Development of virtual surgical planning models and a patient specific surgical resection guide for treatment of a distal radius osteosarcoma using medical 3D modelling and additive manufacturing processes

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Abstract

In this study we will assess the design and fabrication of a patient-specific resection guide to augment surgical procedures, such as bone grafts and implant placement. Medical imaging data was used to form a 3-dimensional, digital template model of the target anatomy to incorporate surface topography information into the guide. The surgical guide was then designed to incorporate slots for bone cutting, holes for drilling of fixation points, and an optimised geometry which ensure ease of placement and use. The final device was then manufactured using additive manufacturing, to accurately replicate the complex surface topography and design features. To validate the design, the target patient anatomy was replicated using additive manufacturing and a 'mock' surgery was performed to assess the device performance. We found our design allowed for efficient placement and use during the mock surgery, confirming the potential of the devised process as a robust methodology for clinical implementation.

1 Introduction

The necessity to derive solutions for the enhancement and streamlining of surgical procedures are a vitally important goal towards achieving improved patient outcomes. From the surgeons perspective such solutions would comprise devices to assist inthe surgical resection process to minimise the removal of healthy bone from a patient, alongside the use of patient tailored, custom solutions to address an underlying condition (e.g. bone replacement implants). In response to these demands, and coinciding with innovations in the fields of material science, advance design and additive manufacturing, devices are now emerging which address these criteria through the so called patient specific paradigm. Using such technologies, many innovative medical device innovations have been demonstrated with applications ranging from medical modelling [1-3], implantable devices [4, 5], prosthetics[6, 7], and orthotics [8, 9].

With respect to surgical interventions, patient specific technologies are a rapidly emerging area in pre-clinical planning, bone resection and implantable devices with demonstrated applications in osteotomies [10], cancer resection [11, 12] and bone replacement [4, 5, 13], amongst others procedures. Osteosarcoma surgeries (removal of bone tumours) can be a somewhat involved process requiring the use of chemotherapeutic action [14, 15], alongside the resection of the offending bone tissue [15, 16] in an attempt to completely remove the compromised tissues and halt any form of

metastatic progression. Once performed, the residual uncompromised bone also requires fixation into its original orientation using either donor bone tissue or a load bearing implant alongside a fixation plate in order for the patient to regain normal use of the anatomy in question. Given the necessity to remove sections of corrupt bone from a patient, such procedures could significantly benefit from the use of patient specific technologies to streamline resection and piloting of drill holes for the fixation plate. Additionally, given the unique topography of a patient's anatomy, it would be desirable to move beyond the typical, generically sized fixation plates, to ones that more accurately mirror the patient's bone topography, thereby realising a better fit amd improving the ability to retain the original orientation of the resected bone. Indeed there is significant potential for the fixation plate to be used in conjunction with a custom resection guide as part of a more comprehensive treatment option.

In this study, we aim to develop a platform by which advanced design and 3D printing concepts can be used as a methodology to examine complex osteosarcoma in a simulated patient case study. Custom resection technology for such procedures have been demonstrated previously [11, 17] but have been relatively crude in their design and could significantly benefit from further innovations. Initially, we replicate a patient case study who presented with a parosteal osteosarcoma of the radius, and replicate the tumour morphology on a publically available patient representative model, derived from CT scans. The advantage of this approach is that we can simulate the particular case study in a platform that is free from typical ethical constraints when using patient specific data yet still be reflective of a working example for examining the logistics of device development. We believe our demonstration to be the first example of such an approach. Using the devised patient representative model, we develop a custom resection guide which integrates functionality to avoid collision with the osteosarcoma, makes use of natural surface contours to provide optimal placement, integrates resection/drill/pin openings and a handle to easily manoeuvre the guide. We believe our guide to be the most sophisticated example of a patient specific guide found in the literature to address surgical intervention of distal radius osteosarcoma resection. The guide fundamentally realises all features required to perform all surgical intervention elements prior to fixation plate and implant/bone donor bone placement. To take the work a stage further, we also develop a patient specific fixation plate and mock, scaffold implant intended for use with the guide, providing a complete system for surgical intervention. In the present study, we focus our attention on the design and product prototyping elements to demonstrate the potential feasibility of our approach. Ultimately, our methodology provides a relatively low cost means of examining the logistics of the device development under simulated circumstances, whereby the anatomical features of a patient are reproduced accurately, at low-cost and with no impact on the patient's wellbeing. We believe there to be significant potential for the devised devices to be 3D printed in biocompatible material for use in actual clinical circumstances.

