SHAPE, an Automated Process for Manufacturing Patients-Specific Fracture Plates.

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Abstract ***– Current fracture treatment development possesses numerous limitations, but the development of the product did not take place for many years. In this paper, I propose a potential option for fracture treatment that combines computer modelling, additive manufacturing, and programming technology. Through these technologies, patients-specific plates are created that provide superior medical performance and freedom to surgeons during the operation. The paper presents the methodology development for fracture treatment and the outcome that was made using the method. Evidence and rationales are presented through thorough research, to back up the key design decisions.***

I. Introduction

Despite significant technological advancements in the field of medicine, the innovation and development of fracture treatments have stalled since the early 2000s. On the other hand, due to increases in average life expectancy (OECD, 2019), fracture-related costs are expected to rise from GBP 4.52 billion to GBP 5.89 billion in the United Kingdom alone over the period of 10 years (International Osteoporosis Foundation, 2018). Currently, the most common treatment for fractures is the insertion of mass-produced flat metal plates, which are then screwed onto the bones. This method is widely accepted, but its clinical performance is questionable.

Flat plates provide structural rigidity and a small amount of protection jarring. However, such plates have numerous limitations. For example, limited screw insertion angles and locations when using flat plates make it difficult for surgeons to choose the optimal location for screws. Additionally, because the anatomical shape of long bones is rarely flat, flat plates often exert excessive stress on bones, screws and the plates themselves. Many studies have suggested that stress must be minimised during bone recovery, as it can cause poor healing or even malunion of the bones (Yoshimine, 1995).

To mitigate some of these problems, researchers have proposed bending a flat plate into a helical shape. A helical plate increases stability and reduces stress on the bone (Krishna, Sridhar and Ghista, 2008). The biggest drawback of such plates is the complexity and difficulty of bending them accurately. Inaccurate bending can cause medical complications and sequelae, and research suggests that poorly bent plates can cause more harm than good (Oka et al., 2010).

Meanwhile, additive manufacturing (AM) technology, otherwise known as 3D printing, has drawn significant attention from researchers in the medical industry. AM's customisability and the increasing number of possible printing materials are important benefits in the medical field. Fully exploiting the technology requires personnel who are familiar with both engineering and biology, but it is undoubtedly a compelling technique.

In light of the limitations of conventional fracture plates and the benefits of AM, this paper considers the applications of the Surgical Helical Automated Patient-specific Plate (SHAPE), a device developed using the Python 3 programming language, computer-aided design (CAD), and medical validations (Fig. 1). The SHAPE enables the creation of a helical bone plate that is designed to fit every patient perfectly. Python code converts CT scans of a bone into a precise CAD model, which is then used to create a patient-specific plate. The SHAPE currently targets forearm (radius and ulna) fractures but could hypothetically be applied to all long bone fractures. It is important to note that the SHAPE is not intended to replace all existing fracture treatments but rather to provide one potential treatment with clear advantages and limitations.

Figure 1. A rendered model and the bone of a plate using SHAPE

Section 2 of the report details the theoretical background on fractures and the potential applications of AM in the medical industry, and section 3 explains the methodological approach to the development of the SHAPE. The result of the project is presented in section 4. The final prototype's significance for patient outcomes is discussed in section 5, and section 6 concludes the report by summing up the notable elements of the research and identifying opportunities for future work.

II. Contextual Investigation

Although age has a positive correlation with bone fracture frequency, the phenomenon can occur at any age (Demontiero et al., 2012. This section will focus on potential AM solutions for treating radius/ulna fractures, which are the second most common fracture type, followed by hip/femur fractures (Curtis et al., 2016).

