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CARLOW

At the Heart of South Leinster

**Bespoke Rapid Manufacturing:**

An investigation into the application of additive manufacturing in the development of customised protection in sports equipment.

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## Abstract

The purpose of the Applied Research Masters was to investigate the role of Additive Manufacturing (AM) and digital technologies in the development of improved customised protection in sports equipment. Sporting injuries have become a major issue within today's health care sector with many injuries having long-term impacts and affecting health in later life. Poor body posture, caused by a sedentary lifestyle, was also identified as a major contributor in sports injuries.

Initial research established that the foot, as the foundation of the body, directly impacts on postural alignment and functional movement. Incorrect foot positioning causes instability, a key contributor to both upper and lower body injuries. The current solution for correcting poor foot posture are Foot Orthoses (FO). Preliminary research identified custom FO as a product area offering the greatest potential for exploring the range of possibilities provided by the application of AM and digital technologies.

The project was undertaken using a research through design approach. A review of the literature followed by key stakeholder interviews provided an understanding of the FO industry, digital technologies and AM techniques which led to the development of a focused design hypothesis.

*It is possible to design a product which supports the correct alignment of the foot, while also allowing its natural behaviour and function within the gait cycle, therefore improving full body alignment, assisting in injury prevention and offering support during play and rehabilitation.*

A combination of case studies, user trips and semi-structured interviews with medical practitioners within the field of physiotherapy, orthopaedics and podiatry provided insights into the current tools, techniques and processes involved in prescribing custom made FO devices. Finally, traditional design techniques were employed in the development of FO prototypes for additive manufacturing and subsequent design research evaluation. The overall research through design approach facilitated the investigation and evaluation of the integration of AM and digital technologies within the design, development and fabrication of customised FO.

Research findings show that current FO devices, produced using traditional fabrication methods, offer poor fit, limited movement and flexibility during sporting activities and provide inadequate support throughout the gait cycles associated with sporting activities.

The research programme identified and investigated numerous digital technologies and explored combinations most likely to advance and improve orthotic devices. The incorporation of digital technologies was found to offer many advantages over traditionally fabricated orthotic devices, and the project looked at how such technologies might help to improved fit; improve material selection; significantly reduce lead times; ensure cost – effectiveness; offer customer -focused solutions and enhance support and mechanical performance during sporting activities. The project also looked at how these digital technologies could be successfully integrated and implemented into existing medical practice for diagnosis, prescription and application.

The primary conclusion of the project is that existing integration of AM and digital technologies fail to exploit their full potential. The integration of AM and digital technologies can offer a more holistic approach in the diagnosis, prescription and application phase of FO. In the diagnosis phase, the implementation of digital technologies saves time, reduces waste and highlights key physical characteristics compared with traditional methods used by podiatrists. In the prescription phase, the scanned data assist in providing a more focused and tailored solution, improving overall fit and function. The use of multi-material AM techniques within the application phase broadened the range of material characteristics available and further assist the podiatrist, the fabricator and, in turn, the patient.

In summary, the integration of multiple digital technologies ensured a more user-focused solution for the design, development and fabrication of customised orthotics.

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## Glossary

<i>Ankle Foot Orthoses</i>	AFO
<i>Additive Manufacturing</i>	AM
<i>Computer Aided Design</i>	CAD
<i>Computer Aided Manufacturing</i>	CAM
<i>Direct Metal Printing</i>	DMP
<i>Design Research Society</i>	DRS
<i>Foot Orthosis</i>	FO
<i>Fused Deposition Modelling</i>	FDM
<i>Health Products Regulatory Authority</i>	HPRA
<i>Laser Sintering</i>	LS
<i>Laminated Object Manufacturing</i>	LOM
<i>Lateral Ankle Sprains</i>	LAS
<i>Medial Ligament Injuries</i>	MLI
<i>Orthoses and Prosthesis</i>	O&P
<i>Protective Sports Equipment</i>	PSE
<i>Research through Design</i>	RtD
<i>Selective Deposition Lamination</i>	SDL
<i>The Food and Drug Administration</i>	TFDA
<i>World Health Organisation</i>	WHO

## 1.0 Introduction

The primary objective of the Applied Research Master's study was to investigate the role of Additive Manufacturing (AM) and digital technologies in the development of improved customised protection in sports equipment. Recent developments in the area of Additive Manufacturing (AM) and 3D scanning technologies are creating a new landscape of bespoke design, manufacture and testing. The advancement of digital technologies and affordable CAD software has allowed designers to produce products tailor fitted to the end user. This project seeks to explore the role of AM and digital technologies in producing a more appropriate, sympathetic and engaging Protective Sports Equipment (PSE).

Before this study could commence it was necessary to identify an appropriate PSE category to investigate and to explore the role of AM and digital technologies in the design, development and fabrication of a unique form of customised protection in sports equipment. Review of the literature and expert interviews helped direct and focus the Research Masters project. Following the literature review, Foot Orthoses (FO) were identified as a PSE category offering the greatest capacity for exploring the role and potential of AM and digital technologies within the PSE industry.

On the basis of the literature and expert interviews, the findings generated highlighted that custom made FO is a proven medical solution used to correct lower body alignment and foot related issues. In effect, FO devices have the potential to reduce and prevent the frequency of movement related injuries. This premise led to the development of the following research questions:

- How can AM and digital technologies be successfully integrated and implemented into the existing medical practice of orthotics and how can these technologies ensure improvements and the advancement of orthotic design?
- How can the unique design capabilities of AM and digital technologies be fully utilised to ensure more user-focused solutions in the design, development, and fabrication of bespoke custom orthotics for all stakeholders?

- How can a product design approach influence and progress the art of custom orthotic supports to not only provide correct foot alignment but also ensuring the foot's natural function and behaviour throughout the gait cycle?

The scope of the study involved investigating the unique capabilities and advantages of AM and digital technologies in the diagnosis, prescription and application of FO solutions. Utilising traditional design techniques, product development of the FO was limited to testing for fit. Due to the time and material development constraints of the project, multiple product iterations and test for function were unachievable. To address the research questions, the researcher focused on the following objectives: investigation of the current tools, techniques and processes involved in the diagnosis, prescription and application phase of FO, exploration and evaluation of the integration of AM and digital technologies within the existing medical procedure of FO and, finally, an assessment and evaluation of the findings generated, to help inform future development of customised protective sports equipment.

This research study followed a Research through Design (RtD) approach. Research through Design is an action – reflection approach involving both theory and practice. Research through Design was selected as an appropriate method to help explore the critical issues associated with sports' injuries and the development of FO devices. This allowed the researcher to propose, research, develop and test AM solutions, best suited to prevent and/or protect against injury during sporting activities.

The overall thesis structure begins with the literature review demonstrating the researcher's acquired knowledge and understanding of the literature within this field and to demonstrate how the review helped to guide, inform and direct the Research Masters project.

The methodology chapter summarises the overall approach carried out during this project and includes an review of the identification, selection and implementation of appropriate project management and design methods used throughout the project.



The field research chapter documents a combination of user trips and expert interviews undertaken to explore and gain further insights into the current state of play and to become familiar with the tools, techniques and processes involved in prescribing custom-made FOs.

Following on, the design chapter documents the use of traditional design methods to propose solutions that not only offered physical solutions but proposed solutions that would integrate and take the fullest advantage of the unique capabilities of AM and digital technologies in the design, development, fabrication, testing and evaluation of an innovative and novel FO solution. The final chapters present and discuss the project findings, limitations and further recommendations and the conclusion outlines and summarises the key findings identified during this research project.

An infographic illustrating the entire process of this Research Masters project can be found in figure 14 on page 36.

## 2.0 Literature Review

### 2.1 Introduction

The aim of the literature review is to explore and establish the current research and knowledge of topics and areas of interest relating to the initial project working title:

*Bespoke Rapid Manufacturing; an investigation into the application of additive manufacturing in the development of customised protection in sports equipment.*

This literature review will demonstrate a developed understanding of the existing literature and knowledge in this field. The investigation of literature will be separated into four main topic areas: sports injuries, bespoke additive manufacturing, medical regulations of custom-made medical devices and design research methodologies. This approach will focus and synthesise the research, helping to answer the original project objectives. As a result, the overall approach will help to bring together knowledge from the disciplinary areas of human factors, health care, user behaviour, digital technologies and design.

The literature review has been divided into four chapters based on the research areas investigated. Chapter one will explore sports injuries, the most common type of injuries occurring within sporting scenarios and the reasons why they happen. This section aims to identify a suitable area of the body and product area to explore the use of Additive Manufacturing (AM) and digital technologies in the design, development, and fabrication of a new form of customised protection in sports equipment.

Chapter Two will discuss the role and importance of AM technology for individualised healthcare purposes. This chapter seeks to explore the advantages and qualities of AM technology for bespoke healthcare products. This chapter will identify gaps in knowledge and limitations of previous studies investigating the use of AM and digital technologies for healthcare products. In effect, this section will summarise the role of AM techniques for bespoke product development within the healthcare industry.

Chapter Three will focus on medical regulations, the classification of a custom-made device within the medical industry, the role of CE marking and the current manufacturing regime of custom made devices. This chapter will seek to identify the regulatory requirements for FO, to document the current process for designing and manufacturing custom-made medical devices and to identify and link areas within the existing process where digital and AM technologies can offer significant advantages over current practice.

In the final chapter, the objective is to identify a design research methodology appropriate for this particular study, to help explore the critical issues and problems associated with sports injury and to propose, research, develop and test solutions, incorporating digital and additive manufacturing techniques, that may prevent, and/or protect against, injury during a sporting activity.

## 2.2 Sport Injuries

### 2.2.1 Introduction.

The purpose of this literature review of sports injuries is to develop an understanding of the cause and impact of sports injuries, the use of Protective Sports Equipment (PSE) and to help identify an appropriate injury best suited to explore the use of Additive Manufacturing

and 3D scanning technologies. This section of the literature review studies the impact of sports injuries, both from a physical and psychological perspective, as well as the financial burden of injuries to the sports person and stakeholders such as the health system providers, family, work colleagues, etc. The current definition and the ethos surrounding protective sports equipment (PSE) will be explored. This chapter will also examine the most common type of injuries occurring in the upper and lower extremity of the human body and seek to identify the cause and effect to better understand how and why they occur.

A sports injury is seen as an inevitable consequence of participation in sport. Research by Frisch et al. (2009) reports that 'rates of injury per 1000 exposure hours were shown to be between 0.5 and 34.4, with highest rates for boys in ice hockey (5–34.4 injuries/1000 h), rugby (3.4–13.3 injuries/1000 h) and soccer (2.3–7.9 injuries/1000 h), and for girls in soccer (2.5–10.6 injuries/1000 h), basketball (3.6–4.1 injuries/1000 h) and gymnastics (0.5–4.1 injuries/1000 h). The risk of injury is unavoidable as a consequence of multifactorial and multidirectional nature of sports and, therefore, this section will further explore the primary causes associated with sports injuries.

It is important to clarify the main cause of injury, as the reason for injury involves multiple factors. Agosta (as cited in Brunker et al. 2012, p. 40) established that poor technique can cause abnormal biomechanics and contribute to injury. They further state that correct biomechanics provides efficient movement and is likely to reduce injury risk. Therefore, biomechanics, which refers to the study of movement, is a major factor in the occurrence and prevention of injury, Brunker and Kahn et al. (2012, p 40). However, the study will highlight the possible reasons associated with abnormal biomechanics. This section, which aims to identify a suitable area of the body and/or product area for this research study, helps to explore the integration of Additive Manufacturing and other digital technologies in the design, development and fabrication of a new form of customised protection in sports equipment.

### 2.2.2 The impact of sports injuries.

Sports injuries can threaten an athlete's career and livelihood. Santi et al. (2013) highlight that some sports injuries are minor and do not have any impact. Instead, others can end a

career and have consequences on an athlete's quality of life. They further state that injuries can incur significant rehabilitation periods, which, in turn, are a significant concern for both athletes and sporting organisations in terms of costs and lost time at work or study.

According to de Putter et al. (2012), the most expensive injuries are hand and wrist injuries, which account for \$740 million (in U.S. dollars). Secondly, knee and lower limb fractures (\$562 million), hip fractures (\$532 million), and skull-brain injury (\$355 million). These initial findings led to the first realisation that the cost of injuries is a significant burden on the healthcare sector, sporting community and athletes themselves and that an actionable solution is needed.

Sports injuries can also create psychological and physical issues for the injured athlete. Santi et al. (2013) argue that injury affects not only the physical capabilities but also contextual and psychological aspects. Further, Santi et al. (2013) state that as a consequence of injury, athletes experience negative emotions, mood disturbance as well as feelings of loss and isolation. These attributes can, therefore, increase life stress and promote re-injury, advancing the idea that a more appropriate, sympathetic and engaging PSE is required to prevent injury.

Depending on the type of sport, protective sports equipment is used to help protect or assist the player from the risk of harm. Bahr (cited in Brunker et al. 2012, p. 74) state that protective equipment has been designed to shield various parts of the body against injury without interfering with sporting activity. Bahr (cited in Brunker et al. 2012, p. 76) most importantly establish that Protective Sports Equipment (PSE) should fit correctly and as a result should provide a psychological benefit by increasing a player's confidence. PSE is used to increase a player's confidence and to shield certain parts of the body against injury, in particular, to prevent abrasion and fracture.

Generally speaking, injuries can occur throughout all regions of the human body. Research suggests that the most common type of injuries which happen in sporting scenarios are head injuries, hamstring strains, muscle strains, knee, shoulder and ankle injuries (Murphy & Blake, 2012). Van Mechlan et al. (1992) propose that the risk factors which contribute to sports injury include high intensity, high velocity, multi-directional activities such as: jumping, landing, running, player contact and the competitive nature of the individual. Simply put, participation in sports involving any of these factors may result in sports injuries.

### 2.2.3 The different types of sporting injuries.

In sport, there are two categories of injuries which occur, namely acute and overuse injuries. Literature by Brunker and Kahn (2012, p 8) establishes that serious injuries occur from a direct blow to the body; either as a result of contact with another player or equipment. Examples of serious injuries can range from fractures to sprains, dislocations to muscle strains. In general, traumatic injuries are considered difficult to predict and prevent. They can be caused by fatigue, poor technique, lack of experience and bad luck.

Overuse injuries occur differently to acute injuries. Brunker et al. (2012, p16) outline that constant stress factors cause overuse injuries to tendons, bones and joints. They further state that the causes of overuse injuries may be the result of doubling of training, poor footwear, a visible biomechanically abnormality or may be more subtle such as running on an inferior surface, muscle imbalance or length discrepancy. Overuse injuries include runner's knee, Achilles tendons, hamstring strains, lateral ankle sprains (LAS), medial ligament injuries (MLI) and shin splints. Most significantly, these type of injuries all occur within the lower extremity of the human body.

A four-year longitudinal study by Blake, Murphy and Gissane et al.(2011) in injury surveillance in Gaelic games, found that the most common type of sports injuries occurred predominately within the lower extremity. The kind of lower limb injuries occurring included thigh, hamstring, knee, ACL, pelvis, groin, ankle, foot, toes and finally shin (see figure 1). Consequently, injury to the lower limb occurred because of poor positioning of lower limb biomechanics as a result of incorrect warm up techniques before play.

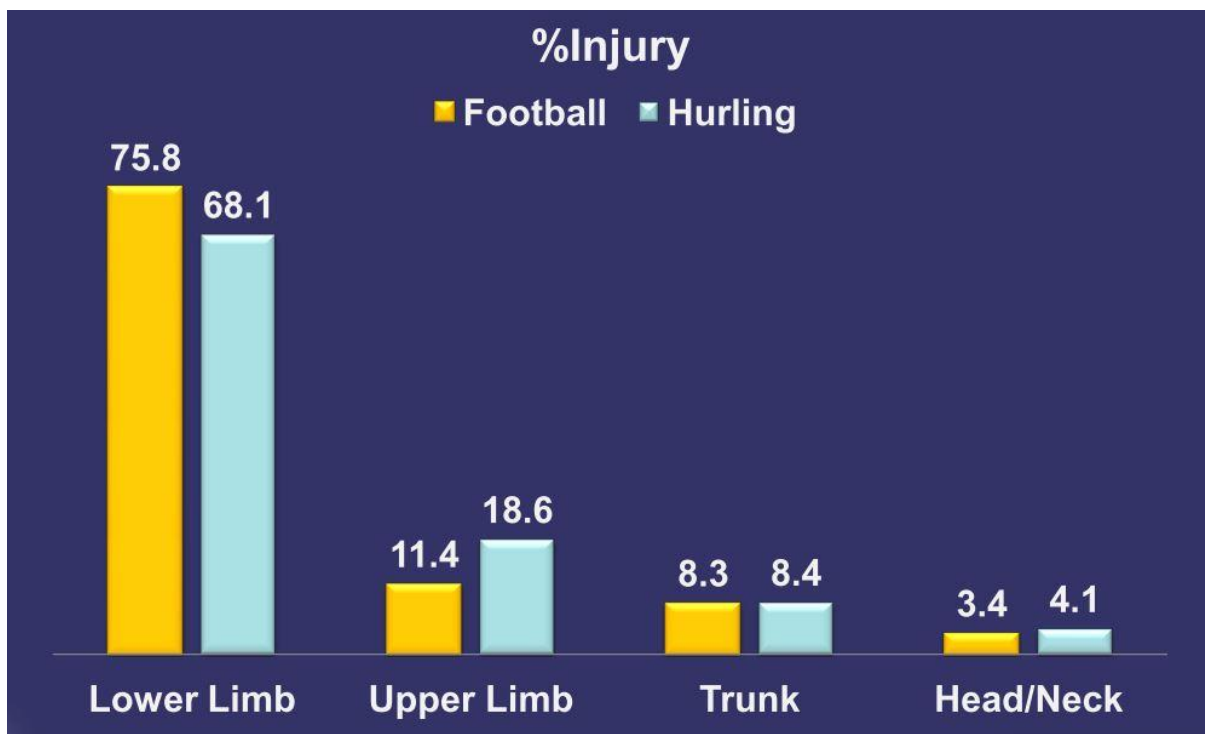


Figure 1: Where an injury occurs mostly in the body. By Blake et al.(2011)

Another factor, linked to overuse injuries and abnormal lower limb biomechanics is poor foot posture. According to Agosta (cited in Bruncker et al. 2012, p. 49), biomechanical abnormalities affecting the lower extremities are caused by excessive foot pronation and supination as well as abnormal pelvic movement. They further state that excessively pronated foot can cause excessive internal rotation of the entire lower limb during weight bearing, which increases the demands on many structures. In effect, the foot plays a significant role in the human body; as a result of acting as the foundation of the human body and forms the basis of standing, walking and running support.



Figure 2: Plantar view of the bones of the foot. By Agosta et al. (2012, pg 647)

#### 2.2.4 The origin of sporting injuries.

Excessive foot pronation or supination can create overuse injuries, which can have significant repercussions throughout the body. In a research paper, reviewing shoe inserts and orthotics for sport and physical activities, Nigg et al. (2001) promotes the idea that overuse injuries are due to excessive foot and leg movements, specifically due to excessive foot pronation. In a comparative study, Hume et al. (2008), claims that the flow of the foot and ankle influences the transfer of forces through the lower limb during locomotion. This promotes the idea that the foot's abnormal alignment can create instability which affects

postural alignment and functional movement and therefore resulting in injury during the gait cycle.



*Figure 3: Highlighting the difference between Abnormal (Left) and Normal (Right) postural body alignment. By Aleviahealthcare (2017).*

Pronation is one of the most common foot miss alignments; in fact, everyone pronates due to arch collapsing and foot rolling inward. Ward (2016) state that pronation occurs to absorb; the foot becomes flexible and mobile as to adapt to the earth below it. However, Nigg et al. (2001) warns that excessive foot pronation and tibia rotation movements have been proposed to increase the chance of overuse syndromes such as patellofemoral pain syndromes, shin splints, Achilles tendinitis, plantar fasciitis and stress fractures. See figure 2 for an example of the different types of injuries which occur in relation to over-pronation in



the foot. Ultimately, over pronation will create prolonged movement during the gait cycle, therefore creating multiple overuse injury throughout the body.

It is becoming quite evident that poor foot posture can lead to abnormal biomechanics and contribute to subsequent injury in sporting scenarios. For example, Hume et al. (2008) report that plantar fasciitis, causing heel pain in active as well as sedentary adults of all ages, is a common condition and is estimated to affect ten percent of runners. They further state that stress fractures are a problem frequently seen by healthcare professionals among people who participate in recreational sports and physical fitness training. Section 2.2.5 will explore the effects of abnormal foot posture in relation to lower limb injury.

Injury	Common biomechanical abnormalities
Sesamoiditis	Pronated foot Abducted gait Limited first ray range of motion Forefoot valgus/planterflexed first ray
Plantar Fasciitis	Pronated foot / High arched foot Abducted gait Ankle equines
Achilles tendinopathy	Pronated foot Ankle equines
Peroneal tendinopathy	Pronated foot at toe-off Excessive supination
Medial shin pain	Pronated foot Ankle equinus Varus alignment Abducted gait
Patellar tendinopathy	Pronated foot Tight quads, hamstrings and calves Anterior pelvic tilt Varus alignment
Metatarsal stress fractures	Pronated foot Supinated foot
Navicular stress fractures	Pronated foot Varus alignment Ankle equines
Fibular stress fractures	Supinated foot Pronated foot Varus alignment
Patellofemoral pain	Pronated foot Anterior pelvic tilt Varus alignment Abducted gait

*Figure 4 : Lower limb injuries and associated biomechanical abnormalities often noted the foot clinically as the primary cause by Agosta et al. (2012, pg. 50).*

#### 2.2.5 The current solutions to preventing lower limb injuries.

Studies by (Brunker et al., 2012, Nigg et al. 2008,) describe the two common solutions to correcting lower limb biomechanics. These solutions are various stretching exercises and the provision of orthoses and proper footwear. Agosta et al. (2012, p 40) outline that it is becoming increasingly evident that correct biomechanics play a key role in both

performance and injury prevention. As a result, there has been the introduction of various stretching programs, to help correct abnormal pelvic mechanics. Professionals who specialise in correcting abnormal pelvic mechanics are medical practitioners, such as a physiotherapist, physical therapist, sports therapist, rehabilitation specialists.

The second solution to redress the foot from excessively pronating or supinating is the use of Foot Orthoses (FO). Agosta et al. (2012, p 60) describes how orthoses are placed in the shoe to correct lower extremity mechanics and alignment. Nigg et al. (2008) propose that there is evidence that inserts or orthotics reduce or prevent movement related injuries. They further state that orthotics could prevent all types of injuries in the lower extremity. For example, in a randomised controlled study exploring the clinical effectiveness of customised sports shoe and orthoses for overuse injuries in runners by Hirschmüller et al. (2010), they found that foot orthoses (FO) are an effective treatment strategy for overuse injuries with a high acceptance by injured runners. In other words, FO is a proven therapy, used to correct the alignment of the foot and lower extremity biomechanics, to prevent injury.

Furthermore, FO is widely accepted and acknowledged within the healthcare sector, as an efficient treatment to help control excessive pronation and correct overall biomechanics. Wensman et al. (2015) state that there will be a growing need for FO due to an ageing population and that the number of persons using foot orthoses is expected to increase from 5.7 million in 1995 to 7.3 million by 2020. Nigg et al. (2008) state that perceived benefits of foot orthoses are:

- To reduce the frequency of movement related injuries,
- To align the skeleton properly,
- To provide improved cushioning,
- To improve the sensory feedback, and
- To improve comfort.

From the benefits outlined above the following section on Foot Orthosis, Section 2.2.6, will focus on the exclusively on the design elements and requirements of foot orthoses.

### 2.2.6 Foot Orthoses.

It is important to be aware that there are currently two types of FO currently available for the treatment of foot and movement related issues: “off the shelf ”and “custom” orthoses. Wensman et al. (2015) argue that Custom Foot Orthoses (FO) can fit the patient’s body and perform better than off the shelf FO. Current thinking by Agosta et al. (2012, p 60) suggests that custom orthoses give greater control of the foot function, therefore being able to alter the mechanics of the foot more significantly. They further state the fact that clinically, many athletes do not tolerate a large degree of control from orthoses and often a degree of movement is helpful. These points recommend that custom FO perform better over standard FO, as well as highlighting the need for movement and flexibility within FO design.

If a proper fit is critical to the comfort and well-being of the patient, it is vital for the designer to achieve compatibility between the FO size and shape, foot dimensions and form. The custom FO design features include arch support, heel lift, heel cupping, heel cushioning, medial flange, wedge, metatarsal bars and pads.

In fact, custom FO is a prescribed device, most importantly the design is primarily guided by the problems and anatomy of the patient. Saleh et al. (2013) outline that the selection of materials for orthoses construction largely depends on the nature of the disease and associated pathological conditions of the foot along with other factors such as weight and activity level of the patient. They further state that the design process is based mainly on addressing the requirements of specific problems in the patient’s foot. Saleh also makes the point that the design process depends on the skills and expertise of the individual podiatrist. To summarise, the podiatrist controls the layout of the foot orthoses, and is, therefore, a key stakeholder in the design process of the FO.

### 2.2.7 The current issues of FO.

The material choice within the FO plays a significant role in the functionality and purpose of an FO. Saleh et al. (2013) outline that the type of orthoses prescribed has a significant role in the selection of combinations of properties and characteristics of the orthoses material. They further state that during the service phase the orthoses have to carry and withstand the whole body weight of the patient while at the same time serving and addressing specific treatment objectives for the user. Essentially, material within FO is chosen to suit the medical needs of the patient and lifestyle demands.



*Figure 5: Foot Orthoses devices. By Podiatry QLD. (2017).*

To date, optimal material selection options are not fully explored due to time, cost and manufacturing constraints. Current materials are grouped as plastics, acrylics, composites, foams and rubber, leather and cork. Saleh et al. (2013) subdivided these materials into three categories: rigid, semi-rigid and soft. However, the range of materials considered is rather limited and there is potential to include a wider range of materials for consideration. For this reason, it is important to explore the potential of AM to increase the material characteristics options provided in FO.

There have been many research studies in the past which have reviewed orthotics from a biomechanical perspective. As a result, FO has caused an ongoing debate within the healthcare sector. A consideration of the literature, entitled "Does Foot Orthoses work?"

by Heiderscheit et al. (2001) reports that FO does have success in reducing pain and symptoms. Interestingly, Hume et al. (2008), cites Nigg (1999) and Heiderscheit (2001) suggesting that the shock-absorbing effects of FOs, and not their ability to correct alignment and control motion, may be their most useful asset. She also argues that the mechanism proposed in realigning the foot is open to question. The current mechanism used to realign the foot is to reduce rearfoot movement, therefore influencing knee motion. As a result, FO acts as a rigid device to help control abnormal foot posture to help correct overall body alignment.

The mechanism employed in FO creates a neutral position within the foot, therefore causing static positioning throughout the body. However, this prevents natural movement to occur within the foot, which can create a false sense of stability. In a research paper analysing the effect of foot orthotics on rear foot and tibia joint coupling patterns and variability, Ferber et al. (2005) state that the variability in movement is necessary to adapt to a changing environment and reduce the risk of overuse injury. To sum up, these findings suggest that there is a need for the implementation of controlled movement or flexibility within an FO device, to adapt to unpredictable environments to prevent overuse injury. FO are designed to solve many problems associated with the foot, however, there has been little progress in the development of the basic design.

Reviewing the literature the researcher found that there is a constant ongoing debate of FO regarding the device's specific function and performance characteristics. Hume et al. (2008) state that there is limited knowledge about the particular role of FOs. They further claim that the same type of FO is often used to solve several different problems. Niggs et al. (2001) report that studies addressing FO which highlight the utilisation of an insert/orthotic are subject to a particular function. Therefore, more research is required within the area, particularly to an unanswered question regarding material and functional characteristics of FO.

Also, there is a need for a more custom and tailored approach in the treatment of foot related injuries. The issue is that the same FO is used to treat a range of problems. Nigg et al. (1999) outline that shape and material properties of inserts and orthotics have a substantial effect on the kinematics and athletes. In a later study, Nigg et al. (2001)'s discussion on the role of impact forces and foot pronation, concluded:

*“That it should be possible to match subject characteristics (shape, alignment, strength, compliance, sensitivity) with insert characteristics (material properties, shape, time, behaviour) to find the optimal solution for insert or orthotic fitting.” Nigg et al. (2001)*

Nigg proposes the idea that changes in material properties might produce adjustments in the muscular response of the locomotor system. To clarify, a more custom approach to the design of FO devices would improve gait comfort and effort as well as improve foot loading characteristics. As a result, this research aims to identify key patient characteristics using the latest gait analysis, 3D scanning equipment in alliance with additive manufacturing techniques in the fabrication of a bespoke custom FO.

#### 2.2.8 Conclusion.

To conclude, literature by Blake, Murphy and Gissane (2011) found that the most common types of injuries occurred within the lower extremity, the majority being overuse related injuries. Overuse injuries in sporting activities are linked to abnormal lower limb biomechanics. The foot is the foundation of the body and the only part which directly impacts functional movement and postural alignment. Incorrect foot positioning can create instability resulting in injury. Therefore, an appropriate and actionable solution for this research would be to address the function of the foot and, subsequently, design requirements for FO.

Many researchers and authors - Agosta, Brunker and Kahn (2012) promote the use of Custom Foot Orthoses to help control excessive pronation and supination within the foot, as a result correcting overall biomechanics and therefore preventing overuse injury. Custom FO can help realign the foot's posture and is a proven clinical method of therapy, linked to realigning abnormal lower limb biomechanics, and as a result preventing overuse injuries. For this reason, future research will explore the design of FO using digital and additive manufacturing technologies to create a more appropriate, sympathetic FO.

Research by Niggs (2001), Heiderscheit (2001) and Hume (2008) indicate that the current material used in FO can be quite rigid and restrictive, therefore promoting the idea that the material can cause discomfort, the impedance of fit and effect function of the device. Jin et al. (2015) state that depending on the range of movement in the joints allowed, the

podiatrist may prescribe 3 types of FO, rigid, semi- rigid and soft. To date, the material options offered within FO are quite limited. Therefore, this research will explore the potential of AM to increase the material or material characteristic options within FO design.

An evaluation of the current mechanism employed within FO device to control rearfoot movement suggest that the current mechanism used can give a sense of false support. Research by Ferber et al. (2004) believes that it is necessary to introduce movement within an FO device in order for the patient to be able to adapt to unpredictable environments in order to reduce/prevent overuse injury. As a result, this research will look at ways to introduce controlled movement and flexibility within an FO device to help reduce/ prevent these injuries.

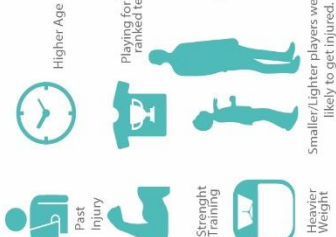
This investigation into shoe inserts and orthotics for sport and physical activities suggest that it should be possible to match patient characteristics with insert features to provide a optimal support for an insert or orthotic solution. Therefore, the aim of this research is to identify key patient characteristics using the latest gait analysis equipment and 3D scanning equipment and to design, develop and manufacture optimal orthotic solutions through 3D solid modelling, additive manufacturing technologies and, when appropriate, the integration of digital materials.



# Head & Face

Crowley et al. 2013 states that facial injuries were the second most frequent injury, the introduction of the hurling helmet saw the majority of these injuries to be eliminated.

Who Was More Likely To Get Injured?



**Mouthguard**  
January 1st 2014 saw the GAA make the mandatory use of mouthguards as a result of one of the most common injuries being sport related.

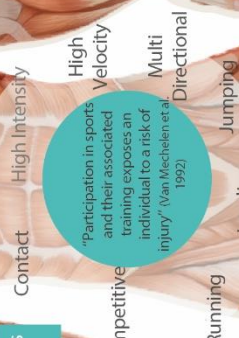
**Shoulder Pads**  
RISUS et al. 2015 reported that shoulder injuries accounted for 13.3% of injuries recorded.

**Health Benefits**  
Engaging in regular exercise has a direct and positive impact on physical health. People can benefit from physical activity, as it supports healthy bone development, and improves motor skills and cognitive function. Regular exercise has also been associated with prevention of several chronic conditions such as cardiovascular disease, diabetes, obesity, cancer, depression.

**Hand Guard**  
EM Quinn et al. 2011 explains that 40% of players responded that they did not believe the handguards to be a necessary piece of equipment for hurling and camogie.

**Upper Extremity**  
Murphy et al. 2012 highlights that Gaelic footballers are subject to considerable biomechanical stress and contact forces, which exposes a player to risk of injury.

## Anatomical Planes of The Body



"Participation in sports and their associated training exposes an individual to a risk of injury" (Van Mechelen et al. 1992)

**Hand Fractures**  
The most common hand fractures are those sustained by players to hurling have been shown to be metacarpals and proximal phalanges.

**3 Lower Extremity**  
Blake et al. 2013 states that lower extremity injuries remain the most prevalent; Football 76.3 percent and Hurling percent.

Percentage of hand related injuries in hurling:  
43%  
3%  
91%

Percentage of players wearing handguards during play:  
Percentage of players not wearing handguard at the time of injury.

## Foot & Ankle

Ward et al. 2015 states that whatever the foot is doing translates into what the ankle is doing, what the hip is doing, pelvis/spine and head.

## Posture

Ward et al. 2015 believe that poor posture equals poor performance and scoliosis. He continues to further abnormalities in the upright posture can be linked back to the 66 joints of the feet are capable of supporting the weight of the 34 parts of the spine.

## Joint Motion

Joint motion which occurs during running and walking is in the pelvis, hip, knee, ankle joint, subtalar joint and forefoot.

## Angle Base of Gait

Posterior Ligament, Collateral Ligament, Tibia, Fibula

## Knee Brace

Sikewitz et al. 2011 highlights that no studies have shown conclusively the functional knee brace in prevention of knee injuries.

## Soft Tissues

Tibialis anterior, Extensor hallucis longus, Extensor hallucis brevis, Extensor digitorum longus, Extensor hallucis longus tendon, Peroneus Longus Tendon, Peroneus Brevis, Inferior Peroneal Nerve, Extensor digitorum longus, Extensor hallucis longus tendon.

## Running

Joint motion which occurs during running and walking is in the pelvis, hip, knee, ankle joint, subtalar joint and forefoot.

## Walking

Line of Progression

## Foot

Talus, Navicular, Mediotarsal, Calcaneus, Cuneiform

## Normal

Pronation, Supination

## Foot & Ankle

Ward et al. 2015 states that whatever the foot is doing translates into what the ankle is doing, what the hip is doing, pelvis/spine and head.

## Running

Line of Progression

## Foot

Talus, Navicular, Mediotarsal, Calcaneus, Cuneiform

## Normal

Pronation, Supination

"The foot is the foundation of the body and the only part of the body touching the ground"

## 2.3 Bespoke Additive Manufacturing.

### 2.3.1 Introduction.

The term “3D printing”, “Rapid Prototyping” and “Additive Manufacturing” by definition refers to any manufacturing process that automatically builds 3D objects, layer by layer, directly from computer data. In a white paper investigating: *Advancing healthcare with 3D printing*. Stratsays (2015). suggest that this technology has proven to become an integral part of the product development process or product manufacturing process in many sectors such as Architecture, Design, Customized Sporting Goods, Engineering, Health Care, Transport and Education. The primary purpose of Additive Manufacturing (AM) technologies is in the creation of building concept models, functional prototypes, factory tooling and, to a certain extent, finished goods. AM, therefore, is an important design and development tool affording designers and engineers the opportunity to quickly create and iterate and test design proposals prior to tooling, therefore helping to reduce/eliminate errors and, in turn, significantly reducing product development times and development costs.

The first method of AM is Stereolithography (SLA). Charles W. Hull of 3D Systems invented the technology in 1984. However, other AM technologies have evolved since, as a result of improving technology, system reliability and increasing model and material quality. To date, these techniques include Poly Jet Printing, Ink Jet printing, Fused Deposition Modelling (FDM), Laminated Object Manufacturing (LOM), Selective Deposition Lamination (SDL), Direct Metal Printing (DMP) and more recently, Multi-Jet Fusion. A detailed prescription of AM technologies will not be provided here but is available from the following references: 3D Systems (2017), Materialise (2017), Mcor Technologies (2017), Stratasys (2017), EOS (2017), Hopkins’ et al. (2006), Gibson, Stucker and Rosen (2010). The following section of the literature review shall focus on key areas of interest and will examine the advantages of the technology within the Orthoses and Prosthesis (O&P) industry and will review some case studies where AM technology has offered bespoke solutions within the healthcare system.

### 2.3.2 The real potential of additive manufacturing.

The process of AM can be exploited to optimise the design process. The process can offer some capacity for design freedom as forms can be built that are impossible using traditional manufacturing methods. For small or limited quantities, the AM process can, in the absence of hard tooling, be more efficient and more cost-effective over traditional manufacturing methods. In a white paper titled, *A new mindset into the development of product design*. Stratsays (2016) Outline that the various advantages in AM lie within the opportunity to design complex components without incurring additional costs; the opportunity to surpass the limitations of conventional, traditional technologies; the opportunity to change the design without complication; as well as to shorten the time to market. For this reason, AM processes have the potential to be applied to a broad range of diverse applications.

Like many emerging technologies, AM can present certain limitations. Baumers et al. 2016, in a study investigating the cost of Additive Manufacturing; machine productivity and the economics of scale highlighted that the current limitations associated with AM technologies were:

- A limited palette of build materials.
- Slow process speed.
- Poor dimensional accuracy compared to some conventional processes.
- Rough surface finish.
- Problems with process predictability and repeatability.
- Cost-effectiveness.

(Baumers et al. 2016)

These findings suggest that AM technologies are not yet able to support high volume production of end-use products. However, further development of AM technologies may soon support higher production volumes.

