SUTD x SGH

Patient-Specific Foot Insole Design Project

Group 6 Final Project Report

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1. Overview of Design Process (end-to-end) for (diabetic) foot insoles

The main goal of this project was to come up with a more efficient workflow/ design process for the mass customisation of (diabetic) foot insoles. So for the design process, our team utilized Creaform's handheld 3D-scanner to capture a 3D scan of both feet from two group members – Shaine and Nuryn. The obtained scans were visualised and refined using Creaform's software suite, VXelements and VXmodel (a specific module within VXelements). Each scanning process took an average of 30 min per foot. After which, an STL file was generated and imported into the Grasshopper environment within Rhino (CAD-modelling software), the main tool in our workflow for designing and customising the (diabetic) insoles. The modelling process took an average of 2-3 days to complete. After which, the finalized *working* model was 3D-printed using a P1S Bambu printer using TPU filament. The average printing time was 7 hours per insole. Following printing, the insoles were fitted to the test users. In total, the entire workflow required less than one week to produce a pair of insoles.

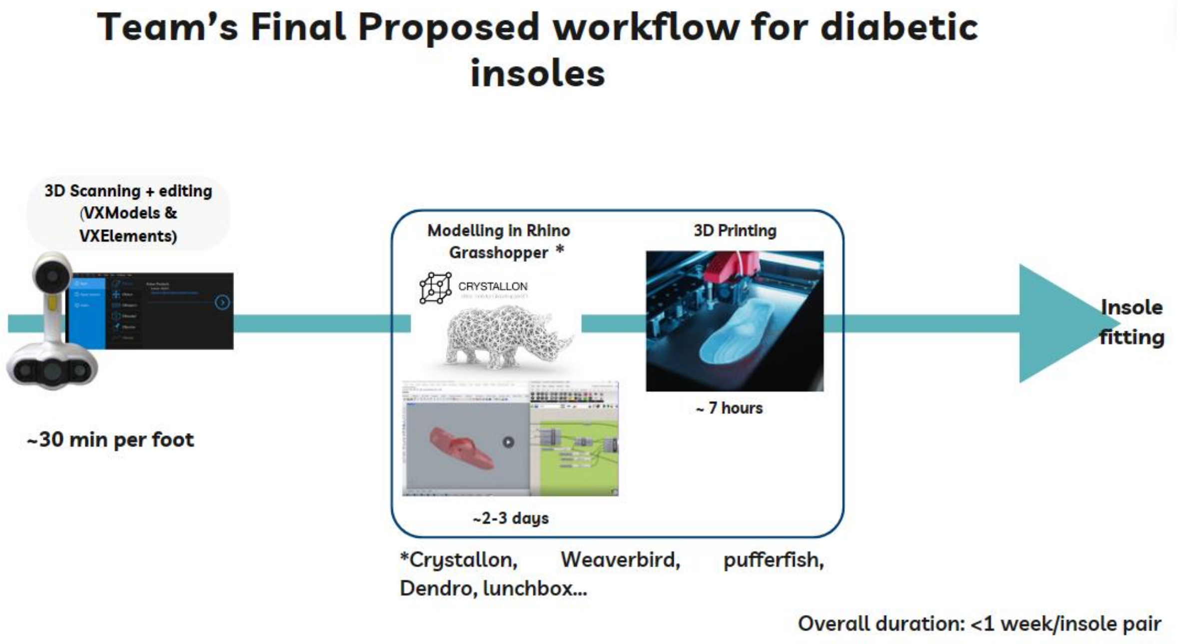


Fig 1: Team's Final Proposed Workflow

2. Step by Step instructions (with optimized times) for:

2.1 Foot Insole Scanning

A. Scanning using an acrylic piece sandwiched between weights

The first attempt of 3D-scanning the foot required the user (Nuryn) to be seated while placing her foot on top of an acrylic platform in a semi-weight bearing position. The whole platform needs to be elevated to allow the scanner to scan the area beneath the foot (insole). To maintain the position, the acrylic piece was sandwiched between weights. As the acrylic is flexible and has much lower strength than other transparent materials like glass, the foot had to be carefully placed in a semi-weight bearing position. This method was time-consuming due to preparation of the setup, difficulty manoeuvring the scanner and random errors during the scanning. The entire process took between 1 to 1.5 hours.