The conventional treatment for forearm fractures is the implantation dynamic compression plates or locking compression plates (Snow et al., 2008). The usual procedure for this treatment is known as ORIF: open reduction (aligning bones to their proper position) and internal fixation (reconnecting bones physically) (Johns Hopkins, 2020). The advantages of ORIF are evident. Müller et al. (1992, p.13) state that internal fixation offers the stability that fractured bones cannot provide. Moreover, internal plates provide protection and reduce physiological forces in the early stages of healing (Müller et al., 1992). Some limitations and disadvantages of ORIF include the necessity of creating holes for the plate and the need to straighten a curved bone that could potentially lead to deformities and stress localisation (Müller et al., 1992, p.172). The need for a second operation to remove the plate is another major drawback of internal fixation (Müller et al. 1992, p.694). Some of current plate designs are shown in Figure 2.

Figure 2. Conventional plate designs

AM, or 3D printing, is drawing tremendous attention for its potential application in medical industries (Campbell et al., 2012). Gibson et al. (2015, p.5) define AM as the process of adding materials layer upon layer to form 3-dimensional objects. Some advantages of AM include design freedom, the control of object properties and the reduction of assembly counts. Some disadvantages of AM are poor surface finish, the need for post-processing and the high cost of the process. The advantages of AM are highly sought-after in the biomedical industry, and rapid development is continuously taking place to overcome the process's limitations.

AM offers numerous advantages in the biomedical industry. Murr et al. (2010) state that the design freedom and complexity of AM can efficiently create desired tissues, bones, and joints. Singh & Ramakrishna (2017) conducted a thorough review of present and future biomedical applications of AM. They suggest that, currently, AM technology can produce simple screws, implants, and joints using biocompatible materials (Singh & Ramakrishna 2017).

Despite the above-mentioned benefits, however, there are concerns about AM. The core problem hindering the use of AM in biomedical applications is a lack of advances in technology. According to Gibson et al. (2015, p.2), due to the manufacturing nature of AM, which adds layers of material, the mechanical properties of the final product are often changed. Moreover, Singh & Ramakrishna. (2017) acknowledge the most critical challenge of AM: the need for post-processing. At this point, post-processing is a necessity that can consume time and money. Finally, only a limited number of materials can be used for AM. The ideal material for biomedical applications of AM has yet to be developed.

Considering both the benefits of AM and the limitations of internal fixation for fractures, AM fracture implants have great potential to improve patient healing. AM's design freedom and ability to create complex shapes can provide implants in shapes and sizes that suit everyone and treat fractures in many different areas. More importantly, AM implants could eliminate the deformities and stress localisations that current ORIF procedures create.

The present findings suggest that AM can be an appealing solution for treating ulna/radius fractures. Additional developments are needed to produce a complete solution, and consumers need to consider the expensive price tag for these implants. As technology advances, AM implants are likely to become a more affordable and powerful treatment for fractures.

III. METHODOLOGY

Due to the nature of this research, the triple triangle method was used to develop the final SHAPE (Medium, 2019). The image of the "three triangles" design process is shown in figure 3. Although a double diamond design was used at the beginning of the project, a different design approach was subsequently chosen after encountering several problems. Double diamond design uses a linear design flow and thus often separates the analysis and discovery of a problem from the identification of a solution (British Design Council, 2005). In triple triangle design, discovery and ideation are progressed simultaneously until the final concept is narrowed down. Accordingly, the final design for the SHAPE was developed through continuous adaptation in response to the research findings over the course of the module.

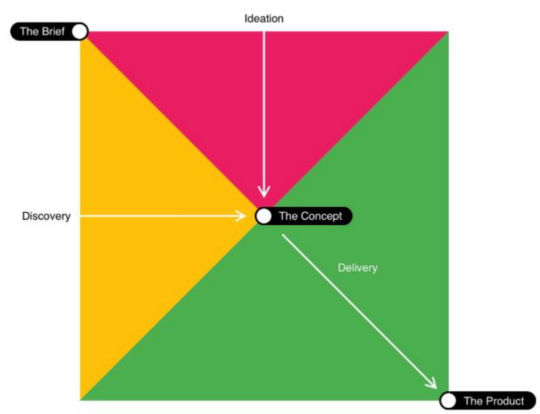

Figure 3. Image of three triangle design process. Ideation and discovery take place simultaneously. Once the concept is narrowed down, delivery phase begins.

