Project Title

Validation Of Lattice Structural Properties Of 3D Printed Insoles for Management Of Diabetic Foot Ulcers Through Mechanical Bench Testing

Project Lead and Members

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Organisation(s) Involved

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Project Period

Start date: 1st February 2023

Completed date: 31st August 2024

Aims

To develop a single-layer multi-density 3D printed insole for pressure offloading in patients with Diabetic Foot Ulcers

The key objective of this project is to determine if early Proof-of-Concept (POC) additive manufactured thermoplastic polyurethane (TPU) with various lattice geometry specifications is comparable to conventional multi-layer thermoplastic foam materials used in custom insoles for DFU through mechanical bench testing.

Background

Offloading modalities form a critical component in the podiatric management of diabetic foot ulcers (DFUs). Customised offloading insoles (orthotic therapy) are often prescribed for patients with DFUs. Such insoles are fabricated by layering multiple single-density sheets of thermoplastic materials into a multi-density structure that provides selective offloading of high pressure areas, and support in force tolerant areas. Offloading insoles fabricated through conventional methods are often bulky and may require to be fitted into orthopaedic footwear, limiting patients' footwear options. Consequently, this can affect patient compliance to intervention.

In recent years, 3D printed insoles have emerged as the next frontier for orthoses product lines. Despite increasing global adoption of additive manufacture thermoplastic polyurethane (TPU) materials in the fabrication of offloading insoles, there is a paucity of evidence demonstrating their effectiveness for pressure relief to facilitate ulcer healing. This project aims to develop a single-layer, multi-density 3D printed offloading insole for patients with DFUs. Such an insole would have reduced bulk compared to conventionally fabricated insoles and able to fit more styles of footwear, with the eventual aim of improving patient compliance and facilitating ulcer healing (Figure 1).

Figure 1. Conventional multi-layer custom-made DFU insole and deep orthopaedic footwear required to accommodate such an insole

This Proof-of-Concept project also seeks to determine if the performance of 3D printed TPUs with variable lattice geometry is comparable to that of multi-layered thermoplastic materials used in offloading insoles through mechanical bench testing.

Methods

Specimen Selection and Preparation

Two control specimens were selected based on conventional materials commonly used by Podiatrists in Singapore for custom-made insoles for DFUs:

1. Control Specimen A: A dual-layer foam material for global pressure redistribution, consisting of 15mm high-density ethylene-vinyl acetate (EVA) (Shore factor 50) and 6mm Conforma material as a top cover (Figure 2).
2. Control Specimen B: A dual-layer foam material for localised pressure offloading, consisting of 6mm Poron material (Shore factor 10) and 6mm Conforma material as a top cover (Figure 3).

Design and Selection of TPU Specimens

Five different TPU lattice structures were developed to replicate the physical properties of the materials used in the control specimens through an iterative design process in collaboration with EOS Singapore Pte Ltd and A*STAR (Figure 4). The initial TPU lattices underwent a subjective evaluation of tactile properties by five podiatrists from Tan Tock Seng Hospital to produce the first iteration of dual-layer TPU specimens comprising of four TPU Specimen A and four TPU Specimen B samples, each made up of different combinations of lattice structures (Figure 5).

Optimization and selection of the TPU specimen designs were conducted based on collective agreement regarding stiffness and material rebound properties. Feedback from the subjective evaluation guided the subsequent iterations of TPU specimen designs. The iterative process was repeated until satisfactory TPU specimens were achieved for benchtesting. Specimen A required two iterations and Specimen B required four iterations to produce suitable samples for bench testing.

Static and Dynamic Mechanical Bench Testing

Three Specimen A and four Specimen B samples met the evaluation criteria for static bench testing to assess their mechanical properties in comparison to the control specimens. Circular samples (100 mm diameter) were prepared for both control and TPU specimens. Samples were affixed between compression plates of a Universal Tensile Machine (UTM) for testing (Figure 6).

