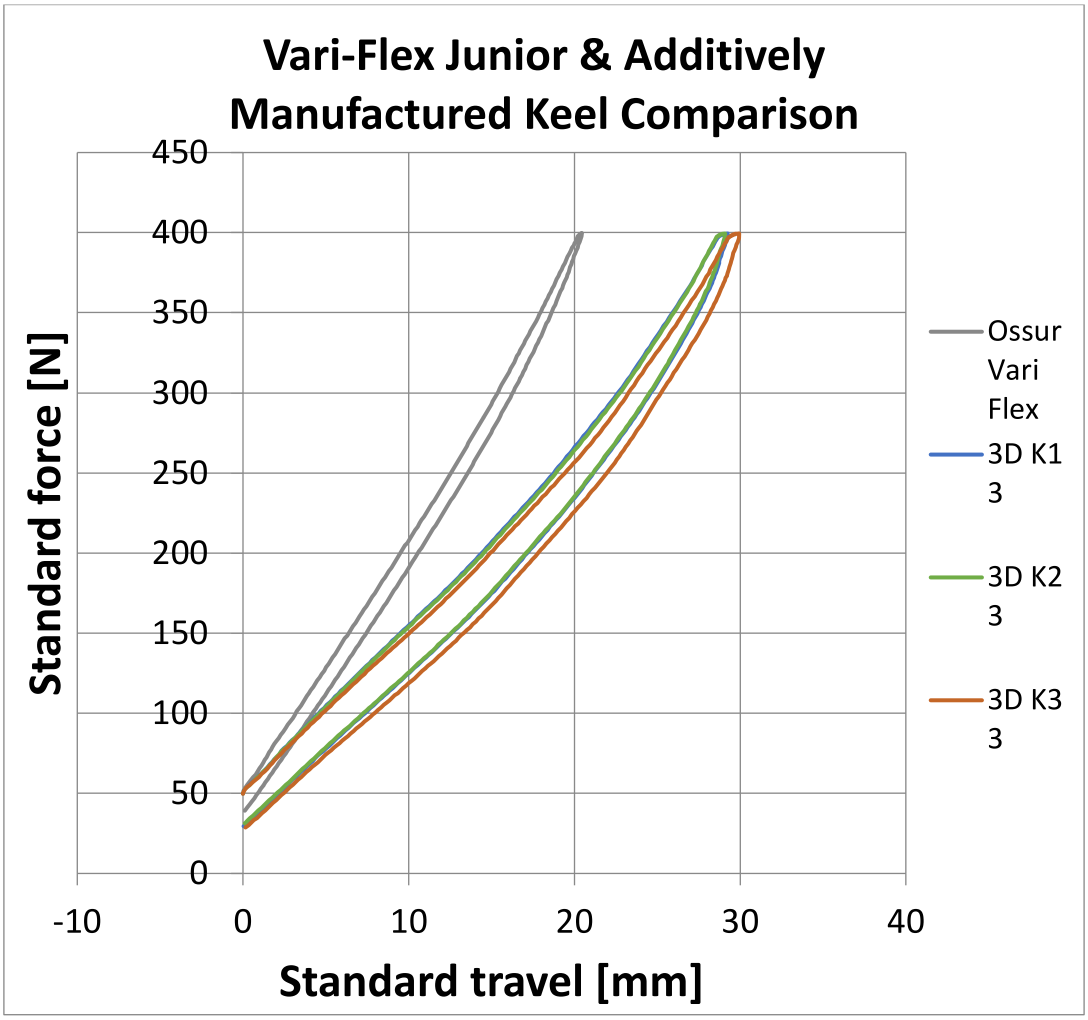

Figure 9.8. Össur Vari-Flex Junior & Additively Manufactured Keel Comparison

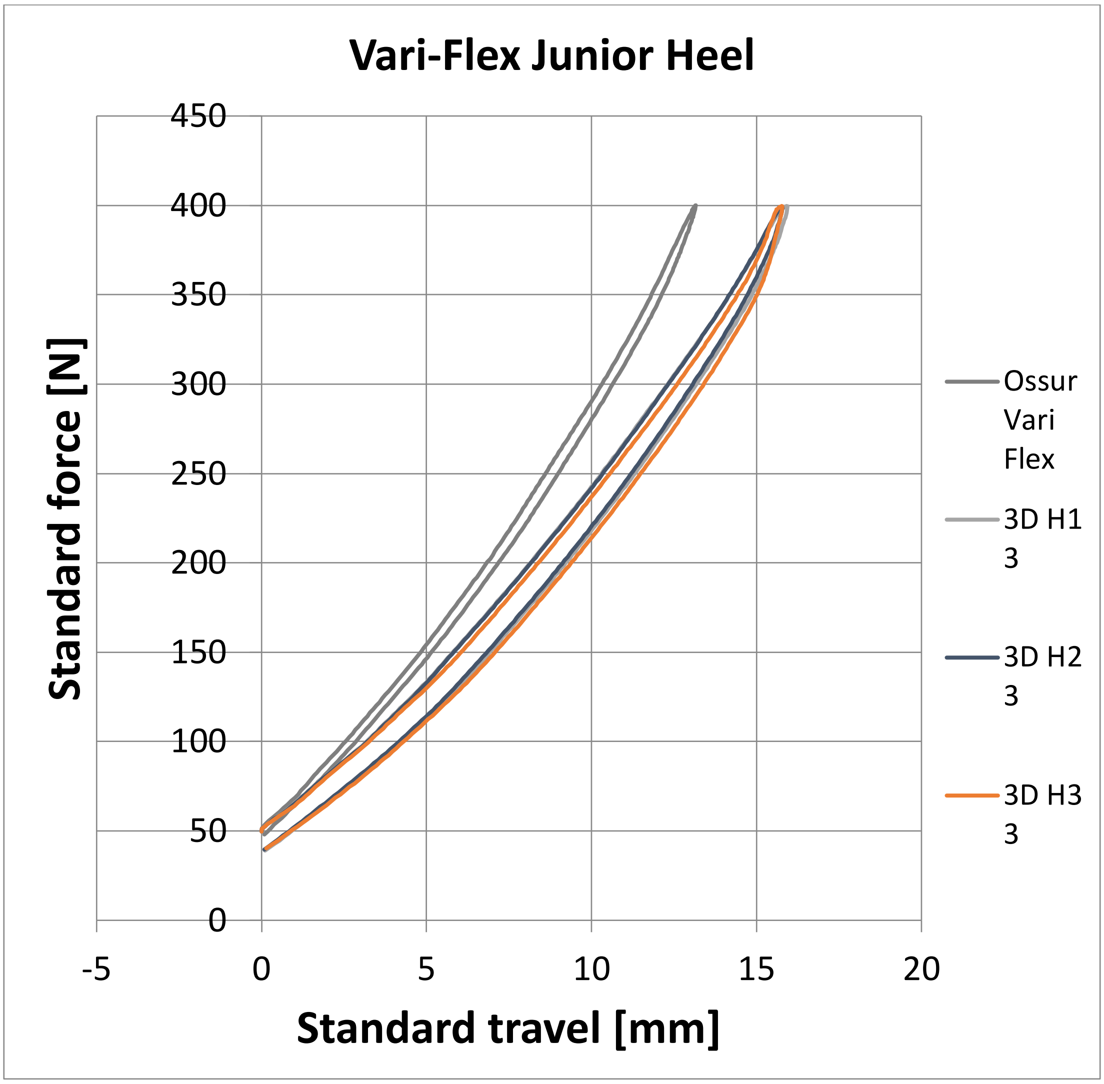

Figure 9.9. Össur Vari-Flex Junior & Additively Manufactured Heel Comparison

The Össur Vari-Flex Junior keel produced an average stiffness of 15.79 N/mm and an efficiency of 92% across five tests. The AM keels achieved an average stiffness of 10.78 N/mm and an efficiency of 85.56%. While the AM keels met the AOPA dynamic classification thresholds (minimum efficiency of 75% and displacement of at least 25 mm), their energy efficiency falls short of the Ossur Vari-Flex Junior, highlighting room for improvement in their energy return capabilities. To determine the necessary parameters to match the Ossur Vari-Flex Junior's efficiency of 92%, the predictive model developed in this research was utilised. Using a calculated K value of 459.04, the model predicts that achieving this efficiency would require 218 reinforcement layers equally spaced throughout the keel.

The Össur Vari-Flex Junior heel exhibited an average stiffness of 19.45 N/mm and an efficiency of 95% across its five tests. The AM heels showed an average stiffness of

15.43 N/mm and an efficiency of 89.04%. Similar to the keels, the AM heels exceeded the AOPA dynamic classification thresholds (minimum displacement of 13 mm or efficiency of 82%). However, they did not reach the superior energy return levels of the Ossur Vari-Flex Junior. Using the predictive model with a calculated K value of 459.04, achieving a 95% efficiency for the heel would require 190 reinforcement layers equally spaced.

This comparison demonstrates the importance and value of the predictive model developed in this research. The model provides a precise, data-driven framework to identify and adjust critical parameters required to match the mechanical properties of high-performance prosthetics like the Össur Vari-Flex Junior. Next, the predictive model was used to determine that increasing reinforcement layers to 218 for the keel and 190 for the heel would achieve the same efficiency values as the Össur prosthetic, it demonstrates that AM is capable of producing prosthetics with comparable energy return and mechanical performance to traditionally manufactured prosthetics. This capability not only validates AM as a viable alternative to traditional methods but also highlights its potential for customisation and optimisation, paving the way for accessible, high-performance paediatric prosthetic solutions.

9.6 Predictive Model Testing and Evaluation

9.6.1 Matching Ossur Vari-Flex

The predictive modelling equation was utilised to estimate the parameters required for the AM prosthetic to achieve efficiency values to match the Ossur Vari-Flex Junior. According to the model, achieving an efficiency of 92% for the keel and 95% for the heel would require 218 reinforcement layers in the keel and 190 reinforcement layers in the heel, with fibre layers evenly spaced throughout the structure (Appendix 5). To validate the accuracy of the predictive model, physical testing was conducted on prosthetic feet manufactured with these predicted configurations. The AM prosthetics were placed in a sealed bag with silica gel, and then placed inside a dry box immediately after fabrication was complete, and tested within 24 hours.

The results of the experimental testing, Figures 9.10 and 9.11, showed that the keel with 218 reinforcement layers achieved an average efficiency of 90%, while the heel with 190 reinforcement layers reached an average efficiency of 92%. Comparing these values to the predicted efficiencies, the keel exhibited a 2% lower efficiency than expected, and the heel was 3% lower than predicted.

