Utility of Computed-Tomography Based Navigation to Guide Fibula Mandible Reconstruction Surgery

by

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ABSTRACT

Fibula free flap mandibular reconstruction is often performed to correct a mandibular defect. When a tumour is found on the mandible (lower jaw); the cancerous tissue is surgically removed and bone segment(s) from the fibula and soft tissue from the patient's calf are used to reconstruct the mandible. Fibula bones segments must closely match the removed sections of the mandible. This is a complicated surgical procedure that has to be performed with a high degree of accuracy in order to restore the patient to an optimal functional outcome following surgery.

In current practice, additive-manufactured surgical guides are used to ensure a surgical plan is accurately followed in the operating room (OR). However, designing, fabricating and sterilizing additive-manufactured models and surgical guides for mandible reconstruction surgery can be time consuming. Once fabricated, the additive-manufactured surgical guides cannot be modified or adjusted, therefore, necessary changes to the surgical plan may not be accommodated due to time, material and equipment constraints. In such cases, traditional freehand techniques may be used to complete the mandible resection and reconstruction.

Digital navigation guides present an alternative to additive-manufactured surgical guides and traditional freehand reconstructions. Digital navigation guides can be used in surgery to guide surgeons during fibula free flap mandible reconstruction by providing the surgical team with visual guides to follow based on medical CT imaging data and a preoperative surgical plan. The resulting CT navigation based surgical guidance can be used by surgeons during fibula mandible reconstruction to ensure the mandible resection and reconstruction is completed

according to the preoperative surgical plan. The feasibility of using navigation was tested experimentally on additive-manufactured anatomical models.

In this study we explored the possibility of using CT navigation based surgical guidance techniques to perform fibula mandible reconstruction surgery. The utility of CT navigation guidance techniques was evaluated and compared with freehand, and additive-manufactured template surgical guidance techniques in a benchtop scenario. Seven head and neck surgeons performed three fibula mandible reconstructions on additive-manufactured mandible and fibula models using three different surgical guidance techniques (freehand, navigation, and template). The mandible reconstructions completed by the participants were analyzed to determine how closely they matched the planned mandible reconstruction.

To a gain a better understanding of the implications of using CT navigation to guide fibula mandible reconstruction surgery, semi-structured convergent interviews were conducted with the surgeon participants following the final benchtop session. The purpose of conducting convergent interviews was to determine the feasibility of using navigation to guide fibula mandible reconstructions, and to identify potential barrier's to clinical adoption, as well as benefits and limitations of CT navigation as a method of guiding fibula mandible reconstruction surgery. As the intended users, it was important to conduct interviews with participating surgeons to gain a better understanding of their perception of CT navigation as a method of guiding fibula mandible reconstruction surgery.

The benchtop study revealed that preoperative surgical planning and surgical guidance positively impacts fibula mandible reconstructions. additive-manufactured template guided surgery seems to produce the most accurate and consistent fibula mandible reconstructions, while freehand surgery produced the least accurate and consistent mandible reconstructions as compared to a planned control model. Computed-tomography surgical navigation guidance resulted in more accurate and consistent fibula mandible reconstructions than freehand surgery but were less accurate and consistent than additive-manufactured templated guided fibula mandible reconstructions.

The convergent interviews conducted following the model benchtop sessions were an effective method to better understand head and neck surgeons' views of the three surgical guidance methods used in the benchtop study. The convergent interviews revealed that surgeon participants prefer additive-manufactured template guided fibula mandible reconstruction but see potential value in computed tomography navigation surgical guidance.

Preface

This thesis is an original work by Rinde Johansson. The research project, of which this thesis is a part, received research ethics approval from the University of Alberta Research Ethics Board, Project Name "Comparative Benchtop Study Evaluating the Use of Image Guided Surgical Navigation and Robotic Technology for Fibula Free Flap Mandible Reconstruction Surgery", ID Pro0008298, May 28th 2019.

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Glossary of Terms

ABS	Acrylonitrile Butadiene Styrene
CAD	Computer-aided Design
CD	Compact Disc
CT	Computed-Tomography
DICOM	Digital Imaging and Communications in Medicine
FRM	Fused Deposition Modelling
GPS	Global Positioning System
IBL	Interfacial Biomechanics Laboratory
iRSM	The Institute for Reconstructive Sciences in Medicine
MMRL	Medical Modelling Research Laboratory- an Institute for Reconstructive Sciences in Medicine laboratory at the Misericordia community hospital.
SLA	Stereolithography
STL	Standard Tessellation Language
UV	Ultra-Violet
VSP	Virtual Surgical Planning

Chapter 1: General Overview of the Thesis

1.1 Introduction

Globally, 550,000 people are diagnosed with head and neck cancer each year (Fitzmaurice et al., 2017 ; Stewart, Wild, & Thompson, 2014). Head and neck cancer has a devastating impact on patients' quality of life and confidence. When a tumour is found on the mandible, fibula free flap mandibular reconstruction is often performed; the tumour and affected tissues are removed and replaced with the patient's bone from the fibula and soft tissue from the calf (Hidalgo, 1988; Wallace, Chang, Tsai, & Wei, 2010). This is a complicated surgical procedure that has to be performed with a high degree of accuracy in order to restore the patient to an optimal functional outcome (Logan, Wolfaardt, Boulanger, Hodgetts, & Seikaly, 2013a; Rohner, Guijarro-Martinez, Bucher, & Hammer, 2013; Roser et al., 2010). This poses a challenge to the surgical team who must execute a very challenging procedure, precisely if the patient is to regain the ability to function following surgery.

Computer aided design (CAD) and rapid prototyping techniques, such as additive-manufacturing, have revolutionized fibula free flap mandibular reconstruction (Hirsch et al., 2009; Seikaly et al., 2019). Surgeries are planned in advance using CAD software, and additive-manufactured guides are used to translate the digital surgical plan into the operating room (Hirsch et al., 2009; Logan et al., 2013a; Rohner, Guijarro-Martinez, et al., 2013; Roser et al., 2010; Seikaly et al., 2019). Medical imaging is used to create a digital model of the patients' anatomy, a virtual surgical plan is created based on the digital model, and cutting and drilling guides are designed and additive-manufactured to help the surgical team execute the plan (Logan et al., 2013a). This method improves accuracy considerably to optimize anatomical and functional results. However, logistical constraints including the availability of 3D printers, as well as time needed to print surgical guides means that some patients won't benefit from additive-manufactured guided surgery. Additive-manufactured surgical guides create tremendous value for the patient and the surgical team by providing the support necessary to execute fibula free flap mandibular reconstruction accurately. However, a new method of guided surgery is needed that provides the same high level of precision as additive-manufactured cutting and drilling guides without the long production time.

The study that will be described evaluates patient specific digital surgical planning using computed tomography (CT) surgical navigation. CT navigation is an alternative method of guided surgery that does not require 3D printing (Abbate et al., 2017; Bettschart et al., 2012; Hoffmann, Troitzsch, Westendorff, Weinhold, & Reinert, 2004; Shan et al., 2016). Surgical plans and guides are displayed on a screen in the operating room to guide the surgeon (Abbate et al., 2017; Bettschart et al., 2012; Hoffmann et al., 2004; Shan et al., 2016). The surgical plans and guides can then be point-checked, confirmed and adapted when necessary with surface landmarks on the different aspects of patient soft tissue and bony anatomy. This allows the surgical team to translate the digital surgical resection and reconstruction plans into real time decisions and actions while performing the procedure without the need for logistics intensive additive-manufactured models. The CT navigation system was be customized for mandible reconstruction and the surgical navigation procedure was compared to freehand surgery and the existing template guided surgery to evaluate utility.

1.1.1 Purpose of this Thesis

The purpose of this thesis is to (1) evaluate the use of surgical design and planning and CT navigation guidance for fibula free-flap mandible reconstruction surgery and (2) assess head and neck surgeons' perceptions of digital pre-surgical planning, additive-manufactured template guided surgery, and image guided surgical navigation. The differences between additive-manufactured surgical guides and digital guides designed for CT navigation were evaluated. with the goal of increasing efficiency when planning and creating surgical guides and models for mandible reconstruction surgeries.

The First Objective was to develop a novel method of performing fibula free flap mandibular reconstruction using CT navigation.

The Second Objective was to determine if there is a difference in surgical outcomes between (A), fibula free flap mandibular reconstruction surgery completed without preoperative planning and guided intuitively by anatomy (B), preoperatively planned surgery completed with digital cutting and drilling guides and CT image guided surgical navigation and (C), preoperatively planned surgery completed with additive-manufactured cutting and drilling guides.

The Third Objective was to determine the perceptions of head and neck surgeons' participating in the proposed study regarding preoperative surgical planning, and image guided surgical navigation. It is important to understand the impressions and preferences of head and neck surgeons who would ultimately be the end users of a new surgical method. If a new method of performing fibula free flap mandibular reconstruction is to be adopted, it needs to add value for head and neck surgeons.

1.1.2 Study Framework

The study design was a mixed methods study. Qualitative and quantitative methods were used to evaluate the utility of a new method of guided fibula free flap mandibular reconstruction and to gauge head and neck surgeons' perceptions of the novel surgical methods and application of technology. It is not enough to simply demonstrate that a new method of guided surgery is accurate without considering surgeons point of view; if surgeons do not like the new technology or method it will not be implemented on a large scale. A qualitative and quantitative mixed method study design was identified as an ideal method to evaluate the qualitative and quantitative considerations listed.

The study outlined in this thesis consisted of two major components. The first was a comparative benchtop model study designed to evaluate three different methods of guided fibula free flap mandibular reconstruction. The model study followed the methods used by Heather Logan et al. (2012); fibula mandibular reconstructions were completed by participating surgeons on additive-manufactured models in separate benchtop sessions (Logan et al., 2013a). The second component was convergent interviews, which were conducted to assess participating surgeons' perceptions of the surgical methods and application of technology used in the model study.

1.2 Background of Fibular Reconstruction of the Mandible

The mandible (lower jaw) is an important facial structure both functionally and aesthetically; deformity of the mandible due to cancer can have a significant impact on oral function as well as self-perception (Zheng et al., 2013). Fibula free flap mandibular reconstruction is often performed following tumor removal, to correct a defect or after trauma; bone and tissue removed from the mandible can be replaced with the patient's tissue from the calf and fibula (Hidalgo, 1988; Wallace et al., 2010). Fibula free flap mandibular reconstruction is a challenging surgical procedure that requires virtual surgical planning (VSP) in order to plan the optimal reconstruction for the future functional and prosthetic outcome of the patient (Logan, Wolfaardt, Boulanger, Hodgetts, & Seikaly, 2013). Patient specific surgical guides are additive-manufactured and temporarily affixed to the patient's jaw and fibula to guide the surgeon where to cut, drill and place dental implants. Virtual surgical planning and additive-manufacturing patient specific surgical cutting and drilling guides significantly improves the accuracy of mandibular reconstruction surgery (Roser et al., 2010 ; Rohner, Guijarro-Martinez, Bucher, & Hammer, 2013). However, producing physical medical models and surgical guides for mandible reconstruction surgery can be time consuming. Once fabricated, the surgical guides cannot be modified or adjusted. Emergency surgeries or last-minute changes might not be accommodated due to time, material and equipment constraints. The proposed study suggests computed tomography navigation surgical guidance as a possible alternative to additive-manufactured template guided surgery. (Rohner, Bucher, & Hammer, 2013; Rohner, Guijarro-Martinez, et al., 2013)

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Chapter 2: Surgical Design and Navigation

2.1 Introduction

2.1.1 Specific Purpose, Hypothesis and Guiding Question

2.2.1.1 Purpose

The purpose of the present study was to evaluate the differences between three methods of fibula free flap mandibular reconstruction in a surgical simulation context. The three methods of guided mandibular reconstruction surgery evaluated were: (A) freehand surgery completed without preoperative virtual planning and guided intuitively by anatomy. (B) CT surgical navigation guided surgery, and (C) additive-manufactured template guided surgery.

2.2.1.2 Hypothesis

There is a difference in surgical outcome between the three methods of fibula free flap mandibular reconstruction tested; (A) fibula free flap mandibular reconstruction surgery completed without preoperative planning and guided intuitively by anatomy. (B) preoperatively planned surgery completed with the use of CT image guided surgical navigation, and (C) preoperatively planned surgery completed with additive-manufactured cutting and drilling guides. Guidance method (C), preoperatively planned surgery completed with additive-manufactured cutting and drilling guides will result in the most accurate and consistent reconstructions when compared to guidance methods B and C. Guidance method (B) preoperatively planned surgery completed with the use of CT image guided surgical navigation, will result is more accurate and consistence reconstructions than guidance Method (A) fibula free flap mandibular reconstruction surgery completed without preoperative planning and guided intuitively by anatomy.

The outcome measurements evaluated:

1. Hausdorff surface distance
2. Model measurements
3. Duration to complete task

4. Number of surgical plan corrections made

2.2.1.3 Guiding Question

The research Question investigated was: How does image guided surgical navigation aid in supporting head and neck surgeons in executing a virtual surgical plan for fibula free flap mandibular reconstruction in a bench top setting?

2.2 Background and Literature Review

In the same way that additive-manufactured surgical guides translate a virtual surgical plan into the operating room physically, image based surgical navigation translates a virtual surgical plan digitally. Image guided surgical navigation gives the surgical team a three-dimensional view of the patient's anatomy and the position of surgical instruments in relation to the patient in real-time (Hoffmann et al., 2004). Surgical navigation provides instantaneous feedback by allowing the surgical team to observe the position of anatomical structures on screen in the operating room that would be difficult to observe otherwise (Abbate et al., 2017; Hoffmann et al., 2004).

Surgical navigation functions in a manner similar to global positioning systems (GPS) that you may have in your car or on your smart phone (Samarakkody & Abdullah, 2016). Surgical navigation systems are made up of three main elements: a localizer, which is comparable to a satellite, an instrument or surgical probe, which is akin to track waves emitted by the GPS system, and CT scan data set, which is similar to a map (Yu et al., 2016). These three components allow the surgical team to see the patient's anatomy, and the position of their surgical tools in relation to the anatomy; just like seeing your location on a map on a GPS system. With a road map showing the surgical team the patients anatomy, surgical precision and patient safety is improved, and there is less ancillary damage done to surrounding tissue (Samarakkody & Abdullah, 2016).

Image guided navigation works by synchronizing the position of the patient's anatomy in real life with medical imaging taken of the patient pre-operatively, this is referred to as the registration process (Abbate et al., 2017). A preoperative CT scan is uploaded into the navigation system and coordinated with the patient's anatomy using reference points, or key facial structures (Samarakkody & Abdullah, 2016). Once the patient is registered the location of Surgical instruments can then be traced by the navigation system. The navigation system displays sagittal, coronal, and axial views of the patients anatomy on a screen in the operating room (Samarakkody & Abdullah, 2016; Yu et al., 2016).

There are two different types of navigation systems; electromagnetic and infrared (more commonly known as optical navigation). In the journal article titled "The use of image guided navigational tracking system for endoscopic sinus surgery and skull base surgery: a review" Samarakkody & Abdulla describe the difference between electromagnetic and infrared navigation systems (Samarakkody & Abdullah, 2016). Electromagnetic and optical navigation systems perform the same function but use different technology to do so. Optical navigation systems use infrared sensors and light emitting diodes (LEDs) that are affixed to the patient; LEDs attached to the patient and surgical instruments have to be 'seen' (within the sensors line of sight) in order for the system to track the position of the surgical tools. Electromagnetic navigation systems use electromagnetic fields and anatomical features or reference points to register the patient and track the position of surgical tools. An electromagnetic Medtronic fusion compact ENT navigation system was used in the benchtop model study. Tools do not need to be 'seen' when using electromagnetic systems.

Surgical navigation relies on medical imaging taken pre-operatively, because of this, it is not possible to navigate structures that move in ways that do not correspond with the pre-operative medical imaging (Hoffmann et al., 2004). The Mandible is a moveable structure that is not fixed to the facial skeleton; movement of the mandible makes it difficult to use surgical navigation techniques when performing fibula free-flap mandibular reconstruction (Bettschart et al., 2012). There are three basic strategies used to enable navigation of the mandible. The first strategy (1) depends on maxillomandibular fixation, which maintains the mandible in a constant position in relation to the facial skeleton (Bettschart et al., 2012; Huang, Shan, Lu, & Cai, 2015; Shan et al., 2016). The second approach (2) uses patient specific dental appliances such as dental splints or bite blocks to place the mandible in an easily reproducible open bite position; when the mandible is in position it is possible to navigate (Bettschart et al., 2012; Chao et al., 2016; Hoffmann et al., 2004; Huang et al., 2015; Shan et al., 2016; Yu et al., 2016). In methods 1 and 2 the localizer is placed on the patient's maxillofacial region, most often in the centre of the forehead. In the third method (3), a localizer is placed directly onto the mandible to allow the navigation system to track the movements of the jaw throughout the surgery (Abbate et al., 2017; Bettschart et al., 2012; Shan et al., 2016). Methods 1 and 2 were used in the benchtop model study, scans were taken with the mandible in occlusion and in an open bite position with a dental splint. The position of the mandible in real life and on screen are synchronized compensating for the mandibles movements and allows the surgical team to navigate the mandible regardless of its position relative to the facial skeleton (Shan et al., 2016).

The first two strategies, (1) intermaxillary fixation and (2) using dental appliances to position the mandible, rely on 'tricking' the navigation system into thinking that the mandible is fused to the facial skeleton allowing the mandible to be navigated as though it was part of the maxillofacial region. Strategies 1 and 2 require pre-operatively acquired medical imaging used for navigation to be taken with the mandible in the exact same position as it will be in during the surgical procedure. If the mandible is in a different position in the medical images than the operating room, the imaging and the patient's anatomy won't match and it will not be possible to use image guided surgical navigation to guide mandible reconstruction. Dental appliances need to be in place when pre-operative medical images are taken to ensure correct positioning and accurate navigation of the mandible. The main advantage of the third method, (3) placing the localizer directly onto the mandible, is that there is no need for custom made dental appliances to be worn during medical imaging or surgery (Abbate et al., 2017).

Image based surgical navigation is a digital method of surgical guidance. Using CT image navigation guidance methods, patient specific surgical guides can be planned, designed and delivered to the surgical team faster than additive manufactured templates. CT image navigation guides are created using digital software tools. The surgical plan and guides are created virtually, converted to DICOM format, saved onto a CD or USB drive, and the digital DICOM surgical cutting guides are then uploaded into a navigation system. Once the surgical plan has been uploaded into the navigation system the surgical team is able to visualize the surgical plan and follow guides. The fully digital pathway eliminates the need for physical guides which take time to design, fabricate and sterilize before they can be used in the operating room. It may be possible to adjust or replan a surgery intraoperatively to accommodate necessary changes to the surgical plan. The surgical plan and navigation guides can be digitally altered, saved and uploaded into the navigation system if necessary.

A virtual pre-surgical plan can be accurately executed using surgical navigation resulting in good functional and aesthetic outcomes following fibula mandibular reconstruction. In the study titled 'surgical navigation-assisted mandibular reconstruction with fibula flaps' Shan et al describe and evaluate their method of performing fibula mandibular reconstruction using navigation (Shan et al., 2016). In this clinical study twenty participants with benign and malignant tumours underwent partial mandibular resection and fibular reconstruction. Surgical interventions were completed with image guided navigation, custom made dental splints, and intermaxillary fixation. The dental splints used in this study were designed to position the participants mandible consistently in relation to the maxilla based on occlusion of the patient's teeth. Virtual surgical planning was conducted using the participants preoperative CT scans which were taken with the dental splint in position to ensure consistency between the surgical plan and the operating room. The dynamic reference frame was affixed to the skull. During the surgical procedure, the maxilla and mandible are fixated with the dental splint in position to ensure there was no unwanted movement of the mandible during the procedure. This method combines mandibular navigation strategies 1 and 2 described earlier in this section. A post-operative CT scan was taken of each study participant one week following surgical intervention and used to create digital stereolithographic models of participant's bony anatomy. Digital models of the actual reconstruction were superimposed over the planned reconstruction models to evaluate how precisely image guided navigation, custom made dental splints, and intermaxillary fixation, translated the surgical plan into the operating room. In each case the resection and reconstructions were completed successfully. Consistency between the preoperative plan and actual reconstruction was reported as being $79.1 \pm 8.6\%$ at within 1 mm, $87.1 \pm 6.7\%$ at within 2 mm, and $91.9 \pm 5.4\%$ at within 3mm. The authors of this study conclude that fibula mandibular reconstruction can be completed accurately using surgical navigation.

It is possible to navigate the mandible without restricting the movement at all, allowing surgeons full access to the mandible at all times during the procedure. In the study titled 'Mandibular Surgical Navigation: An Innovative Guiding Method' Abbate et al. describe a novel method of navigating the mandible while it is mobile by placing the dynamic reference frame (the localizer) directly on the mandible (Abbate et al., 2017). By placing the dynamic reference frame on the mandible, the navigation system can synchronize the movements of the mandible with the display on screen regardless of its location relative to the facial skeleton. Using this method, the mandible does not need to be in a predetermined position to utilize navigation, eliminating the need for intermaxillary fixation or custom dental appliances to reposition the mandible consistently. In this clinical case series four patients underwent fibula mandibular resection and reconstruction completed using CT navigation with the dynamic reference frame placed on the mandible. Postoperative CT scans were taken of each patient three weeks following reconstruction, CT scans were used to create digital standard tessellation language (STL) models of the patients' bony anatomy. The post-operative actual reconstruction model was digitally superimposed over the pre-operatively planned reconstruction model; actual and planned reconstructions were compared to evaluate the accuracy of this method of mobile guided navigation. The actual reconstructions were shown to be very closely matched to the planned reconstructions. The matching standard deviations of comparative measurements between the planned and actual reconstructions ranged from 0.33mm to 8.9mm with a Mean standard deviation of 4.67mm. This method of mandibular navigation could enable accurate resection and reconstruction while allowing the surgical team to navigate the jaw with full range of motion.

Computer aided design and surgical navigation are able to effectively communicate a virtual surgical plan to the surgical team for execution. In a retrospective case series involving 29 patients Yu et al. examined the outcomes of fibula free flap mandibular reconstructions performed freehand, with computer-aided design, and with computer aided design and surgical navigation (Yu et al., 2016). Surgery was performed to resect benign tumours of the mandible; tumour resections and fibula mandible reconstructions were performed by the same surgeon. Of the 29 cases reviewed by Yu et al. ten patients underwent reconstruction completed using freehand techniques, seven patients underwent reconstruction completed with computer aided design, and twelve patients underwent reconstruction completed with computer aided design and surgical navigation. It is important to note that computer aided design as described in this study is quite different from the workflow used at iRSM; pre-operative imaging was used to create anatomical models and virtual surgical plans; digital measurements of the planned reconstructions were communicated to the surgeon to facilitate correct tumour resection, fibula segmentation, and positioning of fibula segments. additive-manufactured cutting and drilling guides were not used in the surgical interventions described by Yu et al. Postoperative multi slice CT scans were taken of the participants six months following reconstruction; digital anatomical models of the actual reconstructions were created based on postoperative medical imaging. Actual reconstructions were digitally superimposed over the planned reconstructions and measured to compare surgical outcomes. Average condyle shift, average gonion shift, mandible angle variation, and operative time were identified as key features in determining the success of mandible reconstruction. The authors report that average condyle shift between actual and planned reconstructions was 18.4 ± 2.9 mm for free hand reconstructions, 10.3 ± 3.9 mm for computer aided design reconstructions, and 9.3 ± 2.6 mm for computer aided design and surgical navigation reconstructions. Average gonion shift was 12,8 ± 3.8 mm for free hand reconstructions, 12.5 ± 3.8 mm for computer aided design reconstructions, and 7.3 ± 2.5 mm for computer aided design and surgical navigation reconstructions. Angle variation 8.7° ± 4.3° for freehand reconstructions, 3.1 ° ± 2.0 ° for computer aided design reconstructions, and 2.6° ± 1.4 ° for computer aided design and surgical navigation reconstructions. Mean operative time was roughly the same for each method of guided surgery. The authors conclude that reconstructions completed with a combination of computer aided design and surgical navigation were more accurate than freehand surgery without taking a significant amount of time.

2.3 Methods

The method used for the present model study was a repeated measures design consisting of three benchtop sessions (A, B, and C). Each head and neck surgeon participating in the present study performed three surgical procedures on additive-manufactured models simulating the mandible and maxillofacial regions. In session A, participants completed a fibula mandibular reconstruction without preoperative virtual surgical planning, the reconstruction completed in session A was guided intuitively by anatomy. In session B, participants were asked to perform a preoperatively planned fibula mandible reconstruction with CT image guided surgical navigation, in session C, participants performed a preoperatively planned fibula mandible reconstruction with additive-manufactured cutting and drilling guides. The reconstructed mandibles created by participants in sessions A, B and C were measured and compared digitally and manually using software and by taking measurements using calipers. Time to complete the task and number of surgical plan corrections made was recorded. The present study was designed to determine if there is a difference in surgical outcomes among surgical methods A, B, and C. Results were compared to measure surgical time, and accuracy. The present model study design follows the methods used by Logan et al. (2013) in the study titled "Exploratory benchtop study evaluating the use of surgical design and simulation in fibula free flap mandibular reconstruction. Details of the benchtop study, measurements, analysis and results will follow.

2.3.1 Study Preparation

2.3.11 Model Design

The design and fabrication of the anatomical models used in the benchtop study reflected purpose and use. The fibula, mandible and skull models used in this study were created using CT scan imaging data taken from a standardized subject; a waiver form was obtained to use CT scan imaging data to create the models used in this study. The CT data was high quality to produce realistic and anatomically accurate models. The CT scans were taken according to iRSM and Medtronic CT scanning protocol. The models were prepared using Mimics (Materialise Inc., Leuven, Flemish Brabant, Belgium), Geomagic Freeform (3DSystems Inc., Rockhill, North Carolina, United States of America), and Preform (Formlabs Inc., Sommerville, Massachusetts, United States of America). Models were prepared by the researcher at the Medical Modelling Research Laboratory (MMRL) at the Misericordia community hospital in Edmonton, Alberta and the Head and Neck Simulation lab at the University of Alberta in Edmonton Alberta. The software programs used to prepare the models were chosen due to availability at iRSM and the University of Alberta.

Anatomical models were fabricated using a form2 Stereolithography (SLA) desktop printer (Formlabs Inc., Sommerville, Massachusetts, United States of America) printer and a 3DSystems Sinterstation 2500 (3DSystems Inc., Rock Hill, North Carolina, United States of America). Printers were chosen due to affordability and availability through the University of Alberta and in Edmonton. The Sinterstation 2500 printer was available through 3D print western (3D print Western, Edmonton, Alberta, Canada) and the Form2 SLA printer was available through the head and neck simulation lab in the clinical sciences building at the University of Alberta. Models of the fibula, mandible, and surgical templates were printed with a Form2 Stereolithography (SLA) printer using white resin RS-F2-GPWH-04. The models of the skulls and reference models were printed with a 3Dsystems sintersation 2500 selective laser sintering (SLS) printer using Nylon 12 material. The software, techniques, equipment, methods, processes, and materials used to create the models were the same for each session and each participant.

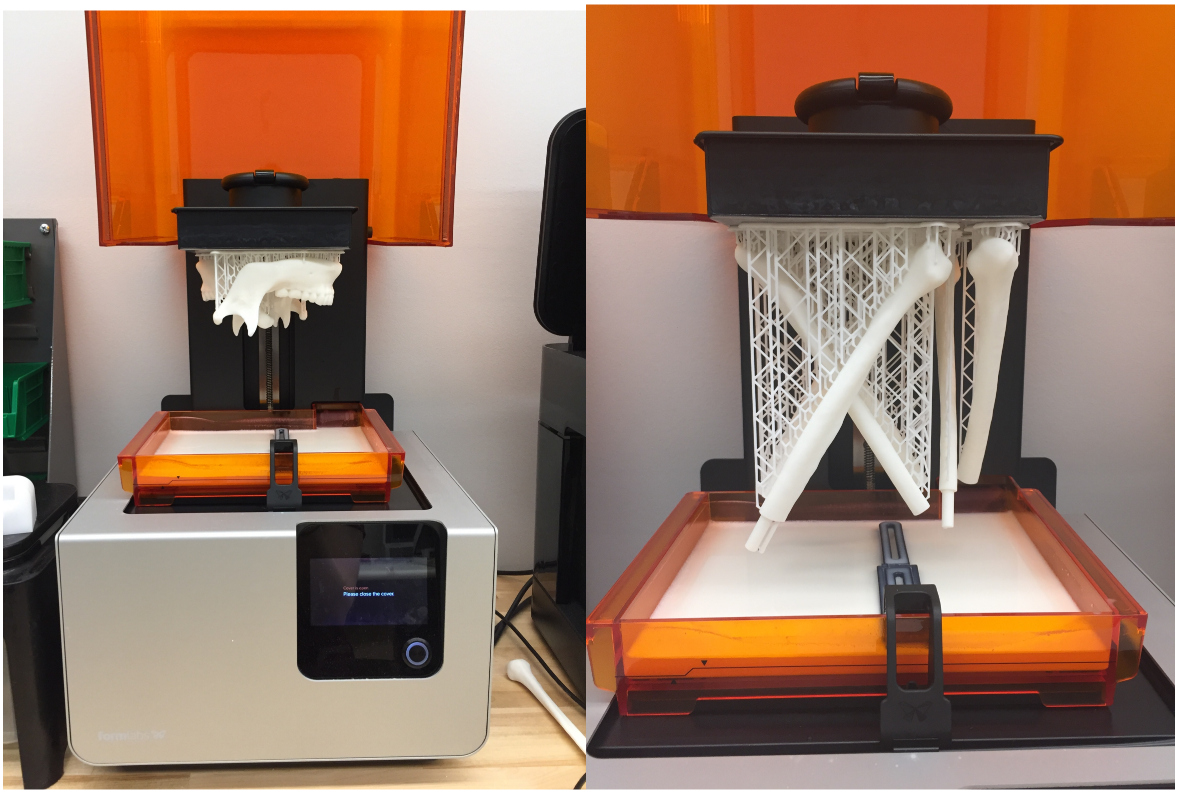


Fig 1. Printing mandible and fibula models

Printed anatomical models were processed for use in the benchtop study. Fibula and mandible models printed with the form2 SLA desktop printer in the head and neck simulation lab were placed in an 99% isopropyl alcohol bath to remove uncured resin which adheres to the model following printing. The form wash (Formlabs Inc., Sommerville, Massachusetts, United States of America) automated cleaning device was used to clean the models. Following cleaning, the additive-manufactured models were placed in a form cure device (Formlabs Inc., Sommerville, Massachusetts, United States of America) where they were heated and cured with LED lights. Print support structure was removed from the models by the researcher. The anatomical models were sanded with 160 grit sandpaper to remove the fragments of the support structure remaining on the model. The models were sanded until they felt smooth to the touch and the support structure fragments were no longer visible.

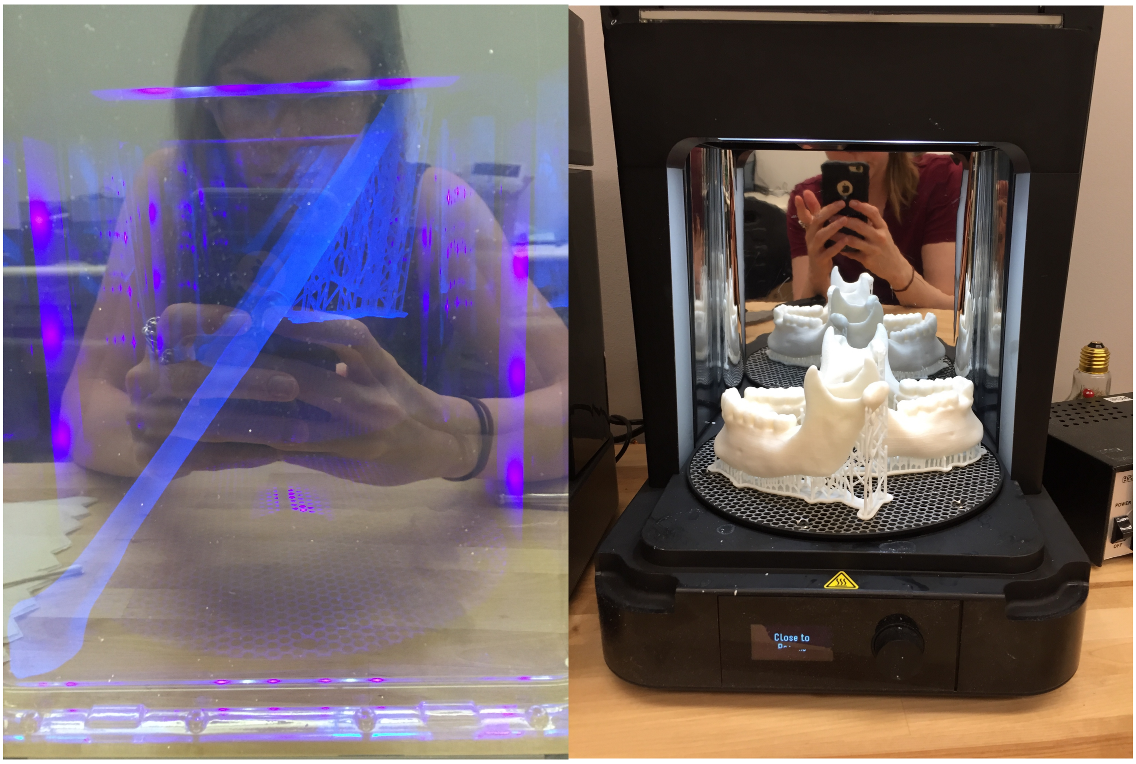


Fig. 2 Curing the additive-manufactured models

Fibula models were assembled following processing. Each fibula model was printed in two separate pieces that were put together following printing. The complete fibula model was too large to fit on the form2 build platform in its entirety; the STL fibula model was divided into two pieces and a double circular mortise and tenon joint was designed to join the two halves of the fibula. Several different types of joints, fit of joint, and adhesives were tested to determine which joint would be most appropriate to join the two halves of the fibula. Double circular mortise and tenon joint was determined to be the ideal joint for unifying the two halves of the fibula. The double circular mortise and tenon joint allowed the researcher to assemble the two fibula pieces precisely without compromising the overall shape and form of the fibula model. Super glue was applied to the tenons before the researcher assembled the fibula. Trial and error was used to determine the optimal type of joinery for the fibula halves.

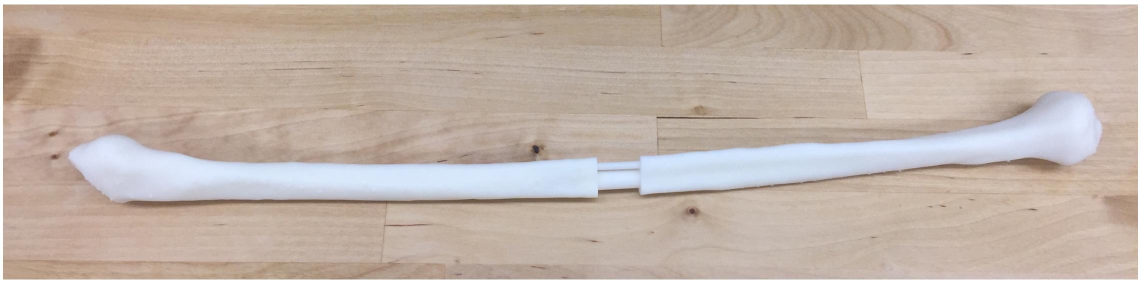


Fig. 3 assembling a fibula model

The temporomandibular joint (TMJ) was altered to better suit the models' end use and function in this study. The TMJ was digitally modified by the researcher using freeform software to create a hinge joint that allowed the mandible to rotate around a horizontal axis at the condyles to open and close the jaw; the hinge was created by altering the mandible condyles and temporal bones of the skull. Several different hinge designs of various styles, sizes and fits were tested to determine the optimal TMJ design for use in the present study. The design of the TMJ hinge allowed the researcher to interchange the mandibles easily to reuse the skull model for each benchtop session and scan the mandible separately from the rest of the skull. Reusing the skull model significantly reduced the amount of printing necessary, reducing the cost of conducting the present study.

Fig 4. Additive-manufactured skull and mandible models.

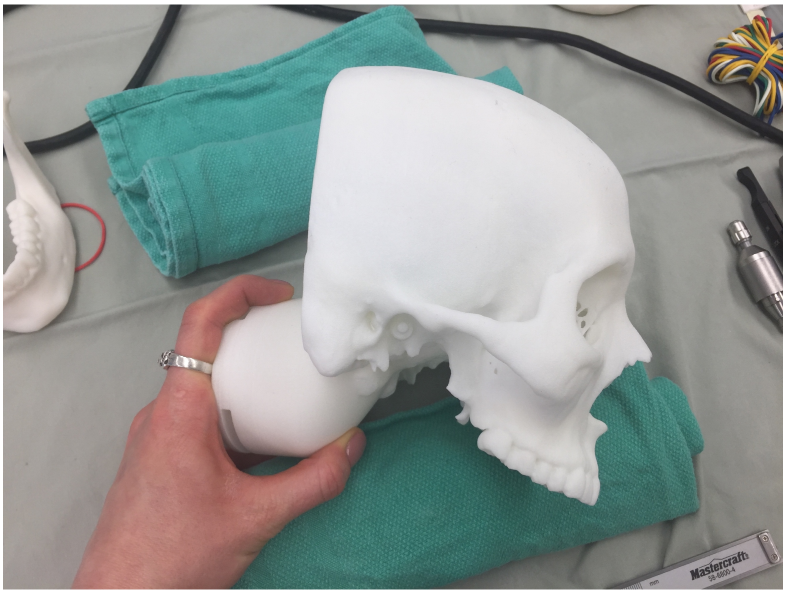


Fig 5. Condyle hinge joint design.

Appropriate tumour margins were determined based on the surgical case and intended end use of the mandible models. The mandible tumour margins were indicated on the additive-manufactured mandible models used in the benchtop study with red markings. A head and neck surgeon was consulted regarding the appropriate tumour margins for the surgical case. The head and neck surgeon drew the appropriate tumour margins on a mandible model which the researcher used to design a stencil. An additive-manufactured three-dimensional stencil was designed and fabricated that fit onto the teeth of the mandible models. The stencil allowed the researcher to consistently outline the tumour margins on each mandible model used in the benchtop study based on the consultation with the head and neck surgeon.

Fig 6. A tumour drawing stencil on a mandible model.

2.3.12 Material Testing

Materials and methods used to fabricate the models used in the benchtop study were chosen to suit the end use of the models. Properties considered for this study were print resolution, material strength, radiological properties, material melting point, material and printing cost, and the availability of the 3D printing technology to the researchers. Materials and models were tested by the researcher to determine the best available materials and 3D printing technology to use for the benchtop study.

Form2 (Formlabs Inc., Sommerville, Massachusetts, United States of America) white resin material was used to print the mandible and fibula models as well as the surgical guides used in Session C of the benchtop study. The Form2 printer (Formlabs Inc., Sommerville, Massachusetts, United States of America) employs stereolithography (SLA) technology in which resin is cured in layers using a UV laser to create an additive-manufactured model. SLA printing technology does not heat and melt the model material during the additive-Manufacturing process as is traditional with fused deposition modelling (FDM) additive manufacturing technology. The finished models created using SLA printing technology are not made with thermoplastic material and as such do not melt when being cut with a surgical saw.

The friction created by the movements of a surgical saw when cutting an additive-manufactured model generates heat which melts thermoplastics such as Acrylonitrile Butadiene Styrene (ABS) which is often used with FDM 3D printing technology. Friction created when cutting an anatomical model printed with a thermoplastic can melt and distort the models leading to inaccuracies in the final reconstruction. Heating and melting the anatomical models slows-down the process of cutting and reconstructing the mandible as it is necessary to wait for the plastic models and saw to cool down before completing the task. The fibula and mandible models created using the Form2 printer and white resin do not melt during cutting and drilling, instead a fine powder is created which is easily brushed away and does not interfere with the completion of the task. Form2 resin is an ideal material for use with surgical cutting and drilling instruments.

In addition to the melting point of the Form2 white resin, the radiological properties and price of the material made it an ideal material to use to print the mandible and fibula models for the benchtop study. The mandible and fibula models fabricated with white resin appeared very clearly on a CT scan. High contrast between the printed anatomical models and the surrounding materials allowed someone viewing the CT scans to easily see the anatomical structures. High visibility of the anatomical structures was important for benchtop session B, when CT navigation was used to guide the resection and reconstruction.

The skull models and reference models were printed using a different 3D printer and material from the mandibles, fibulas and cutting guides used in this study. The skull models could not be printed with the Form2 printer available in the head and neck simulation lab because of their size relative to the Form2 build platform. Skull models and reference models were printed in nylon 12 material with a 3DSystems Sinterstation 2500 SLS printer (3DSystems Inc., Rock Hill, South Carolina, United States of America). The skull models were printed by 3D Print Western (3D print Western, Edmonton, Alberta, Canada) a company in Edmonton, Alberta. The researchers considered several options to fabricate the skull models and determined that the Sintersation 2500 SLS printer and nylon 12 was the best option due to availability, cost, resolution and material properties.

Fig 7. Additive-manufactured skull and mandible models

2.3.13 Assessment of the Accuracy of the Model

All models used in the benchtop sessions had to meet a high standard of accuracy to ensure the results of the study. Additive-manufactured models used in the study were compared to the digital control model before the benchtop sessions took place to ensure accuracy. Accuracy of the printed models was determined by 3D scanning each additive-manufactured model and digitally comparing the additive-manufactured models to the digital control models; the control models were the models created based on CT scans of a standardized mandible and fibula. Mandible models were scanned with a Shapegrabber Ai310 3D surface scanner (Shapegrabber Inc., Ottawa, Ontario, Canada), Fibula models were scanned using a Metra scan 3D (Creaform Inc., Levis, Quebec, Canada). VX elements (Creaform Inc., Levis, Quebec, Canada) was used to process the 3D surface scan data of the fibula models generated by the Metra scan 3D scanner, Geomagics control was used to process the surface scan data of the mandible models generated by the shape grabber scanner (3DSystems Inc., Rock Hill, South Carolina, United States of America). 3D scanners used to assess the accuracy of the printed models had to be at least as accurate as the 3D printer used to create the models. The 3D scanners used to verify the accuracy of the additive-manufactured models were selected the researcher based on accuracy and availability through iRSM and the university of Alberta. The printed fibula models were too large to fit on the Shapegrabber platform; and so the hand-held Metra scan 3D scanner was used to scan the fibula models.

3D scans were used to compare additive-manufactured mandible and fibula models to control models to verify accuracy. Digital surface models of the additive-manufactured models were generated using the 3D scan data were compared to the digital control models using Geomagic Control (3DSystems Inc., Rock Hill, South Carolina, United States of America). The digital STL files generated from the surface scan data were superimposed over the original STL file (the digital control model) used to print the models; A Hausdorff surface distance map or "heat map" was created using Geomagic Control and used to evaluate the accuracy of the printed models. Scanners and software used to process and compare the surface scanning images were chosen due to availability at iRSM and the University of Alberta. Hausdorff surface distance coloured maps were reviewed by the researcher who ensured that the scanned fibula and mandible models did not deviate significantly from the original STL file. All fibula and mandible models were acceptably precise and were used in the model study.

2.3.14 Navigation Testing

A pilot study was conducted by the researchers in preparation for the model benchtop sessions. The pilot study was conducted to assess the feasibility of simulating a surgical navigation scenario using additive-manufactured models. The pilot study was conducted with a Medtronic Fusion CT navigation system (Medtronic plc., Dublin, Ireland), additive-manufactured anatomical models of a skull and mandible, and CT scan data of the models. Equipment and models used in the pilot study were available to the researcher through the university of Alberta hospital and iRSM. The pilot study was conducted in the surgical suites at the University of Alberta hospital. It was determined that additive-manufactured anatomical models were an appropriate mechanism to conduct benchtop session B, preoperatively planned surgery completed with the use of CT image guided surgical navigation. Form2 resin was determined to be an ideal material to use for this study as the radiological properties of form2 resin were ideal for use with a navigation system.

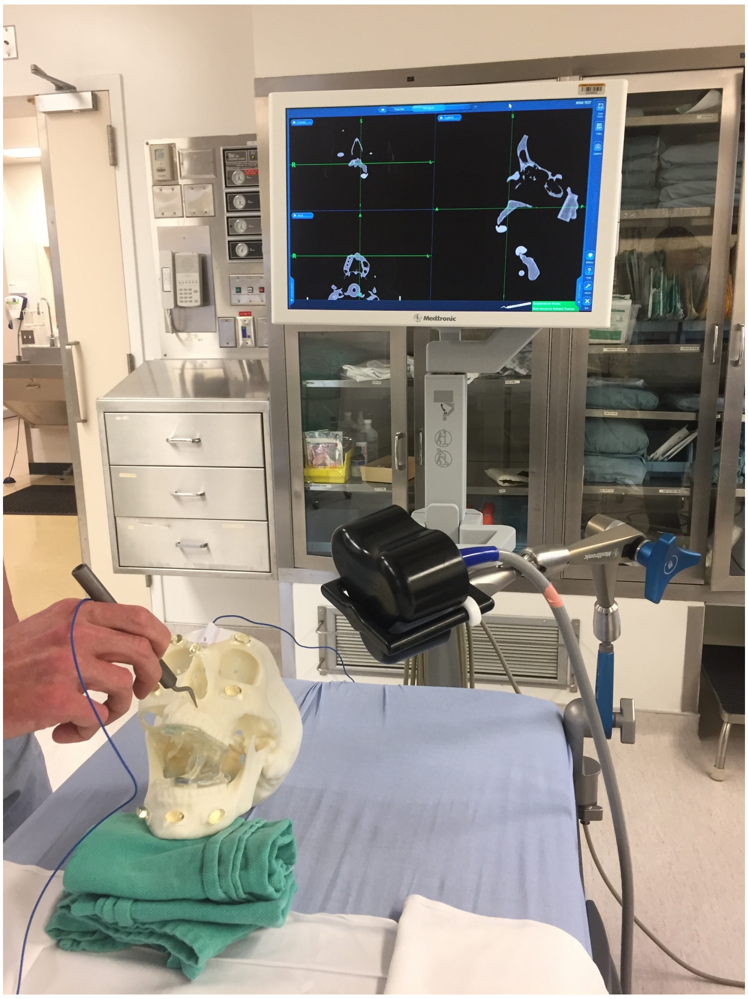


Fig 8. Navigation testing pilot study.

2.3.3 Reconstruction of the Mandible

The surgical case used in the present study was chosen based on the research objectives and guiding research question. A unilateral mandible body reconstruction using a single fibula bone graft segment was used as the surgical case in the present study. This surgical case was chosen after consultation with two head and neck surgeons, a maxillofacial prosthodontist, a surgical design simulationist and a research scientist; individuals consulted regarding the surgical case are knowledgeable about the complexities of planning and performing fibula mandible reconstruction surgeries. The surgical case chosen for this study is defined as a

Brown Class IV, the mandibular reconstruction used in the present study includes the right molars and the ipsilateral canine but not the contralateral canine (Brown, Barry, Ho, & Shaw, 2016). Clinical relevance and compatibility with surgical guidance methods and equipment to be used was considered when choosing the surgical case. A unilateral defect reconstructed using a single fibula segments was determined to be a simple but sufficiently challenging surgical case to evaluate the effectiveness of CT navigation to guide fibula mandible reconstruction surgery. As CT navigation is a novel method of guiding fibula mandible reconstruction, a complicated surgical case requiring many fibula segments to reconstruct a mandible was determined to be too challenging for an initial exploratory study. Future research evaluating CT navigation for fibula mandible reconstruction could employ a more complicated surgical case requiring multiple fibula bone graft segments.

The reconstruction of the mandible with a fibula bone graft was planned by the researcher in collaboration with a head and neck surgeon, maxillofacial prosthodontist and surgical design simulationist. The reconstruction of the mandible was planned according to iRSM standards and protocol to ensure a clinically realistic reconstruction. The mandible reconstruction was planned to provide an optimal dental reconstruction; the position of the fibula bone graft segment relative to the mandible was carefully considered to allow for enough space for a dental prosthesis. While osseointegrated dental implants were not used in this study, implant positions were considered as part of the surgical planning process to ensure that the reconstruction was realistic and could support a dental prosthesis as would be required in a real clinical scenario.

The fibula mandible reconstruction was designed according to iRSM protocol. A distance of 20mm between the upper surface of the fibula and the occlusal plane was planned to allow enough space for a dental prosthesis. The fibula graft used to reconstruct the mandible was at least 20mm in length at the shortest edge. Fibula segments are planned to be at least 20 mm long to ensure the free flap pedicle remains attached to the fibula following surgery to provide adequate blood supply to support the fibula bone graft segment. The reconstruction was design with at least 5mm contact space between the fibula bone graft and the native mandible; this is to allow the fibula bone graft to integrate with the mandible.

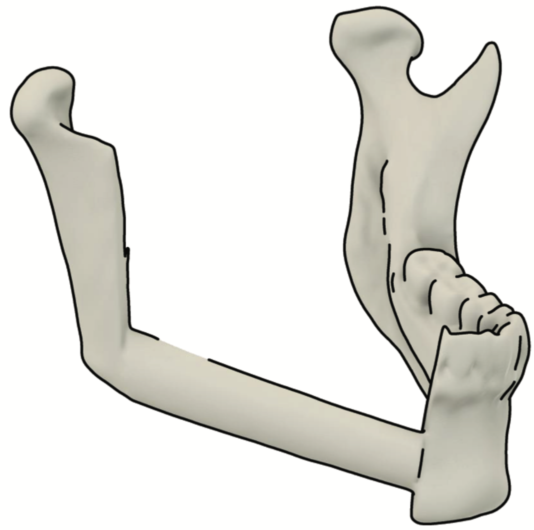


Fig 9. Planned mandible reconstruction.

2.3.4 Freehand surgical guidance design

Materials used in session A were designed based on a clinically realistic surgical toolkit that would be provided to a surgical team performing freehand fibula mandible reconstruction surgery. Freehand surgery is completed without virtual pre-surgical planning and is guided intuitively by the patient's anatomy. Instead of surgical guides and templates a surgical team relies on their own judgement and experience to resect the cancerous tissue and reconstruct the mandible using a fibula. To simulate a freehand fibula mandible reconstruction scenario, participants were provided with an additive-manufactured mandible model with a unilateral cancerous defect. The additive-manufactured mandible model was marked using a fine red marker and a stencil to indicate the tumour margins. Participants were instructed to resect the cancerous tissue and reconstruct the defect using an additive-manufactured fibula model which was provided for them.

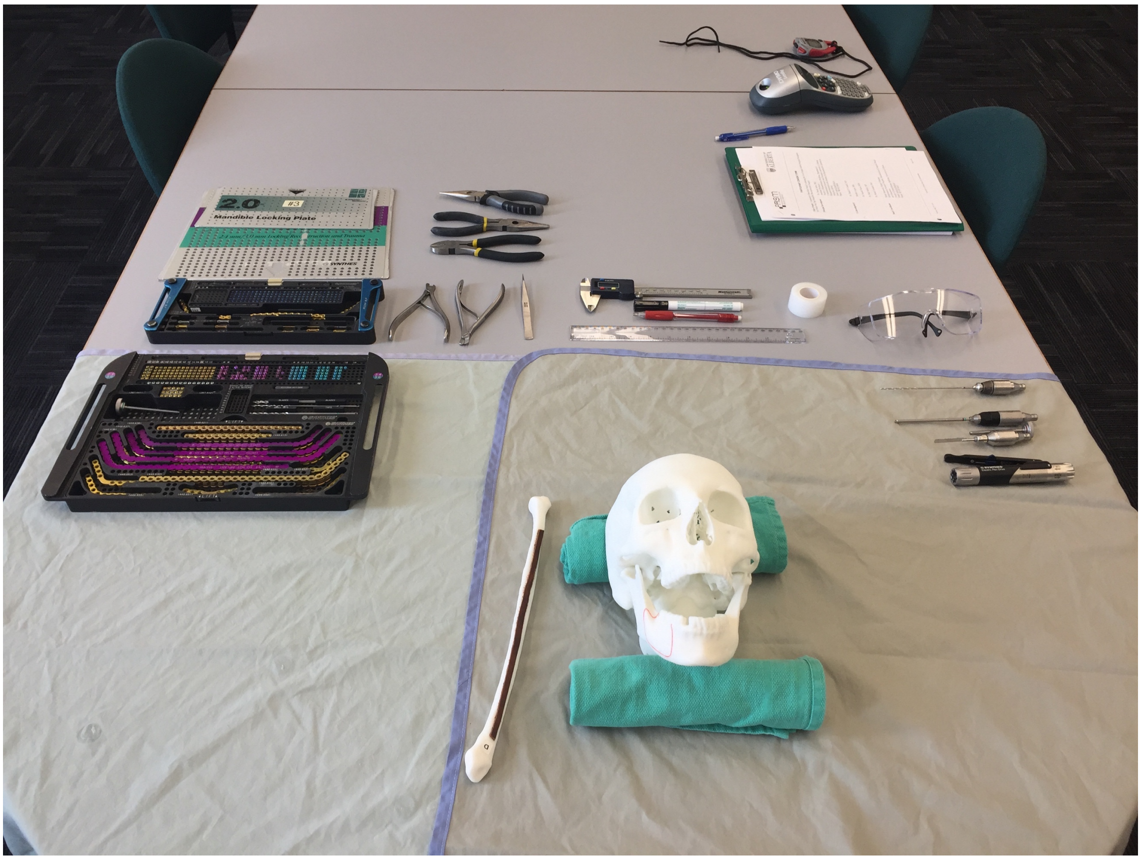


Fig 10. Experimental set-up benchtop session A, Freehand based surgical guidance.

The surgical toolkit provided to the surgeon participants to resect and reconstruct the mandible using the fibula in benchtop session A, included:

Models

- Additive-manufactured fibula
- Additive-manufactured mandible
- Additive-manufactured skull

Equipment

- Synthes electric pen tool and foot pedal
- Synthes reciprocal saw attachment
- Synthes reciprocal saw blade
- Synthes drill attachment
- Synthes drill bit
- Synthes Angled locking reconstruction plate 6x23 holes 44mm x 214mm
- Synthes matrix combo plating set
- Synthes 2.4/3.0mm locking reconstruction and trauma kit
- Synthes 2.0mm Mandible Trauma kit

- Cellphone or other device to take pictures and record video during benchtop session
- Digital stopwatch
- Eye protection
- Lab coat
- Label maker
- Transparent ruler
- Calipers
- Marker, pen, pencil
- Tape
- Scissors
- Green surgical towels

2.3.5 Patient specific digital navigation-based guidance design

Digital CT navigation surgical guides used in benchtop session B were designed based on a clinically realistic surgical toolkit that might be provided to a surgical team. The digital cutting and reconstruction CT navigation guides were developed by the researcher with assistance from a head and neck surgeon, maxillofacial prosthodontist and a surgical design simulationist. The surgeon, prosthodontist and surgical design simulationist have experience creating and using additive-manufactured surgical guides and templates for fibula mandible reconstruction surgery.