The implementation of AM techniques within individualised healthcare has flourished because of AM unique capabilities. In a white paper investigating : *Advancing healthcare with 3D printing* by Stratsays (2015) suggests that AM is well suited for individualised health care, by stating that the economics of AM is ideal for low volume and custom made production. Saleh et al. (2013) state that the scope of AM applications continues to widen in a broad range of disciplines. Its use in the medical and dental industry, for example, continues to be the world's third largest serving industry (15.1%) in the AM sector for the past 11 years, promoting the idea that AM is most efficient and suitable when used to suit the needs of an individual or in the creation of one –off parts or custom pieces. Furthermore, AM technologies do not have the same restrictions as traditional manufacturing techniques, therefore making the technology ideal for custom use purposes. Paterson et al. (2015) established that AM could account for functional, environmental, ergonomic, aesthetic, emotional and user fit requirements, and as such, is a proven viable method for the design and fabrication of customised body-fitting items. An example of customised body fitting parts includes prosthetics, braces, orthotics, splints and casts. In effect, this research further illustrates the suitability of AM technologies for the use of customised PSE.

3D laser scanning equipment is reverse engineering tool an be utilised when designing customised parts for the human body.

Additive Manufacturing (AM) combined with state of the art scanning equipment in the form of laser scanning or touch probe technology (surface scanning), Computerized Tomography (CT) and Magnetic Resonance Image (MRI) (volume scanning ) currently exist and is highly active within the medical device industry. In a study by Friess et al. (2012) titled: *scratching the surface? The use of surface scanning in physical and paleoanthropolog.* The study evaluated the performance of surface and volume scanning technologies, in doing so, they highlighted that the strengths and limitations of both techniques were the following;

Volume scanners based on X-rays or synochron radiation provide:

- Internal structures, but no texture.
- A high degree of automated acquisition, but also a high amount post-processing.

- Resolution down to nanoscale.

Surface scanners provide:

- Non-destructive/ non-invasive measurements.
- Rapid generation of dense point clouds and polygon meshes (low post-processing).
- Texture (not applicable to all models), but no internal structures.
- High degree of mobility - High to very high resolution – Affordability.

Friess et al. (2012).

In effect both surface and volume scanning technologies can capture accurate bone geometries and biological structures within the human body, to facilitate the design and manufacture of patient-specific solutions.

The Orthoses and Prosthesis industry has already embraced the use of several digital technologies to improve care and to satisfy the needs and requirements of patients. Dombroski et al. (2014) state that in recent years, technology has emerged permitting the use of 3D foot scanning, computer-aided design (CAD), and computer-aided manufacturing (CAM) in the fabrication of Orthotic (O) and Prosthetic (P) components. In a paper concerned with the possibilities of creating customised O & P products using additive manufacturing (AM) processes Pallari et al. (2009) note that AM shows potential for improving lead times, quality, consistency and patient care within the O & P industry. They state that AM processes have the potential to offer significant advantages over traditional O& P production. The advantages, as outlined by Pallari et al. (2009), are as follows :

- *Faster production over the traditional process and more consistent quality*
- *A more comfortable experience for the patient as no dirty plaster work is needed anymore,*
- *Fewer and less experienced technicians can be used as there is less need for manual labour and experience is not as crucial,*
- *The Orthoses/orthoses/prosthesis can be tracked/archived/ reproduced when needed,*
- *Less production management and simpler production processes,*
- *Less production equipment and stores needed and*
- *More possibilities in new product development.*

(Pallari et al. 2009)

As can be seen, adoption of AM technologies within the O&P industry offers a broad range of advantages throughout the O&P manufacturing and production process. In reality, the O&P industry still uses traditional and subtractive manufacturing techniques, despite the current process being restrictive and offers little scope for integrated product development. Pallari et al. (2009) argue the point that the manufacturer of O & P devices is currently a craft. They further state that the process is time-consuming and requires experienced artisans who make orthosis based on experience and/or trial and error rather than a systematic engineering approach. Pallari et al. (2009) also argue that these traditional processes limit the possibilities for innovation and product development within the O&P industry. For this reason, the aim of this research is to further explore the potential for digital technologies to facilitate additional product development within the Foot Orthoses (FO) sector.

### 2.3.3 The implementation of additive manufacturing within the orthoses industry.

AM technologies have demonstrated that they are an efficient and feasible clinical tool in contrast to traditional manufacturing techniques within the O & P industry. Jin et al. (2015) reviewed the application of AM to Ankle Foot Orthoses (AFO), Custom FO (Foot Orthoses) and prosthetic socket and compared it to traditional plaster moulding fabrication techniques over the past 25 years. They concluded that AM technology had demonstrated itself to be capable of fabricating custom FOs, AFOs and prosthetic sockets with good fit and adequate strength. They further state that AM devices have the same performance outcomes and qualities of traditional (O) & (P) devices. A modern example of this is the new 'SOLS' AM fabricated FO. (See figure 7).





*Figure 7: 'SOLS' Foot Orthoses (FO) manufactured using Additive Manufacturing technology (AM). By SOLS et al. (2016).*

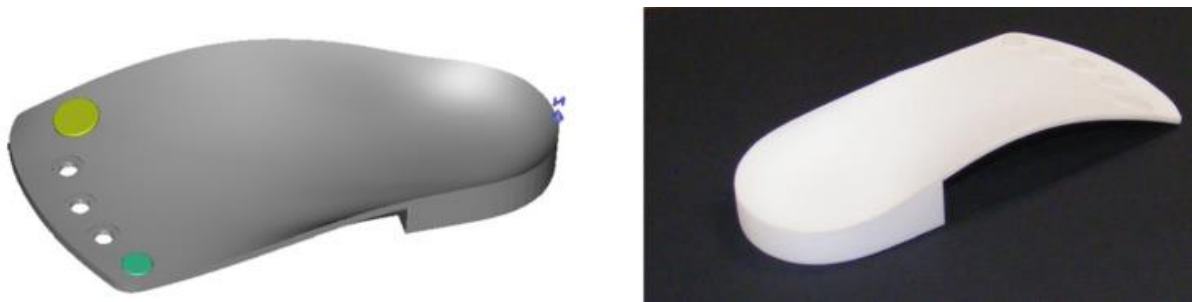
FO fabricated using AM, tend to use similar designs to traditional methods and fail to explore the design freedom of AM. Telfer et al. (2012) state that some papers published presenting Foot Orthoses (FO) and Ankle Foot Orthoses (AFO) fabricated using AM techniques, successfully demonstrate the feasibility of the approach. However, they suggest that these studies have tended to use designs similar to those produced using traditional methods, rather than fully exploit the design freedom provided by the technology. This research suggests that the unique capabilities of AM technology have not been fully explored within this product area.

The creation of new innovative novel features within bespoke FO devices needs to be investigated using AM techniques to produce a wider range of solutions for clinicians and patients. Novel features within FO design include rearfoot posting, heel cup, FO shell and cushioning pads. Telfer et al. (2012) claim that results presented in his research demonstrate the potential design freedom made available by AM. He further states that AM may allow the fabrication of new personalised orthotic devices which are beyond the current state of the art designs. To demonstrate the potential of this approach, Telfer et al. (2012) designed two prototype devices which exploit the design freedom provided by AM. The novel features explored using AM technologies, by Telfer et al. (2012) may have

significant relevance to this particular research study. The two prototype devices are the following:

- FO adjustable metatarsal support elements (see figure 8)
- Adjustable stiffness AFO

Looking more closely at the FO prototype, one factor which demonstrated the design freedom of AM technologies was the incorporation of adjustable metatarsal support elements. Telfer et al. (2012) suggest that the intention of this design was to provide the clinician with the ability to quickly and easily trial some permutations to maximise pain and pressure relief at the metatarsal heads without the need to add or remove material from the device. Telfer et al. (2012) claim that the relatively straightforward placement of functional elements about anatomical landmarks is another potential advantage enabled by AM. This study provides an excellent example of exploring innovative design features within orthotic design, using AM technologies to help aid clinicians. To sum up, future research should focus on exploring the full potential and design freedom of AM within Foot Orthoses design.



*Figure 8: The adjustable metatarsal support elements incorporated into the FO using AM technology by Telfer et al. (2012).*

Despite these advantages, AM technology still faces numerous barriers for adoption within clinical environments. Telfer et al. (2012) outline the barriers for an AM fabricated FO device to succeed within the clinical environment. Some obstacles cited include: cost for equipment, specialist knowledge of equipment and materials, specialised knowledge of design software suggesting that a more simplified version of CAD software should be developed for clinicians and finally, the capturing of 3D scan data for different foot and ankle positions. This research will explore if and how these barriers may be overcome, by



analysing the current tools used by stakeholders within the FO industry and identifying and exploring numerous routes to achieving a successful outcome.

Current research investigating AM technology within the orthotics sector has identified the failure to utilise and exploit the latest gait analysis technology. As a result, the full capabilities of AM technology has, to date, not been fully explored. Telfer et al. (2012) conclude that the design freedom realised by AM, perhaps combined with the most recent advances in gait analysis, may have the potential to provide some new tools and techniques for clinicians to further personalise orthotic devices.

They also suggest that future research should concentrate on the full integration of computer aided design and analysis software. 3D scanning equipment and associated software and the latest gait analysis equipment may be required to fully exploit the technology and allow the devices to be further personalised to suit the patient's medical needs. Given these points, it is important that future research explores the combination of both gait analysis equipment and 3D scanning equipment to support the design and fabrication of bespoke orthotics using additive manufacturing technologies.

A comparative study by A M Paterson, Bibb, & Campbell (2015) comparing four different additive manufacturing (AM) processes to assess their suitability in the context of upper extremity splinting may provide valuable research findings for FO. Paterson exploits the true capabilities and potential of AM technologies instead of the mass manufacturing elements, in her design of customised wrist splints for the upper extremity. Paterson et al. (2015) describes and explores the characteristics and fabrication of six different wrist splints, using four different AM processes; Laser Sintering (LS), Fused Deposition Modelling (FDM), Stereolithography (SLA) and Poly Jet printing on an Objet Connex printer. In her approach, she also used 3D laser scanning technology for initial CAD data files thereby insuring a more tailored and customised design for the participant's arm.

Also highlighted by Paterson was that past studies by (Saleh (2013); Pallari and Neptune (2008); Faustini, Neptune, Crawford, & Stanhope, (2008) only used Laser Sintering (LS) technology in their studies. Paterson et al.(2015) state that previous research in the O&P industry has concentrated only on the use of Laser Sintering (LS), the benefits of which include relatively low part cost compared to other AM processes and the ability to retrieve

and recycle un sintered powder for future use. At the same time, Paterson et al. (2015) found that all of these projects, the focus of a Framework 7 European project called 'A-Footprint', highlighted that, from a European Community perspective, AM technology has many benefits for medical-related applications.

Paterson et al. (2015) explored the strengths and weaknesses of AM technology. Their findings may also have relevance to foot orthoses design. They outline that the primary objective was based on improving aesthetics, fit and function of splints by exploring existing design features in the context of upper extremity splinting. The study concluded that a range of AM processes were suitable for splinting design but exposed a few limitations of existing technologies and, more encouragingly, demonstrated some of the novel and advantageous design features and opportunities for future research and development.

Paterson et al.'s. (2015) overall findings reported, as follows:

- *Stereolithography (SLA) proved to have a good surface, quality and robust materials, the effects of cleaning and non-withstanding*
- *Laser sintering (LS) and Poly Jet material jetting each displayed unique advantage characteristics made feasible by each AM process,*
- *Laser sintering (LS) demonstrated the ability to integrate aesthetically pleasing structures but also incorporating a textile element; she reports that Additive Manufacturing textiles (AMT) have not been previously captured within the context of splinting*
- *The most inappropriate AM process was considered to be Fused Deposition Modelling (FDM) as a result of poor surface quality.*

*Paterson et al.(2015)*

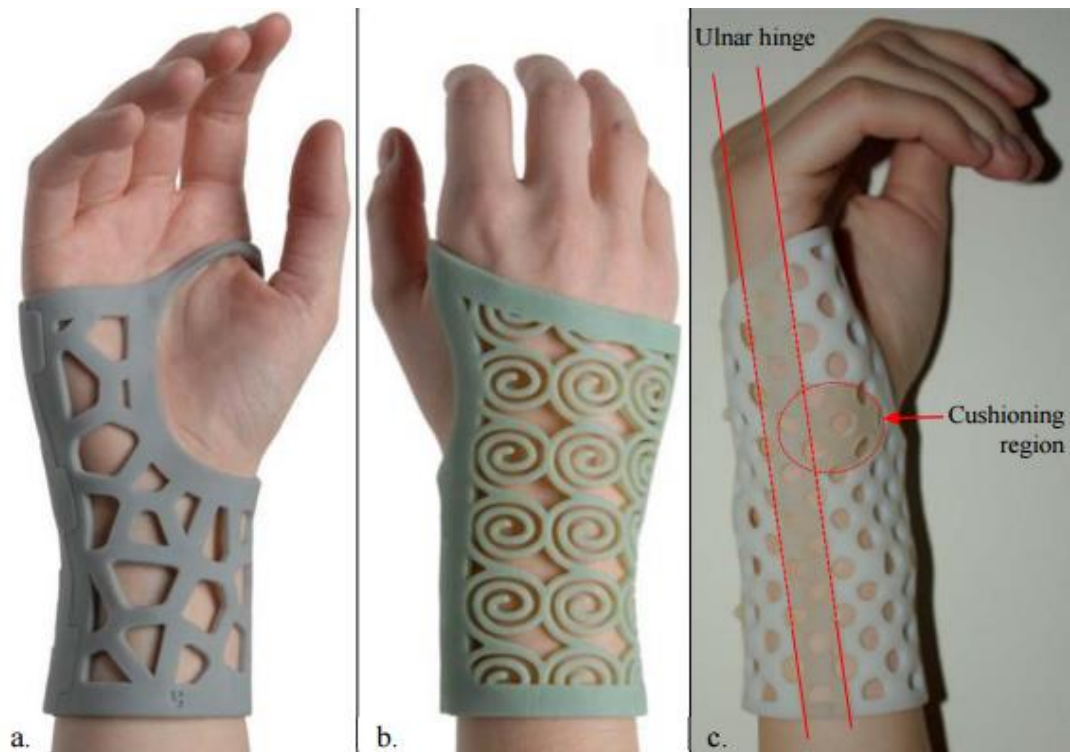
Most significantly their study also reported a favourable consensus amongst therapists about the application of multi-material within splint design:

- *Therapists became interested in new applications as a result of multiple material capabilities, such as protection and cushioning of bony projections without compromising the splint topography*
- *Highlighted new and exciting avenues for exploration within a splint design and fabrication, as well as expanding the opportunity for Object Connex technologies.*

*Paterson et al.(2015)*

These findings also suggest that new innovative design features developed within the design of the splint are a result of allowing the therapist to locate and specify material of varying

shore hardness within the splint design (see figure 9). As mentioned above, the use of multi-material technology using an Object Connex machine offers many advantages within splint design for both therapist and patient. These findings support the exploration of multi-material technology in foot orthoses design.



*Figure 9: A variety of multi-material splints, created using object via Connex technology by Paterson et al. (2012).*

Finally, Paterson et al. (2015) concluded that despite the aesthetic and functional advantages displayed in the results, several developments would be required before such processes may be feasible for adoption in clinical situations. Firstly, the development of biocompatible AM materials suitable for contact with the patient's skin. Secondly, the therapist would need to gain an understanding and knowledge of AM material options. Thirdly, the development of user-friendly 3D CAD software for the therapists. Finally, the development of a suitable 3D capture method to capture the anatomical features in order to improve fit and comfort for splint design. These observations should be noted for future research.

#### 2.3.4 Conclusion.

To summarise, this section has investigated the advantages of Additive Manufacturing (AM) technologies within the Orthoses (O) and Prosthesis (P) industry and reviewed case studies of AM technology of bespoke purpose. Initial research by Stratsays (2017), 3D systems (2017), Materialise (2017), Saleh et al. (2013) and Paterson et al. (2015) suggests that AM technology is most suited for custom and individualised healthcare. They further state that AM technology has the ability to accommodate functional, environmental, ergonomic, aesthetic, emotional, and user fit requirements. In effect, this research illustrates the suitability of AM technology for the use of customised protection in sports equipment.

As a result of AM design capabilities, many researchers and authors –Pallari (2009), Saleh (2013), Telfer (2012), Dombroski (2014) and Jin (2015) have explored the implementation of AM technology within the current production process of O&P products. Their studies on comparing traditional Ankle Foot Orthoses (AFO), Foot Orthoses (FO) and Prosthetics sockets over the past 25 years have concluded that AM have the same performance levels of traditional O&P devices, in particular, FO devices. This supports further research in the design and fabrication of FO devices using AM and digital technologies.

Pallari (2009) research also validated that FO's fabricated by AM have the same performance as traditional FO's, with regards to user fit, strength and performance. However, he also highlighted that the designs used were ones very similar to conventional FO methods and failed to fully exploit the design freedom of AM technology. Therefore, this research project will investigate the design potential and unique capabilities of AM technology for the FO sector.

Research also highlights that previous studies in the O&P industry, have only concentrated on the use of LS and FDM technology. These technologies only offer single material options, therefore, fail to explore the more recent advances in multi-material printing. To date, no research has been undertaken to fully utilise the latest gait analysis equipment and 3D scanning technologies in supporting of the additive manufacture of multi-material FO devices. This research will explore the feasibility of combining these technologies to assist

the design and creation of custom FO devices with new and innovative features that answer the patient's physiological and medical needs.

## 2.4 Medical Regulations of custom-made devices.

### 2.4.1 Introduction.

The design of custom-made foot orthoses are governed by medical regulations to ensure the safety and use of the product before clinical use. World Health Organisation (WHO) et al. (2014) state that medical devices regulation is primarily concerned with enabling patient access to high-quality, safe and effective medical devices and restricting access to those products that are unsafe or have limited clinical use. As a result, it is necessary to investigate the current requirements of medical regulations for custom made devices. The following section will outline the definition and regulatory requirements of a medical device, classification of custom made devices within the medical industry, and finally, the current manufacturing regime of custom-made medical devices in relation to custom foot orthoses.

### 2.4.2 The definition of a custom – made medical devices.

Firstly, it is important to clarify what is meant by a custom-made medical device, as custom made devices can have many different definitions and terminology. Health Products Regulatory Authority (HPRA) (2017) state what 'custom made' means in relation to a device:

- *Firstly, that it is manufactured specifically in accordance with a written prescription of a registered medical practitioner or a professional user who gives, under his/her responsibility, specific characteristics as to its design*
- *Secondly, that it is intended to be used only for a particular named patient*
- *Finally, it does not include a mass-produced product which needs to be adapted to meet the specific requirements of the registered medical practitioner or professional user.*

*Health Products Regulatory Authority (2017)*

Custom-made foot orthoses are considered a custom-made medical device within the medical industry.

### 2.4.3 The classification of custom – made medical devices.

By law all medical devices are classified into one of four categories based on the perceived risk of the device to the patient to ensure safety and intended purpose. IRISH MEDICINES BOARD (2009) state that medical devices are classified into four categories, ranging from low to high risk, depending on product risk to the patient. For example, the low-risk device is categorised as Class I; high risk is Class III. Other types include IIa and IIb. Foot Orthoses are classified as a low-risk class I medical device, in effect, custom made devices need to meet the requirements and regulations of Annex VII to be passed as safe to use (see figure 7).

Annex VII is subject to Class I devices as they are low risk and do not require a notified body (NB). NB assesses whether a product is to be placed on the medical device market, as well as meeting certain market standards in order to gain CE marking approval. As a result, custom-made medical devices do not require CE marking.

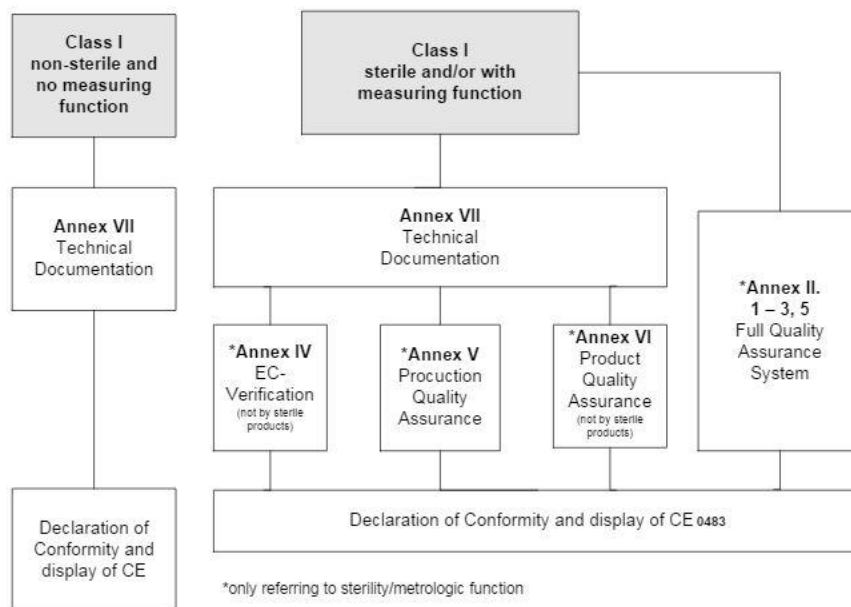


Figure 10: Conformity requirements by medical device certification et al. (2009)

### 2.4.4 CE marking: Custom made devices do not require CE marking.

CE marking is a challenging and long process, which requires the medical device to meet the essential requirements of all relevant European Medical Device directives and legal

requirements prior to being placed on the market within the European Union. However, custom-made devices do not require CE marking, as a consequence of the device being intended for individual use and not mass production purposes. HPRA (2017) Guide for Custom-made Medical Device Manufacturers on Compliance with European Communities ( Medical Devices ) Regulations state that the directives stipulate that custom-made devices and custom-made active implantable medical devices are not required to be CE marked when they are first placed on the market and/or put into service. They further state that CE marked materials should be used or, if not, the manufacturer must guarantee the suitability (including biocompatibility) of the materials by other means. This provides some freedom to explore different biocompatible material options. However, this is a question for future research to address.

#### 2.4.5 The process of manufacturing a custom-made device.

The manufacturing cycle of custom-made devices follows systematic procedures to ensure the device is designed correctly for the patient (see figure 11). A regulatory report for custom-made Medical Device Manufacturers on Compliance with European Communities Regulations (2012) state that in the manufacturing cycle of a 'custom-made' medical device, it is considered that it is the prescriber who undertakes the design of the product and the manufacturer who manufactures it to a predefined specification. Therefore, the researcher will develop the device to the specification provided by the podiatrist, implementing digital and AM technologies whenever warranted.

Furthermore, prescription methods are an important factor in guiding the design of a custom-made device. HPRA (2013) state that a written prescription may take the form of a letter from a qualified person or a moulded impression of the shape of the required device, together with the order specifying patient details and a request to 'make a pattern'. They further state that it is the qualified person who is responsible for determining the particular design characteristics of the product. For this reason, future research should involve the prescriber throughout the design process to ensure the safety of device to the patient.

A process model for custom-made medical devices can be found in fig11, deduced from Pallari et al. (2009).

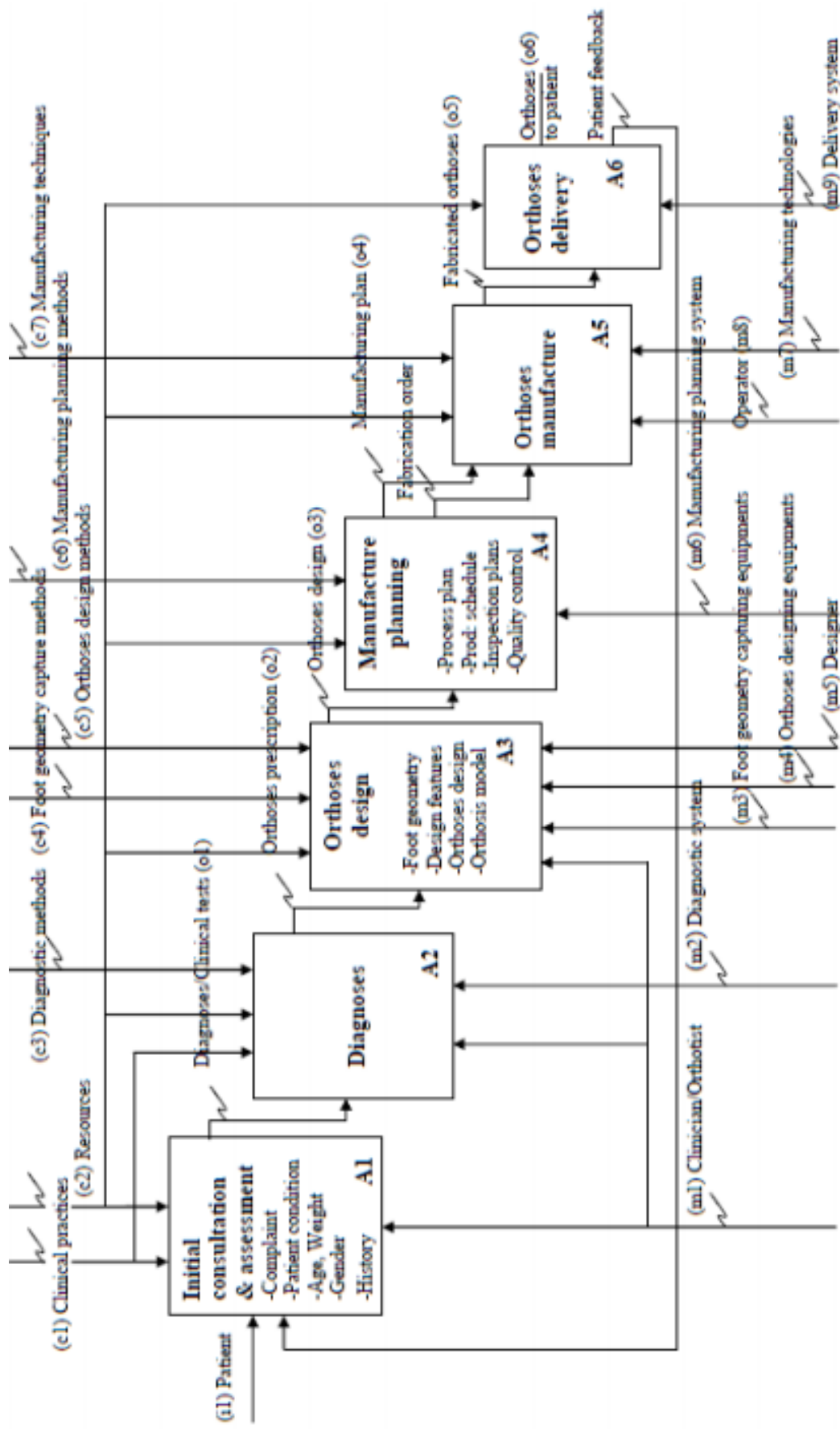


Figure 1.1: The Generic IDEFO process model developed for the customisation of medical devices (Pallari et al. 2009)



#### 2.4.6. Conclusion

To conclude, this section has explored the medical regulations of custom-made medical devices. HPRA (2017) states that custom made devices are defined by being manufactured specifically to the needs of the patient. The current manufacturing regime of custom-made medical devices follows a systematic approach. Therefore, research will work through the current process of designing a custom-made device and highlight areas within the existing process where digital and AM technologies can improve on.

“Custom made” medical devices are classified as Class I medical devices by the HPRA. In effect, foot orthoses are considered a low-risk medical device and because they are custom-made and are prescribed specifically for the individual they, therefore, require no CE marking from a Notified Body. However, the HPRA (2017) in the manufacturing of custom-made devices does state that CE biocompatible materials are needed in the fabrication of custom-made medical devices. As a result, this creates an opportunity for AM materials to be used in the manufacturing of custom-made devices, depending on the biocompatibility of the AM materials. Finally, the integration of digital technologies, such as foot pressure analysis system and 3D scanning equipment, in the diagnosis phase of FO would require further Regulatory Affairs and CE approval to ensure feasibility and technical approval. These regulatory matters would need to be addressed prior to the introduction and implementation of the proposed Orthotic design and manufacturing system.

#### 2.5 Design research methodologies.

Design Research is a relatively new development, which is evolving through research and becoming an integral part of the field of design through online discussions, publications, journal articles and conferences. Erlhoff and Marshall (2008, p 322) state that design research has prevailed in the wider world as a necessary and self-evident component of the whole broad field of design. This section of the literature provides a brief synopsis of the origin of design research and the overall approach of this relatively new paradigm.

It will illustrate the potential of design methods used in continuity with ethnographic research methods as a valuable research tool approach. The aim is to outline and identify a design research methodology deemed appropriate for this particular study, to help explore the critical issues and problems associated with sports injury and to propose, research, develop and test solutions which could prevent or protect against injury using digital and additive manufacturing techniques.

#### 2.5.1. Background of design research.

It is important to understand the origin and history of design research to improve overall knowledge of this emerging field within the design profession. Archer (1981) states that the definition of research is that 'Research is a systematic inquiry, the goal of which is knowledge'. Cross (2007) states that design research evolved from the systematic 1920's modern movement. Designers, such as Le Corbusier, established the groundwork for the 1960's Design Methods movement. He further states that the influential designers of the 1960's believed that design methodology could prescribe an orderly, systematic procedure for arriving at a design solution through a method known as "diagnosis followed by prescription".

It could be argued that the early stages of design research was very much a scientific linear approach, disregarding the user and incapable of tackling complex design problems. Cross (2007) states that Rittel and Webber posed the most severe challenge with their concept of wicked problems, which pointed out, among other things, how inadequate a sequential structured methodology was for understanding complex design problems. Consequently, he further argues that the linear approach may be vital to the practice of science (where it validates results) but not the practice of design (where results do not have to be repeatable). In effect, the establishment of alternative design research methods incorporating intuitive knowing, ethnographic methods and design research methods provide designers with a better understanding of the needs of their users. The combination of the two disciplined approaches allow designers to understand and solve complex design problems.

Design Research and its contribution to the design field is deemed misunderstood. Illinois Institute of Technology (IIT), Institute of Design (2017) state that design research process is

linear in one sense; it begins with a definition and ends with a realisation. They further say it is a highly iterative, learning as we go, often identifying new roadblocks and opportunities, requiring a few steps back before moving forward. Archer (1981) describes good design research as the following:

Many researchers such as Cross (2007), Erlhoff and Marshall (2008) - when describing their research, all refer to the framework formulated by Christopher Frayling, a professor at the Royal College of Art in London. Frayling (1993) outlines three types of design research; into, for and through design. Cross (2007) states that the types of design research map closely with the three bodies of clinical, applied and basic research. In effect, design research is broken down into three main strategies which include the following: Clinical: Research for Design; Applied: Research through Design; and Basic: Research about Design (See Figure 12).

The overall goal of design research is to calculate, generate, validate, articulate and transfer new knowledge. Cross (2006) in his book *“designerly ways of knowing”* states at 1980’s design conferences: ‘Science Method’ of the ‘Design Research Society’ (DRS), design research was defined as the pursuit of knowledge that is either specific to a design project, relevant to a class of design problems or fundamental to the very nature of design. In effect, the overall approach to design research depends on the specific design project, design problem and the nature of the design.

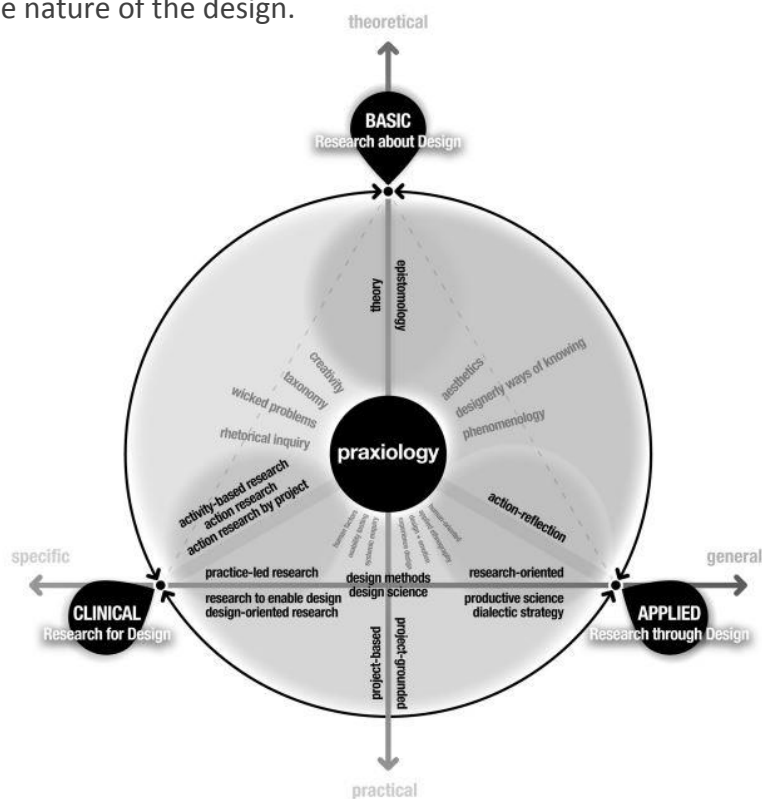


Figure 12: Map of Design Research, Racine et al.(2010)

### 2.5.2. Applied research through design.

The overall approach considered most appropriate for this particular research project is Research through Design, which is an action-reflection approach involving both theory and practice. Erlhoff and Marshall (2008, pg. 336) state that research through design is perhaps the most original and distinctive approach to research in design since it is characterised by a high degree of similarity between the process of design and that of design research. This Research Masters project, is a cross-disciplinary form of research where synthesis occurs in creative product solutions.

The RtD approach is considered quite similar to that of action research. Zimmerman, Stolterman, & Forlizzi. (2010) state that the action research sequence of iterative planning, acting, observing and then reflecting, makes the inquiry approach nearly identical, and both approaches require the integration of knowledge from several disciplines. Zimmerman et al. (2010) describe that RtD forces researchers to focus on research of the future, instead of on the present or the past. They further state that RtD is an inquiry process, revolving around the making of a product, service, environment or system; the knowledge gained can be implicit; residing almost entirely within the resulting artefact. The overall aim of the methodology is to create and share new knowledge for future design activities, through the holistic creation of an artefact or conceptual framework.

Zimmerman et al. (2010) state that RtD allows the researcher to broaden the scope and focus of the design problem, as well as to challenge current perceptions on the role and form of technology. As a result, it allows the researcher to focus on new understandings of technology. This maps closely with the aim of the Research Masters, to explore the role of AM and digital technologies in producing a more appropriate, sympathetic and engaging PSE.

RtD employs methods and processes from design practice as a justifiable method of research inquiry. The RtD process firstly necessitates the researcher to collaborate, and understand the various stakeholders involved within the problem area. Erlhoff and Marshall (2008, pg 336) state that research through design presumes a hermeneutic understanding of design and this works when the design process is open to taking into account an

interactive dialogue with the design situation. Erlhoff and Marshall (2008, pg 336) state that design research and theory at their most intelligent could perhaps be best described as “experienced based “ judgement. Therefore, RtD is a process, in which the researcher immerses themselves within a particular area, gathering knowledge and reflecting on insights collected from the use of qualitative research methods while employing design methods to frame, evaluate and act on the problem.

A Research through Design methodological approach will be utilised in this project to help explore the important issues and problems associated with sports injury and to propose, research, develop and test solutions which could prevent or protect against injury using digital and additive manufacturing techniques. As a result, this research project will use a RtD approach to bring knowledge from the disciplinary areas of human factors, healthcare, user behaviours, 3D scanning and additive manufacturing in the holistic creation of an artefact.

## 2.6 Conclusion.

The purpose of the literature review was to demonstrate a developed understanding of the existing literature and knowledge within this field. The literature review aimed to investigate four subject areas; sports injuries, bespoke additive manufacturing, design research methodologies and medical regulations for custom-made medical devices. The preliminary goal of the review of the literature was to identify factors and mechanisms which contribute to the occurrence and recurrence of sports injuries. In doing so, the literature review will identify a suitable product area to investigate the potential of AM and digital technologies in the design, development, and fabrication of a new form of customised protection in sports equipment.

Research findings indicated that the primary cause of overuse injuries in sporting activities are associated with abnormal lower biomechanics within the gait cycle. In doing so, an investigation into abnormal lower limb biomechanics highlighted poor foot posture as the primary cause of overuse injury in the lower and upper extremity of the human body. Many authors and researchers; Santi et al. (2013), Agosta et al. (2009), Niggs et al. (2008), Heiderscheit (2001), Bruncker and Kahn et al. ( 2012) have identified Custom Foot Orthoses

(FO) as the current solution for correcting poor foot posture and correcting overall body posture. Their evidence alone provides more than an acceptable basis to warrant FO as a product area and to explore the range of possibilities provided by the application of AM and digital technologies.

Research studies by Heiderscheit et al. (2001), Ferber et al. (2004), Niggs et al. (1999 & 2008) and Hume et al. (2008), conclude that current custom Foot Orthoses devices are incapable of supporting the foot throughout the gait cycle. It is believed that Foot Orthoses act as a hard and rigid device, offering poor fit, restricting natural movement and flexibility throughout the gait cycle, further compounded by the current material selection being limited to only three categories; rigid, semi-rigid and soft.

To date, it is evident in the research that optimal material selection is not fully explored due to time, cost and manufacturing constraints. It is for this reason that this research will consider and investigate numerous digital technologies and explore combinations most likely to advance and improve orthotic devices.

Research studies by Jin et al. (2015) , Dombroski et al. (2014) , Piller et al. (2009), Telfer et al. (2012) , Saleh (2013), have explored the application of digital and AM technologies in the design, development and fabrication of Orthoses (O) and Prothesis (P) (O&P) devices. Their research proved to be successful in demonstrating the feasibility of the approach and offering many advantages over traditional fabricated O&P devices. However, their studies fail to exploit the full potential of AM and digital technologies in the design of FO. Therefore, this research project will look at how a similar approach may be used to help improve fit, material selection, reduce lead times, improve product development and to ensure a more custom user-focused solution in the design, development and fabrication of bespoke custom FO.