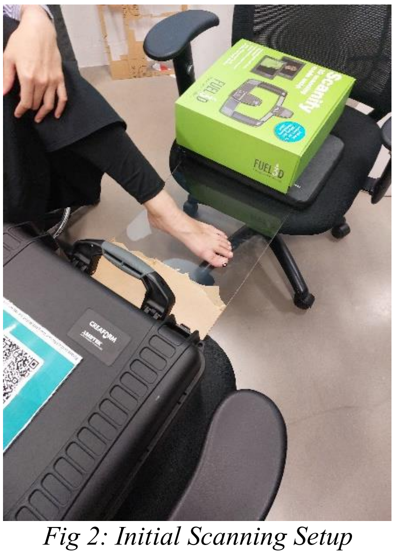


Fig 2: Initial Scanning Setup

B. Scanning using an acrylic stand (optimised)

In the second attempt, we changed to a more stable stand setup. Scanning process remains the same as A (user to be seated/standing while placing their foot on top of an acrylic platform in a semi-weight bearing position) but the new setup resulted in a faster scan time and clearer scan. Thus, less post-scan modifications were required, and the overall process was completed in 30 min.

Fig 3: Optimized Scanning Setup

C. Targets

We placed 3 targets each on the 2 sides, back, sole and the toe area of the foot in triangular manner. In total, we used ~15 targets for one foot. Target positions are shown in black circles.

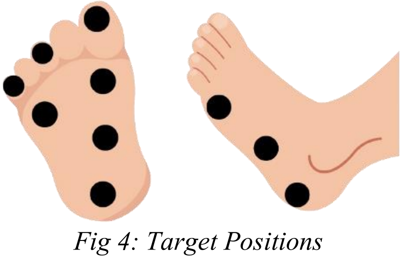


Fig 4: Target Positions

2.2 Foot Insole Design

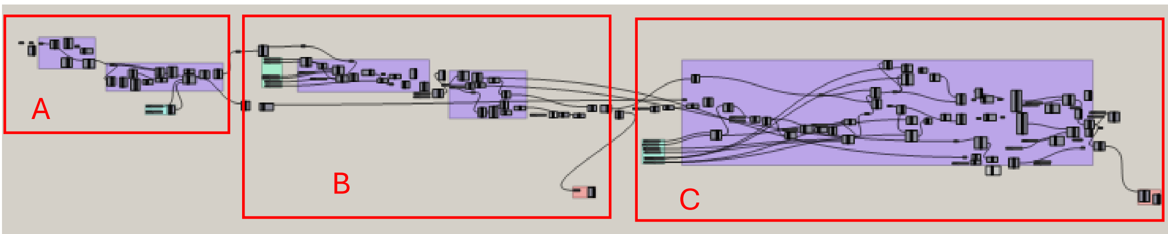
The following program and extensions were used:

- Rhino 7
- Grasshopper plugin (default)
- Pufferfish, Weaverbird, Crystallon, Lunchbox, and Dendro (free plugins)

