Conference Paper

Customised Design of a Patient Specific 3D Printed Whole Mandible Implant

Mazher I. Mohammed*, Angus P. Fitzpatrick, and Ian Gibson

Deakin University, School of Engineering, 75 Pigdons Rd, Waurn Ponds, Geelong, Vic 3216, Australia

Abstract

In this study we investigate the design methodology for the creation of a patient specific, whole mandible implant based on a patient's medical imaging data. We tailor the implant as a treatment option for a patient who will undergo a mandibulectomy due to cancer infiltration of the jaw. We create a 3D representative model of the patient's skeletal structure from CT scan data, and us this to generate the implant from the patient's corrupt mandible. In this particular case study the cancer is restricted to the right region of the mandible, and so the left side is used in a symmetry matching approach to create the final model for manufacturing. The final design was 3D printed in medical grade titanium and finished using a mechanical polishing technique, the yield a near mirror finish. We found the final implant to be highly robust, and an excellent fit to a representative model of the patient's skeletal anatomy. We believe this approach to hold considerable potential for implementation as a treatment option for mandibular complications.

Keywords: Patient Specific, Mandible, Implant, Design, 3D printing

Corresponding Author: Mazher I. Mohammed; email: mazher.mohammed@deakin.edu.au

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1 Introduction

Minimisation of times for surgical intervention and patient recovery are pivotal in reducing financial burdens on healthcare providers/patients, whilst also improving patient care. This goal has led to considerable research interest in the area of patient specific technologies. Modern design techniques and additive manufacturing are beginning to positively impact areas of pre-operative planning leading to the creation of a patient specific assistive and implantable devices [1–3], such as surgical resection guides [4,5], orthopaedics and prosthetics [6–8]. With growing approval from regulatory agencies, such as the US Food and Drug Administration (FDA), the use of additively manufactured parts may eventually become routine clinical practise in complex surgical procedures.

A mandibulectomy is performed following either physical trauma or severe disease infiltration (cancer, etc.), resulting in removal of large sections of the jaw [9,10]. Treatment options typically make use of a fixation plate, which is screwed to the residual section of the mandible to provide structural support, and is augmented by bone grafts

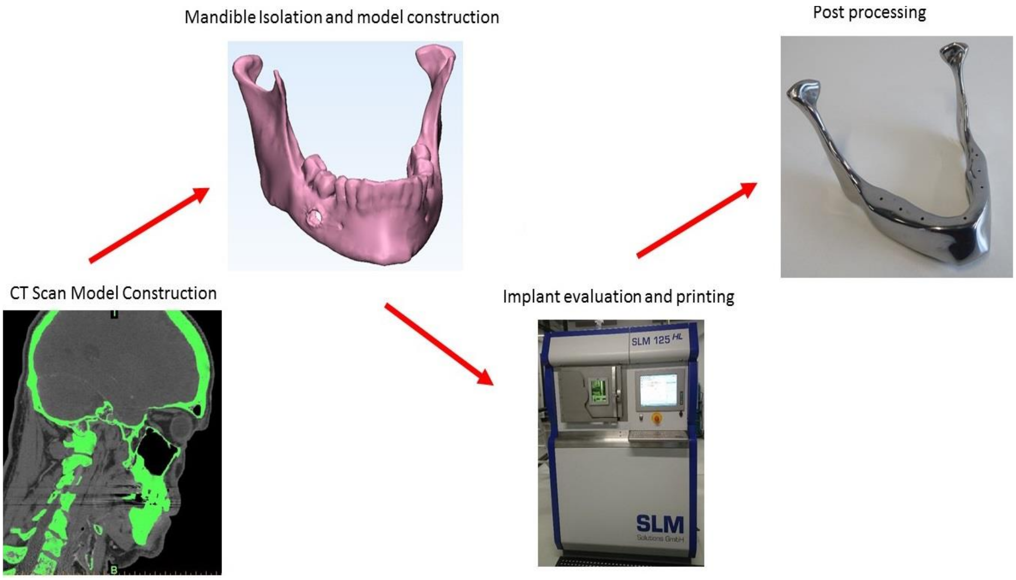

Figure 1: A summary of the process chain for the construction of the complete whole mandible implant.

from the hip/femur. However, the efficacy of this clinical procedure is limited by the high instances of short term failure of the fixation plate (approx. ≤1 yr.), the practise of forming the fixation plate into the desired shape during surgery, and complications such as mandibular fractures resulting from fixation of the plate in structurally compromised regions of the mandible [11,12].

