HYPERHIDROSIS AND BELOW THE LEG PROSTHESIS

Meet the team:

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Introduction to hyperhidrosis and the residual limb:

What is hyperhidrosis; how are amputees with prostheses disproportionally affected?

Hyperhidrosis is excessive perspiration that exceeds what is typical for being in a hot environment, exercising, or experiencing nerves.

Despite only affecting a small percentage of the overall population, over 53% of people with amputations experience discomfort due to hyperhidrosis in their prostheses. Although hyperhidrosis of the residual limb is common there is no specific agreed upon method of treatment However, medical professionals agree its cause is likely due to a lack of ventilation caused by the enclosed environment of the prosthetic socket, as it causes there to be a reduced surface area for heat dissipation which when paired with the occlusive nature of the socket leads to increased temperature and sweating of the residual limb and the nerve-related compensation for the loss of sweat glands. Current prosthesis proves insufficient to solve this issue.

What issues are caused by hyperhidrosis of the residual limb?

Not only does hyperhidrosis create physical discomfort for amputees, but furthermore it is considered a significant contributor to poor skin health, fit and function. It can lead to numerous conditions such as contact dermatitis, recurring skin infections, blisters and hyperplasia all of which require expensive medical treatment and the use of steroids, potentially damaging skin if used for extended periods of time.

Excessive sweat can additionally cause the liner to slip, compromising the suspension of the leg prosthesis, which can lead to prosthesis dysfunction, danger of falling and discourage the user from wearing their prosthetic.

How do climate change and global warming affect hyperhidrosis within amputees?

Global warming increases the global average temperature and causes more extreme heat in summer worsening the symptoms of hyperhidrosis particularly in countries in the Middle East and North Africa, which experience accelerated climate change. These countries are projected to face up to 9 degrees Celsius of warming by 2100 posing severe challenges to amputees. This is due to dry deserts in the regions which cannot cool down properly as there is no soil moisture evaporation. Climate scientist Georgiv Stenchikov warns "Desert regions warm almost as fast as polar regions, and they have much higher temperatures" as the central Arabian Peninsula is currently experiencing global warming at a rate three times faster than the rest of the world". The rising temperatures that accompany climate change will cause those who already suffer with this condition to have worsened symptoms, and those who don't struggle to begin exhibiting this condition and its symptoms, having knock on financial and medical consequences for both amputees, the NHS and The world Health organisation.

Contact dermatitis as a result of hyperhidrosis:

The most reported skin condition in patients with limb amputation is residual limb hyperhidrosis, characterised by excessive sweating in the area of amputation which can lead to severely debilitating skin irritations and dermatitis. The physiological explanation for the condition occurring is not understood but is theorised to be due to the sweat glands in the area of amputation compensating for the lost tissue, in combination with the lack of evaporation of sweat beneath the prosthesis which can be worsened by raised temperatures.

Contact dermatitis is consequently caused by the skin's lack of ability to adapt to the build-up of humidity, pressure, heat and friction in the prosthesis, as well as a greater probability of bacterial accumulation. Dermatitis of residual limbs is characterised by skin maceration, ulceration, swelling and increased trans epidermal penetration which facilitates bacterial infection. Around 75% of limb amputees have related skin conditions, of which the most common treatments are topical corticosteroids, which can cause cutaneous atrophy and reduced efficacy of treatment after prolonged use, and Botulinum toxin, which is successful in reducing sweat production but does not affect pain. Therefore, it is necessary to design an alternative solution to this highly prevalent problem which helps alleviate symptoms, pain and has few side effects with long term usage.

Social acceptability and psychological impact:

A loss or lack of limb can have severe psychological impacts on an individual, with social attitudes playing a major role in self-perception. Many of the countries that are most affected by climate change, such as those in Asia and Africa, often have collectivist ideals, thus leading to some individuals with prostheses having an increased desire to fit societal expectations, and a higher preference for realistic prostheses. Furthermore, some of these regions can be quite aesthetically driven, and so is another determining factor for a greater need for more natural looking prosthetic legs. This contrasts with the western world's preference for bold and personalised prosthesis designs. To cater to both these approaches we have created a flesh toned prosthetic cover, as well as the option to modify the colour of the outer shell to create a more customised prosthesis.

