the fatigue toolkit

10 Page summary

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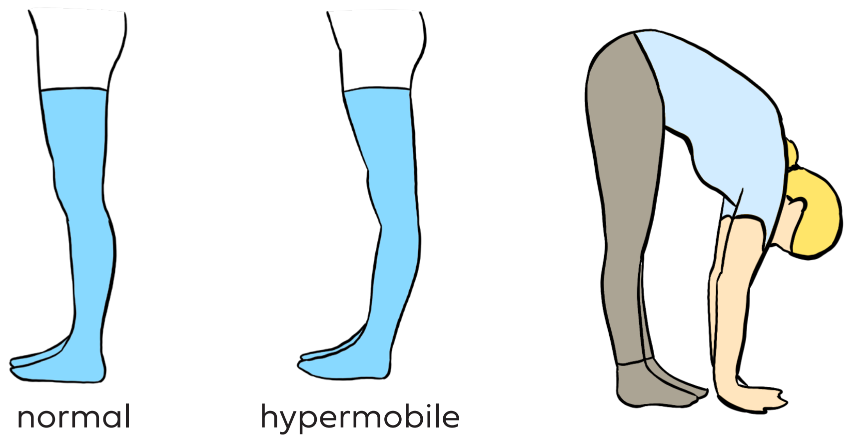
the research

What is Ehlers Danlos Syndrome

Ehlers Danlos Syndrome, more commonly known as EDS, **is a collection of genetic connective tissue disorders**. There are many types, but the most common type is the hyper-mobile type (hEDS).

hEDS can be characterised by stretchy skin, long term pain in muscles and joints, and hyper-mobility of the joints.[12,13,14]



Fatigue and EDS

Fatigue is the most common complaint from EDS patients, as it manifests in a multitude of ways. It can result from over working the body and not resting. It can also result from injury, but often times it can be idiopathic. Patients can find themselves waking up in the morning completely exhausted and in pain, without any explaination.

1/500

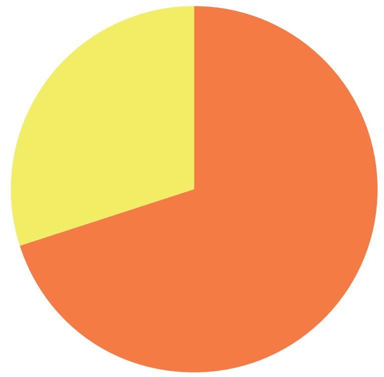
New research suggests that 1 in 500 people worldwide are affected by hEDS/JHS[10]

User insights

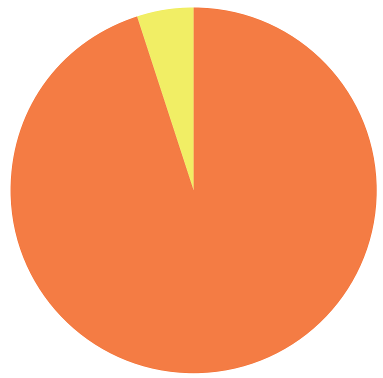
Through reaching out to Ehlers-Danlos Support UK groups, I was able to connect with several EDS patients. I conducted one-on-one interviews throughout the project to garner insight and feedback. The biggest takeaway from this was just how different the EDS experience is from patient to patient. Symptoms vary between patients in their day to day lives, dramatically impacting their livelihood.

Expert insights

From speaking to physiotherapists and hyper-mobility specialists, I was able to learn that physiotherapy is key to ensuring joint health and strength. Typically, EDS patients have issues in lower body joints, such as the knees, ankles and even hips. Physiotherapy techniques have to be incorporated into everyday activities via cues, and it can take a while to establish.



70% diagnosed are women[10]



An estimated 95% of EDS sufferers are incorrectly diagnosed[11]

EDS
EHLERS-DANLOS SUPPORT UK

Current solutions

Currently, EDS patients are left to manage their condition and their multitude of symptoms on their own. As a result, they can find it overwhelming to learn how to properly take care of themselves and how to pace themselves.

Survey insights

I was able to conduct a large survey that was shared in online support groups. From this, I got valuable insight into differing experiences of getting diagnosed and how patients manage their condition. A consistent theme that kept cropping up was that getting a diagnosis is an uphill battle, and people are often diagnosed later in life, when the majority of joint damage has already been done.

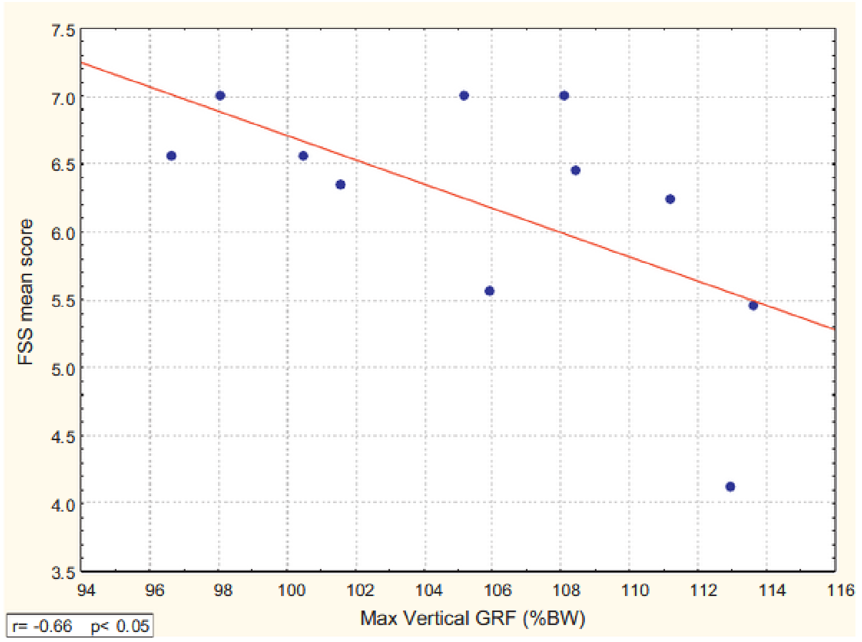
product requirements

the working brief

Create a device to manage, anticipate, and reduce musculoskeletal fatigue for Ehlers Danlos Syndrome patients

Context

Based on research papers which show that the fatigue of hyper-mobile/ EDS patients specifically can be correlated with a measurable parameter, Ground Reaction Force, the working brief focuses on how to utilise this in a practical application.[4]



Product Design Specification

1. Be discreet for the user to wear at all times
2. Allows for both monitoring the fatigue and improving the underlying causes
3. Can fit into existing routines
4. Helps the user understand their physical limitations
5. Gathers data on the users fatigue levels
6. Helps the user to use their joints correctly
7. Be comfortable to use
8. Notify the user to their fatigue level

Context

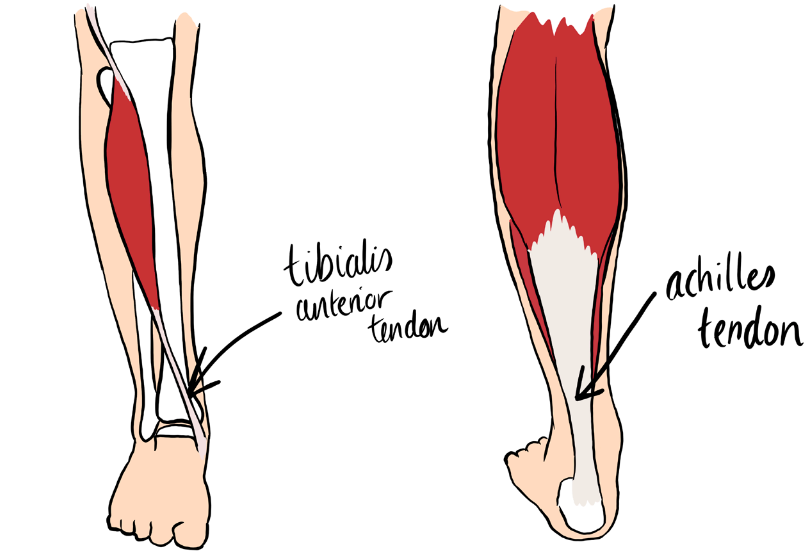
The EDS patients I spoke to had tried out a multitude of different products to help their symptoms, such as compression garments, splints, health monitoring apps, and wearable technology.

