

# **BMET3921**

# **Design Report**

**Supportive Solutions in Lower Limbs for Individuals with  
Neurological Conditions**

**Team 10**

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# 1. Project Aims and Background

## 1.1 Aims

The overall aim of the project is to create a prototype of an orthotic shoe device to increase independence and functional capacity of the lower limbs for Naomi, a 9 year old girl with SATB2 Associated Syndrome (SAS). The orthotic and shoe design and their components should be able to be adapted to an individual's biomechanical needs and thus be used directly, or as inspiration, for solutions for other patients with SAS that also have reduced lower limb functional capacity. The product will be based around correcting biomechanical issues particularly in the areas of; malleolar position (Internal or External tibial Torsion), hip range of motion in extended and flexed, leg length difference, forefoot valgus or varus, resting calcaneal stance position and neutral calcaneal stance position. For Naomi, the key issues resulting in lack of balance are having a toe claw, uneven gaits and ankle instability and thus the orthotic design aims to directly address these. The orthotic part of the product should create support without compromising range of motion to ensure comfort and ease of use for Naomi, ultimately increasing her functional capacity. The shoe part of the product, that the orthotic will be fixed into, should increase Naomi's independence by allowing her to use it by herself or with minimal help from a carer.

Through addressing Naomi's key biomechanical limitations, the product should reduce Naomi's likelihood of falling and injuring herself and in turn reduce the reliance she has on her family. The ability for her to put her shoe on and off with reduced help from a carer further increases her independence. Therefore, it is hoped that both Naomi and her family's quality of life will be improved through an increase in Naomi's independence and functional capacity. This principle will be extended to other patients suffering from SAS and their families as the orthotic created should be adaptable to the specific biomechanical needs of the individuals that require lower limb support.

In addition to the aforementioned aims, the project intends to raise awareness of SAS to inspire future funding and innovation of solutions for various aspects of the disease. Raising awareness addresses the particular aims of our client Dalal, Naomi's mother, who seeks awareness for SAS alongside a creative orthotic based solution to help her daughter.

Some specific deliverables we aim to achieve include:

- An evaluation of our design iterations based on risk, feasibility and if it addresses our defined aims, to select the most appropriate design to move forward with, based on Naomi's needs
- A 3D model of the final orthotic design for Naomi completed on CAD software
- A prototype of our final product catered towards Naomi's biomechanical needs
- Design that can be modified or adapted to different patients with SAS that present with similar biomechanical limitations

## 1.2 Background

### 1.2.1 SATB2 Associated Syndrome

SATB2-associated syndrome (SAS), also known as Glass Syndrome, is classified as a rare disease, only affecting just over 700 people worldwide [1]. It occurs as a result of mutation or deletion of genetic information in the SATB2 gene which is located on chromosome 2q33.1 [2]. The SATB2 gene codes for the SATB2 protein which is responsible for the development of the brain, bones, teeth, and palate. As such, changes to the expected gene have a number of downstream effects, causing a wide range of symptoms including speech anomalies, developmental delay and intellectual disability, dental and palate anomalies, brain anomalies, feeding issues and behavioural issues [3].

A syndrome like SAS with a range of symptoms requires many different innovative devices and therapies to address different symptoms and limitations faced by the individual with SAS to ultimately improve their quality of life. Our project is related to limited functional capacity of the lower limbs caused by the neurological aspect of SAS which involve dilation of ventricles and increased white T2 matter signals around ventricles, having a small corpus callosum

and having abnormal myelination [1]. Naomi, is one of many people with SAS that present with limited balance and coordination which makes it difficult to walk steadily and perform tasks that require precise control over leg movements. For Naomi, this limited mobility in her lower limbs relates primarily to pronation and supination, gait abnormalities like toe-claw and wide based gait which make mobility more challenging. Further, Naomi and others with SAS often present with muscle weakness which can make it difficult to maintain proper posture and walk with ease. Thus, we are developing an orthotic based device to counteract these biomechanical limitations caused by aspects of SAS.

It is important to note that SAS patients, including Naomi, have exhibited an increased pain tolerance, which can make it challenging to recognise discomfort and pain caused [1]. Their lower likelihood to recognise pain must be taken into consideration for all treatments of the disease to ensure no further harm is caused or gone unnoticed.

### **1.2.2 Naomi's clinical needs**

Individuals with SAS, including Naomi, require lower limb support to address the musculoskeletal challenges that reduce their functional capacity and in turn, their ability to carry out daily activities, ultimately reducing independence. They are also prone to falling, which increases the risk of injury. Dalal, Naomi's mother, has explained Naomi is often characterised as 'clumsy' as she falls frequently, which can be attributed to a lack of coordination and muscle strength which causes limbs to feel heavy.

SAS affects each individual in a different way and to a different extent, requiring solutions that can be personalised to the capabilities of each patient. Naomi's main issues with stability are attributed to her toe claw, raised gait and ankle instability. Currently, she uses interventions such as stability shoes, in-shoe orthotics and ankle-foot orthotics (AFOs), however, these products are not fully effective due to a range of factors such as cost, heaviness, rigidity and the materials used. In particular, according to Dalal, she finds the SMO's to be too rigid but do provide her with the most support. Stability shoes are expensive and not that comfortable and AFO's are very rigid and do not provide enough flexibility. Further, the materials used in existing products have been seen to cause severe blisters. Thus, Naomi is looking for a solution with flexibility that fixes her toe claw while offering enough support to give her stability and increase her lower limb functional capacity. Further independence gained from being able to put her shoes on and off would be of additional benefit.

Therefore, there is a need to improve current treatment methods that provide a balance between flexibility and support whilst also being comfortable. The high pain tolerance and nonverbal nature of Naomi also needs to be considered when evaluating the product

### **1.2.3 Impact of project**

Without this project Naomi will remain without a comfortable orthotic that she likes to wear that also provides her with stability without too much rigidity. She will continue to lack independence and maintain her moderate risk of falls and injuries. Thus, Naomi will remain incredibly dependent on her family and support networks which is sad and frustrating for everyone involved.

If this project is successful, Naomi will have an orthotic that will increase her functional capacity and independence. This will decrease their risk of falls and injury which will release stress on Naomi and her support networks as well as having potential reduction in annual medical bills resulting from reduction in need for medical help. Further, if this project is successful there will be greater awareness of, and empathy for, patients with, SAS. This has the potential to encourage and inspire future funding and research into solutions for limitations faced by people with SAS. Ultimately, the success of the project will increase the quality of life for Naomi, her family, other individuals suffering from SAS and their respective families.

### 1.3 Stakeholders

It is important to consider the key stakeholders for the project. The importance of the project to each stakeholder will influence their ranking as a stakeholder, the highest stakeholder being the person who has large control over the direction of the project and who the project influences the most. Understanding the ranking of stakeholders and what each of them wants to achieve will help direct the rest of the project in the right direction to ultimately provide an effective solution. The stakeholders identified for this project listed below are in order of highest priority to lowest.

Table 1 identifies the key groups or individuals who would be impacted by this project. This may include people required to work on the project, people with connections to the project and who the project is designed to provide for. It outlines the impact of the project for the stakeholder, and how they can influence the project outcomes.

**Table 1 - Project Stakeholders, their Impact and Input on Project Direction**

Stakeholder	Impact of project	Control/input on project direction
<b>Naomi Baumgartner:</b> Naomi is a 9-year-old girl living with SATB2 Associated Syndrome.	This project is of great importance to Naomi as she has a number of lower limb issues that affect her daily movement. The main issues affecting her balance are her toe claw, uneven gait and ankle instability as well as having weak lower limb muscles. As such, the project aims to successfully address what Naomi wants to achieve out of the project, being improved stability and greater independence from a comfortable orthotic solution, allowing her to carry out daily activities with more freedom and less risk of falling.	Naomi has large control over the project as her biomechanical issues are the primary focus of the project. Thus, her needs and wants will provide inputs that guide the project as it aims to find a solution to meet these. Naomi provides us with first hand knowledge of SAS and its effects on the lower limbs.
<b>Dalal Dawood</b> <b>Baumgartner:</b> Dalal is Naomi's mother and the founder, and principal director of SATB2 Connect. She is acutely aware of Naomi's needs and her primary communicator as Naomi is non-verbal.	The project is of significant importance to Dalal as she is a primary carer and communicator of Naomi, and witnesses the challenges that Naomi faces as a result of her condition. Further, she has high interest and influence in the SATB2 community and would like to see innovative solutions that help people suffering from SAS. Through the project, Dalal is hoping that her daughter will have increased independence and functional capacity in the lower limbs as she wants the best for her daughter. Additionally, increased independence for Naomi would give Dalal, as a carer of Naomi, greater freedom herself and it will reduce her fear of her daughter falling and injuring herself. Further, Dalal wants to raise awareness about SAS as this could inspire further funding and research into innovative solutions for the issues faced by people with SAS.	As Naomi is non-verbal and quite young, Dalal will provide detailed information about Naomi's specific needs and wants that our solution will directly address. Thus, Dalal has control over the project direction, articulating Naomi's needs and wants as inputs, guiding the direction of the project to meet these.  Further, Dalal is a contact in the SAS community and will potentially be able to help get our product onto the market and be known in this community in the future.

<p><b>Other SATB2 patients and their respective families:</b> This stakeholder involves all other sufferers of SAS, particularly those whose lower limb functional capacity is limited, and their families.</p>	<p>Whilst the project aims to create an orthotic based device specified for Naomi, the device should be adaptable to the individual needs of others with SAS. Ultimately, the project specifically aims to increase the person with SAS's mobility and independence, to reduce risk of falls and injuries to the patient. This will in turn reduce the time and effort the families spend assisting their children. Further, there may be some emotional benefits for both the patient and their families, reducing stress or fear of falls and injury.</p>	<p>Other SATB2 patients and their families will have minimal control and influence over the project direction. However, the solution created will address Naomi's needs that many people with SAS may share to varying extents.</p>
<p><b>Dr Abbie Najjarine (Clinician):</b> Dr Abbie is a well-renowned biomechanical practitioner who specialises in lower limb support. He is the President of the International Association of Clinical Biomechanics, as well as the Principal of the International Institute of Clinical Biomechanics. He has treated over 150000 patients and is best known for the Najjarine Biomechanical Assessment (NBA) which is used to assess patients abilities and diagnose their individual causes of issues within the scope of biomechanics particularly in the feet and lower limbs [4].</p>	<p>This project is important to Dr Abbie as he would value an innovative solution that would increase the quality of life of his patients. He will be able to utilise our product to support Naomi to have an increased functional capacity of the lower limb and independence. He will then be able to use our design as inspiration for other patients he treats with SAS or other neurological disorders that affect lower limb functional capacity.</p>	<p>Dr Abbie will be an important contact for guiding the project through his depth of knowledge and experience with lower limb supportive solutions. He will be able to inform us on what is feasible and the elements of our solution that will effectively meet our goal of helping Naomi's specific needs.</p>
<p><b>SATB2 Connect:</b> SATB2 Connect is a volunteer-governed charity in Australia that aims to support patients and families suffering from SATB2-associated syndrome through raising awareness, conducting</p>	<p>This project is of significant importance to this organisation as it aims to provide solutions for patients with SATB2-associated syndrome and thus, directly supports their cause. Therefore, this project will assist SATB2 Connect in their aims of achieving solutions, support and awareness for SATB2 patients and their families.</p>	<p>SATB2 Connect has no direct control over the project direction although any solution that helps Naomi will inevitably support their cause.</p>

research, advocating and establishing a supportive network.		
<p><b>BMET3921 students working on the project:</b></p> <p>This involves our group and another group working to find a solution to increase Naomi's independence and functional capacity of her lower limbs.</p>	<p>As the project coordinators, the project will have great importance for enabling us to contribute to helping others which is at the heart of biomedical engineering. We want to achieve an effective solution for Naomi that can be adapted to help other people with neurological conditions that affect their lower limb mobility. We further hope to develop an understanding of product development, collaboration and put theoretical technical learnt knowledge into practical solutions.</p>	<p>The project coordinators will be responding to the needs of Naomi and Dalal whilst taking on Dr Abbie's knowledge on our solutions feasibility. Thus, they will be the creative directors and control the direction of the solution but the direction will revolve around Naomi's need.</p>

## 2. Prior Art

### 2.1 Existing Technologies

We have analysed orthotic and support shoe based devices used to improve functional capacity of the lower limbs that are already on the market. We have grouped prior art into categories/ types of orthotics, the most relevant being heel supports, custom in-shoe orthotics, stability shoes, ankle foot orthotic and supramalleolar orthosis brace. These are the types of orthotics based devices Naomi has used, all of which are not perfect. The analysis of strengths of these devices allows for an understanding of what patients are looking for and how their needs are currently being successfully met. This knowledge can be used as inspiration for our own device. Assessing the weaknesses helps us understand what to avoid or change to create an effective and usable device for our client.

Table 2 explores the currently existing market with regards to orthotics and supportive shoes, to identify the need of our project and furthermore the likelihood of future financial success of the product. These existing products are analysed for benefits and downsides to their use with the latter being the considerations our project must consider to improve on existing models.

**Table 2 - Prior Art**

Name / Category	Description	Strengths	Limitations	References
Heel supports (plastic)	 <p>Plastic heel supports are frequently employed in orthotic treatments. They are made to support and stabilise the heel and lower limb. These supports are typically custom-made or can be purchased as over-the-counter inserts.</p>	<p><b>Customization:</b> Plastic heel supports are made to accommodate Naomi's particular foot alignment and form.</p> <p><b>Lightweight:</b> Since plastic heel supports are frequently lightweight, using them for an extended period of time is comfortable.</p> <p><b>Cost-effectiveness:</b> Plastic heel supports are often less expensive than more intricate orthotic treatments.</p> <p><b>Rigidity:</b> They are relatively rigid and offers support for her ankle and heel</p>	<p><b>Upper Limb Concerns:</b> Naomi's SATB2 condition has problems with the upper limbs as well, which plastic heel supports cannot resolve. It also can't address any issues in the toe region of the foot.</p> <p><b>Pronation:</b> Plastic heel supports may not be a viable solution to Naomi's extreme pronation due to deformation of the material.</p> <p><b>Excessive Sweating:</b> It made Naomi sweat a lot more than she usually would. The lack of sufficient ventilation caused by the non-porous plastic material causes moisture to accumulate within the shoe which later resulted in blister formation.</p>	[4]

<p>Custom in-shoe orthotics</p> 	<p>Custom in-shoe orthotics are specialised orthotic devices created to provide ankle and the overall foot structure with specialised support. These orthotics are developed after a thorough analysis of the foot shape, gait, and specific support needs. They are often made from various materials, including fibreglass.</p>	<p><b>Personalised Support:</b> Custom in-shoe orthotics designed to meet Naomi's individual anatomical and biomechanical needs.</p> <p><b>Improved Comfort:</b> By distributing pressure across the foot custom orthotics improve comfort.</p>	<p><b>Blisters:</b> A notable issue with the fibreglass-made personalised in-shoe orthotic has been blisters. These materials' rigidity causes it to rub on Naomi's skin, causing friction-related blisters and pain.</p> <p><b>Lack of Adaptation in the Material:</b> The rigidity of the fibreglass-made orthotics will not adapt to the foot of the user like foam would as a result of foam being more malleable than fibreglass.</p>	<p>[5]</p>
<p>Stability shoes</p> 	<p>As an alternative to using an ankle-foot orthosis (AFO), stability shoes are a type of specialty footwear. They were particularly designed to assist overpronation of the foot. In order to treat biomechanical problems and incorrect gait patterns, these shoes frequently have built-in arch support, cushioning, and stability characteristics such as a wide base. They come in many different patterns and styles.</p>	<p><b>Stylish Design:</b> Stability shoes have a distinct advantage in that they are fashionable. This can be especially enticing for Naomi since they provide an attractive alternative to conventional orthotic devices which appear distinct from conventional footwear..</p> <p><b>Enhanced Comfort:</b> Stability shoes are frequently made with user comfort in mind. They provide support and cushioning that make them more pleasant for regular usage.</p> <p><b>Gait Correction:</b> They are efficient in addressing Naomi's overpronation concerns, assisting in the correction of gait deviations, and enhancing general stability while walking or standing.</p>	<p><b>Weight:</b> Because stability shoes include extra support characteristics, they are heavier than alternatives for Naomi's daily use .</p> <p><b>Cost:</b> Since high-quality stability shoes are of higher price, they are not an affordable option as a long-term fix for use in all types of activities.</p>	<p>[6]</p>
<p>Ankle foot orthotics</p>	<p>Ankle foot orthotics (AFOs) are devices used to minimise problems with gait caused by</p>	<p><b>Personalisable:</b> AFOs are personalisable to allow for maximum benefits to Naomi. Being able to form the AFO to most-aptly correct the</p>	<p><b>Inconvenience:</b> AFOs by nature are rigid, bulky devices. This leads to difficulty in wearing for a long time as it quickly can tire</p>	<p>[7]</p>

	<p>issues surrounding abnormal muscle tone and weakness. AFOs function to prevent an equinus varus position of the ankle as it goes through the swing phase as well as promoting heel strike. Which assists in improving walking ability and stability.</p>	<p>deformations in her foot allow for her to walk better</p> <p><b>Reduced Spasticity:</b> The extra stability provided to the ankle joint and upper limbs helps to reduce ankle and calf spasticity thereby reducing Naomi's pain and increasing walking speed</p> <p><b>Joint Alignment:</b> The extra upper limb support helps in maintaining anterior and posterior alignment of the foot improving walking speed and stability while standing still.</p>	<p>out Naomi and cause pain, sweating and redness. This makes it impractical for Naomi to use for long periods of time</p> <p><b>Rigidity:</b> An AFO's intrinsic rigidity is one of its main drawbacks. Although the stiffness is required for treating Naomi's overpronation, Naomi finds it uncomfortable since it restricts her natural ankle mobility. Dr Abbie is quoted to identify a rigid ankle support hindering ankle development of the user.</p>	
<p>SMO: Supramalleolar orthosis (foot and ankle brace)</p> 	<p>SMOs are external devices that stabilise the ankle, specifically the subtalar joint, which in turn prevents the calcaneus from rotating, keeping it in an upright position. An upright calcaneus is shown to improve stability when standing still and increase walking speed. SMOs provide medial and lateral support while simultaneously allowing full range of plantarflexion and dorsiflexion. These SMOs can be custom made to fit Naomi's exact foot/ankle shape.</p>	<p><b>Stability:</b> The SMO provides a substantial support for the ankle and foot allowing for improved walking ability allowing Naomi to operate more independently.</p> <p><b>Build Quality:</b> The materials used in the production of SMOs (high strength plastic) mean that they are able to withstand impacts and other external forces without being damaged allowing for ease of mind while using it</p> <p><b>Allows for degrees of freedom:</b> The SMO whilst providing support laterally and medially allows for full freedom of movement in the sagittal plane.</p>	<p><b>Impracticality:</b> SMOs are rigid and impractical for every day use as they can be uncomfortable after long periods of use.</p> <p><b>Muscular Issues:</b> As SMOs prevent ankle movement it prevents the ankle from going through its full range of motion necessitating the use of other muscle to compensate. This leads to painful muscle cramps for Naomi, requiring manual therapy to help treat.</p> <p><b>Hindering Muscular development:</b> Similar to the AFO limitation of rigidity, by the SMO taking all the pressure that would usually travel through the ankle, there are no forces encouraging the development of new tissue in this region resulting in an undeveloped ankle.</p>	<p>[8]</p>

<p>Billie Shoe</p> 	<p>The Billie shoe has a high top design, covering the ankles, and is fitted with a full shoe length zipper for easy access to get the shoe on and off or to access the orthotic paired with the shoe.</p>	<p><b>Ankle stability:</b> The high top design offers adequate ankle stability for Naomi without adding excess weight or bulk to the shoe design.</p> <p><b>Easy of use:</b> The zipper on the shoe allows for the whole top part of the shoe to be lifted up, allowing easy access for the foot to fit in the shoe. This easy access increases Naomi's independence as it allows her more chance to get the shoe on and off herself.</p> <p><b>Easy to fiddle with:</b> Whilst the zipper offers ease of access it is also very easy for Naomi to fiddle with. Fiddling can compromise the support and durability of the shoe.</p> <p><b>Poor Tread Design:</b> The shoes are not shown to have tread designs that enhance contact with the floor and therefore may result in greater slipping hazards in wetter environments.</p> <p>[9]</p>
<p>Nike Go Fly Ease</p> 	<p>The Nike Go FlyEase shoe is designed with a bistable hinge joint and secured with an elastic system that allows the shoe to be taken on and off handsfree. It aims to offer independence to people with less functional mobility through increasing accessibility to the shoe.</p>	<p><b>Bistable hinge joint:</b> The bistable hinge joint allows for the product to be put on and taken off only using the lower limbs. This increases independence and ease of use for people with lower functional mobility. For Naomi, she is likely to be able to put the shoe on by slipping her foot in and pressing her heel down which would increase her independence.</p> <p><b>Stylish design/ brand reputation:</b> Nike is a well known brand that has developed consumer trust through consistently producing quality and stylish products. This is enticing for Naomi as it provides both an aesthetically pleasing, colourful design with high quality.</p> <p><b>Difficulty getting off:</b> For people with lower functional capacity of the lower limbs, getting the Go FlyEase shoe off is difficult as it requires significant pressure to be applied to the heel to secure the bistable hinge joint in place.</p> <p><b>Cost:</b> The shoes retail for approximately \$200 dollars a pair and therefore are within the high bracket of shoe prices.</p> <p>[10]</p>

## **2.2 Conclusions from Existing Technology**

### **2.2.1 Common Themes:**

- Personalisation: Many of the orthotics provide varied levels of customization to meet the unique needs of individuals with SATB2 syndrome, like Naomi.
- Support and Stability: These orthotics' main objective is to increase stability while standing and walking, which is crucial for Naomi, with irregular gaits or low muscular tone.
- Improving Accessibility: The Billie Shoe, Nike Go FlyEase and SMO designs all aim to make it easier to use them for individuals with lower control of lower limb functions.

### **2.2.2 Trade-offs Among Devices:**

- Comfort/Foot Development vs. Rigidity: Rigidity and comfort are frequently trade-offs. High amounts of support are provided by devices like AFOs and SMOs, although they can be uncomfortable to wear for long periods of time. Contrarily, stability shoes and in-shoe orthotics place a higher priority on comfort but could not offer as much support.
- Cost vs accessibility: While very effective, custom orthotic devices can be pricey. For certain people, this expense can make access more difficult. Although stability shoes and other alternatives are more cheap, they could not offer the same amount of support and personalisation.

### **2.2.3 Biggest Pain Point:**

- Discomfort and Skin Problems: Discomfort, which can appear as perspiration, redness, or even Medial Malleolus blisters, is one of the most severe pain points associated with these devices.

### **2.2.4 Opportunities:**

- Material Innovation: Investigating novel materials with an emphasis on breathability and moisture-wicking qualities may help lessen pain and skin problems related to orthotic devices.
- Hybrid Solutions: For Naomi, combining the benefits of various technologies may result in a more complete solution.
- Research on Muscle Management: More study into controlling muscle compensation and cramping brought on by orthotic devices may result in more potent cures.

### **2.2.5 Gaps:**

- Long-Term Comfort: Even while certain orthotics provide instant assistance, maintaining long-term comfort with repeated usage is still difficult.
- Material: Lack of a material that can be rigid enough to provide support while reducing Naomi's sweating.

### 3. Requirements

This section serves as a comprehensive outline of specific features and criteria that the orthotic solution must adhere to. The requirements outlined in Table 3 encompass the following categories:

- User Requirements (SPR 1): Properties that enhance the usability and user-friendliness of the solution.
- Technical Requirements (SPR 2): Technical constraints of the solution (i.e., accuracy, precision, reliability).
- Functional Requirements (SPR 3): Properties describing what the solution is expected to do.
- Regulatory Requirements (SPR 4): Regulations and standards the solution must comply with.

Each requirement outlined has been prioritised based on collaborative discussion with Dalal and Dr Abbie, of which has been further informed by research into prior art, and existing solutions in the field of orthotics. Prioritisation will help ensure the most critical aspects of the orthotic design are addressed in each stage of the design process, and executed in the final product. This will not only enhance the quality and validity of the final design, but also optimise resource allocation and project execution. The justification for each priority is noted in Appendix 3.

Table 3 highlights the needs of the project and categorises them into types of requirements including User, Technical, Function and Standards/Regulations. Where the requirements were received from is also important as this will have an impact on the priority rating of which requirement must be considered over another when contradictions occur in the project.

**Table 3 - Specification Requirements**

#	Requirement	Category	Explanation	References	Priority
SPR 1.1	Not too heavy	User	The orthotic should be light enough that the patient can comfortably go about their day with ease of movement.	Dalal Meeting 4	8
SPR 1.2	Not too rigid	User	The orthotic should not be too rigid as to prevent a natural gait, balance, stability nor discomfort when carrying out daily activities.	Dr Abbie Meetings 4 & 8	4
SPR1.3	Does not cause blisters	User	The orthotic should incorporate breathable materials and smooth surfaces that prevent rubbing between the patient's skin and orthotic to reduce the risk of blisters.	Dalal Meeting 4	6
SPR1.4	Fix toe claw	User	The orthotic should be designed to help straighten out clawed toes, increasing the functional capacity of lower limbs.	Dalal, Dr Abbie Meeting 8	1
SPR1.5	User friendliness (ease of use/convenience)	User	Should be easy for the user to put on and remove, without requiring excessive force. The design and materials should ensure easy cleaning for ongoing hygiene and comfort.	Dalal Meetings 1 & 4	12
SPR2.1	Measured padding and support	Technical	Padding and support structures should ensure optimal pressure redistribution and support at different areas of the foot.	Dr Abbie Meetings 4 & 8 & 16	13
SPR2.2	Breathable Materials	Technical	Materials should provide ventilation and air circulation, to minimise moisture build-up and optimise comfort during extended use.	Dalal Meetings 4 & 8 & 16	9

SPR2.3	Durable Construction	Technical	Manufacturing techniques must ensure a durable and robust product that can withstand everyday wear and tear, to maintain its integrity over time.	Dalal, Dr Abbie Meeting 8 & 16	7
SPR3.1	Improve Stability	Functional	The orthotic should provide substantial support to the user's feet, ankles and lower legs to minimise instability, reduce the risk of falls and improve overall confidence.	Dalal, Dr Abbie Meetings 1 & 4 & 8	5
SPR3.2	Improve Mobility	Functional	The design should allow for natural foot mobility, enabling the user to perform tasks (standing, walking, transitioning between positions), without restricting movement.	Dalal Meetings 1 & 4 & 8	2
SPR3.3	Normalise Gait patterns	Functional	Solution should help develop a natural and coordinated gait pattern by providing appropriate alignment, cushioning, arch and tibial support.	Dr Abbie Meetings 4 & 8	3
SPR3.4	Pressure Redistribution	Functional	The orthotic should redistribute pressure away from areas more susceptible to blistering and capillary damage, distributing the load more evenly across the foot.	Dr Abbie Meetings 4 & 8	14
SPR4.1	TGA 25th Feb 2021 Regulatory Amendment Compliance	Standards/ Regulations	<p>On this date the TGA commenced a classification change for customised medical devices, separating devices into classifications of Custom-Made Medical Devices and Patient Matched Medical Devices. The former is required to be listed on the Australian Register of Therapeutic Goods (ARTG) with accommodating records, supplier information and inspection information. The differentiating factor involves if the devices are created and then tailored to the patient with adaptable features or if the device is made for a specific patient.</p> <p>According to the requirements of our project, the custom orthotic made for Naomi would not need to be registered in the ARTG due to it being classified as a Custom-Made Medical Device.</p> <p>However, further production of our orthotic and of the shoe designs to a wider customer audience will be classified as a Patient-Matched Medical Device due to the device being pre-made at this stage and then being adapted to the patient. Our design will therefore need to be listed on the Australian Register of Therapeutic Goods (ARTG), undergo a conformity assessment by a</p>	Therapeutic Goods Administration Meetings 1 & 16	10

			Notified Body, and ensure the product labelling, packaging, and instructions meet TGA requirements. Due to the orthotic being an assistive technology it must be low risk with a low capability to cause injury. Considering the orthotic comes in direct contact with the skin, it will need to comply with biocompatibility standards of ISO 10993.		
SPR4.2	ISO 13458 Compliance	Standards/ Regulations	Design, production, installation and servicing of the orthotic should adhere to the standard quality management system of ISO13485.	International Standards Organisation [11] Meetings 4 & 16	11

#### Most important requirements:

1. Fix Toe Claw: This is the most important requirement due to the drastic effect it has on Naomi's ability to walk. By having her toes clawed up, Dalal explained that she can't balance as well, gets blister formation on her toes and walks with an incorrect gait pattern. It is also a fundamental component of Dr Abbie's current orthotic design, including a toe crest to maintain toe extension. This requirement will thus have significant impact going forward as we will have to ensure our final design includes a raised section under the toes to keep them from curling or an alternate way of correcting Naomi's toe claw.
2. Improve Mobility: This is considered of lower priority than fixing toe claw due to this being a general aim of orthotics in general and is not as specialised within our project as the toe claw is. This must not be understated as a critical requirement however, as if there is no mobility based benefits from our orthotic we have fundamentally failed in this project.
3. Normalising Gait Patterns: Gait patterns are the stages of the walking cycle, of which Naomi has a drastically altered cycle due to her feet pronating, not leading in a step with her heel and toe clawing. This was a key technical goal that Dr Abbie stated needed to be addressed and therefore ranks high. Thus, it will affect the remaining design process as our orthotic must include elements that correct Naomi's gait patterns.
4. Not Too Rigid: Rigidity directly hinders flexibility of the ankle, as explained by Dr Abbie, and is why SMO designs are being disregarded in this project. The orthotic and overall design is made to increase the abilities of her feet, and by restricting their movement we will not be fulfilling requirement 2 and therefore failing the project. As a result this is a critical requirement and, going forward, we will have to find a way to create a flexible device that provides enough stability to increase Naomi's functional capacity of the lower limbs.
5. Improve Stability: This is treated as a high rank due to the strong correlation to requirements 1, 2 and 3. The stability will be increased by fixing the toe claw and an increase in mobility will not be possible if she is not stable during this motion. There is also a connection between normal gait patterns and higher stability, all resulting in this being considered an important requirement.

## 4. Design Risk Analysis

Through diligent risk analysis, mitigation and ongoing assessment, our team aims to enhance the robustness and safety of the orthotic design and minimise the likelihood of unexpected obstacles. This section provides a systematic framework for identifying, assessing and mitigating potential user, technical and functional risks that could arise if the design fails to meet the specified requirements. This has been used to guide ongoing design and development decisions and ensure thorough preparation has been made to address challenges that may arise.

In Table 5, each identified risk has been given a rating out of 25, according to the criteria denoted in Table 4. The severity rating quantifies how serious the consequences of the risk could be if it were to transpire. The likelihood assesses the probability of the risk occurring and is based on historical data, expert judgement and statistical analysis.

Following the initial risk assessment, mitigation methods have been suggested as proactive steps to reduce the severity, and likelihood of the identified risks. The risks have then been reassessed after considering the mitigation measures, which will decipher whether the residual risk is acceptable or not to continue. All ratings have been guided by educated discussions and collaboration with the client and project clinician, as well as informed by prior art research. The justification for each risk rating is noted in Appendix 4.

Table 4 provides a quantitative value for the impact a risk can have on the project by considering the likelihood of the risk occurring and the severity of the impact it would have if it were to occur.

**Table 4 - Design Risk Analysis Rating Criteria**

Likelihood	Frequent (5)	5	10	15	20	25
	Probable (4)	4	8	12	16	20
	Occasional (3)	3	6	9	12	15
	Remote (2)	2	4	6	8	10
	Improbable (1)	1	2	3	4	5
Risk Rating = Severity x Likelihood		Minor (1)	Negligible (2)	Marginal (3)	Critical (4)	Catastrophic (5)
		Severity				

Table 5 is equipped to identify the risks that could impact the degree of success for this project through hindering processes or by stopping the project. These are quantified with regards to the severity of the risk if it were to occur and the likelihood that it will occur through using the Design Risk Analysis Rating Criteria table above.