In this study we assessed the potential of creating custom replacement lower jaw implant as a treatment option 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 SLM printing processes (Figure 1). Publically available CT scan images were used to generate a 3-dimensional representative model of a patient's mandible, before an initial full jaw replacement implant was constructed using a model mirroring approach. As a case study we digitally created a defect into the patient data set to mimic the presentation of cancer infiltration through the right-side of the mandible. Several permutations were examining to investigate the feasibility of constructing a light weight design, with adjustable mechanical properties and the inclusion of dental fixation points. The part was then 3D printed in surgical grade titanium (Ti-64) and manually finished to a standard consistent for implantation. Ultimately, the positive outcomes from this work will provide clinician's with a powerful design and manufacturing supply chain to realise implantable mandibular solutions that overcome the shortcomings of typical fixation plate based treatment option, thereby improving overall patient outcomes.

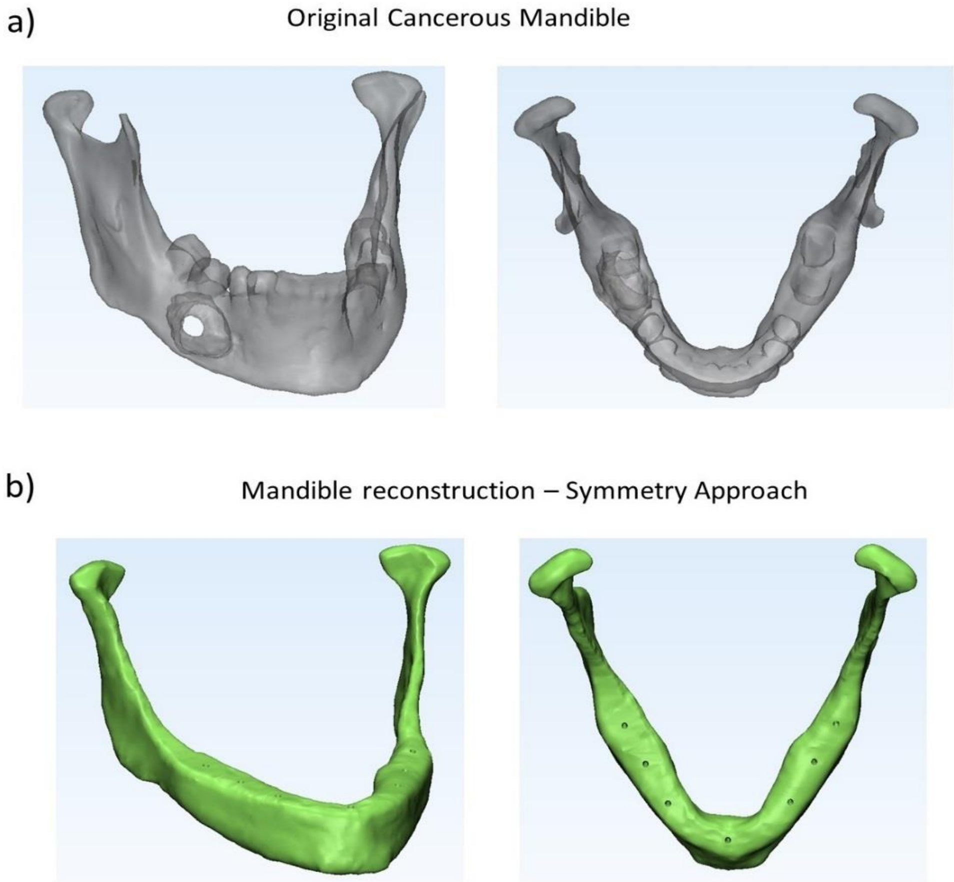

Figure 2: a) The original corrupt mandible and b) outcomes of the symmetry based approach for mandible reconstruction.

2 Methodology

2.1 Anatomical Data Modelling

Models of the patient's anatomical data were constructed based on Digital Imaging and Communications in Medicine (*DICOM*) data from CT scans (http://dicom.nema.org/). The DICOM data comprises a series of slices through the patient's skull, each approximately 0.625mm thick. In this study, the software package Mimics (Materialise, Belgium) was used convert the slice data into a seamless 3D model of the patient's bone tissue, using the systems inbuilt thresholds functions.