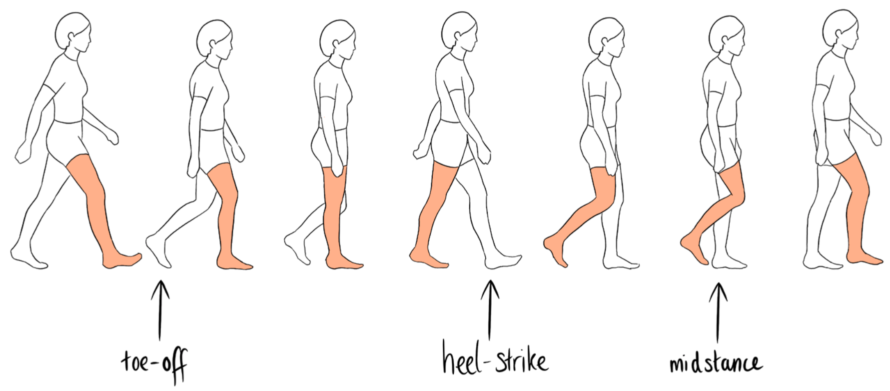
Each product has their own individual purpose, but ultimately **currently there is no EDS specific product to help with the management of the condition.** Thus, it will fall to the patient and their ability to anticipate joint instability or fatigue. **This becomes more difficult as the patients age, as their muscles become weaker and the joints become more painful.**

concept development

Further research

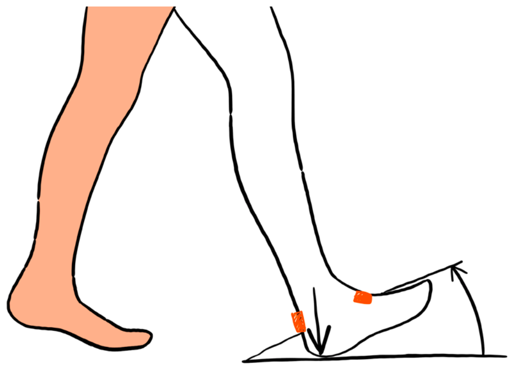
In addition to the study about fatigue in EDS patients, I found another study which shows that irregular gait patterns can be improved via stimulation to the anterior and Achilles tendon. In this study, the stimulation was applied using Linear Resonant Actuators (LRA) motors. Stimulation was applied at specific points of the walk cycle: at the toe off and the heel strike events, which is when the foot is in plantarflexion or dorsiflexion. [1,2,3]





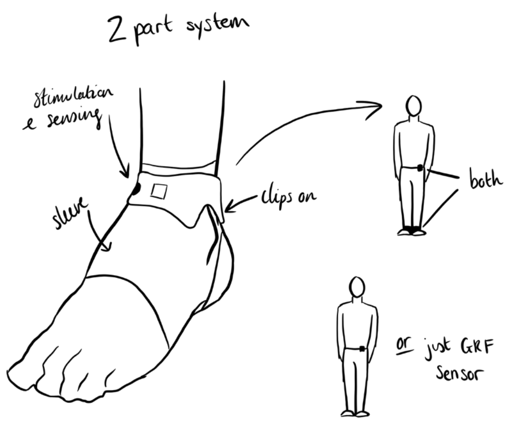
Developing on research

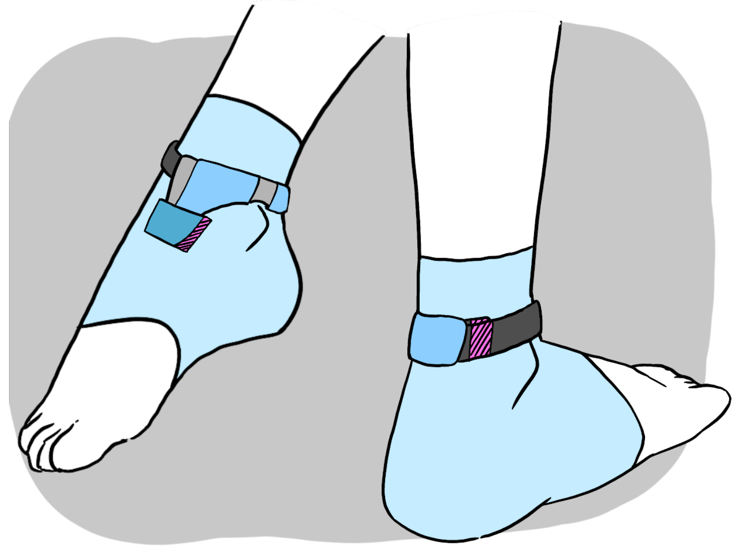
In order to detect the angle of the foot, the product would have to house an accelerometer and gyroscope on the top of the foot. By doing so, the device could then detect when it is appropriate to apply stimulation.

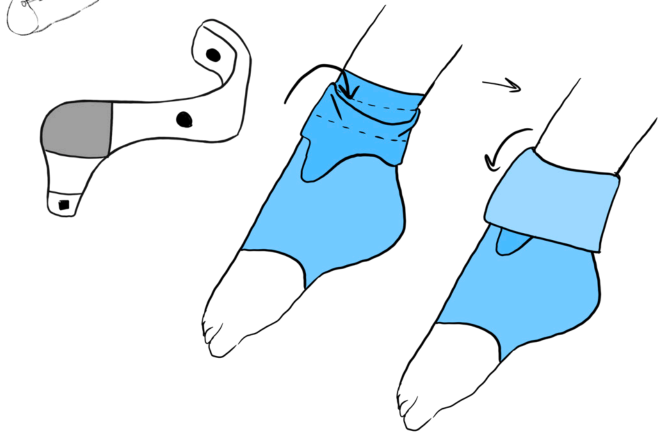


Design mitosis

After some concept generation, I decided to explore how the product, instead of all being housed on the foot, could instead be split in two. By tackling the fatigue monitoring and ankle stimulation separately, the products can be better used by the patient.







user input & refinement

User feedback

After showing the user group my concepts, they gave me crucial feedback. They were most interested in the touchpoint and seeing the data. They liked the idea of being able to input their own data, as some triggers for their fatigue and pain are very specific, such as the weather. They were also interested in being able to use the data to help get a diagnosis and be understood better by doctors.

When considering the ankle device, the patients were hesitant at the idea of wearing it all the time. They brought up that they would be more inclined to wear it for 30 minutes a day, as they have with other joint support products

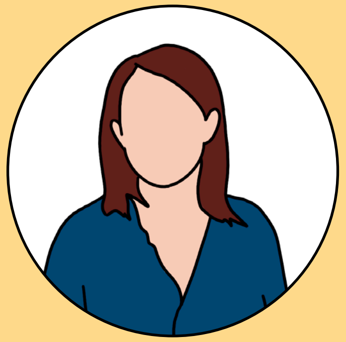
They did, however, like that the product had been split in two, which allows for more flexibility in how the user will be able to use it.

Further Development

A low fidelity prototype was made from socks and polymorph plastic to explore the feasibility of the design. I found that the open toed sleeve made it difficult to inuitively get the sleeve into the right position for the ankle device. I decided that the sleeve should instead be a sock with a pocket for the device.