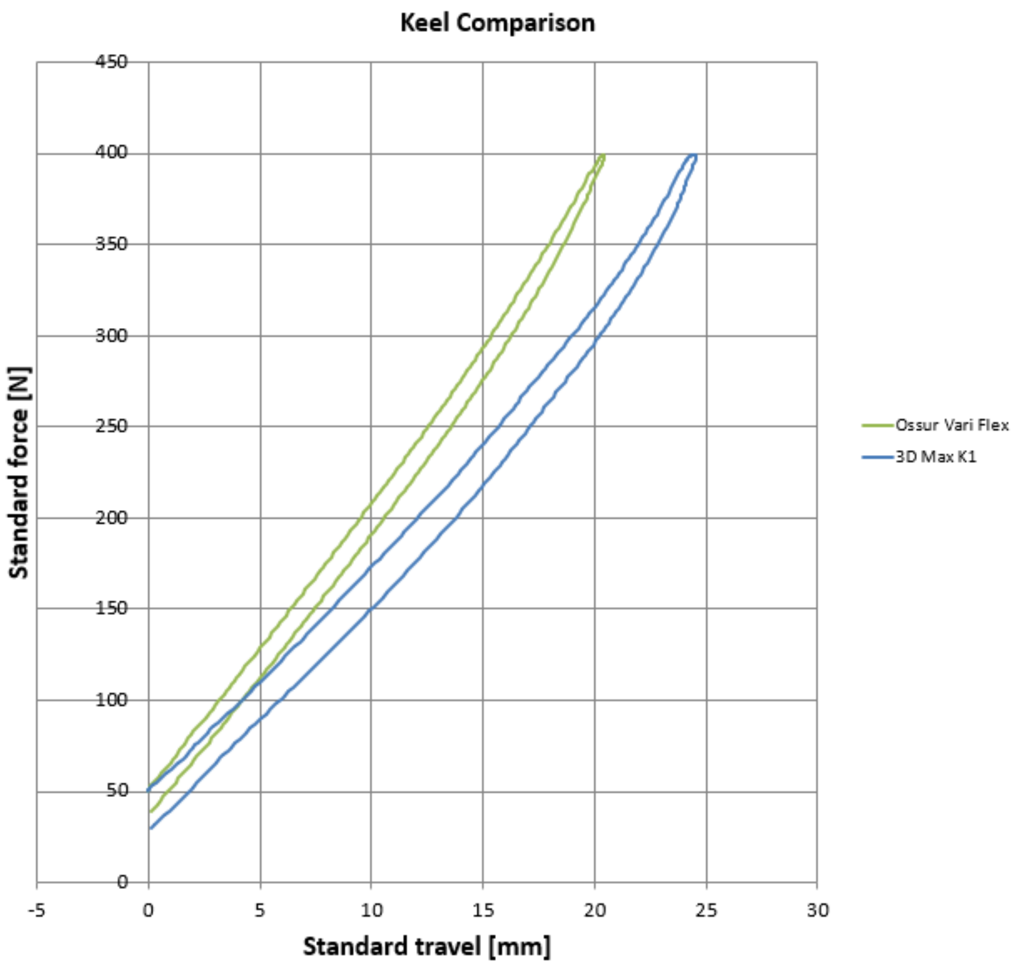

Figure 9.10. Predictive Model Keel Comparison

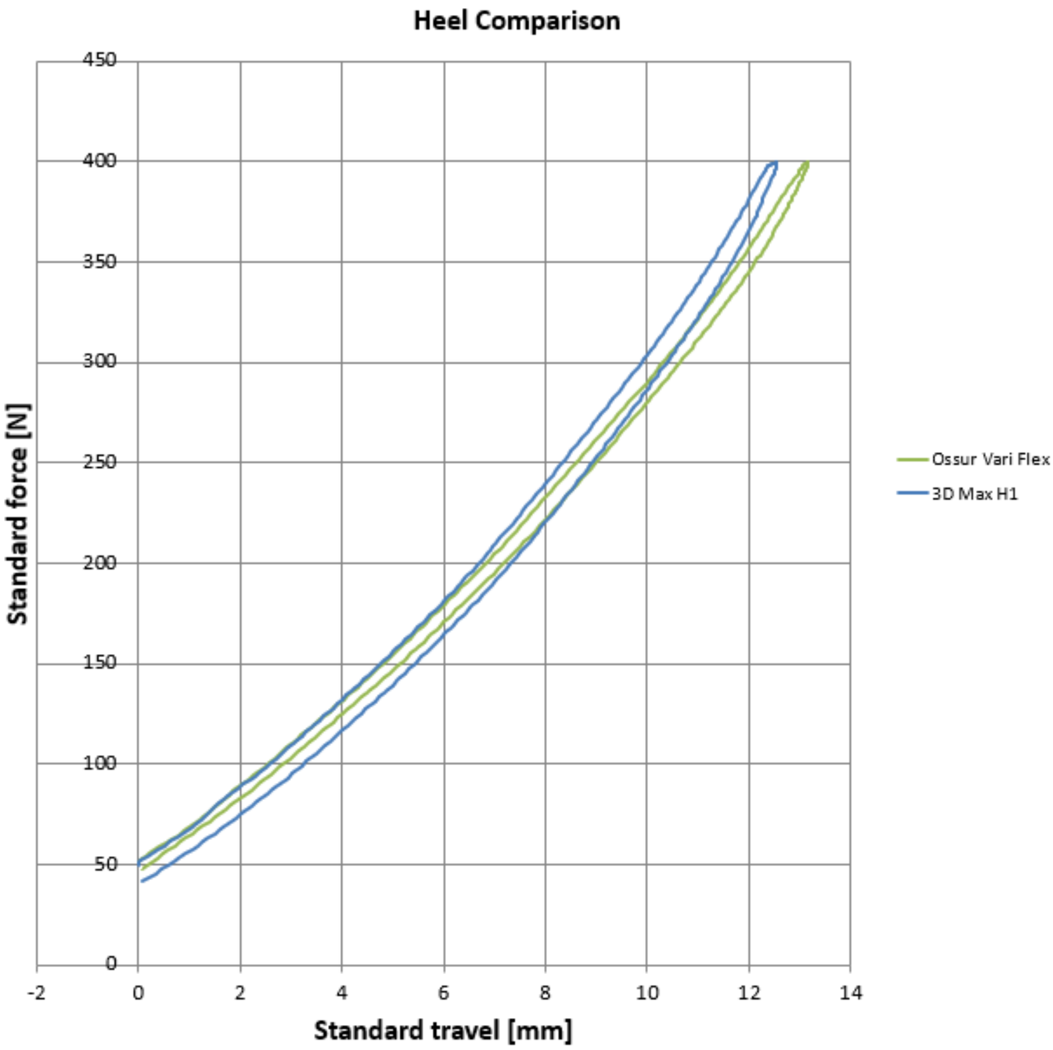

Figure 9.11. Predictive Model Heel Comparison

The accuracy of the predictive model was previously evaluated using the MAPE, which yielded a value of 1.05% for efficiency. This suggests that the model's predictions should deviate by just over 1% from the experimental results. However, in this validation study, the observed deviations of 2% (keel) and 3% (heel) exceed the expected margin of error, indicating a greater discrepancy than anticipated.

Several factors may contribute to this deviation. While the model accounts for key parameters affecting energy efficiency, real-world variations in fibre alignment, layer adhesion, and manufacturing inconsistencies could introduce small inefficiencies that the model does not fully capture. Minor discrepancies in the material properties of components, such as void formation, could lead to slightly lower energy return than predicted. The model assumes identical reinforcement placement, variations in fibre-matrix interactions and microstructural inconsistencies could impact the actual performance of the prosthetic under load.

Despite these deviations, the predictive model remains a highly effective tool for guiding parameter selection in the design and optimisation of AM prosthetic feet. In predictive modelling applications, a MAPE value below 10% is generally considered highly accurate (Moreno et al., 2013). With the values deviating by 2% and 3% for efficiency, the model still demonstrates a high level of predictive reliability, even though the experimental results deviated slightly more than expected. The relatively small discrepancies between predicted and actual values confirm that the model effectively approximates performance trends with a strong degree of accuracy. The use of this model is still able to significantly reduce the reliance on iterative prototyping and enables efficient performance-driven design for producing high-performance, dynamic response paediatric prosthetic feet.

9.6.2 Minimum Thresholds for Dynamic Classification

Using the predictive modelling equation, the minimum reinforcement layers required for the prosthetic keel and heel to achieve dynamic classification under the AOPA thresholds were determined. The model predicted that a keel with 80 reinforcement layers would be sufficient to achieve the minimum efficiency threshold of 75%, while a heel with 91 reinforcement layers would meet the 82% efficiency requirement necessary for dynamic classification. These parameters were applied in physical testing, and the results confirmed that both components met and exceeded the required performance criteria.

The keel, which required a minimum displacement of 25 mm and an efficiency of 75%, successfully exceeded the displacement threshold and achieved an efficiency of 80%, deviating from the predicted value by 6.67%. The heel, which needed an efficiency of at least 82%, achieved an average efficiency of 83%, deviating from the predicted value by 1.22%.

These findings validate the predictive model’s capability in guiding parameter selection to achieve dynamic classification. The predictive model’s efficiency estimations aligned closely with the experimental results, confirming its reliability as a design tool. The minor deviations between the predicted and actual performance are within an acceptable range, reinforcing the model's accuracy. This demonstrates the practical value of predictive modelling in optimising prosthetic design while minimising material use and production iterations.

9.7 Manufacture Time & Cost

The AM of a complete prosthetic foot, comprising both the keel and the heel, using the Markforged Mark Two machine, provides savings in both production time and cost compared to traditional manufacturing techniques. Producing a prosthetic foot with current parameters, achieving 85% efficiency for the keel and 89% efficiency for the heel, took 20 hours and 52 minutes of fabrication time at a material cost of 69.72 USD (£55.71, March 2025). If the parameters were adjusted to match the performance of the Ossur Vari-Flex Junior, with an efficiency of 92% for the keel and 95% for the heel, the production time would increase slightly to 23 hours and 40 minutes, with a material cost of 88.97 USD (£71.09, March 2025).

To get the minimum required efficiency levels to classify as dynamic under the AOPA thresholds, the keel would require 80 layers of reinforcement, and the heel would need 91 layers. Manufacturing to these mechanical properties would take just 20 hours and 39 minutes, with a material cost of 52.47 USD (£41.92).