2.3.5.1 Patient Specific Fibula Cutting guide- Navigation

It was not possible to navigate the fibula using the Medtronic Fusion Compact (Medtronic Navigation, Inc. Dublin, Ireland), navigation equipment used in the present study. It was not possible to register the fibula with the navigation equipment. Fibula navigation guides were created by the researcher and available during benchtop session B. As a replacement for navigation fibula guides participants were provided with 3D PDF digital models, and 2D drawing of the fibula and cutting guides with measurements to guide the fibula cuts during benchtop session B.

A digital 3D model of the fibula and cutting planes was created using Geomagic Control (3DSystems Inc., Rock Hill, South Carolina, United States of America). The 3D PDF model files was uploaded into an iPAD which the study participants could access and refer to throughout the session. The 3D PDF model file was used as a replacement for additive-manufactured reference models which are often included in the template guidance surgical toolkit provided to surgeons performing fibula mandible reconstruction surgery. Study participants could view and rotate the 3D PDF model files showing the fibula and resection planes, the presurgical mandible model, planned resected mandible model, and planned reconstructed mandible model. The 3D PDF model files provided were based on the preoperative virtual surgical plan created by the researcher in consultation with experienced head and neck surgeon, surgical design simulationist and prosthodontist.

A 2D drawing of the fibula model and fibula cutting planes was created as a visual tool to help guide the surgeon participants to complete the fibula cuts according to the virtual surgical plan (see fig. 11). The 2D drawing included lateral, anterior and medial views of the fibula and the fibula cutting planes with measurements. The participants could access the 2D drawing of the fibula and cutting planes at any point during benchtop session B.

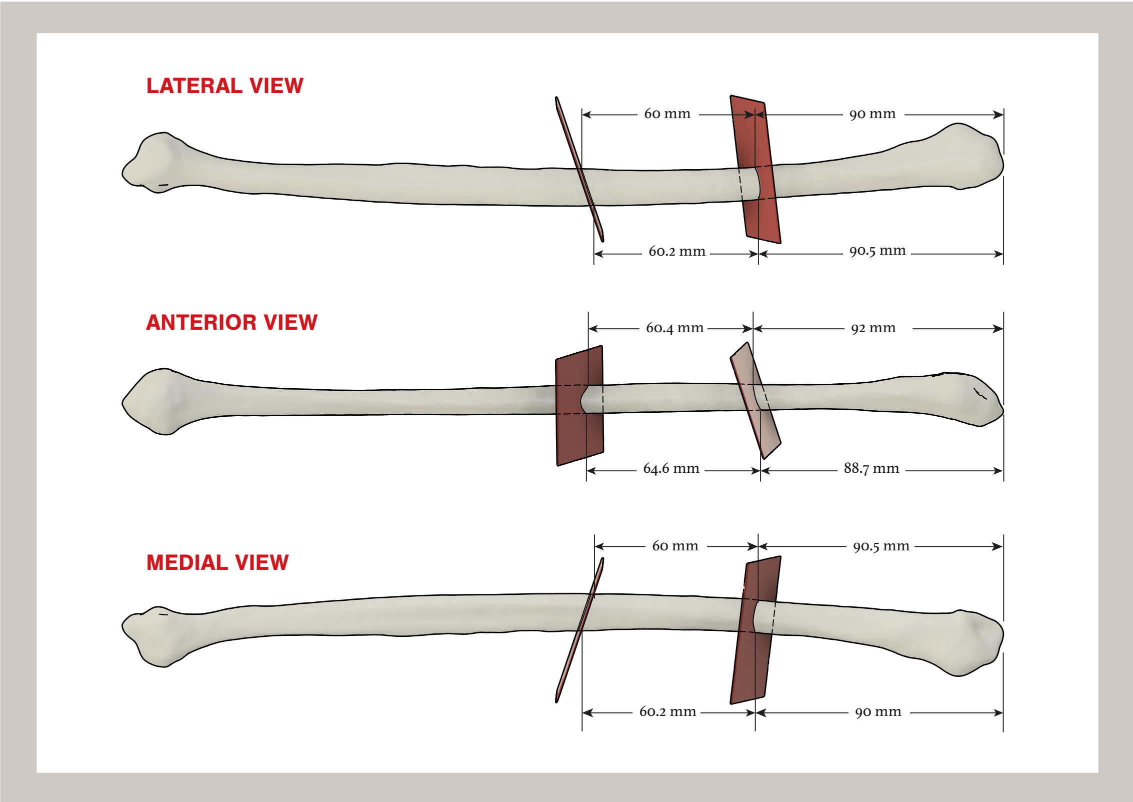


Fig 11. Image of the fibula model and planed cutting planes with measurements.

2.3.5.2 Patient Specific Mandible Cutting guide- Navigation

Three CT scans were taken of the skull model and mandible at the Misericordia Community Hospital. The CT scans of the additive-manufactured mandible and maxilla models were used to create the navigation resection and reconstruction guides used in benchtop session B. One CT scan was taken of a complete mandible model in occlusion. One CT scan was taken of a complete mandible model in open bite, a bite block was used to maintain the mandible in open bite. One CT scan was taken of the planned reconstructed mandible model in occlusion.

The CT scans of the maxilla and mandible were segmented using Materialise Mimics (Materialise Inc. Leuven, Belgium). Once the CT DICOM data was segmented, STL files of the mandible and maxilla were exported from Mimics. The STL files were imported into Geomagic Freeform (3DSystems Inc., Rock Hill, South Carolina, United States of America). Geomagic Freeform had been used to create the planned mandible reconstruction. The STL files of the mandible and maxilla in open bite and occlusion were imported into the same document as the planned mandible reconstruction. To ensure that the position of the cutting planes was consistent between the template surgical guides and the navigation surgical guides the mandible model and mandible cutting planes used to create the planed reconstruction model were duplicated and aligned with the navigation guide mandible/maxilla models in occlusion and open bite. Once the models were aligned the cutting planes used to create the planned reconstruction were correctly positioned relative to the navigation STL models. The cutting planes were imported into the Materialize Mimics (3DSystems Inc., Rock Hill, South Carolina, United States of America) files and their position relative to the DICOM data was verified. The CT scan data with the cutting guides was exported as DICOM data and saved onto a CD. The DICOM data with the cutting guides was uploaded into the Medtronic Fusion compact navigation system.

To ensure that the navigation resection and reconstruction guides were accurate and consistent with the planned mandible reconstruction. The navigation STL file with cutting planes was digitally compared to the planned reconstruction using Huasdorff surface distance tool in geomatic Control (3DSystems Inc., Rock Hill, South Carolina, United States of America). Below are images of the navigation resection guides in occlusion and open bite.

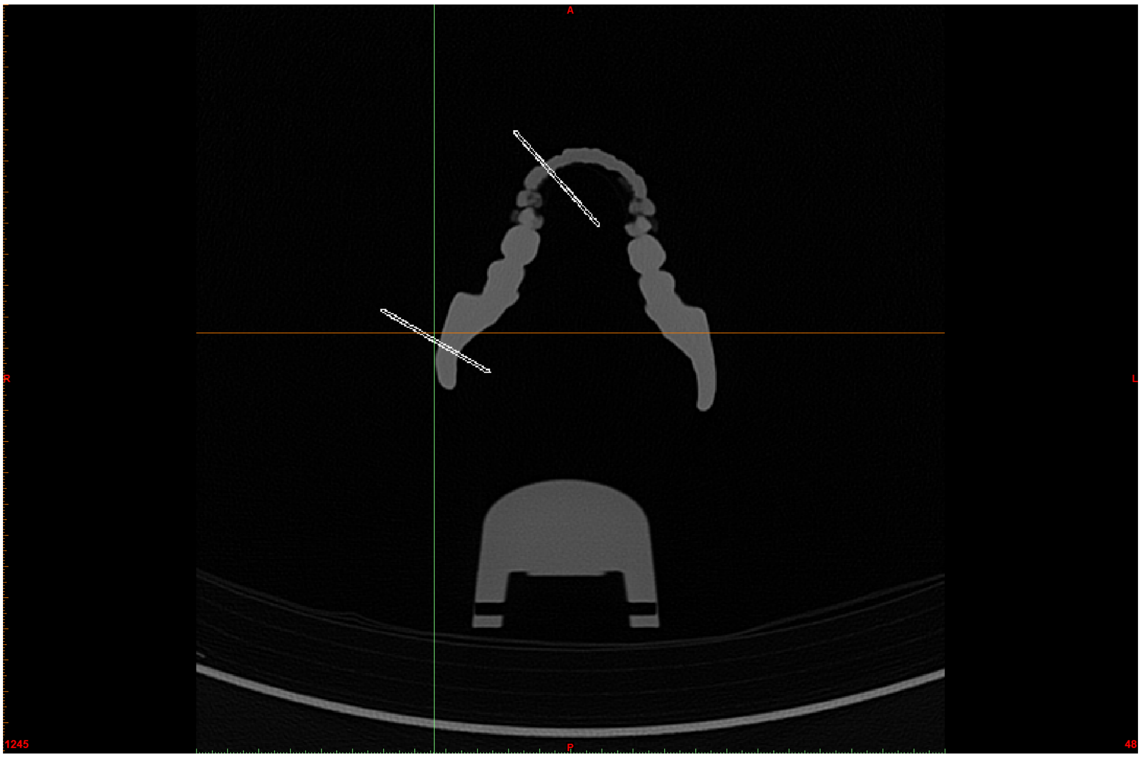


Fig 12. Image of occlusion mandible resection navigation guide.

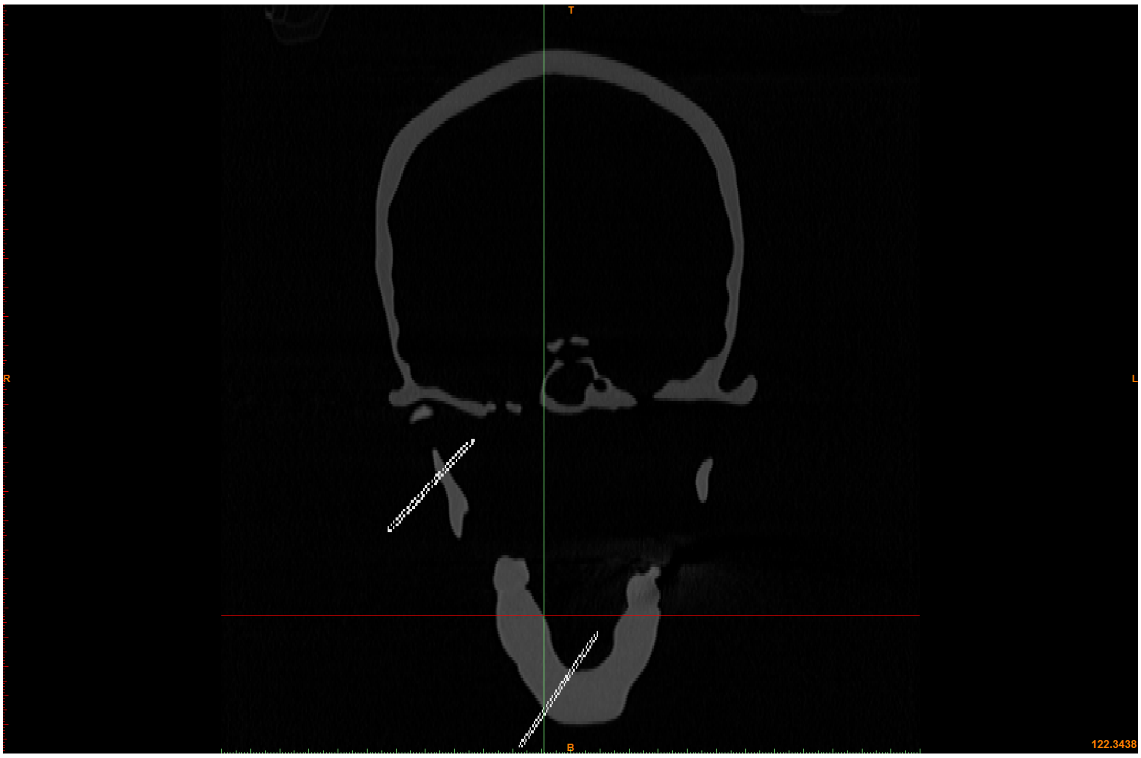


Fig 13. Image of open bite mandible resection guide.

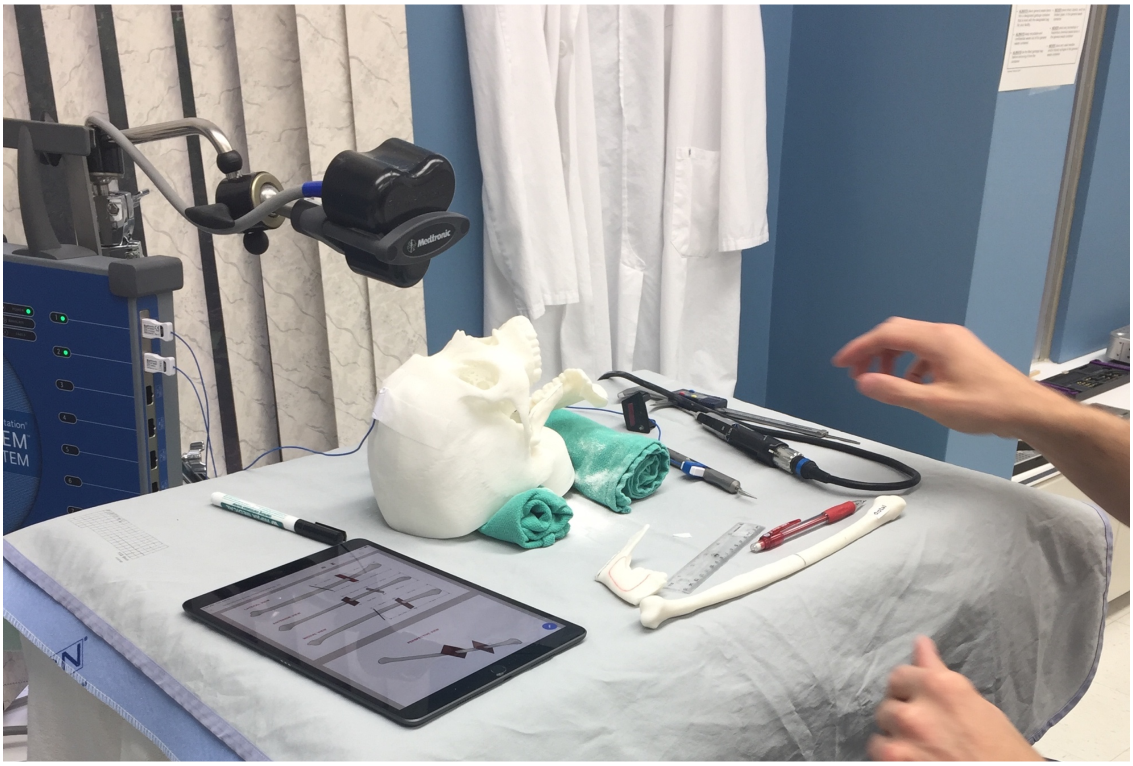


Fig 14. Experimental set-up benchtop session B, Navigation based surgical guidance.

The materials and equipment provided to the surgeon participants to resect and reconstruct the mandible using the fibula in benchtop session B included:

Models

- Additive-manufactured fibula
- Additive-manufactured mandible
- Additive-manufactured skull with base

Equipment

- Medtronic Fusion compact™ ENT Navigation system
- Medtronic AxiEM™ non-invasive patient tracker
- Medtronic ENT registration probe
- Medtronic ENT Straight probe
- Medtronic ENT instrument tracker
- Bite Block
- Fibula Holder
- Synthes electric pen tool and foot pedal
- Synthes reciprocal saw attachment
- Synthes reciprocal saw blade
- Synthes drill attachment

- Synthes drill bit
- Synthes 2.0mm Mandible Trauma kit
- iPad
- Cellphone or other device to take pictures and record video during benchtop session
- Digital stopwatch
- Eye protection
- Lab coat
- Label maker
- Transparent ruler
- Calipers
- Marker, pen, pencil
- Tape
- Scissors
- Cloth drops to cover table
- Green surgical towels

Materials

- Digital surgical plan to simulate planning session
- Edited DICOM data uploaded into the Medtronic fusion compact system

2.3.5.4 Patient specific template based surgical guidance design

Additive-manufactured surgical guides and templates used in benchtop session C were designed according to iRSM standards and protocol to simulate a realistic clinical toolkit typically provided to a surgical team by iRSM. The cutting, drilling, and reconstruction templates were developed by the researcher with assistance from a head and neck surgeon, maxillofacial prosthodontist and a surgical design simulationist. The surgeon, prosthodontist and surgical design simulationist have experience creating and using additive-manufactured surgical guides and templates for fibula mandible reconstruction surgery.

The additive-manufactured mandible fixation frame, and anterior and posterior mandible cutting guides were designed by the researcher to assist the participating head and neck surgeons accurately resect the mandible in benchtop session C. The mandible fixation frame and cutting guides were designed based on the planned reconstruction. The fibula cutting guide was designed based on the mandible cutting guides. The fibula cutting guide was designed to create a fibula segment that would match the mandible resection according to the mandible reconstruction plan.

Fig 15. Mandible fixation frame attached to a complete mandible model.

Fig 16. Mandible fixation frame attached to a reconstructed mandible model.

Fig 17. Mandible fixation frame and cutting guides attached to a complete mandible model.

Fig 18. Mandible Fixation frame and cutting guides attached to a reconstructed mandible model.

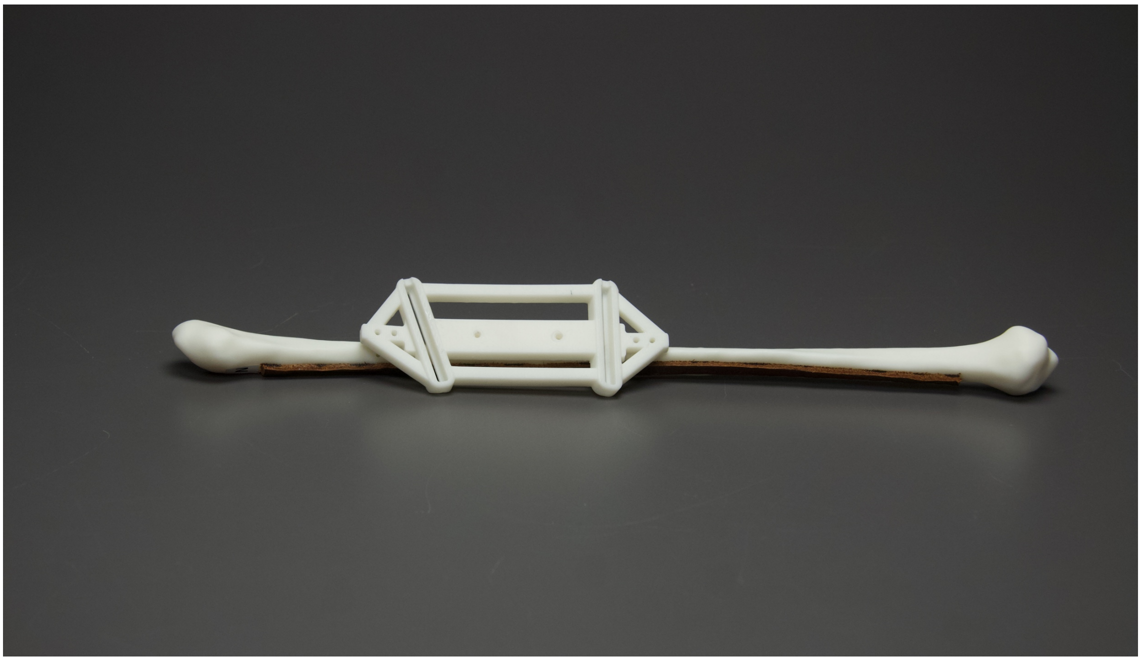


Fig 19. Fibula cutting guide attached to a complete fibula model.

Fig 20. Transfer template attached to a reconstructed mandible model.

Fig21. Additive-manufactured reference models; complete, resected and reconstructed mandibles.

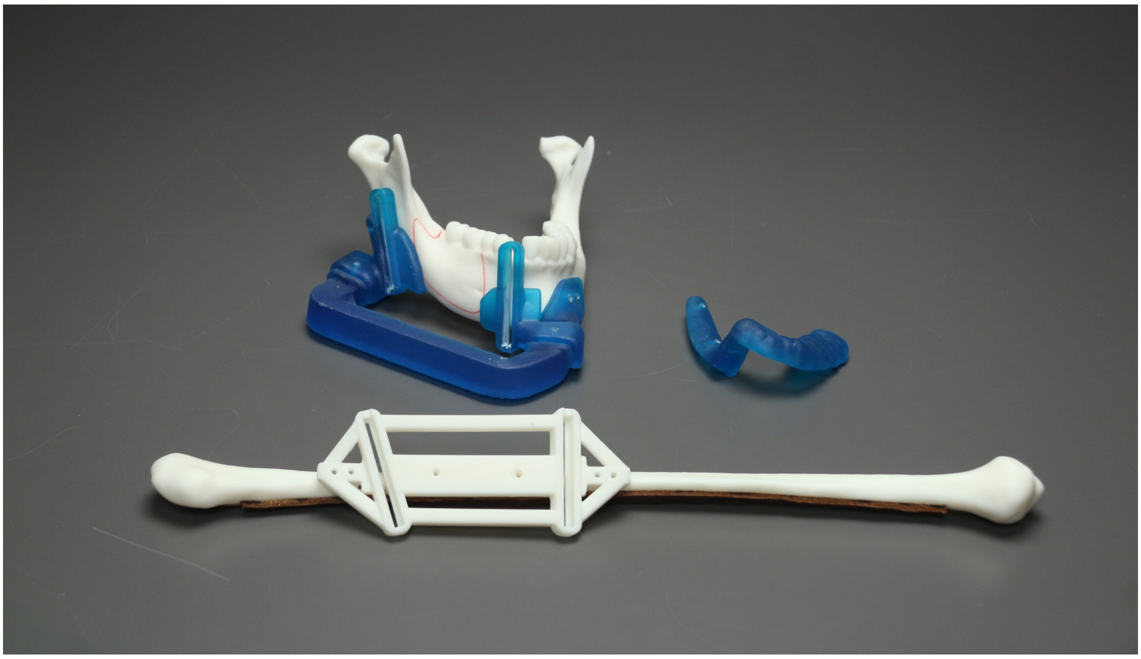


Fig 22. Surgical cutting guides and templates used during benchtop session C.

Fig 23. Experimental set-up benchtop session C, template based surgical guidance.

The surgical toolkit provided to the surgeon participants to resect and reconstruct the mandible using the fibula in benchtop session C included:

Models

- Additive-manufactured fibula
- Additive-manufactured mandible
- Additive-manufactured skull with base
- Additive-manufactured mandible fixation frame
- Additive-manufactured posterior mandible cutting guide
- Additive-manufactured anterior mandible cutting guide
- Additive-manufactured fibula cutting guide
- Additive-manufactured transfer template
- Preoperative anatomical model
- Resected anatomical model
- Reconstructed anatomical model

Equipment

- 40mm cutting guide insert
- Fibula Holder
- Synthes electric pen tool and foot pedal
- Synthes reciprocal saw attachment

- Synthes reciprocal saw blade
- Synthes drill attachment
- Synthes drill bit
- Synthes 2.0mm Mandible Trauma kit
- iPad
- Cellphone or other device to take pictures and record video during benchtop session
- Digital stopwatch
- Eye protection
- Lab coat
- Label maker
- Transparent ruler
- Calipers
- Marker, pen, pencil
- Tape
- Scissors
- Cloth drops to cover table
- Green surgical towels

Materials

- Digital surgical plan to simulate planning session

2.3.6 Participants

Study participants were purposively sampled from among head and neck surgeons practising in Edmonton, Alberta. The participants were trained in using a Synthes (DePuy Synthes Inc., Raynham, Massachusetts, United States of America) e-pen surgical saw and the haptic system was described to them. The participants all had surgical experience. Individuals who participated in this study were required to have very specific expertise in head and neck surgery there is a very small population of head and neck surgeons qualified to participate in the proposed study; for this reason, expert sampling was used to recruit participants. Head and neck surgeons in the Edmonton Alberta area were contacted by the researcher, the surgeons were given information about the study and were asked to sign an informed consent form before proceeding with the study. The researcher scheduled dates and times for the participants to complete three benchtop sessions. It was not possible to schedule participants to complete each benchtop session at the same time and day of the week to eliminate the possibility of outcome variability due to time. Due to the logistical challenges of scheduling benchtop sessions with busy surgeons it was not feasible. Instead, benchtop sessions were scheduled at the participants' convenience.

Inclusion criteria for participating surgeons was as follows:

1. Practices in Edmonton, Alberta Canada
2. Participant has completed 12 weeks of senior rotations in head and neck surgery
3. Participant has experience using image guided surgical navigation
4. Participant has experience performing Fibula free flap mandibular reconstructions

Exclusion criteria for participating surgeons was as follows:

1. Participant does not practice in Edmonton Alberta, Canada
2. Participant has not completed 12 weeks of senior rotation in head and neck surgery
3. Participant does not have experience using image guided surgical navigation
4. Participant does not have experience performing fibula free flap mandibular reconstructions

Seven head and neck surgeons participated in the present study. Three of seven participants were experienced head and neck surgeons and four of seven participants were head and neck surgeon trainees. Participants were assigned a random number which was used by the researcher to identify the participant. The level of experience of the surgeon participants was as follows:

Participant 035	Experienced head and neck surgeon
Participant 253	Trainee head and neck surgeon
Participant 303	Experienced head and neck surgeon
Participant 447	Trainee head and neck surgeon
Participant 747	Experienced head and neck surgeon
Participant 790	Trainee head and neck surgeon
Participant 853	Trainee head and neck surgeon

Table 1. Level of experience of surgeon participants

Participant Withdrawal

Participating surgeons were informed that they could choose to withdraw from the study at any time before conclusion of the data collection phase of the study. After completion of data collection, data was de-identified and the participants could not withdraw from the study.

Consent

Written informed consent was obtained from each participating surgeon prior to their involvement in the study in line with the Declaration of Helsinki. The experimental procedure was approved by the University of Alberta Health Research Ethics Board under study ID Pro0008298.

2.4 Experiments

Surgeons participants were asked to complete three benchtop sessions followed by a convergent interview. The participants were asked to complete three benchtop sessions. In session A, participants were asked to complete a traditional free-hand reconstruction of the prototyped mandible using an additive-manufactured fibula. In Session B, the participants were asked to reconstruct the mandible model using a fibula model using a preoperatively virtually designed surgical plan and digital computed-tomography navigation guides. In session C, the participants were asked to reconstruct the same standardized additive-manufactured mandible using a preoperatively virtually designed surgical plan, and additive-manufactured surgical cutting guides.

Participants completed session A, B and C in the Interfacial Biomechanical Laboratory (IBL) at iRSM or at the Head and Neck Simulation Laboratory in the Clinical Sciences Building at the University of Alberta. At the beginning of each session participants were given instructions and told objectives of the session (Appendix F, G and H). The researcher reviewed the steps of the procedure and walked through a mock planning session with the researcher.

The researcher supervised the benchtop session and was available to answer questions and assist the participant. Once each surgeon completed the reconstruction, the finalized reconstructed model was labelled with the participants ID code and the session number (A,B or C). The models were the locked in a cupboard in the interfacial biomechanics laboratory (IBL) at iRSM.

2.5 Outcome Measures

2.5.1 Time to complete task

Each participating surgeon was timed from the beginning to the end of benchtop sessions A, B, and C. The purpose of timing the duration of each session was to assess and compare the amount of time it took to complete mandible reconstruction using three different methods of guided surgery. The researcher began timing the session when the participating surgeon picked up the first surgical instrument and stopped when the surgeon verbally informed the researcher that they had completed the task. A stopwatch was used to time the duration of each benchtop session.

Recording sheets used by the researcher to record time taken to complete each benchtop session and manual measurements of the reconstructed models were kept in a locked cabinet in the IBL at Misericordia Community Hospital, in the study binder. Participants names or other identifying information was not listed on the recording sheets.

2.5.2 Model Measures

2.5.2.1 Manual measures

The accuracy of the three reconstruction techniques were evaluated by taking manual measurements of the reconstructed models using digital calipers and comparing the reconstructed models with a control model. Manual measurements of the physically reconstructed models were taken to measure: fibula segment length, anterior inferior border distance, posterior inferior border distance, intersegment distance, and number of fibula segments.

2.5.2.2 Digital measures

Reconstructed models were collected and securely stored at the Interfacial Biomechanics Laboratory in the Misericordia Community Hospital following each benchtop session. Following each benchtop session, the researcher scanned all models that were reconstructed using the shapegrabber Ai310 3D surface scanner (Shapegrabber Inc., Ottawa, Ontario, Canada) available through iRSM at the Misericordia community hospital in Edmonton, Alberta. Model scanning calibration protocol was established and followed to ensure that each model was scanned consistently. The researcher transferred the data from the shapegrabber software into the software program Geomagic Control (3DSystems Inc., Rock Hill, South Carolina, United States of America). Geomagic Control was selected due to its effective registration tools. Geomagic control was used to process the scans of the reconstructed models into a binary STL file format and register the reconstructed models created by the participants to the optimal mandible reconstruction. The researcher was interested in aligning the optimal mandible reconstruction to the reconstruction of Sessions A, B, and C in order to assess the accuracy of the reconstructions. The researcher identified three registration points of common geometry on both models. The registration points were selected on the left and right condyles and the left coronoid process- as these regions of the models were unaffected by the surgical procedure and remained consistent. The software then automatically aligned the two models using a global alignment tool.

Binary STL files of the scanned mandible reconstructions were transferred into the software program Rhinoceros 5.0 (Robert McNeel and Associates Inc., Seattle, Washington, United States of America). Rhinoceros was chosen by the researcher due to its accurate measurement tools. Measurement tools were used to measure right coronal angle, the left coronal angle, the right axial mandibular angle, the left axial mandibular angle, the right sagittal mandibular angle, the left sagittal mandibular angle, the condyle distance, the gonion distance. Variance between the optimal reconstruction model and the actual reconstructions were analyzed to evaluate the accuracy of the reconstruction created by the participating surgeons. Scanned digital models of the reconstructed mandibles were kept on a server behind an AHS firewall and an encrypted external hard drive stored in a locked cabinet at in the IBL. The saved files have been de-identified.

2.5.3 Number of Surgical Plan Corrections

The researcher recorded the number of times a participating surgeon revised or corrected the surgical plan during a mandible fibula reconstruction procedure. The number of surgical plan corrections were tallied by the researcher on the benchtop session recording sheets. Corrections included adjusting the angle for a better fit between the native mandible and fibula segment or two fibula segments, adjusting length of the fibula segment, cutting a new fibula segment, cutting more material off of the mandible for a better fit. Benchtop session recording sheets were de-identified and securely stored in a research binder in a locked cabinet in the IBL laboratory at iRSM.

2.6 Results

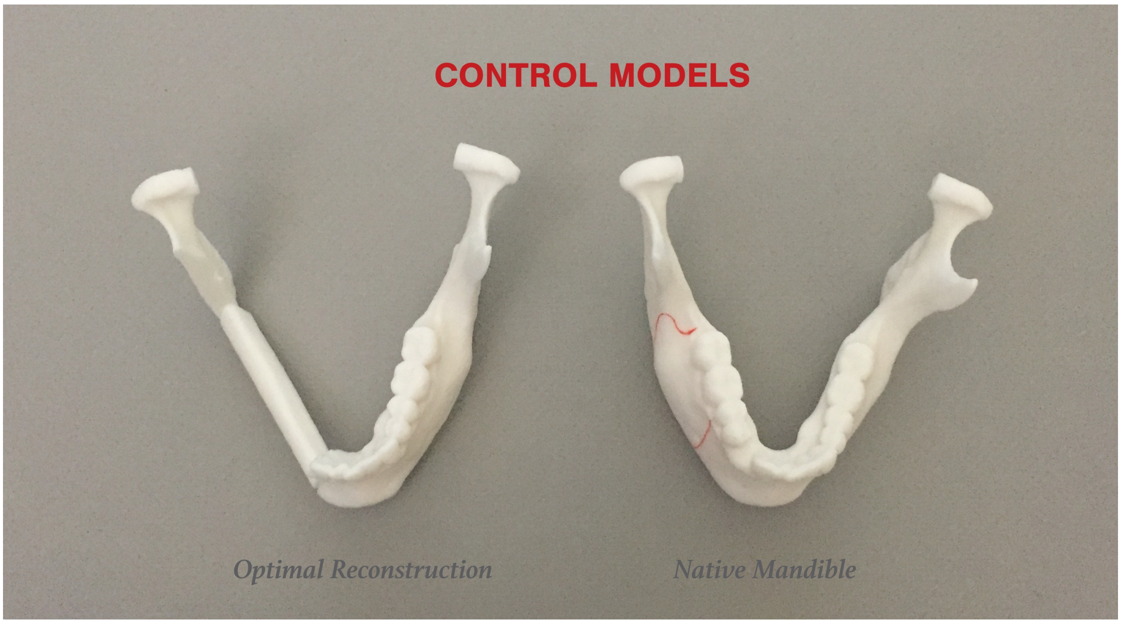


Fig 24. Control mandibles: Left image is the optimal reconstruction and the right is the native mandible with the ‘tumour’ indicated in red.