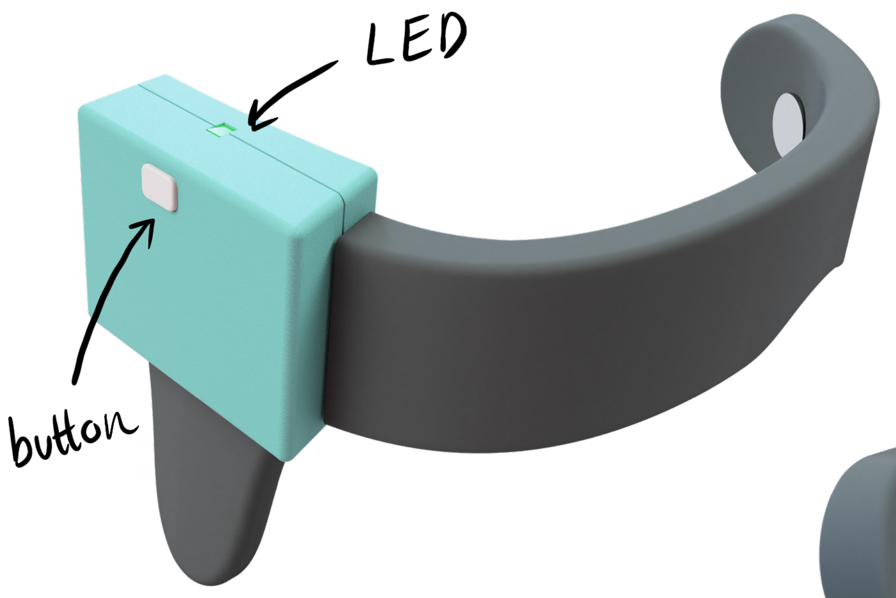
"What if I could put in my own symptoms?"

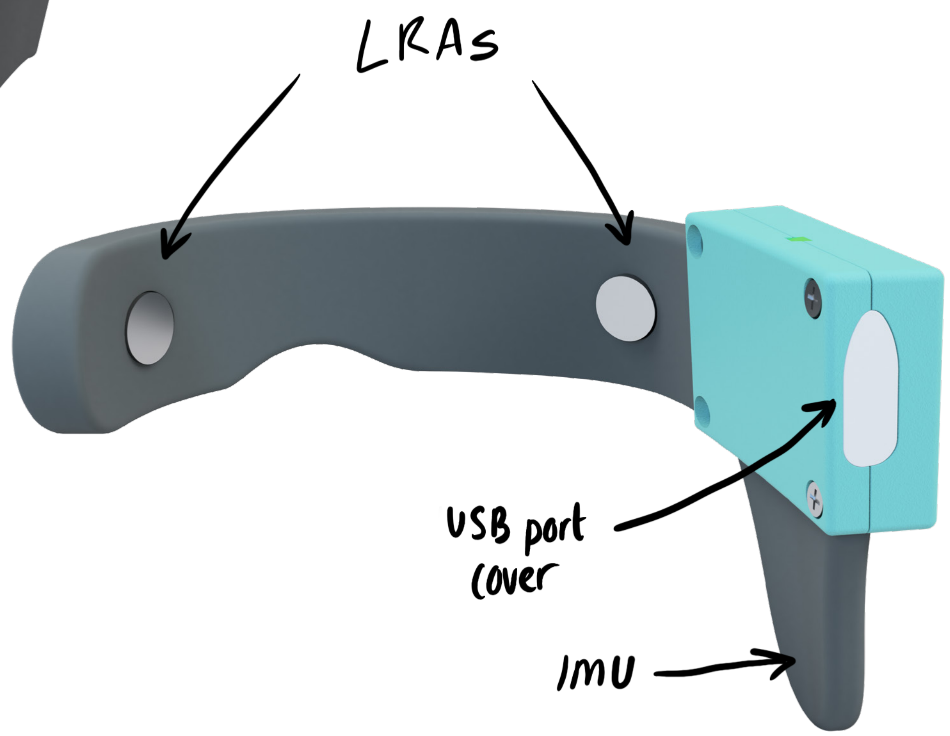
"You can't manage what you don't measure"

