Title
Virtual Orthognathic Surgery: CAD/CAM Splint Generation and Analysis

Permalink
https://escholarship.org/uc/item/4ck5g5xf

Author
Nichelini, Jeffrey Allen

Publication Date
2013

Peer reviewed|Thesis/dissertation

Virtual Orthognathic Surgery: CAD/CAM Splint Generation and Analysis

Jeffrey A. Nichelini DDS

UCSF Division of Orthodontics

Class of 2013

THESIS

Submitted in partial satisfaction of the requirements for the degree of

MASTER OF SCIENCE

in

Oral and Craniofacial Sciences

in the

GRADUATE DIVISION

of the

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

DEDICATION

This Thesis is dedicated to all of my friends, family, and UCSF colleagues. Everybody had been extremely helpful and patient with me over the last 7 years, and without their support and understanding I could not have completed my training.

ACKNOWLEDMENTS

ABSTRACT

Introduction: Cone beam computed tomography (CBCT) technology has many known benefits in diagnosis and treatment planning for both orthodontics and oral surgery, but systems to translate these benefits directly into patient treatment are still early in development. The purpose of this study is to define a protocol that incorporates multiple commercially available technologies into a patient's orthognathic surgery treatment, and to evaluate the accuracy in which a clinician can utilize this protocol to produce an intended result for that patient

Methods and Materials: Presurgical CBCT scans of 14 patients who had previously undergone orthognathic surgery (maxillary LeFort I osteotomy, mandibular bilateral sagittal split osteotomy (BSSO), or both) were segmented to isolate their jaws for independent manipulation. High resolution 3D images (Motion View Software, LLC, Chattanooga, TN) of the patient's dentition were then superimposed onto the segmented DICOM, and virtual surgery was performed using each patient's plaster-model surgery set-up as a guide and the Dolphin 11.7 software (Chatsworth, CA). Virtual splints were then designed and processed into tangible objects using computer aided design (CAD/CAM) printing technology. The difference in mandibular-maxillary relationship defined by the virtually designed splints compared to traditionally designed splints, was measured by calculating the distance between three mandibular fiducials, after superimposing CBCT scans of models mounted using each splint.

Results: Mean linear differences were found to be less than 1mm +/- SD in all dimensions

Conclusions: Virtual simulation of orthognathic surgery coupled to steriolithographic surgical splint generation is reliable, efficient, and potentially accurate to within 1mm of actual procedure outcomes.

TABLE OF CONTENTS

Figures

Tables

INTRODUCTION

Orthodontics and Orthognathic Surgery

The primary functional goals of orthodontic treatment are to correct malocclusions of the dentition, and to ensure that the final positions of the teeth contribute to a balanced harmony of the facial structures. (1)   When these goals are accomplished, the maxilla and mandible relate to each other in such a way that opposing molars and canines occlude in an Angle Class I relationship, upper and lower incisors display 2-3mm of overbite and overjet, and the locations of the jaws, themselves, relate to the face in an aesthetically pleasing way. The extent to which dentofacial orthopedic devices can manipulate tooth position, however, is limited by the amount of alveolar bone present and by the amount of residual growth potential. When the amount of dental and skeletal movement necessary to correct a malocclusion is beyond this capacity, orthognathic surgery is necessary to separate the discrepant jaw from its discrepant position relative to the rest of craniofacial complex, and place it in a more physiologically appropriate location. In these circumstances, orthodontists and oral-maxillo surgeons work in tandem to accomplish the end result. Indications for a surgical supplement to orthodontics treatment is outlined by Proffit's "Envelope of discrepancy", which defines the limits of orthodontic treatment alone, according to the maximum tooth movement possible in each plane of space, and the extent to which orthognathic surgery is able to supplement changes necessary beyond these limitations.(1) Orthognathic surgery is typically indicated when there is a dramatic discrepancy in the maxillary-mandibular relationship, disfiguring malocclusions, craniofacial anomalies, and airway constriction.

1

Milestones in Orthognathic Surgery

The first systemic approach to jaw surgery occurred in the early twentieth century, and has naturally experienced significant advances in technique, predictability, and reduced morbidity since that time.(2) There have been milestones in the development of new techniques of osteotomy, such as the introduction of bilateral sagittal split osteotomy in the 1950's,(2) and in the evolution of skeletal fixation techniques, such as "rigid fixation", popularized in the early 1980's.(3, 4) The introduction of "rigid fixation" was beneficial, because it allowed for the primary healing of bone, while limiting the need for intermaxillary fixation, and allowing patients early mobility of their jaw and improved hygiene.(19) It has also been shown to provide more stable long-term results in two jaw surgeries for both Class II and Class III correction, as well corrections of asymmetries.(3)

Today's milestones relate to the advancement of technology. The increased prevalence and access to cone-beam technology, as well as the development of corresponding powerful software, continues to propel the field into new realms of diagnostic and predictive ability.(5,6,7) As is typical of any rapidly evolving field, however, new methods are being developed faster than their effects and benefits can be analyzed. This is particularly true in the case of interactive software that allows the translation of simulated treatments to be directly applied to patient care.

Orthognathic Surgery Simulation

Due to the difficulties of orthognathic surgery, treatment simulations are required to adequately diagnose and plan for any orthognathic procedure, and it has its roots in predictive-cephalometric-tracing combined with plaster-model surgery.   For several decades, these procedures have been the gold standard method of simulation used to determine the extent and direction of skeletal movements necessary to correct a deforming malocclusion. Historically, two-

2

dimensional lateral cephalograms were traced on acetate paper, with copies of the maxillary and mandibular segments sectioned out. These segments were then moved independently into new positions relative to the cranial base, to provide ideal esthetics and functional occlusion. From these simulations, the surgeon could determine if a single jaw or double jaw procedure was necessary.(8) Plaster-model surgery supplemented the predictive-cephalometric-tracing by allowing the surgeon to precisely measure the amount of movements necessary to achieve ideal intercuspation. This procedure is still common today, and is performed by mounting a patient's pre-surgical models on an anatomic articulator, marking several reference lines, repositioning the maxillary model into the desired position, and measuring the movements in each plane of space.(8) The measurements from this procedure should coincide with the measurements for the cephalometric simulation. This process, however, has been shown to be inaccurate and have a tendency to introduce asymmetries into patients' faces. In 1990, Ellis showed a significant variation of dental relationships in patients following surgery, compared to their plaster-model simulations. The maxillary-central incisor had a difference of 1.2 mm in the antero-posterior dimension, and 1.1 mm in the vertical dimension, while the molars showed a similar, but non-uniform magnitude of changes. The midlines were off by 0.9 mm mesio-laterally. He attributed these differences to three sources of error: Improper mounting of the plaster-models, incorrect placement of reference lines, and incorrect measurement of the segments' surgical displacements.(9) Another study described these errors similarly: 1) user error of the facebow when transferring a registration of the occlusal plane to the articulator; 2) poor simulation of reality in the absence of a link between 2-D radiographs and plaster models; and 3) difficulty controlling translational and rotational movement. (10)

3

Ideally, a surgical simulation procedure should eliminate these sources of error, combine the benefits of radiographic and dental simulations into one process, and allow direct translation of the results to the patient. Fortunately, this concept is becoming a reality, as virtual procedures continue to improve.

Virtual Orthognathic Surgery

Virtual simulation of orthognathic surgery (VOS) can be considered to have started two-dimensionally. Lateral cephalograms have been traced digitally for well over a decade, and proprietary software programs like Dolphin (Dolphin Imaging and Management Solutions, Chatsworth, CA) allow for the two-dimensional movements of the maxilla and mandible in a manner similar to acetate paper. Two systemic reviews of the topic published in 2009 concluded that two dimensional hard and soft tissue predictions using computer programs were not always consistent with actual outcomes, but the margin of error for most measurements was within 2 mm or 2 degrees, which is clinically acceptable.(11,12)

The modern concept of VOS, however, is three-dimensional. Using cone beam computed tomography (CBCT) and 3D imaging software, regions of a patient's skull can be defined, segmented for independent manipulation, and measured for prediction of surgical results. This practice began as early as the late 1990's, and has been extensively studied since that time.(13)   A study published in 2007 looked at the differences between planned and actual results in 5 patients, whose surgery was simulated virtually in three dimensions. They looked at the position of each first molar, the chin point, and the arch midlines, and found the mean linear differences ranged from 0.02 - 0.85 mm in each plane of space. The largest single deviation was 1.99 mm, which was found in the vertical position of the lower left molar.(14)   Another prospective study, published in

4

2012, simulated 8 patients in three dimensions for bimaxillary surgery to correct a skeletal Cl III open bite malocclusion. They measured the difference between predicted and actual results for several skeletal landmarks in each plane of space, and found the mean linear differences ranged between 0.02 - 0.73 mm.(15) These findings are smaller than what were found by Shananhan in 2011, comparing surgeries simulated retrospectively to operating room notes. He found mean linear differences between points ranging between 0.55 - 1.67 mm, with the highest values representing changes in the vertical plane.(16) Despite these errors, though, they represent smaller differences than what has been shown in two-dimensional studies.

The benefits of VOS are undeniable. Not only can they provide more predictable results, but there is an inherent increase in the amount of diagnostic data available in 3D volume renderings, which are not available on mounted plaster models. This information includes definition of bony landmarks, identification of nerve locations or the presence of pathologic lesions, assessment of temporomandibular joint health, occlusal cant, evaluation of asymmetry of facial structures as-well-as the relationship between dental and skeletal midlines, and appreciation of the harmony of structures in all planes of space, not just profile.(17) Working in digital space is also beneficial because it enhances the practitioner's ability to communicate and collaborate with colleagues, work more efficiently, and more accurately treat rotations.(18, 19) Evolving beyond these diagnostic and predictive benefits, contemporary software can now be coupled to CAD/CAM technology to allow for the direct application of virtual predictions to patient treatment. This is reflected in the generation of orthognathic surgery splints.

Orthognathic Surgery Splints

Orthognathic-surgery-splints have played a role in orthognathic surgery for several decades, and serve the purpose of holding the dental arches in the desired occlusion during and after surgery, while also preventing both the jaws from sliding and minor orthodontic tooth movement from occurring.(20) The occlusion dictated by the splint has traditionally been determined by the process of plaster-model surgery, which has already been described. When the process is complete, and the models are in the intended occlusion, acrylic is flowed between the inter-digitated teeth. This acrylic wafer is then used in surgery to replicate the pre-determined occlusion in the patient before the bony segments are fixed into their new position. Unfortunately, the summation of the errors associated with plaster-model surgery is represented in the surgical splint. Using VOS predictions to design and generate surgical splints, however, potentially reduces or eliminate these sources of error.

Integrated Technology

Translating VOS predictions into operating-room quality orthognathic-surgery-splints utilizes advances in multiple integrated technologies. First, a CBCT scan of the patient must be obtained. Next, 3D imaging software can be used to not just visualize and diagnose the patient's initial skeletal condition, but it can used to isolate regions of the DICOM data for independent manipulation and surgical simulation/prediction. Laser technology is capable of generating high resolution 3D images of the dentition for superimposition onto low resolution 3D images generated from the CBCT scans. After these image files are virtually aligned, and surgical simulation is complete, the negative space between the dentition can be used for designing another image file for creation of the surgical splint. The splint-image file is usually saved in a Standard Tessellation

6

Language (STL) file format, which is used in computer-aided design and manufacturing (CAD/CAM) technology to translate 3D images into tangible objects.