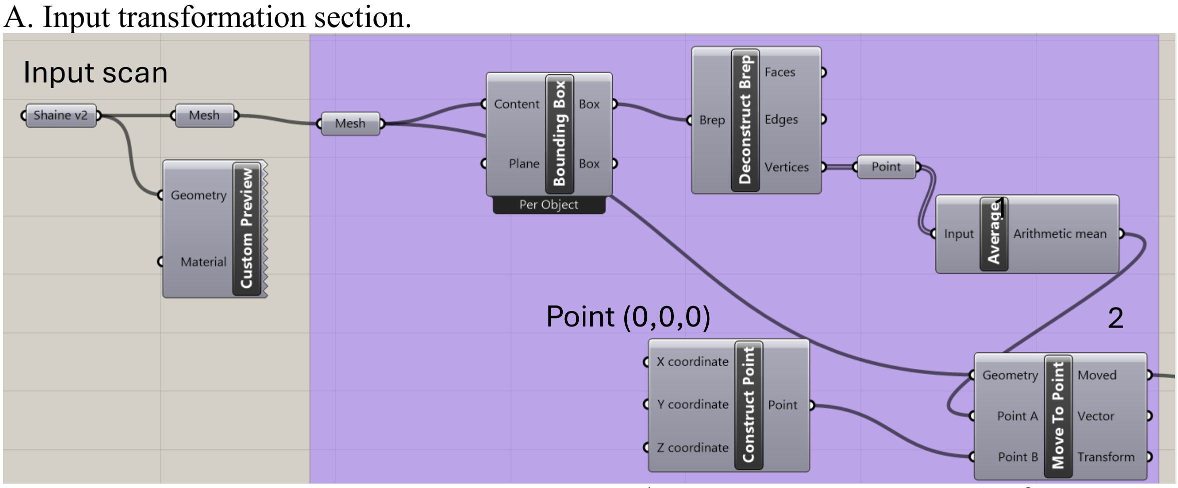
First, open the Rhino file ‘Foot insole.3dm’. In the command tab, type ‘grasshopper’ to open the plugin. Open the Grasshopper file ‘Foot insole.gh’.

<u>Grasshopper script breakdown</u>

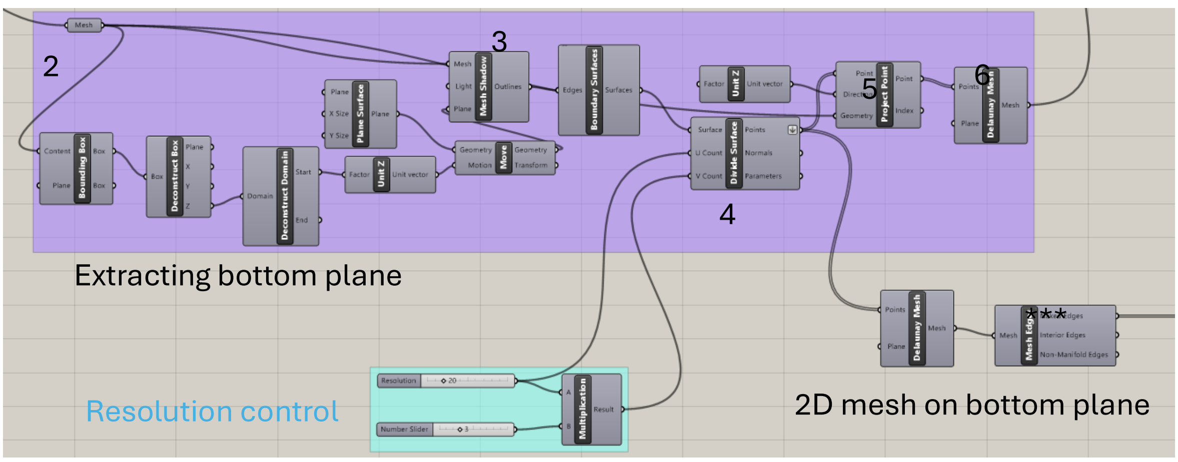
The grasshopper script is made of 3 main portions, input transformation [A], customized topology output [B], and lattice transformation output [C].



A. Input transformation section.

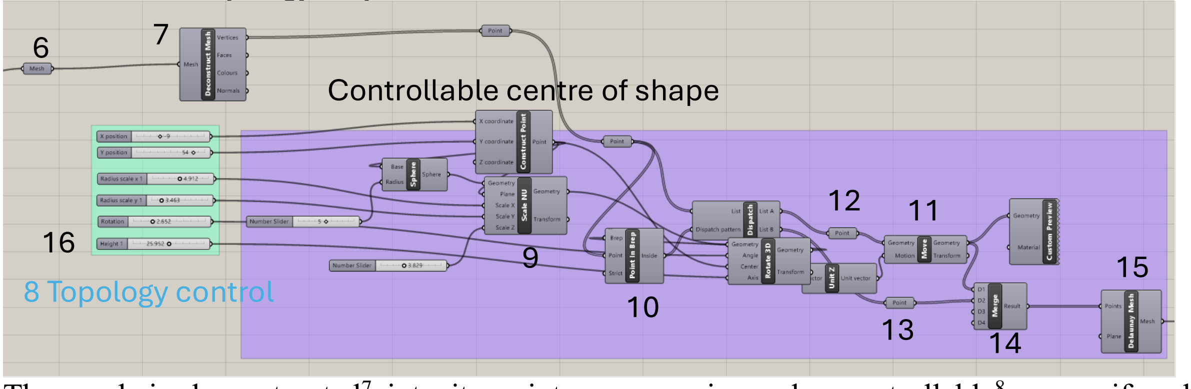


The center of the geometry is found by the average[1] function and is used to move[2] the geometry to the world origin at (0,0,0).