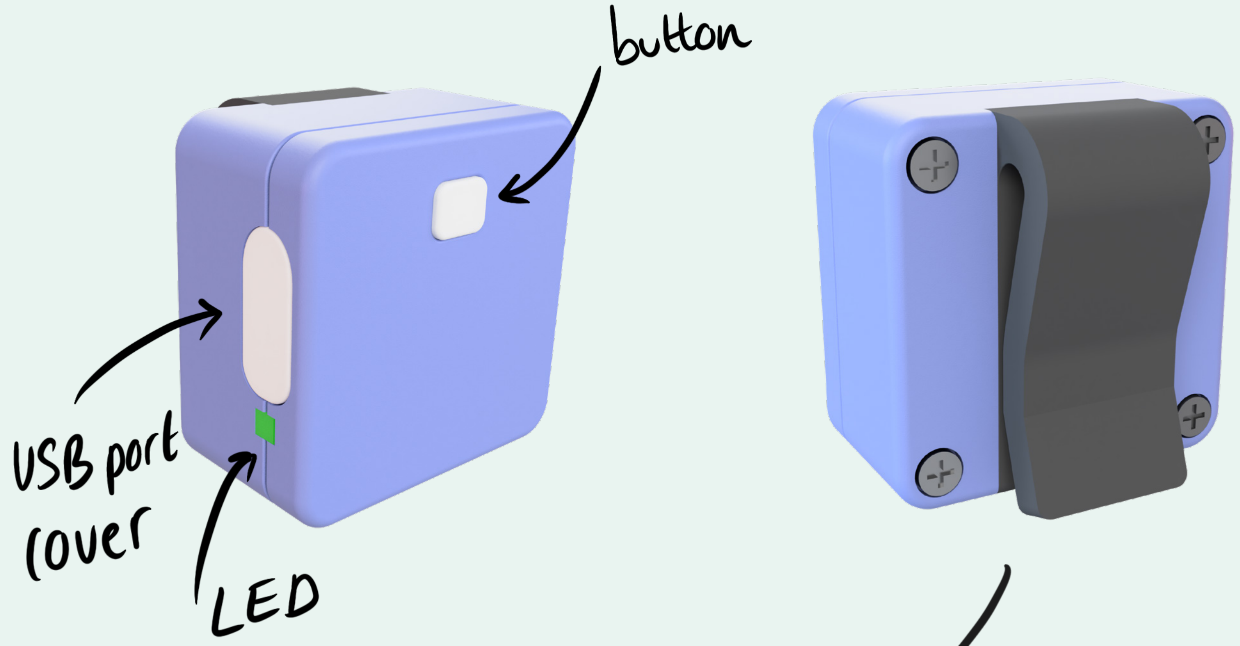


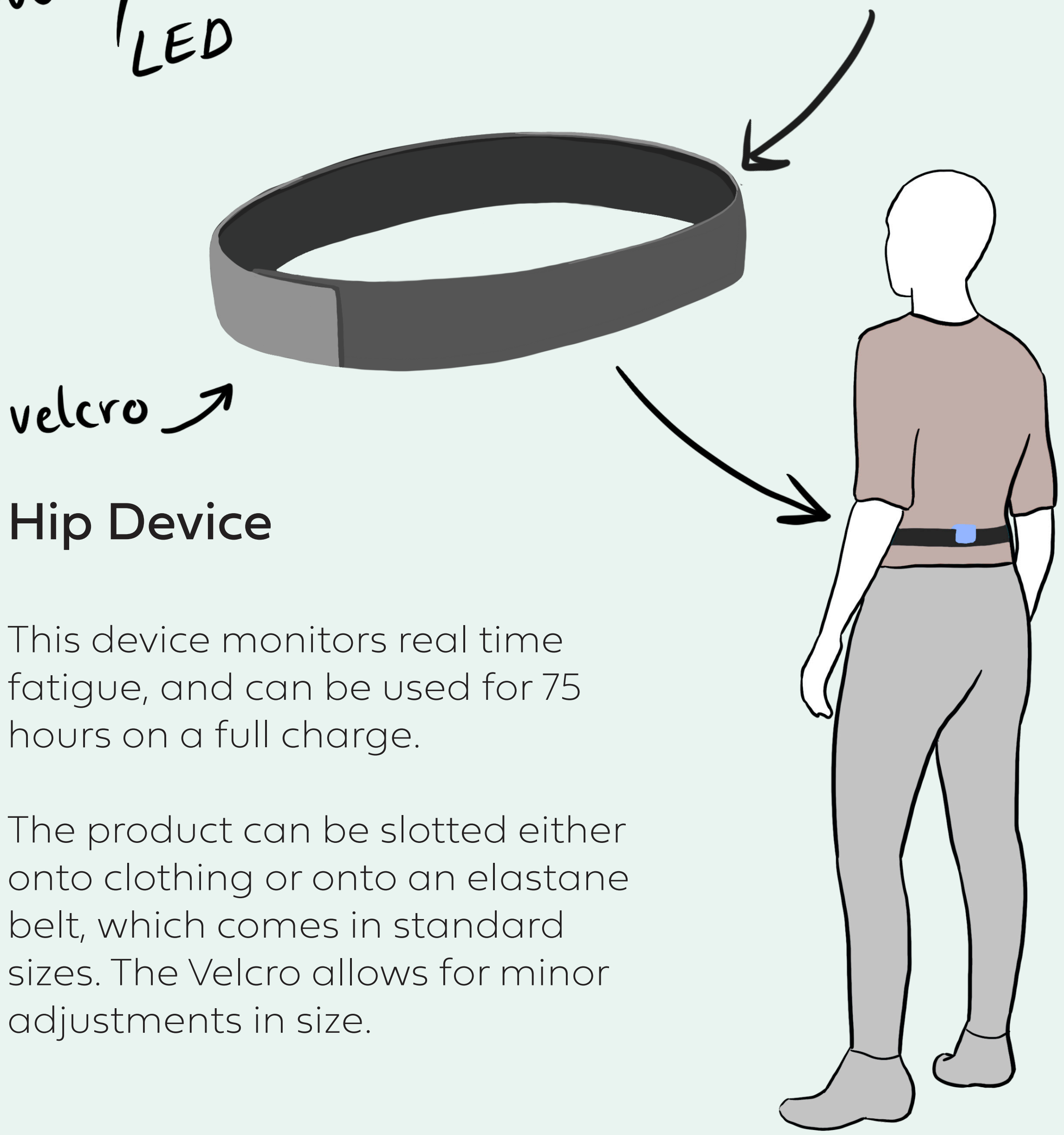
"How long would I have to wear the ankle device?"

product overview









Ankle Device

The physical product comes as a set of two, one for each foot.

The device can be used 6 times on a full charge, each time for 30 minutes.

The device slots into a sock with a pocket, which is then folded over on top of it. The sock is made from elastane and comes in standard sizes S-L.

Hip Device

This device monitors real time fatigue, and can be used for 75 hours on a full charge.

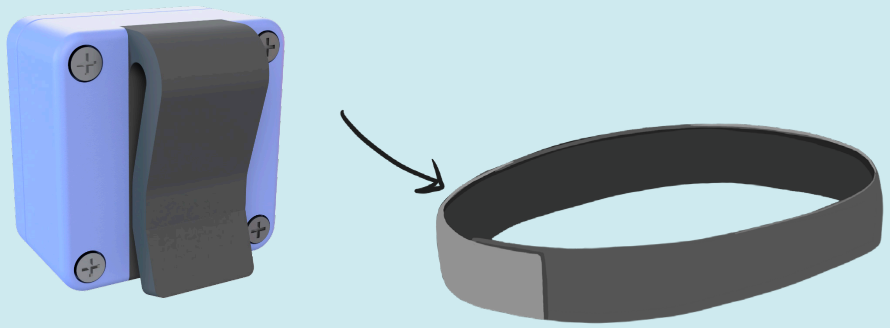
The product can be slotted either onto clothing or onto an elastane belt, which comes in standard sizes. The Velcro allows for minor adjustments in size.

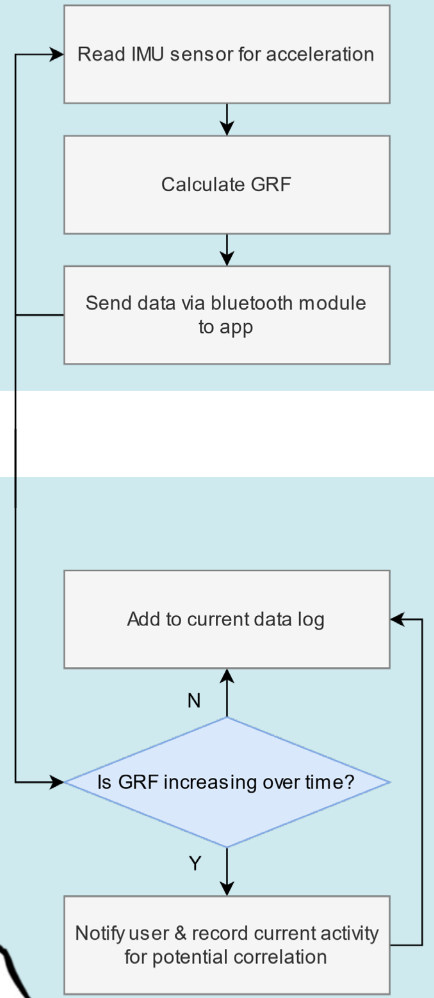
how it works

hip

The fatigue monitoring device is to be placed at the base of the spine, as data from this position has been shown to estimate the Ground Reaction Force of the user with minimal error. [8,9]

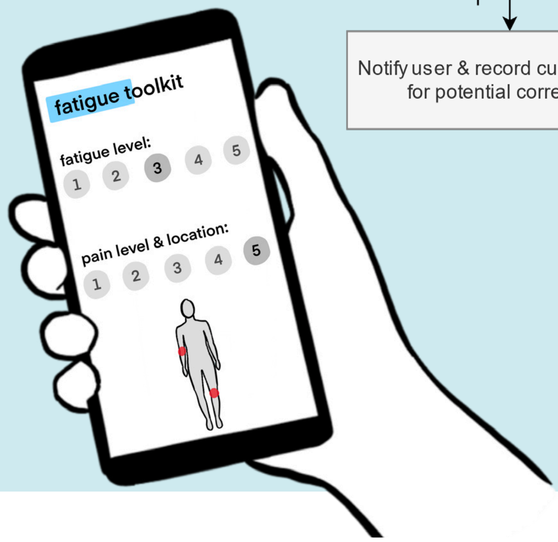
The device contains an IMU, to measure the acceleration which will be used to calculate the GRF, and a Blue-tooth Module, to send this data to the app



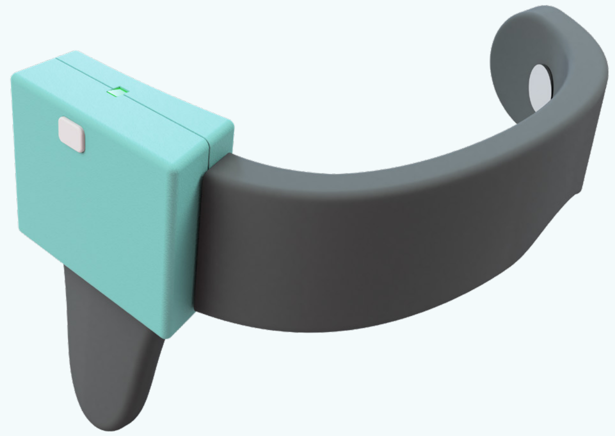


app

This app will be downloaded onto the user's phone and allows the user to view their fatigue data from the hip device, over time.
Should the GRF increase during a time interval, the user will be notified that they are getting fatigued, and will prompt them to rest.
This intervention will assist the user to help learn to pace themselves, and help them learn which activities in particular trigger their fatigue. The app also allows the user to input their own fatigue level and pain.