There are currently multiple software systems available to perform these tasks, but many of them are very sophisticated and proprietary to companies which sell the services of technicians trained to operate them. Dolphin Imaging (Chatsworth, CA), however, has recently developed a user friendly orthognathic surgery simulation module to be used by clinicians, which is capable of performing all aspects of virtual orthognathic surgical simulation including segmenting DICOM data, superimposing high resolution dental images on the segments, manipulating the segments, and designing splints.

CAD/CAM, Orthodontics, and Oral Surgery

To date, the primary limitations to utilizing virtual treatment modalities coupled with CAD/CAM technology has been time and cost. A study published in 2011 found a high concordance between surgical splints generated by traditional and CAD/CAM methods, but they used a costly service which required an offsite technician to perform all virtual maneuvers.(19)   A similar study, published in 2003, also found no perceptible difference in the fit of traditionally generated splints and those made from CAD/CAM, but again, an expensive outside service was used for design and formation of the CAD/CAM generated splint.(12)   Indeed, a paper published in 2008 went as far as to claim the accuracy of 3D printers is beyond question. (13)

As the number of adult orthodontic patients increases, orthodontists are experiencing ever more orthognathic surgery cases. The ideal treatment results will occur through harmony between the dentition relative to the jaws, and the jaws relative to the craniofacial complex. With advent of newer technology, orthodontists have the ability to significantly fine tune their surgical treatment

7

plans prior to surgery. Studies have identified the reliability of virtual surgery and to some extent the reliability of splint fabrication. However, several questions still remain before this technology overcomes the current gold standard using model surgery. Among these questions are the reliability of the splints relative to splints fabricated and used for surgery, cost of the service, and making the process more user friendly. This study aims to define a protocol that incorporates multiple commercially available technologies into a patient's orthognathic surgery treatment, and to evaluate the accuracy in which a clinician can utilize this this protocol to produce an intended result for that patient.

Hypothesis

There are no differences between orthognathic surgery splints generated using CAD/CAM technology from virtual surgery simulations, and splints generated using traditional methods from plaster-model surgery simulation, in their ability to accurately reproduce jaw position.

Specific Aims

a. To determine if the protocol for incorporating patient data, performing virtual-surgery procedures, and designing a virtual splint is both time efficient and cost efficient. We will accomplish this by designing an appropriate protocol, following it for each patient, and then giving our subjective judgment to the efficiency of the process.

b. To determine if a CAD/CAM generated orthognathic-surgery splint can accurately translate virtual surgery predictions to a tangible model of the patient. We will accomplish this by performing virtual-orthognathic-surgery procedures on a group of patients, including surgical-splint design and fabrication. The virtually designed

splint will then be compared to the traditionally designed splint, for differences in inter-maxillary registration in three dimensions.

METHODS AND MATERIALS

Overview

This is a retrospective study evaluating the equivalence of orthognathic surgical splints created using virtual methods and traditional plaster methods. It is a proof of principle procedure that builds upon Ken's work validating VOS procedures to test their clinical application.(16) This study solely focused on the generation of surgical splints, which are the ultimate product of any surgical simulation that allows translation of the occlusal set-up to the patient. To test our hypothesis that splints, generated using CAD/CAM technology from VOS set-ups, are equivalent to the gold standard "acrylic splint", we evaluated their accuracy via superimposition of 3D images obtained from CBCT scans of plaster models mounted using each splint.

The first step in performing Virtual Orthognathic Surgery required obtaining a high resolution 3D dental image of each patient's pre-surgical plaster models, generated using an Ortho Insight 3D machine (Motion View Software, LLC, Chattanooga, TN). These files were superimposed onto each patient's low resolution pre-surgical CBCT scans, obtained with a Kodak 9300 series CBCT machine (Carestream, Rochester, NY), and using Dolphin 3D imaging software (Version 11.7, Dolphin Imaging and Management Solutions, Chatsworth, CA). This same software was used to segment jaws within the fused 3D images, for independent manipulation, and virtual surgery simulation. The goals of virtual surgery were to reproduce the jaw relationships defined by plaster

9

model surgery as closely as possible. Dolphin software was also used to generate virtual surgical-splints, which were then prototyped by Medical Modeling Service (Medical Modeling Inc. Golden, CO).

For comparison of the acrylic splints with the CAD/CAM splints, each splint was used to mount the models that were generated from for CBCT scans, also using the Kodak 9300. The images acquired from these scans represented the jaw relationship defined by each surgical simulation, the discrepancies of which were measured by superimposing them with Dolphin software.

Subjects

With permission from the UCSF Committee on Human Research (CHR#1000564), we obtained a collection of 14 consecutive patients with full orthodontic and surgical records, previously treated by Dr Janice Lee for orthognathic surgery. Subject Inclusion criteria included complete records consisting of a pre-surgical CBCT scan less than one month prior to surgery, intact pre-surgical plaster models, an intact acrylic splint generated from the plaster models and used in surgery, and complete operatory chart notes. The study included surgical procedures that included single jaw and double jaw osteotomies, but was limited to single-piece Le Fort 1 procedures in the maxilla. Multi piece Le Fort procedures were excluded due to necessary variations in the simulation protocol, which would have added unnecessary variability to the study. The patient population did include patients with craniofacial anomalies, atypical dentition, and missing teeth due to limited available records.

Age range for patients in this study was from 15 to 50 years old. The sample was unevenly weighted with 11 females and 3 males, half of whom were missing at least 1 tooth before surgery.
10

7 patients had surgical procedures only on the maxilla, 3 only on their mandible, and 4 patients on both. (Table 1).

Table 1. Patient Descriptive Data

Age (yrs)	Gender	Sx Type (Osteotomy)	Missing Teeth: Quantity (#'s)
18	f	Mx Lefort I	**0**
50	m	Mx Lefort I + Mn BSSO	0
19	f	Mn BSSO	2 (5,12)
15	f	Mn BSSO	1 (10)
20	m	Mx Lefort I + Mn BSSO	2 (7,10)
16	f	Mx Lefort I	2 (6,11)
17	f	Mx Lefort I	0
36	f	Mx Lefort I + Mx BSSO	2 (12,13)
23	f	Mn BSSO	0
20	f	Mx Lefort I + Mn BSSO	4 (7,12,21,28)
23	m	Mx Lefort I	0
17	f	Mx Lefort I	0
35	f	Mx Lefort I	2 (5,10)
17	f	Mx Lefort I	0

Patient CBCT Protocol

All cone beam CT scans for this study were obtained using a Carestream 9300, which has a 0.7mm tube focal spot. All patient scans were 17x13.5cm, 11.3 seconds, and taken with voxel resolution of 0.30mm. They ranged between 85 – 9 0kV and 3.2 - 5 mA, depending on the patient's size.

11

Plaster Model Surgery

Plaster model surgery was performed by residents in the Department of Oral and Maxillofacial Surgery at UCSF. Patient records were obtained one week before surgery and included the CBCT scan, SAM® Facebow registrations (Great Lakes Orthodontics, Tonawanda, NY), bite registrations, and alginate impressions for green stone plaster models. For single jaw surgeries, the models were mounted on Galetti type articulators (Galetti, Vercelli, Italy), and for two jaw surgeries, SAM® 1 Articulators were used.

The magnitude and direction of skeletal changes desired from surgery were determined by clinical evaluation of each patient, as well as two-dimensional surgery simulations of lateral ceph-style images generated from the CBCT scans. These measurements were then applied to the mounted plaster models to set the desired post-surgical occlusion. From this position, acrylic was placed between the opposing models to create surgical splint.

Laser Scanned Dental Images

High resolution, three-dimensional, digital images of the green plaster models used in "plaster model surgery" were created using an Ortho Insight 3D machine (Motion View Software, LLC, Chattanooga, TN). The machine scans each arch individually using three lasers, which register points on along the surface of the models by triangulation, at a resolution of up to 40 microns. Each laser is attached to a motor capable of moving with six degrees of freedom, and allows capture of all points on the model surface, including undercuts. The summation of all points results in a cloud that is reflective of surface anatomy. Images are initially created using a Polygon File

Format (PLY), which then must be transferred to STL file format for compatibility with the Dolphin
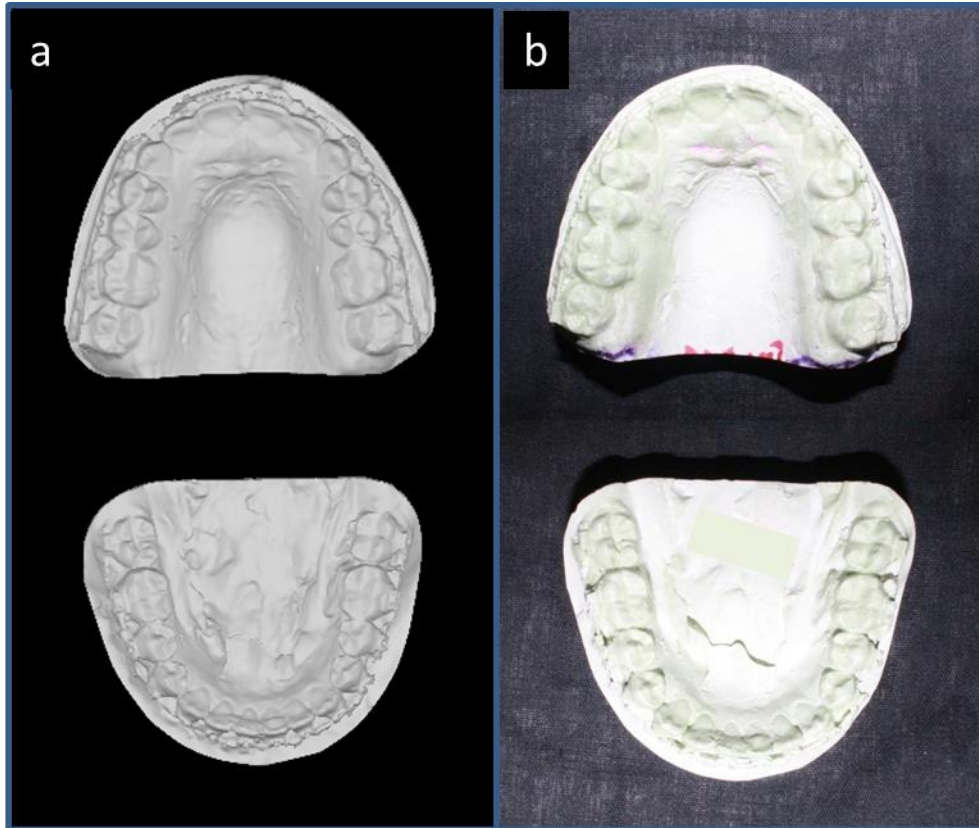
11.7 software (Figure 1).

Figure 1. a) Occlusal view of upper and lower STL images. b) Green plaster models
corresponding to STL images

Fusion of High Resolution STL File with Low Resolution DICOM File

Dolphin Imaging and Management Solutions recently developed a package of software

features which allows a clinician to efficiently integrate all the steps necessary to completely

simulate orthognathic surgery virtually, including the design of a corresponding surgical splint. It is

because of the comprehensive nature of this software (Dolphin Imaging, Version 11.7), that it was

chosen for this study.