A key outcome noted throughout the development of the literature review was that any bespoke FO is a custom-made medical device and not a mass produced product. Equally important was that the design of an FO depends on a qualified medical practitioner, in this case, a podiatrist. For this reason, the podiatrist determines the overall design and specific characteristics embedded within the FO. Also noted, was that the current medical process for creating a custom foot orthoses follows a very systematic regime which involves three

main phases: diagnosis, prescription and application. For this reason, future research will co-create with a qualified podiatrist and work through the current process of designing a custom-made FO to highlight key areas within the existing process, where the implementation of digital and AM technologies can offer a more holistic and engineering approach in the treatment of foot related injuries.

It is important to note that one of the biggest advantages of AM and digital technologies are their design capabilities, which are most efficient and suitable when used to suit the needs of an individual or in the creation of one-off custom pieces. As highlighted by Campbell et al. (2006), AM can account for functional, environmental, ergonomic, aesthetic, emotional and user fit requirements, and as such, is a proven viable method for the design and fabrication of customised body-fitting items. It is these values that can offer a more holistic system approach in the diagnosis, prescription and application phase of foot orthoses.

The primary research methodology is research through design. This is both an holistic and iterative research approach used to integrate knowledge and theories from across many disciplines, where synthesis of research occurs in creative product solutions. In this case, the research methodology will facilitate the investigation of the integration of AM and digital technologies in the design, development and fabrication of customised FO. In effect, the overall approach used will help bring together knowledge from the disciplinary areas of human factors, health care, user behaviours, 3D scanning and additive manufacturing, through the creation of a tangible artefact.

The original aim of this Research Masters project was to investigate the role of AM and digital technologies in the development of improved customised protection in sports equipment. The literature review identified custom foot orthoses as a suitable product area to explore the role and potential of AM and digital technologies. This is because custom orthotics have the ability to correct poor foot posture, thereby improving body alignment and, in turn, helping to prevent movement related injuries. The literature review highlighted that current FO devices, produced using traditional fabrication methods offer poor fit, provide inadequate support throughout the gait cycle and have limited movement and flexibility during sporting activities. The unique design capabilities of 3D scanning and AM technology can help improve fit, material selection, reduce lead time, offer customer-focused solutions and enhance support and mechanical performance during sporting

activities. Previous studies of FO developed using AM and digital technologies failed to fully exploit their specific design. Findings from the literature review led to the development of the following design research questions:

- How can AM and digital technologies be successfully integrated and implemented into the existing medical practice of orthotics and how can these technologies ensure improvements and the advancement of orthotic design?
- How can the unique design capabilities of AM and digital technologies be fully utilised to ensure more user-focused solutions in the design, development, and fabrication of bespoke custom orthotics for all stakeholders?
- How can a product design approach influence and progress the art of custom orthotic supports to not only provide correct foot alignment but also ensuring the foot's natural function and behaviour throughout the gait cycle?



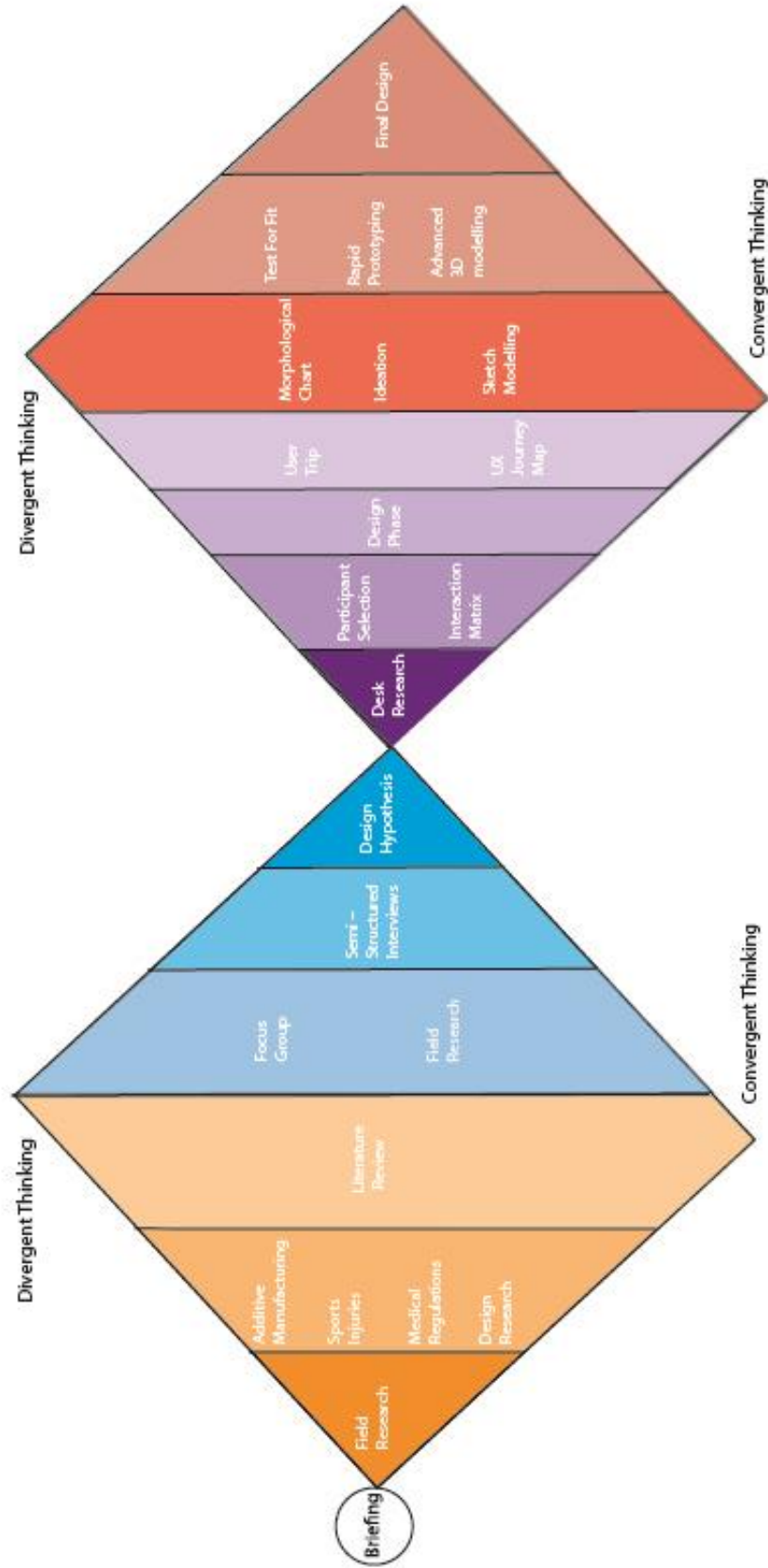
## 3.0 Methodology

### 3.1 Introduction

The central aim of this MA is research and the methodology employed is research methodology. The overall approach considered most appropriate for this particular research masters project was Research through Design (RtD). Research through Design is an action reflection approach involving both theory and practice. This was an iterative and holistic research approach in which knowledge was generated through iterations of designing, making and testing experimental prototypes in real- life settings. The research gathered was synthesised using design research evaluation techniques. The purpose of design research evaluation methods was to collect and evaluate data, in which the product can be improved on.

An early investigation into the Research Masters project was based on a divergent thinking approach (brain storming and mapping of ideas, identifying connections, asking questions and gathering knowledge) and later iterations of research were more convergent in thinking (finding the solution, identifying the known, and refining the solution). As a consequence, research activities, such as the literature review, were repeated throughout the process, on different levels of detail; from global to specific knowledge. In doing so, the overall research process; consisted of both design research methods and practice based design techniques. (See figure 13 )

To summarise, this chapter will look at the methodological framework applied, which guided the Research Masters process. In effect, the framework supported project framing, definition, data collection and analysis to help structure the quantity of research gathered throughout the project. Essentially, the methodological framework was necessary to define the scope of the research, but also to validate and justify the research activities carried out throughout the study. For the purpose of the methodology chapter, the overall RtD approach was categorised into two main phases; Research and Design practice phases.



Preliminary Research Phase

Design Practice Phase

Figure 13: Research Masters Process.(2017).

## 3.2 Research Design

### 3.2.1. Research Practice Phase

Firstly, the design research practice phase involved initial scoping of research derived from the literature review. The aim of the literature review; was to evaluate and investigate existing 'literature' related to the topic area. The literature review was an iterative process, repeated throughout the research and through the design process. The literature review process occurred at different levels of detail, from global to specific knowledge. The gaps of knowledge, identified in the literature review, contributed to investigating areas related to the research project and, in doing so, this allowed the researcher to engage with industry during the early stages of the research process.

Early engagement with industry involved focus group sessions in order to explore and gain an insight into the different types of injuries occurring in a range of sporting scenarios. The data collected and the analysis of focus group findings led to preliminary interviews with medical practitioners.

Preliminary interviews consisted of twelve sample interviews with medical practitioners who specialise in the field of physiotherapy, sports science and rehabilitation. The key objective of these preliminary interviews was, firstly, to understand what were the most common type of sporting injuries occurring and reoccurring in sporting scenarios and, secondly, to understand the cause and reasons for injury. The researcher adopted a semi-structured approach for interviews. Interviews were conducted on a one to one basis with each of the sample interviewees. All interviews were audio recorded and transcribed. The data collected from preliminary interviews was synthesised, organised and analysed. In effect, the key findings emerging from the preliminary research, aided in the development of the design hypothesis.

The design hypothesis, directed and focused the Research Masters project. In doing so, the researcher held focus interviews with medical practitioners within the field of

physiotherapy, orthopaedics and podiatry. The main objective of these interviews was to understand the current tools, techniques and processes involved in prescribing a custom-made orthotic. Similar to preliminary interviews these focus interviews has a semi-structured approach, were carried out on a one to one basis and were audio recorded. The objective of the focus interviews was to understand the current tools, techniques and processes involved in correcting abnormal lower limb biomechanics and preventing movement related injuries.

### 3.2.2. Design Practice Phase

The findings gathered from preliminary and focused interviews, directed and focused the design practice phase of the research masters project. Preliminary and focused interviews established that custom made orthotics was the current medical solution, for correcting abnormal lower limb biomechanics and reducing movement related injuries. In doing so, custom orthotics was identified as a product area offering the greatest potential for exploring the range of possibilities provided by the application of AM and digital technologies.

To inform product development, a participant with a history of lower limb injuries was required to explore the design, development and fabrication of custom-made orthotics. In doing so, a user trip was undertaken early on in the design practice phase. The objective of this user trip was to understand and gain further insight into the current tools, processes and techniques involved in prescribing custom-made orthotics. The researcher followed an unstructured and flexible approach, allowing the qualified podiatrist to carry out the procedures required for prescribing a custom-made orthotics. Throughout the activity, the user trip was documented and recorded using audio and photo recordings.

Following on, a product journey map was employed, to synthesise and capture the key points and insights gathered from the user trip. In doing so the Research Masters project explored how a combination of AM and digital technologies could be successfully integrated and implemented within the existing medical procedure to help improve and advance orthotic design. The researcher explored how it might be possible to successfully integrate AM and digital technologies with existing medical practice.

In the diagnosis and prescription phase, digital technologies, in the form of a foot pressure analysis system and 3D scanning, was explored and tested. In doing so, the data collected aided the researcher in designing a more user-focused and tailored orthotic solution.

Traditional design techniques in the form of concept generation, sketch modelling, model making were employed; to aid in concept generation and the development of FO prototypes for additive manufacturing purposes. The FO prototypes fabricated using AM technologies were tested for fit by the participant and evaluated by the podiatrist for subsequent design research evaluation. Finally, the researcher explored the implementation of multi-material technology within the application phase, to explore the material capabilities of multi-material technology and to further aid the patient, podiatrist and fabricator.

### 3.3 Reliability and Validity of the Research.

As mentioned previously, research through design approach was undertaken throughout the course of the project. For this reason, the researcher took a divergent and convergent thinking approach collecting data, analysing and reacting to the data collected. This was an iterative and repetitive process throughout the project. The data collected, guided the researcher through the project. In effect, this approach allowed the researcher to appreciate and fully understand the topic area and obtain a different perspective on the research issues.

The findings generated during the Research Masters project are considered to be trustworthy as the researcher sought to engage with medical professions throughout the process. The researcher employed multiple research methods to collect data on the same topic area, an approach known as triangulation. To summarise, triangulation of data helped to validate and ensured confidence in the research findings generated. The findings generated informed and focused the research project. In doing so, the researcher is confident that he has helped to demonstrate the reliability and validity of the research.

### 3.4 Ethical Considerations.

The overall ethical approach required that participation was fully informed and voluntary, that the participants' and researcher's safety was considered at all times, and that information collected was confidential and that all data generated was securely stored. Ethical consideration was of the utmost importance involving any interactions with participants and/or external bodies during the research process. The research adhered to the ethical guidelines set by the Institute of Technology Carlow (ITC) Ethics in research policy and referenced by ethical procedures.

The ethical consideration necessary for

- Informing and volunteering consent.
- Privacy and participant anonymity.
- Information Confidentiality.
- Storing and handling of data.
- Ensuring health and safety of participants.

Ethics requirements, participants were contacted and informed of the research. Each participant received a document outlining the following.

- The context of research.
- Research project objective.
- A description of methods used for data collection.
- A rationale for the methods used.
- Ensuring health and safety to participants.

A copy of the document is available for reference in Appendix A. The participant information sheet aimed to explain and ensure the participant was fully aware of the objective and purpose of the research being carried out. The consent form informed the participant of the research activities involved in the study. The overall ethical approach provided the basis for a meaningful exchange between the researcher and each of the participants. Finally, the participants' signature on the consent form provided documentation of agreement to participate in the study; however, the participant was made aware that participation was voluntary and that at any stage during the project the participant could withdraw this consent.

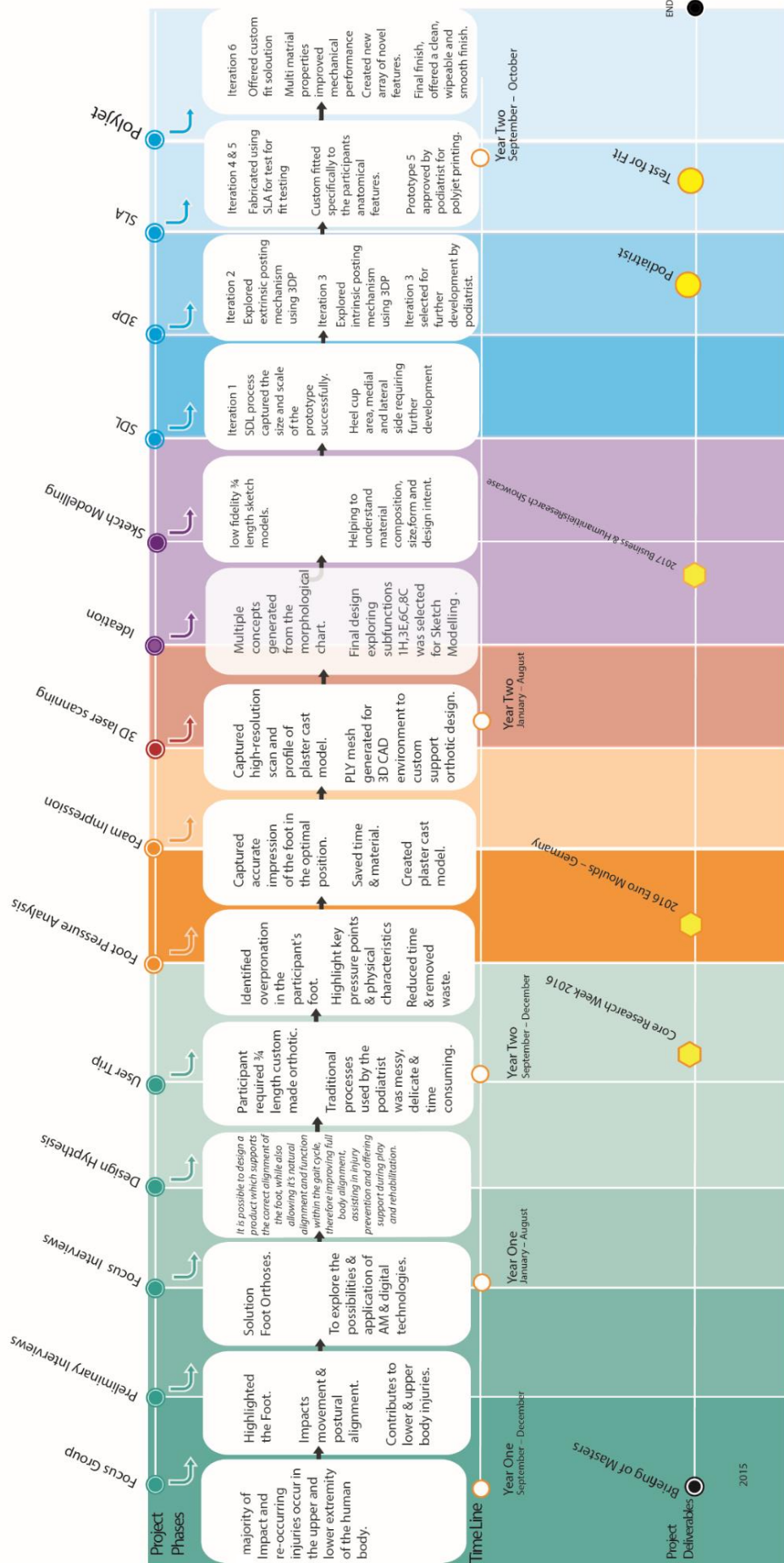


Figure 13: Diagram showing project phase, deliverables and iterations. Self-generated (2017).

## 4.0 Field Research.

### 4.1 Focus Groups.

This chapter outlines the field research undertaken throughout the Research Masters project. A combination of design research methodologies were used to gain an insight into the reason for injuries occurring in sporting scenarios. Design research methodologies involved focus groups, preliminary and focused interviews with medical practitioners and physicians with a background in sports science and rehabilitation, physiotherapy, podiatry and orthopaedics.

#### 4.1.1. Approach and Methods.

The objective of the focus group was to explore and gain insight; into the different types of injuries occurring in various sporting scenarios. Rosenfeld (2013, p 8) states that a focus group is a moderate discussion with 4 to 12 participants in a research facility, often used to explore preferences, the reason for these preferences among different solutions. The focus group was organised by contacting the Head of the Department of Sports Science and Health at the Institute of Technology, Carlow. The researcher made contact with a key gatekeeper.

- To identify the most common type of injuries that occur in sporting scenarios
- To highlight the types of injuries which can be prevented using protective sports equipment.

Before beginning the focus group, the researcher gave a presentation to the participants on the Research Masters project and on the unique design capabilities of additive manufacturing and 3D scanning technologies. The presentation made the participants aware of the project objectives and an overview of the proposed programme of research.

The focus group consisted of 12 participants. The 12 participants were subdivided into groups of 4. A flexible approach was undertaken to help encourage mind mapping and brainstorming techniques, to allow participants to capture their opinions, thoughts, ideas



and attitudes on the issues being addressed. The focus group involved three phases: exploration, synthesis and presentation of ideas.

Mind mapping templates were created to synthesise findings and analysis of focus group findings, which are available for reference in Appendix C.

#### 4.1.2. Focus Groups.

The focus group involved undergraduates from Sports Science and Rehabilitation at the Institute of Technology, Carlow. As part of the Sports Science and Rehabilitation course curriculum students study the following - running and walking biomechanics, nutrition, human anatomy and knowledge on the types of PSE being used to help prevent injury. A key element of their studies is working with special sports equipment, to help build athletes strength and flexibility in order to help prevent injuries to athletes. Therefore, sports rehabilitation and science undergraduates were selected for the focus group.

The students were divided into groups of 4. Each group focused on one particular sport, for example soccer, rugby, Gaelic and hurling. The groups were asked:

- To identify the different types of sporting injuries that occur in their chosen sport
- To categorise the injuries into re-occurring and impact.
- To Identify how these injuries could be prevented using PSE.



*Figure 14: Focus group with sports science and rehabilitation undergraduates.*

<b>Group 1- Gaelic</b>			
<b>Impact Injuries</b>	<b>PSE</b>	<b>Re-occurring Injuries</b>	<b>PSE</b>
Shoulder dislocation	<b>Shoulder strapping and pads</b>	Shoulder dislocation	<b>Shoulder strapping</b>
Collarbone breaks		ACL/MCL	<b>Knee brace</b>
Concussions		Hamstring strains	<b>Kinesotape</b>
Cheek fracture	<b>Protective mask</b>	Ankle sprains/breaks/fractures	<b>Ankle brace/boot brace</b>
Hip dislocations/fractures		Broken wrist	
Rational injuries		Broken Nose	<b>Nose guard/mask</b>
Metatarsal dislocation and breaks		Whip Lash	
Broken arms/legs		Golfer's elbow	<b>Braces, support, padding</b>
Ankle sprains/breaks/fractures	<b>Ankle brace Boot brace</b>		
Fractured spine			
Broken Nose	<b>Nose guard/ mask</b>		
Broken/fractured ribs			

*Figure 15: Focus group 1; Highlighted, the different types of re-occurring and impact injuries occurring in Gaelic football, the types of PSE being used.*

<b>Group 2- Hurling</b>			
<b>Impact Injuries</b>	<b>PSE</b>	<b>Re-occurring injuries</b>	<b>PSE</b>
Elbow	<b>Elbow pads</b>	Shoulders; strains	<b>Strapping</b>
Wrist fractures		Elbow; tennis elbow	<b>Elbow brace</b>
Fingers - fractures, bruising	<b>Hand guard</b>	Wrist; carpal tunnel syndrome	<b>Tape</b>
Back- slipped disk, fracturing	<b>Padded vest</b>	Fingers bruised, sprain, fractures	<b>Hand guard</b>
Ribs - broken, bruised		Back; slipped disc, locked T-spine, nerve damage.	
Knee - ACL, MCL	<b>Shin guards</b>	ACL/MCL/ LCL	<b>Knee brace</b>
Shin - bruising, fracturing	<b>Ankle brace</b>	Hips; minimus	
Ankle - Sprains, breaks, dislocations, tendons.	<b>Ankle brace</b>	Shin splints	<b>Shin guards</b>
Shoulders- AC joint dislocation.	<b>Strapping</b>		
Ears - cuts, bruises	<b>Tap</b>		
Foot - broken, slipped bone, metatarsal break.			
Concussions	<b>Helmet</b>		
Neck - whiplash			
Collarbone fracture			
Shoulder dislocations	<b>Strapping</b>		

*Figure 16: Focus group 2; Identified the various types of re-occurring and impact injuries occurring in Hurling, and how they can be protected using PSE.*

<b>Group 3- Soccer</b>			
<b>Impact Injuries</b>	PSE	<b>Re-occurring injuries</b>	<b>PSE</b>
Vertebrae break		Ankle sprain	<b>Ankle Sprain</b>
Concussion		Hamstring strain/tear	<b>Kinescope</b>
Ankle sprain	<b>Ankle brace</b>	Groin tear	<b>Kinesotape</b>
Shoulder dislocation	<b>Shoulder brace</b>	Quad tear	<b>Kinesotape</b>
Finger breaks	<b>Gloves</b>	Calf tear	<b>Kinesotape</b>
Broken nose	<b>Nose guard</b>	Back injury	<b>Kinesotape</b>
Whiplash		Hip dislocation	
Back injury	<b>Back brace</b>	Hip flexors	
Rotator cuff	<b>Tapping</b>	Patellar rupture	
Carpel tunnel	<b>Wrist strap</b>	Meniseus	<b>Knee brace</b>
Collar bone		ACL	<b>Knee brace</b>
Hip dislocation			
Wrist sprain	<b>Wrist strap</b>		
Jaw impact	<b>Gum shields</b>		
Broken ribs	<b>Brace</b>		

*Figure 17 : Focus group 3; Highlighted the types of re-occurring and impact injuries occurring in Soccer, and how they can be protected using PSE.*

<b>Group 4- Rugby</b>			
<b>Impact injuries</b>	<b>PSE</b>	<b>Re-occurring injuries</b>	<b>PSE</b>
Bicep tendon tears		Concussion	
Concussion		Eye socket	<b>Goggles</b>
Eye socket	<b>Goggles</b>	Cauliflower ears	<b>Tape/scrum cap</b>
Cheekbone		Fingers, hands, thumb	<b>Tape</b>
Broken jaws		Wrist	<b>Tape</b>
Cauliflower ears	<b>Tape</b>	Ankle sprains and strains	<b>Braces</b>
Windpipe		Blisters	<b>Vaseline</b>
Nose break	<b>Protective mask</b>	Shoulder disk	<b>Shoulder brace/strapping</b>
Collarbone break		Nerve compression	
Fingers, hands, thumb, wrist	<b>Protective gloves, thumb strap</b>	ACL	<b>Knee brace</b>
Elbow injuries		Disc bulge	
Shoulder dislocations	<b>Strapping, shoulder brace</b>		
Broken ribs			
AC Joint tears			
Broken legs			
Forearm break	<b>Padding</b>		

*Figure 18: Focus group 4; Highlighted the various types of re-occurring and impact injuries occurring in Rugby, and how they can be protected using PSE*

Focus group; findings concluded that a majority of impact and re-occurring injuries appeared in both the upper and lower extremity of the human body. Furthermore, many impact injuries were a result of contact with other athletes and external factors of play. Findings also highlighted that the risk of fractures, dislocations or bruising can be reduced using various types of PSE. Re-occurring injuries, for example, hamstring strains, ankle sprains, ACL, MCL, back pain and concussion, were highlighted as being more difficult to prevent using PSE.

As a result, these findings; led to preliminary interviews with physiotherapists in order to gain a better understanding of the different types of injury occurring and re-occurring in sporting scenarios and to understand the causes and reasons for these injuries.

## 4.2 Preliminary Interviews

### 4.2.1. Approach and Methods.

Five preliminary interviews, mainly with medical practitioners involved in physiotherapy, were conducted. Preliminary interviews' consisted of five participants. A semi-structured approach allowed participants to comfortably and freely discuss their past and present experiences within clinical practice. This approach allowed the researcher to gain insight into the participants' opinions, beliefs and reasoning for the types of injury, occurring and re-occurring within various sporting scenarios.

The researcher selected the participants based on their professional expertise and experience. Prior to engagement, interviewees were contacted either through email or by telephone. Participant information sheets were emailed to the participants prior to interviews to introduce the interviewees to the research area and research project objectives.

Interviewing of participants was on a one to one basis. Secondary sourcing and scoping of literature provided the researcher with a grounded understanding of the material throughout the interviews. The semi-structured nature of the interview allowed the researcher to follow a list of open-ended questions related to the research issues. This approach allowed the interviewer to control the type of questions being asked, as well as to help categorise and analyse the key findings and themes as they emerged during the interview.

Documentation of transcripts and analysis of each interview can be seen in Appendix B.

### 4.2.2. Preliminary Interviews with Physiotherapists

Physiotherapists were selected for preliminary interviews. Practitioners who specialise in physiotherapy; are professionals who are concerned with helping individuals of all ages return to full health after injury, pain or disability. They have expert knowledge of the human anatomy and understand how the human body works. Also, physiotherapists engage with individuals who participate in sporting activities almost on a day to day basis.

Physiotherapists are also very aware of the different types of injuries occurring in sporting

scenarios and, therefore, were considered key stakeholders in the initial stages of field research.

The main objectives of this field research was:

- To gain an understanding of the different types of injury occurring and re-occurring in sporting disciplines.
- To understand the causes and reasons for injury.
- To best understand constraints and any additional requirements when designing for the human body.
- To identify an area of the body most suitable for designing a new form of PSE.
- Finally, to understand the effects and impacts of injury.

#### 4.2.3. Outcomes.

Preliminary interviews with physiotherapist highlighted the following outcomes;

##### **Occurring and Re-occurring injuries in sporting scenarios:**

- The majority of upper body injuries; occurred in the, Head, Neck, Shoulder, hand Lower back, rib and wrist.
- The most common types of injury, all occurred in the lower body; Hamstring strains, muscle strains, ankle, knee, foot, ACL and MCL injuries.

##### **The effects and impact of injury:**

- Injury can affect an athlete daily routine and livelihood, depending on the injury and job.
- Injury can cause physical implications, financial, emotional and physiological well-being.

##### **Causes and reasons for injury:**

- Causes of injuries include; abnormal running, walking and landing mechanics.
- People lifestyle choices, caused by the sedentary lifestyles of modern-day life.
- External factors such as playing surfaces that are of good quality, which means players are not inclined to build up stability, which can later lead to injury.
- Poor intrinsic muscles and lack of stability.

- Poor footwear.
- Injuries can be traced back to incorrect body posture brought on by poor foot posture.
- The type of sport played by the participant can increase the risk of injury.

**Factors to take into account when designing a device for the human body:**

- To be aware of how to protect an area of the body without taking away the main function of that body part.
- To ensure the device doesn't affect or diminish player performance.
- The device must be lightweight and not restrict movement or mobility in any way.
- The device must not interfere or diminish function, movement and natural body strength.
- The device must permit full and natural movement to occur. It should not be rigid or uncomfortable for the player to wear during the sporting activity.

**Area of the body, most suited for a custom - made PSE.**

- Foot, ankle and big toe, Hip, Fingers, elbow and Head.

Preliminary interview findings concluded that the foot, as the foundation of the human body, directly impacts on functional movement and postural alignment. Incorrect foot positioning causes instability and is, therefore, a key contributor to both upper and lower body injuries. These findings; led to focus interviews, with medical practitioners with a background and expertise in podiatry and orthopaedics.

### 4.3 Focus Interviews.

#### 4.3.1. Approach and Methods.

Similar to preliminary interviews, focused interviews followed a semi-structured approach. Following analysis of preliminary interviews, further secondary sourcing of literature informed the researcher with a grounded theory understanding of the material throughout; focused interviews. Three participants were selected for the focused interviews and were selected based on their medical expertise and experience in orthopaedics and podiatry.

Documentation of transcripts and analysis of each interview can be seen in Appendix B.



#### 4.3.2. Orthopaedic and Podiatry.

**Podiatrist;** provide preventative care, diagnosis of a range of problems affecting the feet, ankles and lower legs.

**Orthopaedics;** is a medical profession that focuses on the diagnosis, care and treatment of patients with disorders of bones joints, muscles, ligaments, tendons, nerves and skin.

A key emphasis placed on focused interviews was to gain insight on the following;

- The biomechanical role of the foot.
- Orthotics.
- Procedures involved in prescribing custom orthotic devices.
- Issues related to orthotics.

#### 4.3.3. Outcomes.

Semi-structured interviews with both orthopaedics and podiatrist highlighted the following conclusions.

##### **Reasons for Injury:**

- Reasons for injuries include; Biomechanical factors, foot posture, over-pronation, tensile stress, and lifestyle changes.

##### **The role of the foot:**

- The foot is controlled by neuromuscular control, the sensory information and signals generated in the brain that teach the body conscious control of a specific movement.
- The talus bone is a key bone of the foot, which has three planes of movement. Adjacent, plantar and transverse plane. These planes dictate the movement of the foot, which dictates and controls the movement of the body.
- Incorrect positioning of the foot can cause further stress on muscles and bones, which can lead to hip, back pain and injuries later on in life. For example, a foot with poor posture can affect the biomechanics of the ankle and, in turn, can transfer misalignment to the hip, the spine, the neck and skull.
- The foot needs to be in the optimal position to prevent injury.

**Current methods for correcting poor foot posture:**

- Orthotics are used to correct poor foot posture.
- Exercises methods, for correcting soft tissue issues in the foot.
- Worst case scenarios, individuals are referred to orthopaedic specialists for surgery.

**Orthotics:**

- The function of orthotics is to relieve pressure from the body, correct individual malfunctions, improve full body alignment and therefore reduce the risk of injury.
- The majority of orthotics; aim to find a neutral position of the subtalar joint, the talus bone of the foot.
- Custom orthotics are specific to the individual abnormalities, issues and specific foot problems.
- The material used in orthotics comes down to the individual health problems and lifestyle demands.
- An orthotic is a custom-made device, because every type of individual is different and no two individuals would require the same prescription.
- Patient compliance is a key element in the success of orthotic devices.

**Procedures involved in prescribing a custom made devices:**

- Prescribing orthotics involves assessing the individual in order to identify any obvious or unusual feature within the foot.
- Biomechanical assessment involves assessing the patient's gait, the patient's stance and overall body posture.
- Traditional methods, such as plaster cast and foam impression kits can be used to capture the foot the contours and external form of the foot in an optimal position.
- Scanning equipment can also be used to capture the patient foot pressure.
- The podiatrist or physician then prescribe an orthotic based on their diagnosis.
- The patient usually receives the orthotic in 3 to 4 weeks.
- Prior to receiving the correctable orthotic the individual is required to build up support and this usually involves wearing a basic insole with a minimal correction.
- The patient is assessed after two weeks and a correctable orthotic is fitted.

- A follow-up consultation is normally required after a six to twelve-month period to check progress and to re-assess the condition.

#### **Issues with Orthotics:**

- Orthotics can sometimes restrict or prevent natural movement occurring within the foot.
- The majority of orthotics don't allow natural movement to occur in the foot so that the body is kept in the neutral position.
- Some practitioners and patients feel orthotics don't work very well because the foot can no longer move naturally and this may create additional issues for the patient wearing the orthotic.

Focus interview findings concluded that the current solution for correcting poor foot posture is custom-made orthotics. Orthotics have been shown to improve full body alignment and, therefore, can reduce the risk of injury. However, findings also concluded that custom made orthotics can prevent natural movement within the foot and it was suggested that the orthotic device design could be refined to ensure that natural foot movement is restored. The researcher identified custom orthotics as a product area offering the greatest potential for exploring the range of possibilities provided by the application of AM and digital technologies.

## **5.0 Design Practice Phase.**

### **5.1 Design Hypothesis.**

A review of the literature followed by key stakeholder interviews provided an understanding of the foot orthoses industry, digital technologies and AM techniques which led to the development of a focused design hypothesis

*It is possible to design a product which supports the correct alignment of the foot, while also allowing it's natural alignment and function within the gait cycle, therefore improving full body alignment, assisting in injury prevention and offering support during play and rehabilitation.*

Prior to exploring custom orthotics as a product area using AM and digital technologies, preliminary and focused interviews noted that custom made orthotics are unique to an individual's abnormalities, issues and specific foot problems. It was, therefore, essential to identify a participant with foot alignment issues that required an orthotic prescription as a key element of their treatment. Finding a suitable candidate would, therefore, assist the researcher in exploring design solutions and in developing and fabricating a custom made orthotic incorporating digital scanning technologies, additive manufacturing technologies and digital materials.

## 5.2 Participant selection.

The aim of participant selection was to select an appropriate case study for the design phase to assist the researcher to explore the design, development and fabrication of orthotic devices.

### 5.2.1. Approach and Methods.

A review of literature informed the participant selection. Synthesis of secondary sourcing of information highlighted a range of problems associated with the cause of injuries. This led to an interaction matrix model being employed. The interaction matrix model was explored and set out in chart form. This approach allowed the researcher to identify and analyse key relationships related to the problem. The results collected were synthesised into a participant criteria sheet and the researcher made contact with staff and practitioners at the Sports Clinic at the Institute of Technology Carlow (ITC). The researcher identified clinical staff at the Sports Clinic, ITC as key gatekeepers in selecting a suitable participant for this phase of the project.

### 5.2.2. Participant Selection.

The Literature Review identified that lower limb injuries occur as a result of various types of biomechanical abnormalities, (see page 9). An interaction matrix model was applied to the research gathered in order to explore and set out in chart form the most common biomechanical abnormalities occurring that related to lower limb injuries (see figure 20) This design research method informed the researcher that over pronation was a key contributor

in the creation of lower limbs injuries. It was felt that the best candidate for participation in the design phase would be a participant with a history of lower limb injuries caused by over pronation in the foot.

The researcher identified clinical staff at the Sports Clinic, at ITC to determine and select a suitable participant. Clinical staff at the sports clinic at ITC were chosen as gatekeepers because of their expertise and experience of helping patients return to full health following injury within the ITC campus. Staff were informed of the ideal candidate through the participant criteria sheet. This assisted and focused the clinical staff in identifying an individual with over pronated feet and a history of lower limb injuries. The injuries listed below were highlighted as the most common injuries caused by over pronation of the foot. These following injuries were outlined in the participant criteria sheet in order to identify a suitable candidate:

- Sesamoiditis
- Plantar Fasciitis
- Achilles Tendinopathy
- Peroneal Tendinopathy
- Navicular Stress Fractures
- Fibular Stress Fractures
- Patellar Tendinopathy
- Medial Shin Pain

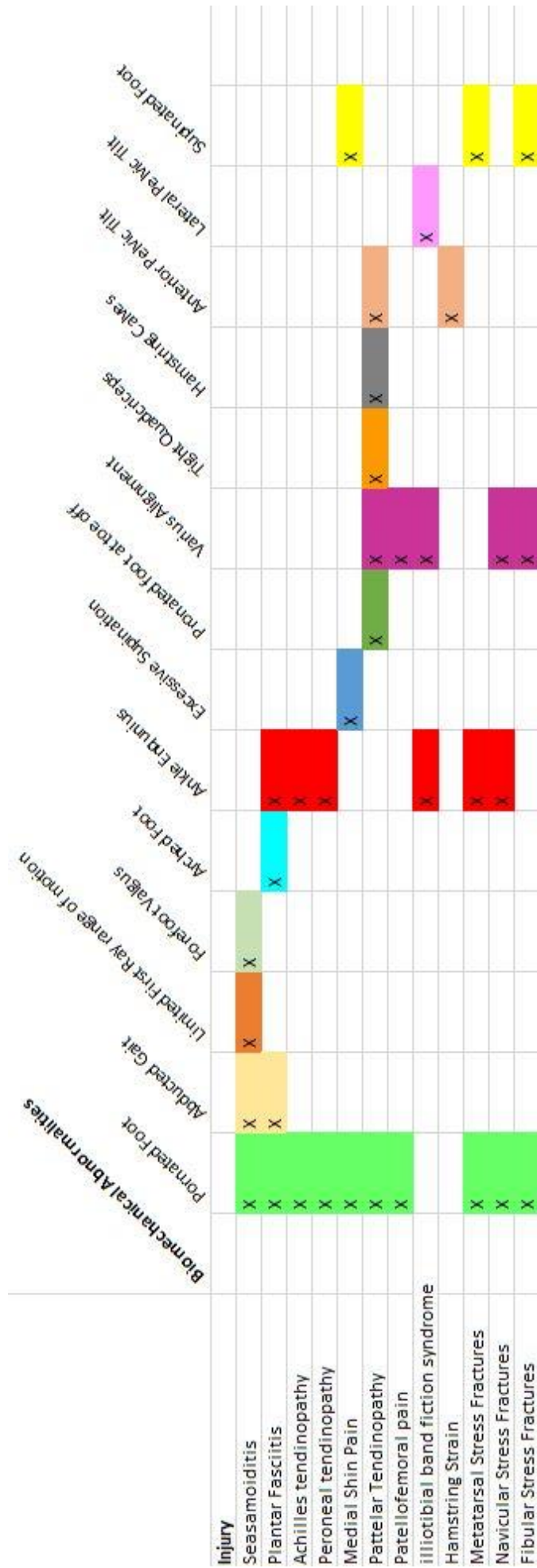


Figure 19: Interaction matrix, identifying the most common type of lower limb injuries and biomechanical abnormalities.