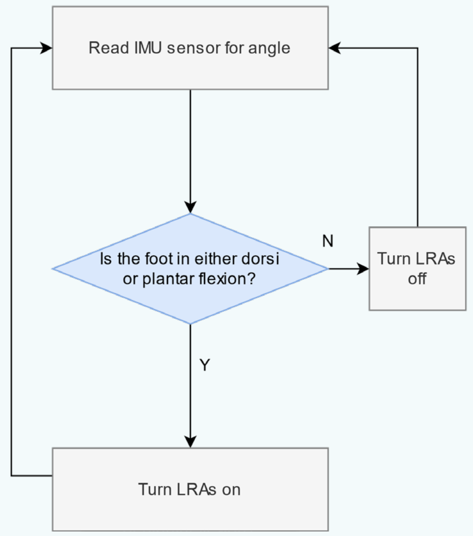


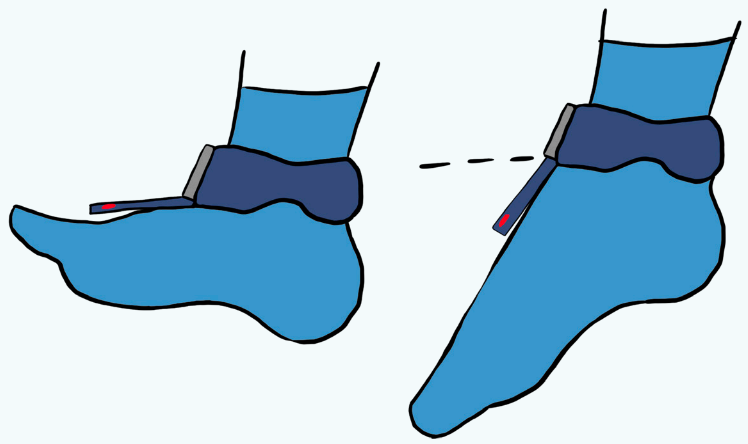
ankle



LRAs, which are housed in over-moulded silicone, provide direct stimulation to the tendons in the ankle. The silicone part will bend to the form of the user's ankle, allowing the device to comfortably fit the majority of ankle sizes.

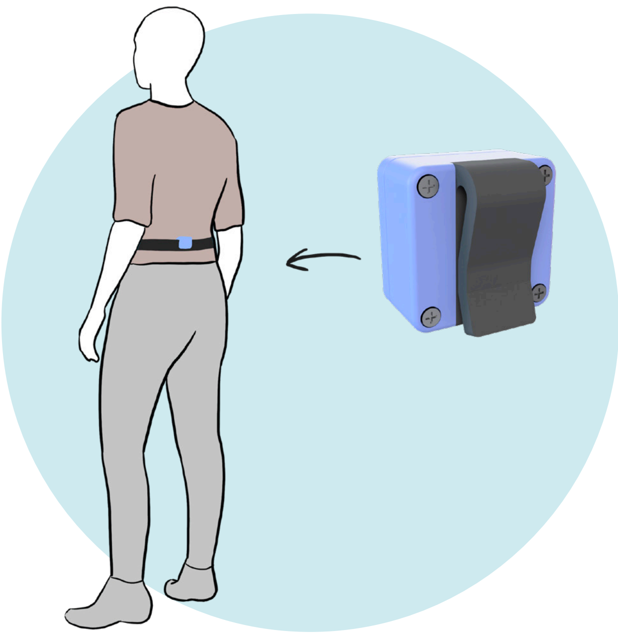
The device will detect angles through an IMU, located in a similarly over-moulded part of the product. This IMU will measure the angle of the foot as it goes into plantar or dorsi flexion. As the angle of the foot is calculated, the device will provide stimulation to the tendons in the ankle by activating the LRAs.



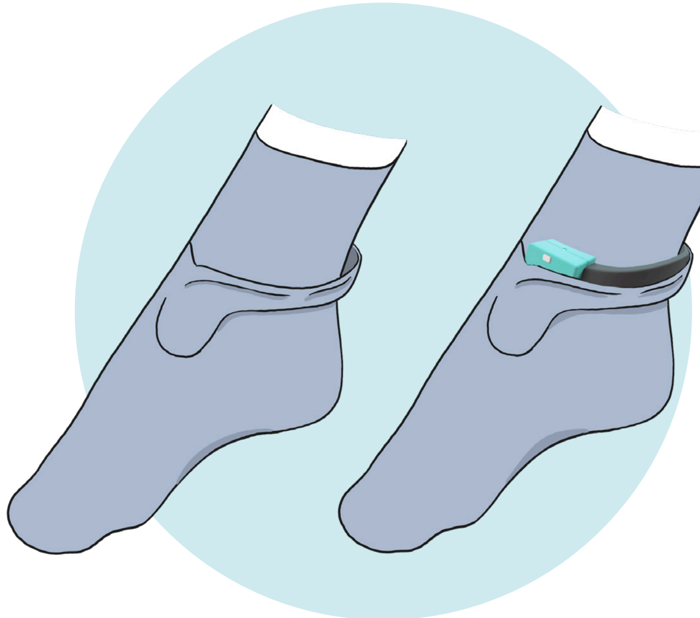


user journey

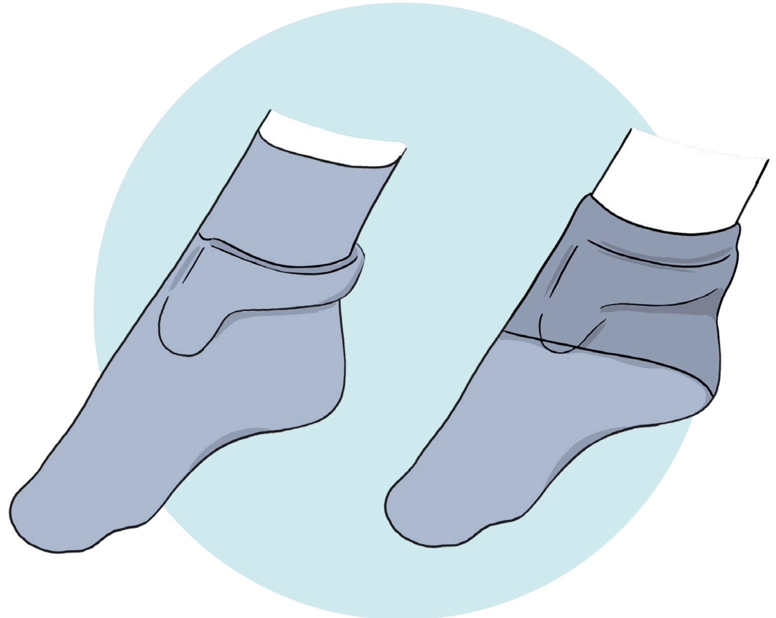
The user inputs their current symptoms at the start of the day



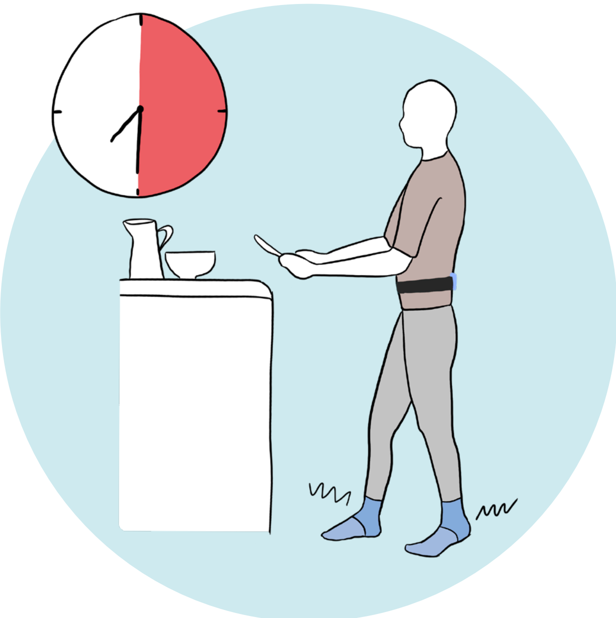
The user puts the fatigue monitor on



The user places the sock for the ankle device on their feet and places device in



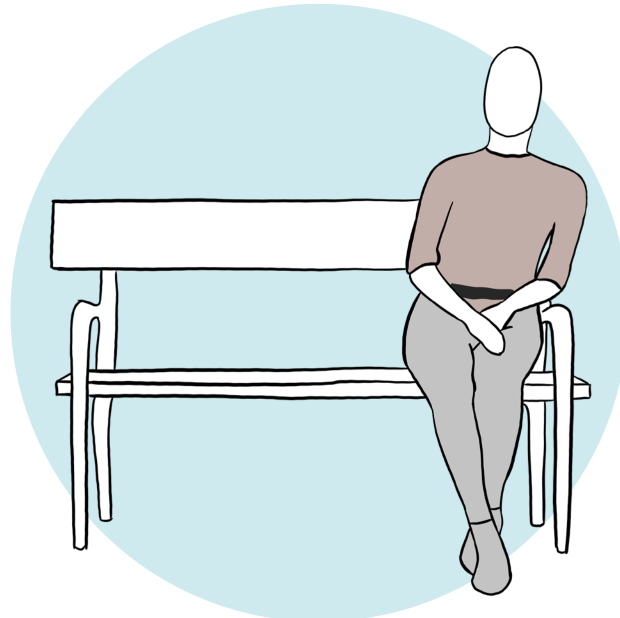
The sock is then folded down to secure the device in place