**Table 5 - Design Risk Evaluation**

#	Risk	Category	Severity (1-5)	Likelihood (1-5)	Rating (/25)	Mitigation Method	Severity (1-5)	Likelihood (1-5)	Rating (/25)	Accept? [Y/N]
RSK1.1	<b>Increased falling:</b> Orthotic may cause decreased stability, increasing the risk of falls rather than improving balance.	User	4	4	16	<ul style="list-style-type: none"> <li>Design the orthotic with support structures that target areas of instability (arches on sole, thickened heel).</li> <li>Incorporate adjustable elements that allow users to alter the orthotic's support to improve their stability</li> </ul>	3	3	9	Y
RSK1.2	<b>Causes blisters on foot:</b> Ill-fitting orthotic components or poor materials could cause friction / skin irritations.	User	3	3	9	<ul style="list-style-type: none"> <li>Design the orthotic with features that promote airflow and moisture wicking to reduce trapped moisture that can lead to blisters.</li> <li>Design the orthotic with smooth/ minimal seams to prevent rubbing against the skin, and pressure points.</li> </ul>	2	2	4	Y
RSK1.3	<b>Undetected injury due to Pain Tolerance:</b> SAS patients have elevated pain tolerance, involving a lack of immediate feedback. This leads to a delay in addressing issues /	User	4	4	16	<ul style="list-style-type: none"> <li>Incorporate visual and tactile indicators (i.e., colour changes) that can signal excessive pressure in certain areas.</li> <li>Encourage regular check-ins with medical professionals to assess orthotic fit/comfort.</li> <li>Involve caregivers in the monitoring process and provide them with information and tools to assess the orthotics fit and alignment to prevent new injuries early on.</li> </ul>	4	2	8	Y

	increases risk of new injuries.									
RSK1.4	<b>Excessive Sweating:</b> Insufficient breathability in orthotics could lead to excess sweating, and cause blistering/discomfort.	User	3	3	9	<ul style="list-style-type: none"> <li>Select breathable materials with moisture-wicking properties for effective moisture management, and air circulation.</li> <li>Incorporate ventilation channel's in the design to facilitate airflow, and reduce moisture buildup</li> <li>Suggest therapeutic approaches such as botox to reduce sweating in the feet (for those with hyperhidrosis.)</li> </ul>	2	2	4	Y
RSK1.5	<b>User Acceptance:</b> SAS users may not readily accept the shoe design due to sensory sensitivity, or resistance to change.	User	3	3	9	<ul style="list-style-type: none"> <li>Involve the user and their caregivers in the design process, gather feedback and make incremental adjustments to address sensory concerns.</li> <li>Offer personalisation, such as customisable colours/designs to allow the user to feel a sense of ownership.</li> </ul>	3	2	6	Y
RSK1.6	<b>Difficulty in Self-Application:</b> Complex or non-intuitive design makes it challenging for the user to put on, or adjust the orthotic.	User	3	3	9	<ul style="list-style-type: none"> <li>Design the orthotic with user-friendly and simple fastening mechanisms (velcro straps / quick release buckles) that are easy to use without assistance.</li> <li>Incorporate colour coding or clear markings to help the user ensure proper alignment and adjustment of the components.</li> </ul>	2	2	4	Y
RSK2.1	<b>Product breaks:</b> Orthotic could experience structural failure due to force or	Technical	4	3	12	<ul style="list-style-type: none"> <li>Analyse the weight-to-strength ratio of materials to ensure they can withstand user movements without breaking.</li> <li>Determine the maximum load the orthotic might experience during</li> </ul>	3	2	6	Y

	overuse, causing it to break or compromise its support.					<p>different activities and ensure the materials can exceed this threshold.</p> <ul style="list-style-type: none"> <li>• Use material combinations that balance strength and flexibility to prevent brittle fracture and enhance durability.</li> </ul>				
RSK2.2	<b>Material Degradation:</b> Interior materials may degrade quickly due to wear and tear, compromising its support, comfort and lifespan.	Technical	3	3	9	<ul style="list-style-type: none"> <li>• Choose high-quality, durable materials that can withstand wear, stress, and exposure to moisture/ sweat.</li> <li>• Conduct accelerated ageing testing and durability testing to simulate conditions over an extended period.</li> <li>• Provide maintenance and cleaning instructions to users to prevent premature material deterioration.</li> <li>• Include modular components that can be easily replaced to extend lifespan.</li> </ul>	2	2	4	Y
RSK2.3	<b>Inaccurate Customisation:</b> Errors in user measurements could lead to inaccurate fit, reducing its support and causing further damage/ discomfort.	Technical	4	3	12	<ul style="list-style-type: none"> <li>• Employ accurate 3D scanning applications to capture the user's dimensions with high precision.</li> <li>• Create a prototype based on the measurements and test on user to assess fit, comfort and alignment</li> <li>• Design the orthotic with adjustability features that allow small modifications to be made post-manufacturing.</li> <li>• Put in place quality control measures at each stage of production to ensure that measurement accuracy is sustained and translated into the final product.</li> </ul>	3	2	6	Y
RSK2.4	<b>Inaccurate Arch Support:</b> Can lead to inadequate	Technical	3	3	9	<ul style="list-style-type: none"> <li>• Conduct a thorough biomechanical assessment (arch height, pronation,</li> </ul>	2	2	4	Y

	support or discomfort, therefore inhibiting mobility / causing further injury.						gait analysis) of users' feet to determine their support requirements.				
RSK2.5	<b>Poor Seam/stitching quality:</b> Can lead to discomfort and irritation for users with sensitive skin, as well as pressure injuries in those regions	Technical	3	3	9		<ul style="list-style-type: none"> <li>Utilise 3D scanning to create precise digital models of the patients' feet, to ensure support accurately matches foot contours.</li> </ul>				
RSK3.1	<b>Decreased Stability:</b> Orthotic alignment is inaccurate, causing imbalance and instability.	Functional	4	3	12		<ul style="list-style-type: none"> <li>Implement high-quality stitching techniques and materials</li> <li>Create 'seamless' design, to avoid high pressure regions, or irritation on skin.</li> <li>Use smooth, non-abrasive materials for lining seams and edges.</li> <li>Conduct stress tests on stitched seams to evaluate resilience under various conditions (flexing/stretching)</li> </ul>	2	2	4	Y
RSK3.2	<b>Product Too Heavy:</b> Excessive weight of material / orthotic design could impact user comfort and mobility.	Functional	3	3	9		<ul style="list-style-type: none"> <li>Employ accurate 3D scanning applications to capture the user's dimensions with high precision to ensure the orthotic aligns with unique anatomical features of the user's foot.</li> </ul>	2	2	4	Y
							<ul style="list-style-type: none"> <li>Choose lightweight materials that provide support and functionality without adding excessive weight.</li> <li>Conduct weight distribution analysis to distinguish how the weight is distributed across the foot, ensuring no specific area is overly burdened.</li> <li>Combine materials with varying densities, to optimise the support while keeping the overall weight low</li> </ul>	3	2	6	Y

RSK3.3	<b>Product Too Rigid:</b> Rigid components restrict natural movement, and cause excessive pressure points - impacts comfort and leads to more severe health concerns.	Functional	4	3	12	<ul style="list-style-type: none"> <li>Choose materials that balance structural support and flexibility (analyse the degree of flexibility in different regions of the orthotic to choose the most suitable material)</li> <li>Create prototypes with different material combinations and assess flexibility/rigidity through tests that simulate different activities.</li> </ul>	3	2	6	Y
RSK4.1	<b>Inadequate User Training:</b> Lack of training for users could result in incorrect usage and application.	Other	3	2	6	<ul style="list-style-type: none"> <li>Develop a comprehensive user manual that includes clear instructions with illustrations.</li> <li>Create educational resources (videos, online tutorials) that users can access for additional guidance.</li> </ul>	2	1	2	Y
RSK4.2	<b>Cost:</b> Shoe design may become too expensive to ensure accessibility, due to the expense of materials during manufacturing, and customisation.	Other	4	3	9	<ul style="list-style-type: none"> <li>Conduct a comprehensive cost analysis of labour, equipment, materials etc. and allocate a budget for each component to control costs.</li> <li>Explore cost-effective sourcing options (i.e. bulk purchase agreements)</li> <li>Adopt smart manufacturing principles to minimise waste, reduce production time and overall efficiency.</li> </ul>	3	2	6	Y

## 5. Design Iterations

### Brainstorming Design Considerations

A brainstorm of key design considerations was created to initiate and inspire the iteration process. These considerations included prior art, Naomi's mechanical issues and key requirements as evident below.

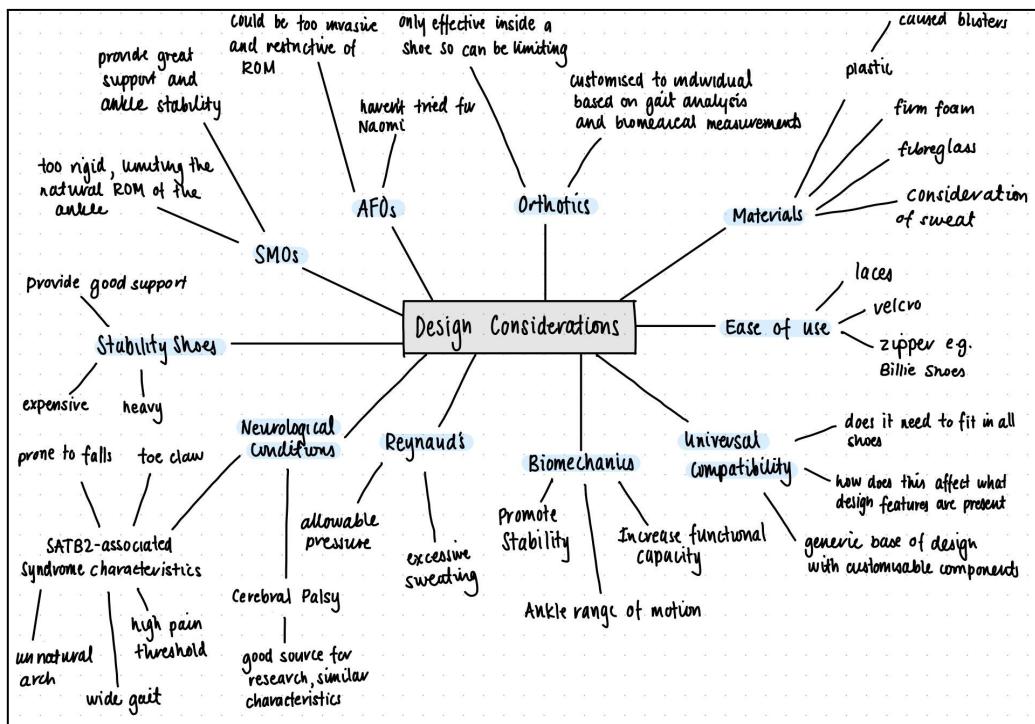


Figure 1 - Design Considerations

### Current Interventions

Naomi's current interventions were photographed and sketched to identify their key components. These were used as inspiration to initiate our first iterations as we attempted to improve the weaknesses Dalal identified of the current solutions. The current orthotic and SMO solutions, discussed in the prior art section of the report are below.

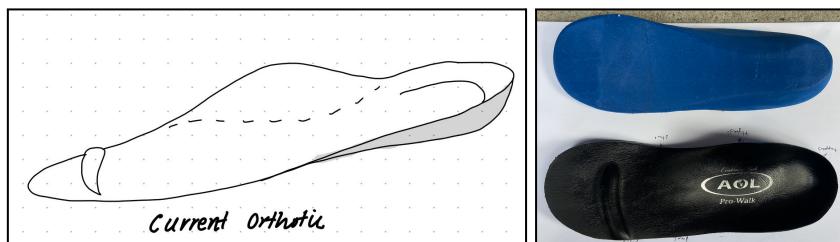


Figure 2 - Naomi's Current Orthotic

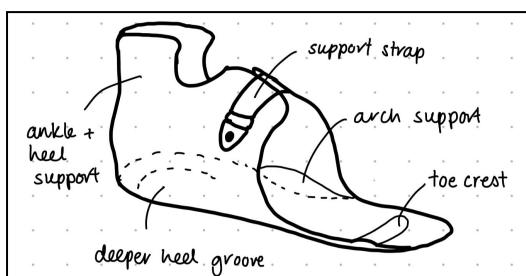


Figure 3 - Naomi's Current SMO

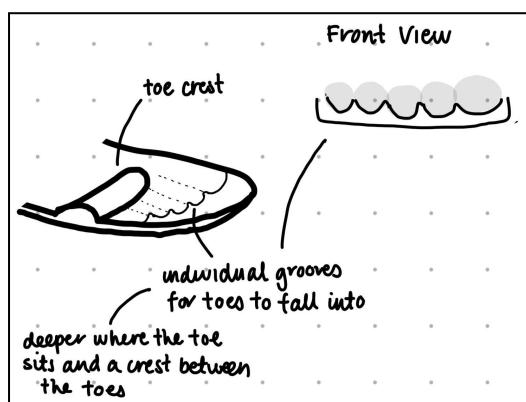
## 5.1 Design Development and Iterations

### 5.1.1 Idea 1 - SMO-orthotic hybrid

After initial consultation with Dalal, the first design idea was to integrate orthotic characteristics into the sole of an SMO to create a hybrid of the two products.



**Iteration 1.1 - SMO with integrated orthotic** - The initial design idea integrates all effective components of current treatments. This would involve customising the sole of the SMO to the same degree as an orthotic is fitted e.g. deeper heel groove, medial and lateral cushioning in the arch of the foot and the toe crest. Through this approach, the user will have greater structural support provided in an orthotic, as well as the ankle stability from the SMO structure.

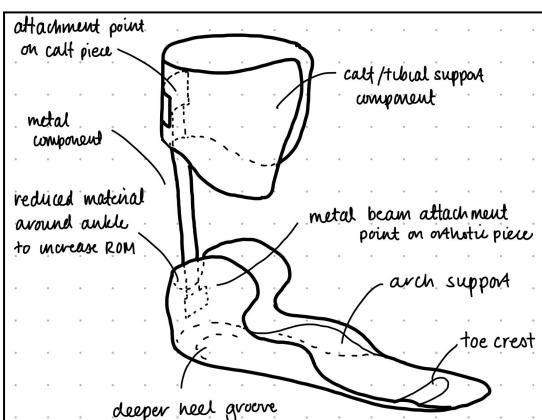


**Iteration 1.2 - Alteration to the toe region to include toe separating trenches** - This addition involves adding trenches in the toe region after the placement of the toe crest from Iteration 1.1. This will encourage toe extension and correct alignment to ensure balance can be achieved. It also limits pressure on the toes to avoid triggering Raynaud's Syndrome

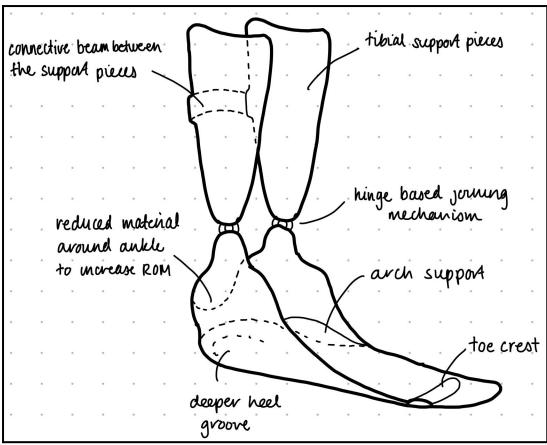
We presented our initial idea to Dr Abbie, however, he was concerned with the restriction that SMOs can create for the ankle range of motion, particularly plantar and dorsiflexion, causing rigidity of the joint and surrounding muscles. We needed to change our design idea to address this limitation. He supported Iteration 1.2 as a solution for reducing the toe claw, which can be used in other ideas.

### 5.1.2 Idea 2 - Orthotic with extended tibial support

Idea 2 integrates the hybrid SMO-orthotic idea but addresses the key limitation of restricted ankle range of motion. It will still have orthotic components in the sole of the device, but has reduced material around the back of the ankle joint, and includes an added support structure through the tibial component. It is hoped that the added support will provide stability around the ankle, while also allowing movements essential for the mobility of the joint. Support is maintained around the medial and lateral ankle to prevent inversion.

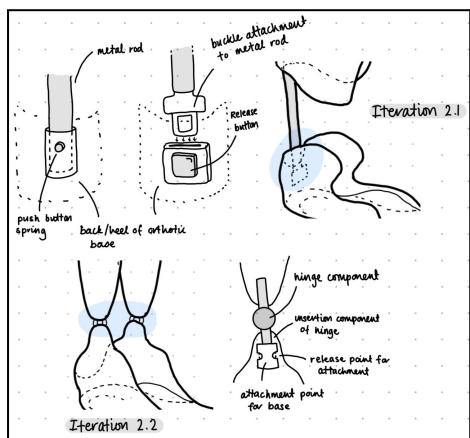


**Iteration 2.1 - Addition of metal rod and tibial support** - This iteration reduces some of the material around the ankle joint so that the range of motion can be achieved, and introduces more stability through a support structure that extends the SMO up the leg with a calf component and metal rod joining the parts. The rod would need to be joined in a way such that flexion is not restricted, but also provides a degree of rigidity.



**Iteration 2.2 - Attaching the tibial support by a hinge mechanism** - A limitation of the previous iteration is that the metal rod would still interfere with the mobility of the ankle as it may still limit the range of plantar and dorsiflexion. Instead, the calf component will be joined by hinges on the medial and lateral aspects of the ankle. This will allow for unrestricted range of motion for flexion, but also provide ankle support to stop inversion. Through removing the support material at the Achilles point of the SMO, the flexion range of motion is restored, while providing structural support to the ankle and foot.

We spoke with Dalal about when Naomi uses her current orthotic devices and she explained that the in-shoe orthotic is great for everyday wear and for longer periods of time, but the SMO is preferred when Naomi needs more stability and support, or is showing weakness. This inspired the next iteration of the idea, which was making the tibial support component detachable so that the device can be customised in different scenarios.

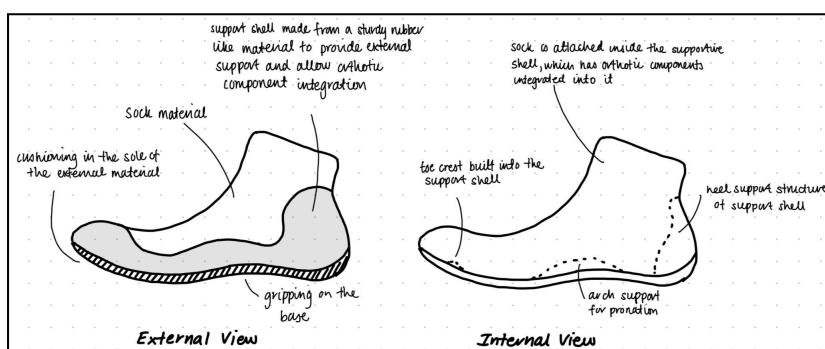


**Iteration 2.3 - Making the tibial support detachable** - We explored the idea of making the tibial support component be detachable. This would mean the base needs to have the capacity to function solely as an in-shoe orthotic, but could also be extended to have added support when needed. We researched different joining mechanisms that could be modified to fit our designs including different clip mechanisms. However, we have concerns about how this would interfere with the strength of the design and would need to consider the tensile strength of the materials used and the integrity of the joining mechanism.

Feedback from Dr Abbie indicated that devices such as this are more suitable for individuals with foot drop, which is not a biomechanical abnormality presented by Naomi.

### 5.1.3 Idea 3- Sock with inbuilt orthotic

In the second meeting with Dalal, she mentioned that orthotics are effective, but only when inside the shoe which means Naomi always has to be in some sort of footwear. We were inspired to create a sock with an inbuilt orthotic and other structural components so that she can easily slip on and off support.

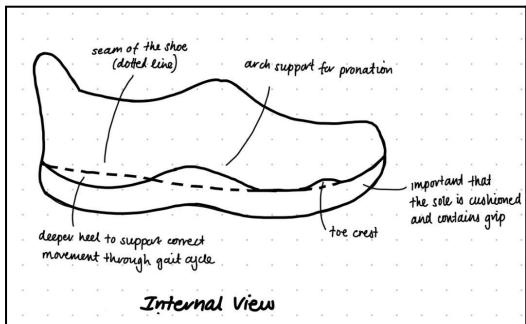


**Iteration 3.1 - Integrated supportive sole into a sock** - This design integrates supportive structures that are lined with a sock to provide support. This includes the integration of structured heel support, the toe crest and arch support in the sole of the sock/shoe. It would allow Naomi to slip in and out of the sock, whilst gaining structural support.

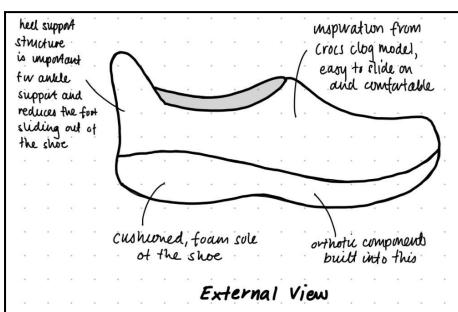
We showed Dr Abbie the idea and he said that it wouldn't be supportive enough or feasible so we didn't create any more iterations.

#### 5.1.4 Idea 4 - Shoes with inbuilt orthotic

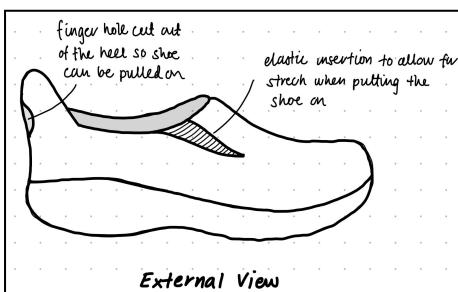
Continuing from the motivation for Idea 3, the inspiration behind this design direction was redesign footwear to have inbuilt orthotic components, with a focus on more casual footwear that can be easily put on, such as crocs or sandals. Each of the iterations are based on the same internal structure and vary in the components integrated to make it easier to slip on and off.



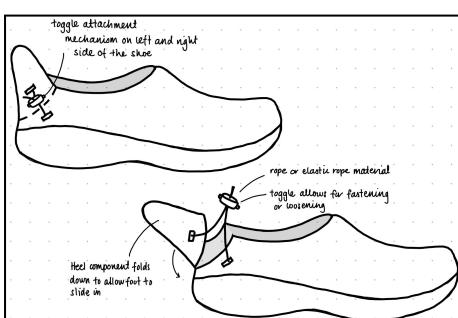
**Uniform internal view for iterations** - The orthotic components will be integrated into the foam/sole of the shoe so that the orthotic doesn't need to be continually changed from other shoes each wear. This includes medial and lateral arch support to prevent pronation and supination, a deeper heel to support toe off in the gait cycle and a toe crest for the toe claw. It is also important that the sole of the shoe is cushioned for added support.



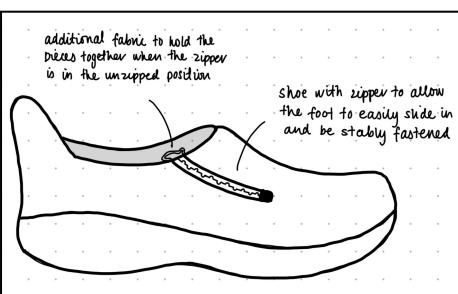
**Iteration 4.1 - Crocs-inspired design with added heel support** - Crocs have a lot of cushioning and are easy to slip on and off, but don't provide a lot of support, particularly around the ankle. The first iteration considers how to implement more supportive characteristics into the shoe to be more appropriate for the users. It has an added heel supported structure which would keep the foot fixed in the shoe and prevent inversion, and support malleolar positioning.



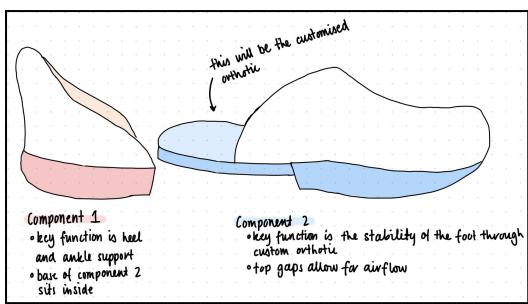
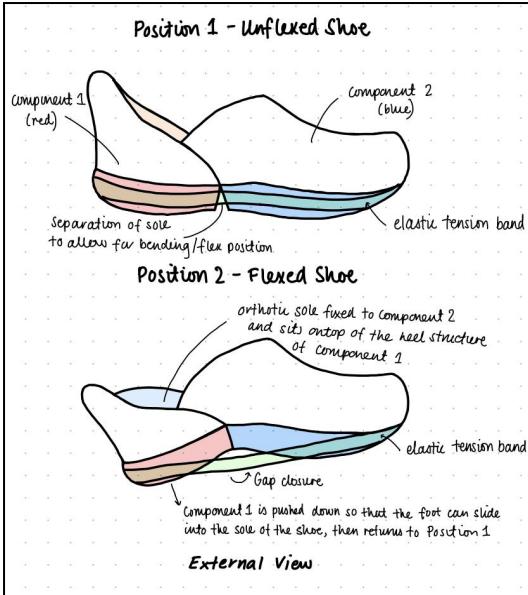
**Iteration 4.2 - Adding elastic components** - Sliding the foot into the design of Iteration 4.1 might be challenging so different adjustment methods were explored to make the experience easier, ultimately increasing Naomi's independence. Inspiration was drawn from characteristics of Sketchers models such as the hole in the heel counter of the shoe and the elastic at the tongue of the shoe. Ideally, this would make the shoe more accessible.



**Iteration 4.3 - Experimenting with toggle attachment component** - This iteration is another adjustment mechanism iteration, having the heel counter fold down to slide the foot in, then fastened with a toggle elastic. This would allow for more flexibility when putting the foot into the shoe because it can easily slide in and then be fastened into place by the toggle. One of the concerns is the strength of elastic to support the pressure of the heel, and provide structural support to the ankle through the gait cycle.



**Iteration 4.4 - Using a zipper as a joining and loosening method** - Having a zipper integrated into the shoe was a strength of the Billie shoes, which Naomi currently wears because they are easy to use. This was incorporated into the design as a method for loosening the shoe so that it can be put on.

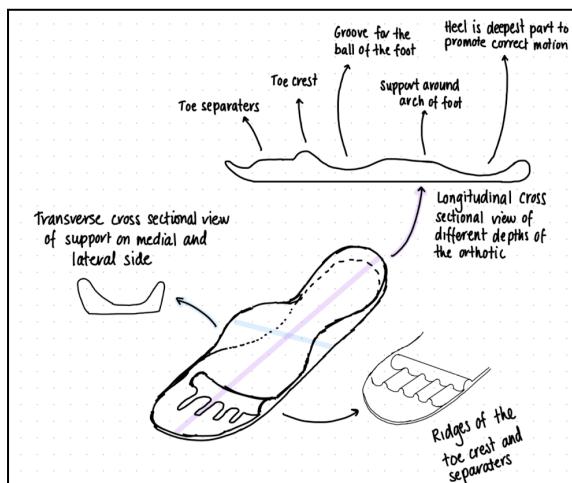


**Iteration 4.5 - Incorporating mechanism inspired by Nike accessibility shoe** - Research into accessibility shoe designs led to the Nike Go FlyEase shoe, which was designed for people with Cerebral Palsy. The mechanisms of the design were integrated into the slip-on croc iteration. The shoe would have 2 components, consisting of the heel and front/sole component. The front component with the integrated orthotic sole sits on top the heel component. When the user wants to put the shoe on, the heel component folds towards the front component and the hinge is closed, allowing the foot to slide in. The two components are kept together by an elastic band which also allows for flexion. However, one of the concerns for this design is the tension required for the elastic band. The shoe requires foot dexterity to put pressure on the back of the shoe to take it off and this may be difficult for Naomi to use by herself, impeding on the aim of increased independence.

After discussing this idea with Dr Abbie, one of his concerns was that it would be challenging and expensive to manufacture customised shoes with in-built orthotics. Orthotics need to be regularly updated and shoe production is not uniform so this process would require intense manufacturing and frequent replacement.

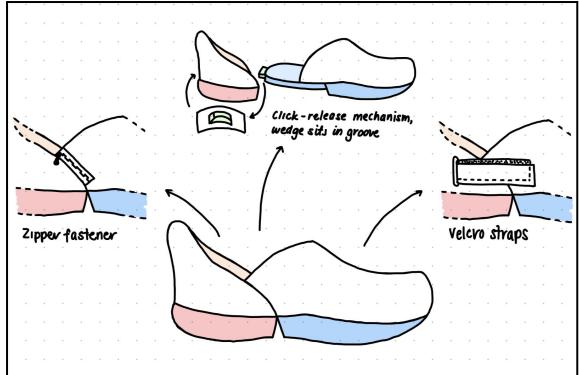
### 5.1.5 Idea 5 - Customised in-shoe orthotic with accessible shoe

For this idea, we are drawing upon approved components from previous iterations to explore viable options for more accessible footwear. This is supported by an in-shoe orthotic, instead of having it built in as iterated in Idea 4.

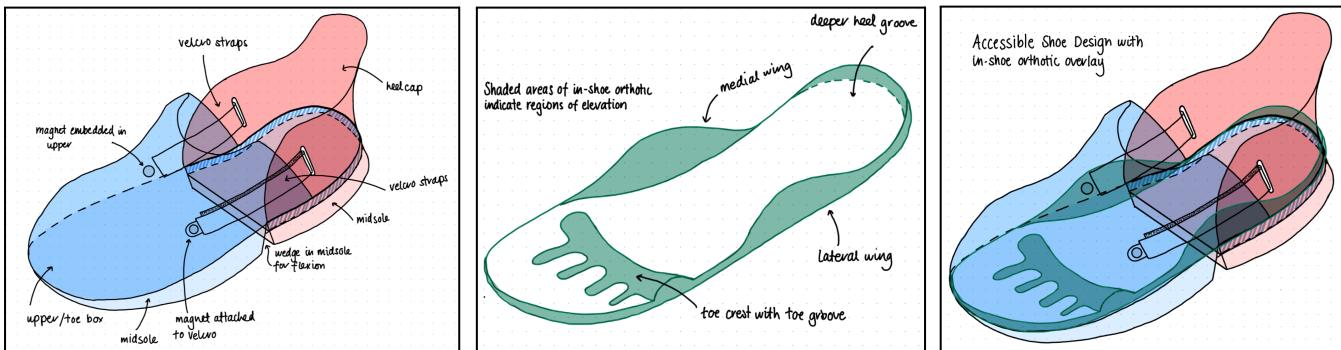


**Iteration 5.1 - customised in-shoe orthotic** - This iteration details the main features included in the customised in shoe orthotic. The addition of ridges between the toes as an extension of the toe crest from Iteration 1.2 was supported by Dr Abbie as a solution to prevent clawing. The design includes medial and lateral wings to prevent pronation and supination, as well as a deeper heel groove to promote toe off during the gait cycle. These features can be included in orthotics for individuals with the same clinical presentation as Naomi, however, it is important to note that all orthotics must be customised to the biomechanical anomalies of each foot.

### **Iteration 5.2 - joining mechanisms for components of the shoe -**



One of the limitations of Iteration 4.5 is the tension in the elastic band holding the components together and how this would impact Naomi's ability to use the shoe independently. This iteration retains the hinge mechanism that allows for flexion but explores different joining mechanisms that could be used to allow for easy use by Naomi. Feedback from Dr Abbie about Idea 4 indicated that velcro straps or zippers could be a viable method for joining components. We also explored a click-release button mechanism.