Clinical validation and accurate customisation of the final prototype were the primary objectives for the SHAPE. Based on various research papers, these broad objectives were then developed into the following goals:

I) determine the factors that hinder bone regeneration (ideation & discovery)

II) create a patient-specific plate that resembles the curvature of the bone as accurately as possible (delivery).

The following sections will describe how the objectives were validated and achieved.

A. Optimising Stress-Inducing Elements of Conventional Plates

Due to the novel and complex nature of the project, research and consultations with expert stakeholders were key elements of the design process. According to existing research, several characteristics of bone plates affect the stress that is applied to bones, including the number of screws, screw insertion angle and shape of the plates (Gudarzi et al., 2012).

The initial starting point for the design of the SHAPE was a conventional flat plate. From this, the design was adapted according to the available evidence. The limitations of existing flat plates include:

I) the necessity of re-bending and/or in-site bending to fit patients' bones as closely as possible

II) limitations on surgeons' ability to select the most appropriate screw angle, number of screws and plate dimensions

III) the creation of a stress focal point due to the plates' limited orientation (Goharian, 2017, p. 104)

Multiple interviews were conducted with Dr Kim, a practicing orthopaedic surgeon, to gather information about fracture surgery sites. Dr Kim provided information on important surgical techniques and the consequences of poorly-performed surgeries. The most important technique described by Dr Kim was the pre-bending and bending of flat plates. Bending is performed by curving the flat plate to match the curvature of patients' bones as closely as possible, usually during the operation. Because the accuracy of this bending determines the patient's recovery rate, it is one of the most time-consuming procedures during an operation. On the other hand, if this bending is not performed properly, complications may occur, including malunion, infection and refracture. These risks can be mitigated using AM technology. The SHAPE provides a patient-specific plate that can reproduce the curvature of the bone with a high degree of accuracy.

The screw insertion angle was another major consideration in the design of the SHAPE. According to Patel, Shepherd, and Hukins (2010), as the screw insertion angle increases, additional stress is applied to the bone. Thus, the default insertion angle for the screws for the SHAPE is 0° (i.e., perpendicular to the surface of the bone). There are, however, some exceptions. The insertion angle is measured not from the surface of the bone but from the fracture site as shown in Figure 4. Inserting screws through the

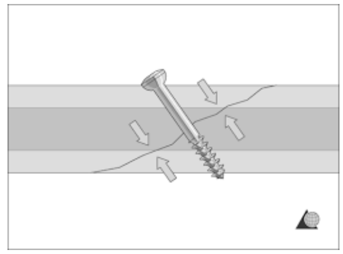

Figure 4 & 5. Figure 4 shows insertion angle of a screw at the fracture site. Figure 5 shows that SHAPE creates optimal angle for screw insertion.

fracture site enables sturdier connections to better hold the bones together (Calafi, 2014). The SHAPE can increase the thickness of different sections of the plate and thus modify the insertion angle (Fig. 5).

Increasing the number of screws used in fracture treatment is a trade-off between the stability and regeneration of the bone (Jung et al. 2020). Placing too many screws results in a higher chance of infection and malunion, whereas placing too few screws can result in refracture and bending of the screws. To better understand the typical number of screws used for forearm fractures and determine the ideal number of screws for the SHAPE, I interviewed Ms Fabiola Mann, a 3rd year medics student at Imperial College London. According to Ms Mann, six or more screws, depending on the magnitude of the fractures, are used during conventional internal fixation operations. However, Nasab, Sarrafan, and Sabahi (2012) suggested that four screws can provide sufficient structural support for forearm internal fixations. Their study showed that four-screw fixation did not result in a significant delay in recovery: the union time using four screws was 74.8 days, 1.2 days longer than plates with six or more screws. Moreover, the infection and union rates were 0% and 92.1%, whereas those of conventional plates with six or more screws were 3.2% and 95.3%. This shows that four-screw plates prevent infection more effectively, with a marginally lower union rate. Through this research and my discussions with Ms Mann, I determined that five was the optimal number of screws for the SHAPE.