The user wears the ankle device for 30 minutes

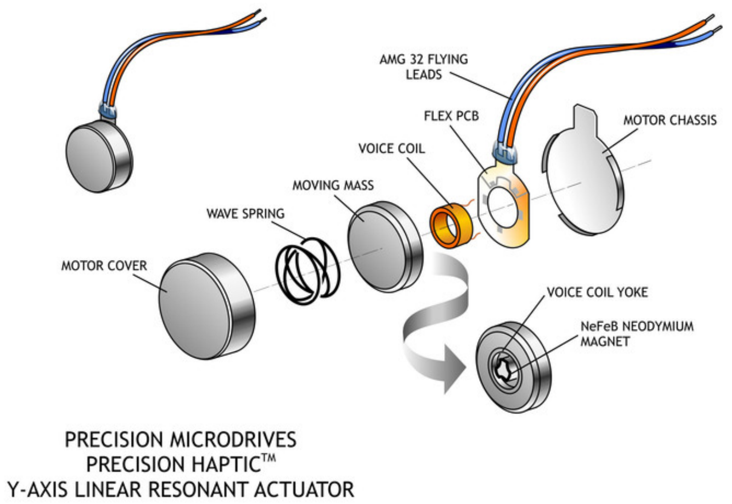
The user removes the ankle device and goes about their day

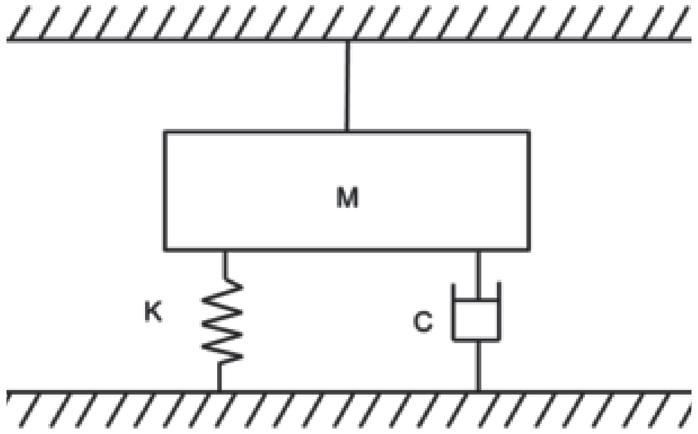
Over the day, the app receives data about the user's energy level, alerting them if it gets too low



If the fatigue of the user is too high, then the user is prompted to rest

technical details



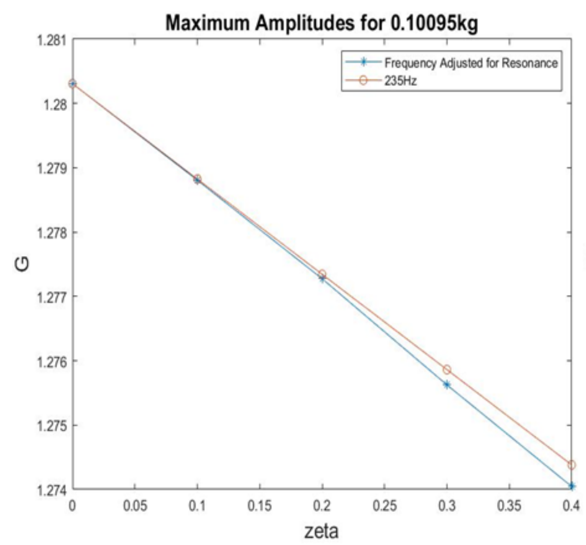


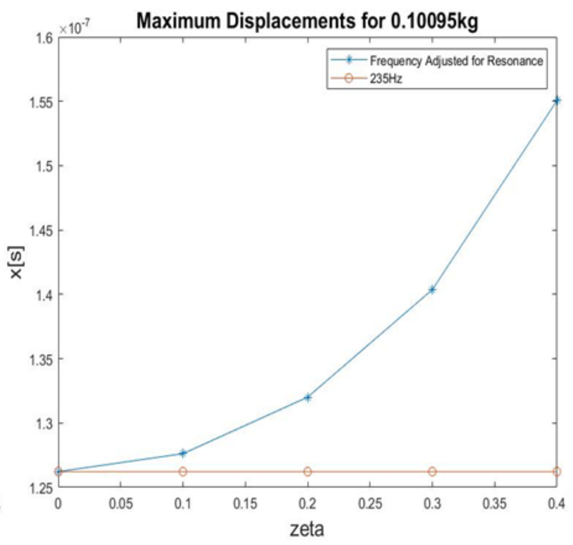
periodic forcing of a 2nd order damped system

$$M\frac{d^2x}{dt^2} + c\frac{dx}{dt} + kx = F_0 \sin(\omega t)$$

LRA Simulation

Linear Resonant Actuators are vibratory motors which move in one axis, and closely resemble a forced, damped, simple harmonic oscillator. By simulating a LRA in MATLAB, the damping effect of the rest of the product has been explored. As the proposed material of silicone will house the LRA, which has a maximum dampening ratio of 0.4, it can be seen that the effects that this will have on the performance of the LRA is minimal.





Battery Calculations

To calculate the appropriate battery sizes for each product, I did some calculations for current draw for the worst case scenario, where:

- the IMU and accelerometer are on all of the time
- the bluetooth is transmitting for approx 1 minute in an hour
- stimulation is applied for 40% of an hour (non-stop walking)

Ankle:
IMU: 300uA

LRA: 6500*2*0.4=5200uA

Total= 5200 + 300 =5500uA
Total= 5.5mA

Hip:
IMU: 300uA

Bluetooth= 4900*0.016=78.4uA

Total= 300 + 78.4 = 378.4uA
Total= .3784mA ~ 0.4mA

Based these on the values, the internal space of each product, and its intended use, appropriate batteries were chosen:

