

Design rules for additively manufactured wrist splints created using design of experiment methods

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Abstract: Research has shown that wrist splints can be made using Additive Manufacturing (AM) with a similar or greater performance than splints created using traditional manufacturing methods. By using AM, many of the problems associated with traditional splinting such as poor aesthetics and poor ventilation could be mitigated. However, work to date typically reviews splints with singular pattern designs (e.g. Voronoi patterns), which have structural and safety implications if similar but untested patterns are created. Using Design of Experiments (DOE) design rules were to enable clinicians to confidently design splints alongside their patients.

Design rules were created by investigating variables of cut out patterns using DOE methods. Finite Element Analysis (FEA) of various combinations of cut out variables was conducted.

Keywords: Additive Manufacturing, Wrist Splints, Finite Element Analysis, Design of Experiments

1. Introduction

Wrist splints can be recommended for a number of wrist pathologies including wrist trauma, such as fractures or sprains, or long term conditions such as arthritis or Carpel Tunnel Syndrome (1). The aim of the splint in these cases is to provide protection and stabilisation to the affected joint, and in some cases correction or prevention of deformities (2). Wrist post-surgery recovery can also benefit from splints to assist with rehabilitation by promoting movement in a controlled manner or through restricting movement of other more mobile joints (1).

Most custom-made wrist immobilisation splints (Figure 1) are fabricated using Low Temperature Thermoplastic (LTT).



Figure 1: Traditional, custom-made wrist immobilisation splints (3)

This traditional splinting process can be very time consuming, and does not always guarantee a satisfactory splint. Furthermore, patient adherence is often a problem (4,5), sparking the need to improve the process and subsequently the outcome.

There are many ways that Additive Manufacturing (AM) can be used to improve the quality of life for someone who needs to wear a splint including making splints easier to clean, more aesthetically pleasing and more breathable by utilising lattice type structures, and using scan data could allow for a perfect fit.

Whilst there have been a number of examples of AM splints (6–9) which have proposed improved aesthetics and ventilation in recent years, there are currently no known design rules specific to splinting which can help guide clinicians to design safe, reliable splints with minimal displacement under reasonable load for AM. It has been proposed by Paterson (10) that the traditional splinting process be replaced with a digitised method. By doing this, the advantages possible with AM as discussed above could be utilised and the manufacturing process taken away from the clinician, allowing them to spend their time and their expertise to design the splint with the patient creating a sense of co-design; this is a strategy (i.e. co-design) developed to increase patient adherence (11).

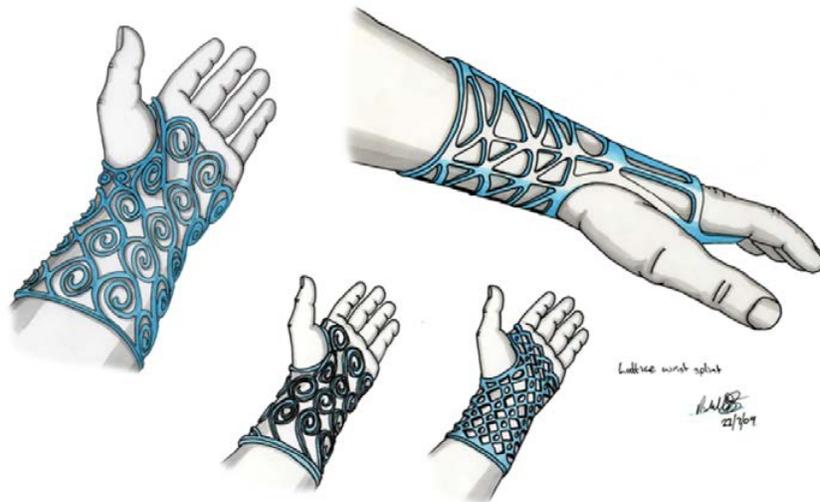


Figure 2: Sketches showing the possibilities to customise the lattice structure [Image courtesy of Richard Bibb 2009]

Giving the power of design to patients should lead to greater compliance but leaves the clinician unable to account for all of the new variables within the design process and therefore unable to guarantee a structurally sound splint.

Although previous work has shown that AM is a real solution to some of the problems discussed previously, most of the work (12–14) consist of testing on one singular cut out pattern. The process of digitising the splinting process is one that requires many aspects to change drastically, from data capture to creating a computer program to allow the clinician to

design the splint, to selecting the right AM process. This research focuses solely on the relationships between the cut-out pattern of a splint and the corresponding displacement under loading.

To continue to bring digitised splinting closer to realisation two studies investigating various factors and their effect on the displacement response have been conducted. The first study screening for significant factors and the second optimising factors, both studies have been conducted using FE (finite element) analyse and DOE (design of experiment) methodology.

As it is expected that variations in cut out patterns of an AM splint have a direct impact on the mechanical properties of a splint, the DOE method was used to identify optimal cut out pattern parameters. The DOE methodology has been applied widely for optimising parameters in many fields.

2. Aim

The aim of this paper is to generate design rules that allow for the creation of splints, with minimal displacement when loaded, through a digitised splinting process for production using Additive Manufacturing. This will be achieved by identifying factors that are significant to the displacement response. A screening study will identify ideal factors and these factors will be optimised in an optimisation study.

3. Material and Methods

Only static wrist immobilisation splints will be considered for this study as they are the most commonly prescribed splints (15) for a wide range of conditions including a sprained wrist, rheumatoid arthritis and carpal tunnel syndrome. This type of splint was also chosen as it is the most simplistic splint type biomechanically.

3.1 FE Model

As custom-made splints are made to fit each individual patient the topography (overall form) of the splint can vary significantly; this in turn would result in varying results with little/no chance of generalisability across testing. Therefore, it was decided to use a simple overall geometry of a cylinder to represent a splint. This helps to remove any variability from the analysis that would come from the bespoke shape of individual splints.