The final design structure of the SHAPE was also based on research. In 2002, Alberto Fernández first proposed using a semi-helical plate for fracture treatment (2002). As the sciences of both physiology and computer simulation have developed,

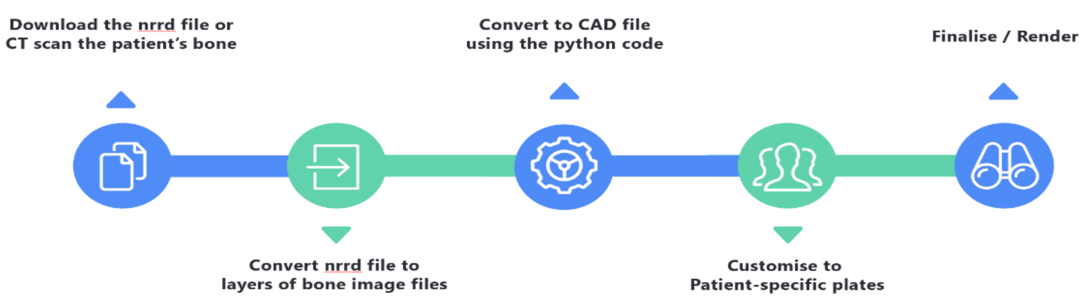

Figure 6. A flowchart describing how personalised plates are created using SHAPE.

many researchers have found that helical plates are superior to conventional flat plates. According to Byun, helical plates can be placed without damaging the radial nerve system (Byun, 2007). A study by Krishna, Sridhar, and Ghista analysed the use of helical plates for bone fractures using finite element analysis (FEA) and concluded that such plates better distribute stress, which promotes improved bone regeneration (Krishna, Sridhar and Ghista, 2008). The critical drawback of the helical plates is similar to the problem with bending a conventional flat plate: achieving an accurate orientation is difficult. This problem, too, can be eliminated using the SHAPE.

B. *Converting Medical Images to CAD & Modelling the Plate*

Numerous design engineering skills were utilised to create the SHAPE. The first step of developing the SHAPE was to create a way to convert CT and X-ray scans into CAD models. CT scans are usually stored as DICOM files, which contain not only the images of the bone but also patients' private information. Thus, the downloadable files were stored as a different file type: nrrd. The nrrd files contained only the anonymised images of bones (Embodi 3D, 2016). Python libraries called VTK and SimpleITK were then used to visualise the nrrd files from Fusion360. For X-rays, a Python library called numpy2stl was used to convert the scans into stl files. The flowchart for creating a patient-specific plates is shown in Figure 6.

After conversion, patient-specific plates, which were 20 mm wide and 10 mm thick, were manually created using Fusion360. To provide a helical rotation, a reference circle was made from the bottom view of the bone. From the centre of the circle, 1.5° were added in 60 layers, resulting in a 90° rotation of the plate. A 3-mm distance was included between each layer to achieve surface layers that matched the patients' bone. The layers of plates were then lofted to form a final device for the specific bone. Figure 7 and 8 show how these layers were constructed.

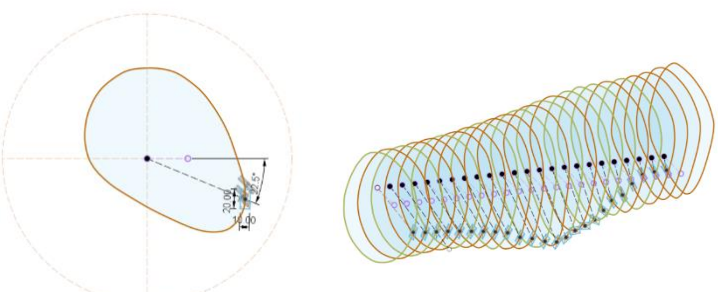

Figure 7 & 8. A repeated process of creating layers and increasing angles created semi-helical patient-specific plates.

