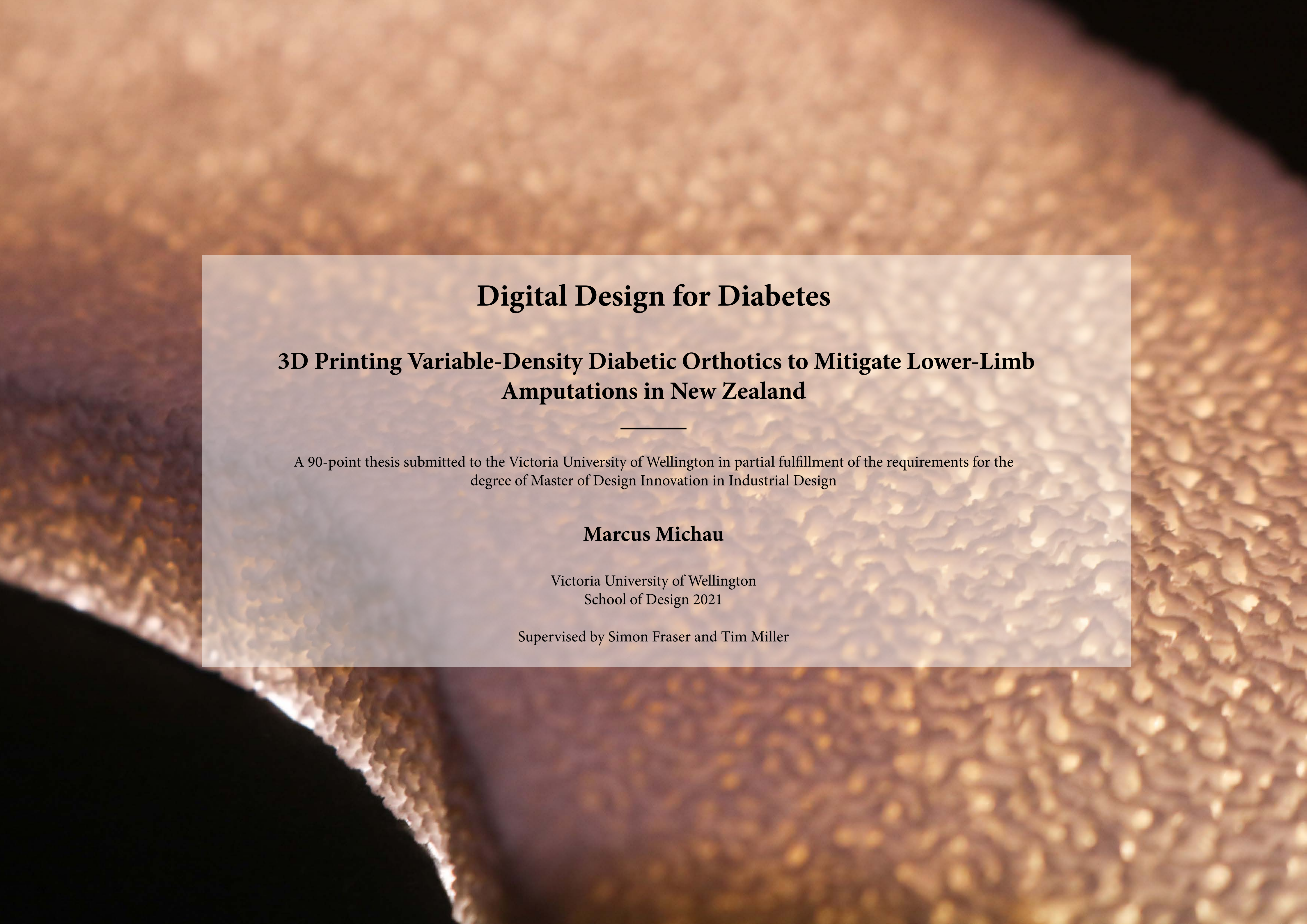

Digital Design for Diabetes

3D Printing Variable-Density Diabetic Orthotics to Mitigate Lower-Limb Amputations in New Zealand

A 90-point thesis submitted to the Victoria University of Wellington in partial fulfillment of the requirements for the degree of Master of Design Innovation in Industrial Design

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Cover:
Figure 1. Close-up of 3D print variable density orthotic.

Abstract

Currently, there are approximately 228,000 people in New Zealand who have been diagnosed with type 2 diabetes. Without critical intervention, this number is projected to reach epidemic proportions within the next 20 years. The development of type 2 diabetes is most commonly seen in those who are obese and can cause significant physical, mental and financial complications for the patient. Arguably the most detrimental of the physical complications is diabetic neuropathy, which is a form of nerve damage caused by the long-term blood vessel damage, and can eventually lead to amputation of the patient's foot or entire lower leg. There are numerous factors that play a role in the eventual need for amputation; however, the presentation and development of diabetic foot ulcers (DFUs) are considered to be the most substantial.

This research focuses on mitigating diabetes-related amputations and improving the overall well-being of those with diabetes in New Zealand by developing a range of customised orthotics to assist in the prevention of DFUs. Contextual research into diabetes, an analysis of current treatment strategies/products, and experimentation with innovative new materials and manufacturing technologies will be used to inform new product concepts. An experimental and iterative research process is used to explore bio-based materials and 'foaming' 3D print filament. Digital control of the 3D printing process combined with data-driven geometry control through parametric software, is then used to generate variable physical and mechanical properties from a single material for use in multi-density orthotic production. The intention is to replicate the properties of the foams and varying density EVAs that are traditionally used to make customised orthotics.

The design output of this research is a digitally-generated, 3D-printed orthotic product that can effectively assist in preventing the presentation and development of DFUs, subsequently mitigating diabetes-related amputations in New Zealand. Additionally, this research aims to provide performance specifications for future bio-based, multi-density materials that can be controlled using additive manufacturing technologies.

Acknowledgments

Thank you to

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My friends and family who have always supported and motivated me. This work would not be possible without those people who are closest to me, who have helped me find a true home in this country and for that I am forever grateful.

The 2021 MDI cohort. The chat, the laughs and the countless cups of coffee or tea made this a memorable year. I am very proud to say that we completed this journey together.

Introduction

The basis of this project started at the end of 2019 during a summer research scholarship at Victoria University of Wellington's School of Design. This research was a collaboration with a Science for Technological Innovation (SfTI) research spearhead group from the National Science Challenge (NSC), as well as specialists from the New Zealand Artificial Limb Service (NZALS), and looked at using bio-based polymers in 3D/4D printing applications. These applications came in the form of medical products that would be used to treat diabetes-related complications and subsequently mitigate the number of lower-limbs amputations in Aotearoa (New Zealand). The background research and speculative design concepts from this summer scholarship set the foundation for numerous projects to be explored further by members of the SfTI spearhead research group.

After the conclusion of this summer research scholarship, further research into diabetes emphasised the need for more development of diabetes treatments and products in order to improve the physical, mental and emotional well-being of those who suffer from the disease and of those who are close to them. With the number of people diagnosed with diabetes rapidly increasing both globally and in New Zealand, any form of innovation in this area is key to helping people overcome the complications and struggles that they face in their day to day life.

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Key Words & Terminology

DFU *- Diabetic Foot Ulcer*

Orthotics *- Shoes or shoe inserts that can help with a variety of foot and lower body issues.*

TPU - (Thermoplastic Polyurethane) *A soft, rubber-like plastic that is extremely flexible and durable.*

G-Code *- Programming language used in computer-aided manufacturing.*

Brep - (Boundary representation) *A digital surface model comprised of faces, edges and vertices.*

Additive Manufacturing *- A manufacturing process that creates physical objects from building materials additively, as opposed to subtractively taking away from stock material (e.g. FDM 3D printing)*

FDM - (Fused Deposition Modelling) *An AM manufacturing technique that most commonly uses thermoplastics. The material is heated until in a semi-molten state and then deposited, layer by layer, onto a bed to create a physical 3D model.*

NZALS - (New Zealand Artificial Limb Service) *A specialist healthcare provider that manufacture and provide individual patients with customised medical devices/products and rehabilitation services.*

NSC - (National Science Challenge) *A government-funded initiative to bring together industry experts from different disciplines to tackle the biggest science-based issues facing New Zealand.*

SfTI Research Group - (Science for Technological Innovation) *A spearhead team working on the additive manufacturing and 3D/4D printing of bio-composites.*

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Methodology

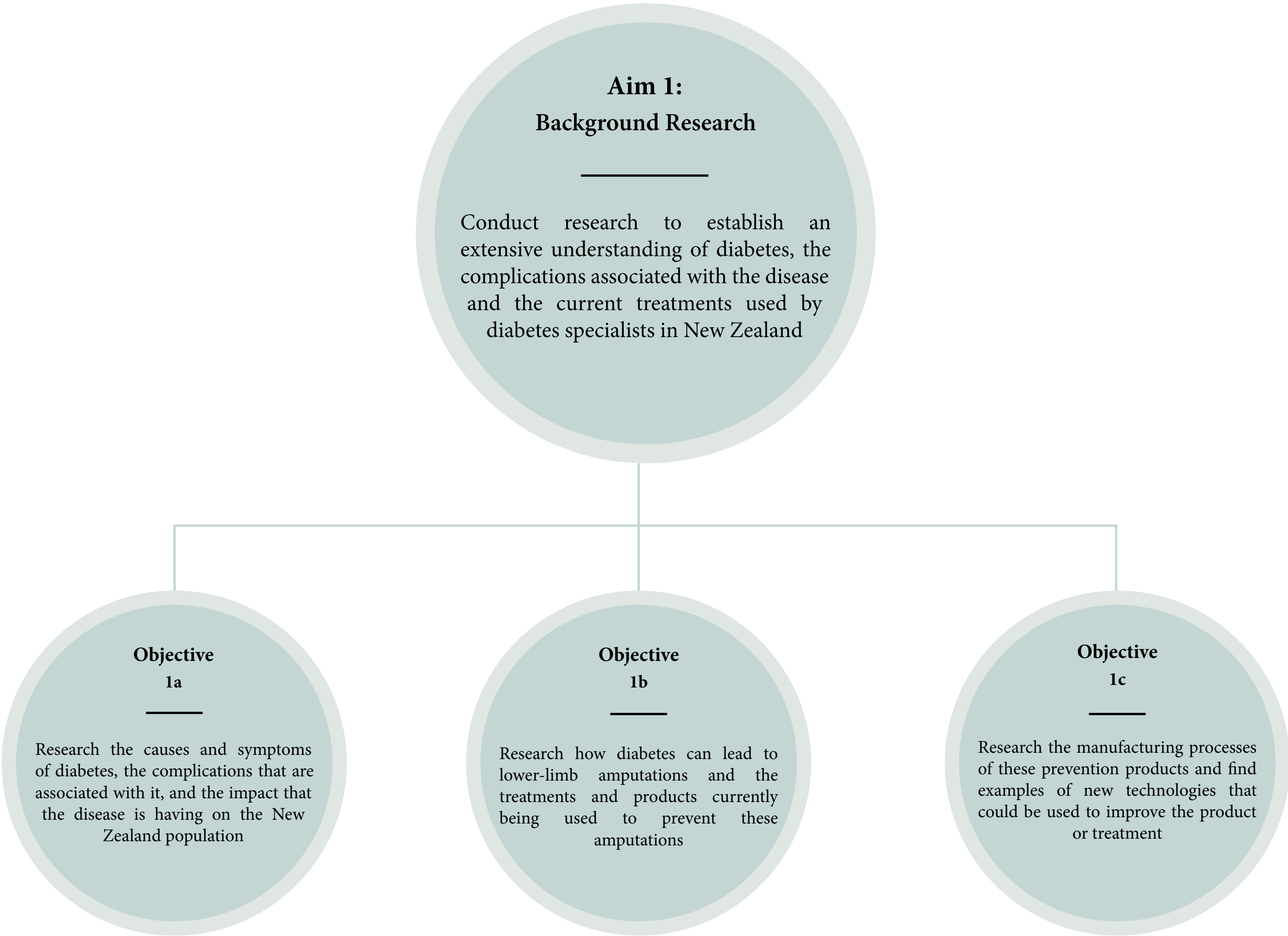


Figure 2. Aims and objectives for background research

Research for Design

Clinical Context

The first objective in the background research stage is to perform a review of statistical and medical literature that will be used to obtain knowledge about diabetes in a clinical context. This will be used to learn information such as what diabetes is, the problems it causes the patients, the specific effect it is having on the New Zealand population, and the professional opinion of those who study and work with diabetes patients regularly. There are numerous complications associated with diabetes, such as physical deformities and the development of diabetic foot ulcers (DFUs). These topics will be specifically researched in depth, as they are very important factors in the process of diabetes-related lower-limb amputations. By analysing peer-reviewed literature and medical journals from recent years, design opportunities will present themselves and can then be explored in a more practical way during the experimentation stage of the project.

Technological Context

The second objective focuses on researching the current treatment and strategies used to prevent the diabetes-related complications that can eventually lead to amputation. In a technological context, this means exploring the processes of these treatments and strategies. For example, diabetes patients are often prescribed customised footwear or orthotics to mitigate the substantial effects that diabetes can have on a patient's foot. Investigation and analysis of the production process for customised footwear can provide guidelines and parameters for both the experimentation stage and design development stage of this research portfolio.
Research into recent breakthroughs and the potential for future advances in production technologies (such as 3D/4D printing) could also prove to be a valuable tool in providing new and exciting possibilities in the concept generation stage.

Material Context

Similar to the technological context, it is important to know what materials are currently being used in diabetes care. These could range from the wound healing gels available on pharmacy shelves, to the specifically-engineered foams used in orthopedic footwear. The vast majority of materials used in treatments and products will be used for a particular reason, such as their physical or mechanical properties. An extensive look into what those properties are and why they are important can assist in the selection of materials used in the design concepts. It can also be used to set parameters and goals that can be referenced during the development of possible alternative materials, such as bio-materials.

Precedent Review

The critical analysis of design precedents will allow for a better understanding of how others have used their own diabetes knowledge and clinical expertise to create effective products and treatments. It will explore the new technologies being used in this area and will be an opportunity to compare the functional effectiveness and design aesthetic of existing products.

Aim 2:
Design and Development

Design and develop a diabetic orthotic product based on the background research as well as the material experiments, 3D printing tests and prototyping conducted over the course of the year

Objective 2a

Explore and experiment with possible bio-alternatives to the materials that are currently used in the production of diabetic orthotics

Objective 2b

Conduct material experiments and 3D print tests with newly-developed materials to understand their properties and how they can be used to optimise my designs

Objective 2c

Create digital and physical prototypes of product iterations to present to the NZALS and the NSC STFI Research group

Figure 3. Aims and objectives for design and development

Research through Design

Material Exploration

The primary aim of the design and development stage is to create a new orthotic product. Before this, however, experimentation must take place so that the materials, production processes and design concepts are all of optimal quality. After conducting the background research, a more defined selection of materials will undergo further tests and experiments. The results from these tests and experiments will greatly inform the final material choice. This experimentation stage is also a good opportunity to attempt the development of new materials (preferably bio-alternatives), and compare them to existing materials that are used in current orthtic products. This is a complex process; therefore, collaborating with material scientists and engineers from the NSC SfTI spearhead research group will provide expertise in this area. By providing them with the researched material parameters and desired material properties, experimentation with a variety of bio-materials can be done to try to develop the ideal material for this project. Once developed, the material can be tested for use in certain manufacturing techniques such as additive manufacturing.

During this stage, there is also an opportunity to experiment with other materials of interest. Even if the material is not bio-based, it may still exhibit interesting properties that could be ideal for use in orthotic products. By experimenting with this material, it allows for a better understanding of the properties it possesses and how it behaves. This newfound information can play a key role in helping to develop bio-materials that are similar to it, and can also be used for proof-of-concept models.

3D Print Tests

For this research portfolio, 3D printing will be used to test the additive manufacturing capabilities of newly-developed materials in the experimentation stage, and to produce high quality physical prototypes in the application stage. The testing of these materials, in relation to 3D printing, will attempt to configure the best print settings, and will document any issues that may arise, for reference in future research.

As part of objective 2c, the physical prototypes will be presented to the collaborating SfTI spearhead research group, and the New Zealand Artificial Limb Service (NZALS), to showcase the potential of 3D printing using these materials in the production of customised diabetic orthotics. The primary 3D printer that will be used is an Ultimaker 3 Extended model.

Software Experimentation

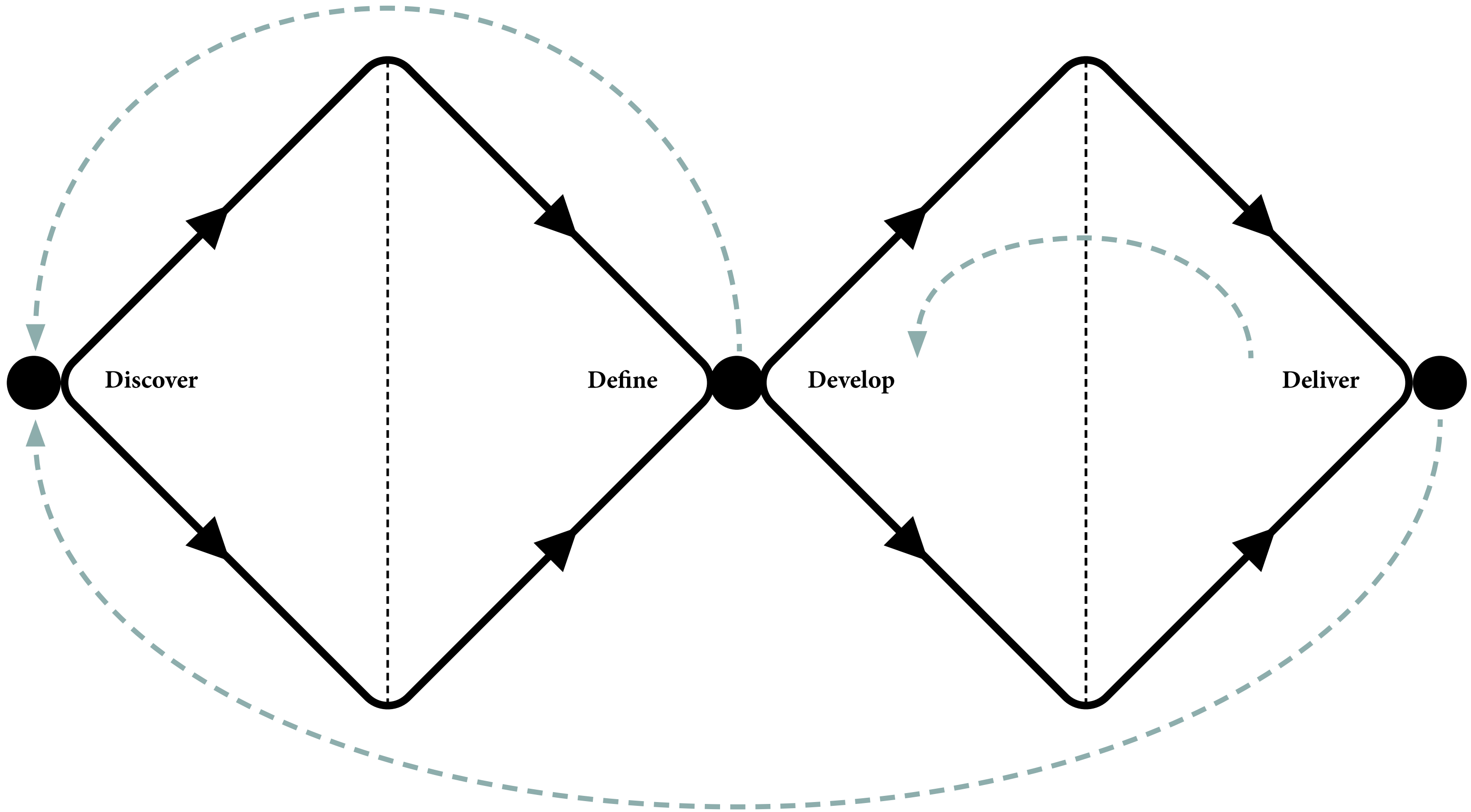
Using the Computer-Aided Design (CAD) software Rhino 6 with parametric modelling software Grasshopper, will allow for digital concept iterations to be created quickly and efficiently during the application stage. These concept iterations can then be put into a 3D printing slicer software, such as Ultimaker Cura, and then be sent to the 3D printer to be made into physical prototypes. During the experimentation stage, an attempt will be made to replicate the slicer software in Grasshopper, in order to simplify the manufacturing process and be able to control the form and print settings in one interface.

Prototypes

Physical and digital prototypes will be made throughout the experimentation and application stages. During experimentation, these prototypes will be developed in a digital form using the parametric modelling script that will be developed. This will be important to understand how the form will theoretically look once made into a physical form. Due to the parametric element of the 3D modelling script, iterations can be produced with ease and will be used to develop the form of the final model. The physical prototypes will be 3D printed using customised G-code created in the Grasshopper script. During the experimentation stage, these prototypes will be used to fine-tune the print settings and to make test samples for mechanical and dynamic testing. Once these tests are complete and better knowledge about the materials is obtained, physical prototypes can be made and used in the application stage. Final physical and digital prototypes will be made and shown in the final presentations.

Professional Opinion

At various stages of this research, experts from collaborating groups and organisations will provide feedback, advice and resources. This outside perspective allows for a broader scope of knowledge to be used to achieve the research aims and creates a connection between academic research groups and relevant industry partners. This connection can then be used in future research and possible commercialisation of the developed products from that future research.



"This is not a linear process as the arrows on the diagram show. Many of the organisations we support learn something more about the underlying problems which can send them back to the beginning. Making and testing very early stage ideas can be part of discovery. And in an ever-changing and digital world, no idea is ever 'finished'. We are constantly getting feedback on how products and services are working and iteratively improving them."
- *(Design Council, 2019)*

Figure 4. The double diamond model

Double Diamond Model

The double diamond represents a process that uses divergent thinking to explore an issue extensively, clearly identifying a problem and then using focused action to find solutions to this problem. The four stages of the model are:

• **Discover:** This stage consists of gathering enough information and knowledge to fully understand what the problem is. It involves extensive research and, in some cases, interacting and learning from people who are affected by the issues (e.g. patients, specialists, clinicians).

• **Define:** With the information and knowledge obtained from the first stage, the designer can accurately define what the problem is and the specific challenges that may come along with it.

• **Develop:** The development stage encourages a variety of solutions to the clearly identified problem. By working within a group of others from different disciplines, it allows for diversity in concept generation and development.

• **Deliver:** The final stage involves the testing of the concepts at a small-scale. By doing so, designers can discard the concepts that they do not think would work and can continue to develop/improve the ones that do. This development may require the designer to take the concept back to the previous stages in order to end up with the best possible final product.

(Design Council, 2019)

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Background Research

Clinical Context

Figure 5. Number of people with diabetes globally and in New Zealand

The Diabetes Problem

A Statistical Overview

There are currently over 250,000 people in New Zealand who have been diagnosed with diabetes. Of the total cases of diabetes in New Zealand, only 5-10% are thought to be type 1 diabetes, which is an autoimmune condition that develops at an early age. The other 90-95% of cases are type 2, which is a metabolic condition that is most commonly associated with obesity (Ministry of Health, 2015). With obesity numbers continuously rising in New Zealand and around the world, the number of people diagnosed with diabetes has also seen a substantial rise. The International Diabetes Federation (International Diabetes Federation - Facts and figures, 2019) estimates the number of people with diabetes rose from 151 million in 2000 to 463 million in 2019, which they calculated to be 9.3% of the global adult population aged 20-79 years old. Recent years have seen global health organisations highlight diabetes as a major health concern. In 2015, the New Zealand Ministry of Health published a 5-year plan that looked at addressing the high personal and social cost associated with diabetes by improving the quality of services available for those with the disease, as well as trying to identify diabetes earlier in its development (Ministry of Health, 2015). This is very important because the health complications caused by diabetes can have a devastating effect on the wellbeing of the patient and those close to them (e.g. family and friends).

The Complications

There are numerous complications that are associated with diabetes including: blindness, heart disease, kidney disease and severe nerve damage that can lead to the amputation of the lower limbs. The nerve damage affects mostly the lower legs and feet, causing poor circulation of blood and reduced sensation in the patient's foot. Morey-Vagas et al. (2015) state that the loss of protective sensation makes patients vulnerable to mechanical or thermal injuries without them realizing it. This can significantly increase their chances of developing diabetic foot ulcerations (DFUs). Adiewere et al. (2018) also highlight this issue but add to it by stating that the motor neuropathy (nerve damage) can lead to physical deformities of the foot which also increases the chances of patients developing a DFU. This is explained further on page 21.

DFUs are a major problem for diabetic patients because, if the body fails to effectively heal them, it can lead to the patient requiring surgical removal of infected tissue, the amputation of toes, and quite possibly, the amputation of the whole foot or lower leg. Between 2014-2019, an NZ study recorded 4,388 amputations performed on patients with diabetes in New Zealand (Podiatrist Board of NZ, 2019) . Before that, a 2005-2014 study conducted by Gurney et al. (2018), recorded 6,352 diabetes-related amputations. 3,762 were considered minor amputations (below the ankle) and 2,570 were major amputations (above the ankle). Of the 2,570 patients who underwent a major amputation, 18% died within 90 days of having the operation and 11% died within just 30 days of having the operation. The authors of this study claim that, although the post mortality rate is substantial, it is consistent with other diabetes literature (Tentolouris et al., 2004; Thorud et al., 2016). One of the most shocking findings in this study however, was the post-operative mortality rate differences between various ethnic groups and social demographics. The most noticeable was the Māori population having a nearly 50% greater risk of dying immediately after a major amputation as well as a 74% greater risk of dying after a minor amputation, compared to the European/other population. Gurney et al. concluded the study by stating that these disparities were unexplained and require further investigation. These signs of disparity have not gone unnoticed by the NZ Ministry of Health. In their 5-year plan, they outlined their aim to improve the quality of services available to better meet the needs of Māori and Pacific population groups (Ministry of Health, 2015).

It is not just the possibility of death that is cause for concern when discussing diabetes-related amputation. There are inconveniences and restrictions that patients have to deal with from the very early stages of diabetes. Arguably the most problematic is the materialisation of DFUs. There are many examples of research that acknowledge these DFUs as the first irrevocable step towards the patient needing surgical intervention to save their lower limbs (Burns et al. , 2008; Eleftheriadou et al., 2019; Gurney et al., 2018), and prevent death (Eleftheriadou et al., 2019). Jeffcoate et al. (2018) claim that the 5-year survival rate of a diabetes patients following the presentation of a new DFU is approximately 50-60%, which is worse than many common cancers. This research portfolio seeks to reduce the number of diabetes-related amputations in New Zealand by extensively researching DFU prevention and developing more effective products and/or therapies, using innovative materials and customised manufacturing techniques, to assist in the treatment of these diabetes-related complications.

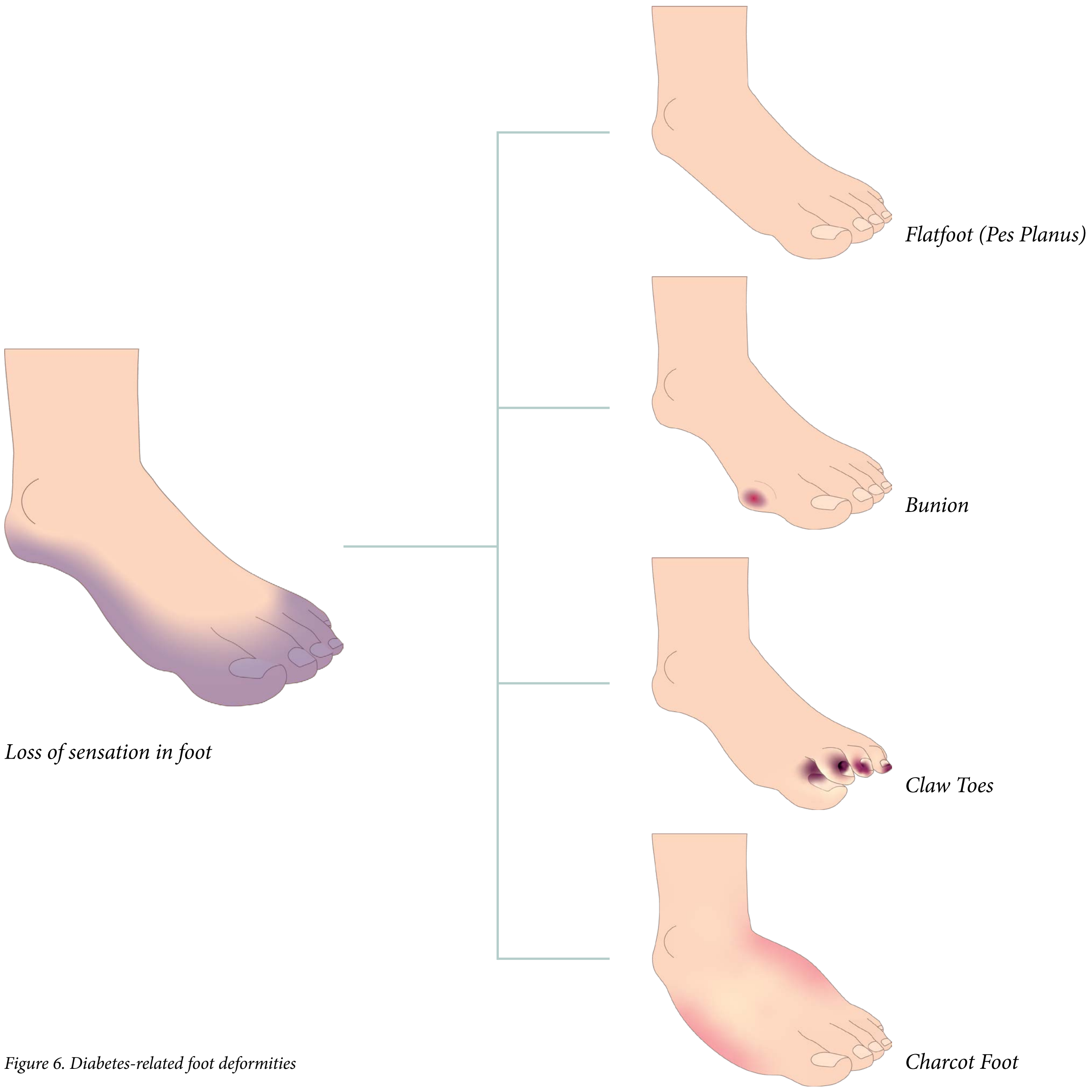

Figure 6. Diabetes-related foot deformities

The Diabetic Foot

Definition

The authors of the Atlas of the Diabetic Foot (2019) define a diabetic foot as "the presence of infection, ulceration and/or destruction of deep tissues associated with neurologic abnormalities and various degrees of peripheral arterial disease (PAD) in the lower limb of patients with diabetes"(Eleftheriadou et al., 2019, p.1).

How does it happen?

A patient with diabetes can suffer from peripheral neuropathy that causes numbness, poor blood circulation and loss of sensation in the hands and feet. This loss of sensation means that any trauma to the feet will be unnoticed by the patient. This trauma can include cuts, friction against the inside of a shoe, repetitive damage to a specific area, and high-pressure points on the sole of the foot. The trauma causes the initial injury which would normally be considered minor, however, for diabetic patients, these injuries are more susceptible to infection and can lead to the presentation of diabetic foot ulcers (DFUs). This will be discussed further in the next section.
Additionally, the loss of sensation caused by peripheral neuropathy can lead to small muscle wasting, gait disturbances and physical foot deformities. These are all associated with callus formation and increased plantar pressures, making the patients at more risk of developing DFUs (Eleftheriadou et al., 2019).

Foot deformations

Another complication that is associated with peripheral neuropathy is the muscle imbalance due to the decreased pain sensation and perception of pressure. If this muscle imbalance occurs over an extended period of time without being treated, it can lead to anatomical deformities of the patient's feet. Some of these deformities, and the problems that they cause, are described below.

Flatfoot (Pes Planus)

Flatfoot is the most common foot deformity and its appearance is just as the name suggests. It is the transverse concavity of the foot to the point where the patient no longer has an arch in the center of the sole of the foot. Although it is considered to be a painless deformity, it can cause the formation of bunions and plantar heel spur pain. The use of foot orthotics and arch supports are considered ineffective and surgical intervention is used mostly to alleviate any pain or if the patient is having trouble walking without assistance.

Bunion

A bunion is an enlargement of bone or tissue around the first metatarsophalangeal joint, or a bony deformity that has grown on the joint itself. They are caused by the failing support of the tendons and ligaments of the first metatarsal. Other deformities such as flatfoot, along with diabetic neuropathy, can be the cause of a bunion and poorly fitting footwear can exacerbate that bunion once it first appears. The development of a bunion can lead to abnormal pressures in the plantar area of the foot, predisposing it to ulceration.

Claw Toes

The weakening and degradation of foot muscles can lead to muscle imbalance which then results in the permanent 'bending' of the toes. This is the most common deformity in diabetic patients and causes the shifting of fat pads underneath the metatarsal heads to the front of the foot, creating the chance for high pressure points to develop under the metatarsal heads. This means that metatarsal heads, as well as the tips of the bent toes, are more at risk of ulceration.

Charcot Foot

The development of Charcot foot can be initiated by a minor trauma to the foot that a diabetic patient, with an insensate foot, would most likely not notice. This minor trauma starts the process of joint and bone destruction in the foot. Without sufficient blood flow and care, this destruction, degeneration and disorganisation of the joints will continue. When this occurs, swelling and physical deformity of the foot can be seen. This leaves the patient susceptible to high plantar pressure areas and skin breakdown caused by friction against the inside of a shoe. Both are precursors to DFUs. Treatment for Charcot foot usually consists of casting the patient's lower leg to ensure immobilisation and reduction of stress on the affected limb.

(Eleftheriadou et al., 2019)

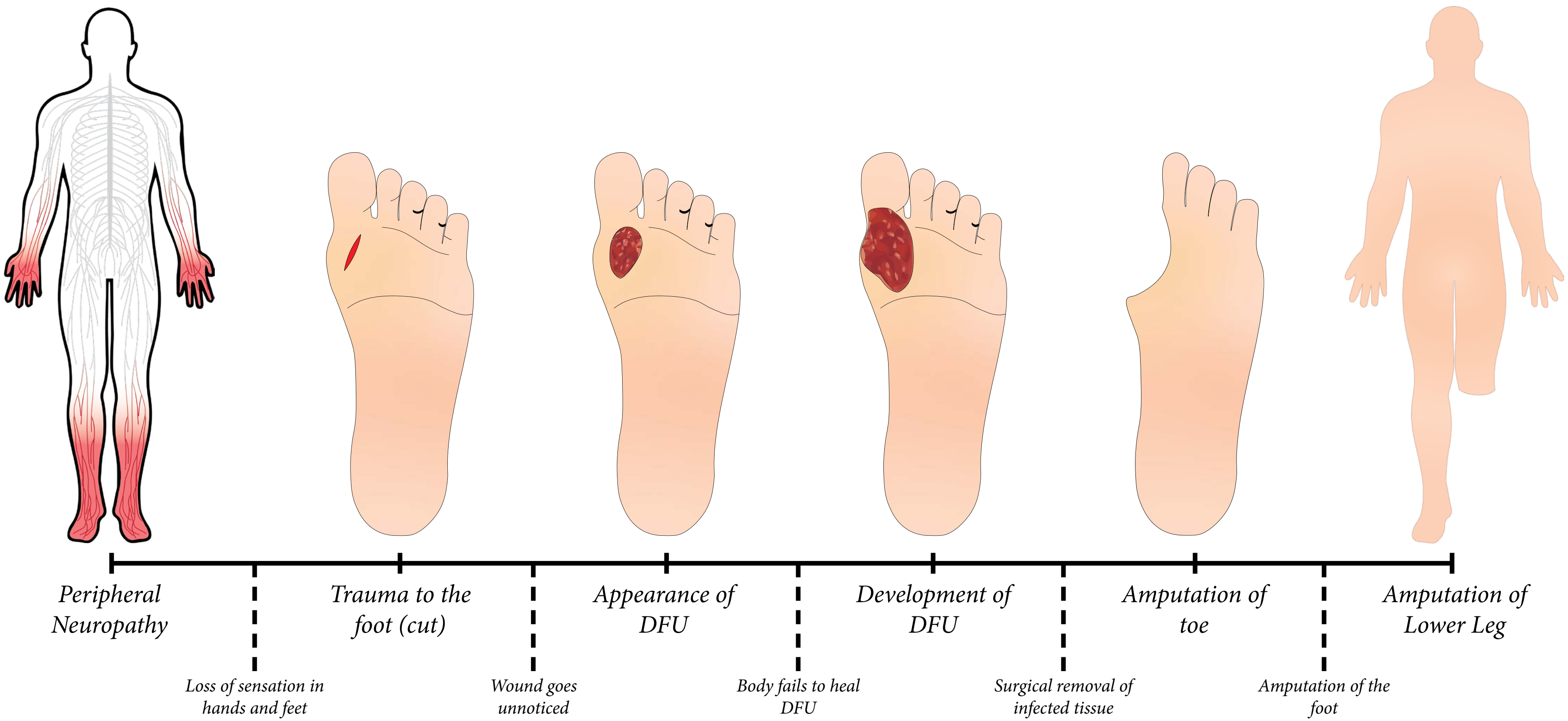

Figure 7. Timeline of DFU development leading to lower leg amputation

Diabetic Foot Ulcers (DFUs)

DFU Stats

The chances of a diabetic person getting a DFU at some point in their lifetime has previously been estimated to be as high as 25% (Singh, 2005). However, Armstrong et al. (2017) proport that when additional data is considered, this percentage could be as high as 34%. Although this number may not seem to be too concerning, it is the issue of recurrence that poses the biggest threat to diabetes patients. Armstrong and his colleagues (2017) also did a review of 19 studies on ulceration recurrence and estimate that 40% of patients have recurrence within 1 year after the initial ulcer healing, and 60% within 3 years. These statistics are significant due to the multitude of issues that a DFU can cause the patient, the most worrying being the increased chance of further infection and the possible need for amputation.

Causes

The presentation of a diabetic foot ulcer is not thought to have one singular contributing factor but is instead caused by a multitude of variables. A study by Macfarlane et al. (1997) concluded that these contributing factors include the breakdown of skin caused by rubbing from footwear, self-inflicted trauma (e.g. cutting toenails), cellulitis, immobilisation resulting from other diseases (such as heart failure or stroke), and the changing of load distribution following some form of amputation. In more recent years, research has shown that the pressure distribution of the foot, even before any type of amputation, has a significant effect on the probability of a patient developing a DFU. A systematic literature review by Ahmed et al. (2020) looked at footwear and insole design features that reduce ulcer risk in people with diabetes. Ahmed and his colleagues believe that the reduction of plantar pressure is a key factor for healing ulcer wounds and for the prevention of ulcer recurrence.

DFU Prevention

With the research clearly underlining the dangers of recurring ulcerations, their prevention is prioritised by diabetes specialists around the world. The advancements in technology and expansion of knowledge in diabetes healthcare opens the door to new and innovative methods that specialists can use to treat and prevent DFUs. A few examples include; topical oxygen therapy; debridement of dead, damaged or infected tissue; and orthotics that create a venous pump effect to assist in improving blood circulation around the foot. These will be discussed further in the precedent review.

Despite these new treatments and techniques emerging on the scene, numerous studies have found that simple patient education could be one of the most effective ways to prevent the diabetes-related complications, especially when it comes to ulcer recurrence (Eleftheriadou et al., 2019). The premise is to regularly educate the patient on the possible symptoms and signs of a diabetic foot ulcer and nerve damage. This is so they can identify the onset, notify a healthcare specialist and seek ways to slow down, stop and possibly reverse the ensuing problems (Eleftheriadou et al., 2019). Some studies have a differing opinion of this however, and claim that there is little evidence to suggest that patient education would reduce the occurrence of new or recurring ulcers (Jeffcoate et al, 2018; Morey-Vargas et al., 2015). One thing that the vast majority of studies agree on is that preventing the presentation of an initial DFU is not only best for the patient, as it will save them from a great deal of physical and emotional stress, but also for the healthcare providers as it will save them considerable time and money.

The prevention of a patient's first diabetic foot ulcer is difficult as there are several contributing factors (Eleftheriadou et al., 2019). Firstly, there is the high possibility of peripheral neuropathy, causing loss of sensation in the feet, leaving the patient vulnerable to undetected physical and thermal injuries. These specific physical and thermal injuries are outlined in the diabetic foot section. The contributing cause that has become increasingly recognised in recent years as being one of the most influential in the emergence of initial (and recurring) DFUs however, is the effect of excessive plantar pressure on the foot (Eleftheriadou et al., 2019). The most common method to reduce this excessive pressure comes in the form of a shoe insole or lower leg cast. The aim of these products is to assist in distributing the stresses that are being applied to the foot during everyday motions (sitting, walking, running etc.). The precedent review, seen in a later section, will take a more detailed look at these products by discussing the general design aesthetic, as well as the product's effectiveness in preventing the presentation of DFUs based on peer reviewed studies.