Studies show that prosthetic devices benefit individuals by aiding their return to work, however the excess perspiration and discomfort caused by the symptoms of hyperhidrosis being heightened by non-breathable prosthetics, can make this return more challenging. By ensuring this breathability, it can help make a patient's return to work more pleasant, allowing them to reap the benefits of returning to a normal lifestyle.

Some individuals also struggle with taking part in certain physical activities and sports for fear of damaging their prosthetic. To ensure that this apprehension is reduced, the foot of the prosthetic can be changed to accommodate other sport-specific attachments, such as paddles for swimmers. This will help amputees to participate in their hobbies, helping them to enjoy their personal interests, and improve their place in society by playing with others.

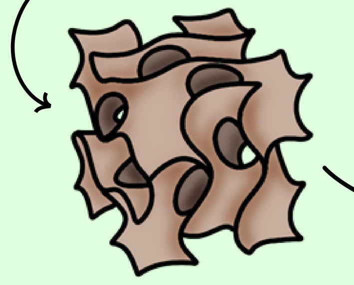
Our Prosthesis:

We have designed a lightweight, secure and breathable prosthetic which will help to provide airflow to the residual limb reducing temperatures surrounding the limb and therefore mitigating the effects of residual limb hyperhidrosis. Our solution will not only counteracts the effects of a condition exacerbated by climate change but may help to solve an even larger prolific problem for all amputees

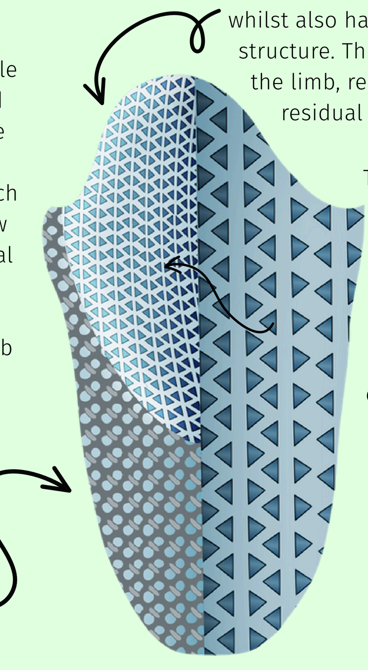
Transtibial amputations are the most common type, so we found it appropriate to focus on a below the knee prosthetic, in order to reach as many amputees struggling with hyperhidrosis as possible. Many individuals rank the fit of their prosthesis as the most important feature, but as many prosthetics require a very tight fit, it worsens the symptoms of hyperhidrosis. Rather cyclically, excess perspiration also makes it harder to attach certain prosthetics. With this in mind, we decided to create a design that would reduce these issues, by increasing ventilation of the limb, whilst also maintaining a high level of functionality to ensure patients can thrive in their day to day lives.

Skin desensitisation is used to prepare the residual limb for prosthetics, which is followed by the use of compressive bandages, though not all individuals may have access to the correct, or most efficient ones, which would reduce ventilation to the limb. One of our concerns when producing the concept for a breathable prosthetic limb, was that its purpose may be defeated by non-permeable compression techniques. Therefore, we took great care to design a built-in compressive liner to guarantee not only just a breathable prosthetic, but an overall breathable experience, unhindered by non-breathable liners. Our prosthetic is body powered, so medical professionals need to be wary of who they provide the prosthetic to, as frailer patients may not be able to produce the effort required, thus it should be ensured that the individual has reasonable strength. This is highly important in order to prevent excess strain on the remaining limb.

We have chosen to use a gyroid structure for the internal structure of the prosthetic limb
We have chosen the gyroid structure as it is used in aerospace and automotive industries due to being able to withstand harsh environments, such as shock and vibration, both of which will be encountered with the day to day use of a leg prosthetic. Furthermore, the structure has a very high surface-to-volume ratio which results in highly efficient heat transfer. This will allow for the rapid removal of heat from around the residual limb, facilitated by airflow from the open triangular lattice shell, effectively reducing heat around the residual limb and reducing the effects of residual limb hyperhidrosis occurring.