**Iteration 5.3 - in-shoe orthotic and shoe with hinge mechanism and hook and loop straps -** The final design iteration combines the orthotic outlined in Iteration 5.1, with the velcro straps from Iteration 5.2 to give a complete design with two aspects: an in-shoe orthotic that is compatible with the accessible shoe design. We also included magnets on the ends of the velcro straps to address Naomi's tendency to fidget and divert away from playing with the velcro, to improve longevity. One of the advantages of this iteration is that the orthotic can be used in other shoes when required. The shoe can also be used by individuals looking for more accessible footwear. Having the orthotic and shoe as separate components accounts for the different lifespans of the components, such that the orthotic can be replaced independent from the shoe.

## 5.2 Evaluation of Design Iterations

Table 6 evaluates each design iteration against predetermined criteria. The criteria and grading justification for each iteration can be found in Appendix 5, 6 and 7.

**Table 6 - Design Iterations**

Iteration Type	Requirement Fulfilment (/30)	Risk Mitigation (/30)	Deliverables (/20)	Innovation (/20)	Total (/100)
<b>Idea 1 - SMO-orthotic hybrid</b>					
<i>Iteration 1.1 - SMO with integrated orthotic</i>	22	13	10	10	55
<i>Iteration 1.2 - Alteration to the toe region to include toe separating trenches</i>	23	13	12	15	63
<b>Idea 2 - Orthotic with extended tibial support</b>					
<i>Iteration 2.1 - Addition of metal rod and tibial support</i>	28	22	15	12	77
<i>Iteration 2.2 - Attaching the tibial support by a hinge mechanism</i>	30	26	20	12	88
<i>Iteration 2.3 - Making the tibial support detachable</i>	29	24	20	13	86
<b>Idea 3 - Socks with inbuilt orthotic</b>					
<i>Iteration 3.1 - Integrated supportive sole into a sock</i>	15	28	20	17	80
<b>Idea 4 - Shoes with inbuilt orthotic</b>					
<i>Iteration 4.1 - Crocs-inspired design with added heel support</i>	22	24	15	13	74
<i>Iteration 4.2 - Adding elastic component</i>	23	25	18	13	79
<i>Iteration 4.3 - Experimenting with toggle attachment component</i>	24	27	19	15	85
<i>Iteration 4.4 - Using a zipper as a joining and loosening method</i>	25	25	17	13	80
<i>Iteration 4.5 - Incorporating mechanism inspired by Nike accessibility shoe</i>	25	28	16	13	82
<b>Idea 5 - Customised in-shoe orthotic compatible with accessible shoe</b>					
<i>Iteration 5.1 - customised in-shoe orthotic</i>	23	21	20	15	79
<i>Iteration 5.2 - developing shoe design from Iteration 4.5</i>	16	21	20	17	74
<i>Iteration 5.3 - in-shoe orthotic and shoe with hinge mechanism and hook and loop straps</i>	30	29	20	19	98

### **5.3 Conclusions from Design Evaluation**

The criteria indicate that the most successful design is Iteration 5.3, which is an accessible shoe with a supportive in-shoe orthotic, with a score of 98. It successfully meets all of the requirements and deliverables, and scored well for risk mitigation and innovation. This iteration will be developed into a prototype to finalise technical components of the design. This will be followed by development of verification and validation testing protocol, to evaluate the technical feasibility of the design.

Grading each iteration against criteria is a good way to indicate the feasibility of designs, however, it is also important to confirm these ratings with a clinical opinion. This could indicate components of the design that are not possible or considerations that we aren't aware of. This was highlighted as Iteration 3.1 received a relatively high score, but was dismissed as a potential design from Dr Abbie as he deemed it unfeasible.

## 6. Design Solution Specifications

### 6.1 Design Solution Components

#### 6.1.1 Overall design

The final design solution has two key aspects; the accessible shoe and in-shoe orthotic. The accessible shoe is made from three components which are the upper, toe box and sole plate (Component 1), and the heel counter (Component 2), which is joined to the continuous midsole of the shoe (Component 3). Finally, the in-shoe orthotic (Component 4) can fit inside the shoe, sitting on top of the sole plate of Component 1.

Figure 4 highlights a detailed sketch of the final design solution, outlining how each component interacts, and Figure 5 is an isometric projection of the design. Details of the noted technical specifications are presented in Table 5 of Section 6.2.

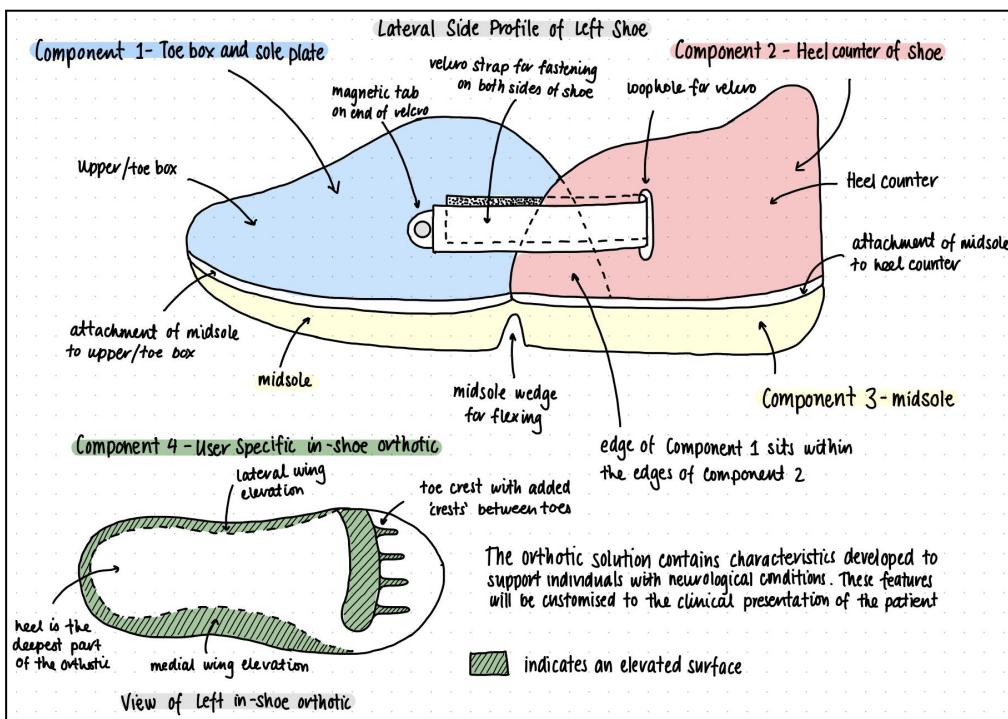


Figure 4 - Detailed Sketch of Final Design Solution

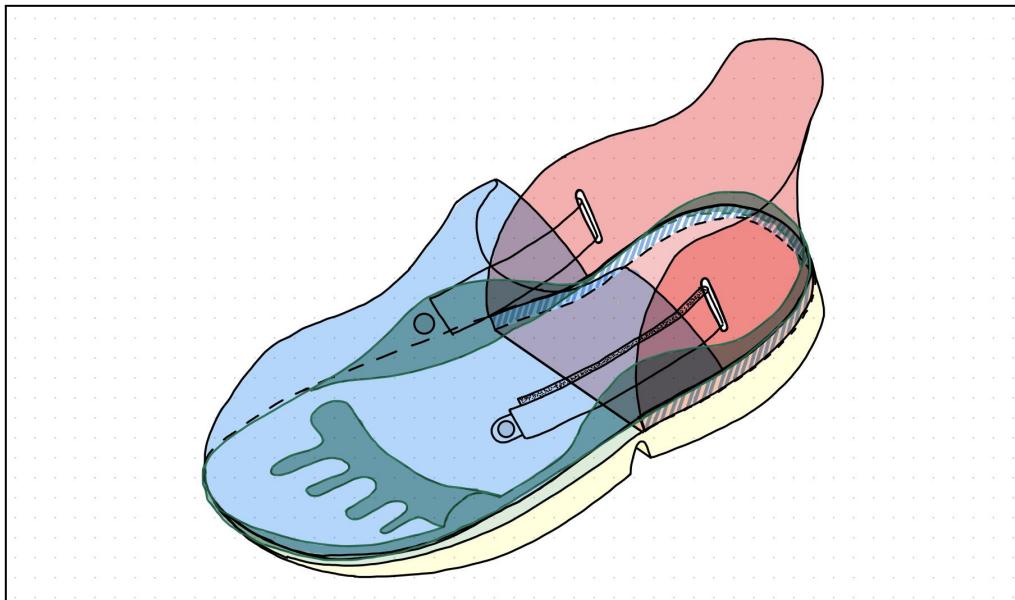


Figure 5 - Isometric Projection of Final Design Solution

### 6.1.2 CAD Model

Solidworks was employed to develop 3D models of each component of the final product, with scaled measurements of Naomi's approximate lower limb parameters. Figure 6 represents Component 1 of the shoe (upper, toe box and sole plate), Figure 7 represents Component 2 (heel counter), Figure 8 indicates how the components fit together, and the functioning of the hinge mechanism within the midsole of the shoe, and Figure 9 represents Component 4 (in-shoe orthotic).

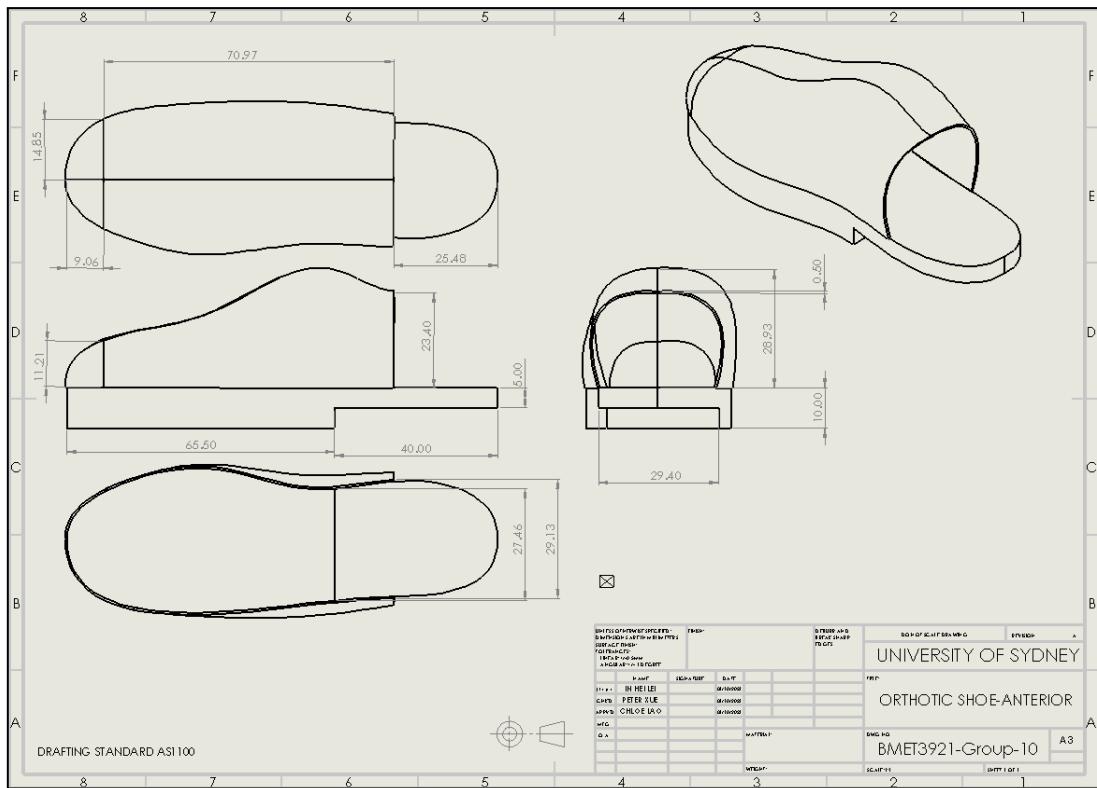


Figure 6 - CAD Projection of the Anterior Shoe Component (Component 1)

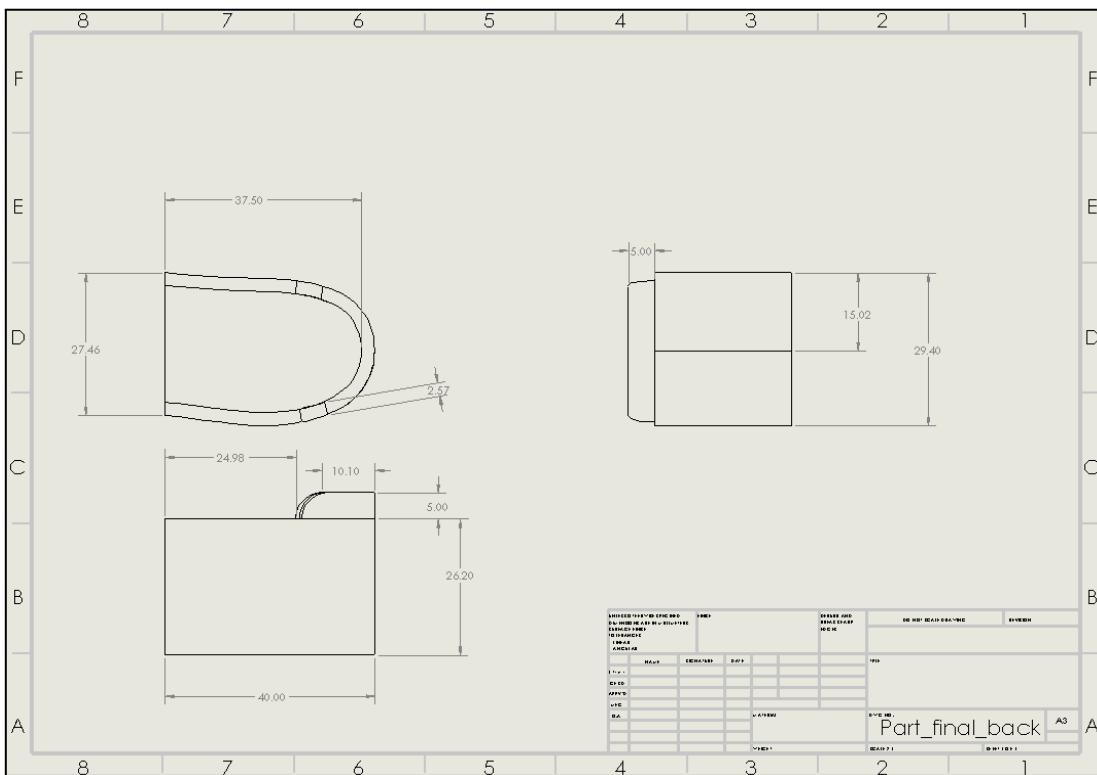


Figure 7 - CAD Projection of the Posterior Shoe Component (Component 2)

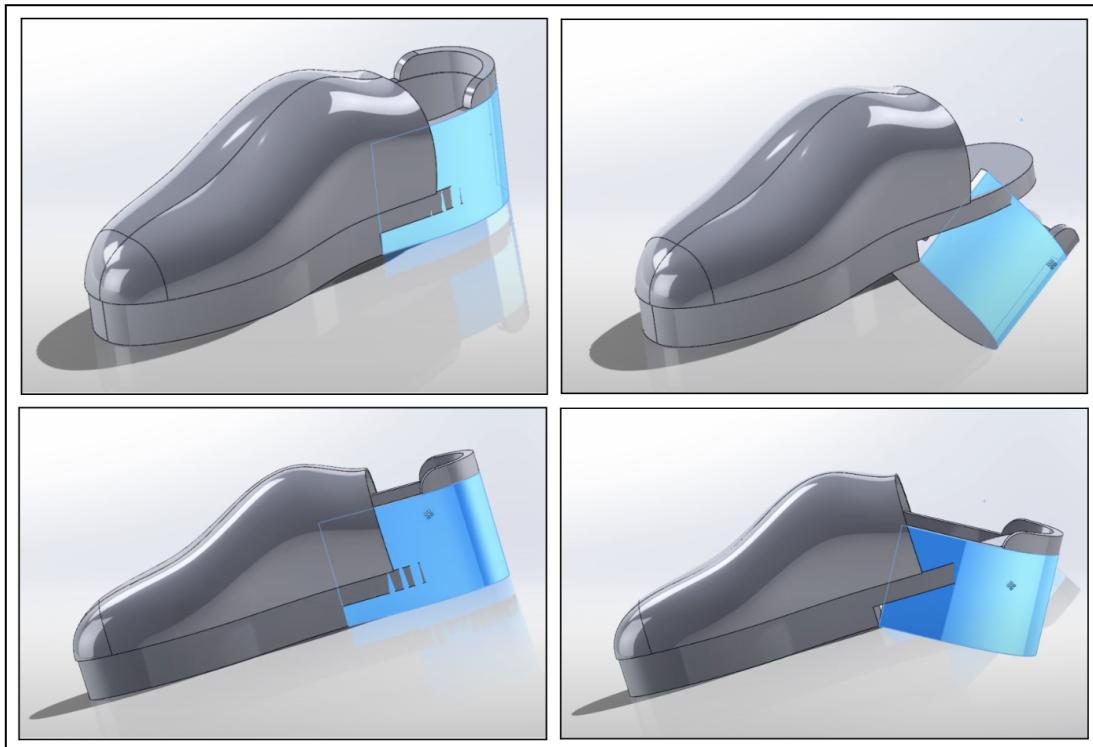


Figure 8 - Hinge Mechanism of Shoe

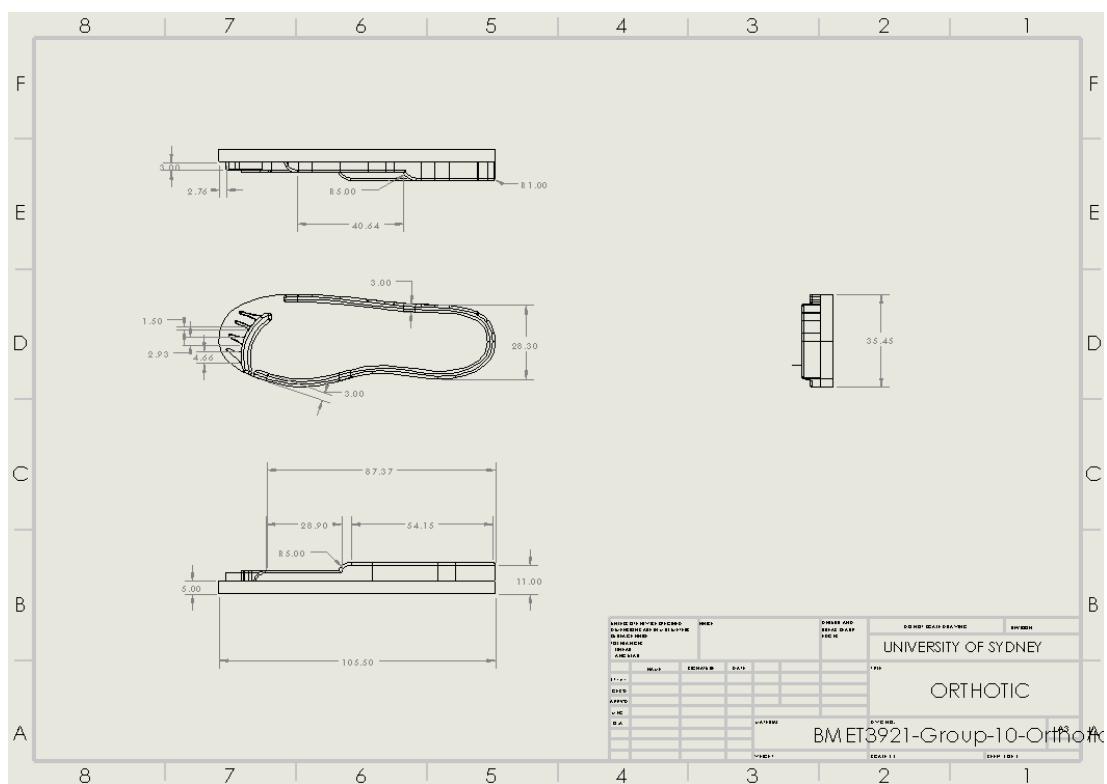


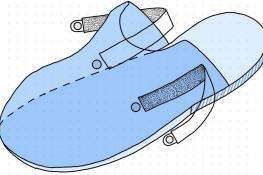
Figure 9 - CAD Projection of the Orthotic Design (Component 4)

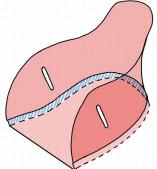
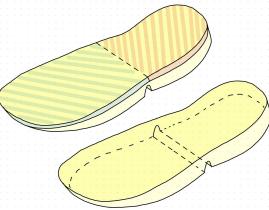
## 6.2 Technical Specifications of Design

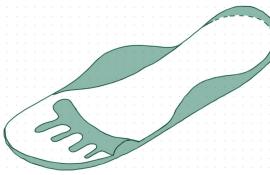
### 6.2.1 Technical Specifications and Design Features

The technical details for each component of the design solution, including key features and the addressed requirements and risks for each case, is outlined in Table 7. The justifications for meeting these risks and requirements are detailed in Appendix 8. Additionally, the materials and dimensions for each component are included, with an evaluation of material properties outlined in Appendix 9. This serves as a clear outline of how the design solution can be translated into production.

**Table 7 - Technical Specifications**

Component of Design	Explanation of Features	Materials	Dimensions	Requirements Fulfilled	Risks Addressed
Component 1 Upper, toe box and sole plate 	<b>Upper</b> The fabric region that keeps the foot in place within the shoe [12]. Hook and loop straps and magnets will be attached to the upper.	<b>Polypropylene fabric:</b> Breathable, sweat wicking fabric to prevent overheating.	The specific dimensions of the shoe are user dependent and need to be determined by the clinician. Naomi currently wears EUR 34. Using this as a guide, the length of the sole plate will be approximately 220 mm [13]. Width measurements are variable along the length of the sole plate, but will follow the general shape of the foot. The sole plate will have a thickness no greater than 5 mm. The dimensions of the upper will be standardised using a pattern developed based on the shoe size.	SPR 1.1 SPR 1.2 SPR 1.3 SPR2.2	RSK 1.2 RSK 1.4 RSK 2.2
	<b>Toe box</b> The toe box refers to the region within the upper and sole plate where the toes sit. A wider toe box is preferred to allow for full toe extension and spreading, to reduce friction. It also accounts for the toe claw.	<b>N/A:</b> The toe box is a space, with the upper and sole plate as its borders.		SPR 1.3 SPR 2.2	RSK 1.2 RSK 1.4 RSK 2.2
	<b>Sole plate</b> The in-shoe orthotic sits on top of the sole plate made from a material that promotes traction and prevents slippage of the orthotic.	<b>Firm foam:</b> Supportive and rigid enough to provide support for body weight.		SPR 2.1 SPR 2.2	RSK 1.1 RSK 2.2
	<b>Fasteners - Hook and Loop straps / Magnets</b> The hook and loop straps are attached to the upper of the shoe, and feed through loopholes in the heel counter, to fasten the components together. Magnets are sewn onto the ends of the hook and loop straps, and attract corresponding magnets that are embedded in the upper.	<b>Hook and loop straps</b> <b>Magnets</b> <b>Fabric casing for magnets</b>	The hook and loop straps will have a width of 20 mm. A 40 mm portion of this is sewn to the upper, followed by the free end of variable length based on the shoe size. The magnets should have a diameter no greater than 10 mm and thickness of 5 mm.	SPR 1.5	RSK 1.1 RSK 1.5 RSK 1.6 RSK 2.1 RSK 2.2

<b>Component 2</b> Heel counter 	<b>Heel counter</b> The heel counter of the shoe is important for rear foot stability, and has been designed to support malleolar positioning. It provides support to the heel during the heel strike phase of the gait cycle [14]. The heel counter includes feed through loops for the hook and loop straps for fastening and keeping the components together.	<b>Thermoplastic polyurethane:</b> Supportive structure and provide rigidity.  <b>Foam:</b> Cushioning.  <b>Polypropylene fabric:</b> Encloses support and is continuous with the upper component.	The dimensions for the heel counter are variable based on the user dimensions, and standard shoe size used. The feed through loops need to have a length of 25 mm, and a width of 7 mm to allow for the hook and loop straps to fit through.	SPR 1.2 SPR 1.3 SPR 2.1 SPR 3.1 SPR 3.2	RSK 1.1 RSK 1.2 RSK 1.4 RSK 2.2 RSK 3.1 RSK 3.2 RSK 3.3
<b>Component 3</b> Midsole and outsole 	<b>Midsole</b> The midsole is designed with curvatures to promote correct motion throughout the gait cycle [12]. The curvature at the toe end of the midsole promotes the toe-off phase. Similarly, the heel will have a slight curvature towards the back to promote the heel strike, and roll through to midstance. The midsole needs to provide cushioning from impact, while also being firm to align gait abnormalities.	<b>EVA foam:</b> Responsive, cushioning, but still firm and able to provide support. It is also easy to mould during manufacturing and commonly used for the midsole of shoes.	The midsole will have varied thickness based on the region of the shoe. It is important that the midsole is thick in regions that require cushioning such as the heel. However, the midsole can't be too thick, such that it interferes with the weight of the shoe.	SPR 1.1 SPR 2.1 SPR 3.1 SPR 3.3 SPR 3.4	RSK 1.1 RSK 2.2 RSK 3.1 RSK 3.2 RSK 3.3
	<b>Hinge mechanism</b> The midsole and outsole has a wedge cut out in the middle, across the width of the shoe. This is the key component that allows the hinge action of the shoe. It allows the heel counter to flex down so that the foot can slide in easily into the upper and sole plate.	<b>N/A:</b> The hinge mechanism is a wedge cut out of the midsole and outsole.	The hinge mechanism is placed at the endpoints of the heel counter, which sits around 110 mm from the back end of the shoe. The specific placement and angle of the hinge is to be determined using verification and validation testing.	SPR 1.5	RSK 1.5 RSK 1.6 RSK 2.2
	<b>Outsole</b> The outsole of the shoe is joined to the bottom of the midsole. It is the part of the shoe that is in contact with the ground so it is important to be made from a durable material, and have a tread pattern to enhance	<b>Carbon rubber:</b> Embodies durable properties and ability to provide traction.	The outsole of the shoe should have a thickness of 4 mm to account for degradation from wear overtime.	SPR 3.1	RSK 2.2

	<p>gripping and stability.</p>				
	<p><b>Joining with Component 1 and 2</b> These components are attached via the midsole of the shoe. Component 1 attaches to the top surface of the front half of the midsole, indicated by the red lines. Component 2 attaches to the top surface of the back half of the midsole, indicated by the blue lines. The sole plate of Component 1 sits within the inner border of Component 2.</p>	<p><b>Invisible stitching:</b> Provides a seamless appearance for joining components. Stitching should not be on exposed surfaces to prevent blisters or irritation.</p>	<p>The front part of the sole plate in Component 1 is fixed to Component 3 (the midsole), while the back/heel portion of the sole plate is free. Component 2 is joined to Component 3 around the edge of the heel midsole. It needs to join such that the sole plate of Component 1 can sit within it.</p>	<p>SPR 2.3</p>	<p>RSK 2.1 RSK 2.2 RSK 2.5</p>
<p><b>Component 4</b> In-shoe orthotic</p> 	<p><b>Toe-crest with toe grooves</b> These are included to align the toe claw by providing a distinct pathway for toes. This will ensure that optimal pressure distribution is achieved in the toes to promote balance and stability.</p>			<p>SPR 1.3 SPR 1.4 SPR 2.2 SPR 3.1 SPR 3.2 SPR 3.3 SPR. 3.4</p>	
	<p><b>Medial and lateral wings</b> Medial and lateral wings provide support to the foot during the mid-stance phase of the gait cycle. They also help to align biomechanical anomalies, and prevent pronation and supination.</p>	<p><b>EVA foam</b> because it is easy to mould, supportive and provides a good level of rigidity.</p> <p><b>Plastazote</b> to line the top of the orthotic for sweat-wicking properties to prevent blister formation.</p>	<p>The dimensions are user specific and must be determined by a Podiatric Biomechanical Practitioner. During the fitting process, the feet are analysed using Foot Plantar Pressure Measurement Systems. The measurements gathered during this process will determine where each feature is placed, and the appropriate level of elevation required to establish optimal biomechanical distribution of forces and pressure.</p>	<p>SPR 1.3 SPR 2.2 SPR 3.1 SPR 3.2 SPR 3.3 SPR. 3.4</p>	<p>RSK 1.1 RSK 1.2 RSK 1.4 RSK 2.2 RSK 2.3 RSK 2.4 RSK 3.1 RSK 3.2 RSK 3.3</p>
	<p><b>Deep heel groove</b> The heel aspect is the deepest part of the orthotic and promotes the correct heel strike motion during the gait cycle. The heel is the first point of contact during the stance phase of gait cycle [14], and the deeper heel groove helps to support this for individuals with an uneven gait. This is also supported by the cushioning of the midsole to reduce impact.</p>			<p>SPR 1.3 SPR 2.2 SPR 3.1 SPR 3.2 SPR 3.3 SPR. 3.4</p>	

## 6.2.2 Biomechanical considerations for the design

Professional insights by Dr Abbie offered a thorough understanding of the gait cycle, as well as foot positioning when travelling through various stages of stride, highlighted in Figure 10 and 11 respectively. This analysis is not only crucial for ensuring comfort, but also for enhancing the therapeutic effectiveness of the product. By closely examining these biomechanical aspects, we tailored our design to achieve a balance between support, flexibility and balance. Moreover, understanding the optimal pressure distribution of the foot (Figure 12), directly informed our design choices to include certain features in the orthotic to avoid pressure injuries, and optimise comfort.

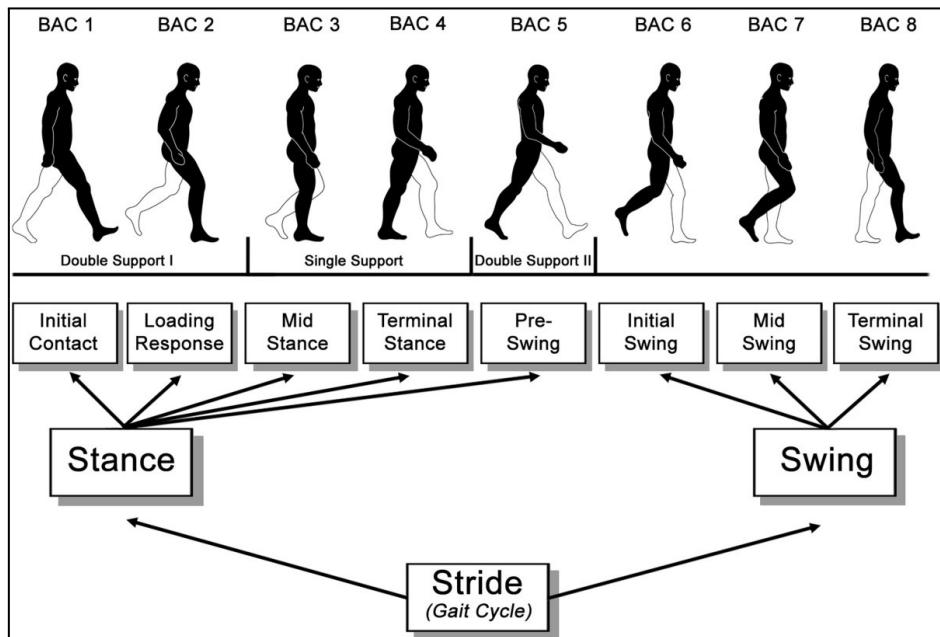


Figure 10 - Stages of the Gait Cycle [15]

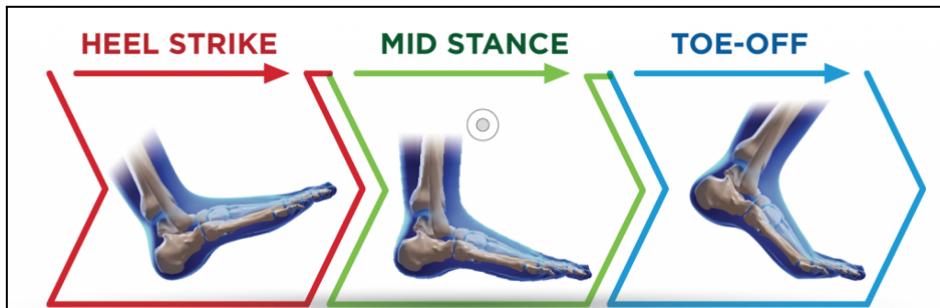


Figure 11 - Foot Positioning during Stages of the Gait Cycle [16]

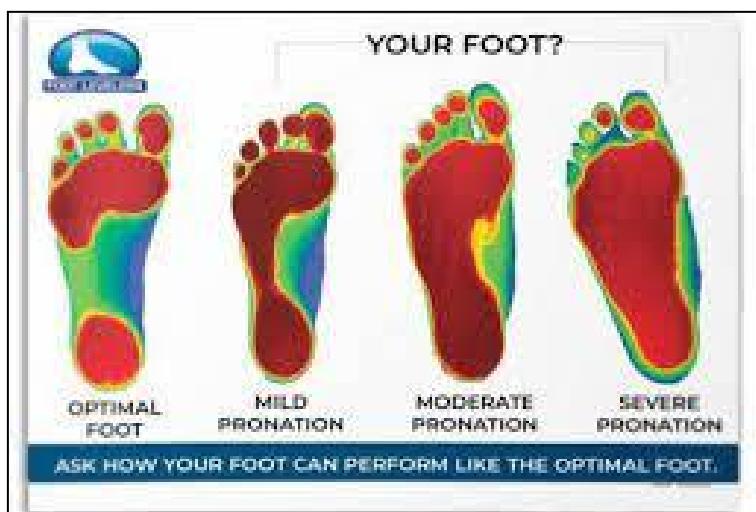


Figure 12 - Different Pressure Distribution in the Foot

## 6.3 Prototype Development and Feasibility of Assembly

### 6.3.1 Prototype Development

The following schematic (Figure 13) breaks down our final design to each component outlined in Table 7, and links them to their respective counterparts of the developed prototype. This offers a visual representation of the modular nature of our solution, and how each component would connect together.