NZALS

Peke Waihanga, Aotearoa

Figure 8. NZALS logo

NZ Diabetes Care

A 2021 report, published by PwC, working alongside organisations such as Diabetes NZ and Healthier Lives, looked at the economic and social cost of type 2 diabetes in New Zealand. It estimated that the current total annual cost of type 2 diabetes in New Zealand is $2.1 billion, which represents 0.67% of the country's total Gross Domestic Product (GDP). This amount is projected to increase over the next 20 years to around $3.5 billion if the issue isn't addressed sufficiently. This increase in total cost is driven by factors such as increased prevalence, a shift towards younger people developing type 2 diabetes, and the greater proportions of people needing expensive treatments for diabetes-related complications (PwC report). Some of these treatments have been mentioned in the previous section and a few examples of diabetes products are reviewed in a later section. One of the key opportunities that was mentioned in the PwC report, to help improve diabetes care, was to provide optimal foot care to all New Zealanders, so to avoid the development of DFUs and further complications. One of the organisations that provide this footcare to the diabetes population is the New Zealand Artificial Limb Service (NZALS).

Who are the NZALS?

The New Zealand Artificial Limb Service is a specialist healthcare provider that manufacture and provide individual patients with customised medical devices/products and rehabilitation services. Back in 2016, they published a 2017-2021 statement of intent report which outlines their 4-year strategic direction to improve the service they provide their patients (NZALS, 2016). One of the main changes they highlighted was to update and improve their service model. The center of that service model has previously focused on the "person with an amputation"; however, the new focus will be on the "person with and at risk of an amputation". This change is due to the statistics from 2016, showing that 57% of the new amputations that year were due to diabetes and vascular-related complications. The report states "if NZALS can responsibly prevent an amputation; this becomes a considerable benefit to the patient, as well as reducing the pressure on our bulk-funding arrangements for health services" (NZALS, 2016, p.13). NZALS patients consist mostly of amputees requiring prosthetic arms, legs and feet. However, NZALS also provide specialist diabetes care products in the form of customised orthotics and footwear through the Peke Waihanga Orthotic Service.

What diabetes products & treatments do they offer?

As cited from their website, the Peke Waihanga Orthotic Service provide "a comprehensive range of ready-to-wear, high-quality braces and orthotics, and custom-made orthotics for patients with particular needs" The patient will meet with a clinician who will do an assessment and will help them through the product selection process to ensure the chosen orthotics support the patient's lifestyle and needs. For diabetes patients in particular, the purpose of orthotics include the reduction of plantar pressures and shear from friction, to assist in the healing of ulcerations and infections, and to provide optimal comfort for the patient throughout their day. A timeline of the NZALS process for providing patients with diabetic orthoses is discussed on page 25, and a more detailed look at the technologies and materials they use is also looked at in more detail at a later stage of this research portfolio.

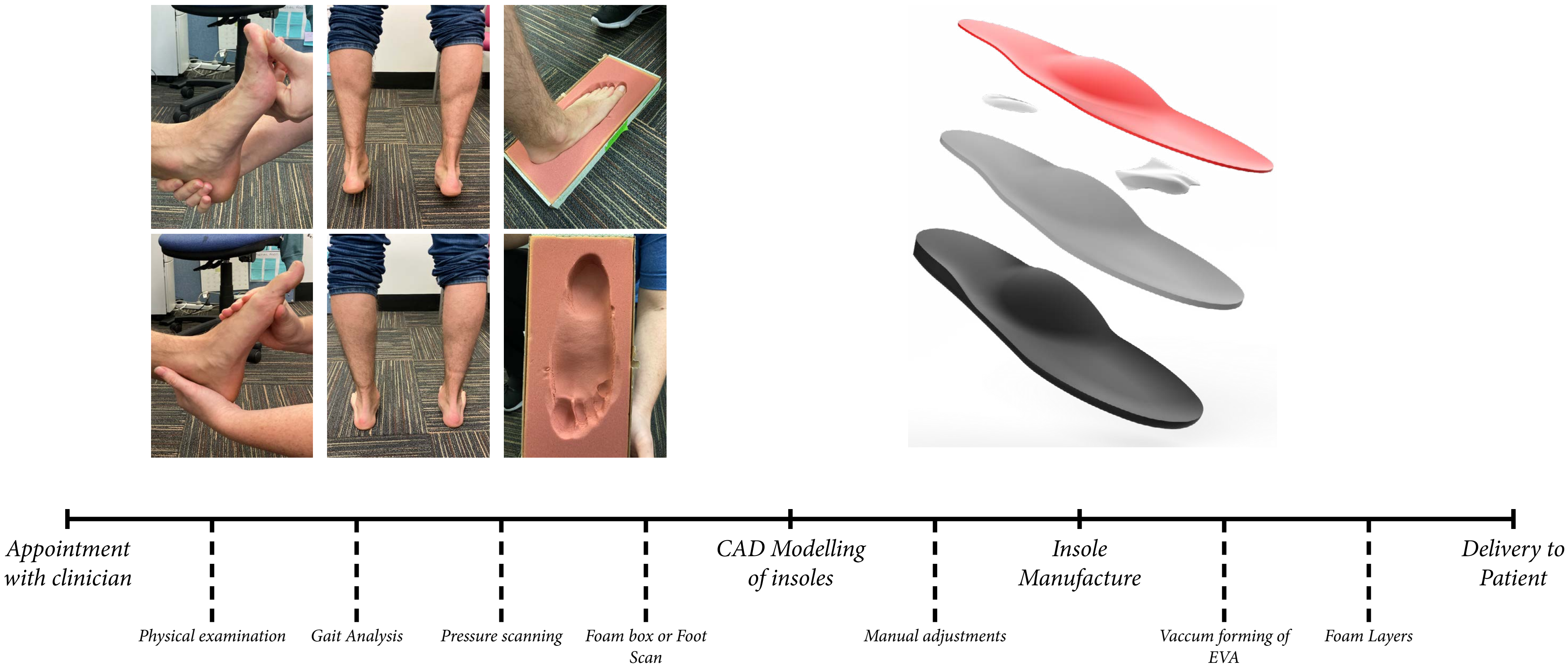

Figure 9. Timeline of the NZALS cutomised orthotic production process

The NZALS Process

Appointment with Clinician

For a diabetic patient to be made customised diabetic insoles, they must first have an appointment with a NZALS clinician who will assess them before the orthotics are made by the technicians. The assessment starts with a discussion between the clinician and the patient about the type of lifestyle that the patient has. This discussion will give the clinician an informative insight so that they can supply them with customised insoles that will be best suited to their lifestyle. The next step is a physical examination of the patient's feet. The clinician will check for abnormalities in sensation, possible foot deformities, and restricted movements in the foot. These will help to identify if the patient is at an increased risk of developing DFUs. They will also look for any high risk areas where a DFU could develop or where one has already developed.

After the physical examination, an analysis of the patient's gait will be performed. By looking at the way the patient stands in a static position and then how they walk at a regular speed, the clinician will be able to identify certain factors that may play a role in DFU development and therefore need to be counteracted, or corrected, by the customised insoles. At this point, a digital 3D model of the foot is obtained by either scanning the patients foot, or by scanning a foam box mould of their foot sole. Pressure mapping data is also recorded at this point to help advise the clinician on the final form of the insole and the materials that should be used to manufacture it.

CAD Modelling of Insoles

NZALS use the specialised insole modelling software, VoxelCare, to create a digital version of the patient's customised insole. VoxelCare allows for the 3D scan of the foot and the pressure data to automatically adjust the shape and material choice of the insole. This will be discussed further in the next section. The clinician will then edit the digital insole form based on the information they gathered from the physical examination and gait analysis. This may include adding particular features that will benefit the patient over time, or by changing the type of materials that should be used. Once the clinician is happy with the final digital model, the insole design is sent to the technicians to be made.

Insole Manufacture

The technicians at NZALS will receive the insole design, as well as any additional information that may be relevant to the manufacturing process, such as specific features or material choice, and will begin the making process. The base layer of NZALS customised insoles are more commonly made from EVA. The EVA can either be milled using a computer aided manufacture (CAM) machine, or it is vacuum formed over a plaster cast of the patient's foot sole that is made from a foam box mould. This EVA base acts as the structural layer. The technician will then add layers of Poron and Nora Foam, as well as any additional features, such as metatarsal domes and bars. Once the insole is complete, and the team at NZALS are satisfied with the final product, the insole is delivered to the patient.

Discussion

From the discussion with an NZALS clinician, it is clear that their diabetic orthotic production process is thorough. They use the expertise of their clinicians and manufacturing skills of their technicians to provide their patients with a high-quality final product. One interesting observation is the minimal use of technology when conducting the assessment on the patient (e.g. plantar pressure mapping). Despite evidence from recent studies showing that importance of pressure distribution for diabetic orthotics, it seems the NZALS are confident enough to rely on the expert opinion and experience of their clinicians to be able to design orthotics for a diabetes patient that can effectively reduce excessive plantar pressure. During the manufacturing process, it is also clear that more traditional techniques (e.g. milling and vacuum forming) dominate the process, with the craftmanship skills of the technicians also being heavily relied on.

Technological Context

Figure 10. Voxelcare 3D foot scanner (Voxelcare, 2021)

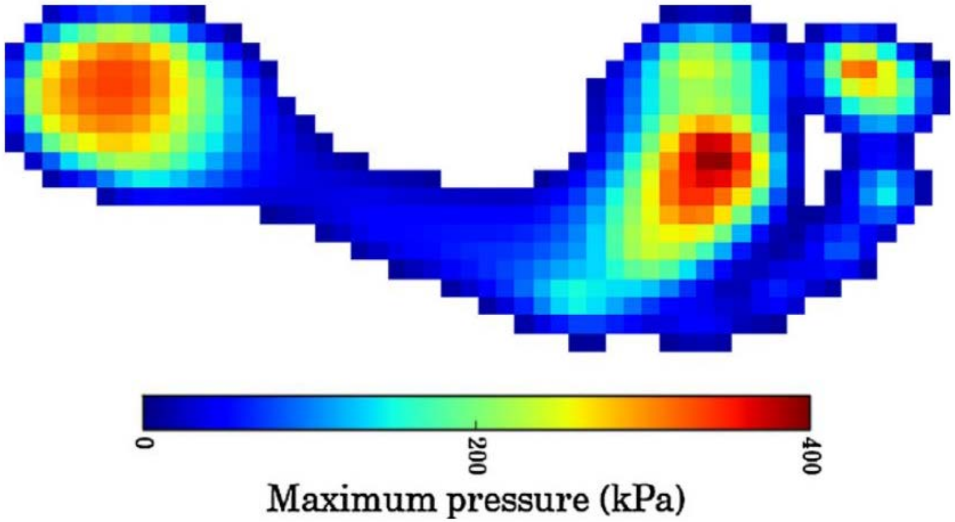

Figure 11. Example of a plantar pressure map (Davia-Aracil et al., 2018)

3D Foot Scanning

Obtaining a 3D scan of a patient's foot has become a key part of the customized insole production process. Using laser scanning technology, the 3D shape of the patient's foot can be imported into digital modelling software. Using this software, clinicians are able to mould the insole shape to the contour of the patient's feet to provide maximum support and comfort. Lee et al. (2014) compared 3D foot scanning with conventional measurement methods, such as digital calipers or digital footprints, and concluded that 3D foot scanning is the recommended method due to its higher precision, accuracy and robustness. There are numerous variations of 3D scanning machines, with many offering software that allows the user to view and edit the 3D form in a digital space. A good example of this is the VoxelCare foot scanner (see figure 10) and online modelling software that is used by the NZALS.

Foot Pressure Scan

For diabetes patients, areas of high plantar pressure can be a leading factor in the development of DFUs, as stated in previous sections. In order for clinicians to create orthotics that will evenly distribute the plantar pressure, they must first know where the most affected areas are. Pressure sensing technology is used by clinicians to capture pressure point data that can indicate the areas in which the patient may experience pain or discomfort when standing, walking or running. Similar to the 3D foot scanning, this data can then be imported into 3D modelling software and can assist in creating the insole shape and choosing the materials that will be used during the manufacturing of that insole. An example of a pressure map can be seen in figure 11.

CAD software (VoxelCare)

There are multiple CAD softwares that are used in the customization of diabetic insoles. This research will focus on VoxelCare, which is a online modelling tool that is used by NZALS to create diabetic orthoses for their patients. It allows the clinician to insert a 3D foot scan and will automatically create an initial insole form based on the shape of the patient's foot. It is then possible to input the pressure data that will subsequently adjust the form of the insole as needed. The design interface allows the clinician to change or add specific features, such as metatarsal bars or dome, if necessary. This allows for clinicians to use their clinical expertise and experience to change certain elements, which is very important and ensures the patient is getting the best product possible. The software also includes a database of common materials used in the manufacturing of orthotics as well as a wide range of default orthotic forms that can be applied to the 3D digital model at any time. Once the clinician is happy with the digital model, they will send the file to a team of technicians that will start the manufacturing process outlined in the previous section.

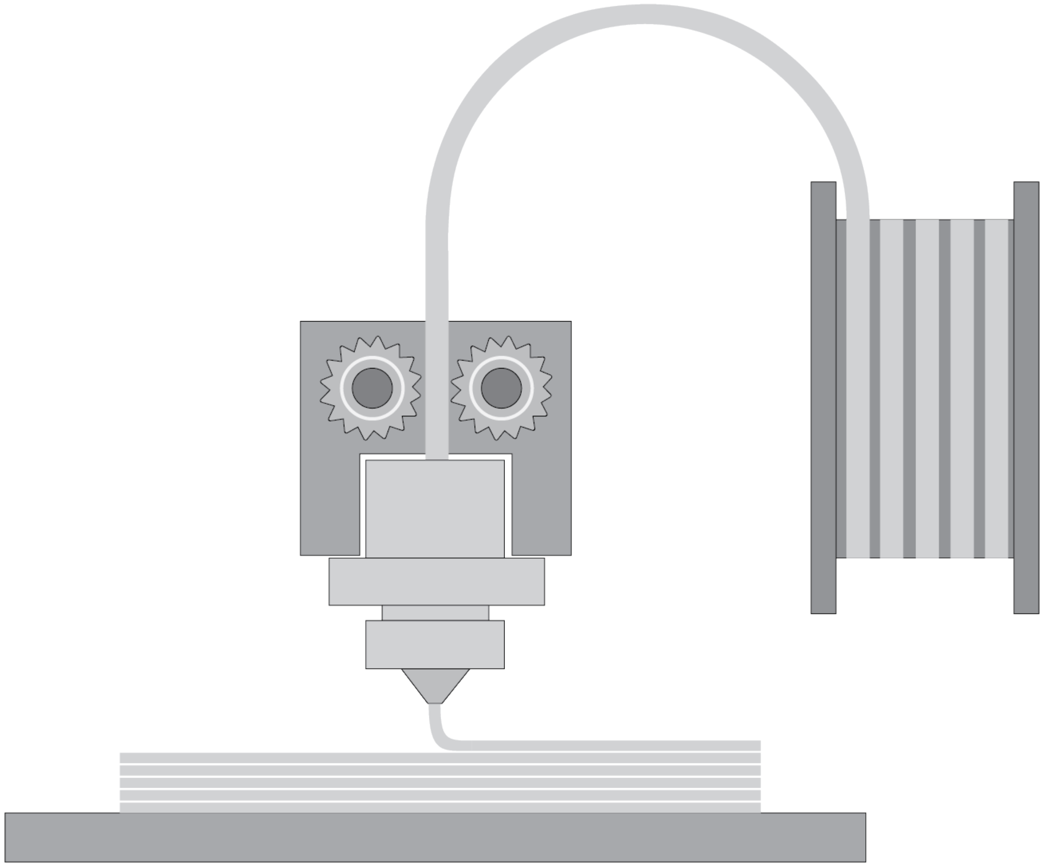

Figure 12. FDM 3D printing process

3D Printing

The ongoing advancements in 3D printing technologies bring about new production possibilities which would otherwise not be possible with traditional manufacturing methods (3D printing of functional anatomical insoles). While there are a growing number of 3D printing methods (e.g. MJF, SLA and SLS), this research will mainly focus on using Fused Deposition Modelling (FDM) printing for material experiments, structural tests and proof of concept models. Gonzalez-Henriquez et al. (2019) lay out a list of advantages that FDM printing has over other Additive Manufacturing (AM) methods, such as, the low price of the machine and materials, fast print speed, and the fact it is easy to use. It is these reasons, as well as a few others, that make FDM printing perfect for the testing and experimenting stages of this research. This thesis may also look at using Polyjet printing in the final stages to question whether the concepts developed during the experimental stage could be advanced further using the more complex Polyjet technology.

4D Printing

4D printing is a manufacturing process that started gaining public interest in 2013 when Skylar Tibbets, the director of MIT's Self-Assembly Lab, published a very interesting paper on the subject. The paper documented a variety of 3D forms that were printed using UV curable polymers which caused them to be able to change form once exposed to external stimuli (e.g. water, UV and temperature) (Tibbits et al., 2014). Campbell et al. (2014) defined 4D printing as the "additive manufacturing of objects able to self-transform in shape and material property when exposed to a predetermined stimulus, such as being submerged in water or exposed to heat, pressure, current, ultraviolet light, or other energy source" (Campbell et al., 2014, p. 2).

In the same publication, a list of potential challenges for the future of 4D printing was included. One of those challenges was the materials that will be used. For 4D printing to reach its full potential, the materials being printed need to have multi-functional properties and embedded logic capabilities (Campbell et al., 2014). Even in the last 7 years since this paper was published, there are little applicable 4D printing materials. Gonzalez-Henriquez et al. (2019) discuss this and make the point that there are a lot of pending issues that need to be addressed to accelerate the development of 4D printing materials.

Material Context

Figure 13. Examples of EVA foams that are used by NZALS

Figure 14. Examples of Poron foams that are used by NZALS

Current orthotic materials

As previously stated in the DFU section, the main products that are used by diabetes patients to help prevent excessive plantar pressure are lower leg casts and orthotics. The materials used in the manufacturing of orthotics play a pivotal role to ensure that the plantar pressure from the patient's foot is evenly distributed. Paton et al. (2007) define six material properties that they believe are pertinent to insole design, these are: density, resilience, compressive stiffness, static coefficient of friction and shear, durability and compression set. A systematic review of existing studies, conducted by Gerrard et al. (2020), evaluated and summarised relevant studies that assessed the effect of different orthotic materials on plantar pressures during walking. The review found that materials such as Polyurethane (Poron), polyethylene (Plastazote) and ethyl vinyl acetate (EVA), reduce peak pressure beneath varying regions of the foot (Gerrard et al., 2020). These materials are commonly used to manufacturer orthotics, but in order to obtained the desired stiffness and mechanical properties to accommodate a specific patient's condition, customized diabetic insoles are made by layering two or more different materials on top of one another, combining the properties of each individual material.

3D printing materials

One of the primary objectives of this research is to use additive manufacturing techniques in the production of diabetic orthotics. This requires the materials being used to be able to be 3D printed. There are currently limited types of 3D printed materials that could be considered in the production of orthotics due to the mechanical properties that are required to provide effective pressure distribution and a general level of comfort. One material that could be used is thermoplastic polyurethane (TPU).

In recent years, there have been a few examples of TPU being 3D printed to create customized insoles (Chatzistergos et al., 2020; Tang et al., 2019). Interestingly, the results from one of these papers show that the 3D printing of customized insoles, made from TPU, achieves optimised cushioning and significantly improved the pressure relieving capacity of footwear (Chatzistergos et al., 2020). It must be noted, however, that this paper focused mostly on the internal density of the insole structure and its relation to the cushioning capabilities. It is assumed that this is due to TPU's inability to produce a range of softness and physical properties that current standard orthotic materials have. This issue could be resolved with the use of a foaming 3D print filament, such as ColorFabb's varioShore TPU (ColorFabb, 2020). Initial research into this foaming filament was intriguing and underlined the need for further research and possible experimentation with the material. This is discussed further on page 45.

Bio-materials

Materials such as polyurethane, polyethylene and EVA are all petroleum-based products. The orthotics that are produced using these materials are unable to be efficiently recycled or to biodegrade in landfills. One of the more important objectives for new products nowadays is to consider the environmental impact and life cycle of the product. To produce orthotics from natural, bio-based materials, that are just as effective in their function as their petroleum-based counterpart, would be a significant achievement and a big step in the manufacturing of bio-based products. Unfortunately, there are not many options for 3D printable bio-materials that would have similar properties as polyurethane or EVA. One material to consider is a bio-based polybutylene succinate (PBS), which is described as having excellent properties by the manufacturer but it is not stated whether or not it can be used in additive manufacturing processes. This will be discussed further in the experimentation section.

NZALS Materials

The collaboration with NZALS provides a valuable insight in the processes and materials that they use to produce their orthotic products. Discussions with the NZALS technicians responsible for making the orthotics revealed the range of materials that are used. EVA of varying densities is used as the structural base, 6mm Poron or Noratech foams are used as the second layer and 3mm foams are used as the top layer. Custom insoles can include additional features such as metatarsal domes and bars that assist in relieving excessive pressure from a certain area of the foot. These are also made out of Poron EVA or foam. The specific type of Poron used to construct these insoles is decided by the clinician, and is based on what material combination they feel would be most beneficial following an assessment of the patient.

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Figure 15: Diaped Duosoft Flow Diabetic Insole (Algeos, n.d.)

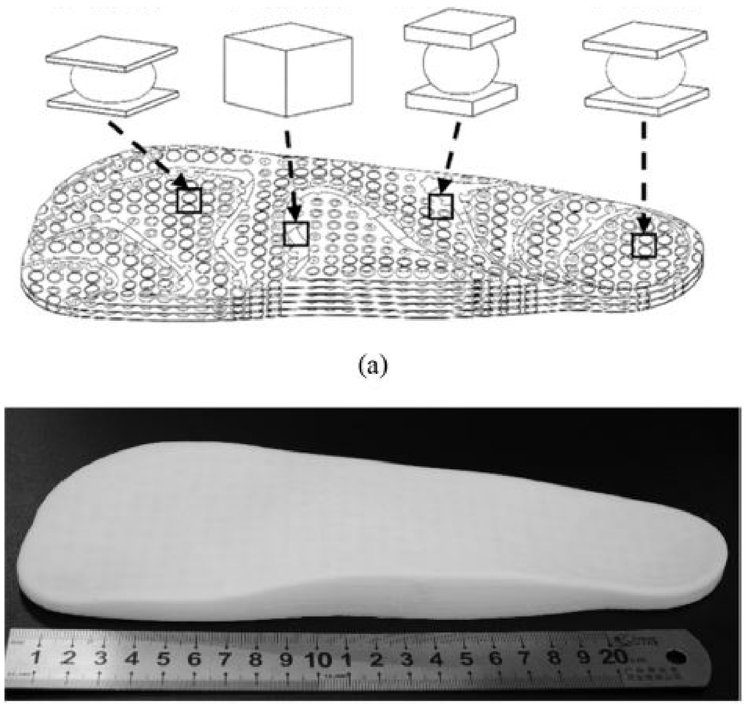


Figure 16. 3D printed adjustable modulus porous strcuture insole (Ma et al., 2019)

Existing Products

There are countless insoles and orthotic products available nowadays that are designed for those with diabetes. The majority of these products claim to be able to reduce plantar pressure of the patient's feet so to reduce their chance of further foot complications, such as physical deformity and foot ulcerations. Some of the products look at alternative ways to reduce the foot complications such as massaging effect or even topical oxygen delivery to help provide sufficient oxygen in the bloodstream to assist in the body's ability to protect and heal itself. This precedent review looks at a range of products that have scientific literature to evaluate their claims in regards to diabetes care and give an honest assessment of their performance and/or design.

Diaped Duosoft Flow Diabetic Insoles

These Diaped insoles are made for people with diabetes, arthritis or other conditions that result in sensitive feet. They are designed with a top layer of medical-grade urethane (Poron) and a bottom layer of 122 individual gel cells. An unpublished paper by Anthony et al. (2013) claims that the gel cells are shaped and positioned to "independently react to the foot striking the floor increasing the available surface area and reducing peak loading with differing levels of resistance and compression, creating a continuous pump effect"(Algeos, n.d., para. 3). They believe that this pumping effect would help to improve blood circulation, allowing for better tissue oxygenation which can make the foot less vulnerable to tissue breakdown, hence preventing ulcers, sores and calluses.

It is true that the improvement in tissue oxygenation makes the tissue less vulnerable to breaking down as many studies have shown (Sen C. K., 2009; Leach, R. et al., 1998). However, in order to improve tissue oxygenation, one must improve the blood-oxygen saturation and without external assistance, such as oxygen therapies, blood must be pumped back up to the heart to be re-oxygenated. Unfortunately, diabetic neuropathy can cause damage to blood vessels in the lower leg, as well as the foot, making it difficult for blood to be pumped back to the heart. Due to the lack of peer-reviewed evidence presented by the creators of this insole, it would be unreasonable to assume that the supposed pump effect created by the gel cells layer would be effective enough to sufficiently pump the blood up the legs, to the heart, to be re-oxygenated.

3D Printed adjustable modulus porous structure insole

This proposed 3D printed insole by Ma et al. (2019) looked at providing a generalised foundation of porous structural design and adjustable gradient modulus for diabetic insoles and other applications with similar demands. The paper initially focused on background research into the symptoms of a diabetic foot, 3D printing, insole manufacturing, and applicable materials that can be used in the 3D printing of insoles. The authors provide statistics on 3D printed insoles being more effective than subtractive milled insoles in lowering peak plantar pressures. Their own experiments consisted of 3D printing ellipsoid structural units of varying size and then conducting compressive tests, finite element analysis (FEA) simulations and other mechanical property tests. These tests were done to accumulate key information about the structure's effective modulus and general mechanical properties to ensure that it would be an applicable option in the design of diabetic insoles. The results showed the ellipsoid structural unit's ability to satisfy both the geometric and the mechanical demands of a diabetic insole or other similar applications.

One limitation that the authors acknowledged was that only one type of porous structural unit was studied. They state that further investigation into other types of porous structural units would allow for a database of the mechanical properties, and the key geometric parameters of those structural units, to be established and be referenced in future low modulus structural design applications.

This research will look at the 3D printing and analysis of other types of porous structural units and will document the results accordingly.

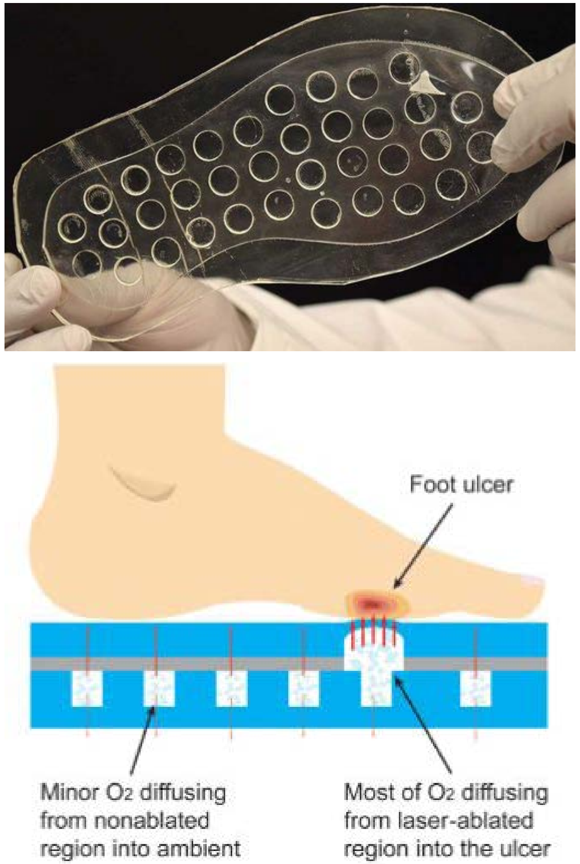


Figure 17. Selective topical oxygen delivery insole (Jiang et al., 2018)

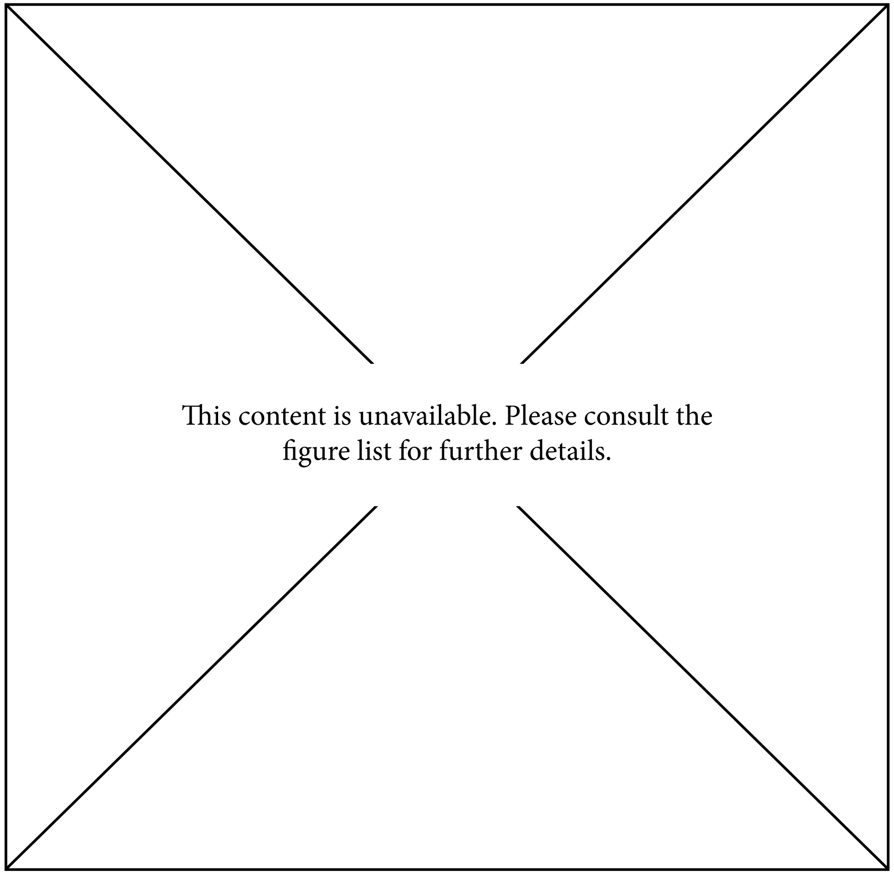


Figure 18. Dr Comfort Diabetic Shoes (Dr Comfort, n.d.)

Selective topical oxygen delivery insole

A paper written by Jiang et al. (2018) looked at the development of insoles that use selective topical oxygen therapy to treat diabetic foot ulcers. As previously stated, the oxygenation of tissue on a diabetic foot can be a very important factor in preventing DFUs, as well as helping to heal them after the prevention fails (Frykberg et al., 2018). Nowadays, there are a few types of oxygen therapy that can be used in chronic wound treatment, such as, hyperbaric oxygen (HBO) therapy, continuous diffusion of oxygen (CDO) and topical oxygen (TO) therapy (Jiang et al., 2018). However, some of these forms of therapy can be very expensive or require large equipment.

Jiang et al. (2018) developed a silicone-based insole with selective laser-ablated regions to deliver oxygen to wound regions on the sole of the foot. The insole consists of two polydimethylsiloxane (PDMS) layers, a thick bottom one and a thin top one. The bottom layer contains pillars for mechanical support as well as space for oxygen to be stored. The top layer is laser-machined with a predetermined or custom pattern based on the condition of the patient's foot and location of any existing wounds. Those two layers are then bonded together, with oxygen being loaded into the insole either during or after fabrication. If manufactured correctly, the pressure applied by standing or walking will force the oxygen to permeate through the machined pattern in the top layer, directly into the wound areas. The authors claim that this direct supply of oxygen is enough to promote optimal oxygen-supplemented wound healing. One drawback of this method, however, is the durability and effective longevity of the insole. Jiang et al. state that the insole was able to withstand "at least one day of wear (including 8 hours of walking time with 5160 steps) without any structural failure". Although this is a positive outcome for the initial development of this insole, there would need to be more investigation into the durability of the materials over extended periods of time and a clear idea of how long it takes for the oxygen supply inside the insole to run out. An insole that can only be used for one day, or even just one week, before it starts to deteriorate or the oxygen runs outs, would require a continuous resupply from the manufacturer or would require the patient to refill the insole with oxygen themselves. These are unrealistic expectations for both the manufacturer and the patient. Although the basic principle of selective topical oxygen therapy in the healing of diabetic wounds is very interesting, it requires a bit more development before it can be considered to be used in products such as diabetic insoles.

Dr Comfort Diabetic Shoes

Dr Comfort specialise in making footwear for people with diabetes. Their range of shoes allows their customers to buy footwear for almost all occasions, whether it be a formal dress shoe, athletic shoes or hiking boots. The materials used in these different shoe types do vary of course, depending on their intended function, but the manufacturers claim that only high-quality material is used in all of their shoes. This shoe brand varies from regular shoes by including and modifying particular features that they claim to be "Dr Comfort Technology". The most noticeable features are the extra width and depth of all their shoes, to ensure less chance of rubbing on the foot, and a 'protective toe box' to act as protection from toe stubbing. Morey-Vargas et al. (2015) claim that ill-fitting footwear and repetitive trauma from day-to-day activities are the leading precipitants of foot injury so by adding more space in the inside of the shoe and the protective toe box, it reduces the chances of shear of the foot and/or repetitive foot trauma. Another common feature is the use of breathable materials for all their shoes in order to regulate heat and keep the feet cool and dry. Multiple papers have discussed heat and humidity regulation as being other important factors in reducing diabetic ulcer formation (Ahmed et al., 2020; Anggoro et al., 2018; Yavuz et al., 2020). Every shoe also has removable insoles in order to accommodate any customised orthotics that patients may have been previously prescribed. Dr Comfort do also sell gel and customised shoe inserts; however, these are not made to specifically distribute plantar pressures, which is a significant contributor to the emergence of DFUs and should be a top priority for diabetic footwear (Anggoro et al., 2018; Adiewere et al., 2018).

Background Research Summary

From this background research, it is clear that diabetes is having a considerable effect on the New Zealand population. With almost 5% of the entire population suffering from type 2 diabetes, and with that number projected to rise by up to 90% in the next 20 years, hundreds of thousands of people are at risk of experiencing the complications that are associated with the disease. These complications can not only hinder a person's physical ability to go about their day to day life, causing significant emotional and financial stress, but can also lead to an early, unexpected death.

The presentation and development of diabetic foot ulcers is one of these complications. These DFUs can lead to the need for surgical removal of infected tissue and the possible amputation of the patient's toes, their whole foot, or their entire lower leg. Many studies have been done to investigate how these DFUs occur and what treatments or strategies are available to prevent them. One of the most effective prevention methods is the offloading of excessive plantar pressure on the sole of the patient's foot using customised orthotics.

NZALS are one of few organisations in New Zealand that can provide diabetes patients with these customised insoles. NZALS are known primarily for providing prosthetic products and rehabilitation services to amputees across the country. However, in recent years, they have updated their service model to concentrate on providing products and services for those at risk of amputation, not just for those who are already amputees. This means they now provide orthotic products to those who may be at risk of problematic foot complications, such as diabetes patients. These products include customised insoles and specialised footwear that are made by NZALS technicians. In order to achieve the highest quality of product for their patients, clinicians and technicians at NZALS are always searching for new, innovative techniques and technologies that can improve the services and products they provide. This is where the collaboration with universities and those in the Med-Tech Sector can be beneficial.

The constant advancement of digital technologies and manufacturing techniques creates opportunities for highly effective products to be made with ease. The precedent review section looked at examples of studies that have used techniques, such as 3D printing, to produce customised insoles and orthotics. The results of these studies, along with further research into additive manufacturing technologies, showcase the potential for 3D printing to be used in the manufacturing of customised diabetic orthotics. Additional research into materials also looked at the possible use of bio-materials and foaming 3D print filament to replicate the properties of the foams and varying density EVAs that are commonly used in customised orthotic production.

Opportunities

• Collaborate with NZALS to design and develop a new product or treatment strategy that will assist in the prevention of DFUs and subsequently mitigate the number of diabetes-related lower limb amputations in New Zealand

• Working with engineers and material scientists from the SfTI research group to experiment with bio-materials that could be used in the manufacturing of diabetic orthotics

• Experimenting with 'foaming' 3D print filament to analyse the material's capabilities and potential to be an alternative to current orthotic foams

3

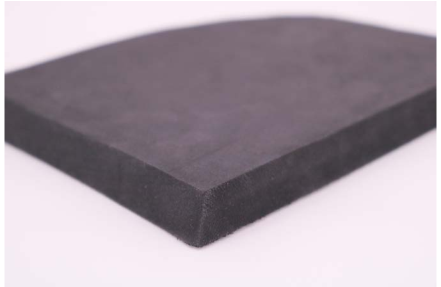
Experimentation

Material Exploration and Experimentation

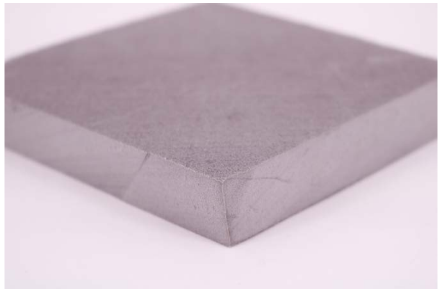
Research and experiment with possible bio-alternatives for current orthotic materials

Experiment with 'foaming' 3D print filaments to replicate current orthotic foams

Test 3D printing technologies that have the ability to create multi-density 3D prints

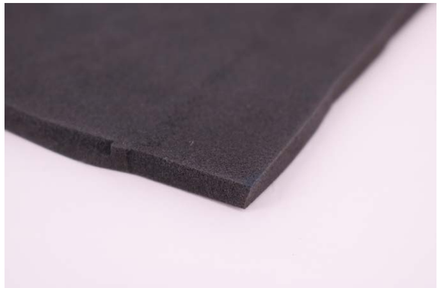


High-Density EVA



Medium-Density EVA

Low-Density EVA



Standard Poron

Poron Pink 94

Poron Pink 96

Poron Vive

Poron XRD

Nora Lunatec Motion

Figure 19. Examples of the orthotic materials used by NZALS

The Current Orthotic Materials (NZALS)

EVA

Ethylene Vinyl Acetate (EVA) is a closed-cell foam that is commonly used as the base material in the manufacture of orthotics, prosthetics and footwear. This lightweight material's properties include good shock absorption, a long life span and the ability to retain its shape well. It is able to be heat moulded or milled, making it easy to create the desired shape needed for an insole or orthotic product.
There are many varying density EVAs available for different applications. The NZALS use 3 different density EVAs (high, medium and low), seen in figure 19. These 3 types of EVA will be chosen by the technicians at NZALS to be used in the manufacturing of a customised insole based on their shore hardness values and compression properties.

Poron Foam

Poron foams are patented open cell polyurethanes that are also used regularly in the manufacture of orthotics, prosthetics and footwear. There are many variants of Poron to accomodate a large variety of specific applications. The open cell structure acts like tiny springs that give the material excellent impact absorption and cushioning properties. It is these properties, as well as it's breathability and durability, that make it a perfect material for use in the orthotic and prosthetic industry.
NZALS use a range of different Poron types to make the custom orthotics for their patients, all of which differ slightly in their properties. For example, Poron Vive has excellent shock absorption which makes it better than other Poron types when it used in the insole of very active person (e.g. a runner).

Nora Lunatec Foam

Nora Lunatech is a form of very soft EVA that is used, like Poron, as a mid- or top-layer foam for orthotics. The properties of the material include excellent damping and bedding capabilities that can distribute load effectively, making it ideal for diabetic orthotics. NZALS tend to use this material when making orthotics for those diabetes patients who weigh less than 70kg.

Discussion

The materials used by NZALS have differing shore hardness values and mechanical properties that will be referred to by the clinicians and technicians when choosing materials for a customised orthotic. In order to create highly effective orthotics, specific properties from the different materials are required. The current method used to achieve this is the layering of the materials so that the EVA acts as the structural base with good shock absorption properties, and the Poron foams provide the cushioning, as well as excellent impact absorption.
One issue with this method is the lack of precision in relation to specific areas of the foot. The top foam layer may provide cushioning to most of the foot; however, as the research into the diabetic foot shows, complications such as physical deformities or the presentation of DFUs mean that smaller, more concentrated areas may require more specific care or intervention.
A solution to this problem would be an orthotic manufacturing process that has finer control over the mechanical properties and shore hardness value of the materials used.