2 Methodology

2.1 Anatomical data modelling

Models of the patient data were constructed using anatomical data sets derived from CT scan data, based on the standardised Digital Imaging and Communications in Medicine (*DICOM*) file type with an image slice thickness of approximately 0.6mm. To convert the data into a working 3D digital model Mimics 19.0 (Materialise, Belgium) was used to isolate and extract the bone data based on a

Hounsfield Unit (HU) threshold of 226-3071. Within Mimics bone models for the hand, wrist, ulna and radius were segmented from the wider data set and exported as STL files for further post processing.

2.2 Cancer Design

The segmented bone STL models were exported into 3-Matic Research 11.0 (Materialise, Belgium) for additional post processing to remove errors and major defects from the Mimics conversion process. To avoid ethical issues relating to the use of clinical patient data, we appealed to a published case study of a parosteal osteosarcoma of the radius [18], which we digitally reproduced as our example case for design of the resection guide (Figure 1). In this patient case, the tumour was defined as being attached to the surface, and wrapped around the bone. CT scan images revealed the outer geometry of the tumour from several reference viewpoints. The written and visual evidence of the osteosarcoma in the patient study provided sufficient information to approximate the geometry of the tumour and to form our hypothetical digital tumour model for examination.

2.3 Resection Guide Design

The combined model of the patient specific anatomy of the arm and the tumour model were used as the template for the resection guide design, which was developed using 3-Matic. To construct the primary features of the resection guide, we manually designed elements in CAD software (Solidworks, DassaultSystemes, France). These features were then integrated onto a surface projection of the patient bone model, adjacent to the tumour site. Using this approach, the patient specific bone projection segments would allow for the ideal placement of the guide and self alignment using the natural contours of the bone as a locator guide. The use of traditional CAD, allows for the precise design of the bulk portions of the resections guide, such as the cutting slots, drill holes, Kirschner wires fixation ports and an ergonomic handle for manoeuvring/placement.

When designing the resection guide consideration needs to be made as to the thickness of the part to ensure sufficient rigidity, but without enlarging the device to a point which results in complications during placement. Rigidity is important to ensure the device does not break during use and that flex it minimised to retain geometrical accuracy. Keeping the device footprint to a minimum is important as to improve the patient recovery and avoid complications resulting from infection, general practise is to minimise the area exposed during a surgical intervention. Therefore the smaller the device the smaller the area that needs to potentially be exposed during surgery. As it is unknown a priori what the ideal geometrical attributes of the device should be, we examined various design iterations until a satisfactory candidate design was achieved, which was then manufactured for virtual surgery.

2.4 Implant Design

In this study we aimed to construct a concept of a patient specific bone fixation plate that could be used in conjunction with the resection guide. To achieve this we built a plate based on the typical design of a standard distal radius surgical plate [19]. The plate is designed in 3-matic based on the surface topography of the mock patient's bone model and around the planned drill holes on the resection guide. Using this methodology we hoped to demonstrate

a precise fit of the final bone fixation plate and alignment of the planned pilot holes. Additionally, as the system has been designed around the original positioning of the bone, once the plate is in position, we anticipate the remaining bone segments to return to their original position. For simplicity in the initial design, screw holes were designed to be non-locking, for use with fully threaded screws, and with an upper tapering section to allow the screws to sit flush with the mock plate.