Internal Gyroid structure



Outer shell of prostheses

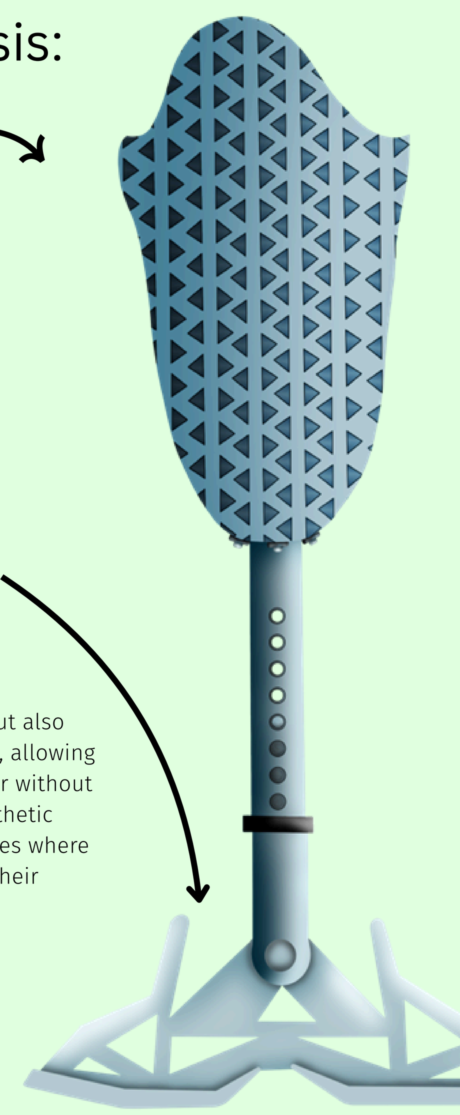
A smaller version of the lattice is added to the housing area for the residual limb, so that the limb can rest comfortably against the smaller triangles, whilst also having access to air flow from the internal structure. This will reduce the heat build up around the limb, reducing sweating and the likelihood of residual limb hyperhidrosis from occurring.

The Outer shell and the support area for the limb is made of a repeating triangular structure. We have chosen this shape because when a load is applied to one of the corners of the triangle, the force is distributed along its sides. The two sides facing the load experience compression whilst the third side is under tension, pulling it sideways. This balance of compression and tension makes the shape very strong and stable, making it ideal for use in a prosthetic, as it will continually have pressure exerted on it. This lattice allows for the prosthetic to have structural integrity whilst allowing airflow through the internal gyroid structure to occur

Design Analysis:

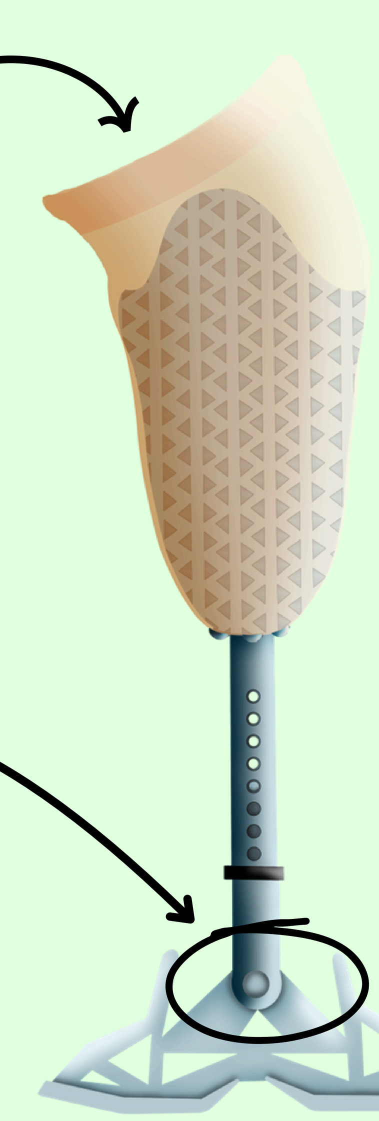
The mirrored use of triangles in the foot section and lattice helps to lightweight the prosthetic whilst also allowing it to keep its structural integrity, putting less demand on the limb, and further reducing exertion and sweat.

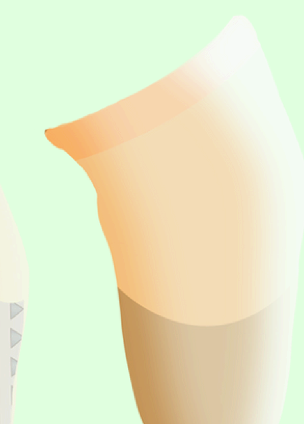
The foot is fitted with grips but also reflects traditional foot anatomy, allowing the prosthetic to be worn with or without a shoe. This makes the prosthetic accessible to certain communities where individuals prefer to hide their prosthetics.