### 5.2.3. Findings and Outcome.

Clinical staff at the sports clinic at ITC identified a participant who was actively involved in a range of sporting activities with the following re-occurring and acute injuries:

- Shin splints
- Calf pain
- History of ankle sprains
- Ligament damage in the right foot.

Clinical staff highlighted that the cause of these injuries was a result of biomechanical abnormalities occurring in the lower limb of the participant body. The clinical staff noted that the participant would require orthotics in the near future to help resolve these ongoing issues.

These findings led to the researcher engaging and inviting the participant to take part in the design phase of the project.

## 5.3 User Trip.

The purpose of the user trip was to understand and gain further insight into the current tools, processes and techniques used in prescribing custom made orthotics.

### 5.3.1. Approach and Methods.

The user trip involved both a qualified podiatrist and the selected participant with a history of lower limb injuries. Following on, both the selected participant and podiatrist were informed of the overall aim of the project using a prepared participant information sheet. The user trip followed an un-structured and flexible approach and this facilitated the podiatrist in carrying out all the procedures required for prescribing a custom made orthotic.

The user trip was conducted in a clinical setting. This allowed the researcher to gain insight into the current tools, processes and techniques used in prescribing custom made orthotics.

Documentation of transcripts and analysis of user trip can be seen in Appendix B.

### 5.3.2. The User Trip.

The user trip involved four main phases: biomechanical assessment, patient examination, plaster casting and the taking of foam impressions.

#### **Biomechanical Assessment and Examination:**

A biomechanical assessment was undertaken by a qualified podiatrist to identify what biomechanical abnormalities were evident in the participant and to develop a diagnosis plan for the participant.

During this assessment the podiatrist inquired about the participant's past injuries, medical history, lifestyle and sporting activities. Next, the podiatrist began to examine the participant's lower body. This phase involved examining the feet, lower leg positioning and length as well as assessing hamstring flexibility and the range of motion within the hip.

Furthermore, the participant's feet were examined in the midfoot, forefoot and rear foot position. The aim of this stage of the examination was to explore the range of motion occurring in the feet and to detect any symptoms of pain, stiffness, muscle weakness and evidence of poor foot posture. (See figure 21).



*Figure 20: The podiatrist: examining and assessing the participant's lower extremity and foot.*



Next, the participant was asked to stand and the podiatrist assessed the participant in a stance position whilst the podiatrist assessed the participant's lower and upper body symmetry. The aim of this method was to highlight any unusual abnormalities and alignment issues occurring in the participant body. (See figure 22)



*Figure 21 : The podiatrist, examining the participant, lower and upper body symmetry.*

The podiatrist then used gait analysis techniques to assess how the patient walks. The podiatrist analysed the participant's walking gait from a distance. At the same time, the podiatrist made visual and written documentation of the patient's gait during the process. The aim of this method was to determine any biomechanical abnormalities or structural changes occurring in the lower limb and feet of the participant. (See figure 23).



*Figure 22 : The podiatrist, examining the participant walking gait.*

## Outcomes and Findings:

### Outcomes and Findings:

- The participant's previous injuries were calf pain, shin splints, ankle sprains and ligament damage to the right ankle
- The participant highlighted that the right foot was heavily 'strapped' for every playing and training session, in order to give support to the ankle
- The Range of Motion (ROM) was restricted in the participant right foot
- The podiatrist identified that the participant only had 10 to 20 degrees ROM in the first metatarsal of the right foot (Normal ROM is around 90 degrees).
- The podiatrist deduced that any restriction of movement in the right foot was most likely due to excessive pressure being applied during the gait cycle.
- The podiatrist diagnosed that the tibia bone leant outwards and, therefore, genu varum tended to occur, which is also referred to as 'bowing of the legs'.
- The gait analysis highlighted 'rolling' of the right foot most likely caused by tilting in the hip and shoulder on the left-hand side of the participant's body.
- The podiatrist cited the over-pronation of both of the participant's feet as main cause or factor associated with the participant's history of re-occurring lower limb injuries.

These findings informed the podiatrist and assisted in formulating a prescription plan for a custom made orthotics. The treatment using an orthotic device was seen as the best approach to help correct the participant's foot posture and, in turn, the participant's overall body alignment. The prescription plan highlighted the following key points:

- The participant required a three quarter length custom-made orthotic
- The orthotic would consist of a flex-firm shell type offering flexibility, strength and durability.
- The prescription recommended that a rear foot posting of 3 degrees was necessary to hold the foot in the optimal position.

Documentation of the prescription can be seen in Appendix C.

### **Plaster Cast:**

The treatment plan began with the podiatrist taking a plaster impression of the participant's feet in the optimal position. Traditionally, these plaster cast impressions are used during the manufacturing stage of orthotics. This plaster cast process involved the following stages:

- The participant was asked to lie on the medical table with both feet overhanging
- Paper towels were placed on the floor and a basin of water was prepared for the casting procedure.
- The podiatrist then measured and cut strips of plaster bandages, as required, to cover the participant's feet

Separately, each of these bandages were drawn through the water in the basin, then rinsed and applied directly to the participant's left foot. The plaster bandages were massaged into the foot in order to remove any air bubbles between plaster bandage strips.

- Once the casting material was applied the podiatrist held the participant's foot in the neutral position until the cast was dry and fully set.
- After drying, the podiatrist slowly removed the cast from the left foot.
- The plaster cast process was then repeated on the right foot.
- Finally, the participant's feet were washed and cleaned in a foot bath.

See figure 24.



*Figure 23: the podiatrist applying strips of plaster to the participant's foot, to create a plaster cast impression.*

### **Foam Impression:**

Following the plaster cast session the researcher elected to explore other methods of capturing the foot in the optimal position, this involved using a standard foam impression kit box, from Novotritt Orthopaedic Services Limited. These kits are inexpensive and, as with the plaster casts, they are also used during the manufacture of orthotic devices. The objective of this session was to achieve an accurate negative impression of the participant's foot. This process involved the following steps:

- The volunteer was asked to be seated with their legs at 90 degrees
- The foam impression box was placed underneath one of the participant's feet.
- The podiatrist held the participant's foot in the neutral position.
- The heel of the participant was firstly placed into the foam impression box.
- The participant was then asked to slowly apply pressure to the foam impression box.
- The podiatrist held the participant's big toe throughout the process in order to prevent the foot from rolling into pronation.

- The participant was asked to stand up and to apply the even pressure across the foam impression box.
- Next, the participant was asked to walk through the foam impression box.
- Finally, the participant was then asked to remove the foot from the foam impression box.
- This process was repeated on the opposite foot (see figure 25 )



*Figure 24: The podiatrist; capturing the optimal positioning of the foot, using the foam impression box.*

### **Outcome and findings:**

- Foam impression kit saves time and material when capturing the optimal impression of the foot.
- No setup or clean-up was required when carrying out this process.
- The foam impression kit produced accurate impressions of the participant's foot.
- The kit was also easy to handle and offered a degree of protection for sending to the fabricator by post.
- The podiatrist felt that the foam impression kit box was more difficult to use than the plaster casting process.

The foam impressions created assisted in capturing a three-dimensional (3D) impression of the participant's feet, in the optimal position. Normally these foam impressions kits aid in the fabrication of custom orthotic devices and are sent to the fabricator with the podiatrist's prescription. However, two of the foam impressions taken during this user trip were reserved for the model making and 3D scanning elements that followed in this project.

#### 5.4 Product Journey map.

As a follow up to the user trip the researcher prepared a product journey map to record, synthesise, capture and frame the insights, individual actions, feelings and perceptions gathered from the user trip.

##### 5.4.1 Approach and Method.

The product journey map was structured and framed; this allowed the researcher to highlight the key interaction points occurring between the patient, podiatrist and manufacturer. The purpose of the product journey map was to structure and capture the current medical procedures involved in the prescription, application, and diagnosis phases of custom-made orthotic devices.

This allowed the researcher to further highlight where both additive manufacturing and digital technologies would be most warranted and needed within the current systematic medical procedure. The design of the product journey map led to how a combination of digital technologies can be integrated within the existing system to help improve and advance orthotic design.





#### 5.4.2 Product Journey map.

The overall design of the product journey map was user-focused. The structured and framed approach allowed the researcher to categorise key stakeholders and their individual tasks at each stage of the journey map. Multiple maps were created to reflect the stakeholders' actions that occur before, during and after product interaction.

In doing so, the approach provided key insights into interaction points occurring between the user, podiatrist and manufacturer. As a result, this method helped visualise the overall journey and experiences involved in the diagnosis, prescription and application phases of the existing medical procedure (see figure 26).

Furthermore, this design activity provided the researcher with a story of individual actions, feelings, perceptions on the current tools, techniques and processes involved in prescribing a custom-made orthotic.

Analysis of the product journey map involved addressing how the current medical procedure can be improved upon, through the integration of additive manufacturing and digital technologies. This was achieved through exploratory sketching of the idea on post-it notes which allowed the researcher to place the idea where appropriate within the existing procedure. This approach led to a combination of various digital technologies and how they can be implemented within the current system to help improve and advance orthotic design. (See figure 27).



Figure 26: Exploring the integration of various digital technologies, within the current orthotic procedure.



### 5.4.3 Outcome and Findings.

The creation of the product journey map from the different perspective of the user, podiatrist and manufacturer led to a number of key outcome and findings:

- The podiatrist is the key stakeholder in assessing the user and prescribing the correct orthotic to help addresses the user biomechanical abnormalities
- The podiatrist dictates and guides the overall design of the orthotic using a prescription form.
- The material selection within foot orthoses design is limited to only three types of CE material, rigid, semi-rigid and soft.
- The purpose of foam and plaster cast impressions is to help aid the manufacturer in the fabrication of custom-made devices.
- The manufacture of custom made orthotics can take up to four weeks using traditional manufacturing techniques, such as vacuum moulding and CNC machining.
- Product development within custom made orthotics is not encouraged due to the inherent limitations of traditional orthotic manufacturing techniques.

The interaction and analysis of the user journey map highlighted the following combinations best suited to help improve and advance orthotic design.

- In the diagnosis phase, digital technologies can be implemented to reduce waste, save time and highlight key physical characteristics compared to the traditional methods currently used by some podiatrists.
- In the prescription phase, scanned data from 3D scanning machines can assist in providing a more user-focused and tailored solution through the importing of this data directly in to CAD packages and thereby ensuring and improving overall fit and function.
- Finally, it is possible that the implementation of multi material printing technology and digital materials within the prescription and application phase can: improve the range of material properties available for consideration by the podiatrist and fabricator and, consequently, promote and ensure better comfort for the patient, reduce the lead-time required to produce the orthotic device and offer opportunities

to create additional iterations of the orthotic device for sport, for commuting, for relaxing, etc.

To summarise, findings identified in the product journey map identified areas and opportunities for exploring and integrating digital technologies and digital materials within the existing medical practice during the diagnosis, prescription and application phases. (See Figure 28)

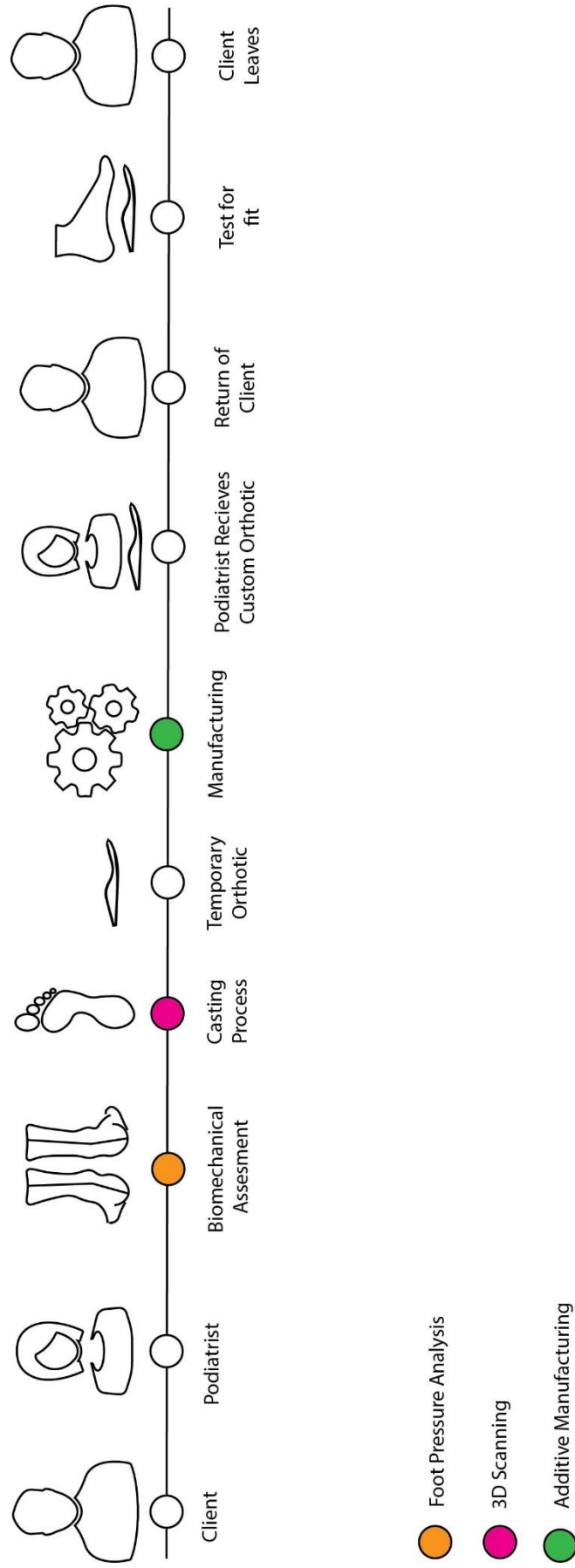


Figure 27: Product Journey Map, highlighting the implementation of digital technologies, within the existing medical procedure

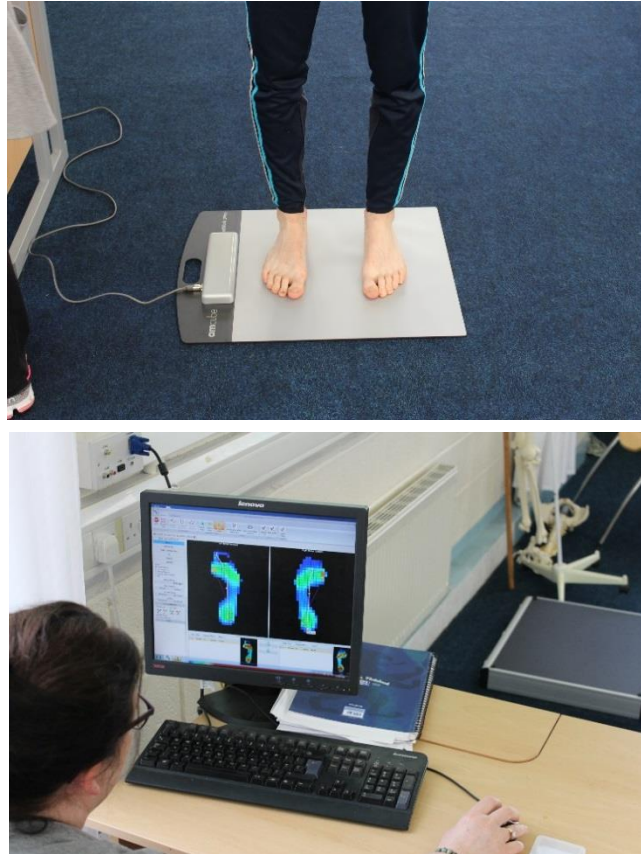
## 5.5 Foot Pressure Analysis.

Foot Pressure Analysis, also known as Pedobarography, detects and examines the pressure fields acting between the plantar surface of the foot and any supporting surface. Foot pressure analysis is often used for biomechanical analysis of gait and posture, and is employed in a wide range of applications including sports biomechanics and gait biometrics. The researcher explored opportunities for better integration of existing foot pressure analysis equipment within the diagnostic phase and also explored opportunities for foot pressure analysis data to augment the 3D digital technologies already cited for consideration. The objectives of this trial were:

- To understand how the foot pressure analysis testing can aid the podiatrist in the diagnosis phase of the existing medical procedure.
- To understand the the clinical impact of weight and pressure distribution across the participant's foot/feet.
- To identify and analyse the significant pressure points occurring in the participant's feet.

### 5.5.1 Approach and Methods.

A foot pressure analysis test was undertaken to capture the participant's weight and foot pressure distribution. The test was conducted by a trained technician and the test was carried out on the project participant. The participant's foot pressure was captured using an AM Cube foot pressure plate and the data collected was processed using the Footwork Pro software package. The test permitted pressure points within the participant's feet to be highlighted and analysed on the PC monitor.



*Figure 28: The foot pressure analysis procedure*

#### 5.5.2 Foot pressure Analysis Test.

The foot pressure analysis test involved the following:

- Firstly, the participant was asked to stand bare-footed on the AM Cube foot pressure plate.
- The technician asked the participant to stand naturally and to look straight ahead
- The technician captured and recorded the results using Footwork Pro computer software.
- Finally, once a sufficient amount of data had been captured the participant was asked to step off the plate.

See figure 29.

### 5.5.3 Outcomes and findings.

The foot pressure analysis test was particularly useful and captured and illustrated the pressure fields between the plantar surfaces of the participant's foot and the detection plate surface. The test was very time efficient and, compared with traditional methods for biomechanical analysis of gait and posture, saved time and reduced or eliminated waste.

Key points identified were:

- The foot pressure analysis demonstrated that the participant had significant pressure to the heel area and only moderate pressure in the forefoot.
- The foot pressure analysis also highlighted that the participant applied 69% more weight on their left foot, as opposed to the 38% being applied on the right foot. Light blue areas indicated very little pressure between the plantar surface and the test plate, light green areas indicated moderate pressure and yellow/red highlights indicated extreme pressure occurring mainly in the participant's heel.

See figure 30.

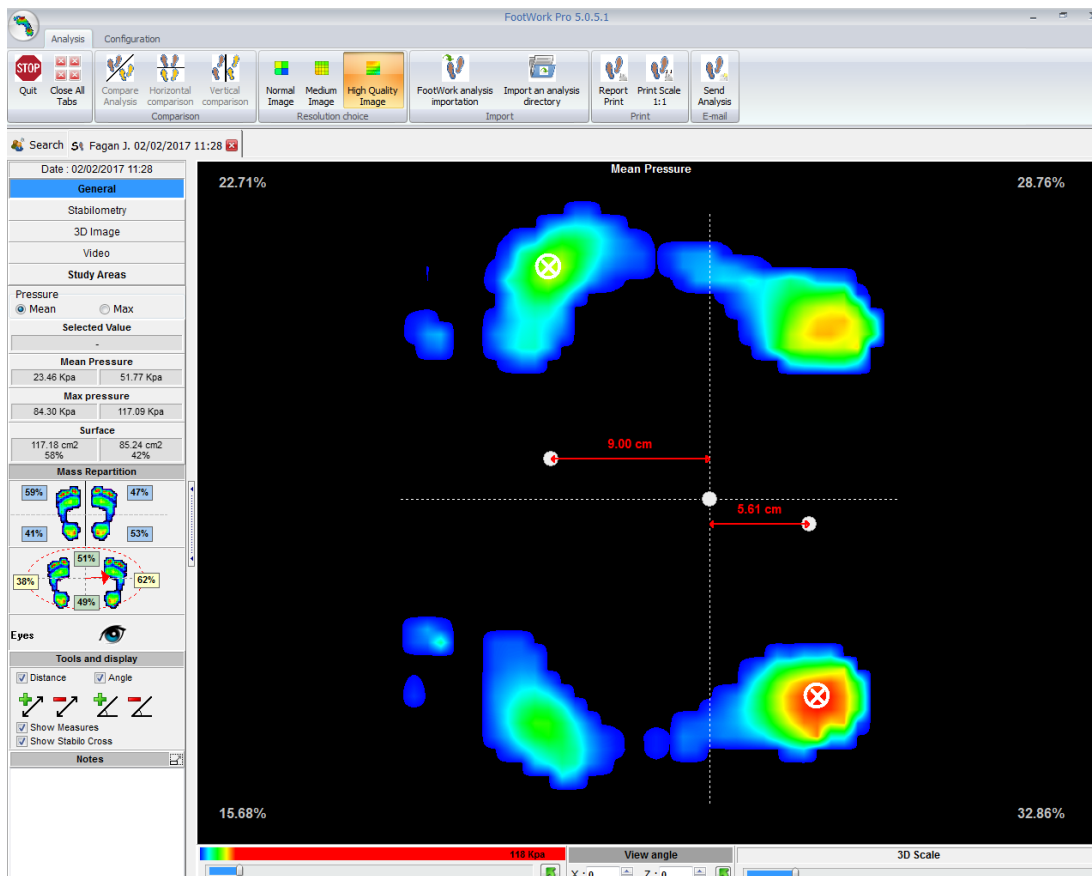


Figure 29: Results of the foot pressure analysis tests

To summarise, the scanned data collected from the foot pressure analysis test assisted in the podiatrist and highlighting key pressure points occurring in the participant's foot. The scanned data collected aided the researcher in introducing new and novel features within the design of the orthotic to help relieve pressure areas on the participant's foot.

## 5.6 Casting Process.

A key project objective was to explore the integration of 3D scanning technology within the prescription phase for orthotics. However, as the 3D scanner is very sensitive to the slightest movement of the subject being scanned it was impossible to scan the participant's foot directly to file. Therefore, to complete a successful scan the researcher required a completely static model of the participant's foot. A plaster cast model was prepared using the foam impression boxes from the user trips as moulds. These static models eliminated concerns of any movement occurring during the scanning process.

### 5.6.1 Approach and Methods.

The foam impression kit box from the assessment phase were repurposed as moulds to capture the participant's foot as a static plaster model. Plaster of Paris powder and water were mixed to form a quick-setting liquid that was then poured into the moulds. Once dry and sufficiently durable the models were removed from the moulds and, where necessary, the models were sanded, sealed and painted a matte white finish. The plaster casting was conducted in a clean and safe laboratory environment.

### 5.6.2 Casting Process.

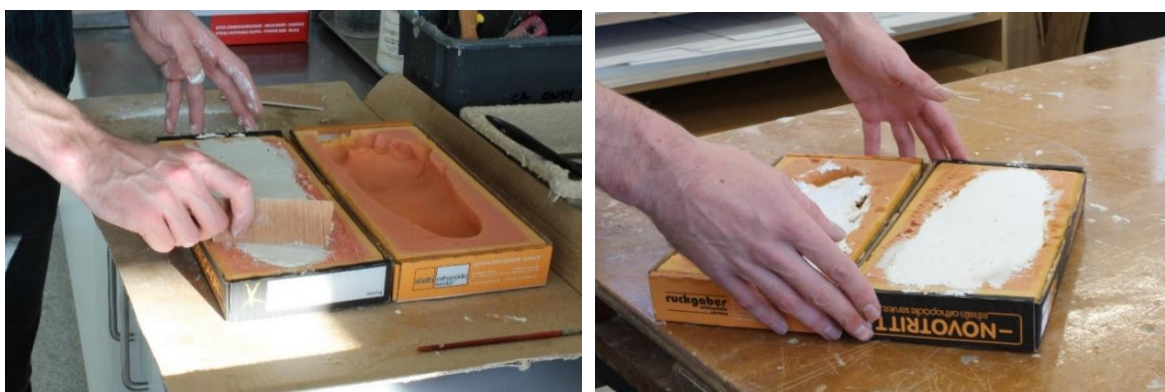
The foam impression moulds were sprayed with a release agent to prevent the plaster sticking to the foam material. Next, the plaster of paris material was prepared for mixing purposes. Preparation of material involved measuring the correct amount of plaster of paris and quantity of water required, before combining the material. The researcher followed a ratio of two cups of powder to every one cup of water. The overall process involved eight cups of powder to four cups of water.

Combining the material involved slowly applying cups of plaster of paris powder to the bucket of water. Before mixing the powder and water together, the powder was allowed to soak into the water first. At the same time, tapping was applied around the bucket of water to help release air bubbles. Following on, the mixture was gently and slowly stirred until an even consistency was created. (See figure 31).



*Figure 30: Mixing of both plaster of paris powder and water, to create the plaster of paris mixture.*

Once an even consistency was achieved, the mixture was poured into the foam impression moulds. The plaster of Paris material was filled to the top of the moulds and the surface of the plaster was made level. The moulds were left to dry and cure for 24 hours. (See figure 32).



*Figure 31: Applying the plaster or paris mixture to the mould (left), the mould after 24 hours of drying (Right).*



The models were removed from the sacrificial foam impression kit box. Excess orange foam was removed from the foot by hand. (See figure 33).



*Figure 32: deconstruction of the mould (left), removal of excess orange foam from casting (right)*

The model required some additional hand finishing and sanding to obtain a cleaner model. (See figure 34).



*Figure 33: Sanding of the plaster cast model.*

Next, further post processing and finishing were required. This process involved filling, sanding and priming the model to remove any imperfections within the plaster cast model. Finally, a matte white finish was applied as necessary for 3D scanning purposes. (See figure 35).



*Figure 34: Sanding and priming of plaster cast model (left), Spraying of model (right).*

### 5.6.3 Outcome and Findings.

- The plaster of Paris material dries extremely quickly once the mixing process begins.
- The foam impressions boxes were sacrificial and could only be used for a single casting.
- The foam impression boxes are quite shallow and, therefore, required very little material.
- Additional post-processing and finishing were required to ensure the plaster cast model would be suitable for 3D scanning.

The overall casting process, led to the creation of a plaster cast model, accurately capturing the participant's anatomical foot features in the optimal position. The model was prepared used to facilitate, explore and validate the application of 3D scanning within the prescription phase and design phase of the orthotic design.

## 5.7 3D Laser Scanning

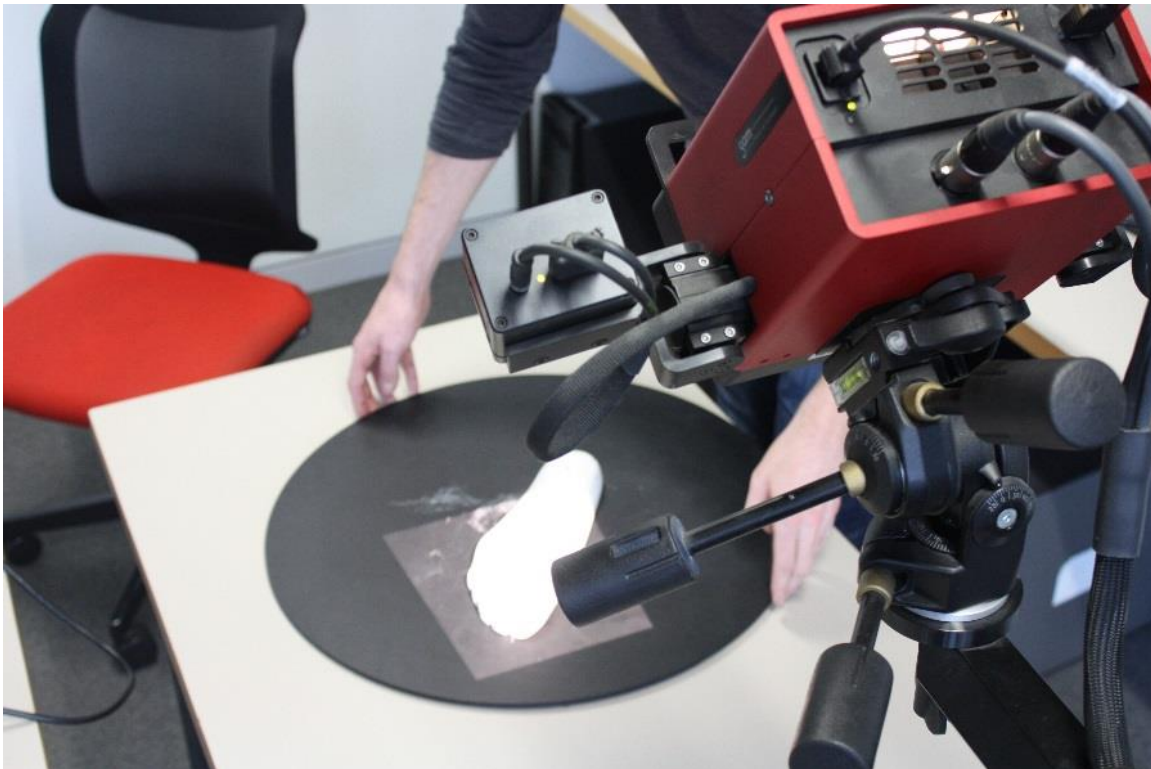
A fundamental requirement of this project was to produce and present a custom fit orthotic for the participant. 3D laser scanning was employed to capture an accurate profile of the participant's foot.

### 5.7.1 Approach and Methods.

The plaster cast model of the participant's foot was 3D scanned using a GOM ATOS II in a clean and controlled environment. The software used to generate the scanned data was a combination of 3D scanning technology and 3D CAD based software allowed for scanned data to be accurately generated from the plaster cast model for CAD manipulation. The plaster cast model was used to eradicate concerns with movement during scanning. Furthermore, the plaster cast model provided a repeatable, static source in case a repeat scan was required later on in the research process.

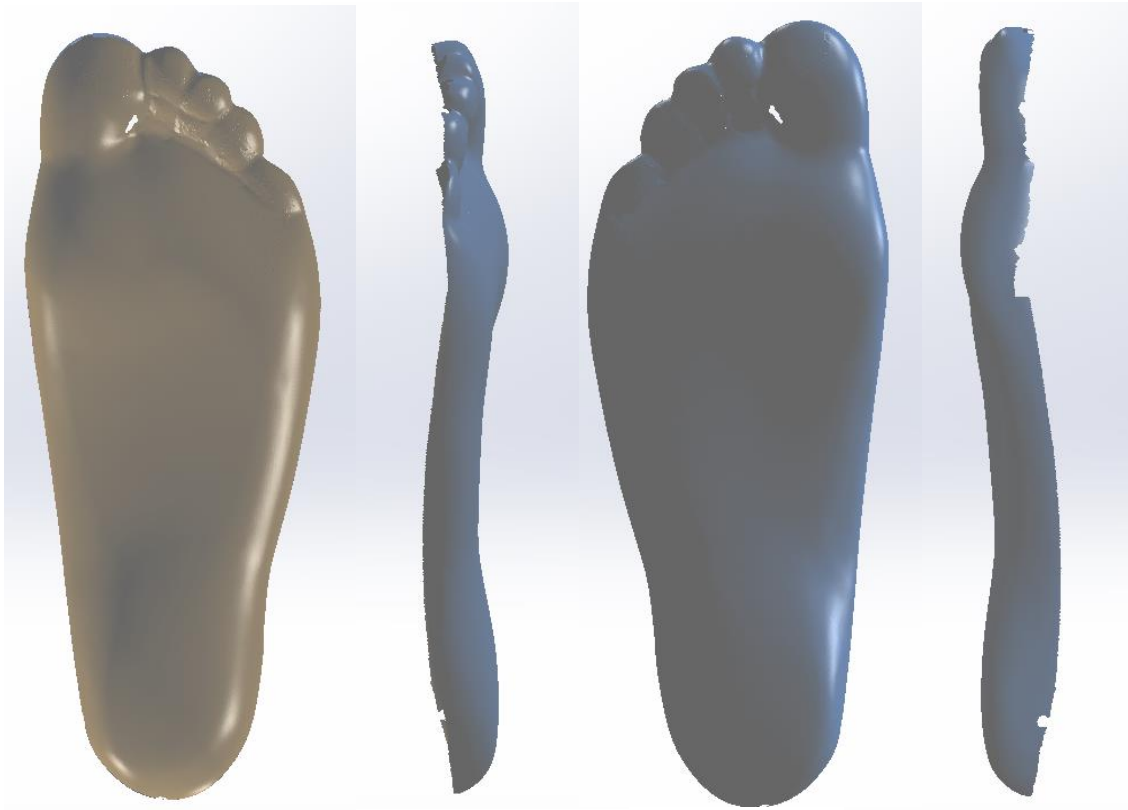
### 5.7.2 3D Laser Scanning.

In advance of 3D laser scanning the plaster cast model, reference points were carefully placed along the plantar surface of the model. Therefore, the 3D scanner was able to capture the key anatomical features and shape of the model. The 3D scanner itself was placed in a fixed position. As a result the plaster cast model was put on a rotating table to allow the model to be orientated and moved, until an sufficient amount of data was collected from the scan. (See figure 36).



*Figure 35: 3D scanning of the plaster cast model.*

The scanned data generated from the model was in the form of point cloud data. Once adequate data was collected from the scan, the post-processing phase could begin. This allowed for hole filling and smoothing operations to correct the point cloud data. The post processing phase involved converting the point cloud data to a polygonal mesh within a 3D CAD based software. In doing so, a polygonal mesh was created for CAD manipulation, to support custom orthotic design. (See figure 37).



*Figure 36 : Polygonal mesh of the plaster paris model from direct 3D scanning.*

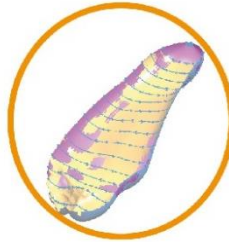
For the post-processing of point cloud data it was necessary to activate the 'Scan to 3D' command, an 'Add in' feature within the Solidworks software package. The 'Mesh Prep Wizard' was employed to convert the .PLY scanned data into a mesh feature and this permitted the successful extraction and creation of an accurate surface model.

Due to the complex shape and form of the plaster of Paris model, a semi-manual approach was undertaken by the researcher for this specific project. This procedure involved using 'Curve Wizard' to create a 3D curve boundary sketch along the mesh. The creation of 3D sketches along the mesh body facilitated advanced surface modelling techniques to be employed and, in doing so, a surface body was generated along the scanned data. The overall process of 'Scan to 3D' can be seen in figure 38, Pg. 85.



Step 1: Open Scanned Data

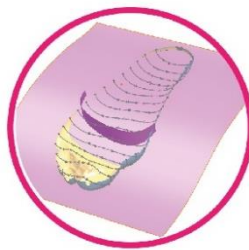
**Open point cloud data or polygonal mesh.**



Step 2: Prepare Data

**Run 'Mesh Preparation Wizard' through the following steps :**

- Align
- Elimante Noise
- Reduce Size
- Smooth
- Fill Holes



Step 3: Convert To Solid

**Solid bodies or surfaces can be created through the following approaches:**

- Create section and boundary curves using 'Curve Wizard'.
- Create 2D or 3D sketch curves along mesh.



Step 4 : Solid Model

- Guided 'Surface Creation Wizard'.

Figure 37: Digital work flow of scan to 3D.



### 5.7.3 Outcome and Findings.

The 3D scanning of the participant's foot highlighted the following findings:

- 3D scanning of the plaster cast model captured an identical and accurate profile of the plaster cast model
- The overall process was quick, therefore producing a high detail and resolution scan of the model
- However, 3D scanning of the plaster cast model failed to capture intricate features, of the foot
- The digital versions of the participant's foot could be stored and kept on file to help aid the podiatrist and manufacturer for future development.

It should be noted that if the digital workflow (see figure38) were to be integrated into a clinical setting, a more user-friendly CAD/CAM system would be required to assist the podiatrist during the prescription phase. As the GOM Atos II scanner is particularly sensitive to subject movement, it was not possible to undertake a direct 3D scan of the patient's foot. To summarise, 3D scanning of the plaster cast model captured scanned data of the participant's foot for CAD manipulation. This allowed for traditional design techniques to be employed in order to design a new form of custom orthotics.

### 5.8 Ideation.

Before sketching concepts a morphological chart was undertaken to generate ideas and forms. The objective was to create a number of functional solutions and to exploit the design possibilities offered by fabrication using AM technology.

#### 5.8.1 Approach and Methods.

The morphological chart is a visual way to generate ideas and forms in an analytical and systematic manner. The method involved a structured approach to explore and consider alternative solutions in order to achieve product functionality. To capture the product functions a list of sub functions were generated. These sub functions formed the content and basis of the morphological chart. The sub functions were listed in columns. In effect, the solutions generated for the sub-functions were placed in rows. A careful selection and a combination process was carried out to generate multiple solutions for concept generation

### 5.8.2 Morphological Chart.

The morphological chart was used generate various ideas and solutions based on the prescription provided by the podiatrist for the selected participant. This prescription guided the product architecture of the orthotic throughout the design process. The morphological chart was structured using a matrix approach. The sub functions, selected were generated to explore the functionality of orthotics and the unique design capabilities of AM technology. The sub functions generated, included the following;

1. Flex
2. Rear View
3. Product Boundary
4. Two Shot Material
5. Key Anatomical Features
6. Multiple Material
7. Section View
8. Pattern

Alternative sub function solutions were captured through sketching of schematic diagrams on Post-it notes. The Post-it notes were placed in their intended row. This approach provided a visual aid to help the researcher select and combine various sub functions to create multiple design concepts. The combination of alternative sub function provided the researcher with a range of possible orthotic solutions. (See figure 39).