Alongside the fixation plate, we design a conceptual scaffold type implant to be used in place of donor bone material. The scaffolds would potentially be representative of titanium implant that could allow for osseointegration or some form of bioprinted device. For now our intension of this element is purely cosmetic and for illustrative purposes, and is not intended as a developed treatment component. In future work we aim to develop this component further.

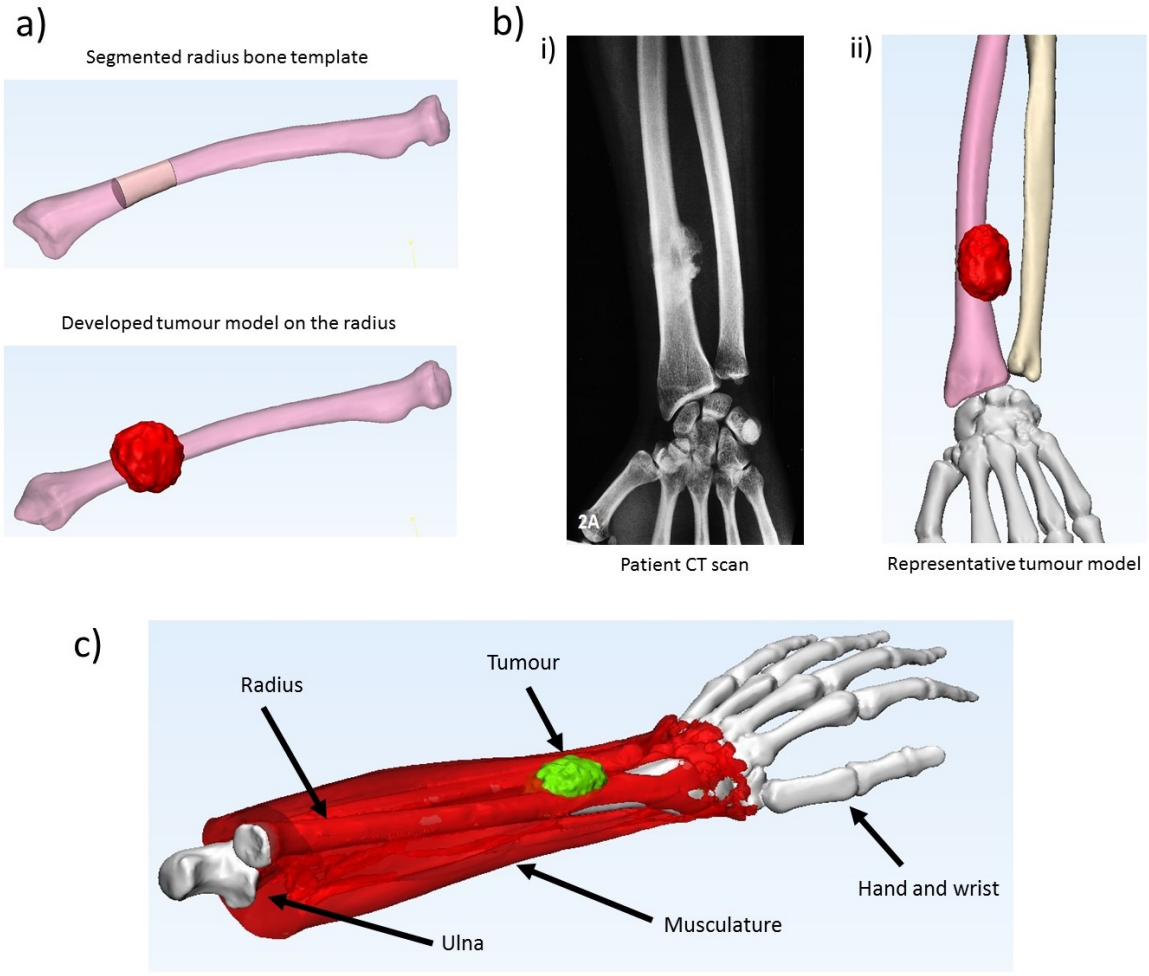

Figure 01: a) Illustration of the surface osteosarcoma model formation process, b) a comparison of the CT scan image of the actual patient case study [18] and the digital representative model of the same case study and c) a concept view of the osteosarcoma on the patient.