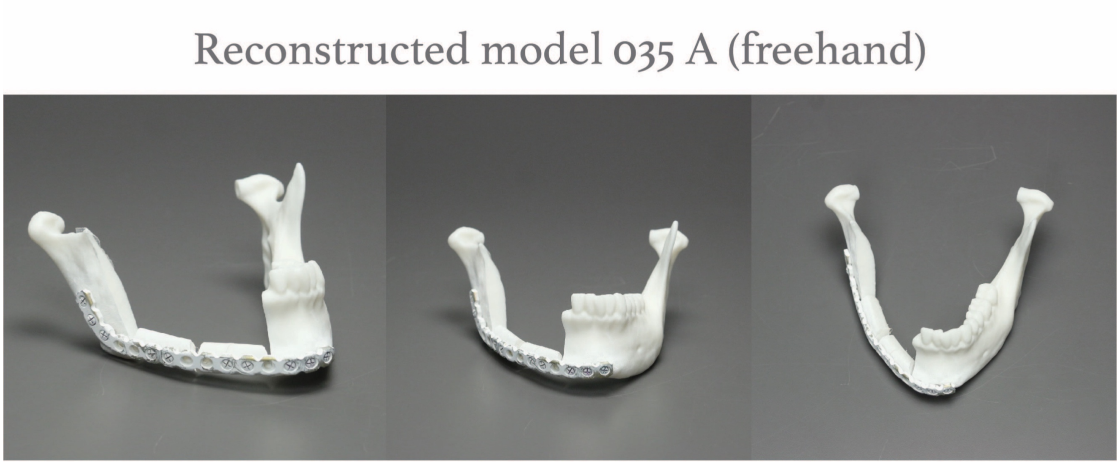


Fig 25. Participant 035 session A (freehand) reconstructed mandible model

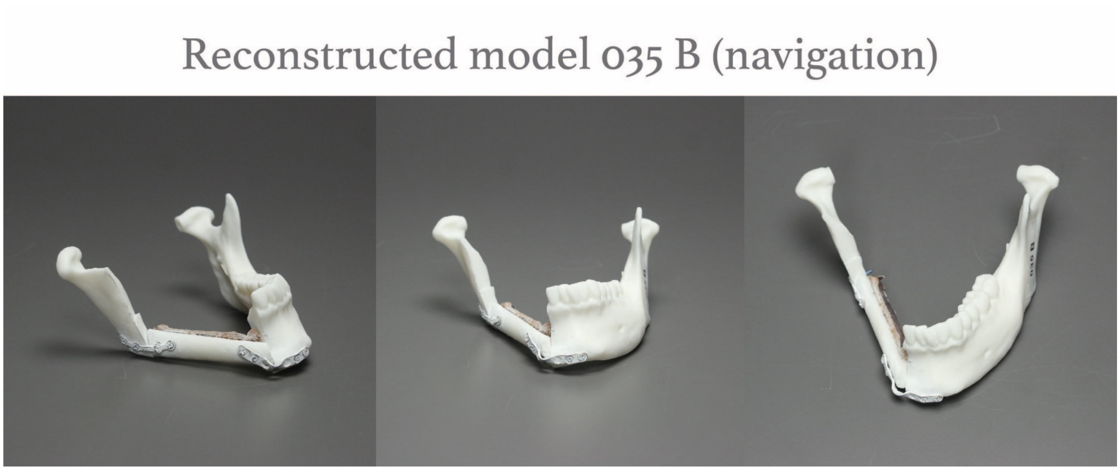


Fig 26. Participant 035 session B (navigation) reconstructed mandible model

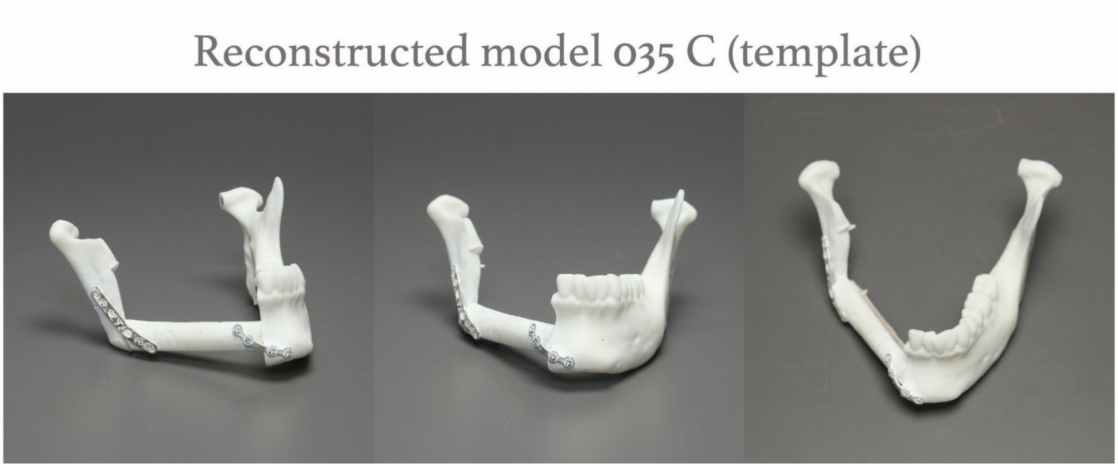


Fig 27. Participant 035 session B (template) reconstructed mandible model

Fig 28. Participant 253 session A (freehand) reconstructed mandible model

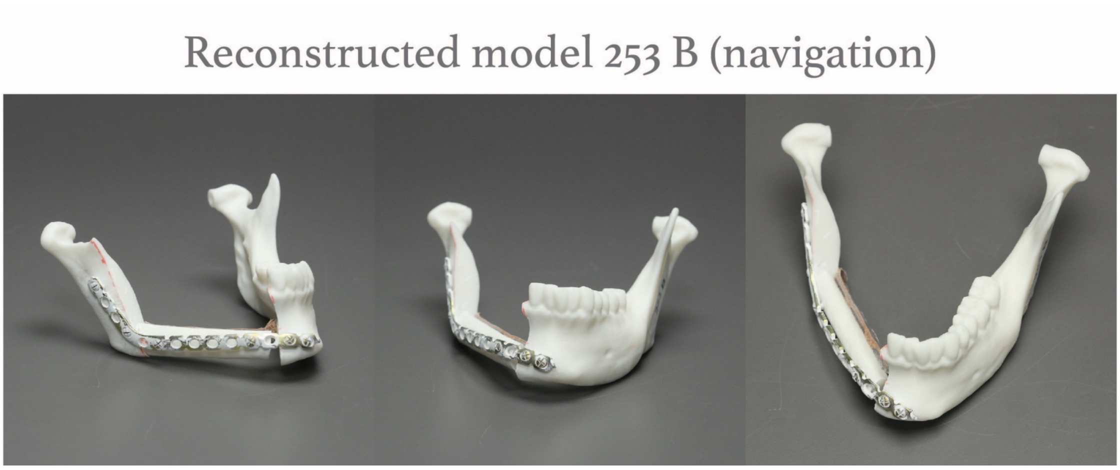


Fig 29. Participant 253 session B (navigation) reconstructed mandible model

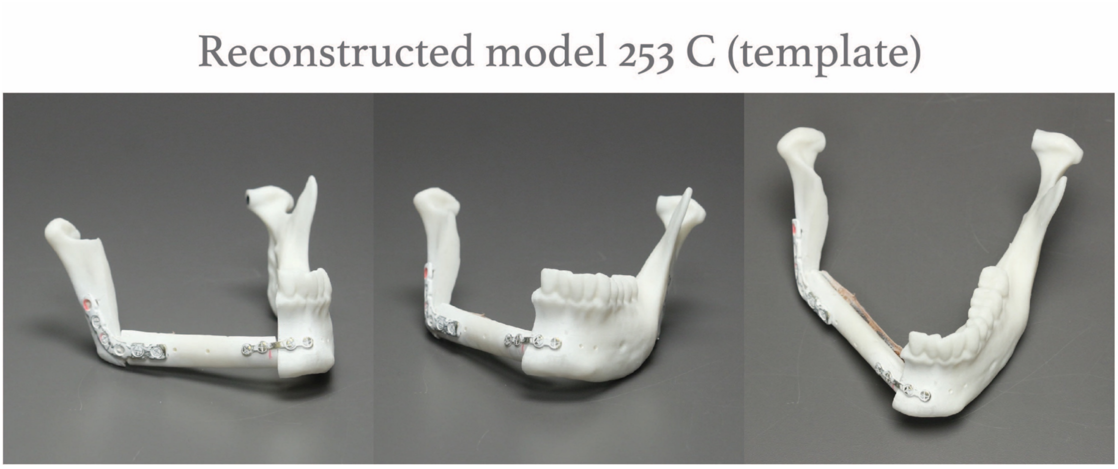


Fig 30. Participant 253 session C (template) reconstructed mandible model

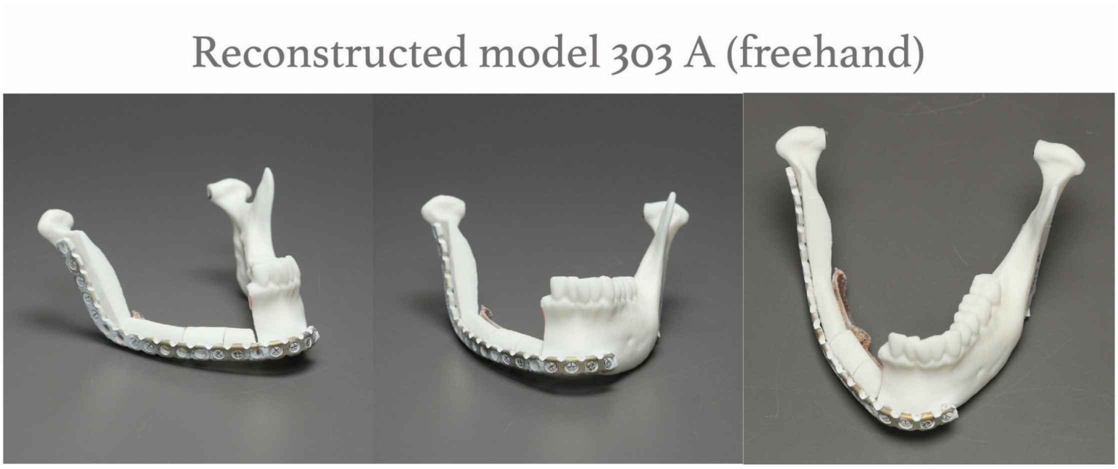


Fig 31. Participant 303 session A (freehand) reconstructed mandible model

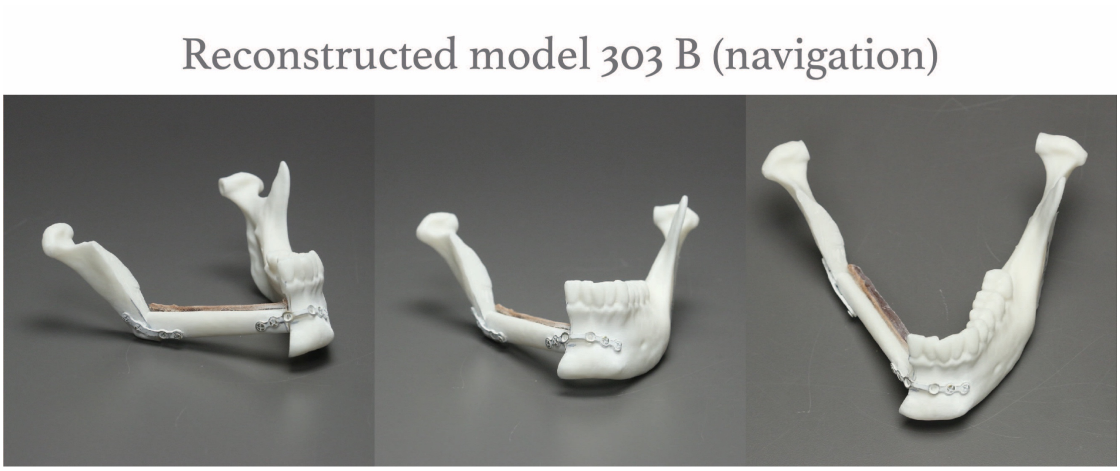


Fig 32. Participant 303 session B (navigation) reconstructed mandible model

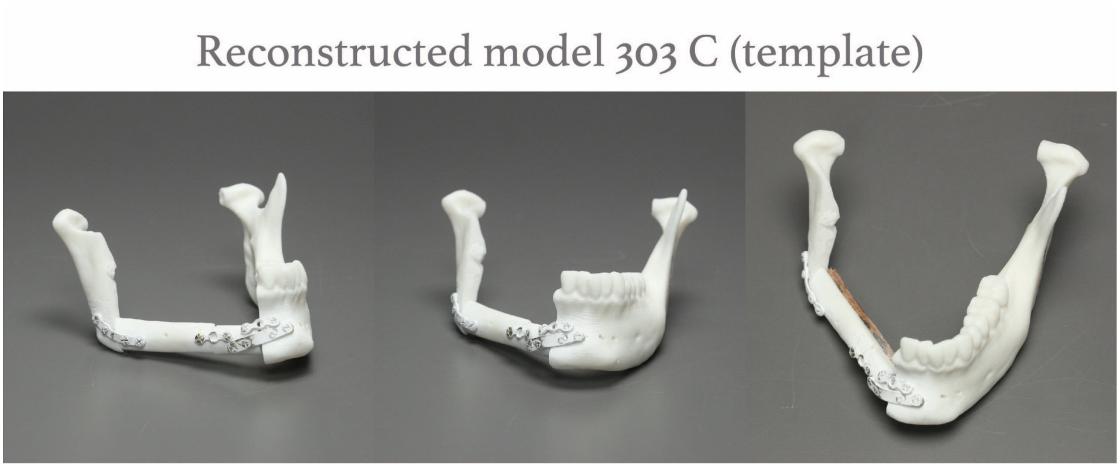


Fig 33. Participant 303 session C (template) reconstructed mandible model

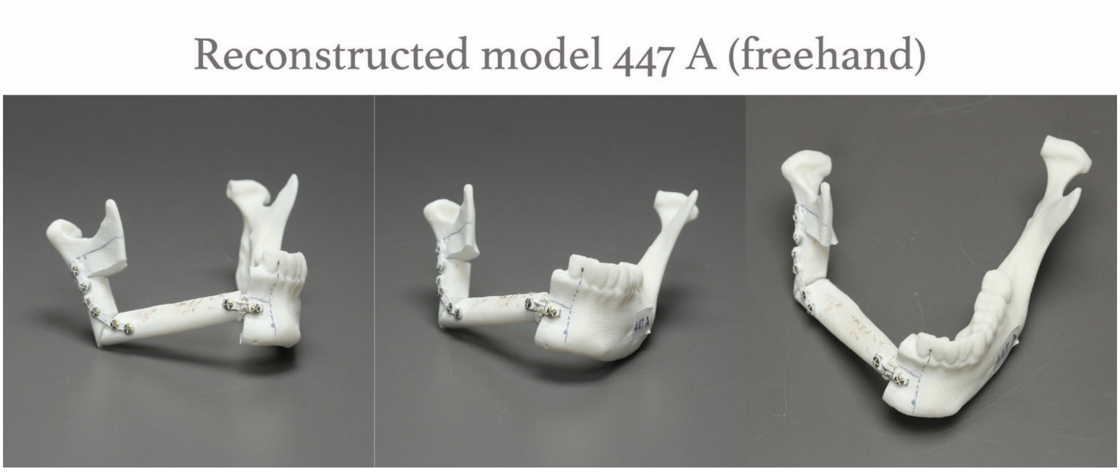


Fig 34. Participant 447 session A (freehand) reconstructed mandible model

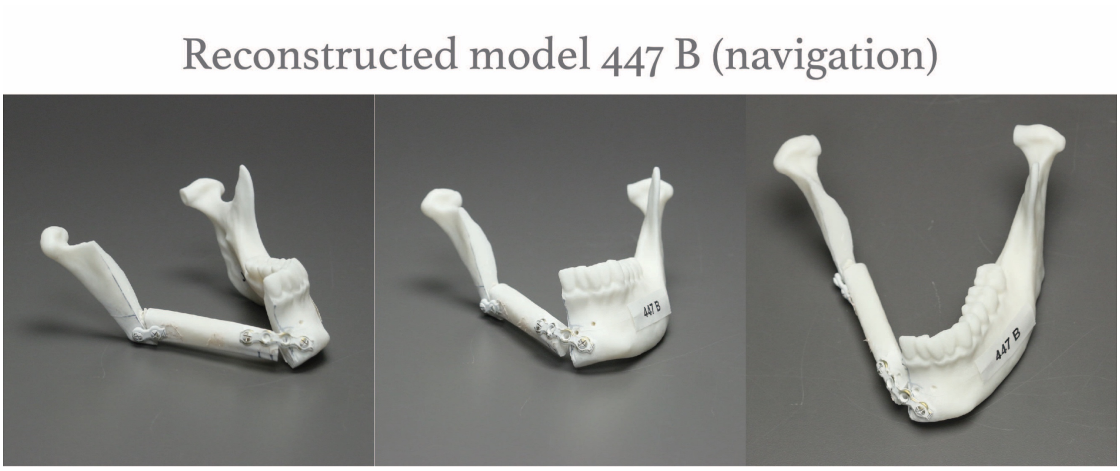


Fig 35. Participant 447 session B (navigation) reconstructed mandible model

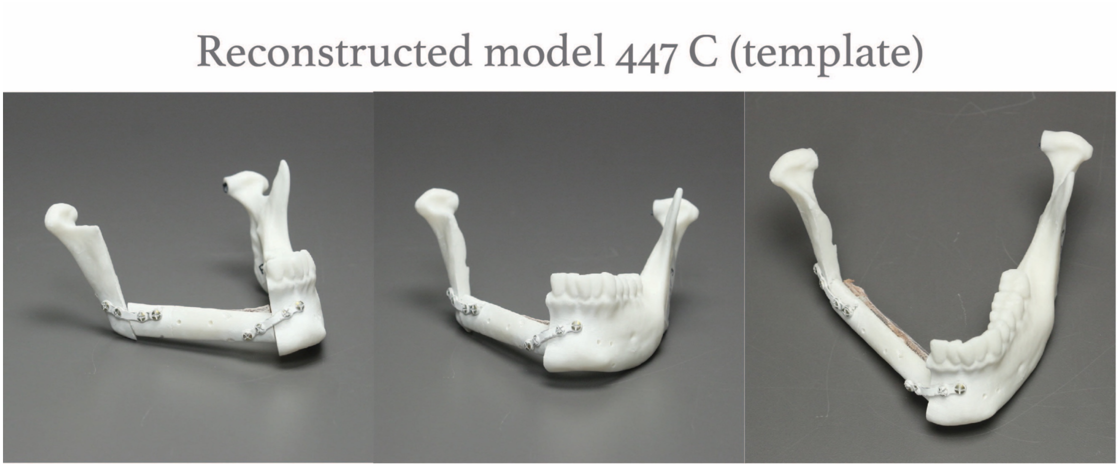


Fig 36. Participant 447 session C (template) reconstructed mandible model

Fig 37. Participant 747 session A (freehand) reconstructed mandible model

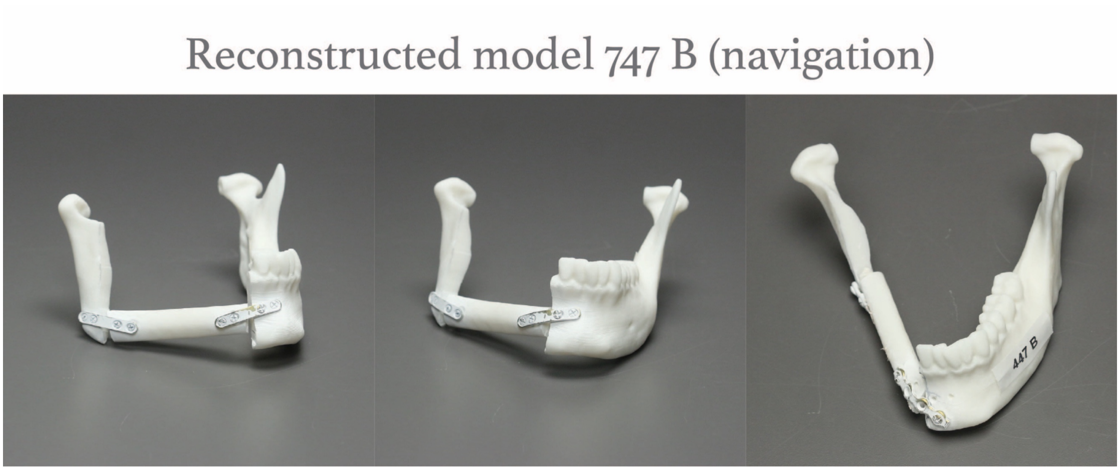


Fig 38. Participant 747 session B (navigation) reconstructed mandible model

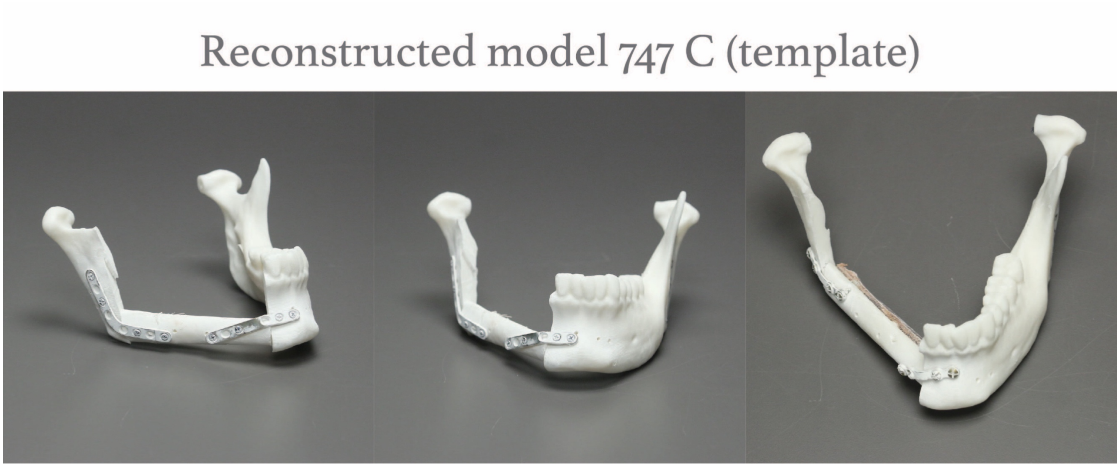


Fig 39. Participant 747 session C (template) reconstructed mandible model

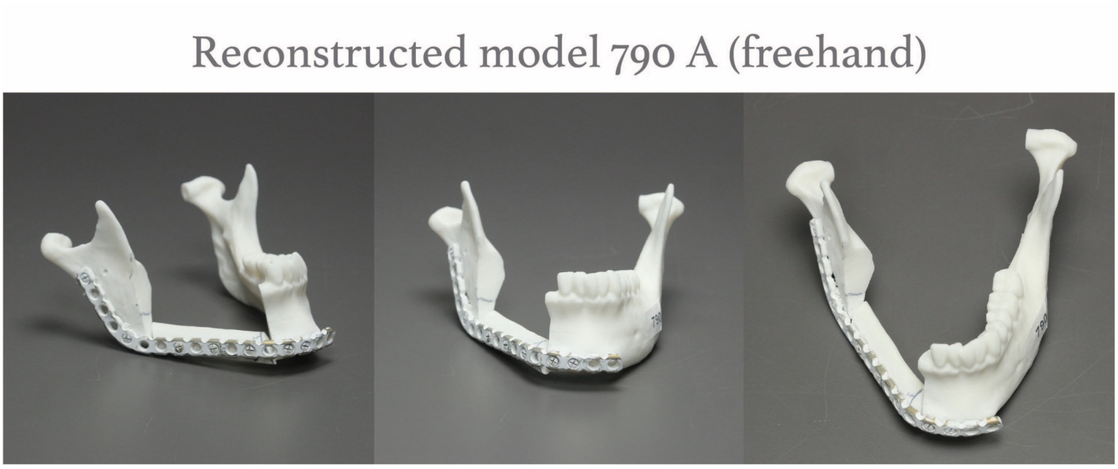


Fig 40. Participant 790 session A (freehand) reconstructed mandible model

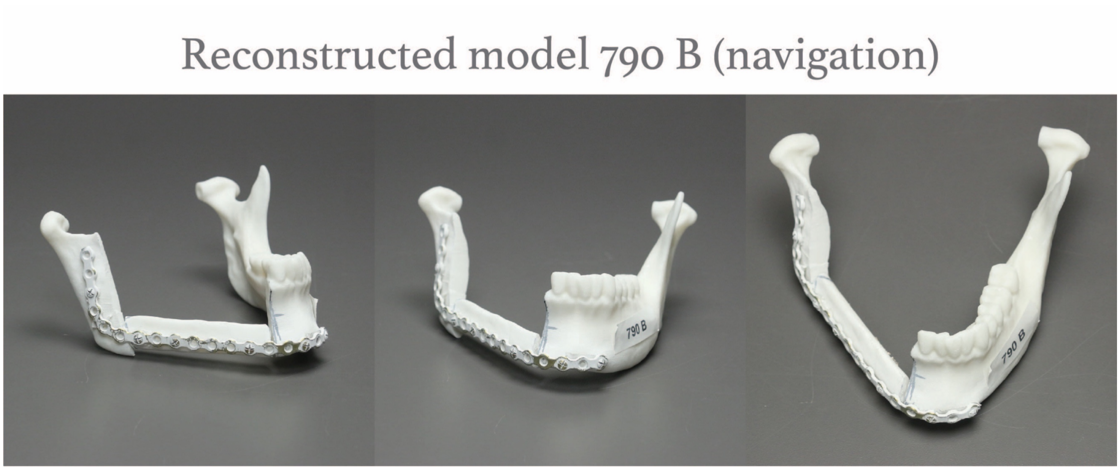


Fig 41. Participant 790 session B (navigation) reconstructed mandible model

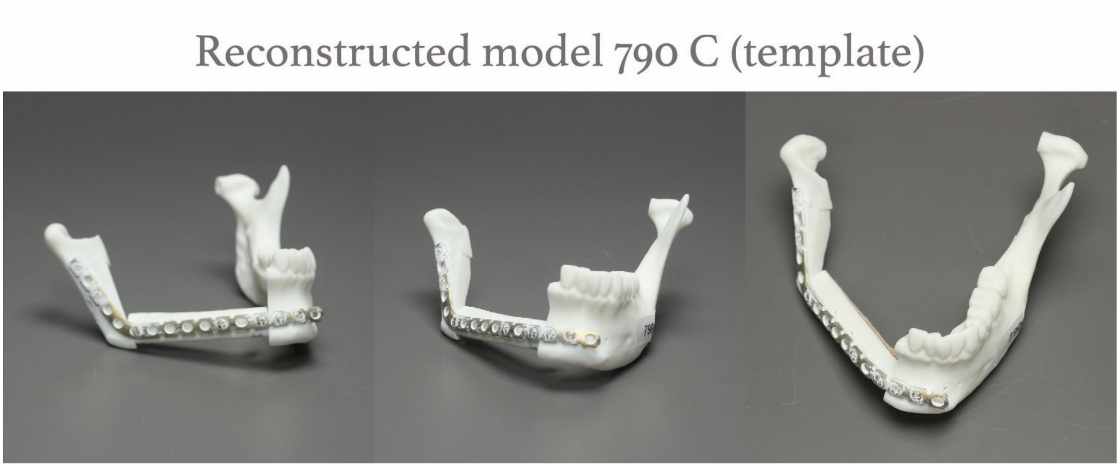


Fig 42. Participant 790 session C (template) reconstructed mandible model

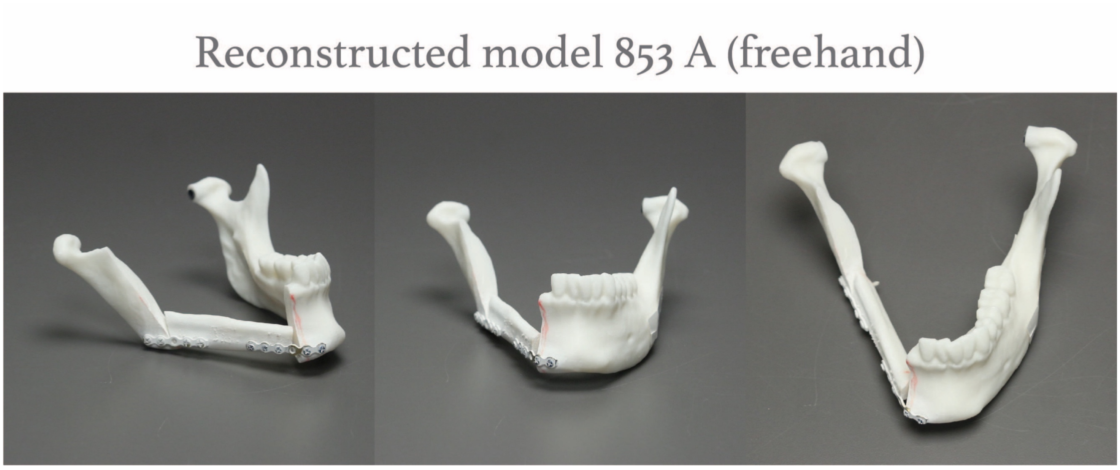


Fig 43. Participant 853 session A (freehand) reconstructed mandible model

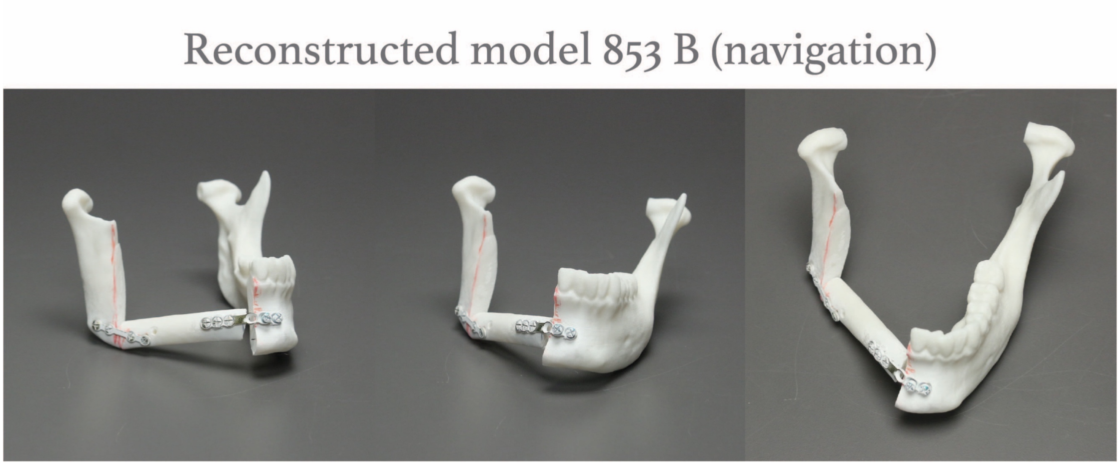


Fig 44. Participant 853 session B (navigation) reconstructed mandible model

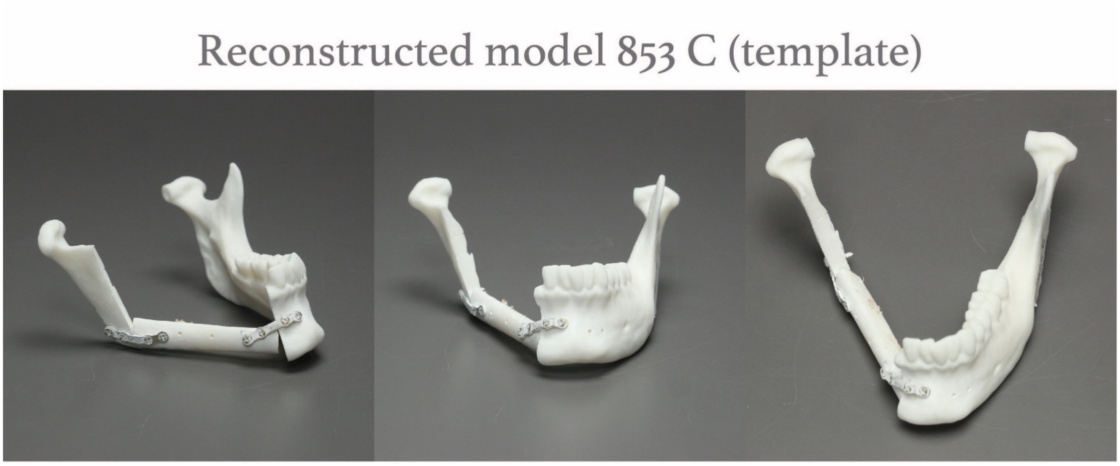


Fig 45. Participant 853 session C (template) reconstructed mandible model

2.6.1 Hausdorff measurements

Hausdorff surface distance maps and measurements are used to compare two digital models to each other. Hausdorff surface distance is based on the average linear distance between two digital models (Tarsitano et al., 2018). An STL file of the planned reconstruction model and an STL file of the actual reconstructed models completed by study participants were compared. The two STL files were aligned using Geomatics Control software (3DSystems Inc., Rock Hill, South Carolina, United States of America) the STL meshes were aligned using the manual and global registration tools. Points were selected on the left and right condyles and the left coronoid process of the planned and actual STL files to align the geometry. Following manual registration, the global registration tool was used to further refine the alignment of the two

STL meshes for a closer match. The compare 3D tool was used to compare the planned and actual reconstructions using Hausdorff surface distances. The report tool was used to generate a detailed report which included coloured surface distance images of the model which visually represent the accuracy of the actual reconstruction. In the image the grey areas indicate where there is no overlapping geometry between the planned and actual STL models. The Geomagic Control (3DSystems Inc., Rock Hill, South Carolina, United States of America) report tool does not calculate the Hausdorff surface distances where there is no overlapping geometry. The grey areas of the images represent areas where there is no overlapping geometry between the planned and actual reconstruction models. The coloured Hausdorff surface distance images created in Geomagic Control (3DSystems Inc., Rock Hill, South Carolina, United States of America) are helpful to visualize the deviation between the planed and actual mandible reconstruction models. However, the Hausdorff surface distance data calculated is not a reliable measure to compare the actual and planned mandible reconstruction models.

Once aligned the mesh models were exported and imported into Meshlab, an open source mesh processing tool (Meshlab; Visual Computing Lab, Pisa, Italy). The actual reconstruction model was compared to the planned reconstruction model using the Hausdorff distance function. The maximum and mean Hausdorff surface distances were reported. In the journal article titled "Accuracy of CAD/CAM mandibular reconstruction: A three-dimensional, fully virtual outcome evaluation method" Tarsitano et al. describe a method to evaluate the accuracy of fibula mandible reconstructions digitally (Tarsitano et al., 2018). The evaluation methods outlined by Tarsitano et al. were followed to generate the following images and data.

2.6.1.1 Reconstructed Mandible Hausdorff Surface Distance

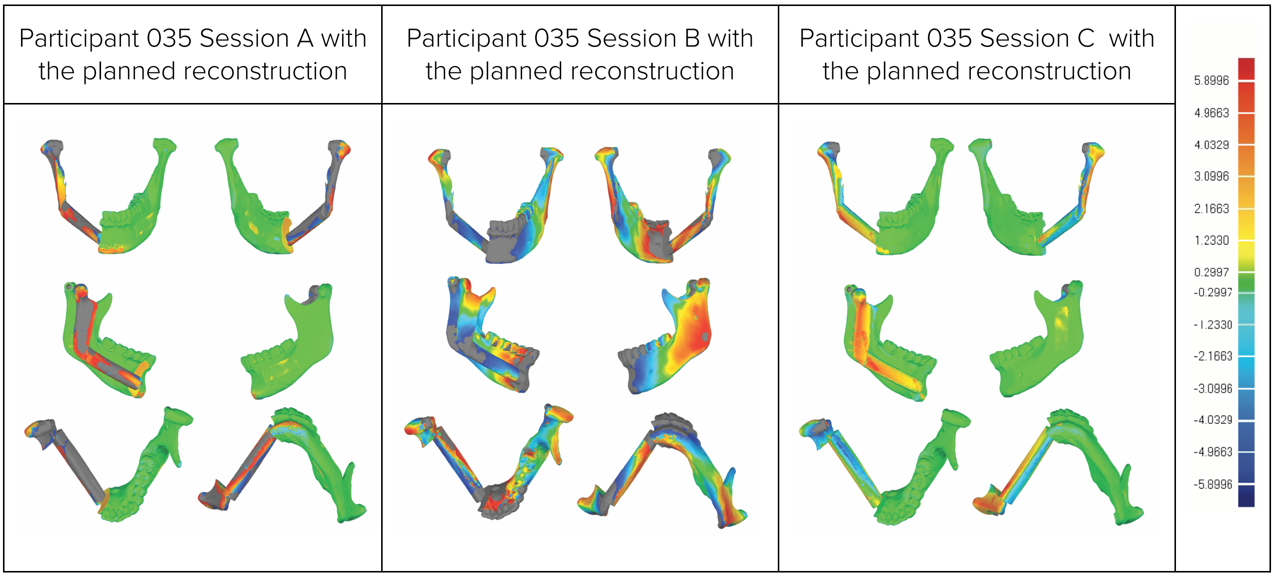


Fig 46. Participant 035 reconstructions completed for session A, B, and C digitally superimposed over the planned reconstruction. Actual reconstructions completed by participant 035 are - compared to the planned reconstruction using a coloured Hausdorff surface distance 'heat map'.

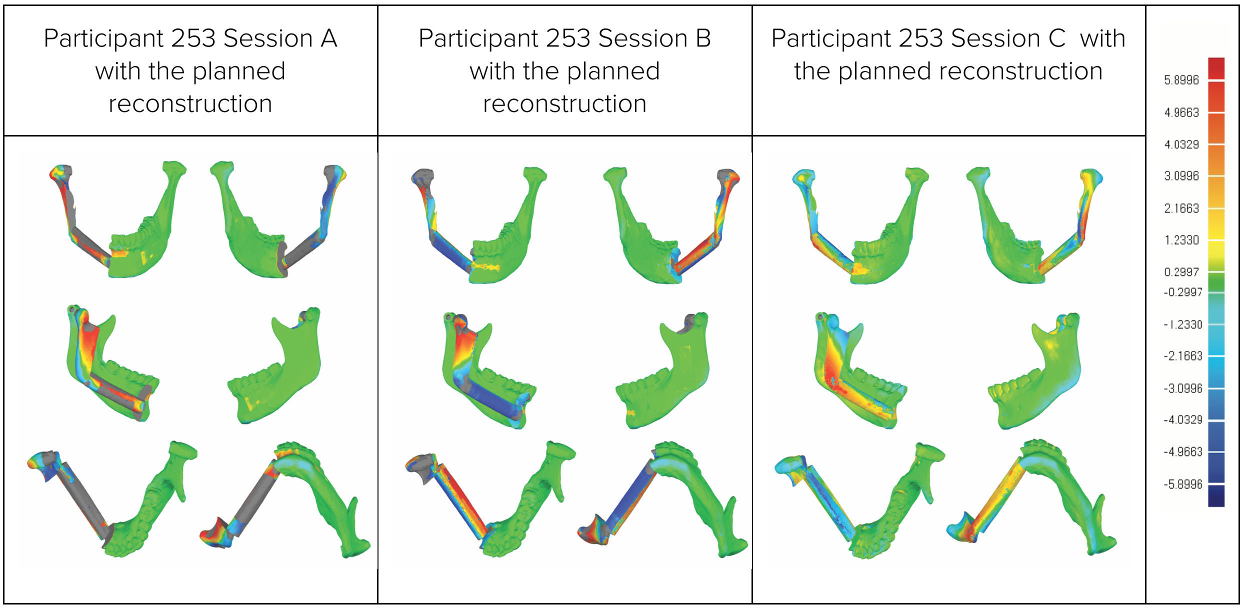


Fig 47. Participant 253 reconstructions completed for session A, B, and C digitally superimposed over the planned reconstruction. Actual reconstructions completed by participant 253 are compared to the planned reconstruction using a coloured Hausdorff surface distance 'heat map'.

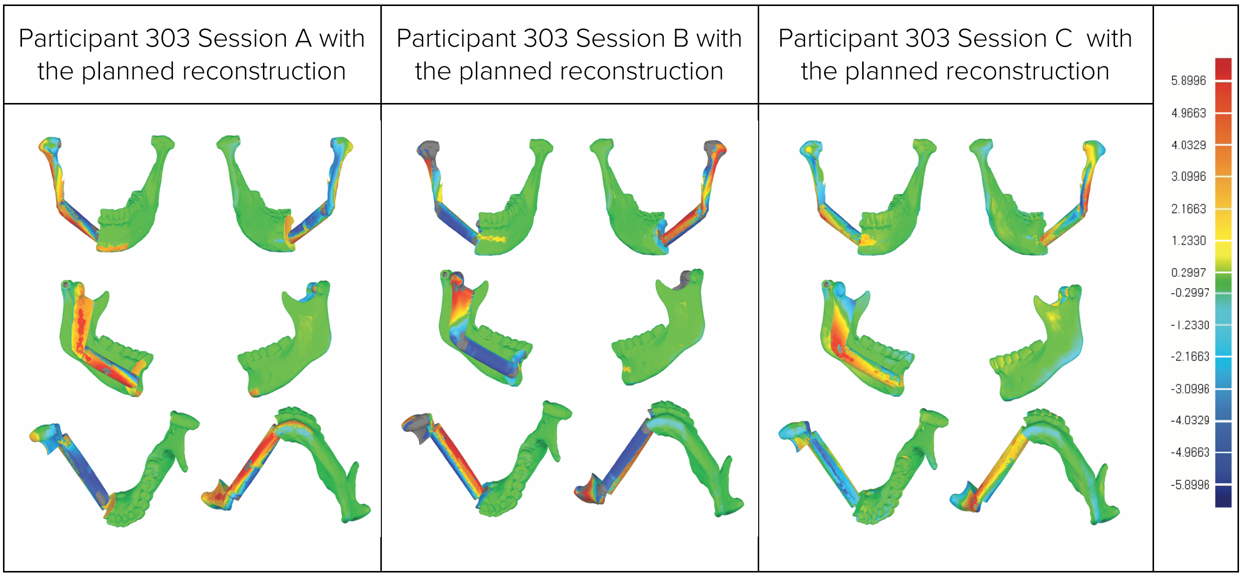


Fig 48. Participant 303 reconstructions completed for session A, B, and C digitally superimposed over the planned reconstruction. Actual reconstructions completed by participant 303 are compared to the planned reconstruction using a coloured Hausdorff surface distance 'heat map'.

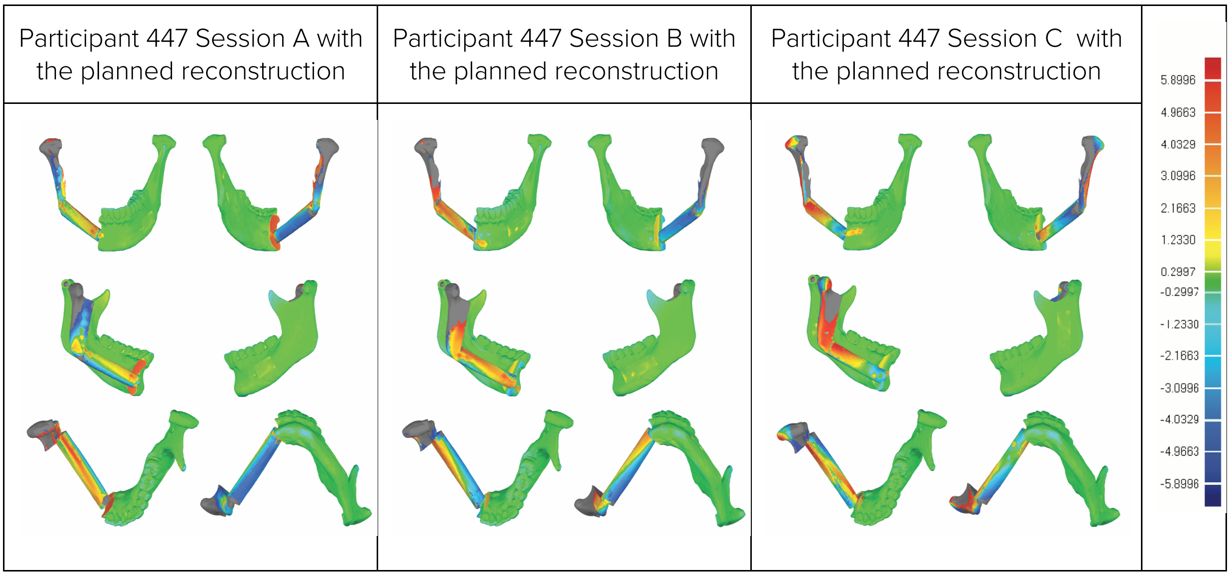


Fig 49. Participant 447 reconstructions completed for session A, B, and C digitally superimposed over the planned reconstruction. Actual reconstructions completed by participant 447 are compared to the planned reconstruction using a coloured Hausdorff surface distance 'heat map'.

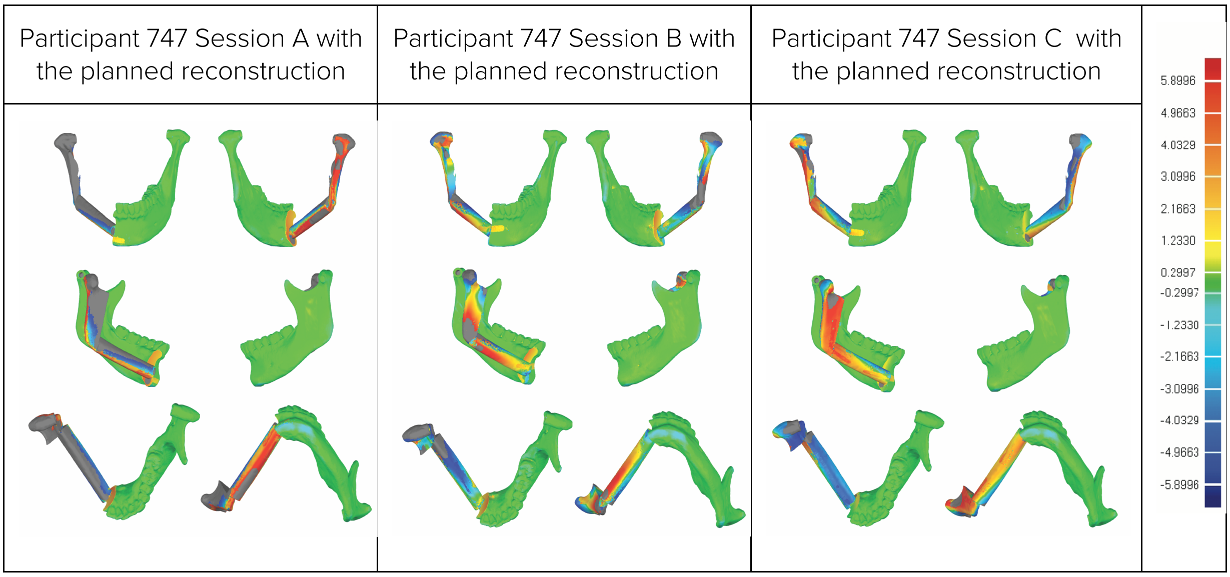


Fig 50. Participant 447 reconstructions completed for session A, B, and C digitally superimposed over the planned reconstruction. Actual reconstructions completed by participant 447 are compared to the planned reconstruction using a coloured Hausdorff surface distance 'heat map'.

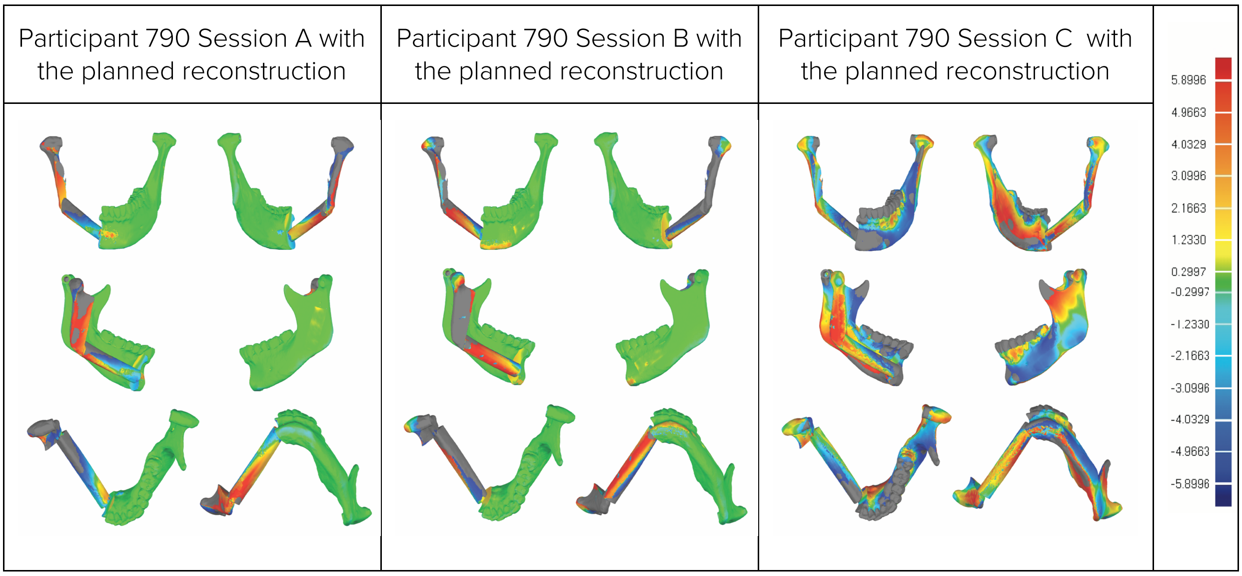


Fig 51. Participant 790 reconstructions completed for session A, B, and C digitally superimposed over the planned reconstruction. Actual reconstructions completed by participant 790 are compared to the planned reconstruction using a coloured Hausdorff 'surface distance heat map'.

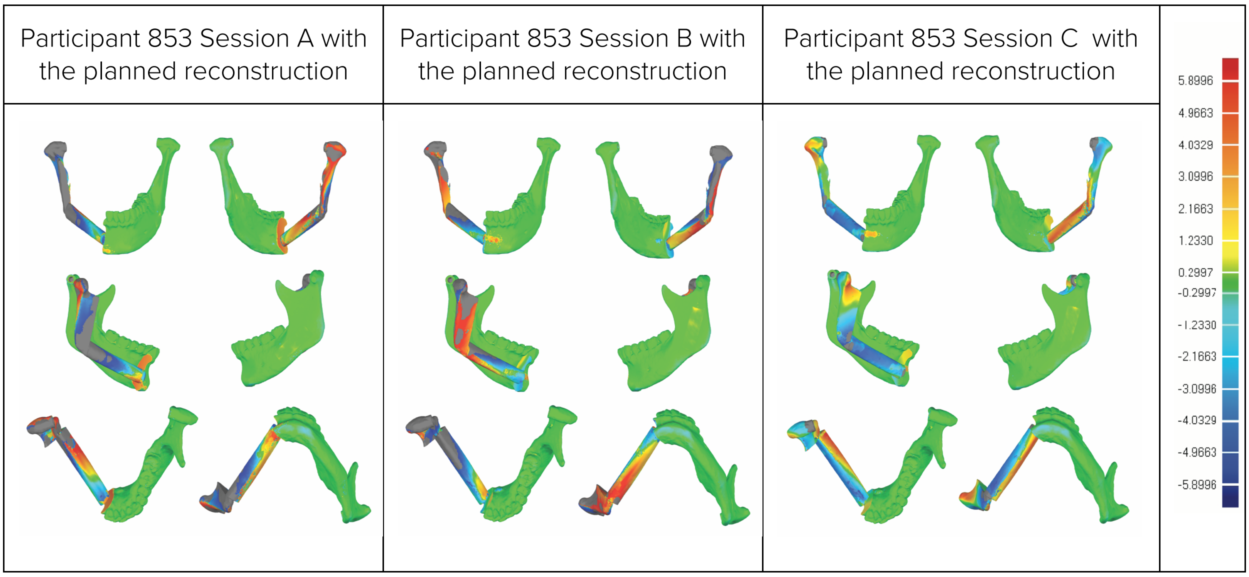


Fig 52. Participant 853 reconstructions completed for session A, B, and C digitally superimposed over the planned reconstruction. Actual reconstructions completed by participant 853 are compared to the planned reconstruction using a coloured Hausdorff surface distance 'heat map'.

	Average Mean Hausdorff Surface Distance (in mm)
Session A	*1.42*
Session B	*1.55*
Session C	*1.66*

Table 2. Average Mean Hausdorff Surface Distance

	Average Maximum Hausdorff Surface Distance (in mm)
Session A	*10.61*
Session B	*11.88*
Session C	*8.39*

Table 3. Average Maximum Hausdorff Surface Distance

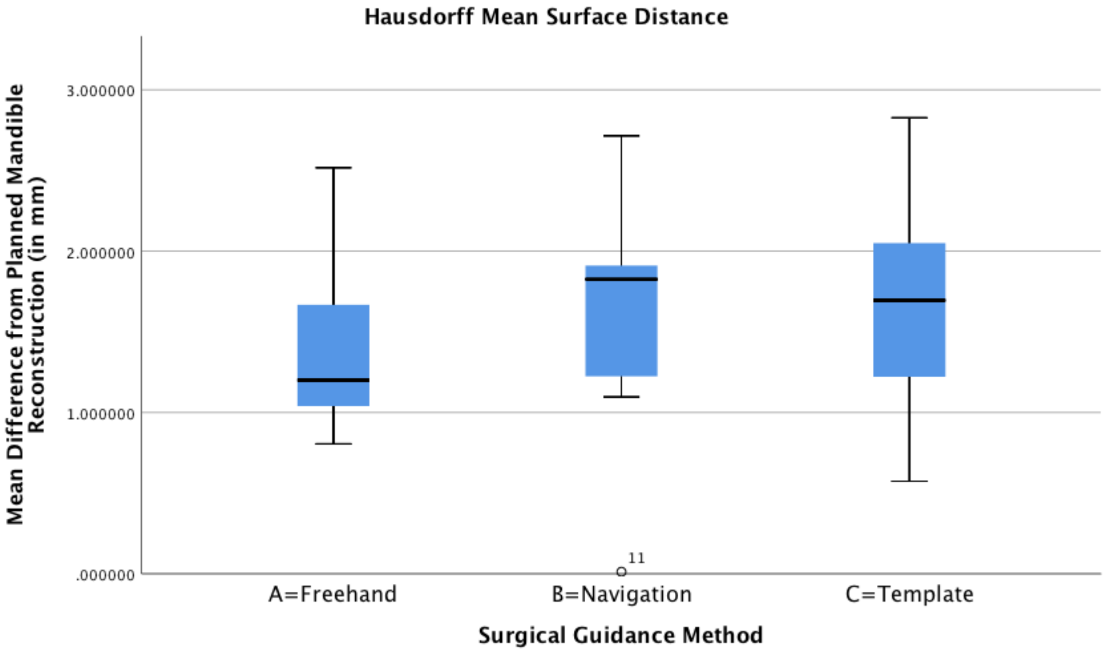


Table 4. Average Mean Hausdorff Surface Distance

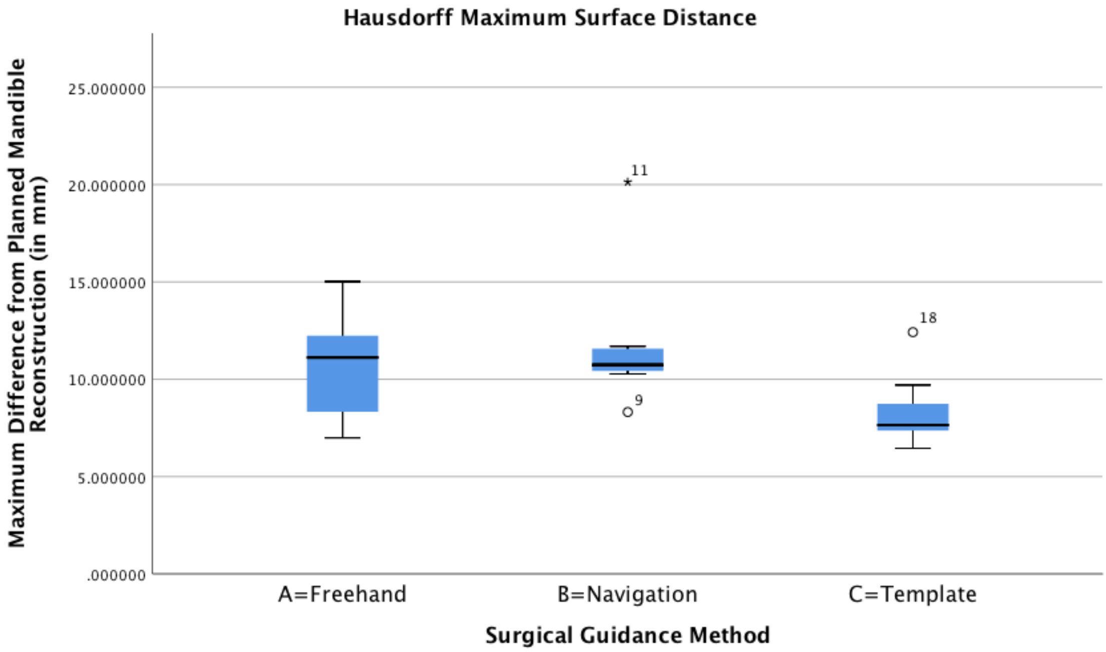


Table 5. Average Maximum Hausdorff Surface Distance

The coloured Hausdorff surface distance maps generated using Geomatic Control 3DSystems Inc., Rock Hill, South Carolina, United States of America) report function allowed the researcher to easily visualize the difference between the planned mandible reconstruction and actual reconstructions. According to the coloured Hausdorff surface distance images the area of greatest deviation from the planned reconstruction was the right condyle, right angle, and the posterior aspect of the fibula segment. The left mandibular body, angle and condyle had the least deviation from the planned reconstruction. It is unsurprising that the areas of greatest deviation from the planned reconstruction are on the right side of the mandible as that is the side which was reconstructed by the study participants.

2.6.1.2 Deconstructed Mandible Right Hausdorff Surface Distance

The precision of the freehand, navigation, and template surgical guidance techniques were assessed by measuring the deviation between planned and actual posterior mandible osteotomies. The digitized reconstructed mandible models created by the surgeon participants were deconstructed by the researcher using computer-aided design (CAD) software. The researcher virtually deconstructed the models by aligning a posterior osteotomy plane to the mandible osteotomy site that was cut by the surgeon participant. The posterior osteotomy plane was used to separate the right side of the mandible from the fibula segment and the left side of the mandible the actual right mandible osteotomy site of the mandible was aligned and compared to the planned right side of the mandible.

Once aligned the mesh models were imported into Meshlab, an open source mesh processing tool (Meshlab; Visual Computing Lab, Pisa, Italy). The actual reconstruction model was compared to the planned reconstruction model using the Hausdorff distance function. The maximum and mean Hausdorff surface distances were reported. In the journal article titled "Computer-assisted versus traditional freehand technique in fibular free flap mandibular reconstruction: a morphological comparative study" De Maesschalalck et al. describe a method to evaluate the accuracy of fibula mandible reconstructions digitally (De Maesschalck, Courvoisier, & Scolozzi, 2017). The evaluation methods outlined by De Maesschalalck et al. were followed to generate the following data sets.

	Right mandible Average mean Hausdorff Surface Distance (in mm)
Session A	*1.162*
Session B	*0.318*
Session C	*0.225*

Table 6. Right Average Maximum Hausdorff Surface Distance

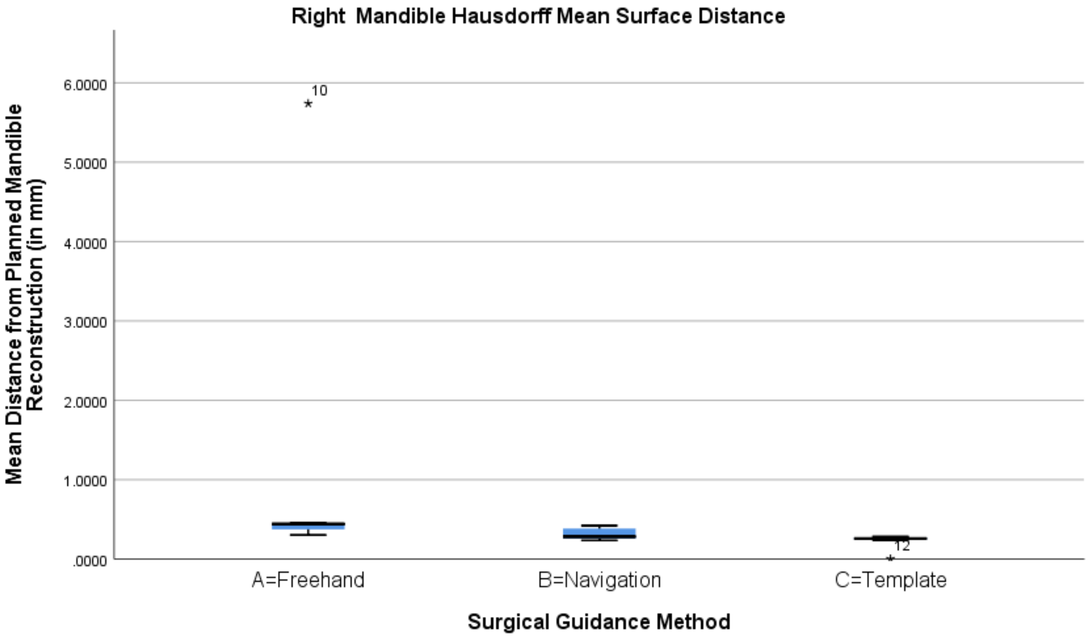


Table 7. Right Average Maximum Hausdorff Surface Distance

	Right mandible Average Maximum Hausdorff Surface Distance (in mm)
Session A	*7.63*
Session B	*3.99*
Session C	*3.29*

Table 8. Right Mandible Average Maximum Hausdorff Surface Distance

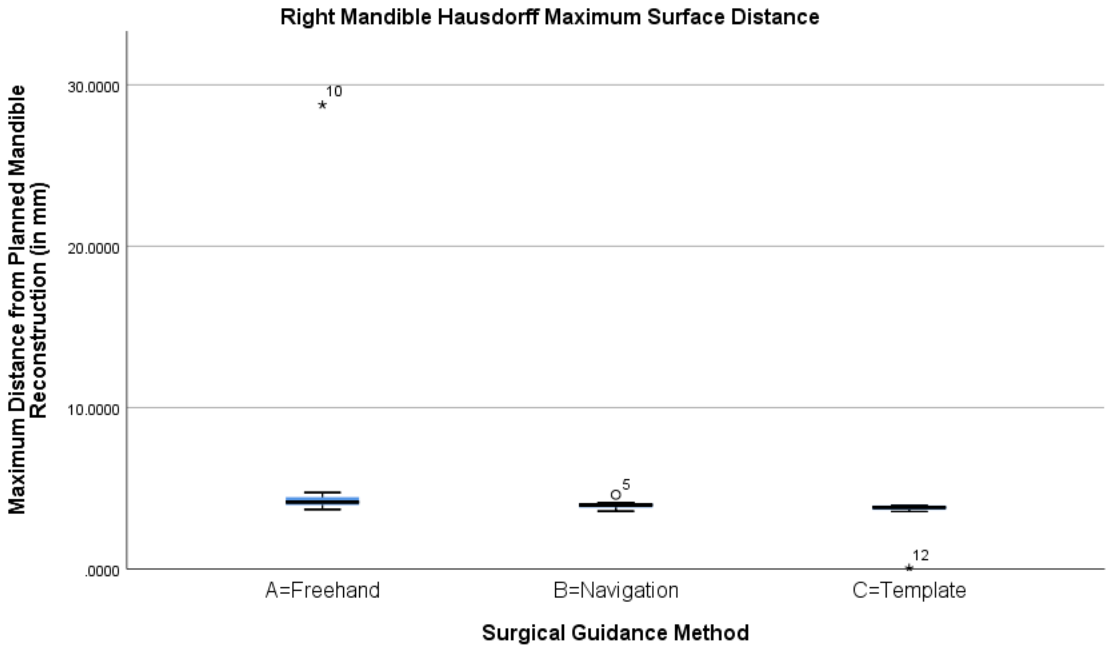


Table 9. Right Mandible Average Maximum Hausdorff Surface Distance

The Hausdorff surface distance data show that fibula mandible reconstructions completed with template guidance deviated from the planned posterior osteotomy plane the least with an average Hausdorff surface distance of 3.29mm. Reconstructions completed with navigation were also very accurate with an average Hausdorff distance of 3.99mm. Reconstructions completed using freehand techniques deviated from the planned reconstruction the most with the average Hausdorff distance at 7.63mm.

2.6.1.3 Deconstructed Mandible Left Hausdorff Surface Distance

The precision of the freehand, navigation, and template surgical guidance techniques were assessed by measuring the deviation between planned and actual anterior mandible osteotomies. The digitized reconstructed mandible models created by the surgeon participants were deconstructed by the researcher using computer-aided design (CAD) software. The researcher virtually deconstructed the models by aligning an osteotomy plane to the anterior mandible osteotomy site that was cut by the surgeon participant. The osteotomy plane was used to separate the left side of the mandible from the fibula segment and the right side of the mandible. The actual anterior mandible osteotomy site of the mandible was aligned and compared to the planned right side of the mandible.

Once aligned the mesh models were imported into Meshlab, an open source mesh processing tool (Meshlab; Visual Computing Lab, Pisa, Italy). The actual reconstruction model was compared to the planned reconstruction model using the Hausdorff distance function. The maximum and mean Hausdorff surface distances were reported. In the journal article titled "Computer-assisted versus traditional freehand technique in fibular free flap mandibular reconstruction: a morphological comparative study" De Maesschalalck et al. describe a method to evaluate the accuracy of fibula mandible reconstructions digitally (De Maesschalck et al., 2017). The evaluation methods outlined by De Maesschalalck et al. were followed to generate the following data sets.

	Left mandible Average Maximum Hausdorff Surface Distance (in mm)
Session A	*7.63*
Session B	*3.99*
Session C	*3.29*

Table 10. Left Mandible Average Maximum Hausdorff Distance

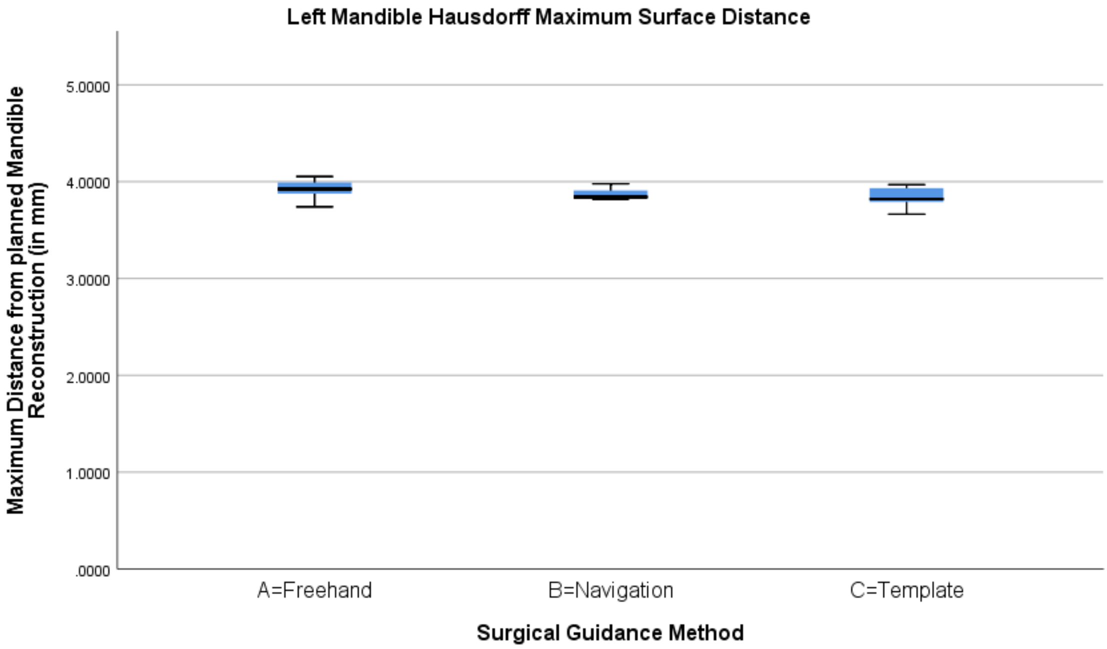


Table 11. Average Maximum Hausdorff Surface Distance

	Left mandible Average Mean Hausdorff Surface Distance (in mm)
Session A	0.20
Session B	0.19
Session C	0.16

Table 12. Left Mandible Average Mean Hausdorff Distance

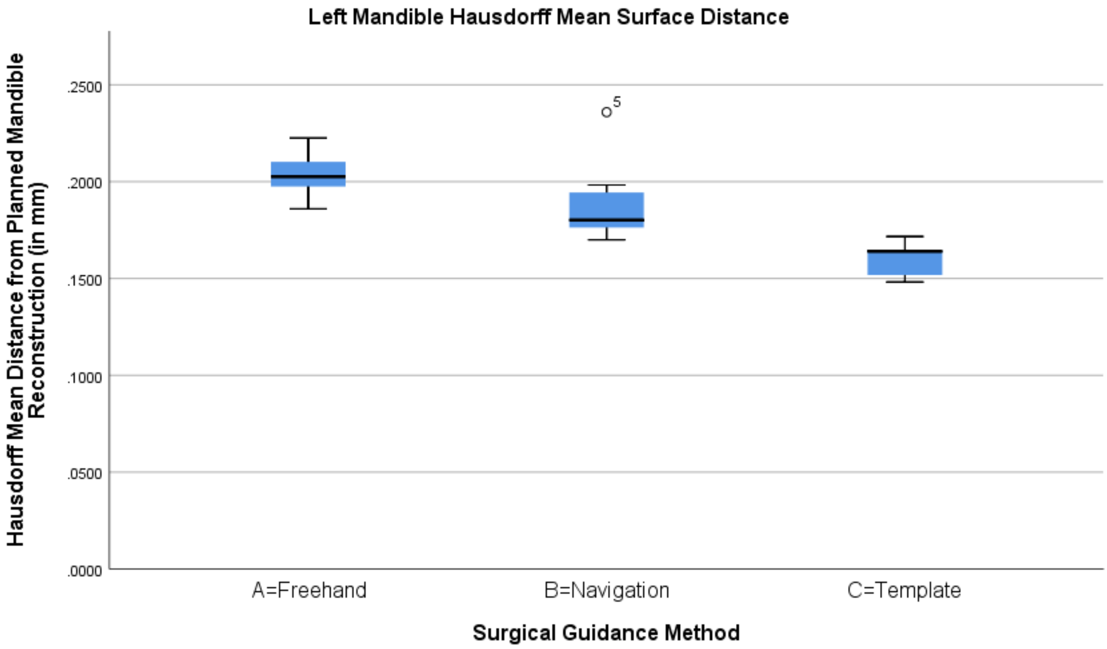


Table 13. Fibula Segment Average Maximum Hausdorff Surface Distance

The Hausdorff surface distance data show that fibula mandible reconstructions completed with template guidance deviated from the planned anterior osteotomy plane the least with an average Hausdorff surface distance of 0.159 mm. Reconstructions completed with navigation were also very accurate with an average Hausdorff distance of 0.19 mm. Reconstructions completed using freehand techniques deviated from the planned anterior osteotomy plane the most with the average Hausdorff distance at 0.20 mm.

2.6.1.3 Deconstructed Fibula Segment Hausdorff Surface Distance

The precision of the freehand, navigation, and template surgical guidance techniques were assessed by measuring the deviation between planned and actual fibula osteotomies. The digitized reconstructed mandible models created by the surgeon participants were deconstructed by the researcher using computer-aided design (CAD) software. The researcher virtually deconstructed the models by aligning osteotomy planes to the fibula osteotomy site that was cut by the surgeon participant. The fibula osteotomy planes were used to separate the fibula segment from the left and right side of the mandible. The actual fibula segment used to reconstructed the mandible was aligned and compared to the planned fibula segment.

Once aligned the mesh models were imported into Meshlab, an open source mesh processing tool (Meshlab; Visual Computing Lab, Pisa, Italy). The actual reconstruction model was compared to the planned reconstruction model using the Hausdorff distance function. The maximum and mean Hausdorff surface distances were reported. In the journal article titled "Computer-assisted versus traditional freehand technique in fibular free flap mandibular reconstruction: a morphological comparative study" De Maesschalalck et al. describe a method to evaluate the accuracy of fibula mandible reconstructions digitally (De Maesschalck et al., 2017). The evaluation methods outlined by De Maesschalalck et al. were followed to generate the following data sets.

	Fibula Segment Average Maximum Hausdorff Surface Distance (in mm)
Session A	11.51
Session B	4.83
Session C	3.56

Table 14. Fibula Segment Average Maximum Hausdorff Surface Distance

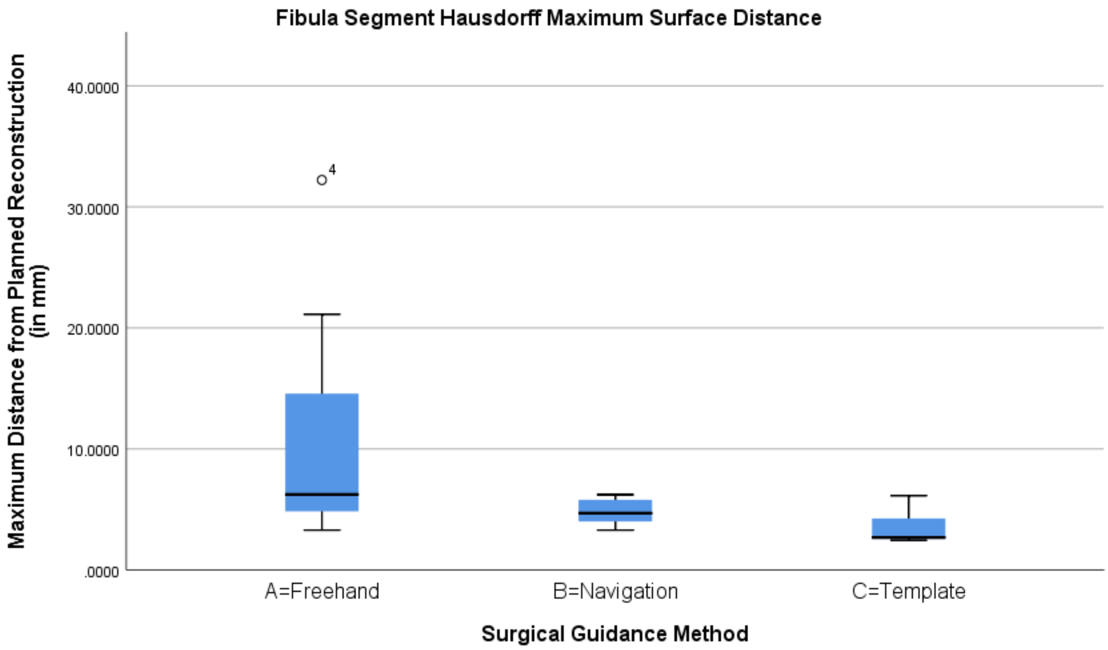


Table 15. Fibula Segment Average Maximum Hausdorff Surface Distance

	Fibula Segment Average Mean Hausdorff Surface Distance (in mm)
Session A	*2.49*
Session B	*0.63*
Session C	*0.45*

Table 16. Fibula Segment Average Mean Hausdorff Surface Distance

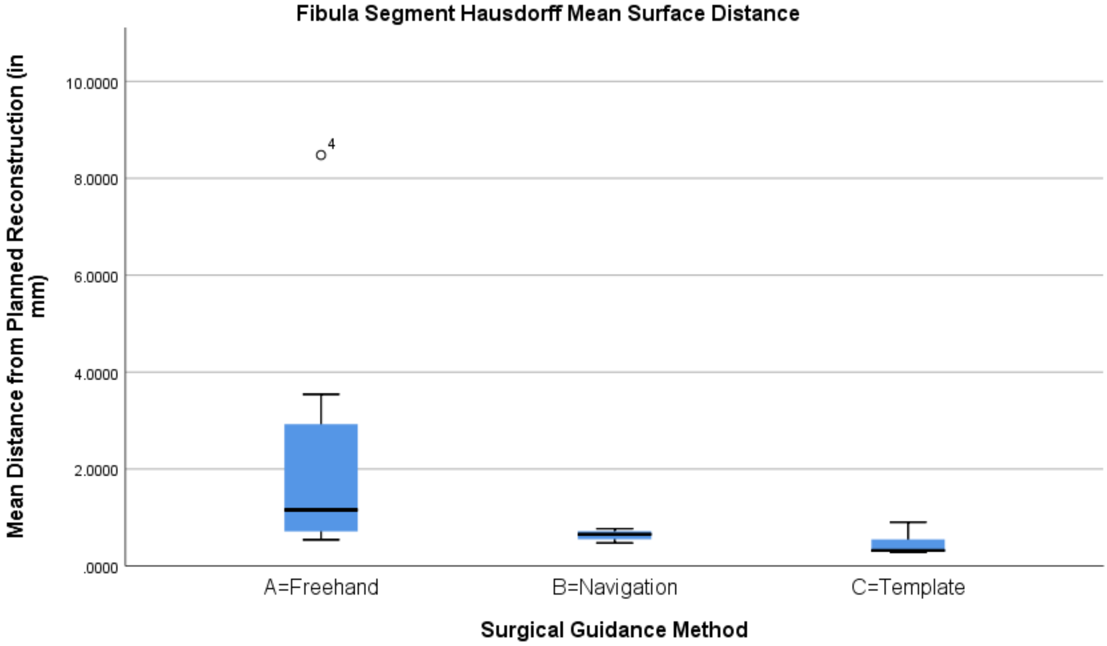


Table 17. Fibula Segment Average Mean Hausdorff Surface Distance

The Hausdorff surface distance data show that fibula mandible reconstructions completed with template guidance deviated from the planned fibula segment the least with an average Hausdorff surface distance of 0.45 mm. Reconstructions completed with navigation were also very accurate with an average Hausdorff distance of 0.63 mm. Reconstructions completed using freehand techniques deviated from the planned fibula segment the most with the average Hausdorff distance at 2.49 mm.