Traditional methods for manufacturing prosthetic feet are far more time-intensive, labour-intensive and expensive. The detailed steps involved in manual lay-up, vacuum bagging, autoclave curing, and precision machining require skilled technicians, expensive equipment, and extended processing times (Bader 2002). AM eliminates many of these constraints, streamlining the production process whilst having the ability to optimise reinforcement and material usage to meet specific performance targets without significant increases in time or cost.

The shorter production times and lower costs associated with AM could have far-reaching implications for the availability of dynamic prosthetic feet, especially for paediatric users. Children require frequent replacements due to growth, and the cost of traditional prosthetics often creates significant financial barriers for families and healthcare systems. By drastically reducing both production time and costs, AM has the potential to make high-performance, dynamic prosthetics more accessible to children around the world. The ability to tailor prosthetic feet to meet industry standards while maintaining affordability and efficiency ensures that children with limb differences are not limited by cost or availability. With a production time of just one day and a material cost well under 100 USD (£79.16), AM opens doors to scalable, customisable, and cost-effective solutions. This could particularly benefit underserved regions or healthcare systems with limited budgets, expanding access to high-quality dynamic prosthetics and improving the quality of life for countless children.

9.8 Chapter Conclusions

This chapter has explored the feasibility of using AM to produce dynamic response paediatric prosthetic feet that meet the performance criteria outlined by the AOPA standards. The results demonstrate that, using composite materials and advanced manufacturing techniques, it is possible to produce prosthetic feet capable of achieving the required efficiency and displacement thresholds to be classified as dynamic. These results highlight the potential that AM has to replace traditional manufacturing methods for paediatric prosthetics.

The compression tests revealed that the AM prosthetic feet consistently met or exceeded the minimum requirements for dynamic response classification. Both the keel and heel components achieved energy efficiency and displacement levels within the dynamic range. The results validate the structural and functional capabilities of the materials and the layered reinforcement strategies used. Additionally, by utilising the predictive modelling developed earlier in this research, the parameters needed to match the performance of the Ossur Vari-Flex Junior prosthetic foot were identified. Adjusting reinforcement layers to achieve a 92% efficiency for the keel and 95% efficiency for the heel demonstrates the versatility and adaptability of AM to meet specific performance targets and be capable of matching mechanical performances of existing paediatric prosthetic feet.

The manufacturing analysis highlighted the significant advantages of AM over traditional methods. Producing a complete prosthetic foot took less than 24 hours and cost 90 USD (£71.25), even when optimised for Ossur Vari-Flex Junior-level performance. For lower levels of reinforcement that still classify as dynamic, the time and cost were further reduced, making these devices highly accessible. These benefits can have big implications for the accessibility of dynamic prosthetics, especially for children, who require frequent replacements due to growth. By eliminating the resource-intensive processes of traditional manufacturing, AM offers a scalable, cost-effective, and customisable solution to meet the growing demand for paediatric prosthetics.

Despite the success of the predictive modelling equation in guiding parameter selection for achieving dynamic response classification, the results indicate that the equation could be considered more as a predictive framework rather than a definitive model for exact mechanical performance outcomes. When applied to the geometric complexity of a full prosthetic foot, the overall percentage error increased beyond the MAPE values achieved during the parametric study, suggesting that additional external factors influence mechanical performance beyond those accounted for in the equation. While the parametric study provided highly accurate predictions for coupon samples, translating these findings to a fully assembled prosthetic foot introduces further complexities. These factors are not explicitly captured within the simplified predictive equation, leading to deviations in efficiency and stiffness predictions.

However, several limitations should be acknowledged to qualify the findings of this chapter. Firstly, the testing was limited to static compression, with no evaluation of fatigue life or dynamic cyclic loading. These are all crucial factors in understanding the long-term durability and in-use performance of prosthetic components, especially for paediatric users engaged in dynamic activities. The impact of different loading angles and off-axis forces, which are common in real-life gait cycles, were not investigated. The prosthetic design was also constrained to one geometry, meaning the findings may not generalise across alternative structural configurations or limb sizes. Finally, while performance was matched to the Ossur Vari-Flex Junior, user comfort, gait symmetry, and real-world usability were not evaluated clinically, limiting the scope of validation to mechanical test environments.

In conclusion, this chapter has directly addressed the primary research question: “Is composite additive manufacturing capable of producing a dynamic response paediatric prosthetic ankle-foot device?” Through mechanical testing and validation against the AOPA dynamic response classification, the findings confirm that composite AM can successfully achieve the necessary stiffness and energy return properties required for a dynamic response prosthetic ankle-foot device. The ability to control mechanical performance through strategic parameter selection, as informed by earlier chapters, reinforces the viability of AM as a manufacturing method for paediatric prosthetic development. This chapter also presents the advantage that AM can offer prosthetic manufacturing in terms of cost, production efficiency, and customisability. These findings provide a strong foundation for expanding the application of AM in prosthetic design, reinforcing its potential to deliver accessible, high-performance prosthetic solutions tailored to the specific needs of paediatric users.

CHAPTER 10: DISCUSSION & CONCLUSIONS

This final chapter brings together the key findings of this thesis and addresses all research questions by consolidating material and manufacturing insights, parametric analysis, predictive modelling, and experimental validation. The chapter begins by addressing each of the sub-questions that guided the research, discussing how the identified material properties, control mechanisms, and optimised fabrication parameters contribute to the viability of composite AM for paediatric prosthetics. It then evaluates how these findings collectively support the feasibility of producing dynamic response prosthetic feet through AM, validating them against AOPA classification.

The discussion also highlights the broader contributions of this research, including the development of a predictive modelling framework, insights into the impact of environmental factors on mechanical performance, and the cost and scalability advantages of AM. The final sections present a comprehensive conclusion, summarising the key contributions of this research to the field of prosthetic manufacturing, limitations of this research, and outlines future work required to build upon these findings.

10.1 Discussion

The research presented in this thesis was structured around one primary research question, supported by a secondary research question and four sub-questions. This chapter explores each of the sub-questions, collating the findings from previous chapters. It then evaluates how the research findings collectively answer the primary research question, providing a comprehensive conclusion to the study.

10.1.1 Sub-question 1: What are the specific material properties, accuracy, and repeatability metrics for various composite additive manufacturing processes and materials?

This research aimed to identify the material properties, dimensional accuracy, and repeatability of composite AM processes to evaluate their effectiveness for producing paediatric prosthetic components. Chapter 4 outlined the strengths of composite AM, particularly the use of continuous fibre reinforcement, which offers significantly enhanced stiffness and tensile strength compared to unreinforced thermoplastics. For example, Markforged's Onyx with continuous carbon fibre reinforcement demonstrated tensile strengths that exceeded those of aluminium, reaching up to 700 MPa. These findings demonstrate the potential of composite AM to meet the mechanical demands of prosthetic components. However, limitations such as fibre pull-out and void formation, which can weaken the fibre-matrix interface, were also highlighted as challenges that may compromise structural integrity.

Chapter 5 expanded on these insights by evaluating the repeatability and reliability of mechanical properties achieved using composite AM. The study revealed that Onyx with continuous carbon fibre exhibited strong repeatability in tensile strength across multiple specimens, with low standard deviations supporting its consistency. However, greater variability was observed when continuous carbon fibres were used, highlighting challenges in achieving uniform fibre alignment and adhesion, particularly for complex geometries. Dimensional accuracy was also assessed, demonstrating that while the Markforged Mark Two machine provided reliable repeatability, deviations from nominal dimensions occurred, particularly with continuous carbon fibre reinforcement.

The findings from these chapters highlight that composite AM processes, particularly those involving continuous fibre reinforcement, possess the mechanical capability to produce reliable and repeatable prosthetic components.

10.1.2 Sub-question 2: What are the existing control mechanisms within composite additive manufacturing, and how do they influence the part strength, quality, and reliability of produced components?

Composite AM processes rely on precise control mechanisms to ensure the strength, quality, and reliability of produced components, particularly for applications requiring high mechanical performance such as paediatric prosthetics. Chapters 4, 5, and 6 of this thesis provide insights into these mechanisms and their influence on the structural and mechanical properties of AM parts.

Chapter 4 identifies key control mechanisms such as fibre orientation, matrix distribution, infill density and layer thickness. These factors contribute to the composite's ability to distribute load, resist deformation, and achieve desired energy return properties. Accurate control over fibre placement and orientation ensures that the composite achieves its designed stiffness and efficiency by effectively reinforcing load-bearing areas. Matrix distribution and infill patterns are critical for achieving uniform material properties and minimising voids that could compromise structural integrity.

Chapter 5 emphasises the role of repeatability and reliability in ensuring consistent quality across multiple parts. This research highlights that control mechanisms must ensure optimal mechanical properties whilst also maintaining consistency between parts. The use of advanced slicing software, such as Eiger, and high-performance AM machines, like the Markforged Mark Two, demonstrates how modern AM implement these controls. The ability to fine-tune parameters, such as fibre layer spacing and number of wall layers, while maintaining minimal variation across parts was shown by minimal deviation in stiffness and efficiency values across multiple samples.

Chapter 6 builds upon this by demonstrating how parameter optimisation enhances the mechanical properties and reliability of components. Parametric analysis revealed that increasing the number of fibre layers substantially improves stiffness and efficiency, whereas uniform fibre distribution optimises energy return by enhancing interlayer bonding. These findings highlight the importance of precise control over fabrication parameters to achieve high-performance outcomes.

In summary, the control mechanisms within composite AM play a crucial role in the mechanical properties and ensuring the reliability of fabricated components. Specific parameter selection and control mechanisms ensures that AM prosthetics can meet the demands of paediatric users. These controls not only improve the mechanical strength and quality of components but also establish the repeatability necessary for scalable and practical implementation in clinical settings.

10.1.3 Sub-question 3: What are the optimal AM parameters for manufacturing a paediatric prosthetic ankle-foot unit that meets dynamic response requirements?

Determining the optimal AM parameters for manufacturing paediatric prosthetic feet capable of dynamic response was a critical focus of this research. This question was addressed through a combination of parametric analysis (Chapter 6) and predictive modelling (Chapter 8), using experimental data and statistical techniques to identify and refine the key parameters influencing mechanical performance.