2.5 Prototype manufacturing

This study focused on the design and surgical device developments facet. As they will not be used for direct clinical use, the various design iterations of the anatomical features, the resection guide and implant were realised using Filament Fused Fabrication (FFF) printing in commercially available ABS plastic. This material provides a good representation of the final medical devices, alongside the patient's representative anatomy. Evaluation prints were performed using a commercially available desktop printer (Flash Forge Dreamer, USA), which allow for a rapid turnaround time for part production. It is anticipated that the final resection guide will likely be printed using either FFF or Polyjet printing methodology in biocompatible materials (PC-ISO, MED 610, etc). However for evaluation purposes, the current ABS models would be comparable to parts made in such materials.

3 Results

3.1 Cancer Anatomical Modelling

The cancerous model was constructed by directly manipulating the patient specific radius bone model to shape the tumour. Initially, a template portion of the distal region of the radius in the approximate location of the tumour, was segmented from the wider radius model of the patient and enlarged in the x-y-z direction by a scale factor of 2, yielding an enlargement of ΔX=25.6mm, ΔY=12.5mm and ΔZ=32.0mm. The resulting section was hollowed performing a Boolean subtraction of the original radius model, and trimmed to match the length of the template segmented region. The model was then segmented into two equal halves along the coronal plane, before being manually extruded to approximate the size of the tumour in all spatial dimensions. As we were not privy to the original patients medical imaging scans, we based the overall shape of the tumour model based on the relative sizes of the x-ray images of the presented case study [18] and by appeal to the typical gross specimen of a resected parosteal osteosarcoma [20]. Figure 1a), illustrates the template segment approach used to form the tumour, alongside the final model on the radius bone. Figure 1b) shows a direct comparison of the patient CT scan and the developed 3D model. Despite the differences in the patient anatomy, the general shape and location of the osteosarcoma has been accurately replicated and would be representative of an actual patient case. Figure 1c) finally shows a representative model of the bone, musculature and tumour as it is likely to be observed.

3.2 Resection Guide Development

Resection of the compromised sections of bone can require the removal of between 6 to 20mm of 'normal' soft tissue, to ensure the complete removal of a tumour, thereby avoiding recurrence [21]. In the process of limb salvage surgical strategies it is important to minimise the removal of health bone tissue, to allow the best platform for functionality recovery. However, a defined consensus has yet to be determined as to the minimal amount of healthy bone removal to ensure local non-recurrence of tumours. This lack of consensus has implications upon the design choices of the given resection guide design, and for this study, we optimised our design around a 10mm tolerance, which would be a good compromise between the ensuring tumour removal while minimising the removal of health bone.

For the present case study, the resection guide will need to be designed to allow for easy fit to the patient's bone but with sufficient clearances to avoid issues with placement over the surface osteosarcoma, which protrudes outward from the bone. We therefore examined an approach of using a surface projection of the bone surface, which will form the basis of the surface locator portion of the resection guide. Figure 2a) illustrates the design process by which the template bone surface data is constructed and manipulated to form the guide. The projection process comprises the initial isolation of a template region of bone, which is approximately 45-50mm from each extremity of the tumour. This region is then enlarged in all directions by 3mm, before a Boolean subtraction of the original bone structure, to create a hollow model which encompasses the whole topography of the template bone section. This is then digitally trimmed, firstly to open the hollow model at each extremity before divided into two halves at the upper and lower section of the model. The lower section is then discarded and a segment approximately 4-5mm either side of the tumour extremities is removed, resulting in the two halves of the resection guide surface locator model. The model is then trimmed at the distal region of the model to avoid placement issues at the interface with the wrist. Developing the guide to use the patient's natural bone surface topography over the selected regions of the radius introduces natural markers for the positioning of the final resection guide, which is based on both the thickness of the bone at each half of the projected bone surface, and the vertical contours of the distal region of the bone. Therefore the guide would only have one ideal placement orientation whereby there was no movement in the guide once in position. This methodology ensures the geometrical accuracy of the pinning, drilling and resection features of the guide. It is also envisaged that to a minor degree, the protrusion of the tumour would provide further insight as to the placement of the guide based on the designed raised section of the guide.