2.6.2 Model Measurements

The accuracy of the mandible reconstructions created by the participants in the present study were determined by calculating the difference between the planned mandible reconstruction and the actual mandible reconstructions. A comparison between the actual and the planned mandible reconstructions was completed by calculating the difference between key linear and angular measurements on the planned and actual reconstructed models. Measurements used to compare the actual and planned reconstructions were the right coronal angle, the left coronal angle, the right axial mandibular angle, the left axial mandibular angle, the right sagittal mandibular angle, the left sagittal mandibular angle, the condyle distance, the gonion distance, the fibula segment length, the anterior inferior border distance, the posterior interior border distance, the intersegment distance, and the number of fibula segments (Fig. 53).

Linear and angular measurements used to evaluate the actual reconstructions and methods used to measure the reconstruction models were selected based on the following published works "Exploratory benchtop study evaluating the use of surgical design and simulation in fibula free flap mandibular reconstruction' by Logan et al. "Computer-assisted versus traditional freehand technique in fibula free flap mandibular reconstruction: a morphological comparative study" by DeMaesschalck et al. and "Accuracy of computer-assisted surgery in mandibular reconstruction: A postoperative evaluation guideline" by van Baar et al (De Maesschalck et al., 2017; Logan et al., 2013a; van Baar, Liberton, Forouzanfar, Winters, & Leusink, 2019).

2.6.2.1 Manual Measurements

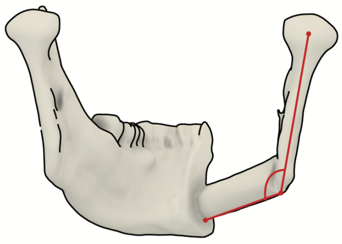
The accuracy of the three reconstruction techniques were evaluated by taking manual measurements of the reconstructed models using digital calipers and comparing the reconstructed models with measurements taken from a control model. Manual measurements of the physically reconstructed models were taken to measure fibula segment length, anterior inferior border distance, posterior inferior border distance, intersegment distance, and number of fibula segments (Fig. 53). The researcher chose to take manual measurements of fibula segment length, anterior inferior border distance, posterior inferior border distance, intersegment distance, because it was faster and easier than taking these measurements digitally.

2.6.2.2 Digital Measurements

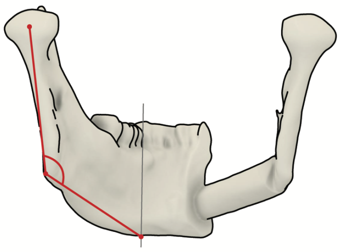
Digitized STL models of the actual mandible reconstructions created by the participants in benchtop sessions A, B and C of the present study were aligned to the planned reconstruction using geomatics control (3DSystems Inc., Rock Hill, South Carolina, United States of America) manual registration and global registration tools. Steps used to align the actual and planned reconstruction models was consistent for each model. The aligned models were imported into Rhino 5.0 (Robert McNeel and Associates Inc., Seattle, Washington, United States of America) to be measured. Rhino 5.0 was used to measure the STL models because of the 'snap' functions which allowed the researcher to easily and accurately select key points on the STL models to base measurements of off and the superior measurement tools that allowed the researcher to take accurate linear and angular measurements of the models. The mandibular measurements taken digitally were the right coronal angle, the left coronal angle, the right axial mandibular angle, the left axial mandibular angle, the right sagittal mandibular angle, the left sagittal mandibular angle, the condyle distance, the gonion distance.

Virtual cephalometric points on the mandible and maxilla models were selected on bony landmarks. Selected virtual points were used to generate measurements and to draw the midsagittal, Frankfurt, nasion, and parasymphysis planes. The midsagittal plane was positioned to intersect the nasion, basion and incisive foramen, the frankfurt plane was aligned with the internal acoustic foramen, and the infraorbital margin, and the nasion plane was aligned with the nasion and pogonion, the parasymphysis plane is a vertical plane drawn distal to the canine tooth. The midsagittal, frankfurt and nasion planes were used to determine the orientation of the top, bottom, left, right, front, and back views in Rhino 5.0 (Robert McNeel and Associates Inc., Seattle, Washington, United States of America). It was essential to maintain a consistent perspective in the CAD space relative to the anatomical STl models being measured to ensure reliable measurements (De Maesschalck et al., 2017; van Baar et al., 2019). The coronal mandibular angles, and axial mandibular angles reported in this document were calculated using the midsagittal plane (De Maesschalck et al., 2017; van Baar et al., 2019). The following section of this document describes the methods and measurements used to compare the planned and actual fibula mandible reconstructions in detail.

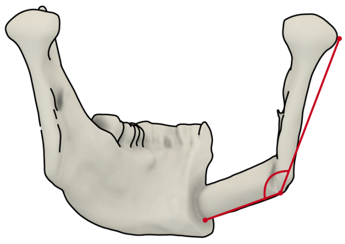
RIGHT CORONAL
MANDIBULAR ANGLE



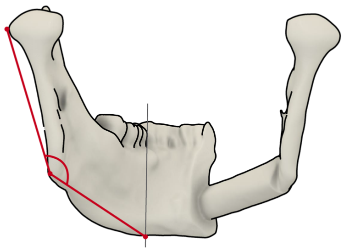
LEFT CORONAL
MANDIBULAR ANGLE



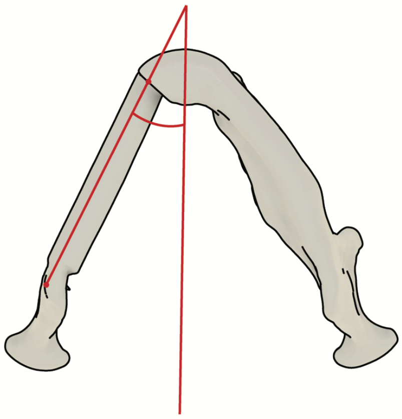
RIGHT CORONAL
MANDIBULAR ANGLE



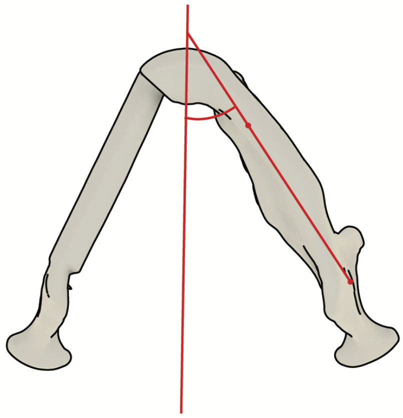
LEFT CORONAL
MANDIBULAR ANGLE



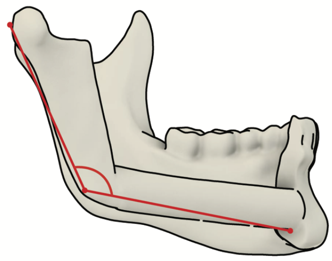
RIGHT AXIAL MANDIBULAR ANGLE



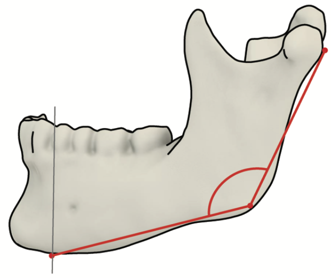
LEFT AXIAL MANDIBULAR ANGLE



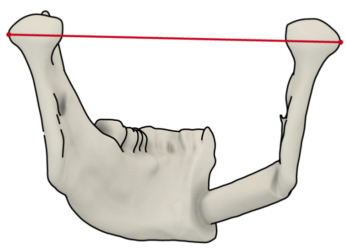
RIGHT SAGITTAL MANDIBULAR ANGLE



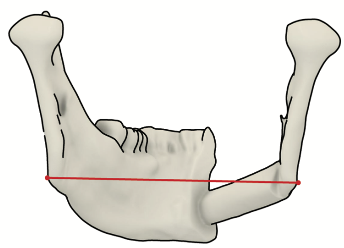
LEFT SAGITTAL MANDIBULAR ANGLE



CONDYLE DISTANCE



GONION DISTANCE



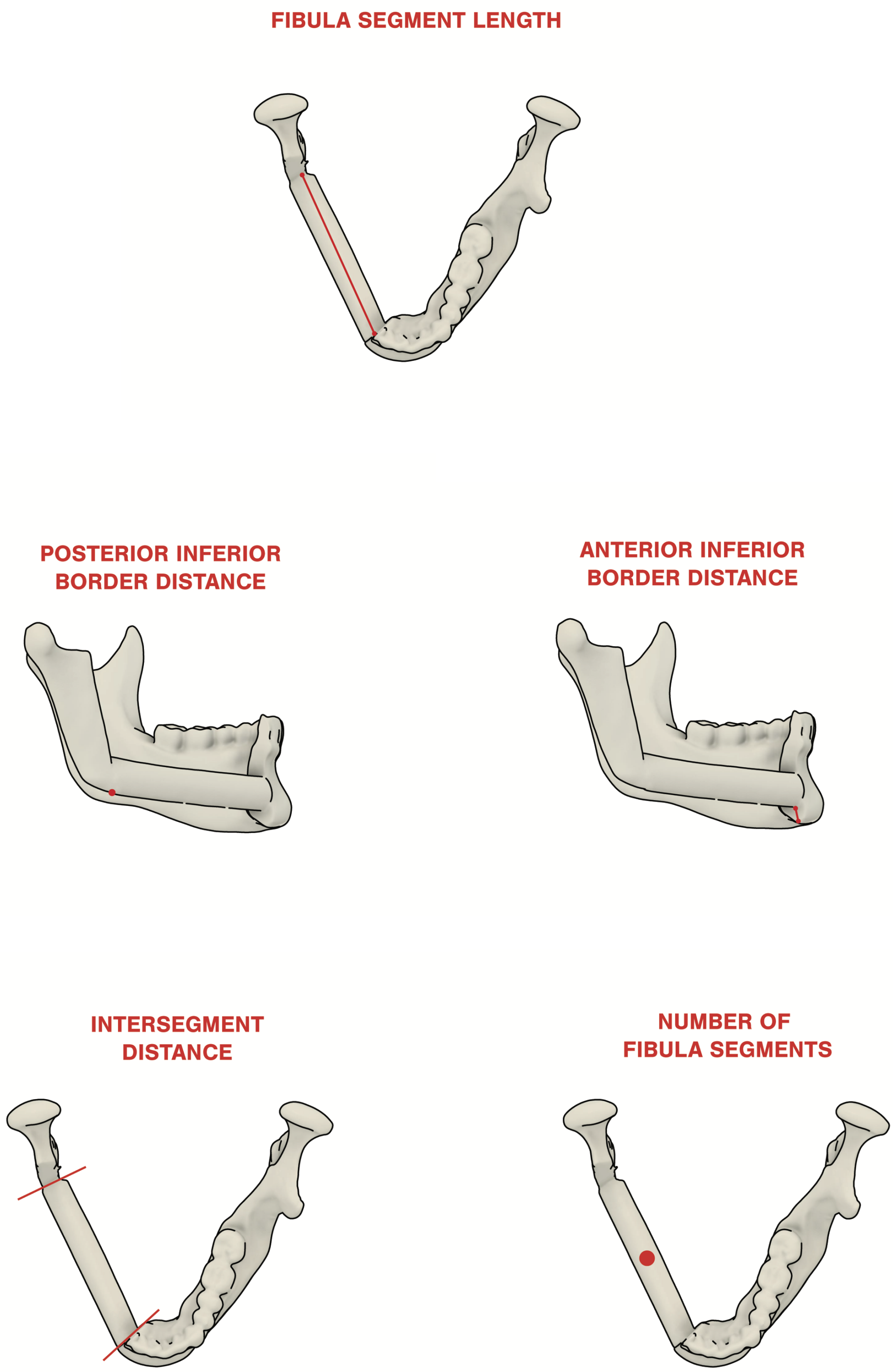


Fig 53. Illustrates the measurements taken by the researcher

2.6.2.3 Right Coronal Mandibular Angle

The right coronal mandibular angle was measured by selecting a point on the right condyle superior and the right gonion angle on the mandible. The right coronal angle was calculated between the line created between the condyle superior and gonion to the midsagittal plane (De Maesschalck et al., 2017; van Baar et al., 2019). The right coronal mandibular angle was calculated using the angle measurement tool in Rhino 5.0 (Robert McNeel and Associates Inc., Seattle, Washington, United States of America).

Actual right coronal mandibula angle was compared to the surgical plan. The planned right coronal mandibular angle was 9 degrees.

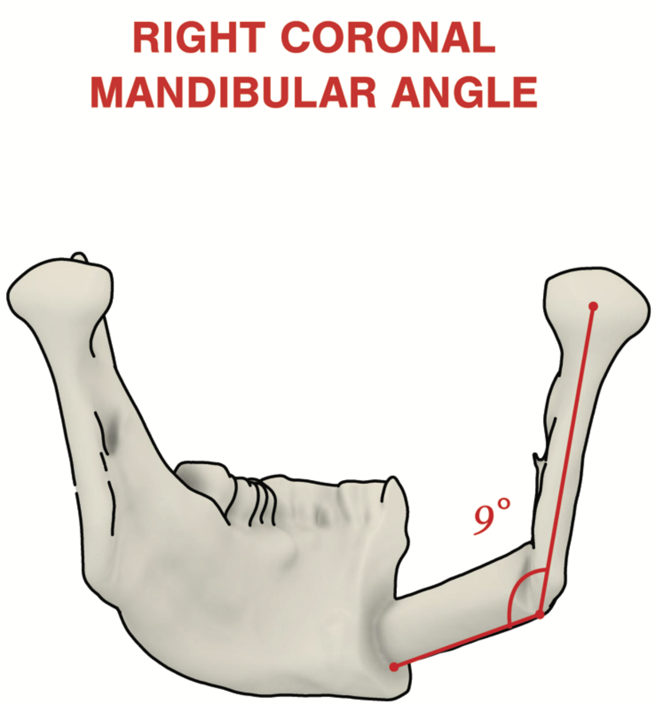


Fig 54. Illustrates the right coronal mandibular angle measurement

	Minumum	Maximum	Mean	Median	Range	SD
Session A	*1.73*	*9.94*	*5.62*	*6.52*	*8.21*	*3.31*
Session B	*1.42*	*12.99*	*5.66*	*3.08*	*11.57*	*4.59*
Session C	*0.56*	*8.11*	*4.86*	*6.83*	*7.55*	*3.24*

Table 18. Descriptive statistics for deviation (in degrees) for the right coronal mandibular angle for session A-freehand guidance, session B - navigation guidance, and session C - template guidance, from the planned reconstructed mandible model.

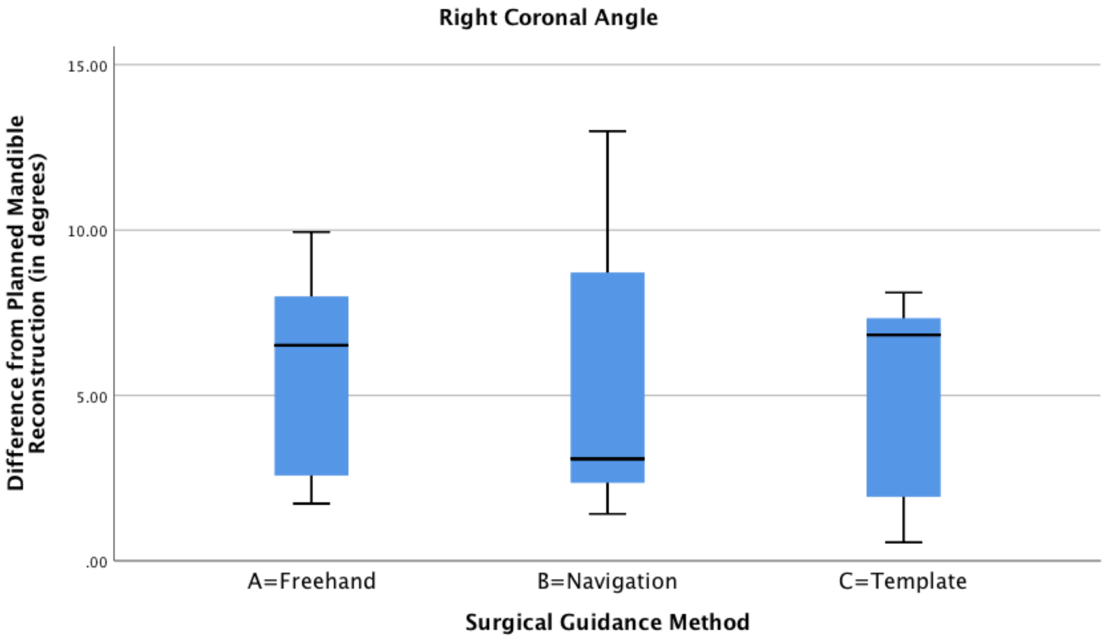


Table 19. Box plot showing the distribution of the deviation measurement (in degrees) of the right coronal mandibular angle for session A - freehand, session B - navigation, and session C - template.

2.6.2.4 Left Coronal Mandibular Angle

The left coronal mandibular angle was measured by selecting a point on the left condyle superior and the left gonion angle on the mandible. The left coronal angle was calculated between the line created between the condyle superior and gonion to the midsagittal plane (De Maesschalck et al., 2017; van Baar et al., 2019). The left coronal mandibular angle was calculated using the angle measurement tool in Rhino 5.0 (Robert McNeel and Associates Inc., Seattle, Washington, United States of America).

Actual left coronal mandibula angle was compared to the surgical plan. The planned left coronal mandibular angle was 7.3 degrees.

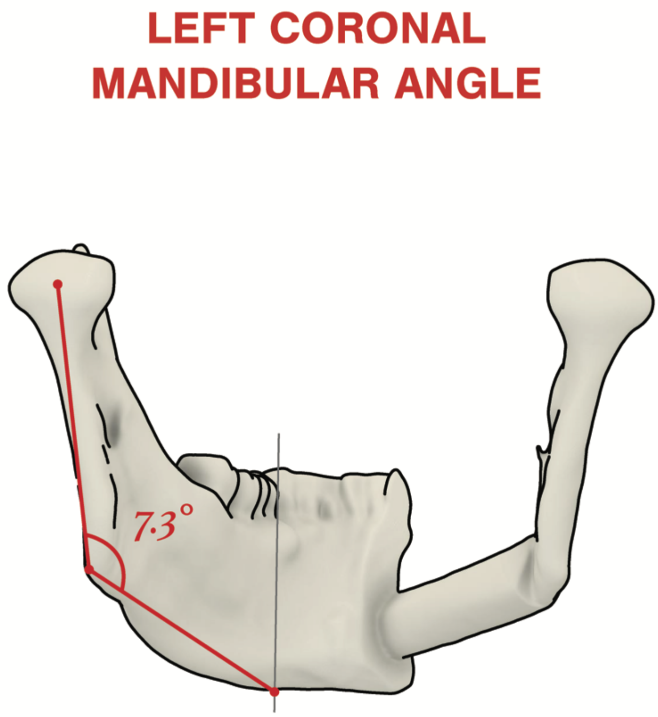


Fig 55. Illustrates the left coronal mandibular angle measurement

	Minumum	Maximum	Mean	Median	Range	SD
Session A	*0.23*	*3.10*	*1.39*	*1.25*	*2.87*	*1.04*
Session B	*0.00*	*4.29*	*1.80*	*1.63*	*4.29*	*1.56*
Session C	*0.13*	*9.62*	*2.76*	*2.15*	*9.49*	*3.20*

Table 20. Descriptive statistics for deviation (in degrees) for the left coronal mandibular angle for session A-freehand guidance, session B - navigation guidance, and session C - template guidance, from the planned reconstructed mandible model.

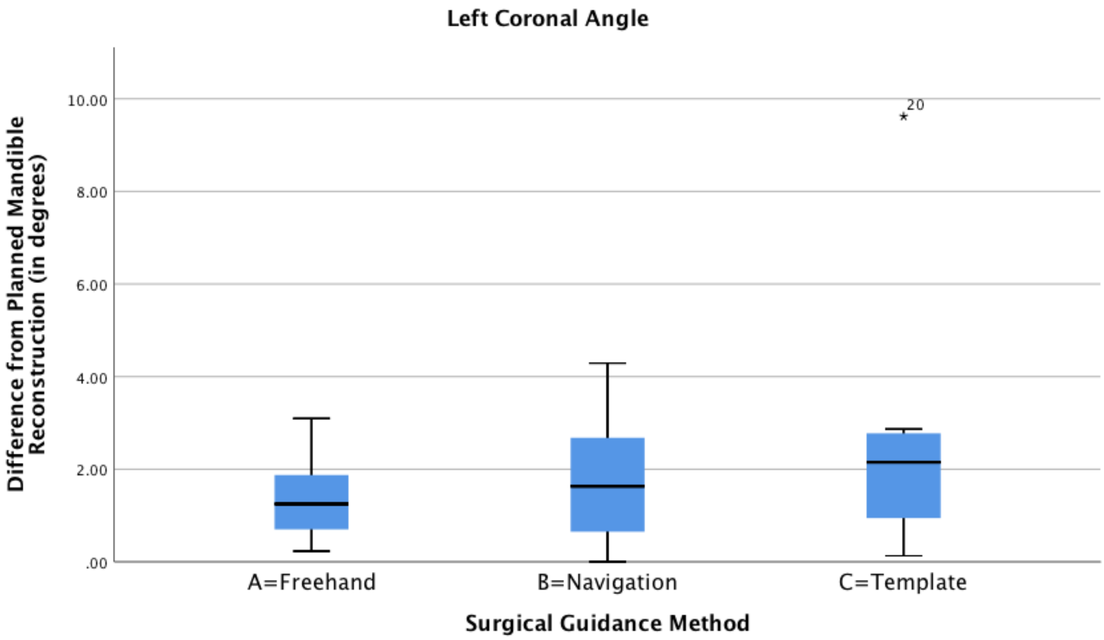


Table 21. Box plot showing the distribution of the deviation measurement (in degrees) of the left coronal mandibular angle for session A - freehand, session B - navigation, and session C - template.

2.6.2.5 Right Axial Mandibular Angle

The right axial mandibular angle was measured by selecting a point on the right gonion, and the and the right parasymphysis on the mandible. The right parasyphysis was included in the resection and could not be used to measure the right axial mandibular angle. The most inferior point of the osteotomy between the two segments of bone graft was selected according to the guideline published by van Barr (van Baar et al., 2019). In the case of a large gap between the fibula segment and the native mandible the most inferior and anterior point on the fibula segment was selected. The right axial angle was calculated between the line created between the gonion to the parasymphysis and the midsagittal plane (De Maesschalck et al., 2017; van Baar et al., 2019). The right axial mandibular angle was calculated using the angle measurement tool in Rhino 5.0 (Robert McNeel and Associates Inc., Seattle, Washington, United States of America).

Actual right axial mandibula angle was compared to the surgical plan. The planned right axial mandibular angle was 31.1 degrees.

RIGHT AXIAL MANDIBULAR ANGLE

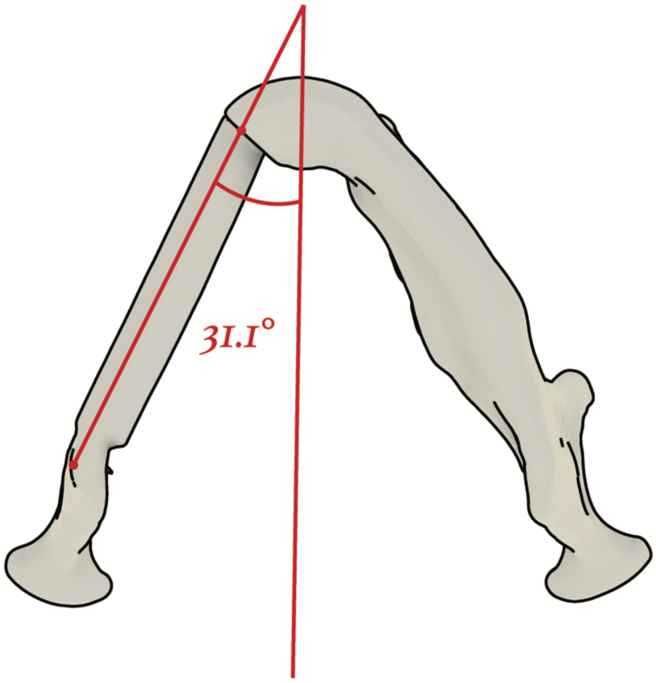


Fig 56. Illustrates the right axial mandibular angle measurement

	Minumum	Maximum	Mean	Median	Range	SD
Session A	*1.04*	*7.23*	*3.51*	*2.12*	*6.19*	*2.56*
Session B	*0.31*	*7.56*	*3.62*	*2.58*	*7.25*	*2.97*
Session C	*2.39*	*12.31*	*6.51*	*5.70*	*9.92*	*3.33*

Table 22. Descriptive statistics for deviation (in degrees) for the right axial mandibular angle for session A-freehand guidance, session B - navigation guidance, and session C - template guidance, from the planned reconstructed mandible model.

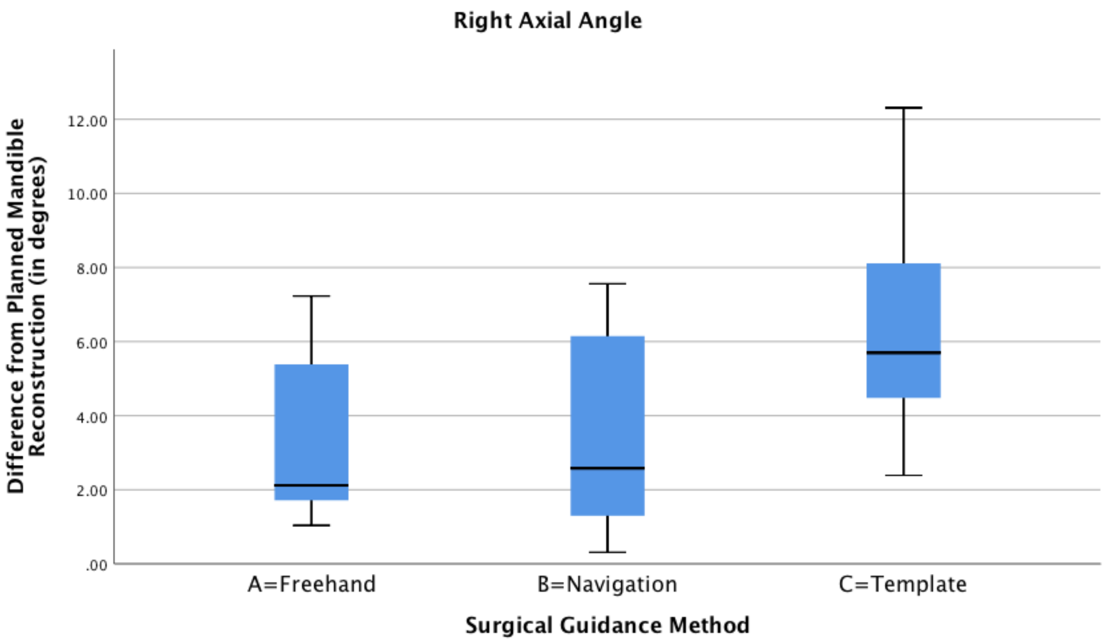


Table 23. Box plot showing the distribution of the deviation measurement (in degrees) of the right axial mandibular angle for session A - freehand, session B - navigation, and session C - template.

2.6.2.6 Left Axial Mandibular Angle

The left axial mandibular angle was measured by selecting a point on the left gonion, and the left parasymphysis on the mandible. The left axial angle was calculated between the line created between the gonion to the parasymphysis and the midsagittal plane (De Maesschalck et al., 2017; van Baar et al., 2019). The left axial mandibular angle was calculated using the angle measurement tool in Rhino 5.0 (Robert McNeel and Associates Inc., Seattle, Washington, United States of America).

Actual left axial mandibula angle was compared to the surgical plan. The planned left axial mandibular angle was 31 degrees.

LEFT AXIAL
MANDIBULAR ANGLE

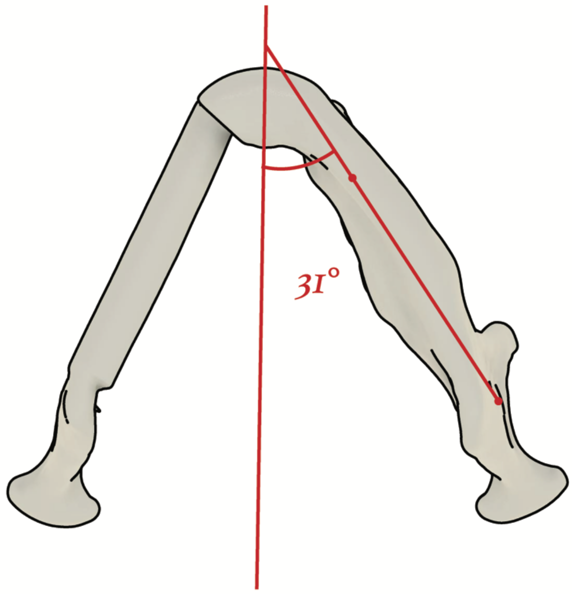


Fig 57. Illustrates the left axial mandibular angle measurement

	Minumum	Maximum	Mean	Median	Range	SD
Session A	*0.16*	*1.15*	*0.54*	*0.53*	*0.99*	*0.32*
Session B	*0.20*	*7.30*	*1.54*	*0.71*	*7.10*	*2.55*
Session C	*0.07*	*1.11*	*0.47*	*0.41*	*1.04*	*0.19*

Table 24. Descriptive statistics for deviation (in degrees) for the left axial mandibular angle for session A-freehand guidance, session B - navigation guidance, and session C - template guidance, from the planned reconstructed mandible model.

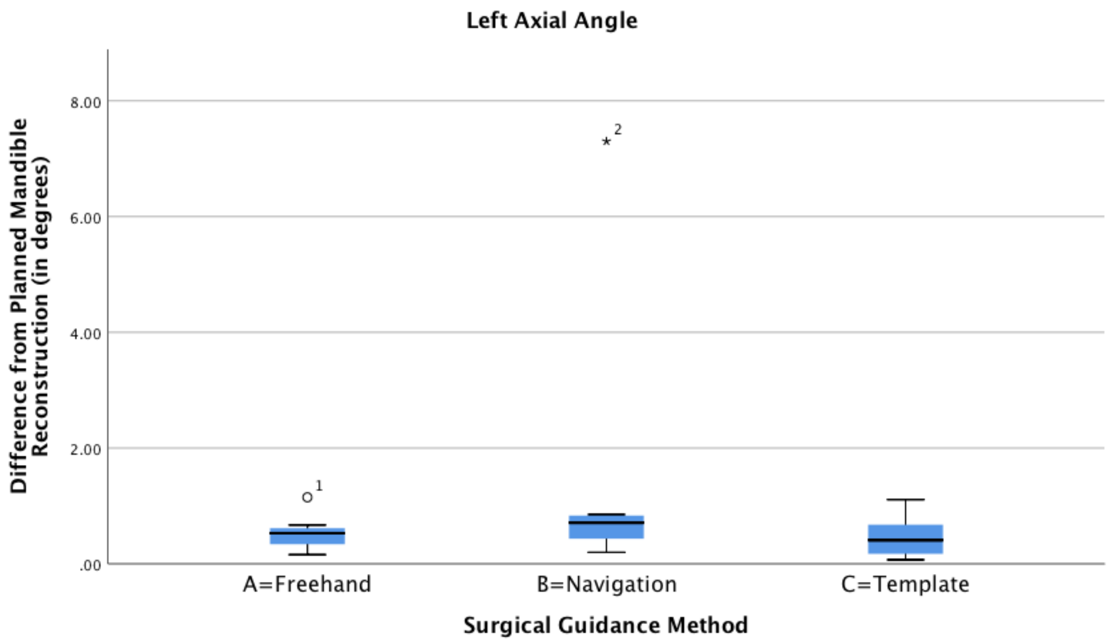


Table 25. Box plot showing the distribution of the deviation measurement (in degrees) of the left axial mandibular angle for session A - freehand, session B - navigation, and session C - template.

2.6.2.7 Right Sagittal Mandibular Angle

The right sagittal mandibular angle was measured by selecting a point on the right condyle posterior, right gonion, and the and the right parasymphysis on the mandible. The right parasymphysis was included in the resection and could not be used to measure the right axial mandibular angle. The most inferior point of the osteotomy between the two segments of bone graft was selected according to the guideline published by van Barr (van Baar et al., 2019). In the case of a large gap between the fibula segment and the native mandible the most inferior and anterior point on the fibula segment was selected. The right sagittal angle was calculated between the line created between the condyle posterior and gonion to the line created between the gonion and the parasymphysis (De Maesschalck et al., 2017; van Baar et al., 2019). The right sagittal mandibular angle was calculated using the angle measurement tool in Rhino 5.0 (Robert McNeel and Associates Inc., Seattle, Washington, United States of America).

Actual right sagittal mandibula angle was compared to the surgical plan. The planned right sagittal mandibular angle was 122 degrees.

RIGHT SAGITTAL MANDIBULAR ANGLE

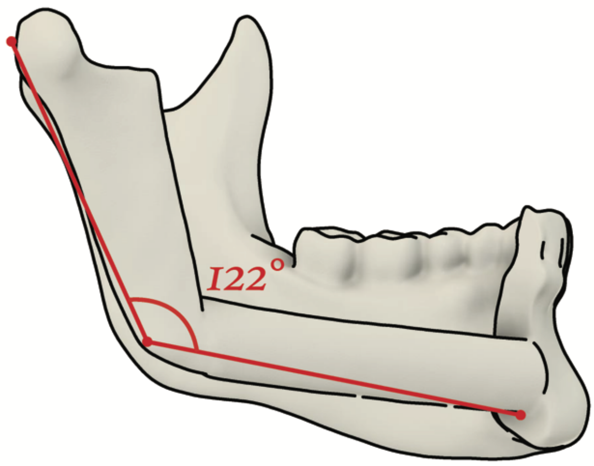


Fig 58. Illustrates the right sagittal mandibular angle measurement

	Minumum	Maximum	Mean	Median	Range	SD
Session A	1.06	18.73	7.99	6.82	17.67	5.40
Session B	0.54	16.78	6.43	7.52	16.24	5.752
Session C	0.32	10.57	4.04	2.17	10.25	4.31

Table 26. Descriptive statistics for deviation (in degrees) for the right sagittal mandibular angle for session A-freehand guidance, session B - navigation guidance, and session C - template guidance, from the planned reconstruction mandible model.

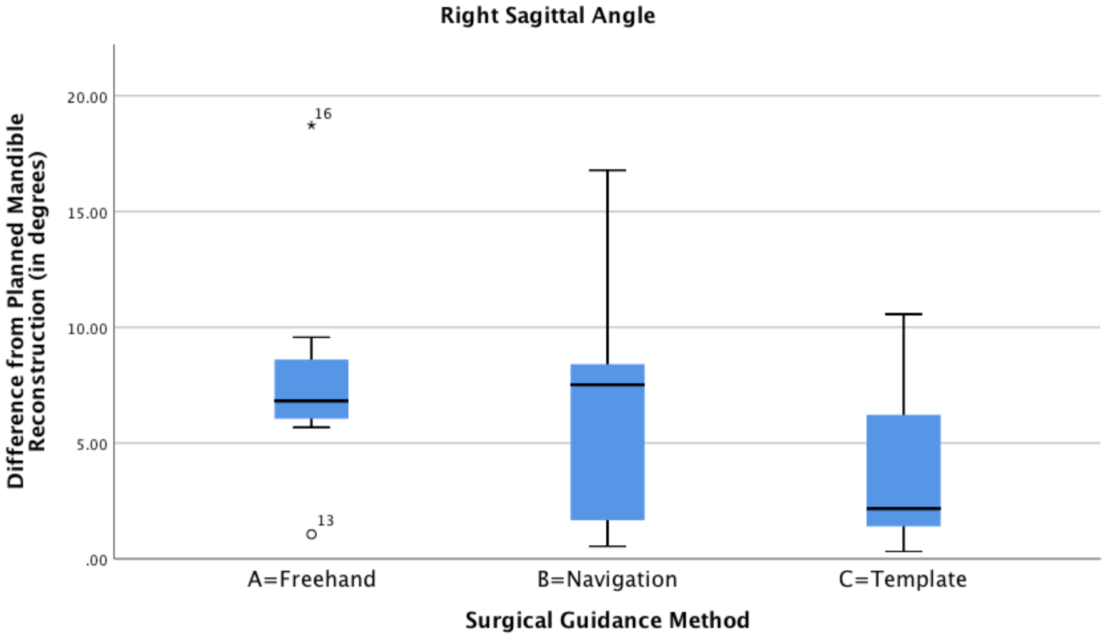


Table 27. Box plot showing the distribution of the deviation measurement (in degrees) of the right sagittal mandibular angle for session A - freehand, session B - navigation, and session C - template.

2.6.2.8 Left Sagittal Mandibular Angle

The left sagittal mandibular angle was measured by selecting a point on the left condyle posterior, left gonion, and the and the left parasymphysis on the mandible. The left sagittal angle was calculated between the line created between the condyle posterior and gonion to the line created between the gonion and the parasymphysis (De Maesschalck et al., 2017; van Baar et al., 2019). The left sagittal mandibular angle was calculated using the angle measurement tool in Rhino 5.0 (Robert McNeel and Associates Inc., Seattle, Washington, United States of America).

Actual left sagittal mandibula angle was compared to the surgical plan. The planned left sagittal mandibular angle was 128 degrees.

LEFT SAGITTAL MANDIBULAR ANGLE

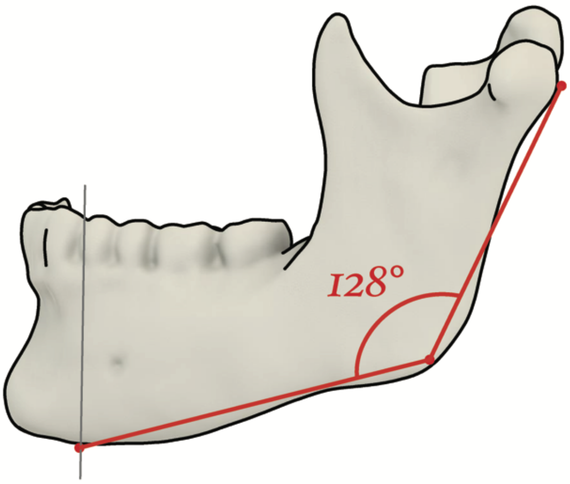


Fig 59. Illustrates the left sagittal mandibular angle measurement

	Minumum	Maximum	Mean	Median	Range	SD
Session A	0.73	3.03	1.42	1.30	2.30	0.83
Session B	0.64	5.50	2.16	1.70	4.86	1.75
Session C	0.92	2.69	1.48	1.42	1.77	0.62

Table 28. Descriptive statistics for deviation (in degrees) for the left sagittal mandibular angle for session A-freehand guidance, session B - navigation guidance, and session C - template guidance, from the planned reconstructed mandible model.

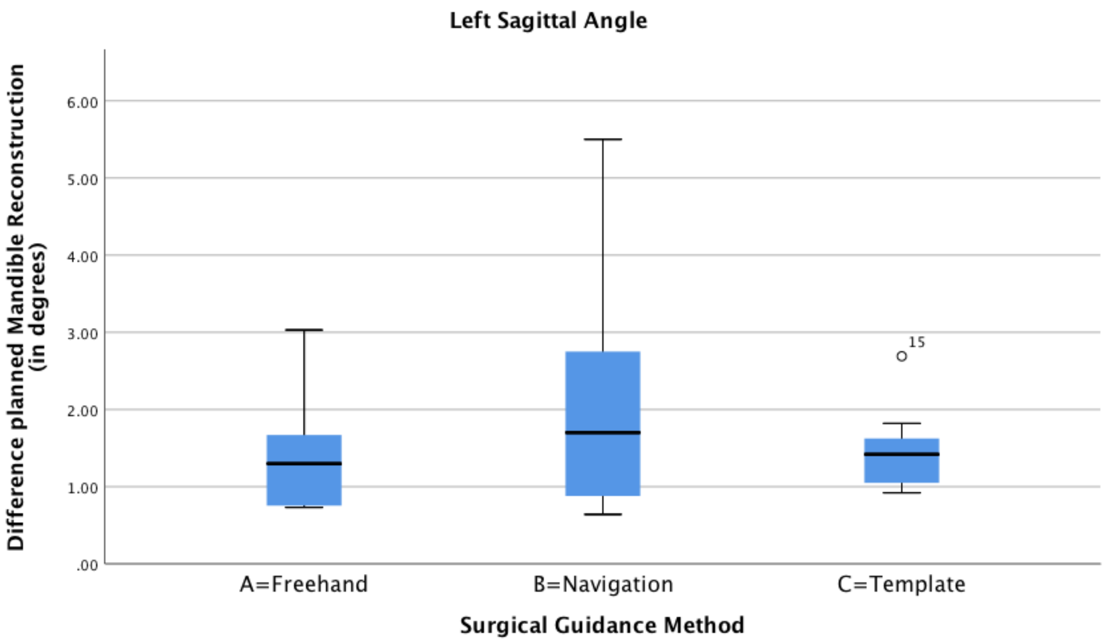


Table 29. Box plot showing the distribution of the deviation measurement (in degrees) of the left sagittal mandibular angle for session A - freehand, session B - navigation, and session C - template.

2.6.2.9 Condyle Distance

The condyle distance was measured by selecting a point on the right condyle superior and left condyle superior. The distance between the left and right condyle superior points was measured (De Maesschalck et al., 2017; van Baar et al., 2019). The condyle distance was calculated using the length measurement tool in Rhino 5.0 (Robert McNeel and Associates Inc., Seattle, Washington, United States of America).

Actual condyle distance was compared to the surgical plan. The planned condyle distance was 101.56 mm.

CONDYLE DISTANCE

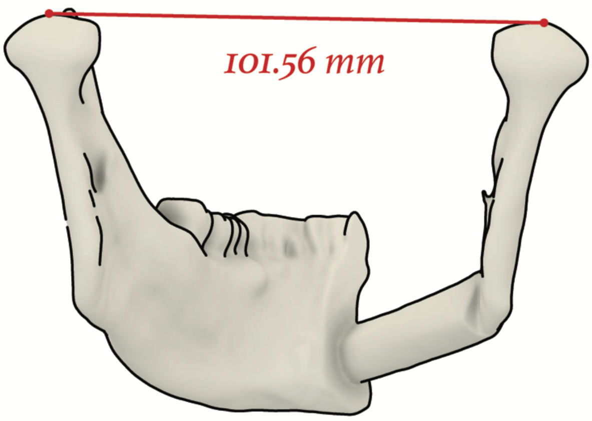


Fig 60. Illustrates the condyle distance measurement

	Minumum	Maximum	Mean	Median	Range	SD
Session A	*1.59*	*10.05*	*5.95*	*5.77*	*8.46*	*3.34*
Session B	*3.60*	*10.55*	*7.21*	*7.15*	*6.95*	*2.79*
Session C	*3.15*	*7.90*	*4.68*	*4.06*	*4.75*	*1.63*

Table 30. Descriptive statistics for deviation (in mm) for the condyle distance for session A-freehand guidance, session B - navigation guidance, and session C - template guidance, from the planned reconstructed mandible model.

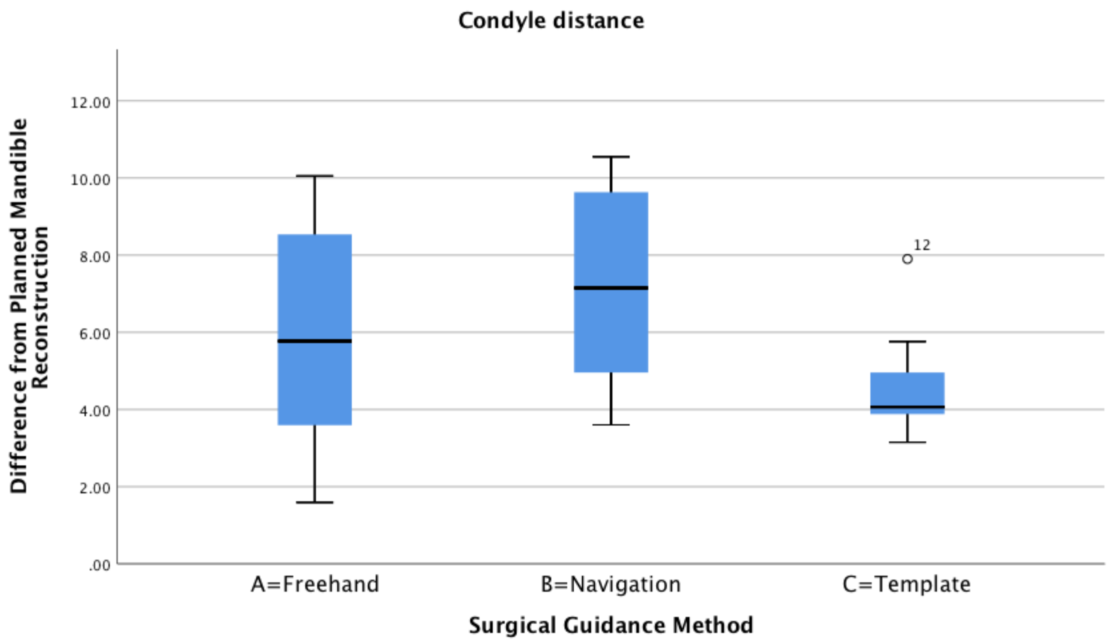


Table 31. Box plot showing the distribution of the deviation measurement (in mm) of the condyle distance for session A - freehand, session B - navigation, and session C - template.

2.6.2.10 Gonion Distance

The gonion distance was measured by selecting the right gonion and left gonion. The distance between the left and right gonion points was measured (De Maesschalck et al., 2017; Logan et al., 2013a; van Baar et al., 2019). The gonion distance was calculated using the length measurement tool in Rhino 5.0 (Robert McNeel and Associates Inc., Seattle, Washington, United States of America).

Actual gonion distance was compared to the surgical plan. The planned gonion distance was 87.79 mm.

GONION DISTANCE

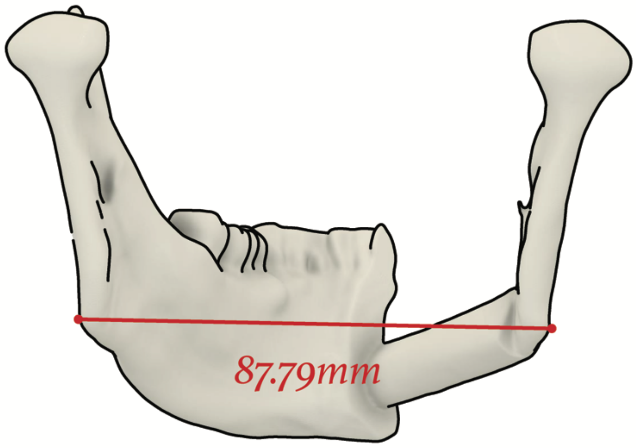


Fig 61. Illustrates the gonion distance measurement

	Minumum	Maximum	Mean	Median	Range	SD
Session A	*0.26*	*9.57*	*3.43*	*2.54*	*9.31*	*3.48*
Session B	*1.72*	*10.77*	*5.79*	*5.59*	*9.05*	*3.72*
Session C	*3.76*	*7.01*	*5.08*	*4.98*	*3.25*	*1.22*

Table 32. Descriptive statistics for deviation (in mm) for the gonion distance for session A-freehand guidance, session B - navigation guidance, and session C - template guidance, from the planned reconstructed mandible model.

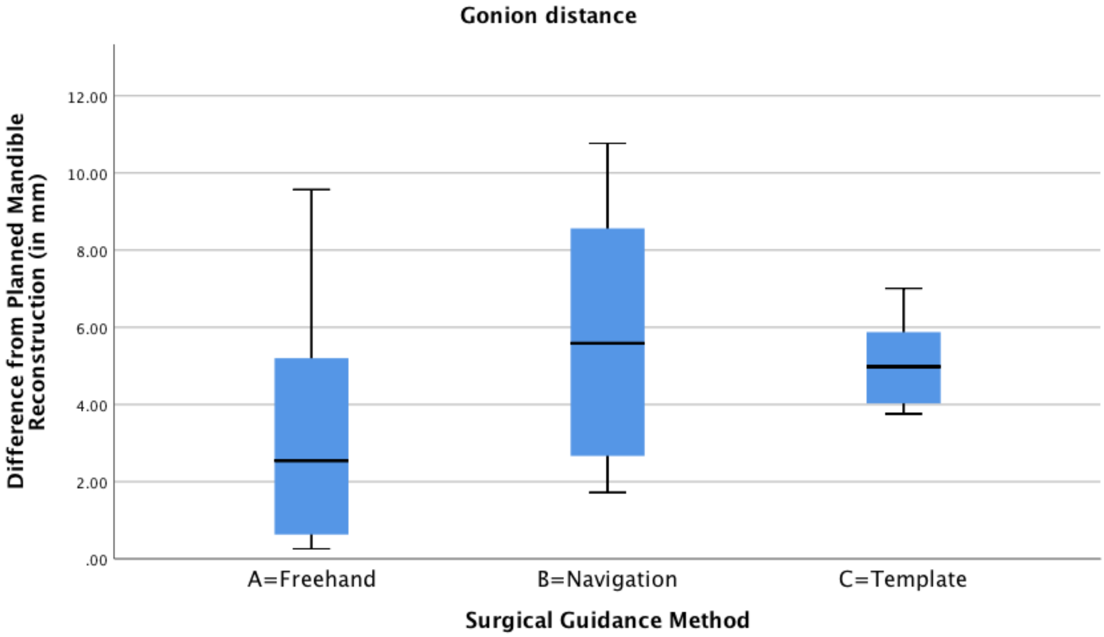


Table 33. Box plot showing the distribution of the deviation measurement (in mm) of the gonion distance for session A - freehand, session B - navigation, and session C - template.

3.6.2.11 Fibula Segment Length

The fibula segment length was measured along the superior surface of the fibula segment. If more than one fibula segment was used in the reconstruction the length of the fibula segments was added. The Fibula segment length was measured by the researcher using digital calipers.

Actual fibula segment length was compared to the surgical plan. The planned fibula segment length was 64.10 mm.

FIBULA SEGMENT LENGTH

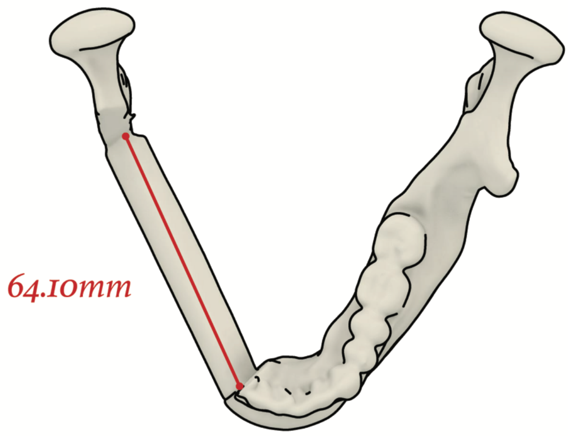


Fig 62. Illustrates the fibula segment length measurement

	Minumum	Maximum	Mean	Median	Range	SD
Session A	*3.34*	*27.94*	*12.25*	*10.06*	*24.60*	*8.09*
Session B	*0.69*	*6.77*	*4.56*	*5.38*	*6.08*	*2.12*
Session C	*0.51*	*2.82*	*1.1*	*0.77*	*0.51*	*0.84*

Table 34. Descriptive statistics for deviation (in mm) for the fibula segment length for session A- freehand guidance, session B - navigation guidance, and session C - template guidance, from the planned reconstructed mandible model.

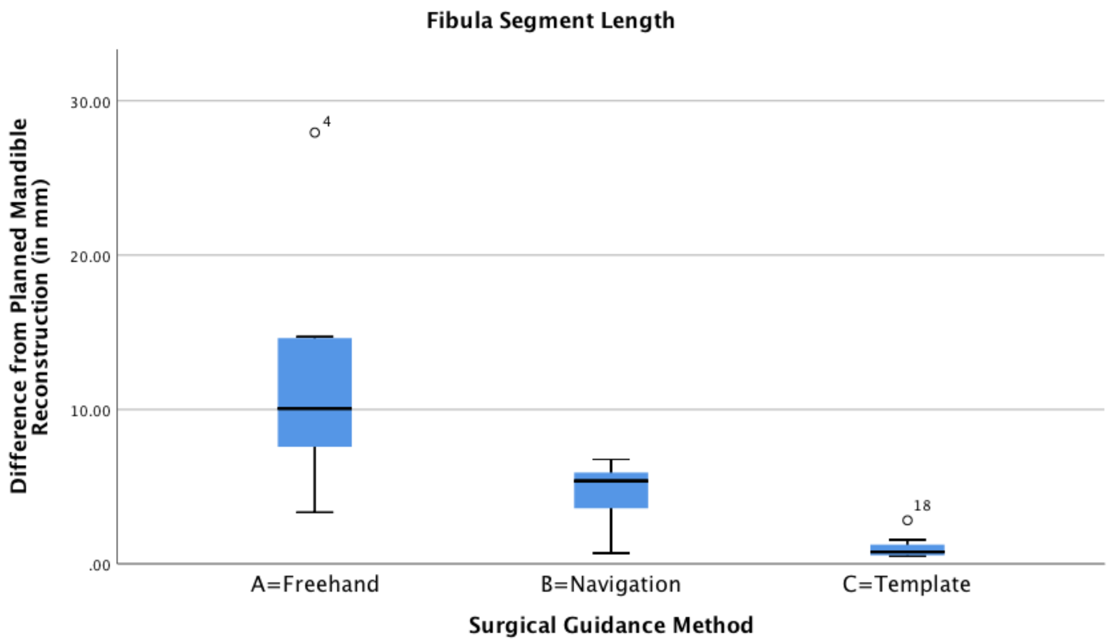


Table 35. Box plot showing the distribution of the deviation measurement (in mm) of the fibula segment length for session A - freehand, session B - navigation, and session C - template.

3.6.2.12 Anterior Inferior Border Distance

The anterior inferior border distance was measured from the most anterior inferior point of the fibula segment to the most inferior point of the anterior mandible osteotomy plane. The anterior inferior border distance was measured by the researcher using digital calipers.

Actual anterior prosthetic space was compared to the surgical plan. The planned anterior prosthetic space was 6.46 mm.