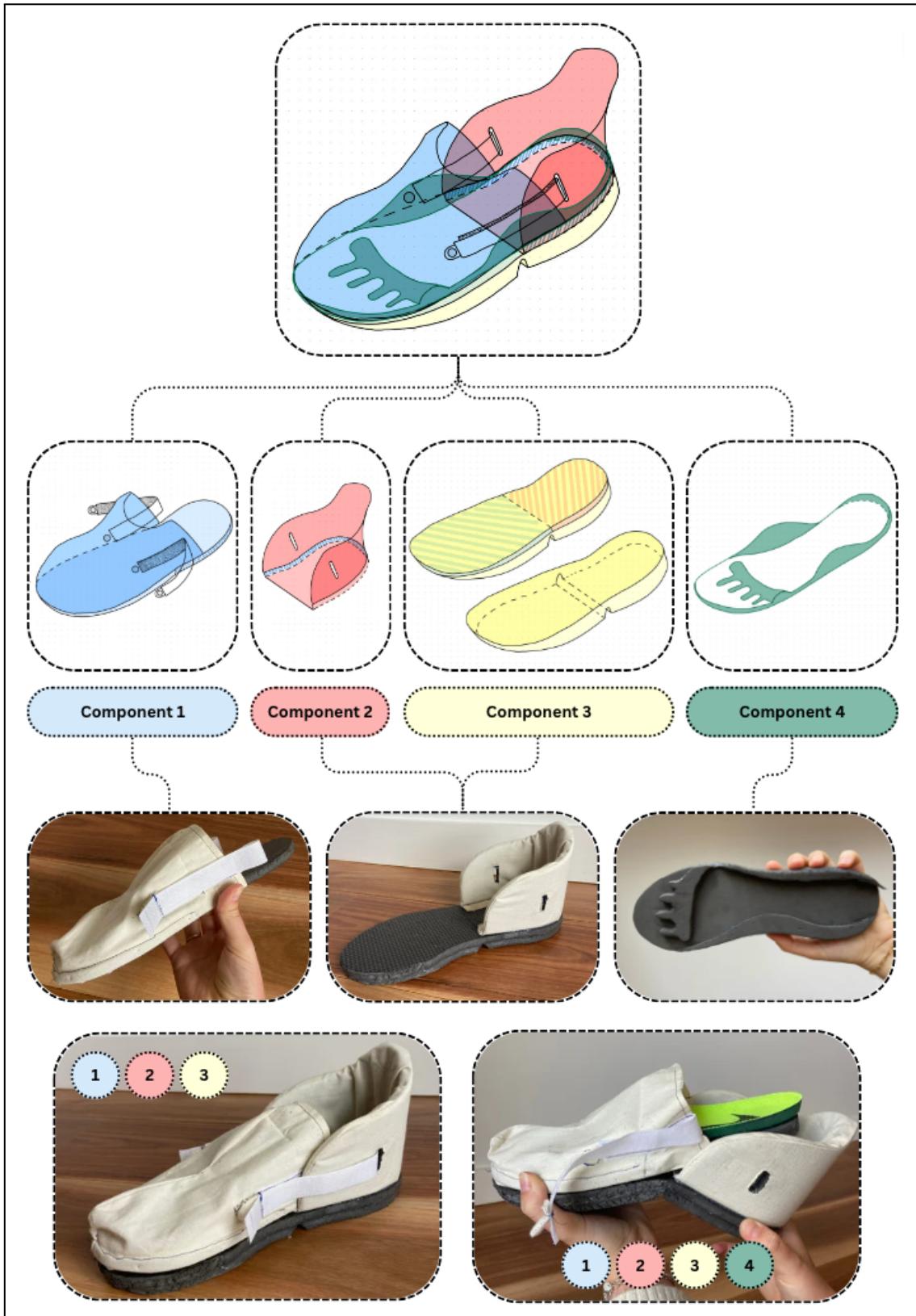


Figure 13 - Prototype Development Flowchart

### **6.3.2 Feasibility of Assembly and Future Manufacturing Processes**

The design solution has two aspects: the accessible shoe and the in-shoe orthotic. It has been designed in a way such that these aspects can be used in cohesion, or on their own. The in-shoe orthotic can be removed and fits into other footwear, and the shoe design could be mass-produced using universal sizing, or function without the orthotic. This means that the in-shoe orthotic, and accessible shoe can be manufactured in different timelines, as they are not entirely dependent on each other.

Manufacturing of the accessible shoe requires consideration of the three components that make up the shoe: the upper, toe box and sole plate (Component 1), the heel counter (Component 2), and the midsole (Component 3). Each component will be manufactured individually, then joined together to generate the final shoe. This process was used for the development of the prototype and is outlined in Figure 13. It served as an effective process, allowing for alterations to each component before joining them all together. Manufacturing processes are dependent on the foot size of the individual. Naomi currently wears a EU 34 shoe size, so the standard measurements would be utilised for the shoe. For universality of the shoe design, patterns will be developed in accordance with standardised sizing. Based on the dimensions acquired in clinical consultation, the standard shoe size for the individual will be determined. The choice to standardise production of the shoe through sizing patterns will reduce costs as shoes aren't entirely customised to the individual, and accounts for potential mass production. It is important that the clinical consultation is the first step in the manufacturing process to ensure the right shoe size is manufactured for the individual.

Manufacturing of the in-shoe orthotic is a highly customisable process and requires clinical evaluation of the individual's biomechanical abnormalities. Assessment involves Foot Plantar Pressure Measurement Systems to understand pressure distribution within the foot when standing and walking, gait analysis to identify abnormalities, and impression moulding to guide placement of features. These assessment procedures will guide the specifications of the orthotic. For our design, this will determine the placement of specific features, such as the toe crest plate. It is important that this consultation occurs before production of the shoe, to ensure that the orthotic will fit within the shoe, and that the shoe will accommodate for the individual's measurements.

WHS regulations are imposed on the manufacturing processes of any assembly line style manufacturing with regards to the workers present at the site. Considerations towards workplace risks such as slips due to liquid spills, contact with heating surfaces when heating the orthotic before the negative model is introduced, moving mechanical parts in the assembly line, helmet and glove usage for handling possibly dangerous materials, cut proof gloves for cutting the foam materials into sizes the machines can use and grinders used for the finalised remove of excess material of the orthotic [17].

## 7. Verification & Validation (V&V) Plan

### 7.1 Verification Plan

Verification testing ensures that the final design solution meets the design requirements. It involves assessing whether a product, service, or system adheres to a regulation, requirement, specification, or imposed condition. For this project, verification testing is concerned with the technical considerations of the design solution, such as the placement of features, materials used and ability to correct biomechanical abnormalities. It is also important that manufacturing processes adhere with regulations for medical devices. Table 8 outlines the verification test plans for the design solution. The corresponding testing protocol are outlined in Appendix 10.

**Table 8 - Verification Test Plans**

V&V	Reqs.	Risks	Description	Category	Protocol	Refs.
1	SPR1.4, SPR3.1, SPR3.3, SPR3.4	RSK1.1, RSK3.1	<b>Toe Crest Efficacy:</b> Measuring the toes angle of depression with reference to a horizontal surface to determine the effectiveness of the toe crest in reducing toe clawing.	User	TPR1.1	[18]
2	SPR1.5, SPR2.3	RSK2.1, RSK2.2	<b>Durability of Hook and Loop Straps:</b> This test utilises a hook and loop fatigue tester to determine durability of the hook and loop straps on the shoe.	Technical	TPR1.2	[19]–[22]
3	SPR2.3	RSK2.1, RSK2.5	<b>Stitching Stress Test:</b> Tensile stress test to evaluate the most effective stitching technique for joining components together.	Technical	TPR1.3	[23]
4	SPR1.5, SPR2.3	RSK2.1, RSK2.2	<b>Hinge Mechanism Stress Test:</b> Employs Finite Element Analysis to explore the maximum allowable stress before deformation, for each stage of the gait cycle at the hinge point.	Technical	TPR1.4	[24], [25]
5	SPR1.1, SPR1.2, SPR1.3, SPR2.2, SPR2.3	RSK1.2, RSK1.4, RSK2.1, RSK2.2, RSK2.5, RSK3.2, RSK3.3	<b>Materials Testing:</b> Using computational and mechanical testing the characteristic features of the materials such as wear, flexibility and weight	Technical	TPR1.5	[26]
6	SPR1.4, SPR3.1, SPR3.2, SPR3.3, SPR3.4	RSK1.1, RSK2.3, RSK2.4, RSK3.1	<b>Correct Realignment Analysis:</b> Using pressure distribution software to quantify the degree of improvement in pronation and gait cycle.	Functional	TPR1.6	[27]
7	SPR4.1, SPR4.2	N/A	<b>Regulations Compliance:</b> Detailed documentation of production process, audited by a member of the regulatory administration party.	Regulatory	TPR1.7	[28]

### 7.1.1 Discussion of Critical Tests

#### Hinge Mechanism Stress Test

The hinge mechanism is cut out of the midsole and could compromise the integrity of the shoe so verification testing is essential to determine the placement of the hinge. This will be guided by the material properties of the midsole, and how it is affected by different stress loads associated with various movements.

#### Materials Testing

The materials used will significantly impact the outcome of the project. Materials testing aims to verify that the chosen materials are able to withstand the stress associated with their use. This is evaluated through stress testing for each material used in the design, and applying a load to observe deformation.

#### Correct Realignment Analysis

It is vital to verify that the design components are capable of correctly realigning biomechanical abnormalities. This is primarily evaluated by the individual's foot plantar pressure, and testing of the gait cycle. Verification will be completed before the device is used, and while the device is used to ensure realignment. Clinician input is required to evaluate acceptance.

## 7.2 Validation Plan

Validation is the assessment of whether a product, system, or process meets its intended purpose and the expectations of the customer. In our case, it involves evaluating the final product to ensure proper functionality and the attainment of desired outcomes. Typically conducted towards the conclusion of the development cycle or during the operational phase, validation aims to demonstrate that the product or system aligns with user requirements and functions as intended. Validation encompasses various activities, including testing and user feedback, aimed at confirming that the product or system effectively addresses user needs and delivers the anticipated benefits.

Table 9 outlines the validation test plans for the design solution. The corresponding testing protocols are outlined in Appendix 11.

**Table 9 - Validation Test Plans**

V&V	Reqs.	Risks	Description	Category	Protocol	Refs.
1	SPR1.5	RSK1.5	<b>User Acceptance:</b> Verbal and written feedback from Dalal and the SAS community will be given to assess the likelihood of Naomi and SAS patient's likelihood of accepting the product.	User	TPR2.1	[29] [30]
2	SPR1.5	RSK1.6, RSK4.1	<b>Usability Test:</b> This tests whether Naomi can put the product on and off by herself after given directions from a team member.	User	TPR2.2	[31]
3	SPR1.3, SPR2.1	RSK1.2, RSK1.3, RSK1.5	<b>User Pain Testing:</b> Aims to identify any areas of friction and thus determine if there are any possible areas of concern related to causing blisters.	User	TPR2.3	[32]
4	SPR1.5, SPR2.2	RSK1.4	<b>Breathability Analysis:</b> Utilises smoke testing to determine	User	TPR2.4	[33]

			breathability of our product compared to Naomi's current and past devices.			
5	SPR1.1	RSK1.1, RSK3.2	<b>Weight of Shoe:</b> Ensures our product lies under the maximum accepted shoe weight from Naomi based on analysing our product against her past and current devices.	Technical	TPR2.5	[34]
6	SPR1.2, SPR3.1, SPR3.2	RSK3.1, RSK3.3	<b>Shoe Rigidity Test:</b> Utilises a rigidity tester to ensure our product is less than the maximum rigidity accepted by Naomi determined through a comparative analysis of our product against her current and past devices.	Functional	TPR2.6	[35]
7	SPR1.5	RSK4.2	<b>Costing Feasibility:</b> A comparative test of our product and current devices on the market it used to ensure the cost of our product is feasible and likely to be accepted by the user.	Other	TPR2.7	[Section 8.4.4 of report]

## 7.2.1 Discussion of Critical Tests

### Usability and acceptance testing

Testing usability and acceptance involves the user acceptance, usability and cost feasibility. Validation that Naomi will accept the product, even though many children with SAS present with reluctance to change, and that Naomi can use the product after appropriate instruction is crucial to meeting the user needs. Further, the cost analysis testing gives additional validation that the product is a feasible solution to increase the functional capacity of the lower limbs in patients with SAS.

### Increased mobility with no adverse effects

This category of testing involves the breathability analysis, weight of the shoe and user pain testing, ensuring the product causes no adverse reactions or pain when being used. The validation of these tests is essential in meeting the needs of Naomi, as the primary user of the product.

## 8. Development and Delivery Plans

### 8.1 Gantt Chart

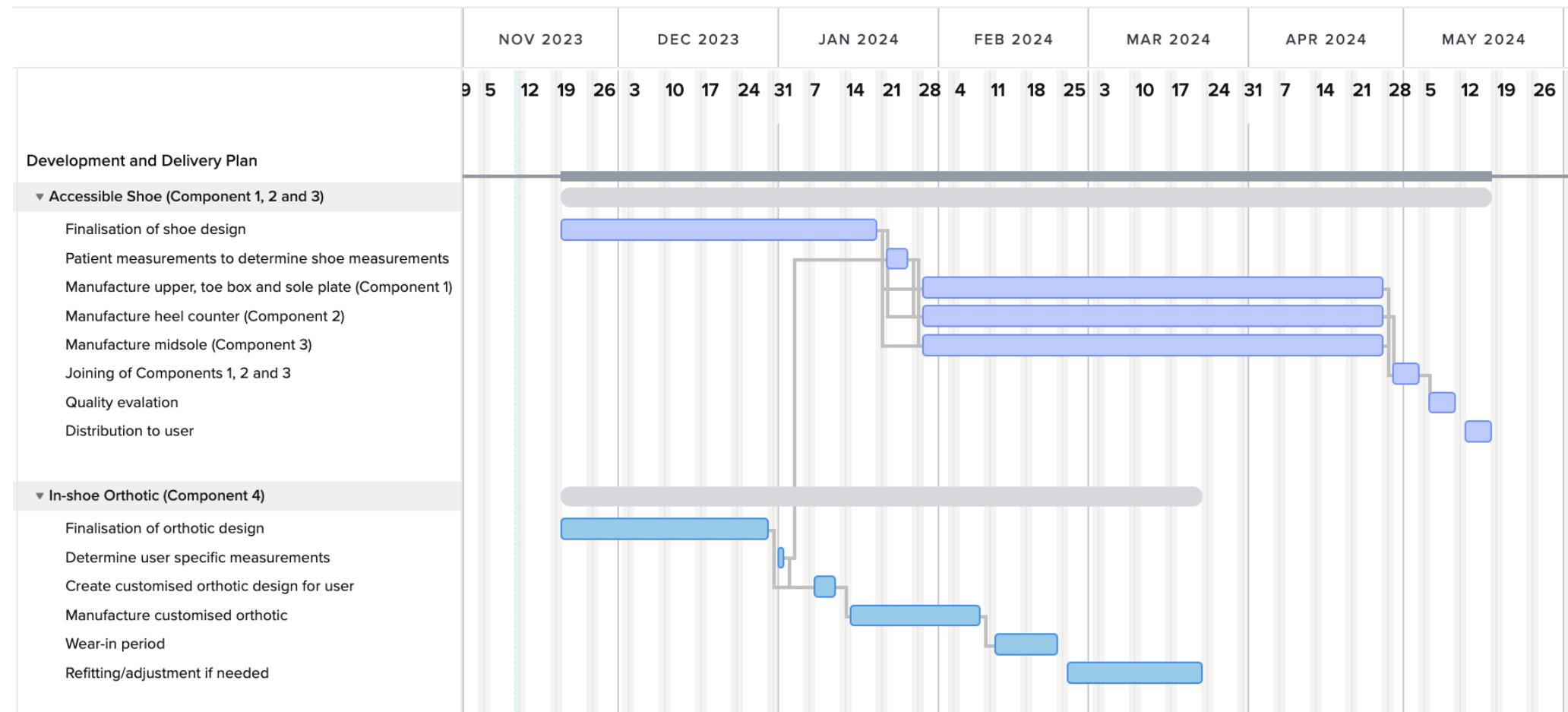


Figure 14 - Gantt Chart for Development and Delivery

Figure 14 details the development and delivery plan for the design solution. The Gantt Chart is separated into the separate components of the design solution, as they have different delivery timelines. The finalisation stage for both the shoe and in-shoe orthotic refers to the development processes, which includes further prototyping, verification and validation and clinical consultation. The subsequent stages are involved in the delivery to the market, including patient appointments for measurements, tailoring the design to the user, manufacturing and distribution. Justifications and further explanation for components of the Gantt Chart can be found in Appendix 12.

## 8.2 Device Classification and Regulatory Implications

In Australia, medical devices are classified by the Therapeutic Goods Administration (TGA) based on the level of risk they pose to patients. All patient-matched orthoses that are prescribed, designed, manufactured and adjusted to the user by trained and certified orthotists are Class 1 medical devices, defined by the TGA as *low-risk* [36]. The Australian Orthotic Prosthetic Association (AOPA) has further declared that this low-risk classification is entirely appropriate for personalised orthoses, assuming appropriately trained and certified orthotists oversee the prescription, manufacture and supply of this device.

The classification of custom orthotic devices remains consistent across an international context, as outlined in Table 10.

**Table 10: Classification of Custom Orthotic Devices According to Different Global Regulatory Agencies.**

Country / Continent	Regulatory Agency	Class	Principles / Compliance
United States (US)	FDA (Food and Drug Administration)	Class I (low risk)	Exempt from premarket notification requirements (510(k)).
European Union (EU)	CE Marking (Conformité Européene)	Class I (low risk)	Custom orthotic devices must be regulated under, and comply with, Medical Devices Regulation (MDR) and In Vitro Diagnostic Devices Regulation (IVDR) - including conformity assessment and CE Marking.
Canada	Health Canada	Class I (low risk)	Require a Medical Device Establishment License (MDEL) for manufacturing and distribution.

The following features of our device justify its suitability to this low-risk classification:

- *Low Invasiveness*: Our orthotic device functions to provide support and respond to biomechanical issues in a non-invasive manner, without implantation or penetration of the body.
- *Limited Duration of Contact*: Considering the lack of implantation, this orthotic is not intended to be used for extended periods of time. It should be applied during the day, and used in conjunction with other footwear.
- *Trained and Certified Orthotist Involvement*: The involvement of Naomi's clinician, Dr Abbie during the design process has ensured all included features and considerations are relevant and serve a function. Healthcare professionals such as orthotists, and prosthetists will be involved during the manufacturing stage to ensure precise assessments and measurements are made.

In order for Class 1 medical devices to be placed on the Australian market, sponsors are required to follow regulatory steps to ensure compliance with the TGA, as outlined in Table 11. In relation to therapeutic goods, 'sponsors' involve those who import, export or manufacture the product in focus.

**Table 11 - Steps Highlighting the Documents Required for Regulatory Compliance and the Mandated Evidence Included.**

Regulatory Steps		Description	Resources	Estimated Time
1	Establishment Registration with TGA	<ul style="list-style-type: none"> <li>Sponsors must register their manufacturing and/or distribution establishments with the TGA, to ensure product quality and traceability.</li> <li>A <i>Manufacturer's Evidence Application</i> must be submitted and accepted by the TGA before registration with ARTG - this is a Declaration of Conformity that demonstrates the manufacturer has undergone appropriate conformity assessment procedures.</li> </ul>	Manufacturer's Evidence Application [38]	~ 1-2 Months. (TGA aims to process this application within 15 working days)
2	Australian Register of Therapeutic Goods (ARTG) Application	<ul style="list-style-type: none"> <li>Documents essential Information about the device, intended use, design, materials, and clinical data [37].</li> <li>Manufacturers must also demonstrate that the device complies with standards and <b>regulations</b>, meets the essential principles and is low-risk.</li> </ul>	Therapeutic Goods (Medical Devices) <b>Regulations</b> [39]	
2a	Compliance with Essential Principles (EP) [40]	<p>Must generate suitable and robust scientific, clinical, and engineering evidence that shows:</p> <ul style="list-style-type: none"> <li>The device performs as intended.</li> <li>Conforms with safety principles in its design and construction (i.e risk analysis and mitigation, specifications, verification protocols, procedures to measure and monitor safety and performance).</li> <li>Meets acknowledged state-of-the-art (i.e. technical standards, guidelines, codes of practice).</li> </ul>	Essential Principles Checklist [41]	TGA takes 156 days on average to process an application [42]
2b	Conformity Assessment	<p>The conformity assessment document must demonstrate:</p> <ul style="list-style-type: none"> <li>The manufacturer has been assessed and has the appropriate QMS in place to manufacture the device</li> <li>Appropriate evidence of product assessment is available.</li> <li>For non-sterile class I devices: Schedule 3, Part 6, Clause 6.6 of the regulations.</li> </ul>	Manufacturer's Declaration of Conformity [43] - of Clause 6.6 of Schedule 3	
2c	Clinical Evidence	<p>As per Subregulation 3.11(1) [44], Clinical evidence is required to substantiate compliance with the essential principles, namely:</p> <ul style="list-style-type: none"> <li>EP 1: Use of medical device not to compromise health and safety</li> </ul>	Clinical Evidence Guidelines (CER Checklist on page 46) [45]	

		<ul style="list-style-type: none"> <li>EP 3: Medical devices to be suitable for intended purpose</li> <li>EP 6: Benefits of the medical devices to outweigh undesirable effects.</li> <li>EP 14: Clinical evidence</li> </ul> <p>To demonstrate compliance with the above, all sponsors will need to obtain clinical data, obtain the clinical expert report of the full curriculum vitae, and complete the clinical evidence report (CER) checklist.</p>		
2d	Generate Labelling and Instructions for Use	<ul style="list-style-type: none"> <li>Labelling should be clear, accurate, and informative. It must include essential details such as the manufacturer's name, address, and contact information, the device's identification, intended use, and any specific instructions or warnings (outlined in <i>Medical Device Labelling Obligations</i>).</li> <li>Instructions for Use (IFU) should accompany the device, including comprehensive guidance on use maintenance and any safety precautions.</li> </ul>	Medical Device Labelling Obligations [46]	
3	Post-Market Monitoring and Reporting	<p>Once registered with the ARTG, the device must continue to meet all the regulatory, safety and performance requirements that were required for approval, such as:</p> <ul style="list-style-type: none"> <li>Corrective actions (changes to device design, construction etc.)</li> <li>Suspension and/or cancellation of the product</li> <li>Recall actions (i.e. safety alerts)</li> <li>Educational resources including website notifications.</li> </ul>	<p>Distribution Records [47]</p> <p>Adverse Event Reporting [48]</p>	Ongoing

### 8.3 Infrastructure

As our project is aimed towards providing a custom orthotic for Naomi while providing footwear for her that encourages independent use of her shoes, we must still consider further developments for which the need for industrial manufacturing processes are required. Our project aims to create a shoe design that will be readily manufactured and an orthotic design that will need to be customised to each user. Therefore, conventional orthotic manufacturing methods may be considered and involve the following stages of orthotic development [49].

The first stage of orthotic development involves tailoring the orthotic to the features of the patient's foot, with this being achieved by scanning the foot using Foot Plantar Pressure Measurement Systems. This would provide a 2D image of which external software would be used to calibrate to the individual's foot creating a 3D model of the orthotic based on regions that have too much pressure and no pressure. Regions of low pressure would have extra material to allow the foot a level contact with the bottom of the shoe. To use systems such as this, materials and cost will be low, with a clinical group only requiring one for use with all patients. The Gait-O-Gram is a model designed to be wireless with little internal circuitry and low power consumption to maintain a high performance to cost ratio [50].

Next is the process of milling the 3D scan into a mould of which a thermoplastic will be placed on, compressed and then grinded to the desired shape.

The final stage is quality control where a 3D model of the patient's foot is created using casting to compare the orthotic to the patient's foot structure to assess the quality of the orthotic. This process will require a low cost plaster, such as Plaster of Paris to be shaped to the foot structure by hand to be compared to the orthotic produced. This inevitably adds to the cost of manufacturing and human resources due to the uniqueness of each design, with the material costing around \$2.25/kg in industrial product stores such as bunnings. This process will tie into the verification of each of the products the industrial team will be producing.

Overall, a manufacturing station would be required to start to produce these products for more than just Naomi, requiring machinery to form, grind and finish the orthotics to be produced.

## **8.4 Human Resources, Consulting, and Outsourcing**

### **8.4.1 Human resources**

Podiatrists or qualified medical professionals will be required to take measurements of an individual's biomechanical abilities including a cast or model of the patient's foot. For our particular product design that is specifically aimed at Naomi, Dr Abbie, her current podiatrist, will take the measurements. These measurements will test for biomechanical issues particularly in the areas of; malleolar position (Internal or External tibial Torsion), hip range of motion in extended and flexed, leg length difference, forefoot valgus or varus, resting calcaneal stance position and neutral calcaneal stance position.

### **8.4.2 Outsourcing**

To produce the orthotic device, the patient's measurements will be sent from the medical professional to an outsourced to an existing orthotic company with easy access to the equipment and materials we intend to use. As our product will not be produced on a large scale it would likely be expensive to buy the equipment and find suppliers for required materials ourselves. However we also need to consider whether a larger company or manufacturer would produce these especially if they have to change their process which they will have to do as it will be a customisable orthotic.

A company that is well equipped to handle the production of orthotics includes Sydney Orthotic Solutions Podiatry [51], producing orthotics within Sydney that can be custom or mass produced. They have equipment for gait cycle analysis and also cater designs to treat issues such as skin splints and runner's knee. Therefore, they have the equipment and are capable of creating our design as well as being local to reduce transportation costs of the orthotic product.

As for the shoe, the manufacturing of this component will be outsourced as we plan to capitalise on a company with shoe making equipment readily available. The team will create a pattern for the shoe and list the required materials for each section before sending these off to a shoe making company. This outsourcing company will then source the materials and put the shoe together before sending it back.

### **8.4.3 Time frame**

As our device is considered Class 1, it will take approximately 156 days on an average to get approved as seen above. After approval, the measurements will be taken at a regular podiatrist appointment and sent to a factory.

### **8.4.4 Approximate cost**

The provided cost breakdown in Table 12, 13 and 14 outlines the precise costs related to Naomi's personalised orthotic and the shoe. It is noteworthy that each product can be obtained separately. The thorough analysis provides

clarity on the various expenses related to the shoe and the orthotic, enabling users to make customised purchases based on their preferences or unique requirements.

**Table 12 - Custom Orthotic Costing [52]**

Item	Price
Initial Consultation with podiatrist	\$80- 89
Biomechanical consultation	\$80- 89
Custom Orthotic x2	\$400 – 498
Subsequent (fitting)	\$70 – 79
Cast/scan x2	\$120 - 138
Individual Manufacturing	\$50
<b>Total Average Cost</b>	<b>\$821.50</b>

**Table 13 - Cost of Raw Materials for a Pair of Shoes[53]**

Item	Price
Upper and lining materials	\$8.00
Insoles	\$12.00
Heels	\$9.00
Stiffeners	\$9.50
Soling	\$5.00
Hook and loop	\$2.00
Magnets	\$1.00
<b>Total Average Cost</b>	<b>\$46.50</b>

#### **Cost of Shoe Manufacturing [54]**

With costs adjusted for a single shoe size, the following offers a thorough analysis of the costs related to creating and manufacturing the shoe design in large quantities. It is noteworthy that the reason for the significant initial outlay is our shoe design's uniqueness, as it has never been produced before. It is important to stress that the numbers displayed do not indicate the retail price, but rather the comprehensive manufacturing costs incurred during the first phases of production.

**Table 14 - Cost of Manufacturing of Shoe**

Item	Cost
Pattern of shoe drawing	\$375.00
Outsole Blueprint	\$375.00
Solid model of outsole design	\$250.00
cast metal foam midsole mould	\$1475.00
cast metal rubber pressing outsole mould	\$1475.00
Injection mould	\$2500.00
logo EVA footbed mould	\$475.00
<b>Total Average Cost</b>	<b>\$6925</b>

## 8.5 Storage and Shelf-life

### 8.5.1 Storage

Our solution incorporates an innovative shoe design with a replaceable, insertable orthotic. As the solution is customisable to order it must be stored in a way that it is protected from any external forces that could change the shape of it or break it. The shoe component should be packaged in a new shoe box with acid free paper that absorbs moisture inside to hold the shape of the shoe and ensure no mould or bacteria growth before it is used [x55]. The orthotic should be packaged in a protective box while it is being transported from the manufacturer to the user.

Once produced and distributed, the product should be stored like a normal shoe, in a cool, dry place to avoid mould growth or in their original shoe box [x56]. The orthotic should be stored inside the shoe and only replaced when it is moved to another shoe or when a new orthotic is needed for changing biomechanical needs or wear. It can also be taken out if it needs to be cleaned or sterilised.

### 8.5.2 Shelf life

Having a replaceable orthotic increases the storage life of the device as, according to Dalal, Naomi goes through orthotics quicker than her shoes due to common wear or changing individual biomechanical needs. As Naomi is still a child and growing, the shelf life of the shoe will be restricted by how quickly her feet grow and thus how quickly Naomi needs new shoes and/or orthotics. This growth will likely overrule any wear of components over time caused by the device being exposed to constant friction between Naomi's foot and the device. The orthotic device's shelf life is dependent on Naomi's changing biomechanical needs and growth which are fairly unpredictable.

Some precautions taken to increase shelf life:

- Eyelets for hook and loop, to increase longevity of fabric around the straps
- Placement of hinge joint to increase durability
- Inclusion of magnets to avoid fidgeting with hook and loop straps

### 8.5.3 Time of replacement

The products will fairly easily be replaced as the design of the device should be reproducible with new measurements. However, as it is customisable, new measurements will have to be taken and sent to the manufacturer. Thus, the time of replacement will be similar to the time of getting the original device which is just under 3 months for the orthotic and just over 3 months for the shoe as seen in the Gantt chart from 8.1 of the report.