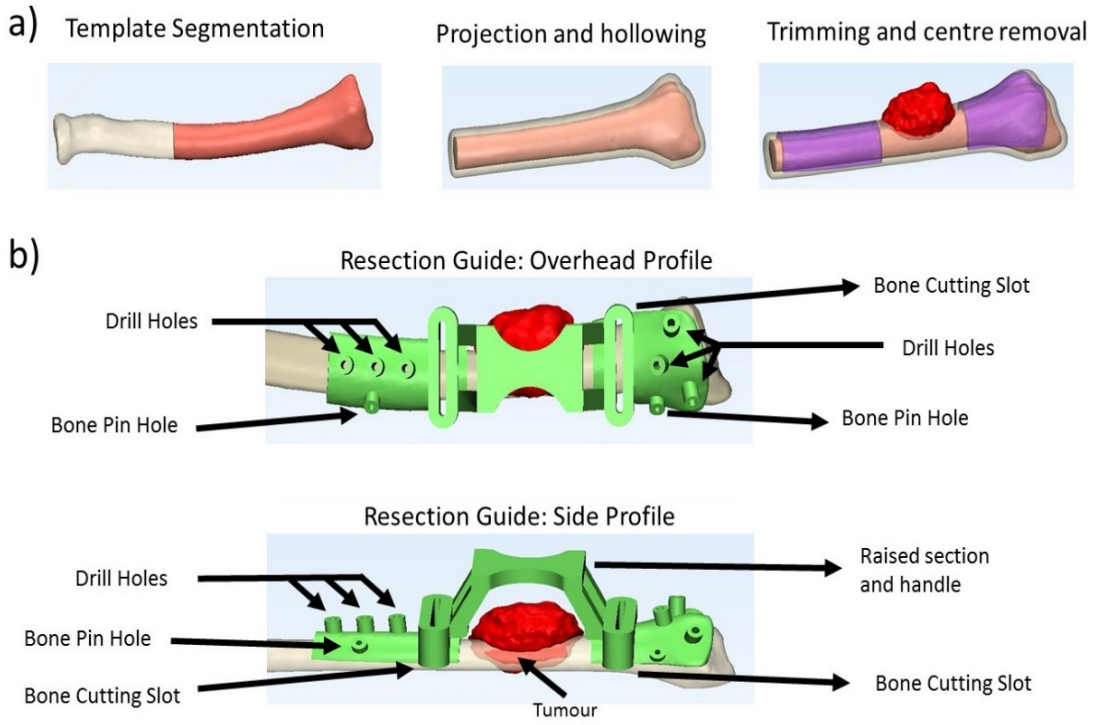

Figure 02: a) Illustration of patient specific bone surface template formation (purple) and b) annotated diagrams of the final resection guide concept.