13

Prior to performing VOS, a patient profile must be created, and her/his DICOM file loaded to it (Figure 2a). When this is complete, the high-resolution surface files of the dentition are imported individually. For the fusion of each arch, the software will initially display two windows, one with the DICOM volume image, and one with the STL file image (Figure 2b). In this step, you are prompted to identify corresponding points on each image, which the software will then use for reference during the superimposition. The user may decide how many reference points to use, but the minimum required is three points. For the purpose of this study, three points were used to increase efficiency. When placing the points, accuracy of the super-imposition has been shown to improve as the distance between the points increases.(23)   Magnifying structures also allows the user to more precisely place the corresponding point.

After the software has completed registering the images according to the points, a subsequent step will allow the user to refine the fusion by use of a widget, which allows manipulation of the surface file in six degrees of freedom (Figures 2c-d). There is a significant learning curve with this procedure, as the user learns to identify the desired center of rotation for bilateral improvement of the super-imposition. Without this understanding, it is difficult to improve a single section of the fusion and not disrupt an opposing section. In addition to the widget, there is an "auto-super-imposition" feature, which will further refine the fusion.

When the superimposition process is complete, the two image files should be indistinguishable from each other in the area of the dentition. A heavy color influence from one image indicates improvement is needed. Portions of the plaster model image that are not reflective of the patient's anatomy need to be removed (Figures 2e). This is accomplished in the final step of the fusion process, by using the software to cut away any unwanted portion of the STL

14

file. It is important to remove the models' base, and any region of the arch apical to the brackets where the alginate from the impression could have warped or torn.   The coronal portions of the dentition are the only critical element of the high resolution file to leave intact (Figure 2f). In the final fused product, the high resolution image can be distinguished from the DICOM image by altering its color (Figure 3).
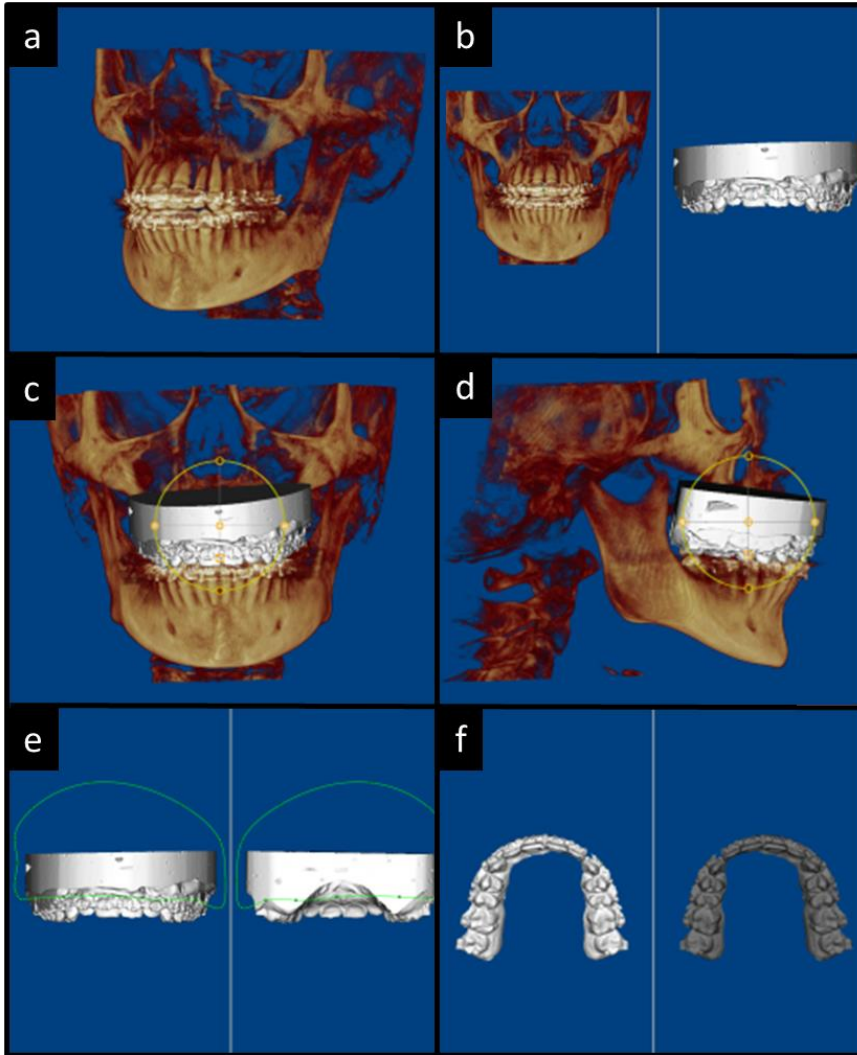
15

Figure 2. a) CBCT Volume Rendering. b) Super Imposition screen with CBCT DICOM and plaster-model STL. c) Frontal view of widget during superimposition process. d) Sagittal view of widget during superimposition process. e) Cut lines for trimming STL image. f) Trimmed STL image.
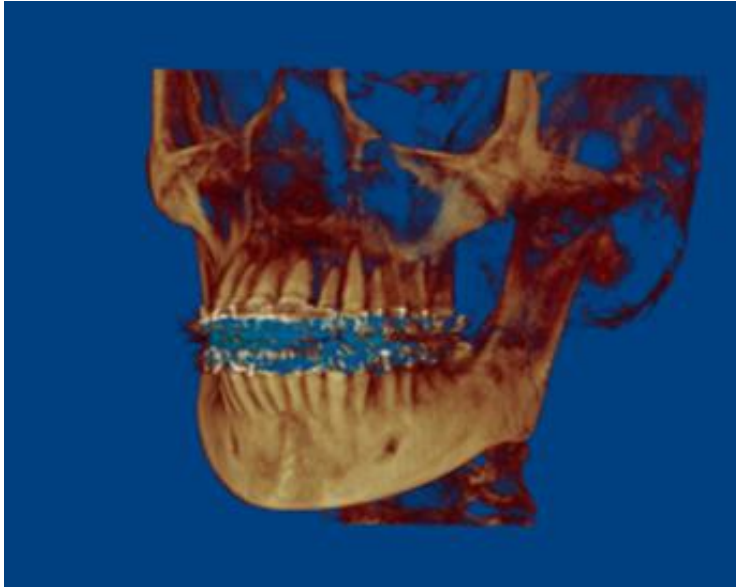
Figure 3. Final DICOM-STL superimposition with high resolution
dentition displayed in blue

Virtual Orthognathic Surgery

The orthognathic surgery tool, within the Dolphin 11.7 software, is a seven-step system.   It

proceeds from segmentation of the DICOM, through virtual surgical manipulation of the jaws, and

ultimately designs the surgical splint.   Prior to beginning this procedure, the user must first

generate a panoramic radiograph-style image using the X-Ray tool, which will be used in step 1 of

the simulation.

After the panoramic radiograph has been developed, the orthognathic surgery tool is

opened. In step 1, the PAN will be displayed, and the user must define the regions of the image:

maxilla, mandible, left ramus, and right ramus (Figure 4a). When this is complete, step 2 displays

3D volume images of the areas defined in 2D by the PAN. During step 2, the boundaries of these

regions are cropped, and threshholding of the voxels allows the user to define the density of

17

structures captured in the image (Figure 4b). This step requires defining an appropriate balance

between capturing delicate structures, such as the condyle, and allowing too much noise in the

regions of denser bone. The hinge point of the condyle should be visible, while there should not be

so much bone that the angle of the mandible is not discernable. This issue is less of a problem with

higher resolution CBCT scans. Any scatter within the image that results from a high voxel threshold

can be removed in step 3, as well realignment of the super-imposed dental image, if necessary

(Figure 5). When step 3 is complete, the process of segmenting the DICOM is complete, and it is

possible to save the images as independent, high resolution, STL files.
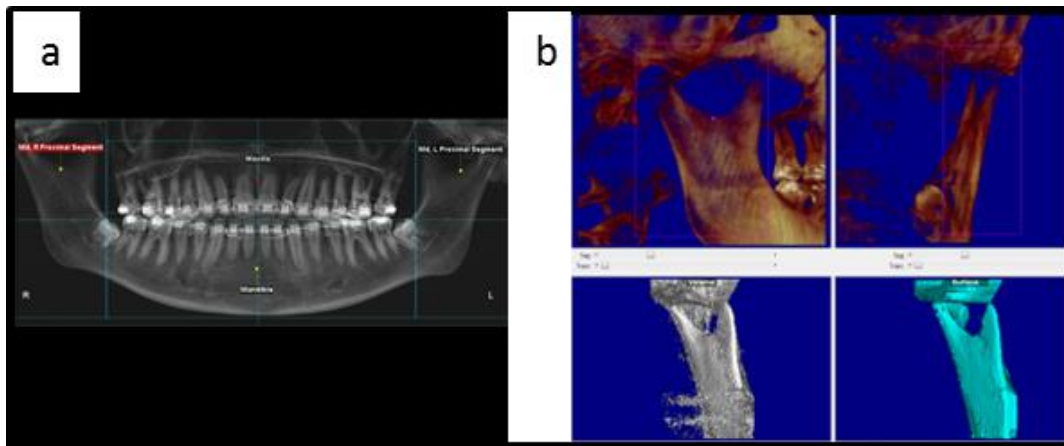

Figure 4. a) Step 1 of the Orthognathic Surgery Tool.   A) Panoramic view to approximately define volumes of interest. b) 4 panels of view of Step 2 to refine volumes of interest
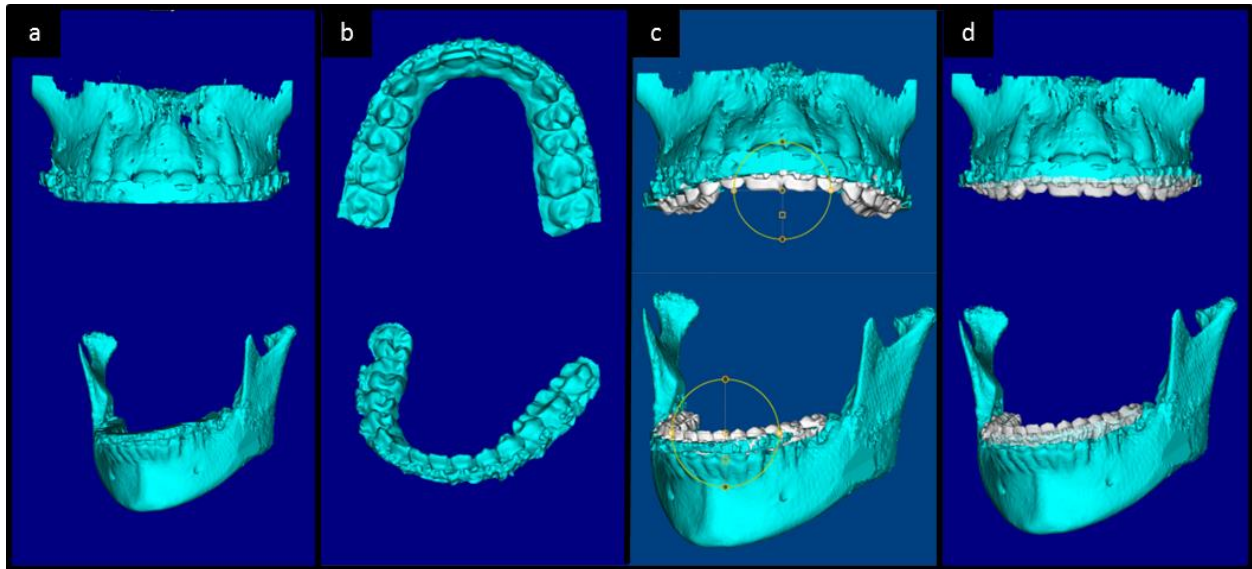
Figure 5. Step 3 of the Orthognathic Surgery Tool. a) Low resolution images segmented from DICOM. b) High resolution images cropped from STL. c) Widget allowing refinement of high-resolution/low-resolution superimposition. d) Final product, with the high-resolution portions of the dentition displayed in white.