In static bench testing, cyclic compressive loading was applied at 1 mm/min up to 80% of the original specimen height. Stress-strain graphs and maximum load tables were generated for each specimen. Young's Modulus graph profiles were compared between Control and TPU specimens to assess stiffness properties and permanent deformation rates. Following static testing, the iterative design process was repeated, with further selection and optimisation of the TPU lattice geometry. Once optimisation was deemed satisfactory, a single TPU Specimen A and a single TPU Specimen B were selected for dynamic bench testing.

In the dynamic bench test, samples underwent cyclic dynamic compression loading of 100,000 cycles at 0.2 Hz, with 40 kg as the lower limit and 200 kg as the upper limit. Shear stress and shear strain values were calculated as follows:

- **Shear stress**: Ratio of shear load to specimen cross-sectional area.
- **Shear strain**: Ratio of change in shear displacement to specimen thickness.

The results of static and dynamic bench testing were analysed to compare the material properties of the 3D-printed TPU specimens against the control specimens.

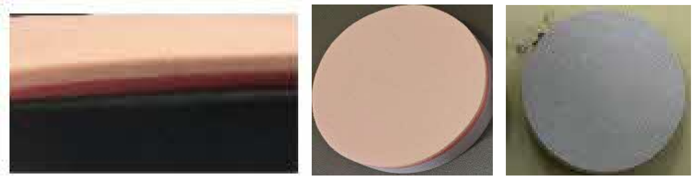


Figure 2. Control Specimen A (Side view, top view, bottom view)

Figure 3. Control Specimen B (Side view, top view, bottom view)

Figure 4. Five initial TPU samples of varying lattice structures developed by EOS Singapore Ptd Ltd and A-star

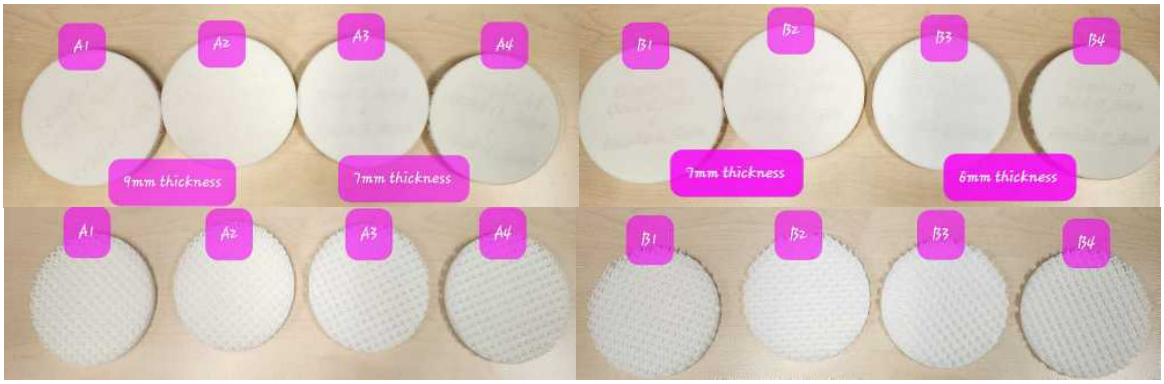


Figure 5. 1st iteration of TPU Specimen A lattice structures (Left) designed for global pressure redistribution and TPU Specimen B lattice structures (Right) designed for localized pressure offloading, shown in top and bottom views.