This cylinder was created using anthropometric data as a guideline (16). Traditional splinting dictates that a splint is two thirds the length of the forearm (17). Anthropometric data was used to gather the length of an average female palm and forearm. This was used to create the dimensions of the cylinder used; 200mm length, 25mm inner radius, and wall (i.e. splint) thickness was dependant on the nature of the study conducted.

The geometries used in this study were created in Rhino (Version 5, Robert McNeel & Associates, Barcelona) using the Grasshopper plugin (Version August-27, 2017, Robert McNeel & Associates, Barcelona). This was used to easily create various geometry in a semi-automatic fashion.

This geometry was then imported into Solidworks Simulation for FE analysis (Solidworks 2016, Dassault Systèmes SolidWorks Corporation, Tennessee). An automatic mesh generator was used with a h-adaptive meshing method. A minimum convergence rate of five percent

was set. The element type was tetrahedral 3D solid elements. Mesh coarsening was used to reduce computational time.

3.2 Material properties

Polyamide 12 (PA12) was the chosen material and a linear elastic isotropic material model was used. This was used as it was predicted that all deformation would occur within the elastic range. Material properties were taken from a Materialise data sheet of Laser Sintered PA12. This material and process were chosen as it is one of the most likely AM process to be used in AM splinting.

3.3 Boundary conditions and loading convictions

In an effort to replicate the wrist joint, the cylinder was constrained in the “forearm” region (Figure 3). A torque was applied to the “palm” region to replicate wrist flexion (Figure 3). This is the most dominant wrist movement.

This torque was 3Nm, a value chosen as it is similar to half the maximum value of an average adult male (18) and is also the value used in many wrist brace testing standards (19,20). This value was deemed sufficient as a wrist splint is used as a movement deterrent, unlike sport braces where the wearer may try to get the maximum range of motion out of the splinted joint.

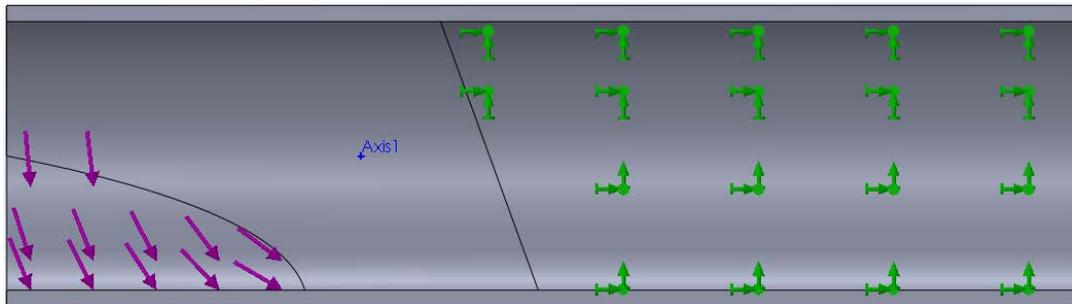


Figure 3: FEA boundary conditions on cross section of cylinder. (Torque depicted in purple, constraint depicted in green)

4. Screening Study

The objective of this study was to investigate how variables within a cut-out pattern affect the stiffness of a splint. A general factorial study was designed with four factors including the ratio of cut out volume to volume of material in the splint, the frequency of the cut outs, the shape of the cut out, and the configuration of the cut outs.

‘Cut out shape’ refers to the shape of the perforations. This factor was chosen as this is one of the main variables patients are thought to want to change.

‘Ratio’ refers to the ratio of the cylinder volume to material removed. For example, a full cylinder with no cut outs would have a ratio of 0 and a cylinder with half the material removed would be 0.5. Ratio was considered as one of the factors to be considered as having a splint with controllable volume could help with heat distribution and make the splint more lightweight.

'Frequency' is the second continuous factor and refers to the frequency or number of cut outs. This factor is included in this study as a single ratio value can be created with many small cut outs or fewer large ones. Again this factor was deemed worthy of investigation as it could be helpful when trying to control heat distribution.

The last factor investigated in this study is 'Cut out Configuration'. This refers to the arrangement of the cut outs on the cylinder; i.e. what pattern they are arranged relative to the surface of the cylinder. This is to investigate if a configuration can be manipulated to control the displacement of the cylinder under loading. As per fractional design methodology, a high and a low level were chosen for each continuous factor. All factors and their levels can be seen in Table 1

Fact ors		Levels	
A	Ratio	2	0.16, 0.5
B	Frequency	2	12, 108
C	Shape	3	Circle, Square, Diamond
D	Configuration	2	Linear, Diagonal

Table 1: Screening Study Factors and Levels

As per DOE methodology a high and a low value for Ratio and Frequency level was tested, these values seen in Table 1 were selected arbitrarily as a starting high and low points for this work.

The three shapes levels were chosen to evaluate the greatest representation of stress concentrations in the east amount of interactions. The circle is a shape that is widely known to have less stress concentrations, where as a square or diamond has a 90 degree corner, which is likely to cause higher stress concentrations and also both allow for more uniform struts between the cut outs.

Configuration levels were linear and diagonal. These variations are depicted in Figure 4.