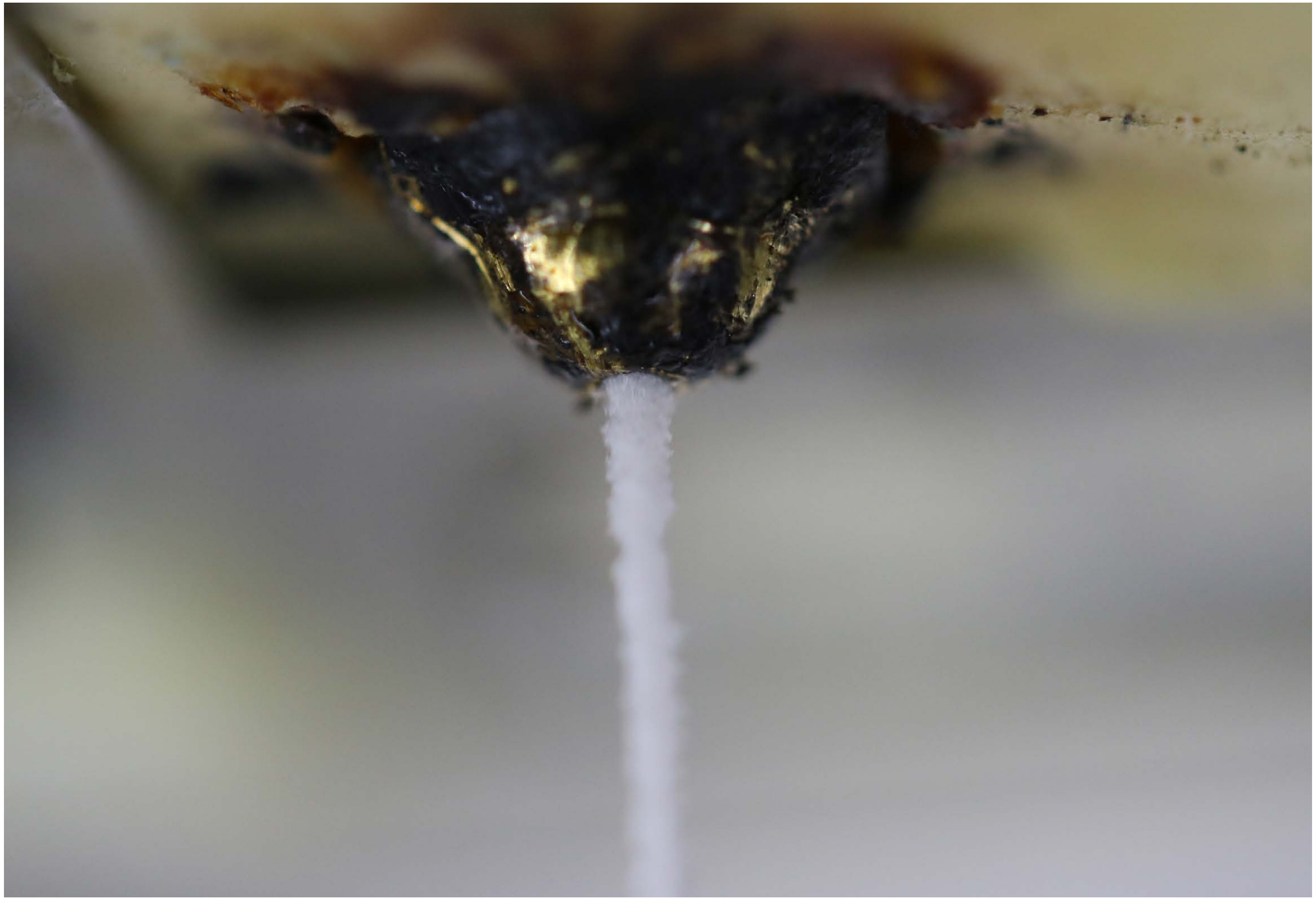


Figure 20. Foaming filament extruding out of a 3D printer nozzle

Foaming Filaments

Overview

The development of foaming 3D print filament is a very new concept, with only a select few companies having sufficiently developed variations of these filaments and made them commercially available. One example is Polymaker, a company with headquarters in Shanghai, who specify the use of an undisclosed foaming technology that is used in their Polywood filament. They claim the addition of this foaming technology creates more lightweight 3D prints with a better surface finish than other wood filaments (PolyWood™, n.d.).

How these filaments work

Foaming filaments have a chemical blowing agent added to the formulation that releases gas once a certain temperature is reached. When the filament is then 3D printed above that certain temperature, the gases are released inside the material, creating gas bubbles. Once printed, the internal structure of the extruded material is cellular, with gas bubbles dispersed throughout the printed material. This means the filament can make 3D prints with decreased density and increased flexibility.
This process of creating gas bubbles through the heating of a chemical blowing agent is similar to the technique used to create EVA foams. During EVA foams production, a plastic blend of raw materials, additives and catalysts will be pressed into large sheets using high pressure. Those sheets will then be heated to specific temperatures to create the final EVA foam sheet (Insider, 2019). The temperature at which it is heated in this final step can affect the density, resilience and quality of the EVA foam sheet, which is very similar to how the 3D printing process affects the foaming of these innovative new types of filament.

Discussion

The research into how different foams are traditionally made and the capabilities of new foaming filaments, has identified many potential opportunities in the additive manufacturing industry. By simply adjusting the print temperature, it is possible to control the level of foaming that occurs and potentially, the material's mechanical response. This process of creating a plastic mixture with chemical blowing agents, and then heating it, is already being used to make EVA foams with differing properties. This existing process highlights the potential for a similar technique to work during additive manufacturing processes. There are currently a very limited number of commercial filaments with foaming capabilities, and none that are made from soft, bio-based materials. With this in mind, the next stage of this research looks at the development and testing of a new foaming filament made from bio-based materials.

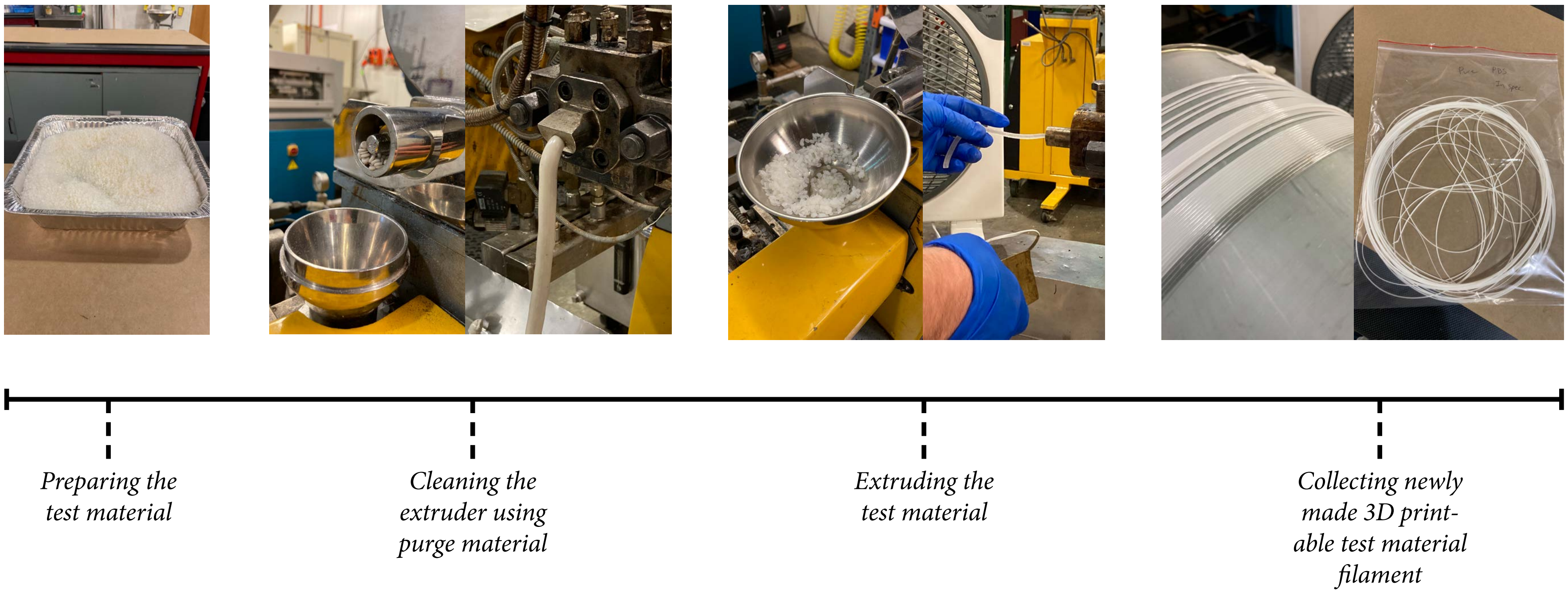


Figure 21. Timeline of the test filament production process

Material Science Internship

Overview and aims

As part of the experimentation stage, a 4-week internship at the Centre for Advanced Materials and Manufacture, at the University of Waikato, took place to develop and test a bio-based 3D print filament that was able to foam when 3D printed. The primary aim of the internship was to develop a filament that was able to create 3D print samples capable of replicating the mechanical properties of the NZALS materials used in the manufacturing of diabetic orthoses.

Preliminary research into potential bio-based materials that could be used, as well as chemical blowing agents that would be suitable for the foaming process, was conducted before the test filament was made using a twin-screw extruder and then tested on a Makergear M2 3D printer.

All the experimentation and testing during this internship was conducted in collaboration with material scientist, and member of the SfTI research group, John McDonald-Wharry.

Filament Production Process

The filament formulations were created by mixing small pellets of a bio-based material*, with precise measurements of a chemical blowing agent*. To achieve a consistent foaming effect with these formulations, the blowing agent needed to be evenly distributed throughout the material.

After cleaning the machine, the filament formulations were ready to be extruded. The filament was allowed to extrude for a few minutes and was then cut off and the newly-extruded material was stretched out and attached to a revolving wheel. This wheel was used to collect the filament and allow it to set after cooling. Once a sufficient amount of filament was collected, it was placed in an air-tight bag, ready for testing.

A number of filament formulations were made using this process, with the primary differences of the formulations being the ratio of the bio-based material to chemical blowing agent. Activated carbon was also added to the some of the formulations to improve the distribution of the gas bubble formation through nucleation. This carbon additive also affected the overall colour of the filaments, turning them from a natural white to a jet black colour.

* *Undisclosed due to ongoing research*

Test filament A

Nozzle diameter = 0.75mm
Print Speed = 58 mm/s
Extrusion Rate = 110%
Layer Height = 0.5mm

Test filament B

Nozzle diameter = 0.75mm
Print Speed = 58 mm/s
Extrusion Rate = 110%
Layer Height = 0.5mm

Test filament C

Nozzle diameter = 0.75mm
Print Speed = 58 mm/s
Extrusion Rate = 110%
Layer Height = 0.5mm

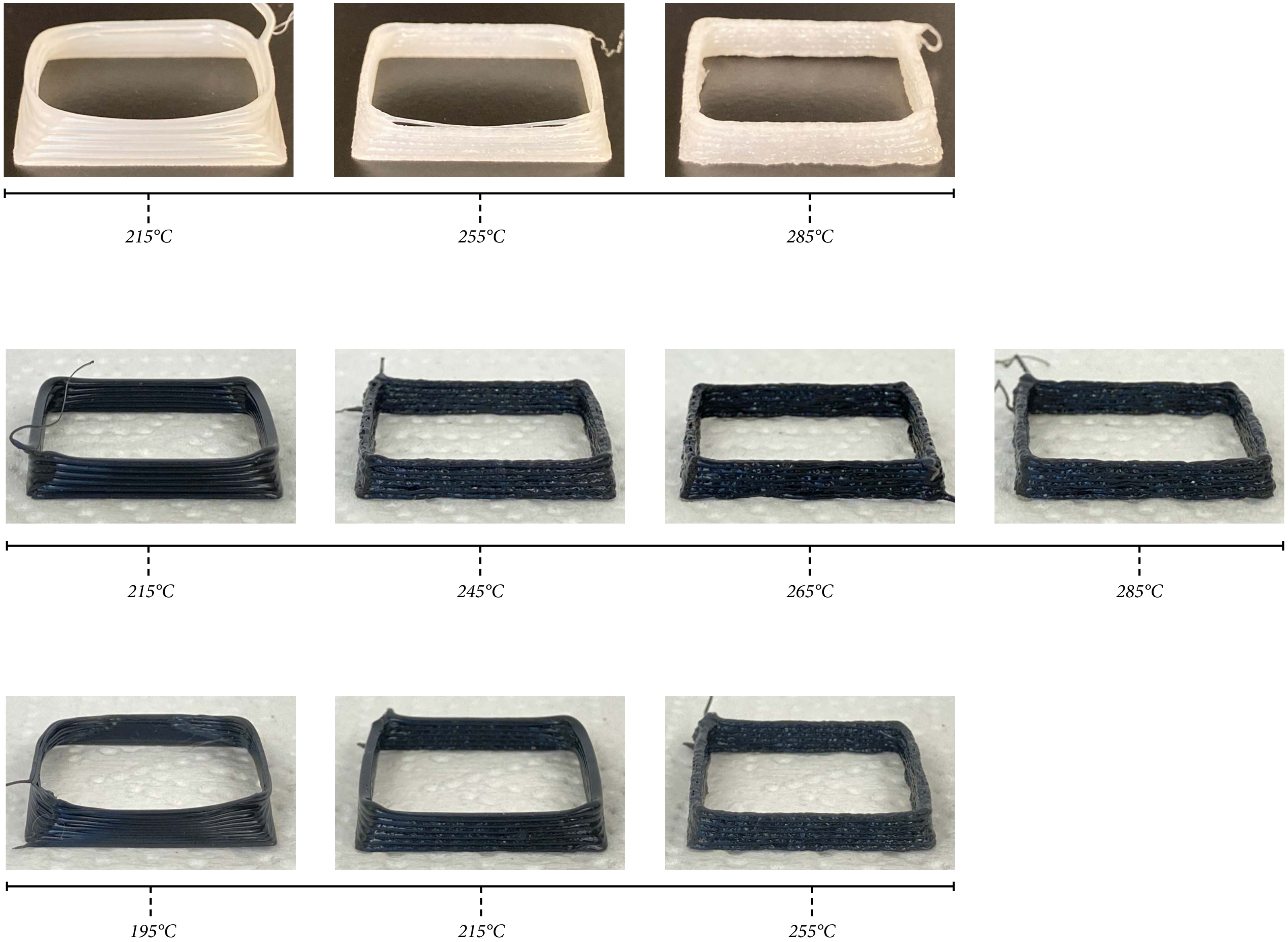


Figure 22. Test filament 3D print results

Test Filament Print Tests

Overview of 3D print tests

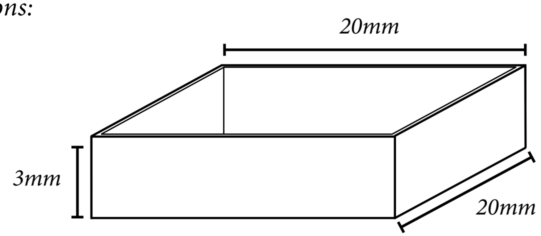
For these 3D print tests, a Makergear M2 printer was used with a 0.75mm diameter nozzle. The optimal print speed, extrusion rate and layer height for the different filament formulations were all determined using unrecorded preliminary print tests.
The recorded 3D print tests looked at the expansion rate of a single wall print in relation to the printing temperature. The range of print temperatures was dependent on the chemical foaming agent used in the filament formulations, with measurements being recorded at increments of 10°C. The different filament formulations were:

Test filament A
Bio-based material + 3wt% chemical blowing agent

Test filament B
Bio-based material w/ activated carbon + 7wt% chemical blowing agent

Test filament C
Bio-based material w/ activated carbon + 12wt% chemical blowing agent

Print Model Dimensions:



wt% = Weight percent

Results

The results from these 3D print tests for all the filament formulations showed only a slight increase in single wall size when the print temperature was increased.
Test filament A was printed first and, as shown in figure 22, some foaming did occurred as the temperature was increased, however, it should be noted that this foaming was inconsistent, with the difference in the four wall thicknesses being quite substantial. The largest wall thickness increase was at 265°C, and was 30% thicker than the average wall thickness of the non-foamed print sample.
Test filament B had a larger percentage of chemical blowing agent in the formulation, as well as added activated carbon. This seemed to improve the foaming consistency and gas bubble distribution. The increase in the amount of chemical blowing agent added slightly increased the amount of foaming that occurred. The largest wall thickness increase was recorded at 275°C and was 42% thicker than the non-foamed sample.
Test filament C had an even larger percentage of chemical blowing agent in the formulation, but surprisingly, this resulted in less foaming occuring during printing. The largest wall thickness increase with test filament C was recorded at 255°C and was only 37% thicker than the non-foamed sample.

Test Filament Conclusions

The results of the 3D print tests using bio-based test filament led to three key conclusions.

Firstly, the results showed increasing the ratio of the chemical blowing agent used in the test filaments did not radically improve the level of foaming that occurs during printing. It was previously thought that with more of the chemical agent added, it would allow for more gases to be released during printing, and therefore, more foaming would occur. This, however, was not the case, as the expansion percentage with the 7wt% test filament was recorded as higher than the 12wt% test filament.

Secondly, the addition of the activated carbon to the formulations was able to improve the distribution of gas bubbles, resulting in a more consistent foaming expansion over the four sample walls.

Finally, although the foaming of the filament did occur, the final print samples were unable to replicate the physical properties of softer foams such as Poron. To be able to replicate these softer foams, the foaming process requires improvement so that the printing of lower density foams can be achieved. The use of a softer bio-polymer in the filament formulations would also be required; however, there are currently a very limited selection of suitable bio-materials that could be used in this process.

Discussion

The results of these 3D print tests made it clear that more research and development of bio-based foaming filaments is required before they can be considered for use in diabetic orthotic production. With more focus being put on using bio-materials in product manufacturing in recent years, there are progressively more bio-alternative materials being developed and made commercially available. The introduction of these new bio-alternatives can fuel the development of specialised filaments made from sustainable, safe bio-materials.

During this internship at the University of Waikato, further investigation into foaming filaments revealed an exciting new filament called varioShore TPU. This filament is commercially made by ColorFabb, and although it is not bio-based, it was speculated to have very promising capabilities. This filament was rigorously tested in the next stage of the material exploration to further understand its capabilities. The suqsequent phase of this experimentation documents these tests, and discusses how the foaming material could be used in the manufacturing of pressure distributing, diabetic orthotics.

Figure 23. varioShore Tpu 700g filament roll

ColorFabb's varioShore TPU

Description

The varioShore TPU uses the same undisclosed foaming technology as another Colorfabb material called LW-PLA. This PLA (Polylactic Acid) variant also has the ability to foam and is advertised as a way to print PLA models that are half the weight of regular PLA prints due to the fact that only half the amount of material is needed. Their new TPU version has additional features such as variable shore hardness and a soft, foam-like texture finish. A natural coloured, 2.85mm version of the filament and a black 1.75mm version are currently available to purchase on a number of online 3D printing stores and on the Colorfabb website (ColorFabb, 2020).

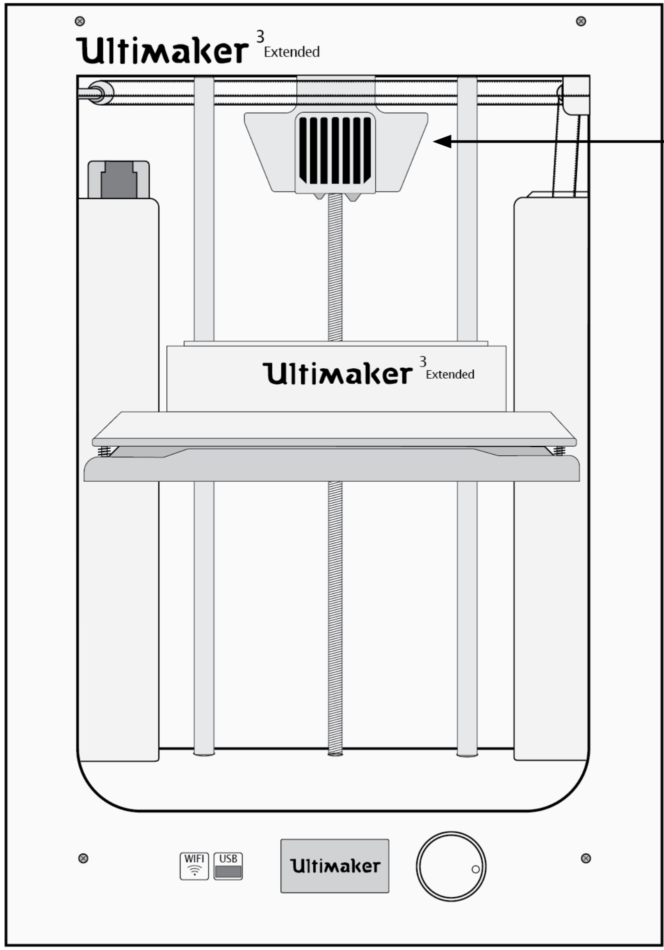
Specifications

Print Temperature Range:	*190C - 250C*
Density (before printing):	*1.2-1.3 g/cm3*
Shore Hardness (before printing):	*92A*
Tensile Strength (before printing):	*58.6 MPa*
Glass Transition Temperature:	*-20C*

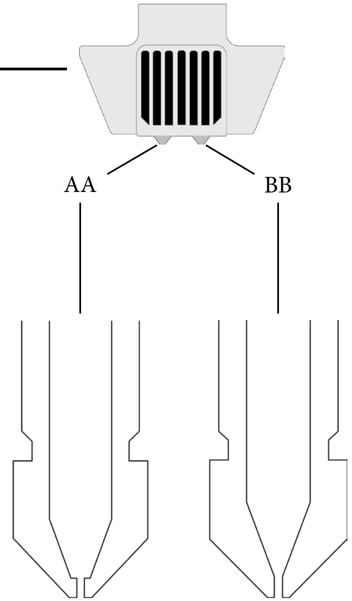
Discussion

This varioShore TPU is the first of its kind in the 3D printing industry. With the ability to have some degree of control over how much the filament can foam, it creates an exciting range of possibilities when combined additive manufacturing. The technical datasheet that colorFabb have available online provides a basic idea about how the material works, and claims that when the foaming process occurs, the volume can increase to 1.4-1.6 times the volume of the 'non-foamed' printed material.
One unknown is the range of shore hardness values that can be attained by printing at certain settings. This data could be very useful when printing objects that may need multiple densities in one print. Combining this information with 3D slicer software or parametric modelling algorithms, could mean it is possible to control the form of a product, as well as the mechanical properties of the material used to manufacture that product.

3D Print Tests



Ultimaker 3 Extended 3D printer



AA and BB Nozzle Differences

Figure 24. Ultimaker 3D printer with close up of dual nozzles

Ultimaker 3 Extended

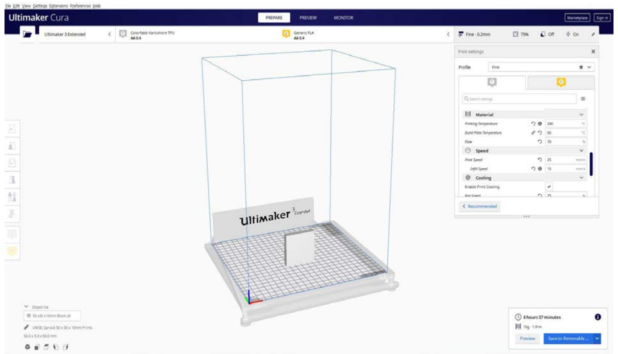
Overview

An Ultimaker 3 extended 3D printer was used in these 3D print tests and during the application stage of this research portfolio. With dual extrusion capabilities, and the seamless integration with the Ultimaker Cura slicer software, this 3D printer is engineered to be consistently reliable and produce high quality results. Specifications for the Ultimaker 3 extended can be seen below.

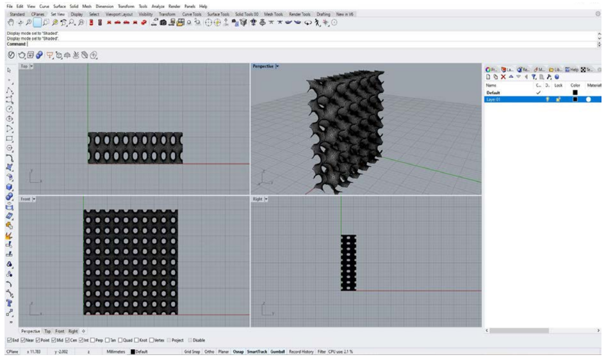
Specifications

Nozzle diameter:	*0.25mm, 0.4mm, 0.8mm*
Dimensions:	*342mm (w) x 380mm (d) x 489mm (h)*
Max Build Size:	*215mm x 215mm x 300mm (Left or Right nozzle)*
	197mm x 215mm x 300mm (Dual extrusion)
Z axis print resolution:	*20-200 microns*
X, Y, Z accuracy:	*12.5, 12.5, 2.5 microns*
Nozzle Temperature:	*180C to 280C*
Weight:	*11.3kg*
Build Plate Temperature:	*20C to 100C*
Print Head travel speed:	*20 - 300 mm/s*
Print Software:	*Cura*
Supported File Types:	*STL, OBJ, 3MF*

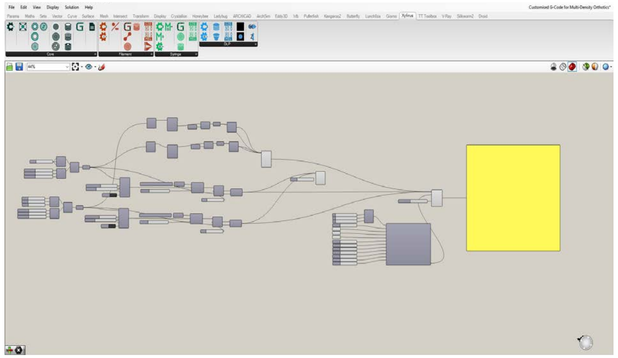
Specifications provided by www.creat3d.shop/3d-printers/ultimaker-3-extended.html



Cura (3D slicer software)



Rhino 6 (3D modelling software)



Grasshopper (Parametric modelling software)

Figure 25. Logos and examples of programme interfaces (Cura, Rhino 6 and Grasshopper)

Ultimaker Cura

The Cura slicer software has been developed to work best with Ultimaker 3D printers (such as the Ultimaker 3 extended), but it is also compatible with a wide variety of other 3D printers. One of the advantages of using Cura is the high level of control the user has when adjusting the print settings. Where some slicer softwares limit the customisation of settings due to the issues it may cause in the final G-code, Cura has very few limitations and even allows users to manually edit the G-code before it is uploaded to the printer.

Rhino 6

Rhino 6 is a 3D modelling software that is used in a variety of industries for rapid digital prototyping, reverse engineering and 3D printing. One advantage of using Rhino is the ability to use plugins and extensions, developed by people from a diverse range of industries, that cover a huge range of applications. Examples of these applications include weather simulations, FEA simulations and parametric modelling. Throughout the design process, Rhino 6 will be the software used to create rapid concepts iterations and the final prototype models.

Grasshopper

Grasshopper is a Rhino 6 plugin that has evolved in recent years to become a valuable tool for those working in architectural and design industries. It is a graphical algorithm editor with extensive capabilities and has the benefit of allowing customised plugins to be easily installed, to accomodate any modelling needs the user may have. These customised plugins can include simulation software, physics engines or G-code generation tools. In this research portfolio, Grasshopper will be an integral part of both the experimentation and design process.

Consistent print settings:

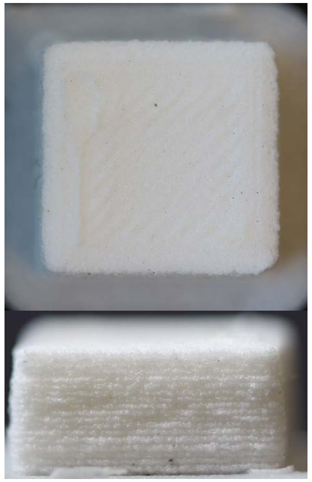
Print Temperature = 240°C

Infill Density = 60%

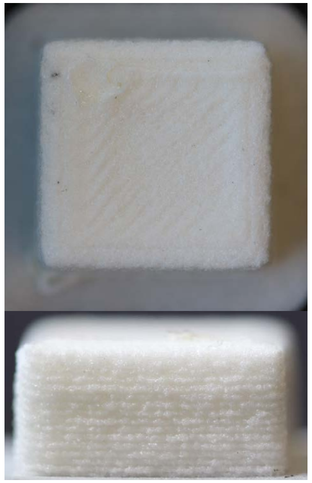
Print Speed = 25mm/s

Flow Rate = 70%

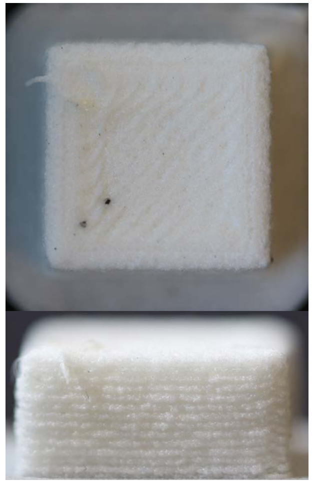
Test Print #1
Layer Height = 0.2mm
Infill Print Speed = 25mm/s



Test Print #2
Layer Height = 0.25mm
Infill Print Speed = 25mm/s



Test Print #3
Layer Height = 0.3mm
Infill Print Speed = 25mm/s

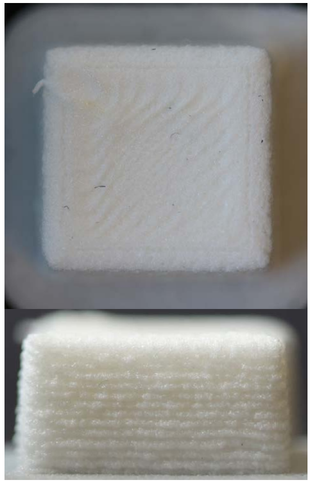


Test Print #4
Layer Height = 0.2mm
Infill Print Speed = 15mm/s

Test Print #5
Layer Height = 0.35mm
Infill Print Speed = 20mm/s

Test Print #6
Layer Height = 0.25mm
Infill Print Speed = 15mm/s

Test Print #7
Layer Height = 0.3mm
Infill Print Speed = 15mm/s



Test Print #8
Layer Height = 0.35mm
Infill Print Speed = 15mm/s

Test Print #9
Layer Height = 0.4mm
Infill Print Speed = 15mm/s

Figure 26. Initial 3D print test results

Initial Print Tests

Overview

The primary aim of these initial 3D print tests was to obtain a preliminary understanding of how specific print settings would affect the print quality and print duration. The consistent settings in these initial print tests, such as print temperature, flow rate, and print speed, were determined based on recommendations provided by the material manufacturer, ColorFabb (Colorfabb, 2020).

Observations

With the print temperature being set at 240°C, the varioShore TPU material seemed to foam very well and expand in size considerably. This expansion had to be taken into consideration when observing the print process and final quality. At all layer heights, the filament looked to be rapidly expanding as it came out of the nozzle and then seemed to almost 'deflate' slightly as it cooled down.
The filament had no issue sticking to the print bed and at no point did it lift off the bed or seem to shrink in size when the material cooled down to room temperature, which can be common for other 3D print materials such as acrylonitrile butadiene styrene (ABS).
At the lower layer heights, such as 0.2 and 0.25mm, it was clear that, due to the rate of expansion of the previous layer, the printer nozzle dragged through it, pushing it outwards and creating a 'smoothing' effect. Although at first it was thought that this may effect the final print quality, it was later discovered that it helped bond the print layers together, resulting in a smooth, matte surface texture.
There was only one print that seemed to fail (as shown in figure 26, test print #5), but after reprinting the sample and getting a much better final print, it is believed that this was due to the print nozzle becoming clogged with residual material from a previous user of the 3D printer. Remnants of this material can be seen on some of the print samples that appear to have black streaks or marks on them.

Conclusions

After printing these initial print samples, it was concluded that the varioShore TPU would be a very compliant material to use for further tests. It was clear that the only comprehensive changes that the layer height had on the final print quality, was the print duration being faster at higher layer heights, however, this did resulted in the final print quality and surface finish being worse.
The printing of these initial samples was also an opportunity to become more proficient with the slicing software, Cura, and to test some of the more complex settings that will be used in future 3D print tests.

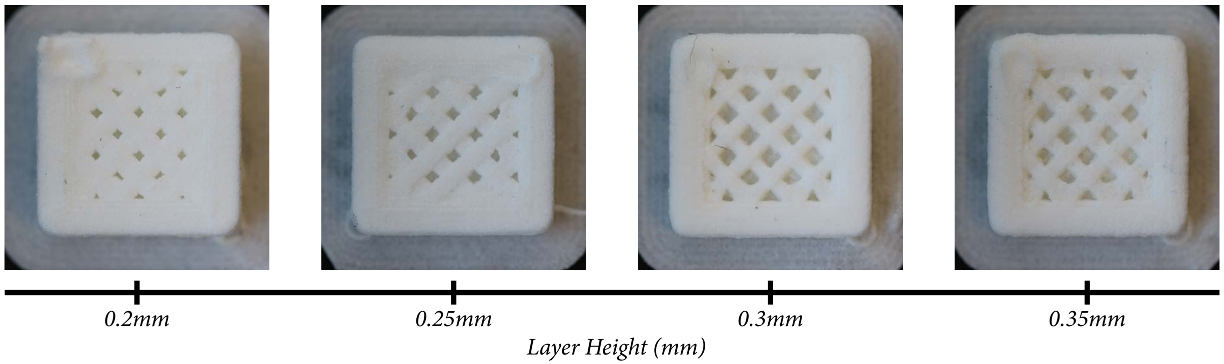
Consistent print settings:

Infill Density = 60%

Print Speed = 25mm/s

Infill Print Speed = 15mm/s

Flow Rate = 70%



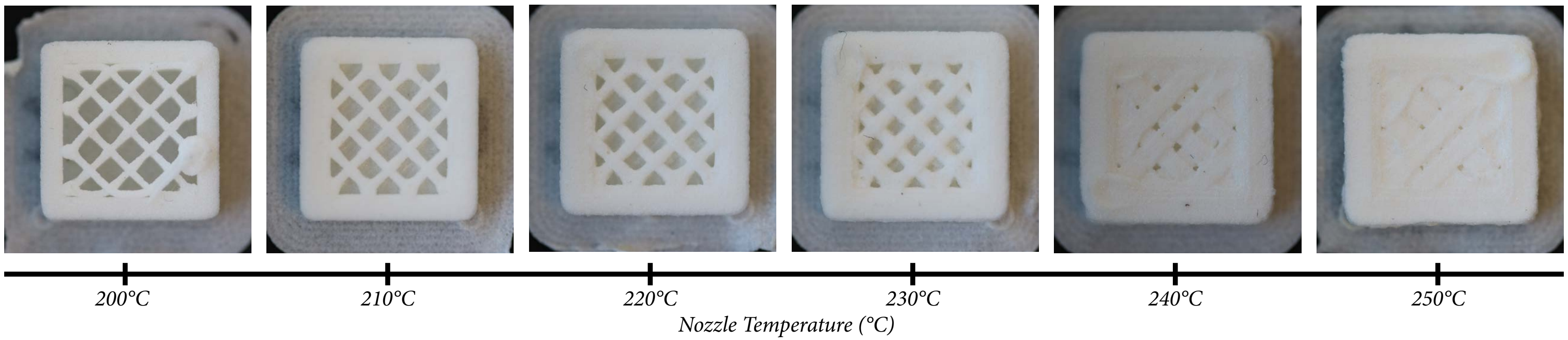


Figure 27. Infill expansion 3D print test results

Infill Density Expansion Print Tests

Overview

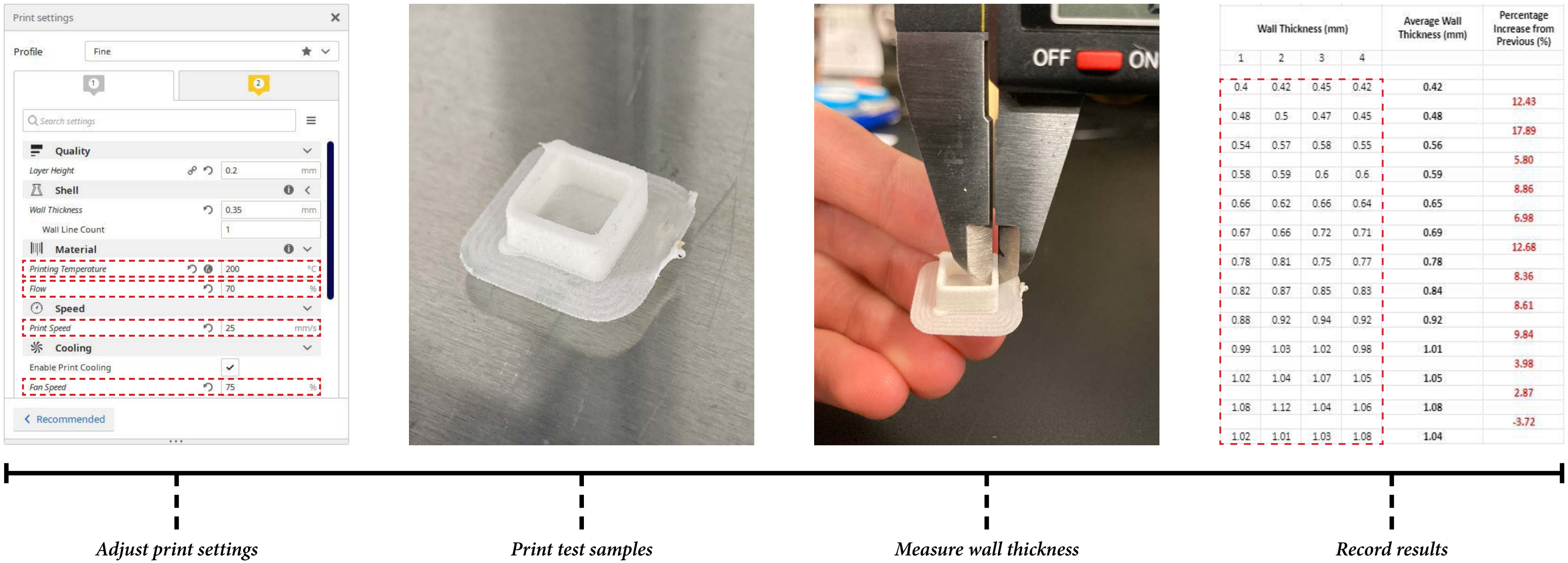
This set of 3D print tests looked at the effect of layer height and temperature on the amount of foaming that occurs and the general quality of the print infill. The layer height test print (shown in figure 27) were printed with consistent settings with a 60% infill density, at a temperature of 230°C, with only the layer height being changed for each print sample. The nozzle temperature test prints (also shown in figure 27) had the same consistent settings, with a 60% infill density, but the layer height remained constant at 0.3mm and the temperature was increased by 5°C for each print sample.

Observations

For the layer height increase test samples, the layer height of 0.2mm almost created a fully infilled print and as that layer height increased, the infill became less dense and the infill pattern became more defined. It was clear that a significant amount of foaming was occurring at this temperature and because of this, at the lower layer heights, the printer nozzle seemed to drag through the previously printed layer. The dragging of the nozzle through the material seemed to push it down and outwards, resulting in the thicker infill pattern lines. Despite this effect of the dragging nozzle, the overall print quality was still very good.
The change in temperature test samples showed that increasing the print temperature definitely increased the level of foaming that occurred. When the layer height was set to 0.3mm, the dragging of the nozzle through the previous print layers was not observed. Therefore, the increase in temperature was the only observed variable that affected the increased infill density. Also, that the temperature increase had an effect on the surface finish of the printed material, with the higher temperatures creating a more matte, foam-like texture and consistency.

Conclusions

From these tests, it is evident that both the layer height and nozzle temperature had an effect on the density of the print infill. However, due to the dragging of the nozzle at lower layer heights arguably having a significant effect on the final print infill density, it was concluded that the change in temperature has more of a definitive effect on the amount of foaming that occurs.
The next step is to test the rate of expansion that takes place when the material is printed using certain print settings. This will allow for reliable data to be collected and then referred to in the later stages of the research portfolio.