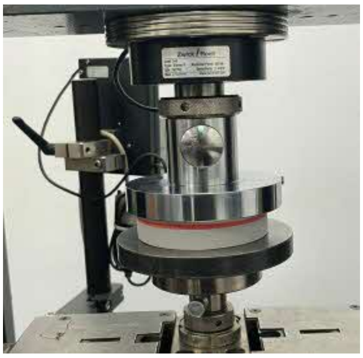


Figure 6. Universal Tensile Machine with specimen sample

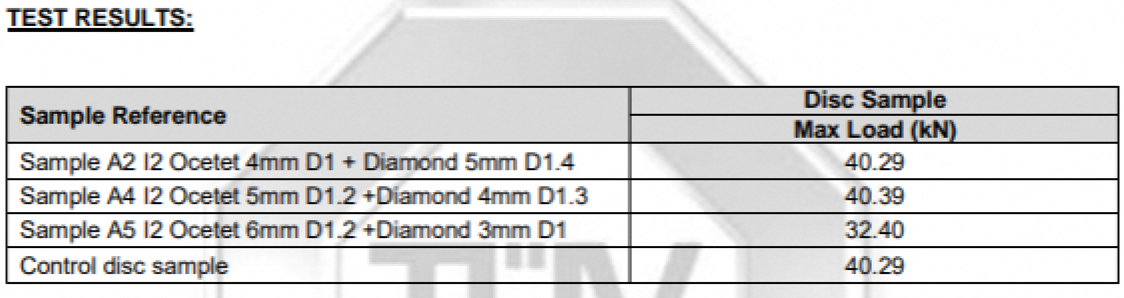
Results

Static Bench Testing

All TPU Specimens A demonstrated comparable durability and stiffness to the control specimen. Control Specimen A exhibited a maximum load of 40.29 kN. TPU Specimens A2 and A4 demonstrated comparable maximum loads of 40.29 kN and 40.39 kN respectively, while TPU Specimen A5 showed a lower maximum load of 32.40 kN (Table 1) . Despite the lower maximum load, the stress vs. crush curve for TPU Specimen A5 displayed the most similar mechanical behaviour to Control Specimen A (Figure 7). All TPU Specimen A samples exhibited distinct behaviour from Control Specimen A, particularly in the 20% to 60% crush segment. Control Specimen A demonstrated low displacement under cyclic loading, indicating high firmness with limited deformation. TPU Specimens A showed greater displacement, indicating less effective support properties. All TPU Specimens A (9mm thick) were about 57% thinner and less bulky than Control Specimen A (21mm thick).

TPU Specimens B demonstrated significantly different mechanical properties from the control specimen. Control Specimen B exhibited a maximum load of 3.94 kN, indicating effective energy absorption under compression with relatively lower force and stress. All TPU Specimen B samples showed significantly higher maximum loads, ranging from 8.01 kN to 15.30 kN, indicating greater resistance to compression as compared to Control Specimen B (Table 2). Stress vs. crush graphs (Figure 8) showed that TPU Specimen B2 most closely resembled Control Specimen B in terms of mechanical behaviour. However, the higher load and stress responses of TPU Specimen B2 indicate increased stiffness, reduced compliance, and lower energy absorption per unit of displacement compared to Control Specimen B, indicative that the TPU alternatives may be less effective at providing selective offloading. All TPU Specimens B (9mm to 10mm thick) were about 40% thinner and less bulky than Control Specimen B (12mm thick).

Table 1: Control Specimen A and TPU Specimen A - Maximum Load (kN)



TEST RESULTS:

Sample Reference	Disc Sample Max Load (kN)
Sample A2 I2 Ocetet 4mm D1 + Diamond 5mm D1.4	40.29
Sample A4 I2 Ocetet 5mm D1.2 +Diamond 4mm D1.3	40.39
Sample A5 I2 Ocetet 6mm D1.2 +Diamond 3mm D1	32.40
Control disc sample	40.29