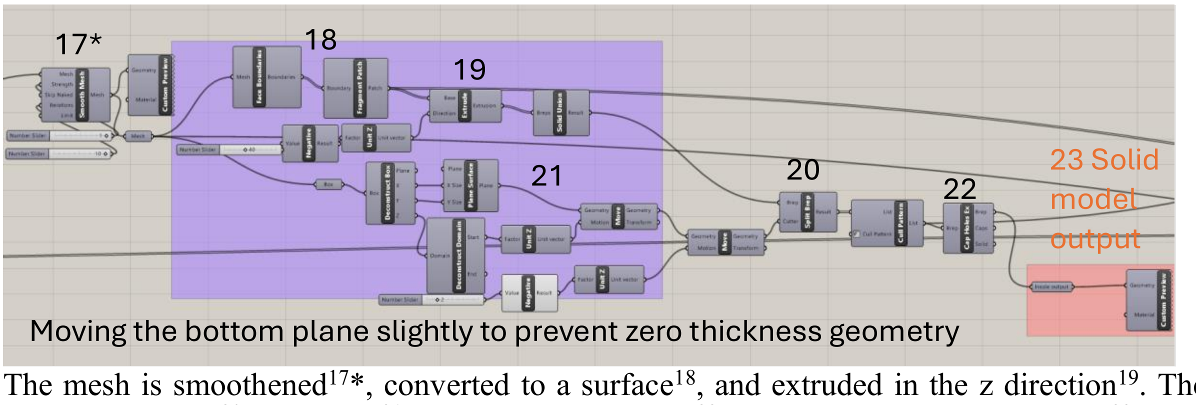
The geometry is projected[3] onto the bottom bounding plane of the geometry. A plane surface is created based on this outline and is divided into normalized UV points[4] (rows and columns). These points are re-projected[5] back to the 3D topology of the geometry and are re-meshed[6].

B. Customized topology output section.



The mesh is deconstructed[7] into its points once again, and a controllable[8] non-uniformly scalable[9] Boolean shape is used to select points[10] of the mesh, which can be given a displacement[11] in the z direction. The transformed[12] and un-transformed[13] points are re-grouped[14], and re-meshed[15] to create the customized topology mesh.

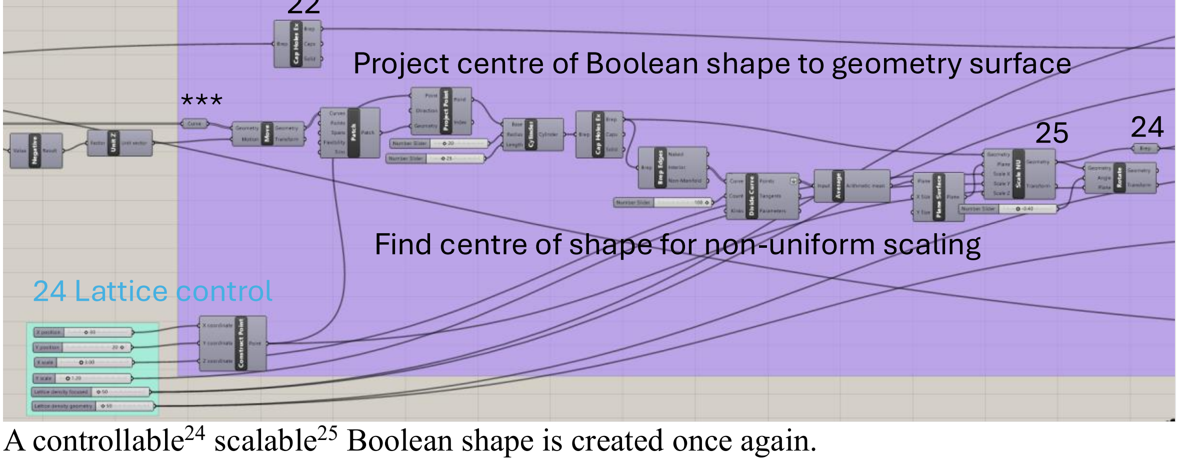
This section can be skipped by setting height = 0 [16] if the customized topology is not required.



