Transactions on Additive Manufacturing Meets Medicine
Trans. AMMM, Vol. 4, No 1, Article ID 664, 4 Pages

Infinite Science Publishing

Original Research Article

Investigation of additive manufactured Split P TPMS elastomeric structures for diabetic foot insoles

F.R. Claybrook[1*], M. Mohammed[1], and D. J. Southee[1]

[1] *School of Design and Creative Arts, Loughborough University, Loughborough, UK*
[*] *Corresponding author, email: f.r.claybrook@lboro.ac.uk*

Abstract: We present preliminary work optimising 3D printed porous triply periodic minimal surface (TPMS) structures, formed using Thermoplastic Polyurethane (TPU) elastomer with Fused Filament Fabrication (FFF). We examine the compressive properties of a Split P TPMS structure for changes in the unit cell porosity for a fixed unit cell size of 10mm. Preliminary results highlight opportunities to apply Split P TPMS structures made in TPU to mimic properties of medical grade foams typically found in diabetic foot orthotics, and through porosity adjustment, can be tailored across a greater range of compressive strengths. Such structures may find usefulness in creating a new generation of diabetic foot insoles whereby the compressive strength can be tailored to the unique loading conditions of the user.

I. Introduction

Diabetes is a debilitating, lifelong disease which not only impacts blood glucose levels but can result in a range of complications to the skin. More specifically, foot disease can manifest in approximately 6% of people with diabetes and can cascade from nerve damage, infections, ulcers, destruction of foot tissue, amputation and in some cases, mortality [1]. Typical treatments for diabetic foot issues are the use of custom cushioning insoles, which aim to reduce the plantar pressures on the foot, as a person with diabetes typically may lose sensation due to resulting neuropathy. Foam, cork, and polymers are the current benchmark materials for the fabrication medical orthotic insoles in a clinical setting. Despite the volume of use cases for clinical insoles, standardization of manufacturing and the efficacy of use have yet to be realized [2]. In a typical clinical setting, insoles are fabricated by hand and have a limited capacity to adjust the intrinsic mechanical properties of the fabrication material, particularly under compressive loading. Given the unique loading conditions people have based on their natural posture, gait, and body mass; mismatching insole mechanical properties can often mean insoles provide sub optimal solutions for diabetic patients at risk of ulceration. This is further complicated due to deformities of the foot, such as Charcot foot [1]. Insoles with tailored compressive properties can limit the discomfort of ill-fitting, intrusive, and destabilizing medical insole supports that lower conformity of use amongst patients [6]. In practical circumstances, the ideal insole would allow for the compressive cushioning capacity to be adjusted regionally on an insole to match the unique loading conditions during typical gait.

The use of additive manufacturing (AM) and computer aided design (CAD) have seen a growing number of medical applications, and which more recently has been applied to bespoke patient specific orthotics [3, 4] and custom insoles [5]. In a recent study by Chatzistergos *et al. (2020)*, they demonstrated the use of AM to create diabetic foot insoles in a Thermoplastic Polyurethane (TPU) material using porous structures [5]. It was found that there was a direct correlation to the insole stiffness and the percentage porosity of the insole structures. This study highlights that through design consideration the mechanical properties of a material can be adjusted, which provides a viable solution to mimic existing diabetic foot insole materials, while providing new stiffness options. However, designs were limited to compressive loading of between 0.1-0.4 MPa and to a single compressive stress capacity throughout the entire insole.

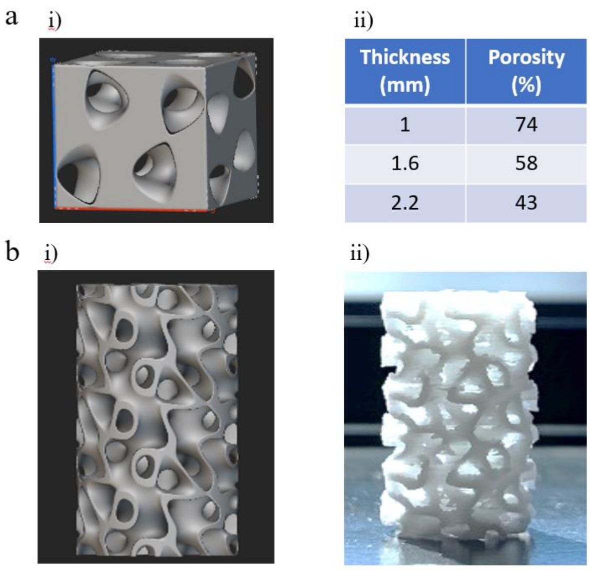
Recent research has seen the investigation of Triply Periodic Minimal Surface (TPMS) structures for the replacement of medical grade foam [7]. In work by Holmes *et al. (2022)*, it was reported that for changes in the internal porosity of Gyroid TPMS structures that the mechanical loading conditions can be tailored to match the compression properties of foams used to make diabetic foot insoles. Their study was limited to the examination of Gyroid structures formed in TPU using Fused Filament Fabrication (FFF) but highlights the potential of elastomeric materials with TPMS architectures to provide alternatives to traditional insole fabrication materials.