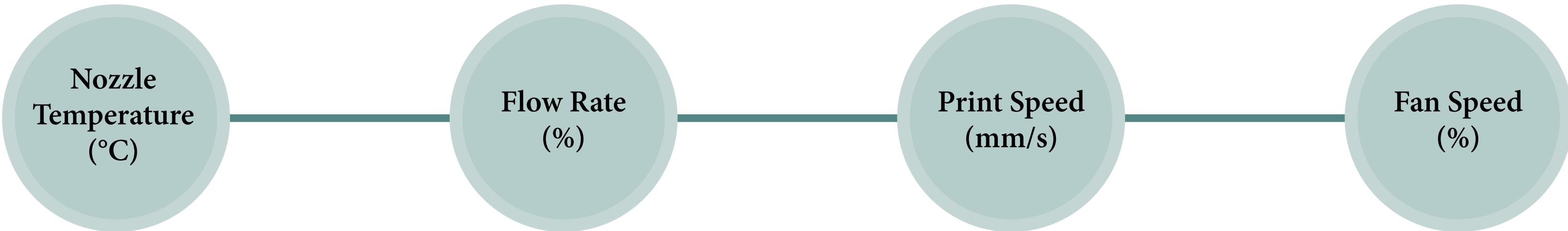
Wall Thickness (mm)				Average Wall Thickness (mm)	Percentage Increase from Previous (%)
1	2	3	4		
0.4	0.42	0.45	0.42	0.42	
0.48	0.5	0.47	0.45	0.48	12.43
0.54	0.57	0.58	0.55	0.56	17.89
0.58	0.59	0.6	0.6	0.59	5.80
0.66	0.62	0.66	0.64	0.65	8.86
0.67	0.66	0.72	0.71	0.69	6.98
0.78	0.81	0.75	0.77	0.78	12.68
0.82	0.87	0.85	0.83	0.84	8.36
0.88	0.92	0.94	0.92	0.92	8.61
0.99	1.03	1.02	0.98	1.01	9.84
1.02	1.04	1.07	1.05	1.05	3.98
1.08	1.12	1.04	1.06	1.08	2.87
1.02	1.01	1.03	1.08	1.04	-3.72

Figure 28. Single wall expansion test process

Single Wall Expansion Tests

Overview

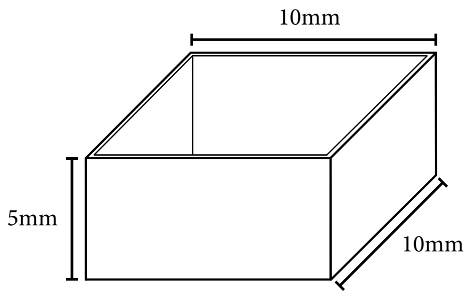
The aim of the single wall expansion tests was to record the degree to which the different 3D printer settings affected the level of foaming that occurred, when using the varioShore TPU. ColorFabb have printing advice on their website which provides a printing temperature range and recommended settings for the print speed, bed temperature and cooling fan. However, they do not specify how those settings would affect the properties and final print quality of the material once it has been extruded. These single wall expansions tests will be used to measure the rate of material expansion when adjusting some of these print settings in small increments. A timeline of this process can be seen in figure 28. The print settings used in these tests were:



Consistent Print Settings:

Layer Height = 0.2mm
Print Bed Temp = 60 °C
Wall Thickness = 0.35mm
No. of Walls = 1

Print Model Dimensions:



Nozzle Temperature (°C) — Flow Rate (%) — Print Speed (mm/s) — Fan Speed (%)

Change in Nozzle Temperature

(5°C Changes)

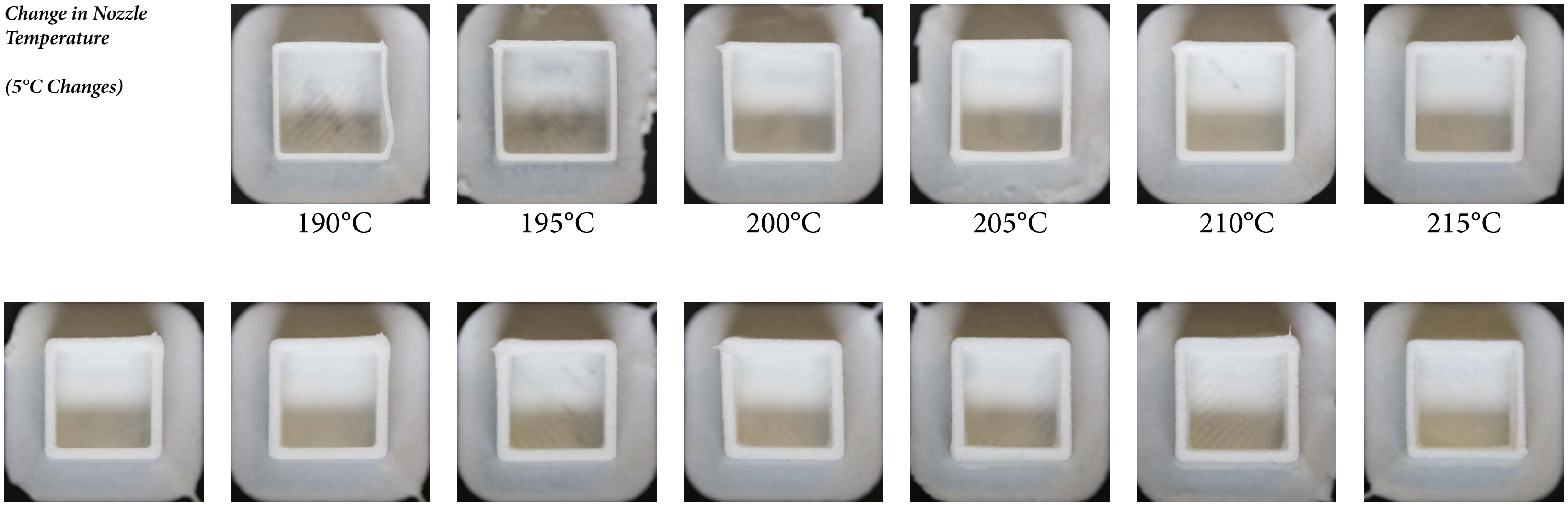
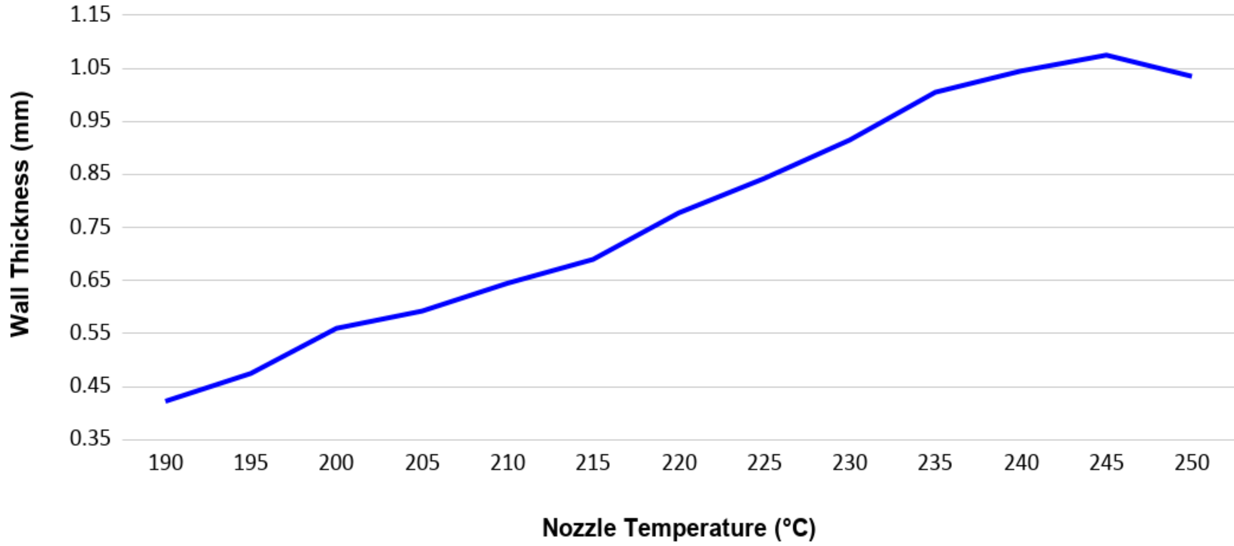


Figure 29. Single wall expansion 3D print test results (change in nozzle temperature)

Change in Nozzle Temperature

Nozzle Temp (°C)	Wall Thickness (mm) 1	2	3	4	Average
190°C	0.40	0.42	0.45	0.42	**0.42mm**
195°C	0.48	0.50	0.47	0.45	**0.48mm**
200°C	0.54	0.57	0.58	0.55	**0.56mm**
205°C	0.58	0.59	0.60	0.60	**0.59mm**
210°C	0.66	0.62	0.66	0.64	**0.65mm**
215°C	0.67	0.66	0.72	0.71	**0.69mm**
220°C	0.78	0.81	0.75	0.77	**0.78mm**
225°C	0.82	0.87	0.85	0.83	**0.84mm**
230°C	0.88	0.92	0.94	0.92	**0.92mm**
235°C	0.99	1.03	1.02	0.98	**1.01mm**
240°C	1.02	1.04	1.07	1.05	**1.05mm**
245°C	1.08	1.12	1.04	1.06	**1.08mm**
250°C	1.02	1.01	1.03	1.08	**1.04mm**



Observations

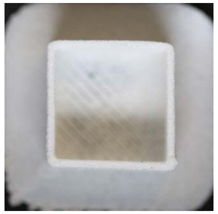
As the images of the test samples (see figure 29) and the line chart show, there is a direct correlation between the increase in nozzle temperature and the increase in wall thickness. A difference in surface finish of the print samples was also observed, with the lower temperature samples looking and feeling like regular TPU and the higher temperature samples having more of a matte surface texture. At the higher temperatures of 245°C and 250°C, the filament was flowing very quickly out of the nozzle due to it being more liquified, which may be a reason for the slight decrease in wall thickness at these temperatures.

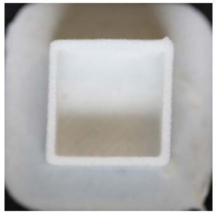
Figure 30. Graph showing change in nozzle temperature test results

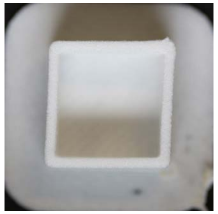
Nozzle Temperature (°C) — **Flow Rate (%)** — Print Speed (mm/s) — Fan Speed (%)

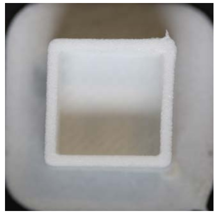
Change in Flow Rate

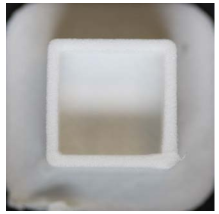
(5% Changes)

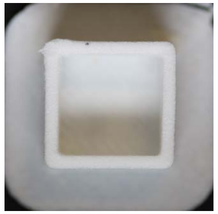

50%

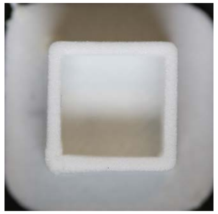

55%

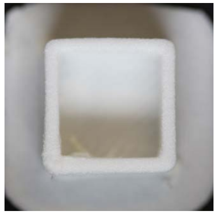

60%

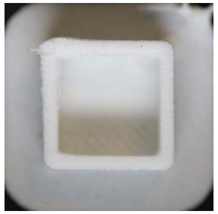

65%

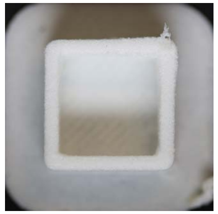

70%


75%


80%


85%


90%


95%

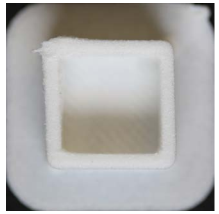
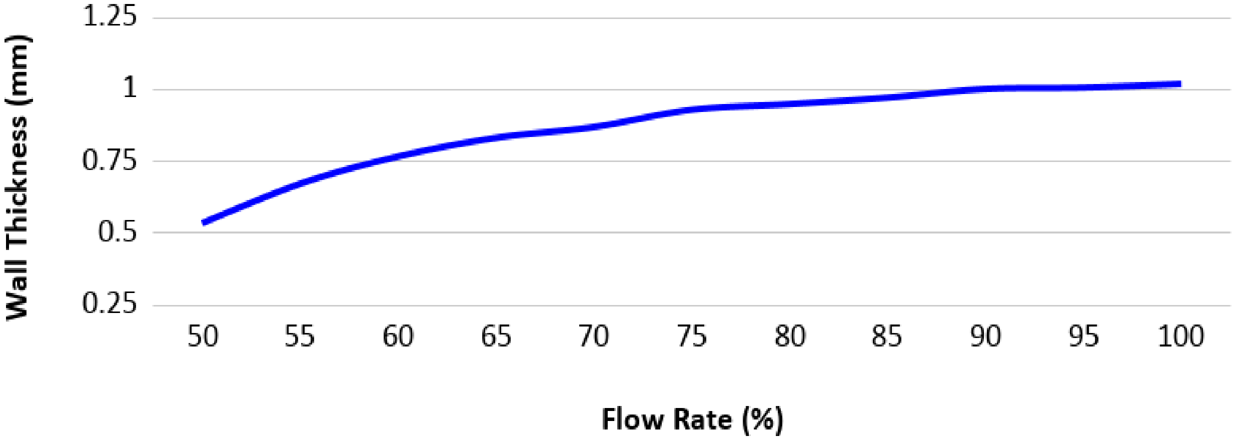

100%

Figure 31. Single wall expansion 3D print test results (change in flow rate)

Change in Flow Rate

Flow Rate (%)	Wall Thickness (mm) 1	2	3	4	Average
50%	0.53	0.55	0.55	0.51	**0.54mm**
55%	0.67	0.68	0.66	0.68	**0.67mm**
60%	0.77	0.80	0.74	0.76	**0.77mm**
65%	0.82	0.82	0.85	0.84	**0.83mm**
70%	0.87	0.87	0.88	0.86	**0.87mm**
75%	0.98	0.90	0.92	0.92	**0.93mm**
80%	0.92	0.94	0.98	0.96	**0.95mm**
85%	1.00	0.99	0.96	0.94	**0.97mm**
90%	1.01	1.00	0.98	1.02	**1.00mm**
95%	1.03	0.99	0.99	1.02	**1.01mm**
100%	0.98	1.03	1.05	1.02	**1.02mm**



Observations

As the images of the test samples (see figure 31) and the line chart show, the increase in flow rate results in an increase of wall thickness. The print quality of all the samples was very good, with only a slight issue with 'bulging' occurring in one of the corners of multiple samples. There were no further observations to note during these tests.

Figure 32. Graph showing change in flow rate test results

Nozzle Temperature (°C) — Flow Rate (%) — **Print Speed (mm/s)** — Fan Speed (%)

Change in Print Speed

(5mm/s Changes)

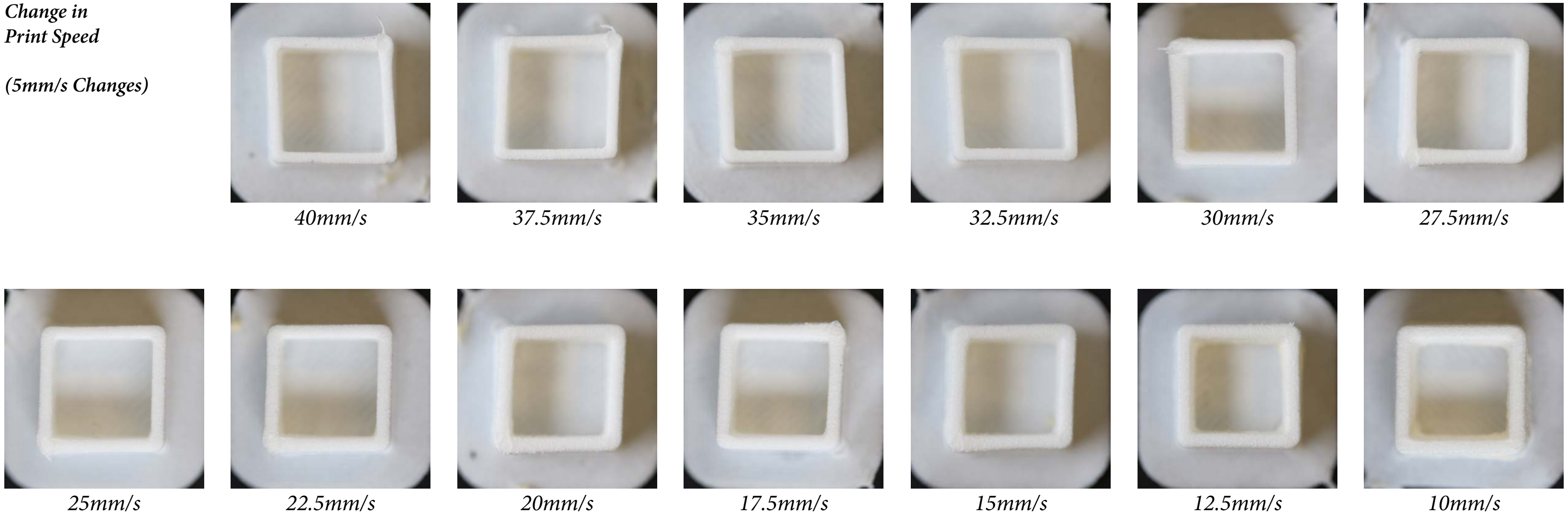
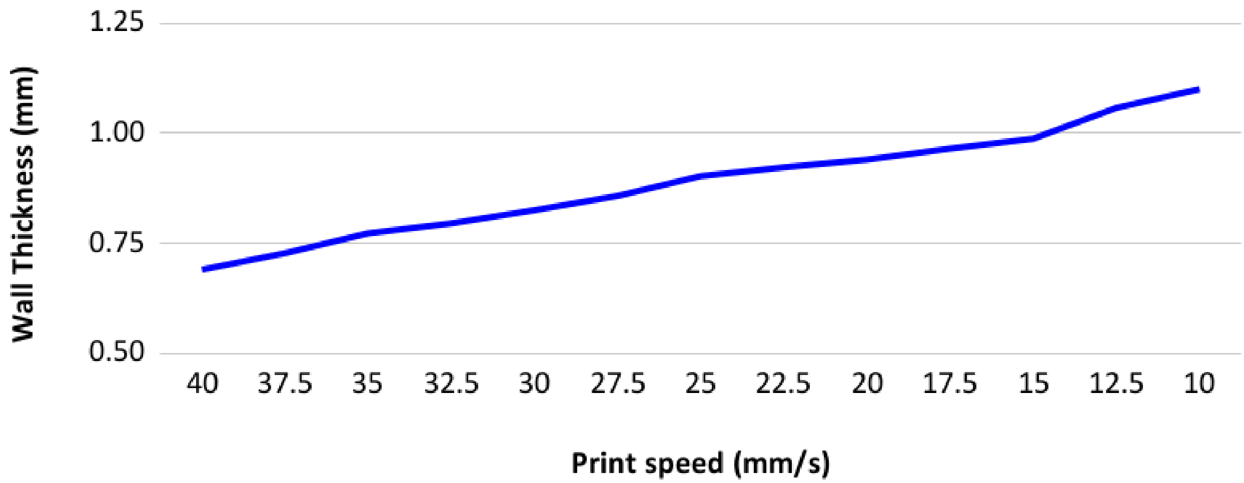


Figure 33. Single wall expansion 3D print test results (change in print speed)

Change in Print Speed

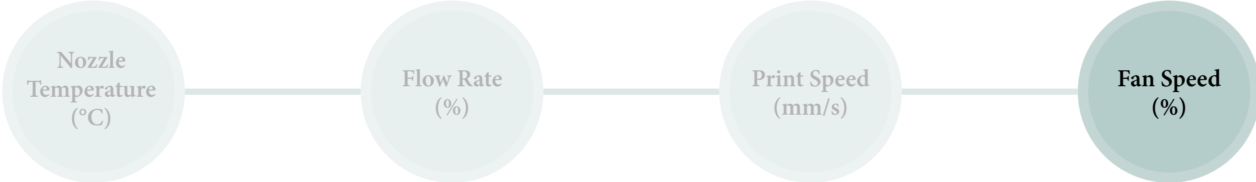
Print Speed (mm/s)	Wall Thickness (mm) 1	2	3	4	Average
40	0.68	0.71	0.68	0.69	**0.69mm**
37.5	0.74	0.74	0.71	0.72	**0.73mm**
35	0.77	0.79	0.76	0.77	**0.77mm**
32.5	0.81	0.79	0.78	0.80	**0.80mm**
30	0.80	0.84	0.82	0.84	**0.83mm**
27.5	0.85	0.84	0.88	0.86	**0.86mm**
25	0.90	0.91	0.89	0.91	**0.90mm**
22.5	0.95	0.90	0.94	0.90	**0.92mm**
20	0.91	0.96	0.94	0.95	**0.94mm**
17.5	0.97	0.95	0.97	0.97	**0.97mm**
15	1.00	1.03	0.95	0.97	**0.99mm**
12.5	1.09	1.05	1.04	1.05	**1.06mm**
10	1.12	1.07	1.13	1.08	**1.10mm**



Observations

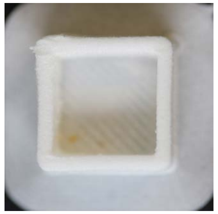
As the images of the test samples (see figure 33) and the line chart show, the decrease of print speed results in an increase of wall thickness. Printing at the lower speeds of 10 and 12.5 mm/s also had an effect on the final print quality, with the samples looking a bit darker in colour and slightly burnt in some areas. The lower print speeds also significantly increased the overall print time of the samples, as was expected.

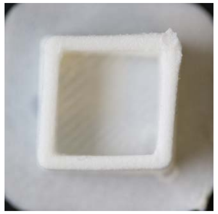
Figure 34. Graph showing change in print speed test results

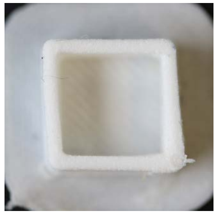


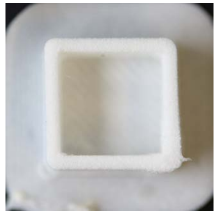
Change in Fan Speed

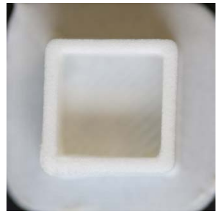
(5% Changes)

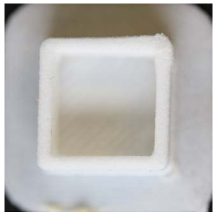

100%

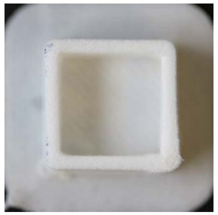

95%

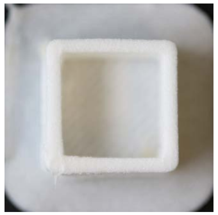

90%

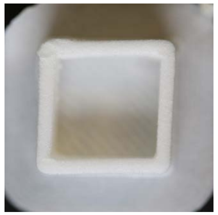

85%

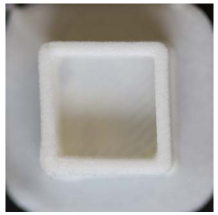

80%


75%


70%


65%


60%


55%

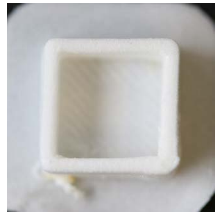
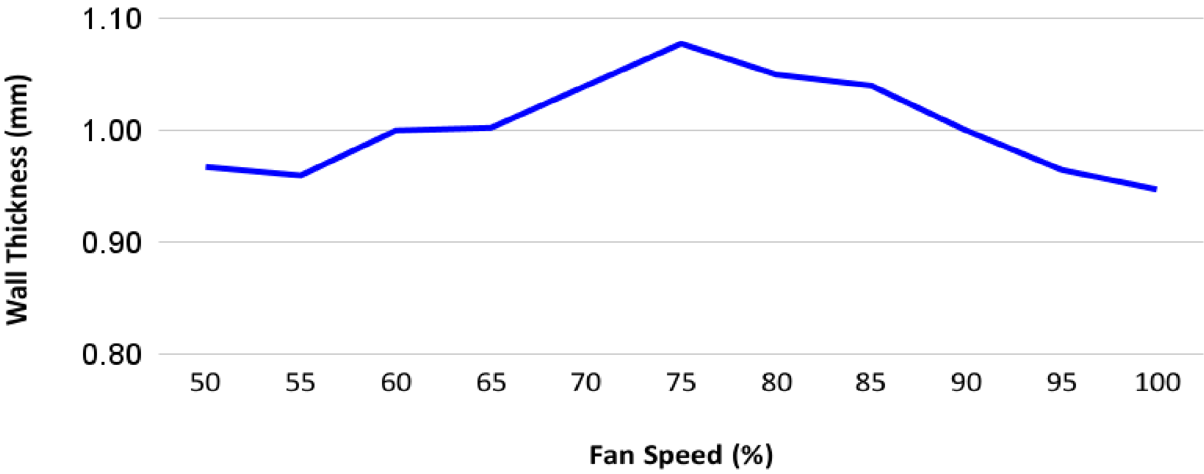

50%

Figure 35. Single wall expansion 3D print test results (change in fan speed)

Change in Fan Speed

Fan Speed (%)	Wall Thickness (mm) 1	2	3	4	Average
50%	0.95	0.98	0.97	0.97	**0.97mm**
55%	0.94	1.00	0.97	0.93	**0.96mm**
60%	1.02	1.01	0.96	1.01	**1.00mm**
65%	1.03	0.97	1.01	1.00	**1.00mm**
70%	1.05	1.01	1.04	1.06	**1.04mm**
75%	1.08	1.10	1.08	1.05	**1.08mm**
80%	1.03	1.08	1.04	1.05	**1.05mm**
85%	1.02	1.05	1.06	1.03	**1.04mm**
90%	1.00	1.02	0.99	0.99	**1.00mm**
95%	0.94	0.99	0.98	0.95	**0.97mm**
100%	0.94	0.95	0.97	0.93	**0.95mm**



Observations

As the images of the test samples (see figure 35) and the line chart show, the fan speed had a minor effect on the wall thickness of the print samples. There was a slight increase as the fan speed was increased from 50% to 75%, however, the increase in fan speed after 75% saw the wall thickness gradually decrease, with the thickness at 100% fan speed being slightly less than the thickness recorded at 50% fan speed. The overall print quality at all speeds was very good, with no issues observed.

Figure 36. Graph showing change in fan speed test results

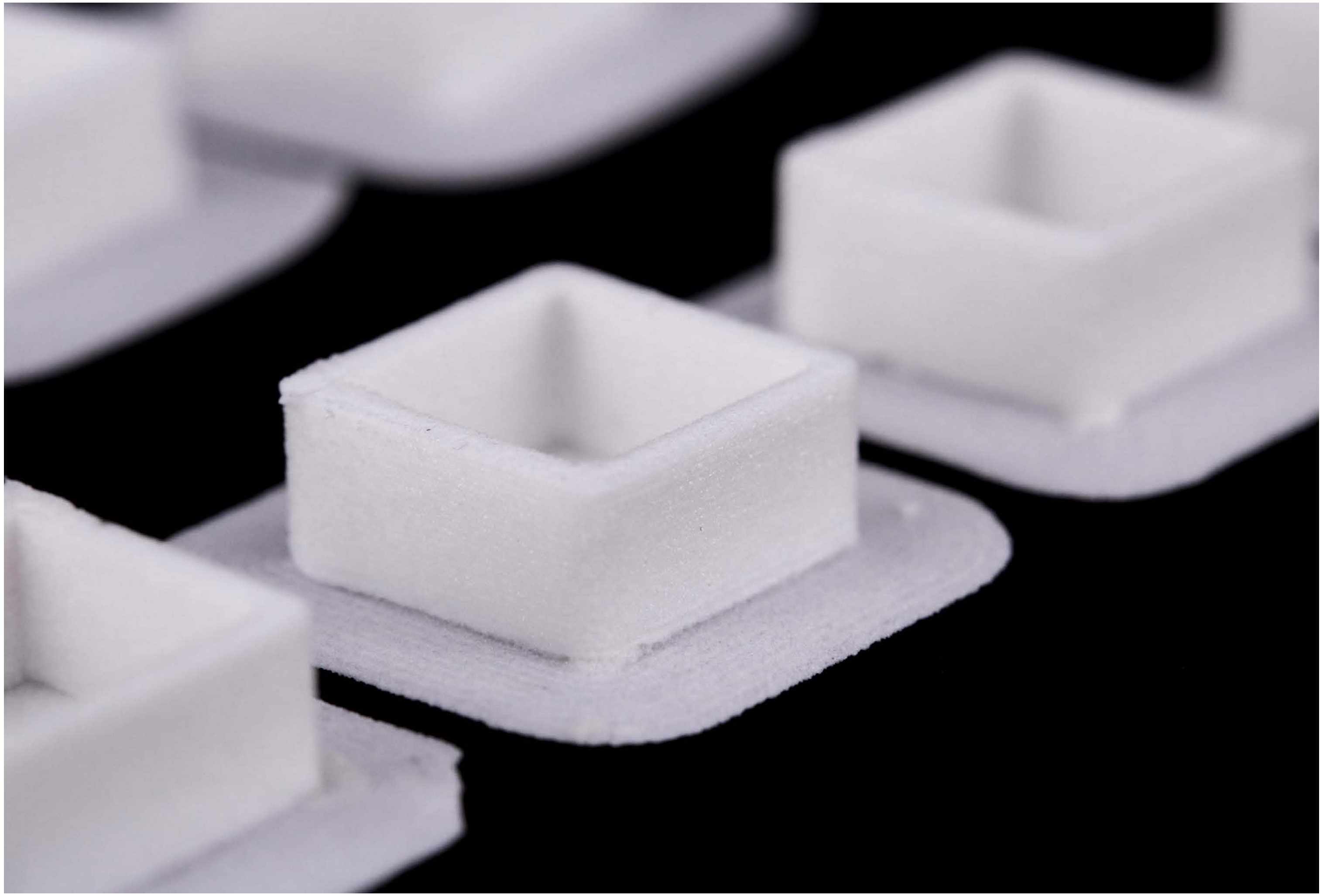


Figure 37. Close-up of single wall expansion test sample

Single Wall Tests Conclusions

Nozzle Temperature (°C)

When testing the change in nozzle temperature, the first sample was printed at 190°C as this was the lowest temperature that ColorFabb recommended the filament is should be printed at. At this temperature, it was clear that no foaming was taking place. The final print quality resembled that of regular TPU and the average wall thickness was only slightly larger than the nozzle diameter of 0.4mm. As the nozzle temperature was increased, the wall thickness of the samples also increased at a consistent rate. The foaming of the filament as it was extruded also became more evident as the temperature increased (as seen in figure 29). At 245°C, the wall thickness of the sample seemed to reach its peak, with the average wall thickness being 170% wider than the diameter of the print nozzle. At 250°C, the print sample had a lower average wall thickness which is speculated to be caused by the gas bubbles being able to escape from the liquified printed material before it has time to cool and set.

Flow Rate (%)

The flow rate was another setting that ColorFabb claimed had an effect on the amount of foaming that occured. In these tests, the increase in flow rate resulted in a constant increase of single wall thickness. This may be due to the increased foaming or, it could also be due to the larger quantity of filament being extruded during printing. With more filament being printed, the dragging of the nozzle through the printed layers was observed. This dragging caused a smoothing effect that pushed the printed layers down and outwards, creating thicker walls at each layer. Although this had no negative effect on the print quality, it does not definitively prove that the increased flow rate causes more foaming during printing.

Print Speed (mm/s)

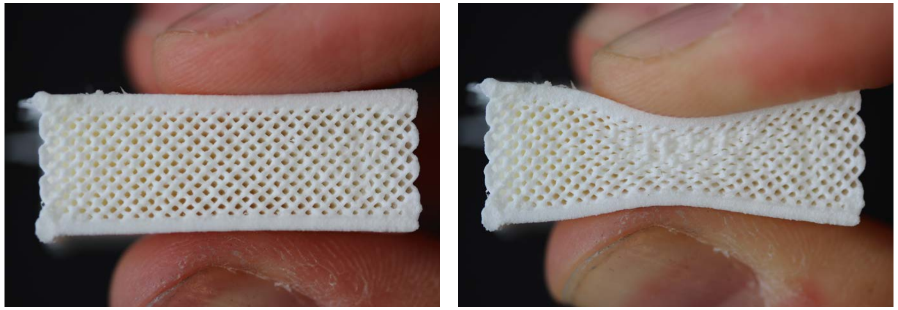
By decreasing the print speed, the filament takes more time to flow through the heated printer nozzle. It is thought that this allows more time for the gases in the filament to be released, resulting in more gas bubbles inside the material, theoretically making it more 'foam-like'. It was very evident from these tests that the slower print speeds caused more foaming to occur; however, the increased time spent in the nozzle as the material was extruded caused the material to burn slightly, resulting in a darker appearance for samples printed at speeds slower than 15mm/s. The sample that was printed at 10mm/s had expanded to almost three times the nozzle diameter, but it did have a much darker appearance and clear signs of burning were observed on some parts of the printed material.

Fan Speed (%)

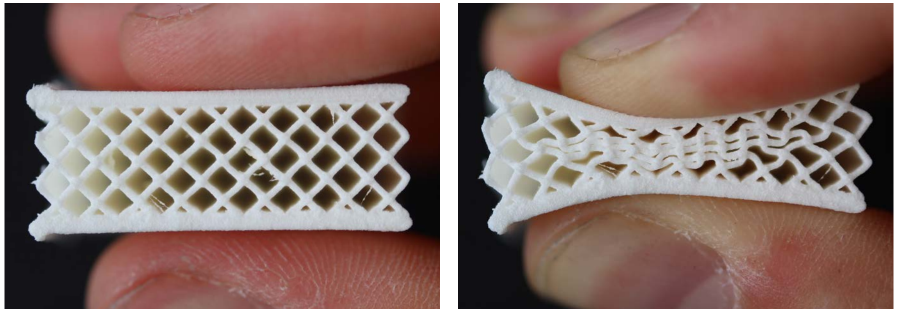
Fan speed was another print setting that ColorFabb claims to have an effect on the amount of foaming that occurs. It is thought that this is due to the reduced cooling of material once it is extruded, allowing for thus allowing more gas to be released inside the material before it cools and sets. In these tests, the fan speed did have an effect on the wall thickness, although it was fairly minor compared to other print settings. The lower fan speed of 50% and the highest fan speed of 100% recorded very similar levels of material expansion, with the peak expansion being recorded at 75%.

Discussion

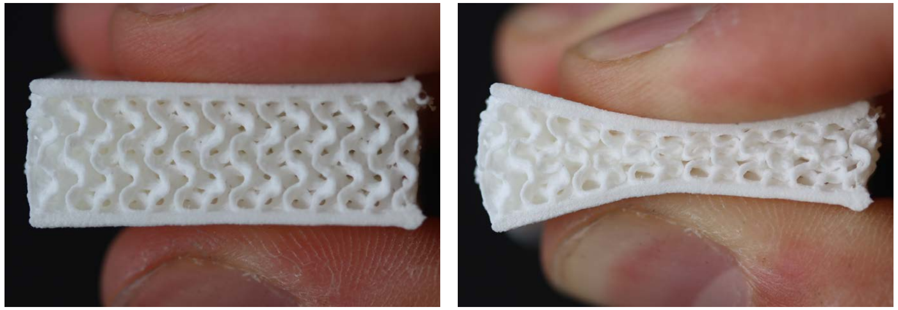
From these single wall expansion tests, it was concluded that the nozzle temperature and print speed had the most definitive effect on the level of foaming that occurred during printing, with the change in fan speed also having a minor effect. Due to the possibility that the wall thickness expansion in the flow rate test samples is more likely caused by a larger quantity of material being extruded, rather than the increase in material foaming, the flow rate should not be considered as a control variable for the level of foaming that occurs.



Lines infill at 40%



Grid infill at 40%



Gyroid infill at 20%

Figure 38. Examples of how different infill patterns compress

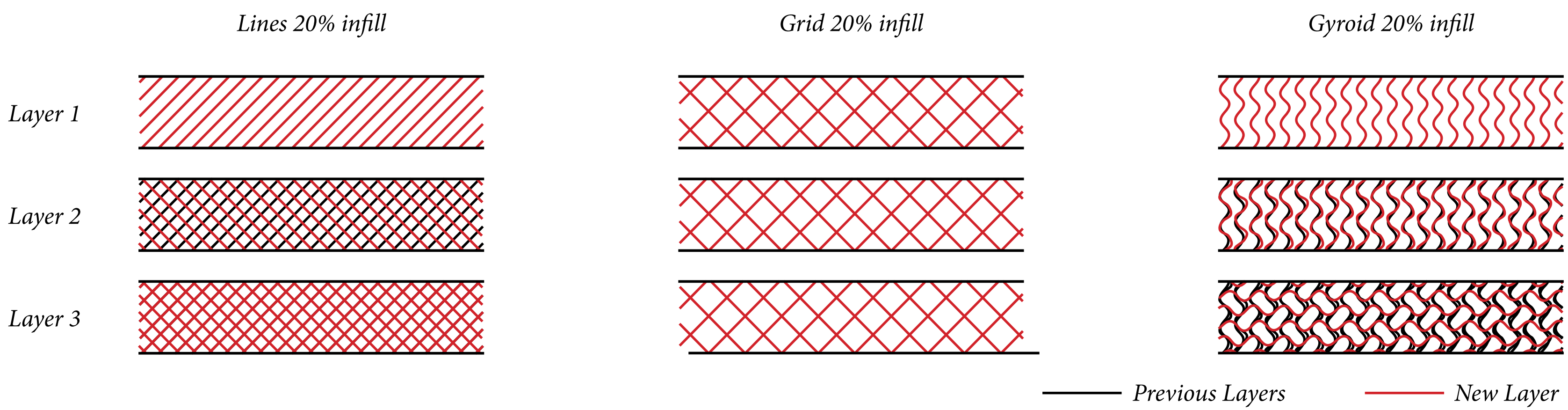
Initial Infill Prints

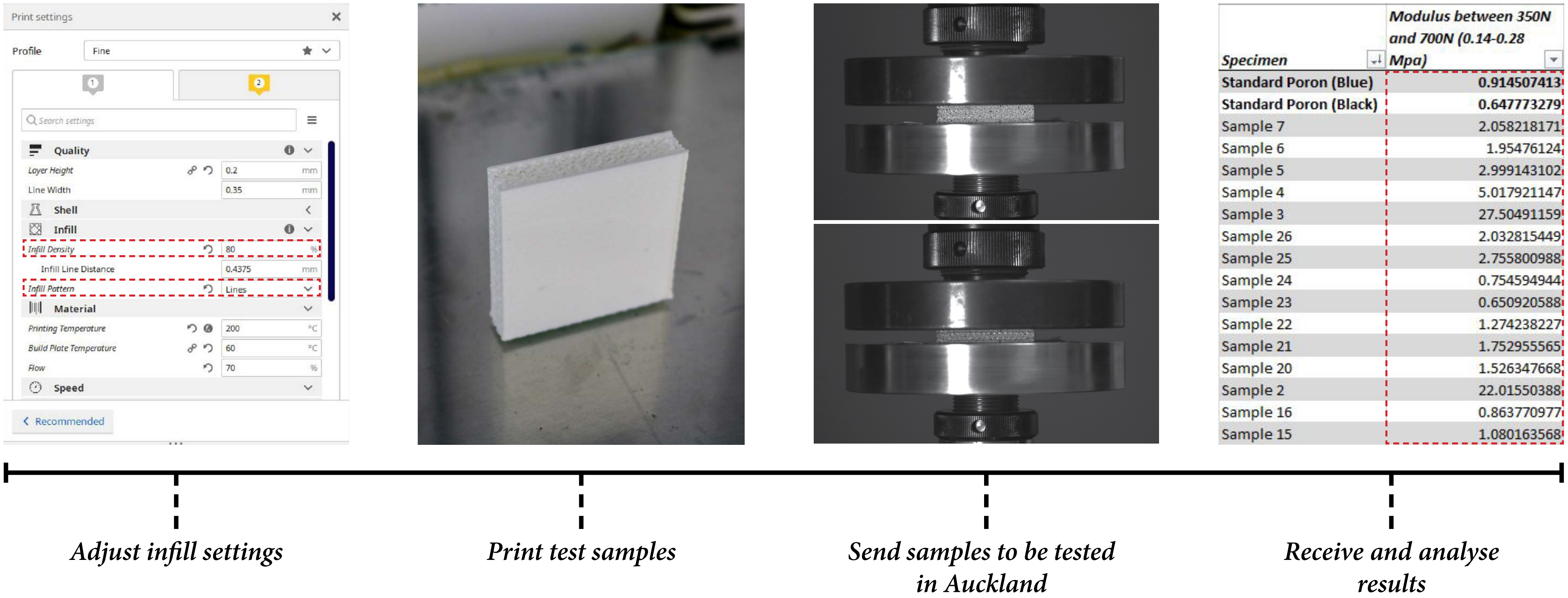
Overview

The single wall expansion tests provided valuable insight into the foaming capabilities of the varioShore TPU filament. Although the material was able to expand to over double its orginal size after it was printed, it was clear, through physical examination, that it was unlikely to provide the same cushioning properties as the poron foams used by NZALS. A solution to this problem was to combine the material's ability to foam with the manufacturing capabilities of 3D printing.
The use of the internal infill patterns, that are available in the Cura slicer software, can also be used as simple geometrical lattice structures inside the print objects. These lattice structures are thought to be able to vastly improve the compression and cushioning properties of the material.
A collection of print samples were produced that had varying infill patterns and densities. Examples of the 3 different infill patterns that were chosen can be seen in figure 38 and examples of how the first 3 layers of these infill patterns are printed can be seen below.