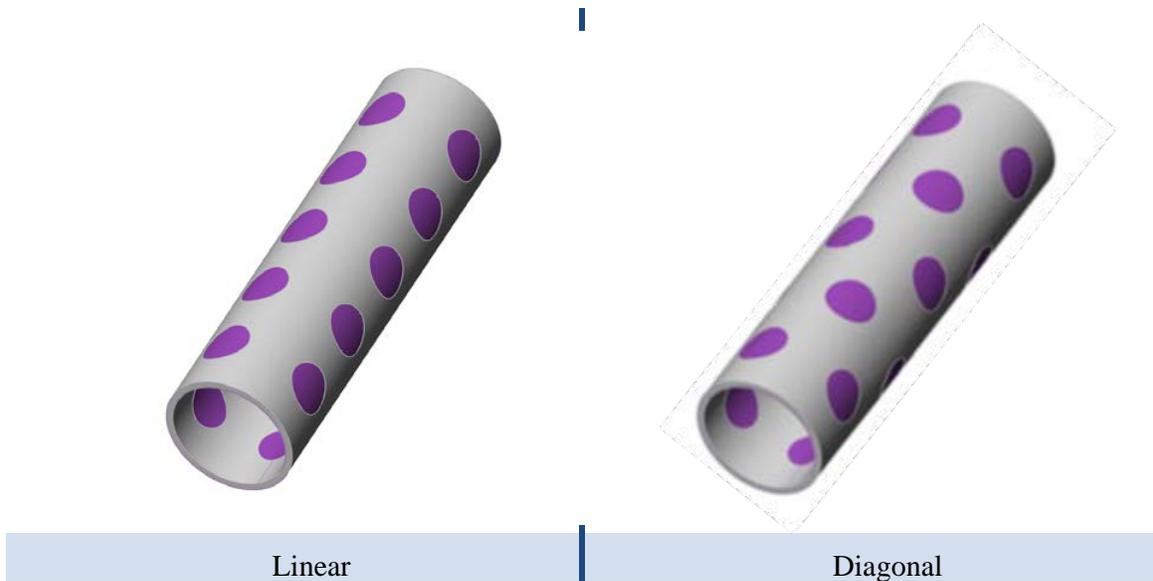


Figure 4: Cut out Configuration levels (purple depicts cut outs through the thickness of the splint)

An experimental design was created in Minitab (Minitab® 18.1, Minitab, Inc., State College, PA) with the four discussed factors all with two levels except shape. This factor was investigated at three levels. There were no replications or blocks. The design run order was randomised.

4.1 Results of screening study

The screening study was conducted and an analysis of the factorial study was conducted in Minitab. A Pareto chart was created and two factors extend past the reference line, this indicates that two of the factors chosen to examine in the study are significant; Ratio and Frequency. Using automatic backward elimination, a second Pareto chart (Figure 5) was created, further confirming that Ratio and Frequency, and their interaction are the most significant factors.

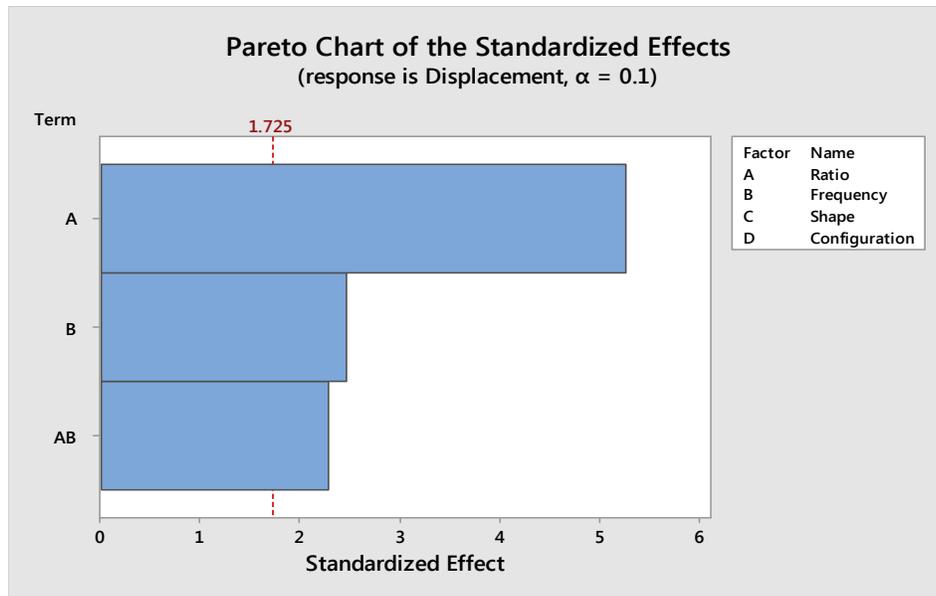


Figure 5: Backward elimination Pareto chart of screening study

The interaction plot showed that low ratio displays little change between other factors. Higher ratio does however have an interaction with other factors (Figure 6A-C). Shape factor levels Circle and Square have no interaction with frequency (Figure 6D), but Diamond does have an interaction with the frequency of the cut outs. Square and Diamond shapes have a high interaction with configuration (Figure 6F).