Following projection of the patient bone surfaces, a classical CAD approach was used to construct the drill/Kirschner wires holes and the resection slots. To aid with the design parameters, we appealed to standard instruments that would be used in an orthopaedic setting and which would be suitable given the size of the radius bone. The first constraint of the resection slot was to be placed 10mm away from each side on the tumour. The maximum width of the radius was digitally measured to be approximately 23mm, therefore opted to design slots suitable for a standard 20mm sagittal blade, with a blade thickness of 1.27mm (Stryker, USA). The slots comprised a rounded rectangular configuration, with a total internal length of 28mm and internal width of 1.8mm, as can be seen in figure 2b). This geometry was selected to ensure that there was sufficient clearances to encompass the full width of the radius bone, while also allowing enough space for the excursion width of the blade (22mm). The slots were also placed to be orthogonal to the bone at their location and made with a thickness of 4mm. To complete the structural components, a bridge section over the osteosarcoma was developed, which raised the guide a height of 25mm above the height of the cutting slots. The bridge section also integrated two arcs, for finger handling of the guide by a user. The bridge section was initially made to a thickness of 3mm, however was found to have considerable flex, to a point where aggressive handling led to breakages. We therefore opted to increase the thickness to 6mm, which considerably increased the rigidity of the final model, to a point where flex was completely eliminated. In future development, we hope to characterise the tensile strength of the model and for now focus on the design for additive manufacturing elements of the guide.

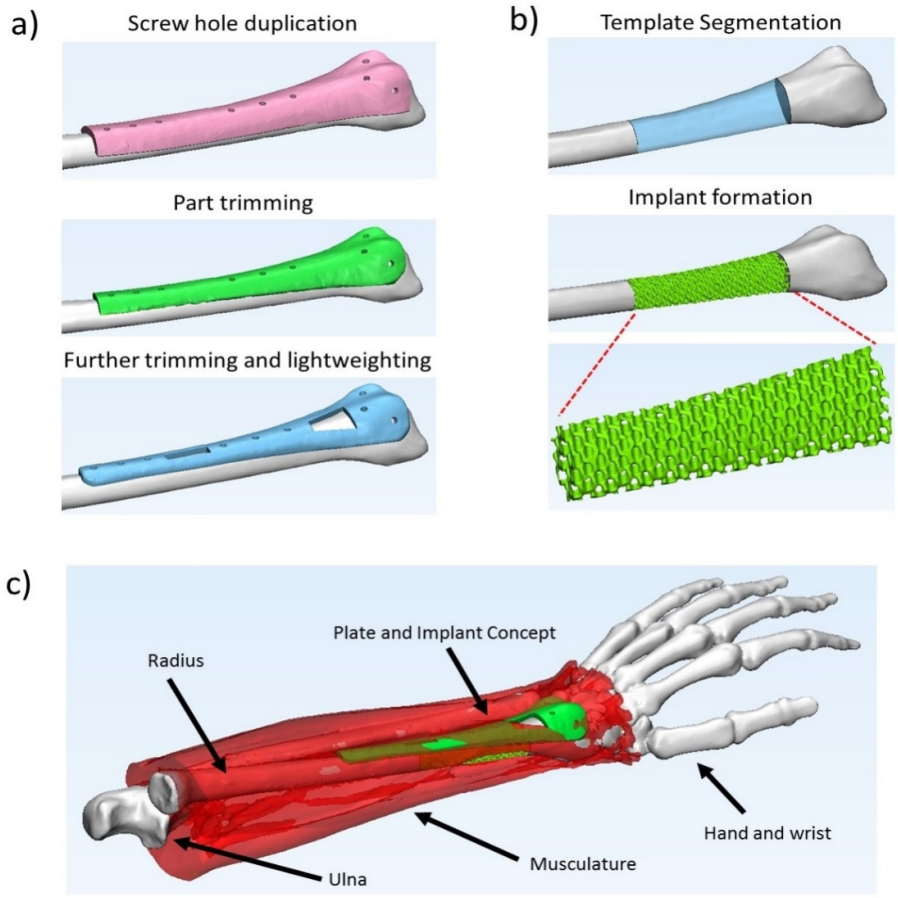

Figure 03: a) Design process for fixation plate development, b) design process for implant scaffold development and c) final digital patient model with fixation plate and implant in place.