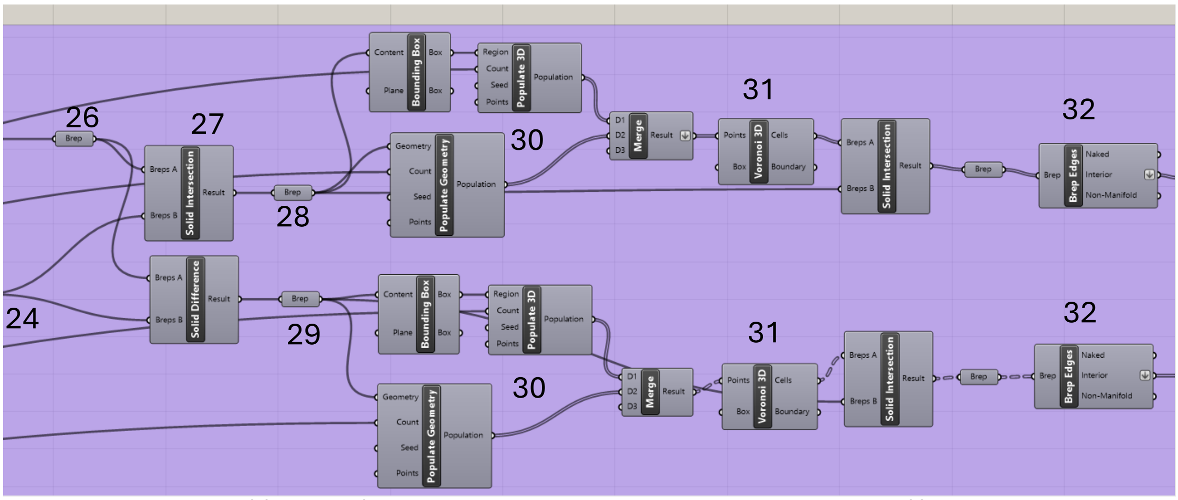
The mesh is smoothened[17]*, converted to a surface[18], and extruded in the z direction[19]. The solid is then split[20] by a plane[21] to give it a flat bottom[22]. This is the solid insole output[23].

**Right click and select 'enable' to toggle program on and off. Useful to easily do topology changes without having to compute the more resource intensive solid model.*

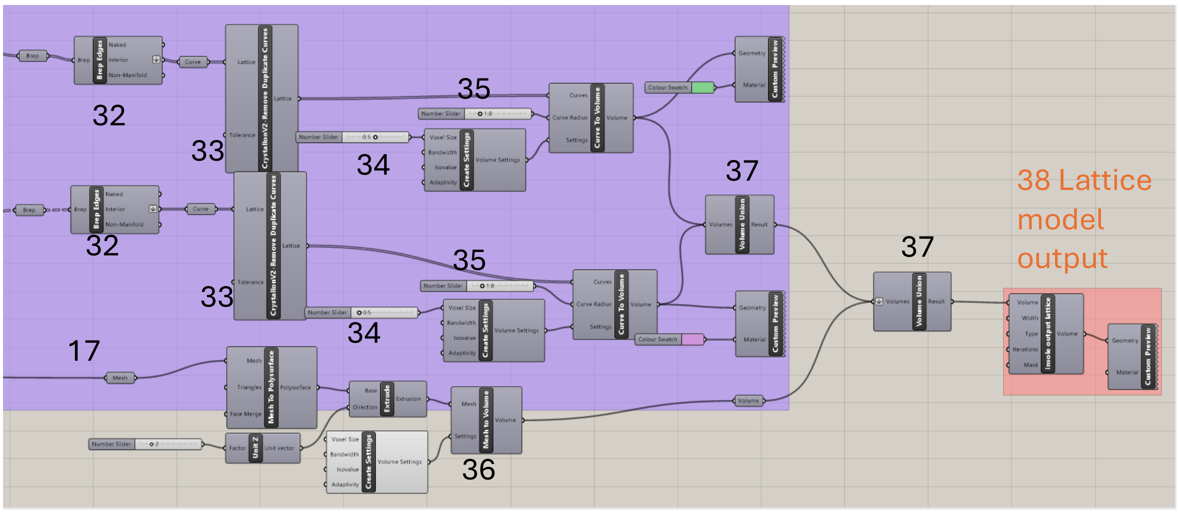
C. Lattice transformation output section.



