Development of a 3D Printed Prosthetic Foot

A manufacturing solution for the optimisation of prosthetic feet

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What

A framework for a dynamic prosthetic foot has been developed with the intention of 3D printing as a manufacturing process. The framework can be tailored to each patient in terms of its dimensions following the data output from patient gait analysis. The adjustments are made to optimise parameters of the foot, like keel and heel thickness, to reduce gait deviations found in the patient. 3D printing was chosen as a manufacturing solution towards prosthetic feet due to its flexible nature, and its cost-effectiveness when producing one-offs or batches. The product involves a service redesign of the current prescription process used in most prosthetic clinics.

Who

The target users are lower limb amputees who have a high activity level (K3 or K4). Meaning that they already have very good ambulation and can walk on different types of terrain at varying speeds. Patients may need a dynamic foot for various activities such as, walking, hiking and playing sports.

Where

A service redesign has been proposed along with a cost analysis to see if in-house manufacturing through 3D printers would be cheaper. The outcome of the analysis shows that a 3D printed foot manufactured within a clinic can be up to 4x cheaper than traditionally manufactured feet. Design and manufacturing of the prosthetic foot within clinics are imperative to the design framework.

Why

Currently, prosthetic feet are ordered in a fashion similar to buying shoes. Patient biomechanics are usually not considered by a prosthetist when prescribing a patient a new foot. Instead, basic criteria like weight, foot length and activity levels are used. Furthermore, prosthetic clinics usually have loyalties to specific manufacturers. Therefore, some patients do not get the foot that is optimal for their needs.

How

Tailoring each foot involves the retrieval of biomechanical data of the patient through gait analysis. A prosthetist/engineer can use data gathered, along with the patient's goals and preferences, to adjust the foot design specific to the patient's needs. FEA stress analysis is used to verify the structural integrity of the design, and to see whether the foot deflects enough at a certain load to be considered a 'dynamic' foot.

Research

Problem

Current prices of prosthetic legs cost between **£3 000 to £50 000**. For adults, a new prosthetic leg is needed every **2-5 years.** Furthermore, lower limb amputees normally have several legs for different purposes. Amputees spend an average of **£100 000** extra compared to non-amputees due to their limb loss and adaptations to their lifestyle.

Inexpensive feet are available on the market for as low as £300. However, their uses are **limited to low impact cases** and are not suited to very active users. Dynamic feet which provide better energy storage and return are most suited to patients who have a high activity level. However, due to the expensive materials, prices for these feet are usually quite high and still need to be replaced every so often.

Expert Insights - Prosthetist

'Clinics are constrained by **budgets**'

'Sometimes patients **don't get prosthetics which are optimal** for them due to cost'

'Cheaper feet means that you can give patients new feet more often, possibly **improving safety**'