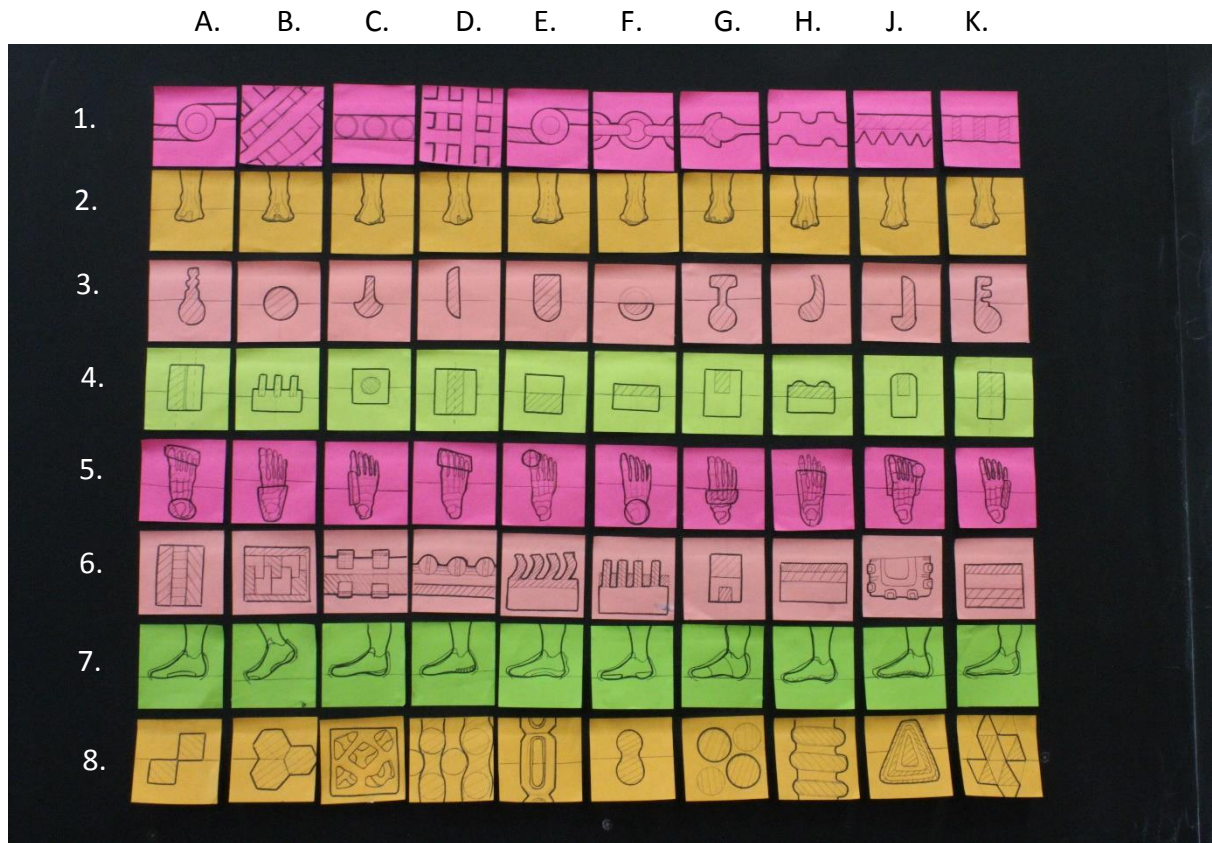
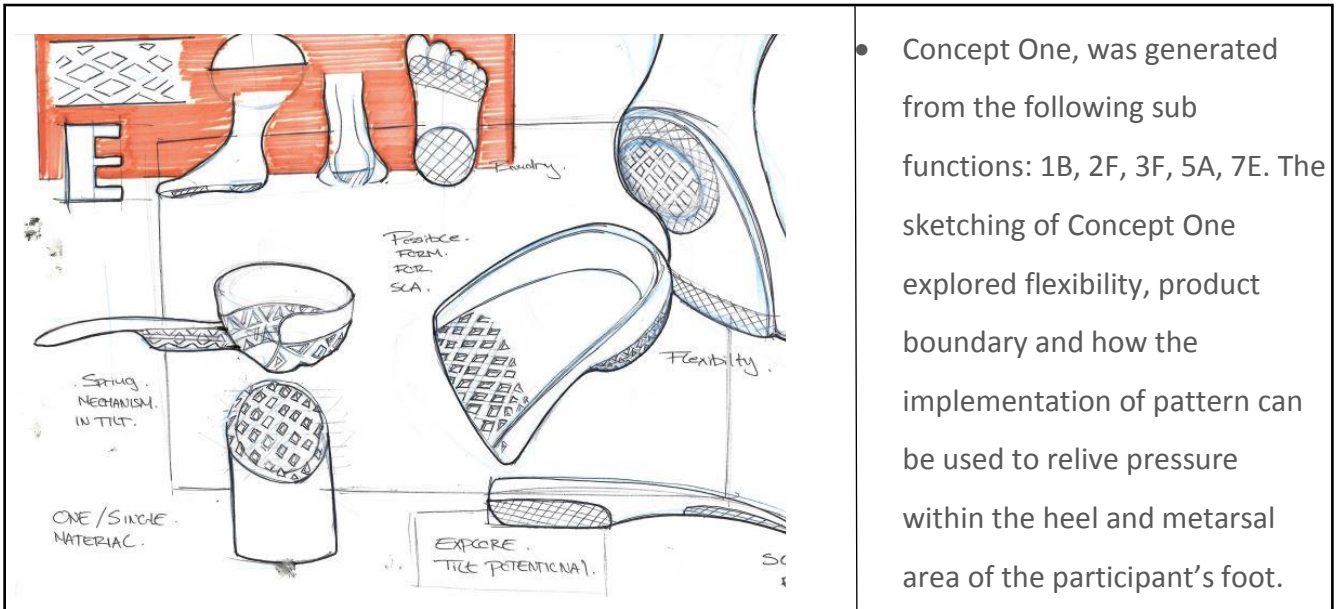


Figure 38: Morphological chart, containing and categorising a range of alternative sub solutions, inspired by AM design capabilities and research findings.

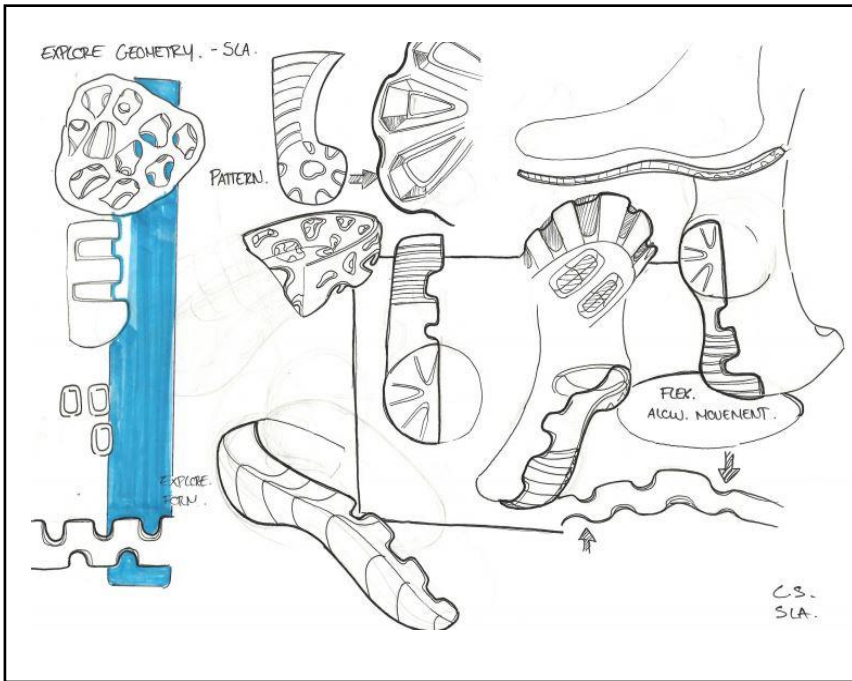
### 5.8.3 Outcomes and Findings.

The combination of alternative sub solutions generated from the morphological chart assisted in concept generation. Multiple concepts were developed and captured through sketching (figure 40 & 41). Following on, from concept selection, further concept development was required. (See Figure 42). In effect, a final design emerged keeping within the functionality of the prescribed orthotic and aiding in exploring the unique design capabilities of AM technology. (See figure 43).

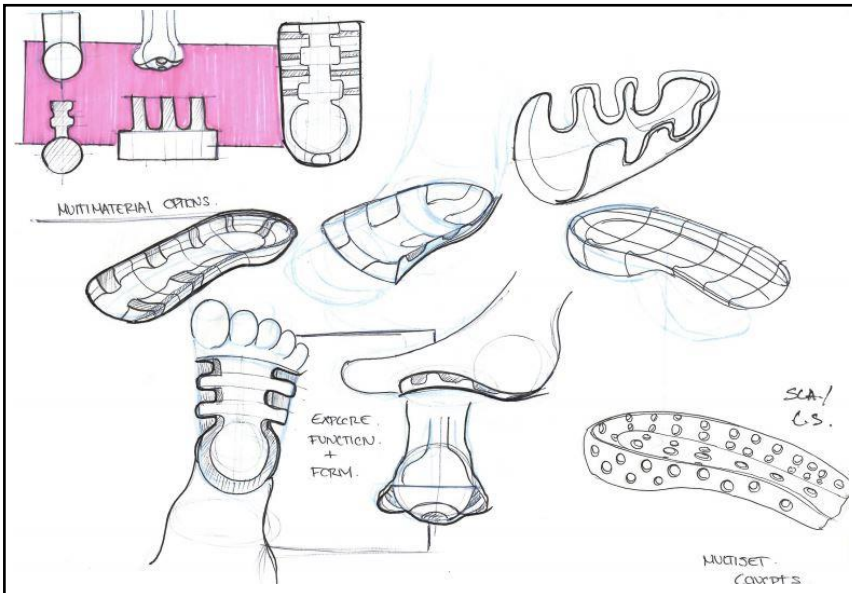




- Concept One, was generated from the following sub functions: 1B, 2F, 3F, 5A, 7E. The sketching of Concept One explored flexibility, product boundary and how the implementation of pattern can be used to relieve pressure within the heel and metatarsal area of the participant's foot.

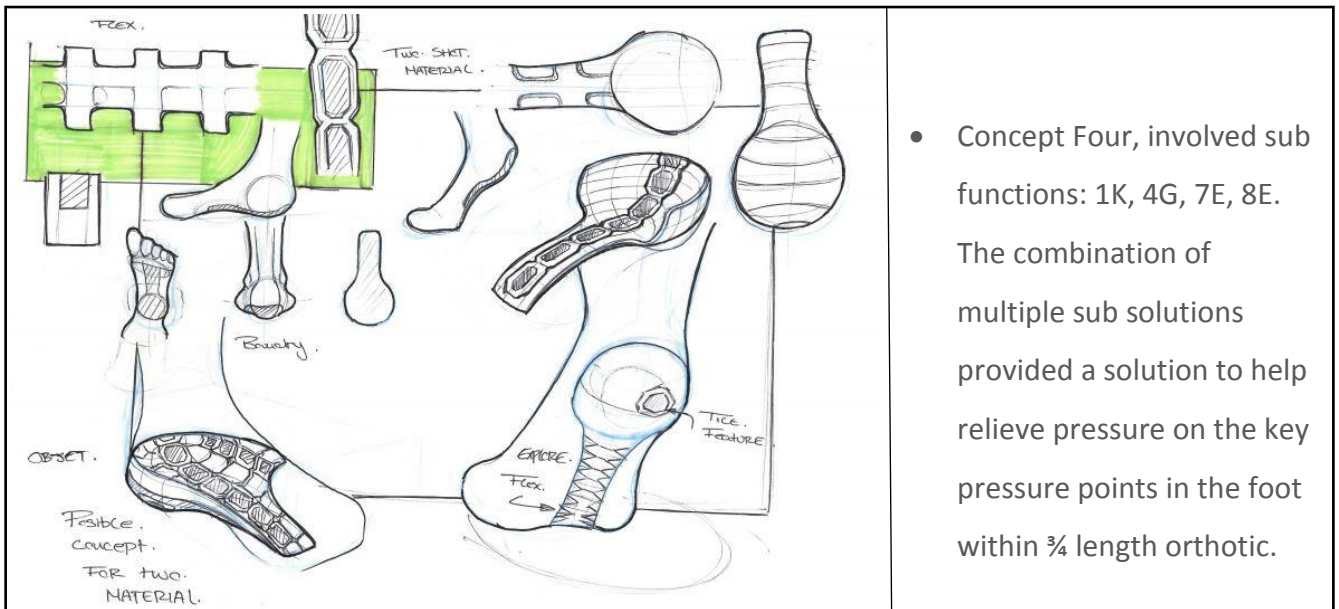


- Concept Two included, sub functions, 1H, 3E, 6C, and 8C. The generation of Concept Two explored the lateral side of the orthotic within in the design pattern options, inspired by nature and the Fibonacci sequence. Flexibility was also explored at the fore front of the foot.

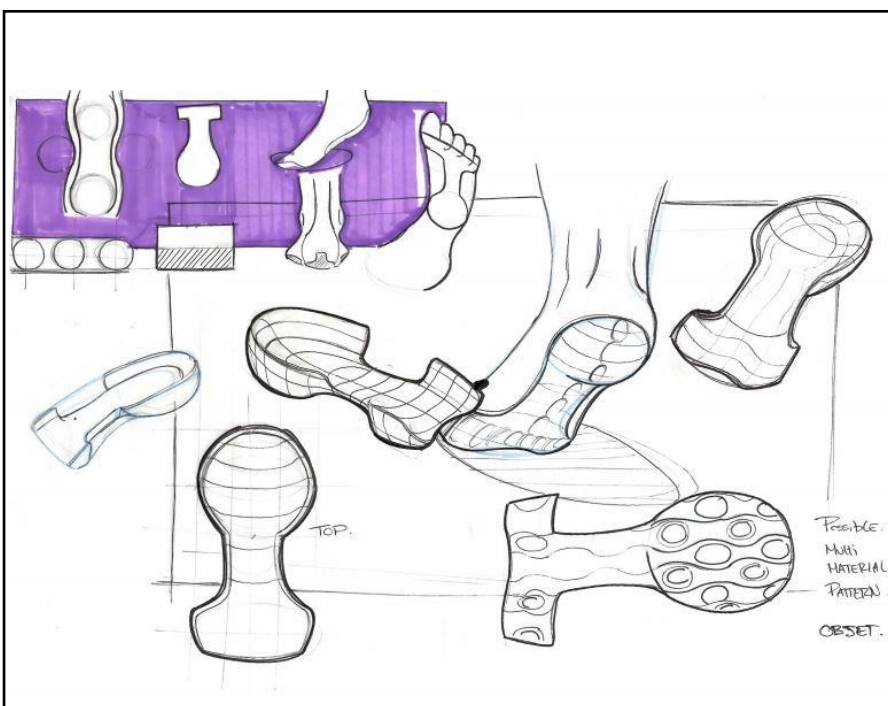


- Concept Three included sub function: 3A, 6F, 2H, 5J. This solution explored the introduction of movement and flexibility within a ¼ length orthotic using multi material technology.

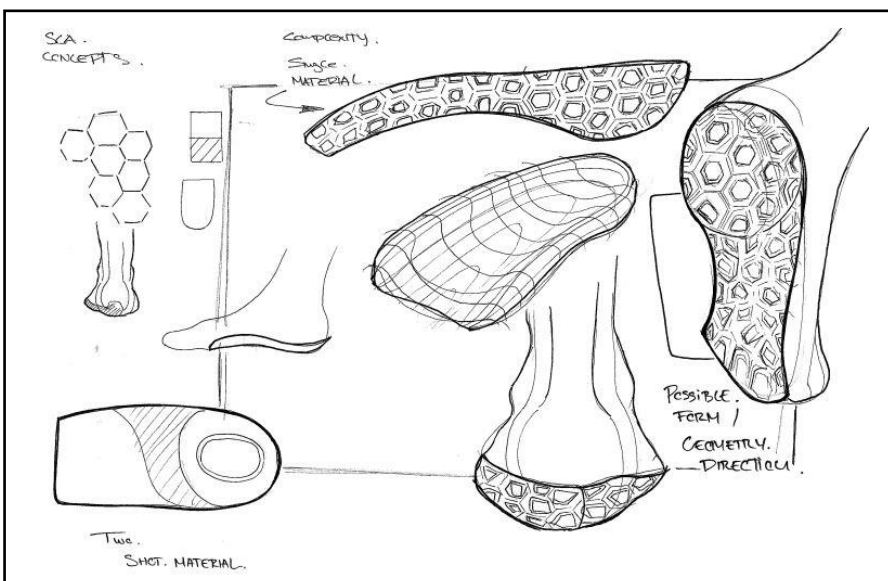
Figure 41: Concept One to Three, created from the morphological chart.



- Concept Four, involved sub functions: 1K, 4G, 7E, 8E. The combination of multiple sub solutions provided a solution to help relieve pressure on the key pressure points in the foot within  $\frac{3}{4}$  length orthotic.



- Concept Five explored sub functions: 1C, 2B, 3G, 8D, 4E. This solution explored how the optimal position of the foot could be supported without supporting the lateral and medial side of the foot. The integration of various shore hardness material would allow the outer shell to be rigid and flexible.



- Concept Six included sub functions: 3E, 4E, 7A, 8B. The combination of sub functions explored the honeycomb pattern to create flexibility, grip and support within a  $\frac{3}{4}$  length orthotic.

Figure 39: Concept four to six, created from the morphological chart.



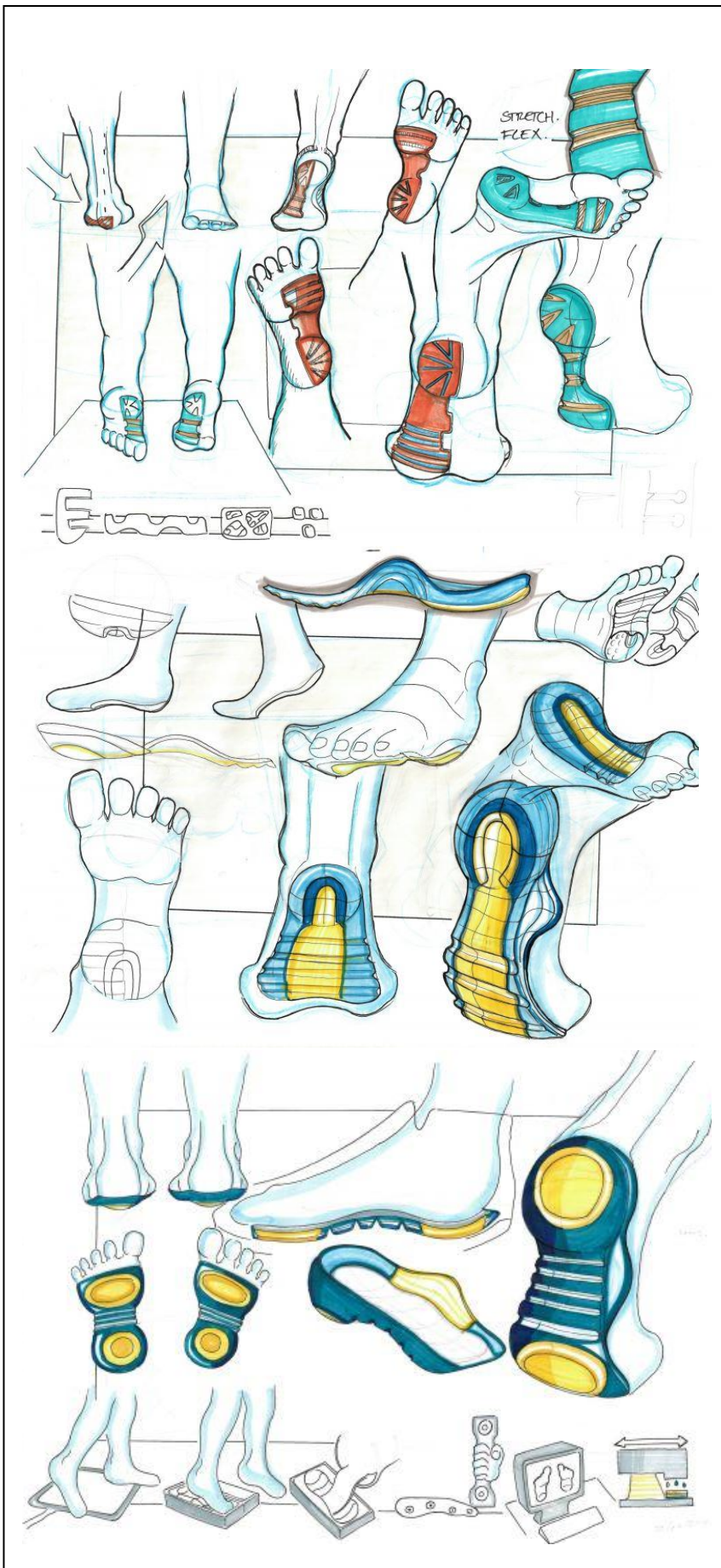


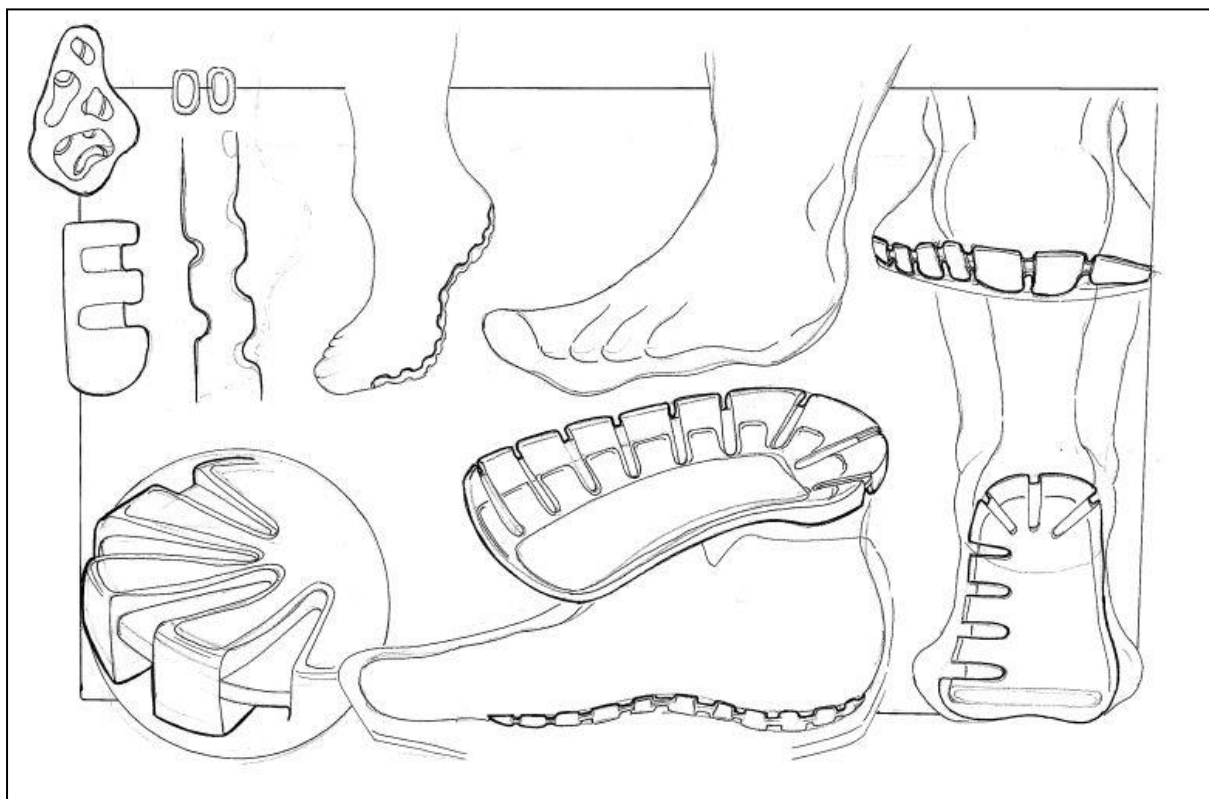
Figure 40: Further concept development, following selection of concept 2.

- Concept development led to exploring concept 2, 3 and 4. The objective of concept development was to explore flexibility and movement within a  $\frac{3}{4}$  length orthotic.
- Posting options; for example extrinsic and intrinsing options were explored, in order to improve on the current mechanism. The objective was to explore how 'posting' could be made flexible while keeping the foot in the optimal position.
- Rendering of sketches was explored to highlight, where different types of shore hardness material could be applied within the orthotic.
- The implementation of multi material, using AM technology, provided the platform to explore the opportunity of relieving pressure.

The final design proposed for sketch modelling and rapid prototyping was a  $\frac{3}{4}$  length orthotic, comprised of alternative sub function solutions: 1H, 3E, 6C, and 8C.

The proposed concept explored controlled movement and flexibility on the lateral side of the orthotic. The implementation of this feature allowed for natural but also controlled movement to occur in the foot through the gait cycle. Organic forms were integrated within the design, in order to explore the unique capabilities of Additive Manufacturing. Patterns were also integrated within the inner shell of the orthotic to act as pressure pads and to help relieve pressure within the participant's feet. (See figure 44).

To conclude, the proposed concept provided the starting point to explore sketch modelling and design intent prior to undertaking advanced 3D solid modelling.



*Figure 41: AM custom orthotic for sketch modelling and rapid prototyping.*

## 5.9 Sketch Modelling.

The objective of sketch modelling was to capture the proposed concept in order to better understand form, size, design intent and to communicate the idea in three dimensional physical form.

### 5.9.1 Approach and Methods.

Sketch modelling is a method used to capture an idea in a 3D physical form. The primary purpose of sketch modelling was to capture and communicate ideas but to also encourage creativity and imagination within the early stages of the design process. Sketch models can be created or mocked up using inexpensive and affordable materials. Materials can range from paper, blue foam, cardboard and clay. Quick iterations of models can be generated to understand form, scale and feel as to how the user interacts with the concept in its chosen context. To summarise, the end goal of sketch models is to capture, generate and communicate ideas in three dimensional physical form.

### 5.9.2 Sketch Modelling.

Before sketch modelling could begin, a negative mould was made to capture the curvature of the participant's foot. The negative mould was formed on a vacuum forming machine from sheet plastic. The plaster model was placed on the stage plate, plastic sheet material was clamped in a fixed frame above the stage plate. The plastic sheet was heated to the desired temperature and a vacuum was applied to remove the air between the plastic sheet and the plaster model to form the negative mould. (See figure 45).



*Figure 42: Vacuum moulding of the plaster cast model.*

This negative mould captured the curvature of the participant's foot and could be used as a mould for sketch modelling purposes.

Following this, further focused and directed sketching was undertaken. Direct and focused sketching involved sketching key features and mechanisms within the orthotic design in order to understand product architecture. An exploded view of how an orthotic might be fabricated was then explored in order to understand the overall design intent, prior to model making. (See figure. 46).

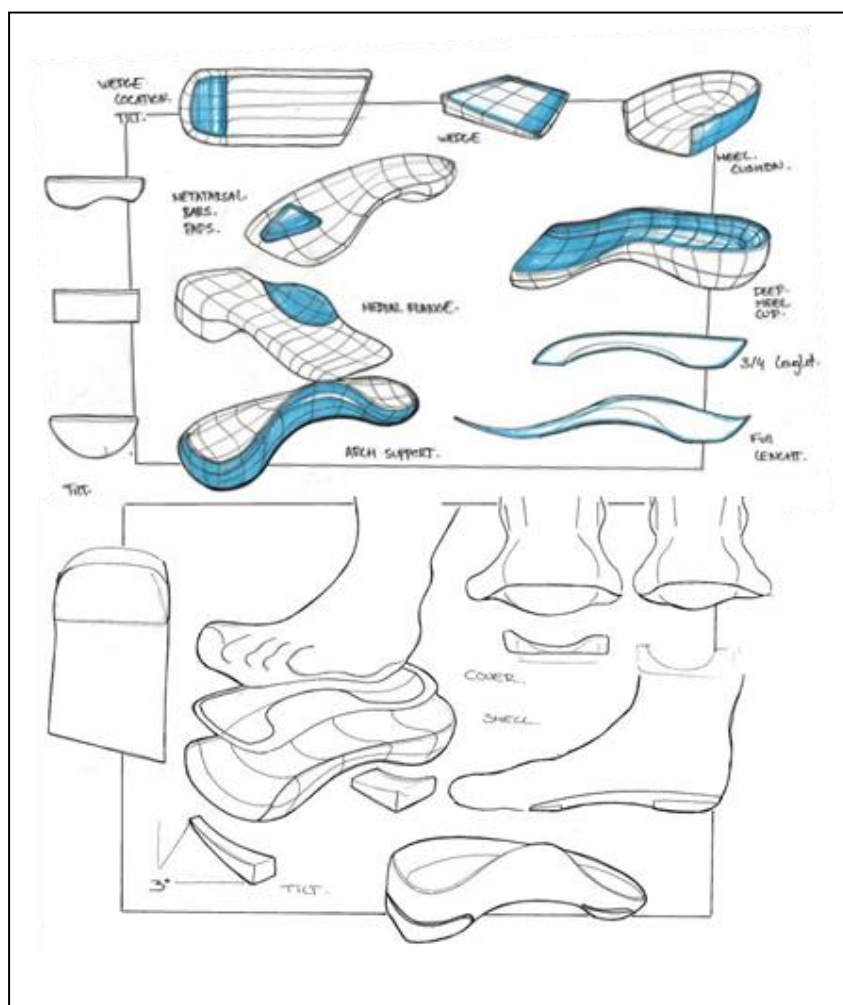


Figure 43: Direct and focused sketching, highlight the components within the orthotic design (top) and exploring design intent (Bottom).

Direct and focused sketching on the fundamentals of orthotic design, provided the researcher, with the realisation that, the shell of the orthotic could be constructed using a layered approach.



The main objective of the layered approach was to create a 3-millimeter shell of the orthotic, using the negative mould created from the participant's foot. The shell would comprise of different colours to help the researcher identify where shore hardness materials and novel features could be integrated into the design. Plasticine was used for sketch modelling for it's easy of use and the availability of contrasting colours to emulate different shore hardness materials within the model.

The layered process began by rolling the plasticine clay into 1-millimeter layers. Each layer comprised of different colours to help represent various shore hardness materials within the model. In effect, each layer was cut out using a template outlining the boundary of the negative mould. The template allowed the 1mm layer to be cut and fitted within the mould. Sketch modelling is an iterative process and three iterations were made for evaluation purposes.

Finally, the models were chilled for 24 hours to allow the layers to combine and harden for testing with the plaster cast model. (See figure 47)



*Figure 44: Sketch modelling process, involved using plasticine clay and a negative to create a sketch model, tailored to the foot anatomical features.*

### 5.9.3 Outcomes and Findings.

The primary objective of the sketch modelling process was to instil creativity and imagination by capturing the proposed concept in a physical three dimensional model.

The outcomes from the sketch modelling stage were as follows:

- A 3mm,  $\frac{3}{4}$  length orthotic can be constructed using a layered approach
- The variation in colour helped identify key boundaries and where new innovative feature could be implemented within the design.
- The  $\frac{3}{4}$  length sketch model covered the heel and metatarsal region of the plaster cast model.
- The process produced low fidelity models in low-cost materials. Over time these sketch models failed to keep overall shape but were very useful in progressing the design.

To summarise, the overall process captured the form, size and scale of the proposed concept. Furthermore, the sketch modelling process allowed the researcher to understand the initial design intent of orthotic design.

The researcher was thus able to translate the sketch models size and scale into a 3D CAD environment for rapid prototyping purposes.



*Figure 45: Sketch models generated, for 3D CAD modelling.*



## 5.10. Rapid Prototyping.

### 5.10.1 Approach and Methods.

The primary objective of this phase of research was to explore the implementation of rapid prototyping to further test the orthotic design proposal. This stage followed a similar design intent and approach as the sketch modelling stage. Concepts were translated into a 3D CAD environment for rapid prototyping purposes. The advanced 3D modelling programme packages and plug in packages were Solidworks version 2016 and Scan to 3D.

It is important to note that the scanned data created from the plaster cast model of the participant's foot was used for all the subsequent orthotic prototypes.

The design objectives were as follows:

- To define the boundary of the custom orthotic to the scanned data of the foot
- To define a material thickness and material possibilities
- To introduce controlled and flexible movement within the orthotic design
- To define the correct posting mechanism and prescribed degree within the orthotic
- To determine alleviating areas within the custom orthotic, in order to help relieve pressure on the participant's foot
- To define fillet edges of the orthotic to ensure comfortable and custom fit.

Four different AM technologies were used throughout this phase of research for custom orthotic fabrication:

- Selective Deposition Lamination (SDL): Mcor Technology Iris HD, made with A4 office paper
- Stereolithography (SLA): 3D systems viper Si2, made with Accura 25 resin
- Three Dimensional Printing (3DP): 3D systems Zcorp Z510 spectior made with ZP 140 powder and ZP 60 binder
- Polyjet multi material jetting: Stratasys Objet Connex 500, made with elastomeric and rigid.

The plaster cast model was used to test each prototype throughout the this phase.

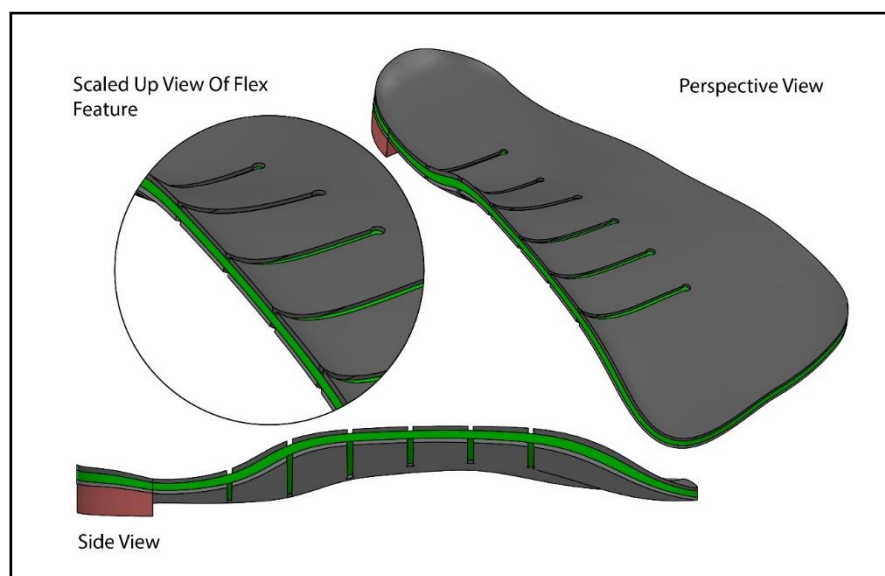
However, at a later stage in the research process, the prototypes were tested for fit on the participant under the podiatrist's supervision. This method ensured that the prototypes

successfully fitted and caused no harm to the participant, as well as keeping within the medical prescription, outlined earlier in the research process.

#### 5.10.2 Rapid Prototyping.

**Prototype One:** adopted a podiform orthotic solution. The ‘podiform’ design offered a slim line shell and a seated heel. The purpose of this design was to offer strength and flexibility whilst maintaining stability. SDL technology was chosen as it provided the researcher with the opportunity to quickly fabricate a low-cost rapid prototype model in order to understand form and size constraints of the orthotic prototype. SDL equipment - Mcor Iris HD and Slice software.

CAD modelling of the first prototype included a flex element on the medial side of the orthotic and seated heel of 3 degrees. The flex element provided the user with controlled and flexible movement within the orthotic. The seated heel allows the foot to be positioned at the optimal position. (See figure 49).



*Figure 46: Orthotic prototype, with Flex feature, colour coded to represent key section. Modelled using Solid works 2016.*

SDL printing technology was the first AM technology used to help create an orthotic prototype. The paper prototype created allowed the researcher, to quickly fabricate a low-cost working model, understand scale, size, product boundary, flex and posting mechanism within the overall design.

### **SDL process:**

The orthotic prototype was fabricated using Mcor IRIS, a paper based system 3D modeller. This process firstly involved attaching a sheet of A4 office paper to a build plate within the build chamber. The .stl file was uploaded and the process was activated. The Mcor machine deposited drops of adhesive on the first sheet. A new piece of paper was then placed and bonded to the first sheet. An adjustable blade, within the build chamber, begins to slice a 2D outline of the part on the bonded piece of paper. This process was repeated and continued until the final layer was cut and bonded.

The post processing phase of SDL involved de-cubbing by separating the part from the solid block of hatched paper. The part is separated from the block of hatched paper using industrial size tweezers. (See figure 50). Further post processing involved applying a liquid hardener or water resistant finish to the part, for sanding and finishing purposes. However, this was not required as the prototype was only used for size and scale evaluation purposes.



