Customised design and development of patient specific 3D printed whole mandible implant

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Abstract

In this study we assessed the design criteria for the creation of a patient specific, whole mandible implant based on a patient's medical imaging data and 3D printing. We tailor this procedure to a patient who will undergo a mandibulectomy due to cancer infiltration of the jaw. The patient CT scan data was used to generate a 3D representation of the patient's skull, before the corrupted mandible was extracted. We examined two approaches based on classical symmetry matching and digital reconstruction of the defect to form the final model for printing. The final designs were then 3D printed and assessed for efficacy against a patient specific representative model of the skull and maxilla, where the final optimised design was found to provide an excellent fit. Ultimately, this technique provides a framework for the design and optimisation of a patient specific whole mandible implant.

1 Introduction

The minimisation of time for surgical procedures and patient recovery are highly pivotal in reducing financial burdens on healthcare providers and patients, whilst also improving patient outcomes. This goal has led to many recent advancements and innovations in medicine, particularly in the area of patient specific treatment options. Disruptive technologies, such as additive manufacturing and digital 3D modelling have positively impacted areas of pre-operative planning and treatment [1, 2], and have led to the creation of a patient specific assistive and implantable devices, such as surgical resection guides [3-5], planning models [3, 6, 7], anatomical teaching aids [8, 9] and prosthetics [10-15]. More recently, the US Food and Drug Administration (FDA) have increased their approval of 3D printed implants under the 510k (pre-market notification) approval system, which permits the use of additive manufactured parts in routine and complex surgical procedures [16]. It is suspected that recent approvals and the wider acceptance of additive manufacturing is likely

the result of increasing maturity of this technology, which has allowed the direct processing of an increasing number of biocompatible materials with ever increasing printing precision.

A mandibulectomy is the removal of large sections of the lower jaw and is performed following either physical trauma or severe disease infiltration (cancer, etc) [17, 18]. Current surgical rehabilitation is performed using a guide plate, screw fixtures and grafted donor bone tissue (hip/femur) inserted into the void space to support the jaw. However, such methods are prone to short term failure (approx. ≤1 yr.), guide plates are predominantly manipulated during surgery to approximately match the patient's contours and treatment arguably does not provide a solid base to allow osseointegration of a patient's bone tissue. It has been more recently found that fixation methodologies traditionally used are leading to complications such as mandibular fractures [6, 19, 20] resulting from fixation in structurally compromised bone tissue. Therefore there is increasing evidence to support the use of whole mandible replacement implants.
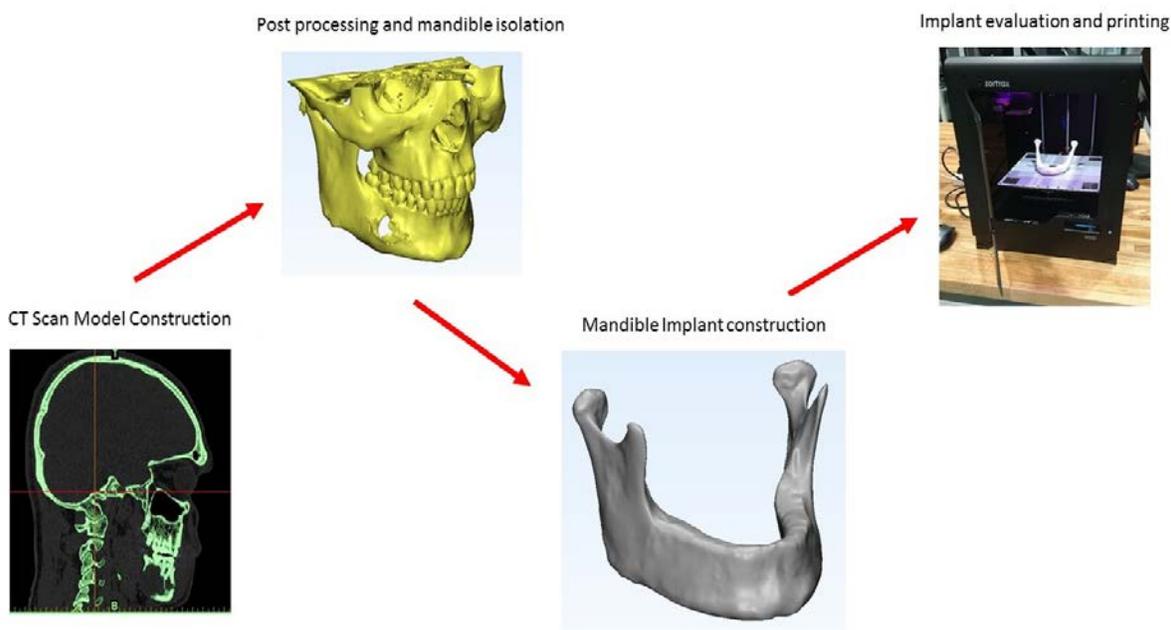

