Templating Bone Shape for Surgical Accuracy

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TEMPLATING BONE SHAPE FOR SURGICAL ACCURACY

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ABSTRACT

This report details the development of the Mobile Assisted Reconstruction in Orthopaedics (M.A.R.I.O) device, an innovative navigation system that enhances the accuracy and efficiency of Total Knee Arthroplasty (TKA).

TKA is a surgical procedure that involves replacing damaged cartilage surfaces at the ends of the femur and tibia with metal components which are cemented or press-fit into the bone. Whilst it is one of the most successful medical reconstruction endeavours, there has been a significant increase in the amount of post-operative complications, with 30% of implants reported as misaligned when utilising conventional TKA procedures [5][6][15]. Currently, TKA is becoming increasingly technology driven, coupled with the invention of PSI and surgical robots. Nonetheless, these have drawbacks which include logistical implementation difficulties as well as a considerable capital investment.

To remedy this issue, a team at Imperial College London's Department of Bioengineering has conceptualised and developed the M.A.R.I.O. The prototype's functionality rests on 3 components: the software-based navigation and control interfaces and the hardware components which include fixtures and sensors. This device leverages smartphone capabilities for surgical navigation. The initial prototype has undergone extensive testing within a laboratory environment concerning femoral implant navigation. Preliminary results demonstrate promising accuracy in placing implants or surgical reference pins. However, the obtained feedback also showcases areas for improvement before commercialisation such as data accommodation for more diverse demographic groups and the inclusion of tibial implant positioning. The focus of our project is based on refining the hardware of the M.A.R.I.O device to guarantee satisfactory functionality for real-world surgical applications using 3D printing to carry out prototype testing.

** Computer Aided Design figures are presented in grey in this report to improve their visibility, but the actual CAD and prototype are white**

1 Introduction

1.1 Project Overview

The project aims to further develop a novel device that works intraoperatively with software that provides navigational assistance during Total Knee Arthroplasty (TKA) procedures. A large research group belonging to Imperial College London works collaboratively on the development of the different aspects of the M.A.R.I.O device.

The M.A.R.I.O system is comprised of a hand-held device, equipped with a smartphone case and a dedicated smartphone application that uses statistical shape modelling to provide anatomic feedback. The device uses a series of plungers placed in an optimal arrangement, so when a reaction force is applied, the surface anatomy of the bone is captured (Figure 1).

Figure 1: Surface Mapping using the M.A.R.I.O device

The focus of our group was solely on the development of the hardware aspects of the device, aiming to facilitate its usage, via testing methods that regularly used 3D printing and computational software for imaging. The development of this system is motivated by the goal of enhancing surgical precision, reducing operation times, and ultimately improving patient outcomes. The desired final product is the full system working with high accuracy and as intended with the additional features implemented, without physical breakage.

1.2 Main Objectives

The main objective of this project was to develop a device that allows surgeons to not rely on patient-specific methods and that addresses the shortcomings of current market products. These can be sub-divided into smaller categories that the team focused on to allow for the device to:

- Increase time efficiency
- Optimise stability
- Increase accuracy
- Reduce manufacturing costs

It must also accommodate for the high variability in bone sizes amongst genders and ethnic groups[8], providing a correct anatomical surface mapping independent of size.

Furthermore, the ease of use for surgeons was prioritised based on feedback from surgeon experience obtained from questionnaires.

Other important factors taken into consideration during the development of the device were avoiding sudden device disassembly, ensuring simple device assembly and sterilisation.

2 Background

2.1 Total Knee Arthroplasty (TKA)

TKA is a surgical procedure that has become increasingly common as a treatment for severe knee damage, primarily caused by osteoarthritis. While TKA can significantly improve the quality of life by reducing pain and restoring function, the success of the surgery heavily relies on the precise alignment of the knee implant. Unfortunately, conventional methods for performing TKA have been associated with a considerable rate of malalignment, leading to suboptimal outcomes, including impaired knee function, early implant failure, and the necessity for revision surgery. These challenges underscore the critical need for innovative solutions that can assist surgeons in improving the accuracy and efficiency of the procedure.

2.2 The initial version of the M.A.R.I.O device

The device was firstly introduced to the team in its early stages of development, with a primary focus on the femur. An overall view of the device can be found in Figure 2.

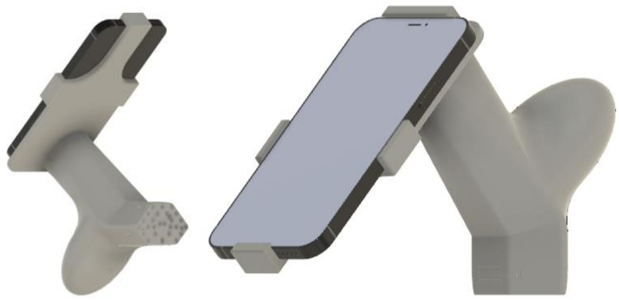

Figure 2: M.A.R.I.O device at the start of the project

The hexagonal head attachment featured an optimal and symmetrical plunger arrangement (Figure 3) to capture all the bone surface anatomical information required for subsequent navigation, without having excess plungers that would increase the cost and the amount of force required to push down on the plungers. The smartphone was held by a casing at four points and a handle that enabled an easy hold for the user.

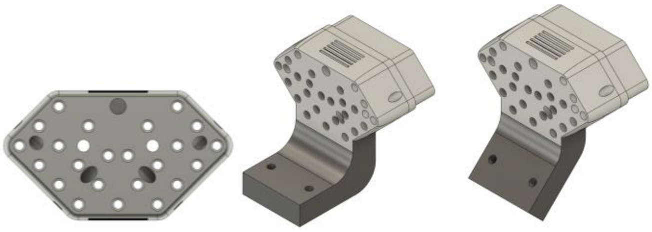

Figure 3: Front and angled views of Hexagonal Attachment

3 Methods and Results

3.1 Design Process Overview

The first step taken in the design process of any assembly part of the MARIO device (Figure 4) is to check whether an initial design of the part is already available. From then onwards, the methodology revolves around carrying out research, Computer Aided Design (CAD) and Computer Aided Manufacturing (CAM) until the design meets the required objectives, after which it will require no further changes:

If there is no first iteration of the design or if said iteration requires improvements, research and CAD (using SolidWorks and Autodesk Fusion 360) are carried out until no more improvements can be thought of, after which the part is 3D printed and tested. If during testing, the part fails to meet the intended purpose or if the improvements don't successfully meet the objectives, more CAD and research are carried out until the objectives are achieved and no further changes are required.

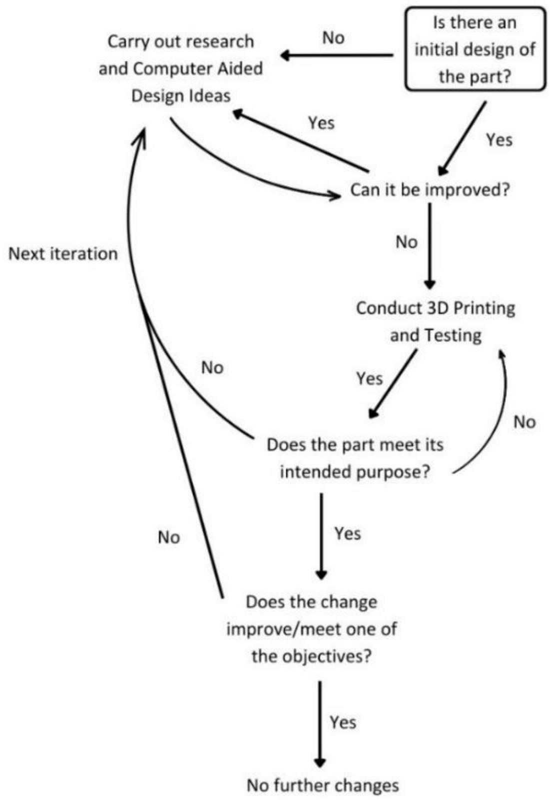

Figure 4: Flowchart representing the Design Process

Testing refers to, once a physical prototype has been manufactured, the part properly fits with the assembly (not too tight, not too loose) and demonstrates durability under the intended operational conditions.