Given the limited investigation of elastomeric formed TPMS structures, in this preliminary study, we examine the Split P TPMS structure and its resulting compressive properties for structures printed of varying porosity using TPU elastomer and FFF AM fabrication.

II. Material and methods

II.I Split P Design and Manufacture

Split P scaffold designs were created using nTopology (3.16.3) with a unit cell size of 10mm, which allowed for 3 repeat units in the 30mm structure. To adjust the porosity, the strut wall thickness of the unit cell was set to 1mm, 1.6mm and 2.2mm, creating scaffold with porosities of 74 %, 58 % and 43 %.



Thickness (mm)	Porosity (%)
1	74
1.6	58
2.2	43

Figure 1: a) i) Split P unit cell and ii) a table relating design strut thickness to the final model porosity. b) i) A image of the designed 40% porosity compression sample and ii) resulting 3D print of this design.

Generated designs were converted to STL files, prepared using slicing software (Prusa Slicer, Prusa Research, Czech Republic) and fabricated using the Prusa i3 MK3S+ (Prusa Research, Czech Republic) in a 90A shore hardness TPU polymer (Technology Outlet, UK). Structures were fabricated using a 0.2 mm layer thickness, print speed 45 mm/s, travel speed 180 mm/s, nozzle size 0.4 mm, nozzle temperature 240 °C and bed temperature of 50 °C.

A limitation to the manufacturing of scaffold structures by AM can be attributed to the need for support material and its removal. In the present study the Split P TPMS structure was found to be a self-supporting structure, meaning support material was not required. Additional constraints when manufacturing can relate to the smallest attainable feature size and the extrusion control of the material, which given its elastic nature leads to a dragging of material when the printer nozzle travels between region on a printer part, an effect commonly referred to as ‘stringing’. It was found that the stringing effect could be minimized by adjustment of the retraction settings of the printer head, where a retraction setting of 3 mm removed the majority of the observable stringing on the printed structures.

II.II Compression Tests

Compression tests were conducted to ASTM-D695-15 standard. Tests comprised of 5 repetitions of cylindrical test coupon samples of 15mm diameter and 30mm height. All samples were tested on an Instron 3366 universal testing machine (Instron, UK) with a 10 kN load cell at 1mm/min strain rate.

III. Results and discussion

III.I Mechanical testing

Elastomers comprise complex mechanical properties owing to the deformable nature of the material. Typically, materials will begin to deform with a linear profile before at a critical point the strain begins to increase for a near constant stress, which is characteristic yield point of the material. This is a typical point of densification for compressed scaffold structures, whereby effectively all the designed porosity is removed from the structure. However, for elastomeric scaffolds yielding does not occur and the scaffolds are able to return to their original form, provided there is no hysteresis in the structure. In the present study to compare the compressive properties between the elastomeric scaffolds, we define the maximum compressive stress (MCS) as the point where the porous test structure begins to collapse, while permanent deformation is absent.

Before testing, scaffolds were fabricated to a height of 30mm, in line of ASTM standards for compression test coupons. It was found that post compression that the scaffolds superficially returned to their original form, but the height has decreased to 29mm. We believe this occurred due to the compressive tests going well beyond the compressive yield and into the plastic deformation stress points, which can be seen in Figure 2. However, may also suggest that there may be modest hysteresis in the structures, which was found across all examined porosities.