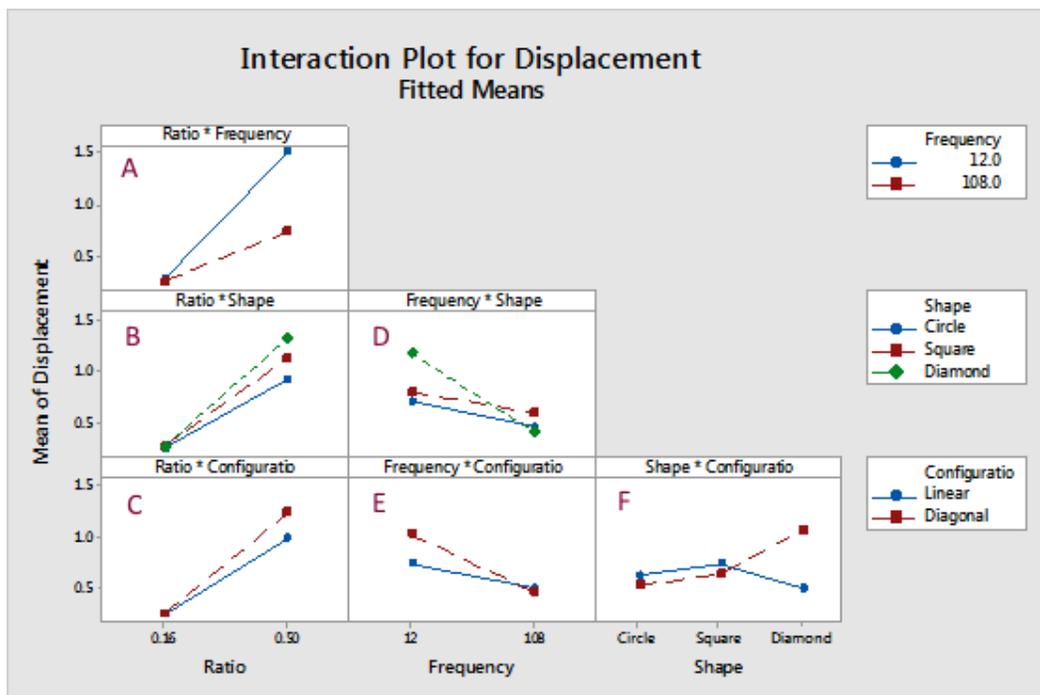


Figure 6: Interaction Plots (A-F) for screening study

The main effects plot shows that Ratio has a strong positive effect on the response as expected as it is a significant factor. This can be seen in Figure 7A. Shape and configuration have very little effect on the response, as shown in Figure 7C + 7D

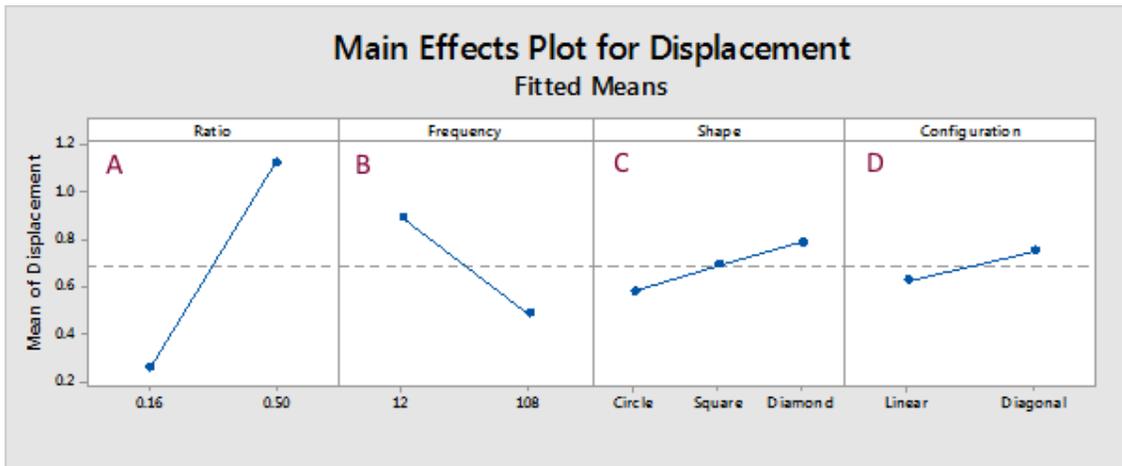


Figure 7: Main Effects Plots (A-D)

Frequency has a negative effect on the response (Figure 7B). This is an unexpected result and lead to further investigation. As main effects plots use the mean response the spread of the response, grouped into ratio was examined.

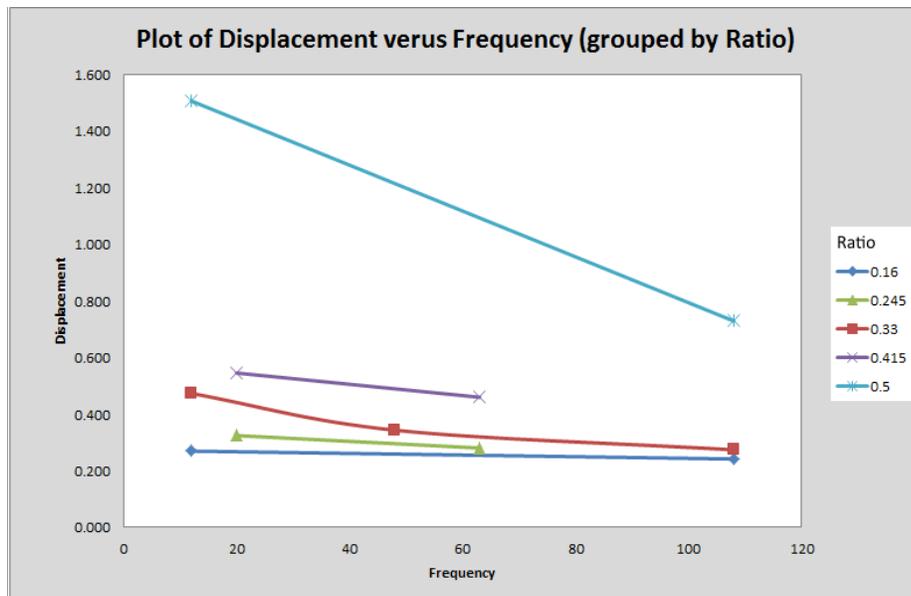


Figure 8: Plot of Displacement versus Frequency (grouped by Ratio)

From this investigation seen in Figure 8, it is evident that frequency does not have as large a negative effect on the response as first supposed. All ratios except 0.5 show a neutral or

slightly negative effect on the response, meaning as the frequency increases the displacement decreases. The results from the 0.5 ratio are the outliers compared to the rest of the data. These inconsistencies lie in factor combinations with large cut outs quite close together.

This can be seen in the points highlighted with a red arrow in Figure 9B.