Prototype manufacture was carried out using 3D printing. Material extrusion with a Prusa and Bambu Lab 3D printers was majorly employed using PLA (polylactic acid) and TPU (thermoplastic polyurethane) filaments for those parts that didn't require extreme detail. In the cases in which a better surface finish and high detail were required, vat polymerisation with a Formlabs resin printer was employed. However, material extrusion was the preferred choice due to the comparatively lower price and higher availability at Imperial College London. Additive Manufacturing techniques ensure that the manufacturing cost per part remains low whilst achieving rapid prototyping cycles (Figure 5).

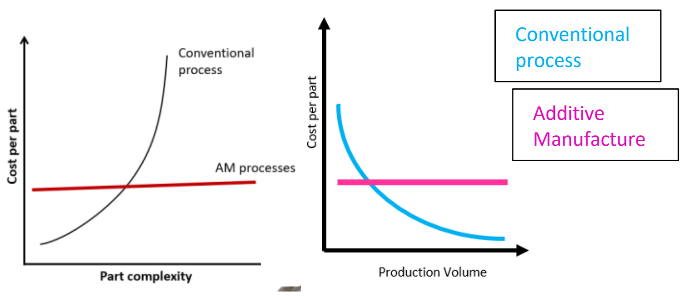

Figure 5 [13]: Graphs representing Cost per part vs Part Complexity and Production Volume

The most common materials choice for material extrusion is PLA or Acrylonitrile Butadiene Styrene (ABS). Petroleum-based plastics such as ABS have many negative environmental impacts [1][12]. Furthermore, PLA has a lower melting point than ABS, 180° vs 200°-260°[12]. Additionally PLA[3], as well as medical grade TPU[11], is biocompatible which is an important point for testing of prototypes. Considering all these factors PLA was our default filament choice.

Figure 6: Initial head attachment design

3.2 ParaView

It is a software which supports post-processing and 3D scientific visualisation. ParaView utilises distributed memory computing and rendering to process complex data and is particularly well suited for large datasets for this reason. The parallel processing capability of ParaView is important for performing the visualisations and measurements of the femoral and tibial datasets. For instance, overlaying multiple bone models at precise coordinates and performing iterative measurements across large datasets. It ensures that data intensive tasks are performed quickly, allowing for iterative and exploratory analysis. Furthermore, the post-processing visualisation feature is crucial since it facilitates detailed examination of specific points and anatomical structures.

ParaView also has high scalability capacity. As the project's data processing demand increases in terms of dataset size and complexity of analyses, distributed memory allows ParaView to scale accordingly without compromising on performance.

3.3 Component design changes and improvements

3.3.1 Head Attachments

Femoral Head Attachment

The main focus of development was the head attachment (Figure 6): refining it to improve its ability to capture the shape of the bone surface (specifically the distal epiphysis) by improving its stability, as this would affect accuracy during surgery. Research was carried out to discover and determine an appropriate attachment mechanism and to increase its versatility, ultimately decreasing manufacturing costs. A snap-fit mechanism was introduced as it cuts down manufacturing time and it is considered sufficiently strong for this purpose.[9][17][18]

Tibial Head Attachment

During a TKA procedure, accurate bone cutting, soft tissue balancing, and adequate coverage of the resected surface are important factors for a successful outcome. Hence, it becomes important to obtain anthropometric data to achieve optimum M.A.R.I.O positioning and the best stability and longevity for implant. One key dimension for selecting suitable implants, which are specific to each individual's anatomy, is the mediolateral or bicondylar width[2]. This is the maximum distance between medial and lateral condyles and is important for providing information about whether the M.A.R.I.O device will fit on the range of tibias in the dataset. Another key measurement is the height difference between the lowest point of the tibial plateau and the highest point. The posterior aspect of the plateau was selected as the lowest point since it declines posteriorly, relative to the long axis of the tibia[2]. The highest point of the tibial plateau is the intercondylar eminence, which is the narrow, raised central part of the intercondylar area located at the centre of the plateau [14].

One key project aim was to analyse anatomical variabilities between ethnicities and gender to inform the design and optimisation of the M.A.R.I.O device. Differences among male and female tibial anatomy is widely reported in the literature, with females having smaller mediolateral to anteroposterior ratio and different proximal tibia geometry[7]. However, ethnic differences haven't received much focus with most prosthesis designs based on Caucasian populations. Accurate placement of prosthesis components is essential for long-term survival of a TKA, however since Caucasian knees are generally larger than Asian knees, [7] this discrepancy may lead to inaccurate bony resections and prosthesis placement in some populations. Therefore, a Korean database was utilised to measure the anatomical variabilities and optimise the M.A.R.I.O for various populations. The entire Korean dataset contained 3D models of 40 female and 32 male tibias, stored as vtk files.

ParaView was utilised to investigate these datasets and the process involved several key steps:

Firstly, each bone from male and female datasets was overlayed at the same coordinates. This allowed for direct visual comparison across the datasets. The initial overlay and alignment were prepared in Python before importing into ParaView, ensuring that the bones were correctly positioned for analysis.
Through visual, iterative measurements within ParaView, the largest, smallest, and middle-sized tibias from each dataset (male and female) were identified (see Appendix 7.3). This step was crucial for understanding the range of anatomical variability within the population studied.

Several specific measurements were taken directly within ParaView to inform the design of the device. The Medial-Lateral Width of the largest and smallest tibia was measured to determine if the current head design of the M.A.R.I.O device could accommodate a wide range of tibia sizes (Appendix 7.3). The distance between the centres of each tibial condyle was measured to aid in optimising pin placement for the device (Appendix 7.3). Additionally, the peak (intercondylar eminence) (figure 11) and the lowest point of the tibial plateau (posterior aspect of the tibial plateau) were identified [2], and their distance measured to determine the minimum pin height necessary for all pins to be captured by the phone camera used in the device operation.

Afterward, images of the different sized tibias were uploaded into the app 'Sketchbook' onto different layers using the same enlarging factor (all scaled equally). The important landmarks were transferred onto different layers and catalogued by colour. This allowed to superimpose them using the midpoint as a reference and selectively turn off the viewing of specific layers,Figure 7.

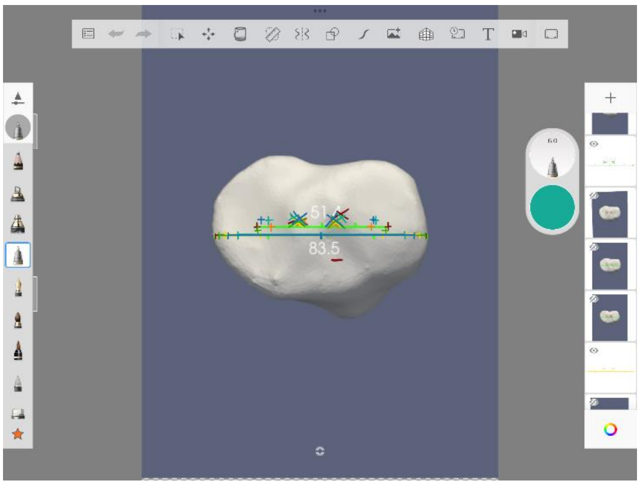

Figure 7: The Sketchbook App workspace. The different layers can be seen on the right hand side

The image of the marked points and the layer containing the biggest sized tibia (Figure 8) was then uploaded onto Fusion 360 using the canvas feature and calibrated to actual size.