Discussion

From these initial infill print tests, samples with the lines, grid and gyroid pattern were printed at different densities to see if they contribute to creating 3D prints that can replicate the mechanical properties of EVA and Poron foams. Although the lines and grid infill patterns were the same shape, it is clear that the lines infill printed considerably more dense than the grid pattern, despite the density setting being the same. This is thought to be due to how the layers are printed.
It was interesting to test how soft the samples felt and how they reacted when a light compression was done using the thumb and index finger. Both the lines and gyroid pattern compressed smoothly and felt similar to either Poron or EVA in terms of a cushioning effect. This was not the case for the grid pattern due to the infill structure collapsing very quickly, even with minimal force applied.
The decision was made at this point to continue experimenting with both the lines and gyroid infill pattern by printing more refined samples and conducting legitimate compression tests. These test will be used to get a broader understanding of the capabilities of varioShore TPU when it is used to 3D print varying density lattice structures.





Specimen	Modulus between 350N and 700N (0.14-0.28 Mpa)
Standard Poron (Blue)	**0.914507413**
Standard Poron (Black)	**0.647773279**
Sample 7	2.058218171
Sample 6	1.95476124
Sample 5	2.999143102
Sample 4	5.017921147
Sample 3	27.50491159
Sample 26	2.032815449
Sample 25	2.755800988
Sample 24	0.754594944
Sample 23	0.650920588
Sample 22	1.274238227
Sample 21	1.752955565
Sample 20	1.526347668
Sample 2	22.01550388
Sample 16	0.863770977
Sample 15	1.080163568

Figure 39. Compression test process

Compression tests

Overview

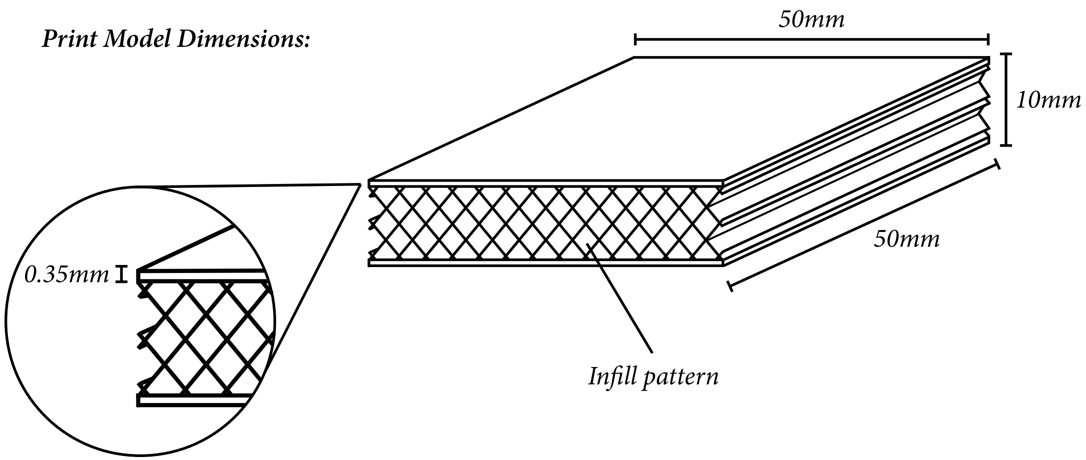
The aim of these tests was to compare samples that were printed using the varioShore TPU, with the materials currently used by NZALS to make customised orthotics, such as the Poron foams and EVAs. The samples of printed varioShore TPU will differ based on the settings used when printing them, as well as the pattern and density of the sample's infill. The majority of the samples were printed as solid blocks using different print settings in order to test the effects that the foaming has on the compression properties of the material. The infill density of these solid block samples was adjusted accordingly to account for the rate of material expansion that occurs when printed with certain settings. The rest of the samples were printed with infill that acts as a lattice structure which allowed them to be 'softer' and a more suitable alternative to the Poron foams used by NZALS. All of the samples were tested by engineer, Dayna Cracknell, who is also a member of the SfTI spearhead research group.
The types of tests conducted were:

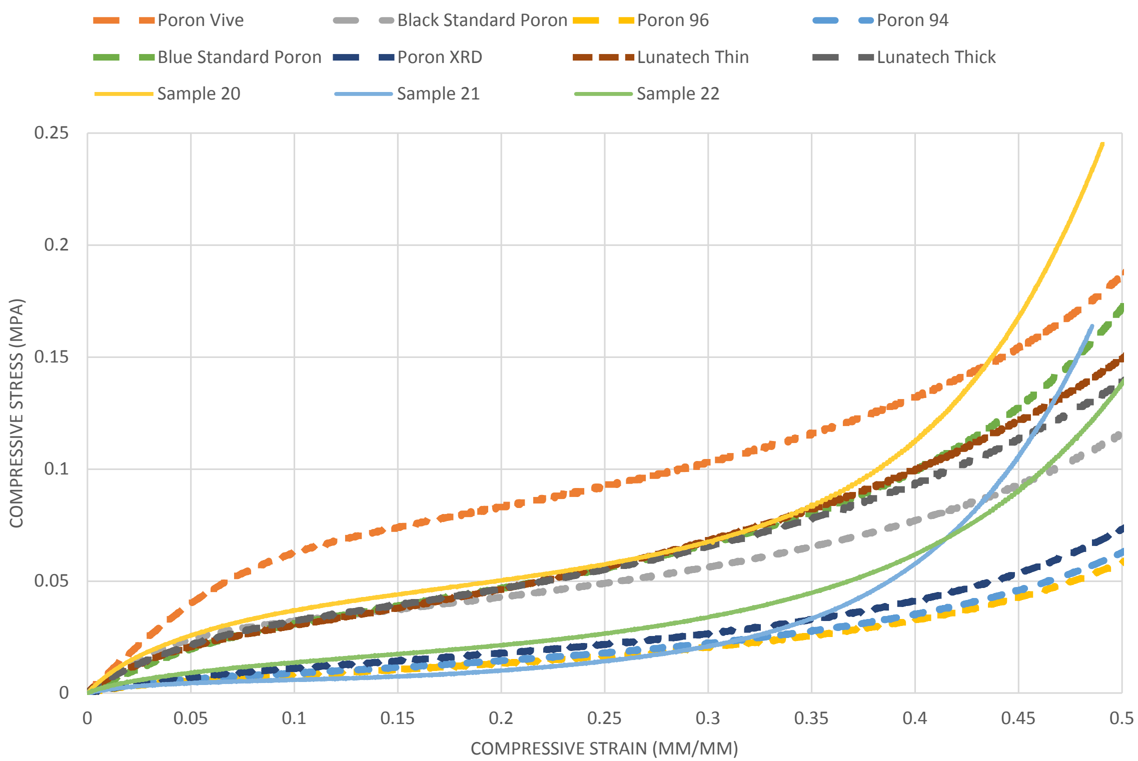
Static Compression Test — **Dynamic Compression Test** — **Shore Hardness Test**

Consistent Print Settings:

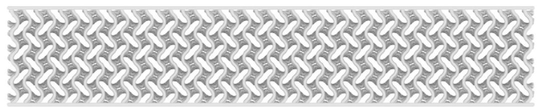
Layer Height = 0.2mm
Print Bed Temp = 60 °C
Infill Line Width = 0.35mm
Wall Thickness = 0.35mm
No. of Walls = 1

Print Model Dimensions:

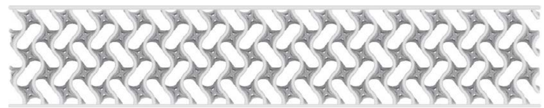




Sample 20 (Gyroid 30% Infill)



Sample 21 (Gyroid 20% Infill)



Sample 22 (Gyroid 25% Infill)

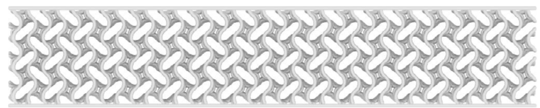


Figure 40 & 41. Static compression test results and example of key samples

Static Compression Testing

Method

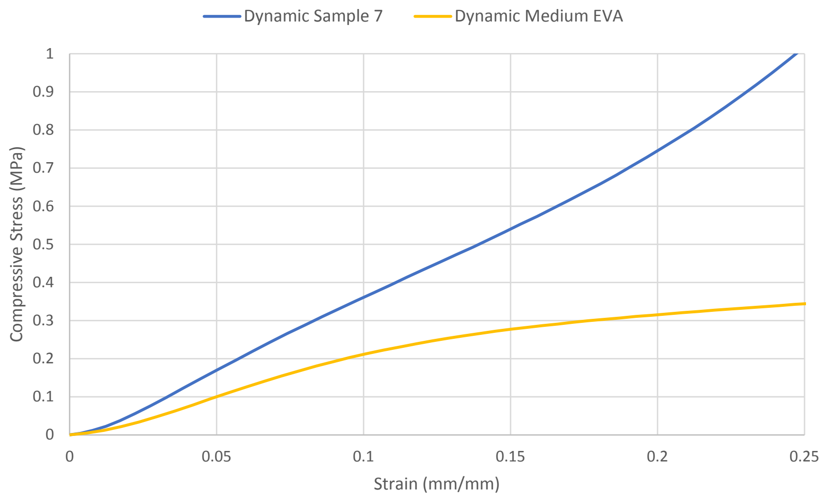
Quasi-static compression testing was conducted on the 3D printed samples and the NZALS materials that are used in current orthotic production. A loading rate of 1mm/min was used on all the samples and a 50N pre-stress was applied to ensure the sample being tested was lying flat on the platform. The material samples were all loaded to a strain of 50% except for some of the stiffer samples that were loaded to 25% strain to avoid damaging them, as they were needed for further testing. The material response was then documented accordingly.

Results

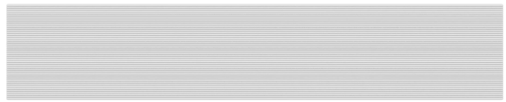
The results from these tests show that the 3D printed samples had a broadly comparable response to the current orthotic material samples. There were three samples (20, 21 and 22) that were printed with a gyroid infill rather than a lines infill. These three samples had most similar compression response when compared to the softer NZALS materials. From these results, it was concluded that samples with a gyroid infill pattern were able to acheive a softer response than samples printed with a lines infill. This is consistent with other studies that found the gyroid structure to be softer than both diamond and primitive (grid and lines) lattice structures (Shi et al., 2020).
Conclusions from the test report stated that the varioshore TPU printed samples could achieve similar properties to that of the materials currently used to manufacture orthotics, such as Poron foams and EVAs, but further development of softer samples is needed to obtain a suitable material stiffness range for orthotic production.

Discussion

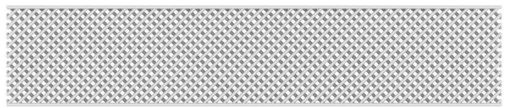
The compression of the samples showed the response had three stages; linear elastic, plateau and densification. The linear elastic stage occurred during low strain, as the lattice walls bend under the load force, and represents the Young's modulus of the sample's structure. The plateau stage occurs as the strain increases and the lattice walls begin to collapse through elastic buckling or plastic yielding, resulting in the slope of response lowering. As the lattice structure becomes compact, the stress data rapidly increases, this is refer to as the densification stage, and represents the modulus of the material itself. This is the process that occurs for all foam materials (Sadighi & Salami, 2012).
The conclusions from this testing highlight the need for softer samples so that a suitable stiffness range can be achieved, therefore making the 3D printed samples a viable alternative to the current foams and EVAs used in orthotic production. The samples that had a lines infill did seem to perform well but were always considered to be in the medium and hard material categories, whereas the gyroid infill samples, which performed the best, were in the soft material category. A full list and description of all the samples can be seen in the appendix.
Samples 20, 21 and 22 were printed between 20-30% gyroid infill density and had the most similar response to the Poron foam samples. Further testing is needed to obtain a broader understanding of how the modulus and other compression properties of these material samples can be controlled by slightly adjusting the density of the lattice structure and adjusting other 3D printer settings that affected the foaming of the material.



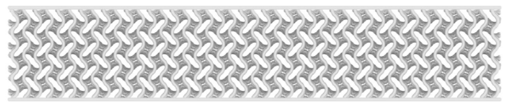
Sample 7 (Solid foamed block)

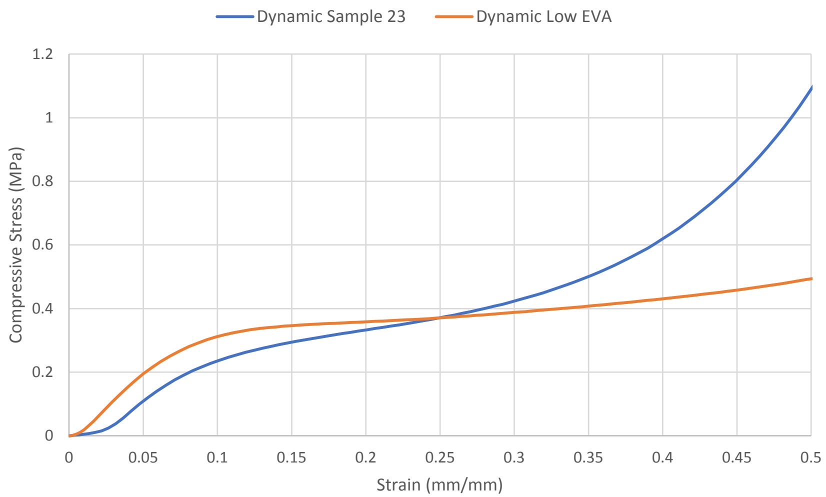


Sample 23 (Lines 50% Infill)



Sample 20 (Gyroid 30% Infill)





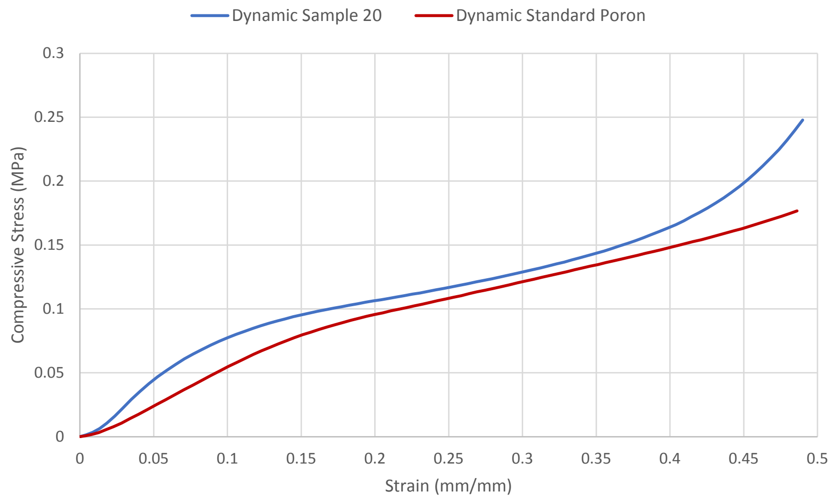


Figure 42 & 43. Dynamic compression test results and example of key samples

Dynamic compression Testing

Method

Due to the materials being used in a dynamic application (orthotics), it is important that dynamic compression tests are also conducted to simulate the natural gait cycle. For this experiment, the loading was simplified to a bi-linear displacement curve that compressed the sample by 5mm before offloading. The compression occured at a speed of 12mm/s for 0.4 seconds and then offloading occurred at the same rate.

Results

The results from these dynamic compression tests show an increase of overall stiffness for most of the samples in each stage of the response, in comparison to the static compression results. This response can be attributed to two factors that have been previously specified in other literature (ref). The first factor is the air trapped inside the foam having less time to escape during dynamic testing, and the second factor is the inertia of the internal lattice structure, which is higher in the dynamic compression. In relation to the approximate modulus in each of the three stages (linear elastic, plateau and densification), in most cases, the dynamic response of the samples was significantly stiffer than the quasi-static response. The results for the low and medium EVAs used by NZALS differed from most of the results, with the two EVA materials being recorded as stiffer at each stage during the static compression.

Discussion

Three of the printed samples, and three of NZALS materials, underwent dynamic testing. One printed material sample was chosen from each of the hard, medium and soft material categories. Selection was based on how the samples performed during the static compression tests.
The conclusions from these dynamic compression tests were that sample 20 had a very similar response to standard Poron, which was also the case for the static compression tests, and sample 23 (see figure 42) had a similar response to the low density EVA.
Sample 7 was a printed as a fully infilled block using certain print settings and was compared to the medium density EVA. The compression response of sample 7 could only be considered similar in the initial seconds of the linear elastic stage, which means further testing of a more comprehensive range of samples would need to be done to identify a sample that can replicate both the static compression and dynamic compression response of the medium density EVA.

Hard Samples

Medium Density EVA	*50 A*
High Density EVA	*65 A*
*	
Sample 1	82 A
Sample 2	82 A
Sample 3	86 A
Sample 4	72 A
Sample 5	65 A
Sample 6	61 A
Sample 7	66 A
Sample 10	72 A
Sample 11	67 A

Medium Samples

Low Density EVA	*35 A / 56 O*
*	
Sample 12	64 A
Sample 13	58 A
Sample 14	47 A
Sample 15	54 A
Sample 16	49 A
Sample 23	66 O
Sample 24	57 O
Sample 25	50 O
Sample 26	40 O

Soft Samples

Standard Poron	*29 O*
Poron Vive	*34 O*
Poron XRD	*25 O*
Pink Poron 94	*19 O*
Pink Poron 96	*20 O*
Nora Lunatech	*27 O*
*	
Sample 20	37 O
Sample 21	34 O
Sample 22	26 O

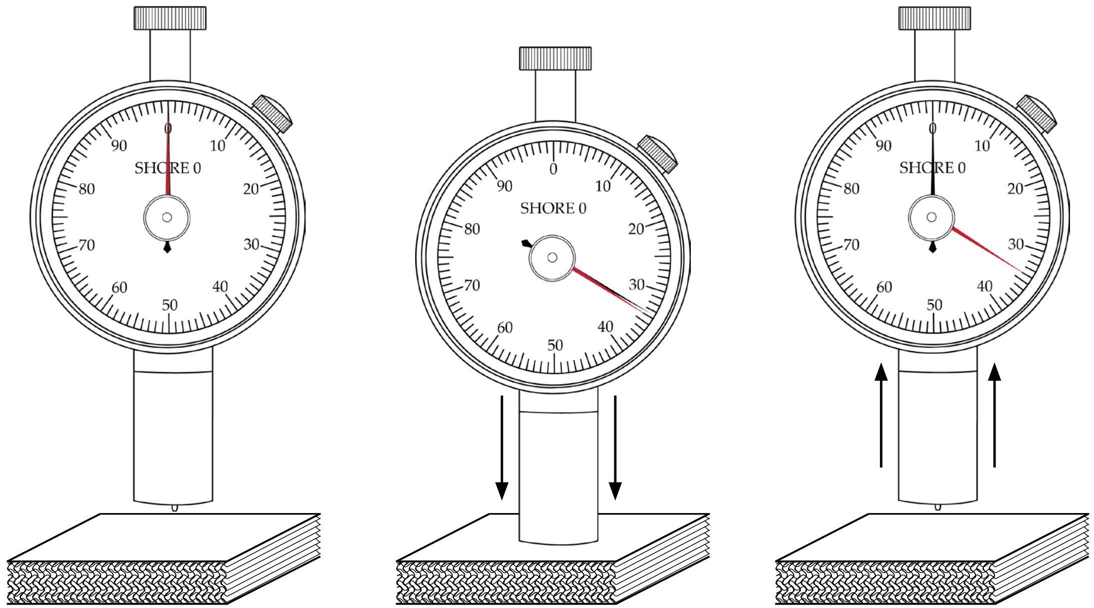


Figure 44. Shore hardness test process

** See appendix for sample details*

Shore Hardness Test

Method

A durometer was used to test the shore hardness of the samples and the NZALS materials. For the stiffer samples and the EVA foams, an A scale durometer was used, and for the softer samples, an O scale durometer was used. The test samples are required to be on a hard, flat surface and the calibration of the durometer using calibration blocks is required before testing in order to obtain reliable results. To measure the shore hardness of a material sample, the durometer is pushed down into the sample with consistent pressure for 5 seconds and then lifted off, relieving the pressure. The measurement on the durometer is then recorded.

Results

The samples and NZALS materials were separated into the same hard, medium and soft sample categories as for the compression tests.
The high, medium and low density EVA had shore hardness values of 65A, 50A and 35A respectively. The majority of the printed samples in the hard material category had a shore hardness that was considerably higher than that of the EVAs except samples 5, 7, 11 and 12 that were very similar to the high density EVA with shore hardness values of 65A, 66A, 67A and 64A respectively.
Samples 14 (47 A) and 16 (49 A) were similar to that of the medium density EVA but were not quite exactly the same. There were no samples measured using an A scale durometer that were similar to the shore hardness of the low density EVA (35 A), but when an O scale durometer was used, the EVA had a value of 56 O, which was very similar to sample 24 (57 O).
The softer foams used by NZALS were all in the lower range of the O scale. Sample 21 recorded the same shore hardness as Poron Vive (34 O), and sample 22 had a shore hardness of 26 O, which was softer than some of the NZALS foams (e.g. standard Poron, Poron Vive and Nora lunatech), but was not quite as soft as the other Poron foams used by NZALS.

Discussion

These results show the promising potential for foaming filament to be able to replicate the current materials that are used to make orthotics. From this small collection of test samples, the majority of the shore hardness values from the NZALS materials were able to be replicated.
The shore hardness of the materials is currently one of the main factors that clinicians, and technicians, use to decide what materials should be used in the manufacture of a patient's custom orthotic. With further sample refinement, a strong case can be made at this stage of the research portfolio that the controlled process of FDM printing varioShore TPU, and potentially future foaming filaments, can be an improved way of creating multi-density orthotics.

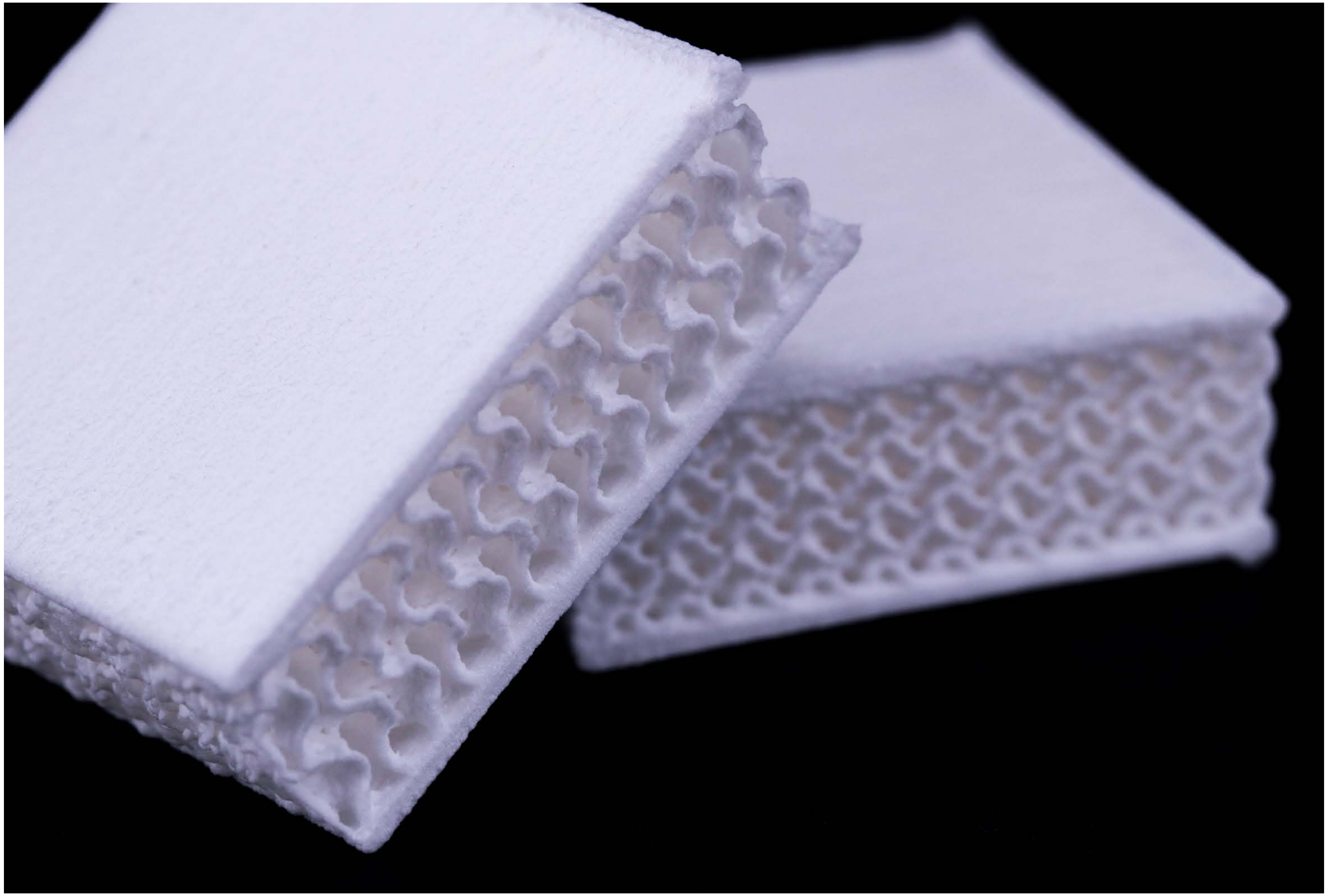


Figure 45. Gyroid infill 3D printed test samples

Material Testing Summary and Discussion

Summary

From the results of these material experiments and 3D print tests, it can be concluded that the 3D printing of foaming filaments, such as varioShore TPU, should be considered as a viable option for the manufacturing of diabetic orthoses. The experiments and tests conducted using varioShore TPU showcase the potential for additive manufacturing technologies to be able to accurately control the material properties of the printed foaming filament.

The infill density and single wall expansion tests allowed for a better understanding of how the 3D printer settings affected the level of foaming that occured. After these tests, it was concluded that the temperature of the nozzle and the print speed were the most influential print settings, with the fan speed also having a minor effect.

From physical examination of the print samples, it was clear that without the assistance of internal lattice structures, the foamed samples printed using varioShore TPU would be unable to replicate the material properties of the softer NZALS materials, such as the Poron foams. Consequently, further samples were printed with internal lattice structures of varying density in an attempt to imitate the open cell structure that is responsible for the soft, cushioning properties exhibited by Poron foams.

Static and dynamic compression testing was performed on samples of the NZALS materials as well as 21 varioshore TPU samples[*], some of which were printed using different settings as well as varying density internal lattice structures. The results from these tests showed that a select few of the 3D printed samples demonstrated very similiar responses to the NZALS materials. From these results, it was concluded that, with further testing of a more refined range of samples, the compression properties of all the NZALS materials would be able to be replicated by samples printed using varioShore TPU. Shore hardness tests were also conducted on all the material samples and the results showed that the printed samples were able to replicate almost the whole range of hardness values exhibited by the NZALS materials.

Discussion

At the start of the material experimentation stage, the initial aim was to attempt to make, and test, a bio-based foaming filament. Numerous attempts at creating this type of filament, during an internship at the University of Waikato's Centre for Advanced Materials and Manufacture, provided valuable knowledge into how these filaments work. However, it also highlighted the need for more research and development to be done before the use of a bio-polymer-based filament could be considered in the 3D printing of diabetic orthoses.

On the other hand, the additional material research during this period did prompt the discovery of the commercially available foaming filament, varioShore TPU. The testing of this material during this experimentation stage, and the results from the tests, has proven it suitable for use in the remainder of this research portfolio, to create proof of concept models as a reference for the future development of bio-based, foaming 3D print filament.

* See appendix for sample details

"The main design factors of diabetic insoles include geometry contour, stiffness, thickness, and other types of variations such as that in metatarsal pads. Among them, the geometry contour was found to be the dominant factor in the determination of the peak contact pressure, and the stiffness was the secondary factor"

- (Tang et al., 2019, p.279)

Parametric Modelling Experimentation and Development

Overview

Until this point of the research portfolio, the test samples were being exported out of modelling software, Rhino 3D, and then imported into the slicer software, Cura, where the 3D print settings can be configured and the G-code can be generated. Although this has proven to be very helpful, the next step in this experimentation stage was to use the parametric modelling software, Grasshopper, to create a script that integrates all the necessary manufacturing elements into one system. The script will automatically create the insole form with the correct level of infill density in specific areas, to ensure efficient pressure distribution, a high level of support and general comfort for the user. It will then be able to generate the G-Code that will instruct the 3D printer how the sample should be printed, and control the print settings that should be used for different areas of the insole. The aim of this parametric script experimentation and development is to have full control over the insole manufacturing process, from the intial data input (e.g. 3D foot scan and pressure data), to the settings used during printing that will influence the amount of foaming that occurs and the density of the infill. All of these elements should contribute to creating a perfect fit insole that provides optimal plantar pressure distribution and comfort. To acheive this, additional Grasshopper plugins were required. Descriptions of these plugins can be seen below. The next few pages show the identification and development of essential script features.

Crystallon

This plugin is used to create lattice structures inside geometries. The shape of the lattice structure, as well as the density, is also able to be customised to accomodate the modelling needs of the user.

Kangaroo 2

Kangaroo is a physics engine plugin that is used for form optimisation, interactive simulations and constraint solving.

Xylinus

This plugin can generate G-code inside Grasshopper, allowing users to have a high degree of control over how the geometries will be 3D printed and the print settings that will be used.

Weaverbird

Weaverbird is a topological modelling plugin that includes additional mesh optimisation tools to help simplify modelling scripts and prepare the model for fabrication.

Figure 46. Grasshopper plugins logos

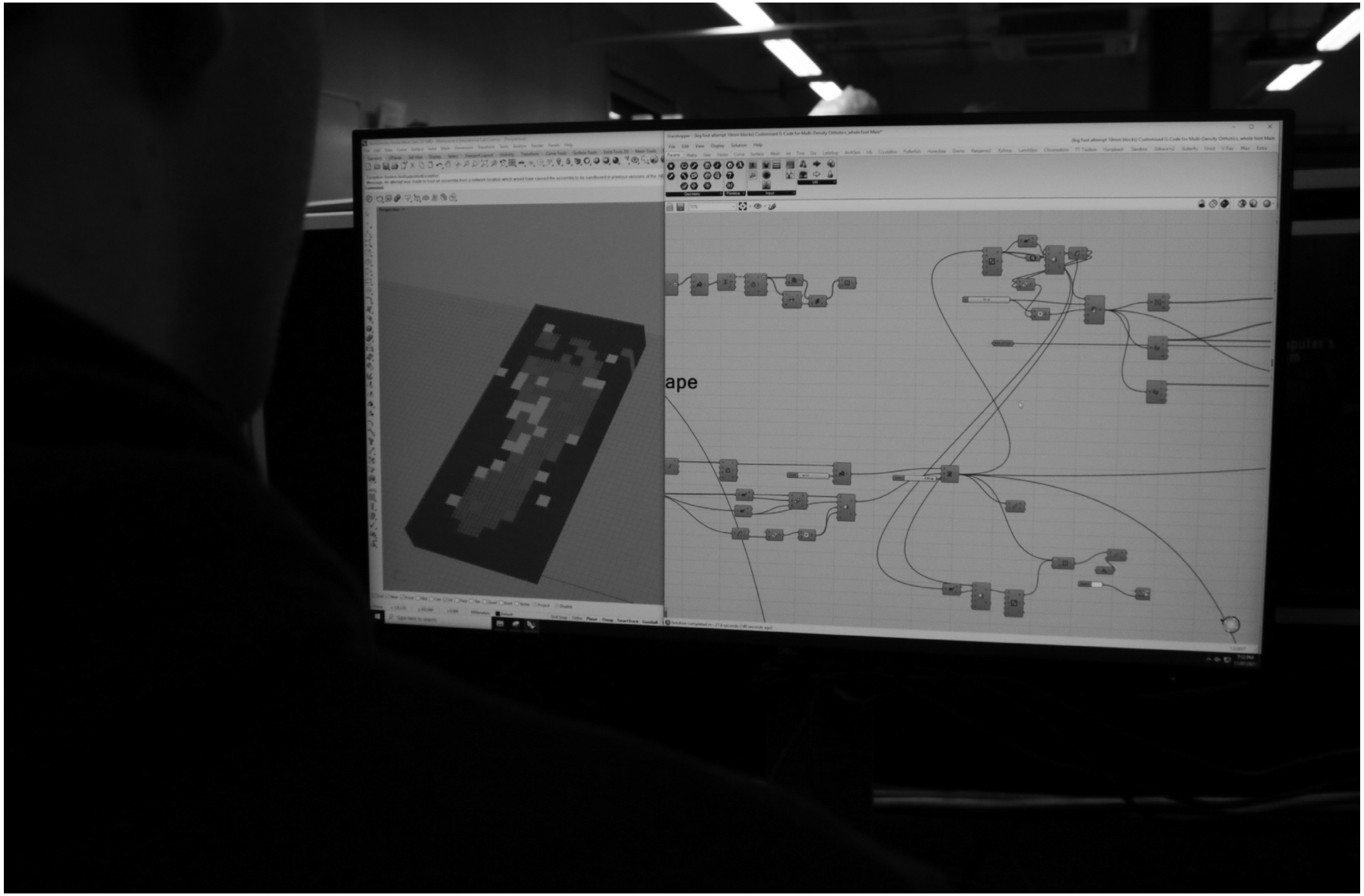


Figure 47. Working on grasshopper script

Essential Script Features

Overview

After conducting research into orthotic production and completing numerous material experiments and 3D print tests, three main elements were considered to be essential inclusions in the parametric modelling script in order to succesfully 3D print highly efficient, variable density orthotics. These three elements were 3D insole form, creating multi-density sections, and the generation of accurate G-code to print the final result.

3D insole form

The shape of an insole is crucial to providing sufficient support and comfort for the user. Custom orthotics are most commonly moulded to the user's foot using foam box moulds or from 3D foot scans (as previously discussed in the background research section). As well as helping to improve balance and reduce lower back pain, the use of customised insoles can also assist in treating certain foot deformities and improving the distribution of plantar pressure. Using the precision that 3D printing can offer, a high resolution of form customisation can be achieved.

Multi-Density 3D Print

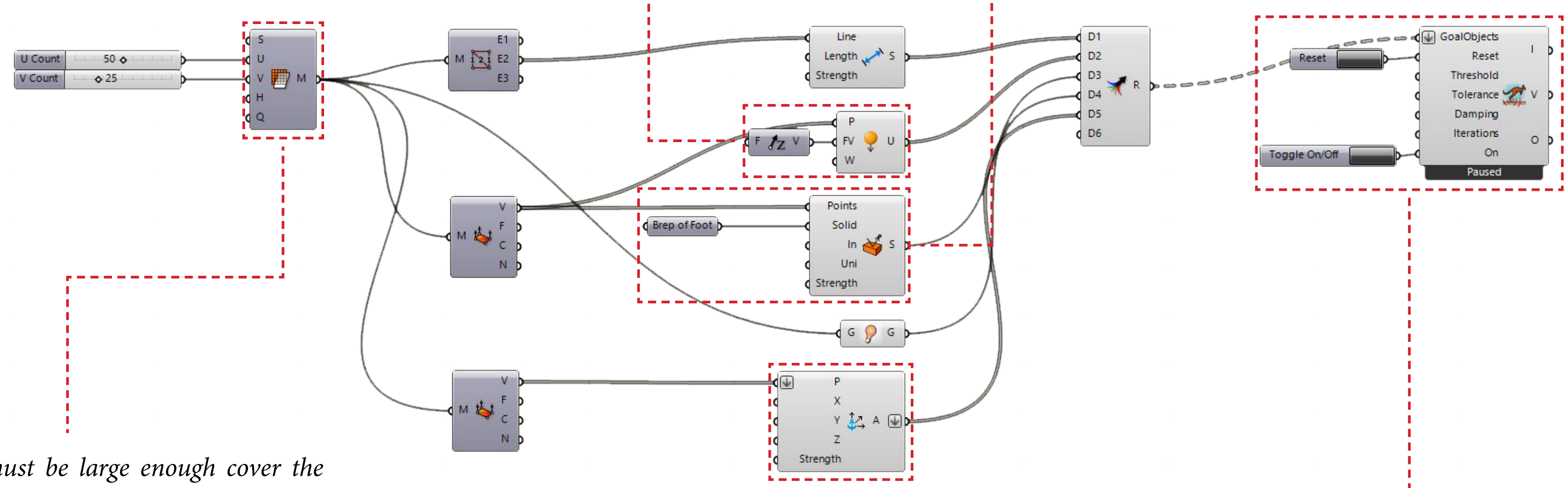
From the results of tests done using the varioShore TPU, it was made clear that the printing of variable density samples was able to achieve similar shore hardness values and compression responses to the currently used NZALS materials. The aim now should be to find a way to print these sample variations in specific areas of the insole in order to acheive multi-stiffness prints that are able to provide support and comfort to precise areas of foot sole.

G-Code Generation

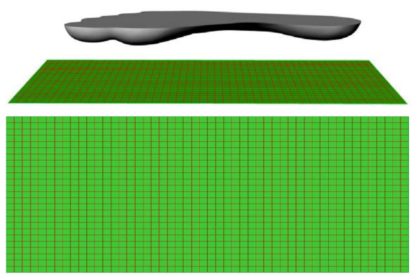
As previously specified, the script will also need to include a section that can automatically generate functional G-code. The G-code should be able to be customised to meet the specifications required for different sections of the insole. For example, if one area of the insole requires a stiffer material, the G-code should be automatically programmed through Grasshopper to adjust the print settings accordingly in order to obtain the required stiffness. This G-code should be synchronised with the Ultimaker 3 extended 3D printer that is used during this research portfolio.

This is the load component of the simulation that specifies the amount of force that should be applied to the movement of the mesh cloth points.

This component instructs the simulation that the points on the mesh cloth should recognise the brep foot as a solid, and collide with it.



The mesh cloth must be large enough cover the whole 3D foot in order for the simulation to run smoothly. The U and V inputs also determine the accuracy of the foot mould that will be made during the simulation.



This was the last component that was added during the experimentation of this section of the script. It ensures that the mesh cloth points only move in the Z axis, making the final mesh surface a lot smoother and less prone to sharp mesh triangle edges.

This component is the solver and is used to reset and run the mesh cloth simulation. An example of the final output can be seen below:

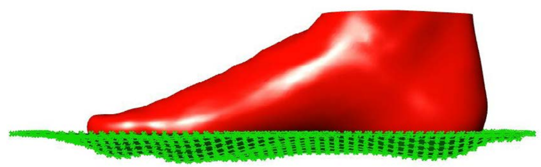


Figure 48. 3D insole form Grasshopper script section

3D Insole Form

To obtain the correct form of a customised insole, the script needed to be able to create a mould that fits perfectly to the contour of the foot. To be able to do this in the Grasshopper software, the Kangaroo 2 plugin was required. As previously mentioned, Kangaroo 2 is a physics engine plugin that can run a wide variety of simulations, such as a cloth simulation that was used in this section of the script.