From direct discussion with orthopaedic surgeons, it was discovered that for a typical radius fixation plate ideally requires a minimum of 3 fixation points at either side of the resected bone to provide adequate support. In light of this, we incorporated this as part of our design constraints for both the resection guide and implant plate. For a typical surgical procedure on the distal radius, 2.4mm surgical locking screws can be used for fixation [10]. We therefore designed the drill holes to have an internal diameter of 2.5mm and outer diameter of 5.5mm, which allowed for easy access of a standard surgical drill guide and the use of a 1.8mm drill bit to form a pilot hole for the screws. The requirement of designing the drill holes to be used with a standard metallic surgical drill guide as opposed to simply using the 3D printed guide eliminates any complications that may occur due to the drill damaging the guide and releasing debris in the surrounding tissue. The drill holes were located long the centre line of the radius, relative to the resection slots and at a regular spacing of approximately 5mm from the outer diameters of either the resection slots or drill holes. This spacing allowed for adequate clearances so that the screws would not intersect each other when placed in the bone. To confirm this, a 'digital screw' was created and used to guide the placement of the drill holes. Finally, Kirschner wires holes were created at either extremity of the guide to ensure the guide could be temporarily pinned in position during resection. Kirschner wires can be used as an effective methodology to hold resection templates in place during surgery [10, 12] and are an important feature to retain the geometrical accuracy of the guide during use. Wire holes with an inner diameter of 1.5mm and outer diameter of 4.5mm were designed based on standard Kirschner wire sizes, and were angled such that when the pins are in position the tension acts to lock the guide in place. The overall final guide concept can be seen in figure 1b).

3.3 Fixation Plate and Implant Concept

To complement the patient specific guide, a concept implant was developed to both replace the resected bone and to provide support to the segmented bone sections. As with the resection guide, these components were designed to be patient specific and match the original anatomical features of the patient. Figure 3a) illustrates the design process for construction of the fixation plate. Initially, using the bone projection that was used to form the base of the guide, the basic form of the plate is realised. As the resection guide had already incorporated the drill holes in the design, we could use the centre point of the holes as a template for the screw holes on the plate. As the final design would likely be manufactured using Ti-64, it is important to reduce the overall mass of the part to a minimum. Therefore, the template systematically underwent topology optimisation to reduce the overall mass of the plate to realise the final design as seen in Figure 3a).

The implant to replace the resected bone will comprise an open scaffolds structure. We have previously reported the rapid development of scaffold structureswhich can be applied in titanium implantable devices for light weighting [4]. However, in this study the scaffold design is primarily for conceptualisation purposes, but potentially could be applied to next generation bioprinted scaffolds or titanium implant as the technologies mature. Briefly, the process for scaffold formation involves the segmentation of the bone template, before applying a fixed geometry unit cell structure throughout the digital model, as described previously [22]. In this instance we opted for a Gyroid lattice unit cell structure, with a unit cell size of 3x3x3mm, and the final scaffold structure can be seen in figure 3b). Finally, a virtual representation of the implant, fixation plate and patient anatomy was constructed to better visualise the parts in situ, and can be seen in figure 3c).

3.4 Mock Surgery

To qualitatively test the efficacy of the devised resection guide, the implant and fixation plate, a mock surgery was performed, whereby the resection guide was pinned onto a 3D printed model of the patient's arm and osteosarcoma as can be seen in figure 4ai). As we did not have access to a sagittal saw, we opted to mark the region of the cut using a thin blade, and the model was cut using a circulating saw. Several repeat cuts were performed and the variance in the cutting position from the midpoint of the cutting guide varied by approximately ±0.6mm. In addition to the cuts, a standard 1.8mm drill bit was used to drill pilot holes in the model to attachment of the screws into the fixation plate concept. It was found that the drill holes were achieved to an accuracy of ±0.3mm of the intended centre point. Once all mock resection and drill piloting had been performed the pins and guide were removed and the implant and plate were screwed into position. The entire procedure from start to finish took approximately 2-3 minutes to perform, reflecting the potential time it would take the surgeon for this portion of the procedure within theatre.