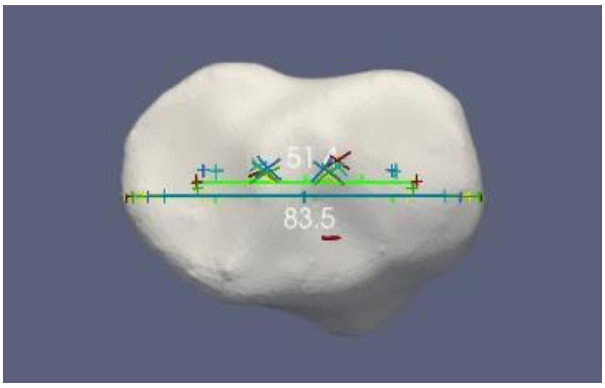

Figure 8: Important landmarks from different sized bones marked over largest tibia: mediolateral/bicondylar width (|), condyle centres (+), intercondylar eminence (x)

The smallest distance between pin centres was established to be 4.8mm to account for the size of the pins, provide enough space between the pin holes for the 3D printer to print it accurately and to allow enough space for the locking mechanism.

It was determined important to have areas of higher pin density around the landmarks, specifically the intercondylar eminence due to its sudden change in gradient. Other pins were placed in such a way that changes in gradient for the condyles were captured whilst making sure pins did not fully cover each other in front of the camera at a 45° angle.

Furthermore, the design of the tibial bone head attachment was optimised such that all pins fell inside the area of the smallest tibia in the database to ensure all pins captured relevant information.

Result: Improved Design

Both the tibial and femoral head attachments have been designed using an optimised plunger arrangement that allows accurate templating of different sized bone anatomies whilst minimising the number of plungers to reduce costs. Arrangement ensures that the plungers don't fully overlap and that they're all visible by the phone camera at a 45° angle so that it accurately captures the bone anatomy, and no information is lost.

Femoral Head Attachment

The current femoral head attachment constitutes 23 plungers of varying heights to account for the varying height of the femoral bone anatomy: shorter 10mm ones on the sides and longer 15mm ones in the centre.
Its oval, symmetric shape allows for increased versatility with the femoral attachment (Figure 9).

A snap fit[4][9] was also implemented with the upper layer and the femoral attachment, reducing manufacturing costs and time (Figure 10).

Figure 9: Improved design for femoral head attachment

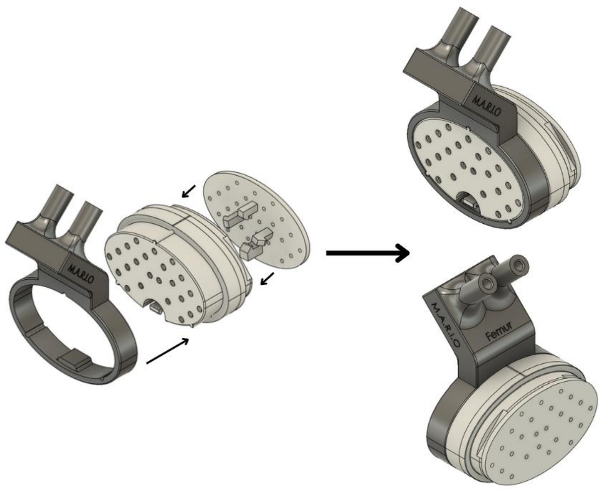

Figure 10: Fitting of the different attachments

Tibial Head Attachment Arrangement

The current tibial head attachment arrangement is comprised of 23 plungers with areas of higher density in the identified important landmarks (as these will provide the most positional information), refer to Figure 13. There is no full overlap at the camera 45° angle to ensure no informational loss and an accurate bone templating (Figure 12). The use of ParaView confirmed the need to employ the longer 15mm plungers to account for both the height between the lowest point of the proximal tibial condyles and the intercondylar eminence, and the difference in height between the posterior and anterior sides of the tibial plateau (Figure 11).

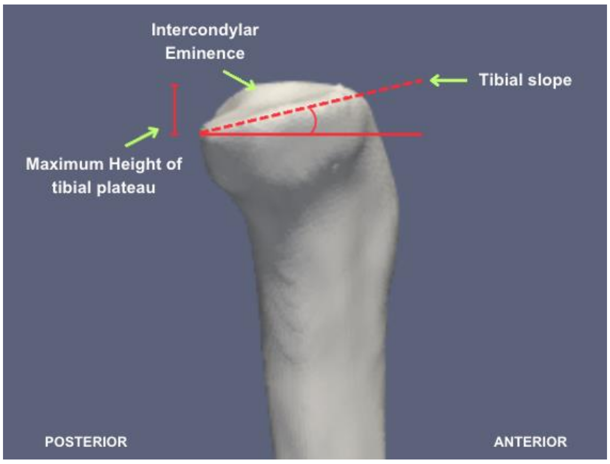

Figure 11: Tibial slope between posterior and anterior sides

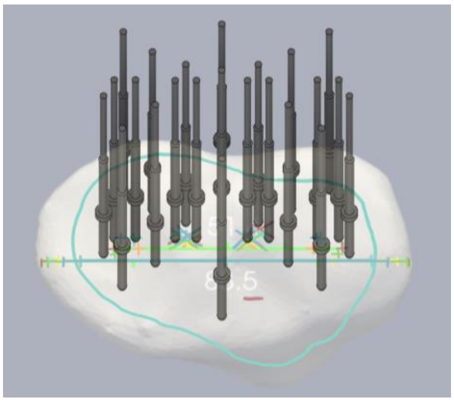

Figure 12: 45° angle (to the transverse plane) camera view of tibial pin arrangement

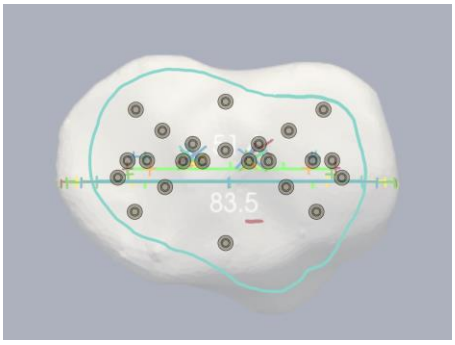

Figure 13: Tibial pin arrangement over biggest and smallest (green outline) tibia bone

3.3.2 Spring Mechanism

The original plungers that were used were custom-made and featured an in-built spring (Figure 14), making them expensive and unfeasible for mass production. As a result, experimentation and testing was conducted to try and implement this mechanism to consist of a minimal number of standardised parts. Through the testing process, a variety of plungers and spring diameters were implemented. The spring constants of the springs were made sure to remain within reasonable limits to avoid causing the surgeon difficulty when applying a force.

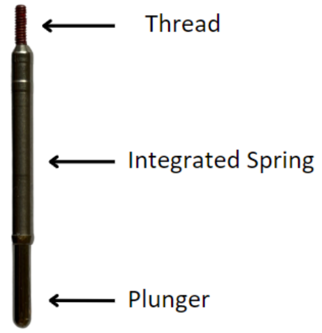

Figure 14: Original Plunger with integrated spring mechanism

Result: Improved Design

The final design for the mechanism to replace the expensive custom-made spring integrated plungers solely consisted of a plunger and a readily available spring, spring constant of 0.008N/mm (Figure 15).

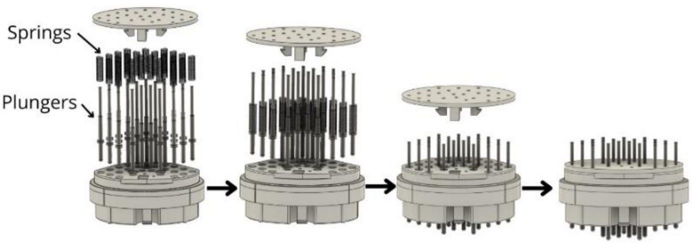

Figure 15: Improved design for spring mechanism

The springs and plungers are held in place through an additional top layer made from TPU that is secured through a snap fit[4][9], instead of screws (Figure 16). This ensures it complies with Design For Manufacturing principles, reducing the time and money associated with assembly process and cost of parts.