IV. Results

Due to the COVID-19 emergency, creating the physical prototype and testing its mechanical function and design were not possible. Instead, the CAD model has been substituted as the final model for the assessment. For the final CAD model, an anonymised arbitrary ulna nrrd file was downloaded and converted into an stl file. As the available bone nrrd files were non-fractured bone scans, a random plane in the metaphyseal section of the bone was set as the fracture plane.

The final codes for converting CT scans and X-rays into stl files are included in the appendix of this report. The outcomes of each X-ray and CT scan are shown in Figure 9, 10, and 11. It is noteworthy that the X-ray model was highly inaccurate compared to the CT scan model. In real-world medical applications, the X-ray model would likely be unusable due to its limited accuracy. On the other hand, the CT scan model showed a high degree of accuracy. It reproduced the curvature of the bone almost perfectly, which is essential for modelling a patient-specific bone plate. Thus, the CT scan code should be the primary means of creating stl files in real-world applications. Fortunately, most patients who require bone plate surgery need CT scans, as well.

Figure 9

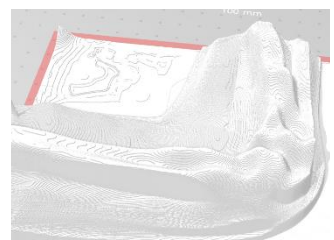

Figure 10

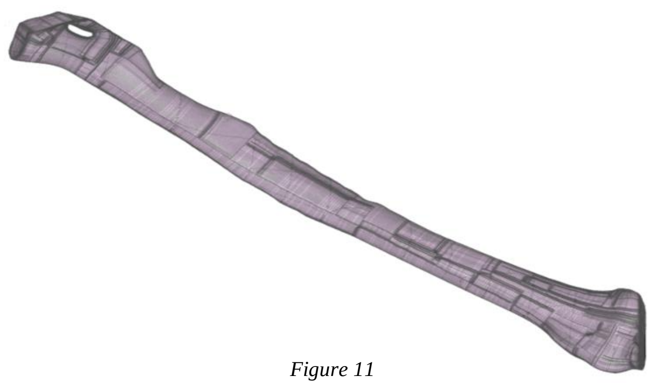

Figure 11

Figure 9 shows the x-ray scan used to convert it to stl file. Figure 10 shows the stl model. Because the code uses the intensity of the white colour, the whiter section of the x-ray scan Figure 11 shows the stl model created from the CT scans. CT scan provide more information compared to the x-ray scans, the outcome is more accurate and suitable for plate creation.

A CAD model of the quarter-helical plate and plate with the bone are shown in Figure 12 and 13. The plate wraps the bone 90° overall, making it convenient to insert under the skin. The plate binds to the metaphyseal section of the bone and is 18 cm long to enable optimal screw location in terms of stability. Short plates tend to bend or crack because they cannot withstand bones' gravitational pull (Chao et al. 2013).

I placed a total of five screw holes on the plate: four screws fix the bone to the plate, and one screw reconnects the fractured bone. The insertion angle of the first four screws is perpendicular to the surface of the bone, minimising the stress exerted while drilling into the bone. The default insertion angle of the screw that connects fractured bones is perpendicular to the fracture plane for the same reason. However, the insertion angle can also be customised based on the fracture location.