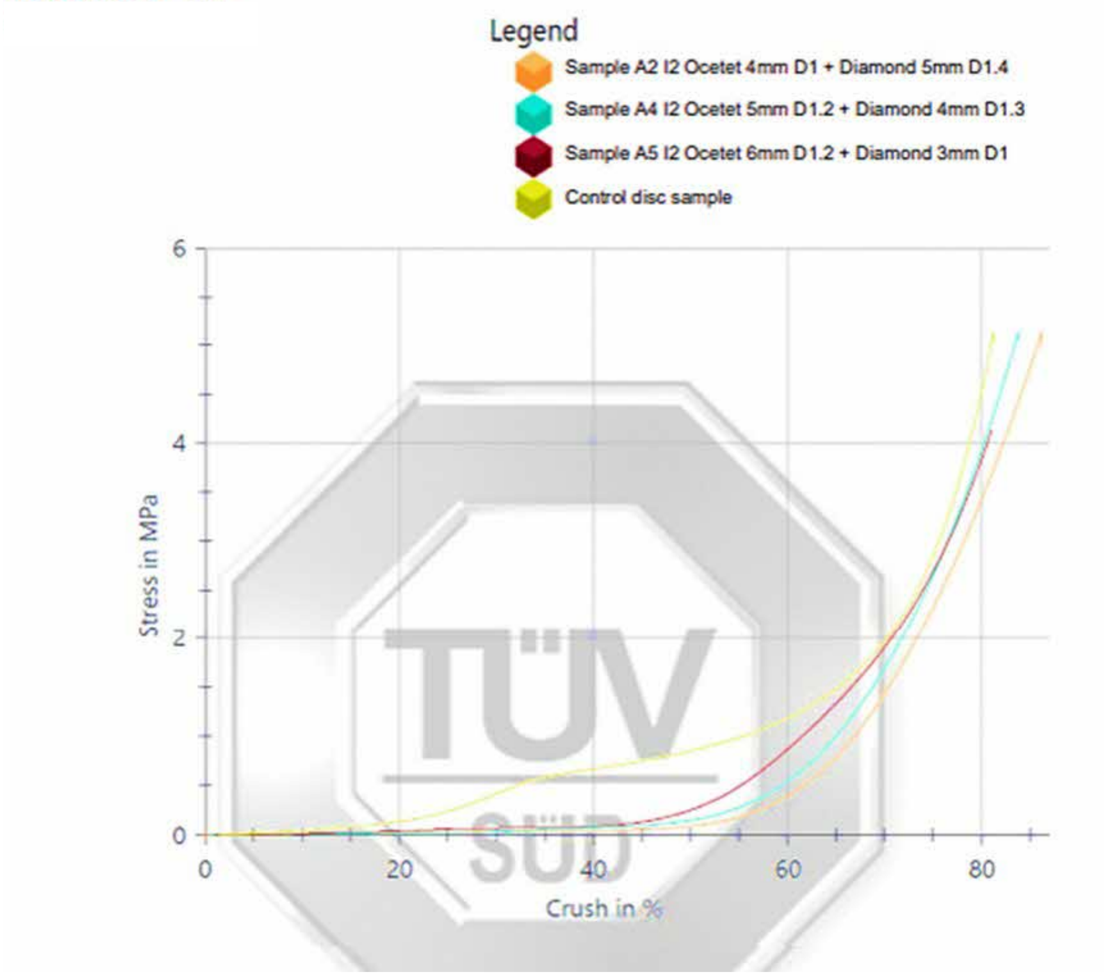


Figure 7. Static Mechanical Benchtesting results for Control Specimen A and TPU Specimen A samples: *Stress versus Strain*

Table 2: Control Specimen B and TPU Specimen B - Maximum Load (kN)

TEST RESULTS:

Sample Reference	Disc Sample
	Max Load (kN)
Sample B1 I4 Skin 1mm + Diamond 8mm D1.4	9.54
Sample B2 I4 Skin 1mm + Diamond 9mm D1.5	8.01
Sample B3 I4 Skin 1mm + Kelvin 8mm D1.4	14.96
Sample B4 I4 Skin 1mm + Kelvin 9mm D1.5	15.30
Control Disc Sample	3.94