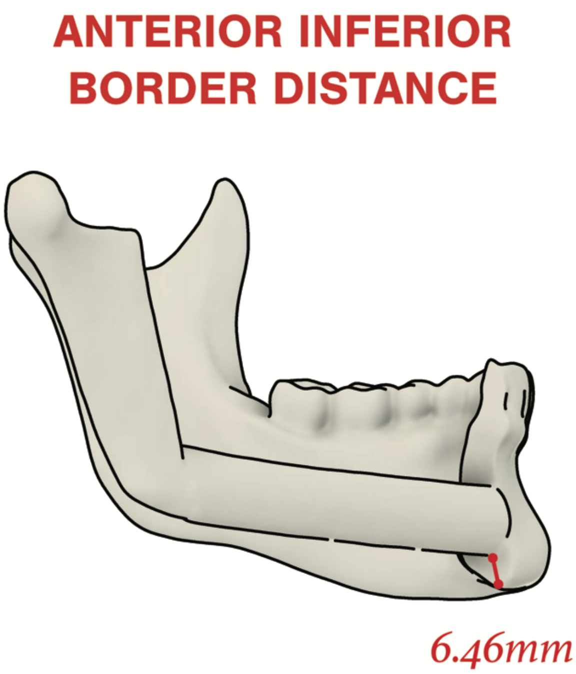


Fig 63. Illustrates the anterior inferior border distance measurement

	Minumum	Maximum	Mean	Median	Range	SD
Session A	2.61	12.11	5.89	4.78	9.50	3.18
Session B	0.28	5.75	2.59	1.81	5.47	2.01
Session C	0.16	3.92	1.92	1.88	3.76	1.39

Table 36. Descriptive statistics for deviation (in mm) for the anterior fibula segment to lower border of the mandible distance or session A-freehand guidance, session B - navigation guidance, and session C - template guidance, from the planned reconstructed mandible model.

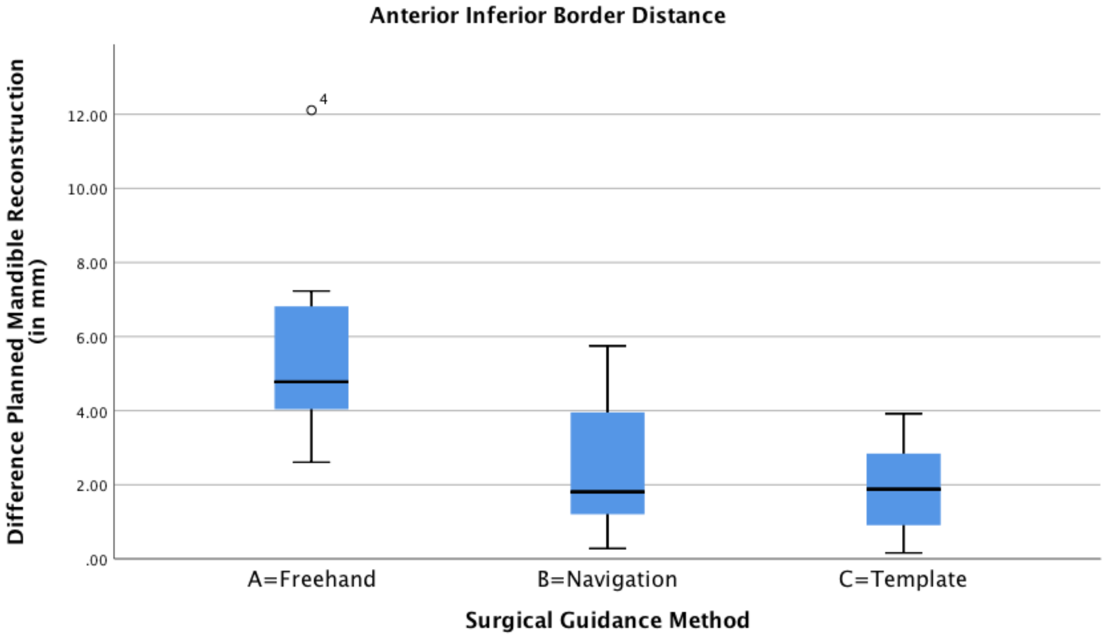


Table 37. Box plot showing the distribution of the deviation measurement (in mm) of the anterior fibula segment to lower border of the mandible distance for session A - freehand, session B - navigation, and session C - template.

3.6.2.13 Posterior Inferior Border Distance

The posterior inferior border distance was measured from the most posterior inferior point of the fibula segment to the most inferior point of the posterior mandible osteotomy plane. The posterior inferior border distance was measured by the researcher using digital calipers.

Actual posterior prosthetic space was compared to the surgical plan. The planned anterior prosthetic space was 0 mm.

POSTERIOR INFERIOR BORDER DISTANCE

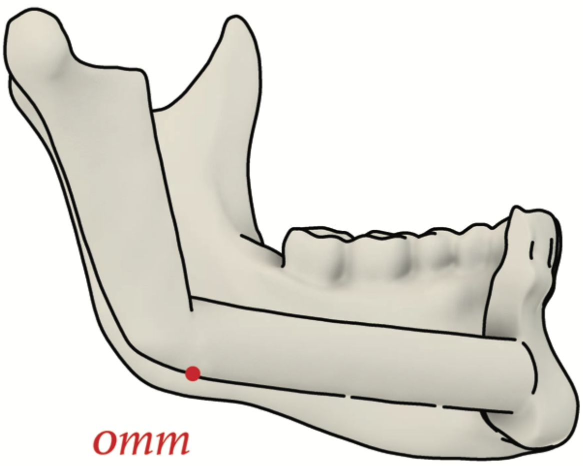


Fig 64. Illustrates the posterior inferior border distance measurement

	Minumum	Maximum	Mean	Median	Range	SD
Session A	*0*	*8.89*	*2.36*	*1.40*	*8.89*	*3.38*
Session B	*0*	*3.43*	*1.18*	*0.54*	*3.34*	*1.23*
Session C	*0*	*2.00*	*1.12*	*1.31*	*2*	*0.71*

Table 38. Descriptive statistics for deviation (in mm) for the posterior fibula segment to lower border of the mandible distance or session A-freehand guidance, session B - navigation guidance, and session C - template guidance, from the planned reconstructed mandible model.

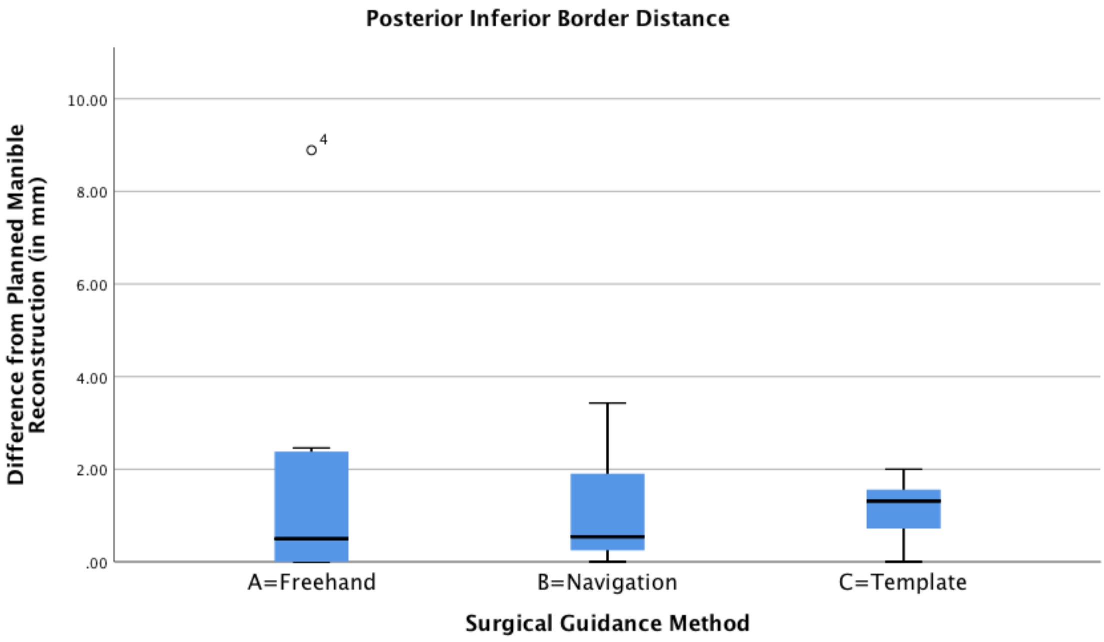


Table 39. Box plot showing the distribution of the deviation measurement (in mm) of the posterior fibula segment to lower border of the mandible distance for session A - freehand, session B - navigation, and session C - template.

3.6.2.14 Intersegment Distance

Intersegment distance was measured from the largest space between fibula segment and native mandible and between fibula segments. Intersegment space was added. Intersegment distance was measured by the researcher using digital calipers.

Actual intersegment distance was compared to the surgical plan. The planned intersegment distance was 0 mm.

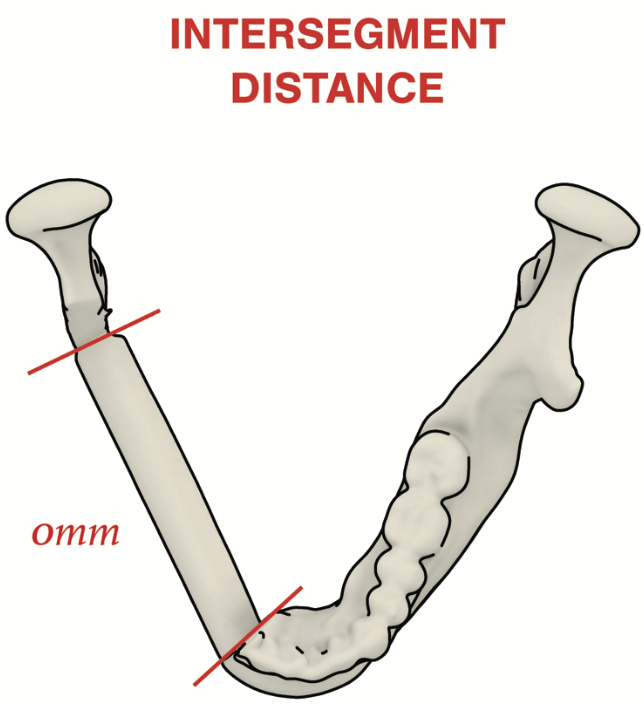


Fig 65. Illustrates the intersegment distance measurement

	Minumum	Maximum	Mean	Median	Range	SD
Session A	*2.35*	*13.94*	*7.44*	*6.62*	*11.59*	*3.57*
Session B	*1.59*	*8.25*	*5.51*	*6.18*	*6.67*	*2.37*
Session C	*0.61*	*5.43*	*3.21*	*3.26*	*4.82*	*1.74*

Table 40. Descriptive statistics for deviation (in mm) for the intersegment distance or session A-freehand guidance, session B - navigation guidance, and session C - template guidance, from the planned reconstructed mandible model.

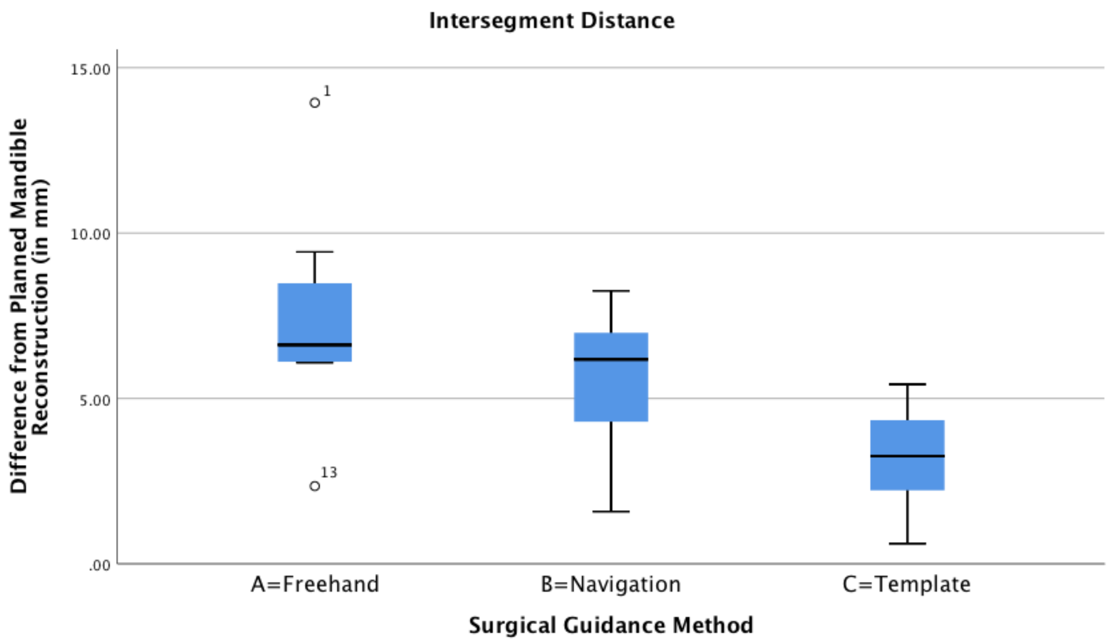


Table 41. Box plot showing the distribution of the deviation measurement (in mm) of the intersegment distance for session A - freehand, session B - navigation, and session C - template.

3.6.2.15 Number of Fibula Segments used to Complete the Reconstruction

The number of fibula segments used to complete the mandible reconstruction was determined by the researcher by counting the number of fibula segments.

Actual number of fibula segments used to complete the reconstruction was compared to the surgical plan.

The planned number of fibula segments used to complete the reconstruction was 1.

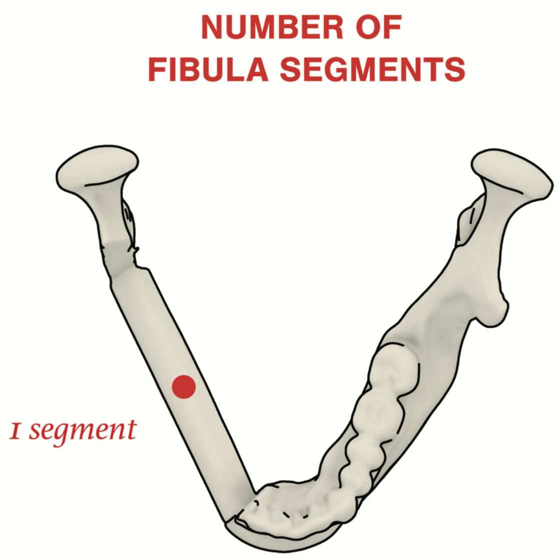


Fig 66. Illustrates the number of fibula segments measurement

In Benchtop session A Participants 035, 303, and 447, used 2 fibula segments each to complete the mandible reconstruction. Participants 253, 747, and 853 used 1 fibula segment to complete the reconstruction.

In Benchtop session B All participants used one fibula segment to complete the reconstruction.

In Benchtop session C all participants used one fibula segment to complete the reconstruction.

Participant ID Code	Session A (# of fibula segments used)	Session B (# of fibula segments used)	Session C (# of fibula segments used)
035	*2*	*1*	*1*
253	*1*	*1*	*1*
303	*2*	*1*	*1*
447	*2*	*1*	*1*
747	*1*	*1*	*1*
790	*1*	*1*	*1*
853	*1*	*1*	*1*

Table 42. Descriptive statistics for the number of fibula segments used in session A-freehand guidance, session B - navigation guidance, and session C - template guidance.

2.6.3 Number of Surgical Plan Corrections Made

The number of surgical plan corrections made was recorded by the researcher during the benchtop sessions. The researcher recorded the number of times the participant corrected the surgical plan in the benchtop recording sheet. Corrections included adjusting the angle for a better fit between the native mandible and fibula segment or two fibula segments, adjusting length of the fibula segment, cutting a new fibula segment, cutting more material off of the mandible for a better fit.

Participant ID Code	Session A (corrections)	Session B (corrections)	Session C (corrections)
035	*2*	*2*	*0*
253	*1*	*0*	*1*
303	*1*	*0*	*0*
447	*5*	*1*	*0*

747	*2*	*0*	*0*
790	*1*	*1*	*0*
853	*2*	*1*	*1*

Table 43. Descriptive statistics for the number of surgical plan corrections in session A-freehand guidance, session B - navigation guidance, and session C - template guidance.

2.6.4 Reconstruction Time

Reconstruction time was recorded by the researcher during the benchtop sessions. The researcher began timing each benchtop session when the participant begin the task and ended recording when the participant verbally informed the researcher they had completed the task. The researcher paused the stopwatch if the participant stopped working to answer a call or take a break and resumed timing when the participant resumed work on the task. The researcher recorded the number of times in the benchtop recording sheet.

The researcher measured reconstruction time using a digital stopwatch.

Participant ID Code	Session A (in minutes)	Session B in minutes)	Session C (in minutes)
035	*48.02*	*73.32*	*50.15*
253	*46.43*	*52.43*	*61.04*
303	*46.28*	*37.24*	*33.28*
447	*132.36*	*57.55*	*83.12*
747	*45.11*	*49.14*	*44.34*
790	*75.56*	*96.38*	*94.04*
853	*82.05*	*80.55*	*95.59*

Table 44. Descriptive statistics for the reconstruction times for session A-freehand guidance, session B - navigation guidance, and session C - template guidance.

	Minimum (in minutes)	Maximum (in minutes)	Mean (in minutes)	SD (in minutes)
Session A	*44.11*	*132.36*	*67.97*	*32.29*
Session B	*37.24*	*96.38*	*63.81*	*20.49*
Session C	*33.28*	*95.59*	*65.94*	*25.07*

Table 45. Descriptive statistics for the number of fibula segments used in session A-freehand guidance, session B - navigation guidance, and session C - template guidance.

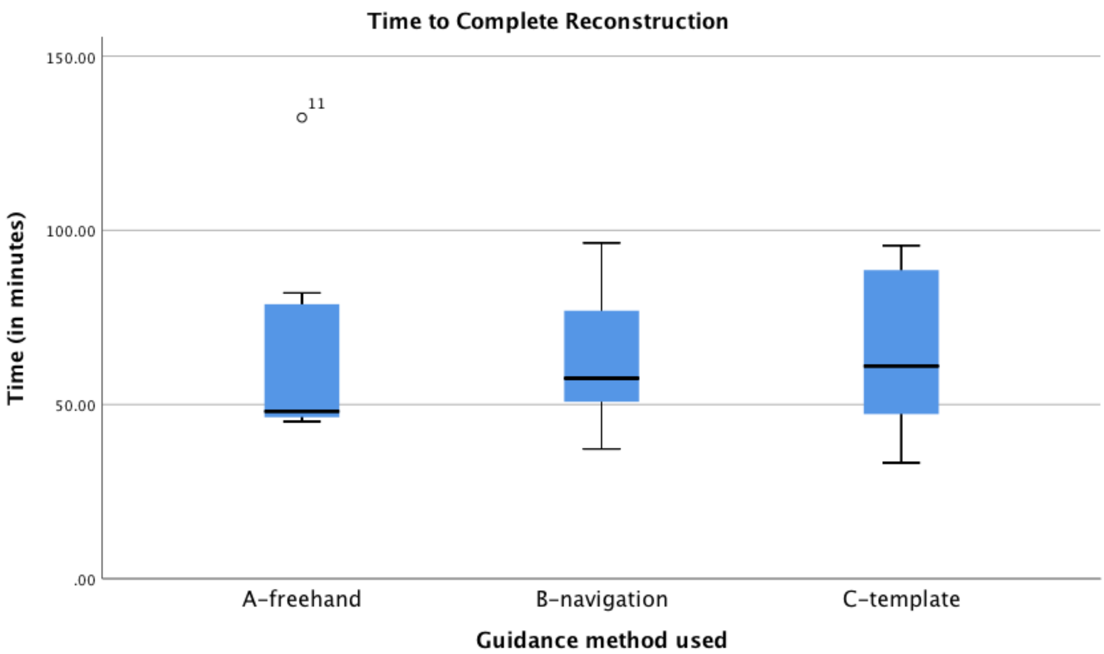


Table 46. Box plot showing the distribution of the deviation measurement (in minutes) of the time to complete reconstruction for session A - freehand, session B - navigation, and session C - template.

Three of seven participants were experienced head and neck staff surgeons and four of seven participants were head and neck surgeon trainees. There was a notable difference in time to complete reconstructions between experienced staff surgeons and surgeon trainees who participated in the benchtop study. Participants 035, 303 and 747 were experienced head and neck surgeons. Participants 253, 447, 790 and 853 were head and neck surgeon trainees. Experiences surgeons completed the benchtop sessions faster than the surgeon trainees.

2.7 Discussion

2.7.1 Hausdorff surface distance

Hausdorff surface distance measurements and coloured 'heat maps' were a valuable tool to compare the reconstructed mandibles completed by participants to the planned reconstruction. The images created using this method are a useful tool to visualize the difference between the actual and planned reconstructions. Using the method outlined in this chapter is was possible to compare two digital reconstructed mandible models (planned and actual). By following the same steps and maintaining the same software program settings the researcher was able to consistently compare the planned and actual mandible reconstruction largely eliminating human error that may influence manual measurements. The images and measurements created with the Hausdorff surface distance functions do not give specific region of location of error, and so it is not possible to trace a specific origin of error. Hausdorff surface distance map tools are very useful when used with manual measurements which can give more specific information regarding the location of the error.

The Hausdorff surface distance data show that fibula mandible reconstructions completed with template guidance deviated from the planned fibula segment the least with an average Hausdorff surface distance of 0.45 mm. Reconstructions completed with navigation were also very accurate with an average Hausdorff distance of 0.63 mm. Reconstructions completed using freehand techniques deviated from the planned fibula segment the most with the average Hausdorff distance at 2.49 mm.

As it was not possible to navigate the fibula during benchtop session B, the researcher wanted to isolate the mandible and fibula osteotomies to determine how accurately navigation assisted the surgeon participants to complete the mandible osteotomies. The reconstructed mandible models created by the surgeon participants were digitally deconstructed by the researcher. Deconstructing the models allowed the researcher to measure how well navigation helped the participants to complete the mandible osteotomies. The Hausdorff surface distance data show that fibula mandible reconstructions completed with template guidance deviated from the planned anterior osteotomy plane the least. However, navigation guidance techniques were a very close second. The Anterior mandible resection plane completed with templates deviated from the plan 0.159 mm on average while navigation resulted in an average Hausdorff surface distance of 0.19 mm. Reconstructions completed using freehand techniques deviated from the planned anterior osteotomy plane the most with the average Hausdorff distance at 0.20 mm. The reconstructions completed with template guidance techniques deviated from the planned posterior osteotomy plane with an average Hausdorff surface distance of 3.29mm. Navigation guidance deviated from the planned posterior osteotomy with an average Hausdorff distance of 3.99mm. Reconstructions completed using freehand techniques deviated from the planned reconstruction the most with the average Hausdorff distance at 7.63mm.

2.7.2 Measures that potentially show a difference between Sessions A, B and C

2.7.2.1 Fibula Segment Length

There was a notable difference in fibula segment length measurements between benchtop sessions A, B and C. The range of fibula segment length was 24.60 mm for benchtop session A, 6.08 mm for benchtop session B and 0.51mm for benchtop session C. 24.09 mm difference in range between benchtop session A and Benchtop session C, and a 5.57 mm difference between benchtop session B and Benchtop session C. The absence of fibula navigation guidance during benchtop session B is reflected in the large range of measurements for benchtop session B. The fibula segment length measurements reflect the consistency achieved through using the additive-manufactured fibula cutting guide and emphasize the importance of using computed-tomography navigation to guide fibula cuts in future studies.

2.7.2.2 Anterior Inferior Border Distance

The anterior inferior border distance indicates how accurately the fibula segment was positioned relative to the native mandible anterior resection plane. In the present study the mean anterior inferior border distance in session A was 5.89 mm while the range was 9.50mm. The mean anterior inferior border distance in session B was 2.59 mm with a range of 5.47 mm. The mean anterior inferior border distance in session C was 1.92 mm with a range of 3.76 mm. This indicates that additive-manufactured surgical templates used in the benchtop session C were the most effective guidance method to accurately positioning the fibula segment relative to the mandible. The freehand technique used in session A was the least effective guidance method to accurately position the fibula segment relative to the mandible anterior resection plane.

2.7.2.3 Intersegment Distance

Intersegment distance measurements revealed a difference between benchtop sessions A, B and C. The mean intersegment distance for benchtop session A was 7.44mm with a range of 11.59mm. The mean intersegment distance for benchtop session B was 5.51 mm with a range of 6.67 mm. The mean intersegment distance for benchtop session C was 3.21 mm with a range of 4.82 mm. The planned intersegment distance was zero, ideally the fibula segment and native mandible should fit flush together for good bone contact. This measurement shows that reconstruction completed in benchtop session C had better contact between fibula segments and native mandible than benchtop session B and A. Contact between fibula segments and native mandible in benchtop session A was the least accurate.

2.7.3 Measures showing potentially no difference between sessions A, B and C

The following measures appeared to show no difference between sessions A, B and C. Right coronal mandibular angle, left coronal mandibular angle, right axial mandibular angle, left axial mandibular angle, right sagittal mandibular angle, left sagittal mandibular angle and posterior inferior border distance. In reviewing the graphs displaying data for the measurements listed above there is significant overlap between the box plots indicating that there is not a significant difference between the three guidance methods used.

2.7.3.1 Condyle distance, and Right Coronal Angle

While there was not a noticeable difference in the mean condyle distance or Mean right coronal angle between sessions A, B, and C it is worth noting that the mean difference from the planned reconstruction in all three benchtop sessions is fairly significant. The mean condyle distance for benchtop session A is 5.95 mm and the range is 8.46 mm. The mean condyle distance for benchtop session B is 7.21mm and the range is 6.95 mm. The mean condyle distance for benchtop session C is 4.68 mm and the range is 4.75 mm. The mean coronal angle measurement for benchtop session A is 5.62 degrees and the range is 8.21 degrees. The mean coronal angle measurement for benchtop session B is 5.66 degrees and the range is 11.57 degrees. The mean coronal angle measurement for benchtop session C is 4.86 degrees and the range is 7.55 degrees.

The large condyle distance and right coronal angle measurements indicate that the condyles may be splayed out of position laterally. The coloured Hausdorff surface maps show that the right condyle typically deviates from the planned reconstruction. The lateral spaying of the reconstructed mandibles could have been caused by the type of hinge joint used to attach the mandible to the skull model during the benchtop studies. A pin hinge joint was used which allowed the condyle to pop out of place once the mandible was cut. It is possible that the hinge style used impacted the condyle distance measurement. The mean condyle distance and right coronal angle is less for benchtop session C and the range of measurements for benchtop session C is significantly less than benchtop session A and B. The mandible fixation frame may have helped to maintain condyle position and reduced the condyle distance measurement.

2.7.3.2 Gonion Distance

There was not a significant difference in the mean gonion distance between sessions A, B, and C however the gonion distance did vary between the three sessions. The mean condyle distance for benchtop session A is 3.43 mm and the range is 9.31 mm. The mean condyle distance for benchtop session B is 5.79mm and the range is 9.05 mm. The mean condyle distance for benchtop session C is 5.08 mm and the range is 3.25 mm.

The large gonion distance measurements indicate that the mandible angles may be splayed out of position laterally. The coloured Hausdorff surface maps show that the right gonion angle often deviates from the planned reconstruction. The pin hinge joint that may be responsible for the lateral splaying the condyle joints may also be responsible the for the gonion distance deviation from the planned reconstruction. A pin hinge joint was used which allowed the condyle to pop out of place once the mandible was cut. The mean condyle distance is less for benchtop session C and the range of measurements for benchtop session C is significantly less than benchtop session A and B. The mandible fixation frame may have helped to maintain the gonion position and reduced the gonion distance measurement.

2.7.3.3 Posterior Inferior Border Distance

There was not a significant difference between sessions A, B and C with regard to the posterior fibula segment to lower border distance. The mean posterior inferior border distance for session A was 2.36 mm and the range was 8.89 mm. The mean inferior border distance for session B was 1.18 mm and the range was 3.34 mm. The mean inferior border distance for session C was 1.12mm and the range was 2 mm. The posterior inferior border distance indicates how accuratly the fibula segment was positioned relative to the native manible posterior resection plane. The planned posterior inferior border distance was 0mm. Traditional freehand fibula mandible reconstruction techniques typically reconstruct the mandible by positioning the fibula on the inferior border of the mandible. The planned reconstuction used in the present study also positioned the fibula segment on the lower border of the mandible which may have lead to greater consistancyin the posterior inferior border distance between sessions A, B and C.

2.7.4 Reconstruction Time

There was not a significant difference in time to complete the reconstruction between Benchtop session A, B and C. The mean reconstruction time for Benchtop session A was 67.97 minutes, the mean reconstruction time for benchtop session B was 63.81 minutes and the mean reconstruction time for benchtop session C was 64.94 minutes. The researcher observed that in general the experienced surgeons completed all benchtop sessions faster than the surgical trainees. Three of seven participants were experienced head and neck staff surgeons and four of seven participants were head and neck surgeon trainees. Participants 035, 303 and 747 were experienced head and neck surgeons. Participants 253, 447, 790 and 853 were head and neck surgeon trainees.

The researcher expected reconstruction times to be faster for benchtop session C than benchtop session A and B. The head and neck surgeons who participated in this study are all experienced using additive-manufactured templates to guide fibula mandible reconstruction surgery, because of participants familiarity with the template guidance method the researcher anticipated that reconstruction times would be faster for session C. Challenges related to additive-manufactured guide fitting could have had an impact on the speed that the reconstructions were completed in benchtop session C. Participants spent more time positioning and repositioning the mandible fixation frame cutting guide than anticipated. The mandible fixation frame and mandible cutting guides were adjusted when placed in the wrong position on the mandible. The small amount of contact space between the mandible and mandible fixation frame and mandible cutting guides may have made them difficult to position correctly.

2.7.5 Surgical Plan Corrections

The number of surgical plan corrections made during the benchtop study was greatest for benchtop session A, and least for Benchtop session C. Each participant made at least one surgical plan correction during benchtop session A with five surgical plan corrections being the most. Four participants made surgical plan corrections during benchtop session B, One participant made two corrections and three participants made one correction three participant did not make a surgical plan correction during benchtop session B. Two participants made one surgical plan correction during benchtop session C, five participants did not make a surgical plan correction during benchtop session C. The number of surgical plan corrections made indicates the ease of use and effectiveness of the surgical guidance method used.

It was anticipated by the researcher that the number of surgical plan corrections made during Benchtop session A would be high because participants were not provided with a surgical plan or a guidance method. Similarly, the novelty of computed tomography navigation guidance, absence of fibula navigation guides, and lack of physical constraints provided during benchtop session B was expected to lead to some errors and corrections. It was however unexpected that participants made corrections during benchtop session C. Additive-manufactured surgical guides provide a high degree of physical support and have been shown to be very accurate in previous studies (Hirsch et al., 2009; Logan et al., 2013a; Roser et al., 2010; Seikaly et al., 2019; van Baar, Forouzanfar, Liberton, Winters, & Leusink, 2018). Surgical plan corrections made during benchtop session C were due to errors caused by an improperly fitting mandible fixation frame. Participants made corrections to the surgical plan to correct errors caused by the misplaced mandible fixation frame and mandible cutting guides.

2.7.6 Occlusion

Dental occlusion is an important factor to consider when evaluating the outcome of a fibula mandible reconstruction procedure. Dental occlusion guides the fibula mandible reconstruction surgical planning process at the Institute for reconstructive sciences in Medicine (iRSM). The researcher followed iRSM's occlusion driven surgical planning processes and procedures to create the fibula mandible reconstruction and surgical guides used in the present study. An experienced prosthodontist was consulted regarding measuring the occlusion of the reconstructed mandible models created by the study participants, it was determined that it was not possible to objectively measure the dental occlusion of the reconstructed models. The additive-manufactured anatomical models used in this study simulated bony anatomy only, it was not possible to measure the occlusion of the reconstructed mandibles objectively without also simulating muscles and soft tissues. Future studies evaluating guidance methods for fibula mandible reconstruction surgery with patients should consider measuring occlusion to evaluate the success of the mandible reconstruction. The researcher is unaware of a method to objectively measure occlusion using additive-manufactured models reconstructed in a benchtop scenario.

2.7.7 Strengths and Limitations

2.7.7.1 Limitations

Additive-manufactured surgical cutting guides used by participants in benchtop session C were not placed correctly on the mandible consistently by the study participants. Improper placement of the mandible fixation frame and mandible cutting guides that attached to the mandible fixation frame may have led to poorer reconstruction outcomes. Reconstructions completed in benchtop session C using the additive-manufactured surgical guides may not be a true representation of additive-manufactured guided surgery. Based on a literature review and pervious experience using additive-manufactured surgical templates Reconstructions completed using additive-manufactured templates were expected to match closely with the planed reconstruction (Hirsch et al., 2009; Logan et al., 2013a; Roser et al., 2010; Schepers et al., 2013; van Baar et al., 2018).

The design of the hinge joint used to attach the mandible to the maxilla was not ideal for use in the present study. The pin hinge joints used did not maintain the condyle position once the mandible had been cut during the benchtop study. The condyles popped out of joint during the benchtop session which was frustrating for the researcher and study participants who had to reposition the mandible frequently. The instability of the condyle position may have also impacted the condyle distance, right coronal angle, and gonion distance measurements.

It was not possible to navigate the fibula using the Medtronic Fusion Compact (Medtronic Navigation, Inc. Dublin, Ireland), navigation equipment used in the present study. Instead of navigation participants were provided with 3D digital models, and 2D illustrations of the fibula and cutting guides with measurements to guide the fibula cuts during benchtop session B. The inability to navigate the fibula during benchtop session B was a limitation of the study. Participants commented that it was difficult to use the 3D digital model and 2D images of the cutting guide and that it may have been easier to complete benchtop session B if they had been able to navigate the fibula.

The benchtop study design was a limitation of the present study. Additive-manufactured models were used to simulate real patient anatomy. Simulating surgery using additive-manufactured models was an effective method to test and compare different methods of surgical guidance however the models used do not replicate human anatomy accurately. Muscles and soft tissues were not simulated in the present benchtop study. Simulating only bony anatomy does not reflect a realistic clinical scenario.

Two of the study participants are members of the researcher's thesis committee. The surgeon participants who were members of the researcher's thesis committee had access to information about the study that could have impacted their behaviour as a study participant. Altered behaviour may have had an impact on the study results.

The small number of participants in the present study was a limitation of the present study. Seven head and neck surgeons participated in the present study. More participants would be necessary to perform inferential statistical analysis.

All participants in this study are familiar with and have experience performing fibula mandible reconstructions using additive-manufactured template guidance. Three study participants had experience completing fibula mandible reconstruction surgery using freehand or unguided methods. No participant had experience using computed-tomography navigation to complete fibula mandible reconstruction. Familiarity with additive-manufactured template guided surgery and freehand reconstruction techniques might have had an impact on the reconstruction outcomes. The following quote was taken from a participant during a convergent interview regarding the potential impact his familiarity with template guided surgery may have had.

> "*A challenge with this study, is that from a surgical perspective, we're all very familiar with this [additive-manufactured template guided surgery]. I've done this many times before. I have practice with it and to go through that process is very quick. With the navigation system, I don't have practice with that. That's the first time I've seen that system. I've used navigation in other circumstances but not for bony reconstruction. So, may not be a completely fair test.*"

All benchtop sessions were completed within a two-week time period. To accommodate the busy schedules of surgeon participants benchtop session were often scheduled and completed within a very short time frame. The short amount of time between benchtop sessions could have resulted in a learning bias. As the participants successfully reconstructed the mandible, they may have brought their experience and practice to progressing benchtop sessions.

2.7.7.2 Strengths

Using additive-manufactured models for this study allowed the researcher to control the surgical case and patient anatomy for each participant and for each condition. Consistency between sessions allowed the researcher to compare reconstructions completed using difference surgical guidance methods directly. Using additive-manufactured anatomical models allowed the researcher to investigate a novel untested method of surgical guidance ethically.

2.7.8 Suggestions for Future Study

The surgical case used in the benchtop model study was relatively simple, single fibula segments was reconstruction surgical case was used. A complicated surgical case requiring many fibula segments to reconstruct a mandible was determined to be too challenging for an initial exploratory study. Future research evaluating CT navigation for fibula mandible reconstruction could employ a more complicated surgical case requiring multiple fibula bone graft segments.

Possible future studies investigating computed-tomography navigation guidance for fibula mandible reconstruction surgery should find a way to navigate or guide the fibula cuts in some way. To perform an acceptable fibula mandible reconstruction both the mandible and fibula cuts should be guided.

Future benchtop studies using similar mandible and maxilla models should consider a different condyle hinge design. The design of the condyle hinge joint should be designed to prevent dislocation of the joint once the mandible has been cut. A ball and socket style joint may me more appropriate hinge design that would allow the mandible to move in a more natural manner and stay in position relative to the skull once cut.

Possible future studies could increase the sample size or alter the study design to allow for inferential statistical analysis to compare freehand, additive-manufactured template guidance, and computed-tomography navigation guidance.

2.8 Conclusion

The purpose of the present study was to evaluate the differences between three methods of fibula free flap mandibular reconstruction in a surgical simulation context. The three methods of guided surgery evaluated were: (A) freehand surgery completed without preoperative planning and intuitively guided by anatomy, (B) CT surgical navigation guided surgery, and (C) additive-manufactured template guided surgery. The outcome measures used to evaluate the three methods of guided surgery were Hausdorff surface distance measures, manual measures, digital measures, duration to complete task, and number of surgical corrections made.

Hausdorff surface distance measurements and coloured 'heat maps' were used to determine the accuracy of the actual reconstructed mandible models completed by participants in benchtop sessions A, B and C compared with the planned mandible reconstruction. Hausdorff surface distance maps were an effective tool to visualize the deviations between the planned and actual reconstructions. The mean and maximum Hausdorff surface distances calculated were a useful to determine what the average and maximum deviations were between the planned and actual mandible reconstructions.

Model measurements were used to evaluate the differences between the planned and actual mandible reconstructions completed by the study participants in the benchtop sessions. Measurements taken of the reconstructed mandible models were taken using digital calipers and using digital measurement tools. The measurements taken from the actual reconstructed models were compared to the planned mandible reconstruction control model. The right coronal mandibular angle, left coronal mandibular angle, right axial mandibular angle, left axial mandibular angle, right sagittal mandibular angle, left sagittal mandibular angle and posterior inferior border distance measurements did not show a significant difference between the three methods of guided surgery. The fibula segment length, anterior inferior border distance, and intersegment length showed a significant difference between A) freehand surgery, (B) computed-tomography navigation guided surgery, and (C) additive-manufactured template guided surgery.

The third outcome measure used to evaluate the three methods of guided surgery was the duration to complete the task. The researcher wanted to determine if there was a difference in time to complete the fibula mandible reconstruction using the three different surgical guidance methods in benchtop sessions A, B, and C. Each benchtop session as timed with a digital stopwatch. The researcher concluded that there was not a significant difference in time to complete task between the three benchtop sessions.

The number of surgical plan corrections made during the benchtop study was the fourth outcome measure used to asses (A) freehand, (B) Computed-tomography navigation guided surgery, and (C) additive-manufactured template guided surgery. The number of surgical plan corrections made indicates the ease of use and effectiveness of the surgical guidance method. Each participant made at least one surgical plan correction during benchtop session A, five participants made surgical plan corrections during benchtop session B, and two participants made surgical plan corrections during benchtop session C.

Based on these four outcome measures preoperative surgical planning and surgical guidance seems to positively impact fibula mandible reconstructions. additive-manufactured template guided surgery seems to produce the most accurate and consistent fibula mandible reconstructions, while freehand surgery produced the least accurate and consistent mandible reconstructions as compared to a planned control model. Computed-tomography surgical navigation guidance resulted in more accurate and consistent fibula mandible reconstructions than freehand surgery but were less accurate and consistent than additive-manufactured templated guided fibula mandible reconstructions.

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Chapter 3: Convergent Interview

3.1 Introduction

Convergent interviewing is a qualitative data collection technique used to gather information through systematic structured interviews (Dick, 2017; Driedger, Gallois, Sanders, & Santesso, 2006; Logan, Wolfaardt, Boulanger, Hodgetts, & Seikaly, 2013b; Rao & Perry, 2003). Convergent interviewing was used in this study to gauge participating head and neck surgeons' perceptions of the three reconstruction methods used during the benchtop sessions. Logan et al. demonstrated that convergent interviewing techniques are an effective method of collecting qualitative information in the field of surgical design and simulation in their article titled 'Pilot study: evaluation of the use of the convergent interview techniques in understanding the perception of surgical design and simulation' (Logan et al., 2013b).

Convergent Interviewing is used to obtain and interpret information regarding individuals experiences, opinions, attitudes, beliefs, and knowledge by conducting a series of interviews that are focused on one topic (Driedger et al., 2006; Rao & Perry, 2003). The researcher conducting the interviews refines and develops questions continuously based on the participants responses in the previous interviews. Issues or disagreement of opinion between the interviewees revealed throughout the interview process were analysed and new questions were developed to probe the identified theme; refined questions were asked in the subsequent interviews (Driedger et al., 2006; Rao & Perry, 2003). Convergent interviewing is a flexible iterative process that allows the researcher to examine new information and converge on key issues raised during data collection (Driedger et al., 2006).

Purpose

The purpose of conducting convergent interviews following the model study benchtop sessions was to determine head and neck surgeon's perceptions of virtual surgical planning, digital surgical guides, surgical navigation, and freehand surgical techniques. Interview questions were designed to gauge the participants perception of the different methods of surgery and technology used in the benchtop sessions A, B, and C. The goal of the interview was to determine the participating surgeon's perceptions of ease of use, utility, and value as well as willingness to adopt the surgical methods used during the benchtop study. For a new method or technology to be successfully adopted by head and neck surgeons it must be useful and easy to use in addition to improving surgical outcomes. Understanding head and neck surgeon's perception of using surgical navigation for fibular reconstruction of mandibular defects is essential to the future application of this research.

3.2 Background and Literature Review

3.2.1 Convergent Interview and Surgical design

Convergent interviewing techniques can be effectively used to collect information regarding clinicians' perceptions of surgical design and simulation. In the study titled 'Pilot study: evaluation of the use of the convergent interview technique in understanding the perception of surgical design and simulation' Logan et al describe and evaluate convergent interview techniques as a method to gain a better understanding of the perception of surgical design and simulation amongst clinicians (Logan et al., 2013). In this study five surgeons were interviewed to gain a better understanding of their perception of virtual surgical planning and medical models, and to examine the effectiveness of the convergent interview technique in the field of surgical design and simulation. The researcher began the interview by asking an opening question that was designed to encourage the respondent to speak freely about their personal experiences. The opening question was "I'm interested in learning about the perceived utility of medical modeling and computer-assisted planning software. Tell me what you think of these two tools in your practice." Following the opening question probe questions were asked such as "can you give me an example of this" or "What are the pros and cons of this situation?" The probe questions were designed to keep the respondent talking and focus the conversation on issues related to virtual surgical planning. Once the participant had no more information to share, the researcher concluded the interview by summarizing what was discussed during the interview. Following the conclusion of the interview the researcher reviewed the notes taken during the interview and listened to the audio recording taken during the interview. The researcher reviewed the data collected during the interview and identified key themes. 15 Important issues were identified. Agreements and disagreements between participants regarding the 15 important issues were identified and explained. Participants disagreed on two of the 15 issues. Eight of the fifteen issues were identified as an advantage of the utility of medical modeling, and computer assisted planning software, 6 were identified as disadvantages, and one was neutral. Three issues identified through the convergent interview process had not been previously reported in the literature. The authors of this study concluded that the convergent interviews were an effective method to collect data on the perception of clinicians that allowed the researcher to explore issues not identified by other methods of qualitative data collection.

3.3 Methods

3.3.1 Participants

Study participants were purposively sampled from among head and neck surgeons practising in Edmonton, Alberta. Each participant gave written consent after being informed about the study in line with the Declaration of Helsinki. The experimental procedure was approved by the University of Alberta Health Research Ethics Board under study ID Pro0008298. The participants all had surgical experience. Individuals who participated in this study were required to have participated in the benchtop study detailed in the previous chapter of this thesis. Head and neck surgeons in the Edmonton Alberta area were contacted by the researcher, the surgeons were given information about the study and were asked to sign an informed consent form before proceeding with the study. The convergent Interview took place following the participants completion of benchtop session C.

Inclusion criteria for participating surgeons was as follows:

1. Participant must have completed benchtop study.
2. Participant practices in Edmonton, Alberta Canada
3. Participant has completed 12 weeks of senior rotations in head and neck surgery
4. Participant has experience using image guided surgical navigation
5. Participant has experience performing Fibula free flap mandibular reconstructions

Exclusion criteria for participating surgeons was as follows:

1. Participant did not complete benchtop study.
2. Participant does not practice in Edmonton Alberta, Canada
3. Participant has not completed 12 weeks of senior rotation in head and neck surgery
4. Participant does not have experience using image guided surgical navigation
5. Participant does not have experience performing fibula free flap mandibular reconstructions

3.3.2 Procedure

The convergent interviews with participating head and neck surgeons were conducted following completion of benchtop session C. Rapport had been established with the participants during the benchtop sessions and the researcher was able to begin the interview by asking an opening question relating to the benchtop study that the respondent had just participated in. The researcher asked the opening question *"I'm interested in learning about the value of surgical navigation and virtual surgical planning. Tell me how these tools could be integrated into your practise."* The opening question was adapted from the journal article "Pilot study: evaluation of the use of the convergent interview technique in understanding the perception of surgical design and simulation." By Logan et al. (2013).

The researcher asked probe questions to encourage the respondent to talk more and to keep the interview on topic. Following the conclusion of a convergent interview the researcher listened to the audio recording of the interview to refine interview notes and identify key issues or themes raised by the participant during the interview. As progressive interviews were conducted the researcher identified common themes reported by the respondents and further refined the probe questions. The researcher repeated this process of conducting an interview, reviewing and comparting the information reported by the respondent until two consecutive interviews did not yield any new information. The researcher determined that the saturation point had been reached and stopped conducting interviews.

The researcher transcribed the convergent interviews and reviewed the data. Important themes were extracted by the researcher and agreements or disagreements amongst the respondents were identified by the researcher and recorded.

The following procedure was followed during the convergent interviews. This procedure was adapted from "Utility of Digital Surgical Simulation Planning and Solid Free Form Modeling in Fibula Free Flap Mandibular Reconstruction" (Logan, 2012) and "convergent interviewing essentials" (Dick, 2017).

Step 1	Instructions and clarification of confidentiality were established before the interview. The interviewee will be asked for permission to tape record the interview.
Step 2	**Opening Question:** "I'm interested in learning about the value of surgical navigation and virtual surgical planning. Tell me how these tools could be integrated into your practise."

Step 3	The following probe questions were used to help focus the interview: 1. “Can you give me an example of this?” 2. “Can you elaborate a little?” 3. “What exactly did you mean by…?” 4. “Is that all? Is there anything you missed?” 5. “How does that compare with what you said before?” 6. “what are the pros and cons of this situation?” 7. “And how did you feel about that?” 8. “Why do you think this is the case?” 9. “What would have to change in order for…?” 10. “How was… different from …?” 11. “What sort of an impact do you think…?” 12. “What criteria did you use to…?” 13. “How did you decide/determine/conclude…?” 14. “What is the connection between… and…?” 15. “How might your assumptions about… have influenced how you are thinking about…?” 16. “How might that impact…?” 17. “Could you tell me how … might apply to…?” 18. “What are the advantages of…?” 19. “What are the disadvantages of…?

Step 4	Inviting a summary: As the interview begins to finish, the interviewer will invite the respondent to review key points from what was discussed. Questions such as **"of all the themes you have mentioned what are the most and least important issues?" and "Could you please prioritize them in order of importance?" "You've participated in three benchtop session using different surgical guidance techniques, could you compare these three methods?"** will be asked.
Step 5	Concluding the interview: When the interviewee can no longer add further information, the interviewer will summarize the interview to confirm the responses. The interviewer will review what will happen to the information and how the interviewee can access it.

Table. 47. Convergent Interview procedure adopted from Logan et al. (2013) and Dick 2017

3.4 Results

6 interviews were conducted before reaching stability. The seventh study participant was not interviewed as the previous two interviews yielded no new information and the researcher determined that saturation had been reached.

3.4.1 Interview interpretation and coding

Summary of Themes Raised in Convergent Interviews

1. The physical support, or physical constraints provided by additive-manufactured surgical templates is an advantage of additive-manufactured based surgical guidance methods.

2. The accuracy of additive-manufactured template guidance method is an advantage of additive-manufactured template based surgical guidance methods.

3. The ease of use of additive-manufactured template guidance techniques is an advantage of additive-manufactured template based surgical guidance methods.

4. The inflexibility of additive-manufactured surgical templates is a disadvantage of additive-manufactured template guided fibula mandible reconstruction surgery.

5. The challenge of correctly positioning or fixating additive-manufactured surgical guides on a patient's anatomy is a disadvantage of additive-manufactured template guided fibula mandible reconstruction surgery.

6. The computed-tomography navigation session (benchtop session B) was more challenging to complete than the additive-manufactured template guided session (benchtop session C) in the present benchtop study.

7. The inability to navigate the fibula model using computed tomography navigation during the present benchtop study was a disadvantage of computer tomography navigation based surgical guidance.

8. The absence of physical support or physical constraints provided by computed tomography navigation is a disadvantage of computed-tomography navigation based surgical guidance.

9. The potential to use CT navigation with other technology, or surgical guidance methods could be beneficial. Technology and surgical guidance methods mentioned by participants included surgical robotics, augmented reality, virtual reality, additive-manufactured surgical templates, tumour mapping, and expanded navigation capabilities.

10.The potential for reduced soft tissue disruption is an advantage of computed-tomography navigation guidance for fibula mandible reconstruction.

11. The potential to make intra-operative surgical plan adjustments is an advantage of computed tomography navigation based surgical guidance.

12. The availability of navigation equipment is a potential advantage of computed tomography navigation based surgical guidance.

13. Computed tomography navigation as a method to guide fibula mandible reconstruction is a work in progress.

14. Freehand surgical guidance methods are less accurate than computed tomography based surgical guidance methods and additive-manufactured based guidance methods.

15. Freehand surgical guidance methods are more challenging than computed tomography based surgical guidance methods and additive-manufactured based guidance methods.

16. It is important for surgical trainees to learn traditional or freehand surgical techniques.

17. Participation in the present benchtop study was a beneficial training exercise for surgical trainees.

Agreements and disagreements on themes raised by study participants

Theme	253	303	447	747	790	853
1	y	y	y	y	y	y
2	y	y	y	y	y	y
3	y	y	y	y	y	y
4	y	y	y	y	y	y
5	y	0	y	y	y	0
6	y	y	y	y	y	y
7	y	y	y	y	y	y
8	y	y	y	y	y	y
9	y	y	0	y	y	y
10	0	0	x	y	y	y
11	y	y	0	0	0	y
12	y	y	0	0	0	y
13	y	y	0	y	0	y
14	y	y	0	y	y	y
15	y	x	y	0	y	y
16	y	y	y	y	y	y
17	y	0	0	y	y	0

Table 48. Agreements and disagreements on these raised by study participants during convergent interviews

Y = agree   *x = disagree*   *0 = neither agree nor disagree*

Theme	Agreement %	Disagreement %	Unfamiliar or not mentioned %
1	*100*	*0*	*0*
2	*100*	*0*	*0*
3	*100*	*0*	*0*
4	*100*	*0*	*0*
5	*67*	*0*	*33*
6	*100*	*0*	*0*
7	*100*	*0*	*0*
8	*100*	*0*	*0*
9	*83*	*0*	*17*
10	*50*	*17*	*33*
11	*50*	*0*	*50*
12	*50*	*0*	*50*
13	*67*	*0*	*33*
14	*83*	*0*	*17*
15	*67*	*17*	*17*
16	*100*	*0*	*0*
17	*50*	*0*	*50*

Table 49. Convergent interview themes agreement and disagreement percentages

Issues 1, 2, 3, 4, 6, 7, 8, and 16 had 100 percent agreement amongst the 6 participants interviewed.

Disagreement on issue 10 *the potential for reduced soft tissue disruption is an advantage of computed-tomography navigation guidance for fibula mandible reconstruction.*

One participant disagreed with the issue. Regarding issue 10, participant 447 said

> "*I'd probably say that this reconstruction, with the additive-manufactured patient specific cutting guides, probably of the three is the one that most eliminates the soft tissue hindrance because you know exactly where it's going to go so you can push just the regional soft tissue out of the way. Whereas, the other ones you're not really sure where your osteotomies are going to be so you might end up being more likely to injure some soft tissue structures."*

Disagreement on issue 15 Freehand surgical guidance methods are more challenging than computed tomography based surgical guidance methods and additive-manufactured based guidance methods.

One participant disagreed with the issue. Regarding issue 15, Participant 303 said

> "*For occlusion-based reconstruction, the cutting guides would be the gold standard. Right now, I would say followed by the intuitive design, and then the navigation…So, it's [navigation] very useful, the technology is there. We have to figure out what's the best way to use it. So, for getting from point A to B, we're not quite there with navigation."*

Issues 5, 9, 10, 11, 12, 13, 14 15 and 17 participants either were unaware or unfamiliar of an issue or the issue did not come up during the convergent interview.

3.5 Discussion

3.5.1 Interpretation of the Results

The purpose of conducting convergent interviews with the head and neck surgeons who participated in the benchtop study was to determine their perceptions of virtual pre-surgical planning, digital surgical guides, surgical navigation, and freehand surgical techniques. The goal of the interviews was to determine the participating surgeon's perceptions of ease of use, effectiveness, and value as well as willingness to adopt the surgical methods used during the benchtop study. Key themes discussed during the convergent interview sessions were identified by the researcher. The important themes listed in the interview interpretation and coding section of this chapter were arranged thematically.

Participants interviewed for the benchtop study had positive views of additive-manufactured surgical templates. They referred to their experience of using the additive-manufactured templates in their clinical practice and during benchtop session C. Participants expressed that additive-manufactured templates were accurate, easy to use, and that the support and control provided by the physical guides was beneficial. Each participant agreed with themes number 1, 2, and 3 which expressed the advantages of additive-manufactured template guides.

> Theme 1. *The physical support, or physical constraints provided by additive-manufactured surgical templates is an advantage of additive-manufactured based surgical guidance methods.*
>
> Theme 2. *The accuracy of additive-manufactured template guidance method is an advantage of rapid-prototyped template based surgical guidance methods.*
>
> Theme. *The ease of use of additive-manufactured template guidance techniques is an advantage of additive-manufactured template based surgical guidance methods.*

Participants expressed that the negative aspects of additive-manufactured surgical guides are that they are inflexible and difficult to position on the patient. Respondents stated that a disadvantage of the additive-manufactured templates is that they are inflexible and cannot be adjusted to accommodate necessary changes in the surgical procedure. Participants reported that additive-manufactured surgical guides can be difficult to manipulate and position on a patient in the operating room due to soft tissue impinging movement or issues placing the surgical guide on anatomy that is difficult to access. Themes number 4 and 5 expressed the disadvantages of additive-manufactured template guides. 100 percent of respondents agreed with theme number 4. *The inflexibility of additive-manufactured surgical templates is a disadvantage of additive-manufactured template guided fibula mandible reconstruction surgery.* 67 percent agreed with theme number 5, while 33 percent did not comment on with theme number 5. *The challenge of correctly positioning or fixating additive-manufactured surgical guides on a patient's anatomy is a disadvantage of additive-manufactured template guided fibula mandible reconstruction surgery.* The following quotes are from respondents who commented on the themes number 4 and 5.