The parametric analysis provided foundational insights into the effects of specific fabrication parameters, such as the number of fibre layers, wall layers, and reinforcement distributions, on mechanical properties, stiffness and energy efficiency. By systematically varying these parameters, it became evident which combinations were most effective for achieving the mechanical thresholds required for dynamic classification. Reinforcement patterns and fibre orientations emerged as crucial factors in ESAR capabilities, while wall thickness directly impacted stiffness and structural integrity. Using R^2 values to determine statistical significance, only parameters with strong correlations ($R^2 > 0.9$) were included in subsequent modelling, ensuring the reliability and robustness of the findings.

Building on these results, the predictive modelling outlined in Chapter 8 quantified the relationships between parameters and mechanical outcomes through log-log equations and regression analysis. This allowed for the development of predictive equations for stiffness and energy efficiency. The stiffness model identified parameters such as force, the number of fibre layers, and wall layers as significant contributors, while the efficiency model expanded to include fibre distribution. These models, validated through the (MAPE method, demonstrated high accuracy, with MAPE values of 2.43% for stiffness and 1.05% for efficiency, underscoring their reliability for both prediction and optimisation.

The predictive models were used to determine optimal fabrication parameters for achieving dynamic response classification as defined by AOPA standards. For the keel, achieving the minimum efficiency threshold required 80 layers of reinforcement, while for the heel, 91 layers were needed. For matching the performance of the Ossur Vari-Flex Junior, higher reinforcement levels, (218 for the keel and 190 for the heel), were predicted. These findings highlight the flexibility of AM in tailoring mechanical properties through precise control of parameter settings.

10.1.4 Primary Research Question: Is composite additive manufacturing capable of producing a dynamic response paediatric prosthetic ankle-foot device?

The primary research question aimed to determine whether composite AM could produce a paediatric prosthetic ankle-foot device capable of dynamic response. This was evaluated through a comprehensive investigation, combining parametric analysis, predictive modelling, and physical testing against ISO 10328 and AOPA standards (Chapters 6, 8, and 9). The findings show that composite AM is capable of achieving this goal, subject to careful selection of materials, fabrication processes and optimised parameters.

The experimental results from Chapter 9 demonstrated that the AM prosthetic foot met the AOPA thresholds for dynamic classification. The keel achieved an average displacement of 27.73 mm and an energy efficiency of 85-86%, while the heel achieved an average displacement of 15.16 mm and an energy efficiency of 89-90%. These results exceeded the minimum thresholds of 25 mm displacement and 75% energy return for the keel, and 13 mm displacement and 82% energy return for the heel, indicating that the AM prosthetic could perform as dynamic response devices do. These outcomes validate the capability of composite AM to produce prosthetics with high energy efficiency, essential for enabling paediatric users to engage in physical activities.

The integration of predictive modelling (Chapter 8) further reinforced this capability by enabling the precise tailoring of parameters to achieve specific performance targets. Increasing reinforcement layers to 218 for the keel and 190 for the heel was predicted to match the energy efficiency of the Ossur Vari-Flex Junior. This demonstrated the adaptability of AM in fine-tuning and tailoring mechanical properties through parameter adjustments.

The study also highlighted the advantages of AM production over traditional manufacturing methods (Chapters 3 and 10). The reduced cost and faster production times, $88.97 and 23 hours 40 minutes to replicate Ossur-level performance, make AM a practical and scalable option for producing dynamic response prosthetic feet. These benefits have the ability to improve the accessibility and affordability of high-performance paediatric prosthetics, especially in resource-limited settings.

10.1.5 Secondary Research Question: Can the use of composite additive manufacturing provide repeatable, and reliable dimensional accuracy and mechanical properties for this purpose?

The secondary research question examined if composite AM could guarantee the repeatability and accuracy necessary for producing dynamic response prosthetic feet. This was evaluated through an in-depth analysis of dimensional accuracy, material consistency, and mechanical performance across multiple manufactured samples (Chapters 5 and 9). The results indicate that composite AM can meet these requirements, although with some considerations for process optimisation.

Dimensional accuracy and repeatability were assessed in Chapter 5, where the composite AM processes demonstrated excellent precision in producing samples with consistent dimensions. Variability was within ±0.2 mm across all measured dimensions, reflecting the accuracy of the Markforged Mark Two machine and the accuracy of the Onyx material. This consistency ensures that prosthetic components fit accurately and function as intended, which is critical for user comfort and safety.

Mechanical properties, including stiffness and hysteresis, were found to be repeatable across multiple tests of the same prosthetic samples. In Chapter 9, three prosthetics underwent five consecutive compression tests each, showing minimal variability in stiffness and energy efficiency. For instance, the keel displayed efficiency values consistently between 85% and 86% and displacement values within a narrow range of 27.6 to 28.4 mm. Similarly, the heel maintained efficiency values between 89% and 90%, with displacements around 15.2 mm. These results validate the mechanical accuracy of composite AM for producing dynamic response prosthetics.

However, the findings from Chapter 7 on environmental conditions introduce an additional consideration for repeatability and reliability. While composite AM demonstrated strong consistency in controlled laboratory conditions, the long-term effects of environmental exposure, particularly humidity, must be accounted for. The results indicated that humidity significantly impacts mechanical properties, with stiffness declining by approximately 30% over 90 days and hysteresis efficiency decreasing from 83% to 72%. This degradation could influence the prosthetic's ability to maintain dynamic response performance over time, particularly if used in humid or variable environmental conditions.

In conclusion, composite AM can reliably and repeatably produce prosthetic components with the dimensional and mechanical precision required for dynamic response devices under controlled conditions. However, real-world environmental factors must be considered, as humidity can significantly impact material performance over time. While the stabilisation of mechanical degradation suggests that prosthetics may still function effectively beyond 90 days, further research is needed to confirm whether they retain their dynamic response classification without intervention. These findings underscore the importance of integrating environmental resilience strategies into the design and manufacturing process, ensuring that AM prosthetic feet remain reliable in practical use.

10.1.6 Contribution to knowledge

This research has contributed to the field of prosthetic manufacture and composite AM through several novel findings and methodological advancements. These contributions are summarised below:

Development of a Predictive Model for Mechanical Properties

A significant contribution of this research is the development of a predictive model capable of estimating the stiffness and energy efficiency of composite AM paediatric prosthetic feet. This model, based on log-log relationships and validated with experimental data, enables the precise tailoring of fabrication parameters to achieve desired mechanical outcomes. The model not only predicts outcomes but also allows for reverse engineering, providing parameter configurations required to meet specific performance criteria. This advancement represents a transformative step toward performance-driven design in prosthetic production via AM.

Validation of Composite Additive Manufacturing for Dynamic Response Prosthetics

This study demonstrates that composite AM is capable of producing paediatric prosthetic ankle-foot devices that meet the dynamic response classification as defined by AOPA standards. The AM prosthetic feet successfully met the displacement and energy efficiency thresholds for both the keel and heel, validating their suitability for high-performance applications. This finding establishes the feasibility of using AM as an alternative to traditional methods, expanding the accessibility of dynamic response prosthetics to underserved populations.

Impact of Individual Parameters on Mechanical Performance

The research has provided detailed insights into how individual parameters, such as reinforcement layers, wall thickness, and fibre orientation, influence the stiffness and hysteresis of AM paediatric prosthetic feet. By systematically analysing these parameters, this study identified statistically significant factors with strong correlations to mechanical outcomes.

Understanding the Role of Environmental Factors

This research highlighted the impact of environmental conditions, specifically humidity, on the mechanical properties of AM paediatric prosthetic feet. The results demonstrated significant reductions in stiffness and hysteresis efficiency due to moisture absorption, emphasising the need to account for environmental factors in material selection, design, and storage strategies. This contribution informs the development of protective measures, such as coatings and controlled environments, to mitigate environmental degradation.

Cost-Effective and Scalable Manufacturing

The research highlights the efficiency and cost-effectiveness of composite AM in producing paediatric prosthetic feet. The ability to produce a dynamic response prosthetic foot in under 24 hours at a fraction of the cost of traditional manufacturing highlights the transformative potential of this approach. This scalability and affordability could significantly improve the accessibility of high-performance prosthetics for paediatric users, especially in resource-constrained settings.

Advanced Understanding of Additive Manufacturing for Prosthetics

Finally, this research provided an overview for evaluating and optimising composite AM for paediatric prosthetics. It integrated advanced testing methodologies, predictive modelling, and parametric analysis, offering a comprehensive approach to understanding and improving the mechanical and functional properties of AM prosthetic devices.

In summary, this research has made substantial contributions to the fields of composite AM and prosthetic manufacture, advancing knowledge in predictive modelling, parameter optimisation, environmental impacts, and the feasibility of composite AM as a scalable and cost-effective solution for dynamic response paediatric prosthetics. These findings now provide a foundation for future innovations and improved access to high-quality prosthetic devices for children worldwide.

10.2 Research Limitations

While this work has demonstrated the feasibility of composite AM to create dynamic response paediatric prosthetic feet, there are limitations to be aware of. These limitations provide context for the findings and highlight areas that require further investigation to enhance the robustness and generalisability of the results.

10.2.1 Sample Size and Generalisability

One of the primary limitations of this research is the relatively small sample size used across the experimental studies. While efforts were made to ensure rigorous testing and statistical validation, a larger sample size would improve the robustness and accuracy of the findings. The mechanical testing of prosthetic samples was conducted on a limited number of parts, which may not fully capture the variability that could arise in a larger-scale manufacturing setting. Expanding the sample size in future studies would allow for greater confidence in the repeatability and accuracy of composite AM processes for prosthetic production.

10.2.2 Use of a Single Machine

The majority of the research was conducted using only one Markforged Mark Two technology. While this machine is a widely used and industry leading machine for composite AM, it does not account for the variability that may occur between different machines, brands, or models. Differences in extrusion systems, fabrication resolution, layer bonding mechanisms, and material handling could lead to variations in mechanical performance, dimensional accuracy, and repeatability. Future research should incorporate multiple technologies to assess whether the findings are consistent across different machines and manufacturing platforms, ensuring that the results are applicable beyond a single model.

10.2.3 Material Selection

The research was conducted using Onyx and continuous carbon fibre reinforcement, by Markforged (Markforged 2021). Whilst these materials demonstrate high mechanical performance, and are industry leading, they represent only a fraction of the available composite materials for AM. This research did not explore other reinforced polymers, alternative thermoplastics, or hybrid composites, which may offer better environmental resistance, improved energy return, or enhanced durability. Investigating a broader range of materials in future studies would help determine the most suitable material compositions for long-term prosthetic use.