Figure 01: A summary of the process chain for the construction of the complete mandible implant

In this study we assessed the potential of creating custom replacement mandible implant following a mandibulectomy. The implant was created using patient specific medical imaging data (CT DICOM) alongside state-of-the-art 3D design/manipulation software, before realising the implant using low-cost Fused Deposition Modelling (FDM) to assess finish the model (Figure 1). It is noted that the FDM printed models are for preliminary verification purposes and would not be used as the final implantable device. This case study was performed on a patient who presented with cancer infiltration through the entire right-side of the mandible. CT scan images were used to generate a three-dimensional representative model of the patient's corrupted mandible, before an initial full jaw replacement implant was constructed. Mandible replacement devices have been attempted previously, however this work differs from previously reported designs as we attempt to retain the major contours of the patient such that

the implant retains the original facial structural contours of the patient. This contrasts favourably to other such examples of this form of treatment where the replacement mandible is generally much smaller that the original bone structure or require bone grafts for reconstruction. We examined and compared the efficacy of reconstruction using anatomy mirroring and by direct mandible digital reconstruction. Ultimately, this work provides a framework for the design criteria to create an optimised patient specific, full mandible implant. The techniques used in this work could equally be applied to alternative patient anatomies, providing a generic methodology for implant design. Such work will provide a powerful tool for clinician's to overcome the shortcomings of typical fixation plate based treatment option, thereby improving overall patient outcomes.

2 Methodology

2.1 Anatomical Data Modelling

Representative models of the patient's anatomical data were constructed based on Digital Imaging and Communications in Medicine (*DICOM*) data from CT scans using a Somotom scanner (Siemens Healthcare, Germany). In the DICOM format, the data is presented as a series of slices through the patient's anatomy, each approximately 0.6mm thick. The software package Mimics (Materialise, Belgium) was used to compile the DIOCM data into axial, sagittal and coronal planes. Using Mimics, the various greyscales can be selectively marked to isolate a particular anatomical tissue type (i.e. bone, muscle, etc) and from this to construct a 3D model of this tissue type. The Mimics software has a series on inbuilt thresholds which allow for the rapid isolation of anatomical tissues and the inbuilt thresholds for bone were used to construct the final model, in additional to manual region growing.

2.2 Implant Design

The model created in Mimics was exported to 3-Matic (Materialise, Belgium) for further processing and construction of the mandible model. Prior to any operations, the CT scan extracted model underwent an initial phase of error correction. This is required to remove excess data point, duplicate triangles, inverted normal, filter small sub shells and unify larger shells into a single model, allowing the model to be fit for 3D printing. The software was then used to segment the skull model to isolate the jaw. In this study two distinct approached were examined whereby the mandible was reconstructed using a mirroring of the patients healthy portion of the mandible and also by direct reconstruction of the cancerous section. Both approaches could potentially offer a high quality matching of the patient's anatomy, but it was unclear which technique would be superior and so both approaches were assessed.

2.3 Implant Prototyping and Manufacturing

In this study, the various design iteration of the jaw model were realised using fused deposition model (FDM) printing in ABS plastic. FDM printing is a low cost technique for part production, and evaluation prints were realised using a Zortrax M200 (Olsztyn, Poland) printer.

This methodology allowed for the rapid printing of the proposed implant design iterations to evaluate model build integrity and patient fitment/sizing against the original jaw anatomy.