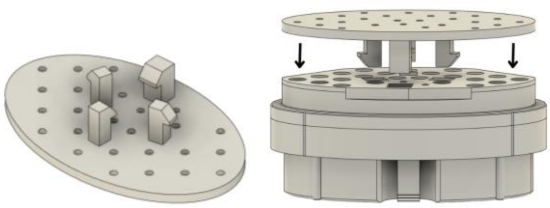
Figure 16: Top base attachment to hold the spring mechanism in place

3.3.3 Plunger Locking Mechanism

Another issue that was tackled was the locking mechanism for the plungers. Once the surgeon has correctly aligned the M.A.R.I.O device on the bone surface, via the aid of the app. The plungers need to be locked into place, otherwise the spring would relax and return them to their original positions, therefore the shape of the surface is lost. Introducing a locking mechanism prevents the movement of the pins.

Figure 17: Initial Locking Mechanism Design

The original mechanism (Figure 17) was made from a single material that consisted of multiple holes to allow for the plungers to move horizontally (side to side). When the pins are in the centre of each unit, they are free to move vertically as the hole is slightly larger than the pin and when the surgeon pushes from either side, the pins are locked in place by the tighter fit (Figure 18). The original mechanism employed an ambidextrous design to accommodate for all surgeon preferences, this characteristic was ensured to be carried through to our improvements.

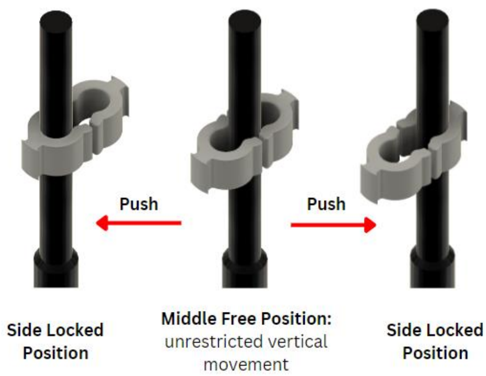

Figure 18: How the plungers lock in place

The original design, combination of PLA material and intricate geometry (Figure 19) suffered from print deformations and breakage upon usage. Therefore, redesigning was needed to eliminate these problems. Criteria for the new mechanism was ability to hold the pins in place for at least five minutes, whilst simultaneously not requiring too much or too little force to switch to the side lock position. The five-minute duration corresponds to the time needed during TKA surgery. Additionally, enduring more than 25 cycles of transitioning between locking and unlock position without damage. Lastly due to the small geometries associated with the part, low likelihood of print deformations were sought after. Each physical design iterations were tested against these criteria.

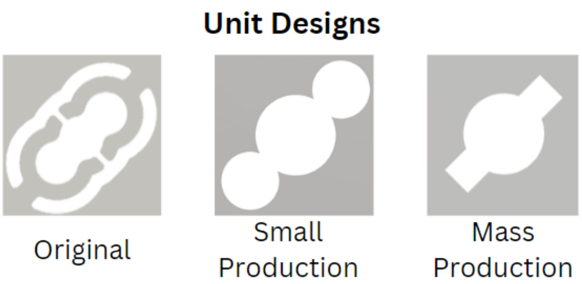

Figure 19: Different lock models under different manufacturing types

Initially, alternative materials were explored to address the brittleness of the intricate sections. Flexible materials such as thermoplastic polyurethane (TPU), manufactured by material extrusion, and Formlabs flexible 80A resin were trialled. However, the units were unable to hold the pins in place when pushed to the side locked position.

Consequently, the unit design needed to be changed to be compatible with the flexible materials. Simplifying the design, to three circles, was chosen to improve quality and reliability of the printing process. An iterative design process was then employed to perfect the dimensions of the three circles. Through iterative adjustments to the dimensions of the circles, compared against test print with the plungers, the final design was achieved, Figure 21.

The part now effectively gripped the pins without breaking. Although, the push-pull wing regions deformed upon force applied and, making it difficult to push the part into the side lock position.

It was concluded that a single material design contradicted with the necessary flexible plunger gripping portion yet sturdy push-pull wing region. Therefore, two material designs were explored next, each consisting of Hard PLA shells with a variety of flexible insides.

Hard PLA shell with a TPU matrix, both manufactured through material extrusion, resulted in a part which was sturdy enough to be pushed into the locking position and an inside that could grip the pins.

Due to the elastic material properties of TPU, the components were prone to low print quality. However, the locking function still held true due to the simple unit design. Material extrusion manufacturing is well suited for small batch manufacturing, as cost effective and in-house manufacturing.

However, this would be unsustainable for mass manufacture. Casting manufacturing methods scale well for mass production. Therefore, this avenue was explored. Different flexible materials were tested using the casting method (Figure 20). Both the shell and template/mould are made from PLA material extrusion. The Prusa 3D printer could not capture the fine detail of the template mould. Consequently, the unit design was simplified to the mass production design (Figure 19).

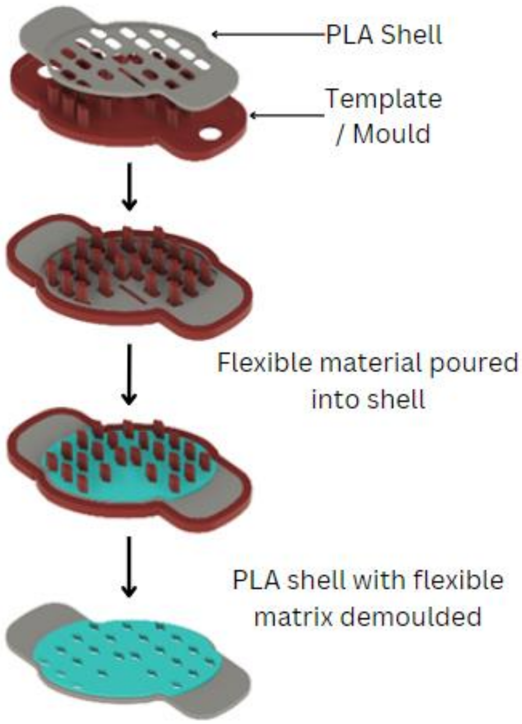

Figure 20: Creation of the locking mechanism mould using flexible material

Formlabs flexible 80A resin required curing to set for the formula, however this caused warping of the PLA shell. Two different two-part silicone rubbers were tested. BBDINO Super Elastic Silicone was too flexible therefore could not grip the pins for over one minute. Bentley advanced materials, Dragon Skin 10 Fast resulted in a matrix sturdy enough to grip the pins for over 5 minutes.

Result: Improved Design

Two new plunger locking mechanisms were introduced, demonstrating reliable performance by effectively restricting plunger movement for over five minutes (Figure 25, Table 5, for tables refer to Appendix 5), enduring more than 25 cycles of transitioning between locking and unlock position without damage (Figure 23, Table 3) and reduced the probability of print deformations by 3-fold when compared to the original design (Figure 24, Table 4). A sample size of 10 prints and or castings for each design were used.

The **small batch design** consists of a PLA shell with a TPU flexible matrix, both components are 3D printed, as seen in Figure 21.