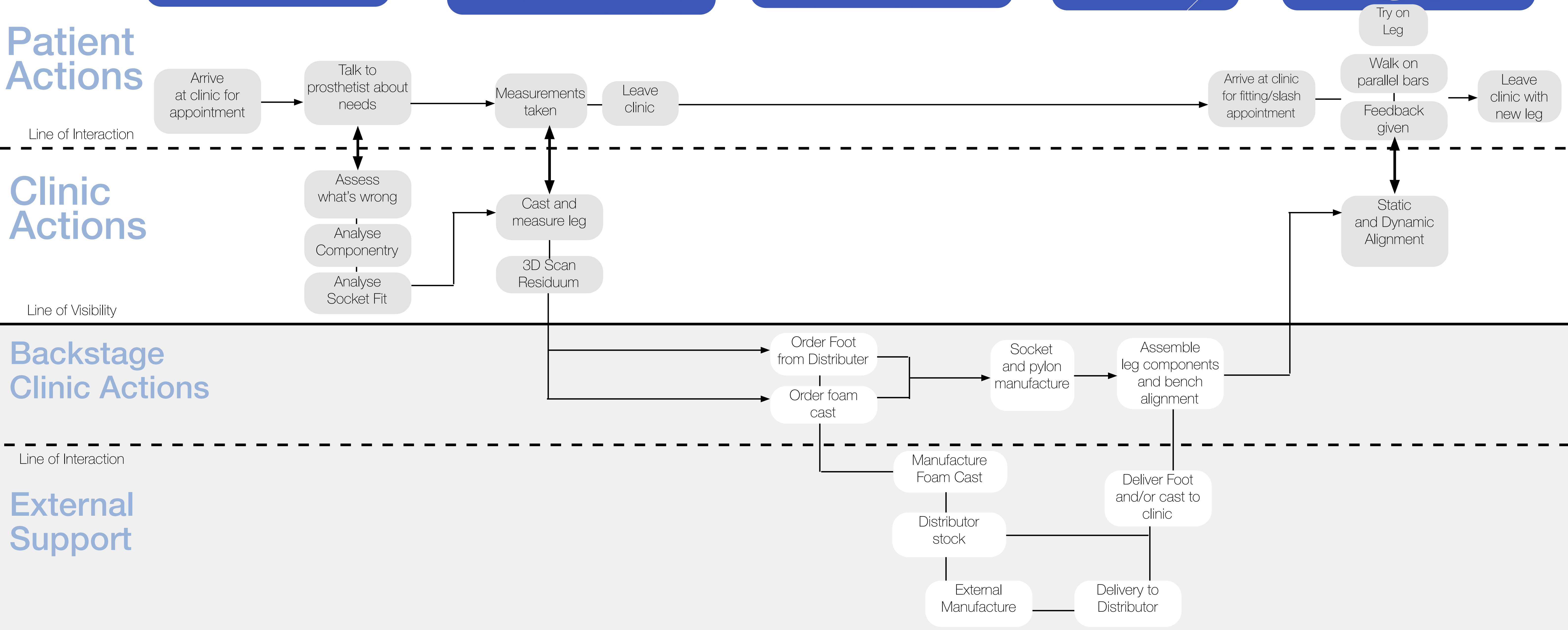
'3D printing could allowing **tailoring of prosthetics** for each patient'

Project Aims

1) Find a method of using **biomechanic data** for influencing the design of a foot
2) Design a dynamic foot framework that can be **adjusted for each patient** to optimise their gait specifically via 3D printing
3) Analyse if the proposed design and manufacturing solution is **cost-effective** compared to traditionally manufactured feet

image: engadget https://www.engadget.com/2019-09-09-eth-zurich-prosthetic-leg-sense-of-touch.html?guccounter=1

Current User Journey - Prescriptions



Friction points

- Lack of data driven gait analysis
- Assessment is mostly subjective
- Assessment outcomes depends on clinician experience and judgement

- Quality of hand cast is dependent on prosthetist skill
- Measurements are either done by eye or laser, 3D scan is more accurate

- Components ordered are not based on collected biomechanic data
- Most clinics have loyalties to specific brands, therefore patients might not get the best product for them
- Shipping can take up to two weeks depending on availability
- Components can be expensive

- Quality of socket dependent on technician skill
- Bench alignment is done only use prosthetist notes and manufacturer recommendations
- Disruptions along supply chain can increase patient waiting time

- Again, no objective biomechanical data is taken to see if the new leg is better than the old one
- High reliance on patient feedback, high percentage of patients have peripheral neuropathy

Design Requirements

A donation of a demo prosthetic leg was received from a clinic in Norwich. This allowed for close inspection of the modular system which is widely adopted in the industry. Analysis of the components allowed me to narrow down the scope of the project to designing of the foot.

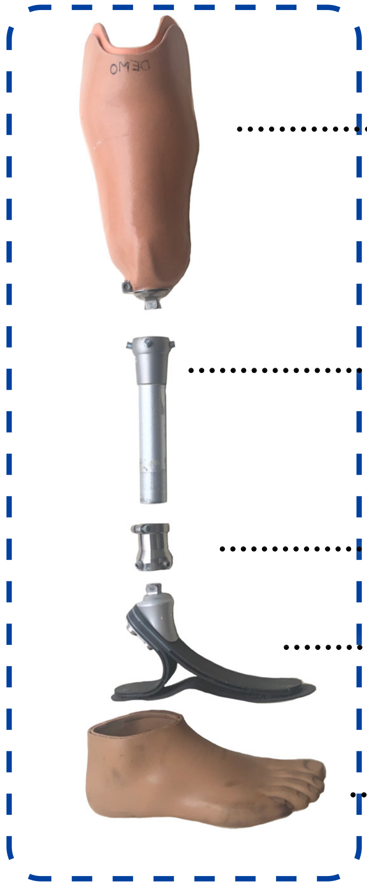
Socket manufacturing and design requires specialist knowledge that only prosthetists acquire during their degree and training

Pylon connects the socket to the foot

Aligners are industry standard and allow for adjustment in rotation in the coronal, sagittal and transverse planes. Also allows for translation in the transverse plane.