3 Results

3.1 Anatomical Modelling

Using the inbuilt threshold function within Mimics (Bone CT- 226-3071), the bone tissue was predominantly isolated. However several features of the soft tissue were also captured at this greyscale value, in additional to several uncaptured data points of the bone. Therefore additional manual processing of the model was required to remove unwanted data point and to add missing bone data point in the CT scan slices across all three dimensional planes. Once this had been achieved to a satisfactory point the highlighted data set was then converted into a representative model of the patient's wider skull, which contained the corrupt mandible.
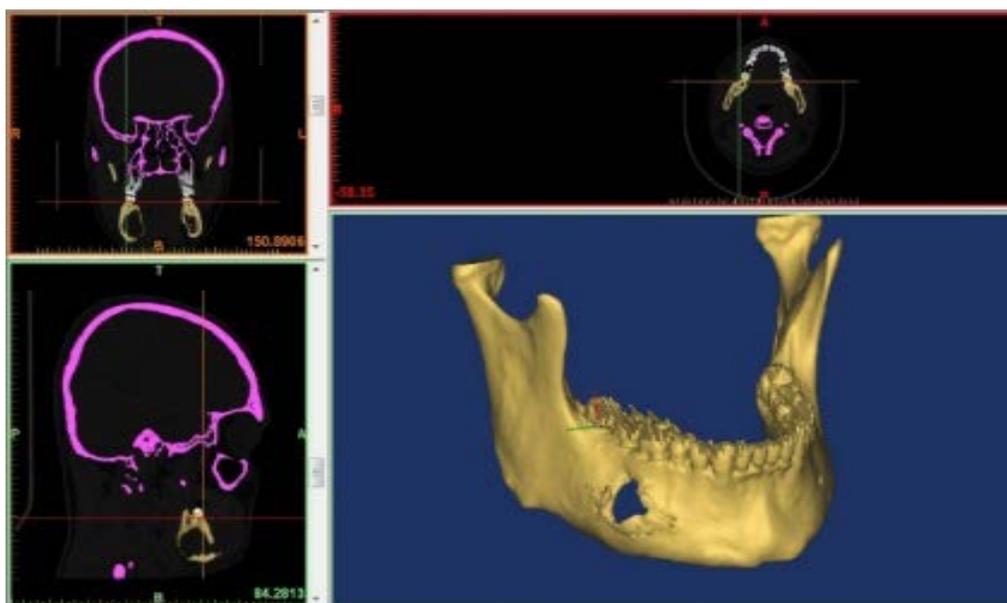

Figure 2: An image of the various planes of the patients CT scan data and the constructed model of the isolated bone tissue segment, containing the corrupt mandible.

This constructed model comprised of a segment of the overall skull, the maxilla and the mandible. Primarily, the mandible was the area of interest in the jaw reconstruction, however inclusion of the skull and maxilla and realisation into a 3D printed model allowed for analysis of the jaw size and fit compared to the original anatomy of the patient. Figure 2 shows the patient's skeletal data and the resulting model that was formed for the mandible. Despite the automated threshold function and manual data point addition/removal, some elements can be missing, in additional to stray noise being present in the final digital model. In such instances a wrapping function can be performed improve the final quality of the model and without adjusting the size threshold of the model. Following wrapping the model was visually inspected

to check that the major features were adequately rendered, before the model is exported as an STL file. The model is then loaded into 3-Matic to perform error corrections, segmentation, reconstruction of the corrupt region of the mandible and additional post processing.

3.2 Implant Design

When the initial model is imported into 3-Matic error corrections are initially performed to ensure the integrity of the model prior to implant production. Next the mandible was isolated to assess the degree of cancer infiltration in the patient. Figure 3a) shows a transparent digital model of the mandible where the cancerous region can be seen as a large cavity. At the extremities the cancerous region was estimated to be 25mm in the vertical and 50mm in the lateral direction.