2.2 Implant Design

The model created in Mimics was exported to 3-Matic (Materialise, Belgium) for further processing to isolate the mandible and to construct the final implant model. 3-Matic provides a means of error corrections, where the DICOM data model can be checked for issues such as multiples shells and inverted normal, such that any produced design would be fit for digital manipulation and the final 3D printing. In this work, an approach of anatomy mirroring was investigated to create the final implant from the patients' healthy portion of the mandible, which could easily be achieved using the functions in 3-Matic. Once a suitable line of symmetry had been established, the uncompromised region was mirrored and the joining points manually finished to produce a single, seamless model. The model was then checked for further errors before moving to the 3D printing phase.

2.3 Implant 3D printing and post processing

Once the implant model was completed, the design was manufactured using a low-cost fused deposition model (FDM) printing process in ABS plastic. FDM printing was performed using a FlashForge Dreamer (Zhejiang, China) printer and allowed for preliminary evaluation of the model and its print integrity, before moving on to the final metal fabrication process. The final implant was printed using Selective Laser Melting (SLM) within a SLM 125 HL (SLM Solutions GmbH, Germany) using medical grade titanium (Ti-64). When a part is removed from the SLM, it will be built using support structures, which are made in the same material as the part. These have to be removed using a grinding wheel. Following support removal, the part is then post processed manually using a high performance mechanical abrasive device, followed by several mop polishing phases with cutting compounds, which realised a near mirror finish with minimal changes to the model thickness tolerances (approximately 10–50 μm).

3 Results

3.1 Anatomical Modelling

The DICOM data was interrogated using the inbuilt thresholds within Mimics (226-3071 HU), which isolates the majority of the bone tissue from other patient tissues. It is found that the automated thresholding generally misses several regions of the tissue of interest, owing largely to variations in the different commercial CT scanners used and their output data. To remedy this, a manual processing of the DICOM data is required to either highlight these missed regions, or to remove unwanted highlighted data mistakenly captured by the auto thresholding function. Once all regions of interest have been highlighted, the software then constructs a 3D representative model of the patient's bone tissue.

The extracted 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. Despite our best attempts to reconstruct the patient's bone tissue, some elements can be missing leading to holes in the model, in additional to stray noise being present. In such instances a wrapping function can be performed to improve the final quality of the model, 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 into 3-Matic.

3.2 Implant Design

The completed bone model from Mimics was loaded into 3-Matic where an initial phase of error correction was performed to ensure the integrity of the digital model. Following this, the mandible was isolated from the wider bone structure to assess the degree of cancer infiltration in the patient. Figure 2a) shows a transparent digital model of the mandible where the cancerous region can be seen as a large cavity, which was estimated to be 25mm in the vertical and 50mm in the lateral direction. As the main area of cancerous infiltration was restricted to the left portion of the patient's mandible, the mandible was divided into two sections and the right half mirrored to construct the final implant. Several locations were examined as the reference point to produce the complete implant, using the original geometric attributes (width, length, etc.) as a guide for the sectioning process. Alongside this the original anatomy of the mandible was made transparent and used as a guide to ensure the correct alignment of the condylar process of the mandible.

It was found that the various examined points of symmetry could not reproduce the entirety of the mandible, without issues relating to either the alignment of the ramus, condylar process and coronoid process, or the region from which the model had been mirrored. This is due to the fact that human physiology is not symmetrical. Therefore an approach of translating the mirrored part to best align the condylar process and the wider mandibular segment to the original corrupt jaw was employed. This was achieved by overlaying of the new segment over the corrupt segment and orientating about the condylar process, which ensure the points of attachment to the skull remained unperturbed. Using this methodology it was difficult to preserve the bulk of the ramus or coronoid process within the correct alignment, and so these elements were removed from the model from both the left and right regions of the mandible. Once this was achieved, the model was then altered manually to ensure the thickness of the new segment matched that of the original mandible. Overall, employing this methodology, the majority of the original contours of the patients mandible could be retained, thereby theoretically reducing alterations to the patients overall facial contours. Dental fixation points were also incorporated into the mandibular model with the intension of augmenting typical subsequent treatment phases.