On the newly created images, the location and type of osteotomies to be performed in surgery are defined in step 4. By default, the cutting blade will produce cuts 0.5 mm in thickness, but it can be changed (Figure 6). In step 5, landmarks are placed on the maxilla and mandible, including defining the hinge access of the condyles, which is important for evaluating auto-rotation during surgery. Virtual surgical manipulation actually takes place once the user reaches step 6 (Figure 7a). At this point, it is important to first check the "virtual collisions color map" (Figure 7b). This map serves as a checkpoint for the previous procedures. In the map, the spaces between the upper and lower dentition, as defined by the STL super-imposition and segmentation process, should be reflective of the patient's physical occlusion (*i.e.,* contacts are in close proximity and areas of open bite are not). There should be no overlap of upper and lower dentition. If areas of overlap exist, or if the occlusion is not appropriate, then the user must return to earlier steps and

19

correct the problems before proceeding. Surgical movements are accomplished using the same widget as in the superimposition step. Due to the unique limitations of each patient's anatomy, it is not always possible to have uniform objective treatment criteria (Figure 8). For example, anterior open bite cases typically finish surgery with an element of posterior open bite, while patients missing teeth may have an indeterminate Angle Classification.   For the purpose of this study, the goals of virtual surgery were to replicate the outcome of plaster-model surgery as closely as possible. To accomplish this, virtual manipulations were performed using the plaster-models held in occlusion with the acrylic splint as a guide, focusing on the midline and intercuspal relationships. Attempting to produce virtual simulations according to surgical notes, or notes from the plaster simulation would have increased variability relative to the precision of the measurements made during those procedures. When virtual surgery is complete, it is important to reference the "virtual collision color map" again, and ensure there are no interferences between opposing dentition.

The final step of the orthognathic surgery tool designs the virtual surgery splint by defining a region of negative space. Using a multiplanar view of the high resolution dental images, isolated and locked into the occlusion defined in the previous step, the user first sets the sagittal and vertical dimensions of the splint, and then manipulates the rotational position of the dentition until there is even distribution of the teeth within the field (Figure 9a). Once this is complete, the image is locked, and the coronal boundaries of the arch can be set. When all boundaries are set, and the dentition is well encompassed (Figure 9b), the virtual splint can be viewed, and a new STL type file can be generated and saved (Figure 9c).
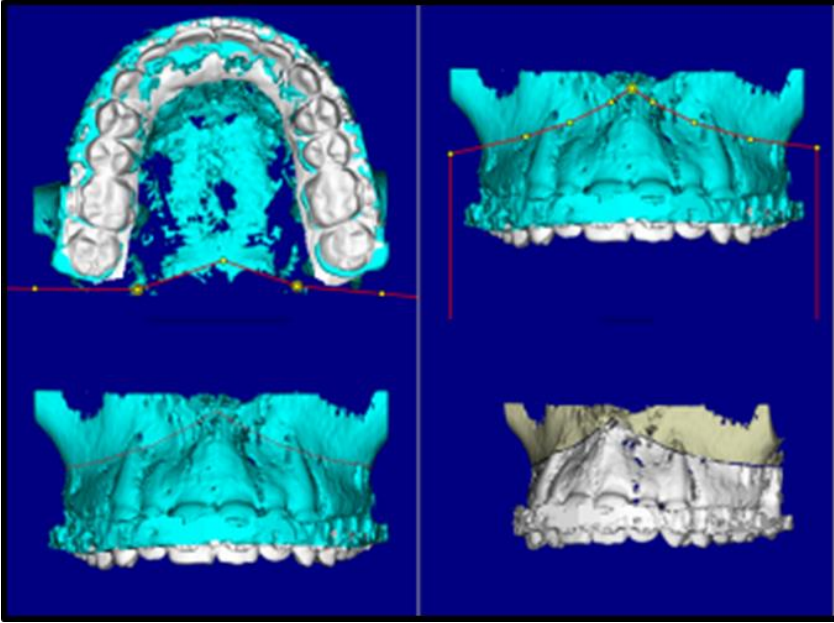
Figure 6. 4 panel views of Step 4 involving sosteotomy.
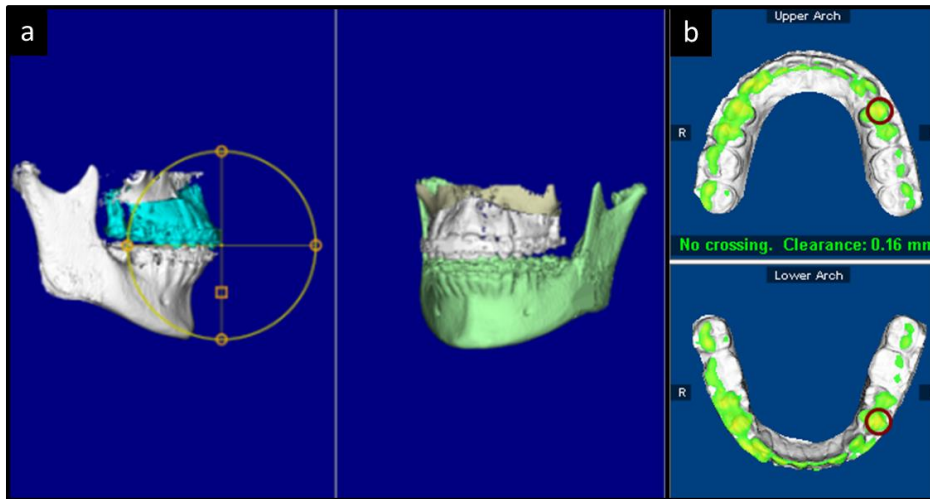
Figure 7. Step 6 showing the virtual surgery planner. a) The widget for image manipulation. Is in the left panel, and the resulting image is in the right panel. b) The virtual collision color map.

21
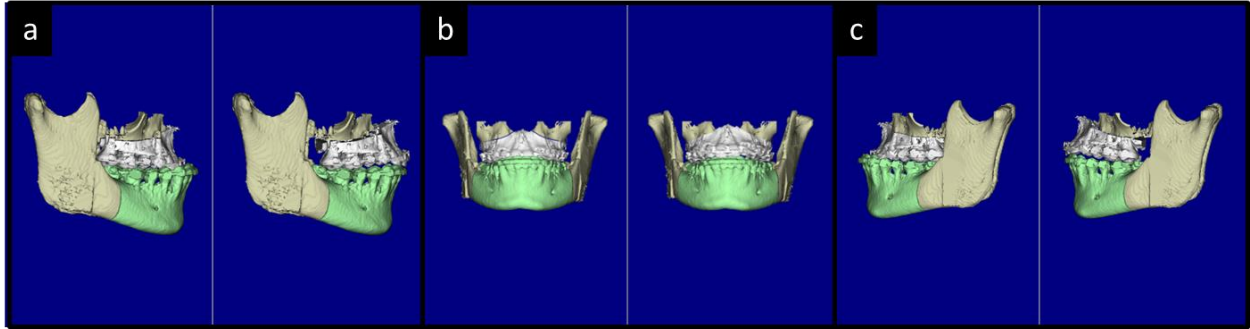
Figure 8. Pre- and post-simulation occlusion: a) right sagittal, b) frontal, c) left sagittal.
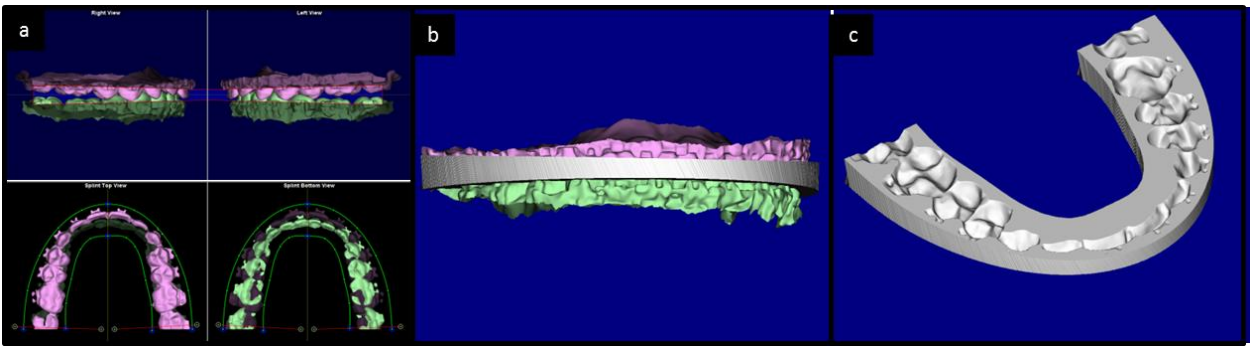
Figure 9. Surgical Splint Design. a) The boundaries of the negative space; b) the defined negative space; and c) the image of the surgical splint.

CAD/CAM, Rapid-Prototyping

Digital splint files are uploaded to the Medical Modeling Services website. Rapid prototyping is achieved through stereolithography, which is an additive process using 0.15 mm layers of ArthroView® material (Medical Modeling Services, Golden, California).   This is a trademarked material, consisting of acrylic and epoxy photopolymers. Splints for this project were supplied at a cost of $100 each, and were delivered less than one week following submission of the file (Figure 10). Retail cost varies between $200-500 depending on the complexity of the image.

22
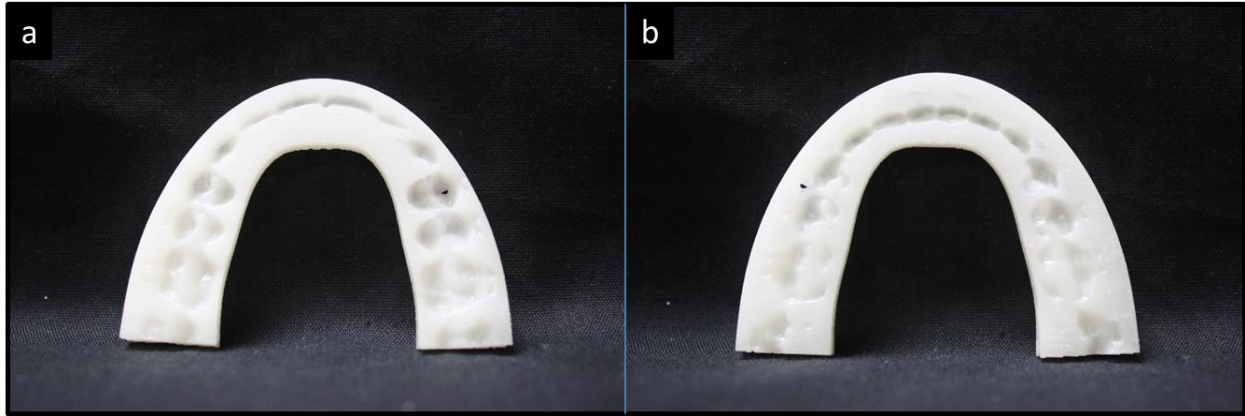
Figure 10. CAD/CAM generated surgical splint, using Arthroview® material with a: a) maxillary view and b) mandibular view.