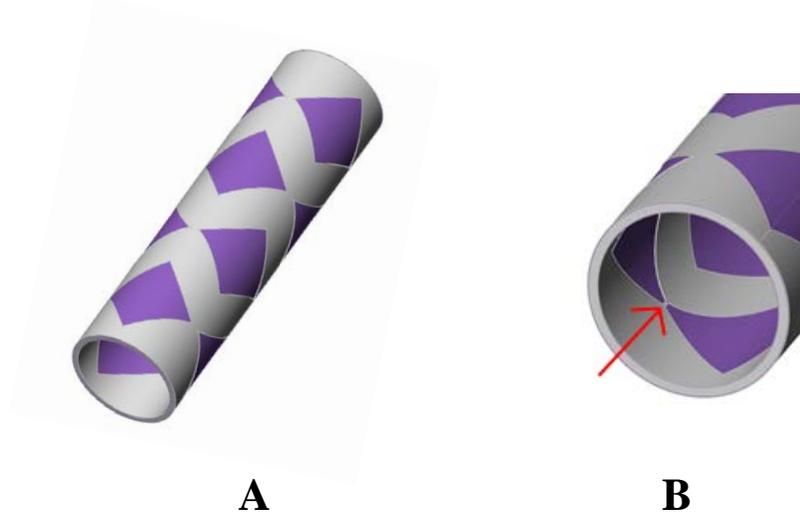


Figure 9: **A** - Diamond cut out, linear configuration, 20 cut out frequency and ratio of 0.5
B - Close up of small struts

These geometries were created in Rhino Grasshopper by cutting a 2D shape on a flat plane perpendicular to the 3D cylinder surface. This creates cut outs in the cylinder that cut linearly inwards (Figure 10 A+B) not radially inwards (Figure 10 C+D) meaning that the inner strut thickness Figure 10 B is smaller than Figure 10 A.

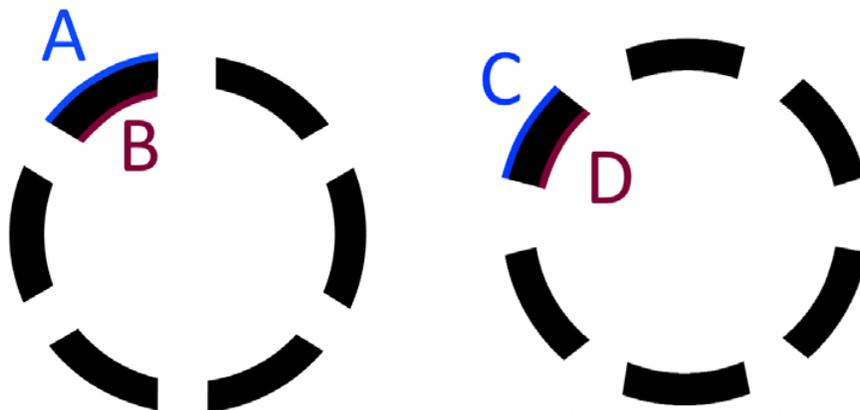


Figure 10: Cross section of cylinder with cut out, linear cut out left, radial cut out right

This can be seen in Figure 9 and these small volumes between the cut outs lead to much larger displacements, skewing the mean responses. These inconsistencies should be addressed in future work.

4.2 Key findings of screening study

Of the four factors investigated in this study, two have been deemed insignificant to the displacement response. Ratio is by far the most important factor. This aligns with the initial assumption that the more material taken away from a structure the less strength the overall geometry maintains.

Shape ties in heavily with ratio and should be investigated further. Shape was deemed insignificant in the screening study, but as this study has non-uniform strut thickness and some of the trials showed much higher displacements when these inconsistent struts were too small it was deemed that shape should be investigated again with consistent struts.

While the configuration was also deemed an insignificant factor, like the shape factor, it should not be discarded. While most configurations showed no interaction with other factors and showed little pull on the response, when the configuration lead to small struts between the cut outs, the response increased severely.

Frequency was deemed a significant factor in this study. As discussed previously, certain combinations of frequency and other factors caused irregularities and upon inspection frequency was not as significant as first thought. The screening study showed how any weakness around the wrist joint affects the displacement response

5. Optimization Study

Based on findings from the optimisation study the objective of this study was obtain significant factors and access how these factors affect the response. Using this understanding design rules could be created.

Four factors were chosen for this screening experiment; Shape, Thickness, Position, Strut. Two factors are categorical; shape and position. The other two factors, thickness and strut are continuous. As discussed in 4.2 Key findings of screening study, shape was investigated further. Shape may also be a key factor to allow patient co-design so it is essential to fully understand this factor

The screening study uses a splint thickness congruent with traditional splinting guidelines. In this study splint thickness was investigated to see if this guideline transfers to AM splints or if new guidelines are needed.

Position refers to the position of the largest density of splint material. This factor could allow for a denser splint in areas such as the wrist joint where the splint needs to be stronger and also allow for a less dense, more breathable splint in other areas. This could also help reduce the weight and the cost of manufacture.

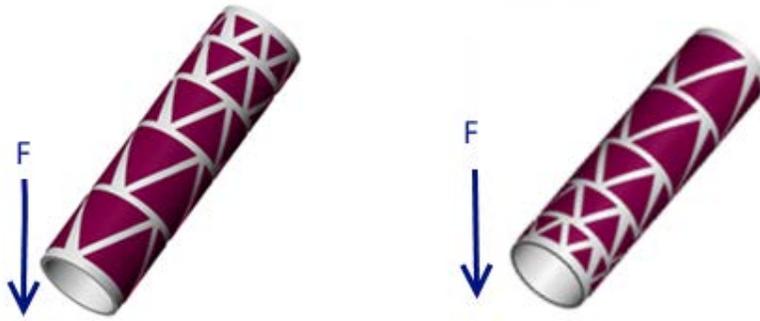


Figure 11: Example of two levels of position factor

As screening study has shown that when struts become too thin splints exhibit much greater displacement, in this optimisation study, the strut thickness was controlled and struts were consistent.

As per fractional design methodology, a high and a low level were chosen for each continuous factor. All factors and their levels can be seen in Table 2.

Fact ors		Levels	
A	Shape	4	Circle, Hexagon, Square, Triangle
B	Thickness	2	2mm, 4mm
C	Position	2	Forearm, Wrist
D	Strut	2	5mm, 10mm

Table 2: Optimisation Study Factors and Levels

An experimental design was created in Minitab with the four discussed factors all with two levels except shape. This factor was investigated at four levels. There were no replications or blocks. The design run order was randomised.