Foot (ESAR) several energy storing and return characteristics that help a patient walk more naturally

Cosmesis is a foot shell that fits over the foot. It has the same geometry as an average foot allowing the prosthesis to fit into regular shoes.



Design Focus

From a design engineering perspective, the foot had the most potential for redesign. Therefore, the design focus of the project was put specifically onto the foot instead of the whole leg. Furthermore, if the socket fit is already optimal for the patient, the next most influential component for a patients gait would be the foot. Research and talks with prosthetists showed that the most important factor of a prosthetic foot is its stiffness. Stiffness has many varying effects on biomechanical parameters like Spatio-temporal, joint angles and powers and muscle activity. Focus was put onto designing a dynamic (ESAR) foot due to their qualities in reducing load on the sound limb, possibility of a more natural gait, and robustness when being used in high impact activities.

1

Design a dynamic foot framework that can be adapted for **stiffness** and **optimised** for each patient.

2

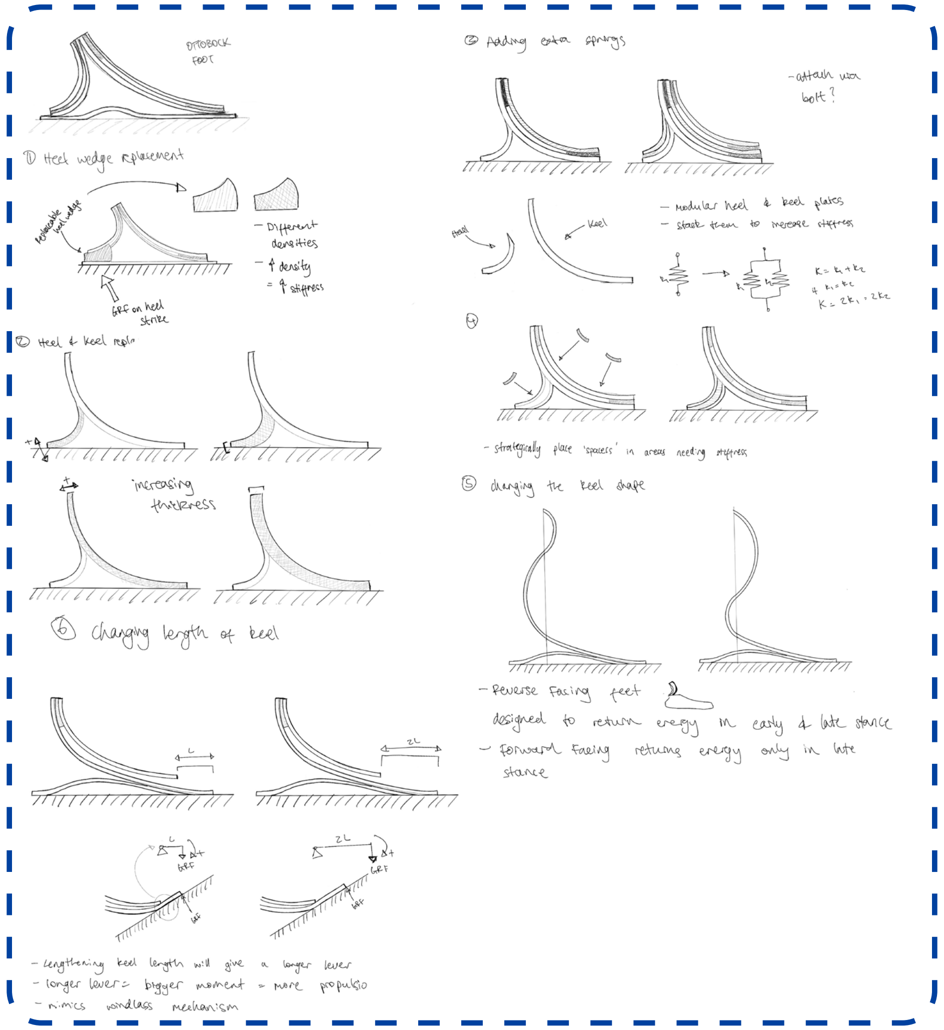
Ensure that the foot can used with **industry standard components**, (aligners and cosmesis) adhering to the modularity of prosthetic leg design