> “ *The advantage is that you get a pretty accurate reconstruction. The disadvantage is that as a tumor grows, your whole plan might be useless, but that's the same for any plan. So, this event is possibly having a useless plan if the tumor grows and you have to go in a resect more, but you can plan that into your plan. The advantage is that you get all of it. You get the whole package. You get the efficiency, you get the accuracy, you get the cost effectiveness, you get the aesthetic reconstruction, which we have shown, and you got the bone in the right place within less than two-millimeter accuracy. It gives you everything. The only disadvantage that it does give you is the plan might not be usable."*

> “ *I think that the hardest thing is getting them secured. Cause again, in the OR there's lots of blood, the bone always has the fascia layer over it, so it makes it quite slippery. You're really trying to anchor this guide on the exact spots where your cuts are right? You're trying to hold it in place, but like I said, there's some blood or whatever the stuffs slippery so it's moving around and then trying to get the screws in the right spot to make sure you get it in. I think from what I've experienced and seen, that's really the toughest part is just getting them anchored in their correct spot without them being off at all. Depending on where the holes are on them. Because the farther back they are that means we have to pull the*

drill, the drill is a very vertical thing it needs a straight shot into where the screw needs to go, So it needs to have an unobstructed straight shot to happen to be able to secure the plate down. That's one challenge with them. If it fits well you get it done, that's great, but I always found that just anchoring the guides on and then anchoring them on correctly was another challenge."

Participants described the disadvantages of using navigation guidance method in benchtop session B during the convergent interviews. Participants reported that the digital surgical guides used with computed-tomography navigation during benchtop session C were more challenging to use than additive-manufactured guides used in benchtop session B. The inability to navigate the fibula was a disadvantage of the navigation session, and the absence of physical support was a limitation of the computed-tomography navigation guidance method. 100 percent agreed with themes number 6, 7, and 8.

> Theme number 6. *The computed-tomography navigation session (benchtop session B) was more challenging to complete than the additive-manufactured template guided session (benchtop session C) in the present benchtop study.*
>
> Theme number 7. *The inability to navigate the fibula model using computed tomography navigation during the present benchtop study was a disadvantage of computer tomography navigation based surgical guidance.*
>
> Theme number 8. *The absence of physical support or physical constraints provided by computed tomography navigation is a disadvantage of computed-tomography navigation based surgical guidance.*

The following quote was taken from a participant during the convergent interview.

> "*You're still relying on the surgeon's hand to make the cuts. It doesn't matter how good you are, you're always going to be off of a little bit in certain directions or [from] tilting the hand a certain way. You're definitely not as precise as with the guides, but it's better than also just freehanding"*

In general respondents were optimistic about the potential of computed-tomography navigation surgical guidance. Participants commented on the potential advantages of computed-tomography navigation guidance during their convergent interviews. The possibility of using navigation with other technology or guidance methods was suggested as a benefit of navigation guided surgery. Participants reported that there was potentially less tissue disruption during navigation guided surgery and that the availability of navigation equipment could be a benefit. Respondents suggested that there would be a learning curve before navigation would be as effective as template guided surgery. 83 percent of the participants agreed with theme number 9 while 17 percent of the participants did not comment. 50 percent agreed, 17 percent disagreed, and 33 percent did not comment on theme number 10. 50 percent agreed and 50 percent disagreed with theme number 11. 50 percent agreed and 50 percent disagreed with theme number 12. 67 percent agreed and 33 percent disagreed with theme number 13.

> Theme number 9. *The potential to use CT navigation with other technology, or surgical guidance methods could be beneficial. Technology and surgical guidance methods mentioned by participants included surgical robotics, augmented reality, virtual reality, additive-manufactured surgical templates, tumour mapping, and expanded navigation capabilities.*
>
> Theme number 10. *The potential for reduced soft tissue disruption is an advantage of computed-tomography navigation guidance for fibula mandible reconstruction.*
>
> Theme number 11. *The potential to make intra-operative surgical plan adjustments is an advantage of computed tomography navigation based surgical guidance.*
>
> Theme number 12. *The availability of navigation equipment is a potential advantage of computed tomography navigation based surgical guidance.*
>
> Theme number 13. *Computed tomography navigation as a method to guide fibula mandible reconstruction is a work in progress.*

The following quotes were said by participants regarding the potential benefits of using computed-tomography navigation-based methods for surgical guidance during the convergent interview process.

> *"Soft tissue considerations are an issue because you're dealing with those as you go along. Navigation, I could see the advantage of that because you're using a single probe that's quite small, that sort of limits the amount of soft tissue manipulation you're going to have to do in order to do your resection. It's sort of a step up from freestyle in that you can still have a surgical plan, but you don't have to worry about the templates attached and, managing soft tissue around that template structure. I can see that potentially is an advantage for that."*

> *It could potentially takeover from the guides. It could. You'd have to get the accuracy pretty much within millimeters. And even if you navigate the instrument, once the instrument tells you you're in the right place, once you turn that instrument on, it doesn't mean that your hands not going to move. You're almost looking at navigation by itself probably won't be great for precise reconstructions, but with robotics you could, cause once the arm locks in you're not going to move. I think that's the ultimate reconstruction, not the navigation. I think the navigation is the way you can navigate a robotic arm or robotic reconstruction."*

An unexpected finding from the convergent interviews was theme number 17. *Participation in the present benchtop study was a beneficial training exercise for surgical trainees.* The researcher hadn't considered that participation in this study could be a learning opportunity for surgical trainees. Participants who agreed with theme number 17 commented that planning and completing a mandible reconstruction from start to finish was a valuable training exercise. Surgical trainees are not typically involved during the surgical planning process and do not often observe or assist fibula mandible reconstruction procedures from start to finish. Three participants agreed with theme number 17, three participants did not comment on theme 17. The following quotes are from two participants who commented on the benchtop study participation during their convergent interview.

“having sessions like this I think is very useful. It’s like carpentry, you have to make sure the joints fit correctly. I think for trainees to focus on the bony side of things and learn how that needs to work, the degree of accuracy you need to have, I think is very beneficial for them. And, the very fact that they can practice on a model like this I think is highly beneficial. Just practicing using the instruments, practicing plating and screwing, things like that. So, as a surgical simulation I think it's a very valuable tool for them.”

“I think this is a very good training tool for us on top of the actual applications. I think doing this without much instruction is quite interesting. because you have some experience and some ideas from what you've seen or heard, but most of us haven't really done this on our own as residents. We've done bits and pieces of it probably but never end-to-end. And I think it's a very cognitive exercise.”

3.6 Conclusion

The objective of conducting convergent interviews with the head and neck surgeons who participated in the benchtop study was to determine their perceptions of A) freehand surgery completed without preoperative planning and guided intuitively by anatomy, (B) computed-tomography navigation guided surgery, and (C) additive-manufactured template guided surgery. The convergent interviews were an effective method to ascertain head and neck surgeons’ view of the three surgical guidance methods used in the benchtop study. Seventeen important issues were reported by respondents. Issues raised by participants included the advantages and disadvantages of additive-manufactured template guided fibula mandible reconstruction, the limitations of computed-tomography navigation guided fibula mandible reconstruction and the potential benefits of computed-tomography navigation guided surgery, and participants reported that freehand surgical techniques and skills were important to learn.

The goal of the interviews was to determine the participating surgeons' perceptions of ease of use, effectiveness, and value as well as willingness to adopt the surgical methods used during the benchtop study. The convergent interview process allowed the researcher to determine the respondent's perceptions of freehand surgery, computed tomography navigation guided surgery, and additive-manufactured template guided surgery. Head and neck surgeon participants consider additive-manufactured surgical templates to be an effective and easy-to-use method of surgical guidance, the only disadvantages reported were that additive-manufactured templates were inflexible and can be difficult to position on the patient in the operating room. Respondents felt that computed-tomography navigation guidance was not as easy to use or as accurate as additive-manufactured templates. Participants reported that some of the potential benefits of computed-tomography navigation guided surgery were the availability of navigation equipment, the potential to adjust the plan intra-operatively, the potential to use navigation with other technologies such as robotics or augmented reality, and the potential to reduce soft tissue disruption. While respondents viewed planned and guided surgery positively all respondents agreed that traditional freehand reconstruction skills and techniques were important to learn.

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Chapter 4: Future Applications of Navigation

4.1 Introduction

Substituting additive-manufactured guides with digital guides and computed-tomography image guided navigation means removing a measure of control and accuracy provided by additive-manufactured guides and templates. The additive-manufactured cutting and drilling guides physically restrict angulation, position, and movement of surgical tools during a procedure; in this way they largely eliminate imprecision due to human errors (Chao et al., 2016). Without the physical control provided by additive-manufactured surgical guides, techniques involving digital guides and image guided navigation have a risk of lower quality surgical outcomes due to inaccuracies (Kong, Duan, & Wang, 2016; Zhu et al., 2016).

Assistive robotic technology is capable of providing physical support to accurately control tool position and angle in relation to the patient's anatomy and the preoperative surgical plan (Chao et al., 2016; Kong et al., 2016; Zhu et al., 2016). Surgical robots can fill the gap left by cutting and drilling guides in the shift from additive-manufactured surgical guides and templates to digital guides and CT navigation. (Carriere, Khadem, Rossa, Usmani, & Sloboda, 2018; Chao et al., 2016; Lehmann, Sloboda, Usmani, & Tavakoli, 2018; Zhu et al., 2016). Robotic technology that has been developed to assist surgeons as they perform fibula free flap mandibular reconstructions has shown promising initial results (Chao et al., 2016; Kong et al., 2016; Zhu et al., 2016). Assistive robotic technology used in collaboration with surgical navigation allows the surgical team to accurately execute the virtual surgical plan.

4.2 Literature Review

4.2.1 Navigation and Robotics

The distribution of actions divided between a human and a robot are classified into three different levels of automation based on level of control shared between the human and robot. Automation level three is when the surgeon has the least control and automation level 1 is when the surgeon has the most control. Level three automation describes a completely automated robotic system that independently executes commands given by a controller, surgeons are not involved in the actions of the robot beyond issuing initial commands; level three automation is not ideal for a clinical setting. (Lehmann et al., 2018). Automation level two describes partial automation, the robotic system follows commands given by a controller while the operator is in charge of the execution of the procedure and the robot supports the surgeon by restricting angulation and movement (Lehmann et al., 2018). Level two automation is referred to as man-in-the-loop, or in the case of a surgical robot, surgeon-in-the-loop; level two automation is essentially a collaboration between the robotic system and the surgeon (Lehmann et al., 2018). With automation level one the robotic system provides feedback to the operator through tactile or visual suggestions based on commands, the operator can exercise their judgement and ignore or accept the suggestions given by the robotic system. Automation level one could be used for surgical applications, but the lack of physical constraints leave room for human error; automation level one does not mimic the physical control provided by additive-manufactured surgical guides as well as automation level two.

Research to date involving robotic systems for executing tasks related to fibula free flap mandibular reconstruction has concentrated entirely on automation level three; the limitations associated with a fully autonomous robotic system make it challenging to integrate into a clinical setting. Robots that have been developed for fibular reconstruction of mandibular defects have been designed to operate autonomously without surgeon involvement (Chao et al., 2016; Kong et al., 2016; Zhu et al., 2016). The major challenge of fully automated surgical robotic systems in a clinical environment is that it is difficult to ensure patient safety without surgeon or clinician involvement. The human body is endlessly complex and variable, this variability creates a difficult environment for a robot to operate in successfully (Lehmann et al., 2018). A pre-programmed robot is not able to respond appropriately to unpredictable outcomes of a procedure or changes in the operating environment, in the context of a human body, in the same way that a surgeon can (Carriere et al., 2018). Robotic technology is an effective tool to assist a surgeon in the operating room, but it cannot yet replace a surgeon.

Surgeon-in-the-loop robotic automation level two enables a collaborative relationship between the surgeon and the assistive robot who share the responsibilities of executing a surgical procedure (Lehmann et al., 2018). Robotic technology developed and tested for other procedures and clinical applications have been designed with automation level two and surgeon participation with good results (Carriere et al., 2018; Lehmann et al., 2018). A level two or surgeon-in-the-loop assistive robot customized for fibula free flap mandibular reconstruction would assist the surgeon as they execute surgical procedures. Surgeons could segment the fibula and position implants with the support of a level two automated robotic system; the robot would restrict angulation and movement of the surgical tools according to the virtual surgical plan while the surgeon remains in control of the execution of the procedure (Carriere et al., 2018). This level of automation leaves the surgeon in control of patients' safety while ensuring that the procedure is executed with a high degree of accuracy (Lehmann et al., 2018).

Assistive robotic technology can be used to segment the fibula accurately and consistently, potentially replacing additive-manufactured cutting and drilling guides. in their article titled 'Pre-programmed robotic Osteotomies for Fibula Free Flap Mandible Reconstruction: a Preclinical Investigation' Chao et al. investigated the feasibility of performing fibula free flap mandibular reconstructions robotically (Chao et al., 2016). The objective of Chao's study was to determine the feasibility of using robotics to reduce the imprecision and unreliability associated with human error when performing fibula osteotomies. In this benchtop study, eighteen osteotomies were performed on additive-manufactured fibulas by an autonomous robot (KUKA robot) according to a virtual surgical plan. The additive-manufactured fibula and virtual surgical plan used in this study were based on an actual patient case. The actions of the autonomous robot were executed according to a virtual surgical plan. Orientation and position of the robot in relation to the fibula was guided by stereotactic navigation, which is similar to image-based navigation. The segmented fibulas were scanned with a high-resolution computed tomography scanner. Following the robotic osteotomies, CT imaging was used to create digital stereolithographic models. The models of the actual fibula segment were superimposed over the models of the planned osteotomies to evaluate how well the robot executed the virtual surgical plan. The two outcome measures used to determine the precision of the osteotomies executed by the robot were fibula segment length variation and osteotomy angle variation. The authors report that the average segment length variation was 1.3 ± 0.4 mm, and the average angular variation was 4.2 ± 1.7°. This means the results of the robotic fibula osteotomies are comparable to osteotomies performed using additive-manufactured cutting guides observed by the authors of this study. 38 fibula osteotomies performed using additive-manufactured cutting guides resulted in a mean difference of 2.4 ± 2.1 mm between planned and actual fibula segment lengths, and a mean angular difference of 3.5 ± 2.7° between planned and actual fibula angles. The authors conclude that the method of performing robotic fibula osteotomies presented in this article achieved a high degree of accuracy and can offer value to surgeons in the operating room.

Autonomous robotic technology is capable of performing fibula mandibular reconstructions as accurately as a surgeon using surgical navigation techniques and more accurately than freehand surgical techniques. In the article titled 'Prospects of Robot-Assisted Mandibular Reconstruction with Fibula Flap: Comparison with a Computer-Assisted Navigation System and Freehand Technique', Zhu et al. investigate the feasibility of robot assisted mandible reconstruction (Zhu et al., 2016). Fifteen fibula mandibular reconstructions were performed on additive-manufactured models simulating the fibula, maxillofacial region, and mandible, and six mandible reconstructions were performed on goats. Reconstructions were completed using three different surgical guidance techniques: an autonomous custom-built robot, image guided surgical navigation, and freehand surgery. Models and animals used in this study were scanned using a multi slice CT scanner; following the reconstructions, imaging was used to create digital stereolithographic models. Digital models of the actual reconstructions were superimposed over the models of the planned reconstructions to evaluate variations between planned and actual outcomes. The mean deviation between actual and planned reconstructions was 1.221 mm from robotic surgery, 1.581 for image guided surgery, and

2.313 mm for free hand surgery. Outcomes for reconstructions performed with the surgical robot were comparable to image guided navigation and far better than freehand surgery. The authors conclude that the robotic system described in their article is a viable option for surgeons when performing fibula free flap mandibular reconstructions.

4.3 Discussion

The results of the model benchtop session and the convergent interviews indicate that CT navigation surgical guidance is a helpful tool to perform fibula mandible reconstruction surgery. However, CT navigation guides as they were used to guide fibula mandible reconstruction surgery in the present study is not currently as precise or as easy to use as additive-manufactured surgical templates. CT navigation and robotics may provide similar results as additive-manufactured surgical guidance. The following quote was taken from a respondent during a convergent interview regarding CT navigation and robotics.

> "*It could potentially takeover from the guides. It could. You'd have to get the accuracy pretty much within millimeters. And even if you navigate the instrument, once the instrument tells you you're in the right place, once you turn that instrument on, it doesn't mean that your hands not going to move. You're almost looking at navigation by itself probably won't be great for precise reconstructions, but with robotics you could, cause once the arm locks in you're not going to move. I think that's the ultimate reconstruction, not the navigation. I think the navigation is the way you can navigate a robotic arm or robotic reconstruction.*"

4.4 Conclusion

CT image guided navigation on its own does not provide the same level of control and accuracy as the current gold standard, additive-manufactured template guidance. Assistive robotic technology used in collaboration with presurgical planning and CT navigation could provide physical support to accurately control tool position and angle in relation to the patient's anatomy and the preoperative surgical plan. The future applications of computed-tomography navigation guidance is in integrating navigation with assistive robotic technology. Surgical navigation used in collaboration with assistive robotic technology could enable the surgical team to accurately execute a virtual surgical fibula mandible reconstruction plan.

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Chapter 5: Conclusion

The First Objective of the present study was to develop a novel method of performing fibula free flap mandibular reconstruction using CT navigation. The researcher successfully applied CT navigation equipment, virtual surgical planning techniques and available software programs to plan and guide fibula mandible reconstruction surgery in a benchtop setting.

The Second Objective was to determine if there is a difference in surgical outcomes between (A), fibula free flap mandibular reconstruction surgery completed without preoperative planning and guided intuitively by anatomy (B), preoperatively planned surgery completed with digital cutting and drilling guides and CT image guided surgical navigation and (C), preoperatively planned surgery completed with additive-manufactured cutting and drilling guides. The researcher determined that there was a difference in surgical outcomes for fibula mandible reconstruction surgery when completed using (A) freehand, (B) navigation and (C) template guidance techniques.

The Third Objective was to determine the perceptions of head and neck surgeons' participating in the proposed study regarding preoperative surgical planning, and image guided surgical navigation. Qualitative convergent interview techniques were used to establish surgeon impressions of the surgical guidance methods used in the model benchtop study.

5.1 Study 1: Model study

5.1.1 Summary

The purpose of the present study was to evaluate the differences between three methods of fibula free flap mandibular reconstruction in a surgical simulation context. The three methods of guided surgery evaluated were: (A) freehand surgery completed without preoperative planning and guided intuitively by anatomy. (B) CT surgical navigation guided surgery, and (C) additive-manufactured template guided surgery.

5.1.2 Conclusion

The model study found that there was a difference in the three methods of fibula free flap mandibular reconstruction. The four outcome measures used to evaluate the three methods of guided surgery, Hausdorff surface distance measures, model measures, duration to complete task, and number of surgical corrections made showed that there was a difference in reconstruction outcomes between (A) freehand surgery completed without preoperative planning or guides of any kind. (B) CT surgical navigation guided surgery, and (C) additive-manufactured template guided surgery. additive-manufactured template guided surgery seems to produce the most accurate and consistent fibula mandible reconstructions, while freehand surgery produced the least accurate and consistent mandible reconstructions as compared to a planned control model. Computed-tomography surgical navigation guidance resulted in more accurate and consistent fibula mandible reconstructions than freehand surgery but were less accurate and consistent than additive-manufactured templated guided fibula mandible reconstructions.

5.2 Study 2: Convergent Interview

5.2.1 Summary

The purpose of conducting convergent interviews following the model study benchtop sessions was to determine head and neck surgeon's perceptions of virtual pre-surgical planning, digital surgical guides, surgical navigation, and freehand surgical techniques. Interview questions were designed to gauge the participants perception of the different methods of surgery and technology used in the benchtop sessions A, B, and C. The goal of the interview was to determine the participating surgeon's perceptions of ease of use, effectiveness, and value as well as willingness to adopt the surgical methods used during the benchtop study.

5.2.3 Conclusion

For a new method or technology to be successfully adopted by head and neck surgeons it must be useful and easy to use in addition to improving surgical outcomes. Understanding head and neck surgeon's perception of using surgical navigation for fibular reconstruction of mandibular defects is essential to the future application of this research.

The convergent interviews were an effective method to ascertain head and neck surgeons' views of the three surgical guidance methods used in the benchtop study. Seventeen important issues were reported by respondents. Themes raised by participants included the advantages and disadvantages of additive-manufactured template guided fibula mandible reconstruction, the limitations of computed-tomography navigation guided fibula mandible reconstruction and the potential benefits of computed-tomography navigation guided surgery, and participants reported that freehand surgical techniques and skills were important to learn.

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Apendix

Appendix A: Information Sheet for Study

Information Sheet for Model Study and Convergent Interview

Title of Research Study: Comparative Benchtop Study Evaluating the Use of Image Guided Surgical Navigation for Fibula Free Flap Mandible Reconstruction Surgery

Contact Names and Telephone Numbers: Please contact any of the individuals identified below if you have any questions or concern

University of Alberta Research Ethics Office:

308 Campus Tower 8625-112 street

Edmonton. Alberta Canada T6G 1K8

Phone: 780-492-0459

Email: reoffice@ualberta.ca

Principal investigator: Dr. Daniel Aalto PhD, MSc.

Communication Sciences and Disorders, Rehabilitation Medicine, University of Alberta

Institute for Reconstructive Sciences in Medicine (iRSM), Misericordia Community Hospital

Email: aalto@ualberta.ca

Researcher: Rinde Johansson

Master's student

Rehabilitation Sciences

Program (MSC-RS) Specialization in Surgical design and Simulation

Edmonton, AB

Email: rinde@ualberta.ca

Background: A graduate student from the faculty of rehabilitation medicine is conducting a study to evaluate the effectiveness of three different surgical guidance techniques. This study is being conducted to determine if there is a difference in surgical outcome between reconstructions of the jaw conducted free hand, with preoperative surgical planning and the fabrication of a additive-manufactured surgical guides, and with preoperative surgical planning and CT image guided navigation.

Purpose: You will also be asked to participate in a benchtop study to evaluate three types of surgical techniques.

Procedures: Participating in this study will involve:

1) Three 60-90 minute study sessions.

   In session A, you will be given a set of surgical instruments and tools, a standardized additive-manufactured model of a mandible with a defect and a standardized additive-manufactured fibula. You will be asked to complete a free-hand reconstruction of the prototyped mandible using the additive-manufactured fibula.

In sessions B, you will be given a set of surgical instruments and tools, a standardized additive-manufactured model of a mandible with a defect, a standardized additive-manufactured model of a fibula, a Medtronic fusion image-guided surgical navigation system, and a digital surgical plan. You will be asked to complete a fibula mandible reconstruction using surgical navigation and digital guides.

In sessions C, you will be given a set of surgical instruments and tools, a standardized additive-manufactured model of a mandible with a defect, a standardized additive-manufactured model of a fibula, additive-manufactured surgical templates and cutting guides, additive-manufactured anatomical models, and a detailed surgical plan. You will be asked to complete a fibula mandible reconstruction using a preoperatively planned surgical plan and bone cutting guides and reconstruction templates.

2) A single 30-60-minute interview will be conducted after the completion of all the benchtop sessions (sessions A, B, and C). The interview will be recorded and all participants can request that the recorder be shut off at any time throughout the interview.

Possible Benefits: There are no direct personal benefits to you as a research participant.

Possible risks: There are no possible risks or hazards.

Confidentiality: Personal information relating to this study will be kept confidential. All model study files and data will be securely stored on and encrypted external hard drive and locked in a filing cabinet in the head and neck simulation laboratory in the clinical sciences building indefinitely. Any research data collected about you during this study will not identify you by name and will be anonymized by a coded number. The coding system will be stored in a locked cabinet at the Head and Neck Simulation Laboratory in the clinical sciences building by the principal investigator. Your name will not be disclosed outside the laboratory. Any report published as a result of this study will not identify you by name.

Voluntary Participation: You are free to withdraw from the research study at any time before the completion of data collection. After completion of data collection data will be de-identified and the participants cannot withdraw from the study. If any knowledge gained from this or any other study becomes available which could influence your decision to continue in the study you will be promptly informed.

Appendix B: Consent form for study

PARTICIPANT CONSENT FORM

Title of Study: Comparative Benchtop Study Evaluating the Use of Image Guided Surgical Navigation for Fibula Free Flap Mandible Reconstruction Surgery

Principal Investigator

Dr. Daniel Aalto, PhD

Assistant Professor,

Faculty of Rehabilitation Medicine, Department of Communication Sciences and Disorders, university of Alberta/ Research Scientist at the Institute for Reconstructive Sciences in Medicine (iRSM)

Email: aalto@ualberta.ca

Phone: 780-492-8938

Co-Investigator(s)

Dr. Daniel O'Connell, MD

Heather Logan, MSc.

Dr. Suresh Nayar, MDS

Dr. Hadi Seikaly, MD

Dr. Mahdi Tavakoli, PhD

Study Coordinator

Rinde Johansson, Master's Student

Rehabilitation Sciences Program, Specialisation in Surgical Design and Simulation

Faculty of Rehabilitation Medicine, University of Alberta

Email: rinde@ualberta.ca

Phone: 587-597-9445

Why am I being asked to take part in this research study? You are asked to be a participant in our study for the development and usability testing of a surgical technique for fibula mandible reconstruction. This will entail using 3D modelling, rapid prototyping, and image guided navigation, to support surgical planning in fibula free flap mandibular reconstruction. If you decide to participate, your participation will help the research team in the prototyping stage of developing a digital method of guided surgery to support surgeons with fibula free flap mandible reconstruction. Approximately five to ten surgeons will participate in this study. Before you make a decision, one of the researchers will go over an information sheet with you. You are encouraged to ask questions if you feel anything needs to be made clearer. You will be given a copy of this form for your records.

What is the reason for doing the study? This study is being done to develop and test a digital method of guided surgery to support surgeons in planning, and executing fibula free flap mandibular reconstructions. The surgical method will be evaluated by conducting a comparative benchtop study. Here you will perform three fibula mandible reconstructions using additive-manufactured models simulating the skull, jaw and fibula using three different surgical methods. Completed reconstructions will be compared to a control model and evaluated to determine how effective the three methods of guided surgery were. An interview will be conducted with you following the comparative benchtop study. The interview will be conducted by the researcher coordinator (Rinde Johansson).

What will I be asked to do? Estimated time required to participate in the study:

-Benchtop session A: 60-90 minutes

-Benchtop session B: 60-90 minutes

-Benchtop session C: 60-90 minutes

-Interview: 30-60 minutes

-Overall time commitment 3.5-5.5 hours

Benchtop Session A: You will be asked to perform a hemimandibulectomy fibula reconstruction on standardized additive-manufactured mandible and fibula. The reconstruction will be performed 'freehand', without a preoperatively designed surgical plan, or surgical guides of any kind.

Benchtop Session B: You will be asked to perform a hemimandibulectomy fibula reconstruction on a standardized 3D additive-manufactured mandible and fibula. The reconstruction will be performed with a preoperatively designed surgical plan, digital cutting guides, and a Medtronic fusion surgical navigation system. The surgical plan and digital cutting and reconstruction guides have been developed by the researcher and designed for use with a Medtronic fusion surgical navigation system. The Medtronic fusion surgical navigation system has been customized for use with additive-manufactured anatomical models.

Benchtop Session C: You will be asked to perform a hemimandibulectomy fibula reconstruction on standardized additive-manufactured mandible and fibula. The reconstruction will be performed with a preoperatively designed surgical plan, and physical additive-manufactured cutting and drilling guides. The surgical plan and additive-manufactured cutting guides have been developed by the researcher

Interview: An interview will be conducted by the researcher.

What are the risks and discomforts? There are no risks associated with the research.

It is not possible to know all of the risks that may happen in a study, but the researchers have taken all reasonable safeguards to minimize any known risks to you.

What are the benefits to me? There are no direct personal benefits to you as a research participant.

Do I have to take part in the study? Being in this study is your choice. If you decide to be in the study, you can change your mind and stop being in the study before data collection is complete, and it will in no way affect you or your clinical practice.

You do not have to answer any questions asked during the convergent interview that you are not comfortable with. The audio and videos recorders can be shut off at any time during the study if you are not comfortable being recorded.

If you choose to opt out of the study, your data will be destroyed, your data will not be used in the publication or dissemination of the results of the study. After completion of the benchtop sessions and the convergent interview your data will be de-identified and you cannot withdraw from the study.

Will my information be kept private? During the study, we will be collecting data about you. We will do everything we can to make sure that this data is kept private. No data relating to this study that includes your name will be released outside of the researcher's office or published by the researchers. Sometimes, by law, we may have to release your information with your name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your information is kept private

Data collected about you during this study such as audio and video recordings will be encrypted and kept securely locked in a filing cabinet at the head and neck simulation lab in the clinical sciences building. Data will be stored indefinitely by the principal investigator; Daniel Aalto.

What if I have questions? If you have any questions about the research now or later, please contact Rinde Johansson (researcher) at 587-597-9445 or Daniel Aalto (principal investigator) at 780-492-8938

If you have any questions regarding your rights as a research participant, you may contact the University of Alberta Health Research Ethics Board at 780-492-2615. This office has no affiliation with the study investigators.

There are no conflicts of interest with respect to remuneration received from the funding agency for conducting or being involved with any part of the study and/or the possibility of commercialization of research findings to declare.

CONSENT

Title of Study: Comparative Benchtop Study Evaluating the Use of Image Guided Surgical Navigation for Fibula Free Flap Mandible Reconstruction Surgery

Principal Investigator: Daniel Aalto | Phone Number: 780-492-8938
Study Coordinator(s): Rinde Johansson | Phone Number: 587-597-9445

Yes		No
	Do you understand that you have been asked to be in a research study?	
☐		☐
	Have you read and received a copy of the attached Information Sheet?	
☐		☐
	Do you understand the benefits and risks involved in taking part in this research study?	
☐		☐

Have you had an opportunity to ask questions and discuss this study?

☐ ☐

Do you understand that you are free to leave the study at any time,

☐ ☐

without having to give a reason and without without penalty

Has the issue of confidentiality been explained to you?

☐ ☐

Do you understand who will have access to your study records?

☐ ☐

Future Contact

Do you agree to be contacted for follow-up or to facilitate future research? ☐ ☐

Who explained this study to you?
____

I agree to take part in this study:

Signature of Research Participant
____

(Printed Name)
____

Date:______________________________

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Investigator or Designee ________________________________ Date __________

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE RESEARCH PARTICIPANT

Appendix C: Model Study Recording Sheets

Benchtop Study Recording Table

Participant ID CODE	
Date	
Benchtop session	
Model ID Numbers	
Time	
Number of Surgical Plan	

Corrections Made	
Comments/Notes / Observations	

Appendix D: Convergent Interview Process Flow Chart

Adopted from: Logan, H. (2012). Utility of Digital Surgical Simulation Planning and Solid

Free Form Modeling in Fibula Free Flap Mandibular Reconstruction. University of Alberta.

https://doi.org/doi:10.7939/R35M62F9W

Logan, H., Wolfaardt, J., Boulanger, P., Hodgetts, B., & Seikaly, H. (2013). Pilot study: Evaluation of the use of the convergent interview technique in understanding the perception of surgical design and simulation. *Journal of Otolaryngology - Head and Neck Surgery*, *42*(JUNE), 1–7. https://doi.org/10.1186/1916-0216-42-40

Rao, S., & Perry, C. (2003). Convergent interviewing to build a theory in under-researched areas: principles and an example investigation of Internet usage in inter-firm relationships. Qualitative Market Research: An International Journal, 6(4), 236–247.

https://doi.org/10.1108/13522750310495328

Reference Group: Surgeons practicing in Edmonton Alberta Canada

1. Contacting the Respondent: Initial contact with potential participants will be established through e-mail of telephone calls. After being given an overview of the research and the purpose of the interview, the respondents will be asked to participate in the interview. When they agree, the venue and time will be decided.

2. Arrange Time and Setting

3. Conduct Interviews

1. State purpose
2. Ask opening question: "opening question?"
3. Keep interviewee talking 45-60 minutes
4. Summary of key issues
5. Follow up on doubtful or ambiguous issues
6. Ask probe question not already answered. (not always used in 1st Interview)

4. Interpret interview: recorded in writing

5. Review the Process: modify approach and/or interview design and probes if needed

1. Interpret Agreements: seek exception
2. Interpret Disagreement: seek explanations
3. Formulate specific questions

6. Recycle: return to Step 3. This is the central cycle of the technique. continue until two succeeding interviews have added no significant information. Then move to step 7.

7. Report: Compile a combined report and decide the next thing to be done.

Appendix E: Convergent Interview Recording Sheet and Interview Script

Convergent Interview Recording sheet and Interview Script

Participant ID CODE	
Date	
Time	
Step 1	Instructions and clarification of confidentiality will be established before the interview. The interviewee will be asked for permission to tape record the interview.
Step 2	Opening Question: “I’m interested in learning about the value of surgical navigation and virtual surgical planning.

	Tell me how these tools could be integrated into your practise."
Step 3	The following probe questions will be used to help focus the interview: 1. "Can you give me an example of this?" 2. "Can you elaborate a little?" 3. "What exactly did you mean by…?" 4. "Is that all? Is there anything you missed?" 5. "How does that compare with what you said before?" 6. "what are the pros and cons of this situation?" 7. "And how did you feel about that?" 8. "Why do you think this is the case?" 9. "What would have to change in order for…?"

	10. "How was… different from …?" 11. "What sort of an impact do you think…?" 12. "What criteria did you use to…?" 13. "How did you decide/determine/conclude…?" 14. "What is the connection between… and…?" 15. "How might your assumptions about… have influenced how you are thinking about…?" 16. "How might that impact…?" 17. "Could you tell me how … might apply to…?" 18. "What are the advantages of…?" 19. "What are the disadvantages of…?

Record Key Points	

Step 4	**Inviting a summary:**

	As the interview begins to finish, the interviewer will invite the respondent to review key points from what was discussed. Questions such as "of all the issues you have mentioned what are the most and least important issues?" and "Could you please prioritize them in order of importance?" "You've participated in three benchtop session using different surgical guidance techniques, could you compare these three methods?" will be asked.
Step 5	**Concluding the interview:** When the interviewee can no longer add further information, the interviewer will summarize the interview to confirm the responses. The interviewer will review what will happen to the information and how the interviewee can access it.

Appendix F: Navigation Study Session A; Objectives and Instructions

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FIBULA MANDIBLE RECONSTRUCTION BENCH TOP STUDY

STUDY PROTOCOL SESSION A: FREEHAND

2019

Material and Equipment list

Models

- ☐ Additive-manufactured fibula
- ☐ Additive-manufactured mandible
- ☐ Additive-manufactured skull with base

Equipment

- ☐ Synthes electric pen tool and foot pedal
- ☐ Synthes reciprocal saw attachment
- ☐ Synthes reciprocal saw blade
- ☐ Synthes drill attachment
- ☐ Synthes drill bit
- ☐ Synthes Angled locking reconstruction plate 6x23 holes 44mm x 214mm
- ☐ Synthes matrix combo plating set
- ☐ Synthes 2.4/3.0mm locking reconstruction and trauma kit
- ☐ Synthes 2.0mm Mandible Trauma kit
- ☐ Cellphone or other device to take pictures and record video during benchtop session
- ☐ Digital stopwatch
- ☐ Eye protection
- ☐ Lab coat
- ☐ Label maker
- ☐ Transparent ruler
- ☐ Calipers
- ☐ Marker, pen, pencil
- ☐ Tape
- ☐ Scissors

- ☐ Cloth drops to cover table
- ☐ Green surgical towels

Materials

- ☐ Benchtop session recording sheet
- ☐ Participant consent form

Objectives:

-Reconstruct the mandible to correct the defect. The defect is indicated by red markings.

-Resect the cancerous tissue with 1cm margins.

-Design the reconstruction to optimize aesthetic and functional outcome.

-Design the reconstruction for oral rehabilitation with osseointegrated implants.

-Design the reconstruction for a 20mm dimension between the upper surface of the fibula and the occlusal plane.

Instructions:

During this benchtop session you will reconstruct a standardized additive-manufactured mandible model using a standardized additive-manufactured fibula. The mandible model is marked with red, the red outline indicates the tumour margins. Please remove the tumor with 1cm resection margins.

A thin strip of leather is attached to the medial aspect of the fibula, the leather strip is designed to simulate the pedicle.

This session will be timed using a stopwatch. I will begin timing this benchtop session when you begin the task, I will stop timing the session when you tell me that you are done. Benchtop session start time, end time, and time to complete task will be recorded by me, however please take as much time as is necessary to complete the task.

Feel free to move or manipulate the models as much as you would like.

I am available to assist you by handing you tools materials, holding models or equipment during this session.

Appendix G: Navigation Study Session B; Objectives and Instructions

FIBULA MANDIBLE RECONSTRUCTION BENCH TOP STUDY

STUDY PROTOCOL SESSION B: NAVIGATION

2019

Material and Equipment list

Models

- ☐ Additive-manufactured fibula
- ☐ Additive-manufactured mandible
- ☐ Additive-manufactured skull with base

Equipment

- ☐ Medtronic Fusion compact™ ENT Navigation system
- ☐ Medtronic AXIEM™ non-invasive patient tracker
- ☐ Medtronic ENT registration probe
- ☐ Medtronic ENT Straight probe
- ☐ Medtronic EM ENT instrument tracker
- ☐ Bite Block
- ☐ Fibula Holder
- ☐ Synthes electric pen tool and foot pedal
- ☐ Synthes reciprocal saw attachment
- ☐ Synthes reciprocal saw blade
- ☐ Synthes drill attachment
- ☐ Synthes drill bit
- ☐ Synthes 2.0mm Mandible Trauma kit
- ☐ iPad
- ☐ Cellphone or other device to take pictures and record video during benchtop session
- ☐ Digital stopwatch
- ☐ Eye protection
- ☐ Lab coat
- ☐ Label maker
- ☐ Transparent ruler
- ☐ Calipers
- ☐ Marker, pen, pencil
- ☐ Tape

- ☐ Scissors
- ☐ Cloth drops to cover table
- ☐ Green surgical towels

Materials

- ☐ Digital surgical plan to simulate planning session
- ☐ Edited DICOM data uploaded into the Medtronic fusion compact system
- ☐ Benchtop session recording sheet
- ☐ Participant consent form

Objectives:

-Reconstruct the mandible to correct the defect.

-Design the reconstruction to optimize aesthetic and functional outcome

-Design the reconstruction for oral rehabilitation with osseointegrated implants

-Design the reconstruction for a 20mm dimension between the upper surface of the fibula and the occlusal plane

-Position the mandible using tape and the bite block provided for proper mandible position and orientation relative to the maxilla.

-Use the illustration of the fibula with cutting planes,and measuring tools to complete the fibula osteotomies.

-Use the pencil or marker provided to mark the position of the cutting planes on the additive-manufactured fibula and mandible models according to the digital cutting guides (Edited CT scan DICOM data). Follow guides for proper angles and dimensions of fibula and mandible osteotomies.

Instructions:

During this benchtop session you will reconstruct a standardized additive-manufactured mandible model using a standardized additive-manufactured fibula. Edited CT scan DICOM data of the mandible has been uploaded into this Medtronic fusion navigation system; these guides have been provided to help you to complete the reconstruction according to a surgical plan. Cutting planes have been included in the CT scans that indicate where to cut the mandible. Use the marking tools (pen, pencil, markers) provided, use the digital DICOM cutting guides to mark the additive-manufactured models to indicate where to cut the *mandible. Using these digital surgical guides, you will perform two mandible osteotomies to resect the mandible.*

Use this illustration of the fibula with cutting planes and measurements to help you to create a fibula segment that matches the and measuring tools to complete the fibula osteotomies. Use the ruler and calipers to measure and mark the resection planes on the additive-manufactured fibula. Use these markings to guide your osteotomies.

The fibula segment will be used to reconstruct the resected mandible. Refer to the digital reconstruction guides to reconstruct the mandible according to the surgical plan.

The mandible model is marked with red, the red outline indicates the tumour margins. A thin strip of leather is attached to the medial aspect of the fibula, the leather strip is designed to simulate the pedicle.

Before we begin, I would like to go over the surgical plan with you (show PDF of mandible resection plan, fibula segmentation plan, mandible reconstruction plan on the iPAD). These images show the surgical plan, you can refer to this document throughout the benchtop session.

You can refer to these digital mandible models throughout this benchtop session. (show the 3D digital presurgical, resected and reconstructed mandible reference models on the iPAD). These models simulate the presurgical mandible, resected mandible and reconstructed mandible.

Please follow the surgical design as closely as possible to ensure the best possible outcome.

This session will be timed using a stopwatch. I will begin timing this benchtop session when you begin the task, I will stop timing the session when you tell me that you are done. Benchtop session start time, end time, and time to complete task will be recorded by me, however please take as much time as is necessary to complete the task.

Feel free to move or manipulate the models as much as you would like.

I am available to assist you by handing you tools materials, holding models or equipment during this session.

Appendix H: Navigation Study Session C; Objectives and Instructions

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FIBULA MANDIBLE RECONSTRUCTION BENCH TOP STUDY

STUDY PROTOCOL SESSION C: TEMPLATE

2019

Material and Equipment list

Models

- ☐ Additive-manufactured fibula
- ☐ Additive-manufactured mandible
- ☐ Additive-manufactured skull with base
- ☐ Additive-manufactured mandible fixation frame
- ☐ Additive-manufactured posterior mandible cutting guide
- ☐ Additive-manufactured anterior mandible cutting guide
- ☐ Additive-manufactured fibula cutting guide
- ☐ Additive-manufactured transfer template
- ☐ Preoperative anatomical model
- ☐ Resected anatomical model
- ☐ Reconstructed anatomical model

Equipment

- ☐ 40mm cutting guide insert
- ☐ Fibula Holder
- ☐ Synthes electric pen tool and foot pedal
- ☐ Synthes reciprocal saw attachment
- ☐ Synthes reciprocal saw blade
- ☐ Synthes drill attachment
- ☐ Synthes drill bit
- ☐ Synthes 2.0mm Mandible Trauma kit
- ☐ iPad
- ☐ Cellphone or other device to take pictures and record video during benchtop session
- ☐ Digital stopwatch
- ☐ Eye protection
- ☐ Lab coat
- ☐ Label maker
- ☐ Transparent ruler

- ☐ Calipers
- ☐ Marker, pen, pencil
- ☐ Tape
- ☐ Scissors
- ☐ Cloth drops to cover table
- ☐ Green surgical towels

Materials

- ☐ Digital surgical plan to simulate planning session
- ☐ Benchtop session recording sheet
- ☐ Participant consent form

Objectives:

-Reconstruct the mandible to correct the defect. The defect is indicated by red markings.

-Resect the cancerous tissue with 1cm margins.

-Design the reconstruction to optimize aesthetic and functional outcome

-Design the reconstruction for oral rehabilitation with osseointegrated implants

-Design the reconstruction for a 20mm dimension between the upper surface of the fibula and the occlusal plane

-Screw external fixator to native mandible for proper ramus orientation.

-Screw patient specific cutting guide to fibula and follow guide for proper angles and dimensions of fibula osteotomies

Instructions:

During this benchtop session you will reconstruct a standardized additive-manufactured mandible model using a standardized additive-manufactured fibula. These additive-manufactured cutting and drilling guides have been provided to help you to complete the reconstruction according to a surgical plan. Using these surgical templates, you will perform two mandible osteotomies to resect the mandible and two fibula osteotomies to create one fibula segment. The fibula segment will be used to reconstruct the resected mandible.

The mandible model is marked with red, the red outline indicates the tumour margins. A thin strip of leather is attached to the medial aspect of the fibula, the leather strip is designed to simulate the pedicle.

Before we begin, I would like to go over the surgical plan with you (show PDF of mandible resection plan, fibula segmentation plan, mandible cutting guides, fibula cutting guides, reconstructed mandible, mandible reconstruction templates). These images show the surgical plan and how to use the additive-manufactured surgical guides.

You can refer to these additive-manufactured mandible models throughout this benchtop session. (shoe the presurgical, resected and reconstructed mandible reference models). These models simulate the presurgical mandible, resected mandible and reconstructed mandible.

Please follow the surgical design as closely as possible to ensure the best possible outcome.

This session will be timed using a stopwatch. I will begin timing this benchtop session when you begin the task, I will stop timing the session when you tell me that you are done. Benchtop session start time, end time, and time to complete task will be recorded by me, however please take as much time as is necessary to complete the task.

Feel free to move or manipulate the models as much as you would like.

I am available to assist you by handing you tools materials, holding models or equipment during this session.

Appendix I: Convergent Interview Transcripts

Convergent Interview Transcript Participant 253

Participant I.D code 253

Interviewer: (00:00)
Participant I.D code two, five, three, convergent interview. I will start with my opening question. I'm interested in learning about the value of surgical navigation and virtual surgical planning. Could you tell me how these tools could be integrated into your practice?

Participant 253 (00:07)

As a trainee in head and neck surgery, I will be working, on treating cancer in the future and both of those techniques should help with guiding the resection as well as the reconstruction for optimal functional outcomes ideally, cause that, functional outcomes is an important aspect of that population.

Interviewer: (00:51)

Okay. Awesome. So now after you've been in this study and you have done the same reconstruction using three different methods, freehand navigation and then template guidance. Could you tell me like a little bit about what that was like? The pros and cons of them, how easy it was to use or even, if you, how you could kind of use them in the OR?

Participant 253: (01:20)
For sure. Yeah. I think from a guidance perspective in terms of what I think really in my level of training and experience with doing the resections and then reconstructions, I think that the more guidance the better. So that's interesting in the fact that you probably need less experience in order to be better at the two guided techniques of the two. The image

guidance and the template guided cuts. I think clearly one of them is a little bit more paint by numbers and that's the, I should say the, the template guide one is, it's a little bit harder to screw up in terms of the cuts and the guide. Whereas if the CT you do, you're figuring out a little bit as you go in terms of, exactly how you're gonna use the tool. I'd be interested from a logistics perspective navigation is probably more common in the world today than places where readily, ready access to, you know, centers that can create template guides. I'm not really sure about that. It'd be interesting if you, if the, the CT navigated or the image navigated technology could be refined if it were, it might be something that's a little bit more accessible and in more remote areas as well. Or at least more centers that are actually using navigation for other reasons, neurosurgery or whatnot. So it depends on, I guess it depends on where you are, but definitely I think it was definitely easier with the guided techniques. And probably easiest in terms of the cutting of the bone with the template guide.

Interviewer: (03:24)
Got It. Okay. That's sweet. You're talking about the common use of navigation. You guys use navigation for sinus surgery.

Participant 253:

Yeah.

Interviewer:

Or, depending on what you're doing, it has a lot of applications.

Participant 253:

Yeah.

Interviewer: (3:43)

So, how was it using, how did it compare using the navigation as we did for reconstructions and resections compared to sinus or whatever you're usually using it for?

Participant 253: (03:54)
So it's in with the sinus. That's a good question. So, with the sinus surgery, a lot of the reasons you're doing this, you're looking in and you have output on the screens. You're using in the scope, you're seeing everything on the inside and you can, you see everything there. But then you don't know what's behind the walls that you're looking at, so you're not really sure what's there. And so that allows you to pinpoint where you are in the field and then within the cavity. Whereas this is a little bit different cause you can, I mean, you can see it, I mean, it's right in front of you, but it does, it tells you exactly where you're supposed to be putting the cuts. So, whereas the sinus you're trying to use the navigation to avoid certain structures and this is more telling you exactly where to go with your cutting. So, it's opposite in terms of what, what the goal is. I think part of, with sinus surgery it's a clean surgery. But it's the, it's relatively easy to keep it sterile as well, but I think that you have any extra moving parts is something that's interesting too. Putting it in the operating room I think it would probably be pretty easy to do it. The other thing too is with the mandible vs sinus surgeries, the mandible moves. So, we talked about that. We you had the two with the mandible closed, or in occlusion, mandible not in occlusion. I think that, I'm glad you thought about that in advance cause otherwise it wouldn't have worked right. But, with sinus surgery is very static and nothing is changing. With a tumor and with science surgery both with navigation and things grow and there is a chance if you don't get things done sooner rather than later and things might be different. But that's the same with template cutting as well. Things could just have a chance of changing.

Interviewer: (06:11)
That was one thing that was brought up in an earlier interview that, because in this case we are talking about this surgical case, cancer patient, there is some sometimes where the tumor grows more than expected or there's, because of the timeframes of things. And it was suggested that navigation could provide the possibility of making adjustments in intraoperatively if that was necessary. Do you think that would be valuable or feasible in the OR?

Participant 253: (06:48)

I think so. I'm trying to think back to what we did yesterday. And I think it could be in a way that with navigation and with software, it probably would be easier to make that plan as opposed to realizing things have changed then have to go back to the lab and get something complete, reprint it in terms of 3D printing. So I think that it's probably a more, would result in a more streamlined process if you had to change the plan on the fly for sure. Yeah. I think that because it's all software or the hardware is going to be in the OR and that doesn't, it's not something that you have to go and get completely changed at a different facility potentially. So I think for sure it has a potential to be more useful in terms of changing the plan on the fly.

Interviewer: (07:45)

Okay, sure. That makes sense. Something else here we're talking about is that it's been a challenge for navigation and doing this surgery using navigation. The mandible is a mobile structure and in this case we are introducing a third structure and trying to kind of make it all come together. How did you find that? That challenge using these three methods of guided surgery?

Participant 253: (08:21)

I think, let's see, I do think that with the one I did it when I did one CT with CT got it, Or the image guided system. I did leave it in, I left it out of occlusion for basically the whole thing. And because I anticipated opening and closing and switching it back and forth on the system would slow me down quite a bit. Whereas with the other systems, even with the template system, it's the same. The mandible moves and you're having to hold it in occlusion and work around the template guides as well, which would be difficult with soft tissue. And I wonder, that's, I mean, that's another point too, is it's probably easier to move around, with the CT or plan with within the soft tissue with this, the image guide as opposed to with the template guide. We talked about that today where the template guides, we want them to be as small as possible with the mandible because of the soft tissue that could get in the way of your instrumentation, whatnot. Whereas with a CT you're not, there is not, you're adding the probe, but if you're, if it really just using to mark it out and kind of create that, it's not going to get in the way once you're actually doing the cuts. I think that'd be something that's useful. The other thing, keeping in mind, keeping that in mind is that once the first cut is made with the CT, or with the image guidance, then you're going to have instability within the structure as well. That's why the fixator is so good with the template guided surgery. It's, the worst of all of them would probably be just freehand for sure, cause it doesn't give you any advantage in terms of where it hinders guessing. It has less moving parts at the same time you're just not going to be as accurate.

Interviewer: (10:24)

Okay, that's good. That's something that, the navigation has been compared it as being a middle ground between freehand and the template guided surgery, do you think that's the case?

Participant: (10:38)

I would say that is accurate for sure. Yeah, absolutely. And I don't, I'm sure down the road it would probably be something important to look at, but costs, you know, cause the cost of the two systems as well. I think having, as opposed to having all the hardware that goes into doing that, the templates, versus just having uploading a CT scan on this, on the NAV system would be a lot cheaper too. So that's where it was. Technically, it's, the planning part of the freehand is free. And I think that's an interesting progression too in terms of the cost. But I think in terms of the, I so wouldn't, I guess speed as well. I'd put it right in the middle of the two of them. In terms of rigidity of the cuts and everything else and their lack of creativity that you need in order to make it happen. It's probably a middle ground here. I think a middle ground is probably a good place to put it. Right in the middle. Yeah. That's good. That's good.

Interviewer: (11:52)

Okay. The other thing that was mentioned before is the template guided surgery, because the cuts are made for you. You just follow the guides.

Participant 253:

Yeah.

Interviewer:

Unless something goes wrong, it's pretty, less cognitively challenging.

Participant 253:

Yeah.

Interviewer:

Whereas with using the CT navigation you have the guides, but you still are trying to mentally stitch together all these 2D images and figure out how to make this 3D model all come together.

Participant: Yeah.

Interviewer:

And then, it's more hands on, you're dealing with something when you're doing freehand.

Partcipant 253:

Yeah.

Interviewer:

Did you, how did you find that?

Participant 253: (12:41)
I think so. It definitely would have, has more of a hands on, you have to think before you do for sure. I picture the learning curve with the image guidance to be quite Steep. So

even though you would get to the accuracy of the templates, I think fairly quickly if you knew how to do a couple of tricks here and there, even after that session that which angle or the proper way to approach it or even with the navigation, making sure that it still was reading close enough to the, or the probe was close enough to actually pick it up. I think that after a few cases, you probably get there, but it does, it would take a little bit of a learning curve, in order to make it a little bit more standardized so that you know exactly what angle you wanted and get you the best points on the mandible to give you your to cuts. whereas, It's pretty hands just completely on your own. But definitely, definitely less cognitively challenging with the templates for sure. It's like you could give that to like a five year old who knows how to put together Lego and they could do that pretty easily. I wouldn't trust them with the saw, but otherwise yeah.

Interviewer: (14:05)
Okay. This is in terms of, how do you feel. With the template guidance where it's set out for you and you have all these external little tools and things. Do you feel like you're losing, as a resident learning how to do mandible reconstruction, that you're losing some of the skills of freehand and do you think that's important?

Participant 253: (14:40)
I do for sure. I think that if someone starts out the training at a centre where they only use template guides and then they ended up in a place where all of a sudden that's not available, which to be honest, I don't really know, but I assume is the vast majority of places. Either they don't have the funding for shipping things in or just don't have the facilities in house. I think that they would be very hard pressed to do that even remotely as accurate as the templates are. For sure, I think as a learning opportunity, it's probably detrimental. In most places you probably do have to do freehand.

Interviewer: (15:39)
Yeah. Right.

Participant 253:

Um, and this is probably close to as much as the experience I've had total in the residency doing this kind of thing. I've done a few sessions, maybe a little bit more in the last four years, but, having done this, I get it is so much easier to get those cuts with that guided template. The free, the free hand, I think you'd be able to just let it go to some degree cause it's like this is all you got and you can kind of do it. There's no way you're gonna get the same accuracy in terms of what your plans are. If you're planning for occlusion or planning for aesthetics or whatnot, the guides is going to be better. That's everything too is what you're planning for may change that a little bit. If you're planning for implants, obviously this is going to be way better, but as a learning opportunity, yeah, I think it's going to be detrimental for sure. Yeah, definitely.

Interviewer: (16:29)
Okay. Something else that's come up is, the soft tissue. We've talked about that a little already, but that has come up in terms of one of the challenges of working with the templates. Because they're, we tried it, I made the footprint on the guide as small I can, but we do have to have some space to fit them on correctly.

Participant 253:

Yeah.

Interviewer:(17:00)

Removing all that soft tissue. How do you feel about that after going through this? How would work with these methods?

Participant 253: (17:13)
I think that flips everything on its head. I think it would be soft tissue would be the most difficult to deal with the templates and preprinted 3D printed templates and obviously the least difficult to deal with, with freehand because you don't have anything in your way. CT is an extra tool. And so, managing that tool around the soft tissue is gonna be difficult. But it would be easier than manipulating the 3d printed templates for sure.