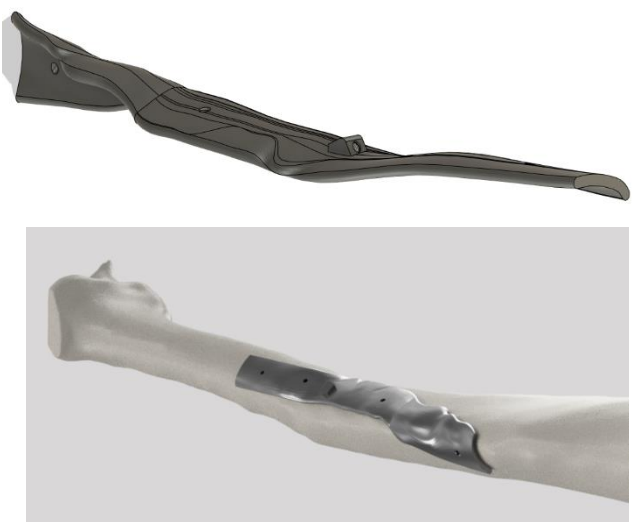

Figure 12 & 13. Completed CAD model of the plate and with the bone. It has 4 regular screw holes, and one fracture site screw hole. It follows the curvature of the bone precisely.

A Fusion360 simulation was conducted to validate the mechanical properties of the helical plate (Fig. 14). Metal was used as the primary material for the plate, and the screw holes were the focal point of stress. Accordingly, all screw holes were loaded with a force of 10 N to the side of the hole. I found that the screw holes experience force of up to 1.9 MPa, which is low pressure compared to the typical pressure that human arms can endure (Özkaya and Nordin, 1999, p. 209). Although the mechanical properties were more than sufficient to withstand the daily stress exerted on an arm, considering that the plate is intended to be tightly joined to the bone, it must be able to withstand a higher level of force. Thus, the helical plate displayed the required mechanical properties.

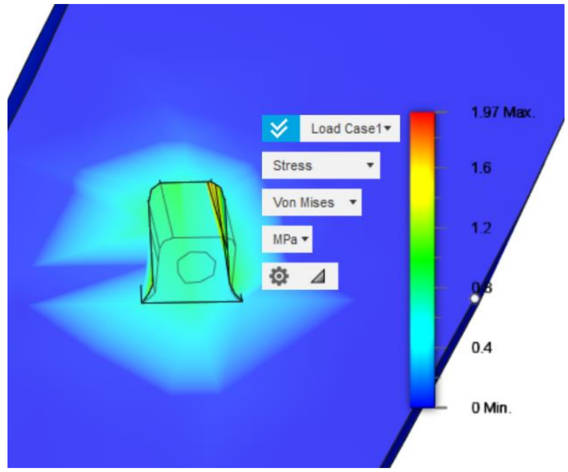

Figure 14. Fusion360 simulation was conducted at the fracture site screw hole to validate the mechanical property of the plate.

V. Discussion

Many characteristics of bone plates have remained unchanged for decades. I developed the methodology for the SHAPE by combining design engineering skills and biochemical research. The SHAPE offers many benefits, but there are also numerous barriers to its commercialisation.

A highly-customised plate is superior to conventional flat plates in terms of medical performance. The SHAPE offers a more accurate plate compared to the manually-bent plates, and can create accurate plates for all patients, regardless of gender, age or race. This results in a better fit and higher recovery rate, as studies have suggested that better fitting of the plate to the bone provides superior osteosynthesis, or bone regeneration (Yoneda, 2016). The SHAPE also removes the need for manual bending, which will reduce surgical theatre time. According to Cheng et al., prolonged operative duration is positively correlated with risk of surgical site infections (SSI) (2017). The global infection rate for open fractures is 13.24% (Fernandes et al., 2014). Although infections are caused by many factors, it is noteworthy that the SHAPE can shorten surgical durations and thus reduce the risk of SSI. Another benefit of reducing surgical durations is improved efficiency; patients can be moved in and out of surgery more quickly, potentially enabling an increase in the number of surgeries possible per day.