10.2.4 Predictive Modelling

The predictive modelling detailed in Chapter 8 was based on log-log relationships derived from experimental data, which were limited to the tested range of parameters. The models demonstrated high accuracy within this range, however they may not be accurate for parameter values outside the tested conditions. Further validation with expanded datasets would provide increased robustness of the model. The model also assumes linear relationships, which may not be true for complex, nonlinear behaviours in composite AM materials.

10.2.5 Real-World Validation and Clinical Testing

This study focused on the quantitative evaluation of mechanical properties of AM manufactured prosthetic feet and has not investigated any clinical evaluation with users. While the results demonstrate that composite AM can achieve dynamic response classification based on AOPA standards, fatigue testing and real-world testing with paediatric prosthetic users would be required to address factors such as comfort, usability, and long-term durability in real-world settings.

10.2.6 Limitations Summary

Despite these limitations, this research has provided a comprehensive understanding of how composite AM can be beneficial in paediatric prosthetic design and manufacture. Although addressing these limitations in future studies will increase reliability, scalability, and understanding of use in real-world applications. Expanding sample sizes, incorporating multiple machines, evaluating alternative materials, conducting long-term environmental testing, and integrating clinical trials will strengthen the validity of AM as a production method for paediatric prosthetics. These future investigations will not only improve mechanical performance and durability but also ensure that AM prosthetic devices are clinically viable, accessible, and optimised for paediatric users in diverse real-world settings.

10.3 Conclusion

This thesis has advanced the field of composite AM and prosthetic design by systematically addressing the potential of AM to produce dynamic response paediatric prosthetic feet. By integrating material and process repeatability and accuracy research, parametric analysis, predictive modelling, and experimental validation, this research has provided a comprehensive framework for understanding and optimising the manufacturing of prosthetic devices for children.

The primary research question, “Is composite additive manufacturing capable of producing a dynamic response paediatric prosthetic ankle-foot device?” has been answered. Through rigorous testing based on ISO 10328 and AOPA standards, it was demonstrated that composite AM prosthetic feet meet the dynamic response classification. The keels and heels successfully achieved the required displacement and energy efficiency thresholds. These findings validate composite AM as a viable alternative to traditional methods, opening avenues for cost-effective, scalable, and accessible solutions for paediatric prosthetics.

A secondary research question explored the repeatability, reliability, and mechanical integrity of composite AM processes. This study showed that composite AM offers consistent dimensional accuracy and mechanical properties, as evidenced by repeatability tests and validation against predictive models. Parameters such as reinforcement layers, wall thickness, and fibre orientation were identified as critical factors influencing stiffness and energy efficiency, while predictive modelling provided a robust tool for parameter optimisation. The predictive model demonstrated accuracy in replicating real-world outcomes and the capability to reverse-engineer parameter configurations to meet desired mechanical properties.

This research has further contributed to understanding the environmental factors affecting composite materials, such as humidity, which was shown to degrade mechanical properties over time. These findings underscore the need for protective measures, such as coatings or controlled storage, to maintain the longevity and performance of AM prosthetics.

The comparative analysis with the Ossur Vari-Flex Junior highlighted the feasibility of matching the mechanical properties of industry-standard prosthetics using AM. By utilising the predictive models, this study demonstrated the specific parameter adjustments required to replicate the stiffness and energy efficiency of the Ossur Vari-Flex Junior, demonstrating the adaptability and precision of composite AM producing dynamic response paediatric prosthetic solutions.

The efficiency and cost-effectiveness of AM were another significant outcome of this research. The ability to produce dynamic response prosthetics in under 24 hours at a fraction of the cost of traditional manufacturing has the potential to revolutionise access to dynamic response paediatric prosthetics.

When compared to recent studies such as Al Thahabi et al. (Al Thahabi et al. 2025), who also explored the use of continuous fibre-reinforced additive manufacturing (CFRAM) for dynamic prosthetic feet, this thesis presents complementary findings. Both studies highlight the potential of additively manufactured composite structures to achieve acceptable ESAR performance at significantly lower cost and weight compared to commercial alternatives. However, while Al Thahabi et al. validated their designs against adult ESR criteria using finite element simulations and multiple prototypes, this thesis extends the application specifically to paediatric users and introduces a predictive modelling framework that successfully minimises the number of physical prototypes required. While both approaches underscore the importance of CFR layer placement and reinforcement distribution, this thesis uniquely integrates these design decisions with a modelling-driven manufacturing workflow that reduces prototyping iterations. Future research could build on both studies by integrating fatigue testing and cyclic loading to assess long-term durability and viability.

In conclusion, this thesis has laid a solid foundation for the use of composite AM in paediatric prosthetic design and manufacture, demonstrating its feasibility, scalability, and adaptability. The methodologies, models, and findings presented in this work provide a roadmap for future innovations in prosthetic manufacturing, enabling tailored, high-performance solutions that improve the mobility and quality of life for children with lower-limb absence. By advancing the knowledge of composite AM within the applications to prosthetics, this research represents a significant step toward a more inclusive and accessible future for paediatric prosthetic care.

10.4 Proposed Further Work

Whilst this research has demonstrated the feasibility of using composite AM to produce dynamic response paediatric prosthetic feet, several areas require further investigation to ensure the long-term reliability, durability, and performance of these devices in real-life scenarios.

10.4.1 Fatigue Testing for Prolonged Usage

Fatigue testing is a critical next step to evaluate how composite AM prosthetics perform under extended cyclic loading, replicating prolonged usage in everyday life. The dynamic loads experienced during activities such as walking, running, and jumping over time can lead to material fatigue, impacting the mechanical properties and overall reliability of the prosthetic device. Future work should involve subjecting these prosthetics to repeated stress cycles to assess wear, deformation, and failure modes. This data will provide valuable insights into the lifespan of these devices and identify potential design or material improvements to enhance durability.

10.4.2 Environmental Conditions and Protective Measures

This research has demonstrated the significant impact of environmental factors, particularly humidity, on the mechanical properties of AM paediatric prosthetics. The findings from Chapter 7 revealed that stiffness and hysteresis efficiency degrade over time due to moisture absorption, but this degradation begins to stabilise after approximately 90 days. This raises a critical question for future work: Can the prosthetic foot still achieve dynamic response classification after natural environmental degradation has occurred, without the need for protective measures? To address this, future research should investigate whether the AM prosthetic, after being exposed to real-world environmental conditions for an extended period, can still meet the AOPA classification thresholds for dynamic response. Conducting post-exposure mechanical testing after the stabilisation period (e.g., beyond 90 days) would provide valuable insights into whether the prosthetic remains functional within acceptable performance limits or if degradation compromises its ability to store and return energy efficiently. This will determine whether environmental exposure alone requires design modifications or if the properties of the composite materials are sufficient to maintain long-term dynamic response functionality.

Future work should explore potential protective strategies to mitigate the effects of environmental degradation and extend the lifespan of these prosthetics. Protective coatings, sealing processes, and material treatments could be evaluated for their effectiveness in preventing moisture absorption while maintaining flexibility and energy return. Investigating alternative composite materials with increased resistance to humidity and temperature fluctuations is another important avenue of study. Beyond humidity, further research should assess how temperature extremes, both high and low, can affect the mechanical behaviour of AM prosthetics. Real-world applications require these devices to withstand a range of environmental conditions, from heat exposure in summer months to cold-induced brittleness in winter conditions. Controlled testing under varying temperature conditions would provide a more comprehensive understanding of the prosthetic's long-term performance and identify any necessary design adaptations.

10.4.3 Customisation for User Variability

Future work could also explore how AM can be used to provide greater customisation of paediatric prosthetic feet. This includes adjusting parameters to account for variability in user weight, activity levels, and specific biomechanical requirements. By integrating user-specific data into the design process, it is possible to create bespoke prosthetics that optimise comfort, mobility, and energy efficiency for each individual.

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APPENDICES

Appendix 1 – Research Ethics Checklists

Research Ethics Checklist

Bournemouth University

About Your Checklist	
Ethics ID	39838
Date Created	13/10/2021 10:32:29
Status	Approved
Date Approved	13/10/2021 11:51:44
Risk	Low

Researcher Details	
Name	Abigail Batley
Faculty	Faculty of Science & Technology
Status	Postgraduate Research (MRes, MPhil, PhD, DProf, EngD, EdD)
Course	Postgraduate Research - FST
Have you received funding to support this research project?	No

Project Details	
Title	Facilitators and barriers for participation in sports and physical activity for children with lower limb absence: A Systematic Review
Start Date of Project	01/06/2021
End Date of Project	31/12/2021
Proposed Start Date of Data Collection	08/06/2021
Original Supervisor	Philip Sewell
Approver	Yi Huang
Summary - no more than 600 words (including detail on background methodology, sample, outcomes, etc.)	
A systematci literature reviewto aid PhD research.	

Filter Question: Is your study solely literature based?

Additional Details	
Will you have access to personal data that allows you to identify individuals which is not already in the public domain?	No
Will you have access to confidential corporate or company data (that is not covered by confidentiality terms within an agreement or separate confidentiality agreement)?	No

Storage, Access and Disposal of Research Data	
Where will your research data be stored and who will have access during and after the study has finished.	
All data is currently stored using a Bournemouth University One Drive account, where the research has sole access during and after the review has been concluded.	
Once your project completes, will your dataset be added to an appropriate research data repository such as BORDaR, BU's Data Repository?	Yes

Research Ethics Checklist

About Your Checklist	
Ethics ID	45762
Date Created	15/09/2022 12:23:38
Status	Approved
Date Approved	15/09/2022 13:31:35
Risk	Low

Researcher Details	
Name	Abigail Batley
Faculty	Faculty of Science & Technology
Status	Staff
Course	Staff - FST
Have you received funding to support this research project?	No

Project Details	
Title	3D Printed Tensile Tests
Start Date of Project	01/08/2022
End Date of Project	01/08/2023
Proposed Start Date of Data Collection	01/08/2022
Approver	Research Ethics Panel
Summary - no more than 600 words (including detail on background methodology, sample, outcomes, etc.)	
Conducting tensile tests on 3D printed composite dog bone samples to analyse matertial properties.	

None of the filter questions apply to my study

I am confirming that my proposed project does not:

- Involve human participants
- Involve the use of human tissue
- Involve medical research requiring NHS ethical / REC Approval
- Involve the use of animals (or tissues/fluids derived from animals)
- Involve access to identifiable personal data for living individuals not already in the public domain
- Involve increased danger of physical or psychological harm for researcher(s) or subject(s)

- Raise any ethical issues associated with the use of genetically modified organisms

On this basis, my proposed project does not require a formal ethics review.