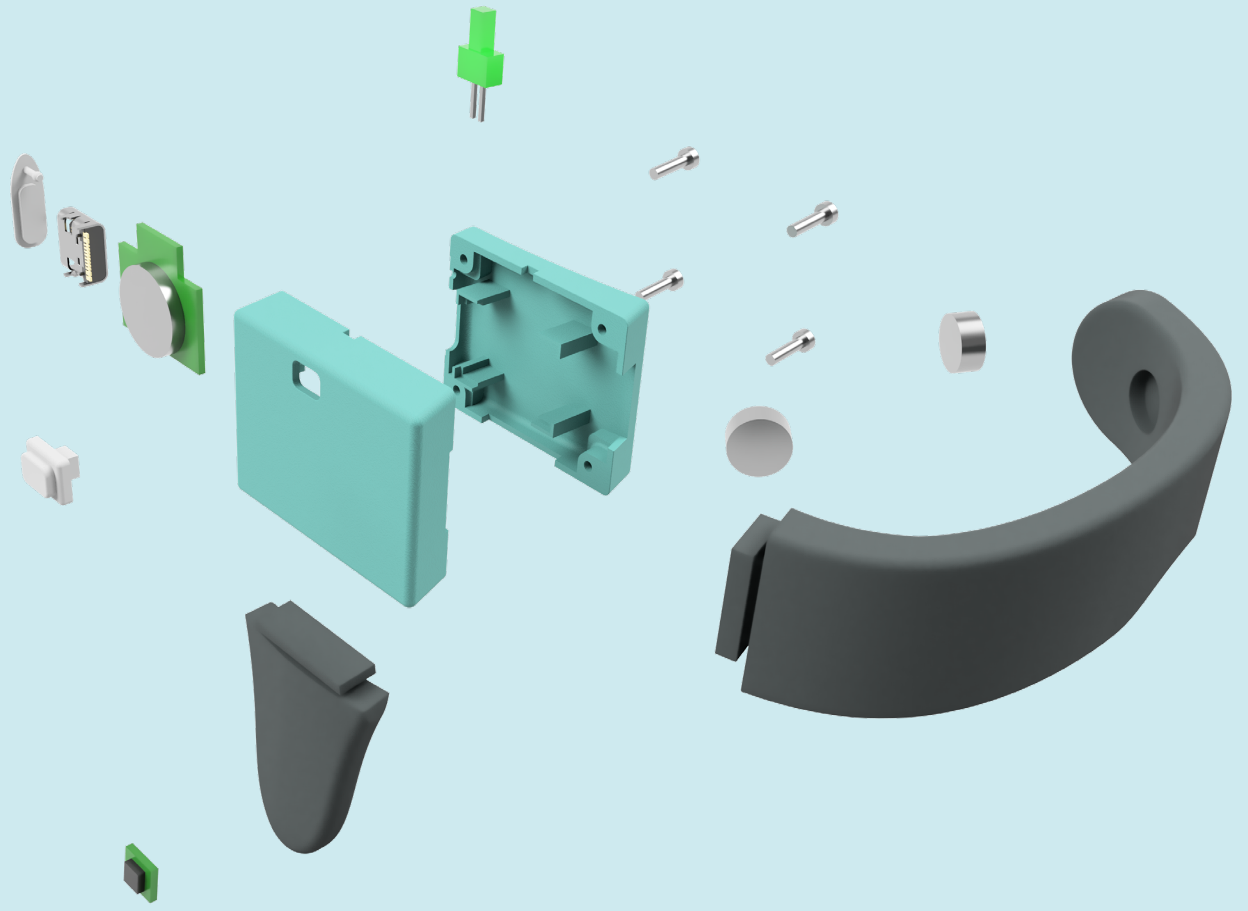
Ankle:
5.5mA *3hrs= 16.5mAh

Battery Capacity= 16.5mAh~ 17mAh

Hip:
.4mA * 75hrs= 30mAh

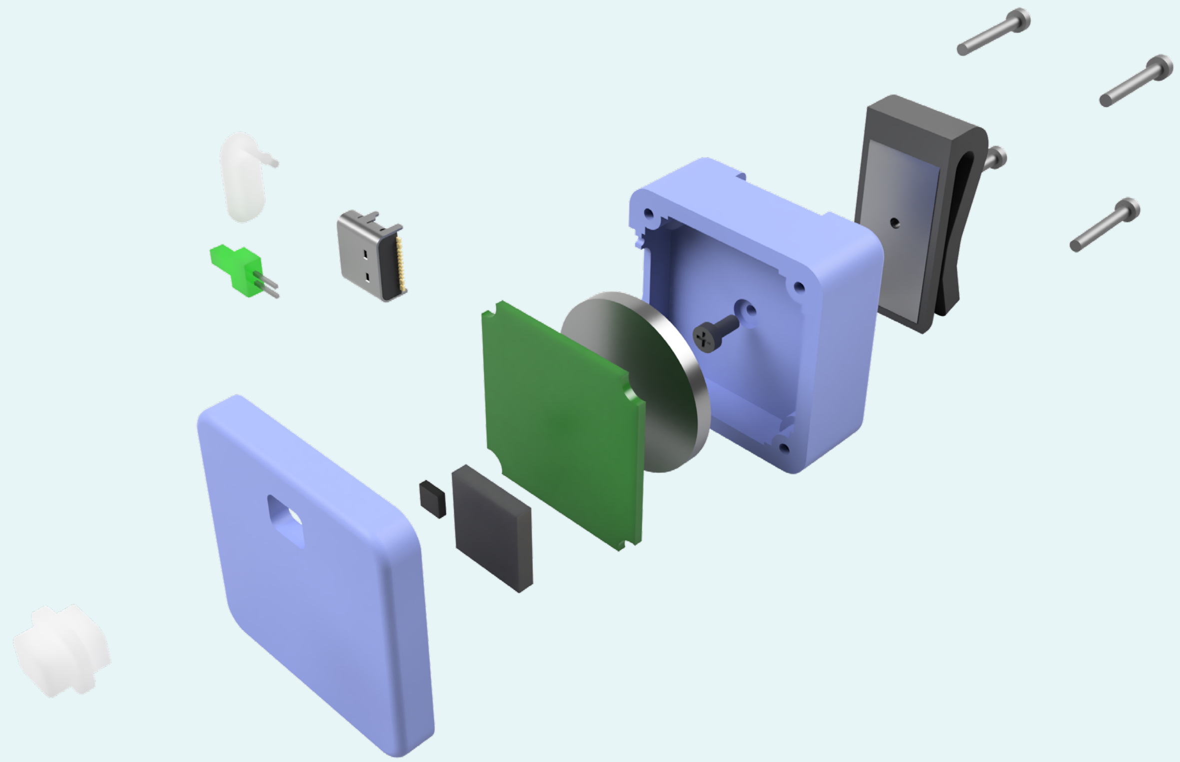
Battery Capacity= 30mAh

parts and assembly

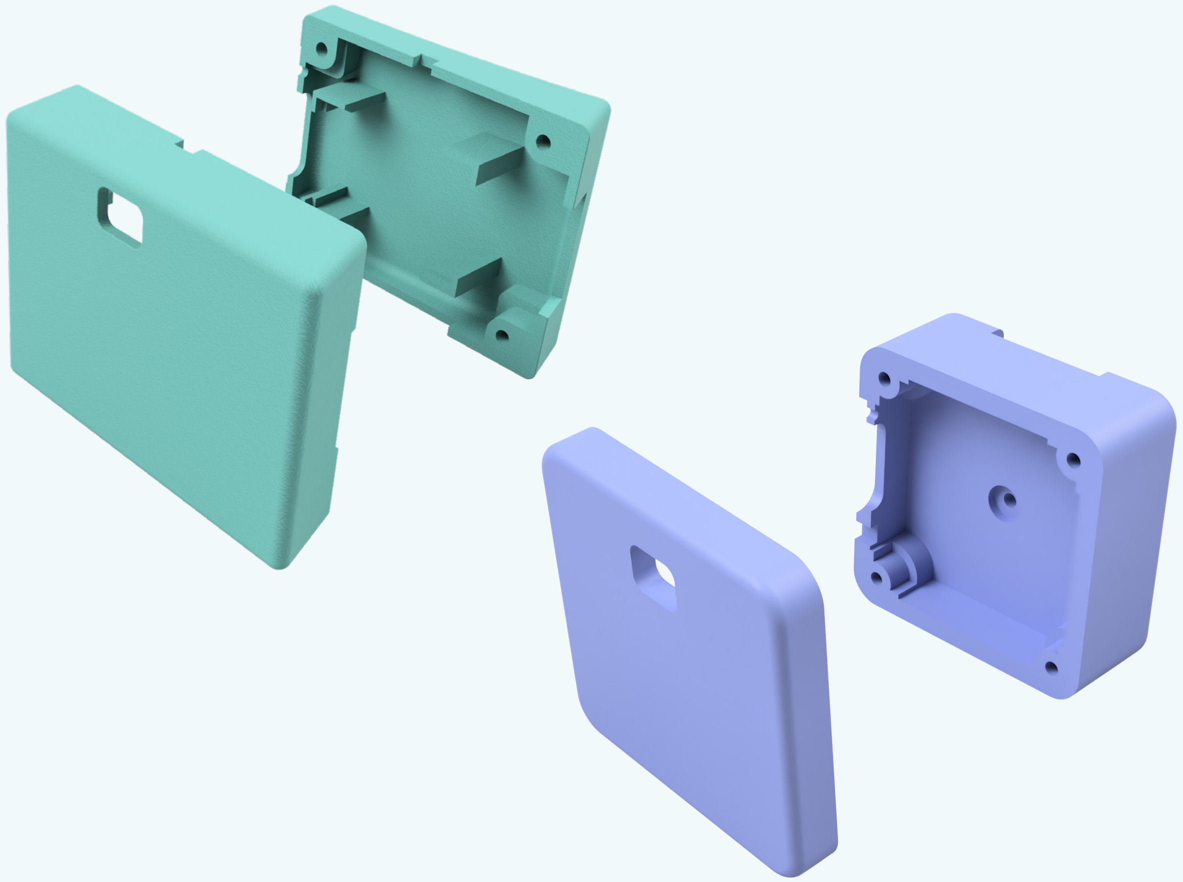


Component	Part Description	Material	Quantity
Front & Back Casing	Casing to house the components	ABS	1
USB Port Type C	To charge the product	N/A	1
3V Battery	17mAh battery	N/A	1
USB Cover	Cover for charging port	Silicone	1
PCB	To mount hardware on to	N/A	1
LED	To indicate charging/ if on or off	N/A	1
Button	To turn product on	Silicone	1
TMP1412-KA18 x4Z Screw	To secure casing	Tempered Steel	4
LRA Housing	To wrap around ankle	Silicone	1
LRA	To stimulate tendon	N/A	2
Sensor Housing	To sit on top of foot	Silicone	1
IMU Sensor	To detect angle of foot	N/A	1

Component	Part Description	Material	Quantity
Front & Back Casing	Casing to house the components	ABS	1
USB Port Type C	To charge the product	N/A	1
3V Battery	30mAh battery	N/A	1
USB Cover	Cover for charging port	Silicone	1
PCB	To mount hardware on to	N/A	1
LED	To indicate charging/ if on or off	N/A	1
Button	To turn product on	Silicone	1
TMP1412-KA18 x4Z Screw	To secure clip	Tempered Steel	1
TMP1412-KA18 x14Z Screw	To secure casing	Tempered Steel	4
Steel Spring Clip	To attach to the belt	Stainless Steel	1
Clip Overmould	To go over the clip	Silicone	1
IMU Sensor	To detect angle of foot	N/A	1
Bluetooth Module	To connect to the phone	N/A	1



materials and manufacture

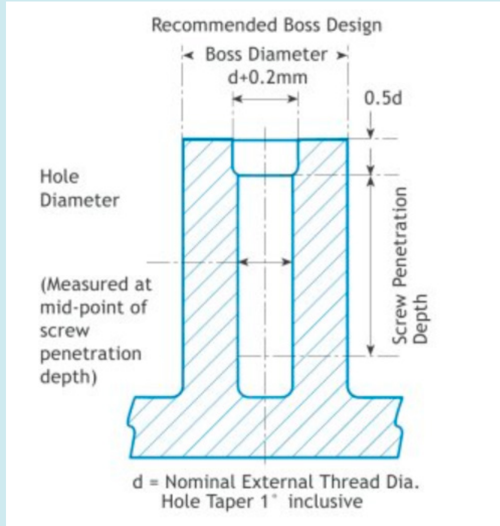


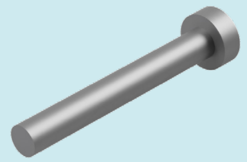
The Casings

Based on its high durability and impact resistance, the casings for each product will be made from ABS, which will allow for the parts to be injection moulded .

Screw Detail