A controllable[24] scalable[25] Boolean shape is created once again.



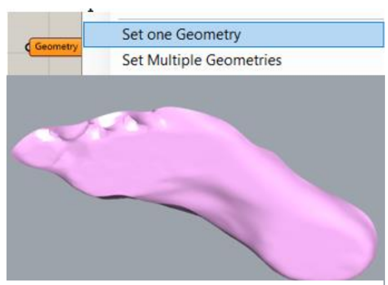
The solid extrusion[26] is spilt[27] by the Boolean shape, to the transformed[28] and un-transformed[29] segments. Both segments are populated with evenly spaced points[30], which are interconnected with lines[31] to form the lattice matrix[32].



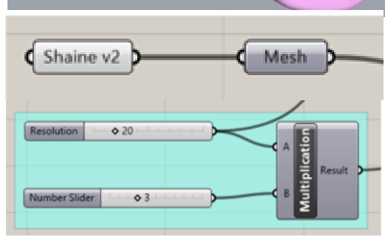
The matrix is cleaned up[33], and given a volume thickness[34] and curvature[35]. The surface mesh of the solid extrusion (from customized topology section) is given a volume[36], and is union together[37]. This is the lattice output[38].

Rhino / Grasshopper program operation

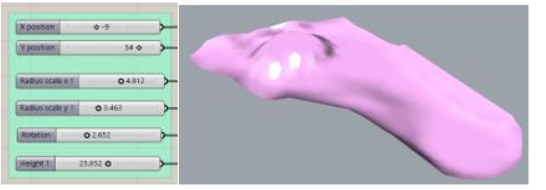
Import the 3D foot scan model into the Rhino environment by typing the command 'import' into the Rhino command tab. In Grasshopper, right click the geometry node, select 'set one Geometry' and click on the imported scan file.



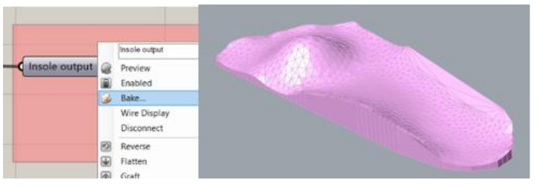
Rename the geometry node (as desired) and connect the input node to the mesh node at the start of the program. The script will now produce the insole output. This takes approximately 1 min, depending on the resolution set. The resolution may be toggled by changing the values on this slider, found in the input transformation section. The default is set to the value 20.



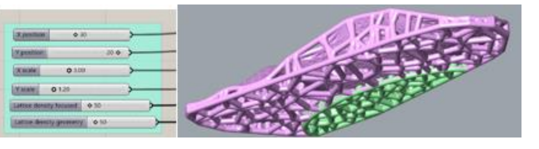
The position, size, rotation, and height of the customized topology (height = 0 if not required) can be toggled by these sliders, found in the customized topology section. It is recommended to customize the topology surface only by disabling the more resource intensive solid model output portion (see 17* above).



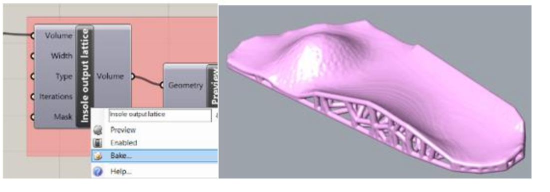
The output insole model with customized topology (if applicable) is produced, select ‘bake’ to transfer the model from Grasshopper to Rhino environment. Type the command ‘export’ and save as STL / 3MF file type.