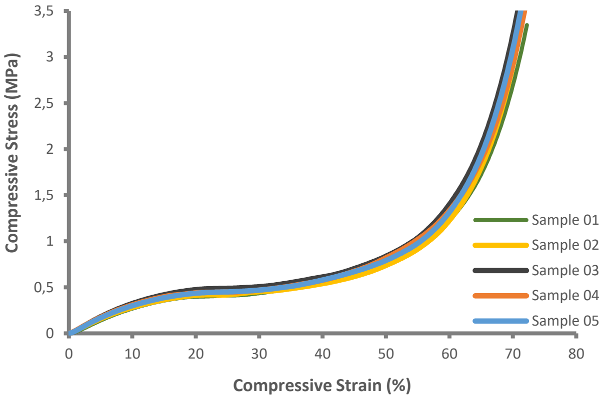


Figure 2 - Stress-Strain curve of 74% porosity Split P.

Following compressive testing, it was found that there was a clear correlation between the porosity and the MCS, whereby increased porosity there was a lower measured MCS (Figure 3a). This was also reflected in the calculations for the Compressive Modulus (CM) (Figure 3b), which imply a reduction in stiffness for increased porosity. It was noted that the calculated error increased for structures with increased porosity for both the MCS and CM. This increase in the error values of the MCS and CM could be attributed to the unpredictable nature of the buckling and twisting of the structures. The structures could have a slight deviation in the interlayer adhesion, which combined could lead to unpredictability in how the structures deform when under compressive load.

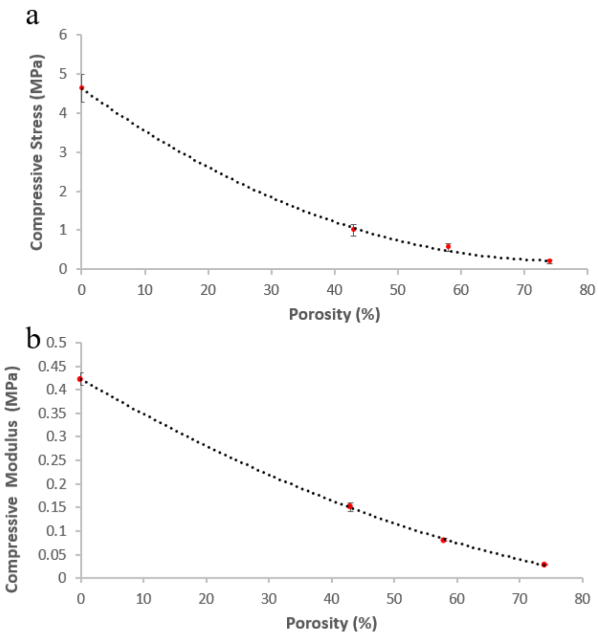


Figure 3: a) Maximum Compressive Stress of the Split P structures for varying porosity and b) Average Compressive Modulus.

A summary of the compressive stress and modulus between the examined structures can be seen in Figure 3. In the study by Holmes *et al.* (2022), it was found that Gyroid TPMS elastomeric structures with a comparable geometry to the Split P structures in this study, had compressive strengths of approximately 0.125 MPa at 10 % strain. Comparatively, the Split P TMPS in this study were found to be approximately 0.2-0.3 MPa indicating twice the compressive stress loading capacity. Comparing this to the compressive properties of typical medical foams, the compressive strength can range between approximately 0.175-0.35 MPa [5]. Therefore, the compressive strength of the TPU Split P structures are within the range of compressive strengths found in clinically utilized foam materials. It has also been found that the compressive strength can be reduced by examining larger unit cell sizes [7].

One additional advantage to the use of AM for insole fabrication compared to the use of foams, are that the compressive properties can be tailored regionally on a given insole. In theory, this can be adjusted and tailored to the unique loading characteristics of the individual. In Figure 4, we showcase a concept of a smart insole, whereby the compressive properties have been adjusted at key contact points of the foot.

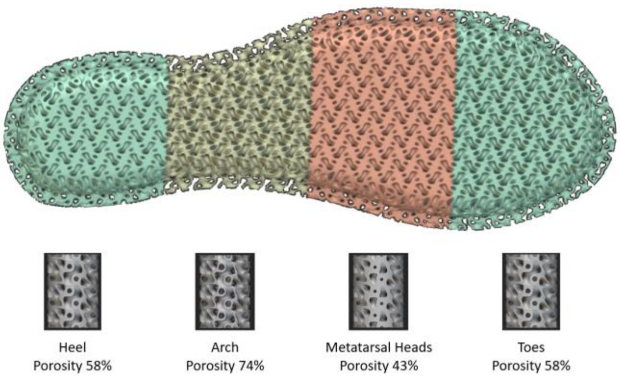


Figure 4: Smart insole concept comprising regional compressive properties by varying Split P Porosity.