## **8.6 Safety: Cleaning and Terminal Sterilisation**

Our product does not involve any biohazards in its production or use it is required to follow the ISO 10993 regulatory standards and as there are no in vivo components or wound contacting points in our design the primary needs for cleaning and sterilisation are in addressing skin contact [57]. Orthotics are not designed to last forever and will eventually need to be replaced. However, to prolong the lifespan the use of water and soap may be used to remove the dirt on orthotics. A means of removing bacteria for the orthotic include the use of alcohol wipes which will clean the surface level bacteria. Due to the porous nature of orthotic materials, the material should never be submerged in liquids as this will only encourage further bacteria and fungal growth within the orthotic's porous region. To ensure the product remains as dry as possible to reduce chances of mould and mildew, it is recommended to place the shoes somewhere warm and dry after washing and if possible in close proximity to a dehumidifier. The use of socks must also be considered as these act as a removable barrier.

Another aspect of the product that may need to be taken into consideration is the presence of potential materials that can cause allergies. Many products contain latex including shoe soles [58] as such if an intended recipient of the product has a latex it could lead to a type 1 allergic reaction. This can severely impact the desired effect of the product as type 1 allergic reactions can lead to symptoms such as swelling, pain and excessive sweating [59], which can all contribute to an increase in discomfort and a reduction in effectiveness of the orthotics. As such a factor that needs to be taken into consideration is alternatives to potential allergens. Potential alternatives include materials such as nitrile and neoprene, which retain the elastic properties that make latex a prime candidate in shoe production but do not have the same potential for allergic reaction [60].

## **8.7 User Groups, Marketing, and Distribution**

Our product specifically addresses the unique biomechanical needs of Naomi, who is non verbal. Naomi's mother, Dalal, and podiatrists are the primary people that take Naomi's orthotic devices on and off her, and have been heavily involved in the design and development of this device. Therefore, they already have a good initial understanding of the device's function and how to use it. Additionally, throughout and after clinical testing, we will ensure both Dalal and Dr Abbie undergo comprehensive training with our guidance, to verify any necessary changes that have been made to the solution, are well understood by all parties. Detailed instructions on how to use, maintain and clean the product will also be supplied with schematics, including key associated risks to be aware of, and necessary steps to take if any adverse effects occur. This will allow individuals outside Naomi's immediate support group to refer to these instructions and aid Naomi in the most accurate and reliable way.

The orthotic design and its components are tailor able to each individual's biomechanical needs, and thus be used directly, or as a foundation to create solutions for other SAS patients with reduced lower limb functional capacity. Dr Abbie, who treats a diverse range of patients with reduced lower limb functionality, will play a pivotal role in raising awareness about the innovative solution within his patient community. Our long term aim is to market the device or specific components of the device to other podiatrists and medical professionals working with patients with limited lower limb functional capacity, ensuring the solution reaches all those who can benefit from it most. Our continued support from, and collaboration with the advocacy group SATB2-Connect, lead by Dalal herself, will ensure other SAS patients are aware of the availability of our solution as well.

## **8.8 Intellectual Property, Licensing, and Partnerships**

### **8.8.1 Final commercialisation goals**

Given the two subcomponents of our design, the Accessible Shoe and the In-Shoe Orthotic, we will explore different commercialisation avenues tailored to their respective role in our overarching solution. Firstly, the In-shoe orthotic is a customised device for which, in this context, has been designed and will be manufactured according to Naomi's unique requirements and specifications. Due to the customisable nature of this component, we hope to build relationships with a larger SAS patient audience, and collaborate with them through an individualised experience to create a product that accommodates their clinical presentation. Given the diverse nature of SAT-B2 symptoms, we would work closely with the client, and medical practitioners to evaluate their specific biomechanical anomalies, and lifestyle challenges, to define the engineering requirements for their own in-shoe orthotic.

Considering the Accessible Shoe component does not require personalisation, we will strive to explore partnerships that can equip us with the necessary resources, funding, global network and patent agreements to produce this device on a larger scale. This would involve reaching out to established organisations with similar initiatives and objectives, and enforcing a collaborative experience to finalise a robust and high quality design, as outlined in Section 8.8.3.

### **8.8.2 Intellectual property considerations**

Our investigation into the Australian patent database (AusPat) did not highlight any intellectual property concerns for specialised SMOs, AFOs, nor similar devices. However, an IP-related overlap was noted with Design Iteration 4.5, which featured the bistable hinge mechanism. This component is currently awaiting patent approval from the United States Patent and Trademark Office (Patent No. US11154115B2) [61]. To circumvent potential infringement, we have considered alternative design avenues to replace this feature, however this does not pose an immediate concern considering our initial product is not commercialised, merely produced for Naomi as an individual product.

In safeguarding our solution, the option of securing a patent may be necessary to avoid other organisations from exploiting and inflating the product's cost, thereby making it less accessible to those who need it the most. Should we decide to pursue a patent, it would most likely be in reference to the 'Accessible Shoe' component, as this is a more generalised design that holds potential to be mass produced. The process moving forward with this would involve exhaustive research to ensure no existing patents cover the same device, filling out a patent application form, then followed by a period of awaiting acceptance. This patent process can be protracted, ranging from 6 months to several years, especially if other entities contest it, making the design susceptible to competition [62]. The financial investment required for obtaining a patent can surpass \$3500 which highlights the considerable investment of time and expenditure. It is therefore important to make a decision that aligns with our overarching goals. Given there are established organisations that have existing initiatives to help individuals with lower limb abnormalities, and products with similar components to ours, it would be wise to form partnerships with them to achieve a united goal instead of competing for patents.

### **8.8.3 Partnerships**

Established organisations such as Nike are well known for using state-of-the-art manufacturing facilities to produce goods that are of the highest calibre. The opportunity to collaborate with Nike will allow us to leverage their experience and resources to improve the production quality of our Accessible Shoe component, giving our clients a robust and reliable product. This may entail collaborating with Nike's engineering and design team to finalise a product and incorporating this into their manufacturing and production processes. This can guarantee the best possible craftsmanship and quality control. In this way, we can more effectively scale production, cutting lead times and solidify a more responsive supply chain. Nike's extensive global distribution network can facilitate a wider reach of markets and demographics through cooperative marketing campaigns and co-branded products. Their highly

regarded reputation will additionally build trust and credibility with both consumers and medical professionals. This will ultimately grant individuals with neurological lower limb disorders the opportunity to access our solution, as well as spread awareness of our SAS initiative on a global scale.

In addition to this, partnering with healthcare institutions and clinics specialising in SAS or other lower limb impairment treatments would provide access to patients, medical expertise, and clinical settings for verification and validation testing. These collaborations would mainly involve establishing relationships with healthcare professionals, obtaining the required approvals for research, and aligning with their goals for patient care. By collaborating with research organisations, the project's scientific robustness can be enhanced as they can offer expertise, access to advanced technologies and opportunities for data analysis. This partnership would involve networking and negotiation to define the scope of the project and their involvement.

Lastly, building relationships with patient advocacy groups and foundations focused on SAS, such as SAT-B2 Connect, is pivotal in raising awareness, securing funding and developing a support network. This partnership would require ongoing communication and engagement through participation in events and awareness campaigns.

These collaborations all involve initial outreach, building relationships, identifying common goals and defining agreements. The timeline for which can vary depending on the organisation, taking months to years for it to evolve. It is therefore important to ensure ongoing communication, collaboration and commitment to our shared objectives.

## 9. Solution Summary

### 9.1 Our Solution

Given the rarity, and diverse symptomatic nature of SATB2-associated Syndrome, there is limited awareness, and thus current available solutions that respond to the unique needs of patients who live with this disease. Current technology available to SAS patients, particularly those who experience lower limb anomalies, embody quite critical limitations. Some of which include, insufficient customisation, the concession of comfort over rigidity, impracticality, as well as skin integrity problems. Our team has built upon these existing technologies with a strong focus on Naomi's biomechanical issues, and lifestyle challenges, to create an all-in-one user-centred orthotic design to improve her lower limb functional capacity, as well as her quality of life (Figure 15). Although the final design responds specifically to Naomi's anatomical impairments, instability, uneven gait and toe claw, the design ultimately offers a tailorable solution that can be adapted to the clinical presentations of other SAS patients. This solution obviates the need for multiple devices to cater for different environments, and instead presents a comprehensive two-fold product with the following design features responding to Naomi's defined requirements:

#### 1. Customised In-Shoe Orthotic

- Toe crest and toe grooves to align Naomi's toe claw, ensuring optimal pressure distribution and promoting balance and stability.
- Raised medial and lateral wings to accommodate midstance of gait cycle, and prevent pronation and supination
- Deep heel groove to correct heel strike motion, and improve uneven gait.

#### 2. Easy-Access Shoe

- Hinge mechanism that joins the heel counter with the upper toe box via the midsole. This enables the heel counter to flex down and allow the foot to easily slide into the upper component.
- Curvatures of the midsole to promote correct gait: top end promotes toe-off phase, and curvature at heel promotes heel strike.
- Fasteners: Hook and loop secures sub-components together. Magnets provide further security, and redirect Naomi's inclination to fiddle from Hook and loop, to increase its longevity.

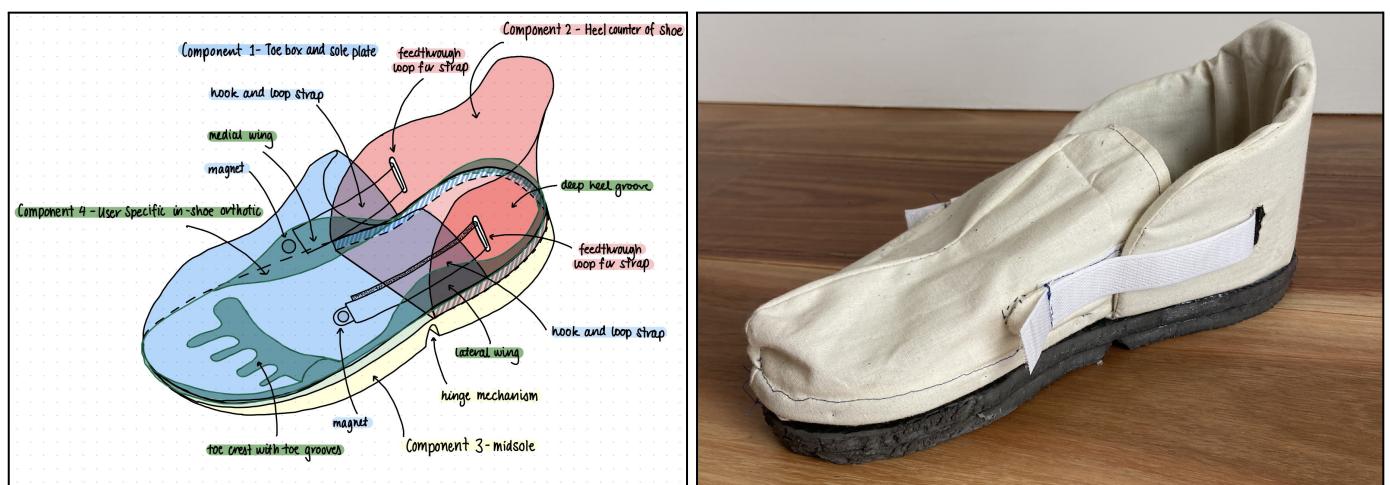


Figure 15 - Design Solution from Sketch to Prototype

## **9.2 Limitations**

### **9.2.1 Resource Constraints**

The absence of the client's anatomical specifications impeded our ability to tailor the orthotic model to Naomi's unique clinical presentation. Moreover, having limited access to advanced manufacturing techniques, such as 3D printing, prevented the production of a highly accurate and patient-specific prototype, to use for verification and validation testing. Although this report employed robust research, adaptable design principles and iterative prototyping techniques, in order to collect relevant and accurate data on the functional capacity of this device, and therefore provide robust data to highlight the product's feasibility, we would require access to these resources.

### **9.2.2 Long term Durability**

Given the novelty of this design, as well as the absence of extensive verification and validation data on the orthotics' performance, its functional capacity and wear characteristics over a long period of time is still unknown. The validation protocols described in this report require in-depth clinician evaluation overtime, as well as user feedback when utilised across various settings, and specialised equipment to measure gait and pressure distribution, for example. All of which has been constrained by time and resources.

### **9.2.3 Cost**

Given the customisation of the design, a key limitation relates to the high cost associated with medical examinations and diagnostics procedures required to obtain accurate anatomical specifications. This includes medical imaging, gait analysis and 3D scanning software to create a personalised model for manufacturing. The complexity of the design may also vary between SAS patients, impacting the type of manufacturing methods required, with cost increasing as higher precision is needed. This can in turn create disparities in access to advanced orthotic care.

## **9.3 Future Development**

### **9.3.1 Verification and Validation**

Given the resource and time constraints of the project, future action would involve carrying out the verification and validation protocols mentioned in Section 7, to ensure the safety and efficacy of the product. By manufacturing a precise prototype with the desired materials, and conducting a range of biomechanical and user-focused tests, we will be able to obtain more extensive and robust data. External parties such as research institutions and healthcare organisations can provide access to specialised testing facilities and resources to conduct these comprehensive clinical trials. Furthermore, the involvement of Dr Abbie and other professional insights, such as Naomi's occupational therapist, would be required to assess the long-term durability and patient usability of the product.

### **9.3.2 Partnerships**

Partnerships with established organisations, research institutes and advocacy groups will hold an integral role in creating reliable and accurate personalised orthotic solutions, as well as enhancing the awareness of this rare disease on a global scale. Collaborating with established organisations in the field, such as Nike, offers the potential to leverage their extensive resources, expertise in shoe design, and existing promotional efforts for individuals with lower mobility impairments. This would be more relevant to the Accessible Shoe component of our solution given this doesn't require customisation, and can be offered to a broader audience for improving quality of life. Collaborating with universities and research centres can facilitate wider access to advanced manufacturing technologies for highly accurate prototypes to carry out verification and validation. Finally, building relationships with patient advocacy groups and foundations such as *SATB2 Connect* can help raise awareness, inform individuals about the availability of our solution and establish a supportive network.

### **9.3.3 Other SAS Patients**

Once successful testing, and long-term evaluation has been carried out on Naomi's personalised product, we will have sufficient clinical data to prove feasibility for a broader audience. Expanding the project's scope to include a larger group of SAS patients will involve an individualised approach to accommodate for variety within the syndrome, as well as various regions and healthcare settings, given the global market. The diverse clinical needs amongst SAS patients would require the development of personalised prototypes, and verification and validation testing of the product in each case. In this context, our in-sole orthotic solution is not simply a product, but an individualised process, given our smaller target market.

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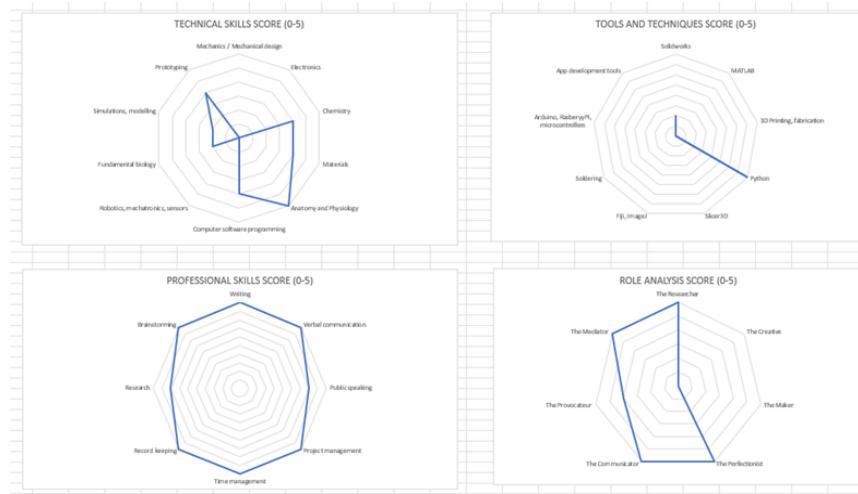
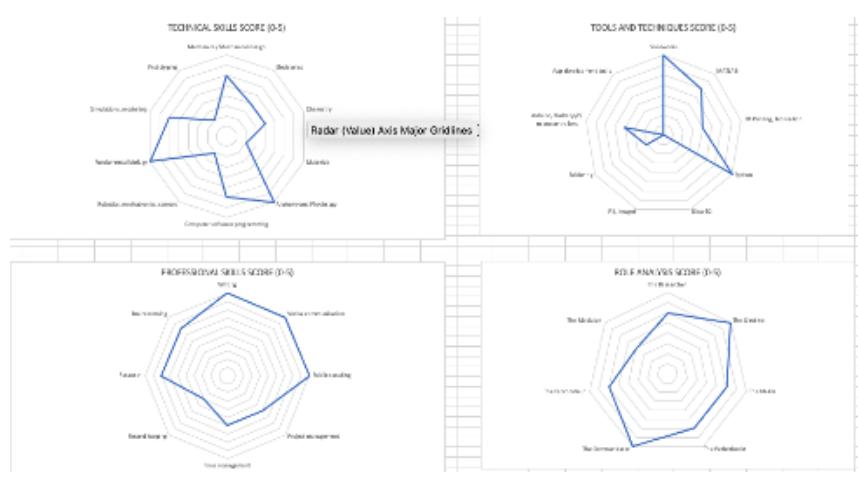
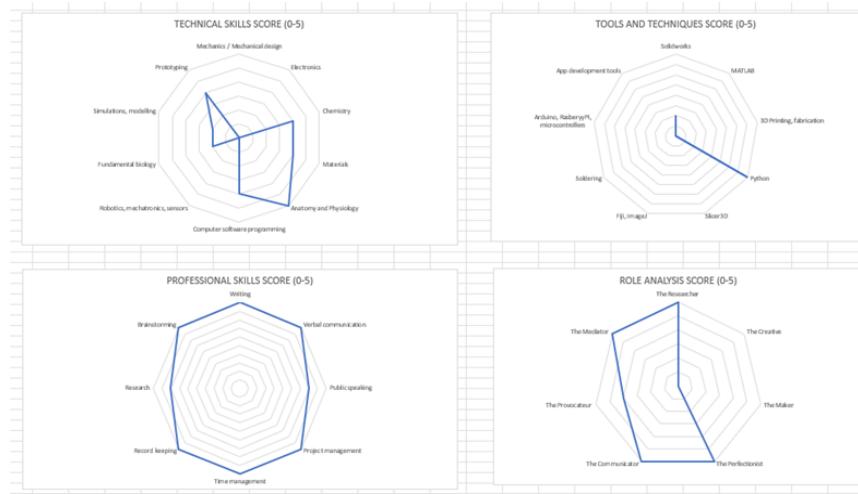
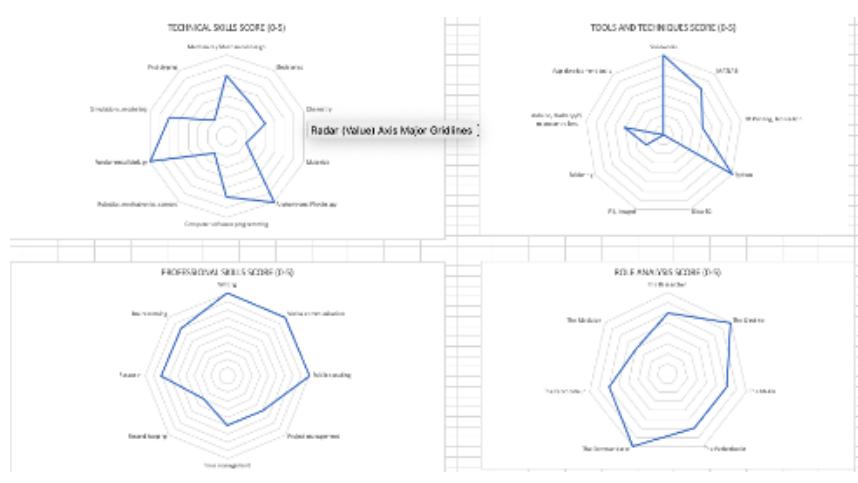
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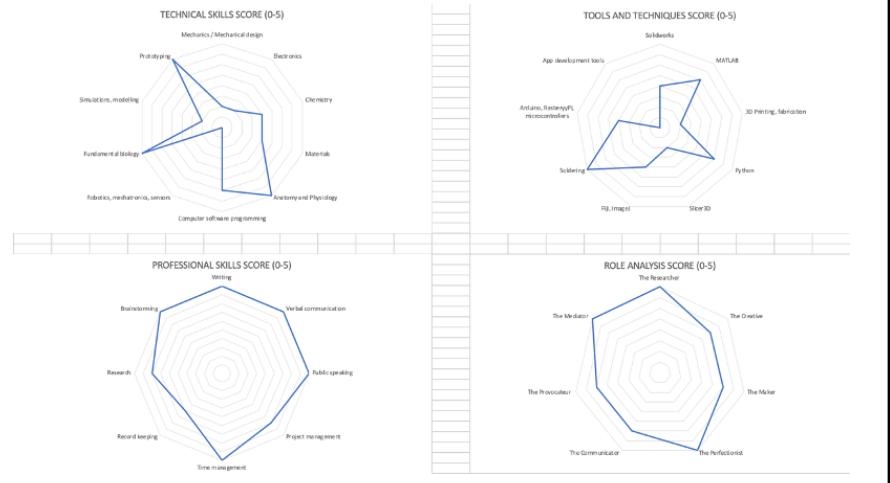
# Appendices

## Appendix 1 – Team Charter

<b>Purpose</b>	The team members are drawn together after submitting preferences for group projects. Thus, all members have an initial interest in the project. We will address the lower limb limitations faced by Naomi, a girl with SAS, through creating an orthotic device. An acceptable outcome involves increasing her functional capacity and independence through creating a device that provides her with stability and flexibility.																																																																																																																																																
<b>Duration and Time Commitment</b>	The group will work together until the end of semester, being November 2023. Each week the group will watch the 2 hour lecture and attend the 1 hour tutorial. On top of this we will meet at least once a week to work on the report and discuss ideas. Beyond this each member will allocate some individual time to work on their specific deliverables they have been allocated at that time in the project and thus will vary week to week.																																																																																																																																																
<b>Scope</b>	<p>The beginning of the project involves meeting the team and familiarisation ourselves with the project brief. From here, introductory background research and contacting primary stakeholders to understand what they want out of the project should enable us to create overall aims.</p> <p>Our project will end when we have created a model and/ or prototype of our orthotic based device for Naomi.</p> <p>Creating the final product or a prototype with the materials we assess appropriate for the product in its final design is outside the scope of our aims and the course.</p>																																																																																																																																																
<b>Members</b>	<p><b>Josie:</b></p> <p>Primarily contributing professional skills to the team with some technical skills in the areas of anatomy, physiology and computer software programming.</p>  <table border="1"> <caption>Technical Skills Score (0-5)</caption> <thead> <tr> <th>Category</th> <th>Score</th> </tr> </thead> <tbody> <tr><td>Mechanics / Mechanical design</td><td>5</td></tr> <tr><td>Electronics</td><td>5</td></tr> <tr><td>Chemistry</td><td>5</td></tr> <tr><td>Maths</td><td>5</td></tr> <tr><td>Anatomy and Physiology</td><td>5</td></tr> <tr><td>Computer software programming</td><td>5</td></tr> <tr><td>Robotics, mechatronics, sensors</td><td>5</td></tr> <tr><td>Fundamental biology</td><td>5</td></tr> <tr><td>Simulations, modeling</td><td>5</td></tr> <tr><td>Prototyping</td><td>5</td></tr> </tbody> </table> <table border="1"> <caption>Tools and Techniques Score (0-5)</caption> <thead> <tr> <th>Category</th> <th>Score</th> </tr> </thead> <tbody> 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<b>Purpose</b>	The team members are drawn together after submitting preferences for group projects. Thus, all members have an initial interest in the project. We will address the lower limb limitations faced by Naomi, a girl with SAS, through creating an orthotic device. An acceptable outcome involves increasing her functional capacity and independence through creating a device that provides her with stability and flexibility.																																																																																																																																																
<b>Duration and Time Commitment</b>	The group will work together until the end of semester, being November 2023. Each week the group will watch the 2 hour lecture and attend the 1 hour tutorial. On top of this we will meet at least once a week to work on the report and discuss ideas. Beyond this each member will allocate some individual time to work on their specific deliverables they have been allocated at that time in the project and thus will vary week to week.																																																																																																																																																
<b>Scope</b>	<p>The beginning of the project involves meeting the team and familiarisation ourselves with the project brief. From here, introductory background research and contacting primary stakeholders to understand what they want out of the project should enable us to create overall aims.</p> <p>Our project will end when we have created a model and/ or prototype of our orthotic based device for Naomi.</p> <p>Creating the final product or a prototype with the materials we assess appropriate for the product in its final design is outside the scope of our aims and the course.</p>																																																																																																																																																
<b>Members</b>	<p><b>Josie:</b></p> <p>Primarily contributing professional skills to the team with some technical skills in the areas of anatomy, physiology and computer software programming.</p>  <table border="1"> <caption>Technical Skills Score (0-5)</caption> <thead> <tr> <th>Category</th> <th>Score</th> </tr> </thead> <tbody> <tr><td>Mechanics / Mechanical design</td><td>5</td></tr> <tr><td>Electronics</td><td>5</td></tr> <tr><td>Chemistry</td><td>5</td></tr> <tr><td>Maths</td><td>5</td></tr> <tr><td>Anatomy and Physiology</td><td>5</td></tr> <tr><td>Computer software programming</td><td>5</td></tr> <tr><td>Robotics, mechatronics, sensors</td><td>5</td></tr> <tr><td>Fundamental biology</td><td>5</td></tr> <tr><td>Simulations, modeling</td><td>5</td></tr> <tr><td>Prototyping</td><td>5</td></tr> </tbody> </table> <table border="1"> <caption>Tools and Techniques Score (0-5)</caption> <thead> <tr> <th>Category</th> <th>Score</th> </tr> </thead> <tbody> 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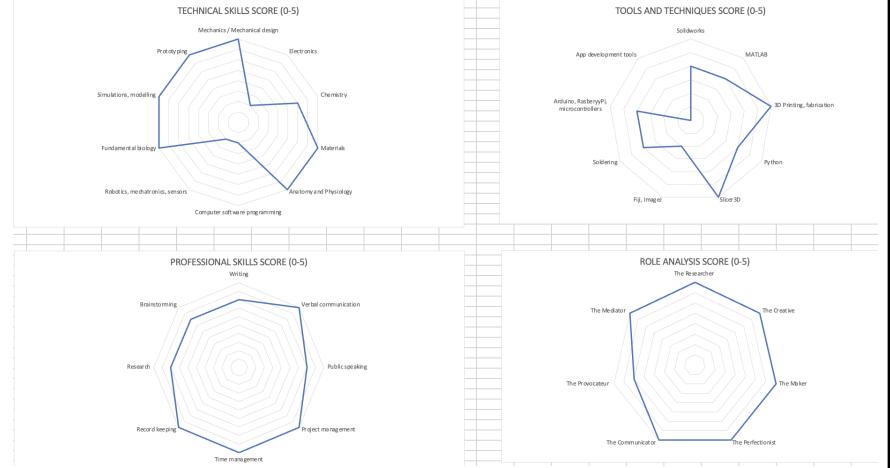
**Milly:**

Strengths in professional communication, in depth knowledge of anatomy and physiology, and good sketching ability.



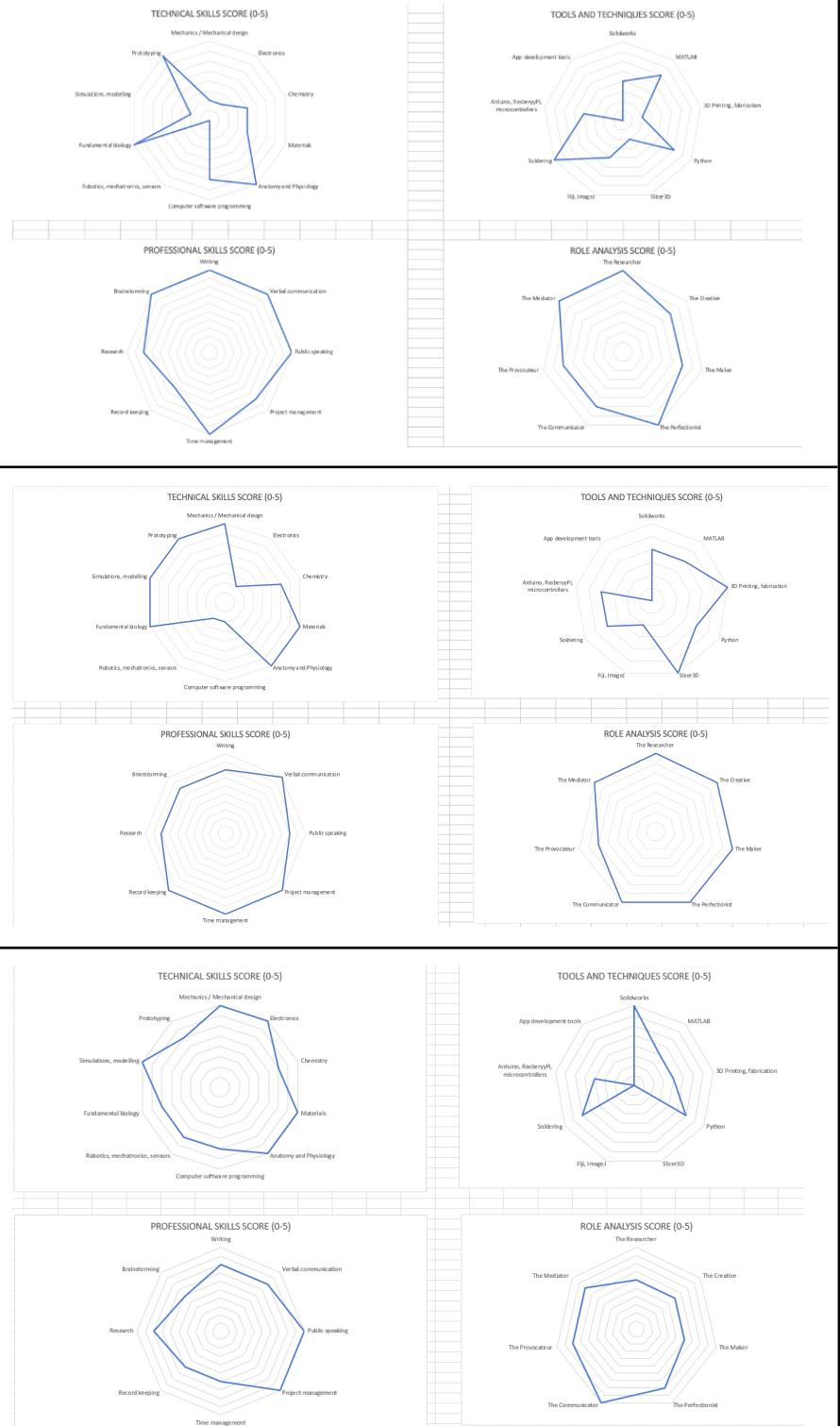
**Holly:**

Confident in professional communication, record keeping and research conduction. Skilled in technical drawings through CAD software, and deep anatomy /physiology understanding.