If any changes to the project involve any of the criteria above, I undertake to resubmit the project for formal ethical approval.

Bournemouth University

Research Ethics Checklist

About Your Checklist	
Ethics ID	52025
Date Created	02/08/2023 12:22:28
Status	Approved
Date Approved	03/08/2023 11:28:56
Risk	Low

Researcher Details	
Name	Abigail Batley
Faculty	Faculty of Science & Technology
Status	Staff
Course	Staff - FST
Have you received funding to support this research project?	No
Please list any persons or institutions that you will be conducting joint research with, both internal to BU as well as external collaborators.	Richard Glithro, Bryce Dyer, Philip Sewell, Diogo Monntalvao

Project Details	
Title	Parametric Study. 3D printing compression study.
Start Date of Project	31/07/2023
End Date of Project	31/12/2023
Proposed Start Date of Data Collection	28/08/2023
Approver	Research Ethics Panel
Summary - no more than 600 words (including detail on background methodology, sample, outcomes, etc.)	
Compression testing parametric study on 3D printed composites samples to analyse how different printing parameters affect the components mechcnial properties.	

None of the filter questions apply to my study

I am confirming that my proposed project does not:

- Involve human participants
- Involve the use of human tissue

- Involve medical research requiring NHS ethical / REC Approval
- Involve the use of animals (or tissues/fluids derived from animals)
- Involve access to identifiable personal data for living individuals not already in the public domain
- Involve increased danger of physical or psychological harm for researcher(s) or subject(s)
- Raise any ethical issues associated with the use of genetically modified organisms

On this basis, my proposed project does not require a formal ethics review.

If any changes to the project involve any of the criteria above, I undertake to resubmit the project for formal ethical approval.

Bournemouth University

Research Ethics Checklist

About Your Checklist	
Ethics ID	58623
Date Created	28/05/2024 11:40:11
Status	Approved
Date Approved	30/05/2024 18:31:26
Risk	Low

Researcher Details	
Name	Abigail Batley
Faculty	Faculty of Science & Technology
Status	Staff
Course	Staff - FST
Have you received funding to support this research project?	No

Project Details	
Title	Effect of humidity on the stiffness and hysteresis of composite 3D printed paediatric prosthetic foot coupon samples.
Start Date of Project	08/01/2024
End Date of Project	07/10/2024
Proposed Start Date of Data Collection	08/01/2024
Approver	Research Ethics Panel

Summary - no more than 600 words (including detail on background methodology, sample, outcomes, etc.)

Compression testing on composite 3D Printed samples to assess how ageing and humidity affects the mechanical properties of the samples.

None of the filter questions apply to my study

I am confirming that my proposed project does not:

- Involve human participants
- Involve the use of human tissue
- Involve medical research requiring NHS ethical / REC Approval
- Involve the use of animals (or tissues/fluids derived from animals)
- Involve access to identifiable personal data for living individuals not already in the public domain

- Involve increased danger of physical or psychological harm for researcher(s) or subject(s)
- Raise any ethical issues associated with the use of genetically modified organisms

On this basis, my proposed project does not require a formal ethics review.

If any changes to the project involve any of the criteria above, I undertake to resubmit the project for formal ethical approval.

Bournemouth University

Research Ethics Checklist

About Your Checklist	
Ethics ID	63448
Date Created	28/02/2025 14:52:14
Status	Approved
Date Approved	04/03/2025 13:50:37
Risk	Low

Researcher Details	
Name	Abigail Batley
Faculty	Faculty of Science & Technology
Status	Postgraduate Research (MRes, MPhil, PhD, DProf, EngD, EdD)
Course	Postgraduate Research - FST
Have you received funding to support this research project?	No

Project Details	
Title	Full prostehtic compression testing
Start Date of Project	01/09/2020
End Date of Project	31/08/2025
Proposed Start Date of Data Collection	01/03/2024
Original Supervisor	Philip Sewell
Approver	Kyungjoo Cha

Summary - no more than 600 words (including detail on background methodology, sample, outcomes, etc.)

Compression testing on a full 3D printed prosthetic foot to analyse the mechcanical properties.

None of the filter questions apply to my study

I am confirming that my proposed project does not:

- Involve human participants
- Involve the use of human tissue
- Involve medical research requiring NHS ethical / REC Approval
- Involve the use of animals (or tissues/fluids derived from animals)
- Involve access to identifiable personal data for living individuals not already in the public domain

- Involve increased danger of physical or psychological harm for researcher(s) or subject(s)
- Raise any ethical issues associated with the use of genetically modified organisms

On this basis, my proposed project does not require a formal ethics review.

If any changes to the project involve any of the criteria above, I undertake to resubmit the project for formal ethical approval.

Bournemouth University

About You & Your Assessment	
Name	Abigail Batley
Email	abatley@bournemouth.ac.uk
Your Faculty/Professional Service	Faculty of Science and Technology
Is Your Risk Assessment in relation to Travel or Fieldwork?	No
Status	Approved
Date of Assessment	29/09/2023
Date of the Activity/Event/Travel that you are Assessing	06/10/2023
In relation to	Other

What, Who & Where	
Describe the activity/area/process to be assessed	Research Activities using the Keyence Microscope
Locations/Description for which the assessment is applicable	Christchurch House labs
Persons who may be harmed	Staff

Hazard & Risk	
Hazard	Working in a lab enviroment
Control Measure(s) for Working in a lab enviroment: Take frequent breaks from use of machinery, every 30 minutes Use correct PPE at all times in the lab (lab coat and safety glasses) Follow lab SOP at all times Conduct the lab induction (already been condcuted)	
Hazard	Working Position
Control Measure(s) for Working Position: Use a height adjustable chair at all times when using the microscope to ensure correct posture is always maintained	
Additional Information	

Review & Approval	
How likely is the event to occur?	
How severe will the injuries be?	
Any notes or further information you wish to add about the assessment	
Names of persons who have contributed	Abigail Batley
Approver Name	Rob Gardiner
Approver Job Title	Innovation Center Manager
Approver Email	rgardiner@bournemouth.ac.uk
Review Date	

Uploaded documents
No document uploaded

About You & Your Assessment	
Name	Abigail Batley
Email	abatley@bournemouth.ac.uk
Your Faculty/Professional Service	Faculty of Science and Technology
Is Your Risk Assessment in relation to Travel or Fieldwork?	No
Status	Approved
Date of Assessment	05/08/2024
Date of the Activity/Event/Travel that you are Assessing	05/08/2024
In relation to	Other

What, Who & Where	
Describe the activity/area/process to be assessed	Travel to Zwick Headquaters
Locations/Description for which the assessment is applicable	Bournemouth to Coventry
Persons who may be harmed	Staff

Hazard & Risk	
Hazard	Use of testing equipment
Control Measure(s) for Use of testing equipment: Wear correct PPE at all times. Conduct their health and safety and introduction briefings.	
Hazard	Car Travel
Control Measure(s) for Car Travel:	
Additional Information	

Review & Approval	
How likely is the event to occur?	
How severe will the injuries be?	
Any notes or further information you wish to add about the assessment	
Names of persons who have contributed	Abigail Batley
Approver Name	Roya Haratian
Approver Job Title	Deputy Head of Department
Approver Email	rharatian@bournemouth.ac.uk
Review Date	

Uploaded documents
No document uploaded

Appendix 2 – American Orthotic Prosthetic Association Prosthetic Foot Project

AOPA'S PROSTHETIC FOOT PROJECT

What It Is, What It Is Not, and What Patient Care Facility Providers/Practitioners Need to Know...

Dear AOPA Members:
We would like to take this opportunity to bring you up-to-date on the status of the **AOPA Prosthetic Foot Project.**

What It Is...

This project, which was begun in 2007 at the behest of the SADMERC, had as one of its goals to improve the accuracy and consistency of the coding of prosthetic feet through the development of standard tests that would validate the existence of certain features of a foot. The participating foot manufacturers provided the engineering input and assistance that allowed such tests to be created and subsequently carried out on a number of existing feet. Based upon the results of these tests, these feet were then categorized into specific recommended HCPCS codes. The second goal of the project was to deliver these results to Medicare in the hope that it would adopt these coding recommendations and the accompanying testing methodology.

What It Is Not...

At no time during this project did AOPA ever intend to develop clinical standards of care for these feet. The project's findings relate only to appropriate coding and do not speak to what foot is most clinically appropriate for a particular patient.

Also, at this time, this is a report/proposal from AOPA to CMS, nothing more and nothing less. **AOPA is NOT recommending that clinicians should use these recommended code descriptors and assignments for your current coding.** AOPA is informing everyone that at this point no one at CMS has given any indication whether the agency will agree with any, some or all of these recommendations in the report. It could be perilous for practitioners/patient care facility owners to misunderstand this, or to believe that this document comprises recommendations on coding that have been endorsed by either AOPA or CMS for purposes of coding TODAY.

What Patient Care Facility Providers/Practitioners Need to Know...

As we reported during the recent National Assembly in Orlando, the final report has been delivered to CMS and a face to face meeting is planned, during which AOPA will urge CMS to accept the findings of this report. While we are hopeful that CMS will accept the report's findings, there are no guarantees. Therefore, unless and until CMS formally agrees to adopt these recommendations, they should not be considered as accepted by CMS. As always, unless these recommendations are adopted and published by CMS, through the PDAC, **your choice of appropriate coding for prosthetic feet remains your decision and responsibility.** In addition, if CMS does decide to accept these findings, ***it is very unlikely that this action would be retroactive to dates of service prior to its decision.***

We hope that you will take a moment to review the full report. We will continue to keep you abreast of new developments, but if you have any questions, please contact Kathy Dodson at *kdodson@aopanet.org* or Joe McTernan at *jmcternan@aopanet.org.*

AOPA Prosthetic Foot Project Report
September, 2010
Introduction

The American Orthotic and Prosthetic Association (AOPA) is the national trade association for patient care facilities, manufacturers and educational institutions in the field of orthotics and prosthetics. With nearly 2000 corporate and affiliate members, it serves as the primary non-federal source for coding guidance for the field.

In this capacity AOPA has for many years offered to its members and to the orthotic and prosthetic field at large advice on the appropriate Medicare Healthcare Common Procedure Code System (HCPCS) codes for prosthetic feet, among other devices and components. However, the basis for these recommendations, which are not and have never been binding on O&P facilities, has been the clinical and coding experience, training and expertise of the members of the AOPA Coding & Reimbursement Committee (CRC). The field lacked a standardized way to test prosthetic feet to assess their mechanical abilities and thus assign them most confidently to the appropriate HCPCS codes.