The detailing for the proposed screws has been based on the Direct Screw Fixings Guide.[15] The ideal boss diameter has been incorporated into the design, and the screws themselves have high resistance to vibration





Over-moulding

Silicone will be over-moulded onto 3 components: the LRAs, an IMU sensor, and the spring steel clip.

This over-moulding with silicone will allow for the LRAs and IMU to flex to the dimensions and angle of the foot when in use. The wires for the hardware would also be within the silicone, and be connected to the battery inside the casing.

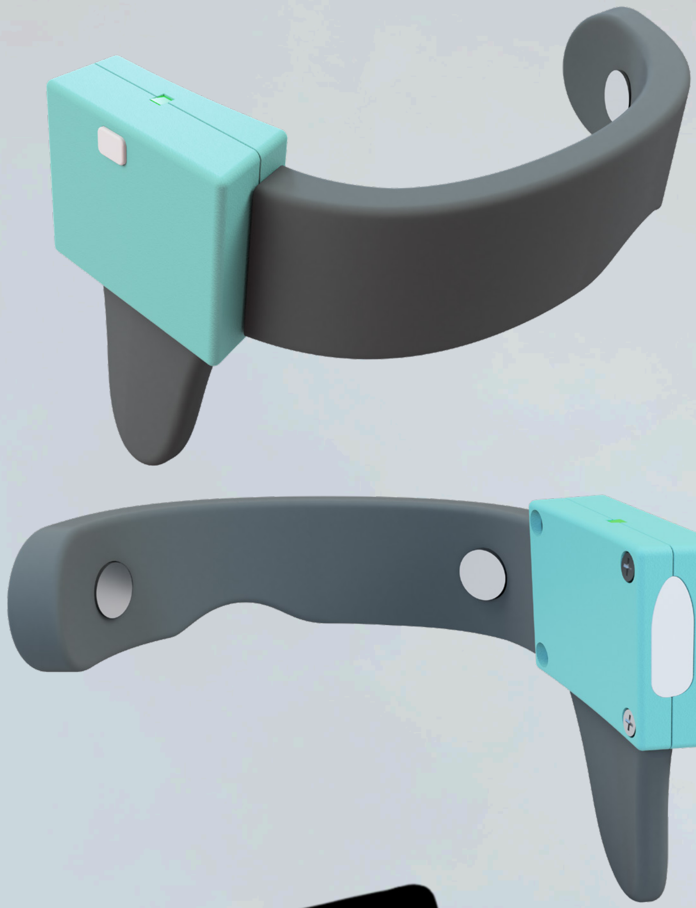
The silicone moulded over the steel clip will help the device be more comfortable for the user to wear. The clip will be affixed to the casing using a 4mm screw, which will then be over-moulded.

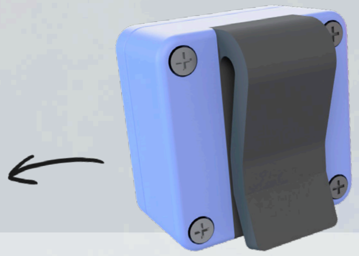
the fatigue toolkit

The Fatigue Toolkit is a collection of products designed to assist the management of fatigue caused by Ehlers-Danlos Syndrome and help target the underlying causes.

The first products are a matching set of devices to be worn on the ankles.

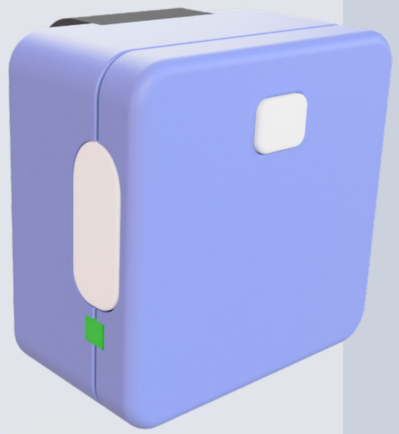
By providing stimulation directly to specific tendons in the ankle, the irregular gait patterns resulting from hypermobility, can be reduced. The device slots into a sock, which will hold it in place on the foot.





The second product is a wearable sensor which will detect the fatigue of the user throughout the day.

This data will be transmitted to an app on the users phone, which will alert them if they are getting fatigued.



The app will also allow the user to input their own symptoms and pain.

The fatigue sensor data along with the user input data will assist the user in learning what triggers their fatigue, and help them avoid it.

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