3

The design of the foot takes advantage of the flexibility of **3D printing**, and can be produced faster and cheaper compared to traditional feet

Concept Generation

2D Ideation - A Modular Foot



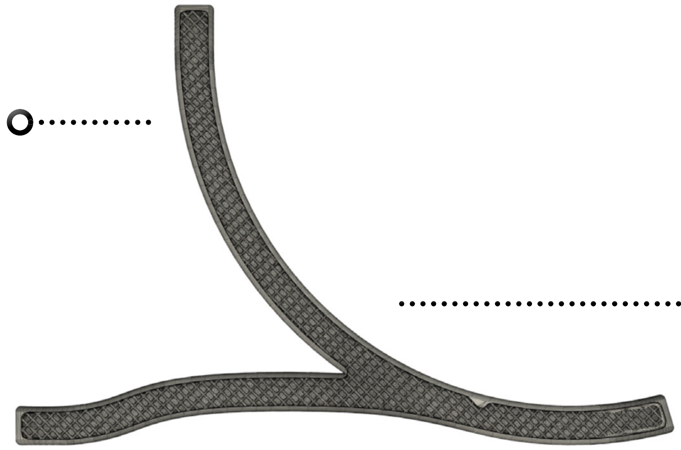
Initial concepts explored the idea of a modular foot, where the stiffness can be adjusted by the patient themselves. Receiving feedback from a prosthetist, she was impressed by the ideation on different ways of adjusting stiffness. However, it was noted that there are already feet in the market that have modular heel wedges. It was said that a modular foot isn't always the best solution. Patients do not always know what's best for them, and self adjustment of prescription could lead to accidents. Therefore, patients shouldn't be able to adjust stiffness of the foot by themselves. Furthermore, a the outcomes of a design selection matrix highlighted that none of these initial concepts made use of 3D printing capabailities. All of the designs could would most likely be manufactured by traditional processes. The modular foot concept was abandoned.

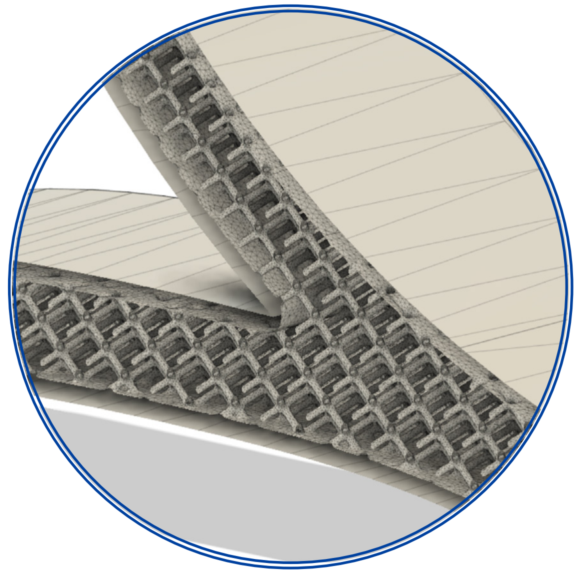
Concept development

Ideation continued to think of different ways of adjusting stiffness. An internal lattice design was developed, where a denser lattice would provide a higher stiffness for the foot. However, this concept was soon abandoned too as there was no way to validate its structural strength through FEA.