Granting more flexibility in terms of screw usage to orthopaedic surgeons is another great strength of the SHAPE. Orthopaedic surgeons treat diverse types of fractures daily, including multifragmentary, diaphyseal and metaphyseal fractures, and the locations and magnitudes of these fractures vary from case to case. For example, multifragmentary fractures require more screws than diaphyseal and metaphyseal fractures. Conventional plate screw holes can provide the necessary support and treatment, but may not always be the ideal support. Also, achieving an appropriate screw insertion angle for every screw is a painstaking process. Some screws are used to maintain the shape of the plates, whereas others are used to hold two separate bones together. Screw insertion angle plays a critical role in determining the screws' functions. Rather than being limited to using screws within the parameters of plates, surgeons using the SHAPE can choose where and how to locate the screws.

Helical plates are extremely difficult to create accurately, especially during surgery. However, the SHAPE manufactures accurate helical plates in advance of patients' operations, enabling easier and more efficient surgeries. Surgeons can determine the best location for open reduction and minimise the size of the opening, lowering the chance of infection (Andalib, 2017). Helical plates can also withstand much more stress than flat plates, reducing the likelihood of plate failure (Krishna, Sridhar and Ghista, 2008).

All of these advantages will directly affect the experiences of patients with fracture injuries. For example, a perfect plate fit minimises the foreign sensation experienced by patients, which often causes discomfort or even severe pain at the fracture site. Furthermore, patients will also benefit from the enhanced recovery rate. Although it is difficult to quantify the benefits that the SHAPE offers, many studies have implied that customised plates can shorten recovery times. Most importantly, the SHAPE can improve the quality of recovery, providing faster and better recoveries while minimising medical complications such as SSI and refractures.

Despite these benefits, the SHAPE also has some practical limitations. The first problem is the price. Conventional flat plates cost about GBP 20 per plate, and this price may be lower for wholesale purchasers. On the other hand, 3D-printed plates are costly. Outsourcing the metal 3D printing costs GBP 60 for 100 grams (3Space, 2019), which is the average weight of a bone plate. This means that 3D-printed plates are double the price of conventional plates based on materials alone, with post-processing adding an additional cost. Most importantly, the labour required to create a customised plate needs to be considered. Completing the SHAPE prototype required 8 hours of CAD modelling. The wage costs of eight hours of work performed by well-paid personnel who are familiar with medicine and 3D modelling will comprise a significant portion of the overall price. Finally, if bioactive glass or other bioinert materials are used for the screws and plate, the price could easily exceed GBP 2,000.

Another limitation is the product's time-consuming production schedule. Although fractures do not require immediate medical attention, 3D-printed plates are inferior to conventional plates in terms of readiness for usage. Because there are so many steps necessary before the final product is made available, patients needing urgent medical attention may not consider the SHAPE to be a viable option. Further technological advances are needed to deliver products that can be ready for use immediately or after a short time.

Given the clear limitations and benefits of the SHAPE, the question remains: is this currently a viable product? To answer this question, I have developed a value chain based on the benefits and limitations of the plate, using cost as the reference point. The minimum expected price for the SHAPE includes:

I) metal 3D printing (GBP 60)

II) eight hours of UK minimum wage labour (UK Government, 2020) for customisation of the plate (GBP 65.60)

III) 1.5 hours of post-processing with UK minimum wage (GBP 12.30)

resulting in a total price of GBP 137.90. As discussed earlier in the paper, some of the benefits of 3D-printed plates include:

I) lower chance of SSI

II) improved medical performance

III) shorter surgery duration (reducing the cost of the operation)

Depending on patients' occupations and lifestyles, these benefits may not be adequately appealing. Given that the demand for a product with such a high price-tag is likely to be low, the early adopters of the product may be athletes and people who need to recover as quickly as possible – that is, people for whom absence from or poor performance at their job is worth more than GBP 140. Because athletes usually retire after only a 20-year career, they tend to spend a great deal of money on their fitness and wellbeing. For top-level players, using bioinert materials could be viable to shorten their recovery period from an injury.