How it works

The script section in figure 48 shows all the Grasshopper components that are required to run the Kangaroo 2 simulation that will create the mould of the 3D foot scan. The left side nodes can be identified as individual instructions for how points will move, the limitations of that movement and classification of what each object will do during the simulation. These are then all merged into one list in order of priority so that the simulation will know what should be considered as the main function, which in this case, is the mesh cloth collision with the Brep foot. This is then all fed into the solver, which has a few additional options such as tolerance and threshold, which can make sure the simulation does not run continuously and stops at a certain point.

Challenges

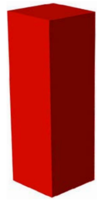
When developing this section of the script, there was some initial frustration with the final output mesh as it had a number of sharp mesh triangle edges in the areas with tighter corners such as between the toes. When a solution to this issue was attempted by reducing the load force that is applied to the mesh cloth points, the resulting output was a simulation that seemed half complete, with the cloth not fully colliding with the brep foot.

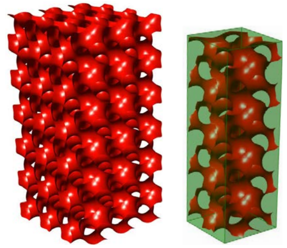
Solutions

With some trial and error simulation tests, and more research into the Kangaroo 2 components, the inclusion of an anchor point component reduced the number of sharp edge mesh triangles. With further adjustments of the component strengths and other inputs, the script was able to work perfectly. The final output is now a smooth mesh surface that will collide with the brep foot until it reaches the top of the foot arch, creating the ideal 3D form for the insole.

Brep (Boundary respresentation)= A surface model comprised of faces, edges and vertices

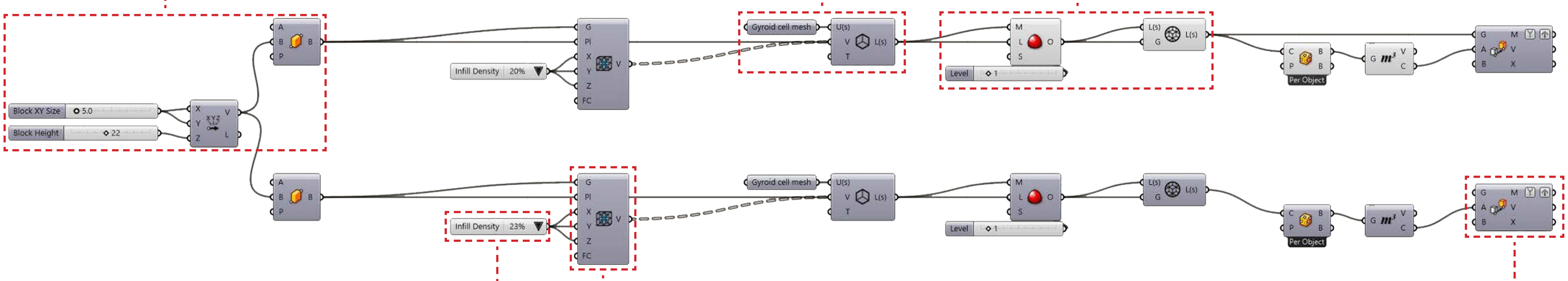
The size of the brep blocks can be altered in this part of the script. The XY size determines the resolution of the multi-density element of this system. The height of the blocks should be larger than the overall height of the entire insole.



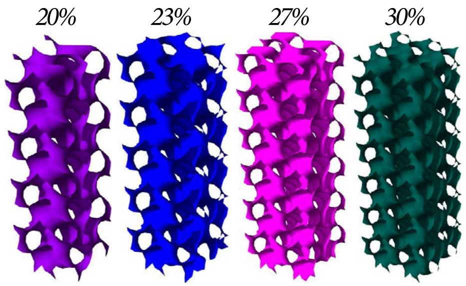


Smoothing and trimming of gyroid lattice. The result is a 5 x 5 x 22mm gyroid lattice block.

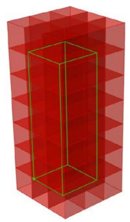
These components are used to turn the voxelised brep into the required gyroid lattice structure.



This drop-down list converts the voxel size to infill density. Below are a few examples of different density blocks:



The cluster component used to voxelise the brep. It will ensure that the entire brep is filled with voxel blocks, as seen below.



This component is used to move the specific density gyroid block to the required areas of the insole.

Figure 49. Multi-density Grasshopper script section

Multi-Density Print

As stated in the overview, the tested print samples were made in Rhino and then imported into the slicing software Cura where the infill pattern, density and print settings are selected. To replicate the control over the infill, the Crystallon Grasshopper plugin was used.

How it works

The Crystallon plugin takes any closed brep, fills it with voxels of a specified size, and then uses those voxels to generate a gyroid lattice structure. The size of the voxels is equal to two times the lines infill distance on the Cura settings. Once the preliminary lattice structure is generated, it is smoothed and trimmed using the initial closed brep. The final result of this script section is a small gyroid lattice block that can be copied and moved to different areas of the insole, creating a multi-density insole geometry.

Challenges

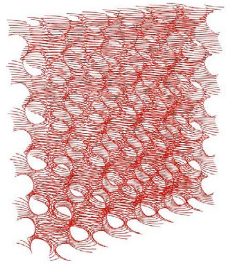
The Crystallon plugin was very easy to work with and presented few challenges when using it. The only issue was that when a brep has a XY size smaller than 3mm, the generated lattice structure is too thin and struggles to be 3D printed accurately. Another minor challenge was finding out how to obtain the exact same infill density settings used in Cura.

Solutions

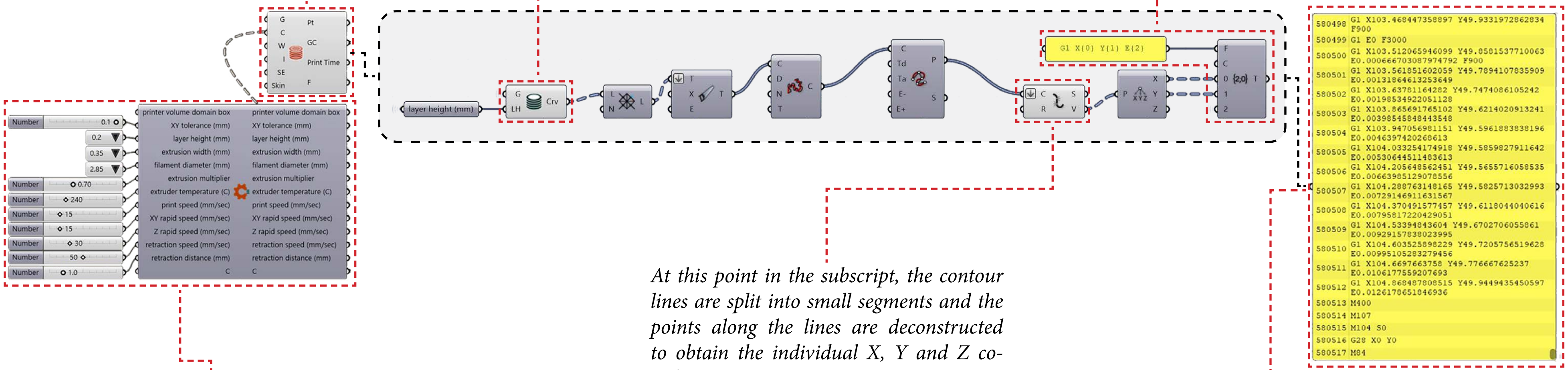
In order to ensure the different density blocks are able to be printed successfully, the minimum XY size of the brep blocks should be 5mm. For the infill density settings, the correlation between voxel size and infill line measurement was discovered to be simply 2 to 1, respectively.

This is a cluster component that contains a complex subscript. The black dotted outline section shows a small but key section of the subscript.

This is the section of the sub-script that takes the input geometry and creates contour lines at sequencial heights. These lines represent the print layers at the distance between them is specified by the layer height.

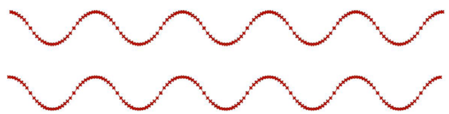


The format component is used to organise the individual points into a code-like structure that the 3D printer will understand.



This component is used to configure the 3D print settings. All the input data that is plugged into this will be automatically inserted into the g-code and can be adjusted easily through sliders.

At this point in the subscript, the contour lines are split into small segments and the points along the lines are deconstructed to obtain the individual X, Y and Z co-ordinates.



The output of the sub-script is a ready-to-use G-code file that has all the necessary start and end code needed to run a 3D printer effectively.

Figure 50. G-code generator Grasshopper script section

G-Code Generator

Once the insole form with multi-density sections was digitally configured, it will will need to be turned into G-Code in order to be 3D printed. Standard slicer softwares have this capability built into them, but in order to replicate the function in Grasshopper, the Xylinus plugin was required.

How it works

There are two main components in this section of the script, with the G-code generator node being made up of a whole sub-script, which is known in Grasshopper as a cluster. The other component is used to determine the 3D printer settings and can be adjusted accordingly. The sub-script takes the inputted geometry, creates contour lines at various heights (specified by the layer height) and then cuts all the lines at each layer into multiple XYZ co-ordinates. These co-ordinates are then formatted into a list and will instruct the precise, step by step movements of the 3D printer head. Other necessary information for 3D printing such as extrusion rate, print speed etc. is specified using the print settings component and is automatically inserted into the G-code where necessary. The final output is a list of customised G-code lines that can be sent the Ultimaker 3 Extended 3D printer to be printed.

Challenges

The main challenge with this section of the script was developing an understanding of how G-Code works and what are the essential elements that will ensure the 3D printer knows exactly how the user would like the digital model to be printed. There were also a few issues with computer processing power due to the script becoming so complex that it would be unable to efficiently generate the G-code and occasional cause the computer to crash.

Solutions

After focused research into G-code, and some experiments with smaller test prints, sufficient knowledge was obtained, making the development of this script section a lot easier. The solution to the processing power issue was to acquire a high performance PC that was able to efficiently run the script and reduce the risk of computational failure.

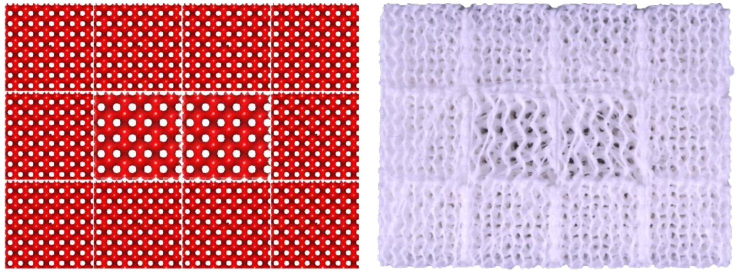


Figure 51. 4x3 multi-density blocks test (digital on left, 3D print on right)

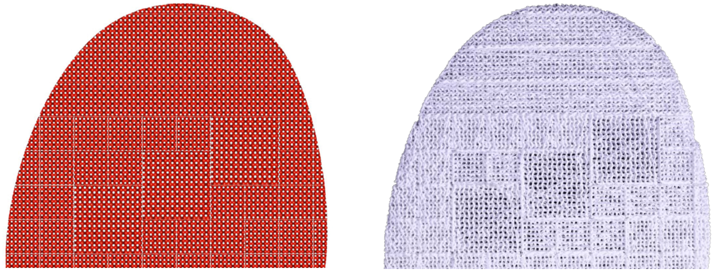


Figure 52. Insole forefoot multi-density block test (digital on left, 3D print on right)

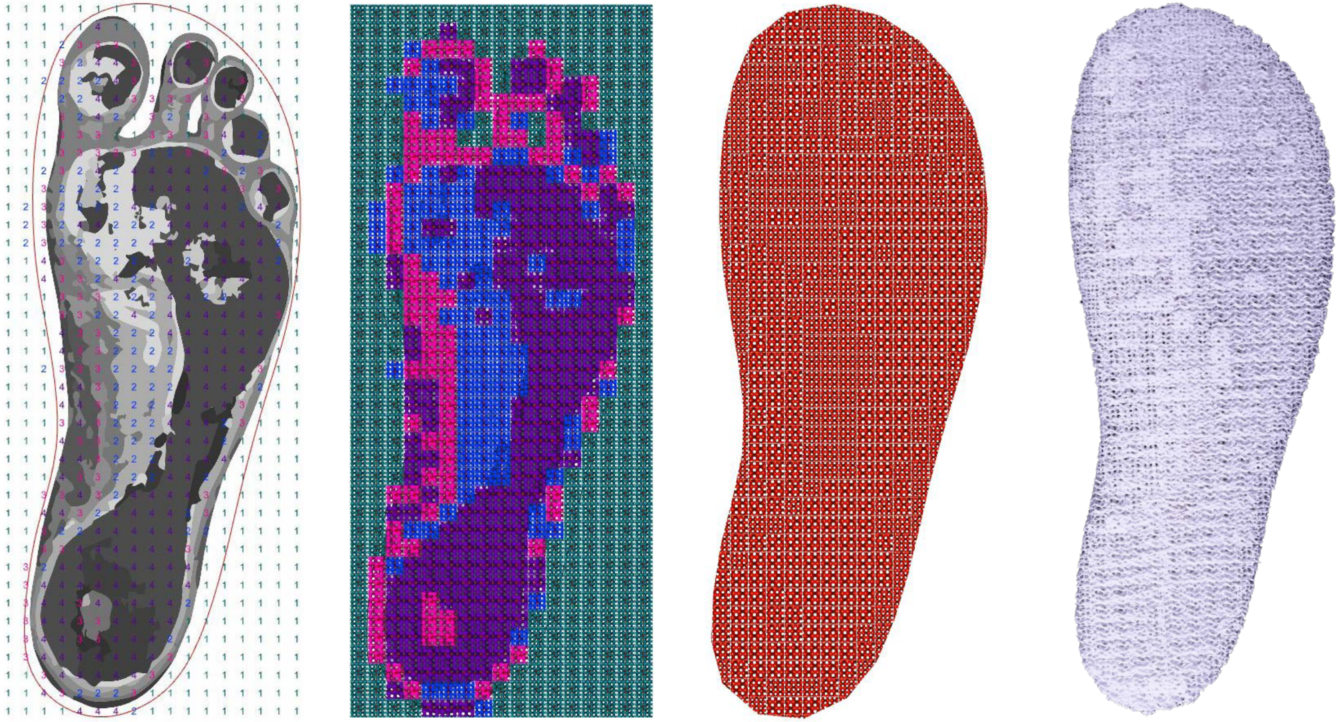


Figure 53. Full Insole multi-density blocks using simulated pressure map data test

3D Print Tests

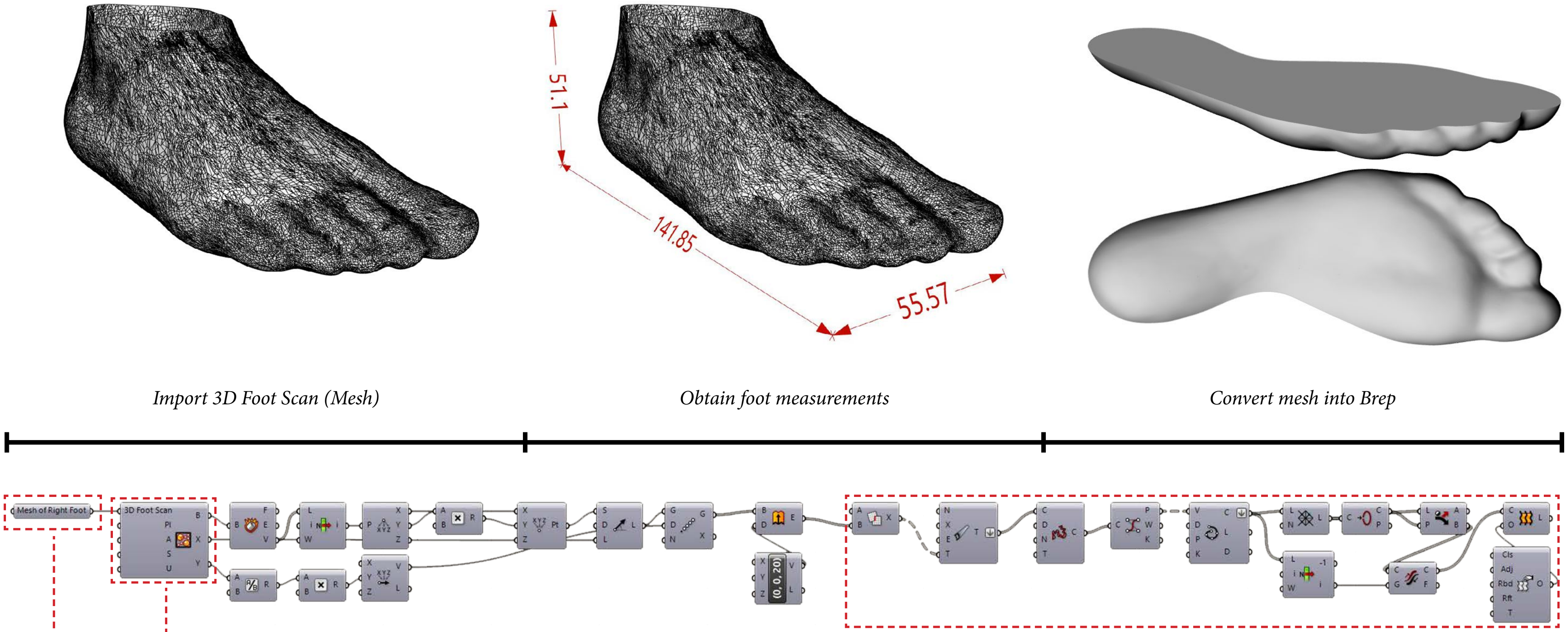
Overview

These newly developed sections of the script were tested by printing a number of smaller, simple 3D prints with two or more different density blocks, and then by printing a scaled full insole shape with multiple densities. The location of the different density blocks for the insole shaped print was determined by running a circle packing simulation, that is part of the Kangaroo 2 plugin. This section of the script was still being developed at this point of the experimentation but was still able to show the potential of using pressure map data to specify where these different density blocks need to be optimally placed.

Results and Conclusions

The results of these print tests showed that the developed grasshopper script was successful at generating accurate G-code that is able to print varying density forms. There was only one slight issue which was that the 3D printed samples had fairly dense print lines where the blocks met eachother. This issue was related to the spacing of the blocks and was corrected soon after these print tests were conducted.
The final step of the experimentation section was to further refine the Grasshopper script to ensure it ran smoothly and was able to successfully generate the G-code for the 3D printing of a customised, variable-density insoles.

Developed Script Analysis

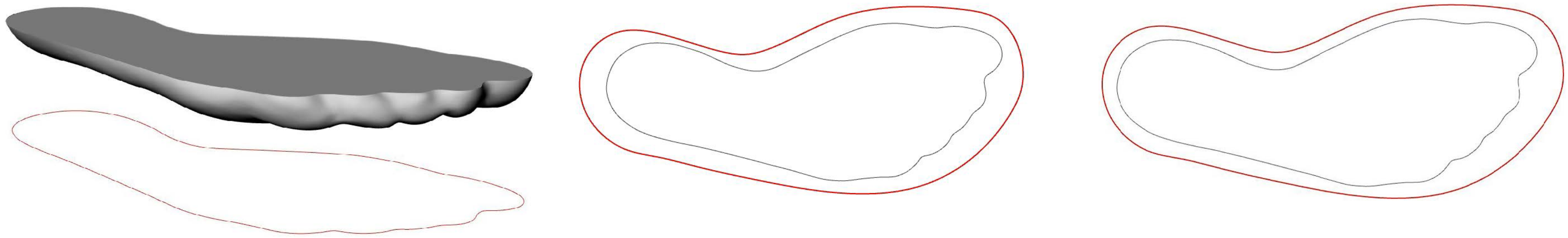


With modern technology, 3D scans are highly accurate and have become a valuable tool in the orthotics industry.

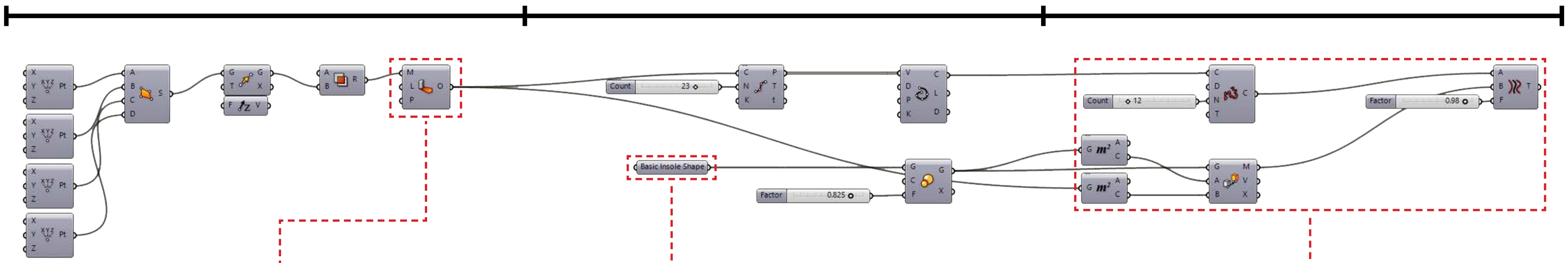
The measurements that are taken from the foot scan will influence multiple sections of the grasshopper script. This is the first step to ensure the output of the script is an orthotic that is accurately customised to the specific patient.

This section of the script is creating a brep version of the foot scan mesh so that it is easier to work with and helps to improve the processing speed of the whole script.
The output is a cropped version of the original 3D foot scan due to only sole of the foot being required to create the 3D insole form.

Figure 54. Timeline of developed Grasshopper script part one



Create 2D outline of foot | *Overlay basic insole outline* | *Insole outline adjusted to be perfect fit*

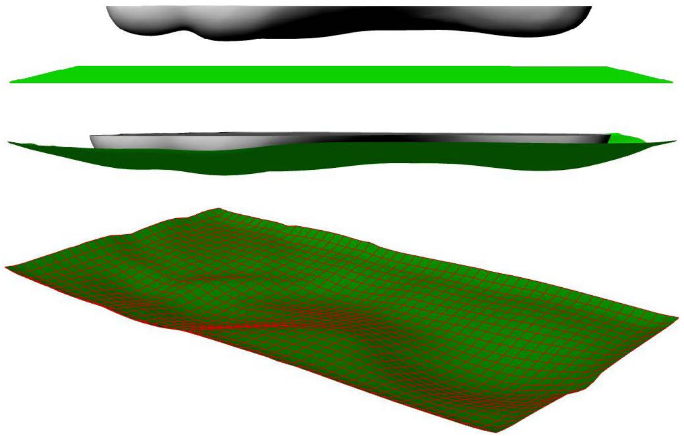


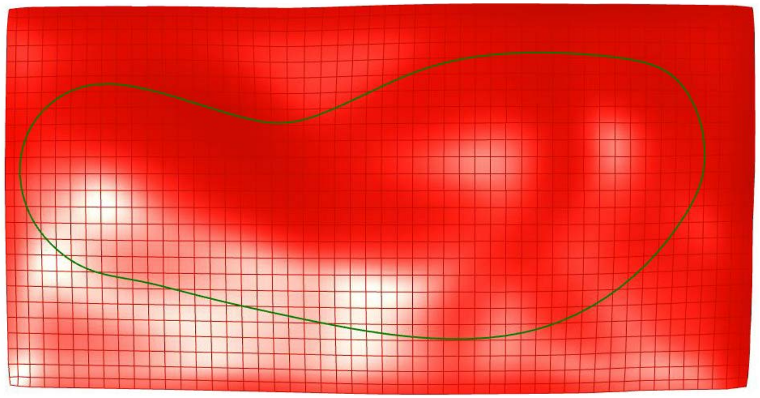
Projecting the outline of the 3D foot scan onto the XY plane.

A 2D outline of a basic insole shape, scaled to fit the size of the patient's foot.

The 2D outline of the foot and the basic insole shape are aligned and scaled to the correct size. The tween curves function then creates the optimal 2D insole shape.

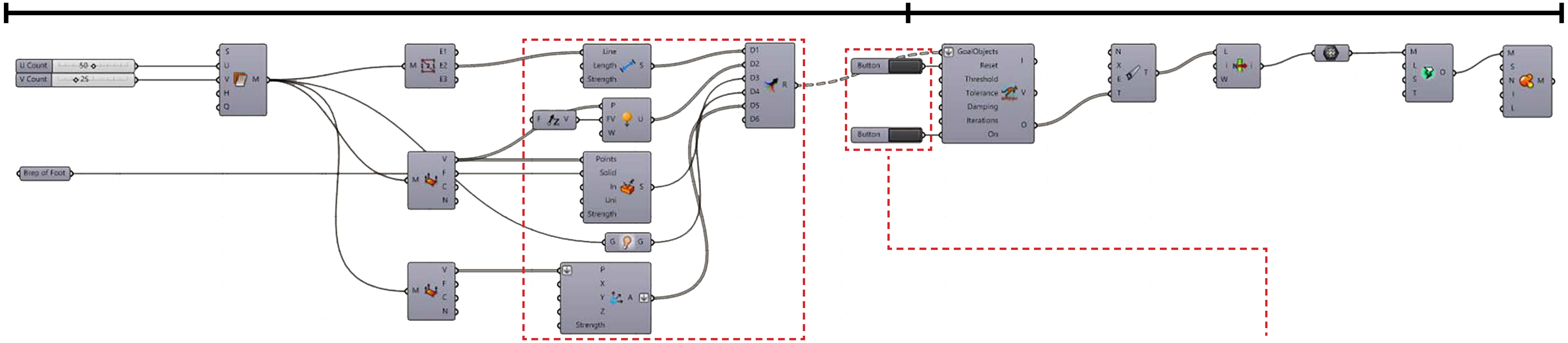
Figure 55. Timeline of developed Grasshopper script part two





Run cloth simulation to obtain 3D insole contour

Smooth mesh cloth surface



In this simulation, the points that make up the mesh cloth are told to move up in the Z axis with a specified amount of force and collide with the brep foot sole. Once the points experience a certain amount of resistance, the simulation is stopped and the result is a mesh surface mould of the foot sole.

When using this grasshopper script, this simulation needs to be reset and then run to obtain the mould of the foot, which will inform the rest of the script. By not resetting and running, the rest of the script will fail to work.

Figure 56. Timeline of developed Grasshopper script part three

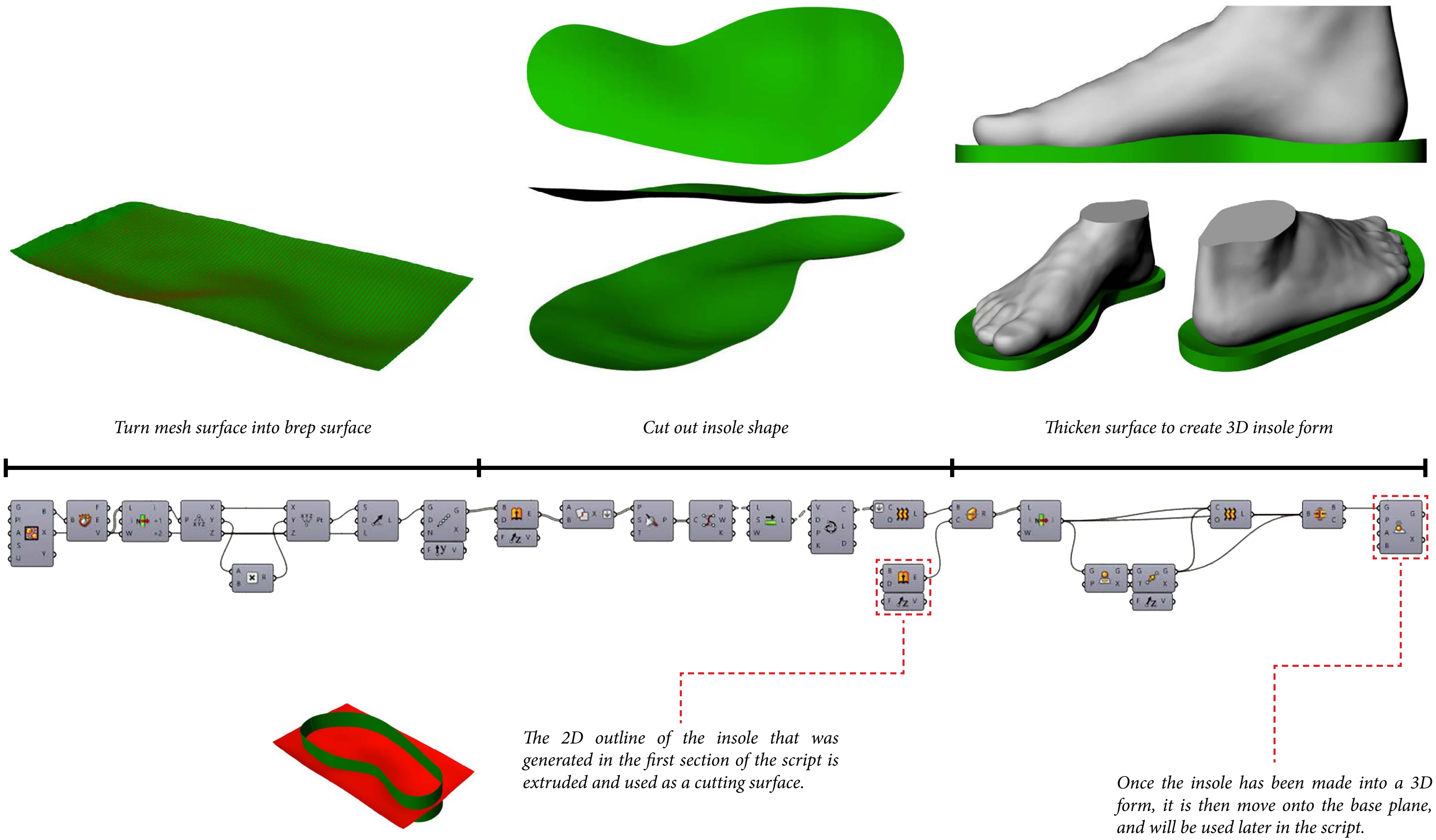
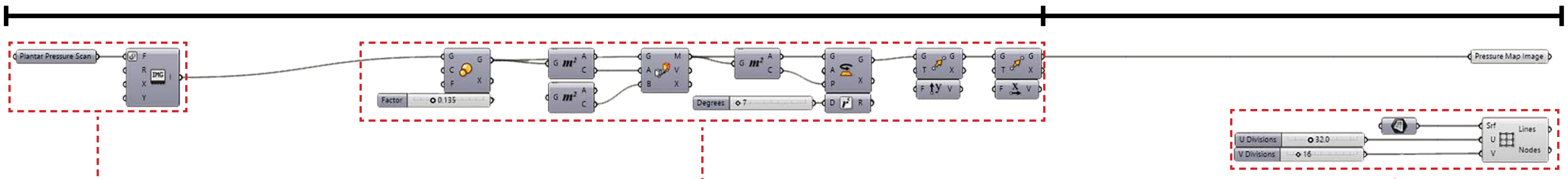


Figure 57. Timeline of developed Grasshopper script part four

Import Simulated Plantar Pressure Data

Create grid to cover pressure map

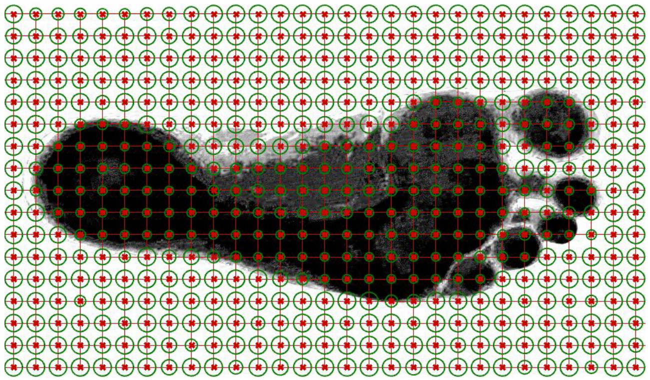


This is a vital component in this grasshopper script. This is where the plantar pressure data of the patient is inserted into the script and will determine the location of the different density blocks.

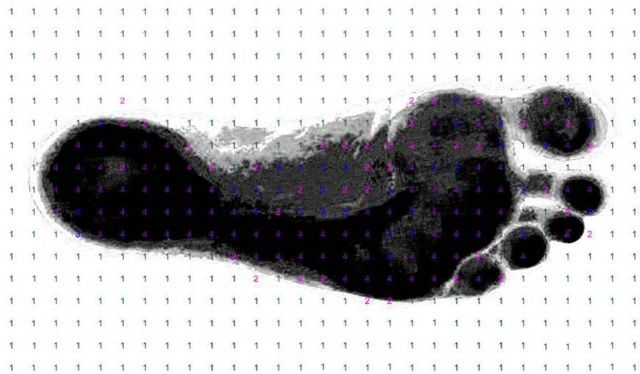
These components are used to align the pressure map image with the 3D foot scan. The accurate alignment of these two data inputs is crucial to ensure that the varying density regions are in the correct position.

The grid must cover the entire pressure map and the UV count should always be adjusted to make sure the size of the grid cells are 5mm x 5mm.

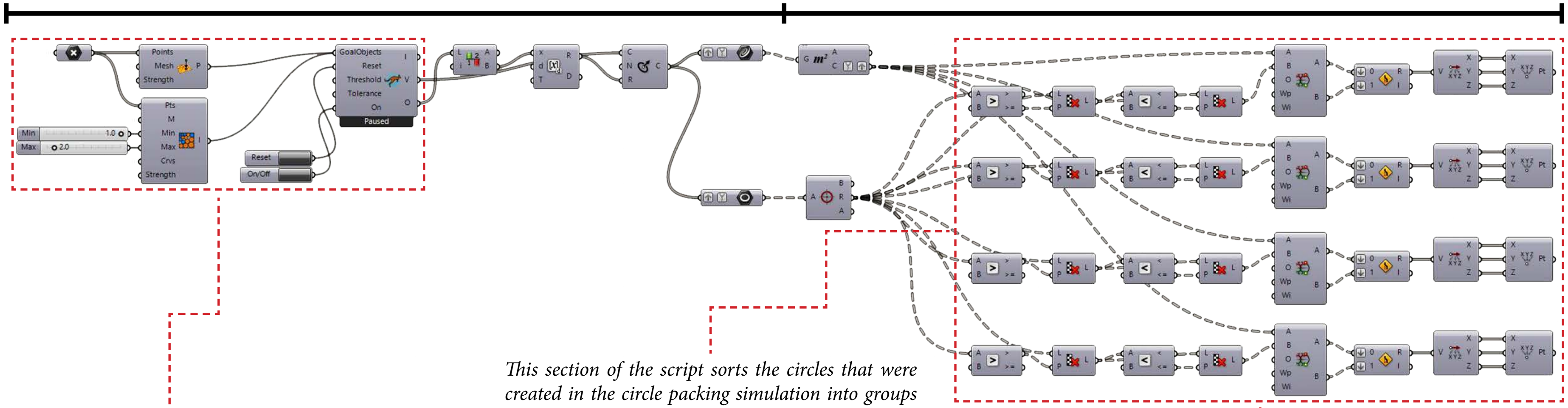
Figure 58. Timeline of developed Grasshopper script part five



Run circle packing simulation



Categorise plantar regions into required densities

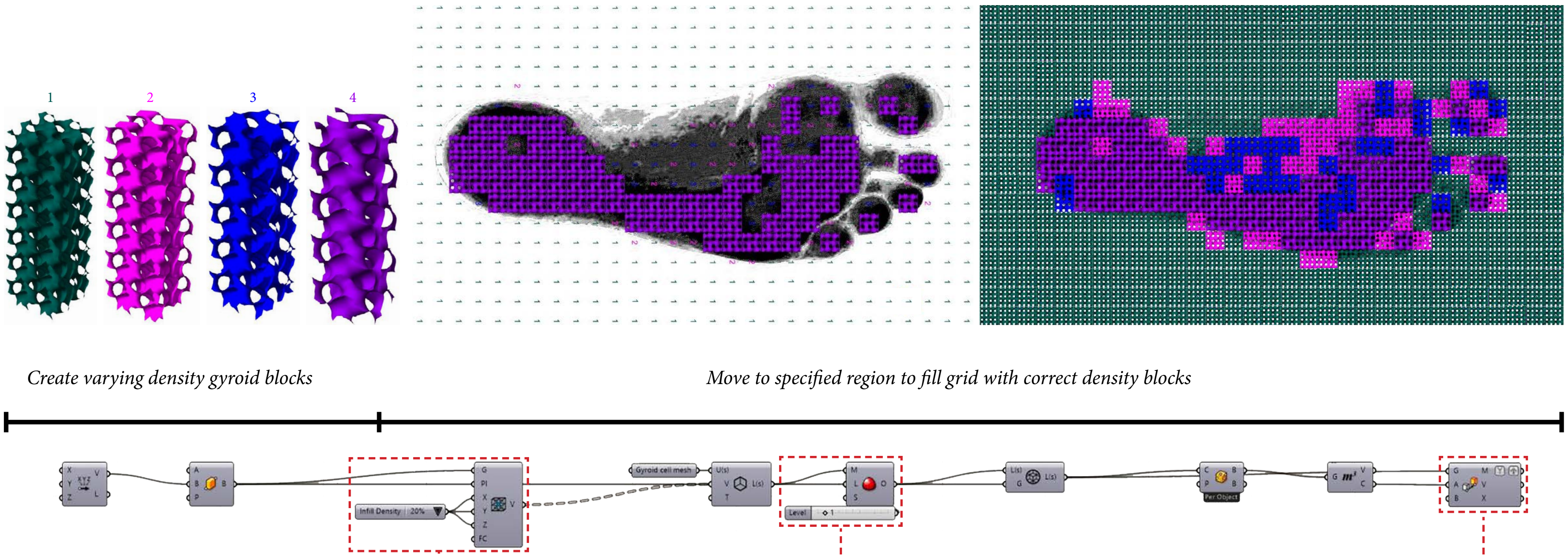


This circle packing Kangaroo simulation is able to scan a greyscale image and create circles of varying diameters at the points on the grid. The darker that section of the image, the smaller the circle diameter.

This section of the script sorts the circles that were created in the circle packing simulation into groups based on their diameter. By categorising each region, the script will later be able to place the different density blocks in the required regions.

In this script, there are only 4 specified categories. This means that a range of 4 different density blocks can be used to make the insole. By simply adding more categories at this section of the script, a wider range of block densities would be able to be used.

Figure 59. Timeline of developed Grasshopper script part six



This is the key part of this script section as it defines the density of this set of blocks. To be able to have multiple densities, this section of the script has to be duplicated.

The smoothing component for the gyroid lattice has 4 levels, with level 0 being very little smoothing, and level 3 being the maximum. With such a large, complex script, setting the smoothing level of all the lattice structures to level 2 or 3 was found to make the whole script run very slowly and in some cases, crash the whole software.

The blocks are copied and moved to the specific points using this component. The B input is connected to the list of categorised points created by the circle packing simulation.