Two distinct approaches were examined to ascertain the best methodology for the implant production, and which comprised reconstruction through mirroring of the uncompromised area and direct reconstruction of the cancerous jaw segment. To assess the fit of the resulting mandible design, a model of the patient's maxilla and temporomandibular joint was created from the patient's DICOM data and printed using an FDM printer. Additionally, the corrupt mandible model was printed to compare against the corrected mandible model.
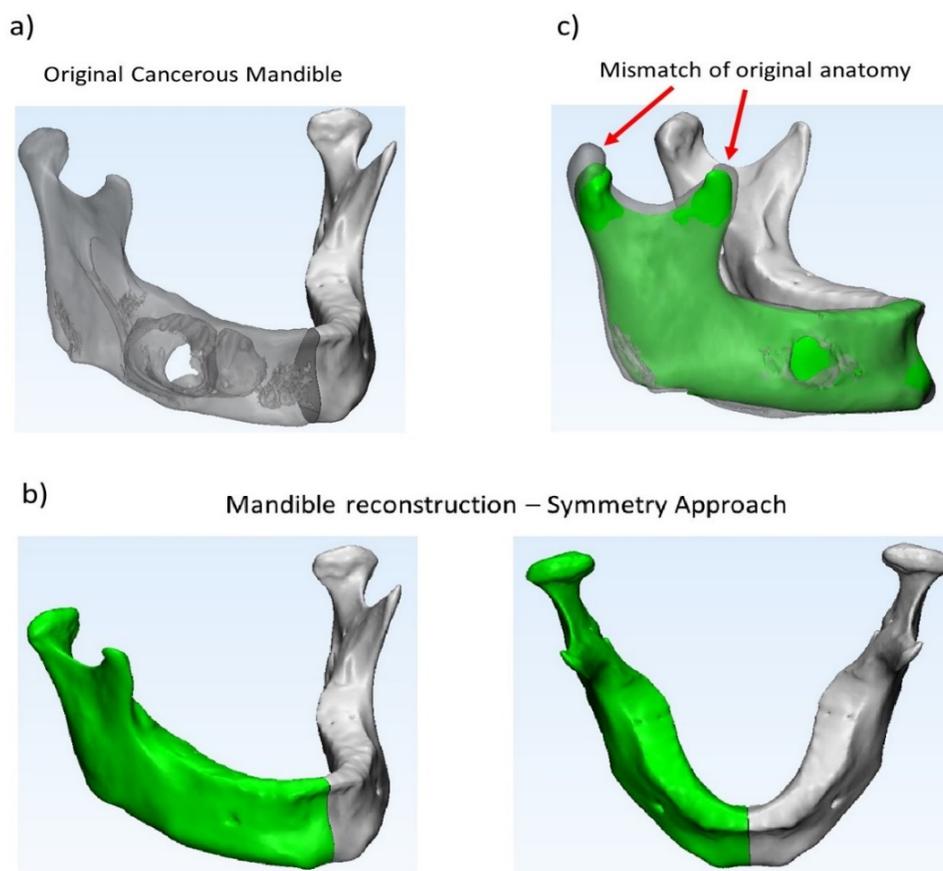

Figure 3: a) The original corrupt mandible, b) outcomes of the symmetry based approach for mandible reconstruction and c) illustration of the anatomy mismatch of the final model against the original mandible.

3.2.1 Anatomy Mirroring

The main area of cancerous infiltration was restricted to the left portion of the patient's mandible. Therefore the mandible was divided into two sections and the right half mirrored to construct the final implant. When attempting to section the mandible, the teeth were retained to help guide the location for sectioning. Upon closer examination of the mandible there were several natural contours in the front of the jaw which could act as a guide point for the sectioning process. Several locations were examined as the reference point to produce the complete implant, with promising results, as shown in figure 3b). Cross referencing of the original compromised section of the jaw revealed that due to asymmetry present in the original jaw, the location of the ramus, condylar process and coronoid process were all out of alignment (Figure 3c). Such misalignment would likely result in placement issues during implantation as well as compromising post-surgical rehabilitation and movement. Several attempts to re-adjust the spatial orientation of the mirrored mandible segments were unsuccessful in achieving a matching orientation to the original mandible anatomy. Based on these results, it was determined that anatomy mirroring in these particular circumstances of execution was not a robust technique for digital reconstruction of the corrupted mandible.
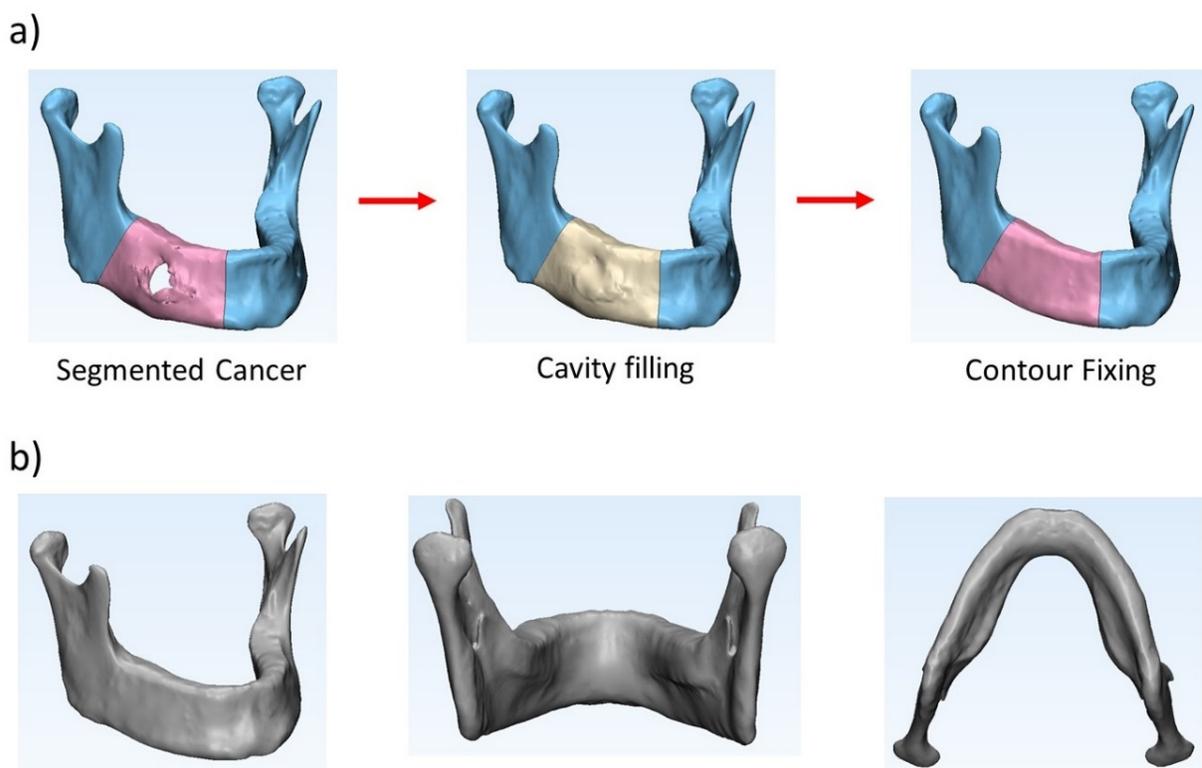