Although the SHAPE may be prohibitively expensive for most people, it has great potential for improvement. Computer modelling and AM are relatively new, and a great deal is being invested in the development of these techniques, which will eventually contribute to a lower price for the final product. According to a report by Wholers (2016), the market value of AM is set to rise from USD 17 million to nearly USD 50 million by 2025. One of the biggest problems of the SHAPE is slow manufacturing. As AM develops further, the SHAPE will be able to produce plates much more efficiently. Developments in materials are also a great opportunity for the SHAPE; as advances are made, the costs of printing metals and bioinert materials are likely to decrease.

Another large part of the SHAPE's cost comes from the manual labour required for customisation. As mentioned in the Methodology section, the customisation process is frequently repeated when using the SHAPE. This process could be dramatically shortened through the development of a Fusion360 application programming interface (API). Although two to three hours' work by experts will still be needed, subsequent processes will be able to be truncated. I expect to develop the first version of this API during the summer, under the supervision of Dr Connor Myant.

At this point, the SHAPE is certainly projected to be an expensive product. However, as discussed above, technological developments are taking place around the world, which will contribute to a decrease in the price of the SHAPE. Within a few years, the SHAPE has the potential to become a powerful and reasonably-priced treatment for fractures.

VI. Conclusion

Although patients' recovery rates may be impacted by a number of factors, including genetics, nutrition and performance of rehabilitation exercises, plates play an important role in their healing as well. Conventional bone plates offer various benefits, including their readiness, ability to be mass-produced and economical price. However, there is plenty of room for innovation to improve upon this existing technology. Because conventional plates are mass-produced, they are not personalised, despite the importance of customisation in medicine. This results in many drawbacks, especially in recovery performance. Mass-produced plates create stress localisation on bones, require an excessive amount of screws and increase the risk of medical complications both before and after treatment.

To tackle these problems, this paper developed a new potential treatment for fractures by merging the technologies of computer programming, AM and computer modelling to provide optimal fracture plates for every individual. Given that the anatomical shapes of bones vary, and the fact that every fracture is different, the optimal plate design must be customisable to every patient's unique case. Using Python, the SHAPE creates perfect duplications of CT scans in stl format, which can be turned into personalised plates by medical experts who are also skilled in CAD. By harnessing AM, the SHAPE can produce plates with complete freedom of design. The SHAPE seeks to minimise the problems caused by the design flaws of conventional plates. In theory, these plates offer superior medical performance compared to conventional plates, including a quicker recovery, better union of the bones and lower risk of medical complications. However, the biggest limitation of the SHAPE is its affordability. Due to its high manufacturing cost, it is presently unlikely to be used by the public.

Thus, further development in areas such as AM and material science is required to reduce its price. Creating an API that automates the customisation of plates could also dramatically reduce the cost of the final plate. Once sufficient technological advancements have been made, the SHAPE will be a compelling product for fracture treatment.

Further research, including API development, is also required to complete the development of the SHAPE. It is important to note that, due to the limited time and resources of the module, clinical trials have also not yet been performed. To fully validate the benefits of the SHAPE, multiple clinical trials and further testing must occur.

VII. Acknowledgement

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Appendix

X-Ray to stl File Code Link:

https://drive.google.com/file/d/1IbQQY5IlT4dv3XF5OfMJwW-50oKUvr_v/view?usp=sharing

CT Scan to stl File Code Link:
https://drive.google.com/file/d/1723pXTKdGwi4CMnD8LEP0W08syjruVkd/view?usp=sharing

Final CAD Model File Link:

https://drive.google.com/file/d/1-5KCf_6_vHV73W8FHskPgR8X-pgFB8yw/view?usp=sharing

Logbook & Project Gantt Chart Link:

https://coda.io/d/SeungHui-Huh-Studentship_d5OmTK-ERw2