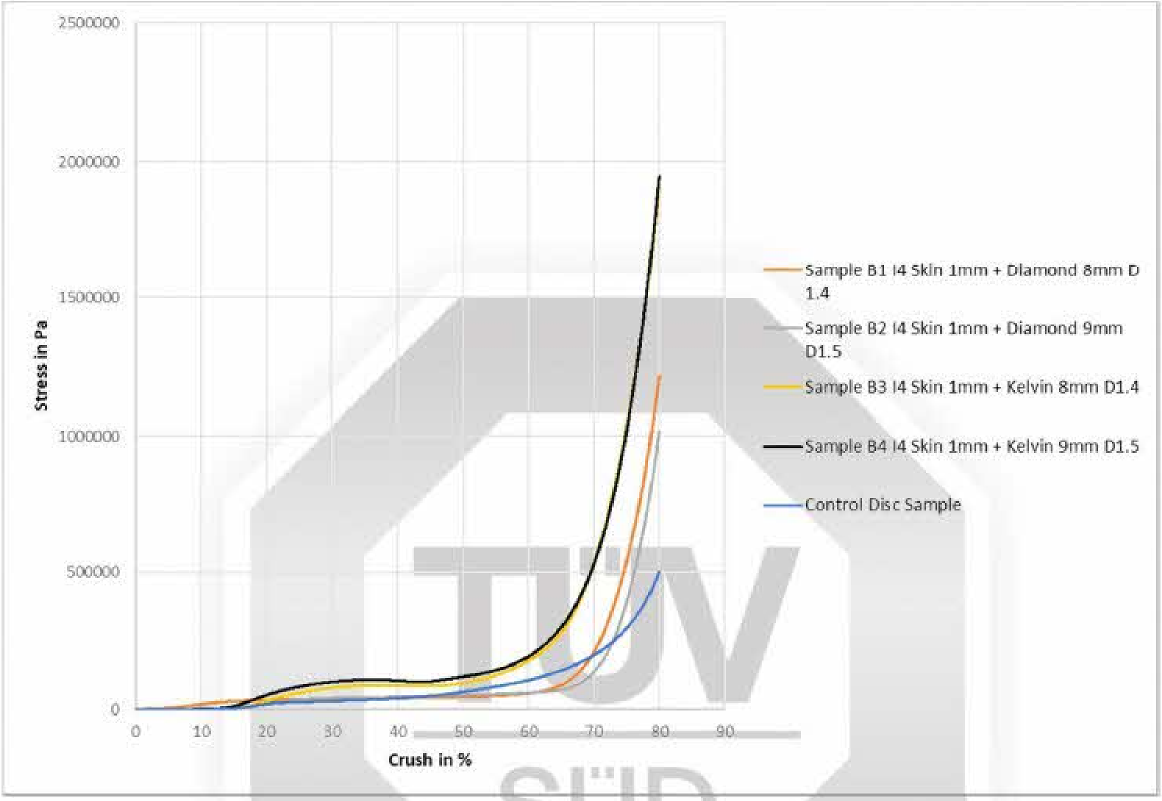


Figure 8. Static Mechanical Benchtesting results for Control Specimen B and TPU Specimen B samples: *Stress versus Strain*

Dynamic Bench Testing

All samples demonstrated similar durability after 100,000 cycles of dynamic compression loading. Both Control Specimens A and B demonstrated less displacement compared to the TPU Specimens. Both Control Specimen A and TPU Specimen Sample A5 exhibited high firmness with minimal displacement (Figure 9), indicating TPU Specimen Sample A5 is a viable alternative to Control Specimen A.

TPU Specimen Sample B2 exhibited poorer cushioning and force dampening properties than Control Specimen B (Figure 10), making it unsuitable as a 3D printed alternative for selective offloading. More work is needed to explore optimisations to lattice structure and geometry for TPU Specimen Sample B to enhance its cushioning properties.