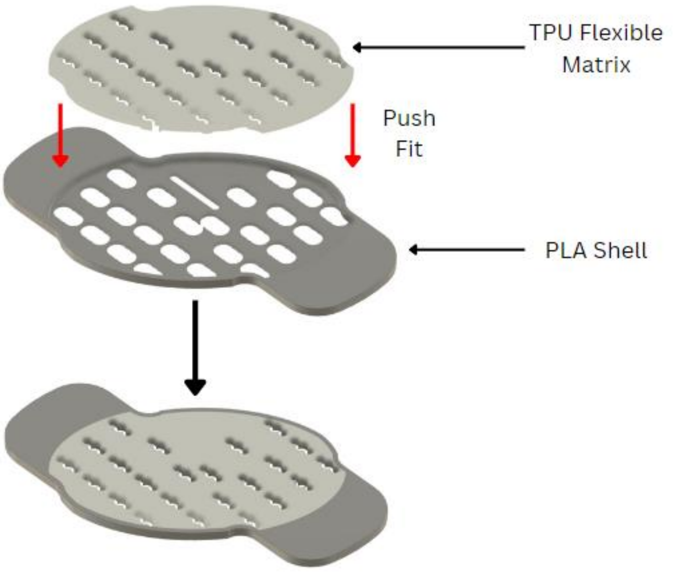

Figure 21: Creation of the locking mechanism mould using TPU for small batch production

The **mass production design** consists of the same PLA shell with a flexible two-part silicone (Bentley advanced materials, Dragon Skin 10) matrix which is casted into a mould/template.

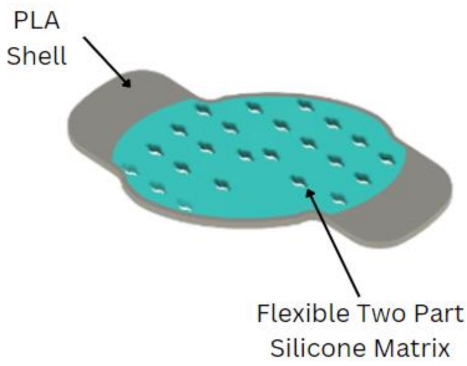

Figure 22: Creation of locking mechanism mould using silicone for mass production

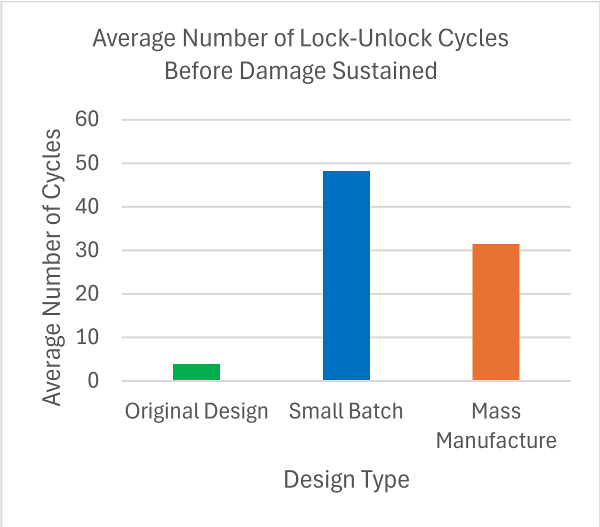

Figure 23: Bar chart representing Lock-Unlock Cycles before damage for different designs

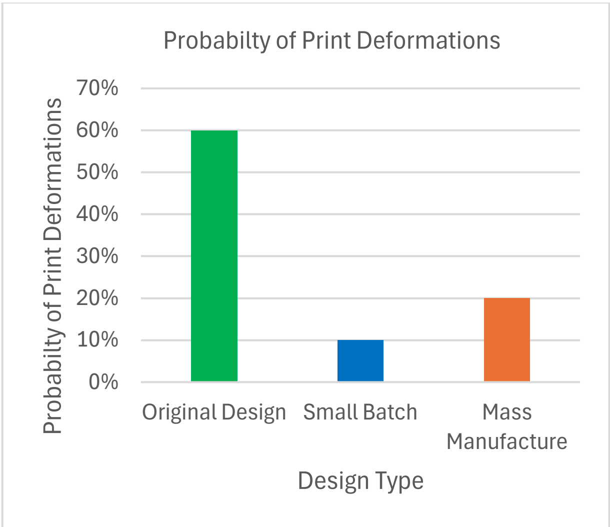

Figure 24: Bar chart representing Probability of Print Deformations for different designs

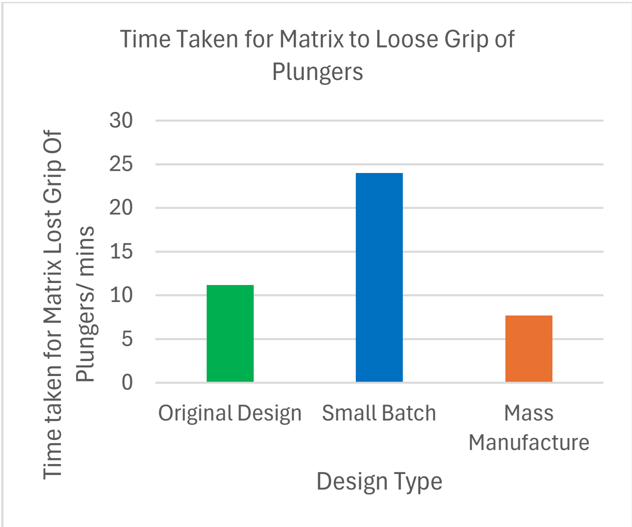

Figure 25: Bar chart representing time taken for flexible matrix to lose grip of the plungers for different designs

3.4 Plungers

After thorough testing of the first version of the MARIO device was completed (i.e. testing the device on a "printed" bone), it was found that the plungers would reflect the light emitted from the flash of the smartphone camera, due to their shiny, silver property (Figure 26). The flash of the camera was important for plunger detection so could not be altered. As a result, intensive research was carried out, looking into possible solutions to overcome this. Initially, options such as changing the optical system, applying optical coatings, using an Arduino camera module, adding a non-polarized filter, and buying a Keyence vision system were considered. Each of these approaches, however, introduced unnecessary complexities or costs, which were impractical for a device intended for single use.

Figure 26: Initial silver metal plunger

Result: Improved Design

The most effective and economical solution was to paint the plungers using black-coloured coating (Figure 27), paired with a device printed using white PLA filaments to enhance contrast. This decision was driven by the black coating's ability to absorb light, thereby reducing reflection, and the white colour provides optimal visibility.

By applying a simple and effective change on the device's physical properties, its functionality was improved, maintaining low-cost and ease of use.

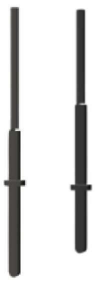

Figure 27: Improved design for plungers (with a black coating)

3.5 Phone Case

The initial encasing used for the smartphone, only consisted of a back cover with holding points at the four edges, as seen in Figure 28.

Figure 28: Initial Phone Case Design

While this allowed for the smartphone to be securely attached to the device, it also brought complications when considering the sterile environment required for surgery. It was deemed unsuitable. The constant exposure of the smartphone to the surroundings posed a significant risk of infection during procedures, even if the smartphone was thoroughly cleaned beforehand.

Extensive 3D printing and testing were carried out throughout the duration of the redesign period. If a full encasing was considered, it was crucial to ensure that interaction between the user and the smartphone remained feasible. Sizing and function were mainly checked to ensure that it worked effectively.

Result: Improved Design

To further develop from the previous phone case design, it was decided that the entire smartphone should be fully encased in a material to improve sterility.

The case now consists of a base and top cover, permanently attached together through a hinge mechanism. A latch can on the opposite edge allows for a temporary attachment that enables the phone to be placed inside the case before surgery and retrieved from it after surgery while ensuring the phone doesn't fall out during surgery. A continuous line that acts as a spacer, lines the perimeter of the smartphone case, offset by 5mm towards the inside allows for the placement of a thin silicone seal/strip, ensuring an air-tight fit. It can be further reinforced with the addition of glue in tight spaces, reducing the possibility of external micro-organisms from entering the system (Figure 29). The design also includes a transparent screen to ensure visibility and act as a barrier between the external environment and the smartphone. It is attached to the smartphone case via attachment points on each edge to fully secure the smartphone into the correct position with the aid of glue. This type of mechanism allowed for a lower cost while also creating a tight and reliable fit that would ensure a sterile environment.