5.1 Results

The optimisation study was conducted as per methods discussed previously in section 3. Material and Methods and an analysis of the factorial study was conducted in Minitab. A Pareto chart was created and the position factor extends past the reference line, indicating that this factor is significant. Using automatic backward elimination, a second Pareto chart (Figure 12) was created. This shows that all factors are significant.

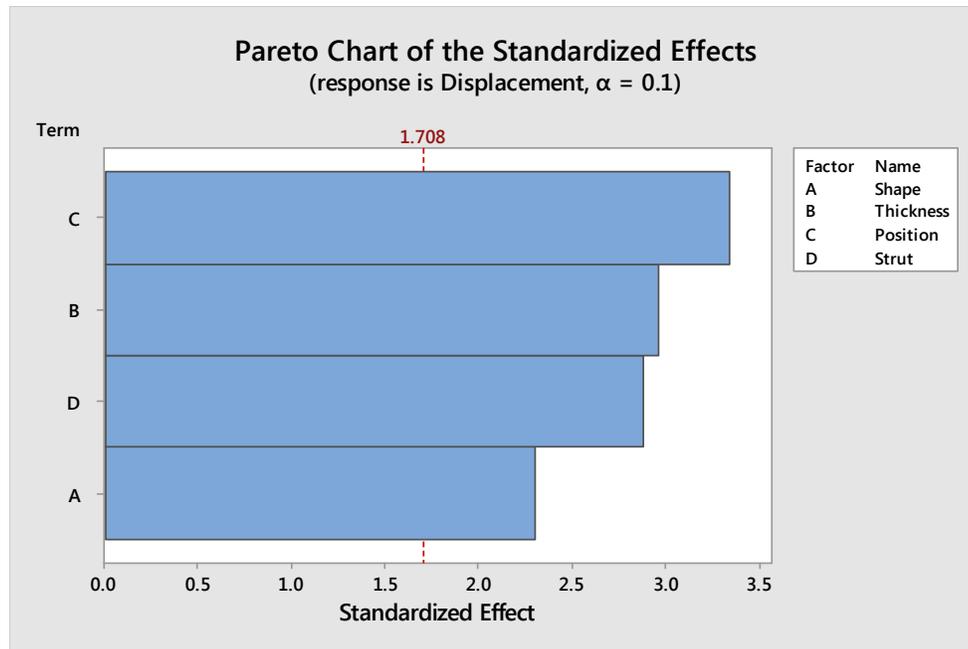


Figure 12: Backward elimination Pareto chart of optimisation study

A main effects plot (Figure 13) was created. it indicated that as expected a thicker splint leads to less displacement, a splint with less material around the wrist joint causes more displacement and a smaller strut thickness causes less displacement.

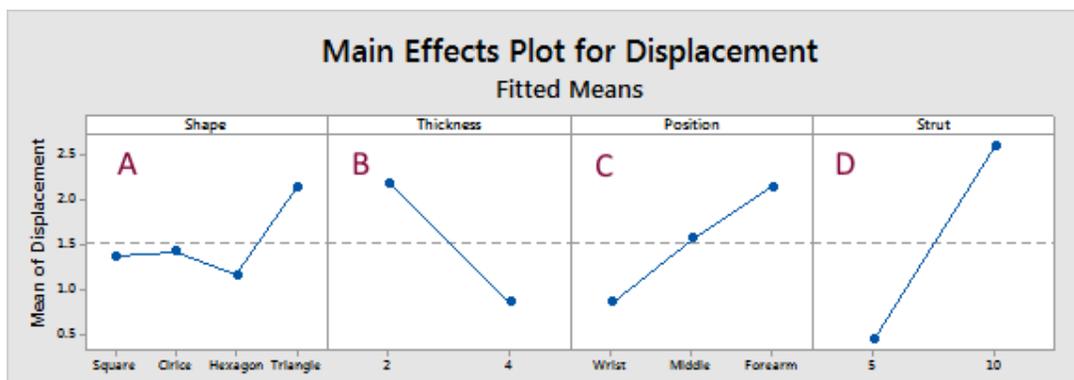
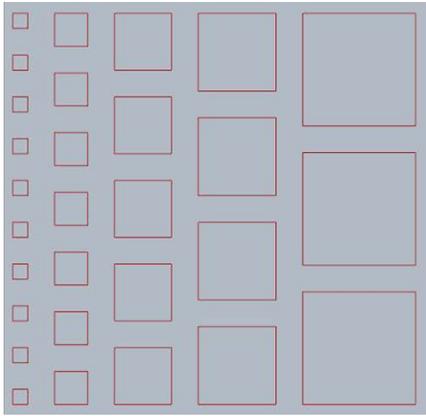
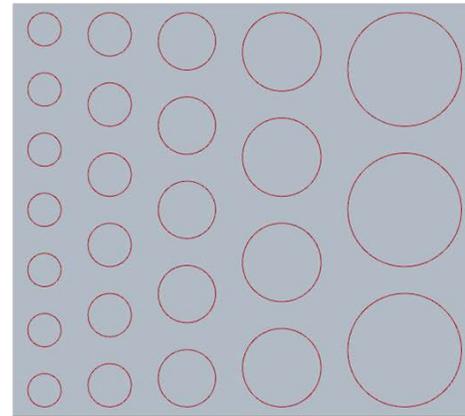


Figure 13: Main Effects plot of optimisation study

Shape is correlated with ratio as to keep the minimum strut thickness consistent the ratio will be different for each shape. This can be seen in Figure 14; here two patterns with the same factors but shape have been depicted in 2D form.



Square - 10mm – 0.356



Circe - 10mm – 0.307

Figure 14: Two dimensional depiction of similar patterns. Label indicates shape, sturt thickness and ratio.

When the ratio is plotted on the same graph it is clear that the relationship between ratio and displacement seen in the screening study hold true.