AOPA and its members concluded that it benefits the industry as a whole to have clear and reproducible testing standards, and it benefits the industry to establish clarity in the application of codes so that practitioners and O&P facilities can prescribe the feet with greater confidence regarding their conclusions as to which HCPCS code is applicable, appropriate and consistent with the prevailing rationale for Medicare reimbursement. This form of testing and reporting is good for the industry and enhances overall quality and reliability in the industry.

Another impetus to carry out this project came from the Centers for Medicare and Medicaid Services Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC.) In 2007 AOPA was approached by SADMERC staff concerning their desire to better classify existing prosthetic feet into appropriate HCPCS codes. To carry this out, they proposed a meeting with prosthetic foot manufacturers to gather input prior to making code assignments. AOPA offered to facilitate a meeting of manufacturers to discuss prosthetic foot coding.

Goals of this Project

Therefore, to gather information to assist the SADMERC and to remedy the absence of standardized coding criteria, the CRC created a Prosthetic Foot Project Task Force, made up of CRC members and staff, with the following objectives:

- Creation of "Context Based Code Descriptors", which support and further describe terminology in the code set
- Creation of practical testing guidelines which would allow reproducible testing results within testing parameters of most foot/ankle product manufacturers
- Creation of testing thresholds which differentiate products into specific mechanical functions and therefore codes
- Creation of a product to code(s) assignment

Methodology

To accomplish this, AOPA invited prosthetic foot manufacturers to participate in a workgroup to achieve these objectives, and almost all chose to be part of this effort. A series of meetings over a three year period took place, involving the aforementioned manufacturers and the Prosthetic Foot Project Task Force. This collective group, the AOPA Prosthetic Foot Manufacturers Workgroup, reviewed the Task Force's initial proposals regarding Context Based Code

Descriptors, made appropriate revisions and then developed testing mechanisms that would validate each mechanical feature defined in the Descriptors. This same group then carried out product testing.

This testing consisted of a "round robin" series of tests where all feet were tested by all manufacturers that had appropriate equipment to carry out such tests. In every case, the same specific foot was tested by all participating testers, through shipping the same device from one manufacturer to another. In addition, all testers used the same protocols, agreed upon by the Workgroup, when developing the testing mechanisms. Once testing was completed, the results allowed the Workgroup to assign specific feet to specific HCPCS codes. Also, participating manufacturers were offered the option to have independent testing done and were invited to sign an acknowledgement regarding their participation in the project (see pages 36 and 38 for a full copy of the acknowledgement and a disclaimer regarding future use of this report).

Note: Testing thresholds were established based on mechanical/functional properties of commercially available products at the time of the testing and are not meant to represent clinical or safety standards of individual feet when used for specific patients

Going Forward and Sunset Date

Initial testing often yielded the need to revise testing guidelines to accurately measure mechanical features. It is important to note that product testing continues to be refined and the testing guidelines and thresholds are subject to future revision as more data is obtained and new products come on the market.

In addition, orthotics and prosthetics is a field where technology and advances in science and technique are relatively frequent. In recognition of this, we are establishing a specific sunset provision for the usefulness of this document. Specifically, in the absence of either a revision to the document or a specific action by AOPA to extend the sunset date, the usefulness of this document will expire three (3) years from the date of publication, specifically, on (date to be inserted upon final publication).

Contents of This Document

Contained in this document are the following:

Section I. Context Based Descriptors

In order to clarify the precise meaning of the terms which appear within each HCPCS code descriptor, the workgroup created Context Based Descriptors. These descriptors further define certain key terms to insure consistent application. For example, a term such as "rigid" has a different application within different contexts or when applied to different types of devices. The term "rigid" when used in reference to a prosthetic foot has a different meaning than when describing that attribute on a spinal orthotic device. Thus, the following Context Based Descriptors can only be applied within the context of prosthetic foot and ankle systems.

1. **Axial Torque Absorbing**: The ability of a prosthetic component to rotate along the longitudinal axis (axial axis) under torsional load.

2. **Cushion Heel**: The heel portion of a prosthetic foot that deflects under load without significant energy return.

3. **Dynamic Response**: The elastic property of a component designed to deflect under load and has the ability to store and return significant energy.

4. **Dynamic Response Prosthetic Pylon**: A structural support that connects two prosthetic components (such as a foot, foot adapter, ankle, socket, knee, or other attribute component) and deflects under load and has the ability to store and return significant energy.

5. **Flexible**: The elastic property of a component designed to deflect under load without the ability to store and return significant energy.

6. **Multiaxial**: Motion around two or more axes of rotation.

7. **Pylon**: A structural support component that connects to the foot or two other prosthetic components such as a foot, foot adapter, ankle, socket, and knee. The pylon can be a separate component or it can be part of another component.

8. **Rigid**: No significant deflection under load.

9. **Single Axis**: Motion around one fixed axis of rotation.

10. **Vertical Shock Absorbing Feature**: The ability of a prosthetic component to compress along its longitudinal axis under axial load.

Section II. Test Descriptions and Methodology

These tests are of a mechanical nature and are designed to assist individuals in determining which HCPCS L codes should be recommended for specific, prosthetic feet, based upon the specific attributes of the prosthetic foot and the characteristics described in the code. The thresholds were developed within the constraints of the existing coding system. These guidelines are designed to relate to the mechanical characteristics of the foot and are not meant to measure clinical effectiveness of any device.

All tests are to be conducted using a standard 27 L foot for an A 80 patient. All tests should be performed with common practice methods and at normal conditions such as temperature, humidity, etc.

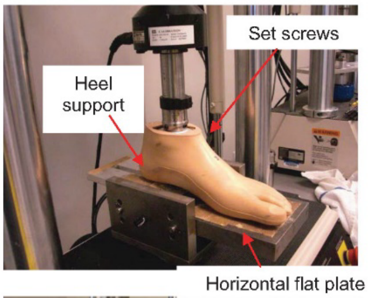
Keel Test

Test Procedure: Dynamic Keel Test

Scope: This test procedure defines test setup and method for evaluating a foot design for keel/toe dynamics. The results of this test define whether the keel is rigid, flexible or dynamic.

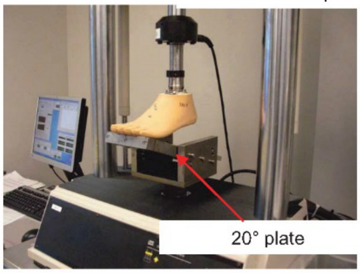
Step 1: Foot Alignment Set-Up

- Place foot on a horizontal plate with the appropriate heel support to match the heel height of the foot.
- Bring the receiver close enough to the foot to allow you to loosely attach the set screws.
- Apply a 50N load to the device and tighten the set screws.
- Remove the load from the device.
- The foot is now aligned for keel, heel and vertical displacement testing.



Step 2: Run the Test 2x

- An angle plate of 20° is positioned under the keel.
- Load the keel to 50N to settle the machine.
- Zero the displacement.
- Load the keel to 1230N and return to 50N.
  - The loading rate is 200N/s.
  - There is no hold at the peak load.
- Zero the displacement.
- Load the keel to 1230N and return to 50N.
  - The loading rate is 200N/s.
  - There is no hold at the peak load.
- Record load and displacement of this run using a minimum of 25 points/sec.

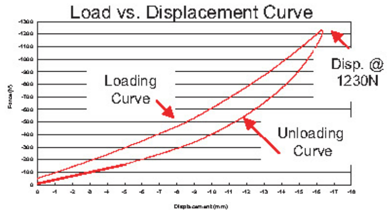


Step 3: Evaluate the Data

- Use the data from cycle #2 to:
  - Determine the displacement at 1230N
  - Calculate the % energy returned using the trapezoidal method to determine the area under the loading & unloading curves.

$$\int_a^b f(x)\,dx \approx (b-a)\frac{f(a)+f(b)}{2}.$$

***Figure 5:* Trapezoidal method**



Step 4: Compare Results to Keel Classification Criteria

Keel Type	Displacement @ 1230N	% Return
Rigid	<25mm	NA
Flexible	≥25mm	<75%
Dynamic	≥25mm	≥75%

NOTE: These tests are of a mechanical nature and are designed to assist individuals in determining which HCPCS L codes should be recommended for specific, prosthetic feet, based upon the specific attributes of the prosthetic foot and the characteristics described in the code. The thresholds were developed within the constraints of the existing coding system. These guidelines are designed to relate to the mechanical characteristics of the foot and are not meant to measure clinical effectiveness of any device.

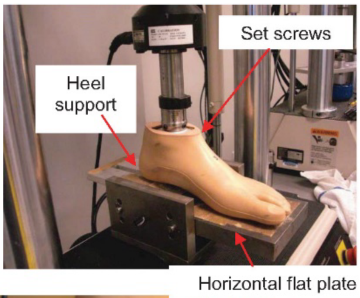
Heel Test

Test Procedure: Dynamic Heel Test

Scope: This test procedure defines test setup and method for evaluating a foot design for heel dynamics. The results of this test define whether the heel is dynamic or cushioned. This test is only done on foot designs that have qualified as “dynamic keel”.

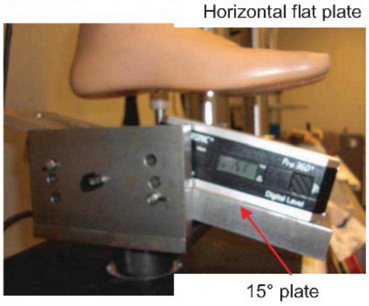
Step 1: Test Setup

- Place foot on a horizontal plate with the appropriate heel support to match the heel height of the foot.
- Bring the receiver close enough to the foot to allow you to loosely attach the set screws.
- Apply a 50N load to the device and tighten the set screws.
- Remove the load from the device.
- The foot is now aligned for keel, heel and vertical displacement testing.



Step 2: Run the Test 2x

- An angle plate of 15° is positioned under the heel.
- Load the heel to 50N to settle the machine.
- Zero the displacement.
- Load the heel to 1230N and return to 50N.
  - The loading rate is 200N/s.
  - There is no hold at the peak load.
- Zero the displacement.
- Load the heel to 1230N and return to 50N.
  - The loading rate is 200N/s.
  - There is no hold at the peak load.
  - Record load and displacement of this run using a minimum of 25 points/sec.