The flesh toned prosthetic cover will help to make the prosthetic look more like a regular limb, making it more accessible to individuals who prefer to hide their prosthetics.

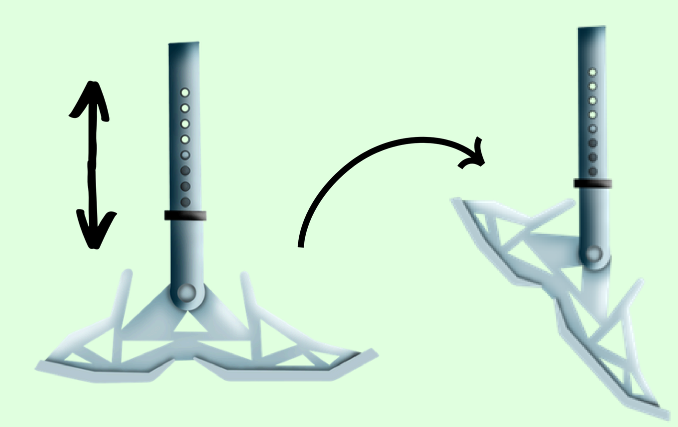
The foot of the prosthetic is fitted on a hinge joint (to mirror the synovial joint of the ankle) allowing the foot to adjust to the terrain the individual is walking on. We have prevented over rotation of the foot by adding rounded stoppers which will press into the pylon preventing rotation. This allows for the prosthetic to mirror the normal rotation and movement of the human foot, making it more functional than the fixed feet often seen in modern day prosthetics.





The prosthetic will be attached using a breathable prosthetic liner made of polyester spacer fabric, fluorocarbon-free DWR, Bamboo fibres and open cell PU foam providing compression for the limb, support and attachment whilst keeping the prosthetic breathable. This liner clips over the main body of the prosthetic using pop buttons positioned at the base section where the prosthetic body meets the pylon. This is then pulled over the limb, acting as both a breathable compression and a means of securely attaching the prosthetic to the leg, by pulling it over the residual limb and knee.

The base of the prosthetic is made of an adjustable pylon. This will allow for a variety of heights, ages and body types to use the prosthetic and adjust it to their desired height. The product is made further accessible by having and internally threaded section (prosthetic body) and externally threaded section (top of pylon) to change the foot attachment for a more sports-oriented attachment, allowing the product to be used in situations where airflow is even more key



Clinical trials:

A three-phase clinical trial will be proposed alongside the production model to ensure global accessibility. This will allow the prosthetic design to meet medical safety standards, whilst also remaining globally accessible.

Pre-clinical Phase: Material Safety & Skin Compatibility
Estimated duration: 6-9 months
Dermatological testing of composite materials (i.e banana fibres, bamboo, polyurethane, and nano-porous silica) used in the prosthetic socket and liner on synthetic skin models. Testing will measure the following factors: allergenicity, prevention of microbial growth, breathability/moisture wicking, and tensile strength. 6-9 months of testing will allow sufficient time to focus on material safety and iterative testing to refine the prosthetic design before human trials.

Phase 1: Skin Health & Comfort (10-20 volunteers)
Estimated duration: 2 weeks
Initial human testing is in a controlled environment, measuring the effects of wearing the prosthesis for 4-6 hours daily over 2 weeks. The aim is to measure the impacts on skin integrity (i.e sweating volume, comfort and any dermatological issues encountered). Feedback from the participants will be used to gather data to adapt the model where necessary.

Phase 2: Functional Testing (50-100 volunteers)
Estimated duration: 4 weeks
In a larger trial amputees will wear the prosthesis over a longer duration of 4 weeks. A range of geographical locations will be selected to test the design in both hot and temperate climates to measure the impact of residual limb hyperhidrosis varying locations. The different parameters assessed will be based around the following factors: stability of the prosthetic, wear and tear, liner slippage, incidence of falls, and skin temperature. Patient satisfaction will be recorded via questionnaires, with common themes for improvement informing further refinement.