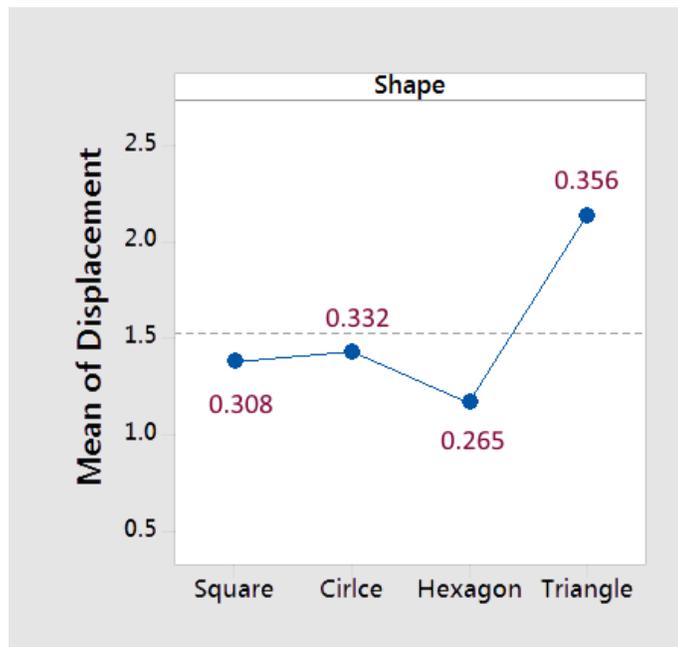


Figure 15: Main Effects Plot of Shape factor (ratio in red)

An interaction plot was created and there are no notable interactions between factors in this study.

5.2 Optimisation Surface Response

As this optimisation is set up in a way that position is not continuous it was decided not to investigate this factor any further in this study. A more in-depth investigation will be conducted as part of future work. As any attempt to change the shape factor will lead to greater changes in other more significant factors it was decided shape would not be investigated any further in this study. Strut and Thickness were investigated further in a surface response study to further understand their effect on the response.

A centre composite design was conducted using methods discussed previously in 3. Material and Methods. A contour plot of the results was created and can be seen in Figure 17. From the plot it is clear a more optimal design space is possible as the optimal region of lowest displacement could be more central. The design space was shifted and another analysis was performed. The date point circle in red in both Figure 17 and Figure 18 represents the same date point and shows how the design space was moved.