Comparison of Traditionally Designed Splints and Virtually Designed Splints

The two splints, termed VOS and AS, generated for each patient, were compared for their ability to register the maxilla and mandible to each other. This was accomplished by superimposing CBCT scans of the plaster models mounted using each splint, and measuring the discrepancies of different points, predetermined to provide the best clarity, in three planes of space.

For each set of splints, the corresponding models were mounted on a Galetti articulator (Figure 11). CBCT scans were then taken of the models (10x10 cm, 6.3 seconds, 90kV, 4mA, 0.18mm voxel size) for each mounting (Figure 12a) During the scans, the splints were removed from between the opposing arches, allowing the plaster teeth to articulate in their new positions. This was important because there is no way to control for splint thickness in the vertical dimension when designing the CAD/CAM splints. Fiducials were also placed on the mandibular models prior to each scan, which consisted of 0.5 mm long segments of .010 gauge lead wire (Figure 12b). They were placed in three locations: buccal embrasures of the first and second molars bilaterally, and on

23

the midline at the level of the gingiva. Fiducials were necessary in order to have distinct and uniform landmarks to measure using CBCT volume images, since occlusal anatomy was blurred from the intercuspation of opposing arches. These locations were set because they were based on anatomy that was easily identifiable, well captured by the plaster, and represented the extreme edges of the dental arch.
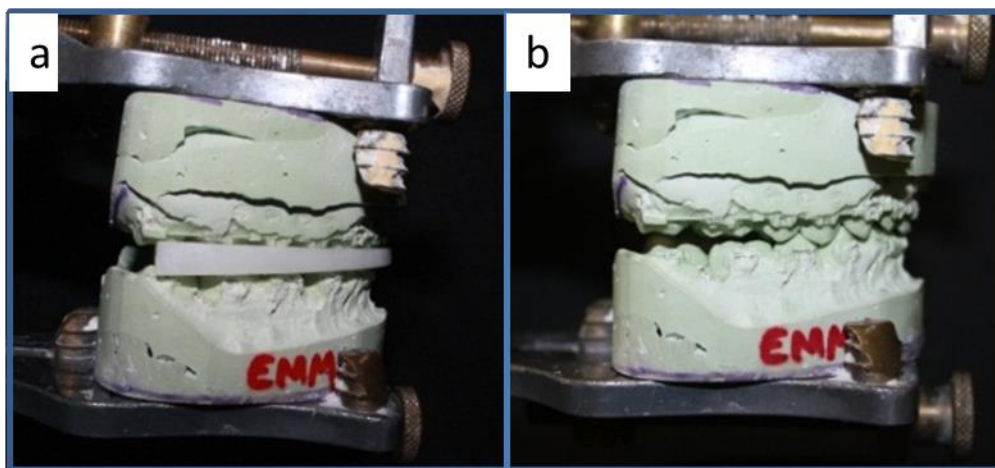
Figure 11. Plaster models mounted with an Arthroview® Splint articulating in the position (a) defined by the splint (b)

After the CBCT scans of the mounted plaster models were acquired, they were analyzed using the standard superimposition tools of Dolphin. Scans from the acrylic splint mounting were first loaded.. The orientation was set in three planes (Figure 12c). In the coronal plane, the maxillary midline was centered and made vertical. In the sagital plane, the functional occlusal plane was made horizontal. In the axial plane, the midline raphe was centered and made vertical. Next, the scans from the CAD/CAM splint mounting were superimposed on just the maxilla, using a similar technique used in fusing the high resolution STL files to patient DICOM (Figures 12d,e).

24

Since the DICOM files were superimposed on just the maxilla, any difference in the splints registration of the upper and lower jaw would be represented in the mandible (Figure 12f), and, consequently, that difference was quantifiable by measuring the distances between corresponding fiducials on the mandibular images.

When the superimposition was complete, the differences in location of corresponding fiducials were measured in all three planes of space. Using the "sliced-volume layout" the center of each fiducial could be located on each scan, and a line drawn between the two (Figure 13). X,Y,and Z coordinates represent the sagittal, axial, and coronal planes, respectively. Measurements were made in millimeters, and one analysis was completed per subject.
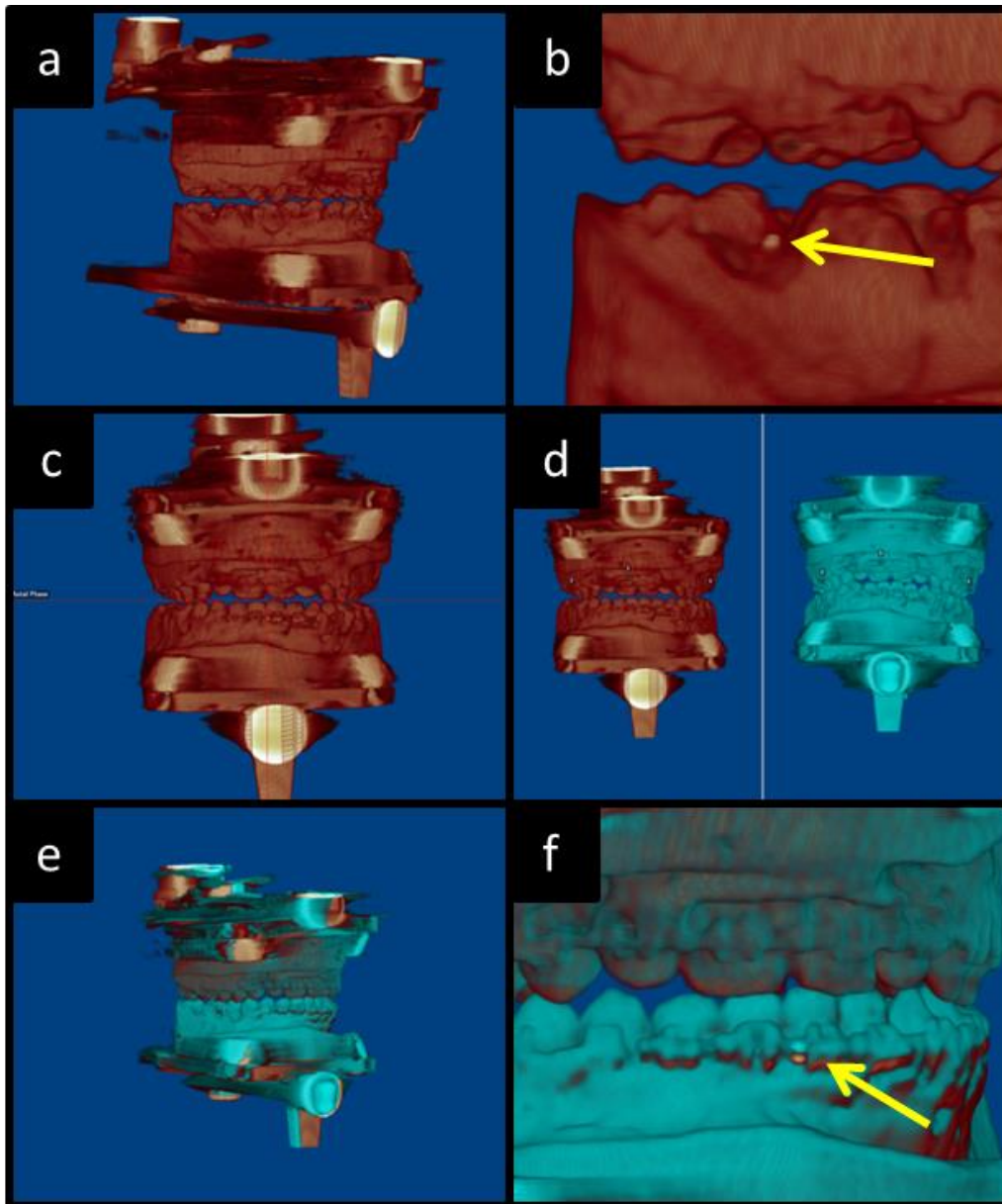
Figure 12. a) Volume rendered image of mounted model CBCT scan, using an acrylic splint, b) 0.5mm fiducial placed on cast, c) orientation of image set, d) acrylic-splint mounted model, next to the corresponding Arthroview®-splint model for superimposition, e) Images superimposed on the maxilla, f) different location of fiducials on the mandible defines the difference in inter-maxillary registration defined by the two different methods of surgery simulation and splint generation
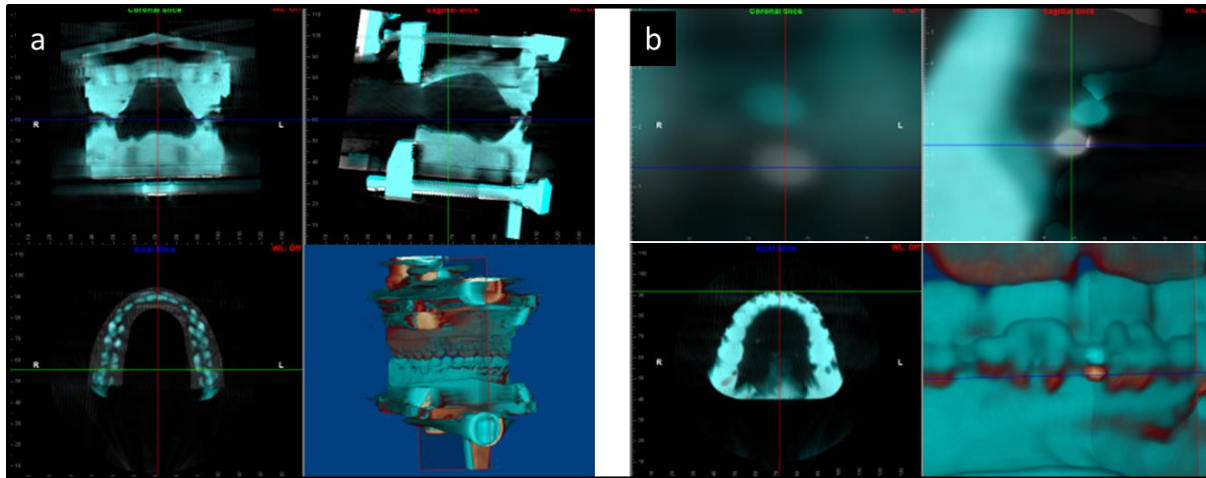
Figure 13. a) cross-sectional view of superimposed images, b) magnified view of a fiducial, used for measuring the distance between them in three planes of space

Controls

Five major sources of error were considered in this project (Figure 14): 1) variability in fusing STL and DICOM images; 2) variability in VOS manipulation; 3) variability in mounting test casts; 4) variability in superimposing DICOM of plaster model CBCT scans; and 5) variability in measuring the distance between corresponding fiducials on superimposed DICOM. All control procedures were performed on one patient, chosen at random. The number of subjects available for use as controls was limited by the patient population, and by the cost of rapid-prototyping.