It was also noted that the final model, if printed directly in titanium, would be significantly heavier that the original bone tissue. Therefore to reduce weight, in addition to

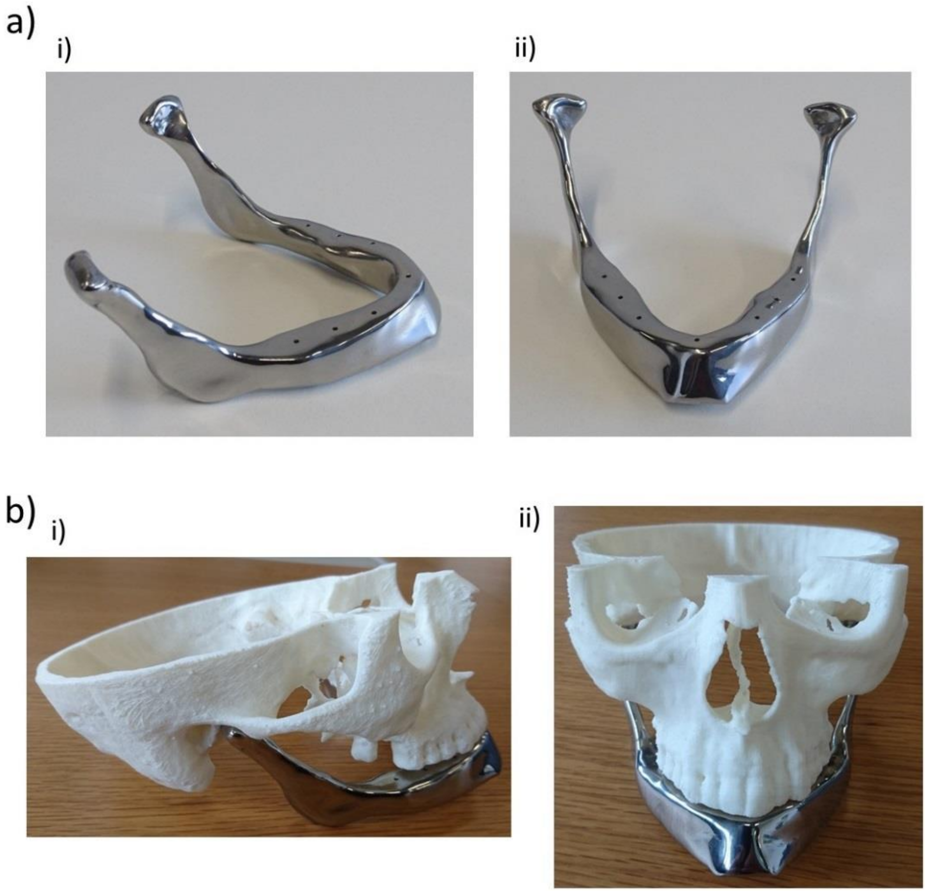

Figure 3: a) Images of the post processed mandibular implant from i) side and ii) front profiles. b) Representative FDM model of the skull/maxilla model with the final implant from i) side and ii) front profiles.

the removal of the coronoid process and sections of the ramus, the part was made to comprise a 2mm outer skin with an internal dode mesh structure, with a repeating unit cell size of 5mm.

3.3 Mandible 3D Printing

The final model was initially 3D printed on the FDM printer to assess the structural integrity and dimensional accuracy of the jaw against a partial skull/maxilla model of the patient's anatomy. It was found that the model printed very well with no perceivable issues with its structural integrity. We then progressed to fabricate the part on the SLM printer and perform the necessary post processing to bring the surface of the part to a near mirror finish. Figure 3a) shows pictures of the final post processed implant from both side and front profiles and where the screw fixation points for dental abutments can be seen in the area which normally contains the teeth.

Figure 3b) shows side and front profiles of the titanium whole mandible implant placed into a representative model of the skull/maxilla. It was found that the devised mandible implant proved an equally excellent fit into the representative model of the patient skull. Given the efficacy of the end product, we are confident that the design and fabrication process could have considerable potential for use in producing actual implantable parts for patients suffering a compromised mandible.

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 was then realised using SLM printing in a medical grade material, showing very good structural integrity. The size and geometric precision of the final implant was also evaluated by reference to a FDM fabricated representative model of the patients surrounding skeletal anatomy and found to be an excellent fit. We found there to be limitation in the mirroring technique to fully reproduce the patient's complete mandible, however, the final result would potentially be a viable treatment option for a patient. Ultimately this work provides a framework for the creation of patient specific full jaw implants, when residual uncompromised bone tissue remains from which the final implant can be modelled. This device will address many of the short comings of current practise such as complications resulting from mandibular fractures, miss-matching fixation plates, and general plate failures. Therefore the outcomes realised in this study provide a powerful tool for clinician's to improve overall patient outcomes.

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