Interviewer: (17:44)

Yeah. Okay. Let's see, what else do I have to go through here? For you, what are your criteria for a good reconstruction and what needs to happen for a good surgical plan to help you to get there? So, you could give me examples of when things have gone really well in the OR using guidance, whether it's freehand or whatever other kinds of methods. Sorry, not freehand, template or something else.

Participant 253: (18:29)

Yeah, I think speed of reconstruction is important. How long something takes and then cost is important too. And I ease of use clearly, making sure that the pieces you need are there. I've seen, I mean, that's what I've seen where, with the templates you need to have all the hardware in place at that time. And I've seen where the one thing is missing and that throws everything off, right. Which obviously is going to be an advantage of with the free hand. I think it depends on your goal of your reconstruction. If your goal is occlusion, then you're gonna want to be as accurate as possible. If your goal is just to put the jaw together then you know, maybe speed is more important in that case. But I think from the U of A, it's really taught me that your functional comes are really important and occlusion being a big part of that. You know, swallowing, mandible configuration does affect that somewhat. And then the ability to put a dental implants in. All of that would be better the more accurate you are. And so, all those would be my things that I would figure would be important in a surgery. Good outcomes. Does that answer your question? I don't know.

Interviewer: (20:04)

Yeah. That's good. So just focusing on the navigation a little bit. With the tools that we had, we couldn't, we had resection plans for the mandible and we had a reconstruction guide for the mandible using the navigation. But, we didn't have, we weren't able to navigate the fibula. How did you find it trying to guide your cuts using that 2d drawing that we had? Was it a useful tool or…?

Participant 253: (20:45)

Yeah, it was useful. Yeah. The 2D tool was useful for sure. And that is a limitation, definitely. The fact that getting those cuts. With my experience I look at. In looking at my reconstruction here, I like it. It's still, the one that I did last night [the reconstruction completed with navigation guidance], I probably put together better. This is probably more accurate [participant pointed at template guided reconstruction] before of course I cut like a quarter of it off and then it doesn't fit together at all. This is good and I also screwed up here. But, I was able to get a good idea of the angles that you were supposed to go at by that 2D picture for sure. Whereas with the free hand, I had no idea, I had no idea what I was aiming for at all. So yeah. Good. Definitely.

Interviewer: (21:41)
Okay. Was the reconstruction guides when you were using, how was it to use the reconstruction guide when you were using the navigation?

Participant 253: (21:52)
When I was using navigation? It was great. In terms of the, the distance to the end of the fibula and the actual length of the segment, that is ideal. I think it gets much, much better than just guessing. For sure. I think it went, I mean it fit in pretty well until I screwed it up. Yeah. It was, it was me. It was operator error.

Interviewer: (22:20)

That's fine. Ok, I don't know which questions I've gone over. oh yeah. Something that came up was tumor mapping. For navigation, what we used it for, like you said, was identifying go here, cut here, put this here. But, would it be valuable to in some way, mark out this is where the tumor is? This was mentioned that there are limitations to that given how we can interpret imaging. I don't think I know anything about but for sure. But would a tool like that'd be useful?

Participant 253: (23:03)
I think so. It's funny cause we had talked about O'Connell and I had talked about doing a study similar to that and with like pet CT scans and guiding resections for tumor margins and that the Oropharynx. I'd be interested to know if that ever became a feasible technology, then that would be more easily integrated with the imaging or the image guidance as well. So you could use it for resection. It's possible. It depends on, I don't

think the technology is there yet. for margin assessment necessarily for the issue of being with CT scans or even with MRIs, it's hard to know exactly where that soft tissue planes are, without taking a look at it directly. That's why the image guidance is good for bone. Like it's a good thing for bones. Bones show up really easily on CT scans. Whereas the issue with tumor mapping is there's a few different modalities that are good at looking at soft tissue one of them is MRI and another one is, not necessarily soft tissue, but tumors. The other is a pet scan. You have to decide, then that still leaves you kind of some uncertainty around it. There's nothing that can really replace the naked eye in terms of tumor margin assessment at this point. But I think the technology could probably, will probably get there eventually. I think that'd be, it'd be interesting considering using it for the guidance for this. If you had margin assessment added on to that I think could be useful tool for sure. Yep.

Interviewer: (24:58)
Okay, cool. let's see, what else do I have to ask? Do you have anything to add to like that you thought of when you were going through this?

Participant 253: (25:07)

I think we talked about ready, but I think that in terms of the time to put everything together, it ended up being the plating, which was I felt, the most variable and difficult to do. I don't, I think that, and that was regardless of the technique, right? You can just make the cuts with the freehand and you can just bend and the plates and then just put in the bone. But, it's the, getting that plate bent properly and getting all the screws in place I found was actually because of the guidance, making it easy and you know, or the template make it easy. I found that, that the actual plating ended up being the hardest thing.

Interviewer: (25:57)
Yes. We spent during these sessions, a lot of time plating the reconstruction, but actually cutting it was kinda easy.

Participant 253: (26:10)
Yeah, for sure. And definitely cause it, the plating, never got any easier. Right? Whereas

the cutting was definitely easier with the different, with the guidance techniques. I don't know if that would change your timings obviously. I don't know by how much.

Interviewer: (26:28)
I asked you already about like experience versus… yes? Okay, good. I think I'm covering everything. If you have, do you feel like you've, do you have anything else to add?

Participant 253: (26:46)
I don't, I don't think so. No, I think I'm good. Yeah, I'm good.

Interviewer: (26:49)
Okay. This was something that was mentioned, going through this as training, to practice. Was doing this study, because in these sessions you essentially have freedom to do this, you have to follow the guides, but to do your reconstruction as you'd like from start to finish. That was mentioned as a useful training tool for residents. Did you find that?

Participant 253: (27:20)
For sure. Yeah, 100%. Like I said, this is, I, got better. I changed my in technique on this last one. And I think if I had just stuck with my technique, I think it would have nailed it. I think it would've been so quick if I just stuck with my original, but I tried to get all fancy.

Interviewer:

So with the big one, big reconstruction plate?

Participant 253:

Yeah, exactly. I would have cause that's what I started with. But even when I learned the first day, and then learned the first morning and the evening, I got better for sure doing it. And then this would have been, if I'd just kept at it my third attempt, I think it would have been much more streamlined even then. I think this is having done three, even though they're all different ways. That's probably, I've done two previous courses, but they're not, the way that this was all set together and the way that the templates were really accurate and fairly high quality. I think that it's probably the best learning experience I've had from this. And that probably includes the OR because you're able to go through it all on your own. It's a great, it was a great learning opportunity for sure. I think could be a great learning tool for residents who would be interested in it. Definitely. Yeah. I think it'd be very important. I really for, I mean, I assume it was [Name redacted] who said that. Cause he'd be in the same position as me and he's really interested in this kind of thing. I'm sure that he found this whole side of this whole sessions super useful, because I know I did.

Interviewer: (28:54)
Okay. That's good to know. Let me, let's see what I've got. Of all the issues that we've talked about related to the pros and cons or how you could integrate these different methods into clinical practice. Could you prioritize what the most important aspects are to some of the least important aspects.

Participant 253: (29:20)

To implementing...? The pros and cons, then implementing them into surgical practice?

Interviewer: (29:26)

Well you could just focus on the pros and cons if that's easier.

Participant 253: (29:29)

Yeah. So I think the pro, probably the, the best pro is, what you're really going for with any kind of guidance is more accuracy. And with more accuracy, you're going to get hopefully better functional outcomes. And I think that functional outcomes are probably top of the list in terms of priorities for reconstruction and then that goes along with patients as well. I think that the patients should always be the number one consideration. And then moving down the list, probably the next. It really, I mean that's a big thing and that's what, that's the goal, right? You want better occlusion. You want better better opportunity to have dental implants. You want to have better functional outcomes.

Obviously, you want your reconstruction to last. I think that works within that as well. but you know, making sure that you have good bone contact and things like that is also important. I guess that would kind of work. I kind of pictured that all as one kind of outcome of the surgery. The next probably most important things would be ease of use, and how quick it goes and then kind of last on the list would be the cost to the system. In terms of how that affects whether or not it's cheap on the freehand side and you balance that out with, you're looking at your least accuracy. But that's really, cost, logistics of actually having the technology, versus accuracy, outcomes, functional outcomes. You're kind of balancing that out between the two. It's hard to list them all. I don't want a spectrum cause I know a lot of the pros go to one side and then a lot of the pros for the opposite end of the spectrum go to somewhere else and then it's more of a balance between, it's hard to say what's better versus worse. I think it's just depends on the system you're working in. But if time and cost wasn't a concern, then obviously functional outcomes and accuracy are going to be number one. But if you're working in a system where you're a little bit strapped for cash, you don't have the technology, you don't have the OR time, then cost effectiveness and speed of the surgery is going to be probably higher. It's different if you're working in Alberta versus like, I don't know, Tasmania or something like that. Or I know Tasmania is pretty good. I think Madagascar or something like that. So that's different. Russia, let's say Russia. I don't even know what's going on in Russia.

Interviewer: (32:12)
Some other, another place.

Participant 253 (32:08)

Yeah, exactly. Another place. Okay.

Interviewer: (32:10)

That's good. Then I think we've done a pretty good job of covering most things.

Participant (32:16)

Okay. I think so. I mean, it's your call and I don't know what I said. I just said lots of words really.

Interviewer: (32:20)

No, it was good. It was really good. Okay. I'll just summarize what we talked about. We talked a little bit about, some of the pros and cons of these different techniques. What it was like to use them, what some of the considerations could be taking this stuff into the OR, or depending on where you are in the world what you're kind of doing.

Participant 253: (32:41)

Yeah.

Interviewer: (32:42)

The challenges of these different methods. let's see, the cognitive challenges associated with some of the different methods. Soft tissue issues, skill level, how that all could impact things and also just training, as a resident, and how that could be helpful.

Participant 253: (33:06)

Definitely helpful

Interviewer: (33:08)

Okay. Did I miss anything? That's kind of a quick summary.

Participant 253: (22:11)

But good.

Interviewer: (33:12)

Okay. I think we're done then. That's it. I'll turn this off.

Convergent Interview Transcript Participant 303

Participant ID code: 303

Interviewer: (00:01)

Okay. You ready to begin?

Participant 303:

Ready.

Interviewer:

Okay. I'm interested in learning about the value of surgical navigation and virtual surgical planning. Could you please tell me how these tools could be integrated into your clinical practice?

Participant 303:

So Which ones?

Interviewer: (00:19)

Surgical navigation and then virtual surgical planning.

Participant 303: (00:23)

Right. So, I guess that's be very different for you because Not different, but I'll tell you what we do. So most of our bone new construction is all digitally planned, virtually plan, we don't use navigation as much. Navigation might help us develop better accuracy, and maybe speed. But already we're at the step where we don't do any of the freehand, the first study that you did, we don't do much of that.

Interviewer: (00:53)

The freehand reconstruction?

Participant: (00:54)

Yes, the freehand one. So almost all of our reconstructions are the last part, the third part, which is, digitally guided cuts, plates and plans. We don't do a lot of a lot of navigation. The navigation that we do is mostly in the floor of the orbit. In the maxilla, where we've done positioning of the different plates in there. So potentially navigation will be very helpful. We'll do general robotics, which is even more helpful.

Interviewer: (01:27)

Okay. So, you already typically, you already use navigation in your clinical practice. How was the way that you use it normally doing reconstruction of the orbit, different than the way we used it today with navigating and reconstructing?

Participant 303: (01:48)

Very similar. So, you put the plate in and then you would actually check where the position of plate is. Orbital floor you reconstruct with a plate, or a prosthesis or bone. but you have to check where that level is so you can get the right bony volume or else the eyeball falls in. So, I don't do that. But we do that at university hospital with Dr. [name redacted]. Yeah. So [name redacted] does that. And I've seen them do that and it works well.

Interviewer: (02:19)

Okay. Then my next question. What are your criteria for an optimal mandible fibula reconstruction? What are you trying to aim for?

Participant 303: (2:33)

Navigation?

Interviewer: (2:35)

Just in general.

Participant 303: (02:36)

You want to get the accuracy within the accuracy of the preplan as opposed to post plan within about 2 millimetres. You need for the mandible, you need to keep the joint in place. You need 3D joint alignment, you need 3D alignment both sides of the mandible. You need the bone realigned with the alveolus so you can get implants and you need the lower border to be cosmetically appealing. Same for myself.

Interviewer: (03:12)

Okay. And how do you determine,

Participant 303: (03:16)

Sorry, for Maxilla you would have to also add nasal patency and the orbits. So, obstructing the orbit, lacrimal system.

Interviewer: (03:23)

Okay. And then I'm kind of working off of that. For you, what are the criteria of a good surgical plan that works well in the OR? You could give an example.

Participant 303: (03:40)

A good surgical plan would be a plan that's efficient. That you use all the implants that you put in. Accurate. Has to be delivered in a timely manner, within two weeks of planning. So, the accuracy of it, the cost effective or cost-effective way to do the reconstruction. That's mostly it.

Interviewer: (04:07)

What do you mean by efficient with the surgical plan?

Participant 303: (04:09)

So efficient means that you're not wasting a lot of time.

Interviewer: (04:13)

Hmm. But with putting it on, taking it off, what?

Participant 303 (04:16)

Right. Yeah. With the, if you saw me with the first experiment, it took me a lot of time to bend that in place. Lots of little cuts, lots of little custom fitting. If you can avoid all of that, you increase your time efficiency, cause time in the OR, I think it's $60 a minute, so very expensive. If you can reduce that time, that'd be better.

Interviewer: (04:39)
Okay. So ,it's just kind of trying to reduce OR time is what you mean, as much as possible.

Participant 303: (04:44)

Yeah.

Interviewer: (04:46)

Okay. How well, in this bench top setting, did the navigation guides meet your criteria of a good surgical plan or a good support to complete the reconstruction?

Participant 303 (05:00)

I would not be able to do the reconstruction of just the guides you gave me. But it allowed me to guide my cuts and get the bone in the right place. As a check, to start, that's a good start. But it's not going to be able to replace the cutting guides that we did, or that free hand bent, cause you saw me cheat a little bit, right? I can't, you can't take the fibula and I tape it to the lower mandible and then make cuts. That's a no, no. But well can't do it. Can't physically do it.

Interviewer: (05:34)

Or the way you marked on the inside of the mandible

Participant 303: (05:39)

Yeah, very hard to do so. I used the navigation advantages to their best abilities. So potentially you could do that. There's no reason why you can't do that with a navigation cutter or marker. But I did cheat a little bit for you. But, but you didn't tell me not to cheat.

Interviewer: (05:57)
I didn't. That's true. It wasn't in the instructions.

Participant 303: (06:02)
But it wouldn't, I would not be able to do the reconstruction without it. Even if I did do the reconstruction would take a long, long time. Because I'd have to recheck all the time, recheck all the time. Recheck, cut, plate, recheck, recheck.

Interviewer: (06:13)
Okay. So, you'd have to be kind of stopping and looking at the nav system constantly.

Participant: (06:16)

Yep.

Interviewer: (06:17)

This was something that was brought up in another conversation, that navigation should only be used as a quick reference. You shouldn't be required to look up all the time or really focus on it very much.

Participant 303: (06:33)
What you really need is what you with the Nav, you really need at an actual navigation on the instruments that your cutting with, which you can do. And you need the navigation up and as you twist it in 3D, when you hit the right parameters that navigation needs to lock. It needs to tell you bullseye, and then once it tells you, pull the button and you cut. You need, it'd be a lot easier if navigation told you where you should stop cutting in 3D.

Interviewer: (07:11)
Would you want some kind of like a sound or some, does it exist? Do you have, have you seen that?

Participant 303: (07:17)
Yep. Yeah, you can do that, but it's just, so this needs to be navigated that the handpiece.

Interviewer: (07:22)

Yeah. The drill.

Participant: (07:24)

And as I'm moving into the right position. As I move it around, you need a target on the screen that tells me where I should be in space. And as I hit the right cuts, it just says this is it. Or, goes green. Red goes green, once it goes green - cut. So that'd be a lot easier than checking with it. With that, I can probably do the surgery. Both for the fibula and the Maxilla, or the fibula and the mandible. But then you'd have to navigate the fibula too and the instruments. I think that's where the leaps going to be because you have to put a screw on the fibula, have to put a screw in the skull but all the technology's there just the navigating screw. So it doesn't move.

Interviewer: (08:21)

What does that, with the system that you're kind of describing, what is it usually used for?

Participant 303: (08:24)

Sinuses.

Interviewer: (8:25)

Sinuses. And is that what you typically use?

Participant 303: (08:29)

Uh huh. navigation used in sinuses. You can, you can navigate the instrument. The technology is there to navigate the instrument with the system so you can navigate the instrument to tell you exactly what you want to go. That would be your next step.

Interviewer: (08:44)

Yeah.

Participant 303: (08:45)

Which you probably won't.

Interviewer: (08:48)

No. Well, no. I mean, I don't think I would want to do giant study like this again probably.

Participant 303: (08:53)

Yeah.

Interviewer: (08:56)

How well the template guides used this benchtop study, meet your criteria for a well-planned guided surgery?

Participant 303: (09:04)

It was perfect. The guides were just bang on.

Interviewer: (09:09)

It's what you want?

Participant 303: (09:10)

Yep.

Interviewer: (09:11)

Okay. And how well did freehand guidance techniques used in this study meet your criteria of a good reconstruction?

Participant 303: (09:17)

Pretty good, but I bet you the free hand techniques didn't get the bone in the right place. You should measure that. The freehand techniques were all along the lower border of the mandible. The lower border of the mandible is not the same as the alveolus.

Interviewer (09:30)

That, is that kind of the traditional way?

Participant 303: (09:35)

That's what everybody does. Lower border of the mandible for cosmesis. And when you come to implant them, you can't because they're not lined up with the maxilla.

Interviewer: (09:43)
All right. Would you say that's what most centers, places or they do use to use a lot of freehand..

Participant 303: (09:50)

99% except us. Everybody except us.

Interviewer: (09:50)

Yeah. Okay, that's really helpful. Thank you. I'm trying to figure out what the order, I should do these questions. If we could figure out a better way to use navigation for doing this reconstruction, what kind of impact do you think navigation and these digital guys that we had for this study would have on planning and performing fibula mandible reconstruction? How could they be integrated into the OR? or how would it impact the way that you work?

Participant 303: (10:31)
It could potentially takeover from the guides. It could, you'd have to get, you'd have to get the accuracy pretty much within millimeters. And even if you, even if you navigate the instrument once, the instrument tells you you're in the right place, once you turn that instrument on, it doesn't mean that your hands not going to move. You're almost looking at navigation by itself probably won't be great for precise reconstructions, but with robotics you could, cause once the arm locks in you're not going to move.

Interviewer: (11:07)
Yes. Yeah. I mean that's something that I think we're all interested in working towards we…

Participant 303: (11:16)
I think that's the ultimate reconstruction, not the navigation. I think the navigation is the way you can navigate a robotic arm or robotic reconstruction.

Interviewer: (11:23)
Have you, this is kind of off topic a little bit. Have you done much with robotic recon surgery, do you use the DaVinci?

Participant 303: (11:32)

Yep. Yeah. For reconstruction of resection of your oral cavity.

Interviewer: (11:34)

Okay. And you like using it?

Participant 303: (11:35)

Yup. Yeah. When you can lock the arms. When you get in the right place you can just lock them.

Interviewer: (11:43)

Yeah, that's pretty cool. The robotics lab that we are working with, they have a DaVinci now to test and practice with, which is pretty cool.

Participant 303: (11:54)
The guys in China now, I don't know if you've ever seen them, but they have a robot that brings the fibula in and places on to the mandible.

Interviewer: (12:04)
Yes. I looked into that study quite a lot. It is cool the way they…

Participant 303: (12:08)
It's cool, but it's very rudimentary. It's not going to help us much. By bringing it in and putting it into the mandible.

Interviewer: (12:14)
And the other thing that we found was challenging is just, as we got into working with the robots and things was just, working in an OR with a space and sterilization procedures and everything. It was just. There's a lot to consider that it was way more complicated than I think we expected.

Participant 303: (12:36)
I think that's going to be, that's going to be the navigation issue too, is you need the system, and then you need to navigate the fibula, you know, navigate the head, navigate the instrument. Sterility and the space is going to be an issue too.

Interviewer: (12:52)
Yeah. That was something that was brought up actually was that, possibly because, because navigation is something that's used in the OR already. The equipment's already there. That was be seen as a benefit of navigation that it wouldn't have to have specialized sterilization procedures or, some of the other, all this external stuff that we have, as a possible benefit. But anyway, I'm asking leading questions now. I'm not supposed to do that.

Participant 303: (13:27)
But you'll probably need two navigation systems.

Interviewer: (13:28)
Yes, yeah.

Participant 303: (13:31)

I'm interviewing you now.

Interviewer: (13:33)

I know, and I've actually, I find it really hard doing these interviews. Not to just start talking. But anyway, what do you see as being the advantages of, the advantages and disadvantages of the template guided surgery?

Participant 303: (13:54)
Yes, there's the advantages is that you get pretty accurate reconstruction. The disadvantages are that as a tumor grows, your whole plan might be useless, but that's the same for any plan. So, this event is possibly having a useless plan if the tumor grows and you have to go in a resect more, but you can plan that into your plan. The advantages is that you get all of it, you get the whole package, you get the efficiency, you got the accuracy, you got the cost effectiveness, you get the aesthetic reconstruction, which we have shown, and you got the bone in the right place within less than two millimeter accuracy. It gives you everything. The only disadvantage that it does give you is the plan might not be usable, and the materials. There's a very few materials that we can print with and sterilize. If that's overcome then it’s a lot easier to translate that plan right now, into 3D from 2D. From virtual to 3D.

Interviewer: (14:56)
Okay. That makes sense. And what are the advantages and disadvantages do you think of navigation and digital guides that we were using in this study today?

Participant 303: (15:07)
Potentially the advantages would be that to get rid of all the cutting darts that you would have. So, sterility might be an advantage to that. The disadvantages that the sheer volume of equipment that you need. The accuracy, efficiency might be okay, depends, we have to do a study about efficiency. And the cost. We’d have to do a cost effectiveness study. Digitally planning and having cutting guides is about eight thousand dollars. I don't know what it would be for the navigation.

Interviewer: (15:48)
Do you think there would be any advantages in terms of, you'd mentioned in talking about the template guided surgery that there is the chance that maybe the tumor grows too much and the plan can’t be used. In terms of equipment and stuff, I don't know. But actually designing the guides, the way we use them for this navigation session was reasonably quick and not more, it would be more expensive to make multiple versions of

the same plan.

Participant 303: (16:24)
Yeah, and we've done that before. To be honest with you, we've never not used a plan, we’ve used part of it. Most of the time the reconstructive surgeons when you teach this part, cause remember we're the only people that do this. When you teach this part, you have to tell your trainees that you have to have the whole package. You'd have to have the free hand intuitive one, packaging and you have to be able to work with navigation. You have to have all the tools. We have done two plans, so [name redacted] I have done two plans before and use one or the other. We've also thrown parts of the plan out. Extending maybe one cut back, parts of plan up and then you just intuitive, intuitive for destruction in the back. You can use 90% of the plan. Most of the time you can use that plan and you could probably do it with your, if you're doing it with navigation or if you're doing it with cutting guides. I don't think It'll change, it's just different plans, different way of doing things. The main disadvantage of these things like navigation and templates is the trainees. If somebody is trained in just this, and this does not work, then they're not doing patients any favors. Cause if they can't reconstruct freehand they have themselves a problem.

Interviewer: (17:36)
Yes. That was something that when we're interviewing some of your, the trainees who are involved in this study. They mentioned the importance of, one of the drawbacks they felt what is inherent in this guided surgery, was they maybe aren't learning. It's still really important to learn the free hand techniques as well. And that maybe if you're becoming too reliant on the technology or the plans and things would be really detrimental to them. As, far as their training. You see that as well?

Participant 303: (18:13)
I would be. You got to think of that. When did we change that plan? We've changed it maybe once in 250 cases.

Interviewer: (18:16)

Really?

Participant: (18:18)

If you could plan it. You plan it correctly.

Interviewer: (18:22)

It's not really necessary.

Participant 303 (18:21)

Yeah.

Interviewer: (18:21)

Okay. So is the worry more than for you training them maybe is that if they end up going to another center where they don't and they'd haven't learned those skills

Participant 303: (18:30)

But they can get it commercially. So yeah. 3Dsystems will do it, Synthes will do it. KLS Martin will do it. No matter where they go they can get those types of instructions.

Interviewer: (18:43)

Have you ever worked with those companies before?

Participant 303: (18:47)

Yeah, they're not cutting edge. What we do here, our reconstruction here is occlusion guided. They're not, they're still on the lower boarder of the mandible. Yeah. And they do it all, so they do the freehand that we, that you saw me do, but to do it digitally. So they even have a huge plate that they print.

Interviewer: (19:11)

Oh yes, I know the one that make custom pre-bent plates.

Participant 303: (19:16)

So they’ve digitized the intuitive portion. You do the intuitive surgery, which you do it on a computer and then they print you plates and guides to translate your intuitive design. Instead of occlusion based. Different. Most people don't see that unless you're pointed out, it's like, hmm. You're still not getting the bone in the right place.

Interviewer: (19:42)

Yeah, I've never seen any of their stuff before.

Participant: (18:43)

Their stuff? It's not bad. It's pretty good. Again, but it's not occlusion based. So we're not looking at reconstructing oral occlusion.

Interviewer: (19:52)

So the prosthodontists here would hate that.

Participant 303: (19:54)

Ya. They hate everything.

Interviewer: (19:58)

Okay. Let me find what the next questions are. In this study how did you feel about using navigation without a fixation frame? That was something that was brought up as being a major drawback.

Participant 303: (20:16)

So navigation was good. I just wouldn't be able to do surgery with the navigation technology right now.

Interviewer: (20:22)

Yeah. Oh I specifically meant, because we, we didn't have any 3D printed tools for the navigation section. Not having the manual fixation frame was mentioned as being…

Participant 303: (20:38)

It would be very helpful to have the mandible fixation frame. But you're trying to get away from that.

Interviewer: (20:45)

Yeah, that was what we were trying to do. Was to have no component of that session 3D printed. I mean, aside from the models that we were cutting the main goal was to have zero 3D printing in that session. So that was what we're trying to do. We had talked a little bit about creating, designing a mandible fixation frame that was adjustable or that could be something that could function like a mandible fixation frame but maybe wouldn't be custom made every single time.

Participant 303: (21:21)

The way you designed it is that nothing is templated, which is fine, which you may not be getting the results that you think you're getting because the difficulty and the time it took to somebody finish with navigation might have been related to the two pieces of the mandible moving at the same time.

Interviewer: (21:41)

Yeah, It was definitely, I mean for me observing it even it was frustrating even. You just want it to hold everything in the right spot.

Participant 303: (21:47)

And that's what a mandible fixation device does for you. Now, there were mandible fixation devices that are commercially available. So the X-fix,

Interviewer: (21:54)

Yes, I was looking at those.

Participant 303: (21:56)

So you could have done an X-fix and navigation that would have worked.

Interviewer: (19:59)

Have you used those before?

Participant 303: (22:00)

Yeah. They were okay.

Interviewer: (22:02)

Do they function more or less the same? What are the advantages of, what do you prefer about the 3D printed patient specific ones?

Participant 303: (22:12)

This is patient specific. It locks in and you get that millimeter accuracy right. Cause with the X-fix, if you screw one wrong turn, one twist more than the other. It just doesn't, it doesn't work. No, it'll just push them out.

Interviewer: (22:31)

Okay. How did you feel about the mandible resection and reconstruction guides that we had available when you're working with navigation here?

Participant 303: (22:36)

That worked okay. Yeah. That worked ok. It wouldn't be very, very difficult though in real life because you can't flip the skull around. And do the back end.

Interviewer: (22:50)

Yeah. You mean cause you were marking the interior of the Manville? And also moving the skull around in weird or lifting it over.

Participant 303: (22:56)

Yeah. And attaching the fibula to it. But the technology is there. We should figure that out. That part. But the technology is there.

Interviewer: (23:21)

What else do I have here that I haven't gone over yet? I'm almost done. Did you have anything else you needed to add? That you felt was important to talk about?

Participant 303: (23:26)

No. You've done great.

Interviewer: (23:27)

Okay, then we can wrap this up and I will… actually before we finish up could I just get you to, with some of the issues that we've talked about relating to these different guidance methods. What were the most important, if you could prioritize them?

Participant 303: (23:47)

So cutting. For occlusion based reconstruction, the cutting guides would be the gold standard. Right now, I would say followed by the intuitive design, and then the navigation.

Interviewer: (24:10)

Okay. That makes sense. One thing that was mentioned, was that, people seem to think that, or rated navigation as being a middle ground between freehand and this [template guidance]. Do you feel, they were maybe talking about it in terms of the guidance that they got because they were still making the cuts freehand, but there wasn't a plan, but you would put it still below freehand?

Participant 303: (24:39)

I would in terms of completing the surgery. It's very useful, the technology is there. We have to figure out what's the best way to use it. For getting from point A to B, we're not quite there with navigation.

Interviewer: (24:51)

Then I guess if you have nothing else to add,

Participant 303: (24:56)

Yeah good.

Interviewer: (24:58)

Okay. I'll summarize then. We talked about some of the pros and cons of these different guidance methods and how they may be or may not be integrated well into the OR. The criteria for good reconstruction, and then also for good surgical planning and a good surgical design. We also talked about, I guess some of the future applications or the future ways that navigation might be used more effectively. And what else? That's a good summary?

Participant 303 (25:31)

Yeah I think so.

Interviewer: (25:33)

Okay, then I'm done. I'll turn this recorder off.

Participant ID code: 447

Interviewer:

Okay thank you. I'm just going to start with my serious question: I'm interested in learning about the value of surgical navigation and virtual surgical planning. Could you please tell me how these tools could be integrated into your clinical practice?

Participant 447:

So personally, this would be a huge benefit in my clinical practise, cause my plan one day hopefully is to have a head and neck cancer surgery based clinical practice, where I'm going to be doing mandibulectomies for patients that have oral cavity cancer and I think that this definitely increases my, the ease with which these reconstructions can be done. It's fairly straightforward, you have these patient specific cutting guides so you don't have to worry about things not fitting properly, pretty much if you just follow the step-by-step approach that's laid out. So, for me I think it would help my practice because it makes things easier for me, more straightforward. And I think it overall, I suspect that the reconstruction would be, at least from my experience doing these three reconstructions, a better reconstruction, so I think it's actually better for the patients cause you have better alignment of the bone with the neo-mandible with the fibula not to mention of course these instructions would be more amenable to dental implantation which would help certainly with patients in terms of dental rehabilitation. So I guess to answer your question, I think in all facets of a patient care this would be very useful in terms of, you know, better functional outcomes, better healing outcomes and better dental rehabilitation.

Interviewer (1:50):

Ok. perfect That's great. What are your criteria for good fibula mandible reconstructions? You're kind of talking about like what would help you to get there, but for you what would you say is a really good reconstruction?

Participant 447:

I would say that a good reconstruction is one that is functional allows the patient to maintain some degree of functionality post-operatively. By that I mean swallowing, speaking, and chewing having the ability to place dental implants should the patient desire that and cosmesis is an important one as well. I would probably say in that order too: functionality, dental implants, and cosmesis would be my criteria for a good reconstruction. So, something that offers those three would be good.

Interviewer:

Ok and what are your criteria. So we've gone through this study using difference methods in terms of the surgical planning and the surgical design what are your criteria for a good a good surgical design and the, talking about even some of the tools that are used, with the templates the 3D printed guides and then with the navigation we had those CT navigation guides. What are the criteria for you for a good surgical plan and guides?

Participant 447:

Well, the one I'm most familiar with is these ones, the patient specific cutting guides the 3D printed models. So, for me, my experience has been that, I've done a few free-hand ones, but I find that, I don't necessarily have a criteria. I find that the one that offers the best reconstruction, that offers those things that we mentioned previously, are is the patient specific cutting guides, the ones with the 3D models and virtual design and simulation. By far.

Interviewer:

What do you like about them?

Participant 447:

I like the ease with which you can do the reconstruction. I feel like you can train people, that you know people that may not be very experienced in this type of reconstruction that may have not done a lot of them. You can relatively easily train people to do this type of reconstruction because it is fairly straight-forward and it's based on a plan that if you follow the steps in the plan, then it's, most of the time I find that you can do it with not tonnes of experience. With, to answer your question, what I find beneficial about this plan or useful about this plan is first and foremost the ease with which it can be done. You don't have to worry so much about getting angles right, which really sometimes your brain doesn't think in that way so you just, so you don't have to think about well am I a few degrees off, or well how well will this angle fit with this neo-mandible, and I think that's really nice. For the patient, you can stabilize the patient in occlusion which is also really nice, you don't have to try to work backwards after you place the mandible try to manipulate it to get better occlusion, it's done for you, which is also helpful.

Interviewer:

Ok. well that's really good. So, in terms of, the 3D printed guides meet your criteria for helping to make a good reconstruction. In this study when we used navigation how, you don't have to just be positive, but how did you find that met your criteria or what were the pros and cons that you found?

Participant 447: The study that we used navigation? The one with the little, that little CT one?

Interviewer:

Yeah.

Participant 447:

What did I, sorry. What was the question again?

Interviewer:

How did it help you to meet your criteria, to create a good reconstruction... or not?

Participant 447:

I thought it was helpful coz it also kind of eliminated the guess work about the angles. I thought it was helpful because it kind of told me where to make my cuts. Which I thought was better than the freehand method where you're kind of relying on a ruler and freehand guess work. So, I found that helpful. Just in terms of the osteotomies. It was helpful in getting the osteotomies right.

Interviewer:

And we had, we weren't able to navigate the fibula so we have that image of the fibula with the measurements how did you find working with that? Was it easy or hard?

Participant 447:

During the, with the navigation one?

Interviewer:

Yeah

Participant 447:

Okay yeah I remember that. I thought it was like, a hardness, I'm going to use my comparison cause that's all I have is the three. I thought it was easier than the freehand, but it was, sorry, but it's harder than the models, than this last session. It was the middle of the road in terms of the ease with which it was able to use.

Interviewer:

When do you usually use navigation in your practice?

Participant 447:

For sinus surgery. Sometimes we'll use it for like skull base biopsies and things like that but put on the sinus surgery or if there's like a sinus tumor that needs to be removed or patients with chronic sinusitis with polyps we use CT navigation to extract tumours or to do polyectomies and things like that.

Interviewer:

And how, was there much difference between the way you use navigation in your normally for sinus surgery versus the way we used it in the study?

Participant 447:

No. No, it was very similar.

Interviewer:

How, what kind of impact, so this is, we talked a lot about and that came up in other conversations is soft tissue being a challenge when you're doing fibula mandible reconstructions. How do you feel that soft tissue displacement is impacted using template guidance, like what we just did, and then also navigation, and freehand.

Participant 447:

I think you know in all three of the cases, soft tissue always makes the reconstruction a little bit more challenging because obviously in our reconstructions we didn't have the soft tissue impinging us or hindering us or our reconstruction but I find a lot of times if you don't get the soft tissue right and you don't get things moved out of the way you risk either injuring the soft tissue like a vessel or nerve or something like or you just, the soft tissue just impedes your ability to get the templates or the fixation devices in place so I think that the soft tissues. I think for all reconstructions I find that there, it's a challenge. I don't think one reconstruction, actually I'd probably say that this reconstruction with the 3D printed patient specific cutting guides probably of the three is the most that eliminates the soft tissue hindrance because you know exactly where it's going to go so you can push just the regional soft tissue out of the way whereas the other ones you're not really sure where your osteotomies are going to be so you might end up being more likely to injure some soft tissue structures.

Interviewer:

Ok more than you would need to if you knew exactly where you needed to be.

Participant 447:

Exactly

Interviewer: (10:49)

Okay what sort of impact. As a trainee are you usually involved with the planned session?

Participant 447: (11:00)

No. No, it's usually that. I personally have been involved myself with them on a personal level cause this is what I want to do. This is what my fellowship is in. But, it's not usual for residents to be involved in the planning. Usually it's the staff surgeons.

Interviewer:

Ok, but l I guess if you've had some experience that's helpful still. What kind of impact do you think navigation and the digital guides that we use in the second session might have on planning and preparing for the surgery, how did I have this question worded? Oh: What kind of impact might navigation and digital surgical guides have on planning and performing fibula mandible reconstruction?

Participant 447: (11:54)

I think that it would help with getting your angles of your osteotomies right. That's the utility that I found with the CT navigation guidance. It tells you where to make your cut and the angle that you should make your cut.

Interviewer: (12:11)

What do you see as being the advantages and disadvantages of template guidance surgery?

Participant 447: (12:17)

I think there are a lot of advantages. One is that your reconstruction is probably the best in terms of the bone to bone apposition for healing, the possibility of placing dental implants, and most important the ease with which the reconstruction can be done the cutting guides are very helpful and it's something that, I think, I haven't timed it, but I think would be faster because you have these it takes a lot of the guesswork out it takes a lot of the trial and error out of the picture so I think it would help with certainly with OR time which will ultimately help with, the faster you can get the patient off of general anesthetics and out of the operating room the better for the patient overall. I think those are probably the benefits. The disadvantages are that it's expensive. It's expensive to do this and you need the right people that can support this type of this type of kind of virtual program. So, you need people that that's know what they're doing and that have the time and the experience with the software which is the majority of the surgeons probably will not have going into it. I think the disadvantages are the prerequisite software knowledge and expense.

Interviewer: (13:58)

So that leads me to another question. In terms of different centers and things like that. How might digital guides impact fibula mandible reconstruction in other centers where some of the tools aren't really used. I'm bringing this up because there was another participant who mentioned the fact that because in Edmonton we do have access to all this but not necessarily every area that does fibula mandible reconstruction has access to these kinds of tools. What kind of impact do you think the digital guides and navigation could have elsewhere, not just in Edmonton.

Participant 447: (14:59)

I think it could have a positive, I think it would certainly have a positive in terms of being able to make osteotomies that are of the right angle and of the right appropriate size and have them specific to the patient I think that is very helpful and I think that if other centres can have that, that would that would help improve their outcomes in terms of function and in terms of bone healing.

Interviewer: (15:40)

Ok. Let's see what I haven't gone through yet. For this study is looking at the third session where we had these template guidance or the 3D printed templates. How were they to use and how did they fit with what you had mentioned as a good surgical plan that was easy to use?

Participant 447: (16:13)

Sorry the first part was how easy were they to use?

Interviewer: (16:14)

Yeah.

Participant 447: (16:15)

Yeah, they were very easy to use. I think in a real scenario where you would have assistants in the operating room it might, I think I could have shaved some time off had I had someone handing me instruments, people holding things in place for me. But apart from the sometimes challenging manipulation of the model. I think it was very very easy. Obviously TMJ's don't pop out of place of real patients every two minutes. I think I thought it was really easy. I took a lot of the guesswork out. I was just putting the templates in place and it basically told me what to do, which was nice.

Interviewer: (17:04)

Ok and what, I skipped ahead of things so I'm going to go back a little bit. What do you see a being the pros and cons of freehand guidance or freehand techniques to do fibula mandible reconstruction?

Participant 447: (17:19)

The pros are that you know it. So that if the computers go down, or for whatever reason you don't have the luxury of having surgical design and simulation and 3D printed templates, or patient specific cutting guides you still know how to reconstruct the mandible and you still know how to reconstruct to give the patient a reasonable reconstruction. So, I think that is the main benefit, is that you don't know what the future has in-store you may end up working a place that doesn't have this, that doesn't have the luxury of these things so I think that's the main benefit of the freehand approaches. That for whatever reason you know you don't have the luxury of any of these surgical design and simulation tools and you still know how to treat a patient that has cancer. The other thing is that it's less expensive, it requires less planning, it requires less people involved in terms of you know, overall less moving parts to get the patient reconstructed. The freehand approach is good for that.

Interviewer: (18:31)

That's something as well that people have mentioned. That you know they really like the cutting guides the 3D printed guides but that's it's still seen as an essential skill to be able to do things freehand and especially for trainees this was mentioned because you guys, you're often not only working in Edmonton, you're leaving and going elsewhere. Cause you're about to leave and go elsewhere

Participant 447:(19:09)

For sure. They don’t do this where I’m going even. Knowing the freehand approach will always will never fail you because you don't need anything except your hands a ruler and the patient and basic cutting instruments. whereas you know, for whatever reason you don't you can't get these templates if it breaks in the middle of the surgery, if something happens. Being able to know how to reconstruct a fibula and being able to do a freehand reconstruction will bail you out of potentially disastrous situations where if someone drops the template or whatever, and the template isn’t sterile anymore, or I don't know, there’s always something that can come up in the operating room that can challenge you. Or if the time between when the templates were made, and the patient got to surgery the cancer spread and those templates are now useless because you're cutting your tumours gotten larger, so your plan is no longer appropriate for the current status of the patient. There’s a lot of times when you might end up aborting your previous plan and having the free hand technique in your back pocket will bail you out of troublesome situations.

Interviewer: (20:34)

How often does it happen where..

Participant 447: (20:38)

plans change?

Interviewer: (20:38)

Yeah.

Participant 447: (20:38)

So far it hasn't happened yet mind you I haven’t done hundreds and hundreds of these. So far it hasn’t happened where we've had to abort the surgical plan to go freehand. Hasn’t happened yet. Maybe if you speak to someone who’s done more of these, I’m sure if you ask Dr. [name redacted] he might have one of two or a few where the plan that he had and what ended up happening weren’t the same.

Interviewer: (21:08)

I know sometimes they do this where if there's any kind of a concern about the tumor growth, or anything like that they might make two plans. One kind of aggressive margins and one that is extra conservative, just in case. I think I'm not interviewing you now I'm just chatting, I think sometimes they do it like prepare for eventualities.

Participant 447: (21:38)

Is that right? Ok. I'm not sure what they do in terms of that in the planning session but that would be very wise cause sometimes you could be months between when the patients get their plan and when they get themselves to surgery. For whatever reason maybe the patient got sicker or they can't make their surgery or a lot of times the cancer just gets worse there are a lot of unforeseen circumstances that it's useful to know what to do if things don't go your way in terms of the plan. But that would be, that would make a lot of sense for them to have a backup plan in case their margins got, in case the tumour has gotten bigger and they need to change their margin status.

Interviewer: (22:21).

Yes

Participant 447: (22:24)

Does that mean you guys would print off two sets of full like designs? Like, 3D model two sets of cutting guides, two sets of everything?

Interviewer: (22:33)

Yeah well, what you could do is just, you could keep most of this the same, but then you would need to, oh no you would have to change quite a lot. But you could keep this, the fixation frame, the same and then maybe have one guide that's here, and then one guide that's here. This kind of like where you would like to cut and this is just in case. If you can, I guess it sort of depends on the scenario. That's how I would do it.

Participant: (23:09)

Ok cool

Interviewer: (23:10)

Anyway, that a little off topic a bit. Let's see what other questions I have for you. This is back to the navigation. In your view, it's not where it needs to be to compete with the 3D printed templates?

Participant: (23:30)

Oh yeah, the navigation system, I found it helpful honestly but compared to this honestly it's like night and day. It's a lot easier to use this system [template guidance]. And with this system you're also seeing exactly where physically things are going and the angle. Whereas with that other one [navigation guidance] you're virtually doing it, if that makes sense? In space. Whereas with this you're actually holding the physical piece in your hand and your angling the physical instruments at the same time as you're cutting it whereas the other one [navigation guidance] I thought there was, it just didn't seem intuitive to me. That little probe that kind of positioned you was more like it was it was just a little bit. I don't know what I'm trying to say, but it I just found that it was it was more intuitive than with these templates and it was with navigation.

Interviewer: (24:48)

Would you say that it was more cognitively challenging? That was something that was brought up

Participant 447: (24:53)

Yeah that's a good way to put it. Cognitively challenging.

Interviewer: (24:57)

This was mentioned before: going from 2D in your mind and then to 3D and then applying it to the models with a challenge

Participant 447: (15:07)

Yeah definitely. It was dimensionally challenging. For sure

Interviewer: (25:11)

Yeah that's a good way to put it.

Participant 447 took a phone call

Participant 447: (25:59)

Sorry

Interviewer: (26:00)

That's fine I'm actually almost done. For all the issues that you had with navigation what kind of tools or technology do you think might make a better or easier to use?

Participant: (26:16)

I don't know enough about navigation systems to answer I'm sorry

Interviewer: (26:18)

Oh that's fine, that's a fine answer. You can say I don't know.

Interviewer: (26:27)

In that case I've pretty much gone through all my questions. I guess do you have anything else to add? Any comments about this?

Participant: (26:36)

I would just say that in terms of comfort, ease and confidence, this last session [template guidance] was the best of the three.

Interviewer: (26:46)

Okay. Oh yes, I'm supposed to ask you summarize things. Of all the issues that you were talking about like in terms of using these different guidance methods and the impact it may have on the reconstruction how would you prioritize them in terms of importance?

Participant: (27:17)

Prioritize which ones, sorry?

Interviewer (27:20)

Some of the issues

Participant: (27: 28)

Number one would be getting the cancer out, so resecting with appropriate margins would be the first most important issue, the second issue in my mind would be giving the patients some degree of functionality, the third one would be, cosmesis. When I say functionality that itself has a little list in my mind; swallowing, speaking, chewing, would go under functional. So it would be making sure you've treated the cancer, that's the highest priority, making sure that they're functional in terms of swallowing, speaking and chewing, and then cosmesis. That would be the way that I would prioritize my goals for a reconstruction.

Interviewer: (28:24)

Ok that's good. Then we can wrap things up. I'll just summarize what we talked about. We talked about pros and cons of these different guides, how you feel about applying them, what you feel is important and what isn't. What else did we talk about? I can't remember. Now I feel like I forget what we just talked about. We talked about freehand vs. navigation, and why it would be important for someone to know how to do it freehand if they had to. You talked a little bit about trainee's, as a less experienced surgeon using these guides and what impact that might have.

Participant: (29:07)

It takes a lot of guess-work out of the picture, which is nice. And it makes a person who may not do a lot of these have the confidence to do them.

Interviewer: (29:18)

Perfect. I think that's a good summary. Thank you for coming in!

Participant ID code: 747

Interviewer: (00:00)

Okay. Participant ID code 747 convergent interview. I will start with my opening question. I'm interested in learning about the value of surgical navigation and virtual surgical planning. Could you tell me how these tools could be integrated into your practice?

Participant 747: (00:23)

Okay. From a practical perspective, we use them right now predominantly for bony reconstruction work. And that's probably in my mind that's probably the greatest use for them right now.

Interviewer: (00:37)

Okay. For bony resection and reconstruction?

Participant 747:

Yup. Yup.

Interviewer:

And how do you usually use them in your clinic daily, could you just…

Participant 747: (00:47)

How frequently do I use them?

Interviewer:

Yeah.

Participant 747: (00.50)

So, for me, I would probably do a bony reconstruction planning, maybe on average maybe once every six weeks or eight weeks.

Interviewer: (00:57)
Oh, okay. And you were talking about similar cases to what we're doing in this session?

Participant 747: (01:05)

Ya. Mandible, maxilla reconstruction.

Interviewer: (01:05)

What are your criteria for a good fibula Mandible reconstruction?

Participant 747: (01:13)
So for me, so good. Good. Yeah, that's a very,

Interviewer: (01:21)
it's a general term, yes.

Participant 747: (01:23)
For me to define good. I would look at that from a couple different perspectives. So good from a patient perspective, which is the most important thing. That would be that I've got a good bony reconstruction, ultimately that's going to facilitate rehabilitation specifically in the form of doing implant therapy for mandible and maxillary reconstructions. It's going to be good contour and function, the ideal function for the patient. From a surgical perspective, from my perspective, it needs to be efficient, so it certainly can't take longer than our standard techniques. Ideally it makes our standard techniques faster, so that we can efficiently get the patient's procedure done, get them OR in a timely fashion. And just from a personal perspective, it needs to be hassle free. Things that are very meticulous and finicky, tend to, really get to you in the operating room. And when you're doing 16 hour surgeries, getting fatigue, mental fatigue is a real challenge for us.

Interviewer: (02:24)

Okay. So, by the standard procedures, do you mean freehand reconstruction techniques?

Participant 747:

Yeah, I would say more traditional techniques, so yeah freehand.

Interviewer:

Okay. And how, what are your criteria, so you've already answered my next question, which is your criteria for a surgical plan in surgical design is that it should be efficient and easy to use, less mental fatigue?

Participant 747:

Yup.

Interviewer:

How well did the navigation guides that we used in this study, in the second session, meet your criteria for good surgical designs?

Participant 747: (03:03)

It's interesting, there might be a learning curve with that. I found that for me, more finicky, and I don't think for me that it necessarily added too much more than me using my freehand technique. So, and again, that might just be a learning curve so far. If I could use that, you know, in 50 cases that might change. I think it was nice that you could very quickly identify with that navigation tool where those cuts were. But in terms of the benefit for that, I can also just identify where I'm gonna do the cuts using my eye and get very close to a one or two centimeter border without having to have that additional technology. The additional technologies that it's actually is a little bit of a challenge cause we actually use in the operating room, there's a fair amount of set up that you have to do to have navigation system in the OR with you. It doesn’t take a long time, but it does take additional time. I think for me that at the time on it might have been a little quicker, but I'm not sure. In terms of the overall time, in a practical perspective, I suspect that would be similar or longer right now. But again, with additional experience it might be less.

Interviewer: (04:21)
Okay, and how well did this session, the third session, were we using 3D printed templates and cutting guides, How well did that meet your criteria for good surgical design?

Participant 747: (04:33)
Well, yeah, I think that worked well. The difference with this and maybe a bit of a challenge with this study, is that from a surgical perspective, we're all very familiar with this. I've done this many times before. I have practice with it and to go through that process is very quick. With navigation system, I don't have practice with that. So that's the first time I've seen that system. I've used navigation in other circumstances but not for bony reconstruction. So, may not be a completely fair test. In terms of your question for technique, I think in specific cases. For fibula or for mandible and maxilla reconstruction I think it was very useful adjunct and I think there is an initial fiddle factor in that we have to plan the case, but I think that probably does facilitate a quicker transfer and getting things set up faster.

Interviewer: (05:22)
Okay. During the actual surgery it speeds things up?

Participant 747: (05:27)
But just the ongoing, so my experience has been that many times we do have to do what I had to do in this case, which is there's a fiddle factor at the end. We do plan it, everything, but something has happened. There's been maybe how the drill hole went and maybe I was screwed in or it just rotates a little bit. And that can add significant complexity if you're trying to force that model to work when there's been a little shift and it's some little shifts are very common in surgery and the other thing that’s very common that happens in surgery is when we're doing our resection lines or resection lines by necessity may not match what our plan was because the cancers expanded. There's anatomy that we didn't

expect.

Interviewer: (06:07)

So that was a good point that you brought up in terms of some of the issues with this particular study. How do you feel that your experience using these templates could have impacted the way you did the freehand reconstruction, the first session, and then also session B when we had the navigation? Your experience using the templates and the surgical planning that we use here in Edmonton. How does that impact the way that you do freehand and used the navigation system do you think?

Participant 747: (06:45)

I'm a little confused about the question. So, when you were talking templates. So, this model. Would that have an effect on how I would use free hand? So basically, am I taking any learnings from this and applying that to other reconstructive techniques?

Interviewer: (06:59)

Yes, exactly.

Participant 747: (06:59)

Okay. Yeah, so I think maybe not necessarily for me, but I think because, like myself and Dr [name redacted], we've gone through the trial and error process, which we've done a lot of freehand and that's probably more influenced how we do this. I think as a new surgeon though, I can see a huge benefit to doing this type of work. And then if you have to do freehand taking those learnings and transferring them on because things like we talked about yesterday, which is when you first start doing reconstructions, you think you have to put that plate on the outside part of the mandible, but you're always going to miss your implant placement cause it's more medial than you expect. I think as a, if you're learning to do this with digital technology, you're quickly gonna learn "oh that's actually a lot more medial than other side because it's based on the inner cortex, not the outer cortex". I think those are quicker learnings for new surgeons rather than going through the trial and error process of freehand and then discovering, oh, we try putting implants in, oh it's always too far lateral. So I think we've learned, it's probably based on your experience, but I think as a new surgeon it's highly valuable

Interviewer: (08:03)
Let me see what my other questions are. Cause you do use navigation quite often in your, in your typical practice.

Participant 747: (08:18)
Well, I almost never use it in practice. Navigation is really a, it started as a sinus tool, it's moved over to the skull base a little bit. And, and for this work, we've tried interoperative X-rays and things like that as sort of a very primitive form of navigation. Still in terms of navigation on a day to day basis. I would rarely if ever use navigation. For most of my practice.

Interviewer: (08:48)
Okay. So that changes my question, I was going to ask how was this different? The way we use navigation in this study than how it would be used for you typically. But if you're not typically using it.

Participant 747: (09.01)

I don't think I've got a good baseline for you. Yeah,

Interviewer: (9.02)

We can ignore that question.

Participant 747:

Sounds good.

Interviewer:

Okay. let's see, what else do I have? Oh yes. You mentioned tissue displacement. What impact did the different guidance techniques that we use in this study, We had, freehand techniques and then the navigation session, and then these 3D printed template guides. What impact did they have on soft tissue displacement, do you think?

Participant 747:

What do you mean by soft tissues displacement?

Interviewer:

Oh, so this was mentioned in other conversations with participants. Talking about how fitting the guides on, removing the soft tissue or clearing space so you can plate or things like that. This is something that I talked about a lot with my supervisor when we were planning this case, designing things as if we were trying to reduce the amount of soft tissue that we had to remove, or displace when you're doing the surgery. How would these different methods impact soft tissue considerations?

Participant 747: (10:04)

I guess freehand is easiest for that, cause it freehand technique, which we talked to Dr. [name redacted], he'll tell you all, I'm a big fan of that. It really allows you to be very flexible in your approaches in surgery so that you're, because you don't necessarily, you have, you have an outcome that you want to get. Your road to getting there can be highly variable and that doesn't affect all the digital planning that you did advance. So digital planning sets you on a specific path that you have to follow. And if you run into issues in the operating room it's hard to do that. I've certainly been involved cases where we've kind of had to abandon the digital planning because of something that's changed. I think there's kind of that consideration. I think the advantage of the freestyle approach is that you have the flexibility when you go into a case. In general, it's very hard to plan a cancer case in advance. You've got to have a general idea what you're going to do, but when you're in there, whatever that tumour is doing, you have the flexibility to sort of improvise your way through that procedure and do what you need to do. So that's a big advantage of that. Soft tissue considerations are an issue because you're dealing with those as you go along. Navigation I could see the advantage of that is that because you're using a single probe that's quite small, that sort of limits the amount of soft tissue manipulation you're going to have to do in order to do your resection. It's sort of a step up from freestyle in that you can still have a surgical plan, but you don't have to worry about the templates attached and, managing soft tissue around that template structure. I can see that potentially is an advantage for that. Then I think the template thing is obviously, that's the most challenging in terms of if you have differences in your soft tissue that you weren't expecting them when you planned. You do have to strip a fair bit of extra space out. I do find that for me personally, a little bit frustrating with particularly with this back, getting up into that area to the Condyle of the mandible to get a template on, a cutting template, can be quite challenging, especially if the mandible is fixed. If there's pterygoid muscle involvement, there's always issues that you run into. It's a fair bit of work just to get the template on sometimes. When you're more used to doing freestyle, which is just where you need to expose them, it could cut through here and everything pops open. it can be a little frustrating. But again, I think that's one of the things we're reporting a little time in it up front, hopefully will save a little time on the backend.