Figure 60. Timeline of developed Grasshopper script part seven

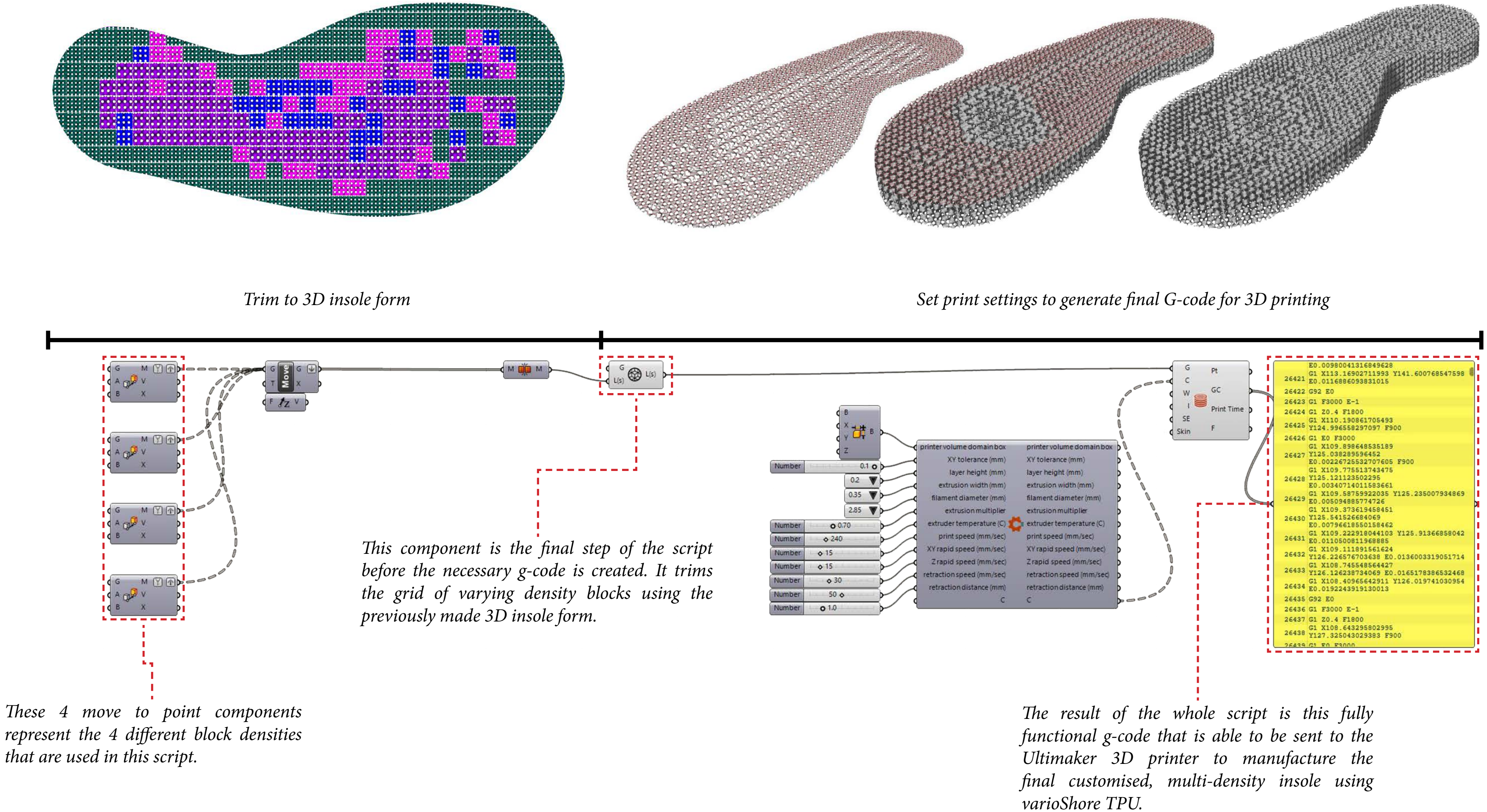


Figure 61. Timeline of developed Grasshopper script part eight

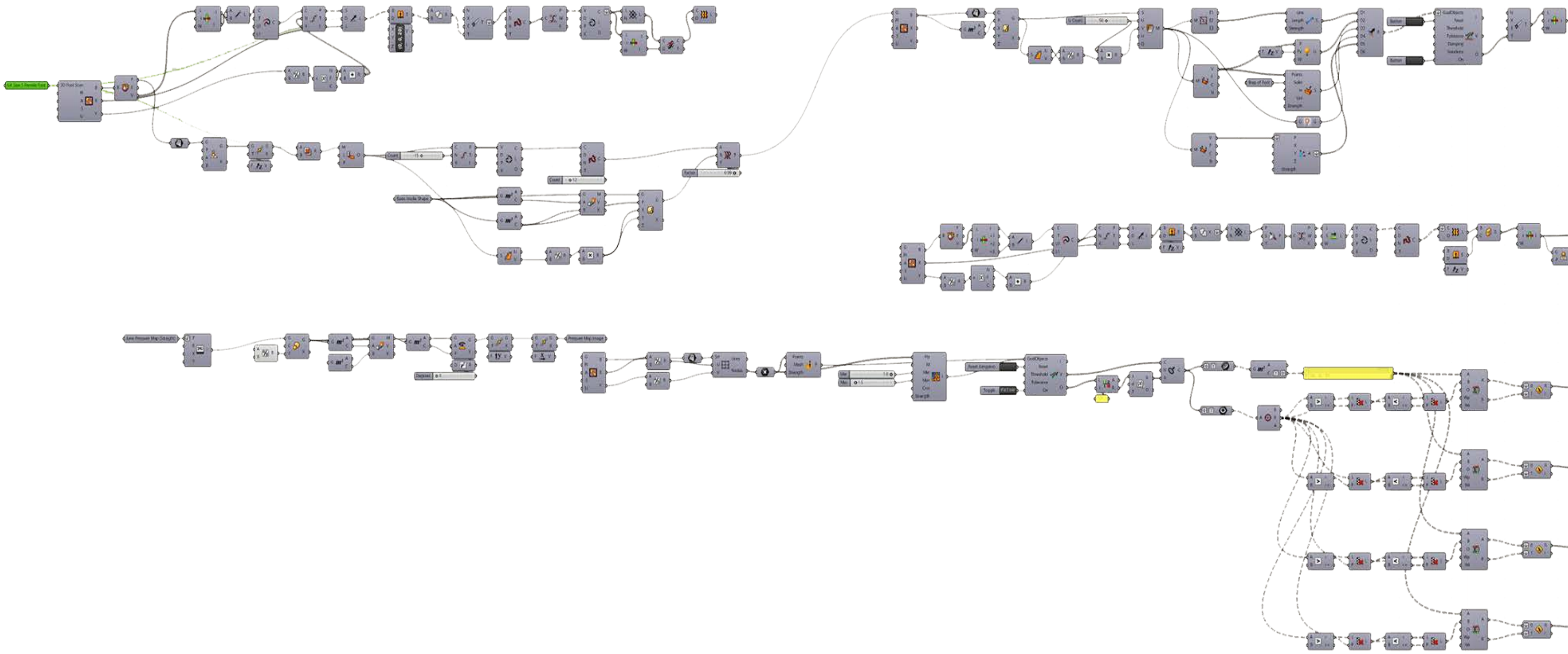
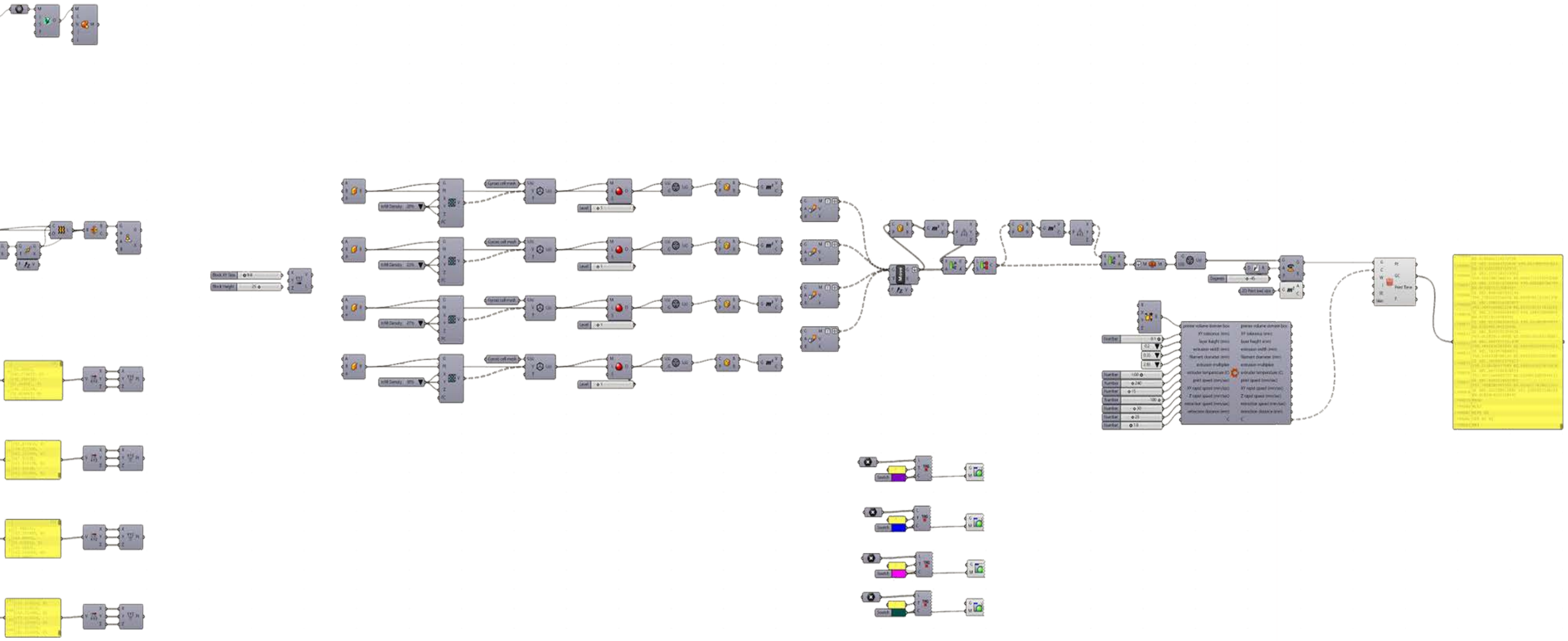
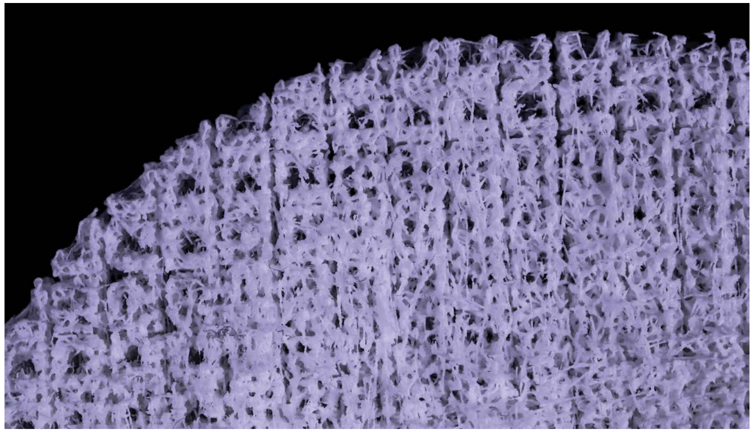


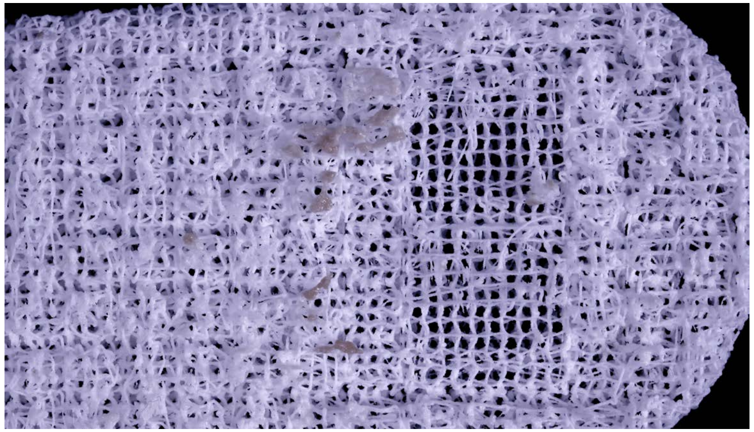
Figure 62. Fully developed Grasshopper script



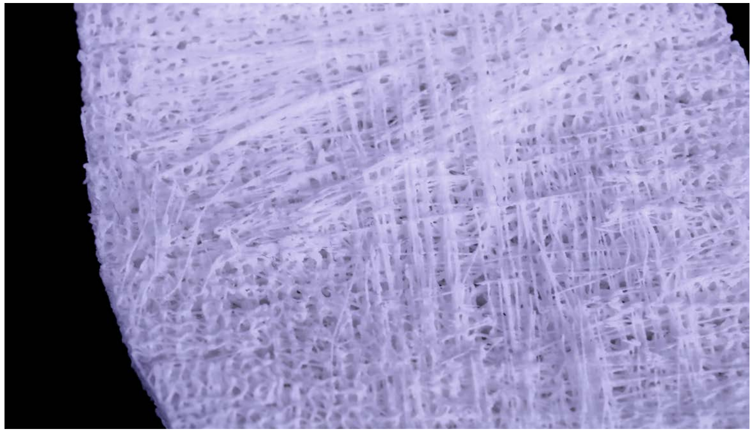
Failed Test Prints



Failed test print #1
Fault in the grasshopper script caused misprinting of density blocks. Issue was fixed with minor correction of script.



Failed test print #2
3D printer stopped extruding due to clogging of nozzle. Regular maintenance and cleaning of nozzle helps to avoid this problem.

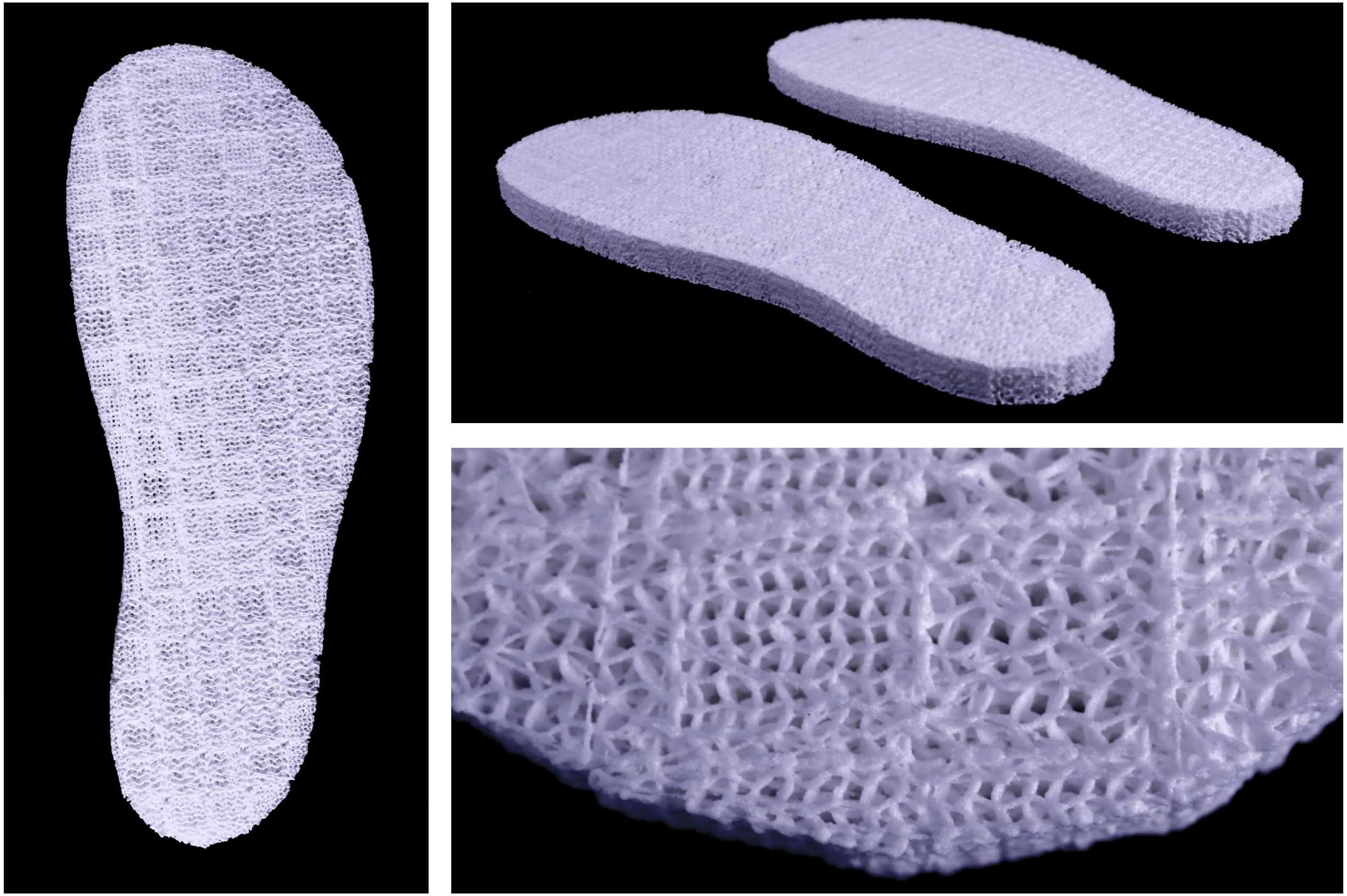


Failed test print #3
Loose filament and print lines streaking across prints. This issue is due to the lack of extrusion control with the Ultimaker 3D printer. Extrusion rate was lowered to reduce occurence and script was altered to optimse print order.

Failed test print #4
Printer calibration failed after maintanance pause which caused the nozzle to drag through the previous layers causing burning. Issue was fixed with a re-calibration and the print was restarted.

Figure 63. Failed test prints

Scaled Insole Test Prints



Figures xx: Flat, lower resolution, multi-density 3D printed insole(s) (created using developed grasshopper script)

Figure 64. Flat, lower resolution, multi-density 3D printed insole(s) (created using developed Grasshopper script)

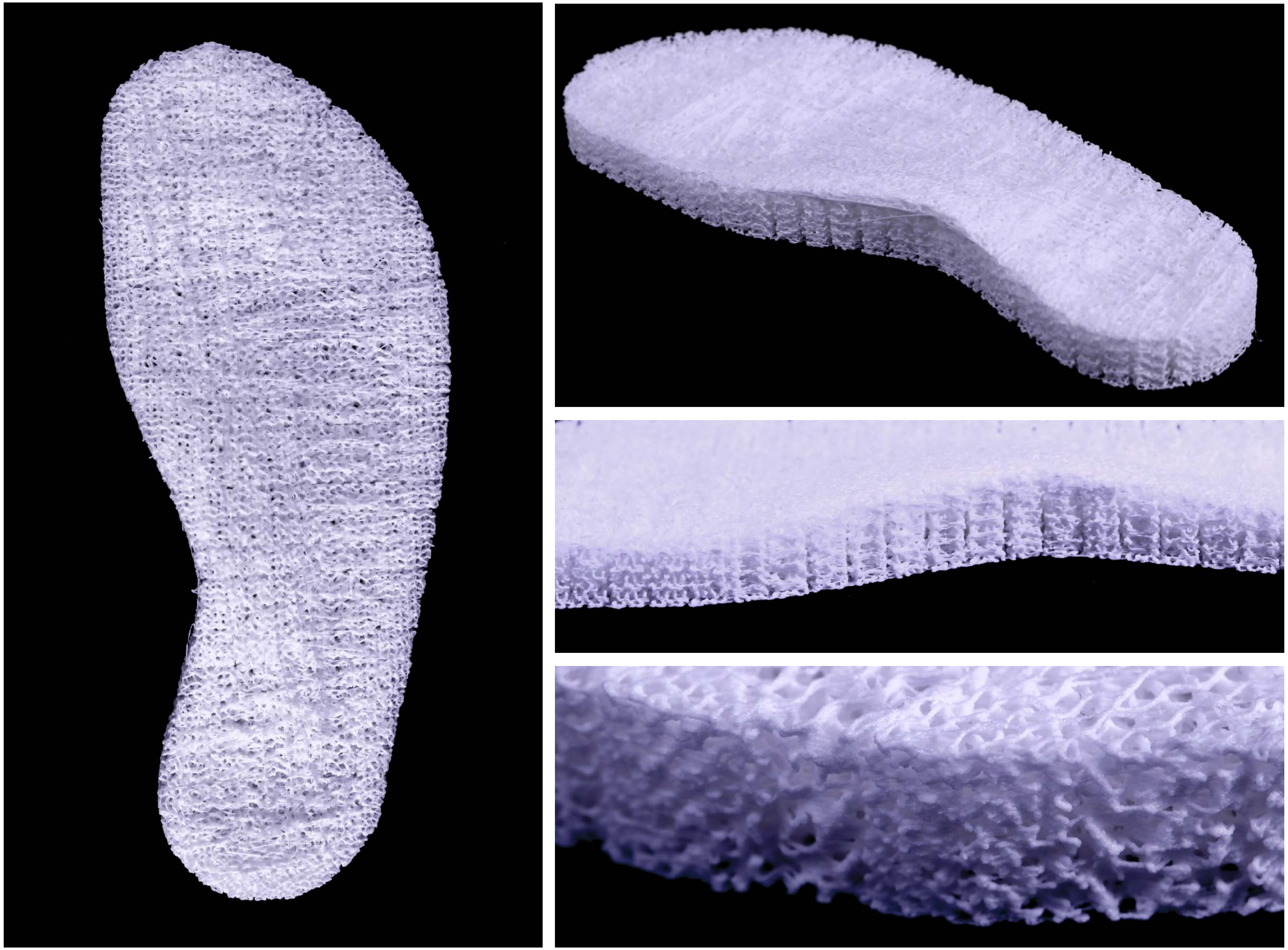


Figure 65. 3D printed multi-density insole (created using developed Grasshopper script)

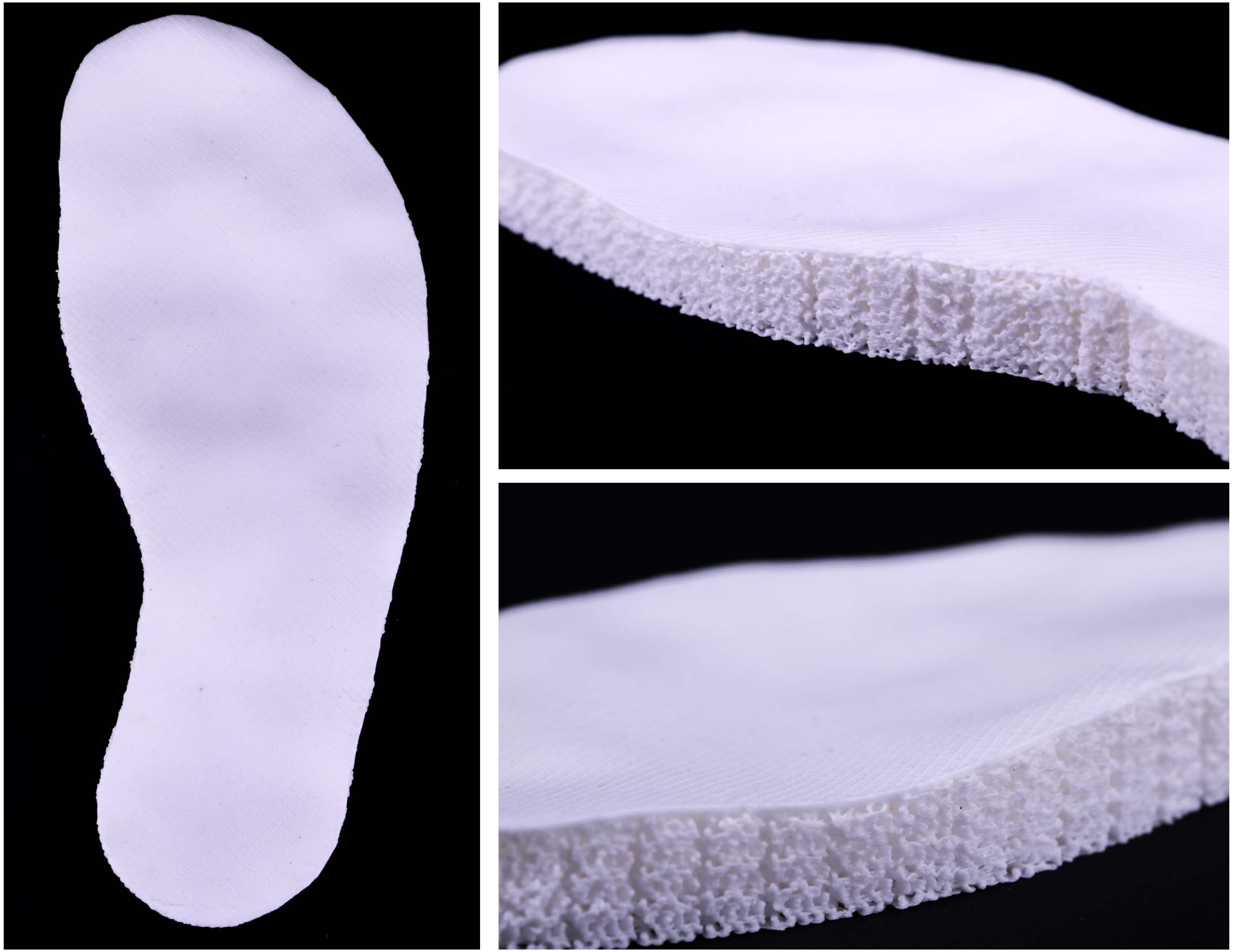


Figure 66. 3D printed mulit-density insole with top skin (created using developed Grasshopper script)

4

Application

Design and Development

Overview

After conducting background research, material experiments and 3D print tests using the developed parametric modelling script, it was time to combine all this information in the form of proof of concept models.
The final section of the experimentation showed the developed grasshopper script's ability to 3D print a customised, multi-density insole. This insole can be used to assist in the even distribution of plantar pressure, reducing the risk of DFU presentation or reccurence.
This application section will look at 3D printing full scale insole models, as well as producing speculative concepts for fully 3D printed diabetic shoes, using the varioShore TPU foaming filament.

Discussion

There are a number of shoe manufacturers that produce specialised shoes for diabetic patients. A good example is the Dr Comfort shoes that were mentioned in the precendent review section of the background research. These specialised shoes have certain features that are beneficial to those with diabetes, such as a larger area around the toes and seamless interiors to ensure that no rubbing can occur, which would make the foot vulnerable to DFU development. Another feature is the use of velcro instead of shoe laces. The purpose of using velcro is to eliminate any chance of rubbing on the top of the foot, as well as making it very easy to open, close and tighten the shoe. There are very few shoe designs that explore alternative ways to open, close or adjust a shoe. The idea of an almost effortless motion to put on shoes is an intriguing concept that would greatly benefit a diabetic person who may also be overweight and therefore, may struggle with tasks such as putting on shoes.
This design and development section will explore possible alternatives to standard shoes that have laces or velcro, and will propose new diabetic shoe concepts. These concepts will then be developed further, and the final iterations will be 3D printed at full scale, using varioshore TPU.

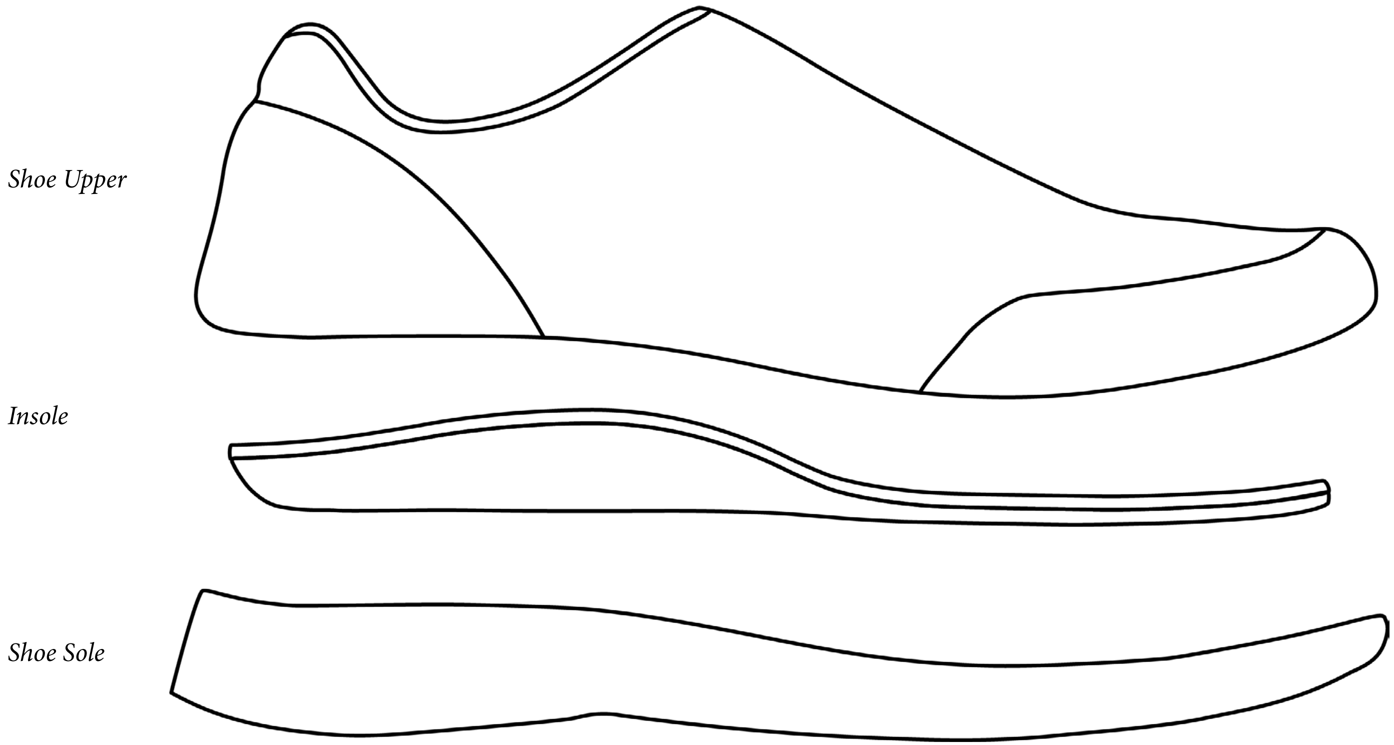


Figure 67. 3 parts of a shoe

Design Objectives

Overview

The next stage of this research will look at applying all the knowledge about diabetes, foaming 3D print filaments and parametric modelling software, to 3D print customised orthotics and speculative shoe concepts for those with diabetes.
To be able to 3D print a shoe using an FDM printing process, it will have to be divided into three parts; the shoe upper, the insole and the outsole. One of the reason for this is to be able to print the upper shoe flat, allowing for very small holes to be integrated into the print which will help with breathability. Another reason is to ensure the integrity and accuracy of all the individual printed parts.
The design objectives for this stage can be seen below:

- Create two or more concepts that exhibit different configurations that facilitate the putting on, tightening and taking off of a shoe.

- Successfully 3D print a full-scale customised insole with variable density, based on simulated pressure map data.

- Develop shoe design concepts using physical prototypes.

- Successfully 3D print the 3 individual parts needed for a full scale model of the final concept.

Concept 1

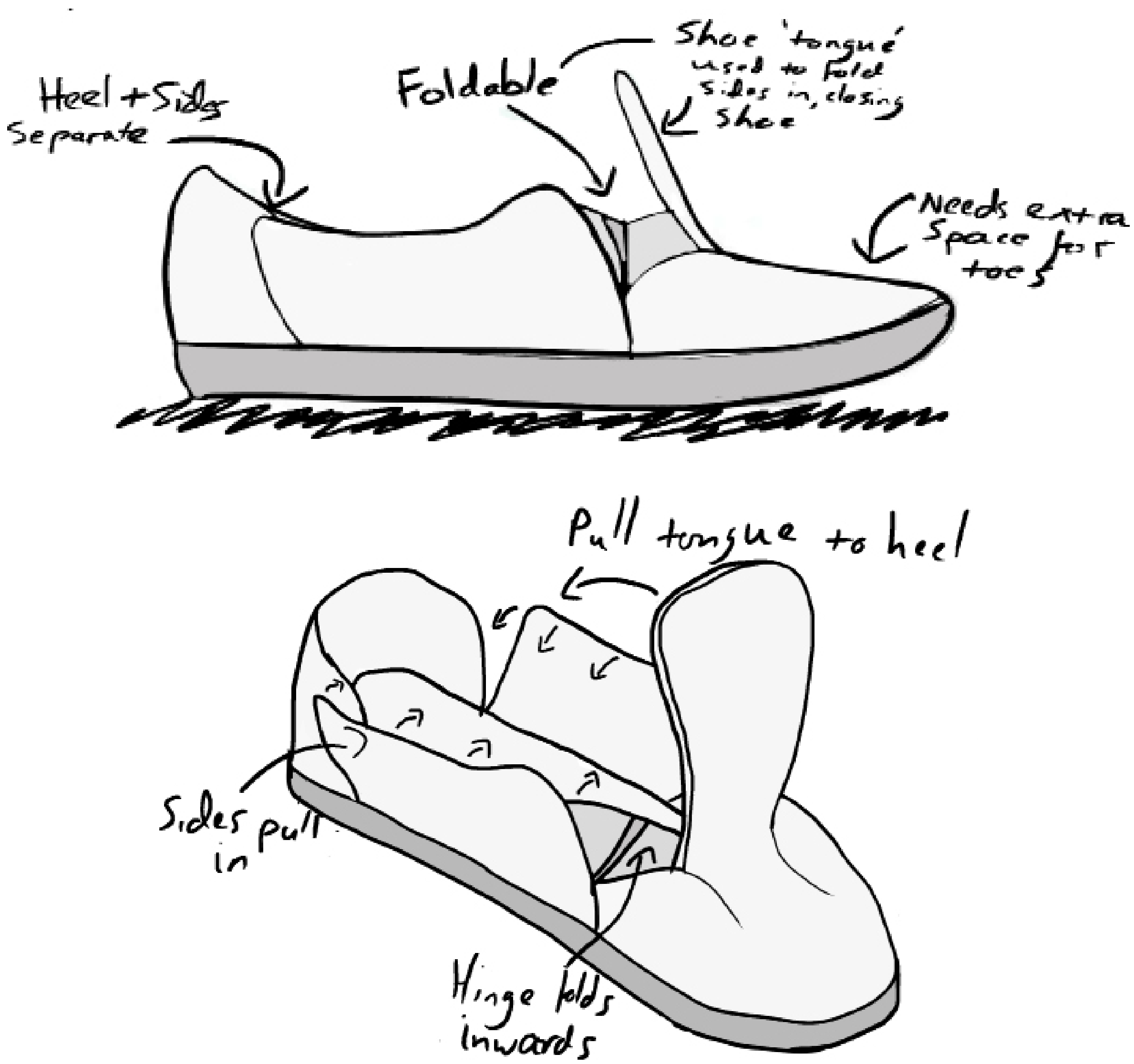
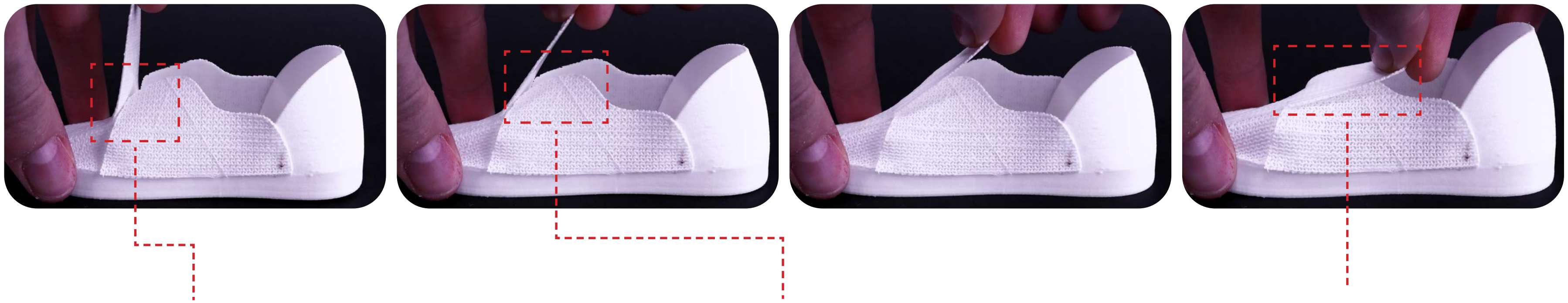


Figure 68. Digital sketches of concept 1

Concept Description

This concept uses the shoe 'tongue' to close the shoe around the users foot. The intial concept sketches show a pleated hinge connecting the sides and the tongue. This hinge is configured to pull the sides of the shoe outwards by pulling the tongue towards the toes, thereby opening up the shoe for the foot fit in with ease. To close and tighten the shoe around the foot, the tongue would be pulled towards the heel of the foot, and the hinge would pull or push the sides inwards. The images below demonstrate the range of motion that would be required.
The system for keeping the shoe closed is not yet established; however, it would most likely be secured with a magnetic or velcro strip.



Specially designed hinge will be here and will connect the shoe tongue to the sides.

The hinge will fold in a way that pulls the sides of the shoe towards each other.

The tongue will cover folded sides and some form of magnet or velcro will keep the closed shoe secure.

Figure 69. Concept 1

Iteration 1

Thin, flexible hinge

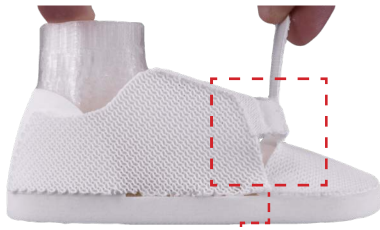
Ideally, this tongue would open further to allow for space for the foot to slip in.

This hinge iteration does fairly well at folding in the sides, but fails to lay to tongue smoothly on top to properly close the shoe.

Iteration 2

This iteration attempted to improve the hinge folding mechanism as well as have the shoe be more open when the tongue is up.

The hinge was a bit too big which resulted in a worse hinge folding mechanism than iteration #1.



The form of the hinge was able to open the sides of the shoe wider when pulling tongue towards the toes, but unable to get it to seamlessly close as hoped.

Figure 70 & 71. Concept 1 iteration 1 and 2

Iteration 3

With this iteration, the hinge was able to stay upright when the shoe was open which is perfect for ease-of-access.

There seemed to be a perfect amount of tension that helped to easily pull the tongue over the folding side.

With this hinge, the shoe was able to push the sides inwards quite well, but again failed to lie smoothly over the folded sides.

Iteration 4

This final hinge iteration went back to the basic version.

Due to the refined hinge, the tongue lies flat over the top of the folded sides. Now all it needs is a magnetic strip to hold it securely in place.

Just enough tension between the tongue and the sides to keep the shoe open when in a neutral position, and then be able to push the sides in when closing the shoe around the foot.

Figure 72 & 73. Concept 1 iteration 3 and 4

Concept 2

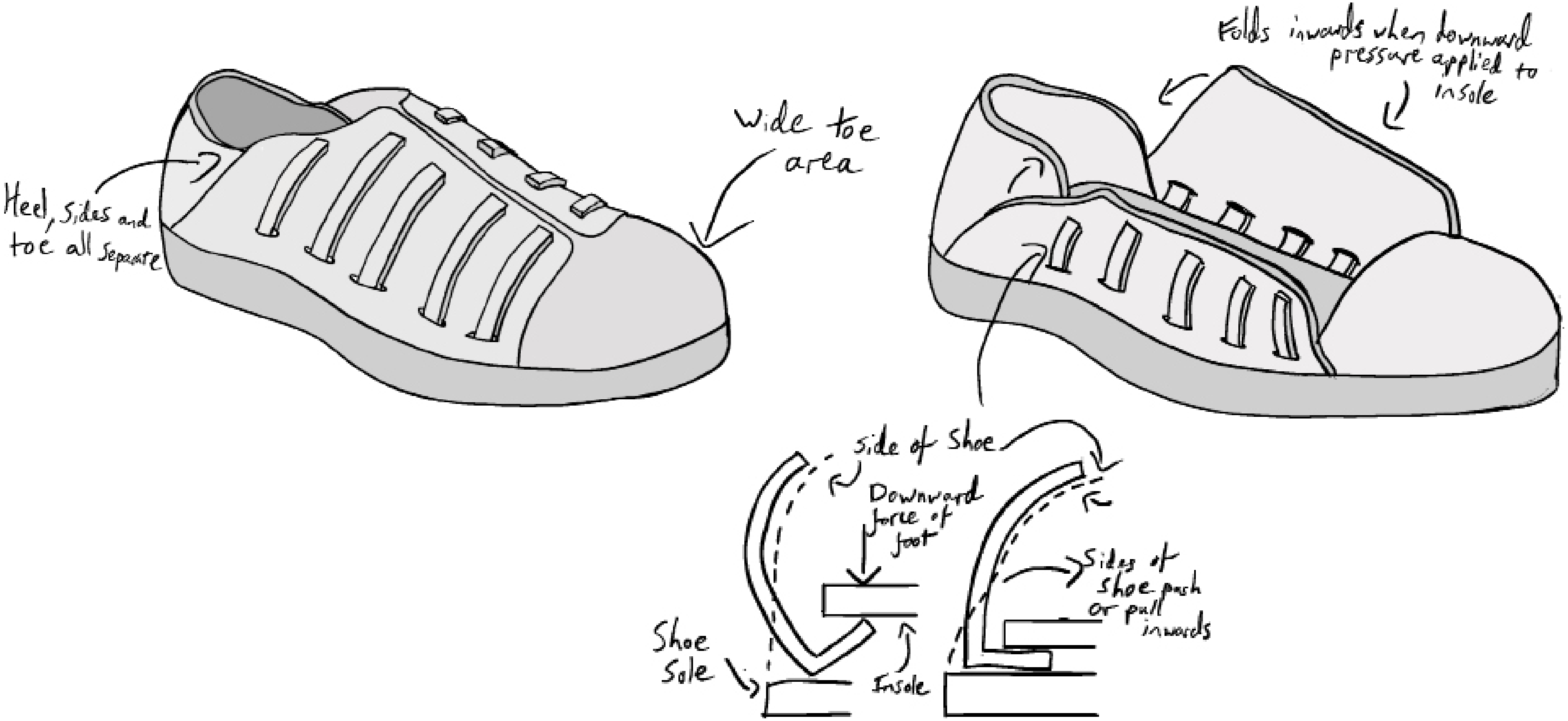
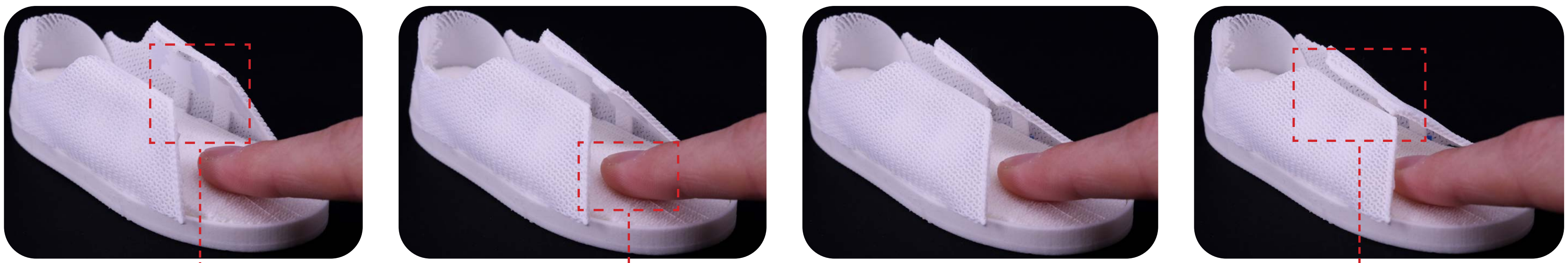


Figure 74. Digital sketches of concept 2

Concept Description

Concept 2 is a completely hands-free shoe that uses the action of stepping into a shoe to push down on the raised insole which pulls the two sides inwards, causing the them to wrap around the foot and meet in the middle. A magnetic strip will keep the shoe closed and secure around the foot. To take off the shoe, the user would simply step on the back of the heel with the opposite foot, and then lift their foot up, heel first. This motion would detach the magnetic strip that keeps the shoe closed and open up the sides up to their neutral position where the users foot is able to easily step out of the shoe. The initial sketches for this concept indicate an almost claw-like mechanism; however, this was reconfigured as internal straps pulling the sides inwards as the user applies downward force with their foot.