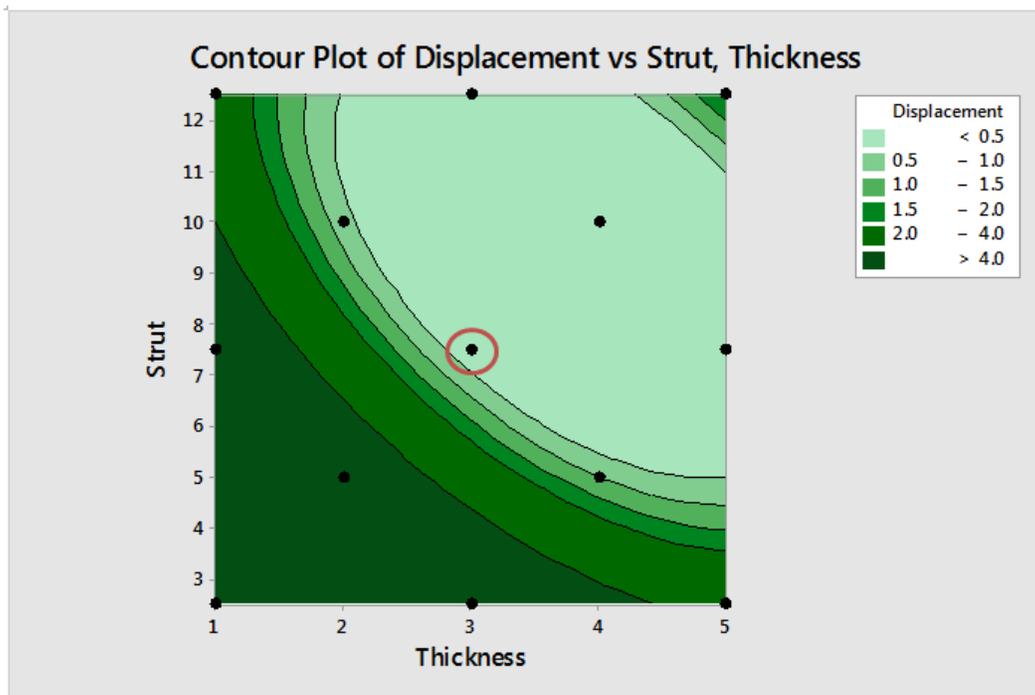


Figure 16: Contour Plot of optimisation surface response

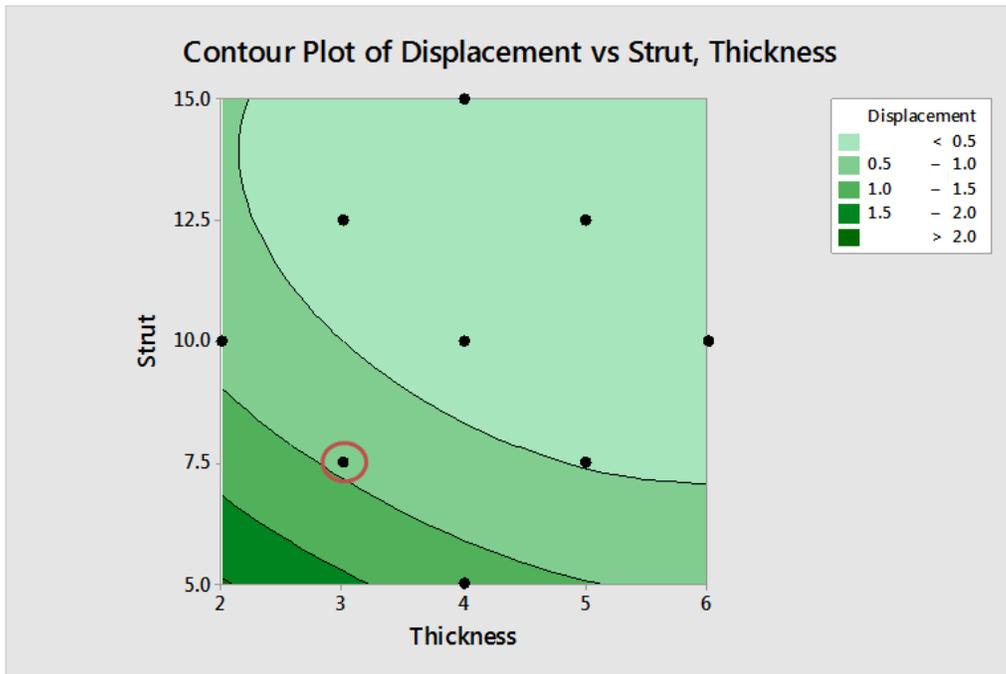


Figure 17: Contour Plot of optimisation surface response

The contour plot Figure 18 shows a clear optimal combination of strut and splint thickness. The diagonals of the contour plot also correspond with cross sectional area (Figure 19). A cross sectional area of 37.5mm and over correlates with displacements less than 0.5mm

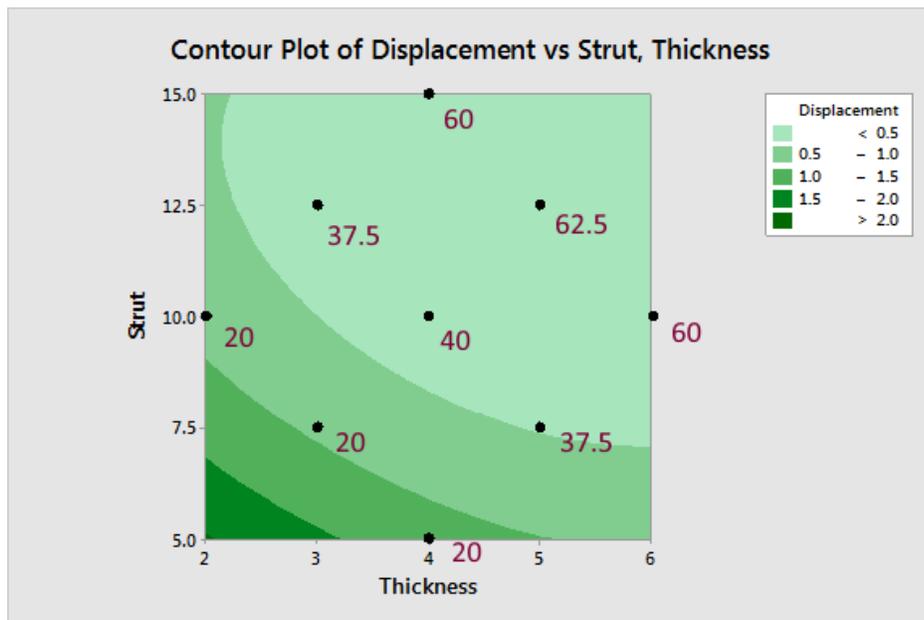


Figure 18: Contour plot of optimisation surface response with cross sectional area in red (mm²)

5.3 *Key finding of Optimisation Study*

From the optimisation study it can be concluded that larger cut outs should be positioned away from the wrist joint, with a greater density of splint material around the wrist joint.

The shape factor is significant as it is connected to the ratio of the splint. Strut and thickness show a clear optimal region for minimising displacement. The ideal thickness is greater than 3mm and the ideal strut is greater than 7.5mm when the cross sectional area is greater than 37.5mm².

6. Conclusion

6.1 *Screening Study*

- Cut outs should be constructed in such a way that the strut thickness is uniform across the thickness of the splint.
- The configuration and shape of the cut outs are insignificant if strut thickness is consistent

6.2 *Optimisation Study*

- Larger cut outs should be positioned away from the wrist joint
- Ideal thickness is 4mm ± 1mm
- Ideal strut is 10mm ± 3mm
- Ideal cross sectional area of struts is 37.5mm² or greater

7. Discussion and Future Work

Although AM splinting is not common place practice yet, many examples can be found including one commercial venture. As with all new technologies it is important to ensure that any medical device is as safe or safer than its predecessor. AM splints are still very untested and clinicians should be cautious when designing them. There are still many factors to be considered, including material and skin contact, optimal strut thickness for minimal pressure on the skin, optimal splint donning and doffing methods, thermal considerations, etc.

It is hoped this research and the research that will follow will allow clinicians to design splint to be manufactured using AM with a greater confidence that the splint will perform as intended and allow the clinician to create splint that gives their patients a better quality of life.

Future work will include continued research into the density of splint material relative to the position on the splint. This will include separate investigations into each of the three main sections of the splint; palm region, wrist region, and forearm region. It is hoped that this will allow for separate design rules for each region meaning a splint could be created that is lighter and could be adjusted for optimal thermal comfort. It should also reduce the cost of manufacture as each region of the splint will be the optimal amount of material. Physical testing will be conducted to validate the methodology of this work.

Future work will also need to include validating design rules for different AM process, materials as this study was only conducted using laser sintering and PA12 as the material. As current technology stands this seems like the most appropriate process and material but as AM technology changes this will need to be updated.

8. Limitations of study

The study was only on conducted on cylindrical forms, and not applied to scan data which will generate different results. This methodology will be tested on splint geometry from scan data.

Flexion is not a true representative of the biomechanical movements of the wrist due to but due to the necessary complexity of FEA that would be needed and difficulty in identifying specific fulcrums of the wrist joint a simple cantilever type boundary condition was used. However this method is a first step towards defining mechanical properties and refinement of associated design rules which define perforations of a splint.

9. Acknowledgements

Funded by Materialise, supported by Loughborough University, under the EPSRC Centre for Doctoral Training in Additive Manufacture.

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