Figure 4a) shows the stages of the model, pre and post mock resection. It was found that the implant fix accurately into the bone model, along with the placement of the screwed fixation plate. Equally, the resection guide had sufficient rigidity to allow for aggressive handling when simulating the placement of Kirschner wires, marking cuts and drilling of the pilot holes. It was noted that there was some ability for the screws to deviate from their desired directional placement, which we believe is due to the constraints of the model being fabricated in ABS plastic as opposed to real bone. It is believed that if the procedure is performed on actual bone that the rigidity of the bone would allow for greater directional conformity of fixation screws. Overall, we are confident that there is considerable potential of our approach for development as a clinical treatment option, should the resection guide be manufactured in biocompatible materials and the implant/fixation plate in Titanium 64, the current benchmark for titanium implants.

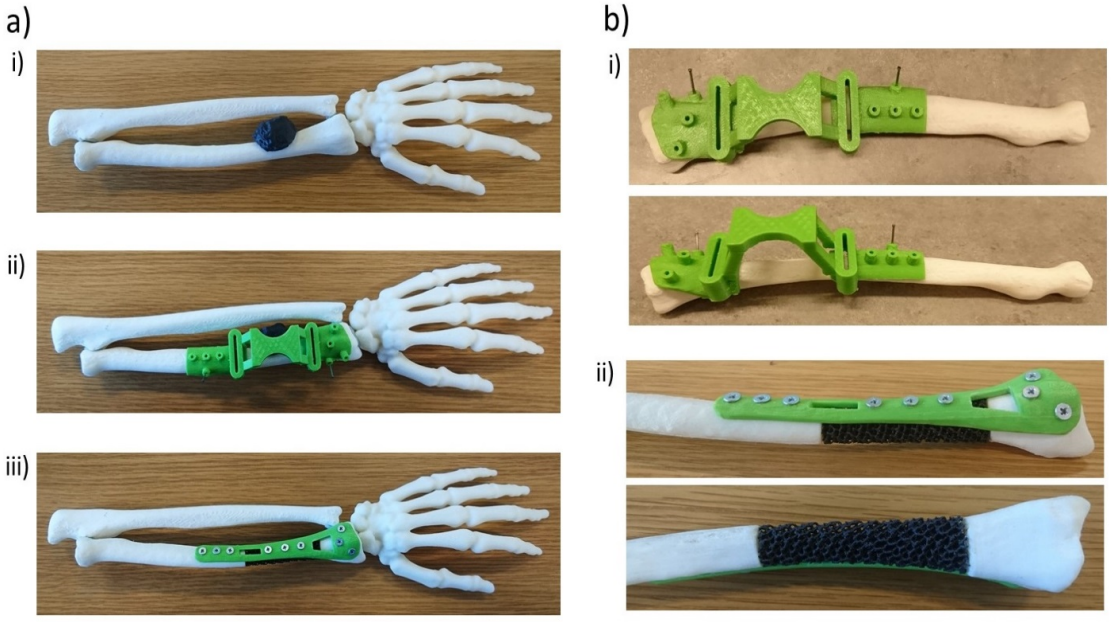

Figure 04: a) 3D printed hand, wrist, ulna and radius models with i) surface osteosarcoma (black), ii) the osteosarcoma and resection guide concept in situ and iii) the resected radius with fixation plate and scaffold implant. b) close up views of the radius with i) the resection guide pinned in place and ii) the fixation plate and scaffold concept.

4 Conclusion

In this study we present our initial findings in the development of a resection guide and implantable treatment concepts, which could serve as methodologies for the treatment of a surface osteosarcoma on the distal radius. The guide was found to accurately match the contours of the mock patients bone anatomy and provided a high degree of efficacy to minimise the removal of potential health bone tissues, with resection tolerances being approximately ±0.6mm from the desired location. We also demonstrate a patient specific fixation plate and mock implant, which conform very well to the bone topography, providing efficacious fixation and reproduction of the patient's original bone anatomy. It is our hope that the methodology outlined in this preliminary study would provide guidance to professionals seeking to develop a robust design methodology for resection guide and fixation plate development and which could be applied to a range of different clinical case studies.

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