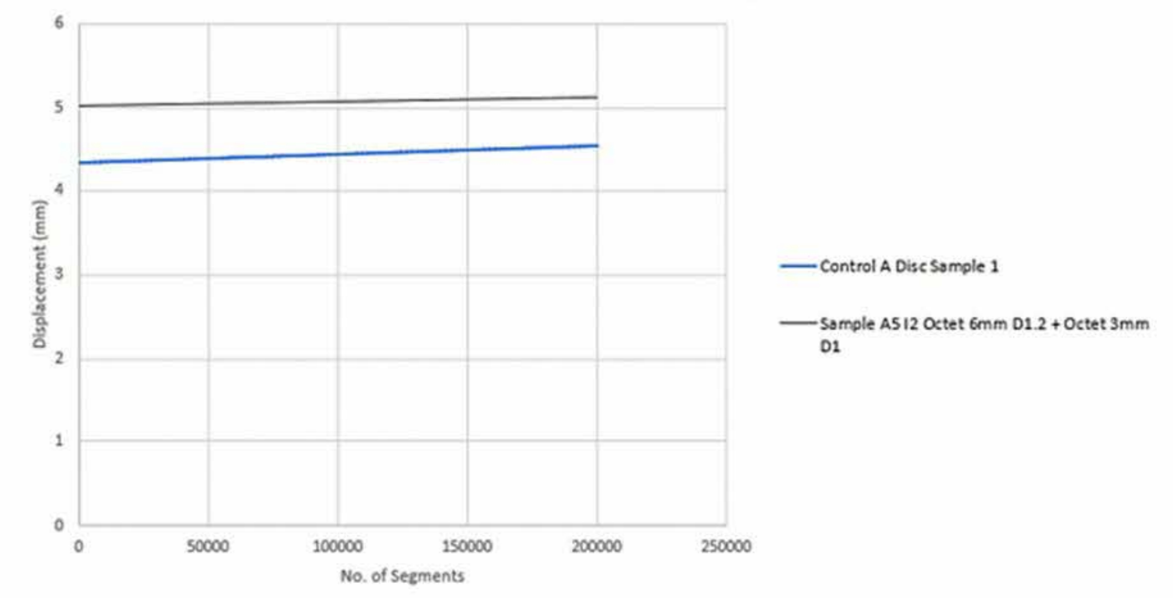


Figure 9. Dynamic Benchtesting results for Control Specimen A and TPU Specimen A5:

Comparison Graph of Displacement versus No. Of Segments

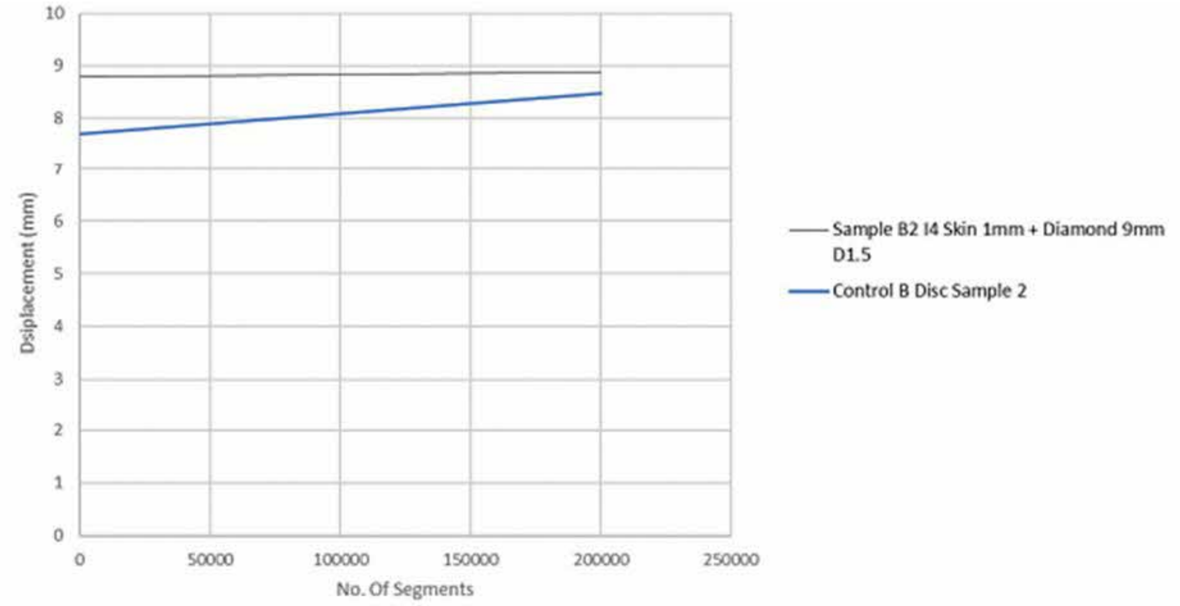


Figure 10. Dynamic Benchtesting results for Control Specimen B and TPU Specimen B2:

Comparison Graph of Displacement versus No. Of Segments

Lessons Learnt

This project, aimed at developing 3D-printed TPU alternatives for DFU insoles, yielded valuable insights into the challenges and opportunities associated with innovative medical device development. The study's findings highlight several key areas for improvement in project management, technical execution, and collaborative processes.