27
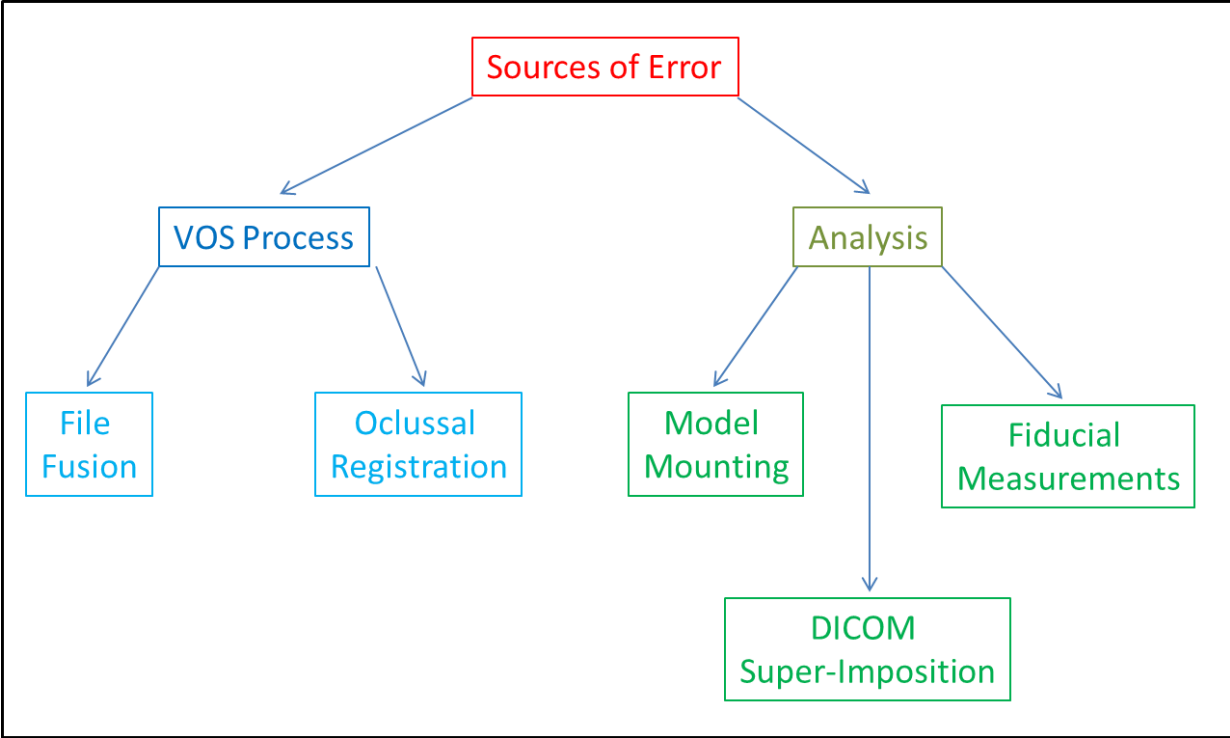
Figure 14. Diagram explaining controls. 2 controls examined the error associated with the VOS Process, while 3 controls evaluated the error of the analysis.

To test the STL/DICOM fusions, CAD/CAM splints were designed and printed to the pre-surgical occlusions. Any variability measured in this relationship would be the result of error in the fusion process, itself. Measurements were obtained using the previously stated analysis process, but they were compared amongst themselves by using subjects from this group for both the base and overlay DICOM during the analysis superimposition. Each STL/DICOM fusion was repeated at least one week apart.

To test the variability in VOS manipulation, one set of fused images was treated three times. A new CAD/CAM split was designed and printed for each simulation, and measurements

were obtained using the previously stated analysis process. The same base CBCT scan of a mounting using the acrylic splint was used for each simulation. Each virtual retreatment was performed at least one week apart.

To test the variability in the mounting portion of the analysis, one CAD/CAM splint was re-mounted and rescanned three times. Using the same acrylic splint base scan, each repeat was reanalyzed for discrepancy in fiducial location. To test the variability in superimposing CBCT scans of plaster models in the analysis, one CBCT scan of an acrylic-splint-mounted-model was superimposed on itself, and the distance between corresponding fiducials measured. This procedure was repeated three times, with each superimposition performed at least one week apart. To test the variability in the rater's ability to measure the distance between corresponding fiducials, one plaster model superimposition was re-measured three times, at least one week apart.

Interpreting Results: Statistical Analysis

The central-tendency of the measurements was determined by mean and standard deviation, with 95% conference interval calculated. Power analysis to determine the necessary sample size to confirm a difference of 1mm +/- 1mm was calculated at n = 16, however, considering that the results are of a much smaller magnitude; the sample size necessary to confirm a difference between the two methods would have been much greater than this number.

Stepwise Protocol

Please see Appendix 1

29

RESULTS

The distances measured between corresponding fiducials for each patient are listed in Table 2. In the sagittal plane (X), a negative value indicates the fiducial on the cast mounted with the virtually designed splint was posterior to the fiducial on the cast mounted with the traditionally made splint. Correspondingly, a negative value in the axial plane (Y) indicates the virtual fiducial was below the traditional fiducial, and a negative value in the coronal plane (Z) indicated the virtual fiducial was to the patient's right of the traditional fiducial. Measurements for the control samples made similarly.

The mean distances measured between corresponding fiducials were less than 1 mm in all planes of space. Mean and standard deviations ranged from (0.44 - 0.94 mm) and (0.35 - 0.96 mm) respectively. These figures were calculated using absolute values in order to give a more accurate representation of the magnitude of discrepancy between the models. Had this not been done, positive and negative values would have cancelled each other to give results unrealistically close to zero.

Control data is listed in Table 3. Control 1 represents a repeat of all steps for one of the patients from the study sample; its purpose is to show the consistency of the process. It would be expected that the mean and standard deviations for this control would be similar in magnitude to the sample as a whole.. The Center Y value is an outlier with a mean of 2 mm+/- 0.61 mm,. With this number excluded, the range of means is (0.3 -0.7 3mm) which is similar to the range of means for the study sample.

Control 2 represents a repeat of just the DICOM/STL file fusion.   Its purpose is to show the consistency of this first critical step, and ideally both the mean and standard deviations would be close to zero. This is not the case, however, as both the mean and standard deviation are similar in magnitude to the study sample numbers, indicating that this step introduces a sizeable amount of variability into the process. The range of means is (0.51 - 0.93 mm).

Table 2. Distances measured between corresponding fiducials, along with mean and SD.

Super Imposition	Patient	Posterior R			Center			Posterior L		
		Xmm	Ymm	Zmm	X	Y	Z	X	Y	Z
EM-AS / EM-VOS 1-1	1	0.2	0	-0.3	-0.2	0.4	0.4	0.2	1.3	0.5
ES-AS / ES-VOS	2	-0.5	3.5	-0.9	-0.9	0.2	-0.3	-0.5	0.3	0.3
BB-AS / BB-VOS	3	0.8	0.3	-1.6	0.2	0	-1	0.8	-0.6	2.5
BA-AS / VA-VOS	4	0.9	2	-0.6	-0.9	-0.5	0.7	0.9	-0.1	2.1
EV-AS / EV-VOS	5	0.6	0.5	-0.6	0.3	0.1	-0.1	-0.8	1.2	-0.7
IG-AS / IG-VOS	6	0.2	-0.1	0.7	0.6	-1	0.3	0	0.5	-0.1
IK-AS / IK-VOS	7	-0.5	0.4	0.6	-0.1	1.7	-0.4	-0.5	-0.4	0
YM-AS / YM-VOS	8	-0.4	1.3	-0.4	0.1	0.2	-0.9	-0.5	0.5	-1.4
TJ-AS / TJ-VOS	9	-1.1	-0.4	-0.2	-0.4	0.3	-0.8	-1.2	-0.1	-1.2
ZA-AS / ZA-VOS	10	-1.4	0.3	2.3	0.9	-0.2	0.4	-1.5	-0.4	-1.5
WW-AS / WW-VOS	11	-1.4	0.6	-0.3	-1.1	-0.1	-0.8	-1.5	-0.5	-1.3
GG-AS / GG-VOS	12	0	-0.1	1	0.7	-0.9	0.6	0.1	-0.2	-0.2
EPi-AS / Epi-VOS	13	0.1	-0.2	0.8	0.1	0.4	0.8	0.1	-0.5	0.8
Epe-AS / Epe-VOS	14	0.8	1.1	-0.6	-0.4	-0.2	0.5	-1.3	-0.6	-0.5
Mean		0.64	0.77	0.78	0.49	0.44	0.57	0.71	0.51	0.94
SD		0.45	0.96	0.56	0.35	0.46	0.27	0.52	0.35	0.76

Control 3 represents a repeat of the analysis portion of the study for one patient. Its purpose is to show the consistency of the analysis, with the magnitude of the mean measurements

not being relevant, but the standard deviation expected to be close to zero. This is shown with the standard deviations ranging from (0.06 - 0.25 mm).

Control 4 represents a repeat of the DICOM/DICOM file fusion step of the analysis. Because the same file was used to measure against itself, the expected difference would be zero, and any variation from zero is purely representative of error in the analysis of the study, not the process of the splint fabrication. The mean and standard deviations for this control are very low, ranging from (0 -0.1 3mm) and (0 -0.12 mm), respectively.

Control 5 represents the final step of the analysis portion of the project. It is simply a re-measurement of the same individual list in Control 3-1. Thus we would expect to see the magnitude of the means to be similar, but not necessarily close to zero. However, the standard deviation indicates the consistency of the step. The range of standard deviations was very low, (0 - 0.15 mm)

Student's t Tests were also performed on the study sample data. The highest magnitude in the sample was for the Poster-L-Z value, at 1.32 mm. 4 values had an upper limit of their 95% confidence interval about 1 mm: Posterior-R-Y , Posterior-R-Z, Posterior-L-X, and Posterior-L-Z.

Table 3. Measurements between corresponding fiducials in control samples.

	Posterior R			Center			Posterior L		
	Xmm	Ymm	Zmm	X	Y	Z	X	Y	Z
Control 1									
1	0.2	0	-0.3	-0.2	0.4	0.4	0.2	1.3	0.5
2	0.3	0.8	0.4	0.6	0.9	0.1	0.3	2.4	-0.3
3	0.4	-1.3	0.2	0	0.9	0.4	0	2.3	-0.4
Mean	**0.3**	**0.7**	**0.3**	**0.27**	**0.73**	**0.3**	**0.17**	**2**	**0.4**
SD	**0.1**	**0.66**	**0.1**	**0.31**	**0.29**	**0.17**	**0.15**	**0.61**	**0.1**
Control 2									
1	0.3	1	0.9	0.1	0.6	1	0.3	1	1.3
2	0.4	1.3	0.8	-0.2	1	0.6	-0.4	1.4	0.5
3	0.8	0.3	0	-0.4	0.3	-0.3	-0.8	0.4	-0.5
Mean	**0.5**	**0.87**	**0.57**	**0.23**	**0.63**	**0.63**	**0.5**	**0.93**	**0.77**
SD	**0.26**	**0.51**	**0.49**	**0.15**	**0.35**	**0.35**	**0.26**	**0.5**	**0.46**
Control 3									
1	0.2	0	-0.3	-0.2	0.4	0.4	0.2	1.3	0.5
2	0.3	0.3	-0.3	0.2	0.3	-0.2	0.4	1.7	-0.1
3	-0.2	0.5	-0.5	-0.3	0.2	-0.3	0	1.7	0.1
Mean	**0.23**	**0.27**	**0.37**	**0.23**	**0.3**	**0.3**	**0.2**	**1.57**	**0.23**
SD	**0.06**	**0.25**	**0.12**	**0.06**	**0.1**	**0.1**	**0.2**	**0.23**	**0.23**
Control 4									
1	0	0	-0.1	0	0	-0.1	0	0	0
2	0	0	-0.1	0.1	0	0.2	0.1	0	0.1
3	0	-0.2	-0.2	0	-0.2	-0.1	0	-0.1	-0.1
Mean	**0**	**0.07**	**0.13**	**0.03**	**0.07**	**0.13**	**0.03**	**0.03**	**0.07**
SD	**0**	**0.12**	**0.06**	**0.06**	**0.12**	**0.06**	**0.06**	**0.06**	**0.06**
Control 5									
1	0.2	0	-0.3	-0.2	0.4	0.4	0.2	1.3	0.5
2	0.2	0	-0.1	0.1	0.1	0.2	0.1	1.2	0.4
3	0.1	0	-0.1	-0.2	0.2	0.2	0.3	1.3	0.4
Mean	**0.17**	**0**	**0.17**	**0.17**	**0.23**	**0.27**	**0.2**	**1.27**	**0.43**
SD	**0.06**	**0**	**0.12**	**0.06**	**0.15**	**0.12**	**0.1**	**0.06**	**0.06**

Table 4: Single Sample T-test + 95% CI

	Posterior R			Center			Posterior L		
	Xmm	Ymm	Zmm	X	Y	Z	X	Y	Z
Student's t Test	(0.9, 0.38)	(1.32, 0.22)	(1.1, 0.46)	(0.69, 0.17)	(0.71, 0.17)	(0.73, 0.38)	(1.01, 0.30)	(0.71, 0.31)	(1.38, 0.5)

DISCUSSION

This study evaluated how effectively one commercial program could be used to perform virtual orthognathic surgery procedures, including design of the surgical splint. For each subject, the comparison between the splint designed virtually and the splint designed traditionally demonstrated similar outcomes, as assessed by the intermaxillary relationship of the plaster models used to create each splint when mounted on an articulator and scanned with a CBCT system. Due to this similarity, we are unable to reject our null hypothesis that there is a difference between the two methods ability to reproduce jaw position.