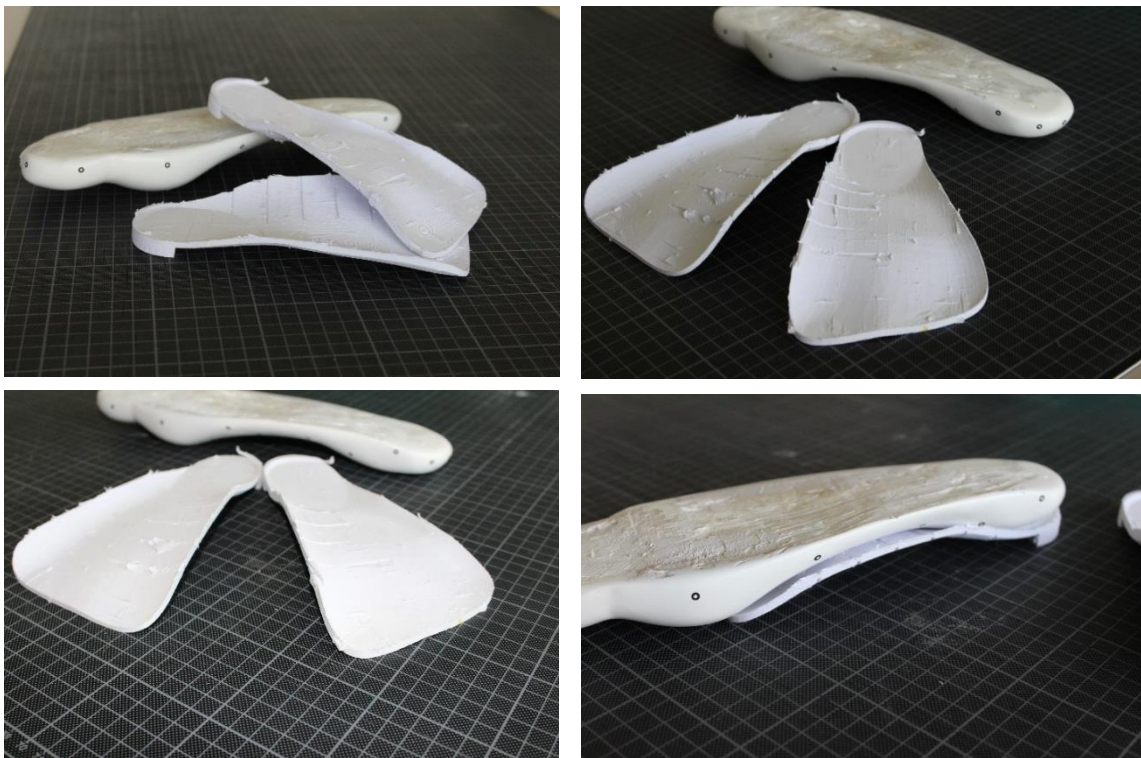
*Figure 47: De-cubbing process; removing the part from the solid block of paper.*

### **Outcome:**

- The overall SDL process successfully captured the size and scale of the orthotic prototype

- The SDL process generated a poor surface quality. As a result, the process failed to capture the flex feature features of the design
- The slim line shell of the orthotic was too large at the base and offered very little support to the medial and lateral side of the foot.
- The heel cupping area of the orthotic was too shallow and failed to offer stability to the foot.
- The material thickness of the prototype was the correct at 3 millimetres
- The seated heel of the prototype was too small and as a result failed to support the heel area of the foot.

See figure 45.



*Figure 48: SDL orthotic prototypes, evaluated for size and scale, using plaster cast model.*

The findings generated from the SDL prototype led to the design of a second prototype in order to improve and resolve the issues highlighted.

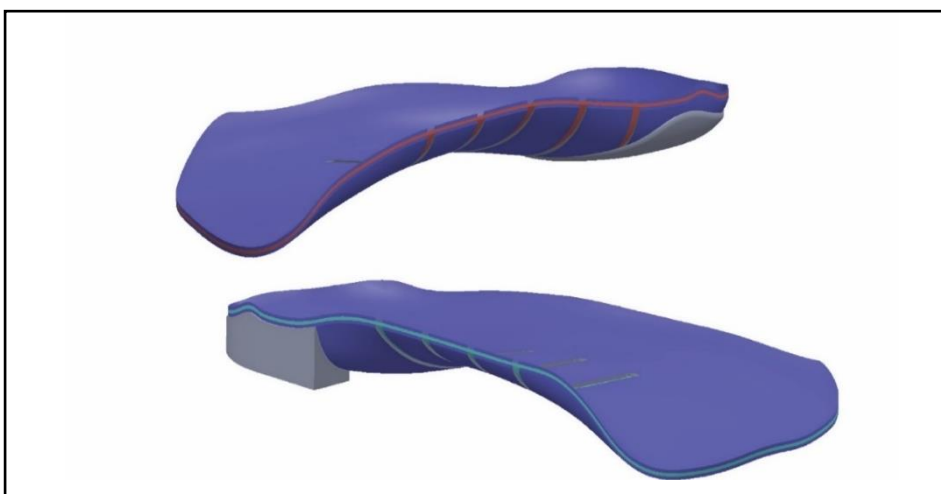
### **Prototype Two and Three:**

The findings generated from prototype one highlighted a number of issues which needed to be addressed, prior to any advancements. The issues were as follows:

- Orthotic shell
- Posting
- Capturing the correct degree.

Through secondary sourcing of literature, the researcher identified that the two most common types of posting options used in FO design were intrinsic and extrinsic posting. The research also identified that the standard  $\frac{3}{4}$  orthotic shell width begins by bisecting the 1<sup>st</sup> metatarsal head to the lateral side of the 5<sup>th</sup> metatarsal head, within the foot. As a result, the aim of this phase in the research process was to explore both extrinsic and intrinsic posting, within a  $\frac{3}{4}$  length orthotic prototype, using 3DP printing.

3D Cad modelling of the intrinsic prototype was generated using solid bodies. The intrinsic rear-foot posting was created by angling the scanned data of the foot, at an angle of 3 degrees. Solid bodies were generated by offsetting from the scanned data. A cut extrude feature was then applied at the medial side of the orthotic shell. As a result, cut extrude would alter the angle of the shell of the orthotic to help create a spot grind. A spot grind is when the inferior surface of the heel of the orthotic shell is ground off- centre and laterally. The spot grind would, therefore, invert the orthotic shell at heel strike, placing the foot in the optimal position during gait. (See figure 46). A similar design intent was undertaken for the extrinsic prototype. However, a solid body was added to the rear-foot of the orthotic shell in order to create the extrinsic posting. The 3-degree extrinsic posting was applied in the form of a horse shoe pad to offer stability, relieve pressure and direct the participant foot in the desired direction.



*Figure 49: Both Intrinsic and Extrinsic prototypes with flex feature on medial side of the orthosis shell.*



### 3DP Process:

Both the extrinsic and intrinsic posting prototypes were fabricated using a 3DP process to further explore and investigate the heel posting area most suited to the participant's medical needs and lifestyle demands. The 3DP process was selected because of its ability to fabricate white plaster models in a short space of time. Furthermore, the size of the print bed was another consideration which allowed for multiple parts to be stacked and nested within a single build. The 3DP equipment used for this phase of Rapid Prototyping was Z-Corporation, Spectrum Z510 and Z-Print software.

The 3DP printing process firstly involved evenly distributing the powder accurately across the build platform. Once the print bed is spread evenly across the build platform, the ink jet print heads begin to print cross sectional areas of the orthotic prototypes. Next, the layer is lowered and a new layer is applied. This is a constant and automatic process which requires very little supervision.

Post processing phase involves careful removal of the fragile prototypes from the powder bed. Further post processing involved the de-powder of the prototypes using an air gun within a sealed de-powdering station. Parts were infiltrated with a two-pack resin to ensure the prototypes had better mechanical characteristics and increased strength.

The overall process was carried out in a clean and controlled laboratory environment.



*Figure 50: The 3DP post processing phase, of both extrinsic and intrinsic prototypes.*

## Outcome:

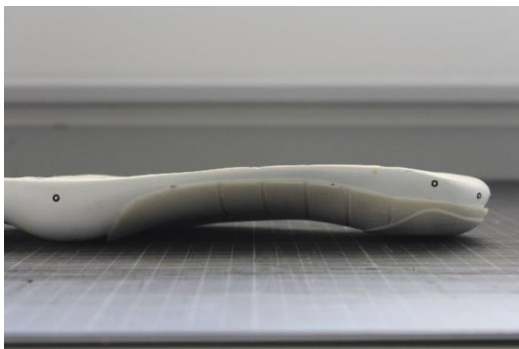
Both the intrinsic and extrinsic prototypes were evaluated by the podiatrist in order to ensure that the product boundary of the orthotic was correct and aligned correctly with the participant's anatomical features. The podiatrist highlighted the following points in regards to the extrinsic prototype:



- The heel cup was not deep enough to offer stability to the participant
- The posting of 3 degrees was correct.
- The extrinsic posting, was too high at the rear foot end of the foot.
- The overall orthotic boundary was correct, keeping within the 1<sup>st</sup> metatarsal head and 5<sup>th</sup> metatarsal head, of the participant's foot.
- Plantar fascist region of the foot, needed more support from the medial side orthotic shell.
- The Horse shoe pad offered the opportunity to relive pressure in the heel area of the foot.

*Figure 51: Prototype 1; extrinsic prototypes, fabricated using 3DP powder process.*

The following points were made in relation to the intrinsic prototype:



- Support was required around the heel cup area in order to offer more stability to the participant
- The heel posting needed to be raised to remove pressure from the plantar fascist region of the foot
- Similar to extrinsic orthotic, the overall  $\frac{3}{4}$  length orthotic boundary was correct.
- The podiatrist felt the flex feature was a good idea as it and that it would offer greater comfort for the participant from first use.

*Figure 49: Prototype 2; intrinsic prototypes created using 3DP process*

To summarise, the evaluation of both the extrinsic and intrinsic prototypes by the podiatrist suggested that the extrinsic prototype was the most suitable design and was seen as a considerable advance in custom orthotic design and fully covered the participant's medical needs.



## Prototype Four:

The design feedback gathered, from the evaluation session with the podiatrist provided the researcher with insights of how best to further develop the orthotic device and the extrinsic prototype was selected for further development. The key issues highlighted, in relation to the initial extrinsic prototype were that:

- The posting was too high at the rear foot of the orthotic.
- The heel cup area was too shallow.
- The plantar fasciit region of the foot required more support on the medial side of the orthotic.

A design recommendation, to improve the posting of the extrinsic prototype was to incorporate a slim line posting, instead of an extrinsic posting. The purpose of the slim line posting was to accommodate the participants sporting activities. In doing so, the device would introduce a moderate degree of biomechanical control.

3D CAD modelling of Prototype Four, similar to the previous prototypes, was generated to include a slim line posting, created by extending the extrinsic posting from the heel to the fore foot of the orthotic, forming a horseshoe pad feature. This feature offered significantly more support to the fore foot and heel of the orthotic. Furthermore, Prototype Four offered a  $\frac{3}{4}$  length orthotic with a flex feature on the medial side of the orthosis. (See figure 49).



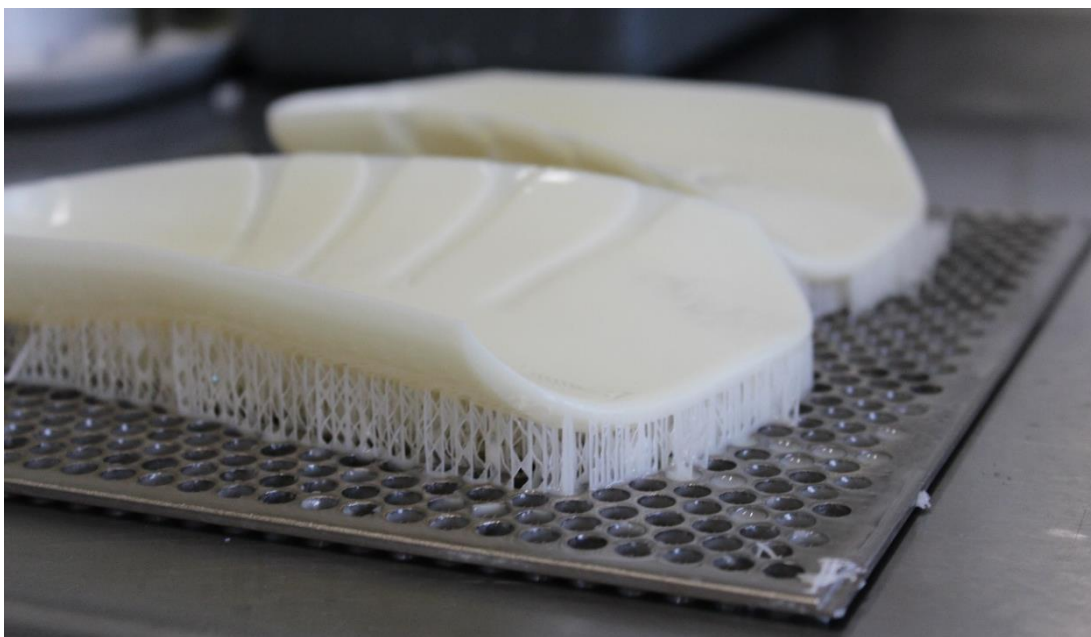
*Figure 52: Prototype four; with flex feature and slime posting, fabricated using SLA technology*

### **SLA Process:**

Prototype Four was fabricated, using the SLA printing process as this printing process produces strong, rigid, functional and more accurate parts in photosensitive resins, in this case Accura 25 resin was selected. The SLA Viper Si<sup>2</sup> machine and 3D systems Lightyear software were used for orientating and for fabricating test-for-fit models. The surface quality of the SLA was of high quality, therefore, allowing the participant to safely apply their load bearing pressure and force to the prototypes. In effect, the SLA printing process was ideal for test-for-fit testing.

Prior to machine set up, the 3D CAD modelling of both prototype four and five were converted into an .stl file format. Once the build file was set up, support structures added and the parts were orientated and spaced correctly the SLA process could begin. The SLA process involves an Ultra Violet (UV) laser within the machine, mapping, outlining and curing the 2D cross sectional area of the design within the tank of Accura 25 resin. The build platform then lowers to the layer thickness and the process repeats itself until the model is complete.

The post processing phase involved removing the support structures from the build platform and the prototypes. Once the support structures were removed from the part, the parts could be cleaned using a solvent solution. The parts were placed in a UV oven to allow the prototypes to cure and harden.



*Figure 53: The post processing phase of SLA technology, the support structures holding the models.*

## Outcome and Findings:

The purpose of the test for fit with the participant was to understand how the orthotic prototype might fit and feel on the participant's feet. The findings were as follows:



- The participant felt the prototype fitted perfectly to their feet
- They felt it was extremely comfortable to wear and would be ideal for football boots.
- The orthotic cupped the heel area and the foot perfectly.
- The orthotic fitted cleanly within the participant's foot wear.
- The participant felt the orthotic was robust and firm, but also offer a degree of flexibility.
- The participant feel better supported and not as vulnerable whilst wearing the device.

*Figure 54: Test for fit testing, using prototype four with the selected participant.*

To summarise, the findings collected confirmed that the orthotic prototypes offered a custom fit solution, tailored to the participant's feet.

## Outcome:

Prototype Four was fitted by the participant and evaluated by the podiatrist.



*Figure 55: Prototype four being evaluated and examined by the podiatrist.*

Test-for-fit findings with the participant and podiatrist highlighted the following key points:

- The heel cupping area was too shallow.
- The participant required two degrees more extrinsic posting in order to allow more support to occur in the plantar surface region.
- Rounded edges were required around the orthotic in order to make the device more comfortable for the participant and to prevent any discomfort from occurring.
- More bevelling was required at the fore foot of the posting for each of the orthotics
- A flat surface was required at the posting area of the heel to prevent rocking of the orthotic within the shoe or boot.
- The orthotic shell was too short as it didn't reach the metatarsal head of the orthotic.



- The orthotic was placed behind the metatarsal heads, therefore could cause discomfort to the patient and blistering of the foot could occur.
- On Prototype Four there was too much of a ledge was occurring at the fore foot of the foot and this could cause discomfort to the participant.
- The podiatrist stated that the orthotic needed to be placed on the metatarsal heads, instead of behind the metatarsal heads.
- The solution required a more 'bevelling' at the fore foot, to help create a more flush orthotic within the participant's footwear.

To summarise these findings led to a final iteration in the form of prototype five.

### **Material Selection:**

Prior to any further development work on the orthotic the podiatrist was consulted on the selection of materials best suited for the medical needs of the participant. The podiatrist was asked to select materials considered clinically appropriate and of a suitable Shore hardness from a sample swatch of Objet 'digital' materials. The Shore hardness of the two extreme materials ranged from Vero White to Tango Black and the swatch offered numerous variations in Shore hardness between these two extremes.



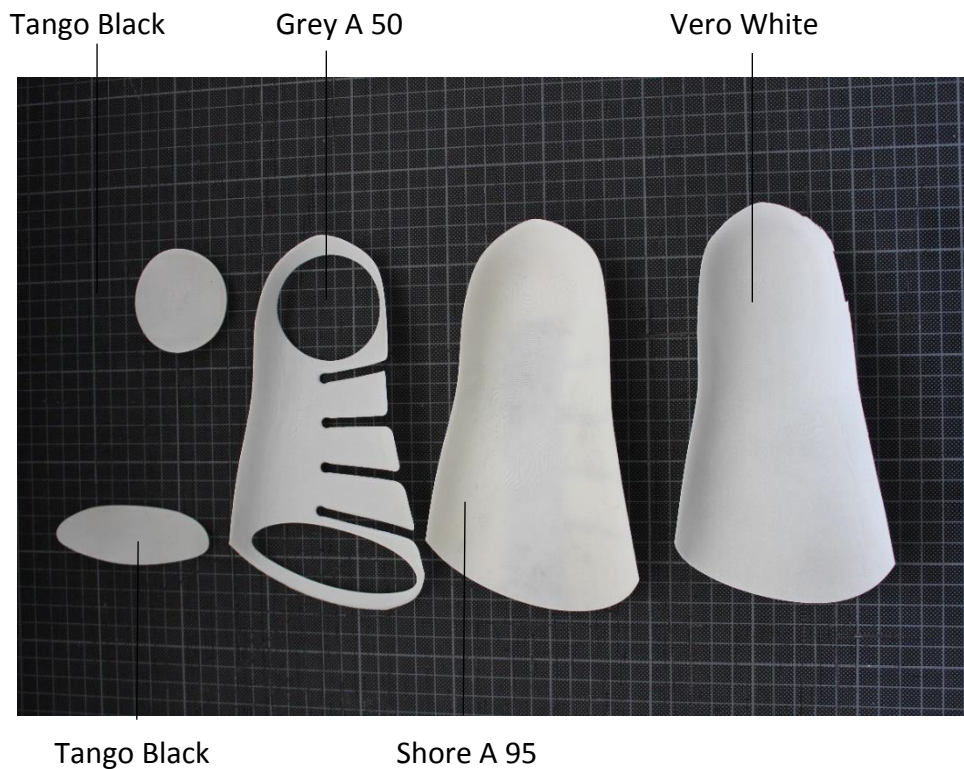
*Figure 56: The podiatrist assigning different shore hardness material, to individual parts within the custom orthotic, suited to the participant individual needs.*

**Outcome:**

The podiatrist cited the following reasons for material selection:

- The podiatrist suggested that the hard and rigid material within the digital material was best suited for the participant’s lifestyle and demands.
- The orthotic needed to be rigid but also flexible to allow for the participant’s sporting demands
- The material also needed to be wipeable for the orthotic to remain clean.

The podiatrist selected the following material to be allocated to individual parts within the custom-made orthotic:



*Figure 57: The shore hardness materials, assigned to individual parts within the orthotic prototype.*

The digital material selected by the podiatrist for the individual parts within the custom orthotic design will be used for multi-material printing of the orthotic.

Technical sheets of MMAM materials, can be seen in Appendix C.

## **Prototype Five:**

Prior to the creation of Prototype Five, the aim of the researcher was to ensure that the issues highlighted by the podiatrist, in the previous test-for-fit session, were corrected and approved by the podiatrist before the final prototype could be fabricated using multi material printing technology.

CAD modelling of prototype five involved the following:

- Increasing the heel cup area of the orthotic shell.
- Increasing the posting to five degrees.
- Creating a bevelling effect at the fore foot of the orthotic shell to prevent a ledge from occurring at the fore foot of the orthotic shell.
- Making sure the orthotic shell would meet at the metatarsal heads, instead of being placed behind the participant's metatarsal heads.
- Exploring flexibility on both the lateral and medial side of the orthosis shell.
- Introducing more support along with the plantar fascia region of the participant's foot.

Prototype Five was also fabricated using SLA technology. The SLA prototypes offered a smooth surface and high detailed prototype.

## **Outcome:**

The prototypes were assisted by the podiatrist, using the plaster cast model of the participant's foot. The following outcome was as follows:

- The podiatrist felt that the double flex idea worked better than the single flex feature in order to allow natural movement to occur in the participant's foot
- The podiatrist identified that the double flex inside the orthosis shell would create discomfort to the participant's foot.
- The orthotic boundary was correct as a result of stopping on the metatarsal heads of the participant's foot.
- The posting was correct at 5 degrees and offered stability to the participant by preventing rocking occurring at the heel of the orthotic.
- The bevelling at the forefoot of the orthotic was correct.

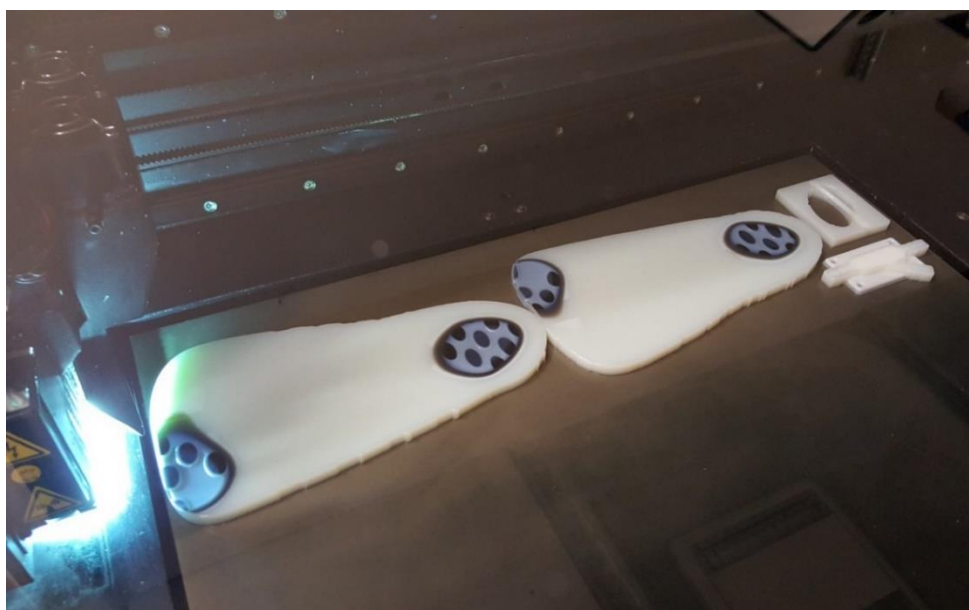
The prototype was approved by the podiatrist for final fabrication on a multi-material 3D printer.

### **Prototype Six**

Prototype Six, the final prototype, was fabricated using Multi Material Additive Manufacturing (MMAM) technology. The objective of the final prototype was to explore the multi material aspect within the custom orthotic design and how improved material selection within foot orthosis industry can help further aid the podiatrist, fabricator and patient. The Connex 500 Additive Manufacturing system and Objet Studio software was used in the fabrication of Prototype Six.

### **Process:**

The multi material process involves multiple print heads depositing droplets of photopolymer materials in parallel lines over the specific build area within the build platform. The multi material jet heads prints two materials at the same time: one is the main build material, the second is a dissolvable support material is printed as required to assist part removal or to support and overhanging details within the model. The printed layers are cured by Ultra Violet (U.V.) light, once the layers were created and cured they build a platform which lowers to the required layer thickness. This layer by layer process was repeated over six hours until the final parts were complete (See figure 55).



*Figure 58: The fabrication of orthotic prototypes using MMAM technology; stratsays objet connex 500.*



Post processing involved of the multi material parts involved removing the parts from build platform using a scraper. The support material was removed from the part by breaking away the support material manually. Next, the parts were washed and cleaned with water and finally dried. The end result produced a final orthotic prototype with a smooth surface finish and exploring the material capabilities of multi material printing. See figure 56.



*Figure 59: Post processing phase of MMAM orthotic prototypes*

Once the post processing of final prototype was completed, the orthotic prototypes were ready for the final test-for-fit evaluation with the podiatrist and the participant.

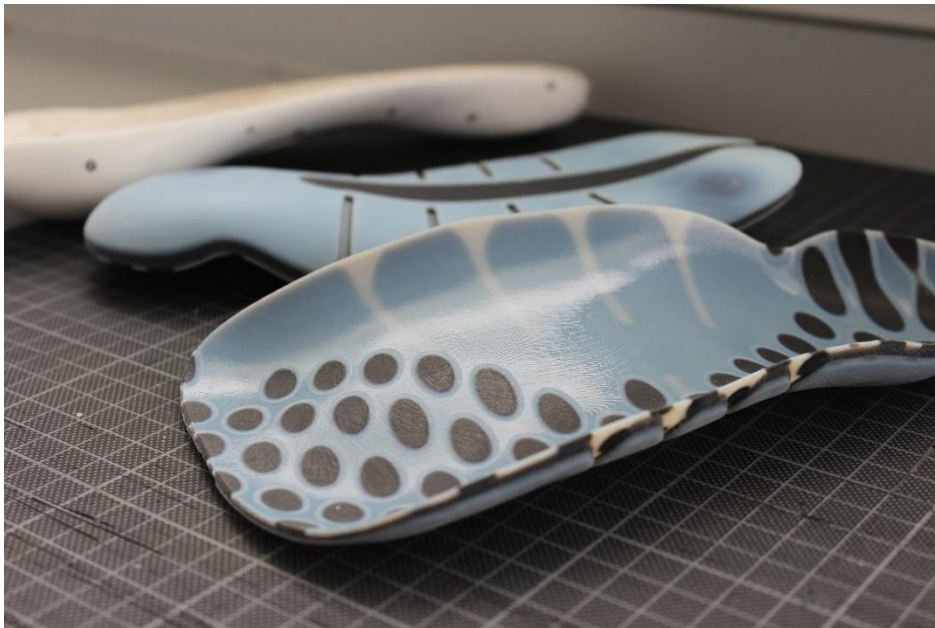
**Outcome:**

The purpose of the final test-for-fit session with the podiatrist and the participant was to gain insight into both the podiatrist and participant's view on the final orthotic prototypes.

The outcomes were as follows:

- The podiatrist felt that the integration of Multi Material AM technology and 3Dscanning equipment, as well as computer aided design programmes, would have great potential to cater for any patient with podology issues.

- The podiatrist highlighted that the introduction of flexibility within the orthotic shell offered the participant more controlled movement and support during sporting activities.
- The mixture and placement of both soft and rigid materials within the orthotic shell offered a custom solution, specific to the participant needs, without compromising the orthotic primary function.
- The multi-material process created a smooth surface finish within the orthotic shell. In doing so the patient was offered a clean and wipeable surface.
- The podiatrist noted that the integration of multiple material printing within the FO industry could create a new array of novel features within orthotic design, for example, compression pads, low-density and high-density orthotic shells.



*Figure 60: Final orthotic prototype fabricated using multi material technology.*

Whilst the multi material printing process demonstrated functional and aesthetic advantages over traditional orthotic devices, for its successful transition into a clinical setting, a range of biocompatible materials would require development, clinical testing and approval.

Proposed FO product development process, arising from the research and design findings, is documented in a revised FO product journey map. (fig 62, pg 117).

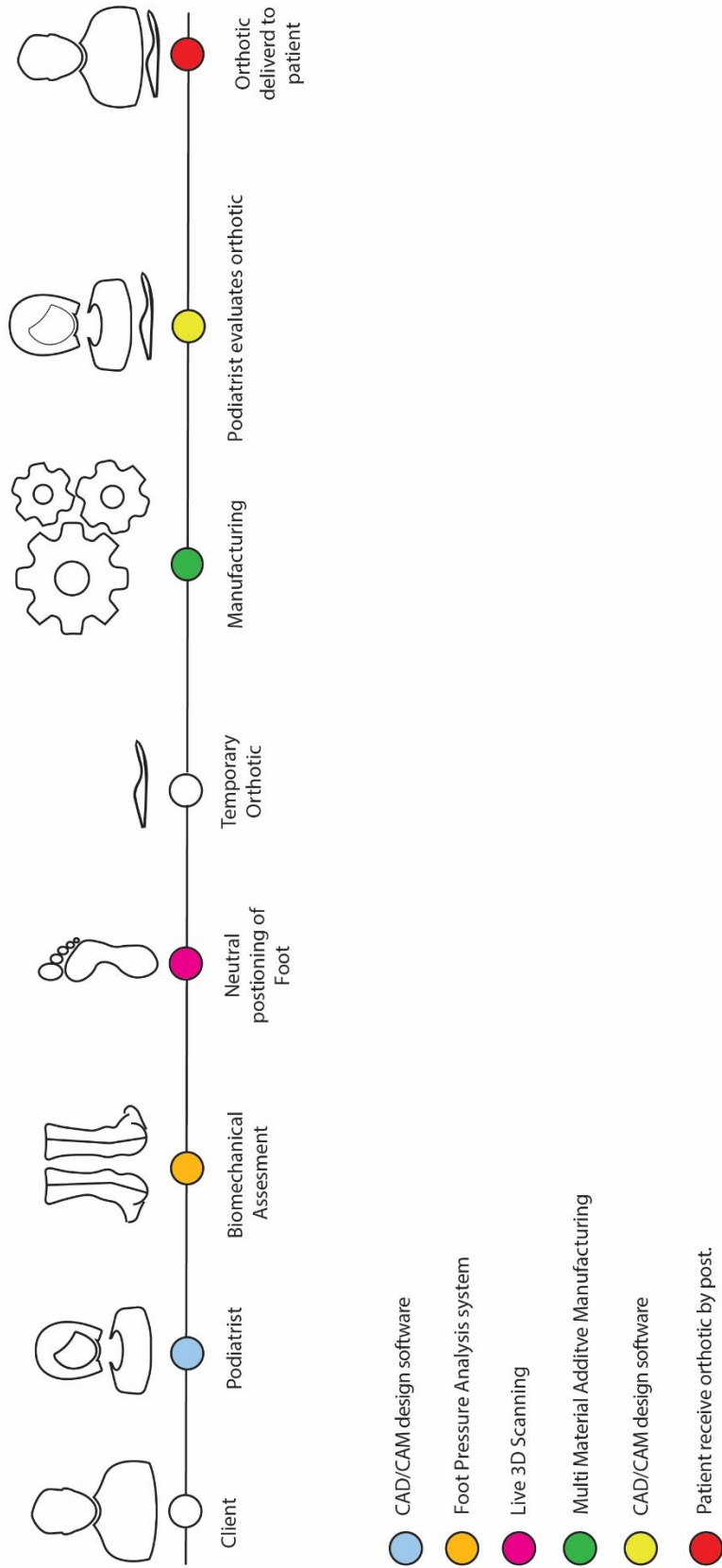


Figure 61: Revised product journey map

## 6.0 Discussion and Findings

The purpose of the Applied Research Master's project was to investigate the role of Additive Manufacturing (AM) and digital technologies within the development of improved customised protection in sports equipment. FO was selected as an appropriate PSE to explore the unique capabilities of both AM and digital technologies. This was a result of preliminary research which found that poor body posture caused by the sedentary lifestyle of modern-day society is the cause for the majority of upper and lower-extremity injuries in sport. It is believed that if the foot isn't positioned correctly, posture can be affected and functional movement issues occur which align the body, mobility and creates instability within the human body resulting in injury. Therefore, an appropriate and actionable solution for this research to address was to design for the foot.

The Research Masters project was undertaken using a Research through Design approach. The overall aim was to create and share new knowledge for future design activities in the area of customised protection in sports equipment, incorporating additive manufacturing and digital technologies, and offering a more holistic approach to the design and creation of FO.

The Research Masters process may aid the healthcare system, existing manufacturing services and the end user. The research process was iterative and holistic, in which knowledge was generated through design iterations, making and testing experimental prototypes together with literature reviews and expert consultations. In doing so, the overall research approach would help bring together knowledge from many disciplinary areas like human factors, healthcare, user behaviour, 3D scanning and additive manufacturing to create a new artefact.

Prior to designing, making and testing experimental prototypes, the researcher engaged in field research consisting of focus groups, preliminary and focused interviews with medical practitioners and physicians with a clinical background in sports science, physiotherapy, podiatry and orthopaedics. Field research findings confirmed that incorrect foot positioning causes instability and is, therefore, a key contributor to both upper and lower body injuries, further revealing that the current medical solution for correcting poor foot posture were custom-made orthotics, using traditional fabrication methods, and that these offered poor

fit, provided inadequate support throughout the gait cycle and offered limited movement and flexibility during sporting activities. This research highlighting the need for better orthotic product development and design. For this reason, the researcher identified custom orthotics as a product area offering the greatest potential for exploring the range of possibilities provided by the application of AM and digital technologies.

Early stage field research identified that custom made orthotics were unique and custom to the patient's anatomical characteristics, features and foot issues. The researcher identified that collaboration with a study or participant, with a history of lower limb injuries related to poor foot posture and requiring orthotics, was essential in order to gain insight into the current tools, processes and techniques used in prescribing custom made orthotic devices. A suitable participant was identified and invited to take part in the study. The role of the participant was to allow the researcher to observe and evaluate existing orthotic procedures in the diagnosis, prescription and application phase of FO. In the prescription phase, this was achieved by the recording and analysis of the user trip. The user trip involved the participant being biomechanically assessed and evaluated by the qualified podiatrist. The user trip involved the participant requiring custom made orthotics, in order to help correct foot posture and overall body alignment. Observations of the user trip noted the difficulties with existing assessment and prescription methods. The methods involved were biomechanical assessment and examination, plaster casting and foam impression techniques.

The plaster casting technique was used by the podiatrist in order to capture a three-dimensional plaster impression of the participant's foot in the optimal position. The advantages of this particular process were that a highly detailed impression of the participant's foot in the optimal position could be created. However, the disadvantage was that the overall process was time-consuming, messy and delicate and the impressions created were extremely fragile and delicate. For this reason, the researcher explored the foam impression method in order to investigate different foot surface capturing techniques used within the diagnosis phase of orthotics.

Similar to the plaster casting technique, the foam impression kit box was utilised to help capture the optimal position of the participant's foot. The foam impression, unlike the plaster casting technique saved time, waste, material when capturing a negative mould of

the participant's foot in the optimal foot position. However, the disadvantage of the process was that the podiatrist felt that the foam impression was difficult to use, specifically when trying to place the participant's foot in the optimal position within the foam impression kit box. However, the overall foam impression process captured a highly detailed mould impression of the participant's foot suitable for model making and 3D scanning purposes.

The final technique explored within the diagnosis phase was the foot pressure analysis system. The primary function of the foot pressure system is to measure and analyse key pressure points and weight distribution within the patient's feet. The foot pressure analysis system investigated the participant's foot pressure and weight distribution within the stance position. The benefit of using such an advanced piece of technology was the ability to discover and gather a greater insight into the key physical characteristics of the participant's feet. The method would provide the podiatrist with greater knowledge of the participant's feet for treatment and diagnosis purposes. However, the foot pressure analysis system does not create or generate a 3D digital profile of the participant's foot to aid the fabricator in the creation of custom orthotics.

Research by Annett and C.L Cross (2016) at Trinity College Dublin have developed a new material called G-Putty. The material consists of graphene suspended in an elastomeric matrix and has shown potential for application in the next generation of electronic pressure measuring and, perhaps, scanning equipment too. If successful, these latest technologies have the potential to capture both static and dynamic 3D dimensional impressions and associated pressure points of a subject's feet.

To summarise, observations and analysis of the user trip allowed the researcher to gain valuable insight into the various tools, techniques and processes used in prescribing custom-made orthotic devices. In doing so, the researcher identified that capturing the participant's foot in the optimal position, using the foam impression, was the most suitable capturing method to assist in 3D scanning purposes. In addition, the data generated from the foot pressure analysis test aided the researcher in identifying key pressure points within the participant's feet, helping to introduce innovative novel features to advance and improve orthotic design. Overall, the findings generated from the user trip aided the researcher in highlighting where AM and 3D scanning technologies

could be successfully integrated and implemented within the existing medical practice for diagnosis, prescription and application phases of custom orthotics.

In order to explore the full potential of 3D scanning technology, a plaster cast model of the participant's foot was required. This was created from the foam impression made in the diagnosis phase. The implementation of 3D scanning technology within the prescription phase aided the researcher in capturing an accurate and digital profile of the participant's foot for CAD manipulation. The scanned data facilitated the development of a more user focused solution, improving overall fit and function, in support of custom orthotic design using AM technology. Furthermore, the scanned data generated could also be stored and kept on file to aid the podiatrist and manufacturer for future orthotic development. While 3D scanning technology did show numerous advantages throughout the study, the one downside was the technology's inability to capture the participant's foot in the optimal position for live scan purposes. This is because of participant movement, hence the need to create a plaster cast model of the participant's foot.

Further development in direct 3D scanning for body form applications would be necessary to capture the optimal position of the patient's foot. Advanced direct 3D scanning would eliminate the need for the casting stage and, therefore, save time, material and help to ensure a better fit. 3D scanning equipment can also be utilised for 3D inspection purposes and would facilitate the manufacturer or podiatrist in the alignment of measuring to normal data, dimensional analysis and creation of a measuring report. The utilisation of 3D inspection could test that the orthotic is both fit for purpose and fully validated and could eliminate the need for the patient to return to the clinic for a 'final fitting'.

The research found that the major advantages of the integration of Additive Manufacturing (AM) within the application phase of the existing medical procedure of FO, in comparison to traditional manufacturing techniques, were the following:

- Customised individualised healthcare is a perfect fit for AM technologies, as a result of single build qualities and one off production of parts.



- The additive manufacturing process can accommodate functional, ergonomic, aesthetic, emotional and user fit requirements.
- The technology offers design freedom and flexibility, in doing so further possibilities can be created in product development of FO design.
- Faster lead times occur in comparison to the traditional process of CNC machining and vacuum forming.

In order to explore and test the advantages of AM technologies for custom orthotic design, traditional design techniques were employed. A morphological chart was utilised to explore and facilitate the development of a wide range of form, materials, functions, feature options. This approach supported concept generation and sketch modelling prior to rapid prototyping of FO devices using a variety of AM technologies, for test for fit and research evaluation purposes. The morphological chart (see figure 35, p 80) helped explore the functionality of orthotic design and unique design capabilities of AM technology. In doing so, selected combinations developed from the morphological chart generated a range of orthotic concepts whilst exploring the unique capabilities of AM. Traditional design methods were key in producing a range of custom fit orthotic prototypes, specific to the participant's medical needs and lifestyle demands for test for fit and research evaluation purposes.