**Steve:**

*My expertise is in communication, documentation, computer-aided design (CAD), and human anatomy and mechanics are strong points of mine.*



	<p><i>Sithma:</i></p> <p><i>Strengths in communication, writing and creativity. Proficiency in simulations &amp; modelling, CAD &amp; Solidworks, and a keen eye for anatomy and physiology.</i></p>	<ul style="list-style-type: none"> <li><b>Technical Skills Score (0-5):</b> Scores range from ~0.5 (Chemistry) to ~4.5 (Mechanics/Mechanical design).</li> <li><b>Tools and Techniques Score (0-5):</b> Scores range from ~0.5 (Soldering) to ~4.5 (Solidworks).</li> <li><b>Professional Skills Score (0-5):</b> Scores range from ~0.5 (Record keeping) to ~5.0 (Writing).</li> <li><b>Role Analysis Score (0-5):</b> Scores range from ~0.5 (The Communicator) to ~5.0 (The Researcher).</li> </ul>
	<p><i>Hamish:</i></p> <p><i>My strengths lie primarily with coming up with new ideas to solve problems and then being able to word those solutions effectively. I have good knowledge in the areas of anatomy and regulatory affairs</i></p>	<ul style="list-style-type: none"> <li><b>Technical Skills Score (0-5):</b> Scores range from ~0.5 (Chemistry) to ~4.5 (Mechanics/Mechanical design).</li> <li><b>Tools and Techniques Score (0-5):</b> Scores range from ~0.5 (Soldering) to ~4.5 (Solidworks).</li> <li><b>Professional Skills Score (0-5):</b> Scores range from ~0.5 (Record keeping) to ~5.0 (Writing).</li> <li><b>Role Analysis Score (0-5):</b> Scores range from ~0.5 (The Communicator) to ~5.0 (The Researcher).</li> </ul>
<b>Desired End Result</b>	<p>The overall goal of the project is to create a prototype of our orthotic device for Naomi. The prototype should be to scale but not necessarily made from the materials we assess appropriate for the product in its final design. To achieve this we will need to sketch a design, create models on solidworks and send this model in to be 3D printed.</p>	
<b>Deliverables</b>	<p><i>This defines the outputs of the projects, the specific things that will be produced in pursuit of the goal. A key element will be developing Key Performance Indicators (KPIs) and an on-going auditing process to help assess how well the deliverables match the intention.</i></p> <ul style="list-style-type: none"> <li>- Use background research to develop primary aims and understand stakeholder interests</li> <li>- Create initial designs iterations</li> <li>- Evaluate design iterations based on risk, feasibility and if it addresses our defined aims</li> <li>- Choose a design iteration to move forward with</li> <li>- Create a 3D model of the design iteration using CAD software</li> <li>- Create a prototype of the design by printing our 3D model</li> </ul>	
<b>Reporting Plan</b>	<p>Brayden, elected as the team captain, will be the main source of contact to higher authorities and represent our group to the tutor, client and clinician. We will rely on email to initiate communications and organise online and in person meetings to communicate with higher authorities.</p>	
<b>Supporting Resources</b>	<p><i>This can be any resource that the team can bring to the project, and can include things like meeting rooms, Canvas, software etc.</i></p>	
<b>Links</b>	<p><i>This considers other departments, organisations, or people that may overlap with the team's purpose. It may also include subject matter experts (SMEs) that can be consulted.</i></p>	

## Appendix 2 – Meeting Minutes

### 2.1 Meeting One

<i>Date and Time</i>	7/8/2023, 17:00 - 18:00
<i>Location</i>	ABS Building: Learning Studio 3100
<i>Apologies</i>	<ul style="list-style-type: none"><li>● NA</li></ul>
<i>Absences</i>	<ul style="list-style-type: none"><li>● Hamish</li></ul>
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"><li>● NA</li></ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"><li>● Meeting the group</li><li>● Initial reading about the project and client information</li></ul>
<i>Action items to be done</i>	<ul style="list-style-type: none"><li>● Everyone to conduct initial research on SATB2 and SAS - find more information about its correlation with lower mobility difficulty.</li></ul>
<i>Proposed next meeting</i>	<ul style="list-style-type: none"><li>● Monday 14/08/23, 1 hour before tutorial + tutorial time (16:00-18:00)</li></ul>

### 2.2 Meeting Two

<i>Date and Time</i>	14/8/2023, 16:00 - 18:00
<i>Location</i>	ABS Building: Learning Studio 3100
<i>Apologies</i>	<ul style="list-style-type: none"><li>● NA</li></ul>
<i>Absences</i>	<ul style="list-style-type: none"><li>● Hamish</li></ul>
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"><li>● Research into orthotics</li><li>● Identification of questions to ask the patient</li></ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"><li>● Delegation of tasks</li><li>● Questions for the client</li><li>● Research comparison</li><li>● Logbook discussion</li></ul>
<i>Action items to be done</i>	<ul style="list-style-type: none"><li>● Email client about availability</li><li>● Research CP for alternative methods</li><li>● Work on aims, background, stakeholders and prior art.</li></ul>
<i>Proposed next meeting</i>	Based on client response

## 2.3 Meeting Three

<i>Date and Time</i>	21/8/2023, 17:00 - 18:00
<i>Location</i>	Zoom meeting
<i>Apologies</i>	<ul style="list-style-type: none"> <li>● Josie</li> </ul>
<i>Absences</i>	<ul style="list-style-type: none"> <li>● Hamish</li> </ul>
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"> <li>● Progression of report, waiting on interview to finalise sections</li> </ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"> <li>● Questions finalised for interview on Wednesday 23/08/23</li> <li>● Update on Project Report progression</li> </ul>
<i>Action items to be done</i>	<ul style="list-style-type: none"> <li>● Finalise Aim &amp; Background and prior art after interview, aim to complete by end of week</li> <li>● Brainstorm requirements - are there any requirements found in prior art research?</li> </ul>
<i>Proposed next meeting</i>	Group 10 & 11 meeting the client on Wednesday at 11am on Zoom.

## 2.4 Meeting Four

<i>Date and Time</i>	23/08/2023, 11:00 - 12:00
<i>Location</i>	Zoom
<i>Apologies</i>	<ul style="list-style-type: none"> <li>● Josie, Steve and Sithma</li> </ul>
<i>Absences</i>	<ul style="list-style-type: none"> <li>● Hamish</li> </ul>
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"> <li>● Ask Dalal questions and learn about Naomi's needs</li> <li>● Write down notes of her answers</li> </ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"> <li>● All necessary questions             <ul style="list-style-type: none"> <li>○ Needs</li> <li>○ Wants</li> <li>○ Issues</li> <li>○ Prior art</li> </ul> </li> </ul>
<i>Action items to be done</i>	Host a group meeting to discuss the future direction of the project on
<i>Proposed next meeting</i>	Friday 25 Aug at 7 pm on Zoom

## 2.5 Meeting Five

<i>Date and Time</i>	25/08/2023, 20:15 - 21:15
<i>Location</i>	Zoom
<i>Apologies</i>	<ul style="list-style-type: none"> <li>● Josie</li> </ul>
<i>Absences</i>	<ul style="list-style-type: none"> <li>● Hamish</li> </ul>
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"> <li>● Recount meeting with Dalal on Wednesday for those who were absent</li> <li>● Discuss design ideation and requirements / user needs</li> </ul>
<i>Points raised and discussed at meeting</i>	<p>Design Ideation</p> <ul style="list-style-type: none"> <li>● Pressure sensors</li> <li>● In-shoe / AFO hybrid design</li> <li>● Toe separators</li> <li>● Soft robotic exo-suit</li> </ul> <p>Requirements</p> <ul style="list-style-type: none"> <li>● Reduce risk of excessive sweating (i.e.,blistering)</li> <li>● Needs some arch support</li> <li>● Respond to toe clawing - gloves for toes?</li> <li>● Requires ankle support</li> </ul>
<i>Action items to be done</i>	<ul style="list-style-type: none"> <li>● Complete Section 1 and 2</li> <li>● Brainstorm design ideas to discuss in next meeting</li> </ul>
<i>Proposed next meeting</i>	In person Tutorial on Monday 28/08/23

## 2.6 Meeting Six

<i>Date and Time</i>	28/08/2023, 14:00 - 18:00
<i>Location</i>	ABS Building Rooms 1070, 3100
<i>Apologies</i>	<ul style="list-style-type: none"> <li>● NA</li> </ul>
<i>Absences</i>	<ul style="list-style-type: none"> <li>● Hamish</li> </ul>
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"> <li>● Proposal of the concepts we have developed to tutor</li> <li>● Development of topics and discussion points for our quick chat with Dalal on Wednesday</li> </ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"> <li>● Development of our designs</li> <li>● Establishing recording methods for Saturday's in person meeting with Dalal and Naomi</li> </ul>
<i>Action items to be done</i>	<ul style="list-style-type: none"> <li>● Printing the topics and action items for the online meeting with Dalal</li> </ul>
<i>Proposed next meeting</i>	Online meeting with Dalal on Wednesday 30th August at 2pm.

## 2.7 Meeting Seven

<i>Date and Time</i>	30/08/2023, 14:00 - 14:30
<i>Location</i>	Online Call with Dalal and Brayden
<i>Apologies</i>	<ul style="list-style-type: none"> <li>Holly, Milly, Steve, Josie, Sithma</li> </ul>
<i>Absences</i>	<ul style="list-style-type: none"> <li>Hamish</li> </ul>
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"> <li>The next stages of the project and the steps to achieve them were established starting with the Saturday meeting with Dr Abbie, Naomi and Dalal</li> </ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"> <li>The direction of our project was analysed prior to the in person meeting with Dr Abbie and Dalal on the coming Saturday</li> <li>Clarification on the desires from this project</li> </ul>
<i>Action items to be done</i>	Creation of technical questions to ask Dr Abbie during the in person meeting
<i>Proposed next meeting</i>	Meeting in Person with Dalal, Naomi, Dr Abbie, Brayden, and Milly on Saturday 2nd September

## 2.8 Meeting Eight

<i>Date and Time</i>	02/09/2023, 14:00 - 14:30
<i>Location</i>	In person clinician meeting at Dr Abbie's clinic in Hornsby
<i>Apologies</i>	<ul style="list-style-type: none"> <li>Holly, Steve, Josie, Sithma</li> </ul>
<i>Absences</i>	<ul style="list-style-type: none"> <li>Hamish</li> </ul>
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"> <li>Debrief on saturday meeting with clinician about current design iteration</li> <li>Limitations to current design ideas, what needs to be improved.</li> </ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"> <li>Redirection of design ideas to consider a product that can be worn inside the house / easy to administer and to use.</li> <li>Consideration of socks with supportive sole/heel - other team is focusing on this design.</li> <li>Product needs to be breathable - inspiration from crocs</li> <li>Inspiration from Nike easy on/off shoes - have a heel that can be slipped on and off.</li> </ul>
<i>Action items to be done</i>	<ul style="list-style-type: none"> <li>Create initial sketches for design iterations that have been discussed</li> <li>Highlight limitations and future directions of each.</li> <li>Add to engineering requirements and risk analysis according to new design considerations.</li> </ul>
<i>Proposed next meeting</i>	Monday 4th September, 16:00 - 18:00

## 2.9 Meeting Nine

<i>Date and Time</i>	04/09/2023 16:00 - 18:00
<i>Location</i>	ABS Building Rooms 1070, 3100
<i>Apologies</i>	<ul style="list-style-type: none"> <li>● NA</li> </ul>
<i>Absences</i>	<ul style="list-style-type: none"> <li>● Hamish</li> </ul>
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"> <li>● The formulation of a new design according to the insights from Dr Abbie</li> </ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"> <li>● The technical questions lead to the critical analysis of our current design and highlighted the fundamental issues underlying it</li> <li>● Further insight into the technical needs of Naomi</li> </ul>
<i>Action items to be done</i>	<ul style="list-style-type: none"> <li>● Create a finalised design to progress further into the project with</li> </ul>
<i>Proposed next meeting</i>	Saturday 9th September, 18:15 - 19:30

## 2.10 Meeting Ten

<i>Date and Time</i>	09/09/2023, 18:15 - 18:45
<i>Location</i>	Zoom
<i>Apologies</i>	<ul style="list-style-type: none"> <li>● NA</li> </ul>
<i>Absences</i>	<ul style="list-style-type: none"> <li>● NA</li> </ul>
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"> <li>● Progress of Design report - identify what is left to be finalised</li> </ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"> <li>● Discussed what sections in the report need to be finalised for the first draft due date (15th sept) - all members were allocated tasks</li> <li>● Reminder to research specific materials of our designs that we can propose to the clinician.</li> </ul>
<i>Action items to be done</i>	<ul style="list-style-type: none"> <li>● Josie: Finalise background/aims</li> <li>● Holly: Add to / finalise requirements and risk analysis tables</li> <li>● Milly: Design iterations (sketches - outline advantages and disadvantages within flowchart)</li> <li>● Brayden: Fill in 'priorities' in the requirement table and write justification below table.</li> <li>● Sithma: Help Milly with design iterations (fill out table)</li> <li>● Steve: write passage for prior art</li> <li>● Everyone: Materials research to propose all designs to Dr Abbie / Dalal</li> </ul>
<i>Proposed next meeting</i>	Monday Tutorial (5-6pm)

## 2.11 Meeting Eleven

<i>Date and Time</i>	11/09/2023, 17:00 - 18:00
<i>Location</i>	ABS Building Rooms 1070, 3100
<i>Apologies</i>	<ul style="list-style-type: none"> <li>Josie, Milly, Brayden, Steve</li> </ul>
<i>Absences</i>	<ul style="list-style-type: none"> <li>Hamish</li> </ul>
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"> <li>Seek feedback and critique from Sid regarding design report progress</li> </ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"> <li>Specific feedback is outlined in google doc comments (*add here*)</li> </ul>
<i>Action items to be done</i>	<ul style="list-style-type: none"> <li>All members read over initial feedback noted in the shared google doc, and make any easy adjustments accordingly</li> </ul>
<i>Proposed next meeting</i>	Tuesday 12th September, 9pm on Zoom.

## 2.12 Meeting Twelve

<i>Date and Time</i>	12/09/2023, 21:00 - 21:35
<i>Location</i>	Zoom
<i>Apologies</i>	<ul style="list-style-type: none"> <li>N/A</li> </ul>
<i>Absences</i>	<ul style="list-style-type: none"> <li>N/A</li> </ul>
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"> <li>Fill in members regarding Design Report feedback from Sid</li> <li>Delegate remaining tasks</li> </ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"> <li>Discussion around what our deliverable / aim is - are we basing our objectives around Dalal's or Dr Abbie's perspectives? - may need to contact Sandhya</li> <li>Explanation of feedback to members who were absent at tutorial</li> </ul>
<i>Action items to be done</i>	<ul style="list-style-type: none"> <li>Steve and Hamish: Finish prior art section (fill out remainder of table, and write paragraphs for each category under table - mini literature review)</li> <li>Josie: Finalise aims/background/stakeholder</li> <li>Milly: Finalise design iteration sketches and reorganise table</li> <li>Sithma: Fill out the design iteration table after Milly has finished sketches. Add justification of ranks in appendix.</li> <li>Brayden: Email Sandhya and Dalal</li> <li>Everyone: add some information to other sections.</li> <li>Everyone: continue to brainstorm material ideas for each design iteration.</li> </ul>
<i>Proposed next meeting</i>	Friday 15th September on Zoom, at 3pm.

## 2.13 Meeting Thirteen

<i>Date and Time</i>	15/09/2023, 15:00 - 15:30
<i>Location</i>	Zoom
<i>Apologies</i>	<ul style="list-style-type: none"> <li>● N/A</li> </ul>
<i>Absences</i>	<ul style="list-style-type: none"> <li>● Hamish</li> </ul>
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"> <li>● What is left to be done with the report?</li> <li>● Is the report consistent? All members to read through together</li> <li>● References?</li> </ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"> <li>● Design Iterations - discussion around ranking for each iteration. Justification is needed to our logic behind why we gave each iteration their respective score.</li> </ul>
<i>Action items to be done</i>	<ul style="list-style-type: none"> <li>● Short justification for each design iteration to be included in the appendix</li> <li>● Some notes to be added to Section 6</li> </ul>
<i>Proposed next meeting</i>	Monday 18th September in tutorial (4-6pm)

## 2.14 Meeting Fourteen

<i>Date and Time</i>	18/09/2023, 16:15 - 16:45
<i>Location</i>	Zoom
<i>Apologies</i>	<ul style="list-style-type: none"> <li>● N/A</li> </ul>
<i>Absences</i>	<ul style="list-style-type: none"> <li>● N/A</li> </ul>
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"> <li>● Choosing a final design</li> <li>● What other sections can we work on in conjunction with the design section?</li> </ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"> <li>● Drawbacks to Nike modular design - will this affect structural integrity of orthotic?</li> <li>● Top designs to send to Dr Abbie - flexy orthotic, nike/croc hybrid design</li> <li>● Adding 'toe' grooves to respond to toe claw</li> <li>● We can start V&amp;V section on broader requirements that are relevant to any design we go forward with.</li> <li>● How do we get measurements? Can we base it off Naomi's previous orthotics? Do we estimate parameters?</li> <li>● Elastic vs magnetic mechanism - which one is more reliable/durable?</li> <li>● Materials used with orthotics- which areas of the orthotic typically use what materials?</li> </ul>
<i>Action items to be done</i>	<ul style="list-style-type: none"> <li>● Brayden: Email Dr Abbie about top design iterations to gather feedback (email Dalal as well for her opinion? - ask about cleaning/sterilisation (section 8.5))</li> <li>● Milly: Continue brainstorming materials (general materials for orthotics)</li> <li>● Holly/Josie: Start V&amp;V Section on broader orthotic requirements</li> <li>● Holly/Josie: Continue working on Section 8</li> <li>● Steve/Hamish: Read Biomechanics Textbook to tailor orthotic design to Dr</li> </ul>

	<p>Abbie's preferences (mechanical forces / pressure points throughout the orthotic).</p> <ul style="list-style-type: none"> <li>Sithma: Research how to integrate existing models into software for CAD designs.</li> </ul>
<i>Proposed next meeting</i>	02/10/2023

## 2.15 Meeting Fifteen

<i>Date and Time</i>	02/10/2023, 18:00 - 18:45
<i>Location</i>	Zoom
<i>Apologies</i>	<ul style="list-style-type: none"> <li>Sithma</li> </ul>
<i>Absences</i>	<ul style="list-style-type: none"> <li>Hamish</li> </ul>
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"> <li>Choosing a final design</li> <li>What other sections can we work on in conjunction with the design section?</li> </ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"> <li>Discussed Dr Abbie feedback</li> <li>Which design to move forward with?</li> <li>What sections of the design report needs to be completed</li> <li>Would Naomi prefer detachable orthotic or built into shoe</li> <li>Mechanism to attach orthotic to the shoe - something small made from PEEK? Is it necessary at all?</li> <li>Section 8.7 - Partnerships with Dalal's organisation, what would be some future partnerships that we could benefit from?</li> </ul>
<i>Action items to be done</i>	<ul style="list-style-type: none"> <li>Milly: Make some more detailed sketches - focus on the detail inside the shoe (toe ridges, attachment mechanisms etc.)</li> <li>Holly: Section 8.1</li> <li>Josie: 8.3 and 8.4</li> <li>Brayden: Section 8.2 and 8.5</li> <li>Steve: Section 6 , finalise materials</li> <li>Steve/Brayden: Start creating some solidworks designs</li> <li>Hamish: Section 8.7</li> </ul>
<i>Proposed next meeting</i>	09/10/2023, 16:00 - 18:00

## 2.16 Meeting Sixteen

<i>Date and Time</i>	09/10/2023, 17:00 - 18:00
<i>Location</i>	ABS Building Rooms 1070, 3100
<i>Apologies</i>	N/A
<i>Absences</i>	N/A
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"> <li>Development of report - what sections need to be worked on</li> <li>Intellectual property issue around Nike's Go FlyEase model patent</li> <li>Specification sections - what's included other than sketches?</li> </ul>

	<ul style="list-style-type: none"> <li>Upcoming appointments with Dalal Naomi</li> </ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"> <li>Materials - need to specify which materials we want to involve in the final product, can include other options in the appendix.</li> <li>Nike patent on flex shoe - how do we get around this? Do we need to change the design? The design can be inspired by this model, but needs to differentiate a bit more. Our focus is on the insole, rather than the exterior shoe. <ul style="list-style-type: none"> <li>Solution: The insole is the component that we create and commercialise for SAS-patients - creating a product that is more accessible, and something that can be replaced and reused with multiple shoes. However we are building a whole system for Naomi, including the insole and the Nike inspired shoe.</li> </ul> </li> <li>Inclusion of mechanical forces of the shoe - flexed vs unflexed.</li> <li>Technical drawings should be provided in the specification section with dimensions.</li> <li>Usability: is it going to be challenging for Naomi to put the shoes on and off? Does she have the strength to push down on the heel herself? Dalal can help however one of our aims is to increase independence.</li> <li>Upcoming appointments: <ul style="list-style-type: none"> <li>Tuesday 17th 3:30pm at Unit 13, 59-63 Captain Cook Dr, Caringbah</li> <li>Tuesday 24th 10:30am at Westmeads Children Hospital.</li> </ul> </li> </ul>
<i>Action items to be done</i>	<ul style="list-style-type: none"> <li>Josie: Updates aims</li> <li>Sithma: Design Iterations - mention that design justification is in the appendix</li> <li>Milly/Sithma: add more detailed version of nike/ insole with toe ridges etc. into design iteration and add this with highest mark in ranking table</li> <li>Holly/Josie/Milly: Add to V&amp;V Section.</li> <li>Everyone: add notes for Gantt chart (what needs to be done, and how long it will take) - can be a draft and then finalised by one person later on.</li> <li>Hamish/Steve/Brayden: Develop CAD model of design.</li> </ul>
<i>Proposed next meeting</i>	16/10/23, 17:00 - 18:00 (Tutorial)

## 2.17 Meeting Seventeen

<i>Date and Time</i>	16/10/2023, 15:30 - 17:45
<i>Location</i>	ABS Building Rooms 1070, 3100
<i>Apologies</i>	Holly
<i>Absences</i>	N/A
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"> <li>Presentation preparation for the following week</li> <li>New design iteration brainstorm/adjusting current design</li> </ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"> <li>Alternatives to the elastic tensioner mechanism of the Nike model</li> <li>Velcro? Will this be an issue for heightened sensory issues (fiddling?)</li> <li>Moving the velcro component down so there's more support at the hinge where the sole bends (concern of structural integrity at this point)</li> <li>Who can go to the meeting in Caringbah on Tuesday 16th Oct.</li> <li>Military grade velcro? Provides enough flexibility for Naomi to move her foot and strength for the shoe. Velcro is a reinforcement to the locking</li> </ul>

	mechanism.
Action items to be done	<ul style="list-style-type: none"> <li>Milly: Prototyping the design in preparation of presentation by checking out some shoes in Kmart</li> <li>Josie: Adjust the aims/storage life</li> <li>Holly/Josie/Milly: Adding on to V&amp;V</li> <li>Brayden/Steve/Hamish: Continue on the solidworks designs considering new info</li> <li>Sithma: adding new iterations and justifications to marking based on new final design proposal</li> <li>Everyone: starting on the presentation for the following week</li> </ul>
Proposed next meeting	23/10/23, 17:00 - 18:00 (Tutorial)

## 2.18 Meeting Eighteen

Date and Time	23/10/2023, 17:00-18:00
Location	ABS Building Rooms 1070, 3100
Apologies	Brayden, Steve
Absences	Hamish
Action items raised and addressed at meeting	<ul style="list-style-type: none"> <li>Presentation Submission - what needs to be done?</li> <li>Report - Sections to complete?</li> <li>Clarification of Requirements feedback from Draft 1</li> </ul>
Points raised and discussed at meeting	<ul style="list-style-type: none"> <li>Presentation: <ul style="list-style-type: none"> <li>Submission: Wednesday/Thursday this week!</li> <li>Maximum 6 minutes</li> <li>At least 2 people must speak (more are allowed)</li> <li>Props, prototypes, models, animations etc are encouraged.</li> <li>Transition of slides: Clinical need → Prior art → Solution → Innovation/design specifications → Feasibility (cost etc.)</li> <li>Really articulate how our solution is <i>significant / what is the impact?</i> Maybe start with a 'shocking' statistic</li> <li>Delivery: Don't make it monotone/reading off a script (No one will listen) Make it engaging and natural.</li> <li>Minimal text on slide, try to use more <b>visuals</b> instead.</li> <li>Include a logo?</li> </ul> </li> </ul>
Action items to be done	<ul style="list-style-type: none"> <li>Milly - finish prototype and take video for presentation</li> <li>Holly - format presentation in canva</li> <li>Brayden and steve - finish CAD and have a photo or video of it for presentation</li> <li>Hamish - create the feasibility slide for presentation (on collaborations on canvas)</li> <li>Josie and Sith - create dot points for presentation and draft a script</li> </ul>
Proposed next meeting	Friday 27/10/23

## 2.19 Meeting Nineteen

<i>Date and Time</i>	27/10/2023, 20:00-21:00
<i>Location</i>	Zoom
<i>Apologies</i>	N/A
<i>Absences</i>	Hamish, Sithma
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"> <li>● Presentation - what's left to do?</li> </ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"> <li>● Don't need to include technical drawings - the youtube videos demonstrating the prototype and CAD are easier to understand for the audience.</li> <li>● Role Delegation for presenting <ul style="list-style-type: none"> <li>○ Brayden: Clinical Need and Prior Art (1-2 mins)</li> <li>○ Milly: Solution (2-3 mins)</li> <li>○ Holly: Innovation (1 min)</li> <li>○ Steve: Feasibility (1 min)</li> </ul> </li> </ul>
<i>Action items to be done</i>	<ul style="list-style-type: none"> <li>● Brayden, Milly, Holly, Steve: Practise Script so delivery is natural.</li> </ul>
<i>Proposed next meeting</i>	Monday 30th October 1pm (to practise presentation before lecture time)

## 2.20 Meeting Twenty

<i>Date and Time</i>	30/10/2023, 17:00
<i>Location</i>	In person, outside Carslaw Building
<i>Apologies</i>	N/A
<i>Absences</i>	Hamish
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"> <li>● Report - What's left to do, and task delegation?</li> </ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"> <li>● Stakeholder table needs to be edited</li> <li>● Make sure everything in Appendix has been mentioned throughout report</li> <li>● Considerations for future development of the project outside university context - add it to section 8?</li> <li>● V&amp;V protocol ideas: <ul style="list-style-type: none"> <li>○ Placement of hinge</li> <li>○ Height of the heel</li> <li>○ Stiffness of the foam around the ankle</li> <li>○ Toe grooves</li> <li>○ Range of motion at the hinge - until it breaks</li> <li>○ Falling</li> <li>○ Test if it will give blisters</li> <li>○ Sweating</li> <li>○ Difficulty of application <ul style="list-style-type: none"> <li>■ Can test putting it on and off one of our feet or dummy foot</li> </ul> </li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>○ Product breaking           <ul style="list-style-type: none"> <li>■ Strength and flexibility tests</li> </ul> </li> <li>○ Material degradation           <ul style="list-style-type: none"> <li>■ Test for material wear - friction</li> <li>■ velcro/magnet - durability testing</li> </ul> </li> </ul>
<i>Action items to be done</i>	<ul style="list-style-type: none"> <li>● Milly, Brayden, Steve: Section 6 (Design Specifications)</li> <li>● Milly and Sith: Section 5 (Design Iteration)</li> <li>● Josie: Write a draft V&amp;V protocol and send to Sid for feedback</li> <li>● Holly and Steve: V&amp;V, add link to regulation segment of Section 8</li> <li>● Brayden: Updating 8.2, 8.3,</li> <li>● Everyone: Gantt Chart (8.1)</li> <li>● Holly: Section 9</li> </ul>
<i>Proposed next meeting</i>	6th November, 5pm on Zoom

## 2.21 Meeting Twenty-One

<i>Date and Time</i>	08/11/2023, 20:30
<i>Location</i>	Zoom
<i>Apologies</i>	Josie
<i>Absences</i>	N/A
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"> <li>● Report - What's left to do?</li> <li>● Task delegation</li> </ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"> <li>● V&amp;V needs to be completed</li> <li>● Do we need to include dimensions in design specifications?           <ul style="list-style-type: none"> <li>○ Not possible, but we can include Naomi's shoe dimensions, and make a point to say each shoe will be customised to the user.</li> </ul> </li> <li>● Label all tables, include description before hand, and reference anything included in appendix</li> <li>● Section 6.3 - Milly made flowchart, might need some explanation below.</li> <li>● Gantt chart - Milly made a table (page 52) with rough estimates</li> <li>● Commercialisation etc. are we collaborating with Nike? They already have the network, and the 'accessibility shoe range', it could ensure an easy integration into the market.</li> <li>● Formatting: Make sure pages with larger tables are landscape</li> <li>● Add description to the CAD models</li> <li>● Mention we are going to outsource CAD modelling (e.g. Orthotic Solutions Podiatry Sydney...)</li> <li>● Have gantt chart at the top of Section 8 so we can refer to it in manufacturing</li> </ul>
<i>Action items to be done</i>	<ul style="list-style-type: none"> <li>● Milly: Short sentence in innovation column for design iteration, add to Gantt Chart, description for 6.3 and finishing off this section</li> <li>● Brayden: Table descriptions if they don't already have one, add table descriptions to all tables, add to Gantt Chart</li> <li>● Holly: Summary (Section 9) + add to V&amp;V section</li> <li>● Steve: Add Nike collaboration to commercialisation section, materials table (6.2)</li> </ul>

	<ul style="list-style-type: none"> <li>● Josie: Add to V&amp;V Section</li> <li>● Sith: Finalising Design Iteration tables (referencing materials), add to V&amp;V section.</li> </ul>
<i>Proposed next meeting</i>	Wednesday 15th November at 8:30am on Zoom

## 2.22 Meeting Twenty-Two

<i>Date and Time</i>	15/11/2023, 8:30
<i>Location</i>	Zoom
<i>Apologies</i>	N/A
<i>Absences</i>	N/A
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"> <li>● Report - What's left to do?</li> <li>● Task delegation</li> <li>● Allocation of sections for proofreading</li> <li>● Gantt Chart Clarification</li> </ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"> <li>● Need to add manufacturing and regulatory elements in section 6.3</li> <li>● Extra prior art has been added to the table after draft 1 - this may need to be added to 'common themes' below</li> <li>● Firm foam - does this have another name?</li> <li>● Do we need to cover all risks and requirements in V&amp;V section? (maybe we can exclude the regulatory requirements)</li> <li>● How do we test for gait? - <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9993011/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9993011/</a>   <a href="https://www.tekscan.com/gait-analysis-systems">https://www.tekscan.com/gait-analysis-systems</a> </li> <li>● Normalising gait pattern/ pressure redistribution can be put within the same V&amp;V test</li> <li>● Need to add to table 10 and 11 in V&amp;V</li> </ul>
<i>Action items to be done</i>	<ul style="list-style-type: none"> <li>● Milly: <ul style="list-style-type: none"> <li>○ Proofread Aims/Background (Section 1)</li> <li>○ Proofread V&amp;V (Section 7) + add to table 11 with paragraph underneath if you can</li> <li>○ Add to gantt chart to include bringing the product to market (move large table in appendix and add in some 'critical points' below the chart.)</li> <li>○ Add final diagram to section 9</li> <li>○ Make sure all table numbers and appendices are in order - move V&amp;V tables to the appendix.</li> </ul> </li> <li>● Brayden: <ul style="list-style-type: none"> <li>○ Proofread Prior Art (Section 2) - make sure the extra prior art that was added after the draft are included (i.e. billie shoes) in the common themes underneath the table. Maybe add pictures to this section?</li> <li>○ Add in some manufacturing and regulatory points in Section 6.3.</li> <li>○ Add to V&amp;V section - write protocol for improving gait</li> <li>○ Make sure what's in section 8.3 matches section 6.1</li> </ul> </li> <li>● Steve: <ul style="list-style-type: none"> <li>○ Proofread Requirements (Section 3)</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>○ Add to cost for Section 8.4 - break it down into 2 sections (for naomi, and for up-scale production)</li> <li>○ Proofread Summary (Section 9)</li>   <li>● Sithma:           <ul style="list-style-type: none"> <li>○ Proofread Risks (Section 4)</li> <li>○ References</li> </ul> </li>   <li>● Josie:           <ul style="list-style-type: none"> <li>○ Proofread design iterations (Section 5)</li> <li>○ Finish table 10 with paragraph under</li> <li>○ Finish Section 8.5 - orthotic and shoe will have a different shelf-life etc.</li> </ul> </li>   <li>● Holly:           <ul style="list-style-type: none"> <li>○ Proofread design specifications (Section 6)</li> <li>○ V&amp;V - write a protocol for hinge placement (FEA)</li> <li>○ Add in description for table 13 in section 8.2</li> <li>○ Proofread Section 8.7, and 8.8</li> </ul> </li>   <li>● Hamish: Section 8.6</li> <li>● When proofreading sections, also read over the appendix attached to it.</li> </ul>
<i>Proposed next meeting</i>	<p>Wednesday 15th November at 9pm on Zoom</p> <ul style="list-style-type: none"> <li>- Colour coding for table headings</li> <li>- Colour coding for risk analysis table</li> <li>- Colour coding for v and v</li> <li>- Each section and appendix on a new page?</li> <li>- 8.1 - does the second row have or need an estimated time?</li> </ul>

## 2.23 Meeting Twenty-Three

<i>Date and Time</i>	15/11/2023, 9:10pm
<i>Location</i>	Zoom
<i>Apologies</i>	N/A
<i>Absences</i>	N/A
<i>Action items raised and addressed at meeting</i>	<ul style="list-style-type: none"> <li>● Report - What's left to do?</li> <li>● Formatting</li> </ul>
<i>Points raised and discussed at meeting</i>	<ul style="list-style-type: none"> <li>● Making table colours consistent, putting each section on a new page</li> <li>● References - need to be in chronological order</li> <li>● Completing V&amp;V tests</li> <li>● Add brief description in V&amp;V table for each test</li> </ul>
<i>Action items to be done</i>	<ul style="list-style-type: none"> <li>● Complete references</li> <li>● Complete the content table numbering</li> <li>● Submit the assignment</li> </ul>
<i>Proposed next meeting</i>	N/A



## Appendix 3 - Justification of Requirement Priorities

Priority	Requirement	Justification for Ranking
1	Fix Toe Claw	This is the highest priority due to its impact on a variety of different components of Naomi's motion. Balance and strength are directly impacted due to the toes not being spread. This was directly referenced by Dr Abbie and Dalal as the highest priority issue and a leading feature in the current orthotic.
2	Improved Mobility	The function of an orthotic is to allow the user to have improved mobility, as a result of the profile of the foot being adjusted for better positioning and placement in footwear. It is a fundamental measure for success.
3	Normalise Gait Patterns	The walking sequence was addressed by Dr Abbie, describing how adjusting foot positioning will lead to less stress on all joints in the legs and feet. Poor gait patterns are responsible for long term implications on these joints, resulting in further diagnosis later in life.
4	Not Too Rigid	Dr Abbie stated that the past iterations of SMO and AFO designs restricted ankle movement, leading to rigidity of the ankle. Dr Abbie stated that this is a critical component as it causes multiple other side effects and leads to muscle degradation over time.
5	Improved Stability	The Orthotic is aimed towards improving the stability of Naomi while walking and leads to the improvement of gait patterns and mobility overall. This is a fundamental requirement but is considered as a by-product of the other above fundamental requirements and therefore ranked lower.
6	Does Not Cause Blisters	A side effect of past iterations of Naomi's orthotics was blistering and due to her high pain threshold led to lasting implications. Dalal requested that the material choice for the design consider fluid buildup and friction rates.
7	Durable Construction	The orthotic must be designed to last a long duration with high use rates. This was specified by Dalal and Dr Abbie being a requirement. Naomi would be using the orthotic in everyday life and as such will require longevity.
8	Not Too Heavy	Naomi will be walking with the orthotic attached to her foot, it was explained by Dalal that her leg strength is not as large as others her age. This requires that the orthotic must consider light weight materials.
9	Breathable Materials	This is identified as the underlying cause of blister formation, as ranked above, but is not the directly addressed requirement from Dalal, therefore it ranks lower, but is still to be considered.
10	TGA Compliance	As our product will not be implemented into the market within the scope of this project and report, the requirements for us to consider these aspects of the project are low ranking, but still required.
11	ISO 13458 Compliance	The legal requirements are ranked lower on this list due to their limited use with our product at the stages we will be addressing. We will not be able to directly implement this product into the market, yet alone with international implications within the scope of this course, resulting in a lower ranking.
12	User Friendliness	The design is meant to be worn by Naomi, but with the consideration that Dalal will be the primary individual to apply the product. Therefore the ability for Naomi to easily take the product off and put it on independently was of lower rank.