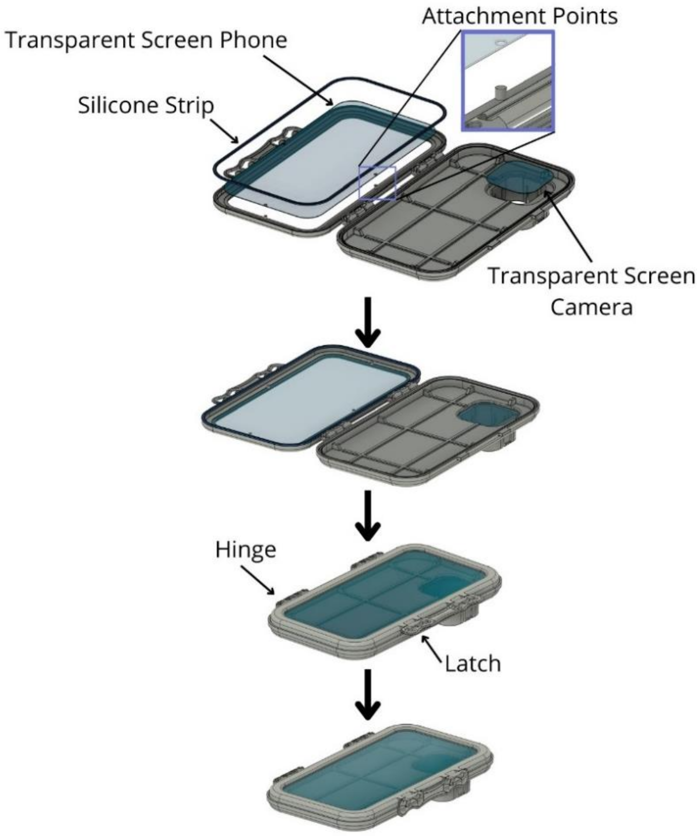

Figure 29: Mechanism for Improved Phone Case

3.6 Reversible Attachment for the Tibial Head

The TKA procedure can either be performed on the left or the right leg of the distal femur epiphysis or the proximal tibia epiphysis of the patient, or potentially on both.

When performing the tibial cut during TKA, the angle at which the surgical guide on the M.A.R.I.O is positioned varies depending on which leg (left or right) the surgery is being performed on. This variation is necessary because the insertion points for the surgical guide pins in the tibia are not directly at the front but are slightly towards the side (laterally). Therefore, the placement cannot be symmetrical, unlike the attachment on the femoral head.

As a result, two separate head attachments would need to be developed. Requiring changing the head attachment mid-surgery for each leg would result inefficient and time-consuming from the surgeon's perspective, so an alternative method that also reduced costs was developed.

Result: Improved Design

The design was determined by creating a two-part attachment: an oval ring that fits around the head and the surgical pin holder. The oval ring can easily be flipped around, immediately providing the angle needed for the cut without requiring different attachments. It is labelled with an L (left) and R (right) to quickly illustrate to the surgeon which side is required (Figure 30).

The small ridges within the perimeter and the complementary extrusion on the head attachment of the M.A.R.I.O device enables them to fit together like a tongue and groove joint to ensure the surgeon uses the unit correctly. The versatility of the attachment ensures only one attachment (instead of two) is required for both legs, effectively reducing costs.

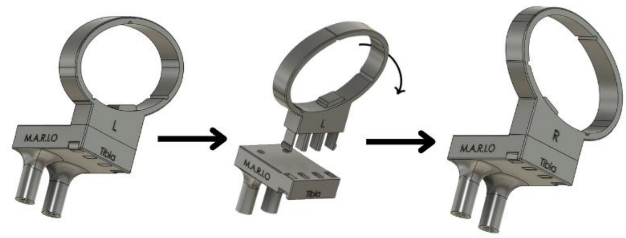

Figure 30: Two-part tibial reversible head attachment mechanism

3.7 Handle

Initially, the handle was made to be ergonomic and included an extrusion to allow for improved hand placement and accommodate for ambidexterity (Figure 31). However, in the context of mass manufacturing, this would prove to be difficult as the main method explored was injection moulding, which does not suit complex shapes and would increase overall costs.

Figure 31: Initial Design of the Handle

Result: Improved Design

To accommodate for injection moulding (for mass manufacturing), the additional handle was removed to simplify its shape but still retain its function.
It was also made a two-part design to allow for easier insertion of the layers of the head attachment and a tongue and groove joint holds both sections together, Figure 32.

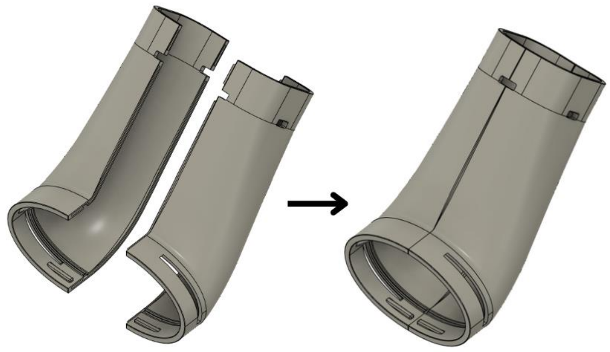

Figure 32: New, two-part Design of the Handle

3.8 Mitigating Risks

During medical device development, ensuring safety and mitigating risks is essential. See Appendix 7.4 for a detailed risk analysis, outlining the various categories of potential risks, including mechanical, biological, electrical, operational, and informational.

Overall, all risks were halved or more than halved post-mitigation except for 'Data leaked', reflecting the effectiveness of the mitigating measures. However, certain risks, particularly 'Incorrect bone cutting' and 'Data leaked', still have relatively high RPNs after applying preventing measures, as they are both difficult to detect even after the mitigation.

4 Discussion

4.1 Overview

The main aim of the M.A.R.I.O device is to equip surgeons with a single-use, hand-held device that allows them to identify implant placements in a cost-effective manner. Alterations have been implemented into the M.A.R.I.O device with an emphasis on improving its overall function through modifications to the head attachments. These enhancements include different pin coatings, new configurations such as the spring and locking mechanism designs and modifications to smartphone case and handle shapes to provide users with security, flexibility and increased accuracy needed for surgical TKA:

The revised spring system is characterised by the implementation of readily available springs that minimise costs whilst maintaining consistent operational efficiency and structural ease during TKA procedures.

An effective locking mechanism has been integrated into the system to allow for increased controlled stability during usage, increasing surgical accuracy and speed.

The introduction of matte black coatings to the plunger design prevents light reflection and improve camera detection capabilities.

The phone case now encapsulates the whole smartphone and paired with a latching mechanism and tight silicone seal increase safety and sterility.

The handle design has been streamlined to adapt to mass manufacturing procedures.

Each of the individual components was trialled for their planned use. Post-testing, the device was assembled (as seen in Figure 33) and re-tested.

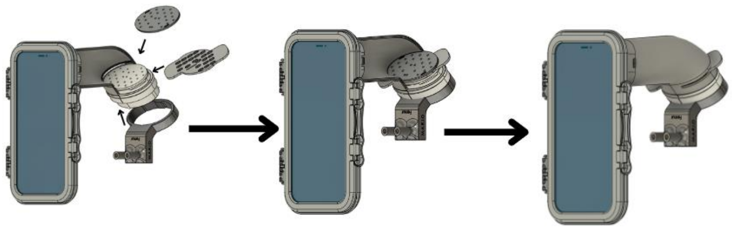

Figure 33: The full assembly of the M.A.R.I.O device, showcasing the positions of each component

4.2 Opportunities for Improvement

One of the main strengths of the device is its cost-optimal nature in contrast with other options such as surgical robots and patient-specific instrumentation using readily available materials and compliance with mass production strategies. Surgical accuracy is enhanced by ensuring accurate implant positioning during TKA procedures thanks to components such as the spring, plunger and locking mechanisms. The user-friendly interface of the design with intuitive labels, simpler handle design and two-part attachment for the tibia, optimise the learning process for surgeons using the device. Implementing testing results of the different design configurations allows the device to satisfy the requirements of surgeons and patients alike.