The position, size, and lattice density for the green (focused) and pink (geometry) can be toggled by these sliders, found in the lattice transformation output portion.



Likewise, the lattice output can be baked to be be exported and saved as STL / 3MF formats in the Rhino enviroment. This takes approximately 2-3 minutes.



2.3 Foot Insole Printing

Polylactide Acid (PLA) was first used with a gyroid infill pattern of 10% and was printed on a Creality Ender-3 V3 KE (Shaine's printer) and a Bambu P1P (Nuryn's printer) to check for sizing upon receiving mesh output from Rhino 7. The infill chosen was 10% Gyroid due to its attractiveness of being low density and cost-efficient yet providing sufficient structural support for the function of insoles while accommodating its flexibility (Lopes, 2023). The main issue faced during the initial results were scaling issues, where the output did not fit the user's foot (refer to images of 1st testing below). The problem was due to omitting a merge of the scan with the edited model on VXmodel, which caused the alignment of the scan to be off axis after exporting the finalized scan to a .stl file. After fixing the issue, the second pair of printed insoles produced much better results for both users (refer to images of 2nd testing below).

User Testing Feedback

After some minor adjustments from the second pair of insoles, Thermoplastic polyurethane (TPU) with a shore hardness of 90A from Yasin was used as the material for the final print of the working model which was printed on a Bambu P1S with the same infill pattern and percentage. Initial results with TPU saw a rough surface finish due to the resolution of the print (initially set to 20), which could be calibrated in Rhino 7. Additional settings were changed in Bambu's slicer software, such as volumetric flow rate set to 2.5mm^3/s, retraction set to none, and the printing speed with overhang was set to 30 mm/s. It was important to note that a constant supply of heat was necessary to allow the TPU to stick to the bed. Therefore, to ensure the best possible print, the bed was set to 80°C with Bambu's **dual-sided textured PEI plate**, extruder set to **240°C** on the first layer and **235°C** on the subsequent layers (according to the specifications of the filament), and the printing was done in an enclosed space with fans speeds at 20%. One pair of insoles consists of an unmodified insole and another that is modified to showcase the implementation of topology from the Rhino grasshopper code.

Initial Prints (Nuryn's Foot): Uneven surface due to blobs & zits

The final prints of the working model were accurate to its printed dimensions +/- 1mm in the slicer. Some comments were regarding the zits found on the surface of the prints, specifically the edges due to the inevitable additional extrusion of TPU after each layer despite the lack of retraction. Prints were occasionally failing (10% of total prints) due to the clogging of the extruder nozzle. A possible deduction could be due to the rate of cooling from the fans, which results in the fluctuation of temperatures and being sub-optimal for the printing of TPU, which is known to be sensitive to surrounding temperature. Another deduction could be due to temperatures being too high, which results in the decomposition of TPU (Wang, 2020). However, the decomposition temperature stated in Wang's paper was found to be 250°C, and while it may vary depending on the material composition of the TPU used, it should not have affected our printing process

Final TPU Print of Working Model (Shaine's Foot): Topology Customization (Left side) vs None (Right Side)

Another print material that was considered was Yasin's thermoplastic elastomer (TPE) with a shore hardness of 85A to investigate the difference of the stiffness of the insoles from the limitations of Shaikh (Shaikh, 2019) and Mancuso's study (Mancuso, 2023). Printing conditions were similar, except for the heat bed which was set to 90°C. However, no successful prints due to adhesion issues of the material to the bed. Potential studies could be further conducted by looking into the applying glue stick to heat bed to create better adhesion, increasing bed temperature further and using a better conducting heating plate such as Bambu's engineering plate.

Lastly, TPU was used to print the lattice models using the same setting as previous working model prints. Various methods were tested to print the lattice structure, such as facing the lattice structure either on the (i) printing bed, (ii) away from the bed or (iii) sideways. A success rate of 16% was achieved only from printing the lattice structure on the printing bed with supports. The reasons for the small success rate are due to clogs and stringing observed on the other orientations, as well as the poor adhesion between the TPU support layer and infill layer, resulting in most of the failed prints. Future studies could investigate the potential of adhesion using a different material as support and better lattice structure designs.