It was noted by the researcher that if the custom orthotic digital workflow were to be introduced successfully into a clinical setting, a more user-friendly CAD/CAM system would be needed as well as an expert understanding of AM materials and processes by the podiatrist and fabricator. Clinical implementation of this system would require the development of CAD/CAM software specifically designed for the podiatrist during the diagnosis and prescription phase. The software would guide the operator in selection of a range of form and feature options such as: size, orthotic shell type, posting, material options, and the elevation degree as required. Hardware and software would require routine calibration to ensure effective and efficient digital workflow and outputs.

Also, for the integration of AM technologies to be made feasible within the current manufacturing procedure of FO, several developments would be required before the digitised process could be adopted for clinical and patient use. This would include further

development of AM technologies, AM material properties, the productivity of AM equipment, further training of CAD/ CAM systems for clinicians and technicians.

Change in the FO industry is likely to occur as AM and digital technologies continue to advance and evolve over time. Further evidence-based research of the overall process would allow change to occur within the FO industry and this could herald a new generation of custom orthotics designed to help improve overall patient care.

The research highlighted the unique properties of multi-material AM technology to address the functional requirements of FO design. The implementation of the multi-material printing within the application phase was to improve overall material selection, to further aid the podiatrist, fabricator and patient. The multi-material printing process was selected as it provided the widest variety of material options within one single build when compared to any other AM processes. The selected process offered a variety and range of digital materials, from rigid to elastomeric engineering materials, combining toughness and flexibility within the fabrication of a single device. This is in contrast to the limited material options within the FO industry, which is limited to only one of the following in a singular build: plastics, acrylics, composites, foams, rubber and cork subdivided into three categories of rigid, semi-rigid and soft. In brief, the implementation of multi-material technology improved material selection within the FO medical procedure.

The final orthotic prototype offered a proof of concept model demonstrating the material, design and functional capabilities of additive manufacturing. In addition, a significant finding to emerge from the implementation of multiple material printing within the existing medical procedure of FO was that the technology could create a new array of novel features for orthotic design, such as compression pads and low-density and high-density orthotic shells. Also important is the multi-material process to facilitate the development of a smooth surface finish within the orthotic shells offering the patient a clean and wipeable surface for hygiene and cleanliness purposes comparable to the poor surface finishes of many traditional orthotic designs.

Despite the aesthetic and functional advantages of multi-material printing displayed in the design phase chapter, further development of suitable digital material would be required in

order for the process to be made feasible for clinical and patient use. Stratasys offer bio-compatible materials in the range of Objets MED610™ transparent, rigid material, which is ideal for applicants who require prolonged skin contact of more than 30 days and short-term mucosal and membrane contact of up to 24 hours, making the material an ideal choice for clinical testing. However, development in the safety of digital materials would be required for long-term exposure to skin and to ensure that AM orthotics would match the product lifecycle of existing orthotic designs fabricated using traditional manufacturing techniques.

In effect, the implementation of multiple digital technologies offered a more holistic approach in the diagnosis, prescription and application phase of FO. As a result, the creation of a custom fit bespoke orthotic, tailored to the patient's medical needs and lifestyle demands helped generate knowledge to aid in future activities within the health care system, existing manufacturing services and overall patient care.

The key findings emerging from the overall Research Masters project was that the utilisation of 3D scanning technology, foot pressure analysis system and AM technologies established a more user-focused solution, improving overall fit and function when compared directly with traditional methods currently employed by podiatrists. Additionally, the scanned data generated could be stored and kept on file to help the podiatrist and manufacturer for future orthotic development. The integration of traditional design process, with AM technologies, facilitated the exploration of the design capabilities and advantages of AM technologies in the design, development and fabrication of customised orthotics.

Finally, the unique properties of multi-material technology within the application phase improved overall material selection used within the FO industry. In doing so, the integration of multiple materials further aided the podiatrist, fabricator and patient in the fabrication of custom orthotics. In brief, the integration of multiple digital technologies within the prescription, diagnosis and application phase of FO, ensured a more custom and user fit solution in the design, development and fabrication of customised orthotics, in comparison to traditional orthotic solutions.

## 7.0 Conclusion

The purpose of the Research Masters project was to investigate the role of Additive Manufacturing and digital technologies within the development of improved customised protection in sports equipment. FO was selected as an appropriate PSE to explore the unique capabilities of both AM and digital technologies. This was a result of preliminary research which found that poor body posture caused by the sedentary lifestyle of modern-day society is the main reason for the majority of sporting injuries. It is believed that if the foot isn't positioned correctly, posture can be affected as well as functional movement issues which align the body, creating instability and resulting in injury. The research identified that the current medical solution used for correcting poor foot posture were custom orthotics. Therefore, an appropriate and actionable solution for this research to address was to design for the foot, with the development of custom orthotics.

Field research findings highlighted that current FO devices produced using traditional manufacturing methods provide inadequate support throughout the gait cycle as well as limited movement and flexibility during sporting activities. This further supported the identification of custom orthotics as a product area and offered the greatest potential for exploring the range of possibilities provided by the application of AM and digital technologies. Therefore, the researcher explored the integration and implementation of AM and digital technologies within the diagnosis, prescription and application phase of FO.

The research demonstrated that the implementation of various digital technologies in the diagnosis and prescription phase of FO saved time, removed waste and helped identify key physical patient characteristics compared with traditional methods used by the podiatrist. Most importantly, the generation of scanned data could also be stored and kept on file to aid the podiatrist and manufacturer for future orthotic development. Also, the unique capabilities of 3D scanning provided an accurate and digital profile of the participant's feet for CAD manipulation, in support of more advanced design development of FO prototypes. As a result, the scanned data generated and established a more user-focused solution, improving overall fit and function in support of custom orthotic design using AM technology.

In the application phases, multi-material AM process was selected to address the unique functional requirements of the FO design. The integration of multi-material AM technology improved material selection in contrast to existing material options within the FO industry. The printing capabilities of multi material AM technology provided a high-quality surface finish, offering future patients a clean and wipeable surface, for hygiene purposes. In fact, the quality of surface finish achieved in the final orthotic prototype replicated the same quality surface finish of traditional orthotic solutions. As a result of this research, it is believed that the unique properties and capabilities of multi-material printing could create a new array of novel features within foot orthoses design, such as compression pads or low-density and high-density orthotic shells. In summary, the integration of multiple digital technologies within the prescription, diagnosis and application phase of FO, ensured a more custom and user fit solution in the design, development and fabrication of customised orthotics. In addition, the integration of AM and digital technologies reduced lead times, enhanced support and mechanical performance during sporting activities.

## 8.0 Limitations

A limitation of this research was that the design phase only focused on designing one orthotic solution specific to the medical requirements of the selected participant. Another limitation was that the only evaluation method used for testing of AM custom orthotic prototypes was test for fit. Ethical considerations demanded that the device could only be tested for fit. Also, AM materials specified were, perhaps, not sufficiently developed to permit full impact user testing.

## 9.0 Future Recommendations

On conclusion of the research, there was considerable scope for future research. The Research Masters project highlighted that there was significant potential for the custom orthotic digital workflow process to be adopted to many different types of foot issues requiring an orthotic solution. Further research and development of the digital workflow could potentially lead into the Prosthesis (P) and Orthosis (O) industry. However, further work must be explored into suitable user-friendly CAD/CAM methods to assist the clinicians and fabricators to fully support the integration of an AM O&P approach to improved form, fit and function.

The research only focused on test for fit as a method of research evaluation of AM fabricated FO prototypes. Further research could look at mechanical and material testing as a form of research evaluation, for example, tensile strength, durability and flexibility. This would involve mechanical and material analysis on a number of proposed designs fabricated using a variety of AM processes to enable a better comparison with traditional orthotic designs. Also, further research and development of AM materials is needed to develop, test and approve a wider range of bio-compatible options. Finally, longitudinal study or clinical trials could be implemented to assess the usability and biomechanical effects of different AM fabricated orthotic solutions.

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## APPENDIX A



## APPENDIX IV

### APPLICATION FOR ETHICAL CLEARANCE FOR A RESEARCH PROJECT

#### (FORM REC2-L9(R)/ L10)

#### Completing Forms

When filling in applications for exemption or for ethical review please ensure that:

- All relevant sections are completed in typed text;
- All responses are placed within the spaces allocated;
- Bold type is not used;
- All sections are completed. Where a section or a question is not relevant to the proposed research project this should be indicated by entering N/A in the relevant section. Sections should not be left blank;
- Applicants shall ensure that responses to questions are not cross referenced to previous answers on the form. For example an answer which states “see above” or “see answer to question 3” is not an adequate response and a form bearing such a response shall be returned for satisfactory completion.
- Jargon or unexplained abbreviation is not used;
- All technical terms are explained in clear terms;
- All technical procedures are adequately described to enable assessors to determine the ethical implications of the proposed research project.

Application for ethical review exemption or for ethical clearance is an essential element in any research project. It represents a clear articulation of the research project, its methods, aims, objectives and outputs. Completed forms should be submitted (in the first instant) to the Head of Department or School (or a designated staff member) for initial screening and endorsement. Forms which have not been completed satisfactorily or which are unclear or ambiguous shall be returned and shall not be tabled before the Ethics Committee for consideration.



**Application to the IT Carlow Research Ethics Committee for  
Ethical Approval of a Research Project involving Human Participants or  
samples donated by Human Participants (e.g. tissue or blood samples)  
(FORM REC2-L9(R)/ L10)**

**Applicants are advised to submit any supporting documentation they may feel is relevant to their research proposal (e.g. sample interview schedules, consent forms, third party licenses or ethical approvals).**

**A. Applicant Details**

**A.1 Researcher Details:**

Name: Mr. Sean Finnegan  
Email: [sean.finnegan@itcarlow.ie](mailto:sean.finnegan@itcarlow.ie)  
Telephone: 086 3093300

**A.2 Principal Investigator / Research Supervisor(s):**

Name: Mr. Bryan Leech  
Email: [leechb@itcarlow.ie](mailto:leechb@itcarlow.ie)  
Telephone: 059 9175362

**A.3 Additional Expertise (if applicable)**

Name: Ms. Carmel Maher  
Email: [carmel.maher@itcarlow.ie](mailto:carmel.maher@itcarlow.ie)

Telephone: 059 9175352

**A.4** Does this research form part of a programme of study?  
No

X Yes

If yes – please give details

Yes - Leading to a Master's Degree by Research and Thesis.

**A.5** I confirm that I have read and understood the following IT Carlow Policies:

Ethics Policy X Yes  No

Ethics Procedures and Guidance notes

On completing this form X Yes  No

Data Protection Policy X Yes  No

Anti-Plagiarism Policy X Yes  No



## **B. Research Proposal**

### **B.1 Title of the proposed research project**

Bespoke Rapid Manufacturing – An investigation into the application of additive manufacturing in the development of customized protection in sports equipment.

### **B.2 To what extent has this topic already been researched and written about (e.g. is there a significant body of existing published work)?**

There has been considerable research conducted in the area of sports related injuries, their causes, preventative procedures and associated impacts. Increased intensity in sport activities has been associated with the rise in acute and overuse sport injuries. Some sport injuries can have a long term impact and affect mobility and impact on health in later life.

A study by Cumps et al (2007) highlighted the substantial economic burden of sport injuries in the Flanders region of Belgium. The study showed that the associated medical costs amounted to over 15 million euro representing 0.07-0.08% of the total health care budget.

Ref: Cumps E., Verhagen E., Annemans L., Meeusen R., (2007). Injury rate and socioeconomic costs resulting from sport injuries in Flanders: data derived from sports insurance statistics 2003. *British Journal of Sports Medicine*, Nov 2007, pp.767-772.

Where once custom form fitting was the expensive realm of medical prosthetics or haute couture, an expanding range of accessible technologies are allowing the capture and replication of the human form. These technologies utilize increasingly less expensive hardware and CAD software allowing designers to produce products precisely fitted to the individual. Recent advancements in the area of 3D scanning and additive manufacture (AM) are creating a new landscape for bespoke design, manufacture and testing.

The quantitative and qualitative data gathered may inform future research in the areas of user behaviors and in the application of 3D scanning and AM technologies in producing more appropriate, sympathetic and engaging protective sports equipment.

**B.3 From that, describe how this proposed research is contributing to what is known about the topic**

This project would seek to identify and address the reason behind the limited uptake of protective sports equipment in some sports and to explore the role of 3-D scanning and AM technologies in producing more appropriate, sympathetic and engaging protective sports equipment.

Sports under consideration are as follows: Rugby, Soccer, Gaelic Football and Hurling/Camogie.

**B.4 Provide a brief description of research (*not more than 200 words in any section*)**

a) The aims and objectives

The objective of this research masters will be to investigate and explore the limited uptake of protective sports equipment (PSE) in some sports. The project aims to identify one or more sporting scenarios for consideration and to design, develop and test, appropriate solutions for protective equipment utilizing digital technologies and digital materials such as 3D scanning and computer aided additive manufacturing.

Another objective is to understand user and product design requirement of participants in the sport or sports identified for investigation. The design researcher will bring together knowledge from the disciplinary areas of human factors, health care, user behavior, 3-D scanning and additive manufacture both to develop an understanding of the problem and to propose an actionable solution for developing a new form of protective sports equipment.

b) The research design

(Note: This section can include an overview of methodology research design proposals regarding for example, evaluation and data gathering. In describing the research design, applicants are required to explain the reasoning behind their choice of method)

The research proposed is to be conducted in three stages. A research phase to investigate the epidemiology of acute and chronic sport injuries in a range of sporting disciplines, an implementation stage to investigate the aetiology and identify factors and mechanisms which play a part in the

occurrence of the sports injuries and to propose design solutions and, finally, a testing stage for evaluation of proposed designs.

The first phase will involve the scoping of the issues surrounding sporting injuries and the issues of protective sports equipment. This will include field research in a particular sport to better understand user behaviour and gather more user centred research. Both desk and field research will provide a broad understanding of user behaviour. Desk research will involve information searches, in order to retrieve information from books, journals, articles and internet sites.

Field research will involve design research methods such as user research, user trips, objective trees, counter planning, interviews with sports participants, focus group sessions and questionnaires. The data collected, will be analysed to map out opportunities, linkages and possible collaborations with community based organisations. Analysis will inform the research and design process towards more effective solutions and an extensive mapping of these opportunities will formulate a hypothesis for developing concepts.

Secondly, an exploration phase to propose and develop appropriate and sympathetic design solutions to eliminate or lessen damage to individuals engaged in sporting activities. The researcher will apply design methodologies which may include brainstorming, classification, forced connections, new combinations, enlarging the search space, ideation and sketch conceptualisation. This design lead research will address the user issues observed during contextual analysis.

Thirdly, there will be an implementation and testing phase where selected design proposals are fabricated and tested. Selected prototypes will be fabricated, evaluated and tested using performance specification methods such as, checklists, user trials, test for fit, etc. Test analysis procedures will be designed to capture user feedback.

c) The size and composition of sample

The initial sample will be purposive. Initially a small number ranging from 1 to 15 interviewees will be selected based on their relevance to the area of study.

- d) The method of how participants are expected to be selected, approached and recruited in conducting this proposed research?

(Note: The process of participant selection is required to be outlined clearly. If for example, participants are being contacted through an organisation, e.g. school, an initial step would be to seek permission from the organisation to approach the participants. Any inclusion or exclusion criteria must also be specified.

The primary sample will be selected from staff and students involved in sport within IT Carlow. Sport and sports rehabilitation staff, as key gate keepers will be contacted first. An information sheet will be provided explaining the purpose and requirements of the study. With gatekeeper's informed consent, students will then be approached. Participants will be over 18 without restriction to gender/age/ability. They will be selected based on their area of study and sporting involvement. They will receive a participant information sheet and consent form prior to participation.

- e) Describe the procedures that will be adopted to maintain the confidentiality of research subject(s).

Voluntary informed consent will be obtained from each participant by means of a participant information sheet and consent form. Where possible memos, field notes, will be devoid of personal identifiers. Participants and their associated institutions will be given numbers or pseudonyms in the research account. Stored audio material descriptors and linked profile questionnaires will use pseudonyms or numbers and the researcher and research supervisors will be the only people with access to real names and identifier details.

- f) Will any member of the intended group of research subjects, to your knowledge, be involved in other research projects or activities? If so, please give details and explain the nature of the engagement with other projects.

N/A

- g) Describe how the information is gathered, stored, handled and anonymised.

All data and study information collected will be stored securely and retained/destroyed in accordance with the Data Protection Act 2003 and the eight Data Protection Principles. Interview audio data will be transcribed. Only anonymised data will be included in the transcription and then all audio tapes will be destroyed.

Transcriptions, study information and consent forms will be stored on the researcher's password protected personal computer. It will not be possible to link the personal data to any particular transcription. All the above research data will be backed up on a password protected external hard drive.

In keeping with principle 5 of the Data Protection Act 2003, data will be retained for five years after the award of the degree. After this period, all personal data will be securely destroyed. Informed consent will be obtained from each participant by means of a participant information sheet and consent form.

Where possible memos, field notes, will be devoid of personal identifiers. Participants and their associated institutions will be given numbers or pseudonyms in the research account. Stored audio material descriptors and linked profile questionnaires will use pseudonyms or numbers and the researcher and research supervisors will be the only people with access to real names and identifier details.

- h) Please state the location(s) the proposed research is to be conducted

Research bodies will include organisations located within I.T Carlow who are involved with Health and Sport. The sporting bodies for consideration are Rugby, Soccer, Gaelic Football and Hurling/Camogie. Community based organisations such as local sporting/ health organisations situated around the Carlow/Dublin region may also be included if deemed necessary.

i) The proposed starting date of research/ study

January 2016

**B.5 Has this research proposal received ethical approval from any other body? – if so please provide details.**

No

**B.6 Does this proposed research require licensing approval? – if so please provide details of licenses obtained.**

No

**B.7 Describe (a) the ethical considerations of this proposal and (b) the steps to be taken to address these.**

The ethical issues of this research relate to the following:

- Making sure participants are fully informed about the purpose, methods and intended possible use of the research. This will be achieved by the means of a participant information sheet which they will be supplied with prior to participation and interviewing.
- Ensuring participants are aware that participation is voluntary and that they may choose at any stage throughout the project to withdraw this consent. This will be communicated to the participant in the participant information sheet. Should the participant agree to participate in the research, they will confirm by signing the consent form.
- Ensuring confidentiality of information supplied. Care will be taken to ensure that the participants and the educational institutions they are associated with are not disclosed in any research outputs. This will be achieved by using pseudonyms for the participants and by removing other possible identifiers such as detailed descriptions, institution names and location details.

- Ensuring all data and study information collected is stored securely and retained/destroyed in accordance with the Data Protection Act 2003 and the eight Data Protection Principles. Interview audio data will be transcribed. Only anonymized data will be included in the transcription and then all audio tapes will be destroyed. Transcriptions, study information and consent forms will be stored on the researcher's password protected personal computer. It will not be possible to link the personal data to any particular transcription. All the above research data will be backed up on a password protected external hard drive. In keeping with principle 5 of the Data Protection Act 2003, data will be retained for five years after the award of the degree. After this period, all personal data will be securely destroyed.
- Ensuring participants are informed of the research outcomes. As a thank you for their participation, all participants will receive a short summary of the research in writing when complete.
- Ensuring safety of participants. There are no anticipated risks to participant's safety. Product development and testing shall be confined to 3D scanning, taking mould impressions and testing for fit and comfort only. See below for details.
  - **3D Scanning**

A 3D scanner is device which captures the physical shape and dimensions of an object digitally. By using a 3D scanner it is possible to replicate the human form to tailor fit protective sports equipment to the individual. This procedure is similar to taking a number of photographs/videos, where the participant needs to remain still for a minute or two for each individual scan. The procedure is not invasive and there are no risks to the participant. This procedure will take place in design core in I.T Carlow at a time agreeable to both the researcher and participant.
  - **Taking Mould Impressions**

It may be necessary to take a mould impression of the area to be protected by the sports protective equipment. A silicone FDA approved material will be used to take the impression. As a precaution, a spot test will be carried out to detect for skin allergies, 24 hours prior to taking the impression. This is to ensure that participants do not react to material used in the impression mould. This procedure will take place in design core in I.T Carlow at a time agreeable to both the researcher and participant.



- **Testing for Fit**

Following the fabrication of the product prototype it will be necessary to test it for fit and comfort to the individual it is designed for. The materials used in the prototype will be FDA approved (or similar) grade materials. As a precaution, a spot test will be carried out to detect for skin allergies, 24 hours prior to testing. This is to ensure that participants do not react to material used in the prototype. This procedure will take place at a time and location agreeable to both the researcher and participant.

Note: Testing is just for fit and comfort. The prototype will not be tested for impact with participants and, for participant safety, will not be worn in play. Impact tests will be performed mechanically without participant involvement.

**B.8 Describe the research procedures as they affect the research subject and any other parties involved.**

Participation involves questionnaires, interviews, focus groups and product development and testing.

- The questionnaires are designed to gain a greater understanding of sports injuries and will take approximately 15 minutes to complete.
- Interviews will last approximately one hour and will be audio recorded. They will take place at a time and location agreeable to both participant and researcher. The interview questions will be open-ended to gain a personal understanding and experience of sports related injuries.
- Focus groups will last approximately two hours. They will involve brain storming sessions, group discussions and mind mapping exercises in the context of sports injuries. They will take place at a time and location agreeable to both the focus groups and the researcher.
- Product development and testing shall be confined to 3D scanning, taking mould impressions and testing for fit and comfort only. See below for details.

- **3D Scanning**

A 3D scanner is a device which captures the physical shape and dimensions of an object digitally. By using a 3D scanner it is possible to replicate the human form to tailor fit protective sports equipment to the individual. This procedure is similar to taking a number of photographs/videos, where the participant needs to remain still for a minute or two for each individual scan. The procedure is not invasive and there are no risks to the participant. This procedure will take place in design core in I.T Carlow at a time agreeable to both the researcher and participant.

- **Taking Mould Impressions**

It may be necessary to take a mould impression of the area to be protected by the sports protective equipment. A silicone FDA approved material will be used to take the impression. As a precaution, a spot test will be carried out to detect for skin allergies, 24 hours prior to taking the impression. This is to ensure that participants do not react to material used in the impression mould. This procedure will take place in design core in I.T Carlow at a time agreeable to both the researcher and participant.

- **Testing for Fit**

Following the fabrication of the product prototype it will be necessary to test it for fit and comfort to the individual it is designed for. The materials used in the prototype will be FDA approved (or similar) grade materials. As a precaution, a spot test will be carried out to detect for skin allergies, 24 hours prior to testing. This is to ensure that participants do not react to material used in the prototype. This procedure will take place at a time and location agreeable to both the researcher and participant.

Note: Testing is just for fit and comfort. The prototype will not be tested for impact with participants and, for participant safety, will not be worn in play. Impact tests will be performed mechanically without participant involvement.

- All this information will be communicated to the participant prior to the commencement of any research activity in the participant information sheet.

**B.9 Please list the investigators (including assistants) who will conduct the research. Please provide details of their qualifications and experience**

N/A

**B.10 Are arrangements for the provision of clinical facilities to handle emergencies necessary? If so, briefly describe the arrangements made.**

No emergencies are envisaged. The materials used for mould taking and prototype development will be FDA approved (or similar) grade materials. As a precaution, a spot test will be carried out to detect for skin allergies, 24 hours prior to mould taking and product fit and comfort testing. This is to ensure that participants will not react to materials used in mould making and prototypes created using proposed additive manufacturing technologies.

**B.11 Specify whether research subjects include students or others in a dependent relationship.**

Research participants are not in a dependent relationship with the researcher.

**B.12 Specify whether the research will include primary respondents such as children, individuals with mental health issues, individuals deemed to be of diminished responsibility, individuals with a physical or intellectual disability. If so, please explain the rationale for accessing these subjects for the proposed research. Please indicate alternative measures investigated to avoid the necessity for direct access to these primary respondents.**

None from this group.

**B.13 Please confirm that no payment will be made to any research subject**

No.

**B.14 Describe the procedures to be used in obtaining a valid consent from the subject. Please supply a copy of the information sheet provided to the individual subject(s).**

Key gate keepers will be contacted first. They will be provided with an information sheet explaining the purpose and requirements of the study. Having secured the consent of gate keepers the sports team members will be approached. Each invited participant will receive an information sheet and consent form prior to any research being conducted. Only after fully informed consent is given will the research commence. Please see attached information sheet and consent form.

**B.15 Please indicate if there are any cultural, social, gender-based characteristics or sexual orientation, practices or behaviour of the subject(s) which have affected the design of the project or which may affect its outcomes.**

None.

**Signed:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Researcher**

**Signed:** \_\_\_\_\_

**Date** \_\_\_\_\_

**Principal Investigator**

**Supervisor)**

**REVIEWER COMMENT IF APPLICABLE FROM HEAD OF DEPARTMENT/GROUP/ INSTITUTE/CENTRE**

Signed: \_\_\_\_\_

Date

\_\_\_\_\_  
(Head of Department/Group/CORE/Institute/Centre)

### **Participant Information Sheet**

**Research Project Title:** Bespoke Rapid Manufacturing: An investigation into the application of additive manufacturing in the development of customized protection in sports equipment.

**Project Researcher:** Sean Finnegan, DesignCore, Institute of Technology Carlow.

**Contact Details:** [sean.finnegan@itcarlow.ie](mailto:sean.finnegan@itcarlow.ie)

**Head Supervisor:** Mr. Bryan Leech, Industrial Design Lecturer, Department of Humanities, Institute of Technology Carlow.

**Contact Details:** [leechb@itcarlow.ie](mailto:leechb@itcarlow.ie)

**Co- Supervisor:** Ms. Carmel Maher, Industrial Design Lecturer, Department of Humanities, Institute of Technology Carlow.

**Contact Details:** [carmel.maher@itcarlow.ie](mailto:carmel.maher@itcarlow.ie)

**Note to ethics committee:** Participation may involve one or more of the activity's outlined below. Only the activity the participant is being invited to take part in will be included in the individual participation information sheet and consent form.

### **Consent Form**

Please  
Initial Box

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask Questions.

- 2. I understand that my participation is voluntary and that I'm free to withdraw at any time, without any giving reason.
- 3. I agree to take part in the above study.
- 4. I agree to the use of anonymised quotes in publications.
- 5. I agree to participate by questionnaire
- 6. I agree to participate in an interview
- 7. I agree to participate in a focus group.
- 8. I agree to be audio recorded.
- 9. I agree to participate in a spot allergy test prior to product development and testing.
- 10. I agree to have a 3D scan taken for the purpose of developing a custom fit sport protective device.
- 11. I agree to have a mould impression taken for the purpose of developing a custom fit sport protective device.
- 12. I agree to test for fit and comfort a protective spots equipment device prototype.

\_\_\_\_\_  
Name of Participant  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_

## Participants Information Sheet

**Research Project Title:** Bespoke Rapid Manufacturing: An investigation into the application of additive manufacturing in the development of customized protection in sports equipment.

**Project Researcher:** Sean Finnegan, DesignCore, Institute of Technology Carlow.

**Contact Details:** [sean.finnegan@itcarlow.ie](mailto:sean.finnegan@itcarlow.ie)

**Project Supervisor:** Mr. Bryan Leech, Industrial Design Lecturer, Department of Humanities, Institute of Technology Carlow.

**Contact Details:** [leechb@itcarlow.ie](mailto:leechb@itcarlow.ie)

This research is funded by the Institute of Technology Carlow as part of the Presidents Research Fellowship Award and is being undertaken at the School of Business and Humanities at Institute of Technology Carlow.

### Context

Engaging in regular exercise has a direct and positive effect on the individual's health. Younger people can benefit from physical activity as it supports healthy bone development, contributes to efficient heart and lung function and improves motor skills and cognitive functions. For older members of the population remaining, physically active maintains functional capacity and helps sustain a better quality of life and independence. However, as a result of higher volumes of engagement and increased intensity in sport activities there has been a rise in acute and overuse sports injuries. Some sport injuries can have a long term impact and affect mobility and impact on health in later life.

### Research Project Objective

The objective of this research masters is to investigate and explore the limited uptake of protective sports equipment in some sports, to identify one or more sporting scenarios for consideration and to design, develop and test appropriate solutions for protective equipment. Proposed design solutions will utilize, where

appropriate, digital technologies such as 3D scanning and computer aided additive manufacturing.

Participation is entirely voluntary. You are free to withdraw at any time, without giving a reason. We are inviting you to participate in this study as we believe your experience and understanding will make an important contribution to the research and development of a new form of protective sports equipment.

### **What Participation Involves**

**Note to ethics committee: Participation may involve one or more of the activity's outlined below. Only the activity the participant is being invited to take part in will be included in the individual participation information sheet and consent form.**

#### **Questionnaire**

Participation involves filling in a questionnaire, to gain greater understanding of sports related injuries, their causes, and associated impacts. This will take approximately 15 minutes to complete.

#### **Interview**

Participation involves an interview with the researcher. This will last approximately one hour and will be audio recorded. It will take place at a time and location agreeable to both the participant and the researcher. The interview questions will be open ended in order to gain your personal understanding and experience of sport related injuries.

#### **Focus Groups**

Participation involves taking part in a group discussion session. This will last approximately two hours. It will involve brainstorming exercises, group discussions and mind mapping exercises within the context of sport injuries. It will take place at a time and location agreeable to both the focus group and researcher.

#### **Product Development and Testing**

Participation involves a number of procedures which would take place at different times. They are 3D scanning, taking mould impressions and product testing for fit.



### **3D scanning**

A 3D scanner is a device which captures the physical shape and dimensions of an object digitally. By using a 3D scanner it is possible to replicate the human form to tailor fit protective sports equipment to the individual. This procedure is similar to taking a number of photographs/videos, where the participant needs to remain still for a minute or two for each individual scan. The procedure is not invasive and there are no risks to the participant. This procedure will take place in design core in I.T Carlow at a time agreeable to both the researcher and participant.

### **Taking Mould Impressions**

It may be necessary to take a mould impression of the area to be protected by the sports protective equipment. A silicone FDA approved material will be used to take the impression. As a precaution, a spot test will be carried out to detect for skin allergies, 24 hours prior to taking the impression. This is to ensure that participants do not react to material used in the impression mould. This procedure will take place in design core in I.T Carlow at a time agreeable to both the researcher and participant.

### **Testing for Fit**

Following the fabrication of the product prototype it will be necessary to test it for fit and comfort to the individual it is designed for. The materials used in the prototype are FDA approved (or) similar grade materials. As a precaution, a spot test will be carried out to detect for skin allergies, 24 hours prior to testing. This is to ensure that participants do not react to material used in the prototype. This procedure will take place at a time and location agreeable to both the researcher and participant. Note testing is just for fit and comfort. The prototype will not be tested for impact and will not be worn in play for participant safety. These tests will be performed

### **Benefits/Risks of taking part.**

Whilst there may be no personal benefits to your participation, the information you provide may contribute to the future development of more appropriate, sympathetic and engaging protective sports equipment. Your participation will also facilitate the learning required to complete my M.A studies. There are no known risks in taking part in this study.

### **Confidentiality and Data Protection Act**

All information provided by you will be kept confidential at all times. All information provided by you will be stored anonymously on a computer. Only members of the research team, researcher and supervisors will have access to it. All responses to

questions and information provided by you will be anonymized in any publications which may result from this research. All data collection, storage and processing will comply with the principles of the Data Protection Act 2003 and the EU Directive 95/46 on Data Protection.

### **Consent Form**

Thank you for taking the time to read this participation information sheet. Your participation is entirely voluntary and you may withdraw at any time. If you decide to participate please sign the attached consent form.

**Research Project Title:** Bespoke Rapid Manufacturing: An investigation into the application of additive manufacturing in the development of customized protection in sports equipment.

**Project Researcher:** Sean Finnegan, DesignCore, Institute of Technology Carlow.

**Contact Details:** [sean.finnegan@itcarlow.ie](mailto:sean.finnegan@itcarlow.ie)

**Project Supervisor:** Mr. Bryan Leech, Industrial Design Lecturer, Department of Humanities, Institute of Technology Carlow.

**Contact Details:** [leechb@itcarlow.ie](mailto:leechb@itcarlow.ie)

### Pre - Assessment Allergy Consent Form

1. I agree to participate in a spot allergy test prior to product development and testing.

**No**

2. I agree to test for fit and comfort a protective spots equipment device prototype.

**No**

3. Do you have any skin allergies in which we should be aware of, if yes please give detail.

Yes  No

4. Please give details of the following: GP, Name, Addresses, and telephone number.

Name of GP	
Addresses of GP	
Telephone Number	

I declare that the information that I have given as part of this application is correct to the best of my knowledge

---

Name of Participant  
Date

---

Signature

## APPENDIX B.

## Transcripts of Interviews;

### Participant One

- It's not that I think it is as simple of stopping the knee doing something, it's what the foot is doing under neat, what the hip and spine is doing above.
- Orthotics could possibly prevent knee and ankle injuries.
- Orthotics all go on the basis of finding a neutral position for your sub tailor joint, which is your talus bone in your foot.
- So orthotics will look at that and say that's not correct and need to put the persons foot into a more neutral position-where it is neither inverted or everted or rotated in or out or dorsiflex or plantar flexion.
- But for extreme sporting situations or even just in walking, your foot is suppose, to pronate and supinate out of it and then pronate and then supinate.
- It is a serious of joints which are suppose, to move and orthotics go down the route of not allowing that movement, because they want to keep you in a neutral position.
- Many feel that it doesn't work very well and that may well be a problem for you to overcome.
- A device in which you can design, which is not able to take you to the extreme of pronation or the extreme of supination is allowed to happen but preventing the extremes.
- A device which can allow your foot to do something but not hold the foot and keep it rigid.
- What is stability? So you introduce movement into your foot, but you have to be able to control the movement, that is what stability is.
- So we have loads of these tiny little cells, that detect pressure, temperature, gradient, detect exactly where it is in space and flood all this up to your brain and then your brain can send this motor information down to use the active stabilizer's to contract or to tell the joint were to go.
- A lot of injuries in young people at the moment occur because people don't train feet to do what their capable of doing.
- But if it was custom made for you and the shape of the foot or ankle, you would be more inclined to wear it.
- Flow motion model, whatever the foot is doing translates into what the ankle is doing, what the hip is doing , pelvis, spine and head.
- For example for walking he maps out running all different sports, and what the foot is doing and the knock on effects of the chain.
- So something that would allow this natural behaviour occur and not to be rigid, would prevent every injury going.
- Because if your foot is doing what it is supposed to be doing, every joint can line up a bit better and has more potential compared to if your foot is locked down.

- Mary feels that a lot of injuries occur because of the position of the foot.
- Injury occurs because of what way your foot is moving as well as depending on what sport you're playing or situation you get yourself into.
- Usually with sport it is to do with reputation, if your foot is doing what isn't suppose, to be doing, everything up the chain gets affected.
- The foot needs to be in the optimal position to prevent injuries from re-occurring.
- It's the only part of the body that is contacting the ground.
- Aim will be to understand the foot mechanics and optimize it.
- You want the foot to move but you just don't want to show where it needs to go, because sometimes feet get locked down in a particular position and get stuck.
- So it's not usually about strengthen the feet, it's about moving them efficiently and properly in the optimal position and getting all the joints stacked on top.

## Participant Two

### Question 1

As a sport therapist is there a particular sport injury which you have seen occur/re-occur in your field of practice?

- Hand injuries, Ankle, Knee injuries , ACL/MCL injuries
- ACL injuries are the most severe because of the due to the recovery time involved, 9months.
- ACL injury can really damage and destroy a player from returning to the game.

### Question 2

In your practice is there any injury, that present it's self which would benefit from a custom made protective sports device?

- The ash is probably the best example of PSE in which you can wear without weakening the muscle but still have good protection at the same time.
- You need to be aware of how to protect an area of the body without taking away the main function of that body part.
- Ankle injuries now, players tend to go over on the ankle a lot, reason people don't build up enough stability and strength within the ankle.
- Surfaces are of good quality now, which means players are not inclined to build up stability. (External Factors).
- Insoles are used to help stability.

### Question 3

Do you feel there is a certain area of the body, where it is possible to design a protective sports device for either protective / prevention or rehabilitation purposes?

- Things to be taken into account such as designing without interfering with the function of the movement of the body, without taking away from the natural body strength.

- Finding something that allows the body to move functionally, but not over laborating on the muscle.
- P.S.E creates safety and security mentally in knowing that they can't do any more damage or gives the player re-assurance that they can't have a re-occurrence of the same injury.

#### Question 4

What area of the body would be most suited for a custom made protective sports device?

- The biggest thing now regarding function and movement is orthotics. To correct the alignment of the foot.
- Explains the importance of orthotics- basically your looking at the foot, as the foundation of the body and everything else is stacked above , if the foot positioning isn't well then it is going to cause functional movement issues align the body.
- Depending on what way that person is moving, that can be anywhere from ankle, knee, hamstring, quad strain, hip flex restrains, lower back and hip.
- Orthotics can affect how a person sits, stands, walk, positioning and body posture.
- Body will always try and re-align, which can use "tilting" of certain body parts to readdress the weight and centralise it which can cause an s-curve to occur in the spine.

#### Participant Three

##### Question 1

As a sport therapist is there a particular sport injury which you have seen occur/re-occur in your field of practice?

- Hamstring, ACL/MCL injuries, Ankle injuries, Concussion,
- ACL injuries can age your knee by 20 years. In Ireland cruciate ligament damage is happening to players as young of age 12, so you can you imagine a 12 year old going around with a 32 year old knee. In United States as young as 8.
- This is due with training errors that their not conditioned enough for sport, current lifestyle and inactivity is causing this. It is an escalated problem which is going to occur a lot more years down the line.

##### Orthotics

- For example if a person is overweight and does very little exercise and suffers from knee, hip pain an orthotic device would be used to stabilize the position and hip.
- However we would do numerous exercises, to try and get the body to correct its self and be strong to stabilize the position.

##### Question 2

In your practice is there any injury, that present it's self which would benefit from a custom made protective sports device?



- Ankle and Wrist

### Question 3

Do you feel there is a certain area of the body, where it is possible to design a protective sports device for either protective / prevention or rehabilitation purposes?

- It is key that the product or device doesn't affect or prevent the player performance.

### Reason for ankle injuries

- People lifestyle, he feels that people are not developing their intrinsic muscles enough.
- Foot wear can have an effect.