Figure 4: a) Stages of the segment reconstruction strategy and b) The final model of the mandible.

3.2.2 Segment Reconstruction

In the segment reconstruction approach, the corrupt portion of the mandible was isolated and reconstructed manually to create a solid portion that matched the original contours of the patients jaw. The advantage of this approach is that the majority of the shape and

geometry of the original mandible are preserved. Initially, the mandible model was made transparent to assess and visualise the extent of the cancer infiltration, as shown in Figure 3a). This methodology allowed for the complete visualisation of the cancerous growth, which aided the digital reconstruction process. This compromised region of the mandible was segmented for additional processing.

To aid the design process, the mandible was segmented into two halves about an approximate midpoint, in a similar manner to anatomy mirroring approach. The uncompromised half of the mandible was then mirrored and used as a reference template for the reconstruction of the segment, to achieve the desired thicknesses and surface contours. The segmented model in its native form comprised a hollow part with openings at both sides of the lateral sections of the mandible. It was also noted that the cancerous growth had caused for an expansion of the surrounding jaw line and so in addition to removal of the hollow sections, the segment required reworking to this lateral displacement. Several trimming and smoothing operations were performed to bring the side of the segment back to a similar dimension to that of the mirrored reference. It was additionally noticed that surface contours of the uncompromised region contained a variety of holes, beyond the natural cavities containing the mental nerve, which were required to be filled to ensure the maximum integrity of the final model. These holes were present on the patient's original CT scan data and so reduced the holes/cavities being the result of digital artefacts during the modelling process. This potentially implied that the mandible was structurally compromised and so should a traditional fixation plate approach be employed this could result in mandibular fracturing. These findings further confirmed the necessity for a total mandibular replacement. The final segment and its placement in the sectioned mandible is shown in Figure 4, where it can be seen that overall a very good reproduction of the original symmetry could be achieved. This final model also matched the original locations of the ramus, condylar process and coronoid process due to only working on the cancer infiltrated region of the mandible, and therefore this reconstruction technique was considered the superior approach for this specific case study.

3.3 Mandible 3D Printing

When constructing models based on data ascertained from medical imaging data, there could be facets of the model, such as low thickness tolerances in regions of the part, which could lead to compromised structural integrity. Given the complexity of such models, it may not always be possible to perform adequate thickness analysis and Finite Element Analysis (FEA) to validate mechanical properties. Additionally, as such parts are intended as an implantable device, a rigorous and robust evaluation procedure is desirable. Therefore a preliminary low-cost polymer printing approach can help provide qualitative validation of a parts structural integrity, before the final, more costly printing in metallic materials.