The creation of a singular head attachment that can map the surface of both the tibial and femoral head would further streamline the surgical process by reducing time needed so surgeons would not need to swap attachments. This also contributes to reducing the overall cost of the device as the plungers are found to be expensive in bulk purchases.

Conducting tests on the newly designed tibia head attachment, regarding its plunger arrangement, is critical to assess its performance. This will be done using trials on the tibia heads which complying with the provided data set. It is important that a more varied data pool is included to allow for further accommodation of different demographic groups. For example, Asian populations have some differing anatomical attributes and therefore are not representative of the entire population [16].

Adding a ball to the pins (Figure 34) will enhance the quality of camera visibility, consequently increasing the precision of the M.A.R.I.O device's navigation system. The ball already having a thread contained within would allow increased stability. Together this would mitigate the possibility of surgical error as the camera would be able to detect the necessary location better.

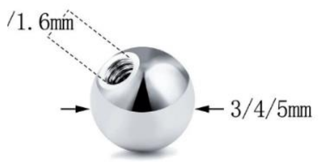

Figure 34: Metal Ball for Plunger

On the one hand, the M.A.R.I.O device presents several assets including cost-optimisation, increased accuracy and simplified usability. On the other hand, it encounters obstacles such as design intricacy, clinical application, technical and training necessities. These challenges will be tackled through continuous research and iterative improvement processes to attain the full scope of the M.A.R.I.O device in TKA.

5 Conclusion

The M.A.R.I.O device is a cost-effective, smartphone-based intra-operative navigation system designed to enhance implant positioning accuracy during surgery. Unlike alternatives in TKA surgery, such as surgical robots and patient-specific instrumentation, which are both expensive, time-consuming and require extensive training, the M.A.R.I.O device offers a more accessible solution. Throughout this project, the device was optimised for bony resections on both the tibia and the femur. This was achieved by modifying the pin arrangement and adjusting the travel distance of each pin in the tibial head attachment to better suit its anatomy. An improved spring mechanism was introduced to enhance the device's cost-effectiveness, paired with a reliable locking mechanism that secures the pins in place once the ideal location is determined, assisting surgeons during procedures. This mechanism proved resistant to cyclic loading and unloading up to 50 times, confirming its suitability for single-use and mass manufacturing. Furthermore, a black, biocompatible coating was applied to the pins to facilitate easier detection by the user's camera. The original phone case was enhanced to improve sterility while maintaining user practicality. Lastly, the device handle was simplified to ensure the M.A.R.I.O is well-suited for mass production. These additions and improvements to the M.A.R.I.O device are designed to enhance its effectiveness in TKA, improving patient outcomes, procedural efficiency, and ergonomics.

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7 Appendix

7.1 Project Management Assessment

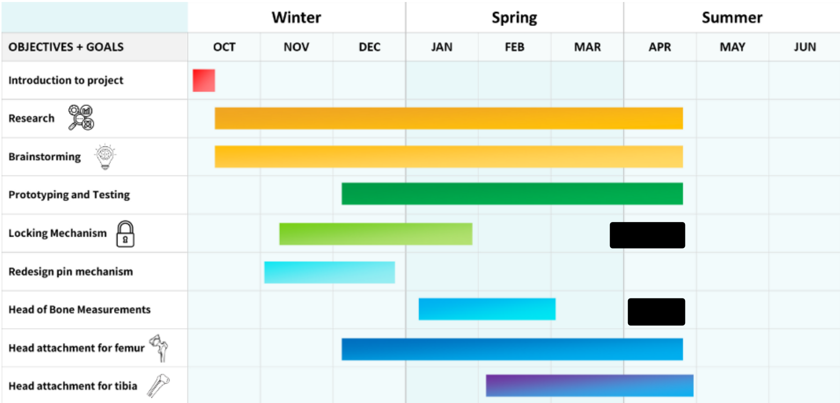


Figure 3528: Project Schedule as laid out in Project Pitch

All objectives and goals have been completed true to the schedule as set out in our project schedule from the project pitch (Figure 35) except for the 'Locking Mechanism' and the 'Head of Bone Measurements'. However, this divergence from the original plan does not signify poor planning. At the time of the project pitch in March we believed that these aspects had been finalized. Subsequently, we have identified opportunities for refinement in both areas which will result in significant improvements, corrections to the project schedule is shown in black on Figure 34.

For the 'Locking Mechanism' we later noted that our solution, later used as small batch design, would only be viable for a prototype or small testing samples as it would not scale to mass production. As the manufacturing method of material extrusion 3D printing for the design could not be reliably converted to injection moulding due to the fine complex geometry. Consequently, we redesigned the manufacturing process to casting, which would scale well to mass production.

Likewise, for the 'Head of the Bone Measurements' our initial goal of collecting data and analysing bone size variation was completed in the time allocated in Figure 35. However, we later discovered the importance of analysing the variation in landmarks on the tibia for accurate navigation.

7.2 Project Management Lessons

3.1 Communication, empathy, and teamwork

We have learned to acknowledge that diverse schedules and commitments we have as university students to foster a good group mentality. Understanding that at different points each group member will have varying availability, empathy towards each other is essential for effective collaboration. We must communicate our differences in availability so that we can synchronize our efforts and maximize our productivity.