Phase 3: Comparative Study (150+ volunteers)
Estimated duration: 12 weeks
The final trials will be used to compare our proposed model against standard prostheses in lower-limb amputees who will be selected from both urban and rural rehabilitation centres across regions with varying climates. Patients will be randomly assigned either the control group (who will continue using their existing standard prosthesis) or the trial group (who will switch to our more breathable prosthesis.) The trial will run for 12 weeks and participants are required to wear their prosthesis for at least 6 hours per day. The following areas will be investigated to enable final adjustments to the design of the prosthesis: incidence of prosthesis removal due to discomfort, severity of skin breakdown, infection rates, temperature and humidity within the socket contributing to hyperhidrosis.

Sustainability & Global Scaling:
Long-term government subsidies would support scale-up in resource-limited areas (where the support of NGOs may further help alleviate the inevitable initial high production costs due to the implementation of a novel design.) Manufacturing guidelines and CAD designs will be publicly available to support the rollout of our prosthetic in areas suffering from humanitarian crises and war zones, where amputation rates are especially high.

Timeline

month 0	Prototype development
month 6	Pre-clinical testing
month 12	Phase I trial
month 18	Phase II trial
month 24	Phase III trial
month 30	Pilot manufacturing
month 36	Scaled rollout

Key:
Development
Clinical trials
manufacturing

Prosthetic socket

Materials	Description	Price - given socket is 300g
Reinforcement – Banana Fibres 25%	Alkali treated Banana fibres have a very high strength to weight ratio making it able to bear a large load. It has a high moisture regain meaning that it absorbs sweat efficiently providing comfort to the limb as well as having a fast moisture release, preventing build-up of dampness unlike other materials which promotes bacterial growth and prevents skin irritation. Has a porous structure allowing airflow, reducing sweat build up. It is also biodegradable, making it eco-friendly and has naturally antibacterial.	75g - £0.29
Matrix – Water borne Polyurethane resin 60% + Silica nanoparticles 5%	Has a high flexibility, making it suitable to make to each individual socket. Is one of the few resins that can be breathable, allowing air flow, reducing sweat build up. The combination of the polyurethane and the silica nanoparticles creates a superhydrophobic membrane making it water repellent, preventing the build-up sweat without compromising the breathability, allowing water vapour to escape	180g - £0.9 15g - £0.26

Prosthetic liner

Outer layer – polyester spacer fabric + Fluorocarbon-Free DWR	The spacer fabric is woven in a 3D structure in such a way that there are air gaps between the layers, to facilitate air flow, to reduce sweat build up as well as acting as a cushioning layer, to provide comfort. The polyester fibres are very durable and lighters than most other materials adding to the comfort. The Fluorocarbon-Free DWR acts as a sweat repellent without compromising the breathability of the liner.	1m^2 – £9.50
Inner layer – Bamboo fibres + Open cell PU foam	The bamboo fibres are ideal for an inner layer as they are naturally moisture wicking, absorbing and releasing sweat very quickly to prevent build-up of sweat. It also has naturally antimicrobial properties to reduce infections and odours. The bamboo fibres are also soft and gentle on sensitive skin. The open cell PU foam is highly breathable allowing sweat vapour to pass through to be evaporated and aids air circulation and is lightweight and flexible to conform to limb shape	100g - £0.243 0.01 m³ - £3

Other

Carbon fibre foot	Lightweight – reduces fatigue and energy expenditure when walking High tensile strength – can support body weight Fatigue resistance – can withstand forces without cracking Corrosion resistance – will not rust or degrade in moisture Customisable - can be moulded into various shapes and sizes according to consumers need	£450
Carbon fibre pylon		£30
Labour costs	–	£1200

Cost Management & Local Production:

Banana fibres – to be sourced from banana farm waste partnerships, targeted in locations where temperatures and amputation rates are high.
Labour costs – form a significant part of the cost of the limb by using 3D technology to make the limb, labour would be reduced over time. Also, manufacturing the limb in countries with lower cost range would make it more affordable.
Government and NGO funding – Grants will allow further research and trialling, and may cover some of the manufacturing cost on this product.
Other materials – mass production of materials from local suppliers will reduce the overall price, by getting the materials at a reduced offer and eliminating cost of exporting. Also given the socket materials are perforated the materials would be less anyway.
3D printing of the socket will enable a custom fit to further enhance the comfortability of the prosthesis.

Manufacturing Strategy:
Partnerships will be established with pilot production hubs in countries with high amputation rates and low-cost labour (where research has suggested that India, Pakistan and Kenya are most fitting). From there, materials can easily be shipped and flat-packed to be assembled locally, thus maximising the global accessibility of our product.