The final model was then 3D printed initially on an FDM printer to assess the structural integrity of the final models and also to ensure correct dimensional accuracy of the jaw against both the corrupt mandible and partial skull/maxilla models. It was found that the model printed very well with no perceivable issues with its structural integrity. Figure 5 shows the printed corrupt and reconstructed mandible, alongside the reconstructed mandible implant placed into a representative model of the skull/maxilla. It can be seen that the reconstruction approach of the jaw was highly effective at reproducing the patients original jaw line, with minimal impact

to the overall structural contours. The resulting mandible models proved an equally excellent fit into the representative model of the patient skull, as can be seen in Figure 5. These qualitative tests confirmed the efficacy of the design and the structural integrity when realising the mandible model by 3D printing processes. We are therefore confident that the design could be equally rendered by SLM processed in titanium, a certified material for medical implantation, and this will be the subject of future studies.
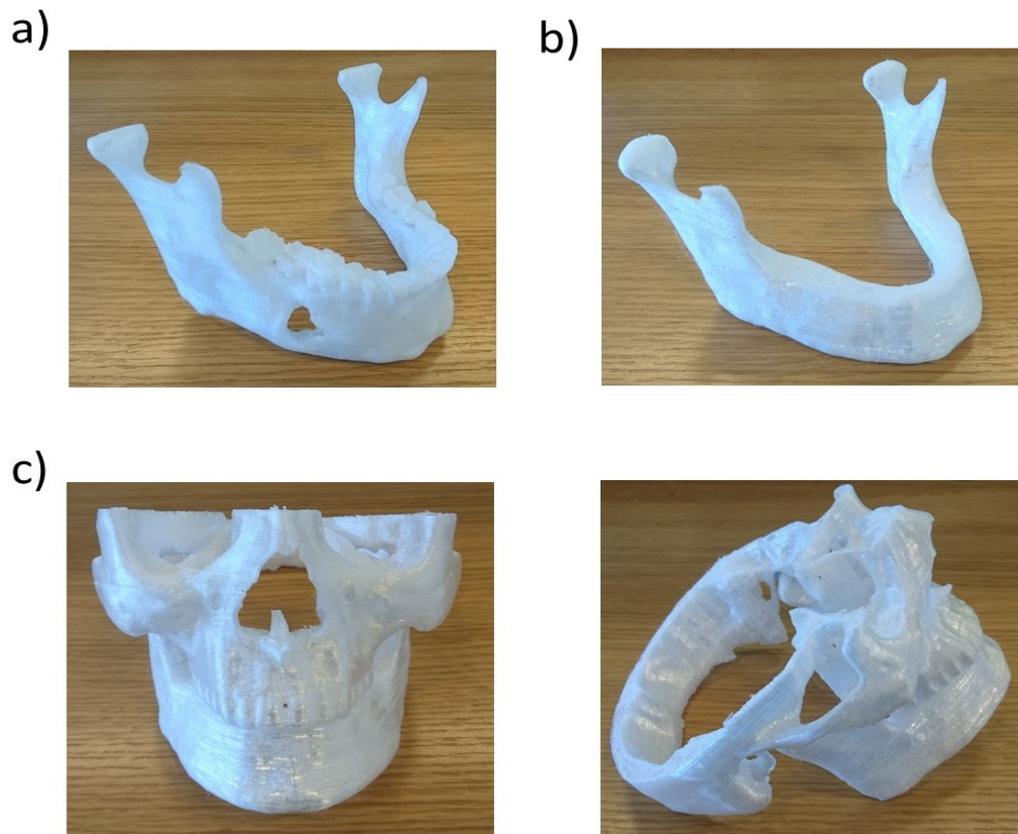

Figure 5: Representative FDM models of a) the original cancerous mandible, b) the reconstructed mandible implant and c) the developed implant placed onto a model of the patient's skull and maxilla.

4 Conclusions

In this study we have examined the use of medical CT scan data to reconstruct a digital model of a patient's skeletal anatomy, and from this, a full replacement mandible to treat a cancerous infiltration. The final model and the patients surrounding skeletal anatomy was then realised using a FDM 3D printing process, to evaluate the size and geometric precision of the final implant. Investigating various design techniques, it was found that a mandible reconstruction approach offered superior fit as compared to the anatomy mirroring approach. Ultimately, this study demonstrates an optimised approach for patient specific mandible reconstruction that could have significant potential for use as a strategy in patient specific, custom implant design.

Acknowledgements

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