3.2 Internal Deadlines

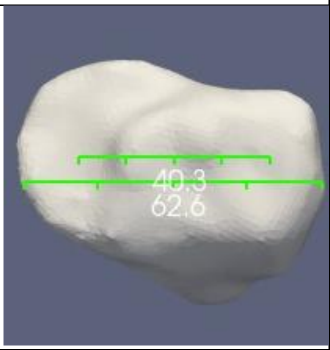
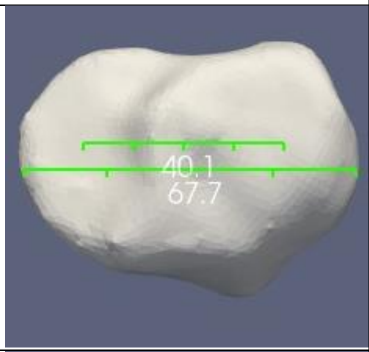
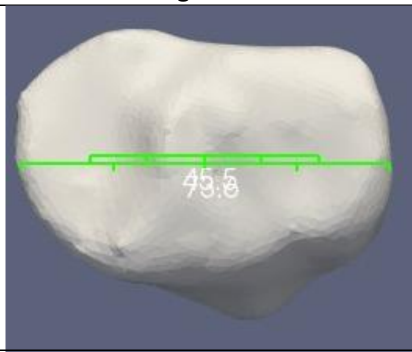
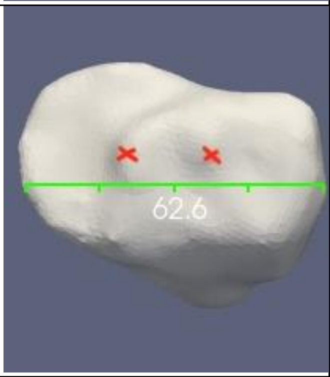
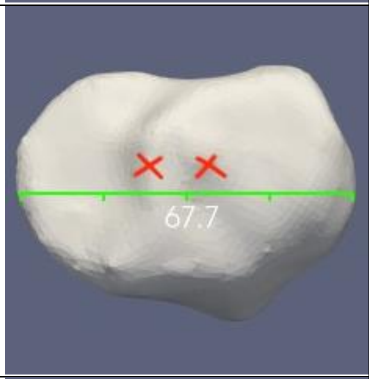
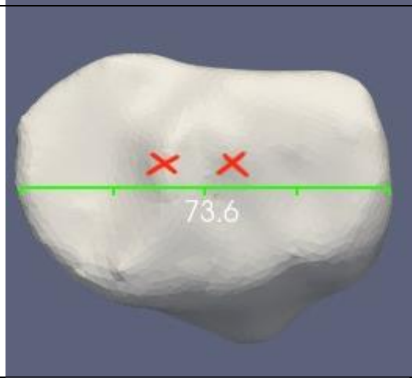
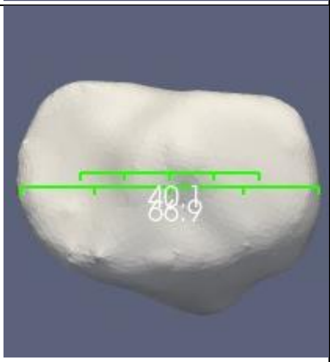
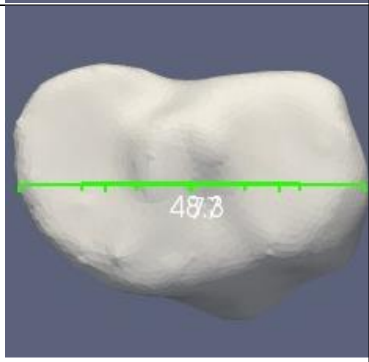
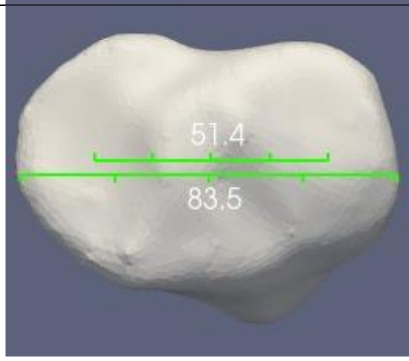
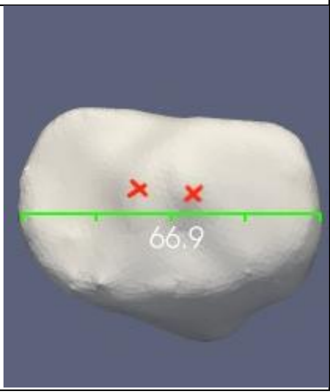
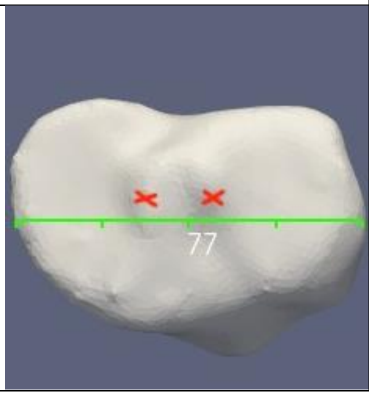
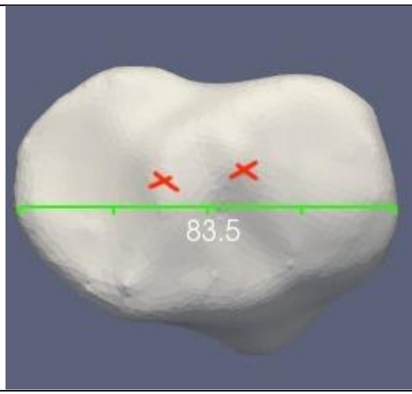
Setting internal deadlines has been found to be imperative to keep momentum and accountability for the project. Building upon the previous point, setting internal deadlines allows individuals to efficiently manage their time as well as facilitating open discussions about the distribution of workload and feasibility.

3.3 Team Leader

We have found the role of a team leader to be necessary to act as an information hub and liaison for all group members. Centralizing the role allows information and updates to seamlessly permeate to all members and ensures each participant stays focused on their tasks. Specifically, a team leader which understands each members strengths and weaknesses allows efficient delegation of tasks, leading to efficient workflow.

7.3 Tibia Sizes

Table 1: Measurements taken on Proximal Tibia Epiphysis

	Type of Measurement	Small Tibia Size	Medium Tibia Size	Large Tibia Size
Female	Mediolateral/Bicondylar Width And Distance Between Condyle Centres			
	Intercondylar eminence And Mediolateral/Bicondylar Width			
Mae	Mediolateral/Bicondylar Width And Distance Between Condyle Centres			
	Intercondylar eminence And Mediolateral/Bicondylar Width			

7.4 *Table for Risk Analysis*

For each identified risk, the severity (S), occurrence (O), and detection (D) were assessed both before and after the implementation of preventative measures, using a Risk Priority Number (RPN) system. Quantifying these risks allows to propose targeted measures that substantially decrease the RPN values, showing a reduction in potential hazards.

Table 2: Detailed Risk Analysis Table

Category	Risk	Cause	S1	O1	D1	RPN before	Preventing measures	S2	O2	D2	RPN After
Mechanical	Device disassembly during surgery	Failure of material	7	2	1	14	Prototype testing	8	1	1	8
Biological	Infection	Incorrect sterilization or Incorrect sealing of the case	7	3	2	42	Check the sealing during assembly and sanitise the device thoroughly before surgery.	6	2	2	24
Electrical	Battery Failure	Battery health decreased during frequent usage	7	2	3	42	Charge the phone before surgery and Replace old batteries	7	1	3	21
Operational	Incorrect bone cutting	Inaccurate prediction in software	8	2	5	80	Computational testing and Updates	8	1	5	40
Operational	Data leaked	Inadequate access control	5	3	6	90	Data encryption and anonymisation	5	2	5	50
Operational	Inconvenient APP navigation	Over-complicating UI	3	4	1	12	Update the UI based on feedback	2	2	1	4
Informational	Incorrect bone cutting	Incorrect usage of device	8	4	2	64	Instruction and training	8	2	1	16

7.5 *Locking Mechanism Data*

Ten of each design, original, small batch and mass manufacture were tested against their ability to withstand damage from locking-unlocking cycles, print without print deformations and grip strength of the flexible matrix.

Table 3: Shows the number of cycles each part took to sustain damage.

	Number of Cycles Until the Part Sustained Damage											
Trial Number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**Mean**	**Standard deviation (3s.f.)**
Original Design	7	1	2	5	11	1	1	2	4	5	3.9	3.08
Small Batch	47	35	20	1	100	34	64	90	13	78	48.2	31.9
Mass Manufacture	55	5	30	82	41	27	23	42	1	8	31.4	23.6

NB: If the part already had print deformations these regions were ignored during these trials.

Table 4: Shows whether the print trial number had print deformations, then calculates the probability of print deformations.

	If Part Printed with Print Deformations (1- Yes, 0- No)											
Trial Number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**Mean**	**Standard deviation (3 s.f.)**
Original Design	1	1	0	1	0	0	1	1	1	0	0.6	0.490
Small Batch	0	0	0	0	1	0	0	0	0	0	0.1	0.300
Mass Manufacture	0	0	1	0	0	0	0	0	1	0	0.2	0.400

Table 5: Shows the time each print trial number held all plungers in place.

	Length of Time Each Part Held All Plungers In Place (mins)											
Trial Number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**Mean**	**Standard deviation**
Original Design	9	15	2	10	8	7	9	18	4	30	11.2	7.678542
Small Batch	14	18	3	15	19	31	19	60	21	40	24	15.22498
Mass Manufacture	5	8	2	1	9	16	24	1	7	4	7.7	7.072353