IV. Conclusions

The study has identified the potential of Split P TPMS scaffold structures when fabricated using FFF in TPU elastomer as a possible alternative to the use of medical grade foams. There is still a wealth of alternative geometrical configurations which remain to be explored, which may allow for a wider range of attainable compressive strengths to be realized. Our findings are also consistent with reported compressive strengths found in gyroid TPMS structures. Finally, we showcase the potential to create complete insole designs which can allow for the embedding of regional porosities, thereby controlling the loading properties, and resulting cushioning afforded to a person using such an insole. We hope to develop this format further in future work to realize pressure ranges in line with emerging clinical recommendations of below 450-700 KPa [8].

This preliminary study highlights the potential of Split P TPMS structures as an alternative material for insole fabrication in a clinical setting. We hope to examine larger unit cells adopted by TPMS geometries in future work, to understand the full range of attainable compressive properties. However, work remains to identify creep, Mullins effect, and hysteresis of the structures to replicate use under repetitive strain and in an everyday environment.

ACKNOWLEDGMENTS

Research funding for this work was kindly provided by the School of Design and Creative arts, Loughborough University, UK.

AUTHOR'S STATEMENT

Authors state no conflict of interest. Informed consent has been obtained from all individuals included in this study.

REFERENCES

[1] Mishra, S. C., Chhatbar, K. C., Kashikar, A. and Mehndiratta, A. (2017) - Diabetic foot - BMJ; 359, https://doi.org/10.1136/bmj.j5064

[2] Mendes, A. A. M. T., Silva, H. J. de A., Costa, A. R. A., Pinheiro, Y.T., Lins, C. A. de A., & de Souza, M. C. (2020). Main types of insoles described in the literature and their applicability for musculoskeletal disorders of the lower limbs: A systematic review of clinical studies. In *Journal of Bodywork and Movement Therapies* (Vol. 24, Issue 4, pp. 29–36). Churchill Livingstone. https://doi.org/10.1016/j.jbmt.2020.06.001

[3] Mohammed, M. and Elmo, F. (2020). Digital design and fabrication of controlled porosity, personalized lower limb AFO splints. *Transactions on Additive Manufacturing Meets Medicine*, *2*(1).

[4] Mohammed, M.I. and Fay, P., 2018. Design and additive manufacturing of a patient specific polymer thumb splint concept. In *2018 International Solid Freeform Fabrication Symposium*. University of Texas at Austin, pp. 873-886.

[5] Chatzistergos, P.E., Gatt, A., Formosa, C., Farrugia, K. and Chockalingam, N., 2020. Optimised cushioning in diabetic footwear can significantly enhance their capacity to reduce plantar pressure. *Gait & Posture*, *79*, pp. 244-250.

[6] Guldemond, N. A., Leffers, P., Schaper, N. C., Sanders, A. P., Nieman, F., Willems, P., & Walenkamp, G. H. I. M. (2007). The effects of insole configurations on forefoot plantar pressure and walking convenience in diabetic patients with neuropathic feet. *Clinical Biomechanics, 22(1), 81-87 https://doi.org/10.1016/j.clinbiomech.2006.08.004*

[7] Holmes, D. W., Singh, D., Lamont, R., Daley, R., Forrestal, D. P., Slattery, P., Pickering, E., Paxton, N. C., Powell, S. K., & Woodruff, M. A. (2022). Mechanical behaviour of flexible 3D printed gyroid structures as a tuneable replacement for soft padding foam. *Additive Manufacturing*, *50*. https://doi.org/10.1016/j.addma.2021.102555

[8] Korada, H., Maiya, A., Rao, S. K., & Hande, M. (2020). Effectiveness of customized insoles on maximum plantar pressure in diabetic foot syndrome: A systematic review. In *Diabetes and Metabolic Syndrome: Clinical Research and Reviews* (Vol. 14, Issue 5, pp. 1093–1099). https://doi.org/10.1016/j.dsx.2020.06.041