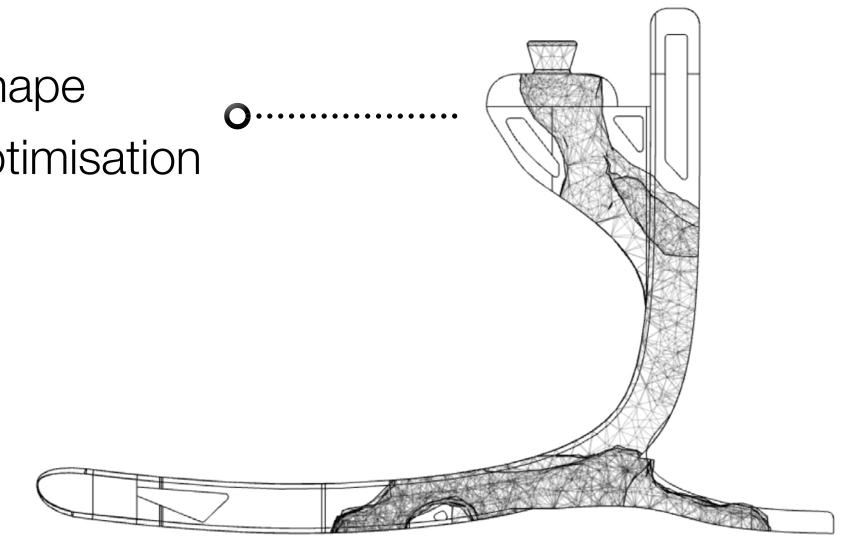
Finally, the concept of varying stiffness by adjusting heel and keel thicknesses was chosen. The simplicity of this allowed for easy concept validation through FEA. Shape optimisation was explored to map the topology of the forces running through the foot. This allows the designer to strategically cut material out of the foot where it was not needed to reduce weight and cost. If stiffness was needed to be reduced, cutouts could be made in areas of critical load path.