### Opinion on Hip

- Damien believes that because the way in which we sit, generally what happens is that your hips are going to be internally rotated, so if my hip is sitting in a relaxed position, hips will automatically turn in. If I later try go and try and run, my hips has already adopted into that positioning, which is therefore going to load the knee and so the foot drops, so now straightaway you're in a disabled position.
- So this is where orthotics come in, people are trying to say ok let's go and try and put a device under neat the foot, were it can put everything in the correct position. (Knee and hip).
- However orthotics (treating from the ground up) are only trying to correct the position, even do Damien uses orthotics, he feels that personally long term these devices are temporary and gives the person a false sense of security.
- Whereas if you don't have the strength their or stabilization, no device is going to stabilize the person body.

### Opinion on Protection

- I suppose looking at soccer injuries, we are looking at a lot of bone bruising and that is because football boots don't have that cushioning and are extremely solid, which causes studs to come up.
- Bruising of your flat pad. (Heel). Silicone gels are used to create softness.
- These pieces of items would be used for protection or after the injury to get the player back playing again.
- Knee brace would be used, unless the athlete done in their MCL, where there is instability there, and then you would have to brace it and stabilise it to stop the valgus from going in.

### Rehab device

- A self-tool is a great device, in which players can use by themselves in working the soft tissue.

- The issue at the moment is that because players are sitting down posture, muscles are tighten a lot quicker and therefore it's hard to go from sitting down, working, driving and then playing sports which can cause injury.

#### Question 4

What area of the body would be most suited for a custom made protective sports device?

- The design needs to protect and allow the body to achieve its function.
- One thing which needs to be taken in consideration in regards of the design is that the device has to be light enough which doesn't affect their play and protect the body.

#### Rehab

- What Damien uses in his therapy to show optimal loading is weighting scales, to actually show a person how much loading your putting on either your left or right foot.
- As a device that can mimic how much loading is correct and how much offloading is correct.
- Landing mechanics, people now have poor landing mechanics is reasoning for ACL injuries, what happens is that stability in the hip.
- Instability in the hip is caused by the hip being already in the internal rotation from driving and sitting down all day.
- So when players are asked to jump and do intensive exercise, players can tend to lend in the valgus position, which can cause ACL damage.
- It is becoming more of a problem with younger people, because all they are doing is sitting around all day and not exercising or playing outside.
- Therefore the landing mechanics and strength development is not there.
- In activity is an issue and when young people are asked to carry out intensive exercise, injury will occur.
- Is there a device which could keep your hip in the optimal position rather than allowing the hip to drop in.

#### Participant Four

As a sport therapist is there a particular sport injury which you have seen occur/re-occur in your field of practice?

- The most common type of injuries in a sport setting would be soft tissue, hamstring strains, muscle strains, Ankle and knee injuries.
- Non sporting population, you're going to be looking at a lot of low back and neck pain that would be more spinal postures that they adopt during the day.
- The secondary lifestyles of the modern lifestyle has become so sedentary that there is a high percentage of the population suffering from back pain.

## Question 2

In your practice is there any injury, that present it's self which would benefit from a custom made protective sports device?

- It's difficult to say whether a protective device would protect against ankle injuries/sprains which are quite common in football.
- It's hard to know whether there is a device which would still allow the players to perform the mobility of the ankle joint, whilst giving them protection.
- I can't think of any, if there was a device which prevented an injury such as ankle sprains, ACL tears, that was light weight and did not restrict movement or mobility in any way. I think that would be a holy grail from an injury prevention point of view.

Why do you think ACL happen?

- There multiple risk factors involved in ACL injuries, such as intense EQ angle, quadriceps and hamstring muscles, landing mechanics, jumping and landing.
- It's difficult to control all of the areas of the risk factors.
- For example the shape of the Q angle, it's very difficult, it's an anatomical shape that people have the notch size where the ligament attaches into is an anatomical shape and is non- controllable.
- 
- What they can control is training loads, nutrition and appropriate strength balances between their quads, hamstrings, glutes, and abductors and try to give them more stability approx...
- Current research suggest that 65 percent of professional footballers in the game, after they have an ACL injury , 3 years later they retire from the game.
- If we can prevent the injury in the first place it would save a lot careers.

## Question 3

Do you feel there is a certain area of the body, where it is possible to design a protective sports device for either protective / prevention or rehabilitation purposes?

Rehabilitation?

- If you can get players into running mechanics early, without putting strain or stress on the ligament under as little pressure or stress as possible, whilst your strengthen the muscle tissue and restoring the normal running mechanics and movements, then the earlier you can do that the better
- So if there was a protective device that could guarantee us that we could start to introduce running in rehabilitation from labour repairs, cam or pincer impingement

repairs in the hip joint or ACL/PLC repairs in the knee or anterior talor fiba ligament reconstruction in the ankle.

- If you can get that type of protective equipment in early enough and go through aggressive rehabilitation point of view, introducing loading earlier without the graft site under pressure that obviously would be hugely successful for us.
- We have to respect physiology at the same time, within the windows of a rehabilitation time frame and healing process. You can't push players to hard or soon because of the fear of the injury re-occurring.
- If you had something that is evident based and there is research there to back it up and that if they wear a specific piece of equipment the percentage changes of having another tear of the ligament for example when they start to do some running exercise movements are reduced and I think players would be happy to take that on board.

#### Question 4

What area of the body would be most suited for a custom made protective sports device?

- I think an area of the body which would be most suited, if we look at team sports in Ireland for example were there are a lot of multidirectional sports, were you get a lot of knee injuries, ankle injuries.
- If you can something that is not bulky, that does not affect the performance of the player and they don't feel it when their playing, that will make a difference.
- What we want to do is tie together pieces of kit that help performance or certainly doesn't reduce performance or the quality but also protects against injury.
- The ball hits their ankle joint at different points and if they have padding, that would reduce the sensitivity and feel on the tissue and skin then the players will not like it.

#### Opinion on Knee Brace?

- The old bulky knee brace will never be worn again.
- You would never see players any more wearing these pieces of protection, because if they require something which is so restrictive, which is almost stopping them from bending and strengthening their knee fully, then they shouldn't really be playing instead they should be rehabilitated to the point where they can tolerate the full range of motion.
- If were talking about something that you are giving to players that haven't had a knee injury or ankle injury. Then it needs to be made sure that it doesn't dis improve their performance in any way.
- So when your introducing a new form of P.S.E it's difficult to get by, unless there is a perceived or real performance benefit, were as players out there are not convinced it is going to stop them from, let's say "broken legs" ( referring to the shin guard).
- But they feel the potential benefits don't out way the reduction and quality of their performance by wearing something that isn't quite bulky.

## Question 5

### How can injury affect an athlete daily routine and livelihood?

- If someone who trains twice a week and plays a match at the weekend or are in college or work fulltime, That release they can get, that joy they experience by playing sport, their social aspect playing with friends, if you take that away from people, not only the physical wellbeing but their physiological wellbeing and emotional health that is something we have to factor in. If we move on from there on to a professional athletes then you can magnify that effect by 1000.

### Question Data Sheet

- ACL tear again, I don't want to say that we know if we wear a protective device you're not going to get an ACL tear, but could it give you a little bit more control, rotative forces?
- It's not unusual for someone to have an ACL to MCL injury at the same time, MCL are more common and yes off course your trying to reduce the stress inside the knee, if you could wear something that would support the knee and not be bulky that would be ideal.
- Need more hard scientific, evidence instead of a placebo effect, then you may have something

## Participant Five

Is a qualified Sports therapist since 2000. Since then he has worked with many GAA clubs, including young Ireland, Kilkenny Hurling Senior team, and most recently Mount Leinster Rangers Senior club. As a result, Patrick has built up great experience and knowledge on the various types of sports injuries occurring in a wide range of different sports. Patrick recently opened up P.A.T.R.I.C. Injury Clinic at Newtown House, Bachelors, Bangenastown, Co.Carlow. In January 2013 he also qualified as Yumeiho Therapist, the first in Ireland and now is Yumeiho representative in Ireland. Patrick also specialises in gait analysis and in the prescription of orthotics.

On the 28<sup>th</sup> of September 2016, an interview took place with Patrick in regard to how a patient is assessed prior to the fitting of an orthotic. The interview began by asking Patrick about the equipment he currently uses to analyse the patient foot and gait analysis. Patrick currently uses a feet 24-7 foot scanner and TOG (The orthotic Group) scanner.

Patrick believes that if the foot is in the incorrect position, it can cause further stress on muscles and bones, which can lead to hip and back pain, later on in life. A common observation which Patrick notices with clients is the inside of their footwear is usually damaged or deformed, therefore instantly highlighting to him that the individual over pronates during gait.

Patrick process in prescribing orthotics involves firstly assessing the individual in order to identify any obvious problems or unusual features within the foot. Then he asks the individual to walk across the gait scanner. As a result, the gait scanner will record the foot impression and key pressure points during motion. The information is then sent to feet 24-7, who specialise in the manufacturing of customised orthotics, as a result, the orthotic is manufactured tailored to the individual's needs. It is important to be aware that the data analysis gathered from the foot scanner, dictates the design of the orthotic.

Patrick states that the incorrect way to capture the foot is in standing point of view, further stating that how one person stands and moves are completely different. Further highlighting the point that to see the individual walking, you can then begin to see a different foot impression in comparison to a stance position.

An old wife tail method used in capturing an individual movement, prior to scanning equipment was to ask the individual to dampen there feet in the water and and to walk along a piece of paper. The dampened feet will, therefore, highlight the individual's foot impression on the piece of paper.

Patrick explains that the foot scanner is used to see the imprint of the foot and what part of the foot is used. Patrick re iterates the point that the gait analysis dictates how the orthotic is designed.

"The through form", Tibia to the second metatarsal (see picture below) is one area of the body where you analyse the foot motion. Patrick states that how a person moves tells a lot about how the body may function.

states that feature in which he concentrates on in the movement of the foot is the hallux ridgus, (big toe) analysing if the flexibility or ROM (Range of Motion) is in the foot. The hallux ridgus determines whether or not a  $\frac{3}{4}$  or full orthotic is needed. Second is applying pressure to the mid foot to see if there is pain occurring (plantar fascist) this is quite common in flat foot individuals. Thirdly dorsiflexion, understanding the range of movement in the midfoot and forefoot, Patrick states that limited dorsiflexion can have an effect on the individual's knee and other parts of the body. Further mentioning that the ability to unload a certain part of the body can, therefore, relieve the pressure within the body.

Patrick believes that 98 percent of people he has prescribed orthotics for have felt the benefits, further stating that of the 300 orthotics prescribed only 2 were returned. He finds that sports players have more energy because of the orthotic, as a result of the orthotic relieving the pressure from the body and correcting the individual malfunctions.

However states that the orthotic dosen't cure all of the injuries presented in the data sheet, but reduces the risk of injury.

## Participant Six

Podiatrist first analyses the patients range of motion in feet, dorsiflexion and plantarflexion.

Podiatrist then asses the patient stance view.

Asks the individual to walk on the spot.

Identifies that the angle of the tibia bone is leaning outwards and therefore is causing genu varum (Bowling legs)

Begins with inquiries about patient's previous injuries.

The patient has re-occurring calf pain and ligament damage in ankles.

Range of motion in left foot is restricted, therefore arthritis has occurred in the first metatarsal.

Range of motion is only 10 to 20 degrees in first metatarsal, average range of motion should be 90 degrees.

Restriction in right foot is created by Applying pressure to the right foot, during gait cycle.

The patient heavily straps his right foot during play and every training sessions, to give support to ankle.

Gait Analysis Assessment begins by getting the patient to walk up and down a straight line.

The podiatrist analyses the patient gait.

Highlights that twisting is occurring on the right foot, known as rolling of foot.

Thus, this is causing tilting to occur within the body. Areas in the body highlighted is tilting occurring in hip and shoulder, on the right side of the body.

Therefore, proves the medical terminology of poor posture and alignment in the right foot is causing tilting to occur within the lower and upper extremity of the body.

After examination and assessment of patient, plaster cast process was by beginning to create a negative cast of the individual feet, in the neutral position.

The process began by applying the plaster paris strips to the individual feet.

Applying the plaster casting process, is extremely time consuming, messy and delicate process.

The material dries extremely quickly and therefore takes a trained and skilled individual to apply the material.

The outcome is a negative plaster cast of the individual feet in the neutral position.

After the process the patient feet is washed down, with a foot bath.

Podiatrist fills out a template to guide the design of the custom orthotic.

The prescription and negative cast are then sent off to the orthotic manufacturer. This process usually takes 3 to 4 weeks, depending on the urgency and need of the orthotic.

In the meantime, the patient is offered a standard stock orthotic, to allow the individual to build up stability and to allow the patient to get use to wearing a device with in his shoe.

When the custom orthotic is delivered to the clinic, the patient will be asked to come back to the clinic to fit the orthotic. The podiatrist will examine the patient wearing the orthotic during the individual gait cycle.

Finally, the podiatrist will book an appointment in 6 months, time to reassess the individual.

The expects the patient to wear the orthotic a least 80 percent of the time, for the patient to feel the full benefits of the orthotic

Choice of four covering materials, EVA, Vinyl, suedette and a cushioning cover.

## Participant Seven

### Podiatrist Interview

On the 7<sup>th</sup> of October, an interview took place with Ashleigh Milne, podiatrist of Pembroke clinic, situated in Carlow.

#### Question 1

Ashleigh stated that heel pain is the most common type of foot injury and stems from plantar fascist, which runs along the arch and the sole of the foot.

Factors which cause this injury, is biomechanical factors, foot posture, over pronated, tensile stress, and lifestyle changes.

High arch, flat foot, all have different problems

Generally, see people with lower back pain, knee pain or general muscle weakness or sore legs after a short period of exercise, which is all generally related to a biomechanical issue, different foot types, creates different injuries.

For example, Pea Cavas is effected by the sub tailor joint which can effect, ankle joints, cause bowed legs and hip. Therefore, the body compensates as a result of abnormalities in the foot.

Type of injury in the foot depends on age, sex, height, profession and individual persona and hobbies. For example ( runners , injuries may be soft tissue, achllies, patellia inflammation)

#### Question 2

Current methods to correcting the alignment of the foot. Firstly focusing on lower limb extremity of the human body. Orthotics, however different type of othothics depends on the particular foot type. Exercises for soft tissue issues in the foot.



Worst case scenarios referred to physiotherapist or orthopedic specialists.

Ashleigh reiterates the point that orthotics are specific to the individual's abnormalities.

Ashleigh takes into account the patient's issues or problems before prescribing any type of diagnosis.

Orthotic treatment is different because every type of individual is different, not one individual is the same.

### Question 3

Osteoarthritis is a common bone injury/joint

The first metatarsal is key with dorsiflexion, 20/30 degrees of dorsiflexion

If that joint is rigid, you find a twist occurs, therefore that can affect the kinetic chain chain, ankle knee, hip and lower back.

Leg length difference is quite common, tilting pelvis and spinal problems.

Everything has a bearing on the feet, for example neck, shoulder etc.

### Question 3

#### Positive and Negative

Generally speaking if someone has a foot problem, that warrants orthotics. As long as the diagnosis is correct the patient will defiantly see an improvement, but obviously everyone is different.

Material choice with the orthotics comes down to the individual

Down side of orthotics, if you get it wrong, you're potentially going to do damage to everything above the foot. Therefore the prescription is key.

Piont's out if you over correct the orthotics, you would rather under correct the orthotics, then overcorrect in general cases. Overcorrection could lead to longterm problems.

Believes that there is a problem in the current system =, by allowing pharamasicst prescribe a devive by just watching an individual walk up and down the room twice and prescribe a prescription.

Patient complence is key for an orthotic to work

Women tend not to wear orthotics, because they can 't fit into shoes or high heels or fashionable shoes

If patients don't wear them it youre never going to see the benefits, Orthotics must be worn consistently in order to work.

Type of orthotic depends on the individual, for example an athlete requires a high density orthotic, shock absorption material.

Where as someone who has a office job, doesn't need that type of orthotic.

An athlete will want to feel better ASAP.

Orthotics depending on how severe the patient or prescription is, takes up to 4 to 6 weeks, to even break them in.

25minutes point in interview.

To Build support, we start with a basic insole, minimal correction.

2 weeks is required to build up support and allow the individual to get use to wearing a device in there shoe.

The individual is then readdressed after two weeks, and a correctable orthotic is applied.

breaking the orthotic in, wearing the orthotic for a few hours each day for 2 weeks.

After two week's they should start to feel the benefits

Following this we will address the situation in 6-12 months.

The orthotic should always be under corrected in terms of degree

For example rearfoot medial wedge, start off with 4 degrees

But in 6 months increase by 2 degrees.

Note manufacturing companies have biomechanical specialist working, with the companies making the orthotic.

An individual is needed to oversee the orthotic design.

Equipment used:

Bevel machines to mould the material on to the foot

Negative to positive cast

Mould the material onto the positive cast, ovens to heat the material

Materials EVA, polypropylene,

Sanding the orthotic onto the orthotic

Suction machines to mould on the plastic

Bevel machine to mould the orthotic

# APPENDIX C

## Documentation of Prescription

PPL biomechanics		Tramore Commercial Park, Tramore Road, Cork, Ireland Tel: +353 (0)21 4320277 / Fax: +353 (0)21 4321159 sales@pplbiomechanics.com www.pplbiomechanics.com					
HANDMADE CASTED ORTHOSES FORM			PLEASE RETAIN CARBON COPY FOR YOUR NOTES				
Practitioner Information	Practitioner Name <b>Ashleigh Milne</b>		Phone Number <b>087 183 5989</b>				
	Account Code/Name & Delivery Address		Email Address				
Patient Information	Patient Name <b>Jack</b>		Sex <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age <b>21</b>	Weight		
	Shoe Size <b>10</b>	Shoe Shape <input checked="" type="checkbox"/> Mens Square Toe Box (3.5 - 14) <input type="checkbox"/> Ladies Narrow Pointed Toe Box (3.5 - 10) <input type="checkbox"/> Child Round Toe Box (Up to size 3)	Device Length	Full Length <input type="checkbox"/>	Cut to Sulci <input type="checkbox"/>		
Shell Type	Shell Colour: <input type="checkbox"/> Blue <input checked="" type="checkbox"/> Black <input type="checkbox"/> Beige	<input type="checkbox"/> Podoflex <small>Ultra-high density EVA. Close contact shell for shock attenuation, control and durability. Suitable for sport, everyday use and orthopaedic problems.</small>	<input checked="" type="checkbox"/> Flexifirm <small>Supralene semi-rigid shell with ultra-high density EVA base. Offers added strength and durability, whilst maintaining flexibility and good contact. Suitable for sport, everyday use especially for heavier wear.</small>	<input type="checkbox"/> Podofirm <small>Supralene semi-rigid type shell with EVA heel post. Slimmer, offering strength and durability, whilst maintaining flexibility. Suitable for everyday use, not recommended for gross instability or deformity.</small>			
	Posting & Device Design	Posting Information	Left	Right	Device Design	Left	Right
Rearfoot posting required to hold in STJ Neutral or optimal position? <small>PPL will use a combination of Intrinsic &amp; Extrinsic posting to achieve this position. Other specific posting instructions can be requested.</small>		<b>3</b> °Medial resist pronation	<b>3</b> °Medial resist pronation	Stability Options	Deep Heel Cup <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Forefoot Inversion <small>How much total forefoot inversion is present?</small>		°Inversion	°Inversion	High Medial Side <input type="checkbox"/>	High Lateral Side <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bony Forefoot Inversion <small>How much of the inversion is bony?</small>		°Inversion	°Inversion	High Lateral Side <input type="checkbox"/>	Low Heel Cup <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other posting & device design instructions:							
Standard Additions	Forefoot Wedging	Left	Right	Forefoot Shaft Pads	Left	Right	
	Total Forefoot Medial Wedging <small>Bony &amp; large forefoot inversion</small>	° Max 8°	° Max 8°	Long Met Shaft Pad <small>(Morton's Pad) Which Met Shaft?</small>	1 2 3 4 5 Please Circle	1 2 3 4 5 Please Circle	
	Total Forefoot Lateral Wedging <small>Supination &amp; forefoot eversion</small>	° Max 8°	° Max 8°	Thickness of Met Shaft Pad?	<input type="checkbox"/> 3mm <input type="checkbox"/> 5mm	<input type="checkbox"/> 3mm <input type="checkbox"/> 5mm	
	Heel & Arch additions	Left	Right	Forefoot Additions	Left	Right	
	Heel Raise Attached <small>Max. 5mm</small>	mm	mm	2-5 Varus Met Lift <small>Reverse Morton's Pad</small>	<input type="checkbox"/> 3mm <input type="checkbox"/> 5mm	<input type="checkbox"/> 3mm <input type="checkbox"/> 5mm	
	Heel Raise Detached <small>Max. 10mm</small>	mm	mm	1st Metatarsal Cut-Out Pad <small>Less bulky than met cushion with cut-out</small>	<input type="checkbox"/>	<input type="checkbox"/>	
	Heel Cushion	<input type="checkbox"/> 3mm <input type="checkbox"/> 5mm	<input type="checkbox"/> 3mm <input type="checkbox"/> 5mm	Metatarsal Cushion <small>Cushioning under met heads</small>	<input type="checkbox"/> 3mm <input type="checkbox"/> 5mm	<input type="checkbox"/> 3mm <input type="checkbox"/> 5mm	
	Extra Cushioning Under Arch	<input type="checkbox"/> 3mm <input type="checkbox"/> 5mm	<input type="checkbox"/> 3mm <input type="checkbox"/> 5mm	Cut Out in Cushion? <small>To which met head? Please sketch</small>	1 2 3 4 5 Please Circle	1 2 3 4 5 Please Circle	
	Midfoot additions	Left	Right	U in Cushion? <small>To which met head? Please sketch</small>	1 2 3 4 5 Please Circle	1 2 3 4 5 Please Circle	
	2-5 Varus Metatarsal Bar	<input type="checkbox"/> 3mm <input type="checkbox"/> 5mm	<input type="checkbox"/> 3mm <input type="checkbox"/> 5mm	Fill Cut-Outs? <small>Pink Poron™ used as standard</small>	1 2 3 4 5 Please Circle	1 2 3 4 5 Please Circle	
2-4 Metatarsal Dome Pad	Low Medium High	Low Medium High	We recommend taking a full size sketch of the foot for devices with midfoot or forefoot additions				
Covering	<input checked="" type="checkbox"/> EVA - 1mm <small>Thin, Soft &amp; Wipeable (Standard cover if none selected)</small>		<input type="checkbox"/> Vinyl - 1mm Black <small>Thin &amp; Wipeable (Not available with Stability Options)</small>		Other Covering Instructions:		
	<input type="checkbox"/> Suedette - 1mm <small>Thin, Soft Touch (Not available with Stability Options)</small>		<input type="checkbox"/> Cushioning Cover - 3mm Beige <small>Cushioning, Soft, Wipeable &amp; suitable for the at risk foot</small>				
Services	Custom Device Services	<input type="checkbox"/> Fast Track Service <small>3 working days (Extra Charge)</small>	Customer Services Contact	<input type="checkbox"/> Office <small>Contact me about courier delivery &amp; collection options</small>	Forms & Boxes Request	<input type="checkbox"/> Prescription Forms (Casted Orthoses)	
		<input type="checkbox"/> Special Fitting Service <small>Extra Charge</small>		<input type="checkbox"/> Technical <small>Hold my order &amp; contact me about my prescription before proceeding</small>		<input type="checkbox"/> Assessment Forms <input type="checkbox"/> Foot Sketch Forms <input type="checkbox"/> Mailing Boxes <input type="checkbox"/> Mailing Labels	
Further Information							



## SHORT BIOMECHANICAL ASSESSMENT FORM

DATE PRESCRIBED \_\_\_\_\_

### PRACTITIONER INFORMATION

Name: Ashleigh Milne

### FOOTWEAR ASSESSMENT

MENS 3 1/2 - 14	<u>10</u>	LADIES 3 1/2 - 10		CHILDS 7 1/2 - 3	
What gradient have you used? to account for patient's shoe pitch	Low	Flat Shoe/Trainer/Walking Shoe		<input checked="" type="checkbox"/>	
	Medium	Heels between 1 & 2" (3-5cm)		<input type="checkbox"/>	
	High	Heels over 2" (over 5cm)		<input type="checkbox"/>	

### 2. LEG & ANKLE

	LEFT				RIGHT			
Ankle Dorsiflexion Non-weightbearing	<u>+5°</u>	0°	-5°	-10°	<u>+5°</u>	0°	-5°	-10°
Ankle Equinus, how much is only? (requires heel raises)	bony				bony			
Leg Length Discrepancy (True)	Left Leg Short by <u>0</u> mm				Right Leg Short by <u>0</u> mm			

### 3. ARCH PROFILE

	LEFT			RIGHT		
Non-weight bearing arch profile	High	<u>Normal</u>	Low	High	<u>Normal</u>	Low

### 4. MEDIAL COLUMN

	LEFT			RIGHT		
Plantarflexed 1st Ray Non-weightbearing	Yes	<u>No</u>		Yes	<u>No</u>	
Mobility of 1st Ray (Non-weightbearing)	Mobile	<u>Limited</u>	Rigid	Mobile	<u>Limited</u>	Rigid
1st MPJ (Hallux)	LEFT			RIGHT		
Mobility of 1st MPJ Non-weightbearing	Mobile	<u>Limited</u>	Rigid	Mobile	<u>Limited</u>	Rigid
Functional (weightbearing) Hallux Limitus	Yes	<u>No</u>		Yes	<u>No</u>	
1st MPJ Position (ie HAV (Bunion))	<u>No</u>			<u>No</u>		

### 5. FOREFOOT (2-5) TO REARFOOT RELATIONSHIP

	LEFT		RIGHT	
Forefoot level with Rearfoot Normal Alignment	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	
Forefoot inverted on Rearfoot	Mild <input type="checkbox"/>	Moderate <input type="checkbox"/>	Severe <input type="checkbox"/>	Mild <input type="checkbox"/>
Forefoot Invertus or Varus	Moderate <input type="checkbox"/>	Severe <input type="checkbox"/>		Moderate <input type="checkbox"/>
Is any of the inversion deformity bony and not passively correctable?	No	FF Invertus	Yes	No
	Yes	FF Varus		Yes
If there is any bony inversion (FF Varus), estimate how many degrees are bony?		<u>0</u> Inv		<u>0</u> Inv
Forefoot everted on Rearfoot (FF Valgus) Always Bony (rare)		<u>0</u> ev		<u>0</u> ev

### FURTHER INFORMATION

Blank area for further information.

### FOR LAB USE ONLY

Ref No: \_\_\_\_\_

### PATIENT INFORMATION

Name: Jack  
 Sex:  Male  Female Age: 21 Weight: Stone  
 Occupation / Sporting Activities: Student  
 Medical / surgical history:  
Lateral ankle sprain on LF & tears to retinaculum around peroneals  
 Presenting Complaints:  
Pain around lateral malleolus & along peroneal pathway  
 Gait Pattern: Internal rotation at pelvis resulting in genu varum.

### REARFOOT COMPLEX

	LEFT	RIGHT
Note any bony limitations of movement in the joints of the rearfoot complex		
G Sub-talar Joint		
G Talo-navicular Joint		<u>limited</u>
G Calc-cuboid Joint		

Please note:

Fill in EITHER Rearfoot Assessment "using" Prescription Platform OR Rearfoot Assessment "without" Prescription Platform

### 6. REARFOOT ASSESSMENT using prescription platform

	LEFT	RIGHT
A What type and how many degrees of posting (wedging) have you used to hold the rearfoot in STJ neutral position?	<u>3</u> MED	<u>3</u> MED
Medial (resisting pronation) or Lateral (resisting supination)		<u>0</u> LAT
C Are you resisting pronation or supination at STJ?	Pronation <input type="checkbox"/>	Pronation <input type="checkbox"/>
	Supination <input type="checkbox"/>	Supination <input type="checkbox"/>

OR

### 6. REARFOOT ASSESSMENT without prescription platform

NEUTRAL CALCANEAL STANCE POSITION (CORRECTED)	LEFT	RIGHT
B NCSP Heel Inversion	<u>0</u>	<u>0</u>
How much rearfoot varus (ie. Tibial Varum + STJ Varus)	inv	inv
Or		
B NCSP Heel Vertical 0°	<input type="checkbox"/>	<input type="checkbox"/>
(Unusual as 5° Inversion is normal due to Tibial Varum)		
RELAXED CALCANEAL STANCE POSITION (UNCORRECTED)	LEFT	RIGHT
C On relaxing from neutral position does the patient	Pronate <input checked="" type="checkbox"/>	Pronate <input type="checkbox"/>
	Supinate <input type="checkbox"/>	Supinate <input type="checkbox"/>
Pronate, Supinate or do they stay still ?	Stay still <input type="checkbox"/>	Stay still <input checked="" type="checkbox"/>
RCSP Heel Eversion	<u>0</u>	<u>0</u>
They are pronating at rearfoot	ev	ev
RCSP Heel Vertical 0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
They are probably pronating at rearfoot		
RCSP Heel Inversion	<u>0</u>	<u>0</u>
Could be pronating or supinating at rearfoot	inv	inv

Mind Maps of Focus Group.



# Gaelic

## IMPACT INJURY

Shoulder dislocation / Impingement ✓ (padding Underlayer)

Collar bone breaks (female) ✓ (padding)

Concussion x scrum caps adopted?

Chest fracture ✓ (protective mask)

mid / lower back slipped discs / muscle injuries ✓ (back brace)

hip dislocation / fracture ✓ (padding)

rotational injuries (non-contact) ✓

metatarsal dislocation / break x some new boots have protective padding

foot (mostly non-contact)

broken arms / legs ✓

ankle sprains / breaks / fractures ✓ (ankle brace)

fractured spine ✓

Slipped disc in back (contact + non contact) ✓ (back brace)

broken nose ✓ (protective mask)

Broken / Fractured ribs ✓

## RE-OCCURRING INJURY

shoulder dislocations ✓ (padding)

rotator cuff ✓

ACL / MCL (non-contact) ✓ (knee braces)

broken / fracture / dislocation fingers ✓ (padding)

hamstring tears (non-contact) ✓ (padding)

ankle sprains / breaks / fractures ✓ (padding)

broken nose ✓

broken wrist ✓ (padding)

cartilage in knee / hips ✓ (padding)

Golfers elbow (non contact) ✓ sleeves to keep the joint warm

Whiplash ✓

1. Shoulder dislocation -> shoulder padding in underlayers.

2. Broken / dislocated / fracture fingers -> padding gloves.

3. Back injuries -> Back Braces + For shoulders, SKIN protection.

# Hurling

## IMPACT INJURY

Shoulders - AC JT dislocation ✓ Strapping ✓

- collar bone fracture ✓ (padding)

- Shoulder Dislocation ✓ (padding)

Elbow - Fracture ✓ Elbow pads -> like skateboards

- ~~shoulder dislocation~~

Wrist - Fractures ✓

Fingers - Dislocation / hand guard ✓

- Fractures ✓ (padding)

- Bruising ✓

Back - Slipped disc ✓

- Fracturing ✓

Ribs - Broken ✓ (padding vest)

- Bruised ✓ (padding vest)

Knee - ACL ✓ (knee brace)

- MCL ✓

- ~~patella~~

Skin - Bruising ✓ shin guards - padded

- Fracturing ✓

Ankle - Sprains ✓ (padding)

- Breaks ✓

- Dislocation ✓

- Tendons ✓

## RE-OCCURRING INJURY

Shoulders - Strains - impingement ✓ strapping

elbow - tennis elbow ✓

wrist - carpal tunnel syndrome ✓

back - slip disk ✓

- locked SI joint ✓

- locked T spine ✓

- nerve damage ✓

- glutes (rotation) sprain / weakness ✓

coll / shoulder strain ✓

quadriceps tear ✓

ACL / MCL / LCL ✓

minisus (cartilage) - (hips too) ✓

skin - splints ✓

1. Back brace - non restricting of movement.

2. Air protector - reduce impact.

3. Baselayer - padding shoulder - elbow - ulnar - spine - ribs

# SOCCER



IMPACT INJURY	RE-OCCURING INJURY
<p>with much do with protection</p> <p>Broken toes. X</p> <p>Compound fractures ✓ (Shin guards) - wears around all legs</p> <p>Shoulder dislocation ✓ (Shoulder brace) (Cast brace)</p> <p>Concussion ✓ (Rugby helmet)</p> <p>Finger break ✓ (Gloves, Fingersafe).</p> <p>Broken nose. ✓ (Nose guard).</p> <p>Whiplash X</p> <p>Back injury ✓ (Belt)</p> <p>Rotator Cuff. ✓ (Kinesio tape).</p> <p>Capitol tunnel ✓ (Wrist strap).</p> <p>Hip dislocation X</p> <p>Collarbone X</p> <p>Wrist <sup>sprain</sup> ✓ (Wrist strap)</p> <p>Testical impact ✓ (Jock strap).</p> <p>Jaw impact ✓ (gun shields)</p> <p>Broken ribs ✓ (Cassak)</p> <p>Vertebrae break X</p> <p>ACL ✓ (knee brace)</p> <p>MENISCUS ✓ (knee brace)</p>	<p>(Ankle brace) ✓ Ankle sprain. (tendonitis Achilles).</p> <p>(Kinesio tape) ✓ Hamstring tear.</p> <p>(Kinesio tape) ✓ Groin tear</p> <p>(Kinesio tape) ✓ Quad tear.</p> <p>(Kinesio tape) ✓ Calf tear</p> <p>(Belt) ✓ Back injury</p> <p>X hip dislocation</p> <p>X Symphysis pubis.</p> <p>X FAI</p> <p>X hip flexors</p> <p>X Patellar Rupture.</p> <p>(knee brace) ✓ Meniscus</p>

# RUGBY

IMPACT INJURY (GPS, Accelerometer)	RE-OCCURING INJURY
<p>Concussion X stop BF - needs research.</p> <p>Eye socket (cut, grazes, breaks) ✓ Goggles - works</p> <p>Check bone X</p> <p>Broken jaw X</p> <p>Anti-player ears. (✓ tape / scrum cap X)</p> <p>Wind pipe X</p> <p>lose break ✓ Fabregas Mask</p> <p>elbow bone break X</p> <p>Finger, hands thumbs wrist ✓ Thumb strap, BB protective <sup>slate</sup></p> <p>elbow <sup>dislocation</sup> X</p> <p>broken ribs impact X</p> <p>to joint hair X</p> <p>broken leg X</p> <p>nerve compression X</p> <p>ACL X</p> <p>Biceps tendon tear X</p> <p>SLAP Lesion X</p> <p>Disc bulge (scatica) X</p> <p>Forearm break ✓ Pad design</p>	<p>Concussion</p> <p>Eye sockets (cuts, grazes)</p> <p>Anti-player ears</p> <p>Finger, hand, thumbs wrist</p> <p>Hamstring strain + tears</p> <p>Ankle, sprains, strains ✓ Braces.</p> <p>Foot sprains and strains</p> <p>Blisters ✓ Vaseline</p> <p>Nerve compression</p> <p>shoulder dis!</p> <p>ACL</p> <p>Disc bulge (sc).</p> <p>Forearm</p>



**PolyJet Digital Material Properties**



**Details PolyJet Digital Materials**

- Standard lead time:** 2 – 4 working days
- Standard accuracy:** 0.1 – 0.3 mm  
(accuracy varies according to geometry, part orientation and print size)
- Surface finish:** Support marks removed
- Maximum part dimensions:** 500x400x200 mm
- Capacity:** 3 Objet Machines
- Primary Materials:** Objet VeroWhitePlus is a general-purpose resin and has a white colour offering enhanced mechanical properties and the ability to withstand bending. Objet TangoBlackPlus is a flexible rubber-like resin, offering exceptional elongation at break, making it suitable for prototypes of rubber components like seals, non-slip surfaces, etc.
- Digital Materials:** Composite materials with preset combinations of mechanical properties Shore A40 – Shore A50 – Shore A60 – Shore A70 – Shore A85 – Shore A95
- Multi-Material Models:** To combine materials with different properties in one model, separate STL files are needed

Datasheet				
PolyJet				
	Units	ASTM#	Objet VeroWhitePlus	Pbjt TangoBlackPlus
Tensile Strength	MPa	D-638	49.8	1.5
Elongation at Break	%	D-638	15% - 25%	218
Modulus of Elasticity	MPa	D-638	2495	
Flexural Strength	MPa	D790	74.6	
Flexural Modulus	MPa	D790	2137	
Notched Izod Impact	J/m	D256	37.5	
Hardness	Shore	Scale	83D	27A
Rockwell	Scale M	Scale M	81.0	
Heat Deflection Temp (0.45MPa)	°C	D648	47.6	
Heat Deflection Temp (1.82MPa)	°C	D648	43.6	
Glass Transition Temperature	°C	DMA, E"	58.0	-10

Glass Transition Temperature	°C	DMA, E"	58.0	-10
Ash Content			<0.40%	
Tensile Tear resistance	Kg/cm	D-324		3
Colour			White	Black
Actual values may vary with build conditions				

Datasheet						
PolyJet Digital Materials						
Primary material: VeroWhitePlus Secondary material: TangoBlackPlus	DM_9840/ Shore A40	DM_9850/ Shore A50	DM_9860/ Shore A60	DM_9870/ Shore A70	DM_9885/ Shore A85	DM_9895 Shore A95
Tensile Strength (MPa)	0.5 – 1.5	0.5 – 1.5	2 – 4	2 – 4	4 – 8	15 – 25
Elongation at Break (%)	150 – 170	130 – 150	80 – 100	50 – 70	50 – 60	25 – 35
Shore (Scale A)	35 – 45	45 – 55	55 – 65	65 – 75	80 – 90	90 – 100
Colour	Black	Black	Black	Black	Black	Black
Actual values may vary with build conditions						

6 The information and values included in these datasheets, although based on Materialise’s knowledge and experience and thus presented in good faith and believed to be accurate, is provided for your guidance only. This information does not release a third party from conducting his own procedures and tests to determine suitability. All guarantees with respect to the information contained herein are explicitly denied.

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