Interviewer: (12:42)
That's a great answer. Thank you. You answered a lot of my other questions going through that. Let's see. So, this was something that came up when, during the navigation session, we weren't able to navigate the fibula using the CT scans that we had. How did you find using the 2D drawing that we had that had the measurements of where the fibula, the resection planes and intersected the fibula?

Participant 747: (13:16)
For me that's where things fell apart in that technique. I think using the navigation in the primary resection site, yeah, I could see there being some benefit to that. But really for jaw reconstruction, this is carpentry. You need to have your angles quite specific. You know, you have to have your miters all set at the right angle. The things that can fit together at the end. I found when I was doing that navigation approach is that it wasn't delicate enough or fine enough to do those fine angles that you need to do and it makes a huge difference. You need a 45 degree angle versus 55 degrees and that affects your bone contact and everything else. I think, the fact that you can't navigate the fibula part of it is

a real challenge. I think as a result that I think quite frankly, I was not happy with the reconstruction I did with the navigation because I don't think I had great bony opposition. I suspect that when you measure, you'll find that. I don't think that we cut the angles quite as nicely. I will say I started it deliberately. I tried to follow through just using that. In a normal circumstance I would have not accepted what I put on there and I certainly would have had freestyle curved that more. but maybe it's just because of the nature of the study, I was trying to be true to that technique.

Interviewer: (14:32)
Yeah. I appreciate that. It makes sense. And the other thing that was mentioned as being a challenge for the navigation also. Maybe I'm leading questions here a little bit, but a dimensional issue of in terms of looking at all these 2D images using the navigation.

Participant 747: (14:51)
Yeah. I found that very difficult actually the images on your iPad in terms of, again, making those angle cuts, what the orientation was. Because what you're looking at a fixed image, it's a picture that's gotta be very specific orientation. If I'm off by that orientation, even if it's a 360 degree rotation and I'm off by 10 degrees, that's going to completely affect the angular cutting, there's going to be a gap, and it's not gonna fit, which is what happened here.

Interviewer: (15:15)
The other thing too that was mentioned, you have experience doing these kinds of reconstructions with all these 3D patient specific templates. Performing the reconstruction without a fixation device to hold the mandible in position. How did you find that in this study? We only had the fixation frame for this last session with template guidance.

Participant 747: (15:41)
Yeah. I don't mind not having a fixation frame. I'm very used to that. I think you have to be very careful about that because it's easy to displace your TMJ joint. You can have it either too far a lateral or too far medial and that affects the occlusion when you're done. I think the fixation frame, it's nice to make sure you're keeping yourself in proper occlusion. But I don't have a huge challenge for me personally, I don't mind not having the

protection for it.

Interviewer: (16:09)

Okay. That makes sense. Let me see what else here. What tools or technology you might have made navigation better to use in this study? The way that we have designed the guides and plan?

Participant 747: (16:26)

I think again, I think the big failure was on the fibula side of things. I think for the cuts on the Mandible, they're relatively straight forward. I think if you were to plan like just doing straight 90 degree cuts through that bone. We got flat surface to deal with. But then having more of a formal, like maybe cutting guides on the fibular side of things might've facilitated making that reconstruction a little bit better. So maybe a bit of a mixed picture help. Again, I think the big failure navigation system is you're not navigating your fibula and that's really, if you want to facilitate reconstruction, you gotta have something on the Fibula side. So you're making your cuts properly to bring it up.

Interviewer: (17:11)

Okay. Perfect. I think my last main question. This was, as I said, we have trainees involved in this study as well.

Participant 747:

Yep.

Interviewer (17:19):

And talking to them, this came up in terms of the impact that using guidance, different methods of guidance has on trainees. Both in the quality of the reconstructions that they end up with when they have the guides and also in their education. For a lot of them, they mentioned the fact that when they leave Edmonton, they won't necessarily have access to surgical planning. Then also these templates and things. What an impact that could have on their education. I guess my question is, what impact do you think surgical design and planning might have on reconstruction outcomes with your trainees?

Participant 747: (18:03)
I think from a training perspective, having sessions like this I think is very useful. Because you're, I think where people really struggled with most is the soft tissue part of things we can manage quite well. And you have a little flexibility there, with bony reconstruction we have very little flexibility. It's like carpentry, you have to make sure the joints fit correctly. I think for trainees to focus on the bony side of things and learn how that needs to work, the degree of accuracy you need to have I think is very beneficial for them. The very fact that they can practice on like a model like this I think is highly beneficial. Just practicing using the instruments, practicing plating and screwing, things like that. As a surgical simulation, I think it's a very valuable tool for them. In terms of transitioning into practice, that's a bit more challenging. So maybe this my own personal perspective, but I don't think there's any way that a resident coming out a training will, should ever do this type of work or without fellowship training. It's too advanced. You need a special set of skills. You need a special center to do that in an academic center, in any academic center, I don't think you would have a general otolaryngologist doing that work. I think what you're talking about more specifically would be fellowship trainings. And from that perspective, I think it is useful. I think that their concerns that this is not available. If you go to other centers, it's probably not realistic at this point in the world because most companies have commercial solutions for this stuff you can access. So Synthes has one, KLM has one, you have one, so we do this at iRSM as well. And I think if they're going out in to practice in pretty much any centre in North America that they can access that. I wouldn't necessarily think that's a particularly valid concern.

Interviewer: (19:40)
Okay. That makes sense. Then I think we've gone through most things. I can just kind of wrap things up. Of all the issues you've used said that are important or crucial when thinking about planning and designing and performing these reconstructions could you prioritize them? What are the most important?

Participant 747: (20:04)
I think for me the most important is just the patient side of it, which would be getting a

reconstruction that works well in all the patient performance metrics. That's straight out of the textbook, which is to have proper form, proper function, specific for bony reconstructions. We want them to be able to place implants and to have the option for rehabilitation down the road. I would put those as kind of the top. Patient perspective. I think a close second for me would be surgeon perspective. The big thing for me is it's got to be simple to use and it can't, it's got to dramatically improve results. Control costs while we're doing that and be efficient for us to use in the OR.

Interviewer:

Okay. That's good. Then we can kind of finish things up then. So today we talked about some of the pros and cons of these different methods of guided surgery, what the criteria for good reconstruction is and also good surgical planning. I'm not sure what else we talked about, some of the issues that specifically with the navigation that we had. And, I guess a little bit about trainees and things like that. Is that a good summary?

Participant 747: (21:20)

I think so. Sounds good.

Interviewer: (21:21)

Okay. Then we are done. I'll turn this off. Perfect, Thank you.

Participant ID code 790

Interviewer: (00:00)
Participant ID code 790 convergent interview. So, what we're doing, I'm going to do a short interview with you, about the session that we've just went through and guiding surgery using these methods. Confidentiality will be established: this is going to be transferred onto an encrypted hard drive and saved and locked in that cabinet. Your identity will be protected. If you want to be extra secure, I just won't mention your name. You don't have to mention your name or either. This is a semi structured interview, my question to begin with: I'm interested in learning about the value of surgical navigation and virtual surgical planning. Tell me how these tools could be integrated into your practice?

Participant 790: (00:57)
Certainly we already use some of that in our sinus surgery as we have mentioned. That's already a, almost a thing that we use daily. Otherwise, in terms of the facial reconstruction stuff, we use it all the time on mandibles, so some familiarity with that. I think as we talked about. I haven't used the navigation for cutting guides before, so that was new. But I see that as a huge benefit because a lot of time we deal with a lot of soft tissue or you know, where it's sometimes hard to get the cutting guides onto things. I think that's a major benefit, If that is an option where in cases where the cuts are in difficult places or we can't necessarily get them in fixation or have a cutting guide put in, I think that's gonna be able to expand our surgery and even move to things like the maxilla and other areas within the face too that we could use it where traditional cutting guides probably wouldn't fit very well.

Interviewer: (02:02)
Okay. How did you find in terms of ease of use that it compared with what you're typically using? The template guides?

Participant 790: (02:15)

In a way. I think the navigation is almost faster because you don't have to put all the external hardware and fixate it and typically in the operating room you need to clear off all that soft tissue to get down to the bony area. Sometimes can take quite a bit of time and fiddling around. Whereas if you can just place the Nav right over the area you want to cut, then it would save you, I believe it would save you, the time in terms of having to get all your external equipment on board.

Interviewer: (02:47)

What do you think some of the disadvantages are of the surgical navigation?

Participant 790: (02:55)

You're still relying on the surgeon's hand to make the cuts. It doesn't matter how good you are, you're always going to be off of a little bit in certain directions or, you know, tilting the hand a certain way. So your cuts definitely not as precise as the guides, but it's better than also just freehanding.

Interviewer: (03:18)

interested in knowing what aspects of the navigation was helpful or not. Was the reconstruction guide useful to you or…?

Participant 790: (03:34)

Ya, I think that was probably one of my favorite parts of using it was to see with the probe where the reconstructed bone would be when looking at after making the cuts. Sort of the exact spots where the bone would line up and I thought that that was quite helpful to see where, what it will look like. I thought that that was something new that we did, we'd never really had and I thought it was probably beneficial, especially for alignment on the bone and stuff like that. I don't know the mandible left behind.

Interviewer: (04:09)

Okay. What would you, what would you change, if you wanted to have more of an ideal scenario, what would you change about the navigation or the templates?

Participant 790: (04:25)

It was certainly nice. I mean we could talk about the fibula for a second. Having the cutting guides for the fibula as well I think would be a big benefit. So that you can, essentially do the same thing. Cause I still think the reconstructive portion you have to, it's up to the surgeon to measure and eyeball it and do the cuts that way. So that would be nice to have the fibula mapped out.

Interviewer: (04:55)

You mean with the way we had it set up here today, where we had navigation to resect the mandible but not for the Fibula?

Participant 790: (04:59)

Exactly. It'd be nice to have a fibula portion because I think again, that would help at least narrow the gap of it fitting a little bit nicer than just by, our own hands. That would be one thing I'd like to see. Otherwise no, again, it's hard to tell because it's the first time seeing it. It's already a big new and cool thing. It's hard to tell with just one use what else I'd like. It was, for the parts that I wanted there for, it worked great. In terms of aligning where the fibula would go and things like that, I wasn't too difficult. Then counter with the guides for the fibula, it would be nice to have the fibula, those cuts would be beneficial.

Interviewer: (05:54)

Okay. And how do you think your experience working with a template guided surgery, the 3D printed guides, impacted the way you used the navigation or even the, how you do the free hand reconstruction?

Participant 790: (05:58)

Having experience with the templates before, it was similar and then the fact that on the CT you can see the plan of, the cuts and things like that. Essentially when doing it you just use that to pencil the drawing. We wanted to cut the different obviously from the templates where you, it's more like the biggest challenge with the templates is just getting them to fit in the hard spot. Once you do that, it's almost brainless. You just cut on the dotted line. It was similar in that way where you're provided with the plan to cut in. So certainly, I think the navigation takes a little bit more attention. Meaning that again, cause you're still essentially free hand cutting so you still have to be a bit more cognitively involved than with the cutting guide, where once it's on and you just essentially go for it.

Interviewer:

Go for it? So, what would be some major, what would be the impacts if in your clinical practice you were using navigation more like how we did today? You've already said that you'd have an impact in terms of soft tissue and things like that, but how about integrating it into the OR, integrating it into your general…?

Participant 790:

I think a big potential benefit of it would be almost in tumor mapping. Especially sometimes when we get really big lymph nodes or tumors that are coming up to important nerves or blood vessels that it could maybe help us identify in the OR with that to see, how far off we are from important structures we don't want to hit. I think that in terms of the soft tissue application, again that might be more suited in the MRI world than the CT world, but I think the raw application would crossover for that.

Interviewer: (08:15)

What is tumor mapping? What do you mean by that? Could you describe it?

Participant 790:

In terms of, if it's soft tissue, we're most likely talking about more MRI and then had it essentially uploaded into here. As you're doing a dissection down and you know, sometimes things get bloody and when we resect the tumor, you know, you're pulling it different ways to try to get certain planes opened up and you can really dislodge it. One of the benefits would be to take this and then place it right down into that tumor bed essentially where you moved the tumor, you can tell your depth, right. More importantly the structures. Just an idea of how close you are. If you're going down further, you might only have a few millimeters before you're onto the carotid artery or something like that. I think that this would be a definitely a useful tool for that application as well.

Interviewer: (09:17)
Would you envision then in terms of the surgical design perspective, you'd have the imaging of the patient's tumor and then you could beforehand make markings, edit the CT scan like we did for this and then have you. this is where the, it looks like on the scans is where the tumor is..?

Participant 790: (09:46)
Ya, if you could map out your normal vs tumor structures. It's just something, and I dunno, I mean definitely an experienced surgeon definitely doesn't require that, but I think it would be it a very good teaching tool for residents'. when they're just starting to do some of the operations to have that from a staff standpoint to know that they're getting close to the structures that you pre mapped out.

Interviewer: (10:12)
Yeah. Okay. So this is something that we talked about as we were doing these bench top sessions too, is an experienced surgeon versus a less experienced surgeon. How do you think these guidance methods come into play there?

Participant 790: (10:34)
I think that they probably can make the less experienced surgeon more efficient. Because again, I think if they are truly a very experienced surgeon, then most of the time you're probably pretty much going to be as fast as you're going to be. But I think somebody who isn't quite as comfortable or experienced with it, it gives them, a hand with that. You're not sitting there debating what angles or what directions to make the cuts so it's, essentially you can move beyond that step. I think it levels the playing field in terms of efficiency a little bit. For the experienced surgeon. I don't know, to be honest, if they use it a whole lot and feel very comfortable and stuff in their way, it's not hard to get the changeover. But again, maybe, they may just like the comfort of having that. It just may be something that there's lots of things that surgeons can do, but we use or nerve

monitoring and certain things. Even though we know we know where the nerve is, we know how to find it, but we'll still use it. So, it may become something like that where it's just a nice, you know, confirmation tool for them.

Interviewer: (11:49)
Okay. Is that how you see, cause this is the guidance as well as a little bit, it does help. I think, but also you could do this surgery freehand and it happens sometimes here still?

Participant 790: (12:10)
Yeah. I mean most of the time here, we will go off but guides or some kind of plan going in. But like we said, sometimes tumors evolve and all of a sudden parts of the mandible we planned to save, all of a sudden we now have to resect. Or our frozen sections come back positive and so now all of a sudden you're taking more bone than you ever thought you were. And now all of a sudden that plan just gets thrown to the side and we have to adapt in the OR and then make it by freehand. So…,

Interviewer: (12:46)
Okay. This is what I mean as a surgical design student, I'm curious to know what for you are good, or criteria for good surgical planning, good guidance in the OR. What would you say are the criteria for good surgical design and plan?

Participant 790: (13:12)
I think that we sometimes look at things from a different angle because we know that some places are very hard to get to or get into. I think in terms of the surgical planning and realizing that one: that we talked about bone, the soft tissue, a lot of soft tissue sometimes can get in the way or make things difficult. It's like working in a cave, sometimes trying to reach around it into it. So that's always one thing to keep in mind. The other thing is, that we're not doing anything too morbid. For trying to preserve function in the patient so that we're taking that into account. There's the oncological resection and then we need to look at that and say, okay, with that, what are we sacrificing and is there any way that we can try to work around that or improve the resection so that the patient isn’t as disabled after the surgery. Those two key areas that we look at. And overall, like I said, I think we like simple things, ease of resection. Being

able to just put things on nice and easy, and make the cuts and that's always appreciated instead of having to dig, you know, a whole lot to just get our guides in place that can be difficult.

Interviewer: (14:37)
What has there been a time in the OR where the guides worked really well or they didn't really work well and what happened there?

Participant 790: (14:49)

I've seen both. I've seen where the guides, we get scrubbed in, we clear everything open and it's like 15 minutes We have everything resected because we cleared the bone off, they snap on, screw them in place and make our cuts sand off the frozen and then work on some other stuff and you know, it takes, there's no problem. Then there's been other times where, again, we're just trying to get right to the back and you know, certain mandibles and it's just, the problem is there is bleeding. We're trying to get this guide to slide in. It's not really clicking where we want it to. Then finally we'll get it in a position, but then there's no way in hell we can get our screws to secure it in that position. I've seen that too, where it's been quite a big fight to try to get that in place. And that one was tough. Then there's times where like we said, where you'd go through all that and make your cuts and then the frozen sections come back positive and then all of a sudden you're taking more bone and your whole fibula reconstruction plan is now no good. Yeah.

Interviewer:

Okay. let me see what else I have to talk about. Could you describe for me the differences between, or the pros and cons, the differences you found in using freehand guidance, template guidance and navigation in this benchtop study?

Participant 790: (16:28)
I think the pros of freehand is that it really makes you, it's very tough and I still find this tough, three dimension in your mind, knowing how to make your cuts and orientating. I think it's definitely a good skill. I think it makes you a better surgeon if you're able to

develop that skill and have that ability to do things freehand.

Interviewer: (16:50)
Do you mean when you're trying to visualize exactly how the fibula for example, is going to fit in the mandible?

Participant 790: (17:04)
Knowing that it needs to be angled this way and this plane and this plane, it needs to be angled that way. And getting that right initially I think is, you know, when you're starting is very hard until you've had some room. I think the free hand technique at least gives you that ability to develop that skill. And I'm kind of that thought. the other benefit is again, when the unexpected happens and things aren't kind of don't turn out the way that the plan was going into the OR that I don't think it's that hard for a person with that skill to adapt. I mean okay, well now that our recon guides are gone, we just do it this way. Obviously, the drawbacks are, it's to get right. I don't think you're anywhere near as close to having the tight fit or the putting things in the right places as what the aides. Obviously you risk when you do a free hand like that, that it may not be, good. You may not be able to implant it later. That's the trade-off. I think in terms of the NAV is sort of a mesh, I still think you need to, even though it helps you with the cuts, I still think you need to be, a bit aware, you're still doing the cutting without free hand. You still have a bit of play in terms of how you want that cut to look. In terms of drawbacks, I think in this one again, you may not develop that ability to just in your mind do it on your own if you're relying a bit on that. But it's probably more precise and more accurate than that when I'm doing it on your own. And then with the cutting guides are great because I think you're getting such a tight degree of accuracy in the fits usually very good. But then I think you lose your, you don't really have to think when you do them right. Just essentially have to clear the bone and get them on. And there's no actual thinking ability or, it's all done preoperatively. But when you're in the OR yourself, you slap a cutting guide on and off you go and if it's pretty easy. The benefits obviously: it's quick, it works well. The drawbacks are: you'd better be ready if it doesn't work and if you don't have that ability or you're kind of screwed.

Interviewer: (19:42)

Do you see that, developing that ability as being something that's more important for yourself as a resident who's going through this? From the perspective of learning, as you're learning how to do this, is that something that you think, is maybe more an issue for a resident then?

Participant 790: (20:13)
For sure. Cause I think you're at the point now is, yeah, most of our resections and recons are done via guides or some kind of planning. Very rarely do we just sort of go on the fly. And then the problem is even when those times do occur, so the odd time where you have the plan doesn't work anymore. It's not really going to be the resident to do that free hand cutting. So, what ends up happening is because it's not that common anymore, is that the staff probably aren't comfortable themselves. They're not going to be comfortable letting the residents try to make those cuts and things. Yes, I think it's a problem is that when you get out on your own and that happens, you're not going to have a whole lot of experience to drawback on, and so that would be very uncomfortable.

Interviewer: (21:06)
Just curious, how often does it happen here in Edmonton where there's, for whatever reason, you end up having to do a reconstruction freehand or a resection or free hand?

Participant 790: (21:19)
In the rotations that I've gone through, I would maybe say once a month, maybe. It's not very frequent. But, and again, a lot of time it has nothing to do with the plan. It's just the tumors are, the margins need to be bigger. It's eroded things that we didn't know going in.

Interviewer: (21:44)
Okay. What else do I have here? How did you find this? I mean we were trying to, as closely as we could to simulate, a somewhat realistic clinical scenario minus obviously the soft tissue. How do you feel that what you experienced doing this study applies? Do you think that it's a good indication of how these things actually work in the OR?

Participant 790: (22:35)

I think it's pretty close to be honest, cause especially using a lot of the same tools in plating. I think that answer will vary resident to resident depending on what their end goals are. For mine going into this, I'll be doing this. I thought that learning experiences kind of invaluable, for using this stuff.

Interviewer: (22:58)
By that you mean because you want to do head and neck reconstruction. You're interested in, you're probably going to be focusing a lot on like mandible reconstruction, that this study was particularly,

Participant 790: (23:12)
Yeah. Applicable to me. Having assisted with these in the OR, I do think it's fairly close. Even if there is no soft tissue, I still think that the thinking and the same cutting guides that we use. Same saw, same equipment. I just think the experiences are very, very close to what it's like.

Interviewer: (23:40)
Okay, then this has been great. Thank you. let me see the time. Okay. Of all the issues that we've talked about, the pros and cons or, how some of this stuff can be applied. What do you think, when we're talking about how these guides can be integrated into the OR? From the most to least important? Some of the things you've mentioned are soft tissue, or just general changes in plans once you get into the OR. Things like that. How would you prioritize those things relating to the guides?

Participant 790: (24:24)

In terms of like most valuable?

Interviewer: (24:26)

Ya, the most important.

Participant 790: (24:32)

I think the most important thing is that you're, you know, you're able to operate without them. Right? That's key. I think the guides are a huge benefit, right? I think just in terms of OR time, it greatly increases our time and it's, as we know, the most detrimental thing to the patient is the number of hours they're on the operating table. For saving an hour or two by using them, then I think that that's a huge benefit, not just to the surgeon, but to the patient. At the end of the day, if you get a better fit on that reconstruction, again, it's really going to help them. In terms of what's most valuable, I think at the end of the day, if you're able to make it better for the person on the table, then for sure. You know, and that's in all our studies and things, we know that the longer they're on the table, the worse they do. I think this is a huge benefit from that standpoint. But at the same time, I think it's still, we can never fully rely on them and that's a skill that we cannot let die. Same with the Nav. I've never used the NAV in an actual case, but I can see at times where we have problems getting the cut guides on because of soft tissue. We can trace it out with your, NAV in the OR just do it that way. So, it's not a huge deal.

Interviewer: (26:00)
You've used, you haven't used the NAV for mandible reconstruction, but you have for sinus.

Participant 790:

Yeah.

Interviewer:

How did you feel it, how do you feel it was to go from using it, for sinus surgery to this in the benchtop study?

Participant 790: (26:16)
I think it's almost the opposite from one another. Because when we use it in sinus, we're using it to stay away from things. You're using it as a, I'm in a snow storm and I want to see what's up the road sort of thing. You're using it for safety essentially in sinus surgery. That's the big catch for it. Whereas in this side of it, I don't think safety's the big concern

when you're operating on the mandible. You know what's around and things like that, where you're using it to simulate what's ahead. But, so you're, what it does is it allows you to imagine what's there before it's there. And that's a very novel thing I think for us in surgery is being able to see our reconstruction before we do it is pretty good. Like I said, being able to use it to trace out the mandible after it's been cut and see right at the point where the junction is going to be between that fibula and that mandible. It gives you a good idea. It is hard to visualize that on your own. When we definitely have it on the NAV, I thought that that was, it was almost eerie, like there was a ghost. It was weird tracing the tracer through air but on the CT there was a bone. That was neat.

Interviewer: (27:40)
I just want to clarify, when you're talking about seeing the reconstruction beforehand, you mean how when we're planning these surgeries, right? You have the model of what it should look like, or you see on a screen how the plan goes and what the end result is going to be beforehand?

Participant 790:

Yeah.

Interviewer:

How important do you think that is? In the freehand session when you didn't have, we didn't go through that plan, mock planning session before. How big of an impact do you think that that is?

Participant 790:

Huge. Cause that the freehand just kind of putting it in and hoping it's in a good spot. Right? And again, we're surgeons, we're trying to get A to B, but now when you start bringing in plans and stuff in the freehand, you're just putting it in and hoping it's in roughly the right spot so that they can use some of it. Whereas I think with the NAV, if you're really concerned about getting this person implants, then like I said, you can track your positioning, right? And you're moving the bone and when you bring it up you can use the NAV to confirm that it is, to the millimeter, almost where it should be. It greatly increases our efficiency of making sure it's good bone for future use. I think when you freehand, you're just kind of hoping you're in the ballpark and that somebody can use it.

Interviewer: (29:20)
I think this, do you have any more information to add? Just general

Participant 790: (29:26)
For sure, like I think this is a very good training tool for us on top of the actual applications. Just getting to, doing this without much instruction is quite interesting because you can, you have some experience and some ideas from what you've seen or heard. But most of us haven't really done this on our own as residents. We've done bits and pieces of probably all of it but never end-to-end. I think it's a very cognitive exercise. How do they do that? I forgot; you know. What are the steps again? So, it reminds you of how I hard it is you know? It sounds easy but…

Interviewer:

Doing this benchtop, participating in this benchtop study was for you, to some degree, an exercise in practicing how to do…?

Participant 790: (30:35)
For sure. Yeah, for sure. I think it definitely was. Yeah,

Interviewer: (30:37)

Meaning the technical skills of actually doing these reconstructions or even just, using these different methods?

Participant 790: (30:47)

I think both. And one thing that I just, from a technical standpoint, everybody's done bits and pieces of this. Everyone's drilled. Everyone's done the cuts. Everyone's done that before. But I don't think anybody's ever gone from A to B. Uninterrupted without any sort of input from your staff member telling you how to do the, you know what I mean? It was an interesting feeling of now I'm doing everything, start to finish, without any input. You're just left your own devices. I suppose was interesting. Starting to adopt the new technologies as you go was interesting. I think as a person who doesn't do this a lot, I think as the new technologies came in, you felt more comfortable. Certainly with the cutting guides, you have a higher level of comfort knowing that the cuts are already been measured around computers you've looked at them, so you're not as scared and you're cutting it freehand, you're kind of going "I hope this works", you know? And there there's no plan to reconstruct, you just have to come up with it. So definitely I think you have a bigger sense of comfort with the NAV or was the cutting guides, makes you feel like you're doing the right thing or to confirm that you're doing the right thing, than just doing it freehand. I think for us, it's definitely a comfort level as we progress through the modules.

Interviewer: (32:19)

It's a way to check that you're in the right spot, or this is how it's supposed to be done.

Participant 790 (32:27)

Yeah. You know you're not straying too far off the path. Whereas in the freehand you could do whatever you want. Take off all the off the whole mandible. You're on your own.

Interviewer: (32:40)
Yeah. There's no checks.

Participant 790: (32:45)
No. Exactly. That's why, for us it feels more comfortable and the cutting guide goes on fits and you're cutting or you're not really worried that you're getting something wrong . Whereas when you're doing it for the freehand it's Like, should I be over here? Should I

have done it this way? Should I have cut my cut on this slant or…without the experience I think you have a lot of doubts about whether or not here you're doing it correctly.

Interviewer: (33:09)
Yeah, I can imagine. I'm just curious how this works then. When you're going through your training as a resident, you've said you've observed these planning sessions that you would go through with your staff who are working with the surgical designer?

Participant 790: (33:31)
Yeah. They'll pull up the software in clinic. Somebody will have a call, their plan will come up and they'll start looking at it and then rotating it and everything and talk about why it's the way it is and so on. So, from that side, that's our degree of preoperative input. We're not really inputting anything, but they'll show us, well they say if you position it this way you can get this many implants. That's why. It may not be the most cosmetic positioning of the bone, but functionally it's much better. Certainly we sit in on the sessions and things.

Interviewer: (34:14)
How do you think that, that kind of give and take? You're having to sacrifice a little bit of this for a little more, whatever this, do you find that is easier or more difficult when you have a guide?

Participant 790: (34:38)
I think it's hard to tell, but I think a lot of it, it depends on what the patient wants. If you're going to take off half their mandible and you ask them before in clinic, when we get to see them, when we diagnose them. What are their goals? What do you care the most about? Right? They say eating, chewing, having teeth. Well then, that's I think what we'll focus on the reconstruction. It may be a bit disfiguring depending on where you have to put that bone. But we know that the patient is happy to give up some of the cosmetic results for functional results. I don't think it really bothers us too much.

Interviewer: (35:28)

Okay. Anything else to add?

Participant 790: (35:31)

No. I think for sure. This is a very, a very beneficial thing. Especially with the NAV too. I think that was pretty nice. Just not having to attach all the bulky things and removing all the soft tissue in the OR. Yeah, I think there's a benefit to that for sure.

Interviewer: (36:01)

By the bulky things you mean like the cutting guides? The 3D printed cutting guides? What makes them hard? What aspect of them is the hardest to attach?

Participant 790: (36:06)

The hardest thing is getting them secured. Cause again, in the OR there's lots of blood, the bone always has the fascia layer over it, so it makes it quite slippery. You're really trying to anchor this guide on the exact spots where your cuts are right? And again, you're trying to hold it in place, but like I said, there's some blood or whatever the stuffs slippery anyway, so it's moving around and then trying to get the screws in the right spot to make sure you get it in. I think from what I've experienced and seen, that's really the toughest part is just getting them anchored in their correct spot without them being off at all.

Interviewer: (36:49)

What helps with that?

Participant 790:

More people to hold stuff.

Interviewer: (37:00)

Oh, okay.

Participant 790: (37:02)
Depending on where the holes are on them, because again, the farther back they are that means we have to pull the drill, the drill is a very vertical things. It needs a straight shot into where the screw needs to go. It needs to have an unobstructed straight shot to happen to be able to secure the plate down. That's one challenge with them. If it fits well you get it done, that's great after, but I always found that was, just anchoring the guides on and then anchoring them on correctly was another challenge.

Interviewer: (37:43)
Okay. You said this a couple of times, I just want to, so then with, you've mentioned that navigation is a method, reduces the amount of soft tissue that would need to be removed. Can you just elaborate on how exactly that would make a difference?

Participant 790: (37:50)

Sorry say that again.

Interviewer: (37:56)

In terms of soft tissue removal within navigation guides, specifically. How would navigation be different from the 3D printed template?

Participant 790: (38:16)
You don't necessarily need an unobstructed view right in, you still have to get the saw or whatever cutting device you're using in but, you really don't need the bulky guide. And the other, I think the other advantage would be, you don't have to clear very far beyond it with the NAV. Or at least I would hypothesize that. Yes to get a plate on after, but that's again, that's a strip on narrow, skinny path that you need. Whereas if you have the bulkiness of a guide to really get a clear path could probably help you in terms of you don't need to be as aggressive to get the cut where you want it.

Interviewer: (39:03)
How could that impact the final reconstruction?

Participant 790: (39:11)

Theoretically if you have more soft tissue around, it's better vascularization, it might take better, on top of the pedicle. It's just also leaving more bulk of the place, right? More muscle certain, the muscles of mastication. If you're not having to cut out as much of that or take off some of the tether points, then again, in theory it's all going to help them eating and drinking.

Interviewer: (39:42)

Okay. I'm just curious about this because I've only really seen surgery done with the guides. If you, when you're not using the guides and you're not removing so much soft tissue, do you essentially just remove the soft tissue in the spot where the plates are anchored or attached to the bone or do you have to take more off?

Participant 790: (40:18)

Depends, usually where the plates are. Cause that's sort of going to be well beyond where your cancer is or we're not really worried about cancer there. Basically, what we do is we've just tried to remove enough to get the plates on because really, after that it doesn't really matter from our standpoint. I'm sometimes just removing it for the sake of getting the plate on or lifting it up. That's what our focus is with that. I certainly, if you have to remove it to get the plate on you will. We try just to scrape it up and then pull it out of the way, get to plate on and let it all kind of come back down. That's usually our or method to do that.

Interviewer: (40:52)

Okay. That makes sense. I'll just summarize what we've talked about today then. We talked a little bit about some of the pros and cons and differences between freehand, navigation and template guidance. Some of the key things that we talked about were soft tissue removal or fitting or things like that of the templates versus the freehand in the navigation method. And you talked about this specifically, how going through this kind of benchtop study as a participant is useful for you as a resident who's currently learning. And then we talked about the differences between the methods of guides. I'm just going to look at my questions. Summarize it a little bit more. You mentioned the importance of still having those sort of surgical skills or the more traditional skills where you could still do it freehand or without having the guidance, as well as what the impact these different kinds of methods of guidance surgery could have on the way, or how they would actually function in the OR. What your criteria of a good guide or good reconstruction are. How your experience, cause you have done your training here in Edmonton where we use guides, for your entire time as a resident you've been working with these 3D printed guides I assume?

Participant 790:

For the most part. Yeah.

Interviewer:

How your experience learning and using the guides could have had an impact in the way that you use the navigation or even perform the freehand reconstruction and the advantages and disadvantages. Do you think that's a good summary of what we talked about? I didn't miss anything. Great. Okay. Then if you don't have anything more to add to this we can conclude this interview. Thank you very much for participating. This was so helpful, and I appreciate your feedback about how this all went. Okay. I'll turn this off actually.

Convergent Interview Transcript Participant 853

Participant ID code: 853

Interviewer: (00:00)
Participant 853. Let's start with the first question. I'm interested in learning about the value of surgical navigation and virtual surgical planning. Could you tell me how these tools could be integrated into your clinical practice?

Participant 853: (00:24)
I think that it improves accuracy in terms of the management of this and approves placement for the application of dental implants. I think that the navigation system also has the potential to do that without all the additional equipment that's included in some of the cutting guides as well too. With the potential to utilize that technology that already exists in the OR as well. That we obviously use for other applications like sinus surgery all the time. It is a system that's already established, really requires a little bit less in terms of other materials and sterilization techniques and things like that, as compared to the cutting guides and all that as well too.

Interviewer: (01:06)
Okay. That's great. Thank you. You talked about, a little bit about, the 3D printed templates versus the navigation system that we were testing in this study. You mentioned some of the benefits being that you're already often using the navigation system in the OR. How did you find using the navigation system, cause you specialize in sinus surgery, you're using navigation all the time. How did you find that your experience using it in your daily practice versus how we used it in this bench top study to reconstruct the mandible?

Participant 853: (01:52)
It was pretty easy, actually, quite useful. I mean, I guess the only thing that I wonder would be a way to make it easier would be if there was a way, well one that the navigation system that we used, the probe in particular isn't sterile. There are sterile versions of that as well too, that it can be sterile cause we use it for a lot of our skull based procedures. But, I wonder if there's a way you can even make that and incorporate a mark that you

can then go and…

Interviewer: (02:20)
Oh yeah. Just use one tool.

Participant 853: (02:23)
Yeah. Instead of going back and forth between a pen and having to probe and then recheck and mark and then recheck. Like if there's a way to incorporate a marker onto that as well too.

Interviewer: (02:33)
You could have this sterile marker that we've been using in this study, somehow have that incorporated. Maybe design something, some sort of specialized tool that we could use for that.

Participant 853: (02:44)
I don't know if there's like even a projection or something that you can have, like a light projection that would be like so that that would be maintained so that you can have a line to cut along them. It is nice with these, with the 3D printing, because it gives you that you that cutting guide that keeps you in a perfectly straight line and is very useful for the 3D perspective. Which, I found to be the hardest part about the navigation, was even looking at the images in both, in all three, both like axial coronal and sagittal cut. It's still hard to incorporate that 3D perspective. Whereas I think having the hands-on models and the 3D printed, helps to incorporate that in a more useful way. Cause I found make taking the two-dimensional pictures and translating it into a 3D perspective and making that the 3D perspective and making the 3D cut was the most challenging part about the navigation.

Interviewer: (03:43)
When you're resecting the mandible, trying to keep the angle correct or whatever the positioning…

Participant 853: (03:52)
I think that would be something that would be significantly challenging more with the

navigation than it is with these [template guides], because this makes it much easier for that. Then that was the part that I found was the most challenging for the navigation.

Interviewer: (04:05)
The physical. Cause with these 3D printed cutting guides, you're physically constrained to cut in exactly this plane and that’s the only option. Whereas that's missing from the navigation?

Participant 853: (04:20)
And even if you try to take it 3D it's never 3D on navigation. So..

Interviewer: (04:25)
That's very true. Yeah. You're saying that too also trying to, in your head, when you have 2D views, three 2D views of a 3D object and you're trying to, in your mind, stitch it all together to create a 3D object that you're trying to navigate is a tricky component of the navigation system.

Patricipant 853: (4:50)

Yeah.

Interviewer: (04:50)

Okay. I think that makes a lot of sense. How are you using navigation typically in your practice when you're doing sinus surgery that's different?

Participant 853: (05:00)
We mostly just use it to avoid dangerous structures. We don't, I mean everything in sinus is 2D anyways. We do everything with endoscopes with two dimensional images, with a two dimensional video image of that. Then essentially, we use, so, the way you should use navigation, is just to intermittently check to make sure you are where you are. But it shouldn't be something that you actually operate off using the navigation. You should be able to identify your usual landmarks and use the video and then occasionally confirm

your locations with navigation. But it's not meant to be something that we use through the whole surgery

Interviewer: (05:44)
Okay. So, You're referring to it “okay, is this correct?”. It's a check.

Participant 853: (05:55)
It's not necessarily, it doesn't have the same, there's almost no need for it to be in 3D because you can confirm in all three planes cause essentially you're just moving into one spot and then putting your probe in one spot and then you can look in all three planes and confirm that you're in the right location or confirm that you haven't entered into the orbit or going into the skull base or anything.

Interviewer: (06:17)
Then would you say compared with what you're using, how you use navigation for sinus surgery versus how we were using it in this study, was more cognitively challenging when you're doing it to do this reconstruction cause you're…

Participant 853: (06:32)
The three dimensional thing, it was really cognitively challenging. I thought that was the, taking the two-dimensional images and converting it. Maybe that's just the way my head works, my brain works is that it was hard to make the 3D cut with the correct angles.

Interviewer: (06:44)
I think that makes sense. Okay. Some things that have come up in other conversations were the pros and cons between the navigation guided surgery and the 3D printed guided surgery and soft tissue. Was something that's been brought up, that these 3D printed guides, because they do have a big landmarks that we have to have placed in the correct position on the mandible, a lot of soft tissue has to be removed or it's difficult to access these positions because there is soft tissue in the way. How do you feel that 3D, the guided surgery using navigation and guided surgery using the templates would compare when you're talking about things like that?

Participant 853: (07:42)
Well, I definitely think that the navigation would be useful to minimize the amount of soft tissue that has to get disrupted. It'd be very useful from that perspective. The only thing is at the end of the day, you still have to have adequate exposure to be able to have the position of your saw and position for your screws and everything to go in anyways. You do have to, maybe you don't have to expose quite as much as you need for the cutting guides, but you still have to expose a reasonable amount of soft tissue no matter what. More than you would think. You still have to be able to plate the other side and you still. But, I would say that there is definitely potential to expose less. I think in terms of a major reconstruction, it could be very useful. I think that the challenging thing, which I think we saw even today is, as the reconstructions become more challenging, minor errors here and there tend to add up to make those things not fit together as well. If you're navigation is off by a millimeter and you're making multiple osteotomies then all of a sudden you could be off by half centimeter and things are not fitting in the same way. Whereas I think the 3D printed ones are just more rigid and force you to get those angles right every time because there's only one way for it to fit together. But that being said, it didn't fit perfectly. It's not without, well, it's not and I'm not. I'm trying to blame it on the technology, but I'm sure it's also partly, I'm sure you'll find much better results with surgeons like Dr. [name redacted] and Dr. [name redacted], who've like done this a lot more. I'm sure that experience plays a huge role in this as well too.

Interviewer: (09:36)
I'm happy to take the blame for design issues though. Cause I'd say, this little bit off topic, but from my perspective, if it's challenging to fit the guides or whatever in position, that's also something that I can be improving on. I'll take the blame for that. It's not only on the surgeon. That's an interesting perspective then. Let's see. Do you think in terms of speed, this was another thing that was brought up, you know ignoring what the timed results of these sessions might've been, that, there's any possibility of a major difference in speed using navigation versus templates to reconstruct a mandible?

Participant 853: (10:33)
I would think that the templates would be faster. I don't know that they were today. But I think that they would be faster.

Interviewer: (10:45)

Cause they have done a lot to speed up freehand versus the template guidance

Participant 853: (10:50)

It's possible to you that it's just partly that it’s what we're used to. Maybe people will get to that point with navigation as well, but I think that it is a bit more of an in-between between the two. I would say that the templates should be faster and in experienced hands would likely be significantly faster than either freehand or navigation.

Interviewer: (11:13)

Yeah, those were two points that also have been brought up. Navigation is seen as a middle ground between template guided surgery and freehand surgery. And also that the difference that these kinds of guidance methods could make depending on skill level of the surgeon. I'll start with the first one: did you feel with, how would you rate or compare freehand surgery, navigation guidance and also template guidance surgery in terms of like the pros and cons are or what you liked or didn't like or found hard to use?

Participant 853: (12:05)

I thought that, well I think this is the most user friendly in theory and just because it guides you completely in terms of the cuts. I think unfortunately it's partly just the study design and everything, but I think not having navigation on the fibula made a big difference as well too. I think that if I could have navigated the fibula that potentially would've made a big difference in terms of opinions or thoughts on how that would have turned out. Cause I think that that really was unfortunately a bit of a drawback to the navigation because in terms of making the cuts, I think making the cuts was actually fairly easy with the navigation. I think the navigation helped a lot in terms of making the cuts. And so, I wonder if it would've been the same for the fibula. In terms of that, I think that I still think that when you're not having soft tissue and it's just purely bone that doing the cuts obviously with this as the fastest, was the fastest by far. But I think in terms of accuracy, I would say the navigation is significantly more accurate than doing it freehand.

Interviewer: (13:23)
I mean hope so anyway. In terms of, back to talking about the Fibula, We didn't have the navigation to, we did have a CT scan plan, but we couldn't actually navigate the physical fibula. And so instead we had that 2D drawing of the fibula with the cutting guides and measurements. How did you find using that?

Participant 853: (13:43)
It was okay. I think it was just in part some of those were just more accurate than I could have measured with a ruler. With accuracy down to like 0.2 of a millimeter, it's just realistically not anything that I could, even when you're making cuts, with the saw, you're going to saw your saw cut are probably more than a millimeter. I think that the accuracy and that was a little bit challenging to translate to the fibula. On this one it's fairly easy, but I would say the first cut is much easier than the second cut, I think that may have been something that made it a little bit more challenging for me moving forward. And I'm actually not sure if [name redacted] or anyone else will actually do it differently to try to optimize that second cut. And I think if I did it again, I would try to reposition on the fibula holder can try to make that a more accurate cut.

Interviewer: (14:55)
Okay. So, you mean because with the template guided surgery over cutting the fibula, once you make the first cut, there's, you lose the stability of the fibula a little bit. So maybe making the second cut that could have an impact on angle or accuracy or something.

Participant 853: (15:12)
And then the other thing that was challenging at least with this because there wasn't that much room at the mandibular Ramus. I think that the having the…the

Interviewer:

oh, the transfer template?

Participant 853: (15:45)

No. The, this one of the, what's that one like the holder, the main one?

Interviewer: (15:30)

The fixation frame?

Participant 853

The fixation frame. Yeah. So, I think that that one unfortunately, cause there wasn't a lot of space, it was really hard to plate it without that being on. Having to you take that off took away all the stability again and then it kind of just translated it almost back to being freehand anyways. In terms of the plating, I think that cuts were done before. The cuts, there's not really any way that that would have affected the cuts but it, but for me, because there was only that 11 millimeters or whatever at the back of the mandibular ramus, it definitely made it challenging to plate. Then we can take one of those off. Then you kind of lose the whole stability.

Interviewer: (16:09)
It affects you had affects how you can reconstruct it, or how well you can.

Participant 853: (16:13)
Whereas like with navigation, if you don't have that on there, but I guess then you don't have anything holding the mandible anyways. You kind of lose the stability factor from the beginning.

Interviewer: (16:25)
Yeah. Speaking of that for the, when you're, navigating with the CT scans and things, we had a resection cutting guide that were just showing where to cut the mandible and then also the reconstruction guide that was showing how to put everything back together in the end. How did you find using that? Was it useful?

Participant 853: (16:49)

I thought it was very useful actually. I found that was helpful in terms of getting, I don't know that I used it well, but, my idea behind how I wanted to use it was to at least use it to help get the position of both the posterior and the anterior, heights of the, of where the fibula was meant to line up. I think could have been particularly useful in someone who was going to go on to have implants and dentition. For my perspective it didn't matter as much because that wasn't the case. I think that getting those heights and using that in terms of the position both within the sagittal plane, and the height of, especially the position of the parasymphysis I think was useful. And I think actually going back, I probably would've tried to use these a little bit more because then I didn't really use them and then looking at them as soon as I was done, I was like, Oh yeah, I guess I could have put that a little bit, positioned it a little bit differently.

Interviewer: (17:50)
You meaning the reference models?

Participant 853:

Yeah. And especially the reconstruction one, that one. No, I thought using it in terms of the reconstruction on the CT was actually have the potential to be quite helpful.

Interviewer: (18:04)

Okay, great. That's useful then. Let me see what else I have to go over. How do you think, cause here we, you're usually doing this reconstruction with these template guides. How do you think that your experience impacted both the freehand session of this benchtop study and then the navigation session as well? Do you think it impacted the way that you approached those sessions?

Participant 853: (18:39)
For sure. Doing it freehand, because I've never done it that way, or even observed so few of them done that way. I felt when we started. And it'll be interesting to see what some of the people who are even more junior than me say. Now, a couple of them are interested in this so, it's a little bit different. But I felt a little bit lost at first. I was like, okay, what

plates do I normally use, what plate should I use? How would I actually do this in the first place? I know here, and here in Edmonton as well too. We always cut off the coronoid process. But other places, other centers don't. And so, then that could also affect how you would've made your preliminary cuts as well too. I definitely think that it, because I had such little exposure to the freehand, it made me even question some of the super basic things that I probably wouldn't have thought twice about normally, like plates. And that'll be the interesting part to see what the variability is in terms of what people use for plates.

Interviewer: (19:48)
Yeah. Do you think the plates have a big impact? Cause this is something I've noticed watching this, where different people have their preferences in terms of how they like to plate things and do their reconstruction, do you think that that has a big impact on the way, the outcome of the reconstruction?

Participant 853: (20:05)
I think potentially, if you're using big recon plates versus mini plates, that's a huge difference in terms of both patient outcomes and everything. I don't think that there's a huge difference in terms of like different types of mini plates or like different types of, those kinds of things. I don't think that really changed as much. But I would say like using the big recon plates versus not, because for the, when you start using big recon plates, there's also a much more significant aspect of bending that comes in. Whereas I barely bent any plates in part because of the segment, but that sort of adds another layer of, of variability to it.

Interviewer: (20:50),

Yeah. I suppose that's just for my own curiosity. This was another question. You had mentioned that you would have wanted more space, at the posterior connection with the mandible fixation frame, that there wasn't enough room left to put a plate on while it was in fixation. I'm just curious, what for you, are there criteria of a good surgical design? With what you're familiar with using these templates and what would you want in navigation if you were to do this surgery with navigation, that would you want for it to be done well?

Participant 853: (21:34)
Yeah. In terms of the 3D printed ones, I think just getting it as accurate as possible, having the cutting guides, easy to manipulate on and off and then minimizing, I do think, I know what [name redacted] is saying in terms of, minimizing the amount of contact, because this one is fairly minimal contact, but once you get it screwed in, it actually does fit fairly well. I think minimizing the amount of contact, having easy access to be able to have a plate, to be able to plate. I don't need to use a big recon plate but to have access to have at least two screws on each component, so enough that you can put in a couple of screws. And then in terms of the navigation, I think having some sort of device that can leave a permanent line as you're doing it. So be that a marker or be that some sort of light or overhead something or other, some way you can put a line that allows you to cut on it to verify the accuracy.

Interviewer: (22:40)
You would want, an easier way to interact physically using the navigation.

Participant 853:

Yeah, so you don't have to keep going back and forth between two instruments essentially.

Interviewer:

And so you're not looking up all the time. Was looking up at the screen so often a problem for you?

Partipant 853:

Nope not at all. No

Interviewer: (23:05)
Okay. So maybe some physical way of interacting more directly with the actual model and plan.

Participant 853:

Yeah, I think that was probably, and then I found the recon, I found the recon navigation component, quite helpful and quite useful to get the height of the segments and those kinds of things in the right spot.

Interviewer: (23:34)

Okay. let's see, what else do we have… this is something else that I was a little surprised, that was interesting and brought up before, is the importance of being able to do a freehand reconstruction or to do some of these skills, without any kind of guidance or templates and things like that. Regardless of whether you are going to be using guidance and surgical planning a lot, that it was still seen as a skill that was necessary to learn. How do you feel about that?

Participant 853: (24:09)

I think it depends on what center you work at. Working in Edmonton, I think there's very limited need for that. Because we typically have the potential in the opportunity and coverage and those things to allow those things to happen. It typically doesn't take that long. Even if you.. but there have been times where we've had a surgical cancellation and had to do something fairly quickly and so that person may not have had the opportunity. I think it's rare that you actually need to, but I don't think it's a bad thing. I think in the cases of like trauma, sometimes you might have to consider doing some of these things without the same kind of navigation or imaging isn't going to be as useful if you don't have any true preoperative imaging and you just have trauma imaging. I think that's a potential if you ended up being in a center where you don't have access. iRSM is quite a unique facility that doesn't really exist anywhere else in Canada. And a lot of places are using much more rudimentary and less technologically advanced skills to do the same thing. And I think a lot of places that are doing almost nothing and so they are completely reliant on freehand reconstruction as the only option.

Interviewer: (25:28)

Okay. Yeah, that's good to know. Another thing that came up that you might, think about more seeing that you do so much sinus surgery. Tumor mapping as a potential useful benefit of the navigation guides. Not planning cutting lines or reconstructions or anything like that, but simply giving an indication using navigation of where the tumor starts and ends or as much as you maybe could do, is that something you'd see as being a useful?

Participant 853: (26:05)
Yeah, for sure. That would be very useful. And especially if you could incorporate into something beyond just plain CT, if you could incorporate it into a pet CT scan where you have a bit more of that metabolic uptake. The potential for that to be more useful I think is, and I know [name redacted] has talked about doing some sort of like navigation and the image directed surgery. I think there's a lot more work that would have to be done around that in terms of verifying the accuracy of the margins and those kind of things. And that can be done either with permanent or frozen sections intraoperatively, I think there's a potential for that for sure. But I think that we don't necessarily have good evidence of what the accuracy of imaging with true pathologic tumor margins are.

Interviewer:

And I could not, I couldn't even guess.

Participant 853:

I think there's, the research essentially would say that we don't have anything on that at this point. I think it definitely has the potential to be useful. But I think a lot of times we just look. It's not necessarily adding a ton more.

Interviewer: (27:10)
Yeah. Okay. So that is a dream thing if you could do it, but maybe not immediately.

Participant 853: (27:20)
I mean, in a perfect world, we'd love to do surgery like paint by numbers fashion where you see tumor or not tumor, tumor, not tumor. I think it's a way of getting to that point. I

don't think there's enough to say that imaging can reliably predict where tumor is because we know tumor also has a lot of fingers and depending on what type of cancer it is, they may have microsatellites and those kind of things.

Interviewer: (27:42)
Okay. Cool. I think that's the main, some of the main things that were brought up that I wanted to touch on from other interviews. But I did want to talk about, Oh God, early on I had something in my mind that I needed to come back to that came up earlier on in the interview and we got talking about things. But maybe it'll come to me later. Do you have anything that you want to add in terms of how you know going through this benchtop study?

Participant 853: (28:19)
No, and I told [name redacted] as well, cause he was asking me how it went. And, I think that the navigation I think is very interesting and I think it was very useful and helpful to make the cuts. I think the 2D to 3D, was a big challenge and I think not having the fibula navigable also limited the applicability of that one.

Interviewer: (28:44)
I think that's a good comment. Ok then, we can start wrapping things up. I still can't remember what I was going to ask.

Participant 853:

Well if it comes up you can always ask me anytime later.

Interviewer:

Yes. I'm sure it will as soon as we're done. Of all of these issues that are related to these guidance methods, maybe some of the pros and cons or the things that need to be considered with these guidance methods, what would you prioritize the most, or the least important for you? If you were trying to use them.

Participant 853: (29:17)

So I think making them user-friendly is very helpful. Which I think is a big pro of the 3D templates. Now, the one thing I have seen with the 3D templates is we template someone out a couple of weeks before their surgery, and it's maybe based on an image that was a month before that, and then their surgery and then their tumor is actually increased. And so there's very limited ability to adjust intraoperatively whereas I think navigation would offer you the potential to adjust intraoperatively a little bit more so than, and I don't know, I guess that would be partly dependent on that programming and things like that, but it may have more potential to adjust on the fly if there was a significant change in terms of the tumor margins or the tumor invasion. And then in terms of the navigation, I think there's also the potential to do exactly like you were saying, that sort of paint by numbers or tumor mapping. I think that that too would have the potential down the road to extend to soft tissue and not just the bony margins. You can potentially use that as well for other soft tissue tumors within the head and neck outside of just the bone. I think there's a lot more potential with that. Now, I know most of the navigation is based on accuracy with bony margins, but if that was something that kind of improved, then that would potentially have a big impact in terms of how to do that surgery and how to ensure you had, how to add more validity and more accuracy to your margin, your tumor margins. Then I think experience is going to play a huge role in any of this and getting, I think starting navigation being at a different thing is going to have its own set of hurdles and challenge until someone gets to the level of expertise that they have obtained now with these 3D printed models. But even that is something that they're constantly working on. I think a lot of it is exactly that. I think the first few times they did this, the cutting guides were in the wrong place, there wasn't that adequate area for plating and so they were taking it off and then ending up having to do things freehand. I think everything has a learning curve. But I think at least in that, I think the navigation has a potential to be very useful. But I think we just have to accept that it would take a while before anyone was good at it. And I think any of them are all challenged by additional osteotomies. More challenging reconstruction is going to introduce more errors in any method, but I think potentially even more in the navigation method. I think navigation would be potentially more useful for us for a straight shot like this. But an anterior mandible reconstruction, if you had to do like a full angle to angle and going through the parasymphysis and symphysis would be potentially very challenging. The more segments or the more things you had to coordinate. I just think it has a potential to introduce more and more errors along the way.

Interviewer: (32:40)
I think that makes sense. In this case we did have a fairly simple, straight forward case with one segment and a straight segment too. Okay. I still can't think of what I was going to ask. So I'll just conclude. I'll summarize what we've talked about today. We talked a little bit about, comparing the different methods and also how things went during the session, what some of the applications could be in a clinical scenario, pros and cons of these methods, etc… those types of things. And then also just the new tools that we're using, like the reconstruction guide for navigation, or even the resection guides for navigation. What else do we have? The speed of doing the two, how your experiences with navigation or with the templates impact things, tumor mapping as a possible maybe far in the future application. What the criteria of good reconstruction, how these guides can help. Did I miss anything? Do you think that's a good summary?

Participant 853: (34:00) Yeah.

Interviewer: (34:02)

Okay. Then I think we can say that we are finished this interview, so thank you very much for coming in. This was really helpful. I appreciate your insights. I'll just turn this off now.