Lattice concept

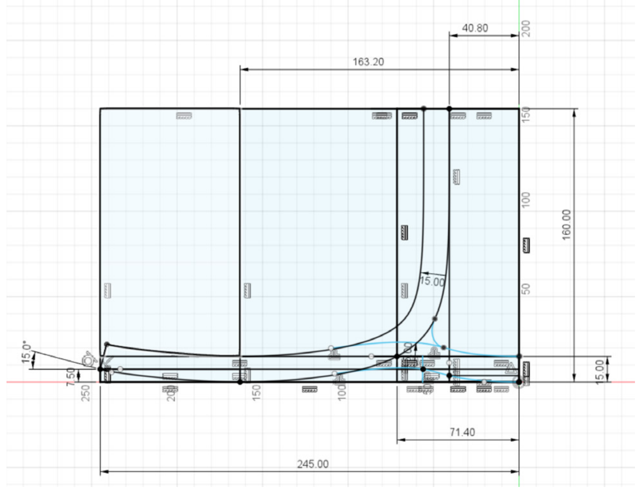


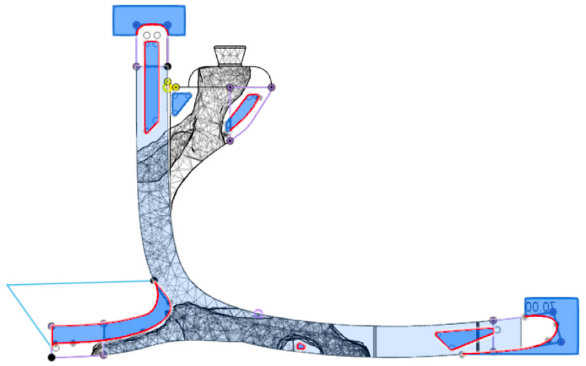


Shape optimisation

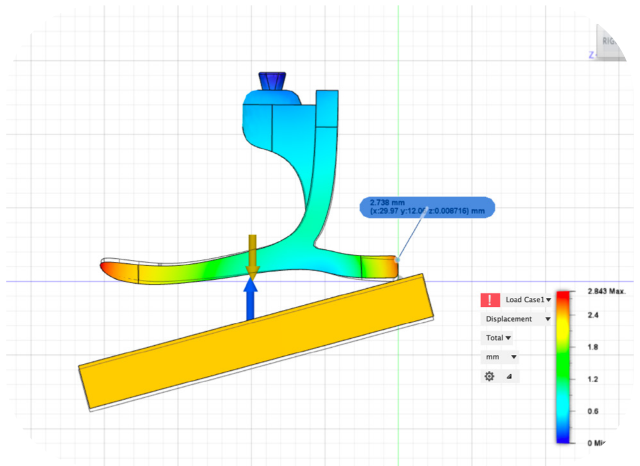


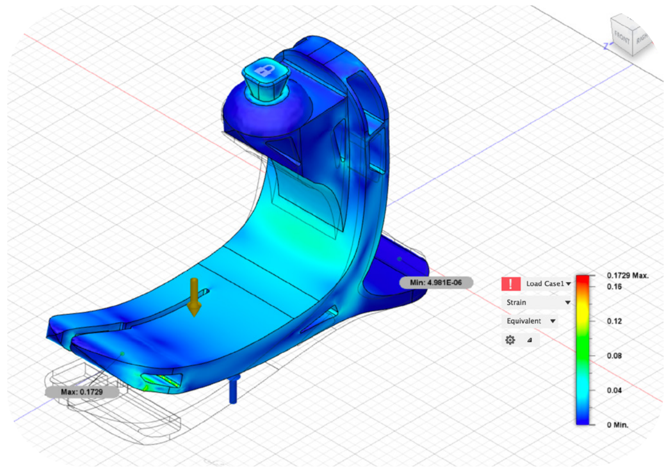
Workflow for design





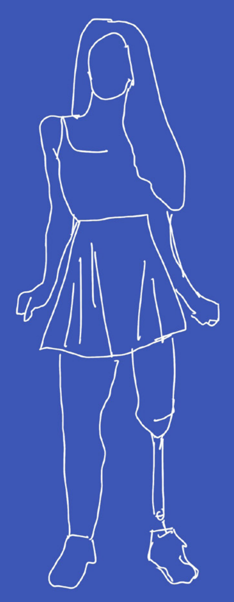
Initial Shape → Adjust for patient → FEA → Shape Optimisation → Final FEA → Print





Through various **iterations** and **experimentation** with the software, a workflow was established for the design and optimisation of the prosthetic foot. The initial shape would be the starting point for the design of a foot for any patient. Data from gait analysis would help adjust the dimensions of this initial shape. Optimisation of the design was done by **iterating static stress tests and shape optimisation**. An Autodesk engineer was asked for **feedback** on the workflow proposed to produce tailored feet for each patient. The engineer approved of the workflow overall, as it made sure that even after modifications made during shape optimisation, the structural integrity of the foot was still tested. He also liked how shape optimisation was used as cutouts were placed strategically with the help of the mesh produced. The feedback also stated that the constant use of fillets was good practice, as this would reduce the number of stress concentrations on the part. In conclusion, feedback from the engineer was very positive, approving every step of the workflow and the final design of the component.

Example Patients



Amputation	Transtibial unilateral left
Weight	50 kg
Foot Length	240 mm
Build Height	130 mm
Activity Level	K4
Goals	High impact activites, tennis
Gait Analysis Note	• Current prescription: Normal stiffness • Residual: Knee flexion angle, braking GRF, vastus medius activity, gluteus medius activity is LOW • Intact rectus femoris activity LOW • Stance time symmetrical • GRFs higher than average in residual
Patient preference	Soft heel and forefoot, flexible foot
Prosthetist prescription	Dynamic ESAR foot