Lattice Structure Design and Material Properties

The project demonstrated the feasibility of combining different TPU lattice structures to achieve desired dual-density material properties that mimic conventional multi-layer materials. The team was able to develop a viable 3D-printed TPU lattice structure for global pressure distribution in DFU insoles through an iterative design process. The TPU alternative is also about 57% thinner than the conventional materials, thus making for a slimmer less bulky device which would be able to fit into a larger variety of shoe designs. More research is required to develop suitable lattice structures for localised pressure offloading. Additionally, the TPU materials were found to be less durable than conventional materials, with increased production costs. More research is required to investigate the long-term durability and performance of 3D-printed TPU insoles in clinical settings to validate their efficacy and cost-effectiveness compared to conventional materials.

Iterative Design Process Optimization

This project saw varying levels of success in developing 3D printed TPU alternatives to conventional materials through an open-design iterative process. The complexity of lattice design variables (structure, cell height, and strut diameter) and how these structures interact with one another in a multi-density structure presented a challenge in developing viable 3D printed materials fit for clinical use within a limited project timeline, with disparities in the project progress for TPU Specimens A and B. While the current project was constrained by time and budget limitations, future studies could benefit from a more systematic approach to exploring these variables.

More research needs to be conducted to investigate the interactions between materials in the lattice structures and their effects on overall mechanical properties. Future projects could conduct preliminary static benchtesting on individual components of control specimens to inform lattice design selection before progressing to multi-layer designs.

Future projects should also establish clear criteria for minimum viable products and define cut-off points for each phase of development. Implementing a standardised evaluation process with quantitative scoring criteria could reduce subjectivity in sample assessment and streamline the iterative design cycle. Additionally, maintaining a focused panel of 3-5 expert evaluators could ensure consistent and timely feedback.

Furthermore, the incorporation of computational modelling and machine learning techniques into the design process to predict optimal lattice designs based on desired material properties, could potentially reduce the number of physical iterations required to produce a minimum viable product. Systematic cataloguing of the various lattice structures and their corresponding mechanical properties into a materials database would facilitate more efficient design iterations.

Vendor Selection and Expert Engagement

Misalignment in team expectations and vendor capabilities posed a challenge during the iterative design process in this project. This highlights the need for more thorough vendor evaluation and selection during the planning phase to ensure alignment of capabilities, timelines, and project requirements. Moreover, the complexity of material behaviour analysis and mechanical testing data interpretation underscores the need for early engagement of subject matter experts. Early involvement of materials scientists and relevant experts could significantly enhance the efficiency of the iterative design process and the accuracy of technical evaluations.

Project Timeline and Risk Management

One of the challenges encountered was the underestimation of project timelines. Unexpected delays in procurement and technical hurdles extended turnaround times from an anticipated 3-4 weeks to 18-20 weeks. Teams embarking on innovation projects should incorporate sufficient buffer time into project schedules to cater for unforeseen challenges. Teams may also implement risk management strategies, such as regular communications with vendors to identify and address potential issues proactively. Adopting a more systematic approach to the iterative design process would also mitigate some of these risks.

Conclusion

In conclusion, this project has demonstrated the feasibility of developing viable 3D-printed alternatives for podiatric clinical applications through an open design iterative process. By addressing the identified learning points and implementing the proposed recommendations, future research teams can enhance project efficiency, improve outcomes, and potentially accelerate the adoption of innovative materials in healthcare applications. The successful development of customizable, less bulky 3Dprinted insoles for DFU patients could significantly impact patient care and open new avenues for personalized medical devices.

Project Category

Tech-Enabled Care

Keywords

3D printing, TPU Lattice Structure, Lattice Geometry, Foot Orthoses for management of Diabetic Foot Ulcers (DFU), 3D printing material properties, Pressure offloading of Diabetic Foot Ulcers, Additive Manufacturing, Benchtesting

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