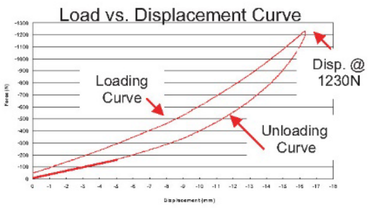


Step 3: Evaluate Data

- Use the data the second run of Step 2 to:
  - Determine the displacement at 1230N.
  - Calculate the % energy returned using the trapezoidal method to determine the area under the loading & unloading curves.

$$\int_a^b f(x)\,dx \approx (b-a)\frac{f(a)+f(b)}{2}.$$

***Figure 5:* Trapezoidal method**



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Step 4: Compare Results to Heel Classification Criteria

Heel Type	Displacement @ 1230N	% Return
Dynamic	≥13mm or pass % Return at heel	≥82% or pass Displacement at heel
Cushioned	Does not meet Displacement and/or % Return criteria for dynamic heel.	

NOTE: These tests are of a mechanical nature and are designed to assist individuals in determining which feet should be assigned to specific HCPCS L codes, based upon the specific attributes of the prosthetic foot and the characteristics described in the code. The thresholds were developed within the constraints of the existing coding system. These guidelines are designed to relate to the mechanical characteristics of the foot and are not meant to measure or evaluate clinical safety or effectiveness of any device.

Appendix 3 – Predictive Modelling Equations

Logarithmic Equation:

$$\log Y = m \times \log(x) + \log(c)$$

$$Y \propto x^a$$

$$Y = x^a \times 10^c$$

Stiffness

F = Force $Y = F^{0.18} \times 10^{1.29}$

L = Fibre Layers $Y = L^{0.49} \times 10^{0.96}$

W = Wall Layers $Y = W^{-0.18} \times 10^{1.85}$

$$Y \propto F^{0.18} \times L^{0.49} \times W^{-0.18}$$

$$Y = K \times F^{0.18} \times L^{0.49} \times W^{-0.18}$$

1.2 Sample:

Y = 60.96

F = 557

L = 40

W = 2

$$60.96 = K \times 557^{0.18} \times 40^{0.49} \times 2^{-0.18}$$

$$K = \frac{60.96}{557^{0.18} \times 40^{0.49} \times 2^{-0.18}}$$

$$K = 3.63$$

Efficiency

F = Force $Y = F^{-0.39} \times 10^{2.95}$

L = Fibre Layers $Y = L^{0.17} \times 10^{1.59}$

D = Fibre Distribution $Y = D^{0.03} \times 10^{1.83}$

W = Wall Layers $Y = W^{-0.08} \times 10^{1.89}$

$$Y \propto F^{-0.39} \times L^{0.17} \times D^{0.03} \times W^{-0.08}$$

$$Y = K \times F^{-0.39} \times L^{0.17} \times D^{0.03} \times W^{-0.08}$$

1.2 Sample:

Y = 74

F = 557

L = 40

D = 10

W = 2

$$74 = K \times 557^{-0.39} \times 40^{0.17} \times 10^{0.03} \times 2^{-0.08}$$

$$K = \frac{74}{557^{-0.39} \times 40^{0.17} \times 10^{0.03} \times 2^{-0.08}}$$

$$K = 459.04$$

Appendix 4 – Predictive Model Validation Equations

Predictive model validation:

$$\text{MAPE} = \frac{1}{n}\sum_{i=1}^{n}\left|\frac{At-Ft}{At}\right|$$

Stiffness

Sample Number	Experimental Values	Predictive Model Values
1.1	59.01	59.29
1.2 (Control)	60.96	60.96
1.3	61.63	62.06
1.4	62.39	62.51
2.2	75.59	74.31
2.3	82.95	85.58
2.4	89.95	95.49
2.5	109.87	104.44
6.1	71.42	69.12
6.3	58.8	56.55
6.4	54.97	53.66

$$\text{MAPE} = \frac{1}{11}\sum_{i=1}^{n}\left|\frac{At-Ft}{At}\right|$$

t	A	F	A - F	(A - F) ÷ A	|(A - F) ÷ A|
1	59.01	59.29	-0.28	-0.0047449584816133	0.0047449584816133
2	60.96	60.96	0	0	0
3	61.63	62.06	-0.43	-0.0069771215317216	0.0069771215317216
4	62.39	62.51	-0.12	-0.0019233851578778	0.0019233851578778
5	75.59	74.31	1.28	0.016933456806456	0.016933456806456
6	82.95	85.58	-2.63	-0.03170584689572	0.03170584689572
7	89.95	95.49	-5.54	-0.061589772095609	0.061589772095609
8	109.87	104.44	5.43	0.049422044234095	0.049422044234095
9	71.42	69.12	2.3	0.032203864463736	0.032203864463736
10	58.8	56.55	2.25	0.038265306122449	0.038265306122449

11	54.97	53.66	1.31	0.023831180643988	0.02383118064398

Sum of |(A - F) ÷ A|:

0.0047449584816133 + 0 + 0.0069771215317216 + 0.0019233851578778 + 0.016933456806456 + 0.03170584689572 + 0.061589772095609 + 0.049422044234095 + 0.032203864463736 + 0.038265306122449 + 0.023831180643988 = 0.26759693643326

$$\text{MAPE} = \frac{100 \times 0.26759693643326}{11}$$

MAPE = 2.4326994221206

Efficiency

Sample Number	Experimental Values	Predictive Model Values
1.1	78.5	78.31
1.2 (Control)	73.88	73.88
1.3	71.33	70.88
1.4	69.75	69.79
2.2	79.00	79.25
2.3	82.00	83.29
2.4	86.00	86.57
2.5	89.80	89.35
3.2	71.00	72.19
3.3	75.00	75.60
3.4	76.30	77.37
6.1	76.67	78.09
6.3	73.88	71.52
6.4	68.70	69.89

$$\text{MAPE} = \frac{1}{11}\sum_{i=1}^{n}\left|\frac{At-Ft}{At}\right|$$

t	A	F	A - F	(A - F) ÷ A	|(A - F) ÷ A|
1	78.5	78.31	0.19	0.0024203821656051	0.0024203821656051
2	73.88	73.88	0	0	0
3	71.33	70.88	0.45	0.0063087060142998	0.0063087060142998
4	69.75	69.79	-0.040000000000006	-0.00057347670250905	0.00057347670250905

5	79.00	79.25	-0.25	-0.0031645569620253	0.0031645569620253
6	82.00	83.29	-1.29	-0.015731707317073	0.015731707317073
7	86.00	86.57	-0.56999999999999	-0.0066279069767441	0.0066279069767441
8	89.80	89.35	0.45	0.0050111358574611	0.0050111358574611
9	71.00	72.19	-1.19	-0.016760563380282	0.016760563380282
10	75.00	75.60	-0.59999999999999	-0.0079999999999999	0.0079999999999999
11	76.30	77.37	-1.07	-0.014023591087811	0.014023591087811
12	76.67	78.09	-1.42	-0.01852093387244	0.01852093387244
13	73.88	71.52	2.36	0.031943692474283	0.031943692474283
14	68.70	69.89	-1.19	-0.017321688500728	0.017321688500728

Sum of |(A - F) ÷ A|:

0.0024203821656051 + 0 + 0.0063087060142998 + 0.00057347670250905 + 0.0031645569620253 + 0.015731707317073 + 0.0066279069767441 + 0.0050111358574611 + 0.016760563380282 + 0.0079999999999999 + 0.014023591087811 + 0.01852093387244 + 0.031943692474283 + 0.017321688500728 = 0.14640834131126

$$\text{MAPE} = \frac{100 \times 0.14640834131126}{11}$$

MAPE = 1.045773866509

Appendix 5 – Full Prosthetic Efficiency Predictions

Efficiency Predictions

F = Force $Y = F^{-0.39} \times 10^{2.95}$

L = Fibre Layers $Y = L^{0.17} \times 10^{1.59}$

D = Fibre Distribution $Y = D^{0.03} \times 10^{1.83}$

W = Wall Layers $Y = W^{-0.08} \times 10^{1.89}$

$$Y = K \times F^{-0.39} \times L^{0.17} \times D^{0.03} \times W^{-0.08}$$

Y = Average of experimental test results on AM Prosthetic Keel = 85.73%

F = 400

L = 154

D = 154

W = 1

$$K = \frac{85.73}{400^{-0.39} \times 154^{0.17} \times 154^{0.03} \times 1^{-0.08}}$$

$$K = 323.92$$

$$85.73 = 323.92 \times 400^{-0.39} \times ?^{0.17} \times ?^{0.03} \times 1^{-0.08}$$

Fibre Layers and Fibre Distribution	Efficiency Value
200	90.33%
205	90.78%
210	91.22%
215	91.65%
218	91.9%%
219	91.99%
220	92.07%

Fibre Layers and Distribution needed to match Ossur 92% efficiency = 218

Fibre Layers and Fibre Distribution	**Efficiency Value**
70	73.22%
75	74.24%
78	74.83%
79	75.02%
80	75.12%

Fibre Layers and Distribution needed for minimum dynamic response classification of 75% predicted efficiency = 79

Ossur Match Heel

F = Force $Y = F^{-0.39} \times 10^{2.95}$

L = Fibre Layers $Y = L^{0.17} \times 10^{1.59}$

D = Fibre Distribution $Y = D^{0.03} \times 10^{1.83}$

W = Wall Layers $Y = W^{-0.08} \times 10^{1.89}$

$$Y = K \times F^{-0.39} \times L^{0.17} \times D^{0.03} \times W^{-0.08}$$

Y = Average of experimental test results on AM Prosthetic Heel = 89.13%

F = 400

L = 138

D = 138

W = 1

$$K = \frac{89.13}{400^{-0.39} \times 138^{0.17} \times 138^{0.03} \times 1^{-0.08}}$$

$$K = 344.23$$

$$85.73 = 344.23 \times 400^{-0.39} \times ?^{0.17} \times ?^{0.03} \times 1^{-0.08}$$

Fibre Layers and Fibre Distribution	**Efficiency Value**
180	93.99%
185	94.51%
189	94.92%
190	95.02%

Fibre Layers and Distribution needed to match Ossur 95% efficiency = 190

Fibre Layers and Fibre Distribution	**Efficiency Value**
80	79.92%
85	80.90%
90	81.86%
91	82.01%
92	82.19%

Fibre Layers and Distribution needed for minimum dynamic response classification of 82% predicted efficiency = 91