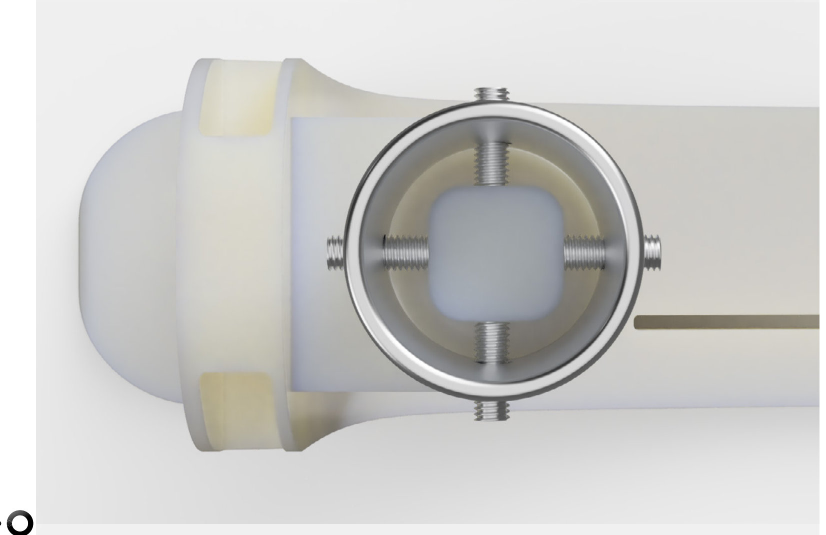
The workflow previously stated will be conducted for each patient. Notes from gait analysis are used to prescribe the patient a specific stiffness of foot optimal to their biomechanics. Different input parameters like size, weight, and stiffness lead to different topologies created from shape optimisation. This leads to differing geometries for the final shape of each patients foot. Full details of the workflow conducted on patient 1 is seen in the technical report.

Amputation	Transtibial unilateral right
Weight	70 kg
Foot Length	265 mm
Build Height	170 mm
Activity Level	K3
Goals	To walk faster
Gait Analysis Note	• Current prescription: multa axis foot • Propulsive GRFs are **LOW** • Residual leg knee joint extensor moments are **LOW** • Residual leg braking impulses are **LOW** • Mediolateral balance is POOR
Patient preference	Medium stiffness foot
Prosthetist prescription	**Compliant dynamic ESAR foot**

Final Design

Split toe for sandals
and lateral propulsion

Iteration leads to
different feet for different
patients



Fits with standard
industry aligners

Dynamic foot
verification through
different load cases
in FEA

Materials, Manufacturing & Cost

Popular 3D printing **materials** were scrutinized through a material selection matrix. The matrix was designed to put higher weightings on important mechanical properties like stiffness and elongation. The material chosen to manufacture the prosthetic foot was PA11 (Nylon). This was due to its low specific stiffness and high elongation at fracture, making it a safer material for the user.

There are 2 main processes for **manufacturing** PA 11, SLS (selective laser sintering) and MJF (multi-jet fusion). Although MJF produces higher accuracy parts, this would only offer a small advantage over SLS due to the higher tolerances on a prosthetic foot. Furthermore, SLS printers usually have a bigger build volume. Therefore, a manufacturer/clinic could print more than just one part per build time. SLS was chosen for the AM process to manufacture the foot.

Decreasing the cost was one of the main objectives of the project. The outcome of the cost analysis was very positive. Both models proved to cheaper than a standard dynamic foot. **Feedback** from a prosthetist was very positive. She explains the great benefits of having a cheaper foot that is optimal for every patient. Firstly, cost savings can be invested into better components of the prosthetic legs, e.g. sockets and liners. This overall gives the patient a better quality of care and service. Secondly, clinics are normally bound by cost budgets, disallowing optimal prescriptions for patients. Having a cheaper customised foot means every patient will receive the same quality of prosthetics regardless of cost constraints on the clinic.

Cost modelling of the manufacture of the prosthetic foot was offered in 2 methods. The first one, the clinic adopts an outsourced manufacturing method. The second model involves the clinic investing in a small AM facility for in-house manufacturing. Most prosthetic clinics have workshops, so there is already the infrastructure for building a small scale AM facility. Retail price was calculated by adding an 80% markup and VAT to the manufacturing costs. Retail prices of both manufacturing models were compared to the retail price of a popular dynamic foot available commercially, the Ottobock Trias. Full details can be seen in the technical report.

Outsourced

Company	Material	Process	Quoted Price [£]	VAT Reduction
Shapeways	PA11	SLS	235.16	188.128
Protolabs	PA11	SLS	208.11	166.488
Average Manufacture cost (C_m)			221.64	177.31