The sides of the shoe will have some form of strap that will feed under the insole and be used to pull the sides in when downward force is applied.

This finger is simulating the downward force that would be applied by the users foot as they step into the shoe.

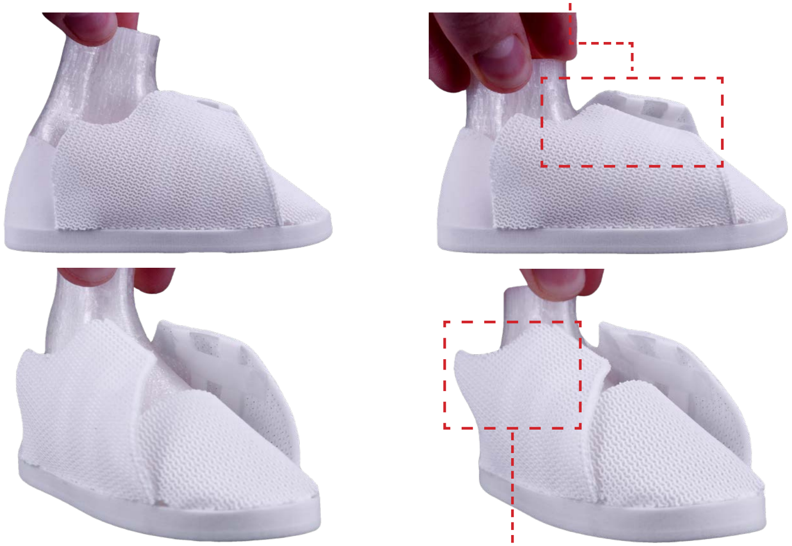
Once the sides have wrapped around the foot, a magnetic strip will keep them connected to keep the shoe closed. There will also be a front part of the shoe that will cover the toes.

Figure 75. Concept 2

Iteration 1

Paper is used to keep the straps close to the sides and help with the wrapping around the foot.

As the foot applies downward force, the sides fail to fold and wrap around the foot properly.

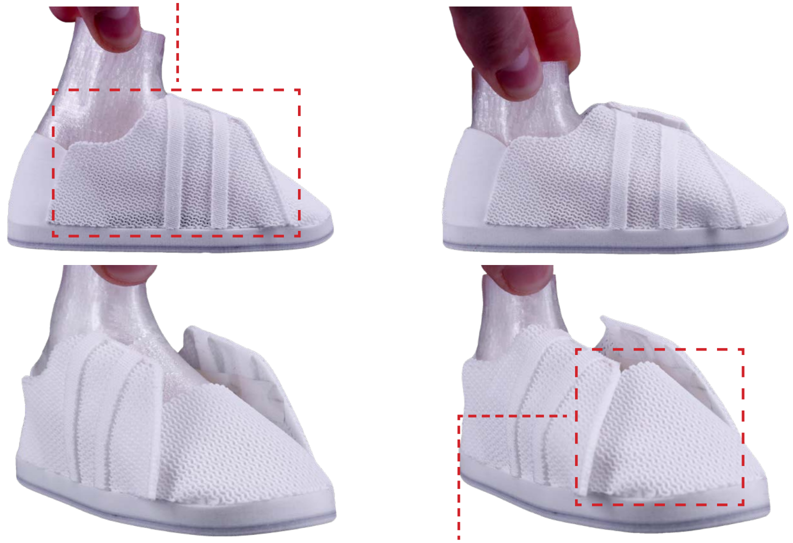


Sides push outwards rather than inwards and are too tall for the size of the foot.

Iteration 2

Thick strips were added to the sides exterior to help with the bending motion and add to the aesthetics.

Shorter sides than iteration #1



Front toe area too tall. It stops the sides from folding inward properly.

Figure 76 & 77. Concept 2 iteration 1 and 2

Iteration 3

Toe area was made higher to allow for extra space around toes.

The internal straps were made longer so the wrapping around the foot was smoother.

Sides wrap smoothly around the foot but are too short to meet in the middle.

Iteration 4

Sides made slightly higher to be able to fully cover the top of the foot when closed.

The top curve of the heel flows seamlessly into the top curve of the sides.

Both sides wrap around the foot well and meet perfectly in the middle.

Figure 78 & 79. Concept 2 iteration 3 and 4

Figure 80. Concept 1 final iteration

Figure 81. Concept 2 final iteration

Concept Review

Concept 1

Concept 1 used the tongue of the shoe as a way to push the sides inwards with a pleated hinge that would fold at the right angle. The iterations mainly focused on the design of that hinge and were able to develop it to the point where it worked reasonably well. Due to foot deformities being common for diabetic patients, there is a possibility that the shape of their feet could be irregular and therefore affect the efficiency of the pleated hinge. The hinge would have to be extensively customised for each patient to ensure that the sides fold accurately around their foot. This would be difficult to integrate into a parametric modelling script and would be very time consuming for the clinician or technician to do manually.

Concept 2

Concept 2 used the natural motion of the user stepping down into the shoe to pull the sides in and around the foot. As a hands-free mechanism, this concept was considered to be more beneficial to a diabetic patient than concept 1. The difficulty with this concept is configuring the geometry of the shoe parts in proportion to the user's foot so that the sides will efficiently wrap around the foot and meet in the middle to successfully closing the shoe. Despite this difficulty, it was decided that due to the hands-free operation, as well as general aesthetic, concept 2 was the better of the two concepts. However, both concepts demonstrate the potential for foaming 3D print filaments to be combined with parametric modelling software, and additive manufacturing technologies, to manufacture customised 3D printed diabetic shoes.

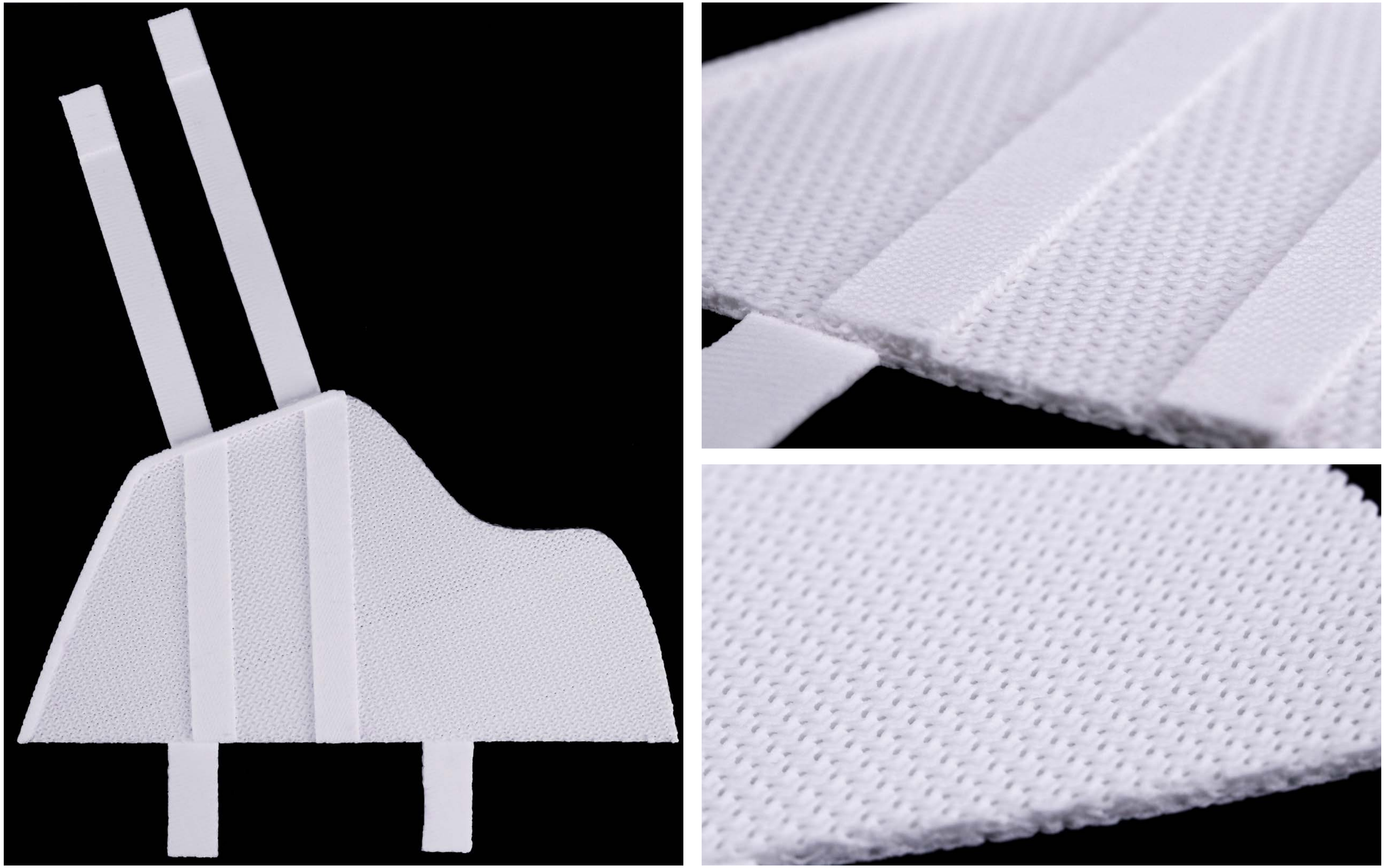


Figure 82. Full scale 3D printed shoe sides

Shoe Upper

Overview

For the upper part of the shoe (e.g. the toe area and sides), some type of printed pattern will be used to replicate the woven fabric found on some regular shoes and provide sufficient flexibility and breathability. To generate the different patterns, the same section of the Grasshopper script that is used to make the gyroid density blocks can be edited accordingly.

For the concept prototyping and concept 2 development, a 40% gyroid infill was used (see figure 82) as it was similar in appearance to a woven fabric and it had very small holes that allows for breathability. Below are some more examples of other print patterns that could be used for future designs.

Gyroid Pattern

(40 and 50% infill)

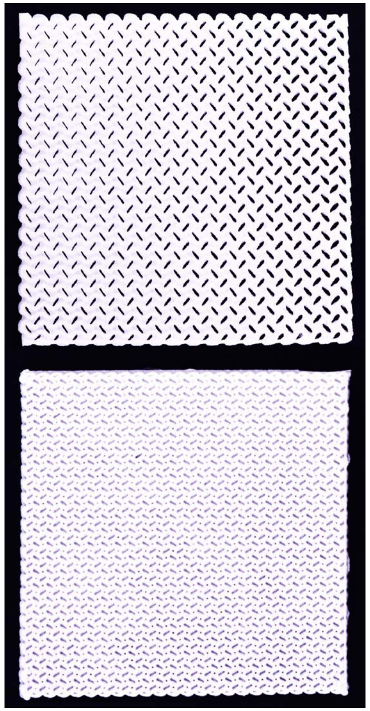


Figure 83. Gyroid pattern samples

Octet Pattern

(50 and 60% infill)

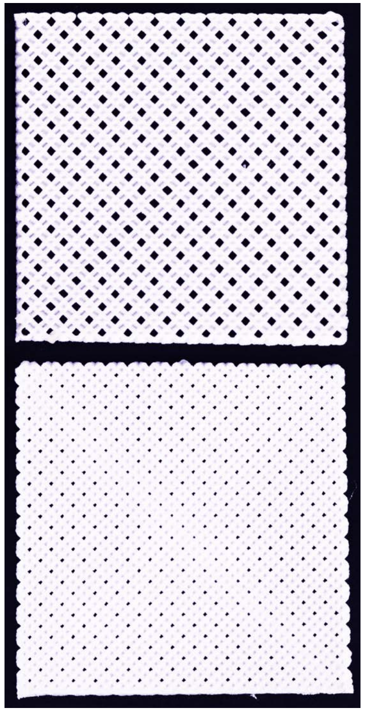


Figure 84. Octet pattern samples

Cubic Pattern

(50 and 60% infill)

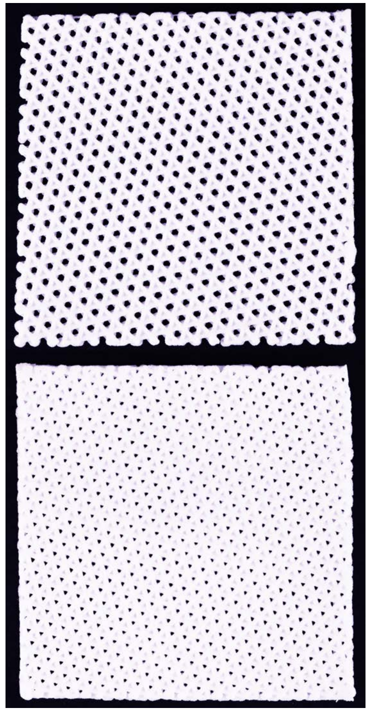


Figure 85. Cubic pattern samples

Figure 86. Full scale 3D printed shoe sole

Shoe Sole

Overview

There are three main features that functional, effective shoe soles require. Firstly, they should be water resistant so that the user can wear them in multiple scenarios and not have to worry about wet weather ruining the shoes and getting wet feet.
Secondly, shoe soles should be durable. Similar to standard rubber shoe soles, the 3D printed soles will be subjected to a fair amount of abrasion and physical trauma as the user is wearing them throughout the day. Therefore, the material used to make the soles should be able to withstand this abrasion and trauma to ensure the shoes stay in a usable condition for a considerable amount time.
Thirdly, a shoe sole needs to have grip to mitigate the risk of the user slipping and falling.

Water Resistance

Printing with TPU is already known to produce water resistant prints. The foaming of the varioShore TPU causes the printed layers fuse to one another and become even more water resistant and even able to create water-tight models. Evidence of this fusion of layers was clear throughout the experimentation stage (see figure 87).

Durable

TPU is known for being durable due to it's flexibility and elasticity. It has previously been used to manufacture products such as phone cases,sporting goods and footwear. All of this applications require a material that is durable. The foaming TPU will improve the elasticity and softness, but will not take away from the material's durability.

Grip

The grip on a shoe sole is reliant on both the material and the geometry or pattern that is made with that material. The geometry on the sole of these 3D printed shoe concepts is able to be easily changed using the Grasshopper script. Examples of some of the patterns that can be printed for grip can be seen below.

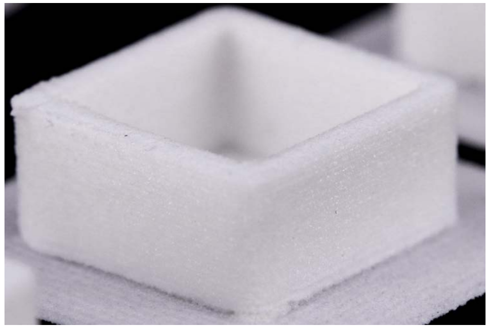


Figure 87. Fully foamed 3D printed sample

Figure 88. 3D printed sole with heel

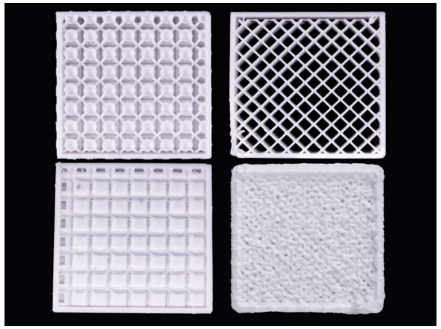


Figure 89. Shoe sole grip samples

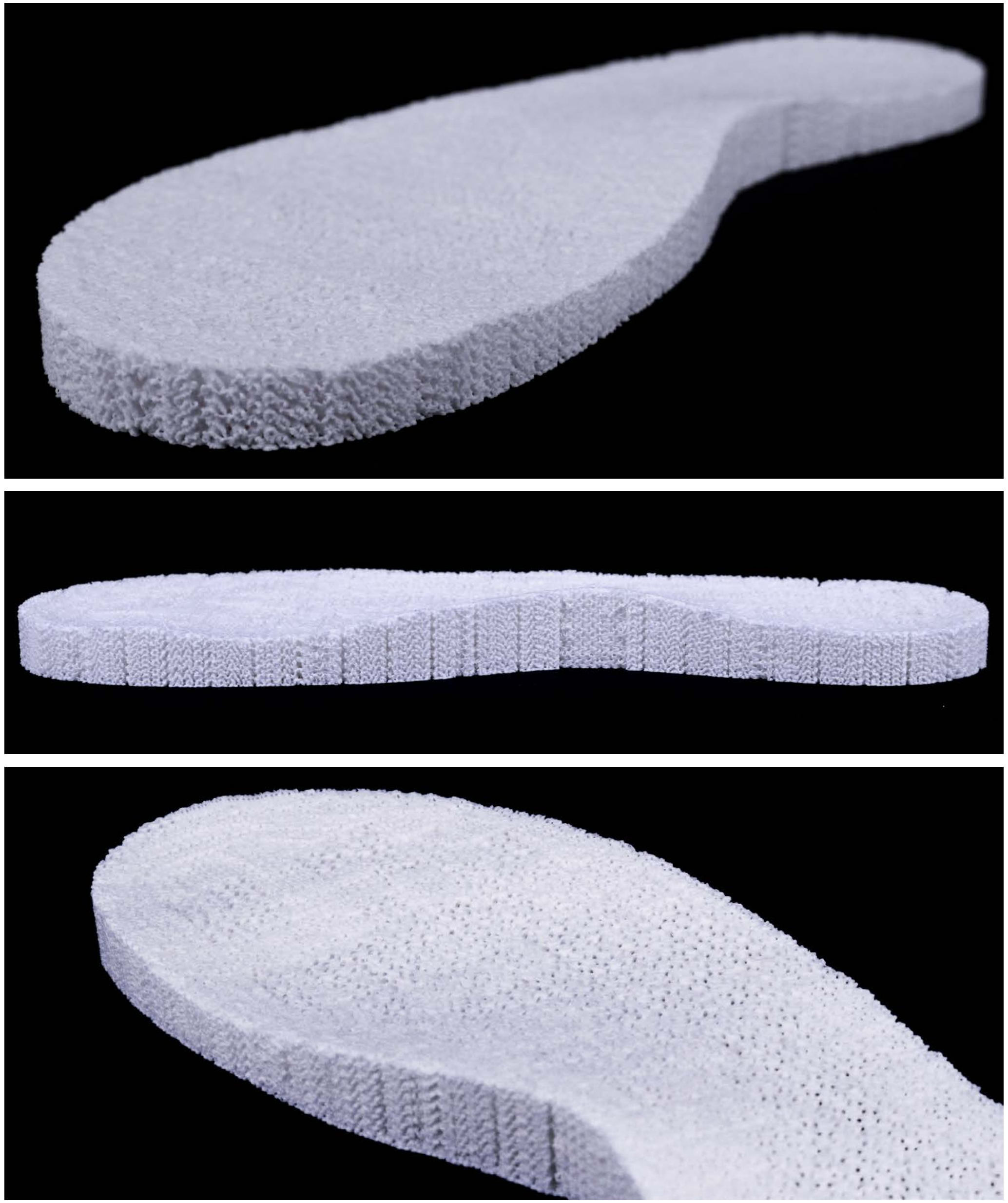


Figure 90. Full scale 3D printed insole

Customised Insole

Overview

As shown in the experimentation section, the customised insole is generated using a 3D foot scan and simulated pressure map data. The grasshopper script used to generate the insole was developed in the experimentation section. The images below show the digital and 3D printed versions of full scale insoles using a 3D foot scan and simulated pressure map data. The insole on the left is made up of 5 x 5mm (W x L) blocks of 4 different densities, and the insole on the right is made with a lower resolution, with the density blocks being 10 x 10 mm (W x L), but still only 4 different densities being used. As previously stated, this resolution can be easily adjusted in the Grasshopper script; however, density blocks smaller than 3 x 3mm struggle to be printed effectively during the FDM printing process.

5mm density block insole

Digital *3D print*

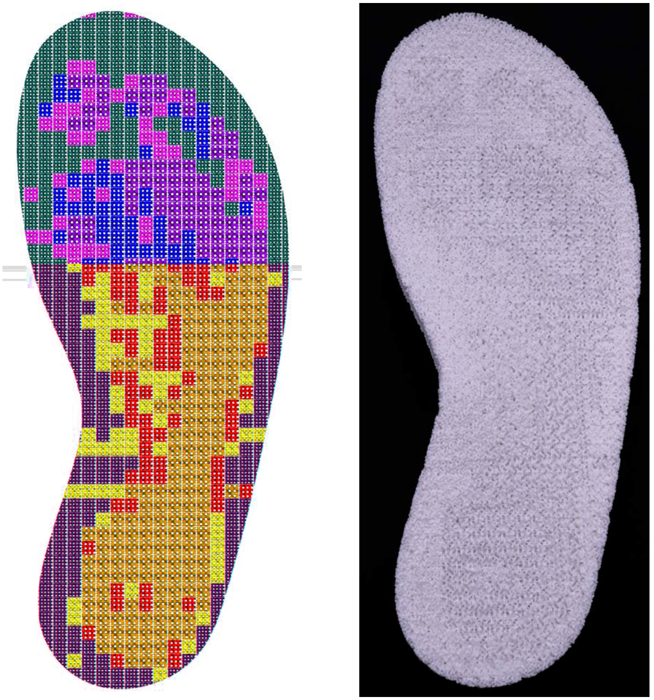


Figure 91. 5mm density block insole (Digital on left, 3D print on right)

10mm density block insole

Digital *3D print*

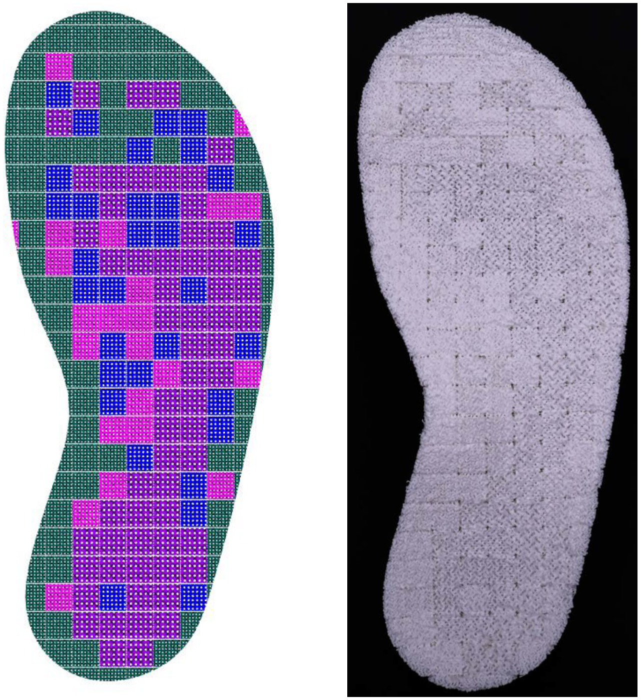
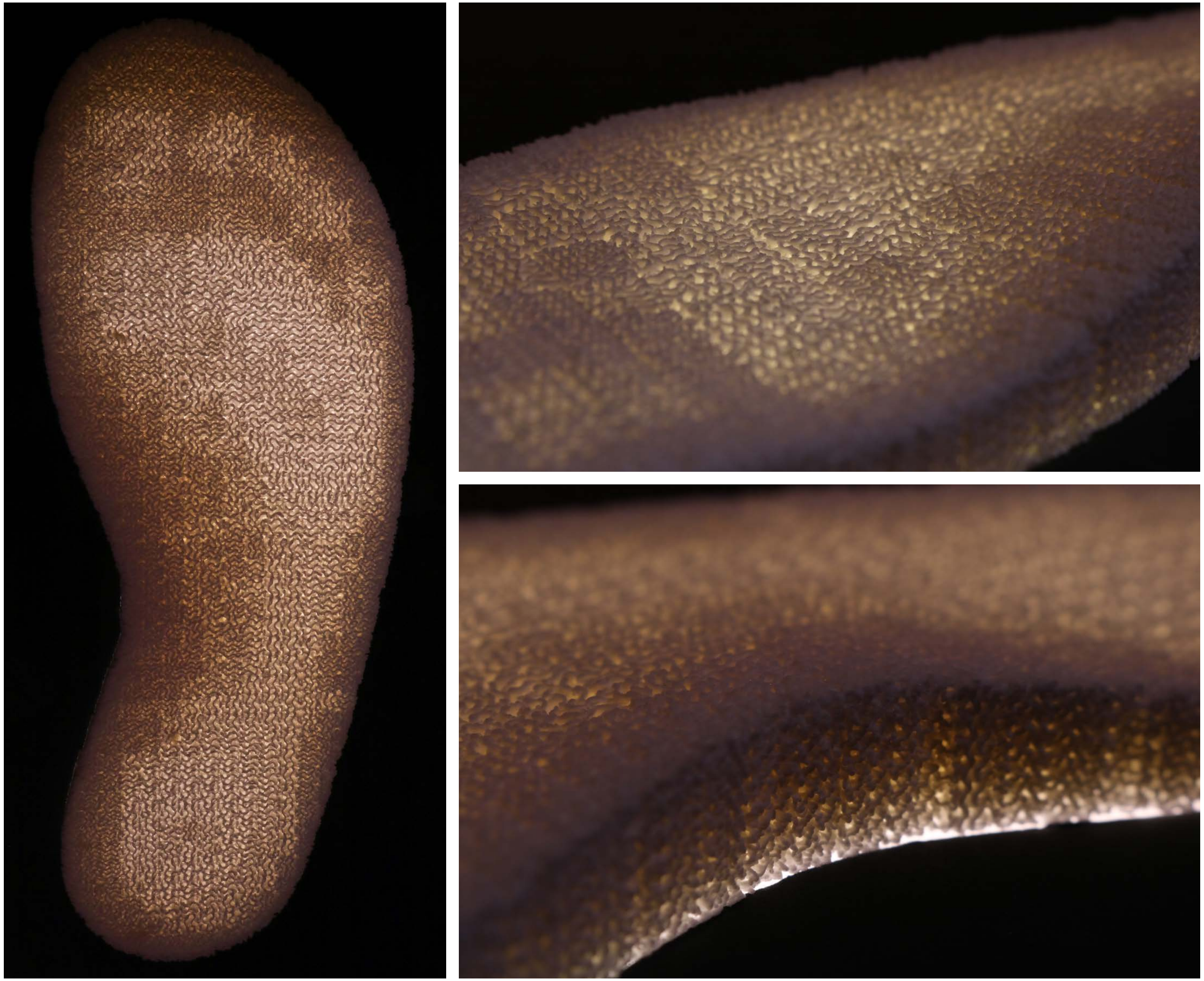
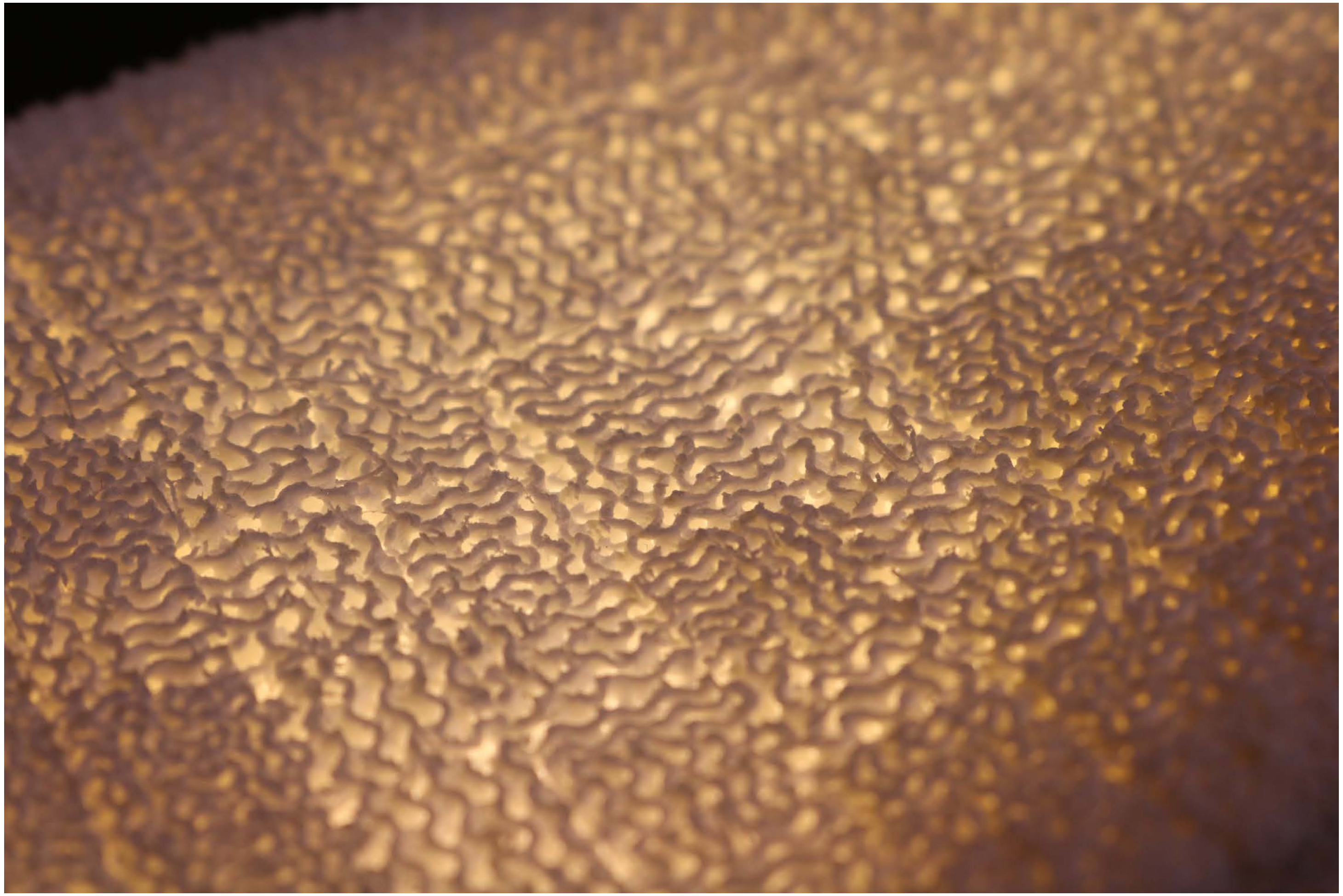


Figure 92. 10mm density block insole (Digital on left, 3D print on right)



Figures 93: 3D printed multi-density insole on lightbox



Figures 94: Close-up of 3D printed multi-density insole on lightbox

5

Discussion & Conclusion

Summary of Key Findings

The purpose of this research was to investigate how additive manufacturing could be used in the production of diabetic orthotics to assist in mitigating diabetes-related lower-limb amputations in New Zealand. The background research into diabetes, the complications associated with it, and the current prevention strategies that are used by organisations such as the NZALS, presented a number of design opportunities that were investigated further in the experimentation and application stage of this research portfolio.

A combination of two research methodologies (Research for Design and Research through Design) and the double diamond process model were used to construct this research portfolio. Frequent discussions about experiment results and observations were used to inform subsequent experiments and 3D print tests, as well as laying the foundation for the generation of innovative 3D printed shoe design concepts.

The development of a parametric modeling workflow was able to successfully produce highly accurate proof-of-concept models that demonstrate the ability of additive manufacturing technologies to be able to control both the form and the meta-material properties of a 3D printed object.

A design and development stage called on all the knowledge obtained from the previous stages of the research to inform the design of concepts for 3D printed diabetic shoes. An iterative design process using the rapid prototyping capabilities of the parametric modelling algorithm assisted in the development of a fully 3D-printed diabetic shoe concept, using just one single material.

Limitations

Computer Processing

To be able to run the complex parametric modelling script that was developed in Grasshopper, a computer with a high degree of RAM and processing power was needed. During the development of this script, there were occasions when the Rhino and Grasshopper programme failed to respond and therefore had to be restarted. At times, this caused a significant disruption to the progess of the research.

3D Printer Extruder

The Ultimaker 3 Extended is a very user friendly 3D printer; however, one constraint was the fact is uses a bowden extruder. This was an issue because the varioShore TPU that was used for the majority of this research is quite a soft filament, which does not extrud as well as harder 3D print filament, such as ABS. Another issue was the lack of control over the material extrusion because the extruder was not able to retract the filament sufficiently. This lack of control resulted in excess material flowing out of the print head as it travelled to the next instructed XY coordinate. Evidence of this excess material leakage can be seen in failed print test #3 on page 108. It is speculated that the use of an alternative 'direct' extruder would eliminate this issue and allow for greater control over the extrusion, and therefore, finer control over the level of foaming that occurs.

Materials

In the early stages of this research, it was hoped that a bio-based material could be developed and used to 3D print the final design concepts and a customised diabetic insole. However, during the material exploration stage, it became clear that the development of a bio-based 3D print filament that was able to replicate the properties of orthotic foams would require a long development period, well beyond the duration of this project. However, the material science research continues to explore potential bio-polymers that are able to foam during the 3D printing process.
Another material-related limitation is the lack of 3D print filaments that are able to foam during printing. With more options being available, further testing would have been done to compare and evaluate the capabilites of the filament variants.

Future Opportunities

3D Printed Orthotics

The use of additive manufacturing technologies in the production of specialised medical products is expanding rapidly. The advancements of these technologies in the coming years will allow them to achieve finer resolutions, greater accuracy and complex multi-material capabilities. For the printing of products such as diabetic insoles, the use of more advanced additive manufacturing technologies, such as polyjet printing, will offer the possibility of control over material deposition at a micron scale. The control of the foaming filaments at this scale would offer variable density products with immense accuracy and control. In addition, this form of additive manufacturing may also allow for control over the chemical formulation of the material as it is printed. This would allow the designer of the orthotic the ability to control the form of the orthotic, the formulation of the material used, and amount of foaming that occurs during the printing process.

Bio-Based Foaming Filaments

As previously stated in the experimentation section of this research portfolio, more research and development of bio-based 3D print filaments is needed before they can be considered for application. It is speculated that the emergence of more comercially available bio-polymers will take place in the coming years. In order to replicate the performance properties of current orthotic materials, or the varioShore TPU that was used in this research, the new bio-polymers will need to have a lower stiffness range than the current bio-based materials that are available.

Conclusion

This research portfolio presents four final outputs. Firstly, the research seeked to explore the potential for additive manufacturing technologies to be used to create customised orthotics that assists in the distribution of plantar pressures to reduce the risk of DFU development and recurrence. This exploration led to a full scale, variable-density insole being created using parametric modelling software and simulated pressure data.

Secondly, the use of foaming 3D print filament to manufacture the insole showed the potential for finer level control to be had over the mechanical properties of materials using an additive manfacturing process. When combined with a parametric modelling software, plantar pressure data can influence the mechanical properties of the insole material at precise locations around the foot, and simultaneously create the G-code required for the final product to be manufactured on the 3D printer.

Thirdly, this research offers speculative diabetic shoe concepts that can be 3D printed entirely from just one material, with concept 2 also boasting a hands-free shoe design that would greatly benefit diabetes patients with flexibility limitations or other physical disabilities.

Finally, through the material experimentation and 3D print test results using the foaming filament, varioShore TPU, this research hopes to provide information and performance specifications for use in the development of future bio-based foaming 3D print filaments.

List of Figures

All figures not cited here are produced by the author.

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Appendix

Sample No.	Print Temp (° C)	Layer Height	Infill Density (%)	Flow Rate (%)	Infill Print speed (mm/s)	Fan Speed (%)	Print Time	Notes
1	200	0.2	100	70	15	100	6 hrs 27 mins	This will act as a base sample. Printing at this temperature creates minimal foaming, but it is enough to fully fill the 50x50x10 block.
2	210	0.2	90	70	15	100	5 hrs 49 mins	
3	220	0.2	80	70	15	100	5 hrs 11 mins	
4	230	0.2	70	70	15	100	4 hrs 33 mins	
5	240	0.2	60	70	15	100	3 hrs 55 mins	
6	240	0.2	50	70	15	100	3 hrs 16 mins	
7	240	0.2	40	70	15	75	2 hrs 39 mins	Made the bed temperature 30C for this print to see if it would affect the misprinting 'wiggly' line infill. It didn't have any effect on it. From looking at the bottom of the print, it does look like the first few layers printed well but then something happened to cause the nozzle to be higher than it should have been.
10	240	0.2	50	100	15	100	3 hrs 17 mins	
11	240	0.2	50	100	10	75	4 hrs 52 mins	This is an print where the settings are all set to the certain value which showed the most expansion in their individual single wall tests, e.g. 240C print temp, 75% fan speed etc.
12	240	0.2	40	100	10	75	3 hrs 55 mins	
13	240	0.2	30	100	10	75	2 hrs 58 mins	

List of print settings used to make 3D printed compression test samples

14	240	0.2	30	70	10	75	2 hrs 58 mins	Not quite fully filled in but seems pretty soft when pressing vertically downwards. squeezing it horizontally is very foam like due to the infill acting as a lattice structure.
15	240	0.2	45	70	10	75	4 hrs 23 mins	
16	240	0.2	40	70	10	75	3 hrs 58 mins	Made this print with a gyroid infill to see if it would have a noticeable effect on the softness. It will be interesting to see the mechanical test results.
20	240	0.2	30	70	15	75	2 hrs 46 mins	Gyroid infill. Printed on its side so that the infill is orientated to act as an internal lattice structure. Feels soft to touch and still seems to have structural stability, very similar to the 6mm standard poron from NZALS
21	240	0.2	20	70	15	75	2 hrs 9 mins	Gyroid infill. Printed on its side so that the infill is orientated to act as an internal lattice structure. Feels very soft to touch, very similar to the 6mm standard poron from NZALS
22	240	0.2	25	70	15	75	2 hrs 30 mins	Gyroid infill. Printed on its side so that the infill is orientated to act as an internal lattice structure. Feels very soft to touch and definitely has foam-like compression
23	240	0.2	50	70	15	75	3 hrs 57 mins	Lines Infill. Printed on its side.
24	240	0.2	40	70	15	75	3 hrs 24 mins	Lines Infill. Printed on its side.
25	240	0.2	30	70	15	75	2 hrs 49 mins	Lines Infill. Printed on its side.
26	240	0.2	20	70	15	75	2 hrs 13 mins	Lines Infill. Printed on its side.

List of print settings used to make 3D printed compression test samples