13	Pressure Redistribution	Studying the pressure distribution is required to identify where to measure and place padding, so is ranked higher. However, due to the lack of foot measurements within the scope of this project and the broadness of the scope of the project, we cannot accurately measure each user's pressure distribution to cater the orthotic to their needs.
14	Measured Padding and Support	The project has a lower capability to study pressure distributions of the foot, therefore won't have any capability to measure the padding and support of the orthotic as a result.

## Appendix 4 – Justification of Design Risk Analysis Ratings

#	Risk	Rating Justification ( <i>before mitigation</i> )	Rating Justification ( <i>after mitigation</i> )
RSK1.1	Increased falling	$4 \text{ (Severity)} \times 4 \text{ (Likelihood)} = 16$ <p>If the orthotic increases the risk of falls, it can result in severe injuries (fractures, head injuries) which are <i>critical</i> and they can lead to long-term disability. The likelihood of this risk is <i>probable</i> because design flaws, improper fitting or material issues could reasonably lead to decreased stability.</p>	$3 \text{ (Severity)} \times 3 \text{ (Likelihood)} = 9$ <p>While discomfort or instability cannot be completely removed, the mitigation methods (designing support structures, incorporating adjustability) can significantly improve stability. Design flaws or fit issues can still occasionally affect stability, but are less likely to occur with adjustments.</p>
RSK1.2	Causes blisters on foot	$3 \text{ (Severity)} \times 3 \text{ (Likelihood)} = 9$ <p>Blisters can be painful and uncomfortable, however they are treatable and unlikely to cause severe or long-term harm. Therefore the severity can be considered <i>marginal</i>. The likelihood is <i>occasional</i> because issues related to ill-fitted components may occur from time to time but may not be constant if quality control measures are in place.</p>	$2 \text{ (Severity)} \times 2 \text{ (Likelihood)} = 4$ <p>Mitigation methods aimed to reduce friction and skin irritations substantially lower the severity - while blisters may still occur, their impact is negligible. The likelihood would now be rated as <i>remote</i> because improved airflow and reduced friction make blister formation highly unlikely.</p>
RSK1.3	Undetected injury due to Pain Tolerance	$4 \text{ (Severity)} \times 4 \text{ (Likelihood)} = 16$ <p>Undetected injuries could lead to prolonged pain to the body, and increase the severity of small ailments to the point of severe complications. This would therefore be considered <i>critical</i>. The likelihood is <i>probable</i>, as Dalal and Dr Abbie have noted this is a common symptom amongst SAS patients, and thus its more likely for injuries to go unnoticed or unreported.</p>	$4 \text{ (Severity)} \times 2 \text{ (Likelihood)} = 8$ <p>Despite mitigation methods, severity rating would remain critical because undetected injuries can still have severe consequences. While mitigation measures reduce the risk, the potential harm is still significant. The likelihood however would be <i>remote</i> because if users maintain regular check-ins, and there are immediate visual indicators on the orthotic, injuries can be sooner detected.</p>
RSK1.4	Excessive Sweating	$3 \text{ (Severity)} \times 3 \text{ (Likelihood)} = 9$ <p>Sweating can lead to discomfort and skin issues, such as blistering, however it is not</p>	$2 \text{ (Severity)} \times 2 \text{ (Likelihood)} = 4$ <p>Using breathable materials and incorporating ventilation channels will</p>

		life-threatening or damaging. The severity is <i>marginal</i> because it primarily affects comfort, and minor instability. The likelihood is <i>occasional</i> because breathability issues and sweating may not be a constant problem if appropriate materials are initially chosen.	significantly reduce the potential severity. Discomfort may still occur but the impact would be negligible. With the aid of these mitigation features, the likelihood would reduce as allowing heat to escape from the shoe will eliminate the probability of sweating to occur.
RSK1.5	User Acceptance	$3 \text{ (Severity)} \times 3 \text{ (Likelihood)} = 9$	$3 \text{ (Severity)} \times 2 \text{ (Likelihood)} = 6$
		While important, user acceptance does not directly pose safety risks. However rejection of orthotic could prevent the necessary support, and cause excessive costs ( <i>Marginal</i> severity). Likelihood is <i>occasional</i> as Dalal has mentioned Naomi likes products that seem familiar (always chooses the same colour) and therefore more resistant to change. However, this may not be a universal issue and could vary among users.	The severity remains <i>marginal</i> because user acceptance usually relates to product adoption and satisfaction which is subjective and its mitigation isn't definite. The likelihood is remote as involving the user in the design process allows for continuous feedback and ensures their acceptability of the final product.
RSK1.6	Difficulty in Self-Application	$3 \text{ (Severity)} \times 3 \text{ (Likelihood)} = 9$	$2 \text{ (Severity)} \times 2 \text{ (Likelihood)} = 4$
		Difficulty in self-application can be inconvenient but generally doesn't pose significant safety risks, therefore can be considered to be <i>marginally</i> severe. Likelihood is <i>occasional</i> as experience with orthotics may vary amongst SAS users, and some may find it easy to adapt to different designs.	User-friendly fastening mechanisms and clear visual markings can ensure the orthotic is applied and adjusted correctly – severity becomes <i>negligible</i> . Likelihood would lower to <i>remote</i> as clear visuals and easy-to-function components make it highly unlikely for users to be challenged.
RSK2.1	Product breaks	$4 \text{ (Severity)} \times 3 \text{ (Likelihood)} = 12$	$3 \text{ (Severity)} \times 2 \text{ (Likelihood)} = 6$
		Structural failure of the orthotic can have <i>critical</i> consequences such as injury, and long-term ailments, especially for users who rely on the orthotic for support. The likelihood would be <i>occasional</i> if the design and materials are well-engineered and quality control measures are in place in each iteration.	Mitigation methods improve material selection and strength analysis, however some risk of structural failure remains, and could still relate to the need for repairs/replacements. Likelihood is remote because ensuring sufficient testing and appropriate material selection, structural failure is unlikely.
RSK2.2	Material Degradation	$3 \text{ (Severity)} \times 3 \text{ (Likelihood)} = 9$	$2 \text{ (Severity)} \times 2 \text{ (Likelihood)} = 4$
		Can lead to reduced support and comfort, but doesn't impose immediate safety risks ( <i>marginal</i> ). The likelihood is <i>occasional</i> because material wear and tear can occur over time but is unlikely to occur short-term, especially if maintained appropriately.	Negligible severity as choosing high-quality materials and ensuring adequate maintenance is maintained will make any degradation less likely to impact support and comfort for the intended lifespan of the orthotic. Likelihood is remote as high quality materials are unlikely to degrade under normal use conditions within the intended lifespan.

		$4 \text{ (Severity) } \times 3 \text{ (Likelihood) } = 12$	$3 \text{ (Severity) } \times 2 \text{ (Likelihood) } = 6$
RSK2.3	Inaccurate Customisation	<i>Critical</i> severity - users with specific needs require the orthotic to match their anatomical dimensions to provide support. Inaccuracy leads to discomfort, further damage, and makes the product redundant. <i>Occasional</i> likelihood because errors in measurements may occur but not if rigorous protocols are in place.	Some risk of inaccurate fit still remains due to human or equipment error. However the severity is now considered marginal because the errors (if any) would be minimal enough to only cause discomfort and misalignment (rather than being unsafe). Likelihood is now remote as efficacy of 3D scanning applications, and thorough quality control measures, make measurement errors highly unlikely.
RSK2.4	Inaccurate Arch Support	$3 \text{ (Severity) } \times 3 \text{ (Likelihood) } = 9$	$2 \text{ (Severity) } \times 2 \text{ (Likelihood) } = 4$
		Marginal severity as inaccurate arch support can cause discomfort, and instability but doesn't pose direct safety risks. The likelihood is occasional because errors in measurements may occur but not if rigorous measurement protocols are in place.	Users are more likely to receive accurate arch support with the aid of precise digital models/thorough biomechanical assessment. Any errors would be minimal, making the severity <i>negligible</i> . Likelihood is also remote because in-depth foot assessments and quality control make it unlikely for users to receive a product so inaccurate to be considered a safety issue.
RSK2.5	Poor Seam/ stitching quality	$3 \text{ (Severity) } \times 3 \text{ (Likelihood) } = 9$	$2 \text{ (Severity) } \times 2 \text{ (Likelihood) } = 4$
		Marginal severity because although pressure injuries, irritation and discomfort can occur, they are generally treatable and may not have severe or long-term health implications. Likelihood would be occasional as issues with seams and stitching can occur due to manufacturing variations, or overtime as the seams wear, but not a constant occurrence.	Creating seamless designs, and smoothing the surfaces of the orthotic will eliminate areas of high pressure. While discomfort may still be a risk, the severity is negligible. Likelihood is now remote because stress tests and high-quality manufacturing techniques are put in place to ensure irritation is improbable.
RSK3.1	Decreased Stability	$4 \text{ (Severity) } \times 3 \text{ (Likelihood) } = 12$	$2 \text{ (Severity) } \times 2 \text{ (Likelihood) } = 4$
		A lowered stability can heighten chances of falling, and thus lead to more dire injuries, rehabilitation and costs ( <i>critical</i> severity). The likelihood is occasional because alignment of orthotic is continuously checked in quality control measures, however equipment or human errors can lead to slight inaccuracies.	Employing accurate 3D scanning applications can ensure precise alignment - some alignment issues may still occur due to equipment/human error, but to a lower extent. The likelihood would be remote, as the efficacy of this software would make significant alignment issues highly unlikely.
RSK3.2	Product Too Heavy	$4 \text{ (Severity) } \times 3 \text{ (Likelihood) } = 12$	$3 \text{ (Severity) } \times 2 \text{ (Likelihood) } = 6$
		Excess weight can impact user comfort and mobility, and increase their chances of tripping or falling, if the orthotic is heavier than their muscular strength. Tripping or falling can lead to more serious injuries, making this a critical severity. If the	Lightweight materials and weight distribution analysis may decrease severity, however there is still a risk that discomfort may occur occasionally, but not to a critical extent. High quality materials are manufactured to be

		product is too heavy, the user may also be less inclined to wear it, and they would have insufficient support for daily activities which could lead to long-term consequences.	lightweight, just remain durable and functional - issues related to excessive weight would be considerably mitigated through these actions.
RSK3.3	Product Too Rigid	<b>4 (Severity) x 3 (Likelihood) = 12</b>	<b>3 (Severity) x 2 (Likelihood) = 6</b>
		High rigidity leads to excessive pressure points and restricting natural movement , leading to severe discomfort and health concerns (can result in pressure ulcers, musculoskeletal issues and long-term health complications). Likelihood is occasional because materials are tested for flexibility and comfort in quality control measures, however may vary between users.	Prototype testing would ensure that any flexibility or structural issues would be flagged, and responded to before the development of the final product. This would make excessive rigidity highly unlikely, and if any residing issues would surface, it would be of a lower severity.
RSK4.1	Inadequate User Training	<b>3 (Severity) x 2 (Likelihood) = 6</b>	<b>2 (Severity) x 1 (Likelihood) = 2</b>
		Marginal severity as inadequate training can lead to incorrect usage and application which results in suboptimal benefits from the orthotic. It however isn't considered a critical risk as user or caregiver experience would be assumed. Likelihood would be remote because caregivers are usually experienced, and clinicians provide thorough instructions. However, some users may find it confusing, or young users trying to be more independent may have a more difficult experience.	Comprehensive user manuals, and educational resources would mitigate areas of confusion, and the probability of misuse would be limited. While there is always a risk for occasional incorrect usage, the consequences would be related to usability, and could be considered negligible.
RSK4.2	Cost	<b>4 (Severity) x 3 (Likelihood) = 12</b>	<b>3 (Severity) x 2 (Likelihood) = 6</b>
		If the orthotic becomes too expensive, it may hinder accessibility and thus limit the users ability to acquire the necessary support, making the orthotic redundant. The likelihood is rated as occasional because cost-related challenges differ between users, and is dependent on the intricacies of the customisation process.	Conducting a thorough cost analysis would allow the team to gain insights into cost factors, allowing for informed decision making, budget allocation, supplier partnership etc. A comprehensive strategy for cost-saving measures, and collaborating with user expectations, would heavily reduce the likelihood.

## Appendix 5 – Justification of Deliverables Mark Allocation

Skill Factors	Description
Material	Availability and accessibility of the material
	Processability of material

	Mechanical properties of the material
<i>Time</i>	Is it a deliverable for the time frame of 13 weeks?
<i>Technical Limitations</i>	CAD implementation?
	3D printing capabilities?
<i>Adaptability</i>	Adjustability or tailorability to general SAS patients who exhibit comparable biomechanical constraints

## Appendix 6 – Justification of Ranks for Design Iterations

Criteria	Description	Marks (up to)
<i>Requirement Fulfilment</i>	<b>To what extent does the design meet the specified requirements for addressing the needs of SATB2?</b>	#
	Does not meet essential requirements ( <i>0-2 requirements</i> )	7
	Partially fulfils essential requirements ( <i>3-7 requirements</i> )	15
	Meets most essential requirements ( <i>8-10 requirements</i> )	22
	Fully meets all essential requirements ( <i>11-14 requirements</i> )	30
<i>Risk Mitigation</i>	<b>How well does the design mitigate potential risks or discomfort for the patient?</b>	#
	Inadequate measures ( <i>13-16 risks</i> )	7
	Basic measures, some improvements needed ( <i>9-12 risks</i> )	15
	Strong measures, minor enhancements possible ( <i>4-8 risks</i> )	22
	Robust measures, no major improvements needed ( <i>0-3 risks</i> )	30
<i>Deliverables</i>	<b>How many of the deliverables address the skill factors of material, time, technical limitations, and adaptability criteria?</b>	#
	Inadequate measure ( <i>1-2 skills</i> )	10
	Basic measures ( <i>3 skills</i> )	15
	Robust measures ( <i>4 skills</i> )	20
<i>Innovation</i>	<b>How similar is the proposed iteration to the current client orthotic/SMO or other products?</b>	#
	Strong relation to current orthotic/SMO/other products	5
	Intermediate relation to current orthotic/SMO/other products	15
	Weak relation to current orthotic/SMO/other products	20

## Appendix 7 – Justification for Allocated Marks for Design Iterations

Iteration	Score	Justification
1.1	55	Fulfilled 10 requirements; was too rigid, heavy, could cause blisters, not breathable. 10 risks associated; RSK1.2, 1.3, 1.4, 1.5, 1.6, 2.3, 3.2, 3.3, 4.1, 4.2. Deliverables: did not deliver on adaptability and mechanical properties of material was not appropriate. Innovation: is a combination of current orthotic and SMO so has a moderate level of innovation.
1.2	63	Fulfilled 11 requirements; could cause blisters, not breathable, and user friendliness is questionable due to complicating components for foot to slide into. 10 risks associated; RSK1.2, 1.3, 1.4, 1.5, 1.6, 2.3, 3.2, 3.3, 4.1, 4.2. Deliverables: similarly the mechanical properties of material was not appropriate but improved slightly on adaptability. Innovation: The inclusion of the individual toe crests is an innovative inclusion as other current orthotics do not have this feature.
2.1	77	Fulfilled 13 requirements; user friendliness was questionable, may require some excessive force to slide foot through the tibial support compartment. 4 risks associated; RSK1.5, 1.6, 2.1, 2.3. Deliverables: adaptability was questionable. Innovation: the design incorporates features from current SMO and orthotic, but is innovative with the added tibial support
2.2	88	Fulfilled all requirements. 2 risks associated; RSK1.5, 2.1. Deliverables: all satisfied. Innovation: the innovation is the same as the previous iteration as they are variations of the same feature of the design
2.3	86	Fulfilled all requirements; questionable ease of use with addition of a detachable component. 3 risks associated; RSK1.5, 1.6, 2.1. Innovation: making the added support structure detachable is quite a unique feature so it ranked better than the previous iterations for innovation
3.1	80	Fulfilled 4 requirements: was not too heavy, was not too rigid, user friendly, and measured padding and support; all other requirements were clearly not fulfilled or questionable. 3 risks associated; RSK1.3, 1.4, 2.2. Deliverables: all satisfied. Innovation: This solution ranked well for innovation because there isn't any similar products available in the orthotic market
4.1	74	Fulfilled 10 requirements; user friendliness was questionable, could cause blisters, excessive pressure distribution to heel, thus affecting stability. 3 risks associated; RSK1.5, 1.6, 2.3. Deliverables: adaptability and tailorability is questionable. Innovation: not similar to current SMO or orthotic, but integrates their key features into current footwear (Crocs)
4.2	79	Similarly fulfilled 10 requirements; user friendliness was improved with the addition of an elastic component. 3 risks associated; RSK1.5, 1.6, 2.3. 1.6. RSK1.5 and 1.6 slightly improved with the addition of an elastic component. Deliverables: Adjustability improved similarly due to elastic. Innovation: integrates mechanisms inspired by other footwear (Skechers) into previous iteration, so same ranking as 4.1
4.3	85	Fulfilled 11 requirements; significantly improved user friendliness as excessive force is not required to place feet inside the shoe, SPR1.3, 3.1, 3.2 not addressed yet. 3 risks associated; RSK1.5, 1.6, 2.3. Similarly, significantly improved design with fixes to RSK1.5 and 1.6 due to addition of toggle attachment component. Deliverables: Adjustability improved similarly due to the toggle attachment component. Innovation: the new feature of this iteration was not seen in other footwear so it ranked higher for innovation.
4.4	80	Similarly to iteration 4.3, Fulfilled same 11 requirements, risk mitigation score is lowered due to possible complication of skin to zipper contact. Zipper is more user friendly and more favoured over the toggle attachment component. Provides familiarity to its users as it

		is already widely used in the general market. Deliverables score is lowered as zipper does not relieve as much area for foot to slide into shoe compared to the toggle attachment component. Innovation: the zipper addition was inspired by the Billie shoes which is a favoured product of Naomi, however, it is used differently in this design so it has variation from the current product.
4.5	82	Fulfilled the same 11 requirements as iteration 4.3. Risk mitigation is increased due to significant increase in user friendliness. Proposed design does not require any excessive force, powered entirely by downward force due to bottom hinge wrapping around the foot. Deliverables score is lowered due to adjustability still being a contention point. Innovation: this iteration is inspired by the mechanism of the Nike Go FlyEase shoe so has similarities, but is still innovative by integrating the orthotic into the sole of the shoe
5.1	79	Fulfilled 11 requirements; SPR1.3, 1.5, 2.3 not addressed yet. Risks associated; RSK1.2, 1.4, 1.6, 2.3, 2.4. Lighter design that could be fitted with any shoe type. Deliverables: adjustability and tailorability is still an issue. Innovation: the final orthotic design has a good level of iteration through the toe crests, whilst also incorporating proven supportive features to ensure functional support.
5.2	74	Fulfilled 8 requirements. SPR1.3, 1.4, 1.5, 3.1, 3.2, 3.4 not addressed. Risks associated; RSK1.1, 1.3, 1.4, 3.1. Significantly lower score due to not addressing any functional components. Deliverables: adjustability and tailorability is still an issue. Innovation: the mechanisms of joinery are the innovative aspect of the design to improve the usability and results in high ranking innovation.
5.3	98	Fulfilled all requirements. Risks associated; RSK2.3. Combined iterations of 5.1 and 5.2 components, resulting in a far higher score. Addresses all user interactions and functional components. Deliverables: all deliverables addressed. Innovation: This iteration is highly innovative, through incorporating several ideas from previous iterations. The inclusion of magnets at the end of the straps is the most inventive aspect of the design as it isn't present in any current footwear and supports the user needs.

## Appendix 8 – Risk and Requirements Checklist

This table outlines the design requirements and risks, and which component of the design addresses these, to ensure that all considerations are accounted for. Requirements and risks are addressed through materials (**M**), design choices (**DC**) about the specifications of the component, or production methods (**P**).

Design Requirements	
Design Requirement	Relevant Components
SPR 1.1 Not too heavy	Upper (M), midsole (M)
SPR 1.2 Not too rigid	Upper (M), Heel counter (DC)
SPR 1.3 Doesn't cause blisters	Upper (M), toe box (DC), heel counter (M and DC), whole orthotic (M)
SPR 1.4 Fix toe claw	Toe crest with toe grooves (DC)
SPR 1.5 User friendliness	Fasteners (DC), hinge mechanism (DC)
SPR 2.1 Measured padding and support	Sole plate (M), heel counter (M). midsole (M)
SPR 2.2 Breathable materials	Upper (M), toe box (M), sole plate (M), whole orthotic (M)

SPR 2.3 Durable construction	Joining with Component 1 and 2 (M, DC and P)
SPR 3.1 Improve stability	Heel counter, midsole, outsole, whole orthotic - M and DC applies for all
SPR 3.2 Improve mobility	Heel counter (DC), whole orthotic (DC)
SPR 3.3 Normalise gait pattern	Midsole (DC), whole orthotic (M and DC)
SPR 3.4 Pressure distribution	Midsole (M), whole orthotic (M and DC)
SPR 4.1 TGA regulations	Manufacturing process outlined in Section 6.3 addresses regulatory considerations for the product (P). Section 8.2 addresses the product classification considerations for the device.
SPR 4.2 ISO 13485 compliance	

Risks	
Risk	Relevant Components
RSK 1.1 Increased falling	Sole plate, fasteners, heel counter, midsole, whole orthotic - DC for all
RSK 1.2 Cause blisters on foot	Upper, toe box, heel counter, whole orthotic - M for all
RSK 1.3 Undetected injury due to pain tolerance	Not directly involved in design, but addressed by regular appointments, and monitoring for signs of distress
RSK 1.4 Excessive sweating	Upper, toe box, heel counter, whole orthotic - M for all
RSK 1.5 User acceptance	Fasteners (DC), hinge mechanism (DC), user input for colours and feedback on design (P)
RSK 1.6 Difficulty in self application	Fasteners (M and DC), hinge mechanism (DC)
RSK 2.1 Product breaks	Joining mechanisms (DC), compatibility of materials used (M), magnets on fasteners (DC), production (P)
RSK 2.2 Material degradation	Material choice for all components, separate orthotic to allow for replacement/adjustments without interfering with lifeline of the shoe (M, DC and P)
RSK 2.3 Inaccurate customisation	Customisation of the whole orthotic in consultation with clinician (DC), manufactured with quality control (P)
RSK 2.4 Inaccurate arch support	Biomechanical assessment to guide measurements for whole orthotic (DC and P)
RSK 2.5 Poor seam/stitching quality	Joining component 1 and 2 to the midsole (M and P)
RSK 3.1 Decreased stability	Heel counter, midsole, whole orthotic (M and DC)
RSK 3.2 Product too heavy	Heel counter, midsole, whole orthotic - M for all
RSK 3.3 Product too rigid	Heel counter, midsole, whole orthotic - M for all
RSK 4.1 Inadequate user training	Not directly related to design components
RSK 4.2 Cost	Material choices and production considers cost (M and P)

## Appendix 9 – Material Properties

Component of Design	Material	Characteristics	Strengths	Weaknesses
<b>Orthotic base -</b> Needs to be firm and supportive, but also easy to manufacture customisations based on user, different users may require different material for their orthotic based on their needs and the properties of the material	Polypropylene	<p>Polypropylene is a thermoplastic polymer known for its stiffness and rigidity.</p> <p>It has good resistance to moisture and chemicals.</p>	<p>Provides excellent support and stability due to its rigidity.</p> <p>Customizable through heat moulding for a more personalised fit.</p> <p>Durable and long-lasting.</p>	<p>May not offer as much shock absorption as some other materials.</p> <p>Not as cushioned or comfortable as materials like EVA.</p>
	Carbon graphite	<p>Carbon graphite is a lightweight and strong material made of carbon fibres.</p> <p>It's known for its stiffness and resilience.</p>	<p>Offers superior strength and support while being lightweight.</p> <p>Suitable for users who require a firm and rigid orthotic.</p> <p>Resistant to wear and tear.</p>	<p>May be relatively expensive compared to other materials.</p> <p>Limited shock absorption, making it less comfortable for some users.</p>
	EVA	<p>EVA is a soft, flexible, and lightweight foam material.</p> <p>It provides cushioning and shock absorption.</p>	<p>Exceptional shock absorption and comfort for users.</p> <p>Easily moldable and customizable to individual foot shapes.</p> <p>Good for users who need cushioning and support.</p>	<p>Not as rigid as some other materials, so it might not provide as much stability for certain users.</p> <p>May wear out more quickly than stiffer materials.</p>
	Neoprene	<p>Neoprene is a synthetic rubber known for its flexibility and water resistance.</p> <p>It is often used in wet or aquatic environments.</p>	<p>Provides good flexibility and comfort.</p> <p>Resistant to moisture, making it suitable for wet conditions.</p>	<p>May not offer the same level of rigidity and support as other materials.</p> <p>Durability can be a concern, especially in dry conditions.</p>

	Plastazote	<p>Plastazote is a closed-cell polyethylene foam known for its softness and conformability.</p> <p>It's often used in cushioning applications.</p>	<p>Highly conformable and moulds to the user's foot shape.</p> <p>Offers good cushioning and pressure relief.</p> <p>Suitable for users with sensitive feet or specific comfort requirements.</p>	<p>Lacks the rigidity and support of stiffer materials.</p> <p>May not be ideal for users who require strong arch support or range of motion control.</p>
Shoe Fabric	Nylon	<p>Nylon is renowned for its remarkable resilience to abrasion and deterioration. This makes it an excellent option for durability in shoe construction, particularly in high-stress and high-friction areas.</p>	<p>Nylon is affordable, easy to clean and can dyed into any colour easily</p>	<p>Nylon has moisture retention and it reduces breathability thereby increasing sweating</p>
	Cotton	<p>Because of its inherent breathability, cotton is a natural fibre that promotes airflow within shoes. This feature offers comfort and aids in moisture management, especially in warm weather.</p>	<p>In comparison to synthetic materials, cotton is a natural fibre derived from plants, making it a more environmentally friendly and sustainable choice. its regenerative origin. decreases perspiration and improves breathability in Naomi's case</p>	<p>Cotton is cosy, but it might not last as long as some synthetic materials. It may degrade more quickly with repeated use or in high-stress environments.</p>
Outsole	Carbon rubber	<p>Carbon rubber is renowned for its remarkable resilience to wear and tear. It is resistant to abrasion and keeps its structural integrity under high-impact circumstances. It has traction on a range of surfaces.</p>	<p>Carbon rubber outsoles are excellent at traction and resist wear on a variety of surfaces. They work well on pavement, trails, and different types of surfaces.Because of their extended lifespan, carbon rubber outsoles are an affordable option for customers. The material's longevity plays a role in the shoe's overall lifespan.</p>	<p>When compared to some lightweight outsole materials, carbon rubber may weigh more. Although this increases its durability, it might make the shoe a little bit heavier all around.</p>

## Appendix 10 – Verification Protocols

TPR1.1: Toe Crest Efficacy	
Requirements assessed	SPR1.4: Fix toe claw, SPR3.1: Improve stability, SPR3.3: Normalise gait pattern, SPR 3.4 Pressure distribution
Risks assessed:	RSK1.1: Increased falling, RSK3.1: Decreased stability
Protocol description	<p><b>Description of test process:</b>  To test the effectiveness of the toe crest a mechanical test of the arch of the toes must be complete before and after the use of the orthosis to determine if the curling of the toes was reduced. A degree based mechanical approach, like using Vettec's claw check [18], may be utilisable with the zero degree angle being treated as a completely front facing natural toe curl when on a flat surface. The test must measure the angle at which the toes align with the horizontal surface with a larger angle representing a greater degree of toe clawing.</p> <p><b>Analysis method:</b>  The numerical comparison of the angle of attack between the toes and horizontal surface will be used to analyse the effectiveness of the toe crest in reducing the impact of the toe clawing.</p> <p><b>Acceptance criteria:</b>  The decrease in angle of attack with a magnitude decrease of greater than 10 degrees will demonstrate a significant improvement in toe clawing.</p> <p><b>Materials required:</b></p> <ul style="list-style-type: none"> <li>● Horizontal Surface</li> <li>● Patient foot</li> <li>● Protractor based measurement system</li> </ul>
Related tests	<ul style="list-style-type: none"> <li>● TPR1.6 - Correct Realignment Analysis</li> </ul>