$$C_m + C_l = £217.31$$

$$C_{retail} = [(C_m + C_l) \times 1.8] \times 1.2$$

$$C_{retail} = £469.39$$

Clinic Manufacturing

$$C_m + C_l = £102.89$$

$$C_{retail} = [(C_m + C_l) \times 1.8] \times 1.2$$

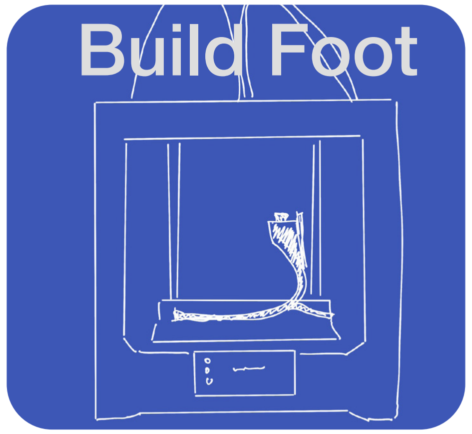
$$C_{retail} = £222.24$$

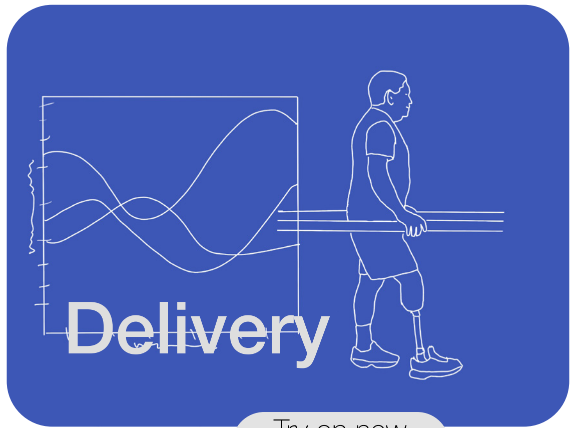
	Cost per part [£/N]
Materials *(LSMCP)*	14.43
Machine *(MCP)*	44.97
Labour *(LCP)*	3.49
Total *(Cm)*	62.89

Comparison to Ottobock Foot

	Ottobock Trias	Outsourced manufacturing	Clinic manufacturing
Retail price	£820	£469.39	£222.24

New User Journey - Prescriptions





Patient Actions

- Arrive at clinic for appointment
- Gait Analysis with current prosthesis
- Gait analysis with demo feet
- Measurements taken
- Gives design input
- Patient approves of design
- Leave clinic
- Arrive at clinic for final appointment
- Try on new Leg
- Gait analysis
- Feedback given
- Leave clinic with new leg

Line of Interaction

Clinic Actions

- Assess quantitative data
- Analyse Componentry
- Analyse Socket Fit
- 3D Scan Residuum
- Adjust foot framework according to patients needs
- Send file to workshop for overnight manufacture
- Analyse quantiative data
- Static and Dynamic Alignment

Line of Visibility

Backstage Clinic Actions

- 3D Print foot
- Post Processing
- Socket and pylon manufacture
- Assemble leg components and bench alignment

Line of Interaction

External Support

- Order Materials if needed

Improvements

- **Gait analysis** is taken with several feet with differing stiffness
- Can infer from **biomechanical data** which stiffness is best for the patient

- Adjustment and optimization of the foot framework specific to the individual is done with the patient
- **Quantitative data** is used along with patient feedback can be used in design of the foot
- Quantitative data can be shown to the patient to give them a **better understanding** of their body and their needs

- **Manufacturing** of the leg happens **in-house**
- Most prosthetic clinics have a workshop so there is space for building an AM infrastructure
- Localised production **shortens the supply chain** which should lead to shorter patient wait time and **less disruptions**

- Quantitative gait analysis is done again
- Data from second gait analysis is **compared to initial data** to see if the new foot improves the patients gait

Prosthetist feedback

'Data is a really useful tool for prescribing prosthetics, as currently the criteria are very subjective. It gives people **evidence for reasonings behind prescriptions** and takes away subjectivity. Currently, all clinics have their own prescription guidelines. But if all clinics adopt the method of using data for prescriptions, the **profession can be standardised**, and patients in all locations will receive the **same quality of care**. The best thing about the service redesign is the shortening of the supply chain. It's good to have in-house production in case of **emergency patients**. Currently, if patients come in with a broken leg, they won't be able to walk until their orders have arrived, which can take weeks. With 3D printing, we can print them the components and get the **patient walking again within a few days**'. Overall, the prosthetist gave very positive feedback about the prosthetic foot framework for optimisation along with the service redesign.