Historically, the "gold-standard" methods of two-dimensional orthognathic surgical simulation have been shown to be greater than 1 mm from the surgical outcome. Mean results from this study show the outcomes were all less than 1 mm from the predicted value, which is consistent with previously published papers on the subject of Virtual Orthognathic Surgery, and indicate that this method is superior to two-dimensional surgical simulation. The upper range of the 95% confidence interval was above 1 mm for four figures, which is close to the expected two-dimensional error, but this would indicate that for these vectors, the three-dimensional simulation is at least as good as the two-dimensional method.

34

It is surprising that the vector showing the greatest variability is the Posterior-L-Z dimension. This is probably due to user error, because there was a tendency to predominantly hold the model looking at the right side while doing most of the virtual manipulation. Due to the steepness of molar cusps, it would have been expected that the greatest variability would be in the Y plane, and greater in the anterior than the poster due to the "wedge effect". Shanahan (16) found greater variability in the Y plane, but he attributed his findings to variability in surgical splint thicknesses that were in place when the images he acquired were measured.

The controls data is consistent with what was expected. Variability of Control 1 is similar in magnitude to the sample population, which indicates there is an inherent error in the process which is not patient specific. The magnitude of error associated with Control 2 suggests that the STL/DICOM fusion step is relatively high, but since it was similar in magnitude to the overall sample, any variability introduced during this step is washed out by ultimate occlusion defined by the Virtual Orthognathic Surgery. In other words, the starting location of the dentition is not necessarily significant in determining the ultimate occlusion, which is the goal of the procedure; but improper fusing of the files pre-surgically would lead to inaccurate values reflecting the amount of movement necessary to reach the ultimate occlusion.

The small values found in Controls 3-5 indicate that the analysis method was highly precise, and the values of the sample population are reflective of the accuracy of the VOS method.

Evaluation of the Process

One of the most exciting elements of this study is witnessing the elegant interaction of four highly advanced technologies, which in, itself, represents a significant leap forward in our technical abilities. Having said this, though, the astonishing pace of innovation is already making elements of the study outdated. The Ortho-Insight 3D scanner is very user friendly, and at 40 µm, its resolution is effective. One drawback to this machine, however, is that it still leaves the practitioner dependent on alginate to obtain impressions of each patient's dentition. This means that all of the error associated with using alginate still needs to be considered (*i.e.,* warping, tearing, and poor ability to capture anatomy gingival to brackets). Using an intra-oral scanner to acquire high-resolution 3D images of the dentition would eliminate this problem, and will probably be more appropriate for implementation of the VOS procedures into patient care. There are already intraoral scanners available that can produce images with resolution comparable to the Ortho-Insight 3D scanner, but looking forward, we may one day be able to obtain high-resolution CBCT images. Currently, the resolution limit of the Kodak 9300 is 150 µm for small field scans, which is almost 4 times less sharp than the laser scanned images.

Dolphin 11.7 software represents a great advancement in user-friendly technology. Until now, fusing electronic files of different format, segmenting DICOM files, and generating novel STL files has required a high level of technical ability and time. Making these procedures simple and efficient puts a powerful tool into the hands of orthodontists and oral surgeons. There is still room for improvement. Control 2, showed there was more variability in fusing the STL and DICOM files, than in performing the virtual surgeries themselves. This step is analogous to mounting models in the appropriate position for "plaster-model=surgery". Error at this step would not affect the

ultimate post-surgical occlusion, but it would alter the magnitude of simulated movements of each jaw which will translate to a variable post-operative position of the jaws relative to the cranial base. It makes sense for there to be a large amount of error in this step, because with one file being very low resolution, it is difficult to identify corresponding points for superimposition. This step can be improved with the preset software, by using more reference points. Three points were used in this study, which represents the minimum the software allows, but up to seven are possible.

The images segmented from the DICOM displayed a large amount of scatter. This may be due to the difficult balance of selecting voxels by CT number thresholds, to view the delicate condylar and alveolar structures and maintain a clean image of the more robust corpus and ramus. Scatter is also increased by the presence of metal appliances bonded to the teeth. Ultimately, the smoothness of the maxillary and mandibular STL images is irrelevant to the simulation process, but accurate pictures are more desirable to use when interacting with patients and colleagues. All elements of the splint design and fabrication are without criticism. The software allows the user complete control over the shape and size of the final product in all dimensions, including inter-occlusal thickness. The prototyped splints fit their respective models tightly, without rocking, and were consistently delivered in a time-sensitive duration.

Limitations of the Study

The sample size of this study was limited by available records and cost. The goal of this study was to test VOS procedures by trying to recreate virtually each patient's traditional-surgery. By using the result of the traditional simulations as the treatment goals of the virtual simulations, we were

37

unable to answer the question "which protocol is better", but rather "how close can we could get VOS to a specific goal". This approach was due to a lack of objective treatment goals for immediate-post-surgical occlusion. The final occlusion of orthodontic treatment can be objectively measured by the American Board of Orthodontics case analysis criteria, which is generally accepted by the orthodontic community. These criteria do not exist for postsurgical occlusion, because each case is unique. For example, it is common to leave a posterior-open-bite after surgery when treating patients for an anterior open-bite malocclusion, but this would not be ideal in other cases. Consequently, planning surgery for competent orthodontic goals may not coincide with oral surgery objectives.

Future Studies

This study can be considered the second-stage of a three-stage study. Dr. Shanahan previously looked at the reliability of VOS using a different commercially available software, and found that the error of his predictions were of the same magnitude as 2D studies.(16) This led him to conclude that VOS is a reliable paradigm for surgical simulation, and should be built upon for use in splint design, which is what we have accomplished here. In the next phase, an *in-vivo* study needs to be performed that compares the surgical outcomes of two subject groups, one treated with surgical splints generated from traditional methods, and another from virtual methods. The treatment of these groups should be compared both objectively for the variation of their outcomes from predictions, but also subjectively for their functional and esthetic results.

38

CONCLUSION

1) Virtual orthognathic surgery simulations developed with a commericailly available software, coupled to stereolithographic surgical splint generation, can be accurate to within 1 mm of actual outcomes.

2) Virtual orthognathic surgery and stereolithographic splint generation using Dolphin 11.7 software is reliable and precise.

REFERENCES

1. Graber T, Vanarsdall R Jr., Musich D. Orthodontics: Current Principles & Techniques fourth edition. *Ch 23 Adult interdisciplinary therapy: diagnosis and treatment*. 2005. pg 973

2. Proffit W, Sarver D. Contemporary Orthodontics, fourth edition. *Ch. 19 Combined Surgical and Orthodontic Tx*. 2007. pg 686

3. Proffit WR, Turvey TA, Phillips C. *The hierarchy of stability and predictability in orthognathic surgery with rigid fixation: an update and extension*. Head Face Med. 2007 Apr 30; 3:21

4. Buckley MJ, Tulloch JF, White RP Jr, Tucker MR. *Complications of orthognathic surgery: a comparison between wire fixation and rigid internal fixation*. Int J Adult Orthognath Surg, 1989; 4(2): 69-74

5. Mah JK, Huang JC, Choo H. *Practical applications of cone-beam computed tomography in orthodontics*. J Am Dent Assoc. 2010 Oct; 141 Suppl 3: 7s-13s

6. Mah J, Hatcher D. *Three-dimensional craniofacial imaging*. Am J Orthod Dentofacial Orthop. 2004 Sep; 126(3): 308-9

7. Hatcher DC, Aboudara CL. *Diagnosis goes digital*. Am J Orthod Dentofacial Orthop. 2004 Feb; 8(1): 2-8

8. Bell W, Hill S. <u>Surgical Correction of Dentofacial Deformities, New Concepts</u>. *Ch 1 simultaneous repositioning of the maxilla, mandible, and chin: cephalometric planning and model surgery*. 1985. pgs 210-226.

9. Ellis E 3rd. *Accuracy of model surgery: evaluation of an old technique and introduction of a new one*. J Oral Maxillofac Surg. 1990 Nov; 48(11): 1161-7

10. Olszewski R, Reychler H. *Limitations of orthognathic model surgery: theory and practical implications*. Rev Stomatol Chi Maxillofac. 2004 Jun; 105(3): 165-9

11. Kaipatur N, Al-Thomali Y, Flores-Mir C. *Accuracy of computer programs in predicting orthognathic surgery hard tissue response*. J Oral Maxillofac Surg. 2009 Aug; 67(8): 1628-39

12. Kaipatur NR, Flores-Mir C. *Accuracy of computer programs in predicting orthognathic soft tissue response*. J Oral Maxillofac Surg. 2009 Apr; 67(4): 751-9

13. Wagner A, Rasse M, Millesi W, Ewers R. *Virtual reality for orthognathic surgery: the augmented reality environment concept*. J Oral Maxillofac Surg. 1997 May; 55(5): 456-62

14. Xia JJ, Gateno J, Teichgraeber JF, Christensen AM, Lasky RE, Lemoine JJ, Liebschner MA. *Accuracy of the computer-aided surgical simulation (CASS) system in the treatment of patients with complex craniomaxillofacial deformity: A pilot study*. J Oral Maxillofac Surg. 2007 Feb; 65(2): 248-54

15. Zinser MJ, Mischkowske RA, Sailer HF, Zöller JE. *Computer-assisted orthognathic surgery: feasibility study using multiple CAD/CAM surgical splints*. Oral Surg Oral Med Oral Pathol Oral Radiol. 2012 May; 113(5): 673-87

16. Shananah K. Virtual 3D orthognathic treatment simulation accuracy: comparison of prediction and surgical outcome. UCSF Master's Thesis 2011

17. Swennen FR, Mollemans W, Schutyser F. *Three-dimensional treatment planning of orthognathic surgery in the era of virtual imaging*. J Oral Maxillofac Surg. 2009 Oct; 67(10): 2080-92

18. Bell RB. *Computer planning and intraoperative navigation in orthognathic surgery*. J Oral Maxillofac Surg. 2011 Mar; 69(3): 592-605