TPR1.2: Durability of Hook and Loop Straps	
Requirements assessed	SPR1.5: User friendliness, SPR2.3: Durable construction
Risks assessed:	RSK2.1: Material breaks, RSK2.2: Material degradation
Protocol description	<p><b>Description of test process:</b>  The hook and loop chosen will be tested using a hook and loop fatigue tester. The machine will repeatedly open and close the hook and loop fasteners at a predetermined force. After a desired number of repetitions, the hook and loop fasteners are taken out to determine the adhesive force and strength [19].</p> <p><b>Analysis method:</b>  For our particular testing, we will use a test speed of <math>60\pm5\text{r}/\text{min}</math> with a test load of <math>1\pm0.1\text{N}/\text{mm}</math> [20]. We will conduct testing of 20 samples, determined by confidence intervals, to find the average amount of repetitions the fasteners last for before failing to meet acceptance strength criteria to determine their likely durability and lifespan on a shoe.</p>

	<p>It is important to note the added magnets for the purpose of redirecting Naomi's fidgeting tendencies away from the hook and loop were considered in calculating average repetitions of opening and closing the hook and loop per year. The average magnet has a durability lasting 700 years [21] and the magnets on our product add no technical value. Thus, magnet durability will not be tested further.</p> <p><b>Acceptance criteria:</b></p> <p>The hook and loop will be accepted if its lifespan is above a year which is the average time it takes a child of nine to twelve years to outgrow their shoes [22]. Thus, if the hook and loop exceeds 1000 repetitions, a generous estimation of how many times the shoe will be taken on and off in a year, it will be accepted.</p> <p><b>Materials required:</b></p> <ul style="list-style-type: none"> <li>● A hook and loop fatigue tester</li> <li>● Military grade hook and loop</li> </ul>
Related tests	<ul style="list-style-type: none"> <li>● Other material degradation tests to address same risks and requirements</li> <li>● Test for best place to put hinge joint to avoid degradation, wear and failure to address same risks and requirements</li> <li>● Testing that the hook and loop is sewn on well enough to address RSK2.5: Poor seam/ stitching quality - refer to TPR1.3 for relevant testing protocol</li> </ul>

TPR1.3: Stitching Stress Tests	
Requirements assessed	SPR2.3 Durable construction
Risks assessed:	RSK2.1: Product breaks, RSK2.5: Poor seam/ stitching quality
Protocol description	<p><b>Description of test process:</b></p> <p>The upper and heel counter are made of polypropylene fabric and will be stitched to the EVA midsole. It is important that the stitching seams are high quality and durable to prolong the lifespan of the shoe. To evaluate the integrity of the seam, a stress test will be conducted following the Standard Test Method outlined in ASTM D1638/D1683M-11 [23]. For an effective test, a rough prototype of the seam should be manufactured using the same materials as the final solution. The result of the testing will indicate the most appropriate seam to ensure durable and high quality joining.</p> <p><b>Analysis method:</b></p> <p>Various stitching techniques will be applied to sample materials and subject to stress testing to evaluate the tensile strength associated with each seam technique. The strength of the seam is evaluated by applying a force perpendicular to the seam. The force is applied until failure occurs. Each technique will be sampled 10 times to generate an average tensile strength for the technique.</p> <p>Based on the seam technique with the greatest tensile strength, further material testing can be conducted such as fatigue testing to verify durability and quality of the seam.</p> <p><b>Acceptance criteria:</b></p> <p>The stitching technique that produces the greatest tensile strength will be accepted as the technique to undergo further stress testing.</p> <p><b>Materials required:</b></p> <ul style="list-style-type: none"> <li>● Tensile Testing Machine</li> <li>● Clamps</li> </ul>

	<ul style="list-style-type: none"> <li>● Sewing Machine</li> <li>● Sewing Threads</li> <li>● EVA foam for midsole, Polypropylene fabric</li> <li>● Ruler</li> <li>● Computer for Analysis</li> </ul>
Related tests	<ul style="list-style-type: none"> <li>● Other stress tests for the seams to evaluate forces in different directions, or the impact of swelling and increasing internal pressure on the seam</li> <li>● Fatigue testing of the seam</li> <li>● TPR1.5 - Materials Testing</li> </ul>

TPR1.4: Hinge Mechanism Stress Test	
Requirements assessed	SPR1.5: User friendliness, SPR2.3: Durable construction
Risks assessed:	RSK2.1: Product breaks, RSK2.2: Material degradation
Protocol description	<p><b>Description of test process:</b>  The position of the hinge mechanism to ensure optimal functionality and to minimise stress can be carried out computationally, through Finite Element Analysis (FEA). This will specifically involve creating a detailed 3D model of the accessible shoe, defining the material properties (i.e. Young's modulus, poissons' ratio, and yield strength) of carbon rubber, the chosen materials involved in this component, and defining the load cases that mimic the different phases of the gait cycle (i.e. heel strike, mid-stance, and toe-off). These parameters will be simulated to observe the stress distribution and deformation under real-life conditions through FEA software. If the results exceed the defined boundary conditions, then the position of the hinge will be moved on the model, until the acceptance criteria is satisfied.</p> <p><b>Analysis method:</b>  The load cases will simulate the movement of force on different areas of the foot, representative of the different stages of gait. For example:</p> <ul style="list-style-type: none"> <li>● Heel Strike: Vertical downward force on the heel section of the sole, when in heel strike position.</li> <li>● Mid Stance: Vertical downward force, uniformly distributed across the sole when the foot is flat on the ground.</li> <li>● Toe-off: Vertical and slightly forward force, when in toe-off phase of stride.</li> <li>● All simulations will use a load of 600N [24] and run for 10,000 cycles to identify areas of high stress and potential failure after multiple uses.</li> </ul> <p><b>Acceptance criteria:</b></p> <ul style="list-style-type: none"> <li>● Stress levels: Maximum stress in any part of the hinge should not exceed the maximum allowable stress of the carbon rubber (0.9Mpa) [25].</li> <li>● Deformation: The total deformation should be &lt;&lt;0.1mm under maximum load to ensure the hinge does not lose functionality.</li> <li>● The hinge should maintain structural integrity and functionality according to the above criteria after a minimum of 10,000 cycles.</li> </ul> <p><b>Materials required:</b></p> <ul style="list-style-type: none"> <li>● FEA software</li> </ul>
Related tests	<ul style="list-style-type: none"> <li>● TPR 1.5 - Materials Testing</li> </ul>

TPR1.5: Materials Testing	
Requirements assessed	SPR1.1: Not too heavy, SPR1.2: Not too rigid, SPR1.3: Does not cause blisters, SPR2.2: Breathable materials, SPR2.3: Durable construction
Risks assessed:	RSK1.2: Cause blisters on foot, RSK1.4: Excessive sweating, RSK2.1: Product breaks, RSK2.2: Material degradation, RSK2.5: Poor seam/stitching quality, RSK3.2: Product too heavy, RSK3.3: Product too rigid
Protocol description	<p><b>Description of test process:</b>  Both computational and physical evaluations will be used in the materials testing. Wear trials, flexibility analysis, and weight measurement are examples of physical tests. We'll use computational techniques like Finite Element Analysis (FEA) to model stress distribution and deformation under different circumstances.</p> <p><b>Analysis method:</b></p> <ul style="list-style-type: none"> <li>● Weight Measurement (SPR1.1, RSK3.2):  Use a calibrated scale to weigh each sample of material.  Determine the average weight and check it against the designated boundaries.</li> <li>● Flexibility Analysis (SPR1.2, RSK3.3):  Use a flexural testing apparatus to determine the material's degree of flexibility.  Determine the amount of bending that occurs before failure by comparing it to predetermined flexibility standards.</li> <li>● Blisters and Comfort Assessment (SPR1.3, RSK1.2, RSK1.4):  Conduct wear trials with human subjects wearing the material.  Get input regarding comfort and keep an eye out for blisters or excessive perspiration.</li> <li>● Breathability Analysis (SPR2.2, RSK1.4):  Use air permeability testing to assess the material's breathability.  Compare the outcomes to predetermined standards for breathability which is thermal Evaporative Resistance (RET) coefficient.</li> <li>● Durability Testing (SPR2.3, RSK2.1, RSK2.2, RSK2.5):  Subject the material to simulated wear and tear conditions.  Inspect for any signs of breakage, material degradation, or poor seam/stitching quality.</li> </ul> <p><b>Acceptance criteria:</b></p> <ul style="list-style-type: none"> <li>● The average weight should fall within specified limits (SPR1.1, RSK3.2).</li> <li>● Without failing at any point, the material should demonstrate the necessary flexibility (SPR1.2, RSK3.3).</li> <li>● No blisters or significant discomfort should be reported during or after the wear trials (SPR1.3, RSK1.2, RSK1.4).</li> <li>● The material should meet or exceed specified breathability standards (ISO 11092 standard)[..26.]</li> <li>● The material should withstand simulated wear and tear, avoiding breakage, degradation, or poor stitching</li> </ul> <p><b>Materials required:</b></p> <ul style="list-style-type: none"> <li>● Weighing scale</li> </ul>

	<ul style="list-style-type: none"> <li>• Flexural testing machine</li> <li>• Air permeability measurement apparatus</li> <li>• Simulated wear and tear apparatus</li> <li>• Human subjects for wear trials</li> </ul>
Related tests	<ul style="list-style-type: none"> <li>• TPR1.2 - Durability of Hook and Loop Straps</li> <li>• TPR1.3 - Stitching Stress Test</li> <li>• TPR2.4 - Breathability Analysis</li> <li>• TPR2.5 - Weight of Shoe</li> <li>• TPR2.6 - Shoe Rigidity Test</li> </ul>

<b>TPR1.6: Correct Realignment Analysis</b>	
Requirements assessed	SPR1.4: Fix toe claw, SPR3.1: Improve stability, SPR3.2: Improve mobility, SPR3.3: Normalise gait pattern, SPR3.4: Pressure distribution
Risks assessed:	RSK1.1: Increased falling, RSK2.3: Inaccurate customisation, RSK2.4: Inaccurate arch support, RSK3.1: Decreased Stability
Protocol description	<p><b>Description of test process:</b>  When the orthotic was being created for the user a preliminary scan of the foot's structure and pressure points was conducted with a Foot Plantar Pressure Measurement System. This maps the foot's pressure through mechanical sensors as the gait cycle is complete, to which will be used as baseline data for this realignment analysis. The second stage of the verification process includes the testing of the gait cycle using Protokinetics Zeno Walkway device [27] after the orthotic has been applied to the patients walking standard for a duration of greater than 1 year to verify that this design benefits the patient in correcting gait cycles.</p> <p><b>Analysis method:</b>  To analyse the data from the Protokinetics Zeno Walkway scans the use of PKMAS software will map the temporal, spatial and pressure distributions of the individual in comparison to the preliminary data collected in the designing of the orthotic. This will allow for the direct comparison of the two data sets to evaluate the effectiveness of the orthotic in correct gait analysis. A key consideration in this verification study is the impact of the accompanying shoe used in conjunction with this orthotics, which will impact the orthotic results. If the shoe provides stability during the gait cycle to a degree that doesn't allow for ankle strength development, the results of the verification test will demonstrate a deteriorating gait cycle as the shoe would have taken the load of the cycle and resulted in temporary improvements that the orthotic would not be able to provide.</p> <p><b>Acceptance criteria:</b>  The clinician will have the greatest ability to quantify the effect of the orthotic through prior engagement with the patient and the use of prior methods to which would be compared to. At a baseline level a significant improvement in pronation degree, degree from forwards facing angle of each foot and an improvement in degree of toe off is required to quantify a beneficial design.</p> <p><b>Materials required:</b></p> <ul style="list-style-type: none"> <li>• Foot Plantar Pressure Measurement System</li> <li>• Protokinetics Zeno Walkway</li> </ul>

	<ul style="list-style-type: none"> <li>• PKMAS software</li> </ul>
Related tests	<ul style="list-style-type: none"> <li>• TPR1.1 - Toe Crest Efficacy</li> <li>• TPR2.3 - User Pain Testing</li> </ul>

TPR 1.7: Regulations Compliance	
Requirements assessed	SPR4.1: TGA Regulations, SPR4.2: ISO 13485 compliance
Risks assessed:	
Protocol description	<p><b>Description of test process:</b>  The production process will be thoroughly catalogued and documented to a high standard with as much detail as possible. This information as well as the final product will be audited and inspected by a member of the relevant regulatory administration such as the TGA in which they can confirm that the design process and product comply with all relevant rules such as ISO 13485.</p> <p><b>Analysis method:</b>  The result of the investigation by the regulatory affairs officer will be presented to the team with all findings. Within this, the officer can outline the areas of the process or product that are in line or out of line and need adjustment to ensure regulatory approval. This can include aspects such as sufficient information supplied about the product, can be transported without damaging the product, long-term safety and many more [28]</p> <p><b>Acceptance criteria:</b>  The test will be considered a success if the regulatory officer does not have any issues with the manufacturing process and the product and allows for a manufacturing licence to be given, thereby allowing production of the device.</p> <p><b>Materials required:</b></p> <ul style="list-style-type: none"> <li>• Fully-functional product</li> <li>• Design Manuscripts</li> <li>• Clear description and information regarding product and manufacturing process</li> <li>• Access to areas of manufacture</li> </ul>
Related tests	<ul style="list-style-type: none"> <li>• No related tests</li> </ul>

## Appendix 11 – Validation Protocols

TPR2.1: User Acceptance	
Requirements assessed	SPR1.5: User friendliness
Risks assessed:	RSK1.5: User acceptance
Protocol description	<p><b>Description of test process:</b>  Initially Dalal and Naomi will be explained the product and shown the prototype and asked for their willingness to try the product. If this is successful, a survey will be</p>

	<p>created and sent via Dalal to the members of the SATB2 Connect group to gauge interest in the product in the wider SAS community. These initial market surveys are needed to ensure acceptance in a market where acceptance could be limited due to sensory sensitivity, or resistance to change.</p> <p><b>Analysis method:</b></p> <p>As our first priority and primary aim is to create a device for Naomi, she will be given and explained the prototype and both her and Dalal will assess their verbal acceptance of it. After this a survey for the wider SAS community will help create an understanding of the product acceptance likelihood if the product was to be taken to the public market. A survey is chosen to conduct this market research as it is a proven method to determine user acceptance [29].</p> <p><b>Acceptance criteria:</b></p> <p>As our first priority and primary aim is to create a device for Naomi, the product will be accepted and both she and Dalal accept the product and agree to work through any potential resistance to change. The product being taken to the public market will be accepted if at least 50% reply to the surveys and if at least 50% of survey respondents indicate their willingness to try the product. 50% of respondents will indicate statistical significance to approximately a 5% degree of error which we deem acceptable [30].</p> <p><b>Materials required:</b></p> <ul style="list-style-type: none"> <li>● Communication with Dalal/ Naomi</li> <li>● Laptop to create a survey</li> </ul>
Related tests	<ul style="list-style-type: none"> <li>● TPR2.2 - Usability Test</li> </ul>

TPR2.2: Usability Test	
Requirements assessed	SPR1.5: User friendliness
Risks assessed:	RSK1.6: Difficulty in self application, RSK4.1: Inadequate user training
Protocol description	<p><b>Description of test process:</b></p> <p>Initially the prototype will be tested by one of the team members, with full lower limb capacity, who will attempt to put the prototype on and off, in an appropriate time, only using their hands. If this is successful, Naomi will be given the chance to test putting on and off the prototype after a detailed explanation and direction from a team member. This will be timed and repeated at least three times to increase reliability of assessment.</p> <p><b>Analysis method:</b></p> <p>Getting a team member then Naomi to test the product will be used as the best method for determining ease of use as it is testing for test success rate, time spent on task and user satisfaction [31]. The only way to test these metrics is physically tested with the primary user or user group, which, for us, is Naomi. Getting a team member with full lower limb mobility to test the prototype first will ensure the prototype works as expected and that the test with Naomi will accurately reflect her ability to use the shoe without being influenced by product faults. Thus, the product will be analysed through physical application to see if Naomi can put the prototype on and off herself. This test will subsequently test if the instructions provided by the team member are easy enough for the user to follow as a successful use of the product by Naomi will indicate this.</p> <p><b>Acceptance criteria:</b></p>

	<p>The product will be accepted if Naomi can successfully put the shoe on or off on both feet by herself or with less help than she currently requires with her current and past shoes.</p> <p><b>Materials required:</b></p> <ul style="list-style-type: none"> <li>● Prototype</li> <li>● Team member with a good understanding of how the product and prototype works</li> <li>● Naomi</li> <li>● Timer or stopwatch</li> <li>● Place to document results (e.g. laptop, notepad or other alternative)</li> </ul>
Related tests	<ul style="list-style-type: none"> <li>● TPR2.1 - User Acceptance</li> </ul>

<b>TPR2.3: User Pain Testing</b>	
Requirements assessed	SPR1.3: Does not cause blisters, SPR2.1: Measured padding and support
Risks assessed:	RSK1.2: Causes blisters on foot, RSK1.3: Undetected injury due to Pain Tolerance, RSK1.5: User acceptance
Protocol description	<p><b>Description of test process:</b>  A member of the team will put the prototype on wearing socks and will be instructed to walk 100m and report on areas of concern that are rubbing and may cause blisters. This will occur three times to ensure all potential blister areas are reported. Once this testing is complete Naomi will be instructed to put the prototype with her custom orthotic and walk for a distance of 30 - 50 metres and then we will ask Naomi if anywhere on her foot hurts.</p> <p><b>Analysis method:</b>  By first getting a team member to test the shoe allows for us to report on the padding and the risk of blisters without injuring Naomi. A distance of 100m is selected as that can be considered a reasonable distance to allow for any potential rubbing to occur and thereby allow us to fix. Once a team member reports no rubbing or pain we allow Naomi to put on the prototype and walk around a less defined distance, as it is unreasonable to force Naomi to walk 100 metres three times. After she has walked we will ask her if she is feeling any pain and if so where. Using this method of walking in the shoes is a reliable way of measuring the potential for blisters and pain [32]</p> <p><b>Acceptance criteria:</b>  The prototype will be accepted if the team member and then Naomi both report a lack of pain after walking around.</p> <p><b>Materials required:</b></p> <ul style="list-style-type: none"> <li>● Prototype</li> <li>● Team member</li> <li>● Naomi</li> <li>● Space to walk around</li> </ul>
Related tests	<ul style="list-style-type: none"> <li>● TPR1.6 - Correct Realignment Analysis</li> </ul>

#### **TPR2.4: Breathability Analysis**

Requirements assessed	SPR1.5: User friendliness, SPR2.2 Breathable materials
Risks assessed:	RSK1.4 Excessive sweating
Protocol description	<p><b>Description of test process:</b>  The breathability of the shoe will be tested through a smoke test. Through completely enclosing the shoe opening and introducing smoke, the shoe's ventilation capability can be analysed through the volume and velocity of the smoke emanating from the shoe. Our product will be compared to Naomi's current and past orthotics.</p> <p><b>Analysis method:</b>  The smoke for the smoke test will be created by boiling dry ice using 1 cup of dry ice and 2 cups of boiling water as this will create an adequate amount of smoke[33]. The smoke will then be pushed through the shoe by a fan for a consistent flow. The test will be filmed in slow motion at 240fps to allow for adequate visual interpretation of results. The volume and velocity of smoke will be graded on a scale of 1 to 5 and will be compared to current products. As there have been some past products that Naomi has found unbreathable and has contributed to causing blisters, testing the breathability of her past and current devices will enable minimum degree of acceptable breathability to be established.</p> <p><b>Acceptance criteria:</b>  The product will be accepted if the breathability of our product exceeds or is equal to the minimum accepted breathability determined by grading previous and current devices on a scale from 1-5.</p> <p><b>Materials required:</b></p> <ul style="list-style-type: none"> <li>● Product</li> <li>● 1 cup of dry ice</li> <li>● 2 cups of boiling water</li> </ul>
Related tests	<ul style="list-style-type: none"> <li>● TPR 1.5 - Materials Testing</li> </ul>

TPR2.5: Weight of Shoe	
Requirements assessed	SPR1.1: Not too heavy
Risks assessed:	RSK1.1: Increased falling, RSK3.2: Product too heavy
Protocol description	<p><b>Description of test process:</b>  The weight of the shoe and orthotic will be calculated by measuring or finding out from the manufacturer the weight of individual materials per gram that make it up. These weights will then be multiplied by how much of the material will be used to make the shoe and orthotic. The aggregate weight of the shoe and orthotic will then be compared to the weights of current and past shoes and orthotic products which will be weighed on scales.</p> <p><b>Analysis method:</b>  Our product's weight will be calculated accurately to two decimal places as this will provide enough accuracy considering the average weight of a sneaker shoe is 500-1000 grams [34]. In addition, Naomi's past shoes and orthotic products will be weighed on the scale and their comfortability, as judged by Naomi, noted. As there have been some past products that Naomi has found too heavy and thus causing discomfort, weighing</p>

	<p>her past and current devices will enable maximum weight before discomfort to be established.</p> <p><b>Acceptance criteria:</b> The shoes will be accepted if the weight of our product is within or less than the range of Naomi's previous products that she finds comfortable.</p> <p><b>Materials required:</b></p> <ul style="list-style-type: none"> <li>● Scale accurate to two decimal places</li> <li>● Naomi's past and current products</li> <li>● Place to document results (e.g. laptop, notepad or other alternative)</li> </ul>
Related tests	<ul style="list-style-type: none"> <li>● TPR 1.5 - Materials Testing</li> </ul>

<b>TPR2.6: Shoe Rigidity Testing</b>	
Requirements assessed	SPR1.2: Not too rigid, SPR3.1: Improve stability, SPR3.2: Improve mobility
Risks assessed:	RSK3.1: Decreased stability, RSK3.3: Product too rigid
Protocol description	<p><b>Description of test process:</b> The shoe will be placed on a shoe stiffness testing device such as the Unuo Shoe Rigidity Tester. The force values from the tester will then be measured and compared against the values of Naomi's current shoes/devices that she finds comfortable.</p> <p><b>Analysis method:</b> By using the Rigidity tester, which measures the angle of bend when 30N of force is applied, we can compare the rigidity of our device to that of one of Naomi's current shoes. By testing against a shoe that Naomi finds comfortable and does not experience any range of motion issues we can ensure the device would be uncomfortable or inhibit her movement in any way. Using a rigidity tester or "bench-testing analysis" is an industry standard in analysing a podiatric device such as an AFO or our device due to its high accuracy and tunability [35]</p> <p><b>Acceptance criteria:</b> The shoes will be accepted if the angle of flex is within a small range compared to shoes that Naomi finds comfortable and don't inhibit her range of motion.</p> <p><b>Materials required:</b></p> <ul style="list-style-type: none"> <li>● Shoe rigidity tester</li> <li>● Prototype</li> <li>● A selection of Naomi's current shoes she finds comfortable and relatively easier to walk in</li> </ul>
Related tests	<ul style="list-style-type: none"> <li>● Further testing may be required to ensure proper range of motion in desired planes outside of plantarflexion/dorsiflexion</li> <li>● TPR 1.5 - Materials Testing</li> </ul>

<b>TPR2.7: Costing Feasibility</b>	
Requirements assessed	SPR1.5: User friendliness
Risks assessed:	RSK4.2: Cost

Protocol description	<p><b>Description of test process:</b>  The predicted cost of our shoe and orthotic will be estimated and compared to prior art and Naomi's current and past devices.</p> <p><b>Analysis method:</b>  The predicted cost of our shoe is \$46.5 and the orthotic is \$871.5 as calculated in Section 8.4.4 of our report. A table comparing this value to the cost of prior art mentioned in Section 2 of our report and Naomi's current and past products, found by speaking to Dalal will be created.</p> <p><b>Acceptance criteria:</b>  The cost of our product will be accepted if it is less than or equal to one and a half of the average cost of all other products assessed. This is because the added benefits of increased independence and stability is worth one and a half times the cost of the products currently on the market.</p> <p><b>Materials required:</b></p> <ul style="list-style-type: none"> <li>● Laptop with Excel</li> </ul>
Related tests	<ul style="list-style-type: none"> <li>● No other tests are required to test these risks and requirements</li> </ul>

## Appendix 12 – Validation and Verification Cross Referencing

Design Requirements	
Design Requirement	Relevant Testing
SPR 1.1 Not too heavy	Verification TPR1.5, Validation TPR2.5
SPR 1.2 Not too rigid	Verification TPR1.5, Validation TPR2.6
SPR 1.3 Doesn't cause blisters	Verification TPR1.5, Validation TPR2.3
SPR 1.4 Fix toe claw	Verification TPR1.1, Verification TPR1.6
SPR 1.5 User friendliness	Verification TPR1.2, Verification TPR1.4, Validation TPR2.1, Validation TPR2.2, Validation TPR2.4, Validation TPR2.7
SPR 2.1 Measured padding and support	Validation TPR2.3
SPR 2.2 Breathable materials	Verification TPR1.5, Validation TPR2.4
SPR 2.3 Durable construction	Verification TPR1.2, Verification TPR1.3, Verification TPR1.4, Verification TPR1.5
SPR 3.1 Improve stability	Verification TPR1.1, Verification TPR1.6, Validation TPR2.6
SPR 3.2 Improve mobility	Verification TPR1.6, Validation TPR2.6
SPR 3.3 Normalise gait pattern	Verification TPR1.1, Verification TPR1.6
SPR 3.4 Pressure distribution	Verification TPR1.1, Verification TPR1.6
SPR 4.1 TGA regulations	Verificaiton TPR1.7
SPR 4.2 ISO 13485 compliance	Verification TPR1.7

Risks	
Risk	Relevant testing
RSK 1.1 Increased falling	Verification TPR 1.1, Verification TPR1.6, Validation TPR2.5
RSK 1.2 Cause blisters on foot	Verification TPR1.5, Validation TPR2.3
RSK 1.3 Undetected injury due to pain tolerance	Validation TPR2.3
RSK 1.4 Excessive sweating	Verification TPR1.5, Validation TPR2.4
RSK 1.5 User acceptance	Validation TPR2.1, Validation TPR2.3
RSK 1.6 Difficulty in self application	Validation TPR2.2
RSK 2.1 Product breaks	Verification TPR1.2, Verification TPR1.3, Verification TPR1.4, Verification TPR1.5
RSK 2.2 Material degradation	Verification TPR1.2, Verification TPR1.4, Verification TPR1.5
RSK 2.3 Inaccurate customisation	Verification TPR1.6
RSK 2.4 Inaccurate arch support	Verification TPR1.6
RSK 2.5 Poor seam/stitching quality	Verification TPR1.3, Verification TPR1.5
RSK 3.1 Decreased stability	Verification TPR1.1, Verification TPR1.6, Validation TPR2.6
RSK 3.2 Product too heavy	Verification TPR1.5, Validation TPR2.5
RSK 3.3 Product too rigid	Verification TPR1.5, Validation TPR2.6
RSK 4.1 Inadequate user training	Validation TPR2.2
RSK 4.2 Cost	Validation TPR2.7

## Appendix 13 – Gannt Chart Justifications

Design component	Action	Justification	Expected Time	Critical Path/Potential to Delay
Accessible shoe, including Component 1, 2 and 3	Finalisation of shoe design - development through further iterations, prototyping, verification and validation testing, clinical consultation	The final shoe design needs to be determined, prototyped and tested before it can be manufactured. This could involve further design iterations, prototyping and testing. A prototype should be manufactured with the exact materials and joining methods, and approximate dimensions for accurate verification and validation testing. The goal of this stage is to create a generic design model that can be altered based on user specifications.	3 months	The rest of the production stages cannot occur without a solution that has been fully developed, verified and validated.
	Use patient measurements to determine the appropriate shoe for user	The shoe dimensions will be impacted by the dimensions of the foot/orthotic. Once the user measurements are taken, they can be used to determine the standard shoe size used. The pattern and design can then be customised to the shoe size.	1 week	Without user measurements, the shoe will not be the right size, or catered to their foot and will not be a relevant intervention.
	Manufacture upper, toe box, and sole plate (Component 1)	Manufacturing of customised shoes can be a lengthy process based on material sourcing, machine availability and human resources. Manufacturing of shoes can typically take around 3 months which includes sourcing of materials, pattern making, cutting and assembly of each component [63].	3 months	Delays in the manufacturing process will delay completion of shoes. As each component can be produced concurrently, any delays in production of one component will delay the joining of the final shoe.
	Manufacture heel counter (Component 2)			
	Manufacture midsole (Component 3)			
	Join Components 1,2 and 3 together	Once the individual components have been manufactured, they can be joined together to create the final shoe design. The final shoe can be evaluated against quality standards.	1 week	Any delays in the joining process will delay the final evaluation of the shoe, which delays the product getting to the user.
	Quality evaluation	It is important to evaluate the quality of the manufactured product against standards to ensure that processes have been effective. It also identifies any faults that may arise from manufacturing processes.	1 week	This is the final stage of manufacturing the shoe, and any delays in evaluation would delay the product getting to the user.

	Distribution to user	Once the shoe has been manufactured, it can be distributed to the user which may take up to a week based on proximity to the manufacturing facility.	1 week	Distribution is the final stage of the shoe delivery, and cannot delay any other processes. Any delays would arise from shipping services.
In-shoe orthotic <b>(Component 4)</b>	Finalisation of final orthotic design - development through clinical consultation, prototyping, verification and validation	The orthotic design needs to be fully developed before it is used by Naomi. This can occur in collaboration with Dr Abbie to evaluate the feasibility of design choices. After a prototype is generated using the desired material, verification and validation testing is conducted to ensure a quality design.	6 weeks	Clinical evaluation of the design may be confined by the availability of clinics, testing facilities and ability to manufacture a prototype.
	Determine user specific measurements	User specific measurements are vital for the design solution to ensure that design features are placed in the appropriate position, with the correct elevation angles to align biomechanical anomalies. This can be done using Foot Plantar Pressure Measurement Systems, or other technology at the discretion of the clinician.	1 day (appointment with Podiatric Biomechanical Practitioner)	Without user specific measurements, manufacturing of the in-shoe orthotic cannot commence. It could also delay manufacturing of the shoe, as its measurements are dependent on the measurements determined in this time.
	Create custom orthotic design for user	After gaining user specific measurements, the exact details of the customised design can be determined. This outlines the placement of each feature, desired elevation and specific angles of inclination.	1 week	Delays in the customisation of the orthotic could arise from the schedule of clinicians, and would impact the manufacturing process as it cannot commence without a specific design.
	Manufacture custom orthotic	Manufacturing of custom orthotics can take around 4 weeks as it is an entirely unique design based on the individual's clinical presentation. It is important to consider material availability and lag time associated with external facilities for manufacturing.	4 weeks [64]	Delays in the manufacturing process could arise from machine faults, availability of materials and machinery required, and demand for customisable orthotics.
	Wear-in period	After the user has the orthotic, they should trial it for a wear-in period of 2 weeks to evaluate effectiveness/comfort of	2 weeks	Clinician availability could interfere with consultation,

		features. If there are any concerns, they should return to the clinician to address these. This is an important validation component of the design process.		leaving this for too long could be detrimental for the user if there are problems with the design .
	Refitting/adjustment if needed	If there are any concerns with the orthotic, alterations can be made to create an updated orthotic. This will follow the same manufacturing process and take around 4 weeks	4 weeks	This is an optional stage of the delivery plan, as some individuals may not have problems with their orthotic. Any delays may be associated with clinician availability.