Lattice Structure: Print failure (Top) vs Success (Bottom)

3. Proposal for a ‘Smart’ Foot Insole (one specific approach)

The main inspiration for the proposed “Smart” Foot Insole was the SurroSense Rx developed by Orpyx Medical Technologies (Abbott, 2019) to reduce diabetic foot ulcer recurrence. The product consists of 0.6mm flexible wireless pressure-sensing inserts underneath the patient’s orthotics to measure foot plantar pressure exerted by patients. The insole system detected plantar pressure exceeding capillary perfusion pressure (>35 mm Hg) in real time and were categorised as high, medium, or low. For one intervention group, pressure readings were wirelessly transmitted and stored in a smartwatch (SurroSense Rx, Orpyx Medical Technologies, Calgary, AB, Canada), where data were stored. For the intervention group, when sufficiently high-pressure time thresholds were reached at a specific plantar site, the smartwatch provided audiovisual and vibrational alerts, encouraging the patient to offload by walking around to shift the weight or sitting down to remove the weight of the affected area of the foot.

Alternative solutions employ the usage of temperature sensors to measure foot temperature to identify inflammation (enzymatic autolysis) in patient’s foot tissue caused by the buildup of mechanical stress from walking (Piezoelectric measurement). However, high foot pressure remains the primary risk factor for diabetic foot ulcers and is a more established and effective approach for optimizing insole design compared to temperature monitoring alone. Current solutions that engage temperature sensors are too bulky and often requires a separate physical attachment to connect to the circuit board (Beach et al., 2021 and Khandarkar et al., 2022)

SurroSense Rx, Orpyx Medical Technologies

Hence, based on the following studies, we have incorporated some of the crucial factors for our proposal of our smart device to measure plantar pressure to help reduce the occurrence of foot ulcer for type 0/1 diabetic patients:

1. Important foot detection zones for effective plantar pressure measurements. There should be a greater emphasis on the three largest area of the foot with the highest plantar pressure, which are at the hindfoot, medial forefoot and the central forefoot (Ang, 2018).
2. An easy-to-use independent monitoring system for patients to monitor their own foot health. This allows patients to monitor their own foot health remotely via daily devices such as smartphones or smartwatches to reduce the need constant assistance from the doctors. Some considerations to take note of would be the ease of the use of the interface for all kinds of users, specifically tools that can overcome cognitive and physical issues (e.g. Audio of different language customisability to provide clarity for patients that who have sight issues).
3. A retrievable data collection system to allow data transfer to hospitals or clinics for future consultations with doctors.
4. Cost-effective materials to produce a fast, responsive device to maximise effectiveness for providing relief to patients while remaining affordable for them. An example would

be to compare the use alternative technologies such as Velostat sensors or Optoelectronic-based Fiber Bragg Gratings (FBG) to provide faster feedback response and reliability against the current solution.

4. Conclusions (reflections and learnings)

In conclusion, we managed to achieve our goal of coming up with a more efficient digitised workflow for the mass customisation of foot insoles by leveraging 3D-scanning, 3D-Modelling on Rhino's Grasshopper and 3D-printing. Our assessment from the fitting process confirms that the insoles accurately conform to users' foot geometry and size. However, we have identified key areas for future improvement. Firstly, simplifying the Grasshopper code to reduce complexity and make it more user-friendly is necessary. Secondly, challenges encountered during the 3D printing phase, particularly with TPU filament, necessitate exploration of alternative materials such as PETG for the choice of material for support and refinement of lattice structure designs to mitigate print failures. Addressing these concerns is vital for the success of our workflow and would result in more practical and organic insoles. Moreover, we can improve the insoles even more by adding smart features like foot sensors for better pressure measurement, systems to monitor foot health independently, using smart materials like FBG to enhance the system's feedback response, and incorporating ways to retrieve the data for future doctor visits. Incorporating these technologies into our workflow will not only enhance the competitiveness of our insoles in the market, but also be beneficial for diabetic patients whom the insoles are targeted for.

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