19. AUTHOR J Craniomaxillofac Surg. *3D planning in orthognathic surgery: CAD/CAM surgical splints and prediction of the soft and hard tissue results- our experience in 16 cases*. 2012 Feb; 40(2): 162-8

20. 7Irving SP, Costa LE 3rd, Salisbury PL 3rd. *The occlusal wafter: simple technique for contruction and its use in maxillofacial surgery*. Laryngoscope. 1984 Aug; 94(8): 1036-41

21. Gateno J, Xia J, Teichgraeber JF, Rosen A, Hultgren B, Vadinais T. *The precision of computer-generated surgical splints*. J Oral Maxillofac Surg. 2003 Jul; 61(7): 814-7

22. Metzger MC, Howlweg-Majert B, Schwartz U, Teschner M, Hammer B, Schmeizeisen R. *Manufacturing splints for a orthognathic surgery using a three-dimensional printer*. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2008 Feb; 105(2): e1-7

23. Noh H, Nabha W, Cho JH, Hwang HS. *Registration accuracy in the integration of laser-scanned dental images into maxillofacial cone-beam computed tomography images*. Am J Orthod Dentofacial Orthop. 2011 Oct; 140(4): 585-91

APPENDIX 1- Stepwise Protocol

     i.   Obtain high resolution 3d image file of Pt's pre-operative plaster models
1. Open Motion View Software
2. Place Lower model in machine with anterior dentition toward the front, and close door
3. Click "Scan New Model"
4. Choose "Lower Trimmed Model"
   a. Untrimmed models and impressions will not create scans with anatomy appropriate for DICOM fusion
5. Choose appropriate mold material and indicate the level of preferred resolution
6. Wait for preview to be generated and ensure the anterior dentition are pointed toward the top of the screen
   a. The preview scanner is a real-time camera
7. Choose "Continue Scan"
8. This will take between 2-4 minutes depending on the resolution
9. When the scan is complete, wait for the mesh to be built and decimated, then click "Hide" on the scan window
10. Save scan and export as STL file type.
11. Repeat process with upper model.

     ii.   Fuse High Resolution STL files with Low Resolution DICOM
1. Open Dolphin Software for patient file of interest
2. Import Pre-Surgical CBCT DICOM
3. In the left column of the screen, click "Add" under "Photos/ Surfaces:", import the file of interest, generated in the previous step
4. Lower the threshold of the CBCT volume to limit scatter and make dental surfaces visible
5. There should be two windows visible on the screen, one with CBCT volume rendering, and one with STL volume. Place the alignment points on corresponding structures.
   a. Strive to place the points on structures that are clearly defined in both images, and spread them out as much as possible
6. Click "Super Impose Now"
7. Move to the "Sculpting" window to remove the plaster base from the STL image, isolate only dental and orthodontic appliance structures

42

8. Move to "Model Overlay Super Imposition" window
9. Use the widget to refine the superimposition generated in the first window.
10. Click "Auto Super Impose".
    a. This is not precise, it is still possible to further refine the super imposition
    b. Click "Save to Database"
11. Repeat for opposing arch

iii. Orthognathic Surgery Planning Tool: segments fused DICOM, perform Virtual Orthognathic Surgery, and designs 3D Surgical Splint file
1. Using the same DICOM as in the previous step, create a Panoramic Radiograph style image using the "Build X-Rays" tool
2. From CBCT Screen, look under "Tools" for "Orthognathic Sugery Planner", follow steps to virtual surgery
    a. "SETUP"- Define Region of bone from PAN
        i. Use turquoise lines to define segmentation units
            1. Right and Left ramus
                a. Include Condyle and lower border
                b. Exclude 2nd molars
            2. Anterior Mandible
                a. Include lower incisors and 2nd molars and lower border
            3. Maxilla
                a. Include area above palatal bone and upper incisors
        ii. Make sure to click on the dot in each field
            1. This will cause a green check mark to appear in the upper left column
            2. You cannot proceed to step 2 until 4 green check marks are present
        iii. Click "SAVE NOW"
            1. Always save before proceeding to next step, otherwise data will be lost
    b. "CROP"- define skeletal region for separate 3D images files (STL)
        i. In the top 2 windows define the boundaries for each jaw, from which to include DICOM voxels.
        ii. In the lower window adjust Voxel threshold.

43

1. There is a fine balance between having enough sensitivity to include the condyle, and having too much noise
2. For the Maxilla, make sure to include PNS and ANS
   iii. This step is rough, it doesn't need to be perfect, error on the side of more not less
   iv. Click "Apply Now"
   v. If the created image is satisfactory click "Save Now", if not adjust and reapply.
   vi. Once the first image is saved, proceed through all segments listed in Upper Left column
c. "CLEAN UP"- smooth segments
   i. Segment out noise
   ii. First priority is to have a clean dentition
   iii. Click "Save Now" for both Mandible and Maxilla segments
   iv. Click "Add Teeth Model Overlay
      1. This imports the high resolution images from the step II.
      2. If necessary, click "Edit Model Merge" to improve the super-imposition
   v. Crop all surfaces of the low-resolution image that overlap the high resolution image.
      1. This prevents redundancy of structures in the final image
   vi. Click "Save Now" and proceed to the next step
d. "Osteotemy"- Define Sx cuts in each segment
   i. In the left column, identify the intended cuts
   ii. In the top two images, use the yellow dots to align the red lines along the path of the intended surgical cuts
   iii. Click "Cut Now"
      1. Repeat if necessary
   iv. In the left column, click the next osteotomy to perform. And repeat the previous procedure until all cuts have been made.
      1. All osteotomies must be defined before moving to the next step
   v. Be sure to click "Save Now" before proceeding

e. "LandMarks" – set points of reference
- i. This is similar to digitizing a 2D ceph.
- ii. Click the point on the image that corresponds to the specified landmark.
    1. You will see a red dot appear
- iii. Identify all landmarks in the list before proceeding
- iv. Be sure to click "Save Now"

f. "Treat"- perform Virtual Orthognathic Movments
- i. First, evaluate the high-resolution dental overlay for collisions within the opposing arches
    1. In the left column, click "Treatment Options"
    2. Click "Show Vertical Collision Color Map"
    3. When the new window appears, it will display how close each region of the arches are to each other. If the images collide, it will be displayed as red
        a. Check to see that the color map makes sense. For example, if the patient has an open bite, make sure the anterior teeth are farther apart than the posterior teeth. Or if not cant is present, make sure there is an even color distribution bilaterally
        b. If the arch relationships do not appear to be reflective of the patients anatomy, or if collisions are present, there are two methods to correct this.
            i. In the color map window, click "Uncross", or
            ii. Return to the "Clean Up" section and correct the super-imposition directly
- ii. Begin Virtual Surgery
    1. In the left window,
        a. Set image to the right-facing-lateral view.
        b. Click the jaw of interest to move.

      c. Center the widget at the tip of the incisors:
- i. With panning function, move the incisors to the correct over-bite and over-jet position
- ii. Use the rotation function, set the correct distance between the posterior teeth

      d. Set image to the frontal view
- i. Set the midlines
- ii. refine over-bite and over-jet
- iii. Correct canting

      e. Set image to the coronal view
- i. Correct rotations

      f. Set image to the left-facing-lateral view.
- i. If all movements in the previous steps were done accurately, there will not be any further adjustments to make here.
- ii. Check for refinements

      g. Check for collision using the "Color Map"
- i. Refine until there is appropriate clearance throughout each arch

      h. Click "Save Now" before proceeding

g. "Present"
- i. This is the next step in "Orthognathic Surgery Planning Tool"
- ii. It is only relevant for presentations
- iii. Skip to "Splint"

h. "Splint"
- i. In the left column, click "Move Both" to design a splint that correlates to your virtual surgery

ii. In the top two windows, use the green dots to set the sagittal and vertical thicknesses of your splint.

　　　　　　　iii. The goals are to make it thick enough to incorporate the occlussal surfaces of each tooth, but thin enough to stay within the high resolution portion of the image

　　　　　　　iv. Adjust the green dots in the top images until the lower images do not show any black-spots on the dentition

　　　　　　　v. In the left column, click "Lock for Splint Contouring"

　　　　　　　vi. Adjust the dots on the lower image to put the green line in close proximity to the teeth.

　　　　　　vii. Click "Preview Splint"

　　　　　　viii. Check the occussal surfaces of the splint to make sure they are smooth and reflective of patient anatomy.

　　　　　　　ix. Refine if necessary

　　　　　　　x. Click "Create Splint STL"

　　　　　　　xi. Your Virtual Surgery is now complete, and your splint is now ready for fabrication.

b. Fabricate Surgical Splint
　　i. STL files uploaded to Medical Modeling Services website
　　ii. Machine: Ortho Insight 3D
　　iii. Material = ArthorView®

c. Compare virtually designed splints with traditionally designed splint
　　i. Add fiducials to Mn models using CyanoAcrylic
　　　　1. Each fiducial is an approximately 0.5mm length of lead wire
　　　　2. Place in 3 locations
　　　　　　a. Midline between L-1's at the height of the orthodontic wire
　　　　　　b. The embrasure between the first and second molar bilaterally
　　　　　　c. These points were chosen because they are:
　　　　　　　　i. Easily reproducible
　　　　　　　　ii. Represents every corner of the Mn dental arch
　　ii. Obtain 3D images of models articulated using each splint
　　　　1. Mount models in Galetti style articulator, using each Sx splint to register the arches

a. The splints are removed after mounting, prior to scanning, to allow teeth to interdigitate
   2. Scan mounting using Kodak 9300 CBCT Machine
          a. Settings: 10x10 cm, 6.3 seconds, 90kV, 4mA, 0.18mm voxel size
iii. Analyze Scans using Dolphin software
   1. Import DICOM of CBCT scan for models mounted using the traditional splint
   2. Set orientation of the maxilla using the Orientation tool
          a. Coronal Plane- a line running through midline set to vertical
          b. Sagittal Plane- a line running through the functional occlusal plane, set o horizontal
          c. Axial Plane- a line running through the median raphe set to vertical
   3. Open the Super Imposition Tool and import the DICOM of the CBCT scan of models mounted using the virtually designed splint
          a. Similar to fusing the high resolution STL files, place the alignment points on corresponding structures on the two images, and click "Super Impose Now"
          b. Click "Method Overlay Super Imposition" to refine superimposition with the widget.
          c. Click "Analysis/Verify Results"
          d. Enter the 4 window sectional view
          e. Open the measurement tool
                i. Make sure it is set to "Line"
          f. Scroll through the sagittal section until the posterior-right fiducial is visible on the traditional-splint scan
          g. Measure the X,Y,Z distance between fiducials on the two scans
                i. On the sagittal section, set the cross planes over the center of the fiducial
                ii. Scroll through the section until the fiducial from the virtual-splint scan is visible.
                      1. Click the center of the cross planes
                iii. Scroll the axial plane line to the center of the fiducial on the virtual-splint scan
                iv. Click the new center of the cross planes
                      1. This line gives you the Y coordinate

v. Click the center of the cross planes again, and then click the center of the visible fiducial
   1. This give you the Z coordinate
vi. Move to the Coronal section to determine the X coordinate in the same fashion.
vii. Repeat all three measurements for the anterior-center fiducial and posterior-left fiducial

Publishing Page

I hereby grant permission to the Graduate Division of the University of California, San Francisco to release copies of my thesis, dissertation, or manuscript to the Campus Library to provide access and preservation in whole or in part, in perpetuity.

_____   _____6/11/13_____

Author Signature   Date